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Effects of Intrathecal Dexmedetomidine as an Additive to Hyperbaric Ropivacaine in Patients Undergoing Elective Infraumbilical Surgeries

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ABSTRACT

Background: Spinal anaesthesia is the preferred regional anaesthesia technique for infraumbilical surgeries due to its rapid onset, effective sensory and motor block, and profound analgesia. Ropivacaine is a long-acting amide local anaesthetic with a better safety profile and less motor blockade compared to bupivacaine. This study aimed to evaluate the effects of intrathecal dexmedetomidine as an additive to hyperbaric ropivacaine in patients undergoing elective infraumbilical surgeries.

Methods: A prospective, randomized, double-blind study was conducted on 72 ASA I and II patients aged 18–60 years, undergoing elective infraumbilical surgeries under spinal anaesthesia. Patients were divided into two groups of 36 each: Group R received 22.5 mg of 0.75% hyperbaric ropivacaine, while Group RD received the same dose with 5 µg dexmedetomidine. Block characteristics, analgesia duration, postoperative pain (VAS), and adverse events were recorded and analysed.

Results: There was no significant difference between the two groups in the onset of sensory and motor block or time to reach T8 level. However, Group RD showed significantly prolonged two-segment sensory regression (125.6±16.5 vs. 62.7±8.3 min; p<0.001) and longer time to rescue analgesia (438.3±22.8 vs. 259.3±14.8 min; p<0.001). VAS scores were significantly lower in Group RD at all postoperative time points. Adverse effects were minimal and comparable between the groups.

Conclusion: The addition of 5 µg intrathecal dexmedetomidine to hyperbaric ropivacaine significantly prolongs the duration of sensory and motor block without affecting the onset of sensory or motor block. It provides superior postoperative pain relief, as evidenced by lower VAS scores, with a favorable safety profile.

Key-words: Intrathecal Dexmedetomidine, Hyperbaric Ropivacaine, Spinal Anaesthesia, Infraumbilical Surgeries, Postoperative Analgesia

INTRODUCTION

Spinal anaesthesia is one of the most widely used regional anaesthesia techniques for infraumbilical surgeries due to its simplicity, rapid onset, and profound sensory and motor blockade [1]. The ideal spinal anaesthesia would provide rapid and adequate surgical anaesthesia, enabling early ambulation, the ability to void, and early discharge, especially in ambulatory surgical settings.

Until recently, 0.5% hyperbaric Bupivacaine was the primary drug used for spinal anaesthesia in India, following the discontinuation of Lidocaine due to concerns regarding transient neurological symptoms. In 2009, Ropivacaine, a long-acting aminoamide local anaesthetic with a better safety profile, was introduced

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into clinical practice. Ropivacaine is a pure S-enantiomer rather than a racemic mixture, exhibiting lower cardiotoxicity and CNS toxicity compared to bupivacaine [2,3]. Its reduced tendency to produce motor block at lower concentrations makes it particularly advantageous in ambulatory surgeries [4].

Hyperbaric Ropivacaine, prepared by adding glucose, has been shown to provide a more predictable and reliable anaesthesia than its isobaric counterpart [5]. However, the duration of sensory and motor blockade achieved with Ropivacaine may not always be sufficient for prolonged surgeries or extended postoperative pain relief. To overcome this limitation, various intrathecal adjuvants have been explored to enhance the block characteristics and to prolong analgesia.

Dexmedetomidine, a highly selective α2-adrenergic agonist with an α2:α1 ratio of 1620:1, is significantly more selective than clonidine [6]. It has both analgesic and sedative properties, and when administered intrathecally, it exerts its effects by binding to presynaptic and postsynaptic α2 receptors in the dorsal horn of the spinal cord. This action inhibits the release of norepinephrine and reduces sympathetic outflow and is found to have antinociceptive action for both somatic and visceral pain [7,8]. Its high lipophilicity facilitates rapid CSF penetration and receptor binding, contributing to its profound analgesic effects with minimal respiratory depression or neurotoxicity [9,10].

Previous studies have shown that intrathecal dexmedetomidine, when added to hyperbaric ropivacaine, improves the onset and quality of sensory and motor block, prolongs postoperative analgesia, and provides superior hemodynamic stability with minimal side effects [11–13]. In this context, the present study was undertaken to evaluate and compare the effects of intrathecal dexmedetomidine (5 mcg) added to 0.75% hyperbaric ropivacaine versus 0.75% hyperbaric ropivacaine alone in patients undergoing elective infraumbilical surgeries.

