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Original Research Article

Comparative study of 0.5% bupivacaine (Heavy) and 0.5% bupivacaine (Heavy) with dexmedetomidine for subarachnoid block in lower limb and lower abdominal surgeries

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Abstract

Background:

Spinal anaesthesia remains one of the basic techniques despite the waxing and waning of its popularity over last 100 years since its introduction various agents have been used with local anaesthetics in spinal anaesthesia to improve the quality of block and to provide prolonged postoperative analgesia.

AIM: In the present study, we tried to study effectiveness of intrathecal 0.5% bupivacaine (heavy) alone and with Dexmedetomidine as an adjuvant for lower limb and lower abdominal surgeries**.**

Material and Methods: The study was conducted in the department of anaesthesiology, KIMS, Narketpally during Oct 2021 to Sep2022.This study was a prospective, randomised controlled, single blind, study conducted in 60 patients of ASA grade I and II undergoing elective surgeries. The patients were divided by random number table into two groups, containing 30 patients in each group. Dosages of drugs selected are divided as Group B: Patients received 3 ml of 0.5% hyperbaric bupivacaine (15mg) and Group BD: Patients received 3 ml of 0.5% hyperbaric bupivacaine (15mg) plus 5 µg Dexmedetomidine. Spinal block characteristics, haemodynamics and side effects were observed.

Results: It was found that in Dexmedetomidine group time to reach T10 sensory blockade and complete motor blockade and was earlier and a higher and prolonged when compared to the control group. Haemodynamic parameters were preserved both intra-operatively and postoperatively. There were a small percentage of patients who had minor side effects.

Conclusion: Intrathecal low dose Dexmedetomidine in a dose of 5µg along with 0.5% hyperbaric bupivacaine given intrathecally prolongs significantly the duration of sensory and motor blockade

Keywords: Dexmedetomidine, hyperbaric bupivacaine, spinal anaesthesia, lower abdominal and lower limb surgeries

Introduction

Regional anaesthesia is the preferred technique for most of lower abdominal and lower limb surgeries. Spinal anaesthesia with cocaine was initially produced inadvertently by J Leonard

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Corning in 1885 and first used deliberately by August Bier in 1898 [1].
Spinal anaesthesia is one of the most common approaches for most of lower limb and lower abdominal surgeries. It is easy to administer, has rapid onset of action and avoids problem associated with airway management. Hyperbaric Bupivacaine 0.5% is extensively used for spinal anaesthesia as intrathecal local anaesthetic. Its spinal analgesic effect lasts for 120-150 minutes. Intrathecal local anaesthetic when used alone is associated with relatively short duration and early analgesic intervention is needed in the postoperative period.
The discovery of opioid receptors and endorphins in spinal and supraspinal regions soon led to the use of spinal opiates. Morphine was the first opioid administered intrathecally to augment neuraxial blocks [2]. Central neuraxial opioids, intrathecal as well as epidural, offer the benefit of analgesia but however the related side effects include sense of dizziness, nausea, vomiting, pruritus, urinary retention and even cases of respiratory depression have been reported [3, 4] and activation of herpes labialis [5] are other side effects.
In order to extend intraoperative analgesia into postoperative period a number of spinal adjuvants have been added to intrathecal bupivacaine; one of which is Dexmedetomidine. It is a new alpha 2-agonist that received FDA approval in 1999 for use as a short-term sedative and analgesic in the intensive care unit [6, 7]. Dexmedetomidine possesses anxiolytic, sedative, analgesic and sympatholytic properties. Sedation and anxiolysis are produced by binding to alpha 2 receptors in the locus coeruleus, which diminishes the release of norepinephrine and inhibits sympathetic activity, thus decreasing heart rate and blood pressure [7]. Systemic and intrathecal injection of dexmedetomidine produces analgesia by acting on laminae VII and VIll of the ventral horns of the spinal cord [8]. Dexmedetomidine as an adjuvant to bupivacaine intrathecally provides stable haemodynamic conditions, good quality of intraoperative and prolonged postoperative analgesia with minimal side effects [5, 6, 9].
Like clonidine it is also used for premedication to attenuate the stress induced sympathoadrenal response to laryngoscopy, intubation and surgery and to provide increased haemodynamic stability [10].
Therefore, the present study was designed to evaluate the effects of dexmedetomidine as an adjuvant to 0.5% bupivacaine (heavy), given intrathecally.

