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Original Article

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Comparison of Transdermal and Intravenous Diclofenac in Acute Post-operative Pain in Intertrochanteric Fractures

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Abstract

Introduction: Early mobilization is the primary goal after operation of hip fracture in the elderly wherein the main impediment despite adequate fixation being surgical site pain. Prolonged post-operative recumbency due to pain could lead to various complications like venous thrombosis and cardio-pulmonary compromise. Over enthusiastic use of NSAIDs or opioids on the other hand can have its own set of complications. Hence this study was carried out to evaluate effectivity and safety profile of a commonly used drug, diclofenac via transdermal route in comparison to iv diclofenac.

Methods: 30 patients meeting the study criteria were alternatively allocated to either groups of IV diclofenac and TD diclofenac. All patients were informed how to monitor post-operative pain on a VAS scale at 2,4,6 and 12 hour intervals. Group TD was applied Trans Dermal Diclofenac 100 mg patch, 1 hour prior to surgery and repeated at 12 hourly intervals. Group IV was given intravenous diclofenac 75 mg 1 hour prior to end of surgery and repeated at 12 hourly intervals. First rescue analgesic used was Intra Venous (IV) Paracetamol, if VAS was more than 6, if administered Its dosage and timing of administration was noted. IV tramadol was kept as a standby rescue analgesic.

Results: both the groups were comparable with regards to age and ASA scores. Time to first rescue analgesia, IV Paracetamol, in group TD was 10.23±2.42 hours while that in group IV was 8.15±2.48 hours. It was statistically significant($p<0.05$). None of our patients required IV tramadol. The mean VAS scores at 2, 4, 6 and 12 hours were lower in group TD in comparison to group IV. There were no significant side effects noted.

Conclusion: We can conclude that transdermal diclofenac patch group patients had lower VAS scores at all measured intervals compared to IV diclofenac group and a significantly longer time of rescue analgesic use. Thus, it seems a safe and effective choice for post-operative analgesia in orthopaedic patients.

Keywords: Hip fractures; Intravenous; NSAIDs; Transdermal

Key Message: Pre-emptive application of transdermal diclofenac patch in geriatric intertrochanteric fractures provides good analgesia in post-operative period and can reduce requirements of opioids with minimal side effects.

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Introduction

Intertrochanteric fractures are common fractures in the geriatric population and with the increase in ageing population, it is one of the most common indication for undergoing emergency orthopaedicsurgery.[1] Hip fracture related pain is usually reported as severe both pre and post-surgery. While the immediate goal of surgery is to shorten the period of recumbency and provide early mobilization, despite adequate surgical fixation these patients are slow in rehabilitation mainly due to pain.[2,3] This also contributes to several other complications like pulmonary compromise, deep venous thrombosis, bed sores etc. A robust pain management plan is therefore important in these patients these patients for early mobilization and recovery.[4] Geriatric population also suffers from several other co-morbid conditions like diabetes, cardiovascular disease, renal and hepatic impairment. Thus pain therapy needs to take into account the safety profile of used drugs. The drug dosages are also modified accordingly and overuse avoided. Inadequate pain management postoperatively in these patients may cause poor or delayed functional recovery, including delayed return to activities of daily living, increased financial burden, or chronic pain, an efficient analgesic regime fastens healing and mobilization, reduces postoperative complications, shortens length of hospital stays, reduces health care costs, and improves patient satisfaction.[4,5,6] Hence we undertook this study to compare the efficacy of transdermal diclofenac with oral diclofenac in providing analgesia postoperatively for 12 hours.

Transdermal drug delivery systems are preferred over other routes of administration because they pose lower systemic risk especially to liver and gastrointestinal tract. It has the potential to yield more stable drug plasma levels and to bypass major organs involved in first-pass metabolism. Our hypothesis was that transdermal diclofenac patch would significantly reduce analgesic requirement over 12 hour post-operative period and might help us in avoiding systemic analgesics like opioids.

Subjects and Methods

We included 60 patients, 30 in each group, in the age group of 50-80 years with stable Intertrochanteric fractures planned for fixation using DHS. Only ASA 1and 2 patients were included in our study. We excluded the following patients from our study:

- Patients having dementia or other neurologic/ psychiatric problems.
- Patients with any bleeding disorders
- Patients with gastric peptic disease
- Patients having chronic hepatic or renal disease
- Patients having known allergy to diclofenac.
- Patients unwilling to cooperate in the study and monitor VAS.
- Surgical duration of more than three hours.

All patients were subjected to routine pre anesthetic evaluation which included detailed history, general physical examination, systemic examination and routine investigations such as complete blood count, random blood sugar, liver function test, renal function test, electrocardiography (ECG), serum electrolytes, prothrombin test (PT) and international normalized ratio (INR). All patients were briefed about the use of Visual Analog Score (VAS). VAS consists of a 10 cm line marked at one end by a label such as "No pain" with a happy face and at other end by a label such as "Worst pain imaginable" and a score of 10.7 All the patients were instructed about VAS and to point out the intensity of pain on the scale. (0-No Pain, 10-Worst Pain). All patients were kept fasted overnight, and given Tablet Alprazolam 0.5mg and Tablet pantoprazole 40 mg on the night before and on the morning of surgery.

The patients meeting the inclusion criteria were distributed into 2 groups using sealed envelopes. Group TD was applied Trans Dermal Diclofenac 100 mg patch, on their left arm 1 hour prior to surgery and repeated at 12 hourly intervals. Group IV was given intravenous diclofenac 75 mg 1 hour prior to end of surgery and repeated at 12 hourly intervals. VAS scores of both groups were noted at 2, 4, 6 and 12 hours postoperatively. First rescue analgesic used was Intra Venous (IV) Paracetamol, in both the groups, if VAS was more than 6. IV tramadol was kept as a standby rescue analgesic, in both the groups, if VAS measured was more than 6 within 6 hours of administration of paracetamol.

Following full aseptic precautions, sub arachnoid block was given in L3-L4 interspace using a 25 Gauge Quincke's spinal needle with patient in sitting position. Bupivacaine heavy (0.5%) was injected into the subarachnoid space after noting the clear free flow of CSF, with the operating table in horizontal position to achieve block level of T6-T8. This was standardized for all patients.

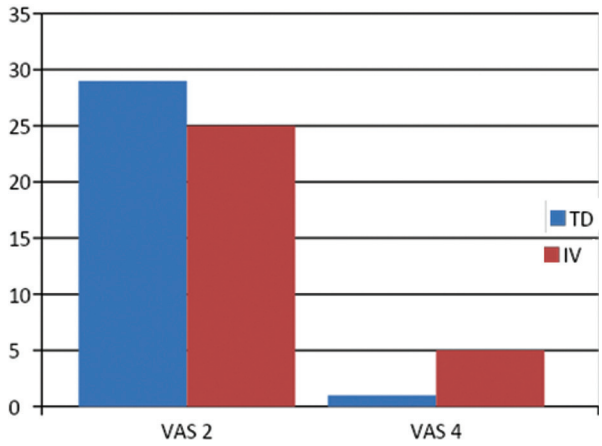
For the statistical analysis, all variables were summarized descriptively. Data was analyzed by software SPSS version 21.0. For continuous variables, the summary statistics of N, mean,

standard deviation (SD) were used. For categorical data, chi square test was use. Unpaired t test was done to compare two group means. P value of less than 0.05 was considered significant.

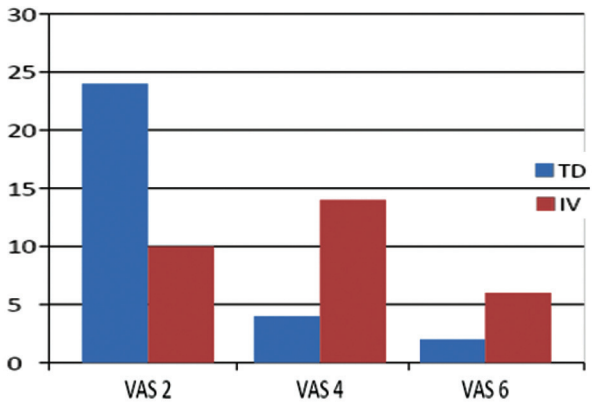
Results

The mean age in group A and B were 63.5±12.2 and 61.8±14.3 respectively and was comparable (p value-0.547). Both the groups were also comparable statistically for gender and ASA grade. The number of ASA grade I patients in group TD was 8 and in group IV was 10. The number of ASA grade II patients in group TD was 22 and in group IV was 20.

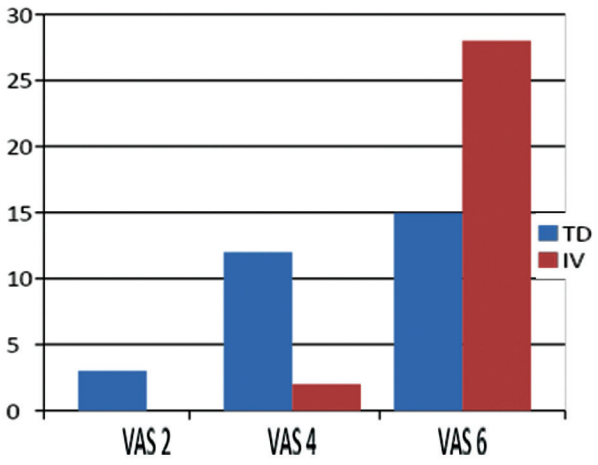
Graph 1: Illustration: 1a VAS scores at 2 hours of both groups.



Graph 2: 1b VAS scores at 4 hours of both groups.



Graph 3: 1c VAS scores at 6 hours of both groups.



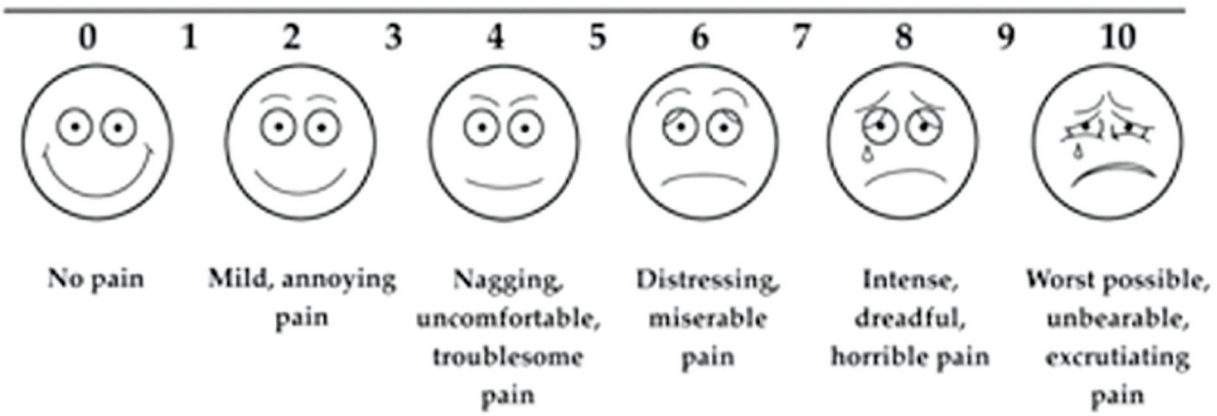


Fig. 1: Visual Analog Scale for pain (VAS).

Time to first rescue analgesia in group TD was 10.23±2.42 hours while that in group IV was 8.15±2.48 hours. It was statistically significant (p<0.05). As per our study protocol, IV Paracetamol was the first drug of choice for rescue analgesia when VAS was more than 6. IV tramadol was kept as a standby rescue analgesic if VAS scores were more than 6 within 6 hours of paracetamol administration. None of our patients required IV tramadol. The mean VAS scores at 2, 4, 6 and 12 hours were lower in group TD in comparison to group IV (table 1,2,3,4).

The side effect profiles were not much different in either groups. There were no cases with delirium, disoriented mentation, stomach pain etc. in either

group. Although local site irritation like dryness, erythema is mentioned in literature to be associated with transdermal patch of diclofenac, we did not encounter any such side effects. It might be due to lesser time period of follow up post application of patch in our study.

Discussion

Intertrochanteric fractures are one of the most common indications for orthopaedic surgery in old age patients.[2,3] Postoperative management of pain remains a very important aspect of early recovery and comfortable hospital stay of these patients. The most common drug used for analgesia in the postoperative period in most institutions currently, is diclofenac, administered via various routes most commonly being oral, intramuscular and intravenous. Diclofenac belongs to Non-steroidal anti-inflammatory class of drugs (NSAID) and acts by inhibiting prostaglandin synthesis by blocking the enzyme cyclo oxygenase (COX 1 and COX 2, non-selectively).

Topical diclofenac is a new preparation that can be used for analgesia and is available in various forms like transdermal patch, ointment or cream. It has various advantages over other routes. Systemic side effects are significantly lower due to low and sustained plasma concentrations compared to other routes like oral and parenteral. An update on NSAIDs noted that parenteral route had similar side effect profile including gastrointestinal symptoms like oral route while topical route was an exception and had considerably fewer side effects.[8]

Gastrointestinal symptoms seen with NSAIDs are mainly dyspepsia and peptic ulcers. Other common side effects include cardiovascular, bleeding disorders due to platelet dysfunction and renal dysfunction. Hepatic dysfunction can also be seen. All these adverse drug effects are less with topical route.[8] The added advantages of topical route include ease of application, patient compliance and easy termination. Topical route bypasses first pass metabolism in liver and is also effective in patients with poor absorption in stomach or in patients who cannot swallow or are not orally allowed. It has better bio availability with no marked peak to trough fluctuations leading to sustained plasma concentrations.[9]

The only catch with this drug delivery system is prolonged onset and offset. Its elimination half time is approximately 12 hours. Thus it has to be given in anticipation of pain and cannot be used as rescue analgesia unlike intravenous or intramuscular route which can be used as and when required. Intravenous, intramuscular and oral, in all these routes, plasma concentrations are achieved within a short time and rapidly decline leading to similar decline in analgesic effects.[10,11,12]

The most common side effects noted with topical route is local site irritation, erythema and dryness. The safety profile of diclofenac patch is studied by Mason et al.[12] Roth and Fuller analysed pooled safety data from two randomized trials which showed topical diclofenac solution to be superior to oral tablets in tolerability profile with respect to gastrointestinal symptoms and derangement in renal and hepatic variables after long term use. Topical solution was also found to be similar in efficacy to oral and therefore presented a useful alternative especially in older patients.[13]

Various studies have been done to compare topical with intramuscular and oral routes but we found very few studies comparing topical with intravenous route in orthopaedic surgeries. Thus we conducted this study to evaluate the same. We found transdermal route to be more efficacious in terms of reduced VAS scores than intravenous route at all times. It might be because we correctly timed the patch to be placed preoperatively so that adequate therapeutic levels were achieved after completion of surgery. The total number and dose of rescue analgesics used in transdermal group was also lower than the intravenous group. Thus we were able to completely avoid opioids and other analgesic drugs use in this group.

Opioids are excellent analgesics but their tolerability is limited due to side effects like nausea, vomiting, pruritus, decrease in bowel motility, constipation and more serious ones like sedation and respiratory depression.[14] It is especially problematic in old age patients who are more susceptible. Also these patients generally have some comorbidities like cardiovascular, hepatic or renal dysfunction. Therefore multiple drugs and higher dosages are better avoided.[15] Taking all these factors into consideration, transdermal diclofenac is an ideal candidate for such patients as a single patch is effective for 12-24 hours with very low but therapeutic plasma levels for sustained duration.[10]

Yadav et al conducted a randomized trial to compare intravenous, transdermal and rectal suppository of diclofenac for postoperative analgesia after gynecological surgeries. They found transdermal patch 200 mg to be comparable to rectal suppository of 200 mg in providing analgesia for 24 hours postoperatively. Both these routes were better than intravenous route for analgesia as found

in our study.[16] Singh et al compared transdermal with intravenous diclofenac for analgesia after head and neck cancer surgeries and found transdermal route to be better than intravenous similar to our study. The intravenous group had faster onset with fluctuating analgesic effects whereas transdermal route had delayed onset but a steady analgesia. Patients were more comfortable in transdermal group.[16]

Krishna et al studied the analgesic effects of transdermal diclofenac patch in patients undergoing elective lower limb orthopaedic surgery under spinal anaesthesia and found it to be comparable. Similarly, Bhargava et al concluded that Diclofenac sodium patch was as effective as intramuscular injection in providing post-operative analgesia. Only concern about patch was that it has longer onset of action, so if applied by proper planning, patch had many advantages.[17]

Conclusion

We can conclude that transdermal diclofenac patch group patients had lower VAS scores at all measured intervals compared to IV diclofenac group and a significantly longer time of rescue analgesic use. Thus, if planned timely TD diclofenac could be a useful option in orthopaedic post-operative pain management and if combined with paracetamol IV as rescue analgesic the need of opioids could be almost negligible. The side effect were also minimal in our study groups however larger scale studies need to be conducted with longer postoperative follow up to evaluate the efficacy and compare safety profile and tolerability of these two routes.

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Original Article

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Comparative Study of Upper Lip Bite Test and Modified Mallampatti Classification in Predicting Difficult Endotracheal Intubation

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Abstract

Objective: To compare sensitivity, specificity, positive and negative predictive values of upper lip bite test and modified mallampatti test to predict difficulty in endotracheal intubation in patients between 16 to 55 years of age.

Methods: One hundred ASA1/2 patients admitted for elective surgical procedure requiring endotracheal intubation were prospectively studied to predict difficult intubation in age group 16-55 years of age after obtaining an informed consent. Preoperative Airway assessment was done with modified mallampatti test and upper lip bite test.

Results: In our study, eighty four had Upper lip bite test (ULBT) class I and II and sixteen patients had class III. Of these two ofthe ULBT class Iand II and five of the ULBTclassIII had Cormack Lehane grade III . There were one hundred patients predicted to be easy for intubation by MMT (i.e. patients who had ULBT class I and II) out of whom however, we encountered difficult intubation in 6 patients. One in MMT class III also had difficult intubation. None of the patients had class IV MMT.Of the entire one hundred patients, a total of seven patients had difficult intubation, all of whom had Cormack Lehane class III on laryngoscopy.

Conclusion: Upper Lip Bite Test (ULBT)is a better test at predicting difficult endotracheal intubation when compared toModified Mallampati Test (MMT). Upper lip bite test and modified mallampatti classification are good predictors of easy intubation rather than difficult intubation. Upper lip bite test should be used in combination with other airway assessment methods viz. Thyromental distance, hyomental distance, inter incisor distance to predict difficult intubation.

Keywords: Upper lip bite test; Modified mallampatti classification; Difficult endotracheal intubation.

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Introduction

Airway management is of prime importance to the Anaesthesiologist. For securing airway, tracheal intubation using direct laryngoscopy remains the method of choice in most of the cases. No anesthetic technique is safe unless deligent efforts are made to secure and maintain an intact airway.

The reported incidence of difficult laryngoscopy and tracheal intubation occurs in 1.5% to 8% of patients in general anaesthesia.[1] In some cases, if Anaesthesiologist is not able to maintain a patent airway, it may lead to serious complications like hypoxic brain damage or death. Of all the anaesthetic deaths 30% to 40% are attributed to the inability to manage a difficult airway.[2] Among the overall claims against anesthetist in closed claims project, 17% involved difficult or impossible intubation.[3]

There are many tests to predict difficult intubation that is Patil's measurement of Thyromental distance, the Modified Mallampati test and the Wilson scoring system. A new, simple bed side test is Upper lip bite test (ULBT).[4,5] In day to day practice, we use MMT to predict the difficult endotracheal intubation, whereas ULBT is not as popular as that. So ULBT needs to be evaluated as a useful test to predict difficult intubation in day to day cases. Hence, we proposed this study to compare ULBT with MMT in predicting difficulty in endotracheal intubation, in patients who are undergoing surgery under general anaesthesia.[6,9,11,14]

Materials and Methodology

After obtaining institutional ethical committee clearance and written informed consent, the study was conducted in 100 male/female patients aged between 16 to 55 yrs of age Patients undergoing elective surgical procedures under general anaesthesia in surgery, ent, orthopaedics, obgy were enrolled in the study. A thorough pre anaesthetic evaluation was carried out in all the patients and the procedure was explained in detail to the patients.

Exclusion Criteria includes Edentulous patients, Patients unable to open the mouth, Patients with cervical spine fractures and deformities, Patients with upper airway tumors, Patients with altered consciousness, confusion.

Preoperatively, two anaesthesiologists not involved in intubating the airway evaluated using Modified mallampatti test and Upper lip bite test. Classification of oropharyngeal view was done according to Modified mallampatti test, wherein the patients were made to be in sitting position with mouth fully open and tongue maximally protruded, and patients were asked not to phonate.[8,12,13]

Modified Mallampatti Classification

Class I	Soft palate, fauces, uvula, and pillars are seen
Class II	Soft palate, fauces, and uvula are seen
Class III	Soft palate and base of uvula
Class IV	Hard palate is visible

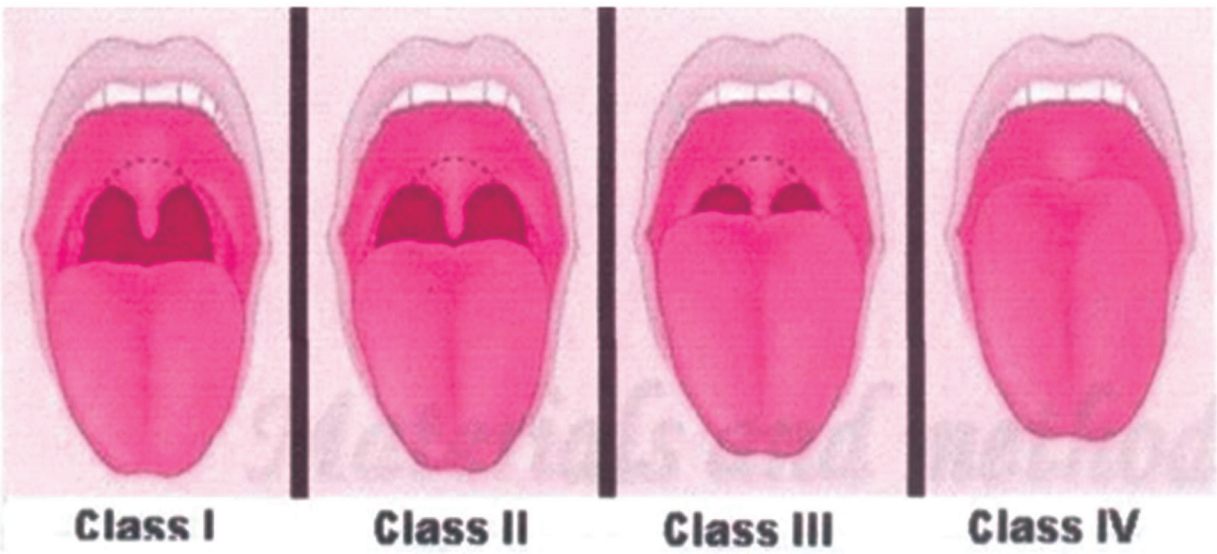
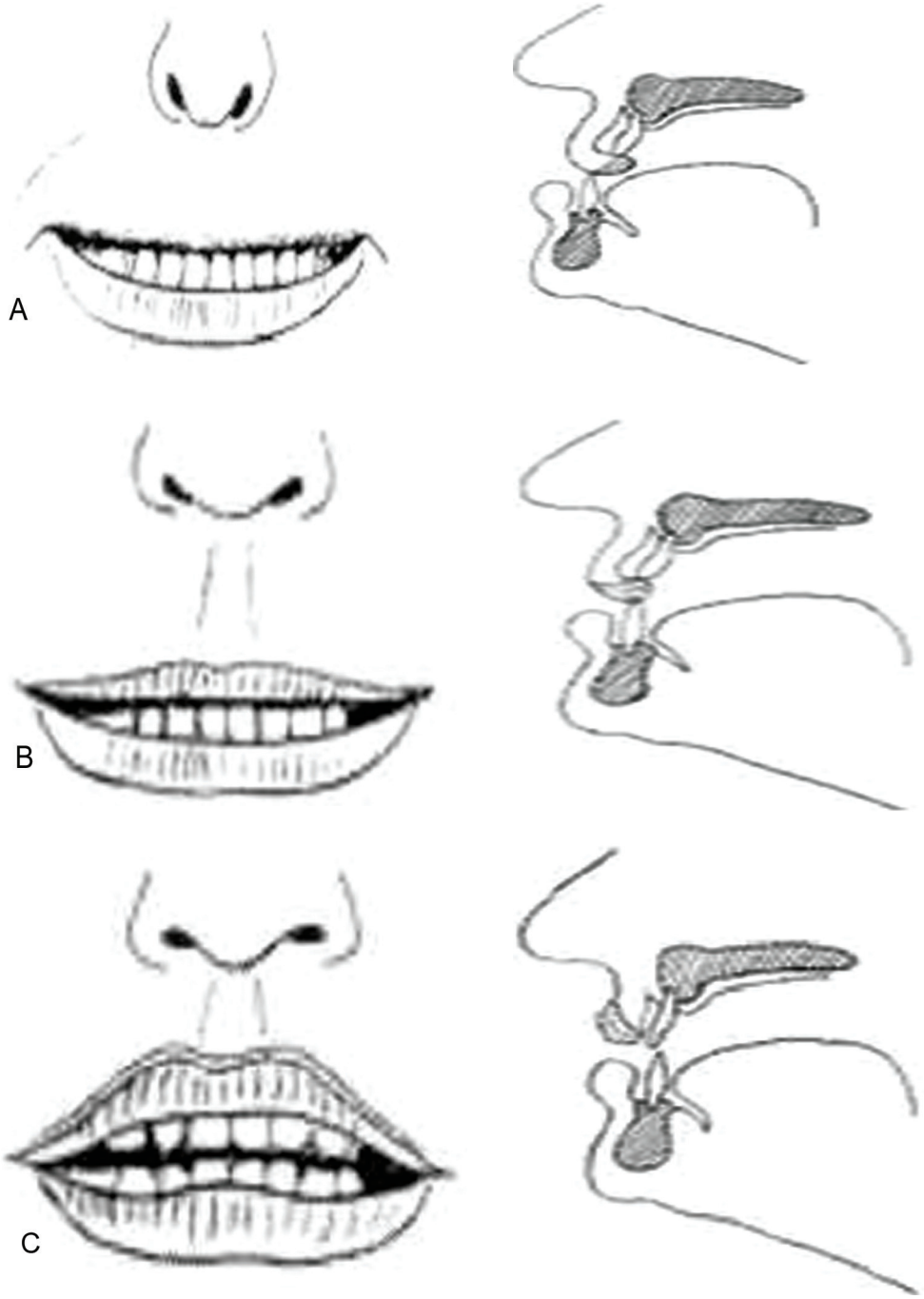


Fig. The Upper lip bite test was performed according to the following criteria.



UPPER LIP BITE TEST

Class 1 - Lower incisors can bite upper lip above the vermillion line

Class II - Lower incisors can bite upper lip below the vermillion line

Class III - Lower incisors cannot bite the upper lip

Procedure

On the day of surgery IV line was secured prior to surgery in the pre operative room, once the patient was shifted to the operating theatre, patients were monitored with electrocardiogram, non-invasive blood pressure and pulse oximeter. Adequate preoxygenation is given for 3 minutes with 100% oxygen. Patients were anaesthetized using balanced anaesthesia technique i.e., premedicated with IV glycopyrrolate 0.004 mg/Kg, IV midazolam 0.03 mg/kg and IV ondansetron 0.08mg/kg. patients were induced with IV propofol 2mg/Kg and the endotracheal intubation was accomplished with suxamethonium 1.5 to 2mg/Kg by Anaes-

thesiologists who were not informed of the preoperative modified mallampatti classification and upper lip bite test.

The patients' head and neck were kept in optimal intubating position with a pillow under the occiput during intubation (sniffing position), laryngoscopy was done using appropriate sized Macintosh blade and glottic view was graded according to the Cormack and Lehane grading.[7]

Cormack Lehane Grading of Glottis

Grade I	Full view of the glottis
Grade II a	partial view of glottis
Grade II b or arytenoids.	Only posterior commissure visible
Grade III	Only tip of epiglottis visible
Grade IV	No glottic structure visible

Patients were intubated with appropriate sized endotracheal tube. Patients vital signs were monitored throughout the procedure. At the end of surgery patients were adequately reversed with inj. glycopyrrolate 0.01 mg/kg and inj. neostigmine 0.05 mg/kg. Patients were extubated after through oral suctioning. After stabilization, patients were shifted to post operative recovery room. The pre operative airway assessment data and the findings during intubation were used to determine the sensitivity, specificity, positive and negative predictive values for each test.

Statistical Analysis

The pre operative airway assessment data and the findings during intubation were used to determine the sensitivity, specificity, positive and negative predictive values for each test. Fisher exact test and McNemar's test was used to calculate statistically significant difference in sensitivity and specificity between these tests respectively.

