



## Original Article

# Medical Comparison of Two Different Doses of Intravenous Ketorolac for Treating of Acute Renal Colic: A Randomized Clinical Trial

Hojat Rastegari Najafabadi<sup>1</sup>, Sheida Mehrdad<sup>2</sup>, Mehdi Galavi<sup>3</sup> , Hoseinali Danesh<sup>4,6</sup> , Ali Abdolrazaghnejad<sup>5,6\*</sup>

<sup>1</sup>Department of Emergency Medicine, Khatam-Al-Anbia Hospital, Zahedan University of Medical Sciences, Zahedan, Iran

<sup>2</sup>Emergency Medicine Resident, Zahedan University of Medical Sciences, Zahedan, Iran

<sup>3</sup>Department of Emergency Medicine, Ali Ibn Abitaleb Hospital, Zahedan University of Medical Sciences, Zahedan, Iran

<sup>4</sup>MD, Plastic Reconstructive & Aesthetic Surgeon, Assistant Professor of Zahedan University of Medical Sciences, Zahedan, Iran

<sup>5</sup>Department of Emergency Medicine, Khatam-Al-Anbia Hospital, Zahedan University of Medical Sciences, Zahedan, Iran

<sup>6</sup>Clinical Immunology Research Center at Zahedan University of Medical Sciences, Zahedan, Iran

## ARTICLE INFO

## Article history

Received: 2021-11-21

Received in revised: 2021-12-05

Accepted: 2021-12-11

Manuscript ID: JMCS-2111-1345

Checked for Plagiarism: **Yes**

Language Editor:

Ermia Aghaie

Editor who approved publication:

Dr. Sami Sajjadifar

DOI:10.26655/JMCHMSCI.2022.3.12

## KEYWORDS

Intravenous Ketorolac

Acute pain

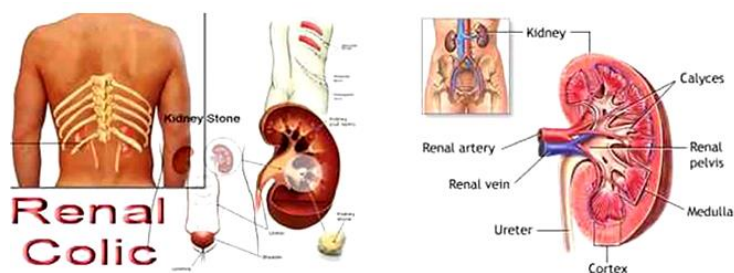
Renal colic

Emergency department

## ABSTRACT

Renal colic is a symptom of urinary tract obstruction, and stones are the most common cause of this pain. His study was performed to compare two single-dose intravenous ketorolac for the treatment of acute renal colic in patients referred to the emergency department with a randomized controlled trial. The present study is a clinical trial and includes 160 patients (15 mg ketorolac group: 80 and 30 mg ketorolac group: 80) over 16 years of age with moderate to severe renal colic referred to the emergency department of Khatam Al-Anbia Hospital in Zahedan in 2020. The sampling method was randomly blocked. The researcher-made checklist including patient demographic information was used to collect information and 25SPSS software was employed for doing the data analysis. The mean pain in patients with renal colic in the two groups before and after ketorolac injection was 7.83 1 1.54 and 7.5 88 0.88, respectively. There was a significant difference between the pain score at 40 and 60 min. The number of people who had nausea was higher in 20 min after consumption than at other times. At 40 min heart rate was high in the 30 mg group. At 60 min, this rate was higher in the 30 mg group than in the 15 mg group. Use of intravenous ketorolac has a high rate of action to reduce the pain and the need for salvage treatment is also less in this drug, while the side effects are not significant.

