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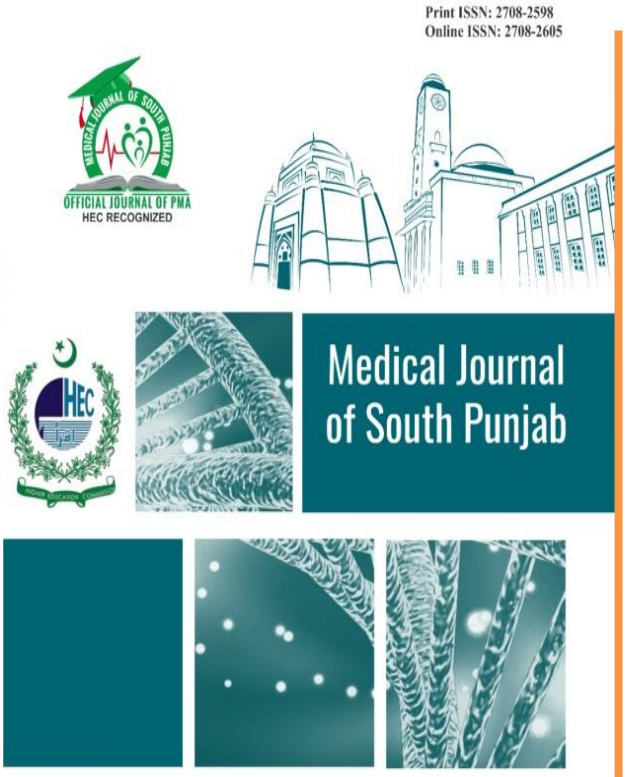

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Original Article

Comparison of solifenacin versus mirabegron for the treatment of double j stent related lower urinary tract symptoms

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ABSTRACT

Objective: To compare the efficacy and tolerability of solifenacin and mirabegron in relieving DJ stent related LUTS.

Methods: This comparative study included 100 patients who underwent DJ stent placement, with 50 patients each allocated to solifenacin or mirabegron. Baseline characteristics including age, gender, stent indications, stent size, and baseline USSQ urinary symptom scores were comparable between groups ($p > 0.05$). Urinary symptoms, pain, quality of life, and adverse effects were assessed after two weeks using the USSQ.

Results: Both groups demonstrated improvement in urinary symptoms; however, mirabegron showed significantly superior efficacy. Post-treatment mean urinary symptom scores were lower with mirabegron compared to solifenacin (16.2 ± 3.8 vs. 20.8 ± 4.3; $p < 0.001$), with a greater reduction from baseline (15.5 ± 3.7 vs. 10.6 ± 3.2; $p < 0.001$). Mirabegron also significantly improved frequency, urgency, and nocturia ($p < 0.001$). Pain outcomes favored mirabegron, including lower body-pain scores (4.3 ± 1.3 vs. 5.8 ± 1.4; $p < 0.001$), along with better general health ($p = 0.03$) and improved work performance ($p = 0.01$).

Conclusion: Mirabegron demonstrated superior efficacy, better quality-of-life outcomes, and significantly fewer adverse effects than solifenacin for managing DJ stent–related LUTS. These findings support the use of mirabegron as a preferred therapeutic option for symptomatic relief in patients with indwelling DJ stents.

Keywords: Double-J stent, lower urinary tract symptoms, mirabegron, solifenacin, USSQ, stent-related symptoms.

1. INTRODUCTION

Lower urinary tract symptoms (LUTS) constitute a prevalent clinical concern worldwide, affecting an estimated 50–70%[1] of adults at some point in their lives, with increasing incidence in aging populations. These symptoms which include urinary frequency, urgency, nocturia, and dysuria significantly diminish patients' quality of life and contribute to considerable healthcare burdens[2]. Among individuals undergoing urological procedures, the likelihood of developing LUTS is even higher, particularly in those who require ureteral stent placement for obstructive uropathy, ureteral stones, or postoperative drainage[3].

The pathophysiology of LUTS associated with double J (DJ) ureteral stents is multifactorial. Mechanical irritation of the bladder trigone by the distal end of the stent induces involuntary detrusor contractions, resulting in storage symptoms such as urgency and frequency[4]. Additionally, stent-related reflux during voiding increases intravesical pressure and triggers discomfort, while local mucosal inflammation contributes to sensory hypersensitivity[5]. Together, these mechanisms lead to bothersome symptoms that impair daily activities, sleep, and overall patient well-being[6].

Solifenacin, a selective muscarinic M3 receptor antagonist, reduces detrusor overactivity by inhibiting acetylcholine-mediated bladder contractions. It has been widely used in overactive bladder (OAB) management and has demonstrated benefit in alleviating urinary urgency and frequency[7]. Its pharmacological profile, characterized by high receptor selectivity, offers improved tolerability compared to older antimuscarinic agents, making it a preferred option for many patients experiencing storage LUTS[8].

