National Board of Examinations - Journal of Medical Sciences
Volume 4, Issue 2, Pages 228–238, February 2026
DOI 10.61770/NBEJMS.2026.v04.i02.011

ORIGINAL ARTICLE

Comparative Study of Dexmedetomidine vs Fentanyl as Adjuvant to Intrathecal Bupivacaine in Infraumblical Surgeries

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Accepted: 22-January-2026 / Published Online: 3-February-2026

Abstract

Background: Spinal anaesthesia is widely used for infraumbilical and gynaecological surgeries, further the addition of intrathecal adjuvants improve the quality, duration of anaesthesia and analgesia. This prospective randomised controlled study was conducted to compare the efficacy and adverse effects of intrathecal dexmedetomidine and fentanyl as adjuvants to hyperbaric bupivacaine. **Aim:** To compare the efficacy and adverse effects of intrathecal dexmedetomidine and fentanyl as adjuvants to hyperbaric bupivacaine in patients undergoing infraumbilical surgeries. **Materials and Methods:** This prospective randomized controlled study included 60 patients scheduled for elective infraumbilical surgeries under spinal anaesthesia. Patients were randomly allocated into two groups. Group BD received 0.5% hyperbaric bupivacaine (13 mg) with dexmedetomidine 5 µg, while Group BF received 0.5% hyperbaric bupivacaine (13 mg) with fentanyl 25 µg intrathecally. The onset and duration of sensory and motor block, duration of postoperative analgesia, haemodynamic parameters, and adverse effects were evaluated. **Results:** The onset of sensory and motor block was comparable between the two groups. The duration of sensory block, motor block, and postoperative analgesia was significantly prolonged in the dexmedetomidine group compared to the fentanyl group ($p < 0.05$). Haemodynamic parameters remained stable in both groups. A higher incidence of hypotension and bradycardia was observed in the dexmedetomidine group, whereas pruritus and nausea were more common in the fentanyl group. No serious adverse effects were noted. **Conclusion:** Intrathecal dexmedetomidine is a safe and effective adjuvant to hyperbaric bupivacaine and provides significantly prolonged anaesthesia and postoperative analgesia compared to fentanyl. It may serve as a suitable alternative to intrathecal opioids for infraumbilical surgeries.

Keywords: Spinal anaesthesia, Infraumbilical surgeries, Intrathecal adjuvant, Dexmedetomidine, Fentanyl, Hyperbaric bupivacaine

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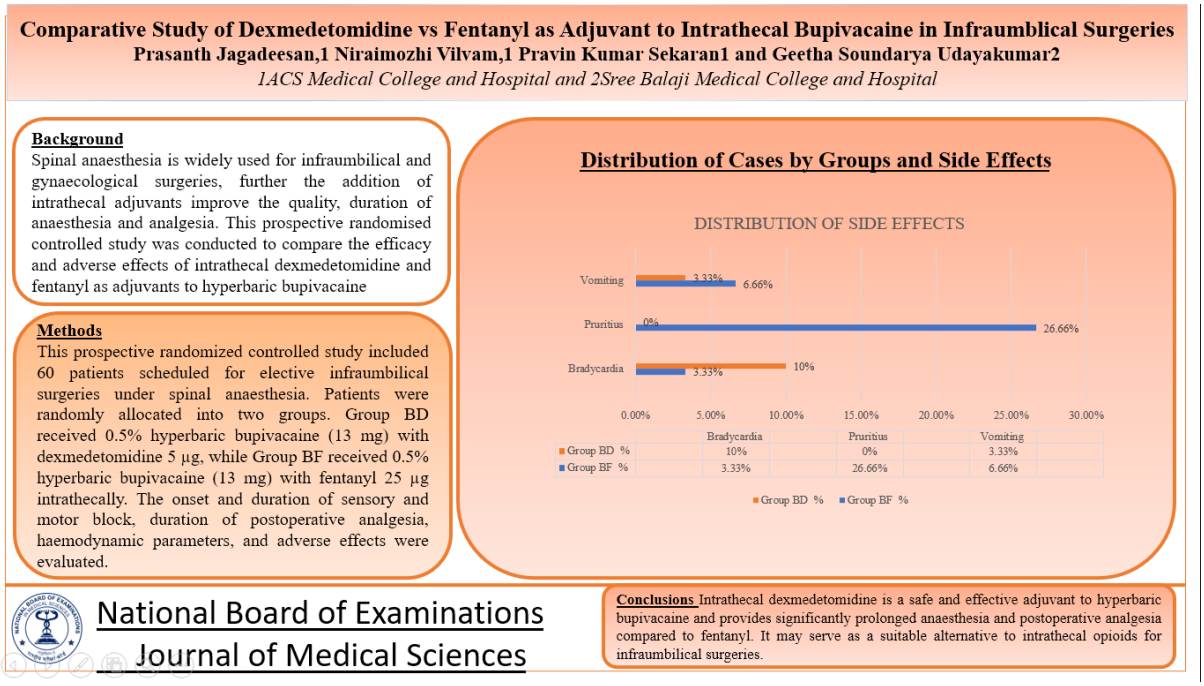
Graphical Abstract



