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Original Research Article

A clinical study of effects of tamsulosin in ureteric stent related morbidity

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ABSTRACT

Background: Most of the Ureteric surgery involves DJ stent Insertion to prevent post operative ureter related morbidity of the patients. This study aims towards the role of tamsulosin in relieving DJ stent related symptoms.
Methods: Prospective study conducted between June 2018 to October 2020 in 58 patients randomised by random-number chart into two groups, group A (Non tamsulosin) group B (Tamsulosin). The international prostate symptom score (IPSS) questionnaire and quality of life (QoL) was assessed on admission as a baseline before patient underwent the surgery and reassessed when the patient came for stent removal.
Results: The mean age of patients in group A (non-tamsulosin) was 39.38 years with range of 20 to 60 years. The mean age of patients in group B (tamsulosin) was 38.55 with range of 20 to 68 years. In group A consisted of 16 men and 13 women whereas group B had 13 men and 16 women. On comparing non tamsulosin and tamsulosin group, patients in which stent is removed at or <28 post operative day, mean IPSS+QoL component of questionnaire score is 14.1 (SD 3.8) and 11.8 (SD 4.1) respectively. While on comparing non tamsulosin and tamsulosin group, patients in which stent removed after 28th post operative day, mean IPSS+QoL component of questionnaire score is 18.9 (SD 1.0) and 6.4 (SD 1.1) respectively.
Conclusions: Oral administration of tablet Tamsulosin 0.4 mg once a daily before sleep at night improves DJ stent related morbid symptoms.

Keywords: DJ stent, Tamsulosin, Cystoureteroscopy, Ureteric stent

INTRODUCTION

Urolithiasis is a very common problem and with the advent of technology every passing day has seen innovations that has lead to better stone clearance in every individual patient. With better access, visualisation and stone fragmenting techniques, endourological procedures have become a mainstay in treatment of stone diseases.

Since the time Young had attempted his first cystoscopy, efforts were always being made to access the urinary tract efficiently and with lesser morbidity as possible.[12]

Despite the vast evidence supporting non stented ureteroscopies[1], worldwide many urologists still prefer to place stents in majority of uncomplicated stone removal procedures in a bid to improve drainage, stone clearance and clear residual fragments and avoid ureteric stricture. As with advances with time ureteric stents have undergone dynamic evolution in a constant search for the ideal design and material and in a bid to surpass or in the least reduce the symptoms associated with it.

Ureteric stents are associated with a wide spectrum of symptoms thereby producing considerable morbidity ranging from 80 to 98% and the discomfort caused varies from patient to patient.[1,2]

The symptoms produced by the stent are predominantly irritative in nature and seems to produce significant bother so as to affect the QoL of the patient, warranting removal in some cases.[2,6]

Alpha adrenergic receptor like α1A and α1D have been documented to be distributed the in the lower urinary tract and the distal ureter and the use of alpha adrenergic receptor blockers like Tamsulosin have shown considerable promise in treating the stent related symptoms.[7-9]

This study, was done in an effort to determine the effect of tamsulosin in improving double-J stent related symptoms and QoL following ureteral stent placement.

Aim of the study is to evaluate the role of Tamsulosin in reliving D J stent related symptoms.

Objective is to evaluate the efficacy of tamsulosin in improving stent related symptoms and QoL in patients with double-J (DJ) Ureteric stents.

METHODS

This was a prospective study conducted among indoor patients of general surgery department of SMIMER, Surat between June 2018 to October 2020 (1.5 year) who are willing to give consent for the study and fall into inclusion criteria.

Sample size calculated considering the proportion of admitted patients in surgical department who are planned for cystoureteroscopy and DJ stenting.

This study was approved by Institutional ethical committee of SMIMER.

Inclusion criteria

All patients of age between 18 to 80 years were included in the study.

Exclusion criteria

Patients less than 18 years of age, pregnant women and patient who refuse to give consent for study.

History was collected and thorough physical examination done. Data collection included age, sex, address, and clinical presentation with respect to abdominal pain, burning micturition, fever, frequency, urgency, insufficient emptying, straining, history of previous episodes and comorbidity were noted.

Routine investigation like complete haemogram, blood urea, serum creatine and urine routine micro were performed. X ray KUB, USG abdomen and pelvis was done routinely to confirm the diagnosis. CT urography was performed as and when required.

