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Comparison of postoperative analgesic outcome between erector spinae plane block and renal peritubal infiltration with 0.25% levobupivacaine in percutaneous nephrolithotomy: an observer-blind, randomized controlled trial

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Abstract

Background: Percutaneous nephrolithotomy (PCNL) involves significant postoperative pain and discomfort. The present study compared the effectiveness of two novel techniques to alleviate postoperative pain following PCNL surgery, namely anatomical landmark guided erector spinae plane block (ESPB) versus peritubal infiltration of local anesthetic. **Methods**: This was a prospective, observer blind, randomized controlled trial in adult patients undergoing PCNL under general anesthesia. Patients were randomized to two groups of 39 each – one undergoing ESPB with 0.25% levobupivacaine (Group A), and the other receiving peritubal infiltration from renal capsule to skin postoperatively (Group B), with the same local anesthetic. Duration of postoperative analgesia (time to first rescue analgesic), visual analog scale (VAS) score assessed at 1, 2, 4, 6, 12, 18, and 24 hours postoperatively and the number of doses of rescue analgesic (IV tramadol) administered in the first 24 hours were recorded. Treatment emergent adverse events were also noted. **Results**: Duration of satisfactory postoperative analgesia was significantly more in Group B than in Group A (15.2 ± 8.35 hours vs. 6.8 ± 1.89; $p < 0.001$). Also in Group B, nearly 49% of the subjects required no rescue analgesic in the first 24 hours in contrast to Group A where all subjects required at least one dose of rescue analgesic ($p < 0.001$). The VAS pain scores were comparable for the first 4 hours but thereafter were higher in those undergoing ESPB. Relatively minor adverse effects were encountered in a few instances in both groups. **Conclusions**: Anatomical landmark guided ESPB is an effective strategy to provide analgesia in PCNL in the early postoperative period, but peritubal infiltration of local anesthetic provides more durable postoperative analgesia, often alleviating the need for rescue analgesic use in the first 24 hours.

Keywords: Percutaneous nephrolithotomy; Erector spinae plane block; Peritubal infiltration anesthesia; Postoperative pain; Levobupivacaine; Local anesthesia.

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Introduction

Percutaneous nephrolithotomy (PCNL) is the gold standard technique for the removal of large (>20 mm) renal and upper ureteric calculi. However, it may be associated with substantial postoperative pain due to stretching of the renal capsule and the parenchymal tract. The nephrostomy tube causes additional discomfort, and it sometimes needs to be kept in situ during the postoperative period[1,2]. Inadequate analgesia in this situation can impair ventilation, prevent early ambulation, and prolong hospital stay with its attendant cost[1].

Over the years many anesthetic-analgesic techniques have been employed in PCNL surgery to address postoperative pain control. However, till date, none of these techniques are established as the standard of care to alleviate postoperative pain in such patients. Parenteral opioids that are widely used in postoperative pain control carry significant adverse effects like nausea, vomiting, respiratory depression, sedation, pruritus, constipation, and urinary retention[1,3]. Patients posted for PCNL surgery often have suboptimal renal function[1] and non-steroidal anti-inflammatory drugs (NSAID) are potentially nephrotoxic. Therefore novel regional anesthetic techniques that would provide optimal pain control without significant adverse effects need to be explored.

The erector spinae plane block (ESPB) is technically a simple regional block that can be used for postoperative pain relief in a variety of thoracic and abdominal surgical procedures[2,4]. In this procedure, the local anesthetic is deposited deep to the erector spinae muscles and superficial to the transverse processes of vertebrae. The chance of pneumothorax and vascular injuries is minimal[2,5]. While USG guidance can facilitate the procedure, USG machines and USG-trained anesthesiologists may not be readily available. The traditional landmark-guided approach to ESPB is also technically simple, can be performed easily in most operative set-ups and can be timesaving[4-6]. Its use in PCNL procedures is relatively novel[7,8].

Another novel modality of pain relief in PCNL surgery is renal peritubular infiltration, that is infiltration of the nephrostomy tract (skin, subcutaneous tissue, renal capsule, and parenchymal tract) with local anesthetic drugs. This can produce significant reduction of pain as assessed by visual analog scale (VAS) score with less demand for rescue analgesia[8,9]. The peritubal infiltration of local anesthetic agent is done under fluoroscopic guidance by the operating surgeon. Since fluoroscopy is an integral part of PCNL, this does not require any extra arrangements or trained manpower.

