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Assessment of Patient's Knowledge Regarding Speciality of Anesthesia and Anesthesiologists: A Questionnaire Based Study

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Abstract

Background: Anesthetist most of the time feel that they have not been given the credit they deserve. They have been treated as behind the screen specialist. Their role has never been appreciated by the patient. Most of the time patient's knowledge about anesthesia andanesthetist is limited. *Aim:* To assess patient awareness regarding anesthesia and anesthetist *Method:* After approval from the institutional ethical committee, 200 participants scheduled for various surgical procedures were randomly selected. After obtaining informed written consent, they were administered a set of questionnaire face to face orally by an investigator and their responses were recorded separately. The data collected were subjected to simple statistical analysis. *Result:* Out of 200 patients, only 40% knew that anesthetist alleviate the pain of surgical procedure by putting the patient to sleep. Only 30% of participants said that anesthetist is a specialist doctor. Hardly very few patients knew about the role of anesthetist outside the operation theatre. *Conclusion*: Awareness of patients about anesthesia and anesthetist is very much limited. Lack of recognition and appreciation of the role of anesthetist by the patients contributes to the frustration of anesthetist. Hence, every opportunity to spread awareness about anesthesia and anesthetist among patients must be utilized for the benefit of both patient and the anesthetist.

Keywords: Patient's Knowledge; Anesthesia; Anesthetist.

Introduction

Since the time anesthesia has been demonstrated to the world, there has been continuous development in the field of anesthesia like the introduction of newer anesthetic agents, techniques, advanced monitoring system, etc. Consequently, the role of anesthetist has extended beyond the traditional operating room into critical care, trauma centers, pain clinics, and conduct of painless deliveries. Despite the fact that advances in the field of anesthesia are on par with that of surgical field, the recognition of anesthetist is not on par with that of a surgeon. Most of the time's anesthesia specialty has been treated as a behind the scene specialty which itself leads to decreased awareness about anesthesiaspecialty among patients. In general, there is feeling that the specialty of anesthesia carries low profile when compared to other clinical specialties. In the last 2-3 decades, there is the tremendous increase in the healthcare awareness all over the world but similar kind of awareness about anesthesia and anesthetist is lacking among patients. This can be found from the numerous relevant studies conducted across the world [1,2,3]. These studies reflect that there is inadequate public knowledge regarding the specialty and the scope of the functions of anesthetists as well as the pivotal role anesthetists play in the health care delivery system. Despite so many advancements and extension of the field of work beyond operation theatre as well as the critical nature of care they provide, anesthetists are hardly recognized and

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their role is hardly appreciated by the beneficiaries. Lack of recognition and decreased appreciation of the role of the anesthetist by the patients contribute to the frustration of the anesthetic practitioner. Better recognition of anesthesia professionals would encourage future recruits to take up the speciality [3]. Hence, with this background information, the present study is planned to assess patient's knowledge about the anesthesia and anesthetists by using the set of questionnaires.

Methods

This current study is a cross-sectional study conducted in our institute. After obtaining ethical clearance, 200 patients scheduled for various surgical procedures who attended pre-anesthetic clinic wererandomly selected. Patient's below 18 years and above 70 years of age were excluded from the study as well as those with psychiatric illness, severe debilitating illness, unable to understand and speak, not willing to participate and those posted for emergency surgeries were also excluded. After obtaining informed consent from an individual participant, a set of questionnaires were administered to patients face to face orally by an interviewer and their responses were recorded. Meanings of various technical words were explained to the patients. Questions in the questionnaire were carefully prepared to keep in mind the knowledge and understanding of the population in the region. There were 24 questions in the questionnaire designed to capturethe baseline demographic profile like age, sex, literacy status, socioeconomic status as well as the patient'sknowledge and perception regarding anesthesia and anesthesiologist.All the data were collected, tabulated and analyzed.

Result

A total of 200 patients had been randomly chosen for the study. After explaining them in detail about

Table 1: the questionnaire

1.	Patient age_____
2.	Gender _____
3.	Educational status _____
4.	Occupation _____
5.	Have you undergone any surgery before?_____
6.	Who will assess you regarding your fitness to undergo surgery? _____
7.	Why is fasting needed before surgery according to you? _____
8.	Who wil mitigate your pain during surgery?_____
9.	Is anaesthesia needed if surgery should be required?_____
10.	How is anaesthesia applied?_____
11.	Is anaesthesia applied to all patient in the same way?_____
12.	Have you heard about anaesthetist?_____
13.	Is anaesthetist, a specialist doctor or one who works under supervision of surgeon? _____
14.	Who will be taking care of your well being once you are given anaesthesia? _____
15.	Do you think that anaesthetists are as important as surgeons for you to undergo surgery?_____
16.	What do you think providing anaesthesia a easier job or involves risk?_____
17.	Do you know that anaesthetist are involved in your postoperative care?_____
18.	Do you know that anaesthetist are involved in the care of critically ill patients?_____
19.	Do you know that anaesthetist are involved in the care of accident and emergency patients?_____
20.	Do you know that anesthetist are involved in the conduct of painless deliveries?_____
21.	Do you know that anaesthetist plays important role in the resuscitation of cardiac arrest patient? _____
22.	Do you know that if any patient in the hospital suddenly becomes serious, anaesthetist are immediately called?_____
23.	Do you know that anaesthetist runs pain clinic?_____
24.	Are you interested to know more about anaesthesia and anaesthetist? _____

Table 2:

Sl. No.	Patient Variables	Number	Percentage
1	AGE		
	18-30 years	70	35%
	30-50 years	106	53%
	50-70 years	24	12%
2	GENDER		
	Male	122	61%
	female	78	39%

the purpose of the study, they were told about the meaning of difficult terminologies used for the interview. The responses to the interview questionnaire were obtained from each individual and recorded and subsequently analyzed. Following facts were found from the study.Among the participants, 53% were between 30 to 50 years of age, 35% were from 18 to 30 years of age and remaining 12% were from 50 to 70 years of age group. Male patients were more (61%) as compared to females (39%)patients (Table 2).

In our study, 37% of respondents had undergone previous surgery. On questioning about who will give you fitness to undergo surgery, 11% of participants said anesthetist, 66% said operating surgeon and remaining 24% said they don't know. As far as the question on purpose offasting before surgery is concerned, 66% replied they don't know, 25% patients said to prevent complications during surgery and 10% respondents said to prevent vomiting.When asked about who will alleviate pain during surgery, 60% said operating surgeon and only 40% acknowledged that it is the anaesthetist.On questioning about how is anaesthesia applied, out of 200 patients, 60 (30%) patients said anaesthesia is provided by holding mask over face whereas 22(11%) patients knew that anaesthesia can be provided either by applying mask to face, by injecting into the veins or by giving injection at the back. When asked have you heard about anesthetist before, 41% respondents said yes. 30% of patients told that anesthetist is a specialist doctor whereas 70 patients (35%) had an impression that anesthetists work under the supervision of the surgeon. On enquiring about who will be looking after you once you are put to sleep, 73% believed that it is the surgeon and 27% believed that it is the anaesthetist. As for as the risk of providing anesthesia is concerned, 36% believed that it is a simpler job and remaining 64% said they don't know. When enquired about the role of anesthetist outside operating room like ICU, trauma care, resuscitation etc. only 5 patients replied that anesthetist also works in ICU. Apart from that, no patient had any idea about the role of anesthetist outside OT.

Discussion

Anesthesia is anever-evolving branch. When started, it was limited to providing anesthesia to surgical patients. Subsequent developments in the field of anesthesia led to the extension of the field of work of anaesthesiologist outside the conventional operation theatre into the critical care, accident and emergency department, pain clinics, conduct of painless deliveries and resuscitation of the patient with cardiorespiratory collapse etc. The practice of anesthesia is considered as the high-risk job. Majority of anesthesia related morbidity and mortality are attributed to the human errors. So, the anesthetist has to very meticulously execute his job. This leads to considerable stress and ultimately leads to deprivation of healthy working atmosphere. Added to this there is lack of recognition and low appraisal among the general population. These factors ultimately result in the frustration of anesthetist. After witnessing these things, future recruits will show less interest to join anesthesia specialty.

When we look at the results of our study we find that only 40% of study population knows that anesthesia is provided by the anesthesiologist. The study conducted in Ghana by Djagbletey R. et al, reported that 62% of the respondent were aware of anesthetist. In a similar study conducted in Saudi Arabia by Baaj J, Takrouri MSM, Hussein BM and Al Ayyaf H, 55% of respondents said that anesthesia is provided by an anaesthetist. In our country, a result of a similar study by Jathar D, Shinde VS, Patel RD and Naik LD revealed that 44% of patients were aware that anesthesia is provided by the anaesthetist, which is very close to that found in our study. When we asked about the role of anaesthesiologist outside OT, only 5 patients knew that anesthetist also work in ICU. Nobody is aware of the role of anesthetist in pain management, trauma care, resuscitation etc. Only 30% of respondents of our study were aware that anesthetist is a specialist doctor. Most of the patients think that anesthetists work under the supervision of operating surgeon.

Last 15–20years have witnessed the sudden spurt in the healthcare awareness among public all over the world. This is partly dueto the explosive growth of the media like television and internet in the recent past [10].

This suddenly increased healthcare awareness has not affected the field of anesthesia in a significant way. Majority population even know also does not know who is anesthetist, whether he is specialist, what role he plays outside operating room etc. They have very limited knowledge about the specialty. Recognition of the anesthesia profession as an independent specialty would help anesthesia practitioner to develop his own individual identity and also, in turn, encourages future recruits to take up the specialty. On the other hand, lack of recognition and decreased appreciation of the role of the anesthesiologist by the patient further contributes to the frustration of the anesthetic practitioner [12].

Public awareness about anesthesia and anaesthesiologist can be brought up in many ways. At an individual level, anesthetist during his preoperative visit can introduce himself to the patient and brief him about the field of anesthesia. Similarly, at a national and international level, public awareness about anesthesia and anaesthesiologist can be improved by showing short video films and documentaries on television, printing special articles in newspapers, distribution of booklets etc. Also, an introduction of small chapters at school level concerning the role of anaesthesiologist may be helpful.

Conclusion

It can be concluded that the anaesthesiologist who takes a lot of stress and struggles to make patient undergo surgery safely without feeling pain, is rarely recognized and appreciated by the patients. Lack of recognition and appreciation can result in frustration among anaesthesiologists. On the other hand, fear of surgical pain prevents many patients from undergoing surgery and it instills a kind of anxiety in surgical patients. So, knowledge of the availability of different types of anesthesia techniques to take care of perioperative and postoperative pain can help patient to overcome fear and anxiety associated with surgery. In this way, both patients, as well as anesthesiologists, will get benefittedby the spread of awareness regarding anesthesia and anesthetists. Hence, every opportunity to spread awareness regarding anesthetists as well as anesthesia among the general population, must be utilized. Print and social media can be of great help in this regard.

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Original Research Article

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Retrospective Audit of Critical Events under Anesthesia at Tertiary Care Nephro-Urology Set Up

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Abstract

Introduction: Critical events under anesthesia can cause sudden and dramatic complications. Recognition and analysis of such events helps to improve OR practices (in order to prevent recurrence of the same); thereby improving the overall quality of anesthetic practice. Unlike other countries which have national registries to capture such incidents, India relies on a voluntary and non-standard reporting of critical incidents under anesthesia. None of these papers have studied anesthesia-related complications in patients who have predominant renal dysfunction. *Materials and Methods:* A retrospective audit was performed of all critical incident reports filed in our department from 01/01/2015 to 31/12/2015. The data was analyzed to identify the incidence, causes and outcomes of these events. *Results*: Of 1217 anaesthetics administered, 2.54% of patients had reported adverse events during surgery. Most complications occurred in the elderly patients (41.9%) and those who were ASA grade III or above (45.1%). More than half (54.8%) of the complications involved the cardiovascular system. There were two deaths during this period (mortality=0.16%). *Conclusions*: Though anesthesia related complications have declined dramatically with the use of advanced monitoring and safer drugs, there is still potential for improvement. Use of checklists and standard protocols can help mitigate much of the human error associated with these critical events. The larger proportion of cardiovascular complications in our patients is probably a reflection of the higher incidence of cardiovascular complications in patients who have renal dysfunction.

Keywords: Critical Events; Critical Incident Reporting; Anaesthesia; Anaesthesia Mortality; Critical Incident Reporting Form; Renal Insufficiency Chronic.

Introduction

Patient safety is of prime importance for good patient care. This is especially important in areas which are vulnerable for adverse events like the operating room setup. In anesthesia there is interaction at three levels- human (anesthesiologist, patient), machines(monitors and workstations) and environment (operating room, surgeons and OR nurses)[1]. An error in one of these can tilt the balance leading to adverse event. Cooper et al in 1978 adopted the critical events recording in anesthesia similar to US Air force analysis of critical events [2,3].

Over the years with improvements in drugs available, newer monitoring devices and development of newer techniques, there is significant drop in anesthesia related mortality but it is still associated with significant morbidity and is concern for public health and can be significantly brought down [4,5]. The errors could be because of judgemental errors in patient management, deviation from set protocols or lack of help available [6]. Therefore critical incident monitoring in anesthesiology is an important tool to assess mishaps in the OR, recognise 'near-misses' and to identify areas for improvement in existing OR practices.

Most of the developed nations have national registry of critical incidents like American Quality

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Institute (AQI), Australian incident monitoring system (Australia), and National learning and reporting system (UK) but in India there is no such reporting system either at national and state levels. There are various studies published on critical incident reporting in anesthesia but there is no study of critical events in a nephro-urology setup.

With this in mind, we conducted a retrospective audit of our Critical Incident Forms (CIR) from January 1 to December 31, 2015. The data was analysed to identify incidence, predisposing factors and outcome of critical incidents in the OR.

Methods

As a part of our quality assurance programme Critical Incident reporting Forms(CIR) were filled and discussed in our monthly departmental meetings. We conducted a retrospective audit of our CIR forms from January 1st 2015 to December 31st 2015. As this was retrospective analysis and an observational study, consent from patient for study was waived.

A critical event was defined as "An event under anesthesia care which had the potential to lead to substantial negative outcome (ranging from increased length of hospital stay to death or permanent disability or cancelled operative procedure) if left to progress" [4,7].

Our hospital is a tertiary care referral centre catering to patients in nephrology and urology departments only; hence most patients coming to our OR have some degree of pre-existing renal impairment and may be categorised as ASA grade 3 and above.

Reporting of anesthesia adverse events is purely voluntary and reported by the anesthesiologist himself. As a part of our departmental quality assurance programme we have developed a Critical incident reporting Form (CIR) which includes demographic parameters age and sex of the patients. Other study parameters included are co morbidities, ASA grade, surgery planned, technique of anesthesia used, phase of occurrence of the complication, grade of severity of the complication, whether the complication was a result of anesthesia/ surgery/patient factors or multifactorial, management and outcome of the cases and strategies to prevent future occurrence.

The data was analysed to identify incidence, predisposing factors and outcome of critical incidents in the OR.

Results

During one year audit period from Jan 2015- Dec 2015, 1217 anesthetics were administered. The details of patient characteristics are listed in Table 1 and Figure 1.

Most of the critical events occurred in elective surgeries as compared to emergency surgery. Of a total of 1217 patients, 31 (2.54%) critical events were reported, with complete recovery in 28 (90.32%), permanent disability in 1 (3.22%) (Above knee amputation following graft thrombosis) and mortality in 2 (6.54%) patients. The severity of harm was graded according to Table 2. Both the patients who died in this period had been taken for emergency surgery. The critical events were seen predominantly in male patients(n=27, 87.09%) vs female patients (n=4, 12.09%). Maximum incidence was in the age group above 60 years (n=13, 41.93%); followed by those between 40-60 years (n=11, 35.48%) and then in the 0-20 age group (6.54%). Most of the critical events occurred in patients with ASA Grade 3 and above 45.16% (14/31), where as 32.25% (10/31) were ASA Grade 2 and 22.58% (7/31) were ASA Grade 1. Most of the events occurred in patients with pre-existing illness and who had multiple co morbidities, including type 2 diabetes mellitus (DM), essential hypertension, chronic kidney disease (CKD) on maintenance hemodialysis, ischemic heart disease with or without Percutaneous transcoronary Angioplasty (PTCA), patients on anticoagulant therapy etc.

Maximum number of complications were related to the cardiovascular system-54.83% (17/31). The cardiovascular complications most frequently seen were hypotension, hypertension,bradycardia and arrhythmias.The others included airway related complications, pulmonary complications such as respiratory depression, pulmonary edema, laryngospasm. Other complications seen were disseminated intravascular coagulopathy (DIC) and drug reactions. These are tabulated in Figure 2.

One surgery had to be postponed—a patient who needed a biopsy of oral tumour could not be intubated as there was extension of growth in tonsillar fossa and vallecula. Laryngeal Mask Airway (LMA) was placed and patient was ventilated, later he was reversed from anesthesia and was referred to higher centre for further management.

Incidents occurred more frequently in patients who received general anesthetic 58.06% (18/31) as compared to 41.93 %(13/31) in patients who received regional anesthesia.

According to phase of occurrence of critical events, maximum events 45.16% occurred in intra-operative phase, 25.80% occurred during induction while 16.12% were seen in post-operative period (Figure 3). Critical events and mortality were correlated with factors attributable to patient or anesthesia, surgery or multifactorial. Out of 31 events maximum 45.16% were attributable to anesthesia, 22.58% were due to surgery related while 25.80% events were due to patients pre-existing condition while 16.12% were due to more than one factor. 90.32% critical events occurred in elective surgeries as compared to 9.67% in emergency surgery.

Table 1: Characteristics of Critical Event

		No. of Patients	Percentage (%)
Age	0-20	2	6.45%
	21-40	5	16.12%
	41-60	11	35.48%
	60 and above	13	41.93%
Gender	Male	27	87.09%
	Female	4	12.90%
ASA Grading	ASA Gr 1	7	22.58%
	ASA Gr 2	10	32.25%
	ASA Gr 3 & above	14	45.16%
Type of Surgery	Elective	28	90.32%
	Emergency	3	9.67%

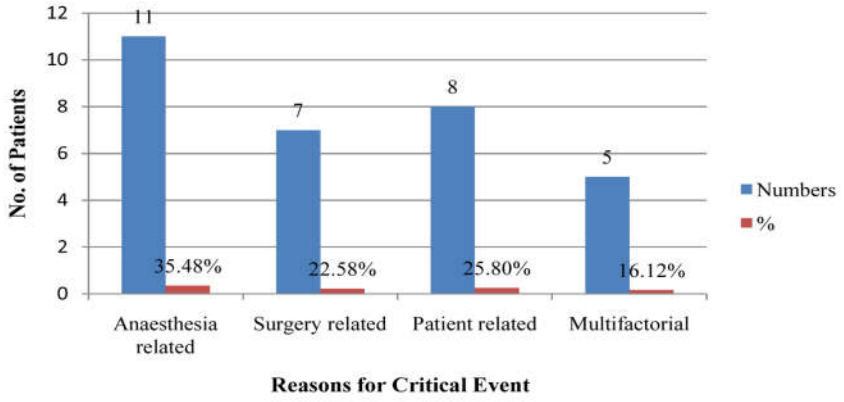

Fig. 1: Analysis of Critical events

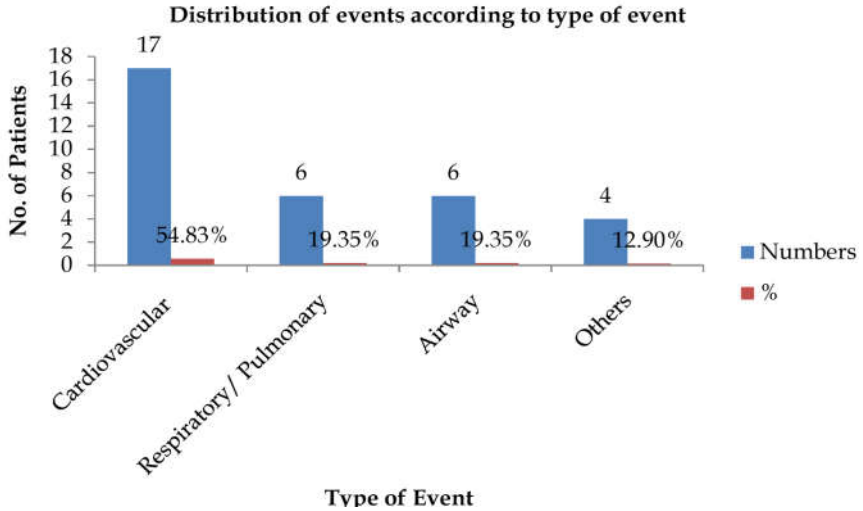

Fig. 2: Type of critical events

Table 2: Severity of Harm

Grading	Description	No. of Patients	Percentage (%)
Grade 1	Transient abnormality unnoticed by patient	2	6.40%
Grade 2	Transient abnormality with full recovery	24	77.41%
Grade 3	Potentially permanent not disabling	1	3.22%
Grade 4	Potentially permanent disabling damage	1	3.22%
Grade 5	Death	2	6.40%

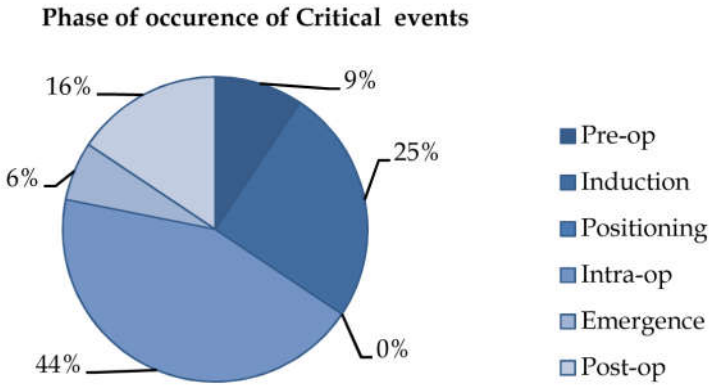

Fig. 3: Phase of occurence of Critical events

Discussion

One of the important components of patient safety movement is to analyse and learn from adverse events and near misses [8]. Anesthesia draws a parallel with aviation industry in adapting its incident reporting system (Cooper et al 1978). Recording and audit of critical incidents in anesthesia department helps in bringing out changes in prevalent practice and protocols, to improve the standards of anesthesia care and thus helping in designing policies to prevent their recurrences [8-11].

Anesthesia related critical events get obscured by various factors like skill of the operating surgeons, complexity of surgery and the patient condition.

The total complications in our hospital were 2.54%.The incidents reported from different institutions varies from 0.28%to 2.8% [12,13], while higher incidence of 12.1% [14] and 10.6% [15] have been also reported. Our centre being a tertiary care and a standalone nephro-urology set up, we deal with patients with multiple co morbidities and most of our patients are ASA Grade 3 [14,16] and above, which may in itself explain the higher incidence of critical events.

Slightly higher incidence of critical events [14] and mortality [9,16] is seen in emergency surgeries as compared to elective surgeries. In our audit 58.06% of critical events were seen in general anesthesia as compared to regional techniques which is similar to most of the studies published [15,16]. Interestingly, however, both the mortalities occurred in patients who were taken up for emergency surgeries and had received regional anesthesia/IV sedation. This could be because of the fact that they were ASA grade 4 & 5 respectively, with multiple co morbidities; hence regional techniques were preferred in them.

Critical events mostly occurred during day time in our hospital similar to other study [16].

Operating room is observed as a vulnerable site for occurrence of critical events [7,16]. Like aviation industry, take off and landing are considered as critical time period similarly in anesthesia induction and reversal periods are considered to be incident rich [5,16] but we found higher events in intra-operative period as compared to induction and post-operative phase which is similar to other studies [12,13,16]. Factors responsible for critical events were analysed and were categorised as anesthesia related, surgery related, patient related or multifactorial. We found anesthesia related critical events were 35.48% and more seen in induction and emergence phase which are similar to other studies [2,3,7]. Surgery related factors were mostly bleeding and in one case of pheochromocytoma, tumor handling lead to hemodynamic disturbances.

Critical events related to airway management have been found to be 17-34% [12,13,14]. A quarter of anesthesia related deaths have been associated with airway management. The airway and respiratory complications seen in our institute were pulmonary edema (as CKD patients are prone for fluid overload), respiratory depression due to morphine, LMA slippage , laryngospasm and difficult airway. But in our institute we found higher incidence of cardiovascular complications as similar to Manghani et al in their article in 2004 [7]. This is likely because most of our patient population has CKD associated morbidity [17].

Independent predictors of operative mortality cited in literature include advanced and pediatric age group as well as male gender. This should be correlated to the fact that in audit period; of total anesthetics administered, 71.73% (873/1217) were in male patients [11,18].

Many variables (patient status, surgical procedure, and surgical expertise) make the delineation of anesthesia related factors obscure. Of the total critical events, 35.48% (11/31) of the complications were purely anesthesia related; 22.58% (7/31) events were surgery related while 25.80% were due to patient related complications.

Recent studies define anesthesia mortality as death under, as a result of, or within 24 hours of anesthetic administration. In literature, crude anesthesia mortality (i.e. combined anesthetic and surgical mortality) ranges between 10-30/10,000 [19,20] anesthetics. In our audit we found crude anesthesia mortality as 16.4 per 10,000 anesthetic. In most developed countries, anesthesia mortality ranges between 0.12-1.4 per 10,000 anesthetics [21] while in our institution the anesthesia mortality was 8.2 per 10,000 anesthetics which is higher than the developed countries. The reasons for higher mortality rates is likely because most of our patients have CKD associated comorbidities and are sicker.

Conclusion

Complications related to anesthesia have reduced dramatically over the decades from 1978; when Cooper et al introduced the first critical incident analysis of preventable anesthesia related mishaps but still anesthesia remains to be associated with morbidity and mortality. Use of checklists in OR, protocols and increased awareness among anesthesiologists about critical incidents and their reporting can improve the quality of anesthesia care delivered. As reporting of critical events is voluntary, under reporting of critical events can be of concern.

In our institution, majority of critical events were related to cardiovascular system , preoperative optimization and risk stratification of all these patients prior to surgery is very important.

In view of the fact that human error is the single most important factor in the majority of these incidents, we suggest that policies and protocols be adhered to and updating knowledge base to avoid errors. That however is not a reason for complacency. Such incidents continue to occur as the specialty now caters to sicker patients who require more complicated surgeries. The complications which occurred purely due to anesthesia are preventable with the use of thorough preoperative optimisation and better equipment for monitoring and airway management. Safety does not happen by accident it requires teamwork.

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Comparison of Haemodynamic Changes with or without Leg Elevation in Elective LSCS under Spinal Anaesthesia

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Abstract

Background: Spinal blockade provides excellent anaesthesia for patients undergoing lower segment cesarean section (LSCS). However hypotension after spinal anaesthesia is a common adverse effect that is commonly experienced in patients undergoing cesarean section. So our aim is to analyze a simple technique like leg elevation for decreasing the incidence of post spinal hypotension and vasopressor requirement in parturients undergoing cesarean section under spinal anesthesia. *Materials and Methods*: Sixty full term patients posted for elective cesarean section belonging to ASAI and II were divided into two groups. Patients preloaded with Ringer lactate at 10 ml/ kg prior to the spinal anesthesia. Spinal anesthesia was given with 0.5% Bupivacaine heavy 2ml. Patients in Group C lower limbs will not be raised and in Group LE will have their legs elevated at 30° with two pillows underneath the calf muscles after spinal anesthesia. The hemodynamic parameters were monitored every 3 minutes until the delivery of the baby and every 5 minutes till the end of surgery. If hypotension occurred, then along with crystalloid loading a bolus dose of inj Mephentermine 6 mg was given. *Result:* Incidence of hypotension in Group C (46.6 %) was significantly more compared to group LE (23.3%). Dose requirement of vasopressor was also significantly less in Group LE. *Conclusion:* Legs elevated with two pillows underneath the calf muscles was the simple ,easiest and effective method of controlling post spinal hypotension in caesarean patients and needs to be practiced routinely.

Keywords: Postspinal Hypotension; LSCS; Leg Elevation; Vasopressor.

Introduction

Spinal anaesthesia has increasingly became the technique of choice for LSCS and use of general anaesthesia has drastically decreased [1]. Risk of general anaesthesia includes failed endotracheal intubation, failed ventilation, aspiration pneumonitis, postoperative nausea, vomiting and neonatal depression [2,3]. Spinal anaesthesia has the advantage of simplicity of technique [4,5], rapid onset of action and provide excellent anaesthesia. It is associated with adverse effects like hypotension with incidence up to 60-70%. Hypotension depends on level of block achieved [6]. The common methods used to prevent hypotension are preloading with crystalloids or colloids, use of wedge below right hip, use of vasopressors and mechanical compression devices [7]. Current techniques used for prevention of hypotension are fluid and vasopressor administration like ephedrine, phenylephrine and mephentermine. Vasopressors have adverse effects such as anaphylaxis, hypertension, tachyphylaxis and cardiac dysrhythmias [8,9]. Uncontrolled use can even lead to impaired uteroplacental circulation caused by vasoconstriction [10,11].

Non pharmacological simple and cost effective technique of leg elevation with pillows found to be comparable with use of vasopressor in prevention of post spinal hypotension in cesarean patients. It is not only devoid of any side effect and can be used

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on a daily basis to prevent hypotension. So far limited evidence toward its likelihood of being effective, easy and safe [12,13]. In this study we evaluated the efficacy of leg elevation with two pillows under the calf in order to minimize hypotension in cesarean section under spinal anaesthesia.

Materials and Methods

A prospective, randomized study design with two parallel groups was used. After prior approval of institutional ethics committee study was conducted in 60 full term parturients of ASA I and II booked for elective LSCS. Informed consent was obtained from all the parturients. Exclusion criteria was ASA III and more, patients with known sensitivity to local anaesthestics, coagulopathies, patient not willing to be a part of study and any contraindication for spinal anaesthesia.

Randomization was done using computer generated random number table.

Group C (non leg elevation) (n=30)

Group LE (leg elevation) (n=30)

All patients were subjected to pre anaesthetic evaluation with relevant laboratory investigation, they were counseled with regards to spinal anaesthesia and leg elevation as well as operative procedure. Demographic profile like age, height, weight, gestational age was recorded. All patients were kept fasting for 8 hours prior to surgery, for all patients an IV line secured using 20G intracath in left forearm. All patients received inj. ranitidine 50 mg and inj. metaclopromide 10 mg IV 30 min prior to the cesarean section. Baseline blood pressure and heart rate were measured in supine with left wedge position. Baseline values were taken as the average of three successive readings, preloading was done with 10ml/kg of ringer lactate solution prior to spinal anaesthesia.

Under all aspetic precautions spinal anaesthesia was performed in sitting position using a 26 G quinckes needle in L3-L4 or L4-L5 inter space through midline approach . All patients received 2 ml of 0.5% hyperbaric bupivacaine intrathecally. Patients were monitored by anaesthesiologist who was unaware of the groups.

In Group C patients lower limbs were not raised, but they were simply covered to hide them from anaesthesiolgist recording hemodynamic parameters. In Group LE patient legs were elevated at 30 degree with two pillows underneath calf muscles immediately after spinal anaesthesia and covered with drapes.

Fluid replacement was maintained with ringer lactate solution. 20 units of oxytocin was given as iv infusion after delivery of baby. ECG and SPO2 were monitored continuously and heart rate and NIBP measured every 3 min for first 15 min and every 5 min thereafter till end of surgery. Duration of surgery, the level of block achieved and blood loss monitored.

Hypotension was defined as fall in systolic blood pressure to > 20% of base line and immediately treated by increased rate of IV ringer lactate and by bolus of 6mg of inj. mephentermine. Parameters were recorded in a specially prepared proforma.

All data collected was evaluated statistically using statistical software. All quantitative data such as age, weight, height, duration of surgery, vasopressor requirement was expressed as mean +/- standard deviation. Unpaired students t test was used for quantitative data analysis and chi square for qualitative data analysis. $P < 0.05$ was taken as significant.

Results

Sixty patients were entered in the study from which 2 patients had an inadequate block which had converted to general anaesthesia & were excluded from study. The remaining 29 patients in each group were matched for age, weight, height, gestational age & ASA grade (Table 1). No significant difference was found. There was no difference in the groups with respect to duration of surgery, level of sensory block achieved & intraoperative blood loss.

Table 1: Comparison of demographic data between group C and group LE

Parameter	Group C	Group LE	P value	Significance
Age (Years)	52.9 ± 8.35	48.96 ± 11.9	0.07151	Not Significant
Weight (Kg)	62.9 ± 6.5	63.9 ± 6.9	0.55	Not Significant
Gender (M:F)	17:13	16:14	-	-
ASA Grading	Grade I- 22 Grade II- 8	Grade I- 23 Grade II- 9	-	-
Gestational Age	39.22 ± 0.73	39.13 ± 0.61	0.623983	Not Significant

There was no significant difference in HR between the two groups after spinal anaesthesia (Figure 1).

There was a significant decrease in MAP at 3, 6, 9, 12, 15 and 25 min in control group. The leg elevation group had decrease in MAP at 3, 6 min after spinal anaesthesia & thereafter it remained higher throughout the measured interval (Figure 2).

Vasopressor requirement per patient was significantly high in group C as compared to group LE. In group C, 14 patients (46.6%) developed hypotension and in group LE only 7 patients (23.3%) developed hypotension. There is significant difference in incidence of hypotension between two groups (Table 2).

Table 2: Vasopressor requirement in two groups

	Group C (n=29)	Group LE n=29)	P value	Significance
Number of patients required vasopressor (%)	14(46.6%)	7(23.3%)	0.0495939	Significant
Mean vasopressor requirement per patient (mg)	3.766667	1.580645	0.037397	Significant

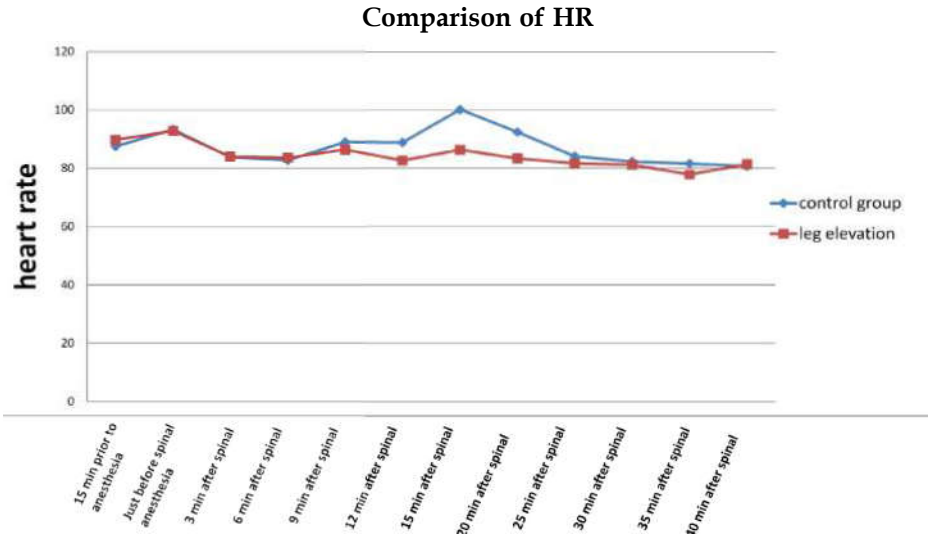

Fig. 1: Comparison of Heart rate between group C and group LE

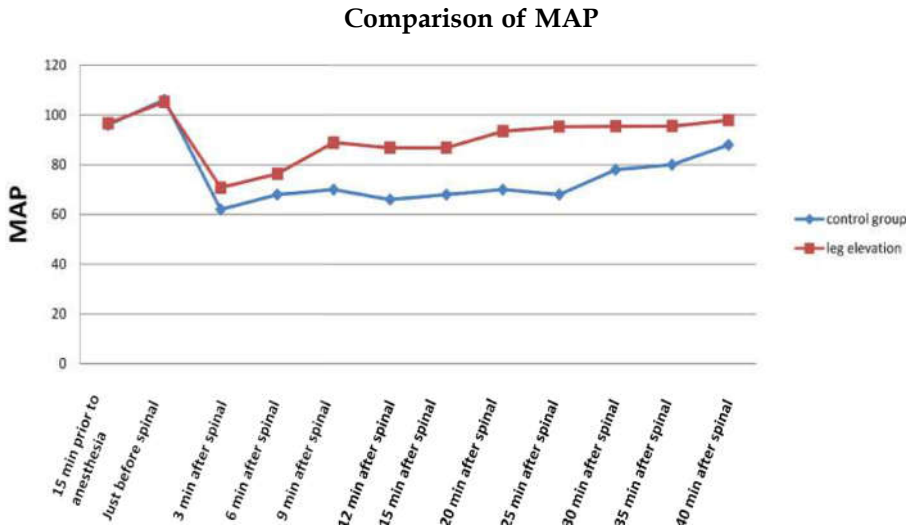

Fig. 2: Comparison of Mean arterial blood pressure (MAP) between group C and group LE

Discussion

Spinal anaesthesia is the safest regional anaesthesia technique for LSCS. Spinal anaesthesia is preferred as it allows the mother to be awake & interact immediately with her baby. But commonly associated adverse reaction with spinal anaesthesia is hypotension. Hypotension is caused by an increase in venous capacitance because of sympathectomy causing vasodilatation in the lower part of body. This decrease in arteriolar & venous tone secondary to sympathetic block causes a reduction in systemic vascular resistance & redistribution of central blood up to 500-600ml to peripheral compartment. The situation is further aggravated in pregnancy by aortocaval compression [14]. This aortocaval compression decreased by uterine displacement by placing wedge under the right buttock. Prolonged maternal hypotension leads to decrease in utero-placental blood flow which is detrimental to fetus & leads to decrease in Apgar Score [15].

Various techniques are in practice to prevent hypotension which include fluid preloading, lateral tilt, use of vasopressor like ephedrine, mephentermine or phenylephrine and use of mechanical interventions like esmarch bandages, compression leg stockings, crepe bandages which increase central blood flow but there is no ideal established method [16,17].

The ideal fluid for preloading is a matter of debate. Crystalloid fluid is cheaper but less effective when used alone. Colloid fluids are more reliable to prevent post spinal hypotension but they are costly, possibility of anaphylactic reactions & risk of excessive volume expansion causing pulmonary edema. Vasopressor has known adverse effects like tachycardia, arrhythmias. Though they increase mean arterial blood pressure, but their effect on neonatal outcome is debatable [16].

We therefore studied simple technique of leg elevation using two pillows underneath the calf muscle immediately after spinal anaesthesia to decrease the incidence & severity of hypotension. The advantage of raising legs immediately after spinal injection is that it increases venous return and cardiac output & hence decreasing the requirement of vasopressors .In group C 46.6% patients had hypotension as compared to group LE 23.3%. There was a significant decrease in MAP in group C as compared to group LE; results found in our study differed from pout et al findings who reported no advantage for patients leg elevation on the incidence of hypotension.

Although the incidence of hypotension was lower with leg elevated group (46.6% Vs 23.3%), also mephentermine consumption was significantly low in LE group. In leg elevated patients there was auto transfusion of blood from lower extremities to the central circulation; thus leg elevation increases the cardiac preload & consequently the cardiac output [4,5]. Which helps in decreasing the incidence of hypotension.

A previous study using radio-labeled erythrocytes reported a reduction of 34±4% in counts from the radiolabeled intravascular spacer from the calves following leg elevation that is corresponding to about 150 ml [18]. Although the volume transported during leg elevation is not large, we assume that it is quite effective in decreasing the incidence and severity of post spinal hypotension.

Our findings give a simple, rapid & cost effective method for prevention of spinal hypotension without affecting the level of spinal block. In our study leg elevation had a moderate effect that produced a significant but not huge reduction in incidence of post spinal hypotension.

Conclusion

We conclude that legs elevated with two pillows underneath the calf muscles is the simple, easiest and effective method of controlling post spinal hypotension in caesarean patients by preventing the pooling of central blood in to the lower limbs. It results in less reduction in blood pressure and needs to be practiced routinely.

Limitations

The sample size was small for more accuracy, study need to be conducted with larger sample size. We did not study changes in cardiac output due to leg elevation, as cardiac output is a better indicator of uteroplacental blood flow than upper arm blood pressure measurement. The incidence of Post Spinal Hypotension (PSH) is still high with most of the available prophylactic measures; thus combination of leg elevation with other pharmacological and non pharmacological approaches for more effective prevention of PSH during LSCS.

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Prevention of Propofol Injection Pain: A Comparison between Ondansetron, Dexamethasone and Lidocaine

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Abstract

Introduction: Propofol (2,6 di-isopropyl phenol) is widely used agent for induction of anaesthesia, although the pain during its injection remains a concern for all anaesthesiologists. The incidence of Propofol injection pain (PIP) varies between 28% to 90% in adults. Despite several interventions and pretreatment with drugs to alleviate pain, the failure rate is 13-32%. The aim of this study was to find the most efficacious method of alleviating PIP by combining intervention of venous occlusion along with Lignocaine, Dexamethasone or Ondansetron pretreatment. *Methods:* This is a double blinded randomized prospective clinical study on adult patients between the age group of 18-59 years scheduled for elective general surgical procedures. 150 patients were randomly allocated through computer generated table into three groups scheduled to receive 2ml of Lignocaine (20mg), Ondansetron (4mg) or Dexamethasone (6mg). Drugs were administered after tourniquet application inflated to 40mm Hg and occlusion was released after 30 seconds and then 0.5mg/kg of propofol was administered at the rate of 0.5ml / sec. The blinded investigator evaluated the pain score using the four point scale at 15 second interval. Statistical analysis was made by SPSS version 16. *Results:* The incidence and intensity of pain in patients receiving Lidocaine and Dexamethasone were significantly lower than those receiving Ondansetron ($p<0.001$). *Conclusion:* Pretreatment with intravenous Dexamethasone and Lidocaine along with venous occlusion for 30 seconds was found to be equally effective in reducing Propofol injection pain. Both these drugs were found to be superior to Ondansetron in achieving this goal.

Keywords: Propofol; Ondansetron; Dexamethasone; Lidocaine; Pain; Injection.

Introduction

Propofol is the most popular intravenous anesthetic agent. But the concern to all anaesthesiologists is the pain on its bolus dose injection. The incidence of Propofol injection pain (PIP) varies between 28% to 90% in adults if a vein on dorsum of hand is used [1]. A number of pharmacological and non-pharmacological approaches have been tried but have failed to find its remedy with just one intervention in all patients.

Individually Dexamethasone, Ondansetron and Lidocaine have been used as pre-treatment to alleviate PIP [2,3,4]. Due to paucity of data comparing these drugs and identifying the best among these three drugs along with venous occlusion to reduce the incidence of PIP, we did this study.

Materials and Methods

After obtaining Ethical committee clearance, all consenting patients who were posted to undergo elective surgical procedures under general anesthesia at St Johns Medical College hospital from October 2017 to January 2018 were enrolled for the study. A

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double blinded randomized prospective clinical study was done in adult patients between the age group of 18-59 yrs. 150 patients belonging to American society of Anesthesiologists (ASA) Physical Status I and II class were randomly allocated through computer generated table into three groups scheduled to receive study drug in a 2ml syringe. Group 1 received pretreatment with Ondansetron (4mg diluted to 2ml), Group 2 received pretreatment with Lignocaine (20 mg of 2% solution diluted to 2ml) and Group 3 received Dexamethasone (6mg diluted to 2ml). A written informed consent was taken from the patients for participation in the study. Patients having problems in communication, requiring rapid sequence induction and history of allergic response to either propofol or 5HT 3 antagonists, patients on medications with pain modifying drugs, with small caliber veins, pregnant or lactating patients were excluded from this study. As per standard practice, all patients were thoroughly examined clinically and pre anesthetic checkup was done. Airway was assessed using modified Mallampati classification. Patient were instructed to be NPO (nil per oral) pre-operatively for 6 hours. They were pre-medicated with Tab Alprazolam 0.5mg and Tab Ranitidine 150mg night before surgery. On arrival to operation theatre, baseline vital parameters-Blood pressure, heart rate (EKG) and oxygen saturation (SpO2) were recorded. A 20G intravenous access was secured on the largest vein on the dorsum of the non-dominant hand and lactated Ringer's solution was infused.

After limb elevation for 15 sec, venous drainage was occluded by placing a tourniquet inflated to 40 mm Hg. The study drug consisting of 2ml of Lignocaine (20mg), Ondansetron (4mg) or Dexamethasone (6mg) stored at room temperature was administered by a consultant anesthesiologist who was blinded to the drug. Tourniquet was deflated after 30 seconds and then 0.5mg/kg of Propofol (Neorof 1% from Neon laboratories) was administered at the rate of 0.5ml/sec. The intensity of pain was assessed by a second anesthesiologist who was unaware of the group to which the patient had been allocated. Although visual analogue scale (VAS) is the reference standard for measuring acute pain, it has practical limitation in its use, particularly in this setting because the pain in this study was measured just before patient lost consciousness, so we decided to use verbal rating scale which is relatively easy to use and simple to respond compared to VAS. Assessment included standard questions asked to the patient about the comfort of the injection, verbal response and behavioral signs (such as facial grimacing, arm withdrawal or tears from the eyes). Pain was graded using a four point scale which is called the Mc Crirrick and Hunter pain intensity scale.

Mc Crirrick and Hunter pain intensity scale

Pain Score	Degree of Pain	Response
0	None	Negative response to pain
1	Mild	pain reported only in response to questioning without any behavioral signs
2	Moderate	pain reported in response to questioning and accompanied by a behavioral sign or pain reported spontaneously without questioning
3	Severe	Strong vocal response or response accompanied by facial grimacing, arm withdrawal or tears.

Later anesthesia was induced with intravenous Fentanyl 2µg/kg and Propofol 2mg/kg. Tracheal intubation was facilitated with Injection Atracurium and anesthesia was maintained with Isoflurane. Hemodynamic parameters were monitored. In the post-operative period, the trachea was extubated and patients were assessed for pain, swelling or allergic reaction at the site of injection by a blinded anesthesiologist.

Statistical Analysis

Considering previous studies, the incidence of PIP was assumed as 80% and 50% reduction was considered significant. Based on the alpha value of 0.05 and a power value of 80%, our study required at least 41 patients per group. Assuming drop-outs, the sample size was increased to 50 per group. Continuous data are reported as mean±standard deviation. Categorical data were analyzed using Chi-square test. Since measurements for pain are in scores, non- parametric methods were used for analysis. Kruskal-Walli's ANOVA was used for multiple group comparisons followed by Mann-Whithey U test for group wise comparison. A $p < 0.05$ or less was considered for statistical significance. SPSS version 16 software was used for analysis.

Results

There were no significant difference in demographic characteristics between the three groups (Table 1). No incidence of pain or discomfort was reported during the injection of pre-treatment solution in any group. The overall incidence of pain was 22% in lidocaine group, 66% in Ondansetron group and 34% in Dexamethasone group as shown in figure 1. The average pain scores expressed as Mean±SD pain score in Group 1 was 0.9±0.8, Group 2 was 0.2±0.4 and Group 3 was 0.3±0.5 as depicted in Table 2. The incidence of pain was significantly less ($p < 0.001$) in patients receiving lidocaine and dexamethasone than those receiving Ondansetron (Table 3).

Moderate to severe pain was seen in 66% of study population in Ondansetron group compared to 22% in lidocaine group and 34% in dexamethasone group which was statistically significant ($p<0.001$). The difference in moderate to severe pain between lidocaine and dexamethasone groups was not statistically significant as shown in Table 3 ($p = 0.18$).

Table 1: Subjects information

		Gr 1 Ondansetron	Gr 2 Lignocaine	Gr 3 Dexamethasone	Significance
No. of cases		50	50	50	-
Age (Yrs)	Mean ± SD	39.8 ± 12.0	40.4 ± 12.4	37.9 ± 11.9	ANOVA, F = 0.62,
	Range	19 - 59	18 - 59	22 - 59	P =0.54,NS
Sex	M	26	31	25	$X^2 = 1.67$,
	F	24	19	25	P=0.43, NS

Demographic data of the patients in all the three groups. Gr-Group, No-Number, yrs-Years, SD- Standard Deviation, NS-No Significance

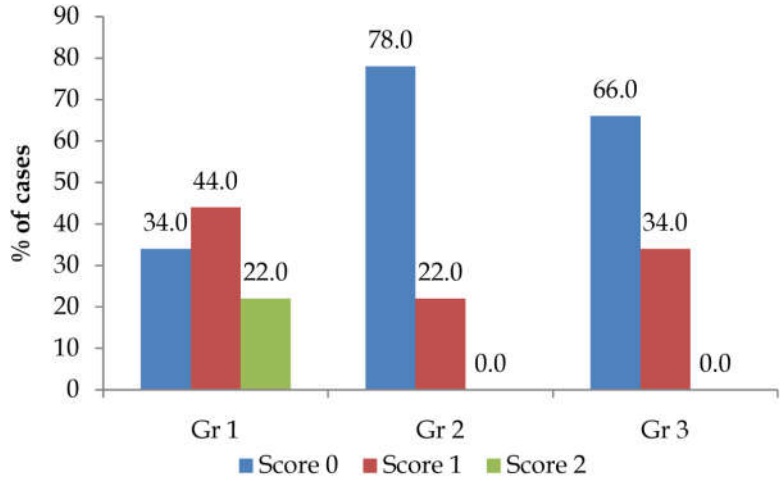

Fig. 1: Percentage distribution of cases in three groups with corresponding pain score
Group 1- Ondansetron, Group 2-Lidocaine, Group 3- Dexamethasone

Table 2: Comparison of Pain scores

Groups	Pain score Mean ± SD	Median	Range
Gr 1	0.9 ± 0.8	1	0 - 2
Gr 2	0.2 ± 0.4	0	0 - 1
Gr 3	0.3 ± 0.5	0	0 - 1

Kruskal-Walli's ANOVA, $\chi^2 = 26.92$, $p < 0.001$, HS

Group wise comparison of the pain scores.
Group 1- Ondansetron, Group 2-Lidocaine, Group 3- Dexamethasone
Gr-Group, SD-Standard Deviation, HS- High Significance.

Table 3: Groupwise comparisons*

Groups compared	P value	Significance
1 v/s 2	< 0.001	HS
1 v/s 3	< 0.001	HS
2 v/s 3	0.18	NS

Mann-Whitney's Test
Intergroup comparison. Group 1- Ondansetron, Group 2-Lidocaine, Group 3- Dexamethasone
HS-High significance, NS-No Significance.

Discussion

Patient satisfaction in perioperative care setting is assuming more importance in recent years. With the development and improvement of surgical and anesthetic techniques, critical incidents like cardiac arrest or death during peri-operative period have been obviously minimized. Thus more attempts have been made to address minor but potentially distressing clinical anesthetic problems such as pain, post-operative nausea and vomiting (PONV) to further improve the quality of anesthetic care. PIP is one such intriguing problem and the quality of pain is described as extremely sharp, aching or burning. The incidence of pain with intravenous Propofol varies between 28% to 90% in adults [1] if a vein on dorsum of hand is used. Most patients remember it as one of the unpleasant encounters with anaesthetists. It has been arranged as the seventh most important problem in current practise of clinical anaesthesia by American society of Anaesthesiologist [5].

Many factors appears to affect the incidence of pain, which includes site of injection, size of the vein, varying speed of injection and carrier fluid, buffering effect of blood, temperature of propofol and concomitant use of drugs such as local anaesthetic, antiemetics, ketamine, magnesium and opioids [6,7]. Despite several interventions and pretreatment with drugs, the failure rate is 13-32% [8]. Considering the extensive use of propofol in clinical practice, the pain frequently reported on induction of anesthesia cannot be neglected.

Propofol belongs to group of sterically hindered phenol that can irritate the skin, mucous membrane and venous intima. PIP can be immediate or delayed. The immediate pain could be the results of a direct irritant effect, but the Kallikrein-kinin cascade is probably the cause of delayed pain [9]. Peripheral veins are innervated with polymodal nociceptors, which mediate the pain response to the injection of certain anesthetic agents like Propofol. Scott et al speculated that the pain on injection is caused by activation of Kallikrein-kinin system either by Propofol or the lipid solvent, there by generating kinins probably bradykinin [10].

Bradykinin, by producing local vasodilatation and hyperpermiability, may increase the contact between the aqueous phase Propofol and the free nerve ending involving myelinated Aδ fibres [11], resulting in pain of injection. This pain has latency of 10-20 seconds in onset.

Several methods for prevention of pain have been tried with varying degree of success, with lidocaine pretreatment being the most commonly used [12,13]. Analgesic effects of lignocaine may occur because of local anesthetic effect or an inhibitory effect on the enzymatic cascade which leads to release of kinins. However literature reports the failure rate between 13-23% [14]. Also it is reported that addition of lidocaine may destabilize the emulsion formulation of Propofol with a potential risk of causing pulmonary fat embolism along with risk of bacterial contamination or anaphylaxis [16]. Hence, the search for a drug which can alleviate PIP completely is a need for all anesthesiologists.

There are fewer studies on the use of pretreatment with steroid based drug and anti-emetics like Ondansetron for amelioration of PIP, hence, we performed this study. We combined the use of pre-treatment of drugs along with interventions like venous occlusion using a tourniquet raised to 40 mmHg [16]. Since the incidence of PIP being as high as 80% it was deemed unethical to inject this drug with saline as pretreatment, hence we decided to compare the efficacy of commonly used antiemetics drugs like Ondansetron and Dexamethasone with Lidocaine which is the most commonly used pretreatment to alleviate PIP.

In this study, we found the overall incidence of moderate to severe pain was 66% in Ondansetron group (Group 1) whereas in the Lignocaine group (Group 2) and Dexamethasone group (Group 3), patients experienced only moderate pain with the incidence being 22% and 34% respectively. No patients in either group experienced severe pain.

Ondansetron, a specific (5HT3) 5-hydroxytryptamine receptor antagonist, is a routinely used anti-emetic drug which is demonstrated to provide relief from PIP [17]. Its action is proposed to be multifaceted as a Na channel blocker and (mu) μ opioid agonist. Thus Ondansetron pretreatment may be used to reduce the incidence of PIP with an added advantage of prevention of PONV. Previous studies have demonstrated Ondansetron to be 15 times more potent than lignocaine [18] and also they have found it to be as effective as Tramadol [19].

Similar to the study done by Sumalatha et al, We found that Ondansetron was less effective when compared to Lidocaine [4] and Dexamethasone with an incidence of moderate to severe pain being about 66%. When compared to Lignocaine and Dexamethasone, patients in the Ondansetron group experienced more pain which was statistically significant ($p<0.001$).

Dexamethasone is a commonly used glucocorticoid, which is proven to minimize post-operative pain and nausea/vomiting without any increase in infection or altered hyperglycemic response in the postoperative period [3]. It is demonstrated the dexamethasone reduces the nitric oxide production associated with PIP. Although both these drugs are individually found to relive propofol injection pain, there are no studies comparing the effects of pretreatment of these drugs with Lignocaine. In a study done previously they found the incidence of PIP after Dexamethasone pretreatment was 31% with moderate to severe pain noted in 17.14% [20].

We found the incidence of moderate pain to be 34% which is similar to previous study done by Singh et al. Also we found that Dexamethasone was as effective as Lignocaine in alleviating PIP. The pain scores comparison in Lignocaine was 0.2±0.4 with a Median of 0 and that of Dexamethasone was 0.3±0.5 with a Median of 0. Group wise comparisons of these two groups were found to be statistically insignificant.

Pretreatment with Dexamethasone 6mg and Lidocaine 40mg along with venous occlusion was associated with significant reduction of Propofol injection pain when compared to Ondansetron 4mg. These drugs are routinely used and are cost effective, thus seems to be the most pragmatic option for preventing PIP. This effective and convenient method allows the clinician to use routinely available drugs and avoids delay in busy operating room schedules. In our study pretreatment was administered 30 seconds prior to the administration of Propofol which may be a short contact time. We believe that with higher contact time of about 60 seconds, the incidence of PIP can be reduced further [12,21].

Thus this technique is useful in elective surgery with an added advantage of prevention of post-operative nausea and vomiting.

Conclusion

A multimodal approach, combining intervention like venous occlusion and pretreatment with drugs should be routinely used to eliminate Propofol injection pain. The analgesic efficacy of Ondansetron is less effective in preventing PIP in comparison to Lidocaine and Dexamethasone. Dexamethasone given as a pretreatment before Propofol is as effective as Lignocaine in preventing PIP along with an added advantage of preventing post-operative nausea and vomiting.

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Comparision of Intubating Conditions at 60 Seconds with Different Doses of Rocuronium Using the Train of Four Monitoring

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Abstract

Objective: To evaluate the intubating conditions with rocuronium at 0.6mg/kg (2*ED95) and 0.9mg/kg (3*ED95) at 60 seconds using the timing principle. *Methods*: 60 patients were divided into 2 groups of 30 each. Group A received 0.9mg/kg and group B received 0.6mg/kg of rocuronium. Intubation was done at 60 s. The Train of four monitoring was done at the adductor pollicis muscle. The TOF count at intubation and time to loss of TOF were noted and compared. *Results*: Intubating conditions were excellent 13 (65%) in group A compared to 9 (45%) in group B and was statistically significant. The TOF count at intubation was not statistically significant (p=0.677) between the groups where as time to loss of TOF (p=0.03) were significant between the groups. *Conclusion*: Intubating conditions were better in group A in comparision with group B but both the groups provided clinically acceptable conditions for intubation. The use of train of four count at the adductor pollicis as a guide for laryngeal muscle paralysis is questionable.

Keywords: Rocuronium; Train of Four; Intubating Conditions.

Introduction

A rapid sequence induction of anaesthesia and endotracheal intubation are indicated in emergency situations in the presence of full stomach or conditions with increased risk of aspiration.

The ease with which endotracheal intubation is performed depends upon degree of muscle relaxation, depth of anaesthesia and skill of anaesthesiologists.

Succinyl choline has been for a long time the NMBD (Neuro muscular blocking drug) of choice for RSII (Rapid sequence induction and intubation), because of the quick onset along with excellent intubating conditions. However it is desirable to look for an alternative due to its side effect profile.

Rocuronium bromide, a non depolarising neuromuscular blocking drug has a faster onset of action with a stable hemodynamic profile. The TOF(Train of Four) pattern of twitch stimulation was developed in 1970 by Ali [1] and colleagues, in an attempt to provide a clinical tool to assess neuromuscular block in the anaesthetized patient. The pattern involved stimulating the ulnar nerve with a TOF supramaximal twitch stimuli, with a frequency of 2 Hz, that is, four stimuli each separated by 0.5 s. The TOF was then repeated every 10 s [2].

When a non-depolarizing agent is given, a typical pattern is observed. The number of twitches (TOF count) correlates with the degree of neuromuscular block.

With this basic knowledge in our study we evaluate the intubating conditions with rocuronium at 0.6mg/kg (2*ED95) and 0.9mg/kg (3*ED95) at 60 seconds using train of four monitoring.

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Materials and Methods

Study Area

Department of Anaesthesiology, SSIMS-RC, Davangere.

Study Population

Adult general anaesthesia cases in ENT OT.

Study Duration: 2 months (June-July 2017)

Sample Size

Based on the proportions taken from the previous study [3] sample size was estimated using appropriate formula and power of the study to be 80% and 95% significance level. And the total calculated sample size was 20 in each group.

Randomisation

Cases were randomly allocated to 2 groups by using block randomisation method, in which all the odd numbers were categorised to group A and even numbers to group B.

Group A: Patients receive rocuronium 0.9 mg/kg as a bolus dose

Group B: Patients receive rocuronium 0.6mg/kg as a bolus dose.

Methodology

After the approval from the institutional ethical committee, written informed consent were taken from the patient. Exclusion criteria included ASA 3 and 4, Mallampati grade 3 and 4, Anticipated difficult airway, Neuro muscular disorders and Allergy to the drugs.

After the pre anaesthetic evaluation, the patients were fasted overnight. On the day of surgery, antacid prophylaxis was given in the morning. The patient was shifted to OT (operation theatre), an appropriate size cannula secured. Basic monitors such as ECG, Pulse oximeter, NIBP (Non invasive blood pressure) were attached and the baseline reading noted. The nerve stimulator applied to ulnar border of the forearm and its monitor is also attached.

Patients were premedicated with glycopyrrolate 0.01mg/kg and fentanyl 2mcg/kg. Preoxygenated for 3 minutes.

Variables	Intubating Conditions		
	Acceptable		Unacceptable
	Excellent	Good	
Ease of laryngoscopy	Easy	Fair	Difficult
Vocal cord position	Abducted	Intermediate	Closed
Vocal cord movement	None	Moving	Closing
Airway reaction	None	Diaphragm	Sustained
Movement of limbs	None	Slight	Vigorous

Patients were induced with propofol 2mg/kg. After loss of eye lash reflex a baseline TOF (Train of Four) count is taken and rocuronium was administered.

