Comparison of Post-Operative Pain in Patients Undergoing Percutaneous Nephrolithotomy receiving Oral Post-Operative Analgesia Augmented by Bupivacaine versus Post-Operative Intravenous Analgesia Alone

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ABSTRACT

Objective: To compare peri-tract infiltration of Bupivacaine augmented by oral post-operative analgesia versus post-operative intravenous analgesia alone in patients undergoing percutaneous nephrolithotomy in terms of mean post-operative pain score.

Study Design: Quasi-experimental study.

Place and Duration of Study: Armed Forces Institute of Urology Rawalpindi, Pakistan from Apr to Oct 2019.

Methodology: Total number of 68 patients planned for percutaneous nephrolithotomy were randomly divided into two equal groups with 34 patients in each group by lottery method. Group-A patients received peri-tract local anesthesia infiltration with 0.25% Bupivacaine while group-B patients received post-operative intra-venous analgesia. Both groups were compared in terms of postoperative pain scores.

Results: The mean pain score as per visual analogue scale at 1 hour was 4.53 ± 0.62 in Group-A vs 5.21 ± 0.85 in group-B with p=0.004. The mean score of pain at 3 hours was 3.85 ± 0.50 in group-A vs 6.79 ± 0.73 in group-B with p<0.001. The mean score at 6 hours was 3.38 ± 0.78 in group-A vs 6.03 ± 0.90 in group-B with p<0.001. The mean pain score at 12 hours was 1.21 ± 0.77 in group-A vs 5.26 ± 0.99 in group-B with p<0.001.

Conclusion: Peri-tract infiltration of Bupivacaine was associated with significantly less postoperative pain as compared to standard intravenous analgesia in patients undergoing percutaneous nephrolithotomy.

Keywords: Bupivacaine, Local Anesthesia, Percutaneous Nephrolithotomy, Postoperative Pain.

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INTRODUCTION

Kidney stones are among the most commonlypresenting pathology in urology clinics with a lifetime risk of 12% in males and 6% in females, and an annual financial burden of nearly \$2 billion in the US alone.^{1,2} Pakistan lies in the Afro-Asian stone belt with a high incidence of urolithiasis in its population and recurrence rates of untreated renal stones at 10%, 35% and 50% at 1, 5 and 10 years respectively.^{3,4}

In the present age of minimally or non-invasive interventions, modalities such as extracorporeal shock wave lithotripsy (ESWL), percutaneous nephrolithotomy (PCNL) and retrograde intrarenal surgery (RIRS) are very popular due to reduced post-operative pain, decreased hospital stays and increased patient satisfaction, with PCNL the standard treatment of stones larger than 2 cm.⁴⁻⁶

As with all surgical interventions, post-operative pain is dreaded by patients undergoing surgical procedures. Traditionally, usage of opioids has been used to control this, but is associated with a multitude of side effects ranging from simple nausea, vomiting and constipation to more sinister effects like drowsiness, ileus, urinary retention and respiratory depression.⁷ To avoid these unpleasant side effects, different options like multi modal analgesia regimens, mini PCNL, tube-less PCNL and peri-tract local analgesia infiltration have been explored with varying degree of success.⁷

Different studies have reported that the difference between the mean post-operative pain assessed by Visual Analogue Score (VAS) in Bupivacaine versus control group at hours 1 and 4 of the procedure was statistically significant ($p \le 0.001$).^{7,8}

There is lack of data on the efficacy of peri-tract infiltration of Bupivacaine with no previous study in the Pakistani population comparing it with standard routine postoperative intravenous analgesia that is given in most centers in the country. Therefore, this study was carried out to determine the best evidencebased practice for our population.

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METHODOLOGY

This quasi-experimental study was conducted at Department of Urology, Armed Forces Institute of Urology Rawalpindi, Pakistan, from April to October 2019, after seeking approval from the hospital Ethical Review Committee (uro-Adm/Trg/IRB/2019/22).

Inclusion Criteria: Patients of either gender aged between 12 and 65 years undergoing percutaneous nephrolithotomy (PCNL), with normal renal functions, no history of chronic aches and pains, with ASA classes I, II & III were included.

Exclusion Criteria: Patients with history of local anesthesia allergy, redo PCNL, multiple punctures during PCNL, excessive intra-operative bleeding, diabetes mellitus, coagulopathy, mental disorders, ASA classes IV or V and active urinary tract infection were excluded.

A sample size of 68 patients was calculated using WHO sample size calculator. Written informed consent was obtained from all the patients included in the study, who were recruited using non-probability consecutive sampling.

Patients were divided into two equal groups, group-A and group-B (Figure) containing 34 patients each by lottery method. Demographic data of all patients was documented. Group-A patients were administered per-operative peri tract local anesthesia infiltration with 0.25% Bupivacaine augmented by post-operative oral analgesia with a combination of Paracetamol 650 mg and Orphenadrine 50mg 6 hourly while group-B patients were only given post-operative Paracetamol intra-venous analgesia by 1gm intravenous 8 hourly augmented with a combination of Tramadol 50mg and Dimenhydrinate 50mg as and when required.