Material and Methods

After institutional ethics committee approval, sixty patients of American Society of Anaesthesiologists (ASA) physical status I or II, either sex, aged between 20-60 years, scheduled for elective lower limb and lower abdominal surgeries were included in this prospective controlled study during the period 01 Oct 21 to 30 Sep 22. An informed written consent was obtained from all the participants.

- Patients with neurological disorders, allergy to study drug, coagulation disorders, local infection at the site of injection, spine deformities, heart block/dysrhythmias', patients on adrenergic receptor antagonists, calcium channel blockers, ACE inhibitors, ASAIII and above, pregnancy were excluded.
- Preanesthetic Assessment was done at least one day prior to the surgery. Patients were evaluated for any systemic diseases and relevant laboratory investigations recorded. The procedure of SAB was explained to the patients and written consent was obtained. The patients were educated about the use of visual analogue scale.
- Preparation of patients included period of overnight fasting.
- Patients were premedicated with Tab.Rantidine150 mg and Tab. Alprazolam 0.5 mg the

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night before surgery.

Preparation of operating theatre

Anaesthesia workstation was checked as per protocol. Appropriate sized endotracheal tubes, working laryngoscope with medium and large size blades, stylet and working suction apparatus were kept ready before the procedure as per hospital standard operating procedure.

- Emergency drug tray consisting of atropine, adrenaline, phenylephrine, ephedrine and dopamine were kept ready.

Procedure

- Patients shifted to OR table, IV access was obtained on the forearm with No 18G IV cannula and all patients were given in j MIDAZOLAM 1 mg iv for anxiolysis and preloaded with 15ml/Kg, lactated Ringer s solution.
- Patients were allocated into the two groups as per computer generated random number table.
- Baseline vitals were recorded.
- Under strict asepsis, using 25 G Quincke spinal needle, lumbar puncture was performed at L_3-L_4 interspace in sitting position. Intrathecal injection was given over approximately 10-15 sec immediately after completion of injection patient were made to lie supine.

Group B received 3ml, 0.5% hyperbaric bupivacaine.
Group BD received 3ml, 0.5% hyperbaric bupivacaine + 5 µg Dexmedetomidine (vol. 0.5 ml) (dexmedetomidine 100µg/ml was diluted in preservative free normal saline).

- Intraoperatively patients were monitored with pulse oximetry, automated non-invasive blood pressure and electrocardiogram. SpO_2 were recorded, every 2 minutes for the first 10 minutes, every 10 minutes for the next 50 minutes and every 15 minutes till the end of surgery.
- Sensory block was tested with loss of pin prick sensation to 25G hypodermic needle and dermatomal levels were noted every 2 min until the highest level was stabilized in consecutive readings.
- Time of onset of T_{10} sensory block and time to reach highest sensory block was noted, Bromage 3 motor block was noted.
- Surgery was allowed when the sensory blockade level was T10 and above.
- Motor block was assessed with Modified Bromage scale [11].

Bromage 0: The patient is able to move the hip, knee and ankle.
Bromage 1: The patient is unable to move the hip but is able to move the knee and ankle.
Bromage 2: The patient is unable to move the hip and knee but able to move the ankle.
Bromage 3: The patient is unable to move the hip, knee and ankle.

- Modified Ramsay sedation scale [12] was used for intraoperative sedation scoring.

1 = Agitated, restless.
2 = Cooperative, tranquil.
3 = Responds to verbal commands while sleeping.
4 = Brisk response to glabellar tap or loud noise while sleeping.
5 = Sluggish response to glabellar tap or loud noise while sleeping.
6 = No response to glabellar tap or loud noise while sleeping.

- Following parameters were defined and recorded.

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Hypotension (> 20% fall of baseline blood pressure) was treated with bolus dose of 6 mg ephedrine i.v.
Bradycardia (pulse rate < 50 bpm), was treated with 0.6 mg atropine iv If SpO_2 less than 90%, oxygen was administered using Hudson's mask @ 2L/min.

