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Original Research Article

A Comparative Evaluation of Epidural Anesthesia with Ropivacaine Combined with Dexmedetomidine versus Plain Ropivacaine for Lower Limb Surgeries

Muppidi Dilip Kumar[1], Mrunalini Alugolu[2], Gouthami M.[3], Polugari Anand Vijaya Bhasker[4]

[1]Assistant Professor, Department of Anesthesiology, Kakatiya Medical College, and MGM Hospital, Hanumakonda, Warangal

[2]Associate Professor, Department of Anesthesiology, Government Medical College, Vikarabad, Telangana State.

[3]Associate Professor, Department of Anesthesiology, Government Medical College, and Hospital, Kamareddy, Telangana State.

[4]Associate Professor, Department of Anesthesiology, Government Medical College, and Hospital, Jangoan, Telangana State.

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Corresponding Author: Dr. Polugari Anand Vijaya Bhasker

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Abstract

Background: Epidural administration of ropivacaine offers effective analgesia, minimal motor blockade, and cardiac stability. The incorporation of adjuncts such as dexmedetomidine extends the duration of analgesia, prolongs motor blockade, and ensures sufficient sedation. Our research directly compares the effects of ropivacaine alone versus ropivacaine combined with dexmedetomidine on block characteristics, postoperative pain relief, and sedation levels.

Methods: A total of 60 cases were identified and included in the study during the duration of the study. They were equally and randomly allotted by a computer-generated random number into one of the two groups. Group I (n=30) received 15 ml of 0.75% ropivacaine (Ropivacaine 0.75% preservative-free 0.75% 20 ml ampoules. Group RD (Number of patient-50) 15ml of 0.75% ropivacaine + 0.6µg/kg of dexmedetomidine (inj.1ml = 100µg, 1ml ampoule).

Results: There were no significant differences between the two groups regarding age, sex, height, weight, or body mass index. On average, Group II achieved a slightly higher level of sensory block, but the difference wasn't statistically significant. Group I experienced a more complete motor block (no leg movement) compared to Group II. Patients in Group II had deeper sedation levels compared to Group I. The sensory and motor blocks lasted significantly longer in Group II compared to Group I. Group II experienced a significantly faster onset of both sensory and motor blocks compared to Group I. Overall, the findings suggest that adding Dexmedetomidine to Ropivacaine (Group II) might lead to deeper sedation but result in a less complete motor block compared to using Ropivacaine alone (Group I).

Conclusion: The Dexmedetomidine group exhibited a rapid onset of action, prolonged duration of sensory and motor block, improved sedation scores, and a more pronounced motor block. No difference was noted in the maximal dermatomal level of analgesia, and any associated side effects such as bradycardia and hypotension did not pose significant challenges to the hemodynamic profile.

Keywords: Ropivacaine, Dexmedetomidine, Sedation Score, Bromage Score, Hemodynamic Profile.

Introduction

Epidural blockade has become an increasingly common procedure, both for providing anesthesia and relieving pain during and after surgeries. Epidural anesthesia is perfect for lower limb surgeries, pelvis and perineum surgeries, and lower abdomen. It allows ongoing anesthesia through the use of the epidural catheter and is perfect for surgeries that take a lot of time. Furthermore, the utilization of epidural anesthesia can diminish the use of intravenous pain medications during the follow-up phase, for which the main benefit is the provision of pain relief [1-3]. Ropivacaine, a long-acting amide local anesthetic from Bupivacaine, is reported to have fewer cardiovascular effects than

