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A Comparative Study of Intrathecal Dexmedetomidine with 0.5% Bupivacaine and 0.5% Bupivacaine with Placebo in Lower Abdominal Surgeries

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Abstract

Introduction: Spinal anaesthesia represents an attractive proposition for day-case anaesthesia, being associated with less postoperative nausea and vomiting (PONV) and better postoperative pain relief than general anaesthesia. However, significant concerns restrict the more widespread use of spinal anaesthesia for day-case procedures: the risk of PDPH (post dural puncture headache); the effect on bladder function; and delay in recovery of motor function. *Methodology:* This study was conducted on 60 patients between the age group of 18 to 60 years, of either sex, belonging to ASA grade I & II who were posted for elective lower abdominal, urological surgeries under spinal anesthesia .Only those patients were selected for the study from whom informed consent was obtained. *Results:* The time taken to achieve maximum sensory block in DB group was 5.20 minutes compared to 6.07 of PB group. In this regard the DB group is faster than PB group and this difference in attaining sensory block was statistically significant.The time taken to achieve maximum motor block in DB group was 5.57 minutes compared to 6.23 of PB group. In this regard the DB group is faster than PB group and this difference in attaining motor block was statistically significant. *Conclusion:* DB group is faster than PB group and this difference in attaining motor block was statistically significant.

Keywords: Dexmedetomidine; Bupivacaine; Placebo.

Introduction

The International Association for the Study of Pain (IASP) define pain as 'an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage', which indicates that, in the conventional sense, pain is caused by noxious stimuli, but may also be experienced in the absence of such stimuli.[1]

Anesthesia means "loss of sensation". Anesthesia can be general, regional or local. Lower abdominal surgeries can be performed under regional (spinal or epidural) or general anesthesia.

Spinal anesthesia is still the first choice. Spinal anesthesia, defined, as 'the regional anesthesia obtained by blocking nerves in the subarachnoid space' is a popular and common technique used worldwide. The advantages of an awake patient, simple to perform, offers rapid onset of action, minimal drug cost, relatively less side effects and rapid patient turnover has made this the choice of many a surgical procedure [2].

History of spinal anaesthesia may give the impression that it is a simple technique with little sophistication. However, much has been learned recently regarding the anatomy, physiology, pharmacology, and applications of spinal anaesthesia.

Spinal anaesthesia represents an attractive proposition for day-case anaesthesia, being associated with less postoperative nausea and vomiting (PONV) and better postoperative pain relief

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than general anaesthesia. However, significant concerns restrict the more widespread use of spinal anaesthesia for day-case procedures: the risk of PDPH (post dural puncture headache); the effect on bladder function; and delay in recovery of motor function [3]. The use of smaller, a traumatic spinal needles has greatly reduced the incidence of PDPH and the incidence has not been shown to increase when spinal anesthesia is used in the day-case setting.

Complete recovery of motor block after spinal anesthesia is required before discharge. The ability to flex the ankle, knee and hip joints is usually taken as a sign of complete regression of motor block, but it must be stressed that functional balance may remain impaired for longer so that a controlled assessment of independent ambulation is also necessary before discharge [4].

Therefore, both the drug and dose used for day-case spinal anesthesia must be chosen carefully to allow successful ambulation, but maintain block efficacy.

Hyperbaric bupivacaine 0.5% is the most commonly used anesthetic for spinal anesthesia and bupivacaine is three to four times more potent than lignocaine. Though bupivacaine has a long duration of action, it is not enough to produce prolonged post-op analgesia. Hence a number of adjuvant drugs have been tried & studied to prolong the analgesic effect of hyperbaric bupivacaine [5].

Bupivacaine is more commonly used for spinal anesthesia Although hyperbaric local anesthetic solutions have a remarkable record of safety, their use is not totally without risks. To prevent unilateral or saddle blocks, patients should move from the lateral or sitting position rapidly and after mobilization of the patients, extension or early return of the block may be seen. Hyperbaric solutions may cause sudden cardiac arrest after spinal anesthesia because of the extension of the sympathetic block [6].

