ORIGINAL RESEARCH PAPER
Volume - 14 | Issue - 02 | February - 2025 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

A DOUBLE-BLIND RANDOMIZED CONTROL TRIAL TO COMPARE POSTOPERATIVE ANALGESIA WITH EPIDURAL BUPIVACAINE 0.25% AND ROPIVACAINE 0.2% IN LUMBAR SPINE SURGERY

Anaesthesiology

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ABSTRACT

Background: Postoperative pain after spinal surgery delays mobility and discharge from hospital. Bupivacaine and ropivacaine have similar nerve-blocking effects but differ in their impact on motor function. The study aimed to compare these two drugs for epidural analgesia. **Methods:** After ethical permission and informed consent, a prospective double blind randomized study was conducted at tertiary care hospital, from June 2022 to January 2024 in ASA Grade I or II patients aged 18 and older undergoing lumbar spine surgery under general anaesthesia. Eighty patients were randomly assigned, 40 in each group, to receive either bupivacaine (0.25%) or ropivacaine (0.2%) via epidural infusion with fentanyl. The patients were evaluated for VAS score, motor blockade at pre decided time points (0, 8, 16, 24, 36, 48 hours) and time taken to perform specific manoeuvres. **Results:** Both the groups were comparable with respect to demographic data and ASA grading. The visual analog scale (VAS) scores were comparable at rest and during coughing between the bupivacaine and ropivacaine groups at 0, 8, and 36 hours, but ropivacaine provided significantly better pain relief at 16 and 24 hours. The VAS scores at mobilization showed no significant differences between Bupivacaine and Ropivacaine at 0, 8 hours. However, Ropivacaine showed better pain relief at 16, 24, 36 and 48hours. The motor block assessment showed no significant differences between Bupivacaine and Ropivacaine at 0, 8, 24 and 36 hours. However, at 16 hours with Ropivacaine showed less motor blockade. Ropivacaine was associated with better functional outcomes in terms of maneuvers like turning, standing in front of the bed, walking, and using the toilet, compared to Bupivacaine. **Conclusion:** For postoperative pain, ropivacaine was more effective than bupivacaine, providing better VAS scores, less motor blockade, and earlier mobility.

KEYWORDS

bupivacaine, postoperative pain, ropivacaine, epidural analgesia, spine surgery

INTRODUCTION:

Low back pain is the leading cause of disability worldwide, and its burden is growing as the population ages [1]. Spinal surgery, particularly with decompression, is now considered one of the most effective treatments for spine-related issues. However, the use of spinal instrumentation in these surgeries often leads to significant postoperative pain, causing discomfort for most patients and potentially prolonging their hospital stay and rehabilitation. [2]. Studies have found that the pooled prevalence of persistent pain after spinal surgery is approximately 14.97% (95% confidence interval: 12.38-17.76) The pain is severe and typically lasts for 3 days [3,4].

Given these challenges, effective pain relief is a critical aspect of postoperative care as it promotes early mobilization and expedites hospital discharge [5,6]. Multimodal analgesia is the preferred approach for managing pain after spine surgery [7]. In recent years, Epidural anesthesia has become the standard treatment for postoperative pain. While systemic opioids are commonly used, their effectiveness depends on the dosage, and excessive opioid use can lead to complications [8]. Among the various pain management strategies, epidural techniques have emerged as the most effective. Epidural drug administration offers several advantages, including extended pain relief, improved safety, and reduced risks of respiratory and thromboembolic complications, making it a promising method for postoperative analgesia [9].

Commonly used local anesthetics in epidurals include bupivacaine, ropivacaine, and levobupivacaine, often combined with additives such as fentanyl, clonidine, buprenorphine, ketamine, and dexmedetomidine [10]. These can be administered as intermittent boluses or continuous infusions. However, there is limited evidence to suggest that continuous Epidural analgesia with bupivacaine or ropivacaine is superior to injectable analgesics like paracetamol, diclofenac, or tramadol for spine surgery.

Bupivacaine, a long-acting amide anesthetic, has been widely used for regional anesthesia due to its prolonged duration and ability to block sensory nerves more effectively than motor nerves. It works by binding to the inner part of sodium channels, preventing sodium from entering nerve cells, which stops depolarization [11]. Ropivacaine, a long-acting amide anesthetic, blocks sodium ions in nerve fibers like bupivacaine but is less lipophilic. This reduces its impact on large, myelinated motor fibers, leading to less motor blockade and potentially preserving motor function better [12]. There is a lack of comprehensive data comparing these two drugs. Therefore, study aimed to compare the therapeutic effects of bupivacaine and ropivacaine epidural analgesia in the postoperative period in patients who had lumbar spine surgery.

