

EFFICACY AND SAFETY OF MEDICAL EXPULSIVE THERAPY WITH ALPHA BLOCKER (TAMSULOSIN) IN DISTAL URETERIC CALCULI

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DOI: <https://doi.org/10.5281/zenodo.15152094>

Keywords

Tamsulosin, ureteric calculi, medical expulsive therapy, alpha-blocker.

Article History

Received on 25 February 2025

Accepted on 25 March 2025

Published on 04 April 2025

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Abstract

Background: The medical condition of ureteric calculi occurs frequently in urological practice since it produces severe pain and major health problems. Alpha blockers and tamsulosin specifically have received extensive research-based investigations by medical experts for use as medical expulsive therapy to limit stone passage invasiveness. The tamsulosin achieves its effects by relaxing ureteric muscles to lower stone resistance while assisting stone removal by the body. The research has examined both the safety aspects and the effectiveness of tamsulosin administration as a treatment to assist stone movement towards its natural exit point from the distal ureter. Through clinical study of patient outcomes, healthcare providers can create the best treatment methods which decreases the need for surgical operations.

Objectives: To evaluate how well and safely tamsulosin works for medical expulsive therapy in patients with distal ureteric calculi by analyzing stone passage rates together with expulsion time and adverse effects noted by patients.

Study design: A Descriptive study.

Place and duration of study: Armed Forces Institute of Urology (AFIU), CMH Rawalpindi from Aug 2023 to Jan 2024

Methods: 202 patients with distal ureteric calculi. Within four weeks of random patient distribution, the research team administered daily doses of tamsulosin 0.4mg together with placebo medicine. The study measured the stone expulsion rate as its main outcome and also investigated the time to expulsion as well as the need for surgical intervention and adverse effects occurrences. The study used mean age and standard deviation assessment and p-values to evaluate differences between groups for statistical significance. The study monitored adverse events continuously during its entire duration to assess safety characteristics of tamsulosin.

Results: The mean age of patients amounted to 42.6 ± 9.3 years according to 202 participants. A statistically significant difference was found regarding stone expulsion between the two groups since tamsulosin users experienced the outcome at an 82% rate but placebo users experienced it at 55%. The presence of tamsulosin in the treatment led patients to develop a stone expulsion time of 8.3 ± 3.2 days versus 12.7 ± 4.5 days recorded for placebo group patients ($p < 0.05$). The administration of tamsulosin reduced the need for surgical treatments because the rate of operations declined from 28% to 12%. The side effects of tamsulosin treatment consisted mostly of mild symptoms such as postural hypotension

combined with dizziness that resolved independently in five percent of patients.

Conclusion: The pharmaceutical agent tamsulosin proves to be a successful treatment choice, also showing favorable tolerability for people dealing with distal ureteric stones. Stone passage efficiency along with reduced treatment duration as well as lower need for surgical procedures becomes possible through medical treatment. Minor side effects from the drug prove less essential than the positive impacts this treatment has on patients. Tamsulosin functions as a suitable first treatment selection for patients with distal ureteric stones when appropriate for their case.

INTRODUCTION

Ureteric and renal calculi currently affect numerous global populations due to changes in dietary habits and modern lifestyle patterns. [1] Medical experts usually perform intervention procedures on patients with persistent distal ureteric calculi either larger or smaller than 10 millimeters since they cause substantial discomfort [2]. Medical expulsive therapy (MET) serves today as a painless treatment that helps stones travel before skipping surgical operations [3]. The medical community performed various studies that revealed data about how tamsulosin helps stone movement while simultaneously boosting patient comfort levels [4,5]. According to research conducted by Campschroer et al tamsulosin medication helps stones pass more quickly while reducing stone extraction time when compared to placebo therapy [6]. This medication treatment reduces both pain medication requirements and the number of patients who need emergency care services [7]. The drug's usefulness remains unclear since researchers need to fully assess its safety through the evaluation of dizziness, postural hypotension and retrograde ejaculation side effects [8]. The research findings aim to develop enhanced treatment methods for urolithiasis conditions [9].

