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Comparative Study of the Efficacy of Intrathecal Fentanyl with Intrathecal Dexmedetomidine as Adjuvants to Hyperbaric Levobupivacaine 0.5% in Patients Undergoing Infraumbilical Surgeries: A Double Blind Randomised Control Study

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Abstract: ***Intrathecal adjuvants are commonly used to enhance the quality and duration of spinal anaesthesia. This study aimed to compare dexmedetomidine with fentanyl as adjuvants to hyperbaric levobupivacaine in patients undergoing infraumbilical surgeries. Materials and Method: This prospective, randomized, double-blind study included 70 patients undergoing infraumbilical surgeries. Patients were divided into two groups: a) Group A: levobupivacaine + fentanyl 25 µg b) Group B: levobupivacaine + dexmedetomidine 5 µg. The study assessed the onset of sensory and motor block along with the duration of sensory and motor block. Vital parameters were closely monitored intraoperatively and postoperatively along with the post-surgical pain using the VAS score[1](Visual Analogue Scale). Results: Sensory and motor block onset times were similar in both groups. However, dexmedetomidine group showed significantly prolonged sensory block duration of 462.34 ± 50.18 minutes vs. 180.94 ± 3.56 minutes in fentanyl group and motor block duration 415.11 ± 46.73 minutes vs. 144.8 ± 3.45 minutes across the two groups B and A respectively. Intra operative heart rate and oxygen saturation showed no significant fluctuations across both groups. While systolic, diastolic, and mean arterial pressures showed transient statistically significant elevations in the dexmedetomidine group, they remained clinically stable. The rescue analgesic was required 6.00 ± 1.59 hours in group B vs. 1.90 ± 0.68 time in hours in group A. Additionally, the mean VAS[1] pain scores during the first 3 hours postoperatively was significantly higher in Group A 2.46±2.23 as compared to Group B 0.21±1.14 with p < 0.0001, indicating superior postoperative pain control. Conclusion: Both agents are safe, with stable haemodynamics and minimal side effects. While onset of sensory and motor block times is comparable, dexmedetomidine significantly lengthened the duration of sensory and motor block, delayed the need for rescue analgesia, and provided superior pain control in the intraoperative and postoperative period without significant haemodynamic instability. These outcomes demonstrated the efficacy of dexmedetomidine more effective for surgeries requiring prolonged analgesia, whereas fentanyl remains suitable for shorter procedures with faster recovery goals.***

Keywords: Dexmedetomidine, fentanyl, spinal anaesthesia, levobupivacaine, intrathecal adjuvants, infraumbilical anaesthesia

1. Introduction

Spinal anaesthesia is commonly employed as regional anaesthetic technique, particularly effective for infraumbilical surgeries.[2] It involves the intrathecal injection of a small volume of local anaesthetic into the subarachnoid space to produce a dense neural blockade over a large portion of the body. A key challenge in spinal anaesthesia lies in controlling the spread of the anaesthetic within the cerebrospinal fluid to achieve an adequate yet safe level of block. Due to its simplicity, predictable anatomical landmarks, rapid onset, and effective surgical conditions, spinal anaesthesia remains widely practiced and preferred in clinical anaesthesia.[2,3]

Local anaesthetics exert their action by inducing conformational changes in voltage-gated sodium (Na^+) channels, thereby inhibiting nerve impulse conduction.[4] However, when used alone, local anaesthetics may provide a limited duration of postoperative analgesia.[5]

To overcome this limitation, various intrathecal adjuvants are commonly added to local anaesthetic solutions to enhance the quality and duration of spinal anaesthesia while minimizing systemic side effects [6,7].

Opioids such as fentanyl act primarily on µ-opioid receptors in the dorsal horn of the spinal cord to provide effective analgesia; however, their duration of action is relatively limited and may be associated with adverse effects such as pruritus and respiratory depression[8].

