

A comparative evaluation of 0.25% bupivacaine and 0.25% levobupivacaine in peritubal infiltration in percutaneous nephrolithotomy



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ABSTRACT

Background: Percutaneous nephrolithotomy (PCNL) is a routine endourologic procedure in patients with renal calculi. Although it is less painful than open surgery, pain around the nephrostomy tube is a clinical problem; therefore, good post-operative analgesia is required to alleviate pain. Peritubal infiltration can be one of the choices to alleviate pain around the nephrostomy tube. **Aims and Objectives:** The aim of this study was to evaluate the efficacy of peritubal infiltration of local anesthetics for post-operative pain following PCNL. **Materials and Methods:** A total of 60 patients with American Society of Anesthesiologists Grade I/II scheduled for elective PCNL surgeries were randomly allocated into two groups. Group L received levobupivacaine 0.25% (30 mL) and Group B received bupivacaine 0.25% (30 mL). The duration of rescue analgesia, total dose of tramadol consumption in 24 h, hemodynamic parameters, and adverse events during the post-operative period were noted. **Results:** The mean duration of rescue analgesia in Group L was 274.50 ± 24.89 min and in Group B was 275.33 ± 23.04 min which was not significant ($P > 0.05$). **Conclusion:** Peritubal infiltration of 0.25% levobupivacaine and 0.25% bupivacaine is efficient in alleviating post-operative pain after PCNL. Both drugs can be used for infiltration around nephrostomy tubes in PCNL surgeries safely and are associated with minimal side effects.

Key words: Levobupivacaine; Bupivacaine; Percutaneous nephrolithotomy; Post-operative analgesia; Peritubal infiltration

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INTRODUCTION

The International Association for the Study of Pain defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage or in terms of such damage.”¹ Since 1976, percutaneous nephrolithotomy (PCNL) has been the most preferred surgical intervention for kidney stones. This has been due to the successful cases that Fernstrom and Johansson² were able to accomplish. Despite the progress that has been made in our understanding of pain physiology and management, most patients still do not have adequate analgesic medication following surgery. This insufficiency leads to delayed mobilization, associated new-onset morbidity, and increased treatment costs.³ Opioid and non-opioid analgesics and local anesthetics are the preferred means of post-operative pain

management.⁴ Although opioid analgesics are most effective their side effects, limit their use to the effective optimal dosage.⁵ Therefore, “balanced” or “multimodal” protocols that combine opioids with non-steroidal anti-inflammatory or local anesthetics were developed to increase the quality of analgesia and decrease the mentioned undesired effects related to opioids.^{4,6,7} Non-steroidal anti-inflammatory drugs and opioids can have side effects and may not be the best choice for patients with renal problems. Skin infiltration with local anesthetic has not been very effective after PCNL; however, infiltration of the renal capsule has been shown to facilitate painless insertion of the nephrostomy tube.⁸ In this study, we aim to evaluate and compare the efficacy of peritubal infiltration with 0.25% levobupivacaine (30 mL) and 0.25% bupivacaine (30 mL) in PCNL for post-operative analgesia, hemodynamic changes, and adverse effects if any.

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Aims and objectives

The aim of this study was to evaluate the efficacy of peritubal infiltration of local anesthetics for post-operative pain following PCNL.

MATERIALS AND METHODS

We conducted a prospective, randomized, comparative, double-blind study in 60 patients admitted to super specialty J.A. Group of Hospitals, GRMC Gwalior, belonging to the physical status of American Society of Anesthesiologists (ASA) Grade I and II, aged 20–60 years, undergoing PCNL surgeries, after obtaining approval from the Ethics Committee of the Institute and informed and written consent from the patient and relatives.

Inclusion criteria

The following criteria were included in the study:

- ASA physical Grade I and II
- Age group 20–60 years of either sex of average weight
- Weight 50–90 kg.

Exclusion criteria

The following criteria were excluded from the study:

- Patient's refusal
- Uncooperative patients/not able to understand pain assessment test
- History of clinically significant cardiovascular, pulmonary, hepatic, renal, neurological, psychiatric, or metabolic disease
- Patients who are unable to understand visual analog scale (VAS) assessment,
- Patients having severe obesity (body mass index >35 kg/m²), coagulation disorder, on anticoagulants, or any sensitivity to local anesthetics.
- Patients with a history of drug allergy
- Drug addict/patient on long-term steroid therapy
- Pregnancy
- Surgery converted to open procedure will be excluded from the study.

All 60 patients satisfying the inclusion criteria randomly allocated into two groups, Group L (n=30) levobupivacaine 0.25% (30 mL) and Group B (n=30) bupivacaine 0.25% (30 mL), using envelop method were investigated for routine baseline pre-operative complete blood count, red blood cells, chest X-ray, and 12-lead electrocardiogram. Patients were explained about the procedure and their consent was taken in written format.

