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## Effects of tamsulosin and tamsulosin+solifenacin combination therapy for the treatment of ureteral stent related lower urinary tract symptoms

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#### Abstract

**Objective:** To evaluate the effect of tamsulosin and tamsulosin+ solifenacin combination therapy in improving the lower urinary tract symptoms of patients with indwelling double-J ureteral stents.

**Study design:** Prospective observational comparative study

**Place and duration of study:** Department of urology & Renal transplantation (dr. psims and rf) from March 2019 to October 2020.

**Methods:** Total 100 patients having lower urinary tract symptoms after DJ stent insertion were selected for the study. DJ stenting was done in these patients following ureterorenoscopy (URS) and intracorporeal lithotripsy, percutaneous nephrolithotomy (PCNL), ureterolithotomy, pyelolithotomy, pyeloplasty and in patients with obstructive uropathy. All the patients were allocated two different groups. Group A received Tamsulosin 0.4 mg & Group B received Tamsulosin 0.4 mg and Solifenacin 5 mg daily once a day every day. The IPSS questionnaire was filled on day of per urethral catheter removal and on the day of DJ stent removal. Results were made on the day of DJ stent removal by comparing the mean change in IPSS in both groups. Independent sample t-test and paired t-test were applied. P-value < 0.05 was taken as significant.

**Result:** Mean age was 41.6±13.75 years in Group-A and 38.24±12.24 years in Group-B. Total number of male patients was 25 (50%) in Group-A and 31 (62%) in Group-B. Female patients in Group-A were 25 (50%) and 19 (38%) in Group-B. Mean IPSS was 9.32 ±2.39 in Group-A and 9.52 ±3.39 in Group-B at baseline (p=0.62). After 2 weeks IPSS was 3.98 ±1.74 in Group-A and 2.36 ±1.51 in Group-B (p=0.0001). There was a statistically significant difference between group A and group B in the IPSS score.

**Trial registration:** The study protocol was registered on Clinical Trials Registry- India (ICMR-NIMS) on April 30th, 2020 (registration number: CTRI/2020/04/024945).

**Conclusions:** The mean change in IPSS by combined treatment of Tamsulosin and Solifenacin was significant when compared to Tamsulosin alone in treatment of DJ stents related LUTS.

**Keywords:** tamsulosin and tamsulosin+solifenacin, combination therapy, ureteral stent related lower urinary tract symptoms

#### Introduction

The term "stent" first appeared in the literature about a new dental impression material described by an English dentist, Charles T. Stent, and subsequently manufactured by himself and his sons, Charles R., and Arthur H., at home [1]. In the 1800s, Dr. Gustav Simon was the first to describe inserting a tubular inert material into the ureter, an early version of the ureteric stent [2].

Dr. Paul Zimskind and his colleagues reported on the use of a straight tube that was open ended and made of silicone to relieve ureteric obstruction in 1967, referring to it as the "ureteral splint." [3] Dr. Roy P. Finney described the existing double J stent with curls at both ends in opposing directions in 1978. These curls provided the stents with the necessary fixity, preventing migration in either direction [4].

Adverse symptoms associated with ureteric stent use are common, and this has an adverse effect on the patient's physical and psychosocial well-being and overall health-related Quality of life. Lower urinary tract symptoms after D-J placement are still common and include frequency (50–60%), urgency (57–60%), dysuria (40%), incomplete emptying (76%), urge incontinence (25%), and hematuria (25 %) [5]. The D-J-related discomfort could be caused by (1) irritation of the bladder mucosa, particularly the trigone, by the stent's bladder coil; (2) smooth muscle spasm;

and (3) urine reflux [6]. Various attempts had been made to minimize these symptoms, like periureteral anesthetic injection, but pharmacological treatment is the simplest and a noninvasive option. In this study, we assessed the efficacy of tamsulosin, and the combination therapy of tamsulosin and solifenacin both agents for the treatment of LUTS using a validated questionnaire.

