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ORIGINAL ARTICLE

Comparison of Monotherapy Tamsulosin or Solifenacin alone Versus Combination Therapy Tamsulosin plus Solifenacin in the Management of JJ Stent related Urinary Symptoms

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ABSTRACT

Background: Ureteral stents are inserted to relieve the ureteral obstruction, reduce obstructive renal pain, increases the urine flow and to avoid the complications. The insertion of ureteral stent can lead to several stent-related complications that comprise lower urinary tract symptoms and dysuria. These complications can affect the QoL and sometimes can cause emergency department or outpatient early visits.

Objective: To compare the efficacy and safety of monotherapy with tamsulosin or solifenacin alone versus their combination in the treatment of JJ stent related symptoms.

Study Design: Non-randomized control trial comparative study

Place and Duration of Study: Department of Urology, Jinnah Hospital Lahore from 1st December 2022 to 31st May 2023.

Methodology: One hundred and sixty eight patients who developed JJ stent related symptoms were enrolled. Patients were selected using consecutive sampling technique and randomly allocated one of the three treatments using lottery method. Group A: 56 patients receiving Tamsulosin 0.4 mg daily; Group B: 56 patients receiving Solifenacin 5mg daily; and Group C: 56 patients receiving Combination of Tamsulosin 0.4 mg and Solifenacin 5 mg. The stent related urinary symptoms of all these patients were evaluated by using USSQ before initiation of therapy and fortnightly till the removal of JJ stent after two months by using USSQ.

Results: The mean ages were 35.71±7.622 years of Group A (Tamsulosin), 32.43±8.844 years of Group B (Solifenacin) and 32.71±9.400 years of Group C (Tamsulosin + Solifenacin). Significant results in USSQ score were obtained at baseline, first visit, second visit, third visit and fourth visit (P=0.000). The significant results (P≤0.05) were found between Group A and Group C at first visit, second visit, third visit and fourth visit while insignificant results (>0.05) at baseline. However, between Group B and Group C, significant results were found at baseline and all visits.

Conclusion: The combination therapy with Tamsulosin plus Solifenacin is more effective than monotherapy with Tamsulosin or Solifenacin alone for JJ stent related urinary symptoms.

Keywords: Comparison, Tamsulosin, Solifenacin, Monotherapy, Combination therapy, JJ stent related urinary symptoms.

INTRODUCTION

The ureteral stents have become a crucial tool in urology that are used for management of both severe and persistent ureteral blockade by ureteric dilatation as well as urine drainage.[1]

Pigtail stent or JJ (double-J) stent is the catheter/tube placed inside the ureteral lumen in an antegrade/retrograde manner so as to uphold its patency.[2] The JJ stent catheter offers a self-retaining ability because of a dual coil design at distal and proximal ends which work to firmly fasten the stent in the bladder and upper urinary tract (upper calyx and renal pelvis).[3]

The local irritation may leads to pain as well as lower urinary tract symptoms (LUTS) because of ureter and bladder spasm.[4] The lower urinary tract symptoms and pain owing to stent placement was found associated with pressure spread to renal pelvis during the urination and to lower ureteric as well as bladder spasm caused by local irritation.[5]

To reduce in SRSs incidence, material, design, position and length are the preliminary exertions have been carried to make improvement in ureteral stents physical properties. Although, designs and size of the stent to decrease the SRSs seems inadequate, there is still need to develop an optimal stent.[6]

The solifenacin, as antimuscarinic agent impedes muscarinic receptor which has been approved to treat the overactive bladder.[7] Tamsulosin is a selective *α*-blocker that impedes the smooth muscles contraction in the distal ureter, neck, bladder trigone, alleviating lower urinary tract symptoms as well as flank pain.[8] The most commonly reported side effects of tamsulosin were dizziness (5.3%), after that retrograde ejaculation (4.5%).[9] The most common adverse effect at 5 to 20 mg daily in studies evaluating the safety as well as efficacy of solifenacin are dry mouth (71.4%), constipation (15.1%) and nausea (11.6%).[10]

