

# Comparison of Postoperative Analgesic Effect of Ultrasound-guided Erector Spinae Plane Block and Local Anaesthetic Infiltration with 0.375% Ropivacaine in Percutaneous Nephrolithotomy Patients: A Randomised Clinical Study

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## ABSTRACT

**Introduction:** The Erector Spinae Plane Block (ESPB) is a novel procedure that has shown benefits in postoperative pain management for various surgeries. It involves the systemic infiltration of anaesthesia into the surrounding tissues, which helps to suppress local pain responses.

**Aim:** To compare the efficacy of Ultrasound-guided (USG) ESPB with local anaesthetic infiltration in postoperative pain management for patients undergoing Percutaneous Nephrolithotomy (PCNL). The comparison was based on the Numeric Rating Scale (NRS) score and the time taken for the first rescue analgesic requirement, along with its total consumption within 24 hours.

**Materials and Methods:** A randomised clinical study was conducted in the Department of Anaesthesia at Velammal Medical College and Hospital, Madurai, Tamil Nadu, India. The duration of the study was two months, from September 2022 to October 2022. A total of 70 patients were randomly assigned to either group L (n=35) (local anaesthetic infiltration) or group E (n=35) (USG-guided ESPB). Demographic details, NRS pain scores, time taken for the first rescue analgesia, and

total consumption within 24 hours were noted and analysed. Descriptive analysis was performed, and a comparison between the groups was made using the Mann-Whitney U test or Chi-square test. Analysis was conducted using coGuide V1.0.3.

**Results:** The mean age (mean±SD) of the study participants in group L and group E was found to be 49.31±13.96 years and 46.37±13.72 years, respectively. A total of 35 patients were included in each group, consisting of 16 (45.71%) females and 19 (54.29%) males in both groups. The difference in NRS scores was significant at 30 minutes, one hour (p-value <0.001), and six hours (p-value <0.011). The median time required for the first rescue analgesic was found to be 480 and 30 minutes in group E and group L, respectively (p-value <0.001). The median total consumption within 24 hours was 50 mg in both groups.

**Conclusion:** The USG-guided ESPB provided a longer-lasting analgesic effect in postoperative pain management for PCNL patients, as evidenced by the NRS pain scale, postoperative opioid consumption, and time for the first rescue analgesia.

**Keywords:** Analgesia, Erector spinae plane block, Opioid consumption, Pain management

## INTRODUCTION

The prevalence of renal calculi is constantly increasing and has reached 14% [1]. PCNL is the preferred treatment choice for larger renal calculi due to its less invasive nature and reduced morbidity compared to open surgery. However, the guidelines for PCNL have changed significantly in recent years with advancements in procedures like Extracorporeal Shockwave Lithotripsy (ESWL) and other techniques. With the miniaturisation of instruments and advancements in energy and optics, PCNL is now being considered even for smaller stones, resulting in improved clearance rates and reduced morbidity [2].

Some surgeons choose ESWL over PCNL due to persistent residual stone fragments and the shorter procedural time associated with ESWL, which leads to a higher stone-free rate and lower risk [3]. PCNL is associated with pain caused by incision, dilatation of the renal capsule, and placement of a nephrostomy tube. While post-procedure pain management for PCNL has been extensively studied, no standard strategy or approach has been defined [4]. Various pain management techniques are employed, including multimodal therapy, opioids, non opioid analgesics such as paracetamol, Non-steroidal

Anti-inflammatory Drugs (NSAIDs) like ibuprofen, local analgesics like bupivacaine or ropivacaine, the use of smaller nephrostomy tubes, and tubeless procedures [5-7]. However, due to renal compromise, NSAIDs and non opioid analgesics are not prescribed for PCNL patients, and opioids are also used sparingly due to their side effects. Therefore, multimodal pain management approaches such as ESPB and local infiltration have gained popularity [8].

The ESPB can be performed under the guidance of fluoroscopy or ultrasound. Regardless of the guidance used, ESPB involves a single injection or catheter placement for continuous infusion. During the procedure, the needle is inserted between the erector spinae muscle and the thoracic Transverse Processes (TP), and anaesthesia is injected to achieve a multidermatomal sensory block [9]. On the other hand, local anaesthetic infiltration involves the systemic infiltration of an analgesic mixture into the tissues surrounding the surgical field, thereby suppressing inflammatory and local sensitising responses [10]. The efficacy of this procedure depends on factors such as the surgical technique, the type and dosage of the local anaesthetic used, its concentration, and the differences in infiltration mechanisms [11].