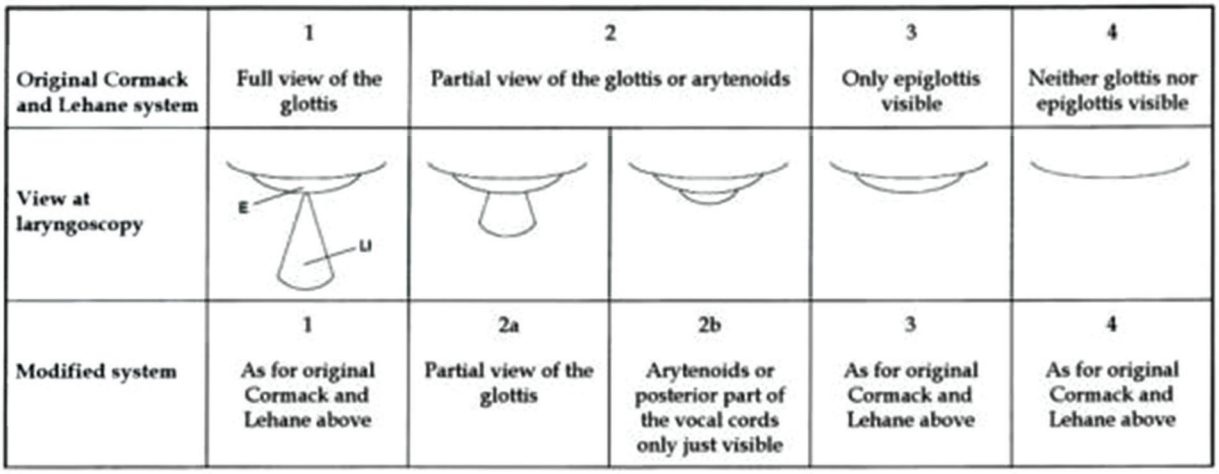


Fig. 1: Description of the two scoring system used, E = epiglottis, LI = laryngeal inlet.

Results

In our study MMT class III and IV along with ULBT class III were considered as predictors of difficult endotracheal intubation. On laryngoscopy Cormack Lehane view of III and IV were considered as difficult to intubate. In our study, eighty four had ULBT class I and II and sixteen patients had class III. Of these two of the ULBT class I and II and five of the ULBT class III had Cormack Lehane grade III as shown in the table 4 & graph 4. As shown in table 3, there were one hundred patients predicted to be easy for intubation by MMT (i.e. patients who had ULBT class I and II) out of whom however, we encountered difficult intubation in 6 patients. One in MMT class III also had difficult intubation. None of the patients had class IV MMT. Of the entire one hundred patients, a total of seven patients had difficult intubation, all of whom had Cormack Lehane class III on laryngoscopy. There were no cases of failed intubation in our study.

Table 1: Age Distribution.

Age (Years)	No. of Cases
16-25	30
26-35	36
36-45	23
46-55	11
Total	100
Mean	32.35
SD	9.94

Table 2: Gender Distribution.

	No. of Cases
Male	53
Female	47

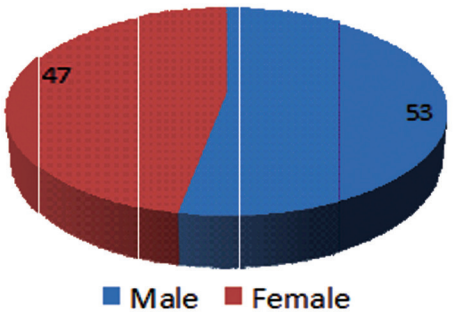


Fig. Gender Distribution.

Table 3: Body Mass Index

Body Mass Index	No. of Cases
16-19.99	16
20-24.99	67
25-29.99	13
30-34.99	4

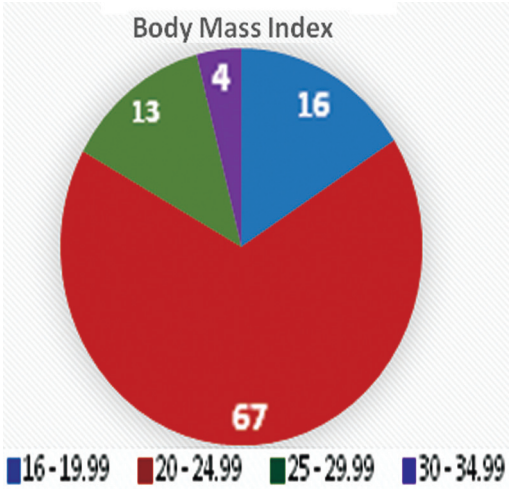


Fig. Body Mass Index.

Table 4: Cormack Lehane Grading.

ULBT	Difficult	Easy	Total
Difficult	6	10	16
Easy	1	83	84
Total	7	93	100

Difficult: Grade III & IV, Easy: Grade I & II.

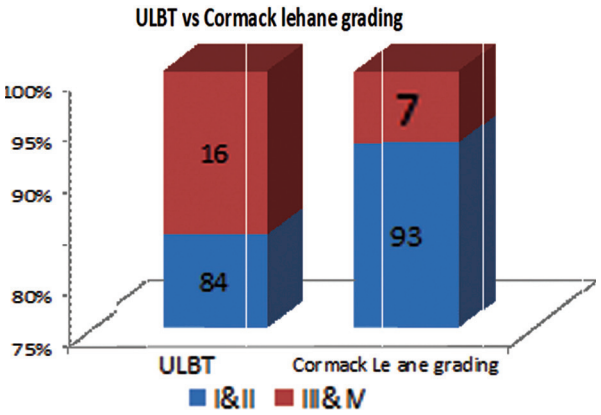


Fig. Relation between various classes of Upper lip bite test (ULBT) and Cormack Lehane gradings.

Out of 100 patients 84 had ULBT easy intubation and 16 patients had difficult intubation.

Table 5: Ulbt Vs Cormack Lehane Grading.

Parameter		95% C I
True Positives	6	
False Positives	10	
False Negatives	1	
True Negatives	83	
Sensitivity	85.71%	(48.69, 97.43)
Specificity	89.25%	(81.33, 94.05)
Positive Predictive Value	37.50%	(18.48, 61.36)
Negative Predictive Value	98.81%	(93.56, 99.79)
Diagnostic Accuracy	89%	(81.37, 93.75)

Table 6: Cormack Lehane Grading.

MMT	Difficult	Easy	Total
Difficult	1	3	4
Easy	6	90	96
Total	7	93	100

Difficult: Grade III, Easy: Grade I & II.

Relation between various classes of Modified Mallampatti test (MMT) and Cormack Lehane gradings.

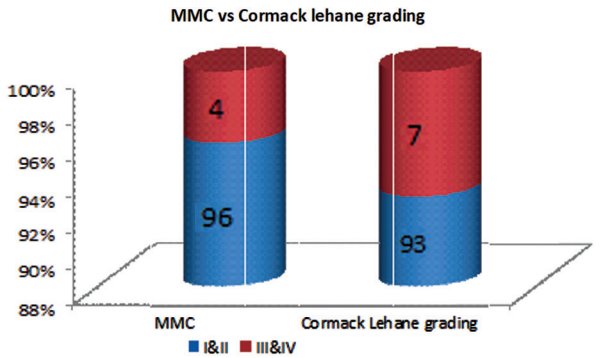


Fig. Out of 100 patients 96 had easy intubation and 4 had difficult intubation.

Table 7: Mmt Class Vs Cormack Lehane Grading.

Parameter		95% C I
True Positives	1	
False Positives	3	
False Negatives	6	
True Negatives	90	
Sensitivity	14.29%	(2.568, 51.31)
Specificity	89.25%	(81.33, 94.05)
Positive Predictive Value	9.09%	(1.623, 37.74)
Negative Predictive Value	93.26%	(86.06, 96.87)
Diagnostic Accuracy	84%	(75.58, 89.9)

Table 8: Comparison of Difficult Intubation.

Grades	ULBT	MMT	Cormack Lehane grading
I&II	84	96	93
III&IV	16	4	7

Of one hundred patients, 84 patients had ULBT class I and 96 patients had MMT class I, in whom there were no cases of difficult intubation. Five out of the sixteen cases of ULBT class III and one out of two cases in MMT class III had difficult intubation. In our study there were no cases of MMT class IV.

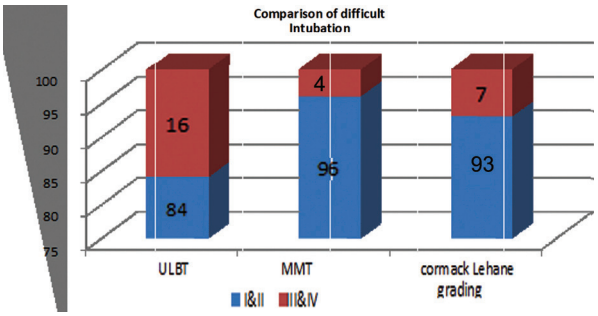


Fig. Comparison of difficult intubation.

Discussion

The incidence of unanticipated difficult intubation varies between 1.3% to 13% in various studies and the search for predictive tests that has ease of applicability, reliability and accuracy continues.

Khan et al's Upper Lip Bite Test was such an attempt. They proposed this test a combination of jaw subluxation and buck teeth as an alternative to the widely used test the Modified Mallampati Test .For Upper lip bite test the sensitivity was 85.7%,specificity was 89.25%,positive predictive value was 37.5%,The negative predictive value was 98.4%.For Modified mallampatti classification ,the sensitivity of MMT in our study was 14.29%the specificity was 89.25% Positive predictive value was 9.09%. The Negative predictive value was 93.26%.

On comparing both the tests, we found that, ULBT is more sensitive (85.71%) than MMT (14.29%), but both tests had high specificity and NPV. Difference in the sensitivity between the two tests was found to be statistically significant.

Although MMT had higher specificity, which is statistically significant ($p< 0.05$), it has a very poor sensitivity , making it an unreliable test to screen the patients for difficult intubations.

Both the tests have a negative predictive value more than 90%, thus stressing the fact that all these tests can be good predictors of easy intubation, rather as positive predictors of difficult intubation. ULBT has diagnostic accuracy of 87% .The accuracy that testifies lower false positives and negatives values in predicting difficult intubation was observed to be highest in UPPER LIP BITE TEST. Test with high accuracy is an optimal test for prediction of difficult intubation.Limitations of upper lip bite test are its is not appropriate for for edentulous patients since its consideration of buck teeth.Due to ethnic variations in craniofacial configuration of population and racial variatiions in morphology and morphometry of human mandible and maxillary bones.So upper lip bite test may not applicable for some populations

Conclusion

Upper Lip Bite Test (ULBT) is a better test at predicting difficult endotracheal intubation when compared to Modified Mallampati Test (MMT).

Upper lip bite test and modified mallampatti classification are good predictors of easy intubation rather than difficult intubation. Upper lip bite test should be used in combination with other airway assessment methods viz. Thyromental distance, hyomental distance, inter incisor distance to predict difficult intubation.

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Original Article

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Post-Operative Analgesia with Preventive and Post-Operative Rectal Diclofenac in Patients undergoing Caesarean Section Under Spinal Anesthesia: A Comparative Study

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Abstract

Background and aims: To study the analgesic efficacy of preventive rectal Diclofenac in comparison to post-operative rectal Diclofenac in elective caesarean section surgeries.

Methodology: After obtaining approval from institution ethics committee, patients undergoing elective caesarean section under spinal anesthesia were included in the study and divided into two groups ED(Early Diclofenac) & LD(Late Diclofenac), differing in the time of administration of first dose of 100mg rectal Diclofenac. Pain scores were noted at 12 & 24 hours post administration of first dose of rectal Diclofenac, using the numerical rating score. Rescue analgesia was given in form of Tramadol infusion. Time to first rescue analgesia, post-operative pain scores at 12& 24 hours, cumulative opioid requirements and side effects if any were noted.

Results: We observed a statistically significant difference in the time to first rescue analgesia between the two groups. There was no statistically significant difference in the average pain scores, cumulative opioid requirements and side effects between the two groups.

Conclusion: Rectal Diclofenac is an effective modality for treatment of postoperative pain after caesarean section. Preventive rectal Diclofenac, in comparison to postoperative Diclofenac significantly prolongs the duration to first rescue analgesia. The two groups did not differ significantly in the cumulative opioid consumption at 24 hours. There was no statistically significant difference in pain scores at 12 and 24 hours between the two groups. The average pain scores in both groups were around 3/10.

Keywords: Diclofenac; Preventive; Multimodal analgesia; Postoperative; Caesarean.

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Introduction

Post-operative pain, both acute and chronic, has significant bearing on the overall recovery and satisfaction of the patient. Traditionally, opioids are used for post-operative pain relief, but have side effects such as nausea, vomiting, sedation and respiratory depression. Use of multimodal analgesia helps in reducing opioid requirements and thereby associated side effects. The role of preventive analgesia in reducing acute and chronic pain is well documented. Severe post-op pain after caesarean section can be distressing for a mother who's sitting up and nursing her baby. When planning for postoperative analgesia for caesarean section, these concepts of multimodal and pre emptive analgesia could be made use of, to ensure better results.

Rationale

Preventive analgesia is based on the principle that administration of analgesics even before the first incision gives better post-operative pain relief.[1] Use of rectal Diclofenac in immediate postoperative period after caesarean is widely practiced. Common practice in our institution is to give Diclofenac suppository post operatively once patient reaches the Obstetric ICU. Rescue analgesia is given in the form of parenteral Tramadol. Through this study we aim to find out whether early administration of rectal Diclofenac has a better postoperative analgesic effect in comparison to late administration of rectal Diclofenac in patients undergoing caesarean section.

Review of Literature

Pain is defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage".[2] Traditionally opioids like Morphine, Pethidine, Tramadol and Fentanyl are used to provide postoperative analgesia.

Altered processing of afferent pain input can result in amplification of postoperative pain. Preventive analgesia is an antinociceptive treatment, which prevents the altered processing of this afferent input.[3] An editorial on preventive analgesia in the British Journal of Anaesthesia has commented on the significance of preventive analgesia in reducing chronic pain.[4]

The concept of multimodal analgesia is very popular and refers to the administration of two or more drugs that act by different mechanisms for providing analgesia which may be administered via the same route or by different routes.[5] Addition of analgesic adjuvants like NSAIDs (Diclofenac, Paracetamol, Ketorolac), alpha-2 agonists (Dexmedetomidine) and local anesthetic infusion (Lignocaine) has shown excellent analgesic and opioid sparing effects.[6–8]

In patients undergoing caesarean section, poor pain control results in reduced maternal satisfaction and longer hospital stay. Pain scores of 4/10 or above are unacceptable and need to be treated.[9] The incidence of chronic post-surgical pain at 3 months after caesarean section is as high as about 18% according to studies by Nikolajsen et al.[10] and Jin et al.[11] In patients undergoing caesarean section, for postoperative analgesia, National Institute for Health and Care Excellence, (NICE) UK recommends the administration of intrathecal Diamorphine, I.V. Patient Controlled Analgesia (PCA) using Morphine and non-steroidal anti-inflammatory drugs, provided there are no contraindications to it.[12] In Indian scenario, Diamorphine is not available and PCA Morphine may be available only at few centres.

Hence, postoperative analgesia for caesarean section mostly comprises of a combination of parenteral opioids (Morphine, Pethidine, Tramadol) and NSAIDs (Diclofenac, Paracetamol). Intramuscular administration of Diclofenac is painful. Diclofenac administered rectally, is a safe and convenient approach resulting in complete absorption and sustained release of drug providing early onset and long duration of post-operative analgesia. Study by Olofsson et al has shown that addition of rectal Diclofenac significantly reduces the postoperative opioid requirements in caesarean section patients.[13]

The other techniques of analgesia described in patients undergoing caesarean section are wound infiltration analgesia, Bilateral Tranversus Abdominis Plane(TAP) block, Continuous Epidural Analgesia and Intrathecal Morphine.[14] Wound infiltration technique is useful but limited by the duration of action of local anaesthetics.[15] This can be overcome by use of wound soaker catheters.[16] Bilateral TAP blocks have demonstrated opioid sparing effects.[17] Continuous epidural technique offers excellent analgesia, both for labour pain and post-operative pain. Intrathecal Morphine gives longer duration of pain relief, but at the expense of side effects such as nausea, vomiting and pruritus.[18]

Aims and Objectives

Aim:To study the analgesic effectiveness of

preventive rectal Diclofenac in comparison to postoperative rectal Diclofenac in elective caesarean section surgeries.

Objectives

- To compare time to first rescue analgesia in patients given rectal Diclofenac preventively and post operatively.
- To compare the pain scores in patients in the two groups at 12 & 24 hours post-surgery.
- To compare total opioid requirements of patients in the two groups in the first 24 hours.
- To evaluate side effects like nausea, vomiting and increased bleeding.

Materials and Methodology

This study was done as part of an ICMR STS (Indian Council of Medical Research- Short Term Studentship) program, which is time limited and to be completed over two months. After getting Institutional Ethics Committee approval(Ref-MOSC/IEC/287/2018), we did this prospective observational study in post-operative ICU and wards of Obstetrics and Gynaecology in our Medical College Hospital, over a period of two months, June to July 2018.

Sample size was calculated for true probability that mean Numerical Rating Score(X) of LD group (post-operative analgesia) would be greater than the mean score(Y) ED group (preventive analgesia) of i.e. P[A>B]>1/2. Sample size calculated using the Mann-Whitney U test.

$$n = \frac{\left(Z_{\alpha/2} + Z_{\beta}\right)^2}{12c(1-c)(p^n - 0.5)^2} \qquad \text{where,}$$

P^n = Probability of a score from X being larger than a score from Y is greater than ½, c=1/(1=k), where k is the allocation ratio.

$Z_{\alpha/2}$ =1.96, Z_{β} =0.84

For a power of 80% and alpha error of 5%, sample size is 54; hence two groups of 27 subjects each were included.

Patients selected were parturients with no comorbidities (ASA Class II) undergoing elective caesarean section under spinal anaesthesia and given Diclofenac suppository perioperatively .Patients coming under ASA Class III or more, receiving general anaesthesia or epidural anaesthesia, receiving adjuvants like Clonidine along with spinal anaesthetic, patients with contraindication to Diclofenac (Asthma, Peptic ulcer, allergies to NSAIDs, renal and hepatic diseases) and pregnancy induced hypertension(PIH) were excluded from the study.

Methodology

54 parturients undergoing elective caesarean sections done under spinal anaesthesia were included in the study. All patients received oral premedication, Tab Metoclopramide 10 mg and Tab Ranitidine 150 mg, two hours prior to surgery. Patients were met preoperatively and informed consent was taken. They were educated about pain assessment using the Numerical Rating Scale. Intravenous access using 18 G cannula was routine for all subjects and Ringer Lactate was started. Routine patient monitoring including ECG, Non Invasive BP and Pulse Oximetry was initiated.

Under strict aseptic precautions, spinal anaesthetic was administered in the left lateral decubitus position using 25 Gauge Whitacre spinal needle. All patients received the standard dose of 2ml 0.5% heavy Bupivacaine and Fentanyl 10 micrograms intrathecally. We had two groups of 27 patients each, Early Diclofenac (ED) group receiving rectal Diclofenac immediately after the spinal anaesthetic, before the surgery starts (preventively) and Late Diclofenac (LD) group of patients receiving rectal Diclofenac after the spinal anaesthetic only after reaching the ICU (post-operatively).

Both groups receive rescue analgesia in the form of parenteral Tramadol as intravenous infusion (100 mg in 100 ml NS over 15 minutes as the first dose and 50mg in 100 ml NS over 15 minutes for subsequent doses, if required upto a maximum of 4 doses) in the first 24 hours. Another dose of rectal Diclofenac, 50 mg was given to all patients, 8 hours after the initial dose, thus limiting it to the maximum daily dose of Diclofenac-150mg/day. Inj. Ondansetron 4 mg I.V was prescribed as antiemetic for all patients receiving Tramadol.

Time of first administration of 100mg Diclofenac is taken as Time Zero (To) in the two groups. Time to first rescue analgesia is compared between the two groups. The pain score of patients in the two groups are compared at 12 & 24 hours using numerical rating scale (0-10). Cumulative opioid requirements in first 24 hours is compared between the two groups. Side effects like nausea, vomiting and increased bleeding were assessed.

The results were tabulated and subjected to statistical analysis. The time to first rescue analgesia was analyzed statistically using the Mann Whitney

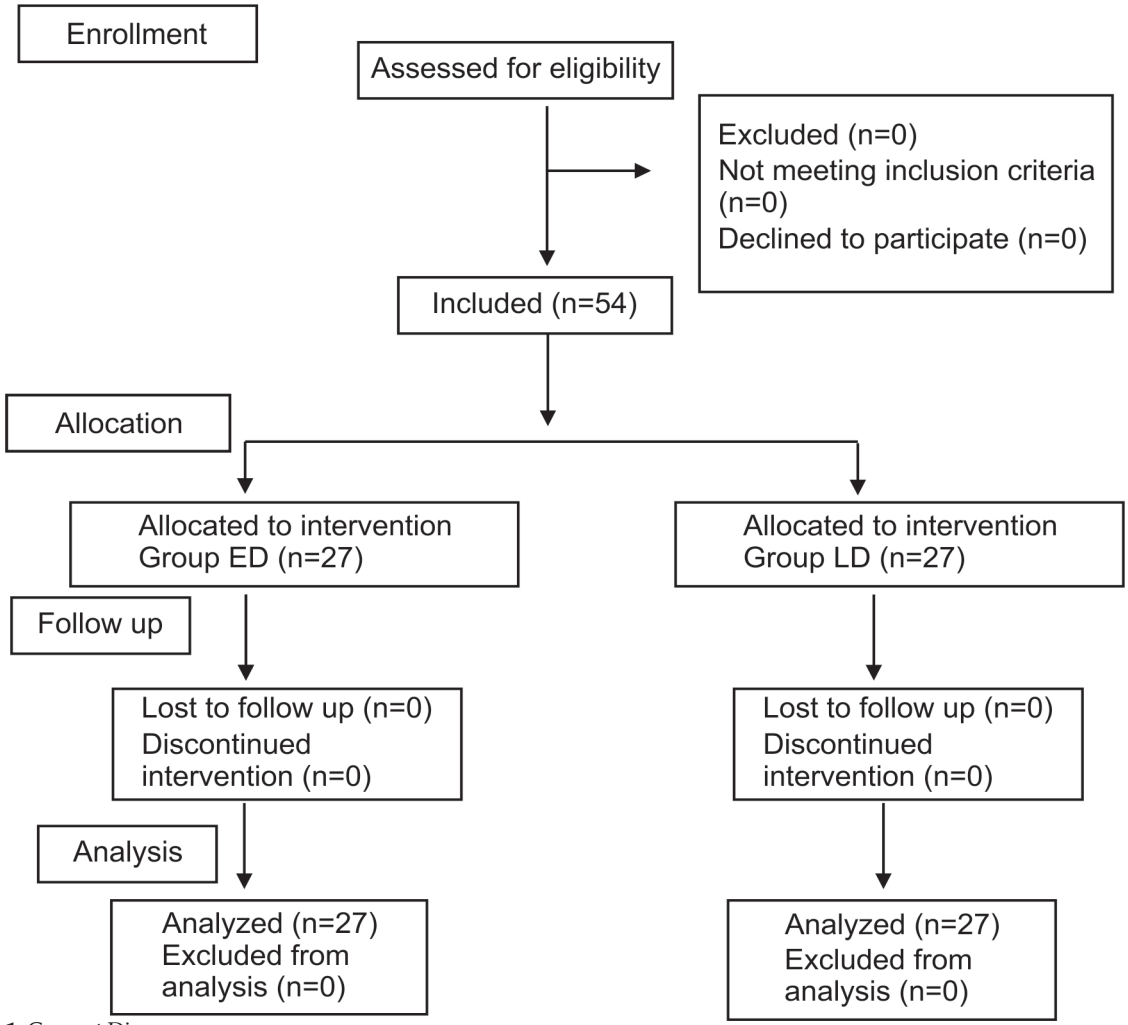

Fig. 1: Consort Diagram.

U test. The pain scores were analyzed statistically using the Repeated Measures Anova test and the total opioid requirement was analyzed using the Mann Whitney U test.

Results

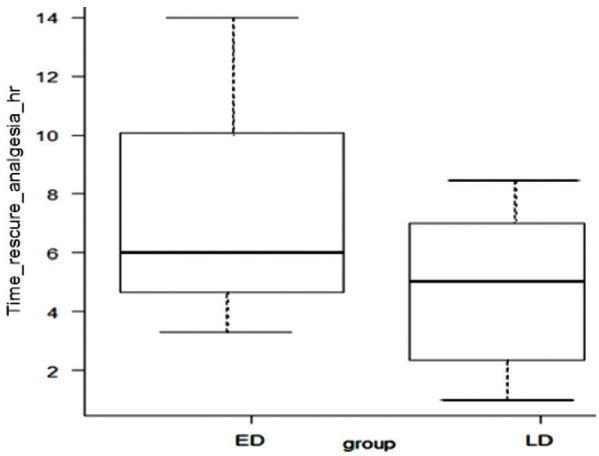

Fig. 2: Median time to rescue analgesia in Groups ED and LD.

The patient demographics such as age and weight were comparable in both the groups as evident from table 1. All patients included in the study had high school education or above.

Table 1: Patient Demographics.

Parameter	Group ED	Group LD
Age	29.29 +/- 4.03	27.96 +/- 4.36
Weight	64.11 +/- 2.06	64.59 +/- 1.60
Duration of surgery	63.14 +/- 5.05	63.03 +/- 4.33

Table 2: Median time to rescue analgesia in Groups ED and LD.

Group	Median	Q1, Q3	U Statistic	P value
ED	6	4.3, 10.15	190	0.011
LD	5.05	2.32, 7	-	-

The median time to rescue analgesia in Groups ED and LD was 6 hours and 5.05 hours respectively. Refer table 2 and Figure 2. We have performed Mann-Whitney U test to check if there is any difference in average time to rescue analgesia between ED and LD groups. There was a statistically significant difference between the two groups in the average time to first rescue analgesia. (p= .01)

Table 3: Average pain scores at 12 and 24 hours in Groups ED and LD.

	Mean (SD)	
Groups	**12 hr.**	**24 hr.**
ED	2.96 (1.22)	2.89(1.34)
LD	2.93 (1.07)	3.15 (1.46)

Table 4: Average Tramadol consumption in 1st 24 hours in Groups ED and LD.

Group	Median	Q1,Q3	U Statistics	P value
ED	100	100,125	294	0.43
LD	100	100,100	-	-

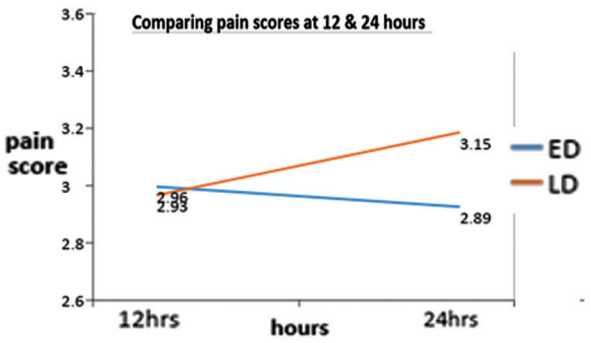

Fig. 3: Average pain scores at 12 and 24 hours in Groups ED and LD.

The average pain scores in groups ED and LD at 12 hours were 2.96 and 2.93 and 2.89 and 3.15 at 24 hours respectively. We performed Repeated Measures Anova to check if there is any significant difference in pain scores between ED and LD groups at 12 & 24 hours. It was observed that there was no significant difference in the average pain scores between ED and LD groups at 12 and 24 hours (p=.73). It was also observed that there was no significant difference in the average pain scores between the two different time points i.e. 12 and 24 hours (p= .63). Refer figure 3 and table 3.

The median dose of Tramadol used in 24 hours was same in both groups- 100 mg. We have performed Mann Whitney U test to check if there is any statistically significant difference in the cumulative opioid requirement between ED and LD groups. It was observed that there was no statistically significant difference between the groups (p= .43). Refer table 4. None of the patients had nausea, vomiting or excessive bleeding.

Discussion

This study was undertaken to evaluate the effect of preventive rectal Diclofenac in the management of post-operative pain in patients undergoing caesarean section under spinal anesthesia. The analgesic efficacy was assessed in terms of time to first rescue analgesia, mean pain scores at 12 and 24 hours and cumulative opioid requirements at 24 hours. Side effects such as excessive bleeding, nausea and vomiting if any, were noted.

Preventive analgesia has a clear role in the management of acute pain and to some extent in prevention of chronic pain.[19] It reduces the postoperative opioid requirements and also prevents establishment of central sensitization thereby, reducing the incidence of chronic pain[3] Preventive administration of rectal Diclofenac has shown to be effective in management of post-operative pain in a variety of surgical settings.[6,13,20,21] Addition of rectal Diclofenac significantly reduces the postoperative opioid requirements in caesarean section patients as demonstrated in the study by Oloffson et al. and Rashid et al.[13,21]

Multimodal analgesia offers superior analgesia and reduced opioid consumption. The options for components of multimodal therapy for caesarean section pain include opioids, NSAIDs, Paracetamol, Local Anaesthetic infiltration, TAP block, Epidural local anaesthetic with or without opioid and intrathecal opioid.[13] We have used a combination of Tramadol (Opioid) and Diclofenac (NSAID) as analgesic regime for caesarean section.

