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Original Research Article

Role of tamsulosin a selective alpha 1a-1d blocker vs. combination therapy of tamsulosin and solifenacin M3 antagonist in DJ stent related morbidity: obstructive and irritative scores

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ABSTRACT

Background: nowadays Urolithiasis is very common in general population. Due to the advent of newer lithotripsy techniques, endoscopic procedures are used in most of the cases and to promote stone clearance DJ stents are kept after all the endoscopic procedures.
Methods: This is a prospective study conducted among indoor patients from January 2021 to May 2022 in 90 indoor patients of tertiary care hospital.
Results: In our study go 90 patients, pre DJ insertion, IPSS score in group A was 10.22 and Group B was 9.64, Mean Quality of Life in Group A was 1.77 and group B was 1.37, Visual analogue scale in group A was 2.08 and group B was 2.24. On Day 1 Post DJ insertion, IPSS score in group A was 12.26 and Group B was 11.68, Mean Quality of Life in Group A was 1.44 and group B was 1.28, Visual analogue scale in group A was 2.55 and group B was 2.28.
Conclusions: Use of combination of selective alpha 1a-1d blocker and M3 antagonist significantly reduces the DJ stent related morbidity after endoscopic treatment for urolithiasis.

Keywords: DJ stent, Tamsulosin, Solifenacin

INTRODUCTION

As urolithiasis is a very common problem, it is a great challenge to invent a newer instrument to tackle the burden of all the varieties of the stone. Since the first cystoscope attempted by Young all the efforts were being made to access the whole urinary tract efficiently and with minimal iatrogenic damage.[1] All the newer inventions like semirigid and flexible ureteroscopes were an extensions of the basic available technology at the point of time like fibre optics and rod lens system.[2,3] Though the majority of evidence supports ureteroscopies without stunting, many urologist from all over the world still prefer to put stent in majority of stone removal surgeries to improve post operative drainage, avoid ureteric stricture and get rid of residual fragments. Ureteric stents can produce a wide range of symptoms that can lead to significant morbidity ranging from 80-98% and which can vary from patient to patient.[4,5] The symptoms produced by the stent are predominantly irritative in nature and seems to produce significant bother so as to affect the quality of life of the patient, warranting removal in some cases.[5,6] Reflux of urine into the upper tract is inevitable with a patent stent in position and around 80% of patients were observed to have reflux during voiding stage and this produces flank pain.[5,6] Alpha adrenergic receptor like α lA and α lD 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] Stent-related symptoms are similar to overactive bladder symptoms (urinary frequency, urgency,

and urge incontinence) caused by involuntary bladder contraction mediated by muscarinic receptors. Antimuscarinic agents have been used to improve overactive bladder symptoms. Hence this study, was done in an effort to determine the effect of Tamsulosin Vs tamsulosin and solifenacin combination therapy in improving double-J stent related symptoms and quality of life following ureteral stent placement.[10] Aim of our study is to evaluate role of single drug therapy and combination drug therapy in DJ stent related Lower urinary tract symptoms.

METHODS

This is a prospective study conducted among indoor patients from January 2021 to May 2022 at Department of General Surgery, SMIMER, Surat. Sample size calculated considering the proportion of admitted patients in surgical department who are planned for Ureteroscopic DJ stenting. A total of 90 patients were enrolled in this study after following the inclusion and exclusion criteria.

Inclusion criteria

Patient of either sex, age more than 18 years, with consent, who underwent DJ stent insertion for urolithiasis by either open or endoscopic procedure with stone <15mm size were included.

Exclusion criteria

Exclusion criteria for current study were; Bilateral ureteral stents, Patient who had LUTS before stenting, Patients who develop hypersensitivity/drug reaction, Pregnant women, Patient refusing to give consent for study, Patients who were previously diagnosed with benign prostatic hyperplasia or overactive bladder and who were already prescribed a selective alpha-1-blocker or antimuscarinic agent, Diabetic patient, Patient having active infection and Residual stones. History was collected and thorough physical examination done. Data collection included age, sex, address, and clinical presentation with respect to abdominal pain, burning micturation, fever, frequency, urgency, insufficient emptying, straining, history of previous episodes and co-morboidites were noted.