- Sensory level testing was repeated every 10 min until 2 segment regression. Further testing was repeated every 20 min until time of return of pin prick sensation to S1 dermatomal area.
- Side effects such as nausea, vomiting shivering, hypotension, bradycardia, if any were noted. Post operatively regression of the sensory block and the motor blockade to reach modified Bromage 0 was noted. Two segment regression of the block was observed.
- Postoperatively Pain was assessed using "Visual Analogue Scale" (VAS) [13] advocated by Revell and Robinson in 1976. It is linear scale, consists of 10 cm line anchored at one end by a label such as "No pain" and other end by "Worst pain imaginable.
- Visual analogue scale [13] was used to assess post-operative pain.

0 = no pain, 10 = severe pain.

- Initially Every hour for the first 2 hours, then two hourly for next eight hours, followed by four hourly till 24 hours.
- Patient simply marks the line to indicate the pain intensity. Supplemental analgesia was given for visual analogue score of more than 6. Time of supplemental analgesia was noted.

Statistical Methods [14, 15]: Descriptive statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean ± SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5% level of significance.

- The following assumptions on data is made, Assumption: 1.Dependent variables should be normally distributed, 2.Samples drawn from the population should be random, Cases of the samples should be independent
- Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups.
- **Study design:** A Comparative two group randomized clinical study with 60 patients with 30 patients in Group B and 30 patients in Group BD(Dexmedetomidine) is undertaken to study the changes in hemodynamics and side effects.
- Statistical analysis was done by applying Chi-square test, A-nova test and student's 't' test to analyze the data, p value was determined.

$p>0.05$ is not significant $p<0.05$ is significant.
$p<0.001$ is highly significant.

Results

Table 1: Comparision of Demographics in Both Groups

	Group BD (n=30)	Group B (n=30)
Mean Age in Years	42.1±7.81	40.60±7.95
Mean weight in kilograms	57.6±8.98	58.27±8.94
Male	24(80.33%)	25(83.33%)
Female	6(20.67%)	5(16.67%)
155-164	18(60%)	16(53.33%)
165-174	12(40%)	14(46.64%)

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The mean age in the dexmedetomidine and control groups 42+/-7.81 and 40+/-7.95 years respectively,
The mean weight in the dexmedetomidine and control groups 57.6+/-8.98 and 58.27+/-8.94 kilograms respectively.
The total male patients in the dexmedetomidine and control groups is 24 and 25 respectively and female patients were 6 and 5 respectively.

Table 2: Comparision of Onset and Duration (Minutes) of Analgesia/Motor Blockade in Both the Groups

	Group BD	Group B	P Value
Time of Onset of Analgesia	2.18±0.1	2.4±0.2	$p<0.05$
Time of Onset of Motor Blockade	3.78±0.175	5.38±0.14	$p<0.05$
Time of 2 Sement Regression	126±7.25	86.7±9.5	$p<0.05$
Time of Duration of Motor Blockade	279±19.6	163.4±14.4	$p<0.05$
Duratrion of Analgesia	310.9±20.0	184.4±13.6	$p<0.05$

In the present study, mean duration of 2 segment regression in the dexmedetomidine and control groups is 129+/-7.25 and 86.7+/-9.5 minutes respectively. It is prolonged in dexmedetomidine group which is statistically significant ($p<0.05$).
In the present study, mean duration of analgesia in dexmedetomidine and control groups is 310+/-20 and 184+/-13.6 minutes, so duration of analgesia is more in dexmedetomidine group.

Table 3: Comparision of Maximum Height Wise Distribution of Sensory Blockade in Both the Groups

Maximum height of sensory BOCKADE (Segments)	Group BD	Group B
T4	3(10.0%)	1(3.33%)
T6	13(43.33%)	12(40%)
T8	11(36.66%)	15(50%)
T10	3(10.0%)	2(6.67%)
Mean of Max Height of Sensory Blockade	T6-T8	T6-T8

The maximum height of sensory blockade in dexmedetomidine group was (T6-T8) compared to (T6-T8) level in control group.