Dexmedetomidine, a highly selective α_2-adrenergic receptor agonist, has emerged as a promising alternative intrathecal adjuvant. It produces analgesia by inhibiting nociceptive transmission at the spinal level and reducing sympathetic outflow, thereby prolonging both sensory and motor blockade without significant respiratory depression [9].

Recent systematic reviews and meta-analyses have demonstrated that intrathecal dexmedetomidine significantly prolongs the duration of sensory and motor block and improves postoperative analgesia compared with fentanyl, without increasing adverse effects such as hypotension and bradycardia [10].

Although several studies have evaluated the efficacy of dexmedetomidine and fentanyl as intrathecal adjuvants, variability in dosing, choice of local anaesthetic, and study populations necessitates further evaluation to establish their comparative effectiveness in routine clinical practice [9,10].

This study was conducted to compare dexmedetomidine and fentanyl as intrathecal adjuvants to hyperbaric levobupivacaine in patients undergoing infraumbilical surgeries, with respect to block characteristics, postoperative analgesia, and haemodynamic stability.

2. Materials and Methods

After obtaining Institutional Ethical Committee approval, this randomised double-blind study was carried out on 70 patients. The duration of the study was 18 months. Informed written consent was obtained from all the patients before participation. Inclusion Criteria: 1. ASA (American Society of Anaesthesiologists) I & II [11] 2. All men and women 3. Adult 18-60 years 4. Elective infraumbilical surgeries under spinal anaesthesia lasting for 2-3 hours. Exclusion criteria: 1. Patients with significant neurological deficit. 2. Spinal column surgeries. 3. Patients on anticoagulants. 4. Allergic to local anaesthetic. 5. Allergic to fentanyl and dexmedetomidine. 6. Hypotension. 7. Patient included in another study.

3. Methodology

A preoperative evaluation, along with baseline vitals, general physical examination, and relevant investigations, was done. The nature of the study was explained to all the patients. All patients were shown the Visual Analogue Scale and were apprised about the same during the pre-operative visit one day prior to the surgery, and familiarised with the measurement of postoperative pain. All the patients received alprazolam 0.5 mg as premedication the night before the day of the surgery.

4. Procedure

Patients were kept nil per oral for 6 hours for solids and 2 hours for clear liquids before surgery. On the day of surgery, baseline vital parameters were recorded and monitoring was done using a multiparameter monitor including pulse oximetry, electrocardiogram (ECG), and non-invasive blood pressure (NIBP). All patients were preloaded with Ringer's lactate at 10 ml/kg body weight.

Seventy patients were randomly divided into two groups of 35 each using block randomization. Seventy slips (35 for each group) were placed in an envelope, and one slip was drawn before the procedure by an anaesthesiologist not involved in the study. The same anaesthesiologist prepared the study drug. The attending anaesthesiologist, surgeons, and researchers involved in patient assessment were blinded to the group allocation.

Group A (Fentanyl group): 12.5 mg (2.5 mL) of 0.5% levobupivacaine + 25 µg fentanyl (0.5 mL) intrathecally (total volume 3 mL).

Group B (Dexmedetomidine group): 12.5 mg (2.5 mL) of 0.5% levobupivacaine + 5 µg dexmedetomidine with normal saline to make a total volume of 3 mL.

Subarachnoid block was performed in the left lateral position under aseptic precautions at the L3–L4 interspace using a 23- or 25-gauge Quincke needle via the midline approach after local infiltration with 2% lidocaine. After confirmation of free cerebrospinal fluid flow, the drug was injected slowly. Patients were immediately placed supine with a 15° head-down tilt to achieve a sensory block up to T6. Oxygen was administered via face mask at 4–5 L/min.

The onset and duration of sensory and motor block, time to first rescue analgesia,haemodynamic parameters, and side effects were recorded. Onset of sensory block was defined as the time from intrathecal injection to loss of pinprick sensation at T6 dermatome. Duration of sensory block was defined as regression to the S2 dermatome. Motor block was assessed using the Modified Bromage scale[12]; Onset of motor block was defined as achievement of Bromage score 3, and complete recovery as Bromage score 6.