Neuromuscular monitoring using the train of four at the adductor pollicis muscle is commenced. At 60 s a TOF count is recorded and tracheal intubation is done by an experienced anaesthesiologists. The time to loss of TOF will be noted.

Intubating conditions will be assessed as excellent, good and poor according to the grading scale based on criteria of good clinical practice [4].

SBP (Systolic blood pressure), DBP (Diastolic blood pressure), HR (Heart rate), and SpO_2 (oxygen saturation) were recorded at intubation, 1, 3 and 5 minutes following intubation.

Statistical Analysis

Statistical tests used were descriptive statistics (mean age, weight) chi square test (Yates correction wherever required) and software used was SPSS version 20.

Results

The intubating conditions were excellent in 13 (65%) in group A and 9 (45%) in group B. And they were good in 7(35%) in group A and 11(55%) in group B. (Table 1,2 and Graph 1).

There was no statistically significant difference in TOF at intubation between the groups whereas time to the loss of TOF was significantly different. (Table 3).

Table 1: Table showing the comparision of assessment of intubating conditions

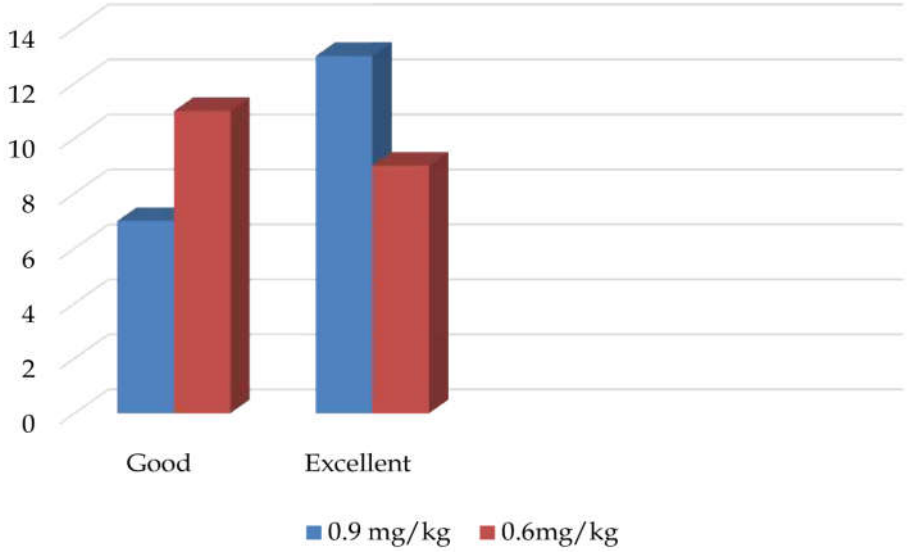
Variables		0.9mg/kg N (%)	0.6mg/kg N (%)	Total	P value
Ease of laryngoscopy	Easy	16(80)	18(90)	20(100)	0.331
	Fair	4(20)	2(10)	20(100)	
Vocal cord position	Abducted	17(85)	12(60)	20(100)	0.078
	Intermediate	3(15)	8(40)	20(100)	
Airway reaction	None	20(100)	12(60)	20(100)	0.007
	Diaphragm	0(0)	6(30)	20(100)	
	Sustained	0(0)	2(10)	20(100)	
Movement of limbs	None	20(100)	14(70)	20(100)	0.02
	Slight	0(0)	6(30)	20(100)	

Table 2: Table showing the comparision of intubating conditions

Variables	0.9MG/KG n (%)	0.6MG/KG n (%)	Total	P value
Excellent	13(65)	9(45)	20(100)	**0.036**
Good	7(35)	11(55)	20(100)	

Table 3: Table showing the TOF at intubation and time to loss of TOF

Variables		Rocuronium dose 0.9MG/KG N (%)	0.6MG/KG N (%)	Total	P value
TOF at intubation	1	4(20)	3(15)	20(100)	0.677
	2	16(80)	17(85)	20(100)	
Time to loss of TOF	<120s	15(75)	7(35)	20(100)	0.039
	<180s	4(20)	11(55)	20(100)	
	<240s	1(5)	2(10)	20(100)	



Grpah 1: Bar Graph Showing Intubating conditions

Discussion

The ideal neuromuscular blocking agent is one which has brief duration of action, provides profound relaxation and is free from hemodynamic changes.

Succinylcholine is the commonly used muscle relaxant for RSII due to its fast onset, excellent intubating conditions and short time course of action. However, it may have adverse effects which can limit or even contraindicate its use at times.

An alternative drug suggested and used in recent times for rapid sequence induction is rocuronium in the dose of 0.6 to 1.2mg/kg. Rocuronium bromide is a steroidal non depolarising muscle relaxant that is useful to produce a rapid onset of action [5].

Onset time of a neuromuscular blocker is considered important because it serves as a predictive parameter for the rate of development of ideal intubating conditions [6].

Hence in our study we decided to compare the intubating conditions between 0.6 and 0.9mg/kg of rocuronium along with the train of four count at intubation and time to loss of train of four count and we found that the intubating conditions were better with 0.9mg/kg when compared with 0.6mg/kg and the results were statistically significant.

But the intubating conditions were clinically acceptable in both the groups.

A similar study by Usha devi et al. [7] in cesarean sections also concluded that conditions after 0.9mg/kg are better than those offered by 0.6mg/kg of rocuronium. Cheng et al. [8] did a similar study with thiopentone and alfentanyl induction and concluded that intubating conditions were adequate after 0.9 mg/kg of rocuronium but found 0.6mg/kg dose inadequate.

Heggeri M et al. [9] concluded that 3xED95 dose of Rocuronium achieves more intense NMB and better conditions for intubation at 60 seconds than 2ED 95 dose. Similar observations were done by Bunburaphong P et al. [10].

When a non-depolarizing agent is given, a typical pattern is observed. There is a reduction in the amplitude of the evoked responses, with T4 affected first, then T3, followed by T2, and finally T1. Adequate relaxation for intubation is obtained when TOF responses are 2 or 1 when NMB is 80% [11].

The TOF value at intubation were either 3/ 4 or 4/4 in majority of the cases in both the groups and the values are also not statistically significant between the two groups. This implicates that monitoring the TOF at adductor pollicis is not correlating with the intubating conditions.

This finding of ours is substantiated as Meistelman et al. [12] concluded that monitoring the adductor pollicis for onset of blockade might be misleading, further Donati et al. [13] also concluded from his study that neuromuscular block at adductor pollicis lags behind that of laryngeal muscles.

But Haller G et al. [14] concluded from his study that Monitoring neuro-muscular activity of the AP using TOF to determine the appropriate tracheal intubation time and conditions in patients paralysed with rocurorium is more clinically relevant than monitoring the Orbicularis Occuli muscle.

The mean time to the loss of TOF is 115 seconds with 0.9mg and 132 seconds with 0.6mg which is statistically significant. Similar results were seen in the study by Mathias sluga et al. [15] where the median time for loss of TOF was 130 seconds with 0.6 mg/kg dose of rocuronium and by Veena chathrath et al had the median time for loss of TOF at 110 seconds with 0.6mg /kg of drug.

Conclusion

Intubating conditions were better in group A in comparision with group B but both the groups provided clinically acceptable conditions for intubation.

The use of train of four count at the adductor pollicis as a guide for laryngeal muscle paralysis is questionable.

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Assessment of Paramedical Staff's Knowledge Regarding Speciality of Anesthesia and Anesthesiologists: A Questionnaire Based Study

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Abstract

Background: Paramedical staff is the cornerstone of health care system. Knowledge of paramedical staff regarding different specialty is of paramount importance for the efficient delivery of healthcare services. As anesthetist are frequently involved in the emergency care of a patient, knowledge of paramedical staff regarding anesthesia and the role played by anaesthetist can help in the efficient and timely delivery of health care needs of patient which ultimately results in the better patient outcome. *Aim*: To assess paramedical staff's knowledge regarding anesthesia and anesthetist. *Method:* 100 paramedical staff posted in the different department were selected for the study. They were administered a set of questionnaire face to face orally by an investigator and responses from individual participant were recorded. The data collected were subjected to simple statistical analysis. *Results*: 75% of paramedical staff knew that anesthetist is a specialist doctor. 40% of participant knew that anesthetist are concerned with the post-operative care of a patient and only 25% of candidates were aware of role of anesthetist in ICU. Very few participants knew about the role of anesthetist in providing trauma care and labor analgesia. *Conclusion*: Every paramedical staff should be made aware of the different roles played by the anesthetist apart from providing anesthesia to surgical patients. This will finally result in the better utilization of anesthesia services, better patient satisfaction, and better patient outcome.

Keywords: Paramedical Staff's Knowledge; Anesthesia; Anesthetist.

Since the time anesthesia has been demonstrated to the world, there has been immense development in the field of anesthesia and consequently, the role of anesthetist has extended beyond the traditional operating room into critical care, trauma center pain clinics, and conduct of painless deliveries. In the last 2-3 decades, there is the tremendous increase in the healthcare awareness all over the world but similar kind of awareness about anesthesia and anesthetist is lacking among patients as revealed by recent studies [1,2,3]. Our paramedical staff is not an exception [4,5]. Paramedical staff forms the backbone of any healthcare delivery system. It is impossible to run efficiently any health care facility without having well trained paramedicalstaff. They are involved in the care of the patient right from the OPD consultation, admission, preoperative preparation, intraoperative care and postoperative care till patient discharge. They form the link between patient and doctor. They are the mainstay population who come into the front face. In case of health care need, any inpatient first contacts the staff nurse because they are easily approachable and it is convenient for the patient to explain his problem. Hence, the paramedical staff should be able to understand the patient's problem and should know whom to contact. They should also be able to understand and recognize any emergencies and complications and should inform the concerned specialist on the priority basis. Because the anesthetists are frequently involved in the care of medical and surgical emergencies, paramedical staff should have adequate knowledge about anesthesia and anesthetist so that they should understand

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when to call anesthetist. Hence, we have undertaken this study to assess paramedical staff's knowledge about anesthesia and anesthetist.

Method

The present study is a prospective cross-sectional questionnaire-based study. After obtaining informed written consent, about 100 paramedical staff posted in different departments were selected for the study. Those staff who are on leave and are not willing to participate were excluded from the study. All the participants were interviewed using the set of questionnaires administered face to face orally by an investigator and responses for each question were recorded. Questions are designed to capture a demographic profile of staff, qualification, work experience as well as to assess the knowledge of paramedical staff regarding anesthesia and anaesthesiologist. Data collected thus were subjected to simple statistical analysis.

Table 1: The questionnaire

1. Age _____
2. Gender _____
3. Educational status _____
4. Work experience _____
5. Who will assess patient regarding fitness to undergo surgery? _____
6. Why is fasting needed before surgery according to you? _____
7. Is anaesthesia needed if surgery should be required? _____
8. How is anaesthesia applied? _____
9. Is anaesthesia applied to all patient in the same way? _____
10. How many different types of anaesthesia you know? _____
11. Have you heard about anaesthetist? _____
12. Is anaesthetist, a specialist doctor or one who works under supervision of surgeon? _____
13. What anaesthetist will do once the patient is anaesthetised? _____
14. Do you know that anaesthetist are involved in your postoperative care? _____
15. Do you know that anaesthetist are involved in the care of critically ill patients? _____
16. Do you know that anaesthetist are involved in the care of accident and emergency patients? _____
17. Do you know that anaesthetist are involved in the conduct of painless deliveries? _____
18. Do you know that anaesthetist plays important role in the resuscitation of cardiac arrest patient? _____
19. Do you know that if any patient in the hospital suddenly becomes serious, anaesthetist are immediately called? _____
20. Do you know that anaesthetist runs pain clinic? _____
21. Are you interested to know more about anaesthesia and anaesthetist? _____

Result

The analysis of the data collected from our study showed that the majority (82%) of participants were in the age group 17 to 25 years. A majority (61%) of them were females and only 14% were graduate while rest 86% completed diploma nursing. Among 100 candidates, only 36% were having experience above 1 year while remaining candidates were beginners or are having less than 1-year experience.

Table 2: Demographic profile

Sl. No.	Patient Variables	Number	Percentage
1	Age		
	17-25 years	82	82%
	26-40 years	13	13%
	41-50 years	5	5%
2	Gender		
	Male	39	39%
	Female	61	61%
3	Education		
	Diploma	86	86%
	Graduate	14	14%
4	Work experience		
	New recruits	42	42%
	1-6 months	12	12%
	7-12 months	10	10%
	1-5 years	27	27%
	6-10 years	3	3%
	11-20 years	3	3%
	21 and above	3	3%

When the participants were asked about who will assess the fitness of patient to undergo surgery 56% replied anesthetist, while to a question regarding the need for fasting before surgery, 68% replied to prevent complications. 75% of participants knew that anesthetist is a specialist doctor. When asked about how is anesthesia applied, 70% of them knew that anesthesia is applied using face mask or injection into back or block of the upper limb. 40% participant knew that anesthetist are involved in the post-operative care. 25%, 10%, 0% and 0% of participants know that anesthetist has a role in ICU, trauma care, the conduct of painless labor and pain clinics respectively. Fortunately, 75% knew that anesthetist has a major role to play in the resuscitation of the collapsed patient. All most all of the participants expressed the desire to know more about anesthesia and anesthetist.

Discussion

Paramedical staff is cornerstone of any health care system. They are the people who stay with the patients most of the times, listen to their queries and deliver the care. They are involved right from the entry of patient, OPD consultation, admission, bedside caretill patient discharge. They form the backbone of the health care system. Hence, it is mandatory for them to have knowledge about different specialties, different ailments, methods of patient assessment and consultation with respective specialist etc. This is useful especially if staff nurse knows about the role of anesthetist as they are the people who are involved in the emergency care of a patient. It may so happen that, after parenteral administration of a drug, staff nurse may witness that patient is collapsing. If the staff nurse knew that it is time to call anesthetist, who are available round the clock especially in the institutional setup, precious time can be saved before the emergency care is delivered. This ultimately results in the better outcome. It has been found from few studies that not all paramedical staff are aware of anesthesia and anesthetist. Bhattarai B, Kandel S, Adhikari N [4] in their study found that out of 120 paramedical staff who were interviewed, only 49.20 said it to be a different specialty and 72.5% said anaesthesiologist work differently in the theatre whereas 70% knew anaesthesiologist did something in the post-operative period too.In contrast to this, only 40% of participants in our study knows that anesthetists are involved in post-operative care.

Hiremath DA [5] conducted the survey on 105 participants and found that majority of 90.28% of respondents felt that anesthesia was necessary for surgery. 40.80% knew that it was given by anesthesiologists. 18.38% of respondents knew that besides anesthetizing, anesthesiologists monitor the vital signs till the completion of surgery. 5.60%, 9.11% & 3.8% of respondents were aware of their role in ICU, labor analgesia and pain clinic respectively. Only 22.81% patients had knowledge about anesthesia risks given in consent form. In contrast to the study by Hiremath DA, the higher number (25%) of participants in our study knows that anesthetist have the role in ICU whereasno participants of our study knew that anesthetist has the role in labor analgesia and pain clinic.

Conclusion

Hence, we have come to a conclusion that, the awareness of paramedical staff regarding specialty of anesthesia and anesthetist needs to be enhanced using various methods like in-house training programs, use of pamphlets, internet etc so that patient can avail anesthesia related services effectively.

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Original Research Article

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Real-time Ultrasound-guided Catheterisation of the Internal Jugular Vein: A Prospective Comparison with the Landmark Technique

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Abstract

Central venous access has become a mandatory part for clinical management of critically ill patients, both in acute care setting and chronic long term care. However, anatomical landmark guided technique for IJV cannualation is not devoid of complication like carotid arterial puncture and pneumothorax. In this prospective, randomized, controlled, clinical trial, we compared and assess the anatomical landmark guided technique for IJV cannulation with USG guided technique in terms of success rate, no. of attempts and complications. Sixty four patients of either sex, between age group of 18 –70 years requiring either elective or emergency CVC placement, were randomly divided to 2 groups, Group USG: USG guided technique and Group ALG: Conventional or anatomical landmark guided technique. Venous access time and catheterization time both were found to be statistically significantly less in USG group compared to ALG group ($p<0.0001$). Successful cannulation in 1st attempt could be done in more no. of patients in USG group (26 patients) compared to ALG group (6 patients) ($p<0.00001$). Success Rate was 87.5% in Group ALG while it was 100% in Group USG. Which was statistically highly significant ($p<0.05$). Overall Complications rate was 25% versus 3.125% in Group ALG and group USG respectively which was statistically significant.($p<0.05$).Ultrasound guided central venous catheter placement is easy, safer and prudent approach than anatomical landmark guided technique hence should be encouraged to improve patient's safety and quality care.

Keywords: Internal Jugular Vein Cannulation; Ultrasonography; Anatomical Landmark Guided Technique.

Introduction

Central venous catheterization has become an integral part of management in emergency as well as in critical care medicine [9], required for the administration of hyperosmotic or vasoactive compounds, cytotoxic drugs, parenteral nutrition, and rapid infusion of large volume of fluid or for continuous or intermittent monitoring of biochemical and physical parameters [9]. Hermosura et al. described right internal jugular cannulation in 1966 and since then it has become one of the most popular route for central venous cannulation [5]. IJV has gained popularity among different central cannulation route due to its consistent anatomical position, large diameter and less chances of catheter misplacement and obstruction [14].

However, placing central venous line entails risks and rate of major and minor mechanical complications can be as high as 10% [9]. Failure to cannulate the vessels may occur in >19% of patients [11]. Complications like puncture of the carotid artery, neck or mediastinal hematoma, pneumothorax, injury or irritation of brachial plexus, phrenic nerve or recurrent laryngeal nerve and stellate ganglion can be encountered [6]. Standard technique for placing central venous catheter is by using anatomical landmarks but patients with coagulopathies, vascular and skeletal deformities, obesity, edema, h/o previous catheterisation or

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unusual small habitus, neck burn contracture make cannulation more difficult [11,12].

In 1978, Ulman and stoelting described the first use of ultrasonography for accessing central veins. They reported this new technique would increase the success rate of IJV catheterization and decreases accidental puncture of carotid artery compared with the traditional technique using only anatomical landmarks [8]. In 1986, Yonei et al reported the use of real time ultrasonographic guidance for IJV cannulation [8].

The agency for Health Care Research and Quality in USA and National Institute of Clinical Excellence in United Kingdom have recommended the use of USG guidance for CVC placement to improve success rate, reducing no. of attempts and decreasing complications and hence patient care.[8] Advances in speciality care and availability of portable ultrasonography (USG) units in hospitals have made the use of USG for bedside procedures possible [9].

In this study, we compared and assess the anatomical landmark guided technique for IJV cannulation with USG guided technique in terms of success rate, no. of attempts and complications.

Materials and Method

After approval from institutional ethical committee, written informed consent was taken from all patients. Sixty four patients of either sex, age group of 18 – 70 years requiring either elective or emergency CVC placement were included in this study. Patients were randomly divided into 2 groups: (32 patients in each group)

Group USG: USG guided technique and Group ALG: Conventional or anatomical landmark guided technique.

The Patients were subjected to detailed history, thorough clinical examination and laboratory investigations including coagulation profile, Chest X-ray and ECG.

Exclusion Criteria

- Non-cooperative patient
- Skin infection over puncture side
- Children (<18yrs of age)
- Anatomical deformity, eg. Neck surgery, malignancy
- Cellulitis, severe dermatitis, Burns on site of insertion
- Vasculitis
- Bleeding disorders
- Cardiac arrhythmia
- Pneumothorax / hemothorax
- compromised unilateral lung

In this study, CVC placement was done by Seldinger technique in both USG and anatomical landmark group. A technique introduced in the 1953 and called the *Seldinger technique* after its founder-Dr. Sven-Ivar Seldinger.

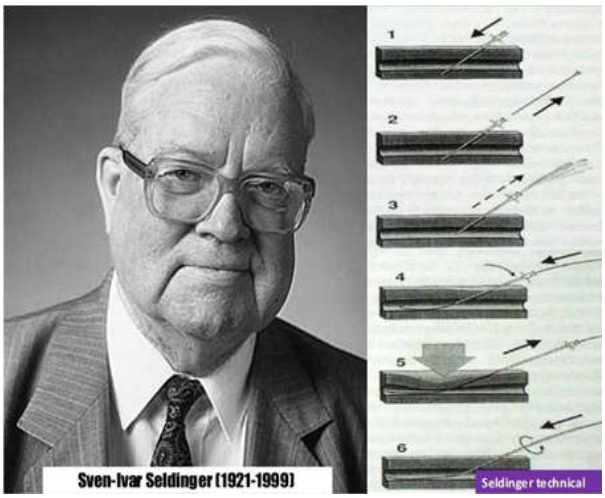

Fig. 1: Steps of seldinger's technique

Peripheral venous cannula was assured in all patients and Standard monitoring (pulse, BP, SpO_2 and ECG) were applied. Right sided internal jugular vein (IJV) was first planned for cannulation in this study.

Position of the Patient

The patient was placed in supine position with slightly head down around 10-30° (Trendelenburg position) and neck rotation (30°) contra-lateral side. Wedge was placed between shoulder blades. Part preparation & draping was done, taking all aseptic and antiseptic precautions.

A portable ultrasound "Sonosite Micromaxx" machine with 7.5 MHz Linear array (vascular) probe was used in this group. Probe was cleaned with antiseptic solutions, sterile jelly was applied and covered with sterile sheath. Probe was placed perpendicular to the area at apex of the triangle formed by two heads of sternocleidomastoid (SCM) muscle and clavicle. In the longitudinal plane, the

probe was oriented with the marker towards the patient's head and in the transverse plane, the marker facing towards the patient's right side. Internal carotid artery (ICA) was seen as a circular pulsatile structure while IJV as an oval non-pulsatile structure. On applying downward pressure with probe, IJV get compressed whereas ICA remained as such. Once vein was identified, probe was positioned so that vein was visualized in centre of the screen. 2% inj. Lignocaine hydrochloride was injected overlying access site for local anesthesia and skin puncture utilizing sterile needle was commenced. Needle was kept at the same distance from transducer as the distance between transducer and vessel and making angle 45 degree with transducer in case of short axis view.

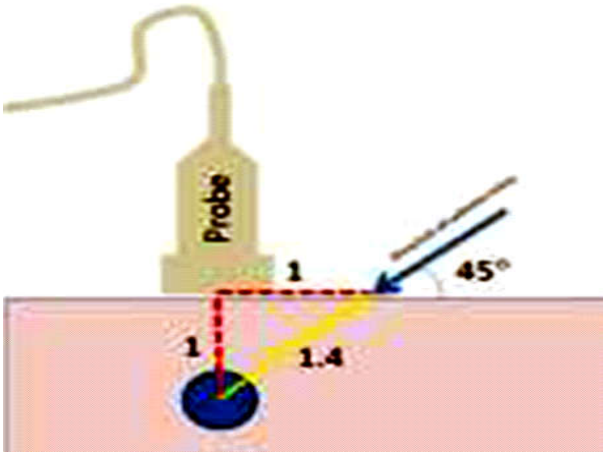

Fig. 2: Needle direction in short axis view

For long axis view needle was kept just outside to the edges of probe and 30 degree angle to the skin surface. Introducer needle could be seen on monitor either puncturing the vein or compressing the vessel wall, by identifying needle tip echo. Needle was further advanced till visualization of entrance of the needle into vessel lumen, thereby avoiding a double-wall puncture. After successful aspiration of blood, a guide wire was inserted through it by visualizing ultrasound image in longitudinal plane. Then after CVC placement was done using seldinger technique.

Fig. 3: Placement of probe parallel and perpendicular to IJV

Anatomical Landmark Guided Technique

Apex of the triangle formed by two SCM was palpated for carotid pulsations. With fingers of the left hand, carotid artery was pressed slightly medially and introducer needle inserted lateral to pulsation point, directing toward the ipsilateral nipple at an angle of 20-30 degree with the skin. After successful aspiration of blood, a guide wire was inserted through it and introducer needle was withdrawn. Rest of the procedure was similar to that in group USG. (Seldinger technique) Vital parameters were checked during and after procedure.

Statistical analysis was done using SPSS software. P value<0.05 was considered statistically significant and p<0.01 was highly significant.

Results

Both groups were comparable with respect to age, sex, body weight and indication for IJV cannulation. (p>0.05)

The mean duration of Venous Access Time (1.28±1.03 minutes) in Group USG was significantly less compared to (5.78±2.75 minutes) Group ALG (p < 0.0001).

The mean duration of Catheterisation time in Group ALG was 8.3±2.17 minutes compared to Group USG (3±1.25 minutes), which was found to be statistically extremely significant (p < 0.0001). (Table 1) 6 no. of patients (18.75%) in Group ALG while 26 patients (81.25%) in Group USG out of 32 patients could be cannulated successfully in 1st attempt. (p<0.00001) So, successful cannulation in 1st attempt could be done in more no. of patients in USG group compared to ALG group.

Success Rate was 87.5% (28 patients out of 32 patients) in Group ALG while it was 100% (32 patients out of 32 patients) in Group USG. This result was statistically highly significant (p<0.05).

Overall Complications rate was 25% versus 3.125% in Group ALG and group USG respectively which was statistically significantly less (p<0.05)(Table 2).

Discussion

Central venous catheterization has become an integral part of management in emergency as well as in critical care medicine [9]. Even with

Table 1: IJV catheterization characteristics in group ALG and USG

Parameters	Group ALG(n=32 patients)	Group USG (n=32 patients)	P value
Mean venous access time(minutes)	5.78±2.76	1.28±1.03	P<0.0001
Mean catheterization time(minutes)	8.3±2.17	3.00±1.25	P<0.0001

Table 2: Comparison of complications

Complications	Group ALG		Group USG		P value
	n=32 patients	Per. (%)	n=32 patients	Per. (%)	
Carotid artery puncture	3	9.375	1	3.125	P<0.002
Pneumothorax	0	0	0	0	
Hemothorax	1	3.125	0	0	
Others	4	12.5	0	0	
Other parameters					
Change of puncture site	3	9.375	0	0	P<0.076
Failure rate	4	12.5	0	0	P<0.04

experienced hands, complications rates of 12.3% have been reported for CVC using the anatomical landmark guidance [7]. Considering increased use of CVC efforts should be made to minimize & prevent the occurrence of complications and thereby improving patient safety and quality care.

Ultrasound technology has become essential tool for everyday practice of anesthesiology i.e. the placement of central, arterial and peripheral lines as well as peripheral nerve blocks [8]. Modern Ultrasound machine are compact, portable & handy with good resolution, real time guidance & safety to patient and operator [7]. (No radiation) Ultrasound has been first described in 1984 by Legler and Nugent as either a prelocating device or a real-time guidance device for central venous cannulation. With availability of portable USG machine, USG guided interventions can save the time & increases accuracy, efficacy & safety [7]. Thus USG is a valuable tool to reduce the medical errors and to improve the medical care [9]. "The Stanford evidence based practice centre" has recommended ultrasound guidance in central venous catheter insertion as one of the 11- point recommendations in "A critical analysis of patient's safety practices" in 2001 [7].

"The agency for healthcare quality and research" (AHRQ), in its 2001 report on reducing medical errors in the United States, placed ultrasound guidance for CVC placement in the list of ways to reduce medical error [3].

In 2011, the CDC (Centre for Disease Control and Prevention) recommended use of ultrasound guidance to place central venous catheter to reduce no. of attempts and mechanical complications [8].

Based on meta-analysis in 2002, "National Institute for clinical excellence" in UK has recommended that the use of 2 D ultrasound guidance should be considered in the most clinical situations where a central venous line is necessary electively or in an emergency [7].

In this study, mean venous access time and mean catheterization time, both were shorter in group USG compared to group ALG and statistically extremely significant (p<0.0001).

Bikas R Ray et al. in 2013 [5] compared both ultrasound guided technique: prelocation of the IJV or real time image with anatomical landmark guided technique. It was found that both the median venous access time (9.5sec, 11sec) and the median catheterization time (167.5sec, 165sec) were shorter in ultrasound groups than in anatomical landmark technique. Difference was statistically significant. ($P = 0.024$). Findings of this study and Ankit agrawal et al. [4] are accordance with our study.

In our study the mean no. of attempts for successful cannulation was more in group ALG (2.1±0.72) than the group USG (1.18±0.49), which was statistically extremely significant (p<0.0001).

The average number of needle punctures and the percent of successful cannulations on the first attempt are important factors in central venous cathterisation, since these parameters are strongly associated with the rates of failure and complications [10].

Ultrasound helps to locate IJV, carotid artery and other important surrounding structure before cannulation. So, ultrasound guided prelocation and real-time ultrasound imaging of the needle during cannulation increases the incidence of IJV cannulation in 1st attempt [8].

Results of Adam H. miller et al. 2000 [13], Dr. Sidhharth kumar et al. 2012 [7] and Hadim Akoglu et al. 2012 [10] were consistent with present study.

In present study, we needed more than 3 attempts for IJVcannulation in 4 patients in group ALG with failure of 12.5% and success rate of 87.5%. Success rate was high 100% (81.25%-first attempt, 18.75%-second attempt) in group USG and 3rd attempt was not required. Overall complications rate was 25% in group ALG and 3.13% in group USG. Denys and Reddy in 1993 [6] and Karakitsos et al in 2006 [11] observed similar results in their study. Susan T. Verghese in 1999 [16] observed significantly less carotid artery puncture even in infants with USG guided technique. Mechanical complicatios may lead to life threatening outcomes like cardiac arrhythmia, tamponade and migration of cathter. Under real time USG guidance, location of CVC tip can be confirmed and we can assess immediately for any sign of abnormality for prompt and appropriate management. Thus, reduces complication rate.

Conclusion

From present study we concluded that:

- Ultrasound guided technique for placement of CVC is superior to ALG technique as far as time required and no. of attempts required for insertion of cannula.
- Real time ultrasound guidance decreases incidence of carotid artery puncture and overall complications during CVC placement.

This study evaluated a change in practice of CVC placement. USG guided CVC placement is easy, safe, accurate and prudent approach than ALG technique. So it should be encouraged for all CVC placement and thereby improving patient's safety and quality care. But major impediments to widespread implementation are the purchase cost of the ultrasound machine and training require for operators to get familiar with the technique.

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Original Research Article

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Comparison of Proseal Laryngeal Mask Airway and Endotracheal Tube for intubation in Paediatric Patients for Surgical Procedures of Short Duration

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Abstract

Introduction: Proseal LMA produce very less sorethroat and cough when compared to the endotracheal tube in paediatric patients for short duration surgeries. *Aim:* To compare the paediatric proseal LMA with endotracheal tube for intubation in paediatric patients undergoing elective surgeries short duration under general anaesthesia with respect to ease of insertion, haemodynamic response and complications. *Methodology*: After getting consent and Ethical committee approval eighty patients were selected based on the inclusion and exclusion criteria and randomly allocated into one of the 2 equal groups GROUP P-Proseal laryngeal mask group and GROUP T-Endotracheal group. General anaesthesia given as per routine in our hospital. Group P Proseal LMA of 2 size inserted. GROUP T*:* Appropriate sized Endo tracheal tube inserted. Maintained with nitrous oxide 66% and oxygen 33% with sevoflurane 0.2-0.4%. Hemodynamics, number of attempts and failure of insertion noted. *Results*: Using endotracheal tube 92.5% patients were intubated in the first attempt, 3 (7.5%) required a second intubation attempt. In the proseal laryngeal mask airway group, the first attempt success rate was 82.7% (31 patients). A second attempt was required in 17.3% (9 patients). Heart rate was significantly higher in ETT group during the first Ten minutes of insertion than the Group P. More incidence of cough with ETT while more incidence of blood on the device with proseal LMA. Data analysed using chi square and student t test. *Conclusion*: we concluded that the proseal laryngeal mask airway could be an effective alternative to endotracheal intubation in children undergoing short duration elective procedures under general anaesthesia.

Keywords: Proseal LMA; Endo Tracheal Tube; Number of Attempts; Paediatric Surgery**.**

Introduction

The endotracheal tube remains the gold standard in securing the airway. Supraglottic airway devices forms an important adjunct in securing the airway with minimal injury to oro-pharyngeal structures and less haemodynamic response compared to endotracheal tube. The PROSEAL LMA was introduced by Dr. Archie Brain in 2000, has an effective glottic seal favouring positive pressure ventilation, ease of insertion of device, less haemodynamic response to insertion and less postoperative complications. Hence a prospective randomised single blinded study was designed to compare the paediatric Proseal LMA with the endotracheal tube in terms of placement of device, haemodynamic response and postoperative complications.

Aim of the Study

The aim of the study is to compare the paediatric proseal laryngeal mask airway with the endotracheal tube for intubation in paediatric patients undergoing elective surgeries short duration under general anaesthesia with respect to ease of insertion, haemodynamic response and complications.

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Materials and Methods

Study Design

Randomization done using sealed envelope method. Patients posted for short duration surgery (< 1 hr) of age 2–8 years of weight 10–20 kg belonging to ASA I and II were selected for the study. Institutional ethical committee approval was obtained. The procedures were explained to the parents of patients in their own language and written informed consent were obtained from them.

A thorough pre-operative assessment was done before surgery with detailed history of the patient, clinical examination with appropriate investigations and they were assessed for the respective surgeries. Pre-operative fasting guidelines (8hrs for solid foods, milk till 6 hrs and clear liquid till 4hrs) were given to them.

Patients with difficult airway, history of obstructive sleep apnoea, febrile seizures, upper respiratory tract infection and emergency cases were excluded.

Methodology

After getting consent, the patients were assessed and kept on fasting guidelines. They were randomly allocated into one of the 2 groups

GROUP P-Proseal laryngeal mask group

GROUP T-Endotracheal group

Patients were brought into the theatre, monitors of pulse oximeter, non-invasive blood pressure, precordial stethoscope, ECG were connected, and intra venous line secured and base line parameters were recorded.

They were pre-medicated with inj.glycopyrrolate 0.01mg/kg body weight and inj.fentanyl 2micro gram/kg body weight five minutes prior to induction. Pre oxygenation was done for 3 minutes. Anaesthesia was induced with inj.propofol as an inducing agent with 2mg/kg body weight with inj. lignocaine 0.5mg/kg I.V body weight. Atracurium 0.5 mg/kg body weight was used as neuro muscular blocking agent with incremental boluses of 0.1 mg /kg body weight when required.

Group P

PROSEAL laryngeal mask airway size 2 was selected, cuff deflated after checking the patency. Posterior surface of the device was lubricated with 2% lignocaine jelly. The child's head was kept in neutral position. The proseal laryngeal mask was inserted through the oral cavity using index finger technique. The cuff was inflated with 7-10 ml of air. After obtaining an effective airway which was confirmed by normal thorocoabdominal movements, bilaterally audible breath sounds on auscultation, square wave form on capnograph, pulse oximeter readings, the PLMA was fixed to the chin by tape.

Three attempts were allowed for securing the airway before the device was considered as failure and it was replaced with an ET tube. This is termed as a failed attempt. Gastric tube number 10 was introduced through the drain tube, in this two attempts were allowed for gastric tube insertion before it was considered as a failure, and repositioning of the PLMA was done.

Group T

In group T patients, appropriate size endotracheal tube was used for securing the airway.

All the patients were maintained with nitrous oxide 66% and oxygen 33% with sevoflurane 0.2-0.4% and manually ventilated with Jackson Rees paediatric circuit. Vital parameters were recorded post intubation immediately after placing the PLMA or endotracheal tube. Haemodynamic monitoring was done at the interval of 5 minutes and subsequently after 10 minutes of placing the device.

After the procedure was over, the patients had spontaneous ventilator efforts and were reversed with inj.neostigmine 0.05mg and injection glycopyrrolate 0.01mg/kg body weight. Thoroughly oral suctioning done and PLMA group gastric drain tube suctioning done. The patients were extubated after good recovery.

At the time of emergence any complications of cough, bronchospasm, or laryngospasm were noted in both the groups. After removal of airway device, blood staining of the endotracheal tube and posterior aspect of proseal laryngeal mask airway were assessed.

Patients were continuously monitored in post anaesthesia care unit and followed up for next 24 hours for any complication of sore throat or hoarseness of voice.

Statistical analysis were done by using SPSS software 16 version. Descriptive standards like mean, median, range, are calculated for all the variables. Student T tests and Chi square tests are used to find the significance between two groups

at the level of 5% confidence (alpha error). Student t test is used for descriptive data and Chi square test for categorical variables.

Both groups were comparable with respect to hemodynamics. Increased incidence of male patients was noted as most of the patients were posted for herniotomies and circumcision.

Results

We were able to intubate the patients in 92.5% in the first attempt using an endotracheal tube. 3 of them (7.5%) required a second intubation attempt.

In the proseal laryngeal mask airway group, the first attempt success rate was 82.7% (31 patients). A second attempt was required in 17.3% (9 patients) in this group. The increase in heart rate and blood pressure after 5 minutes of intubation with the proseal laryngeal mask airway group was found to be lesser than the endotracheal tube.

After 10 minutes of intubation with proseal laryngeal mask airway the hemodynamic parameters were much reduced compared to the endotracheal tube. The hemodynamic response was found to be present even after 10 minutes of intubation with an endotracheal tube.

PLMA has less incidence of cough, bronchospasm and sore throat.there was more percentage patient shaving blood on device with PLMA group compared to the ETT.

Table 1: Heart rate

	ETT	PLMA	P Value
baseline	88.2±4.86	95.7±7.16	0.00
Post intubation	107.675±5.3	102.65±6.9	0.00
After 5 min	99.2±5.12	97.2±4.3	0.04
After 10 min	96.75±5.55	92.15±6.3	0.001

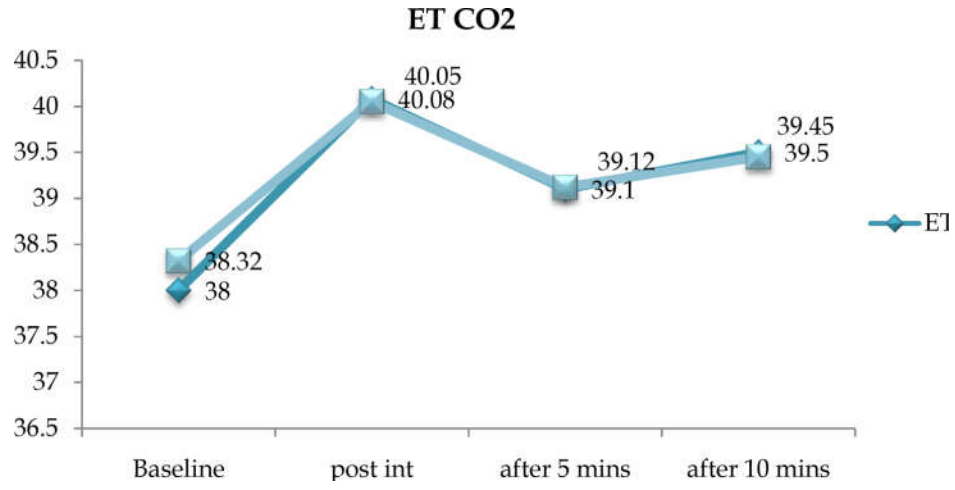
Table 2: Mean arterial pressure

	ETT	PLMA	P Value
baseline	85.55±3.29	85.912±3.44	0.64
Post intubation	87.37±3.95	86.42±3.96	0.21
After 5 min	78.64±3.27	79.75±3.42	0.14
After 10 min	83.12±3.57	78.3±3.52	0.001

Table 3: Complications

		ETT	PLMA	P Value
Cough	yes	10	3	0.03
	no	30	37	
Bronchospasm	yes	4	1	0.17
	no	26	39	
Blood on device	yes	4	11	0.01
	no	36	29	

Fig. 1:



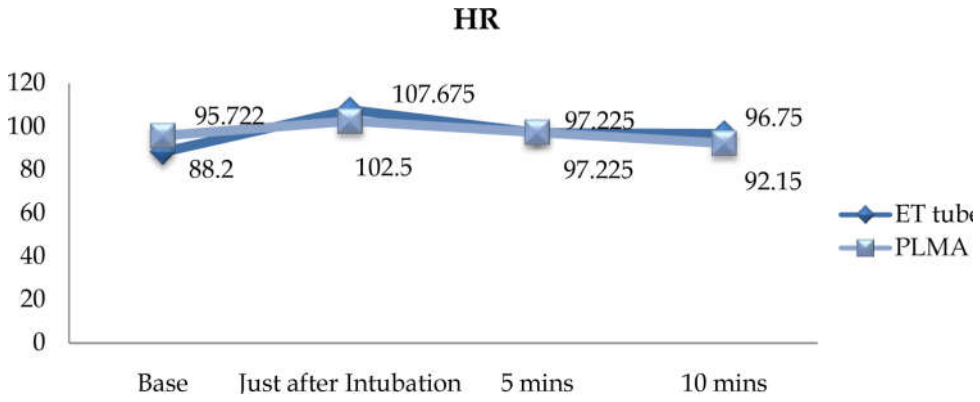


Fig. 2:

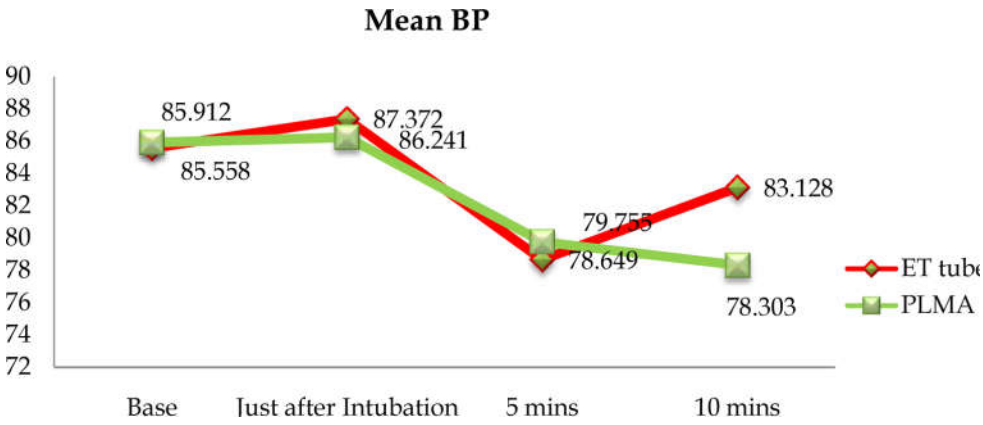


Fig. 3:

Discussion

The supra glottic airway device is being used widely in paediatric practise and have become a pivot component in airway management in children [1,2,4].

It has been introduced as a replacement of face mask but now been used successfully for airway management in areas where endotracheal tube was considered mandatory [19-22].

The Classic laryngeal mask airway provides a lesser effective oro- pharyngeal seal, leading to gastric distension inflation, regurgitation and aspiration of gastric contents [6,9,10].

It could not be used for positive pressure ventilation because of the ineffective seal produced at the laryngeal inlet [3,10,11].

The Proseal laryngeal mask airway introduced in 2000 provided many added features for an effective and safe airway. It has become a modified form of Classic laryngeal mask airway [4].

The main features of Proseal laryngeal mask airway are oesophageal drain tube, integral bite block, modified cuff design, increased depth of the bowl which makes an effective oropharyngeal seal. This enables the device to be used for positive pressure ventilation [1,4,7,9,10,14].

The presence of the drainage tube forms an effective channel for passive drainage of gastric contents. A gastric tube inserted through the drainage tube helps in the prevention of gastric aspiration and also it is useful to identify the position of the device [6].

In our study we compared the number of attempts of the insertion of the device, hemodynamic parameters, heart rate, systolic & diastolic and mean arterial blood pressures, SpO_2 and $EtCO_2$ values. Further we observed the post-operative complications the emergence and in 24 hour post-op period.

Intubation of Device

In our study we were able to intubate the patients in 92.5% in the first attempt using an endotracheal tube. 3 of them (7.5%) required a second intubation

attempt. In the proseal laryngeal mask airway group, the first attempt success rate was 82.7% (31 patients). A second attempt was required in 17.3% (9 patients) in this group.

This result coincided with the studies conducted by the following authors.

Jaya Lalwani [4] – who reported that the incidence of first attempt endotracheal intubation was 96.67% and correspondingly proseal laryngeal mask airway was used to intubate in 83.3%

Brimacombe [13]– reported successful first attempt intubation of both endotracheal tube and proseal laryngeal mask airway of 85% each of the devices.

Mamtha G. Patel [1]– also reported the first time insertion of the endotracheal tube was found to be 100% and for the proseal laryngeal mask airway was 90%.

Misra et al [5] reported 100% placement of the endotracheal tube in patients in first attempt and was able to place the proseal laryngeal mask airway in 88%.

Raufgul [2]– also reported the same incidence of placement in both the proseal laryngeal mask airway and endotracheal tube as mentioned above.

Hemodynamic Stability

The proseal laryngeal mask airway provided a stable hemodynamic status when used as a supraglottic airway device in paediatric patients undergoing elective surgery. The increase inhemodynamic response is minimal and the effect is sustained for a short time compared to the endotracheal tube intubation.

The baseline parameters of heart rate, mean arterial blood pressure, SpO_2 and $EtCO_2$ values were compared in both the groups.

The endotracheal tube intubation is associated with an increase in heart rate and blood pressure and this is established in various studies.

The proseal laryngeal mask airway as an intubation device produced a lesser increase in heart rate, systolic, diastolic and mean arterial blood pressure after intubation and subsequently in 5 and 10 minutes of the observation.

The increase in heart rate and blood pressure after 5 minutes of intubation with the proseal laryngeal mask airway group was found to be lesser than the endotracheal tube. After 10 minutes of intubation with proseal laryngeal mask airway the hemodynamic parameters were much reduced compared to the endotracheal tube. The hemodynamic response was found to be present even after 10 minutes of intubation with an endotracheal tube.

The results obtained were found to be consistent with the work of other authors like

1. Misra et al., Sinha, Shani, Sood [5,18]– they reported that there is increase in hemodynamic response with the endotracheal tube intubation which was sustained for a longer time than the proseal laryngeal mask airway when it was used as an airway device.
2. Jaya Lalwani et al.[4]– who compared the proseal laryngeal mask airway and the endotracheal tube in paediatric patients undergoing short surgical procedures also found that the endotracheal tube group patients had an increased hemodynamic response to intubation which was found to be statistically significant.
3. Lim Y Goel, S Brimacombe [25] et al. observed that hemodynamic response to endotracheal intubation was found to be greater when compared to the proseal laryngeal mask airway group.
4. Mamta Patel [1]– compared the study of proseal laryngeal mask airway with the endotracheal tube for airway management in children under general anaesthesia and reported a significant change in hemodynamic parameters observed with endotracheal airway group compared to the proseal laryngeal mask airway group.

Changes in SpO_2 and $EtCO_2$ Values

The above values were comparable in both the groups during intraoperative and post-operative periods providing a good ventilator strategy. There were no significant changes observed by us in our study in both the groups.

Malty al. [26] and Sharma et al. [18] also reported that there was no significant difference observed while using proseal laryngeal mask airway and endotracheal tube while securing the airway.

Complications during Emergence

We found in our study that there is an increase in incidence of cough in the endotracheal tube group compared with the proseal laryngeal mask airway and it is found to have an important effect during emergence in anaesthesia and in the postoperative period. This result coincided with the study of the following authors who reported the same findings.

Mamta G. Patel [1]– reported an incidence of 13.3% of patients reported cough after surgery.

Rauf Gul [2]- also reported proseal mask airway when it was used as an intubation device an increased incidence of cough with the endotracheal tube group patients compared to the proseal laryngeal mask airway group

Jaya Lalwani [4] – the author observed that when using endotracheal tube as an intubation device cough was present in 30% of patients and it continued in the post-op period also and it was treated with bronchodilators.

There was no such incidence noted in the proseal laryngeal mask group.

Bronchospasm

This complication was found to be more with the endotracheal group compared with the proseal laryngeal mask airway group.

This finding is in concordance with the study of the following authors who reported that the complication of bronchospasm was found to be more with the endotracheal group compared to the proseal laryngeal mask airway.

Mamta G. Patel [1]– reported an incidence of increased bronchospasm with the endotracheal group when it was used as an intubating device.

Jaya Lalwani [4]– also reported that the endotracheal tube intubation was associated with an increased incidence of bronchospasm of 6.6% in the group. She also noted that the proseal laryngeal mask airway group produced less laryngeal irritation.

Rauf Gul [2]– found that there is an increased incidence of bronchospasm noted in the endotracheal tube group compared with the proseal laryngeal mask airway when it was used as an airway device.

Blood on Device

In our study we found that the blood staining on the posterior surface of proseal laryngeal mask airway was found in 9 persons (22%) when used for airway intubation.

There was only a reduced percentage in (4%) in the endotracheal group.

Mamta [1] and Rauf Gul [2] – observed the same incidence of parameters of blood staining on the device following intubation.

The above result was found to be consistent with the finding of various other authors also.

Aspiration

In our study we found that there was no incidence of aspiration in either of the groups, proseal laryngeal mask airway or the endotracheal tube group during the entire induction, intra-operative and post-operative periods.

This coincided with the report of the other authors.

Sore Throat

The incidence of hoarseness and sore throat was not associated with any of our patients in the immediate post-operative period and also for 24 hours following the surgery.

Hiiggins et al and SHROFF et al– found a greater incidence of sore throat in the patients undergoing intubation with endotracheal tube than with the proseal laryngeal mask airway when it was used as an intubation device.

Positive Pressure Ventilation

The proseal laryngeal mask airway which has a modified cuff that produce a good effective oropharyngeal seal preventing air leak. This enhanced seal pressure helped in positive pressure ventilation in paediatric patients who were undergoing surgeries under general anaesthesia. This is confirmed by various studies comparing the classic laryngeal mask airway and the proseal laryngeal mask group by the following authors.

David Rr Lardner [10], Bikram Jitdas [7] reported an increased incidence of oropharyngeal seal pressure observed with proseal laryngeal mask airway and it provided effective positive pressure ventilation.

Goldman and Jacob [3] – found the modified cuff of proseal laryngeal mask airway provided an effective oropharyngeal seal enhancing the positive pressure ventilation.

M Lopez, Brimacombe [13]– found that the proseal laryngeal mask airway with an increased oropharyngeal seal provided effective positive pressure ventilation in patients undergoing general anaesthesia.

Drainage Tube

The proseal laryngeal mask airway has a drainage tube placed lateral to the main airway

tube. This helps in the channelling of gastric contents and prevents gastric inflation, regurgitation and gastric aspiration.

A gastric tube passed into the drainage tube helped in the assessment of placement of the device.

This is supported by the author A.I.J. Brain [6] who stated that the aim of the drainage tube is to provide a safe effective airway device to be used for positive pressure ventilation.

Conclusion

The observation of the study showed that the proseal laryngeal mask airway proves to be as safe and suitable airway device in paediatric patients undergoing elective surgical procedures.

Hence we arrived at the conclusion that the proseal laryngeal mask airway could be used as an effective alternative to endotracheal intubation in children undergoing short duration elective procedures under general anaesthesia.

Acknowledgement

We like to acknowledge our patients who willingly participated in the study

Conflict of Interest: Nil

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Effects of Hypercarbia on Spontaneous Ventilation in Short Laparoscopic Procedures

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Abstract

Context: Carbon dioxide is most commonly used to insufflate the abdominal cavity to facilitate short laparoscopic surgeries, where the real challenge lies in management of pathophysiological changes due to hypercarbia. *Aim:* To study the effects of hypercarbia on respiration in short laparoscopic procedures such on diagnostic laparoscopy and laparoscopic sterilization. *Settings and Design:* An observational study on 60 female subjects aged between 25-45 years presenting for diagnostic laparoscopy forinfertility, laparoscopic sterilization of ASA I & II category. *Methods and Material:* Anaesthesia was given by ketofol Intravenous induction and sevoflurane 1% with CO_2/N_2O insufflation of abdomen. The pre, intra, postoperative pulse, BP, O_2 saturation, Respiratory rate, $EtCO_2$ were noted with special reference to preinsufflation, during insufflation & deflation of abdomen. *Statistical analysis used:* Descriptive analysis was carried out by mean and standard deviation and presented in trend line diagram, error bar diagram for quantitative variables, frequency and proportion for categorical variables. *Results:* Pre anesthesia Respiratory rate was 13.13±1.09. A1.75 time rise was noted in Respiratory rate (24.43±3.42) to maintainnormocarbia during insufflation. *Conclusions:* Spontaneous Ventilation is effective in maintaining normocarbia during short laparoscopic procedures. Endotrachal intubation and paralysis to maintain normocarbia could be avoided.

Keywords: Hypercarbia; Spontaneous Ventilation; Laparoscopic; $EtCO_2$.

Introduction

Laparoscopy involves inspecting the abdominal cavity through an endoscope [1-3]. It provides excellent post-operative conditions [4]. Carbon dioxide is commonly used to insufflate the abdominal cavity [5] in laparoscopy, but the challenge remains in management of hypercarbia [6,7]. Insufflation of peritoneum with carbon dioxide and a trendelenberg position could produce respiratory distress [8-10] which may require Endotracheal intubation and paralysis to maintain normocarbia. A thorough understanding of these pathophysiological changes is fundamental. So, we studied the effects of hypercarbia, CO_2 level variations in short laparoscopic procedures with the objective to document the efficacy of spontaneous ventilation in maintaining normocarbia as it has not been explored before.

Subjects and Methods

We did an observational study on 60 female subjects aged between 25-45 years presenting to Dhanalakshmi Srinivasan Medical College and Hospital, Siruvachur, Perambalur between June 2016-2017 for short laparoscopic procedures lasting less than 30 minutes like diagnostic laparoscopy for infertility, laparoscopic sterilization. The subjects belonged to ASA I & II category with mallampatti airway status I & II. We excluded subjects with

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Difficult airway, Co morbidities, Obesity, who needed Prolonged procedures or intubation or IAP of morethan 12mm Hg. Ondansetron 4mg and Ranitidine 50mg IVwere given as Pre medication one hour before the procedure. Anaesthesia was given by ketofol Intravenous induction and tight fitting 3 size Pvc mask with sidestream probefor $EtCO_2$ monitoring with sevoflurane 1% with CO_2/ N_2O insufflation of abdomen. This necessitates reducing the awareness by sedation and monitoring the $EtCO_2$. The safety of spontaneous ventilation was evaluated in short laparoscopic procedures for less than 30 minutes with a constant intra abdominal pressure of 12mmhg. The pre, intra, post operative pulse, BP, O_2 saturation, Respiratory rate, $EtCO_2$ were noted with special reference to pre insufflation, during insufflation & deflation of abdomen.14 out of 60 left the procedure for surgical reasons (n=7) and prolongation of surgery necessitating tracheal intubation(n = 7). Totally 46 subjects were eligible for final statistical analysis. The data was entered in Microsoft excel and IBM SPSS version 22 was used for statistical analysis. P value < 0.05 was considered statistically significant. Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. Data was also represented using appropriate diagrams like trend line diagram, error bar diagram.

Results

A total of 46 participants were included in the final analysis. The pre anaesthesia mean $EtCO_2$ was 26.48 in the study population. The minimum level was 10 mm Hg and maximum level was 38 mm Hg. The pre anaesthesia mean RR was 13.13 in the study population. The minimum level was 10 and maximum level was. The induction mean $EtCO_2$ was 27.67 in the study population. The minimum level was 22 mm Hg and maximum level was 32 mm Hg. The induction mean RR was 13.89 in the study population.

The minimum level was 10 and maximum level was 16. The pre insufflation mean $EtCO_2$ was 28.43 in the study population. The minimum level was 24 mm Hg and maximum level was 32 mm Hg. The pre insufflation mean RR was 14.28 in the study population. The minimum level was 9 and maximum level was 16. The insufflation mean $EtCO_2$ was 36.91 in the study population. The minimum level was 22 mm Hg and maximum level was 42 mm Hg. The insufflation mean RR was 24.43 in the study population. The minimum level was 12 and maximum level was 28. The deflation mean $EtCO_2$ was 30.61 in the study population. The minimum level was 28 mm Hg and maximum level was 34 mm Hg. The deflation mean RR was 19.91 in the study population. The minimum level was 12 and maximum level was 28. The recoverymean $EtCO_2$ was 26.83 in the study population. The minimum level was 14 mm Hg and maximum level was 30 mm Hg. The recovery mean RR was 16.15 in the study population. The minimum level was 12 and maximum level was 30 (Table 1). The study findings also showed the increase in the spontaneous respiratory rate closely corresponding with the raise in $EtCO_2$ levels (Figure 1 to 3).

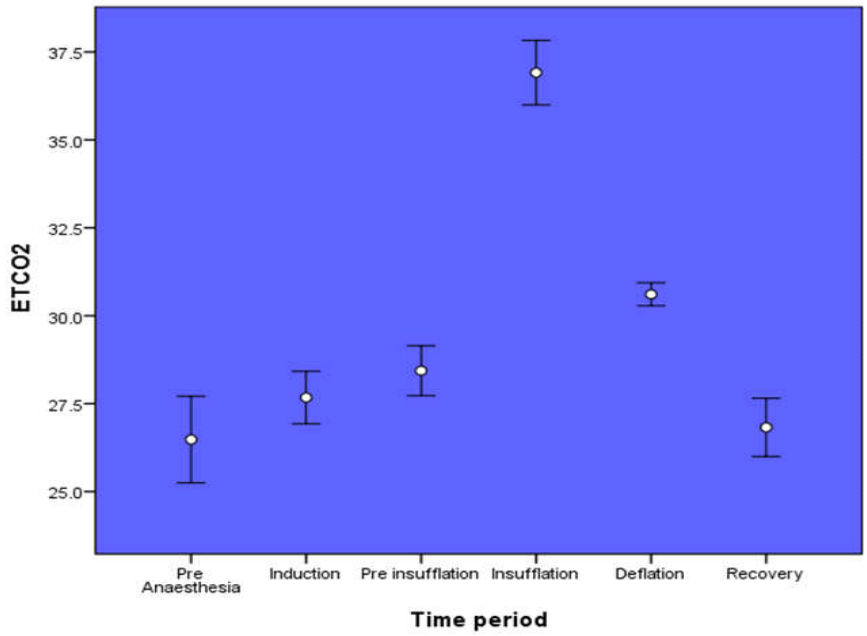

Fig. 1: Error bar chart of comparison of mean different time periods in $EtCO_2$ (N=46)

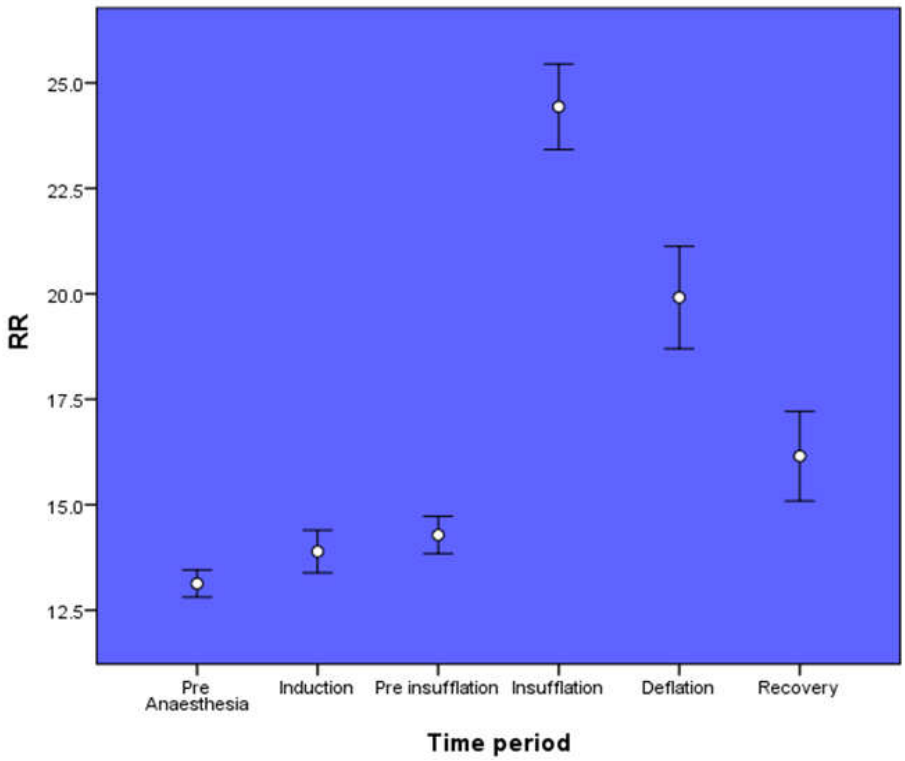

Fig. 2: Error bar chart of comparison of mean different time periods in RR (N=46)

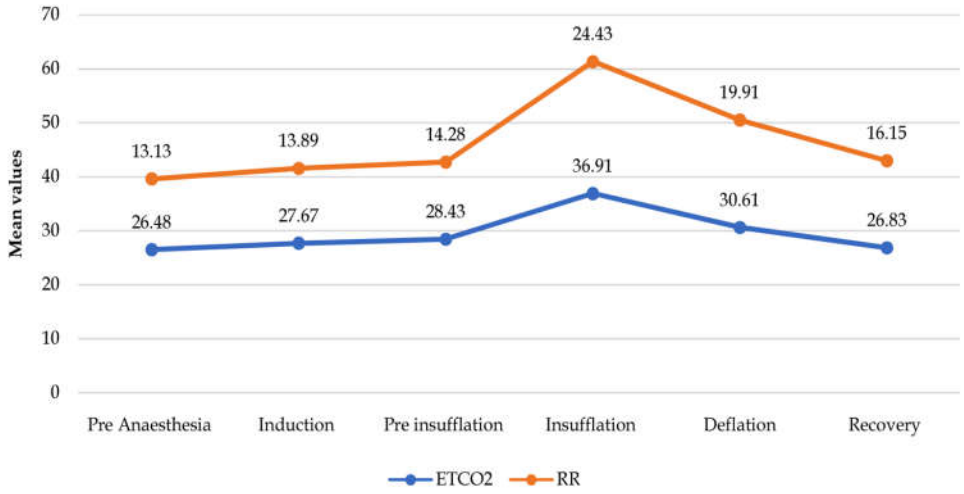

Fig. 3: Trend linefor different time periods in study population (N=46)

Table 1: Descriptive analysis for time periods in study population (N=46)

Time period	Parameter	Mean ±SD	Minimum	Maximum
Pre Anaesthesia	ETCO2 (mm of Hg)	26.48 ± 4.16	10.00	38.00
	RR (per minute)	13.13 ± 1.09	10.00	14.00
Induction	ETCO2	27.67 ± 2.5	22.00	32.00
	RR	13.89 ± 1.7	10.00	16.00
Pre insufflation	ETCO2	28.43 ± 2.39	24.00	32.00
	RR	14.28 ± 1.49	9.00	16.00
Insufflation	ETCO2	36.91 ± 3.1	22.00	42.00
	RR	24.43 ± 3.42	12.00	28.00
Deflation	ETCO2	30.61 ± 1.11	28.00	34.00
	RR	19.91 ± 4.09	12.00	28.00
Recovery	ETCO2	26.83 ± 2.78	14.00	30.00
	RR	16.15 ± 3.58	12.00	30.00

Discussion

Laparoscopic procedures necessitate carbon dioxide insufflation to produce pneumoperitoneum [3,4]. As carbon dioxide is more rapidly soluble in blood than oxygen, hypercarbia is definite and the effects of CO_2 such as peripheral vasoconsiction, hypertension, respiratory compromise in late phases are well known. The factors mainly contributing to the ill effects of hypercarbia are prolonged duration of pneumoperitonum more than 1 ½ to 2 hours and increased intra abdominal pressure of more than 12 mm hg. An increase in end tidal carbon dioxide of more than 20% of pre-insufflations level is associated with increase in respiratory rate of 1.5 to 2 times and is sufficient enough to maintain normocarbia.