Our study showed that preventive rectal Diclofenac in comparison to postoperative rectal Diclofenac, prolonged the time to first rescue analgesia. This result was consistent with the meta analysis study findings by Ong et al.[19]

In our study we could not observe any statistically significant difference in pain scores at 12 and 24 hours between the two groups. The mean pain scores at 12 hours was 2.96 in ED group and 2.93 in LD group, while at 24 hours, the pain scores were 2.89 in ED group and 3.15 in the LD group. Although the mean pain score was lower in the ED group compared to LD group at 24 hours, it was not statistically significant. The mean pain scores at 12 and 24 hours postoperatively was around 3/10 in our study population, which was fairly good.

There was no statistically significant difference in the cumulative opioid consumption between the patient groups in the first 24 hours. The average 24 hour opioid consumption in our study population was fairly low (Tramadol 100 mg). This reflects excellent postoperative analgesia when using this combination of parenteral Tramadol and rectal Diclofenac. Side effects such as nausea and vomiting were absent. This could be consistent

with reduced opioid requirements and use of Ondansetron as antiemetic in both the groups. There was no incidence of significant bleeding in either of the groups.

Limitations

Pain is a subjective entity which necessitates a large sample size for proper interpretation of the results. Due to the limited time period allotted for the study, we had to limit ourselves to a smaller sample size. As there was no formal follow-up of these patients after discharge from the hospital, the incidence of chronic postsurgical pain could not be evaluated.

Conclusion

Rectal Diclofenac, as part of multimodal analgesia, is effective for treatment of post-operative pain after caesarean section. Preventive rectal Diclofenac in comparison to postoperative rectal Diclofenac, significantly prolongs the time to first rescue analgesia. Cumulative opioid consumption at 24 hours did not vary between the two groups. There was no statistically significant difference between the groups in terms of average pain scores at 12 and 24 hours postoperatively. No side effects such as nausea, vomiting or increased blood loss were noted in either of the groups.

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Original Article

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Nalbuphine versus Dexmeditomedine Effect on Hemodynamic Stress Response During Intubation

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Abstract

Aims: Sympathetic system gets stimulated ondirect laryngoscopy and intubationand catecholamines are released. This response though of short duration, is hazardous to compromised subjects with brain and cardiac dysfunction. Vagus nerve also can be stimulated during laryngoscopy and intubation.

Ourstudy is to find out the effects of Nalbuphine Hcl 5mgm and Dexmedetomidine 25mgm on hemodynamic variables SBP, DBP, MAP and HR at the time of laryngoscopy and intubation. Study was carried out in Pushpagiri Institute of Medical Sciences. Consecutive sampling technique was used to select study population.

Methodology: We selected 100 subjects, ASA1 and 2, were randomly grouped into 2 groups of 50 each. All our subjects received 500ml crystalloid solution. Allsubjects were induced on Propofol and intubated on succinylcholine. The stress response was assessed by observing hemodynamic variables SBP, DBP, MAP and HR.

Statistical Analysis: Data was digitized and analyzed using SPSS22.0. Independent sample test was used to assess the difference in parameters. Data was stratified on the basis of age and weight of 2 groups. P-value of less than 0.05 was considered statistically significant.

Conclusions: Dexmedetomidine influences HR and the effect is more as age advances. In subjects heavier than 80kg, mean HR was higher. The effect of Dexmedetomidine on heart rate was statistically significant at a P value less than 0.05. Nalbuphine, according to studies, increases BP and HR. In our study, this rise in MAP was observed in subjects heavier than 70kg. But this finding was not statistically significant.

Keywords: Nalbuphine Hcl; Dexmedetomidine; Laryngoscopy; Intubation stress.

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Introduction

General anesthesia involves direct laryngoscopy, intubation and mechanical ventilation. Direct laryngoscopy stimulates proprioceptors at the base of the tongue and the hypothalamic pituitary axis is stimulated. Sympathetic system in turn release catecholamines and blood pressure and heart rate increases. The sympathetic response though brief can adversely affect subjects with compromised brain functions and cardiac functions.Vagus nerve stimulation can cause bradycardia and even cardiac arrest.Various pharmacological methods are being formulated to alleviate this stress response.

Nalbuphine hydrochloride is a phenanthrene opioid derivative N-Cyclobutyl methyl 4 5. a-c poxy[3,6] a1[4] Morphine.[8] Analgesic potency of Nalbuphine is 0.8 to 0.9 times that of morphine. Nalbuphine 10mgm=10mgm Morphine=75mgm Pethidine. It is a partial agonist at both mu and kappa receptors and possess agonist–antagonist property. Unlike Morphine,Nalbuphine is cardiac stable and does not produce respiratory depression and bronchospasm. It has antipruritic property too. Routes of administration can be IM,IV or S/C. Onset of action after iv route isin 2 to 3 mts and is metabolized in the liver. The dose given is 0.5 to 3mgm/kg.[8] We have used 0.1 mgm for our study in Group 1 and given a fixed dose of inj.5 mgm Nalbuphine iv as the first drug of iv induction for all our subjects in group 1.

Dexmedetomidine an alpha2 agonist dexorotatoryS. enantiomore of medetomidine an imidazolederivative.[8] It is a sedative hypnotic with sympatholytic and analgesic properties. It suppresses shivering and preserves hypercapnic response.Premedication dose is 0.33-0.67ugm iv. Different doses of the drug have been tried to find the ideal dose of drug to alleviate the pressor response during laryngoscopy and intubation.We have used 25 mic.gm iv as the first drug of iv induction for all our subjects in Group2. inj. Dexmedetomidine. Both drugs were diluted and given by second person and observer monitor hemodynamic variabilities from the time of induction every 3 minutes for next 15 mts.

Our observational study considered 100 subjects all belonging to ASA1 and 2. We have followed standard protocol for preanesthetic checkup, premedication and period of fasting. Our subjects were randomly grouped into 2 groups of 50 each Group 1 received 5mgm Nalbuphine diluted to 5ml as the first drug during induction and Group 2 received 25ugm Dexmedetomidine. Technique of anesthesia followed standard protocol. All our subjects received 500 ml ringer lactate. All our subjects were induced with inj. Propofol 2mgm/kg and intubated on 100mgm succinyl scholine. Anesthesia was maintained with nitrousoxide, O_2, vecuronium and sevoflurane. Standard monitors were used to observe the hemodynamic variants.

Objectives

- To observe MAPandHR of Subjects from the time of induction and then, every 3 minutes for 15 minutes after inj. Nalbuphine Hcl 5mgm IV was given as first drug of induction.
- To observe whether age of the subjects affect the hemodynamic variability in Group1. (Nalbuphine Hcl 5 mg).
- To observe whether weight of the subjects affect hemodynamic variability in Group1 (Nalbuphine Hcl).
- To observe MAP and HR of Subjects from the time of induction, andthen every 3 minutes for 15 minutes after inj. Dexmedetomidine 25mcg IV was given as first drug of induction (Group 2).
- To observe whether age of the subjects affect the hemodynamic variability in Group2 (inj. Dexmedetomidine 25mcg IV).
- To observe whether weight of the subjects affect hemodynamic variability in Group2 (inj. Dexmedetomidine 25mcg iv).

Methods

Study Design

A consecutive sampling technique was used to select study population.

Sample Size

Minimal sample size per each group using the formula $\frac{2(\mathrm{sd})^2(\mathrm{za}+\mathrm{zb})^2}{\Delta^2}$

Sample size is 50 per group

Sampling Method

By block randomization and allocation concealed by sealed envelope.

Ethical Clearance

An ethical clearance was obtained from institution and an individual written and informed consent was obtained from each subject before enrolling them

Procedure

Exclusion Criteria

- Subjects with known allergy.
- Subjects with difficult airway(Mallampatti 3and 4).
- Age below 18 years and above 70 years.
- Emergency surgeries.
- Pregnancy with surgical problems.
- Subjects with cardiac problems.

We have observed 100 subjects coming for various surgical procedures under general anesthesia age between 18 to 70 years with Mallampatti score 1 and 2. All of them belonged to ASA1 and 2 considering the exclusion criteria given above. Preanesthetic checkup was done the day before. All of them were given Tab. Ranitidine 150mgm, Tab. Metaclopramide 10mg and Alprazolam 0.5 mg orally 2hrs. before surgery. All our subjects followed standard protocol for fasting. After getting informed risk consent our subjects were taken to the operation theatre. All our subjects were given 500 ml crystalloid through 20g iv cannula on nondominant hand. Standard monitors were used to monitor the hemodynamic variables.

All our subjects were monitored with ECG, NIBP, SPO_2. Preoxygenation was given for 3 minutes. Group1 received 5mg of Nalbuphine Hcl diluted to 5 ml as the first drug of iv induction and group 2 received 25 mcgm of Dexmed diluted to 5ml as first drug of induction. Hemodynamic variabilities were noted.Baseline value was taken as SBP, DBP, and HR at the onset of induction andthen every 3 mts for 15 mt. Values were collected, recorded and statistically analysed.

A rise in MAP more than 20% from baseline was considered hypertension and a fall in MAP less than 20% from baseline was treated with 3mgm ephedrine iv. A fall in HR less than 40/ mt was treated with rescue drug (inj. Atropine 0.6 mg iv) None of our subjects needed rescue drugs.

Results

Data was digitized using Microsoft excel and analyzed using SPSS 22.0. The mean and standard deviation of HR, SBP, DBP and MAP of the 2 groups at various time points were found out. The differences in these parameters between the 2 groups were assessed using Independent Sample t–test. The data was stratified on the basis of age and weight to compare the 2 groups. Pvalue of less than0.05 was taken as statistically significant.

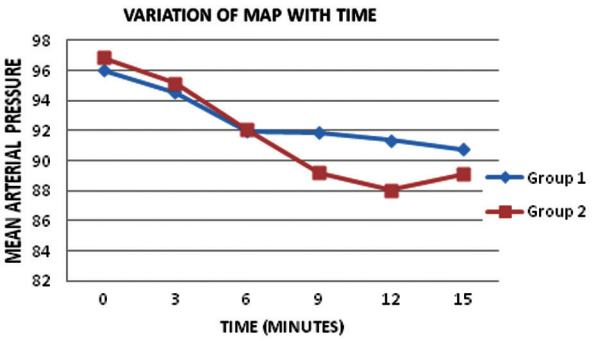

Fig. 1: Comparison of Mean Arterial pressure between the 2 groups in relation to time.

Mean Arterial Pressure of two groups were comparable. There is a significant fall in MAP from baseline between 3 and 6 minutes in both groups. No significant statistical difference was noted between the 2 groups.

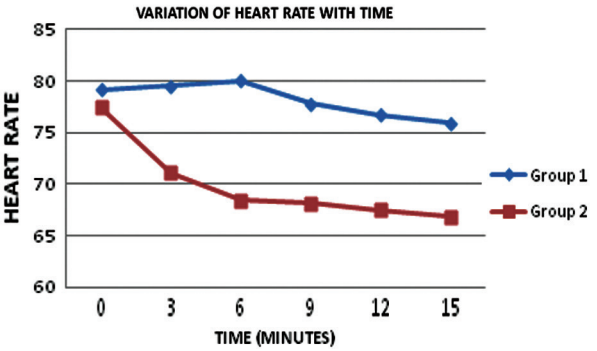

Fig. 2: Comparison of mean heart rate between group1 and group2 in relation with time.

Mean Heart rate of two groups are comparable. There is a statistically significant fall in HR from baseline in group 2 from 3 to 15 minutes. Significant p value (<0.05) noted between 2 groups at 3 to 15 minutes. Dominant action of Dexmed on the heart is decreasing tachycardia through blocking cardioaccelerator nerves and vagomimetic action through alpha 2A-AR receptor.

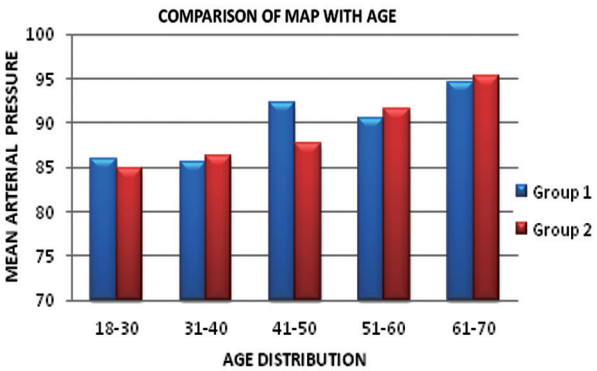

Fig. 3: Comparison of Mean Arterial Pressure in group 1 and group2 in relation to age.

MAP of Group 1 was found to be higher than Group 2 for the age group of 40-50 years but on statistical analysis there was no significant difference. The subjects were divided into 2 groups inrelation to age in both groups.[1] Group 18 to 40 years and the other 40 to70 years for statistical analysis. Dexmed evokes a biphasic response on BP. A short hypertensive response and subsequent hypotensive response mediated by 2 alpha-AR subtypes. Alpha 2 AB-AR for hypertensive response and hypotension by 2 alpha A-AR receptor.[11]

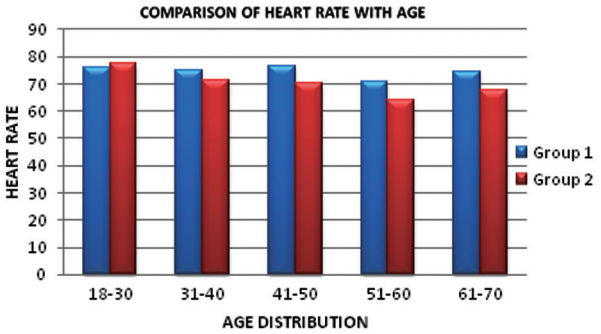

Fig. 4: Comparison of Mean Heart Rate in Group 1 and 2 in relation to age of the subjects.

Mean Heart rate in both groups were comparable with age up to 40 years. There is a significant (p value <0.05) fall in Heart rate in age between 40-70 years in Group2.In our study we had kept a HR of 40/mt as lower limit.None of our subjects needed rescue drug Atropine.[11]

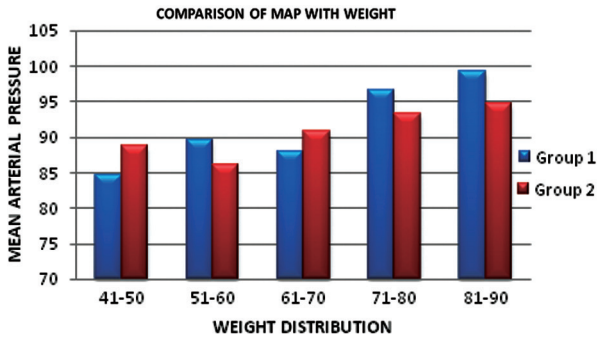

Fig. 5: Comparison of Mean Arterial Pressure in Group 1 and 2 in relation to weight of the subjects.

Mean Arterial Pressure in both Groups were comparable with weight. MAP was found to be higher in Group 1 between 70-90kg. On statistical analysis there was no significant difference with weight. These group of subjects may need higher dose of Inj Nalbuphine Hcl.The stimulation of alpha 2 b receptors on vascular smooth muscles is postulated to be the cause of increase in BP with Dexmed when given as single IV dose.

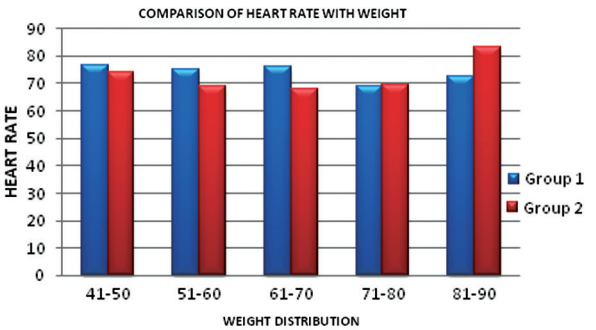

Fig. 6: Comparison of Mean Heart in Group 1 and Group 2 in relation to weight of the subjects.

Mean Heart Rate of both groups were comparable with relation to weight of the subjects. On statistical analysis there was no significant difference between the 2 groups. The Mean Heart rate was higher in subjects with Weight more than 80kg Group 2. Dexmed is a very short acting drug which gets distributed in 6mts. May be an iv infusion would have been more effective than single dose.[4]

Discussion

Group 1 subjects who received Nalbuphine were hemodynamically stable from the time of induction to next 15 minutes on observation.The MAP was higher in subjects with weight more than 80 kg. The dose of Nalbuphine was not enoughto nullify sympathetic response in these subjects. Dexmedetomidine lowered HR in Group 2. The fall in HR was more obvious in subjects above 50 years. But in subjects weighing more than 80kg, the MAP was higher indicating the need for continuous level of drug concentration through an IV infusion. Dexmed being a very short acting drug the hypotensive response is short.[6] The statistical significance was noted with HR on comparison between 2 groups and is related to its alpha 2 agonist property.

Nalbuphine a drug with agonist antagonist property is mainly used for perop and post-operative analgesia.[11] NNSudafule[12] in their comparative study on efficacy of Nalbuphine with pentazocine noted a rise in heartrate and blood pressure after intubation with Nalbuphine.Their iv dose was 0.3 mg / kg. Our drug dose is 0.1mg/kg.But we have given a fixed dose of inj. Nalbuphine Hcl(5mgm) to all our subjects and did not find any significant change in HR and.None of our subjects showed a significant rise or fall in MAP in Group1. Our induction agent Inj. Propofol 2 mgm/kg might have influenced the results.

Hariprasad et al[6] in their study on Nalbuphine

did not find any statistically significant risein heart rate. His study was on 4o patients. We also agree with his findings. Our Group 1 included 50 subjects and our drug dose was 0.1 mgm/kg. Their dose was 0.2mgm/kg. Hariprasad used isoflurane where as we used sevoflurane. Chowda et al.[5] agree to the above finding. Sohaib Basheer et al.[9] noted a significant rise in HBP, DBP and MAP with Nalbuphine. Tariq Mohammed[14] had used 0.02mg/kg Nalbuphine and found it to have stable hemodynamics in his subjects.

Dexmedetomidine is an alpha 2 agonist with sympatholytic properties.[7] It is a sedative, amnestic, analgesic with antishivering property. Dexmed is used as a safe anaesthetic adjuvant in both general and regional anesthesia.[7] It is the active dextroen antiomore of medetomidine a methylated derivative of etomidate. Sandeep Kundra[13] has used Dexmed in his study and states that it provides goodhemodynamic stability. We had given single bolus dose of Dexmed diluted to 5ml iv over 5 minutes as the first drug of iv induction. We have noted a fall in HR from baseline in our study,but not below 40/ mt.[8] A brief biphasic dose dependent cardiovascular response has been reported after initial administration of Dexmed resulting in an initial increase in BP and Fall in HR.[1] This response is more in young and healthy. Our study agrees with this finding. Manpreet Kaur et al[8] describes Dexmed can be used safely in controlled hypotension and the dose advised is 1micgm/kg to suppress laryngeal reflex during intubation.

Bajwa and Kulashethra[3] state that dexmedetomidine blunts hyperdynamic response to laryngoscopy and surgery. In the heart, dominant action is to decrease tachycardia by blocking cardio accelerator and bradycardia via vagomimeticaction. Due to its central sympatholytic effect it can be used to alleviate pressor response.Anilo Nova[2] suggests 1mcgm/kg Dexmedbolus dose to suppress hemodynamic response to laryngoscopy and intubation.

We have noted a rise in HR in group 2 in subjects aged above 60 years. This group may need a higher dose. Misra[10] in his study, found Dexmed better than Nalbuphine to suppress laryngotracheal reflex during intubation. We also noted a fall in HR from baseline. Our lower limit was 40/ mt. Lowest HR we observed in this study was 42/mt.

Conclusion

Nalbuphine maintains hemodynamic stability during laryngoscopy and intubation. It can be safely given intra venously. Dexmedetomidine gives stable MAP at our doseof 25 micgm iv. The effect of Dexmedetomidine on heart rate was statistically significant with a P value less than 0.05. Vagolytic effect was more than that on blood pressure. The fall in HR was more in older age group. Weight of the subjects modified the results in both groups.

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Original Article

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A Comparative Study of Dexmedetomidine and Tramadol for Prevention of Post-Spinal Anesthesia Shivering

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Abstract

Background: Shivering is an unpleasant and stressful symptom for the patient undergoing surgery. It occurs as a thermoregulatory response to hypothermia. Shivering obscures intraoperative monitoring. It can be detrimental to patients with low cardiorespiratory reserve as it increases oxygen demand, produces arterial hypoxemia and lactic acidosis. This study aimed to evaluate the relative efficacy of intravenously administered Inj. Dexmedetomidine 0.5µg/kg in 100 ml NS and Tramadol 0.5 mg/kg in 100 ml NS and 100 ml NS as a placebo group in controlling shivering posted for lower abdominal surgeries and lower limb general surgeries under spinal anaesthesia.

Method: 120 participants, aged 18 to 65 years, of ASA Physical status I and II, scheduled for lower abdominal surgeries and lower limbgeneral surgeries under spinal anaesthesia. The patients were randomly allocated into 3 groups of 40 each and were named as group D (Dexmedetomidine 0.5µg/kg), group T (Tramadol 0.5mg/kg) and group N (100ml Normal Saline) as aplacebo. Vital parameters of the patients such as heart rate, blood pressure, spo2, temperature and shivering score, sedation score were monitored at regular intervals as per protocol. Statistical tests like Chi square test, Student's t test (unpaired and paired) were applied to the data collected.

Results: Both the dexmedetomidine and tramadol were effective in the prevention of post-spinal shivering. Dexmedetomidine had better sedation profile (P value <0.0001) without any respiratory depression and had fewer incidences of nausea and vomiting when compared to Tramadol. Thus, it can be used as a better alternate for shivering prophylaxis for patients undergoing surgeries under regional anesthesia.

Conclusion: Dexmedetomidine is more effective in the prevention of shivering when compared with tramadol and placebo (normal saline). Dexmedetomidine has an added advantage of adequate reliable sedation. Hence we conclude that Dexmedetomidine at 0.5µg/kg is most effective in the prevention of shivering when compared with tramadol.

Keywords: Subarachnoid Block; Dexmedetomidine; Tramadol; hyperbaric Bupivacaine; Normal Saline; Sedation; Shivering; Lower abdominal surgeries and lower limb general surgeries.

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Introduction

Shivering is a common and distressing experience to many patients which occurs either during or immediately after the surgery. It is defined as an involuntary, repetitive activity of skeletal muscles. The incidence of shivering varies but is very high and the incidence is approximately[1] 40 – 50%.

Human core temperature normally ranges from 36.50C to 37.50C. Anterior hypothalamus integrates thermal inputs from different tissues of the body and compares peripheral information with a set point or threshold value.[8] Temperature lower than this set point will result in responses to warm the body while temperatures higher will trigger reflexes to cool the body.

Studies in recent years have shown that even mild hypothermia[2] (10C–20C) can triple the incidence of adverse cardiac outcomes. An increase in surgical blood loss and increase in need for blood transfusion by 20% is also noted. All these factors leads to a prolonged hospitalization.

In patients undergoing neuraxial anaesthesia, shivering is a normal thermoregulatory mechanism as evidenced by the presence of vasoconstriction before shivering. Spinal anaesthesia impairs the thermoregulatory system by inhibiting vasoconstriction, which plays an important role in temperature regulation. Spinal anaesthesia results in redistribution of core heat to the periphery from the trunk [below the level of block]. Both these effects predispose patients undergoing spinal anaesthesia to hypothermia andshivering.[5]

Shivering during surgery leads to an uncomfortable experience to the patient along with that leads to an increase in oxygen consumption and carbon dioxide production by two to three fold. Shivering can also increase catecholamine production, lactic acidosis, intraocular pressure, intracranial pressure. Mild shivering increases oxygen consumption like that produced[7] by light exercise but severe shivering can increase oxygen consumption and metabolic rate by 100–600%. This can prove detrimental to patients with limited cardiac reserve. Shivering also creates difficulty in monitoring the patients as most of the multi parameter monitors used for anaesthesia show erroneousvalues.

Treatment of shivering consists of both non-pharmacological and pharmacological methods. Non-pharmacological methods of treatment include external heating like use of blankets, forced air warmers and warmed fluids, maintaining operating room temperature etc.[6]

Pharmacological methods for treatment of hypothermia is the next resort to treat all these patients. A number of drugs were studied and are being used. Most commonly used drugs include tramadol, dexmedetomidine, magnesium sulphate, etc.[4]

Many studies on tramadol showed its efficacy in the treatment of shivering. Tramadol produces adverse effects like nausea, vomiting, dizziness etc., which can create further discomfort to the patient. Dexmedetomidine is a selective α2 adrenergic agonist and has 1600 times greater selectivity for the α2 adrenoceptor compared with the α1 receptor.[3] It produces sedation, anxiolysis, hypnosis, analgesia, sympatholysis and has anti shivering properties.

Material and Methods

This study on patients undergoing lower abdominal surgeries and lower limb general surgeries under spinal anaesthesia was approved by the Institutional Ethical Committee, [(IRB (HEC) No.888/2019) & (CTRI registration no. CTRI/2020/01/023040)] Government Medical College, Bhavnagar. This was a prospective study conducted on 120 patients over a period of 12 months. Pre-anaesthetic evaluation was done, recording a detailed history and performing a complete physical examination. Complete blood count, renal function test, random blood sugar, HBsAg, HCV and antiretroviral screening tests were done. After discussion of anaesthetic options, a written preoperative consent wasobtained.

Sample Size and Randomisation

The sample size was calculated as 120 based on the pilot study and statistical reports of previous studies. The group sizes (n=40) were calculated to find out the efficiency of study drugs in prevention of shivering with a power of 90% [assuming a variability (sd) of ±10%] and a significance level of 0.05. The patients were randomly allocated into 3 groups of 40 each and were named as group D (Dexmedetomidine 0.5µg/kg), group T (Tramadol 0.5mg/kg) and group N (100ml Normal Saline) as a placebo. The investigator prepared 120 lots numbered serially from 1-120. A coding sheet was also simultaneously prepared that allotted each number randomly to a group.[8] The observer is allowed to take a lot and the selected number was marked in the proforma. Then the observer is blinded for drug being infused and performs the procedure. At the end of the study coding sheet was revealed. For the serial numbers which were selected and excluded as per the exclusion criteria,

the same serial number was mixed again in the lot by the investigator.[10]

Inclusion Criteria

- ASA grade I orII
- Age 18 to 65 years
- Undergoing Spinalanaesthesia
- Patients scheduled for elective lower abdominal, lower limb, gynaecological procedures as well as caesarean section, orthopedics and plastic surgeriesunder spinal anaesthesia included in the study.

Exclusion Criteria

- known hypersensitivity or allergy tostudy drugs.
- Cardio-pulmonary, renal or hepaticim -pairment.
- known history of substance or alcoholabuse
- patients who received anypre-medication
- an initial core temperature >37.5˚Cor<35.0˚C
- blood transfusion duringsurgery
- hypo- orhyperthyroidism
- convulsions or psychiatricdisorder
- patientrefusal
- pregnancy andlactation

Materials

The following equipments, drugs and monitors were kept ready for the conduct of anaesthesia.

Equipments

- 18 Gauge IVcannula
- Sterile towels and gauze packs
- Sterile gloves
- Surgical Spirit Solution
- Sponge holding forceps
- 2 ml and 5 ml syringes
- 25G quincke needle
- IV fluids
- 100ml Normal saline with study drugs

Drugs

- Inj. Dexmedetomidine 0.5µg/kg
- Inj. Tramadol 0.5mg/kg
- Inj. 100ml Normal Salinepint
- Inj. Ondansetron 4mg
- 15 mg of 0.5% hyper baric bupivacaine
- 2ml of 2% lignocaine for local infiltration

Monitors

A multi parameter monitor with following was made available.

- Electrocardiography
- Non-invasive BloodPressure
- Pulse Oximetry
- AxillaryTemperature

An emergency drugs and all equipment as required was kept ready.

Methodology

120 consented patients of age group 18 – 65 years belonging to American society of anaesthesiologists class I or II and posted for lower abdominal surgeries and lower limb general surgeries under spinal anaesthesia were randomly allocated to any one of the three groups.

- Inj. Dexmedetomidine 0.5µg/kg in 100 mlNS
- Inj. Tramadol 0.5mg/kg in 100 mlNS
- Inj. Normal Saline 100ml

Shivering was monitored by a grading system as described by wrench.

Grade 0: No shivering.

Grade 1: One or more of the following: Piloerection, peripheral vasoconstriction,

peripheral cyanosis, but without visible muscle activity.

Grade 2: Visible muscle activity confined to one musclegroup.

Grade 3: Visible muscle activity in more than 1 muscle group.

Grade 4: Gross muscle activity involving the whole body.

Sedation was assessed by a four point scale as per Filoset al

Grade 1: Awake and alert

Grade 2: Drowsy, responsive to verbal stimuli

Grade 3: Drowsy, arousable to physical stimuli

Grade 4: Unarousable

Patients baseline heart rate, blood pressure, temperature and spo2, was monitored and monitoring of all these parameters were done for every 5 minutes till 15 minutes and then every 15 minutes till 120 minutes.

