ORIGINAL ARTICLE

The efficacy of 0.25% bupivacaine infiltration in tubeless percutaneous nephrolithotomy in singular stone of the pelvis: A randomized clinical trial

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Background: Postoperative pain is a significant concern following percutaneous nephrolithotomy (PCNL). While tubeless PCNL has reduced discomfort, effective and simple analgesic techniques are still needed. **Materials and Methods:** A double-blind, randomized controlled trial was conducted at two tertiary hospitals with 120 adult patients having solitary renal pelvic stones <3 cm. Patients were randomized into two groups: the intervention group received 20 mL of 0.25% bupivacaine infiltrated into the tract at surgery end, and the control group received no infiltration. Postoperative pain was assessed using the visual analog scale (VAS) at 6, 12, and 24 h. Both patients and outcome assessors were blinded. Data from 57 intervention and 56 control patients were analyzed. **Results:** Baseline demographic, anatomical, and perioperative characteristics were well-matched between the two groups (all $P > 0.05$). Repeated-measures analysis of variance revealed a significant main effect for both time ($P < 0.001$) and treatment group ($P = 0.006$). The bupivacaine group consistently reported significantly lower mean VAS pain scores at 6 h (4.33 ± 0.97 vs. 4.85 ± 1.05, $P = 0.008$), 12 h (2.68 ± 0.81 vs. 3.16 ± 0.95, $P = 0.005$), and 24 h (1.53 ± 0.68 vs. 1.84 ± 0.71, $P = 0.018$) than the control group postoperatively. **Conclusion:** Infiltration of the nephrostomy tract with 0.25% bupivacaine is a simple and effective method for significantly reducing postoperative pain at 6, 12, and 24 h after tubeless PCNL. This technique provides a sustained analgesic benefit and should be considered for routine implementation to enhance patient recovery.

Key words: Nephrolithiasis, percutaneous nephrolithotomy, postoperative pain

How to cite this article: Kazemi R, Najafabadi HM, Norouzi M, Ghandehari AH. The efficacy of 0.25% bupivacaine infiltration in tubeless percutaneous nephrolithotomy in singular stone of the pelvis: A randomized clinical trial. J Res Med Sci 2025;30:68.

INTRODUCTION

Kidney stones are one of the most common reasons for patients to visit urology clinics worldwide, and their prevalence has increased significantly in recent decades. In many cases, large kidney stones require surgical interventions for treatment. Recent advances in surgical techniques and instruments have led to a shift from open surgical treatments to less invasive methods, such as percutaneous nephrolithotomy (PCNL).[1,2]

PCNL is a minimally invasive urological procedure that is widely used for the treatment of kidney stones. According to guidelines, PCNL is considered the standard surgical treatment for large kidney stones with a high success rate, fewer complications, and shorter hospital stay compared to open surgery. Although this method is associated with fewer complications compared to open methods, complications such as postoperative pain still pose a challenge for patients.[3,4]

Distension of the renal capsule and parenchyma, movement of the access sheath, irritation of the diaphragm, pleura, and retroperitoneum due to the dilator, stretching of the skin, subcutaneous tissue, muscles, and the presence of a nephrostomy tube are possible causes of postoperative pain following PCNL.[5]

There are various methods for managing pain in patients after PCNL; in clinical practice, the use of opioid

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Quick Response Code:

Website: https://journals.lww.com/jrms

DOI: 10.4103/jrms.jrms_963_25

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Submitted: 01-Sep-2025; **Revised:** 01-Nov-2025; **Accepted:** 25-Nov-2025; **Published:** 30-Dec-2025

analgesics and systemic nonsteroidal anti-inflammatory drugs (NSAIDs) is an effective and widely used method to reduce pain in these patients, but major concerns about the side effects of these drugs limit their use, especially in high-risk patients, such as the elderly or those with renal failure. Treatment with NSAIDs and opioids may be associated with gastrointestinal, renal, and cardiovascular problems, respiratory depression, sedation, and other side effects.[6-8]

