e-ISSN: 0975-9506, p-ISSN:2961-6093

Available online on www.ijpqa.com

International Journal of Pharmaceutical Quality Assurance 2025; 16(8); 239-246

Original Research Article

Comparative Evaluation of Intrathecal Bupivacaine and Ropivacaine with Dexmedetomidine in Lower Limb Orthopaedic Surgeries: A Prospective Observational Study

Sourav Karmakar[1], Abik Mallik[2], Subrata Kumar Mandal[3]

[1]Senior Resident, M.B.B.S, M.D, Department of Anaesthesiology, North Bengal Medical College & Hospital, Darjeeling, West Bengal, Pin-734012

[2]Assistant Professor, M.B.B.S, M.D, Department of Anaesthesiology, North Bengal Medical College & Hospital, Darjeeling, West Bengal, Pin-734012

[3]Associate Professor, M.B.B.S, M.D, Department of Anaesthesiology, North Bengal Medical College & Hospital, Darjeeling, West Bengal, Pin-734012

Received: 25-06-2024 / Revised: 23-07-2025 / Accepted: 25-08-2025

Corresponding Author: Dr. Sourav Karmakar

Conflict of interest: Nil

Abstract:

Background: Effective postoperative analgesia is crucial in lower limb orthopaedic surgeries. While bupivacaine is a standard intrathecal anaesthetic, ropivacaine—with lower cardiotoxicity—may benefit from adjuvants such as dexmedetomidine to prolong analgesic effects.

Objectives: To compare the efficacy and safety of intrathecal 0.5% bupivacaine heavy versus 0.75% ropivacaine heavy combined with 10 µg dexmedetomidine in terms of sensory and motor block characteristics, analgesia duration, and hemodynamic stability.

Methods: This prospective, observational study included 100 adult patients (ASA I/II) undergoing lower limb orthopaedic surgeries under spinal anaesthesia. Participants were allocated into Group A (bupivacaine + saline) and Group B (ropivacaine + dexmedetomidine). Key parameters included block onset and duration, analgesia duration, rescue analgesia requirements, and hemodynamic parameters. Statistical significance was defined as $p<0.05$.

Results: Demographics and surgical variables were comparable between groups. Block onset times were similar ($p>0.05$). However, Group B showed significantly longer duration of sensory block (226.6±41.1 min vs. 198.8±44.2 min), motor block (172.6±44.9 min vs. 154.8±52.8 min), and analgesia (278.4±51.2 min vs. 234.6±39.6 min) ($p<0.001$). Time to rescue analgesia was prolonged ($p<0.001$) and total analgesic requirement reduced in Group B ($p=0.002$). Hemodynamic stability and adverse events were similar across groups ($p>0.05$).

Conclusion: Intrathecalropivacaine combined with dexmedetomidine offers prolonged postoperative analgesia and reduced analgesic need without compromising safety, making it a viable alternative to bupivacaine in spinal anaesthesia for orthopaedic surgeries.

Keywords: Bupivacaine, Ropivacaine, Dexmedetomidine, Spinal Anaesthesia, Orthopaedic Procedures.

Introduction

Pain, defined by the International Association for the Study of Pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage," is a central concern in surgical care.[1] Effective pain management, particularly in orthopaedic surgeries of the lower limb, is critical for patient comfort, early mobilization, and reduced postoperative morbidity.

Regional anaesthesia, especially subarachnoid (spinal) blocks, plays a key role in achieving intraoperative and postoperative analgesia.[2] Intrathecal administration of local anaesthetics is preferred in many orthopaedic settings due to its reliability and ease of administration.[3] Among commonly used local anaesthetics, bupivacaine has long been the agent of choice for its potent and long-acting sensory blockade. It provides effective postoperative analgesia, reduces opioid requirements, and facilitates recovery, but carries risks such as cardiotoxicity at high plasma concentrations.[4]

Ropivacaine, a structurally related amide local anaesthetic, offers a favorable profile with a reduced risk of cardiotoxicity and less motor blockade, making it especially suitable for epidural and peripheral nerve blocks. [5] However, its slightly shorter duration of action compared to

bupivacaine has led to exploration of adjuvants to extend its analgesic effects.[6]

Dexmedetomidine, a selective alpha-2 adrenergic agonist, has gained attention as an adjuvant due to its analgesic, sedative, and sympatholytic properties.[7] When used intrathecally or epidurally, it enhances the quality and duration of sensory and motor blockades while minimizing opioid-related side effects.[8] Its mechanism involves inhibition of norepinephrine release, producing both central sedation and spinal analgesia without causing significant respiratory depression.

