Original Research

Comparative Evaluation of the Onset and Duration of Sensory and Motor Blockade with Intrathecal Fentanyl-Hyperbaric Bupivacaine versus Intrathecal Dexmedetomidine-Hyperbaric Bupivacaine: A Randomized Controlled Study

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Abstract

Background: Spinal anesthesia is a widely used technique for lower limb surgeries. The addition of adjuvants like fentanyl and dexmedetomidine to hyperbaric bupivacaine can enhance the quality and duration of analgesia. Objectives: This study aimed to compare the onset and duration of sensory and motor blockade, as well as postoperative analgesia, between intrathecal fentanyl-hyperbaric bupivacaine and intrathecal dexmedetomidine-hyperbaric bupivacaine in patients undergoing lower limb surgeries. Methods: This prospective, double-blind, randomized controlled study included 90 patients undergoing lower limb surgeries under spinal anesthesia. Patients were randomly allocated into three groups: BF (fentanyl-hyperbaric bupivacaine), BD (dexmedetomidine-hyperbaric bupivacaine), and BN (control group). The onset and duration of sensory and motor blockade, as well as postoperative analgesia, were assessed. Results: The results showed that the BD group had a faster onset of sensory block, lower VAS scores, and longer duration of sensory and motor block, as well as postoperative analgesia, compared to the BF and BN groups. Conclusion: Intrathecal dexmedetomidine-hyperbaric bupivacaine provides better analgesic efficacy and longer duration of analgesia compared to intrathecal fentanyl-hyperbaric bupivacaine in patients undergoing lower limb surgeries.

Keywords: Spinal anesthesia, Intrathecal Fentanyl, Intrathecal Dexmedetomidine, Hyperbaric Bupivacaine, Lower Limb Surgeries, Postoperative Analgesia.

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Introduction

Spinal anesthesia is the predominant method employed for lower limb procedures due to its cost-effectiveness and ease of administration. In addition to its cost-effectiveness and ease of administration, spinal anesthesia offers both pain relief and muscle relaxation, with a quick beginning of action. The subarachnoid blockade is the prevailing regional anesthetic approach utilized for lower limb surgery.

Local anaesthetic adjuvants enhance the painrelieving efficacy of local anaesthetics in a unique way. The range of local anesthetic adjuvants has developed throughout time, progressing from traditional opioids to a diverse selection of medicines that belong to different classes and have different methods of action.⁴ Several medications, such as opioids, $\alpha 2$ agonists, neostigmine, and vasoconstrictors, have been utilized as adjuvants in

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spinal anesthesia to extend the duration of analgesia during and after surgery. Clonidine and dexmedetomidine are two drugs that act as $\alpha 2$ agonists by targeting both pre- and post-synaptic $\alpha 2$ receptors.⁵

Dexmedetomidine, a novel $\alpha 2$ -agonist with great selectivity, is currently being assessed as a neuraxial adjuvant due to its ability to maintain stable hemodynamic circumstances, offer excellent intraoperative quality, and give long-lasting postoperative analgesia with minimal adverse effects. 6,7

Fentanyl is an opioid that acts as an agonist on lipophilic µ-receptors. It is an extremely powerful medication due to its strong affinity for fat. ^{8,9} Fentanyl exerts its effect intrathecally by binding to opioid receptors in the dorsal horn of the spinal cord. It may also have a spread and function outside the spinal cord.8 It is commonly used as an adjuvant in spinal anesthesia due to its fast onset and brief duration of action, while causing minimal dissemination to the cephalic region. ^{8,9}

Dexmedetomidine and fentanyl have been utilized as supplementary agents to local anesthetics in various surgical procedures in order to enhance pain relief and extend the duration of the anesthetic block. 10-12 Therefore, this study aims to assess and compare the impact of fentanyl and dexmedetomidine, when used as additional drugs to hyperbaric bupivacaine through intrathecal administration, on patients undergoing lower limb procedures.