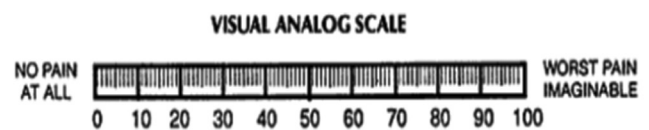
Technique

All patients were uniformly premedicated with injection glycopyrrolate 0.005–0.01 mg/kg intravenous (IV), injection pentazocine 0.3–0.6 mg/kg IV, injection ondansetron 2 mg/kg IV, and injection ranitidine 25 mg/kg IV. Anesthesia was induced with injection propofol 1–2 mg/kg IV and succinylcholine 1–2 mg/kg IV and maintained with O₂:N₂O (40:60), isoflurane, and atracurium at maintenance dose of 0.1 mg/kg IV. At the end of the procedure, but before extubation, a 23-gauge spinal needle was passed along the nephrostomy tube (22–24 Fr) under fluoroscopy guidance (to confirm the direction of the needle along nephrostomy tube) so as to puncture the renal capsule at 6 o'clock and the 12 o'clock position. At each site, 10 mL of 0.25% bupivacaine in Group B and 10 mL of 0.25% levobupivacaine in Group L were infiltrated along the kidney capsule. Another 10 mL was infiltrated in muscle, subcutaneous tissue, and skin (Total 30 mL in both groups). Patients were reversed with injection neostigmine and injection glycopyrrolate I/V after return of spontaneous respiration. Post-operative pain was assessed by VAS (score between 0 and 100) at rest by an independent observer blinded to infiltration, at 0 h, every half hour for 2 h, every 2 h for 6 h, and every 4 h till 24 h. In VAS, 0 means no pain and 100 means maximum intolerable pain. When the score was ≥40, IV tramadol was given in the dose of 1 mg/kg as a rescue analgesic for up to 24 h. The duration of analgesia was taken as the time from infiltration to the first demand for rescue analgesic. The total requirement of tramadol within 24 h and any side effects such as nausea, vomiting, and sedation were observed.

VAS at first pain medication

0	No pain
1–25	Mild pain
26–50	Moderate pain
51–75	Severe pain
76–100	Very severe pain

Scale



Statistical analysis

All the observations and particulars of each patient were recorded in a proforma. Data were composed in a suitable spreadsheet, that is, Excel and SPSS. After compilation, data were analyzed statistically by SPSS software version 20.0. To compare the two groups, either a Chi-square test or an unpaired t-test was applied. The significance level was 95% confidence level (P<0.05). Data were described as a frequency (percentage) distribution as well as in mean±standard deviation (SD).

RESULTS

There was no significant difference in MAP (mean arterial pressure) between group B and group L (Figure 1).

There was no significant difference in time for rescue analgesia (Figure 2) and VAS score (Figure 3) between both the study groups.

There was no significant difference in total analgesic consumption in 24 hours (Figure 4) in the two groups.

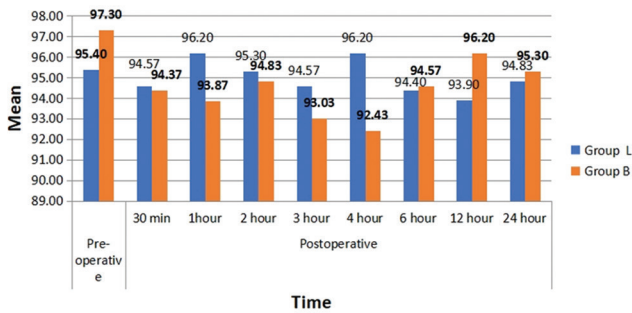


Figure 1: Comparison of peri-operative mean arterial pressure in the two groups.

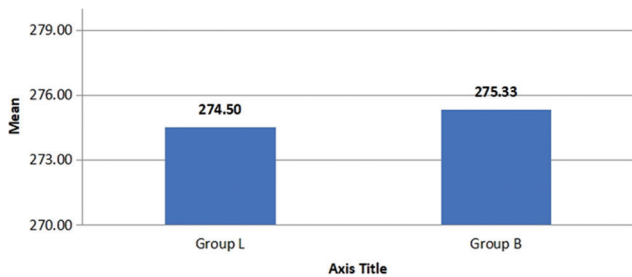


Figure 2: Time for first rescue analgesia (min.) in the two groups.

