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Efficacy of IV Paracetamol in Patients with Renal Colic in Emergency Department

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ABSTRACT

Background: Renal colic, characterized by excruciating flank pain radiating to the groin, arises from urinary tract obstruction, triggering prostaglandin production and increased intra-renal pressure. NSAIDs are the first-line analgesics but have limitations in vulnerable populations. Intravenous paracetamol has emerged as a safer alternative with rapid analgesic effects and fewer adverse outcomes, especially in resource-limited settings. **Objective:** The objective is to compare the analgesic efficacy of the intravenous paracetamol and intra muscular diclofenac sodium, in the early resolution of pain in acute renal colic. **Methods:** This randomized controlled trial was conducted from February 2024 to April 2024 at the Emergency Department of Mayo Hospital Lahore. Patients showing clinical signs and symptoms of acute renal colic were randomly assigned to two groups. Group I (n=35) received 1 gram of intravenous paracetamol, while Group II (n=35) was given 50 mg of intramuscular diclofenac sodium. The pain intensity was evaluated using the Verbal Rating Scale (VRS) 30 minutes after treatment. **Results:** In this study, there were 47 male patients and 23 female patients. The mean age was 38 ± 12 years old. After 30 minutes of administration, the pain relief in the paracetamol group (p value: <0.01) was similar to that of diclofenac group (p value: <0.01). However, the requirement of rescue analgesia was lower in the paracetamol group than diclofenac group. **Conclusion:** In acute renal colic patients, with the heralded side effects of non-steroidal anti-inflammatory drugs, IV paracetamol is an excellent alternative, with low risk profile and a higher analgesic efficacy.

INTRODUCTION

Pain is one of the most debilitating issues encountered in the Emergency Department, requiring prompt treatment. Renal colic, is usually sudden in onset, with a crescendo of excruciating pain originating in the flank, extending over the abdomen, and radiation into the groin (1). Between episodes of colic, a constant dull discomfort in the flank is frequent. Hyper-peristalsis of the smooth muscle within the calyces, pelvis, and ureter is the

primary cause of severe colicky flank pain. In contrast, a dull ache may result from tension on the renal capsule and acute obstruction. This pain is often accompanied by additional symptoms, including nausea, vomiting, and hematuria (2).

Urinary stones are a major cause of urinary tract obstruction, leading to distension. This distension sets off a chain reaction, increasing wall



tension and stimulating sub-mucosal nerve endings, ultimately resulting in an episode of renal colic. (3). The pressure in the renal pelvis triggers the local production of prostaglandins, leading to vasodilation, increased urine output, and elevated intra-renal pressure. The estimated lifetime risk of suffering an acute attack of renal colic ranges from 1% to 10% (4). Irrespective of the precipitating event, the first step is effective analgesia. NSAIDs (non-steroidal anti-inflammatory drugs) are recommended to be used as first-line followed by opioids if pain control is not achieved (5). The primary complications linked to NSAIDs include nephrotoxicity, cardiovascular issues, gastrointestinal effects, and impaired wound healing. As a result, they are no longer deemed safe for vulnerable populations, such as the elderly or those with multiple risk factors. On the other hand, opioids have the potential to cause apnea, dependence and addiction (6). In recent times, paracetamol (acetaminophen) has become popular due to its high safety profile, lower adverse effects, and satisfactory analgesic effects in patients with renal colic. (7).

The Emergency Department of our tertiary care hospital receives a population with multiple comorbidities for whom NSAIDs cannot be used as a first-choice medication due to any risk factor involved or contraindication. In such individuals, switching to other drugs is necessary before opioids are administered (8). Paracetamol when given through the intravenous route has remarkable efficacy in reducing pain and patients usually experience analgesic effects within 30 minutes of administration (7, 9). In our resource limited setup, we have observed good outcomes in patients of acute renal colic when treated with IV paracetamol. Not only the pain control was achieved earlier, but there was also no further need to give any other pain reliever. Due to the lack of any available evidence of our setup, we conducted this study in which the analgesic effects of IV paracetamol were compared with the intramuscular diclofenac sodium, the widely used NSAID in patients presenting to ED with renal colic.

MATERIALS & METHODS

This randomized controlled trial was conducted from February 2024 to April 2024 at the Emergency Department of Mayo Hospital Lahore.

Participants were selected through consecutive sampling, and informed consent was obtained from each participant. The study received approval from the Institutional Review Board (IRB).

The study included patients aged between 14 to 55 years, with the diagnosis of renal colic, having a ≥ 5 score on the verbal rating scale (VRS) of pain intensity. Acute renal colic was diagnosed based on the clinical judgment of the emergency physician (5) taking into account the signs and symptoms typical of the condition, including flank pain, dysuria, increased frequency of urination, hematuria, and tenderness in the costovertebral angle. Exclusion criteria was allergy or contraindications to either paracetamol or diclofenac, use of any analgesic within the past 06 hours of emergency presentation, ischemic heart disease, hemodynamically unstable, history of renal or hepatic failure, history of any renal, prostate or bladder malignancy, any history of chronic pain syndrome and pregnant women.