Given the clinical potential of dexmedetomidine to augment the effects of local anaesthetics, this study aims to compare the analgesic efficacy of intrathecal bupivacaine heavy with that of ropivacaine heavy combined with dexmedetomidine in patients undergoing lower limb orthopaedic surgeries.

Materials and Methods

This study was designed as a prospective, observational, analytical investigation conducted at the Department of Anaesthesiology, North Bengal Medical College and Hospital. It was carried out in the Orthopaedics Operation Theatre over a period extending from November 2022 to June 2024. The study population comprised adult patients of either sex, aged between 18 and 60 years, who were scheduled to undergo lower limb orthopaedic surgeries under spinal anaesthesia. Eligible participants were classified as American Society of Anesthesiologists (ASA) physical status I or II.

The sample size was calculated based on the formula for estimating the difference between two means, using findings from a previous study by Campbell et al. Assuming a standard deviation of 4.0 minutes in one group and 4.5 minutes in the other, with an expected mean difference of 1.4 minutes and a 90% confidence level, the required sample size was determined to be 50 participants per group, totalling 100 participants. A consecutive sampling technique was employed to recruit eligible patients until the desired sample size was achieved.

Exclusion criteria included refusal to give informed consent, the presence of spinal deformities or history of prior spinal surgery, bleeding disorders, neurological deficits, local infections at the site of needle insertion, and hemodynamic instability.

After obtaining ethical approval from the Institutional Ethics Committee and clearance from the West Bengal University of Health Sciences, informed written consent was obtained from all participants in their native language. During the pre-anaesthetic check-up, a detailed history was recorded and physical, neurological, and laboratory assessments were performed. Participants were then randomly allocated into two equal groups: Group A received 3 mL of 0.5% bupivacaine heavy with 0.1 mL of 0.9% normal saline, and Group B received 3 mL of 0.75% ropivacaine heavy combined with 10 μg (0.1 mL) of dexmedetomidine intrathecally.

All patients were kept fasting prior to surgery and received preload with Ringer's lactate solution at 10 mL/kg body weight. Standard monitoring was initiated, including continuous pulse rate, blood pressure, oxygen saturation (SpO_2), and ECG. Premedication included oral ranitidine 150 mg and intravenous ondansetron 4 mg. Under strict aseptic precautions, a subarachnoid block was performed at the L3–L4 interspace using a 25G or 26G spinal needle. The assigned study drug was then administered intrathecally. No sedatives or opioids were administered during the perioperative period to avoid confounding the outcome study.

Patients were taught to use the Visual Analogue Scale (VAS) for pain assessment prior to surgery. During the intraoperative period, patients were monitored for vital parameters, onset and duration of sensory and motor blocks, and any adverse effects. Sensory block was assessed using pin-prick method and motor block was assessed using the modified Bromage scale. Postoperatively, patients were observed for at least six hours in the recovery room and ward, and data were collected regarding duration of analgesia, block regression, and any complications.

All relevant preoperative investigations were performed, including complete blood count, serology (HIV, HBsAg, Anti-HCV), renal function tests, coagulation profile (PT, INR, aPTT), chest X-ray (PA view), and 12-lead ECG. Data collection was carried out using a structured case record form. Statistical analysis was performed using SPSS version 25. Continuous variables were expressed as means and standard deviations, and categorical variables as frequencies and percentages. Appropriate statistical tests (Student's t-test, Chi-square test) were applied, and a p-value of less than 0.05 was considered statistically significant.

Results

Table 1: Sociodemographic and Clinical Characteristics (N=100)

Parameters		Group A		Group B		Student's t-test value/ Chi-square value	p-value
		Mean/ frequency	SD/ %	Mean/ frequency	SD/ %		
Age (years)		45.6	10.2	44.8	11.1	0.389	0.708
Sex	Male	28	56	30	60	0.164	0.685
	Female	22	44	20	40		
Residence	Rural	28	56	27	54	0.041	0.841
	Urban	22	44	23	46		
Type of surgery	Total knee replacement	10	20	12	24	0.399	0.982
	Hip arthroplasty	13	26	12	24		
	Ankle surgery	9	18	10	20		
	Fracture femur repair	11	22	10	20		
	Tibia fracture repair	7	14	6	12		
Duration	Duration of surgery (min)	126.5	14.5	120.4	14.8	1.085	0.098
	Onset of sensory block (min)	4.2	0.5	4.1	0.8	0.384	0.702
	Onset of motor block (min)	5.5	0.5	5.3	0.4	1.21	0.083
	Duration of sensory block (min)	198.8	4.2	226.6	4.1	33.492	<0.001
	Duration of motor block (min)	154.8	8.2	172.6	4.9	13.181	<0.001
	Duration of analgesia (min)	234.6	3.9	278.4	3.1	42.178	<0.001

