

Original Research Article

COMPARATIVE STUDY OF EPIDURAL 0.75% ROPIVACAINE WITH DEXMEDETOMIDINE AND 0.75% ROPIVACAINE ALONE IN LOWER ABDOMINAL AND LOWER LIMB SURGERIES

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Received : 22/04/2025
Received in revised form : 02/06/2025
Accepted : 23/06/2025

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DOI: 10.70034/ijmedph.2025.3.20

Source of Support: Nil,
Conflict of Interest: None declared

Int J Med Pub Health
2025; 15 (3); 114-119

ABSTRACT

Background: Subarachnoid and epidural blocks are widely used regional anesthesia techniques for lower abdominal and limb surgeries. Epidural anesthesia offers effective surgical anesthesia, extended duration, and prolonged postoperative analgesia with fewer hemodynamic changes. Ropivacaine, a newer amide local anesthetic, has lower cardiovascular toxicity than Bupivacaine but causes less motor block. Dexmedetomidine, a highly selective α_2 agonist, provides sedation, stable hemodynamics, and prolonged analgesia. This study compares 0.75% Ropivacaine with and without Dexmedetomidine in epidural anesthesia for enhanced postoperative pain control.

Materials and Methods: One hundred patients, scheduled for various elective lower abdominal and lower limb surgical procedures belonging to ASA class I and II were included in the study. The patients were normotensive with ages varying from 18 to 65 years. The study population was randomly divided into two groups with 50 patients in each group Group R - 15ml of 0.75% Ropivacaine Group RD - 15ml of 0.75% Ropivacaine + 0.6 μ g/kg of Dexmedetomidine. Onset and duration of sensory blockade, Onset and duration of motor blockade, Haemodynamic changes, Maximum dermatomal level of analgesia, Intensity of motor blockade, and any adverse effects.

Results: The dexmedetomidine group had a rapid onset of action ($p < 0.05$), prolonged duration of sensory and motor block ($p < 0.05$), better sedation score and postoperative analgesia ($p < 0.05$), and more intense motor block ($p < 0.05$). There was no difference in the maximal dermatomal level of analgesia, incidence of hypotension, and bradycardia ($p > 0.05$). The occurrence of side effects (tremors, nausea, and $SpO_2 < 90\%$) was low and similar between groups ($p > 0.05$).

Conclusion: There is a clear synergism between Dexmedetomidine and Ropivacaine compared with plain Ropivacaine in epidural anesthesia without increased morbidity.

Keywords: Dexmedetomidine, Epidural Anaesthesia, Ropivacaine, Lower Abdominal Surgeries.

INTRODUCTION

Subarachnoid block and Epidural block are the most popular regional anesthesia techniques used for

lower abdominal and lower limb surgeries because of their efficacy and safety profiles. However, there are several limitations of such blocks which include short duration of action, and inability to extend

anesthesia for prolonged surgeries. There is a rapid onset of sympathetic blockade in cases which can cause profound hypotension and shorter postoperative analgesia. Moreover, it also carries the risk of post-dural puncture headache (PDPH) due to a dural breach.^[1] Due to these drawbacks, epidural anesthesia has gained preference in many surgical settings for its flexibility and improved safety. There are several advantages of epidural anesthesia,^[2] it is an effective surgical anesthesia and can be titrated to accommodate the prolonged demands of the surgical procedures. It offers prolonged postoperative pain relief and it does not cause hemodynamic disturbances as compared to SAB since it produces a segmental blockade and not a total sympathetic blockade. The next important benefit is the absence of PDPH since the dura mater is not pierced during the procedure.

Several anesthetics have been employed for epidural anesthesia,^[3] and the most popular in India are lidocaine and bupivacaine. Nonetheless, the intermediate duration of action of lidocaine and cardiotoxicity associated with bupivacaine following accidental intravascular injection because of its narrow cardiovascular/central nervous system (CV/CNS) toxicity margin,^[4] have led to the search for better alternatives. A few among them are ropivacaine and levobupivacaine these are newer long-acting amide local anesthetics with improved safety profile and reduced cardiac toxicity.^[4] Ropivacaine has become an active area of clinical interest based on its positive pharmacological characteristics. It offers a longer duration of action like bupivacaine besides much less cardiotoxicity, a factor that makes it an ideal agent in epidural anesthesia.^[5] Its effectiveness and safety have been indicated across several studies,^[6-10] as an epidural anesthetic. Richard Arthur et al,^[11] also observed that ropivacaine had lower potency to block A and B fibers as compared to bupivacaine, but was more effective at blocking A and C fibers, thereby having a better analgesic effect. Its less lipid solubility (2.9 against bupivacaine solubility of 3.9) can help it reduce CNS toxicity, which further explains why it was incorporated in the current research.

