

Original Article

The efficacy of Tamsulosin and Solifenacin versus Tamsulosin alone in double-J stent associated with lower urinary tract symptoms.

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Abstract

Background: Lithotripsy procedures, especially, Ureterorenoscopy is considered instrumental in treating ureteral stones effectively. In endourological surgery, a pigtail ureteric stent is a widely used method to resolve or prevent ureteral obstruction, promote healing, and reduce the incidence of ureteral strictures. The current study aimed to compare the efficacy of Tamsulosin with Solifenacin and Tamsulosin alone in double-J stents associated with lower urinary tract symptoms using IPS-Score.

Methodology: This study was conducted at the Urology Department, Institute of Kidney Diseases (IKD) Peshawar, Pakistan, from Aug 30, 2018, to Feb 28, 2019. Patients with DJ stents were randomly assigned to two groups (Group A & B). Group A received Tab Tamsulosin and Solifenacin, while Group B received Tab Tamsulosin alone; the IPS score was calculated at baseline and after 14 days.

Results: A total of 100 subjects undergoing unilateral DJ ureteral stenting participated in this study. The post-treatment IPSS Irritative score suggested that Group A has an average IPS score of 4.38 ± 1.77 , while in Group B, 6.4 ± 1.55 , which was significant with a p-value of 0.000.

Conclusion: Post-treatment average IPSS Irritative score of Tamsulosin and Solifenacin combination was less than Tamsulosin alone in patients with unilateral DJ stent.

Keywords

Ureterorenoscopy, Double-J Stent, Urinary Tract Infections, Tamsulosin, Solifenacin.



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Introduction

The Double-J (DJ) stent is commonly used in Ureteroscopy (URS) for ureteral stones and steinstrasse, ureteral obstruction, pyeloplasty for pelviureteric junction (PUJ) obstruction, Percutaneous Nephrolithotomy, and prior to extracorporeal shockwave therapy for renal stones¹. In spite of the many advantages of stents, some patients may experience lower urinary tract symptoms, such as increased urinary frequency, dysuria, urgency, and suprapubic pain². There is considerable evidence to suggest that lower urinary tract symptoms are a prevalent problem that affects both male and female genders' quality of life, health, and sexuality^{3,4}. The lower urinary tract symptoms are caused by the irritation of the lower urinary tract due to stents that lead to the lower ureter and bladder spasms⁵. The International Prostate Symptom Score (IPSS) questionnaire is one of the common outcome measures to determine whether an individual has lower urinary tract symptoms due to DJ stents or benign prostatic hyperplasia. The IPSS scores increase following the DJ stent insertion and decrease toward the end of the first week⁶.

The DJ stent-related lower urinary tract symptoms are similar to benign prostatic hyperplasia and involuntary bladder contractions caused by muscarinic stimulation due to an overactive bladder. The studies have shown that antimuscarinics and alpha-blockers can help to improve lower urinary tract symptoms due to DJStent^{1,7}. Compared to the placebo, Tamsulosin helps individuals with DJ stents reduce stent-related symptoms and improve quality of life^{8,9}. In a clinical trial, Tamsulosin and Solifenacin were compared with placebo; Tamsulosin increased DJS-related irritative symptoms by 7.68 ± 3.66 and Solifenacin by 6.62 ± 3.92 , which indicates that IPS irritative scores were higher than placebo⁶. Solifenacin is an antimuscarinic and is widely used for treating overactive bladder and is effective for DJ Stent-related symptoms. In another controlled trial, Solifenacin was found effective in reducing DJS-related lower urinary tract symptoms compared to placebo in both genders¹⁰.

The studies conducted in Pakistan have not explored the management of DJ Stent-related lower urinary tract symptoms, particularly the irritative symptoms. The studies carried out in different populations have shown significant differences. Thus, studies in the local population were needed to examine the effects of drugs used for BPH and overactive bladders, such as Alpha-Blockers and Antimuscarinics. Therefore, the present study aimed to compare the efficacy of Tamsulosin with Solifenacin and Tamsulosin alone in double-J stents associated with lower urinary tract symptoms using IPS-score.

Methodology

This study was carried out at the Institute of Kidney Diseases Urology Department, Peshawar, Pakistan. A total of 100 subjects with Unilateral DJ Stenting were recruited using non-probability purposive sampling. The sample size of 100 subjects with two parallel groups of 50 subjects in each study group was estimated using Open epi software and with the following parameters; Mean change in Tamsulosin plus Solifenacin group 0.36 ± 0.836 , Mean change in Tamsulosin alone group 3.43 ± 1.126 , Confidence interval 95%, Power of test 90% $n=6$, which is very less, so according to CPSP assumption criteria, the total sample size calculated was 100⁶.

