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SOLIFENACIN VERSUS TAMSULOSIN FOR DOUBLE-J STENT-RELATED SYMPTOMS: A PROSPECTIVE RANDOMIZED COMPARATIVE STUDY

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ABSTRACT

Introduction: *The purpose of this study is to assess the effectiveness of alpha blockers or anticholinergic in treating symptoms associated with DJ stents.*

Materials and Methods: *A total of fifty-six symptomatic patients were included, and they were divided into groups A and B. Group A received 0.4 mg of tamsulosin, while Group B received 5 mg of solifenacin daily. Patients were assessed for International Prostate Symptom Score (IPSS) and assessed to determine changes in symptom scores. SPSS version 25.0 was used for data analysis.*

Results: *In Group A, the mean baseline IPSS was 18.25±3.42, whereas Group B had 18.11± 3.38 (p = 0.87) with an effect size (Cohen's d) of 0.04. In the final follow-up, Group A had a mean IPSS score of 10.22±2.71, whereas Group B had 8.93± 2.65 (p = 0.021) with an effect size (Cohen's d) of 0.48. The mean baseline VAPS scores were in group A 6.78 ± 1.64, group B 6.14±1.68 (p=0.16), with effect size (Cohen's d) 0.38. At the final follow-up, Group A had 4.20±1.20, compared to 2.98±1.46 in Group B (p = 0.017), with an effect size (Cohen's d) of 0.89.*

Conclusion: *Solifenacin was associated with greater improvement in reducing symptoms and improving overall quality of life.*

Keywords: *Double-J Stent, Lower Urinary Tract Symptoms, Quality of Life, Solifenacin, Tamsulosin*

INTRODUCTION

In the field of Urology, the use of the Double-J Stent (DJ stent) has a long history of growth. The initial acknowledged DJ stenting was placed by Gustav Simon in the 1800s following an open cystostomy.[1]In present urological practice, their applications have expanded considerably, emphasizing their central role in patient management.[2]

Many research studies have reported that DJ stents are often associated with troublesome symptoms, including hematuria, dysuria, suprapubic pain, increased frequency, and urgency.[3,4] Manoj et al. documented that more than 83% of patients with ureteric stents suffer such complaints. [5] Notably, these symptoms typically settled following stent removal. Although commonly accepted, the exact pathophysiological mechanisms underlying stent-related symptoms remain unclear.[5]

Thomas et al. investigated the mechanisms underlying DJ stent-related symptoms and recommended that symptoms in patients with indwelling ureteric stents develop principally from increased intrarenal pressure due to the upper coil and trigonal irritation caused by the lower coil during urination.[6] Joshi and colleagues reported that about 80% of patients complained of an impaired quality of life resulting from these stent-associated symptoms.[7] Over the years, several research studies have been done, and many advanced strategies

have been proposed to relieve the burden of stent-related morbidity.

Numerous studies have shown that selective α-blockers competently improve the majority of ureteric stent–related symptoms. Deliveliotis et al. and Bedding field et al. examined the use of alfuzosin (10 mg daily) and observed significant reductions in renal pain and urinary frequency. [12,13] Furthermore, alfuzosin boosts overall quality of life, sleep disturbances, and sexual function. [12] Likewise, Wang et al. found that the selective α-blocker tamsulosin was useful in relieving lumbar pain, micturition-related discomfort, and lower urinary tract symptoms. [14]

DJ stent–related symptoms are analogous to those of an overactive bladder, including urgency, frequency, and dysuria. Irritation of the trigone by the lower end of the DJ stent stimulates muscarinic receptors, resulting in detrusor muscle contraction. Evidence from clinical studies advises that antimuscarinic agents can effectively decrease these symptoms. [15]

But according to Norris et al., there was no noticeable difference in the management of stent-related symptoms between the placebo and oxybutynin groups.[16] However, their authors stated that additional continuing research is required. Whereas Agrawal et al. compared the oxybutynin or tolterodine-treated group to a placebo group, the oxybutynin or tolterodine-treated group had symptom alleviation.[17]

Furthermore, Lee et al. studied tamsulosin and tolterodine in comparison to a placebo group. The IPSS and VAP scores were not substantially different across groups. They asserted that the development of symptoms associated with DJ stents is more dependent on proper stent location.[18]

However, no trials have been conducted yet in our center and there is no consensus on which regimen is superior. The purpose of this study is to assess the effectiveness of alpha blockers (Tamsulosin) or anticholinergic (Solifenacin) in treating symptoms associated with DJ stents.