Routine investigation like complete haemogram, blood urea, serum creatine and urine routine micro and culture sensitivity 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 Surgery and DJ stenting. Pre operative 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 quality of life component of the chart. Scoring is done after adequately explaining about each component of the chart. 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 2nd and /3rd post operative day if there is no significant event and are prescribed medicines as per the group they are allotted to based on the random number chart. Patients were divided into two groups: Group A comprised of patients who receive Tab Tamsulosin 0.4mg once daily and Group B comprised of patients who receive Tab tamsulosin 0.4 mg and solifenacin 5 mg daily. Every patients in both groups were given 100 ml of tramadol on demand for post operative management of pain unless contraindicated during their hospital stay. The international prostate symptom score questionnaire was used to assess patients. Patients will be evaluated the day before surgery, on postoperative day 1, day 3 and at the day of stent removal. Each patient will complete written International Prostate Symptom Score/quality of life (IPSS/QoL) and visual analogue pain scale (VAPS) Questionnaires. The IPSS questionnaire consists of 7 questions, four relating to voiding(obstructive) and three to storage (irritative) symptoms, each will be compared Responses were grade on a five-point rating scale. The maximum scores for voiding and storage symptoms are 20 and 15, respectively; the higher the score, the worse are the symptoms. Data were analysed using independent T test.

RESULTS

prospective study conducted among indoor patients from January 2021 to May 2022 In 90 indoor patients of SMIMER.

Demographic data

The mean age of patients in group A (single drug) was 38.02±8.54 years with an age range of 20 to 60 years. In group B (combination therapy) was 39.64±9.64 years with an age range of 20 to 60 years. P value for age group is 0.4, which is statistically not significant. Group A consisted of 21 women and 24 men while Group B consisted of 23 women and 22 men. On comparing both the groups, the mean of total IPSS score of group A 10.22±1.91 and in group B the mean of total IPSS score is 9.64±1.92. The p value of the above mean compared between these two groups were 0.152 which is not statistically significant. The mean of quality of life scores were 1.77±0.99 In group A and 1.37±0.93 in group B respectively. p value for this was 0.05, which is not statistically significant. The mean of visual analogue pain score of both groups A and B is 2.08±0.76 and 2.24±0.80 respectively. p value is 0.34 which is not statistically significant. So, the chosen sample population in both the groups were the same at baseline, since the difference between them were not statistically significant.

Table 1: Age and sex distribution.

Group	Mean age (years)	SD
A	38.02	8.54
B	39.64	9.64

The mean of total IPSS score of group A was 12.26±2.21 and group B was 11.68±1.89. The p value for this was 0.188, which is not statistically significant. The mean of quality of life scores were 1.44±0.84 In group A and 1.28±0.50 in group B respectively .p value for this was 0.29, which is not statistically significant. The mean of visual analogue pain score of both groups A and B is 2.55±0.84 and 2.28±0.54 respectively, p value is 0.07 which is not statistically significant. The mean of total IPSS score of group A was 11.95±2.36 and group B was 10.37±2.04. The p value of the means compared between these groups were 0.001 which is statistically significant. The mean of quality of life scores were 1.22±0.59.

Table 2: Comparisons of IPSS/QoL and VAP score in group A and B: before stenting.

Parameters	Group A		Group B		P value
	Mean	SD	Mean	SD	
Quality of life	1.77	0.99	1.37	0.93	0.053
Visual analogue pain score	2.08	0.76	2.24	0.80	0.34
Obstructive subscore	3.91	1.18	3.53	1.01	0.10
Irritative subscore	4.53	1.19	4.73	1.33	0.45
Total IPSS score	10.22	1.91	9.64	1.92	0.152

Table 3: Comparisons of IPSS/QoL and VAP score in group A and B post DJ stenting: day 1.

