A comparison of the efficacy of intercostal nerve block and peritubal infiltration of ropivacaine for post-operative analgesia following percutaneous nephrolithotomy: A prospective randomised double-blind study

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ABSTRACT

Background and Aims: Intercostal nerve blockade (ICNB) and peritubal infiltration of the nephrostomy tract are well-established regional anaesthetic techniques for alleviating pain after percutaneous nephrolithotomy (PCNL). This prospective study compared the efficacy of ICNB and peritubal local anaesthetic infiltration of the nephrostomy tract in providing post-operative analgesia following PCNL. Methods: Sixty American Society of Anesthesiologist physical status 1 and II patients scheduled for PCNL requiring nephrostomy tube were randomised to receive either peritubal infiltration or ICNB. At the completion of the procedure, patients in Group P received peritubal infiltration and those in Group I received ICNB at 10, 11, 12th spaces using fluoroscopy guidance. Postoperatively, patients were followed for 24 h for pain using Visual Analogue Scale (VAS) and Dynamic VAS. Rescue analgesia was inj. tramadol 1 mg/kg IV when pain score exceeded 4. Time to first rescue analgesia, number of doses and patient's satisfaction were noted in all patients. Results: Pain scores were lower in the group I at all points of measurement than group P. The mean time to first demand for rescue analgesia was higher in Group I (13.22 ± 4.076 h vs 7.167 ± 3.92 h P - 0.001). The number of demands and the amount of analgesics consumed were less in Group I. Conclusion: ICNB provided superior analgesia as evidenced by longer time to first demand of analgesic, reduced number of demands and consumption of rescue analgesic. Peritubal infiltration, although less efficacious, may be a safe and simple alternative technique.

Key words: Intercostal nerve, nerve blocks, percutaneous nephrolithotomy, peritubal infiltration, ropivacaine

Access this article online

Website: www.ijaweb.org

DOI: 10.4103/ija.IJA_88_17

Quick response code



INTRODUCTION

Percutaneous nephrolithotomy (PCNL) is currently the treatment of choice for kidney stones >2 cm, staghorn calculi and multiple renal calculi. [1] The clearance rate with PCNL is better compared to the less invasive extracorporeal shockwave lithotripsy and is achieved with lower morbidity than open surgery. The procedure of PCNL is associated with a significant post-operative pain, which though mostly due to dilatation of the renal capsule and parenchyma, may also be due to pain along the nephrostomy tube.

Recent changes in the practice of PCNL include the introduction of 'mini-perc' technique and tubeless

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How to cite this article: Jonnavithula N, Chirra RR, Pasupuleti SL, Devraj R, Sriramoju V, Pisapati MV. A comparison of the efficacy of intercostal nerve block and peritubal infiltration of ropivacaine for post-operative analgesia following percutaneous nephrolithotomy: A prospective randomised double-blind study. Indian J Anaesth 2017;61:655-60.

procedures as well as the use of smaller nephrostomy tubes.[2,3] 'Mini-perc' (minimally invasive PCNL) technique is a less invasive alternative to standard PCNL and causes minimal trauma to the tissues.[4] However, these methods may not be applicable in all the patients, and it may not be possible to avoid the use of the nephrostomy tube totally. This requires continued efforts for improvement of analgesia because good post-operative pain control not only decreases complications but also facilitates faster recovery.[5] Several studies which investigated post-operative pain after PCNL focused on traditional measures such as the use of nonsteroidal anti-inflammatory drugs and opioids. These drugs have their own side effects and limitations particularly in patients with potential renal failure.[6-8] Regional techniques offer many advantages: Pain is cured close to the damaged tissue area, and when local anaesthetics are used, they provide analgesia without the side effects attributed to opioids. It was earlier reported by us that peritubal infiltration of the nephrostomy tract from the skin to renal capsule provides good pain relief for nearly 14 h postoperatively with reduced demand for rescue analgesia.[6] Honey et al.[9] studied the efficacy of ipsilateral intercostal nerve blocks (ICNBs) of the 10, 11 and 12th nerves and found that ICNB was effective in alleviating pain for up to 6 h after PCNL. To date, there is no literature comparing the ICNB and peritubal infiltration in providing analgesia following PCNL. In this study, we sought to compare the analgesic efficacy of ICNB and peritubal infiltration with 0.5% ropivacaine in providing post-operative analgesia.