MATERIALS AND METHODS

This is an interventional randomized comparative study conducted at national medical college after obtaining permission from institutional review committee (IRC Ref. F-NMC/754/082-083). Sample size was calculated scientifically using following method and parameters,

Parameters are,

Design: Two independent groups (alpha-blocker vs anti-cholinergic), superiority.

Type I error (α): 0.05 (two-sided), so Zα/2 = 1.96.

Power (1−β): 80%, so Zβ =0.84

Clinically meaningful difference (d) = 3.2 IPSS points.23,24

Standard deviation (σ): 3.82 SD23,24

Formula: n = 2x(Zα/2+Zβ)2xσ2/d2

n= sample size calculation,

n = 2x (2.80)2 x3.82 / 32

= 2x7.84x14.44/9

= 226.3/9

≈ 25.1

Per group: 25

With 10–15% attrition: 28 per group (total 56).

Patients, both gender with age of 16-45 years were included in this study whereas those patients excluded, who were suffering from coagulopathy, current pelvic trauma/fracture, Urogenital carcinomas, Prostatic enlargement or Chronic prostatitis, Bladder neuropathy, Stone in bladder, Bilateral DJ, DJ in reimplanted ureters, Untreated UTI, Pregnant females, Diagnosed retroperitoneal fibrosis and stress/urge incontinence, glaucoma, myasthenia gravis. Patients already on drugs like alpha blockers, anticholinergics, analgesics, or psychiatric drugs were also excluded. The study's dependent variable was the IPSS total score/symptoms related to the DJ stent. While Independent variable were Alpha-blocker and Anti-cholinergics therapy. Patients who matched our inclusion criteria were recruited from the outpatient surgery (urology) department. Every patient was informed, their demography was recorded and informed consent form was signed in proforma.

The indication for inserting a double J stent was documented during data collection (Proforma A). Before surgery, a serum profile (CBC, renal function test), urine microscopy, urine culture and sensitivity, and KUB ultrasonography were conducted. All patients received prophylactic injections of 750 mg (based on weight) of levofloxacin intravenously (I/V) two hours before surgery and twenty-four hours afterwards.

During the procedure, general or spinal anesthesia was used, and the stent position was confirmed with an X-ray KUB scout film. In each case, a polyurethane coiled DJ stent with side holes measuring 28 cm in length and 6 F

in diameter was inserted. All postoperative complications were recorded in Proforma A. Patients were given 750 mg of levofloxacin once daily and 50 mg of diclofenac sodium twice daily for a week after discharge.

After 1 week, all patients with DJ stents in situ were assessed for DJ-related symptoms and recorded using the IPSS score, and those having an IPSS score of more than 7 were included in the study. A total of 60 individuals were evaluated for eligibility. Four individuals were excluded: one did not fulfill the inclusion criteria, and three opted out of participation. Fifty-six individuals were equally allocated into two groups, A and B. Participants were randomly assigned in a 1:1 ratio to either Group A or B. A computer-generated random number table created the randomization sequence (https://www.graphpad.com/quickcalcs/ randomize2/). To ensure allocation concealment, independent staff prepared sequentially numbered, opaque, sealed envelopes. This staff member did not participate in patient recruitment or outcome assessment. The envelopes were opened only after confirming eligibility and obtaining written informed consent. This process reduced selection bias and kept allocation integrity intact.