Due to the complications and limitations of previous methods, physicians are looking for new methods to control the pain of these patients. The use of local anesthetic infiltration (LAI) is one of the newest methods of controlling pain in patients undergoing PCNL surgery. Recently, studies have been published on the efficacy of LAI in pain control after PCNL, reporting favorable results with significant methodological differences in terms of blinding, block time, and type of anesthetic agents.[9-13] Some of these studies have investigated the use of local infiltration of 0.25% bupivacaine as a method of pain control.[6,14,15]

Bupivacaine is an amide local anesthetic that acts by blocking sodium channels on nerve cells' membranes, preventing the initiation and conduction of nerve impulses. The onset of action is usually 2–10 min after administration, and the duration of anesthesia usually lasts 4–8 h, which is longer than that of lidocaine or ropivacaine. The half-life of bupivacaine is approximately 3.5 h. Bupivacaine is approximately 95% protein-bound in the body, metabolized in the liver by conjugation with glucuronic acid, and excreted in the urine.[16]

To reduce postoperative complications and pain, various technical modifications to standard PCNL procedures have been proposed over the past decade, thereby making them more acceptable to patients. These include reducing the size of the PCNL device (miniperc) and avoiding nephrostomy tubes after PCNL (tubeless PCNL).[17] Studies on the use of LAI for pain control after PCNL have suggested the use of peritubal or tubular LAI to reduce postoperative pain.

Although some studies have investigated the effect of LAI in pain control after PCNL, few studies have been conducted on its effect in tubeless PCNL, and the use of this pain control strategy in tubeless PCNL remains controversial and requires further studies.

Considering that performing PCNL using the tubeless method is a strategy for reducing postoperative pain, and there is also positive evidence regarding the use of LAI for controlling post-PCNL pain, this study aimed to evaluate and compare the efficacy of local infiltration of bupivacaine 0.25% for postoperative pain management in patients undergoing tubeless PCNL.

MATERIALS AND METHODS

Study design and participants

This study was a double-blind, parallel-group randomized controlled clinical trial with a fundamental-applied approach conducted between October 23, 2023, and March 19, 2025, at two tertiary teaching hospitals, Al–Zahra and Khorshid, affiliated with Isfahan University of Medical Sciences. The study population comprised adult patients aged 18 years or older who underwent PCNL for a solitary renal pelvic stone smaller than 3 cm. Preoperative evaluation and all surgical procedures were performed by a single experienced endourologist. Data collection and outcome assessment were performed by trained researchers who were independent of the operating surgeon.

Inclusion and exclusion criteria

Patients eligible for enrollment were adults aged 18 years or older requiring PCNL for a solitary pelvic stone smaller than 3 cm, irrespective of associated hydronephrosis or renal impairment. Exclusion criteria comprised ureteropelvic junction obstruction, simultaneous bilateral PCNL, body mass index >40, history of double-J stent placement, history of any malignancy, substance use disorder, prior nephrolithotomy or any renal surgery, requirement for more than one percutaneous tract during surgery, intraoperative injury to the pleura or other organs, and the need for postoperative nephrostomy placement. Consecutive patients who met the inclusion criteria and did not meet any exclusion criteria were invited to participate.

Ethical approval and informed consent

Ethical approval was obtained from the Research Ethics Committee of Isfahan University of Medical Sciences under approval code IR.MUI.MED.REC.1404.094. All eligible patients received a standardized verbal and written explanation of study procedures from a trained researcher and provided written informed consent prior to enrollment. This trial is registered with the Iranian Registry of Clinical Trials under IRCT20221108056446N17 (available at https://irct.behdasht.gov.ir).

Sample size

The sample size was determined to detect a clinically important difference of 0.5 points on the Visual Analog Scale (VAS), assuming a standard deviation of 0.7 from previous studies,[18] with a significance level of 0.05 and 95% power. This calculation required 50 participants per group. To account for a potential 20% dropout rate, 60 patients were randomized to each arm.