Materials and Method

The present study was designed as a prospective, double-blind, randomized clinical trial, conducted in the Department of Anaesthesiology at Rama Medical College, Hapur, Uttar Pradesh. The study was carried over a period of 24 months, from June 2022 to June 2024. The study population comprised 90 patients who underwent lower limb surgeries under spinal anesthesia. Prior to the commencement of the study, ethical clearance was obtained from the Institutional Ethical Committee, and informed written consent was obtained from each patient.

Patients were eligible for inclusion if they were admitted to the hospital for elective lower limb surgeries under spinal anesthesia, were between 18 and 60 years old, and had an American Society of Anaesthesiologists (ASA) physical status of I or II. Patients of all genders were included. Conversely, patients were excluded from the study if they had a preoperative heart rate of less than 60 beats per minute or greater than 120 beats per minute, a preoperative systolic blood pressure of less than 100 mmHg, or an ASA physical status of III or IV. Additionally, patients with contraindications to spinal anesthesia, those who refused the procedure, or had skin infections at the site of blockade were

excluded. Patients with a history of allergy to local anesthetics or the study drugs, central or peripheral neuropathies, coagulopathies, significant cardiovascular, neurological, psychiatric, or neuromuscular disorders, bleeding disorders, or those on anticoagulant therapy were also excluded. Furthermore, surgeries extending beyond 120 minutes were not included in the study. In cases where the sensory block height was less than T10, the block was considered a failure, and the patient was excluded from the study.

A total sample size of 90 patients was recruited for the study, divided equally into three groups of 30 patients each using a 'slips in the box technique' into one of the following groups:

Group BF – Received intrathecal hyperbaric bupivacaine 12.5 mg (2.5 ml)

+ Fentanyl 25 μg (0.5 ml)

Group BD – Received intrathecal hyperbaric bupivacaine 12.5 mg (2.5 ml)

+ Dexmedetomidine 10μg (diluted to 0.5 ml normal saline)

Group BN – Receiving intrathecal hyperbaric bupivacaine 12.5 mg (2.5ml)

+ normal saline (0.5 ml).

Data collection involved selecting patients who met inclusion criteria and provided informed consent. Patients were familiarized with the Visual Analog Scale (VAS) for postoperative pain assessment and underwent preanesthetic evaluation, including vital sign monitoring and premedication with alprazolam. Spinal anesthesia was administered at L3-L4 intervertebral space using a 25G Quincke needle, with a total volume of 3ml study drug. Patients were then placed in a supine position. Intraoperative monitoring included pulse rate, respiratory rate, ECG, SpO2, and blood pressure.

The time of onset of sensory and motor block were monitored and total duration of sensory and motor block were noted in postoperative period in recovery the room

The duration of analgesia was defined as the period from spinal injection to the first rescue analgesia given in the postoperative period and first rescue analgesia given when visual analogue scale VAS >5. The rescue analgesia was given in the form of injection Tramadol (2mg/kg) IV infusion. Injection Paracetamol 1gm IV infusion was given to all study groups. Scale of 5 and the dose of administration was noted. All durations were calculated considering the time of spinal injection as time zero.

Data was analyzed using SPSS software, with categorical data represented as frequencies and proportions, and continuous data as mean and standard deviation. Statistical significance was set at p < 0.05. Analysis of variance (ANOVA) was used to compare the effects of intrathecal fentanyl and dexmedetomidine with hyperbaric bupivacaine.

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Results

Table 1: Age group wise distribution of study subjects among the groups

Age	BD Group		BF Gro	oup	BN Group				
Group									
(Years)	Frequency	Percent	Frequency	Percent	Frequency	Percent			
<20	1	3.3	2	6.7	7	23.3			
21-30	9	30.0	6	20.0	16	53.3			
31-40	8	26.7	7	23.3	2	6.7			
41-50	11	36.7	9	30.0	3	10.0			
51-60	1	3.3	6	20.0	2	6.7			
Total	30	100.0	30	100.0	30	100.0			
Chi square v	Chi square value-24.13; p value- 0.002*								

Table 1 shows age group wise distribution of study subjects among the groups results revealed that one subject of BD group 2 subjects of BF group and 7 subjects of BN group belonged to age <20 years, 9 subjects of BD group, 6 subjects of BF group, and 16 subjects of BN group belonged to age group of 21-30 years, 8 subjects of group BD, 7 subjects of group BF and 2 subjects of group BN belonged to age 31-40 years, 11 subjects of BD group, 9 subjects of BF group and 3 subjects of BN group belongs to 41-50 years and one subject of BD group, 6 subjects of BF group and 2 subjects of BN group belonged to age 51-60 years it shows statistically significant.

