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Post-Operative Pain Score Comparison of Bupivacaine Vs Placebo in Patients Undergoing Percutaneous Nephrolithotomy

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ABSTRACT

Objective: To compare post-operative pain of Bupivacaine vs placebo in patients undergoing percutaneous nephrolithotomy.
Study Design: Quasi-experimental study.
Place and Duration of Study: Armed Forces Institute of Urology, Rawalpindi Pakistan, from Aug 21 to Aug 22.
Methodology: Eighty-eight patients undergoing percutaneous nephrolithotomy who fulfilled the inclusion criteria were included in study and randomized in two equal groups (44 patients each) by lottery method, Group-A received 20ml/50mg of 0.25% Bupivacaine and Group-B received 20ml normal saline around nephrostomy tube. Post-operatively, the visual analogue scale used to measure pain score at 6, 12 and 24 hours by an independent observer, blinded to randomization. After 24 hours mean of VAS calculated and noted.
Results: Mean age of patient in Group-A was 39.40±8.42 years and in Group-B 38.00±8.67 years. There were 65 male (73.86%) and 23 female (26.13%) patients. Mean stone size was 3.00±0.68 cm and 3.006±0.63 cm in Group-A and B respectively. Median pain at 6, 12 and 24 hours was low in Group-A in comparison to Group-B with *p*-value <0.001. Similarly, overall pain score in 24 hours was also low in Group-A in comparison to Group-B with median (IQR) score being 4(4.33-3.67) vs 6.33(7.24-4), *p*<0.001. Demand of first post-operative analgesia was significantly prolonged in Group-A (256.68±23.70 minutes) than Group-B (168.72±30.86 minutes, *p*-value<0.001).
Conclusion: The peritubal Bupivacaine infiltration is highly effective in reducing postoperative pain for patients undergoing PCNL as compared to placebo.

Keywords: Bupivacaine, Local anesthesia, Postoperative pain, Percutaneous nephrolithotomy, Visual analogue scale.

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INTRODUCTION

Percutaneous nephrolithotomy (PCNL) is a minimally invasive surgical procedure and treatment of choice for complex and large kidney stones because of higher stone clearance with less complications.[1,2] It is being frequently performed under general anesthesia, although in selected cases spinal anesthesia can be availed. During surgery after removal of kidney stones, nephrostomy tube is placed for drainage of urine and to achieve adequate hemostasis by tamponade.[3,4] Postoperative pain is the major challenge, which is because of dilation of parenchymal tract and renal capsule during surgical procedure.[5] It results in increased morbidity with prolonged hospital stay and additional analgesia requirements. Different analgesics have limitations due to adverse effects.[6]

There is no standard approach for postoperative pain management, however various treatment modalities suggested includes thoracic paravertebral block, patient controlled analgesia through epidural catheter, local anesthetic infiltration and intravenous narcotics and non-narcotics analgesics.[7] Small sized nephrostomy tube also decreases postoperative pain but it does not provide significant relief to the patient and hinders postoperative recovery.[8,9]

The post-operative pain control efficacy of peritubal anesthetic agent infiltration is still controversial,[8], although few local and international studies have revealed reduction in postoperative analgesia with Bupivacaine infiltration into skin, subcutaneous tissue, muscle and renal capsule around nephrostomy tube but they have few limitations as patient having stone >3cm and ASA >2 were excluded from study.[10] In addition, there is no consensus regarding infiltration site of local anesthetic agents. The objective of this study is to evaluate the peritubal infiltration efficacy of Bupivacaine on post-operative pain control in patients undergoing percutaneous nephrolithotomy.

METHODOLOGY

The quasi-experimental study was conducted from August 2021 to August 2022 at Armed Forces Institute of Urology Rawalpindi Pakistan, after

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approval from the Institutional Ethical Review Board (IRB/2021/002).

Inclusion Criteria: Patients of either gender diagnosed with renal stones by ultrasound or CT scan Kidney-Ureter-Bladder (KUB), within age group of 20-60 years and undergoing PCNL surgery with nephrostomy tube placement, were included.

Exclusion Criteria: Patients who developed complications of PCNL including massive hemorrhage, pneumothorax, hydrothorax and those who were converted to open surgery or multiple tracts utilized for stone clearance were excluded from the study.

Sample size was calculated by WHO calculator by taking mean±standard deviation of pain at 24 hours in Bupivacaine (4.1±1.1 vs 5.1±1.7, with 90% power of the test and level of significance 5%.[11] The total sample size was 88 (44 patient in each group). Patients were recruited using non-probability consecutive sampling technique and randomized into two groups using lottery method (Figure-1).

