Research Article

The Comparison of Analgesic Efficiency of Intravenous Tramadol and Paracetamol in Patients with Renal Colic

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Citation: Arş E, Yüksel A, Yıldırım A, Çanakçı C, Pelit ES et al. (2016) The Comparison of Analgesic Efficiency of Intravenous Tramadol and Paracetamol in Patients with Renal Colic. Emerg Med Invest 2016: 27-30.

Received: 20 May, 2016; Accepted: 7 July, 2016; Published: 21 July, 2016

Abstract

In this prospective study, it is targeted to compare the treatment efficiency of intravenous Tramadol and paracetamol treatments in relieving pain for patients who apply to emergency room because of renal colic.

Material and Methods: In this study, two groups of patients with renal colic diagnosis who applied to emergency room were included. One group (Group 1, n=50) receiving Tramadol (100 mg intravenous) treatment and another group (Group 2, n=50) that receives paracetamol (1 gr intravenous) treatment. Pain level of the patients was scored at the application and at the end of the treatment using the “Visual Analogue Scale” (VAS). In both groups, pain levels were rated between 0 (no pain) and 10 (intolerable pain). VAS scores for the groups were compared. For definitive diagnosis, “urinalysis, full abdominal CT Scan and direct urinary system graph and urinary ultrasound” were performed.

Findings: The initial VAS scores (before treatment) values were recorded as; 9.2±1.3 for Group I, and 9.7±0.8 for Group II. It is detected that, in the tenth minute, the average VAS scores measured between the groups with paracetamol and Tramadol treatment did not have a significant difference rate (p=0.502). VAS Scores in twentieth and thirtieth minutes are, in Group I; 5.3±1.4/3.04±1.6 and in Group II; 5.9±1.3 / 3.8±1.9 respectively. Pre-treatment VAS Scores between these two groups had a significant difference (p=0.044). Accordingly, score average of Tramadol-treated patients was higher with (9.7±0.8), than paracetamol-treated patients who had an average score of (9.2±1.3).

Result: Considering the findings of our study, it is seen that paracetamol shows quite good results in treatment of renal colic pain. Taking into consideration that it has less side effects than Tramadol, paracetamol can be considered a good alternative in renal colic treatment.

Keywords
Paracetamol; Renal colic; Tramadol; VAS

Introduction
Renal colic is a commonly met emergency situation frequently developing related to kidney stone disease,
diagnosed and treated in Emergency Rooms (ER), showing itself with severe pain [1]. Pain is usually seen in areas from under pants to belly area, or spreading to lower quadrant of abdomen, or even to testicles and labium. Frequently this clinical situation is accompanied by nausea, vomiting, agitations. In acute renal colic, prior treatment is to relieve the pain [2,3]. Renal colic cases are from the patient groups where pain medications are frequently used. Both NSAIDs and opioids are effective in treating renal colic. However, a Cochrane meta-analysis showed that NSAIDs are more effective than opioids in reducing the pain from renal calculi and are associated with fewer side effects when patients were assessed 30 min after drug administration [4]. Tramadol is a popular agent for treatment of pain, belongs to the group of medicines called opioid analgesics and is used to relieve moderate to moderately severe pain, including renal colic. It acts the central nervous system to relieve pain. But Tramadol can include serious side effects like seizures, mood problems, hyper sensitivity reaction. In situations where NSAIDs and Tramadol are contraindicated, medications such as paracetamol have come into question recently [5,6]. Paracetamol is amongst the most widely used analgesics in the world. It is widely prescribed in doses up to 1 gm [7,8]. Paracetamol has a lower side effects profile of nephrotoxicity and hepatotoxicity than opioids and NSAIDs in therapeutical doses.

In this study, it is aimed to compare the efficiency of pain relief in intravenous Tramadol and paracetamol treatments using Visual Analogue Scale (VAS), for patients applying to ER because of renal colic.

**Material and Methods**

After the approval from ethics committee was obtained, our study was performed on patients applying to Emergency Room prospectively. Patients above 17 years of age, who received no pain medication in the last 6 hours before admission to ER were included in the study. Patients with asthma, chronic renal failure and liver failure, and those allergic to paracetamol and Tramadol were not included. Pregnant and nursing women are also excluded from the study. In the study protocol and methods, Helsinki declaration principles were followed and approvals from all participants are obtained. Patients diagnosed with renal colic and receiving Tramadol (100 mg intravenous) treatment (Group 1, n=50) and paracetamol (1 gr intravenous) treatment (Group 2, n=50) were included in the study. The ultimate diagnosis of renal colic was confirmed using patient history file, Ultra Sonography or CT to identify the stone. Ultra Sonography was the first choice for detecting a renal stone. And CT was performed if a stone was not detected by ultrasonography. After CT, patients not having urolithiasis or found to have pathologies other than renal colic were excluded from the study. VAS scores in the beginning and in the tenth, twentieth and thirtieth minutes were calculated for the patients. VAS scores in all groups were rated between 0 (no pain) and 10 (intolerable pain) and side effects observed during the treatment were recorded.

**Statistical Analysis**

During the evaluation of the findings from the study, SPSS (Statistical Package for Social Sciences) for Windows 17.0 software (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. Along with the definitive statistical methods (Average, Standard Deviation, Frequency, Percentage), Chi-square test was also used for comparison of qualitative data, t-test for paired samples and t-test for independent samples in comparison of quantitative data during the evaluation of the study data. Results were assessed in 95% confidence interval and p<0.05 significance level.