## GRAPHICAL ABSTRACT



\* Corresponding author: Ali Abdolrazaghnejad

✉ E-mail: Email: [Mghsepehr137600@gmail.com](mailto:Mghsepehr137600@gmail.com)

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## Introduction

According to the International Association for the Study of Pain, "Pain is whatever the experiencing person says it is, existing whenever he says it does" [1]. Pain is a defense mechanism for the body that occurs when tissue is damaged [2-4]. However, it may have some side effects including, respiratory depression, nausea, vomiting,

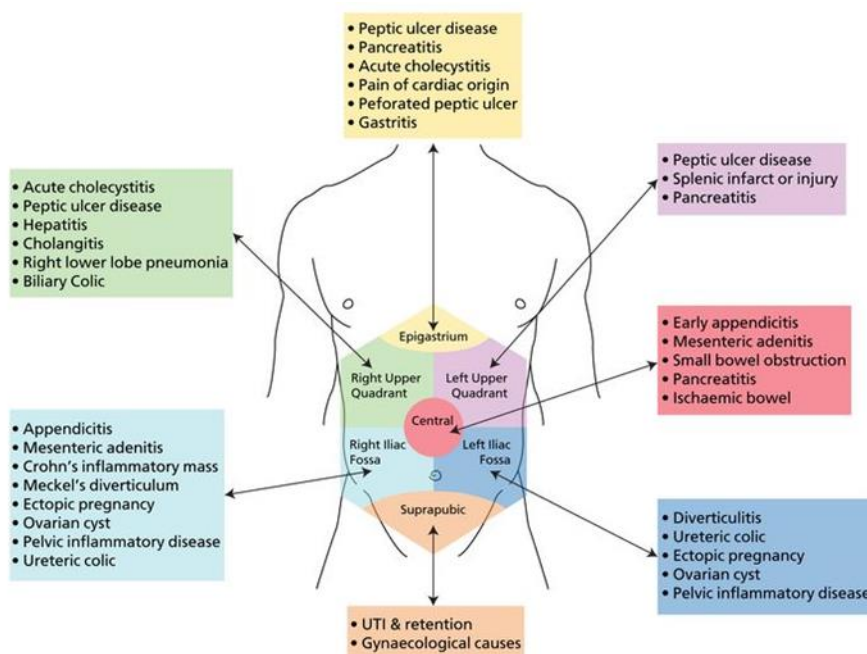
dizziness, and fatigue follow. To reduce the side effects and the amount of drug use, Ketorolac can be used as an alternative drug in this field [5-7]. Urinary tract stones are a common painful cause of emergency department [8]. Patients' satisfaction with the quality of treatment in the emergency department largely depends on how they manage their pain [9-11].



**Figure 1:** Ketorolac IM, 60 mg/2mL, SDV, 2 mL vial

Ketorolac tromethamine is a nonsteroidal anti-inflammatory drug (NSAID) that is used to treat moderately severe pain and inflammation, usually after surgery [12-14]. By inhibiting cyclooxygenase activity and prostaglandin synthesis, it reduces pain and inflammation. Ketorolac ampoules are now widely used as an

injectable analgesic in the United States and Europe (Figure 2). Non-complication of respiratory depression, lack of dependence and prolonged sedative effect are the most important advantages of ketorolac ampoules over injectable opioids [15-17].



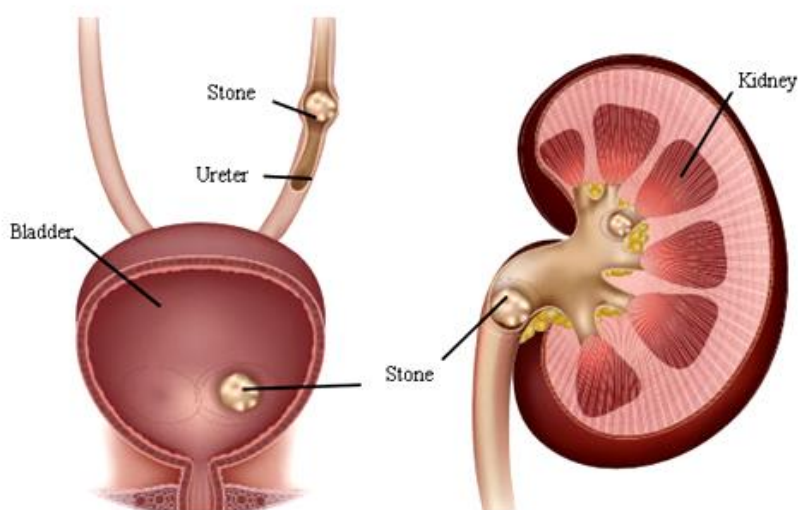
**Figure 2:** Renal colic mimics, Emergency Medicine Kenya Foundation

