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ASSESSMENT OF TREATMENT OUTCOMES OF A1-ADRENERGIC BLOCKER THERAPY IN PATIENTS WITH URETERAL CALCULI

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Abstract

This prospective comparative single-center study evaluated the efficacy of α 1-adrenergic blockers as a component of combination therapy in patients with ureteral calculi. A total of 118 patients with a solitary ureteral stone located in various ureteral segments were enrolled. After achieving adequate pain control, all participants received conservative treatment aimed at promoting spontaneous stone expulsion for up to 30 days, with weekly ultrasonographic follow-up.

Patients in the control group received drotaverine (40 mg three times daily) together with analgesics, whereas patients in the intervention group additionally received tamsulosin 0.4 mg once daily. The rate of spontaneous passage of distal ureteral stones was significantly higher among patients treated with α 1-blockers ($p = 0.02$). Furthermore, these patients experienced superior pain relief during the follow-up period, even in cases where stone expulsion was not achieved.

Although proximal-to-distal stone migration occurred more frequently in the α 1-blocker group (52% versus 32%), the difference did not reach statistical significance ($p = 0.17$). The overall incidence of adverse events was comparable

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between groups; however, dizziness, orthostatic hypotension, and general weakness were observed more often in patients receiving α 1-blocker therapy. Both univariate and multivariate proportional hazards analyses demonstrated that the addition of α 1-blockers significantly enhanced the likelihood of spontaneous distal ureteral stone passage and shortened the time required for stone expulsion. Treatment with α 1-blockers was associated with a 4.11-fold increase in the probability of spontaneous stone passage.

Key words: α 1-blockers, ureteral stones, drug treatment.

Introduction

Despite continuous advances in endourological technologies and surgical techniques for stone removal, conservative approaches aimed at facilitating the spontaneous passage of urinary calculi and their fragments remain clinically important. Traditionally, increased fluid intake, diuretics, and antispasmodic agents have been employed for this purpose. However, growing understanding of the molecular and biochemical mechanisms regulating ureteral smooth muscle function, together with progress in pharmacotherapy, has stimulated interest in medical expulsive therapy.

Particular attention has been directed toward pharmacological agents capable of accelerating spontaneous stone passage. Among these, α 1-adrenergic receptor antagonists have attracted considerable interest because of their effects on ureteral physiology. By reducing ureteral smooth muscle tone and peristaltic activity, these drugs may facilitate stone migration and expulsion when incorporated into conservative treatment protocols for ureteral calculi. In addition, α 1-blockers have been shown to decrease the frequency of recurrent renal colic episodes and reduce the overall severity of pain during treatment.

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The aim of the work was to evaluate the efficacy and safety of α 1-adrenergic blockers as part of the conservative management of ureteral calculi.

The specific objectives of the study were: (1) to compare the effectiveness and treatment outcomes of α 1-blockers with those of conventionally used antispasmodic agents in patients with ureteral stones; (2) to assess the likelihood of spontaneous stone passage according to stone size and location during treatment with α 1-blockers versus standard antispasmodic therapy; (3) to evaluate the probability of stone migration from the proximal to the distal ureter under α 1-blocker therapy compared with standard treatment; (4) to determine the predictive value of stone size, stone location, and treatment modality on the likelihood of spontaneous stone expulsion; (5) to assess pain severity during conservative treatment with α 1-blockers; and (6) to evaluate the safety and tolerability of α 1-blockers in the conservative management of ureteral calculi.

Materials and Methods

A prospective, comparative, single-center study was performed involving 118 patients with a solitary ureteral stone located in different segments of the ureter. Following adequate pain control, all patients received conservative treatment aimed at facilitating spontaneous stone passage. The maximum duration of conservative management was 30 days, and ultrasonographic monitoring was performed weekly throughout the observation period.

Based on previous studies demonstrating marked differences in the distribution density of α 1-adrenergic receptors along the ureter, particularly between the distal third and the remaining segments, stone location was categorized as either proximal or distal relative to the pelvic brim. Stones located in the upper and middle thirds of the ureter were classified as proximal, whereas those located in the lower third were classified as distal.

