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# A randomised prospective comparative study between ropivacaine and nalbuphine used in erector spinae block as a mode of postoperative analgesia in cervical instrumentation surgery

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## Abstract

**Background:** Spine surgeries are notorious for postoperative pain and delayed early rehabilitation. Various modalities are used to achieve analgesia in post-spinal surgery. Recently, the Erector Spinae Plane (ESP) block has improved the outcome of analgesia in various abdominal and thoracic surgeries.
**Aim and Objectives:** To compare the effects of Ropivacaine versus Nalbuphine in ESP block. Also, various postoperative outcomes.
**Materials and Methods:** This prospective randomised study involved 40 patients posted for elective cervical spine instrumentation surgery and classified as American Society of Anaesthesiologists (ASA) grade I or II. Patients were divided into two groups. Group R received 20 ml of 0.2% Ropivacaine, and Group N was administered 20 mg of Nalbuphine diluted in 20 ml of normal saline on both sides. Following the induction of anaesthesia, patients were positioned prone, and ESP block was performed at the C7-T1 level under sterile conditions.
Statistical Analysis: Data collection and formulation were analysed using ANOVA, Student's t-test, and Paired t-test. The statistical analysis was conducted with SPSS version 21 for Windows. P value of $< 0.05$ was considered statistically significant.
**Result:** Group R receiving Ropivacaine for ESP block showed a significant postoperative pain reduction for the first 8 hours ($P = 0.02$), and the total analgesic consumption was lower in Group R compared to Group N ($90 \pm 160.15$ versus $90 \pm 160.15$). The mean time for the first rescue analgesics was 189.72 vs 120.24 minutes in Group R & N, respectively ($P = 0.03$). The total number of patients requesting rescue analgesics was lower in Group R: 4 (40%) vs 11 (55%). Side effects were similar between the two groups and not significant.
**Conclusion:** ESP block is a safe and effective postoperative pain relief method in spine surgeries. Ropivacaine provided effective pain relief with prolonged time to rescue analgesia. At the same time, Nalbuphine has shown effective analgesia with an acceptable safety profile as a sole agent in ESP blocks. However, mild sedation was observed and should be factored into clinical decision-making.

**Keywords:** Spine instrumentation surgery, Erector spinae plane block, Analgesia, Ropivacaine, Nalbuphine.

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## 1. Introduction

Spine surgeries are notorious for postoperative pain and delayed early rehabilitation. The different modalities used to achieve analgesia after spine surgeries include neuraxial blockade with local anaesthetics alone or with adjuvants like clonidine, dexmedetomidine, opioids, etc., high-dose parenteral opioids, infusion pump opioid therapy controlled by the patient itself, and non-steroidal anti-inflammatory agents.[1,2] Drugs given via the parenteral route can cause nausea, vomiting, respiratory depression, gastrointestinal side effects, etc. While drugs via neuraxial techniques can cause respiratory depression, motor blockade, wound infection, spinal hematoma, etc.,[3] Various tools are available for assessing pain, with the Numerical Rating Scale (NRS) and Visual Analogue Scale (VAS) being the most widely used. These scales help quantify pain intensity effectively and are common in clinical practice.[4] The VAS consists of a 10

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cm line indicating a range of pain, from one end marked as "0" for no pain and "10" for worst pain.

Recently, the Erector Spinae Plane (ESP) block has improved the outcome of analgesia in various abdominal and thoracic surgeries. It also improves chronic neuropathic pain.[5] However, its use in spine surgeries remains underexplored due to limited research data. In the ESP block, a local anaesthetic is injected into the fascial plane above the transverse process and beneath the erector spinae muscle. This allows the anaesthetic to spread in a cranio-caudal direction, achieving multi-segment coverage from a single injection and diffusing into the paravertebral and intercostal spaces to provide analgesia by targeting the ventral and dorsal rami. ESP block has a wider margin of safety due to the absence of major blood vessels.[6]