Up till now, both alpha blockers as well as anticholinergic agents can relieve these distresses and eventually boost the life quality.[11] Michel–Ramirez *et al*[12] evaluated 72 patients after JJ placement on day 7 and 14 using ureteral stent discomfort test (USDT). Although, there are yet not much researches are available regarding comparison between monotherapy as well as combination. Moreover, several papers that have recently been published showed different results: however, former researches along with international prostate symptom score (IPSS) found that the combined therapies offered better results, a few recent researches highlighted that monotherapies equally functioned when compared with combination therapies in USSQ evaluation.[13]

Now-a-days, JJ stents are regularly utilized to avoid blockage, expand the ureter, and urine passage that accelerates the tissue healing after TUL (transureteral lithotripsy) and ureteroscopy.[14] Because the SRSs pharmacological treatment is yet controversial, hence, it is very significant to discover a solution for minimizing the complications. Most of the trials reported that the efficacy of both solifenacin and tamsulosin are comparable on relieving flank pain, bladder distress and urgency after JJ stenting. However, long term effects of the monotherapies, tamsulosin or solifenacin, were found not less to combination treatment, Tamsulosin plus solifenacin but the tamsulosin has better safety profile than solifenacin or combination therapy.

MATERIAL AND METHODS

This non-randomized control trial comparative study was conducted at Urology OPD, Jinnah Hospital Lahore from 1st

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December 2022 to 31st May 2023. The sample size was 168 patients with a significance level 5%, power of study 80% and confidence interval 95%. Age of the patient between 18 to 50 years, both male and female gender, undergoing retrograde unilateral JJ ureteric stenting before extracorporeal shockwave lithotripsy (ESWL), following ureteroscopic lithotripsy (URSL), ureteric stricture, and endoscopic endopyelotomy, who agree to be randomly allocated for treatment were included. All patients who had UTI, pregnant women, bilateral or long-term ureteric stenting, bladder pathological conditions like OAB and BPH, those under concurrent or previous use of selective α1-blockers and/or antimuscarinic medications were excluded.. The patients were assessed for JJ stent related urinary symptoms by using USSQ proforma for pre-treatment baseline score. Urinary tract infection (UTI) was ruled out in all patients before initiation of therapy. These patients were randomly and equally divided into three groups tamsulosin, solifenacin and tamsulosin+solifenacin, each comprising of 56 patients. Only those patients were given treatment developed stent related symptoms. Treatment groups were screened fortnightly for UTI by urine culture of mid-stream morning sample of urine. If any patient developed UTI during study period was excluded from treatment group and managed accordingly. Stent related urinary symptoms of these patients including in treatment groups were assessed fortnightly till the removal of JJ stent by using USSQ. All the patients were assessed for the adverse effects of tamsulosin such as dizziness, abnormal ejaculation, hypotension, headache, dry mouth and blurred vision, and adverse effects of solifenacin like dry mouth, constipation, GI disturbance and blurred vision, before starting drug therapy and on each visit fortnightly. If stent related symptoms persist despite two weeks' therapy, it labeled as treatment failure and patient was managed accordingly, by the medication or early removal of JJ stent was also be considered.

All the data was entered and analyzed using SPSS-23. The chi-square test was used to compare categorical data between groups. The ANOVA test was applied to compare numerical data between the three groups and the *post hoc* Dunnett's *t*-test to compare all other groups. The *t*-test was used when appropriate. $P<0.05$ was considered to indicate statistical significance.

RESULTS

In tamsulosin group, 16 (28.6%) were 18-30 years old and 40 (71.4%) were 31-50 years old and mean age was 35.71±7.622 years. In solifenacin group, 24 (42.9%) were 18-30 years old and 32 (57.1%) were 31-50 years old and mean age was 32.43±8.844 years. In tamsulosin + solifenacin group, 24 (42.9%) were 18-30 years old and 32 (57.1%) were 31-50 years old and mean age was 32.71±9.400 years (Table 1).

