Sarcouncil Journal of Medical Series

ISSN(Online): 2945-3550

Volume- 05| Issue- 01| 2026

Research Article

Received: 25-12-2025 | Accepted: 20-01-2026 | Published: 03-02-2026

The Efficacy of Combining Solifenacin with Tamsulosin in the Treatment of Symptoms of Benign Prostatic Hyperplasia

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Abstract: Background: Alpha-blockers are commonly used to manage lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH), while antimuscarinic agents are prescribed for overactive bladder (OAB). Combining these therapies may improve symptoms, but concerns remain regarding safety in men with bladder outlet obstruction (BOO). Objective: To evaluate the safety of combined solifenacin (SOLI) and tamsulosin oral controlled absorption system (TOCAS) therapy compared with tamsulosin monotherapy in men with LUTS and BOO. Methods: This comparative study included men aged over 45 years with LUTS and BOO for at least three months, total International Prostate Symptom Score (IPSS) ≥ 8, BOO index ≥ 20, maximum urinary flow rate (Qmax) ≤ 12 mL/s, and voided volume ≥ 120 mL. Participants were divided into two groups: one received tamsulosin 0.4 mg alone, and the other received tamsulosin 0.4 mg plus solifenacin 10 mg. Primary safety outcomes were Qmax and detrusor pressure at Qmax (PdetQmax). Secondary assessments included post-void residual volume (PVR), IPSS, and voided volume. Results: At the end of treatment, both groups showed significant improvements in PdetQmax and Qmax. However, the mean increase in PVR was significantly higher in the combination therapy group at all follow-up points, particularly at weeks 2, 12, and end of treatment. Urinary retention occurred in only one patient receiving combination therapy. Study limitations included lack of evaluation of prostate size, high prostate-specific antigen levels, drug cost, and adverse effects. Conclusion: The combination of TOCAS 0.4 mg and solifenacin 10 mg demonstrated efficacy without clinically significant increased risk of urinary retention in men with LUTS and BOO, supporting its safe use in appropriately selected patients.

Keywords: The Efficacy, Solifenacin, Tamsulosin, Symptoms, Benign Prostatic Hyperplasia.

INTRODUCTION

Lower urinary tract symptoms (LUTS) represent a group of storage and voiding symptoms that are highly prevalent among men aged over 45 years and have a substantial impact on health-related quality of life (HRQL) (Wein, A. J. *et al.*, 2012; Kaplan, S. A. *et al.*, 2013; Irwin, D. E. 2006; Rosen, R. *et al.*, 2003). Storage symptoms, such as urinary frequency, urgency, and nocturia, are among the most commonly reported urological complaints. In healthy adults, normal voiding occurs approximately five to six times daily, with an average voided volume of about 300 mL per episode. Increased urinary frequency may result from either polyuria or reduced bladder capacity, whereas voiding symptoms, including weak urinary stream and decreased force of urination, are often associated with bladder outlet obstruction (BOO), most commonly due to benign prostatic hyperplasia (BPH) or urethral stricture (Wein, A. J. *et al.*, 2012; Kaplan, S. A. *et al.*, 2013; Irwin, D. E. 2006).

Alpha-1 adrenergic blockers (α-blockers) are widely prescribed as first-line therapy for LUTS associated with BPH because of their proven efficacy in improving urinary flow and symptom scores. However, bothersome storage symptoms frequently persist despite α-blocker therapy, possibly due to underlying detrusor overactivity or persistent BOO (Wein, A. J. *et al.*, 2012; Kaplan, S. A. *et al.*, 2013). Earlier nonselective α-blockers such as phenoxybenzamine were effective but limited by significant adverse effects, while selective α1-blockers such as prazosin demonstrated improved tolerability (Wein, A. J. *et al.*, 2012 ; Rosen, R. *et al.*, 2003). Subsequent development of long-acting α-blockers, including terazosin, doxazosin, tamsulosin, and extended-release alfuzosin, enabled once-daily dosing and improved safety and efficacy profiles in BPH management (Wein, A. J. *et al.*, 2012; Irwin, D. E. 2006). Among these agents, tamsulosin is currently one of the most widely used α1-blockers and exhibits relative selectivity for the α1A-adrenergic receptor subtype, contributing to its favorable clinical profile (Wein, A. J. *et al.*, 2012; Kaplan, S. A. *et al.*, 2013). Antimuscarinic agents have long been considered the gold standard for the treatment of overactive bladder (OAB), acting primarily during the storage phase by reducing urgency and increasing bladder capacity (Wein, A. J. *et al.*, 2012). Although high doses may

