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The efficacy of intradermal sterile water application in severe renal colic: a randomised clinical trial

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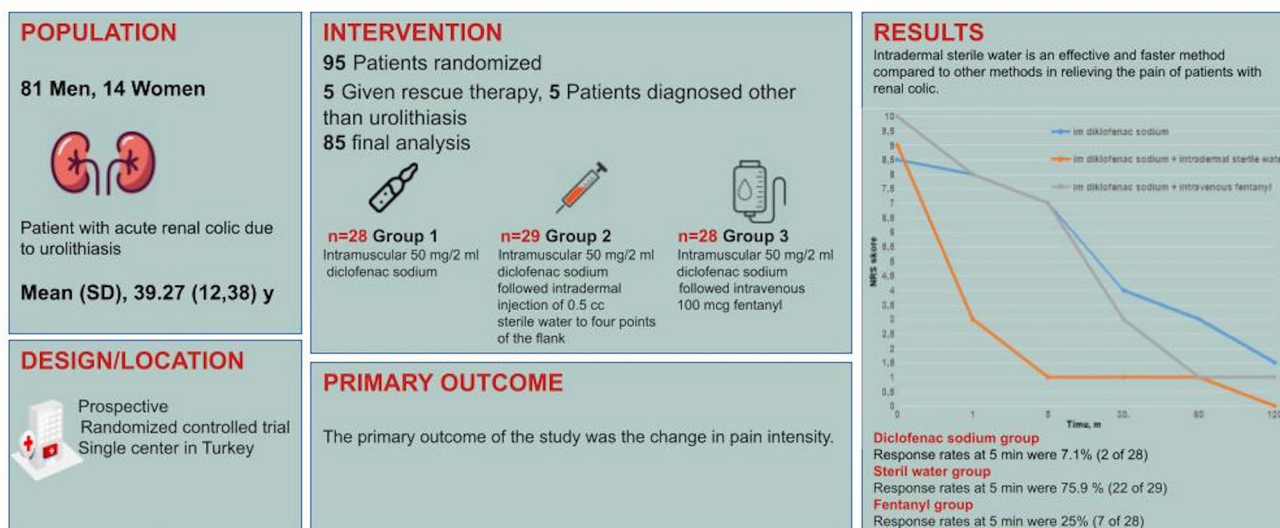
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Abstract

It is important to do a fast and effective treatment for patients with renal colic pain in emergency departments for both patients' comfort and clinicians' patient management. In this study, we aimed primarily to test the efficacy of intradermal sterile water application as a rapid and effective treatment in severe renal colic. This is a single-centre, prospective, randomised controlled trial. Study group consists of patients with severe renal colic related to urolithiasis. Patients were randomly divided into three groups. The first group received only intramuscular diclofenac sodium, the second group received intramuscular diclofenac sodium and intradermal sterile water, and the third group received intramuscular diclofenac sodium together with intravenous fentanyl. Numerical Rating Scale was used to determine the level of pain before and after the treatment at the 1st, 5th, 15th, 30th, 60th and 120th minutes. 95 out of 201 patients with severe renal colic pain randomly divided into 3 groups. The pre-treatment pain severity of the groups was similar ($p=0.228$). We found that the decrease in pain intensity was significantly faster in the intradermal sterile water group than the other groups even in the first minute. Percentages of patients who had 50% pain reduction, which is considered as successful treatment, was higher in the intradermal sterile water group (which had 75.9% success rate) in the first 5 min compared to the IM diclofenac sodium group (which had 7.1% success rate) and IV fentanyl group (which had 25% success rate) ($p<0.001$). According to the results, pain control was achieved much faster than the other methods with intradermal sterile water injection. All methods were found to be effective in relieving the pain of the patients.

Graphical abstract

RCT: The Efficacy of Intradermal Sterile Water Injection in Severe Acute Renal Colic



Keywords Renal colic · Pain · Intradermal sterile water · Diclofenac sodium · Fentanyl

Introduction

Acute renal colic is the very common urological type of admission in emergency departments (EDs). It is mostly seen with acute onset, intermittent cramping pain in the flank.