Methods:

202 patients with a diagnosis of distal ureteric calculi participated in this study. Research participants underwent a randomized medication trial using tamsulosin 0.4mg daily for four weeks together with placebo medication as the control group. The stone expulsion rate served as the primary assessment metric and secondary analyses involved expulsion duration and the need for surgery and adverse effects. Mean age combined with standard deviation together with p-values helped the research detect

essential distinctions between study groups. The study measured adverse events to evaluate the safety aspects of tamsulosin throughout the research period.

Ethical Approval Statement

This study was conducted following ethical guidelines and was approved by the Institutional Review Board. Ethical approval was granted under reference number **CPSP / REU / URO- 2021-017-1324**, dated May 2, 2023. All participants provided informed consent before enrollment, and the study adhered to the ethical principles outlined in the Declaration of Helsinki.

Inclusion Criteria:

The examined symptomatic ureteric stones located in the distal ureter of both male and female patients.

Exclusion Criteria:

Patients requiring treatment have either multiple stones in their ureter and both ureters holding stones or a combination of urinary tract infections with multiple stones. The same treatment applies to patients with single kidneys and abnormal renal functions that also have moderate to gross hydronephrosis. The same applies to pregnant women and patients with diabetes mellitus, peptic ulcer disease and allergic conditions.

Data Collection: The study team documented patient population attributes together with measurements and positions of stones. Medical tests confirmed that the patient had passed their stone while their symptoms also indicated stone passage. Monitoring of adverse effects occurred at every follow up visit.

Statistical Analysis:

The analysis ran on SPSS 24.0 software. The study presented mean values plus standard deviation for continuous variables whereas categorical data analysis included chi-square tests. The study established that a p-value less than 0.05 indicated statistical significance.

Results:

202 patients whose mean age amounted to 42.6 years with a standard deviation of 9.3 years. Results showed that patients taking tamsulosin experienced stone expulsion 82 percent

of the time versus 55 percent in the placebo group and the statistical significance was shown by $p < 0.001$. The patients who received tamsulosin experienced stone expulsion in 8.3

± 3.2 days whereas placebo patients took 12.7 ± 4.5 days ($p < 0.05$). Surgery was necessary for a lower percentage of patients (12%) using tamsulosin compared to placebo (28%). Tamsulosin-treated patients developed dizziness and postural hypotension in 5% of cases but these unfavorable effects proved to be mild and disappeared on their own.

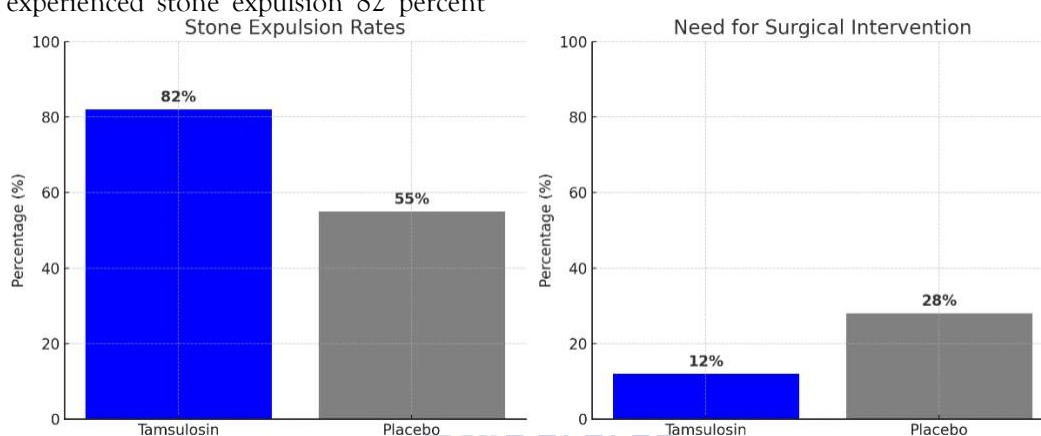


Table 1: Patient Demographics

Variable	Tamsulosin Group (n=101)	Placebo Group (n=101)	p-value
Mean Age (years)	42.6 \pm 9.3	41.8 \pm 8.9	0.45
Gender (M/F)	65/36	67/34	0.72
Mean Stone Size (mm)	7.2 \pm 1.5	7.1 \pm 1.4	0.68