Table 2: Comparison of mean time of onset for block of study subjects among the groups at different time intervals

	Groups	Mean	Std. Deviation	F value	p value
	BF	6.78	0.44		
Time of onset of sensoryblock	BD	6.51	0.26		
	BN	6.58	0.20	5.701	0.005*
	BF	6.53	0.71		
Time of onset of motorblock	BD	7.43	1.19		
	BN	7.20	1.25	5.627	0.005*

Table 2 shows comparison of mean time of onset for block of study subjects among the groups at different time intervals results revealed that mean time of onset of sensory block was observed 6.78 minutes in BF group, 6.51 minutes in BD group and 6.58 minutes in BN group it shows statistically significant (P=0.005) (graph 5a). Mean time of onset of motor block was observed 6.53 minutes in BF group, 7.43 minutes in BD group and 7.20 minutes in BN group it shows statistically significant (P=0.005).

Table 3: Comparison of mean VAS scores of study subjects among the groups at different time intervals

	Groups	Mean	Std. Deviation	F value	p value
VAS score	BD	1.83	1.64		
	BF	3.3	1.39		
	BN	5.20	1.45	38.084	<0.001*

Table 3 shows comparison of mean VAS score which was observed 1.83 in BD group, 3.3 in BF group and 5. 20 in BN group it was statistically significant (P<0.001).

Table 4: Comparison of mean total duration of study subjects among the groups at different time intervals

	Groups	Mean	Std. Deviation	F value	p value
	BF	120.03	4.99		
	BD	166.20	13.26		
Sensory block	BN	116.63	4.09	317.36	<0.001*
	BF	199.03	15.64		
	BD	285.53	13.11		
Motor block	BN	160.33	6.16	1530.578	<0.001*

Table 4 shows comparison of mean total duration of study subjects among the groups at different time intervals results revealed that mean time of sensory block was found 120.03 minutes in BF group,166.20 minutes in BD group and 116.63 minutes in BN group it was statistically significant (P<0.001) (graph 7a).

Mean time of motor block was found 199.03 minutes in BF group, 285.53 minutes in BD group and 160.33 minutes in BN group it was statistically significant (P<0.001)

Table 5: Comparison of mean total duration of post op analgesia among the groups at different time intervals

	Groups	Mean	Std. Deviation	F value	p value
	BF	270.43	20.99		
	BD	386.73	25.51		
Post OP analgesia	BN	223.37	27.01	300.008	<0.001*

Table 5 shows comparison of mean total duration of post op analgesia among the groups at different time intervals results revealed that mean duration of post op analgesia was found 270.43 minutes in BF group, 386.73 minutes in BD group and 223.37 minutes in BN group it was found statistically significant (P<0.001).

Table 6: Distribution of study subjects among groups according toneed for rescue analgesia

Rescue analgesia	BD		BF		BN			
	Frequency	Percent	Frequency	Percent	Frequency	Percent		
No	26	86.7	24	80	10	33.3		
Yes	4	13.3	6	20	20	66.7		
Chi square value-22.8; p value- <0.001*								

Table 6 shows distribution of study subjects among groups according to need for rescue analgesia results revealed that rescue analgesia was needed in 4 subjects of BD group, 6 subjects of BF group and 20 subjects of BN group study participants it was found statistically significant (P<0.001).

Discussion

The present prospective, double-blind, randomized clinical trial compared the effects of intrathecal fentanyl and dexmedetomidine with hyperbaric bupivacaine on patients undergoing lower limb surgeries and found that dexmedetomidine (BD group) had a faster onset of sensory and motor block, lower VAS scores, and longer duration of sensory and motor block, as well as postoperative analgesia compared to fentanyl (BF group) and control (BN group) groups.

