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ORIGINAL RESEARCH

Comparison of the analgesic efficacy of dexketoprofen trometamol, meperidine, and paracetamol in patients presenting with renal colic

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Abstract

This study aimed to compare the analgesic effectiveness of intravenous (IV) dexketoprofen trometamol, IV meperidine and IV paracetamol in patients with renal colic at the Emergency Department of Erciyes University Medical School. Ninety patients, aged 18–65, were enrolled in a double-blind, randomized trial and divided into three groups of 30. Each group received either 50 mg IV dexketoprofen trometamol, 50 mg IV meperidine or 1000 mg IV paracetamol, administered in 250 mL saline over 15 minutes. Pain intensity was assessed at 15, 30 and 60 minutes using a 100-mm visual analog scale (VAS) and a 4-point verbal rating scale (VRS). A successful treatment outcome was defined as a $\geq$50% reduction in VAS at 30 minutes and patients with a VAS score $\geq$40 mm at 30 minutes were given fentanyl as rescue analgesia. Results showed significant reductions in VAS scores (±Standard deviation (SD): 53.9 ± 17.6 mm in the dexketoprofen trometamol group, 62.8 ± 14.6 mm in the meperidine group, and 41.7 ± 19.8 mm in the paracetamol group (Probability value, $p < 0.001$). The percentage reduction in VAS scores (±SD), was 67.3 ± 20.2% for dexketoprofen trometamol, 71.7 ± 14.2% for meperidine and 51.3 ± 21.0% for paracetamol ($p < 0.001$). Both dexketoprofen trometamol and meperidine were more effective than paracetamol, but there was no significant difference between them. Rescue analgesia was required in 4 (13.3%) of dexketoprofen trometamol patients, 2 (6.7%) of meperidine patients, and 11 (36.7%) of paracetamol patients. Adverse effects were more common in the meperidine group (33.3%) compared to paracetamol (3.3%) and dexketoprofen trometamol (none) ($p < 0.05$). In conclusion, IV dexketoprofen trometamol and IV meperidine are equally effective for renal colic and superior to IV paracetamol.

Keywords

Analgesic efficacy; Dexketoprofen trometamol; Emergency department; Meperidine; Paracetamol; Renal colic

1. Introduction

Renal colic (RC) is a urological emergency caused by kidney stone disease, which results in severe pain and is frequently seen in emergency departments. Over 1 million patients in the United States visit emergency clinics annually due to RC [1, 2], and the risk of experiencing an RC attack during one's lifetime is between 1–10% [3]. In the past, morphine and pethidine were the primary agents used to treat renal colic. Still, non-steroidal anti-inflammatory (NSAID) drugs with proven effectiveness started to be used in the 1970s. NSAIDs are now preferred as they do not cause side effects such as addiction, constipation, respiratory depression, and mental changes seen in opioids [4].

Dexketoprofen trometamol is a preferred NSAID agent due to its rapid onset of action, low gastrointestinal side effect profile, and shallow effect on bleeding complications [5]. Meperidine is an opioid analgesic that primarily acts by binding to μ-opioid receptors in the central nervous system. It is an effective painkiller for the majority of moderate and severe pain and is commonly used in patients who visit the emergency department due to various painful conditions such as toothache, migraine headache, musculoskeletal pain, mechanical low back pain and RC. However, it has side effects such as hypotension, respiratory depression, and increased risk of seizures [6]. Paracetamol is an agent that exerts its analgesic and antipyretic effects by centrally inhibiting prostaglandin synthesis [7].

Patients often describe RC as the most painful experience they have ever had. The primary goals in treating RC are to relieve and control pain effectively and to eliminate obstruction without causing renal function loss [4]. Our study aims to compare the analgesic effectiveness of intravenous (IV) dexke-

toprofen trometamol, IV meperidine, and IV paracetamol in patients who present to the emergency department with RC.

2. Materials and methods

2.1 Study design

This clinical trial was conducted at a single center, involving a prospective, randomized, double-blind study. The main objective was to compare the analgesic effectiveness of three different medications—IV dexketoprofen trometamol, IV meperidine, and IV paracetamol in patients who arrived at the emergency department with renal colic.