Ropivacaine is a long-acting amide local anaesthetic with lower cardiotoxicity and neurotoxicity than bupivacaine. It provides prolonged analgesia with minimal motor block, making it ideal for cervical spine surgeries where early postoperative mobilization is desirable. Nalbuphine is an opioid agonist-antagonist that provides effective analgesia with minimal respiratory depression and a reduced risk of opioid-induced side effects such as pruritus and nausea. Its use in ESP blocks enhances analgesic duration and quality, with mild sedation being the only notable side effect.[7]

This study described using a USG-guided ESP block to manage postoperative analgesia in cervical spine instrumentation surgery. The advantages included effective pain management after surgery, stable hemodynamics, early mobility during recovery, reduced need for additional pain medications, and overall patient satisfaction. This study aimed to compare the effects of Ropivacaine and Nalbuphine in ESP block. Various postoperative outcomes were also compared, like nausea, vomiting, respiratory depression, sedation, urinary retention, bradycardia, and hypotension. The specific objectives were to compare the efficacy of these drugs in terms of postoperative pain relief, incidence of postoperative nausea and vomiting, occurrence of respiratory depression, level of sedation, rate of urinary retention and incidence of bradycardia and hypotension

## 2. Materials and Methods

This randomised, prospective, double-blind study was conducted in a tertiary care institute at Varanasi from September 2021 to May 2022 after approval from the Institutional Ethics Committee (letter no. Dean/2021/EC/2822). Before recruitment, written informed consent was obtained from all study participants.

A total of 40 patients, aged 18-60 years, of either gender, classified as ASA grade I or II, posted for elective cervical spine instrumentation surgery via a posterior approach in the prone position were included in the study. Exclusion criteria were patients <18 or > 60 years, ASA physical status ≥ 3, pre-existing neurological or neuropsychological disorders, cardiovascular or respiratory diseases, history of abuse of drugs or history of drug allergy, and a BMI >30. Patients unable to understand the VAS were also excluded.

### *2.1. Procedure*

Patients were randomly assigned to two groups (Group R and Group N) using computer-generated random numbers, with each group comprising 20 participants. After fasting overnight, all patients received preoperative instructions for pain assessment using the Visual Analog Scale (VAS). Intravenous fluids (normal saline) were administered @ 2 ml/kg after securing the IV line. Standard monitoring procedures were initiated, and baseline vital signs were recorded. All patients were pre-oxygenated for 3 minutes. General anaesthesia was induced with propofol (1% at 2 mg/kg), fentanyl (2 mcg/kg), and vecuronium (0.1 mg/kg). A cuffed flexo-metallic endotracheal tube was inserted, and anaesthesia was maintained with a mixture of 50% oxygen, 50% air, 1% isoflurane, and intermittent muscle relaxants. Vitals were closely monitored. End-tidal CO2 (EtCO2) was maintained between 35-40 mmHg. No additional intraoperative analgesics were administered.

At the end of the surgery, patients were placed in a prone position, and an erector spinae plane block was performed at the C7-T1 level under aseptic conditions. An 18G Tuohy needle was inserted caudally under ultrasound guidance until it reached the posterior tubercle of the transverse process. After confirming negative aspiration, 5 ml of the study drug was injected, and its distribution between the erector spinae muscle and the C7 transverse process was verified. A 19G catheter was then advanced 3 cm beyond the needle tip, followed by an additional 5 ml of the drug, and then the remaining 10 ml was injected. The needle was withdrawn, leaving the catheter in place, which was then tunnelled and secured after skin preparation

Operator bias during ESP block administration was minimised by:

1. Standardising the procedure with a single experienced anesthesiologist performing all blocks.
2. Using ultrasound guidance to ensure consistency in needle placement and drug deposition.
3. Documenting and cross-verifying technique parameters such as needle depth and drug spread to ensure uniformity across cases.

### *2.2. Group assignments*

1. Group R received 40mg Ropivacaine (0.2% Ropivacaine, dilution: 20 ml NS) bilaterally followed by intermittent top-ups of the same dose with a maximum volume of up to 80 ml/day. A concentration of 0.2% was selected based on its established efficacy in providing sensory blockade with minimal motor blockade, which is critical for

early mobilisation post-cervical spine surgery. The dosage ensured adequate dermatomal coverage without exceeding safe systemic limits.