theoretically impair detrusor contractility and lead to urinary retention, clinical evidence suggests that antimuscarinic therapy at therapeutic doses rarely causes significant voiding dysfunction (Wein, A. J. *et al.*, 2012). Solifenacin, a tertiary amine antimuscarinic agent with relative selectivity for M3 receptors, has demonstrated efficacy in reducing detrusor overactivity and storage symptoms in LUTS and OAB at daily doses of 5–10 mg (Wein, A. J. *et al.*, 2012; Rosen, R. *et al.*, 2003). Recent studies indicate that combination therapy with α-blockers and antimuscarinics may provide superior symptom control compared with α-blocker monotherapy, without a clinically significant increase in postvoid residual volume or risk of acute urinary retention (Wein, A. J. *et al.*, 2012; Kaplan, S. A. *et al.*, 2013; Irwin, D. E. 2006; Rosen, R. *et al.*, 2003). The International Prostate Symptom Score (IPSS) remains a widely used tool for evaluating LUTS severity and monitoring treatment outcomes (Wein, A. J. *et al.*, 2012; Kaplan, S. A. *et al.*, 2013; Irwin, D. E. 2006; Rosen, R. *et al.*, 2003; Sexton, C. C. *et al.*, 2009). Despite growing evidence supporting combination therapy, concerns regarding safety in men with BOO persist. Therefore, the present study aimed to investigate the safety of combined solifenacin and tamsulosin oral controlled absorption system (TOCAS) therapy in men with LUTS and BOO.

METHOD

Study design and patients

This prospective comparative study was conducted in private hospitals and private clinics in Baghdad, Iraq. between December 2023 and May 2024. A total of 110 male patients aged 45–70 years with a mean age of approximately 60 years were enrolled. Eligible participants presented with lower urinary tract symptoms (LUTS) and bladder outlet obstruction (BOO) for at least three months. Inclusion criteria were a total International Prostate Symptom Score (IPSS) ≥ 8, maximum urinary flow rate (Qmax) ≤ 12 mL/s, BOO index ≥ 20 (defined as detrusor pressure at Qmax [PdetQmax] − 2 × Qmax), and voided volume ≥ 120 mL during free uroflowmetry at baseline. All patients underwent a screening period of 1–3 weeks before randomization. Participants were randomly allocated into two equal groups (n = 55 each). One group received tamsulosin oral controlled absorption system (TOCAS) 0.4 mg once daily, while the second group received combination therapy with TOCAS 0.4 mg plus solifenacin (SOLI) 10 mg once daily for 12 weeks. Exclusion criteria included history of urinary retention within the preceding 12 months, neurogenic bladder, chronic prostatitis, other causes of urinary outflow obstruction, prior pharmacological treatment for BPH, history of catheterization or pelvic radiotherapy, previous transurethral procedures (TURP, TUIP, TUNA), and neurological disorders such as Parkinson's disease or myasthenia gravis (Wein, A. J. *et al.*, 2012; Kaplan, S. A. *et al.*, 2013; Irwin, D. E. 2006; Rosen, R. *et al.*, 2003; Sexton, C. C. *et al.*, 2009).

Assessments and outcomes

The primary objective was to assess the safety of combination therapy compared with TOCAS monotherapy using urodynamic parameters. Primary endpoints were changes in PdetQmax and Qmax from baseline to the end of treatment. Secondary endpoints included postvoid residual volume (PVR), IPSS, number of micturitions per 24 hours, urgency and incontinence episodes, and voided volume per micturition .

Statistical analysis

Urodynamic and efficacy analyses were performed using the full analysis set, including patients who received at least one dose of treatment and had postbaseline measurements. Safety analyses were conducted in all treated patients. Statistical significance was evaluated using appropriate comparative tests, with a significance level set at $p < 0.05$.

RESULTS

A total of 110 patients were randomized equally into two treatment groups and included in the safety analysis (Fig. 1). Overall, 101 patients (92%) completed the study: 49 patients in the TOCAS 0.4 mg plus solifenacin (SOLI) 10 mg group and 52 patients in the TOCAS 0.4 mg monotherapy group. Participants were recruited from multiple clinical centers in Baghdad and other Iraqi cities.

At baseline, clinical characteristics were comparable between the two groups. The mean total IPSS ranged from 17.5 to 18.2, the mean number of micturitions per 24 hours ranged from 10.5 to 10.7, and the mean voided volume per micturition ranged from 165 to 175 mL (Table 1).