ED management of renal colic is aimed at reducing pain, assessing renal function and determining the possibility of spontaneous stone dislodgement [1]. Due to the severe and intermittent nature of renal colic, one of the main priorities in the management of this patient group is to apply patients with rapid and effective analgesia. However, various factors such as efficacy, safety, ease of rapid administration and availability should be considered in the preference for analgesia [2]. Updated in 2022, the European Association of Urology (EAU) urolithiasis guideline recommends non-steroidal anti-inflammatory drugs (NSAIDs) as the first choice for pain management and opioid group analgesics as the second choice [3]. Besides these drug options, dipyrrone has been identified as a notably effective analgesic for colic pain, demonstrating superior efficacy to both tramadol and butylscopolamine in pain relief within the first hour of administration [4]. There are furthermore studies in the literature recommending combination therapies. In addition to their efficacy, combination drug therapies have also been shown to reduce ED hospitalisation [5–7]. This is very substantial data, particularly for crowded EDs.

The Intradermal Sterile Water Injection (IDSWI) method has recently been utilised to manage many acute painful processes. In particular, there are studies on its use to manage pain during labour and in the treatment of low back pain [8, 9]. In addition, there are studies stating that it reduces acute pain in renal colic [10].

The aim of this study is to investigate the efficiency of Intramuscular (IM) diclofenac sodium, IM diclofenac sodium plus intravenous (IV) fentanyl and IM diclofenac sodium plus IDSWI on pain relief in patients admitted to the ED with acute severe renal colic pain.

Materials and methods

Study design and setting

This study was designed as a single-centre, prospective, randomise-controlled and open-label. The study was conducted in the Emergency Medicine Clinic of Health

Sciences University Fatih Sultan Mehmet Training and Research Hospital between April 1st 2021 and July 31st 2021. This tertiary care hospital has a capacity of 310 beds and admits an annual ED visit of approximately 300,000.

The study was approved by the local ethics committee (Decision no: FSMEAH-KAEK 2021/10, date: 28.01.2021). Written informed consent was obtained from each patient. A research team of five emergency medicine specialists and residents was formed and trained for IDSWI application before the study.

Sample size and patients

In our study, as a result of the power analysis performed using G*Power software version 3.1.2, when effect size d : 0.781 and SD: 1 were taken for the Numeric Rating Scale (NRS) score, the minimum sample size for power: 0.80 and α : 0.05 was determined as $n = 27$ for each group.

The study groups included all patients who initially came to the ED with acute renal colic and were later diagnosed by non-contrast enhanced computed tomography (CT) with ureteral or kidney stones. Inclusion criteria were: being aged 18 years and older, being admitted with renal colic pain and being prescribed analgesics with a prediagnosis of urolithiasis according to the examination and available investigations, and being with severe pain (NRS > 6). Exclusion criteria were: patients' decision to not participate in the study, the existence of infection at the injection site, renal failure, pregnancy or breastfeeding, NSAID and/or opioid drug allergy, being used any analgesic drug 6 h before admission, NRS score less than 7 at the first examination, having a history of chronic opioid use and addiction for any reason, been used monoamine oxidase inhibitors, tricyclic antidepressants, tricyclic antidepressants, hypnotic sedatives or cytochrome P450 inhibitors in the last 2 weeks, being known diagnosis of asthma, acute abdominal findings accompanying colicky pain, an unclear diagnosis or being diagnosed with other than urolithiasis. Patients were divided into three groups:

Group 1: IM diclofenac sodium (75 mg) (control group)

Group 2: IM diclofenac sodium (75 mg) + IDSWI (four points of 0.5 cc each) (intervention group)

Group 3: IM diclofenac sodium (75 mg) + IV fentanyl (1 mcg/kg), infusion in 100 cc 0.9% isotonic (1 min infusion time) (intervention group)

Rescue medication: Morphine IV 0.1 mg/kg IV was applied as needed.

Randomisation

A chart creating 1:1:1 randomisation into three groups in blocks of four patients was obtained using the “randomizer.org” interface. According to the obtained output, the randomisation groups were written in sealed and invisible envelopes in order the envelopes were sealed. Patients who met the inclusion criteria were enrolled as study patients; the first randomisation envelope in the sequence was opened and the treatment protocol of the group in it was applied. Patients assigned to groups were evaluated in the group to which they were assigned in terms of outcome even if they did not receive the assigned treatment without changing their groups. The entire randomisation process was performed with a computer-assisted design. Investigators were blinded to randomisation. No patient was excluded after randomisation.

