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Original Article

COMPARATIVE ANALYSIS OF EPIDURAL ROPIVACAINE 0.75% VERSUS ROPIVACAINE 0.75% WITH CLONIDINE IN LOWER LIMB SURGERIES: EFFICACY, HEMODYNAMICS, AND SAFETY PROFILE

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ABSTRACT

Objective: Epidural ropivacaine is extensively used for lower limb surgeries due to its effective analgesic properties and safety profile. The addition of clonidine as an adjuvant may enhance these effects, but its implications on efficacy, hemodynamics, and safety are not fully established.

Methods: In a double-blind, randomized controlled trial, 80 patients undergoing lower limb surgeries were assigned to receive either ropivacaine 0.75% or ropivacaine 0.75% with clonidine epidurally. Parameters such as onset and duration of sensory and motor blocks, hemodynamic changes, postoperative pain scores, and side effects were meticulously recorded and analyzed.

Results: Clonidine significantly improved the onset and duration of sensory and motor blocks, maintained better hemodynamic stability, and provided superior pain control compared to ropivacaine alone. There were no significant adverse effects requiring intervention beyond standard care.

Conclusion: Clonidine is an effective adjuvant to ropivacaine in epidural anesthesia for lower limb surgeries, enhancing analgesic quality and duration while being hemodynamically stable and safe.

Keywords: Epidural anesthesia, Ropivacaine, Clonidine, Lower limb surgery, Postoperative pain, Hemodynamic stability

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INTRODUCTION

Epidural anesthesia is a pivotal technique in the arsenal of regional anesthesia, particularly for lower limb surgeries. It not only provides effective perioperative analgesia but also significantly attenuates the surgical stress response. Among local anesthetics, ropivacaine has gained prominence due to its favorable safety profile, characterized by a reduced potential for cardiotoxicity and central nervous system toxicity compared to other amide local anesthetics like bupivacaine. Ropivacaine, in its 0.75% formulation, offers a balanced anesthetic and analgesic effect, making it an optimal choice for surgeries requiring profound sensory block with moderate motor blockade [1-3].

The addition of adjuvants to epidural ropivacaine has been explored as a strategy to enhance the quality and duration of analgesia. Clonidine, an α2-adrenergic agonist, is one such adjuvant that has been extensively studied. Its analgesic properties stem from its ability to modulate pain pathways centrally at the spinal cord level, as well as through peripheral mechanisms. When combined with local anesthetics, clonidine is hypothesized to prolong the duration of analgesia by reducing the reuptake and increasing the local concentration of the anesthetic agent around nerve fibers [4, 5].

This comparative study aims to evaluate the efficacy, hemodynamic stability, and safety profile of epidural ropivacaine 0.75% versus ropivacaine 0.75% with clonidine in patients undergoing lower limb surgeries [6]. The primary focus is to assess whether the addition of clonidine enhances the analgesic efficacy without compromising patient safety. Efficacy will be gauged through parameters such as the onset of sensory and motor blockade, the duration of analgesia, and the need for supplementary analgesics. Hemodynamic parameters, including heart rate and blood pressure, will be closely monitored to evaluate the stability provided by each regimen, and any episodes of hypotension or bradycardia will be recorded as measures of hemodynamic impact. Safety assessments will focus on potential side effects such as nausea, vomiting, pruritus, and neurological symptoms, which are critical for evaluating the tolerability of the anesthetic regimen [7, 8].

Given the increasing emphasis on optimizing perioperative outcomes and enhancing recovery pathways, this study holds significant relevance. It promises to contribute valuable insights into refining analgesic practices for lower limb surgeries, thereby improving patient experiences and surgical outcomes. Through meticulous methodology and rigorous assessment, this study seeks to delineate the balance between maximal analgesic efficacy and minimal adverse effects, paving the way for evidence-based enhancements in epidural anesthesia protocols.

MATERIALS AND METHODS

This prospective, randomized, double-blind study was conducted in the Department of Anaesthesia at Jhalawar Medical College, Jhalawar, following approval from the institutional ethics committee. Informed written consent was obtained from all patients. The study period spanned from January 2023 to January 2024.

Study population

A total of 80 patients scheduled for elective lower limb surgeries under epidural anesthesia were included in the study. These patients were randomly assigned into two groups, with 40 patients in each group:

- **Group RS:** Received epidural 0.75% Ropivacaine 20 ml combined with 1 ml Normal Saline (total 21 ml).
- **Group RC:** Received epidural 0.75% Ropivacaine 20 ml combined with 1 ml Clonidine (90 mcg dissolved in NS, total 21 ml).

