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COMPARATIVE OBSERVATIONAL STUDY ON ANALGESIC EFFICACY OF INTRAVENOUS VERSUS INTRATHECAL DEXMEDITOMIDINE AS AN ADJUVANT TO HYPERBARIC BUPIVACAINE IN SUBARACHNOID BLOCK FOR BELOW KNEE ORTHOPAEDIC SURGERY

Anaesthesiology

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ABSTRACT

Background and Aims: Orthopedic surgeries, particularly those involving procedures below the knee, necessitate effective pain management strategies to ensure optimal patient comfort and postoperative recovery. Subarachnoid block (SAB) with hyperbaric bupivacaine has emerged as a widely utilized anesthesia technique for such surgeries. However, achieving prolonged postoperative analgesia remains a challenge, prompting the exploration of adjunctive agents to enhance the analgesic profile of bupivacaine. the study aims to evaluate the analgesic efficacy, hemodynamic stability, adverse event profiles, and overall patient satisfaction associated with intravenous versus intrathecal dexmedetomidine as adjuvants to hyperbaric bupivacaine. **Materials and Methods:** This study is intended to compare the analgesic efficacy of intravenous (Group A, n=48) vs intrathecal (Group B, n=48) dexmeditomidine as an adjuvant to hyperbaric bupivacaine in subarachnoid block. The pain scores of the patients will be assessed using a 10 point visual analogue scale (VAS) for 24 h in the postoperative period, post operative sedation between two groups, time to request for first rescue analgesia (pain free interval), frequency of rescue analgesia required and total dose of analgesics are noted. **Results:** Comparison of post-operative analgesia through VAS score between these two groups became statistically significant from 2nd post operative hours and mean VAS score is more in IV group. The mean of maximum level of sedation through RSS score was (1.4±0.4) for IT group and (2.2±0.7) for IV group. No participant in the IT group had sedation but 31.9% participants in the IV group had sedation among them, 12.8% had sedation for 60 min and 19.1% had sedation for 90 min. Mean time to give rescue analgesia in IT group is (430±27) min and in IV group is (233±33) min.Mean frequency of rescue analgesia in IT group is (1.13±0.33) and in IV group is (2.09±0.50) mins. All the comparisons are statistically significant (p=<0.05). **Conclusion:** Post operative analgesia is better in IT group but if we consider level of sedation then IV group shows better results.

KEYWORDS

Dexmeditomidine, post operative analgesia, sedation.

INTRODUCTION

Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.[1] Orthopedic surgeries, particularly those involving procedures below the knee, necessitate effective pain management strategies to ensure optimal patient comfort and postoperative recovery. Subarachnoid block (SAB) with hyperbaric bupivacaine has emerged as a widely utilized anesthesia technique for such surgeries owing to its efficacy, rapid onset, and reliable block characteristics and reduced adverse effects leading to shortened stay in the hospital.[2,3] However, achieving prolonged postoperative analgesia remains a challenge, prompting the exploration of adjunctive agents to enhance the analgesic profile of bupivacaine.[4] Various adjuvants were used in central neuraxial block to improve the quality of block and post-operative pain relief for prolonged period. These adjuvants range from opioids like fentanyl, nalbuphine, tramadol, benzodiazepines like midazolam, ketamine, anticholinesterases like neostigmine, alpha-2 agonists like dexmedetomidine, clonidine etc.[5-9] Among these adjuncts, dexmedetomidine, a highly selective α2-adrenergic agonist, has garnered considerable attention for its potential to prolong the duration of sensory and motor blockades when administered via intrathecal or intravenous routes.[10] The selection between intravenous and intrathecal routes of dexmedetomidine administration remains pivotal, as it may influence not only the analgesic efficacy but also the systemic and central nervous system effects. Intravenous administration ensures rapid systemic distribution, allowing for systemic analgesic effects while potentially minimizing central nervous system side effects.[11] Conversely, intrathecal administration enables direct access to the spinal cord, thus maximizing the local analgesic effects while potentially reducing systemic exposure and associated adverse events.[12] The present study aims to conduct a comprehensive comparative observational analysis to evaluate the analgesic efficacy, hemodynamic stability, adverse event profiles, and overall patient satisfaction associated with intravenous versus intrathecal dexmedetomidine as adjuvants to hyperbaric bupivacaine in SAB for below knee orthopedic surgeries.