METHODS:

After Institutional Ethics Committee permission and written informed consent, a prospective double blind randomized study was conducted at tertiary care hospital, from June 2022 to January 2024 in ASA I and II patients, of either sex, aged 18 years or older, and who had undergone lumbar spine surgery under general anaesthesia. Patients with a history of allergy to local anaesthetics or opioids, previous spine surgery, or those exhibiting sensory and motor deficits were excluded.

Every patient posted for Lumbar spine surgery was randomized by Envelope method (research randomizer) to either group bupivacaine (injection bupivacaine 0.25% with Fentanyl 1 mcg/ml by epidural infusion rate of 5-8 ml/hour) or group ropivacaine (injection ropivacaine 0.2% with Fentanyl 1mcg/ml by epidural Infusion rate of 5-8ml/hour). Both assessor and patients were blinded to group allocation and also.

Prior to surgery, all patients had an intravenous (IV) line established and received midazolam (1 mg) as prescribed. After applying standard ASA monitors in the operating room, anesthesia was induced with fentanyl (1.5–2 mcg/kg) and propofol (1.5–2 mg/kg), followed by non-depolarizing neuromuscular blockers such as atracurium, vecuronium, or rocuronium for tracheal intubation and maintained with sevoflurane in an oxygen and nitrous oxide or air mixture (60:40). Additional analgesia with inj. Fentanyl was administered if vital signs deviated by more than 20% from baseline. An epidural catheter was placed before surgical wound closure. Glycopyrrolate and neostigmine were given to reverse neuromuscular block, and paracetamol was administered regularly. Postoperatively, after confirming motor power, a test dose of lignocaine with adrenaline was administered.

Postoperatively, pain at rest, during coughing and movement (VAS), motor function (Modified Bromage Scale) and time taken to perform specific maneuvers like turning in bed, standing in front of the bed, walking, and using the toilet were assessed every 8 hours first 24 hours to every 12 hours in next 24 hours. The principal investigator was blinded to the drugs given. The data was collected as per proforma and unblinding was done after the completion of study for statistical evaluation.

The postoperative epidural infusion rate was increased from 5 ml/hr to 8 ml/hr after the VAS score on mobilization was found to be greater than 3. This is categorized as Rescue Analgesia 1. If the VAS score continues to

exceed 3 on mobilization, Inj Tramadol 50 mg in 100 ml Normal Saline is recommended, which is considered Rescue Analgesia 2

Statistical Analysis

Data were analyzed using Statistical Analysis System (SAS) version 9.4. Continuous variables and categorical variables were tested using 2-sample t-test and Chi-square test, respectively. The primary and secondary efficacy endpoint analysis were done using repeated measures analysis of covariance (ANCOVA) or 2-sample t-test. All safety parameters were analyzed using 2-sample t-test and descriptive statistics. P<0.05 was considered statistically significant.

RESULTS:

A total of 80 patients were randomized in the study, with 40 patients assigned to each of the bupivacaine and ropivacaine groups. The baseline demographic characteristics of the patients are summarized in Table 1. These characteristics were comparable between the two groups. The mean (SD) age of patients in the bupivacaine and ropivacaine groups was 55.8 (13.0) years and 56.7 (13.0) years, respectively (P=0.573). In the bupivacaine group, 50.0% of the patients were female and 50.0% were male, while in the ropivacaine group, 37.5% were female and 62.5% were male. In the bupivacaine group, 25.0% of the patients were classified as ASA grade 1, and 75.0% as ASA grade 2, whereas in the ropivacaine group, 17.5% were ASA grade 1, and 82.5% were ASA grade 2. (Table 1).

Table 1: Baseline Characteristics Of The Study Population

Parameters	Bupivacaine (N=40)	Ropivacaine (N=40)	p-value
Age, Mean ±SD (years)	55.8 ± 13.0	56.7 ± 13.0	0.573
Gender			
Male	20 (50.0)	25 (62.5)	0.260
Female	20 (50.0)	15 (37.5)	
BMI, Mean ±SD	24.2 ± 3.1	24.4 ± 3.1	0.686
Diagnosis			
Lumbar canal stenosis	22 (55.0)	23 (57.5)	0.415
Spondylolisthesis	10 (25.0)	4 (10.0)	
Anterolisthesis	1 (2.5)	1 (2.5)	
Compression fracture	2 (5.0)	3 (7.5)	
Prolapsed intervertebral disc	5 (12.5)	9 (22.5)	
ASA grading			
I	10 (25.0)	7 (17.5)	0.412
II	30 (75.0)	33 (82.5)	
Type of Surgery			
Transforaminal lumbar Interbody fusion	12 (30.0)	14 (35.0)	0.806
Posterior spinal fusion	8 (20.0)	6 (15.0)	
Posterior lumbar fusion	3 (7.5)	5 (12.5)	
Decompression with fixation	6 (15.0)	4 (10.0)	
Laminectomy	4 (10.0)	2 (5.0)	
Posterior spine fixation	4 (10.0)	7 (17.5)	
Others	3 (7.5)	2 (5.0)	