Baseline vitals were recorded 5 minutes before spinal injection and then every 10 minutes intraoperatively until completion of surgery. Postoperative haemodynamic parameters were recorded at 1, 2, 4, 6, 9, 12, and 24 hours. VAS was assessed in the postoperative period every ½ hourly then 1 hourly, 2 hourly, 3 hourly, 4 hourly, 6 hourly, 12 hourly till 24 hours.

In the post-anaesthesia care unit (PACU), sensory block regression and motor recovery (Modified Bromage score 6)[13] were assessed every 15 minutes until two-segment regression from the maximum sensory block level. Time to first rescue analgesia was defined as the interval between intrathecal drug administration (zero time) and the patient reporting pain with a Visual Analogue Scale (VAS)[1] score ≥3. Patients with VAS ≥3 received intravenous tramadol 1 mg/kg, and the time was recorded. Side effects such as nausea, vomiting, pruritus, respiratory depression, and hypotension were monitored for 24 hours. Hypotension was defined as a ≥30% decrease in systolic blood pressure from baseline.

Statistical analysis was performed using SPSS version 28.0. Data were summarized using descriptive statistics and frequency distribution. Chi-square or Fisher's exact test was used for categorical variables, and Student's t-test for continuous variables. A p-value <0.05 was considered statistically significant.

5. Results

Table 1: Demographic Variables in Both Groups

Variable	Group A	Group B	P-value
Age	39.6	39.69	0.9787
Duration of Surgery	21.16	18.12	0.3659
Distribution of gender Male:Female	45.71:4.29	38.57:11.43	0.1006
ASA physical status Male:Female	28.57%:21.43%	31.43%:18.57%	0.6256
Mean heart rate	80.97 bpm (±13.1)	81.03 bpm (±10.26)	0.952
Mean Systolic blood pressure	135.14 mmHg (±17.8)	139.4 mmHg (±16.4)	0.3018
Mean Diastolic blood pressure	(80.8 ± 8.89 mmHg)	(79.57 ± 7.67 mmHg)	0.5379
Mean arterial pressure	(98.91 ± 11.04 mmHg)	(99.51 ± 9.77 mmHg)	0.8105
Mean SpO_2 Levels	(99.67 ± 0.52%)	(99.5 ± 0.58%)	0.0059

Table 2: Post Operative Vitals and Oxygen Saturation

Variable	Group A	Group B	P-value
Mean HR postoperatively	75.97 to 77.31 bpm	73.29 to 74.71 bpm	0.1488 to 0.2446
Mean SBP postoperatively	115.71 to 118.97 mmHg,	120.69 to 123.34 mmHg	>0.05
Mean DBP postoperatively	65.17 to 67.89 mmHg	66.2 to 69.29 mmHg	>0.05
Mean arterial pressure post operatively	82.72 to 84.05 mmHg,	84.83 to 86.86 mmHg	0.0417
Postoperative Comparison of Oxygen Saturation	98.43% to 98.94%	98.31% to 98.66%	0.0351

Table 3: Quality of Spinal Anaesthesia

Variable	Group A	Group B	P-value
Onset Time of Sensory Block	7.09 ± 0.74 minutes	6.91 ± 0.74 minutes	0.3375
Onset Time of Motor Block	8.11 ± 1.05 minutes	8.14 ± 0.88 minutes	0.9022
Time Taken to Achieve Maximum Sensory Block	13.34 ± 1.97 minutes	13.09 ± 1.48 minutes	0.5392
Time taken to achieve maximum level of motor block (in minutes)	14.49 ± 1.77 minutes	13.94 ± 1.53	0.1749
Mean Duration of sensory block (minutes)	180.94 ± 3.56 minutes	462.34 ± 50.18 minutes	<0.0001
Mean Duration of motor block(minutes)	144.8 ± 3.45	415.11 ± 46.73 minutes	<0.0001
Time of first rescue analgesia (Hours)	1.90 ± 0.68 hours	6.00 ± 1.59 hours	<0.0001
Mean Postoperative VAS Scores during first 3 hours	2.46±2.23	0.21±1.14	< 0.0001