Statistical Analysis

The statistical analysis was done by statistical software package SPSS 22.0 using chisquare test and ANOVA.

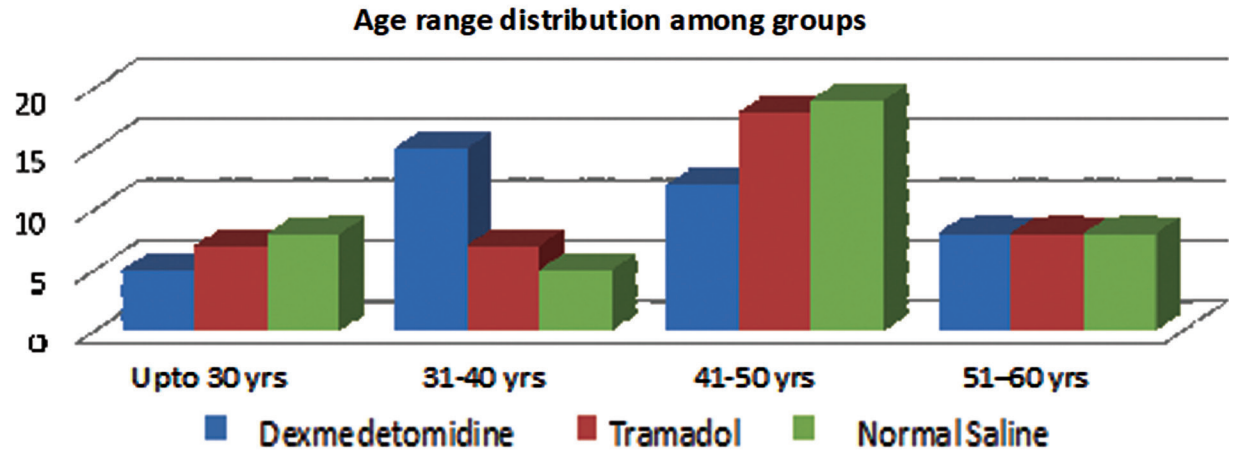

Fig. 1: Age distribution between study group.

Observation and Results

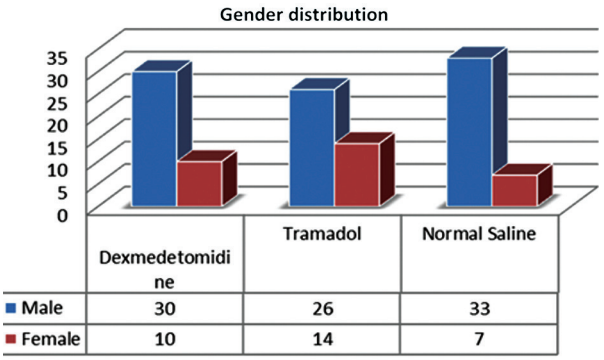

Fig. 2: Sex distribution between groups.

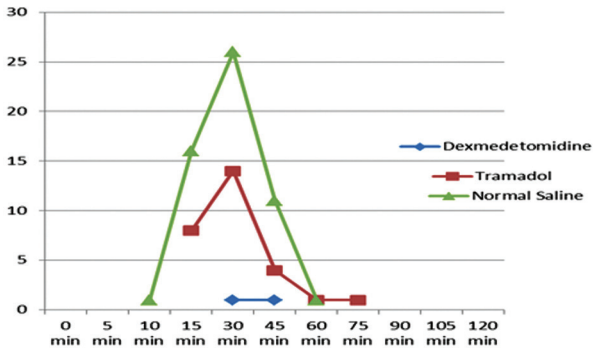

Fig. 4: No. of patients who had shivering.

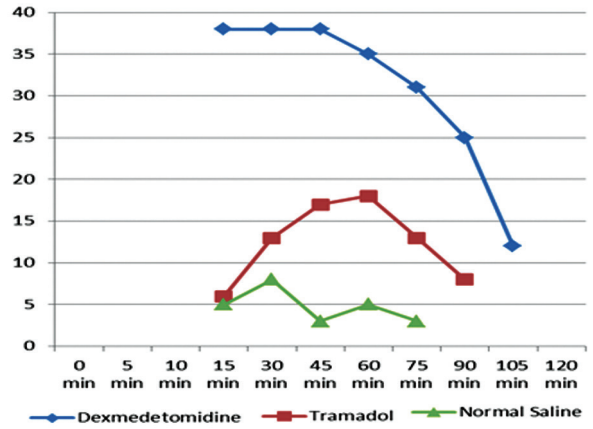

Fig. 6: No of patients sedate.

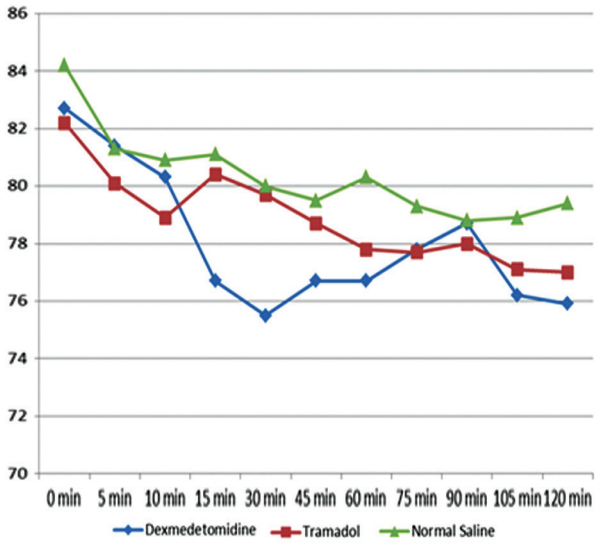

Fig. 7: Heart rate variation between the groups.

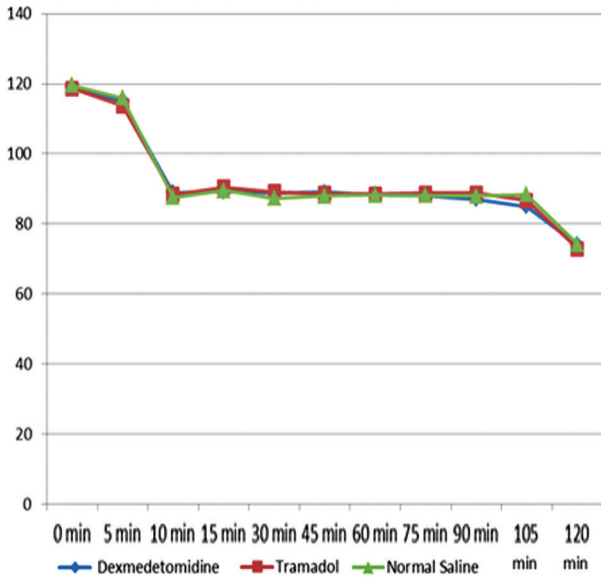

Fig. 8: Mean arterial pressure variation between the groups.

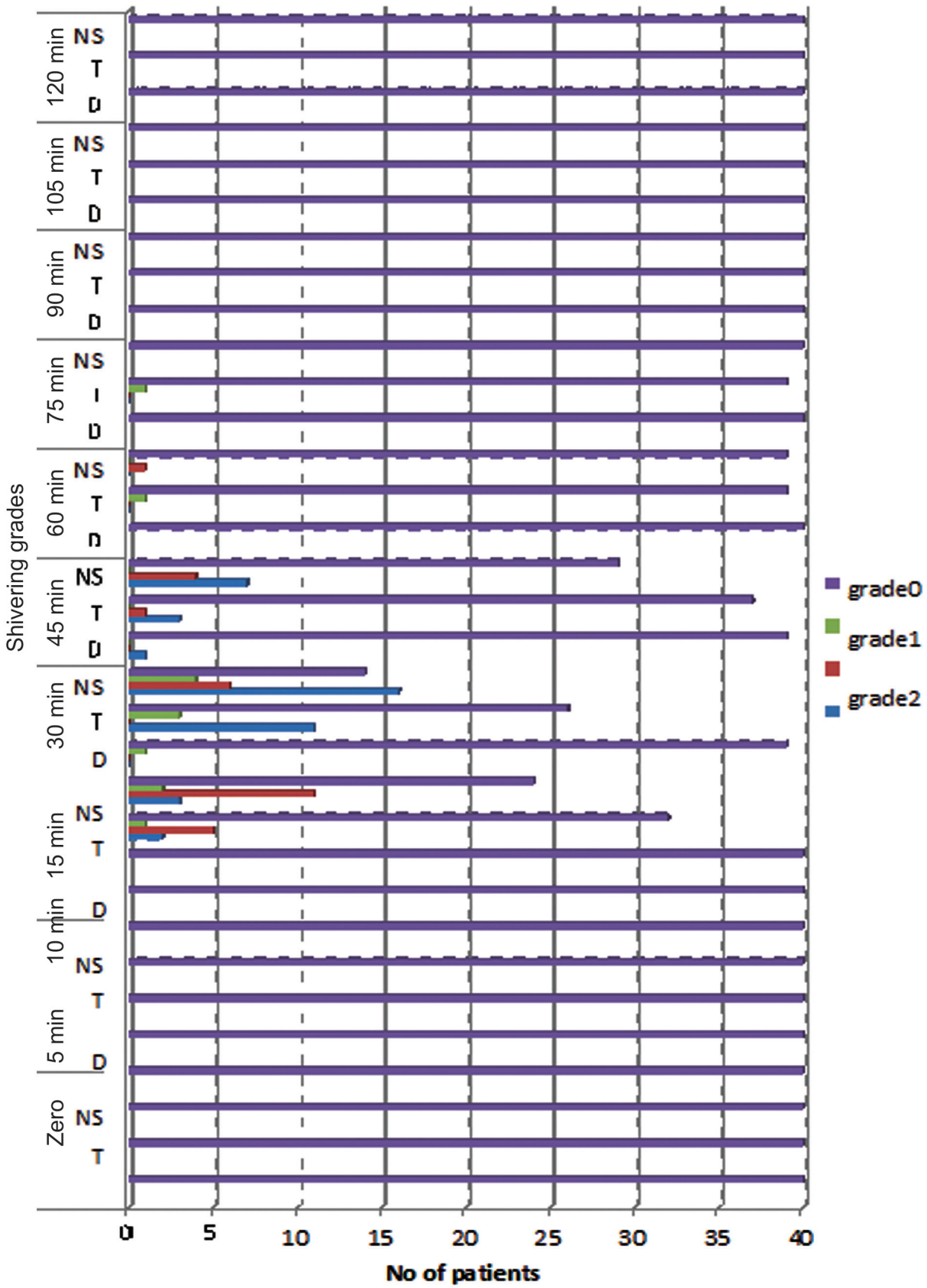

Fig. 3: Grades of Shivering in three groups.

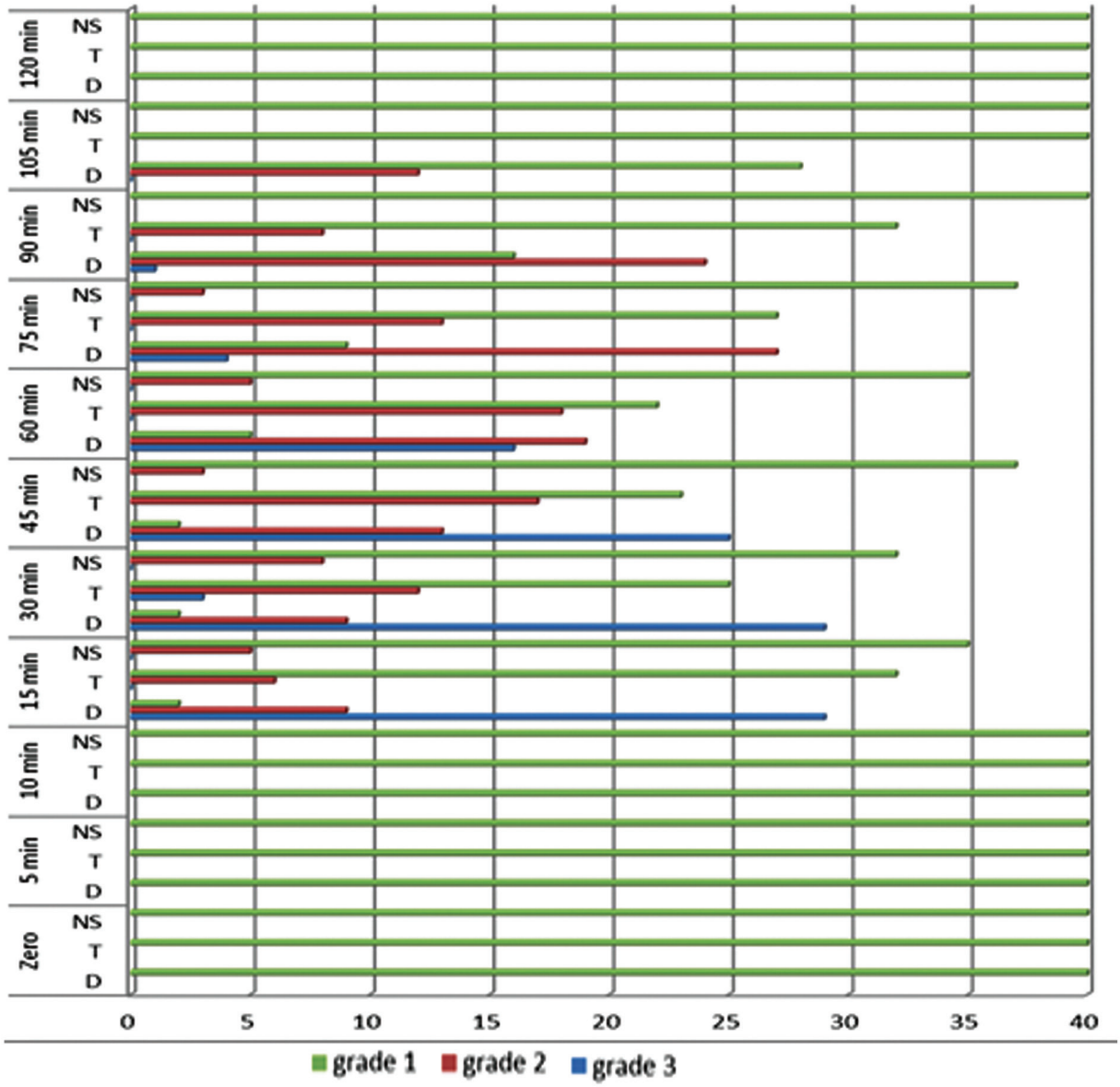

Fig. 5: Grades of Sedation.

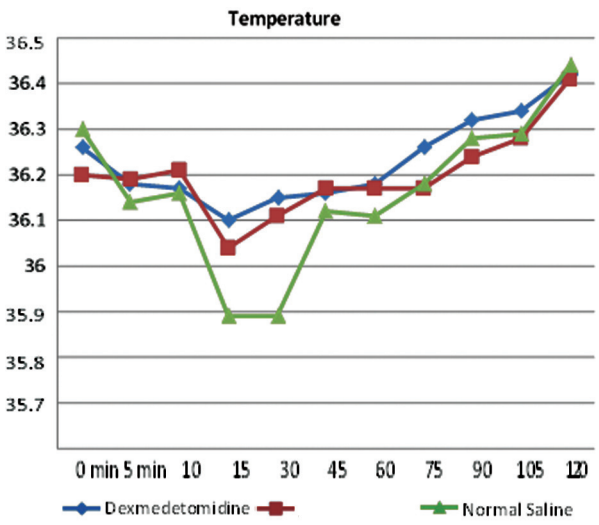

Fig. 9: Mean axillary temperature between the three groups.

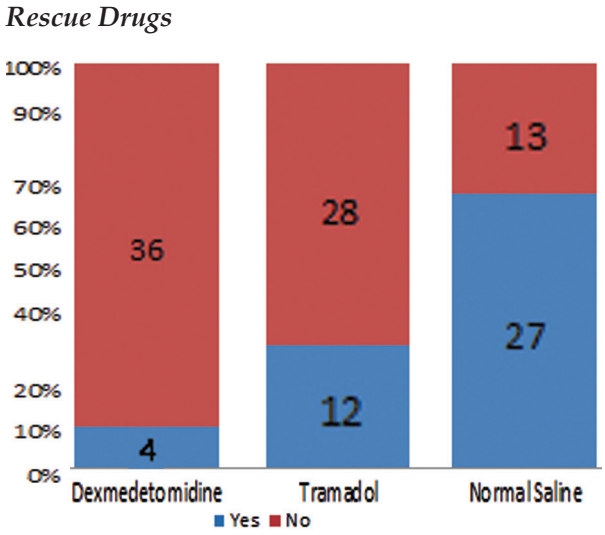

Fig. 10: Rescue drug usage.

Hypotension

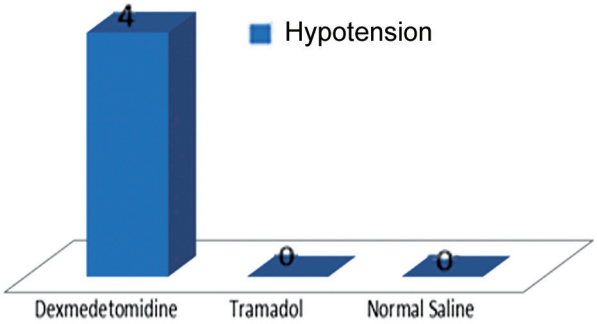

Fig. 11: Hypotension during the study.

Bradycardia

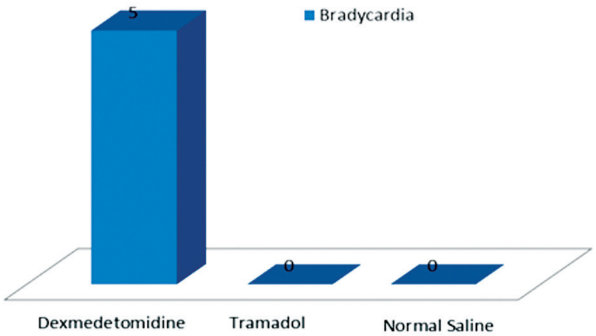

Fig. 12: Bradycardia during the study.

Discussion

Lower abdominal and lower limb surgeries are usually done under spinal anaesthesia. The most common surgical procedures done under spinal anaesthesia include inguinal hernioplasty, Trendelenburg procedure for varicose veins, excision and eversion of sac for hydrocele, split skin grafting in lower limbs, appendicectomy, hemorrhoidectomy, lateral anal sphincterotomy, lower limb debridement, VAAFT, abdominal hysterectomy, vaginal hysterectomy, LSCS, laparotomy, tubal recanalization, Orthopedic surgery like patella TBW, calcanium plate, calcanium CC screw, distal and proximal tibia plate, femur nail, femur plate, PFN, tibia nail, MM tbwetc.[6] In our current study, most of the surgeries done were hernioplasty, excision and eversion of sac for hydrocele, Trendelenburg procedure for varicose veins, STSG, lower limb debridement, appendicectomy, Orthopedic surgery like patella TBW, calcanium plate, calcanium CC screw, distal and proximal tibia plate, femur nail, femur plate, PFN, tibia nail .

One of the least addressed and a very distressing complaint in many of the patients is shivering during the surgery and in the immediate postoperative period. The reason for shivering during spinal anaesthesia is multiple.[10] If patients are uncomfortable it will lead to agitation of the patient. A number of steps are usually taken to prevent shivering during the surgery and one important step is administration of drugs to prevent shivering during surgery.

Since the time the technique of spinal anaesthesia was discovered by August bier in 1898, one of the most common reason for failure of the procedure continues to be anxiety and fear from the patient which leads to failure of block and so, it is essential to adequately sedate the patient after administration of spinal anaesthesia. Most of the sedatives have problems like hypotension, bradycardia and also provides unreliable sedation.

This study was formulated in such a way to address these two problems. Dexmedetomidine, a selective α 2 agonist produces arousable sedation, hypnosis, anxiolytic and antishivering properties. It can cause decrease in heart rate and blood pressure. Tramadol is a semi synthetic opioid which controls shivering and also sedation. It has a high incidence of vomiting and in various studies, it is found to be approximately 70% 7. So, all the patients in our study were given Inj. Ondansetron 4mg I.V. irrespective of the study group.

We planned a study to find out the efficiency of study drugs in the prevention of shivering. Our study was planned in a prospective, randomized double blind manner to study the efficacy of these three drugs in the prevention[8] of shivering. The study was double blinded wherein the patient and observer were blinded. In our study the sample size was calculated as 120 based on previous studies to obtain results of the study with a power of 90% and a significance level of 0.05.

Patients between the age of 18 and 65 were selected as the pediatric patients are not suitable for spinal anesthesia and the geriatric patients will have age related changes which can confound the variables. On analysing the demographic profile, the distribution of age, sex and weight of the patients in both the groups are comparable.

Conclusion

Dexmedetomidine is more effective in the prevention of shivering when compared with tramadol and placebo (normal saline). Dexmedetomidine has an added advantage of adequate reliable sedation.

Hence we conclude that Dexmedetomidine at 0.5µg/kg is most effective in the prevention of

shivering when compared with tramadol at 0.5 mg/kg. Success in any work can only be achieved by blessings, proper guidance and support given by a teacher. At the end of this task, with great sincerity and deep sense of gratitude, I thank my guide Dr. Komal S Shah, Associate Professor Department of Anesthesiology Government Medical College, Bhavnagar, who has guided me with her vast experience. I am especially thankful for her constant inspiration and suggestion during the entire phase of my work. I can never thank her enough for her advice, constructive criticism and novel suggestions throughout my study.

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Original Article

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Comparative Study of Recovery and Cognitive Dysfunction Following Desflurane versus Sevoflurane in General Anesthesia in Elderly Patient Undergoing Major Surgery

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Abstract

Geriatric patients (age 65 years and above) are more prone to POCD who undergo general anesthesia. Also the geriatric patients with co morbidities and substance abuse have higher chances for POCD.

Objective: To compare Post-operative cognitive status and recovery (time specific) in geriatric patients undergoing general anesthesia with sevoflurane or desflurane, by MMSE score. Also to compare other side effects and recovery.

Materials and Methods: This is prospective, randomized, interventional, single blind study. A study of 70 patients of either sex, ASA-I/II/III in the age group of above 65 years who were operated under general anesthesia and randomly allocated in two equal groups. Group S consisted of 35 patients who were given sevoflurane. Group D consisted of 35 patients who were given desflurane. MMSE score was taken pre-operatively and patients with score more than 27 were selected for this study.

Results: Statistically significant immediate recovery from general anesthesia was noted in group D compared to group S. But difference in post-operative MMSE score at 1 hour, 3 hours and 6 hours between group S and group D was statistically insignificant.

Conclusion: Patients given General Anesthesia with Desflurane showed early recovery signs, i.e. eye opening, following of verbal commands and extubation compared to patients given sevoflurane which is statistically proven. But MMSE score was lesser in desflurane than sevoflurane, which was insignificant.

Keywords: MMSE-Mini mental state examination; POCD- Post-operative Cognitive dysfunction.

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Introduction

Age more than 65 years is called geriatric population. This group is rapidly growing part of population in both the developing and developed countries. With advanced healthcare facilities, life expectancy of the population is increasing but because of the lifestyle and food habits the probability of this group for undergoing surgery is also increasing.

With the aging, there occurs progressive loss of functional reserve of all organs. In brain, there is decrease in gray matter volume, neuronal shrinkage leading to reduction in efficient functioning of the brain. 40% of population with age more than 60 years show decline in memory.[12] Decrease in brain reserve is manifested by decrease in Activity in Daily Living and also leads to increase in sensitivity for the anaesthetic drugs, increase in risk of post-operative delirium and POCD 7-8. Short term changes in cognitive functions are noted after GA during first few days after surgery.[5-6] POCD is important because it affects quality of life mentally, physically, socially and financially. Criteria to check POCD is based on comparing the cognitive functions pre-operatively and post-operatively. MMSE score is used to analyse and measure the cognitive functions.[14]

As the sensitivity to anaesthetic drugs increases in this group, lesser dose of medication is required and recovery after general anaesthesia is slow.[2] Our main goal in perioperative period in elderly individuals is speedy recovery without functional declination. And for that, detailed pre-operative assessment of vital organ systems is required and accordingly, proper selection of anaesthetic technique, anaesthetic drug and its dosage is very important.[10-12]

Methods and Approach

Prospective, randomised controlled, interventional, single blind study was conducted after obtaining permission from Institutional Ethical Committee. Written and informed consent was taken from patients. Total 70 patients of American Society of Anaesthesiologists (ASA) physical status I, II and III, aged 65 years and above undergoing major surgeries under General Anaesthesia with sevoflurane or desflurane were randomly allocated in two equal groups (n = 35 in each group). Group S consisted of 35 patients who were given sevoflurane and Group D consisted of 35 patients who were given desflurane. In my study, patients which gave consent for the study, age more than 65 years, ASA physical status I, II and III and MMSE score above 27 were included for the study. While the patients who refused to give consent, ASA grade IV and V, age below 65 years, obese (body mass index >30), MMSC score below 27, having known allergy to anaesthetic drugs, hemodynamically and/or clinically unstable, alcoholic, having neurological or psychiatric disorders were excluded from the study.

After taking informed and written consent, Standard monitors were applied, Two IV lines were secured, Injection fentanyl (2 μg/kg), ondansetron (0.15mg/kg) and glycopyrrolate (0.004 mg/kg) as premedication were given to all the patients. After pre-oxygenation with 100% oxygen for 3mins, induction of anesthesia was done with injection propofol (2mg/kg), Inj. Vecuronium (0.1mg/kg) given. Intubation done with conventional laryngoscope. Anesthesia was maintained with: in Group D: 50% oxygen, 50% nitrous oxide, desflurane (5-6%), Group S: 50% oxygen, 50% nitrous oxide, sevoflurane (2-3%), Intermittent IV Vecuronium (0.05 mg/kg) was given. Sevoflurane or desflurane were discontinued when skin closure was started and time noted. Residual neuromuscular blockade was reversed with inj. neostigmine 0.05 mg/kg and glycopyrrolate 0.008 mg/kg IV. During recovery, the time to open the eyes, follow verbal commands, extubation, orientation, sitting, standing and discharge from the recovery room was noted. Side effects like vomiting, nausea, etc. were also noted. Post op MMSC score at 1, 3, and 6 hours were noted. Emergence time (Time of anaesthetic discontinuation to eye opening), Extubation time: (Time of anaesthetic discontinuation to extubation), Recovery time: (Time of anaesthetic discontinuation to ability to recall name, date of birth were also noted. (Aldrete scoring evaluated at every 5mins till maximum score of 10 reached and after that Cognitive behaviour evaluation with MMSE done).

Study End Point: After six-hours post operatively.

Sample size of 70 determined by using power analysis on assumption that incidence of reduction of cognitive functions post-operative after general anaesthesia would be 50% (reduction of more than 70% is clinically significant). Data was collected and analysed by using SPSS (statistical package for social science) for Windows 10.0. Data was compiled and mean value with variability was expressed as standard deviation SD. For parametric data, unpaired t-test and ANOVA (analysis of variance) tests were used, and for non-parametric data chi-square test was used and p value obtained. P value less than 0.05 suggested statistically significant difference.

Table 1: Demographic Data.

Parameters	Group D	Group S	P value
Age years	69±2	70±3	-
BMI(kg/m2)	22,6±1.1	23.5±1.8	-
Sex Male: Female	14:16	13:17	-
Duration of surgery (min)	98.5±9.39	94.5±7.69	0.0762
Duration of anesthesia(min)	107.83±8.06	110.33±9.27	0.2696

Result

70 patients of more than 65 year of age, both genders and their demographic data was studied.

As per Table. 1 Demographic data like age, gender, BMI, duration of surgery, duration of anesthesia was clinically insignificant.

Table 2: Immediate recovery.

Parameters	Group D n = 35	Group S n= 35	P value
Eye opening time (min)	5.03 ± 0.80	7.47± 0.86	<0.0001
Extubation Time (min)	6.96 ± 0.80	9.20± 0.76	<0.0001
Follow verbal command time (min)	8.76 ± 0.85	11.87± 1.04	<0.0001

Table 3: side effect.

	Group D	Group S
Dizziness	0	4
Headache	3	1
Nausea	5	3
Vomiting	2	1

As per data of table 2, we compared eye opening time, extubation time and following verbal command time in both the groups, group D shows faster immediate recovery parameters, as compare to group S and P value of data shows statistically significant difference. Hence group receiving desflurane shows faster recovery compare to sevoflurane.

Table 3 shows side effects noticed post-operatively. In Group D, 3 patients had complain of headache, 5 patients had complain of Nausea and 2 patients had vomiting for 1-2 times while among Group S, 4 patients had dizziness, 1 patient had complain of headache, 3 patients had nausea and amongst them 1 patient had vomiting. No life threatening side effects were noticed in either of the drugs. Thus, both the drugs are safe for patients.

Table 4: MMSE score.