METHODS

Permission from the institutional ethics committee was obtained before starting the study. Written informed consent was taken from all the participants. Pre-anesthetic check-up and optimization of the participants were done from PAC outdoor. On arrival of the patient in the operating room, standard monitoring equipment (ECG leads, non-invasive blood pressure cuff, and peripheral oxygen saturation) were attached and baseline parameters were noted. An 18-gauge intravenous cannulation was done and Ringer lactate solution was infused as preload at 15 ml/kg over 10 to15 minutes and the infusion was continued to a rate of 4ml/kg/hour thereafter. Every patient has received Inj. Ondansetron 4mg intravenously before subarachnoid block. Patients were assigned to two groups (Group IT, n=48 & Group IV, n=48) as per simple random sampling. In IV group (n = 48), every patient has received intravenous dexmedetomidine 0.5 µg/kg in 100 mL of 0.9% NS over a period of 15 minutes. Subarachnoid block was instituted using intrathecal (IT) 0.5% heavy bupivacaine 12.5 mg (2.5 mL) with 0.3 mL of NS in the lateral decubitus position using a midline approach with a 25-G Quincke needle inserted at the L3-L4 intervertebral space 5 to 10 min after completion of infusion. Whereas, IT group (n = 48), every patient has received 100 mL 0.9% normal saline IV over a period of 15 minutes. Subarachnoid block was instituted using 0.5% bupivacaine (H) 12.5 mg with 3µg of dexmedetomidine (0.3 mL) in the lateral decubitus position using a midline 57 approach with a 25-G Quincke needle inserted at the L3-L4 intervertebral space 5 to 10 min after completion of infusion. Immediately after spinal injection, all patients were turned into the supine position.

All patients were administered oxygen through an oxygen mask at 4 Liters per minute and were monitored intraoperatively for systolic, diastolic, mean blood pressure, heart rate, oxygen saturation, and respiratory rate every 5 minutes for the first 30 minutes and then every 10 minutes till the end of surgery in the operating room and thereafter every 15 minutes in the recovery room for 1 hour. Any hypotension (SBP < 20% of baseline or <100 mm Hg) was treated with injection phenylephrine 100 mcg iv bolus and bradycardia (HR <50 beats/min) with intravenous atropine 0.01 mg/kg. After placing the patient in the supine position, the sensory level was assessed by pinprick sensation using a blunt 25-G needle along the mid-clavicular line bilaterally at 3, 6, 9, 12, 15, 20, 25, and 30 minutes after which assessment was done every 30 minutes. The time to reach the sensory level up to T10 dermatome and the time for regression to the S1 segment were recorded. Assessment of motor block was done by the Bromage scale.

Time to reach Bromage 3 block and regression to Bromage 0 block were noted. The level of sedation was recorded on the scale of 1 to 6 utilizing the Ramsay Sedation Score [RSS] at 15-minute intervals during surgery and every 30-minute interval in the recovery room.

The pain scores of the patients were assessed using a 10-point visual analogue scale (VAS) for 24 hours in the postoperative period, at hourly intervals for the next 6 hours after subarachnoid block and then at the 8th, 10th, 12th, 15th, 18th, and 24th hour. The postoperative rescue analgesia was provided by diclofenac sodium 1.5 mg/kg slow infusion (VAS >3), and if not relieved within 30 minutes, then intravenous tramadol (1 mg/kg) was given. Duration of analgesia was taken as the time interval between onset of sensory blockade and the first dose of rescue analgesic given to the patient. The time to request for first rescue analgesia (pain-free interval), frequency of rescue analgesia required, and total dose of diclofenac and tramadol for 24 hours were noted. Patients having inadequate analgesia requiring IV analgesics or general anesthesia were excluded from the study.

RESULTS

Demographic data and clinical parameters were similar in both the groups in our study. The difference in VAS score at 0 and 1st hour were not statistically significant, but statistically significant differences in VAS score across both the groups started to appear postoperative 2nd hour onwards (Table 2, Figure 1). As seen in Table 3 and Figure 2, the mean of maximum level of sedation through RSS score was (1.4±0.4) for IT group and (2.2±0.7) for IV group. There was statistically significant difference between the two study groups (p=<0.001).

