Original Article

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Effect of Alpha Blocker in Improving Double-J Ureteral Stent - Related Morbidity: A Prospective Randomized Study

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Abstract

Introduction: Ureteral stents are commonly used by urologists for various urological procedures. These stents are often a source of stent-related morbidity such as flank pain, voiding symptoms etc.

Objective: This randomized controlled study was conducted to evaluate the effect of Tamsulosin 0.4 mg in improving stent-related morbidity in patients with Double-j (DJ) stents.

Materials and Methods: The study was conducted from September 2012 to August 2013. A total of 84 patients who underwent DJ stent following ureterorenoscopic removal of stone, were prospectively randomized into two groups of 42 patients. Group I received tamsulosin 0.4 mg once daily orally and Group II received placebo for 2 weeks. All patients received same post-operative antibiotic and analgesics. All patients completed the International Prostate Symptom Score (IPSS) and the Numeric Pain Rating Scale Scores post-operatively.

Results: The IPSS irritative and obstructive symptom scores were significantly lower in Group I than Group II at 1 and 2 weeks. The Numeric Pain Rating Scale Scores were also significantly better in Group I than Group II at 1 and 2 weeks.

Conclusion: Administration of tamsulosin 0.4 mg once daily improved both Stent-related urinary symptoms without causing serious side-effects.

Key words: Double-j stent, International Prostate Symptom Score, Numeric Pain Rating Scale, Tamsulosin

INTRODUCTION

Ureteral stents are very often used by urologists for various urological procedures since the time of their first description by Zimskind *et al.*, in 1967.[1]

Ureteral stenting may be used as an adjunct to pre extracorporeal shockwave lithotripsy, post-percutaneous nephrolithotomy, post-ureterorenoscopic removal of stone, post-endopyelotomy, open/laparoscopic ureteral surgery, ureteric injury and renal transplantation.[2] It is used for managing ureteral obstruction for stones, strictures, tumors, tuberculosis, retroperitoneal fibrosis, hydroureteronephrosis and conservative management of genitourinary fistulas in women.[3]

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However, these stents are often a source of stent related symptoms such as frequency (50-60%), urgency (57-60%), dysuria (40%), incomplete emptying (76%), flank pain (19-32%), suprapubic pain (30%), incontinence and hematuria (25%).[4-10]

The mechanisms leading to the above mentioned symptoms:

Frequency results from mechanical stimulus that comes from the bladder coil. Daytime frequency distinguished by

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the lack of coexisting nocturia suggests that mechanical stimulation relates to physical activities and/or awareness of this stimulation during the day, which would not be significant during the night.[6]

Urgency is thought to be a direct result from the presence of the stent, which may also unmask or exacerbate pre-existing subclinical detrusor overactivity.[6]

Dysuria is usually experienced at the end of voiding. It has been proposed that the dysuria is secondary to trigonal irritation by the distal end of the stent when it crosses the midline or forms an incomplete loop.[10]

Flank pain is most likely a result of urine reflux towards the kidney that leads to an excessive rise in intra-pelvic pressure that ultimately translates into pain.[11,12] It is usually mild to moderate and is not influenced by the position of the proximal coil either in the upper calyx or in the renal pelvis.[13,14]

Suprapubic pain can result from local bladder irritation by the distal coil or as a secondary sign of associated complication such as encrustation or infection.[15]

Hematuria may result from surgical management of existing disease and from the stent placement itself as well.[14]

Incontinence typically occurs in association with episodes of urgency or as a result of stent migration beyond the bladder neck into the proximal urethra bypassing the urethral sphincteric mechanism of continence.[16]

The role of alpha-blockers for treating the symptoms related to Double-j (DJ) ureteric stenting was investigated by Deliveliotis, *et al.*, in 2006, and found alfuzosin 10 mg once daily for 4 weeks caused a decrease in the mean urinary symptom index, frequency of stent-related pain and improvement in the general health score index.[17]

The aim of this study was to evaluate the effect of tamsulosin 0.4 mg once daily in improving stent-related symptoms in patients with DJ stents after ureterorenoscopic lithotripsy. Tamsulosin was used in this study as both tamsulosin and alfuzosin are safe and equally effective in reducing lower urinary tract symptoms.[18,19]

MATERIALS AND METHODS

This study included 84 patients who underwent DJ stent following ureterorenoscopic lithotripsy for lower ureteric stones between September 2012 to August 2013 at Vijayanagar Institute of Medical Science, Bellary. Ethical clearance was taken from Ethical Committee of Vijaynagar Institute of Medical Science, Bellary.

