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CLINICAL STUDY

Tamsulosin versus nifedipin in medical expulsive therapy for distal ureteral stones and the predictive value of Hounsfield unit in stone expulsion

Melih Balci[1], Altug Tuncel[1], Omur Aydin[2], Yilmaz Aslan[1], Ozer Guzel[1], Ugur Toprak[3], Fazli Polat[4], and Ali Atan[1]

[1]Third Department of Urology, Ministry of Health, Ankara Numune Research and Training Hospital, Ankara, Turkey, [2]Department of Urology, Ministry of Health, Dr. Ersin Arslan State Hospital, Gaziantep, Turkey, [3]Department of Radiology, Ministry of Health, Ankara Numune Research and Training Hospital, Ankara, Turkey, and [4]Department of Urology, Gazi University School of Medicine, Ankara, Turkey

Abstract

We evaluated the efficacy of tamsulosin and nifedipine in medical expulsive therapy (MET) in patients with distal ureteral stone. In addition, we tried to determine the predictive value of Hounsfield Unit (HU) of the stone in the success of MET. A total of 75 patients with a distal ureteral stone of 5–10 mm diameter were randomly divided into three groups. Group 1 ($n = 25$) received tamsulosin 0.4 mg/d; group 2 ($n = 25$) received nifedipine 10 mg/day p.o and group 3 ($n = 25$) received diclofenac sodium 50 mg p.o. when required. At the beginning of each treatment, the HU of the stone was also measured using a non-contrast computerized tomography in all the patients. The results were evaluated at week four. The mean age of the patients was 36.8 (range, 16–68) years. Stone expulsion was observed in 19 (76%) patients in group 1, 16 (64%) patients in group 2 and 9 (36%) patients in group 3 ($p_{group1\text{-}3} = 0.004$, $p_{group2\text{-}3} = 0.048$ and $p_{group1\text{-}2} = 0.355$). The mean expulsion time was 9, 9.1 and 10.3 d, respectively ($p_{group1\text{-}3} < 0.001$, $p_{group2\text{-}3} < 0.001$ and $p_{group1\text{-}2} = 0.619$). The mean diclofenac sodium dose per patient was 544, 602 and 1408 mg in groups 1, 2 and 3, respectively ($p_{group1\text{-}3} < 0.001$, $p_{group2\text{-}3} < 0.001$ and $p_{group1\text{-}2} = 0.977$). The mean HU of the stone in patients with and without a successful MET was 363 and 389, respectively ($p = 0.462$). Our results showed that MET with both nifedipine and tamsulosin provided a similar increase in the expulsion rate for distal ureteral stones. HU does not seem to be a predictive parameter for stone expulsion.

Keywords

Hounsfield unit, nifedipine, tamsulosin, treatment, urolithiasis

History

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Introduction

In Europe and North America 8–15% of people suffer from urolithiasis in a certain period of their lives.[1] Renal colic is one of the most severe types of abdominal pain one can experience and generally occurs due to ureteral stones, and it is a common issue with over one million emergency admissions per year.[2] Therefore, renal colic treatment constitutes an important part of our daily urological practice. Alternatives to surgery for the treatment of ureteral stones are conservative follow up and watchful waiting.[3] The efficiency of the minimal invasive techniques, such as extracorporeal shock wave lithotripsy (ESWL) and ureterorenoscopy (URS) are shown in several studies.[4–7] Nevertheless, these techniques are not totally risk-free and they are not cost-effective treatment options. Thus, conservative treatment is an attractive alternative to invasive procedures for many patients. As a conservative approach, medical expulsive therapy (MET) is an alternative to ESWL and URS since it is non-invasive, easy and cost-effective. Several studies have reported an increase in the rate of stone expulsion, shortened expulsion times and a decrease in analgesic consumption.[8–11] Tamsulosin, doxazosin, alfuzosin, silodosin, nifedipine and naftopidil are the most commonly used drugs in MET.[8,10,12]

In this study, we compared the efficacy of tamsulosin and nifedipine in MET for distal ureteral stones in patients with renal colic. In addition, during these treatment modalities, we evaluated the value of Hounsfield Unit (HU) of the stone detected in a non-contrast computerized tomography (NCCT) in the prediction of MET success rate.