Study procedures

Patients who met the inclusion and exclusion criteria and whose informed consent was obtained were included in the observation area. Patients were divided into three groups by suitable randomisation. Patients who were diagnosed with other than urolithiasis after randomisation and who decided not to continue the study were not included in the final analyses. All patients received IM diclofenac sodium (75 mg). In addition, IDSWI (application time 1 min) was administered to one group immediately after IM injection and IV fentanyl were administered as a 1 min infusion to the other group. The timer was started 1 min after IM diclofenac was administered in the first group, and after IDSWI and fentanyl administrations in the other groups. Surgical field sterilisation of the costovertebral area where the patient's pain was located was performed with 70% alcohol (Derhand Plus, Oksa Kimya Sanayi, Turkiye). The injection was performed in a sitting position using disposable 0.45×13 mm long 26 gauge needles (hypodermic needle syringe, Berika Teknoloji medical, Turkiye). Sterile water of 0.5 ml was injected as intradermal into 4 points at a depth of 1–3 mm to form papules (Fig. 1).

Outcomes

The primary outcome of the study was the change in pain intensity. Therefore, NRS was used to determine the pain level at 1, 5, 15, 30, 60 and 120 min before and after treatment. The NRS can be described as a verbal or graphical scale to describe pain intensity. The patient is evaluated on



Fig. 1 Intradermal sterile water injection application site

a scale from 0 (no pain) to 10 (most intense possible pain), verbally indicates this number, and graphically marks it; if there is a speech problem, he/she shows the numerical value with his/her fingers. A 50% reduction in the NRS score was considered a successful treatment [11].

Statistical analysis

Statistical analyses were performed using the SPSS version 25 statistical package programme (IBM Corp., Armonk, NY). The conformity of the numerical data to normal distribution was evaluated by kurtosis and skewness values. If these values were between -1.5 and $+1.5$, it was considered to fit the normal distribution. Accordingly, the NRS scores of the participants at 0, 1, 5, 30, 60 and 120 min were not normally distributed. Descriptive statistics were performed. Categorical data were expressed as numbers (percentage), numerical data conforming to the normal distribution were expressed as mean \pm standard deviation, and non-conforming ones were expressed as median [interquartile range]. In the comparison of numerical data for the three treatment groups, the one-way ANOVA test was used for those fitting the normal distribution, the Kruskal–Wallis test was used for those not fitting the normal distribution, and the Tamhane test was used in post hoc analysis in cases where significance was determined by Kruskal–Wallis test. The relationship between categorical data and each other was analysed by the Chi-square test. The statistical significance level was taken as $p < 0.05$.

Results

During our study, 95 out of 201 patients who were admitted to the ED with renal colic were included in the randomisation. The justifications of the patients who could not be randomised were as follows: 35 patients refused the interventional procedure, 38 patients could not exclude acute abdomen, 18 received analgesic medication 6 h before admission, 5 patients had known chronic renal failure, 8 patients were not age-appropriate, 1 patient had asthma, and 1 patient was in the breastfeeding process. After randomisation, patients with different diagnoses in their imaging (1 patient in Group 1 cholelithiasis, 1 patient with appendicitis; 1 patient in Group 2 aortic dissection; 1 patient in Group 3 cholelithiasis, 1 patient without stones) were excluded from the study. All patients have completed the follow-up period of our study. In the final analysis, 85 patients were included. Patients were randomised to receive intramuscular diclofenac sodium ($n=28$), intramuscular diclofenac sodium plus intravenous fentanyl ($n=28$), intramuscular diclofenac sodium plus intradermal sterile water ($n=29$) (Fig. 2). The patients included in our study ranged in age from 19 to 65. The average age of the patients was 39.27 ± 12.38 . When comparing the three groups, no significant difference was observed in terms of average age. Specifically, the average age for those administered IM diclofenac sodium was 37.27 ± 12.65 , for those given IM diclofenac sodium + IDSW, it was 39.50 ± 13.39 , and for those treated with IM diclofenac sodium + IV fentanyl, it was 41.03 ± 11.13 . Examining the gender distribution of the patients, out of those included in the study, 77 were male (85.6%), and 13 were female (14.4%). When comparing

the groups in terms of gender, no significant difference was observed. In the IM diclofenac group, there were 24 males and 4 females. In the IM diclofenac + IV fentanyl group, there were 25 males and 4 females. Lastly, in the IM diclofenac sodium + IDSW group, there were 24 males and 4 females.

