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ORIGINAL ARTICLE

A COMPARATIVE STUDY OF PERITUBAL INFILTRATION OF BUPIVACAINE, ROPIVACAINE AND PLACEBO IN PERCUTANEOUS NEPHROLITHOTOMY FOR POST-OPERATIVE ANALGESIA

Jagadish Vaddineni[1], Krishna Chaithanya K[2], Narasimha Reddy P[3], Sangamitra Gandra[4]

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ABSTRACT: BACKGROUND AND AIMS: Percutaneous nephrolithotomy (PCNL) is a safe and effective endourologic procedure in patients with renal calculi. Though it is less painful than open surgery, effective postoperative analgesia is required to reduce the pain around the nephrostomy site. Objectives of this study are to compare and evaluate the peritubal infiltration of bupivacaine, ropivacaine, and placebo from renal capsule to skin along the nephrostomy tract for postoperative analgesia in percutaneous nephrolithotomy (PCNL). **MATERIALS AND METHODS:** A randomized controlled double blinded study was designed in 60 American Society of Anesthesiologists (ASA) grade I and II patients to assess & compare the impact of peritubal infiltration of bupivacaine, ropivacaine, saline with 23-gauge spinal needle along the nephrostomy tract after PCNL under fluoroscopic guidance. Patients were randomized into 3 groups B (bupivacaine), R (ropivacaine), S (saline/control). Each group containing 20 patients were given 20mL of respective drug at the conclusion of the procedure. Postoperative pain score and analgesic requirement for the first 24 hours were assessed by visual analog scale second hourly. Rescue analgesia with inj. Tramadol 2mg/kg was given intravenously to a maximum total dose of 400mg when pain score exceeded 4. **RESULTS:** Pain scores and analgesic requirement for the first 24 hours postoperatively were lesser in the B (bupivacaine) & R(ropivacaine) groups than in the S(saline/control) group of patients at all points of time and were statistically significant ($p<0.005$). **CONCLUSION:** In this study a significant difference in the pain scores and analgesic requirement was noted in saline and drug groups. Peritubal infiltration of 0.25% bupivacaine or 0.375% ropivacaine solutions is equally efficient in alleviating postoperative pain after PCNL.

KEYWORDS: Percutaneous Nephrolithotomy, Ropivacaine, Bupivacaine.

INTRODUCTION: Percutaneous nephrolithotomy (PCNL) is a safe and effective endourological procedure for the management of patients with renal calculi as it is less invasive than the open surgery, less time consuming and is associated with less chances of infection. It is also associated with lower morbidity and faster recovery. However, placement of nephrostomy tube results in distressing peritubal pain requiring administration of effective analgesia postoperatively.

Inadequate analgesia can result in delayed mobilization, impaired ventilation, and prolonged hospitalization. Analgesics such as non-steroidal anti-inflammatory drugs and opioids have side effects limiting their use in patients with potential renal problems. Several investigators have focused on reduction of postoperative discomfort and pain associated with nephrostomy tubes.(1)

We hypothesized that peritubal infiltration from renal capsule to skin would alleviate postoperative pain after PCNL. So we investigated the analgesic efficacy of peritubal infiltration of

0.25% bupivacaine and 0.375% ropivacaine for postoperative pain relief under fluoroscopic guidance, after PCNL.

MATERIALS AND METHODS: A randomized controlled double blinded study was designed in 60 American society of anesthesiology (ASA) grade I and II patients to assess & compare the impact of peritubal infiltration of bupivacaine, ropivacaine, and saline with 23-gauge spinal needle along the nephrostomy tract after PCNL under fluoroscopic guidance. The patients enrolled were aged between 20 and 65 years, weighing between 45 and 85 kg and belonging to either sex.

Institutional ethical committee's approval and informed consent from the patient were obtained for the study. Patients with body mass index(BMI) >30, age more than 65 years, patients of ASA III & IV, renal stones requiring more than a single puncture, excess bleeding during the procedure, surgical procedure extending more than 3 hours, delayed recovery, or requiring postoperative ventilation, incomplete data acquisition, and patient withdrawal from the study were excluded.

