Original Article

The Effects of Pre-Emptive Bupivacaine Infiltration of the Nephrostomy Tract in Patients Undergoing Percutaneous Nephrolithotomy: A Randomized Controlled Study

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Abstract

Background Percutaneous Nephrolithotomy (PCNL) is a surgical procedure used for the removal of renal stones. The technique is minimally invasive and is often used for the removal of renal stones that are located near the pelvis. The topical administration of local anesthetics in the surgical area has been proven effective in minimizing post-operative pain after various surgical procedures. *Purpose* This study was conducted to compare the mean post-operative pain score in patients with pre-operative Bupivacaine infiltration of nephrostomy tract with placebo in control group of patients undergoing percutaneous Nephrolithotomy. Methods A randomized controlled trial was carried out in Department of General Surgery, Kuwait Teaching Hospital, Peshawar with diagnosis of renal stones. A total of 66 patients (33 males and 33 females) age: 16-50 years were admitted with diagnosis of renal stones. Statistical analysis was performed by using SPSS version 17. Results Patients with renal stones who underwent PCNL were randomly divided into Group A (Bupivacaine) and Group B (Placebo). The overall Average pain score for Group A was 4.15 ± 1.48 range (2 to 7) on visual analogue scale (VAS), while that for Group B was $6.06 \pm$ 1.02 range (4 to 8) p-value < 0.05, which indicates that preoperative infiltration of bupivacaine significantly decreases the postoperative pain in patients undergoing Percutaneous Nephrolithotomy. *Conclusion* The study concludes that local bupivacaine infiltration along the nephrostomy tract is an effective method of management of postoperative pain after PCNL, regardless of age and gender as shown by results of the study.

Keywords

Percutaneous Nephrolithotomy, Bupivacaine, Urolithiasis, Post-Operative Pain, Bupivacaine Infiltration

Introduction

Percutaneous Nephrolithotomy (PCNL) a pioneering technique of early 1970s to treat renal stones gain popular demand due to its less invasive technique and lower rate of complications as compared to open technique (Lahme, et al, 2002; Margel, David, et al.2005; Kurtulus, Fatih Osman, et al.2008; Kessaris, Dimitri N, et al.1995). PCNL requires placement of post-operative indwelling nephrostomy tube requiring diligent post-operative management and its

complications (Kessaris, D, et al. 1995). This nephrostomy tube is major contributing factor of post-operative discomfort (Pietrow, Paul K et al. 2003; Cormio, Luigi et al.2013; Maheshwari, Pankaj N et. Al. 2000) but it is necessary in complicated stones for cases with co-morbid as it prevents parenchymal bleeds, urinary extravasations and promotes healing (Dore, B. 2006; Mousavi-Bahar et. al. 2011; Yanqun, Qian Qingpeng Zhang Xiaochun1 NA. 2007).

In late 1990s tubeless PCNL was introduced with an indwelling stent to provide drainage and promote healing (Bellman, Gary C et al. 1997; Limb, Jerry, and Gary C Bellman. 2002; Choi, Michael et al. 2006). Tubeless **PCNL** has decreased post-operative discomfort, hospital stay and cost but it can only be performed in selected cases (Lojanapiwat, B, S Soonthornphan, and S Wudhikarn, 2001). Due to use of tubeless only **PCNL** in selected patient's nephrostomy tube is a necessity in PCNL, and the subsequent post-operative discomfort associated with it. It requires comprehensive pain management (Pietrow, Paul K et al. 2003).

Post-operative pain is mainstay of every surgical suit of hospital and requires single or multimodal pain management protocols which have been thoroughly researched or standardized with regard to certain surgical procedures. (Williams, Amy. Morrison, R Sean et al. 2003; Ray, Albert. 1994). Analgesics used in post-operative pain management mainly are opioids, NSAIDS and local anesthetics. (McQuay, Henry. 1999; Hyllested, M et al. 2002; Goldstein, Andrei et al. 2000). Opioids are known for their efficacy and quick pain relief but their side-effects limit their use so that multi-modal pain management protocols are devised in combination of opioids with NSAIDS or NSAIDS with local anesthetics. (Stein, Christoph, Michael Schäfer, and Halina Machelska 2003; Furlan, Andrea D et al. 2006; Furlan, Andrea D et al. 2006; McNicol, E et al. 2005; Jin, Fengling, and Frances Chung. 2001).

