Original Article

Efficacy of intercostal nerve block with 0.25% bupivacaine in percutaneous nephrolithotomy: A prospective randomized clinical trial

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Abstract

Introduction and Aim: Several techniques have been used to lower the morbidity of percutaneous nephrostomy (PCN) tube after percutaneous nephrolithotomy (PCNL). The outcomes of intercostal nerve block (ICB) versus peritubal block (PTB) with 0.25% bupivacaine to alleviate post-PCNL pain were compared.

Materials and Methods: After obtaining an informed written consent and local institutional ethics clearance, 64 patients undergoing PCNL were computer randomized to receive either an intercostal block/ICB (Group I) or a peritubal block/PTB (Group II) using 0.25% bupivacaine infiltration, after termination of the procedure. They were evaluated for visual analog scale (VAS) score, first analgesic requirement, and the total analgesic demand along with fall in hematocrit, PCN indwelling time, blood transfusion rate, complications, and mean hospital stay in the postoperative period. The protocol was registered with CTRI/2018/03/012717.

Results: Patients in both the groups were comparable on the basis of demographic data, preoperative renal function, stone burden, and hematocrit value. The mean VAS score at 6, 12, 24, and 48 h was significantly lower in the Group II versus Group I ($P < 0.001$). The total mean analgesic requirement was 160.16 and 103.13 mg of diclofenac sodium in Group I and Group II, respectively, which was significantly higher in Group I versus Group II ($P < 0.001$). The time to first analgesic demand was significantly higher in PT group (8.06 ± 1.99 h vs. 12.97 ± 1.96 h) in Group I/ICNB and Group II/PT, respectively ($P < 0.001$). Both the groups were comparable in terms of postoperative hematuria, hematocrit fall, nephrostomy site leak, hospital stay, need of blood transfusions, stone-free rate/retreatment rate, postoperative urinary tract infections, and overall complication rate (Modified Clavien–Dindo classification) which were not statistically significant.

Conclusion: Post PCNL, PTB was associated with significantly lower post operative pain and discomfort versus ICB as demonstrated by the significantly lower DVAS pain scores, higher mean time to first analgesic demand and lower mean total analgesic demandt with ICB. Bupivacaine was a safe and effective local anesthetic agent for PTB in select patients for facilitating quick relief from the morbid postoperative pain and discomfort following PCNL.

Keywords: Bupivacaine, intercostal block, percutaneous nephrolithotomy, peritubal block

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INTRODUCTION

Percutaneous nephrolithotomy (PCNL) is the preferred treatment for renal stones >2 cm or resistant to Shock wave Lithotripsy (SWL) therapy. It often necessitates the placement of a percutaneous nephrostomy (PCN) tube drain at the termination of the procedure[1] to ensure unimpeded drainage of the pelvicalyceal system. The PCN tube facilitates tamponade of the percutaneous tract, minimises bleeding and also serves as an access tract for the pelvicalyceal system should a re-look nephroscopy be necessary for any residual calculi. However the PCN tube often culminates in distressing peritubal (PT) pain and discomfort in many patients that may require additional analgesia. Inadequate analgesia can result in increased morbidity with delayed mobilization, impaired ventilation, and prolonged hospitalization, which may increase the overall cost of the procedure. To lower the morbidity of PCNL, proper and adequate management of postoperative pain remain an integral component of PCNL.[2]

Several techniques have been documented in the literature that has been used to lower the morbidity of PCN tube after PCNL, such as tubeless or totally tubeless PCNL,[3-5] or using a lower caliber PCN tube[6]/narrow caliber nephroscopes, and postoperative peritubal block (PTB),[1,7-11] or an intercostal nerve block (ICNB)[12,13] with a local anesthesia (LA). In this study, we have compared the outcome efficacy analysis of intercostal nerve block versus PTB with 0.25% bupivacaine to alleviate post-PCNL pain by comparing postoperative pain (visual analog scale [VSA]), analgesic requirement, and other differences if any in the above-mentioned two techniques.