The addition of low doses of opioids to local anesthetics during spinal anesthesia decreases the incidence of local anesthetic related side-effects, reduces the time of onset of the anesthetic effect, and increases the quality of intra- and post-operative analgesia by reducing the administered dose of the local anesthetic. Spinal adjuvants are extensively being researched to enhance sensory blockade and analgesia effects.

The most commonly used adjuvants were opioids (such as morphine, fentanyl & sufentanil), morphine was the first opioid administered intrathecally to augment neuraxial blocks. The addition of fentanyl to bupivacaine improves the quality of intraoperative and early post operativesubarachanoid block but the addition of opioids does have its own disadvantages, such as pruritus, respiratory depression and urinary retention. Other drugs like midazolam, neostigmine, ketamine, were used but because of the adverse effects like vomiting, hallucinations & bradycardia, a search for a better adjuvant was initiated and during that period alpha -2 adrenergic receptor agonist such as clonidine and dexmedetomidine came into existence.

Alpha (α)-2-adrenergic receptor agonists have been utilized in a host of clinical scenarios secondary to the hemodynamic-stabilizing properties, sedative, analgesic, and sympatholytic effects of the agent. Commonly used Alpha (α)-2-adrenergic receptor agonists are clonidine anddexmedetomidine. Clonidine is added to hyperbaric bupivacaine in spinal anesthesia. Doses of 15-45 μg intrathecal clonidine prolongs the duration of sensory analgesia. Side effects such as hypotension have restricted its more extensive use.

Dexmedetomidine is a selective Alpha (α)-2-adrenergic receptor agonist with evidence of an increased ratio of α2-to-α1 activity of 1620:1, as compared to 220:1 of clonidine. Dexmedetomidine possesses analgesic, sedative and anxiolytic properties and it lacks respiratory depression, and that makes it useful and a safe adjunct in many diverse clinical applications. The hypnotic and sedative actions of dexmedetomidine are thought to be mediated primarily by postsynaptic α2- adrenergic receptors and the effects differ depending on receptor in the Locus Ceruleus, the stimulation of this receptor provides sedation [7].

While clonidine as an adjunct has been well documented and tried, not many studies of intrathecaldexmedetomidine have been documented. Hence, we have chosen this study to evaluate the effects of adding dexmedetomidine with intrathecal hyperbaric bupivacaine (0.5%) in patients scheduled for lower abdominal surgeries.

Methodology

This study was conducted on 60 patients between the age group of 18 to 60 years, of either sex, belonging to ASA grade I & II who were posted for elective lower abdominal, urological surgeries under spinal anesthesia. Only those patients were selected for the study from whom informed consent was obtained. The study was conducted at Dr. B.R. Ambedkar Medical college & hospital after approval from the

hospital ethical committee. The duration of the study was from 1st October 2013 till august 31st 2015.

60 patients selected for this study were randomly divided into two groups;

Each group comprised of 30 patients each.

Group DB (Study group)	0.5% hyperbaric bupivacaine 3ml (15mg) + Dexmedetomidine 5µg (0.5ml), total volume 3.5ml
Group PB (PLACEBO group)	0.5% hyperbaric bupivacaine 3ml(15mg) + Sterile saline 0.5ml, total volume 3.5ml

Inclusion Criteria

- Adults aged between 18-60 years
- Patients belonging to ASA grade I & II
- Patients giving valid informed consent
- Patients posted for elective lower abdominal, urological surgeries under spinal anesthesia
- Patients of either sex

Exclusion Criteria

- Patients belonging to ASA grade III & IV
- Patients with history of cardio-respiratory, hepatic and renal disorders
- Patients with history of convulsions & neurological deficits
- Pregnant women.
- Patients with severe anemia, hypovolemia, septicemia and shock.
- Patients with psychiatric illness.
- Patients with bleeding disorders, coagulopathies or on anticoagulant therapy.
- Local infection at site of proposed puncture for spinal anesthesia.
- Patients with raised ICT, spinal deformities, head injuries.

Results

In DB group, the proportion of male was 40% and female was 60%.

In PB group, the proportion of male was 30% and female was 70%.

The difference in gender distribution between two groups is not statistically significant.