Materials and methods

A total of 75 patients who were referred from the hospital's emergency department to our clinic between January 2010 and February 2011 due to acute renal colic were included in this study. All the patients were evaluated using the results of physical examination, serum creatinine measurement, urine analysis, plain X-ray, abdominal ultrasonography and NCCT.

NCTT examination was performed using a Hitachi Radix Turbo scanner (Kashiwa, Chiba, Japan). No oral contrast

Address correspondence to Dr. Altug Tuncel, Third Department of Urology, Ministry of Health, Ankara Numune Research and Training Hospital, 06120, Sihhiye, Ankara, Turkey. Tel: + 90 555 331 33 93; Fax: + 90 312 310 34 60; E-mail: tuncelaltug@yahoo.com

agent was administered. Scanning parameters were as follows; 120 kVp, 175 mAs and one revolution/s gantry rotation speed. After obtaining scan projection radiography, unenhanced CT was performed to identify urinary stones. A collimation of 3 mm, a table speed of 3 mm per revolution and an image reconstruction interval of 3 mm were used. A region of interest was drawn around the edge of stones in each slice. The HU measurement of each pixel in the affected area was performed by our radiologist. The maximum value of HU was accepted as the main HU value of the stone.

All patients received intramuscular diclofenac sodium as part of their first-line treatment for painful manifestations. The population of our study was composed of patients with stones of 5–10 mm diameter in the one-third lower part of the ureter (below the common iliac vessels). Exclusion criteria were as follows: the proximal or intramural part of ureteral stone, active urinary tract infection, ureterohydronephrosis, acute renal failure, fever, multiple ureteral stones, a history of surgery or endoscopic procedures for urolithiasis, chronic renal failure, diabetes mellitus, peptic ulcer, concomitant treatment with α-blocker and β-blocker, calcium antagonists or nitrates, pregnancy, lactation or patient desire for immediate stone removal. Patients provided a written informed consent at the time of enrolment. The study protocol was approved by the local ethics committee (2009/56).

Randomization was performed using the Power Analysis & Sample Size Software (PASS®) for Windows (NCSS Inc., Kaysville, UT). According to the software, the patients were randomly assigned to one of the following three groups; group 1 ($n = 25$) received 0.4 mg tamsulosin (Flomax, Boehringer Ingelheim Ilac Tic. A.S, Istanbul, Turkey) p.o. once a day; group 2 ($n = 25$) received 30 mg nifedipine (Adalat Crono, Bayer Turk Kimya Ltd. Sti, Istanbul, Turkey) p.o. once a day and group 3 ($n = 25$) was used as the control group and received only symptomatic therapy with 50 mg diclofenac sodium (Voltaren, Novartis Saglik Gida A.S, Istanbul, Turkey) p.o. All participants were encouraged to maintain a water intake of 2–2.5 L/day. Diclofenac sodium 50 mg p.o. was prescribed for patients when required. The treatment period lasted 28 days or until stone expulsion in all three groups. All the patients were advised to filter their urine and were asked to stop taking their medication if they passed their stones in the course of treatment.

At our outpatient clinic, all the patients were evaluated every seven days using the results of physical examination, abdominal ultrasonography and serum creatinine measurement. NCCT was performed on days 14 and 28. During the follow-up visits, patients were asked whether they had suffered from any acute episodes of renal colic and the side effects of the drugs. The overall diclofenac sodium consumption and frequency of pain relief medications were also recorded. The absence of expulsion after four weeks was considered to be a sign of therapy failure. ESWL or URS was performed on these patients.

In this study, the primary endpoint was the overall stone expulsion rate and the HU of stones. The secondary endpoints were the expulsion time, the rate of pain relief therapy, the mean analgesic consumption for the recurrence of renal colic and the incidence of adverse effects.