MATERIALS AND METHODS

This study was conducted on consenting patients who had undergone a standard PCNL for urolithiasis in our department. A prospective randomized control study was performed on 64 eligible patients with the primary intent to treat with whatever that was necessary being adhered to, after meeting the inclusion (18–80 years giving consent, in whom PCNL operation was indicated/necessary) and exclusion criteria (known history of hypersensitivity/anaphylaxis/contraindications to bupivacaine or its components pregnancy, mental disorders/illness, uncorrected coagulopathy, chronic renal failure, large stone burden [>3 cms] and/or ureteric/bilateral renal stone, high ASA grade unfit for anesthesia/surgery/PCNL). Of the 64 patients, 32 patients were computer randomized to either the intervention group (ICB-intercostal nerve block) or the comparator group (PTB). In the intervention arm, 32 patients were subjected to intercostal infiltration of 10cc of 0.25% bupivacaine at the termination of PCNL after test dose. In the comparator arm, 32 patients were subjected to a single dose of PT infiltration of 10cc of 0.25% bupivacaine on completion of PCNL. A 24-size nephrostomy tube was placed at the end of the procedure in each patient to drain the system.

All patients were worked up and followed to ensure comparability in terms of stone size/location, renal function, excretory urography, serum calcium, serum phosphate, serum uric acid, X-ray kidney, ureter, and bladder, X-ray chest, renal ultrasound, and preanesthetic evaluation. PCNL was done in the standard fashion similar to as previously described by us elsewhere,[6,12,13] with modification of infiltrating 10 ml ~0.25% bupivacaine (max permissible dose of 2 mg/kg body weight) for PTB or intercostal block[14] (11 and 12 ribs). The flow of the study protocol is depicted in Figure 1. Post-PCNL patients were assessed for pain intensity pain by VAS scoring at 2, 4, 6, 12, 24, and 48 h. The total analgesic requirement (TAR) in terms of diclofenac sodium in mg intravenous/oral and the time to first analgesic demand in hours were also documented. The time to first analgesic demand, TAR, and VAS score were the primary outcome measures.

Post-PCNL nephrostomy site was observed every 24 h till the time of discharge for noting the PCN indwelling time (hours) and for noting the leakage around PCN (by noting the duration [hours] of urine leak and the amount

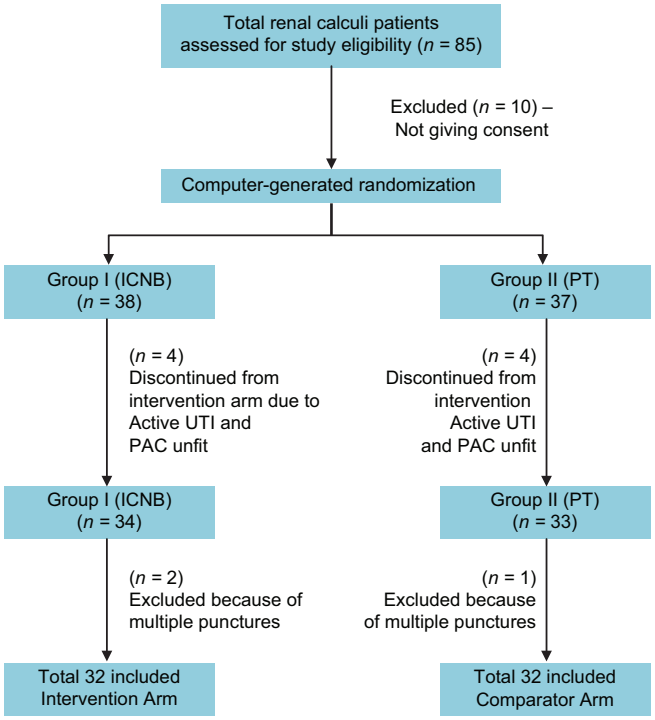

Figure 1: Study flowchart

of leak [number of pads soaked each day]). The duration of leak after the removal of PCN was also noted (two consecutive dry pads were assumed as stoppage of leak)[2] till the day of discharge. Renal ultrasound was done after 24 h to look for sepsis/collection/urinoma. Patients were also observed for fall in hematocrit, renal function, stone clearance, need for auxiliary procedures, hospital stay, return to work, and modified Clavien–Dindo score. The comparison of the overall differences if any in the two techniques (PTB vs. ICN) in two groups of PCNL patients was taken as the secondary outcome measures.