The exclusion criteria were open surgery of ureter, bilateral ureteric stents, pregnancy, long term use of alpha-blocker as in benign prostatic hyperplasia, prostate cancer, history of chronic prostatitis, post-operative residual stone, renal stones and chronic use of analgesics.

All patients were evaluated with a history, physical examination, laboratory tests and radiological investigations such as ultrasonography, intravenous pyelogram or non-contrast computerized tomography scan.

Ureterorenoscopic lithotripsy was performed in all patients using swiss lithoclast and 6/7.5 Fr semirigid ureteroscope with complete removal of stones. All patients were inserted 4.5 Fr/26 cm, DJ ureteric stents made up of biocompatible polyurethane. Stents were removed at 2 weeks.

All patients were informed regarding the potential side-effects of tamsulosin, and all patients signed informed consent.

Patients were randomized into two groups using computer generated random-number table. Group I (n = 42) were given tamsulosin 0.4 mg once daily, and Group II (n = 42) were given a placebo once daily for 2 weeks.

The study was double-blinded by giving tamsulosin and placebo in numbered containers to patients by pharmacist and symptom scores were recorded by junior residents. Finally, data analysis was done by first and second authors.

The International Prostate Symptom Score was used to assess the symptoms at 1 and 2 weeks post-operatively.[16]

The numeric pain rating scale scores were used to assess pain at 1 and 2 weeks post-operatively.[20]

Data were analyzed using SPSS windows version 20.0. $P < 0.05$ was considered as statistically significant.

RESULTS

There was no statistically significant difference between the two groups with respect to age and sex distribution of study patients. Similarly, there was no statistically significant difference with respect to stone size among the patients of two groups (Table 1).

Irritative symptom scores were calculated in both groups at week 1 and week 2 and it was significantly lower in Group I as compared to Group II (week 1, $P < 0.001$; week 2, $P < 0.002$) (Table 2).

Obstructive symptom scores were calculated in both groups at week 1 and week 2 and it was significantly lower

in Group I than Group II (week 1, $P < 0.043$; week 2, $P < 0.048$) (Table 3).

Numeric pain rating scale score were calculated in both groups at week 1 and week 2 and it was significantly lower in Group I than Group II (week 1, $P < 0.00001$; week 2, $P < 0.00001$) (Table 4).

Pain scores using numeric pain rating scale score were calculated in both groups at week 1 and it was significantly lower in Group I than Group II ($P < 0.00001$) (Graph 1).

Table 1: Age, sex and ureteral stone size distribution of patients

	Group I Tamsulosin group	Group II Control group	*P* value
Patient number (*n*)	42	42	
Age (in years) mean range	42 (20-64)	39 (19-59)	0.4994
Gender			0.6465
Male	28	30	
Female	14	12	
Stone size			0.81443
5 mm	3	2	
6 mm	8	6	
7 mm	10	14	
8 mm	9	11	
9 mm	8	6	
10 mm	4	3	

Table 2: Irritative symptom scores

Irritative symptoms	Group I Tamsulosin group *n*=42	Group II Placebo group *n*=42	*P* value
At week 1 (patients)	3 (Mean IPSS=4.33)	17 (Mean IPSS=7.65)	<0.001
At week 2 (patients)	3 (Mean IPSS=3.67)	14 (Mean IPSS=9.14)	0.002

IPSS: International Prostate Symptom Score

Numeric pain rating scale score were calculated in both groups at week 2 and it was significantly lower in Group I than Group II ($P < 0.00001$) (Graph 2).

DISCUSSION

DJ stent is common useful tool in urology. Despite the improvement in design and material, many patients still develop stent related symptoms, sometimes requiring early removal.