All the patients received standard general anaesthesia using glycopyrrolate, midazolam, thiopentone sodium with fentanyl at a dose of 2 μg/kg/wt. PCNL was performed with single sub costal nephrostomy tract. Patients were randomized into 3 groups B (bupivacaine), R (ropivacaine), S (saline/control). Each group containing 20 patients were given 20mL of respective drug at the conclusion of the procedure. Postoperative pain score and analgesic requirement for the first 24 hours were assessed by visual analog scale second hourly. Rescue analgesia with injection tramadol hcl 2mg/kg was given intravenously to a maximum total dose of 400mg when pain score exceeded.

At end of the procedure before extubation under fluoroscopy guidance, the respective drug was infiltrated in all the three groups (B, R, & S groups) with a 23-gauge spinal needle (10cm length) along the nephrostomy tube at 3 o'clock and 9 o'clock positions (10mL in each tract) including renal capsule, muscles, subcutaneous tissue, and skin. Postoperative pain was evaluated by an independent observer blinded to the infiltration.

The pain score was assessed by visual analog scale (VAS), a 10-point scale ranging from "0, " minimum or no pain, to "10, " the maximum pain score perceived by the patient, second hourly for 24 hours from the time of extubation. The duration of the block was taken as the time from block administration to the time for first demand of analgesia. Analgesic consumption for the first 24 hours, that is, number of demands and amount of analgesia required, was noted. Rescue analgesia with injection tramadol at a dose of 2mg/kg intravenously was administered if the pain score exceeded 4 on VAS. Ondansetron 4mg intravenously was given to all the patients prior to the administration of tramadol.

Statistical analysis was performed using SPSS version 20 (Chicago, IL). Data are expressed as means and standard deviation for continuous variables. Normal distribution of continuous variables was tested using Kolmogorov–Simronov test. Comparison of continuous variables with normal distribution between three groups was performed using one way ANOVA followed by Tukey-HSD post hoc test.

Categorical variables were compared using chi-square tests. The ordered categorical variables (VAS) were compared using Kruskal Wallis-test. A two tailed p-value of <0.05 was taken as statistically significant. The comparison of the longest possible pain-free period between the groups was performed using Kaplan–Meier survival plots.

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RESULTS: The demographic data were comparable and similar [Table 1]**.** Visual analog scores were <4 in the immediate postoperative period in Group B and Group R and remained low for a prolonged period of 14 hours in the study group than that of the control group.

The first demand of analgesia in Group R was after 14hrs and in group B was 13.45hrs (P= 0.00) [Table 2] [Figure 1]. Total consumption of tramadol in control group was 352.5 mg, which was higher than in group R (110.0 mg) and group B (120.0mg) (P=0.00).[Table 2]. Total number of demands for analgesia in control group were 3.55 where as in Group R was 1.20 and in Group B was 1.10 (p=0.00) [Table 2] [Figure 2].

DISCUSSION: The treatment of renal calculi has evolved during the last three decades from open surgical procedures to non-invasive modalities like extracorporeal shockwave lithotripsy and less invasive procedures like PCNL. The surgical approach to renal calculi depends largely on stone size, location, and composition. PCNL is one of the common endourological procedures at our centre, and we extended our indication to smaller stones (<2 cm) for the patients who preferred single intervention for complete removal of stone.

Placement of nephrostomy tube (22=24F) after completion of PCNL is a standard procedure to provide haemostasis, adequate drainage, and access for additional endoscopic procedures for 48 hours. Recently, tubeless PCNL has come into vogue with significant reduction in the postoperative pain in selected group of patients.[2] However, nephrostomy tube cannot be dispensed in cases like complex stones, perforation, and excess bleeding.

It has been hypothesized that the pain after PCNL surgery, which requires insertion of nephrostomy tube, could be due to structures beyond the skin puncture site like renal capsule. Placement of the nephrostomy tube is the last surgical step in PCNL and it provides hemostasis along the tract, avoids urinary extravasations, and maintain adequate drainage of the kidney.