Statistical analysis

Statistical analyses were performed using the Statistical Packet for Social Sciences version 13.0 for Windows (SPSS Inc., Chicago, IL). One-way ANOVA and chi-square test were used to compare parameters between the groups. A p value less than 0.05 was considered significant.

Results

The mean age of the patients was 36.8 ± 11.3 (range: 16–68) years. There were no statistically significant differences between the groups in terms of age, gender, stone size and HU of ureteral stones (Table 1).

Stone expulsion occurred in 19 (76%), 16 (64%) and 9 (36%) patients in groups 1, 2 and 3, respectively. Groups 1 and 2 showed a significantly higher rate of expulsion when compared with group 3 (group 1 vs. 3 $p = 0.004$; Group 2 vs. 3 $p = 0.048$). On the contrary, no significant difference was found between the groups 1 and 2 ($p = 0.355$). Stone expulsion was more rapid in groups 1 and 2 than in group 3. However, no statistically significant difference was observed in expulsion time between the groups ($p = 0.619$). The decrease in the dose of analgesic used by groups 1 and 2 was statistically significant compared with group 3 ($p < 0.001$). In addition, no statistically significant difference was observed in the dose of analgesic between the groups 1 and 2 ($p = 0.977$). The results of the treatments are listed in Table 2.

In tamsulosin and nifedipine groups, the success rate of treatment was similar in females and males ($p_{tamsulosin} = 0.557$, $p_{nifedipine} = 0.393$).

The frequency of the observed adverse effects was not different between the groups ($p = 0.807$). Two patients in group 1 had dizziness, one patient in group 2 had dyspepsia while another one in the same group had diarrhea, and one patient in group 3 had dyspepsia. None of the patients withdrew from the study due to adverse effects. Adverse effects are listed in Table 2.

Table 1. Demographic characteristics of the patients.

Parameters	Group 1 ($n = 25$)	Group 2 ($n = 25$)	Group 3 ($n = 25$)	p Value
Age (year)	39.5 ± 12.1	36.4 ± 11.5	34.5 ± 10.2	0.292*
Gender (Male/Female)	18/7	17/8	18/7	0.938*
Stone diameter (mm)	7.1 ± 1.5	6.4 ± 1.1	6.3 ± 1.5	0.099*
Hounsfield unit	377.4 ± 135.9	368 ± 153.9	378.6 ± 166.7	0.965*

Notes: Data presented as mean ± standard deviation.
*One-way ANOVA test.

Table 2. Results.

Parameters	Group 1 ($n = 25$)	Group 2 (n = 25)	Group 3 (n = 25)	p Value
Stone expulsion rate (%/*n*)	76/19	64/16	36/9	0.013*
Stone expulsion time (d)	9	9.1	10.3	0.619**
Analgesic use (mg)	544 ± 493	602 ± 434	1408 ± 622	<0.001**
Adverse effect (%/*n*)	8/2	8/2	4/1	0.807*

Notes: Data presented as mean ± standard deviation.
*One-way ANOVA test.
**Chi-square test.

The mean HU of the ureteral stone in patients with and without a successful MET was 363 ± 161 (range: 148–759) and 389 ± 136 (range: 225–700), respectively ($p = 0.462$).

Discussion

The possibility of spontaneous ureteral stone expulsion depends on several factors; such as the diameter and location of the stone, possible ureteral strictures and a history of spontaneous expulsion. The factors that cause stone retention and can be modified are spasm, edema and infection.[9] The main objective of conservative treatment is to prevent the factors that can be modified and to control the pain until the expulsion.