2. Group N received 20 mg of Nalbuphine (dilution: 20 ml NS) bilaterally, followed by intermittent top-ups of the same dose, with a maximum dose of 80 mg/day. As demonstrated in prior clinical studies and pharmacological data, a single dose of 20 mg was chosen, considering its proven analgesic efficacy in regional anaesthesia with minimal side effects. This dose strikes a balance between optimal pain relief and safety.

Neostigmine and glycopyrrolate were used for reversal, and patients were extubated after reversal. Postoperative pain intensity was assessed using the VAS at 30 minutes, 2, 4, 8, 12, 18, 24, 30, 36, 42, and 48 hours after transfer to the PACU. Patients experiencing moderate to severe pain were given IV Diclofenac (75 mg) as rescue analgesia. The time to the first request for rescue analgesia and total analgesic consumption within the first 24 and 48 hours were recorded. The Ramsay Sedation Scale (RSS) was used to assess sedation levels.

The ambulation time was noted from when patients were transferred to the PACU until they could ambulate. Patients were shifted from the PACU to the ward when the modified Aldrete score was ≥9, the patient voided urine without catheterisation, and oral intake was resumed. Adverse effects include nausea, vomiting, and sedation. Respiratory depression, urinary retention, bradycardia, and hypotension were monitored for 48 hours. The two groups recorded, tabulated, and compared all postoperative data.

### *2.3. Statistical methods*

The sample size was calculated based on prior studies investigating the analgesic efficacy and safety of ESP blocks in similar surgical settings. Using a mean difference in postoperative pain scores as the primary endpoint, a power analysis (80% power, $\alpha = 0.05$) indicated the required sample size. Pilot data from our institution supported these estimates, accounting for a potential 10% dropout rate to ensure statistical validity.

Data were collected and analysed using ANOVA, the student's t-test, and the paired t-test. Statistical analysis was performed using SPSS version 21 for Windows (SPSS Inc., Chicago, IL), with a P-value of <0.05 considered statistically significant.

## 3. Results

All the patients in Group R and Group N were compared for age, weight, sex, and duration of surgery (**Table 1**).

The VAS was assessed at 30 minutes (after being transferred to the recovery ward) and at two, four, eight, twelve, eighteen, twenty-four, thirty, thirty-six, forty-two and forty-eight hours. The mean VAS in Group R was 0.3 (30 minutes), 0.65 (two hours), 1.0 (four hours), 1.55 (eight hours), 2.3 (twelve hours), 2.45 (eighteen hours), 2.55 (twenty-four hours), 2.8 (thirty hours), 3.2 (thirty-six hours), 3.4 (forty-two hours) and 3.55 (forty-eight hours). For Group N, The mean VAS was 0.6 (30 minutes), 0.9 (two hours), 1.54 (four hours), 2.3 (eight hours), 2.48 (twelve hours), 2.56 (eighteen hours), 2.8 (twenty-four hours), 2.9 (thirty hours), 3.7 (thirty-six hours), 3.85 (forty-two hours) and 3.55 (forty-eight hours).

Group R demonstrated a statistically significantly lower VAS compared to Group N at 30 minutes (P=0.029), as well as at two (P=0.031), four (P=0.039), and eight hours (P=0.028). However, no statistically significant differences in VAS were observed between the two groups at twelve hours (P = 0.116), eighteen hours (P = 0.182), twenty-four hours (P = 0.265), thirty hours (P = 0.445), thirty-six hours (P = 0.078), forty-two hours (P = 0.067), and forty-eight hours (P = 0.123). (**Table 2**).

The mean time taken for the first requirement for rescue analgesia was 189.72 minutes in Group R and 120.24 minutes in Group N, which was statistically significant (P = 0.03). The total number of patients requesting analgesics was lower in Group R than in Group N: 8 (40%) vs 11 (55%) (**Table 3**).