In DB group, the most common procedure was A (33.3%) followed by TAH (26.7%),BAT (23.3%) and IH (16.7%).

In PB group, the most common procedure was TAH (46.7%) followed by A & IH (20% each), and BAT (13.3%).

Table 1: Distribution based on Gender

Gender	Group- DB		Group-PB		Total
	N	%	N	%	
Male	12	40%	09	30%	21 (35%)
Female	18	60%	21	70%	39 (65%)
Total	30	100%	30	100%	60 (100%)
Chi square value - 0.65			df-1		p value-0.40

Table 2: Distribution based on procedure

Procedure	Group- DB		Group-PB		Total
	N	%	N	%	
A	10	33.3%	06	20.0%	16 (26.7%)
BAT	07	23.3%	04	13.3%	11 (18.3%)
IH	05	16.7%	06	20.0%	11 (18.3%)
TAH	08	26.7%	14	46.7%	22 (36.7%)
Total	30	100%	30	100%	60 (100%)
Chi square value – 3.54			df-3		p value-0.31

Table 3: Onset of sensory and motor block (in minutes)

Parameters	Group- DB		Group-PB		P value*
	Mean	SD	Mean	SD	
Sensory block onset	1.23	0.43	2.27	0.45	0.001
Motor block onset	1.30	0.46	3.43	0.62	0.001
*Independent T test					

The difference in gender distribution between two groups is not statistically significant.

The mean time for onset of sensory block in group DB was 1.23±0.43 minutes and in group PB it was 2.27±0.45 Minutes. The onset of sensory block in groups DB was faster compared to group B and highly significant with P value 0.001.

The mean time for onset of motor block in group DB was 1.30±0.46minutes and in group PB was 3.43±0.62minutes There was statistically highly significant difference with regard to onset of motor block between two group (P <0.001).

The time taken to achieve maximum sensory block in DB group was 5.20 minutes compared to 6.07 of PB group. In this regard the DB group is faster than PB group and this difference in attaining sensory block was statistically significant.

The time taken to achieve maximum motor block in DB group was 5.57 minutes compared to 6.23 of PB group. In this regard the DB group is faster than PB group and this difference in attaining motor block was statistically significant.

In this study, in group DB, 80% of patients attained maximum sensory block of T4 level, 13.3% attained T6 level and 6.7% attained T5 level.

Whereas in group PB, 63.3% of patients achieved T6level followed by 13.3% at T4 level, 13.3% at T8 level, 6.7% at T7 level and 3.3% at T5 level

This difference is statistically significant.

The time of two segment regression was considerably slower in group DB with 136.3 min compared to group PB which was 77.8 min. The difference was statistically significant.

The mean duration of sensory recovery (time for complete sensory recovery) in group D was 403 min and in group B was 194.6.

The mean duration of motor recovery in group D was 313.3 min and in group B was 171.3mim.

Table 4: Time for maximum sensory and motor block (in minutes)

Parameters	Group- DB		Group-PB		P value*
	Mean	SD	Mean	SD	
Max.Sensory block	5.20	0.71	6.07	1.11	0.001
Max.Motor block	5.57	0.85	6.23	1.13	0.003

*Independent T test

Table 5: Levels of Maximum sensory blockade

Levels	Group- DB		Group-PB		Total
	N	%	N	%	
T4	24	80.0%	04	13.3%	28 (46.7%)
T5	02	6.7%	01	03.3%	03 (05.0%)
T6	04	13.3%	19	63.3%	23 (38.3%)
T7	00	00	02	06.7%	02 (03.3%)
T8	00	00	04	13.3%	04 (06.7%)
Total	30	100%	30	100%	60 (100%)

Chi square value – 30.40 df-4 p value-0.001

Table 6: Recovery parameters (in minutes)

Parameters	Group- DB		Group-PB		P value*
	Mean	SD	Mean	SD	
Two segment regression	136.3	12.2	77.8	10.7	0.01
Sensory recovery	403.1	30.9	194.6	15.6	0.001
Motor recovery	313.3	37.4	171.3	15.2	0.001

*Independent T test

Table 7: Duration of analgesia (in Minutes)

Parameter	Group- DB		Group-PB		P value*
	Mean	SD	Mean	SD	
Duration of analgesis	373.6	34.4	188.3	14.4	0.01

*Independent T test

There was statistically significant difference in duration of motor and sensory recovery.