$EtCO_2$ is the partial pressure or maximal concentration of carbon dioxide (CO_2) at the end of an exhaled breath, which is expressed as a percentage of CO_2 or mm of Hg [11-13]. In our study, Pre anesthesia Respiratory rate was 13.13±1.09as shown in Table 1. A 1.75 time rise was noted in the Respiratory rate (24.43±3.42) to maintain normocarbia during insufflation as shown in Figure 3.There was also a rise in End Tidal CO_2 pressure from Pre anesthesia levels of 26.48 to insufflation levels of 36.91 mm of Hg as shown in Figure 3. In Gynaecological laparoscopy, Vegfors M et al. (1994) [14] reported that in spontaneous breathing Group, PET CO_2 increased soon after insufflation and remained above 44 mmHg throughout the procedure whereas in controlled ventilation groups all PET CO_2 values were less than 41 mm of Hg. Occasional episodes of arrhythmia were also noticed and hence they concluded that Spontaneous breathing should be avoided in contrast to our study. But our findings suggest that during laparoscopy, ventilation could be well maintained by spontaneous breathing, although there is increase in respiratory work load as indicated by increase in Respiratory rate. We recommend that ventilation and oxygenation should be closely monitored during laparoscopy to avoid hypercapnia and hypoxia.

Nishio I et al (1993) [7] in their study on Forty five women undergoing laparoscopy for gynecological procedure, also observed that ventilation could be well maintained by spontaneous breathing in laparoscopy, although the increase in tidal volume and costal breathing indicate the increase in respiratory work load.

But some authors [15] strongly put forward that End-tidal CO_2 ($PETCO_2$) monitoring may not be a sufficient guide to adjust pulmonary ventilation during laparoscopic surgery, and arterial CO_2 ($PaCO_2$) monitoring is not always indicated. But our study emphasizes the essence of maintaining the hyperventilatiory response to the increase in CO_2 levels in spontaneously breathing patients.

Spontaneous Ventilation is effective in maintaining normocarbia during short laparoscopic procedures. Endotrachal intubation and paralysis to maintain normocarbia could be avoided. There was also no events of Extensive subcutaneous Emphysema in our study as reported by other authors [8,16].

But our study was justified enough only for formulation of Hypothesis and further evidence is required from various RCTs to support and confirm our hypothesis. The smaller sample size and convenient sample used without any comparison is a big limitation of our study. Due to practical and financial reasons, we could not also have a whole picture by including Arterial gas analysis. We mainly demonstrated the effectiveness of spontaneous ventilation in maintaining normocarbia during the short laparoscopic procedures. Our patients were young enough with no comorbidities or airway compromise and the intra-abdominal pressure was kept constant at 12 mm hg and duration of pneumoperitonum never exceeded 30 minutes. Our study also emphasizes the monitoring needs during laparoscopic procedure especially if patients are not given endotracheal general anesthesia. The sedation offered to the patient should be carefully planned and just adequate to maintain the spontaneous breathing drive.

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Conflict ofo Interest

None declared

Key Messages

In short laparoscopic surgeries, real challenge lies in management of pathophysiological changes due to hypercarbia. Spontaneous ventilation is effective in maintaining normocarbia during these procedures. Endotracheal intubation and paralysis to maintain normocarbia can be avoided.

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Original Research Article

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A Comparative Study on Safety of Combined Spinal and Epidural Anesthesia verses Epidural Anesthesia for Orthopedic and Gynecological Surgery

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Abstract

Background: In major surgeries, anesthesia plan requires modification as per patient's need for safe outcome. Orthopedic and gynecological surgeries require excellent surgical conditions and prolonged and effective postoperative analgesia. *Objective:* To compare the safety measures of combined spinal epidural anesthesia verses epidural anesthesia. *Materials and Methods:* The randomized prospective study was conducted on 20 to 60 years old ASA grade (I and II) patients posted for orthopedic and gynecological surgeries. Sixty patients were divided into two groups of 30 each such as group A (combined spinal epidural) and group B (epidural anesthesia). Various parameters were studied to compare safety parameters of combined spinal epidural anesthesia and epidural anesthesia in terms of quality of analgesia, hemodynamic changes and opinion feedback (patient's opinion regarding comfort and acceptance of technique, surgeon's opinion regarding quality of relaxation and preference of technique). Data was analyzed using unpaired t test and chi square test with the help of MS Excel and SPSS software. *Results:* The quality of analgesia was excellent in group A (CSE) as compared to group B (EA). Hemodynamic changes during anesthesia and surgery were comparable in both the groups. Surgeon's opinion regarding motor blockade and preference of technique was in favor of group A compared to group B. Patient's acceptance revealed equivocal in both groups. *Conclusion:* Our study concludes that CSE anesthesia is more safe technique over EA for patients as well as surgeons.

Keywords: Epidural Block; Combined Spinal Epidural Block; Analgesia; Hemodynamics.

Introduction

Conventional spinal anesthesia is safe, cost-effective and reliable form of anesthesia. It is superior to epidural, because of better quality of anesthesia produced, less toxic as the volume of drug and dose is comparatively less, less time consuming. But the disadvantages include precipitous hypotension, PDPH (postdural puncture headache), difficulty in controlling the level of analgesia and not possible to extend the duration of analgesia [1]. In recent times, the use of regional anesthesia in major surgeries is increasing worldwide. Spinal anesthesia (SA) and epidural anesthesia (EA) are still the two most popular regional anesthetic techniques, with proven efficacy in a variety of surgical procedures across the globe [2]. However, EA has advantages in the form of a better control of analgesia, can be extended for long duration surgeries as well as postoperative pain relief. But, the drawbacks include delayed onset of anesthesia, patchy anesthesia, inadequate motor blockade large volumes and dose of drug requirement leading to more chances of side effects and complications not common with spinal anesthesia [3,4]. The combined spinal and epidural (CSE) anesthesia provides benefits of spinal block along with flexibility of an epidural catheter so as to modify and prolong the block for a longer period. In CSE, two anesthetic techniques, each with a different mode of action has to be considered. A

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local anesthetic injected into the subarachnoid space is immediately in close contact with spinal nerves and spinal cord causing neural blockade in a relatively short time span [5,6]. Therefore, CSE is a sort of balanced anesthesia, which uses combination of techniques instead of drugs to accomplish the ideal kind of anesthesia for almost all patients of any age. Later, many modifications and different methods came with some advantages over the other. CSE block can be used for a variety of surgeries [7] and also for relief of labor [8] and postoperative pain [9]. Thus, to compare safety, we conducted this prospective randomized study between combined spinal epidural anesthesia verses epidural anesthesia for orthopedic and gynecological surgery in terms of quality of analgesia, hemodynamic changes and opinion feedback (patient's opinion regarding comfort and acceptance of technique, surgeon's opinion regarding quality of relaxation and preference of technique).

Materials and Methods

Study Design

This prospective study was completed in two years after the approval from the Institutional Ethical Committee. Informed consent was obtained from each patient. Sixty patients with ASA (American Society of Anesthesiologists) physical status I and II aged 20 to 60 years posted for elective surgery were randomized in two groups of 30 each, after thorough clinical and routine laboratory examinations.

Inclusion Criteria

Patients with age group 20 to 60 years, under ASA I and II and posted for various elective surgical procedures of lower abdomen where regional anesthesia was indicated included for the study.

Exclusion Criteria

Patient's refusal, anticoagulant therapy, bleeding diathesis, infection on the back, spinal deformities, history of peripheral neuropathy, neurological disorders, allergic to local anesthetics, blockade is more than T_8 level were excluded from the study

Methods

The patient was positioned in sitting or lateral position with the help of an assistant. Under all aseptic conditions the back was prepared with 5% povidine iodine solution, spirit and area was draped. The L_{3-4} interspace was identified; skin was infiltrated with 2mL of 2% Xylocaine.

Group A: Combined Spinal and Epidural (CSE) Anesthesia

After infiltration of local anesthetic, by using needle through needle single interspace technique, with a 18 gauge 'Weiss' needle via L_{3-4} interspace, epidural space was identified with loss of resistance technique. A long 27g 'Whitacre' spinal needle was inserted through the epidural needle until the tip was felt to penetrate the duramater and cerebrospinal fluid back flow, 3 mL of 0.5% hyperbaric bupivacaine injected with intent of achieving T_8 level block. The spinal needle was then withdrawn. A 20G epidural catheter was inserted into the epidural space via the Weiss needle. After negative aspiration for blood or cerebrospinal fluid a test dose of 3mL ligonocaine 2% adrenaline 1:200000 was given. After positioning the patient in supine position the level of sensory blockade was checked by loss of sensation to pin prick. Once the motor blockade was established by paralysis and the maximum level of sensory analgesia confirmed and the patient was put in required position and surgery was started.

Group B: Epidural Anesthesia (EA)

After infiltration of local anesthetic at L_{3-4} space a 18g 'Tuohy' needle was introduced, epidural space was identified with loss of resistance technique. An 20G catheter was threaded through the epidural needle into the epidural space in cephalad direction, the epidural needle was slowly pulled out without disturbing the catheter and the epidural catheter is kept up 4 to 5 cm in epidural space. After negative aspiration for blood or cerebrospinal fluid a test dose of 3mL lignocaine 2% with adrenaline 1:200000 was given. In all the patients 0.5% bupivacaine was given through the epidural catheter to achieve T_8 level blockade in fractionated doses. This would amount to about 12 to 16 mL and was deposited through the epidural catheter. Once T_8 level of analgesia and adequate blockade was established, the patient was suitably placed and surgery was commenced.

Outcome Parameters

• *Quality of Analgesia: It was compared in both study groups with the following criteria:*

During surgery, patients were given IV sedation midazolam (0.02mg/kg) and supplementary IV

analgesic fentanyl (1 mcg/kg). A criterion for giving sedation was when the patient reported discomfort. The criterion for giving analgesics was when the patient complained of pain.

Excellent: When no sedatives/analgesic was required

Good: When only sedatives was required

Fair: When both sedative and analgesic were required

Poor: When general anesthesia with oral endotracheal tube was required

Hemodynamic Changes: It was noted down and compared in both study groups as follows:

Systolic blood pressure and pulse pressure before administrating anesthesia and throughout intraoperative period. Hypotension (defined as 30% decrease of systolic blood pressure [SBP] controlled with preoperative control level) was treated with intravenous fluid and IV Mephentramine (6mg/kg). Clinically significant bradycardia was defined as a heart rate less than 50 beats/min and was treated with IV atropine (0.5mg/kg). Incidences of clinically significant hypotension and bradycardia were noted as incidence of hemodynamic adverse event. All the patients were monitored in post anesthesia care unit till they were shifted to general ward after they fulfilled PACU (post-anesthesia care unit) discharge criteria.

Opinion Feedback: Postoperatively patient's and surgeon's opinion were taken and analyzed in both the study groups as follows:

Patient: Analgesic comfort during procedure and would he opt for the same technique, if needed in future.

Surgeon: Quality of relaxation and his preference to epidural or CSE.

Statistical Analysis

All clinical data were presented as mean ± standard deviations. Statistical analysis was carried out using MS Excel and SPSS software. The unpaired two tailed student's t test and chi square test was used wherever appropriate. A p value of <0.05% was considered statistically significant.

Results

Demographic Data

Sixty patients (30 in each group) with ASA (American Society of Anesthesiologists) physical status I and II were studied. Patients were in between 20 to 60 years.

Group A (CSE) and group B (EA) both were comparable in terms of age, weight, height and nature of surgery as shown in Table 1. The p value for all parameters was statistically not significant (p>0.05).

Quality of Analgesia

The quality of surgical analgesia was excellent in group A as compared to group B, as shown in Table 2. The p value was highly significant (p<0.001).

Hemodynamic Changes

Hemodynamic changes during anesthesia and surgery were comparable in both the groups.

Table 1: Demographic data in both study groups

Parameters	Group A (CSE)	Group B (EA)	P value	Significance
No of patients	30	30	1.000	Not significant
Age (years)	47.37 ± 9.75	48.66 ± 8.75	0.589	Not significant
Height (cm)	158.76 ± 4.62	156.93 ± 4.22	0.115	Not significant
Weight (kg)	55.00 ± 5.43	55.53 ± 5.09	0.697	Not significant
Surgery (Orthopedic/Gynecology)	16/14	14/16	0.606	Not significant

CSE: combined spinal and epidural anesthesia, EA: epidural anesthesia. The values quoted as the Mean ± Standard deviation. Unpaired t-test was used to compare the results between two groups. The *p* value of <0.05 was considered statistically significant difference

Table 2: Quality rating of analgesia in both study groups

Quality Rating	Group A (CSE)	Group B (EA)	p value	Significance
Excellent	12 (40%)	3 (10%)	< 0.001	Significant
Good	16 (53%)	13 (43%)		
Fair	2 (7%)	12 (40%)		
Poor	0 (0%)	2 (7%)		

CSE: combined spinal and epidural anesthesia, EA: epidural anesthesia. Chi square-test was used to compare the results between two groups. The *p* value of <0.05 was considered statistically significant difference

Maximum number of patients in both were fall of < 30% in heart rate and systolic blood pressure as shown in Table 3 and Table 4.

Heart rate raised above 30% in an only 1 (3%) patient of CSE group; whereas all EA group patients showed no increase in heart rate above 30% (Table 3).

Systolic blood pressure increased above 30% in 3 (10%) patients of CSE group; whereas 2 (7%) patients in EA group showed increase in systolic blood pressure above 30% (Table 4).

The p value for heart rate and systolic blood pressure in both study groups was not significant i.e. p = 0.122 and p = 0.589 respectively.

Patient and Surgeon Opinion Feedback

Surgeon's opinion regarding quality of relaxation (motor blockade) and preference of technique was in favor of group A when compared with group B. The patient's acceptance (analgesic comfort during procedure) revealed equivocal in both groups, as shown in Table 5. The p value for surgeon's opinion is 0.001 highly significant and p value for patient's opinion is 0.150 not significant.

Discussion

Regional anesthesia (RA) is preferred over general anesthesia for lower limb orthopedic surgery and spinal anesthesia is often a choice [2,10]. Spinal anesthesia is a simple and quick technique but it has risk of severe hypotension. New drugs, new needle designs, and developments in catheter technology have contributed to improving the quality and safety of regional anesthesia. Epidural and spinal blocks are major techniques with long history of effective use for various surgeries and pain relief. Nevertheless, both techniques have their drawbacks. Major disadvantage of subarachnoid blockade is precipitous hypotension and inability to obtain desired level. Epidural blockade with catheter *in-situ* provides better control of analgesia and postoperative care. Although it has its own demerits like slower onset, large dose of local anesthetic drug requirement, patchy anesthesia.

Table 3: Percentage fall heart rate in both study groups

% Fall in heart rate	Group A (CSE)	Group B (EA)	p value	Significance
<10%	14 (47%)	17 (57%)	0.122	Not significant
10-20%	12 (40%)	9 (30%)		
20-30%	3 (10%)	4 (13%)		
>30%	1 (3%)	0		

CSE: combined spinal and epidural anesthesia, EA: epidural anesthesia, %: Percentage. Chi square-test was used to compare the results between two groups. The *p* value of <0.05 was considered statistically significant difference

Table 4: Percentage fall systolic blood pressure in both study groups

% Fall in Systolic BP	Group A (CSE)	Group B (EA)	p value	Significance
<10%	1 (3%)	6 (20%)	0.589	Not significant
10-20%	8 (27%)	14 (47%)		
20-30%	18 (60%)	8 (27%)		
>30%	3 (10%)	2 (7%)		

CSE: combined spinal and epidural anesthesia, EA: epidural anesthesia, %: Percentage, BP: Blood pressure. Chi square-test was used to compare the results between two groups. The *p* value of <0.05 was considered statistically significant difference.

Table 5: Comparison of opinion feedback in both study groups

Opinion feedback	Group A (CSE)		Group B (Epidural)		p value	Significance
	Excellent	Good	Excellent	Good		
Surgeon's opinion	23 (76.70%)	7 (23.30%)	2 (7%)	26 (92.70%)	< 0.001	Significant
Patient's opinion	30 (100%)	0 (0%)	28 (93.30%)	0 (0%)	0.150	Not significant

CSE: combined spinal and epidural anesthesia, EA: epidural anesthesia, %: Percentage. Chi square-test was used to compare the results between two groups. The *p* value of <0.05 was considered statistically significant difference.

Combined spinal epidural (CSE) techniques combine both features of subarachnoid block and continuous epidural anesthesia. CSE is an effective method to reduce the drug dosage used for anesthesia, and choice of medication is based on concept of anti-nociceptive synergy [11]. The subarachnoid injection allows rapid onset of analgesia with minimal dosage, flexibility to extend the block depending upon the surgical incision required [5,6]. The safety of CSE is enhanced by keeping a catheter *in-situ*, thereby avoiding overshooting with regard to duration of spinal anesthesia. Many studies confirm that low dose local anesthetic and low dose opioid confer sufficient analgesia without any motor or proprioceptive impairment [12-14]. This selective block render patient to bear weight and return to their casual routine even after any moderate to major surgery. In another words it hastens the recovery of surgical patients postoperatively.

In present study, majority of the patients who were given CSE had good quality of analgesia when compared to epidural route alone. The need for supplementary sedatives and analgesics were significantly higher in epidural group patients. The higher incidence of supplementation and failure rate in patients receiving epidural block has been reported by many authors.

Hemodynamic changes were assessed by using heart rate and systolic blood pressure. Hemodynamically the incidence of hypotension and bradycardia was almost similar in both the groups. The majority of the CSE group patients had a fall of 20-30%, majority of EA group had a fall of 10-20% in heart rate and systolic blood pressure only 1 patient of CSE group and none of EA group had fall of >30% in heart rate which responded to atropine. Hypotension of >30% was seen in 3 patients of CSE group and 2 patients of EA group which were treated with mephentaramine. In CSE, although spinal block is given initially, significant hemodynamic changes are not observed because of less extensive spinal block (T_8). Nikhil Swarnkar et al.[15] in their study of CSE in comparison to EA for total abdominal hysterectomies found out that there is no significant change in the hemodynamic parameters observed in both the groups. The explanation given by them for this finding is, in CSE although spinal block is given initially, significant hemodynamic changes are not observed because of less extensive spinal block (T_{7-8}) due to sequential CSE technique combined with slower onset of epidural block allowing time for compensatory mechanism to occur. The absence of hemodynamic changes in CSE group in our study is comparable with the above study and may be explained by the relatively low dose of bupivacaine used in the spinal phase of CSE, and by the gradual administration of local anesthetics in the EA group and also due to preloading with IV fluids.

Postoperative questionnaire revealed equivocal patient acceptance of the CSE and EA technique reflecting the patients comfort and adequate analgesia in the preoperative period. On the other hand surgeon's response weighed heavily in favor of CSE, which they attributed to early commencement of surgery and better relaxation in abdominal operations. In this study we did not come across complications like cardiorespiratory and neurological catastrophes, total spinal, inadvertent dural puncture, etc. none of the patients complained of post dural puncture headaches. The use of 27g spinal needle may have contributated to the absence of headache in our study. We have used the single segment block technique in CSE, which appears to be safer, time saving and less traumatic.

Conclusion

Both anesthetic techniques provide good quality analgesia and stable hemodynamics but CSE provides significantly more comfort with feasibility to prolong block. Thus, CSE should be preferred over epidural anesthesia in high risk patients especially for orthopedic and gynecological surgeries.

Conflicting Interest: None Decleared

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Dexemedetomidine and Clonidine as Adjuvant to Local Anaesthetic Agent in Epidural Anaesthesia

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Abstract

Background: Many anesthetic drug combinations have been used in patients to improve regional anaesthesia. This study was planned to compare the analgesic and sedative effects of dexmedetomidine and clonidine as an adjuvant to bupivacaine in patients undergoing lower limb surgeries. *Material and Methods:* This prospective study was conducted in 50 patients of ASA grade I and II, aged between 18-65 years. Patients were randomly allocated to Group BC receiving 30ml of 0.5% bupivacaine + 2 μg/kg of clonidine and group BD receiving 30 ml solution of 0.5% bupivacaine + 1.5 μg/kg of dexmedetomidine. Onset and duration of sensory and motor blocks, duration of analgesia, sedation, and complication if any were recorded. *Results:* Group BD resulted in an earlier onset (8.52±2.36 min) of sensory analgesia at T_{10} as compared to Group BC (9.76±3.44 min). ($p<0.05$) Time to onset of motor block was significantly shorter in group BD (17.42±5.16 min) as compared to group BC (19.76±4.06). ($p<0.05$) Time for rescue analgesia was comparatively shorter in group BC (310.76±23.75 min) as compared to group BD (344.88±28.16). ($p<0.05$) Mean sedation score 3 was significantly higher in group BD (40%) as compared to group BC (16%). ($p<0.0001$) The incidence of dry mouth was higher in both the groups but it was statistically non-significant in both the groups ($p>0.05$). *Conclusion:* Dexmedetomidine was found to be better adjuvant than clonidine with bupivacaine because of better analgesia effect, sedative effect and also hemodynamically stable during the surgical procedures under anaesthesia.

Keywords: Bupivacaine; Clonidine; Dexmedetomidine; Sensory and Motor Block.

Introduction

The anaesthetic techniques in last twenty years have improved and evolved for the management of postoperative pain. Effective pain management is essential for optimal care of surgical patients and patient satisfaction is improved when the anaesthetic technique choosen for the procedure is associated with less post-operative side-effects [1]. Many techniques and drug regimens have been used in patients to improve regional anaesthesia [2,3]. Effective postoperative analgesia prevents increase in catecholamine secretion, decreases incidence of respiratory and cardiovascular complications, avoids catabolic state, causes early return of gastrointestinal motility, results in early ambulation, reduces patient's anxiety, accelerates recovery and reduces hospital stay [4].

Various adjuvants in regional anaesthesia are being used to produce smooth and prolonged post operative analgesia along with good sedation and stable hemodynamic properties [5,6]. These properties are produced by both clonidine and dexmedetomidine which are α-2 adrenergic agonists and commonly used in anaesthetic practice. These drugs inhibit the release of neurotransmitters and help in modulating pain transmission [7,8]. Clonidine is being used since long but Dexmedetomidine is being highly selective α_2 adrenergic agonist with less side effects as compared

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to clonidine so this can be used in low dose [9-11]. They decrease the anesthetic dose because of increase in augmentation of both sensory and motor blockade of local anesthetics. Few studies have demonstrated the effect of these adjuvants with bupivacaine which is a commonly used local anesthetic. This study was planned to compare Dexmedetomidine and Clonidine when used epidurally as an adjuvant to bupivacaine in patients undergoing lower limb surgeries.

Materials and Methods

The present prospective study was conducted in the department of anaesthesiology and critical care at a tertiary care teaching hospital only after getting approval from Institutional ethics committee. Fifty patients of American society of anaesthesiologists (ASA) grade I and II, aged between 18-65 years scheduled for lower limb surgeries were included in the study. The patients with coagulation disorders, blood dyscrasias, psychiatric illness, diabetes, and history of allergy to local anaesthetics were excluded from the study.

Patients were randomly allocated to two treatment groups; bupivacaine + clonidine (BC) and bupivacaine + dexmedetomidine (BD). Written informed consent was taken from all the patients. Patients had continuous ECG, pulse oximetry, blood pressure monitoring. After taking base line parameters patients were administered epidural block with 18 gauge needle and catheter was secured 3-4 cm into epidural space and a test dose of 3 ml of 2% lignocaine hydrochloride solution containing adrenaline 1:200,000 was injected. After 4–6 minutes of administering the test dose, patients in group BC received 30ml of 0.5% bupivacaine + 2 μg/kg of clonidine. Patients in group BD were administered 30 ml solution of 0.5% bupivacaine +1.5 μg/kg of dexmedetomidine.

The bilateral pin-pricking was used to test the sensory level while a modified Bromage scale for motor block. It was measured at 5, 10, 15, 20, 25 and 30 minutes intervals after the epidural administration of the drugs.

Onset of sensory blockade and motor blockade, duration of motor block (mins.), duration of sensory block (mins.) and adverse effects if any were observed and recorded. Ramsay Sedation Score was used to grade sedation which was evaluated in five point likert scale. Sedation scores were recorded just before the initiation of surgery and thereafter every 15 minutes during the surgical procedure.

All vital parameters were checked and recorded every 5 min until 30 min and at 10 min interval, thereafter up to 60 min and then at 15 min interval for next hour and finally at 30 min in the third hour. Hypotension (systolic pressure falling more than 20% mmHg) was treated with inj. mephenteramine 3–6 mg in bolus doses and bradycardia (heart rate <50 beats/min) was treated with 0.3 mg of inj. atropine. The onset of pain was managed by giving 10 ml of 0.25% bupivacaine after operation. Complication if any like anxiety, nausea, vomiting, pruritis, shivering, etc. were also recorded.

All the data was expressed in mean±SD or in percentage. Data was analyzed using suitable statistical tests like 'Analysis of variance and chi-square test'. A p value of less than 0.05 was considered significant.

Results

Both dexmedetomidine and clonidine groups were comparable demographically and mean duration of surgery was also comparable in both the groups and statistically non-significant ($p > 0.05$). (Table 1)

Group BD resulted in an earlier onset (8.52±2.36 min) of sensory analgesia at T_{10} as compared to Group BC (9.76±3.44 min). The p value in both the group was < 0.05 i.e. statistically significant. Group BD also helped in achieving the maximum sensory anaesthetic level in a shorter period (13.26±3.96 min) as compared to Group BC (15.76±4.86 min). The p value in both the group was<0.05 i.e. statistically significant. Time to onset of motor block was significantly shorter in group BD (17.42±5.16 min) as compared to group BC (19.76±4.06). The p value

Table 1: The demographic characterstics of patients of both the groups

Demographic characteristics	Group BD (n = 25)	Group BC (n = 25)
Age (years)	35.38 ± 8.64	33.06 ± 6.36
Sex (M/F)	20/5	20/5
ASA (I/II)	21/4	20/5
Duration of surgery (mins.)	84.34 ± 14.58	83.78 ± 13.68

*P value > 0.05 for all parameters (non-significant)

in both the group was<0.05 i.e. statistically significant (Table 2).

Time to two segmental dermatomal regression was found significantly more in group BD (135.36±8.22 min) as compared to group BC (128.08±7.54) (P < 0.05). As a result the time for rescue analgesia was comparatively shorter in group BC (310.76 ± 23.75 min) as compared to group BD (344.88±28.16) (P < 0.05) (Table 2).

Mean sedation score 3 was significantly higher in group BD (40%) as compared to group BC (16%). The p value in both the group was < 0.0001 i.e. highly significant (Table 3).

Respiratory rate, heart rate and systolic and diastolic blood pressure in both the groups were found non-significant at all intervals. (P>0.05) The incidence side effects like nausea, vomiting, headache, shivering and dizziness were comparable in both the groups and statistically non-significant (Table 4).

Discussion

Good pain relief and early mobilization are possible during epidural analgesia when it is given with an adjuvant drugs [3]. Because of respiratory depression, higher cost and also postoperative nausea and vomiting, opioids are being less used with local anesthetic for postoperative pain relief [8]. Alfa 2 agonists like clonidine have been used successfully to achieve faster onset of action of local anaesthetics, rapid onset of sensory and motor blockade, prolonged duration of analgesia during post-operative period, stable hemodynamically in regional anaesthesia [12-14]. But the introduction of dexmedetomidine has further increased the scope of α-2 agonists in regional anaesthesia [15].

In present study demographic characteristics of both groups of patients were comparable. Both the groups in present study have not only faster onset of sensory block, prolonged duration of analgesia but also provides a good sedation as compared to

Table 2: Comparison of both sensory and motor block characteristics in both the groups

Block characteristics (Time in minutes)	Group BD (n = 25)	Group BC (n = 25)
Onset of sensory block	8.52 ± 2.36	9.76 ± 3.44
Onset of motor block	11.54±42	12.96±76
Time to maximum sensory block level	13.26± 3.96	15.76 ± 4.86
Time for complete motor block (mins.)	17.42± 5.16	19.76 ± 4.06
Time to two segmental regression	135.36 ± 8.22	128.08 ± 7.54
Time to sensory regression at S1	314.64 ± 42.36	295.72 ± 34.52
Time to first rescue analgesia	344.88 ± 28.16	310.76 ± 23.76
Duration of motor block	326.34±27.54	296.42±26.52
Duration of sensory block	338.74±24.64	301.22±24.42

*p<0.05 for all parameters (significant)

Table 3: Sedation scores in both the groups

Sedation scores during surgery	Group BD (n = 25) N (%)	Group BC (n = 25) N (%)	P value
1	4 (16)	9** (36)	<0.0001
2	11 (44)	12 (48)	>0.05
3	10** (40)	4 (16)	<0.0001
4	0	0	-
5	0	0	-

Table 4: Incidence of complications in both the groups

Adverse effects	Group BD (n = 25) N (%)	Group BC (n = 25) N (%)
Dry mouth	7(28)	6 (24)
Nausea/vomitting	5 (20)	6 (24)
Shivering	1 (4)	1 (4)
Headache	1 (4)	2 (8)
Dizziness	2 (8)	1 (4)

established data with bupivacaine alone [16,17]. But dexmedetomidine group in present study was found significantly more effective as compared to clonidine group for these characteristics and also for duration of sensory and motor block, prolonged post-operative analgesia and a lesser amount of total bupivacaine used post-operatively. Similar results have been shown by other studies in which dexmedetomidine was used as adjuvant [3,18,19].

In present study dexmedetomidine has produced significantly profound sedation as compared to clonidine group. Overall, the sedation scores were highly significant statistically with administration of dexmedetomidine. Similar results were found in other study which has used ropivacaine as local anesthetic [18].

Blood pressure and heart rate were found stable throughout the study period. It can be concluded that both drugs are hemodynamically stable. Similar results were shown in other studies [5,7,18,20]. Both the dexmedetomidine and clonidine groups were having higher incidence of dry mouth in the post-operative period which was non-significant on comparison. One study has also shown a higher incidence of nausea and dry mouth during the postoperative period. Profound deep sedation or respiratory depression was not found in any of the patient in either group which is common with opioids. Similar results were found in other studies [5,18].

Conclusion

Dexmedetomidine was found to be better adjuvant than clonidine with bupivacaine because of better analgesia effect, sedative effect and also hemodynamically stable during the surgical procedures under anaesthesia.

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A Randomized Controlled Study to Compare the Efficacy of Ropivacaine and Bupivacaine in Spinal Anesthesia in Children

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Abstract

Aim: To evaluate the efficacy of Ropivacaine and Bupivacaine in spinal anaesthesia in children for infraumblical surgeries as regional anaesthesia in children and ambulatory setup is gaining popularity. *Materials and Methods:* This is a randomized controlled study involving 60 children of age between 7 and 12 years posted for elective infraumblical surgeries under spinal anaeshesia. They are allotted into two groups, Group R receiving 0.5% ropivacaine and Group B receiving 0.5% bupivcaine. The onset of sensory block, maximum height of sensory block, time taken to reach the maximum height of sensory block, two segment regression time, onset of motor block, mean duration of sensory & motor block and quality of block were noted. The hemodynamic parameters noted are pulse rate, systolic and diastolic blood pressure, oxygen saturation with pulse oximeters. *Statistical Analysis used:* Chi-Square test. *Results*: There was significant delay in onset of sensory and motor block in ropivacaine group. There was earlier two segment regression time, earlier offset of sensory and motor block and time taken for micturition was earlier in ropivacaine group. The quality of block was adequate in both groups. The hemodynamic parameters were well maintained in both groups. *Conclusion:* Ropivacaine provides a good alternative to bupivacaine in case of short duration of surgeries. It is more suitable in cases of ambulatory surgeries where the patients meet the discharge criteria earlier and can be discharged from the hospital.

Keywords: Spinal Anaesthesia; Ropivacaine; Bupivacaine.

Introduction

Spinal anaesthesia is the most common choice for infraumblical surgeries [1]. Though general anaesthesia is most popular in children, regional anaesthesia is gaining popularity with advent of newer drugs and ultrasound techniques [2,3].The most common drugs used for spinal anaesthesia are Lignocaine and Bupivacaine [4].

Lignocaine has faster onset and short duration of sensory and motor blockade and used for short duration surgeries. Lignocaine produces sudden and severe hypotension and bradycardia soon after block. It also produces transient neurological symptoms in a few patients.

Bupivacaine produces intermediate to long duration of sensory and motor blockade and thus is a good alternative to lignocaine in surgeries of longer duration. But the longer duration of motor blockade makes it unsuitable for ambulatory surgeries.

Ropivacaine provides an alternative to bupivacaine, with lesser duration of motor blockade [5,6]. It has a good hemodynamic stability, with lesser systemic toxicity when compared to bupivacaine [7].

Aim

To evaluate the efficacy of Ropivacaine and Bupivacaine in spinal anaesthesia in children for infraumblical surgeries.

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Materials and Methods

Prospective randomized controlled double blind study conducted in a tertiary care centre with 60 children taken up for elective infraumblical surgeries under spinal anaesthesia. ASA I & II patients of age 7 – 12 years(both gender) were randomly allotted into two groups Group B for isobaric Bupivacaine 0.5% and Group R for isobaric Ropivacaine 0.5%. Children with bleeding disorders, hypersensitivity to local anaesthetics, local site infection, neurological deficits were excluded.

The parents and patients were educated about the study and informed written consent obtained from the parents. Premedication was avoided in these patients in order not to confound with the results. An appropriate IV line was secured in the operating room and started with ringer lactate infusion. The patient was then placed in lateral decubitus position and was held firmly by the assistant. With sterile precautions, subarachnoid block was performed at L4–L5 interspace using 27G Quinckie's needle. After confirming CSF with aspiration, local anaesthetic drug was injected according to the group allotted. The dosage of local anaesthetic drug was taken according to the weight of the child (< 5kg - 0.5mg/kg, 5 -15kg – 0.4mg/kg, >15kg–0.3mg/kg) and the maximum dose was taken as 20mg [8,9].

Parameters Recorded

1. *Hemodynamic Parameters*:

a. Pulse rate, non invasive blood pressure and oxygen saturation were recorded at base line and monitored every 2 minutes for the first 10 minutes, then every 5 minutes till first 60 min and every 15 minutes upto 90 minutes or till the surgery is over and then in recovery room

b. Any drop in mean arterial pressure 20% from baseline is taken as hypotension and ephedrine 3mg given

c. Any decrease in pulse rate less than 60/min was treated with atropine 0.04mg/kg.

2. *Sensory Blockade*:

Sensory blockade was determined by whisp of cotton along the mid axillary line at about a interval of 1 min until the level of block reached upto L1. The maximum height of the sensory blockade was noted.

Onset of sensory block was defined as the time taken from injection of drug to sensory block at L1 and offset of sensory block was determined by return of sensation at S5 dermatome. The duration of sensory block was determined by the time interval between onset and offset of sensory block.

3. *Motor Blockade*:

Motor block was determined by the modified Bromage score

0 - No motor loss

1 - unable to flex hip

2 – unable to flex knee joint

3 – unable to flex ankle joint

This is assessed at a gap of 1 minute till complete motor blockade develops. Onset of motor block was defined as the time taken from injection of drug to development of complete motor block (bromage score 3). Bromage score 0 is taken as complete recovery from motor block. The duration of motor block was determined by the time between onset and offset of motor block.

4. The highest dermatomal level of sensory block was noted.

5. The Time taken to achieve the highest dermatomal level was noted.

6. The Two segment regression time (ie., the time taken to decrease from maximum sensory level by two segments from initial level) was noted.

7. Quality of block was determined as adequate when no sedation or analgesia used, inadequate when there is need for additional analgesia, and as failed when converted to general anaesthesia. If analgesia was inadequate then fentanyl injection 1microgram/kg was given. If the regimen was switched to GA then the patient was excluded from the study.

8. Time of micturition was noted.

9. Duration of surgery was noted.

Data analysis was done with the help of computer using *Epidemiological Information Package (EPI 2010)* developed by Centre for Disease Control, Atlanta. Kruskul Wallis chi-square test was used to test the significance of difference between quantitative variables and Yate's chi-square test for qualitative variables. A 'p' value less than 0.05 is taken to denote significant relationship.

Results

The demographic data analysis among the group was compared and no statistically significant difference was found among the groups.

The average time taken for onset of sensory block is 6.2 minutes for ropivacaine group and 4.6 minutes for bupivacaine group and this delayed onset in ropivacaine group is found to be statistically significant The time taken to achieve the maximum height of sensory block is acheived in about 8.4minutes in bupivacaine group and about 12.4 minutes in ropivacaine group and the delay is statistically significant in this study [10,11].

The onset of motor block is about 4.4 minutes in bupivacaine group and about 9 minutes in ropivacine group and delay is found to be statistically significant [10]. The two segment regression time is 63.5 minutes in bupivacaine group and about 39.8 minutes in ropivacaine group and fasterer regression is found to be stasistically significant [10].

The mean duration of sensory block is about 147.7 miutes in bupivacaine group and about 117.7 minutes in ropivacaine group and the lesser duration in ropivacaine group is statistically significant [12]. The mean duration of motor block is about 100 minutes in ropivacaine group when compared to bupivacaine group of about 118 minutes and it is found to be statistically significant [12]. The mean time of micturition is after 214 minutes in ropivacaine group when compared to bupivacaine group of after 317 minutes and it is found to be statistically significant [10]. The average level of maximum sensory block in ropivacaine group is T7, which is lower than that achieved in bupivacaine group of T5 [10].

As of the Hemodynamic parameters concerned there is no significant difference between both the groups as of drop in pulse rate, drop in blood pressure. The oxygen saturation was well maintained in both groups and there was no significant difference.

Discussion

The average time taken for onset of sensory block is more for ropivacaine group than bupivacaine group which is similar to that found in study conducted by V.Gupta, Mehta and colleagues. The lower lipid solubility character of ropivacaine is the cause for delayed onset of sensory block when compared to bupivacaine.

Table 1: Demographic datas

Group	Age(years)	Sex		Height(cm)	Weight (kg)
		Male	Female		
Group B	8.9	27	3	110.2	15.8
Group R	8.7	26	4	108.6	16.5
p-value	0.4	0.5	0.5	0.32	0.34

Table 2: Clinical Parameters

Parameters	Group B (Time in minutes)	Group R (Time in minutes)	p value
Onset of Sensory Block	4.6 ± 0.5	6.2 ± 0.6	0.0001
Time to achieve maximum height of sensory block	8.4 ± 0.5	12.4 ± 0.6	0.0001
Duration of sensory block	147.7 ± 8.6	117 ± 9.4	0.0001
Onset of motor block	4.4 ± 0.5	9.1 ± 0.8	0.0001
Duration of motor block	118.3 ± 8.7	100 ± 8.3	0.0001
Time of micturition	317 ± 13.7	214 ± 13.8	0.0001
Two segment regression time	63.5 ± 4.2	39.8 ± 4	0.0001

Table 3: Maximum height of sensory block

Level of block	Group B		Group R	
	n	%	n	%
T4	12	40	-	-
T5	16	53.3	-	-
T6	2	6.7	3	10
T7	-	-	19	63.3
T8	-	-	8	26.7
Total	30	100	30	100

The maximum height of sensory block was T6–T7 in ropivacaine group and T4-T5 in bupivacaine group. The maximum height of sensory block is less in ropivacaine group when compared to bupivacaine group which is similar to that found in study by Marc Malinovskgy, Charles and Montouvalou and colleagues. As less number of segments is blocked and also the level of block is lesser, it avoids cardiovascular and respiratory alterations.

The average time taken to reach the maximum height is more in case of ropivacaine group when compared to bupivacaine group which is similar to the study of Malinovsky, Florence Charles.

The mean two segment regression time is lesser in ropivacaine group compared to that of bupivacaine group which is similar to that of study conducted by Mantouvallou and colleagues where the two segment regression time is shorter in ropivacaine group.

The duration of sensory block is less in ropivacaine group when compared to bupivacaine group which is similar to that of study conducted by Metha and colleagues, Neval Boztuz and colleagues, Mantouvalou and colleagues. Early recovery of sensory block in case of ropivacaine makes the drug more suitable for ambulatory surgeries.

Thus the onset of motor block is delayed in ropivacaine group which is similar to the study found by Metha and colleagues, Neval Boztuz and colleagues, Mantouvalou and colleagues where the onset of motor block is delayed in ropivacaine group.

The duration of motor blockade is less in ropivacaine group which is similar to study conducted by those of Metha and colleagues, Neval Boztuz and colleagues, Mantouvalou and colleagues. So the patients can be mobilized early in case of ropivacaine. This property makes it ideal for short surgeries and ambulatory surgeries.

The mean time taken for micturition was earlier in case of ropivacaine group compared to bupivacaine group which is similar to that study conducted by Neval Boztuz and Zekiye and colleagues. As the patient micturates earlier in case of ropivacaine, the patient meets the discharge criteria earlier. The quality of block was adequate in both groups which is similar to that of study conducted by McChelland and colleagues.

On overall comparision, ropivacaine in spinal anaestheisa had delayed onset of sensory and motor block, but earlier regression of sensory and motor block occurred. This property may be due to lower lipid solubility of ropivacaine. The earlier regression of blockade is helpful for ambulatory and day care surgeries where discharge criteria are met at earlier stages. Thus ropivacaine proves to be good alternative to bupivacaine in case of infraumblical surgeries. Ropivacaine is more suitable for shorter duration of surgeries.

Conclusion

Ropivacaine used for spinal anaesthesia in children has delayed onset of sensory and motor block. It also has faster offset of sensory and motor block with adequate quality of block compared to that of bupivacaine. Hence, Ropivacaine can be used as a good alternative to Bupivacaine in case of shorter duration of surgeries especially in ambulatory setup.

Key Messages

As regional anaesthesia is gaining popularity in children, earlier discharge with shorter acting drugs like ropivacaine can be used in these surgeries.

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Comparision of Fentanyl and Dexmedetomidine when Added to Lignocaine in Intravenous Regional Anesthesia

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Abstract

Background: Introduction-Intravenous regional anesthesia (IVRA) is a simple,reliable and cost effective technique for surgeries involving the distal arm.It has the advantage of speed of onset,rapid recovery, reliability of blockade and cost effectiveness. Various adjuvants have been added to local anesthetics to increase the speed of onset and duration of post operative analgesia.The aim of the present study is to compare the effects of adding fentanyl versus dexmedetomidine to lignocaine during IVR. *Materials and Methods:* This study included 60 patients of ASA class 1 and 2 of either sex aged between 20-50 years scheduled for various upper limb surgeries.Patients were randomly divided in to two groups of 30 each.Group LF received 40ml of 0.5% lignocaine with fentanyl 2µg/kg and group LD received 40ml of 0.5% lignocaine with dexmedetomidine 1µg/kg. Postoperative pain score was recorded using Visual Analogue Scale (VAS). Injection paracetamol 1gram intravenous infusion was given as rescue analgesic when VAS score reached >4. Duration of postoperative analgesia was noted from deflation of torniquet to VAS score of 4. Patients were observed for adverse effects like skin rash,bradycardia and sedation intraoperatively and postoperatively following torniquet deflation in both the groups. *Result:* Earlier onset time of both sensory block (4.80±0.60min)and motor block (8.60±3.20min)were noted in group LD compared to sensory block(6.82±1.50min)and motor block (10.80±1.20min)in group LF.Postoperative analgesia was also considerably prolonged in group LD(350.52±42.5min)compared to group LF(204.42±32.5min). Adverse effects like bradycardia and sedation were noted in two and four number of patients respectively in group LD. *Conclusion:* The addition of 1µg/kg dexmedetomidine to lignocaine when compared to 2µg/kg fentanyl in IVRA reduces the time for onset of block, increases the duration of block. Improves quality of anarsthesia prolonged post operative analgesia and reduced rescue analgesia requirement.

Keywords: Fentanyl; Dexmedetomidine; IVRA; Lignocaine.

Introduction

International Association for Study of Pain (IASP)defines pain as –An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage [1]. IVRA is a technically simple and reliable method which can be performed in outpatient extremity suegeries lasting less than one hour[2] with success rates between 94-98% [3].

The main disadvantages include the torniquet pain and inability to provide postoperstive analgesia [4]. Various studies are being done with the aim of decreasing the torniquet pain and improving the duration of postoperative analgesia by adding various adjuvants [5] to LA such as ketamine [6], opioids [7], alpha adrenergic agonists [8] etc. Addition of opioids (morphine) as adjuvant to lidocaine has been shown to improve postoperative analgesia and sensory block with little effect on torniquet pain, motor block quality, analgesia duration or analgesic consumption [7]. Dexmedetomidine an α_2-adrenoceptor agonist has a ratio of selectivity towards α_2/α_1receptors of 1620:1 with more potent neurological and less

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cardiovascular effects [8]. Dexmedetomidine-lignocaine mixture used in IVRA has been shown to improve the quality of anesthesia,reduce torniquet pain and post operative analgesia requirement [9]. Our present study was done to compare the effects of adding either fentanyl or dexmedetomidine to lignocaine for IVRA.

Materials and Methods

This prospective randomized was conducted after obtaining clearance from institutional ethical committee and informed written consent from all the patients. Sixty patients of either sexes aged between 20 and 50 years with ASA physical status 1 or 2 scheduled for elective and emergency upper limb procedures lasting less than 90 minutes were included in this study. Exclusion criteria included history of drug allergy/hypersensitivity to LA, patients with severe peripheral vascular and neurological disease, patients with hemolytic disease like sickle cell anemia, hypertension, diabetes mellitus, liver disease and kidney disease.

Design of the Study

Patients were randomly divided in to two groups (30 patients each)

Group LF-received 40ml of 0.5% lignocaine (preservative free) with fentanyl 2µg/kg in 2.0ml to make final volume to 42ml.

Group LD-received 40ml of 0.5% lignocaine (preservative free) with dexmedetomidine 1µg/kg in 2.0ml to make final volume to 42ml.

Technique

Premedication was not given to any patients. Resuscitation equipments and emergency drugs were kept ready to deal with any complications during the procedure. Monitoring with pulse rate, non invasive blood pressure, electrocardiogram and pulse oximetry were started. Intravenous line was secured in the contralateral arm with either 18G or 20G cannula. Another 22 Gcannula was secured on the operating limb for injecting the drug in a peripheral vein distal to the operative site preferably on the dorsum of the hand.

Esmarch bandage was used for exsanguination of the operative arm and a premature torniquet was placed around the upper arm followed by the inflation of proximal cuff to 250mmHg. It was confirmed by the absence of radial pulse and circulation in the arm followed by the loss of waveform tracing in pulse oximetry in the ipsilateral arm. Then a dose of 40ml lignocaine 0.5% with fentanyl 2µg/kg (2ml) or dexmedetomidine 1µg/kg (2ml) was injected slowly depending on the group mentioned earlier.

Assessment of Sensory Blockade

After injecting the drug, the sensory block was assessed every 30 seconds starting 2 minutes after injection until complete sensory block was established in the dermatomal distribution of the ulnar, median and radial nerves by a pinprick sensation in all the three skin areas was considered as complete sensory block.

Assessment of Motor Block

Motor function was evaluated by adding the patient to flex and extend his wrist and fingers. Inability to do so was taken as motor blockade.

Distal cuff was inflated to 250mmHg after 20 minutes to drug injection followed by deflation of the proximal cuff so as to avoid torniquet pain. After that the surgeons were allowed to proceed. Following the completion of surgery, torniquet cuff is deflated with repeated deflation inflation technique. The cuff was not deflated until 30 minutes after LA injection even if surgery was completed and not inflated more than 90 minutes. Patients were observed 30 minutes after surgery.

Assessment of Quality of Block

The quality of overall block was assessed according to the grading described by Ware. R.J. (1979) as follows-

1. Excellent-Complete anesthesia(lack of any sensation to pinprick and no movements of wrists/fingers)
2. Good-Complete anesthesia (touch sensation may be preserved but no pain to pin prick and minor movement of fingers.
3. Fair-Adequate anesthesia (slight discomfort but tolerabla without any supplementation)
4. Poor-Inadequate anesthesia (requiring supplementation with either sedative systemic analgesics or general anesthesia).

Assessment of Postoperative Pain

Postoperatively, VAS was used for recording the pain score which varies between 0-10 (0-no pain to

10-most severe pain).Injection Paracetamol 1g i.v. infusion was given as rescue analgesic when VAS score reached >4. Duration of postoperative analgesia was noted from deflation of torniquet to VAS score of 4.

Patients were also observed for any possible side effects like skin rash, bradycardia, sedation and hypotension intraoperatively and postoperatively following torniquet deflation in both the groups.

Statistical Analysis

All recorded data were entered using MS Excel and analyzed using SPSS 22 version software for determining the statistical significance.

Descriptive statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean SD and results on categorical measurements are presented in Number (%). Student t test (two tailed, independent) has been used to find the significance of study parameters between two groups. Chi-square test was used to test the association.

"p" value of >0.05 was considered not to be statistically significant, <0.05 was considered to be statistically significant, a value of <0.01 was highly statistically significant & a "p" value of <0.001 was considered as extremely statistically significant.

Sample Size

Total Sample Size is studied is 60, and 30 in each group.

Results

In Group LF, out of 30 patients, the maximum number of patients (40%) was noted in the two age groups of 30- 40 and 40-50 years, followed by 20% in the age group 20-30 years. With mean 37 and SD 7.5 years. In Group LD, out of 30 patients, the maximum number of patients (46.7%) was noted in the age group of 30- 40 and 40-50 years, followed by 36.7% in the age group 40-50 years and 16.7% of the study subjects were in the age group 20-30 years.

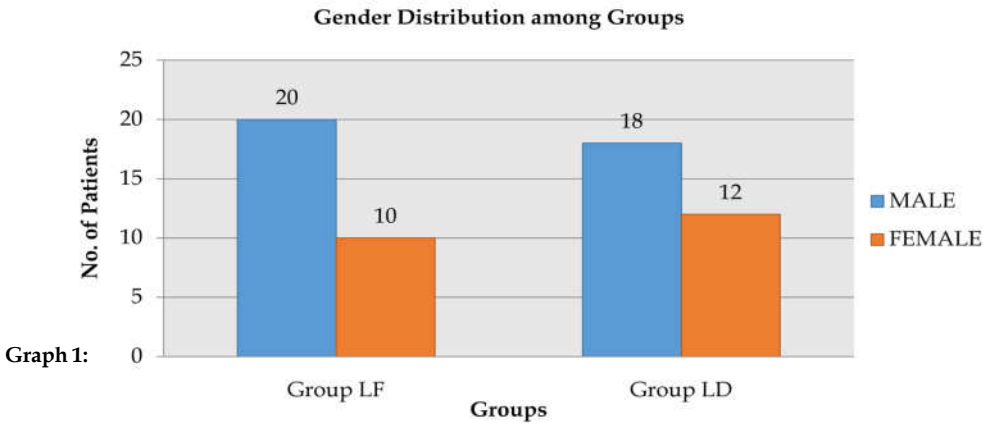
Table 1: Age-Distribution of Patients

Age (years)	Group LF		Group LD	
	No.	%	No.	%
20-30	6	20.0	5	16.7
30-40	12	40.0	14	46.7
40-50	12	40.0	11	36.7
Total	30	100.0	30	100.0
Mean ± SD	37 ± 7.5		37 ± 7.0	
	t-statistic = 0.000		p value = 1.000	

Table 2: Gender-Distribution of Patients

Gender	Group LF		Group LD	
	No.	%	No.	%
Male	20	66.7	18	60.0
Female	10	33.3	12	40.0
Total	30	100.0	30	100.0
	Chi-square = 0.2871		p value = 0.5920	

Graph 1:



With mean 37 and SD 7 years. Since p >0.05 was considered not to be statistically significant (Table 1).

In Group LF, out of 30 patients, the maximum number of patients (66.7%) were male and 33.3% were females. In Group LD, out of 30 patients, the maximum number of patients (60.0%) were male and 40.0% were females. Since p>0.05 the result is not significant, there is an association between Gender and Groups. (Table 2 and Graph 1).

In Group LF, out of 30 patients, the maximum number of patients (33.3%) were in group 45- 50 kg, followed by 26.7% in the group 50-55 kg, and 20% of patients were in two groups 40-45 and 55-60 kg. With mean 49.8 and SD 13.8 kg. In Group LD, out of 30 patients, the maximum number of patients (40%) were in group 45-50 kg, followed by 30% in the group 45-50 kg, and 16.7% patients were found in 55-60 kg and 13.3% were in 40-45kg. With mean 50 and SD 13.8 kg. Since p>0.05 was considered not to be statistically significant (Table 3).

In Group LF, Quality of Block, 66.7% were Excellent, 26.7% were Good and 6.7% Fair. In Group LD, Quality of Block, 70% were Excellent, 23.3% were Good and 6.7% Fair. There were no Poor qualities in both the groups. (Table 4 and Graph 2).

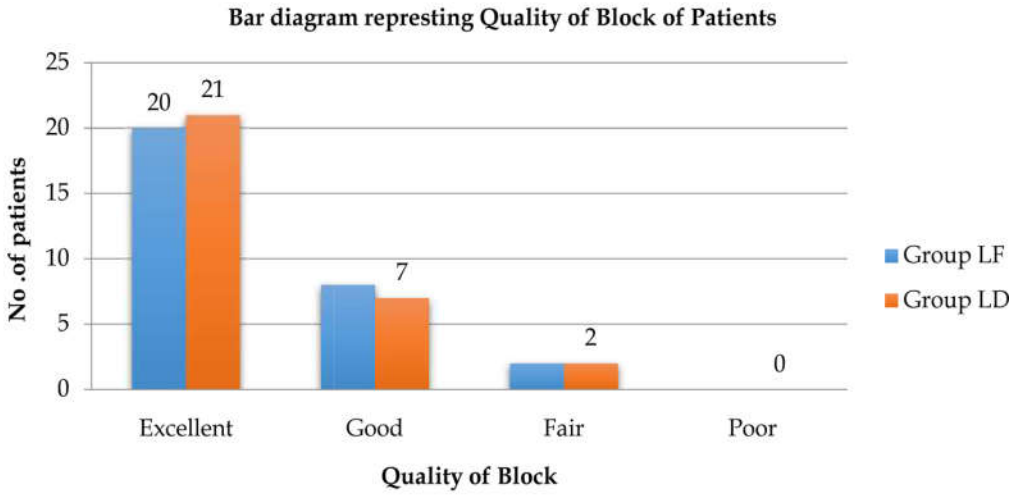
Surgery time (min) and Time of torniquet application (min) were staistically not significant. Sensory block onset time, motor block onset time,

Table 3: Weight-Distribution of Patients

Weight (kg)	Group LF		Group LD	
	No.	%	No.	%
40-45	6	20.0	4	13.3
45-50	10	33.3	12	40.0
50-55	8	26.7	9	30.0
55-60	6	20.0	5	16.7
Total	30	100.0	30	100.0
Mean ± SD	49.8 ± 13.8		50 ± 13.8	
	t-statistic = 0.0561		p value = 0.9554	

Table 4: Quality of Block of Patients

Quality of Block	Group LF		Group LD	
	No.	%	No.	%
Excellent	20	66.7	21	70.0
Good	8	26.7	7	23.3
Fair	2	6.7	2	6.7
Poor	0	0.0	0	0.0
Total	30	100.0	30	100.0



Graph 2:

Table 5: Comparison of Parameters between the Groups

Parameters	Mean ± SD		t-statistic	p value
	Group LF	Group LD		
Surgery time (min)	44.0 ± 16.8	48.2 ± 14.2	1.0458	0.3000
Time of torniquet application (min)	54.0 ± 10.2	58.2 ± 8.8	1.7076	0.0931
Sensory block onset time (min)	6.82 ± 1.50	4.8 ± 0.6	6.8484	0.0001
Motor block onset time (min)	10.80 ± 1.20	8.60 ± 3.20	3.5258	0.0008
Duration of postoperative analgesia (min) vas >4	204.42 ± 32.25	350.52 ± 42.5	14.9993	0.0001

duration of postoperative analgesia (min) vas Ã4 were statistically significant. (Table 5)

The two groups were comparable in respect of their distribution in age, gender and weight (Table 1, 2 & 3). Though the parameters like surgery and torniquet application time were statistically not significant, other parameters like sensory onset time (6.82±1.50 min in LF v/s 4.80±0.6 min in LD), motor block onset time (10.80±1.20 min in LF v/s 8.60±3.20 min in LD), duration of postoperative analgesia with VASÃ4 (204.42±32.25 min in LF v/s 350.52±42.5 min in LD) were statistically significant between the two groups (Table 5). Quality of block was excellent (66.7% in LF v/s 70% in LD), good (26.7% in LF v/s 23.3% in LD) and fair (6.7% in both the groups) with no reported poor quality of block (Table 4). The notable side effects reported in LD group include sedation in four patients and bradycardia (HR<50/min) in two patients which was reversed with injection atropine 0.6mg intravenously.

Discussion

Intravenous Regional Anesthesia (IVRA) is a simple and reliable method of providing anesthesia for extremity surgery. The administration of IVRA requires only the skill to perform a venipuncture. Limitation of IVRA has been torniquet pain and the inability to provide postoperative analgesia as compared to peripheral nerve blocks [10].

To improve the quality of IVRA as well as to prolong the duration of postoperative analgesia,the addition of various drugs to local anesthetics with controversial results such as tramadol [11], clonidine [12], neostigmine [13] and NSAIDS. Recent studies have been tried with use of α2-agonists like clonidine and dexmedetomidine as adjuncts in IVRA.The use of α2-agonists improves the quality of IVRA mainly through their action at the central and peripheral sites [15].