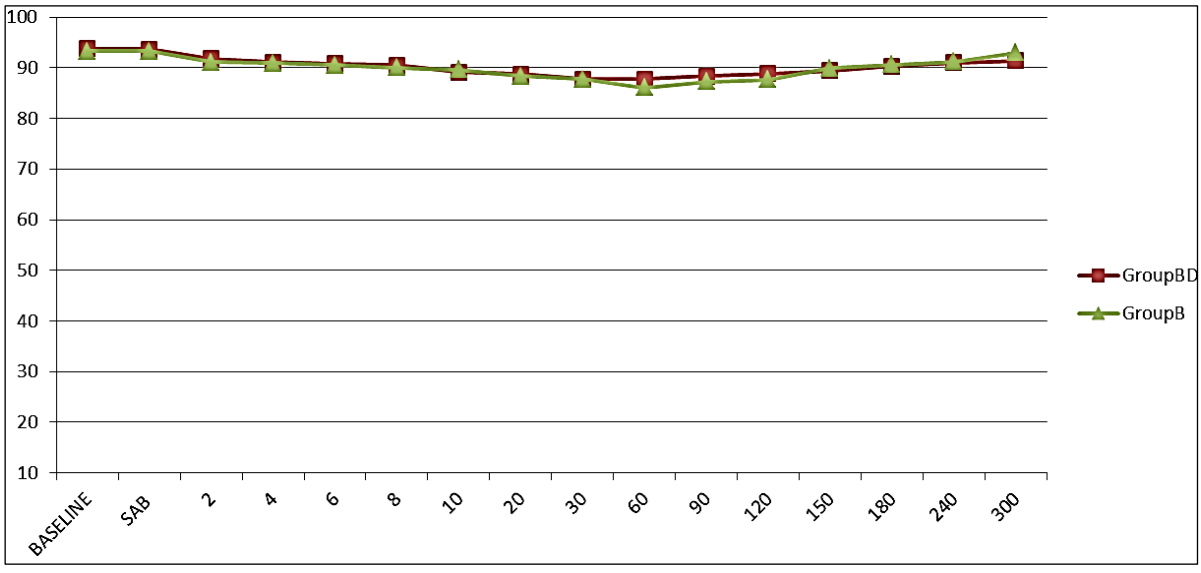

Fig 1: Comparision of Maximum Heart Rate in Both the Group

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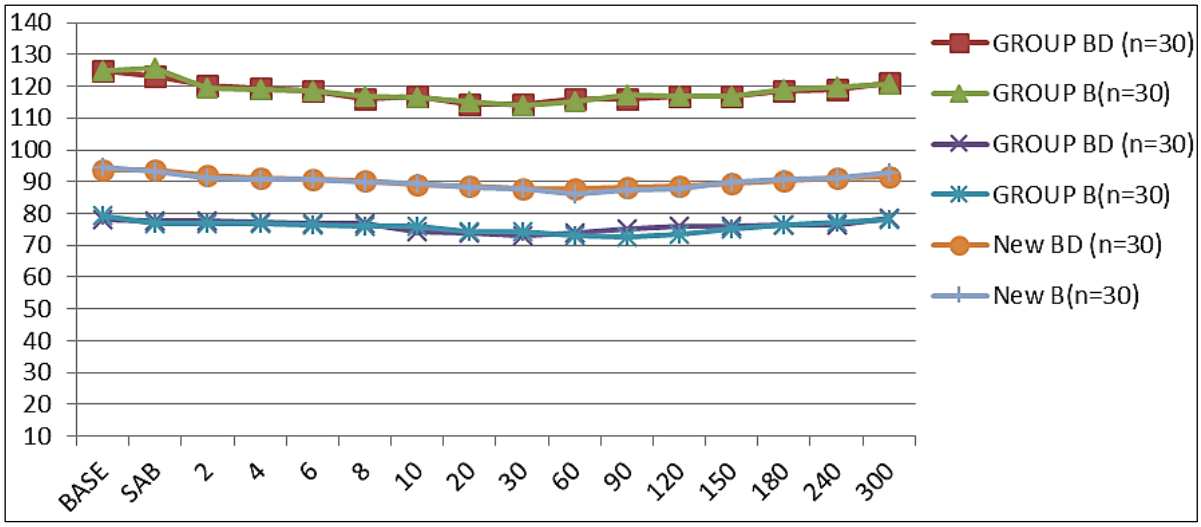

Fig 2: Comparision of Systolic and Diastolic Blood Pressure (mmHg) and Mean Arterial Pressure in Both the Groups

In the present study, the changes in the mean values of mean arterial pressure in both the groups, after administration of study drug are statistically not significant (<0.05) at various intervals of time.

