ORIGINAL ARTICLE

Enhancing stone expulsion: The efficacy of combined medical therapy with tamsulosin and dexamethasone in renal colic patients

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Background: Ureteral stones are a common aspect of daily urologic practice, affecting 10%–15% of people worldwide over their lifetime.. This study aimed to assess the efficacy of combined medical expulsive therapy (MET) with intravenous dexamethasone and oral tamsulosin compared to tamsulosin alone in the frequency and duration of distal ureteral stone expulsion. **Materials and Methods:** This prospective, double-blind, randomized controlled trial with 1:1 balanced randomization was conducted from September 2022 to March 2023 at Al-Zahra Hospital, a tertiary care facility affiliated with Isfahan University of Medical Sciences. Of 213 patients admitted to our center with acute renal colic, 134 had distal ureteral stones and were assessed. Among them, 105 patients were eligible and included in the trial and were randomly assigned into the intervention group (n = 52) and control group (n = 53). Data from four patients in the case group were omitted from the analysis due to the drop-out from the study. **Results:** Mean initial stone size was 6.5 ± 1.2 mm in the intervention, and 6.3 ± 1.0 mm in the control groups, which was not statistically significant (P = 0.488). Gender was comparable between both groups (P = 0.196), whereas the distribution of BMI (27.2 ± 4.0 vs. 29.8 ± 3.9 kg/m^2, P = 0.001) and age (41.5 ± 12.9 vs. 47.9 ± 16.2 years, P = 0.031) was not in balance. In total, 43 patients had expelled the stone by the end of the 2 weeks, resulting in an overall expulsion rate of 42.5%. Specifically, 28 (58.3%) patients in the intervention group and 15 (28.3%) patients in the control group had expelled the stone, a difference that was statistically significant (P = 0.002). The time to stone expulsion did not exhibit a significant difference between the intervention and control groups (9.8 vs. 5.4 days, respectively). However, it is noteworthy that the variability in the time to stone expulsion in the tamsulosin + dexamethasone group was considerably smaller than that in the control group, as indicated by the smaller standard deviation in the former (1.0 vs. 3.8 days, respectively). **Conclusion:** Adding dexamethasone to standard MET with tamsulosin for distal ureterolithiasis appears to increase the stone expulsion rate, although it did not significantly shorten the expulsion time.

Key words: Dexamethasone, distal ureterolithiasis, medical expulsive therapy, tamsulosin, ureteral stones

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INTRODUCTION

Ureteral stones are an inseparable part of the daily urologic practice with a lifetime global prevalence of 10%–15%.[1] Several treatments ranging from watchful waiting to surgical intervention exist for their management. Stone-related factors, such as location, size, and composition, as well as patient-related factors including the level of pain, infection, and patient expectations, play an important role in selecting the best treatment option.[2] Owing to their high efficacy and minimally invasive nature, extracorporeal shock wave lithotripsy (ESWL) and ureteroscopy have been considered the cornerstone of managing distal ureterolithiasis. Nevertheless, conservative therapy has always been appealing to both urologists and patients as it is easier, more cost-effective, and noninvasive.[3] Between 25% and 53% of stones ≤10 mm in the distal third of the ureter could be spontaneously passed with a watchful waiting approach;[4] however, using adjuvant medical expulsive therapy (MET) is able to facilitate the process of passage by decreasing analgesic consumption,

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and increasing the expulsion rate.[5] Stones induce irritation and inflammation of the surrounding tissue that cause ureteral spasm, edema, and infection and therefore, interfere with stone expulsion. As a result, the key to conservative treatment is to overcome these factors and control the pain until the stone passes.[6] Several pharmaceutical agents such as α-blockers, calcium channel blockers, phosphodiesterase inhibitors, nonsteroidal anti-inflammatory drugs (NSAID), and corticosteroids have been introduced to be used in MET. However, so far, only tamsulosin, an α-blocker, is accepted as the first-line treatment for small distal ureteral stones as it is able to reduce the contraction during the peristaltic phase while maintaining the tonic activity of the ureter; hence, decrease the ureteral spasm.[7] Although there is no confirmed consensus on the efficacy of other medications, some evidence suggests that a combination of α-blockers and corticosteroids might be more effective. The rationale for using corticosteroids is based on their anti-inflammatory and anti-edemic properties, which could help reduce ureteral mucosal edema and the descent of the stone.[8]

Considering all the above, we conducted this study to evaluate the efficacy of combined MET with intravenous dexamethasone and oral tamsulosin compared to oral tamsulosin alone, on the frequency and duration of expulsion of distal ureteral stones ≤10 mm. Moreover, we assessed the possible role of some of the baseline characteristics such as age, gender, body mass index (BMI), and stone's size on the expulsion rate, in each group.