Addition of dexmedetomidine to lignocaine in IVRA in a randomized controlled study by Kumar A, Sharma DK,Dutta B showed the onset of sensory block to be 4.3±0.6 seconds which was comparable to our study with onset at 4.8±0.6 seconds. Memis D,Turan A et al studied the addition of 0.5μg/kg of dexmedetomidine to lignocaine and their results were almost identical to our study in sensory block onset time(5±2 min) and motor block onset time (10±4 min). Our results were also comparable to the results of the study conducted by Chatrath V, Sharan R et al in terms of onset of sensory block (4.85±0.49 min) and motor block (10.91±0.6 min) by adding 1μg/kg of dexmedetomidine to lignocaine [17]. Sertoz N, Kocauglu N et al in their study of adding 2ml (100μg) fentanyl to lignocaine in IVRA resulted in the sensory block onset time of 6.73±1.49 min and motor block onset time of 8.73±1.58 min which was almost comparable to our study [18].

Dubey K, Paddalwar S, Chandak A in their study of adding 1μg/kg fentanyl to lignocaine in IVRA obtained the sensory block onset time of 7.13±0.81 min and motor block onset time of 11.90±1.18 min. Our results were of slightly earlier onset because of addition of 2μg/kg of fentanyl [19]. Our study concluded that addition of 1μg/kg of dexmedetomidine to 40 ml of 0.5% lignocaine resulted in faster sensory and motor block onset time with considerable increase in the duration of postoperative analgesia compared to addition of fentanyl 2μg/kg to 40 ml of 0.5% lignocaine in IVRA for upper limb surgeries.

Conclusion

The addition of 1μg/kg dexmedetomidine to lignocaine when compared to 2μg/kg fentanyl in IVRA reduces the time for onset of block, increases the duration of block. Improves quality of anarsthesia prolonged post operative analgesia and reduced rescue analgesia requirement.

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Original Research Article

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Intrathecal Bupivacaine with Neostigmine versus Clonidine as an Adjuvants in Lower Abdominal Surgeries

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Abstract

Background: A number of adjuvants to local anesthetics have been used intrathecally to prolong analgesia. So, the present study was planned to study the effect of intrathecal bupivacaine with neostigmine versus clonidine as an adjuvants in lower abdominal surgeries. *Material & Methods:* 128 patients of ASA physical status grade I and II, aged 30-50 years, scheduled for lower abdominal surgeries under spinal anesthesia of a tertiary care teaching hospital were randomly selected in two groups of 64 each; Group BN:12.5 mg (2.5 ml) of 0.5% bupivacaine + 25 µg neostigmine with total volume made up to 3.0 ml with normal saline and Group BC:12.5 mg (2.5 ml) of 0.5% bupivacaine + 50 µg clonidine with total volume made up to 3.0 ml with normal saline. Sensory block characteristics, motor block characteristics, time to first rescue analgesic were recorded. Any adverse effects were also noted. *Results:* Time to reach T_{10} sensory level was 2.53±0.58 min in Group BC and 2.33±0.60 min in Group BN which was statistically comparable (p= 0.06). But time to reach peak sensory level was 8.14±0.77 min in Group BC as compared to 6.38±0.79 min in Group BN (p<0.01). The mean duration of sensory block was 321.72±8.32 min in Group BC and 301.72±27.6 min in Group BN (p<0.01). All patients of both groups achieved Bromage score of 3 signifying complete motor block. Duration of motor block was significantly longer in group BC (223.36±14.39 min) as compared to group BN (204.53±10.64 min) (p<0.01). *Conclusion:* Clonidine as adjuvant to bupivacaine results in significant prolongation of duration of sensory blockade and analgesia as compared to intrathecal neostigmine.

Keywords: Clonidine; Neostigmine; Analgesia; Intrathecal Bupivacaine.

Introduction

Subarachnoid block is one of the most versatile regional anesthesia technique available today. Regional anesthetic techniques may lead to blockade or reduced pain ranged from several hours to several days. Better pain control may result in an earlier hospital discharge and may improve the patient's ability in postoperative period. In addition, it is usually easy to administer and readily available [1]. Local anesthetics are the commonest agents used for spinal anesthesia, but their relatively short duration of action may lead to early analgesic intervention in the postoperative period [2]. Ekblom and Widman were the pioneer workers who employed bupivacaine for spinal analgesia and reported its low toxicity and long duration of action [3].

A number of adjuvants to local anesthetics have been used intrathecally to prolong the intraoperative as well as postoperative analgesia [3,4]. Opioids are commonly used as intrathecal adjuvants to improve the quality of intraoperative analgesia and also prolong analgesia in the postoperative period without significant motor or autonomic blockade [2]. However, side effects such as pruritus, nausea, vomiting, urinary retention, and delayed respiratory depression have prompted further research toward non-opioid analgesics as adjuvants with less serious side effects [5].

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Clonidine, a selective partial α_2 -adrenergic agonist, is being extensively evaluated as an adjuvant to intrathecal local anesthetics and has proven to be a potent analgesic free of opioid-related side effects. It is known to increase both sensory and motor blockade of local anesthetics. Intrathecal clonidine has been used as an adjuvant to local anesthetics in various surgical procedures without any clinically significant side effects. Previous studies have described the use of clonidine in a wide range [6,7]. Neostigmine is a reversible cholinestrase inhibitor quaternary ammonium compound used as cholinomimetic analgesic in human. Intrathecal neostigmine prolongs the sensory and motor block induced by bupivacaine spinal anaesthesia and at the same time causes no haemodynamic or respiratory depression in intraoperative and post operative period [8].

On literature research we could find few studies in which intrathecal clonidine versus intrathecal neostigmine was investigated in spinal anesthesia for lower abdominal surgeries [9,10]. No study was investigated efficacy of 50µg clonidine versus 25µg neostigmine in combination with 12.5 mg bupivacaine in spinal anesthesia. This study was planned to study the effect of intrathecal bupivacaine with neostigmine versus clonidine as an adjuvants in lower abdominal surgeries.

Materials and Methods

This hospital based randomized double blind study was conducted in the department of Anesthesiology at tertiary care teaching hospital with due permission from institutional ethical committee after obtaining written informed consent from all patients before participation. One hundred twenty eight patients of ASA physical status grade I and II, aged 30-50 years, scheduled for lower abdominal surgeries under spinal anesthesia were included in the study. Patients not willing to participate in the study, history of chronic disease like hypertension, diabetes mellitus, respiratory disease, epilepsy, cardiac disease, spinal disorders, chronic history of headache and backache, infection in the back, any absolute or relative contraindication to study drug, uncooperative patients were excluded out. After taking written informed consent, patients were randomly allocated into two groups (n=64) using chit in box technique:

Group BN: 12.5 mg (2.5 ml) of 0.5% bupivacaine + 25 µg neostigmine with total volume made up to 3.0 ml with normal saline and *Group BC:* 12.5 mg (2.5 ml) of 0.5% bupivacaine + 50 µg clonidine with total volume made up to 3.0 ml with normal saline intrathecally. Pre-anaesthetic checkup was done a day before the surgery. Patients were connected to monitors and baseline vitals like blood, pulse rate, respiratory rate were recorded. Vitals just before lumbar puncture were noted. Spinal anaesthesia was performed at L3-L4 interspace with the patient in left lateral position by using a 25 Gauge spinal needle under strict aseptic conditions. Free flow of cerebrospinal fluid was verified before injection of the anesthetic solution, which was administered over 30 seconds according to allocated group. The direction of the needle aperture was cranial during the injection. All patients were immediately placed in a supine position following the injection with a 15^0 head down tilt to achieve level of block of T5-T6. Vitals were checked immediately after block, 2 min, 5 min, 10 min and every 5 min till surgery. The level of sensory block was tested by pin pricking bilaterally at mid-clavicular line which was done every minute till the maximum sensory level was achieved and then after one hour at half an hour interval. Time of onset of motor block was assessed using Bromage scale. Onset of motor block was taken as the time taken to achieve Bromage grade 3 block from the time of subarachnoid injection. Side effects hypotension (SBP < 90 mmHg, bradycardia (Pulse < 50/min), respiratory depression (Arterial oxygen saturation less than 90%), pruritus and nausea and vomiting were also noted.

Postoperatively the pain score was recorded by using Visual Analogue Scale (VAS) between 0 and 10 (0 = no pain , 10 = worst pain). Intramuscular diclofenac (1.5 mg/kg) was given as rescue analgesic. Time from intrathecal injection to the first request of analgesics (i.e. duration of analgesia) was noted. Total analgesic dose in first 24 hours were recorded. Patients were kept under observation for total period of 24 hours to look for any side effects.

Data were entered and analyzed with the help of MS excel, SPSS version 17. Quantitative data were represented as arithmetic mean, (SD), and analyzed by using student t test, qualitative data were presented as number, [proportion (%)] and analyzed by chi square test. P <0.05 was considered as statistically significant.

Results

Both the neostigmine and clonidine groups were statistically comparable regarding mean age, mean weight, height, sex, ASA grading, and duration of surgery (Table 1).

Time to reach T_{10} sensory level was 2.53 ± 0.58 min in Group BC and 2.33±0.60 min in Group BN which was statistically comparable (p= 0.06). But time to reach peak sensory level was 8.14±0.77 min in Group BC which was statistically longer as compared to 6.38 ± 0.79 min in Group BN (p < 0.01). The mean duration of sensory block was 321.72±8.32 min in Group BC and 301.72±27.6 min in Group BN which was significantly longer in Group BC (p<0.01). All patients of both groups achieved Bromage score of 3 signifying complete motor block. Time to reach Bromage score of 3 (motor onset) was significantly shorter in group BN (2.77±0.68 min) as compared to group BC (3.58±0.813 min) (p<0.01). Time to regression to Bromage 0 (duration of motor block) was significantly longer in group BC (223.36±14.39 min) as compared to group BN (204.53±10.64 min) (p<0.01) (Table 2).

Heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and oxygen saturation (SpO_2) showed no significant change from baseline during intra-operative period in Group BN. Fall in heart and systolic blood pressure was occurred in Group BC at 5, 10, 15 mins interval which was significant as compared to Group BN. (p < 0.05). (Figure 1-3). Hypotension, bradycardia and sedation were more common in group BC as compared to group BN (Table 3).

Table 1: Demographic characteristics of both the groups

	Group-BC (Mean ± SD)	Group-BN (Mean ± SD)	
Age(yrs)	49.78+11.29	49.44+9.59	p>0.05
Height (cms)	156.70±3.26	157.89±4.43	p>0.05
Weight (kgs)	60.84+6.23	59.91+5.54	p>0.05
Sex (M/F)	29/35	33/31	p>0.05
ASA I/II	56/8	58/6	p>0.05
Duration of surgery (min)	59.22±7.16	57.03±7.16	p>0.05

Table 2: Comparison of block characteristics in both the groups

	Group-BC (Mean ± SD)	Group-BN (Mean ± SD)	P value
Time to reach T_{10} (min)	2.53±0.58	2.33±0.60	p>0.05
Time to reach peak sensory level (min)	8.14±0.77	6.38±0.79	p < 0.01
Highest sensory level block	$T_{5.72±0.79}$	$T_{5.73±0.65}$	p>0.05
Time to sensory regression to S1(min)	321.72±8.32	301.72±27.6	p < 0.01
Duration of analgesia (min)	267.84 ± 27.95	219.27 ± 22.65	p < 0.01
Time to reach bromage score 3 (min)	3.58±0.81	2.77±0.68	p < 0.01
Duration of motor blockade (min)	223.36 ± 14.39	204.53± 10.64	p < 0.01

p>0.05 (non-significant), p < 0.01 (significant)

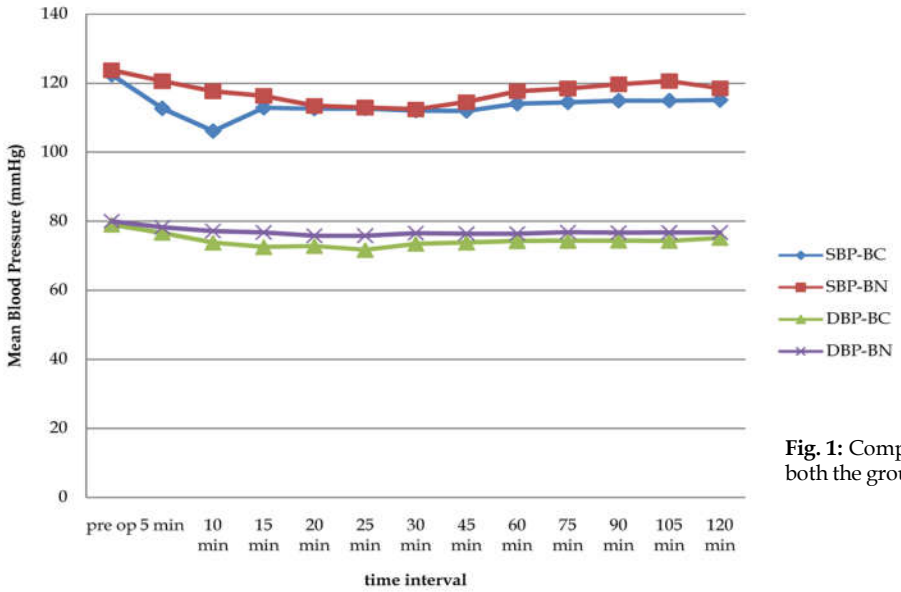

Fig. 1: Comparison of blood pressure in both the groups

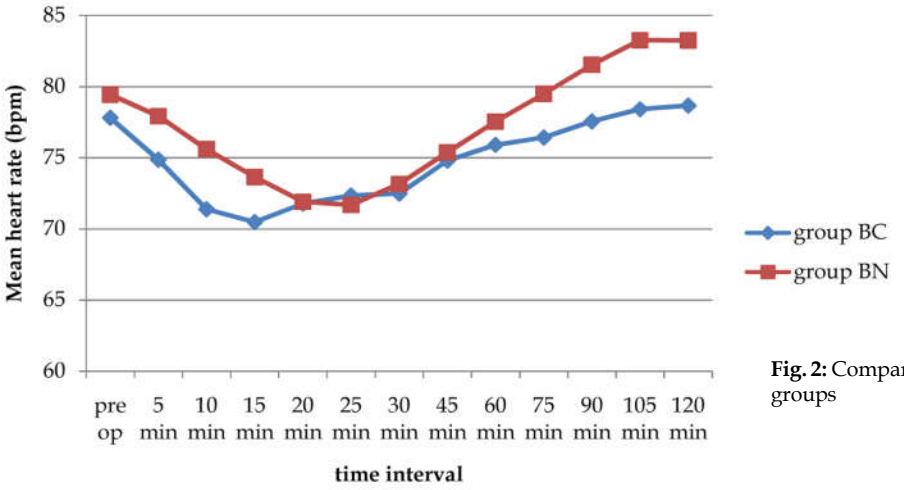

Fig. 2: Comparison of Heart rate in both the groups

Table 3: Adverse effects in both the groups

	Group-BC n (%)	Group-BN n (%)
Hypotension	18 (28.1%)	2(3.1%)
Bradycardia	13(20.3%)	2(3.1%)
Nausea	5(7.8%)	9(14.1%)
Vomiting	0	3(4.7%)
Sedation	14(21.9%)	0
Respiratory Depression	0	0
Others	0	0

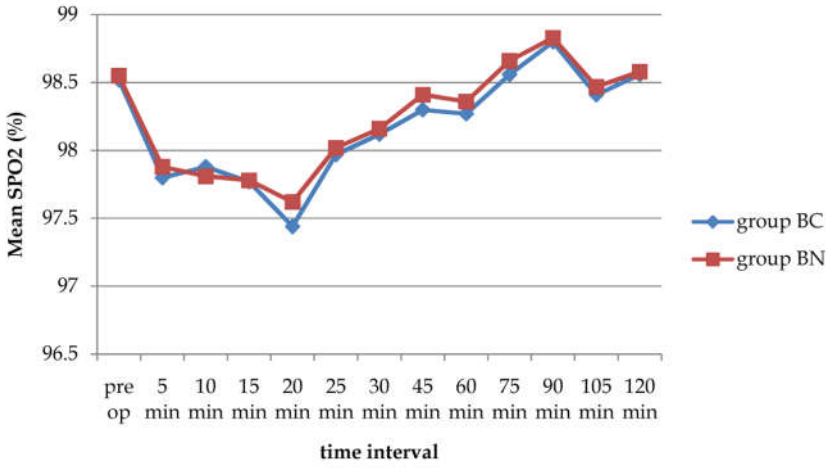

Fig. 3: Comparison of SpO_2 in both the groups

Discussion

Local anesthetics are the commonest agents used for spinal anesthesia. A number of adjuvants to local anesthetics have been used in pain management [3,4]. In present study clonidine and neostigmine were compared for its effects as adjuvant to bupivacaine. In present study both the groups were comparable demographically.

In present study time to reach T_{10} sensory level was 2.53±0.58 min in Group BC and 2.33±.60 min in Group BN which was statistically comparable. But time to reach peak sensory level was 8.14±0.77 min in Group BC which was statistically longer as compared to 6.38±0.787 min in Group BN. Similar results were obtained by Yoganarasimha et al study which has used 75 µg of clonidine [9]. Adhikari et al. conducted study using bupivacaine 0.5% -3 ml (hyperbaric) with 0.1ml of normal saline intrathecally in Group A and bupivacaine 0.5% -3 ml (hyperbaric) with 50 µg neostigmine methylsulfate (0.1 ml)) in group B and reported onset time for sensory block was 136.80± 13.45 sec in group A and 136.6±12 .87

sec which was comparable in both groups [11]. Jamliya et al. studied 3ml of 15 mg hyperbaric bupivacaine 0.5% plus 0.2 ml saline in group A and 15 mg (3ml) of hyperbaric bupivacaine 0.5% plus 30 µg clonidine in group B and reported that time of onset of adequate level of sensory block (T10) was longer for group B (126±14sec.) than group A (95±10sec.) [12]. It was observed that adding neostigmine to bupivacaine resulted in significant shortening of peak sensory onset time as compared to intrathecal clonidine with bupivacaine. It might be due to that intrathecal administration of cholinergic receptor agonist or cholinesterase inhibitors produces antinociceptive effect which is mediated by spinal muscarinic receptors in animals and human beings [13].

In present study, Group BC achieved peak sensory level of $T_{5.72 \pm 0.79}$ [median T8 range (T6-T8)] which was statistically comparable with $T_{5.73 \pm 0.65}$ in Group BN. Similar comparable results were also found in Yoganarsimha et al. and Klamt et al. study [9,14]. It might be concluded that addition of neostigmine or clonidine as an adjuvants do not affect peak level of sensory block.

The mean duration of sensory block was 321.72±8.32 min in Group BC and 301.72 ± 27.6 min in Group BN which was significantly longer in Group BC. Yoganarasimha et al also reported the total duration of analgesia was significantly prolonged in (362 ± 32 min) Group BC as compared to (300 ± 25 min) Group BN but not mentioned the duration of sensory block [9]. Similar significant results were also found in other studies [2,11,12,15]. It can be concluded that clonidine enhances the duration of sensory block more as compared to neostigmine.

All patients in both groups achieved Bromage score of 3 signifying complete motor blockade. Yoganarasimha et al and jamliya et al also reported complete motor block in lower abdominal surgeries [9,12]. Time to reach Bromage score of 3 (motor onset) is significantly shorter in group BN (2.77±0.68 min) as compared to group BC (3.58±0.813 min). Yoganarasimha et al also reported that 110±15 secs in group BN compared to 210±20 secs in group BC. In addition to the potential direct inhibition of motor activity by administration of neostigmine, it was speculated that increased spinal levels of acetylcholine may augment motor block as a result of axonal conduction block from spinal bupivacaine [9]. That might be the reason in present study in which there was hastened onset of motor block with neostigmine.

In present study duration of motor block was defined as return of Bromage score 0. Time to regression to Bromage 0 (duration of motor block) was significantly longer in group BC (223.36±14.39 min) as compared to group BN (204.53±10.64 min). Similarly, Yoganarasimha et al reported significantly shorter motor block duration 185 ± 40 mins in group BN compared to 210±50 mins in group B [9]. Jamliya et al and kayalha et al also showed similar results [11,15]. Clonidine has more prolonged duration of motor block as compared to neostigmine. Intrathecal clonidine when combined with local anaesthetic significantly potentiates the intensity and duration of motor blockade possibly due to the fact that α2 adrenoreceptor agonists induce cellular modification in the ventral horn of the spinal cord and facilitate the local anaesthetic action and prolongation in sensory block can be due to vasoconstrictive effect of clonidine [2].

In present study, time of requirement of first rescue analgesic dose (duration of analgesia) was significantly longer in group BC as compared to group BN. Similar results were obtained in other studies [9,11,12]. Potency of intrathecal neostigmine is increased in post operative period, because descending noradrenergic or cholinergic antinociceptive spinal system is activated by ongoing pain causing an increase in release of acetylcholine which in presence of neostigmine results in augmented selective analgesia [11].

In our study, HR, SBP, DBP, and SpO_2 showed no significant change from baseline during intraoperative period in Group BN. Fall in systolic blood pressure and heart rate was seen in Group BC which was significant as compared to Group BN just after spinal anaesthesia at 5 ,10 ,15 mins interval. In Group BC 28.1% patients had developed hypotension and 20.3% patients bradycardia. In previous study by Yoganarasimha et al. intraoperative blood pressure was well maintained in the neostigmine group and clonidine group. None of the patient in both groups developed pruritus, tremors, arrhythmia, and respiratory depression. In Yoganarasimha et al. study also, no patients of either groups had sedation, nausea and vomiting, pruritus, post dural puncture headache or transient neurological symptoms at intraoperative period or during post operative follow up [9]. This showed that intrathecal clonidine and neostigimne can be used safely in spinal anesthesia without affecting hemodynamic variables significantly.

Conclusion

Clonidine as adjuvant to bupivacaine results in significant prolongation of duration of sensory

blockade and analgesia as compared to intrathecal neostigmine. Both clonidine and neostigmine in lower doses can be used as an adjuvant to local anesthetic alternative to commonly used opioids in spinal anesthesia for lower abdominal surgeris without serious adverse effects. Intrathecal clonidine has better clinical profile than intrathecal neostigmine in terms of analgesia.

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To Study the Changes in Intraocular Pressure during various Steps of General Anesthesia using Thiopentone Sodium or Ketamine for Induction and Succinylcholine for Neuromuscular Blockade

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Abstract

Background: Several general and local anesthetic techniques have been employed to try and prevent increase in intraocular pressure during surgery. Interest in general anesthesia for intraocular surgery is relatively recent. Many surgeons now prefer full anesthesia and indeed the increasing scope of ophthalmic surgery demands it. This study was therefore undertaken to know the changes in intraocular pressure, during various steps of general anesthesia using thiopentone sodium or ketamine for induction and suxamethonium (succinylcholine) for neuromuscular blockade. *Material and Methods:* Sixty patients between the age group of 1-75 years were selected for this study. These patients were divided into two groups –I and II. The patients in groups were given general anesthesia and were operated for either ophthalmic or non – ophthalmic indications. A detailed general examination (including measurement of blood pressure) and systemic examination was done to rule out any systemic disorder which would directly or indirectly affect the measurement of intraocular pressure during the course of the study. Routine blood and urine investigations were done. *Results:* The mean fall in intraocular pressure after induction as compared to mean baseline intraocular pressure was 2.48±1.32 in group – I. The mean rise in intraocular pressure after induction as compared to mean baseline intraocular pressure was 2.67±2.08 in group-II. This difference in the intraocular pressure after induction in group -I was statistically highly significant as compared to group -II ($p<0.01$). *Conclusions:* Thiopentone sodium can be safely used as an inducing agent in any intraocular surgery done under general anesthesia. Ketamine, as far as possible, should be restricted to extraocular ophthalmic surgeries.

Keywords: Thiopentone Sodium; Intraocular Pressure; Suxamethonium; Ketamine.

Introduction

The maintenance of intraocular pressure, along with analgesia and akinesia, is very important during an intraocular surgery. Any increase in the intraocular pressure while the globe is open, may cause expulsion of vitreous and subsequent loss of vision. Several general and local anesthetic techniques have been employed to try and prevent increase in intraocular pressure during surgery. Whether the patient is operated under general or local anesthesia, the desirability of a soft globe for anterior segment surgery is generally an accepted surgical principal. A reduced intraocular pressure with a concave vitreous face can help the procedure to be carried out smoothly. Preoperative intraocular pressure reduction is thought to minimize the risk of vitreous loss and expulsive haemorrhage during cataract surgery. To obtain a soft eye preoperatively is quite difficult in patients being operated under general anesthesia, whereas in local anesthesia, there is a major advantage of obtaining this with the help of various methods [1].

Interest in general anesthesia for intraocular surgery is relatively recent. Many surgeons now prefer full anesthesia and indeed the increasing scope of ophthalmic surgery demands it. A large series of intraocular operations carried out under

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general anesthesia suggest that the surgical results are neither better nor worst than those done under local, but there may be an irreversible gain, firstly in that the patients are spared a trying ordeal and secondly that patients previously refuse surgery because their cooperation was in doubt, are now having sight restored by operations performed under general anesthesia.

General anesthesia may vary from a technique which utilizes anesthesia, muscle paralysis and ventilation with intubation on one hand to reliance on spontaneous breathing and a laryngeal mask on the other [2].

Most of the agents commonly used for induction in general anesthesia reduce intraocular pressure [3]. Thiopentone sodium, for example, significantly reduces intraocular pressure [3-7]. Ketamine, a useful inducing agent for paesiatric ophthalmic examination and short procedures on the other hand, causes a rise in intraocular pressure [3,6,7]. Syxamethonum, a muscle relaxant, used before intubation also causes a rise in the intraocular pressure [3,6,7].

Some investigators have reported that ketamine, but not propofol, provides additional effects on decreasing the incidence of EA in pediatric patients [8], and ketamine induction provides less EA when compared to thiopental induction for desflurane anesthesia for a tonsillectomy and adenoidectomy without delayed recovery[9]. However, another report showed that the EA after sevoflurane anesthesia was significantly reduced by propofol induction, as compared with thiopental sodium [10].

However, general anesthesia may produce problems in many elderly patients and especially in those with concomitant systemic disease. Further, straining, coughing and vomiting associated with it may cause serious increase in intraocular pressure which may be disastrous [11]. Local anesthesia, on the other hand, has become increasingly popular for a variety of surgical procedures. The trend towards local anesthesia in preference to general anesthesia in eye surgery increases apace for several reasons, not least of which is the move towards day care surgery [12].

There are advantages and disadvantages of both the local anesthetic techniques. Since all these procedure appear to work well in experienced hands, most surgeons, however, continue to use the techniques they know best.

It is seen that though both these techniques of local anesthesia provide a good amount of akinesia and anesthesia, they produce a rise in the intraocular pressure, after their injection, which might be hazardous after opening the globe [13]. This study was therefore undertaken to know the changes in intraocular pressure, during various steps of general anesthesia using thiopentone sodium or ketamine for induction and suxamethonium (succinylcholine) for neuromuscular blockade.

Objectives

To study the changes in intraocular pressure during various steps of general anesthesia using thiopentone sodium or ketamine for induction and succinylcholine for neuromuscular blockade.

Materials and Methods

Sixty patients between the age group of 1-75 years were selected for this study. These patients were divided into two groups –I and II. The patients in groups were given general anesthesia and were operated for either ophthalmic or non – ophthalmic indications.

Group – I contained 30 patients who were given Inj. Thiopentone sodium intravenously for induction of anesthesia. Group – II contained 30 patients who were given Inj. Ketamine intravenously for induction of anesthesia. In both the groups, succinylcholine (suxamethonium) was used for neuromuscular blockade before intubation.

A detailed history was taken which included history of any systemic disorders like diabetes mellitus, hypertension, bronchial asthma, ischaemic heart disease etc.

A detailed general examination (including measurement of blood pressure) and systemic examination was done to rule out any systemic disorder which would directly or indirectly affect the measurement of intraocular pressure during the course of the study. Routine blood and urine investigations were done.

All the patients were started on systemic and local antiobiotics preoperatively and were given Inj. Atropine 0.6 mg intramuscularly half prior to surgery. Lignocaine sensitivity test was done in patients who were to be operated under local anesthesia. Written consent was taken for surgery, anesthesia and for relevant examination.

Materials

And all the materials necessary for induction of anesthesia and intubation.

General Anesthesia	
Inj. Thiopentone sodium	500 mg or 1 gm vial
Inj. Ketamine	50 mg/cc 10 cc vial
Inj. Succinylcholine	50 mg/cc 10 cc vial
Syringes	2 cc

Schiotz Tonometer [14,15]

In this study the intraocular pressure was measured with the help of Schiotz tonometer.

This is a prototype of indentation instruments. With the help of this instrument, the deformation or indentation of the globe in response to a standard weight applied to the cornea is measured.

The instrument consists of a metal plunger that slides through a hole in a concave metal foot plate. The plunger supports a hammer device that is connected to a needle that crosses a scale. The plunger, hammer and needle weigh 5.5 gm. This can be increased to 7.5 gm, 10 gm or 15 gm by addition of appropriate weights. The more the plunger indents the cornea, higher is he scale reading and lower is the intraocular pressure. Each scale unit represents a 0.05 mm protrusion of the plunger.

Measurement of Intraocular Pressure [14,15]

Following method and guidelines were followed for measuring intraocular pressure in both the groups.

- The patient was given appropriate anesthesia depending on the group of anesthesia under study.
- A drop of topical anesthetic (4% xylocaine) was instilled in eye after explaining the nature of the test to the patient.
- Patient's lids were retracted without placing any tension on the globe.
- The tonometer was placed directly over the eye and when the patient relaxed, the tonometer was lowered gently on to the cornea.
- The intraocular pressure measurement was repeated until three consecutive readings were within 0.5 scale units.
- The average scale reading was converted to intraocular pressure in millimeters of Mercury using a conversion chart.
- After each use, the tonometer plunger and foot plate were cleaned with spirit followed by normal saline and then wiped dry lint free material.

Pre - Medication

Inj. Pentazocine 0.3 mg/kg and Inj. Glycopyrolate 0.004 mg/kg was given intramuscularly 30 minutes prior to induction.

Induction

- After taking the patient on the operation table, intraocular pressure was measured after putting 1-2 drops of 4% xylocaine in the eye.
- Prior to and during the procedure, special care was taken to avoid any pressure on the patients eye and to prevent any respiratory disturbances e.g. coughing, straining, laryngospasm etc. since these disturbances produce a rise in intraocular pressure due to rise in venous pressure.
- Pre – oxygenation was done with 100% oxygen for 3 minutes.
- In group A-I, induction was done with thiopentone sodium 5 mg/kg intravenously and succinylcholine 2 mg/kg intravenously was given to obtain muscular paralysis.
- In group A–II, induction was done with ketamine 2 mg/kg intaravenously and succinylcholine 2 mg/kg was used to facilitate endotracheal intubation.
- Intubation was done after adequate muscle relaxation.
- Anesthesia was maintained with O_2-NO_2-halothane combination.
- Patient was reversed with neostigmine 0.04 -0.06 mg/kg and Inj. Glycopyrolate 0.008 mg/kg intravenously and extubation was done.

Recording of Intraocular Pressure

Intraocular pressure was measured at following stages:

1. Before induction
2. After the patient was induced with thiopentone sodium i.e. before giving succinylcholine
3. Immediately after tracheal intubation.
4. After the patient was extubated.

Statistical Analysis

Descriptive statistics such as mean, SD and percentage was used. Comparison between two groups was done by using t-test. A p-value less than 0.05 were considered as significant. Statistical analysis was performed by using software SPSS v16.0

Results

Group – I consisted of 30 cases in which there were 11 males (36.7%) and 19 females (63.3%). Group – II also consisted of 30 cases in which there were 9 males (30%) and 21 females (70%).

There were more females in group A because most of the cases selected in this group were being operated for either obstetrical or gynecological indications.

In group – I, there were 17 cases (56.7%) which belonged to age group 21-30 years followed by 5 cases (16.7%) in the group 0-10 years and 4 cases (13.3%) in the age group 41-50 years.

In group – II, there were 10 cases (33.3%) which belonged to 21-30 years followed by 7 cases (23.3%) each in the age group 11-20 years and 31-40 years.

In the present study, it was seen that the mean pre-induction intraocular pressure was 13.84+2.75 and the mean post – induction intraocular pressure was 11.35+2.52. After applying the student 't' test the difference between these 2 values was found to be statistically highly significant ($p<0.01$).

The mean fall in intraocular pressure after induction as compared to mean baseline intraocular pressure was 2.48+1.32.

Table 1: Sex-wise distribution

Sex	Group – I Thiopentone sodium + succinylcholine		Group – II Ketamine + succinylcholine	
	No. of Cases	Percentage	No. of Cases	Percentage
Males	11	36.7	9	30.0
Females	19	63.3	21	70.0
Total	30	100.00	25	100.00

Table 2: Age-wise distribution

Age (years)	Group – I Thiopentone Sodium + Succinylcholine		Group – II Ketamine + Succinylcholine	
	No. of Cases	Percentage	No. of Cases	Percentage
0-10	05	16.7	----	----
11-20	02	6.7	7	23.3
21-30	17	56.7	10	33.3
31-40	01	3.3	7	23.3
41-50	04	13.3	03	10.00
Above 51	01	3.3	03	10.00
Total	30	100.00	30	100

Table 3: Mean intraocular pressure in group-I (thiopentone sodium + succinylcholine)

	Intraocular Pressure (IOP) Recording in mmHg (n=30)			
	Pre – Induction	Post – Induction	Post – Intubation	Post - Extubation
Mean ± SD	13.84 ± 2.75	11.35 ± 2.52	16.50 ± 2.10	12.56 ± 2.06
Range	8.5 – 18.9	8.5 – 18.9	12.2 – 20.6	7.1 – 18.9
Mean change in IOP as compared to mean baseline IOP	-----	2.48 ± 1.32	2.68 ± 1.60	1.74 ± 1.46

Table 4: Mean intraocular pressure in group-II (ketamine + succinylcholine)

	Intraocular Pressure (IOP) Recording in mmhg (N=30)			
	Pre – Induction	Post – Induction	Post – Intubation	Post - Extubation
Mean ± SD	12.17 ± 2.08	14.84 ± 1.94	17.18 ± 1.02	12.14 ± 1.72
Range	9.4 – 15.9	10.2 – 17.3	15.9 – 19.0	9.4 – 14.9
Mean change in IOP as compared to mean baseline IOP	-----	2.67 ± 2.08	5.16 ± 1.21	0.008 ± 0.65

Table 5: Comparison of intraocualr pressure (mmhg) between groups

Steps of Anesthesia	Group-I Mean ± SD	Group-Ii Mean ± SD	S.E.	t – value	P- value
Pre – Induction	13.84 ± 2.75	12.17 ± 2.08	----	----	----
Post – Induction	11.35 ± 2.52	14.84 ± 1.94	0.64	5.45	<0.01
Post – Intubation	16.50 ± 2.10	17.18 ± 1.02	0.47	1.44	>0.05
Post – Extubation	12.56 ± 2.06	12.14 ± 1.72	0.54	0.78	>0.05

In the present study, it was seen that the mean pre-induction intraocular pressure was 12.17+2.08 and the mean post – induction intraocular pressure was 14.84+1.94. The difference between these 2 values was found to be statistically highly significant ($p<0.01$).

The mean rise in intraocular pressure after induction as compared to mean baseline intraocular pressure was 2.67±2.08.

From the above table it was seen that there was a fall in intraocular pressure after induction in group-I (13.84+2.75 to 11.35+2.52) whereas in group– II there was a rise in intraocular pressure after induction (12.17+2.08 to 14.84+1.94).

This difference in the intraocular pressure after induction in group-I was statistically highly significant as compared to group -II ($p<0.01$)

Discussion

Intraocular pressure after induction with thiopentone (group -I):

Thiopentone is an ultrashortacting thiobarbiturate which even today is the most common intravenous inducing agent. While studying the changes in intraocular pressure due to thiopentone, we noted a fall in intraocular pressure.

In the present study, it was seen that the mean pre – induction intraocular pressure was 13.84+2.75 mmHg and mean post – induction intraocular pressure was 11.35+2.52 mmHg. After applying the student 't' test the difference between these two values was found to be statistically highly significant ($p<0.01$). The mean fall in intraocular pressure after induction as compared to mean baseline intraocular pressure was 2.48+1.32 mmHg. The fall in intraocular pressure ranged from 0.8–5.1 mmHg, the maximum fall being 5.1 mmHg.

Stone H H has studied the effects of barbiturates and paraldehyde on aqueous humour dynamics in rabbits [16]. In this study he found a marked fall in intraocular pressure caused by these two drugs. Similar findings were also seen by Kornbleuth [4].

Many general anesthetic agents have been shown to reduce intraocular pressure. The exact mechanism is not known but may be related to the relaxation of the extraocular muscles and the depression of ocular centres in diencephalon, midbrain and hypothalamus. This was suggested by Von Sallman et al. [17]. This was supported by Kornbleuth et al [4], who also believed that increased facility for outflow drainage might also be an associated cause.

Sathe ND [18] has studied the fall in intraocular pressure after thiopentone induction in 30 patients between 18-60 years of age. In this study he found a fall in intraocular pressure which varied from 2-17 mmHg immediately after the sleep dose of thiopentone. In this case premedication was given; the drugs used were Inj. Atropine 0.6 mg and Inj. Pethidine 50 mg intramuscularly. In the present study, we also found a fall in intraocular pressure which varied between 0.8–5.1 mmHg. The increased fall in intraocular pressure in ND Sathe's study could be due to additional intraocular pressure lowering effect of pethidine.

Another study was carried out by Joshi C and Bruce DL [19]. They measured intraocular pressure in 18 patients and found a consistent fall in intraocular pressure after the sleep dose of pentothal (3 mg/kg). They found that the fall in intraocular pressure was statistically significant thus correlating well with the findings of the present study.

Col. Banerjee Sc et al. [20] studied the effects of general anesthesia on intraocular pressure. In this series they studied the effects of pentothal on intraocular pressure on 100 patients. The intraocular pressure reading was taken 3 minutes after the induction of anesthesia. They found a fall in intraocular pressure which ranged from 1-12 mmHg. The increased fall in this study might have been due to use of premedication agents like inj. Atropine and inj. Morphine.

Verma RS [21] studied 15 cases who were induced thiopentone. Premedication consisted of diazepam 10 mg intramuscular given 30-45 minutes before operation. Atropine 0.6 mg was given simultaneously with thiopentone. He found a significant reduction

in intraocular pressure after induction. Reductions ranged from 4.5-13 mmHg. Again the increased fall in his study might be due to the additive intraocular pressure lowering effect of the premedication agents. These findings were comparable with the findings of the present study.

Intraocular Pressure after Ketamine (group -II)

Ketamine was introduced by Corsen G and Domino EF [22]. It is related to phencyclidine and causes a dissociative type of anesthesia which is characterized by catalepsy, light sedation, amnesia and marked analgesia.

In the present study, it was seen that the mean pre – induction intraocular pressure was 12.17 + 2.08 mmHg and the mean post – induction intraocular pressure was 14.84+1.94 after applying the student 't' test the difference between the two values was found to be statistically highly significant ($p<0.01$). The mean rise after induction as compared to the mean baseline intraocular pressure was 2.67+2.08 mmHg, range being 0- 5.7 mmHg.

The factors which raise intraocular pressure under ketamine anesthesia may be systemic hypertension, hypercarbia and the use of suxamethonium as reviewed by Adams and Barnett [23].

Corssen G and Hoy JE [24] used this anesthetic n 46 patients in the age group 6 months to 77 years. They observed that the intravenous administration of 2-3 mg/kg of ketamine led to an increase of 2-7 mmHg in the intraocular pressure. There was no correlation between these changes, patients age or change in systemic blood pressure.

Yoshikawa K and Murai Y [25] studied 18 patients aged between 4-7 years of age and observed an increase of 18% in intraocular pressure as compared to the baseline values 5 minutes after the injection of ketamine and this value rose to 37% after 15 minutes. Ketamine was administered intramuscularly in a dose of 4-5 mg/kg.

Dave B et al. [26] studied 60 patients of both sexes undergoing different surgical procedures. They found rise in intraocular pressure ranging from 2-6 mmHg in 36 out of 60 patients. No fall in intraocular pressure was noted in any patient.

Thus the findings of the present study were in close correlation with the studied conducted by Corssen G and Hoy JE [24], Yoshikawa R and Murai Y [25] and Dave B et al. [26].

Whatever the cause of rise in intraocular pressure after ketamine induction, Adams [27] suggestion seems a valuable one. He says that ketamine is not contraindicated for ophthalmic examination solely on account of its effects on intraocular pressure provided the difference from baseline is remembered. He suggests that it would be wise to examine the child under the same agent if truly comparable readings are to be obtained. Ketamine, he says, is unlikely to be a satisfactory agent for major ophthalmic surgery.

Intraocular Pressure after Intubation

Succinylcholine is one of the most widely used muscle relaxants in anesthetic practice today. In the present study also we sued succinylcholine to facilitate intubation after induction with either thiopentone or ketamine and we found a definite rise in intraocular pressure after injection of succinylcholine for intubation.

In the present study, in group -I the mean post – intubation intraocular pressure was 16.50+2.10 mmHg and the mean pre – induction intraocular pressure was 13.84+2.75 mmHg, after applying the student 't' test it was found that this rise from baseline intraocular pressure was statistically highly significant ($p<0.01$). The mean rise in intraocular pressure after intubation as compared to the baseline value was 2.68+1.60 mmHg range being 0-7.1 mmHg.

In group – II, the mean pre – induction intraocular pressure was 12.17+2.08 mmHg and the mean post – intubation intraocular pressure was 17.18+1.02 mmHg, After applying the student 't' test it was found that the difference in these two values is statistically highly significant ($p<0.01$). The mean rise in intraocular pressure after intubation as compared to the baseline was 5.16+1.21 mmHg, range being 1.4–7.1 mmHg.

De Roeth A and Schwartz H [28] suggested that the transient rise in intraocular pressure may be caused by a peak depolarizing effect of succinylcholine.

Dillon JB et al. [29] have shown contracture of extraocular muscles in invitro study following succinylcholine injection. This, along with rise in internal jugular venous pressure and apnea due to succinylcholine, raised intraocular pressure.

Wynands JE and Crowell DE [30] showed even bigger and prolonged rise in intraocular pressure following succinylcholine and postulated that succinylcholine caused a rise in cerebrospinal fluid pressure due to increased cerebral blood flow and vascular dilatation. They have shown that intubation causes a further rise in intraocular pressure which is due to stimulation of sympathetic system causing tachycardia and hypertension.

Crythorne NWB et al. [31] used tonometry to measure intraocular pressure and found that following succinylcholine there was an average increase of 7.5 mmHg.

Taylor TH et al. [32] studied selected 50 adult patients presenting for ophthalmic surgery and anesthetised them by a simple technique in which succinylcholine was used to facilitate endotacheal intubation. They found that when intraocular pressure was measured within 1 minute of injection of succinylcholine, a rise in intraocular pressure was found in 20 of 29 patients. Maximum rise was 12 mmHg. The rise was transient and came down within 6 minutes before beginning the surgery.

Pandey K et al. [33] studied the intraocular hypertension action of succinylcholine. They found that the rise in intraocular pressure manifests in 1 minute. Endotracheal intubation following succinylcholine exaggerated the intraocular hypertension. Mean intraocular pressure before intubation was 17.96 mmHg which rose to a mean intraocular pressure of 21.17 mmHg after intubation.

Upadhyaya MR et al. [34] evaluated the efficacy of topical timolol to prevent the intraocular pressure response of succinylcholine and endotracheal intubation. In control group, in which timolol was not used, the intraocular pressure increased significantly and continued to remain above basal level even after 5 minutes (from basal value of 14.96 mmHg to 20.13 mmHg).

The results found in the present study were in close correlation to those conducted by Wynands JE and Crowell DE [30], Taylor TH et al. [32], Pandey K et al. [33] and Upadhyaya MR et al. [34].

Intraocular Pressure after Extubation

In the present study, it was seen that in group -I the intraocular pressure after extubation was 12.56+2.06 mmHg and in group -II it was 12.14+1.72 mmHg. As all the cases in this study were extubated under deep levels of anesthesia so as to avoid any strenuous efforts like coughing, the mean intraocular pressure after extubation did not show any rise.

Comparison of Mean Intraocular Pressure Values between Groups

In the present study, it was seen that there was a fall in intraocular pressure in group -I after induction with thiopentone i.e. from a mean pre – induction intraocular pressure of 13.84+2.75 mmHg to 11.35+2.52 mmHg.

However there was a rise in intraocular pressure in group-II after induction with ketamine i.e. from a mean pre – induction intraocular pressure of 12.17+2.08 mmHg to 14.84+1.94 mmHg.

After applying the student 't' test it was found that the difference in intraocular pressure after induction in group A-1 was statistically highly significant as compared to the intraocular pressure after induction in group A-II ($p<0.01$).

The rise in intraocular pressure after intubation in both the groups was almost same and the difference in these values was not statistically significant ($p>0.05$). This similar rise in intraocular pressure after intubation in both the groups may be because of succinylcholine which was used in both the groups to facilitate intubation.

The intraocular pressure after extubation was similar in both groups and was found to be statistically insignificant ($p>0.05$). This was because in both the groups the patients were extubated under deep levels of anesthesia so as to avoid any strenuous effort.

Murphy DF [35] reviewed that with the exception of ketamine all the agents commonly used for induction of anesthesia, especially thiopentone and pentobarbital, decrease intraocular pressure.

Shaffer – Becker [36] reviewed that intraocular pressure reduced in proportion to the depth of anesthesia after induction with thiopental. They also reviewed that ketamine anesthesia increased intraocular pressure.

Thus, based on the observations cited in the present study, it can be said that thiopentone sodium significantly reduced intraocular pressure after induction whereas ketamine caused a significant rise in intraocular pressure after induction.

Conclusion

- Thiopentone sodium can be safely used as an inducing agent in any intraocular surgery done under general anesthesia.
- Ketamine, as far as possible, should be restricted to extraocular ophthalmic surgeries.

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A Randomised Control Study to Compare the Pretreatment Effect of Rocuronium and Atracurium on Succinylcholine Induced Post Operative Myalgia

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Abstract

Background: Succinylcholine is a depolarizing muscle relaxant, provides ideal muscle relaxation for surgical procedures along with anesthetics. Which is extensively used short acting muscle relaxant, with several undesirable side effects. These side effects are muscular fasciculations, postoperative muscle pains, rise in serum potassium, rise in intraocular tension and intragastric pressure. Nondepolarizing muscle relaxants like Atracurium and Rocuronium are better in reducing the fasciculation and myalgia in comparison with other drugs. Hence,our main aim of this study to compare the effect of Rocuronium and Atracurium on Succinylcholine induced myalgia. *Methodology:* We compared the incidence of postoperative myalgia (POM) with Atracurium (ATR) and Rocuronium (ROC) in different groups prior to Succinylcholine for tracheal intubation by using ASA class 1 or 11 in all patients posted for surgery under general anesthesia.The subjects were assigned to one of three groups: group 1 received Normal saline 5ml; group 2 received 0.05 mg/kg Rocuronium; and group 3 Atracurium 0.05mg/kg. Thiopentone was administered 1min 45 sec after pretreatment to induce anesthesia. Three minutes after, Succinylcholine 2 mg/kg was given, and fasciculations were recorded on a scale of 03. Postoperative myalgia was assessed at 6,12 and 24hrs by questionnaire and graded 03. *Results:* Patient demographic profile and baseline parameters were comparable and there were no differences between these groups. Post operative myalgia though it is seen more with NS and Atracurium than Rocuronium. There was no statistical differences seen at 6, 12 and 24 hrs after surgery. *Conclusion:* The severity of Succinylcholine induced Post operative myalgia was reduced significantly with Rocuronium than Atracurium.

Keywords: Atracurium; Fasciculation; Myalgia; Rocuronium; Succinylcholine.

Introduction

Succinylcholine is the only standard depolarizing neuromuscular blocker as an adjuvant to general anesthesia for rapid sequence intubation due to its ability to produce intense and rapid relaxation (30 to 60 s) and a short duration of action (3 to 5 minutes) [1]. myalgia are minor but frequent adverse effects of Succinylcholine [2]. reported incidence of myalgia is 0.2-89% [2,3]. This is accompanied by biochemical evidence of muscle damage as evidenced by raised serum creatine kinase and hyperkalemia in many subjects [4]. Although self-limiting, it is generally agreed that iatrogenic postoperative myalgia is unacceptable in modern anaesthetic practice [5].

Postoperative myalgia due to Succinylcholine is commonly described as pain. One might suffer after an unaccustomed degree of physical exercise, appears on the first day after surgery lasting for 2 or 3 days but occasionally persists for a week and is usually located in the neck, shoulder and upper abdominal muscles [6,7].

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So different treatment modalities individually have been advocated to reduce the incidence and severity of myalgia with Diclofenac, Ketorolac, Diazepam, Lignocaine, small dose of Succinylcholine as self-taming Cis Atracurium, Remifentanyl, Gabapentin, d-Tubocurarine, Pancuronium, Vecuronium [4] and even with non-depolarizing agents like Rocuronium [8] and Atracurium [9].

Hence , present study has been taken to compare the efficacy of pretreatment with Rocuronium and Atracurium in reducing the incidence and severity of Succinylcholine induced myalgia in HIMS, HASSAN.

Materials and Methods

A randomized control study was conducted from department of Pharmacology in Department of Anesthesia and Pharmacology. Among 90 patients posted for surgery under general anesthesia. After written consent.

Study Period: December-2015 to December-2016,

Inclusion Criteria

1. Patients undergoing surgery under general anesthesia aged between 18- 60 yrs of either sex.
2. Patients who fulfill ASA(American Society of Anesthesiologists) criteria I and II [2,9,10].

Exclusion Criteria

1. Pediatric patients (<18 yrs)
2. Patients aged above 60 yrs

Preanesthetic check up was done in all patients before taking up for the surgery. Then they were divided into three groups by simple randomization, each group containing 30 patients undergoing elective surgery under general anesthesia.

Group 1 - 0.9% normal saline (control)

Group 2 - Rocuronium 0.05mg/kg

Group 3 - Atracurium 0.05mg/kg .

Monitoring for continuous electrocardiogram (ECG), heart rate, noninvasive blood pressure (NIBP), and pulse oximetry (SpO_2) was started. After administration of Atracurium, Rocuronium or saline, anesthesia is induced, followed by Succinylcholine 2 mg/kg IV. Patients were maintained on O_2 in 50% N_2O, isoflurane 1%-2%, injection vecuronium for maintainance of muscle relaxation. Postoperative myalgia was recorded at 6,12 and 24 hrs after surgical intervention and graded based on standard questionnaire [11,12].

0: No pain

1: Pain at one site without functional disability

2: Pain involving more than one site without functional disability

3: Pain involving more than one site with functional disability

Statistical Analysis

Data were analyzed by using descriptive statistics, Fisher exact test and Chi-square test.

Ethical clearance has been obtained from Institutional ethics committee, HIMS, HASSAN.

Results

Table 1: Mean age in study group

	N	Minimum	Maximum	Mean	Std. Deviation
Age	90	19	58	38.56	12.629

Age of the patients varied from 19-58 yrs and Mean age -38.56± 12.629

Table 2: Post-operative myalgia at 6hr

Drugs	6^{th}hr		Total
	Present	Absent	
Atracurium	12	18	30
Rocuronium	12	18	30
NormalSaline	13	17	30
Total	37	53	90

ATR and ROC groups show equal incidence of myalgia (12) and NS group shows the higher incidence(13) but the results are not statistically significant with the P value< 0.995 (Chi-square test)

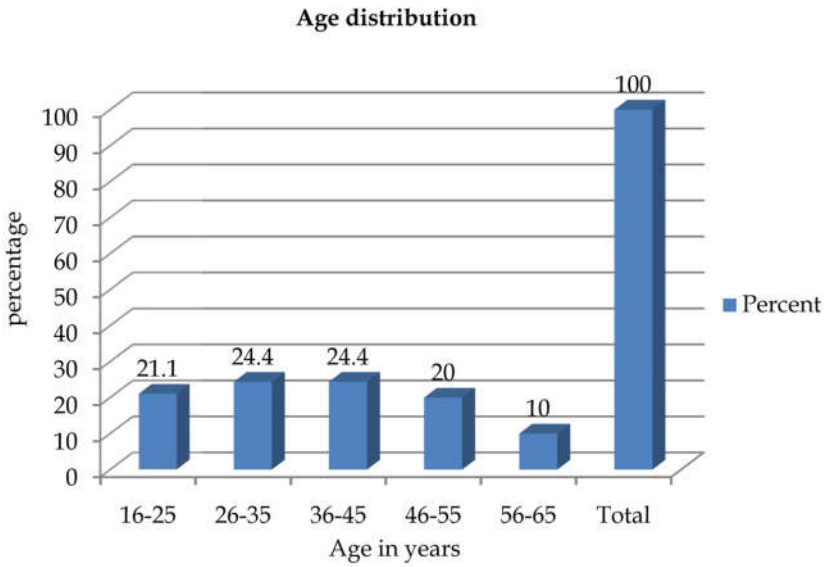

Fig. 1: Age Distribution
There were more number of patients in age group between -26-45 Yrs

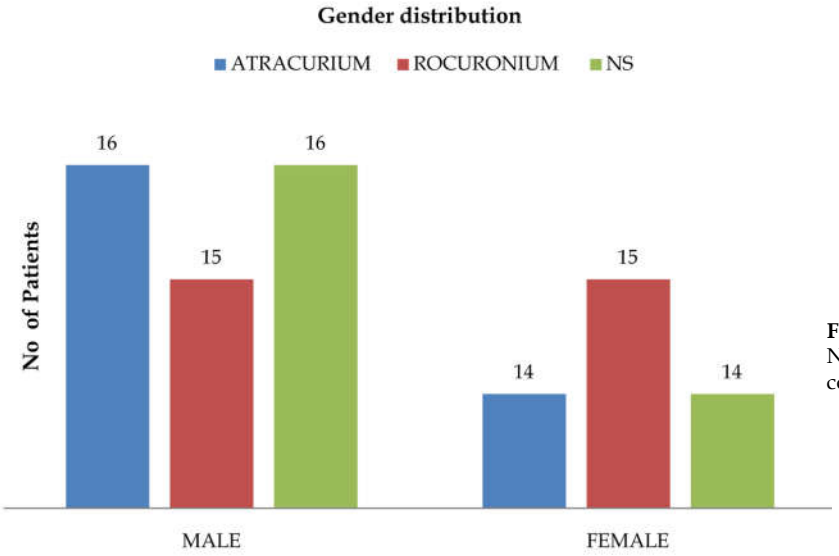

Fig. 2: Gender distribution
Number of males were more compared to females

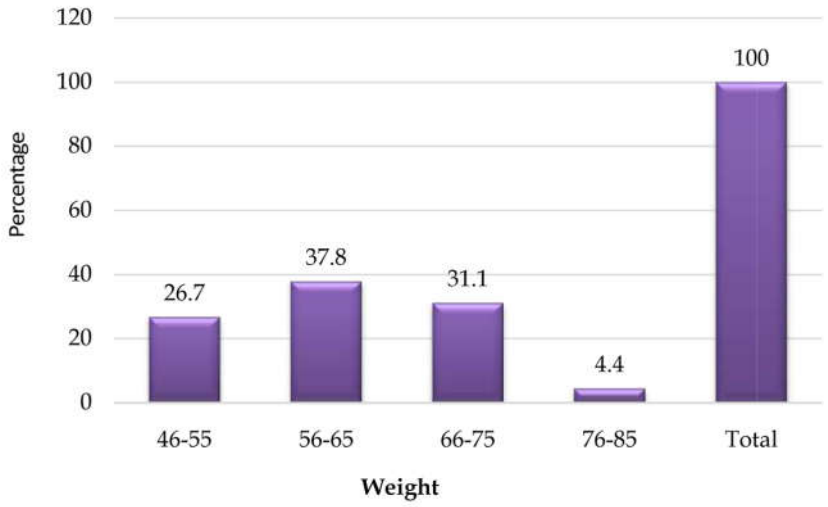

Fig. 3: Weight Distribution
Most of the patients were weighing around 56-65 kgs

Table 3: Grades of myalgia after 6 hrs

Drugs	Grade				Total
	0	1	2	3	
Atracurium	18	1	7	4	30
Rocuronium	18	5	5	2	30
NormalSaline	17	6	6	1	30
Total	53	12	18	7	90

ATR group shows the higher grades of myalgia than ROC and NS group but the results are not statistically significant with the P value < 0.438(Fisher exact test)

Table 4: Incidence of myalgia after 12 hrs

Drugs	12 hrs		Total
	Present	Absent	
Atracurium	20	10	30
Rocuronium	18	12	30
NormalSaline	21	9	30
Total	59	31	90

NS group shows the higher incidence of myalgia after 12 hrsbut the results are not statistically significant with the P value <0.709(Chi-square test)

Table 5: Grades of myalgia after 12 hrs

Drugs	Grade				Total
	0	1	2	3	
Atracurium	10	0	13	7	30
Rocuronium	12	6	8	4	30
NormalSaline	9	10	8	3	30
Total	31	16	29	14	90

ATR group shows the higher grades of myalgia (P value < 0.035)Fisher exact test.

Table 6: Incidence of myalgia after 24 hrs

Drugs	24 hrs		Total
	Present	Absent	
Atracurium	25	5	30
Rocuronium	18	12	30
NormalSaline	17	13	30
Total	60	30	90

ATR group shows the higher incidence of myalgia but the results are not statistically significant with the P value < 0.058 (Chi Square test)

Table 7: Grades of myalgia after 24 hrs

Drugs	Grade				Total
	0	1	2	3	
Atracurium	5	1	16	8	30
Rocuronium	12	4	9	5	30
NormalSaline	13	2	7	8	30
Total	30	7	32	21	90

ATR group shows the higher grades of myalgia and the results are not statistically significant with the P value < 0.093 (Fisher exact test).

Table 8: Grades of myalgia after 12 hrs

Drugs	Grade				Total
	0	1	2	3	
Atracurium	10	0	13	7	30
Rocuronium	12	6	8	4	30
NormalSaline	9	10	8	3	30
Total	31	16	29	14	90

ATR group shows the higher grades of myalgia (P value < 0.035)Fisher exact test.

Table 9: Incidence of myalgia after 24 hrs

Drugs	24 hrs		Total
	Present	Absent	
Atracurium	25	5	30
Rocuronium	18	12	30
NormalSaline	17	13	30
Total	60	30	90

ATR group shows the higher incidence of myalgia but the results are not statistically significant with the P value < 0.058 (Chi Square test)

Table 10: Grades of myalgia after 24 hrs

Drugs	Grade				Total
	0	1	2	3	
Atracurium	5	1	16	8	30
Rocuronium	12	4	9	5	30
NormalSaline	13	2	7	8	30
Total	30	7	32	21	90

ATR group shows the higher grades of myalgia and the results are not statistically significant with the P value < 0.093 (Fisher exact test).

Discussion

Succinylcholine is a depolarizing skeletal muscle relaxant that remains as standard treatment in facilitating endotracheal intubation, because it shows quick onset of action and spontaneous recovery. Despite its limitations and side effects, Succinylcholine is still a drug of choice for endotracheal intubation in operating rooms.

Myalgia is also one of the side effect of Succinylcholine. Several mechanisms have been proposed to explain the phenomenon of postoperative myalgia. Postoperative myalgia is often described as being similar to myalgia after unaccustomed exercise. Fasciculations involve vigorous contraction by muscle bundles with no possibility of shortening and without synchronous activity in adjacent bundles. This might produce fibre rupture or damage, thus causing pain [5].

In the present study post operative myalgia evaluated at 6, 12 and 24 hrs post surgery for who have received either of the pretreatment drugs.

The incidence of myalgia after 6 hrs of surgery among three groups in which ATR and ROC groups show equal numbers of myalgia [12] and NS group shows the higher incidence [13] but the results are not statistically significant with the P value < 0.995.

The grades of myalgia after 6 hrs of surgery among three groups in which ATR group shows the higher grades of myalgia than ROC and NS group but the results are not statistically significant with the P value < 0.438.

The incidence of myalgia after 12 hrs of surgery among three groups in which NS group shows the higher incidence (21) where the ATR shows 20 and ROC shows 18 but the results are not statistically significant with the P value < 0.709.

The grades of myalgia after 12 hrs of surgery among three groups in which ATR group shows the higher grades of myalgia than ROC and NS group and the results are statistically significant with the P value < 0.035.

The incidence of myalgia after 24 hrs of surgery among three groups in which ATR group shows the higher incidence (i.e 25) where the ROC shows 18 and NS shows 17 but the results are not statistically significant with the P value < 0.058.