bupivacaine. [4] Nevertheless, ropivacaine needs to have higher dosages administered to obtain the required analgesic and anesthetic effects. Dexmedetomidine in addition to ropivacaine can facilitate the reduction in the amount of drug required and the use of more dilute solutions which both increase the effect of painkilling as well as lower the side effects of the higher doses of ropivacaine [5] Besides opioids, ketamine, and α2 agonists like clonidine and dexmedetomidine which are all adjuvants to local anesthetics in different regional anesthesia techniques, each having its pharmacological profile comes with its side effects [6]. These agents are effective in prolonging the duration of anesthesia, intensifying analgesia, providing amnesia, improving sedation, removing, or reducing patient anxiety, and maintaining hemodynamic stability when given via the epidural route. The use of dexmedetomidine especially lowers the number of anesthetics and analgesics needed due to its analgesic properties and its ability to improve the effect of local anesthetics by causing the hyperpolarization of nerve tissues through the changes of transmembrane potential [7]. Important properties of adjuvants for neuraxial anesthesia are sedation, hemodynamic stability, and prolonged postoperative analgesia. α2 adrenergic agonists have sedative and analgesic qualities that are greatly valued in regional anesthesia.

Dexmedetomidine, which is a very selective and centrally acting α2 adrenergic agonist, demonstrates an affinity eight times greater than that of clonidine [8]. The study also has shown that the recommended dose of clonidine is 1. 5 – 2 times higher than that of dexmedetomidine, which works by inhibiting the ion channels at the locus ceruleus in the brainstem [9]. The capacity of dexmedetomidine to sustain steady hemodynamic parameters and reduce oxygen demand because of improved sympathoadrenal stability suggests that it can be a functional pharmacological agent. In our current study, the combination of ropivacaine and dexmedetomidine (at a dose of 1 µg/kg) was administered for procedures involving the lower limbs.

Material and Methods

This cross-sectional comparative study was conducted in the Department of Anesthesiology, Kakatiya Medical College, and MGM Hospital, Warangal. Institutional Ethical approval was obtained for the study. Written consent was obtained from all the participants of the study after explaining the nature of the study in the vernacular language.

Inclusion Criteria

1. Age of the patient between 18 to 65 years.
2. Males and females.
3. ASA class I and II
4. Undergoing elective lower limb surgeries

Exclusion Criteria

1. History of allergy to the drugs used in the study.
2. Emergency surgical procedures.
3. Pregnant females.
4. With significant systemic diseases.

A total of 60 cases were identified and included in the study during the duration of the study. They were equally and randomly allotted by a computer-generated random number into one of the two groups given below.

Group I (n=30) received 15 ml of 0.75% ropivacaine (Ropivacaine 0.75% preservative-free 0.75% 20 ml ampoules.

Group II (n=30) 15ml of 0.75% ropivacaine + 0.6µg/kg of dexmedetomidine (inj.1ml = 100µg, 1ml ampoule)

Pre-anesthetic Assessment: A history and general examination of each of the patient was done followed by an assessment of Mallampatti grading. Measuring height and weight of the patient CVS, RS, and CNS examination of the patient. Spinal column examination. The investigations included a complete blood picture, FBS, Serum urea, creatinine, LFT, and 12-lead ECG recording. On the surgery day, patients had 18G IV cannulae placed, and multipara monitors for vital signs were attached. Before the procedure, 500 ml of RL was infused. Patients, under aseptic conditions, received epidural anesthesia via the midline approach at L2-3 or L3-4 interspace. An epidural catheter was inserted and secured at 4 cm depth. After a test dose, the study drug was incrementally injected. Patients were moved to a supine position after the procedure. Sensory and motor blockade onset, maximum level, intensity, and sedation score were assessed minutely [10]. Sensory blockade was evaluated using a 22G needle on the chest, trunk, and lower limbs bilaterally. Motor blockade was assessed by a modified Bromage scale [11]. Blood pressure, heart rate, and oxygen saturation will be monitored every 5 minutes during the first hour, and then every 15 minutes during surgery. Intraoperative and postoperative complications such as hypotension (systolic BP < 90 mmHg or >30% decrease) and bradycardia (<60 beats/min) will be managed and documented. Hypotension will be treated with fluid boluses and mephentermine increments, while bradycardia will be addressed with atropine. Patients will be transferred to the post-anesthesia care unit (PACU) until sensory and motor blockade recovery. Epidural top-ups with 8ml of 0.2% ropivacaine will be administered upon pain complaint. Vital signs will be monitored every 15 minutes

postoperatively, along with the duration of sensory and motor blockade, and any adverse events. Sensory blockade onset is defined as the time from drug injection to loss of sensation at T10, while motor blockade onset is from injection completion to Bromage 1. Motor blockade duration is from injection to Bromage 0, and sensory blockade duration is from injection to pain at T10.