Based on this data, diagnosis was made and planned for cystoureteroscopy and DJ stenting. Anaesthetist fitness was obtained for surgery accordingly. A written consent for surgery was obtained from the patient after clearly explaining about the procedure and the implications. Indication for stent placement in each case was noted. Patients are given a questionnaire to assess the baseline symptoms using the IPSS questionnaire along with the QoL component of the chart. Scoring is done after adequately explaining about each component of the chart.

Under spinal anesthesia, patient was placed in the lithotomy position. After painting and draping cystoscopy was done using 30 degree scope. The entire urethra assessed and bladder visualised for any associated pathology. Both ureteric orifices were visualised and 0.032 inch guide wire passed into the ureter which required stenting. Then the cystoscope was removed and 8 Fr infant feeding tube was passed into the bladder. Ureteroscope was passed into the ureter under normal saline irrigation and passed proximally up into the ureter.

In case of ureteric stone, using pneumatic lithotripter stone is fragmented completely. Following this, patients underwent DJ stenting. Post-operatively patients were explained about the presence of DJ stent, and the need to come for stent removal after required duration.

A post-operative imaging is done to confirm the position of the stent. Then the patients are discharged on the $2^{nd}/3^{rd}$ post operative day if there is no significant event and was prescribed medicines as per the group they are allotted to based on the Random number chart.

A clinical randomised comparative prospective observational study-Group A comprised of patients who did not received Tab. tamsulosin 0.4 mg till removal of DJ stent and group B comprised of patients who received Tab. tamsulosin 0.4 mg once daily till removal of DJ stent.

The IPSS questionnaire[3,4] was used to assess patients symptoms on admission as a baseline before patient underwent the surgery and again reassessed when the patient came for stent removal.

QoL was assessed on admission as a baseline before patient under went the surgery and again reassessed when the patient came for stent removal using the QoL section of the IPSS questionnaire.

Statistical day analysed using data were analysed using $\chi 2$ test, Student's t test, independent sample T test and paired sample T test.

RESULTS

This was a prospective study was conducted among indoor patients admitted between June 2018 to October 2020 (1.5 year) in surgical department of SMIMER who

underwent cystoureteroscopy with DJ scenting and gave consent for the study.

Table 1: Demographic data.

Variables	Non tamsulosin (Group A)	Tamsulosin (Group B)
Age group (years)		
20-29	9	9
30-39	7	7
40-49	6	6
50-59	5	4
60-69	2	3
Grand total	29	29
Gender		
Male	13	16
Female	16	13

The 58 patients were prospectively randomised by random-number chart into two groups.

The mean age of patients in group A (non tamsulosin) and was 39.38 years with an age range of 20 years to 60 years.

The mean age of patients in group B (tamsulosin) was 38.55 with an age range of 20 years to 68 years.

In group A consisted of 16 men and 13 women. Group B had 13 men and 16 women.

Group A comprised of patients who did not received tablet tamsulosin 0.4 mg till removal of DJ stent. Group B comprised of patients who received tablet tamsulosin 0.4 mg once daily till removal of DJ stent.

On comparing both the groups A and B based on the symptom scores assessed at baseline the following observations were made. The mean IPSS score of group A was 9.17 (SD 1.53) and in group B the mean IPSS score is 9.38 (SD 1.39). The P value of the above mean compared between these two groups were 0.5865 for IPSS score, indicating that there was not much difference between the two groups.

The mean of QoL scores were 2.1 (SD 0.86) and 2.21 (SD 0.86) for group A and B respectively. Again they indicate that there was No difference in symptoms between the two groups.

The mean of TOTAL IPSS + QoL Questionnaire score of both groups A and B is 11.28 (SD 1.6) and 11.62 (SD 1.59) respectively.

So, the chosen sample population in both the groups were the same at baseline since the difference between them were not statistically significant.

On comparing both the groups A and B based on the symptom scores assessed at stent removal the following observations were made.

The mean IPSS score of group A was 14.41 (SD 3.34) in group B the mean of IPSS score is 7.69 (SD 3.8). The P value of the means compared between these two groups were all <0.001 indicating, that the difference between these two groups based on these symptom scores were all statistically significant.

The mean of QoL scores were 2.76 (SD 1.12) and 1.31 (SD 0.7) for group A and B respectively. Again both the above observations indicate that the difference in symptoms between the two groups were statistically significant.