The use of selective alpha-blocker e.g., Tamsulosin has reduced stent related [7] symptoms and improved the quality of life. Alpha-blocker helps in reducing the symptoms by blocking alpha-adrenergic receptors that result in decreasing the muscle tone of the ureter, bladder trigone and prostatic urethra. This ultimately leads to decreasing bladder outflow resistance and force during urination. Anticholinergics acts on the muscarinic receptors, thereby reducing over activity of the bladder and contraction by blocking them, [8] which assists in reducing urinary symptoms.

In one study by Lim KT *et al.*, combination therapy of Tamsulosin and Solifenacin for treatment of LUTS was found effective in improving international prostate symptom score (IPSS) score by 7.16+3.37 as compared to Solifenacin alone in which improvement [9] occurred in IPSS score by 11.04+5.29. Double J stenting may cause lower urinary tract symptoms which may be settled by using antimuscarinics and alpha blockers. Antimuscarinics monotherapy has been widely used as treatment for stent related LUTS. The combination therapy of antimuscarinics and alpha blockers improves lower urinary tract symptoms better than anti muscarinic [9] monotherapy.

### Materials and Methods

A total of 100 patients will be chosen after assessing inclusion/exclusion criteria. The patients will be divided into two groups by using single-blind randomization: Group A 50 patients received only 0.4 mg of tamsulosin. Group B 50 patients received tamsulosin 0.4 mg + solifenacin 5 mg once a day. Patients with a prior diagnosis of benign prostatic hyperplasia or overactive bladder, Pregnant women, Patients on Psychiatric medication, Urinary tract infections, Previous use of selective alpha-1- blocker and or antimuscarinic agent or with a known history of orthostatic hypotension, allergy, hypersensitivity to one or more alpha-blockers, Patients under ICU management and CRF Patients on dialysis.

The study protocol was approved by the ethics committee of the participating hospitals, and all patients enrolled in this study provided written informed consent. Before and two weeks after stent insertion, all patients completed written International Prostate Symptom Score/quality of life component of IPSS (IPSS/QoL), and Visual Analogue Pain Scale (VAPS) questionnaires. The IPSS was divided into the total score, voiding symptom score, and storage symptom score, and each one was compared. Visual Analogue Pain Scale graded from 1 (minimal or no symptoms) to 10 (symptoms of maximal severity). The day of per urethral catheter removal, and on the day of stent removal, each patient completed written International Prostate Symptom Score/quality of life (IPSS/QoL) and visual analogue pain scale (VAPS) questionnaires. Independent sample t-test and paired t-test were used for comparisons between two groups. Values of  $p < 0.05$  were considered statistically significant. Statistical analyses were performed by using SPSS for windows version-16 {2007}.

### Results

A total of 100 patients were enrolled in the study, and All patients completed the study. Group A (50 patients) consisted of 25 men and 25 women (mean age: 41.6±13.75 years), group B (50 patients) consisted of 31 men and 19 women (mean age: 38.24±12.24 years). The main indication of ureteral double-J stent placement was URS and ureterolithotomy. Therapies were well tolerated, and no patients discontinued the treatments because of side effects.

All patients completed the necessary questionnaires. There were no statistically significant differences between groups regarding patient's demographics, treatment indications, and preoperative questionnaires scores (Tables 1 and 2).

**Table 1:** Basic characteristics of studied patients

Variables	Group A	Group B	P value
Number of patients	50	50	
Mean age (years)	41.6±13.75	38.24±12.24	0.2
Sex			0.31
Male	25	31	
Female	25	19	