In this study we evaluated the efficacy of using local anesthetic in a nephrostomy tract to evaluate whether the local anesthetic provided effective analgesia for post-operative PCNL patients compared to a

placebo-controlled group in a randomized study set by means of 6 hourly VAS and checking for significance.

Methodology

A randomized controlled trial was carried out in Department of General Surgery, Kuwait Teaching Hospital, Peshawar with diagnosis of renal stones. A total of 66 patients (33 males and 33 females) age: 16-50 years were admitted with diagnosis of renal stones. The research was reviewed from the institutional ethics committee. consent was obtained from Informed patients undergoing the clinical trial. The inclusion criteria were subcostal access, adult age and uncomplicated stones. The exclusion criteria were severe cardiomyopathies, co-morbidities, calculus size greater than 3 cm, calculus requiring multiple access, deranged liver and renal profiles, deranged coagulation profiles and operation time greater than 120 minutes.

Statistical analysis was performed by using SPSS version 17. The variables were divided into continuous and categorical variables. Chi-square test was performed with p-value of less than 0.05 considered as significant along with independent T-test.

All operations were performed under Local Anesthesia, the site of incision was first infiltrated with local anesthetic xylocaine 0.25% with Adrenaline to provide preemptive analgesia before the establishment of nephrostomy tract, then fluoroscope guided nephrostomy tract was established by a 22 F spinal needle through which 0.25% of bupivacaine, 10 ml was infiltrated along the nephrostomy tract and renal capsule. Group A (Bupivacaine, 33 patients), Group B (Placebo, 33 patients). The placebo used was normal saline 0.9%. Post-operative pain was assessed by VAS immediately and then 6

hourlies by a doctor. Independent of study and blinded to the protocol. If the score was greater or equal to 4, a rescue analgesia in the form of Toradol (1mg/kg) with maximum dose of 240 mg/24 hours. The nephrostomy tube used was 24 F and removed on 3rd post-operative day and patient would be assessed 6 hourly post-nephrostomy tube removal for 12 hours. There would be no indwelling stent remained in-situ. The duration of the study was 6 months from January 2016 to June 2016.

Results

A total of 66 patients with renal stones who underwent PCNL were randomly divided

into Group A (Bupivacaine) and Group B (Placebo). Mean age in Group A was 32.2 years \pm 2.7 (18 to 56), Mean age in Group B was 31.09 years \pm 2.6 (18 to 58). In Group A, out of 33 patients, 20 (60.61%) were male and 13 (39.39%) were female with male to female ratio of 1.54:1. In Group B, out of 33 patients, 18 (54.55%) were male and 15 (45.45%) were female with male to female ratio of 1.2:1. The average duration of the procedure, defined as the time from the insertion of cystoscope to the application of the flank dressing, for Group A was 70.66 \pm 7.41 minutes, range 53 to 91 minutes and for Group B was 72.12 ± 7.65 minutes. 88 minutes. range 55 to

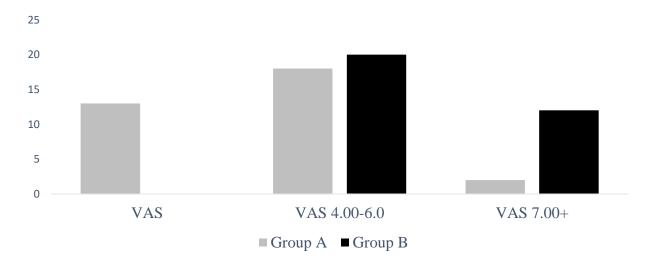


Figure 1: VAS Pain Scores

The overall Average pain score for Group A was 4.15 ± 1.48 range (2 to 7) on visual analogue scale, while that for Group B was 6.06 ± 1.02 range (4 to 8) p-value < 0.05, which indicates that preoperative infiltration of bupivacaine significantly decreases the postoperative pain in patients undergoing Percutaneous Nephrolithotomy.

Table 1: Average Pain Score of Both Groups. (n=66)

Average Pain Score of Both Groups						
	Group	Number of	Mean	Std.	Std. Error	p-value
		Patients		Deviation	Mean	_
Pain	Group A	33	4.1515	1.48158	0.25791	
	Group B	33	6.0606	1.02894	.17912	< 0.05

The Average Pain Score for Female patients in Group A was 4.07, range (2 to 7) and that for Group B was 6.13, range (4 to 8). The Average Pain Score for Male patients in Group A was 4.12, range (2 to 7) and that for Group B was 6.0, range (4 to 7). It shows that there is no effect of gender difference on pain score in either group. The effect of age on pain perception was not significant in this study as we have only included adult patients i.e. > 14 years and mixed response was observed in both groups' patients of different age groups.

