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Comparison of intrathecal dexmedetomidine and intrathecal fentanyl as an adjuvant with hyperbaric bupivacaine for spinal anaesthesia in lower limb surgeries: A prospective randomized clinical trial

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ABSTRACT

Background and Aim: Subarachnoid block is the most common technique employed for lower limb surgeries. When used as an adjuvant to intrathecal local anaesthetic, both fentanyl and dexmedetomidine have the ability increase perioperative analgesia. This study aimed to compare and evaluate the effective profile of dexmedetomidine and fentanyl as an adjuvant to intrathecal bupivacaine in lower limb surgeries. Materials and Methods: In this clinical trial, 90 patients undergoing elective lower limb surgeries under spinal anaesthesia were randomly allocated to two groups. In group BD, the patients received 0.5% hyperbaric bupivacaine 12.5 mg + dexmedetomidine 5 mcg. In group BF, the patients received 0.5% hyperbaric bupivacaine 12.5 mg + fentanyl 25 mcg. Onset, duration, regression of sensory and motor blockade along with haemodynamic variations and side effects were compared between both the groups. **Results:** The onset of sensory block was earlier in Group BD, while the onset of motor block was earlier in Group BF. However, the differences with the onset of sensory and motor block remained statistically insignificant (P = 0.4988 and 0.4918). The mean time for two-segment sensory regression, time for regression to L1 dermatome and duration of motor block was significantly less in Group BF. The analgesic requirement in the early postoperative period and the haemodynamic variation remained statistically insignificant in both the groups.

Conclusion: Intrathecal dexmedetomidine provided prolonged sensory as well as motor blockade thereby enhancing postoperative analgesia.

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1. Introduction

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There are various anaesthetic modalities for the execution of lower limb surgeries; such as local infiltration, neuraxial blocks and general anaesthesia. Out of which, the neuraxial block is the most preferred technique. Spinal anaesthesia has the advantages of rapid onset, dense block, reducing stress responses, avoiding postoperative pulmonary complications, reducing chances of deep vein thrombosis in addition to being cost-effective. However, the limited duration of intrathecal local anaesthetics is a major concern, which necessitates the administration of post-operative analgesics. $^{1,2} \ \ \,$

Additions of various agents to intrathecally administered local anaesthetics have been proved to prolong the effective analgesic duration along with a reduction in systemic analgesia consumption and demands.³ Some of the agents used successfully as an adjuvant to intrathecal anaesthetics includes opioids, $\alpha 2$ agonists, vasoconstrictors, neostigmine, magnesium sulpate, etc.

 $\alpha 2$ agonists such as clonidine and dexmedetomidine act on presynaptic and postsynaptic $\alpha 2$ receptors.⁴ Dexmedetomidine offers anxiolysis, analgesia, sedation, neuroprotection, and anaesthetic-sparing profile. It is due to

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all these advantages, dexmedetomidine drastically enhance the analgesic duration in epidural block, spinal block and caudal block as well. $^{5-7}$

Fentanyl belongs to the class of synthetic opioids which has a central action. Intrathecal fentanyl not only lowers the dose requirement of local anaesthetics but also improves the overall analgesic property of the local anesthetic at the cost of minimal or insignificant side effects.⁸

In this study, we compared and evaluated the perioperative effective profile of dexmedetomidine and fentanyl as an adjuvant to intrathecally administered hyperbaric bupivacaine in patients posted electively for operative procedures of lower extremity under subarachnoid block.

2. Materials and Methods

This prospective double-blind, randomized study was conducted at orthopedic operation theatre of Mahatma Gandhi Medical College and Hospital, Jaipur, Rajasthan after due clearance and permission from institutional ethics committee. During the preanaesthetic evaluation, all the patients were elaborately informed about the study procedure along with the advantage, and the disadvantages and that they have the right to deny. Thereafter, consent for same was taken and those denying the consent were not included in the study.

Ninety patients aged 18-60 years belonging to the physical status class either I or II of American Society of Anaesthesiologists (ASA) and posted for elective lower extremity operative procedure under subarachnoid block were enrolled in the study. Exclusion criteria were patients with severe anemia, compromised cardiopulmonary status, haemodynamic instability, mental instability, and any obvious drug allergy. Similarly, unwilling, noncooperative patients and patients requiring emergency surgical procedures were not included in the study.