The nephrostomy tube produces local inflammatory reaction which causes the post-operative pain and discomfort in PCNL. Dalela et al [3]. Performed PCNL under renal capsular block by infiltrating renal capsule with 2% lignocaine. They emphasized that most of the pain during PCNL is felt at the time of dilatation of renal capsule and parenchyma as it is richly innervated by pain conducting neurons.

The traditional old time management of post-operative pain by intramuscular administration of narcotics has been limited by elaborate array of checks and counter checks. The administered dose has its inherent delayed onset and erratic absorption pattern resulting in under treatment of discomfort and frequent over sedation of the patient.

Effective pain management is essential and has been recognized as a prime concern for anaesthesiologists.[4] Local infiltration of local anaesthetics has been introduced as a promising step forward in reducing postoperative pain and side effects from analgesics. Local infiltration at the surgical site has become relatively common for a number of surgical procedures and can produce effective analgesia and has the advantage of relative simplicity compared with other regional anaesthesia techniques.

Local anaesthetics reversibly block nerve conduction near their site of administration, thereby producing temporary loss of sensation in a limited area. Nerve impulse conduction is blocked by inhibition of sodium channels at the nerve endings and along the axon. This causes a decrease in nerve cell membrane permeability to sodium ions, possibly by competing with calcium-binding sites

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that control sodium permeability. This change in permeability results in decreased depolarization and an increased excitability threshold that ultimately prevents the nerve action potential from forming.[5,6,7]

Aravantinos et al[8] performed PCNL under assisted local anaesthesia in selected patients. They placed a 16 fr nephrostomy tube under local anaesthesia and kept it for 1 week. After infiltration of the tract and renal parenchyma with lignocaine, PCNL was performed later. They found this method safe and effective in selected patients.

Various studies have been done to reduce the pain by reducing the size of the nephrostomy tube or performing tubeless PCNL. The tubeless approach is safe in selected patients with uncomplicated percutaneous procedure and has a low calculus burden. Bellman et al.,[9] Karami et al.,[10] and Lojanapiwat et al.[11] performed tubeless PCNL in 50, 60, and 37 selected patients, respectively, and concluded that tubeless PCNL reduces postoperative patient discomfort, analgesic requirement, hospital stay, and cost to the patient.

Placement of small size nephrostomy tube is another option to reduce pain after PCNL. A small bore (8-12 Fr) nephrostomy tube is preferred in patients in whom the incidence of stent dysuria is likely or who may require percutaneous access for subsequent calculus manipulation, while conventional large bore nephrostomy tube drainage may be reserved for procedures with a large complex calculus, significant bleeding, prolonged procedure, infected calculi, or major perforations.

In our institute, it is routine to pass a nephrostomy tube of 22-24 Fr size in all PCNL patients. Desai et al[12] did comparative study of type of nephrostomy drainage following PCNL, i.e., large bore (20 Fr) versus small bore (9 Fr) versus tubeless PCNL. Large bore nephrostomy tube patients had significantly higher analgesic requirement (218 mg of diclofenac sodium) than small bore and tubeless patients (140 and 88 mg of diclofenac sodium, respectively). Pietrow et al[13] used 10 Fr and 22 Fr catheters for drainage after PCNL in 30 patients. They found lower pain score in immediate postoperative period with less narcotic requirement in small drainage catheter after PCNL.

The other modalities of pain relief after PCNL are subcutaneous infiltration, tract infiltration, systemic analgesics, etc. Halebian et al.[14] studied subcutaneous infiltration of 1.5 mg/kg, of 0.25% bupivacaine in 25 patients. Their results showed reduced rescue analgesia requirement but no significant difference in VAS score and pain relief around nephrostomy site area after PCNL.

Ugras et al[15] assessed the effect of local anaesthetic infiltration on postoperative pain status and pulmonary functions using either 0.2% ropivacaine or saline into renal puncture site, nephrostomy tract, and skin. Patients received parenteral metamizol (500 mg/dose) on demand. Their results showed that the combination of ropivacaine instillation with metamizol decreased pain and analgesic use and improved peak expiratory flow more than the use of metamizol alone.