Even though ropivacaine offers sufficient sensory analgesia, the quality of depth and extent of analgesia may be inconsistent. Additionally, high doses of sedatives or general anesthesia used to ensure intraoperative comfort can defeat the purpose of regional techniques possibility of constant communication and interaction with the patient is lost.^[12] Thus, to increase the analgesia with local anesthetics, it is good to use adjuvants that sedate and are hemodynamically stable. The adrenergic agonists of α_2 adrenergic receptors such as clonidine and dexmedetomidine have been identified as useful adjuvants due to their sedative and analgesic properties. Dexmedetomidine is a selective α_2 agonist 8 times more affinity as clonidine. It potentiates the effects of local anesthetic by producing hyperpolarized nerves and

altering ion conductance at locus coeruleus. It also decreases the oxygen requirement and helps to stabilize the hemodynamics of the thus it is also an asset to the regional anesthesia regime. Because of these pharmacological advantages, we decided to conduct this study to compare the efficacy of 0.75% ropivacaine alone versus 0.75% ropivacaine with dexmedetomidine in epidural anesthesia for lower abdominal and lower limb surgeries.

MATERIALS AND METHODS

This cross-sectional observational study was carried out in the Department of Anesthesiology, SVS Medical College and Hospital, Mahabubnagar, Telangana. Institutional Ethical approval was obtained from the Ethical committee. Written consent was obtained from all the participants of the study after explaining the nature of the study in vernacular language.

Inclusion Criteria

1. Adult patients aged between 18 to 65 years.
2. Males and Females
3. Patients belonging to ASA class I and II were posted for elective lower abdominal and lower limb surgical procedures.
4. Weight > 50 kg
5. Height 150-180cms

Exclusion Criteria

1. The patient refused regional anesthesia.
2. Allergy to local anesthetics and Dexmedetomidine
3. Pregnancy and lactation.
4. Patients posted for Emergency surgeries.
5. Obese patients with BMI >30.
6. Raised intracranial pressure
7. Severe hypovolemia
8. bleeding coagulopathy
9. Local infection
10. Uncontrolled Hypertension/ Diabetes mellitus
11. Neurological disorders and deformities of the spine
12. Cardiac disease and Hepatic disease

One hundred patients, scheduled for various elective lower abdominal and lower limb surgical procedures belonging to ASA class I and II were included in the study. The study population was randomly divided using computer-generated randomization numbers into two groups with 50 patients in each group.

1. Group R (n=50) - 15ml of 0.75% Ropivacaine (Ropivacaine 0.75% preservative free)
2. Group RD (n=50) -15ml of 0.75% Ropivacaine + 0.6 μ g/kg of Dexmedetomidine

A routine pre-anesthetic examination was conducted on the evening before surgery, assessing the history and general condition of the patient and airway assessment by Mallampatti grading. Nutritional status, height, and weight of the patient. A detailed examination of the Cardiovascular system, Respiratory system, and Central nervous system and examination of the spine.

The following investigations were done in all patients Hemoglobin estimation, Bleeding time and clotting time, Fasting blood sugar, Blood urea and Serum creatinine, and Standard 12-lead electrocardiogram. The patients were premedicated with a tablet of Alprazolam 0.5 mg and a tablet of Ranitidine 150 mg orally at bedtime on the previous night before surgery. They were kept nil orally from 10 pm onwards on the previous night.