Inclusion criteria

- Age between 35-65 y.
- Weight between 50-70 kg.
- ASA grade I and II.
- Patients undergoing elective lower limb surgeries.
- All laboratory investigations within normal range.

Exclusion criteria

- Patient refusal.
- Contraindications to epidural block, including:

○ Coagulation disorders.

○ Pre-existing neurological diseases.

○ Anatomical abnormalities of the spine.

○ Infection at the injection site.

○ Known allergy to local anesthetics.

- Patients with diabetes, those who received corticosteroids or immunosuppressants within the last 6 mo.
- Patients with compromised renal, pulmonary, or cardiac status.
- Patients on medications such as hypnotics, narcotic analgesics, or sedatives.
- Presence of hypotension or any vascular disease.
- History of seizure disorders.
- Anticipated difficult intubation.

Preoperative evaluation

All patients underwent a thorough pre-anesthetic checkup on the day before surgery, which included:

- Complete medical history, including any known allergies.
- General physical and systemic examination, airway assessment, ASA grading, and local examination of the vertebral column area.
- Baseline measurements of pulse rate, blood pressure, respiratory rate, height, and weight.
- Laboratory investigations including Hb, TLC, DLC, BT, CT, RBS, blood urea, serum creatinine, LFT, chest X-ray (PA view), and ECG.
- Patients were kept nil per oral as per fasting guidelines.

Materials required

- Epidural set with a 16 G Tuohy's needle and multi-hole catheter.
- 10 cc and 20 cc syringes.
- Sterile swabs, bowls, sponge-holding forceps, hole towel, povidone-iodine.
- Drugs: Ropivacaine 0.75%, Clonidine (preservative-free), and normal saline.
- Anesthesia machine and breathing circuit.
- Patent IV line and emergency resuscitation equipment.

Methodology

- After a thorough pre-anesthetic checkup and obtaining informed consent, the patient was brought to the operating theater.
- Standard monitoring techniques were attached, and baseline parameters were recorded.
- An 18 G IV cannula was secured, and 500 ml of Ringer's Lactate was started.
- Under strict aseptic conditions, epidural anesthesia was administered using the loss of resistance technique at the L3-L4 level, with the patient in a sitting position. A 16 G Tuohy's needle was used, and the skin was infiltrated with 3 ml of local anesthetic.

Assessment of sensory block

Sensory block was evaluated using the pinprick test with a 22-gauge blunt hypodermic needle at 5-minute intervals until the T10 dermatome level was reached, and then every 15 min until no further change in level was observed. The onset of sensory block, maximum level achieved, time to reach maximum sensory block, and duration of sensory block (from administration until regression to L5 dermatome) were recorded.

Assessment of motor block

Motor block was assessed using the Modified Bromage Scale at 5-minute intervals for the first 30 min, then every 15 min until a Modified Bromage score of 3 was achieved.

Sedation score

Sedation was monitored using the Ramsay Sedation Scale at 5-minute intervals for the first 30 min, then every 15 min until the completion of surgery.

Monitoring and data collection

Mean arterial pressure (MAP), systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate (HR), oxygen saturation (SpO2), and respiratory rate were measured before and after epidural anesthesia. These parameters were recorded every 5 min for the first 30 min, then every 15 min until the end of surgery, and subsequently every 2 h postoperatively for the next 24 h.

Assessment of analgesia

The quality of analgesia was assessed using the Visual Analog Scale (VAS) on a 0-10 scale, with 0 indicating no pain and 10 indicating the worst pain imaginable. VAS was measured every 30 min for the first 3 h, then every hour for 6 h, followed by every 2 h until 24 h postoperatively. The duration of analgesia was defined as the time from epidural block activation to the first requirement for epidural analgesia. The total dose of rescue analgesic consumed during the 24 h postoperative period was also recorded.

Adverse effects

Any adverse effects, such as nausea, vomiting, itching, bradycardia (HR<50 beats/min or a fall>30% from baseline), hypotension (SBP<60 mm Hg or a fall>20% from baseline), excessive sedation, shivering, or respiratory depression (RR<10/min or SpO2<90%), were recorded. Patient satisfaction with the procedure was assessed using a satisfaction score: 1=Excellent, 2=Good, 3=Fair, 4=Poor.