METHODS

A prospective randomised controlled study was conducted in sixty patients undergoing PCNL under general anaesthesia after obtaining Institutional Ethics Committee approval and written informed consent from the patients [Figure 1]. This study was carried out for 6 months from February to July 2015. This clinical trial was registered at Clinical Trial Registry India CTRI/2017/06/008821. Patients aged between 18 and 60 years, belonging to the American Society of Anesthesiologists grades I and II, weighing 40-80 kg and belonging to either gender scheduled for elective standard PCNL with single subcostal nephrostomy tract and requiring 14/16 French nephrostomy tube at the end of procedure were enrolled for the study. The exclusion criteria included renal stones requiring more than a single puncture, supracostal punctures, body mass index >30 kg/m², uncontrolled diabetes and hypertension, excessive bleeding during the procedure, surgical procedure lasting >3 h, patients with delayed recovery or requiring post-operative ventilation.

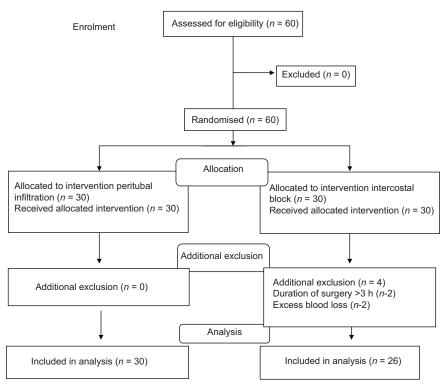


Figure 1: Consort flow diagram

All patients received general anaesthesia; induction of anaesthesia was with inj propofol 1.5-2 mg/kg and 2 µg/kg of fentanyl was administered and were intubated or ally with Portex® endotracheal tube (Smiths Medical international Ltd. Kent, CT216JL, UK) facilitated with inj. atracurium 0.6mg/kg. IV and maintained with air oxygen (60:30) mixture along with intermittent dose of atracurium and isoflurane titrated to maintain haemodynamics $\pm 20\%$ of baseline. The patients were randomly allocated into two groups by computer-generated random numbers. Group P (n-30) patients received 15 ml of 0.5% ropivacaine along the nephrostomy tract and Group I patients received intercostal nerve blockade along 10, 11 and 12th intercostal spaces with 0.5% ropivacaine 5 ml in each space. Both interventions were performed under fluoroscopic guidance at the end of the procedure and before tracheal extubation. Intercostal nerve block was performed under aspectic precautions using following technique. Spinous processes of the dorsal vertebrae in the midline at the 10, 11 and 12th intervertebral spaces were identified. Intercostal space was then determined by palpation aided with fluoroscopic guidance at each level to be blocked, and the insertion point for needle was 5-7 cm lateral to the midline, at the angle of the rib (lateral to sacrospinalis muscle). A 1.5 inch 22 guage needle was inserted at 20° cephalad angle with skin stretched in between the fingers. Once the needle touched the rib. maintaining the same angle it was walked off the inferior border of the rib and then advanced by another 3 mm. The solution was injected after negative aspiration with the goal of placing it in the neurovascular bundle (between the internal and innermost intercostal muscle). The process was repeated for other level of blockade.

At the end of the PCNL procedure, aroutine nephrostogram was performed, and the nephrostomy tube was clamped. The retained contrast in the tube helped to guide the needle during peritubal infiltration from renal capsule to the skin. Under fluoroscopic guidance a 23G spinal needle was introduced along the nephrostomy tube at 6 and 12 O' clock position till it reached the renal capsule, then the needle was slowly withdrawn by injecting the study drug along the tissue planes i.e., the renal capsule, muscles, subcutaneous tissue and the skin. The trachea was extubated after reversal of residual neuromuscular blockade, and after the patient was warm, awake and responding to commands.

Post-operative pain was assessed by Visual Analogue Scale (VAS) and Dynamic VAS (pain on deep breathing and coughing - DVAS), a 10-point scale ranging from '0' minimum or no pain to '10' the maximum pain score perceived by the patient. The assessment was done by an independent observer blinded to the study, every 4th hourly for 24 h from the time of extubation. The duration of block was taken from the time the study drug was administered by either of the technique to the time for the first demand of analgesia. Rescue analgesia was provided by inj. tramadol 1 mg/kg IV if pain score was 4 or more on VAS. Duration of analgesia (time to first demand for analgesic), number of rescue analgesic demands and total analgesic consumption were noted. Patient's satisfaction was noted on a 10-point scale ranging from '0' (least satisfaction) to '10' (maximum satisfaction). Occurrence of procedure related complications such as pneumothorax, haemothorax, wound site haematoma were noted.