Data presented as n (%), unless otherwise specified.
ASA, American Society of Anaesthesiologists; BMI, body mass index; SD, standard deviation.

The study evaluated VAS (Visual Analog Scale) scores at rest in patients receiving Bupivacaine and Ropivacaine over a 48-hour period. No significant differences were found between the groups at 0, 8, and 36 hours (p > 0.05). However, Ropivacaine provided significantly better pain relief at 16 hours (p = 0.001) and 24 hours (p = 0.010). By 48 hours, both groups achieved complete pain relief, with all patients reporting a VAS score of 0 (Figure 1)

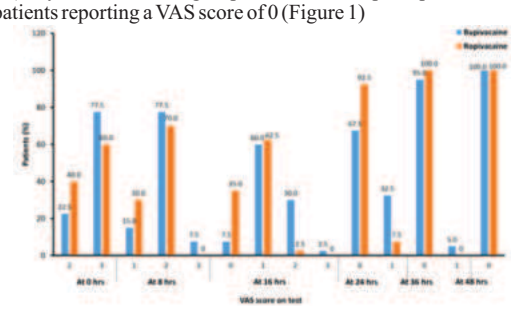

Figure 1: VAS score at rest between groups

The VAS scores during coughing showed no significant differences between Bupivacaine and Ropivacaine at 0, 8, and 36 hours. However, there were significant differences at 16 and 24 hours, with Ropivacaine showing better pain relief. By 36 hours, both groups achieved similar levels of pain relief (figure 2).

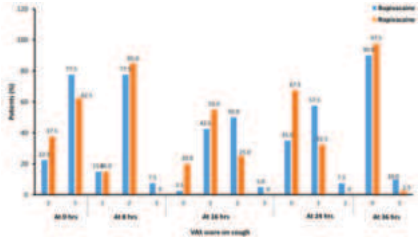

Figure 2: VAS score during cough between groups

The VAS score during the mobilization, at 0 and 8 hours, there were no significant differences between the groups (p > 0.05). However, Ropivacaine provided significantly better pain relief at 16 hours (p = 0.009), 24 hours (p = 0.013), 36 hours (p < 0.001), and 48 hours (p = 0.001). By 48 hours, 97.5% of Ropivacaine patients had a VAS score of 0 compared to 70.0% in the Bupivacaine group, demonstrating superior pain relief with Ropivacaine during mobilization at later time points (figure 3).

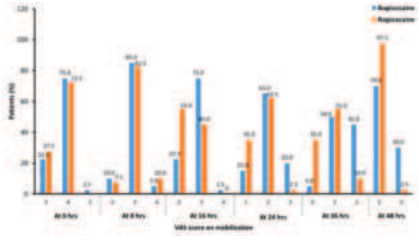

Figure 3: VAS score on mobilization between groups

The study examined the need for rescue analgesia among patients receiving Bupivacaine and Ropivacaine. In the Bupivacaine group, 70.0% of patients did not require any rescue analgesia, 30.0% required one instance of rescue analgesia, and none required two instances. In the Ropivacaine group, 65.0% of patients did not require any rescue analgesia, 32.5% required one instance, and 2.5% required two instances. This suggests that most patients in both groups managed their pain without the need for additional analgesia. Overall, the distribution of rescue analgesia needs was similar between the two groups.

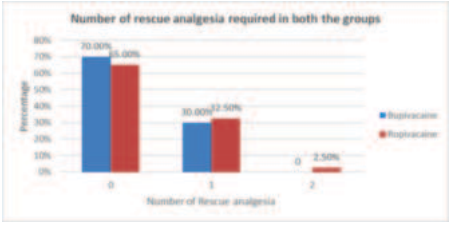

Figure 4 : Distribution of patients according to number of rescue analgesia required in both the groups

The motor block assessment was comparable between the bupivacaine and ropivacaine groups at 0, 8, 24, and 36 hours. At 16 hours, the majority of patients (92.5%) in the ropivacaine group had a motor block score of 6, while 52.5% of patients in the bupivacaine group achieved the same score (P<0.001). Bupivacaine resulted in a higher degree of motor blockade compared to ropivacaine (figure 4).