It is well known that alpha-adrenergic receptors (α-1a and α-1d receptors) present in the distal ureter, bladder trigone and proximal urethral smooth muscle.[21] Tamsulosin acts as a selective inhibitor of α-1a and α-1d mediated contraction of the distal ureter, trigone, and proximal urethral smooth muscle. Relaxation of these smooth muscles decreases bladder outlet resistance and voiding pressure, thereby decreasing renal reflux and voiding symptoms.[17]

Table 3: Obstructive symptom scores

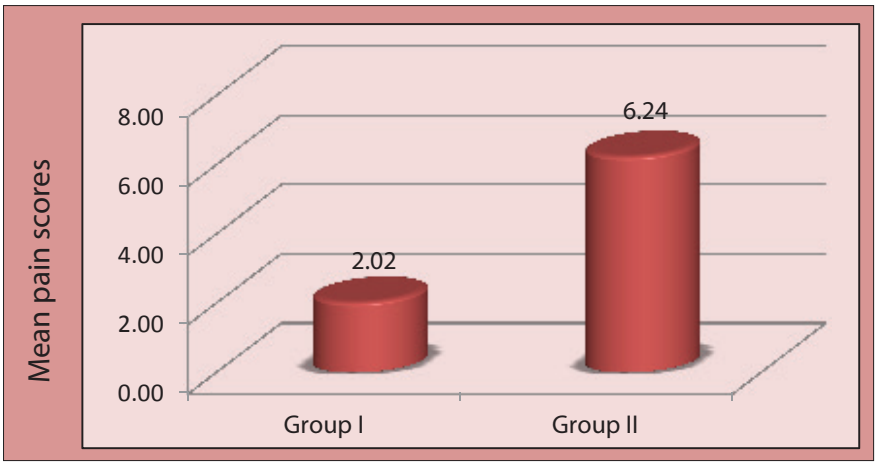
Obstructive symptoms	Group I Tamsulosin group *n*=42	Group II Placebo group *n*=42	*P* value
At week 1 (patients)	2 (Mean IPSS=2.5)	8 (Mean IPSS=4.75)	0.043
At week 2 (patients)	1 (Mean IPSS=2)	6 (Mean IPSS=2.87)	0.048

IPSS: International Prostate Symptom Score

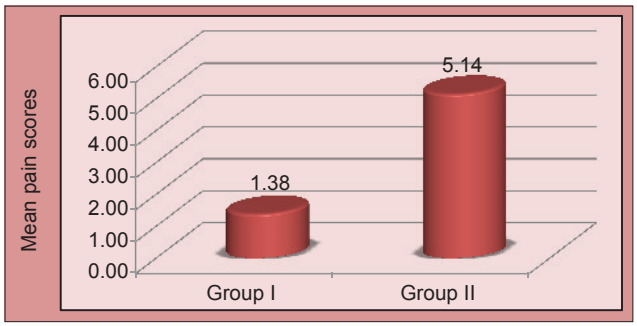
Table 4: Numeric pain rating scale scores

Descriptive statistics	Group I	Group II	*t'* statistic	*P* value
Pain score at week 1				
Mean	2.02	6.24	14.084	<0.00001
SD	1.093	1.605		
Pain score at week 2				
Mean	1.38	5.14	14.552	<0.00001
SD	1.103	1.260		

SD: Standard deviation



Graph 1: Comparison of pain scores at week 1 among the patients of two groups



Graph 2: Comparison of pain scores at week 2 among the patients of two groups

Damiano *et al.,* conducted a prospective randomized study in 75 patients (38 of whom received tamsulosin) comparing the efficacy of tamsulosin 0.4 mg daily versus placebo for stent-related symptoms. The stent-related morbidity was evaluated with Urinary Symptom Score Questionnaire. They reported that tamsulosin had positive effects on stent-related urinary symptoms.[22]

Wang *et al.,* conducted a prospective, randomized study in 79 patients with DJ stents comparing tamsulosin with placebo and found that tamsulosin improved stent-related symptoms and quality of life.[23]

Beddingfield and colleagues, in a prospective, randomized and placebo-controlled study, revealed that alfuzosin lessened the complaints in patients in whom the ureteral stent was used.[24]

In the present study, all patients tolerated the indwelling DJ stent for 2 weeks postoperatively. Irritative and obstructive symptoms at 1 and 2 weeks were lower and bodily pain was better in patients who received tamsulosin compared to the placebo group.

CONCLUSION

Stent-related morbidity is a reality in the majority of patients. Use of selective alpha 1- blocker, such as tamsulosin improves ureteric stent-related urinary symptoms after ureterorenoscopic lithotripsy.

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