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Comparison of Efficacy of Combination Therapy (Tamsulosin + Solifenacin) Versus Monotherapy (Tamsulosin) Alone for Double J Stent Related Lower Urinary Tract Symptoms

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ABSTRACT

Objectives: To compare the efficacy of combination therapy (Tamsulosin + Solifenacin) versus monotherapy (Tamsulosin) in relieving DJ stent-related LUTS. **Methodology:** The study was conducted at Department of Urology, Allied Hospital, Faisalabad from 31 January 2025 to 30 April 2025. Sixty patients aged between 18 and 40 years who underwent unilateral DJ stent placement were selected through non-probability consecutive sampling and randomly divided into two groups: Group A received combination therapy, while Group B received monotherapy. The International Prostate Symptom Score (IPSS) questionnaire was administered at baseline and at four weeks following surgery to assess LUTS severity. **Results:** Patients in the combination group showed a significantly greater reduction in mean IPSS scores (from 9.55 ± 1.94 to 4.79 ± 1.92) compared to the monotherapy group (from 10.95 ± 2.17 to 6.33 ± 1.64), with a post-treatment p-value of 0.001. **Conclusion:** Combination therapy with Tamsulosin and Solifenacin is significantly more effective than Tamsulosin alone in managing DJ stent-related LUTS. These findings support the routine use of dual pharmacotherapy to improve symptom relief and patient comfort during stent indwelling.

INTRODUCTION

The placement of ureteral stents is a routine intervention frequently employed in urological procedures. The Double-J (DJ) stent is commonly used in for renal stones.[1-3] Despite the wide clinical usage of the ureteral stent, it causes lower urinary tract symptoms (LUTS), and ultimately deteriorates the quality of life (QoL) of patients.[4-5] There is considerable evidence to suggest that LUTS are a prevalent problem that affects both male and female genders' QoL, health, and sexuality. The LUTS are caused by the irritation of the lower urinary tract due to stents that lead to the lower ureter and bladder spasms.[6-7]

The precise mechanisms underlying LUTS are not fully understood, but various hypotheses have been suggested. These include spasms of the ureteral smooth muscle, stimulation of the trigone area by the intravesical coil of the stent causing bladder spasms, and elevated retrograde pressure during urination. The IPSS questionnaire serves as a validated tool to evaluate the severity of LUTS in conditions such as DJ stent placement or benign prostatic hyperplasia. [8]

In the treatment of male lower urinary tract symptoms, tamsulosin—a long-acting α1-blocker—is widely utilized for its ability to relieve obstruction and prevent retention. Despite its benefits, monotherapy often falls short in achieving comprehensive symptom control, especially based on IPSS outcomes. [9] To address irritative symptoms like urgency and frequency, solifenacin, an anticholinergic targeting M3 receptors, is frequently added. While effective, its action on other M3 sites in the body often leads to side effects such as dry mouth, constipation, blurred vision, and the risk of acute urinary retention.[10]

To evaluate symptom relief in DJ stent-associated LUTS, Hafiz et al.[11] compared the therapeutic outcomes of tamsulosin monotherapy versus a combination of tamsulosin and solifenacin, using the IPSS questionnaire. Their study included 100 patients who had undergone unilateral ureteral stent placement. Pre-treatment IPSS

score was 10.04±2.37 in Group A (Tamsulosin and Solifenacin) and 9.78±2.43 in Group B (Tamsulosin). The post-treatment IPSS suggested that Group A (Tamsulosin and Solifenacin), has an average IPSS of 4.38±1.77, while in Group B (Tamsulosin), 6.4±1.55, which was significant with a p-value of 0.002.

The aim of the study is to compare the outcome of combination therapy (Tamsulosin + Solifenacin) Versus monotherapy (Tamsulosin) alone for Double J stent related Lower Urinary Tract Symptoms. There are studies in Pakistan that explored the management of DJ Stent-related LUTS, particularly the irritative symptoms but the local data is scarce. Thus, studies in the local population were needed to examine the effects of drugs.