Total IPSS + QoL questionnaire score of both the group A and B are 17.24(SD 3.25) and 8.62(SD 3.8) respectively. Hence it indicates that patients in group B who received tablet tamsulosin 0.4 mg showed lesser quantum of symptoms and benefited as compared to those who did not receive it (group A) and the difference is statistically significant.

In group A at baseline the mean of IPSS score was 9.17 (SD 1.53), the QoL score was 2.1 (SD 0.86) and Total IPSS + QoL questionnaire score 11.28(SD 1.6), but at stent removal the mean scores were 14.41 (SD 3.34) for IPSS, and 2.76 (SD 1.12) for QoL score and Total IPSS + QoL questionnaire score 17.24 (SD 3.25).

These p values of the corresponding means for the variables like IPSS score and QoL scale were statistically significant (<0.05) indicating that the among patients who underwent stenting and did not receive tablet tamsulosin 0.4 mg the symptom scores compared to baseline had worsened.

In group B at baseline the mean of IPSS score was 9.38 (SD 1.39), the QoL score was 2.21 (SD 0.86) and total IPSS + QoL questionnaire score 11.62 (SD 1.59), but at stent removal the mean of these scores were 7.69 (SD 3.77) for IPSS and 1.31 (SD 0.66) for QoL score and Total IPSS + QoL questionnaire score 8.62 (SD 3.84)

The p values of the corresponding means for the variables like IPSS score, QoL scale were all statistically significant (<0.05) indicating that among patients who underwent stenting and received tablet Tamsulosin 0.4 mg the symptom scores at baseline did not show worsening of symptoms after stenting and also showed considerable improvement in symptom scores over the baseline.

In this study we have compared use of tamsulosin and its effects on IPSS score compared with number of days for removal of DJ stent.

As shown in table in non tamsulosin group there are 10 cases out of 29 cases in whom DJ stent is removed earlier than or at 28th post operative day and 19 cases in whom DJ stent is removed after 28th post operative day. Mean of

both is 14.1 (SD 3.8) and 18.9 (SD 1.0) respectively.

In Tamsulosin group there are 12 cases out of 29 cases in whom DJ stent is removed earlier than or at 28th post operative day and 17 cases out of 29 in whom DJ stent is removed after 28th post operative day. Mean of both is 11.8(SD 4.1) and 6.4 (SD 1.1) respectively.

Thus, this indicates that as the days of removal of DJ stent increases in non tamsulosin group there is increase in mean IPSS+QoL component of questionnaire score, suggestive of worsening of stent related symptoms.

While for Tamsulosin group as the days of removal of DJ stent increases there is decrease in mean IPSS+QoL component of questionnaire score, suggestive of improvement of stent related symptoms.

On comparing both non Tamsulosin and tamsulosin group, the group of patients in which stent is removed at or less than 28 post operative day, Mean IPSS+QoL component of questionnaire score is 14.1 (SD 3.8) and 11.8 (SD 4.1) respectively.

While on comparing both non Tamsulosin and tamsulosin group, in group of patients in which stent removed after 28th post operative day, mean IPSS+QoL component of questionnaire score is 18.9 (SD 1.0) and 6.4 (SD 1.1) respectively.

Thus, this indicates that, group of patients in which stent is removed at or less than 28 post operative day there is reduction in mean IPSS+QoL component of questionnaire score in tamsulosin group than non tamsulosin group and in group of patients in which stent is removed after 28th post operative day there is significant reduction in mean IPSS+QoL component of questionnaire score in tamsulosin group compared to non tamsulosin group.

This is suggestive that tamsulosin is not only beneficial in stent related morbidity but it is also more effective if given for longer duration.

No any significant adverse effects of the drug reported in our study.

DISCUSSION

In various studies there is comparison between base line IPSS score and comparison of IPSS score post stent removal in non tamsulosin and tamsulosin group.

In our study, in non tamsulosin group there is increase in IPSS score (17.24) as compared with base line IPSS (11.28), while in tamsulosin group, there is decrease in IPSS score (8.62) as compared with base line IPSS (11.28)

The study by Pitchaibalashanmugham Karrupaiah et al in non tamsulosin group there is increase in IPSS score (16.8) as compared with base line IPSS (10.57), while in tamsulosin group, there is decrease in IPSS score (7.2) as compared with base line IPSS (10.57).[10]

Study by Rehman et al in non tamsulosin group there is increase in IPSS score (5.28) as compared with base line IPSS (2.47), while tamsulosin group, there is decrease in IPSS score (2.22) compared with base line IPSS (2.47).[9]

The findings of other study are similar to our study.

