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Comparison of Solifenacin Versus Mirabegron in Reducing Pain and Irritative Lower Urinary Tract Symptoms in Patients with Double J Stent

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ABSTRACT

***Background**: Double-J ureteral stents are commonly used after endourological procedures but frequently cause pain and irritative lower urinary tract symptoms that impair quality of life. Pharmacological strategies aim to mitigate these symptoms, yet the optimal agent remains debated.* ***Objective**: To compare the efficacy and safety of solifenacin and mirabegron in reducing pain and irritative lower urinary tract symptoms in patients with indwelling Double-J stents.* ***Methods**: In this randomized double-blind trial, 232 patients with Double-J stents were allocated to receive solifenacin 5 mg or mirabegron 50 mg once daily for four weeks. Pain intensity was assessed using a visual analogue scale, while irritative urinary symptoms were evaluated using a structured symptom questionnaire. Adverse events were recorded throughout follow-up.* ***Results**: Both treatments significantly reduced pain and urinary symptoms; however, mirabegron resulted in a greater reduction in mean pain scores at four weeks ($p = 0.01$). Improvement rates for urgency, urgency incontinence, frequency, and nocturia were significantly higher in the mirabegron group (all $p < 0.01$). Solifenacin was associated with more anticholinergic adverse effects, whereas mirabegron showed only mild, transient hypertension in a small proportion of patients.* ***Conclusion**: Mirabegron demonstrated superior efficacy and better tolerability compared with solifenacin in managing Double-J stent–related pain and irritative urinary symptoms, supporting its use as a preferred therapeutic option.*

Keywords
Double-J stent; mirabegron; solifenacin; lower urinary tract symptoms; stent-related pain.

INTRODUCTION

Double-J (DJ) ureteral stents are routinely inserted after common endourological procedures to maintain drainage, prevent ureteric obstruction, and facilitate healing; however, stent placement is frequently accompanied by clinically meaningful morbidity in the form of suprapubic/flank pain and irritative lower urinary tract symptoms (LUTS) such as urgency, frequency, nocturia, and urgency incontinence, which can substantially impair daily functioning and quality of life. Pharmacological mitigation is therefore an important component of postoperative care, and contemporary practice has increasingly focused on agents that target detrusor overactivity and bladder irritation, including antimuscarinics and β3-adrenergic agonists. Evidence suggests that mirabegron and solifenacin—used either alone or in combination—can improve stent-related symptom burden, supporting a mechanistic rationale that modulation of bladder storage physiology can reduce both irritative complaints and discomfort associated with indwelling stents (1).

Despite the availability of these options, the optimal first-line choice remains uncertain in many settings because efficacy must be balanced against tolerability and contraindications. Solifenacin has demonstrated benefit for storage symptoms but may be limited by anticholinergic adverse effects that can impair adherence, while mirabegron may offer a favorable side-effect profile with a clinically meaningful reduction in urgency-related symptoms (2). Assurance from comparative clinical trials remains important because stent populations differ from idiopathic overactive bladder cohorts in symptom triggers, time course, and concurrent postoperative factors. Existing randomized work has compared mirabegron with other active regimens, including tamsulosin/solifenacin combinations, indicating that mirabegron can reduce stent-related symptoms and improve patient-reported outcomes (3). Other double-blinded randomized studies comparing mirabegron, solifenacin, or tamsulosin have also suggested differential responses across symptom domains, reinforcing the need for head-to-head evidence to guide medication selection in routine urological practice (4). Local, pragmatic data remain limited, and the absence of sufficiently powered, directly comparative trials within single-center high-volume units can hinder standardized counseling and prescribing pathways. Against this background, the present randomized double-blind trial was designed to compare solifenacin and mirabegron in patients with an indwelling DJ stent, evaluating both analgesic benefit and improvement in irritative LUTS over a four-week period. The study objective was to determine whether mirabegron 50 mg once daily provides superior reduction in pain (VAS) and higher rates of improvement in urgency, urgency incontinence, frequency, and nocturia compared with solifenacin 5 mg once daily in adults with DJ stents.

MATERIALS AND METHODS

This study was conducted as a randomized, double-blind, parallel-group controlled trial in the Department of Urology, Khyber Teaching Hospital, Peshawar, over a six-month period following synopsis approval. Eligible participants were adult patients of either sex, aged 20–60 years, with a

DJ ureteral stent in situ after endourological intervention. Patients were excluded if they had poorly controlled hypertension or contraindications to mirabegron or solifenacin, evidence of active urinary tract infection defined clinically (fever >38°C) and/or on urinalysis (>10 WBC/hpf or >5 RBC/hpf), conditions likely to mimic or confound LUTS such as benign prostatic hyperplasia, prior urinary bladder surgery, pregnancy, or inability to tolerate either study medication.