METHODOLOGY

Following the approval of the research synopsis, a six-month randomized controlled trial was conducted at the Department of Urology, Allied Hospital, Faisalabad. Sixty patients fulfilling the study's inclusion and exclusion criteria were recruited through non-probability consecutive sampling. Sample size estimation was performed using OpenEpi, based on a 5% alpha error, 90% power, and expected mean IPSS scores of 4.38 ± 1.777 for the combination therapy group and 6.4 ± 1.557 for the monotherapy group, leading to a calculated requirement of 30 patients in each arm.

Patients of both genders, aged 18 to 40 years, who underwent unilateral Double J (DJ) stenting were included. Exclusion criteria comprised patients with known bleeding disorders, pregnancy or lactation, prior use of anticholinergics or alpha-blockers, and those with comorbid conditions such as hypertension, diabetes mellitus, malignancy, urinary tract infection, bladder outlet obstruction, or prostatitis as documented in medical records.

After obtaining ethical approval and informed written consent, baseline investigations were performed, including complete blood count, renal function tests, urine routine and microscopy, prothrombin time, activated partial thromboplastin time, international normalized ratio (INR), and X-ray KUB to confirm stent placement and side. The IPSS was recorded two weeks post-surgery, prior to initiating medication.

Patients were then randomly allocated into two groups using a computer-generated sequence. Group A received a combination therapy of Tamsulosin 0.4 mg and Solifenacin 5 mg once daily, while Group B received Tamsulosin 0.4 mg once daily, both for a duration of two weeks. At the end of the treatment period (four weeks post-surgery), IPSS was re-evaluated to assess the outcome.

Data were recorded on a predesigned proforma and analyzed using SPSS version 25. Mean and standard deviation were calculated for continuous variables such as age, weight, height, BMI, and IPSS (pre- and post-treatment). Categorical variables like gender and indication for stent placement were expressed as frequencies and percentages. The primary outcome—difference in IPSS scores between groups—was analyzed using the independent sample t-test. Stratification was performed for potential effect modifiers such as age, gender, BMI, indication of stenting, and stent duration. Post-stratification t-tests were applied, and a p-value ≤ 0.05 was considered statistically significant.

RESULTS

A total of 60 patients were included, with the majority aged between 18 and 30 years (56.7%), while 43.3% were between 31 and 40 years. Males constituted 63.3% of the sample, and females accounted for 36.7%. Regarding BMI classification, 45.0% of patients had a BMI ≤25 kg/m^2, while 55.0% were categorized as overweight (BMI >25). The most common indication for DJ stent insertion was ureterolithotomy (38.3%), followed by PCNL (36.7%) and URS (25.0%). The mean BMI and age of the patients were 25.54 ± 4.03 kg/m^2 and 28.78 ± 6.19 years, respectively.

Table 1

Demographic and Clinical Characteristics

Variable	Category/Value	Frequency	Percent
Age Group	18–30	34	56.7
	31–40	26	43.3
Gender	Male	38	63.3
	Female	22	36.7
BMI Group	1.00	27	45.0
	2.00	33	55.0
Indication	URS (Ureterorenoscopy)	15	25.0
	PCNL (Percutaneous Nephrolithotomy)	22	36.7
	Ureterolithotomy	23	38.3

As shown in Table 2, patients receiving combination therapy with **Tamsulosin + Solifenacin** demonstrated significantly greater improvement in urinary symptoms than those on **Tamsulosin monotherapy**. The baseline IPSS score was significantly lower in the combination group (9.55 ± 1.94) compared to the monotherapy group (10.95 ± 2.17), with a **p-value of 0.011**. More notably, the post-treatment IPSS was significantly reduced to 4.79 ± 1.92 in the combination group, whereas the monotherapy group showed a lesser decline to 6.33 ± 1.64 (**p-value = 0.001**). These findings suggest that combination therapy is more effective in alleviating DJ stent-related lower urinary tract symptoms.