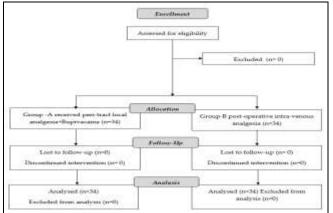


Figure: Patient Flow Diagram (n=64)

Patient demographics were recorded before the surgery. Postoperatively, all the patients specified their pain at 1, 3, 6 and 12 hours on a 10 cm linear scale of pain. Data in both the groups were recorded on a pre-validated questionnaire. The exclusion criteria was precisely followed to control confounders and bias in the study.

Data was entered in and analyzed using Statistical Package for Social Sciences (SPSS) version 23. Mean and standard deviation were calculated for the quantitative variables like age, stone size and VAS pain score at 1, 3, 6 and 12 hours. Qualitative variables like gender and ASA class were expressed as frequency and percentages. Male to female ratio in the sample was calculated. Post-operative pain score at 1, 3, 6 and 12 hours amongst the two groups was Independent sample compared using t-test. Chi-square test was applied, taking *p*-value ≤ 0.05 as significant.

RESULTS

The mean age of patients overall was 39.06 ± 13.17 years. In group-A (peri tract local anesthesia group), it was 41.06 ± 12.56 years and in group-B (intravenous analgesia group) 37.06 ± 13.64 years. The age distribution of the patients in both groups was statistically non-significant (*p*=0.213). Majority of the patients (51.47%) were between 30 to 47 years of age.

Our study comprised of 41(60.29%) male patients. The gender distribution of patients in group-A was 22(64.71%) male and 12(35.29%) female, while group-B had 19(55.88%) male and 15(44.11%) female. The gender distribution between the two groups was statistically non-significant (p=0.457). Most of the patients included in the study (30 out of 68 patients, 44.12%) belonged to ASA class II. The distribution of patients according to ASA class were ASA I 12(35.29%), ASA II 15(44.12%) and ASA III 7(20.59%) in group-A while group-B had 14(41.18%) ASA I, 15(44.12%) ASA II and 5(14.71%) ASA III.

The mean stone size overall was 2.40 ± 0.59 cm. The mean stone size of patients in group-A was 2.29 ± 0.52 cm and in group-B it was 2.52 ± 0.64 cm.

The mean post-operative pain score as per VAS (Table-I) at 1 hour after PCNL was 4.53 ± 0.62 in group-A, while it was 5.21 ± 0.85 in group-B. The difference between the two groups was statistically significant (*p*=0.004). The mean post-operative pain score as per VAS at 3 hours was 3.85 ± 0.50 in group-A while it was

6.79±0.73 in group-B. The difference between the two groups was statistically significant (p<0.001).

The mean post-operative pain score as per VAS at 6 hours after PCNL was 3.38 ± 0.78 in group-A while it was 6.03 ± 0.90 in group-B. The difference between the two groups was again statistically significant (p<0.001). The mean post-operative pain score as per VAS at 12 hours was 1.21 ± 0.77 in group-A while it was 5.26 ± 0.99 in group-B. The difference between the two groups was statistically significant (p<0.001).

Table-II shows stratification of pain score as per VAS at 1 hour, 3 hours, 6 hours and 12 hours with respect to age groups, whereas Table-III stratification of pain score as per VAS at 1 hour, 3 hours, 6 hours and 12 hours with respect to stone size.

Table-I: Distribution of Patients according to Mean Postoperative Pain Scoree as per Visual Analogue Scale (n=68).

Duration after Percutaneous	Group-A (n=34)	Group-B (n=34)	<i>p</i> -value
Nephrolithotomy	Mean±SD	Mean±SD	<i>p</i> -value
1 hour	4.53±0.62	5.21±0.85	0.004
3 hours	3.85±0.50	6.79±0.73	< 0.001
6 hours	3.38±0.78	6.03±0.90	< 0.001
12 hours	1.21±0.77	5.26±0.99	< 0.001

Table-II: Stratification of Pain Score as per Visual Analogue Scale at 1 Hour, 3 Hours, 6 Hours and 12 hours with Respect to Age Groups. (n=68)

	Group-A (n=34)	Group-B (n=34)		
Age	Pain score (1	Pain score (1		
Groups	hour)	hour)	<i>p</i> -value	
(years)	Mean±SD	Mean±SD		
12-29	4.40±0.55	5.30±1.01	0.290	
30-47	4.47±0.51	5.19±0.66	0.006	
48-65	4.70±0.82	5.21±0.99	0.374	
	Pain score	Pain score		
	(3hours)	(3hours)		
12-29	3.60±0.55	6.80±0.42	0.002	
30-47	3.84±0.50	6.75±0.86	< 0.001	
48-65	4.00±0.47	6.88±0.84	0.003	
	Pain score	Pain score		
	(6hours)	(6hours)		
12-29	3.20±0.84	6.00±1.25	0.035	
30-47	3.53±0.70	6.06±0.77	< 0.001	
48-65	3.20±0.92	6.00±0.76	0.003	
	Pain score	Pain score		
	(12hours)	(12hours)		
12-29	1.00±0.71	5.20±1.55	0020	
30-47	1.37±0.68	5.31±0.60	< 0.001	
48-65	1.00±0.94	5.25±0.89	0.012	