Gokten et al[16] studied the efficacy of the levobupivacaine infiltration to nephrostomy tract in combination with intravenous paracetamol on postoperative analgesia in patients of PCNL and concluded that levobupivacaine infiltration through the nephrostomy tract in combination with intravenous paracetamol infusion was safe and effective as an analgesia method after PCNL.

We observed that infiltration of 0.25% bupivacaine and ropivacaine to skin, subcutaneous tissue, nephrostomy tract, and renal capsule significantly reduced VAS, prolonged the time to demand analgesia, and reduced consumption of rescue analgesic for first 24 hours. Our results are in accordance with the study by Jonnavithula et al[17] except that in their study duration of block was

prolonged in both control as well as study group and the total consumption of tramadol in 24 hours was also less as compared to our study. This difference was probably related to small nephrostomy tube size (14-16 Fr) used by them compared to large nephrostomy tube (22-24 Fr) used in our study.

CONCLUSION: Local analgesic techniques are of increasing interest in recent years because they are simple, safe, in expensive and provide effective postoperative analgesia. The peritubal infiltration of the nephrostomy tube is highly effective and a safe technique in postoperative pain management for patients undergoing standard PCNL.

Our randomized controlled study demonstrated excellent postoperative analgesia with peritubal local anaesthetic infiltration of 0.25% bupivacaine and ropiacaine which led to a significant reduction in VAS scores, reduced analgesic requirement, and led to longer pain-free period without any adverse effects in patients undergoing PCNL.

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		N	Mean (Std. Deviation)	95% Confidence Interval for Mean	
				Lower	Upper
Age (yrs)	Control	20	47.45 (12.467)	41.62	53.28
	Ropivacaine	20	47.30 (12.942)	41.24	53.36
	Bupivacaine	20	45.45 (12.202)	39.74	51.16
Weight (kg)	Control	20	61.35 (9.488)	56.91	65.79
	Ropivacaine	20	60.25 (7.880)	56.56	63.94
	Bupivacaine	20	65.00 (9.526)	60.54	69.46

Table 1

		N	Mean (Std. Deviation)	95% Confidence Interval for Mean		P value
				Lower	Upper	
Time for first demand of analgesic (hrs)	control	20	1.45 (.605)	1.17	1.73	
	Ropivacaine	20	14.00 (2.248)	12.95	15.05	
	bupivacaine	20	13.45 (2.438)	12.31	14.59	.000
Total consumption of tramadol (mg)	control	20	352.50 (49.934)	329.13	375.87	
	Ropivacaine	20	110.00 (20.520)	100.40	119.60	
	bupivacaine	20	120.00 (29.912)	106.00	134.00	.000
Max VAS	control	20	6.90 (1.021)	6.42	7.38	
	Ropivacaine	20	4.40 (.821)	4.02	4.78	0.00
	bupivacaine	20	4.20 (.616)	3.91	4.49	
No. of analgesic demands	control	20	3.55 (.510)	3.31	3.79	
	Ropivacaine	20	1.20 (.410)	1.01	1.39	
	bupivacaine	20	1.10 (.308)	.96	1.24	.000

