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Effect of daily versus twice per day tamsulosin in management of ureteral stent symptoms among patients visiting a tertiary level hospital

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ABSTRACT

Introduction: Currently, tamsulosin 0.4 mg daily is the dosage indicated for lower urinary tract symptoms for patients with an indwelling stent. In treating benign prostatic hyperplasia, a total maximum dose of 0.8 mg tamsulosin is used (either 0.4 mg twice daily or 0.8 mg daily), which has shown increased efficacy compared to the 0.4 mg daily dose without an increase in adverse effects

Objective: To compare the effect of two different dosing regimens (0.4 mg daily vs. 0.4 mg twice per day) of tamsulosin for patient with ureteral stent-related discomfort.

Methodology: A prospective comparative study was conducted in Kathmandu Medical College Teaching Hospital, Kathmandu among 60 patients who had unilateral ureteral stent placed. Patients who have undergone DJ stenting on the odd days of the calendar were advised to take once a day 0.4 mg tamsulosin, and the patients undergoing stenting on the even days of the calendar were advised to take twice a day 0.4 mg tamsulosin who had developed lower urinary tract symptoms (LUTS), with Ureteral Stent Symptom Questionnaire (USSQ) Score >10 on seventh post-operative day. Both the groups were asked to fill USSQ after informed consent at four weeks before stent removal to assess mean change in USSQ score.

Result: It was observed that mean USSQ score was 38.36 ± 16.07 (Range: 12-77) in once-a-day tamsulosin group whereas mean USSQ score was 14.87 ± 8.62 (Range: 3-32) in twice a day tamsulosin group. The USSQ score significantly reduced in patients taking 0.8 mg tamsulosin ($p = 0.001$). The incidence of adverse events like headache, abnormal ejaculation, and orthostatic hypotension was more frequent with tamsulosin 0.8 mg but not significant. Only dizziness was significantly more frequent in twice a day tamsulosin group ($p < 0.001$).

Conclusion: The administration of twice a day tamsulosin improves stent-related urinary symptoms as compared to once daily dosage without much increment in side effects.

Keywords: stent related side effects; ureteral stent symptom questionnaire score; tamsulosin 0.4 mg; tamsulosin 0.8 mg.

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INTRODUCTION

Ureteral stent placement is an increasingly common procedure in urological practice.[1] Tamsulosin is a selective α1A and α1D adrenoceptor antagonist, relaxing smooth muscle in the prostate, bladder neck, and distal ureter. It improves stent-related symptoms and quality of life, and can be applied in routine clinical practice.[2] The Ureteral Stent Symptom Questionnaire (USSQ) was developed in 2003 by Joshi and colleagues to quantify patients' discomfort relating specifically to ureteral

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stents.[3] The USSQ measures several domains relating to stent pain including general health, urinary issues, pain, work performance, sexual matters, and quality of life with stent in situ. The USSQ has been validated and translated and is currently a widely used measure.[4]

While commonly used for treatment of benign prostatic hyperplasia, several studies have evaluated the efficacy of α-blockers for stent pain and have demonstrated a significant improvement in USSQ scores using α-blockers. In treating benign prostatic hyperplasia, a total maximum dose of 0.8 mg tamsulosin is used (either 0.4 mg twice daily or 0.8 mg daily), which has shown increased efficacy compared to the 0.4 mg daily dose without an increase in adverse effects.[5] Currently, tamsulosin 0.4 mg daily is the dosage indicated for lower urinary tract symptoms for patients with an indwelling stent.[6] Very few to date, has evaluated the clinical impact of a higher daily dose of tamsulosin (0.8 mg) on stent-related symptoms. The objective of this study is to assess two different dosing regimens (0.4 mg daily vs. 0.4 mg twice per day) of tamsulosin for ureteral stent-related discomfort.

METHODOLOGY

This was a prospective comparative study conducted at the Department of Urology, Kathmandu Medical College Teaching Hospital (KMCTH), Kathmandu, Nepal over a period of four months (from 2022 December to 2023 March) after taking ethical approval from Institutional Review Committee, KMCTH (Reference number: 04122022/02). As all the patients had their stents placed after stone surgery, sample size calculation was done using prevalence rate of renal stone in Asian population from study by Liu et al.[7] as 1-8%. In this study, prevalence was taken as 4% and the sample size formula, $n = z^2pq/e^2$ was used, where $p = 0.04$, $z = 1.96$ at 95% confidence level, $q = 1-p$ and $e = 0.05$ at five percent margin of error, the sample size calculated was 59. Total 60 patients of age group between 18 years and 70 years with ASA status one and two, who can read and understand English language were enrolled in the study. All patients who had unilateral ureteral stent placed and had developed lower urinary tract symptoms (LUTS) such as frequency, urgency, nocturia, weak stream, intermittency, sense of incomplete bladder emptying, hesitancy, and dysuria, with USSQ Score >10 on seventh post-operative day were included in the study.

