Original Article

Comparison of efficacy of intercostal nerve block versus peritract infiltration with 0.25% bupivacaine in percutaneous nephrolithotomy: A prospective randomized clinical trial

Sushil Gyawali*, Bhoj Raj Luitel[1], Amit Sharma Bhattarai[2], Uttam Kumar Sharma[1]

Departments of General Surgery, [1]Urology and Kidney Transplant Surgery and [2]Anesthesiology, Institute of Medicine, Tribhuvan University Teaching Hospital, Kathmandu, Nepal

*E-mail: drsushilgyawali@gmail.com

ABSTRACT

Introduction: Postoperative pain following percutaneous nephrolithotomy (PCNL) adds to the morbidity of patients requiring additional analgesia. Various modalities of pain control techniques, such as intercostal nerve block (ICNB) and peritract infiltration (PTI), are being studied for better pain management. This study compares the efficacy of ICNB with PTI for postoperative pain management.

Methods: A double-blinded, prospective, randomized control study was conducted, in which 0.25% bupivacaine, either ICNB or PTI, was given at the puncture site at the end of PCNL. The primary outcome was a comparison of postoperative pain score measured with resting Visual analogue Scale (r-VAS) and dynamic VAS (D-VAS) recorded at 2 h, 4 h, 8 h, 10 h, 12 h, 24 h, and at discharge. Injection ketorolac was given as rescue analgesia. Secondary outcomes include time to first rescue analgesia and total analgesic requirement (TAR).

Results: Sixty patients were randomized into two equal groups with 63.3% male and 36.6% female, with a mean age of 37.25 ± 13.09 years. In Group ICNB, 24 (40%) and 6 (10%) patients and in Group PTI, 21 (35%) and 9 (15%) patients underwent standard and mini PCNL, respectively, in each group. All cases were PCNL doen in prone position. The mean R-VAS and D-VAS scores at 2, 4, 8, 12, 24, and 48 h were similar in both groups. The mean TAR was 56.84 ± 0.33.00 mg and 55.54 ± 0.29.64 mg of injection ketorolac in Group ICNB and PTI, respectively ($P < 0.894$). The time to first rescue analgesic demand were 7.11 ± 4.898 h and 6.25 ± 3.354 h ($P < 0.527$). Both the groups were comparable in terms of length of hospital stay, stone clearance rate, and complication rate.

Conclusion: The ICNB was as efficacious as PTI for postoperative pain control with 0.25% bupivacaine following PCNL.

INTRODUCTION

Percutaneous nephrolithotomy (PCNL) is considered the "gold standard" for the management of large renal calculi because it is less invasive and morbid than open surgery.[1] The main sources of acute postoperative pain after PCNL are visceral pain originating from the kidney and ureter and somatic pain from the incision site. Visceral pain is primarily transmitted through the T10 to L2 spinal nerves, and incisional pain is conducted via T8 to T12 due to the incision site, often at the 10th to 11th intercostal space. The kidneys are densely innervated by both afferent nociceptive sensory fibers and efferent sympathetic nerve fibers. Significant postoperative pain can occur with PCNL in the 1st 24 h along the nephrostomy tract or due to dilatation of the renal capsule and parenchyma. It may vary with individual pain perception, use of

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nephrostomy tubes, choice of analgesic route, anesthetic agents, etc.[2]

Regional anesthesia is the most effective method to treat postoperative pain, with the advantage of direct action at the site of surgery with minimal adverse effects of analgesic drugs.[3] The role of intercostal nerve block (ICNB) as a regional anesthesia technique is well-established in thoracic and abdominal surgery and is being used for postnephrectomy pain relief.[4] Another method, peritubal infiltration, also known as peritract infiltration (PTI), instilled from the renal capsule to the skin has been equally effective for postoperative PCNL pain.[5] The optimal method for pain control after PCNL remains controversial. Studies comparing ICNB and PTI for post-PCNL pain are lacking and there is no consensus. This study aims to compare the efficacy of ICNB and PTI with 0.25% bupivacaine for post-PCNL pain control.

MATERIALS AND METHODS

We conducted a double-blinded, prospective randomized control study from November 2020 to November 2021, after ethics approval from the institutional review board of the Institute of Medicine, Nepal (reference number: 408/6-11 E2/076/077; approval on March 10, 2020). The study adhered to the ethical guidelines of the Declaration of Helsinki and its amendments. Written, informed consent was taken from the participants before enrolling in the study.