The primary objective of the present study was to investigate the efficacy of ICNB and peritubal infiltration with 0.5% ropivacaine under fluoroscopic guidance in attenuation of post-operative pain after PCNL in terms of duration of analgesia. The secondary objectives included the number of requests for rescue analgesia, the level of patient's satisfaction and any complications associated with the procedures such as pneumothorax and bleeding.

Statistical analysis was performed using SPSS Version 17; (SPSS Inc. Chicago, Il, USA) Data were expressed as means with 95% confidence intervals for continuous variables. Continuous data were described as mean ± standard deviation, and categorical variables were given as number (%).

Continuous variables were compared using t-test for two independent samples, and Chi-square test was used for the categorical data. The ordered categorical data (VAS and DVAS) were compared between the groups using Mann-Whitney U test. The Kaplan – Meier curves for time to event (which was the occurrence of pain in this study) was compared between the groups using log rank test. P < 0.05 was considered as statistically significant.

The pilot study with 6 patients in each group resulted in mean duration of analgesia of 7.6 h (± 4.4) for group P and 12.8 h (± 6.7) for group ICNB. We tested the null hypothesis that both group means are 7.6 h and the alternative hypothesis that the mean of group ICNB was 12.8 h with estimated group standard deviations of 4.4 and 6.7 and with a significance level (alpha)

of 0.05 using a two-sided two-sample *t*-test and determined that a sample size of 27 each would have a 90% power to detect a difference of 5.2 h between the groups. Hence, thirty patients were recruited in each group.

RESULTS

Four patients were excluded from the study after inclusion [Figure 1] and finally 56 patients, 30 in Group P and 26 in Group I were analysed. Demographic data were comparable between the groups, and there was no statistical difference [Table 1]. There was a significant difference between the VAS and DVAS at 8 and 12 h [Tables 2a and b]. The comparison of the longest possible duration of pain-free interval between the groups was done using Kaplan–Meier survival curves [Figure 2]. The mean duration of analgesia was 13.22 ± 4.076 h in Group I and 7.167 ± 3.92 h in Group P; P being 0.001 which is statistically significant. The mean number of analgesic dose was 1.30 ± 0.451 in Group I and 2.2 ± 0.594 in Group P

Table 1: Patient's characteristics							
Parameter	Group P (n=30)	Group I (n=26)	P				
Age (years)	42.5±11.6	41.3±13.4	0.738				
Gender (male:female)	21:9	19:7					
Duration of surgery (h)	1.56±0.29	1.43±0.37	0.79				
Analgesic time (h)	7.167±3.92	13.22±4.07	0.000*				
Mean no. of demands	2.2±0.594	4 1.3±0.451					
No. of demands							
0	3 (10%)	8 (30.8%)					
1	8 (26.7%)	8 (30.8%)					
2	7 (23.3%)	6 (23.1%)	0.163				
3	7 (23.3%)	2 (7.7%)					
4	2 (6.7%)	2 (7.7%)					
5	3 (10%)	0					

^{*}Statistically significant

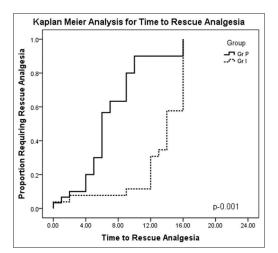


Figure 2: Kaplan-Meier curves showing time to rescue analgesia

and *P* being 0.018. Patient's satisfaction score was 5.76 ± 0.76 in Group I and 3.27 ± 0.16 in Group P with *P* 0.000 [Figure 3].

DISCUSSION

The results of the present study showed that ICNB was more effective than peritubal infiltration in mitigating post-operative pain. The time to first demand of analgesia in Group I was 13.22 h and in Group P 7.16 h. The VAS and DVAS scores were low in both groups but more so with ICNB group. In a well-matched randomised study[9] where ICNB was administered with 0.5% bupivacaine following PCNL, the analgesic consumption was much lower than in the control group. In another randomised study in which ICNB was given guided by ultrasound following PCNL the authors found similar results.[10] In the present study, the local anaesthetic used was 0.5% ropivacaine. Ropivacaine is a long-acting amide local anaesthetic agent, a pure S-enantiomer and is less lipophilic than bupivacaine and is less likely to penetrate large myelinated motor fibres, resulting in a relatively reduced motor blockade. Thus, ropivacaine, with its efficacy, lower propensity for motor block and reduced potential for central nervous system toxicity and cardiotoxicity, appears to be an important option for regional anaesthesia and for the management of post-operative pain.[11]