There are randomized trials on postoperative analgesia in PCNL surgery with ESPB or renal peritubal infiltration, comparing these techniques individually with standard intravenous analgesia.[1,8-10] The current study aimed to compare the postoperative analgesia outcome in PCNL surgery between ESPB and renal peritubal infiltration with injection levobupivacaine (0.25%). It was planned as a head-to-head comparison of the two novel approaches towards postoperative analgesia in patients undergoing PCNL surgery with the duration of analgesia (time from the successful completion of the block procedure till the first administration of rescue analgesic on patient demand or when VSS score exceeded 4) as the primary outcome measure. Secondary objectives were to assess time to complete the block/infiltration procedure, number of rescue analgesia doses required in first 24 hours, changes in hemodynamic parameters and frequency of adverse events during block procedure or thereafter.

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Methods

The study was conducted as a prospective, observer-blind, randomized controlled trial in the urology operation theatre, recovery room and wards of the urology department of our tertiary care teaching hospital. The study conformed to the Declaration of Helsinki, was cleared by the Institutional Ethics Committee (IEC) for clinical research and required written informed consent from all study participants. It has been registered with the Clinical Trials Registry, India [CTRI/2022/11/047001].

Patients of both sexes, aged between 18 and 65 years, belonging to American Society of Anesthesiologists (ASA) classes I or II, undergoing PCNL surgery under general anesthesia were included. Patients scheduled for second look PCNL, multiple-tracts or bilateral PCNL, bleeding diathesis, solitary kidney, or serious co-morbidities were excluded from the study. Patients unable to handle VAS scoring during screening, despite adequate explanation, were also excluded.

All the participants were briefed about the procedure during pre-anesthesia check-up sessions and taught to respond to the VAS scale. After appropriate preoperative preparation, patients were shifted to the OT. Standard monitoring was set up with electrocardiography, non‑invasive blood pressure, pulse oximetry, and baseline readings recorded. The anesthetic technique and surgical procedure were identical in both study groups. An 18‑G intravenous (IV) line was secured, and general anesthesia was achieved with IV glycopyrrolate 0.2 mg/kg, fentanyl 2 mcg/kg, propofol 2 mg/kg, and skeletal muscle relaxation with IV atracurium 0.5 mg/kg. Patients were intubated with an appropriate-size endotracheal tube after 3 min of mask ventilation. After confirming the endotracheal tube position, the patients were connected to the anesthesia workstation. Anesthesia was maintained using 60% nitrous oxide in oxygen, and isoflurane. The concentration of the latter was adjusted to maintain a minimum alveolar concentration (MAC) between 1 to 1.3. Patients were positioned prone for surgery with appropriate precautions to prevent injury. They received IV paracetamol 1000 mg at the beginning of surgery and IV ondansetron 30 min before extubation to prevent postoperative nausea and vomiting (PONV).

Following the completion of surgery and before making them supine for extubation, patients were randomized to undergo either ESPB or peritubular infiltration by simple randomization using a computer-generated list. Anatomical landmark guided ESPB was achieved with 20 ml of 0.25% levobupivacaine injection. A point 3 cm lateral to the T8 or T9 spine was marked with skin marking pencil, and, with due aseptic precautions, a 100 mm B Braun Stimuplex A insulated needle was introduced perpendicular to all planes to hit the transverse process at a depth of 3 to 5 cm. After the contact, the study drug was injected through the side port after a negative aspiration of blood. The other group underwent peritubal infiltration of 20 ml of 0.25% levobupivacaine injection under fluoroscopic guidance through the nephrostomy tube. The renal capsule was punctured at the 6 and 12 o'clock positions with 18G initial puncture needle to deliver local anesthetic to each site postoperatively, from renal capsule to muscle to subcutaneous tissue and skin by the operating surgeon after PCNL procedure.

Postoperative pain was assessed through VAS scoring administered to the patient by an independent observer, unaware of the technique of analgesia used, at 1, 2, 4, 6, 12, 18, and 24 hours postoperatively. The VAS scale ranged from 0 (no pain) to 10 cm (worst pain imaginable)[11]. If the score was ≥4, IV tramadol was given as rescue analgesic in a dose of 1 mg/kg (maximum 100 mg) and repeated as required during the study period. Rescue analgesia was also offered on demand. The total dose of tramadol was restricted to 400 mg in 24 hours. The duration of postoperative analgesia in the case of ESPB was the time from successful completion of the block to the time for first rescue analgesic and in case of peritubal block, the time from infiltration to first dose of rescue analgesia. If there was no

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requirement for rescue analgesic in the first 24 hours postoperatively, the time to rescue analgesia was taken as 24 hours. The number of doses of rescue analgesic administered in 24 hours was recorded as a secondary outcome parameter. Time to complete the block/infiltration procedure and the total dose of rescue analgesic required were noted. Systolic and diastolic blood pressure (mmHg) and heart rates (bpm) were monitored and treatment-emergent adverse events (e.g. nausea, vomiting, sedation, pneumothorax, hemorrhage, sepsis etc.) were recorded.