Table 4: Side Effects in Both Groups

Variable	Group A	Group B	P-value
Incidence of Nausea, Yes: No	4 (5.71%):31 (44.29%	3 (4.29%):32 (45.71%)	1
Incidence of Hypotension yes: no	2(2.86%):33(47.14%)	0 (0.00%):35 (50.00%)	0.5551
Incidence of Bradycardia Yes: No	0(0%):35(50%)	1 (1.43%):34 (48.57%)	0.3138
Incidence of Tinnitus Yes: No	0(0%):35(50%)	0(0%):35(50%)	NA
Incidence of Blurred Vision Yes: No	0(0%):35(50%)	0(0%):35 (50%)	NA
Incidence of Allergic Reaction to Intrathecal Drug Yes: No	0 (0%):35 (50%)	0 (0%):35 (50%)	NA

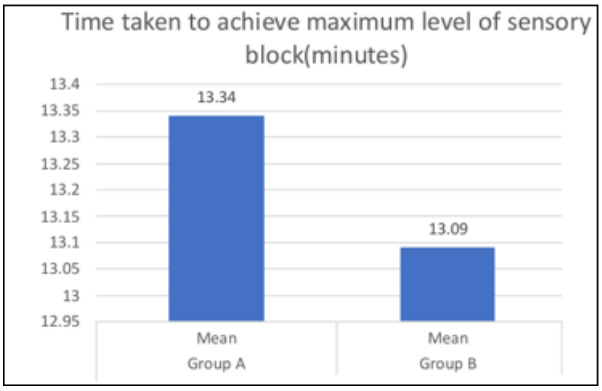
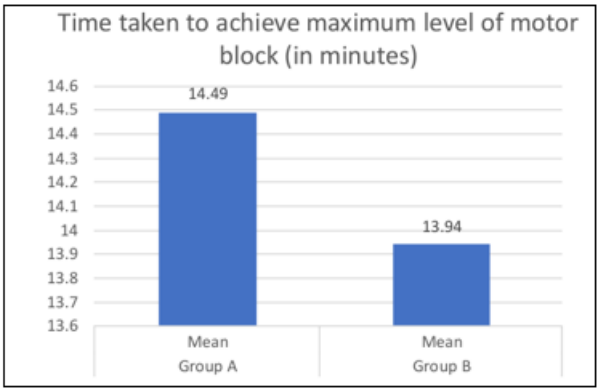


Figure 1



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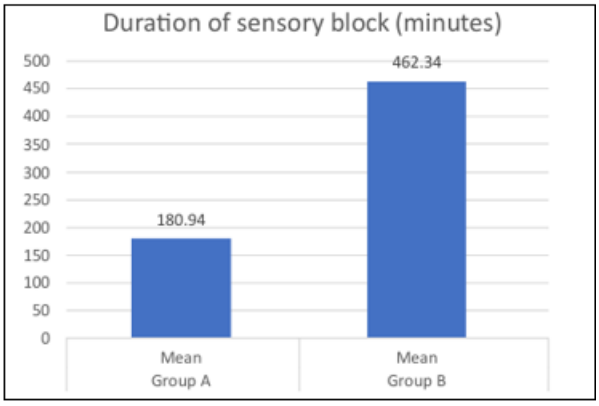