All the patients fulfilling the inclusion criteria were enrolled in the study and divided into two equal groups (Group BD and Group BF). The group assignment was done randomly with help of a computer-generated list. Allocation of specific group was done using a sealed opaque envelope to maintain better concealment of allocation sequence. The opaque sealed envelope was subsequently opened by an anaesthesiologist who although was responsible for preparation of the desired drug solution as per the randomization but, was not directly involved in the study process. The anaesthesiologist responsible for performing the block procedure and observing the study outcomes was blinded to the group treatment. Anaesthesiologist responsible for data collection was also unaware of the group allocation. Patients of group BD received combination of hyperbaric bupivacaine (0.5%) 12.5 mg and dexmedetomidine 5 mcg. Patients of group BF received combination of hyperbaric bupivacaine (0.5%) 12.5 mg and fentanyl 25 mcg.

All the patients were visited and evaluated thoroughly a day before the surgery. All the patients were prescribed oral alprazolam 0.5 mg for the night before surgery.

On the operative day, standard ASA monitoring including the 5 leads echocardiography, non-invasive blood pressure, and oxygen saturation with pulse oximetry were connected and baseline vital parameters were noted. Venous access was secured using an 18 G cannula on the dorsum of the limb opposite to that undergoing surgery. Using all aseptic precautions, patient was positioned in left lateral position and subarachnoid block was performed by lumbar puncture at L₃₋L₄ interspace level using a 25G standard spinal needle. The study drug was carefully administered into the intrathecally after aspiration of the free flow of clear cerebro-spinal fluid with the operating table being flat. Immediately after injection of the entire study drug, the patients were turned supplemental oxygen was provided to all the enrolled patients through a nasal cannula at 4 L/min.

Each patient was assessed at various predetermined timepoints for 3 hours post-spinal injection of test drugs for assessment of various outcome measures.

Evaluation of sensory and motor block was done at an interval of 5 min after block execution until half-hour and then every half hourly interval post completion of operative procedure or until the block had completely worn off.

2.1. Evaluation of sensory block with sensation to pin-prick on a 3-point scale was done

- 1. No block at all
- 2. Appreciation of loss of sensation to pin-prick
- 3. Complete absence of tactile sensation.
 - a. The onset of sensory block was marked from the end point of drug injection to attainment of sensory block characterized by appreciation of loss of sensation to pin-prick (grade 2).

b. The sensory block duration was marked from the interval between the appearance of a grade-2 block on pin-prick to the point to regression from complete grade-3 sensory block to grade-1 block on pin-prick. c. The analgesic duration was analyzed as the interval between the sensory block onset and the first analgesic dose administered to the patient.

2.2. Evaluation of motor block was done by using modified bromage scale:

- 1. Complete absence of paralysis
- 2. Difficulty to elevate the extended knee
- 3. Difficulty in knee flexion
- 4. Difficulty in ankle joint flexion.
 - a. The motor block onset was marked from the end point of drug injection to difficulty in ankle joint flexion (grade 3).

b. The motor block duration was marked from maximum motor block to point of complete movement of the knee and ankle joint.

A complete block was defined as grade-3 sensory block and motor block as well. Patients achieving complete block criteria were considered for further study. Patients with a sensory block of grade-1, 2 or motor block of grade-0, 1 and 2 were considered as block failure and were converted to general anaesthesia and hence were excluded from further analysis.

2.3. Evaluation of haemodynamic stability in terms of pulse rate, systolic blood pressure, and diastolic blood pressure

2.4. Evaluati

on of analgesic demands in the immediate postoperative period with the visual analogue scale (VAS) score.

Post-operative pain was analyzed using a visual analogue scale (VAS) (where, 0 denotes 'no pain' while, 10 denotes 'worst possible pain') for every hourly until the block worn off completely. Rescue analgesia was considered using diclofenac sodium 75 mg intramuscularly when VAS \geq 4.