On the day of surgery, the patient's basal pulse rate and blood pressure were recorded. A peripheral intravenous line with an 18-gauge cannula after local anesthesia was secured in one of the upper limbs. All the patients were preloaded with 500 ml of Ringer lactate 30 minutes before the epidural procedure. A multiparameter monitor was connected which records heart rate, non-invasive measurement of systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), continuous electrocardiogram (ECG) monitoring and oxygen saturation (SPO2). With the patients in a sitting position under aseptic precautions, epidural space was identified by loss of resistance technique to air using an 18G Tuohy needle via the midline approach at either L2-3 or L3-4 interspinous space. An epidural catheter was threaded and fixed at 3 cm inside the epidural space. A test dose of 3 ml of 2% lignocaine with 1:200000 Adrenaline was injected through the catheter after aspiration. After ruling out intrathecal and intravascular placement of the tip of the catheter, the study drug was injected in increments of 5 ml. The patients were turned to the supine position after 1 minute.

Assessment of sensory and motor blockade was done at the end of each minute with the patient in the supine position after completion of the injection of 15 ml of the study drug, which is taken as the starting time. The onset time for sensory and motor block, the maximum level of sensory block, the intensity of motor block and sedation score were recorded. Sensory blockade was assessed using a short bevel 22-gauge needle and was tested in the midclavicular line on the chest, trunk, and lower limbs on either side. Motor blockade in the lower limbs was assessed using a modified Bromage scale. Measurements of blood pressure, heart rate, and oxygen saturation were recorded every 5 minutes till the end of 1 hour and then every 15 minutes till the end of surgery. Intraoperatively and postoperatively, complications like fall in blood pressure, variation in heart rate were noted, treated and tabulated. Hypotension is defined as a reduction of systolic blood pressure by more than 30% from basal systolic blood pressure or SBP less than 90 mmHg and is treated with an increased rate of intravenous

fluids and if needed injection of Mephentermine 3 mg (I.V) given in increments. Bradycardia (<60 beats/min) was treated with an injection of Atropine 0.6mg (I.V).

After the surgery, patients were shifted to the PACU (post-anesthesia care unit) where they remained until there was a complete recovery of sensory and motor blockade. Epidural top-up was given with 8ml of 0.2% inj. Ropivacaine once the patient complains of pain. Postoperatively vital parameters were recorded every 15 minutes, and also the duration of sensory and motor blockade, and any adverse events like nausea, vomiting, pruritis, and shivering were noted.

The onset of sensory blockade: is taken as the time from the completion of the injection of the study drug till loss of sensation at T10 level.

The onset of motor blockade: is taken from the completion of the injection of the study drug till the patient develops modified Bromage scale grade 1 motor blockade at T 10 dermatome.

Duration of motor block: is taken from the time of injection till the patient attains complete motor recovery (Bromage 0).

Duration of sensory block: is taken from the time of injection till the patient complains of pain at the T10 dermatome.

Statistical Analysis: All the available data was uploaded to an MS Excel spreadsheet and analyzed by SPSS version 23 in Windows format. The continuous variables were represented as frequency, mean, standard deviation, and percentages. The categorical variables were estimated by Pearson's chi-square test to determine differences between the two groups. The values of p (<0.05) were considered significant.

RESULTS

Table 1 presents the age-wise distribution of patients in both groups. The mean age of the group R was 36.55 ± 5.6 years versus group RD's 33.21 ± 8.7 years the differences between the mean age were ($p=0.857$) and not significant. The distribution of cases across the age groups was not statistically significant differences between Group R and Group RD ($p=0.432$). The minimum and maximum ages were comparable across both groups, indicating age homogeneity. This similarity in age distribution ensures that the observed outcomes of the study were not influenced by age as a confounding factor, making the comparison between groups valid.

Table 1: Age Distribution of Patients

Age Group (years)	Group R (n=50)	Group RD (n=50)	Total (%)
15-25	10 (20%)	8 (16%)	18
26-35	8 (16%)	11 (22%)	19
36-45	10 (20%)	11 (22%)	21
46-55	11 (22%)	12 (24%)	23
56-65	11 (22%)	8 (16%)	19
Total	50 (100%)	50 (100%)	100

Table 2 depicts the sex-wise distribution of cases in Group R and Group RD. Group R included 36 males and 14 females, while Group RD had 31 males and 19 females. Although there was a male predominance in both groups, the difference in sex distribution was not statistically significant ($p=$

0.322). This parity in gender distribution indicates that sex-related physiological differences are unlikely to have effects on the study outcomes, ensuring balanced representation across both groups.

