Original Article

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Surgery Section

A Prospective, Randomised, Double-blind Comparative Study for Efficacy of Paravertebral Block by Ropivacaine in Postoperative Analgesia after Percutaneous Nephrolithotomy

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ABSTRACT

Introduction: Percutaneous Nephrolithotomy (PCNL) is a painful procedure that involves placement of large bore access sheath in the flank through which stones are fragmented and then removed. Inability to control this pain may hamper discharge from hospital and might lengthen their return to work.

Aim: To evaluate the efficacy of Paravertebral Block (PVB) with ropivacaine on postoperative pain management in patients after PCNL.

Materials and Methods: A prospective randomized double-blind comparative study was conducted from January 2012 to December 2013 in 60 adult patients posted for PCNL. Sixty patients were randomized into two groups of 30 each: Group A received PVB with ropivacaine while Group B was the control group who did not receive PVB. In the postoperative period, the pain status of patients was evaluated at postoperative 6 and 24 hours by using the Visual Analogue Scale (VAS).

Continuous data were described as mean±standard deviation and categorical variables are given as number (%). Continuous variables were compared using t-test for two independent samples. Percentages were compared using Chi-square analysis.

Results: There was no statistically significant difference between the two groups regarding the demographic characteristics, surgical complications, and postoperative hospital stay. Our findings revealed that in Group A, VAS score was lower significantly at 6 hours ($p<0.001$) but not at 24 hours ($p=0.082$). Requirement of rescue analgesia was lower ($p<0.05$), when compared with the Group B.

Conclusion: PVB by Ropivacaine was shown to be safe and efficacious as an analgesia method after PCNL.

Keywords: Pain, Rescue analgesia, Visual analogue scale

INTRODUCTION

PCNL is an established treatment for management of renal calculi advantages being lower morbidity, shorter operative time, shorter duration of stay in hospital and earlier return to work over open renal surgery [1]. Though minimal invasive, PCNL is a painful procedure that involves placement of large bore access sheath in the flank through which stones are fragmented and then removed [2]. Inability to control this pain may hamper discharge from hospital and might lengthen their return to work. Managing this pain with opioids would further defeat the purpose of this minimal invasive procedure as these medications lead to nausea, vomiting, sedation and constipation [3].

PVB is associated with less postoperative nausea and vomiting, low chances of urinary retention and also less hypotension [4]. Ropivacaine has been used for peritubal instillation in controlling postoperative pain of PCNL [5]. Ropivacaine is efficacious with lower propensity for motor blockade and has reduced cardiovascular side effect profile which makes it an important option for regional anaesthesia in management of postoperative pain [6].

This study analyses the efficacy of PVB of 0.25% ropivacaine administered for postoperative pain relief after PCNL.

MATERIALS AND METHODS

The present study was carried out at department of Urology in collaboration with department of Anaesthesiology at Aditya Birla Memorial Hospital, Pune, Maharashtra, India).

Anticipating 2 cm difference in the VAS as the desired difference with a Standard Deviation (SD) of 2 cm (observed in a previous study of PVB) [3,5], the estimated sample size was 22 per group with a = 0.05 and power of 90%. Assuming 10% attrition, we aimed to include 30 patients per group in the study.

A prospective randomized double-blind comparative study was conducted from January 2012 to December 2013 in 60 American Society of Anaesthesiologists physical status I-III adult patients posted for PCNL surgery after Institutional Ethics Committee's approval and informed consent. They were randomly divided into two equal groups with 30 patients in each group by closed envelope method. Group A was ropivacaine group (15 mL of 0.25% ropivacaine given as PVB) while Group B was the control group.

Inclusion Criteria

A 20-60 years of age, 35-85 kg weight having body mass index <30, renal stone size <3.0 cm with a single nephrostomy tube (22 F) and duration of surgery <3 hour.

Exclusion Criteria

Patients having tubeless/mini PCNL, more than one puncture and patients with deranged coagulation profile were excluded from the study.

Study drug was prepared by a person blinded to the actual study and findings were recorded by a third person. All patients were pre-medicated with intravenous ondansetron 8 mg, intravenous fentanyl of 2 µg/kg and intravenous glycopyrrolate 0.04 mg/kg. Balanced

GA was administered, induction done using thiopentone 5-6 mg/kg and intubation facilitated by succinylcholine 1.5 mg/kg. After endotracheal intubation, patients were maintained with O_2/N_2O with a muscle relaxant and isoflurane. Surgery was performed in the prone position. After insertion of nephrostomy tube and before the extubation, Group A patients received PVB using ropivacaine (15 mL of 0.25% ropivacaine). Patients were extubated and kept in post anaesthesia care unit under observation for 24 hour. The primary end point was to compare pain at rest in patients with or without a PVB block using a VAS.

Technique of Paravertebral Block

PVB was first performed in 1905 [7,8]. It is a very effective way of providing analgesia for unilateral surgical procedures or painful conditions of the thorax and abdomen.

Preparation

Intravenous access, standard non-invasive monitoring, full resuscitation facilities and a trained assistant was confirmed. Full aseptic precautions were taken during the whole procedure.

Positioning

Lateral decubitus with the operative side up. The back was assumed kyphosis and the patient was supported by an attendant.

Equipment

A standard regional anaesthesia tray is prepared with the following equipment:

- Sterile towels, 4″ × 4″ gauze packs, sterile gloves and 20 mL syringes with local anaesthetic;
- Marking pen, one 1½″ 25-gauge needle for skin infiltration (for awake or sedated patients);
- A 10 cm long, 22-gauge, Quincke or Tuohy tip spinal needle.