The significant (P=0.000) results in mean USSQ score were obtained at baseline, first visit, second visit, third visit and fourth visit [Table 2). According to ANOVA test, significant (P=0.000) results in USSQ score were obtained at baseline, first visit, second visit, third visit and fourth visit (Table 3). When Post Hoc Dunnet's t-test was applied in groups, significant results ($P\leq0.05$) were found between Tamsulosin group and Tamsulosin + Solifenacin group at first visit, second visit, third visit and fourth visit while insignificant results (>0.05) at baseline. However, between Solifenacin group and Tamsulosin + Solifenacin group, significant results were found at baseline and all visits (Table 4).

Table 1: Comparison of age in all groups

Age (years)	Tamsulosin (n=56)		Solifenacin (n=56)		Tamsulosin + Solifenacin (n=56)	
	No.	%	No.	%	No.	%
18-30	16	28.6	24	42.9	24	42.9
31-50	40	71.4	32	57.1	32	57.1
Mean±SD	35.71±7.622		32.43±8.844		32.71±9.400	
P value	0.000					

Table 2: Comparison of mean USSQ score in groups

USSQ score	Tamsulosin	Solifenacin	Tamsulosin + Solifenacin	P-value
Baseline	34.14±7.617	39.71±4.724	36.57±8.405	0.000
First visit	24.00±6.427	35.00±4.143	18.29±7.291	0.000
Second visit	23.57±5.417	31.43±5.417	12.43±3.846	0.000
Third visit	23.57±5.831	30.29±5.165	10.14±2.825	0.000
Fourth visit	22.57±4.276	30.14±4.867	11.14±2.186	0.000

Table 3: Comparison of USSQ Score in Groups (ANOVA ANOVA test)

		Sum of Squares	Df	Mean Square	F	Sig.
Baseline	Between Groups	873.905	2	436.952	8.682	.000
	Within Groups	8304.000	165	50.327		
	Total	9177.905	167			
First visit	Between Groups	8083.048	2	4041.524	108.618	.000
	Within Groups	6139.429	165	37.209		
	Total	14222.476	167			
Second visit	Between Groups	10208.762	2	5104.381	208.412	.000
	Within Groups	4041.143	165	24.492		
	Total	14249.905	167			
Third visit	Between Groups	11781.333	2	5890.667	257.405	.000
	Within Groups	3776.000	165	22.885		
	Total	15557.333	167			
Fourth visit	Between Groups	10246.857	2	5123.429	328.753	.000
	Within Groups	2571.429	165	15.584		
	Total	12818.286	167			

Table 4: Comparison of USSQ Score in Groups Post Hoc Dunnet's T-Test

Dependent Variable	Groups		Mean Difference	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Baseline	Group-A (Tamsulosin)	Group-C (Tamsulosin+ Solifenacin)	-2.429	1.341	.128	-5.42	.56
	Group-B (Solifenacin)	Group-C (Tamsulosin+ Solifenacin)	3.143	1.341	.038	.15	6.13
First visit	Group-A (Tamsulosin)	Group-C (Tamsulosin+ Solifenacin)	5.714	1.153	.000	3.14	8.29
	Group-B (Solifenacin)	Group-C (Tamsulosin+ Solifenacin)	16.714	1.153	.000	14.14	19.29
Second visit	Group-A (Tamsulosin)	Group-C (Tamsulosin+ Solifenacin)	11.143	.935	.000	9.06	13.23
	Group-B (Solifenacin)	Group-C (Tamsulosin+ Solifenacin)	19.000	.935	.000	16.91	21.09
Third visit	Group-A (Tamsulosin)	Group-C (Tamsulosin+ Solifenacin)	13.429	.904	.000	11.41	15.45
	Group-B (Solifenacin)	Group-C (Tamsulosin+ Solifenacin)	20.143	.904	.000	18.13	22.16
Fourth visit	Group-A (Tamsulosin)	Group-C (Tamsulosin+ Solifenacin)	11.429	.746	.000	9.76	13.09
	Group-B (Solifenacin)	Group-C (Tamsulosin+ Solifenacin)	19.000	.746	.000	17.34	20.66