Patients above 16 years of age undergoing PCNL in the Department of Urology were included in the study. Patients excluded were: ≤16 years of age, history of hypersensitivity/anaphylaxis or contraindications to bupivacaine, systemic diseases (chronic kidney disease (CKD), active urinary tract infection, untreated sepsis), relook surgery, American Society of Anesthesiologist grade >2, contraindications for PCNL (pregnancy, coagulopathy) and patients who decline to participate in the study. The sample size calculated was based on the reference study published by Choi *et al*.[5]

PCNL were performed in a prone position under general anesthesia. Tract dilatation was done with sequential fascial dilators (Amplatz). A 6 Fr both end open double-J ureteral stent was placed in all the cases. However, a nephrostomy tube (16–20 F) was placed at the surgeon's discretion in selected cases.

Patients were equally randomized into two groups using "sealed envelope method," the envelope was drawn before the surgery by the nurse who is not related to the study, into ICNB group and PTI group. All the patients and the investigators were blinded to the intervention given. The patient was premedicated with prophylactic antibiotics with an injection ceftriaxone 1 g intravenously.

a. Group ICNB: ICNB was administered by the surgeon in the 10^{th} and 11^{th} intercostal space at the termination of PCNL, under fluoroscopy guidance in the prone position. A 23Ggauge spinal needle was inserted just lateral to the mid scapular line, and located above the innermost intercostal muscle. After negative aspiration for blood, 20 mL of 0.25% bupivacaine was injected in divided amount, i.e., 10 mL each, between the innermost intercostal muscle and pleura below the 10^{th} and 11^{th} ribs
b. Group PTI: A 23G spinal needle was inserted up to the renal capsule along the nephrostomy tract at 6 and 12 o'clock under visualization and fluoroscopic guidance, 20 mL of 0.25% bupivacaine was infiltrated into the nephrostomy tract from renal capsule to the skin area, 10 mL for each position. This was performed by the operating surgeon.

Injection paracetamol was given as regular postoperative analgesia, round the clock as per institutional practice, according to the body weight 15–20 mg/kg/dose intravenously, given 6 hourly but not exceeding 4 g/day adult dose. The intensity of pain was recorded by the principal investigator or by an independent ward nurse, at postoperative 2, 4, 8, 10, 12, 24 h and at the time of discharge. The pain score was assessed by VAS, a 10-point scale ranging from 0 for minimum or no pain, to 10 for the maximum pain score perceived or imagined by the patient, at rest (R-VAS) and on deep breathing or coughing known as D-VAS. Patients who had a VAS score of >4 or intractable pain were given rescue analgesia, injection of ketorolac 30 mg/dose, given 4–6 hourly via intravenous route. The dosage was adjusted according to pain severity and response. Any side effects or complications such as nausea, vomiting, headache, fever, hemorrhage, and injury to adjacent organs and viscera, hydrothorax, or pneumothorax were recorded and managed as per institutional protocol.

On the first postoperative day, all patients underwent routine plain X-ray KUB to check for residual stone fragments. In cases of supracostal approach and ICNB, the plain chest X-ray was performed to identify a hydro/pneumothorax. The patients were followed till discharge.

Statistical analysis

The results were expressed as numbers with percentages for qualitative variables and mean ± standard deviation for quantitative variables. The outcomes of both groups were compared using the Student's *t*-test for continuous variables with normal distributions. Continuous data were analyzed using unpaired Student's *t*-test. Categorical data were analyzed using the Chi-square test. $P < 0.05$ was considered statistically significant. The statistical analysis was performed using IBM SPSS Statistics version 24 (IBM Corp, Armonk, NY, USA. The principal investigator was blinded to the intervention groups during the intervention and the

data collection, the decoding was done, and intervention groups were revealed at the time of analysis only. The study was reported as per revised CONSORT guidelines as far as possible.[6]

RESULTS

A total of 75 patients with renal calculi planned for PCNL were assessed for eligibility. After the exclusion of 15 patients who did not fulfill the criteria, 60 patients were randomized into two equal groups and included for data analysis. [Figure 1]

The demographics and patient characteristics are shown in Table 1 and the PCNL characteristics with outcomes are shown in Table 2. Both the groups were comparable in all aspects.