**Table 2:** Comparisons of IPSS/QoL and VAPS in group A and B

		Group A	Group B	t value	P value
IPSS total score	At the day of PUC removal	9.32 ±2.39	9.52 ±3.39	-0.34	0.73
	At the day of DJ stent removal	3.98 ±1.74	2.36 ±1.51	4.97	<0.0001
IPSS storage Sub score	At the day of PUC removal	5.32 ±1.57	6.04 ±2.47	-1.74	0.08
	At the day of DJ stent removal	2.68 ±1.25	0.98 ±1.2	6.92	<0.0001
IPSS voiding Sub score	At the day of PUC removal	3.84 ±1.79	3.46 ±2.64	0.84	0.4
	At the day of DJ stent removal	1.08 ±1.07	1.34 ±1.24	-1.13	0.26
QoL	At the day of PUC removal	2.46 ±0.79	2.18 ±1.0	0.13	0.28
	At the day of DJ stent removal	0.74 ±0.66	0.44 ±0.54	2.48	0.02
VAPS	At the day of PUC removal	1.96 ±0.81	2.14 ±1.07	-0.95	0.34
	At the day of DJ stent removal	0.54 ±0.57	0.24 ±0.43	2.94	0.004

IPSS/QoL: International Prostate Symptom Score and Quality of Life, VAPS: Visual analogue pain scale, p-value of interaction, PUC per urethral catheter.

### Discussion

The clinical observations and reports of the studies indicate a variety of symptoms and significant morbidity associated with indwelling ureteral stents. Stent discomfort affects over 80% of patients who underwent DJ stenting for ureteral stent intervention. Patients with indwelling stents have been known to

experience a wide range of stent-related symptoms, including storage, voiding, OAB symptoms, hematuria, and pain. These symptoms negatively affect the patient's activities, work performance, and QoL. The cause of stent-related symptoms and the mechanisms involved are not fully understood. Still, it is thought that involuntary bladder contraction due to trigone

irritation contributes to bothersome urinary symptoms. Also, increased bladder outlet resistance and pressure produced during micturition cause urinary reflux.

Urinary symptoms (frequency, urgency, and hematuria) are related to trigonal irritation or pressure transmitting to the renal pelvis during urination (causing flank pain). It could be due to lower ureteral smooth muscle spasms and local irritation to neuronal-rich trigonal mucosa, which contains  $\alpha$ -1D receptors, and bladder instability, which causes symptoms similar to benign prostatic hyperplasia.

Alpha-blockers are the first-line treatment for LUTS/BPH. Antimuscarinics have been widely used for the treatment of OAB for a long time. So, alpha-blockers or antimuscarinics are effective in improving stent-related symptoms. Alpha-blockers may relax the prostate smooth muscle, the bladder neck, and the distal ureter smooth muscle to decrease bladder outlet resistance and voiding pressure, thus explaining the beneficial effects on stent related LUTS. The sympathetic nervous system was reported to have a modulating role over ureteric peristalsis. Stimulation of  $\alpha$ -receptors in the human ureters increases the force of ureteral contraction in response to the presence of a stone. Davenport *et al* demonstrating that  $\alpha$ -blocker might significantly reduce the peak contraction pressure and lead to ureteral dilation. Flank pain may be from spasms of the ureter in patients with a stent. Antimuscarinics have been thought to block muscarinic receptors on the efferent in the detrusor muscle and reduce the involuntary bladder contraction caused by trigone irritation, thus alleviating the stent induced OAB symptoms [10].

Alpha-blockers have previously been shown to be successful in controlling double-J stent-related symptoms. Wang *et al.*, in a prospective randomized trial, compared Tamsulosin to placebo in 79 patients using (USSQ), that Tamsulosin enhanced stent-related urinary symptoms and QOL, and they recommended its routine use [11]. In contrast, Lee *et al.*, in their prospective randomized study over 20 patients using a combination of Tamsulosin and tolterodine, reported no statistically significant difference when compared to placebo, and when combination therapy was compared to tamsulosin monotherapy, no beneficial effect was reported. They stated that correct stent positioning and verification of its location were more important than medication for lessening stent-related storage symptoms [12]. Kuyumcuoglu *et al.* reported in a prospective randomized study that Tamsulosin was not different than placebo in controlling stent-related symptoms [13]. Damiano *et al.* stated that there were no symptoms differences between stents of different sizes but that small-diameter stents tended to dislodge more frequently [14]. In our study, the mean age of Group A was (41.6 $\pm$ 13.75) years, while that of Group B was (38.24 $\pm$ 12.24) years. The number of patients in both groups was equal, thus limiting the chances of discrepant results.