Shows the grades of myalgia after 24 hrs of surgery among three groups in which ATR group shows the higher grades of myalgia than ROC and NS group and the results are not statistically significant with the P value < 0.093.

In a study conducted by Spencer et al where Rocuronium is compared with Lidocaine, which showed post operative myalgia at 24 and 48 hrs . In which Lidocaine showed more number of incidence than that of the Rocuronium group but the result was not statistically significant and the same outcome noted in case of 24 hrs with P value >0.05. But at 48hrs Lidocaine found to be better than that of Rocuronium in controlling myalgia with the statistically significant P value 0.0213 [13].

In another study conducted by Nighat Abbas there were 60 patients out of ehich 30 was given Rocuronium and the remaining 30 was given

Placebo. The statistical analysis showed the frequency of post operative myalgias with Rocuronium (16.66%) to be significantly less than with placebo (76.66%, p< 0.001) at 6 and 12 hours after surgery. After 24 hours the frequency of myalgias was (23.33%) in the Rocuronium group and (93.33%, p<0.001) in the placebo group [14].

Sosis et al conducted astudy on 44 ASA class I or II girls and women aged 16-50. The subjects were randomly assigned to one of three groups: group 1 (n = 13) received 0.025 mg/kg ATR, group 2 (n = 17) 0.05 mg/kg DTC, and group 3 (n= 14) saline (NS). Severe POM was not experienced by any patient. On postoperative day 1, the only myalgia in ATR patients was mild, occurring in 15%. POM was mild in 35% and moderate in 6% of DTC patients. The corresponding results for NS were 43% and 14%) respectively. Significantly more ATR patients (85%) than NS patients (43%) were free of POM. There was no significant difference between ATR and DTC or between DTC and NS in this regard. On the third postoperative day, POM was rare and there were no significant differences among the groups. Of the six ATR patients who had fasciculations, only one had myalgia on postoperative day 1. After DTC, two patients had fasciculations but neither had POM on day 1. After NS, 11 patients had fasciculations but only five of these had POM on postoperative day 1. Of the seven patients given ATR who had no fasciculations, one had POM on day 1. Of the 15 patients given DTC who had no fasciculations, seven had POM on day 1. After NS, three patients had no fasciculations but all them had POM on postoperative day 1 [15].

A study by Pagani et al showed Myalgias on the postoperative day were observed in 80% of patients treated with saline solution, but only in 36% of patients who received atracurium. The difference between atracurium and saline solution was statistically significant (p less than 0.001) either for fasciculations or myalgias incidence. These findings show that atracurium 5 mg i.v. is effective in preventing succinylcholine-induced fasciculations and postoperative myalgias, and suggest atracurium as the drug of choice for this purpose, particularly in muscular subjects [16].

The present study showed that Rocuronium is the better drug when compared with Atracurium and NS with respect to the fasciculations by blocking presynaptic nicotinic receptors [17]. But it is not same with respect to myalgia current result showed no statistically significant difference between the groups though Rocuronium showed the better results. Certain studies showed that there is no clear relationship between fasciculations and myalgia. Studies also suggest that post treatment of myalgia after the sugery should be considered with NSAIDs or Opioids since there is no superiority of pretreatment over the post-treatment is reported [18,19].

Conclusion

Pretreatment with intravenous Rocuronium found to be superior to Atracurium at the dose of 0.05 mg/kg over 3 minutes, prior to induction of general anaesthesia with Thiopentone sodium in reduction of incidence and severity of Succinylcholine (2mg/kg) induced Myalgia .

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Evaluation of Perioperative outcomes of Delayed Recovery Cases from GA and their Correlation with Standard Anaesthesia Scoring Systems: An Observational Study

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Abstract

Context: The critical period for a patient who was given general anaesthesia is the time during immediate recovery from anaesthesia. The PACU is a dynamic entity that greatly benefits the delayed recovery patients from research directed interventions to guide the next level of care for post-operative health status. *Aim:* The aim of this study is to determine peri-operative risk factors, morbidity and mortality of delayed recovery cases and correlate the outcomes of these patients with ASA physical status and Modified Aldrete's recovery scores in the Post Anaesthesia Care unit (PACU**)** *Methodology:* After institutional ethics committee approval and written, informed consent, 434 adult patients belonging to both genders posted for general surgical elective procedures were included in this observational study. Delayed recovery patients were identified at the end of surgery using Modified Aldrete's Recovery Score and shifted to PACU for further follow up until their discharge and morbidity and mortality was recorded. *Results:* Mean intra-operative blood loss and mean duration of surgery were proportionally increased as the ASA physical status is high = 0.000, statistically significant. As the pre-operative ASA physical status grading is increased the percentage of patients that had more than 48 hrs PACU stay also increased and it was statistically significant with p = 0.029. As the ASA grade increases the recovery scores were inversely proportional, p=0.029 statistically significant. *Conclusion:* Preoperative co-morbid conditions, ASA physical status and Modified Aldrete's Recovery Scores are good predictors of postoperative outcomes for patients given general anaesthesia.

Keywords: Delayed Recovery; Post Anaesthesia Care Unit; ASA Grading; Modified Aldrete's Recovery Score.

Introduction

The critical period for a patient who has been administered general anaesthesia is the time during immediate recovery from anaesthesia. In 1950, Dr. Philip Lowenthal and Dr. Arch Russel, presented guidelines for recovery area that are still relevant today [1]. Now-a-days, Post Anaesthesia Care Unit is the preferred location for the immediate recovery of post-operative patients requiring intense observation to enable early detection of complications from surgery [2]. Despite the recent advances in the field of clinical anaesthesiology with availability of sophisticated equipment , improved standards of monitoring systems and newer anaesthetic agents, delayed recovery has still been a continuous problem even today [3]. Several factors can be attributed to delayed recovery from general anaesthesia. Preoperative ASA physical status, surgical procedure and duration, type and choice of anaesthesia, intra-operative blood loss, certain metabolic, endocrine and electrolyte imbalances and patients' tolerance to anaesthetics and various medications are all the factors which contribute to delayed recovery from general anaesthesia [4,5]. The PACU is a dynamic and evolved entity that greatly benefits the delayed recovery patients from research directed interventions to guide the next level of care for post-operative health status [6]. A study done

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on large no. of patients determined that the ASA classification system has good inter-rater reliability and is a valid predictor of patients' pre-operative health conditions [7]. Quantitative assessment tools like Aldrete's recovery score are widely used in predicting post-operative outcomes that may help guide medical and anaesthetic interventions [8].

The aim of this study is to determine peri-operative risk factors, morbidity and mortality of delayed recovery cases and correlate the outcomes of these patients with standard anaesthesia grading and scoring systems like ASA physical status and Modified Aldrete's recovery scores in the Post Anaesthesia Care unit (PACU).

Methodology

After institutional ethics committee approval and written, informed consent, 434 adult patients belonging to both genders posted for general surgical elective procedures over a period of 4 months in general surgical operation theatres complex in a tertiary care hospital were included in this single centered, prospective ,observational study. The patients who had delayed recovery from general anaesthesia were identified at the end of surgery using Modified Aldrete's Recovery Score and have been shifted to Post Anaesthesia Care Unit (PACU) for further monitoring and follow up until their discharge to the surgical ward or critical care unit. Patients who satisfied the recovery scores at the end of surgery were shifted to the recovery area, observed for 2 hours and then shifted to the surgical ward.

This study was designed to evaluate the relative importance of peri-operative factors affecting delayed recovery from general anaesthesia and their correlation to standard anaesthesia scoring systems like ASA grading and Modified Aldrete's Recovery Scoring. This study was undertaken for a period of four months i.e.; from September 2017 to December 2017. The surgical procedures performed on the patients were general surgeries including thyroid surgeries, breast surgeries, laparotomies, laparoscopic cholecystectomies etc; Thorough preoperative evaluation was done in all the patients in their routine pre-anaesthetic check up with respect to history, physical examination, systemic examination and general examination. Routine Laboratory investigations like haemogram, blood grouping and typing, renal function tests, electrocardiogram, chest x-ray etc; were done. Specific evaluation of cardiac or pulmonary system through echocardiography or pulmonary function tests and Thyroid profile, serum amylase or liver function tests were done pre-operatively. Patients with co-morbid conditions were optimised appropriately depending up on their disease. All the patients were administered standard general anaesthetic regimen comprising of Glycopyrrolate, Fentanyl, Propofol, Vecuronium, Sevoflurane, Nitrous oxide- oxygen @ 60:40% and reversed with reversal agents Neostigmine and Glycopyrrolate according to standard doses per/ kg body weight.

Patients were extubated in the operating room if they met the criteria for extubation at the end of surgical procedure and then they were shifted to PACU for further observation and monitoring. Patients were shifted to PACU with endo tracheal tube insitu if they did not meet the extubation criteria and connected to the ventilator or T-piece breathing system if needed.

On arrival at PACU, the following parameters were recorded in all patients:-

- Pre-operative ASA physical status (represented in Table 1) to stratify the overall risk.
- Glass Gow Coma Scale Scoring to ascertain the level of consciousness.
- Modified Aldrete's Recovery Scoring to assess the recovery condition of the patient (represented in Table 2).
- Any uneventful intra-operative history was noted.
- Review of pre-operative Pre-anaesthetic check up data ,investigations and co-morbid conditions
- Necessary emergency investigations to identify the cause of delayed recovery from general anaesthesia like Arterial Blood gases, Serum electrolytes, Random blood sugar etc;were done as dictated by the patients' general condition.

In the PACU all the cases were followed up till their discharge and morbidity and mortality was recorded.

Statistical Analysis

All the data was tabulated and analysed using the software graphpad.com. Demographic data was analysed using Fischer exact test. Mean intra-operative blood loss, Mean duration of surgery and length of PACU stay were analysed with One-way ANOVA test. $p < 0.05$ was considered statistically significant. Categorical data was represented as percentage.

Results

A total of 434 patients posted for general surgical cases under general anaesthesia were included in this Prospective, Single Centered and Observational study. Out of 434 patients, 30 patients had delayed recovery in the immediate post anaesthesia recovery phase as assessed by Modified Aldrete's Recovery score (represented in Table 2). All the 30 patients who had delayed recovery from general anaesthesia were shifted to PACU and followed up for complications and continuously monitored until their discharge from PACU.

Population Demographics like age, weight, height, ASA grading, Male: Female ratio were expressed as Mean or absolute numbers or Ratio and represented in Table 3. Different surgical interventions that lead to delayed recovery were represented in Table 4.

Intra-operative factors like mean duration of surgery and mean intra-operative blood loss in relation to ASA grading were represented in Table: 5. Mean intra-operative blood loss and mean duration of surgery were proportionally increased as the ASA physical status is high, p = 0.000, statistically significant. The length of PACU stay with respect to ASA physical status is represented in table 6. As the pre-operative ASA physical status grading is increased the percentage of patients that had more than 48 hrs PACU stay also increased and it was statistically significant with p = 0.029. Post-operative factors in relation to ASA grading was represented in Table 7 which indicates that percentage of patients that required mechanical ventilation post-operatively, percentage of patients that required tracheotomy and percentage of patients that died in the Critical Care Unit were proportional to ASA grade. Modified Aldrete's recovery scores in the PACU were depicted in Figure 1. During the first 24 hours of PACU stay 80% (24) of patients satisfied recovery criteria according to Aldrete's ≥ 9 compared to 20% (6) of patients who did not satisfy the recovery scores (<9) and they had to be followed up further in the PACU. Preoperative risk factors were shown in table: 8. Out of the 30 patients that had delayed recovery, 17 patients (56.6%) had pre-operative risk factor for anaesthesia and surgery which suggests that was a strong correlation between pre-operative co-morbid condition and postoperative outcome. Modified Aldrete's Recovery scores were correlated with ASA physical status, there was a positive correlation as it was represented in Table 9. As the ASA grade increases the recovery scores were inversely proportional, p=0.029 statistically significant. Peri-operative complications were represented in figure: 2. Length of stay in PACU was plotted against modified aldrete's recovery score (MARS) in figure: 3 which shows that 80% (24) Patients with MARS ≥ 9 in the PACU were discharged to the ward in the first 24 hours or less while 20% (6) patients with MARS <9 had prolonged stay in the PACU for 48 hrs or more.

Table 1: ASA Physical status Grading

ASA Physical status	Definition	Examples
ASA I	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use
ASA II	A patient with mild systemic disease	Examples include (but not limited to): current smoker, social alcohol drinker, pregnancy, obesity (30<BMI<40) etc;
ASA III	A patient with severe systemic disease	poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction etc;
ASA IV	A patient with severe systemic disease that is a constant threat to life	Recent (< 3 months) MI,CVA,TIA,CAD/stents, ongoing cardiac ischemia or severe LV dysfunction, Sepsis, DIC etc
ASA V	A moribund patient who is not expected to survive without the operation	Examples include (but not limited to): ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction
ASA VI	A declared brain-dead patient whose organs are being removed for donor purposes	

*The addition of **"E"** denotes Emergency surgery: (An emergency is defined as existing when delay in treatment of the patient would lead to a significant increase in the threat to life or body part) ASA Grading: American society of physical status grading

Table 2: Modified Aldrete's Recovery Score

Parameter	Modified criteria	score
Activity Level	Moves all extremities voluntarily /on command	2
	Moves two extremities	1
	Cannot move extremities	0
Respirations	Breathes deeply and coughs freely	2
	Is dyspnoeic with shallow limited breathing	1
	Is apnoeic	0
Circulation	Blood Pressure ± 20 mmHg of normal	2
	Blood Pressure ± 20 – 50 mmHg of normal	1
	Blood Pressure > ± 50 mmHg of normal	0
Consciousness	Fully awake	2
	Arousable on calling	1
	Not responsive	0
Oxygen saturation as determined by pulse oximetry	SpO_2 > 92% on room air	2
	SpO_2 > 90% on oxygen	1
	SpO_2 < 90% on oxygen	0

Maximum score is 10, A score of ≥ 9 is required for discharge

Table 3: Population Demographics

Demographic variable	Mean/Absolute Numbers/Ratio
Age in years	42.4
Weight in Kgs	69.6
Height in cms	156.9
Male : female ratio	2:3
ASA I/II/III	10/16/4

Table 4: Types of surgeries

Type of surgery	Number of cases(30)
Thyroid surgery	6
Laparoscopic cholecystectomy	5
Modified radical mastectomy	5
Whipples Procedure	2
Sub acute intestinal obstruction	4
Incisional hernia	3
Partial gastrectomy	4
Benign retroperitoneal mass resection	1

Data expressed in absolute numbers

Table 5: Surgical factors in relation to ASA grading

Surgical factor	ASA I	ASA II	ASA III	p-value
Mean duration of surgery (min)	135	155	245	0.000*
Mean intra-operative blood loss (ml)	850	1225	2050	0.000*

Data expressed as Mean /SD
ANOVA test, *p-value <0.05, statistically significant

Table 6: Length of PACU Stay in relation to ASA grading

Factor	ASA I (n =10)	ASA II (n=16)	ASA III (n=4)	p-value
No of patients < 48 hrs of PACU stay	9	14	1	**0.029***
No. of patients >48 hrs of PACU stay	1	2	3	

Data expressed as percentage and absolute numbers
3×2 Fischer exact test,*p-value < 0.05, statistically significant

Table 7: Post –operative factors in relation to ASA grading

Factor	ASA I (n =10)	ASA II (n=16)	ASA III(n=4)
No. Of patients required mechanical ventilation	-	1(3.3%)	2(6.6%)
No. Of patients underwent tracheotomy	-	1(3.3%)	-
No of patients died in the ICU	-	1(3.3%)	1(3.3%)

Data expressed as percentage and absolute numbers

Table 8: Pre-operative Risk factors

Co-morbid condition	Total no of Patients, n = 30 No of Patients(percentage) with risk factors
Diabetes under control	6(20%)
Hypertension under control	4(13.3%)
Known hypothyroid on Eltroxin	3(10%)
Known epileptic on Eptoin	2(6.6%)
Obstructive Jaundice	2(6.6%)

Data expressed as absolute numbers and percentage

Table 9: Modified Aldrete's Recovery Score as a function of ASA grading

ASA Status	MARS ≥ 9	MARS < 9	
ASA I (n=10)	9	1	*p-value 0.029
ASA II (n=16)	14	2	
ASA III (n=4)	1	3	

3×2 contingency table, Preoperative ASA status correlated well with Recovery scores Data expressed as absolute numbers. *p-value significant statistically.

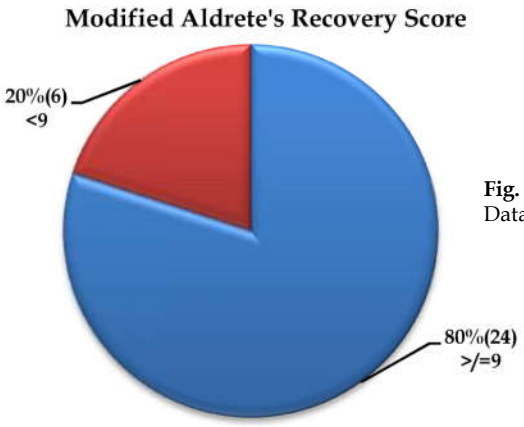

Fig. 1: Modified Aldrete's Recovery Scores in PACU
Data expressed as absolute numbers and percentage

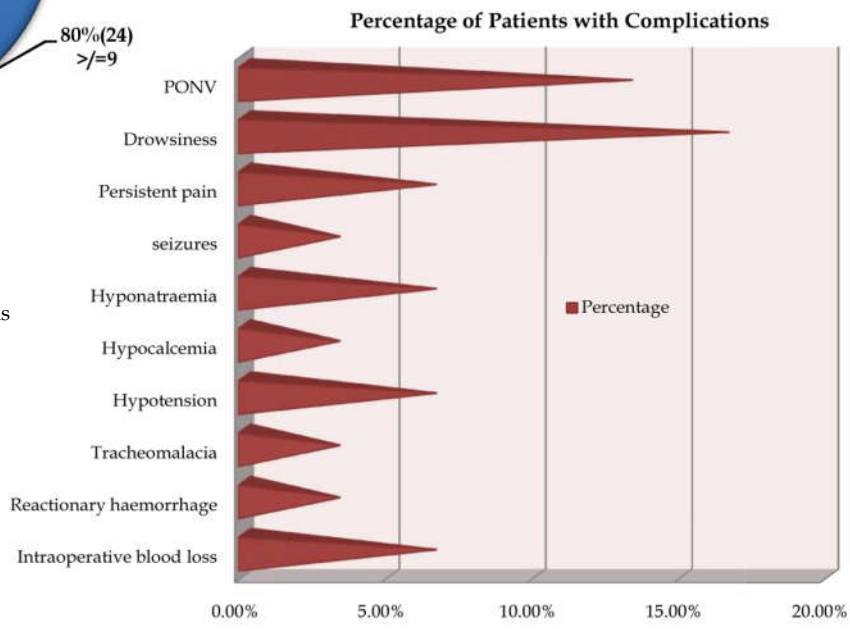

Fig. 2: Peri-operative complications
Data expressed as percentage

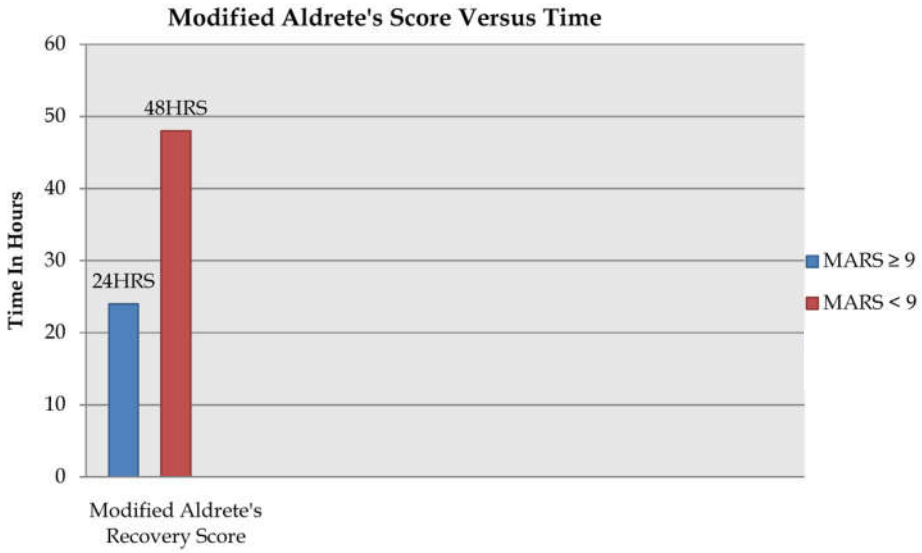

Fig. 3: Modified Aldrete's Recovery score versus PACU stay

Discussion

The present study demonstrates that delayed recovery from general anaesthesia, though rare can lead to significant morbidity and also mortality in the peri-operative period, despite of meticulous peri-operative anaesthetic management and advances in the speciality of clinical anaesthesiology.

Thirty cases of delayed recovery due to various peri-operative factors were reported over a period of 4 months in general surgical operation theatres and they were followed up in the Post Anaesthesia Care Unit (PACU) till discharge. Various factors related to the patient per se like pre-operative co-morbid conditions, factors related to surgical procedure and duration of surgery, factors related to anaesthetic technique and anaesthetic drugs, preoperative metabolic status etc; are all the factors responsible for delayed recovery and subsequent physical health of the patients [9]. Standard anaesthesia grading and scoring systems like ASA physical status and Modified Aldrete's Recovery Score were used to correlate the outcomes of patients with delayed recovery in the present study.

One of the important goals of this study is to identify factors that have contributed to delayed recovery. Out of 30 cases of delayed recovery, 70% (21) were observed to have peri-operative complications, of them 13.3% (4) of complications were major due to peri-operative blood loss, tracheomalacia and reactionary haemorrhage and rest of them were minor. In this study, the length of PACU stay was proportionately increased to the severity of peri-operative complications. Several clinical trials reported the factors that contribute to delayed discharge but no universal definition for increased length of stay was established [10]. Duration of general anaesthesia, duration of surgery and intra-operative cardiac events are the common factors identified in different studies to be the cause for delayed discharge from PACU [11]. In the present study, none of the patients had delayed discharge due to peri-operative cardiac events.

Pre-existing co-morbidities are important factors that lead to delayed recovery and prolonged length of PACU stay [12]. In the present study 56.6% of patients had pre-existing co-morbid conditions which have correlated well with the rate of peri-operative complications that have lead to prolonged length of PACU stay. Type of surgical procedure and also duration of surgery significantly correlated with the length of PACU stay in this study. Though the anaesthetic technique is similar in all the patients, duration of surgery definitely has its impact on the recovery as the duration of anaesthesia also increases.

Frost EA in his review mentioned that antiepileptic drugs are known to reduce the responsiveness of non depolarising neuromuscular blocking drugs administered chronically [13]. In this study, 2 patients with pre-existing epilepsy on Eptoin 100mg for more than 5 years were observed to have delayed recovery and stayed in the PACU for less than 48 hrs, later met the discharge criteria and were shifted to the surgical ward. Electrolyte

imbalances like hypocalcaemia occurred after thyroid surgery and hyponatraemia occurred after Whipple's operation in this study. Wolters et al studied the association between ASA physical grading, peri-operative risk factors and peri-operative outcomes in surgical patients and showed a significant correlation between ASA grading and factors like intra-operative blood loss, duration of post-operative ventilation and duration of PACU stay [14]. Wolters et al findings were correlated with the observations of our study when ASA grading was related to peri-operative factors like mean duration of surgery (p=0.000) and mean intra-operative blood loss (p=0.000) as represented in table 5 and length of PACU stay (p=0.029) as represented in table 6. The morbidity of the patients assessed by the percentage of patients required mechanical ventilation, percentage of patients required tracheotomy and percentage of patients died also correlated well with the pre-operative ASA physical status as well as Modified Aldrete's Recovery scores in this study.

ASA grading has been found in some studies to be a good predictor of post-operative resource utilisation and mortality in numerous surgical fields [15]. Also considerable variations in the ASA classification has been reported in the previous clinical trials as ASA physical status neither takes in to account the demographic characteristics, the nature of surgical procedure and expertise of the anaesthesiologist nor the facilities for adequate postoperative management of patients [18]. Association between ASA physical status and post-operative mortality at 48 hrs was studied by Thomas J Hopkins et al and they observed that mortality risk within 48 hrs is decreased for elective and emergency procedures for ASA IIE through ASA IVE and increased for ASA VE as surgeries were offered to high risk cases in ASA grade V [17]. They analysed that the possible causes of improvement in the mortality risk is due to the improvement in the perioperative standard of care to the patients and improvement in the public health. Inspite of variable opinions of researchers about ASA physical status, various studies proved that ASA Physical status is a good predictor of post-operative outcome similar to the observations of this study.

Modified Aldrete's criteria is a quantitative assessment and traditional scoring method of evaluating patients in the immediate post-anaesthetic recovery period (Phase-I) for discharge of patients either from the operating room or from the Post Anaesthesia Care Unit [18]. It is simple to implement, easy to memorise, poses low burden on PACU staff, applicable to all post-operative patients and accepted internationally. B Burke and M Kyker evaluated recovery in outpatients with Speeds criteria versus Modified Aldrete's, screening tests were highly specific in identifying patients who would require nurse and patient interventions [19]. In this study, 80% of patients with Modified Aldrete's recovery scores ≥ 9 were discharged from the PACU at or before 24 hours while 20% of patients with Modified Aldrete's recovery scores < 9 had to stay in the PACU for 48 hours and even more.

In this study, 4 (13.3%) patients required mechanical ventilation, 1 (3.3%) patients required tracheotomy and 2 (6.6%) patients died after shifting them to the ICU, indicating that Modified Aldrete's recovery scores well correlated with the outcomes like length of PACU stay, requirement of mechanical ventilation, requirement of tracheotomy and mortality. The above observations have correlated well with the studies of B Burke and Mark Kyker as well as other studies [20]. The limitation of Aldrete's score is, it does not take in to consideration about most common problems in the post-operative period like PONV, postoperative pain and drowsiness. As all the patients in this study are in-patients, they were treated appropriately for these complications in the PACU. According to previous studies, Pain, PONV and drowsiness significantly contribute to increased length of PACU stay, an observation which correlates with this study [21,22].

The main limitation of this study is, this is a single centered study, hence not generalizable, sample size is also small and population belonging to ASA IV and higher grade are not represented in this study. Though the ASA grading and Modified Aldrete's scoring are internationally accepted, due to their limitations, a quantitative clinical scoring system that meets the dynamic needs of surgical population and easy to be used by the PACU staff is recommended for future implications.

Conclusion

To summarise this study demonstrated that

- Preoperative co morbid conditions well correlated with the postoperative outcomes for patients of delayed recovery from General anaesthesia
- ASA physical status has correlated with the perioperative morbidity, no. of post operative interventions and mortality as well.

- Modified Aldrete's Recovery Score strongly correlated with the length of PACU stay , no. Of postoperative interventions and mortality of delayed recovery cases in the PACU
- There was positive correlation between ASA physical status and Modified Aldrete's Recovery Score though each of the tools has their own limitations.

Hence it can be concluded that preoperative co-morbid conditions, ASA physical status and

Modified Aldrete's Recovery Scores are good predictors of postoperative outcomes for patients given general anaesthesia for general surgical procedures.

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Conflicts of Interest: Nil.

Key Message

ASA physical status classification is a valid predictor of surgical risk and Modified Aldrete's recovery score is a valid quantitative assessment tool to predict postoperative outcomes in surgical patients.

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A Critical Evaluation of an Effect of Nalbuphine as an Adjuvant to Bupivacaine for Ultrasound Guided Interscalene Brachial Plexus Block

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Abstract

Context: The use of Brachial plexus block under Ultrasound guidance for Anesthesia has increased recently. Various adjuvants are added to enhance the analgesic effect of local anesthetic agents namely opioids, alpha 2 agonist, dexamethasone, etc. *Aim:* The aim of this study was to evaluate the effect of analgesic efficacy of nalbuphine as an adjuvant to 0.5% bupivacaine for interscalene brachial plexus block. *Settings and Design:* This is a prospective randomized double blind control study conducted in Melmaruvathur Adhiparasakthi Institute of Medical Science & Research over a period of one year from June 2016 to June 2017. *Methods and Material*: Sixty patients of ASA I and II undergoing elective shoulder surgery under Ultrasound guided Interscalene brachial plexus block were randomly allocated into two groups of thirty patients each to receive either 20mL of 0.5% bupivacaine with 1 mL normal saline (Group I-Bupivacaine with control group) or 20mL of 0.5% bupivacaine with 1 mL of Nalbuphine 10mg (Group II- Bupivacaine with Nalbuphine). Onset and duration of sensory and motor block and duration of postoperative analgesia were observed. *Statistical analysis used:* Statistical analysis was performed using appropriate test with Graphic prism 5.0 software. *Results:* Addition of Nalbuphine with bupivacaine has faster onset of sensory and motor block and enhanced duration of sensory motor block compared to bupivacaine alone with statistically significant difference ($p<0.0001$). Nalbuphine prolongs the duration of analgesia significantly ($p<0.0001$). None of the patients experienced any adverse hemodynamic changes and complications. *Conclusion:* The present study explains that Nalbuphine 10 mg added to 0.5% bupivacaine in interscalene brachial plexus block has significant increase in the duration of analgesia with no adverse effects.

Keywords: Nalbuphine; Bupivacaine; Interscalene Brachial Plexus Block.

Introduction

Interscalene brachial plexus block is relatively safe and effective regional anesthetic technique for upper arm and shoulder surgeries. It is an effective alternative to general anesthesia for most patients as it avoids the undesired effect of general anesthetic drugs and stress of laryngoscopy. Various adjuvants like Opioids, Alpha 2 agonist, Dexamethasone etc are added to local anesthetic to prolong the block effect and to reduce the toxicity of local anesthetics [1-3].

Nalbuphine is a phenanthrene opioid derivative which is a strong analgesic with partial agonist at kappa receptors and antagonist at μ receptors. Nalbuphine have ceiling analgesic and respiratory depressant effect, but still it can be as effective as full μ agonist action in providing analgesia [4,5]. After going through the literature, Nalbuphine was studied several times as an adjuvant to local anesthetics in spinal, epidural and caudal. Very minimal study has been done in peripheral nerve blocks [6-9] .

The aim of the present study is to evaluate the clinical efficacy of Nalbuphine as an adjuvant to 0.5% bupivacaine for interscalene brachial plexus block for various arm and shoulder surgeries under ultrasound guidance.

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Materials and Methods

It was a prospective randomized double blind control study conducted over a period of one year from June 2016 to June 2017 in the Department of Anesthesiology, Melmaruvathur Adhiparasakthi Institute of Medical Sciences & Research, after obtaining approval of the ethical committee. This study included sixty patients of American society of Anesthesiologist physical status I & II of both male and female, aged 18 to 60 years scheduled for elective shoulder and arm surgeries in orthopedic operation theatres .The patients with infections at the injection site, coagulopathy, cardiovascular, pulmonary, renal, hepatic disease, allergy to local anesthetics, failure of block and neurological deficit were excluded from this study .Patients were randomly allocated into two groups according to computer generated random number. Group I (Bupivacaine with control group) patients received 20 ml of 0.5% Bupivacaine with 1ml of normal saline and GroupII (Bupivacaine with Nalbuphine) patients received 20 ml of 0.5% bupivacaine with 1ml of Nalbuphine (10mg) for Interscalene Brachial Plexus under ultrasound guidance.

All patients were assessed and explained about visual analogue pain score, where zero indicates no pain, ten indicates severe unbearable pain. The patients were premedicated with tablet alprazolam 0.25 mg and tablet Ranitidine 150mg orally at night before surgery. On arrival to the preoperative room, patient was cannulated with 18 gauge IV cannula into the peripheral vein, Ringer lactate infusion were started as per perioperative fluid requirement. Monitors like Heart rate, Non invasive blood pressure, Electrocardiogram and pulse oximetry were connected. Patients then shifted to operative room. Patient were positioned in supine position with head turned 45 degree to opposite side. The interscalene brachial plexus block was performed with a transportable ultrasound machine (sonosite inc) with 6-13 MHz, 38mm linear high frequency probe. Under strict aseptic precautions and local infiltration of skin, supraclavicular fossa is scanned first to identify the subclavian artery as it passes over the first rib. Brachial plexus is identified as bunch of grapes lying superolateral to the artery. The plexus is followed medially and cephalad along its course till the trunk is seen between the anterior scalene and middle scalene muscles. Now 23 gauge 5cm echogenic needle was advanced lateral to medial in long axis of the probe. The needle is advanced till the needle tip is in close proximity to C6 nerve root. The prepared local anesthetic volume of 21ml is injected. The spread of local anesthetics should expand the interscalene space and cover C5, C6 and C7 nerve roots. Patient were assessed for onset of sensory and motor block, duration of motor block and duration of analgesia. The onset of sensory block was assessed from the drug administration to first loss of pinprick sensation in any dermatome (C5-T1). The onset of motor block was analysed from the drug administration to reduction of muscle power (grade 2). Motor onset was assessed by using a modified Bromage scale. Duration of analgesia was the time from the onset of sensory block and the need of rescue analgesia. Rescue analgesia used in the form of diclofenac 75 mg IV. Intraoperative vital parameters of heart rate, Respiratory rate, NIBP, oxygen saturation were monitored. Any adverse effects like hypoxia, hypovolemia, and bradycardia were also monitored.

Statistical analysis were done by using the graph pad prism 5.0 software. The data were expressed as a mean and standard deviation or number and percentage. The p-value of <0.0001 was considered statistically significant.

Results

A total of 60 patients were enrolled in this study ,and they were randomly divided into two groups, 30 patients in each. The demographic data of Age, Gender and Weight were comparable. About 75% of them were ASA Class I (Table 1). This study evaluated the clinical efficacy of nalbuphine as an adjuvant to 0.5% bupivacaine for interscalene brachial plexus block under USG guidance for various arm and shoulder surgeries. Onset of sensory and motor block was found to be rapid in patients receiving Nalbuphine as an adjuvant to 0.5% bupivacaine (Group II) that is (6.23±0.79 min, 11.63±1.32 min) when compared to Group I (9.10±1.02 min, 14.67±1.06 min) and it was statistically significant ($p<0.0001$). Duration of analgesia was also significantly prolonged in patients of Nalbuphine group(Group II) in comparison with control bupivacaine (Group I) and it was 482±19.72 min and 317±12.64 min respectively and it showed statistically significant p-value ($p<0.0001$), Thus Group II showed a delayed regression in the sensory block when compared with the control group (Group I). Regarding the duration of motor block Group II was found to last for 276±15.74 min when compared to group I 227±7.39 min and is also statistically significant The blockade was effective and succeeded in all patients. No hemodynamic and local anesthetic toxicity changes related to block was found (Table 1 & 2).

Table 1: Demographic Data

Data	Group I	Group II	P value
Age	41.07±9.14	39.90±10.73	0.6521
Sex(M:F)	20:10	21:9	
Weight	68.70±9.59	68.17±8.48	0.8204
ASA(I:II)	22:8	23:7	
Duration of surgery	142.9±13.35	136.9±12.51	0.0809

Data are presented as mean±SD, SD: Standard Deviation, number of patients as percentage ASA: American Scoiety of Anesthesiologist.

Table 2: Onset and duration of sensory and motor block

Parameters	Group I	Group II	P-value
Onset of sensory block	9.10±1.02	6.23±0.79	<0.0001
Onset of motor block	14.67±1.06	11.63±1.32	<0.0001
Duration of motor block	227±7.39	276±15.74	<0.0001
Duration of analgesia	317±12.64	482±19.72	<0.0001

Data are presented as mean=±SD, p<0.0001 is stastitcally significant, SD: Standard Deviation

Discussion

Upper limb surgeries are commonly done under brachial plexus block as it provides good surgical anesthesia and analgesia. Interscalene brachial plexus is easy to perform and has been used for various shoulder surgery [10-16]. After searching the literature, it was found that various opioids were added to local anesthetics for peripheral nerve blocks to achieve faster onset, to enhance the duration of motor and duration of analgesia [17].

Nalbuphine is an agonist –antagonist opioid that is chemically related to oxymorphone and naloxone. It is equal in potency as an analgesic to morphine. Its agonist action at kappa receptors result in sedation and analgesia. In contrast to pentazocine and butorphanol, nalbuphine does not increase systemic blood pressure, heart rate or atrial filling pressures. Hence it is a good cardiovascular stability agent with very minimal respiratory depression. The mode of action is upon binding the opioid receptors, the GP protein gets activated on neurons leads to inhibition of adenyl cyclase, decreases the conductance of voltage gated calcium channel or opening of potassium channels. Opioid receptor also modulate phospho inositide signaling cascade & phospholipase C. These effects resulting in hyperpolarisation of cell membrane potential thus preventing excitation and propagation of action potential. The prevention of calcium inflow results in suppression of neurotransmitter release (substance P) in many neurons [1].

Nalbuphine was used as an analgesic and adjuvants in spinal, epidural, caudal and peripheral nerve blocks. Jothi et al. [16] compared the analgesic effect of different doses of nalbuphine hydrochloride with bupivacaine and concluded that nalbuphine has earlier onset of sensory and motor block with significant prolongation of sensory and motor block and delayed analgesic requirements.

Now a days peripheral nerve blocks was done under ultrasound guidance rather than the conventional technique [2]. This helps in the performance of interscalene block with more precision and without any injury to the adjacent vascular structures and complications of nerve injury [3,4]. Also Ultrasound helps in the performance of the block effectively with reduced volume of local anesthetic and avoidance of hemdiaphragmatic paresis [18].

The present study demonstrates that the addition of nalbuphine to 0.5% bupivacaine significantly prolonged the onset of sensory and motor block. Ankit et al. [14]. demonstrated the use of nalbuphine as an adjuvant to 0.75% bupivacaine in supraclavicular block resulted in earlier onset of sensory and motor block with statistical significance this was well correlated with our study. The present study also demonstrates that there was a prolongation of motor block and also significant increase in the duration of analgesia is noted in nalbuphine bupivacaine group (482+30.6 min) as compared to bupivacaine (317=23.7 min).

Mohamed A et al. [5] demonstrated that 20 mg of nalbuphine as an adjuvant to 25 ml of 0.5% bupivacaine for supraclavicular block for upper arm surgeries has resulted in significant increase in the duration of both sensory and motor block with

enhanced duration of analgesia it was concurrent with our study. Kumkum gupta et al.[13] concluded nalbuphine 10 mg as an adjuvant to 0.5% bupivacine has significantly extended the duration of analgesia of brachial plexus block with no adverse effects this results was similar to our study.

Conclusion

The current study found that the addition of 10 mg nalbuphine to 0.5% bupivacaine in ultrasound guided intersaclene brachial plexus block for shoulder and arm surgeries is associated with significant increase in the duration of analgesia without any adverse effects.

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Conflict of Interest: No conflict of interest.

Key Messages

Nalbuphine is a good adjuvant for bupivacaine . It increases both the sensory and motor block thereby prolongs the duration of the analgesic effect. Hence it can be used as an effective adjuvant both intraoperatively as well as postoperatively.

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Original Research Article

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Comparison of Nalbuphine Versus Buprenorphine as an Adjuvant to Intrathecal Bupivacaine for Postoperative Analgesia in Lower Abdominal and Lower Limb Surgeries

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Abstract

Introduction: Opioids when added to local anaesthetics in sub-arachnoid block decreases the dose of local anaesthetics and offers stable hemodynamics. Nalbuphine is an agonist-antagonist act on kappa receptors providing analgesia. Buprenorphine is a mixed agonist-antagonist narcotic with high affinity at both μ and kappa opiate receptors. *Aim:* In this study we have compared the analgesic efficacy of buprenorphine and nalbuphine when added with bupivacaine in spinal anaesthesia. *Material and Methods:* A randomized, double blinded, prospective study on 60 patients of ASA I and II undergoing lower abdomen and lower limb surgery under subarachnoid block was done. Patients were randomly allocated into two groups (n=30). Each group received 15 mg of 0.5% of injection bupivacaine heavy along with either 60ìg of buprenorphine (Group B) or 0.8 mg nalbuphine (Group N). Characteristics of sensory and motor blocks, haemodynamic changes, duration and quality of analgesia, adverse effects, sedation, visual analog score (VAS) score and analgesic requirement were studied at different time intervals. *Results:* Onset of sensory block for Group N is 1.519±0.367 and Group B is 2.665±0.462. Onset of motor block for Group N is 4.639±0.976 and Group B is 3.686±0.373. Duration of sensory block in Group N is 170.60±24.42 and Group B is 237.93±16.43. Duration of motor block in Group N is 257.17±27.74 and Group B is 410.93±17.79. The duration of analgesia (in minute) was 295.60±18.95 in N Group and 566.43±42.19 in Group B. There was no significant difference regarding block characteristics and haemodynamic parameters. The adverse effects were less in N Group. *Conclusion:* Onset of sensory and motor block was faster in Group N compared to Group B. The VAS scores showed that post operative analgesia lasted significantly longer in patients in group B than in group N. No significant side effects were observed in either of the two groups. Sub-arachnoid buprenorphine provides longer duration of post-operative analgesia compared to nalbuphine.

Keywords: Buprenorphine; Intrathecal; Local Anaesthetics; Nalbuphine; Opioids.

Introduction

Sub-arachnoid block is the most commonly performed anaesthetic technique. Pain relief is of most importance in postopera-tive period for lower abdominal and lower limb surgeries. Bupivacaine heavy, the commonly used local anaesthetic when used alone acts for 90 to 120 minutes. Various adjuvants have been tried to prolong the analgesic effect of bupivacaine [1]. Opioids when used as additives in sub-arachnoid block have been found to prolong both anaesthesia and analgesia. They enhance the sensory blockade of local anaesthetics without affecting the sympathetic activity thus improves the quality of analgesia with haemodynamic stability.

Nalbuphine in dose of 0.8 mg, when given intrathecally with bupivacaine heavy, improved the quality of intraoperative and postoperative analgesia. Respiratory depression and abuse potential with nalbuphine is very less on comparing with other centrally acting opioid [2,3]. Buprenorphine in dose of 60 mcg when given intrathecally with bupivacaine heavy, improved the

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quality of intra and postoperative analgesia, as it dissociates slowly from μ-opioid receptor has less addiction potential [4].

Here we have compared the analgesic efficacy of nalbuphine with buprenorphine and their adverse effects. Few studies have investigated intrathecal nalbuphine and buprenorphine individually with hyperbaric bupivacaine, but no study in the literature has compared nalbuphine and buprenorphine [2,5]. Hence, we took up this study to compare the duration of post-operative analgesia when nalbuphine or buprenorphine added to bupivacaine as an adjuvant.

Materials and Methods

This study was conducted in a Medical College Hospital after approval from institutional ethical committee. A bilingual written informed consent was obtained from all the participating patients. A double blinded randomized clinical study was conducted on 60 adult patients of American Society of Anaesthesiologists (ASA) I and II, posted for lower abdominal and lower limb surgeries under subarachnoid block.

Inclusion criteria were; age between 18-60 years, either sex, patients with ASA I and II status and undergoing lower abdominal and lower limb surgery in subarachnoid block which were expected to be of 60-180 minutes. Exclusion criteria were; Patients under ASA III and IV, any contraindication to central neuraxial block, patient with known hypersensitivity to any of the study drugs, pregnancy, coagulation disorders, neurological disorders and spinal abnormalities. Sample size was calculated based on published clinical trials done comparing the adjuvants in subarachnoid blockade. Among total sample size of 60, 30 were allocated in each group. Complete pre anaesthetic check up was done to all the patients posted for surgery. Standard ASA fasting guidelines were followed**.** Patients were divided into group N & B randomly. All patients were premedicated before night with tablet ranitidine 150 mg, tablet metoclopramide 10 mg & tablet alprazolam 0.25mg. Patients were preloaded with ringer lactate 10 ml/Kg for 20 minutes after shifting to OT. In group N the patients received 15mg of 0.5% hyperbaric bupivacaine plus 0.8mg nalbuphine in sub-arachnoid block. In group B the patients received 15mg of 0.5% hyperbaric bupivacaine plus 60mcg buprenorphine.

Randomization is done by sealed envelope technique. Preparation of drugs is done by an independent anaesthesiologist who is not involved in the study and the drug mixture is administered by another anaesthesiologist who will be blinded and performing subarachnoid block. Spinal anaesthesia is performed in all patients in sitting position using 25G Quinckie spinal needles at L3-L4 or L4-L5 level under aseptic precautions. After observing free flow for CSF spinal solution was administered over 10-15sec. Patient will be moved to supine position immediately after drug administration. Completion of injection was taken as Zero time of induction of anaesthesia. Recordings done during the study were, time to onset of sensory block, time to onset of motor block, quality of sensory block by pinprick/spirit swab, quality of motor relaxation graded according to modified bromage scale, quality of surgical analgesia by surgical incision, intraoperative sedation by Ramsay sedation scoring, post op intensity of pain assessed by visual analog scale (VAS), duration of analgesia, first rescue analgesia. Adverse effects like nausea, vomiting, respiratory depression and pruritis were also recorded.

Surgery was allowed to proceed when T6 level block was achieved. ECG, pulse rate, mean arterial pressure, respiratory rate and arterial oxygen saturation was monitored for every 5 minutes in the initial 30 minutes of surgery, every 10 minutes in the next 1 hour of surgery and every 15 minutes for rest of the procedure. Systolic B.P <90mmhg or >30% decrease from baseline value was treated with Inj. Mephenteramine 6mg IV and extra fluid bolus of 100ml. Bradycardia with HR<50bpm was treated with Inj.Atropine 0.6mg. Oxygen 5L/min is administered via face mask when necessary. Nausea and vomiting was treated with inj. Ondansetron 4mg. Pruritis was treated with anti-histaminics.

The quality of surgical analgesia was scored as: Excellent: No supplementary drug required, Good: Analgesia required, Fair: More than one analgesic required, Poor: General anaesthesia required. Sensory blockade was assessed using pinprick method or using spirit swab .Onset of sensory block was taken as the time taken to attain sensory level of T6 dermatome. Duration of sensory block was defined as the time to two segment regression from the highest level of the sensory blockade. The degree of motor blockade was assessed with modified Bromage scale: O: No paralysis, 1: inability to raise extended knee, 2: inability to flex the knee, 3: inability to flex the ankle joint. Onset of motor block was considered as the time to achieve Grade 3 block from the time of subarachnoid injection. Duration was defined as the time to achieve Grade 0 block. Sedation was assessed using Ramsay sedation

scoring. 1: awake and alert, 2: sedated but responds to a verbal stimulus, 3: sedated but responds to mild physical stimulus, 4: sedated but responds to moderate or strong physicals, 5: not arousable.

Visual analogue scale - VAS consisted of a 10cm horizontal paper strip with two endpoints labelled "no pain" (0) and "worst pain"(10). When patient complains of pain he/she is asked to mark the strip at a point that corresponds to the level of pain intensity they felt presently. VAS was assessed at every 30min intervals from 60 min to 300min or until rescue analgesic was given. Post operatively sensory and motor block was evaluated every 30min during first 2hr, every 60min for next 6hr and at 12 hr and 24hr after entering recovery room. The duration of pain relief was defined as the time from spinal injection to the first request for rescue analgesics. The attending anaesthesiologist was advised to give rescue analgesia on demand with intravenous paracetamol 1gm, if not relieved 100 mg intravenous tramadol as needed. Analgesic requirement was on demand only.

Statistical Analysis

The statistical analysis was done using Statistical Package for Social Science evaluation (presented as mean, standard deviation and range) version 22.0 and data entry was entered in Microsoft excel 2011. Analysis of variance is used to test the hypothesis that several means are equal. The Independent-Samples T Test procedure was used to compare means for two groups. A p-value of 0.05 or less was considered significant.

Results

All the sixty enrolled patients had successfully completed the study. The groups were comparable in demographic data in terms of age, gender, weight, ASA class distribution and duration of the surgery.

The onset of block was significantly earlier group N compared to group B. Onset of sensory block in Group N was 1.519±0.367min, whereas in Group B it was 2.665±0.462 with *P*= 0.000. (Table 1)

Duration of sensory block was 170.60±24.42 in Group N and 237.93±16.43 in Group B with p = 0.000. (Table 2). Group B had significantly prolonged duration of sensory block.

Duration of analgesia was 295.60±18.95 in Group N and 566.43±42.19 in Group B with p = 0.000. Group B had significantly prolonged duration of block (Table 3).

Onset of motor block in Group N was 4.639± 0.976 min, whereas in Group B, it was 3.686±0.373 min which was found to be statistically significant with p = 0.000 (Table 4).

Table 1: Onset of sensory block

Drug	Onset of sensory block (min)		
	Mean	S.D	
Nalbuphine	1.519	.367	t value = -10.63 &
Buprenorphine	2.665	.462	p-value = 0.000

Table 2: Duration of sensory block

Drug	Duration of sensory block (min)		
	Mean	S.D	
Nalbuphine	170.60	24.42	t value = -12.532 &
Buprenorphine	237.93	16.43	p-value = 0.000

Table 3: Duration of analgesia

Drug	Duration of analgesia (min)		
	Mean	S.D	
Nalbuphine	295.60	18.95	t value = -32.073 &
Buprenorphine	566.43	42.19	p-value = 0.000

Table 4: Onset of motor block

Drug	Onset of motor block (min)		
	Mean	S.D	
Nalbuphine	4.639	0.976	t value = 4.990&
Buprenorphine	3.686	0.373	p-value = 0.000

Duration of motor block was 257.17±27.74 in Group N and in Group B was 410.93±17.79 with *P* = 0.000. Duration of motor blockade is significantly prolonged in Group B (Table 5a). Duration of requirement of first rescue analgesia was 296.57±18.95 in Group N whereas 567.43±42.19 in Group B with p = 0.000, thus highlighting the fact that group B had prolonged post operative analgesia (Table 5b).

There was no significant difference in various hemodynamic parameters intra and post operatively between the two groups. (Figure1 and 2).

Three patients in group N and five patients in group B had nausea and vomiting. One patient in Group B had sedation as side effect.

Table 5: Duration of motor block

Drug	Duration of motor block (min)		
	Mean	S.D	
Nalbuphine	257.17	27.74	t value = -25.554 & p-value = 0.000
Buprenorphine	410.93	17.79	

Table 5: Time for rescue analgesia

Drug	Time rescue analgesia (min)		
	Mean	S.D	
Nalbuphine	296.57	18.95	t value = -32.078 & p-value = 0.000
Buprenorphine	567.43	42.19	

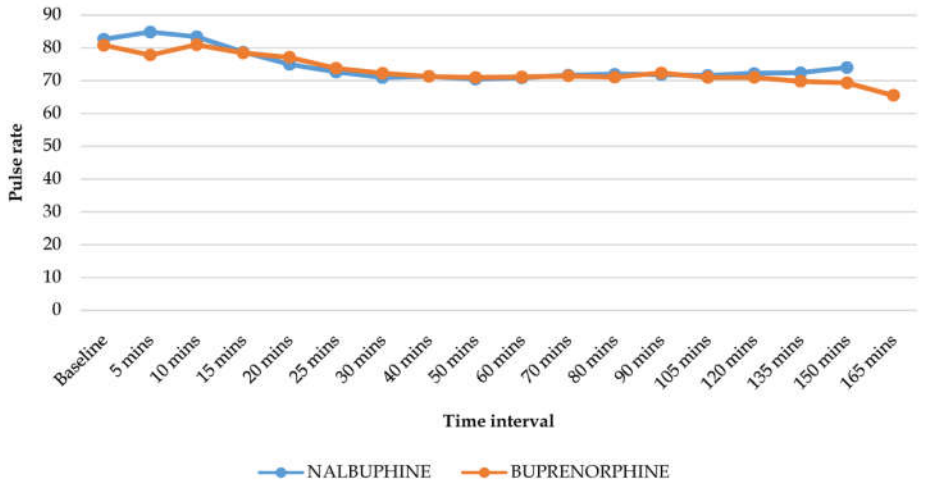

Fig. 1: Heart rate

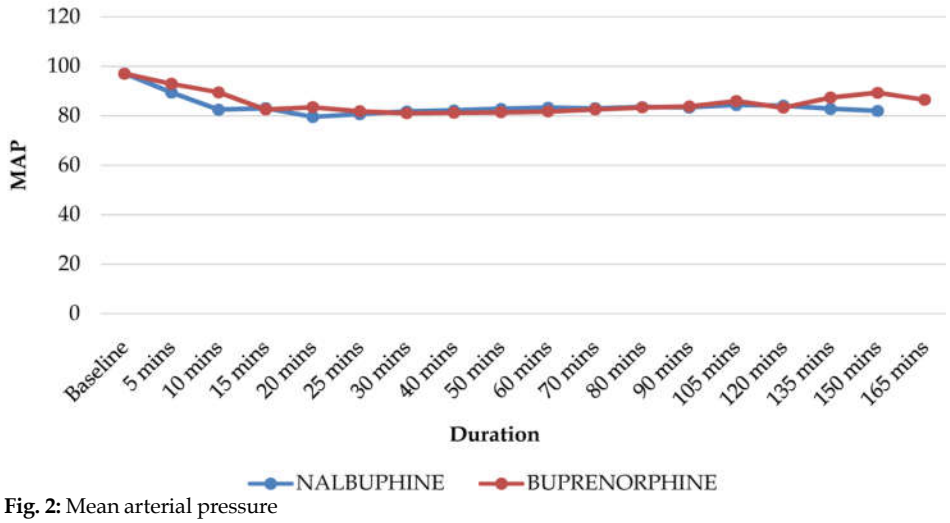

Fig. 2: Mean arterial pressure

Discussion

Spinal anaesthesia is the most commonly used technique for the lower abdominal and lower limb surgeries. Intrathecal opioids are quite commonly used as adjunct to local anaesthetics in regional anaesthesia with multiple advantages like they provide better perioperative sensory and motor blockade with prolonged postoperative analgesia. By reducing the local anaesthetic dosage, they decrease local anaesthetic toxicity and the side effects associated with high spinal. To overcome the side effects of opioids (mu), the partial agonist-antagonist opioids action has been studied extensively. Buprenorphine and nalbuphine competitively displaces other μ antagonists from the receptors without any agonistic effect when bound to the ì receptors. As they bind to kappa receptors, it has agonistic effect. Hence, they are mixed agonist-antagonist. They produce analgesia with minimal ì side effects.

Fournier et al reported faster onset of pain relief with intrathecal nalbuphine compared to intrathecal morphine [6]. Tiwari AK et al., Mukherjee et al., Mostafa MG et al., reported that nalbuphine prolonged duration of analgesia with reduced VAS pain score [7,8,9,10]. Culebras X et al., compared intrathecal morphine with nalbuphine in different doses viz., 0.2 mg, 0.8 mg and 1.6 mg concluded that nalbuphine 0.8 mg prolong postoperative analgesia, without side effects [11]. Ahluwalia et al., also observed Nalbuphine dose of 0.8mg as safer and effective dose, as nalbuphine exhibits a ceiling effect to analgesia [12]. Studies done by Gomaa *et al.*, comparing fentanyl and nalbuphine say prolonged duration analgesia with nalbuphine but results were statistically insignificant [13].

Sapkal et al., and sandhya gujar et al., had proven nausea and vomiting was higher in sub-arachnoid buprenorphine compared to sub-arachnoid clonidine [14,15]. Vadivelu et al. observed that nausea vomiting and light headedness were much prevalent with buprenorphine [16]. Studies done by Khan et al., and Capogna et al., state prolonged duration of analgesia with buprenorphine [17,18].

Our study results were well correlating with above studies. Sedation was also compared in both groups but none of the patients had sedation score more than two except one in buprenorphine group which contradicted our study with others. As studies state that both nalbuphine and buprenorphine produce sedation, which was correlating with study done by Prabhakaraiah et al., comparing nalbuphine with fentanyl [19].

In our present study, we have used preservative free nalbuphine 0.8mg and buprenorphine 60mcg as adjuvants to bupivacaine heavy intrathecally and compared their onset, duration and postoperative analgesia. Our study results showed that onset of sensory block and motor block were quicker in nalbuphine group. But the duration of sensory block, motor block and postoperative analgesia was prolonged in buprenorphine group compared to nalbuphine group. In our study we did not find any statistically significant difference in hemodynamics in both groups which shows that both the opioids did not have any significant sympatholytic activity. Side effects like nausea, vomiting, pruritis, sedation were minimal in both the groups but nalbuphine group has advantage over buprenorphine group. There are differences in pharmacological properties in nalbuphine and buprenorphine which needs to be further evaluated.

Conclusion

From our study, we conclude that both nalbuphine and buprenorphine are good choice of adjuvants to subarachnoid blockade. They shorten the onset of sensory and motor block. Buprenorphine compared to nalbuphine prolongs the duration of sensory and motor blockade and also prolongs postoperative analgesia and duration for first rescue analgesia, with minimal side effects.

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Comparative Analysis of Oral Clonidin against Oral Midazolam as Premedication in Adults

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Abstract

Introduction: The comparison was made between the clonidine 200 ug and midazolam 15 mg to check the clinical efficacy in respect to the sedative, attenuation of hemodynamics, anxiolytic and antisialogogue response in adult patient undergoing general anesthesia. *Material and Methods:* Total of 100 patients were included in the study, included patient belong ASA 1-2 physcial status and the age group of 20 – 50 years. Males and females, both genders were included in the study. Of the total 100 patients; they were randomly divided into two groups with 50 patients in each group. Patients included in the group 1 were given Oral clonidine 200 ug, 90 mins prior to the surgery. Patients included in the group 2 were given oral midazolam 15 mg, 90 mins prior to the surgery. General anesthesia with thiopentone sodium, vecuronium, fentanyl, oxygen, nitrous oxide and sevoflurane were given to all the patients. Five point sedation score was used to assess the patient's level of sedation. We recorded the baseline values before medication and 90 mins after medication. After intubation period of 1, 5 and 10 mins the hemodynamic parameters were recorded. *Results:* The extent of sedation was seen in the patient given Midazolam as compared to the clonidine pretreated patients. In the clonidine group we see the antisialogogue effect. In the clonidine group all the haemodynamic parameters were well maintained throughout the period of study. *Conclusion:* There was significant attenuation of pressor response to laryngoscopy and intubation in the clonidine group as compared to midazolam therefore drug of choice for premedication.

Keywords: Clonidine; Laryngoscopy; Midazolam; Premedication.

Introduction

According to Rendell baker it is stated that no one, however phlegmatic, can contemplate the prospect of an operation without some apprehension or nervousness [1]. Before operation the premedication is an important step before giving the anesthesia to the patient. It is found that the premedication named midazolam which is benzodiazeoine has short duration of action, there is report of muscular relaxation, sedation and hypnosis in higher dose, amnesia in lower dose, casues anxiolysis. Other medication names clonidine which is an alpha agonist causes reduction of analgesic and anesthetic requirement; there is stability of hemodynamic parameters and antisialogogue effect [2].

The present study was conducted with the aim of comparison between the clonidine 200 ug and midazolam 15 mg to check the clinical efficacy in respect to the sedative, attenuation of hemodynamics, anxiolytic and antisialogogue response in adult patient undergoing general anesthesia.

Materials and Methods

Before conduction of the study, we obtained the approval from the ethical committee. We also

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obtained the informed consent from the patients who were included in the study. Total of 100 patients scheduled for the surgeries under the general anesthesia in different department likes orthopaedics, ENT, surgery and gynecology were included in the study. The duration of the surgery was one to three hours average in all the patients. All the patients included in the study were divided into two different groups with each group containing 50 participants. The patients included in the group 1 were planned to receive premedication oral clonidine 200 ug. The patient included in the group 2 were planned to receive premedication oral midazolam 15 mg. Both the oral predications were given 90 mins prior to the surgery.

Patient; male and female both with age group of 18–60 years, weight ranging between 50–70 kg with ASA physical status 1–2 were included in the study. Patients with renal dysfunction, obesity, baseline pulse rate < 50 beats/minute, pulmonary and psychiatric disorders, hypertension, anticipated difficult airway and known hypersensitivity to the drugs were excluded from the study.

Baseline resting parameters were recorded prior to premedication in the operation theater and 90 mins after the administration of oral premedication in both the groups. Detailed history, airway evaluation and physical examination were assessed for each and every patients included in the study. Visual Analog Scale was used for the assessment of anxiolytic effect. Five point sedation score was used to assess the sedative effect [3]: Grade 1- Patient is awake; Grade 2- Patient is drowsy but easily arousal to alert state by oral commands; Grade 3- Patient is asleep, there is no reaction to speech but there is immediate reaction to the tactile stimuli; Grade 4- Patient reacts only to the stronger tactile stimuli; Grade 5- There is difficulty in arousing patient and if awaken patients immediately asleep again. The IV access was secured with help of 18 gauge IV cannula and there was administration of lactate ringer solutions. Sufficient preoxygenation was administered with 100% oxygen for five minutes. IV thiopentone sodium 2.5% 4-5mg/kg was given for the induction.