Primary and secondary outcomes

The primary outcome was postoperative pain score: Resting VAS score and D-VAS scores, recorded postoperatively at 2 h, 4 h, 8 h, 10 h, 12 h, 24 h, and at time of discharge were as depicted in Table 3.

The pain scores were not statistically significant when compared between the groups. The mean TAR was 56.15 ± 30.9 mg overall, 56.84 ± 33.007 mg and 55.54 ± 29.643 mg of injection ketorolac in groups ICNB and group PTI, respectively, which was not statistically significant (P < 0.894). The time to first rescue analgesic demand was 6.67 ± 4.14 h overall: it was 7.11 ± 4.898 h in group ICNB and it was 6.25 ± 3.354 h in group PTI (P < 0.527). In subgroup analysis, with regard to mini versus standard PCNL and tube versus tubeless PCNL, all the pain scores, the TAR and time to first rescue analgesia were not statistically significant.

The complications were comparable between the two groups and were not statistically significant. The most common complication seen following PCNL was fever, followed by urine tract infection (UTI), postrenal acute kidney injury, nausea, vomiting, headache, and urinary leakage as depicted in [Tables 4-6]. Severe adverse effect was not present in any patient. Most of the complications were mild and were managed with conservative treatment. No complications were attributable to the interventions of the study (i.e., ICNB or PTI) but were related to the surgery itself. The complications of PCNL were categorized according to the Clavein–Dindo Classification, as shown in Table 5. One case had urine leakage from the puncture site, managed with proper dressing and abdominal evaluation with ultrasonography (USG), which revealed mild perinephric collection, and was managed with USG-guided aspiration under local anesthesia. One patient received a unit of packed red cell transfusion for fall in hemoglobin.

DISCUSSION

Kidney stone is a common health problem and one of the most common causes of visit to the emergency

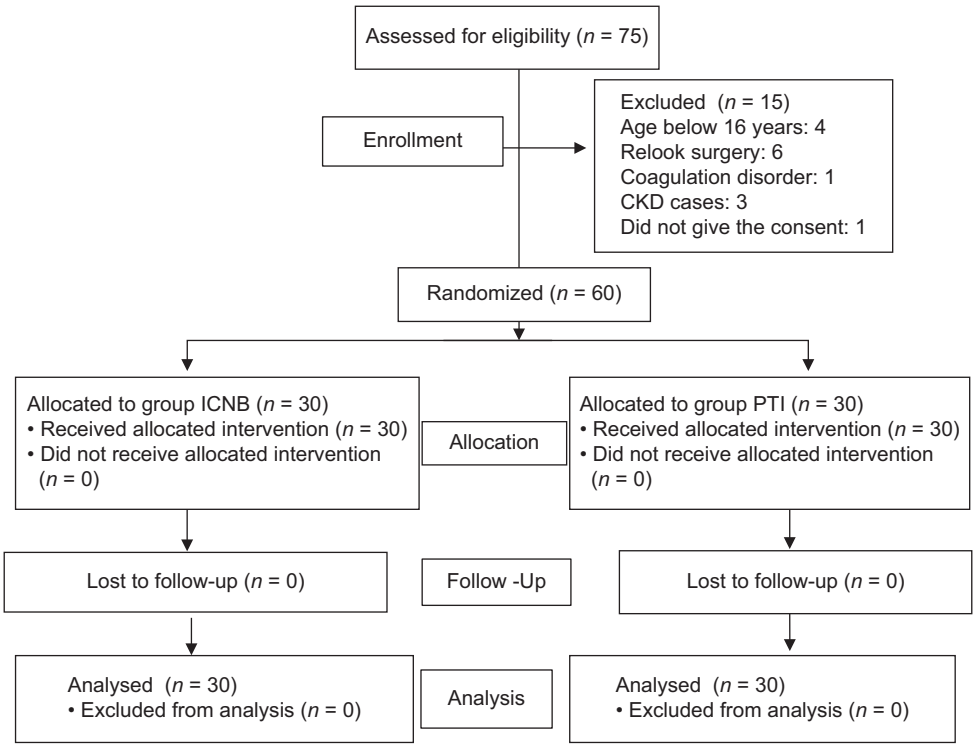

Figure 1: CONSORT diagram. CKD = Chronic kidney disease, PTI = Peritract infiltration, ICNB = Intercostal nerve block