The sample size for the study was calculated based on the difference in mean duration of postoperative analgesia as the primary outcome measure. It was calculated that 37 subjects would be required per group so as to detect a difference of 2 hours (deemed as the minimum difference that is clinically meaningful) in this parameter between the groups, with 80% power and 5% probability of Type 1 error. This calculation assumed standard deviation of 3 hours for the duration of postoperative analgesia, two-sided testing and 1:1 allocation. Keeping a 10% margin for dropouts, the recruitment target was kept at 41 subjects per group. Continuous variables were normally distributed (by Kolmogorov-Smirnov goodness-of-fit test) and are reported as mean ± standard deviation and compared between groups by Student's independent samples t-test. Categorical variables are presented as counts (percentages) with intergroup comparison by Pearson's chi-square test or Fisher's exact test. Analyses were two-tailed and a p-value of less than 0.05 was considered statistically significant. Key variables have been presented with 95% confidence interval (CI) values. Sample size calculation and statistical analysis were done using MedCalc version 19.6 (MedCalc Software Ltd., Ostend, Belgium, 2020) software[12].

Results

Eighty-two patients were screened for inclusion; 78 meeting the eligibility criteria and consenting to participate, were randomized into two groups of 39 each. The disposition of study participants is indicated in the CONSORT-style flow diagram in **Figure 1**.

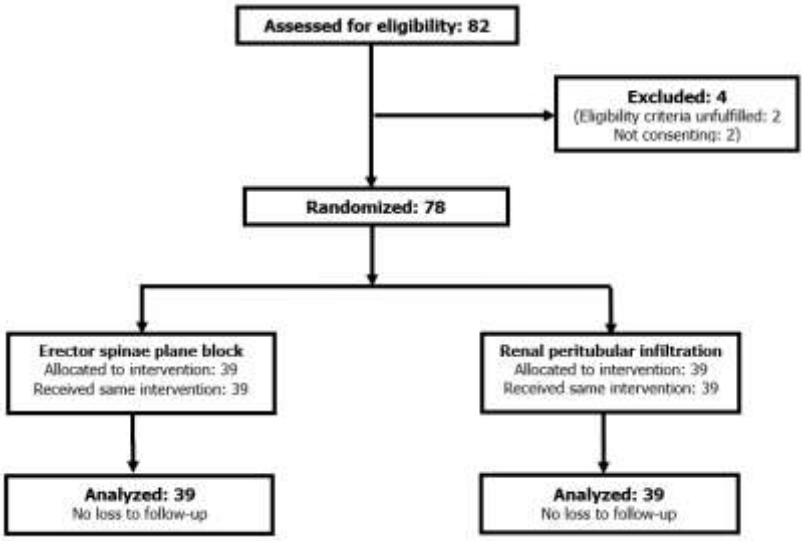

Figure 1: Flow of study participants.

The baseline demographic and clinical characteristics of the study arms were comparable. There was no significant difference in age, gender, anthropometry, ASA status, co-morbidities, or the side on which PCNL surgery was performed. These baseline characteristics are summarized in **Table 1**. As shown in **Table 2**, the duration of surgery and time to complete block were also comparable between the two groups.

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Table 1: Baseline demographic and clinical characteristics of the two study groups.

Parameter	Erector spinae plane block (n = 39)	Renal peritubal infiltration (n = 39)	*p* value
Age (years)			0.063
Mean ± SD	43.6 ± 11.80	43.8 ± 8.76	
Gender			0.814
Male	24 (61.54%)	25 (64.10%)	
Female	15 (38.46%)	14 (35.90%)	
Height (cm)			0.311
Mean ± SD	160.9 ± 8.94	164.9 ± 5.62	
Weight (years)			0.255
Mean ± SD	60.9 ± 7.11	62.2 ± 5.44	
Body mass index (kg/m^2)			0.655
Mean ± SD	23.6 ± 2.91	22.9 ± 2.72	
Clinical status			0.725
ASA-I	27 (69.23%)	25 (64.10%)	
ASA-II	12 (30.77%)	14 (35.90%)	
Comorbidities			0.725
Nil	22 (56.41%)	23 (58.97%)	
Hypertension	10 (25.64%)	09 (23.08%)	
Diabetes	05 (12.82%)	03 (7.69%)	
COPD	02 (5.13%)	04 (10.26%)	
Side of PCNL procedure			0.650
Right	19 (48.72%)	21 (53.85%)	
Left	20 (51.28%)	18 (46.15%)	

- Abbreviations: ASA = American Society of Anesthesiologists; COPD = chronic obstructive pulmonary disease; PCNL = percutaneous nephrolithotomy; SD = Standard deviation.
- Figures indicate count (%) unless otherwise stated.
- *p* value in the last column is from Student's unpaired *t* test for numerical variables and Chi-square test or Fisher's exact test for categorical variables.

