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Comparison Of 0.75% Ropivacaine Versus 0.75% Ropivacaine with Dexmedetomidine in Epidural Anaesthesia in Elective Lower Limb Surgeries: A Randomized Double-Blind Study

Dr. Dropadi Choudhary[1], Dr. Rakesh Kumar Nigam[2], Dr. Surbhi Banjare[3], Dr. Madhumita G. Murthy[4], Dr. Sakshi Rathore[5], Dr. Sheetal Das[6]

[1]PG resident, Department of Anaesthesia, Chhattisgarh Institute of Medical Sciences
[2]Professor and HOD, Department of Anaesthesia, Rajmata Shrimati Devendra Kumari Singhdeo Government Medical College, Ambikapur (Surguja), Chhattisgarh.
[3]Assistant Professor, Department of Anaesthesia, Chhattisgarh Institute of Medical Sciences
[4]Professor and HOD, Department of Anaesthesia, Chhattisgarh Institute of Medical Sciences
[5]PG resident, Department of Anaesthesia, Chhattisgarh Institute of Medical Sciences
[6]Assistant Professor, Department of Anaesthesia, Chhattisgarh Institute of Medical Sciences

Corresponding Author:

Dr. Dropadi Choudhary
PG resident, Department of Anaesthesia
Chhattisgarh Institute of Medical Sciences

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ABSTRACT

Background Epidural anaesthesia is widely used for lower limb surgeries because it provides effective intraoperative anaesthesia and prolonged postoperative analgesia. Addition of adjuvants such as dexmedetomidine to local anaesthetics may enhance block characteristics and improve postoperative pain relief.
Aim To compare the efficacy of 0.75% ropivacaine alone and 0.75% ropivacaine with dexmedetomidine for epidural anaesthesia in elective lower limb surgeries.
Materials and Methods This randomized double-blind study was conducted in 60 patients aged 18–65 years belonging to ASA grade I and II undergoing elective lower limb surgeries. Patients were randomly divided into two groups of 30 each. Group R received 20 ml of 0.75% ropivacaine with 2 ml normal saline, whereas Group RD received 20 ml of 0.75% ropivacaine with dexmedetomidine 1 µg/kg diluted in 2 ml normal saline epidurally. Sensory and motor block characteristics, haemodynamic parameters, sedation score, postoperative pain score using Visual Analogue Scale (VAS), duration of analgesia, rescue analgesic requirement, and complications were assessed and compared.
Results The onset of sensory block was significantly faster in Group RD (13.16 ± 2.4 minutes) compared to Group R (19.83 ± 1.57 minutes) (p=0.0001). Similarly, onset of Grade 3 motor block was earlier in Group RD (16.3 ± 2.2 minutes) than Group R (21.3 ± 2.86 minutes) (p=0.0001). Duration of motor block was significantly prolonged in Group RD (18.8 ± 1.86 hours) compared to Group R (11.3 ± 1.84 hours). Mean time to first rescue analgesia was significantly longer in Group RD (627.6 ± 122.4 minutes) compared to Group R (375.6 ± 43.2 minutes) (p=0.0001). Sedation scores were significantly higher and postoperative VAS scores were lower in Group RD. Haemodynamic parameters remained stable in both groups, although mild bradycardia and hypotension were more common in Group RD. No major adverse effects were observed.
Conclusion Addition of dexmedetomidine to epidural ropivacaine significantly improves sensory and motor block characteristics, prolongs postoperative analgesia, reduces rescue analgesic requirement, and provides better sedation with acceptable haemodynamic stability. Dexmedetomidine appears to be an effective and safe epidural adjuvant for elective lower limb surgeries.