Total analgesic consumption was lower in Group R compared to Group N (90 ± 109.9 versus 116 ± 160.15), but no significant difference exists between groups. All the patients were allowed movement with cervical collar support after 24 hours of complete immobilisation. There was no significant score for Group R and Group N.

Total analgesic consumption was lower in Group R compared to Group N (90 ± 160.15 versus 90 ± 160.15), but no significant difference exists between groups. All the patients were allowed movement with cervical collar support after 24 hours of complete immobilisation. No significant difference was noted in both the groups regarding the ambulation time as the median value of 36 ± 5.65 hours and 38 ± 5.09 hours in Group R and Group N, respectively. **(Table 4)**

In Group R, postoperative nausea and vomiting occurred in three patients and one patient, respectively. However, hypotension was reported in three patients in Group R. In Group N, nausea and vomiting occurred in one and two patients, respectively, respiratory depression in one patient, and urinary retention in one patient. These incidences were not statistically significant between the groups. In Group N, sedation occurred in five patients, which was statistically significant (P = 0.02). Sedation delayed postoperative recovery but improved patient satisfaction by reducing perioperative anxiety and providing a calming effect (**Table 5).**

**Table 1:** Demographic characteristics of the patients in the group R and group N

| Demographic Parameter | Group R (mean) | Group N (mean) | p-value |
|---|---|---|---|
| Age | 42.8 | 43.3 | 0.84 |
| Weight | 75.8 | 73.6 | 0.66 |
| **Sex:** | | | |
| Male | 11 | 12 | |
| Female | 09 | 08 | |
| Duration of surgery (min) | 189.2 ±12.10 | 182.9±14.16 | 0.08 |

**Table 2:** Comparison of visual analogue score (VAS) between group R and group N

| Time | Group R | Group N | *p-value |
|---|---|---|---|
| | (Mean ± SD) | (Mean ± SD) | |
| VAS at 30 min | 0.3 ± 0.458 | 0.6 ± 0.49 | 0.029 |
| VAS at 2hr | 0.65 ± 0.792 | 0.9 ± 0.049 | 0.031 |
| VAS at 4hr | 1.0 ± 0.768 | 1.54 ± 0.74 | 0.039 |
| VAS at 8hr | 1.55 ± .921 | 2.3 ± 1.077 | 0.028 |
| VAS at 12hr | 2.3 ± 0.6 | 2.48 ± 0.669 | 0.116 |
| VAS at 18hr | 2.45 ± 0.0726 | 2.56 ± 0.853 | 0.182 |
| VAS at 24hr | 2.55 ± 1.2440 | 2.8 ± 1.03 | 0.265 |
| VAS at 30hr | 2.8 ± 1.03 | 2.9 ± 1.1 | 0.445 |
| VAS at 36hr | 3.2 ± 1.122 | 3.7 ± 1.005 | 0.078 |
| VAS at 42hr | 3.4 ± 0.995 | 3.85 ± 1.014 | 0.067 |
| VAS at 48hr | 3.55 ± 1.023 | 3.55 ± 0.973 | 0.123 |

*p-value <0.05 is statistically significant.

**Table 3:** Time taken and number of patients requesting rescue analgesic between group R and group N

| | Group R (N=20) %, SD | Group N (N=20)% | *p-value |
|---|---|---|---|
| Time taken for the first requirement for rescue analgesia | 189.72±23.15 | 120.24±22.53 | **0.03** |
| Number of patients requesting rescue analgesic in 48 hours | 8 (40%) | 11 (55%) | |

*p-value <0.05 is significant

**Table 4:** Postoperative analgesic requirement and time of ambulation between group R and group N

| Parameters | Group R | Group N | *p-value |
|---|---|---|---|
| Total analgesic consumption (mg) in form of inj. Diclofenac sodium 75 mg i.v. | 90 ± 109.9 | 116 ±160.15 | 0.279 |
| Time of ambulation (hours) | 36 ± 5.65 | 38 ± 5.09 | 0.1446 |

