



## The effect of local tramadol infiltration in post pyelolithotomy pain.

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**ABSTRACT... Objective:** To compare the analgesic efficacy of tramadol wound infiltration with normal saline wound infiltration in patients undergoing Pyelolithotomy. **Study Design:** Randomized Controlled Trial. **Setting:** Department of Anesthesia, ICU and Pain Medicine, DG Khan Teaching Hospital, Dera Ghazi Khan. **Period:** July 2019 to September 2019. **Material & Methods:** Total 60 patients were included in this study. There were 30 patients in whom normal saline was used for wound infiltration and in other 30 patients tramadol was used for wound infiltration. Analgesic outcomes were noted in terms of Numerical Rating Scale (NRS) of pain in the recovery room, at 06 hours and 24 hours after surgery, mean time of first rescue analgesia and total dose of tramadol within 24 hours after surgery. **Results:** Mean pain score in the recovery room was  $5.20 \pm 2.10$  in saline group versus  $2.60 \pm 1.13$  in tramadol group ( $p < 0.001$ ). Mean post-operative pain score after 06 hours of surgery was  $5.43 \pm 1.45$  in saline group versus  $2.30 \pm 1.05$  in tramadol group ( $p < 0.001$ ). Pain score was  $3.63 \pm 1.40$  in saline group versus  $1.67 \pm 0.80$  in tramadol group after 24 hours of surgery ( $p < 0.001$ ). Mean time of first rescue analgesia was  $6.16 \pm 2.47$  hours in tramadol group versus  $0.97 \pm 1.46$  hours in saline group ( $p < 0.001$ ). Total dose of tramadol used for analgesia within 24 hours after surgery was  $56.67 \pm 70.38$  mg in tramadol group versus  $253.33 \pm 73.02$  mg in saline group ( $p < 0.001$ ). **Conclusion:** Wound infiltration with tramadol provides better analgesia as compared to normal saline in patients undergoing Pyelolithotomy.

**Key words:** Normal Saline, Pyelolithotomy, Tramadol, Wound Infiltration.

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### INTRODUCTION

Pain is defined as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage”.<sup>1</sup> Most common adverse effects of pain are hypertension, tachycardia, increased myocardial irritability, increased minute ventilation, decreased tidal volume, increased CO<sub>2</sub> production, enhanced sympathetic tone and excessive release of catabolic hormones.<sup>2</sup>

In our region, renal stones are quite common. Pyelolithotomy is a procedure in which stones are removed from renal pelvis surgically.<sup>3</sup> Most commonly it is done under general anaesthesia and after recovery, pain is the most common complaint. Various modalities are in use for control of postoperative pain like multimodal analgesia,

skin infiltration by local anaesthetic solution, local nerve blocks and continuous infiltration of surgical site. As a component of multimodal analgesia, infiltration of local anesthetic at the surgical site is widely practiced. Bupivacaine 0.25% is the commonest local anaesthetic which is used for this purpose. But due to its cardio toxic effects, various other drugs have been tried for local wound infiltration as sole drug.<sup>4,5</sup>

Tramadol, a weak opioid is administered for moderate to severe pain. Several studies have reported its local anesthetic effect.<sup>6,7</sup> For pain relief after arthroscopy of knee joint, tramadol has been administered as intra articular injection.<sup>8</sup>

Khazai compared pain relief after wound infiltration with tramadol and normal saline; they found that

tramadol is superior to normal saline in reducing post- appendectomy pain.<sup>9</sup>

During the past three decades, the prevalence of renal stone has doubled in United States, most of the European countries and South Asian countries like Pakistan.<sup>10</sup> Rizvi reported its prevalence as high as 16% in Pakistan.<sup>11</sup>

In order to improve pain relief, reducing untoward effects of opioids by minimal requirement and relatively rapid recovery, wound infiltration is used as a part of multimodal analgesia. Wound infiltration with local anesthetic is practiced in ambulatory surgery.<sup>12</sup> Yayuz Demiran observed wound infiltration with tramadol is better than bupivacaine and saline for pain relief in children after repair of hernia.<sup>13</sup>

This study is aimed to evaluate the effect of tramadol infiltration for the postoperative analgesia after pyelolithotomy.

Our objectives were to compare the effects of infiltration with tramadol and normal saline in pyelolithotomy;

1. Pain score in the recovery room, 6 hours and 24 hours after pyelolithotomy.
2. Time requiring rescue analgesia after operation
3. Total dose of analgesic required during 24 hours after operation.