The loss of consciousness was assessed by loss of reflax of eye lashes and 0.1 mg/kg dose of IV vecuronium was given. Nitrous oxide 60% and oxygen 40% were used for mask ventilation for three minutes. Laryngoscopy and tracheal intubation with appropriate sized cuffed tube were done. For analgesia, IV fentanyl 2μg/kg initial dose and top up of 1μg/kg was given as required. End tidal carbon dioxide was maintained around 35-40mmHg. One gram IV paracetamol infusion was given towards the end of surgery. At the end of surgery, neuromuscular blockade was reversed using IV neostigmine 0.05mg/kg and IV glycopyrrolate 0.01mg/kg.

Parameters for hemodynamics were assessed with the help of pulse rate, diastolic and systolic blood pressure and mean arterial pressure at different time intervals. P0 – Prior to premedication; baseline parameters, P1–90 mins after premedication; preinduction, P2 – post induction, P3 – one minute after intubation, P4 – five minutes after intubation, P5 – ten minutes after intubation. Rate pressure product (RPP) was calculated using the following formula: systolic blood pressure in mm of Hg x pulse rate (beats/minute). Patients were monitored for adverse effects such as bradycardia [4], hypotension [5], dysrhythmias [6], respiratory depression [7] and grade 5 sedation.

Statistical Analysis

Qualitative data will be expressed as percentages and proportions. Quantitative data will be expressed as mean and standard deviation. The differences between two groups with respect to continuous variables will be analysed using t-test while categorical variables will be analysed using chi-square test. All the statistical tests will be performed in SPSS version 15 software. p value <0.05 will be considered as statistically significant while p value < 0.01 will be considered as statistically highly significant. The between group comparison of compressive strength of samples in Group A and B was done using One-way ANOVA test. Within group comparison was done using Bonferroni correction test. In the tests, p value of ≤ 0.05 was considered as statistically significant.

Results

When comparisons were done in respect to the sex, weight and age no significant difference was found between the two groups. Antianxiety effect with respect to VAS score was similar in both the groups.

Sedation score: the patient who were included in group 2; who were given midazolam premedication were found to be significantly more sedated as compared to the patients included in the group 1; who were given clonidine premedication, with P value is less than 0.05. Of the total 50 patient included in the group 1, 36 did experienced

antisialogogue effect, however none of the patients in group 2; who were given midazolam had any antisialogogue effect.

Pulse Rate

When the comparison was between the two groups in respect to the baseline mean pulse rate, it was found to be 82.44 beats per minute in group 1 and was found to be 82.92 beats per minute in group 2. Following the induction of anesthesia, the pulse rate was found to be significantly lower in group 1 when compared to the base line, 1 minute (p3), following intubation i.e. p2 of 74.60 beats per minutes ($p<0.05$) and p3 of 77.88 beats per minutes ($p<0.05$). however in group 2, there was significant rise in the p2 that is 80.04 beats/mins and p3 that is 88.48 beats/mins when compared to base line ($p<0.05$). Figure 1 shows the pulse rate inter group comparison.

Blood Pressure

There was no significant difference in respect to the diastolic, systolic and mean arterial blood pressure between the both groups. The values of mean DBP, MAP and SBP one minute after intubation were found to be low as compared to base line values in group 1. However there was significant increase in the values in group 2 as compared to base line values. Thus increase in blood pressure in group 2 was statistically significant ($p<0.05$) in the intergroup comparison (Figure 1).

Rate Pressure Product

In group 1 the baseline mean rate pressure product is 9869.68 units and in group 2 it was found to be 9859.76 units. The difference was not found to be significant between the two groups with p value = 0.969. One minute after the administration of the intubation the RPP remained significantly lower in clonidine group with 9017.76 units as compared to base line with $p < 0.05$ whereas in group 2, it was found to be significantly increased to 12,462.40 units when compared to baseline with $p < 0.05$. Two patients developed transient dysrhythmias during intubation which got subsided without any pharmacological intervention in the midazolam groups.

Discussion

The purpose of using premedication is to remove preoperative anxiety and fear, to produce analgesia and amnesia, to depress the vagal activities, to reduce the salivary gland secretions, to produce sedation, to reduce the risk associated with aspiration an regurgitation and mainly to reduce the stress and reduce the amount of general anesthesia required. The mean weight of the

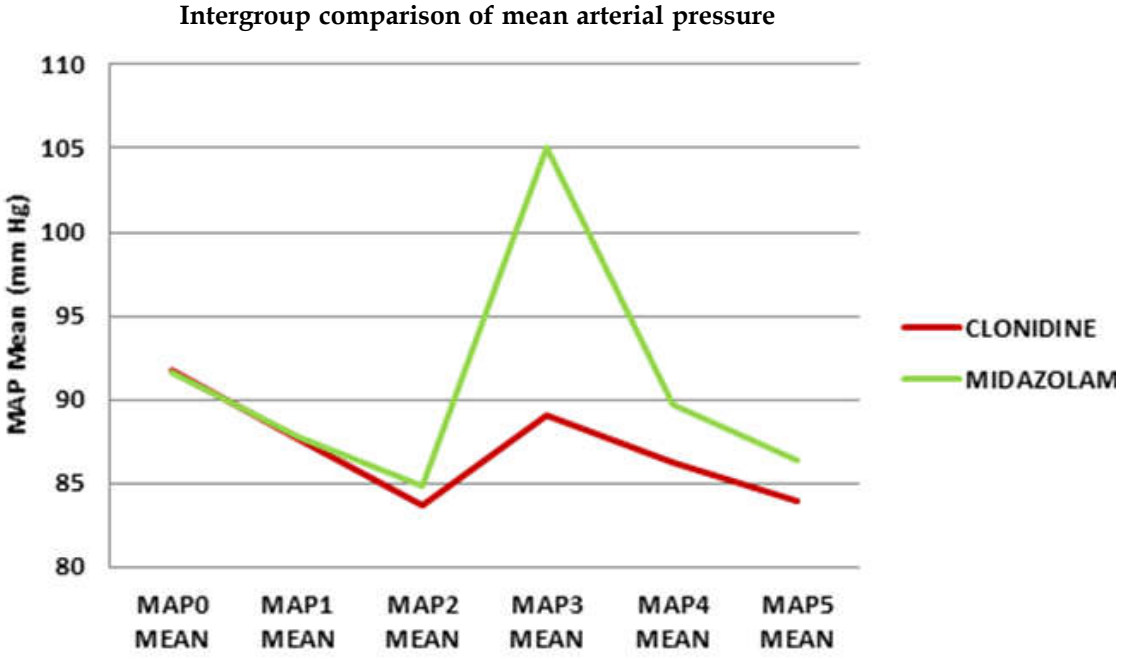

Fig. 1: Intergroup Comparison of Mean Arterial Pressure

participants included in the study was approximately 60 kg. Taking the weight into consideration, the mean dose of oral midazolan used in the study was 0.25 mg/kg and that of oral clonidine was approximately 3.3 ug/kg. In the present study, the anxiolytic effect was calculated with VAS. Of the two oral medication used both of them showed positive anxiolytic effect. Similar results were also obtained by Frank T et al. [8] and Paris A et al. [16].

A five point sedation score was use to assessed the sedation, 90 min after the sedation was administered. It was seen from the present study that midazolam was found to cause more sedation than oral clonidine. All the patients included in the midazolam group were sedated whereas in clonidine group 26% of the patient did not experienced any sedation. There were cases of dryness of mouth in few patients included in the clonidine group. Total of 72% patients did experienced mouth drying. Oral clonidine is found to cause decrease in salivary flow and so dryness of mouth was experienced with patients taking oral clonidine. None of the individuals in the midazolam group experienced any type of dryness of mouth. Chaurasia SK et al. [9] reported similar results.

Hypertension, dysrhythemic elevation in arterial pressure and tachycardia starts within five seconds of laryngoscopy, they reach to highest level in one or two minutes and return to normal level in five seconds [10]. Patients with limited coronarty or myocardial reserves, Ptients with glaucoma and having open eye surgery have less tolerance power to haemodynamic response [11-13].

There is sowing of heart rate with the use of Clonidine as it stimulates the parasympathetic out flow and decreases the central sympathetic outflow [14]. Similar results was obtained by Paris et al [16]. found that with the use of oral clonidine the increase in heart rate is prevented however the same was not obtained with use of midazolam.

The decrease in diastolic, systolic and mean arterial pressure was obtained in both the study group after the premedication. Because of the seductive and anxiolytic property there is decrease in systolic blood pressure. The decrease in diastolic, systolic and mean blood pressure wa seen in both the groups after the induction of anesthesia with thiopentone. In the oral midazolam premidicae group; one minute after the intubation there was increase in diastolic, systolic and blood pressure. However in the oral clonidine pre medicated group there was no rise of parameters above the baseline.

The above results were in accordance with the result obtained by Paris A et al.[16], he founded that clonidine augmented hemodynamic stability and blunted stress responses as determined by adrenocorticotropic plasma levels. Attenuation of haemodynamic response to intubation and intraoperative haemodynamic stability with clonidine was also demonstrated in tudies conducted by Talebi H et al. [17], Laurite CE et al [18]., Traill R, Gillies R [19], Wawrzyniak K et al [20]. and Singhal SK et al [21].

Rate pressure product is defined as the product of pulse rate and peak systolic blood pressure. There is a correlation between rate pressure product and myocardial blood flow, myocardial oxygen consumption as a result of which it correlates with signs of ischaemia. This study shows that Clonidine effectively attenuates increase in rate pressure product following laryngoscopy and intubation; in accordance with studies conducted by Thomas MG et al [22]. and Montazeri K et al [6].

Conclusion

Clonidine, when used as premedication showed an comparable anxiolytic effect, with no sedation, better antisialogogue effect and well maintained haemodynamic parameters following laryngoscopy and intubation as compared with midazolam therefore constitutes optimal choice of two drugs.

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Original Research Article

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Comparison of Efficacy of Dexmedetomidine with Ketamine for Anaesthesia in Dilatation and Curettage

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Abstract

Background: Anaesthesia in dilatation and curettage (D & C) is administered with the dual goals of rapidly and safety establishing satisfactory procedural condition for the performance of therapeutic or diagnostic procedures while ensuring rapid predictable recovery with minimal post operative sequel.Therefore, we decided to use Dexmedetomidine in 2 doses (1µg/kg and 0.6µg/kg) with Ketamine (1 mg/kg) to provide procedural sedation in D&C and compare the efficacy and safety of dexmedetomidine 1µg/kg + 1mg/kg ketamine versus dexmedetomidine 0.6µg/kg + 1mg/kg ketamine for the procedure. *Material & Methods:* This prospective randomized double blind study was conducted in department of Anaesthesiology of a Tertiary care hospital. In this study 80 patients scheduled for elective Dilatation and Curettage were included and divided equally in two groups.Group A- In this group 1µg/kg lnj. Dexmedetomidine was given, along with 1mg/kg lnj. ketamine IV and group B- Inthis group 0.6µg/kg lnj. Dexmedetomidine was given, along with 1mg/kg lnj. Ketamine IV. *Results:* In our studythe mean age of patients in group A (41.5007 years) and group B (4 1.1008 years) differed insignificantly with p-value of 0.8254. The comparison of mean between two groups after giving dexmedetomedine was statistically significant in heart rate, DBP and SBP but respiratory rate & SpO_2 was statistically not significant. *Conclusion:* We have concluded that the comparison of baseline, intraoperative (after Ketamine) and post operative values of heart rate, systolic BP and diastolic BP showed that the values were better maintained in group A as compared to group B. Hence both the combination were comparable in safety but since the vital parameters were better maintained in group A, 1 µg/kg Dexmedetomidine + 1 mg/kg Ketamine is better than 0.6 µ/kg.

Keywords: Dexmedetomidine; DBP; SBP; Respiratory Rate; SpO_2; Anaesthesia.

Introduction

Procedural sedation is a seamless continuum of an altered state of consciousness, varying from mild anxiolysis to anaesthesia. The greatest threat to the safety of sedated patients is airway compromise and/or respiratory arrest. To decrease the risk of airway and respiratory complications, careful attention must be directed towards the appropriate selection of medications, adherence to dosing recommendations, and the identification of the high-risk patient [1].

Anaesthesia in dilatation and curettage (D & C) is administered with the dual goals of rapidly and safety establishing satisfactory procedural condition for the performance of therapeutic or diagnostic procedures while ensuring rapid predictable recovery with minimal post operative sequel.

Ketamine is in clinical use since 1970. Unique features of ketamine which make it particularly attractive for procedural sedation, include the provision of amnesia, sedation, immobilization and profound analgesia along with limited deleterious effects on hemodynamic and respirator function.

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These characteristics allow for the completion of short, painful procedures such as fracture reduction, abscess incision and drainage, but debridement under optimal conditions [2].

Ketamine is an N-methyi-Daspartate (NMDA) receptor antagonist, causing dissociative anaesthesia, currently making a comeback in Office Based Anaesthesia owing to excellent analgesic properties with a low incidence of respiratory depression [1].

Ketamine in low doses in combination with other drugs provides effective and safe sedo-analgesia in short surgical procedures like patients undergoing colonoscopy and short gynecological procedures. As co-induction agent in low doses and in combination with other drugs like propofol/ midazolam/fentanyl and dexmedetomidine, ketamine has gained increasing popularity [3].

Anecdotal experience and a few large series from the literature demonstrate the utility of a combination of dexmedetomidine with ketamine for procedural sedation. When used together, dexmedetomidine may limit the tachycardia, hypertension, salivation, and emergence phenomena from ketamine, whereas ketamine may prevent the bradycardia and hypotension that has been reported with dexmedetomidine. When compared with other agents used for procedural sedation, these two agents have limited effects on ventilatory function than other more commonly used agents. Dexmedetomidine-ketamine combination effectively achieves the desired level of sedation while minimizing the potential for adverse effects [4].

Though Dexmedetomidine has been used in different doses, the most commonly used dose has been 1µg/kg [5-15] Dexmedetomidine as premedication in minor gynaecological surgeries was studied in doses of 0.167, 0.33, 0.67, and 1µg/ kg. The dose found to be most effective was 0.67µg/ kg. Therefore, we decided to use Dexmedetomidine in 2 doses (1µg/kg and 0.6µg/kg) with Ketamine (1 mg/kg) to provide procedural sedation in D&C and compare the efficacy and safety of dexmedetomidine 1µg/kg + 1mg/kg ketamine versus dexmedetomidine 0.6µg/kg + 1mg/kg ketamine for the procedure.

Material & Methods

This prospective randomized double blind study was conducted in department of Anaesthesiology of a Tertiary care hospital. In this study 80 patients scheduled for elective Dilatation and Curettage were included anddivided equally in two groups.

The patients were randomized to following two groups by systematic random sampling.

- Group A- In this group 1µg/kg lnj. Dexmedetomidine was given, along with 1mg/ kg lnj. ketamine IV.
- Group B- Inthis group 0.6µg/kg lnj. Dexmedetomidine was given, along with 1mg/ kg lnj. Ketamine IV.

Inclusion Criteria

1. ASA grade I or II patients
2. Age 18-50 years.
3. BMI < 25 kg/m^2
4. patient willing to give informed con sent

Exclusion Criteria

1. Renal and Hepatic insufficiency
2. Uncontrolled Diabetes Mellitus & Hypertension
3. Ongoing Beta blocker therapy.
4. Ischemic heart disease, Valvular heart disease & heart blocks
5. Known allergy to either Dexmedetomidine or Ketamine

Methods

In the morning of surgery on entering the OT, standard monitoring modules including NIBP, Pulse oximetry and EGG were attached to the patient. After establishing intravenous access using an 20G cannula, lnj. Ringer Lactate was started at the rate of 100ml/hour. Pre-operative vitals were recorded.

In group A, total dose of 1 µg/kg of Dexmedetomidine and in group B total dose of 0.6 µg/kg was given. The calculated dose of Dexmedetomidine was rnixed with 100ml normal saline and given over 10m ins. 10 mins after infusion of dexmedetomidine was completed Ketamine 1 mg/kg was given IV.

- After 2 mins of Ketamine administration patient was allowed to be put in lithotomy position and external cleaning and draping, cleaning of vagina was allowed. If patient did not move in response to this stimulus, D & C was allowed to proceed.

- If patient moved in response to stimulus of internal cleaning or at any time during procedure, if haemodynamic parameters like heart rate (> 160/min) and BP (180/120mmHg) was found raised, Propofol in 10mgincrements was administered I.V.

The anaesthesiologist preparing the infusion of the study drug wasdifferent from the one who conducted the proceedings.

Observation

1. Following were recorded every 2 mins till completion of procedure-
- Pulse rate
- Heart rate
- NIBP
- Respiratory rate Ventilation was assisted with Bain's circuit in case of respiratory rate less than 8/min.
- Maintenance of airway
- Any desaturation (SpO_2 less than 94% on room air). If it occurred, it was treated with 4Umin Oxygen on mask With Hudson mask.

2. Total dose of Propofol required during surgery.
3. Total duration of surgery.

After surgery the patient was shifted to the Post Anaesthesia care Unit (PACU) and observed there for 2 hours. The observer in the PACU was unaware of the group that the patient belonged to. Bradycardia (heart rate <50/min) was treated with lnj. Atropine 0.6mg IV.

Hypotension (Systolic BP less than 30% of the baseline value or absolute value less than 80 mm of Hg)with lnj. Mephentermine 3mg/IV in incremental doses.ventilation was assisted with Bain's circuit incase of respiratory rate lessthan 10/min.

Hypertension (180/120 mm Hg) was defined as BP hmore t an 30% ofbaseline, tachycardia (heart rate > 160) both were treated with I.V. Propofol in10mg increments.

Analgesic in the form of lnj.Diclofenac was given on demand or at the VAS score of 4. Nausea and vomiting was treated with lnj. Ondansetron 4 mg IV.Emergence delirium was treated with lnj. Midazolam in 1 mg IV increments.

Patients were shifted to the ward after 2 hours observation or afterAldrete score was 9, whichever was later. Patient was visited after 4 hoursand before discharge know the occurrence of nausea, vomiting.

Results

In our studythe mean age of patients in group A (41.5007 years) and group B (4 1.1008 years) differed insignificantly with p-value of 0.8254, as obtained using t-test for independent samples. Thus, the baseline age profile of patients in two groups was statistically similar (Table 1).

At the pre-operative stage the comparison of mean value of time of surgery, heart rate, diastolic blood pressure, systolic blood pressure, respiratory rate and SpO_2 was statistically insignificant (Table 2).

The comparison of mean between two groups after giving dexmedetomedine was statistically significant in heart rate, DBP and SBP but respiratory rate & SpO_2 was statistically not significant (Table 3).

The study showed that the heart rate for group (A) there is highly significant difference between pre-operative stage and after giving Dexmedetomedine case with p-values< 0.0001. However, there is insignificant difference for rest of cases. For group (B), there is a significant difference between pre-operative stage with rest of cases with p-value

Table 1: Distribution of patients according to age in two treatment groups

Age (in year)	Group [No. (%)]	
	A (N=40)	B (N=40)
22-32	3 (7.50)	5 (12.50)
33-42	21 (52.50)	20 (50.00)
43-52	13 (32.50)	11 (27.50)
≥53	3 (7.50)	4 (10.00)
Mean	41.500	41.000
Median	40.500	40.000
SD	7.136	8.924
Range (Min, Max)	(23, 55)	(24, 65)

< 0.05. Thus, we can conclude that mean heart rate of patients are significantly different between pre-operative stage and case of after giving Dexmedetomedine for both groups of treatment (Table 4).

The descriptive statistics of mean diastolic blood (DBP) at pre-operative stage and their comparison with after giving dexmedetomedine, intra-operative and post-operative stage for two groups and highly significant difference between pre-operative stage and after giving dexmedetomedine case with p-values < 0.0001 and insignificant difference *for* rest of cases. For group B, there is a significant difference between preoperative stage with rest of cases with p-value < 0.05 (Table 5). The mean SBP of patients are significantly different between pre-operative stage and case after giving dexmedetomedine for both groups (Table 6).

In present study showed that the mean of respiratory rate of patients are insignificant different at each stage of operation (Table 7) and the mean of SpO_2 were significant different at each stage of operation for group A patients (Table 8).

Discussion

An ideal intravenous anaesthetic regime used in minor surgeries like dilatation and curettage (D & C) should provide rapid recovery and early discharge from the post anaesthesia care unit with

Table 2: Descriptive statistics for different vital parameters in two groups at pre-operative stage

Parameters	Group [(mean ± SD)]		
	A (N=40)	B (N=40)	P-value
Time of Surgery (Min.)	8.205 ± 2.05	8.351 ± 2.07	0.7521 (NS)
Heart Rate (/min.)	78.00± 11 .28	74.90± 10.62	0.2268 (NS)
DBP (mmHg)	75.35± 9.08	73.45± 8.67	0.3418 (NS)
SBP (mmHg)	129.00±1 0.05	126.20± 9.57	0.2058 (NS)
RR (/min.)	23.85 ± 3.82	23.40± 3.93	0.6055 (NS)
SPO2 (%)	99.32± 0.85	99.00± 1.03	0.1312 (NS)

Table 3: Descriptive statistics for different vital parameters and comparison between two groups after administering Dexmedetomedine

Parameters	Group [(mean±SD)]		
	A (N=40)	B (N=40)	P-value
Heart Rate (/min.)	62.02 ± 10.79	68.88 ± 11.18	0.0066(S)
DBP (mmHg)	62.90± 11 .37	68.78± 08.93	0.0122 (S)
SBP (mmHg)	109.15±16.68	119.20± 12.73	0.0034 (S)
RR (/min.)	22.73 ±03.61	22.35± 03.68	0.6468 (NS)
SPO2 (%)	98.12± 01.90	98.60± 01.03	0.1694 (NS)

Table 4: Descriptive statistics for heart rate and its comparison between pre, after Dexmedetomedine, intra and post operation times in two groups

Group	Hear rate (Mean±SD)		P-value
A	Pre-Operative 78.00±11.28	After Dexmedetomedine 62.02±10.79	<0.0001(HS)
		Intra-operative 77.375±12.313	0.8135 (NS)
		Post-operative 77.175±9.636	0.7261 (NS)
B	Pre-Operative 74.90±10.62	After Dexmedetomedine 68.88±11.18	0.0157 (S)
		Intra-operative 82.875±11.122	0.0016(S)
		Post-operative 82.15±11.026	0.0037 (S)

Table 5: Descriptive statistics for diastolic blood pressure and its comparison between pre, after Dexmedetomedine, intra and post operation times in two groups

Group	DBP (Mean±SD) (mmHg)		P-value
A	Pre-Operative 75.35±9.08	After Dexmedetomedine 62.9±11.37	<0.0001(HS)
		Intra-operative 74.95±9.737	0.8499 (NS)
		Post-operative 74.95±7.884	0.8341 (NS)
B	Pre-Operative 73.45±8.67	After Dexmedetomedine 68.78±8.93	0.0200 (S)
		Intra-operative 77.325±8.144	0.0428(S)
		Post-operative 77.025±7.011	0.0462 (S)

Table 6: Descriptive statistics for systolic blood pressure and its comparison between pre, after Dexmedetomedine, intra and post operation times in two groups

Group	SBP (Mean±SD) (mmHg)		P-value
A	Pre-Operative 129.00±10.05	After Dexmedetomedine 109.15±16.68	<0.0001(HS)
		Intra-operative 129.1±13.865	0.9706 (NS)
		Post-operative 130.425±10.170	0.5303 (NS)
B	Pre-Operative 126.20±9.57	After Dexmedetomedine 119.2±12.73	0.0069 (S)
		Intra-operative 133.25±9.535	0.0015(S)
		Post-operative 133.375±10.312	0.0018 (S)

Table 7: Descriptive statistics for respiratory rate and its comparison between pre, after Dexmedetomedine, intra and post operation times in two groups

Group	RR (Mean±SD)		P-value
A	Pre-Operative 23.85±3.82	After Dexmedetomedine 22.73±3.61	0.1801 (NS)
		Intra-operative 24.10±3.365	0.7572 (NS)
		Post-operative 24.175±3.234	0.6828 (NS)
B	Pre-Operative 23.40±3.93	After Dexmedetomedine 22.35±3.68	0.2216 (NS)
		Intra-operative 24.10±3.747	0.4176 (NS)
		Post-operative 24.75±3.342	0.1022 (NS)

Table 8: Descriptive statistics for SPO2 (%) and its comparison between pre, after Dexmedetomedine, intra and post operation times in two groups

Group	SPO2 (Mean±SD) (%)		P-value
A	Pre-Operative 99.32±0.85	After Dexmedetomedine 98.12±1.9	0.0006 (S)
		Intra-operative 98.775±1.025	0.0112 (S)
		Post-operative 98.975±0.733	0.0536 (S)
B	Pre-Operative 99.00±1.03	After Dexmedetomedine 98.6±1.03	0.0880 (NS)
		Intra-operative 99.025±1.097	0.9169 (NS)
		Post-operative 99.175±0.813	0.4039 (NS)

minimal side effects. A very commonly used anaesthetic technique for dilatation and curettage is Total Intravenous Anaesthesia (TIVA). Comfort of the patient and avoidance of movement is of great significance during D & C for the procedure to be effectively completed. Propofol is a frequently chosen agent because it can be easily titrated, is generally effective, and allows for rapid awakening once the procedure is completed. However, in patients with co-morbid respiratory or cardiovascular diseases, there may be a relatively high incidence of adverse effects including hypotension, hypoventilation, upper airway obstruction and apnoea. Although these effects are generally dose dependent and more likely with higher doses as deeper levels of sedation/anaesthesia are achieved, there is significant interpatient variability regarding the potential for adverse effects [4].

Ketamine is an agent that provides sedation, analgesia and amnesia and it might be an appropriate option for short–lasting procedures. Its value has been established because of its lack of cardiovascular and respiratory depressant effects and preservation of airway reflexes. Cardiostimulatory effects, drug induced delirium and secretion increment are the main drawbacks of ketamine. Hence Ketamine has been used in combination with different drugs like benzodizepines, opioids and propofol to mitigate these side effects.

With the addition of midazolam to ketamine for procedural sedation, there was a statistically significant increase in recovery times as well as an increased risk for adverse respiratory events. The only positive attribute was a reduction in the incidence of emesis during the recovery period. Recent studies suggest that routine use of adjunctive midazolam with ketamine does not effectively reduce the incidence of emergence phenomena [2].

Ketamine-fentanyl combinations have accepted anesthetic period, but there was prolonged recovery with respiratory and central nervous depression. Other adverse effect of fentanyl is emesis (nausea and vomiting) which are the most common side effects of opioids [5].

Ketamine-propofol combinations in TIVA showed less intra- and post-procedural hemodynamic stability, more PONV more postoperative cognitive dysfunctions and longer recovery time [6].

Combination of dexmedetomidine-kitamine makes a pharmacologic sense as each of the two medications has the potential to balance the hemodynamic and adverse effects of the other. Dexmedetomidine may prevent tachycardia, hypertention, salivation, and emergence phenomena from ketamine, whereas ketamine may prevent bradycardia and hypotension that have been reported with dexmedetomidine [7].

In this double blind, randomized study we compared 2 doses (1 µg/kgand 0.6µg/kg) of dexmedetomidine with Ketamine (1 mg/kg) to provide procedural sedation in D & C and compared the efficacy and safety of the two combinations for the procedure. Dexmedetomidine has been widely used indose of 1 µg/kg (5-15). Riku E. Aantaa et al. compared four diferent doses (0.167, 0.33, 0.67, and 1.0µg/kg) of dexmedetomidine in minor Gynecologic surgery and found that optimal dose of dexmedetomidine for single-dose intravenous premedication in minor surgery appears to be in the range of 0.334-0.67 µg/kg [8]. Hence, we chose 1µg/kg as the dose of dexmedetomidine in group A and 0.6 µg/kg in group B.

This study was conducted on 80 patients coming to the operation theatre for elective D & C after Institute's Ethics Committee approval for the conduct of study. In our study no statistically significant difference was found in age and in both groups ($p>0.05$).

In our study, the mean heart rate in the two groups A and 8 were 62±10.79 and 68.88±11.18 respectively after the administration of the calculated dose of dexmedetomidine over 10 minutes. This difference is statistically significant with p value < 0.0066, after the administration of 1 mg/kg lnj. Ketamine IV, the procedure was started. The intraoperative comparison of the mean heart rate of both groups showed an increase from baseline starting from the first observation point at 2 minutes which continued till the patient was shifted from the OT table after 12 minutes and in the Post Anaesthesia Care Unit (PACU). Comparison of mean heart rates of the patients in group A preoperatively, intra-operatively and in PACU showed that the values do not have statistically significant difference. On the other hand, in group B, there was a statistically significant difference between the mean heart rate intra-operatively (after Ketamine) and postoperatively from the base line mean heart rate. The mean heart rate in group B and group A showed a statistically significant difference at 6, 8, 10 and 12 minutes intra-operative. This could be because the patients in group B had lighter sedoanalgesia than patients in group A though they were sedated enough to prevent any purposeful movementintra-

operatively. Also the effect of Ketamine on heart rate could have been more effectively countered by 1 µg/kg dexmedetomidine than 0.6µg/kg. We had planned to give additional dose of anaesthetic (propofol) if the patient showed any movement. This was in accordance to the study of Heard C, Burrows F,Johnson K et al. [9] where they used prevention of movement to optimize the anaesthetic. The mean heart rate in group A was never more than preoperative (baseline) value.

In the PACU also patients of group A had a statistically significant less mean heart rate than the patients of group B. The decrease in heart rate found In our study is in accordance with studies of Sethi P, Sindhi S, Verma A et al. [10], Antaa RE et al. [8], Verma R, Gupta R, Bhatia VK et al. [11], Rasheed MA et al. [12], Koroglu A. et al. [13], Sinha SK et al. [14], and Sayeda AA et al. [5]. The study results of Gunduz M et al. [15], Gupta K et al. [16], Celik M. et al. [17] are in partial concurrence with our results.

Thus the systolicas well as the diastolic blood pressure showed a fall from the baseline values in both groups with group A showing lower values as compared to group B.comparison of mean systolic and diastolic values between the groups is alsostatistically significant (p value 0.0034) and (p value 0.0122) respectively.

Intraoperatively, after the administration of Inj· Ketamine 1 mg/kg, the meansystolic as well as diastolic BP increased in both group. This Increase was never more than the preoperative value in group A. If the baseline, meansystolic BP in group A is compared with intraoperative and posto-perative values, it can be seen that the difference is not significant with p value of 0.9706 and 0.5303 respectively. This comparison in group B shows the intraoperative and post-operative difference to have p value of 0.0015 and 0.0018 respectively and both values are significant. This means that the meansystolic and diastolic blood pressures after administration of Ketamine were better maintained as compared to baseline values in group A than in group B. On comparison of mean systolic and diastolic values of group A and group B, it was seen that the difference was statistically insignificant at all time points intraoperatively. Our results are comparable to the studies of Gundu MA [15].

In the PACU the mean systolic and diastolic blood pressures in the two groups were comparable and there was no statistical significance in the difference of the values of the two groups (all p values >0.05). These results in our study are comparable with Shaaban A. M. et al [7].

The mean respiratory rates in our study groups were 23.85±03.82 in group A and 23.40±03.93 in group B at baseline. The difference between the groups was not significant. After dexmedetomidine, group A patients had a mean respiratory rate of 22.73±03.61 and group B had a mean respiratory rate of 22.35±03.68 breaths/min. which did not show any statistically significant difference. Intraoperatively as well as postoperatively the mean respiratory rates in the two groups remained comparable with p value>0.05 at all time points.

Our results are comparable with Gunduz M et al. [15], Gupta K et al. [16], verrna R, Gupta R, Bhatia VK et al. [11], Raseed MA et al. [12], Sinha S. K et al. [14], Koroglu A. et al. [13] found a decrease in respiratory rate in their patients after dexmedetomidine which is contrary to our study.

Conclusion

We have concluded that the comparison of baseline, intraoperative (after Ketamine) and post operative values of heart rate, systolic BP and diastolic BP showed that the values were better maintained in group A as compared to group B. Hence both the combination were comparable in safety but since the vital parameters were better maintained in group A, 1 µg/kg Dexmedetomidine + 1 mg/kg Ketamine is better than 0.6 µ/kg.

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Impact of Education of the Ventilator Associated Pneumonia (VAP) Prevention Bundle on the Incidence of VAP Infections in the Intensive Care Unit (ICU)

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Abstract

Introduction: Ventilator Associated Pneumonia (VAP) is reported to be one of the most common nosocomial infection among patients who are mechanically ventilated in the Intensive Care Unit (ICU). The aim of the present study was to evaluate the effectiveness of implementation of VAP prevention bundle on the incidence of VAP and also to assess the microbiological profile of VAP infection. *Material and Methods:* This thirteen-month study was conducted in the ICU of a tertiary care hospital in Northern India. First month was used for introducing the VAP bundle in the unit through education sessions and the remaining 12 months were used for assessing the effect of the VAP bundle on the rates of VAP infections. VAP bundle included head-of-bed elevation (between 30° to 45°), daily sedation interruptions and assessment of readiness to wean, maintenance of endotracheal cuff pressures of 20-30 cm of H_2O, daily oral care with Chlorhexidine 2%, use of endotracheal tubes with subglottic suctioning system, peptic ulcer prophylaxis and deep vein thrombosis prophylaxis. VAP bundle compliance chart had to be filled daily. Patients aged more than 18 years and who were mechanically ventilated for more than 48 hours in the ICU were enrolled in the study. Patients who were intubated or on mechanical ventilation for more than twelve hours in areas outside the ICU, prior to admission, were excluded from the study. VAP was diagnosed by Clinical Pulmonary Infection Score (CPIS) and microbiological study of their sterile endotracheal aspirates. *Results:* The overall incidence of VAP was found to be 23.2 VAP episodes per 1000 ventilator days which was low as compared to the VAP incidence before VAP prevention bundle implementation. The most predominant pathogen was found to be Acinetobacter species (48.21%). 48.21% isolates were Multi Drug Resistant (MDR) with Acinetobacter being the most common isolate. *Conclusion:* Education and compliance with VAP bundle implementation helps to decrease the rate of VAP incidence. VAP with MDR organisms affects a significant proportion of patients who are mechanically ventilated in the ICU.

Keywords: Ventilator Associated Pneumonia; VAP Bundle; Intensive Care Unit; Mechanical Ventilation; MDR.

Introduction

Ventilator Associated Pneumonia (VAP) is the most common complication associated with mechanical ventilation and occurs in 9-27% of the patients receiving it [1,2]. It is the leading cause of morbidity and mortality in Intensive Care Unit (ICU) [3]. Patients developing VAP are reported to require a significantly longer duration of mechanical ventilation, ICU days and length of hospital stay [2]. Critically ill patients who develop VAP appear to be twice as likely to die compared with similar patients without VAP [4].

VAP is defined as pneumonia that occurs 48-72 hours or thereafter following endotracheal intubation and is characterized by the presence of a new or progressive infiltrate in the lungs, signs of systemic infection (fever, altered white blood cell count), changes in sputum characteristics, and detection of a causative agent [1]. Reducing mortality due to VAP requires an organized process that guarantees early recognition of pneumonia and

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consistent application of the best evidence-based practices. The Ventilator Bundle is a series of interventions related to ventilator care that, when implemented together, will achieve significantly better outcomes than when implemented individually [5]. The traditional VAP bundle as popularized by the Institute of Healthcare Improvement (IHI) [5] consists of:

1. Daily sedation vacation and daily assessment of readiness to extubate,
2. Elevation of the head of bed to 30-45 degrees,
3. Peptic ulcer disease (PUD) prophylaxis and
4. Deep venous thrombosis (DVT) prophylaxis (unless contraindicated).

The NGC (National Guideline Clearinghouse) and the ICSI (Institute for Clinical Sciences Improvement, November 2011) health care protocol on prevention of Ventilator Associated Pneumonia, recommends the addition of, maintenance of cuff pressure in the endotracheal tube to 20-30 cms of H2O, providing oral care with 2% Chlorhexidine and the use of specially designed endotracheal tubes which have an additional port for subglottic suctioning [6,7].

Previous study in our ICU revealed a VAP incidence of 37.5% with 40.1 infections per 1000 MV days [8]. Hence the present study was conducted to study the effect of implementation of VAP prevention bundle on the rate of VAP infections in the ICU. For effective implementation, educational sessions were conducted throughout the study period to increase the awareness of the healthcare staff about the significance of the components of VAP bundle.

Aims and Objectives

1. To evaluate the rate of VAP infections in the ICU following the implementation of VAP prevention bundle.
2. To assess the microbiological profile of VAP infections.

Material and Methods

This study was conducted in a mixed medical-surgical tertiary level ICU in Northern India after approval from the Institutional Ethics Committee. This was a thirteen-month prospective study in which the first month was used for introducing the VAP bundle in the unit, and the remaining 12 months used for assessing the effect of the VAP bundle on the rates of VAP infections in the ICU.

All health care professionals (resident doctors, nurses, ICU technicians) working in the ICU were educated on the VAP bundle [5,6,7]. Educational sessions were introduced in the first month of the study and then continued throughout the year, with at least 3 lectures conducted every month. The sessions were focussed on the definition of VAP, mechanism of infection, role of individual components of the VAP bundle, with emphasis on their consistent and regular implementation. Pre- and post-test questionnaires were administered to the health care professionals to assess the changes in the knowledge, attitude and practices of healthcare workers. Visual reminders in the form of posters (on the various components of the VAP bundle) were also displayed in the ICU so as to reinforce its implementation.

All adult patients who were mechanically ventilated for more than 48 hours in the ICU were included and who were mechanically ventilated for more than twelve hours outside the ICU, prior to admission, were excluded from the study. Basic demographic profile of the patient (name, age, sex, unit number), date of hospital and ICU admission, date of initiation of mechanical ventilation were all noted at admission. VAP wasdiagnosed based on the Clinical Pulmonary Infection Score (CPIS score) [9,10] as shown in Table 1.

Table 1: CPIS Score

CPIS points	0	1	2
Temperature	≥36.5 and ≤38.4	38.5 and ≤38.9	≥39.0 or ≤36.5
White Blood Cell Count	≥4,000 and ≤11,000	<4,000 or >11,000	<4,000 or >11,000 AND band forms ≥50%
Tracheal Secretions	None or scant	Non Purulent	Purulent
PaO_2/FiO_2 (*ARDS is defined as a PaO_2/FiO_2 ≤200, PAOP ≤18 mmHg, and acute bilateral infiltrates)	>240, ARDS* or pulmonary contusion	-	≤240 and no ARDS*
Chest Radiograph	No infiltrate	Diffuse (or patchy) infiltrate	Localised infiltrate

Table 2: Bundle Compliance Chart

Daily VAP bundle compliance chart for all mechanically ventilated patients																
Pt name/unit no	**Staff nurse name: morning evening night**											**DOHA:**	**DOIA:**	**DOI**	**DoE:**	
Intervention	**Days**											**Resident name: morning night**				
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
1 HoB elevation 30-45	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
2 Subglottic aspiration q2h	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
3 ETT cuff pressure 20-30cm of H2O	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
4 sedation vacation	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
5 PUD prophylaxis	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
6 DVT prophylaxis	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
7 Oral care with chlorhexidine q8hrly	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Reason for not following intervention	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	

DOHA- Date of hospital admission, DOIA- Date of ICU admission, DOI- Date of intubation, DoE- Date of extubation, HoB- Head of bed, ETT-endotracheal tube, PUD – Peptic ulcer disease, DVT- Deep vein thrombosis**.**

A sterile endotracheal aspirate was sent from patients suspected of VAP. The culture results were recorded and microbiological patterns were noted. All patients were followed up to record their date of extubation . A VAP Bundle Compliance Chart (shown in Table 2) was filled for each patient enrolled in the study by the nursing staff and resident on duty.

Statistical Analysis

Statistical analysis was performed using a statistical software package (SPSS Inc., Chicago, IL) for windows version 10.0. Descriptive frequencies were expressed using mean and standard deviation. Differences between means of continuous variables were compared using Mann-Whitney U–test and categorical variables were compared using chi-square (χ^2) test. A p-value < 0.05 was considered significant.

Results

A total of 202 patients were enrolled in the study. The overall incidence of VAP was found to be 14.85%with 23.2 VAP episodes per 1000 ventilator days. The device utilization rate during the study period was 0.91.

Nursing awareness was evaluated before and after educational programmes at regular intervals during the study period. We found that the median nursing scores were 80%, 60% and 80% in the pre-education phase, after six months and after one year, respectively.

The median VAP bundle compliance among health care workers during the study period was found to be 75% (min-max 59.70%-90.70%, Inter quartile Range 73.9% -87.1%). We also found that patients who eventually developed VAP infections had the components of the VAP bundle implemented on them on an average of 73.6% (min-max 61.40%-90.60%, Inter quartile Range 72.6% -87.1%) of the time, as compared to 75.1% (min-max 59.70%-90.70%, Inter quartile Range 74.1% -87.5%) compliance followed, among patients who did not develop VAP infections as shown in Table 3. This difference was statistically significant (p<0.005).

A total of 56 positive cultures were identified from the 30 patients with VAP infections. Out of the 56 microorganisms that were isolated, the major pathogen was Acinetobacter species (27 isolates, 48.21%), followed by Klebsiella (11 isolates, 19.64%) and Pseudomonas species (10 isolates, 17.86%). 27 isolates out of the 56 positive cultures were Multi Drug Resistant (MDR). The highest number of MDR organisms belonged to the Acinetobacter species

Table 3: Bundle compliance

AVG bundle compliance	**VAP**	**NO VAP**	**p value**
Number of patients	30	172	<0.005
Median	73.60%	75.10%	
Min-Max	61.40%-90.60%	59.70%-90.70%	
Inter quartile Range	72.6% -87.1%	74.1% -87.5%	

(14 isolates, 51.85%), followed by Klebsiella species (9 isolates, 33.33%).

Discussion

In our study population of 202 patients, 30 patients developed VAP (14.85%); this translates to an incidence of 23.2 episodes of VAP per 1000 ventilator days.

Similarly, a multicentric surveillance conducted in 55 ICU s of 8 developing countries of the International Infection Control Consortium (INICC), concluded that VAP posed the greatest risk (41% of all device-associated infections) with incidence of 24.1 cases [range, 10.0 to 52.7 cases] per 1000 ventilator days [11].

Educational programme included regular educational sessions, assessment of knowledge of nurses regarding VAP and VAP bundle prior and during the programme. No improvement in scores in questionnaires, were seen (p=0.818) which could be due to high degree of awareness among healthcare workers even prior to the educational sessions leading to insignificant difference on statistical analysis.

The median VAP bundle compliance among ICU health care workers during the study period was 75%. It was found that patients who developed VAP infections had less components of the VAP bundle being followed on them as compared to their counterparts (73.6% versus 75.1%). This difference was statistically significant ($p<0.005$).

Previous study done in this ICU, before implementation of VAP prevention bundle, showed an overall incidence of VAP to be 37.5% which translated to 40.1 VAP episodes per1000 ventilator days [8]. In our study, after implementation of VAP prevention bundle, the incidence had decreased to 23.2 VAP Episodes per 1000 ventilator days. This shows the importance of timely visual and verbal bedside reminders at the point of care in the ICU besides education. Repeatedly emphasizing on implementation of bundles, attaching bundle compliance chart onto the medical records of patients, positive reinforcement for implementation of VAP bundle had a greater effect on reducing the incidence of VAP. Thus, the VAP bundle if adhered to has an important role to play in reducing VAP infections in the ICU. Implementation of multiple preventive measures including the components of traditional Ventilator care bundle as popularized by the Institute of Healthcare Improvement (2006) [5] in 44 ICUs in 14 developing countries was associated with 56% reduction in VAP rate [12]. The ventilator bundle is believed to improve the outcome of ICU patients with VAP by setting priority, standardizing patient care, promoting adherence, and enhancing reliability and accountability.

In our study population, among the positive cultures, the most predominant was found to be Acinetobacter species (48.21%), followed by Klebsiella (19.64%) and Pseudomonas species (17.86%). Similar observation was made by Chastre and Fagon [2], who compiled data from 24 published studies and found that 58% of the isolates were gram negative bacteria, of which the most common organism was Pseudomonas followed by Acinetobacter species and Proteus species.

In our present study, out of the 56 cultures positive, 27 isolates were Multi Drug Resistant (MDR). The highest number of MDR belonged to Acinetobacter species (51.85%) followed by Klebsiella (33.33%) species. This was in concordance with a prospective study conducted in a tertiary care hospital which reported Acinetobacter as the most common MDR pathogen (47.9%) followed by Pseudomonas (27%) [14].

Conclusion

Continuous education of healthcare workers regarding the significance of the components of VAP prevention bundle and its positive reinforcement for its implementation has a great effect in reducing the incidence of VAP infection. The major organisms isolated in VAP patients were Gram negative bacilli. Choosing appropriate therapy for VAP includes knowledge of organisms likely to be present, local resistance patterns within the ICU and a rational antibiotic regimen. Early effective therapy for VAP is associated with reduced mortality and morbidity [15].

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Original Research Article

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Ultrasound Guided Femoral Nerve Block: an Advanced Technique for Pain Relief in Emergency Department in Fracture Femur

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Abstract

Background: Regional anaesthesia is an established method to provide analgesia for patients in the operating room and during postoperative phase. Ultrasound (USG) guided femoral nerve block offers advantage over intravenous anaesthesia in the acute phase of traumatized patients and during the initial transport of injured patients.The primary objective was to evaluate the pain relief in fracture femur patients using USG guided femoral nerve blocks on arrival in the emergency department. The secondary objective was to compare requirement of supplementation of analgesic and complications in both groups. *Methods:* This prospective interventional study enrolled a sample of 60 patients with fracture femur, 30 in each group. Control group includes patient with conventional analgesia while, in study group ultrasound-guided femoral nerve block was given with inj. bupivacaine 0.25% 10ml in plane approach. Pain score on movement and rest were assessed at baseline and 1 hourly after the procedure for 24 hours. *Results:* All procedures required one attempt, no complications and there was 66% pain relief in study group as compared to control where only 44% relative decrease in pain scores was observed,(P<.005) 1hr to 24hr after procedure. *Conclusions:* USG guided femoral nerve blocks are feasible to perform in the emergency department. Significant and sustained decreases in pain scores were achieved with this technique.

Keywords: Fracture Femur; Femoral Nerve Block; Emergency Department; Ultrasound.

Introduction

Hip fractures are a common presentation to the emergency department and are very frequent among elderly patients. Pain management in such patients is often a challenge due to their advanced age, comorbidities, and increased predisposition to develop adverse effects from medications. Parenteral administration of narcotics has been the mainstay of pain control for such patients which requires intravenous access and has common adverse effects like allergies, sedation, apnea and nausea [1]. There has been an increase in the use of regional anesthesia for a variety of medical procedures. Peripheral nerve blocks result in improved pain control, decreased complications, and a reduced length of stay in the hospital [2]. Ultrasound (USG) guidance to peripheral nerve blocks not only improves accuracy during infiltration of anesthetic but has also decreased the procedural time and time to onset of anesthesia [3]. Patient safety has improved as well because smaller dose of anesthetic agent is required when USG guides the procedure [4]. Femoral nerve blocks are an attractive alternative for pain relief. Peripheral nerve blockade in the acutely injured patient may blunt the systemic inflammatory stress response and reduce the associated risks of thromboembolism and immunesuppression. Additional benefits include reduced risk of opioid- associated complications. Despite the strong evidence supporting their efficacy, safety, and ease of execution, femoral nerve blocks remain relatively underutilized in the emergency department. This study aimed to to compare the pain relief provided by USG guided femoral nerve block

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and that by routine analgesics. The study also aimed to assess the hemodynamic changes in the patients after receiving USG guided nerve block and any requirement for rescue analgesia.

Methodology

Study Design and Sample

We performed an interventional study of patients who were admitted for fracture femur in the Emergency Department, Bharati Vidyapeeth Medical College and Research Center, Pune from June 2015 till May 2017. We included patients aged 18 to 80 years with fracture femur, of either gender and belonging to American society of anaesthesiologist (ASA) Grade I,II and III. Patients who had hypersensitivity to amide local anaesthetics, had peripheral neuropathy, were haemodynamically unstable, or had head injury with Glasgow coma scale score less than 10 or polytrauma were excluded from the study. We also excluded patients who had wound at the puncture site or infection, had coagulopathies or on anticoagulants, or refused to give consent for inclusion in the study. Patients were assigned randomly to either the study group or the control group. Patients in the study group received USG guided femoral nerve block on arrival in emergency department and patients in the control group received injection Paracetamol 1gm intravenously 6 hourly as per orthopaedic department protocol.

Procedure

Patient was positioned supine with legs slightly abducted: the groin was painted and draped in sterile drape. The USG was placed to the right of the patient's bed, and USG gel was applied to the probe, which was held by an assistant. The probe was placed to the patient's groin with the probe's indicator (a small notch, light, or nub) pointing towards the patient's right leg. In supine position with high frequency linear probe (6-13MHz) femoral artery was identified as a round pulsating vessel and nerve as a triangular or elliptical hyper echoic structure immediately lateral to femoral artery as in Figure 1 and 2. The drug was injected using a 23-gauge spinal needle attached to a syringe with 10 ml of 0.25% bupivacaine, which was inserted 2 cm distal to the inguinal ligament in a lateral to medial direction at a 30-degree angle. The needle was viewed on the USG monitor, the tip was positioned as close as possible to the femoral nerve and aspiration was done to insure there is no infiltration into a vessel. The local anaesthetic was seen spreading in cephalad direction and appeared as an expanding hypo echoic area within the facial space surrounding the nerve sheat as shown in Figure 3.

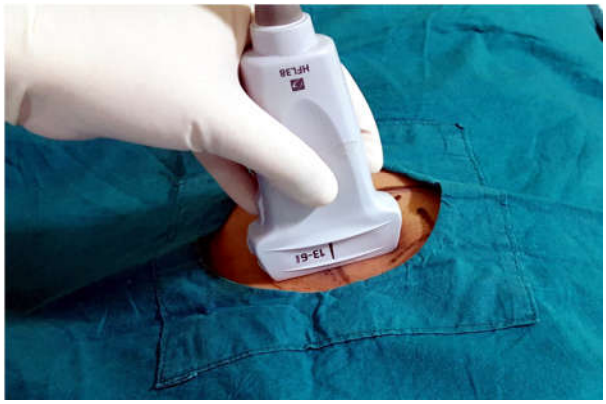

Fig. 1: Ultrasound probe on right side of patient's groin

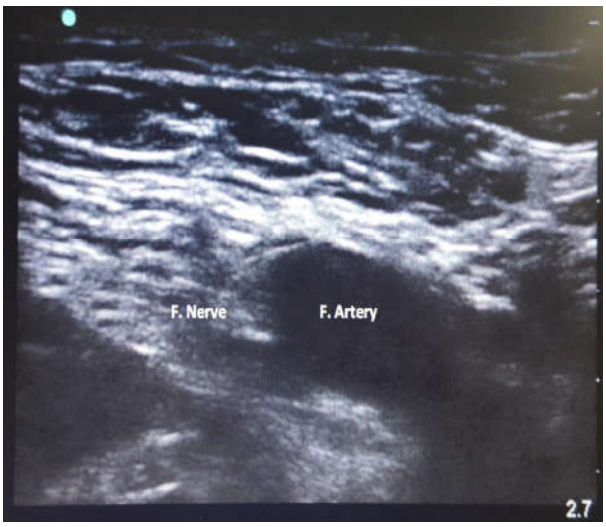

Fig. 2: Right side femoral nerve as a triangle lateral to femoral artery

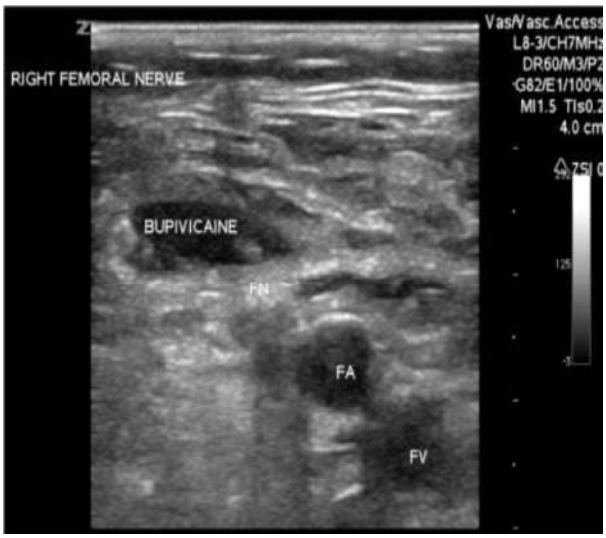

Fig. 3: Ultrasound image of femoral vein, artery (FA), nerve (FN) and inguinal ligament (IL) and expanding bupivacaine around FN

The femoral nerve was anesthetized. Rescueanalgesia was used when the VAS pain score was above 4 and included injection diclofenac and paracetamol 75mg and injection tramadol 100 mg.

Data Collection and Data Analysis

After obtaining approval of the institutional ethics committee, eligible patients were explained the purpose and procedure of the study in the emergency department. A written informed consent was taken from each patient. Baseline demographic information of the patients was collected. Using the visual analogue scale (VAS) pain was assessed for all the patients at rest and at movement [5]. Pulse rate and systolic blood pressure measurements were also noted for all the patient. All observations were made at regular intervals for a period of 24 hours after administration of analgesia. The data was collected using a pre-tested semi-structured proforma. Any requirement of additional analgesia was also noted for all patients. The data were statistically analyzed using Statistical Package for Social Sciences (SPSS ver. 16.0, IBM Corporation, USA) for MS Windows. Qualitative data were compared between the two groups using chi-squared and continuous variables were compared using unpaired t test. The underlying normality assumption was tested before subjecting the study variables to the 't' test. The p-values less than 0.05 are considered to be statistically significant.

Results

Demographic data was comparable in both groups as shown in (table 1) . On arrival in emergency department the mean VAS pain score was significantly higher i.e 8-9 in the both the groups (Table 2). After receiving US guided femoral nerve block in study group VAS score was reduced to 1 from 8 and remained same till 12th hour. However in control group after receiving intravenous paracetamol (1gm) VAS score reduced to 3.07 till 4 hours. This difference in VAS score was statistically significant (p value = 0.001). Due to weaning off action of injectable analgesicsin control group VAS score at the 8th hour increased up to 6.37. However in study group VAS score remained same i.e. 1.03.

Second parameter studied was pain score on movement during transportation. On receiving USG guided femoral nerve block in study group VAS score reduced to 1.03 and remained 3.66 i.e. mild pain over 24 hour duration even on movement for transportation of patient to ward and for imaging. In control group VAS score varied from 2.27 to 6.43 which was mild to moderate pain till 24 hour after receiving intravenous analgesics during movement of patient. Pulse rate was significantly higher at baseline in patients in the study group. However, later during the observation period, pulse rate did not differ between the two groups significantly (Table 3). Mean systolic blood pressure was not

Table 1: Baseline characteristics of patients included in the study

	Study group	Control group	p value
N	30	30	
Mean age (SD*)	68.9 (14.9)	68.1 (17)	0.83
Gender			
Males	15	14	0.99
Females	15	16	

Table 2: Comparison between study and control groups in mean pain score at rest and movement

Time-line	Mean pain score at rest			Mean pain score at movement		
	Study	Control	p value	Study	Control	p value
Baseline	8.41(0.82)*	9.43(0.50)	0.001	9.72 (0.53)	9.07 (0.74)	0.001
1-Hr	1.00(0.00)	2.13(0.68)	0.001	1.03 (0.19)	2.67 (0.48)	0.001
2-Hr	1.00(0.00)	3.07(1.20)	0.001	1 (0)	2.27 (1.11)	0.001
3-Hr	1.00(0.00)	3.07(1.34)	0.001	1.07 (0.26)	3.87 (1.74)	0.001
4-Hr	1.00(0.00)	3.77(1.33)	0.001	1.41 (0.5)	6.7 (1.51)	0.001
8-Hr	1.00(0.00)	6.37(1.22)	0.001	2 (0)	7.47 (1.22)	0.001
12-Hr	2.07(0.26)	1.60(1.00)	0.018	2.76 (0.43)	1.8 (1.29)	0.001
16-Hr	2.76(0.91)	3.17(0.53)	0.039	3.03 (0.19)	5.63 (0.93)	0.001
20-Hr	3.00(1.31)	2.63(0.56)	0.164	3.59 (0.95)	4.6 (0.89)	0.001
24-Hr	2.62(0.49)	3.93(0.83)	0.001	3.66 (0.67)	6.43 (0.82)	0.001

*Number in parenthesis is standard deviation

Table 3: Comparison between study and control groups in hemodynamic parameters

Time-line	Mean pulse rate			Mean systolic blood pressure		
	Study	Control	p value	Study	Control	p value
Baseline	90.73(5.84)*	81.27(9.04)	0.001	121 (17.7)	118.6 (12.7)	0.549
1-Hr	79.87(5.61)	80.73(7.75)	0.621	113.8 (8.5)	118.3 (11.1)	0.080
2-Hr	80(5.32)	80.53(7.74)	0.760	113.6 (8.2)	116.1 (9.4)	0.273
3-Hr	80.27(5.32)	79.5(7)	0.635	113.6 (7.9)	117.5 (9.4)	0.085
4-Hr	80.33(6.06)	80.27(6.7)	0.968	114.4 (8.4)	117.9 (10.4)	0.162
8-Hr	78.67(5.71)	80.63(6.14)	0.204	116.3 (7.5)	117.5 (8.8)	0.592
12-Hr	79.53(5.79)	80.8(6.53)	0.432	116.7 (6.4)	117.6 (7.3)	0.614
16-Hr	79.8(4.52)	81.93(6.4)	0.134	116.7 (6.9)	119.3 (8.9)	0.211
20-Hr	80.07(4.88)	80.6(6.31)	0.716	116.8 (6.1)	118.6 (8.9)	0.367
24-Hr	80.27(5.06)	80.67(6.57)	0.792	116.4 (5.5)	118.5 (8.3)	0.260

*Number in parenthesis is standard deviation

Table 4: Inter-group comparison of incidence of requirement of additional analgesia

Rescue analgesia	Study group (n=30)	Control group (n=30)	P value
Required	3 (10%)	11 (36.7%)	0.03
Not required	27 (90%)	19 (63.3%)	

different between the two groups at baselines or anytime during the observation period however overall haemodynamic stability was better in study group.

Requirement of rescue analgesia was only 10% in the study group while it was 36% in the control group. (p value = 0.03). These additional doses of analgesia were required during transportation of patients in control group.

Discussion

Nerve block is a relatively new concept in the emergency department for pain relief. Considering the importance of pain management in emergency department and the scarce literature on ultrasound-guided nerve blocks from India, we aimed to evaluate the benefit of femoral nerve block. Finlayson and Underhill first reported applications of regional anestheisa in the emergency department in the late 1980s [6]. Despite its availability for so many years, it has remained relatively underutilized, specially in India [7]. Lack of expertisein performing the procedure, perception that narcotics alone are effective, and safety concerns of the procedure may have hindered the effective implementation of the procedure. Baseline VAS pain score in both the groups in the present study were high i.e 8-9. After receiving USG guided femoral nerve block in study group VAS score reduced to 1. At the same time in control group it was reduced to 3-4. This shows that the control of pain was steady and prolong in study group. However fluctuations over a period of time were seen in control group as the action of conventional analgesia weaned off. Also, VAS pain score on movement was variably high in the control group as compared to a sustain pain relief in study group and this difference was statistically significant. In control group on transportation and movement of patient VAS score fluctuated from 3 to 8 at different intervals of time during 24 hours and required additional drugs for pain control round the clock and patient were discomfortable. However in study group during movement and transportation pain relief was sustained and prolonged and VAS score remained 3.

There are several clinical trials which suggest superiority of USG guided procedure to the one which is landmark or nerve stimulator guided. Marhofer et al found that USG significantly reduced the onset time of the anestheisa, improved the quality of sensory block and reduced the dose of anesthetic required [3]. Ningawal et al. conducted preoperative femoral nerve block in extracapsular femoral neck fractures and evaluated pain relief during transportation to operation theatre [8]. The authors concluded that femoral nerve block provided total pain relief and abolition of muscle spasm within few minutes and caused little change in hemodynamic parameters in patient compared to intramuscular tramadol. Furthermore, Mutty C et aldemonstrated that acute pain of a diaphyseal or distal femoral fracture can be significantly decreased through the use of a femoral nerve block, which can be administered safely in the hospital emergency department [9].