Table. 2

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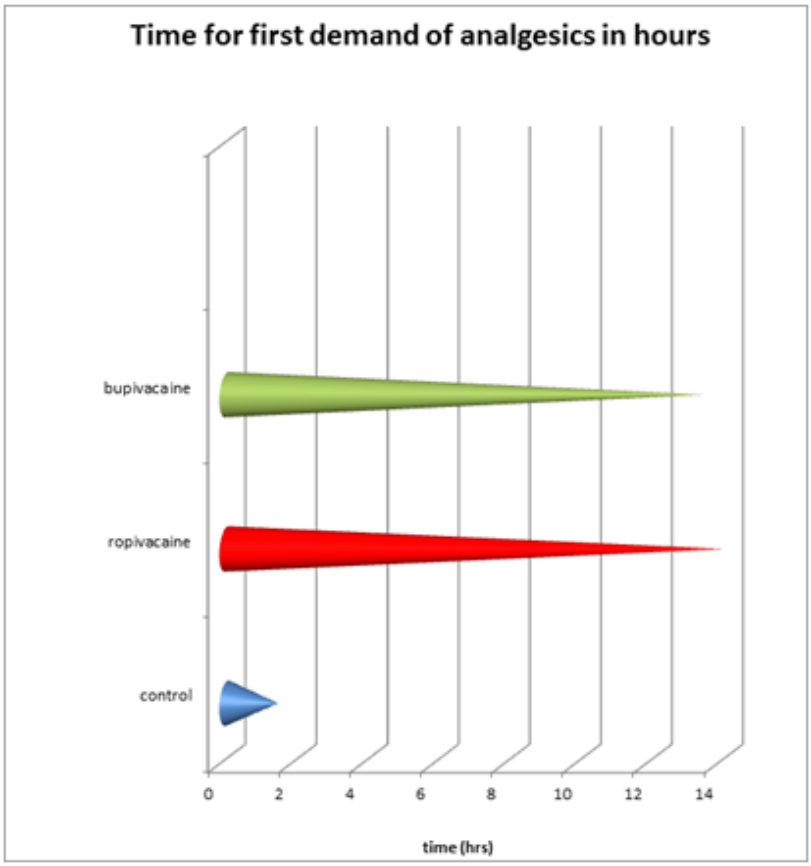

Figure 1

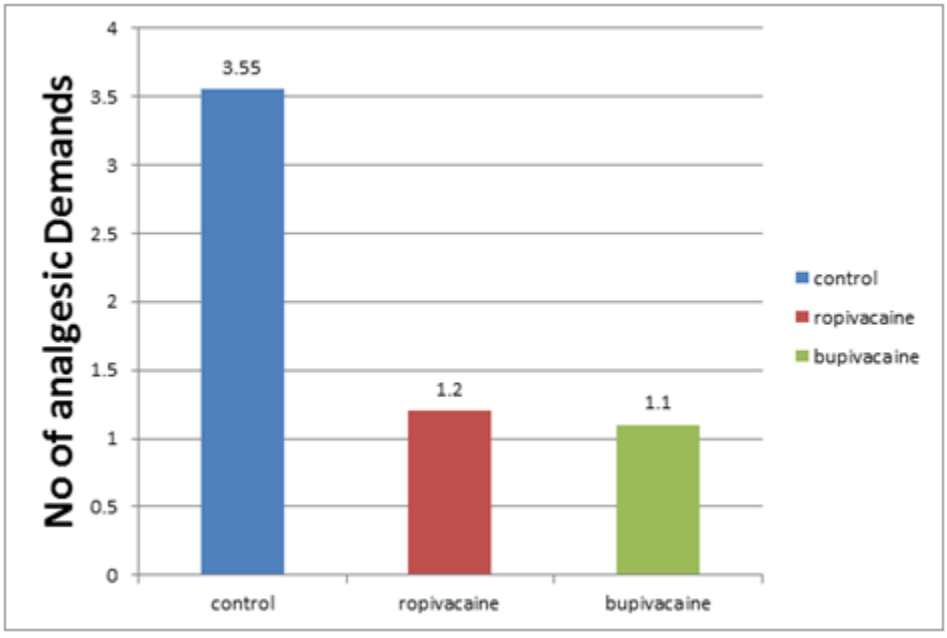

Figure 2

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AUTHORS:

1. Jagadish Vaddineni
2. Krishna Chaithanya K.
3. Narasimha Reddy P.
4. Sangamitra Gandra

PARTICULARS OF CONTRIBUTORS:

1. Assistant Professor, Department of Anaesthesiology, Narayana Medical College, Nellore, Andhra Pradesh.
2. Assistant Professor, Department of Anaesthesiology, Narayana Medical College, Nellore, Andhra Pradesh.
3. Professor, Department of Anaesthesiology, Narayana Medical College, Nellore, Andhra Pradesh.
4. Senior Resident, Department of General Medicine, Narayana Medical College, Nellore, Andhra Pradesh.

NAME ADDRESS EMAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Krishna Chaithanya,
Flat No. 3A,
Krishna Sanjeeva Homes,
Gomathy Nagar,
Nellore-524003,
Andhra Pradesh.
Email: chaithu8@gmail.com

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