EFFECT OF PREOPERATIVE BUPIVACAINE INFILTRATION OF NEPHROSTOMY TRACT ON POST-OPERATIVE PAIN IN PATIENTS UNDERGOING PERCUTANEOUS NEPHROLITHOTOMY: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACTS

OBJECTIVES: To see the effect of bupivacaine infiltration of nephrostomy tract in reducing the postoperative pain and analgesic requirements in patients undergoing percutaneous nephrolithotomy.

METHODOLOGY: This randomized controlled study was conducted at institute of kidney diseases Hayatabad Medical Complex, Peshawar, Pakistan, from June 1, 2011 to May 31, 2012. Total 66 patients (33 patients in each group) were included in the study through consecutive non-probability sampling technique and were randomly divided into group A (bupivacaine, 33 patients) and group B (placebo, 33 patients).

RESULTS: Mean age was 32.2+2.7 & 31.09+2.6 years in group A & B respectively. The mean duration of the procedure was 70.66±7.41 & 72.12±.65 minutes for group A & B respectively. The overall average pain score for group A was 4.15±1.48 on visual analogue scale, while that for group B was 6.06±1.02 ($p < 0.05$). The average pain score for female patient was 4.07, (range 2-7) & 6.13 (range 4-8) in group A & B respectively. The average pain score for male patient was 4.12 (range 2-7) & 6.0 (range 4-7) in group A & B respectively. The effect of age on pain perception was not significant in this study as we included only adult patients (≥14 years of age) and mixed response was observed in both groups patients of different age groups.

CONCLUSION: Preoperative bupivacaine infiltration of the nephrostomy tract is safe and an effective way of reducing the postoperative pain and analgesic requirements avoiding the adverse effects of the opioids or non-opioids analgesics.

KEY WORDS: Percutaneous Nephrolithotomy (PCNL), Renal Stones, Postopeative Pain.

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INTRODUCTION

The nephrolithiasis is a common disease that affects 2-5% of the people in Asia[1]. The treatment of renal calculi has evolved during the last thirty years from open stone extraction to less invasive modalities including percutaneous stone removal[2]. Percutaneous nephrolithotomy (PCNL) is well accepted technique for the removal of large and complex renal calculi.[3] In 1976, Firestorm and Johannson first reported the establishment of percutaneous access with specific intention of removing the renal stone[4]. The primary goal of surgical management is to achieve maximal stone clearance with minimal morbidity to the patient.[5]

Pain score after percutaneous nephrolithotomy is lower when smaller nephrostomy tube is placed at the end of the procedure[6]. The topical administration of local anesthetics in the surgical area has proven effective in reducing post-operative pain after various surgical procedures.[7] Peritubal infiltration of the bupivacaine along the nephrostomy tract after PCNL significantly reduces the post-operative pain and analgesics requriment[8]. However another research study shows that preoperative bupivacaine infiltration of the nephrostomy tract is associated with decrease analgesic requirements but does not significantly decreases the postoperative pain[2]. The mean postoperative pain score after PCNL is 5±2.86 and 3.3±1.92 on visual analogue scale at 2 hours in patients with bupivacaine infiltration of the nephrostomy tract and control group respectively[2].

Bupivacaine, a aminoacyl local anesthetics, modulate peripheral pain transduction by inhibiting the transmission of noxious impulses from the site of injury[9]. Clinically, the order of loss of nerve function is as follows: (1) pain, (2) temperature, (3) touch, (4) proprioception

and (5) skeletal muscle tone. The onset of action with bupivacaine is rapid and anesthesia is long-lasting. The duration of anesthesia is significantly longer with bupivacaine than with any other commonly used local anesthetic. It has also been noted that there is a period of analgesia that persists after the return of sensation, during which time the need for strong analgesics is reduced. In cases of increased systemic absorption of bupivacaine above optimal level can produce cardiac and central nervous system disturbances[10].

The pain relief can be obtained by injection of local anesthetics at the incision site at the beginning of surgery[11]. Analgesia given before the onset of pain, that is, pre-emptive analgesia, prevents the plasticity of central nervous system and hence gives more effective pain relief[11]. The purpose of this study was to observe the effects of bupivacaine infiltration of nephrostomy tract in reducing the postoperative pain and analgesic requirements postoperatively in patients undergoing percutaneous nephrolithotomy at institute of kidney diseases, Hayatabad medical complex, Peshawar, Pakistan.