*p-value <0.05 is significant

**Table 5:** Comparison of side effects between group R and group N

| Side effect | Group r | Group n | *p-value |
|---|---|---|---|
| Nausea | 3 (15%) | 1 (5%) | 0.22 |
| Vomiting | 1(5%) | 2(10%) | 0.32 |
| Respiratory depression | 0 | 1(5%) | 0.23 |
| Sedation | 0 | 5(25%) | 0.02 |
| Urinary retention | 0 | 1(5%) | 0.23 |
| Bradycardia | 1(5%) | 0 | 0.23 |
| Hypotension | 3(15%) | 0 | 0.11 |

*p-value <0.05 is significant

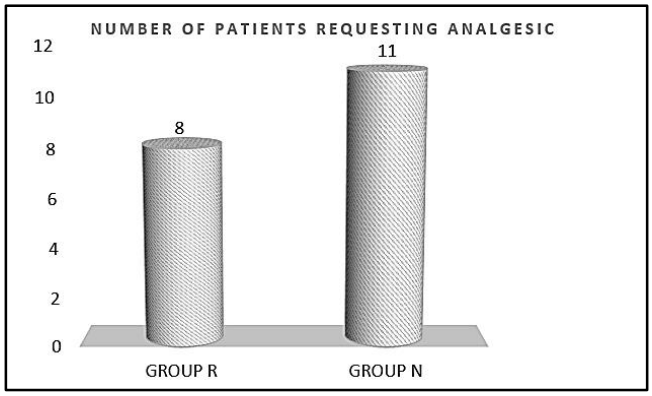


**Figure 1:** Graphic representation of the number of patients requesting analgesics in Group R and Group

## 4. Discussion

Various interfascial plane blocks have been introduced recently to achieve postoperative analgesia in cervical, thoracic, and abdominal surgeries. Among these, the ESP block has gained attention. Forero et al. used a first-time USG-guided EPS block for severe thoracic neuropathic pain.[5] Since then, numerous clinical studies and randomised trials have explored its utility. It is a novel regional anaesthesia technique offering effective pain relief, reduced opioid use, and simplicity of execution. The ESP block is easy to perform due to the easily identifiable sonographic anatomy of the erector spinae muscle group, allowing for straightforward catheter placement.[6] It is considered safer and requires less expertise than epidural or paravertebral blocks, as it carries a lower risk of needle-related injuries due to the absence of vital structures nearby.[7] Additionally, it is associated with fewer complications, such as hypotension (seen in epidural analgesia), drug spread to the epidural space, and vascular puncture (associated with paravertebral blocks). The ESP block also avoids risks like spinal cord or pleural injury, pneumothorax (related to intercostal nerve blocks), and complications of intrapleural blocks.[8,9]

Our study compared the efficacy of Ropivacaine and Nalbuphine in bilateral ESP blocks for perioperative analgesia, aiming to minimise complications typically associated with other regional blocks. The extensive craniocaudal spread of the anaesthetic without affecting the surgical field and the focus on sensory blockade make the ESP block a superior choice.

Tulgar et al. showed effective pain relief and reduced postoperative analgesic requirements within the first 12 hours following laparoscopic cholecystectomy by using this block.[10] Chen et al. compared ultrasound-guided multiple-injection paravertebral blocks (PVB) with single-injection ESP blocks and intercostal nerve blocks (ICNB), concluding that PVB offered superior analgesia. Conversely, ICNB and single-injection ESP blocks were similarly effective in managing postoperative pain following thoracoscopic surgery.[11] However, patients who received the ESP block required more morphine for postoperative pain relief.[12]

In contrast, Oksuz et al. found that bilateral ESP blocks provided superior pain control and decreased analgesic requirements following mastectomy.[13] At the same time, Ueshima et al. argued that ESP blocks were not as effective for breast surgeries.[14] Fang B et al. reported that ESP and thoracic paravertebral blocks had similar efficacy in open thoracic surgery.[15]