So, there is no significant difference in both non tamsulosin and tamsulosin group at base line (Pre DJ stenting), in both our study and study done by Karrupaiah et al.[10]

In comparing both study groups (Non tamsulosin and tamsulosin), total IPSS+QoL. Questionnaire score is high in non tamsulosin group and low in tamsulosin group. Similar results are found in our study and study done by Karrupaiah et al.[10] This comparison of IPSS score in non tamsulosin group pre-DJ stenting and post DJ stent removal suggest that, pre DJ stenting IPSS score is less and post DJ stent removal score increases and difference is significant. These results are same in both studies, i.e. Our study and study done by Karrupaiah et al.[10]

Table 2: Comparison of both group pre DJ stenting.

Comparison of both group pre-DJ stenting	Non tamsulisin, group A		Tamsulisin, group B		P value
	Mean	SD	Mean	SD	
Total IPSS score	9.17	1.53	9.38	1.39	0.5865
QoL	2.1	0.86	2.21	0.86	0.6281
Total IPSS+ QoL questionnaire score	11.28	1.6	11.62	1.59	0.4204

Table 3: Comparison of both groups post stent removal.

Comparison of both group post DJ stent removal	Non-tamsulisin, group A		Tamsulisin, group B		P value
	Mean	SD	Mean	SD	
Total IPSS score	14.41	3.34	7.69	3.8	<0.0000001
QoL	2.76	1.12	1.31	0.7	0.000000148
Total IPSS + QoL questionnaire score	17.24	3.25	8.62	3.8	<0.0000001

Table 4: Comparison within the groups.

Comparison within non tamsulosin group	Pre DJ stenting		Post DJ stent removal		P value
	Mean	SD	Mean	SD	
Total IPSS score	9.17	1.53	14.41	3.34	<0.0000001
QoL	2.1	0.86	2.76	1.12	0.01473
Total IPSS + QoL questionnaire score	11.28	1.6	17.24	3.25	<0.0000001

Table 5: Comparison within tamsulosin group.

Comparison within tamsulosin group	Pre DJ stenting		Post DJ stent removal		P value
	Mean	SD	Mean	SD	
Total IPSS score	9.38	1.39	7.69	3.77	0.0274
QoL	2.21	0.86	1.31	0.66	0.00003849
Total IPSS + QoL questionnaire score	11.62	1.59	8.62	3.84	0.000268

Table 6: Comparison of effects of non tamsulosin vs tamsulosin on days of removal of DJ stent.

Stent removal day	Non tamsulosin			Tamsulosin		
	N	Mean	SD	N	Mean	SD
≤ 28 days	10	14.1	3.8	12	11.8	4.1
>28 days	19	18.9	1.0	17	6.4	1.1
Grand total	29	17.2	3.3	29	8.6	3.8

Table 7: Comparison of both group pre DJ stenting.

Comparison of both group pre DJ stenting	Non tamsulisin		Tamsulisin		P value
	Mean	SD	Mean	SD	
In our study					
Total IPSS score	9.17	1.53	9.38	1.39	0.5865
QoL	2.1	0.86	2.21	0.86	0.6281
Total IPSS + QoL questionnaire score	11.28	1.6	11.62	1.59	0.4204
Karrupaiah et al[10]					
Total IPSS score	7.68	2.18	7.91	1.77	0.431
QoL	2.89	0.68	3.06	0.61	0.084
Total IPSS + QoL questionnaire score	10.57	2.86	10.97	2.38	0.478

Table 8: Comparison of both group post DJ stent removal.

Comparison of both group post DJ stent removal	Non tamsulisin		Tamsulisin		P value
	Mean	SD	Mean	SD	
In our study					
Total IPSS score	14.41	3.34	7.69	3.77	<0.0000001
QoL	2.76	1.12	1.31	0.66	0.000000148
Total IPSS + QoL questionnaire score	17.24	3.25	8.62	3.84	<0.0000001
Karrupaiah et al[10]					
Total IPSS score	13.37	2.13	5.12	0.67	<0.001
QoL	3.43	0.81	2.08	0.74	<0.001
Total IPSS + QoL questionnaire score	16.8	2.94	7.2	1.41	<0.001

Table 9: Comparison within non tamsulosin group.

