

## TROSPIUM CHLORIDE *VERSUS* TAMSULOSIN IN THE TREATMENT OF DOUBLE-J STENT RELATED LOWER URINARY TRACT SYMPTOMS (LUTS)

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TROSPIUM CHLORIDE *VERSUS* TAMSULOSIN IN THE TREATMENT OF DOUBLE-J STENT RELATED LOWER URINARY TRACT SYMPTOMS (LUTS): A CASE-CONTROL STUDY (Abstract): Double-J ureteral stents frequently cause lower urinary tract symptoms (LUTS), including urinary urgency and pollakiuria, which significantly affect patient comfort. This study compared the efficacy and safety of trospium chloride versus tamsulosin in patients with stent-related LUTS. **Materials and methods:** We conducted a retrospective 6-year study comparing patients with LUTS in the presence of double-J stents who had received trospium for 4 weeks (39 patients) with patients who had received tamsulosin (52 patients). **Results:** Both trospium and tamsulosin relieved LUTS symptoms ( $p < 0.05$ ). Trospium relieved pollakiuria (82.05% vs. 61.53%,  $p = 0.034$ ) and urinary urgency (87.17% vs. 59.61%,  $p = 0.003$ ) in a higher percentage than tamsulosin. However, there was no statistically significant difference in the improvement of urinary urgency incontinence (80% vs. 47.05%, not significant at  $p < 0.05$ ), hypogastric pain (64% vs. 40%,  $p = 0.103$ ), foreign body sensation (64.28% vs. 38.09%,  $p = 0.128$ ) and macroscopic hematuria (37.5% vs. 18.18%, not significant at  $p < 0.05$ ); side effects occurred rarely, with no statistically significant difference between the two groups (5.12% vs. 5.76%, not significant at  $p < 0.05$ ). **Conclusions:** Trospium chloride is a safe and effective option for managing LUTS associated with double-J stents and provides superior improvement in pollakiuria and urinary urgency compared with tamsulosin. **Keywords:** TROSPIUM CHLORIDE, TAMSULOSIN, DOUBLE-J STENT, LOWER URINARY TRACT SYMPTOMS, LUTS, STENT-RELATED SYMPTOMS.

### INTRODUCTION

Trospium chloride is a quaternary ammonium derivative of nortropanol (1), a competitive cholinergic receptor antagonist (2). Its activity is predominantly peripheral, non-selective antimuscarinic, and it has no effects on the central nervous system (3). Trospium is commonly used for overactive bladder to relieve urinary incontinence

associated with urinary urgency and pollakiuria (4). It is also used to relieve these symptoms in neurogenic detrusor overactivity (5) and to reduce postoperative bladder irritation and radiation-induced cystitis (6). Trospium is an anticholinergic agent that has been used in Europe since the 1990s and in the USA since 2004 (7). Over the past 30 years of experience, only a few

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side effects have been reported, the most common being dry mouth, constipation, and headache (8, 9). This safety profile has been confirmed in studies involving more than 10,000 patients (1). Trospium can be administered orally in one or more doses not exceeding 45-60 mg per day (9-11).

Urinary catheters or stents are commonly used in clinical practice, and many patients wear them for weeks, months, or even years (12). The presence of these catheters predisposes patients to urinary tract infections (13, 14), hematuria, pollakiuria, urinary urgency, and urge incontinence (15, 16). They relax the smooth muscle fibers of the bladder neck and the prostate, which leads to lower micturition pressure and urinary reflux (17). The effect can be measured by urodynamic studies, which have shown normalization of intravesical pressure and increased cystometric bladder capacity (18). Several drugs have been proposed to treat these symptoms, including tamsulosin, silodosin, or their combination (19, 20). Tamsulosin is an alpha-blocker used not only to treat LUTS associated with benign prostatic hyperplasia (BPH), but also to promote the passage of ureteral stones or fragments formed during extracorporeal lithotripsy and to treat symptoms associated with double-J catheters (21). However, both tamsulosin and solifenacin have certain side effects, such as arterial hypotension and retrograde ejaculation in the case of tamsulosin, and central nervous system effects-particularly in the elderly-in the case of solifenacin (22, 23).

As trospium chloride is the only antimuscarinic drug that has no effects on the central nervous system (22) and lacks the adverse effects associated with tamsulosin (orthostatic hypotension, retrograde ejaculation), we aimed to determine whether it could be a viable alternative for the treat-

ment of secondary LUTS in double-J stent carriers. To our knowledge, this is the first study in the literature to evaluate the efficacy and safety of trospium in this specific patient group.