The ESP block's low incidence of side effects is one of its most notable advantages. Taketa et al. found that the ESP block offers effective pain relief by blocking lateral cutaneous branches, though it was not superior to paravertebral or intercostal nerve blocks.[16] In our study, we performed ultrasound-guided bilateral ESP blocks with catheter placement during cervical instrumentation surgery. Few studies have explored its role in spine surgeries. However, Goyal et al. demonstrated reduced analgesic requirements and stable hemodynamics during C5-C7 cervical rod fixation surgeries with ESP blocks.[17] Elsharkawy et al. conducted a cadaveric study, demonstrating dye spread in the prevertebral compartment, staining the dorsal rami and brachial plexus, which suggests the ESP block's potential application in shoulder and cervical spine surgeries.[18] These findings support the ESP block's mechanism of drug diffusion in the cephalocaudal direction through the erector spinae plane.[19] Studies by Schwartzmann et al. and Adhikary et al. using nuclear magnetic resonance indicated that contrast agents can spread into the paravertebral and epidural spaces, a finding supported by additional cadaveric studies.[20,21]

However, Ropivacaine, the local anaesthetic used in our study, can cause significant side effects if it enters the paravertebral space or if the catheter migrates intravascularly. In comparison, Nalbuphine, used in lower doses in our study, is less likely to cause such side effects while providing equivalent analgesic effects. In contrast, studies by Otero PE et al. and Ivanusic et al. using a porcine model and cadaveric studies, respectively, found no anterior spread of dye to the paravertebral or epidural spaces, challenging the hypothesis of paravertebral diffusion.[22,23]

In the available literature, local anaesthetics have generally been used in ESP blocks, resulting in effective sensory blockade. In contrast, our study utilised an opioid-based block, which provided effective analgesia without sensory blockade, leading to a more physiological response and reduced patient anxiety, especially in contrast to the loss of sensation often associated with local anaesthetics. Supporting our findings, Zhang et al. conducted an observational study with 12 volunteers, showing a loss of cutaneous sensation following local anaesthetic lignocaine.[24] A case series by Jain et al. reported similar results with sensory loss after using local anaesthetic bupivacaine in ESP blocks.[25] Ropivacaine provided excellent pain relief through strong sensory blockade, effectively managing somatic pain in cervical spine surgeries. However, the associated sensory loss led to discomfort and reduced patient autonomy, while

its vasodilatory effects caused hemodynamic variability, necessitating frequent monitoring and heightening patient anxiety. In contrast, Nalbuphine offered adequate analgesia without significant sensory impairment or hemodynamic instability. Nalbuphine's favourable safety profile, minimal sensory impairment, and stable hemodynamics are particularly relevant for cervical spine surgeries, where patient mobility, comfort, and reduced monitoring requirements are critical. Its utility highlights the potential for safe and effective opioid-based analgesia in real-world perioperative settings. Intermittent bolus administration may lead to fluctuating drug concentrations, causing variable analgesia and requiring close monitoring. Continuous infusion provides consistent drug delivery, maintaining stable analgesia while potentially minimising peaks and troughs. Future studies comparing these methods could yield more conclusive data. ESP blocks have shown variable effectiveness in thoracic surgeries, often attributed to anatomical differences affecting drug spread. In cervical spine surgeries, the proximity of the cervical plexus to the injection site may enhance drug efficacy. This underscores the importance of tailoring ESP block techniques to surgical regions and individual patient needs.

## 5. Conclusion

The ESP block is a safe and effective regional anaesthesia technique for postoperative pain relief in spine surgeries. Ropivacaine provides prolonged pain relief and delays the need for rescue analgesia, but its sensory blockade and hemodynamic variability require careful management. As a sole agent, Nalbuphine demonstrated effective analgesia with a favourable safety profile, though mild sedation must be considered during clinical planning. Future research should explore ESP blocks in diverse surgical procedures, assess continuous infusion versus bolus methods, and evaluate long-term patient outcomes to optimise these agents' applications.

## 6. Source of Funding

None.

## 7. Conflict of Interest

None.

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