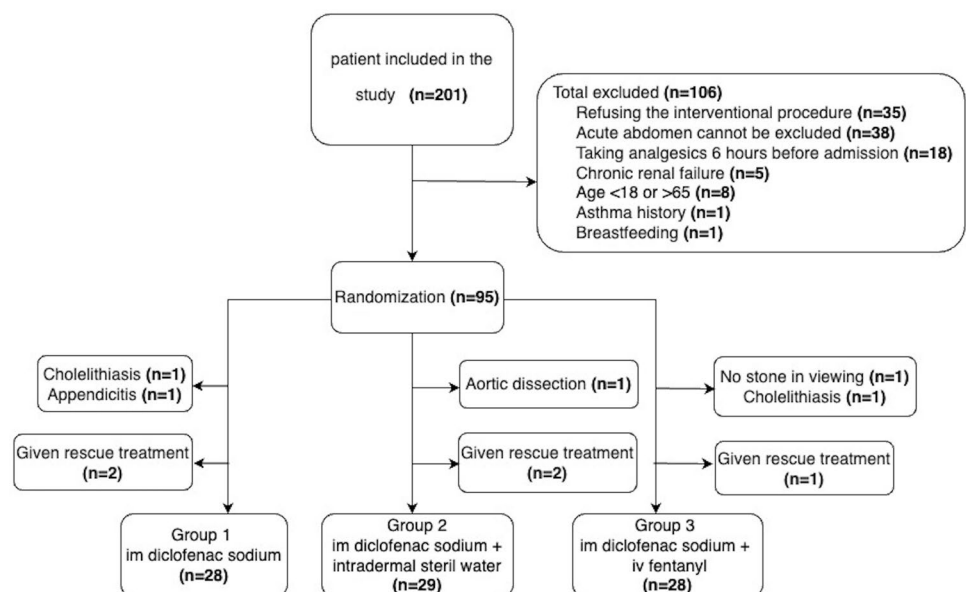
The pain intensity of the patients was calculated according to NRS. NRS was obtained from all patients only graphically. Pain intensity at the time of admission was recorded at the 1st, 5th, 30th, 60th and 120th minutes after the analgesia procedure. Cases in which rescue medication was administered were excluded from the analysis as of the minute they were administered.

When all cases were evaluated regardless of the procedure applied, the median pain intensity at admission was 9 [8–10], median pain intensity at 1st minute 8 [5–8], median pain at 5th minute 6 [2–8], median pain at 30th minute 3 [1–5], the median pain intensity at the 60th minute was 2 [0–4], and the median of the pain intensity at the 120th minute was 1 [0–3], and it was observed that the pain intensity gradually decreased.

Median pain severity at the time of admission was found in the groups to be as follows: in the IM diclofenac group 8.5 [8–9.75], in the IM diclofenac + IDSW group 9 [8–10], and in the IM diclofenac + IV fentanyl group 10 [8–10]. There was no significant difference found between the three groups in terms of pain severity at the time of admission ($p=0.228$).

When the pain intensity of the groups was compared after randomisation and analgesia, the median pain intensity at 1st min was determined as 8 [8–9] in the IM diclofenac group, 3 [0.5–5] in the IM diclofenac + IDSW group, and 8 [7–9] in the IM diclofenac + IV fentanyl group. There was

Fig. 2 Flow diagram of study cohort



a statistically significant difference between the 1st-minute pain intensities between the three groups ($p < 0.001$) (Table 1).

The pain intensity decreased in all groups, gradually, after the procedure was conducted. When all three groups were compared, the median pain intensity at 120th min was determined as 1.5 [1–3] in the IM diclofenac group, 0 [0–3] in the IM diclofenac + IDSWI group, and 1 [0–4] in the IM diclofenac + IV fentanyl group. When all three groups were compared in terms of pain outcome, it was not found to be statistically significant ($p = 0.319$) (Table 1).