DISCUSSION

The ureteral stents are crucial medical devices utilized in the urology to manage several conditions affecting the urinary system. Mostly ureteral stent placement leads to several stent-related symptoms that comprise LUTs, dysuria and lower back pain. Age plays a leading role in early recovery of the patients. It was found during study that most of the patients in all 3 groups were above 30 years old. In Group A (tamsulosin), Group B (solifenacin) and Group-C (tamsulosin + solifenacin), 28.6%, 42.9% and 42.9% patients were 18-30 years old while remaining proportion of patients in all groups was 31-50 years old. The mean age of the patients in group A was 35.71+7.622 years, in group B was 32.43+8.844 years and in group C was 32.71+9.400 years. The result was found statistically significant (P=0.000). The findings of our study are better than the study undertaken by Salih et al[15]

reported that mean age of the patients treated with tamsulosin, solifenacin and combined therapy was 39±1, 40±4 and 39±7 years, respectively. Shalaby et al[16] reported that mean age of the patients treated with tamsulosin, solifenacin and combined therapy was 41.3±17.1, 40.5±18.6 and 43.6±17.6 years, respectively. Another study performed by Abdelaal et al[17] also confirmed that mean age was 37.2±11.8, 41.9±10.3 and 38.9±9.4 years respectively.

It was also found that USSQ score, improvement in mean urinary symptoms was observed after treatment at fourth visit in all groups but Group-C patients demonstrated much better improvement than Group-A and Group-B patients indicating the better efficacy of combined therapy. According to USSQ score at baseline, the mean score of urinary symptoms was 14.43+4.698 in Group-A, 18.29+2.395 in Group-B and 17.29+2.455 in Group-C while at fourth visit, the mean score of urinary symptoms was 9.57+1.777 in Group-A, 11.71+1.498 in Group-B and 4.29+1.289 in Group-C. The p-value for comparison of mean score of urinary symptoms between groups was found statistically significant (P=0.000) in this study. The findings of our study are comparable with a study undertaken by Shalaby and associates[18] who also stated that tamsulosin+solifenacin combined therapy significantly improved the urinary symptoms related to JJ stents when compared with either medicine alone. The combination of tamsulosin and solifenacin can be a promising approach to enhance the therapeutic outcomes and overall patient experience in those undergoing double J stent placement. Dellis and colleagues in 2017 reported that the efficacy of these medications in improving stent-related symptoms. Study concluded that tamsulosin and solifenacin, whether used alone or in combination, effectively improved stent-related symptoms. The combination therapy was particularly beneficial in reducing urinary symptoms at fourth week. Another study conducted by Abdelaal and colleagues[17] reported that there was improvement in mean urinary symptoms after treatment. However, the patient treated with combination therapy showed better improvement than treated with tamsulosin and solifenacin alone.

The findings of our study showed that there was improvement at fourth visit among all groups but patients in Group-A showed better improvement than patients in Group B and Group-C. According to USSQ at baseline mean score for pain was 4.00±0.763 in Group-A, 3.29±0.706 in Group-B and 2.29±0.706 in Group-C while at fourth visit the mean score for pain was 2.00±0.539 in Group-A, 3.43±0.499 in Group-B and 2.14±0.645 in Group-C. The p-value for comparison of mean score for pain between groups was found statistically significant (P=0.000). A study carried out by Imrul Tareq and Islam[19] reported that after treatment better improvement in pain score was observed among patients treated with combination therapy (tamsulosin+solifenacin) than patients treated with tamsulosin or solifenacin alone indicating the better efficacy of combination therapy. After treatment, the mean score for pain was 3.79±1.32 in tamsulosin group, 4.28±1.41 in solifenacin group-B and 1.39±0.86 in combination therapy group. This significant reduction in the mean pain score in the combination therapy group indicates a more substantial improvement in pain compared to the other treatment groups. Both medications have unique mechanisms of action that contribute to pain relief. Tamsulosin, an alpha-blocker, helps relax the smooth muscles in the urinary tract, while solifenacin, an anticholinergic, reduces bladder spasms and decreases urinary urgency. Another study conducted by Salih and coworkers[15] highlighted that after treatment better improvement in pain score was observed among patients treated with combination therapy (tamsulosin+solifenacin) than patients treated with tamsulosin or solifenacin alone. After treatment, the mean score for pain was 4.0 in tamsulosin group and also 4.0 in solifenacin group-B while 3.0 in the combination therapy group. The p-value for comparison of mean score for pain between groups was found statistically significant (P=0.021).