Statistical methods

Statistical analysis was performed using Statistical Package for the Social Sciences version 20.0 IBM, New York, USA. The data were expressed as mean with 95% confidence interval for continuous variables. Continuous data were analyzed by unpaired Student's *t*-test. Categorical data were analyzed by Chi-square test and Fisher's exact test. $P < 0.05$ was considered statistically significant.

RESULTS

The patients were randomized to Group I (ICB) and Group II (PTB) with 32 patients in each group and were evaluated in the postoperative period till discharge. Patients in both the groups were comparable on the basis of demographic data, preoperative renal function, stone burden, and hematocrit value. The salient outcome measures are depicted in Table 1. The modified Clavien–Dindo score with major and minor complications are depicted in Table 2. The total mean analgesic requirement was 160.16 and 103.13 mg of diclofenac sodium in Group I and II, respectively, which was significantly higher in Group I versus II ($P < 0.001$). The time to first analgesic demand was significantly higher in the PT group (8.06 ± 1.99 h vs. 12.97 ± 1.96 h in Group I/ICNB and II/PT, respectively ($P < 0.001$). Both groups were comparable in terms of postoperative hematuria, fall in the hematocrit, nephrostomy site leak, hospital stay, need of blood transfusions, stone-free rate/retreatment rate, postoperative urinary tract infection, and overall complication rate (modified Clavein–Dindo classification) which were not significantly different.

DISCUSSION

In our study, PTB was found to be more efficacious in pain relief as compared to ICB. The mean total analgesic requirement after PCNL as reported in other similar studies is depicted in Table 3.

Kıraç *et al*.[3] showed that the TAR was statistically lower in bupivacaine group (156.7 mg vs. 209.8 mg), suggesting that PT bupivacaine was effective in alleviating postoperative pain, which was also supported by Shah *et al*.[15] Parikh *et al*.[2]

Table 1: Summary comparison of primary outcome parameters between the two groups

Outcome parameters	Group 1 ICNB	Group 2 PTB	*P*
Mean age	35.84±11.917	36.91±11.30	0.717
Mean preoperative hematocrit (%)	35.84±3.068	35.84±3.42	0.999
Mean postoperative D1 hematocrit (%)	34.8±2.65	34.9±3.175	0.895
Mean change in hematocrit (%)	1.04±0.78	0.94±1.36	<0.001
Mean duration of hematuria (days)	2.59±0.615	2.63±0.660	0.253
TAR (mg of diclofenac sodium)	160.16±45.72	103.13±41.59	<0.001
Mean postoperative leak (pads/day)	5.00±1.778	4.56±1.554	0.297
Mean VAS score			
6 h	7.16±1.051	6.00±1.10	<0.001
12 h	5.53±0.983	4.53±0.803	<0.001
24 h	4.47±1.016	3.47±1.164	<0.001
48 h	3.06±1.014	2.34±1.066	<0.001
Mean hospital stay (days)	4.57±1.09	4.69±0.93	0.639
Mean PCN indwelling time (h)	48.34±5.011	50.03±5.69	0.139
Mean blood transfusion rate (U)	9.3	6.2	0.999
Mean stone burden (mm^2)	19.13±5.01	19.22±6.05	0.946
Mean stone clearance (%)	94	97	0.557
Mean auxiliary procedure rate (%)	6.25	3.12	0.557
Complications (%)			
Mean Clavien I score	9.375	6.25	-
Mean Clavien II score	15.625	12.5	-
Mean Clavien IIIA score	3.125	3.125	-
Mean Clavien IIIB score	0	3.125	-
Mean Clavien IVA score	0	0	-
Mean Clavien IVB score	0	0	-
Mean Clavien V score	0	0	-
Mean Clavien score (mean complications rate)	28.125	25	0.878

Group 1 - ICNB was intervention arm and Group 2 - PTB was the comparator arm. ICNB: Intercostal nerve block, PTB: Peritubal block, TAR: Total analgesic requirement, PCN: Percutaneous nephrostomy, VAS: Visual analog scale