Both the groups were age and sex-matched such that there was no statistical significance between these two parameters. The Tamsulosin group had 25 males (50%) and 25 females (50%), and Tamsulosin plus solifenacin group had 31 males (62%) and 19 females (38%). There were no statistically significant differences between the two groups. However, in our study, 56% of the total cases were men, 44% were women, both genders are almost equally affected due to stent-related lower urinary tract symptoms.

In a study done by Lim *et al.*, the baseline Mean IPSS score on a postoperative day one was 12.53 $\pm$ 4.79 in the tamsulosin Group and 11.47 $\pm$ 3.98 in the drug combination group (p-value 0.6). However, in our study, the baseline mean IPSS score on the day of PUC removal in tamsulosin group A was 9.32  $\pm$ 2.39 and in

combination drug group B was 9.52  $\pm$ 3.39, (p-value 0.7), which was not significant in both studies [9].

Lim and his colleagues reported that combination therapy of Tamsulosin and Solifenacin was found effective in improving IPSS total score by 7.16 $\pm$ 3.37, for treatment of LUTS as compared to Tamsulosin alone in which improvement occurred in IPSS total score by 12.77 $\pm$ 5.24. There were significant differences in the IPSS total score between the control group and group that received a combination of Tamsulosin and solifenacin (p= 0.015), and between-group received Tamsulosin, and group received a combination of a drug (p=0.031) [9].

In shalaby *et al.*, study When comparing post stenting scores among different groups, there were statistically significant differences in IPSS score in favor of the tamsulosin group (7.68  $\pm$  3.66), solifenacin group (6.62  $\pm$  3.92), and combination group (4.66  $\pm$  3.24) as compared to control group (8.24  $\pm$  3.44) (value < 0.005). Combination therapy showed a statistically significant difference in IPSS score compared to monotherapy groups Tamsulosin and solifenacin (value < 0.001) [15].

Similar to our study, the difference of IPSS at the day of stent removal in the tamsulosin group (Group A) was 3.98  $\pm$ 1.74, while that among the Tamsulosin + solifenacin group (Group B) was 2.36  $\pm$ 1.51. Here the difference in terms of IPSS between the groups was thus significant with a p-value < 0.001.

In contrast to our study, Park *et al.*, compared 112 patients divided into four equal groups with one control group using the ureteral stent symptom questionnaire (USSQ); results shown that 0.2 mg tamsulosin and 5 mg solifenacin as monotherapies and as taken together as a combination therapy for two weeks following urinary stent insertion do not provide beneficial effects for the relief of DJ stent related LUTS [16]. However, the study of Abedelal *et al.*, used the USSQ questionnaire, randomized 260 patients in four groups, including the control group, showed that the medicated groups had significant improvements in the USSQ compared with the control group. There was an insignificant difference between the tamsulosin and solifenacin group for the USSQ domains, while combined therapy significantly improved stent-related symptoms compared with monotherapy with either one of the drugs [17]. Yan *et al.*, did metanalysis study showed beneficial effects of antimuscarinics alone in reducing stent-related symptoms. The combined use of antimuscarinics and alpha-blockers results in additive favorable effects in patients with ureteral stent-related symptoms compared with antimuscarinics monotherapy. The alpha-blockers may synergize the efficacy of the antimuscarinics, which is beneficial for the treatment of ureteral stent-related symptoms [18]. In another study done by Noor *et al.*, compared 170 patients allocated in two groups, the solifenacin group and Tamsulosin and solifenacin combination group, in lowering stent related LUTS. Mean IPSS was 9.01 $\pm$ 1.29 in the combination group and 9.10 $\pm$ 1.23 in the solifenacin Group at baseline (p=0.62). After six weeks, IPSS was 4.69 $\pm$ 0.89 in the combination Group and 6.87 $\pm$ 1.25 in the solifenacin Group (p=0.0001). The study has shown that combination therapy improves stent related LUTS symptoms better than solifenacin monotherapy [19].