METHODOLOGY

It was a randomized controlled trial conducted at institute of kidney diseases, Hayatabad Medical Complex, Peshawar from June 1, 2011 to May 31, 2012. Sample size was estimated by using the WHO software for sample size calculation. A total of 66 patients with renal stones who underwent percutaneous nephrolithotomy, selected through consecutive nonprobability sampling technique, were included in the study. Patients were randomized into two groups, Group A (Bupivacaine, 33 patients) and Group B (placebo, 33 patients) by sequentially numbered opaque sealed envelopes. All adult patients of either gender undergoing percutaneous nephrolithotomy for renal calculi with single puncture access and nephrostomy tube size 12 Fr were included in the study. The age was more than 14 years because younger patients may not be able to give correct pain score on visual analogue scale. Patients with multiple puncture access, tubeless percutaneous nephrolithotomy, and nephrostomy tube size other than 12 Fr were excluded from the study, because they affect the pain score. Also patients with allergy to bupivacaine, on chronic analgesics and diabetes mellitus diagnosed by blood sugar levels and from medical record and peripheral neuropathy by clinical examination were exclude from the study, because they can affect the perception of pain.

All patients who were undergoing PCNL for the treatment of renal stones, and meeting the inclusion criteria were considered. They were admitted through our out patients department (OPD) and were sent to the ward for further evaluation. The purpose and benefits of the study were explained to all patients, and they were assured that the study is purely done for data publication and research purpose. All the patients were explained about potential benefits and risks involved and a written informed consent was obtained from all patients included in the study.

Patients were worked up with detailed history and clinical examination followed by baseline preoperative investigations. The patients were randomly allocated in two groups by lottery method. Patients in group A were given pre operative 20 ml of 0.25% Bupivacaine while patients in group B were given 20 ml of Normal Saline as placebo before surgery at the nephrostomy site. Peroperative tramadol used during anesthesia, were standardized for all patients enrolled in the study to control for potential variability in drug administration by different anesthesiology staff and to avoid its effect on the postoperative pain score.

All the patients were prepared for the PCNL on the next OT day which was done under general anesthesia and a 12 Fr nephrostomy tube was placed in situ at the end of the procedure. All the surgical procedures in both groups were done by single experienced urologist of a consultant level. Post operatively, all patients were carefully followed at the 6th hour after operation and all patients were examined to determine the pain scores using visual analogue scale. Visual analogue scale is a measurement instrument that measures a characteristic across a range of values from zero to ten where zero means none and ten means the highest possible value. As in pain measurement, zero means no pain and ten means worst possible pain.

RESULTS

We had patients from all age groups but younger population was predominant in both groups. Mean age in group A was 32.33 years + 2.7 with age range of 18 to 56 years. The greatest representation was found in less than 30 years age groups i.e. 21 patients (63.6%). In the fifth and sixth decades, the number of patients were 3 (9.1%) and 8 (24.2%) respectively.

Mean age in group B was 31.09 years + 2.6 with age range of 18 to 58 years. In this group too the greatest representation was found in the less than 30 years age groups i.e. 21 patients (63.3%). So in this study the major contribution is from young patients less than 30 years which constitutes 42 patients (63.6%), followed by the patients more than 51 years age group which contributed 14 patients (21.2%). The age distribution for both groups is shown in Table 1.

In group A, out of 33 patients, 20 (60.61%) were male and 13 (39.39%) were female with male to female ratio 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 1.2:1. In group A, stones were on the right side in 16 patients (48.49%) and on the left side 17 patients (51.51%). In group B, stones were on the right side in 19 patients (57.58%) and on the left side 14 patients (42.42%).

The average duration of the pro-

TABLE I: AGE DISTRIBUTION

Age (in years)	Group		p-value
	Group A (n=33	Group B (n=33)	
≤ 30	21	21	>0.05
31 - 40	1	4	>0.05
41 - 50	3	2	>0.05
51 +	8	6	>0.05

TABLE II: STRATIFICATION OF PATIENTS ACCORDING TO PAIN SCORES IN BOTH GROUPS

Pain	Group		p-value
	Group A (n=33	Group B (n=33)	
≤ 3.00	12	0	< 0.05
4 - 6	19	21	>0.05
7 +	2	12	< 0.05

cedure, defined as the time from the insertion of cystoscope to the application of flank dressing, for group A was 70.66 ± 7.41 minutes, (range 53 to 91) and for group B was 72.12 ± 7.65 minutes, (range 55 to 88). There was no significant difference in the duration of procedures between the two groups (p-value > 0.05).

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) with a p-value < 0.05, which clearly indicate that preoperative infiltration of Bupivacaine significantly decreases the postoperative pain in patients undergoing percutaneous nephrolithotomy.

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) with a p value >0.05. It shows that there is no significant difference in the pain perception between the males and females within each 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 63.6% of our patients were less than 30 years old. Mixed response was observed in both groups patients of different age groups. The pain score stratification according to gender and age in both groups is shown in Table II.

