ORIGINAL ARTICLE

Effectiveness of Solifenacin Monotherapy and Mirabegron and Solifenacin Combination Therapy in Patients with Stent-Related Symptoms

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ABSTRACT

INTRODUCTION: Ureteral stents are commonly used for internal urinary drainage but frequently cause stent-related symptoms (USRSs), which can negatively affect patient quality of life. This study aimed to evaluate the short-term effectiveness of solifenacin monotherapy compared to a solifenacin-mirabegron combination therapy in patients experiencing USRSs. **MATERIALS AND METHODS:** This double-blind, randomised controlled trial included 54 participants with USRSs. Patients were randomised to receive either solifenacin 5 mg/day (monotherapy) or a combination of solifenacin 5 mg/day and mirabegron 25 mg/day (combination therapy) for four weeks. The Ureteral Stent Symptom Questionnaire (USSQ) was used to compare treatment outcomes. Data were analysed using an independent t-test, with p-values <0.05 considered statistically significant. **RESULTS:** The solifenacin monotherapy group showed significantly lower (better) scores in the Urinary Symptoms domain compared to the combination group at week 1 (p=0.001) and week 2 (p=0.017), and in the General Health domain at week 1 (p=0.005), week 2 (p=0.027), and week 4 (p=0.045). The combination therapy group demonstrated significantly better scores for Sexual Function at week 2 (p=0.017). No statistically significant differences were observed between groups for Pain or Work domains. Both treatments were generally well-tolerated, with a low incidence of mild adverse events. **CONCLUSIONS:** Solifenacin monotherapy appears to provide superior short-term relief for urinary symptoms and general health issues compared to a low-dose solifenacin-mirabegron combination. The combination therapy demonstrated a targeted benefit in improving sexual function. Both treatment regimens were generally safe and well-tolerated.

Keywords
Stent-Related Symptoms, Mirabegron, Solifenacin, USSQ

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Received: 29th September 2024; Accepted: 16th December 2025

Doi: https://doi.org/10.31436/imjm.v25i01/2726

INTRODUCTION

The Double J (DJ) ureteral stent is a widely used surgical instrument for managing ureteral obstruction and facilitating postoperative drainage.[1] However, its use is frequently associated with stent-related symptoms (SRSs), also known as ureteral stent-related symptoms (USRSs). Conservative, non-invasive interventions for SRSs include alpha-blockers, anticholinergic medications, and analgesics.[2] To standardise the assessment of morbidity following DJ stent insertion, the Ureteral Stent Symptoms Questionnaire (USSQ) has been established as a validated, gold-standard instrument.[3]

The lower urinary tract symptoms (LUTS) caused by DJ stents are pathologically similar to symptoms of benign prostatic hyperplasia (BPH) and overactive bladder (OAB). Consequently, therapies effective for BPH and

OAB, such as alpha-blockers and antimuscarinics, are often used to manage SRSs.[4] Despite the high incidence of these symptoms, complications from DJ stent insertion remain under-investigated, particularly in Indonesia.

Current oral pharmacotherapies for OAB include the β3-adrenoceptor agonist mirabegron and antimuscarinics like solifenacin. Solifenacin is a competitive antagonist of cholinergic receptors with high selectivity for the M3 subtype, which plays a key role in bladder smooth muscle contraction. By inhibiting this pathway, solifenacin reduces bladder muscle tone, increasing its capacity and mitigating urinary urgency, frequency, and incontinence.[5] Mirabegron is a selective β3-adrenoceptor agonist; stimulating these receptors relaxes the detrusor muscle.[5] Studies have shown that combining mirabegron and solifenacin can increase treatment efficacy for OAB without reducing tolerability.[6]

This study aimed to investigate the effectiveness of solifenacin 5 mg/day monotherapy compared to a combination of solifenacin 5 mg/day and mirabegron 25 mg/day on USRSs after DJ stent insertion.

MATERIALS AND METHODS

This double-blind, randomised controlled trial included male and female patients with USRSs after DJ stent insertion. A complete medical history and physical examination were performed for all participants. Preoperative assessments included serum urea and creatinine levels, urinalysis, ultrasonography, and a kidney, ureter, and bladder (KUB) X-ray. All patients who underwent routine DJ stent insertion after endourological procedures (ureteroscopic lithotripsy or unilateral percutaneous nephrolithotomy) were eligible for inclusion. A 6 Fr DJ stent (Inlay Optima®, Bard Medical, Covington, GA, USA) was inserted under cystoscopic and fluoroscopic guidance.