Table 1: Demographics and patient characteristics

Characteristics	Group ICNB	Group PTI	*P*
Number of patients	30	30	-
Mean age (years)	33.57±11.377	40.93±13.831	0.28
Sex, *n* (%)			
Male	18 (30)	20 (33.33)	0.287
Female	12 (20)	10 (16.66)	
BMI (kg/m^2)	23.103±1.595	23.090±1.8914	0.977
ASA score, *n* (%)			
1	30 (50)	28 (46.6)	0.15
2	0	2 (3.3)	
Guys stone score			
1	3	6	0.409
2	11	7	
3	4	7	
4	12	10	
Stone laterality (right: left), *n* (%)	14 (23.3): 16 (26.6)	10 (16.6):20 (33.33)	0.292
Stone burden (mm^2)	766.9±573.933	548.07±370.006	0.084
Number of stones	2.33±1.269	2.33±1.184	1.000
Stone maximum size (mean) (mm)	29.3±11.058	26.63±9.034	0.342

BMI=Body mass index, ASA=American Society of Anesthesiologist, ICNB=Intercostal nerve block, PTI=Peritract infiltration

Table 2: Percutaneous nephrolithotomy outcomes and characteristics

Parameters	Group ICNB	Group PTI	*P*	Remarks
Standard: mini, *n* (%)	24 (40):6 (10)	21 (35):9 (15)	0.8	
Operative time (min)	128.6±26.23	128±24.34	0.928	
Approach				
Subcostal	29	30	1.0	
Supracostal	1	0		
Use of PCN tube, *n* (%)	8 (26.6)	10 (33.33)	0.573	
Duration of tube placement (days)	5.43±1.618	5.10±1.480	0.667	
Stone clearance, *n* (%)	11 (36.6)	13 (43.3)	0.598	40% over all clearance
Mini PCNL	2	5	0.398	
Standard PCNL	9	8	0.967	
Total LOS	4.7±1.685	4.47±1.252	0.545	
Change (drop) in Hb level	1.9033±2.3128	1.47±1.370	0.381	
Changes in creatinine level	9.743±76.76	6.2±34.012	0.818	

LOS=Length of stay, PCNL=Percutaneous nephrolithotomy, PCN=Percutaneous nephrostomy, Hb=Hemoglobin, ICNB=Intercostal nerve block, PTI=Peritract infiltration

Table 3: Primary and secondary outcome: Comparison of postoperative pain scores, time to rescue analgesia, total analgesia requirement

Variable	Group ICNB	Group PTI	*P*
RVAS score			
2 h	1.93±0.923	2.13±1.196	0.471
4 h	2.76±1.618	3.07±1.837	0.498
8 h	3.62±1.720	3.07±1.507	0.193
10 h	3.21±0.902	3.03±1.326	0.560
12 h	2.90±0.86	3.23±1.431	0.280
24 h	2.34±1.045	2.03±0.809	0.205
Discharge	1.31±0.471	1.30±0.596	0.941
DVAS score			
2 h	2.30±1.179	2.30±1.466	1.00
4 h	3.13±1.655	3.47±1.889	0.470
8 h	3.90±1.689	3.77±1.695	0.761
10 h	3.60±1.163	3.37±0.999	0.408
12 h	3.17±1.020	3.73±1.639	0.113
24 h	2.50±1.137	2.37±0.765	0.596
Discharge	1.57±0.679	1.43±0.626	0.432
Time to first rescue analgesia demand			
Time (h)	7.11±4.898	6.25±3.354	0.527
Total analgesic requirement (injection ketorolac)			
Dose (mg)	56.84±33.007	55.54±29.643	0.894