DISCUSSION

Percutaneous nephrolithotomy (PCNL) is currently the treatment modality of choice for renal

stones.⁹ Post-operative pain relief is a significant factor in the recovery of the patient and is a primary concern of the operating urologist. A number of different techniques have been attempted with variable success. Peri-tract infiltration of local anesthetic has been coupled with oral pain killers to relieve postoperative pain in patients undergoing PCNL.¹⁰

Table-III Stratification of Pain Score as per Visual Analogue
Scale at 1 Hour, 3 Hours, 6 Hours and 12 Hours with Respect
to Stone Size (n=68)

	Group-A (n=34)	Group-B (n=34)	
Stone	Pain score (1	Pain score (1	<i>p</i> -value
size	hour)	hour)	1
5120	Mean±SD	Mean±SD	
>2.5 cm	4.46±0.52	5.33±0.90	0.035
<2.5 cm	4.57±0.68	5.11±0.81	0.082
	Pain score (3	Pain score (3	
	hours)	hours)	
>2.5 cm	3.85±0.38	6.60±0.74	< 0.001
<2.5 cm	3.86±0.57	6.95±0.71	< 0.001
	Pain score at 6	Pain score at 6	
	hours	hours	
>2.5 cm	3.54±0.66	6.00±0.76	< 0.001
<2.5 cm	3.29±0.85	6.05±1.03	< 0.001
	Pain score at 12	Pain score at 12	
	hours	hours	
>2.5 cm	1.23±0.73	5.27±0.59	< 0.001
<2.5 cm	1.19±0.81	5.26±1.24	< 0.001

The mean age of patients included in our study was 39.06±13.17 years. Khan et al. reported a mean age of 37.23±11.31 years, while Moharari et al. reported a mean age of 35.5±8 years in patients undergoing PCNL.^{11,12} Nawaz *et al.* reported a mean age of 52.11±16.33 years in patients undergoing PCNL.¹³

Most patients included in our study were males (60.29%). Lojanapiwat *et al.* reported a frequency of males of 67.62%.⁷ Similarly Khan *et al.* and Nawaz *et al.* reported the frequency of male patients to be 73.4% and 74.4% respectively.^{11,13} On the contrary Falahatkar *et al.* reported a comparably lower frequency of male patients (51.72%) in their study.¹⁴

Lojanapiwat *et al.* reported that most patients belonged to ASA class II, which was in line with our findings, but the frequency was slightly higher (58.1%) than our result (44.12%).⁷ The mean stone size of patients included in this study was 2.40 \pm 0.59 cm. Falahatkar *et al.* reported a mean stone size of 2.66 \pm 1.44 cm which was comparable to our study.¹⁴

Our study found a statistically significant less mean postoperative pain score at 1, 3, 6 and 12 hours

in the peri-tract Bupivacaine administration group versus the routine intravenous analgesia group-after PCNL (p<0.001). These results are comparable to other studies that reported a significantly less post-operative pain and analgesic requirement in the local infiltration group versus without infiltration group at 6, 12 and 24 hours after PCNL (p<0.05).^{11,15}

Lojanapiwat *et al.* found significantly less pain in Bupivacaine infiltration group after 1 hour (p=0.018), however the study reported no significant difference between the two groups at 4, 12 and 24 hours after PCNL (p>0.05) which was contrary to our results.⁷ Dundar *et al.* also reported that there was significantly less pain at 2 hours after PCNL in the local infiltration group (p=0.004), however there was no difference between the groups at 4,6 and 8 hours respectively (p>0.05).¹⁶

Ceyhan *et al.* concluded that preemptive use of local anesthesia infiltration reduces requirement of analgesics post operatively, better patient comfort and overall satisfaction in pediatric population, which is in line with our study, as well as another international research.^{17,18}

CONCLUSION

Our study concluded that peri-tract local infiltration of local anesthetic (Bupivacaine) augmented with oral analgesics was led to a significant reduction in postoperative pain as compared to intravenous analgesia alone in patients undergoing percutaneous nephrolithotomy (PCNL).

Conflict of Interest: None.

Funding Source: None.

Authors' Contribution

The following authors have made substantial contributions to the manuscript as under:

MUJ & AA: Conception, study design, drafting the manuscript, approval of the final version to be published.

MU & AH: Data acquisition, data analysis, data interpretation, critical review, approval of the final version to be published.

SHS & NA: 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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