Keywords: *Epidural anaesthesia, Ropivacaine, Dexmedetomidine, Lower limb surgery, Postoperative analgesia, Sensory block, Motor block, Visual Analogue Scale (VAS).*

INTRODUCTION

Pain is defined as an unpleasant sensory and emotional experience associated with, or resembling that associated with actual or potential tissue damage.[1] It is one of the most common and distressing symptoms experienced by patients undergoing surgical procedures. Inadequate perioperative pain control may result in exaggerated neuroendocrine stress response, sympathetic overactivity, delayed ambulation, prolonged hospital stay, increased postoperative morbidity, and poor patient satisfaction.[2] Acute postoperative pain, if inadequately managed, may also progress to chronic pain syndromes, thereby adversely affecting the quality of life and functional recovery of patients.[3,4] Hence, effective perioperative pain management remains a fundamental responsibility of the anaesthesiologist and plays a crucial role in enhanced recovery after surgery protocols.Orthopaedic surgeries involving the lower limbs are commonly associated with significant postoperative pain due to extensive tissue manipulation, periosteal injury, and muscle dissection. Adequate perioperative analgesia in such procedures not only improves patient comfort but also facilitates early mobilization, rehabilitation, and reduction in postoperative complications such as deep vein thrombosis and pulmonary complications.[5] Regional anaesthesia techniques, particularly epidural anaesthesia, are widely preferred in lower limb orthopaedic surgeries because of their ability to provide excellent intraoperative anaesthesia along with prolonged postoperative analgesia. Epidural anaesthesia offers several advantages including segmental blockade, reduced surgical stress response, lower blood loss, decreased thromboembolic events, and improved cardiopulmonary stability.[5]The use of epidural catheters also permits continuous administration of local anaesthetics and adjuvant drugs, thereby extending postoperative pain relief and reducing the requirement of systemic opioids. Epidural analgesia has become an integral component of modern orthopaedic anaesthesia practice because it provides effective sensory blockade while allowing preservation of respiratory function and early postoperative recovery.[5] However, the quality and duration of epidural blockade depend largely on the local anaesthetic agent used and the addition of suitable adjuvants.Among the available local anaesthetic agents, Ropivacaine is a long-acting amide local anaesthetic that has gained widespread popularity due to its favourable pharmacological profile. It is a pure S(-) enantiomer structurally related to bupivacaine but possesses reduced cardiotoxicity and neurotoxicity.[6] Ropivacaine preferentially blocks sensory nerve fibres over motor fibres, thereby providing effective analgesia with relatively less motor blockade, which is particularly advantageous in orthopaedic procedures requiring early mobilization.[7] In comparison with bupivacaine, ropivacaine has been shown to produce similar analgesic efficacy with improved safety and haemodynamic stability.[6,7]To further enhance the efficacy of epidural anaesthesia, various adjuvants have been combined with local anaesthetic agents. The addition of adjuvants helps in reducing the dose requirement of local anaesthetics, hastening the onset of blockade, prolonging the duration of analgesia, improving block quality, and minimizing adverse effects.[8] Commonly used epidural adjuvants include opioids, clonidine, dexamethasone, neostigmine, and alpha-2 adrenergic agonists.[8]Among these, Dexmedetomidine has emerged as a promising adjuvant in regional anaesthesia. Dexmedetomidine is a highly selective alpha-2 adrenergic receptor agonist possessing sedative, analgesic, anxiolytic, and sympatholytic properties.[9] Its analgesic action is mediated through activation of alpha-2 receptors in the dorsal horn of the spinal cord, resulting in inhibition of substance P release and modulation of nociceptive transmission.[10] When administered epidurally as an adjuvant to local anaesthetics, dexmedetomidine has been reported to hasten the onset of sensory and motor blockade, prolong the duration of analgesia, reduce postoperative analgesic consumption, and provide better haemodynamic stability.[11,12] In addition, dexmedetomidine produces a unique form of cooperative sedation without significant respiratory depression, making it a useful adjunct in regional anaesthesia techniques.[13]Several studies have evaluated the efficacy of dexmedetomidine as an adjuvant to epidural local anaesthetics in various surgical procedures, demonstrating improved quality of anaesthesia and prolonged postoperative pain relief.[9-13] However, limited data are available regarding its use with 0.75% ropivacaine in elective lower limb orthopaedic surgeries. Therefore, the present study was undertaken to compare the efficacy of 0.75% ropivacaine alone with 0.75% ropivacaine combined with dexmedetomidine for epidural anaesthesia in elective lower limb surgeries.