Table 1: Comparison of Demographic and Clinical Parameters in the Two Study Groups:

Characteristic	IT (n=48)	IV (n=47)	p Value
Age (years), mean ± SD	37.3 ± 10.1	35.8 ± 8.0	0.419
Male, n (%)	23 (47.9%)	24 (51.1%)	0.759
Female, n (%)	25 (52.1%)	23 (48.9%)	
BMI (kg/m²), mean ± SD	24.2 ± 2.4	24.4 ± 2.4	0.719
ASA-PS I, n (%)	30 (62.5%)	32 (68.1%)	0.568
ASA-PS II, n (%)	18 (37.5%)	15 (31.9%)	
Duration of surgery (min), mean ± SD	74.1 ± 9.1	73.2 ± 8.9	0.640

Table 2: Comparison of Post-operative Analgesia Through Vas Scores Between the Two Groups:

VAS Score	IT Mean	IT Median	IT SD	IV Mean	IV Median	IV SD	p Value
VAS-0	0.1	0	0.2	0.0	0	0.3	0.677
VAS-1	0.3	0	0.4	0.4	0	0.5	0.346
VAS-2	0.3	0	0.5	1.4	1	0.5	<0.001
VAS-3	0.3	0	0.5	2.4	2	0.5	<0.001
VAS-4	0.3	0	0.6	3.4	3	0.5	<0.001
VAS-5	1.3	1	0.5	2.6	2	0.7	<0.001
VAS-6	1.1	1	0.3	3.6	3	0.7	<0.001
VAS-8	2.1	2	0.3	3.6	3	0.7	<0.001
VAS-10	3.1	3	0.3	3.9	3	1.2	<0.001
VAS-12	2.1	2	0.3	2.6	2	1.0	0.003
VAS-15	1.1	1	0.4	2.1	2	0.9	<0.001
VAS-18	2.1	2	0.4	3.7	4	0.9	<0.001
VAS-24	3.1	3	0.4	4.5	5	0.9	<0.001

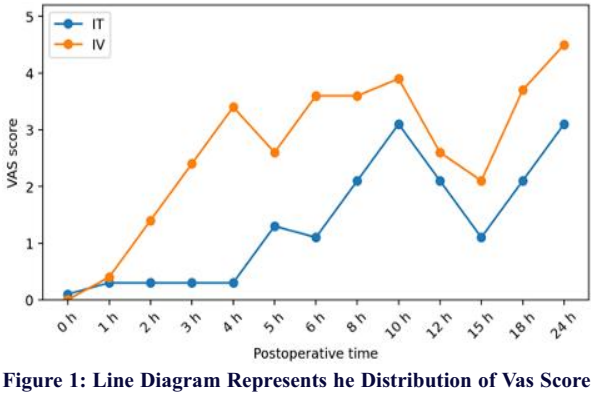

Figure 1: Line Diagram Represents he Distribution of Vas Score Among Patients of Two Study Groups for 24 Hours.

Table 3: Comparison of Maximum Level of Sedation Through Rss Score Between the Two Study Groups:

Maximum level of sedation	IT Mean	IT Median	IT SD	IV Mean	IV Median	IV SD	p Value
RSS score	1.4	1	0.4	2.2	2	0.7	<0.001

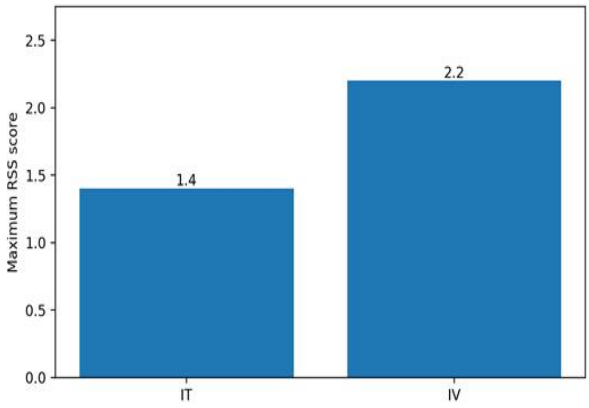

Figure 2: Bar Diagram Showing Difference in Mean Rss Score Between the Two Study Groups.