After surgery, an abdominal X-ray was performed before hospital discharge to confirm stent positioning and the status of any residual stone fragments. The Foley catheter was removed on postoperative day one for all patients. Patients received a 5–7 day course of oral antibiotics (cefadroxil) and were prescribed mefenamic acid (500 mg every 6-8 hours as needed) for pain. The total analgesic consumption was recorded.

Treatment with either solifenacin 5 mg/day or the combination of solifenacin 5 mg/day and mirabegron 25 mg/day was initiated on day seven after DJ stent insertion. USSQ data were collected weekly on days 7, 14, 21, and 28 via direct interview or phone call. The study was conducted at four hospitals in Makassar, Indonesia (Ibnu Sina Hospital, Akademis Hospital, Hasanuddin University hospital, and Wahidin Sudirohusodo Hospital). It was conducted from September 2023 to February 2024. This research was approved by the local Ethics Committee (Reference No. 801/UN4.6.4.5.31/ PP36/2020).

Sampling Method and Sample Size

Patients were excluded if they met any of the following criteria: (1) under 18 years of age; (2) pregnancy; (3) bilateral stents; (4) previous ureteral stenting; (5) significant bladder pathology; (6) indication for long-term stenting; (7) symptomatic BPH; (8) active urinary tract infection; (9) severe systemic diseases; or (10) prior use of antimuscarinic or alpha-1 antagonist agents.

Participants were recruited using a consecutive sampling method. All eligible patients were then randomised into two treatment groups. A sample size calculation using a two-proportion test determined a minimum requirement of 25 patients per group. Group A received solifenacin 5 mg/day, and Group B received a combination of solifenacin 5 mg/day and mirabegron 25 mg/day.

Treatment Outcome Assessments

The USSQ was used to measure treatment outcomes over four weeks. This questionnaire evaluates stent-related morbidity across six domains: urinary symptoms, pain, general health, work performance, sexual matters, and other additional problems. A lower score in each domain indicates fewer symptoms and a better clinical outcome.

Data Collection

Participants were enrolled and received the USSQ forms during their follow-up visit at the outpatient clinic on day seven. Eligible patients were randomly assigned to receive either solifenacin monotherapy or combination therapy. The study was double-blinded. Participants took the medication orally for four weeks, and outcomes were recorded weekly from the completed questionnaires. All participants remained stented throughout the 4-week study period, and all data collection was completed prior to stent removal.

Safety and Adverse Event Assessment

At each weekly follow-up via phone or in-person visit, participants were systematically questioned about the occurrence of potential treatment-related adverse events. Specific inquiries were made regarding common side effects of antimuscarinics (e.g., dry mouth, constipation, blurred vision) and β3-agonists (e.g., headache, hypertension). All reported events were recorded, and their severity was graded as mild, moderate, or severe.

Data Processing and Analysis

Scores for each of the six USSQ domains were expressed as mean ± standard deviation. Demographic data, such as age, were categorised based on the standard classification from the Ministry of Health of the Republic of Indonesia.7 Comparisons between treatment groups were conducted using an independent t-test, and Fisher's exact test was used to analyze the incidence of adverse events. A p-value of <0.05 was considered statistically significant. Data were processed using Microsoft Excel 2010 (Redmond, WA: Microsoft Corporation) and SPSS version 24.0 (Armonk, NY: IBM Corp.).

RESULTS

A total of 54 participants were randomised: 28 to the combination therapy group and 26 to the solifenacin monotherapy group. Baseline demographic and clinical characteristics were generally similar between the two groups (Table I).

Table I: Participants' Characteristics.