2.2 Selection of participants

Patients who had taken any analgesic medication in the six hours preceding their arrival, those who had a regular medication schedule, individuals under 18 years of age or over 65, hemodynamically unstable patients, patients with renal, hepatic, cardiac or respiratory failure, those allergic to the drugs used in the study, pregnant or breastfeeding women, those with a history of renal transplantation, patients with only one kidney, individuals with serum creatinine levels exceeding 2 mg/dL, those with a history of gastrointestinal bleeding and peptic ulcer, and patients unable to fill out the pain scale due to vision problems were excluded from the study.

The patients were randomized and numbered using a computer. Ninety eligible patients diagnosed with renal colic and who agreed to participate in the study were included. Thirty patients were assigned to each of the three groups—dexketoprofen trometamol, meperidine and paracetamol.

2.3 Interventions

All patients who presented to our emergency department with symptoms and signs indicative of renal colic were interviewed to gather information on their medical history. A detailed physical examination was then performed, and exclusion criteria were assessed. The patients were informed about the study and consent was obtained. Vascular access was established for all patients, and Complete Blood Count (CBC), Blood Urea Nitrogen (BUN) Creatinine, Sodium, Potassium and Aspartate aminotransferase (AST), Alanine transaminase (ALT), and urinalysis tests were requested for diagnosis and differential diagnosis. During the blood draw, the physician who evaluated the patient ordered the analgesic X. Before the evaluation, the patients were informed about the pain scales to be used in the study, namely the visual analog scale (VAS) and verbal rating scale (VRS). The patients then made VAS and VRS markings on the evaluation forms without looking at the previous marking location. Neither the patients nor the physicians knew which study group they were in during the clinical practice phase, as the study was double-blind.

The study drugs were administered to patients suspected of having renal colic in random order: dexketoprofen trometamol IV 50 mg (ampoule containing Dexalgin 50 mg injectable solution), meperidine IV 50 mg (Aldolan 100 mg ampoule) and paracetamol IV 1000 mg (Perfalgan 10 mg/mL infusion solution) was prepared as a 250 mL solution in standard saline, with the same appearance. The nurse who prepared the solution was informed about the study, but the nurse who administered the drug did not know which group the patient was in. The drugs were given as a single dose over 15 minutes.

Direct Urinary System X-ray and Urinary Ultrasound Sonography (USG) were conducted to detect stones and signs of urinary system obstruction in patients with renal colic. In cases where the diagnosis of renal colic was unclear, Computed Tomography was conducted for diagnosis and differential diagnosis. The study included 90 patients of both genders, aged between 18 and 65, who were diagnosed with renal colic after anamnesis, physical examination, laboratory and imaging tests, and who gave their consent to participate in the research. Statistical analyses were then performed.

If any unexpected effect was observed in the patients during the study period, the patient did not accept the treatment or wanted to leave the study; such patients were excluded from the study in the preparation phase. Fortunately, no such situation was encountered during the follow-ups.

2.4 Methods of measurements

The time at which treatment began was recorded as 0th minutes and pain levels were measured using the VAS scale, which ranges from “0 mm (no pain)” to “100 mm (unbearable pain)”. The pain levels were measured before treatment and at the 15th, 30th and 60th minutes after the treatment. Pain severity was evaluated using VRS and classified as “none”–“mild”–“moderate”–“severe”.

A treatment was considered successful if there was a 50% or greater reduction in the VAS score at the 30th minute [8]. If a patient’s VAS score was $\geq$40 mm at the 30th minute, they were given 1 mcg/kg of Fentanyl IV as a rescue medication. All patients were monitored for at least 60 minutes, and any side effects and vital signs were recorded during this period.

2.5 Data analysis

Statistical analysis conducted in this study involved the use of various methods such as *t*-test independent samples, one-way variance analysis, and variance analysis in repeated measurements. The categorical variables were analyzed using the chi-square test. The numerical variables were expressed as arithmetic mean standard deviation (mean $\pm$ SD). Any *p*-value less than 0.05 was considered statistically significant. The statistical analysis was performed using version 22 of the “SPSS for Windows” package program (IBM, Armonk, NY, USA).