Although the efficacy of both procedures is known, their direct head-on comparison in patients undergoing PCNL for renal calculi has not been extensively studied [12]. The current study aimed to compare the efficacy of these two techniques using 0.375% ropivacaine in PCNL patients [13].

## MATERIALS AND METHODS

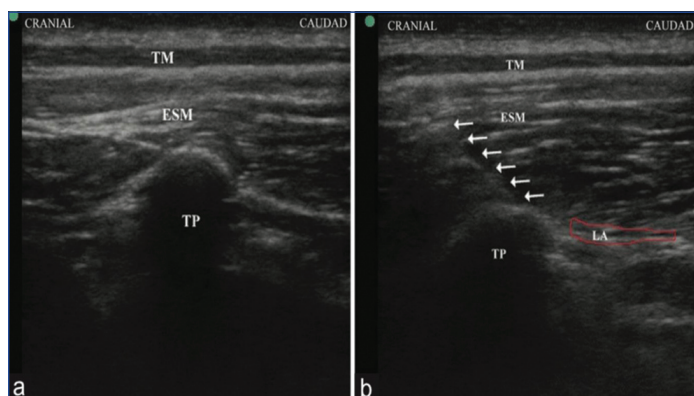
A double-blinded randomised clinical study was conducted in the Department of Anaesthesia at Velammal Medical College and Hospital, Madurai, Tamil Nadu, India. The duration of the study was two months, from September 2022 to October 2022. The study received approval from Institutional Ethics Committee (IEC) (IRB: IEC No: VMCIEC/18/2022) and was registered under CTRI (CTRI/2022/05/042829).

**Inclusion criteria:** Patients aged 18-70 years of any gender who were undergoing PCNL under General Anaesthesia (GA) and classified as American Society of Anaesthesiologists I and II (ASA I and II) were included in the study.

**Exclusion criteria:** Patients classified as ASA-III, intravenous drug users, and those contraindicated for peripheral nerve blocks and the patients with a Body Mass Index (BMI) of  $>35$  kg/m<sup>2</sup>, bacteraemia or sepsis, and cognitive disability were excluded from the study.

### Study Procedure

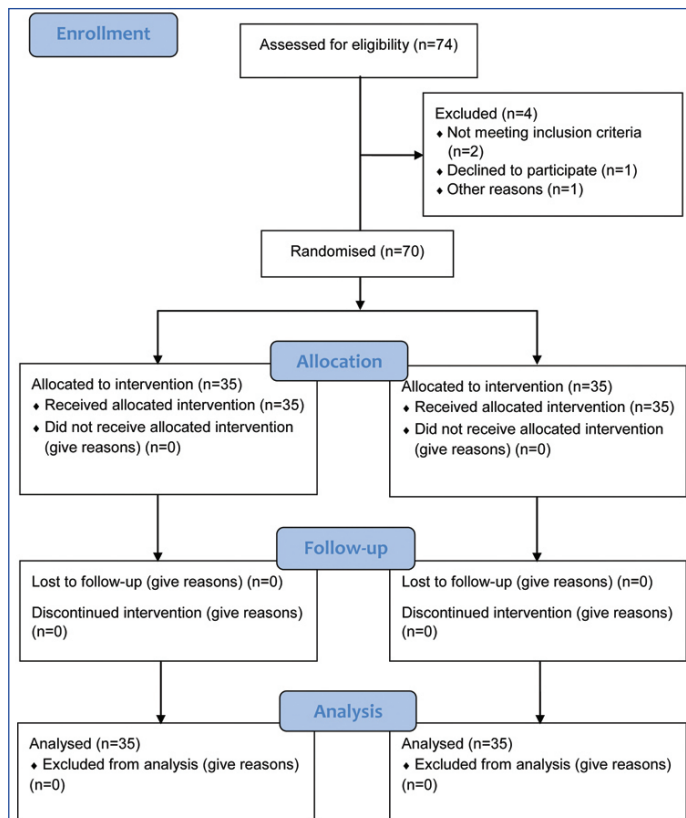
All eligible patients were provided with an explanation of the study objectives and purpose and had their doubts cleared. Those who consented to participate in the study were randomised into two groups: group L and group E, using a computer-generated random sequence. Patients in group L received subcutaneous infiltration of 20 mL of 0.375% ropivacaine at the incision site [14]. [Table/Fig-1a] shows an ultrasound image of the ESP plane block, with the needle traversing the trapezius muscle and erector spinae muscle until the needle tip contacts the Transverse Process (TP). [Table/Fig-1b] demonstrates the injection of 1-3 mL of local anaesthetic in the plane above the TP to confirm proper injection plane by visualising a spread deep to the erector spinae muscles and superficial to the TP, completing the nerve block with the remaining local anaesthetic.