	Group D	Group S	P value
Baseline (pre op)	28.97± 0.71	28.67±0.71	0.107
1 hour post op	27.57± 1.22	27.03±1.06	0.072
3 hour post-op	27.97 ± 0.96	27.70±0.83	0.248
6 hour post-op	28.77 ± 0.77	28.50±0.62	0.140

Table 4 shows MMSE score after 1 hr, 3 hr and 6 hr post-operatively. Average MMSE Score of Group D at 1 hour was 27.57±1.22 whereas of Group S was 27.03±1.06 which is statistically insignificant. Similarly, after 3 hours and 6 hours post-operatively the difference between the average MMSE score of both the groups was statistically insignificant.

Amongst the patients on desflurane, at 1 hour post operatively, 5 patients had score less than 27, while amongst those on sevoflurane, at 1 hour post operatively, 10 patients had score less than 27. At 3 hours postoperatively, 2 patients from Group D and 3 patients from Group S had score less than 27 and at 6 hours post-operatively, all the 70 patients had score more than 27 and had normal cognitive function. But this data is not statistically significant.

Discussion

Brain function is altered immediately after general anaesthesia. Memory loss, disorientation, impairment of attention and reaction time are altered. In some cases, complete amnesia also can occur post-operatively.

Short term cognitive dysfunction is not uncommon few hours or days after surgery. To assess we used MMSE screening test. And for evaluating immediate recovery we used eye opening time, extubation time, and following verbal command time.

In our study, results show that immediate recovery after general anaesthesia is faster in group receiving desflurane as a maintenance anaesthesia. Parameters of immediate recovery like eye opening time, extubation time and following verbal command time post-operatively was average 2-3 min faster in group receiving desflurane as compared to sevoflurane and this difference is statistically significant. Such 2-3 min difference might not affect adult population but it definitely affects geriatric patients with or without co-morbidity.

As per J. E. Heavner[2] and Chen PL[7] study, desflurane shows faster recovery as compared to any other inhalational anaesthetic agent because

of low lipid solubility and low blood/gas partition coefficient (1.29±0.05). So desflurane shows early washout from the lung hence shows early recovery. In both the studies, they used eye opening as a sign of immediate recovery. Magni, Giuseppina[17] study results show time to extubation was 2 min faster and time to recovery was 6 min faster in group receiving desflurane as compared to sevoflurane in neuro surgery. So definitely desflurane shows excellent immediate recovery after anaesthesia due to its property and that is why desflurane is the preferable drug for day care surgeries. Minimal side effects are noted with both the agents. Desflurane is also cost effective drug. J. Golembiewski[18] study and Robercht de medts[19] study results show that desflurane is cheaper than sevoflurane. At equivalent MAC value the cost of desflurane is one third that of the cost of sevoflurane.

For cognitive function, in our study, pre-operative MMSE score of patients acts as a control for each individual participant. And at the end of the study we compared post-operative score at different times with pre-operative scores in both the groups. We chose elderly population for study because cognitive dysfunction is common in elderly age group. Results of our study shows that immediate post-operative MMSE score of group receiving desflurane as maintenance anaesthesia was higher than other group receiving sevoflurane but not statistically significant.

After analysis of data, both sevoflurane and desflurane are equally good for the geriatric patients. They do not affect cognitive functions. After 1st hour post-operatively MMSE score of patient given desflurane is more as compared to sevoflurane but that was not statistically significant. For immediate recovery desflurane is inhalational drug of choice but for POCD both the drugs are equally good. In Xiaoguang Chen[3] study, similar results were obtained. They used MMSE score for evaluation of cognitive function in elderly undergoing general anaesthesia for total knee and hip replacement and they concluded that emergence from the anaesthesia was rapid with desflurane but for cognitive impairment they failed to conclude which drug is better.

We used MMSE screening test because it has high validity and high relativity and also ease of application for elderly.[21] This test concentrates only on cognitive functions and excludes mood and mental stability and abnormal experience after general anaesthesia. Edwards H 22, noticed cognitive dysfunction after 2 days to 7 days but maximum at 4th day of general anaesthesia but now recent study Chung F 23, suggests that by using recently emerging inhalational anaesthetic agents, cognitive dysfunction is noticed on first post-operative day only.

Further study is required to collect more precise data. Statistically insignificant difference in this study does not exclude the possibility of cognitive dysfunction. May be larger group for study is required, or more post-operative time period for assessment or standard tool of investigation for POCD other than screening test like MMSE is required.

Conclusion

In our study, we conclude that signs of recovery from general anaesthesia like eye opening; extubation and following of verbal commands was faster with desflurane than sevoflurane which is statistically proven, But post-operative cognitive dysfunction was lesser in desflurane then sevoflurane which was insignificant.

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Comparative Evaluation of Supraclavicular and Infraclavicular Approaches to Brachial Plexus Block for Upper Limb Surgeries Using Ultrasonography

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Abstract

Background and Aim: Brachial plexus blocks when administered adroitly offer numerous benefits over general anaesthesia for upper limb surgeries. It is especially beneficial in patients with substantial comorbid conditions such as diseases involving the respiratory and cardiovascular system, life-threatening obesity, and those with an anticipated difficult airway. Out of its many approaches, we aim to compare and assess the Supraclavicular and Infraclavicular techniques utilising ultrasonography.

Methods: Sixty consenting ASA I–II patients, aged 18–65 years, scheduled for elective upper limb surgery were randomly divided into two groups of 30 each: Supraclavicular (S) and Infraclavicular block Groups (I). Blocks were performed under ultrasound-guidance. The quality of the block intra-operatively, patient satisfaction post-operatively, duration of the sensory & motor block, and complications were observed.

Results: Demographics, number of attempts, mean pain score felt during the administration of the block, mean duration of motor and sensory blockade and incidence of complications were all comparable between the two groups & statistically not significant. However, at 5 and 10 minutes after the execution of the block, the Infraclavicular group showed a higher level of blockade, indicating that the onset of action of the block was significantly quicker.

Conclusion: Time taken to perform & rapidity of onset were more in the Infraclavicular block with no difference in adequacy of both blocks at 30 minutes.

Keywords: Brachial plexus blocks; Ultrasonography; Supraclavicular; Infraclavicular.

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Introduction

Regional anaesthesia, on account of its benefits, which involve not losing consciousness, avoiding the side effects of the multitude of drugs used in general anaesthesia, better haemodynamic stability, better handling of comorbidities and excellent post-operative pain relief has gained immense popularity.[1,2]

The Supraclavicular approach has the anatomical upper hand of providing the block at a position where the brachial plexus components are tightly clustered, aiding a single point injection.[3] The Infraclavicular block combines the postulated advantages of Axillary and Supraclavicular techniques, a tight anatomical distribution of the plexus that allows a single injection of local anaesthetics, and a decreased risk of pneumothorax.[4]

With this study we aim to compare and evaluate both the blocks with respect to time taken, number of attempts, onset and duration of both sensory and motor components and incidence of complications.

Material and Methods

After approval from the Institutional Ethical Committee, this randomized prospective comparative study was conducted in the attached teaching hospital, consisting of 60 patients who were undergoing upper limb surgeries. They were randomly divided into 2 groups of 30 each by chit system, namely Group S who were administered the Supraclavicular block and Group I where Infraclavicular block was given.

Patients of both genders/sexes belonging to American Society of Anesthesiology (ASA) Grade I/II, in the age group between 18 to 65 years undergoing upper limb surgery were included in this study. Meanwhile, patients unwilling or unable to give consent for regional anaesthesia, those with allergy to local anaesthetics, presence of chest deformities/significant pulmonary pathology or neurological disorders, patients with coagulopathies, or infections at the needle insertion site were excluded.

Pre anaesthetic examination was done as per standard protocol and appropriate investigations were advised before the patient was posted for surgery. After arriving in the operation theatre an IV line was secured, ECG leads placed, and a blood pressure cuff and a pulse oximetry probe attached to the non-operative arm. Patients were given a mild anxiolytic in the form of Inj. Midazolam 0.02mg/kg IV. All the blocks were performed with a mixture of Inj. Lignocaine-Adrenaline at 5mg/kg and Inj. Bupivacaine 0.5% at 2mg/kg. The ultrasound imaging was performed using a high-frequency linear probe.

The Infraclavicular approach was administered after placing the patient supine, elbow flexed, and the arm abducted to ninety degrees. This method helped to decrease the distance to the plexus from the skin, elevate the clavicle, 5 and altogether improved visualization of the needle, the pectoralis muscles, and the brachial plexus cords.[6] Ultrasound scanning was initiated medial to the coracoid process and once the axillary artery was identified, the needle was inserted through the pectoralis muscles while being directed toward the artery's posterior part. It was carefully observed that the injectate dispensed downward and upward to encompass the medial and lateral cords, respectively.

For the Supraclavicular block, the transducer was oriented just above the midpoint of the clavicle, in the transverse plane and an in-plane approach taken after identifying the subclavian artery and the nerve plexus adjacent to it.

The pain caused while administering the block was assessed just after the needle was removed. The patient was asked to give a verbal estimate of his/her grade of pain on a scale between 0 and 10 (0 signifying no pain and 10 for severe pain). The time between disinfecting and draping, to the removal of the needle was identified as the performance time of block and taken note of, along with the number of needle pricks needed to successfully administer the block, which signified the number of attempts.

The sensory block was analysed for each nerve considered, using the pin-prick method in each nerve territory in comparison to the contralateral limb. (graded as: 0 = no change from baseline; 1 = diminished pin-prick sensation; 2 = no pin-prick sensation). Similarly, the motor block was assessed by checking for the thumb and second digit pinch, finger abduction, thumb abduction, and forearm flexion (for the median, ulnar, radial, and musculocutaneous nerves, respectively) graded as follows: 0 = no decrease in force; 1 = decreased force in comparison to the contralateral arm; 2 = incapacity to overcome gravity. Both sensory and motor effects of the block were evaluated at 5, 10, 15, 20, 25, and 30 minutes.

After 30 minutes, the total block quality was assessed and decided to be either Satisfactory (complete motor and sensory block with no nerve-sparing), Unsatisfactory (presence of nerve-sparing and/or requirement of supplementation/sedation) and Complete Failure (if the patient complained of pain regardless of maximum possible

supplementation/anesthesiologist induced general anaesthesia). Post-operatively, the patient was followed up to assess the duration of action of block. Incidence of certain anticipated complications or side-effects, such as pneumothorax, blood vessel puncture, diaphragmatic paresis, and Horner syndrome, etc. were taken note of.

Statistical Analysis

The inter-group statistical comparison of distribution of categorical variables was tested using Chi-Square test or Fisher's exact probability test and that of continuous variables was done using independent sample T test. In the entire study, the p-values less than 0.05 are considered to be statistically significant.

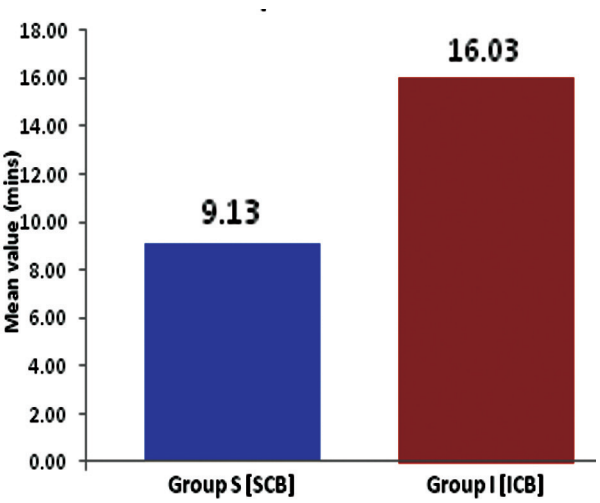
Results

The study included 60 patients who were randomly allocated into two equal groups. The patient demographics (mean age, sex and BMI distribution) were comparable between the two groups as seen in Table 1. (Group S & Group I, n=30).

Table 1: Demographic Characteristics of patients, operative data in studied groups.

Variable	Mean		P value	Statistical Significance
	Group S (n=30)	Group I (n=30)		
Age (years)	42.9	41.53	0.518	NS
Sex				
Males	16	15	0.796	NS
Females	14	15		
BMI	25.7	26.03	0.592	NS

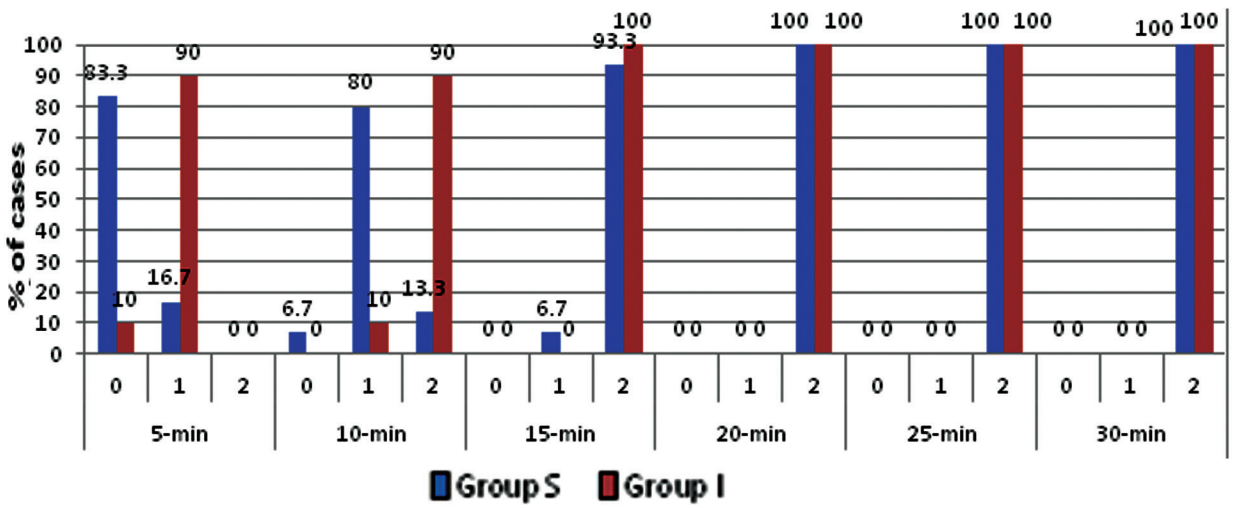
Graph 1: Inter-group comparison of mean performance time of block (SCB – Supraclavicular Block, ICB – Infraclavicular Block).



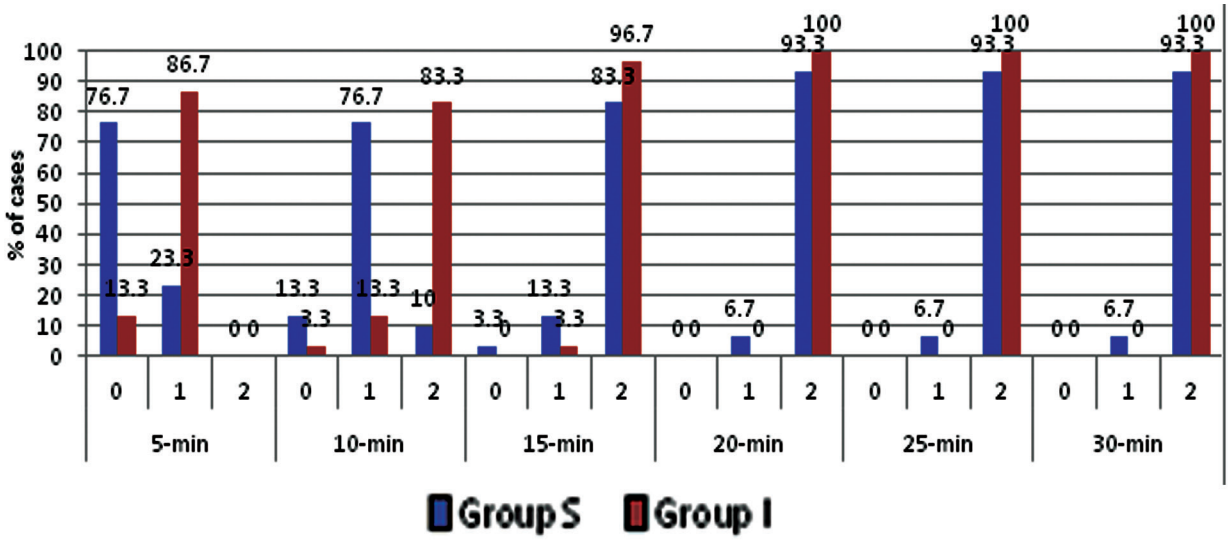
Graph 1 shows the distribution of the mean performance time of the two blocks. The range of minimum-maximum performance time of blocks in Group S and Group I were 6 – 13 minutes (mean time – 9.13 minutes) and 10 – 20 minutes (mean time – 16.03 minutes), respectively, which was statistically significant (P<0.001).

All 30 of the Supraclavicular blocks were done within two attempts, while 2 out of the 30 Infraclavicular blocks required more than two attempts. This, however, was not statistically significant. The pain experienced by the patients while performing the block, were comparable in both the groups with a score of approximately 3/10.

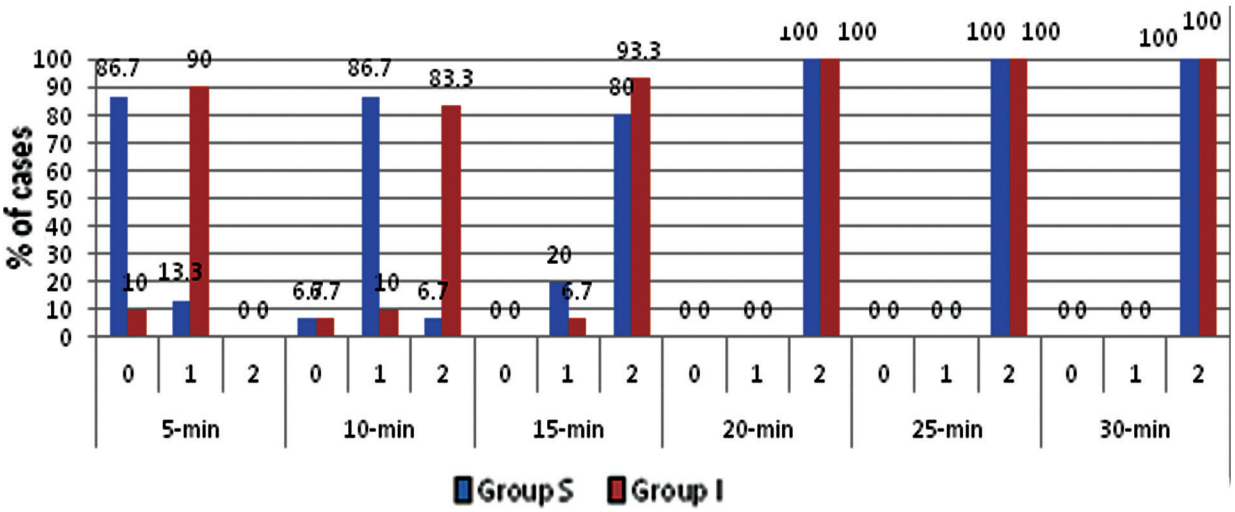
Graph 2: Inter-group comparison of status of median nerve in the onset of sensory blockade.



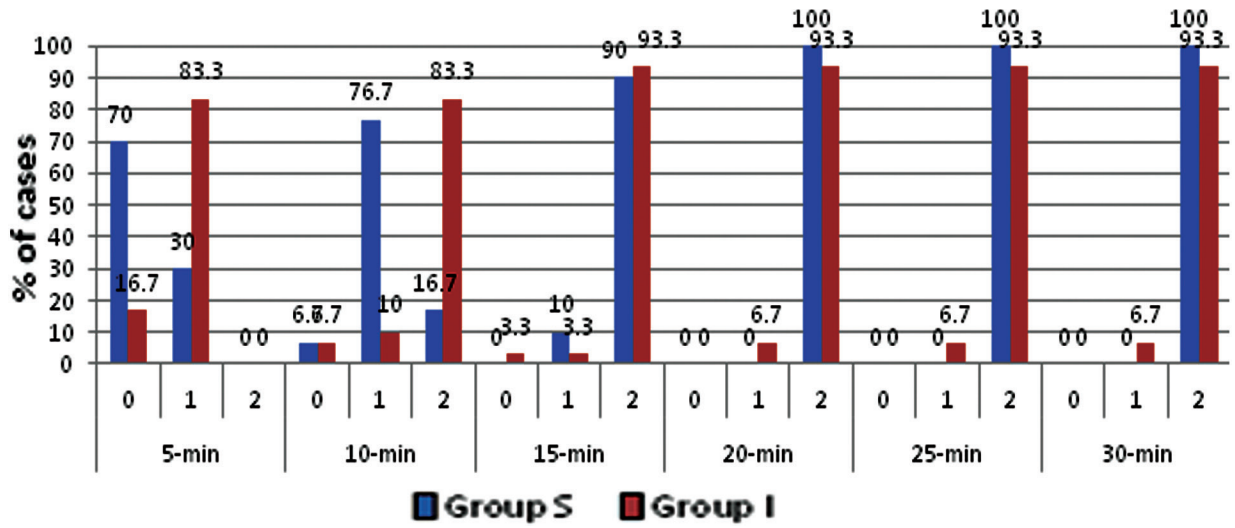
Graph 3: Inter-group comparison of status of ulnar nerve in the onset of sensory blockade.



Graph 4: Inter-group comparison of status of radial nerve in the onset of motor blockade.



Graph 5: Inter-group comparison of status of musculocutaneous nerve in the onset of motor blockade.



Supraclavicular and Infraclavicular groups were compared on the status of the onset of sensory blockade in the median, ulnar, radial, and musculocutaneous nerve regions. In all four groups, the level of sensory blockade was significantly higher in the Infraclavicular group at 5 and 10 minutes after completing the block, which indicated faster onset of action in Group I (P<0.001) as seen in Graphs 2 & 3. Likewise, in Graphs 4 and 5, onset of motor blockade in the same four nerves at 5-minute intervals were compared, and again, was faster in the Infraclavicular group, with the degree of motor blockade at 5 and 10 minutes being superior to that seen in the Supraclavicular group (P<0.001). By 30 minutes, though, there was no difference between the groups in terms of quality of block.

The mean duration of motor blockade in Groups S and I were both approximately 7 hours, while sensory blockade was 7.5 hours (as seen in Table 2), which was comparable and hence, statistically insignificant.

Table 2: Inter-group comparison of mean duration of sensory and motor blockade.

Duration (Hrs)	Group S (n=30)		Group I (n=30)		P-value
	Mean	SD	Mean	SD	
Sensory blockade	7.45	0.55	7.42	0.51	0.808NS
Motor blockade	6.93	0.57	6.92	0.51	0.905NS

Values are mean and SD, P-value by independent sample t test. P-value<0.05 is considered to be statistically significant. NS – Statistically non-significant.

Discussion

With time, regional anaesthesia, particularly nerve blocks, have grown in popularity due to a myriad of reasons. One of the most important of these is the significant decrease in perioperative risk to the patient that accompanies the administration of general anaesthesia. This modality is especially beneficial when it comes to surgeries for patients with a multitude of comorbidities, such as cardiopulmonary, renal, hepatic, or neurologic disturbances, in whom the plethora of anaesthetic drugs used, could prove to be dangerous.

Apart from this, when an operative procedure is conducted under regional anaesthesia, there is a notable decrease in the requirement of postoperative analgesia, lower incidence of postoperative complications, higher levels of patient satisfaction, and reduced duration of hospital stay. The arrival of nerve stimulation and ultrasound technologies only strengthened their position by improving the ease of administration and increasing the safety margin.

There are various approaches to a brachial plexus nerve block, which include, but are not limited to, Interscalene, Supraclavicular, Infraclavicular, and Axillary, each of which come with their own set of pros and cons. We aimed to compare and evaluate the efficacy of ultrasound guided Supraclavicular (Group S) and Infraclavicular (Group I) blocks in this study consisting of 60 patients undergoing upper limb surgeries. The demographic data of our patients pertaining to age, gender, and BMI were comparable between the two groups.

Our observations showed a statistically significant difference (Graph 1) in the performance time of the two blocks with the Infraclavicular block taking longer to complete (P<0.001). The increase in time could be due to the increased depth at which the posterior cord of the brachial plexus is located in the Infraclavicular region, compared to the lateral and medial cords.[7] A study conducted by De Jose Maria B et al.[8] comparing the two blocks in eighty children between the ages 5-15, also showed similar results. The mean time to perform the block in Group I was 13 minutes, which significantly differed (P<0.05) from Group S, which was 9 minutes.

In terms of number of attempts taken to administer the block, there was no statistically significant difference in between both groups. At the same time, pain felt by the patient during block administration was comparable. Similar studies conducted by Arcand G et al.[7] consisting of 80 patients and Satani TR, Shah SS, et al.[4] consisting of 100 patients, also reached a similar conclusion, where the block performance-related pain in both the approaches was minimal and did not differ.

We observed that the onset of sensory action was faster in all four nerve regions with a denser level of blockade noted at 5 and 10 minutes in the Infraclavicular group (Graphs 2 &3). This was statistically significant (P<0.001). However, there was no compelling difference in the level of blockade at the 15, 20, 25- and 30-minute marks. Abhinaya RJ, et al[9] conducted a similar study on 60 patients, analyzing the two approaches, and noted that the start of sensory blockade was attained later in Group S (8.45 minutes, P = 0.006) than Group I (6.43 minutes).

Ultrasound-guided Supraclavicular and Infraclavicular blocks were administered as part

of a study, in 120 patients undergoing upper limb surgeries, by Koscielniak Nielsen, et al.[10] which showed fewer cases in the S group (P=0.017) were prepped for surgery at twenty minutes after the block, leading them to conclude that the Infraclavicular block had a faster onset. The same statistically significant conclusion regarding motor blockade was reached by us as seen in Graphs 4 & 5.

Both groups S and I had two cases each in which the quality of the block was unsatisfactory, and supplementation was required, hence insignificant. Similar conclusion was reached by Harrison TK, et al.[12] who in fifty patients compared the efficiency of Infraclavicular and Supraclavicular blocks using through the catheter, ultrasound-guided bolus anaesthesia. 100% in the Infraclavicular and 88% of the candidates in the Supraclavicular groups (P=0.088), achieved satisfactory sensory blockade within thirty minutes.

Neither of the groups showed any incidence of the anticipated complications, such as diaphragmatic paresis, pneumothorax, blood vessel puncture, or Horner's syndrome. Yuan JM, et al in 2012, in their study, concurred that ultrasound guidance decreases the risks of complications like hemi-diaphragmatic paresis or vascular puncture.11 However, a larger sample size may be required for the purposes of comparing the incidence of complications, which is beyond the scope of our study.

Conclusion

Our study concludes that the Supraclavicular block takes a shorter time to administer, however, the onset of sensory and motor blockade at 5 and 10 minutes after administration was faster in the Infraclavicular group, with no difference in adequacy of both blocks at 30 minutes.

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Original Article

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Comparison of Bag and Mask Ventilation versus I-Gel use in Electroconvulsive Therapy

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Abstract

Background: Electroconvulsive therapy formerly known as electroshock is a psychiatric treatment in which seizures were electrically induced to provide relief from psychiatric disorder. The most common technique of anaesthesia used during ECT is General Anaesthesia with bag and mask ventilation which is being used for a long time. However, there are case reports of pulmonary edema, bronchospasm, hemodynamic changes during this technique, so we want to compare the effectiveness of I-gel over bag and mask ventilation in ECT.

Methods: In our study 50 patients were randomized and 25 of them were ventilated with bag and mask. The other 25 patients were ventilated with I-gel. Vital parameters were monitored intra-operatively and postoperatively we observed nausea, vomiting, bronchospasm, sore throat, laryngospasm.

Results: Statistically significant difference were found in mean heart rate and blood pressure values in both the groups. Also we noticed 2 cases of nausea, 1 case of vomiting 2 cases of sore throat in bag and mask group whereas 2 cases of bronchospasm in I-gel group.

Conclusion: Hemodynamic variables were better controlled in I-gel group. Also the post operative complications were less in I-gel group.

Keywords: Electroconvulsive therapy; I-gel; Bag and mask ventilation.

Introduction

Electroconvulsive therapy (ECT), is routinely used in psychiatric treatment in which seizures are electrically induced in patients to provide relief from psychiatric disorders.[1] However, ECT has its systemic effects as follows.[2]

- Cardiovascular effects result from autonomic nervous system activation during ECT procedure.
- There is an increase in cerebral metabolic rate which results in a marked increase in cerebral blood flow and intracranial pressure.
- There is an increase in intraocular pressure and intra-gastric pressure.

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The most preferred and oldest method of ventilation during maintenance of anaesthesia in the patients of ECT was bag and mask ventilation. However, recent literature has documented a rare but severe complication like, negative pressure pulmonary edema. Recently, few studies have shown that use of laryngeal mask airway (LMA), is a safe and effective method of ventilation in ECT.

Haeck et al in year 2011[3], suggested that laryngeal mask could be a good method of controlling hyperventilation and obtaining a longer convulsion time. I-gel is a novel and innovative supraglottic airway device, made of a thermoplastic elastomer (styrene ethylene butadiene styrene), which is soft and gel like. Its advantages:

- Easy to insert.
- Effective seal pressure, prevents aspiration and maintains effective ventilation.
- Lack of inflatable cuff results in lower incidence of sore throat.

Therefore, we decided to compare the effectiveness of a bag and mask ventilation versus I-gel for ECT.