### **MATERIALS AND METHODS**

**Study Population and Design.** We conducted a retrospective case-control study of patients with double-J ureteral stents who underwent Extracorporeal Shock Wave Lithotripsy (ESWL) at Elytis Hospital between 1 January 2018 and 31 December 2024. Of the total number of urological patients admitted, 289 had double-J stents. Among these, 42.56% (123 patients) presented with bladder symptoms related to the presence of the double-J stents. All patients had only one double-J stent inserted. These patients were eligible for inclusion in the study. The study was approved by the Ethics Committee of Elytis Hospital (Protocol No. 3927/07.05.2025).

Patients with LUTS who also had benign prostatic hyperplasia (3 patients), those who received tamsulosin in combination with solifenacin or other drugs for LUTS due to the presence of double-J stents (6 patients), those who developed urinary tract infections during treatment (2 patients), and patients with incomplete data in hospital records (21 patients) were excluded. In all patients, urine culture was performed, to exclude urinary tract infection, a well-known complication of double-J stents, even with multidrug-resistant bacteria (24).

**Study Procedure.** The study group consisted of patients with LUTS and double-J stents who were administered trospium chloride (Inkontan™, Montavit, Austria), and the control group consisted of patients with LUTS and double-J stents

who were administered tamsulosin (Fokusin™, Zentiva, Czech Republic). The indication for treatment with tamsulosin was the presence of symptoms secondary to the double-J stents, as well as to promote the elimination of lithiasis fragments smaller than 4 mm occurring after ESWL.

Trospium chloride was administered at a dose of 15 mg twice daily (morning and evening), and tamsulosin was administered 0.4 mg once daily in the evening. No patient received 15 mg of trospium three times daily, so the maximum recommended dose of 45 mg per day was not reached, in order to avoid known anticholinergic side effects.

Patients who underwent ESWL and had LUTS started treatment three days after the procedure. During this period, they completed a voiding calendar to assess the severity of pollakiuria. Treatment with trospium or tamsulosin lasted four weeks, after which patients returned for follow-up. Before each new ESWL session and follow-up, an ultrasound scan and X-ray of the kidneys were performed to detect calcifications or misplacement of the double-J catheters, especially at the distal intravesical end, as these could influence treatment response and represent potential bias.

The ureteral catheters were made of polyurethane, 6-7 Ch thick and 24-28 cm long, adjusted to the individual patient height and according to the manufacturer specifications. The length of the distal end in the bladder was not measured, but all patients had a complete distal loop of the double-J stent in the bladder.

**Patient Assessment and Outcome Measurement.** The following variables were collected from hospital records: age, gender, history of urinary tract infections, underlying condition requiring stent inser-

tion, right-left localization of the double-J catheter, and comorbidities potentially influencing LUTS, such as diabetes and neurological disorders. In both groups, the drug dose, administration frequency, and treatment duration were analyzed. The presence of hematuria, pollakiuria, urinary urgency and urge incontinence, intravesical foreign body sensation, and hypogastric pain (bladder tension or persistent pain) were recorded.

Visual Analog Scale (VAS) questionnaires for pain were not used, as facial expression was considered subjective and patients generally requested removal of the stent if discomfort was significant. Therefore, all included patients were presumed to have moderate pain. To assess the reduction in daily micturitions, a voiding calendar was used for three consecutive days before and at the end of treatment. Treatment discontinuation due to side effects or lack of efficacy was also recorded.

All patients were evaluated and managed by the same two attending urologists, who followed identical departmental protocols for the treatment of double-J stent-related symptoms. Tamsulosin was prescribed primarily to relieve stent-related LUTS and to facilitate the passage of residual stone fragments <4 mm after ESWL, whereas trospium chloride was preferentially used in patients whose predominant symptoms were urinary urgency and frequency without the need for expulsive therapy. Baseline symptom presence was similar across groups.

Patients with LUTS following ESWL were treated for one month with either trospium or tamsulosin and then re-evaluated. The presence of symptoms and subjective improvement were recorded at baseline and after one month of therapy.

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The micturition calendar was reviewed during the control visit.

**Statistical Analysis.** Quantitative variables were described by mean and standard deviation, and qualitative variables by percentages. Quantitative variables were compared using the t-test for normally distributed data and the Mann-Whitney U-test for non-normally distributed data. Normality of data distribution was verified using the Kolmogorov-Smirnov test. Qualitative variables were compared using the chi-square test or Fisher's exact test when fewer than five observations were present. Statistical significance was considered at  $p < 0.05$ . Data were processed using *Microsoft Excel version 2019* (Microsoft, Redmond, WA, USA) and *SPSS version 24.0* (IBM, Chicago, IL, USA).