[Table/Fig-1]: Ultrasound image.

TM: Trapezius muscle; ESM: Erector spinae muscle; TP: Transverse process

Allocation concealment was performed using sequentially numbered sealed envelopes by a person not involved in the study. The assessor and statistician were blinded. A Consolidated Standards of Reporting Trials (CONSORT) diagram was provided as [Table/Fig-2]. The sample size was calculated assuming the median value of NRS scores as 3 and 5 in the ESPB (group E) and local anaesthetic group (group L), respectively, based on a study by Ramachandran S et al., and a pooled Standard Deviation (SD) of 2.5 [12]. Other parameters considered in the sample size calculation were 80% power and a 95% confidence interval. The sample size derived using this information was 35 in each group (after considering a 20% loss to follow-up, resulting in 28 cases in each group).



[Table/Fig-2]: Consolidated Standards of Reporting Trials (CONSORT) diagram representing the study presented.

Patients with renal calculi scheduled for PCNL were informed about the study and educated about the NRS for measuring pain. The NRS scale ranges from 0 to 10, where 0 denotes no pain and 10 denotes extreme pain. Postoperatively, the patients' pain was assessed using the NRS, and a score was recorded at 30 minutes, 60 minutes, 6 hours, 8 hours, 12 hours, and 24 hours. Additionally, the time taken for the first rescue analgesia and the total consumption of analgesia within 24 hours were noted.

The ESP block was performed by the same anaesthesiologist who had five years of experience with USG regional blocks. In the operating room, all routine monitors were attached, and baseline parameters were recorded. A standard protocol for anaesthesia induction was followed for all patients, and the airway was secured with an appropriately sized cuffed endotracheal tube. Anaesthesia was maintained using inhalational anaesthetics and non depolarising blockade. The patient was then positioned prone, and the PCNL procedure was performed.

After the completion of the procedure, an ultrasound-guided technique was used to perform the ESP block. The ultrasound probe was placed on the ninth rib, which was identified by counting down from the first rib. The high-frequency linear probe was positioned parallel to the vertebral axis at the level of the ninth rib and moved medially to identify the TP, which is more superficial and broader than the rib. A 23G spinal needle (BD™, NJ, USA) was inserted in a craniocaudal direction until it contacted the TP. The needle was then withdrawn slightly, and 2 mL of normal saline was injected to confirm the correct plane. Subsequently, 20 mL of 0.375% ropivacaine was injected.

For group L, at the end of the procedure, the surgeon performed skin and subcutaneous infiltration using a 21G 38 mm hypodermic needle with 0.375% ropivacaine. During the postoperative period, if the NRS score was greater than 4, intravenous tramadol 50 mg diluted in 10 mL normal saline was administered slowly over five minutes. If the pain persisted for 30 minutes following the tramadol injection, intravenous paracetamol 1 gm was given. If

the pain rating remained above 4 after six hours from the previous dose, intravenous tramadol and, if necessary, paracetamol were repeated. The NRS scores were considered as the primary outcome variable, while the first analgesic requirement and total analgesic consumption within 24 hours were considered as secondary outcome variables.

## STATISTICAL ANALYSIS

The study group (L vs E) was considered as the primary explanatory variable. All quantitative variables were checked for normal distribution within each category of the explanatory variable through visual inspection of histograms and normality Q-Q plots. For normally distributed quantitative parameters, the mean values were compared between study groups using a two-group independent sample t-test. In the case of non normally distributed variables, the median and Interquartile Range (IQR) were used for comparison using the Mann-Whitney U test. Categorical outcomes were compared between study groups using the Chi-square test or Fisher's-exact test. A p-value <0.05 was considered statistically significant. The data was analysed using coGuide V.1.0.3 [15].