The male and female patients aged 18-60 years of American Society of Anesthesiologists (ASA physical status I and II) admitted in the hospital undergoing elective lower limb surgeries under spinal anesthesia were enrolled in the present study. The patients were divided into three groups with 30 patients in each group; in group BF, patients received intrathecal hyperbaric bupivacaine 12.5 mg (2.5 ml) + fentanyl 25 μg (0.5 ml); in group BD, patients received intrathecal hyperbaric bupivacaine 12.5 mg (2.5 ml) + dexmedetomidine 10 μg (diluted to 0.5 ml normal saline) and group BN patients received intrathecal hyperbaric bupivacaine 12.5 mg (2.5ml) + normal saline (0.5 ml).

In this study, it was discovered that the average time it took for the sensory block to occur was 6.78 minutes in the BF group, 6.51 minutes in the BD group, and 6.58 minutes in the BN group. The results demonstrate a statistically significant distinction (P=0.005). In the BF group, the average time it took for motor block to occur was 6.53 minutes. In the BD group, it was 7.43 minutes, and in the BN group, it was 7.20 minutes. The observed difference is statistically significant, as indicated by a p-value of 0.005. Patients who were administered dexmedetomidine had a faster onset of sensory

effects compared to those who received bupivacaine and fentanyl or bupivacaine and normal saline. The time it took for sensory effects to begin was 6.78±0.44 minutes in the bupivacaine and fentanyl group, 6.51±0.26 minutes in the bupivacaine and dexmedetomidine group, and 6.58±0.20 minutes in the bupivacaine and normal saline group. This difference was statistically significant. In a study conducted by Kanazi GE et al⁷, it was shown that a little amount of intrathecal dexmedetomidine to bupivacaine spinal block resulted in a faster onset of motor block and a longer duration of sensory and motor block compared to using bupivacaine alone. The administration of Dexmedetomidine at a dose of 3 µg and clonidine at a dose of 30 µg produces similar effects on the block's properties, without causing any notable changes in blood pressure or sedation levels. 9 Al-**Ghanem SM et al**⁶ conducted a study to investigate the effects of adding 5 µg dexmedetomidine or 25 ug fentanyl intrathecally to 10 mg isobaric bupivacaine in vaginal hysterectomy.

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The researchers discovered that administering 5 μg of dexmedetomidine resulted in a longer period of motor and sensory block as compared to administering 25 μg of fentanyl. Al-Mustafa MM et al¹³ did a study to investigate the effects of dexmedetomidine, administered at doses of 5 and 10 μg , in combination with bupivacaine, on urological procedures. The study demonstrated that dexmedetomidine had a dosage-dependent effect on prolonging the duration of spinal anesthesia. Kalbande JV et al¹⁴ found that patients who received dexmedetomidine experienced a quicker initiation of sensory effects (1.54 \pm 0.38 minutes), and this difference was statistically significant. The results of our study align with the findings of the

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investigations conducted by Khosravi F et al¹⁵ and Shukla D et al¹⁶, which also reported a shorter onset time for 5 µg dexmedetomidine. A study conducted by Gupta R et al¹ showed that adding 5 μg of dexmedetomidine to hyperbaric bupivacaine significantly prolongs the duration of both sensory and motor block. Injecting a small dose of dexmedetomidine (3µg) directly into the spinal canal, along with bupivacaine, has been shown to speed up the start of motor block and prolong the duration of both motor and sensory block in people. The average modified Ramsay and VAS scores of the study participants in each group at various time intervals indicated that the mean modified Ramsay score was 2.23 in group BD, 1.6 in BF group, and 1.00 in BN group. This difference was statistically significant (P<0.001) (graph 6a). The mean visual analog scale (VAS) score was 1.83 in the BD group, 3.3 in the BF group, and 5.20 in the BN group.

This difference was statistically significant (P<0.001). Fukushima K et al¹⁷ provided a dose of 2 μg/kg of epidural dexmedetomidine to alleviate postoperative pain in individuals. Nevertheless, the researchers did not detect any neurological deficits and chose not to incorporate this data into their analysis. In a similar study conducted by Mohamed **AA et al,** 18 it was observed that the average VAS score was consistently low across all groups. This aligns with the regulations of the Intensive Care Unit at the study hospital, which promote the goal of keeping the VAS score for post- surgery patients at or below 3. The levels of reduction were significantly diminished both immediately and 12 hours post-surgery in the group that received dexmedetomidine alone and the group that received dexmedetomidine in conjunction with fentanyl.