Randomization allocation concealment and blinding

Randomization was performed in a 1:1 ratio using permutation block randomization with variable block sizes

of 4 and 6 to ensure balance between arms while reducing the predictability of allocation. The random allocation sequence was generated by an independent statistician who had no role in patient recruitment, clinical care, or outcome assessment and was encoded as sequentially numbered allocation identifiers. Allocation concealment was maintained by placing each identifier into opaque, sequentially numbered, sealed envelopes prepared and secured by the independent statistician; envelopes were opened only after confirmation of eligibility and completion of baseline data collection. Because the assigned intraoperative procedure required active administration by the operating surgeon, the surgeon was aware of the assigned treatment at the time of the procedure. All other key study personnel, including patients, postoperative outcome assessors, and nursing staff involved in postoperative analgesic delivery, remained blinded to group assignment. The allocation code list was held securely by the independent statistician and was not accessible to blinded personnel until after database lock and completion of the predefined primary analysis, at which point formal unblinding procedures were executed.

Interventions and perioperative management

All patients underwent standardized preoperative evaluation, including appropriate imaging modalities, urinalysis and culture, complete blood count, serum biochemistry, and coagulation tests. PCNL was performed under general anesthesia by a single urologist experienced in endourological procedures. A 6-Fr ureteral catheter and a 14- or 16-Fr Foley bladder catheter were placed for all patients. Patients were positioned prone, and percutaneous renal access was achieved under fluoroscopic guidance using an 18-gauge needle and guidewire. Tract dilation was performed with an Amplatz sheath or balloon dilator up to 30-Fr. Lithotripsy was undertaken with pneumatic or ultrasonic devices, and stone fragments were removed through a 24-Fr rigid nephroscope until no residual fragments were seen on fluoroscopy and endoscopic inspection. All procedures were performed as tubeless PCNL, and a double-J ureteral stent of 5-Fr or 6-Fr was placed by an antegrade or retrograde approach for all patients. At the conclusion of surgery, patients in the intervention arm received 20 mL infiltration of 0.25% bupivacaine into the tract prior to removal of the Amplatz sheath, whereas patients in the control arm underwent removal of the Amplatz sheath without bupivacaine infiltration. All patients received 50 mg meperidine (pethidine) hydrochloride in the operating room as part of routine perioperative analgesia.

Outcomes postoperative pain management and follow-up

The primary outcome was postoperative pain intensity measured by the VAS, a 0–10 scale with 0 indicating no pain and 10 indicating the worst imaginable pain, recorded at 6, 12, and 24 h after surgery. On the first postoperative day, pain control was managed with intramuscular meperidine administered at 1 mg/kg per dose up to a maximum of 50 mg per dose when the VAS exceeded 4. Additional analgesics were provided on patient request, and every administered dose was recorded; the total meperidine dose was capped at 200 mg on the first postoperative day. Analgesic consumption and adverse events were documented for each participant. Patients with successful PCNL, defined as no residual stones on intraoperative imaging and endoscopic inspection, were typically discharged on the day after surgery and scheduled for doubleJ stent removal between 14 and 21 days postoperatively. Follow-up contacts and assessments were performed by blinded outcome assessors according to the trial protocol.

Statistical analysis

Continuous variables were summarized using means ± standard deviations, while categorical variables were reported as frequencies and percentages. The normality of continuous data distributions was assessed using the Kolmogorov–Smirnov test and visual inspection of the Q-Q plot.

Baseline comparisons between the intervention and control groups were conducted using an independent samples *t*-test for continuous variables and either Pearson's Chi-square test or Fisher's exact test for categorical variables, as appropriate.

The primary comparison of mean analgesic consumption between groups was performed using an independent samples *t*-test. Changes in pain intensity over time, measured via the VAS, were analyzed using repeated-measures analysis of variance (ANOVA). The assumption of sphericity was evaluated using Mauchly's test; in cases where sphericity was violated, multivariate ANOVA was applied as a robust alternative.

To adjust for the marginal baseline difference in mean age between groups, repeated-measures analysis of covariance was employed, incorporating age as a covariate. In addition, between-group comparisons of mean VAS scores at 6, 12, and 24 h postoperatively were conducted using independent samples *t*-tests, with Bonferroni correction applied to account for multiple testing.

A two-tailed $P < 0.05$ was considered statistically significant. All analyses were performed using SPSS software, version 27 (IBM Corp., Armonk, NY, USA).

RESULTS

Of 150 patients assessed for eligibility, 130 met the inclusion criteria and 120 provided informed consent, and 120 were

randomized equally between the two arms (n = 60 per group). 57 and 56 participants in the intervention and control group completed the trial and were included in the final analysis [CONSORT flow diagram, Flowchart 1].