Primary outcome analysis demonstrated significant within-group improvements in urodynamic parameters. In the TOCAS 0.4 mg plus SOLI 10 mg group, mean PdetQmax significantly decreased at week 12 and at the end of treatment (EOT) compared with baseline ($p < 0.005$) (Fig. 2).

Similarly, Qmax significantly increased at week 12 and EOT in both treatment groups compared with baseline ($p < 0.0005$) (Fig. 3).

Between-group comparisons showed that both treatment regimens were effective in improving PdetQmax and Qmax at week 12 and EOT, within the predefined noninferiority margins (Table 2). However, the TOCAS 0.4 mg monotherapy group demonstrated a statistically greater improvement in Qmax compared with the combination therapy group.

Regarding postvoid residual volume (PVR), the combination therapy group exhibited a significant increase from baseline at all follow-up points (Fig. 4). At EOT, the adjusted mean increase in PVR was 30 mL in the combination group and 20 mL in the TOCAS monotherapy group. When groups were compared, the adjusted mean change in PVR remained higher in the combination group at all-time points (Table 3).

No clinically significant changes were observed in laboratory parameters, electrocardiographic findings, or vital signs. Treatment-emergent adverse events (TEAEs) were generally mild to moderate. Drug-related TEAEs occurred in 36% of patients receiving combination therapy and 35.1% of those receiving TOCAS alone (Table 4). Dry mouth was the most frequently reported adverse event. Urinary retention occurred in only one patient receiving combination therapy (two episodes), with one episode requiring catheterization and classified as serious.

Secondary efficacy outcomes demonstrated significant improvements in the number of micturitions per 24 hours and voided volume per micturition in both groups over time. Significant reductions in micturition frequency were observed at week 2 and EOT, while significant increases in voided volume were observed at weeks 4, 8, 12, and EOT in both groups, with earlier improvement at week 2 in the combination therapy group (Fig. 5).

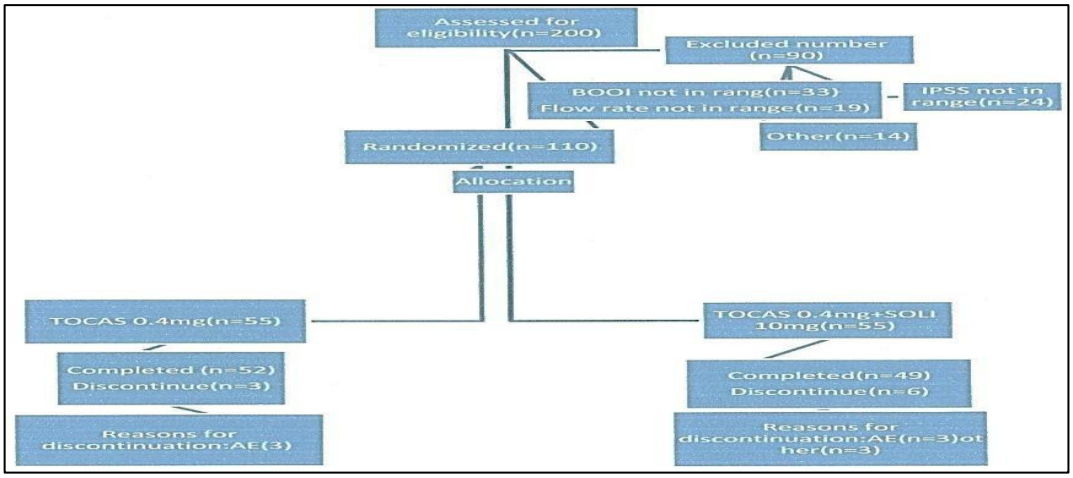

Fig 1: Study flow diagram.

Table 1 – Primary, secondary, and safety variables at baseline

	TOCAS 0.4 mg + SOLI 10mg (n=49)	TOCAS 0.4 mg (n=52)
Primary variables, mean _ SD		
PdetQmax, cm H2O	74.6± 27.3	71.1 ± 26.8
Qmax, ml/s	8.7 ± 3.3	8.5± 1.8
Efficacy assessments, mean _ SD y		
IPSS total score	22.4 ± 4.6	21.4 ± 5.2
IPSS storage score	8.5± 2.4	8.4 ± 2.2
IPSS voiding score	10.3± 3.5	10.4± 4.1
Micturitions per 24 h, no.	8.7 ± 2.1	9.7 ± 3.2
Urgency episodes z per 24 h, no.	2.9 ± 3.3	2.9 ±4.2
Incontinence episodes per 24 h yy, no.	1.5 ± 1.4	2.2 ±1.7
Volume voided per micturition, ml	165.5 ± 61.7	175.0 ±58.0
Safety variables, mean _ SD		
PVR, ml §	30. ±20	20 ±28.0