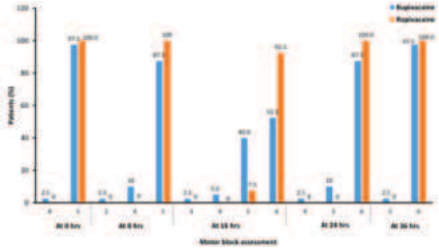

Figure 5: Motor block assessment between groups

The mean time required to perform maneuvers such as turning in bed, standing in front of the bed, walking, and using the toilet was significantly shorter in the ropivacaine group than in the bupivacaine group (P<0.001) (Figure 5).

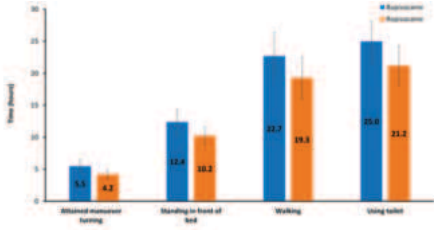

Figure 6: Time to attain manuevers in both the groups

DISCUSSION:

Spinal surgery with decompression is now thought to be one of the best ways to treat spine problems. Postoperative pain following posterior lumbar stabilization surgery primarily arises from soft tissue and muscle dissection, as well as the manipulation and removal of structures at the surgical site. Patients often report intense pain while at rest during the first 12 hours post-surgery. This pain tends to worsen significantly with movement, due to the reflexive spasm of the paraspinal muscles triggered by the initial wound pain. In the subsequent 48–72 hours, back pain at rest typically decreases to a moderate level, but remains intense with movement, causing discomfort that can hinder patient mobility and may potentially delay discharge. [4] Perioperative pain management plays a crucial role in promoting favorable outcomes, including prompt mobilization and timely discharge from the hospital.

Epidural analgesia with local anaesthetics is a highly effective treatment for postoperative pain relief with substantial reduction in pain scores and narcotic consumption, that may improve patient outcomes. Its safety, extended analgesia and decreased incidences of respiratory and thromboembolic events making it a promising route of drug delivery for postoperative analgesia.

Piet Waelkens, etal in his systemic review analysis of pain management after complex spine surgery, in 2021 assessed seven studies where epidural analgesia was used as postoperative analgesia. Pain scores were significantly lower in epidural groups and lower doses of iv opioids were required and concluded as effective way for postop pain management. (13)

While many studies have compared epidural analgesia with systemic or oral analgesic methods, very few have compared two different drugs, with or without additives, with mixed conclusion. Similarly Juan P. Cata etal., patients receiving Patient Controlled Epidural Analgesia had a lower median VAS pain score than patients receiving IV Patient Controlled Analgesia, after adjusting for the relevant covariables. The occurrence of opioid use was significantly higher among patients in the IV Patient Controlled Analgesia group than among patients in the Patient Controlled Epidural Analgesia group. [21], Yichen meng etal ,also expressed that Epidural Analgesia provided significantly superior analgesic effects compared with IV-PCA [17].

We conducted this prospective double-blind randomised control study to compare the efficacy of 0.25% of inj. Bupivacaine and 0.2% of inj. Ropivacaine as epidural analgesia for patients who had lumbar spine surgery in terms of pain relief at rest and mobility, motor blockade and attainment of manouvers. Both the groups were comparable demographically.

The VAS scores at rest, while coughing and at mobilization were significantly better with ropivacaine as compared to bupivacaine especially after 16 hours where patients are likely to be more mobile. Also, continuous epidural infusion of bupivacaine resulted in a higher degree of motor blockade compared to ropivacaine at 16 hours. Consequently, the infusion rate of bupivacaine was tapered due to its significant motor blockade effects. These patients were also assessed for the time taken to attain certain maneuvers like turning in bed, standing near bed, walking and using toilet. There was statistically significant difference in both the groups where patients receiving ropivacaine significantly attained these manouvers early as compared to bupivacaine.

The postoperative epidural infusion rate was increased from 5 ml/hr to 8 ml/hr after the VAS score on mobilization was found to be greater than 3. This is categorized as Rescue Analgesia 1. If the VAS score continues to exceed 3 on mobilization, Inj Tramadol 50 mg in 100 ml Normal Saline is recommended, which is considered Rescue Analgesia 2, where most patients in both groups managed their pain without the need for additional analgesia, Overall, the distribution of rescue analgesia needs was similar between the two groups, similarly T. Mahesh Kumar et al. where ropivacaine 0.2% was compared with 0.125% bupivacaine In group B (Bupivacaine), requirement of analgesia was observed in 8(16%) patients. In group R (Ropivacaine) there was no requirement of rescue analgesia observed in any of the patients. The difference in requirement of rescue analgesia among both study groups was found to be statistically significant. (P<0.05) [14].