Table 2: Comparison of two groups with respect to their intraoperative hemodynamic parameters (n=100)

Parameters		Group A	Group B	Student's t value	p-value
HR	0 mins	70.2 ± 2.1	68.5 ± 4.0	1.132	0.07
	5 mins	72.1 ± 1.2	70.2 ± 1.1	0.844	0.62
	10 mins	71.5 ± 1.1	69.4 ± 1.1	0.346	0.15
	15 mins	69.2 ± 2.0	67.1 ± 2.1	0.231	0.57
	20 mins	70.1 ± 1.0	68.1 ± 1.0	0.734	0.19
	30 mins	68.9 ± 1.0	68.6 ± 1.0	0.144	0.82
SBP	0 mins	120.4 ± 3.7	118.5 ± 3.5	1.452	0.15
	5 mins	121.5 ± 3.6	119.5 ± 3.4	1.316	0.19
	10 mins	122.6 ± 3.5	120.5 ± 3.3	0.981	0.33
	15 mins	121.7 ± 3.8	119.3 ± 3.6	1.218	0.23
	20 mins	120.3 ± 3.7	118.1 ± 3.5	1.576	0.12
	30 mins	121.3 ± 3.6	119.0 ± 3.4	1.47	0.14
DBP	0 mins	80.3 ± 2.5	78.1 ± 2.3	1.254	0.21
	5 mins	81.5 ± 2.4	79.5 ± 2.2	1.145	0.26
	10 mins	82.1 ± 2.3	80.7 ± 2.1	0.968	0.34
	15 mins	81.1 ± 2.6	79.7 ± 2.4	1.398	0.17
	20 mins	80.6 ± 2.5	78.3 ± 2.3	1.306	0.2
	30 mins	81.9 ± 2.4	79.1 ± 2.2	1.382	0.18
MAP	0 mins	93.2 ± 2.8	90.3 ± 2.6	1.123	0.26
	5 mins	94.2 ± 2.7	91.2 ± 2.5	1.056	0.29

	10 mins	95.5 ± 2.6	92.0 ± 2.4	0.976	0.33
	15 mins	94.7 ± 2.9	91.1 ± 2.7	1.341	0.18
	20 mins	93.7± 2.8	90.1 ± 2.6	1.214	0.23
	30 mins	94.1 ± 2.7	91.6 ± 2.5	1.287	0.2
RR	0 mins	16.2 ± 2.1	15.2 ± 2.0	1.21	0.23
	5 mins	16.2 ± 2.0	15.2 ± 1.9	1.11	0.27
	10 mins	17.1 ± 1.9	16.1 ± 1.8	0.95	0.34
	15 mins	16.1 ± 2.2	16.4 ± 2.1	1.32	0.19
	20 mins	16.4 ± 2.1	16.5 ± 2.0	1.28	0.2
	30 mins	17.4 ± 2.0	16.6 ± 1.9	1.15	0.26

Table 3: Comparison of two groups with respect to their time to requirement of rescue analgesia (mins) (n=100)

Time to requirement of rescue analgesia	Group A	Group B	Student's t-test value	p-value
Mean	247.6	298.9	21.461	<0.001
SD	12.1	11.8		

*Statistically significant

Table 4: parison of two groups with respect to their total dose of rescue analgesia needed (mg) (n=100)

Total dose of rescue analgesia	Group A	Group B	Student's t-test value	p-value
Mean	51.8	44.2	3.758	0.002
SD	10.8	9.4		

*Statistically significant

Table 5: Comparison of two groups with respect to their incidence of adverse events (n=100)

Adverse events	Group A	Group B	Chi-square test	p-value
Nausea	8 (16)	7 (14)	3.467	0.347
Hypotension	4 (8)	5 (10)		
Bradycardia	5 (10)	7 (14)		
None	33 (66)	32 (64)		
Total	50 (100)	50 (100)		