RESULTS

In this prospective randomized study, we compared two groups, designated as Group RS and Group RC, to evaluate various parameters and effects of regional anesthesia block. The findings reveal significant differences in the onset and duration of sensory and motor blocks, the level of blockade achieved, intraoperative hemodynamics, postoperative pain scores, and duration of analgesia.

Onset of Anesthesia

The onset times for both sensory and motor blocks were significantly faster in Group RC compared to Group RS. The mean time to sensory onset was 13.53±1.24 min for Group RC and 15.90±1.39 min for Group RS ($p<0.001$). Similarly, motor onset occurred at 15.28±1.40 min for Group RC, markedly quicker than the 19.08±1.38 min observed in Group RS ($p<0.001$). Maximum sensory and motor levels were reached more rapidly in Group RC, suggesting a more efficient block progression in this group.

Level of blockade

Regarding the maximum level of blockade achieved, Group RC showed a higher percentage of patients reaching a T5 level (17.50%), whereas no patients in Group RS reached this level, showing a statistically significant difference ($p = 0.006$). The most common maximum blockade level in Group RS was T6 and T7, with no significant differences observed in reaching T8 between groups.

Intraoperative hemodynamics

Intraoperative mean systolic blood pressure (SBP) was consistently higher in Group RS across all time points, with significant differences noted from the 10-minute mark (114.80±3.60 for Group RS vs.

112.53±2.77 for Group RC, p = 0.002) through the 60-minute mark (114.50±3.11 for Group RS vs. 112.65±3.81 for Group RC, p = 0.020). Diastolic blood pressure (DBP) also showed significant differences at multiple time points, notably at 20 min (69.00±6.00 for Group RS vs. 65.23±2.69 for Group RC, p<0.001).

Postoperative pain management

The Visual Analog Scale (VAS) for pain demonstrated lower pain scores in Group RC at all measured postoperative intervals, with significant differences evident as early as 1.5 h post-operation (0.60±0.67 for Group RS vs. 0.25±0.44 for Group RC, p = 0.007) and most pronounced at 4 h (2.05±0.64 for Group RS vs. 0.80±0.91 for Group RC, p<0.001). Interestingly, the VAS score at 10 h post-operation was lower for Group RS compared to Group RC (1.40±0.71 vs. 3.53±0.78, p<0.001), suggesting a rebound in pain levels for Group RC.

Duration of anesthesia

The duration of both sensory and motor blocks was significantly longer in Group RC. The motor block lasted an average of 395.30±21.24 min in Group RC, compared to 354.38±24.83 min in Group RS (p<0.001). Sensory block duration was 441.35±22.07 min for Group RC versus 392.48±23.92 min for Group RS (p<0.001). Furthermore, the overall duration of analgesia was extended in Group RC, with mean durations of 477.55±26.74 min, compared to 424.45±24.00 min in Group RS (p<0.001).

These findings underscore significant efficacy and prolonged analgesic benefits of the anesthetic protocol used in Group RC, suggesting that it may be preferable for surgeries requiring extensive and durable pain management. The choice of anesthetic technique and agents should consider these outcomes to optimize postoperative recovery and patient comfort.

Table 1: Onset of different parameters of block

Parameters	Group RS (Mean±SD)	Group RC (Mean±SD)	p value
Sensory Onset (min)	15.90±1.39	13.53±1.24	<0.001
Motor Onset (min)	19.08±1.38	15.28±1.40	<0.001
Max. Sensory (min)	23.18±1.30	20.30±1.34	<0.001
Max. Motor (min)	27.10±1.55	22.18±1.30	<0.001

Table 2: Max level of blockade achieved

Levels	Group RS (No., %)	Group RC (No., %)	p value
T5	0 (0.00%)	7 (17.50%)	0.006
T6	19 (47.50%)	24 (60.00%)	
T7	19 (47.50%)	7 (17.50%)	
T8	2 (5.00%)	2 (5.00%)	

Table 3: Intra-operative mean systolic blood pressure in both groups

Time	SBP group RS (mean±SD)	SBP group RC (mean±SD)	p value
10 min	114.80±3.60	112.53±2.77	0.002
15 min	114.40±3.70	112.30±2.98	0.007
20 min	114.85±3.75	112.58±3.36	0.005
25 min	114.93±3.80	112.63±3.08	0.004
30 min	115.58±3.84	113.23±3.08	0.003
60 min	114.50±3.11	112.65±3.81	0.020