**RESULTS**

During the study period, a total of 91 patients underwent ESWL and experienced LUTS due to the presence of double-J stents. Of these, 39 patients received trospium chloride (study group) and 52 patients received tamsulosin (control group).

**Demographic and Clinical Characteristics**

First table presents the demographic and clinical characteristics of patients in both groups.

There were no statistically significant differences in age, sex, laterality of the stent, stone location, or comorbidities such as diabetes or obesity between the two groups. No patient had neurological disorders that could have influenced LUTS or treatment response.

TABLE I.  
**Demographic and Clinical Characteristics of Patients  
in the Trospium and Tamsulosin Groups**

Characteristic	Trospium Group (n = 39)	Tamsulosin Group (n = 52)	p-value	Test
Age (years, mean $\pm$ SD)	48.85 $\pm$ 14.12	47.69 $\pm$ 11.94	0.677	Student's <i>t</i> -test
Sex (Male/Female), n (%)	15 / 24 (38.5% / 61.5%)	22 / 30 (42.3% / 57.7%)	0.877	Chi-square
<b>Indication for stent insertion</b>				
Infected hydronephrosis, n (%)	34 (87.2%)	44 (84.6%)	0.729	Chi-square
Recurrent renal colic, n (%)	5 (12.8%)	8 (15.4%)	0.729	Chi-square
<b>Stent laterality</b>				
Right ureter, n (%)	17 (43.6%)	26 (50.0%)	0.544	Chi-square
Left ureter, n (%)	22 (56.4%)	26 (50.0%)	0.544	Chi-square
<b>Stone location (pre-ESWL)</b>				
Ureteral calculus, n (%)	23 (59.0%)	34 (65.4%)	0.531	Chi-square
Pyelocaliceal calculus, n (%)	16 (41.0%)	18 (34.6%)	0.531	Chi-square
<b>Comorbidities</b>				
Diabetes mellitus, n (%)	2 (5.1%)	3 (5.8%)	N.S.	Fisher's exact
Obesity (BMI > 30), n (%)	4 (10.3%)	5 (9.6%)	N.S.	Fisher's exact

N.S.-non-significant

There were no statistically significant differences in age, sex, laterality of the stent, stone location, or comorbidities such as diabetes or obesity between the two groups. No patient had neurological disorders that could have influenced LUTS or

treatment response.

**Baseline Symptoms**

In the second table are presented the baseline prevalence of stent-related LUTS prior to treatment.

TABLE II.  
**Baseline Prevalence of Stent-Related Lower Urinary Tract Symptoms in Each Group (Pre-Treatment)**

Symptom	Trospium Group (n = 39)	Tamsulosin Group (n = 52)	p-value	Test
Urinary urgency, n (%)	39 (100%)	52 (100%)	N/A	—
Urge urinary incontinence, n (%)	10 (25.6%)	17 (32.7%)	0.619	Chi-square
Urinary frequency (pollakiuria), n (%)	39 (100%)	52 (100%)	N/A	—
Voids per day (mean ± SD)	13.55 ± 4.31	13.45 ± 3.88	0.771	Mann-Whitney U
Suprapubic (hypogastric) pain, n (%)	25 (64.1%)	35 (67.3%)	0.749	Chi-square
Intravesical foreign body sensation, n (%)	14 (35.9%)	21 (40.4%)	0.663	Chi-square
Gross hematuria, n (%)	8 (20.5%)	11 (21.2%)	0.940	Chi-square

The frequency of the six symptoms recorded in the study was similar in both groups, with no statistically significant differences between the groups. We found that the only symptoms that occurred in all patients in both groups were pollakiuria and urinary urgency. There were no differences between the two groups in the total number of micturitions per day. The other

symptoms occurred in much smaller percentages, namely urge urinary incontinence and hematuria, which occurred in about a quarter of patients in both groups.

**Symptom Improvement After Four Weeks**

Table III summarizes symptom improvement after four weeks of treatment.