Statistical analysis: All the available data was refined and uploaded to an MS Excel spreadsheet and analyzed by SPSS version 21 in Windows format. The continuous variables were represented as mean, standard deviation, and percentage, and categorical variables were analyzed by chi-square test for differences between two groups, and values of p (<0.05) were considered as significant.

Results

Table 1 shows the initial demographic features of the 60 subjects who were selected for the comparative study assessing epidural anesthesia through Ropivacaine with Dexmedetomidine versus plain Ropivacaine for lower limb surgeries. No statistically significant differences were observed between the two groups (Group I: Group I: Ropivacaine only, Group II: Ropivacaine + Dexmedetomidine, for age (35. 4.51 ± 0.76 years. 33. 43 ± 3. 73 years; p=0. 419), sex distribution (M/F: 10/20 vs. 21/9; p=0.991), height (162. 37 ± 5. 57 cm vs. 166.42 ± 4.89 cm; p=0. 271), weight (63. 44 ± 2. 31 kg in comparison with. 65.27 ± 1.91 kg; (p=0.882). The BMI comparison between the groups showed (26. 18 ± 0. 61 kg/m² or less. 26. 11 ± 0. 55 kg/m²) None of the p values were found to be significant and this shows that both groups were well-matched based on demographics, including age, gender, ethnicity, and other baseline characteristics, suggests that there was no significant influence of confounding factors on the study outcomes.

Table 1: Demographic profile of 60 cases included in the study

Variable	Group I (N=30)	Group II (N=30)	P value
Age in years	35.76 ± 4.51	33.43 ± 3.73	0.419
Sex (M/F)	20/10	21/9	0.991
Height in cms	162.37 ± 5.57	166.42 ± 4.89	0.271
Weight in Kgs	63.44 ± 2.31	65.27 ± 1.91	0.882
BMI (kg/m^2)	26.18 ± 0.61	26.11 ± 0.55	0.916

Table 2 compares the time it takes for sensory and motor block to begin (onset time) between two groups (likely Group I and Group II) who presumably received some form of anesthesia. Sensory Block Onset: Group II has a faster average sensory block onset time (6.94 minutes) compared to Group I (11.27 minutes). The p-value was (0.01) indicating a statistically significant difference in sensory block onset between the two groups. Group II likely experiences sensory block onset quickly. Motor Block Onset: Group II also has a faster average motor block onset time (11.97 minutes) compared to Group I (16.28 minutes). The p-value was (0.01) a statistically significant difference in motor block onset as well. Similar to sensory block, Group II likely experiences motor block onset quicker. Therefore, the anesthesia used in Group II appears to result in a faster onset of both sensory and motor block compared to Group I.

Table 2: Comparison of onset of sensory and motor blocks (min) recorded in two groups

Groups	Onset of sensory block		P value	Onset of motor block		P value
	Mean	SD		Mean	SD	
Group I	11.27	3.12	0.01*	16.28	2.21	0.01*
Group II	6.94	1.54		11.97	1.67	

*Significant

Table 3 shows the maximum levels of sensory blockade achieved in both groups. The common level of sensory blockade achieved in both groups was T6 (43.3% in Group I and 50.0% in Group II). No patients in Group I achieved a sensory block as high as T5, while 2 patients (6.7%) in Group II were found to have sensory blockade up to the level of T5. Eight patients (26.7%) in Group I achieved a sensory block up to T10, whereas none in Group II did. Overall, the sensory block appeared to be slightly higher in Group II compared to Group I, but the p-value (0.432) suggests this difference is not statistically significant.