Table 2: Sex Distribution

Sex	Group R (n=50)	Group RD (n=50)
Male	36 (72%)	31 (62%)
Female	14 (28%)	19 (38%)

The anthropometric measurements of the two groups of cases are depicted in Table 3. The analysis of the table shows that the mean body weight was slightly higher in Group R (58.64 ± 5.17 kg) compared to Group RD (56.10 ± 6.11 kg), the p values were ($p=0.27$) and not significant. Similarly,

we found no statistical difference between the mean values of height between the groups. These findings suggest that the groups were well-matched in terms of anthropometric parameters, which reduces the risk of bias due to physical constitution when evaluating anesthetic effects.

Table 3: Anthropometric Characteristics

Parameter	Group R (Mean \pm SD)	Group RD (Mean \pm SD)	p-value
Body Weight (kg)	58.64 ± 5.17	56.10 ± 6.11	0.27
Height (cm)	170.02 ± 8.6	169.03 ± 6.2	0.341
Height Range (cm)	150 - 180	152 - 180	

Table 4 presents the distribution of surgical procedures and the mean duration of surgeries. The most frequent surgical procedure was the management of fractures of the femur followed by inguinal hernioplasty and fractures of the tibia/fibula. The distribution of surgery types was

similar in both groups, and the mean duration of surgery did not differ significantly (Group R: 96.83 ± 27.49 mins; Group RD: 90.83 ± 23.12 mins). This suggests that the nature and duration of surgery were uniform across groups, thus controlling for surgical complexity as a variable.

Table 4: Type of Surgical Procedures and Duration

Type of Surgery	Group R (n=50)	Group RD (n=50)
Fracture of Tibia/Fibula	13 (26%)	12 (24%)
Femur of Fracture	25 (50%)	23 (46%)
Inguinal hernioplasty	12 (24%)	15 (30%)
Mean duration (mins)	96.83 ± 27.49	90.83 ± 23.12

Table 5 gives the onset and intensity of sensory and motor block in two groups. Group RD had a significantly faster onset of both sensory (5.26 ± 1.49 mins) and motor block (11.22 ± 2.61 mins) compared to Group R (10.04 ± 2.55 mins and 15.36 ± 3.28 mins, respectively), with $p<0.001$ for both.

While both groups reached high levels of sensory block, Group RD achieved more cephalad spread, with five patients reaching T5. The enhanced speed and extent of sensory-motor blockade in Group RD highlights the potentiating effect of dexmedetomidine.

Table 5: Onset and Intensity of Sensory and Motor Block

Parameter	Group R (Mean \pm SD)	Group RD (Mean \pm SD)	p-value
Sensory onset (mins)	10.04 ± 2.55	5.26 ± 1.49	$<0.001^*$
Motor onset (mins)	15.36 ± 3.28	11.22 ± 2.61	$<0.001^*$
Max Sensory Level - T5	0	5	0.10
Max Sensory Level - T6	31	38	
Max Sensory Level - T8	17	6	
Max Sensory Level - T10	2	1	

*Significant

Table 6 gives the intensity of motor block and sedation scores. Group RD demonstrated a more

intense motor block, with 16 patients achieving Bromage grade 4, compared to none in Group R

($p < 0.001$). Sedation was also significantly higher in Group RD, with most patients attaining scores of 3 or 4, while Group R patients largely remained at score 2 ($p = 0.001$). These findings confirm that

dexmedetomidine enhances both the depth of motor block and sedation, contributing to better intraoperative conditions and patient comfort.

Table 6: Motor Block Grade (Bromage Scale) and Sedation Scores

Bromage Grade	Group R	Group RD	p-value
2	15	0	<0.001*
3	35	34	0.35
4	0	16	<0.001*
Sedation Scores			
S1	17	0	0.001*
S2	33	15	
S3	0	29	
S4	0	6	

*Significant

The estimation of systolic blood pressure, diastolic blood pressure and mean arterial pressure was done in the cases at various intervals as given in Figure 1. There is no statistically significant difference in systolic blood pressure between both groups. 7 patients in group RD and 4 patients in group R developed hypotension which was treated with intravenous fluids and inj. Mephentermine. There is no statistically significant difference in diastolic blood pressure and mean arterial pressures between both the groups the values were not significant. There is no statistically significant difference in the mean heart rate between groups at various intervals. 4 patients in the RD group developed bradycardia which was treated with inj. Atropine 0.6mg and they recovered.