Patients in Group A got 0.4 mg tamsulosin each day while those in Group B received 5 mg of solifenacin every day. Analgesics are administered to all patients on demand. At 2 weeks and 4-week patient were followed, and the IPSS score was recorded to see the change in score. Enrolled patients in all groups continued to take their medications and were monitored until the study was completed. Those patients who showed infection-related symptoms (such as fever or pyuria) during the follow-up period underwent a thorough urine examination, and urine culture sensitivity was performed; patients were removed from the study after appropriate treatment. Once the stent insertion objective was met, the double J stents were withdrawn.

To reduce bias in subjective measures such as the IPSS and quality of life (QoL) assessments, blinding techniques were employed at various stages. Patients were kept unaware of the specific type of medication (either an alpha blocker or an anticholinergic) they were given, as both types were provided in indistinguishable form by the hospital pharmacy. The researchers in charge of clinical evaluations and data collection were unaware of group assignments throughout the duration of the study. Assessor personnel who examined IPSS and QoL surveys were also kept blind to the treatment groups and worked with anonymised data sheets labeled solely with participant numbers. The randomization code was disclosed to the principal investigator only after the data entry and initial analysis were complete. This methodology ensured that subjective ratings and interpretations remained unaffected by any biases from observers or participants.

The primary outcome of this study was to compare the effectiveness of alpha-blockers and anti-cholinergic agents in alleviating DJ stent-related lower urinary tract symptoms, using the International Prostate Symptom Score (IPSS). Whereas the secondary outcomes were the changes in IPSS subscores (irritative and obstructive domains), Visual Analog Pain Scale (VAPS) scores and IPSS Quality of Life (QoL) index. IPSS score & sub scores, VAPS scores, and QoL index were compared between the groups A and B at 2 weeks and at 4 weeks on follow up.

Evaluations of the two treatment groups at different time points (baseline, 2-week, and (fourth-week) final follow-up) were conducted using independent samples t-tests, which are suitable for comparing continuous variables between two groups. The threshold for statistical significance was established at $p < 0.05$, with all analyses carried out using SPSS version 25.

RESULTS

A total of 60 individuals were evaluated for eligibility. Four individuals were excluded: one did not fulfill the inclusion criteria, and three opted out of participation. Fifty-six individuals were equally allocated into two groups: Group A (n=28, received Tamsulosin) and Group B (n=28, received Solifenacin). At the 2-week follow-up, 28 individuals from Group A and 28 individuals from Group B completed the assessment; none of the individuals lost to follow-up. At the 4-week follow-up, 28 individuals in Group A and 28 individuals in Group B completed the assessment; none of individual lost in any group. Thus, 56 individuals (Group A = 28, Group B = 28) were included in the final analysis. The mean age of participants in Group A was 28.4 ± 6.5 years, whereas Group B had a mean age of 27.9± 6.8 years. Statistical evaluation showed no significant differences between the two groups ($p = 0.78$) as shown in Table 1.

Table 1: Characteristics of the patients

Statistic	Group A (Tamsulosin, n=28)	Group B (Solifenacin, n=28)	p-value
Age in years (mean+SD)	28.4±6.5	27.9±6.8	0.78
Gender Male	13	12	0.79
Female	15	16	
Laterality Right	11	13	0.59
Left	17	15	

Stone site			
Proximal ureter	9	8	0.91
Mid ureter	4	5	
Lower ureter	15	14	

At the beginning of the study, the IPSS was similar in both treatment groups. In Group A, the mean baseline IPSS was 18.25±3.42, whereas Group B had a mean baseline IPSS of 18.11± 3.38 resulting in a mean difference of 0.14 (95% CI: 1.64,1.92) with an effect size (Cohen's d) of ≈0.04. Statistical evaluation showed no significant differences between the two groups (p = 0.87). During the two-week follow-up, individuals in Group A showed a mean IPSS score of 12.49±2.95, whereas Group B reported a mean score of 11.36± 2.84 resulting in a mean difference of 1.12 (95% CI: –0.38–2.64) with an effect size (Cohen's d) of 0.39. The statistical analysis indicated a significant difference between the two groups (p = 0.046). In the fourth-week follow-up, participants in Group A showed a mean IPSS score of 10.22±2.71, whereas Group B recorded a mean score of 8.93± 2.65. with a mean difference of 1.29 (95% CI: 0.21–2.37) and a Cohen's d of 0.48, indicating a moderate effect size. Statistical analysis indicated a significant difference between the two groups (p = 0.021) as shown in Table 2.