Parameters	Group A		Group A		P value
	Mean	SD	Mean	SD	
Quality of life	1.44	0.84	1.28	0.50	0.29
Visual analogue pain score	2.55	0.84	2.28	0.54	0.07
Irritative subscore	6.06	1.67	5.62	1.19	0.14
Obstructive subscore	4.75	1.70	4.777	1.12	0.94
Total IPSS score	12.26	2.21	11.68	1.89	0.18

In group A and 1.75±0.77 in group B respectively, p value for this was 0.004, which is statistically significant. The mean of visual analogue pain score of both groups A and B is 2.46±1.0 and 2.37±1.07 respectively p value is 0.69 which is not statistically significant. The mean of total IPSS score of group A was 11.4±2.55 and in group B was 8.84±2.54, the p value of the means compared between these two groups were <0.001 indicating that the difference between these two groups based on these symptom scores were all statistically significant.

Table 4: Comparisons of IPSS/QoL and VAP score in group A and B post DJ stenting: day 3.

Parameters	Group A		Group A		P value
	Mean	SD	Mean	SD	
Quality of life	1.22	0.59	1.75	0.77	0.004
Visual analogue pain score	2.46	1.0	2.37	1.07	0.69
Obstructive subscore	4.93	1.43	4.242	1.43	0.02
Irritative subscore	5.8	1.98	4.37	1.38	0.002
Total IPSS score	1.22	0.59	1.75	0.77	0.004

Table 5: Comparisons of IPSS/QoL and VAPS score in group A and B on stent removal day.

Parameters	Group A		Group A		P value
	Mean	SD	Mean	SD	
Quality of life	1.46	0.66	2.51	1.05	<0.001
Visual analogue pain score	2.15	1.02	1.84	2.97	0.14
Obstructive subscore	4.55	1.357	3.35	1.40	0.0001
Irritative subscore	5.377	1.88	2.97	1.43	<0.001
Total IPSS score	11.4	2.55	8.84	2.54	<0.001

Table 6: Mean hospital stay (days) in both the groups.

Group	Mean	SD
A	3.95	1.52
B	3.97	1.35

Table 7: Stent removal days in both the groups.

Group	Mean	SD
A	33.88	9.66
B	34.42	8.48

Hence it indicates that patients in group B (combination) showed lesser quantum of symptoms and benefited as compared to those who received only tamsulosin. The mean of quality of life scores were 1.46±0.66 in group A and 2.518±1.05 in group B respectively, p value for this was <0.001, which is statistically significant. The mean of visual analogue pain score of both groups A and B is 2.15±1.02 and 1.84±2.97 respectively. p value is 0.14 which is statistically not significant. On comparing both the groups, mean of hospital stay in group A was 3.95±1.52 while in group B was 3.97±1.35 and p value was

0.94 which is statistically not significant. Mean of stent removal day in group A was 33.88±9.66 days while in group B was 34.42±8.48 days.

Patients in both group were given 100 ml of tramadol as per demand. So, on day 1 mean of need for analgesia in both A and B were 295.55 and 284.44, p value for this was 0.08, which was statistically insignificant. While on day 3 need for analgesia with single drug mean was 186.66 while in combination group mean was 102.22. P value for this was <0.001, which was statistically significant.

Table 8: Need for analgesia during hospital stay among both groups.

Days	Group A		Group B		P value
	Mean	SD	Mean	SD	
Day 1	295.55	20.84	284.44	36.65	0.08
Day 3	186.66	50.45	102.22	54.30	<0.001

Table 9: Comparison between our study and Lim KT study post DJ stent day 1.

Post DJ stent day 1	Our study		Lim KT et al11	
	Single drug	Combination	Single drug	Combination
Total IPSS	12.26	11.68	12.53	11.47
Obstructive subscore	4.75	4.77	4.74	4.03
Irritative subscore	6.06	5.62	7.7	7.09

Table 10: Comparison between our study and Lim KT study at stent removal.

Post DJ stent day 1	Our study		Lim KT et al11	
	Single drug	Combination	Single drug	Combination
Total IPSS	11.4	8.84	12.77	7.16
Obstructive subscore	4.55	3.35	4.72	2.94
Irritative subscore	5.37	2.97	8.05	4.22

DISCUSSION

In our 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. In our study, Irritative IPSS on day 1 (after DJ stent insertion) in group A (tamsulosin group) was 6.06 and in group B (combination) was 5.62. Irritative IPSS at stent removal day in group A was 5.37 while group B was 2.97.