3. Results

Out of the total patients involved in the study, 58 (64.4%) were male, and 32 (35.6%) were female. There was no statistically significant difference between the gender distribution of the patients in the study groups ($p = 0.124$). The average age of the patients was 35.4 $\pm$ 12.5 and there was no significant difference between the study groups’ mean age ($p = 0.301$) (Table 1). Plain X-rays were performed on 33 patients, ultrasounds on 14 patients, and computed tomography on 76 patients.

The study found that the mean and standard deviation of

TABLE 1. Demographic characteristics of patients.

	Dexketoprofen	Meperidine	Paracetamol	Total	*p* value
Number (n (%))	30 (33.3%)	30 (33.3%)	30 (33.3%)	90 (100.0%)	
Gender					
Male n (%)	21 (70.0%)	15 (50.0%)	22 (73.3%)	58 (64.4%)	0.124
Female n (%)	9 (30.0%)	15 (50.0%)	8 (26.7%)	32 (35.6%)	
Age (Mean ± SD)	32.6 (±10.8)	36.7 (±13.9)	37.1 (±12.4)	35.4 (±12.5)	0.301

SD: Standard Deviation.

VAS score change at the 30th minute after drug administration in the dexketoprofen trometamol group was 53.9 ± 17.6, the meperidine group was 62.8 ± 14.6 and 41.7 ± 19.8 in the paracetamol group. The study groups showed a significant difference concerning VAS score change at the 30th minute after drug administration ($p < 0.001$). The dexketoprofen trometamol and meperidine groups showed a more significant decrease in VAS levels than the paracetamol group, but there was no statistical difference between the dexketoprofen trometamol and meperidine groups. Table 2 shows the VAS and VRS score changes of the study groups 15 minutes, 30 minutes and 60 minutes after drug administration.

In the dexketoprofen trometamol group, the average and standard deviation of the reduction in VAS score percentage from before (0 min) and 30 min after drug application was 67.3 ± 20.2%; 71.7 ± 14.2% in the meperidine group; and 51.3 ± 21% in the paracetamol group. A statistically significant disparity was noted among the groups in terms of the VAS score reduction percentages pre-application (0 min) and post-application (30 min) ($p < 0.001$). It was ascertained that the VAS score reduction percentage was notably higher in the dexketoprofen trometamol and meperidine groups compared to the paracetamol group. However, there was no significant difference between dexketoprofen trometamol and meperidine groups. The percentage changes in VAS scores were recorded 15, 30 and 60 min after drug administration and are shown in Table 3.

In terms of additional analgesic treatment, 4 (13.3%) patients in the dexketoprofen trometamol group, 2 (6.7%) patients in the meperidine group, and 11 (36.7%) patients in the paracetamol group required further medication. There was a significant difference between the groups regarding the need for additional analgesic treatment ($p = 0.009$). The need for additional analgesic treatment at the 30th minute is shown in Table 4.

Side effects were also evaluated during the study. No side effects were reported in the dexketoprofen trometamol group. However, 10 (33.3%) patients in the meperidine group experienced at least one side effect, while 20 (66.7%) patients did not report any side effects. In the paracetamol group, only 1 (3.3%) patient experienced side effects, while 29 (96.7%) patients did not report any side effects. There was a statistically significant difference between the groups regarding side effects ($p < 0.05$) shown in Table 5.

4. Discussion

Renal colic (RC) is a urological emergency that is commonly caused by kidney stone disease and is characterized by severe pain. It is frequently encountered in emergency departments with more than one million patients in the United States requiring emergency care annually due to RC. In Europe, RC accounts for 7–9% of emergency ambulance calls for pain [1, 9].

Attacks of RC tend to occur in individuals in their 30s to 50s [3]. In a study conducted by Alkhayal *et al.* [10] which contained 1057 RC diagnoses, the average age was found to be 42.33 ± 16.12 years. Similarly, Brown's study, which evaluated over one million patients admitted to the emergency department with RC and conducted with the urology clinic,

TABLE 2. Comparison of pain score changes of the groups at 15, 30 and 60 minutes.