## RESULTS

After randomisation, each group (group L and group E) was assigned 35 patients (50%) for the study. The study included 45.71% females and 54.29% males in both groups, which was statistically insignificant. The mean±SD of age in both groups was 49.31±13.96 years and 46.37±13.72 years, respectively. All demographic details shown in [Table/Fig-3].

Parameters	Groups		p-value
	L (n=35)	E (n=35)	
Age (in years) (Mean±SD)	49.31±13.96	46.37±13.72	0.377*
<b>Gender n (%)</b>			
Female	16 (45.71%)	16 (45.71%)	1.000†
Male	19 (54.29%)	19 (54.29%)	
<b>Weight</b> (in kg) (Mean±SD)	66.17±9.42	64.37±9.57	0.431*
<b>Height</b> (in cm) (Mean±SD)	164.17±10.43	163.03±8.39	0.615*
<b>BMI</b> (kg/m <sup>2</sup> ) (Mean±SD)	24.53±2.56	24.13±2.35	0.495*
<b>ASA n (%)</b>			
1	19 (54.29%)	20 (57.14%)	0.810†
2	16 (45.71%)	15 (42.86%)	
<b>Duration of surgery</b> (in minutes) (Mean±SD)	78.86±17.36	78.14±13.47	0.848*
<b>Intraoperative fentanyl</b> (in mg) (Mean±SD)	125.43±13.36	126±12.41	0.853*

**[Table/Fig-3]:** Comparison of baseline characters between the 2 groups of the study. \*Independent sample t-test, †Chi-square test; BMI: Body mass index; ASA: American society of anaesthesiologists

The median (IQR) of the pain score according to the NRS at different time points as both groups is presented in [Table/Fig-4]. There was

Parameters	Groups		p-value
	L (n=35)	E (n=35)	
<b>NRS</b>	<b>Median (IQR)</b>	<b>Median (IQR)</b>	
30 minutes	5 (4,6)	3 (2,4)	<0.001†
1 hour	4 (4,5)	3 (2,4)	<0.001†
6 hours	4 (3,4)	4 (3,4)	0.011†
8 hours	4 (4,5)	5 (3,5)	0.327†
12 hours	4 (3,4)	3 (3,5)	0.543†
24 hours	3 (3,4)	3 (2,3)	<0.001†

**[Table/Fig-4]:** Median (IQR) of Numeric Rating Scale (NRS) score values in both the groups with p-values as tested using Mann-Whitney U test. †Mann-Whitney U test; IQR: Interquartile range

a significant difference in the pain score between the groups at 30 minutes, one hour, six hours, and 24 hours.

[Table/Fig-5] presents the comparison of the secondary objectives of the study. All secondary outcomes, such as the time required for the first rescue analgesia and the total consumption of tramadol in 24 hours, were found to be statistically significant with a p-value <0.001.

Parameters	Groups {Median (IQR)}		p-value
	L (n=35)	E (n=35)	
1 <sup>st</sup> analgesia (in minutes)	30 (30,60)	480 (480,720)	<0.001†
Total tramadol in 24 H (mg)	50 (50,100)	50 (50,50)	<0.001†
Patients requiring 2 <sup>nd</sup> analgesia	14 (40.0%)	1 (2.86%)	<0.001†
Total paracetamol is given in 24 hours (gm)	1 (2.86%)	1 (2.86%)	1†

**[Table/Fig-5]:** Time taken for first analgesia and no. of patients required the second analgesia in both the groups along with p-values.

†Mann-Whitney U test, †Chi-square test; IQR: Interquartile range

## DISCUSSION

The objective of the current study was to compare the postoperative analgesic effect of ESPB and local anaesthetic infiltration in patients undergoing PCNL. The study found that ESPB had a longer duration of action, as evidenced by lower NRS pain scores at various time points. The time taken for the first rescue analgesia was significantly lower in group L compared to group E.