MATERIALS AND METHODS

This randomized double-blind comparative study was conducted in the Department of Anaesthesiology at Chhattisgarh Institute of Medical Sciences, Bilaspur, Chhattisgarh. The study was initiated after obtaining approval from the Institutional Ethics Committee and Scientific Research Review Committee. The study was carried out in patients undergoing elective lower limb surgeries in the major operation theatre complex and was continued until the required sample size was achieved.A total of 60 patients scheduled for elective lower limb surgeries under epidural anaesthesia were enrolled in the study.

Inclusion Criteria

Patients fulfilling the following criteria were included in the study:

- Patients willing to provide valid informed written consent
- Patients aged between 18 and 65 years
- Patients of either gender
- ASA physical status grade I and II
- Patients scheduled for elective lower limb surgeries

Exclusion Criteria
Patients with the following conditions were excluded from the study:

- Bleeding disorders or anticoagulant therapy
- Infection at the site of injection
- Spinal deformity
- Morbid obesity
- Neuromuscular or neurological disorders
- Psychological disorders
- Chronic analgesic therapy
- Hypersensitivity to study drugs

Pre-Anaesthetic Evaluation
All patients underwent a detailed pre-anaesthetic check-up one day prior to surgery, which included complete medical history, general physical examination, systemic examination, airway assessment, and spinal examination. Relevant laboratory investigations were reviewed and recorded. A lignocaine sensitivity test was performed on the day of surgery and confirmed to be negative.Patients fulfilling the inclusion criteria were explained about the purpose of the study, procedure, merits and demerits of epidural anaesthesia, and interpretation of the Visual Analogue Scale (VAS) score in their own language. Written informed consent was obtained from all patients. Patients were advised fasting for solids and liquids for 6 hours prior to surgery.

Study Groups
Patients were randomly allocated into two groups:

- Group R (n = 30): Received 20 ml of 0.75% ropivacaine with 2 ml normal saline epidurally.
- Group RD (n = 30): Received 20 ml of 0.75% ropivacaine with dexmedetomidine 1 μg/kg diluted in 2 ml normal saline epidurally.

The total volume of drug administered was maintained at 22 ml in both groups.

Anaesthetic Procedure
In the operation theatre, standard monitors including non-invasive blood pressure (NIBP), electrocardiography (ECG), and pulse oximetry (SpO_2) were attached and baseline parameters were recorded. Intravenous access was secured using an 18G/20G cannula and preloading was performed with Ringer lactate solution at 10–15 ml/kg body weight.

Injection glycopyrrolate 0.2 mg intramuscularly was administered 30 minutes prior to the procedure. Premedication with injection ondansetron 4 mg intravenously was given immediately before the procedure.

Under strict aseptic precautions, epidural anaesthesia was administered in the sitting position using a midline approach at the L3–L4 intervertebral space (L2–L3 in case of difficulty). Skin infiltration was done with 2% lignocaine with adrenaline. Epidural space was identified using an 18G Tuohy needle by the loss of resistance technique. The epidural catheter was advanced 3–4 cm into the epidural space and fixed securely.

After negative aspiration, a test dose of 3 ml of 2% lignocaine with adrenaline (1:200,000) was administered to exclude intrathecal or intravascular catheter placement. Following confirmation, the study drug was administered slowly through the epidural catheter. Oxygen supplementation at 4–5 L/min was provided to all patients via face mask.

Assessment of Block Characteristics
Sensory block was assessed using a pinprick test with a 22G hypodermic needle every 2 minutes until the T10 dermatome level was achieved and subsequently every 5 minutes until stabilization of block height.
Motor block was assessed every 5 minutes up to 30 minutes using the Modified Bromage Scale:

- Grade 0 – Full movement of hip, knee, and ankle
- Grade 1 – Inability to move hip; able to move knee and ankle
- Grade 2 – Inability to move hip and knee; able to move ankle
- Grade 3 – Complete motor block

Surgical incision was permitted only after achieving sensory block up to T8 dermatome and Grade 3 motor block.

Sedation Assessment
Sedation was assessed using the Modified Ramsay Sedation Scale at 10-minute intervals during the first 30 minutes and thereafter every 15 minutes until completion of surgery.