MATERIALS AND METHODS

This prospective, comparative study was conducted for six months in the Department of Anaesthesiology at a tertiary care hospital in Bangalore. A total of 72 patients, aged 18 to 60 years, scheduled for elective infraumbilical surgeries under spinal anaesthesia were enrolled after obtaining written informed consent.

Inclusion and Exclusion Criteria- Inclusion criteria consisted of patients aged 18 to 60 years of either sex, scheduled for elective infraumbilical surgery, with ASA physical status I or II, and who provided written informed consent. Patients were excluded if they had morbid obesity (BMI > 40 kg/m²), height less than 150 cm or more than 180 cm, were posted for emergency surgeries, had known hypersensitivity to any study drug, were on α-adrenergic blockers, calcium channel blockers or ACE inhibitors, or had contraindications to spinal anaesthesia such as increased intracranial pressure, bleeding diathesis, hypovolemia, or local infection at the site of injection.

Randomization- Patients were randomly divided into two equal groups (n=36 per group). Group R received 22.5 mg of 0.75% hyperbaric ropivacaine (3 ml) with 0.1 ml of normal saline. Group RD received 22.5 mg of 0.75% hyperbaric ropivacaine (3 ml) along with 5 µg dexmedetomidine. The study drugs were injected intrathecally over 15–20 seconds at the L3–L4 or L4–L5 interspinous space through a midline approach using a 23-gauge Quincke spinal needle. The patients and the anaesthesiologists recording the data were blinded to group allocation.

Preoperative and Intraoperative Management- All patients were preloaded with 15 ml/kg of Ringer's Lactate using an 18-gauge intravenous cannula. Standard intraoperative monitoring included non-invasive blood pressure (NIBP), electrocardiography (ECG), heart rate (HR), and arterial oxygen saturation (SpO_2). Following spinal anaesthesia, the patients were positioned supine. Hemodynamic parameters were recorded at 2, 5, 10, 20, 30, 40, 50, 60, 70, 80, 90, 120, 140, 160, and 180 minutes after the block.

Block Assessment- Sensory block was assessed bilaterally along the midclavicular line using the pinprick method, and the higher dermatome level was recorded for analysis if asymmetry was present. Motor block was evaluated using the modified Bromage scale (0–3), and sedation levels were measured using the Ramsay Sedation Scale (RSS), ranging from 1 to 6. The onset of sensory block was defined as the time from drug injection to loss of pinprick sensation at the T10 dermatome.

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The onset of motor block was defined as the time taken to reach a Bromage score of 1. Time to achieve T8 sensory level, time to two-segment sensory regression and duration of analgesia (time to first rescue analgesic) were recorded.

Postoperative Monitoring and Analgesia- Postoperatively, patients were monitored for vital parameters, sedation levels, and pain scores using the Visual Analogue Scale (VAS) at 2, 8, 12, and 24 hours. Rescue analgesia was administered as intravenous fentanyl 25 µg when VAS is ≥4 and could be repeated every 2 hours if needed.

Adverse Event Management- Adverse events were closely monitored throughout the study period. Hypotension, defined as a systolic blood pressure <90 mmHg or >30% fall from baseline, was treated with intravenous fluids and mephentermine 6 mg boluses as required. Bradycardia, defined as HR<50 beats/min, was managed with atropine 0.3–0.6 mg IV. Respiratory depression, defined as a respiratory rate <8/min or SpO_2<95%, was treated with oxygen supplementation and ventilatory support if necessary.

Statistical Analysis- Statistical analysis was performed using IBM SPSS version 26. The normality of data distribution was assessed using the Kolmogorov–Smirnov test. Continuous variables were compared between groups using the unpaired Student's t-test for normally distributed data and the Mann–Whitney U test for non-normally distributed data. Categorical variables were analysed using the Chi-square test or Fisher's Exact test as appropriate. A p-value of less than 0.05 was considered statistically significant.

RESULTS

A total of 72 patients were enrolled in the study and equally distributed into two groups: Group R (Ropivacaine alone) and Group RD (Ropivacaine with Dexmedetomidine), with 36 patients in each group. The groups were comparable concerning age, gender distribution, height, weight, and ASA physical status (Table 1). There was no significant difference in the type and duration of surgery.