Introduction

Spinal anaesthesia is widely employed for lower abdominal and lower extremity surgical procedures owing to its well-established advantages over general anaesthesia, including rapid onset, reliable sensory and motor blockade, reduced perioperative morbidity, and enhanced postoperative recovery. Commonly used local anaesthetic agents for spinal anaesthesia include lignocaine, bupivacaine, and ropivacaine [1]. To improve the quality and duration of neuraxial blockade, various adjuvants such as opioids and alpha-2 adrenergic agonists are frequently combined with local anaesthetics [2]. The rationale for using adjuvants is to achieve synergistic analgesic effects, thereby allowing dose reduction of individual agents while maintaining analgesic efficacy and minimise the adverse effects [3]. Surgical procedures involving the uterus and other pelvic organs performed under spinal or epidural anaesthesia are often associated with visceral pain, intraoperative discomfort, nausea, and vomiting [4]. Previous studies have demonstrated that the addition of intrathecal fentanyl to bupivacaine prolongs the duration of analgesia and reduces the incidence of intraoperative nausea and vomiting [5]. Dexmedetomidine, a highly selective alpha-2 adrenergic receptor agonist, is approved for intravenous use as a sedative and co-analgesic agent and has recently gained interest for intrathecal administration [6]. While most clinical studies on intrathecal alpha-2 adrenergic agonists have focused on clonidine, dexmedetomidine, due to its greater receptor selectivity, may provide enhanced analgesia with a favourable side-effect profile [7]. The present study aimed to evaluate and compare the efficacy and side-effect profile of intrathecal dexmedetomidine (5 µg) and intrathecal fentanyl (25 µg) when used as adjuvants to

bupivacaine in spinal anaesthesia for lower abdominal and gynaecological procedures.

Materials and Methods

This prospective, randomised controlled study was conducted following approval from the Institutional Ethics Committee, and written informed consent was obtained from all participants. A total of sixty patients classified as American Society of Anesthesiologists (ASA) physical status I or II, scheduled for elective infraumbilical surgery under subarachnoid block, were included in the study. The participants were randomly allocated into two equal groups of 30 patients each. Group BD received intrathecal 0.5% hyperbaric bupivacaine (2.8 ml) combined with dexmedetomidine 5 µg (0.5 ml), while Group BF received intrathecal 0.5% hyperbaric bupivacaine (2.8 ml) with fentanyl 25 µg (0.5 ml). The total intrathecal volume was standardised to 3.3 ml in both groups.

Inclusion Criteria

Patients aged 18 years and above scheduled for elective infraumbilical surgery under spinal anaesthesia

Patients belonging to American Society of Anesthesiologists (ASA) physical status I and II

Exclusion Criteria

History of hypersensitivity or allergy to any of the study drugs

Presence of renal or hepatic dysfunction
Coagulation disorders or bleeding diathesis

Statistical analysis

Study variables were summarised using descriptive statistical methods and displayed in two-way tables. Categorical data were presented as counts and percentages, whereas continuous data were expressed using measures of central tendency (mean and median) along with measures of variability (standard deviation and range). Associations between categorical variables were assessed using the chi-square test. For comparison of two independent groups, non-parametric tests such as the Mann–Whitney U test (Wilcoxon rank-sum test) were employed, and the Kruskal–Wallis H test was used for comparisons involving more than two groups where applicable. One-way analysis of variance (ANOVA) was applied for comparisons of continuous variables. Statistical significance was defined as a p-value less than 0.05.