ICNB=Intercostal nerve block, PTI=Peritract infiltration, DVAS=Dynamic Visual Analog Scale, RVAS=Resting Visual Analog Scale

department and hospital admission. The prevalence and incidence of kidney stones have increased worldwide, and environmental factors seem to play a major role in this issue.[7,8] Dalela *et al*.[9] have demonstrated that the majority of pain at the time of PCNL might originate from dilatation of the renal capsule and the parenchymal tract, which is richly innerved by pain-conducting neurons. PCNL can be regarded as grade IV renal injury. Expansion of cutaneous, subcutaneous, and muscular layers might also contribute to post-PCNL pain. The concept of tubeless procedure was first introduced by Limb and Bellman *et al*.[10] Honey *et al*.[11] first introduced ICNB for post-PCNL pain management. They concluded that ICNB can improve post-PCNL pain and health-related quality of life. However, the effectiveness of bupivacaine disappears within 6 h of surgery, after which narcotic use (patient-controlled analgesia) becomes indistinguishable. Shah *et al*.[12] have reported the impact of nerve tract infiltration (NTI) using 0.25% bupivacaine in tubeless PCNL. Kirac *et al*.[13] and Parikh *et al*.[14] also demonstrated that the VAS score in the infiltration group was significantly lower with a lower requirement of analgesia as compared to the control group, and that peritract infiltration with bupivacaineis a suitable method of postoperative pain relief.

Table 4: Complications of percutaneous nephrolithotomy

Complications	ICNB	PTI	Remarks (modified Clavein-Dindo)
Fever, *n* (%)	6 (10)	3 (5)	I
Vomiting	0	1	I
Headache	0	1	I
UTI	2	2	II
Urinary leakage	1	0	III
Derangement in RFT	2	2	IVa
Blood transfusion	1	0	II

ICNB=Intercostal nerve block, PTI=Peritract infiltration, UTI=Urine tract infection, RFT=Renal Function Test

Table 5: Complications of percutaneous nephrolithotomy based on modified Clavien–Dindo grading

Complications (Clavein-Dindo grading)	ICNB, *n* (%)	PTI, *n* (%)
Grade I	6 (10)	5 (8.3)
Grade II	3 (5)	2 (3.3)
Grade III	1 (1.6)	-
Grade IV	2 (3.3)	2 (3.3)
Grade V	-	-

ICNB=Intercostal nerve block, PTI=Peritract infiltration

Similar to our study, three studies compared postoperative pain with VAS score between ICNB and PTI. Jonnavithula *et al*.[15] compared PTI and ICNB with 0.5% ropivacaine; R-VAS and D-VAS scores were less for 1st 12 h in the intercostal group than the infiltration group, i.e., significant difference between the VAS and DVAS at 8 and 12 h, after 12 h, the pain scores were comparable, showing that the effect of ropivacaine lasted for around 10–12 h, which is more than bupivacaine. Singh *et al*.[2] performed ICNB and PTB with 0.25% bupivacaine in standard PCNL with placement of 24 F nephrostomy tube in all cases, and reported low VAS scores in PTB group in 6, 12, 24 and 48 h, all values were statistically significant ($P < 0.001$). Similarly, Choi *et al*.[5] compared ICNB, NTI, and control groups with 0.5% ropivacaine and epinephrine, and reported the mean RVAS scores at 2 and 8 h for PTI were significantly less than those for the control group. Mean R-VAS scores at 24h had borderline significance ($P = 0.050$) among the three groups. Differences in mean D-VAS scores among groups were statistically significant ($P = 0.002$) only in the 1st 2 h. The D-VAS scores were not significant then after till 12 h. In our study, the RVAS and DVAS scores in ICNB and PTI groups were comparable and not statistically significant, which was similar to the finding suggested by a recent meta-analysis by Chen *et al*.[4] The reason for no difference could be attributed to the patient factors, i.e.,, Nepalese population as well as subjective perception and expression of the pain. The sedation level and mental status following general anesthesia and the anxiety after surgery might have played a role in the proper expression of pain and demand for analgesia. Similarly, the level of knowledge and understanding regarding the correct assessment of pain using VAS scale from 1 to 10 might have brought subjective variation during pain scoring.

The mean time to first analgesic demand was 6.67 ± 4.14 h and the mean TAR was 56.15 ± 30.9 mg, with no statistical significance between the groups. It signifies that the analgesic effect of bupivacaine lasted around 6–7 h and