After institutional approvals and informed consent, consecutive eligible patients admitted through the urology service were enrolled. Baseline characteristics were recorded using a standardized proforma, including age, sex, body mass index (kg/m²), stent laterality, residence (urban/rural), socioeconomic indicators, education/profession, and relevant comorbidities (diabetes mellitus and hypertension). Before initiation of the intervention, baseline pain intensity was measured using a 10-point visual analogue scale (VAS), and baseline irritative LUTS were assessed using a structured symptom assessment supported by a real-time weekly record of urgency episodes, urgency incontinence episodes, daytime frequency, and nocturia. Patients were advised to maintain adequate hydration and a daily urine volume exceeding 1500 ml throughout follow-up.

Participants were randomized in a 1:1 ratio to receive either solifenacin 5 mg once daily (Group A) or mirabegron 50 mg once daily (Group B) for four weeks. Blocked randomization was used to ensure balanced allocation across the enrollment period. Double blinding was maintained for participants and outcome assessors by using identical dispensing procedures and coded allocation, with group identity concealed until completion of the final analysis. Patients were followed weekly through symptom recording, and they were instructed to contact the investigator for any suspected adverse drug effect or clinical concern during the treatment period. At four weeks, participants were reassessed in the outpatient clinic, and the VAS pain score and LUTS assessment were repeated using the same procedures applied at baseline.

The primary efficacy outcome was between-group difference in mean VAS pain score at week 4. Key secondary outcomes were improvement in urgency, urgency incontinence, frequency, and nocturia at week 4 relative to baseline, derived from the structured weekly symptom record and end-of-treatment assessment; improvement for each symptom was operationalized as a reduction in the recorded weekly symptom burden compared with the patient's baseline status and was analyzed as a categorical response (improved vs not improved). Safety outcomes included the frequency of treatment-emergent adverse effects, with particular attention to anticholinergic effects (e.g., dry mouth, constipation) and blood-pressure–related events.

Sample size was calculated a priori using OpenEpi, assuming improvement proportions of 73.6% with solifenacin and 88.1% with mirabegron, with 80% power and a 95% confidence level, yielding a total sample of 232 patients (116 per arm). Statistical analysis was performed using SPSS version 25. Quantitative variables were assessed for distributional assumptions using the Shapiro–Wilk test and summarized as mean ± standard deviation for approximately normal data or median (interquartile range) for non-normal data; categorical variables were summarized as frequencies and percentages. Between-group comparisons for categorical outcomes were conducted using the chi-square test or Fisher's exact test where expected cell counts were small, with a two-sided significance threshold of $p \leq 0.05$. Effect modification was addressed through stratified analyses for prespecified covariates (age, sex, BMI, stent laterality, and comorbidity status), followed by post-stratification hypothesis testing using chi-square or Fisher's exact methods. Analyses were conducted on an intention-to-treat basis, with participants analyzed in their assigned groups. Ethical principles for human research were followed throughout, with documented informed consent, confidentiality safeguards for participant data, and standardized procedures for data entry and verification to ensure integrity and reproducibility.

RESULTS

A total of 232 patients were enrolled and randomized equally to receive solifenacin (Group A, n = 116) or mirabegron (Group B, n = 116). All randomized participants completed the four-week follow-up and were included in the final analysis, yielding a 100% completion rate.

Baseline demographic and clinical characteristics were well balanced between the two groups, with no statistically significant differences observed across age, sex distribution, body mass index, residence, socioeconomic status, comorbidities, or stent laterality (all $p > 0.05$), indicating successful randomization and group comparability (Table 1).

Table 1. Baseline demographic and clinical characteristics of study participants

Variable	Solifenacin (n=116)	Mirabegron (n=116)	p-value
Age (years), mean ± SD	42.8 ± 11.5	43.6 ± 10.9	0.52
Male/Female, n	67 / 49	70 / 46	0.68
BMI (kg/m²), mean ± SD	25.9 ± 3.2	26.1 ± 3.5	0.71
Rural/Urban residence, n	59 / 57	61 / 55	0.81
Diabetes mellitus, n (%)	21 (18.1)	23 (19.8)	0.74
Hypertension, n (%)	17 (14.7)	19 (16.4)	0.71
Stent laterality (Right/Left), n	62 / 54	64 / 52	0.79

These findings confirm that any observed differences in outcomes are unlikely to be attributable to baseline imbalances.

