Comparison of peritubal infiltration of ropivacain and Placebo in percutaneous nephrolitholapaxy for post operative analgesia at soetomo hospital surabaya

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COMPARISON OF PERITUBAL INFILTRATION OF ROPIVACAIN AND PLACEBO IN PERCUTANEOUS NEPHROLITHOLAPAXY FOR POST OPERATIVE ANALGESIA AT SOETOMO HOSPITAL SURABAYA

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ABSTRACT

Objective: To observe the effects of ropivacain peritubal infiltration in reducing postoperative pain and analgesic requirements postoperatively in patients underwent percutaneous nephrolithotomy (PNL). **Material & method:** Double blind randomized controlled trial on 32 patients with renal stone who underwent PNL at Soetomo General Hospital Surabaya from February until August 2017, divided into 2 groups. Experimental group (A) who received peritubal infiltration of ropivacain pre-operative, and control (placebo) group (B) Evaluation using Wong Baker pain score 2 hour post operation, time from operation until first rescue analgesia, and total analgesia given in first 24 hours. **Result:** Mean age was 51.81 ± 9.13 and 49.31 ± 10.53 years in group A and B respectively. Mean operation time 49.31 ± 10.53 and 89.69 ± 17.74 hours in group A and B respectively. There was no significant difference in stone complexity, nephrostomy placement and stenting between two groups. There was no significant difference of Wong Baker pain score 2 hours post operation between group A and B (p 0.72). There was no significant difference in total analgesia in the first 24 hours between group A and B (p 0.74). There was no significant difference in total analgesia in the first 24 hours between group A and B (p 0.74). The time of first rescue analgesia demand was significantly longer in the experimental group (p 0.00). **Conclusion:** Peritubal infiltration of ropivacain in percutaneous nephrolitholapaxy is safe and effective to prolong the need of first rescue analgesia in post operative pain management which result in patients convenience.

Keywords: Percutaneous nephrolitholapaxy, ropivacaine, renal stone, postoperative pain.

ABSTRAK

Tujuan: Mengetahui efek infiltrasi ropivacain peritubal terhadap nyeri paska operasi dan kebutuhan obat analgesia paska operasi percutaneous nephrolithotomi (PNL). Bahan & Cara: Penelitian double blind randomized controlled trial pada 32 pasien dengan batu ginjal yang menjalani PNL di RSUD Dr. Soetomo Surabaya dari Februari sampai Agustus 2017 yang terbagi dalam 2 grup. Grup experimantal (A) menerima infiltrasi ropivacain peritubal pre-operasi PNL, dan grup kontrol (B) menerima placebo. Evaluasi menggunakan skala nyeri Wong Baker 2 jam paska operasi, waktu yang dibutuhkan untuk first rescue analgesia, dan total analgesia dalam 24 jam pertama. Hasil: Rerata umur grup A 51.81 \pm 9.13 tahun dan grup B 49.31 \pm 10.53 tahun. Rerata waktu operasi grup A 95.31 \pm 22.25 menit dan grup B 89.69 \pm 17.74 menit. Tidak terdapat perbedaan signifikan dalam kompleksitas batu, pemasangan nephrostomi dan pemasangan stent antara kedua grup. Tidak terdapat perbedaan signifikan pada skala nyeri Wong Baker 2 jam paska operasi antara grup A dan B (p 0.72). Tidak terdapat perbedaan signifikan dalam total analgesia 24 jam pertama antara kedua grup (p 0.48). Waktu yang dibutuhkan untuk first rescue analgesia secara signifikan lebih panjang pada kelompok perlakuan (p 0.00). Simpulan: Infiltrasi ropivacain peritubal merupakan tindakan yang aman dan efektif untuk memperpanjang waktu yang dibutuhkan untuk first rescue analgesia pada managemen nyeri paska operasi PNL sehingga dapat meningkatkan kenyamanan pasien.

Kata Kunci: Percutaneous nephrolitholapaxy, ropivacain, batu ginjal, nyeri paska operasi.