DISCUSSION

Open stone surgery is now rarely indicated for the management of renal stone disease, and endourological procedures, such as extracorporeal shock wave lithotripsy (ESWL), uretero-renoscopic stone removal (URS), and PCNL, are more common modalities to deal with renal stones.[12] In the modern era of endourology, open stone surgery is only recommended in patients with severely distorted intrarenal anatomy.[13] Synder and his colleagues compared the success rate, procedure duration, complications, and recovery time for percutaneous and anatrophic nephrolithotomy in patients with staghorn stones.[14] They demonstrated a decreased cost, earlier return to activity, decreased requirement for either blood transfusion or narcotic drug, and shorter operative time in favor of patients undergoing PCNL.

Pain is one of the most important considerations after any surgical procedure. There is a clinical evidence that local anesthetics infiltration and instillation at operative site can improve the postoperative analgesia and decreases the analgesic requirements.[15,16] Local analgesic wound instillation through an indwelling irrigation apparatus provides safe and effective postoperative analgesia after a variety of abdominal surgeries, such as hernioplasty,[17] open and laparoscopic cholecystectomy,[18,19] cesarean delivery[20] and abdominal hysterectomy.[21]

Percutaneous nephrolithotomy is safe and effective procedure for the treatment of renal calculi. Although it is less morbid than the open surgical procedure for renal calculi, Patients still complains of postoperative pain and demands effective analgesia. Various strategies have been used to reduce the postoperative pain after percutaneous nephrolithotomy. Pietrow PK et al,[22] concluded that the use of small nephrostomy catheter (10 Fr pigtail catheter) instead of standard 22 Fr councill-tip catheter is associated with significantly lower pain score in the immediate postoperative periods, yet no statistically significant benefits with regard to comfort is demonstrated beyond 6 hours postoperatively, so we used a small nephrostomy catheter of 12 fr in all our patients. Ugras MY et al.[23] used 0.02% ropivacaine, infiltrated in to the skin , puncture site and nephrostomy tract at the end of the procedure and noticed a significant decrease in the postoperative pain(visual analogue score), analgesic requirements and improved ventilatory function in the early postoperative period. Jonnayitula N et al.[7] used

0.25% bupivacaine for the peritubal infiltration of the nephrostomy tract after the percutaneous nephrolithotomy and there was significant decrease in the postoperative pain score on visual analogue scale and analgesic requirements. Whereas Haleblian GE and coworkers 2 reported that marcaine infiltration of the nephrostomy tract at the end of the percutaneous nephrolithotomy did not significantly reduces the postoperative pain score as compared to placebo group, although the postoperative analgesic requirement was reduced but it was not statistically significant. In this study we used the 0.25 % bupivacaine for the nephrostomy tract infiltration before the puncture for the percutaneous nephrolithotomy tract dilatation. We notice a significant decrease in postoperative pain score using visual analogue scale in patients in the Bupivacaine group as compared to the placebo group. There was no significant difference in male and female pain scores within each group.

Tissue injury causes the CNS hyperexcitability resulting in postoperative pain. So analgesia given before the incision i.e. the pre-emptive analgesia prevents or reduce the CNS hyperexcitability and hence reduces the postoperative pain.[24,25] The pre-emptive analgesia is now effective in varieties of surgeries with good postoperative pain control. Pre-emptive infiltration of the bupivacaine provides more effective analgesia postoperatively, decreases the parenteral analgesics requirements and postoperative nausea in patients undergoing lumber laminectomy,[26] unilateral pediatric herniorrhaphy[27] and has significant longer the time for the first analgesic dose postoperatively than the pre-closure bupivacaine infiltration. Preoperative intravenous administration of flurbiprofen reduces postoperative pain after tonsillectomy, spinal fusion surgery, hysterectomy, and arthroscopic rotator cuff repair surgery.[28] Whereas preemptive analgesia in patients undergoing gynecologic laparoscopy does not reduces the postoperative pain nor does it decreases the time to return to normal activities after the procedure.[29]

After extensive literature search we did not find any study on pre-emptive analgesia of the nephrostomy tract in patients undergoing percutaneous nephrolithotomy. So this is the first study of its kind, in which the effect of preoperative Bupivacaine infiltration of the nephrostomy tract is evaluated. We hope that this study will be particularly helpful to all endo-urologist involved in the management of renal stones through Percutaneous Nephrolithotomy.

CONCLUSION

Percutaneous nephrolithotomy is the procedure of choice for large renal stones that cannot be treated with extracorporeal shockwave lithotripsy. Preoperative Bupivacaine infiltration of the nephrostomy tract is safe and an effective way of reducing the postoperative pain and analgesic requirements avoiding the adverse effects of the opioids or non-opioids analgesics.

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AUTHOR'S CONTRIBUTION

Following authors have made substantial contributions to the manuscript as under

MKK: Conception and design, acquisition of data, drafting the manuscript, final approval of the version to be published

AU: Acquisition of data, analysis and interpretation of data, final approval of the version to be published

AUR: Conception and design, critical revision, final approval of the version to be published

CONFLICT OF INTEREST

Author declares no conflict of interest

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