Result

This prospective study included sixty (60) patients. The patients were randomly allocated into two groups. Group BF received 2.8 mL (13 mg) of 0.5% hyperbaric bupivacaine combined with 25 µg (0.5 mL) of fentanyl. Group BD received 2.8 mL (13 mg) of 0.5% hyperbaric bupivacaine combined with 5 µg (0.5 mL) of preservative-free dexmedetomidine. In both groups, the total intrathecal drug volume administered was 3.3 mL.

Onset of Sensory Block T10 Level

The onset time to achieve a sensory block up to the T10 dermatome after subarachnoid block, evaluated by loss of cold sensation using an alcohol swab, was 2.83 ± 0.53 minutes in Group BF and 2.67 ± 0.47 minutes in Group BD. The difference between the two groups was not statistically significant ($p = 0.207$) (Table 1).

Table 1. Distribution of Mean Onset of Sensory Block [T10] in Minutes by Groups

Parameters	Group BF	Group BD	'P' Value
No. of Cases	30	30	0.207
Mean	2.83	2.67	
S.D	0.531	0.479	

To reach sensory block T6 level

The time required to attain the maximum sensory block at the T6 dermatome after subarachnoid block, assessed by loss of cold sensation using an alcohol swab, was 4.80 ± 0.76 minutes in Group BF and 4.77 ± 0.68 minutes in Group BD. No statistically significant difference was observed between the two groups (p = 0.207) (Table 2).

Table 2. Distribution of Mean Sensory Block [T6] in Minutes by Groups

Parameters	Group BF	Group BD	'P' Value
No. of Cases	30	30	0.207
Mean	4.80	4.77	
S.D	0.761	0.679	

Time to reach Bromage Grade 3 motor block

Onset of motor block following subarachnoid block was evaluated using the Modified Bromage Scale. The mean time to achieve motor block was 6.63 ± 0.69 minutes in Group BF and 6.53 ± 0.62 minutes in Group BD, with no statistically significant difference between the groups (p = 0.623) (Figure 1)

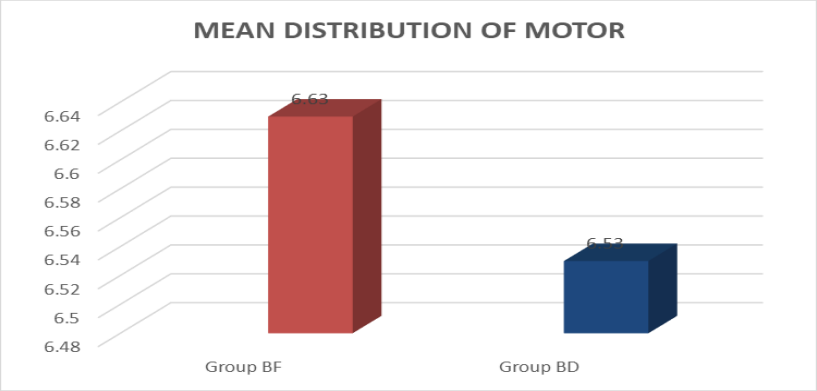


Figure 1. Distribution of Mean Time to Reach Motor Block [Bromage Grade 3] Minutes By Groups

Duration of sensory block

The mean time for regression of sensory block to the S1 dermatome was 358.97 ± 46.73 minutes in Group BF and 459.03 ± 56.9 minutes in Group BD. The difference in sensory block duration between the two groups was statistically significant ($p < 0.001$) (Figure 2).