The rate of reduction in pain intensity by 50% or more of the treatment methods used in our study was received as a successful treatment. Regardless of the method applied between the groups, it was determined that 50% or more decreased pain intensity has been observed as follows: 23.5% ($n = 20$) of the patients at the 1st minute, 12.9% ($n = 11$) of the patients at the 5th minute, 40% ($n = 34$) of the patients at the 30th minute, 11.8% ($n = 10$) of the patients at the 60th minute, and 2.4% ($n = 2$) of patients at the 120th minute (Fig. 3).

The 50% or more reduction in pain intensity in the first minute is as follows: 0% ($n = 0$) in the IM diclofenac sodium group, 62.1% ($n = 18$) in the IM diclofenac + IDSWI group, IM diclofenac sodium + intravenous fentanyl group 7.1% ($n = 2$). At the 5th minute, these rates are as follows: 7.1% ($n = 2$) in the IM sodium group, 13.8% ($n = 4$) in the IM

diclofenac sodium + IDSWI group, and 17.9% in the IM diclofenac + intravenous fentanyl group ($n = 5$) (Table 2).

When the treatment methods used in our study were not effective in reducing pain rapid and effectively, the demand for rescue medication occurred. Rescue medication was administered to two patients in the IM diclofenac group, to three patients in the IM diclofenac + IDSWI group, and to two patients in the IM diclofenac + IV fentanyl group, a total of seven patients. There was no statistically significant difference between the three groups in terms of the necessity for rescue medication ($p = 0.878$).

The side effects of the applied methods have also been observed. In the diclofenac sodium group, five patients had pain at the injection site and in three patients, nausea had occurred. In the IDSWI group, two patients conveyed nausea. In the fentanyl group, dizziness appeared in two patients, nausea in three patients, and pain at the injection site in four patients.

Discussion

In this study, the efficacy of IM diclofenac, IDSWI and IV fentanyl for relieving severe renal colic pain was examined. According to the outcomes of the study, all three treatments were found to be successful in pain management. However, IDSWI treatment was found to reduce pain in a shorter time

Table 1 Comparison of the change in pain intensity between the groups before and after the analgesia procedure

Pain severity	Total	IM diclofenac sodium	IM diclofenac sodium + intradermal sterile water	IM diclofenac sodium + intravenous fentanyl	<i>p</i> value* (**)
0th minute	9 [8–10]	8.5 [8–9.75]	9 [8–10]	10 [8–10]	0.228 (¹ 0.836, ² 0.219, ³ 0.701)
1st minute	8 [5–8]	8 [8, 9]	3 [0.5–5]	8 [7–9]	< 0.001 (¹ < 0.001, ² 0.874, ³ < 0.001)
5th minute	6 [12–8]	7 [6–8]	1 [0–4.5]	7 [5–8]	< 0.001 (¹ < 0.001, ² 0.566, ³ < 0.001)
30th minute	3 [1–5]	4 [2.25–5]	1 [0–3]	3 [1.25–6]	< 0.001 (¹ < 0.001, ² 0.936, ³ 0.005)
60th minute	2 [0–4]	3 [1–4.25] rescue medication was administered to 2 patients	1 [0–3]	1 [1–4] Rescue medication was administered to 1 patient	0.039 (¹ 0.055, ² 0.804, ³ 0.437)
120th minute	1 [0–3]	1.5 [1–3]	0 [0–3] Rescue medication was administered to 2 patients	1 [0–4] Rescue medication was administered to 1 patient	0.319 (¹ 0.674, ² 0.891, ³ 0.967)

Bold indicates $p < 0.05$

*Kruskal Wallis test

**Full digit test (¹comparison of IM diclofenac group vs IM diclofenac + intradermal distilled water group, ²IM diclofenac group vs IM diclofenac + intravenous fentanyl group, ³IM diclofenac + intradermal distilled water group vs IM diclofenac + intravenous fentanyl group)

Fig. 3 Error bar graph depicting the mean and 95% confidence intervals for pain intensity at different time intervals for three treatment modalities