In studies conducted by T. Mahesh Kumar et al. where ropivacaine 0.2% was compared with 0.125% bupivacaine for postop analgesia in spine surgeries concluded ropivacaine to be more effective as postoperative analgesic and statistically significant in motor blockade in bupivacaine group [14]. The decreased motor block ropivacaine confers an advantage in terms of early mobility over bupivacaine when the sensory block potency is approximately equivalent. While he compared the analgesic efficacy and the motor blockade, functional outcome in terms of attainment of manouvers were not compared. Rapid patient mobilization is an integral part of speedy recovery after spine surgeries, and this leads to a decrease in duration of hospitalization by one to two days.

Ropivacaine causes reversible inhibition of sodium ion influx, and thereby blocks impulse conduction in nerve fibres [3]. This action is potentiated by dose-dependent inhibition of potassium channels. Ropivacaine is less lipophilic than bupivacaine and is less likely to penetrate large myelinated motor fibres; therefore, it has selective action on the pain-transmitting A β and C nerves rather than Aβ fibres, which are involved in motor function. Thus, bupivacaine is more likely to penetrate large myelinated motor fibres, resulting in relatively increased motor blockade [12].

Muldoon T et al., in their study they have compared motor block produced by extradural infusions of ropivacaine 0.2% and bupivacaine 0.2% after total knee arthroplasty for 24 h after operation had similarly indicated that bupivacaine tends to cause more frequent motor blockade compared to ropivacaine at equivalent concentrations and doses [15].

Contrary, Surabathuni S et al., a comparative study of post-operative epidural analgesia between 0.125% bupivacaine and 0.2% ropivacaine in lower limb surgeries. 60 patients were randomly assigned to receive either 0.2% ropivacaine (Group A) or 0.125% bupivacaine (Group B) for 48 hours. Patients in group A had higher VAS scores after 1 hour (p=0.0126), 12 hours (p=-0.0311), and 24 hours (p=0.042) after epidural infusion. Study concluded that both bupivacaine and ropivacaine were equally safe, causing minimal motor blockade and facilitating early mobilization [16].

Yichen meng etal, in his comparative meta-analysis of postoperative analgesic efficacy between epidural and intravenous analgesia in major spine surgery included 28 articles and 17 trials. The patients included adolescent idiopathic scoliosis (AIS) correction and other major spine surgeries divided the trial into two comparison, epidural opioids versus intravenous opioids; and epidural opioids and a local anesthetic versus intravenous opioids. The meta-analysis results demonstrated that, overall, EA provided significantly superior analgesic effects compared with IV-PCA at all time points, while on third day no significant difference was observed between epidural analgesia and IV PCA in lumbar spine surgery while epidural provided better analgesia in scoliosis surgery. In all the studies no significant difference was found in nausea, vomiting, pruritic, paresthesia. Overall patient satisfaction was more in epidural analgesia group [17].
Cat, Juan P, etal in their retrospective review of 245 spine surgeries concluded that the use of patient controlled epidural analgesia provided better postoperative analgesia and decreased amount of opioid consumption compared with patient controlled intravenous analgesia [18]. Similarly in a prospective randomised clinical trial by Si Young Park, et al patients were randomised into two groups- the

epidural group and IV PCA group. Patients were assessed by determining the pain score, cumulative opioid requirement, adverse effects and satisfaction. The pain scores were significantly lower, with less opioid requirement and high patient satisfaction in epidural group [19].

Thus, use of ropivacaine in epidural analgesia for major spine surgery offers the advantage in terms of better analgesia, less motor blockade and early attainment of manouvers. This increases the patient satisfaction and overall surgical outcome with les postoperative morbidity. Considering ERAS protocol where early postoperative recovery and discharge is aimed, the epidural protocol with ropivacaine may be advantageous and beneficial [20].

The limitations of our study were the reliability on patient's feedback for the observations regarding the attainment of manoevers.

CONCLUSION:

In postoperative analgesia for lumbar spine surgeries, epidural administration of Inj. ropivacaine with fentanyl proved more effective than Inj. bupivacaine with fentanyl. Ropivacaine resulted in better VAS scores both at rest and during mobilization, with less motor blockade compared to bupivacaine. This allowed patients to perform various maneuvers earlier and pain-free, which aligns well with ERAS protocols.

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