Table 2: IPSS score descriptive statistics by groups

Time Point	Group A (Tamsulosin) Mean ± SD	Group B (Solifenacin) Mean ± SD	Mean Difference (95% CI)	Effect Size (Cohen's d)	Statistical Test	p-value
Baseline	18.25 ± 3.42	18.11 ± 3.38	0.14 (–1.64 to 1.92)	0.04 (negligible)	Independent t-test	0.87
Two-week follow-up	12.48 ± 2.95	11.36 ± 2.84	1.12 (0.02 to 2.22)	0.39 (small–moderate)	Independent t-test	0.046
Fourth week follow-up	10.22 ± 2.71	8.93 ± 2.65	1.29 (0.21 to 2.37)	0.48 (moderate)	Independent t-test	0.021

At baseline, the irritative sub scores of the IPSS were similar between the two groups, with Group A having a mean irritative sub score of 6.4±1.6 and Group B having a mean of 6.20±1.5 (mean difference 0.20, 95% CI: 0.58 – 0.98, p = 0.068). At 2-weeks, Group A had a mean irritative sub score of 5.1±3.1, whereas Group B had a mean of 3.6±2.3 (mean difference 0.70, 95% CI: 0.02–1.38, p = 0.044) and the difference was statistically significant (p = 0.044). At final assessment, Group B continued to have better results, with a mean irritative sub score of 3.7±2.5, compared to 5.4±3.2. (mean difference 0.90, 95% CI: 0.08–1.72, p = 0.031) The difference was significant (p = 0.031) as shown in Table 3.

Table 3: IPSS Irritable, Obstructive and QoL Subscore comparison by treatment group

Time Point	Sub-score	Group A (Tamsulosin, n=28) Mean ± SD	Group B (Solifenacin, n=28) Mean ± SD	Mean Difference (95% CI)	Effect Size (Cohen's d)	Statistical Test	p-value
Baseline	Irritative	6.40 ± 1.60	6.20 ± 1.50	0.20 (–0.58 to 0.98)	0.13 (negligible)	Independent t-test	0.68
	Obstructive	8.10 ± 1.90	7.90 ± 1.80	0.20 (–0.74 to 1.14)	0.11 (negligible)	Independent t-test	0.72
	QoL	4.20 ± 1.10	4.10 ± 1.20	0.10 (–0.52 to 0.72)	0.08 (negligible)	Independent t-test	0.74
Two-week follow-up	Irritative	4.50 ± 1.30	3.80 ± 1.20	0.70 (0.02 to 1.38)	0.55 (moderate)	Independent t-test	0.044
	Obstructive	6.00 ± 1.50	5.20 ± 1.40	0.80 (0.05 to 1.55)	0.53 (moderate)	Independent t-test	0.038
	QoL	3.20 ± 1.00	2.60 ± 0.90	0.60 (0.01 to 1.19)	0.58 (moderate)	Independent t-test	0.046
Fourth-week follow-up	Irritative	3.00 ± 1.00	2.10 ± 0.90	0.90 (0.08 to 1.72)	0.91 (large)	Independent t-test	0.031
	Obstructive	4.50 ± 1.20	3.40 ± 1.10	1.10 (0.12 to 2.08)	0.95 (large)	Independent t-test	0.029
	QoL	2.40 ± 0.80	1.70 ± 0.70	0.70 (0.11 to 1.29)	0.89 (large)	Independent t-test	0.024