2.5. Evaluation of complications in perioperative period (bradycardia, hypotension, respiratory depression, etc was also recorded

- 1. Bradycardia was defined as one-fifth decrease from the baseline value or an absolute heart rate <50 beats per min; which was treated by atropine 1 ml bolus intravenously.
- 2. Hypotension was defined as one-fifth decr_{ea}se from the baseline or an absolute mean blood pressure <60 mmHg; which was treated by administration of IV crystalloids (200 ml bolus) or incremental dosage of mephentermine 3 mg IV.
- 3. Respiratory depression was defined as SpO2 < 90% on room air; which was treated by the supplementation of oxygen through a nasal cannula at 4 L/min.
- 4. Shivering; which was treated by administration of IV tramadol 0.5 mg/kg.
- 5. Nausea and vomiting; was treated by administration of IV ondansetron 4 mg.

2.6. Statistical analyses

Assuming, a 30 min difference in prolongation of sensory analgesia with 90% study power along with type I error (α = 0.05) and type II error (β) at 0.1, the sample size of 43 patients in each group was obtained. For better evaluation of outcome measures we considered 45 patients in each group.

Statistical analysis was executed using SPSS, version 19.0 for Windows statistical software package (SPSS Inc,

Chicago, IL, USA). A chi-square test was applied for age, sex, and ASA grades. Unpaired t-test was considered for the remaining parameters of the demographic data, all the haemodynamic parameters, sensory/motor block onset and duration, and analgesic duration. P-value was considered significant if <0.05 and highly significant if <0.001.

3. Results

A total of ninety patients were enrolled in our study and none were excluded as shown in the consort chart [Figure 1]. Demographic data, hemodynamic parameters, sensory and motor block onset time, two-segmental sensory regression time, and average block and analgesic duration, and perioperative complications (intraoperative and postoperative) were evaluated for each patient. Demographic parameters were comparable among both the groups [Table 1].

The sensory block onset was comparatively faster in Group BD than Group BF ($6.95 \pm 1.82 \text{ min} \text{ vs. } 7.37 \pm 2.40 \text{ min}$), while the motor block onset was found to be earlier with Group BF in comparison to Group BD ($12.00 \pm 1.27 \text{ min} \text{ vs. } 12.04 \pm 1.79 \text{ min}$). However, the differences with the sensory and motor block onset remained statistically insignificant (P = 0.4988 and 0.4918) [Table 2].

The two-segmental sensory regression time and time for regression to L1 dermatome was significantly less in Group BF (75.80 \pm 8.56 min and 111.95 \pm 8.06 min) than Group BD (103.11 \pm 13.45 min and 129.91 \pm 10.45 min); (P<0.00001) [Table 2].

The motor block duration was increased in Group BF than Group BD (156.62 \pm 13.30 min vs.150.20 \pm 13.77 min), and this difference was also statistically insignificant (P =0.6660). The analgesic demand in the immediate postoperative period was statistically insignificant among both the groups (P = 0.0907) [Table 2].

The haemodynamic parameters were well preserved within the presumed range of significant variation, i.e., 20% from baseline throughout the surgery. Statistically insignificant difference were found in haemodynamic variables among both the groups at any time point [Tables 3, 4, 5 and 6].

The incidences of perioperative complications were higher in Group BD in comparison to Group BF; hypotension (17.7% vs. 11.1%), bradycardia (5.5% vs. 13.3%), shivering (11.1% vs. 8.8%) [Table 7]. Out of the total fourty five participants included in each study group, none had to be dropped off.

4. Discussion

In the current study, we compared and evaluated the perioperative effective profile of dexmedetomidine and fentanyl as an adjuvant to intrathecally administered hyperbaric bupivacaine in patients posted electively for