All the Patients with Unilateral DJ Stenting with ages between 18 to 40 years of either gender and duration of DJ Stent between 1-6 weeks were included in this study. Whereas patients with any history of Solifenacin or Tamsulosin contraindication, pregnancy (as detected on History, confirmed on Ultrasound and Serum Beta-hCG), History of bleeding disorders (Prolong PT, APPT, INR), LUTS prior to DJS insertion, used alpha-blockers during the last month (determined subjectively) Symptoms of UTI or Prostatitis or overactive bladder and chronic use of analgesics were excluded in this study.

Using a computer-generated, randomized sequence number, the study participants were allocated into their respective study groups (Group A & B). The random allocation sequence was

generated with the assistance help of a statistician; the principal investigator enrolled participants and assigned them to the study groups according to the randomized sequence. The Participants in Group A received Tab. Tamsulosin 0.4 mg plus Solifenacin 5 mg OD and Group B participants received Tab. Tamsulosin 0.4 mg OD for two weeks. After the approval from the hospital ethical Committee, subjects were screened and enrolled from Urology OPD of IKD and written informed consent was obtained from each participant. The participant's details related to contraindication to using Tamsulosin or Solifenacin were screened (pregnancy, bleeding disorders, use of alpha-blockers, prostatitis or overactive bladder symptoms, chronic use of analgesics, diabetic status).

At baseline, investigations such as full blood count, Renal Function Test, Urine Routine & Microscopy test, Prothrombin time, activated partial thromboplastin time, INR, Beta-HCG (to exclude pregnancy in case of females), X-ray KUB to confirm presence & side of DJ Stent were performed. Moreover, IPSS Irritative scores were calculated using the IPSS Questionnaire for irritative symptoms. On follow-up after two weeks, a Post-treatment IPSS Irritative score was recorded from the study participants.

Data were analyzed using SPSS version 21.0. Numerical variables like age, duration of DJS, Baseline IPSS Irritative score, Post-treatment IPSS Irritative score, and change in IPSS Irritative score were reported using mean & standard deviation. Categorical variables like gender, the indication of the DJ Stent, and the side of the DJ stent were described in terms of frequencies and percentages. The mean change in IPSS Irritative score within a group was compared using paired t-tests. The mean change in IPSS Irritative score was compared between the groups using an unpaired t-test; a p-value of < 0.05 is considered significant. Mean change in IPSS Irritative score was stratified with regards to age, gender, side of DJS, an indication of DJS, and duration of DJS to see the effect of these within a group and between the groups by applying paired t-test and un-paired t-test respectively.

Results

There were 44% male and 56% female patients in Group A, while 38% were male and 62% were female in Group B. In both study groups, majority of the participants lies in the age group between 26 to 35 years. In group A, the mean age of the participants was 28.96 ± 6.71 , and in group B, 29.08 ± 5.91 .

Table 1: Gender and age-wise distribution in both the groups.

Variable	Group A	Group B	p-value
Age (Years); Mean \pm SD	28.96 \pm 6.71	29.08 \pm 5.91	
Age Group	\leq 25 years	17(34%)	0.277
	26-35 years	21(42%)	
	\geq 36 years	12(24%)	
Gender	Male	22(44%)	0.342
	Female	28(56%)	

IPSS Irritative score-wise distribution shows that Group A has an average post-treatment score of 4.38 ± 1.77 , while in Group B, it was 6.4 ± 1.55 , which was significant with a p-value = 0.000. Although the same was compared to pre-treatment, it showed insignificance with p-value = 0.590, indicating that patients were allocated with almost the same IPSS Irritative score among the two groups (Table 2).

Table 2: Comparison of pre and post-treatment scores in both the groups.

Variables		Group A	Group B	p-value
IPSS Total score	Pre-treatment	10.04±2.37	9.78±2.43	0.590
	Post-treatment	4.38±1.77	6.4±1.55	0.000*

*p<0.05 is considered significant.

When the IPSS Irritative score was stratified across the age groups, it was shown that except for the age of fewer than 25 years, the rest of the age groups reported significance in both groups. Additionally, when IPSS Irritative scores of patients were stratified by gender, an indication of stents, and duration, it shows that all have a significant effect in both the groups except for ureterolithotomy. The mean value of post IPSS in group A is low than in group B, throughout various categories that invalidate relatively better improvement. IPSS lower score suggests no or milder symptoms (Table 3).