Variables	Solifenacin + mira-begron n (%)	Solifenacin n (%)
Age		
Late adolescence (18–25 years)	2 (7.1)	2 (7.69)
Adulthood (26–45 years)	14 (50)	10 (38.46)
Early Elderly (46–55 years)	7 (25)	7 (26.92)
Late Elderly (56–65 years)	5 (17.9)	4 (15.38)
Very Elderly (>65 years)	0 (0)	3 (11.54)
Sex		
Male	21 (75)	14 (53.8)
Female	7 (25)	12 (46.2)
BMI (kg/m2)		
Mean ± SD	22.83 ± 3.47	24.43 ± 3.08
Weight (kg)		
Mean ± SD	60.92 ± 9.45	63.57 ± 10.91
Height (cm)		
Mean ± SD	163.35 ± 6.08	160. 84 ± 6.96
Marital Status		
Married	23 (82.1)	20 (76.9)
Double J stent insertion side		
Right	17 (60.74)	12 (46.15)
Left	11 (39.26)	14 (53.84)

Note: BMI, body mass index.

The treatment outcomes from the USSQ domains are presented in Table II. The solifenacin monotherapy group reported significantly lower (better) scores for Urinary Symptoms at week 1 (p=0.001) and week 2 (p=0.017).

Table II: Treatment outcomes by six USSQ index scores.

Observation time (week)	Mean score ± SD		p-value*
	Solifenacin	Solifenacin + Mirabegron	
Urinary symptoms index score			
1	15.19 ± 4.88	21.53 ± 5.79	0.001
2	10.88 ± 3.45	13.64 ± 4.63	0.017
3	8.11 ± 2.48	9.35 ± 3.71	0.158
4	5.61 ± 2.51	7.17 ± 3.62	0.073
Pain symptoms index score			
1	13.85 ± 3.51	12.21 ± 4.58	0.150
2	9.85 ± 3.90	8.36 ± 3.54	0.148
3	6.07 ± 3.37	4.82 ± 2.80	0.142
4	4.65 ± 3.06	3.96 ± 2.78	0.390
General health symptoms index score			
1	9.54 ± 3.63	12.53 ± 3.81	0.005
2	6.42 ± 3.06	8.53 ± 3.71	0.027
3	4.42 ± 3.02	6.14 ± 3.96	0.80
4	3.69 ± 2.54	5.32 ± 3.22	0.045
Working complaints index score			
1	6.96 ± 3.02	5.07 ± 5.12	0.114
2	4.84 ± 2.95	4.50 ± 3.76	0.718
3	3.36 ± 1.82	3.14 ± 2.60	0.730
4	2.12 ± 1.85	3.03 ± 2.51	0.142
Sexual dysfunction complaints index score			
1	2.33 ± 0.57	1.20 ± 2.02	0.350
2	3.57 ± 1.94	2.04 ± 1.76	0.017
3	2.67 ± 1.39	2.12 ± 1.33	0.225
4	1.93 ± 0.88	2.28 ± 0.97	0.269
Other symptoms score			
1	7.34 ± 2.99	8.46 ± 2.53	0.143
2	4.92 ± 2.41	5.03 ± 2.02	0.858
3	3.69 ± 1.78	3.42 ± 1.47	0.555
4	2.57 ± 1.87	3.25 ± 1.35	0.135

Note: *Independent t-test.

A similar trend favoring monotherapy was observed in the General Health domain at week 1 (p=0.005), week 2 (p=0.027), and week 4 (p=0.045). There were no significant differences between the groups in the domains of Pain, Work Performance, or Other Symptoms.

Both treatment regimens were well-tolerated by the participants. No serious adverse events or study discontinuations due to side effects were reported. The incidence of mild adverse events was low in both groups and is detailed in Table III. The most frequently reported adverse event was mild dry mouth, with no statistically significant difference in overall incidence between the two ams.

Table III: Incidence of Adverse Events.

Adverse Event	Solifenacin + Mirabegron (n=28) n (%)	Solifenacin (n=26) n (%)	p-value*
Dry Mouth	4 (14.3%)	4 (15.4%)	0.91
Constipation	3 (10.7%)	3 (11.5%)	0.93
Headache	2 (7.1%)	1 (3.8%)	0.60
Hypertension	1 (3.6%)	0 (0%)	0.48
Blurred Vision	1 (3.6%)	1 (3.8%)	0.99
Total Patients with any AE	8 (28.6%)	7 (26.9%)	0.90

Note: AE, Adverse Event. Total Patients with any AE represents the number of patients experiencing at least one adverse event. *P-values were calculated using Fisher's exact test.