These were similar to those in a study by Lim et al where tamsulosin group was 7.7 and combination group was 7.09 after stent insertion (day 01).[11] While at stent removal, single drug group was 8.05 while combination drug group was 4.22. Thus, irritative symptoms showed better improvement with combination therapy than mono therapy. In our study, obstructive IPSS on day 1 (after DJ stent insertion) in group A (tamsulosin) was 4.75 and in group B (combination) was 4.77. Obstructive IPSS at stent removal day in group A was 4.55 while group B was 3.35. These were similar to those in a study by Lim et al where tamsulosin group was 4.74, combination group was 4.38 after stent insertion (day 01) while at stent removal single drug group show 4.72 while combination drug group show 2.94, difference was statistically significant at stent removal day.[11] In a study conducted by Anand et al obstructive IPSS at stent removal day in single drug was 1.08 while in combination group was 1.34, similar to our study.[12] There was significant decrease in obstructive scores at stent removal in group B (combination group) than in group A. So obstructive symptoms like weak stream and straining were better tolerated with tab tamsulosin and solifenacin than tab tamsulosin alone. In this study, total mean IPSS on day 1 (after DJ stent insertion) in group A (tamsulosin group) was 12.26 and in group B (combination) was 11.68. Total mean IPSS at stent removal day in group A was 11.4 while group B was 8.84. These were similar to those in a study by Lim et al.[11,] where tamsulosin group was 12.53, combination group was 11.47 after stent insertion (day 01). While at stent removal, single drug group show 12.77 while combination drug group show 7.16**,** which was statistically significant. In another study conducted by Anand et al total mean IPSS at stent removal day in single drug was 3.98 while in combination group was 2.36.[12] There was significant decrease in total mean IPSS scores at stent removal in combination group than single drug group. In this study, on day 1 (after DJ stent insertion) QoL score in group A (tamsulosin group) was 1.44 and in group B (combination) was 1.28. QoL score at stent removal day in group A was 1.46 while group B was 2.51. These were similar to those in a study by Lim et al where tamsulosin group was 2.44, combination 2.34 after stent insertion (day 01) while at stent removal single drug group show 3.07 while combination drug group show 1.07.[11] In a study conducted by Anand et al QoL score at stent removal day in single drug was 0.74 while in combination group was 0.44.[12] There was significant decrease in QoL score at stent removal in combination group than single drug group. So,

the patients QoL improved more in combination drug therapy. In our study, VAPS on day 1 (after DJ stent insertion) in group A (tamsulosin group) was 2.55 and in group B (combination) was 2.28. VAPS at stent removal day in group A was 2.15 while group B was 1.84. There was no significant decrease in VAPS at stent removal in group B (combination group) and in group A. These were similar to those in a study by Lim et al where tamsulosin group was 2.88, combination 2.44 after stent insertion (day 01), while at stent removal single drug group show 3.67 while combination drug group show 2.69.[11] In a study conducted by Anand et al VAPS at stent removal day in single drug was 0.54 while in combination group was 0.24, similar to our study, It was statistically not significant. Our study concluded that, there was improvement in pain in both the groups, but no significant improvement of pain with combination therapy. Hence our study proved there was a statistically significant difference in total IPSS as well as QoL after combination therapy on LUTS complaints in patients with post-DJ stent insertion than in mono therapy. This study shows that there was difference in the form of a decrease in total obstructive & irritative IPSS. This decrease was statistically significant compared to single drug therapy ($p<0.0001$) at stent removal day. The results were consistent with those obtained by Lim et al in which the administration of 5 mg solifenacin along with tamsulosin daily for 2 weeks has decreased total, irritation and obstructive IPSS.

Limitations

Limitations of this study include the fact that it is based on patients recruited from a single setting. our sample size may not be adequate to determine potential confounders.

CONCLUSION

From current study we can conclude that oral administration of tablet tamsulosin 0.4 mg along with tab solifenacin 5 mg once a daily before sleep at night improves DJ stent related morbid symptoms.

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