Utilization rates of USG guided nerve blocks are expected to increase with increasing availability of

portable USG machines, and growing evidence suggesting the superiority of ultrasound guidance over landmark and nerve stimulator needle guidance.

Conclusion

Results of the present study show that USG guided femoral nerve block for pain management in the emergency department is an effective method to provide prolonged and sustained pain relief. Additionally, better haemodynamic control was achieved after adequate pain relief using USG guided femoral nerve block. Future studies should assess association of USG guided femoral nerve and the development of delirium and length of stay in the hospital. More research is required to describe different techniques of peripheral nerve blocks which can improve the safety of the procedure.

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Original Research Article

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A Randomized Prospective Double Blind Comparative Study of Caudal Ropivacaine 0.2% versus Caudal Bupivacaine 0.125% for Postoperative Analgesia in Pediatric Surgeries

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Abstract

Introduction: Pain relief is important for reduction of postoperative morbidity necessitating continuing search for safe and efficient method in pediatric patients due to difficulty in pain assessment and concern of potential side effects. Single dose caudal epidural block is simple, effective and easy technique to perform due to anatomy of sacrum of child. There are reports of ropivacaine/bupivacaine being used routinely for caudal anaesthesia (Bramwell, Kapsten) and the extension of its analgesic action in the postoperative period. *Aims & Objectives:* To study and compare the effects of caudal ropivacaine and caudal bupivacaine for postoperative analgesia in pediatric patients w.r.t. duration and quality of postoperative analgesia, duration of motor blockade, hemodynamic effects and adverse effects if any. *Methods:* Comparative double blind prospective study included 100 patients of ASA grade I/II in age group of 2 years to 12 years posted for elective surgeries (circumcision, herniotomy, hydrocoele repair etc). General anesthesia was given followed by a single shot caudal epidural in the left lateral position after completion of surgery. They were randomly divided into two groups of 50 each, Group B – 0.2% ropivacaine 0.75 ml/kg. Group A – 0.125% bupivacaine 0.75 ml/kg. *Results:* The mean duration of analgesia using caudal ropivacaine was 5.43 hrs and caudal bupivacaine was 5.38 hrs. The mean duration of motor blockade with caudal bupivacaine was prolonged 6.10 hrs and caudal ropivacaine was 3.16 hrs. No hemodynamic instability and adverse effects. *Conclusion:* 1. caudal ropivacaine showed quality and duration of postoperative analgesia comparable to that of caudal bupivacaine. 2. The duration of motor blockade with caudal ropivacaine was short as compared to that of caudal bupivacaine 3. Hemodynamic parameters were stable. 4. No any adverse effects.

Keywords: Postoperative Analgesia; Pediatric Surgery; Technique-Caudal Block; Drug-Bupivacaine/ Ropivacaine.

Introduction

Pain causes physical damage and fear. Pain relief is important for reduction of morbidity after surgery. Children have been neglected for effective postoperative pain relief due to difficulties in assessing their pain perception and concern of giving drugs with potential side effects.

Single dose caudal block is a simple, efficient and easy technique to perform due to the anatomy of the sacrum of the child. Caudal with local anesthetics after induction of general anesthesia prior to surgery has advantage of adequate intraoperative anesthesia, adequate postoperative analgesia, the presence of a tranquil recovery, calm child. There are reports of ropivacaine/ bupivacaine being used routinely for caudal anesthesia (Bramwell, Kapsten) and the extended analgesic action in the postoperative period.

This study was conducted to find out whether the caudal ropivacaine offers any advantage regarding duration of block and postoperative pain relief, compared with caudal bupivacaine.

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Aims and Objectives To study and compare, the effects of caudal ropivacaine 0.2% and caudal bupivacaine 0.125% w.r.t. 1. The quality and duration of postoperative analgesia. 2. Duration of motor block. 3. hemodynamic effects 4. Adverse effects.

Material and Methods

Study was prospective randomized comparative double blind clinical study. Approval from the institutional ethical committee was taken.

Inclusion Criteria

Hundred children, between the age group of 2 years to 12 years of either sex and ASA grade I/II who were posted for elective surgery involving the lower abdomen, genitourinary system and lower limbs.

Exclusion Criteria

The sacral hiatus pathology or deformity, neurological disease, obvious spine deformities, nutritional disorders, anaemia, known hypersensitivity to bupivacaine, coagulopathies, local infections, cardiorespiratory compromise, liver and renal dysfunction.

The children were selected by computer generated random numbers. The children were randomly assigned to two groups.

Group A: 50 patients, caudal plain bupivacaine (0.125%) 0.75 ml/kg.

Group B: 50 patients, caudal ropivacaine (0.2%) 0.75ml/kg

Informed parental consent was obtained in each case, after the procedure had been explained to them. Preoperatively thorough preanaesthetic evaluation was performed of all children. Detailed physical examination was done. Investigations haemogram, bleeding time, clotting time, urine examination were done.

Procedure: All children were kept nil by mouth for 6 hours prior to surgery. All children were given general anesthesia and the caudal block was then performed after completion of surgery.

Premedication: inj.Glycopyrrolate5ug/kgIV, Inj. Ondansetron 0.08mg/kgIV Inj.Midazolam 0.03mg/kgIV, Inj.Pentazocine 0.3mg/kg IV

Induction: Inj.Pentothal Sodium 5 mg/kg IV Inj. Suxamethonium2 mg/kgIV.

Intubation –plain PVC portex ETT of proper size using laryngoscope

Maintenance 50% O_2+50% N_2O on IPPV, Isoflurane as inhalational agent. Atracurium as muscle relaxant.

Caudal block was given using complete aseptic precautions after completion of surgery and before reversal of general anaesthesia by a short bevelled 22G 1" hypodermic needle. The correct placement of the needle into the epidural space was confirmed by using a smooth 2cc glass syringe and eliciting the 'loss of resistance' test. After negative aspiration for blood and CSF, the total calculated dose was given slowly. The needle was then withdrawn and a benzoin seal was placed and supine position given.

Recording - Heart rate, blood pressure, oxygen saturation, surgery duration recorded. The duration of motor blockade was charted as the time taken from the caudal block to the full return of muscle power in the lower limbs. Similarly duration of sensory blockade was also checked by pinprick. Pain assessment in the post operative period was done by using OPS score & duration of analgesia noted. If the OPS score more than 4 in 2 subsequent measurements or if patient showed obvious signs of pain they were given oral paracetamol 10 mg/kg as rescue analgesia.

Duration of motor block was assessed by using motor power scale. Complete motor recovery indicates score 10 (Table 2).

Table 1: Objective Pain Scale (OPS)

Sr. No.	OPS variable	Score
1	Crying	0-2
2	Facial expression	0-2
3	Verbal response	0-2
4	Position of torso	0-2
5	Motor restlessness	0-2

(0-none, 1-moderate, 2-severe)

Table 2: Motor power scale

Muscle Tone	Flaccid	Hypotonia	Normal
Muscle Power (Flexion)	0 Unable	1 Partial	2 Normal
Ankle	0	1	2
Knee	0	1	2
Thigh	0	1	2
Ability to stand	0	1	2

The occurence of complications were noted: *Immediate complications:* Dural puncture, Intravascular injection, Vasovagal attack, Severe hypotension. *Late complications:* Respiratory depression, Nausea, vomiting, Urinary retention.

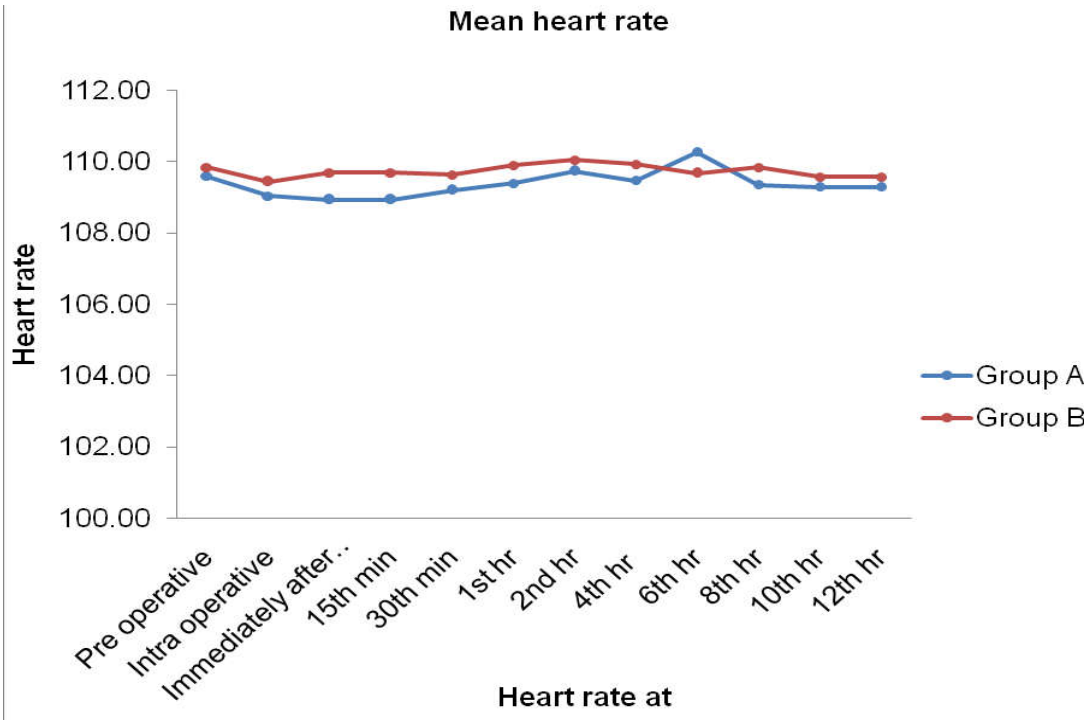
Statistical Analysis: ASA grade by chi-square test, gender by 2 sample proportion test. 2 independent sample t-test for age, weight, duration of surgery, heart rate, blood pressure, respiratory rate, duration of postoperative analgesia, duration of motor block. Mann-Whitney U test for Objective pain score, sedation score.

Results

Table 3: Demographic data

Variables	Group A	Group B	P Value	Statist. Signi.
Age (yrs) Mean ± SD	4.35 ± 1.02	4.38 ± 1.05	0.885	>0.05-NS
Gender (M/F)	34/16	33/17	0.804	>0.05-NS
Weight (kg) Mean ± SD	15.06 ± 2.08	14.42 +1.88	0.110	>0.05-NS
Asa grade (i/ii)	21/29	20/30	0.999	>0.05-NS
Surgery Duration Mean ± SD (min.)	46.40 ± 6.23	46.90 ± 5.61	0.110	>0.05-NS

(SD- Standard Deviation, NS- Not Significant)



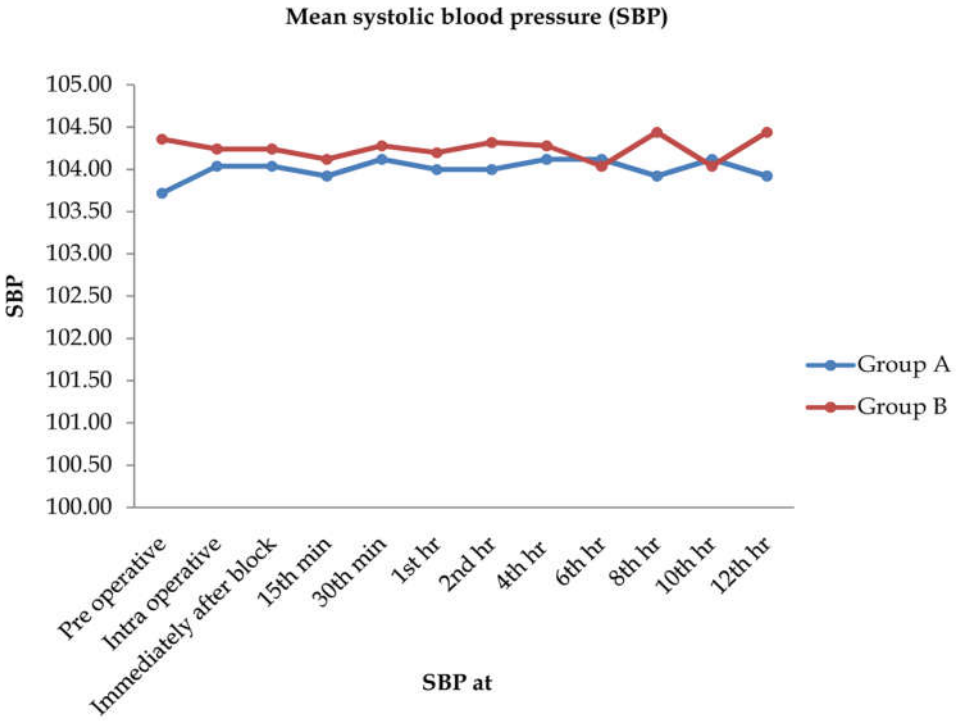
Graph 1: Comparison of mean heart rate in group A and group B at pre operative, intra operative, immediate after block, 15th min, 30th min, 1st hr, 2nd hr, 4th hr, 6th hr, 8th hr, 10th hr and 12th hr

(SD- Standard Deviation, NS- Not Significant)

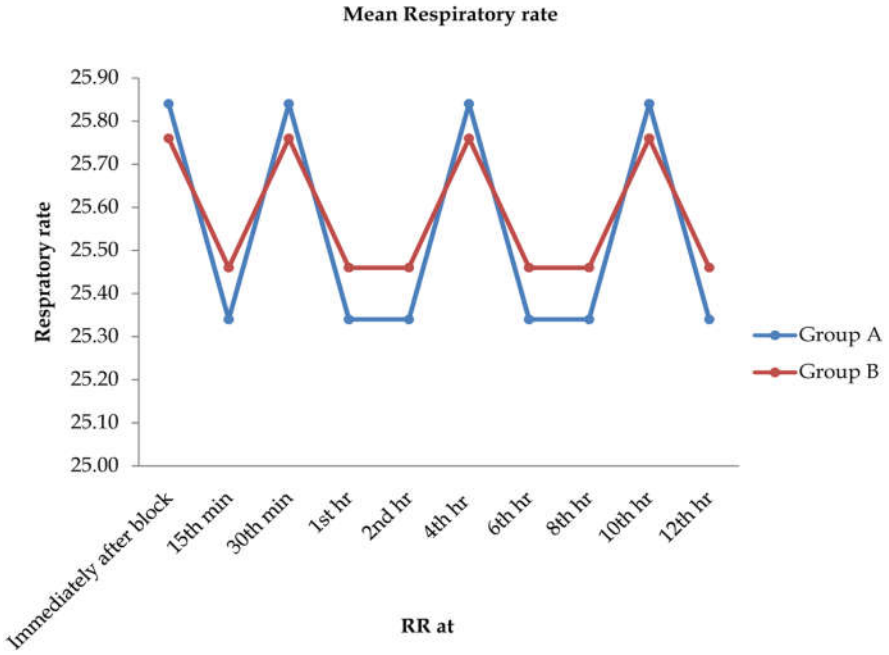
Graph 1: By using 2 independent sample t-test p-value > 0.05 therefore there is no significant difference between mean heart rate in group A and group B immediate after block, 15th min, 30th min, 1st hr, 2nd hr, 4th hr, 6th hr, 8th hr, 10th hr and 12th hr.

Graph 2: By using 2 independent sample t-test p-value > 0.05 therefore there is no significant difference between mean SBP in group A and group B immediate after block, 15th min, 30th min, 1st hr, 2nd hr, 4th hr, 6th hr, 8th hr, 10th hr and 12th hr.

Table 4: By using Mann-Whitney U test p-value >0.05 therefore there is no significant difference between median pain score immediately after block to 8th hr.



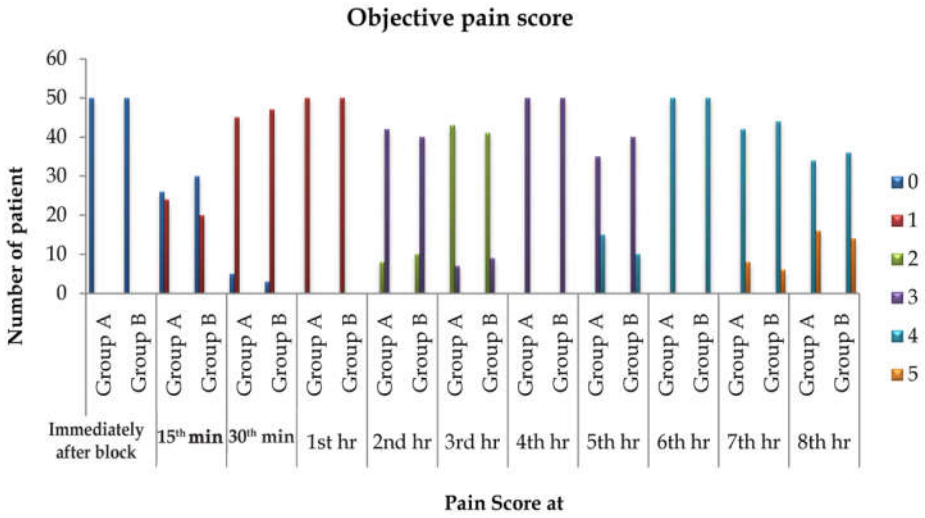
Graph 2: Comparison of mean systolic blood pressure (SBP) in group A and group B at pre operative, intra operative, immediate after block, 15th min, 30th min, 1st hr, 2nd hr, 4th hr, 6th hr, 8th hr, 10th hr and 12th hr.



Graph 3: Respiratory Rate

Table 4: Median Pain Score

	Median pain score		p-value
	Group A	Group B	
Immediately after block	0	0	0.423
15th min	0	0	0.423
30th min	1	1	0.463
1st hr	1	1	0.999
2nd hr	2	2	0.604
3rd hr	2	2	0.622
4th hr	3	3	0.999
5th hr	3	3	0.251
6th hr	4	4	0.999
7th hr	4	4	0.586
8th hr	4	4	0.664



Graph 4: Comparison of objective pain score in group A and group B at immediate after block, 15th min, 30th min, 1st hr, 2nd hr, 4th hr, 6th hr, 8th hr, 10th hr and 12th hr.

Table 5: Comparison of motor power scale in group A and group B at immediate after block, 15th min, 30th min, 1st hr, 2nd hr, 3rd hr, 4th hr, 6th hr, 7th hr

	Median MPS		p-value
	Group A	Group B	
Immediately after block	0	0	0.999
15th min	2	2	< 0.001
30th min	3	4	< 0.001
1st hr	3	6	< 0.001
2nd hr	4	8	< 0.001
3rd hr	5	10	< 0.001
4th hr	6	10	< 0.001
5th hr	8	10	< 0.001
6th hr	10	10	0.002
7th hr	10	10	0.999

Table 6: Comparison of duration of analgesia and motor blockade

Group	Group A	Group B	p-value	Statistical significance
Duration of analgesia (Mean± SD)	5.38 ± 0.33	5.43 ± 0.32	0.430 (>0.05)	Not significant
Duration of motor blockade (Mean± SD)	6.10 ± 0.80	3.16 ± 0.19	<0.001 (<0.05)	Statistically significant

Discussion

In our study, we found this technique to be a simple, safe and easy to perform. Dalens Bernard [3] studied 750 patients using both lidocaine and bupivacaine and found a success rate of 96.5%. Most of the failures occurred in an older age groups. No respiratory or neurological problems were noted.

Fortuna [4] reported on 170 children in the age group of 1 day to 10 years and found an incidence of 91.5% of successful analgesia.

Mc grown [5] studied 500 cases upto the age of 10 years and found a success rate of 86.8%. He described it to be a technically simple and safe procedure. In our study, caudal block was performed in the left lateral position using a 22G hypodermic short, beveled needle, No failures were noticed in our study. Pediatric age group is a suitable age group as regards the caudal block because of anatomic peculiarities.

Arthur D.S. [6] documented that sacrum in children is straighter and the sacral cornu are more prominent making identification of the hiatus easier.

Murat [7] attributed the success of caudal block to incomplete ossification of the sacral vertebrae and more fluid in epidural fat thereby allowing local anesthetic agent to diffuse freely.

In our study, we have randomly chosen 100 children in the age group between 2 year to 12 years belonging to ASA I or ASA II grade. The two groups were comparable in age, sex, ASA grading and weight (Table 3). Proper patient selection is an important aspect of success of a caudal block. Children below the age of 6 months are more prone for toxicity of local anesthetic agents because of incomplete myelinization of the nervous system, lower plasma proteins and higher elimination half life and thus were excluded from our study.

Both sexes were included in this study. However the number of male children far outnumbered the number of females. This was because the majority of the operations for which caudal anesthesia was given were commoner in males (Table 3). The various surgeries performed were herniotomies, hydrocoelectomy, cystolithotomy, circumcision, repair of hypospadias and orchidopexy.

General anesthesia was induced which ensured that the child is motionless during the block, thereby minimizing the chances of complications like dural puncture, intravascular puncture or breakage of needle, resulting in high success rate, proper painting of the area thus reducing the risk of sepsis as well as failure to identify the hiatus.

Kay B [8] has used the technique of general anesthesia with caudal epidural using O_2 (33%), N_2O (66%), Halothane (1% to 0.5%) by mask, while Cook, Crubb have used the laryngeal mask airway to secure the airway and O_2, N_2O and halothane to maintain light anesthesia.

Arthur D.S. advocated the combined use of caudal epidural with general anesthesia as it also produced amnesia as regards the caudal block and surgery

In our study all the blocks were performed in the left lateral position after completion of surgery and before reversal of general anaesthesia. A short, 22G beveled hypodermic needle was used for the block. Since the distance between the skin and epidural space in children is much less thus a short needle (1") had been used to effectively enter the epidural space and also prevent dural puncture, after negative aspiration for blood and CSF, the volume of anesthesic solution was injected slowly.

In our study we used bupivacaine as local anesthetic agent in a concentration of 0.125% and ropivacaine 0.2%. Bupivacaine is a potent, highly lipophilic drug with a long duration of action.

Hemodynamic Stability

A feature of caudal anesthesia in children below 5 years of age is the hemodynamic stability observed postoperatively. By using 2 independent sample t-test p-value > 0.05 therefore there was no significant difference between mean heart rate and systolic blood pressure in group A and group B, immediate after block, 15th min, 30th min, 1st hr, 2nd hr, 4th hr, 6th hr, 8th hr, 10th hr and 12th hr , with no case of bradycardia or hypotension (Graph 1,2).

Bromage too noted this hemodynamic stability despite higher mg/kg dosage of local anesthetic. Several reasons have been put forward for this beneficial effect (Murat, Dalens) - Reduced size of the lower part of the body, Low level of systemic vascular resistance, Effectiveness of the sympathetic system in the non blocked areas to compensate for vasodilatation in the blocked area.

Pain Score Method: In this study we used OPS pain score system and duration of analgesia was noted post operatively. Each variable (Crying, facial expressions, verbal response, position of torso & motor restlessness) scored between 0-2 (0-None, 1 moderate, 2-severe) to give cumulative score of 0-10. If the OPS score is more than 4 in two subsequent measurement or if patients showed obvious signs of pain they were given oral paracetamol 10 mg/kg as rescue analgesia.

Aruna Parameswari [9] and her colleagues have used FLACC pain score, which includes assessment of face, leg, activity, cry, consolability. Five parameters were given score of 0-2 each and total score was taken to assess pain.

Hannalah [10] and his colleagues used a 5 point pain assessment chart which included cry, pulse, BP, movement, posture.

Lunn J [11]. N used a visual analogue scale 10 cm long with asleep at one end and violently restless at the other.

Pain Score: The difference in pain score indicating quality of pain relief was statistically not significant when median pain score was compared between Group A & Group B. (Table 4).

P value of median pain score at 8th hr after block was 0.664. It is >0.05, therefore there is no significant difference between median pain score in both groups. This means that children receiving caudal ropivacaine had comparable quality of pain relief as that of caudal bupivacaine.

Duration of Postoperative Analgesia: The mean duration of postoperative analgesia using bupivacaine caudally in our study was 5.38 hrs. and using caudal ropivacaine was 5.43 hrs. This was comparable in both groups (Table 6). Warner using 0.25% bupivacaine 1 ml/kg. found postoperative analgesia to be between 4-8 hours and Hannalah reported it to be 4 hrs 40 mins. Vater et al using 0.25% bupivacaine 0.5 ml/kg found analgesia lasting between 4-6 hrs.

The Mean Duration of Motor Blockade: The mean duration of motor blockade with caudal bupivacaine was 6.10 hrs.and with caudal ropivacaine was 3.16 hrs. which was for less time, helps in early ambulation of children. By using 2 independent sample test p-value < 0.05 therefore there was significant difference between mean duration motor blockade (Table 6).

Adverse Effects: There was no case of dural puncture, intravascular puncture, transient apnea, severe hypotension or urinary retention. This was possible with scrupulous attention to technique and proper patients selection. No toxic reactions to the local anaesthetic drugs were noticed which was due to our utmost care of dose calculation.

Conclusion

1. Ropivacaine provided the quality and duration of analgesia comparable to that of bupivacaine.
2. The duration of motor blockade was short with caudal ropivacaine as compared to that of bupivacaine.
3. Hemodynamic parameters remained stable.
4. No any adverse effects occurred.

We observed the effectiveness of caudal ropivacaine in providing postoperative analgesia with less duration of motor blockade as compared to caudal bupivacaine in pediatric patients with no occurance of adverse effects. We feel that child undergoing lower abdominal surgery would definitely benefit from postoperative caudal analgesia using caudal ropivacaine. The reward of pain free, happy child and appreciative parents would definitely be a guiding point in the use of this technique in pediatric anesthesia.

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Effects of Intravenous Ondansetron and Granisetron on Hemodynamic Changes and Blockade Characterestics Induced By Spinal Anesthesia: A Prospective Observational Study

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Abstract

Background: Spinal anaesthesia has many advantages for elective surgeries, but the undesired effect of hypotension is to be managed by different interventions. Induction of the Bezold Jarisch reflex in the setting of decreased blood volume, mediated through serotonin is hypothesised to be one of the factors contributing to hypotension. Recent studies suggested that ondansetron, a 5-hydroxytryptamine subtype 3 receptor antagonist, given prior to spinal anaesthesia may reduce the hemodynamic changes. *Aims:* To evaluate the effects of two serotonin receptor antagonists, ondansetron and granisetron in the spinal anaesthesia induced hypotension, bradycardia, sensory and motor blockade using hyperbaric bupivacaine in patients undergoing elective surgeries. *Methods:* A prospective observational study on 300 patients scheduled for elective surgery under spinal anaesthesia was donedividing them into 3 with 100 in each group, receiving intravenous ondansetron 4mg granisetron 1mg and saline 2mL respectively. Spinal anaesthesia was given using 3 ml 0.5% heavy bupivacaine. Mean arterial pressure, heart rate, vasopressor use, sensory and motor blockade, their regression were assessed. Chi-square test was used for analysing incidence of hypotension, ANOVA test for changes in mean arterial pressure, vasopressor use, motor and sensory blockade characteristics. p value<0.05 was considered statistically significant. *Results:* The ondansetron group, compared to granisetron and control groups showed a lower incidence of fall in mean arterial pressure, and vasopressor use [$p< 0.05$] No significant changes in heart rate, onset and regression ofsensory and motor blockade were noted among three groups. *Conclusion:* Intravenous ondansetron 4mg given before spinal anaesthesia in elective surgeries significantly decreased hypotension and vasopressor usage. There were no significant inter group differences in incidence of bradycardia, motor and sensory blockade.

Keywords: Spinal Anaesthesia; Ondansetron; Granisetron; Hemodynamic Changes; Motor and Sensory Blockade.

Inroduction

Orthopaedic procedures can be particularly challenging for anaesthesiologists. Patients ranging from an elderly patient with multiple comorbid conditions, to a youngdeceptively healthy trauma victim with associated injuries that can have significant impact on the type of anaesthetic administered would have to be dealt with. Spinal anaesthesia is usually preferred for elective lower limb surgeries due to many advantages like avoiding risks of general anaesthesia, better postoperative pain relief etc. It is a simple technique with low failure rate. But certain problems after giving spinal anaesthesia like hypotension, bradycardia and failure of block are the other side of the coin. The incidence of hypotension is about 13 to33%, which is the most frequent complication [1].

This study concentrated on two drugs, which can minimize the occurrence of hypotension after spinal anaesthesia namely ondansetron and granisetron, which are selective 5-hydroxytryptamine 3 ($5\text{-}HT_3$) receptor antagonist [2] These receptors are located peripherally as cardiac chemoreceptors on the cardiac vagal afferent, and centrally in the chemoreceptor trigger zone [3].

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Animal studies have demonstrated that serotonin (5-HT) could be associated with the induction of the Bezold–Jarisch reflex in the setting of decreased blood volume [4] Triggering of chemoreceptors sensitive to serotonin in the intra-cardiac wall by a reduction inblood volume due to decreased venous return may lead to increased vagal nerve activity, decreased sympathetic activity leading to bradycardia and vasodilatation [5]. This effect can be blocked at 5-HT_3 receptors. Recent studies suggestedthat ondansetron, and granisetron,

Five hydroxytryptamine subtype 3 (5-HT_3) receptor antagonists generally usedfor prophylaxis and treatment of nausea and vomiting, may also reduce the hemodynamic changes induced by spinal anaesthesia. The mechanism of action is believed to be inhibition of the Bezold-Jarisch reflex. Whether ondansetron can be used routinely to prevent spinal anaesthesia induced hemodynamicchanges is still unclear.

Moreover, 5-HT_3 receptors are present also in the dorsal horn of spinal cord, and serotonin have antinociceptive effect, which can be antagonized by selective 5-HT_3 receptor antagonist [6] So administration of intravenous 5HT_3 antagonists could affect the intensity or duration of sensory and motor block after spinal anaesthesia.

Our study was done to evaluate the effects ofondansetron and granisetron in spinal anaesthesia induced hypotension,bradycardia,sensory and motor blockade in patients undergoing elective lower limb surgeries.

Materials and Methods

After getting approval from The institutional Ethics Committee, a prospective observational cohort study was conducted in the elective operation theatre of Government Medical College, Kozhikode from January 2015 to February 2016, on 300 patients. ASA 1 and ASA 2 Patients scheduled for elective lower limb surgeries, of age 18 to 60 years with expected duration of surgery 1to 3 hours were selected for the surgery.

Patients who refused, those with contraindications for neuraxial block (coagulation defects, local infection) hypersensitivity to ondansetron and granisetron, uncontrolled hypertension, cardiovascular insufficiency were excluded.

After getting informedconsent, patients were randomly allocated into three groups using a random number table with 100 patients in each, named as group O, G and C, receiving intravenous ondansetron 4mg ie 2ml, granisetron 1mg with 1 ml normal saline, and normal saline 2 ml respectively. All patients received oral ranitidine150 mg and metoclopramide 10 mg on previous night of surgery and on morning of surgery. On the operation table, basal non-invasive BP, pulse rate and SpO_2 were recorded and patients were coloaded with 20 ml/kg of normal saline.

Five minutes before providing spinal anaesthesia, Group O patients received ondansetron 4 mg, Group G received granisetron 1 mgin 1ml saline and Group C received 2 ml normal saline intravenously. Spinal anaesthesia was given in the lateral position using 0.5% heavy bupivacaine at L3-L4 level through a 23 gauge Quincke needle.

The parameters assessed were mean arterial pressure, heart rate, vasopressor use, time for sensory and motor blockade and their regression.

Mean arterial pressure and heart rate were observed from starting of spinal anaesthesia at 2 min intervals for the initial 10 min, then at 15 minutes, 20 minutes, and then every 10 min till 60 minutes. Upper sensory level was assessed using a 26 gauge IM needle by bilateral loss of pinprick at the midclavicular line every 2 min till the fixation of the sensory level at 2 consecutive times and this was taken as the maximum sensory level. Then, the patients were evaluated every 15 minutes for two segment regression of sensory level.

The time to upper sensory block (defined as the time between intrathecal injection and achievement of the highest level of sensory blockade), two-segment regression (defined as the time between achievement of the highest level of sensory blockade and its regression to a level two segments lower) were recorded and analysed.

Modified Bromage scale

Grade	Criteria	Degree of block (%)
I	Free movement of legs and feet	Nil (0)
II	Just able to flex knees with freemovement of feet	Partial (33)
III	Unable to flex knees, but withfree movement of feet	Almost complete(66)
IV	Unable to move legs or feet	Complete (100)

Motor block was assessed every 2 min by the modified Bromage scale till the achievement of complete motor block, then every 15 minutes till complete motor recovery. Decrease in MAP more than 20% of baseline value was treated with 6mg mephentermine, decrease in heart rate less than 50/minute treated with atropine and shivering treated with 25 mg tramadol.

Data collected were entered into a master chart and necessary statistical tables were constructed. Statistical analysis was performed using SPSS programme version 18. Data was reported as mean ± SD. Chi-square test was used for the analysis of incidence ofhypotension & ANOVA test were employed for the analysis of changes in mean arterial pressure, vasopressor use, motor and sensory blockade characteristics. A p value<0.05 was considered statistically significant.

Observations and Results

The demographic data were analysed using student's t test. The study groups were comparable in terms of age, height and duration of surgery, as shown in Table 1. (p value =0.575, 0.159, 0.117 respectively).

Mean arterial pressure was assessed before giving spinal anaesthesia (Basal MAP), and at 2 min, 4 min, 6 min, 8 min,10 min 15 min, 20 min, 30 min, 40 min and 60 min. after giving spinal anaesthesia. (Shown in Table 2) There were no significant differences in basal MAP among three groups. Incidence of hypotension was analysed by Chi-square test.

Decrease in mean arterial pressure was significantly lower in Group O than Group G and Group C at 6 minutes, 8 minutes,15 minutes,30 minutes, 40 minutes and 60 minutes with a P value of 0.03, 0.038, at 6 and 8 minutes. 0.001, at 15, 30, 40 minutes, and 0.004 at 60 minutes respectively. A comparison of changes in mean arterial pressure among the three groups were done by Post Hoc test as shown in Table 3. It showed that the decrease in mean arterial pressure was significantly lower in group O than other two at 6, 8, 15, 30, 40 and 60 minutes.

Table 1: Demographic data

	Group O	Group G	Group C	P value
Age (years)*	43.1 ± 10.2	44.1 ± 10.3	44.6 ± 9.6	0.575
Height (centimeters)*	164.14 ± 6.5	163.9 ± 7.3	164.43 ± 7.9	0.159
Duration of surgery (minutes)*	91.8 ± 23.5	93.2 ± 24.9	91.7 ± 23.3	0.117

Table 2: Mean arterial pressure

	Group O Mean ± SD	Group G Mean ± SD	Group C Mean ± SD	P value
0 min	86.5 ± 7.8	84.4 ± 7.8	82.9 ± 8.5	0.12
2 min	74.9 ± 5.6	73.6 ± 6.8	74.3 ± 7.2	0.37
4 min	68.9 ± 7.3	69.63 ± 7.7	67.9 ± 7.4	0.27
6 min	70.4 ± 7.6	68.7 ± 6.8	67.8 ± 6.7	0.03*
8 min	73.2 ± 6.5	71.7 ± 6.9	70.7 ± 7.4	0.038*
10 min	72.6 ± 7.7	74.4 ± 7.5	73.6 ± 8.3	0.27
15 min	77.5 ± 7.6	74.5 ± 7.2	73 ± 7.5	0.001*
20 min	74.7 ± 5.9	75.7 ± 6.4	73.8 ± 8.1	0.124
30 min	80.4 ± 6.8	79.3 ± 6.9	74 ± 7.8	0.001*
40 min	83.3 ± 7.4	81.5 ± 7.7	77.8 ± 8.5	0.001*
60 min	83.9 ± 8.2	82.9 ± 8.9	80.3 ± 6.9	0.004*

Table 3: Comparison of fall in mean arterial pressure

Dependent variable	Group 1	Group 2	Mean difference	P value
6 min	Group O	Group C	2.6	0.03
8 min	Group O	Group C	2.5	0.001
15 min	Group O	Group C	4.1	0.001
15 min	Group O	Group G	3.4	0.02
30 min	Group O	Group C	6.1	0.001
30 min	Group O	Group G	2.1	0.03
40 min	Group O	Group C	6.3	0.001
60 min	Group O	Group C	4.2	0.004
60 min	Group O	Group G	2.3	0.02

Mean value of mean arterial pressure was charted as shown in Figure 1. It is seen that mean arterial pressure lies above 70 mm Hg throughout the observation period in the ondansetron group.

On comparing the need for mephentermine as a rescue vasopressor, significant difference was seen among the groups, with decreased amount of vasopressor needed in Group O with a mean value of 5.76 mg, (SD of 4.46); when compared to 7.08 mg in Group G (SD of 4.77) and 7.44 mg in Group G, (SD of 5.40) as shown in Figure 2. On statistical analysis, a significant P value of 0.03 was obtained among the three groups; as well as when tested between groups using Post-hoc test.

Heart rate less than 50 beats/minute was taken as bradycardia, and there were no significant difference in incidence of bradycardia among three groups, with a p value of 0.828.

Time taken for (in minutes) the attainment of upper sensory level and 2 segment regression was assessed and analysed statistically. There were no significant difference among three groups with a P value of 0.294 and 0.74 respectively (Figure 3).

Table 4: Time taken for the attainment of modified Bromage grade 3

	Group O	Group G	Group C	P value
Time for modified bromage 3 (minutes)	122	125	123	0.294

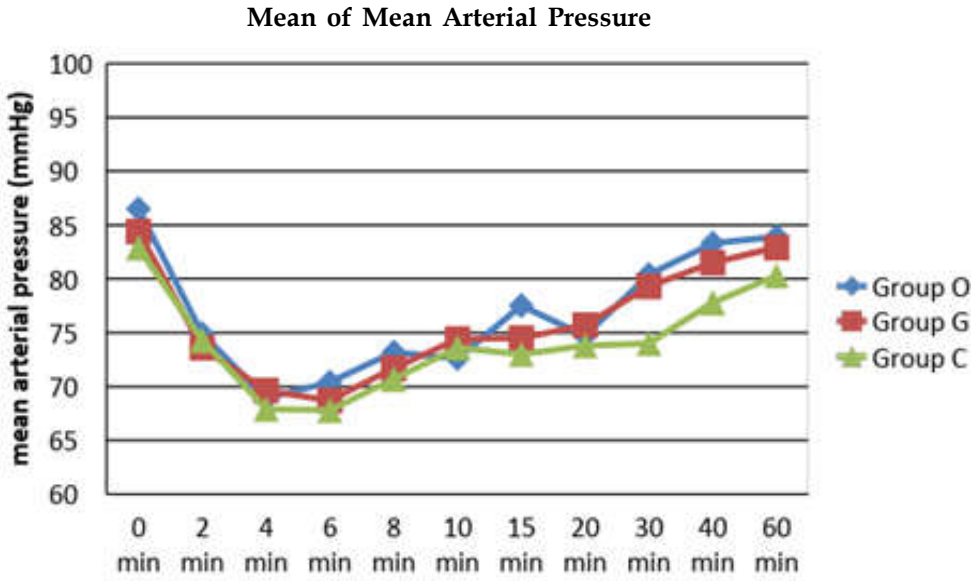

Fig. 1:

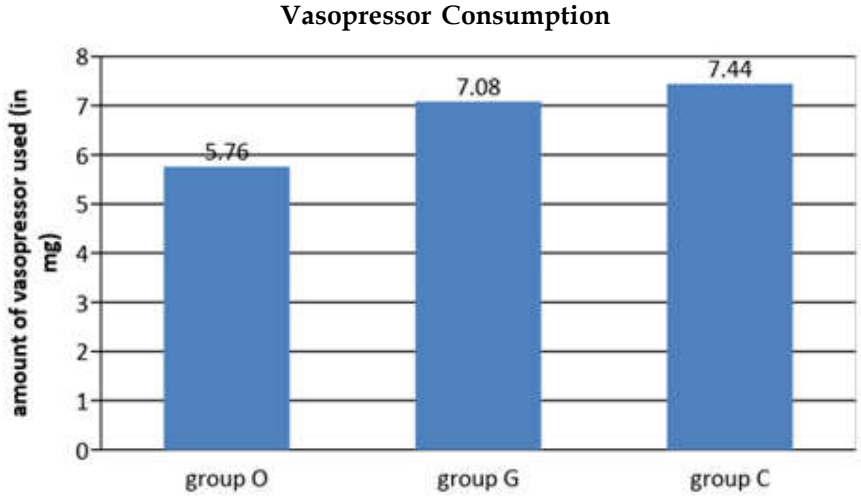

Fig. 2:

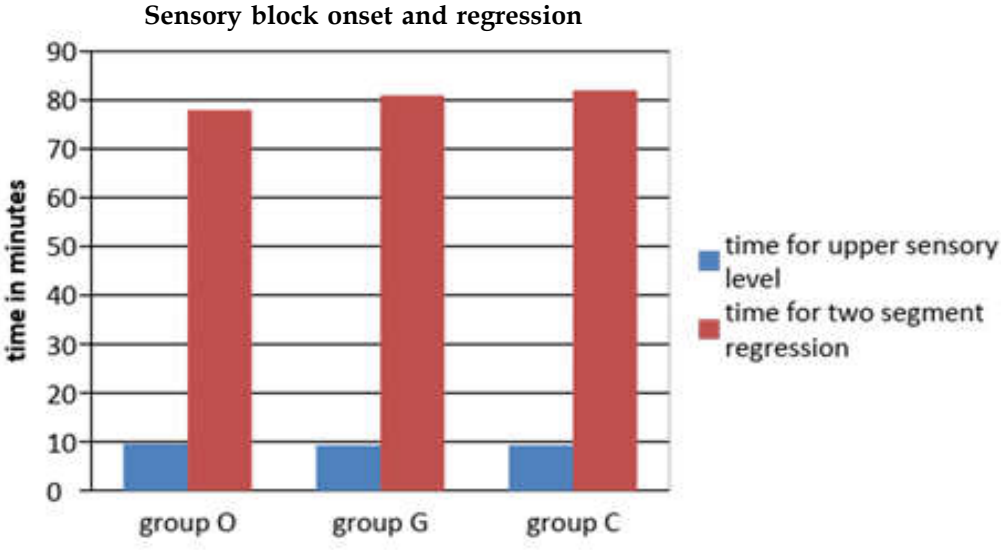

Fig. 3:

Timetaken (minutes) for the attainment of Modified Bromage scale was assessed.There was no significant difference among three groups with a P value of 0.294 (Table 4).

Discussion

Spinal anaesthesia is a simple, fast, reliable, and cost-effective technique which has emerged as the technique of choice for routine lower limb surgeries. It avoids the risk associated with general anaesthesia, but has some undesired effects associated with it, the most common being hypotension due to sympathetic block. Several studies were done in a trial to prevent undesired cardiovascular effects of spinal anaesthesia like hypotension, which in turn leads to multiorgan involvement.

Hypotension during subarachnoid block occurs due to a marked decrease in systemic vascular resistance by blockade of the sympathetic nerve fibres, which control vascular smooth muscle tone. The rate of onset and spread of the neuraxial blockade determines the extent of the sympathetic involvement and the severity of hypotension. Decreased stroke volume and heart rate is caused by blockade of the peripheral (T1-L2) and cardiac (T1-T4) sympathetic fibres as well as adrenal medullary secretion.

Bezold Jarisch reflex is also a cause of profound bradycardia and circulatory collapse after spinal anaesthesia, especially in the presence of hypovolemia. Mechanoreceptors of this reflex are located mainly in left ventricle.These receptors are activated by a rapid decrease in ventricular blood volume, induced by spinal anaesthesia, and gives feedback via the vagus nerve which triggers a vasodepressor response by increasing the activity of parasympathetic system. Systemic vasodilatation, hypotension and bradycardia occur as a consequence of this.

Serotonin can induce Bezold Jarisch reflex. The afferent limbis unmyelinated type C fibres that pass via the vagus nerve to the brainstem. 5-HT_3 receptors are mainly located in this infra cardiac afferent vagal and sympathetic neurons. $5HT_3$ receptors mediate the most dramatic cardiovascular effect of serotonin-The Bezold Jarisch reflex. Few seconds after intravenous administration of serotonin, a very strong bradycardia is observed followed by hypotension. These effects are due todepolarization and activation of afferent vagal nerve endings in the heart carrying $5HT_3$ receptors [8,9]. Direct stimulation of the cardiac 5-HT_3 chemoreceptors located on cardiac vagal afferents with serotonin or with 5-HT_3 agonists elicited BJR in several mammals [10,12]. Animal studies proved that intravenous or direct pericardial administration of $5HT_3$ antagonists completely abolished Bezold Jarisch reflex,induced by serotonin or $5HT_3$ agonists [4,7,11].

This study was designed to test the effectiveness of pre-treatment with intravenous granisetron and

ondansetron for the prevention of spinal anaesthesia induced hypotension and bradycardia due to Bezold Jarisch reflex. Current research in animals, obstetric and nonobstetric populations indicates that 5-HT3 antagonism may abolish the Bezold-Jarisch reflex.

We also attempted to study the effect of ondansetron and granisetron on sensory and motor blockade characteristics induced by spinal anaesthesia, sinceserotonin has got a definite role in antinociception. Serotonin acts as a neurotransmitter in the descending system that inhibits signals from peripheral nociceptors. 5-HT_3 receptors are present also in the dorsal horn of spinal cord and have antinociceptive effect, which can be antagonized by selective 5-HT_3 receptor antagonist [6].

Previous studies have concluded that 5HT_3 receptor antagonists are effective in preventing spinal anaesthesia induced hemodynamic changes [13,14,19,20].

There have been only a few studies which assess the effectiveness of ondansetron and granisetron for prevention of hemodynamic changes induced by spinal anaesthesia as wellas motor and sensory blockade characteristics.

In our study, onanalysis of the incidence of fall in mean arterial pressure, we found that the drop in mean arterial pressure were less for ondansetron group compared with granisetron and control group, at many time intervals, and the difference was statistically significant. The total amount of mephentermine as the vasopressor used to correct hypotension was significantly lower in ondansetron group compared with granisetron and control group, with a mean value of 5.76 mg, 7.08mg and 7.44 mg in ondansetron, granisetron and control group respectively.

Ondansetron is one of the medications studied before by Sahoo et al. [14] and proved that it attenuated hypotension induced by spinal anaesthesiaif given intravenously in caesarean section patients beforespinal anaesthesia and our results agreewith it. Tsikouris et al. [16] in their study with granisetron found that, it decreased heart rate and BP changes occurring during the head-up tilt table test due to Bezold Jarisch Reflex. In our study, it was found that granisetron has no effects on the hemodynamic variables, and this is in agreement with the study of Mowafi et al [6].

Bradycardia was considered when heart rate was below 50 per minute. Analysingbradycardia, there were no significant difference in the incidence of bradycardia between three groups.This finding is comparable with those of Rashad MM et al. [18], who studied the effect of ondansetron and granisetron on hemodynamic changes induced by spinal anaesthesia inparturients undergoing caesarean section and found that there were no significant difference in the incidence of bradycardia among three groups.

Animal studies clarified that serotonin has antinociceptive effect at the spinal cord level by inhibiting the excitatory transmittersand increasing the inhibitory transmitters [21,22] Consequently, serotonin antagonists decrease the nociceptive threshold as proved by Giordano and Dyche [23].

When we studied the effects of ondansetron and granisetron on sensory regression and motor block of subarachnoid anaesthesia it was found that intravenous ondansetron and granisetron did not affect sensory or motor block of intrathecal bupivacaine, similar to the observation made by Samra et al. in their study [17].

They did the study in 60 patients for TURP surgery under spinal anaesthesia, and found thattime to attain peak sensory block,time to two segment regression ,regression to the S_1 dermatome, and mean duration of motor block did not significantly differ between the ondansetronand control group. But Sasaki M et al. [24] found that systemic ondansetron enhance the sensory block regression after intrathecal lidocaine.

These differences between the effects of ondansetron and granisetron, both of them being in the same category and mechanism of action, may be due to the action of ondansetron on mixed receptors and the high selectivity of granisetron on 5-HT_3 receptors than to other 5-HT receptors [25].

Conclusion

Prophylactic intravenous use of 4 mg ondansetron reduces the severity of spinal anaesthesia induced hypotension and the need for rescue vasopressor than with granisetron and control groups.

There were no significant differences in the incidence of bradycardia,sensory and motor blockade characteristics among groups.

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Original Research Article

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A Comparative Study of Low Doses of Intrathecal Ketamine and Midazolam with Bupivacaine for Infraumbilical Surgeries

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Abstrct

Aim: The aim of this study is to evaluate the effect of the low doses of ketamine and midazolam with bupivacaine intrathecally in terms of duration of analgesia and haemodynamic parameters. *Materials and Methods:* This prospective randomized double blind study conducted in patients posted for Infra umbilical surgeries. Patients with physical status ASA I and ASA II with Infra umbilical surgeries like herniorrhaphy, varicose vein surgery, orthopaedic surgeries with less than 3 hr duration were taken up for the study. *Results:* All demographic details are not significant. With addition of midazolam and ketamine the mean onset of sensory block is quicker compared to other two groups. with addition of midazolam and ketamine the mean onset of motor block is quicker compared to other two groups. With addition of Midazolam and ketamine the maximum sensory level and reached in higher compared to other two groups. With addition of midazolam and ketamine the duration of sensory block and motor block is prolonged compared to other two groups. With addition of ketamine and Midazolam the mean duration of pain free interval is prolonged and rescue analgesics required are less compared to other two groups. In all three groups the mean systolic blood pressure was comparable and they are not statistically significant. The Vasopressors required in Group A and C were compared and they are not statistically significant. In Group B and Group C the sedation score was higher compared to Group A. *Conclusion:* Low doses of preservative free ketamine (0.1mg/kg) and midazolam (0.02mg/kg) when added to bupivacaine intrathecally provides prolonged post operative analgesia without any significant side effects.

Keywords: Intrathecal Ketamine; Midazolam; Bupivacaine; Infraumbilical Surgeries.

Introduction

The term "Spinal Anaesthesia" was coined by Leonard Corning in 1885. In 1898, the first deliberate spinal anaesthesia was given to August Karl Gustav Bier by his assistant Dr. Hildebrandt. The second attempt was done on the theca of Dr. Hildebrandt. Twenty three minutes after the injection of cocaine, Dr. Bier noted "A strong blow with an iron hammer against the tibia was not felt as pain." The simplicity of the technique of spinal anesthesia and its reliability had made it one of the preferred techniques in infraumbilical surgeries.

Bupivacaine when used alone intrathecally produces analgesia for three to four hours, making it unsuitable in cases where the duration of surgery is longer. Different adjuvants such as opioids, clonidine or neostigmine may be added to enhance spinal anesthesia, though their use is limited because of side effects.

Ketamine is a potent analgesic acting as an antagonist at N - Methyl - D aspartic acid receptor sites and has a local anaesthetic action. Intrathecal ketamine has been used as a sole agent or in combination with local anaesthetics. It provides stable haemodynamics but shorter duration of action.

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Midazolam has a spinally mediated anti-nociceptive effect and enhance the analgesic effect of local anaesthetics when used intrathecally. It improves the duration and quality of the spinal anaesthesia, though it does not prevent the haemodynamic instability produced by intrathecal bupivacaine. Hence this study is done to evaluate the effect of small doses of ketamine and midazolam with bupivacaine intrathecally in terms of duration and quality of analgesia and side effect profile.

Materials and Methods

This prospective randomized double blind study conducted in patients posted for Infra umbilical surgeries. Approval from the Ethical Committee was obtained and Written informed consent was taken from all patients

Inclusion Criteria

Patients with physical status ASA I and ASA II with Infra umbilical surgeries like herniorrhaphy, varicose vein surgery, orthopaedic surgeries with less than 3 hr duration were taken up for the study.

Exclusion Criteria

Morbidly obese patients, pregnant women, patient with neurological disease or any contraindication for regional technique were excluded from the study.

Three groups were selected. Patients were randomly assigned to one of the three groups. Patients and anaesthesiologist were blinded to the test drug. The volume of the test drug was kept 3.5 ml in all patients. After attaching the patients to monitors, baseline values of heart rate, systolic, diastolic, mean arterial pressure and oxygen saturation were noted. They were preloaded with 10 ml/kg intravenous crystalloid solution.

Procedure

Under strict aseptic precaution, lumbar puncture was performed at L3-L4 interspace using a 25-G Quincke's needle. After achieving free flow of cerebrospinal fluid the study drug was injected into the subarachnoid space.

Study Groups

Each study group consisted of 30 patients. Patients in all 3 groups received 3 ml of bupivacaine (heavy) 0.5%. In addition, patients in group B received preservative free ketamine 0.1 mg/kg and those in group C received preservative free ketamine 0.1mg/kg and midazolam 0.02 mg/kg intrathecally. The exact amount of ketamine and midazolam were measured using a tuberculin syringe and the final volume of the test drug in all the groups was made up to 3.5 ml by adding normal saline.

Heart rate, non invasive blood pressure and SPO_2 were measured at 2.5 mt interval of the drug injection for the first 20 minutes and thereafter every 10 mt until the end of the surgery. Any decrease in MAP below 20% of the baseline or systolic pressure less than 90mmHg was treated with a bolus dose of ephedrine (6 mg).

Sensory Blockade

Sensory blockade was assessed by pin prick in the mid axillary line at 1 mm intervals until the level of block reached T10. The maximum height of the sensory blockade was noted at 20 minutes. Onset of sensory block was defined as the time taken from injection of drug to sensory block at T 10 and offset of sensory block was assumed when pinprick sensation at the S2 dermatome has returned. Duration of sensory block was defined as the time interval between onset of sensory block at T10 to regression of sensory block to S2.

Motor Blockade

Motor block was assessed by the Modified Bromage score.

0	-	No motor loss
1	-	Inability to flex hip
2	-	Inability to flex knee joint
3	-	Inability to flex ankle

This was assessed at 1 minute interval until complete motor blockade occurred. Onset of motor block was defined as the time taken from injection of drug to development of complete motor block. (Bromage Score-3). Bromage score '0' was considered as complete recovery from motor block. Duration of motor block was defined as time taken from onset of complete motor block to complete recovery of motor block.

Pain

Pain was assessed by an 11 point verbal rating scale (Score 0 - 10) which was explained to the

patient preoperatively. If any patient complained of pain at any time in the intraoperative period, he/ she was given general anaesthesia and was excluded from the study. Post operatively pain was assessed at 2 hour interval for the first 12 hours and then at 4 hour interval for 24 hours. Rescue analgesia in the form of Inj. Tramadol 100 mg IM was given if the pain score was equal to or more than 4. Duration of pain free period was measured from the time of spinal administration of the drug to the time when the patient needed the first rescue analgesia drug. The total number of doses of rescue analgesic requirement in 24 hr was also noted.

Sedation

The level of sedation of the patients was assessed by the Ramsay sedation score.

1 - Anxious and agitated

2 - Co-operative

3 - Asleep but brisk response to loud voice

4 - Asleep with sluggish response to loud voice

5 - No response to loud voice

6 - No response to pain

It was assessed every 15 mm after injecting the drug until the sedation score was 2. All patients were followed after surgery upto 24 hrs for any behavioural side effects, confusion, dizziness, nystagmus, nausea, vomiting or any neurological complications like numbness or pain in the opposite leg, incontinence or retention of bowel or bladder or genital dysaesthesias.

The main end points of our study were

1. Postoperative pain free interval
2. Haemodynamic stability shown in terms of requirement of ephedrine to treat hypotension.
3. Any neurological complication in 24 hrs.

Statistical Tools

The information collected regarding all the selected cases were recorded in a Master Chart. Data analysis was done with the help of computer using. Using this software range, frequencies, percentages, means, standard deviations, chi square and 'p values were calculated. Kruskul Wallis chi-square test was used to test the significance of difference between quantitative variables and Yate's test for qualitative variables. A 'p' value less than 0.05 is taken to denote significant relationship.

Results

In this randomized double blind study conducted in 90 patients, the subjects were allocated into three groups. All 3 groups were comparable in age, height, weight, duration of surgery. In all the three groups the mean age were comparable and they are not satisfactorily significant. In all the three groups the sex distribution were comparable and they are not satisfactorily significant. In all the three the mean weight were comparable and they are not satisfactorily significant. The ASA physical status in all the three groups were comparable and they are not satisfactorily significant (Table 1).

Table 1: Demographic distribution

Age Group	Group A		Group B		Group C	
	No.	%	No.	%	No.	%
Up to 30 yrs	7	23.3	2	6.7	4	13.3
31 – 40	16	53.3	20	66.7	6	20
41 – 50	5	16.7	7	23.3	10	33.3
> 50	2	6.7	1	3.3	10	33.3
Total	30	100	30	100	30	100
Gender						
Male	24	80	21	70	25	83.5
Female	16	20	9	30	5	16.5
Total	30	100	30	100	30	100
ASA physical status						
I	23	76.7	25	83.3	25	83.3
II	7	23.3	5	16.7	5	16
Range	26-63 yrs		28-60 yrs		23-61 yrs	
Mean	37.93		38.77		41.67	
SD	8.87		6.94		10.6	
'P' Value for	0.1433 Not significant					

Table 2: Onset of Sensory and Motor Block (minutes)

Onset of Sensory Block	Group A Bupi	Group B Bupi/Ket	Group C Bupi/ket/mida
Range	4.5-6.5	3.5-10	3-5
Mean	5.55	7.2	3.92
SD	0.54	2.04	0.5
'P' Value for			
A.B & C		0.0001 Significant	
A & B		0.0033 Significant	
A & C		0.0001 Significant	
B & C		0.0001 Significant	
Onset of Motor Block	**Group A**	**Group B**	**Group C**
Range	7.5-10	7.5-10	5.5-7.5
Mean	8.55	8.55	6.78
SD	0.63	0.63	0.6
'P' Value for			
A.B & C		0.0001 Significant	
A & B		1.0 Significant	
A & C		0.0001 Significant	
B & C		0.0001 Significant	

With addition of midazolam and ketamine the mean onset of sensory block is quicker compared to other two groups. with addition of midazolam and ketamine the mean onset of motor block is quicker compared to other two groups (Table 2).

Maximum sensory level of T4 was reached in 13.3% of cases in Group A. Maximum sensory level of T4 was reached in 13.3% of cases in Group B. Maximum sensory level of T4 was reached in 70% of cases in Group C. With addition of Midazolam and ketamine the maximum sensory level and reached in higher compared to other two groups (Figure 1).

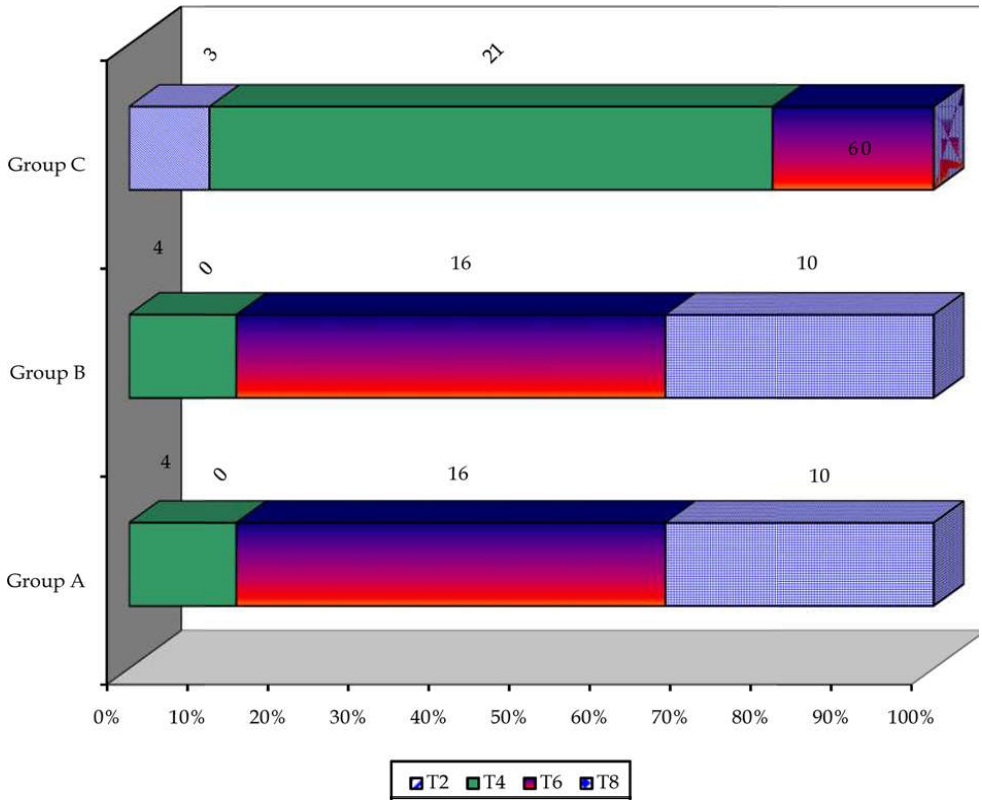

Fig. 1: Maximum Sensory Level

Table 3: Duration of Sensory and motor Block

Onset of sensory Block	Group A	Group B	Group C
Range	160-240	180-280	200-360
Mean	199.7	207	266.3
SD	17.3	21.4	41.6
'P' Value for			
A.B & C		0.0001 Significant	
A & B		1.2436 Not Significant	
A & C		0.0001 Significant	
B & C		0.0001 Significant	
Range	100-180	150-240	160-240
Mean	159.7	181.3	208.7
SD	15.6	20.1	22.7
Duration of Motor Block			
'P' Value for			
A.B & C		0.0001 Significant	
A & B		0.0001 Significant	
A & C		0.0001 Significant	
B & C		0.0001 Significant	

With addition of midazolam and ketamine the duration of sensory block is prolonged compared to other two groups. with addition of ketamine and midazolam the mean duration of motor block is prolonged compared to other two groups (Table 3).