Mirabegron, a β3-adrenergic receptor agonist, represents an alternative therapeutic strategy by promoting detrusor muscle relaxation during the storage phase. Through a mechanism distinct from antimuscarinics, mirabegron enhances bladder capacity without impairing voiding efficiency and is generally associated with fewer anticholinergic side effects such as dry mouth and constipation. Its efficacy in OAB has prompted investigation into its role in stent-related LUTS, where detrusor overactivity is a prominent contributor[9,10].

Given the clinical burden of DJ stent–associated LUTS and the need for effective, well-tolerated therapeutic options, comparing solifenacin and mirabegron is essential for optimizing patient management. Evidence remains limited regarding their relative efficacy in this specific clinical context[11]. Therefore, this study aims to compare the effectiveness of solifenacin versus mirabegron in reducing stent-related LUTS, thereby guiding clinicians in selecting the most appropriate treatment to improve patient comfort and postoperative outcomes.

2. METHODOLOGY

This comparative clinical study was conducted at the Multan Institute of Kidney Diseases (MIKD), Multan, to evaluate the effectiveness of solifenacin versus mirabegron for the treatment of Double-J (DJ) stent–related lower urinary tract symptoms (LUTS). The study duration was from 28 November 2023 to 27 May 2024. Patients aged 18–70 years who underwent unilateral DJ stent placement and developed stent-related LUTS within the first week were included, while those with pre-existing overactive bladder, neurogenic bladder, urinary tract infection, severe renal or hepatic impairment, pregnancy, lactation, or known contraindications to the study drugs were excluded. Ethical approval was obtained from the Institutional Review Board of MIKD, and written informed consent was secured from all participants to ensure confidentiality and adherence to ethical research standards.

A total of 100 patients were enrolled through consecutive sampling and were allocated into two equal groups: Group A received solifenacin 5 mg once daily, and Group B received mirabegron 50 mg once daily for two weeks. Baseline demographic

and clinical data were recorded, and symptoms were assessed using the validated Ureteral Stent Symptom Questionnaire (USSQ) at baseline and after two weeks of treatment. Primary outcome measures included improvement in urinary symptom scores, while secondary outcomes assessed changes in pain, quality-of-life domains, and drug-related adverse effects. Data were analyzed using SPSS version 27, with quantitative variables compared using the independent t-test and qualitative variables analyzed using the chi-square test, considering a p-value of ≤0.05 as statistically significant.

3. RESULTS

In this study, 50 patients were included in each group, with comparable baseline characteristics including age, gender, DJ stent indications, stent size, and baseline USSQ urinary symptom scores ($p > 0.05$). After two weeks, both solifenacin and mirabegron improved urinary symptoms, but mirabegron showed significantly greater efficacy, with lower mean urinary scores (16.2 ± 3.8 vs. 20.8 ± 4.3; $p < 0.001$) and larger reductions from baseline (15.5 ± 3.7 vs. 10.6 ± 3.2; $p < 0.001$). Frequency, urgency, and nocturia were also significantly lower with mirabegron ($p < 0.001$).

Pain and quality-of-life outcomes favored mirabegron, including lower body pain (4.3 ± 1.3 vs. 5.8 ± 1.4; $p < 0.001$), better general health ($p = 0.03$), and improved work performance ($p = 0.01$). Adverse effects were more frequent with solifenacin, especially dry mouth (28% vs. 6%) and constipation (20% vs. 4%; $p < 0.05$), with overall adverse events in 44% vs. 22% of patients ($p = 0.02$). Overall, significant symptomatic improvement was reported by 82% of mirabegron users versus 56% of solifenacin users ($p = 0.004$), indicating superior efficacy and tolerability of mirabegron for DJ stent–related LUTS.

Table 1:Baseline Demographic and Clinical Characteristics

Variable	Solifenacin (n = 50)	Mirabegron (n = 50)	p
Mean Age (years)	41.8 ± 11.2	42.6 ± 10.7	0.72
Gender (Male/Female)	32 / 18	30 / 20	0.68
Indication for DJ Stent			
• Ureteric stone	36 (72%)	34 (68%)	0.66
• Post-ureteroscopy	10 (20%)	12 (24%)	0.62
• Other	4 (8%)	4 (8%)	1.00
Stent Size (Fr)	5.0 ± 0.4	5.1 ± 0.3	0.41
Baseline USSQ urinary symptom score	31.4 ± 4.9	31.7 ± 5.2	0.81

Table 2: Comparison of symptoms after 2 weeks of treatment

Outcome Measure	Solifenacin (n = 50)	Mirabegron (n = 50)	p
Urinary symptoms score (USSQ)	20.8 ± 4.3	16.2 ± 3.8	**<0.001**
Mean reduction in urinary score	10.6 ± 3.2	15.5 ± 3.7	**<0.001**
Frequency episodes per day	9.2 ± 2.1	6.8 ± 1.9	**<0.001**
Urgency episodes per day	7.5 ± 2.0	5.1 ± 1.7	**<0.001**
Nocturia (times/night)	2.6 ± 0.9	1.7 ± 0.7	**<0.001**