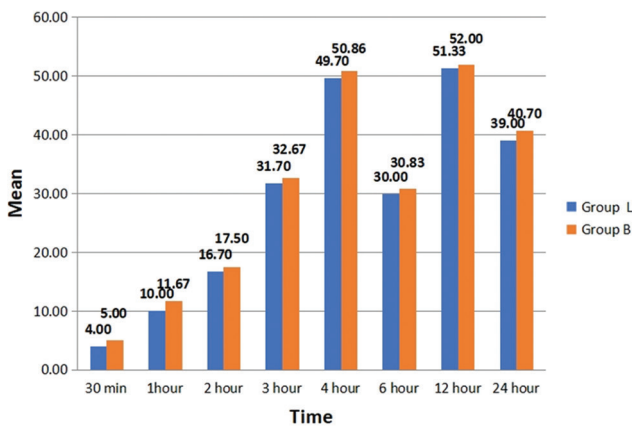


Figure 3: Comparison of VAS score in the two groups

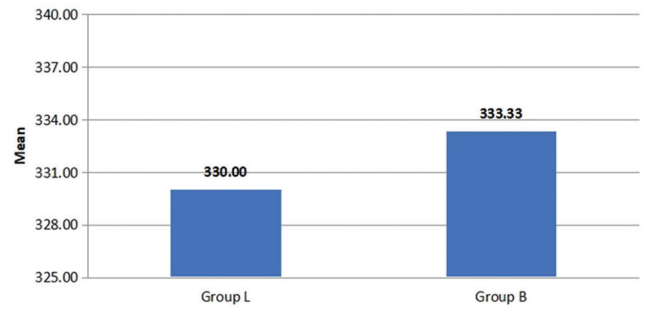


Figure 4: Total analgesic consumption in 24 hours in the two groups.

Adverse effects

Fewer adverse effects were seen in both groups and found to be statistically not significant ($P > 0.05$) which shows the adverse effects of both groups are comparable.

DISCUSSION

We have studied peritubal infiltration of levobupivacaine 0.25% and bupivacaine 0.25% for post-operative analgesia in PCNL. Patients were randomized into two groups, that is, Group L received 0.25% levobupivacaine (30 mL) and Group B received 0.25% bupivacaine (30 mL). We assessed the effect of peritubal infiltration of local anesthetics in our study in terms of the time of first rescue analgesia, total tramadol consumption in 24 h, hemodynamic changes postoperatively, and side effects if any were recorded.

There was no statistically significant difference in demographic data, ASA grade, and duration of surgery distribution in both groups ($P > 0.05$).

There was no significant difference in hemodynamic parameters found in both groups (Fig. 1). These findings were in accordance with the study conducted by Karaduman *et al.*⁹ to investigate the effect of peritubal infiltration of bupivacaine and opioids on pain scores and analgesic consumption in patients who underwent PCNL. The study concluded that on comparison of vital findings (SpO_2 , heart rate, and mean arterial pressure) at arrival in the operating room, after sedation, and at perioperative 5th, 15th, 30th, 45th, 60th, 75th, 90th, 105th, and 120th min. Did not indicate any significant difference between the groups ($P > 0.05$). Saroa *et al.*¹⁰ also supported our study by conducting a prospective double-blind randomized study to ascertain the relative analgesic efficacy of levobupivacaine and ropivacaine when administered in ultrasound-guided paravertebral block in patients undergoing PCNL. The post-operative hemodynamic variables were also

comparable in both groups (group levobupivacaine block and group ropivacaine block).

The mean (\pm SD) time for first rescue analgesia in Group L was (Fig. 2) 274.50 ± 24.9 min and Group B was 275.33 ± 23.04 min (Fig. 2), respectively. On comparison and application of statistical analysis, there was no significant difference in time for first rescue analgesia in both groups ($P > 0.05$). Our findings are in accordance with the study conducted by Subwongcharoen and Udompornmongkol,¹¹ a randomized control trial to compare the effect of extraperitoneal infusion of 0.25% levobupivacaine, 0.25% bupivacaine, and placebo in patients undergoing totally extraperitoneal (TEP) laparoscopic inguinal hernioplasty procedure in terms of pain reduction. They draw the inference that the median time to first rescue analgesia was lowest for patients treated with levobupivacaine among the three groups. However, the difference was not significant ($P > 0.05$). Compagna *et al.*¹² conducted a comparative study between levobupivacaine and bupivacaine for hernia surgery in the elderly. Furthermore, this supported our results by concluding that, in the levobupivacaine group, the average time to first request of paracetamol was approximately 226 min (about 4 h), and in the bupivacaine group was about 367 min (approximately 6 h). Hence, there was no significant difference in both groups ($P = 0.14$).