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INTRODUCTION

Urinary stone disease has afflicted mankind for millennia, was found in an Egyptian mummy in a tomb dating to approx 4400 bc. ¹⁻³ Incidence of urinary stone in USA: 300/100.000 male and 100/100.000 female. ² The lifetime prevalence of stone 10% for men and 4% for women. ³ Increase in the incidence of stone disease over the last three decades. ^{1,2,4}

The management of renal calculus disease underwent drastic changes in the early 1980s. PNL has been developed as the standard procedure for large renal calculi. ^{2,5,6}

Fernstrom and Johansson described a percutaneous approach to the renal collecting system for the management of renal calculi. Nowadays PNL has become integrated part of modern urology education. Stone free rate of PNL 76-90%.

Pain is one of the most important considerations after any surgical procedure. 10,11 This condition may result in delayed mobilization, impaired ventilation, and prolonged hospitalization. 10

Analgesics i.e NSAID and opioids have side effects limiting their use in patients with potential renal problems.² Ropivacaine Aminoacyl local anesthetics.^{10,11} It works by modulating peripheral pain transduction by inhibiting the transmission of noxious impulses from the site of injury. Rapid onset and long lasting.¹² Duration of anesthesia is significantly longer than any other commonly used local anesthetic.^{11,12} There is a period of analgesia that persists after the return of sensation, during which time the need for strong analgesics is reduced.¹²

OBJECTIVE

The purpose of this study was to observe the effects of ropivacain infiltration in reducing the postoperative pain and analgesic requirements postoperatively in patients undergoing percutaneous nephrolithotomy.

MATERIAL & METHOD

This was an experimental study with double blind randomized controlled trial, enrolling 15 patients with renal stone who underwent PNL at Soetomo Hospital Surabaya. The inclusion criteria were patients with renal stone who underwent PNL; patient with PS ASA 1-2 and general anesthesia; age 18-65 year old; normal complete blood count, hemostasis, and electrolyte; willing to participate and sign the inform consent. The exclusion criteria were multipuncture PNL, PNL more than 3 hours, sistolic blood pressure >140 mmHg and diastolic >100 mmHg, anatomical abnormalities of the kidney (horseshoe kidney, stenosis ureteropelvic junction, stenosis infundibulum), pregnant and lactating, BMI >30 kg/m², abnormalities of hemostasis, patient with heart disease, patient with impaired renal function and diabetes mellitus, patient alergic to ropivacain. The drop out criteria were unwilling to participate in the study, there was adverse effect of ropivacain or major complication of PNL causing urological emergencies.

PNL were done under general anesthesia, without premedication. PNL with single puncture, using lithotriptor EMS and Storz. Stone location and puncture with fluoroscopy. Ropivacaine infiltration was at 3 and 9 o'clock, 10 ml each (spinal needle 25G) with fluoroscopy guidance (renal capsule, muscle, subcutaneous tissue, and skin).

Pain evaluation using Wong Baker Pain Score every two hours. If Wong Baker pain score >4 patient will be given rescue analgesia (Tramadol 2mg/kgbw). Time from operation until first rescue analgesia will be recorded. Total analgesia given in first 24 hours will be recorded.

RESULTS

Mean age was 51.81 ± 9.13 and 49.31 ± 10.53 years in group A and B respectively. Mean operation time 49.31 ± 10.53 and 89.69 ± 17.74 hours in group A and B respectively. There was no significant difference in stone complexity, nephrostomy placement and stenting between two groups (Table 1).

There was no significant difference of Wong Baker pain score 2 hours post operation between group A and B (p 0.72) (Table 2).

The time of first rescue analgesia demand was significantly longer in the experimental group (p 0.00) (Table 3).

There was no significant difference in total analgesia in the first 24 hours between group A and B (p 0.48) (Table 4).

Table 1. Sample characteristic.