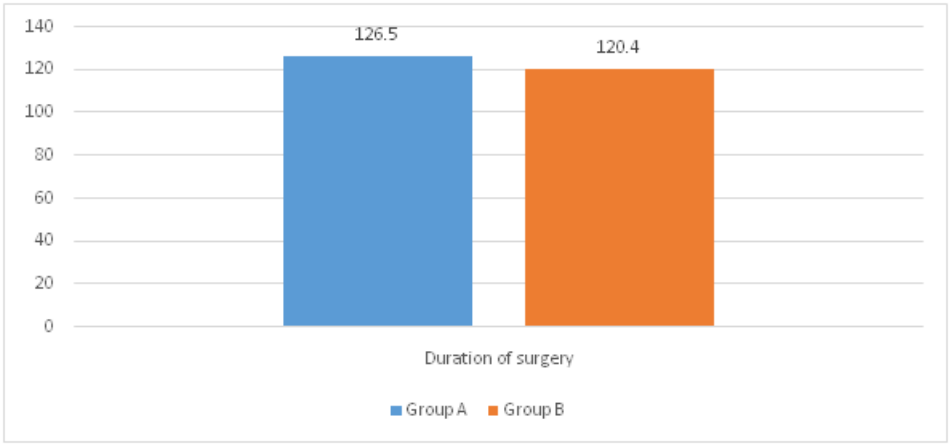

Figure 1: Comparison of two groups with respect to their duration of surgery (min) (n=100)

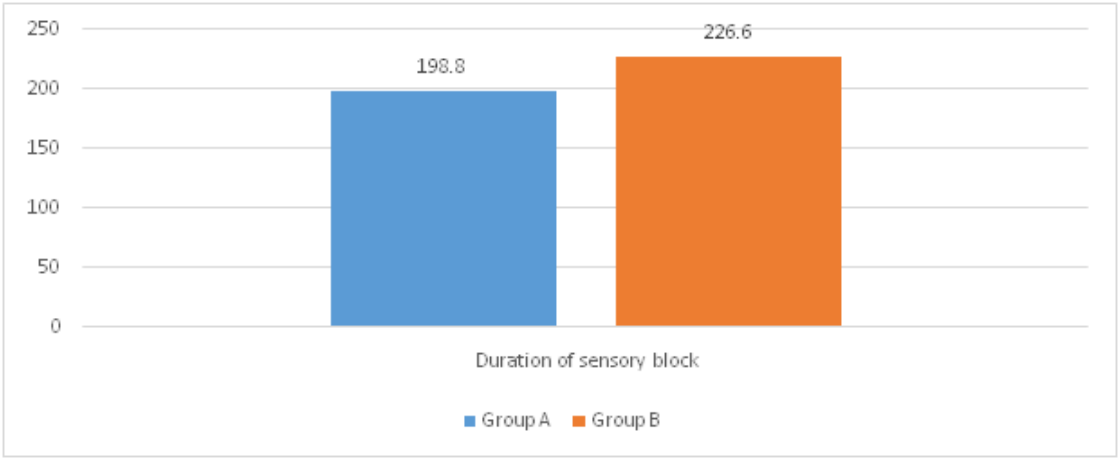

Figure 2: Comparison of two groups with respect to their duration of sensory block (mins) (n=100)