Table 3: Stratification of IPSS over age, gender, indication, duration of DJS.

Variable		Post IPSS		P-value
		n(Mean ± SD)		
		Group A	Group B	
Age Group	≤ 25 years	17(4.94±1.89)	12(6.08±1.44)	0.09
	26- 35 years	21(4.38±1.66)	29(6.45±1.59)	0.000*
	≥ 36 years	12(3.58±1.62)	9(6.67±1.66)	0.000*
Gender	Male	22(4.50±1.95)	19(6.05±1.58)	0.008*
	Female	28(4.29±1.65)	31(6.61±1.52)	0.000*
Indication of Stent	URS	20(4.60±1.54)	23(6.22±1.62)	0.001*
	PCNL	24(4.12±1.98)	23(6.48±1.53)	0.000*
	Ureterolithotomy	6(4.67±1.75)	4(7.00±1.41)	0.057
Duration of Stent	≤ 3 weeks	24(4.08±1.89)	16(6.94±1.18)	0.000*
	≥3 weeks	26(4.65±1.65)	34(6.15±1.65)	0.000*

*p<0.05 is considered significant.

Discussion

Our study results suggest that combined therapy with Solifenacin significantly reduced double-J stent-related LUTS and International Prostate Symptom Score (IPSS) compared to Tamsulosin alone. Zimskind et al. were the first to place an endoluminal stent cystoscopically¹¹. Currently, ureteral stents are routinely used to bypass ureteral obstruction due to various causes. A high prevalence of stent-related symptoms exists, causing complications and compromising the quality of life (QoL). These symptoms can evaluate systematically by different scoring systems¹²⁻¹⁴. In an effort to evaluate these symptoms, Joshi, and colleagues designed and validated the Ureteral stent symptom questionnaire (USSQ) and evaluated stent-related morbidity. According to

Joshi et al. study, 80% of patients with a DJ ureteral stent reported urinary symptoms and pain, and 40% experienced sexual dysfunction¹⁵. Double J stents (DJS) are commonly used in urological practice and are made from synthetic biomaterials. Bacterial colonization of DJS normally remains clinically silent but colonized DJS may cause the origin of local infection, bacteremia, and sepsis, particularly in immunodeficient patients^{16,17}. The morbidity associated with ureteral stents is well documented, and general health, sexual activity, and work performance are affected by bothersome urinary symptoms in 78% of cases, and pain is seen in 80%^{18,19}.

The stent placement indications were similar in both groups. In Group A, indication percentage

were PCNL (48%), URSL (40%) & Ureterolithotomy (12%) and in Group B, indication percentage were PCNL (46%), URSL (46%) & Ureterolithotomy (8%). Moradi et al. evaluated the effectiveness and safety of Tamsulosin, Solifenacin, and Combination in reducing double-J stent-related LUTS and IPSS. Three hundred and thirty-eight patients who had double-J ureteral stenting were randomized into four groups and given Tamsulosin 0.4 mg daily, Solifenacin 10 mg daily, placebo, or a combination of both. The combined use of Tamsulosin and Solifenacin alleviated LUTS associated with DJS and significantly reduced IPSS compared with either drug alone²⁰. In a study by Lim and colleagues in 2011, combined therapy (Tamsulosin and Solifenacin) effectively reduces the stent-induced irritation of the lower urinary tract and IPSS²¹. These findings were consistent with our study results.

In contrast to monotherapy with either agent alone, Tamsulosin and Solifenacin appear to significantly reduce symptoms of stent-associated irritability and IPSS²¹. A meta-analysis of Zhou et al. shows that combination therapy of Tamsulosin (Alpha-blockers) and Solifenacin (Antimuscarinic) is significantly more effective than Alpha-blockers alone. Their findings suggest that combination therapy has a significantly lower International Prostate Symptom Score (IPSS) than Alpha-blocker monotherapy²². The present study was conducted at a single center, which serves as a major limitation; we suggest larger multicenter studies should be conducted in Pakistan to understand the disease.

Conclusion

This study's results suggest that a combination of both Tamsulosin and Solifenacin is more effective in reducing IPS Irritative score than Tamsulosin alone in patients with unilateral DJ stent. Therefore, the combination of both should be considered in patients with stent-related LUT symptoms.

Conflicts of Interest

None to disclose.

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