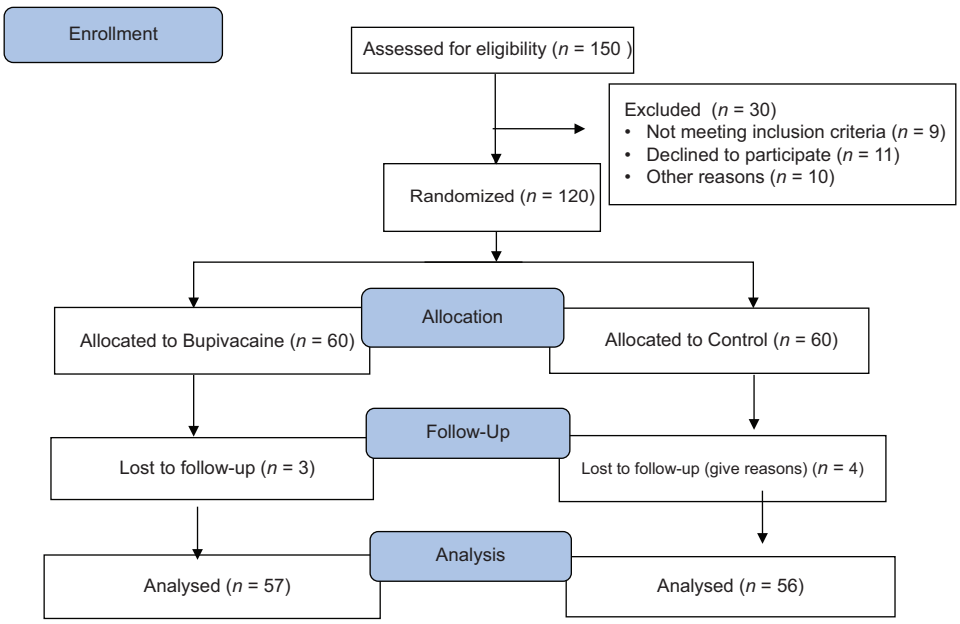
A total of 113 patients participated in this study, 57 patients in the bupivacaine group and 56 patients in the control group. Baseline characteristics were well matched between the bupivacaine and control groups, with no statistically significant differences across demographic, anatomical, or perioperative variables. Both groups exhibited comparable profiles in terms of age, body mass index, and stone size, suggesting similar patient demographics and disease burden at study entry. Operative duration and fluoroscopy time were also evenly distributed, indicating procedural consistency across cohorts. In addition, categorical variables–including gender distribution, renal pelvis anatomy, and hydronephrosis grade–showed no significant variation between groups. The lack of meaningful differences (all $P > 0.05$) supports the internal validity of the study by confirming baseline equivalence and reducing the likelihood of confounding effects in subsequent outcome analyses [Table 1].

Repeated-measures analysis results represented in Table 2 showed a highly significant decline in pain scores over time in both arms (time effect $P < 0.001$), with mean VAS falling from 4.33 ± 0.97 to 2.68 ± 0.81 to 1.53 ± 0.68 in the bupivacaine group and from 4.85 ± 1.05 to 3.16 ± 0.95 to 1.84 ± 0.71 in controls. The between-subjects effect of group was also significant ($F_{1,111} = 7.88$, $P = 0.006$), indicating that, on average, patients receiving bupivacaine infiltration experienced lower pain intensity than those in the control arm. The nonsignificant time × group interaction ($P = 0.867$) confirms that both groups followed a parallel trajectory of pain reduction [Figure 1]. *Post hoc* independent t-tests further demonstrated that the bupivacaine group reported significantly less pain at each time point: 6 h (mean difference − 0.51, 95% confidence interval [CI] −0.89–−0.14; $P = 0.008$), 12 h (−0.48, 95% CI − 0.80–−0.15; $P = 0.005$) and 24 h (−0.31, 95% CI − 0.57–−0.05; $P = 0.018$). Inclusion of age as a covariate did not notably alter the significance of the group effect, underscoring the robustness of the analgesic benefit imparted by bupivacaine. Clinically, these findings support the use of 0.25% bupivacaine infiltration to achieve sustained postoperative pain relief after tubeless PCNL [Table 2].