Bilgin MU et al., conducted a study that reported lower NRS scores ranging from 0 to 1, which were statistically significant when compared to the control group. Although their scores differed from the current study, the significant difference between the groups aligns with the present study's findings [16]. Liu J et al., conducted a systematic review and meta-analysis, which reported greater improvement in pain for patients who received ESPB, resembling present study's results [17]. Studies by Gultekin MH et al., and Bryniarski P et al., reported ESPB as an effective procedure for postoperative pain management in PCNL patients using the Visual Analogue Scale (VAS), unlike the NRS scale used in the present study. However, their findings showed significantly lower pain scores (p-value <0.005) and a longer duration for the first rescue analgesic requirement compared to the control group, aligning with the results of the current study [18,19]. Despite the difference in pain assessment scales, the results were similar. Similarly, a study by Pehlivan SS et al., reported significantly different VAS pain scores, with a median pain score of 3 at the 6<sup>th</sup> and 12<sup>th</sup> hour and 3.5 at the 24<sup>th</sup> hour, closely matching with the results of the present study [20].

The study conducted by Ramachandran S et al., found similarities with the current study in terms of the duration for the first rescue analgesic requirement [12]. Studies by Sarkar S et al., and Ibrahim M and Elnabtity AM suggest that ESPB could be effective in pain management even when bupivacaine is used as the anaesthetic agent [21,22]. Ibrahim M and Elnabtity AM found that intraoperative and postoperative analgesic requirements significantly reduced when ESPB was performed at the T11 level preoperatively [22]. In a case report by Kim E et al., ESPB performed postoperatively at the T8 level in a PCNL patient resulted in no requirement for rescue analgesia for 36 hours [23].

Saadawi M et al., reported in a systematic analysis that ESPB also provides benefits in postoperative analgesia for thoracic and abdominal surgeries [24]. Positive results in postoperative pain management and opioid requirement were reported in a case series by Chin KJ et al., for patients undergoing bariatric surgery [25]. De Cassai A et al., reported that 3.4 mL of local anaesthesia was needed for each dermatomal level for a successful ESP block [14]. ESPB has been found to be beneficial for patients undergoing breast



cancer surgery, laparoscopic cholecystectomy, major abdominal surgeries, thoracotomy, complex scapular resection, and cardiac surgery [13,26-29]. Radiological investigations, such as Computed Tomography (CT) imaging studies, have revealed the caudal and cranial spread of the injected anaesthesia, which is responsible for the multidermatomal sensory block [30]. Magnetic Resonance Imaging (MRI) studies have further shown the spread of ESPB via both epidural and transforaminal routes, resulting in paravertebral epidural and circumferential spread, along with superficial intercostal muscle spread [31]. However, the primary mechanism of action is through interfascial spread towards the posterior rami of spinal nerves [32].

Ropivacaine is a long-acting anaesthetic agent that has a lower incidence of cardiac side effects compared to bupivacaine [33]. According to a study by Graf BM et al., bupivacaine has a greater effect on increasing the atrioventricular conduction time compared to ropivacaine [34]. Therefore, the authors chose ropivacaine over bupivacaine due to its better safety profile. Ropivacaine is less lipophilic, which means it penetrates less into large myelinated motor fibers, making it more selective for A-delta and C fibers, rather than A-beta fibers (motor fibers). Ropivacaine also has a significantly higher threshold for cardiotoxicity and central nervous system toxicity compared to bupivacaine. Considering that the time required for the first analgesic dose and the total duration of postoperative pain relief largely depends on the dose and concentration of the anaesthetic agent used, we selected ropivacaine over bupivacaine due to its greater sensory blockade compared to motor blockade and its better safety profile [34].

### Limitation(s)

The major limitations of the study were the smaller sample size and the short duration of the study. Although the CTRI registration expected a sample size of 100 participants for a duration of one month, the authors were unable to recruit that many cases due to their unavailability, even after extending the study for two months. As a result, authors could only recruit 70 participants within the two-month duration, which reduced the power of the study. This is a significant limitation of the current study.

### CONCLUSION(S)

The study found that USG-guided ESPB was more effective than local anaesthetic infiltration in managing postoperative pain in PCNL patients. This was demonstrated by lower NRS pain scores at various time points, improved time required for the first rescue analgesia, and reduced total analgesic consumption in the 24 hours postoperatively. Based on these findings, USG-guided ESPB can be recommended as a pain management technique for patients undergoing PCNL. However, further confirmation of these benefits should be obtained through prospective or randomised trials with a higher power of the study.

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