Postoperative Pain Assessment
Pain was assessed using the Visual Analogue Scale (VAS). VAS scores were recorded preoperatively, intraoperatively, and postoperatively at half-hour intervals during the first hour, hourly for the next 12 hours, and then every 3 hours up to 24 hours.

Rescue analgesia was administered when the VAS score was ≥5 in the form of intravenous diclofenac sodium 75 mg or intravenous tramadol 50 mg slow injection if required. Time to first rescue analgesia, total number of rescue analgesic doses, and timing of repeated doses were recorded.

Injection ondansetron 4 mg intravenously was used for the treatment of nausea and vomiting whenever required.

Dropout Criteria
Patients were excluded from analysis if:

- Sensory block did not reach T10 dermatome within 30 minutes
- Grade 3 motor block was not achieved within 30 minutes
- Patients experienced pain intraoperatively requiring conversion to general anaesthesia

All such cases were considered as failed or partial epidural blocks and converted to general anaesthesia.

Study Variables
Independent Variables

- Age
- Gender
- ASA grade
- Ropivacaine
- Dexmedetomidine

Dependent Variables

- Heart rate
- Systolic blood pressure
- Diastolic blood pressure
- SpO_2
- Sensory block characteristics
- Motor block characteristics
- Visual Analogue Scale (VAS) score
- Ramsay Sedation Score

Statistical Analysis
All collected data were entered into Microsoft Excel (Windows 7, Version 2007) and analysed using SPSS software version 22.0. Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were expressed as frequency and percentage.

Comparison of continuous variables between the two groups was performed using Student's t-test, whereas categorical variables were analysed using the Chi-square test. A p-value <0.05 was considered statistically significant.

RESULTS
A total of 60 patients undergoing elective lower limb surgeries under epidural anaesthesia were included in the present study. The patients were randomly allocated into two equal groups of 30 patients each. Group R received 0.75% ropivacaine alone, whereas Group RD received 0.75% ropivacaine with dexmedetomidine.The baseline demographic and clinical characteristics of the study participants are presented in Table 1 and Figure 1. The mean age of patients in Group R was 33.8 ± 8.97 years, while in Group RD it was 38.4 ± 11.4 years. Male patients predominated in both groups, accounting for 83.3% in Group R and 76.7% in Group RD. The mean height and weight of patients were comparable between the groups. Similarly, ASA physical status and Mallampati grading showed no statistically significant difference between the two groups (p>0.05), indicating that both groups were demographically comparable at baseline (Table 1, Figure 1).

Table 1: Baseline Demographic and Clinical Characteristics of Study Participants

Variable	Group R (n=30)	Group RD (n=30)	p-value
Age (years), Mean ± SD	33.8 ± 8.97	38.4 ± 11.4	0.000
Male	25 (83.3%)	23 (76.7%)	0.518
Female	5 (16.7%)	7 (23.3%)	
Height (cm), Mean ± SD	167.30 ± 8.28	167.13 ± 6.56	0.931

Weight (kg), Mean ± SD	64.60 ± 7.86	66.33 ± 6.78	0.364
ASA Grade I	17 (56.7%)	20 (66.7%)	0.278
ASA Grade II	13 (43.3%)	10 (33.3%)	
Mallampati Grade I	17 (56.7%)	17 (56.7%)	1.000
Mallampati Grade II	13 (43.3%)	13 (43.3%)	