Nifedipine, which is a calcium channel blocker, inhibits calcium entry in cells and prostaglandin synthesis. As a result, it blocks spontaneous rhythmic contractions in human ureter.[10] α_1 adrenergic receptor blockers inhibit α_1 adrenergic receptors located on the smooth muscle of the ureter and they also block ureteral contraction, decrease its basal tonus and the frequency of the ureteral peristaltism.[11] As mentioned above, the results of this study are supported by a previous study that detected the effect of tamsulosin and nifedipine on ureteral contraction, frequency, pressure and speed using a ureteral pressure transducer.[13]

Nifedipine was used in 1994 as the first MET drug.[14] In that randomized, double-blind, placebo-controlled study, 40 mg nifedipine and 16 mg methylprednisolone were orally administered to patients with 15 mm or smaller ureteral stones. The success rate was reported to be 87%, and the expulsion time was reported to be 11.2 days. The authors concluded that the combination of nifedipine and methylprednisolone was effective in facilitating the ureteral stone passage. In a study by Porpiglia et al., 96 patients were randomized into two groups; 30 mg nifedipine and 30 mg/day deflazacort p.o. The treatment increased the expulsion rate in 10 mm or smaller distal ureteral stones compared with the control group (79% vs. 35%, $p < 0.05$). The treatment also shortened the expulsion time (7 vs. 20 days, $p < 0.05$), reduced analgesic requirement (15 mg vs. 105 mg, $p < 0.05$) and was reported to be effective and reliable.[15]

Since the first report on tamsulosin in 2002,[11] it has become a commonly used agent for MET.[9,11,16–19] In a randomized double blind study consisting of 104 patients with stones located in the lower ureter, the expulsion rate was 80.4% in the 0.4 mg tamsulosin group and 62.8% in the control group. The authors concluded that α_1 adrenergic receptor blockers potentiated the spasmo-analgesic action of drugs used in standard methods of treatment.[11] Kupeli et al. reported their experience with the addition of tamsulosin to medical therapy or to ESWL in the treatment of lower ureteral stones.[16] Kupeli et al., randomized 78 patients who had lower ureteral stones into four groups and reevaluated all patients after two weeks. The first group consisted of 30 patients with stones less than 5 mm in size (range: 3–5), who were randomly divided into two subgroups. The difference in the stone-free rates of the tamsulosin 0.4 mg daily and the control group was statistically significant (53.3% and 20%). The second two groups consisted of 48 patients with stones of larger than 5 mm (range: 6–15) who underwent ESWL. The difference between the ESWL plus tamsulosin 0.4 mg daily group and ESWL group in terms of the stone-free rates was statistically significant (70.8% vs. 33.3%). The authors concluded that the addition of tamsulosin to conventional treatment seemed to be beneficial in terms of clearance of lower ureteral stones, and this effect was more evident in larger stones, especially when combined with ESWL. In another study involving 100 patients with stones of ≤ 10 mm (51 of them ≤ 5 mm) located below the common iliac vessels, patients were followed up until the passage of the stone, or for a maximum of four weeks, and the expulsion rate was reported to be 82% in the 0.4 mg tamsulosin group and 61% in the placebo group ($p = 0.02$).[18] The expulsion time was 6.4 days in the tamsulosin group and 9.8 days in the placebo group, and the amount of analgesic agent used was 67.5 mg and 127.2 mg in the tamsulosin and placebo groups, respectively. In the tamsulosin group, side effects developed in 9 of 50 patients. The authors concluded that tamsulosin is a safe and effective drug that enhances the spontaneous passage of distal ureteral stones 10 mm or smaller in size. Recently, two meta-analyses have been published that evaluated the efficacy of tamsulosin in MET. In the first meta-analysis, Lu et al. identified 29 clinical trials, working with 2.763 patients (1.051 tamsulosin 0.4 mg/day, 145 tamsulosin 0.2 mg/day and 1.567 control) with upper and lower part of ureteral stones.[20] The authors reported a 19% improvement in stone clearance with tamsulosin. They concluded that tamsulosin has become a safe and effective MET choice for ureteral stones. The authors also recommended that tamsulosin should be the first recommendation for most patients with distal ureteral stones when the stone size is less than 10 mm. In the second meta-analysis performed by Fan et al., 20 randomized clinical trials were assessed after the use of tamsulosin for the treatment of upper and lower part of ureteral stones.[21] At the time of treatment, 799 patients were randomly assigned to the tamsulosin group and 794 patients to the control group. Compared with the control group, the tamsulosin group had an increased expulsion rate of 51% and a decreased expulsion time of 2.6 days. Furthermore, tamsulosin was found to have reduced the risk of ureteral colic by 40% during treatment, and the risk of requirement of auxiliary procedures was also reduced by 60% during follow up. The authors concluded that tamsulosin facilitated the expulsion of ureteral calculi by providing a higher expulsion rate, a shorter expulsion time, a lower incidence of ureteral colic during treatment and a lower requirement of auxiliary procedures.