Methods

After obtaining an approval from the ethical committee, a prospective randomized controlled trial study was conducted in tertiary care hospital. 50 patients belonging to ASA I & II, posted for an elective ECT were included in the study. Patients with co-morbid condition and pregnant patients were excluded from the study. Written informed consent of the patient and their relatives were obtained. On the day of procedure standard monitors were attached in the ECT Room and vital parameters were noted. A common protocol of general anaesthesia was followed for all the patients as given:

Premedication with Inj. Glyopyrrolate (0.2mg IV/ IM),

Induction with Inj. Propofol (2mg/kg IV),

INJ Succinylcholine as muscle relaxant (1mg/kg IV).

Then 25 patients in (group 1) were ventilated with bag and mask. The other 25 patients (group 2) were ventilated with I-gel. Vital parameters (heart rate, blood pressure, Spo_2, and end tidal CO_2) were closely monitored for each patient throughout the intra-operative period. And post operatively we observed following complications: nausea, vomiting, laryngospasm, bronchospam and sore throat for 24 hours.

Statistical Analysis

Results were tabulated and were analysed using T-test and SPSS software.

Results

The gender, age group and BMI amongst both the study groups were statistically not significant as shown in (Table 1). Intra-operative heart rate were higher in 25 % of patients in group 1 as compared to group 2 after the induction of ECT and it was statistically significant (p value<0.05) as shown in (Table 2). Intra-operative systolic and diastolic blood pressure were higher in group 1 from baseline after the induction of ECT for 2-5 minutes as compared to group 1 as shown in (Figure 3, 4).

Postoperatively, we observed 2 cases of sore throat, 1 case of nausea and 2 cases of vomiting in group 1. However 2 cases of bronchospasm were observed in group 2.

Table 1: Demographic characteristics of patients in both groups.

Age (years)	Group 1 (n=25)		Group 2 (n=25)		P-value
	Mean	SD	Mean	SD	
Age (years)	40.04	11.23	34.96	11.22	0.116NS
Sex					0.390
Males	12(48)		9(36)		
Females	13(52)		16(64)		
BMI	22.98	3.79	23.88	4.28	0.438NS

Discussion

Electroconvulsive therapy is a biological treatment procedure involving a brief application of electric stimulus for the treatment of refractory or resistant psychiatric disorders. The oldest and safest method of ventilation in ECT was bag and mask ventilation as it did not cause post ictal confusion or agitation in the patients.

A rare and severe complication was noticed due to forced inspiration against closed glottis causing negative pulmonary pressure edema. Janaki R. Manne, Yusuf Kasirye in year 2011[4] showed in their study that pulmonary edema occurred due to forced inspiration against a closed glottis while performing ECT.

Our primary objective was to compare the haemodynamic variables like pulse rate, systolic blood pressure (SBP), diastolic blood pressure (DBP), end tidal CO_2($EtCO_2$), SpO_2 in both the groups.

Table 2: Intra operative comparison of mean intra-op pulse rate.

Pulse rate (per min)	Group 1 (n=25)		Group 2 (n=25)		P-value
	Mean	SD	Mean	SD	(Inter-group)
Baseline	84.64	4.30	87.96	6.79	0.067NS
1-min	85.92	3.81	88.16	5.32	0.093NS
2-min	87.52	3.66	88.16	5.32	0.623NS
3-min	87.24	4.56	89.76	4.81	0.063NS
4-min	86.17	4.71	89.44	4.18	0.013*
5-min	84.33	4.11	89.76	6.51	0.001***
6-min	83.25	4.64	88.76	4.43	0.001***
7-min	83.29	4.24	87.12	2.59	0.001***
8-min	83.17	4.37	86.80	4.55	0.006**
9-min	82.00	3.73	87.00	4.05	0.001***
10-min	82.50	4.31	86.76	4.49	0.001***

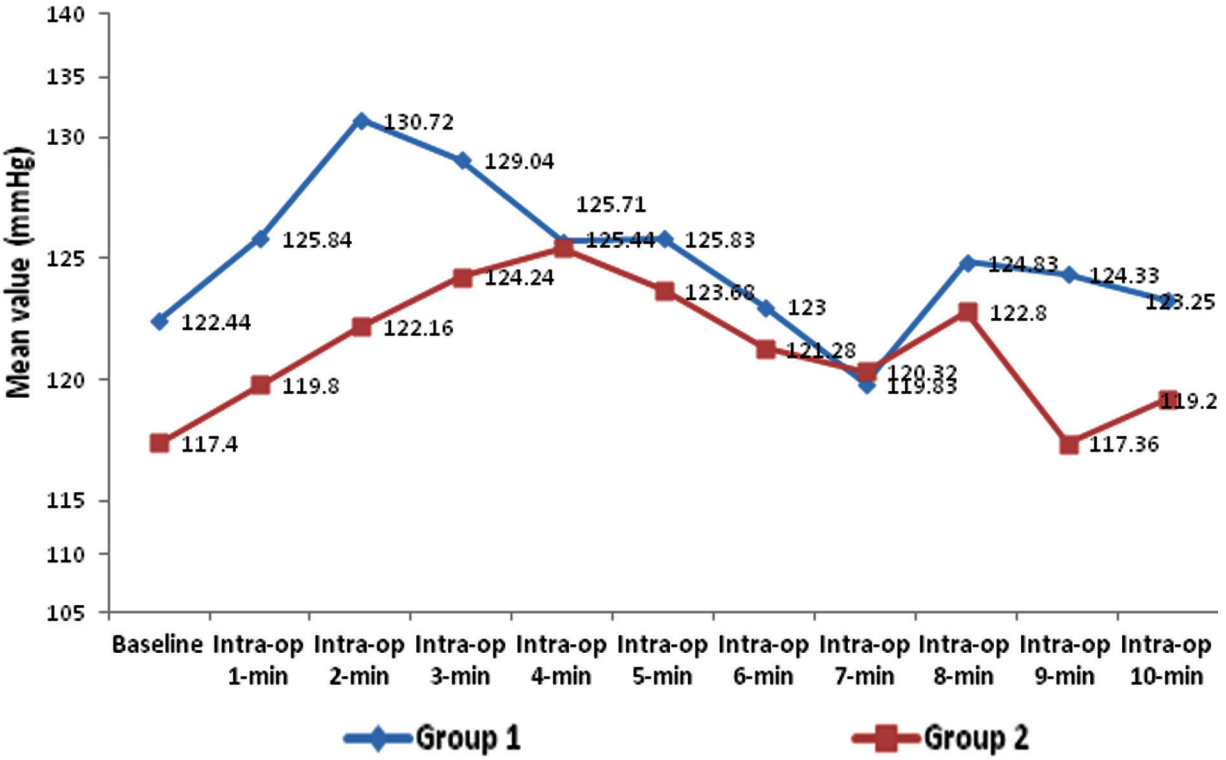

Fig. 3: Intraoperative comparison of mean systolic Blood Pressure.

We observed that after giving ECT intra-op mean pulse rate, systolic blood pressure and diastolic blood pressure was higher in group 1 as compared to group 2 from baseline for 4-5 minutes (p value<0.05), it was statistically significant

These parameters were comparable with a study done by Fumio Nishihara, Makio Ohkawa, Haruhiko Hiraoka, Naoya Yuki, and Shigeru Saito, in year 2003[5] compared the haemodynamic changes during ECT between two groups where they used bag and mask and laryngeal mask airways for ventilation. They observed that mean pulse rate was higher in bag and mask group than the LMA group at 2 minutes after ECT. Similar change in blood pressure was observed after 5 minutes of ECT in bag and mask group. Whereas in laryngeal mask group, it was increased after 3 minutes of ECT. They hypothesised that because of accumulation of carbon dioxide, the haemodynamic changes were observed. They also observed increase in seizure threshold in these patients. Our second objective was to observe post-operative complications like

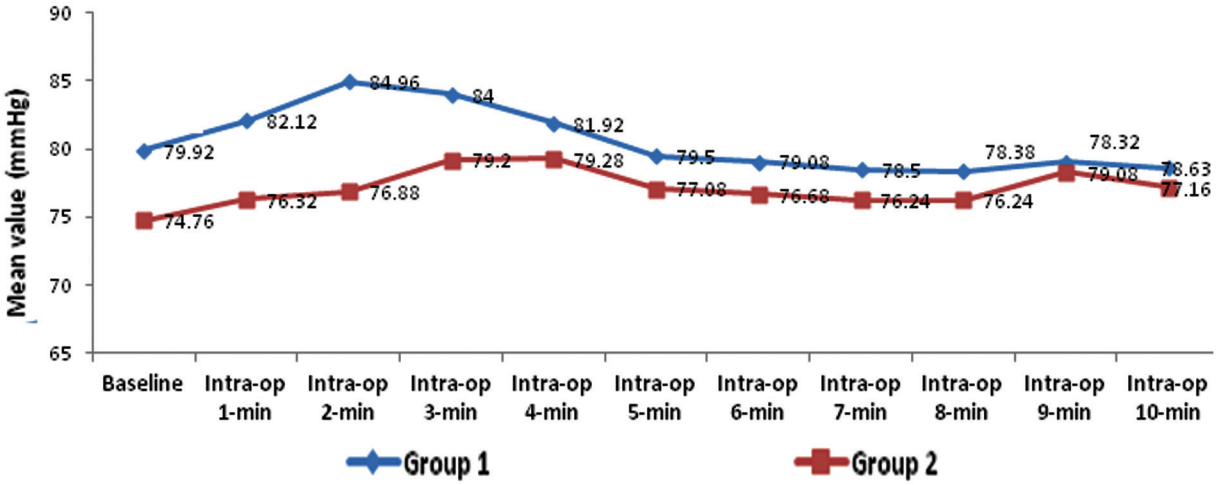

Fig. 4: Intraoperative comparison of mean intra-op diastolic Blood Pressure.

sore throat, nausea, vomiting, laryngospasm and bronchospasm, every 15 minutes after patient was shifted out for 1 hour, then every 2 hourly for 1st 4 hours and every 4th hourly for remaining 24 hours.

We observed bronchospasm in 2 cases of group 2 whose BMI were 30kg/m2 and 25kg/m2, but there were no such cases noticed in group 1. We also noticed that there were 2 cases of sore throat, 1 case of nausea and 2 cases of vomiting in group 1 .

Our findings were comparable with the study done by Joseph Brimacobe in year 2000.[6] He compared the incidence of post-operative sore throat, pharyngo-laryngeal discomfort between bag and mask and laryngeal mask airways and concluded that incidence of bronchospasm was seen due to improper mask size or tight fitting mask. He also found jaw discomfort in laryngeal mask airways group due to improper insertion. J. Dingley in year 1994[7] compared the incidence of post-operative sore throat between laryngeal mask airways and bag and mask ventilation and observed that incidence of sore throat was higher in Laryngeal mask groups as compared to bag and mask.

The incidence of sore throat in bag and mask were present in those patients where ventilation was difficult and Guedel's airway was used for proper ventilation.

Therefore, from our study we can conclude that I-GEL can be used as an alternative way of ventilation instead of Bag and mask in ECT.

Conclusion

We conclude that I-GEL is a better and effective way of ventilation in electroconvulsive therapy as compared to bag and mask ventilation. However, more studies are needed to prove its efficacy

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Comparison of Peng Block versus Ficb in Hip Surgeries, A Randomised Control Study

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Abstract

Background: Hip surgeries are among the common surgeries performed in orthopaedics especially in geriatric age group. A recent anatomical study on hip innervation led to the identification of relevant landmarks to target the hip articular branches of femoral nerve and accessory obturator nerve making Pericapsular nerve group (PENG) block popular. However there are other commonly performed blocks for hip surgeries including Fascia Iliaca block, 3 in 1 block, Femoral nerve block. This study is aimed at comparing the efficacy of Pericapsular nerve group (PENG) block and Fascia Iliaca Block (FICB) in terms of post operative analgesia.

Aims and objectives: To compare the efficacy of post- operative analgesia in Pericapsular nerve group (PENG) block and Fascia Iliaca block in hip surgeries.

Material and Methods: Total 90 patients scheduled for hip surgeries under combined spinal epidural anesthesia were selected for the study. In 30 patients ,ultrasound guided PENG block was given, in other 30 ultrasound guided Suprainguinal Fascia Iliaca block was given and other 30 patients were used as control group in the post operative period and duration of analgesia was assessed by numeric rating scale (NRS) and visual analogue scores (VAS)

Results: In our study of 90 patients posted for hip surgeries, PENG block showed better results in terms of reduction in pain scores, time of first analgesia requirement and quantity of rescue analgesics used in the post operative period.

Conclusion: The newer PENG block is better than Fascia Iliaca block in hip surgeries in delaying post opioid consumption, its associated side effects and delirium especially in geriatric patients.

Keywords: Hip surgeries; Pericapsular nerve group block; Fascia Iliaca Compartment block; Post-operative analgesia.

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Introduction

Hip fracture is a devastating injury in most cases especially in geriatric patients.[1] Surgical reduction and fixation are the definitive treatment in most patients.[2] Total hip arthroplasty is also one of the most common major orthopaedic procedures to improve patient's functional status and quality of life. However, the immediate postoperative period can be associated with severe pain that delays mobilisation and increases hospital stay and risk of thromboembolic events.[3,4] Effective perioperative analgesia minimizes the need for opioids and related adverse effects such as delirium.[5,6] Hence regional analgesia techniques are commonly used as they provide opioid-sparing effect and are relatively safe.[7]

The anterior hip capsule receives innervation from the femoral nerve, obturator nerve and the accessory obturator nerve.

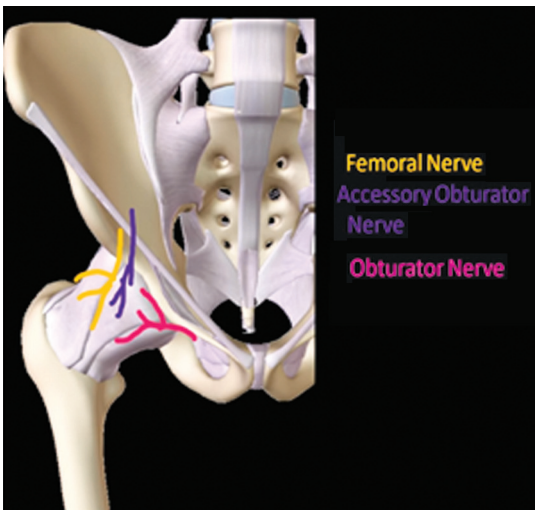


Fig. 1: Anterior Hip Capsule Innervation.

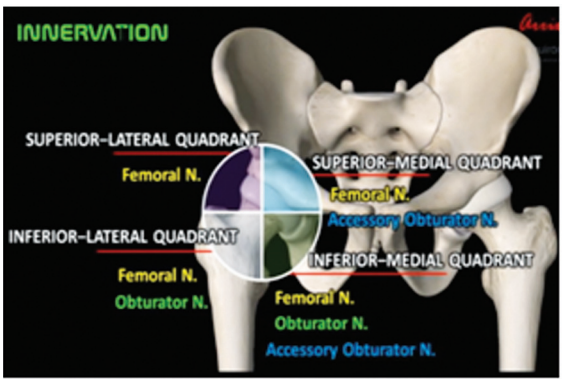


Fig. 2: Quadrant Wise Nerve Suplly Innervation.

An anatomic study by Short et al. demonstrated that high and low branches of femoral nerve (above and below inguinal ligament) provided majority of innervations to all quadrants more to lateral and superomedial hip capsule. High and low branches of obturator nerve (proximal and distal to obturator canal) provided focussed innervation to inferomedial hip capsule. Accessory obturator nerve (found in 56%) was found to innervate the medial aspect of capsule.[8] It is understood that anterior hip capsule receives major sensory innervation whereas posterior and inferior hip capsule have no sensory innervation.[9]

These studies also evaluated the relationship with these nerves and other bony or soft tissue landmarks visible by ultrasound guidance. The relationship of articular branches from these 3 nerves to inferomedial acetabulum (radiographic teardrop) and the space between anterior inferior iliac spine and iliopubic eminence may suggest potential target.[8] Previous studies have found histologically that the anterior capsule has predominantly nociceptive fibers, while the posterior capsule is largely made up of mechanoreceptors.[10]

A fascia iliaca compartment block under ultrasound guidance can provide superior analgesia with minimal side effects with high success rates. It blocks both femoral and lateral femoral cutaneous nerve.[11] However Pericapsular nerve group (PENG) block described in 2018 aimed to target the articular branches of hip which are femoral nerve and accessory obturator nerve providing more complete analgesia to hip with motor sparing effects.[12-14] In addition, this injection may prevent or decrease the postoperative spasm of iliacus muscle which is common cause of post operative pain after hip arthroplasties.[15]

Aim and Objectives

The primary objective of the study was to compare

- The reduction in pain scores following blockade

The secondary objectives were to compare

- Time period at which first analgesic was requested
- 24 hour analgesic requirement
- Side effects

Criteria

Inclusion Criteria

Patients scheduled for hip surgeries e.g. hip hemiarthroplasty, total hip arthroplasty, proximal femur fracture fixation under combined spinal epidural (CSE) anesthesia.

Type of block	Procedure
Pericapsular Nerve Group Block (PENG Block)	It blocks the articular branches of anterior capsule that is femoral nerve, obturator nerve and accessory obturator nerve to the anterior capsule.. Procedure: A low frequency curvilinear ultrasound probe (2-5 MHz) was placed over anterior superior iliac spine (ASIS) in the transverse plane and then turned 45 degree clockwise placing the probe over the line joining anterior superior iliac spine and pubic tubercle (PT) keeping lateral margin at anterior superior iliac spine (ASIS) to get a sonoanatomic view for PENG block.

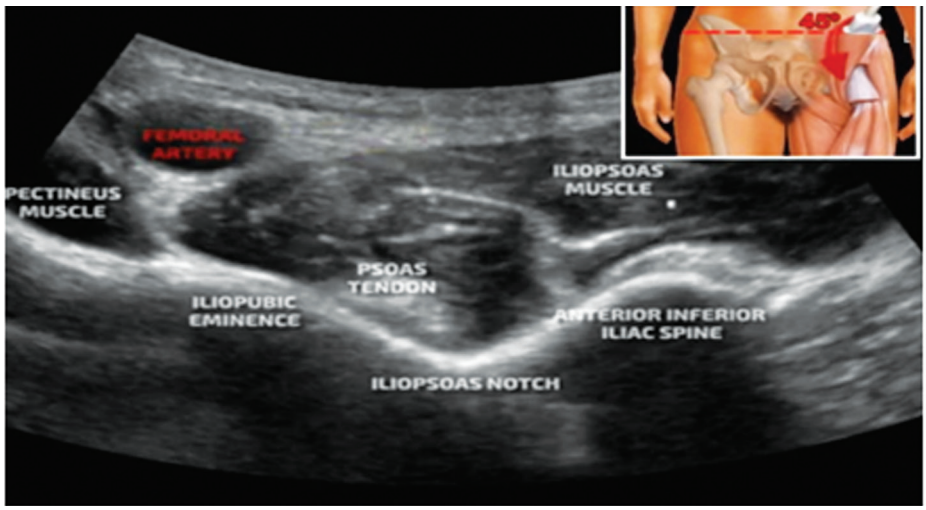


Fig. 3: The needle entry point was selected on the skin in such a manner that perpendicular needle entry will guide needle near target point (IPE).

The needle entry point was anaesthetised with 2 ml 1% lidocaine and block needle was inserted "in plane" to reach the bony rim near Ileopubic eminence (IPE) avoiding injury to femoral nerve (visible just lateral to femoral artery). On bony contact, before injecting , the correct needle position was confirmed by drug spread under illo-psoas muscle. In a successful block, the local anesthetic should lift the psoas tendon off of the ilium and should track both medially and laterally.[7,16]

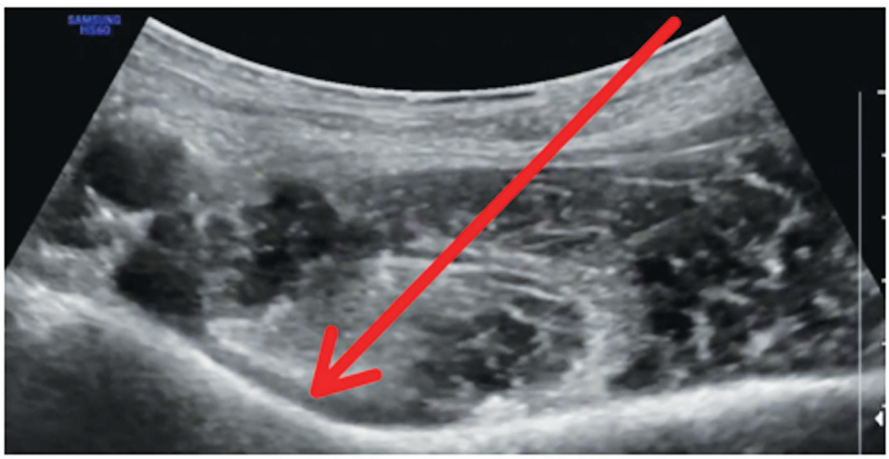
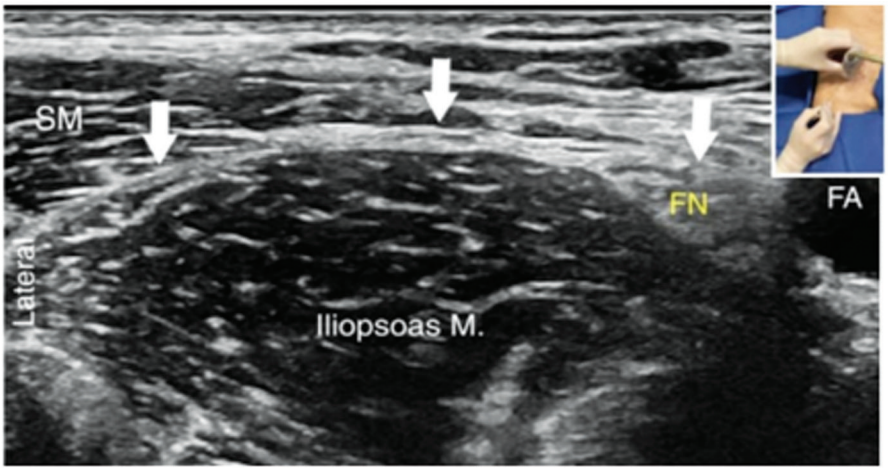
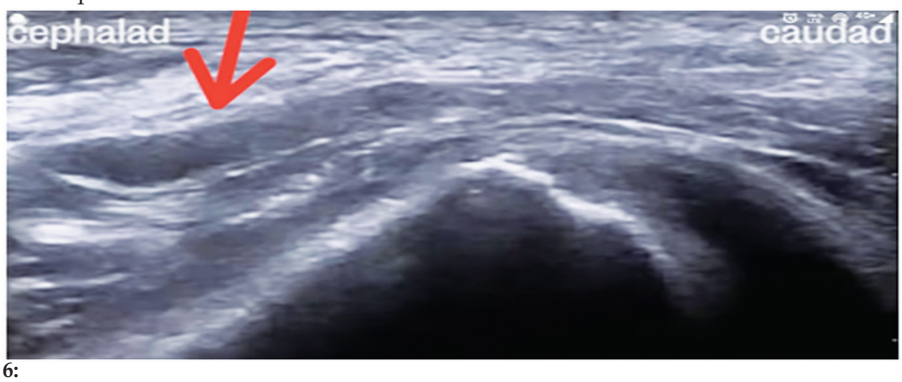


Fig. 4: Needle entry.

20 ml of 0.25% Ropivacaine was injected slowly with repeated aspiration to avoid intravascular injection.

Number of patients-30

Suprainguinal Fascia Iliaca Block (FICB)	It blocks femoral nerve and lateral cutaneous femoral nerve. Procedure :In supine position, a high frequency linear probe was placed in the inguinal crease. Scan starting laterally from the femoral artery and nerve in inguinal crease to identify the sartorius muscle, tracing the muscle until it's origin to anterior superior iliac spine.  **Fig. 5:** The shadow of the bony of iliac crest & iliacus muscle was seen, the end point of the injection was deep to the fascia iliaca and above the iliacus muscle in the lateral part of the iliacus muscle. After negative aspiration, 20 ml of 0.25% Ropivacaine was injected under the fascial plane incrementally, aspirating every 5 ml , same time avoiding the deep circumflex iliac vessels. Observe for unzipping of the fascia iliaca from the underlying muscle planes to confirm spread between the hyperechoic fascia iliaca and the more heterogeneous iliacus muscle beneath it in the picture given above. Number of patients - 30  **Fig. 6:**

Exclusion Criteria

- Coagulopathy
- Infection at the injection site
- Allergy to local anesthetics
- Severe cardiopulmonary disease (≥ASA IV)
- Diabetic or other neuropathies
- Patients receiving opioids for chronic analgesic therapy
- Contraindication to spinal anesthesia
- Inability to comprehend visual analog scale (VAS).

Materials and Methods

After obtaining ethical committee clearance and informed consent, 90 ASA 1 and 2 patients aged between 18 and 80 years posted for fixation of Traumatic hip fractures and Hip Arthroplasties were selected and were scheduled for surgery under combined spinal epidural anaesthesia 30 patients of them were given Pericapsular nerve group block (PENG) and 30 others Fascia Iliaca Block (Suprainguinal) and 30 others were considered control groups. Standard hospital protocol regarding medical optimisation, intravenous line placement, premedication, and antibiotic prophylaxis was followed. In operation room,

monitors for non-invasive blood pressure (NIBP), 3 leads continuous electrocardiogram (ECG), and pulse oximeter (SPO2) were attached. Taking all aseptic precautions, patient was given combined spinal epidural anaesthesia and proceeded with the surgery followed by post-operative Pericapsular Nerve Group (PENG) block or Suprainguinal Fascia Iliaca block.

Thirty more cases were taken as control group with no block given to any of these cases. Pain scores were assessed using Visual analogue score (VAS) and Numeric rating scale (NRS) for the next 24 hours period. Reduction in the pain score, duration of sensory blockade, total duration of analgesia, request to time of first analgesic requested was recorded. Rescue analgesia used were IV paracetamol, IM diclofenac, epidural bupivacaine 0.125% and any side effects were noted.

Results

Reduction in Pain Scores Following Blockade

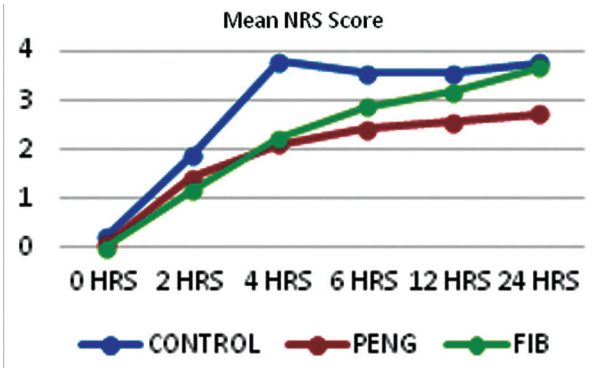


Fig. 9: The graph depicts the significant reduction in numeric rating pain score in the group of PENG block compared to FIB group of block.Comparing the reduction in pain scores using NRS among the three groups was found to be significant at all hours in the 24 hours period (p<0.05).

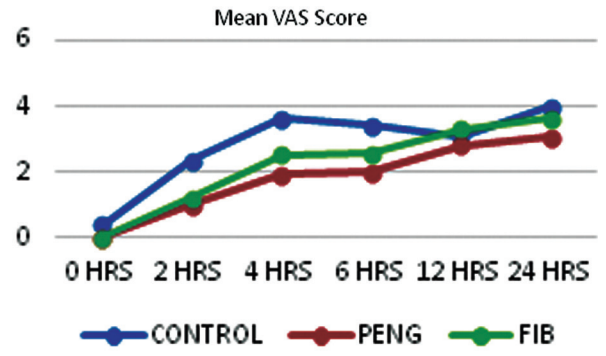


Fig. 10: The graph depicts the significant reduction in Visual Analogue Score in the group of PENG block compared to FIB group of block. Comparing the reduction in pain scores using NRS among the three groups was found to be significant at all hours in the 24 hours period (p<0.05) except at 12 hours.

Time Period at which First Analgesic was Requested: The mean difference in the time of first analgesia required in PENG group and FIB group in comparison with that of control group was found to be -13.800 hours and -4.900 hours respectively and was found to be statistically significant ($p<0.05$) based on the Post Hoc test for Anova. amount of Additional Analgesia Required: The mean difference for amount of additional analgesia required in PENG group and FIB group on comparison with that of control group was found to be 1.300 and 1.033 respectively and was found to be statistically significant ($p<0.05$) based on the Post Hoc test for ANOVA thus showing a greater requirement of analgesia in the Fascia Iliaca block compared to Pericapsular Nerve Group block.