As indicated in Figure 2, the bupivacaine group required a significantly lower mean dose of analgesic compared with the control group. An independent-samples t-test confirmed that this difference was statistically significant ($P < 0.05$), indicating that bupivacaine infiltration effectively reduces postoperative analgesic requirements [Figure 2].

DISCUSSION

This study was designed and implemented to investigate the effect of local infiltration of 0.25% bupivacaine in patients undergoing tubeless PCNL on postoperative pain scores and the need for postoperative analgesics. The results of this study indicate that although the trajectory of pain reduction in both groups was similar over time, but at all times of pain measurement (6, 12, and 24 h after surgery), patients in the bupivacaine group reported a lower pain score on the VAS than the patients in the control group; this difference was statistically significant. Furthermore, patients in the bupivacaine group required a lower mean dose of analgesics



Flowchart 1: CONSORT flow diagram of participant recruitment in our randomized controlled trial

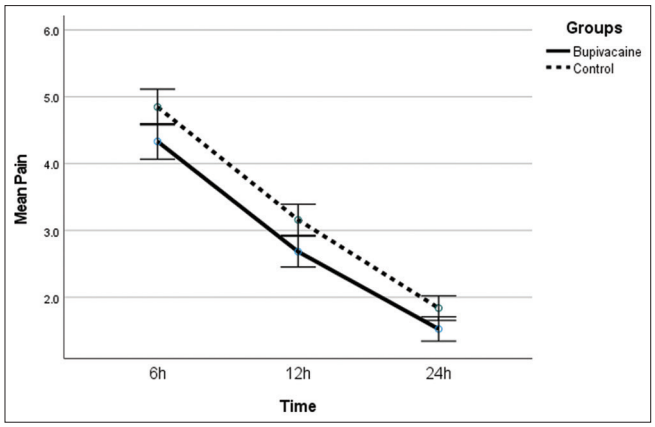


Figure 1: Temporal trend of pain intensity following surgery: Bupivacaine versus control

Table 1: Baseline characteristics of study groups

Variable	Bupivacaine (*n*=57), *n* (%)	Control (*n*=56), *n* (%)	*P**
Age, years	52.09±11.87	47.98±12.03	0.070
BMI (kg/m^2)	24.93±2.78	25.11±3.44	0.763
Stone size (mm)	22.39±7.22	21.55±6.97	0.534
Surgery duration (min)	123.25±31.00	127.32±30.69	0.484
Fluoroscopy time (s)	76.32±14.19	76.88±11.74	0.820
Gender			
Female	18 (31.6)	16 (28.6)	0.727
Male	39 (68.4)	40 (71.4)	
Pelvis type			
Extrarenal	8 (14.0)	10 (17.9)	0.579
Intrarenal	49 (86.0)	46 (82.1)	
Hydronephrosis grade			
Grade 1	12 (21.1)	10 (17.9)	0.525
Grade 2	26 (45.6)	21 (37.5)	
Grade 3	17 (29.8)	20 (35.7)	
Grade 4	2 (3.5)	5 (8.9)	

*Resulted from Independent samples *t*-test for continuous and Chi-square or Fisher's exact test for categorical variables. BMI=Body mass index

compared to the control group; the analyses revealed that this difference was also statistically significant.

To reduce postoperative complications and pain, various technical modifications have been made in performing PCNL; reducing the size of the PCNL device (miniperc) and avoiding nephrostomy tubes after PCNL (tubeless PCNL) are among the most important modifications to reduce postoperative pain.[19,20] Several recent studies have evaluated postoperative pain relief, discomfort, and nephrostomy tube-induced pain in tube- and tubeless PCNL procedures, which have demonstrated the efficacy of tubeless PCNL in reducing postoperative pain.[17,21]

Currently, there is no standard approach to postoperative pain management in patients undergoing PCNL. In clinical practice, the use of opioid analgesics and NSAIDs is considered a common method for pain management in