	Dexketoprofen	Meperidine	Paracetamol	*p* value
VAS score change (Mean ± SD)				
15. min	34.6 ± 20.3^a	40.5 ± 16.1^a	22.9 ± 14.0^b	<0.001
30. min	53.9 ± 17.6^a	62.8 ± 14.6^a	41.7 ± 19.8^b	<0.001
60. min	68.1 ± 14.4^a	74.1 ± 14.6^a	57.4 ± 17.7^b	<0.001
VRS score change (Mean ± SD)				
15. min	36.4 ± 18.4^a	40.8 ± 18.4^a	21.9 ± 15.8^b	<0.001
30. min	55.9 ± 15.6^a	63.8 ± 15.0^a	39.3 ± 17.8^b	<0.001
60. min	69.5 ± 12.6^a	72.9 ± 19.2^a	54.7 ± 19.7^b	<0.001

Note: VAS: visual analog scale; VRS: verbal rating scale; SD: Standard Deviation.
According to the multiple comparison test, the difference between groups with the same letters of the alphabetic superscripts is insignificant, whereas different letters are significant.

TABLE 3. Comparison of VAS score percentage changes of groups at 15, 30 and 60 minutes.

	Dexketoprofen	Meperidine	Paracetamol	*p* value
VAS % change (Mean ± SD)				
15. min	43.1 ± 22.8[a]	47.0 ± 19.4[a]	28.3 ± 15.2[b]	<0.001
30. min	67.3 ± 20.2[a]	71.7 ± 14.2[a]	51.3 ± 21.0[b]	<0.001
60. min	84.6 ± 12.6[a]	84.7 ± 13.6[a]	70.5 ± 17.6[b]	<0.001

Note: VAS: visual analog scale; SD: Standard Deviation.
According to the multiple comparison test, the difference between groups with the same letters of the alphabetic superscripts is insignificant, whereas different letters are significant.

TABLE 4. Comparison of groups in terms of additional treatment (analgesic) need.

	Dexketoprofen		Meperidine		Paracetamol		*p*-value
	N	%	N	%	n	%	
Needs additional treatment							
Yes	4[a,b]	13.3	2[b]	6.7	11[a]	36.7	
No	26[a,b]	86.7	28[b]	93.3	19[a]	63.3	0.009
Total	30	100	30	100	30	100	

According to the multiple comparison test, the difference between groups with the same letters of the alphabetic superscripts is insignificant, whereas different letters are significant.

TABLE 5. Evaluation of side effects observed after drugs administration by groups.

	Dexketoprofen	Meperidine	Paracetamol	*p* value
	n (%)	n (%)	n (%)	
Side Effect				
Dizziness	0 (0.0%)	6 (20.0%)	1 (3.3%)	
Nausea	0 (0.0%)	2 (6.6%)	0 (0.0%)	
Dizziness and Nausea	0 (0.0%)	2 (6.6%)	0 (0.0%)	0.014
No side effect	30 (100.0%)	20 (66.7%)	29 (96.7%)	
Total	30 (100.0%)	30 (100.0%)	30 (100.0%)	

reported that patients were generally middle-aged and male [11]. Our study found that the average age of patients was 35.4 ± 12.5 years, which is consistent with the literature. It has been noted in most studies that RC is three times more common in men than in women [2]. In our research, RC was 1.8 times more common in men.

Azizkhani *et al.* [12] conducted a randomized controlled study to compare the effectiveness of IV paracetamol and IV morphine in reducing pain among patients who visited the emergency room with RC. The study analyzed 124 patients and found that both drugs were effective. Morphine was found to be more effective in reducing pain, but it caused more side effects compared to IV paracetamol [12]. Other studies in the literature indicate that IV paracetamol is similar to or more effective than IV morphine [13, 14]. However, in our research, we found that IV meperidine, an opioid similar to morphine was more effective than IV paracetamol.