Discussion

Post operative pain management after hip surgeries has always been a challenging goal to achieve. Multiple regional techniques have been used in the past but there is no 'best proven intervention' for post operative analgesia.[18]

The innervation of hip joint is complex and is by both lumbar (L1-L4) and sacral (L4-S4) plexus receiving its sensory innervations from Femoral, Obturator, Accessory obturator and Sciatic nerves with contribution from Nerve to Quadratus Femoris and Superior Gluteal Nerve.[19]

PENG block is a novel ultrasound guided myofascial plane block where the target area is the pelvic rim (superior pubic ramus) near the ileopubic eminence, deep to fascia of iliopsoas muscle thus blocking the articular branches of femoral nerve, obturator nerve and accessory obturator nerve which cross over the bony rim.[7,20] However by increasing the volume of local anesthetic, other nerves (Genitofemoral nerve and lateral cutaneous femoral nerve) can be blocked.[12] Other than its perioperative use for hip surgeries, it is used an 'arrival block', anesthesia for dislocated hip and varicose vein stripping procedure.[21,22] One of the major advantage is the preservation of quadriceps motor function due to its diffusion zone blocking only the articular branches to the anterior hip capsule and sparing the motor branches of the femoral nerve.[13]

Suprainguinal Fascia Iliaca Block is a compartmental block and is an important armament of hip analgesia gaining rapid popularity.[9,23] However there is disagreement about the exact neuroanatomy targeted by Fascia Iliaca Block 24 and they may not provide sufficient analgesia in

hip surgeries as articular branches originate at a higher level along the course of nerves.[25] Moreover the cephalad local anesthetic spread does not consistently cover the obturator nerve.[26]

Our study aimed at comparing the two blocks in terms of reduction in pain scores, time at which first analgesic was requested and quantity of additional analgesia used in the 24 hour post operative period. However larger comparative studies are required to establish the efficacy and superiority over one another.

In a similar randomized comparative study by Bhatacharya et al[27] PENG group had significantly quicker onset of action compared to Suprainguinal Fascia Iliaca block (average of 13.6 and 22 minutes) respectively. In a similar double blinded randomized control trial by Shankar et al[28] the duration of block was comparable between PENG and FICB (8.16 hours versus 7.85 hours). Patient satisfaction about pain relief after the blocks was assessed by Jaden et al[29] and showed 97% were highly satisfied.

EOSP scores (ease of spinal positioning) was better in PENG group when compared to Fascia Iliaca Block.

Kim and Tsui[30] raised a valid point that periosteal injury and tissue damage vary between fracture fixation and replacement surgeries and suggested a subgroup analysis comparing the pain outcome in future studies. Furthermore in their experience difference in postoperative pain in hip surgeries tend to be more apparent at a later time than Day 0, especially when patient starts mobilsing . This is most likely due to micromotion at the fracture site in the different subgroups.

Our results were similar to other studies that have reported better post operative analgesic efficacy in PENG group when compared to Fascia Iliaca Block. No patient reported any local anesthetic toxicity, block related complications like vascular puncture or ureteric injury and quadriceps weakness.

Further randomized control studies need to determine its efficacy as a solo block is also warranted. Also cadaveric and magnetic resonance imaging studies are recommended for better understanding of the anatomic spread of local anesthetic and nerves covered with both blocks.

Conclusion

The PENG block and SIFICB are potential supplements for regional analgesic techniques for post operative analgesia in hip surgeries. They can be easily performed in supine position without any discomfort of patient positioning. PENG block showed better reduction in pain scores, delayed request for first analgesic and less requirement of additional analgesia in 24 hours period.

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Original Article

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Effect of Intravenous Dexamethasone on Prolongation of Analgesia Following Supraclavicular Brachial Plexus Block

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Abstract

Objective: Intravenous dexamethasone prolongs the duration of analgesia and motor block provided by brachial plexus block with plain 0.5% bupivacaine.

Material and Methods: After obtaining Ethical Committee's approval, informed consent was taken from the patients involved in the study. The 60 patients included in the study were divided randomly into two groups with 30 patients in each. In group P, ultrasound guided supraclavicular brachial plexus block was given with 30 ml of plain 0.5% bupivacaine without any additive followed by 2 ml of normal saline intravenously. In group D, ultrasound guided supraclavicular brachial plexus block was given with 30 ml plain 0.5% bupivacaine followed by 8 milligrams (2 ml) dexamethasone intravenously, injected after giving the block. Following this, duration of analgesia and duration of motor block was calculated for both the groups.

Results: The mean duration of analgesia in group P (plain bupivacaine 0.5% in block with 2 ml normal saline iv) was 365±20 minutes (approx 6 hours) while the mean duration of analgesia in group D (plain bupivacaine 0.5% in block with 8 mg dexamethasone iv) was 902±30 minutes (approx 15 hours). The duration of motor block noted in group P was 253±32 minutes (approximately 4 hours) and that in group D was 572±36 minutes (approximately 9.5 hours). Both these results were highly significant. ($p<0.001$).

Conclusion: Intravenous (IV) administration of dexamethasone along with supraclavicular brachial plexus block with 0.5% bupivacaine significantly prolongs analgesia as well as motor block provided by the block. As dexamethsone is still not approved for perineural use by the various drug regulatory authorities around the world including FDA and long term effects of perineural dexamethasone are still under study, IV administration of dexamethasone should be preferred over perineural use in contemporary practice of anaesthesia.

Keyword: IV dexamethasone; Brachial plexus block.

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Introduction

Brachial plexus block is a widely used and efficacious regional anaesthesia technique used for upper extremity orthopaedic surgeries.[1] Supraclavicular approach for this block is used for surgeries around the elbow and distal to it. A longer duration of analgesia postoperatively enables patients comfort and reduces morbidity. Various adjuvants have been added to local anaesthetic drugs in this block to achieve a longer duration of perioperative anaesthesia and analgesia. In contemporary practice drugs like epinephrine, sodium bicarbonate, opioids, clonidine etc have been used as additives for the same.[2,3]

Dexamethasone has also been used off label as an additive perineurally in supraclavicular block and has proven to prolong the effect of block although it is not FDA approved for use in peripheral nerve blocks.[4] Multiple studies have been conducted that have shown its safety in this use but there is still lack of literature on long term follow up of these patients.[5] More number of such long term follow up studies need to be conducted to ascertain the safety of dexamethasone perineurally before it can be used without any hesitation by contemporary anaesthesiologists. Meanwhile intravenous dexamethasone is widely used.

The mechanism of action of analgesia by dexamethasone is unclear. But it has been postulated that it inhibits synthesis of cyclooxygenase-2 in the peripheral tissues and central nervous system thereby reducing the prostaglandin production and thus inflammation and pain.[6,7] Intravenous corticosteroids have been used since a long time and single time use is very common by anaesthesiologists for its antiemetic and anti inflammatory effects and does not cause any serious side effects. Thus we conducted this study to find if intravenous dexamethasone had any effect on prolongation of duration of supraclavicular block.

Materials and Methods

We included 60 patients posted for elective upper extremity orthopaedic surgeries belonging to ASA 1 and 2 groups between the age groups of 20 to 60 years. We excluded patients who were diabetic, had hepatic or renal dysfunction, peripheral neuropathy, any associated head injury or who had any history of allergy to local anaesthetics or steroids. These 60 patients were divided into two groups of 30 each. First group received ultrasound guided supraclavicular block using 30 ml 0.5% bupivacaine plain without any additive. The second group received the same along with 8 mg dexamethasone intravenous after block application.

A standard preanaesthetic examination was done and written informed consent taken from the patients. The procedure was explained to the patient during pre anaesthetic checkup. Patients were premedicted with tablet alprazolam 0.5 mg and tablet pantoprazole 40 mg orally in the night before surgery and on the morning of surgery with sips of water. Inside the operation theatre, all standard monitors (electrocardiogram, non invasive blood pressure, pulse oximeter) were attached, baseline vitals noted and an intravenous catheter was inserted.

The 60 patients were allocated into two groups with 30 patients in each. In group P, ultrasound guided supraclavicular brachial plexus block was given with 30 ml of plain 0.5% bupivacaine without any additive followed by 2 ml of normal saline intravenously. In group D, ultrasound guided supraclavicular brachial plexus block was given with 30 ml 0.5% bupivacaine plain followed by 8 milligrams (2 ml) dexamethasone intravenously. Following the block, patients were evaluated every 5 minutes for sensory and motor block. Sensory block was examined using pinprick along the dermatomes of radial, median, ulnar and musculocutaneous nerves. Motor block was assessed using modified bromage scale for upper extremity as per department protocol. Surgery was started after adequate block was achieved.

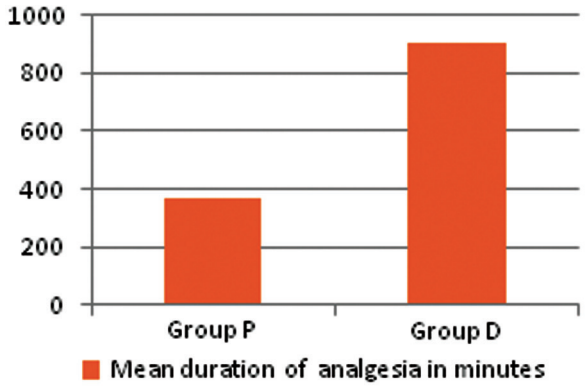
The patients with failed block were excluded from our study. After the completion of surgery, pain was assessed using VAS score. Postoperative assessment for motor block and pain was done at 2,6,10,16,24 hours. Both duration of analgesia and motor block were calculated from the time of giving drug in the block. Duration of postoperative analgesia was calculated till VAS score of patients was more than.[4] When VAS>4, rescue analgesia was used in the form of injection diclofenac 75 mg intravenously. Adverse effects like nausea, vomiting and paraesthesias in the affected limb was also noted. Any pain on tourniquet application was also noted. Patients with failed block were excluded from the study. Data analysis was done using SPSS version 21.0. Categorical data were compared using chi square test. $P<0.05$ was considered statistically significant.

Results

The study was conducted in 60 patients. Both groups were comparable in age, sex, weight, ASA

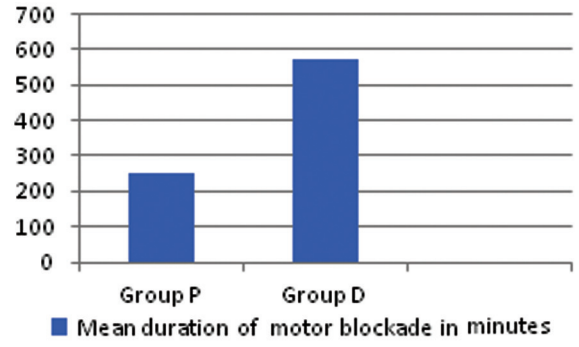
status and duration of surgery. We calculated the duration of analgesia as the time from injection of drug in supraclavicular block under ultrasound guidance to the time of demand for first rescue analgesic when the patient complained of pain with a VAS score of >4. The first rescue analgesic drug used was injection diclofenac 75 mg (intravenous). We also noted the total duration of motor block. It was calculated as the time from start of motor blockade as interpreted from the modified bromage scale for upper extremity to the recovery of full power in the affected limb.

Graph: Mean duration of analgesia in minutes.



There were no cases with failed block so no exclusions were made.

Graph: Mean duration of motor blockade in minutes.



The mean duration of analgesia in group P (plain bupivacaine 0.5% in block with 2 ml normal saline iv) was 365±20 minutes (approx 6 hours) while the mean duration of analgesia in group D (plain bupivacaine 0.5% in block with 8 mg dexamethasone iv) was 902±30 minutes (approx 15 hours)(table 1). It was highly statistically significant ($p<0.001$).

The duration of motor block noted in group P was 253±32 minutes (approximately 4 hours) and that in group D was 572±36 minutes (approximately 9.5 hours)(table 2). These results were also statistically significant ($p<0.001$).

There were no paraesthesias or tourniquet pain in either group.

The incidence of nausea and vomiting was lesser in group D but it was not statistically significant.

Discussion

Post operative analgesia plays a very important role in early recovery of the patient after any surgery. It also has a major role in the complete experience of the patient in the hospital. Regional techniques of anaesthesia are therefore becoming increasingly popular, rather preferred technique of anaesthesia, wherever applicable, as it provides good intraoperative as well as postoperative analgesia.[8] Any technique that ensures prolonged pain relief after surgery is a welcome one.

Brachial plexus block has been widely used in surgeries of the upper limb1. Supraclavicular approach for the same is very safe, effective and relatively simple to perform. Generally the local anaesthetic agents used for this block are effective for 4 to 6 hours only after the block.[9] Therefore various modalities have been used to prolong the said duration. One is the use of catheters. But again, catheters are prone to complications such as malfunction, migration or local anaesthetic systemic toxicity. The other is using adjuvants with the local anaesthetic perineurally. The commonly used adjuvants are opioids, clonidine, dexmedetomidine, ketamine, dexamethasone etc.[2,3] Dexamethasone has been commonly used perineurally but it is not FDA approved for the same.[4] Although it seems to be fairly safe but long term follow up studies are still lacking to show its toxic effects on local nerve roots.

Dexamethasone is a synthetic glucocorticoid which has anti inflammatory and immuno suppressive actions. It is a water soluble compound and has been commonly used in anaesthesia practice as an effective anti emetic for post operative nausea and vomiting. Recently its analgesic effects have been studied.

In the study conducted by us, the demographic profiles of both group regarding age, sex, weight, ASA status and mean duration of surgery were similar and not statistically significant ($p>0.05$).

We noted the mean duration of analgesia and motor block in the two groups. The mean duration of analgesia in group P (plain bupivacaine 0.5% in block with 2 ml normal saline iv) was 365±20 minutes (approx 6 hours) while the mean duration of analgesia in group D (plain bupivacaine 0.5% in block with 8 mg dexamethasone iv) was 902±30

minutes (approx 15 hours). The duration of motor block noted in group P was 253±32 minutes (approximately 4 hours) and that in group D was 572±36 minutes (approximately 9.5 hours).

The mechanism of action of analgesia by dexamethasone remains unclear. Although many studies have shown it to be due to interruption of transmission by nociceptive C fibres. Johanssen et al found reduction in transmission of nociceptive C fibres on application of corticosteroids in rats6. Other mechanisms are also involved like reduction of inflammatory mediators, ectopic neuronal discharges and inhibition of K+ channels on nociceptive C fibres.[10]

Desmet et al conducted a prospective, double-blind, randomized placebo-controlled study and compared the analgesic duration of dexamethasone in three groups: 0.5% ropivacaine plain, 0.5% ropivacaine and perineural dexamethasone(10 mg) and 0.5% ropivacaine with intravenous dexamethasone (10 mg). Analgesia in the plain bupivacaine group lasted 757 minutes (12.6 hours), whereas analgesia lasted 1,405 minutes (23.4 hours) and 1,275 minutes (21.25 hours) in perineural versus intravenous dexamethaosne respectively.[11] These results are similar to our study.

In a similar study conducted by Abdallah et al, 75 patients were divided into 3 groups: 0.5% bupivacaine plain, 0.5% bupivacaine with intravenous dexamethasone, 8 mg and 0.5% bupivacaine with perineural dexamethasone, 8 mg. Analgesic duration was around 25 hours in both groups that included dexamethasone, whereas the control group with plain bupivacaine had analgesia for 13 hours after the block ($P < 0.001$).[12] The analgesic duration in this study are also similar to our study.

There have been studies conducted and various meta analysis to see the effect of intravenous dexamethasone over postoperative analgesia and the results are promising as also in our study. In a meta-analysis by De Oliveira et al, it was concluded that IV dexamethasone decreased opioid consumption and improved postoperative analgesia compared with placebo.[13] The meta-analysis included orthopedic, laparoscopic, and ear, nose, and throat surgical procedures. Recently in 2019, Hewson D also suggested that intravenous dexamethasone has good analgesic and anti emetic effect and this drug should be used in all cases with or without peripheral nerve block.[14]

Heesen et al in their meta analysis on use of intravenous dexamethasone in the setting of spinal anaesthesia, found it to be significantly effective in prolonging analgesic duration of spinal block.[15]

In the Indian setting, a study conducted by Dhanger et al used low dose dexamethasone (2 mg) intravenously with supraclavicular block with 25 ml 0.5% bupivacaine and compared it with supraclaviular block with plain bupivacaine 0.5%.[16] They concluded that low dose dexamethasone significantly prolongs the duration of analgesia.

Perineural and intravenous dexamethasone have been directly compared in various studies with regards to analgesic efficacy and motor blockade duration. Most studies have found it to be comparable. Recently McHardy et al in their study in 2019 found no advantage of perineural over intravenous dexamethasone in terms of analgesia or motor block in interscalene block.[17]

Chong et al in their meta analysis in 2017 showed that analgesic duration of perineural versus intravenous route is comparable with the former just 3.77 hours longer duration than the latter18. They therefore question the justification of use of the perineural over the intravenous route routinely and suggest that perineural use should be limited to patients where it is of use.[19] Although perineural dexamethasone is widely used in practice and various studies have proclaimed it to be safe, long term follow up is lacking and the exact mechanism of action of perineural route is also unclear. Perineural route is also not yet approved by the drug regulatory authorities around the world. Our study shows that intravenous dexamethasone as an adjuvant to 0.5% bupivacaine prolonged analgesic duration and assured good motor blockade for a significant duration after supraclavicular brachial plexus block as compared to that with plain bupivacaine 0.5%. Thus we suggest that intravenous dexamethasone should be preferred over perineural route until bigger, long term studies and trials are conducted that ensure safety of perineural use.

There are some limitations to our study. De oliviera and some other studies have associated intravenous dexamethasone with hyperglycemia although surgical stress may also be a contributing factor for the same. We did not study hyperglycemia as a side effect in our study. Also bigger study groups need to be used to accurately distinguish the analgesic role of intravenous dexamethasone.

Conclusion

A single dose of dexamethasone 8 mg given intravenously along with supraclavicular brachial plexus block prolonged analgesic duration to

upto 15 hours compared to 6 hours with plain supraclavicular block. It also prolonged the duration of motor block significantly (9.5 hours vs 4 hours) without any major adverse effects. Dexamethasone is a cheap, easily available drug that has a high safety profile when used through intravenous route. Its analgesic and anti emetic effects make it very useful for routine use and it may be preferred over perineural dexamethasone when prolonged analgesia is required after peripheral nerve blocks.

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Original Article

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Arterial Hypertension and Diabetes Mellitus in Adult Surgical Patients: Prevalence and Perioperative Impact

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Abstract

Background: Arterial hypertension and diabetes mellitus are prevalent co-morbidities in surgical patients, and they might have an impact on perioperative care. Many times, the health-care team will conduct a preoperative test for diabetes that has gone unnoticed. However, it is rarely assessed how much these disorders affect perioperative anaesthetic care.

Aim: The aim of the study was to determine the prevalence of new, managed, and uncontrolled hypertension, diabetes mellitus, and their perioperative sequelae in adult surgical patients.

Methods: This prospective observational study was conducted in a tertiary care teaching hospital. Total 186 adults of both sexes, planned for elective non-cardiac surgery were included. Arterial hypertension (AHTN) and Diabetes Mellitus (DM) was defined as per JNC-7 and ADA definition. The prevalence of new, controlled, uncontrolled AHTN and DM and their perioperative anaesthetic were assessed.

Results: Total 186 patients' 98 (53%)cases posted were evaluated were with hypertension, 67(36%) cases with diabetes mellitus followed by 21 (11%) cases with both HTN and DM.

The prevalence of these co morbidities was found to be highest in 6th decade. The prevalence of DM was also higher in male than female , but the differences were statistically insignificant for AHTN, DM and for both . The prevalence of renal failure and coronary artery diseases, mean age in the patients with both the comorbidity were higher than either of hypertensive and diabetic group and both the differences were statistically significant.[12] (12.2%) hypertensive and 2 (3%) diabetic and patients were in the range of postponement of elective surgery.

Conclusion: Adults have a high prevalence of AHTN and DM, which increases dramatically with age. Both men and women are affected in the same way. The prevalence of uncontrolled AHTN and DM is concerning, demanding immediate action to treat these serious noncommunicable diseases.

Keywords: Arterial Hypertension; Diabetes Mellitus; Perioperative Impact.

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Introduction

Currently, there are approximately 22 million people in the United States diagnosed with diabetes.[1,2] Unfortunately, it is estimated that more than 8 million additional persons have diabetes but are undiagnosed.[1,4] The National Health and Nutrition Survey (NHANES) indicates that nearly 13% of patients older than 20 years have diabetes; alarmingly, 40% of these cases are undiagnosed.[1,2]

There are many effects of diabetes on the human body that complicate the administration of anesthesia. It is imperative that ambulatory anesthesiologists understand the association between type 2 diabetes and these comorbid conditions and the complications that may present during sedation and general anesthesia. The stress of surgery, anesthesia and illness increases secretion of counter-regulatory hormones (cortisol, glucagon, growth hormone, catecholamines), which in turn causes decreased insulin secretion, increased insulin resistance, decreased peripheral utilization of glucose, increased lipolysis, and proteolysis.

As a consequence, gluconeogenesis and glycogenolysis increase, which subsequently results in worsening hyperglycemia termed as stress hyperglycemia. Uncontrolled hyperglycemia instigates osmotic diuresis (causing fluid and electrolyte imbalance), ketogenesis, and increased generation of pro-inflammatory cytokines with resultant mitochondrial injury, endothelial dysfunction, and immune deregulation.[4,5] Hence, achieving good glucose control during the perioperative period is associated with beneficial post-surgical outcomes.

The degree of hyperglycemia is also affected by the type of anaesthetic and operation used, with higher glucose levels reported with general anaesthesia or thoracic/abdominal surgeries versus epidural/local anaesthesia or peripheral/ laparoscopic surgeries. The purpose of this study was to determine the prevalence of new, managed, and uncontrolled hypertension and diabetes mellitus in adult non-cardiac surgery patients, as well as their perioperative impact. The findings will aid us in better understanding, anticipating, and planning perioperative treatment for these patients.

Materials and Methods

In a tertiary care teaching hospital, a hospital-based, cross-sectional, observational, sub-group study was done. The data was collected between December 2018 and May 2019. Participants must be 18 years of age or older, male or female, and attend a preanaesthetic evaluation clinic (PAEC). If a patient presented to the PAEC with systolic blood pressure (SBP)>140 mmHg and/or diastolic blood pressure (DBP)>90 mmHg, according to Joint National Commission report 7 (JNC-7). If a patient reported to the PAEC with hyperglycemia, as defined by the American Diabetes Association (ADA), but no prior documentation or treatment history, the patient was identified as a new case of diabetes. If the HbA1c result is between 5.7 and 6.4 percent, the patient was previously unknown. The numbers of new, controlled, and uncontrolled cases were counted based on demographics, physical status, surgery category, clinical/medical history, and the number of new, controlled, and uncontrolled cases. Serum creatinine level was noted as abnormal (high)if the value was >1.2 mg% and the patient was designated to have renal injury/failure.

The information was provided in absolute numbers on a percentage scale. Male and female prevalence numbers were also estimated separately and compared to national and international data. There were additional considerations for perioperative anaesthesia and patient management. It was considered influential if the assessing anaesthesiologist requested a consultation/ referral, retesting, or further investigation based on the blood sugar report and/or blood pressure level. Measures of central tendencies and dispersions werecalculated and comparisons of the groups were done using Graph Pad Prism Software Ap< 0.05 was considered statistically significant.

Results

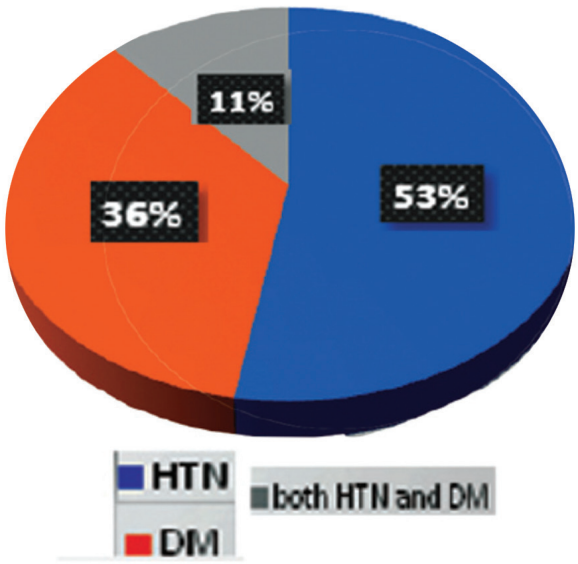

Fig. 1: Pie diagram showing distribution of hypertension and diabetes mellitus in cases.

Data from 621 adult patients were collected during the study period. 10 patients' data were excluded due to insufficient follow up till the day of surgery and incomplete data and 211 patients' of which 186 patients are with Hypertension, Diabetis mellitus or both.

98 (53%)cases posted were evaluatedwere with hypertension, 67(36%) cases with diabetes mellitus followed by 21 (11%) cases with both HTN and DM.

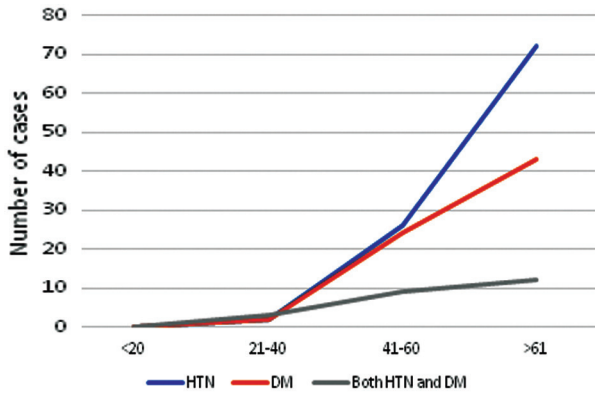

Fig. 2: Prevalence of age in all 3 groups.

With the increasing age, the prevalence of AHTN and/or DM increased. The prevalence of AHTN and/or DM in <20 year, 21 – 40 year , 41-60 years and above 61 year agegroups were 3.8 %, 32% and 68% respectively(p< 0.0001). The prevalence of these co morbidities wasfound to be highest in 6th decade of life.

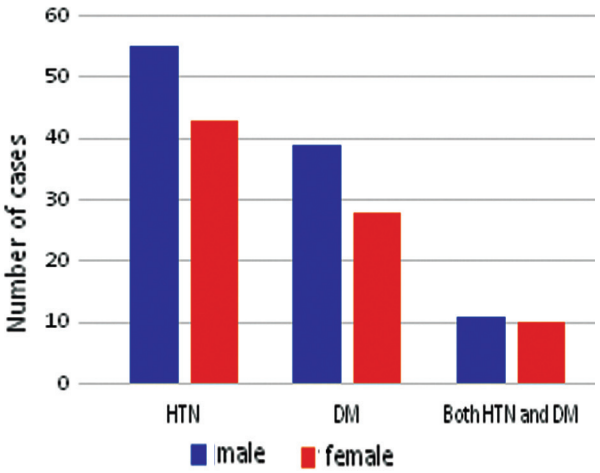

Fig. 3: Distribution of males and females in the study.

Half of both male and female patients were suffering from AHTN. The prevalence of DM was also higher in male than female, but the differences were statistically insignificant for AHTN, DM and for both

Table 1: Correlation of controls with hypertension.

Parameter	Controls (n-435)	HTN(n=98_	P-Values
Mean age in years	40 ± 9.1	54 ± 10.6	<0.0001
Mean weight in kgs	59 ± 12.1	61 ± 12.9	0.78
Obesity (n%)	10(2.3%)	3(3.1%)	0.14
Renal failure (n%)	1(0.2%)	7(7.1%)	<0.001
CAD(n%)	1(0.2%)	11(11.2)	<0.001

Mean age, renal failure and CAD are increase in Hypertensive diagnosed patients that in controls and the differences were statistically significant.

Table 2: Correlation of controls with DM.

Parameter	Controls (n-435)	DM(n=67)	P-Values
Mean age in years	40 ± 9.1	56 ± 11.3	0<0.001
Mean weight in kgs	59 ± 12.1	61 ± 13.5	0.21
Obesity (n%)	10(2.3%)	2(2.98%)	0.12
Renal failure (n%)	1(0.2%)	6(8.9%)	<0.001
CAD(n%)	1(0.2%)	8(11.9%)	<0.001

Mean age, renal failure and CAD are increase in Diabetes diagnosed patients that in controls and the differences were statistically significant.

Table 3: Correlation of controls with both.

Parameter	Controls (n-435)	HTN and DM(n=21)	P-Values
Mean age in years	40 ± 9.1	55 ± 12.3	<0.001
Mean weight in kgs	59 ± 12.1	62 ± 14.2	0.26
Obesity (n%)	10(2.3%)	4(19%)	<0.001
Renal failure (n%)	1(0.2%)	5(23.8%)	<0.001
CAD(n%)	1(0.2%)	6(28.5%)	<0.001

Mean age, obesity, renal failure and CAD are increase in Hypertensive and Diabetes diagnosed patients that in controls and the differences were statistically significant.

The prevalence of renal failure and coronary artery diseases, mean age in the patients with both the comorbidity were higher than either of hypertensive and diabetic group and both the differences were statistically significant.

12 (12.2%) hypertensive and 2 (3%) diabetic and patients were in the range of postponement of elective surgery.

Discussion

In our study out of 621 adult patients were collected during the study period 186 patients are with Hypertension, Diabetis mellitus or both of which 98 (53%) cases posted were evaluated were

with hypertension, 67(36%) cases with diabetes mellitus followed by 21 (11%) cases with both HTN and DM.