There were no differences in age, gender and clinical properties between two groups (Table 1). Beginning VAS values (pre-treatment) for patients in ER with renal colic pain were found as 9.68±0.84 in Group I and 9.2± ±1.27 in Group II. VAS values for tenth, twentieth and thirtieth minutes were 7.48±1.32, 5.88±1.36, 3.84±1.93 for Group I and 7.26±1.81, 5.24±1.39, 3.04±1.57 for Group II respectively (Table 1).

|                | Paracetamol (n=50) | Tramadol (n=50) | p value |
|----------------|-------------------|----------------|---------|
| Age (years)    | 38.38±10.44       | 36.08±11.48    | 0.297   |
| Male/Female    | 36/14             | 33/17          | 0.517   |
| Family History | 24 (48%)          | 23 (46%)       | 0.217   |
| Stone History  | 26 (52%)          | 35 (70%)       | 0.065   |
| Starting Time  | 15.18±22.51       | 11.26±17.52    | 0.334   |
| Stay in ER (hours) | 2.3±0.5        | 2.4±0.5        | 0.144   |
| VAS (beginning) | 9.68±0.84       | 9.24±1.27      | 0.044   |
| VAS (10. min)  | 7.48±1.32         | 7.28±1.81      | 0.502   |
| VAS (20. min)  | 5.88±1.36         | 5.24±1.39      | 0.022   |
| VAS (30. min)  | 3.84±1.93         | 3.04±1.57      | 0.025   |

Table 1: Demographics of the facts and clinical measurement values.

It is detected that, there is a significant (p=0.000) decrease in VAS scores in 10th and 20th minutes, compared to the beginning score for the patients in Group 1. In comparison of VAS scores in 22th and 30th minutes with results in 10th minute, it is detected that the decrease in 20th and 30th minutes have a more significant decrease than 10th minute's (p=0.000). In comparison of VAS scores in Group 2 between 10th and 20th minutes; it is detected that the decrease in VAS scores in 10th and 20th minutes is more significant than the VAS score in the beginning (p=0.000). In comparison of VAS scores of patients for 20th and 30th minutes; it is detected that the decrease in score is more significant than the decrease in 10th minute, for 20th and 30th minutes (p=0.000) Figure1.

In DUTR and USG examinations with diagnosis purposes, no significant difference was detected in calculus and hydronephrosis existence. (Table 2)

Considering both groups, 80-85% supportive findings for diagnosis (76% in Group 1, 84% in Group 2) were detected in
Different scales are used in measurement of pain value. VAS is the most commonly used one of these scales [11,12]. For patients with renal colic pain and that have been treated with intravenous lidocaine treatment by Soleimanpour, they have found the VAS value average before treatment as 8.87±0.99 [13]. Çayan, reported that 40 patients where the efficiency of NSAIDs and spasmolytics, the average VAS value was found as 7.8 [14]. In examination of the findings of our study, VAS values of patients with renal colic were high, in compliance with the studies in the literature. In our study, besides both the groups’ the pre-treatment VAS value being high, in severe pain group (Group I: 9.24±1.27, Group II: 9.68±0.84), they had a significant difference between.

The visual analogue scale (VAS) consists of a line, usually 100 mm long, whose ends are labeled as the extremes (‘no pain’ and ‘pain as bad as it could be’); the rest of the line is blank. The patient is asked to put a mark on the line indicating their pain intensity at the 0th, 10th, 20th and 30th minutes after treatment. The distance between that mark and the origin is measured to obtain the patient’s score. Sometimes descriptive terms, such as ‘mild’, ‘moderate’ and ‘severe’, or numbers are provided along the scale for guidance [15,16].

In renal colic treatment, in studies where paracetamol and other analgesic treatments are compared, it is shown that intravenous application of paracetamol is more efficient and safer than other analgesic treatments. Contrary to these studies, Xue, have shown that sterile water injection is more efficient than paracetamol, in their studies performed on 45 pregnant patients where they have compared oral paracetamol and sterile water injection [17]. In studies of Grissa and Ayan, intravenous paracetamol and NSAIDs were compared. In these two studies, VAS scores in 30th minute were found as 48/100, 36/100 (P=0.039) and 3.73±1.93, 2.33±1.77 (p=0.002) for NSAIDs and paracetamol respectively. In both studies, it is shown that paracetamol is more efficient in renal colic treatment [17,18]. In their randomized controlled trials, Bektas and Serinken compared morphine, which is an opioid derivative and paracetamol. In a study for two groups, using paracetamol and morphine, both authors have shown that there are no statistical differences between the changes in two groups’ VAS scores in 30th minute (2 mm [CI 95% -13-16], 7.1 mm [CI 95% 18-4]). In these studies, they have reported that in renal colic treatment, paracetamol has a similar effect to morphine, which is a stronger opioid agonist than Tramadol, and paracetamol has a smaller side effects rate [19,20]. Different from these studies, in our study paracetamol is compared with Tramadol, rather than NSAIDs and morphine, but complying with these studies, VAS scores in 30th minute are in paracetamol’s favor and side effects incidence is smaller [21].

In our study, when both groups’ VAS scores for twentieth and thirtieth minutes were compared, VAS scores for paracetamol group were smaller compared with Tramadol group (p=0.022 and p=0.025, respectively). In a placebo controlled, randomized study where intravenous paracetamol and morphine were compared and 165 patients included, VAS scores in 30th minute were compared and it is shown that paracetamol decreases the VAS values as the same amount the morphine does [22].

This study has some limitations. These are limited number of patients, patients not being randomized and being performed by a single center. Some adverse events such as...
as nausea and vomiting may be due to the renal colic rather than study drugs.

Consequently, intravenous paracetamol is an effective and safe treatment in renal colic in Emergency Rooms. Intravenous paracetamol may be used as an alternative, or supportive to the existing treatments, with its low side effect profile. When we considered the results of our study, we can say ‘The Best Treatment Model for Renal Colic Is Paracetamol’.

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