The mean VAS score at 30th min postoperatively was 4 ± 7.24 (Fig. 3) in Group L and 5 ± 8.61 (Fig. 3) in Group B and was comparable ($P = 0.62$). The mean VAS score at 1st h postoperatively increased to 10 ± 7.88 (Fig. 3) in Group L and 11.67 ± 9.13 (Fig. 3) in Group B and was comparable ($P = 0.45$). On statistical comparison of VAS scores at 30 min, 1, 2, 3, 4, 6, 12, and 24 h, there was no significant difference observed in Group L when compared to Group B ($P > 0.05$). These findings are in accordance with the study conducted by Parikh *et al.*,¹³ who compared the analgesic efficacy of bupivacaine (0.25%) with normal saline (0.9%) and inferred that bupivacaine group had significantly lower VAS scores compared to normal saline group. Our findings are in accordance with the study conducted by Gokten *et al.*¹⁴ to evaluate the efficacy of periportal levobupivacaine (0.25%) infiltration in combination with IV paracetamol infusion on post-operative pain management in patients who underwent percutaneous nephrolithotomy. Group LP (levobupivacaine+paracetamol) had significantly lower VAS scores compared to the control group. Our findings also correlate with the study conducted by Bay-Nielsen *et al.*,¹⁵ a randomized, double-blind study to compare the anesthetic and analgesic efficacy of levobupivacaine with that of bupivacaine in patients undergoing inguinal herniorrhaphy. The study concluded that average VAS score in both the study groups were almost identical for all assessments ($P > 0.05$).

Tuzel *et al.*¹⁶ and Subwongcharoen and Udompornmongkol¹¹ also correspond to our findings with respect to VAS score.

Total analgesic consumption in 24 h in the two groups, patients in both the groups were found to required similar dose of tramadol in Group L (330.00 ± 46.60) mg (Fig. 4) and Group B (333.33 ± 47.94) mg. There was no significant difference in total analgesia consumption required in 24 h in both groups ($P > 0.05$). Our findings also correlate with the study conducted by Bay-Nielsen *et al.*,¹⁵ a randomized, double-blind study to compare the anesthetic and analgesic efficacy of levobupivacaine with that of bupivacaine in patients undergoing inguinal herniorrhaphy. They concluded that there was no difference in the need for post-operative ibuprofen in both groups ($P = 0.55$). These findings in accordance with the study conducted by Subwongcharoen and Udompornmongkol,¹¹ a randomized control trial to compare the effect of extraperitoneal infusion of 0.25% levobupivacaine, 0.25% bupivacaine, and placebo in patients undergoing TEP laparoscopic inguinal hernioplasty procedure in terms of pain reduction. They inferred that the total IV-patient-controlled analgesia (device to give bolus dosage of morphine) morphine requirement did not differ among the three groups. There was no significant difference in 24 h morphine consumption among the three groups ($P > 0.05$). Compagna *et al.*¹² also found similar results.

Patients in Group L experienced shivering as the most common adverse effect and those in Group B experienced nausea and vomiting as the most common adverse effect. Shivering was noted in 4 out of 30 (13.34%) patients of Group L, but only in 2 out of 30 (6.67%) patients in Group B. Nausea and vomiting were seen in 2 out of 30 (6.67%) patients of Group L and in 3 out of 30 (10%) patients belonging to Group B. There was no any incidence of hypotension, bradycardia, dyspnea, chest pain, or dysrhythmia. There was no significant difference found for post-operative side effects in both groups ($P > 0.05$). Compagna *et al.*¹² conducted a comparative study between levobupivacaine and bupivacaine for hernia surgery in the elderly. Furthermore, we supported our result by concluding that there was no significant difference in both the study groups in view of post-operative side effects ($P = 0.67$). These findings are also in accordance with the study conducted by Subwongcharoen and Udompornmongkol.¹¹

Limitations of the study

Pain being a subjective experience is impossible to be quantified with accuracy, thereby affecting its reliability as a statistical parameter. VAS scores, although an attempt to quantify the descriptive nature of pain, still remain a subjective variable highly dependent on patients' self-reporting. All our study participants belonged to ASA Grade 1 or II and were aged between 20 and 60 years, and

thus our results may not be directly extrapolated to patients belonging to the extremes of age or ASA Grades III and IV.

CONCLUSION

From the present study, it is concluded that peritubal infiltration of 0.25% levobupivacaine and 0.25% bupivacaine is efficient in alleviating post-operative pain after PCNL. Both drugs can be used for infiltration around nephrostomy tubes in PCNL surgeries safely and are associated with minimal side effects.

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Authors' Contributions:

NT- Concept and design of the study, prepared the first draft of the manuscript; **DS**- Interpreted the results; reviewed the literature and manuscript preparation; **KJ**- Concept, coordination, statistical analysis, and interpretation; **AT**- Preparation of manuscript and revision of the manuscript.

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