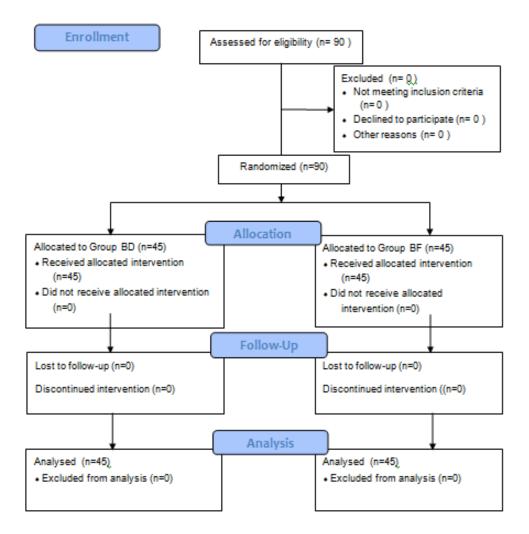


Fig. 1: Consort flow diagram

Table 1: D	istribution of	f demographic	data among the	studied groups

Description	Mea	n±SD	
Parameters	Group BD (n=45)	Group BF (n=45)	
Age (years)	.4±13.5	29.2±14.3	0.785*
Sex (%)			
Male	40	39	0.606*
Female	5	6	
Weight (kg)	68.8±7.4	66.2 ± 7.9	0.110#
Duration of surgery (min)	132±9.4	$134{\pm}10.6$	0.346#
ASA grade (%)			
I	32	31	0.606*
П	13	14	

*Chi-square test; [#]Unpaired t-test. n – Number ofpatients; SD – Standard deviation; ASA – American Society of Anesthesiologists

	Group BD			Group BF			Dit		
	Mean	SD	SE	Range	Mean	SD	SE	Range	P*
Onset of sensory block	6.95	1.82	0.27	4.0-12.0	7.37	2.4	0.35	4.0-12.0	0.498
Onset of motor block	12.04	1.79	0.26	9.0-17.0	12	1.27	0.19	9.0-15.0	0.491
Mean time for two segment sensory regression	103.11	13.45	2	75.0-135.0	75.8	8.56	1.27	60.0- 95.0	<0.00001
Mean time for regression to L1 dermatome	129.91	10.45	1.55	96.0-145.0	111.95	8.06	1.2	92.0- 128.0	< 0.00001
Duration of motor block	150.2	13.77	2.05	112.0- 174.0	156.62	13.3	1.98	109.0- 175.0	0.666

Table 2: Comparison of block outcomes in between the groups

*Unpaired t-test. SD - Standard deviation, SE -Standard error.

Table 3: Comparison of heart rate in different time interval in between groups

Heart Rate	Group BD		Group BF		P *
Heart Kate	Mean	SD	Mean	SD	F *
Baseline	73.2	5.2	74.3	5.4	0.327
Immediately after block	73.6	6.7	71.8	5.6	0.170
5 min after block	69.6	4.8	70.1	3.9	0.589
10 min	70.8	4.3	70.6	4.9	0.837
20 min	74.2	4.2	73.3	4.4	0.323
30 min	73	5.3	72.8	4.6	0.848
1 hour	73.4	5.8	71.2	4.9	0.055
At end of surgery	73.2	4.9	74.6	4.1	0.145

*Unpaired t-test. SD - Standard deviation

Table 4: Comparison of SBP indifferent time interval in between groups

	Group BD		Grou	D4	
	Mean	SD	Mean	SD	P *
Baseline	128.4	4.6	127	4.8	0.161
Immediately after block	124.3	6.9	125.1	4.9	0.527
5 min after block	119.9	5.4	120.5	5.8	0.612
10 min	122.6	5.6	123.4	5.2	0.484
20 min	128.4	4.9	125.9	9.5	0.120
30 min	128.7	6.2	126.8	6.5	0.159
1 hour	126.9	5.9	125.2	13.4	0.438
At end of surgery	125.4	6.1	126.3	5.9	0.478

*Unpaired t-test. SBP - Systolic blood pressure, SD - Standard deviation

Table 5: Comparison of DBP in different time interval in between groups

1		0 1			
DBP	Group BD		Group BF		Р*
DBP	Mean	SD	Mean	SD	P*
Baseline	82.4	7.8	84.8	7.2	0.132
Immediately after block	81.3	7.4	83.2	5.9	0.181
5 min after block	80.4	7.3	79.9	8.4	0.763
10 min	81.3	7.9	79.7	7.2	0.318
20 min	84.5	6.9	81.4	8.4	0.059
30 min	82.3	7.5	80.9	5.9	0.327
1 hour	81.6	5.9	79.8	6.1	0.158
At end of surgery	82.8	6.1	81.3	5.8	0.235