As far as sexual life is concerned, the findings of our study indicated that combination therapy (tamsulosin+solifenacin) was better than tamsulosin or solifenacin alone. Among Group-C patient, a significant improvement while among Group-A and Group-B patients, no improvement was noticed regarding sexual life. According to USSQ at baseline, the mean score for sexual life was 2.29±1.592 in Group-A, 1.86±1.976 in Group-B and 2.14±2.497 Group-C while at fourth visit the mean score for sexual life was 2.57±1.412 in Group-A, 2.14±1.742 in Group-B and 1.43±1.857 in Group-C. The p-value for comparison of mean score for sexual life between groups was found statistically significant (P=0.000) in this study. The findings of a study conducted by Abdelaal and collaborators[17] exhibited similar scenario that combination therapy was found better among patients treated with combination therapy than patients treated with tamsulosin or solifenacin alone. After treatment the mean score of sexual life was 5.2±7.2 in tamsulosin group, 5.5±7.6 in solifenacin group and 2.4±2.3 in combination group (tamsulosin+solifenacin). The p-value for comparison of mean score of sexual life between the groups was found statistically significant (P=0.001) in this study. However, a study carried out by Dellis and colleagues[20] reported that sexual life was positively improved among patients treated with either tamsulosin or solifenacin alone as well as who received the combination therapy.

Quality of life is a most important factor among patients study showed very encouraging results that improvement in quality of life was noticed in all groups, patients at their fourth visit however, patients in Group-C again demonstrated much better improvement than Group-A and Group-B patients. According to USSQ, the mean score at baseline for quality of life was 3.71±0.456 in Group-A, 4.71±456 in Group-B and 4.43±0.912 in Group-C, while at fourth visit the mean score for quality of life was 2.43±0.499 in Group-A, 3.86±0.841 in Group-B and 1.14±0.645 in Group-C. The p-value for comparison of mean score for quality of life between groups was found statistically significant (P=0.000) in this study. Imrul Tareq and Islam[19] also confirmed in their study that quality of life was improved among all groups patients after treatment but patients treated with combination therapy (tamsulosin+solifenacin) demonstrated much better improvement than patients treated with tamsulosin or solifenacin alone. After treatment the mean score of quality of life was 1.7±0.8 in tamsulosin group, 1.7±0.8 in solifenacin group and 0.5±0.7 in combination group (tamsulosin+solifenacin) and statistically significant (P=0.001).

When the overall mean USSQ score among three groups was compared, study showed improvement from baseline to fourth visit in all groups but Group-C patients demonstrated much better improvement than Group-A and Group-B patients. The total mean USSQ score at baseline in Group-A, Group-B and Group-C was 34.14±7.617, 39.71±4.724 and 36.57±8.405 while at fourth visit was 22.57±4.276, 30.14±4.867 and 11.14±2.186, respectively. The findings of a study performed by Sajid et al[21] also confirmed that combination therapy showed better improvement than tamsulosin and solifenacin alone. After treatment the mean score among patients treated with solifenacin alone was 9.20±2.67 while among patients treated with combination therapy B (solifenacin+tamsulosin) was 7.88±2.63. Another study conducted by Abdelaal et al17 reported highly significant lower ureteral stent symptom questionnaire (USSQ) score in combination group (tamsulosin+solifenacin) than tamsulosin or solifenacin alone. The findings of study highlighted that after treatment the total mean score was 22.9±2.4 in tamsulosin group, 22.0±2.8 in solifenacin group and 16.6±2.4 in combination group (tamsulosin+solifenacin). The p-value for comparison of total mean score of USSQ between groups was found statistically significant (P=0.001).

CONCLUSION

The stent-related urinary symptoms and pain negatively affect the general condition and life quality of patients. The combination therapy with tamsulosin plus solifenacin is more effective than monotherapy with tamsulosin or solifenacin alone for JJ stent related urinary symptoms.

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