Further, we also compared the IPSS obstructive sub score and storage sub score of group A and group B. Storage mean sub score was higher in group A (2.68  $\pm$ 1.25) as compared to group B (0.98  $\pm$ 1.2). This difference was statistically significant (p<0.0001). The obstructive mean sub score was marginally higher in group B (1.34  $\pm$ 1.24) than group A (1.08  $\pm$ 1.07). This difference was not statistically significant (p=0.26). A combination drug was more effective in lowering storage symptoms than tamsulosin monotherapy. This finding matched

with the earlier study by Lim *et al.* in improving the storage symptom score in the Tamsulosin + solifenacin group compared to the Tamsulosin alone group.

In our study comparing group A IPSS, storage, obstructive, VAPS, and QOL mean score at the day of PUC removal was  $9.32 \pm 2.39$ ,  $5.32 \pm 1.57$ ,  $3.84 \pm 1.79$ ,  $1.96 \pm 0.81$  and  $2.46 \pm 0.79$  respectively, and  $3.98 \pm 1.74$ ,  $2.68 \pm 1.25$ ,  $1.08 \pm 1.07$ ,  $0.54 \pm 0.57$  and  $0.74 \pm 0.66$  respectively at the day of stent removal shown statistically significant differences in all scores ( $p$ -value  $< 0.0001$ ), whereas in the Lim *et al.* study, the IPSS total score, storage sub score, QoL, and VAPS did not indicate statistically significant differences in the tamsulosin monotherapy group. However, the disparity in the obstructive sub score was statistically significant, and there were statistically significant differences in the IPSS total score and storage sub score in the solifenacin group. The VAPS and QOL scores were not significantly different. Similarly, the study of shalaby *et al.* solifenacin monotherapy, poorly controlled stent-related symptoms whereas pre-and post-stent insertion storage sub score, showed statistically significant differences.

In our study, combination therapy of Tamsulosin and Solifenacin was found effective in improving Visual analog pain score by  $0.24 \pm 0.43$ , as compared to Tamsulosin alone in which improvement occurred in VAPS score by  $0.54 \pm 0.57$ . Here the difference in VAPS between the groups was SIGNIFICANT with a  $p$ -value of 0.004. there was no significant difference found between group A and group B in improving quality of life. ( $p$ -value-0.02). on comparing to Lim *et al.*, study IPSS and QoL showed statistically significant differences in the tamsulosin and solifenacin combination treatment group. However, there was no significant difference in the VAPS score [9]. Shalaby *et al.*'s study of combination therapy showed a statistically significant difference in VAPS and QOL compared to monotherapy [15].

### Conclusion

According to the results of the study, we conclude that the Combination of Tamsulosin and solifenacin significantly better than both drug monotherapies in lowering LUTS symptoms associated with DJ stenting. No difference in the improvement of obstructive symptoms on comparing with tamsulosin monotherapy. Combination therapy controls storage symptoms much better than tamsulosin monotherapy and reduces the need for analgesic drugs in the postoperative period due to better control on LUTS symptoms; thus, patient should be given the benefit of having the stent while also having his symptoms relieved by the judicious use of a combination of drugs, Tamsulosin, and solifenacin once daily for 14 days. However, there is a need for further studies with a larger patient sample to correlate the effects of the combination of different alpha-blockers and antimuscarinic agents to optimize medical therapy to treat symptoms related to DJ stent placement.

### Conflicts of Interest

The authors have nothing to disclose.

**Ethical Approval:** This study was accepted by the institution's ethics committee CDSCO Reg.No: ECR/804/Inst/AP/2016-RR-19 with approval No. PG/379/19.

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