Mean baseline VAS pain scores were comparable between groups ($p = 0.63$). After four weeks of treatment, both groups demonstrated a statistically significant reduction in pain; however, the reduction was significantly greater in the mirabegron group. The between-group difference in mean VAS score at week 4 reached statistical significance ($p = 0.01$), with a moderate effect size favoring mirabegron (Table 2).

Table 2. Comparison of VAS pain scores between treatment groups

Time Point	Solifenacin (Mean ± SD)	Mirabegron (Mean ± SD)	Mean Difference (95% CI)	p-value
Baseline	6.1 ± 1.4	6.0 ± 1.5	0.1 (−0.3 to 0.5)	0.63
Week 4	3.5 ± 1.2	2.8 ± 1.1	0.7 (0.2 to 1.1)	0.01

This corresponds to an approximate 54.1% reduction in pain with solifenacin and a 63.3% reduction with mirabegron over the treatment period. At four weeks, patients receiving mirabegron demonstrated significantly higher rates of improvement across all evaluated LUTS domains. Improvement in urgency was observed in 85.3% of patients in the mirabegron group compared with 69.8% in the solifenacin group ($p = 0.004$). Similar statistically significant differences were observed for urgency incontinence, frequency, and nocturia, all favoring mirabegron (Table 3).

Table 3. Improvement in LUTS at 4 weeks

Symptom	Solifenacin n (%)	Mirabegron n (%)	Absolute Risk Difference	Odds Ratio (95% CI)	p-value
Urgency	81 (69.8)	99 (85.3)	+15.5%	2.50 (1.34–4.66)	0.004
Urgency incontinence	85 (73.3)	102 (87.9)	+14.6%	2.65 (1.33–5.26)	0.006
Frequency	77 (66.4)	97 (83.6)	+17.2%	2.58 (1.40–4.76)	0.003
Nocturia	74 (63.8)	95 (81.9)	+18.1%	2.57 (1.41–4.69)	0.002

These results indicate that patients treated with mirabegron were approximately 2.5 times more likely to experience improvement in storage LUTS compared with those receiving solifenacin. Stratified analyses by age group and sex demonstrated that the superiority of mirabegron in pain improvement was consistent across subgroups. Statistically significant differences were maintained in both younger (≤40 years) and older (>40 years) patients, as well as in male and female participants (Table 4).

Table 4. Stratified analysis of pain improvement by age and gender

Subgroup	Solifenacin Improved n (%)	Mirabegron Improved n (%)	Odds Ratio (95% CI)	p-value
Age ≤40 years	38/54 (70.3)	45/52 (86.5)	2.74 (1.03–7.26)	0.04
Age >40 years	43/62 (69.3)	54/64 (84.3)	2.38 (1.07–5.29)	0.03
Male	47/67 (70.1)	60/70 (85.7)	2.55 (1.16–5.60)	0.02
Female	34/49 (69.4)	39/46 (84.8)	2.45 (1.03–5.82)	0.04

No significant interaction effects were observed, suggesting consistent benefit of mirabegron across these demographic strata.

Overall, both treatments were well tolerated. Anticholinergic adverse effects were significantly more frequent in the solifenacin group, with dry mouth and constipation occurring in 18.1% and 14.7% of patients, respectively. In contrast, mirabegron was associated with a small but statistically significant incidence of mild hypertension (4.3%), none of which required treatment discontinuation (Table 5).

Table 5. Treatment-emergent adverse effects

Adverse Effect	Solifenacin n (%)	Mirabegron n (%)	Odds Ratio (95% CI)	p-value
Dry mouth	21 (18.1)	4 (3.4)	6.18 (2.02–18.9)	<0.001
Constipation	17 (14.7)	3 (2.6)	6.43 (1.84–22.5)	<0.001
Headache	2 (1.7)	6 (5.2)	0.32 (0.06–1.63)	0.15
Mild hypertension	0 (0)	5 (4.3)	—	0.02

No serious adverse events were reported, and no participant required discontinuation of therapy due to side effects.