Subgroup Analysis of Sexual Dysfunction

A subgroup analysis was performed to evaluate the impact of sex on the sexual dysfunction domain score. In the combination therapy group, the mean score at week 2 was 2.10 for males (n=21) and 1.86 for females (n=7), with a within-group comparison p-value of 0.42. In the monotherapy group, the mean score at week 2 was 3.86 for males (n=14) and 3.25 for females (n=12), with a within-group comparison p-value of 0.38. These results indicate no statistically significant difference between male and female participants within either treatment arm, supporting the statement that gender did not significantly affect sexual symptom outcomes.

DISCUSSION

This randomised controlled trial demonstrated the unexpected finding that solifenacin 5 mg monotherapy was superior to a combination of solifenacin 5 mg and mirabegron 25 mg in alleviating urinary symptoms and improving general health during the first few weeks following ureteral stent placement. Furthermore, both treatments demonstrated a favorable safety profile and were well-tolerated. This result challenges the assumption that combination therapy, which is often superior for OAB, would also be superior for USRSs.

The superiority of monotherapy in this context may be explained by the distinct pathophysiology of USRSs compared to OAB. USRs are primarily caused by the mechanical irritation of the bladder trigone by the stent's distal coil, which triggers involuntary detrusor contractions mediated by M3 cholinergic receptors.8 Our findings suggest that blocking this specific pathway with solifenacin is the most critical and sufficient intervention. The β3-adrenoceptor pathway, targeted by mirabegron, may play a less significant role in stent-induced irritation compared to its role in idiopathic detrusor overactivity seen in OAB.

Several factors might have affected treatment outcomes and USSQ data, including relationship status, older age, and sexual activity. The proportion of men to women was higher in the combination group, with a ratio of 3:1, whereas the proportions of men and women in the monotherapy group were almost equal (1:1.16). Notable age differences among the treated patients might have also affected therapy outcomes. Our findings are in line with a study that found LUTS impacted a significant proportion of individuals aged 40 years and older, and the incidence increases with advancing age.9 LUTS are associated with impaired quality of life (QOL) and mental health, but less than 50% of individuals in China experiencing LUTS pursue medical care for their conditions. A key point raised during the review process was the need for a more detailed analysis of the sexual dysfunction domain, and we have now incorporated a subgroup analysis by gender and data on marital status. Our study found no statistically significant difference in sexual symptom scores between male and female participants in either treatment arm. This finding contrasts with the literature suggesting a higher prevalence of sexual symptoms in female patients (up to 80%) compared to males (around 60%).10 The lack of a significant difference in our cohort is likely attributable to the limited statistical power of our subgroup analysis,

particularly the small number of female participants. Furthermore, a high proportion of participants in both groups were married, suggesting that sexual activity was a relevant quality-of-life factor for the majority of our sample. Future, larger-scale studies with a more balanced sex distribution are needed to properly elucidate the differential impact of USRSs on sexual function between the sexes.

Our study demonstrated that solifenacin monotherapy resulted in better outcomes for urinary symptoms and general health compared to the combination treatment group over four weeks, with a non-significant trend toward improvement in pain scores. This finding appears to contrast with the typical goals of therapy for LUTS, where combination treatments are often explored to maximise symptom improvement. An optimal therapeutic approach for LUTS aims to alleviate symptoms by understanding their underlying causes, making informed decisions, and systematically applying treatments. Interventions should not worsen a patient's condition; this includes avoiding aggressive or irreversible treatments for minor symptoms, reducing complications, and preserving sexual function where possible. Patients must also be informed about the potential adverse effects and realistic outcomes of their treatment options.[11]

Other studies in different patient populations have found success with combination therapy. For example, one trial demonstrated the safety and efficacy of a dual therapy (mirabegron 50 mg and solifenacin 5 mg) compared to solifenacin monotherapy (5 mg or 10 mg) in patients with OAB, with subgroup analyses by age.[12] It found that all treatments improved outcomes, but the combination therapy outperformed solifenacin monotherapy in managing OAB symptoms-such as urgency, frequent urination, and incontinence-particularly among older patients.