Table 3: Pain and quality-of life outcomes

Parameter	Solifenacin (n = 50)	Mirabegron (n = 50)	p
Body pain score	5.8 ± 1.4	4.3 ± 1.3	**<0.001**
General health score	4.9 ± 1.1	4.4 ± 1.0	0.03
Work performance disturbance	3.8 ± 1.0	3.2 ± 0.9	0.01

Table 4: Adverse effects

Adverse effect	Solifenacin (n = 50)	Mirabegron (n = 50)	p
Dry mouth	28%	6%	<0.05
Constipation	20%	4%	<0.05
Overall adverse events	44%	22%	0.02

Table 5: Overall treatment effectiveness

Treatment Outcome	Solifenacin	Mirabegron	p-value
Patients reporting "significant improvement"	28 (56%)	41 (82%)	**0.004**
Patients with minimal/no improvement	22 (44%)	9 (18%)	**0.004**

4. DISCUSSION

In this randomized comparative study of 50 patients per group, we found that mirabegron produced significantly greater improvement in double-J (DJ) stent–related lower urinary tract symptoms (LUTS) than solifenacin after two weeks. Specifically, the mean USSQ urinary score in the mirabegron group (16.2 ± 3.8) was much lower than in the solifenacin group (20.8 ± 4.3), and the reduction from baseline was larger (15.5 ± 3.7 vs. 10.6 ± 3.2). Mirabegron also more effectively reduced frequency, urgency, and nocturia, and led to better pain and quality-of-

life outcomes, all with fewer adverse effects (notably, far less dry mouth and constipation).

In a recent network meta-analysis of 16 trials including mirabegron, solifenacin, and tamsulosin for ureteral stent–related symptoms (SRS), Xiang et al[12] ranked mirabegron highest for body pain relief and lowest adverse-event risk, while solifenacin had a slight edge in urinary symptoms but at the cost of tolerability. Data of this study align with that, showing mirabegron's superior safety profile and still robust efficacy in improving urinary symptoms and pain.

In a trial of 97 DJ-stent patients, Abdelaziz et al[13] compared mirabegron 50 mg vs solifenacin 5 mg and found both drugs reduced USSQ urinary and body-pain scores, without a statistically significant difference in urinary scores by the time of stent removal. In contrast, findings of this study favor mirabegron more strongly, both in magnitude of urinary symptom improvement and tolerability.

Interestingly, these results also build on the safety and efficacy profile of mirabegron in overactive bladder (OAB) populations. In a Phase IIIb noninferiority trial of OAB patients unsatisfied with previous antimuscarinics, mirabegron (50 mg) and solifenacin (5 mg) afforded similar reductions in micturition frequency over 12 weeks, though mirabegron had a lower incidence of dry mouth[14]. Furthermore, in a retrospective cohort of 342 women with OAB, Di Núñez et al[15] observed similar reductions in voids and urgency episodes with both drugs, but solifenacin had significantly more constipation and dry mouth.

In a double-blinded RCT of 150 patients receiving DJ stents, Piedad et al[16] (or the authors of that trial) found that mirabegron, solifenacin, and tamsulosin had broadly comparable reductions in urinary domain scores, though mirabegron conferred better general health indices. The modest differences reported in that trial contrast with our larger effect sizes, suggesting that mirabegron may be particularly potent when applied early post-stent, or that patient population differences influence treatment response.

A systematic review and meta-analysis of RCTs also supports mirabegron's favorable risk benefit profile in stent patients: Lu et al[17] pooled five RCTs (total 546 patients) and showed that mirabegron significantly improved urinary symptom score, general health, quality-of-life, and even reduced analgesic use, without a significant rise in adverse events.

However, our results differ somewhat from a study conducted in Indonesia[18], which compared solifenacin 5 mg/day to mirabegron 50 mg/day in DJ-stent patients. In that cohort, the authors reported *insignificant* differences in overall symptom reduction except in work-activity and "other complaints," and solifenacin had a somewhat larger but non-significant decrease in urinary scores.

Future studies should evaluate the longer-term efficacy and safety of mirabegron versus antimuscarinics in larger, multicenter randomized trials, with stratification by stent dwell time and baseline symptom severity. Research should also investigate cost-effectiveness, adherence, and patient preference in real-world settings. Additionally, combination therapy (mirabegron plus low-dose solifenacin) warrants exploration for patients with refractory stent-related symptoms, based on evidence from OAB studies showing improved outcomes without significant added side effects[19,20].

5. CONCLUSION

Mirabegron demonstrated superior efficacy, better quality-of-life outcomes, and significantly fewer adverse effects than solifenacin for managing DJ stent–related LUTS. These findings support the use of mirabegron as a preferred therapeutic option for symptomatic relief in patients with indwelling DJ stents.

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