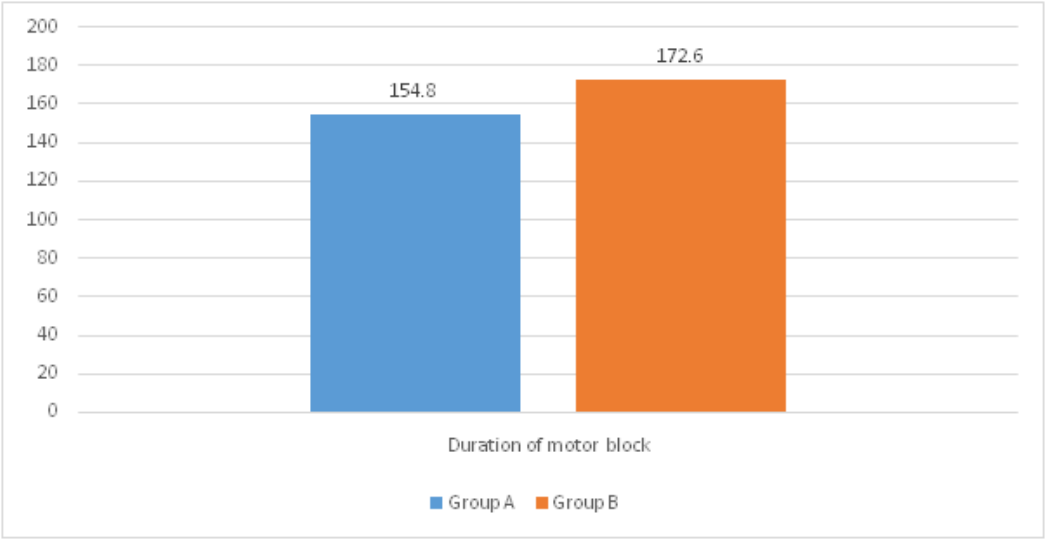

Figure 3: Comparison of two groups with respect to their duration of motor block (mins) (n=100)

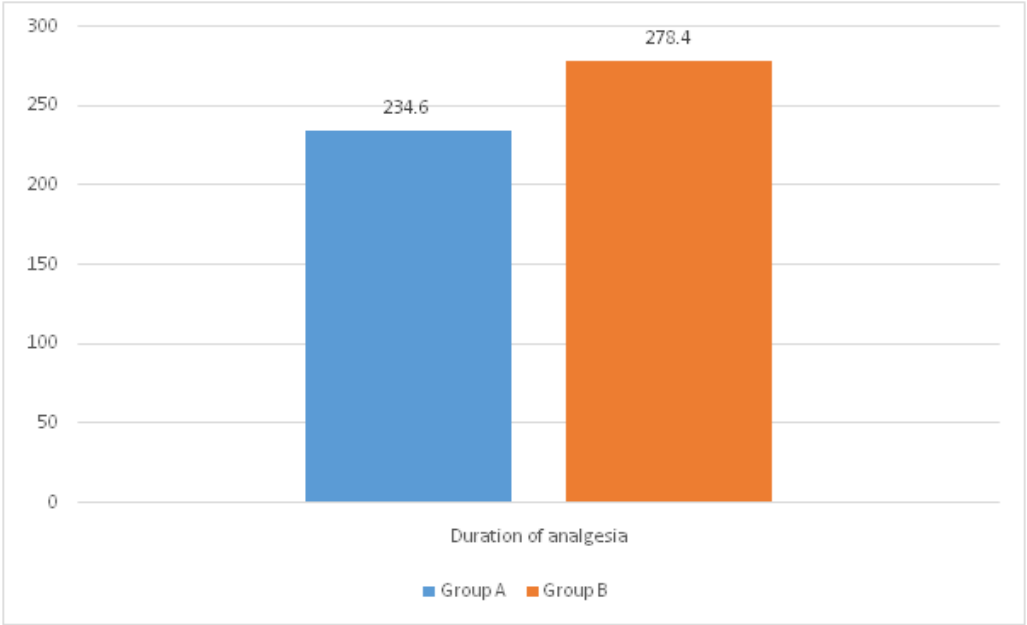

Figure 4: Comparison of two groups with respect to their duration of analgesia (mins) (n=100)

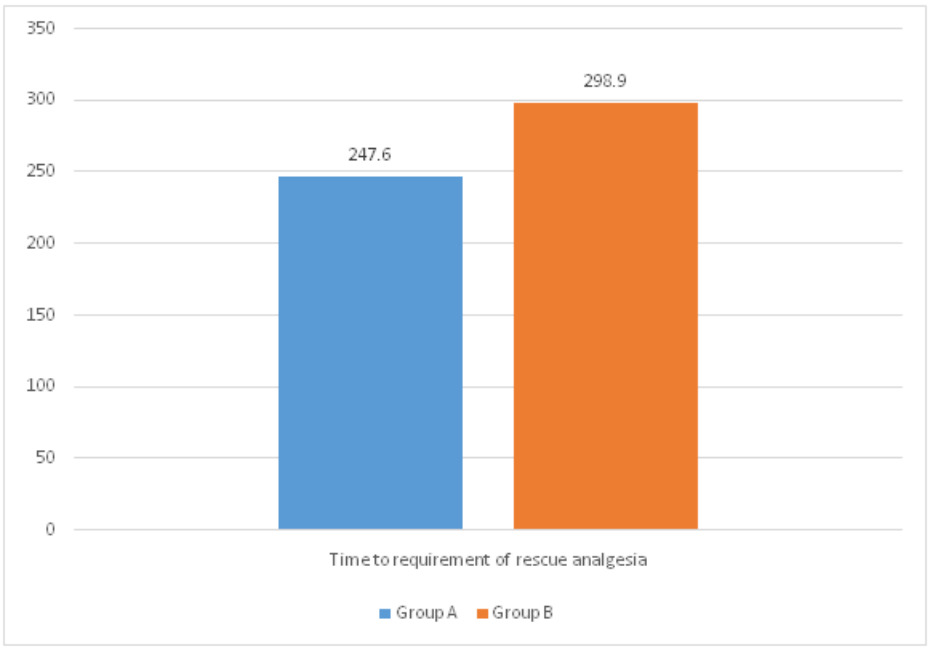

Figure 5: Comparison of two groups with respect to their time to requirement of rescue analgesia (mins) (n=100)