Discussion

Pathophysiology of pain and surgical procedures results from tissue trauma leading to tissue changes and cytokines production with activation along coagulation cascade. (Deumens, Ronald et al. 2013). This surgical trauma requires a stress response with release of epinephrine and nor-epinephrine leading to increased CVS demand and pulmonary functions so that pain results in an increased morbidity for post-operative patients (White, Paul F, and Henrik Kehlet. 2010).

In this era of revolutionized pharmacology patients with mismanaged post-operative pain is a matter of concern and needs revision for existing protocols (Gatchel, Robert J, et al. 2014). PCNL – its advent in early 1970s has a post-operative pain profile it requires a nephrostomy tube catheter. The nephrostomy tube catheter is a major contributing factor in post-operative pain in PCNL patients. (Pietrow, Paul K et al. 2003). Multiple studies in the fields have been conducted to study the fact of using different size catheters and its effect in postoperative pain and recovery time. Cormio et al explores the issue and concludes that if a nephrostomy tube has to be placed it should be a large bore one, as it reduces the post-

operative bleeding and complication rate, albeit the fact that a large bore Nephrostomy tube results in increased post-operative discomfort (Cormio, Luigi et al. 2013). Pietrow et al. concludes that the use of a small drainage catheter after PCNL is associated with lower pain scores in the immediate postoperative period, yet no statistically significant benefit to the patient with regard to comfort is demonstrated beyond 6 hours. In addition, there is a trend toward reduced narcotic requirements. Finally, there is no apparent increase in patient morbidity from the use of the smaller nephrostomy tubes (Pietrow, Paul K et al.2003). De Sio et al. in his study concludes that a small bore nephrostomy catheter may reduce pain in the immediate postoperative time. It does not affect blood loss and hospital stay so it can safely be used instead of a large size nephrostomy tube, after uneventful percutaneous procedures (De Sio, Marco et al. 2011).

In late 1990s tubeless PCNL has provided a new modality for selected group of patients who can forego the use of nephrostomy tube and the drainage provided by indwelling stent (Bellman, Gary C et al. 1997). Tubeless PCNL has a shorter recovery time and decreased post-operative pain and decreased cost. (Mishra, Shashikant et al. 2010).

The use of local anesthetic infiltration in a nephrostomy tract and renal capsule has demonstrated efficacious post-operative pain relief in the first 24 hours as reported by Parikh et all as well as Jona Vithula et all (Parikh, Geeta P et al. 2011; Jonnavithula, Nirmala et al.2009; Dalela et al. 2004). explores renal capsular block and concurs that local anesthetic infiltration allows the procedure to be done without added anesthesia.

Furthermore, Gotkin et all have combined continuous analgesia in the form of IV paracetamol in combination with local levobupivacaine reported a significant decrease in post-operative pain as compared to controlled groups (Gokten, Ozgur Elvan et al. 2011). Furthermore, a concept of perceptive analgesia has been further explored and prevents the plasticity of CNS and hence gives more effective pain relief (Katz, Joel. 1995; Khan, Rumman, Yousaf Jan, and Ihsan Ulhaq Waqas. 2014). Nesioonpour et al. concludes in his study that the pre-operative local infiltration of bupivacaine reduces pain, nausea, vomiting and opioid use in the first 24 hours after inguinal hernia surgery under spinal anesthesia. Therefore, further evaluation of the efficacy of this technique as a modality of preemptive analgesia is suggested (Nesioonpour, Sh et al.2013).

Conclusion

According to the results of our study local bupivacaine infiltration along nephrostomy tract is an effective method of management of postoperative pain after PCNL, regardless of age and gender as shown by results of the study. The patients who were excluded from this study, such as the pediatric patients and patients with co-morbids such as Cardiac severe Dysfunction and Respiratory Insufficiency / Distress which could have affected the pain scores, may become part of our another study on the effect of local bupivacaine infiltration in PCNL and its effect on postoperative-pain and early mobility.

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Conflict of Interest

There are no competing interests.

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