Table 2

Comparison of Efficacy of combination and monotherapy therapy

Variable	Group	N	Mean	Std. Dev.	p-value[a]
IPSS_Pre	Combination	30	9.553	1.9438	0.011
	Monotherapy	30	10.950	2.1743	
IPSS_Post	Combination	30	4.787	1.9217	0.001
	Monotherapy	30	6.330	1.6375	

[a]: *t test*

Table 3 presents the stratified comparison of IPSS scores based on key demographic and clinical subgroups. Among patients aged 18–30 years, a significant reduction in post-treatment IPSS was observed in the combination group (4.39 ± 1.62) compared to monotherapy (6.37 ± 1.62), with a **p-value of 0.001**. However, for the 31–40 age group, the differences in post-treatment scores were not statistically significant (p = 0.176), although a trend favoring combination therapy persisted. When stratified by gender, both males and females in the combination group showed lower post-treatment IPSS scores compared to monotherapy, with statistically significant results for

males (**p = 0.007**) and a borderline p-value for females (**p = 0.058**). This indicates consistent efficacy across genders, though the effect may be more prominent in males.

The analysis across BMI categories revealed that patients with normal BMI (18–25 kg/m^2) had a statistically significant difference in post-treatment IPSS between combination (4.63 ± 1.88) and monotherapy (6.34 ± 1.74) groups (**p = 0.022**). A similar trend was noted among overweight individuals (BMI >25), where combination therapy again showed greater symptom improvement (**p = 0.031**). Finally, the subgroup analysis based on clinical indication showed that patients undergoing **PCNL** and **ureterolithotomy** benefited significantly from combination therapy in terms of post-treatment IPSS, with **p-values of 0.039 and 0.051**, respectively. Although patients treated with **URS** also experienced symptom improvement (**p = 0.198**), potentially due to the smaller subgroup size.

Table 3

Stratified Analysis of IPSS Scores by Age, Gender, BMI, and Indication

Variable		Group	IPSS_Pre treatment (Mean ± SD)	IPSS_Post treatment (Mean ± SD)	p-value (Pre)[a]	p-value (Post)[b]
Age(years)	18–30	Combination	9.78 ± 1.42	4.39 ± 1.62	0.070	0.001
		Monotherapy	10.98 ± 2.29	6.37 ± 1.62		
	31–40	Combination	9.33 ± 2.39	5.19 ± 2.16	0.088	0.176
		Monotherapy	10.89 ± 2.07	6.26 ± 1.74		
Gender	Male	Combination	9.62 ± 1.74	4.41 ± 2.23	0.062	0.007
		Monotherapy	10.76 ± 1.88	6.14 ± 1.49		
	Female	Combination	9.45 ± 2.30	5.36 ± 1.22	0.101	0.058
		Monotherapy	11.34 ± 2.74	6.72 ± 1.93		
BMI	18-25	Combination	9.28 ± 2.10	4.63 ± 1.88	0.122	0.022
		Monotherapy	10.52 ± 1.92	6.34 ± 1.74		
	>25	Combination	9.77 ± 1.85	4.91 ± 2.00	0.045	0.031
		Monotherapy	11.33 ± 2.37	6.33 ± 1.60		
Indications	URS	Combination	9.61 ± 2.76	5.21 ± 1.42	0.240	0.198
		Monotherapy	11.35 ± 2.67	6.31 ± 1.71		
	PCNL	Combination	9.79 ± 1.38	4.34 ± 2.35	0.306	0.039
		Monotherapy	10.52 ± 1.86	6.25 ± 1.69		
	Ureterolithotomy	Combination	9.34 ± 1.95	4.90 ± 1.87	0.057	0.051
		Monotherapy	11.15 ± 2.24	6.44 ± 1.69		

[a&b] *t test*

DISCUSSION

In the present randomized controlled trial conducted at Allied Hospital, Faisalabad, a total of 60 patients aged 18–40 years were enrolled to compare the efficacy of combination therapy (Tamsulosin + Solifenacin) with Tamsulosin monotherapy for DJ stent-related lower urinary tract symptoms (LUTS). Most patients were between 18–30 years (56.7%), with a male predominance (63.3%) and a higher percentage of overweight individuals (55.0% with BMI >25). These demographic findings are consistent with the observations of Sajid et al[12] who also reported a majority of young adult male patients with DJ stents in their randomized trial. Similarly, Tareq et al[13] found a predominance of male patients aged below 40 years undergoing DJ stent placement.