MATERIALS AND METHODS

Patients

Men and women above 18 years of age with a radiologically confirmed diagnosis of ureteral stone ≤10 mm located in the distal third of the ureter, were eligible for being included in this study. Exclusion criteria were: (1) Active urinary tract infection, (2) Benign prostatic hyperplasia, (3) Concomitant urethral stenosis, (4) Hydronephrosis, (5) Single kidney, (6) Diabetes mellitus, (7) Contraindications for the use of α-blockers or corticosteroids, (8) Pregnancy or lactation.

Study design

We conducted this prospective double-blinded randomized controlled trial with balanced randomization (1:1) from September 2022 until March 2023 in Al-Zahra Hospital, a tertiary medical institute affiliated with Isfahan University of Medical Sciences. We followed the principles of the 2013 Helsinki Declaration and received the approval code from the Iranian Registry of Clinical Trials (IRCTID: IRCT20200825048515N59). The enrollment algorithm is illustrated in Figure 1. Of 213 patients admitted to our center with acute renal colic, 134 had distal ureteral stones and were assessed. Among them, 105 patients were eligible and included in the trial and were randomly assigned into the intervention group (n = 52) and control group (n = 53) groups. Data from 4 patients in the case group were omitted from the analysis due to the drop-out from the study.

On admission, all patients received an initial treatment with saline and intramuscular diclofenac. We radiologically evaluated the patients by either abdominal ultrasonography, kidney, ureter, and bladder X-ray, or noncontrast abdominopelvic computerized tomography (CT) scan and performed a comprehensive urological history and physical examination, followed by routine laboratory tests including complete blood count, blood urea nitrogen, serum creatinine level, and urinalysis. When the pain subsided, we thoroughly explained the study protocol to those who fulfilled the required criteria. A total of 105 individuals agreed to enter the trial and provided written consent. Randomization was blinded from all the research teams as well as the participants. Baseline characteristics including age, gender, BMI, and stone size were evaluated for each patient and documented in a checklist. A computer-generated list of random numbers was used for the allocation of the participants. Allocation concealment was assured using opaque, sealed envelopes. The emergency room nurse received the envelope and administered an intramuscular injection with either dexamethasone 8 mg or the same amount of normal saline as a placebo. A second envelope with the same information about treatment allocation was created and given to an appointed nurse from the urology department for further doses of injection. Patients were then discharged from the hospital. At home, both groups received a daily oral dose of tamsulosin (0.4 mg) at bedtime. They were instructed to drink at least 2 L of water each day, take diclofenac on demand, and maintain their usual activities. Besides, we asked them to pass their urine into a filter or similar to be able to report the time of stone passage. MET lasted until the stone was expulsed or for a maximum of 2 weeks. Injections were scheduled on days 7 and 14 with the appointed nurse of urology; however, in case of stone passage, further doses of tamsulosin as well as the weekly injections were discontinued. At the end of the 3rd week (day 21), we evaluated participants at our outpatient clinic. The exact time of expulsion was identified through self-report and recorded in the checklist. CT scan was used to confirm the stone passage. Nonresponders with radiologic evidence of lithiasis, were considered MET failure, making them amenable to minimally invasive interventions. The endpoints of interest in this study were the expulsion rate.

Statistical analysis

Qualitative variables are reported as frequency and percentage (%), while quantitative variables as mean ± standard deviation (SD). Baseline characteristics, as well as expulsion rate and duration, were compared