In another randomised study^[12] the authors studied peritubal block under ultrasound guidance with ropivacaine and found the mean time to first demand of analgesia in the ropivacaine plus morphine group to be 13.7 h and 10.7 h in the ropivacaine group (P = 0.0004). They also concluded the mean total consumption of tramadol and the mean number

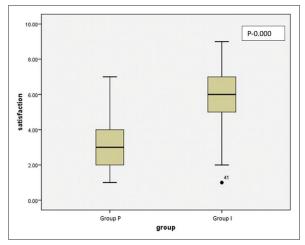


Figure 3: Box plot graph showing patient's satisfaction

Table 2a: Visual Analogue Scale pain score at 4th hourly intervals								
Group	Median (IQR)							
	VAS 0	VAS 4	VAS 8	VAS 12	VAS 16	VAS 20	VAS 24	
Group P	2 (1-3)	2 (1-3)	4 (4-5)	5 (4-6)	4 (2.7-5.5)	2 (2-4)	3 (2-4)	
Group I	1 (0-2)	1 (0.75-2)	1 (0.75-2)	2 (1-3)	4 (3-5)	4 (3-5)	2 (1.75-3)	
P	0.12	0.005*	0.000*	0.00*	0.306	0.004*	0.268	

VAS - Visual Analogue Scale; IQR - Interquartile range

	Tab	Table 2b: Dynamic Visual Analogue Scale pain score at 4th hourly intervals					
Group	Median (IQR)						
	DVAS 0	DVAS 4	DVAS 8	DVAS 12	DVAS 16	DVAS 20	DVAS 24
Group P	2.5 (1-4)	3 (2-4)	5 (4-6)	6 (4.75-7)	4 (3-5)	3 (1.75-4)	3 (1.75-4)
Group I	1 (1-2)	1 (1-2)	2 (1-3)	2.5 (1-3)	5 (4-6)	4 (3-5)	3 (2-3.25)
P	0.09	0.000*	0.000*	0.000*	0.318	0.009*	0.737

IQR - Interquartile range; DVAS - Dynamic Visual Analogue Scale

of analgesic demands required during the initial post-operative period was also significantly less in the ropivacaine-morphine group. Another study by the same authors compared 0.25% bupivacaine and ropivacaine along the nephrostomy tract and found that the mean duration of analgesia to be 10.54 h in ropivacaine group and 7.91 h in bupivacaine group.[13] Our study results also concur well with this study. The mean time for the first demand of analgesia was 13.7 h in Group I and in Group P, it was 7.16 h. The difference in the period of analgesia was probably the concentration of ropivacaine used. We have used 0.5% ropivacaine as against 0.25% with the other authors. A study[14] on the primary evaluation of local anaesthetic properties of ropivacaine concluded that ropivacaine in low concentrations (0.25-1%) was distinctly longer acting than bupivacaine on infiltration. Moreover, they suggested that ropivacaine was capable of producing some vasoconstriction over a wide range of low concentrations, compared to bupivacaine which may explain its longer duration of action. In our previous study^[6] of peritubal infiltration of nephrostomy tract with 20 ml 0.25% bupivacaine, we have noted analgesia of 14 h with reduced analgesic demand and good patient's satisfaction. In another study, we found the addition of 100 µg of buprenorphine to 0.25% of bupivacaine prolonged the duration of analgesia for 20 h.[15]

Local analgesic techniques are of increasing interest in the recent years because they are simple, safe and provide effective analgesia without any adverse effects and more so in patients with a potential for compromised renal functions. Peritubal infiltration provided effective post-operative analgesia and ICNB provides even more effective analgesia with good patient satisfaction. Meticulous attention has to be paid while administering the ICNB; otherwise, the chances of pneumothorax may be high. The use of fluoroscopy improved the precision, safety and efficacy without additional cost to the patient. Although ICNB provided longer duration of analgesia, it is technically more difficult. Peritubal infiltration does not require any expertise and is not associated with the potential complications of ICNB.

Peritubal infiltration and ICNB with 0.5% ropivacaine is a simple and safe method which has significantly increased the duration of analgesia without any adverse effects and with reduced analgesic requirement.

CONCLUSION

ICNB provided superior analgesia as evidenced by longer time to first demand of analgesic, reduced number of demands and consumption of rescue analgesic. Peritubal infiltration, although less efficacious, may be a safe and simple alternative technique.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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