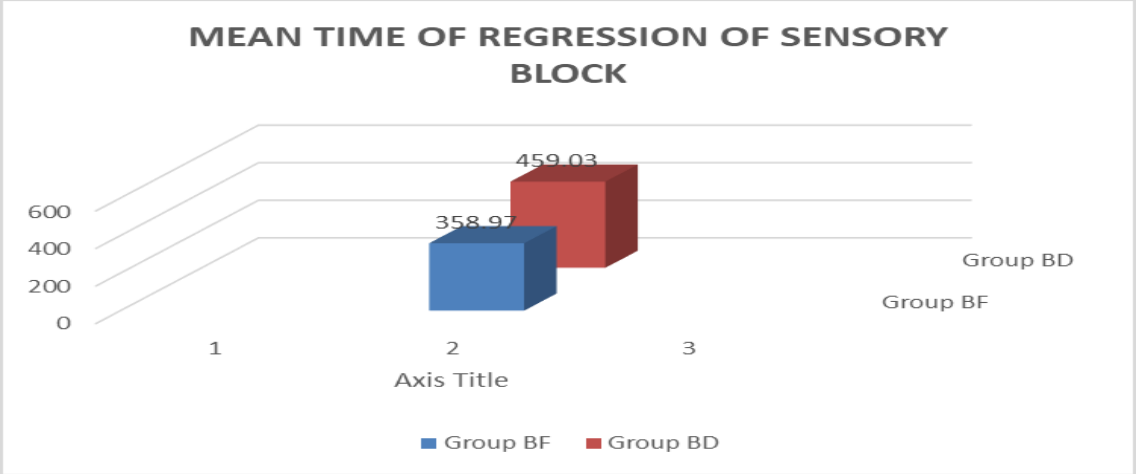


Figure 2. Distribution of Mean Time for Regression of Sensory Block [S1] In Minutes by Groups

Duration of motor block

The mean time for complete regression of motor block to a Modified Bromage score of 0 was 231.83 ± 39.96 minutes in Group BF and 288.63 ± 31.13 minutes in Group BD. This difference in motor block duration between the groups was statistically significant ($p < 0.001$) (Figure 3)

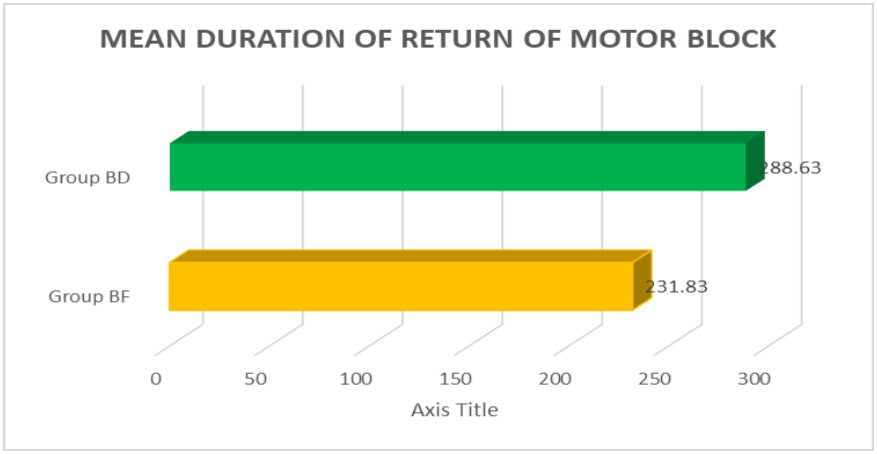


Figure 3. Distribution of Mean Time for Regression of Motor Blockade [Bromage 0] In Minutes by Groups

Duration of time for Rescue analgesia

The mean time to first request for analgesia (defined as the point at which the patient requested pain relief) was 212.67 ± 38.97 minutes in Group BF and 276.73 ± 49.32 minutes in Group BD. The difference between the groups was statistically significant ($p < 0.001$) (Figure 4).