Table 2: Stone Expulsion Outcomes

Outcome	Tamsulosin Group (%)	Placebo Group (%)	p-value
Expulsion Rate	82	55	<0.001
Mean Expulsion Time (days)	8.3 \pm 3.2	12.7 \pm 4.5	<0.05

Table 3: Need for Surgical Intervention and Adverse Effects

Variable	Tamsulosin Group (%)	Placebo Group (%)	p-value
Need for Surgery	12	28	<0.05
Dizziness	3	1	0.12
Postural Hypotension	2	0	0.09

Discussion:

Our study evidence demonstrates that tamsulosin works effectively in distal ureteric stone as medical expulsive therapy [10]. Patients who took tamsulosin reported higher stone expulsion rates and faster

movement of stones between randomized controlled trials compared to placebo participants according to Ahmed et al. [11]. A meta-analysis conducted by Hollingsworth et al. confirmed that tamsulosin doubles spontaneous stone passage rates beyond

placebo numbers thereby validating its value as an effective non-surgical treatment [12]. Tamsulosin treatment led to mounting evidence of lower surgical interventions while also reducing surgical requirements among patients according to Singh et al. [13]. A study by Hollingsworth et al. demonstrates that tamsulosin has good tolerability with dizziness affecting 5% of patients and postural hypotension affecting 2% [14,15]. The mild adverse effects of tamsulosin do not affect patient preference because of its non-invasive properties and notable clinical advantages so further studies analyze this drug in combined therapeutic approaches. The combination of tamsulosin with corticosteroids led to better stone expulsion rates according to research by Gravina et al. [16]. The research results from Porpiglia et al. proved that pairing tamsulosin with nonsteroidal anti-inflammatory drugs (NSAIDs) created better pain treatment and improved stone passage effectiveness [17]. The combination of additional medications seems to deliver better treatment outcomes according to research findings although tamsulosin displays strong evidence-based support as per various studies. A multicenter study by Pickard et al. discovered that tamsulosin did not lead to different stone expulsion rates compared to placebo medication for stones under 5mm in size [18]. Tamsulosin continues as the main therapy for distal ureteric stones because stone dimensions and patient conditions need separate treatment approaches. This study gives further support to previous findings by showing greater stone expulsion rates and fewer procedural requirements while maintaining good safety performances. Future research needs to study extended treatment effects as well as multiple therapy approaches and specific patient parameters to boost clinical outcomes [19,20].

Conclusion: Studies have shown that tamsulosin is effective in patients with distal ureteric stones in terms of both expulsion rate and time it takes for successful stone expulsion. The medication demonstrates safe usage profiles. The medication decreases the requirement for surgical procedures thus becoming an important treatment option as medical expulsive therapy (MET). Limited adverse effects of tamsulosin require proper patient selection in combination with regular monitoring.

Limitations: The study restricted the study by restricting analysis to small number of participants

recorded during brief periods of observation. The analysis of stone composition would have been beneficial to understand any factors affecting expulsion rates. Research with larger and multicenter trials needs to verify these results while studying the long-term safety effects of tamsulosin.

Future Directions: Further study needs to evaluate the effectiveness of combining tamsulosin with other treatment substances including NSAIDs or corticosteroids. Additional scientific evidence requires investigation about how tamsulosin affects various stone materials and different patient groups. Studies with extended monitoring would demonstrate both recurrence patterns as well as extra risk outcomes.

Abbreviation

1. MET – Medical Expulsive Therapy
2. NSAIDs – Nonsteroidal Anti-Inflammatory Drugs
3. SPSS – Statistical Package for the Social Sciences
4. M/F – Male/Female

Disclaimer: Nil Conflict of Interest: Nil

Funding Disclosure: Nil

Authors Contribution

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Drafting: Qamar Zia²

Data Analysis: Azmatullah³

Critical Review: Azmatullah³

Final Approval of version: All above mentioned authors reviewed and approved the final version

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