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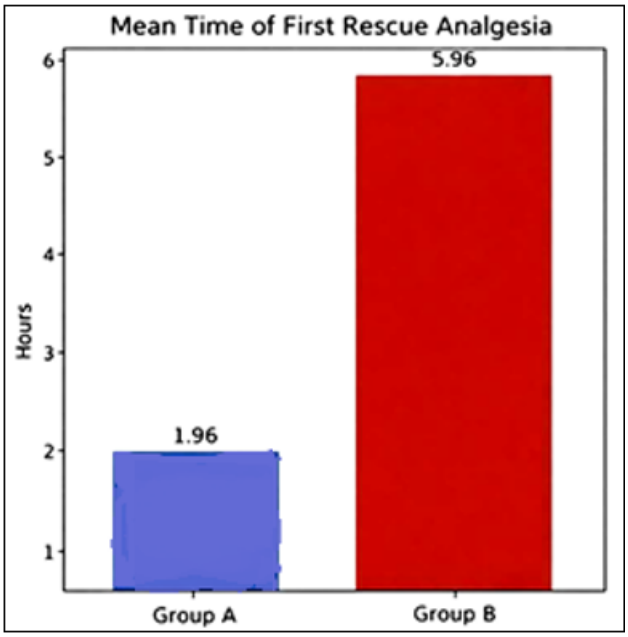

Figure 5

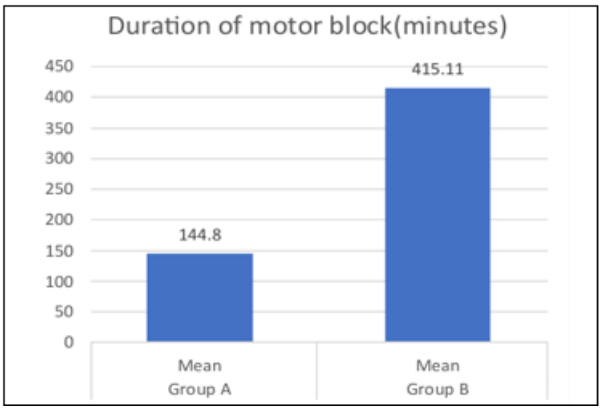

Figure 4

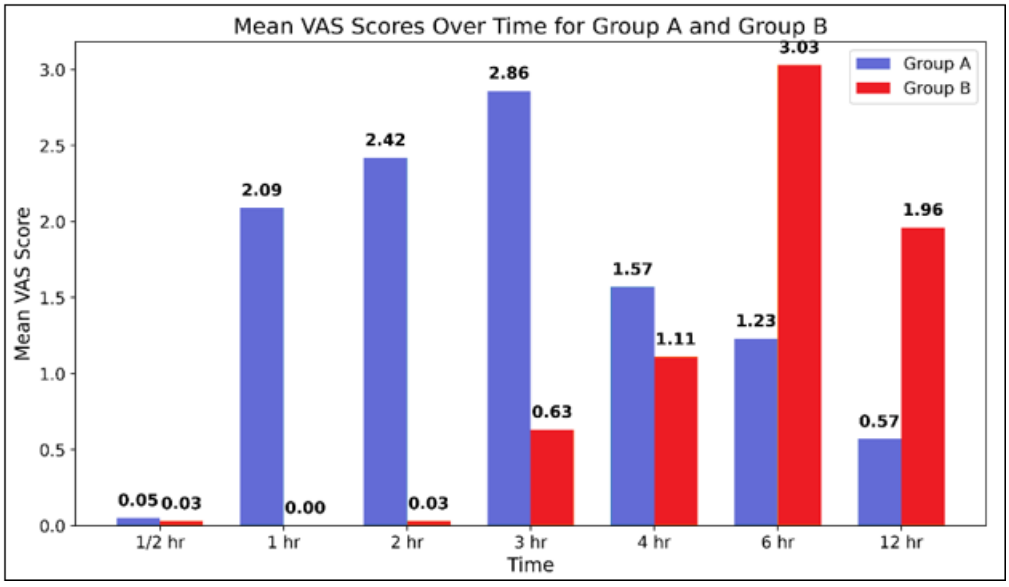

Figure 6

6. Discussion

Intrathecal anaesthesia is a neuraxial technique in which local anaesthetic is injected into the subarachnoid space. Besides intraoperative anaesthesia,it provides better postoperative analgesia, reduced blood loss, avoidance of airway manipulation.