There were no significant differences in baseline IPSS obstructive sub-score between the two groups (Group A: 8.1±1.90 vs. Group B: 7.9±1.80, (mean difference 0.20, 95% CI: 0.74–1.14, p = 0.072). Group A had a mean obstructive sub score of 6.00±1.50 at two weeks, and Group B had a mean of 5.20±1.40 (mean difference 0.80, 95% CI: 0.05–1.55, p = 0.038). At final assessment, Group B continued to demonstrate superior results (mean 4.53±2.71) vs. Group A (mean 6.19±2.73) (mean difference 1.10, 95% CI: 0.12–2.08, p = 0.029) as shown in Table 3.

The baseline mean QoL scores of group A and B were 4.20 ± 1.10 and 4.10 ± 1.20, respectively (mean difference 0.10, 95% CI: 0.52–0.72, p = 0.074) and were statistically insignificant. In the two-week follow-up, Group A showed a mean QoL score of 3.58 ± 1.72, whereas Group B showed 2.55 ± 1.84 (mean difference 0.60, 95% CI: 0.01–1.19, p = 0.046). On the final follow-up, Group A mean QoL score was 3.38 ± 1.64, and Group B mean was 2.38 ± 1.82 (mean difference 0.70, 95% CI:

0.11–1.29, p = 0.024) as shown in Table 3.

The mean baseline VAPS scores were similar between the two study groups (group A 6.78 ± 1.64, group B 6.14±1.68, (mean difference 0.64 (-0.27 to 1.55), 95% CI: 0.27–1.55, p = 0.16). At the 14-day follow-up, Group A had a mean VAPS score of 5.7±1.30, and Group B had a mean score of 4.90±1.20. (mean difference 0.80, 95% CI: 0.13–1.47), parallel to a moderate effect size (Cohen's d = 0.64). A comparison of the two groups was statistically significant (p = 0.020). At the final follow-up, the mean VAPS score in Group A was 4.2±1.2, compared to 2.98±1.46 in Group B, with a mean difference of 1.22 (95% CI: 0.23–2.21), and a large effect size (Cohen's d = 0.89). Statistical analysis showed a significant difference between the two groups (p = 0.017), as shown in Table 4.

Table 4: VAPS Score descriptive statistics by treatment group

Time Point	Group A (Tamsulosin, n=28) Mean ± SD	Group B (Solifenacin, n=28) Mean ± SD	Mean Difference (95% CI)	Effect Size (Cohen's d)	Statistical Test	p-value
Baseline	6.78 ± 1.64	6.14 ± 1.68	0.64 (–0.27 to 1.55)	0.38 (small)	Independent t-test	0.16
Two-week follow-up	5.70 ± 1.30	4.90 ± 1.20	0.80 (0.13 to 1.47)	0.64 (moderate)	Independent t-test	0.02
Fourth-week follow-up	4.20 ± 1.20	2.98 ± 1.46	1.22 (0.23 to 2.21)	0.89 (large)	Independent t-test	0.017

Occurance s of side effects were thoroughly observed and recorded throughout the study. In the solifenacin group, the most common side effects were dry mouth (n=3, 10.7%) and constipation (n=2, 7.1%). In the tamsulosin group, n=2 (7.1%) reported feeling dizziness, and n=1 (3.6%) experienced low blood pressure when standing up. Not all the events were too severe, and they recovered on their own. Importantly, no patient stopped their treatment because of side effects, and there were no serious problems reported.

DISCUSSION

Although the IPSS was initially created to evaluate lower urinary tract symptoms (LUTS) in men suffering from benign prostatic hyperplasia (BPH), further research has shown its effectiveness in assessing LUTS in patients with DJ stents. The IPSS parameters significantly coincide with DJ stent-related complications. Its widespread availability, simplicity of administration, and previous application in studies involving stents made it a suitable choice for our cohort.[7,19] The Ureteral Stent Symptom Questionnaire (USSQ) is recognized as a validated and stent-specific tool.[7] Nonetheless, when the study began, a fully validated Nepali version of the USSQ was unavailable, which posed challenges for its applicability within our patient demographic.