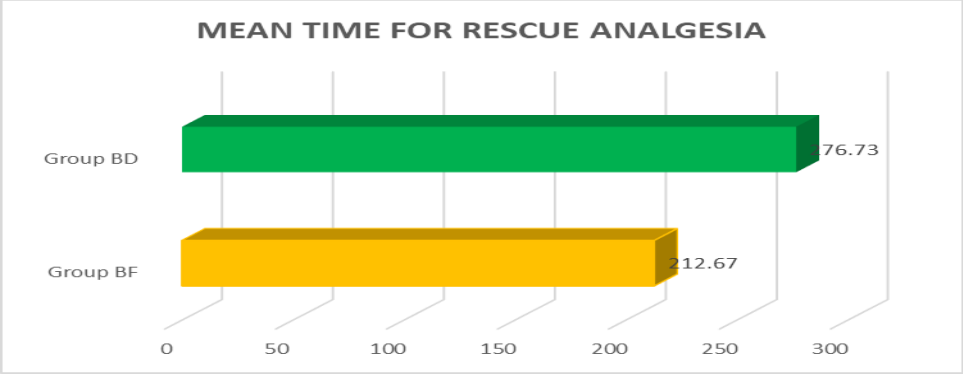


Figure 4. Distribution of Mean Time for Rescue Analgesia in Minutes by Groups

Maximum grade of motor block

Both groups achieved a maximum motor block of Grade 3. There was no statistically significant difference between the groups with respect to the highest grade of motor block achieved (p = 1.000) (Table 3).

Table 3. Maximum Grade of Motor Block by Groups

Parameters	Group BF		Group BD		'P' Value
	No	%	No	%	
No. of Cases	30		30		1
Grade 3	30	100	30	100	
Grade 2	0	0	0	0	

Maximum level of Sensory Block [T4-T6]

The maximum level of sensory block ranged from T4 to T6 in both groups, with a median sensory level of T6. In Group BF, 13.3% of patients achieved a maximum block at T4 and 86.6% at T6, whereas in Group BD, 10% reached T4 and 90% attained T6. The distribution of maximum sensory block levels between the two groups was not statistically significant (p = 1.000) (Table 4)

Table 4. Maximum Level of Sensory Block By [T4 - T6] Groups

Parameters	**Group BF**		**Group BD**		**'P' Value**
	No	%	No	%	
No. of Cases	30		30		0.086
T4	4	13.3	3	10	
T6	26	86.6	27	90	

Quality of surgical Anaesthesia

Quality of surgical anaesthesia was excellent in all patients. There was no statistically significant difference among two groups p < 1 (Table 5).

Table 5. Distribution of Cases by Groups and Quality of Surgical Anaesthesia

Parameters	**Group BF**		**Group BD**		**'P' Value**
	No	%	No	%	
No. of Cases	30		30		1
Excellet	30	100	30	100	
Good	0	0	0	0	

Bradycardia occurred in 3.33% of Group BF and 10% of Group BD, with no statistically significant difference in either group (p < 0.30). The incidence of pruritus in Group BF was 26.66%, while there were no cases of pruritus in Group BD (p 0.002). The incidence of vomiting was 6.66% in Group BF and 3.33% in Group BD, which was statistically insignificant (p 0.55). (Figure 5).