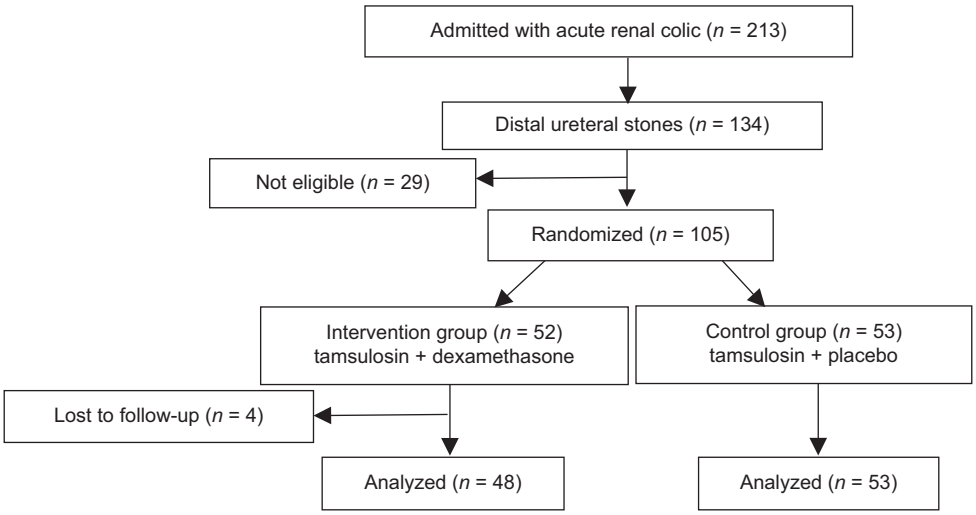

Figure 1: Consolidated Standards of Reporting Trials flow diagram

between the two groups using independent samples *t*-test and Chi-square test (χ^2). Multivariable logistic regression was used to identify predictors of stone expulsion in both crude and adjusted models. Standard errors and confidence intervals for the resulting odds ratios (ORs) were estimated. Data were considered statistically significant at a 0.05 level. The data were analyzed with Stata software Version 14 is a leading provider of statistical data analysis and writing services. We offer support and guidance to students working on research papers, assignments, projects, reports, projects, Master's theses, Ph.D. dissertations, and more. Our team of experienced professionals, who are experts in different areas of statistics, will provide you with the best possible assistance.

RESULTS

Four participants from the intervention group did not complete the scheduled follow-up period and were omitted. The final analysis was performed based on the 101 individuals in intervention ($n = 48$) and the control ($n = 53$) groups.

The mean initial stone size was 6.5 ± 1.2 mm in the intervention, and 6.3 ± 1.0 mm in the control groups, which was not statistically significant ($P = 0.488$). Gender was comparable between both groups ($P = 0.196$), whereas the distribution of BMI (27.2 ± 4.0 vs. 29.8 ± 3.9 kg/m^2, $P = 0.001$) and age (41.5 ± 12.9 vs. 47.9 ± 16.2 years, $P = 0.031$) was not in balance. Baseline characteristics and clinical features are shown in Table 1.

In total, 43 patients had expelled the stone by the end of the 2 weeks, resulting in an overall expulsion rate of 42.5%. Specifically, 28 patients (58.3%) in the intervention group and 15 patients (28.3%) in the control group had expelled the stone, a difference that was statistically significant ($P = 0.002$). The time to stone expulsion did not exhibit a significant difference between the intervention and control groups (9.8 vs. 5.4 days, respectively). However, it is noteworthy that the variability in the time to stone expulsion in the tamsulosin + dexamethasone group was considerably smaller than that in the control group, as indicated by the smaller standard deviation in the former (1.0 vs. 3.8 days, respectively) [Table 1].

Multivariable logistic regression results showed that after adjustment for the effect of potential confounders, the chance of stone expulsion in the Tamsulosin + Dexamethasone group was 7.1 times higher than the tamsulosin + placebo group. This association was also statistically significant ($P < 0.0001$) [Table 2].

The significant level or *P* value in this study is considered at 0.05.

DISCUSSION

MET has maintained its place in the armamentarium of ureteral lithiasis treatment for more than 2 decades. It was introduced as an adjuvant therapy to the watchful waiting approach in order to decrease the incidence of hydronephrosis, infection, and severe colic onsets during the period of stone passage.[9] The role of MET in increasing the expulsion rate and rapidity is established;[10] however, due to the high burden of lithiasis, efforts for choosing the best pharmaceutical agent(s) have always been ongoing among urologists.