The mean duration of sensory block was 120.03±4.99 minutes in the BF group, 166.20 minutes in the BD group, and 116.63 minutes in the BN group. This difference was statistically significant (P<0.001). The mean duration of motor block was 199.03 minutes in the BF group, 285.53 minutes in the BD group, and 160.33 minutes in the BN group. This difference was statistically significant (P<0.001). The present study reported longer duration of sensory block and motor block in bupivacaine and dexmedetomidine group. In a study by Khan AL et al, there was no significant difference between the two groups in terms of the maximum level of sensory block attained. However, the percentage of patients who reached a T6 level of block was larger in the group that received dexmedetomidine supplementation (42.50%) compared to the group that received fentanyl supplementation (30%).

However, there was a notable disparity between the two groups in terms of the length of time the sensory block lasted. Group D had a duration of 129.50 minutes, while Group F had a duration of 77.50 minutes.

Additionally, the motor block lasted 377.25 minutes for Group D and 187.00 minutes for Group F, which is statistically significant. The analgesic efficacy of two medications was evaluated, with the group supplemented with dexmedetomidine demonstrating a considerably longer duration of blocks and analgesic effect compared to the group supplied with fentanyl.

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The mean total duration of postoperative analgesia was measured across different groups at various time intervals. The results showed thatthe mean duration of postoperative analgesia was 270.43 minutes in the BF group, 386.73 minutes in the BD group, and 223.37 minutes in the BN group. This difference was found to be statistically significant (P<0.001). Similar results are reported by **Gupta R** al¹, reported that both fentanyl dexmedetomidine effectively provided high-quality pain relief during surgery. The analgesia was more effective in group D than in group F, although the difference was not statistically significant. However, our study found statistically significant results. HA Eid et al¹⁹ studied the effects of dexmedetomidine on a dose related manner (control, 10 µ g and 15µ g)and confirmed the prolongation of **duration** of analgesia.

Rescue analgesia was required by 66.7% patients in only control group, 20% in bupivacaine with fentanyl and least 13.3% in bupivacaine with dexmedetomidine group with the difference being statistically significant (P<0.001). In a similar study conducted by Mohamed AA et al18, it was discovered that the period at which the first rescue analgesic was needed was substantially longer in the dexmedetomidine group (3.30 hours) and the dexmedetomidine +fentanyl group (5.41 hours) compared to the control group (0.233 \pm 0.11 hours). The average amount of intravenous tramadol consumed within the first 24 hours after surgery was significantly lower in the dexmedetomidine (142.85 \pm 13.04) and dexmedetomidine+ (131.25 \pm 11.96) groups, compared to the control group (310.00 \pm 12.08). However, there was no significant difference tramadol consumption between dexmedetomidine and dexmedetomidine+fentanyl groups. Khan AL et al²⁰ observed a greater percentage of patients in the dexmedetomidine group (17.5%) experienced bradycardia compared to the fentanyl augmented group (5%). Bupivacaine possesses a bradycardic action. Simpson RK et al²¹ also observed similar studies.

The mechanism may arise from an additive or synergistic impact resulting from the distinct modes of action of local anesthetics and $\alpha 2$ -adrenoceptor agonists.

The limitation of our study is that the sample size is small a hence larger sample size will establish further conclusive evidence.

Conclusion

To conclude, it was found that the dexmedetomidine (BD group) with hyperbaric bupivacaine on patients

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undergoing lower limb surgeries had a faster onset of sensory block, lower VAS scores, and longer duration of sensory and motor block, as well as postoperative analgesia compared to the intrathecal fentanyl (BF group) and control (BN) groups. Additionally, the need for rescue analgesia was significantly lower in the BD group. These findings suggest that intrathecal dexmedetomidine with hyperbaric bupivacaine provides better analgesic efficacy and longer duration of analgesia compared to intrathecal fentanyl with hyperbaric bupivacaine, making it a suitable option for lower limb surgeries.

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