Table 1: Demographic and Baseline Characteristics

Parameter	Group R (Mean±SD / n)	Group RD (Mean±SD / n)	p-value
Age (years)	38.25±12.56	37.94±12.34	0.91
Sex (M/F)	20 / 16	25 / 11	0.33
ASA Grade (I/II)	21 / 15	19 / 17	0.81
Average weight (kg)	58.2±6.5	56.5±8.3	0.47
Height (in cm)	149.73±4.76	149.03±5.77	0.610

The mean onset time of sensory block was 4.09±1.02 minutes in Group R and 4.53±0.85 minutes in Group RD. This difference was not statistically significant. Similarly, the mean onset time of motor block was 5.74±1.12 minutes in Group RD and 6.13±1.38 minutes in Group R, which was also statistically insignificant (Table 2).

Table 2: Block Characteristics and Analgesia Duration

Parameter	Group R (Mean±SD)	Group RD (Mean±SD)	p-value
Onset of Sensory Block (min)	4.09±1.02	4.53±0.85	0.45
Onset of Motor Block (min)	6.13±1.38	5.74±1.12	0.42
Time to reach T8 level (min)	10.7±1.7	11.1±1.6	0.18
Time of two segments regression from highest sensory level (min)	62.7±8.3	125.6±16.5	<0.001
Time of rescue analgesia (min)	259.3±14.8	438.3±22.8	<0.001

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There was no difference between Group R and Group RD in the time to reach T8 level (10.7±1.7 and 11.1±1.6). The time for two-segment sensory regression was significantly prolonged in Group RD (125.6±16.5 minutes) versus Group R (62.7±8.3 minutes; p=<0.001). Similarly, the duration of analgesia concerning time to rescue analgesia was significantly longer in Group RD (438.3 ±22.8 minutes) compared to Group R (259.3±14.8 minutes; p=<0.001), reflecting an extended block duration with the use of dexmedetomidine. (Table 2)

Postoperative pain was assessed using the VAS at various time intervals. VAS scores were significantly lower in Group RD at all observed intervals compared to Group R: at 2 hours (2.3±0.5 vs. 3.5±0.6; p=0.001), 8 hours (3.1±0.6 vs. 4.1± 0.7; p=0.001), 12 hours (3.1±0.8 vs. 4.8±0.9; p=0.001), and 24 hours (4.6±0.9 vs. 6.1±1.0; p=0.001). These findings indicate significantly better postoperative analgesia in the dexmedetomidine group (Table 3).

Table 3: Postoperative VAS Scores

Parameter	Group R (Mean±SD)	Group RD (Mean±SD)	p-value
VAS at 2 hrs	3.5±0.6	2.3±0.5	0.001
VAS at 8 hrs	4.1±0.7	3.1±0.6	0.001
VAS at 12 hrs	4.8±0.9	3.1±0.8	0.001
VAS at 24 hrs	6.1± 1.0	4.6±0.9	0.001

Adverse effects were monitored throughout the intraoperative and postoperative period. Hypotension occurred in 2 patients (5.6%) in Group R and 4 patients (11.6%) in Group RD, which was not statistically significant (p=0.40). Bradycardia was observed in 2 patients (5.6%) in Group R and 3 patients (8.3%) in Group RD (p=0.65). Nausea and/or vomiting were noted in 2 patients (5.6%) in Group R and 1 patient (2.8%) in Group RD (p=0.55). There were no cases of respiratory depression, pruritus, or sedation reported in either group. Overall, the incidence of adverse effects was low and comparable between the two groups (Table 4).

Table 4: Adverse Effects

Adverse Effect	Group R (n=36)	Group RD (n=36)	p-value
Hypotension	2(5.6%)	4(11.6%)	0.40
Bradycardia	2 (5.6%)	3 (8,3%)	0.65
Respiratory Depression	0 (0.0%)	0 (0.0%)	-
Nausea/Vomiting	2 (5.6%)	1 (2.8%)	0.55
Pruritus	0 (0.0%)	0 (0.0%)	-
Sedation	0 (0.0%)	0 (0.0%)	-

DISCUSSION

This prospective comparative study was conducted to evaluate the efficacy and safety of intrathecal dexmedetomidine (5 µg) as an adjuvant to hyperbaric ropivacaine (0.75%) in patients undergoing elective infraumbilical surgeries [14-17]. A total of 72 patients were equally divided into two groups—Group R (ropivacaine alone) and Group RD (ropivacaine with dexmedetomidine)—and various parameters related to block characteristics, postoperative analgesia, and adverse effects were compared.