In DB group, the mean duration of analgesia was 373.6 minutes and in PB group, it was 188.3 minutes. This difference is statistically significant.

Discussion

In the present study, the mean time for onset of sensory block in group DB was 1.23±0.43 minutes and in group PB it was 2.27±0.45 Minutes. The onset of sensory block in groups DB was faster compared to group B and highly significant with P value 0.001.

The mean time for onset of motor block in group DB was 1.30±0.46 minutes and in group PB was 3.43±0.62 minutes There was statistically highly significant difference with regard to onset of motor block between two group (P <0.001).

Al-Mustafa et al [8] In their comparative study on 66 patients with different doses of dexmedetomidine (D5) 3 µg and 10 µg (D10) with hyperbaric bupivacaine in spinal anesthesia and compared the results with control. They concluded that onset of sensory and motor blockade faster in dexmedetomidine group when compared to control group.

Sherif A Abdelhamid et al [9] A double blinded randomized controlled study conducted in 62 patients with dexmedetomidine (5µg) with hyperbaric bupivacaine and compared the result with control (P) group. They concluded that onset of sensory and motor blockade faster in dexmedetomidine group.

Deepika Shukla et al [10] A prospective double blind study to evaluate onset and duration of sensory and motor block with intrthecaldexmedetomidinc and magnesium sulphate. They concluded that onset time of both sensory and motor block was rapid indexmedetomidine group Our results correlates with the above mentioned study. Hence we concluded that addition of dexmedetomidine has faster onset of sensory and motor blockade.

In this study, in group DB, 80% of patients attained maximum sensory block of T4 level, 13.3% attained T6 level and 6.7% attained T5 level.

Whereas in group PB, 63.3% of patients achieved T6 level followed by 13.3% at T4 level, 13.3% at T8 level, 6.7% at T7 level and 3.3% at T5 level.

Rajni Gupta et al [11] conducted a study on 60 patients to evaluate the effect between dexmedetomidine and fentanyl as intratehcal adjuvant to bupivacaine In their study they concluded that dexmedetomidine group patient had higher sensory level of T5 compared to T8 in control group.

From the above results we conclude that addition of dexmedetomidineintrathecally to hyperbaric bupivacaine results in higher level of sensory blockade and faster onset when compared to bupivacaine.

In our study, the mean duration of sensory recovery (time for complete sensory recovery) in group D was 403 min and in group B was 194.6.

The mean duration of motor recovery in group D was 313.3 min and in group B was 171.3mim.

Al-Mustafa et al [8] Their study concluded that sensory recovery in group D was 277 min and group B was 165 mm. The motor blockade in group D 246 min and group B was 140 min. They concluded significantly prolonged motor and sensory blockade in group D patient. GE. Kanaziet al [7] In their study, they concluded that sensory recovery time in group D patient was 303±75 min and 190±48 in group B. The motor recovery time in group D was 250±76 min and 163±47 min in group B showed significantly prolonged motor and sensory blockade in dexmedetomidine group. Hala EA Eid et al [12] concluded that sensory recovery time in group D 320 min and 238 min in group B.

Rampal Singh et al [13] prospective randomize, single blind trial carried in 90 patient to evaluate effect of intrathecal dexmedetomidine (D group) and clonidine (C group). They showed duration of sensory blockade was 404 min group D and 210 group B. The duration of motor blockade 309 min and 172 min group B.

They concluded that intrathecal dexmedetomidine significantly prolongs motor and sensory blockade.The prolongation of sensory and motor blockade in our study was comparable with studies by Al-Mustafa et al, GE Kanazi et al and Hala-EA Eid et al So, we conclude intrathecal dexmedetomidine 5 µg along with bupivacaine significantly prolonged sensory and motor blockade.

Conclusion

- There was statistically significant difference in duration of motor and sensory recovery with group DB attaining full motor and sensory recovery at a much later time than group PB.
- DB group is faster than PB group and this

difference in attaining sensory block was statistically significant.

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