With addition of ketamine and Midazolam the mean duration of pain free interval is prolonged compared to other two groups (Table 4).

With addition of ketamine and Midazolam the number of rescue analgesics required are less compared to other two groups. In all three groups the mean systolic blood pressure was comparable and they are not statistically significant (Figure 2).

Table 4: Duration of pain free Interval (in Minutes)

Duration of pain free interval	Group A	Group B	Group C
Range	240-440	200-360	360-900
Mean	303	296	473
SD	57.4	32.5	136.2
'P' Value for			
A.B & C		0.0001 Significant	
A & B		1.0002 Significant	
A & C		0.0001 Significant	
B & C		0.0001 Significant	

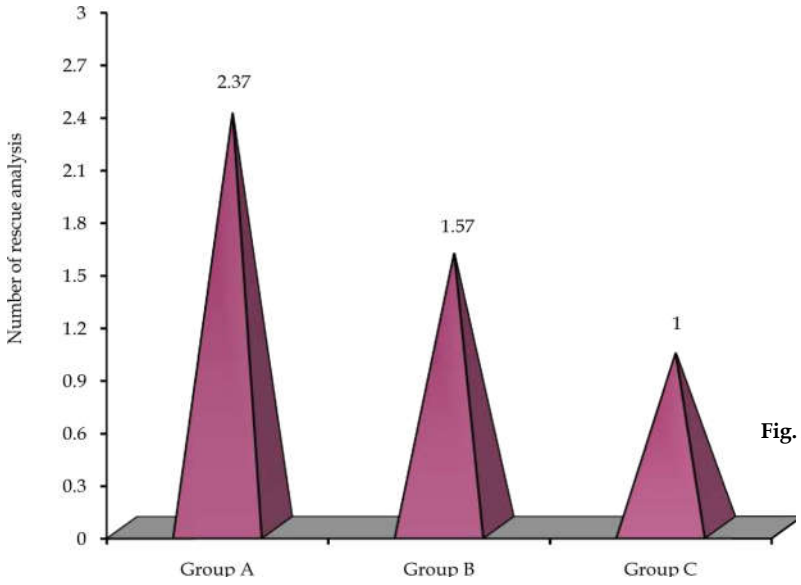

Fig. 2: Number of rescue analgesics

The minimum systolic blood pressure in Group A is comparable to Group C. The minimum systolic blood pressure in Group B and C are not significant and this finding is an added advantage to ketamine midazolam group. In Group B the fall in systolic blood pressure is less comparable to other two groups. (Table 5).

The Vasopressors required in Group A and C were compared and they are not statistically significant. In both these groups the vasopressor requirement was comparable. In Group B the Vasopressor requirement is less compared to other two groups. (Figure 3).

In Group A the range of sedation score was 1-2. In Group B the range of sedation score was 2-3. In Group C the range of sedation score was 2-3. In Group B and Group C the sedation score was higher compared to Group A. (Table 6).

Table 5: Minimum Systolic Blood Pressure

Minimum Systolic B.P	Group A	Group B	Group C
Range	84-110	88-120	80-110
Mean	95.4	104.7	94.9
SD	8.0	8.3	8.0
'P' Value for			
A.B & C		0.0001 Significant	
A & B		0.0002 Significant	
A & C		0.9402 Not Significant	
B & C		0.0001 Significant	

Table 6: Sedation Score

Sedation Score	Group A		Group B		Group C	
	No.	%	No.	%	No.	%
1	5	16.7	–	–	–	–
2	25	83.3	8	26.7	7	23.3
3	–	–	22	73.3	23	76.7
Range	1-2		2-3		2-3	
Mean	1.83		2.73		2.77	
SD	0.38		0.45		0.43	
'P' Value for						
A.B & C			0.0001 Significant			
A & B			0.0001 Significant			
A & C			0.0001 Significant			
B & C			0.7675 Not Significant			

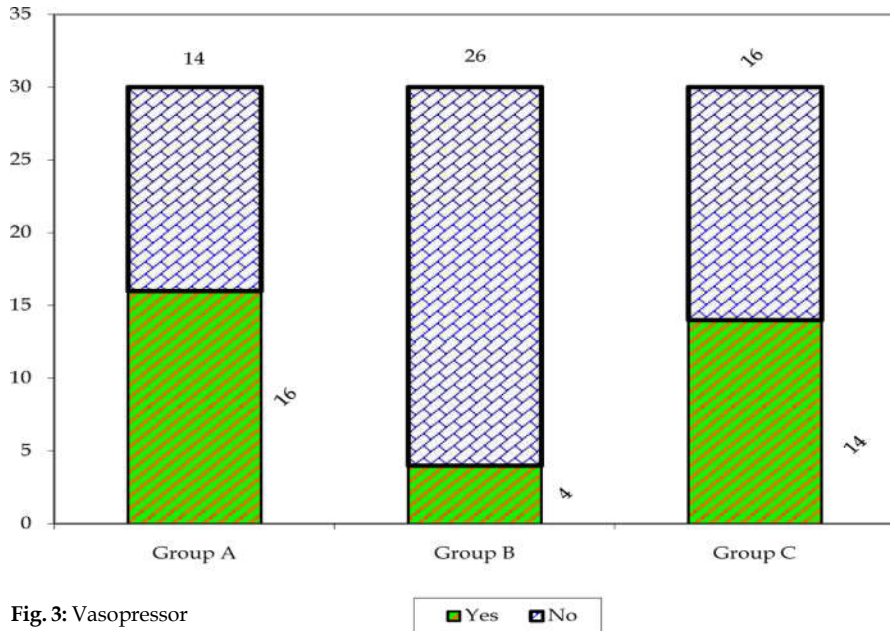

Fig. 3: Vasopressor

Discussion

Ketamine and midazolam are two important anaesthetic drugs which are administered in various routes. Ketamine as slow intrathecal agent was used by Bion and colleagues in 1984 [1]. Kathirvel and colleagues [2] were the first to use ketamine with local anaesthetics intrathecally. Spinal ketamine binds to the phencyclidine site of the NMDA receptor gated calcium channel and inhibits the NMDA receptors non competitively. Its direct axonal blocking effect produces some local anaesthetic activity.

Intrathecal midazolam has been shown to have analgesic properties and potentiates the effects of local anaesthetics. It is an agonist at the benzodiazepine site on a subunit of the pentomeric GABA a receptor. Midazolam tends to suppress afferent evoked excitation in the substantia gelatinosa and motor horn of the spinal cord. Bharti and colleagues [3] had found that postoperative pain Scores were lower in patients who received intrathecal midazolam with bupivacaine.

Kim and colleagues [4] used intrathecal midazolam in doses of 1 and 2 mg along with bupivacaine and found that the duration of postoperative analgesia was significantly prolonged by addition of intrathecal midazolam and was dose dependent.

In this study addition of ketamine and midazolam to bupivacaine (Group C) prolongs the duration of sensory and motor blockade. The mean pain free period was also significantly prolonged. The numbers of reserve analgesics were comparatively less. This finding is consistent with the study done by T. Murali Krishna and colleagues [5] who used low doses of ketamine and midazolam with bupivacaine for orthopaedic surgeries.

In this study addition of ketamine to bupivacaine (Group B) does not alter significantly the time for onset or duration of sensory and motor blockade. The duration of pain free period was also less compared to the midazolam Ketamine group. This finding is consistent with the study done by T. Muralikrishna and colleagues [5], Kathirvel and colleagues [2].

This infers that midazolam in (dose 0.02 mg /kg) when added to ketamine in dose (0.1 mg/kg) and bupivacaine prolongs significantly the duration of post operative analgesia. This might be due to synergistic action of intrathecal midazolam. Ketamine and bupivacaine.

In this study addition of low dose of ketamine with bupivacaine (group B) resulted in stable haemodynamics with decreased incidence of hypotension. This finding is consistent with the previous studies by T. Murali Krishna and colleagues Kathirvel and colleagues and Bion and colleagues [1,2,5]. This may be due to diffusion of ketamine into the venous system of spinal cord which in turn results in cardiovascular stimulation and hemodynamic stability after spinal anesthesia [7,8,9].

In this study the level of sedation was assessed by Ramsay sedation score [6]. The level of sedation at 15 and 30 mm after the block was higher in Group B and C compared to Group A. The maximum level of sedation observed is any patient was 3. No patient required any manoeuvre to maintain airway. Thus intrathecal midazolam and ketamine in low doses had minimal effect on the level of sedation. This finding is consistent with the observation made by T. Murali Krishna and colleagues [5].

Conclusion

From the study it was concluded that low doses of preservative free ketamine (0.1mg/kg) and midazolam (0.02mg/kg) when added to bupivacaine intrathecally provides prolonged post operative analgesia without any significant side effects.

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Original Research Article

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Comparative Study of Ultrasound Guided Transversus Abdominis Plane Block with Caudal Epidural for Infraumbilical Surgeries in 1 to 7yr old Children: A Double Blind Randomised Prospective Study

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Abstract

Background: Transversus abdominis plane block (TAPB) has emerged as a safe and effective regional anaesthesia technique for providing postoperative analgesia following lower abdominal surgeries. Complications associated with ultrasound guided TAPB are rare and pose a lower overall risk to the patient receiving TAPB versus caudal block (CEB), which is considered as gold standard for paediatric lower abdominal surgeries. Our study hypothesis was that TAPB would initially be equivalent to caudal block in providing postoperative pain control but would also show improved pain relief beyond the anticipated caudal duration. *Methods:* This was a randomised controlled trial involving 80 children, 1-7yrs old, randomly allocated into one of the two equal groups; TAPB group (T-group) and CEB group (C group). Children underwent lower abdominal surgeries. All children received general anaesthesia using ketamine 2mg/kg and 1% sevoflurane. Group T received 0.5ml/kg of 0.25% bupivacine and group C received 0.75ml/kg of 0.25% bupivacaine under ultrasound guidance. Primary outcome measures were pain scores and duration of analgesia. Pain scores were assessed using Wong Baker FACES scale and FLACC scale. Secondary outcome measured were time taken for instilling the block, hemodynamics, and parent satisfaction and any other adverse events. *Results:* TAPB patients had significantly longer duration of analgesia compared to CEB patients ($p<0.001$). Regarding pain scores, after 6hrs, there was a significant difference in the pain scores ($p=0.02$) between two groups with group T having low pain scores. There was no statistically significant difference in the time taken for instilling the block ($p=0.139$). There was statistically significant increase in HR and MAP intra-operatively in group T patients ($p<0.001$) at 10 and 15min post block time. There was no statistically significant difference between two groups regarding parent's satisfaction. ($p=0.136$).Thus pain scores were significantly lower in group T and duration of analgesia also lasted longer. None of our patients had any complications postoperatively nor did we have any exclusions. *Conclusion:* Both CEB and TAPB give adequate analgesia during the early Post-operative period. However, TAPB results in prolonged analgesia beyond the anticipated CEB duration. Considering the safety profile of TAPB and avoiding the narcotics related side effects, this should be considered a preferred regional technique over CEB for lower abdominal surgeries whenever possible.

Keywords: Transversus Abdominis Plane Block; Caudal Epidural; Ultrasound Guided Abdominal Blocks.

Introduction

Management of postoperative pain is still unsatisfactory in paediatric patients. Most of the western studies using TAPB or CEB for analgesia have used them as a component of multimodal analgesia, which also included use of opioids in postoperative period. Opioids used for postoperative analgesia are frequently associated with adverse effects like nausea, vomiting, constipation, excessive sedation or inadequate pain relief. Because of these adverse effects and inadequate training in postoperative pain assessment and management by nursing staffs in most of the hospitals in India, and due to difficulty in obtaining licence for getting opioids, opioids are not used in postoperative period. Regional anaesthesia techniques are widely used to improve postoperative analgesia and reduce requirement of

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intravenous analgesics.

Caudal extradural block is gold standard technique followed around the globe, in conjunction with general anaesthesia for perioperative pain management in procedures involving lower abdominal surgeries including genitourinary surgeries. It blocks both somatic and visceral pain and thus reduces the requirement of general anaesthetics and attenuates the stress response to surgery. The caudal block has low complication rates (0.7 per 1000) [1], provide 4 to 6 hrs of analgesia, and results improved pain scores than in patients receiving general anaesthesia alone [2,3,4]. Nevertheless, as a neuraxial block, the potential complications are more serious than those associated with peripheral nerve blocks [5] and it is contraindicated in cases of impaired haemostasis, bacteraemia and neuraxial abnormality. Ultrasound is increasingly used to perform caudal block as an adjunct tool to guide cannula placement and to demonstrate accurate deposition of local anaesthetics in the caudal space; however its utility for decreasing the complication is yet to be determined [6,7].

An increasing understanding of abdominal wall anatomy has led to the introduction of Transversus abdominis plane block (TAPB) for managing pain after abdominal surgeries. It comprised of deposition of local anaesthetics into the anatomical plane between the transversus abdominis and internal oblique muscles, where thoraco-abdominal nerves (T6 – L1) contribute to the main sensory supply of skin, muscles and parietal peritoneum of the anterior abdominal wall [8,9].These nerves branch and communicate extensively with each other in this plane. TAPB provides reliable unilateral sensory block with single injection and results in significant reduction in opioid requirement and postoperative pain scores for 15 to 24 hours [10] after major abdominal surgeries. Complications associated with TAPB are rare, especially when performed under direct ultrasound visualisation, lack long-term consequences, and do not require additional interventions [11,12].

So we conducted this randomised controlled trial to compare the efficacy of ultrasound guided (USG) caudal epidural block (CEB) with that of USG guided TAPB for providing analgesia for children undergoing infraumbilical abdominal surgeries and also to know the effectiveness of these blocks in avoiding the need for additional anlgesics.

Materials and Methods

Source of Data

Ethical committee approval was obtained for this study from our hospital ethical committee (ICE NO: SIMS & RC/IECC/07/2017).The study was conducted on ASA1 and ASA2 children of 1yr to 7yrs patients admitted for elective infraumbilical abdominal surgeries under general anaesthesia. Purposive Sampling technique was used in selecting the patients for the study. Total number of abdominal surgeries per month at the department of paediatric surgery in our hospital is approximately 20. Study was planned for a duration of 6months [2017 Aug to 2016 Jan]. Considering the duration of study, number of surgeries in the department and exclusion criteria, we selected 40 patients in each group.

Exclusion Criteria

Parent Refusal

Allergy to local anaesthetics

Contraindication to caudal and TAP block due to local infection.

Hypospadiasis repair, PSARP, anorectal procedures where TAPB can't be given for pain relief.

Method of Study

Informed written parental consent was obtained from all. All children were premedicated with 0.1mg glycopyrrolate and 0.2mg/kg ketamine i.v. at receiving area. Once child is sedated, quickly shifted to operation theatre and preoxygenation was done for 3min while connecting the monitors. Monitoring included SpO_2, NIBP, ECG and $EtCO_2$. Then induction was done using sevoflurane3% inhalation in 33% O_2 and 66%N_2O. Fentanyl 1mcg/kg i.v. was given. Then appropriate size laryngeal mask airway [LMA] or i-gel was inserted when conditions were satisfactory. [Jaw relaxed, regular respiration, lash reflexes disappeared]. If endotracheal intubation [ETI] to be done, inj. atracurium 0.3mg/kg was given and mask ventilation was done for 3min.Then intubation was done using appropriate sized endotracheal tube.

Patients were randomised by sealed envelope technique to TAPB (group T) or to CEB (group C). Skin was prepared with betadine solution and a high frequency (8-13MHz) linear Ultrasound probe cleaned with same betadine solution was used for the block. Then USG guided TAPB was given at mid axillary line using **in plane** approach with 21G hypodermic needle connected to a 10cm extension

tube loaded with LA. TAPB given using 0.5ml/kg of 0.25% bupivacaine or USG guided CEB was done using o.75ml/kg of 0.25% bupivacaine. For pyeloplasty we used 1ml/kg of 0.25% bupivacaine for CEB. For midline incision surgeries bilateral USG guided TAP was given with 0.5ml/kg of 0.25% bupivacaine. For doing CEB, first linear US probe cleaned with betadine was placed over the sacral cornuae to visualise frogeye appearance. Then USG guided CEB was given using **out of plane** method to visualise the needle tip and widening of the frogmouth appearance. Time taken for instilling the block, i.e. from placement of USG probe till LA injection, was noted. After the block sevoflurane was reduced to 1%. An increase in blood pressure and heart rate by more than 15% from pre procedure value for skin incision was considered as insufficient analgesia and was supplemented with fentanyl 1mcg/kg and sevoflurane 2% in N_2O and O_2. Intraoperatively all children received fluids [500DNS+10meqKCL] according to Holiday Seggars formula. All children received antiemetic, inj. ondansetron 100mcg/kg towards the end of the surgery before extubation or removal of LMA or i-Gel. LMA /i-gel was removed when the child was, awake and airway reflexes were present. Intubated children were reversed with 0.05mg/kg neostigmine and 0.001mg/kg glycopyrrolate. Extubation was done when the child was fully awake. Then the child shifted to post-anaesthesia care unit.

Assessment

Pain was assessed using age appropriate scales, Wong Baker FACES scale and FLACC scale after shifting to PACU. First assessment of pain was done once the child started taking orally which is usually 3hr after the surgery in our institution. This is to avoid the bias of crying due to irritability or due to NPO status rather than the pain. Then assessment was done after 6 Hrs, 9 Hrs, 12 Hrs and 24 Hrs in

Fig. 1: Wong- Baker Faces Pain Rating Scale

Table 1: FLACC Scale

Face	0	1	2
	No particular expression or smile	Occasional grimace or frown, withdrawn,disinterested	Frequent to constant frown,clenched jaw,quivering chin
Legs	0	1	2
	Normal position or relaxed	Uneasy,restless,tense	Kicking,or legs drawn up
Activity	0	1	2
	Lying quietly, normal position,moves easily	Squirming, shifting back and forth,tense	Arched,rigid, or jerking
Cry	0	1	2
	No cry (awake or asleep)	Moans or whimpers, occasional complaint	Cries steadily,screams or sobs,freqent complaints
Consolability	0	1	2
	Content, relaxed	Reassured by occasional touching,hugging, or talking to; distractible	Difficult to console or comfort

the following manner.

Pain assessment was done by post-operative ward staff. Both, the patients and staffs were blinded to the group. All patients received paracetamol syr.15mg /kg 8th hrly. At any given point of time if the score is >4, it was instructed to give additional analgesia of inj paracetamol 15mg/kg. And that was considered the end point for assessment of postoperative analgesia. If pain still not relieved, diclofenac suppository 1mg/kg was advised. Those children whose NPO lasted more than 6hrs, received IV paracetamol 15mg/kg 8th hrly. Postoperative recordings also included heart rate and mean arterial pressure for two hrs.

Other complaints like irritability, nausea, vomiting, time when the child passed urine were recorded. Any other medications given were noted. Recovery room staff involved in assessment were blinded to the study groups.

Primary outcome measures were pain scores and duration of analgesia. Secondary outcome measures were time taken for instituting the block, hemodynamics, and any bladder dysfunction, parent satisfaction and any other adverse events.

Statistical Analysis

Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean±SD (Min–Max) and results on categorical measurements are presented in number (%). Significance was assessed at 5% level of significance. Student t – test and chi square test is used to find and compare the difference in each group. If P <0.005 is considered statistically significant [18,19,20].

Results

From aug 2017 to jan 2018, 80 patients were enrolled for the study. There were no exclusion since CEB and TAPB were done under USG guidance. Due to the nature of surgeries performed, there were more male patients than female; however, male to female ratio was similar in both the study groups. Data such as age (p=0.526), gender (p=1.00) and type of surgeries in both the groups were comparable.

Pain scores were comparable amongst two groups during initial postoperative period. (P=0.516; Table 2). However, after 6hrs, pain scores were better with TAPB. (Table 2). Similarly FLACC scores were comparable amongst both the groups during the initial 6hrs. After 6hrs there was a significant difference with pain scores between

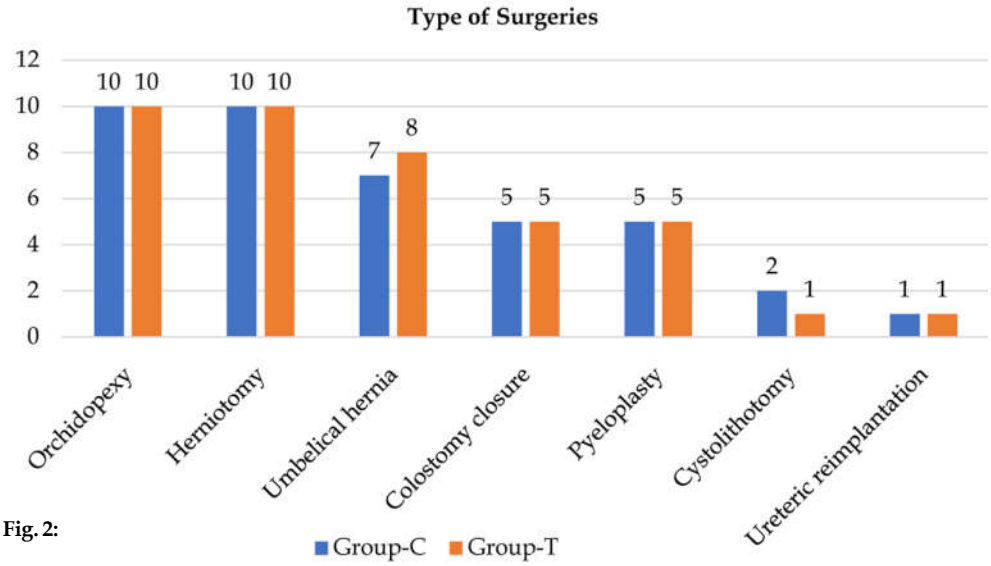


Fig. 2:

Table 2: Comparison of Pain Score in two groups of patients studied

Pain score	Group C	Group T	P value
3hr	0.50±0.88	0.63±0.84	0.516
6hr	0.55±0.90	0.95±0.93	0.055+
9hr	1.65±1.69	1.05±0.96	0.054+
12hr	1.70±1.60	1.05±0.90	0.028*
24hr	1.70±1.62	0.98±1.05	0.020*

both the groups (Table 3, p = 0.020).

TAPB patients had significantly long duration of analgesia compared to CEB (p < 0.001).

Time when rescue analgesia was given also was longer with TAPB than with CEB (p <0.001; Table 4). Analgesia lasted for more than 10hrs in all TAPB patients whereas none of the patients in CEB had analgesia more than 10hrs (Table 4)

Only two patients in CEB group who underwent orchidopexy and a patient in TAPB group who underwent ureteric re-implantation had postoperative vomiting which was treated with

Inj.ondansetron. None of our patients had any other problems like spasmodic pain, urinary retention, and respiratory problems.

Regarding the time taken for instituting the block, there was no significant difference (p=0.139, Table 5). There were no block related complications and all blocks were completed within 5 min.

Figure 3 and Figure 4 shows that the mean arterial pressure (MAP) and heart rate (HR) were comparable in both the groups except at 10 min and 15 min time. In patients who received TAPB there was increase in MAP and HR 10min and 15min. the difference was significant (p=0.01 at 10min and <0.001 at 15min). However, all the changes were within clinically accepted range.

There was no statistically significant difference between two groups with regard to parents

Table 3: FLACC SCORE- Comparative assessment in two groups of patients studied

FLACC Score	Group C	Group T	P value
3hr	0.50±0.88	0.60±0.78	0.591
6hr	0.55±0.90	0.83±0.84	0.164
9hr	1.50±1.68	0.93±0.86	0.058+
12hr	1.50±1.60	0.93±0.97	0.056+
24hr	1.70±1.62	0.98±1.05	0.020*

Table 4: Time when rescue Analgesia (Hrs.) given

Rescue Analgesia (hrs)	Group C	Group T
<8	17(42.5%)	0(0%)
8-16	23(57.5%)	11(27.5%)
>16	0(0%)	29(72.5%)
Total	40(100%)	40(100%)

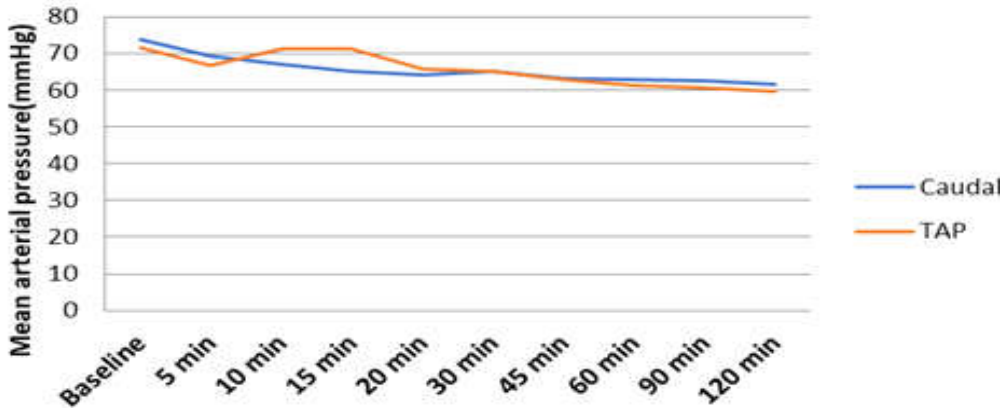
p<0.001**

Table 5: Procedure time (seconds)

Procedure time (seconds)	Group C	Group T
<80	3(7.5%)	19(47.5%)
80-160	33(82.5%)	9(22.5%)
160-240	0(0%)	4(10%)
>240	0(0%)	6(15%)
Total	40(100%)	40(100%)

P=0.139

Fig. 3:



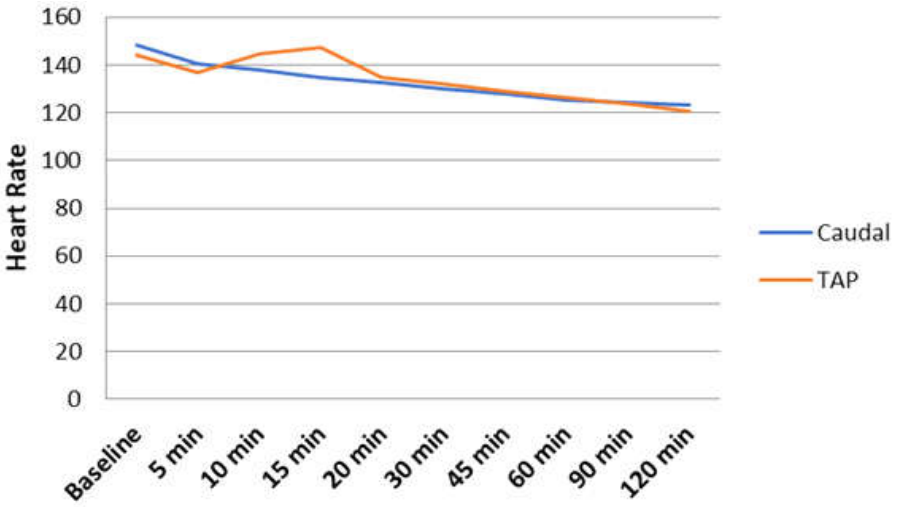


Fig. 4:

Satisfaction (chi sq value =2.222; p=0.136).

Discussion

TAPB has emerged as a safe and effective block for lower abdominal analgesia in children. Multimodal analgesic regimens are often limited by side effects. Even though caudal epidural is gold standard technique for perioperative pain management for lower abdominal surgeries in children, being neuraxial block, it carries its own disadvantages. Duration of analgesia also lasts for short duration. Recent studies suggest that the TAPB is an effective regional technique for postoperative analgesia following abdominal surgeries [21].

We carried out this study to compare the duration of analgesia provided by USG guided TAPB with that of USG guided CEB for variety of infraumbilical surgeries in children. Our results showed that TAPB provided superior analgesia compared with the CEB at 8 to 20hrs after the block placement, as demonstrated by statistically significant low pain scores (p=0.028), hemodynamic parameters and prolonged duration of analgesia (p <0.001).

TAPB block serves as a simple and effective analgesic technique, with the added advantage of preserved motor and bladder function and avoids hooking up the patient to infusion devices and IV poles, thereby allowing earlier ambulation.

Bryskin et al. [21] in their study found that the TAPB would initially be equivalent to caudal block in providing postoperative pain control but would also show pain relief beyond the anticipated caudal duration. But they had used multimodal in analgesia for pain management. We assessed the analgesic efficacy of TAPB with CEB without using any other supplementation. Our results correlate with their study. Avoiding opioids in the postoperative period may be the reason none of our patient had any vomiting, urinary retention. Only two patients in group C who underwent orchidopexy, and one patient of group T who underwent ureteric reimplantation had vomiting which was not significant. It was treated with inj.ondansetron 100cmc/kg.

Guidance on best volume and dose for the TAPB is lacking [16]. In a pilot study, we found 0.5ml of 0.25% bupivacaine is sufficient to provide analgesia for infraumbilical surgeries in children. This is also the dose used by Sahin et. al. [16] and Bryskin et. al. [21]. Also we selected this dose to avoid over dosage in case of bilateral blocks. Sandeman et al. [22] performed ultrasound guided bilateral TAPB in a group of children undergoing laparoscopic appendectomy. Contrary to our study, authors reported no difference in the proportion of patients requiring postoperative morphine compared to the control group. However, in their study, cases of complicated appendicitis were more frequent and duration of surgery was significantly longer in the TAPB group. Nevertheless, pain control was superior in the TAPB group in the postoperative period.

Intra operatively there was clinically significant increase in HR and MAP at 10min (p=0.031) and 15min (p<0.001) from preblock value in patients who received TAPB. This may be due to the pulling of the peritoneum and TAPB will take time for complete analgesia. This response was managed with additional dose of fentanyl 1mcg/kg and

2%sevoflurane. None of our patients received any additional analgesics during the postoperative period. TAPB supposed to provide analgesia for only somatic and parietal pain. Since our patients were comfortable without any additional analgesics, we assume that the local anaesthetics deposited in TAPB plane must have spread to the paravertebal space, resulting in visceral analgesia. Our findings correlate with those of Bergamans et. al [13].

We defined "adequate pain relief" as pain scores less than 4 during the observation period.

Adequate pain relief was achieved in all our patients. None of our patients required intravenous opioids in the postoperative period as long as the analgesic effect of the blocks lasted. Our results show the good quality of perioperative analgesia achieved with TAPB in children undergoing abdominal surgeries. Thus, TAPB may eliminate the need for IV opioids during first postoperative day when the pain severity is high. Our results show that TAPB gives adequate pain relief for 12 to 20hrs avoiding the need for additional analgesics and their associated adverse effects. Later pain relief can be achieved with the conventional analgesics.

An important methodological note was, our use of ultrasound guidance for all the blocks in both the groups and a predetermined end point for needle placement. Live verification of local anaesthetic spread avoided block failures.

Conclusion

Both caudal and TAPB block give adequate analgesia during the early post-operative period. However, TAPB results in prolonged analgesia beyond the anticipated caudal duration. Considering the safety profile of TAPB and avoiding the narcotic related side effects, this should be considered a preferred regional technique over caudal for lower abdominal surgeries wherever possible.

Limitations of the Study

Firstly, we could observe the patients for only 24 hrs because of the discharge criteria in the paediatric surgery clinic. Only pyeloplasty and colostomy closure patients were kept for more than 24hrs. Secondly TAPB cannot be given for hypospadiasis repair, PSARP and other anorectal procedures where still caudal is considered gold standard. Thirdly, we have compared the effectiveness of analgesia indifferent types of surgeries where the intensity of pain differs. However, we have tried to compensate it by comparing the analgesic effect of TAPB and CEB in each group of surgeries separately (Figure 2). Fourthly, we did not compare TAPB and CEB with ilioinguinal block. One comparison with USG ilioinguinal block found that it provided more effective analgesia than TAPB [17].

Conflict of Interest: Nil.

Acknowledgement

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Efficacy of Right Superficial Cervical Plexus Block and Intravenous Dexmedetomidine for Relief of Shoulder Pain in Laparoscopic Surgery Under Spinal Anaesthesia: A Feasibility Study

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Abstract

Background and Aim: Laparoscopic procedures are conventionally done under general anaesthesia for avoiding patient discomforts and shoulder pain due to pneumoperitoneum that occur during laparoscopy under spinal anaesthesia. Here a study was designed to look for the possibility of using right superficial cervical plexus block and intravenous dexmedetomidine infusion to reduce shoulder pain in patients undergoing laparoscopic surgery under spinal anaesthesia. *Materials and Methods:* 50 patients of age between 18-60years with ASA grade I/II undergoing elective laparoscopic surgeries were given spinal anaesthesia with 0.5% hyperbaric bupivacaine and grouped as technique used. Group S (n=25) received right superficial cervical plexus block. Group D(n=25) received Dexmedetomidine intravenously. *Result:* No patients required conversion to general anaesthesia. VDS score for referred shoulder pain was statistically lower in group S compared to group D**.** Injection dexmedetomidine was associated with lower heart rate and blood pressure. *Conclusion:* Right superficial cervical plexus block is more effective than dexmedetomidine for reduction of referred shoulder pain during laparoscopic surgery under spinal anaesthesia.

Keywords: Dexmedetomidine; Laparoscopic Surgery; Referred Shoulder Pain; Right Superficial Cervical Plexus Block.

Introduction

In modern anaesthesia practice regional anaesthesia gains widespread acceptance for many surgeries including upper abdominal surgeries, thoracic surgeries, laparoscopic surgeries and others. General anaesthesia with endotracheal intubation is the anaesthesia of choice for laproscopic surgeries since many years. But it is associated with some disadvantages in terms of the stress response, lack of postoperative analgesia, vomiting and postoperative shoulder pain. Regional anaesthesia offers many advantages over general anesthesia in terms of cost, postoperative analgesia, intact respiratory control mechanism which in turn prevents hypercapnia and complications associated with it. Many studies showed that laparoscopic surgery can be done safely under spinal anaesthesia. [1-4] Shoulder pain which is a common complication of the laparoscopic surgery can be alleviated by adding various adjuvants to local anesthetics or by giving sedative analgesics during spinal anaesthesia. [5,6,12].

In laparoscopic surgeries, shoulder pain is a referred pain due to irritation of the diaphragm which is supplied by the phrenic nerve. Phrenic nerve is formed in the neck within the cervical plexus having root value C3, C4, C5. Blockade of superficial cervical plexus is easy to perform and results in anaesthesia of cutaneous nerves of anterolateral neck and shoulder. Superficial cervical plexus block has been used to alleviate shoulder pain due to lung surgery and laparoscopic surgery [7-9].

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Injection dexmedetomidine is a newer alpha2 adrenergic agonist which provides sympatholysis, consious sedation, anxiolysis and analgesia without respiratory depression. Intravenous as well as intrathecal dexmedetomidine has been used as an adjuvant to hyperbaric bupivacaine for shoulder pain during laproscopic surgery [12-15]. Hence we designed this research to study the effects of right superficial cervical plexus block and intravenous dexmedetomidine on reduction of shoulder pain, haemodynamic parameters and side effects if any in laproscopic surgery under spinal anaesthesia.

The primary objective was to study the effect of right superficial cervical plexus block and intravenous dexmedetomidine for relief of shoulder pain in laparoscopic surgery under spinal anaesthesia. The secondary objective was to study the effect on haemodynamic parameters intraoperatively in both groups and side effects if any in both groups.

Materials and Methods

After receiving approval from the hospital ethical committee and written informed consent, 50 patients of either sex in the age group of 18-60 years belonging to American Society of Anesthesiologists (ASA) physical status I or II scheduled laparoscopic surgery during March 2016 to December 2016 in our institute under spinal anesthesia were included in this study. The Exclusion criteria included patient refusal, contraindications to spinal anaesthesia, ASA grade> III, weight >80kg, Height <150cm, duration of surgery >120min, patients on medication causing bradycardia, patients with major cardiac, respiratory, liver and renal disease.

All patients were informed about the possibility of conversion to general anesthesia at any time intraoperatively. All patients underwent a through preanaesthesia check up. Th verbal descriptor scale for pain (VDS)[0=no pain 2 = mild pain 4=moderate pain 6=severe pain 8=extreme pain 10=worst pain] and the anaesthetic procedure was explained in detail during the pre-anaesthetic visit. All routine blood investigations and other investigations as per need were carried out.

In the operating room, after the establishment of intravenous (IV) line and attachment of standard monitors [non-invasive blood pressure (NIBP), electrocardiography (ECG), and pulse oximetry (SpO_2)], baseline parameters were recorded and Ringer's solution started intravenously.

Premedication was given with inj.ranitidine 1mg/kg, inj.ondansetron 0.1mg/kg, inj.glycopyrrolate 4mcg/kg, inj. midazolam 0.02mg/kg intravenously. Standard spinal anesthesia with 25 gauge spinal needle with 3.5-4 ml of 0.5% heavy bupivacaine depending upon the patient height was given in sitting position. After 10 min of spinal anaesthesia as per the convenience of anesthetist right superficial cervical plexus block or intravenous dexmedetomidine infusion were performed on the patients and grouped as:

Group S: received right superficial cervical plexus block at the midpoint of the posterior border of the sternocleidomastoid muscle subcutaneously in a caudad and cephalad direction with 10ml of 0.25% bupivacaine by 24G, 4cm needle.

Group D: received inj. dexmedetomidine 1mcg/kg over 10min followed by maintenance dose 0.4 mcg/kg/hr.

All patients were provided with supplemental oxygen via a face mask at a rate of 2-4 L. min^{-} [1] to keep saturation more than 95%. Intra-abdominal CO2 pressure was kept around 12-14mmHg. All patients were monitored for blood pressure, heart rate and oxygen saturation and recorded every 15min till the end of surgery. Bradycardia was defined as a heart rate of less than 60 beats/minute and was treated with 0.6 mg of intravenous atropine. Hypotension was defined as systolic blood pressure < 90 mmHg and was treated with 50-100 ml of intravenous crystalloid fluid replacement and a bolus of inj.mephentermine 6mg. Patients experiencing shoulder pain intraoperatively with VDS <4 were treated with pentazocine 0.3mg/kg intravenously and those with VDS ≥ 4 were treated with ketamine 0.5-1 mg/kg intravenously. Those patients experiencing shoulder pain even after intravenous ketamine received general anaesthesia and were excluded from the study.

Data was managed in a Microsoft excel spreadsheet. Data was represented as mean, standard deviation, standard error of mean, minimum and maximum observation. Unpaired t test and chi square test was used to compare the results of various parameters. A p value <0.05 was considered statistically significant. All statistical analysis was done using graph prism software.

Results

There was no statistically significant difference between two groups in demographic data i.e age, weight, height, sex distribution (Table 1). Mean

duration of surgery was 70.2 ± 26.43 in both groups. Both groups were also comparable regarding types of laparoscopic surgeries which included appendicectomy (9), cholecystectomy (6), diagnostic scopy(4), hysterectomy (3), ovarian cystectomy (3) (Figure 1).

There was statistically highly significant reduction in VDS score for referred shoulder pain in group S ($p<0.001$) than group D (Figure 2).

There was statistically very highly significant reduction in mean heart rate in group D than group S ($p<0.0001$). There was also a statistically very highly significantly lower minimum mean systolic and minimum mean diastolic blood pressure observed in patients receiving dexmedetomidine infusion than in patients receiving right superficial cervical plexus block($p<0.0001$) (Table 2).

Side effects observed during surgery are shown in (Table 3). None of the patient complained of nausea,vomiting and respiratory depression from both groups. Three patients from group S and six patients from D complained of referred shoulder pain. Out of which four patients received inj.pentazocine 0.3mg/kg while three patients was treated with inj.ketamine 0.5mg/kg and two patients required 1mg/kg of inj.ketamine. Two patients experienced abdominal discomfort from group S which was relieved by inj.pentazocine 0.3mg/kg. Bradycardia and hypotension was observed in patients received dexmedetomidine infusion. Bradycardia occurred in ten patients all of whom were corrected by 0.6 mg of atropine. Hypotension occurred in three patients. Two of them were treated with intravenouies fluid while one patient required additional dose of mephentermine 6mg iv.

None of the patient required conversion to general anaesthrsia and all operations were completed laparoscopically without conversion to open surgery.

Table 1: Comparision of demographic data and duration of surgery between two groups

Parameters	**Group S** (Mean±SD)	**Group D** (Mean±SD)	Remarks
Age (years)	35.48 ±9.691	35.36 ±9.661	P=0.96 NS
Weight (kg)	57.92 ±7.807	57.76 ±7.721	P=0.98 NS
Height (cms)	156.88 ±5.616	156.8 ±5.556	P=0.9 NS
Duration of surgery(min)	70.2 ±26.437	70.2 ±26.437	P=1.00 NS
Sex distribution Male/Female	13/12	13/12	

(P value is significant if $p < 0.05$, NS- not significant)

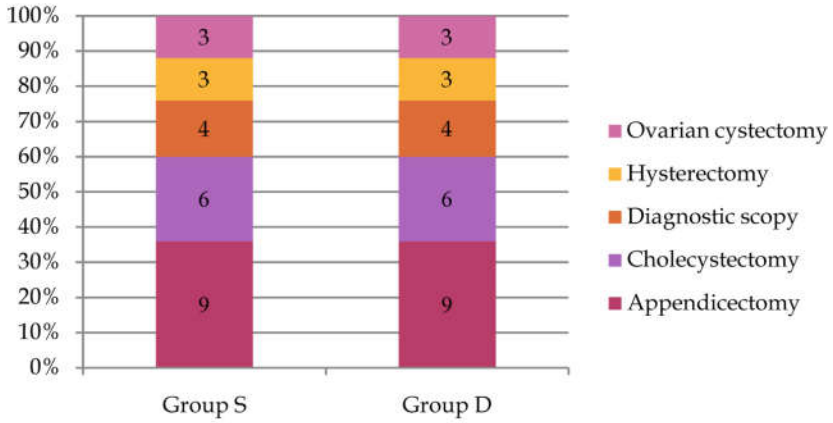
Table 2: Comparision of Haemodynamic parameters between two groups

Parameter	Group S (Mean ± SEM)	Group D (Mean ±SEM)	Significance
Basal HR	82.72 ± 1.125	82.80 ± 1.143	P=0.964 NS
MIN HR	65.92 ± 0.852	60.20 ± 0.905	P =0.0001
MAX HR	76.08 ± 0.941	77.04 ± 1.078	P = 0.506 NS
Basal Systolic BP	127 .9 ± 1.892	126 ± 1.911	P = 0.478NS
MIN Systolic BP	102.6 ± 0.955	93.04 ± 0.836	P = 0.0001
MAX Systolic BP	133.6 ± 1.742	132.5 ± 1.218	P= 0.940 NS
Basal Diastolic BP	77.36 ± 1.441	77.92 ± 1.329	P = 0.776 NS
MIN Diastolic BP	62.44 ± 0.938	55.92 ± 0.535	P = 0.0001
MAX Diastolic BP	81.84 ± 1.077	83.44 ± 0.898	P = 0.259 NS

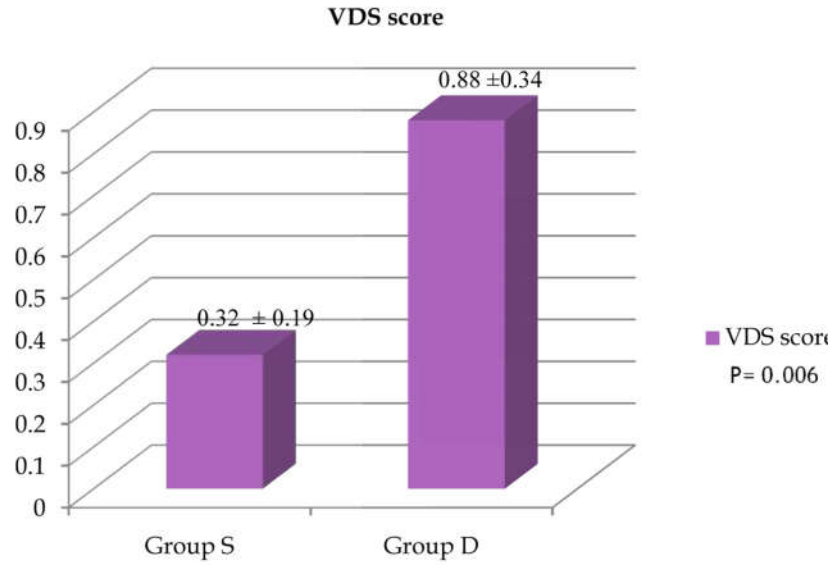
(P value is significant if $p<0.05$, NS- not significant)

Table 3: Comparison of Side effects between two groups

Parameter	Group S	Group D
Referred shoulder pain	+(3)	+(6)
Nausea, Vomiting	-	-
Bradycardia	-	+(10)
Hypotension	-	+(3)
Abdominal discomfort	+(2)	-
Respiratory depression	-	-



Graph 1:



Graph 2:

Discussion

In this study, 50 patients underwent laparoscopic surgery under spinal anaesthesia with either right superficial cervical plexus block or intravenous dexmedetomidine infusion though few patients complained of shoulder pain and abdominal discomfort, but these were managed with inj. pentazocine or inj.ketamine .

Proper management of shoulder pain, discomfort, and anxiety during intra-abdominal carbon dioxide pneumoperitoneum is a major concern during the use of regional anesthesia for laparoscopic surgery. Amongst all carbon dioxide pneumoperitoneum-induced shoulder pain under regional anaesthesia is the most distressing and it is a one of the leading cause of conversion to general anaesthesia.

Several studies have been conducted for relief of shoulder pain during laparoscopic surgery under spinal anaesthesia [1-6] . However, very few studies are there on use of right superficial cervical plexus block and dexmedetomidine infusion [10-11,13].

Superficial cervical plexus mainly contains five sensory nerves of which supraclavicular nerve supply anterolateral part of neck and shoulder. Supraclvicular nerve (C4, C5) has same root value as that of phrenic nerve (C3, C4, C5). Blockade of supraclavicular nerve during superficial cervical plexus block results in relief of shoulder pain during laparoscopic surgery under spinal anaesthesia. S.Kanawati et al conducted a study of awake laparoscopic sleeve gastrectomy under paravertebral block with superficial cervical plexus block and observed no shoulder pain in any patient [11]. We found only three patients complained of shoulder pain which may be because of inadequate block.

Analgesia with dexmedetomine is mainly due to two mechanisms.

a. Efflux of potassium ions results in hyperpolarization of the excitable cell membrane which in turn causes decrease in neuronal firing.
b. Suppression of calcium ion entry causes decrease in release of neurotransmitter and terminates pain signals. Analgesic and sedative effects of dexmedetomidine is expected to resolve the shoulder pain and abdominal discomfort during laparoscopic surgery under spinal anaesthesia. Two studies reported 24 out of 60 patients and 8 out of 26 patients complaining of referred shoulder pain while using intravenous dexmedetomidine [11,13]. We also observed 6 patients out of 25 complaining of shoulder pain. It might be because of fixed dose of dexmedetomidine infusion for different types of laparoscopic surgery where severity shoulder pain differs and resulted in inadequate analgesia.

Hypotension and bradycardia are common adverse effects associated with dexmedetomidine as well as with spinal anesthesia. The incidence of dexmedetomidine-related hypotension and bradycardia were 30% and 9% respectively, in a phase-III study of 401 patients [15]. The incidence of hypotension, but not of bradycardia, increases as the dose of dexmedetomidine increases [16]. In contrast, a meta-analysis study showed that dexmedetomidine use during spinal anesthesia is associated with more frequent bradycardia but did not increase the incidence of hypotension [12]. In another study too there was a higher incidence of bradycardia than hypotension [13]. We also observed a higher incidence of bradycardia than hypotension in our study.

The low incidence of hypotension and high incidence of bradycardia in the present study may have been due mainly to the effects of pneumoperitoneum. At intra-abdominal pressures of <15 mmHg, venous return, cardiac filling pressure, and cardiac output are increased as blood is squeezed from the splanchnic venous bed and by sympathetically mediated peripheral vasoconstriction [17]. In addition, insertion of the veress needle or trocar and pneumoperitoneum-induced peritoneal stretching can cause vagal stimulation, which can lead to significant bradycardia [18].

In our study none of patient complained of nausea and vomiting. This result correlates with the another study where there was a 11 fold decreased risk for nausea and vomiting in patients receiving regional anaesthesia compared to general anaesthesia [19].

There were several limitations to this study. This observational study was done in very small population. There was no control group or placebo for comparison. Two different techniques were studied, one was block and other was drug infusion which has different mechanisms for relief of shoulder pain. We did not evaluate effects of various maintenance doses of dexmedetomidine(0.2-0.7mcg/kg/hr).We included different types of laparoscopic surgery where intensity of shoulder pain may not remain the same.

Conclusion

Our study concluded that both right superficial cervical plexus block and dexmedetomidine infusion are feasible for relief of shoulder pain during laparoscopic surgery under spinal anaesthesia . Right superficial cervical plexus block is more effective than dexmedetomidine infusion for relief of shoulder pain during laparoscopic surgery under spinal anaesthesia. Dexmedetomidine infusion was associated with more haemodynamic alteration with increasing incidence of bradycardia. However careful monitoring and adequate dose adjustment helped us tide over this issue.

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Case Report

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Anaesthetic Management of a Case of Severe Pulmonary Artery Hypertension for Excission of A Vulval Mass

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Abstrat

It is known that patients with pulmonary hypertension are at high risk for anaesthesia and surgery. Primary pulmonary hypertension (PPH) has now been replaced byidiopathic pulmonary hypertension or pulmonary artery hypertension (PAH). PAH is arareform of progressive fatal disease. Occasionally these patients may be posted for non cardiac surgeries.Ideal anaesthetic technique involves maintaining of stable pulmonary and hemodynamicparameters for a possible good outcome. Here we present a 31 year old female with severe pulmonary artery hypertension who underwent successful excision of a hugevulvalmass.

Keywords: Pulmonary Hypertension; BiPAP; Regional Anesthesia.

Introduction

Pulmonary hypertension (PH) is a disorder characterized by abnormally high blood pressures in the pulmonary vasculature. PH is a progressive, fataldisease [1] associated with high mortality due to the stress of surgery andanesthesia [2]. A detailed understanding of PAH as well as associated risks must be known for safe and smooth conduct of anesthesia andpost operative care. Patients with pulmonary hypertension are amongst the most challenging for anaesthesiologists to manage. Furthermore, such patients undergoing surgery have a high perioperative morbidity and mortality. Any factor contributing to further increase in pulmonary hypertension will lead to decompensation of a stable disease which can lead to unfavorable results. This case report describes successful management of non-cardiac, non-obstetric surgery in a 31 year old female with severe PH who underwent excision of vulval

Case Report

A 31 year old female was admitted to our hospital with history of fever and cough for three days. She wasa known case of primary pulmonary hypertension and hypothyroidismon regular medications and following up at our hospital clinics. She had no drug allergies. Her medications included bosentan, iloprost and thyroxin. Patient deteriorated during her hospital stay and developed respiratory distress. She was put on oxygen via face mask @ 5l/min. Vital parametersat thistime were, heart rate of 135/min, tachypnoea with respiratory rate of 22-24/min, blood pressure130/70mmhg, SpO_2 87-90%. Chest revealed bilateral equal air entry with scattered crepitations.

A big vulval mass measuring 20x23 cm in size, pedunculated, non-tender with areas of necrosis and foul smelling was noticed on examination. This swelling was having a thick peduncle.A historyof recent increase in the size of swelling was noticed.

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Patient's condition worsened further in the intensive care unit, where she was diagnosed to be suffering from sepsis. The vulval mass was attributed to be the source of infection and hence the gynaecologists advised excision of the vulval mass.Laboratory investigations showed a high neutrophil count. Coagulation profile and other biochemical parameters were within normal limits. EKG showed right ventricular strain with right axis deviation. Transthoracic echocardiogram was carried that showed the following, a good systolic function with EF 58%. Tricuspid valve calcification with moderate tricuspid regurgitation, normal left ventricular dimension and wall thickness, no regional wall motion abnormality, dilated right ventricle (RV) with impaired right ventricular function, no pericardial effusion, no vegetation's and pulmonary arterial systolic pressure recorded as 100mmhg Before the surgery and during the ICU stay the patient deteriorated further. She became further tachypneic. She was placed on, BiPAP of 15/5cm H_2O. SpO2 was maintained at 90-92% with BiPAP support. As the vulval swelling was assumed to be the source of infection, it was decided to excise the mass . Patient was accepted as ASA 4E in view of sepsis and severe pulmonary artery pressures of100mmhg. Patient was wheeled into the operation room with BiPAP, where she was connected to the standard ASA monitors. She was anxious looking, with HR112 -114/min, SpO_2 88-90%. She had right radial artery canula. Invasive blood pressure could be monitored BP 112/67 mmhg. Blood gas carried out, showed features of respiratory acidosis.The plan was to institute local anaesthesia into the peduncle of the mass and get it excised. However the peduncle was very vascular and local infiltration could not be given. It was decided to give her subarachnoid block. Under all aseptic precautions 1.5ml of 0.5% heavy bupivacaine was administered intrathecally at lumbar 3/4 levels using 27G pencil point needle in the sitting position. later she was placed 45 degrees head up and in lithotomy position. BiPAP 15/5cmh_2o continued during the whole procedure. Her vital parameters remained stable, HR 115-118/min, blood pressure 100/64-110/68mmhg, SpO_2 90-92%. Her temperature was also kept with in normal limits. All those factors that could have resulted in precipitation of the symptoms of PH were avoided .

Surgery lasted for hour and a half. After the procedure, patient was shifted back to ICU on BiPAP. She was gradually weaned off from BiPAP, the next day and placed on oxygen via face mask. She remained stable in ICU and was shifted to gynaecology ward after 3 days. She was discharged home 8 days after surgery. She is being regularly followed up at our hospital clinics. Her cardiac status remains stable. She is continuing her medications for pulmonary hypertension.

Discussion

Although mild PH does not affect anaesthetic outcome, patients with moderate to severe PH can have adverse outcome [1]. Patients with PH are at high risk to undergo cardiac as well as non cardiacsurgery [2].

Accordingto 4th world symposium[3] Pulmonary hypertension is as mean pulmonary arterial pressure of more than 25 mmhg at rest or more than 30mmhg at exercise.

WHO classifiesPH into five groups based on the mechanism causing the disease:

1. Pulmonary artery hypertension (PAH), idiopathic and develops over the years
2. Pulmonary hypertension owing to left heart disease
3. Pulmonary hypertension secondary to lung disease
4. Pulmonary hypertension associated with chronic embolic/thromboembolic disease.
5. Pulmonary hypertension secondary to disorders affecting pulmonary vasculature

PH Is a progressive fatal disease [4]. The median life expectancy for non-treated patients is approximately 2-3 years from the time of its discovery. Price et al in their study have shown that there is 15% mortality at 1 year after diagnosis. PH is due to a combination of pulmonary arterial vasoconstriction, and in situ thrombosis. Eventually in PH pulmonary artery pressures and pulmonary venous pressures are raised. These high pressures lead to load on left ventricle that in turn leads to right ventricular hypertrophy and dilatation and eventually right ventricular failure. Patients with PH usually have non-specific symptoms like dysponea, fatigue, dizziness, syncope, chest pain, palpitations, cough, peripheraledema, ascites, hepatomegaly, tachycardia, tachypnea and raised jugular veinous pressure. Factors like hypoxemia, hypothermia, hypotension, acidosis, hypervolemia, pain and, increased intrathoracic pressures aggravate PH. In severe PH, surgery should only be considered if it is lifesaving.

A proper pre-operative evaluation should be carried out and involves multidisciplinary approach and includes clinical examination, ECG, Chest X-ray,

arterial blood gas analysis, echocardiography and metabolic profile. Echocardiography provides useful tool for diagnosis of PH. However, Right heart catheterization is gold standard for measuring the hemodynamic pressures in the pulmonary circulation and getting information about the right heart functionality.

Various treatment options are available and they include, Calcium channel blockers: Nifedipine, diltiazem and amlodipi Prosteinoids, they are potent vasodilators, delivered by continuous intravenous infusion. Endothelin receptor antagonist, bosentan [5] is taken orally Phosphodie sterase inhibitors, Sildenafil and milrinone are pulmonary and cardiac inodilators. Inhaled vasodilators includeiloprost [6] and Nitric oxide.

In elective cardiac as well as non-cardiac surgeryall undiagnosed causes of PH should be identified and optimized. On the other hand, in emergency situations we may not have adequate time to correct and optimize the patient condition and surgery may be done with explained risks.Our case was also an emergency surgery where there was not much time for properly optimizing the patient condition.

A proper preoperative evaluation should be carried out and includes clinical examination, ECG, Chest X-ray, arterial blood gas analysis, echocardiography and metabolic profile. Right heart catheterization is gold standard for measuring the hemodynamic pressures in the pulmonary circulation and getting information about the right heart functionality. All undiagnosed causes of PH should be identified and optimized. On the other hand in emergency situations we may not have adequate time to correct all the underlying causes and surgery may be done with risks explained.

Allanesthetic techniques can in principle beapplied to patients with pulmonary hypertension. Regional anaesthesia offers an advantage over general anaesthesia in terms of notimpairings pontaneous breathing and avoidingelevated pulmonary pressures induced by laryngoscopy and mechanical ventilation [14].

Martin et alshowed that operative mortality in patients with Eisenmengers syndrome was 18% with general anaesthesia Vs 5% with regional anaesthesia [7]. Price et al. also suggest in their study that the use of general anesthesia in PH was linked to worse patient outcome than regional anesthesia [8]. Most of these patients are anticoagulants and they need to be stopped before planning regional anesthesia [9] .

Local anesthesia applied alone in a field around surgical site can be the safestapproach. Continuous techniques should be preferred over bolus administration of local anaesthetics to avoid uncontrolled drops in blood pressure, decrease in myocardial perfusion and precipitation of right heart failure. For limb surgery ultrasoundguided plexus or peripheral nerve blocks are the best choices. Spinal anaesthesia when given as bolus can cause sharp fall in peripheral vascular resistance and decrease myocardial perfusion. However saddle block performedwith low dose of local anaesthetic can prevent sudden changes in hemodynamic parameters. In obstetrics, successful application of lumbar epidural anaesthesia has been repeatidly described [15], even though recent literature describes higher morbidity of pregnant women with pulmonary hypertension. Antanasoff P. et al. used epidural anaesthesia for caesarian section [10] in a case of severe pulmonary artery hypertension General anaesthesia on the other hand provides the uncompromised airway and safe oxygenation. Moreover, selective pulmonary vasodilators like iloprost [11] can be administered through the breathing circuits. For abdomen and thoracic surgeries general anaesthesia can be combined with epidural anaesthesia for better haemodynamic control [12]. If general anaesthesia is employed, transesophageal echocardiography (TEE) may provide the best real time monitor of cardiac preload and status of right to left shunting. Patientneeds tobe observed in the ICU for first few dayspost operatively as there is a high risk of sudden death [13]. Finally theyshould be put back totheir usual oral anticoagulants post-operatively.

Conclusion

Perioperative management of patients with PH presents an interdisciplinary challenge that requires adequate involvement of anaesthesiologist, surgeons, cardiologist and intensivist. Although anaesthetic management of PH patients continues to be challenge, athorough assessment of the patient andameticulous attention to details minimizes the possibility of complications and allow best possible outcome.

Risk Disclosure

Patients with PH have increased morbidity and mortality. A pre-operative assessment of risks and possible benefits of surgical intervention plays a vital role. All these risks should be addressed andexplained well to the patient.

Conflict of Interest None of the authors involved in this study have any conflicts of interest to disclose.

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Standard abbreviations should be used and be spelt out when first used in the text. Abbreviations should not be used in the title or abstract.

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