## MATERIAL & METHODS

The study was completed in department of anaesthesia, ICU and Pain medicine, Teaching Hospital, Dera Ghazi Khan, from July 2019 to September 2019. On the basis of previous related study, thirty patients were allocated to each group.<sup>9</sup>

This sample size was calculated by taking mean Numeric Rating Scale score of  $3.36 \pm 1.22$  after 06 hours of surgery in tramadol group versus  $5.36 \pm 1.38$  hours in normal saline group<sup>9</sup> power of the test 90% and level of significance 95%. Sample size for this study calculated was 20 patients in each group. We allocated 30 patients in each

group to minimize the bias in study outcomes

After approval by Institutional Review Board (116/PHY/DGKMC), a total number of 60 patients planned for elective Pyelolithotomy were selected in the study. All pyelolithotomy candidates were informed about the project. The patients were assigned into research project who agreed and eligible for inclusion criteria. Inclusion criteria included ASA physical status 1 and 2, Patients diagnosed of having renal stones (diagnosed by surgeon on X ray KUB, Ultrasound and clinical examination in patients with pain in flanks) and planned for elective Pyelolithotomy, having age 15 to 65 years. Patients were excluded from the research if any of the followings was present; Hypersensitivity to drugs increasing serotonin, History of fits/seizures, taking antidepressant inhibiting reuptake of serotonin. (SSRI/SNRI).

Patients were randomly divided into 2 equal groups by simple random sampling technique by envelope method. General anesthesia was administered to all patients with 0.2 mg/kg Nalbuphine, 0.05 mg/kg Midazolam, 2-2.5 mg/kg Propofol, 0.5 mg/kg Attracurium & Endotracheal intubation with IPPV (Intermittent Positive Pressure Ventilation) was done. Neuromuscular block was Reversed with  $10\mu\text{g}/\text{kg}$  Glycopyrrolate and  $40\mu\text{g}/\text{kg}$  Neostigmine. Standard monitoring like SpO<sub>2</sub>, NIBP, Pulse rate and ECG was applied.

Before skin closure, surgeon was provided a syringe containing 10 ml normal saline or 100 mg tramadol, diluted with saline up to 10 ml, in sterile condition. The content in both the syringes was exactly similar in color and transparency. The surgeon did not know the content of the syringes, after washing the wound with normal saline, infiltrated the content across the length and sides of the wound. Then, the skin closure was done with 2/0 nylon sutures.

Analgesic outcomes were noted in terms of, Numeric Rating Scale pain score in Recovery room, 06 hours and 24 hours after surgery, mean time of first rescue analgesia and total dose of tramadol used for analgesia within 24 hours after surgery. All the study related information was

noted on the pre-designed Performa.

Data analysis was done using SPSS v.23. Mean and standard deviation used to present age, post-op Numeric Rating Scale Pain score, time of first rescue analgesia and total dose of tramadol required within 24 hours after surgery. Gender presented as frequency and percentage. Independent sample t-test applied to compare, post-op Numeric Rating Scale Pain score, time of first rescue analgesia and total dose of tramadol required within 24 hours after surgery between the groups.

## RESULTS

The study was conducted in 60 patients. In 30 patients normal saline was used for wound infiltration and in other 30 patients tramadol was used for wound infiltration. Regarding age of the patients, range was 15 to 65 years while mean was  $31.41 \pm 12.41$  years. There were 33 (55.0%) female patients and 27 (45.0%) male patients in this study. Table-I

On comparison of average intensity of pain in the recovery room between the groups, mean pain score was  $5.20 \pm 2.10$  in normal saline group versus  $2.60 \pm 1.13$  in tramadol group ( $p$ -value  $< 0.001$ ). Mean post-operative pain score six hours after surgery was significantly higher in normal saline group ( $5.43 \pm 1.45$ ) than tramadol group ( $2.30 \pm 1.05$ ). {P-value of  $< 0.001$ }. Mean post-operative pain score after 24 hours of operation was also significantly higher in normal saline group ( $3.63 \pm 1.40$ ) versus tramadol group ( $1.67 \pm 0.80$ ) { $p$ -value  $< 0.001$ }. Table-II

The patient requested for postoperative analgesic significantly earlier in normal saline group ( $0.97 \pm 1.46$  hours) than Tramadol group. ( $6.16 \pm 2.47$  hours) ( $P$ -value  $< 0.001$ . Total dose of tramadol used as rescue analgesia within 24

hours was also significantly higher in normal saline group ( $253.33 \pm 73.02$  mg) than in tramadol wound infiltration group ( $56.67 \pm 70.38$  mg). P-value of  $< 0.001$ } Table-III.

**Age & Gender of Patients**

Mean age (Years)	$31.41 \pm 12.41$ (15 -65)
Gender	Male=27(45%), females=33(55%)

**Table-I. Descriptive statistics of age (Years) & gender.**

	Tramadol Group	Saline Group	P-Value
In the Recovery room	$2.60 \pm 1.13$	$5.20 \pm 2.10$	$< 0.001$
After 06 Hours	$2.30 \pm 1.05$	$5.43 \pm 1.45$	$< 0.001$
After 24 Hours	$1.67 \pm 0.80$	$3.63 \pm 1.40$	$< 0.001$

**Table-II. Descriptive statistics of mean post-operative pain score.**

## DISCUSSION

The results of this study reflect significantly better pain relief in tramadol infiltration group against saline infiltration group in the recovery room, 6 hours and 24 hours after operation. The patients infiltrated with tramadol required rescue analgesia later and in lesser doses than control.