Choosing the Level

If only one to four dermatomes need to be blocked, a single level PVB at or below the mid-dermatomal level was sufficient. If spread greater than four dermatomes were required, then multiple injections would block the area more reliably. Iliac crest (corresponds to L3-4) and tips of scapulae (corresponds to T7) are helpful to identify spinal levels [2].

Technique

Having decided the level and number of blocks to be performed, the skin was marked at the tips of the appropriate spinous processes and at points 25 mm lateral to these. If the block was being performed awake or under sedation, skin infiltration with dilute local anaesthetic would be required. Insertion of needle was performed at the lateral landmark described above, in an anteroposterior direction, perpendicular to skin, in the sagittal plane seeking bony contact with the transverse process. If this was not achieved, then the needle was withdrawn to the skin and redirected in a slightly caudal direction. If this failed, slight cranial angulation was tried.

Once contact with bone has been made, the depth was noted, the needle was then be withdrawn and 'walked off' the TP caudally, advancing until it is 10 mm deeper than the depth of first bone contact. If it was not possible to walk-off bone, the needle was re-inserted more caudally or cranially and the process repeated. A click might be sometimes palpable on passing through the costotransverse ligament. After careful aspiration to confirm that the needle tip was not intravascular or intrathecal, the predetermined dose of local anaesthetic was slowly administered. Bupivacaine, levobupivacaine and ropivacaine are the most widely used local anaesthetic agents for PVB in current practice [9]. A single injection of 15 mL of local anaesthesia produces a somatic block over a median of three dermatomes and a sympathetic block over eight dermatomes [9].

During follow up, patients were assessed for pain and side effects by an independent observer blinded to the infiltration, immediately after extubation, after 6 hour and 24 hour. The pain score was assessed using 0-10 point VAS at rest.

When VAS score >4, the patient was administered injection diclofenac sodium (50 mg) or injection paracetamol (100 mg) as a rescue analgesia, and the patient was reassessed. Intravenous ondansetron was given if there was nausea and vomiting. Time for first demand of rescue analgesic was noted to assess the duration of analgesia. Number of doses of analgesics in 24 hour and haemodynamic parameters was noted.

STATISTICAL ANALYSIS

Statistical analysis was performed using, statistical considering a hypothesis that after administration of PVB, the first demand of rescue analgesia was longer by 40%, with a power of 90% and an α error of 0.05, the sample size was estimated as 30 patients in each group. Continuous data were described as mean±standard deviation and categorical variables are given as number (%). Continuous variables were compared using t-test for two independent samples. Percentages were compared using Chi-square analysis. The $p < 0.05$ was considered to be statistically significant.

RESULTS

There were no dropouts from the 60 patients enrolled in the study.

[Table/Fig-1] shows that the demographic data regarding age and sex were comparable. VAS (at rest) was low in both groups in the postoperative period, but significantly lowers in Group A (3.3±1.62) as compared with Group B (6.3±1.56) at 6 hour ($p<0.001$). VAS score at 24 hour was 1.3±1.06 in Group A which was not significantly different than Group B (1.8±1.13). Fourteen patients required rescue analgesia in Group A while 29 patients required it in Group B ($p<0.001$). The mean time for first demand of analgesia was 10.2 hours in Group A and 4.6 hours in Group B ($p<0.001$). The mean number of analgesic demands required during initial 24 hour was 0.4 doses in Group A and 1.3 doses in Group B ($p=0.004$).

Parameters	Group A	Group B	p-value
Age (years)	38.3±14.29	37.6±11.63	0.836
Sex (M:F)	17:13	14:16	0.438
VAS at 6 Hours	3.3±1.62	6.3±1.56	<0.001
VAS at 24 Hours	1.3±1.06	1.8±1.13	0.082
Number of patients requiring rescue analgesia	14	29	<0.001
Average number of analgesic doses given in 24 hours	0.4	1.3	0.004
Time required for first rescue dose (h.)	10.2	4.6	<0.001

[Table/Fig-1]: Parameters analysed in Group A and Group B.

DISCUSSION

Management of pain in post-PCNL period has been dealt by several investigators in different ways. Some of them have focussed on reducing the size of percutaneous catheter [10], while others have focussed on instillation of local anaesthetics at the puncture site [11].

Ropivacaine 0.25% has been successfully used by Parikh GP et al., as peritubal infiltration [5]. It was double blind, randomized study. They found significantly lower VAS score in ropivacaine than control group in first 24 hour. They also noticed increased mean time requirement to first rescue analgesia in ropivacaine group.

The present study has demonstrated efficacy of ropivacaine 0.25% PVB in PCNL for management of postoperative pain and reduced requirement of rescue analgesia. This is the first study which has used PVB with 0.25% ropivacaine as analgesia in post-PCNL

settings. Borle AP et al., used 0.5% bupivacaine PVB in pre-induction period [3]. They found reduced intraoperative fentanyl requirement in bupivacaine group. They also noticed decreased VAS at rest, 1 hour, 6 hour and 12 hour in postoperative period.

We have found significantly lower VAS at 6 hour, less number of patients requiring rescue analgesia in ropivacaine group. We have also noticed statistically significant increased mean time required for first rescue analgesia.

LIMITATION

Our study was limited by few factors. First, all cases included in the study were with single subcostal puncture and hence, this study cannot be valid for PCNL with multiple punctures. Second, we have not used ultrasound guidance for effective instillation of ropivacaine as previous studies did [12,13]. Third, we did not study the haemodynamic parameters of the patients.

CONCLUSION

Unilateral PVB with 0.25% ropivacaine in immediate postoperative period significantly reduces pain as measured with VAS at 6 hour. It has also improved time for first rescue dose of analgesia and reduced number of patients who required rescue anaesthesia. However, further studies may be required to document this.

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