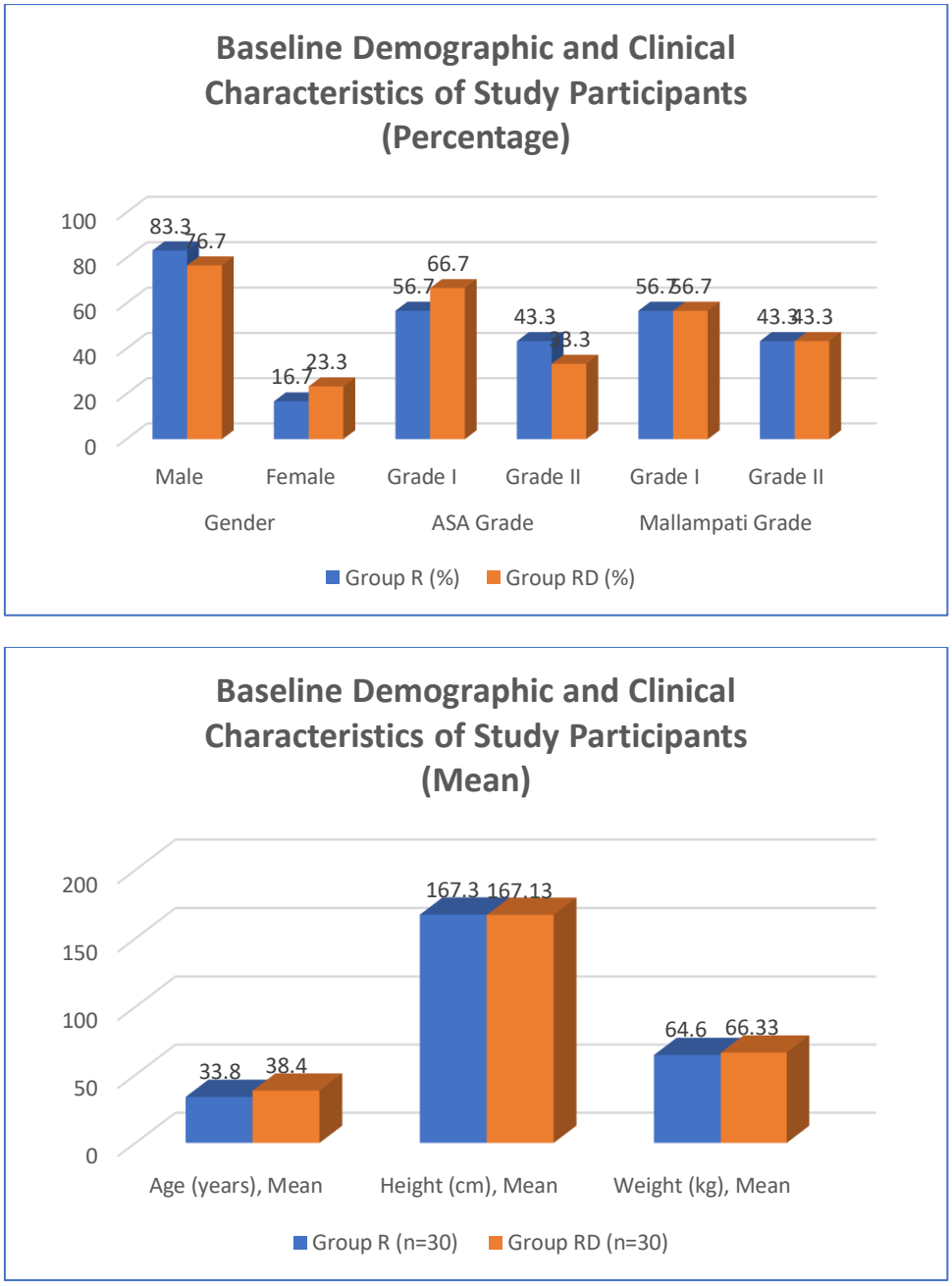

Figure 1 Baseline Demographic and Clinical Characteristics of Study Participants

The comparison of sensory and motor block characteristics between the groups is shown in Table 2 and Figure 2. The mean time to onset of T8 sensory block was significantly shorter in Group RD (13.16 ± 2.40 minutes) compared to Group R (19.83 ± 1.57 minutes), which was statistically highly significant (p=0.00001). Likewise, the onset of Grade 3 motor block was significantly faster in Group RD (16.3 ± 2.20 minutes) than in Group R (21.3 ± 2.86 minutes). The duration of motor block was markedly prolonged in Group RD (18.8 ± 1.86 hours) compared to Group R (11.3 ± 1.84 hours). Two-segment regression time was also significantly prolonged in Group RD. These findings indicate that addition of dexmedetomidine to ropivacaine significantly improved the quality and duration of epidural blockade (Table 2, Figure 2).