Table 4: Comparision of Occurrence of Side effects in Both Cases

Complications	Group BD	GROUP B
Nausea	2(6.66%)	1(3.33%)
Sedation	1(3.33%)	0
Dry mouth	2(6.66%)	1(3.33%)
Bradycardia	4(13.3%)	1(3.33%)
Hypotension	5(16.66%)	3(10.33%)

In the present study, occurrence of complications like nausea is 2(6.66 percent) and 1 (3.33 percent) in case in control group, sedation is 1(3.33%) case in dexmedetomidine group, bradycardia is 4(13.33%) in dexmedetomidine group and one in case of control group (3.33%) and hypotension is 5(16.66%) cases in dexmedetomidine group and 3 (9.99%) in control group. ECG monitoring showed sinus bradycardia in 4 (13.33percent) in dexmedetomidine group and 1 (3.33percent) control group. There are no ST-T changes or dysrhythmias in ECG in any of the patients of the either group.

Discussion

Dexmedetomidine is anew highly selective ὰ-2agonist which can be used as a sedative and analgesic in intensive care Units [4]. Systemic and intrathecal injection of dexmedetomidine produces analgesia by acting at spinal level, laminae 7 and 8 of the ventral horns of the spinal cord. So in this context dexmedetomidine may be very useful drug along with the bupivacaine 0.5 percent heavy for spinal anaesthesia.

In the present study, mean duration of motor blockade in dexmedetomidine and control groups is (279+/-19.6 and 163.4+/-14.4) minutes respectively and it is statistically significant (p<0.05). The mean duration of motor blockade in the study by Kanazi GE *et al*. [16] (250+76 and 163+47 minutes) and in Singh R [17] (377.25‡11.32 and 18716.87 minutes) in dexmedetomidine and control groups respectively. Thus it is seen that mean duration of motor blockade is prolonged in dexmedetomidine group as compared to control group.

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Literature review does reveal number of RCTs have been conducted on similar lines. There is heterogenicity in time duration but all the authors have consistently observed prolonged effect and good safety profile on addition of adjuvant dexmedetomidine to local anaesthetic.

Table 5: Summary of results from individual studies [18]

Study	Year	Duration of Motor Blockade	Pain Free Period	Hypotension/ Bradycardia	Pruritus	Side effect
Qi *et al*. [19]	2016	146.31±40.72		0/3	0	15
Suresh and Prasad [20]	2016	407.53±18.91	231.93±17.83	5/9	0	6
Gupta *et al*. [21]	2011	421±21	251.7±30.69	3/1	0	1
Al-Ghanem *et al*. [22]	2009	240±64		4/2	0	2
Mahendru *et al*. [23]	2013	273.3±24.6	295.5±44.3	0/1	0	0

In present study, mean duration of motor blockade in dexmedetomidine group is 279.9+19.6 minutes.

The mean duration of motor blockade in the study by Qi *et al*. [17] (2016) (146.31 ± 40.72 minutes), Suresh and Prasad [18] 2016 (407.53±18.91 minutes), Gupta *et al*. [19] (2011) (421±21 minutes) Al-Ghanem *et al*. [20] (2009) (240±64 minutes) Mahendru *et al*. [21] (2013) (273.3±24.6 minutes) respectively. Thus there is homogeneity in prolongation of the duration of blockade by all the above authors.

Conclusion

Dexmedetomidine 5µg, used as adjuvant to 3ml of 0.5% bupivacaine (heavy) intrathecally for spinal anaesthesia prolongs the duration of sensory and motor blockade, as compared to control group. It is hemodynamically stable with insignificant side effects and faster onset of sensory and motor blockade. It is better alternative to opioids for prolonging spinal anaesthesia.

Conflict of Interest: None.

Funding Support: Nil.

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