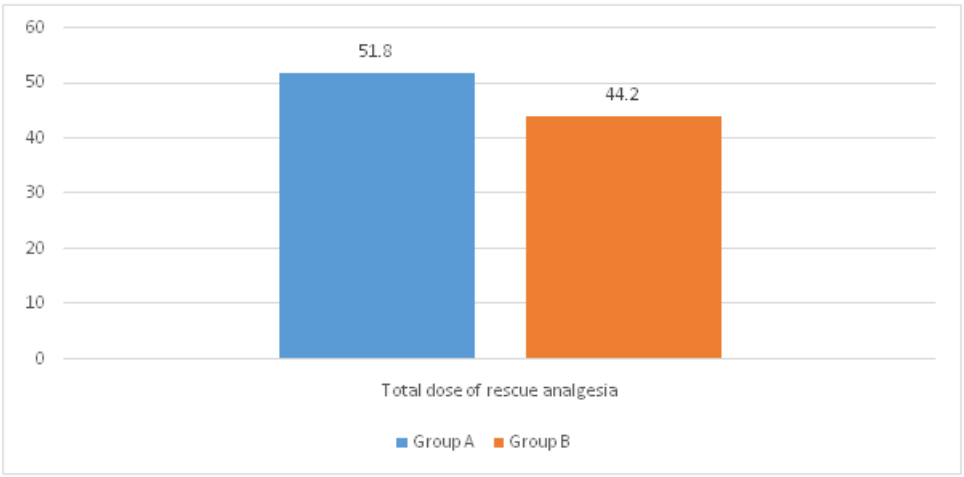

Figure 6: Comparison of two groups with respect to their total dose of rescue analgesia needed (mg) (n=100)

The present study included a total of 100 adult patients scheduled to undergo lower limb orthopaedic surgeries under spinal anaesthesia. These patients were evenly divided into two groups: Group A received intrathecal 0.5% bupivacaine heavy with 0.1 mL normal saline, while Group B received intrathecal 0.75% ropivacaine heavy combined with 10 µg (0.1 mL) dexmedetomidine.

The demographic profiles of the two groups were comparable. The mean age of participants in Group A was 45.6 ± 10.2 years, while in Group B it was 44.8 ± 11.1 years. Statistical analysis revealed no significant difference in age distribution between the two groups ($p = 0.708$). In terms of gender distribution, Group A included 28 males (56%) and 22 females (44%), whereas Group B comprised 30 males (60%) and 20 females (40%). The difference in sex distribution was not statistically significant ($p = 0.685$). Similarly, residential distribution showed that the majority of patients in both groups were from rural areas, with 56% in Group A and 54% in Group B, again with no statistically significant difference ($p = 0.841$).

Regarding the type of surgical procedure performed, the most common surgeries were hip arthroplasty and total knee replacement. Specifically, hip arthroplasty accounted for 26% of surgeries in Group A and 24% in Group B, while total knee replacement constituted 20% in Group A and 24% in Group B. Other surgeries included fracture femur repair, ankle surgery, and tibia fracture repair, with distribution among the groups being statistically non-significant ($p = 0.982$). The

mean duration of surgery was also comparable between the groups, measuring 126.5 ± 14.5 minutes in Group A and 120.4 ± 14.8 minutes in Group B. The difference was not statistically significant (p = 0.098). The onset of sensory block occurred at 4.2 ± 0.5 minutes in Group A and 4.1 ± 0.8 minutes in Group B, with no significant difference between them (p = 0.702). Similarly, the onset of motor block was noted at 5.5 ± 0.5 minutes in Group A and 5.3 ± 0.4 minutes in Group B, which was also statistically non-significant (p = 0.083).

In summary, both groups were comparable in terms of demographic variables, type and duration of surgery, and the onset of sensory and motor blocks. This comparability provides a sound baseline for assessing the differential effects of the two drug regimens on duration of analgesia and other outcomes, as will be elaborated in the subsequent discussion.