Table 2: Comparison of Sensory and Motor Block Characteristics Between the Groups

Variable	Group R	Group RD	p-value
Mean time to onset of T8 sensory block (minutes)	19.83 ± 1.57	13.16 ± 2.40	0.00001

Mean time to onset of Grade 3 motor block (minutes)	21.3 ± 2.86	16.3 ± 2.20	0.00001
Two-segment regression time (hours)	2.5 ± 0.5	2.6 ± 0.5	0.00001
Duration of motor block (hours)	11.3 ± 1.84	18.8 ± 1.86	0.00001

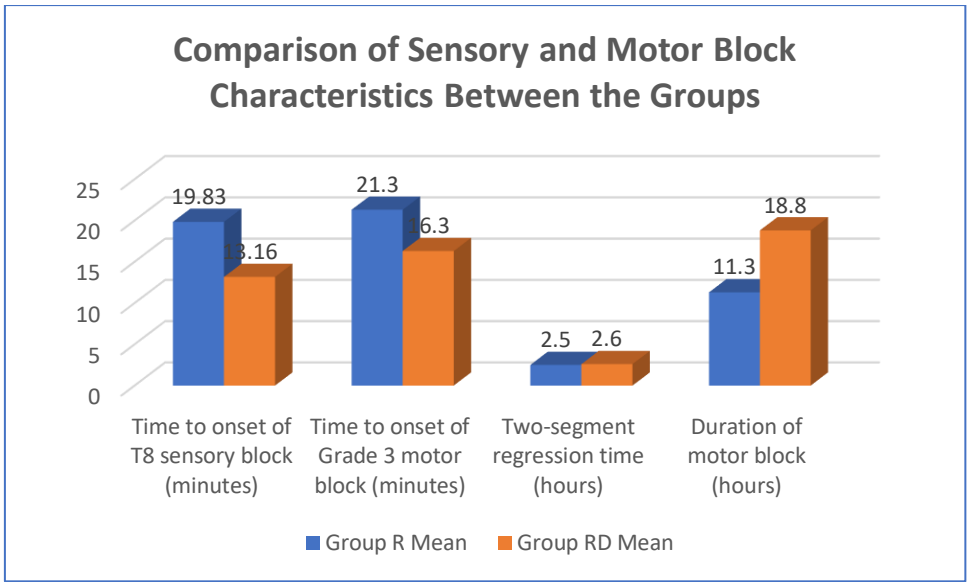

Figure 2 Comparison of Sensory and Motor Block Characteristics Between the Groups

Hemodynamic parameters among the two groups are summarized in Table 3. Baseline heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and oxygen saturation were comparable between the groups with no statistically significant difference ($p>0.05$). During the postoperative period, Group RD demonstrated comparatively lower heart rate and blood pressure values at several time intervals, indicating better hemodynamic stability. Significant reductions in heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure were observed in Group RD at multiple postoperative intervals ($p<0.05$). However, oxygen saturation remained stable and comparable throughout the study period in both groups without any clinically significant desaturation episodes (Table 3).

Table 3: Comparison of Hemodynamic Parameters Between the Groups

Parameter	Group R	Group RD	p-value
Baseline Heart Rate (beats/min)	85.90 ± 7.99	84.93 ± 8.56	0.653
Baseline Systolic BP (mmHg)	141.60 ± 6.45	139.90 ± 6.09	0.298
Baseline Diastolic BP (mmHg)	87.20 ± 3.17	86.33 ± 2.93	0.276
Baseline MAP (mmHg)	105.2 ± 3.7	104.2 ± 3.4	0.255
Baseline SpO_2 (%)	98.30 ± 0.70	98.47 ± 0.51	0.296
Significant postoperative reduction in HR, SBP, DBP and MAP	Less pronounced	More pronounced	<0.05 at multiple intervals
SpO_2 changes during study period	Stable	Stable	>0.05

The comparison of sedation, analgesia, and complications between the groups is depicted in Table 4. The mean time to first rescue analgesia was significantly prolonged in Group RD (627.6 ± 122.4 minutes) compared to Group R (375.6 ± 43.2 minutes), which was highly statistically significant ($p=0.0001$). All patients in Group R required three doses of rescue analgesia, whereas 40% of patients in Group RD required only two doses, indicating prolonged postoperative analgesia in the dexmedetomidine group. Bradycardia was observed in 10% patients in Group R and 23.3% patients in Group RD, although the difference was not statistically significant ($p=0.299$). Hypotension was observed only in Group RD in 10% patients, while shivering was noted only in Group R in 13.3% patients. No patients in either group developed nausea, vomiting, or local anaesthetic toxicity. Overall, both groups showed good safety profiles with manageable complications (Table 4).