According to the treatment regimen, patients were assigned to one of two groups. The control group (n = 58) received standard conservative therapy consisting of

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antispasmodic agents and analgesics as required. Drotaverine was used as the antispasmodic agent at a dose of 40 mg three times daily. Its mechanism of action is associated with nonspecific inhibition of phosphodiesterase, a key enzyme involved in smooth muscle cell function.

The study group (n = 60) received standard therapy in combination with the α 1-adrenergic receptor antagonist tamsulosin. As a selective antagonist of the α 1A and α 1D receptor subtypes, tamsulosin has minimal affinity for the α 1B subtype predominantly expressed in vascular smooth muscle, which contributes to its favorable tolerability profile and low incidence of adverse effects. Tamsulosin was administered at a standard dose of 0.4 mg once daily.

Cases requiring modification of the initial treatment strategy were considered censored observations. Patients who discontinued α 1-blocker therapy were also included in the censored analysis.

Exclusion criteria included obstruction of a solitary functioning kidney, ureteral anomalies, significant spinal pathology, previous upper urinary tract surgery, marked dilatation of the upper urinary tract, refractory renal colic, severe decompensated comorbid conditions, markedly reduced renal function (glomerular filtration rate <30 mL/min/1.73 m²), a predisposition to hypotension, and a history of intolerance to α 1-blockers.

Pain intensity during treatment was assessed using the Numerical Rating Scale (NRS).

Results

The distribution of patients according to stone location was comparable between the two treatment groups (Table 1). Distal ureteral stones were the most common finding, occurring in 83 patients (79%).

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Table 1. Distribution of patients depending on the location of stones in the ureter.

| Localization of the stone | Main group n=60(%) | Control group n=58(%) |
|---------------------------|--------------------|-----------------------|
| Lower third | 42(70) | 41(70,6) |
| Intramural department | 10(16,7) | 10(17,2) |
| Juxtavesical region | 32(53,3) | 31(53,4) |
| Proximal part | 18(30) | 17(29,3) |
| Middle third | 6(10) | 7(12,1) |
| Upper third | 12(20) | 10(17,2) |

The two study groups were comparable with respect to baseline demographic and clinical characteristics, including age, sex distribution, stone laterality, and mean stone size. Treatment outcomes were analyzed according to the initial stone location.

The Kaplan–Meier analysis demonstrated that the overall probability of spontaneous passage of distal ureteral stones was significantly higher in patients receiving α 1-blocker therapy than in those treated with standard therapy alone (85% vs. 66%, respectively; $p = 0.02$).

Assessment of pain severity revealed that recurrent episodes of severe pain occurred significantly more frequently in the control group than in the α 1-blocker group (25% vs. 9%, respectively; $p = 0.03$). Comparative analysis of pain dynamics during treatment showed superior pain control among patients receiving α 1-blockers, even in cases where spontaneous stone passage was not achieved.

Among patients with proximally located stones, the overall probability of stone migration to the distal ureter was higher in the α 1-blocker group than in the control group (52% vs. 32%); however, the difference did not reach statistical significance ($p = 0.17$). The median time to stone passage was 6 days in the α 1-blocker group, whereas no comparable outcome was observed in the control group.

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Pain intensity during the first seven days of treatment differed significantly between treatment groups ($p = 0.046$). Longitudinal analysis further demonstrated better pain control in patients receiving $\alpha 1$ -blockers throughout the entire follow-up period, including days 21 and 28. During this interval, the median pain score was 4 points in the $\alpha 1$ -blocker group compared with 6 points in the control group ($p = 0.031$).

The overall incidence of adverse events was similar between groups. However, dizziness, orthostatic hypotension, and generalized weakness were observed significantly more frequently among patients receiving $\alpha 1$ -blocker therapy (Table 2)

Table 2. Frequency of occurrence of undesirable effects depending on the treatment regimen.

| Undesirable effect | Main group (%) | Control group (%) | P |
|----------------------|----------------|-------------------|-------|
| Dizziness | 9(15) | 4(6,9) | 0,031 |
| Postural hypotension | 4(6,7) | 1(1,7) | 0,024 |
| Nausea | 7(11,7) | 8(13,8) | 0,411 |
| Headache | 6(10) | 5(8,6) | 0,814 |
| Rhinitis | 2(3,3) | 1(1,7) | 0,46 |
| Weakness | 13(22,4) | 7(12,1) | 0,012 |

The results of the analysis of the risks of stone passage using the proportional hazards model are shown in Table. 3.