Discussion

This study was conducted to compare the efficacy of intrathecal 0.5% bupivacaine heavy and 0.75% ropivacaine heavy combined with 10μg dexmedetomidine in lower limb orthopaedic surgeries. The parameters assessed included onset and duration of sensory and motor block, total duration of analgesia, and hemodynamic stability.

The baseline demographic characteristics—including age, sex, residence, and type of surgery—were well-balanced across the two study groups, ensuring a high level of comparability and minimizing the risk of confounding variables. In Group A (bupivacaine + saline), the mean age was 45.6±10.2 years, while in Group B (ropivacaine + dexmedetomidine), it was 44.8±11.1 years, with no statistically significant difference (p = 0.708). The sex distribution was also similar, with a near-equal representation of males and females in both groups (p = 0.685). Additionally, residence distribution was consistent, with slightly more rural participants in each group but no significant disparity. The types of surgeries performed—including total knee replacement, hip arthroplasty, ankle surgeries, and fracture repairs—were distributed similarly between the groups (p = 0.982). This homogeneity in baseline parameters enhances the internal validity of the study, as differences in outcomescan more confidently be attributed to the anaesthetic regimens rather than demographic or procedural variability. When comparing the onset times of sensory and motor block between the groups, no significant differences were observed. The mean sensory block onset time in Group A was 4.2±0.5 minutes, compared to 4.1±0.8 minutes in Group B. Similarly, the onset of motor block was 5.5±0.5 minutes in Group A and 5.3±0.4 minutes in Group B. These minor variations were statistically insignificant, indicating that both bupivacaine and ropivacaine—with or without adjuvants—produced comparable onset profiles. Previous studies, including those by McNamee et al. and Whiteside et al., have reported similar findings, suggesting that the pharmacodynamics of these agents are alike in terms of initial action, even when adjuncts like dexmedetomidine are added.[9,10]

However, notable differences emerged in the duration of both sensory and motor blocks. Group B demonstrated a significantly prolonged sensory block duration of 226.6±44.1 minutes compared to 198.8±44.2 minutes in Group A (p<0.001). Although specific values for motor block duration are not quoted here, a similar trend was observed with a statistically significant prolongation in Group B. This effect is primarily attributed to dexmedetomidine, an alpha-2 adrenergic agonist known to enhance the duration of both sensory and motor blockade when used intrathecally. Studies by Ammou et al., Sarkar et al., and others have consistently shown that dexmedetomidine acts synergistically with local anaesthetics, prolonging the duration of nerve blockade by hyperpolarizing nerve tissues and inhibiting nociceptive transmission.[11,12,13]

The benefits of dexmedetomidine extended beyond block durations. Group B also exhibited significantly longer analgesia (278.4±51.2 minutes vs. 234.6±39.9 minutes in Group A) and a delayed time to first rescue analgesia (298.9±11.8 minutes vs. 247.6±12.1 minutes). Additionally, patients in Group B required a lower total dose of rescue analgesia (44.2±9.4 mcg) compared to Group A (51.8±10.8 mcg). These findings are consistent with previous reports by Campbell et al. and Mohamed et al., which highlight the analgesia-prolonging and opioid-sparing effects of dexmedetomidine, improving patient comfort and reducing postoperative analgesic requirements.[14,15]

In terms of intraoperative safety, hemodynamic parameters—including heart rate, blood pressure, and respiratory rate—remained stable across both groups. No statistically significant differences were noted at multiple intraoperative time points, suggesting that the inclusion of dexmedetomidine did not compromise cardiovascular stability. This aligns with prior studies by McNamee et al. and Maratha et al., which reported similar stability with both bupivacaine and ropivacaine during spinal anaesthesia.[9,16] Adverse events such as hypotension, bradycardia, nausea, or sedation were infrequent and comparable between the two groups, with no significant difference observed (p=0.347). This indicates that the addition of dexmedetomidine did not elevate the risk of side effects, confirming findings from Whiteside et al.

and Ammar et al., who reported similar safety profiles with its intrathecal use.[10,11]

Conclusion

It was seen that while both bupivacaine and ropivacaine provided effective spinal anaesthesia, the addition of dexmedetomidine to ropivacaine significantly prolonged postoperative analgesia without compromising patient safety or delaying recovery. This combination may offer an advantageous alternative in clinical settings where prolonged pain relief and early mobilization are desired. Further studies with larger sample sizes and varied surgical populations are recommended to validate these findings and explore long-term outcomes.