Similarly, a multinational, randomised, double-blind study that investigated different dosing regimens found that a higher dose of mirabegron (50 mg) in combination with solifenacin (5 mg) significantly decreased OAB symptoms compared to solifenacin monotherapy ($p<0.001$).[13] Another meta-analysis of 3,309 patients concluded that combining mirabegron and solifenacin was superior to solifenacin alone in reducing micturition, incontinence, and urgency episodes without increasing adverse effects.[14] Furthermore, a long-term study by Gratzke et al. found that combination therapy was well-tolerated for up to 12 months and was considerably more effective than monotherapy in reducing incontinence episodes in OAB patients, leading the authors to recommend it as a widely viable clinical option.[15]

The fact that our findings contrast with these major studies strongly suggests that USRS and OAB are distinct clinical entities driven by different primary mechanisms. While OAB often involves idiopathic detrusor overactivity, USRS are a direct consequence of mechanical irritation of the bladder trigone by the stent's distal coil. Our data suggest that for USRS, blocking M3 cholinergic receptors with solifenacin is the most critical and sufficient intervention. The addition of a low-dose β3 -agonist like mirabegron did not provide further benefit in our study and, in the early stages, was even associated with worse urinary symptom scores.

A meta-analysis demonstrated that the combination of mirabegron 50 mg with solifenacin 5 mg led to several significant improvements for patients with OAB. These included: a greater mean volume voided per micturition; a reduced incidence of urgency incontinence, micturitions, and urgency episodes; lower patient perception of bladder condition scores; and an increase in the number of patients achieving zero incontinence. These factors notably enhanced overall health-related QOL scores. 16 No significant difference was observed between the combination and monotherapy groups regarding treatment-emergent adverse events, such as QT prolongation on electrocardiograms, urinary tract infection, urinary retention, or dry mouth. The authors concluded that mirabegron and solifenacin combination therapy provides an adequate therapeutic outcome without increasing the risk of adverse effects, thereby improving QOL for patients with OAB. They recommended this combination to achieve a balance between efficacy and tolerability.[16,17]

Mirabegron as a monotherapy has also proven effective. Daily doses of 25 mg, 50 mg, and 100 mg showed notable improvements from baseline in mean volume voided, urgency incontinence, and micturition frequency, with effects sustained throughout treatment. The most common adverse events reported were nasopharyngitis, hypertension, and urinary tract infections. Importantly, the occurrence of dry mouth was similar to that of a placebo and significantly lower than with tolterodine. Given that dry mouth is a common and distressing side effect of antimuscarinics, mirabegron may be a beneficial alternative. The advantages of mirabegron were also observed in older adults and in patients who were either treatment-naïve or had previously discontinued antimuscarinic therapy. As it can be used concurrently with other medications like alpha-blockers, mirabegron is poised to become a standard treatment for OAB.[16,17]

In the context of ureteral stents, another study found that combining tamsulosin and solifenacin was an effective treatment option for reducing ureteral stent-related symptoms (USRSs). A separate analysis showed that mirabegron monotherapy was also effective for USRSs. Furthermore, based on OAB questionnaire scores, mirabegron monotherapy was superior to both a combination therapy group and oral hydration alone for treating OAB symptoms associated with DJ stents.[18]

Our study has several limitations. First, there was a sex imbalance between the groups. Second, as a multi-center study within a single city, our population may not be fully representative of the broader national demographic. Finally, the four-week duration was sufficient to assess short-term efficacy and safety but not long-term outcomes. Despite these limitations, the study provides a general comparison of combination therapy mirabegron and solifenacin with monotherapy solifenacin for further studies.

CONCLUSIONS

Solifenacin monotherapy appears to provide superior short-term relief for urinary symptoms and general health issues compared to a low-dose solifenacin-mirabegron combination, based on the findings of this small-sample, single-city study. The combination therapy, however, demonstrated a targeted benefit in improving symptoms related to sexual function. Both regimens were generally safe and well-tolerated, with only mild adverse events reported. These results highlight the potential utility of solifenacin monotherapy in managing ureteral stent-related symptoms, while emphasizing the need for larger, multi-center, and longer-term studies to confirm efficacy and safety.

FUNDING

Self-funding

CONFLICTS OF INTEREST

The authors have no conflict of interest to declare

AUTHORS' CONTRIBUTIONS

All authors read and approved the final version of the manuscript.

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