*Unpaired t-test. DBP - Dystolic blood pressure, SD - Standard deviation

Table 6: Comparison of MBP in different time interval in between groups	Table 6:	Comparison	of MBP in different	time interval	l in between groups
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MDD	Group BD		Group BF		P *
MBP	Mean	SD	Mean	SD	P*
Baseline	94.5	2.9	95.3	3.1	0.209
Immediately after block	93.8	3.8	95.2	3.2	0.062
5 min after block	96.4	3.7	95.8	3.9	0.456
10 min	94.4	3.4	93.2	4.2	0.139
20 min	93.5	3.6	94.2	4.1	0.391
30 min	92.7	3.8	91.9	3.9	0.327
1 hour	94.5	4.2	95.4	4.9	0.352
At end of surgery	93.7	4.1	92.8	4.4	0.318

*Unpaired t-test. MBP - Mean blood pressure, SD - Standard deviation

Table 7: Distribution of complications

	Group BD (n=45)	Group BF (n=45)
Intraoperative complications		
Hypotension	17.70%	11.11%
Bradycardia	15.50%	13.33%
Shivering	11.11%	8.89%
Itching	4.44%	8.89%
Nausea	11.11%	11.11%
Postoperative side effects		
Hypotension	6.67%	0.00%
Headache	6.67%	0.00%
Shivering	2.22%	2.22%
Nausea	2.22%	2.22%

operative procedures of lower extremity under subarachnoid block.

The time to sensory block onset was found to be compartively less in dexmedetomidine group. On the contrary, the time to motor block onset was found to be less in fentanyl group. However, the differences with both the sensory as well as motor block onset remained statistically insignificant between both the groups.

Mahendru et al.⁹ also found statistically insignificant difference in the motor block onset between dexmedetomidine and fentanyl groups. Various other studies have also reported a relatively rapid sensory block onset with dexmedetomidine.^{9–16} All these results were in conjunction with observations of our study. While Yektas et al.¹⁰ Ravipati et al.¹² reported rapid motor block onset with dexmedetomidine.

The exact mechanism behind property of dexmedetomidine in escalating both the sensory as well as motor block is not yet known. Selective $\alpha 2$ agonist activity of dexmedetomidine provides surplus analgesia by suppressing the release of transmitters of type C fiber and by causing hyperpolarization of the neurons postsynaptically.¹⁰

None of the patients required analgesics during the intraoperative period.

The mean time for two segments of sensory regression and regression to L1 dermatome was significantly longer when dexmedetomidine was used as an adjuvant instead of fentanyl to hyperbaric bupivacaine. While the opposite effect was seen with motor block duration being was higher with fentanyl instead of dexmedetomidine. Reduced requirement of postoperative analgesics with stable haemodynamic parameters along with significantly heightened sensory and motor block with dexmedetomidine have been reported in several other studies comparing dexmedetomidine with a variety of other drugs such as clonidine, fentanyl, and sufentanil.^{13,16–20} Various studies have claimed better results with dexmedetomidine in comparison to fentanyl especially in orthopedic operative cases of the lower extemity.^{9,10}

The haemodynamic parameters were found to be well maintained without any significant difference in both the groups. Similarly, other studies did not report any statistically significant difference between fentanyl and dexmedetomidine regarding haemodynamic status.^{9,10,12–15}

Bradycardia and hypotension are generally associated with opioid administration. The variation in haemodynamic parameters can be justified owing to the individual response to the drug, the injectate volume and diluent used. Side effects may occur with any anaesthesia medication but, the quality of the best medication is the highest efficacy with the lowest side effects. Although we observed increased incidences of hypotension and shivering with dexmedetomidine and bradycardia with fentanyl; but the ratio was minimal and insignificant.

To attain better effective profile, increment in dose of the dexmedetomidine can be attempted. Gupta et al.¹⁶ reported that dexmedetomidine dose increment from 2.5 mcg to 10 mcg offers superior quality of sensory as well as motor block at cost of minimal or no side effects.

5. Conclusion

In conclusion, addition of dexmedetomidine as an adjuvant to intrathecally administered hyperbaric bupivacaine offers a significantly heightened of sensory and motor block duration, and superior perioperative analgesia with utmost haemodynamic stability and minimal side effects.

6. Source of Funding

None.

7. Conflict of Interest

None.

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