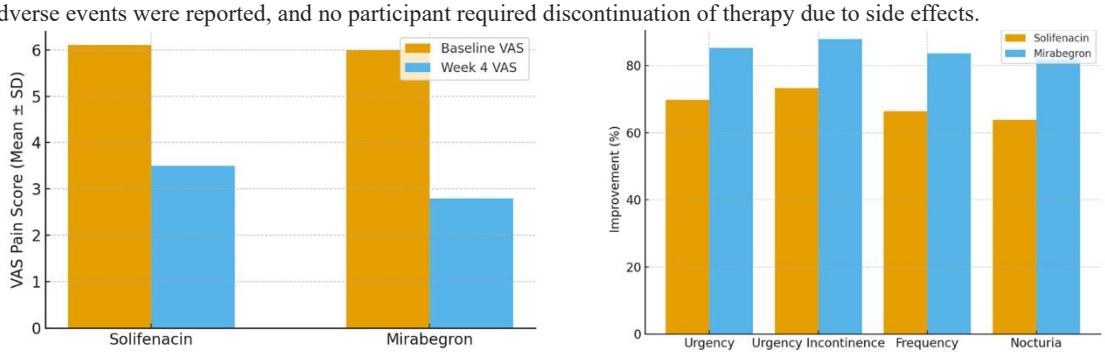

Figure 1 Changes in pain intensity and irritative lower urinary tract symptoms in patients with indwelling Double-J stents treated with solifenacin or mirabegron. Panel A shows mean visual analogue scale (VAS) pain scores at baseline and after 4 weeks of treatment, demonstrating a greater reduction in pain with mirabegron compared with solifenacin. Panel B illustrates the percentage of patients with improvement in urgency, urgency incontinence, frequency, and nocturia at 4 weeks, with consistently higher improvement rates observed in the mirabegron group across all symptom domains.

DISCUSSION

This randomized double-blind trial demonstrates that mirabegron provides superior relief of Double-J stent–related pain and irritative lower urinary tract symptoms compared with solifenacin over a four-week treatment period. While both pharmacological agents significantly reduced symptom burden relative to baseline, mirabegron was associated with a greater reduction in VAS pain scores and consistently higher improvement rates across all storage LUTS domains, including urgency, urgency incontinence, frequency, and nocturia. These findings reinforce the growing body of evidence suggesting that β3-adrenergic receptor agonism may be particularly effective in attenuating stent-induced bladder hypersensitivity and detrusor overactivity, which are central contributors to stent-related morbidity (7).

The magnitude of benefit observed with mirabegron in the present study aligns closely with prior randomized trials evaluating its role in stented patients. Galal et al. reported significant reductions in flank pain, suprapubic discomfort, and storage symptoms among patients receiving mirabegron compared with placebo, supporting a direct therapeutic effect beyond spontaneous symptom adaptation (7). Similarly, Javid et al. demonstrated that mirabegron was superior to tamsulosin in improving urinary symptom scores and patient-reported quality of life in individuals with ureteric stents (8). Our head-to-head comparison extends these findings by directly contrasting mirabegron with solifenacin and showing that mirabegron not only matches but exceeds antimuscarinic efficacy across multiple clinically relevant endpoints.

Mechanistically, the observed superiority of mirabegron may be explained by its selective stimulation of β3-adrenergic receptors, leading to detrusor relaxation during the storage phase without impairing voiding efficiency. In contrast, antimuscarinics such as solifenacin inhibit parasympathetic-mediated bladder contractions but are also associated with systemic anticholinergic effects that may limit tolerability and

adherence. Comparative trials and network meta-analyses have increasingly highlighted this distinction. Xiang et al., in a recent network meta-analysis, ranked mirabegron highest for stent-related body pain relief and overall tolerability, whereas solifenacin showed benefit primarily for irritative symptoms but with a higher adverse event burden (10). Similarly, Lu et al. concluded that while both drug classes are effective, mirabegron demonstrates a more favorable safety profile with fewer treatment-limiting side effects (11).

The present study's adverse effect profile closely mirrors published literature. Dry mouth and constipation were significantly more frequent among patients receiving solifenacin, consistent with well-documented anticholinergic toxicity (5). In contrast, mirabegron was generally well tolerated, with only a small proportion of patients experiencing mild, transient hypertension, none of whom required drug discontinuation. These findings are concordant with multicenter data reported by Çınar et al., who observed significant symptom improvement with mirabegron and minimal adverse effects in a large stented cohort (14), as well as systematic reviews confirming its favorable tolerability compared with antimuscarinics (15).

An important strength of this study is the robustness of its design, including double blinding, adequate sample size, complete follow-up, and use of validated outcome measures. The consistency of mirabegron's benefit across age and gender strata further supports the generalizability of the findings within the studied population. Nonetheless, several limitations merit consideration. The single-center setting may limit external validity, and the follow-up period was confined to four weeks, precluding assessment of longer-term outcomes beyond the usual stent dwell time. Additionally, combination pharmacotherapy—such as mirabegron with alpha-blockers or antimuscarinics—was not evaluated and may offer additive benefit in selected patients, as suggested by prior studies (1,3).