Table 4: Comparison of Duration of Sedation Between the Two Study Groups:

Duration of sedation (min)	IT, n (%)	IV, n (%)	p Value
0 min	48 (100%)	32 (68.1%)	<0.001
60 min	0 (0%)	6 (12.8%)	
90 min	0 (0%)	9 (19.1%)	

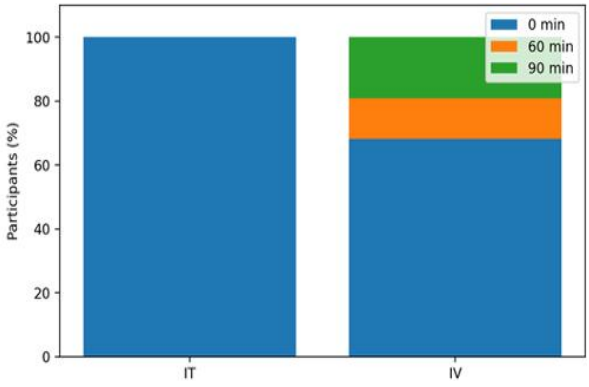

Figure 3: Bar Diagram Showing Difference in Duration of Sedation Between the Two Study Groups.

Table 5: Comparison of Pain Free Interval (time to Give First Rescue Analgesia) Betweenthe Two Study Groups:

Pain free interval	IT Mean	IT Median	IT SD	IV Mean	IV Median	IV SD	p Value
Time to give first rescue analgesia (min)	430	440	27.3	233	235	33.3	<0.001

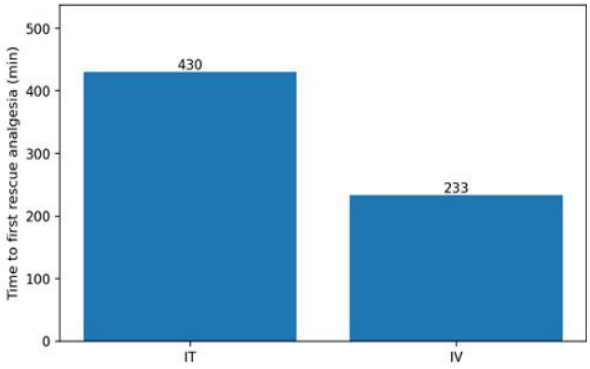

Figure 4: Bar Diagram Showing Difference in Mean Time to Give First Rescue Analgesia in Between the Two Study Groups.

Table 6: Comparison of Frequency of Rescue Analgesia Between the Two Study Groups:

Frequency of rescue analgesia	IT Mean	IT Median	IT SD	IV Mean	IV Median	IV SD	p Value
Frequency of rescue analgesia	1.13	1.00	0.33	2.09	2.00	0.50	<0.001

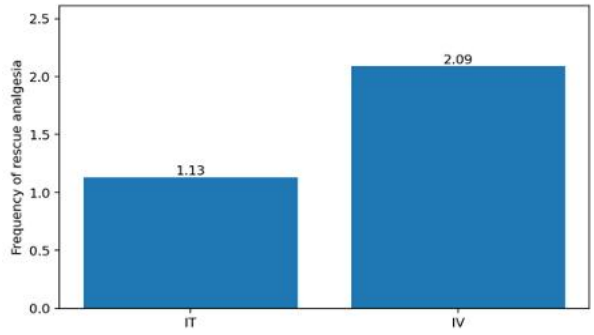

Figure 5: Bar Diagram Showing Difference in Mean Frequency of Rescue Analgesia Between the Two Study Groups.

As seen in Table 4 and Figure 3, no participant in the IT group had sedation but 31.9% participants in the IV group had sedation among them 12.8% had sedation for 60 min and 19.1% had sedation for 90 min. There was statistically significant difference between the two study groups(p=<0.001). Moreover, beyond 2 h of surgery, none of the patients had sedation. As seen in Table 5 and Figure 4, the mean time to give rescue analgesia in IT group is (430±27) min and in IV group is (233±33) min. There was statistically significant difference between two study groups(p=<0.001). As seen in Table 6 and Figure 5, the mean frequency of rescue analgesia in IT group is (1.13±0.33) and in IV group is (2.09±0.50) mins. There was statistically significant difference between two study groups(p=<0.001).