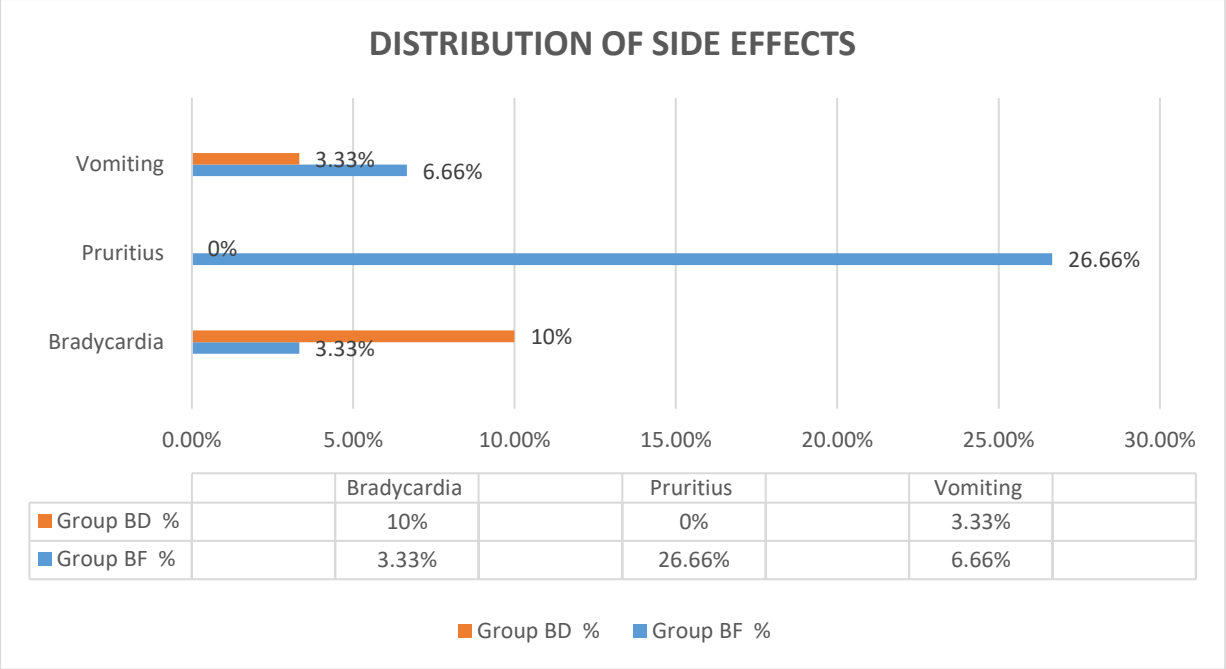


Figure 5: Distribution of Cases by Groups and Side Effects

Discussion

Spinal anesthesia is a widely used technique for infra-umbilical procedures. There is growing interest in the use of adjuvant analgesics to enhance the effects of spinal local anesthetics [8]. The purpose of this study is to compare the onset and duration of sensory and motor blockade, quality of intraoperative analgesia, and incidence of adverse effects between fentanyl and dexmedetomidine when used as intrathecal adjuvants to hyperbaric 0.5% bupivacaine for subarachnoid block in patients undergoing infra-umbilical surgeries. In the present study, 60 patients who underwent infra-umbilical surgery received either 5 µg of dexmedetomidine or 25 µg of fentanyl, in combination with 13 mg (2.8 ml) of 0.5% hyperbaric bupivacaine. Patients received 25 µg of fentanyl (0.5 ml) combined with 2.8 ml of hyperbaric bupivacaine constituted the control group, while those receiving 5 µg of dexmedetomidine (0.5 ml) with 2.8 ml of hyperbaric bupivacaine formed the intervention group. The mean time to onset of sensory block at the T10 level was 2.83 ± 0.53 minutes in the BF group and 2.67 ± 0.48 minutes in the BD group. In the present study, the addition of 5 µg dexmedetomidine to hyperbaric bupivacaine did not significantly shorten the onset of sensory block compared to 25 µg fentanyl. The onset of sensory block at the T10 level was comparable between the two groups. These findings are consistent with those of Subhi M. Al-Ghanem et al. who compared the effects of 5 µg dexmedetomidine versus 25 µg fentanyl added to 10 mg intrathecal plain bupivacaine and found no statistically significant difference between the groups in terms of the duration of sensory and motor block [9]. Similarly, Ibrahim F. A. Khalifa et al. reported no significant difference in the onset of sensory block at T10, with Group BD = 5.5 ± 3.7 minutes and Group BF = 6.2 ± 1.3 minutes (p = 0.69) in a comparative study evaluating 5 µg dexmedetomidine versus 5 µg sufentanil

added to 10 mg hyperbaric bupivacaine [10].