Another randomized, double-blind, placebo-controlled study was conducted outside the RC clinic to compare the analgesic effectiveness of IV paracetamol and IV dexketoprofen trometamol after hysteroscopy. The study found that IV dexketoprofen trometamol provided more effective pain relief compared to IV paracetamol and placebo [15]. Similar to this study, we also found that patients who received IV dexketoprofen trometamol in our research experienced significantly higher pain relief compared to those who received IV paracetamol.

A meta-analysis was conducted by Holdgate and Pollock to compare the effectiveness of NSAIDs and opioids in treating patients with RC. They found that NSAIDs were more effective in decreasing pain scores than opioids, and patients taking NSAIDs required less additional analgesic medication in the short term. Vomiting was also more common with opioids, particularly pethidine (meperidine), compared to NSAIDs. Therefore, the authors recommended the use of NSAIDs instead of opioids in treating renal colic [16]. The studies in this meta-analysis used 30-minute VAS scores to evaluate pain. In contrast, our study found no significant difference in pain scores between dexketoprofen trometamol and meperidine, but like the study by Holdgate and Pollock, we observed more side effects in patients taking meperidine, which is an opioid, than in those taking dexketoprofen trometamol, which is an NSAID.

Another study by Larkin *et al.* [17] compared the analgesic effects of IM ketorolac tromethamine and IM meperidine in

70 patients admitted to the emergency department with RC. They found that IM ketorolac was more effective than IM meperidine and allowed patients to be discharged from the emergency department earlier [17]. Similarly, Cordell *et al.* [18] conducted a randomized, double-blind study with 154 patients suspected of having RC. One group was given IV ketorolac, one group was given IV meperidine and one group was given IV ketorolac and meperidine together. They found that IV ketorolac and IV ketorolac with meperidine were more effective in reducing pain scores than IV meperidine alone [18].

A study was conducted by Ay *et al.* [19] to compare the effectiveness of IV dexketoprofen trometamol and IV meperidine in treating patients with renal colic. The study found that dexketoprofen trometamol was more effective in reducing pain scores compared to meperidine. The authors recommended the use of dexketoprofen trometamol as the first choice drug for treating renal colic due to its better analgesic effectiveness and tolerance compared to meperidine [19]. The study evaluated the analgesic efficacy using the 30th-minute VAS score and renal colic symptom score. Unlike our study, IV dexketoprofen trometamol was more effective than IV meperidine. Another study compared IV ketorolac and IV meperidine and found that IV ketorolac was as effective as meperidine and had fewer side effects [20].

Another study by Eken *et al.* [21] showed that IV paracetamol, IV dexketoprofen, and IV morphine had similar analgesic effectiveness in treating low back pain.

Various studies have shown that NSAIDs and opioids are effective in treating renal colic pain [22]. However, due to their side effects and contraindications, researchers are exploring alternative drugs. In our study, we found that although paracetamol was not superior to opioids and NSAIDs in analgesic effectiveness, it was effective in treating pain in patients with renal colic.

5. Conclusions

According to our study, it was discovered that dexketoprofen trometamol, which belongs to the NSAID group, and meperidine, which belongs to the opioid group, have no difference in their analgesic effectiveness. Both drugs are more effective than paracetamol. Although paracetamol is not as effective as these two drugs in terms of analgesic efficacy, our study has shown that it can still be useful for pain relief in patients with RC. Paracetamol can be used as an alternative analgesic treatment when NSAIDs and opioids are not recommended due to their side effects.

AVAILABILITY OF DATA AND MATERIALS

The data presented in this study are available on reasonable request from the corresponding author.

AUTHOR CONTRIBUTIONS

OLA and IT—designed the research study and analyzed the data. IT—performed the research and wrote the manuscript. Both authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study received approval from the Erciyes University Faculty of Medicine Ethics Committee (Date: 28 August 2015 Decision no: 2015/398) and the Ministry of Health Turkish Medicines and Medical Devices Agency (2014-AKD-100 Date: 27 October 2015 Letter number: 132271), and was registered at ClinicalTrials.gov (Unique Protocol ID: ErciyesUniversity-IT01, Identification No NCT06558916). The patients were informed about the study and consent was obtained.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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