Table 4: Intra-operative mean diastolic blood pressure in both groups

Time	DBP group RS (mean±SD)	DBP group RC (mean±SD)	p value
20 min	69.00±6.00	65.23±2.69	<0.001
90 min	68.75±4.56	70.93±4.08	0.027
105 min	69.45±5.97	72.00±3.15	0.019

Table 5: Duration of motor block

Group RS (mean±SD)	Group RC (mean±SD)	p value
354.38±24.83	395.30±21.24	<0.001

Table 6: Duration of sensory block

Group RS (mean±SD)	Group RC (mean±SD)	p value
392.48±23.92	441.35±22.07	<0.001

Table 7: Intra and post-op vas score in both groups

Time	VAS group RS (mean±SD)	VAS group RC (mean±SD)	p value
1.5 H	0.60±0.67	0.25±0.44	0.007
2 H	1.08±0.83	0.30±0.46	<0.001
3 H	1.20±0.82	0.40±0.63	<0.001
4 H	2.05±0.64	0.80±0.91	<0.001
6 H	3.25±0.74	2.48±0.64	<0.001
10 H	1.40±0.71	3.53±0.78	<0.001
12 H	1.53±0.72	1.90±0.93	0.046

Table 8: Duration of analgesia

Group RS (mean±SD)	Group RC (mean±SD)	p-value
424.45±24.00	477.55±26.74	<0.001

DISCUSSION

The present study aimed to compare the efficacy, hemodynamic stability, and safety profile of epidural ropivacaine 0.75% alone and combined with clonidine for lower limb surgeries. The addition of clonidine to ropivacaine significantly improved the onset and duration of both sensory and motor blocks, which is consistent with previous research suggesting that clonidine enhances local anesthetic action due to its hyperpolarizing effect on nerve endings and possible vasoconstrictive effects that prolong the contact time between the anesthetic and nerve fibers [9].

Onset and duration of blocks

Our findings indicated that the sensory and motor block onset was quicker in the clonidine group (Group RC), which aligns with studies suggesting that clonidine may accelerate the onset of neural blockade by facilitating the spread of the local anesthetic within the epidural space. Moreover, the duration of both sensory and motor blockade was significantly extended in Group RC, supporting the hypothesis that clonidine prolongs the analgesic effects of ropivacaine. This is particularly advantageous in the context of lower limb surgeries, where prolonged postoperative analgesia is crucial [10, 11].

Hemodynamic effects

Regarding hemodynamics, Group RC exhibited lower mean systolic and diastolic blood pressures throughout the surgery, which could be attributed to the systemic absorption of clonidine and its central sympatholytic effects. Although this could be seen as a beneficial effect in reducing perioperative stress responses, it necessitates careful monitoring to avoid hypotension and bradycardia, which were managed effectively in this study without significant adverse outcomes [12].

Postoperative pain and analgesia

Postoperative pain management, assessed through VAS scores, showed significantly lower pain scores in the clonidine group during the initial postoperative hours. This suggests an enhanced analgesic profile of the ropivacaine and clonidine combination, which could decrease the need for additional systemic analgesics and reduce the risk of opioid-related side effects. However, the unexpected lower pain scores in Group RS at 10 h post-operation indicate the potential for rebound pain, suggesting that while clonidine extends the duration of analgesia, it may also delay the transition to other pain management strategies [13, 14].

Safety profile

The safety profile was commendable in both groups, with no significant neurological symptoms, severe hypotension, or bradycardia that required intervention beyond standard clinical management. This highlights the relative safety of adding clonidine to epidural ropivacaine, provided that patients are carefully selected and monitored.

CONCLUSION

The addition of clonidine to epidural ropivacaine for lower limb surgeries significantly enhances the onset and duration of analgesia, improves hemodynamic stability during surgery, and provides superior postoperative pain control without compromising safety. These findings support the use of clonidine as an adjuvant to ropivacaine in clinical settings, particularly for procedures where extended pain relief is beneficial. Future studies could explore the optimal dose of clonidine to maximize benefits while minimizing side effects to further refine this analgesic regimen.

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Nil

AUTHORS CONTRIBUTIONS

All authors have contributed equally

CONFLICT OF INTERESTS

Declared none

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