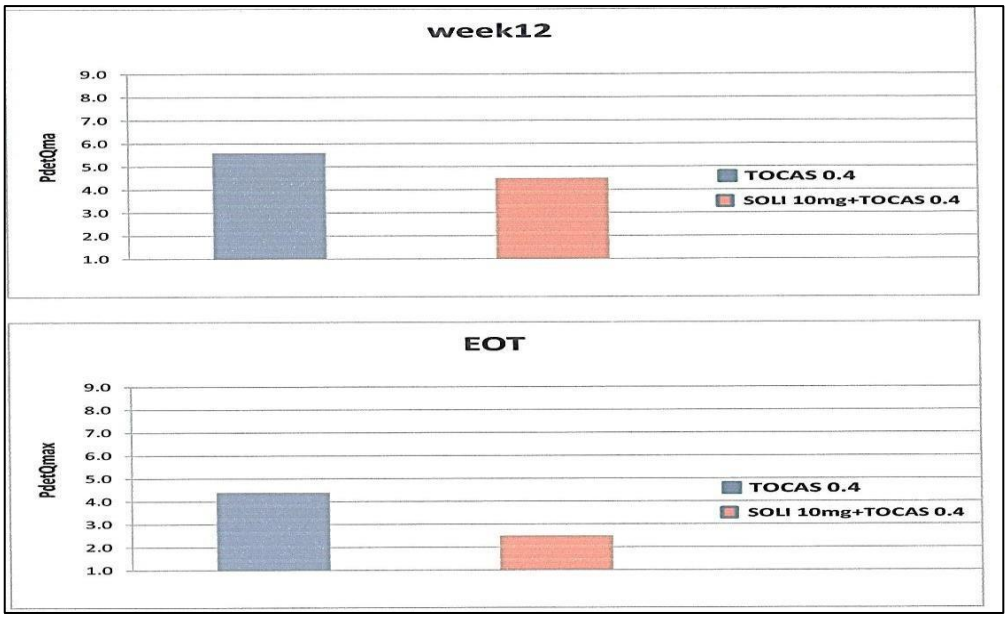

Fig 2: Detrusor pressure at maximum flow rate (PdetQmax)

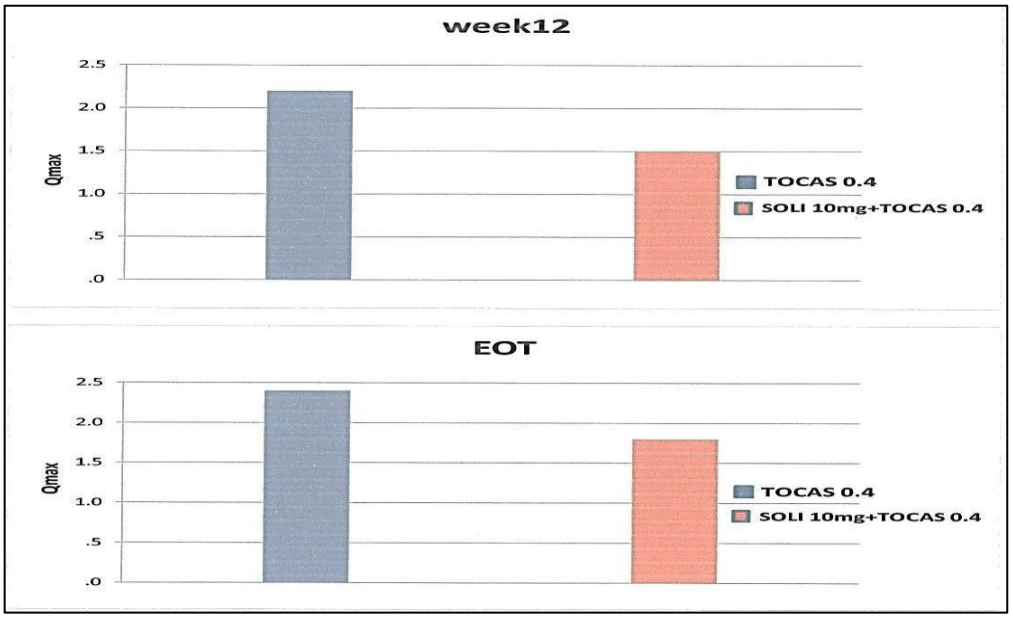

Fig 3: Maximum flow rate (Qmax).