Ketorolac also has a synergistic effect with injectable opioids and can reduce the dose of narcotics by co-administering injectable ketorolac and injectable opioids [18-21]. Ketorolac is associated with common side effects such as headache, stroke, dyspepsia,

gastrointestinal pain, and nausea. Studies comparing the effects of these drugs on postoperative analgesia so far have shown that Ketorolac at 30 and 90 mg has an effect equivalent to morphine at 12 mg for the first 3 h and more effect in the next 4 h. Morphine side

effects including respiratory depression, nausea, and drowsiness were not observed (Figure 3). Therefore, ketorolac has been reported as a safe

and effective drug for controlling pain in patients after surgery [22].



**Figure 3:** Kidney Stones and Acute Renal Colic

It seems that if it is possible to choose a drug with the right dose that can better control pain in patients with renal colic (pain that occurs due to a stone in the urinary tract). Not use analgesics that have many causes including insufficient equipment for acute analgesia, lack of acute pain services, protocols, and comprehensive clinical guidelines for appropriate pain treatment in the hospital. According to importance of subject the aim of current study was comparison of Intravenous Ketorolac at Two Single-Dose for Treating Acute Pain of renal colic in the Emergency Department.

### Material and Methods

The present study is a Randomized Controlled Trial on 160 patients (80 patients treated with 15 mg ketorolac, 80 patients treated with 30mg ketorolac) over 16 years of age with moderate to severe acute renal colic referred to the emergency department of Khatam-al- Anbya Hospital in Zahedan in 2020 and selected by block randomization method.

Patients over 70 years of age, pregnancy or lactation, gastrointestinal problems such as gastritis, Acute bleeding peptic ulcer, NSAID hypersensitivity, unstable vital signs (systolic BP <90 or 180<mmHg, 50>HR>150), patients with a history of analgesia including diclofenac suppositories, were excluded from the study.

Initially, a group of patients referred to the emergency department who received intravenous Ketorolac for renal colic analgesia was selected. All subjects were informed about the manner of conducting the research and its purpose, the optionality of participating in the study and the confidentiality of the collected information, and all patients were asked to sign an informed consent containing complete information about how to conduct the study. Patients were also reassured that they could withdraw at any stage of the study they wished. All patients referred to the emergency department of Khatam-al- Anbya Hospital in Zahedan who presented with renal colic symptoms and were treated with renal colic based on clinical findings if they had inclusion and exclusion criteria and moderate to severe pain with a score greater than or equal to 5 entered the study. The standard diagnosis of a patient with renal colic pain is based on clinical judgment, ultrasound findings or CT scan without abdominal contrast performed by an emergency medicine specialist. Patients were randomly divided into two groups (Treated with 15mg and 30 mg of ketorolac) (manufactured by Daru Pakhsh Company, Tehran, Iran). Since the approved dose in the use of this drug is not known yet and also the higher dose of ketorolac due to its pathophysiology and its effect on GFR