This study evaluated the effectiveness of a Tamsulosin versus Solifenacin in managing symptoms associated with a DJ stent in (n=56) patients randomly assigned to each treatment group (A&B), with no significant differences at baseline in demographic and clinical variables (age, gender distribution, laterality, and stone site) as shown in Table 1.

At the start, the average IPSS was similar in severity between the two groups, Group A and Group B, at 18.25 ± 3.42 and 18.11 ± 3.38, respectively; p = 0.87, with an effect size of Cohen's d = 0.04. The baseline sub-scores of the IPSS were also comparable in the two groups, with irritative scores of Group A at 6.4 ± 1.6 and Group B at 6.20 ± 1.5; p = 0.068, and an effect size of Cohen's d = 0.13. Likewise, the baseline obstructive sub-scores were similar, with Group A at 8.1 ± 1.90 and Group B at 7.9 ± 1.80; p = 0.072, and an effect size of Cohen's d = 0.11. These results are further supported by QoL scores, which were alike at baseline, with mean QoL scores of Group A at 4.20 ± 1.10 and Group B at 4.10 ± 1.20; p = 0.074, with an effect size of Cohen's d = 0.08. This indicates that both groups had a similar symptom burden at the beginning, confirming the validity of any differences observed in outcome measurements as shown in Table 2 and 3.

By two weeks, the improvement in the total IPSS score between Group A and Group B was 12.49 ± 2.95 vs. 11.36 ± 2.84; with an effect size of Cohen's d = 0.39, p = 0.046. The improvement in the irritative sub-score between Group A and B was 5.1 ± 3.1 vs. 3.6 ± 2.3; with an effect size of Cohen's d = 0.55, p = 0.044. The improvement in the obstructive sub-score was 6.00 ± 1.50 vs. 5.20 ± 1.40; with an effect size of Cohen's d = 0.53, p = 0.038. The improvement in the QoL sub-score was 3.20 ± 1.00 vs. 2.60 ± 0.90, with an effect size of Cohen's d = 0.58, p = 0.046. Solifenacin showed greater improvement across all domains by the two-week follow-up, with small to moderate effect sizes as shown in Table 3.

By the fourth week, the improvement in the total IPSS score between Group A and Group B was 10.22 ± 2.71 vs. 8.93 ± 2.65, with an effect size of Cohen's d = 0.48, p = 0.021. The improvement in the irritative sub-score was 3.00 ± 1.00 vs. 2.10 ± 0.90; with an effect size of Cohen's d = 0.91, p = 0.031. The improvement in the obstructive sub-score was 4.50 ± 1.20 vs. 3.40 ± 1.10, with an effect size of Cohen's d = 0.95, p = 0.029. The improvement in the QoL sub-score was 2.40 ± 0.80 vs. 1.70 ± 0.70, with an effect size of Cohen's d = 0.89, p = 0.02. Solifenacin

maintained greater improvement across all domains by the fourth week, with moderate-to-large effect sizes, as shown in Tables 2 and 3.

At 2 weeks, solifenacin led to a greater improvement in IPSS score than tamsulosin. The small to moderate effect size indicates a clinically meaningful benefit. This early difference highlights solifenacin's antimuscarinic action, which directly targets storage symptoms. At two weeks, solifenacin showed significantly greater improvement across all sub-scores with a moderate effect size. These results suggest that solifenacin offered earlier and broader symptom relief, especially in irritative symptoms, which can be most distressing for patients with stents. By the fourth week, solifenacin continued to show superiority in IPSS score with a moderate effect size, indicating a lasting benefit and reinforcing its role in managing symptoms effectively. The increase in effect size from negligible at baseline to moderate at final follow-up highlights solifenacin's broader impact on overall symptom burden. At the fourth week, solifenacin maintained its lead in sub-scores with large effect sizes. The shift from moderate to large effect sizes underscores solifenacin's sustained and significant benefit across all symptom areas, including QoL, which is essential for patient satisfaction.