Table 6: Comparison with the similar studies

Study	Year	Results	Conclusion
Jonnavithula *et al*.[15]	2017	Lower pain scores, less number of demands and amount of analgesics and higher time to first demand for rescue analgesia in group I than group P	ICNB provided superior analgesia than PTI
Choi *et al*.[5]	2018	Significant lower VAS scores in NTI group at 2 and 8 h and lesser total analgesic requirement, however not statistically significant	NTI was efficacious in early postop pain control than ICNB
Singh *et al*.[2]	2019	Significantly lower VAS scores and lower requirement of analgesic with PTI and early requirement of rescue analgesia in the ICNB group	ICNB was not efficacious as PTI
Chen *et al*.[4]	2021	No difference in pain scores at 6–8 h, 12 h and 24 h and the time for the first analgesic demand	ICNB efficacy may not be greater than PTI
Our study	2021	No differences in VAS scores, time to first rescue analgesia, and total analgesia requirement in both groups	ICNB was as efficacious as PTI

ICNB=Intercostal nerve block, PTI=Peritract infiltration, VAS=Visual Analog Scale, NTI=Nerve Tract Infiltration

on an average <2 doses of 30 mg injection ketorolac were required as extra analgesia. In our study, the pain scores were higher at 8–10 h and at 12 h, which were lower; this was because when the pain was more at around 8–10 h, patients would have received rescue analgesia, following which the pain intensity decreased. In Jonnavithula*et al*. study[15] with ropivacaine, the time for analgesia demand was early and more frequent in PTI compared to Group I, but the mean total analgesia requirement was more in Group PTI. However, in Singh *et al*. study[2] with bupivacaine, the time for rescue analgesia (Injection sodium diclofenac) demands were early and the mean total analgesia requirement was more in ICNB as compared to PTB. As per Choi *et al*.[5] the total rescue analgesia amount used was less in NTI than in ICNB and control groups, but there were no statistically significant differences among groups. In comparison with ropivacaine in different studies, the duration of action of bupivacaine was observed less and the time to first rescue analgesia demand was early.

Shin *et al*.[16] first studied the modified Clavien system in 282 patients after PCNL. Transient perinephrostomy urine leakage (15.2%) was the most common complication, followed by fever (11%) and blood transfusion (6.9%). In patients with staghorn stones, grade I, II, IIIb, and IVa (including bowel injury) complications were more common, and all grade IVb (sepsis in 0.6%) and grade V (0.4%) complications occurred in patients with staghorn stones.[16] Seitz *et al*. [17] reported postoperative fever as a common complication, with an overall incidence of 10.8%.(range: 2.8%–32.1%) and access tract leakage >12 h up to 4.6%.[17] In our study, the most common complication was fever, six patients from ICNB and 3 from Group P, among which two patients from each group had culture-proven postoperative UTI, and deranged renal functions in four patients. Modified Clavein Dindo grades were Grade I (15%), Grade II (8.3%), Grade III (1.6%), and Grade IV (6.67%) in total. None of the complications were due to the interventions in our study, but they were the complications due to the surgery i.e., PCNL. Hence, injection of bupivacaine was safe for regional analgesia in PCNL.

Hence, the findings were similar to those of Singh *et al*.[2] and Shah *et al*.[12] where fever was the most common complication observed and most of them were of the minor grade, i.e., Clavien–Dindo grade I and II. Singh *et al*.[2] reported that the mean complication rate in ICNB and PTI was 28.1% and 25%, which were not statistically significant. However, in the study by Choi *et al*. [5], complications were 5.4%, with only grade I complications in the ICNB group and no complications occurring in the NTI group. None of the above studies reported complications attributable solely to anesthesia technique, ICNB, or PT infiltration, except pneumothorax or hydrothorax. A comparison of the efficacy of ICNB and PTI or NTI with other similar studies is shown in Table 6.

The limitation of our study was single-center study with a relatively small sample size. More samples with subgroups like mini and standard PCNL tubed and tubeless PCNL, etc., would have obvious advantages. The difference in subjective perception and objective assessment of pain scoring with the VAS scale might have limited the exact evaluation of pain. In our study, we had two groups with no control group, and if the third arm had been used as a control, the results could have been different. Local or regional analgesic techniques have been widely used in recent years because they are simple, safe, and provide effective analgesia with very few side effects. However, comparing the technical difficulty of the instillation, PTI would be an easier procedure than ICNB. In our study, the null hypothesis was accepted and it was concluded that ICNB provided good postoperative analgesia as effective as PTI.

CONCLUSION

ICNB was as efficacious as PTI with 0.25% bupivacaine in alleviating postoperative pain following PCNL in terms of postoperative pain scores, time for first rescue analgesia, and total analgesia requirement.

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