Table 2: Comparison of postoperative complications after percutaneous nephrolithotomy between the two groups

Complications	Clavien grade	ICNB	PT	Management
Minor	Grade I			
	Fever (nausea/ vomit/headache)	3	2	Antipyretics
	Grade II			
	BT	3	2	BT
	Infection	2	2	Change of antibiotics
Major	Grade IIIa	1	2*	ICD insertion
	Grade IIIb	-	-	-
	Grade IVa	-	-	-
	Grade IVb	-	-	-
	Grade V	-	-	-

*In one patient - ICD insertion and another patient - Angioembolization. BT: Blood transfusion, ICNB: Intercostal nerve block, PT: Peritubal, ICD: Intercostal drainage

Table 3 (a-b): Table 3(a) Depicting the comparison of the mean total analgesics requirement compared with previous similar studies & the present study. Subset Table 3(b) depicting the mean time(hrs) to the first analgesic demand after PCNL as compared with previous similar studies & the present study.

Author	Study group	Control group	*P*
a. Comparison of the mean total need of analgesics after PCNL of previous similar study designs with the present study			
Haleblian *et al*. (2007)	24.7 mg (Bp)	32.1 mg (Sl)	-
Parikh *et al*. (2011)	119.3 mg (Bp)	276.8 mg (-)	<0.0001
Shah *et al*. (2012)	94.81 (Bp)	124.22 (-)	-
Kirac *et al*. (2013)	156.7 mg (Bp)	209.8 mg (Sl)	<0.0001
Jonnavithula *et al*. (2017)	Less (ICNB)	More (PT)	-
Present study	160.16	103.13	<0.0001
b. Comparison of the mean first demand of analgesics (h) after PCNL of previous similar study designs with the present study			
Parikh *et al*. (2011)	9.08	2.66	<0.0001
Tuzel *et al*. (2014)	4.04±2.57	1.2±1.05	0.009
Parikh *et al*. (2014)	7.91±1.96	10.54±2.24	<0.0001
Karaduman *et al*. (2017)	4.22±3.44	2.28±1.50	-
Jonnavithula *et al*. (2017)	7.16±3.92 (ICNB)	13.22±4.07 (PT)	<0.001
Present study	8.06±1.99 (ICNB)	12.97±1.96 (PT)	<0.001

ICNB: Intercostal nerve block, PT: Peritubal, Bp: Bupivacaine, Sl: Saline, PCNL: Percutaneous nephrolithotomy

showed a lower TAR in the bupivacaine (0.25%) versus control/saline group (119.3 mg and 276.8 mg, respectively). Haleblian *et al*.[10] demonstrated a reduced analgesic requirement with 0.25% bupivacaine skin infiltration without any significant difference in the pain score. Jonnavithula *et al*.[16] demonstrated a higher TAR, a lower time duration for demand of analgesia, and a raised VAS in PTB group as compared to ICNB group (7.167 ± 3.92 vs. 13.22 ± 4.07 h) with ropivacaine.

Karaduman *et al*.[17] had also compared the effect of PT infiltration with bupivacaine and morphine on postoperative analgesia in patients undergoing PCNL and compared the first analgesic demand between the two groups and demonstrated that it was 4.222 ± 3.44 h and 2.288 ± 1.50 h in the PT group and the control group, respectively, which was similar to our study. However, we did not use morphine in the study. Tüzel *et al*.[18] showed that pain relief was more in levobupivacaine infiltration in the PT space as compared to the saline infiltration. The time to first analgesic demand was found to be 4.04 ± 2.57 h and 1.2 ± 1.05 h in LA and saline infiltration groups, respectively ($P = 0.009$), which was statistically significant and similar with our result.