In the present study both the BD and BF groups, the median upper limit of sensory block was T6. There was no statistically significant difference in the maximal sensory block between the two groups. The addition of 5 µg dexmedetomidine to hyperbaric bupivacaine did not alter the onset of sensory block compared to 25 µg fentanyl. These findings are in agreement with Kanazi et al., who reported no significant difference in the maximal sensory block when 12 mg of 0.5% bupivacaine was administered alone or in combination with 3 µg dexmedetomidine or 30 µg clonidine ($p = 0.3$) [11]. In contrast, Mahmoud M. Al-Mustafa et al. demonstrated that higher doses of dexmedetomidine (5 µg and 10 µg) combined with 12.5 mg intrathecal bupivacaine increased the level of sensory block in a dose-dependent manner [12]. In the present study the mean time to achieve T6 sensory block was 4.80 ± 0.76 minutes in Group BF and 4.77 ± 0.68 minutes in Group BD, with no significant difference. This aligns with Subhi M. Al-Ghanem et al., who reported comparable times to peak sensory level with 5 µg dexmedetomidine or 25 µg fentanyl added to 10 mg intrathecal bupivacaine (19.34 ± 2.87 vs. 18.39 ± 2.46 min, $p = 0.12$).[9] The onset of motor block was also similar between groups. The time to reach Modified Bromage Score 3 was 6.53 ± 0.68 min in BD and 6.63 ± 0.56 minutes in BF. Ibrahim F. A. Khalifa et al similarly reported no significant difference in motor block onset between 5 µg dexmedetomidine and 5 µg sufentanil with 10 mg intrathecal bupivacaine. The duration of sensory block was significantly prolonged with dexmedetomidine: 459.03 ± 56.93 minutes in BD versus 358.97 ± 46.74 minutes in BF [10].

The mean duration of motor block was significantly longer in Group BD (288.63 ± 31.13 minutes) compared with Group BF (231.83 ± 39.96 minutes). The addition of 5 µg dexmedetomidine to 0.5% hyperbaric bupivacaine markedly prolonged motor blockade. These findings are consistent with Subhi M. Al-Ghanem et al., who demonstrated prolonged motor block with intrathecal dexmedetomidine compared to fentanyl when added to hyperbaric bupivacaine [9]. Kanazi et al. similarly reported prolonged motor block with dexmedetomidine or clonidine combined with bupivacaine, attributed to α_2-agonist action on spinal motor neurons [11]. Dexmedetomidine, an α_2-adrenergic agonist, has been shown to prolong both sensory and motor blockade and to provide extended postoperative analgesia.

Dexmedetomidine, when administered intrathecally as an adjuvant to hyperbaric bupivacaine, produced a significant prolongation of both sensory and motor blockade compared to fentanyl. Patients receiving dexmedetomidine demonstrated a markedly longer duration of sensory block as well as delayed regression of motor block, indicating superior neuraxial blockade. In addition, the duration of postoperative analgesia, as assessed by the time to first request for rescue (demand) analgesia, was significantly prolonged in the dexmedetomidine group. This reflects enhanced and sustained analgesic efficacy of dexmedetomidine when used intrathecally. However, no statistically significant difference was observed in the onset time of either sensory or motor blockade between the fentanyl and dexmedetomidine groups, suggested that

both adjuvants have a comparable effect on the initiation of spinal anaesthesia. With regard to adverse effects, patients receiving intrathecal dexmedetomidine experienced side effects primarily in the form of hypotension, bradycardia, and occasional vomiting. These effects were manageable and consistent with the known pharmacological profile of dexmedetomidine. Conversely, the incidence of pruritus was significantly higher in patients who received intrathecal fentanyl, which is a well-recognized opioid-related side effect, and was comparatively uncommon in the dexmedetomidine group.

Conclusion

Dexmedetomidine given intrathecally augments the subarachnoid block than intrathecal fentanyl because dexmedetomidine provides sustained sensory & motor block. This form of block is clearly more appropriate for lower abdomen and lower extremity procedures. The increased duration of motor block caused by Dexmedetomidine enhanced spinal block features may not be preferred for short duration surgeries or ambulatory surgery.

Ethical clearance

The Institutional Human Ethics Committee has reviewed our proposal on 23.02.2020, and it was approved (SBMC/IHEC/2020/1455)

Statements and Declarations

Conflicts of interest

The authors declare that they do not have conflict of interest.

Funding

No funding was received for conducting this study.

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