Table 2: Detrusor pressure at maximum flow rate (PdetQmax) and maximum flow rate (Qmax): adjusted mean change between treatmentgroups from baseline to week 12 and end of treatment in the full analysis set

	TOCAS 0.4 mg + SOLI10 mg(n=49)	TOCAS 0.4 mg(n=52)
Change in PdetQmax, cmH2O, adjusted mean (SE)		
Week 12	4.5 (1.9)	5.6 (2.1)
EOT	2.9(1.7)	4.5 (2.0)
Change in Qmax, ml/s, adjusted mean (SE)		
Week 12	1.5 (0.6)	2.2 (0.9)
EOT	1.9 (0.8)	2.4 (1.2)

Table 3: Drug-related treatment-emergent adverse events occurring in >5% of patients in the safety analysis set.

	TOCAS 0.4 mg (n=55)	TOCAS 0.4 mg + SOLI 10 mg(n=55)
Patients with TEAEs, no. (%)	29 (50.2)	29 (50.2)
Patients with drug-related AEs, no. (%)	20 (30.)	18 (30.4)
Constipation	6 (10.1)	7 (12.7)
Dry mouth	10 (11)	16 (29)
Headache	2 (3.1)	2 (3.1)
Patients discontinuing study medication due to AEs, no. (%)	3 (5.4)	3 (5.4)

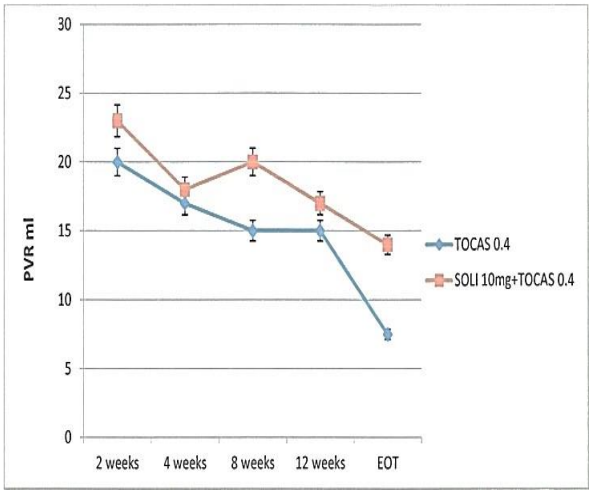

Fig. 4: Postvoid residual volume (PVR)

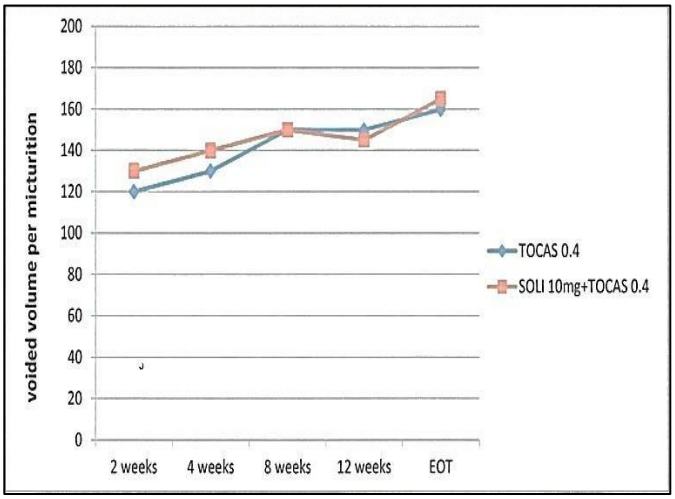

Fig. 5: Average voided volume per micturition

Table 4. **Safety Outcomes and Treatment-Emergent Adverse Events (TEAEs)**

Safety Parameter / Adverse Event	TOCAS 0.4 mg + SOLI 10 mg (n=55)	TOCAS 0.4 mg Alone (n=55)
Laboratory abnormalities	No clinically significant changes	No clinically significant changes
ECG abnormalities	No clinically significant changes	No clinically significant changes
Vital sign abnormalities	No clinically significant changes	No clinically significant changes
Any drug-related TEAEs, n (%)	20 (36.0%)	19 (35.1%)
Severity of TEAEs	Mild–moderate	Mild–moderate
Most common TEAE: Dry mouth, n (%)	12 (21.8%)	3 (5.5%)
Urinary retention (UR), n (%)	1 (1.8%)	0 (0%)
Serious UR requiring catheterization, n (%)	1 (1.8%)	0 (0%)