Parikh *et al*.[19] conducted a ultrasonography-guided PT infiltration of 0.25% bupivacaine versus 0.25% ropivacaine for postoperative pain relief after PCNL and noted that the mean time for the first rescue analgesic dose was statistically lower in the bupivacaine group (7.91 ± 1.96 h and 10.54 ± 2.24 h) as compared with ropivacaine. Parikh *et al*.[2] studied the analgesic efficacy of PTB with 0.25% bupivacaine in PCNL and demonstrated that bupivacaine PTB is a good method of postoperative pain relief. Haleblian *et al*.[10] conducted a study on subcutaneous bupivacaine infiltration and postoperative pain perception after PCNL and noted that the postoperative VAS scores were lower in the bupivacaine group as compared to the saline group. However, the differences between the groups were not statistically significant. Sharifi *et al*.[20] evaluated the efficacy of intermittent perirenal instillation of bupivacaine posttubeless PCNL under spinal anesthesia and observed that the pain score (VAS) at various time intervals and concluded that bupivacaine provided a more acceptable analgesia; however, it was statistically insignificant. Shah *et al*.[15] demonstrated that the VAS score at various time intervals was lower in the bupivacaine infiltration group after the tubeless PCNL. The difference between the two groups (bupivacaine vs. control) was statistically significant.

Karaduman *et al*.[17] compared the effect of PT infiltration with bupivacaine and morphine on postoperative analgesia in patients undergoing PCNL and found the mean VAS score/Dynamic visual analogue scale (DVAS) to be significantly lower in bupivacaine group. Kıraç *et al*.[3] demonstrated that the VAS after bupivacaine infiltration was significantly lower as compared to the control group and this was statistically significant. Parikh *et al*.[2] studied the analgesic efficacy of PT infiltration of 0.25% bupivacaine in PCNL and demonstrated that the VAS score for the first 24 h was significantly lower in bupivacaine group. Kıraç *et al*.[3] demonstrated stone-free rates of 85.2% in the study group and 85% in the control group, which were statistically insignificant between the two groups. This was also supported in another study by Shah *et al*.[15]

In our study, 30/32 (94%) and 31/32 (97%) patients had complete stone clearance in Group I and Group II, respectively. Statistical analysis with Fisher's exact test revealed

insignificant difference ($P = 0.557$). In the present study, the complication rates of Group I patients included eight minor complications (Clavien I and II) which were managed by antipyretics, blood transfusion, and change in antibiotics with one major complication (Clavien IIIa) which required intercostal drainage (ICD) insertion in view of hemothorax. In Group II, six patients had minor complications (Clavien I and II) that were managed conservatively by antipyretics, blood transfusion, and change in antibiotics, whereas two patients had major complications (Clavien IIIa) of which one required angioembolization and one required an ICD insertion for hemothorax.

Seitz *et al*.[21] in another study had reported postoperative fever as a common complication, with an overall incidence of 10.8%, which was concurred by Kumar *et al*.[22] in another similar study. It was graded as I in 8.46% of patients that could be managed without a change in antibiotics and as Grade II in 3.04% of patients requiring a change in antibiotics. Seitz *et al*.[21] in another study reported that blood transfusion was required in 0%–20% of patients with an overall incidence of 7%, whereas Kumar *et al*.[22] in their study had documented that bleeding was a complication accounted for in up to 9.76% of their patients and these authors had categorized the same as Grade I in 5.86% of patients where bleeding was controlled by single episode of nephrostomy clamping, skin compression, or pressure dressing and as Grade II in 3.91% of patients who required blood transfusion. They also demonstrated that nine of their patients had developed hydrothorax which was managed with ICD under LA. Lojanapiwat and Prasopsuk[23] reported that 15.3% (26 patients) developed hydrothorax through supracostal puncture with only 5.3% (9 patients) requiring ICD.

The complication rates in the present study were comparative to previous studies. There were few limitations in the current study. No control group was used in this study as we did not deem it properly to deny benefits of pain relief to post-PCNL patients. Comparison of bupivacaine with other anesthetic such as ropivacaine was not evaluated in the current study. From this study, it can be concluded that ICB was not as efficacious as PTB in alleviating postoperative pain following PCNL. Bupivacaine is a safe and effective local agent for PT infiltration in selected post-PCNL patients for postoperative pain relief.

Informed consent statement

The authors also certify that informed consents were obtained from all the human participants in this study as per protocol registered with the Clinical Trials Registry of India (CTRI/2018/03/012717).

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that names and initials will not be published and due efforts will be made to conceal identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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