can have destructive effects, therefore the two doses of this drug and its side effects are investigated and if Failure to respond to treatment is the next treatment for morphine use. Patients' pain intensity was assessed during referral (before drug injection), as well as 20, 40 and 60 minutes after injection. Pain determination minutes were performed based on a study by Sergey Motov [15]. First, the researcher completed the checklist and the patient's pain score was measured using the visual analog scale (VAS). The pain score in this scale is classified from zero (no pain) to 10 (maximum possible pain) and the patient evaluates the integers between these two numbers based on mental perception in different stages. Drug groups were prepared in doses of 15 mg (group A) and 30 mg (group B) of Ketorolac and in both groups of morphine 5 mg in 5cc syringes with the same appearance. The classification of patients and the type of medication used for the people involved in the blinded study and the patient evaluating researcher are not aware of the drug group prescribed for patients during the study. For this purpose, all syringes of both groups had the same appearance and volume with the same frequency of use in both groups. Other common treatments also apply to both groups. Therefore, the study was performed in a double-blind manner. After recording the initial pain, the patient randomly admitted to a group of patients. The goal is to achieve a degree of analgesia without causing side effects that the patient feels satisfied (pain score less than 5 on the VAS scale).

The patient's vital signs were assessed at baseline, at 20, 40, and 60 min after injection. HR, BP, Pulse oximetry and heart rhythm changes are performed based on monitoring and in case of rhythm change, they are recorded by ECG. Ketorolac is associated with common side effects such as headache, stroke, dyspepsia, gastrointestinal pain, and nausea [13].

*The incidence of treatment complications includes:* drop in arterial blood oxygen saturation below 90% for more than 60 seconds, change in pulse rate or blood pressure (increase or decrease), change in respiration rate (increase or decrease)

and complications Lateral was evaluated. Over a period of 60 minutes, possible side effects from two doses of the drug, including hypotension, nausea and vomiting, bradycardia, seizures, loss of consciousness, itching and skin rash, and respiratory depression and urinary retention, are also recorded. In cases where pain was not controlled by drug injection, Rescue dose of intravenous morphine 0.1 mg / kg was used as an alternative. The number of times morphine rescue dose was administered to patients with renal colic was determined in two groups receiving ketorolac 15 and 30 mg. The total Rescue dose of morphine is calculated and recorded until acceptable pain is achieved.

**Primary outcome:** Includes numerical reduction of pain reported by the patient within 30 minutes after injection.

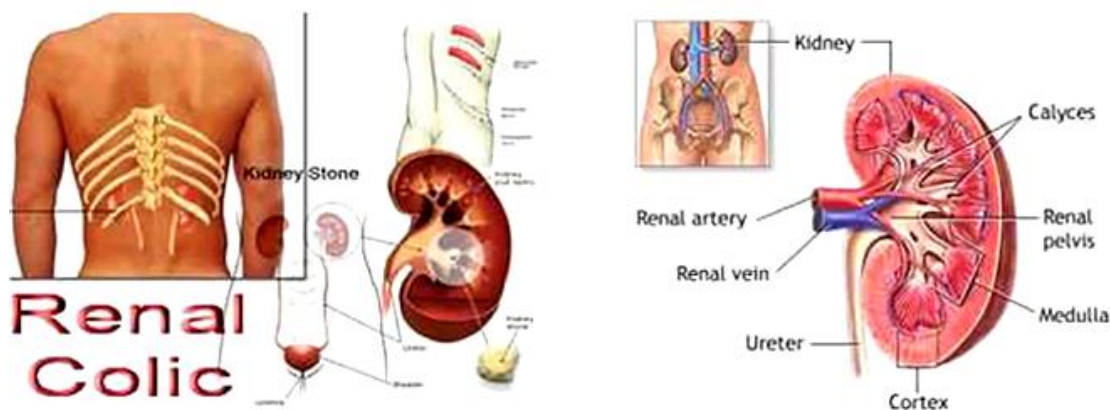
**Secondary outcomes:** Includes people with side effects as well as need for Rescue dose

At the end, the patient declares satisfaction with the treatment and is recorded by the researcher. Global Satisfaction was assessed on a 5-point scale (Poor=0; Fair: 1; Good: 2; Very good: 3; and Excellent: 4) within 60 min after receiving the drug or at the time of prescribing Rescue dose. Data analysis was performed using IBM SPSS Statistics. V25. Chi-square tests were used to compare quantitative variables and chi-square was used to compare qualitative variables. T-test was also used to compare the reduction of pain in the two groups.