Table 3: Maximum level of sensory blockade achieved in two groups

Max sensory level	Group I (N=30)	Group II (N=30)	P value
T5	00(0.00%)	2 (6.7%)	0.432
T6	13(43.3%)	15 (50.0%)	
T8	10(33.3%)	13 (43.3%)	
T10	8(26.7%)	00 (0.00%)	
Total	30(100.0%)	30 (100.0%)	

Table 4 presents the motor blockade assessment using the Modified Bromage Scale in two groups of patients (likely Group I and Group II) who received some form of anesthesia (possibly the same as Table 2).

Modified Bromage Scale [10]: This scale grades motor block in the lower limbs, with:

M0 - No motor block (full strength)

M1 - Just perceptible weakness (able to move but with reduced force)

M2 - Almost complete block (movement possible only with strong effort)

M3 - Complete motor block (no movement possible)

More complete motor block in Group I: A significantly higher proportion of patients in Group I (12, 40%) achieved a complete motor block (M3) compared to Group II (0, 0%) (p-value = 0.001). No significant difference in M1 and M2: There's no statistically significant difference between the two groups for patients with M1 or M2 (almost complete block). Overall Group I appears to have experienced a more complete motor block compared to Group II.

Table 4: Grade of motor blockade assessed by Modified Bromage scale

Modified Bromage Scale	Group I (N=30)	Group II (N=30)	P value
M1	2 (6.7%)	0 (0.0%)	0.012*
M2	16 (53.3%)	14 (46.7%)	0.992
M3	12 (40.0%)	16 (53.3%)	0.001*
Total	30 (100.0%)	30 (100.0%)	----

*Significant

The sedation scores in the two groups are depicted in Table 5. Higher sedation levels in Group II: A significantly higher proportion of patients in Group II achieved deeper sedation levels compared to Group I (p-value = 0.002). No patients in Group I reached S3 (deep sedation) or S4 (very deep sedation), while 17 (56.7%) and 1 (3.3%) patients in Group II did, respectively. More patients in Group II (40.0%) achieved S2 (moderate sedation) compared to Group I (70.0%). Less sedation in Group I: Patients in Group I appear to have experienced a lighter level of sedation compared to Group II.

Table 5: Assessment of sedation scores recorded in two groups

Sedation score	Group I (N=30)	Group II (N=30)	P value
S1	9 (30.0%)	0 (00.0%)	0.002*
S2	21 (70.0%)	12 (40.0%)	
S3	0 (00.0%)	17 (56.7%)	
S4	0 (00.0%)	1 (3.3%)	
Total	30 (100.0%)	30 (100.0%)	----

*Significant

Table 6 compares the duration of sensory and motor blocks between the two groups. Group I has a shorter average sensory block duration (201.27 minutes) compared to Group II (289.94 minutes). The p-value (0.012*) indicates a statistically significant difference in sensory block duration between the two groups. Group II likely has a longer-lasting sensory block. Group I also has a shorter average motor block duration (149.57 minutes) compared to Group II (232.91 minutes). The p-value (0.015*) suggests a statistically significant difference in motor block duration as well. Similar to sensory block, Group II likely has a longer motor block duration.

Table 6: Comparison of duration of Sensory and Motor Blocks (In Minutes) recorded in both groups

Groups	Duration of sensory block		P value	Duration of motor block		P value
	Mean	SD		Mean	SD	
Group I	201.27	20.19	0.012*	149.57	14.67	0.015*
Group II	289.94	24.67		232.91	18.24	

*Significant

Discussion

This study utilized epidural ropivacaine at a concentration of 0.75%, both on its own and in combination with dexmedetomidine, for surgeries involving the lower abdomen and lower limbs. Our main focus was on assessing various parameters including the onset of blockage, duration to achieve maximum sensory and motor block, degree of motor block, sedation levels, total analgesic duration, and extension of sensory and motor block duration. Our findings indicate that combining ropivacaine with dexmedetomidine enhances the duration and quality of sensory and motor block, leading to superior postoperative analgesia compared to the administration of ropivacaine alone.