Table 4: Comparison of Sedation, Analgesia, and Complications Between the Groups

Variable	Group R	Group RD	p-value
Mean time to first rescue analgesia (minutes)	375.6 ± 43.2	627.6 ± 122.4	0.0001
Patients requiring 2 rescue analgesic doses	0 (0%)	12 (40%)	0.0001
Patients requiring 3 rescue analgesic doses	30 (100%)	18 (60%)	
Bradycardia	3 (10%)	7 (23.3%)	0.299
Hypotension	0 (0%)	3 (10%)	NA

Shivering	4 (13.3%)	0 (0%)	NA
Nausea/Vomiting	0 (0%)	0 (0%)	NA
Local Anaesthetic Toxicity	0 (0%)	0 (0%)	NA

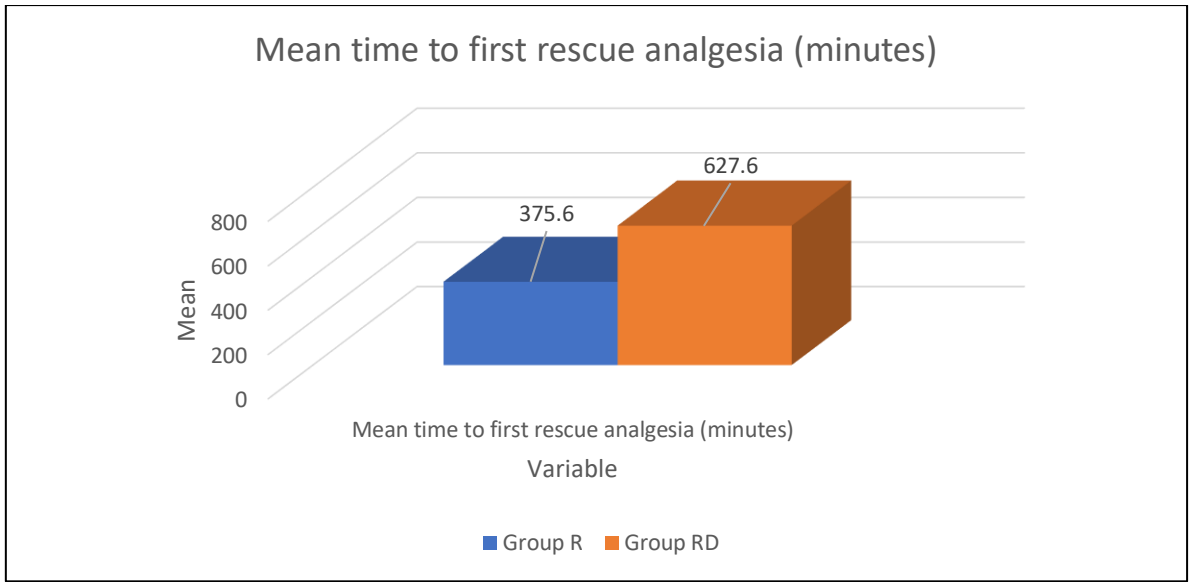

Figure **4:** Mean time to first rescue analgesia (minutes)