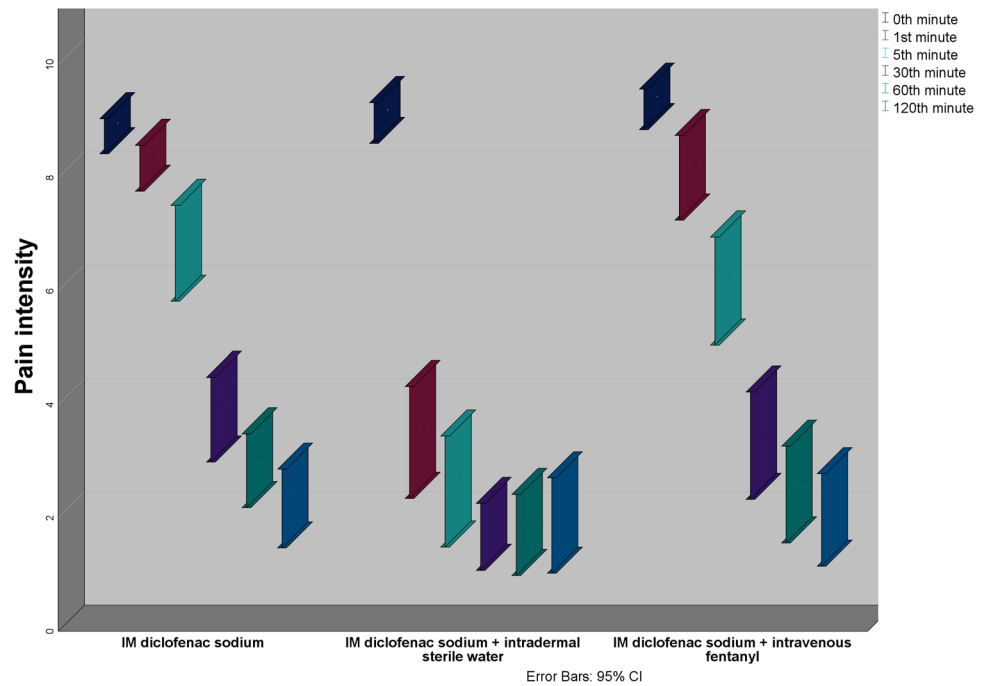


Table 2 Rates of 50% or more reduction in pain intensity

	Total	IM diclofenac sodium	IM diclofenac sodium + intradermal sterile water	IM diclofenac sodium + intravenous fentanyl
1st minute	20 (23.5)	0 (0)	18 (62.1)	2 (7.1)
5th minute	11 (12.9)	2 (7.1)	4 (13.8)	5 (17.9)
30th minute	34 (40)	17 (60.7)	6 (20.7)	11 (39.3)
60th minute	10 (11.8)	3 (10.7)	0 (0)	7 (25)
120th minute	2 (2.4)	0 (0)	0 (0)	2 (7.1)

Data are shown as N (%)

and was deemed to be superior to the other two treatment methods in this regard.

Pain due to renal colic is one of the frequent causes for urolithiasis patients to visit EDs [12]. Renal colic management relies on rapid diagnosis and effective pain control. Reducing the pain of patients during the diagnosis and treatment process will increase patient comfort. Treatment methods such as NSAIDs, opioids, acupuncture, and sterile water injections are suggested for managing the pain. However, it is required to comprehend the conditions that limit the use of these drug groups and their various side effects. For instance, NSAIDs should not be utilised in patients with coagulopathy and renal failure at risk for bleeding [13]. Fentanyl, an opioid drug, has side effects such as nausea, vomiting, hypotension, chest wall rigidity, and respiratory depression [14].

IDSWI has recently been applied in the pain management of various diseases. There are different theories to describe the mechanism of action of this method, such as

classical gate-control mechanism, hyper-stimulation or counter-irritation [15]. The injection of sterile water into the skin causes skin irritation. This is supposed to be caused by the osmotic changes following the intrusion of water. It is believed that normal saline causes fewer osmotic changes and less pain relief. These changes trigger afferent cutaneous fibres. It is believed to cause the release of endogenous endorphins similar to that in acupuncture. The mechanism of hyper-stimulation analgesia is often represented by the gate-control theory defined by Melzack, who states that the somatic component is more dominant than the visceral component [8]. According to the gate-control theory, skin stimulation evokes large-diameter fibres, which suppresses small-diameter fibres carrying the pain transmission and prevents the passage of pain triggers [16].