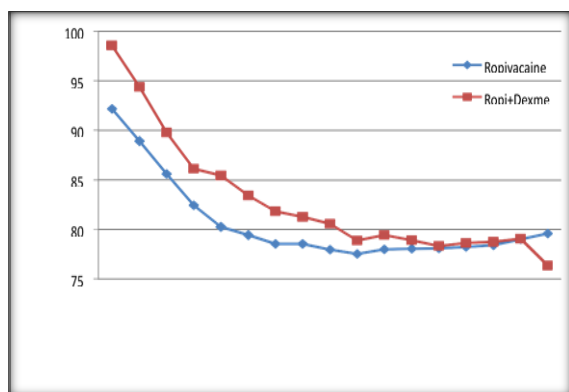


Figure 1: Shows mean arterial pressure (mmHg) at various time intervals

DISCUSSION

The present comparative study was done to evaluate the efficacy of 0.75% Ropivacaine alone versus 0.75% Ropivacaine with Dexmedetomidine as an adjuvant in epidural anesthesia for lower abdominal and lower limb surgeries. Ropivacaine is an amide type of local anesthetic that is preferred to bupivacaine due to its lower cardiotoxicity. However, ropivacaine at a lower concentration (0.5%) may not produce inadequate sensory and motor blockade. Therefore, we chose the ropivacaine concentration of 0.75% for our study to

ensure adequate block quality. Dexmedetomidine is a highly selective α_2 -adrenergic agonist it is used as a potent adjuvant in regional anesthesia. Its sedative, analgesic as well as sympatholytic properties enhance the action of local anesthesia. Several studies conducted in this have shown its efficacy and safety.^[13-17] However, there is limited data available from Indian studies with ropivacaine in epidural use. Dexmedetomidine tends to cause hypotension due to its sympatholytic actions at $1\mu\text{g/Kg}$ dose therefore we used a reduced dose of $0.6\mu\text{g/Kg}$ in our study.

Ropivacaine has lower lipid solubility (partition coefficient 9 vs. 2.89 for Dexmedetomidine) it supports more selective sensory blocking. However, its motor-blocking profile improves when combined with dexmedetomidine.^[18] We found that the combination used in our study showed statistically significant reductions in sensory (5.26 ± 1.49 vs. 10.04 ± 2.55 mins) and motor block onset times (11.22 ± 2.61 vs. 15.36 ± 3.28 mins). The duration of sensory block in this study was 359.30 ± 61.94 mins and motor block (233.70 ± 15.36 mins) was significantly prolonged in the combination group compared to the Ropivacaine group. The results of this study are in concordance with the observations of Bajwa et al,^[19] and Chinnappa et al,^[20] who observed superior block characteristics and sedation scores with Dexmedetomidine. Additionally, the combination group showed a greater proportion of intense motor block (Bromage 4) and deeper sedation scores (S4). Assessment of the hemodynamic stability of our cohort showed that both groups were hemodynamically stable although bradycardia and hypotension occurred in the dexmedetomidine group. These cases were effectively managed with atropine and mephentermine, respectively, and did not lead to significant clinical concern. Overall, the side effect was found to occur similarly in both groups and was manageable this supports the safety profile of dexmedetomidine in the studied dosage.

CONCLUSION

In conclusion, we found that the addition of Dexmedetomidine to 0.75% Ropivacaine for epidural anesthesia significantly improves block quality, reduces onset time, and prolongs the duration of both sensory and motor blockade. Dexmedetomidine also enhances sedation without any adverse hemodynamic effects at 0.6µg/kg. Therefore, dexmedetomidine appears to be a valuable and effective adjuvant to ropivacaine in epidural anesthesia for lower abdominal and lower limb surgeries. Although cases may require careful monitoring for potential side effects of bradycardia or hypotension the combination is considered as safe and efficacious for clinical use

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