References

1. Raja SN, Carr DB, Cohen M, Finnerup NB, Flor H, Gibson S, et al. The revised International Association for the Study of Pain definition of pain: concepts, challenges, and compromises. Pain. 2020;161(9):1976-82.
2. Moro ET, da Silva MA, Couri MG, da Silva Issa D, Barbieri JM. Quality of recovery from anesthesia in patients undergoing orthopedic surgery of the lower limbs. Brazilian Journal of Anesthesiology (English Edition). 2016; 66(6): 642-50.
3. Smith LM, Cozowicz C, Uda Y, Memtsoudis SG, Barrington MJ. Neuraxial and combined neuraxial/general anesthesia compared to general anesthesia for major truncal and lower limb surgery: a systematic review and meta-analysis. Anesthesia& Analgesia. 2017; 125(6):1931-45.
4. Vyas KS, Rajendran S, Morrison SD, Shakir A, Mardini S, Lemaine V, et al. Systematic review of liposomal bupivacaine (Exparel) for postoperative analgesia. Plastic and Reconstructive Surgery. 2016;138(4):748e-56e.
5. Sun N, Wang S, Ma P, Liu S, Shao A, Xiong L. Postoperative analgesia by a transversus abdomen is plane block using different concentrations of ropivacaine for abdominal surgery: a meta-analysis. The Clinical Journal of Pain. 2017;33(9):853-63.
6. Reinikainen M, Syväoja S, Hara K. Continuous wound infiltration with ropivacaine for analgesia after caesarean section: a randomised, placebo-controlled trial. Acta Anaesthesiologica Scandinavica. 2014; 58(8): 973-9.
7. Lee S. Dexmedetomidine: present and future directions. Korean Journal of Anesthesiology. 2019;72(4):323.
8. Zhang X, Wang D, Shi M, Luo Y. Efficacy and safety of dexmedetomidine as an adjuvant in epidural analgesia and anesthesia: a systematic review and meta-analysis of randomized controlled trials. Clinical Drug Investigation. 2017;37:343-54.
9. McNamee DA, McClelland AM, Scott S, Milligan KR, Westman L, Gustafsson U. Spinal anaesthesia: comparison of plain ropivacaine 5 mg ml–1 with bupivacaine 5 mg ml–1 for major orthopaedic surgery. British Journal of Anaesthesia. 2002;89(5):702-6.
10. Whiteside JB, Burke D, Wildsmith J.A. Comparison of ropivacaine 0.5% (in glucose 5%) with bupivacaine 0.5% (in glucose 8%) for spinal anaesthesia for elective surgery. British Journal of Anaesthesia. 2003; 90(3): 304-8.
11. Ammar AS, Mahmoud KM. Ultrasound-guided single injection infraclavicular brachial plexus block using bupivacaine alone or combined with dexmedetomidine for pain control in upper limb surgery: A prospective randomized controlled trial. Saudi Journal of Anaesthesia. 2012;6(2):109.
12. Sarkar A, Baflia NS, Singh RB, Rasheed MA, Choubey S, Arora V. Comparison of epidural bupivacaine and dexmedetomidine with bupivacaine and fentanyl for postoperative pain relief in lower limb orthopaedic surgery. Anesthesia Essays and Researches. 2018;12(2):572-80.
13. Rahimzadeh P, Faiz SH, Imani F, Derakhshan P, Amini S. Comparative addition of dexmedetomidine and fentanyl to intrathecal bupivacaine in orthopedic procedure in lower limbs. BMC Anesthesiology. 2018;18:1-7.
14. Campbell DC, Zwack RM, Crone LA, Yip RW. Ambulatory labor epidural analgesia: bupivacaine versus ropivacaine. Anesthesia & Analgesia. 2000;90(6):1384-9.
15. Mohamed T, Susheela I, Balakrishnan BP, Kaniyil S. Dexmedetomidine as adjuvant to lower doses of intrathecal bupivacaine for lower limb orthopedic surgeries. Anesthesia Essays and Researches. 2017;11(3):681-5.
16. Maratha V, Kapil M, Kumar S, Dhamija A, Manchanda J. Comparative evaluation of ropivacaine versus dexmedetomidine and ropivacaine in epidural anesthesia in lower limb orthopaedic surgeries. International Archives of Integrated Medicine. 2016; 3(10): 36-41.