Dexmedetomidine, an innovative alpha-2 agonist, provides pain relief via a mechanism independent of opioids, presenting a preferable alternative to opioids when combined with local anesthetics for surgical analgesia. [8, 9] Dexmedetomidine demonstrates analgesic effects at both the spinal cord and supraspinal levels. Its high selectivity for alpha-2 receptors over alpha-1 receptors, at a ratio of 1620:1 compared to clonidine's 200:1, allows for specific targeting of synaptic dorsal horn neurons. This specificity results in the inhibition of transmitter release and hyperpolarization of postsynaptic dorsal horn neurons. The combined actions of Dexmedetomidine and adrenergic agonists contribute to its prolonged analgesic effects. [12, 13] Furthermore, Dexmedetomidine exhibits synergistic interactions with local anesthetic agents, enhancing their efficacy.

In our investigation, the average onset of analgesia in Group I was 11.27 ± 3.12 minutes, whereas in Group II, it was 6.94 ± 1.54 minutes (see Table 2). This indicates a faster onset of anesthesia in Group II compared to Group I ($p<0.001$), a difference of high significance. A study conducted by Bajwa et al. [9] which compared dexmedetomidine and clonidine in epidural anesthesia, similarly, reported a shorter onset of analgesia in the dexmedetomidine group, along with a prolonged duration of analgesia compared to the ropivacaine group. The mean onset time was 8.52 ± 2.36 minutes in the dexmedetomidine group and 9.72 ± 3.44 minutes in the ropivacaine group.

In our investigation, the highest level of sensory block observed in Group II was at T5, whereas in Group I, it was at T6. Notably, the range of blocks spanned a wide area in both groups, from T12 to T5. A study conducted by Bajwa SI et al. demonstrated a similar pattern, with the maximum sensory block level at T5-T6 in the RD group compared to T6-T7 in the RC group, aligning with our findings. Our study also compared the duration of the sensory block between the two groups, revealing a significantly longer duration in Group II compared to Group I, with durations of 289.94 ± 24.67 minutes and 201.27 ± 24.67 minutes, respectively (Table 6). These results are consistent with those reported by Bajwa et al. [9] where they observed a mean analgesic duration of 366.62±24.42 minutes in the RD group compared to 242.16 ±23.86 minutes in the RF group, demonstrating high statistical significance.

In Group I, the highest score recorded was 2, whereas in Group II, it reached 4. Dexmedetomidine yielded higher scores compared to ropivacaine [14, 15], indicating a highly statistically significant difference between the groups. Sedation reflects the alpha-2 adrenergic effect, as sedation induced by epidural clonidine can be reversed by the specific antagonist yohimbine in postoperative patients. The sedative-hypnotic effects of alpha-2 adrenergic agonists result from their action on the locus coeruleus. Our findings are consistent with those of similar studies done in this area [16, 17], which observed dose-dependent sedation with alpha-2 adrenergic agonists. There were no significant differences in heart rate, blood pressure, or oxygen saturation between both groups for up to 24 hours. None of the patients required active intervention or experienced side effects such as nausea and vomiting.

Conclusion

The Dexmedetomidine group exhibited a rapid onset of action, prolonged duration of sensory and motor block, improved sedation scores, and a more pronounced motor block. No difference was noted in the maximal dermatomal level of analgesia, and any associated side effects such as bradycardia and hypotension did not pose significant challenges to the hemodynamic profile. Therefore, it can be concluded that epidural administration of Dexmedetomidine alongside Ropivacaine produces a synergistic effect, resulting in profound and prolonged sensory blockade. Ropivacaine combined with dexmedetomidine proves to be a safe and effective option for epidural blockade in lower abdominal and lower limb surgeries.

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