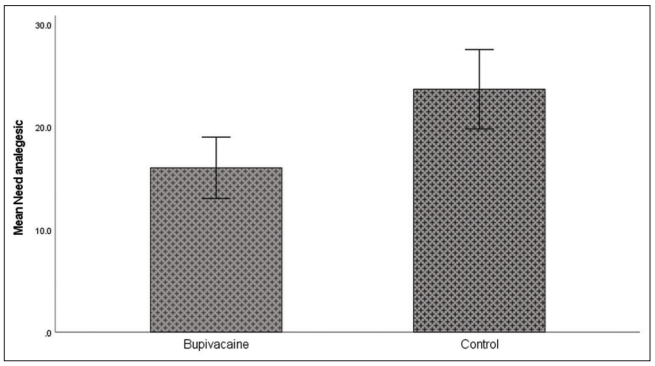


Figure 2: Comparison of mean analgesic dose (meperidine mg) between bupivacaine and control group

these patients.[22,23] Although the use of these drugs is an effective strategy for postoperative pain control, they can be accompanied by side effects that limit their use, especially in people with underlying diseases or the elderly.[24] The use of opioid analgesics can lead to risks and complications such as respiratory depression, drowsiness, dizziness, and cardiovascular problems. NSAIDs are also associated with negative effects on the gastrointestinal tract and cardiovascular system, an increased risk of bleeding, and the development of kidney problems and renal failure.[16]

It seems that the use of LAI can be an effective strategy for pain control after PCNL. Recent studies have shown the efficiency and effectiveness of LAI for pain control after PCNL. Although these studies differed in terms of methodology, blinding, and the type of anesthetic used, they reported favorable results in terms of the need for analgesics and VAS pain scores after PCNL.[9-13]

In 2017, a study was conducted by Dundar *et al*. regarding the effect of LAI on pain control after PCNL, which showed the positive effects of using LAI in postoperative pain relief.[6] The results of a 2018 study by El-Khalid compared the use of bupivacaine infiltration and placebo in two groups of patients undergoing PCNL regarding postoperative pain scores and reported the safety and high effectiveness of bupivacaine infiltration in controlling pain after PCNL.[14] Recently, another study in 2024 reported an association between less postoperative pain with peri-tract local anesthesia by bupivacaine infiltration in patients undergoing PCNL.[25]

Most of these studies have investigated LAI around the nephrostomy tube (peritubal), and few studies have been conducted on the use of LAI in tubeless PCNL. Some studies have reported positive results on the effect of LAI in controlling postoperative pain in patients undergoing tubeless PCNL, but more studies are still needed on the use of local infiltration of bupivacaine in patients undergoing tubeless PCNL.[18,26]

Table 2: Visual Analog Scale pain scores over time in bupivacaine versus control groups

Group	6 h, mean±SD	12 h, mean±SD	24 h, mean±SD	*P* (time)**	*P* (Group)**	*P* (time×group)**
Bupivacaine	4.33±0.97	2.68±0.81	1.53±0.68	<0.001	0.006	0.867
Control	4.85±1.05	3.16±0.95	1.84±0.71	<0.001		
Between-groups*	0.008	0.005	0.018			

*Obtained from Independent samples t-test; **Obtained from RM-ANOVA. SD=Standard deviation; RM-ANOVA=Repeated-measures analysis of variance

Study limitations and strengths

Based on the provided methodology and results, this study's key strength lies in its robust randomized controlled trial design, featuring double-blinding, allocation concealment, a sample size calculation with high power, and analysis by intention-to-treat, which collectively minimize bias and strengthen the internal validity and reliability of the findings. The demonstration of a statistically significant and sustained reduction in postoperative pain with bupivacaine infiltration is a clear and clinically relevant advantage. However, a notable limitation is the single-surgeon design, which, while ensuring procedural consistency, may limit the generalizability of the results to a broader urological practice. Furthermore, the follow-up was restricted to the immediate 24-h postoperative period, leaving the longer-term analgesic effects and potential impact on other outcomes like hospital stay or patient satisfaction unexplored.

CONCLUSION

The results of this study revealed that the use of local infiltration of 0.25% bupivacaine in patients undergoing tubeless PCNL is an effective and safe strategy to reduce postoperative pain and reduce the need for analgesics in these patients. This method can help overcome the challenge of post-PCNL pain, improving surgical outcomes and convenience for patients, while also preventing unwanted complications and waste of resources and costs in the healthcare system by reducing the need for analgesics.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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