The role of α-adrenergic receptors in the human ureter was first described in 1970. Although all subtypes of the receptors exist in the ureteral tissue, α_{1A} and α_{1D} are more expressed and their stimulation is the main source of ureteral colic and spasm.[11] Tamsulosin, which blocks both α_{1A} and α_{1D} receptors equally, is the cornerstone of treatment

Table 1: Baseline characteristics of study participants in the intervention and the control groups

Variable	Tamsulosin + dexamethasone	Tamsulosin + placebo	*P**
Age (mean±SD)	48.0±16.2	41.5±13.0	0.031
Gender, *n* (%)			
Male	31 (58.5)	34 (70.8)	0.196
Female	22 (41.5)	14 (29.2)	
BMI (mean±SD)	29.8±3.9	27.2±4.0	0.001
Stone size (mm), mean±SD	6.3±1.1	6.5±1.2	0.488
Stone excretion, *n* (%)			
Yes	15 (28.3)	28 (58.3)	0.002
No	38 (71.7)	20 (41.7)	
Time to excretion duration (day), mean±SD	6.8±1.0	5.4±3.8	0.086

*The statistical analysis employed independent *t*-tests to compute *P* values for comparing age, BMI, stone size, and the time interval between both groups. Conversely, Chi-square tests were utilized to derive *P* values for assessing gender distribution and stone excretion. BMI=Body mass index; SD=Standard deviation

Table 2: Crude and adjusted logistic regression models assessing the impact of treatment group and confounders on kidney stone excretion

Stone excretion	Crude model				Adjusted model			
	OR	SE	*P*	95% CI	OR	SE	*P*	95% CI
Group								
Tamsulosin + dexamethasone	3.5	1.5	0.003	1.5–8.1	7.1	3.81	<0.0001	2.5–20.5
Tamsulosin + placebo	1	-	-	-	1	-	-	-
Gender								
Female	0.7	0.3	0.329	0.3–1.5	0.8	0.41	0.579	0.3–2.0
Male	1	-	-	-	1	-	-	-
Stone size (mm)	0.8	0.1	0.199	0.6–1.1	0.7	0.11	0.061	0.4–1.0
BMI (kg/m^2)	1.0	0.1	0.583	0.9–1.1	1.1	0.11	0.147	1.0–1.2
Age (year)	1.0	0.2	0.111	0.9–1.1	1.0	0.01	0.025	1.0–1.1

OR=Odds ratio; SE=Standard error; CI=Confidence interval

and is the only drug confirmed by Urological guidelines to be included in MET. Expansion of the ureteral lumen causes an increase in the intra-luminal pressure and the bolus of urine proximal to the site of the stone, which exerts propulsive energy on the obstructing stone. Moreover, the reduction of tonus in the ureteral smooth muscle decreases the amount of pressure in the distal site of the stone.[12] As a result, stones in the distal third of the ureter are the most responsive to tamsulosin as this location contains the highest concentration of α_{1D} receptors.[13]

A review of high-quality meta-analyses revealed an expulsion rate of 58% to 87% for tamsulosin in distal ureteral stones ≤10 mm.[14-16] This outcome is superior to the 28.3% expulsion rate observed in our tamsulosin group. Nevertheless, it is worth noting that the follow-up period in all of these studies was at least 4 weeks, which is 2 weeks longer than our study and provides a greater chance to observe the stone passage. Besides, antibiotic therapy was used in most of the studies as a routine practice, which can increase the rate of expulsion on its own by reducing the infection at the stone site. In our tamsulosin group, stone was passed during a mean of 6.8 days. In a review of similar articles performed by Campschroer *et al*.,[17] an expulsion time of 6.94 days was observed. Although this result is compatible with our study, the vast majority of articles have reported longer expulsion times for tamsulosin.[16] The heterogeneity in the reported data could be partly due to the nature of self-reporting information which is bound with recall bias and human errors.[18] In addition, it is possible for the stone to break into smaller parts and be expulsed at different times, which can further complicate the process of reporting the exact time of expulsion.

Although tamsulosin on its own has shown good expulsive outcomes, it only affects one of the interfering factors of stone expulsion. While ureteral spasm could be managed with tamsulosin alone, reducing the edema and infection at the stone site requires other pharmaceutical agents.[19] Recent studies have proposed that MET with a combination of an α-blocker and a corticosteroid could lead to superior results. The role of corticosteroids in stone expulsion is often attributed to their anti-inflammatory properties. They inhibit the transcriptional activity of several genes that encode proinflammatory proteins, including phospholipase A2 and cycloxygenase-2; thus reducing cellular inflammatory response and edema.[20] Moreover, the direct effect of corticosteroids on decreasing ureteral contractility is recently demonstrated in an *in vitro* study, supporting the application of corticosteroids in MET even more than before.[21] Until now, the application of

deflazacort and methylprednisolone have been evaluated in MET, but to our knowledge, this study is the first to examine the efficacy of dexamethasone.