## Results and Discussion

The mean age of patients in group A was  $45.93 \pm 12.11$  and in group B was  $43.06 \pm 5.8$  years, two groups were the same age ( $p = 0.17$ ). There was no statistically significant difference between the levels of education in the two groups ( $p = 0.62$ ). 55% and 47% of patients were male and 36% and 42% were female, in groups A and B, respectively. There was no statistically significant difference between the homogeneities of the two groups ( $P = 0.32$ ).

According to Table 1, the mean pain scores before and after injection were significantly different in the two groups and the mean after injection was significantly reduced ( $P = 0.00$ ) (Figure 4).



**Figure 4:** Renal colic pain causes, symptoms, diagnosis and treatment

**Table1:** Comparison of mean of pain in patients with renal colic between groups A and B before and after injection

	mean	Standard deviation	t	p-value
Before injection	7.83	1.54	17.8	<0.001
After injection	5.07	0.88		

Table 2 reveals that 20 min after injection in two different doses, there was no significant difference in pain score between the two groups and had the same therapeutic effect on the mean pain; in 40 min after injection a significant difference was observed between the therapeutic effects in the two groups; Also, in 60 min after injection, it was observed that the mean pain score decreased in both groups, which was significantly lower in the 35 mg group than in the 15 mg group.

In group A, the number of patients who had more nausea increased at 20 min after injection than at

other times, in 40 min after injection the patients had nausea between 2 and 5 times, and finally in 1 h after injection 5 patients had nausea only once and only one person had nausea twice, indicating that patients showed fewer complications over time. In group B, 7 patients who had nausea occurred in the first 20 min, between 1 and 5 times, this number decreased over time, so after 1 h, only 3 people had nausea (Table3).

**Table2:** Comparison of mean of pain in patients with renal colic between two groups at 40, 20 and 60 min after injection

	group	mean	Standard deviation	t	p-value
20 minutes after injection	15 mg	6.16	1.18	2.38	0.054
	30 mg	5.91	1.06		
40 minutes after injection	15 mg	6.18	1.17	2.57	0.04
	30 mg	5.07	0.66		
60 minutes after injection	15 mg	4.4	1.56	4.38	0.001
	30 mg	3.07	2.17		

**Table3:** Frequency of nausea in people at different times in two groups

group	Vomit	20 minutes after injection	40 minutes after injection	60 minutes after injection
15 mg	yes	20	13	6
	no	60	67	74
30 mg	yes	17	11	3
	no	63	69	77



As seen in Table 4, There was no significant difference in mean systolic blood pressure between two groups at 20 min after injection and they had statistically the same systolic mean (p=0.48). At 40 min, blood pressure was higher in the 30 mg group, but this increase was not statistically significant (p=0.14); Finally, 60 min

after the injection, observed that the mean systolic blood pressure in 30 mg group was higher and more normal than 15 mg group, and statistically showed higher blood pressure versus 15 mg and had a better performance than 15 mg (p=0.00).

**Table 4:** Comparison of systolic and Diastolic blood pressure, heart rate and SpO2 between two groups at 20, 40, 60 minutes after injection

	group	Mean±SD systolic blood pressure	p-value	Mean±SD Diastolic blood pressure	p-value	Mean±SD HR	p-value	Mean±SD SpO2	p-value
20 minutes after injection	15 mg	127.66±8.4	0.48	62.61±4.76	0.014	89.66±11.97	0.992	99.2±6.23	0.2
	30 mg	128.61±8.6		61.07±2.90		88.1±5.38		98.41±11.47	
40 minutes after injection	15 mg	125.4±3.08	0.14	69.88±4.37	0.002	86.56±3.54	0.01	96.9±9.15	0.73
	30 mg	124.6±3.89		71.68±2.77		89.66±2.32		96.5±5.36	
60 minutes after injection	15 mg	117.3±4.9	<0.001	74.24±8.37	0.13	83.18±6.62	0.4	95.3±9.6	0.018
	30 mg	120.9±4.7		77.03±5.36		83.91±5.20		93.2±4.11	