Statistical analysis was done using SPSS 20. A sample size of 70 (35 in each group) was calculated, taking significance level (α) as 0.05, power ($1-\beta$) as 80%, ratio of both groups as 1 and margin on risk difference scale as 0.3 (10). VRS (verbal rating scale) for pain intensity was used before and 30 minutes after the intervention and the response was recorded. Pain intensity ≤ 3 was taken as a cutoff for adequate pain relief.

Patients fulfilling the eligibility criteria were randomly assigned to two groups (I and II) using a balanced block randomization method. In this study, the evaluator assessing the response was blinded to the drug administered.

RESULTS

We conducted an evaluation of 70 patients with renal colic who were presented to the Emergency Department at Mayo Hospital, Lahore. The study comprised of 47 male patients (67%) and 23 (33%) female patients. The mean age of our patients was 38 ± 12 years old. Frequencies and descriptive are listed below:

Table 1
Frequency of the study variables

Variable	Frequency	Percent age (%)
Adequate Pain Yes	49	70
Relief No	21	30

Extra Analgesic Drug Required	Yes	16	22.85
	No	54	77.14
Disposition	Discharged	61	87
	Referred to Specialty	9	13

Table 2*Mean \pm SD of the study variables*

Variables	Mean	Standard Deviation (SD \pm)
Time Since Onset of Pain	3.74 hr	1.8
Pain Score Before Intervention	7.90	0.91
Pain Score After Intervention	2.80	1.27

Table 2*Efficacy of paracetamol in acute renal colic*

Variable	Frequency	Percentage	p-value
Patients receiving Paracetamol	35	100	
Adequate Pain Relief	27	77.14	0.01
Rescue Analgesia Required	5	14.28	0.01
Discharged	32	91.42	0.01

Table 3*Efficacy of diclofenac sodium in acute renal colic*

Variable	Frequency	Percentage	p-value
Patients receiving Diclofenac Sodium	35	100	
Adequate Pain Relief	22	62.86	0.01
Rescue Analgesia Required	11	31.42	0.01
Discharged	29	82.86	0.05

DISCUSSION

Prompt recognition, accurate assessment and effective pain management are part and parcel of Emergency Medicine. The imprecise pain evaluations result in frequent representations to the ED, lack of trust in the treating physicians and violence (4). The most accurate, dependable and evidence-based way to gauge a patient's response to pain and its management is through scoring systems. Rather than focusing on a certain (maximum) analgesic dosage, pain management

should aim to reduce the pain score—such as by 50%, to below 4 out of 10, or categorized as mild to moderate or severe (1).

Renal colic is frequent diagnosis in the Emergency Department, and treatment varies based on its severity, requiring either a medical or surgical approach. Most cases are caused by partial obstructions and are typically managed conservatively, with a primary focus on effective pain relief (5, 6). Currently, the primary medical approach for pain relief involves either an NSAID or an opioid (11). Opioids provide immediate pain relief, while NSAIDs have prolonged effects. According to the European Association of Urology guidelines, NSAIDs are recommended as the first-line treatment for acute renal colic, followed by opioids (12). NSAIDs usually cause GI ulceration, nephrotoxicity and cardiovascular compromise whereas opioids are associated with vomiting, nausea, drowsiness and respiratory depression, warranting limited use in the high-risk population (13, 14). For years, paracetamol (acetaminophen) has been used for post-operative analgesia and its use in the management of renal colic needs to be established.

In our study, we compared the analgesic efficacy of intravenous paracetamol and intramuscular diclofenac sodium in cases of acute renal colic, assessed 30 minutes post-administration. Our findings indicated that paracetamol was superior to diclofenac, as evidenced by a greater reduction in the initial pain score (a decrease of 50% or to ≤ 3), a lower requirement for rescue analgesia, and a shorter duration of stay in the Emergency Department.

The study of Grissa et al. demonstrates that IV paracetamol outperforms piroxicam in treating renal colic statistically. These results are consistent with the present study, further underscoring the superiority of paracetamol in treating renal colic. (8). Contrary to that, the study of Ayan et al, states diclofenac sodium given intramuscularly to be more effective than intravenous paracetamol (15).

In the studies conducted by Serinken et al. and Masoumi et al., intravenous paracetamol was compared to morphine, revealing comparable efficacy while demonstrating fewer side effects associated with paracetamol (9, 16).

Pathan et al. performed a randomized

controlled trial that assessed the analgesic efficacy of intramuscular diclofenac sodium, intravenous paracetamol, and intravenous morphine. This study found intramuscular diclofenac sodium to be superior to both other agents in pain reduction (17). A subsequent meta-analysis by Pathan et al. corroborated these results, favoring diclofenac sodium (18). Conversely, Sin et al. reported that intravenous paracetamol was more effective than both intravenous morphine and intramuscular diclofenac sodium in providing analgesia for renal

colic (19).

CONCLUSION

Our research demonstrates that intravenous (IV) paracetamol is equally effective in providing pain relief compared to intramuscular (IM) diclofenac sodium. However, the requirement for rescue analgesia was significantly higher in the IM diclofenac sodium group than in the IV paracetamol group.

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