From a clinical perspective, these findings have direct implications for postoperative management of patients with DJ stents. Given its superior efficacy in pain reduction, higher rates of LUTS improvement, and lower incidence of bothersome adverse effects, mirabegron appears to be a more suitable first-line option than solifenacin for most patients without contraindications. Future multicenter trials with extended follow-up and evaluation of combination regimens are warranted to refine individualized treatment strategies and optimize patient comfort during stent indwelling.

CONCLUSION

Both solifenacin and mirabegron were effective in alleviating Double-J stent–related pain and irritative lower urinary tract symptoms; however, mirabegron demonstrated significantly greater reductions in pain intensity and higher improvement rates across urgency, urgency incontinence, frequency, and nocturia, with a more favorable tolerability profile. These findings support mirabegron as a preferred pharmacological option for managing stent-related discomfort in patients with indwelling ureteral stents

REFERENCES

1. Tang QL, Zhou S, Liu YQ, Wu J, Tao RZ. Efficacy and safety of combination of mirabegron and solifenacin in patients with double-J stent-related overactive bladder: a prospective study. Sci Rep. 2022;12(1):18844.
2. Abdelaziz AS, Salama NM, Ghoneem AM. Mirabegron vs solifenacin in control of endoscopically inserted ureteral stent-related symptoms. World J Urol. 2022;40(8):2113–9.
3. Sahin A, Yildirim C, Yuksel OH, Urkmez A. Treatment of ureteral catheter-related symptoms: mirabegron versus tamsulosin/solifenacin combination. Arch Esp Urol. 2020;73(1):54–9.
4. Chandna A, Kumar S, Parmar KM, Sharma AP, Devana SK, Mete UK, et al. Comparison of stent-related symptoms in patients taking mirabegron, solifenacin, or tamsulosin: a double-blinded randomized clinical trial. Urologia. 2022;89(4):589–96.
5. Wang J, Zhou Z, Cui Y, Li Y, Yuan H, Gao Z, et al. Meta-analysis of the efficacy and safety of mirabegron and solifenacin monotherapy for overactive bladder. Neurourol Urodyn. 2019;38(1):22–30.
6. Zhou Z, Gao Z. RE: Meta-analysis of the efficacy and safety of mirabegron and solifenacin monotherapy for overactive bladder. Neurourol Urodyn. 2019;38(6):1792–9.
7. Galal E, Ali M, Abozaid H, El-Tatawy H. The role of mirabegron in relieving double-J stent-related discomfort: a randomized controlled clinical trial. Arab J Urol. 2021;19(2):191–7.
8. Javid M, Raza K, Hamid A, Mughal S, Ali S, Rehman A, et al. Tamsulosin versus mirabegron in relieving ureteric stent-related symptoms: a prospective double-blinded randomized controlled trial. BMC Urol. 2023;23:123.
9. Elmarakbi AA, Elsayed OM, Mohamed TR, Lotfy AM. Relief of double-J stent-related symptoms: a comparison between mirabegron, tamsulosin and solifenacin. Beni-Suef Univ J Basic Appl Sci. 2024;13(1):62.
10. Xiang N, Hu Y, Peng W, Luo M, Yang Y, Zhang Q. Comparing efficacy and safety of mirabegron, tamsulosin, and solifenacin in ureteral stent-related symptoms: outcomes from a network meta-analysis. Transl Androl Urol. 2024;13(5):699.
11. Lu Y, Li Q, Zou Q, Cui Y. Mirabegron and antimuscarinics for treating ureteral stent-related symptoms: a systematic review and meta-analysis of randomized controlled trials. Front Pharmacol. 2023;14:1266636.
12. Van Besien J, Keller EX, Somani B, Pietropaolo A, Claessens M, Merckx L, et al. Mirabegron for the treatment of ureteral stent-related symptoms: a systematic review and meta-analysis. Eur Urol Focus. 2022;8(4):1031–41.
13. Hinojosa-Gonzalez DE, Segall MR, Eisner BH. Pharmacological management of ureteral stent-related symptoms: a systematic review, Bayesian network meta-analysis, and meta-regression. J Urol. 2023;210(5):739–49.
14. Cinar O, Tanidir Y, Ozer S, et al. Effects of mirabegron on JJ stent-related symptoms: a multicentric study. Int J Clin Pract. 2021;75(2):e13857.
15. Li Z, Cui Y, Chai Y, Zhang Y. The efficacy and safety of mirabegron in treating ureteral stent-related symptoms: a systematic review and meta-analysis. LUTS. 2022;14(1):27–34.