Table 2: The duration of surgery and time to complete block compared between study groups.

Parameter	Erector spinae plane block (n = 39)	Renal peritubal infiltration (n = 39)	*p* value
Duration of surgery (hours)			0.191
Mean ± SD	2.1 ± 0.35	2.3 ± 0.44	
95% CI	1.99 to 2.21	2.16 to 2.44	
Time of complete block (min)			0.134
Mean ± SD	5.1 ± 0.72	6.9 ± 0.86	
95% CI	4.87 to 5.33	6.63 to 7.17	

- Abbreviations: CI = Confidence interval; SD = Standard deviation.
- *p* value in the last column is from Student's unpaired *t* test.

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There was, however, marked difference in the effective duration of postoperative analgesia between the two groups i.e. in the time from successful completion of the block or infiltration procedure to the first requirement of intravenous analgesic medication. This was 6.8 ± 1.89 hours in the ESPB group versus 15.2 ± 8.35 hours in the peritubal block group ($p < 0.001$). In the latter group, nearly 50% had no requirement for rescue analgesic doses in the 24-hour postoperative observation period, as opposed to no such patient in the ESPB group. These figures are presented in **Table 3**.

Table 3: Duration of postoperative analgesia and rescue doses rescued compared between study groups.

Parameter	**Erector spinae plane block (n = 39)**	**Renal peritubal infiltration (n = 39)**	***p* value**
Time to first rescue analgesic (hours)			< 0.001
Mean ± SD	6.8 ± 1.89	15.2 ± 8.35	
95% CI	6.21 to 7.39	12.58 to 17.82	
No. of rescue doses in 24 hours			< 0.001
Nil	0	19 (48.72%)	
One	20 (51.28%)	18 (46.15%)	
Two	19 (48.72%)	2 (5.13%)	

- Abbreviations: CI = Confidence interval; SD = Standard deviation.
- *p* value in the last column is from Student's unpaired *t* test for time to rescue and Chi-square test for number of rescue doses required.

The VAS scores recorded at intervals in the 24-hours postoperative period showed a significant difference between the two groups at 4 hours ($p = 0.009$) and 6 hours ($p < 0.001$) after the operation, the ESPB arm having higher scores than renal peritubular block arm. At other time points the differences in VAS scores were not significant statistically. The trends in VAS scores are depicted in **Figure 2**.

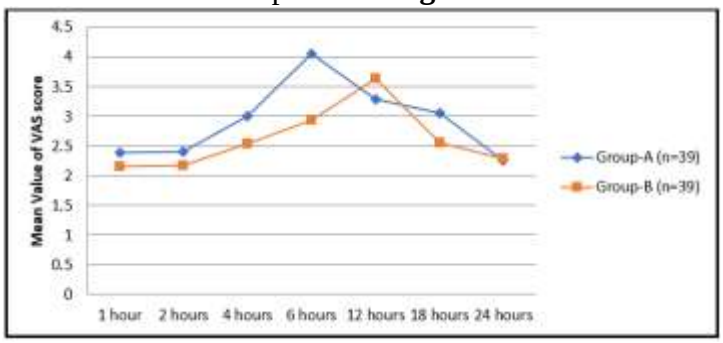

Figure 2: Trend in VAS pain scores in the two study groups in the 24-hour postoperative period. Group A underwent erector spinae plane block while Group B received renal peritubal infiltration of local anesthetic.

The patients' heart rates, systolic and diastolic BP were recorded at baseline and during postoperative assessment hours. The results (data not shown) were comparable in both groups and in the acceptable range. Hypotension in a few patients was treated with bolus dose of 500 ml IV normal saline. There were no serious adverse events in any group. Few patients

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developed fever, nausea, vomiting, hypotension, etc., which were self-limiting and without statistically significant differences between groups (**Table 4**).

Table 4: Frequency of adverse events in the study arms.