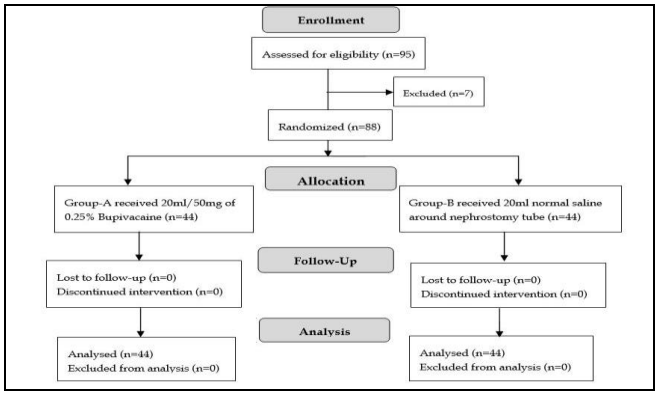

Figure-1: Patient Flow Diagram (n=88)

Group-A patients were given 20ml/50mg of 0.25% Bupivacaine and 20ml of normal saline was infiltrated in Group-B patients. Patients of both groups received general anesthesia and operated by single surgical team with standard surgical technique. After induction of anesthesia ureteric catheter was passed in lithotomy position with cystoscope/ureteroscope and ureteric was fixed with Foley's catheter. Patient position was changed to prone position. After giving 1-2cm loin incision, percutaneous nephrostomy needle was passed into pelvis of kidney with fluoroscopy guidance, guidewire was passed and working sheath was introduced after dilatation with metallic dilator. The nephroscope was then passed through working sheath and stone removed after fragmentation. Twelve Fr Nephrostomy tube was placed through puncture site in all patients and secured. After fixation of nephrostomy tube, 22-gauge spinal needle was used for infiltration of Bupivacaine in Group-A and normal saline in Group-B from renal capsule to skin at 6 and 12 O clock position around nephrostomy tube (10ml in each tract). Visual analogue scale (VAS 0 meaning no pain at all and VAS 10 meaning unbearable pain) was used post-operatively to measure the pain by Registrar Urology at 6, 12 and 24 hours, who was blinded for randomization. Mean VAS calculated after 24 hours and noted in proforma. Injection Ketorolac 30mg was given as additional analgesic requirements and time for first postoperative analgesia demand was also noted. Demographics, including hospital registration number, gender and age were recorded in the proforma along with data of pain score using visual analogue scale.

Data analyzed using Statistical Package for the social sciences (SPSS) version 28. Quantitative variables, including pain score and age were calculated by using descriptive statistics in terms of median and inter-quartile range (IQR). Qualitative variables including gender were analyzed in terms of frequencies and percentages. Mann-Whitney U test applied to compare mean VAS at 24 hours post-operatively in both groups and p value ≤0.05 taken statistically significant.

RESULTS

Eighty-eight patients undergoing standard PCNL were included in study. Patients in Group-A (44 patients) were given 20ml of 0.25% Bupivacaine and Group-B patients (44 patients) were given 20ml of normal saline as local peritubal infiltration. The average age of patients was 39.40± 8.42 years in Group-A and 38.00±8.67 years in Group-B (Figure-2). Average stone size in Group-A 3.00±0.68 cm and in Group-B was 3.006±0.63 cm. Average age (p=0.26) and stone size (p=0.48) were not significant in between groups. There were 65 male (73.86%) and 23 female (26.13%) patients (12 female and 32 male in Group-A and 11 female in Group-B and 33 male). Pain score at 6, 12 and 24 hours was significantly lower in test Group-A in comparison to control Group-B with p value <0.001. Similarly, pain score in 24 hours was also low in Group-A in comparison to Group-B with median-IQR 4(4.33-3.67) vs 6.33(7.24-4), p<0.001 as shown in Table-I. Moreover, first postoperative analgesia demand was significantly

longer in Group-A (256.68±23.70 minutes) than Group-B (168.72±30.86 minutes, *p* value<0.001).

Analysis for gender was also performed that revealed 24-hour pain score was lower in Group-A than Group-B, as median–IQR of pain score in males was 4(4.33-3.67) vs 5.50(7.08-4), *p*<0.001 and in females 4. 16(4.33-3.67) vs 6.67(7.33-4.24), *p* value <0.001 as shown in Table-II.

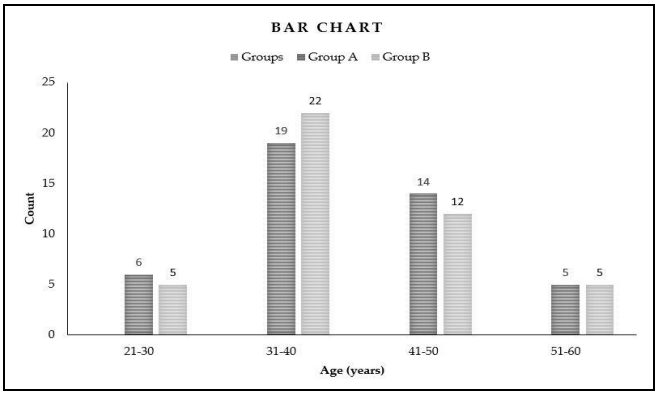

Figure-2: Age Distribution of Patients (n=88)

Table-I: Comparison of Median (IQR) Pain Score Between Groups (n=88)