TABLE III.  
**Patients Reporting Improvement of Symptoms After 4 Weeks of Treatment**

Symptom	Trospium Improved n/N (%)	Tamsulosin Improved n/N (%)	p-value	Test
Urinary urgency	34/39 (87.2%)	31/52 (59.6%)	0.003	Chi-square
Urge urinary incontinence	8/10 (80.0%)	8/17 (47.1%)	N.S.	Fisher's exact
Urinary frequency (pollakiuria)	32/39 (82.1%)	32/52 (61.5%)	0.034	Chi-square
Suprapubic pain	16/25 (64.0%)	14/35 (40.0%)	0.103	Fisher's exact
Intravesical foreign body sensation	9/14 (64.3%)	8/21 (38.1%)	0.128	Fisher's exact
Gross hematuria	3/8 (37.5%)	2/11 (18.2%)	N.S.	Fisher's exact

N.S.-non-significant

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In the study group, only pollakiuria, urinary urgency and urge incontinence improved by more than 80%, while macroscopic hematuria, hypogastric pain and foreign body sensation improved in more than 60% of patients. In the control group, on the other hand, the percentage of patients reporting an improvement in symptoms was significantly lower than in the study group, with only pollakiuria and the percentage of improvement of more than 50% was achieved. For urge incontinence, hypogastric pain and intravesical foreign body sensation, the percentage was less than 50%, and for macroscopic hematuria even less than 20%. However, statistically significant differences were found only for pollakiuria ( $p = 0.03$ ) and urinary urgency ( $p = 0.003$ ).

For urge incontinence, hypogastric pain,

foreign body sensation and hematuria, there was no statistically significant difference in the number of patients who reported an improvement in these symptoms, while the total percentage of patients who subjectively reported an improvement showed a statistically significant difference in favor of the group receiving Trospium 30mg/day.

The mean number of micturitions/day calculated from the micturition calendar before treatment and at the end of treatment was significantly reduced in both the study group ( $13.68 \pm 4.08$  vs.  $10.43 \pm 5.28$ ,  $p < 0.001$ ) (Wilcoxon test) and the control group ( $13.67 \pm 3.87$  vs.  $11.08 \pm 5.08$ ,  $p < 0.001$ ) (Wilcoxon test).

### **Adverse Events**

Treatment-related side effects are presented in the fourth table.

TABLE IV.  
**Treatment-Related Adverse Events Reported in Each Group**

<b>Adverse Event</b>	<b>Trospium Group (n = 39)</b>	<b>Tamsulosin Group (n = 52)</b>	<b>p-value</b>	<b>Test</b>
<b>Dry mouth</b>	1 (2.6%)	0 (0%)	N.S.	Fisher's exact
<b>Constipation</b>	0 (0%)	0 (0%)	N/A	—
<b>Dizziness (lightheadedness)</b>	0 (0%)	3 (5.8%)	N.S.	Fisher's exact
<b>Diarrhea</b>	1 (2.6%)	0 (0%)	N.S.	Fisher's exact
<b>Total side effects</b>	<b>2 (5.1%)</b>	<b>3 (5.8%)</b>	N.S.	Fisher's exact

N.S.-non-significant

The incidence of side effects was low in both groups, with no statistically significant differences. Despite the occurrence of these side effects, this did not lead to discontinuation of treatment by the patients, with the exception of one patient with diarrhea in the study group who discontinued treatment after 10 days. We note that in the control group, no patient reported constipation and only one patient reported dry mouth, which are recognized side effects of

parasympathomimetic. In the control group, a small number of patients reported dizziness. Although retrograde ejaculation is a common complication in male patients, we did not investigate its occurrence due to the mixed-sex group. However, no patient discontinued tamsulosin treatment due to the presence of this side effect.

### **DISCUSSION**

To our knowledge, this is the first

study to evaluate the efficacy and safety of trosipium chloride in patients with LUTS due to double-J stents. We found that trosipium demonstrated superior efficacy compared to tamsulosin in the treatment of pollakiuria and urinary urgency, with both drugs being well tolerated and associated with a low rate of side effects.

The demographic characteristics of patients were similar between groups in terms of age, sex, stent laterality, and stone location. The mean age of participants was consistent with other studies investigating trosipium (25, 26), typically ranging between 45 and 60 years. Equal distribution of diabetic patients and the absence of neurogenic bladder disorders minimized confounding factors affecting LUTS or drug response. We included only patients with lithiasis and double-J stents, excluding those with other causes of LUTS such as radiotherapy or urinary tract infections, to further reduce bias.