Parameter	Erector spinae plane block (n = 39)	Renal peritubal infiltration (n = 39)	*p* value
Hypotension	02 (5.13%)	04 (10.26%)	0.497
Fever	02 (5.13%)	03 (7.69%)	0.057
Nausea-vomiting	01 (2.56%)	06 (15.38%)	0.331
Allergic reaction	01 (2.56%)	02 (5.13%)	0.494

Discussion

Postoperative pain is acute pain from surgical trauma with an inflammatory reaction and initiation of an afferent neuronal barrage. It is a combined constellation of unpleasant sensory and mental experiences precipitated by surgical trauma and associated with autonomic, endocrine-metabolic, physiological, and behavioral responses[13]. PCNL surgery involves significant tissue damage due to the stretching of the renal capsule and insertion of the nephrostomy tube, which causes local inflammatory reaction and pain. Inadequate pain management leads to complications like pulmonary dysfunction and delayed recovery. Dalela *et al.*[14] performed PCNL under renal capsular block by infiltrating the renal capsule with 2% lignocaine. They emphasized that most of the pain during PCNL is felt at the time of dilatation of renal capsule and parenchyma as it is richly innervated by pain conducting neurons.

In our study, one group of patients received landmark-guided erector spinae block with single shot injection of 20 mL of 0.25% Levobupivacaine. Chavan *et al.*[2] studied erector spinae block with 0.25% bupivacaine injection for postoperative analgesia in PCNL surgery against a control group receiving intravenous analgesics according to institutional protocol. They concluded that landmark guided ESPB is an effective and simple method to alleviate immediate postoperative pain in PCNL surgeries under general anesthesia. Ramachandran *et al.*[8] in their study comparing USG-guided ESPB with local infiltration of incision site with 0.25% bupivacaine concluded that there was significant difference in the time to first analgesia in the ESPB group (12 hours) to 30 minutes in the control group. Bryniarski *et al.*[7] compared perioperative pain control with USG-guided ESPB given prior to surgical intervention. They reported that ESPB is an effective strategy for perioperative pain, but its shorter duration is a disadvantage in comparison with paravertebral block or epidural anesthesia. They used PCA with intravenous opioids as rescue analgesia. However, the simplicity of performing ESPB and the virtual lack of complications after this procedure supports its wide use before PCNL[3,8].

The other group underwent peritubal infiltration of local anesthetic. Parikh *et al.*[1] conducted a RCT comparing postoperative analgesia in PCNL surgery by peritubal infiltration of 0.25% bupivacaine against similar infiltration with normal saline. The difference with placebo was striking – the mean time to first demand analgesia was 9.1 hours in the study group against 2.7 hours in the control group. Karaduman *et al.*[15] aimed to investigate the effect of peritubal local anesthetic and opioid infiltration on pain scores and analgesic consumption in patients who underwent percutaneous nephrolithotomy. They concluded that peritubal infiltration of bupivacaine with morphine after percutaneous nephrolithotomy is an effective method for postoperative pain control and reduces analgesic consumption. Lojanapiw *et al.*[16] have documented that peritubal local anesthetic infiltration with 0.25% bupivacaine alleviates

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immediate postoperative pain after PCNL surgery even with supracostal access. There was lower incidence of early postoperative pain, lower usage of morphine and longer time to first rescue analgesic as compared to intravenous morphine only group.

The current study compared the two block techniques, namely landmark-guided ESPB and peritubal infiltration of 0.25 % levobupivacaine, head-to-head, for postoperative analgesia in PCNL surgery. The mean time required to complete the block procedure showed statistically non-significant difference between the two groups, but a marked difference in mean time to rescue analgesia (6.8 in the ESPB arm versus 15.2 in the peritubal infiltration arm; $p < 0.001$). The VAS scores were also significantly lower at 4 and 6 hours after operation with peritubal infiltration and the same group showed lower requirement of rescue analgesia. Thus the postoperative analgesic performance was superior with peritubal infiltration compared to ESPB. Both procedures were safe. No serious complications like vascular injury, pneumothorax or local anesthetic toxicity were encountered. Relatively minor adverse effects occurred in both groups, but all were self-limiting.

The study had limitations, primarily the unicentric nature and the relatively rigid inclusion criteria which limit, to some extent, the generalizability of the results. However, we can still conclude that both ESPB and peritubal infiltration with 0.25% bupivacaine are satisfying options for postoperative analgesia in PCNL surgery. However, ESPB though effective in alleviating early postoperative pain often requires rescue analgesia beyond 4 to 6 hours, while peritubal infiltration of local anesthetic into the renal capsule, muscles, subcutaneous tissue, and skin can offer prolonged analgesia without the need for additional rescue.

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