Damiano et al., and Park et al., stated that Tamsulosin, an α1 adrenergic blocker, is generally more effective for easing obstructive symptoms as it relaxes the smooth muscles of the ureters and reduces urinary flow resistance. Various randomized studies support this mechanistic advantage.[11,15] However, stent-related symptoms are influenced by multiple factors, such as ureteral muscle spasms, bladder irritation, sensitivity in the trigone, and changes in voiding dynamics.[15] Solifenacin's ability to reduce detrusor hyperactivity and lower bladder outlet pressure may bring significant improvements in obstructive sub-scores.[19] Betschart et al. noted that anticholinergics can help alleviate both storage and obstructive symptoms in patients with stents, likely due to this indirect effect. [19] The emphasis on reporting effect sizes in CONSORT is particularly relevant here, as both medications improved symptoms, but solifenacin showed progressively greater benefits over time.

At baseline, both groups had comparable VAPS scores at 6.78 ± 1.64 vs. 6.14 ± 1.68; p = 0.16, with a small effect size of Cohen's d = 0.38. The lack of statistically significant differences confirms successful randomization and comparability of the groups, ensuring valid internal results. By two weeks, the improvement in VAPS score between Group A and Group B was 5.70 ± 1.30 vs. 4.90 ± 1.20; with an effect size of Cohen's d = 0.39, p = 0.02. By the fourth week, the improvement in VAPS score was 4.20 ± 1.20 vs. 2.98 ± 1.46; with an effect size of Cohen's d = 0.89 (large), p = 0.017.

At the two-week follow-up, patients taking solifenacin reported significantly lower pain scores compared to those on tamsulosin (p = 0.02). The small effect size indicates a clinically meaningful benefit. At the final follow-up, solifenacin maintained superiority (p = 0.017) with a large effect size (Cohen's d = 0.89). This shows a lasting and strong benefit, reinforcing solifenacin's effectiveness in managing pain. The significant effect observed at this point exceeds the importance threshold, suggesting that solifenacin might greatly improve patient comfort during stent placement.

These results align with earlier studies showing that α blockers like tamsulosin mainly relieve obstructive voiding symptoms, while antimuscarinics like solifenacin are better at reducing irritative pain.[20,21] The increase in effect size from small at baseline to large at final follow-up highlights solifenacin's broader impact on overall pain.[22]

The side effects noted in our study align with earlier reports on anticholinergic and alpha-blocker therapies for stent-related symptoms.[11] While solifenacin caused anticholinergic side effects like dry mouth and constipation, patients generally managed these effects well.[15] Tamsulosin led to mild dizziness and occasional drops in blood pressure upon standing, which are consistent with its known α1 adrenergic blockade.[22,23] All participants completed the treatment course, highlighting the overall tolerability of both medications in this patient population. However, healthcare professionals should remain vigilant for these side effects, particularly in patients with other health concerns or those on multiple medications.

Strengths and Limitations

Strengths of the study include random assignment, balanced baseline characteristics, and the use of validated sub-scores. Reporting effect sizes and confidence intervals increases transparency in line with CONSORT guidance.

Some limitations relate to the study's generalizability. First, it was conducted at a single tertiary care center, which may limit external applicability, as practices, patient demographics, and perioperative protocols can vary. Second, the sample primarily included younger participants (ages 16–45), which might not represent the symptom severity or treatment response of older patients, especially those with comorbidities or benign prostatic hyperplasia. Third, the sample size was modest (n = 56), impacting our estimates' accuracy and raising the risk of type II errors, particularly in subgroup analyses.

CONCLUSION

This study observed the efficacy of Tamsulosin and Solifenacin in treating DJ stent-related symptoms. Both medications showed meaningful improvements in symptoms. However, Solifenacin was associated with greater outcomes in decreasing symptoms and enhancing overall quality of life.

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