The results of our study are similar to study conducted by Khazai et al. They found mean pain score  $3.08 \pm 1.44$  in Tramadol group versus  $5.36 \pm 2.02$  in normal saline group in the recovery room,  $3.36 \pm 1.22$  after 06 hours of surgery in tramadol group versus  $5.36 \pm 1.38$  in normal saline group, while pain score of  $2.08 \pm 0.76$  in tramadol versus  $3.08 \pm 1.15$  in normal saline group after 24 hours of appendectomy.<sup>9</sup>

Kaki found that infiltration with tramadol before closing wounds after hernia surgery provided better and prolonged analgesia as compared to bupivacaine.<sup>14</sup>

	Tramadol Group	Saline Group	P-Value
Time of First Rescue Analgesia.(hours)	$6.16 \pm 2.47$	$0.97 \pm 1.46$	$< 0.001$
Total Dose of Tramadol Required for Analgesia within 24 hours after Operation(mg)	$56.67 \pm 70.38$	$253.33 \pm 73.02$	$< 0.001$

**Table-III. Descriptive statistics of mean time of first rescue analgesia and total dose of tramadol required for analgesia within 24 hours after operation.**

Amr Samir Wahdan et al compared inguinal canal and intra incisional infiltration of tramadol, 0.25% bupivacaine and normal saline; Visual analogue scale scores were 2, 2, and 5 in tramadol, bupivacaine and saline groups respectively at 2 hours. The pain scores were 2, 4 and 4 in tramadol, bupivacaine and saline groups respectively at 6 hours. Time for first analgesic requirement was  $149 \pm 30$  in tramadol group,  $125 \pm 25$  min in bupivacaine group and  $30 \pm 10$  min in saline group, Total dose of Mepridine required for postoperative pain relief was  $26 \pm 7$  mg in tramadol group,  $60 \pm 17$  mg in bupivacaine group and  $99.5 \pm 19$  mg in saline group.<sup>15</sup> The results were consistent with our study.

Demiraran et al. observed prolonged pain relief and lesser doses of rescue analgesic after wound infiltration with tramadol as compared to levobupivacaine in patients who underwent cesarean section.<sup>16</sup> Murat Haliloglu et al compared 40 mg tramadol and 20 ml normal saline wound infiltration in patients undergoing C- Section under general anesthesia. They observed lower numeric rating scale in tramadol group than saline group, 15 minutes after operation. The requirement of rescue analgesic was significantly less in tramadol group as compared to normal saline group ( $P < 0.001$ ).<sup>17</sup>

Ugar et al observed significantly lower Visual Analogue Scale in tramadol infiltration group into peritonsillar area than placebo after awakening of child. ( $P = 0.015$ ). One child in tramadol group and nine children in placebo group required rescue analgesia during first postoperative hour ( $P = 0.036$ ).<sup>18</sup> Atef A et al evaluated post-tonsillectomy pain relief after sub mucosal infiltration of tramadol and saline. They observed better analgesia and lesser requirement of rescue analgesics in tramadol group than saline group.<sup>19</sup>

Akbay BK et al compared pain relief after tonsillectomy by application of swabs soaked with tramadol and normal saline. The Pain scores measured were significantly lower in the tramadol group than in saline group. The measured pain scores were  $0.34 \pm 0.21$  on day 1 and  $0.11 \pm 0.08$  on day 7 in the tramadol group while 0.53

$\pm 0.14$  on day 1 and  $0.42 \pm 0.15$  on day 7 in the saline group.<sup>20</sup> Georgia Georgia GG Georgia G et al concluded that peritonsillar infiltration of tramadol resulted in significant reduction in post tonsillectomy pain intensity up to 24 hours.<sup>21</sup>

Tugce Simsek et al compared the trans mucosal application in nasal packing infiltrated with tramadol, Lidocaine and saline. They suggested that patients in tramadol group were most satisfied and required least additional analgesics compared with Lidocaine and saline group.<sup>22</sup>

Limitation of study: We compared postoperative analgesic effects of infiltration of tramadol with normal saline. We did not consider infiltration of local anesthetic in comparison. Moreover, our sample size is limited. More studies in various centers are required to establish efficacy and potency of tramadol infiltration for postoperative analgesia.

## CONCLUSION

The pain relief was significantly better in tramadol infiltration group than saline infiltration group. The time of rescue analgesia required was prolonged in tramadol infiltration group. Patients in tramadol group required less rescue analgesia than in saline group.

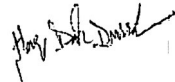
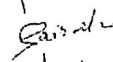


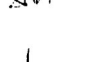
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1	Haq Dad Durrani	Conceptualization of conducting study, approval from ethical committee, designing the Performa, Communication with the journal.	
2	Sairah Sadaf	Modification Alteration of Designed Performa and Manuscript writing (Introduction)	
3	Syed Aushtar Abbas Naqvi	Acquisition, Interpretation, Performing, Analysis of data, Writing of results, Tables.	
4	Manzoor Hussain Bajwa	Literature search and manuscript writing (Introduction & discussion).	
5	Mirza Shakeel Ahmad	Manuscript writing (abstract) and manuscript editing with expert research opinion.	
6	Muhammad Khalid	Critical revision of article.	