The two groups in our study were statistically comparable concerning age, gender distribution, weight, and type of surgeries. This demographic balance strengthens the internal validity of the study. Similar demographic distributions were reported in studies by Bi *et al.* [14] and Mo *et al.* [15], who also included patients in the 18–60-year age group with ASA I and II status when evaluating intrathecal dexmedetomidine with ropivacaine during cesarean and infraumbilical surgeries. Our study found that there was no statistically significant difference between the two study groups on parameters

of sensory block onset, Motor block onset, and time to achieve maximum sensory block. Our results are comparable to the results of Salgado *et al.* [18].

Al-Ghanem *et al.* [19], who studied synergistic effect of dexmedetomidine with ropivacaine, bupivacaine, and fentanyl, found that dexmedetomidine did not affect the onset time of sensory block and time taken to achieve maximum sensory block level, reflecting a similar, if not better, efficacy on these parameters.

In our study, the time for two-segment sensory regression was significantly prolonged in Group RD: 125.6±16.5 minutes compared to Group R: 62.7±8.3 minutes; $p<0.001$. This suggests that the addition of intrathecal dexmedetomidine enhances the duration of sensory blockade. Our findings are consistent with those reported by Yadav *et al.* [20], who also demonstrated a significantly prolonged time for two-segment regression in patients receiving dexmedetomidine as an adjuvant to spinal anaesthesia. The prolongation of sensory block in both studies may be attributed to the synergistic effect of dexmedetomidine on spinal α2-adrenergic receptors, which reduces nociceptive transmission and enhances local anaesthetic action.

The duration of analgesia, as measured by the time to first rescue analgesia, is a key indicator of the efficacy of intrathecal adjuvants. In our study, the administration time for rescue analgesia was significantly prolonged in the dexmedetomidine group (464.4±18.9 minutes) compared to the ropivacaine-only group (254.7±46.7 minutes), highlighting the enhanced analgesic profile of dexmedetomidine. These findings are consistent with those of Yadav *et al.* [20], who also reported a significant delay in the requirement for rescue analgesia following intrathecal administration of dexmedetomidine. This reinforces its utility as an effective adjuvant in prolonging postoperative analgesia in infraumbilical surgeries.

VAS scores were significantly lower in Group RD at all time intervals (2, 8, 12, and 24 hours postoperatively), indicating better postoperative pain control. This analgesic benefit of dexmedetomidine aligns with findings from studies by Bi *et al.* [14] and Nethra *et al.* [17], both of whom documented prolonged analgesia and reduced rescue analgesic requirements with intrathecal dexmedetomidine.

Adverse effects were minimal and statistically comparable between the two groups. Hypotension occurred in 11.6% of patients in Group RD and 5.6% in Group R ($p=0.40$), and bradycardia was observed in 8.3% and 5.6% of patients in Group RD and R, respectively. These findings mirror those of Mo *et al.* who concluded that intrathecal dexmedetomidine, when used in low doses (3–5 µg), does not significantly increase the incidence of bradycardia or hypotension [15]. Additionally, no respiratory depression, sedation, or pruritus were noted in either group, affirming the safety profile of dexmedetomidine at low doses.

CONCLUSIONS

The addition of 5 µg intrathecal dexmedetomidine to hyperbaric ropivacaine significantly prolongs the duration of sensory and motor block without affecting the onset of sensory or motor block. It provides superior postoperative pain relief, as evidenced by lower VAS scores, with a favorable safety profile. These findings support its use as a safe and effective adjuvant in spinal anaesthesia for infraumbilical surgeries. Further clinical studies are recommended to validate its efficacy, safety, and optimal dosing.

CONTRIBUTION OF AUTHORS

Research concept–Varun TD, Neha Sanjeev Adhyapak
Research design–Varun TD, Neha Sanjeev Adhyapak
Supervision–Rupam Sinha
Materials–Neha Sanjeev Adhyapak, Bendi Reshma
Data collection–Varun TD, Neha Sanjeev Adhyapak, Bendi Reshma
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