In the first 20 min, mean Diastolic blood pressure in 15 mg group was higher than 30 mg and a significant difference was observed between this difference (p=0.014). But 40 minutes later, mean Diastolic blood pressure was higher in 30 mg group than 15 mg group (p=0.02). Finally, 60 minutes after injection, there was no statistically difference between two groups (p=0.13) (Table 4). There was no significant difference between 20 min after injection in the two groups (0.992) of heart rate, but in 40 min later the heart rate in 30 mg group was higher than 15 mg group (p=0.01), finally after one hour of injection there was no significant difference between heart rate in two groups and had the same heart rate at the end (p=0.4) (Table 4).

there was a significant difference between two groups. Who received a dose of 30 mg had a lower SpO2 than other group.

The mean score of satisfaction in two groups before (2.41±3.21) and after (4.6±1.12) injection was significantly different and the mean after injection was significantly reduced (p=0.00).

According to Table 3, no significant difference was observed between two groups 20 min after injection of SpO2 (p=0.2). In 40 min later, SpO2 in 30 mg group was statistically equal to other group, and finally after one hour of injection,

According to the p-value in Table 5, there was no significant difference between the frequencies of people who needed additional doses between two groups. They were less than the others and were given an additional dose, which was equal to 5 people in the 15 mg group and 3 people in the 30 mg group. Among those who needed a Rescue dose of intravenous morphine, a total of 30 mg rescue dose was injected between 5 patients in group A and a total of 18 mg rescue dose was injected among 3 patients in group B.

**Table 5:** Number of patients require additional dose in two groups

group	additional dose	20 minutes after injection	40 minutes after injection	60 minutes after injection	p-value	Rescue dose
15 mg	Yes	0	0	5	0.91	30
	No	80	80	75		0
30 mg	Yes	0	0	3		18
	No	80	80	77		0

Colic pain is one of the most common urological problems [16]. Drugs used in acute renal colic are found in two main categories of Nonsteroidal anti-inflammatory and Narcotic [17]. NSAIDs are one of the most widely used drugs. The gastrointestinal and renal effects of NSAIDs have limited their use. However, their injectable generation, such as Ketorolac, has minimized this complication. Renal colic is a complex of sudden severe pain, nausea, and sometimes vomiting that requires proper diagnosis and treatment [18]. In Europe, 72% emergency calls to ambulance dispatch are caused by pain, of which about 9% are due to renal colic [7,19]. Shaker *et al.*, 2016 [17] which was performed with the aim of comparing the effect of ketorolac and intravenous morphine in patients with acute renal colic in the emergency department of Hazrat Rasool Akram and Firoozgar hospitals showed that the rate of pain reduction at 60, 40, 20 min was  $4.04 \pm 1.75$ ,  $7.16 \pm 2.51$  and  $9.57 \pm 0.95$ , respectively, while the rate of pain reduction in the present study was 40 and 20 min higher in the 15 mg group. The rate of pain reduction at 60 min in the 15 and 30 mg groups was 4.04 and 3.7, respectively. Overall, NSAIDs (except ketorolac) are less effective in reducing pain as well as slower in controlling pain in patients with renal colic. One of the problems of NSAIDs lack of preparation with intravenous injection, for intramuscular injection or oral administration of the increase took effect and pain in patients coincided [20]. With the introduction of Ketorolac into the drug market as the only form of intravenous injection, this drug has become the preferred drug in the treatment of patients with renal colic [21]. Motov *et al.*, 2017 [22] a double-blind clinical trial study entitled "Comparison of intravenous ketorolac in three single doses for the treatment of acute pain in the emergency department" was performed in patients aged 18 to 65 years with moderate to severe acute pain referred to the emergency department. The effect of intravenous ketorolac was evaluated at three doses of 10, 15 and 30 mg at the patient's visit, at 15, 30, 60, 90 and 120 min after injection. A significant reduction in pain was observed within 30 min after injection. The mean pain scores in 3 doses of 10, 15 and 30 mg were