VAS	Group-A Median (IQR)	Group-B Median (IQR)	*p*-value
VAS at 6 hours	2(3-2)	5.50(7-3)	<0.001
VAS at 12 hours	5(5-4)	7(8-5)	<0.001
VAS at 24 hours	5(5.75-5)	6(7-5)	<0.001
Mean VAS in 24 hours	4(4.33-3.67)	6.33(7.24-4)	<0.001

adequately drain kidney and provide hemostasis by tamponade, it can also provide access for future additional endoscopic intervention. Although tubeless PCNL has become routine and it results in significant pain reduction postoperatively in selected group but nephrostomy cannot be avoided in cases of perforation, excess bleeding and patients having complex stones.[13,14] In different surgical procedures local infiltration of analgesics have produced effective analgesia postoperatively. In this study, Bupivacaine or normal saline was infiltrated around nephrostomy tube from renal capsule to skin at 6 and 12o' clock position using fluoroscope with the help of 22-gauge spinal needle after PCNL. Same technique of peritubal infiltration was used by Jonnavithula *et al*.[8] Similar study was carried out by Kirac *et al*.[11] in which Group-1 patients undergoing PCNL received 20 ml of 0.25% Bupivacaine around nephrostomy at 3, 6, 9 and 12 o'clock position (5ml per tract) from renal capsule up to skin under fluoroscope. In our study, average age was 38.70±8.52 years with 73.86% male and 26.13% were females, similar distribution of age and gender was seen in other studies.[1,10,15]

In this study, Group-A patients were given peritubal infiltration of 20ml of 0.25% Bupivacaine and Group-B patients were given normal saline. Pain score at 6, 12 and 24 hours was significantly higher in Group-B than Group-A, similar significance of 24 hour mean pain score was observed among the groups. Moreover time for first analgesia demand was significantly longer in Group-A as compared to Group-B. Similarly Karami Jonnavithula and colleagues[16]

Table-II: Comparison of Pain Score (Median-IQR) Between Groups for Male and Female Cases (n=88)

VAS	Group-A (males) n=32	Group-B (males) n=33	*p*-value	Group-A (Females) n=12	Group-B (Females) n=11	*p*-value
VAS at 6 hours	2(3-2)	4(7-3)	<0.001	2.50(3-2)	6.50(7.25-2.75)	<0.001
VAS at 12 hours	4.5(5-4)	6.50(8-4)	<0.001	5(5-4)	7(8-5)	<0.001
VAS at 24 hours	5(5-5)	6(7-5)	<0.001	5(6-5)	6(8-5.75)	<0.001
VAS in 24 hours	4(4.33-3.67)	5.50(7.08-4)	<0.001	4.16(4.33-3.67)	6.67(7.33-4.24)	<0.001

DISCUSSION

Management of renal stones in last decades evolved from open surgical procedure to less traumatic procedure like PCNL and non-invasive modalities like ESWL (Extracorporeal Shock Wave Lithotripsy). PCNL revolutionized the management of renal calculi because of less complications and high stone clearance.[12] Nephrostomy tube placement after PCNL surgery is standard procedure and it is placed to

observed their technique associated significantly reduces pain score and analgesia requirements in randomized controlled study, (4.6±5.4 hours, 105± 85mg vs 14.7±9.6 hours, 31±44mg, respectively). Malik *et al*. noted similar results of peritubal Bupivacaine infiltration in 60 patients, in which pain was lower in Bupivacaine Group-As compared to control Group-And also lesser analgesia requirement in Bupivacaine arm.[17] A meta-analysis and systemic review and conducted by Wang *et al*.[4] and revealed that infiltration

of local anesthetic agent around nephrostomy tract offers some potential advantages over control group in terms of requirements of analgesia, the first analgesia demand time and VAS score at 24 hour after the surgery, as noted in our study.

Andreoni et al. noted in controlled trial that single dose of spinal analgesia before surgery with morphine along with nephrostomy tract infiltration with Bupivacaine resulted in significant decrease in requirement of parenteral pain medication.[13] The study conducted by Hemendra *et al*. subcutaneous injection of 1.5mg/kg of 0.25% Bupivacaine vs normal saline also showed reduced requirement of rescue analgesia in Bupivacaine group with no difference in pain score among groups.[18] Contrary to these findings, Hantrakun *et al*. did not find any benefit of local anesthetic over saline infiltration when by using 20ml of 0.25% levoBupivacaine in entire nephrostomy tract before PCNL puncture.[19] Similarly, Lojanapiwat *et al*. found that in PCNL surgery peritubal use of 0.25% Bupivacaine is not effective for postoperative pain control.[20]

CONCLUSION

The peritubal Bupivacaine infiltration is highly effective in pain control postoperatively in PCNL surgery, resulting in lower postoperative pain score and longer time for first analgesia requirement.

Conflict of Interest: None.

Authors Contribution

Following authors have made substantial contributions to the manuscript as under:

AS & MRZ: Data acquisition, data analysis, critical review, approval of the final version to be published.

AA & MA: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

ZIM & MSA: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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