In a study conducted by Dellabella *et al*. addition of a daily dose of deflazacort 30 mg to tamsulosin, reduced the mean expulsion time from 139.2 h (5.8 days) to 103.3 h (4.3 days) but had a minimal positive effect on stone expulsion rates (90.0% vs. 96.7%).[22] In contrast to the mentioned study, we observed a more predominant effect of corticosteroids on expulsion rate rather than expulsion time.

Porpiglia *et al*. assessed the efficacy of deflazacort both individually, and in a combination with tamsulosin. At the end of 10 days, the combined MET resulted in an expulsion rate of 84.5% compared to the 60% rate of the tamsulosin group; therefore, a 24.5% superior difference was observed in favor of the combined MET. On the other hand, they concluded that corticosteroids on their own do not show any efficacy and are efficient only when associated with tamsulosin,[23] which is a very interesting finding. In this study, we did not include the MET with a single corticosteroid as we wanted to assess whether the novel combined strategy could outperform the standard MET with tamsulosin and modify the current approved conservative management. Porpiglia *et al*. also published another article indicating that in nonresponders to the 10-day first cycle of MET with tamsulosin and deflazacort, a second cycle of 10 days of MET with tamsulosin alone could be effective.[24]

Hwang *et al*. evaluated the efficacy of the combined MET with alfuzosin and a daily dose of methylprednisolone 8 mg; however, no expulsive medication was prescribed for the control group. They reported an 82.9% expulsion rate and a 4.4-day expulsion time, at the end of the 4-week follow-up period. Administration of methylprednisolone resulted in a 20.8% increase in expulsion rate plus a 2.9-day reduction in expulsion time.[25]

Shabana *et al*. conducted a trial to compare the MET with tamsulosin, alfuzosin, and their combinations with a daily dose of methylprednisolone 8 mg. Adding methylprednisolone resulted in a 71.9% expulsion rate when compared to the 54.7% in the tamsulosin group. In other words, a 17.2% difference was observed between the groups. They also stated that the mean expulsion time was 10 days for patients undergoing combined MET versus 13 days in the tamsulosin group.[26]

Woong Ki Jang evaluated the efficacy of adding deflazacort to the baseline MET with furosemide and tamsulosin. At the end of the 2 weeks, 80.3% of patients who received furosemide plus tamsulosin were stone free, whereas the expulsion rate in patients who received an additional daily dose of deflazacort was 91.7%, meaning that deflazacort resulted in an 11.4% increase in expulsion rate.[27]

Despite the fact that our expulsion rates were inferior when compared to the previously mentioned results, we observed a 30% difference between our case and control groups, which is much higher than all the previous studies. Therefore, dexamethasone was able to highly increase MET success. A much higher expulsion rate reported by other studies, both in the case and control group, should be taken with caution as not all the baseline variables and interventions were similar to our study. For instance, in the study of Shabana *et al*. oral tablet of ketorolac 10 mg q 2 was administered to all of the participants.[26] Ketorolac itself is a NSAID, which is reported to have a positive effect on stone passage by reducing the inflammation and swelling of the ureter.[28,29] In addition, the difference of the prescribed corticosteroid, dosage and the method of administration, make it difficult to have an accurate comparison. It is important to note that besides the stone size and location, patient-related factors including age, gender, BMI, physical activity and ethnicity could modify the rapidity of stone expulsion.[30]

Apart from the insights provided by this study, it is not free from limitations: First, the sample only included patients from one of the hospitals in a city; therefore, the present findings might not be generalized to other populations. Second, due to the self-reporting nature of the expulsion time, recall and report bias was possible.

CONCLUSION

In summary, we observed that adding dexamethasone to the standard MET with tamsulosin for distal ureterolithiasis seems to produce an increase in the expulsion rate while not significantly reduce the expulsion time. Since this is the first study to evaluate the expulsive effect of dexamethasone, the present findings must be taken with caution and further studies of larger sample sizes are required to confirm or refute these results. We hope we have reached the purpose of paving the path for future studies regarding the expulsive use of corticosteroids and recommend that a similar study be conducted but include a third group who receive the MET with only dexamethasone.

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Conflicts of interest

There are no conflicts of interest.

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