In our study with the increasing age, the prevalence of AHTN and/or DM increased . The prevalence of AHTN and/or DM in groups were significant (p< 0.0001). The prevalence of these co morbidities was found to be highest in 6th decade of life. Our study is similar to study done by Habib Md Reazaul Karim et al. 6Among the steadily increasing population of surgical patients aged 65 yr and older, the fastest growing sector is individuals of 85 yr or older. As a result, greater numbers of patients are presenting for surgery with ageing-related, pre-existing conditions that place them at greater risk of an adverse outcome, such as cardiac or pulmonary disease or diabetes mellitus. It is, therefore, not surprising that the elderly have the highest mortality rate in the adult surgical population. Postoperative adverse effects on the cardiac, pulmonary, cerebral systems, and on cognitive function are the main concerns for elderly surgical patients who are at high risk.The function capacity of organs reduces with ageing, resulting in decreased reserve and ability to endure stress. Advanced age is, therefore, a significant risk factor for increased mortality. Co-existing disease further depresses organ function and/or reserve, exacerbating risk.[7,8,9]

In our study prevalence of DM was also higher in male than female, but the differences were statistically insignificant for AHTN, DM and for both. Data from USA also showed near similar prevalence (i.e. age- adjusted prevalence of hypertension among persons aged ≥18 years was 29.6%). Similar results were also noted with regard to DM. 10Although the prevalence of DM in male patients was nearly similar; the prevalence of was higher for female patients in the Habib Md Reazaul Karim et al.6 study (12.73% versus8.6%) as compared to prevalence of hyperglycemia reported in NFHS-4.

In our study HTN , Dm and both HTN and DM groups have statistically significance between controls with renal failure and coronary artery diseases, mean age in the patients with both the comorbidity. Both the disease has significant impact in the perioperative management of surgical patients as uncontrolled condition can cause morbidity and even increased mortality.[11,12]

However both anaesthesiologists and surgical specialists are more related to the acute care of these patients. As far as the anaesthesia services (both in operation theatre and intensive care) are concerned; anaesthesiologists are capable of controlling both the condition (i.e.high BP and hyperglycemia) relatively faster even if there are derangements.

Hypertension affects over 70 percent of patients with type 2 diabetes.[17] When hypertension and diabetes are combined, the risk of perioperative myocardial infarction, cerebrovascular accident, and microvascular illness, such as retinopathy and autonomic and sensory neuropathies, increases. Diabetic people have a 2–3 fold increased risk of congestive heart failure (CHF). Both anaesthesiologists and surgeons must be more pragmatic in their service utilisation to avoid unnecessary referrals, delays, and inconvenience to patients, particularly the elderly. Fourth, a large proportion of the DM cases were new, suggesting that a screening for DM could be beneficial.

Conclusion

Adults have a high prevalence of AHTN and DM, which increases dramatically with age. Both men and women are affected in the same way. The prevalence of uncontrolled AHTN and DM is frightening, indicating the need to take immediate action to combat these critical non-communicable illnesses at the grass roots level.

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Comparative Study of 20ml of 0.5% Ropivacaine with 250mg Magnesium Sulphate and 20ml of 0.5% Ropivacaine with 500mg of Magnesium Sulphate in Supraclavicular Approach to Brachial Plexus Block under Ultrasound Guidance

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Abstract

Context: Available evidence on efficacy of adjuvants to local anesthetics (LAs) in supraclavicular BPB is of varying strengths and levels. Several studies have been conducted in which Magnesium Sulphate ($MgSO_4$) was administered (with placebos and other drugs) as adjunct to LAs in supraclavicular BPB, and they revealed varying degrees of efficacy with or without side effects

Aim: To study efficacy of 20ml 0.5% ropivacaine with 250mg $MgSO_4$ and 20ml 0.5% Ropivacaine with 500mg of $MgSO_4$ in supraclavicular approach to brachial plexus block under ultrasound guidance

Settings and design: Prospective Randomized Controlled Comparative Interventional study was conducted at KIMS Hospital, Kondapur, Hyderabad.

Methods: 80 patients undergoing upper limb surgeries were included. They were randomly assigned in two groups of 40 each; with one group receiving MgSO4 250mg and the other MgSO4 500mg. two groups were compared for different parameters.

Statistical Analysis: Chi Square Test was applied for categorical data and t test for the continuous data.

Results: Baseline parameters, pre-anesthesia vital parameters were comparable in two groups ($p>0.05$). Duration of onset of sensory and motor block and completeness of block was similar in two groups ($p>0.05$). But duration of block was significantly more both for sensory and motor in Mg-500 compared to Mg-250 group ($p<0.05$). Heart rate, Mean Arterial Pressure (mmHg) were comparable in two group at all durations from pre-operative to 24 hours ($p>0.05$).

Conclusion: Duration of sensory and motor blockade is prolonged by addition of MgSO4 in two doses (500mg and 250mg) to Ropivacaine in USG-guided supraclavicular BPB. Action of MgSO4 is dependent on the dose, more the dose longer the action.

Keywords: Ropivacaine; Magnesium sulphate; Supraclavicular; Brachial plexus; Ultrasound.

Key messages: 20ml of 0.5% ropivacaine with 500mg of magnesium sulphate in supraclavicular approach to brachial plexus block under ultrasound guidance can be used instead of 250mg magnesium sulphate.

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Introduction

Regional Anesthesia (RA) limits the physiological side effects and stress associated with surgery. The advantages include, but limited to, the reduction of blood loss of 20-50% in many procedures; less interference with immuno-competence; avoids polypharmacy; provides better hemodynamic stability; excellent post-operative analgesia; less interference with normal metabolic process and vital functions of most patients and reduction in hospital stay.[1,2]

As the Ultrasonography (USG) guided techniques developed, there has been enormous increase in the use of local Anesthetic peripheral nerve blocks for surgical Anesthesia and postoperative pain management.[3]

With regard to upper extremity surgeries, brachial plexus blockade (BPB) has been significantly and widely used as an alternative to GA. BPB is a simple, safe and reliable method. Patients can also enjoy postoperative period free from nausea, vomiting, cerebral depression and immediate postoperative pain.[4] Therefore, BPB is flexible and improves patient satisfaction.[5] The USG guided BPB has remarkably improved precision.[3]

The most common technique for regional anesthesia is Interscalene BPB. It is effective in alleviating pain in cases of surgery of the shoulder. But it is associated with the complications like "hoarseness, ipsilateral hemi diaphragmatic paresis and Horner's syndrome." Hence research was carried out and from Meta analysis, it was concluded that supraclavicular approach is more effective and also has lesser side effects.[6] Now, among all BPBs, supraclavicular BPB is most commonly used technique. Supraclavicular approach gives the most effective block for all portions of upper extremity and is carried out at the level of trunks of brachial plexus. The plexus is blocked where it is most compact i.e. at the middle of brachial plexus, resulting in homogeneous spread of Anesthetic throughout the plexus with a fast onset and complete block.[7]

Dureja J et al[8] compared the three techniques (Conventional Blind (CB), Nerve Stimulator (NS) Guided, and USG Guided) of supraclavicular BPB in a prospective, randomized clinical trial and concluded that the success rate and effective quality of the block were more satisfactory with USG technique than the NS or CB technique.

So, USG guided supraclavicular BPB has been the technique of choice and has been widely and significantly used for the upper limb surgeries. BPB also minimizes the local Anesthetic volume, thereby reducing the incidences of their systemic toxicity.[1]

Topical anesthetics are used commonly used for nerve blocks. They not only have less adverse effects but also help in the control of pain after surgery. The BPB in particular is a widely used option in upper extremity surgeries. While the procedure of BPB, along with the local anesthetics, a variety of drugs have been used with the objective of reducing the effect onset time, to increase the period of anesthesia and to increase the success rates. With regard to this, hundreds of studies have been conducted, with varying results.[9] Presence of additives to LAs has the advantages of improving onset and duration of blockade, gaining patient satisfaction, maintaining proper hemodynamic, together with reducing the need to postoperative analgesics.[10]

The available evidence11-14 with regard to the efficacy of adjuvants to LAs in supraclavicular BPB is of varying strengths and levels. Several studies have been conducted in which Magnesium Sulphate ($MgSO_4$) has been administered (with placebos and other drugs) as adjunct to LAs in supraclavicular BPB, and those studies have revealed varying degrees of efficacy with or without side effects.

"$MgSO_4$ has N-methyl-D-aspartate (NMDA) receptors antagonist property and is a calcium channel blocker.[15,16] it stimulates the peripheral nociceptive and thus prevents the central sensitization. Thus it is a useful adjuvant to the LAs. But there is lack of degree of evidence of $MgSO_4$ in surgeries of upper limbs using BPB along with LAs. Also knowledge on dose of $MgSO_4$ is conflicting.

We therefore studied the efficacy of $MgSO_4$ in two doses (250mg and 500mg) as an adjuvant to Ropivacaine in USG guided supraclavicular BPB.

Methods

The Prospective Randomized Controlled Comparative Interventional study was conducted from August 2019–June 2021; on either gender, patients age group 20-70 years, ASA physical status I & II, posted for elective upper arm surgeries at KIMS Hospital, Kondapur, Hyderabad.

The permission of ethical committee was taken. Written informed consent was taken from all patients on a separate "Patient Consent Form".

Sample Size Calculation

Sample size was determined (based on the previously

conducted study) 17 for the two independent study groups for continuous variable for this comparative prospective randomized controlled study. In that study by Verma V et al[17] mean time to first request for rescue analgesic medication was 450±50 min and 517±125.01 min in the 125 mg and 250 mg Magnesium Groups respectively when compared with the Control (Bupivacaine) Group which was 399±97 min. We calculated a minimum sample size assuming alpha (type 1) error (two-tailed) of 0.05, beta error as 0.2, and power as 80% i.e. total sample size of 8 (4 in each arm) is required, however we have considered a total sample size of 80 i.e. 40 in each arm.

Inclusion Criteria

- Age group 20-70 years
- ASA Grade I and II
- Admitted into hospital for elective upper limb surgeries

Exclusion Criteria

- Patient refusal
- Infection at the site of injection
- ASA Grade III and IV
- Known allergy to local anesthetic agents
- Coagulation disorders (including patients on anticoagulants)
- Patients with neurological deficits and musculoskeletal disease
- Pregnant and lactating women
- Emergency upper limb surgery
- Pneumothorax or previous Pneumectomy on the opposite side

Methodology

Pre-Anesthesia (Pre-Block Preparation)

- Patients of ASA I - II aged between 20 and 70 years undergoing upper limb surgeries were taken.
- Procedure was explained to the patients during pre-operative visits.
- A thorough preoperative evaluation was done with written informed consent (complete medical history and physical examination was done for all the patients).
- Basic hematological and laboratory investigations like complete hemogram, blood sugar, renal function test, etc. were reviewed. Where indicated ECG and Chest X-RAY were also reviewed.
- All patients were made to fast (NBM) for a minimum of 2 hours prior to anesthesia for liquids and overnight for solids.
- On the day of surgery, an appropriately sized IV cannula was secured.
- On arrival at the operating theatre, a 5 lead ECG monitor, pulse oximeter and an automated non-invasive arterial blood pressure monitor were applied.
- Pre-operative Heart Rate, Blood Pressure, and Saturation (SPO2) were noted in the Operating Room and those were considered as baseline Heart Rate, Blood Pressure, and Saturation.
- Ensured that there were no contraindications for the procedure.
- Correct side of the block was confirmed (through 'Time Out Process').

Practical Conduct of the Block was ensure by appropriate Scanning Technique using the ultrasound probe. Nerve Localization was done by Anatomic Correlation. Appropriate technique was followed for Needle Insertion. Test Drug Injection was injected as per the study protocol.

Randomization

1. Through computer generated random sampling method, patients were randomly divided into following two groups:

Group Mg250 (Magnesium Sulphate 250 mg Group) (n=40)

Group Mg500 (Magnesium Sulphate 500 mg Group) (n=40)

Test Drugs

Group Mg250 (n=40): Inj Ropivacaine (0.5%) 19 ml + Inj Magnesium Sulphate 250 mg (0.5 ml MgSo4 plus 0.5ml NS).

Group Mg500 (n=40): Inj Ropivacaine (0.5%) 19 ml + Inj Magnesium Sulphate 500 mg (1 ml).

Intra-Operative Assessment

1. Every patient of each group was assessed for the following parameters, in the minimum, intra-operatively:

a. Onset of sensory and motor block

b. Quality of block

i. Complete

ii. Incomplete

iii. Failed

c. Total duration of sensory and motor bock

d. Complications (Adverse Events) like vascular puncture, hematoma, pneumothorax, and drug toxicity were noted

2. Incomplete blocks were supplemented with propofol.

3. Failed blocks were supplemented with full GA with intubation.

Post-Operative Assessment

Postoperatively, all the patients were followed-up for 24 hours in the wards, and the following parameters were assessed (in both the groups).

Pain severity on 10mm Visual Analogue Scale (VAS) scores of 0 being no pain, and 10 as the worst imaginable pain. VAS Score was assessed and recorded at 2h, 4h, 8h, 12h, and 24h. Patient with VAS score more than 4 was given Inj. Paracetamol 1gm IV as a rescue analgesia. Total Paracetamol consumption in the first 24 hours in both the groups was noted for comparison.

Hemodynamic changes (Heart Rate, Mean Arterial Pressure, SpO_2) at 0 Minutes, 5 Minutes, 10 Minutes, 20 Minutes, 30 Minutes, 60 Minutes, 2 hours, 4 hours, and at 6 hours post-operatively as secondary outcomes. Overall patient satisfaction was also assessed.

Sensory Blockade Assessment and Scoring

Onset of Sensory Blockade

- Onset time is the time from the completion of injection of the local anesthetic to first loss of pinprick sensation in any of the dermatomes C5-T1

Duration of Sensory Blockade (Duration of Analgesia)

- Duration of sensory blockade is the time from the onset of the sensory blockade till the patient complaints of pain at the site of surgery (wound site).

Grading for Sensory Block by Pin Prick

- 0 = No pain
- 1 – 3 = Annoying (Mild Pain)
- 4 – 6 = Uncomfortable (Moderate Pain)
- 7 – 10 – Dreadful (Severe Pain)

Method of Sensory Block Assessment

Pin-prick with 23G Needle in an area innervated by:

- Musculocutaneous nerve: Lateral side of forearm
- Medial cutaneous nerve: Medial side of forearm
- Median nerve: Thenar eminence
- Radial nerve: Dorsum of hand over 2nd metacarpophalangeal joint
- Ulnar nerve: Little finger

Pain Score

Visual Analogue Score was explained to patients preoperatively (VAS: 0-10, 0=No pain, 10=worst pain possible), presented as a 10 cm horizontal line with verbal anchors at each end of 'no pain' and 'worst pain possible'. Post-operative VAS scores were recorded at 3h, 6h, 12h, 18h and 24h. Patient with VAS score more than 4 were given Inj. Paracetamol (1gm IV TID) as rescue analgesia.

Motor Blockade Assessment and Scoring

Onset of Motor Blockade

- The total time required to achieve complete paralysis of the upper limb
- Duration of Motor Blockade

1. Duration of motor blockade is the interval between the onsets of motor blockade to the time patient first experiences movement of the blocked limb

- Grading for Motor Block by Modified Lovett's Scoring.
- Grade 6 = Normal
- Grade 5 = Slightly reduced muscular force
- Grade 4 = Pronounced reduction
- Grade 3 = Slightly impaired mobility
- Grade 2 = Pronounced mobility impairment
- Grade 1 = Almost complete paralysis
- Grade 0 = Complete paralysis

Method of Motor Block Assessment

It is evaluated by examining the following response:

- Musculocutaneous nerve: Elbow flexion
- Median nerve: Third finger flexion
- Radial nerve: Thumb abduction
- Ulnar nerve: Little finger flexion

Block Performance Time (BPT – Time Taken for the Procedure).

This is defined as the interval between preparations of the injection site to the administration of total dose of local anesthetic.

Quality of Block (Scoring)

Quality of block assessed as scale for sensory and motor blockage:

- Complete block – 2
- Incomplete – 1
- Failed – 0

Total Duration of Analgesia

Duration of Analgesia is the time from the onset of the sensory blockade till the patient complaints of pain at the site of surgery (wound site). Rescue analgesia is given after that only.

Method of Data Collection

Upon assessment, the pre-operative, intra-operative, and post-operative data was recorded on the pre-designed and structured patient proforma

Statistical Analysis

Data was entered into Microsoft Excel and statistical analysis was done. Level of significance was set at $p<0.05$. P value <0.05 was considered to be significant. P value <0.0001 was considered to be highly significant. Chi Square Test was applied for categorical data and t test for the continuous data.

Results

The baseline parameters were comparable in two groups ($p>0.05$). (Table 1). The pre-anesthesia vital parameters were comparable in two groups ($p>0.05$). (Table 2).

Duration of onset of sensory and motor block and completeness of block was similar in two groups ($p>0.05$). But the duration of block was significantly more both for sensory and motor in the Mg-500 compared to Mg-250 group ($p<0.05$). (Table 3).

The heart rate was comparable in two group at all durations from pre-operative to 24 hours ($p>0.05$). (Table 4). The Mean Arterial Pressure (mmHg) was comparable in two group at all durations from pre-operative to 24 hours ($p>0.05$). (Table 5).

The SpO2 was comparable in two group at all durations from pre-operative to 24 hours ($p>0.05$). (Table 6). The duration of analgesia was significantly more in Mg-500 group compared to Mg-250 group ($p<0.05$). (Table 7).

Table 1: Comparison of baseline parameters in two groups.

Variable		Mg-250 (n=40)	Mg-500 (n=40)	Chi square	t value	p value
Age (years)	Mean±SD	39.45±12.86	44.85±12.01	--	0.9527	0.1718
ASA grades	ASA grade I [N (%)]	34 (85%)	35 (87.5%)	0.1054	--	0.7454
Sex	Male [N (%)]	23 (57.5%)	25 (62.5%)	0.2083	--	0.6481
Weight (kg)	Mean±SD	57.97±9.15	53.93±8.22	--	1.3019	0.0979
Duration of surgery (min)	Mean±SD	103.88±26.97	107.0±30.50	--	0.48538	0.314

Table 2: Comparison of pre-anesthesia vital parameters in two groups.

Variables	Mg-250 (n=40)	Mg-500 (n=40)	t value	p value
Heart rate (min)	79.98+9.36	79.30+10.01	0.098	0.46
Systolic blood pressure (mmHg)	134.34+11.33	132.352+13.61	0.142	0.44
Diastolic blood pressure (mmHg)	80.20+8.73	80.66+8.94	0.743	0.23
Mean arterial pressure(mmHg)	97.95+9.40	98.25+8.77	0.836	0.31
SPO_2	99.66+0.56	99.60+0.57	0.648	0.26

Table 3: Comparison of sensory & motor block parameters in two groups.

Variables		Mg-250 (n=40)	Mg-500 (n=40)	t/chi square	p value
Duration of onset	Sensory block onset (min)	5.16±0.49	5.14±0.43	0.167	0.434
	Motor block onset (min)	10.72±0.43	10.62±0.52	0.924	0.179
Duration of block	Sensory (hours)	7.16±0.92	8.92±0.42	**12.08**	**< 0.001**
	Motor (hours)	6.5±0.63	8.63±0.50	**16.82**	**< 0.001**
Quality of block	Complete	37 (92.5%)	38 (95%)	0.213	0.644

Table 4: Comparison of Heart Rate in two groups.

Heart Rate (per min)	Mg-250 (n=40)	Mg-500 (n=40)	t value	p value
Pre-operative	79.30±10.01	79.98±9.36	0.031	0.97
0 min	78.52±11.36	79.66±10.63	0.83	0.41
5 min	77.68±10.60	78.94±10.73	0.10	0.92
10 min	77.38±10.88	78.32±11.14	0.40	0.691
20 min	77.80±9.98	77.42±9.42	0.67	0.51
30 min	77.26±9.81	77.22±9.23	0.43	0.67
60 min	76.74±9.93	79.22±10.10	0.06	0.95
2 hours	76.48±10.651	79.21±10.91	1.74	0.09
4 hours	76.72±10.96	79.21±10.0	4.62	0.12
6 hours	76.46±10.58	79.3±10.81	1.79	0.08
12 hours	76.69±9.48	78.69±9.95	0.76	0.45
24 hours	76.12±9.90	79.1±9.73	0.03	0.05

Table 5: Comparison of Mean Arterial Pressure (MAP) in two groups.

Mean Arterial Pressure (mmHg)	Mg-250 (n=40)	Mg-500 (n=40)	t value	p value
Pre-operative	97.95±9.40	98.25±8.77	0.201	0.841
0 min	93.83±9.26	93.81±9.59	1.05	0.301
5 min	91.53±9.11	92.47±9.66	0.251	0.803
10 min	90.32±8.56	92.36±9.27	1.125	0.269
20 min	89.18±7.36	91.60±9.20	0.489	0.628
30 min	89.00±7.31	91.45±9.25	0.138	0.891
60 min	87.08±6.28	90.46±8.19	0.952	0.348
2 hours	93.82±8.33	96.96±7.58	0.742	0.278
4 hours	93.75±6.56	95.16±7.11	0.711	0.318
6 hours	92.37±6.05	94.88±6.88	0.47	0.567
12 hours	91.47±5.55	93.35±7.33	0.832	0.711
24 hours	91.17±5.34	89.87±7.39	0.592	0.375

Table 6: Comparison of post brachial plexus block SpO_2 in two groups.

SpO_2	Mg-250 (n=40)	Mg-500 (n=40)	t value	p value
Pre-operative	99.60±0.57	99.66±0.56	1.139	0.263
0 min	99.58±0.54	99.68±0.51	0.51	0.102
5 min	99.74±0.49	99.72±0.54	0.465	0.645
10 min	99.80±0.45	99.70±0.51	0	1
20 min	99.64±0.56	99.74±0.44	0.238	0.813
30 min	99.60±0.57	99.74±0.56	0.441	0.662
60 min	99.68±0.55	99.70±0.46	0.827	0.414
2 hours	99.70±0.46	99.66±0.48	0.911	0.534
4 hours	99.56±0.58	99.66±0.48	0.876	0.458
6 hours	99.60±0.57	99.74±0.53	0.569	0.576
12 hours	99.64±0.53	99.70±0.51	0	1
24 hours	99.66±0.48	99.64±0.53	0.511	0.732

Table 7: Post brachial plexus block: duration of analgesia.

Duration of analgesia	Mg-250 (n=40)	Mg-500 (n=40)	t value	p value
(in minutes)	529.68±53.32	699.36±45.99	12.05	< 0.0001

Discussion

In our study the mean age was 39.45±12.86 for the Mg-250 group and 44.85±12.01 for the Mg-500 group (p=0.1718). Our age distribution was comparable to other similar studies.[18,19]

The gender distribution in both the groups was also comparable (p=0.839). In all the studies that made a mention of gender, the groups were comparable. The weight distribution too, in both the groups, was comparable (p=0979). Not many studies mentioned about the weight distribution. Weight distribution, in the studies which mentioned, was however comparable. The mean duration of surgery, in our study, was 103.88±26.97 minutes and 107.02±30.50 minutes in Mg-250 and Mg-500 Groups respectively. There was no statistically significant difference between the groups. (p=0.314). Similar comparable groups were seen in all the studies.[16,18,19]

The mean HR was 79.98±9.36 and 79.30±10.01 (p=0.46); the mean SBP was 134.34±11.33 and 132.52±13.61 (p=0.44); the mean DBP was 80.20±8.73 and 80.66±8.94 (p=0.23); the MAP was 97.95±9.40 and 98.25±8.77 (p=0.31) and; the mean SPO_2 was 99.66±0.56 and 99.60±0.57 in the Mg-250 group and the Mg-500 group (p=0.26) respectively. All the relevant similar studies[16,18,19] ensured that the pre-block vital parameters are comparable in their study groups.

The dosages in our study were in accordance with other studies. Verma V et al[17] used doses of 125mg and 250mg of $MgSO_4$ (Group Mg250 (n=40) received Inj Ropivacaine (0.5%) 19 ml + Inj Magnesium Sulphate 250 mg (0.5 ml MgSo4 plus 0.5ml NS) and Group Mg500 (n=40) received Inj Ropivacaine (0.5%) 19 ml + Inj Magnesium Sulphate 500 mg (1 ml); in Goyal et al[20] study, Group I patients received 20 ml of 0.5% $MgSO_4$ given in axillary sheath, Group II patients received 20ml of 1.0 % $MgSO_4$ given in axillary sheath, and Group III patients received intramuscular diclofenac sodium 1mg/kg.

In our study, the mean duration of onset of sensory block in Mg-250 Group was 5.16±0.49 min and in Mg-500 Group was 5.14±0.43 min (p=0.434). Mean duration of onset of motor block was 10.72±0.43 min in Mg-250 Group and was 10.62±0.52 min (p=0.179) in Mg-500 Group. There was no statistically significant difference between the groups–both in the onset of sensory block as well as the motor block. Similar findings were reported by Verma V et al[17] and Bansal et al[21] Rao LN 22 observed the mean onset of sensory block in case Group M (0.5% bupivacaine (1.5 mg/kg) with $MgSO_4$ 20% (3ml)) was 15.5±2.16 and the onset block in control Group P (0.5% bupivacaine (1.5 mg/kg) with normal saline (3 ml) as a placebo) was 12.73±1.18 (p<0.49); statistically not significant). The mean onset of motor block in case Group M was 23.5±1.1 and the onset block in control Group P was 41±3 (p<0.53; statistically not significant). Reza Akhondzade 23 observed that Sensory and Motor blocks onset and duration were statistically longer in group M than group N (P<0.0001) [group M (Lidocaine 1% (4 mg/kg) plus Fentanyl 50µg and MgSO4 20%) than group N (Lidocaine 1% (4 mg/kg) plus Fentanyl 50µg and Normal Saline (5ml))].

In this study, the duration of sensory block was 7.16±0.92 hours in the Mg-250 Group and it was 8.92±0.42 hours in the Mg-500 Group (p<0.00001). The duration of motor block was 6.50±0.63 hours in the Mg-250 Group and it was 8.63±0.50 hours in the Mg-500 Group (p<0.00001). We found statistically significant difference between the two groups – both in the duration of sensory block as well as motor block. Gunduz A et al[24] observed that the mean duration of sensory block in both of the perineural magnesium groups was statistically different than in groups I and II (P<.001). Mukherjee K et al[25] too concluded that adding $MgSO_4$ to supraclavicular BPB may increase the sensory and motor block.

None of the previously conducted studies made a specific mention about failed blocks in their studies. In our study, hemodynamically (HR, MAP, SPO_2) there were no statistically significant differences intra-operatively and post-operatively in both the Mg-250 Group and Mg-500 Group. In almost all the studies 17-44, 46, 48-54, we found no statistically significant between the groups hemodynamically.

We found the mean duration of analgesia in the Mg-250 group was found to be 8.83±0.89 hours while those in the Mg-500 group found to be 11.66±0.72 hours – a statistically significant difference between the performance of both the drugs (p<0.00001). Similar findings were reported by Verma V et al, 17 and Mukherjee K et al.[25] Goyal P et al 20 concluded that, for the first-time magnesium was used independently in a small dose in axillary sheath which results in good analgesia as determined by decreased uses of rescue analgesia without producing any major side effects.

None of the studies except Verma V et al[17] mentioned about the requirement of supplementation to block. Although the authors made a mention of supplementation to block, no specific objective information with regard to supplementation was detailed in the study. We did

not observe any kind of significant perioperative adverse events in either of the Group. The findings of study was in agreement with several other studies (Verma V et al[17], Mukherjee et al[25], Goyal P et al[20]).

Conclusion

Duration of sensory and motor blockade is prolonged by addition of $MgSO_4$ in two doses (500mg and 250mg) to Ropivacaine in USG-guided supraclavicular BPB. Action of $MgSO_4$ is dependent on the dose, more the dose longer the action.

The limitations of the study include, but not limited to the following:

- All types of surgeries were not included in the study.
- The sample size of study Groups was very limited, so cannot generalize this study results to the entire population.
- We did not use placebo group.
- A lower volume of local anesthetic could have been used, especially under USG guidance.
- Systemic absorption of magnesium may have contributed to the beneficial effects.

Therefore, further studies are required in this regard.

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[1] Flink H, Tegelberg Å, Thörn M, Lagerlöf F. Effect of oral iron supplementation on unstimulated salivary flow rate: A randomized, double-blind, placebo-controlled trial. J Oral Pathol Med 2006; 35: 540–7.

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Article in supplement or special issue

[3] Fleischer W, Reimer K. Povidone-iodine antisepsis. State of the art. Dermatology 1997; 195 Suppl 2: 3–9.

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[4] American Academy of Periodontology. Sonic and ultrasonic scalers in periodontics. J Periodontol 2000; 71: 1792–801.

Unpublished article

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Reference from electronic media

[9] National Statistics Online—Trends in suicide by method in England and Wales, 1979–2001. www.statistics.gov.uk/downloads/theme_health/HSQ20.pdf (accessed Jan 24, 2005): 7–18. Only verified references against the original documents should be cited. Authors are responsible for the accuracy and completeness of their references and for correct text citation. The number of reference should be kept limited to 20 in case of major communications and 10 for short communications.

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