DISCUSSION

The efficacy and safety of intrathecal dexmedetomidine as adjuvant to local anaesthetic has been the topic of debate for years. In the study done by Yektas A et al. [9], the patients undergoing surgeries under subarachnoid block with dexmedetomidine as adjuvant to intrathecal bupivacaine, were assessed for neurological parameters utilising magnetic resonance imaging (MRI) scanning. The authors observed normal study of lumbar and thoracic spine during patient's yearly neurological examinations. There were no radiculopathy findings in lower extremities of patients in the electromyographic (EMG) studies, ensuring safety of intrathecal dexmedetomidine. In our study, 96 patients were randomly assigned to two groups of 48 each (Group IT and Group IV). Group IV received an intravenous infusion of 0.5 µg/kg dexmedetomidine in 100 mL of 0.9% normal saline over 15 minutes, followed by a subarachnoid block with 12.5 mg of 0.5% heavy bupivacaine and 0.3 mL normal saline, administered via a 25-G Quincke needle at the L3-L4 intervertebral space 5 to 10 minutes post-infusion. Group IT received 100 mL of 0.9% normal saline intravenously over 15 minutes, followed by a subarachnoid block with 12.5 mg of 0.5% heavy bupivacaine and 3 µg of dexmedetomidine (0.3 mL), administered similarly 96 to Group IV. After the spinal injection, all patients were placed in the supine position. One patient was excluded from the study because of conversion to general anaesthesia in group IV. Thereby remaining ninety-five, forty-eight in group IT and forty-seven in group IV completed the study successfully.

Sudheesh K et al. [8] did a randomised controlled study to compare two doses of intrathecal dexmedetomidine as adjuvant with low dose hyperbaric bupivacaine in ambulatory perianal surgeries. a total of 50 patients scheduled for elective perianal surgeries were randomly allocated to groups C or D (n = 25). Group D received hyperbaric bupivacaine 0.5% (4 mg) + dexmedetomidine 5 µg and group C received hyperbaric bupivacaine 0.5% (4 mg) + dexmedetomidine 3 µg intrathecally. The authors concluded that the duration of analgesia was comparable in two groups D and C (337.86 ± 105.11 min vs 340.78 ± 101.81 min), respectively. The postoperative pain scores were also comparable amongst two groups.

Therefore, dexmedetomidine in the dose of 3 µg seems to be a safer choice as intrathecal adjuvant to local anaesthetic.

In our study the duration of analgesia is more with IT group than IV group. The mean time to give rescue analgesia in IT group is (430±27) mins and in IV group is (233±33) mins. Our results are comparable to study finding of Abdou AMH et al. [13] where they concluded that both intrathecal and intravenous dexmedetomidine were safe adjuvants to bupivacaine during spinal anaesthesia in knee arthroscopies, however the intrathecal route provided more stable haemodynamic, better postoperative analgesia and lesser overall side effects. Similar results were observed by, Sharma et al.[14] in relation to the duration of analgesia. The duration of 98 analgesia was prolonged in group II (median [IQR]: 5 (6-7.5) h than in group I (median [IQR]: 4[2-4.5] h, P = 0.000). However, contradictory results were observed in a study by Elgebaly AS et al. [15] with the requirement of first rescue analgesic significantly earlier in intrathecal dexmedetomidine group as compared to intravenous group (270.15 ± 25.00 vs 371.25 ± 88.54 min). In their study, the intravenous dexmedetomidine was given as loading dose [1 µg/kg] followed by maintenance infusion [0.4 µg/kg/h] throughout the study interval.

In our study, 15 patients had mild sedation [Ramsay Sedation Score 3] in group I vs II (31.9% vs 0%). The positive outcome of our study was that none of the patients in either group showed sedation score beyond 3 in RAMSAY sedation Scale.

Similar result observed in a previous study done by Sharma I et al. [14] comparing IV vs IT dexmedetomidine as adjuvant to bupivacaine in parturient undergoing lower limb orthopaedic surgery found that 33% of IV group were mildly sedated.

CONCLUSION:

Post operative analgesia is better in IT group but if we consider level of sedation then IV group shows better results.

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