In the literature, there are studies examining the usefulness of IDSWI treatment in the palliation of pain in various diseases. A study by Moussa et al. compared the efficacy of IDSWI and IM diclofenac sodium versus placebo for

reducing pain in patients with renal colic admitted to the ED. A total of 150 patients included in the study were divided into 3 groups. The outcomes of the study concluded that IDSWI and IM diclofenac significantly lowered patients' pain versus placebo [17]. In a study by Tekin et al., they analysed the efficacy of IV dextetopofen treatment and IV dextetopofen combined treatment with IDSWI in patients who were admitted to the ED with low back pain. As an outcome of the treatments delivered by randomly dividing 112 patients into 2 groups, it was determined that IDSWI plus IV dextetopofen was more practical in relieving low back pain compared to IV dextetopofen, independently [9]. Furthermore, it was observed that opioid consumption in ED and analgesic consumption within 24 h decreased in the IDSWI group. In a study conducted by Ahmednia et al. in 2004, they intended to examine the efficacy of analgesia by applying IDSWI to patients with renal colic who were admitted to ED. In their study, a total of 100 patient was randomly divided into 2 groups and IDSWI (study group) and intradermal isotonic saline (control group) were administered. The pain severity of the patients who were practised IDSWI decreased from 9.86 ± 3 to 1.02 ± 2.63 according to the VAS score. According to the results of the study, post-injection pain relief was observed in 100% of the patients who experienced IDSWI [10]. Derry et al. compared the effects of intradermal and subdermal injections of sterile water with the placebo group for pain management during labour. They found that sterile water reduces labour pain by 50–60%, and placebo reduces it by 20–25% [8].

The outcomes of this study are consistent with other studies in the literature evaluating the effectiveness of IDSWI in controlling/managing many different types of pain. In addition, it is most likely to state that it can be suggested as an important alternative treatment for the rapid control of severe renal colic pain in EDs, based on the outcome it has been revealed that IDSWI treatment can provide pain control as early as the 1st and 5th minutes.

Limitations

This study has carried some limitations. Eligibility for the study group was only possible during the researchers' active duty time. During the study, it has been taken into consideration to have a researcher at each shift. However, it may not have been achievable to evaluate the suitability of the admitted case with severe renal colic pain under crowded ED conditions. Therefore, only patients with severe pain were included in the study. With these data, it is not conceivable to comment on patients who have lower pain scores. The intradermal treatment method is ultimately an invasive procedure. Although to a certain extent, there may have been differences depending on the practitioner.

Conclusion

In this study, the consequences of IM diclofenac, IM diclofenac + IDSWI and IM diclofenac + IV fentanyl for pain palliation in patients with severe renal colic pain were compared. According to the outcomes of the study, all three methods were found to be practical in relieving pain. In addition, it was concluded that pain control could be achieved much faster with IDSWI treatment in the study group than with other methods. The rapid and safe relief of severe pain, its low cost and easy accessibility, and the absence of serious adverse side effects other than minimal local pain are the advantages of IDSWI treatment. IDSWI treatment can be used as an influential alternative treatment for rapid control of severe renal colic pain in EDs.

Author contributions MCA: conceptualisation, methodology, investigation, resources, writing—original draft, writing—review and editing, supervision, project administration. MK: conceptualisation, methodology, investigation, writing—original draft. TCÖ: methodology, investigation, writing—original draft, writing—review and editing. İÜ: investigation, writing—review and editing. RAK: writing—review and editing.

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Data availability The authors agree to the conditions of the publication including the availability of data and materials in our manuscript.

Declarations

Conflict of interest The authors declare that they have no conflicts of interest.

Ethical approval This study was approved by the Ethics Committee of Fatih Sultan Mehmet Education and Research Hospital (ethics committee ruling number: FSMEAH-KAEK 2021/10, date: 28.01.2021).

Informed consent Written informed consent was obtained from each patient.

Human rights The principles outlined in the Declaration of Helsinki have been followed.

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