The addition of intrathecal adjuvants to local anaesthetics has been shown to enhance block characteristics, prolong analgesia, and reduce the requirement for systemic analgesics. The present randomized double-blind study compared the efficacy of fentanyl and dexmedetomidine as intrathecal adjuvants to 0.5% hyperbaric levobupivacaine in patients who underwent infraumbilical surgeries.

The demographic characteristics and duration of surgery were comparable between the two groups, confirming adequate randomization and homogeneity of the study population. The onset of sensory and motor blockade was similar in both groups, suggesting that the choice of adjuvant does not significantly influence the speed of block establishment. However, dexmedetomidine significantly prolonged the duration of both sensory and motor blockade compared to fentanyl. This prolonged effect can be attributed to its action on presynaptic and postsynaptic α_2-adrenergic receptors in the spinal cord, leading to inhibition of nociceptive transmission and enhanced analgesic efficacy.

A key finding of the present study was the significantly prolonged time to first rescue analgesia in the dexmedetomidine group, along with lower postoperative VAS scores, indicating superior postoperative pain control. The enhanced analgesic effect of dexmedetomidine is likely due to its synergistic interaction with local anaesthetics and its ability to inhibit the release of substance P.

These findings are consistent with previous studies. Shweta et al. (2016)[13] demonstrated that intrathecal dexmedetomidine (5 µg) significantly prolonged sensory and motor blockade and improved postoperative analgesia compared to fentanyl (25 µg) when used with hyperbaric levobupivacaine. Similarly, Mohammed Loay et al. (2021)[14] reported superior block characteristics and reduced postoperative analgesic requirements with dexmedetomidine. Zafar M et al. (2021)[15] also observed prolonged blockade duration and improved analgesic profile with dexmedetomidine, with comparable side effect profiles.

Fentanyl, a lipophilic µ-opioid receptor agonist, enhances analgesia by acting on opioid receptors in the substantia gelatinosa of the spinal cord. However, due to its shorter duration of action, it provides effective but shorter-lasting analgesia compared to dexmedetomidine, making it more suitable for shorter procedures or ambulatory settings.

Haemodynamic parameters, including heart rate and blood pressure, remained stable and comparable between the two groups. The slightly lower heart rate observed with dexmedetomidine may be attributed to its sympatholytic effects, although this did not result in clinically significant bradycardia. Oxygen saturation remained consistently within normal limits in both groups, highlighting the respiratory safety of both agents, particularly the minimal respiratory depressant effect of dexmedetomidine.

The incidence of adverse effects such as nausea, vomiting, hypotension, and bradycardia was low and comparable between the groups. No cases of respiratory depression, allergic reactions, or neurological complications were observed, confirming the safety of both adjuvants when used intrathecally.

Overall, dexmedetomidine demonstrated clear advantages in prolonging sensory and motor blockade and providing superior postoperative analgesia, whereas fentanyl offered shorter block duration and earlier recovery. Therefore, the choice of intrathecal adjuvant should be individualized based on the duration of surgery, analgesic requirements, and the need for early postoperative mobilization.

Although several studies have evaluated intrathecal dexmedetomidine and fentanyl, the present study reinforces their comparative efficacy using a standardized dose of hyperbaric levobupivacaine in infraumbilical surgeries. The findings highlight a clinically meaningful prolongation of analgesia with dexmedetomidine without significant haemodynamic compromise, supporting its preferential use in prolonged procedures.

7. Conclusion

Both drugs are safe, with stable haemodynamics and minimal side effects. Although the onset of sensory and motor block was similar in both groups, dexmedetomidine significantly prolonged the duration of blockade and postoperative analgesia, delaying the need for rescue analgesia and providing lower pain scores. The haemodynamic changes with dexmedetomidine were minimal and clinically manageable. Overall, dexmedetomidine proved superior to fentanyl for prolonged anaesthesia and postoperative analgesia, whereas fentanyl may be preferable in shorter procedures requiring faster recovery.

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