initially 7.7, 7.5 and 7.8, respectively; in the next 30 min it improved to 1.5, 0.5 and 4.8. The results of this study are consistent with the present study which stated that the amount of pain was significantly reduced. Hosseinejad *et al.*, 2017 [23] showed that the combination of 30 mg of ketorolac relieves pain more effectively and reduces the need for analgesia. The results of this study are in line with the present study which shows that the rate of pain reduction in the 30 mg group at 60, 40 and 20 minutes were 5.91, 5.7 and 3.07, respectively. The findings of the present study are consistent with the findings of the study of Safdar *et al.*, 2006 [24], that in a double-blind study of 76 patients, they compared 30 mg of intramuscular ketorolac with 100 mg of intramuscular meperidine; Result showed ketorolac was associated with better pain relief, fewer side effects, and less need for analgesic pain than meperidine. Shaker *et al.*, 2016 [17] showed highest frequency of symptoms was related to vomiting. The present study also showed that nausea increased in 20 min after consumption compared to other times. Consistent with the present study was study by Otov *et al.*, 2017 [22] which states that the most important side effects in the secondary study were dizziness, nausea, and headache. Hosseinejad *et al.*, 2017 [23] Showed that there was no significant difference between the groups in terms of changes in blood pressure, heart rate, respiration rate or oxygen saturation. In the present study, blood pressure was not significantly different in 20 and 40 min, but in 60 min after ketorolac injection, the mean blood pressure in the 30 mg group was higher and more normal than in the 15 mg group, and statistically higher blood pressure was higher than 15 mg and performed better than 15 mg. Also, at 60, 40 and 20 min, there was no significant difference in heart rate between the two groups, the results of this study are in line with the present study. At 20 and 40 min, the amount of Oxygen saturation in the two groups was not statistically significant, and at 60 min, those who received a dose of 30 mg had a lower percentage of oxygen saturation than the other group. Shaker *et al.*, 2016 [17] reported in total,

patients who needed a rescue dose of ketorolac (20%), this rate was statistically significant, which is not consistent with the results of the present study. The present study had some limitations, including: The number of patients in the present study was low, patients in the acute phase of pain may not be able to fill in the numerical scale of pain intensity and it is not ethically possible to fill out the form when the patient is in pain. Therefore, the forms became painful after relative control.

### Conclusions

In the first 20 min after intravenous ketorolac, no significant difference was observed between the pain scores in the two groups, but in the 40th min this difference became significant and in the 60th min the mean pain score decreased in the two groups, which was significantly lower in the 30 mg group than 15 mg group. In general, the use of Ketorolac injection has a great speed of action to reduce pain and the need for salvage treatment is less in this drug, while the side effects are not significant. It is suggested that this study be conducted with a larger number of samples to provide more reliable results to future researchers. It is recommended to compare the therapeutic effect of ketorolac with other drugs such as (Apotel and morphine).

### Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

### Authors' contributions

All authors contributed toward data analysis, drafting and revising the paper and agreed to be responsible for all the aspects of this work.

### Conflict of Interest

We have no conflicts of interest to disclose.

### ORCID

Mehdi Galavi:

<https://www.orcid.org/0000-0002-6821-0501>

Hoseinali Danesh:

<https://www.orcid.org/0000-0002-0385-2597>

Ali Abdolrazaghnejad:

<https://www.orcid.org/0000-0002-4121-1643>

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#### HOW TO CITE THIS ARTICLE

Hojat Rastegari Najafabadi, Sheida Mehrdad, Mehdi Galavi, Hoseinali Danesh, Ali Abdolrazaghnejad. Medical Comparison of Two Different Doses of Intravenous Ketorolac for Treating of Acute Renal Colic: A Randomized Clinical Trial, *J. Med. Chem. Sci.*, 2022, 5(3) 376-384

DOI: 10.26655/JMCHMSCI.2022.3.12

URL: [http://www.jmchemsci.com/article\\_141762.html](http://www.jmchemsci.com/article_141762.html)