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Table 3. Risk ratio (OR) for stone passage depending on the influence of various factors (univariate and multivariate analysis options).

| Analyzed factor | OR | 95% DI | P |
|---|-------|------------|---------|
| Univariate analysis | | | |
| Patient gender | 1,13 | 0,43-2,4 | 0,656 |
| Localization side(right/left) | 0,08 | 0,86-1,79 | 0,127 |
| Treatment option (main regimen/control regimen) | 4,11 | 2,03-5,61 | <0,0001 |
| Localization of the stone (distal/proximal) | 9,67 | 7,45-11,82 | <0,0001 |
| Stone size (<7mm/≥7mm) | 6,10 | 5,11-8,86 | <0,0001 |
| Multivariate analysis | | | |
| Therapy option | 4,36 | 2,92-5-61 | <0,0001 |
| Stone size (<7mm/≥7mm) | 8,89 | 6,34-10,01 | <0,0001 |
| Localization of the stone (distal/proximal) | 10,03 | 7,34-12,23 | <0,0001 |

Discussion

The management of ureteral calculi has two principal objectives: facilitating stone migration through the ureter and reducing the severity of pain associated with stone passage. Among the factors that may impede stone progression and are amenable to pharmacological intervention are ureteral wall edema, ureteral spasm, and concomitant urinary tract infection. Therefore, the primary goal of conservative treatment is to create favorable conditions for urine flow distal to the obstructing stone, thereby promoting its spontaneous passage.

Reduction of recurrent renal colic episodes and overall patient discomfort is achieved through suppression of excessive ureteral smooth muscle activity and attenuation of pain signal transmission via afferent neural pathways to spinal pain centers. α 1-Adrenergic receptor antagonists represent a pharmacological class capable of addressing both therapeutic objectives simultaneously.

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Previous studies have demonstrated the presence of multiple α 1-adrenergic receptor subtypes throughout the ureteral wall, with the highest receptor density located in the distal ureter. Experimental evidence indicates that α 1-blockers reduce ureteral peristaltic activity, decrease basal smooth muscle tone, and lower intraluminal pressure. Collectively, these effects may facilitate urinary drainage and improve the likelihood of spontaneous stone passage. Comparative pharmacological studies have further suggested that α 1-blockers exert a more pronounced influence on these ureteral functional parameters than other classes of medications used for medical expulsive therapy.

Tamsulosin was selected for the present study because of its favorable safety profile, good tolerability, and convenient once-daily dosing regimen. The findings demonstrated that the addition of tamsulosin to standard conservative therapy significantly increased the likelihood of spontaneous stone passage or distal migration. Furthermore, patients receiving tamsulosin experienced superior control of pain symptoms, including lower pain intensity scores and a reduced frequency of recurrent severe pain episodes during both the first week of treatment and the subsequent follow-up period.

The beneficial effect of α 1-blocker therapy was most evident during the first two weeks of treatment. Beyond this period, no additional stone passage events were observed, and outcomes did not differ significantly from those achieved with conventional antispasmodic therapy alone.

The combination of tamsulosin with phosphodiesterase inhibitors was generally well tolerated and was not associated with a substantial increase in adverse events. The most common side effects were those expected from α 1-adrenergic receptor blockade in vascular smooth muscle, including dizziness and orthostatic hypotension. Only one patient discontinued treatment because of adverse effects, confirming the overall safety and tolerability of the therapeutic regimen

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Conclusion

Thus, the findings of the present study, supported by both univariate and multivariate proportional hazards analyses, indicate that the treatment modality significantly influences the likelihood of spontaneous passage of distal ureteral stones. The incorporation of an α 1-adrenergic blocker into the conservative treatment regimen was identified as an independent predictor of successful stone expulsion, increasing the probability of spontaneous stone passage by 4.11-fold. These results confirm the clinical value of α 1-blockers as an effective component of medical expulsive therapy for ureteral calculi.

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