Characteristics	Treatment Group	Control Group	p value
Gender			
Men	12 (75.0)	11 (68.8)	1.00^{a}
Women	4 (25.0)	5 (31.3)	
Age (Mean \pm SD) (years)	51.81 ± 9.13	49.31 ± 10.53	0.48^{b}
BMI (Mean \pm SD) (kg/m ²)	24.60 ± 2.94	24.15 ± 2.62	0.58^{b}
Hb Pre Op (Mean \pm SD) (g/dL)	14.07 ± 2.14	12.88 ± 1.78	0.10^{b}
Hb Post Op (Mean \pm SD) (g/dL)	12.61 ± 1.76	11.23 ± 2.04	0.05^{b}
Blood Lost (Mean ± SD) ml	184.38 ± 122.09	242.50 ± 190.70	0.43°
Creatinin Serum Pre Op (Mean ± SD) (mg/dL)	1.48 ± 0.98	1.98 ± 2.11	0.25°
Creatinin Serum Post Op (Mean ± SD) (mg/dL)	3.36 ± 4.80	3.45 ± 4.68	0.60°
Duration of Surgery (minute)	95.31 ± 22.25	89.69 ± 17.74	0.43 ^b
Kind of Stone $(N(\%))$			0.43
simple	7 (43.8)	7 (43.8)	1.00^{d}
complex	9 (56.2)	9 (56.2)	1.00
Redidual Stone (N(%))			
Exist	3 (18.8)	4 (25)	1.00°
Not Exist	13 (81.2)	12 (75)	1.00
Nephrostomi (N(%))			
To do	14 (87.5)	15 (93.8)	1.00°
Not to do	2 (12.5)	1 (6.2)	1100
Stenting $(N(\%))$			
To do	2 (12.5)	1 (6.2)	1.00°
Not to do	14 (87.5)	15 (93.8)	
Puncture Site (N(%))			
Middle pole	3 (18.8)	3 (18.8)	
Lower pole	12 (75)	11 (68.7)	
Pyelum	1 (6.2)	2 (12.5)	

a: Fisher test; b: Independent T-test; c: Mann-Whitney test; d: Chi-Square

Table 2. Wong Baker pain score 2 hours post operation.

Variable -	Treatment Group	Control Group	P value
variable	Median (Min - Max)	Median (Min - Max)	
Wong Baker 2 hours post-surgery	2 (0 -2)	2 (0 -2)	0.72

Table 3. Time of first rescue analgesia.

Variable	Treatment Group	Control Group	P value
variable	$mean \pm SD$	$mean \pm SD$	
First Rescue Analgesia (hours)	14.06 <u>+</u> 1.48	5.31 <u>+</u> 1.01	0.00

Table 4. Total analgesia in the first 24 hours.

Variable	Treatment Group Median (Min - Max)	Control Group Median (Min - Max)	P value
Total Analgesia (mg)	100 (100 - 200)	150 (100 - 200)	0.48

DISCUSSION

Pain during PCNL can be caused by dilatation of the renal capsule and parenchymal tract (rich in pain-sensing nerves) not because of the operation performed inside the renal system, ^{13,14} swing and movement of Amplatz sheath, ¹⁵ expansion of the skin, subcutaneous tissues, and muscles. Therefore, the infiltration of ropivacain peritubal was done before concentric dilatation with metal dilatator.

No significant differences in Wong Baker pain score 2 hours post PNL between research group and control group (p 0.72) may be caused by the effect of analgesia during operation still persistent.

There was significant difference in first rescue analgesia post PNL between research group and control group (p 0.00). In the research group, first rescue analgesia at 12 hours until 16 hours (14.06 ± 1.48 hours) while in the control group, first rescue analgesia was needed at 4 hours until 6 hours (5.31 ± 1.01 hours).

The mechanism of Ropivacaine is selective inhibition of afferent nociceptive sensitization pathways and delay in sensory recovery after motor recovery following local anesthetic infiltration around the nephrostomy tract. 16,17

No significant differences in total analgesia 24 hours post PNL between research group and control group (p 0.48), however in research group, 62.5% sample (10 patients) only need one rescue analgesia compared with control group, 50% sample (8 patients) need one rescue analgesia.

Parikh et al, showed in their study that the impact of infiltration of 0.25% bupivacaine along the nephrostomy tube Peritubal infiltration of 0.25% bupivacaine reduces analgesic requirements and delayed the time of first request for demand analgesia after percutaneous nephrolithotomy. Ugras et al, in their study also mentioned that postoperative pain and analgesic requirements were

decreased in combination of ropivacaine instillation with the metamizol group than the metamizol-alone group. Peak expiratory flow rate was also improved. Haleblian et al, found that subcutaneous infiltration of 0.25% bupivacaine in 25 patients had reduced postoperative analgesia requirement although no significant difference in VAS after PCNL. P

CONCLUSION

Peritubal infiltration of ropivacain in percutaneous nephrolitholapaxy is safe and effective to prolong the need of first rescue analgesia in post operative pain management which result in increase of patients convenience.

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