There are a few studies in the international literature comparing the efficacy of nifedipine and tamsulosin in MET. Porpiglia et al. compared nifedipine 30 mg/d plus deflazacort 10 mg/d and tamsulosin 0.4 mg/d plus deflazacort 10 mg/d treatments with the control group in 86 patients with stones of less than 10 mm located in the lower ureter.[22] Expulsion was observed in 24 of 30 patients in the nifedipine group (80%), 24 of 28 in the tamsulosin group (85%) and 12 of 28 in the control groups (43%). The average expulsion time for the nifedipine, tamsulosin and control groups was found to be 9.3, 7.7 and 12 days, respectively. The authors claimed that medical treatments with nifedipine and tamsulosin combined with deflazacort proved to be safe and effective as demonstrated by the low incidence of side effects and the increased

expulsion rate. In a multicenter prospective randomized trial, the authors compared nifedipine 30 mg/d with tamsulosin 0.4 mg/d for distal ureteral stones at the size of 4–7 mm and obtained a stone-free rate of 73.51% for nifedipine and 95.86% for tamsulosin ($p < 0.01$).[23] They concluded that tamsulosin should be offered as a first-line drug for MET.

In this study, the stone expulsion rate in tamsulosin, nifedipine and control groups was found to be 76%, 64% and 36%, respectively. Tamsulosin and nifedipine both had a significantly higher expulsion rate compared with the control group. Tamsulosin had a higher expulsion rate compared with nifedipine, but the difference was not statistically significant. In tamsulosin and nifedipine, the expulsion time was shorter, and the mean analgesic consumption was lower than that of the control group, but there was no difference between tamsulosin and nifedipine. Our results are also consistent with the results of these international studies.

To our knowledge, the use of HU in the prediction of MET success rate has been described only in one study. In this recent study, 44 patients with a 5–10 mm distal ureteral stone were divided into two groups.[24] Group 1 consisted of 18 patients (43.9%) who passed stones after MET. Group 2 comprised 23 patients (56.1%) with no stone passage after MET. In group 1, the mean stone size was 7.7 mm and the mean HU was 507. In group 2, the mean stone size was 8.25 mm and the mean HU was 625. Although the HU value in group 2 was higher than in group 1, there was no statistically significant difference ($p = 0.85$). The authors concluded that the HU value cannot be used to predict the chances of success for MET. In our study, in patients that received MET, HU was found to have no statistically significant additional contribution to the prediction of distal ureteral stone expulsion.

MET is advantageous in that the risks associated with surgical intervention are not present. Moreover, MET with tamsulosin or nifedipine is a cost-effective strategy for the management of ureteral stones. Bensalah et al. found that MET is more cost-effective because it obviates the need for URS, which is 170 times more costly than medication.[25] In our country, a box of tamsulosin (for one month treatment) costs $11.5, and a box of nifedipine (for one month treatment) costs $7.6, and MET is the most cost-effective approach for ureteral stones with an $320 benefit over URS and $140 benefit over ESWL.

Finally, our results showed that MET with either nifedipine or tamsulosin provided an increased expulsion rate with low adverse effect rates for distal ureteral stones. However, HU does not seem to be a predictive parameter for stone expulsion. The small number of patients and the absence of upper ureteral stones can be considered as the limitations of our study.

Declaration of interest

The authors report no conflicts of interest.

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