Although most studies investigating trosipium for overactive bladder used doses of 40-60 mg/day (27, 28), in our study we administered 30 mg/day in two doses to minimize side effects. Increasing the dose to 45 mg/day might have enhanced efficacy, as previous reports suggest 40 mg/day as optimal for balancing efficacy and tolerability (30), with potential additional benefits at 60 mg/day (30). Trosipium is known for good safety even in elderly patients with dementia or Parkinson's disease (22, 25), although such patients were not included in our analysis.

In the literature, only one study has assessed trosipium for catheter-related LUTS, specifically in patients with Foley urethral catheters (12), but none have focused on double-J stents. Similar to other investigations (12, 19, 27, 28), we

evaluated improvement in individual symptoms rather than overall pain or quality-of-life scores (20, 29), allowing a clearer understanding of specific drug effects.

All patients continued therapy, except one in the trosipium group who discontinued due to diarrhea. The discontinuation rate for trosipium is reported to be lower than for other anti-muscarinics (31).

Our findings showed significantly greater improvement in pollakiuria and urinary urgency with trosipium compared to tamsulosin. Pollakiuria improved by an average of 3.19 micturitions per day, consistent with previous studies (9), and higher than those reporting a reduction of fewer than two micturition per day (19). The proportion of patients reporting improvement (> 80%) was greater than in other studies (approximately 62%) (27). Because we assessed total daily micturition, we could not differentiate between day and night improvements; other research indicates greater benefit during daytime (28). We defined pollakiuria as  $\geq 10$  micturitions per 24 hours, compared with thresholds of  $> 8$  (19, 27) or even  $> 30$  (32) used elsewhere. Clinically, patients with  $< 10$  micturitions per day often did not require therapy, while those exceeding 30 generally needed stent removal rather than medication.

Urinary urgency improved in both groups but more markedly with trosipium (87.17% vs. 59.61%). This difference of nearly 30% highlights trosipium's superior efficacy. Comparable benefits have been reported in other studies examining trosipium for overactive bladder (5, 9, 25).

For urge urinary incontinence, the improvement was greater with trosipium, though not statistically significant, likely

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due to the small number of affected patients. We did not count daily incontinence episodes as in some trials (9) but relied on subjective reporting, since patient self-monitoring of these episodes is often unreliable.

Hypogastric pain and intravesical foreign body sensation improved less than pollakiuria and urgency in both groups, possibly reflecting subjective variability in symptom perception. Some patients may have expected complete symptom resolution, while others reported satisfaction with partial relief. Similar findings have been observed in studies of Foley catheter users (12).

Hematuria showed the least improvement, with no difference between groups. This likely reflects mechanical irritation from the stent, which persists despite pharmacologic relaxation of bladder smooth muscle. No cases of clot-forming hematuria occurred, and this symptom did not lead to treatment discontinuation.

Adverse effects were mild in both groups. In the trospium group, one case each of dry mouth and diarrhea was reported, with no constipation, neurological impairment, or other systemic symptoms, consistent with the literature (5, 26). No sedation or sleep disturbances occurred (33). In the tamsulosin group, dizziness was reported in a few cases, likely secondary to orthostatic hypotension. Retrograde ejaculation, although a known adverse event, was not investigated due to the mixed-sex population, but no patient discontinued tamsulosin therapy due to such complication.

Overall, trospium chloride demonstrated superior efficacy to tamsulosin in reducing urinary urgency and frequency among double-J stent carriers, with similar

tolerability and safety.

This study has some limitations. First, its retrospective design inherently restricts the ability to control for potential confounding variables, including treatment selection bias arising from routine clinical prescribing patterns rather than random allocation. Second, symptom assessment relied on patient-reported improvement without the use of standardized instruments such as the USSQ, which were not validated in Romanian language at the time of patient's admission. Only pollakiuria could be quantified objectively through the three-day voiding calendar.

### **CONCLUSIONS**

Trospium chloride showed superior efficacy compared to tamsulosin in the treatment of pollakiuria and urinary urgency among patients with double-J stents. It demonstrated similar efficacy to tamsulosin in relieving urinary urge incontinence, intravesical foreign body sensation, hypogastric pain, and hematuria. Adverse effects were rare and did not significantly increase the rate of treatment discontinuation.

Overall, trospium chloride represents a safe and effective therapeutic option for managing LUTS associated with double-J stents. Prospective studies with larger patient populations are needed to validate these findings and to better define the role of trospium chloride in the pharmacologic management of stent-related urinary symptoms.

### **CONFLICT OF INTEREST AND FUNDING**

The authors declare no conflict of interest and no financial support was received for perfecting this article.

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