Comparison within non tamsulosin group	Pre DJ stenting		Post DJ stent removal		P value
	Mean	SD	Mean	SD	
In our study					
Total IPSS score	9.17	1.53	14.41	3.34	<0.0000001
QoL	2.1	0.86	2.76	1.12	0.01473
Total IPSS + QoL questionnaire score	11.28	1.6	17.24	3.25	<0.0000001
Karrupaiah et al[10]					
Total IPSS score	7.68	2.18	13.37	2.13	<0.001
QoL	2.89	0.68	3.43	0.81	<0.001

Table 10: Comparison within tamsulosin group.

Comparison within tamsulosin group	Pre DJ stenting		Post DJ stent removal		P value
	Mean	SD	Mean	SD	
In our study					
Total IPSS score	9.38	1.39	7.69	3.77	0.0274
QoL	2.21	0.86	1.31	0.66	0.00003849
Total IPSS + QoL questionnaire score	11.62	1.59	8.62	3.84	0.000268
Karrupaiah et al[10]					
Total IPSS score	7.91	1.17	5.12	0.67	<0.001
QoL	3.06	0.61	2.07	0.74	<0.001
Total IPSS + QoL questionnaire score	10.97	1.78	7.19	1.41	<0.001

This comparison of IPSS score in tamsulosin group pre DJ stenting and post DJ stent removal suggest that, pre DJ stenting the IPSS score is more and post DJ stent removal the score decreases, and the difference is significant. These results are same in both studies, i.e. Our study and study done by Karrupaiah et al.[10]

Comparison of days of removal of DJ stent on IPSS score in both non tamsulosin and tamsulosin group.

In our study, as the days of stent removal increases, in non tamsulosin group there is increase in IPSS score while in Tamsulosin group there is decrease in IPSS score, thus it is suggestive that if tamsulosin given for more longer duration its effects are more beneficial.

While comparing IPSS score for stent removal at or less than 28 days study group, for non tamsulosin and tamsulosin group, the IPSS score is less (11.8) in tamsulosin group as compared to Non Tamsulosin group (14.1). It is suggestive that Tamsulosin is beneficial.

While comparing IPSS score for stent removal more than 28 days study group, for non tamsulosin and tamsulosin group, the IPSS score is significantly less in tamsulosin group (6.4) as compared to non tamsulosin group (18.9). It is suggestive that Tamsulosin is more beneficial if given for longer duration.

While comparing IPSS score in non tamsulosin group there is increase in IPSS score as the days of DJ stent removal increases, this shows that as the duration of removal of DJ stent prolongs there is worsening of stent related morbid symptoms.

While comparing IPSS score in tamsulosin group there is decrease in IPSS score as the days of DJ stent removal increases, this shows that as the duration of removal of DJ stent prolongs there is improvement of stent related morbid symptoms.

In study done by Navanimitkul et al there is comparison between IPSS score of both, non tamsulosin group and Tamsulosin group at 2 week and 4 week post DJ.[11]

Stenting, at 2 weeks post DJ stenting there is decrease in IPSS score of tamsulosin group (5.81) as compared to non tamsulosin group (7.81). While at 4 weeks post DJ stenting there is more decrease in IPSS score of Tamsulosin group (3.38) as compared to IPSS score in non tamsulosin group (8.19).

While in non tamsulosin group there is increase in IPSS score at 4 weeks post DJ stenting as compared to 2 weeks post DJ stenting IPSS score.

In tamsulosin group, there is significant decrease in IPSS score at 4 weeks post DJ stenting as compared to 2 weeks post DJ stenting.

This shows that as exposure to tamsulosin increases there is significant decrease in DJ stent related morbid symptoms.

These findings are same as compared with our study.

Limitations

As the sample size (number of patients) in our study is less. so, there is no accurate evidence regarding efficacy of the drug(tamsulosin). To evaluate evidence-based efficacy of the drug(tamsulosin), further studies needed having larger sample size.

CONCLUSION

Definitely, patients those of whom are prescribed α adrenergic receptor blockers like tamsulosin following stenting, seem to benefit significantly because not only did they experience much lesser symptoms, but they also improved over their symptoms with which they presented at admission.

From our study we can conclude that oral administration of tablet Tamsulosin 0.4 mg once a daily before sleep at night improves DJ stent related morbid symptoms.

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