DISCUSSION

The present study demonstrated that the combination of tamsulosin oral controlled absorption system (TOCAS) and solifenacin (SOLI) was effective in improving key urodynamic parameters, particularly detrusor pressure at maximum flow (PdetQmax) and maximum urinary flow rate (Qmax), in men with lower urinary tract symptoms (LUTS) and bladder outlet obstruction (BOO). These findings support the therapeutic benefit of combining an α-blocker with an antimuscarinic agent in this patient population. The observed improvements at the end of treatment (EOT) are consistent with results reported in several international studies, which showed numerical improvements in Qmax without a statistically significant increase in the risk of

acute urinary retention (AUR) when antimuscarinics were added to α-blocker therapy (Kaplan, S. A. *et al.*, 2013).

However, the evidence regarding the impact of antimuscarinics on Qmax remains inconsistent. A 2006 meta-analysis of randomized and observational studies reported that antimuscarinic therapy did not significantly alter Qmax in men with LUTS suggestive of benign prostatic hyperplasia (BPH) (Lemack, G. E. 2007). Similarly, a 2011 systematic review found no clinically meaningful changes in Qmax with antimuscarinic use for storage LUTS (Abrams, P. 1999). Despite these findings, subsequent placebo-controlled trials demonstrated modest numerical improvements in Qmax with combination therapy, reinforcing the potential benefit of adding antimuscarinics to α-blockers without increasing AUR risk (Kaplan, S. A. *et al.*, 2013).

In the current study, the combination of TOCAS and SOLI was generally well tolerated, consistent with the established safety profiles of both agents. Although a slight increase in postvoid residual (PVR) volume was observed in the combination group, this increase was not clinically significant and was not associated with a higher incidence of urinary retention. These findings align with previous reports showing mild PVR increases with antimuscarinic therapy that did not translate into clinically significant adverse outcomes, as observed in the TIMES, VICTOR, and ADAM trials (Chapple, C. 2010; Lee, K. S. *et al.*, 200). Furthermore, a meta-analysis and subsequent reviews reported low AUR rates and minimal clinically relevant changes in PVR among men treated with antimuscarinics, either alone or in combination with α-blockers (Lemack, G. E. 2007; Abrams, P. 1999; Athanasopoulos, A. *et al.*, 2011; Chapple, C. 2010)

Additional evidence from studies involving add-on antimuscarinic therapy, such as fesoterodine, also supports the safety of combination treatment, with greater improvements in storage symptoms and only modest, clinically insignificant changes in PVR and low AUR risk (Lee, K. S. *et al.*, 200). In our study, improvements in voided volume and micturition frequency were also observed, although the clinical relevance of these changes warrants further investigation.

Several limitations should be acknowledged. Prostate size and prostate-specific antigen (PSA) levels, which are known predictors of LUTS severity and AUR risk, were not assessed in this study (Van Kerrebroeck, P. 2010, Marberger et al. 2000). Moreover, the relatively short follow-up period and local economic constraints affecting drug accessibility may limit the generalizability of the findings. Nevertheless, the low incidence of urinary retention and favorable safety profile observed in this six-month study suggest that TOCAS plus SOLI represents a promising therapeutic option. Further long-term studies are required to confirm the sustained safety and efficacy of this combination therapy in men with LUTS and BOO.

CONCLUSION

TOCAS combined with SOLI at a 10 mg dosage demonstrated efficacy at the endpoint for the primary urodynamic parameters, PdetQmax and Qmax, in males with lower urinary tract symptoms and bladder outlet obstruction. No statistical evidence indicated an elevated incidence of AUR, implying no adverse impact on bladder function during voiding in these blocked individuals. This research examines the safety of a combined therapy using an antimuscarinic and an alpha-blocker in males with bladder outlet obstruction (BOO), resulting in an enhancement of Qmax.

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Source of support: Nil; **Conflict of interest:** Nil.

Cite this article as:
Zaki, A. W. M., Khalaf, Y. S. and Mohammad, E. J. " The Efficacy of Combining Solifenacin with Tamsulosin in the Treatment of Symptoms of Benign Prostatic Hyperplasia." *Sarcouncil Journal of Medical Series* 5.1 (2026): pp 29-35.