DISCUSSION

Epidural anaesthesia is an effective regional anaesthetic technique for lower limb surgeries because it provides excellent sensory and motor blockade, stable haemodynamics, prolonged postoperative analgesia, and early mobilization. Addition of adjuvants to local anaesthetics further improves block quality and duration of analgesia. Dexmedetomidine, a selective alpha-2 adrenergic agonist, enhances the effect of local anaesthetics through synergistic action at the spinal cord level, resulting in improved analgesia and sedation.In the present study, demographic variables including gender distribution, height, weight, ASA status, and Mallampati grading were comparable between the two groups. Male predominance was observed in both groups, with 83.3% males in Group R and 76.7% in Group RD. Similar baseline comparability was also reported by Gujral S et al.[14], Bajwa SJ et al.[5], and Singh M et al.[15].The onset of sensory block at T8 dermatome was significantly faster in Group RD (13.16 ± 2.4 minutes) compared to Group R (19.83 ± 1.57 minutes; p=0.0001). Similarly, onset of Grade 3 motor block was significantly earlier in Group RD (16.3 ± 2.2 minutes) compared to Group R (21.3 ± 2.86 minutes; p=0.0001). These findings suggest that dexmedetomidine accelerates epidural blockade through its synergistic action with ropivacaine. Similar findings were observed by Kiran S et al.[16], Soni P et al.[17], and Gujral S et al.[14], who also reported earlier onset of sensory and motor blockade with dexmedetomidine.Two-segment regression time was prolonged in Group RD (2.6 ± 0.5 hours) compared to Group R (2.5 ± 0.5 hours), indicating prolonged sensory blockade. Similar observations were reported by Shaikh SI et al.[18], Paul A et al.[19], and Karhade SS et al.[20]. The duration of motor block was also significantly prolonged in Group RD (18.8 ± 1.86 hours) compared to Group R (11.3 ± 1.84 hours; p=0.0001), which is comparable to findings by Shukla U et al.[8], Arunkumar et al.[21], and Singh M et al.[15]. Haemodynamic parameters remained stable in both groups during the intraoperative period. However, Group RD demonstrated significantly lower heart rate and blood pressure values during later postoperative hours due to the sympatholytic effect of dexmedetomidine. Similar mild reductions in heart rate and blood pressure without major instability were also reported by Bajwa SJ et al.[5], Soni P et al.[17], and Saravana Babu MS et al.[22].Sedation scores were significantly higher in Group RD from 10 minutes onward, producing cooperative and arousable sedation without respiratory depression. Comparable sedation profiles were reported by Channabasappa SM et al.[23], Karhade SS et al.[20], and Soni P et al.[17].Postoperative analgesia was significantly superior in Group RD. VAS scores remained lower in Group RD during multiple postoperative intervals, indicating prolonged analgesic action. The mean time to first rescue analgesia was significantly delayed in Group RD (627.6 ± 122.4 minutes) compared to Group R (375.6 ± 43.2 minutes; p=0.0001), demonstrating nearly 4 hours longer analgesia. Similar prolongation of postoperative analgesia was reported by Bajwa SJ et al.[24], Shukla U et al.[8], and Soni P et al.[17]. In addition, all patients in Group R required three rescue analgesic doses, whereas 40% of patients in Group RD required only two doses, indicating reduced analgesic consumption with dexmedetomidine. Similar findings were documented by Gujral S et al.[14] and Kiran S et al.[16].

Regarding complications, both groups showed acceptable safety profiles. Bradycardia was more common in Group RD (23.3%) compared to Group R (10%), though clinically manageable. Hypotension occurred only in Group RD, while shivering was observed only in Group R. No patients developed respiratory depression, nausea, vomiting, or local anaesthetic toxicity. Similar complication profiles were reported by Pallapati AP et al.[25], Kiran S et al.[16], and Soni P et al.[17].

CONCLUSION

The present study concludes that addition of dexmedetomidine to 0.75% ropivacaine for epidural anaesthesia in elective lower limb surgeries provides significantly faster onset of sensory and motor blockade, prolonged duration of analgesia, and reduced postoperative rescue analgesic requirement compared to ropivacaine alone. Dexmedetomidine also produced better sedation and satisfactory haemodynamic stability with minimal and manageable side effects. Thus, dexmedetomidine appears to be an effective and safe epidural adjuvant to ropivacaine for improving perioperative and postoperative analgesic outcomes in lower limb surgeries.

LIMITATIONS

The present study was conducted on a relatively small sample size at a single tertiary care centre, which may limit the generalizability of the findings. Long-term postoperative follow-up and assessment of chronic pain outcomes were not performed. The study was limited to ASA grade I and II patients undergoing elective lower limb surgeries; therefore, the results may not be applicable to high-risk patients or other surgical populations. Additionally, serum drug levels and detailed pharmacokinetic assessments were not evaluated.

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