Regarding clinical indications, ureterolithotomy (38.3%) was the most common reason for stent placement in our study, followed by PCNL and URS. This trend is reflective of the findings of Shalaby et al[14] who highlighted that DJ stents are frequently used post-ureterolithotomy and PCNL procedures. The mean BMI and age of the participants in our study were 25.54 ± 4.03 kg/m^2 and 28.78 ± 6.19 years, respectively—comparable to findings by Guitynavard et al[15] who studied a similar patient population in terms of age and BMI.

In our study, patients receiving combination therapy showed a significantly greater reduction in mean IPSS scores compared to those receiving monotherapy (4.79 vs. 6.33; p = 0.001), confirming the superior efficacy of Tamsulosin + Solifenacin. This aligns with the findings of Hasbi et al[16] who demonstrated that combination therapy yielded better symptom control than Tamsulosin alone across urinary, sexual, and work-related domains. Piedad et al[17] also emphasized that both alpha-blockers and antimuscarinics improve stent-related symptoms, with combination therapy showing the most consistent benefits.

Sajid et al[12] observed a significantly greater reduction in IPSS scores in patients treated with the combination regimen, further validating our results. Likewise, Shalaby et al[14] confirmed that combination therapy significantly alleviated LUTS and improved quality of life in patients with DJ stents. The benefit of combined therapy has also been demonstrated by Tareq et al[13] who found that patients receiving both agents experienced fewer irritative LUTS and lower back pain compared to those on single agents.

Stratified analyses in our study revealed that combination therapy remained consistently more effective across subgroups, including age, gender, BMI, and indication for stenting. Notably, male patients and those with normal BMI showed statistically significant improvement in IPSS scores. These findings are consistent with the work of Sajid et al[12] and Shalaby et al[14] who also reported sustained benefits of combination therapy across varied patient demographics and procedural contexts.

These results allow us to reject the null hypothesis, which posited no difference in IPSS outcomes between combination and monotherapy. The significant post-treatment improvement in the combination group supports the alternative hypothesis and confirms that Tamsulosin + Solifenacin is more effective than Tamsulosin alone in managing DJ stent-related LUTS. The

evidence is reinforced by several randomized controlled trials.[12,14,16]

This study has several limitations. The sample size, although calculated to detect a statistically significant difference, was relatively small and limited to a single tertiary care center, which may affect the generalizability of findings. The follow-up duration was short, focusing only on symptom outcomes over a four-week period. Additionally, side effects of solifenacin such as dry mouth and constipation were not systematically evaluated. Moreover, quality of life indices and other patient-reported outcome measures were not assessed, which could have provided more comprehensive insights into treatment benefit.

Future studies should include multicenter designs with larger sample sizes and extended follow-up to evaluate long-term efficacy and safety. The inclusion of quality of life assessments and cost-effectiveness analyses would provide a more holistic understanding of the impact of combination therapy. Comparative studies on newer drug combinations and biodegradable stents could also open new directions for improved patient-centered care in urology.

CONCLUSION

Our study reinforces the evidence that combination therapy with Tamsulosin and Solifenacin offers superior relief from DJ stent-related LUTS compared to Tamsulosin monotherapy, with consistent benefits across demographic and clinical subgroups. The incorporation of combination pharmacotherapy into routine urological practice, guided by symptom severity and patient preference, can substantially improve postoperative comfort and quality of life.

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