The patients who were already taking an alpha-blocker, patients with hypersensitivity or known adverse side effects of tamsulosin, and patients who had medical conditions known to be associated with chronic pain were excluded from the study. Also, women who were pregnant or planning to become pregnant, those who had incomplete clearance of stone, major complications during or after surgery (avulsion or perforation), bilateral stent insertion, concomitant urinary tract infection, overactive bladder syndrome, neurogenic bladder, any history or current treatment for urge/stress mixed incontinence were excluded from study.

To standardise the study, Ureteral stent (five Fr, 26 cm polyurethane Double J stent) was placed in all patients who had undergone rigid ureteroscopy, flexible ureteroscopy or percutaneous nephrolithotomy (PCNL). An X-ray was taken on the first post-operative day to ensure and confirm the stent correct position. All patients were discharged as per routine protocol, on regular painkiller of same group. Post-operatively, on seventh day ureteral stent related symptoms were documented on USSQ and tamsulosin was started if USSQ score was >10. All patients had their stents removed by cystoscopy on the 30th post-operative day. Patients who have undergone DJ stenting on the odd days of the calendar were advised to take once a day 0.4 mg tamsulosin, and the patients undergoing stenting on the even days of the calendar were advised to take twice a day 0.4 mg tamsulosin from seventh post-operative day if USSQ score was >10. Both the groups were asked to fill USSQ after informed consent at four weeks before stent removal to assess mean change in USSQ score. Data were analysed using the statistical package for social sciences, IBM SPSS Statistics for Windows version 27 (IBM Corp., Armonk, N.Y., USA)

RESULT

A total of 60 patients were enrolled and patients completed the study with no one lost to follow-up. Patient demographic data were comparable between the two groups (Table 1).

It was observed that mean USSQ score was 38.36 ± 16.07 (Range: 12-77) in once-a-day tamsulosin group whereas mean USSQ score was 14.87 ± 8.62 (Range: 3-32) in twice a day tamsulosin group. The USSQ score significantly reduced in patients taking 0.8 mg tamsulosin. (p-value 0.001). Also, in male (p-value 0.001) and female (p-value 0.001) patients, mean USSQ score was significantly decreased in patients taking 0.8 mg tamsulosin. The mean global quality of life score with stent in situ was improved in patients taking 0.8 mg tamsulosin but not statistically significant. (p-value 0.696, Table 2).

The incidence of adverse events like headache, abnormal ejaculation, and orthostatic hypotension was more frequent with tamsulosin 0.8 mg but not significant. Only dizziness was significantly more frequent in twice a day tamsulosin group (p-value < 0.001, Table 3).

DISCUSSION

Double-J stents have been commonly used for numerous purposes for more than two decades.[8,9] Literature reported the symptoms related to ureteric stents, including frequency (50-60%), urgency (57-60%), dysuria (40%), incomplete emptying (76%), flank (19-32%) and suprapubic pain (30%), incontinence, and haematuria (25%).[10] Damiano et al. performed a prospective randomised study comparing the efficacy of tamsulosin versus placebo for stent-related symptoms. The stent-related morbidity was evaluated with USSQ QoL questionnaire. The authors reported that tamsulosin had positive effects on stent-related urinary symptoms and QoL.[11] In this study, all patients tolerated the ureteral stents for the four weeks post-operative period. The USSQ scores were significantly lower and the QoL scores were better in patients who received 0.8 mg tamsulosin. In a meta-analysis by Lamb et al. and by Yakoubi et al. there was a substantial decrease in USSQ concerning body pain and urinary symptoms, also reductions in other aspects of the USSQ, such as the general health score and sexual matters score.[12,13] Many studies recommend 0.4 mg tamsulosin for stent related symptoms; however only very few studies have evaluated the clinical impact of a higher daily dose of tamsulosin (0.8 mg) on stent-related symptoms. In current study the USSQ Score was evaluated and score significantly decreased after increasing the dosage of tamsulosin (p -value <0.001). Furthermore, with respect to gender, change in USSQ score showed significant decrease after increasing the dose of tamsulosin to 0.8 mg (p- value <0.0001).

Table 1: Characteristics of patients

Characteristics	Tamsulosin once a day (n = 30)	Tamsulosin twice a day (n = 30)	p-value
Age (years) mean ± SD	35.57 ± 10.73	33.78 ± 13.55	0.27
Gender			
Male	20	22	0.545
Female	10	8	
Indication			
Rigid Ureteroscopy	8	6	0.799
Flexible ureteroscopy	16	17	
PCNL	6	7	

Table 2: Comparison of ureteral stent symptoms questionnaire (USSQ) score among two groups

Symptoms	Once daily tamsulosin (n = 30)	Twice daily tamsulosin (n = 30)	p-value
USSQ score	38.36 ± 16.07	14.87 ± 8.62	0.001*
USSQ score			
Male	42.29 ± 14.91	16.03 ± 8.30	0.001*
Female	31.33 ± 15.88	12.79 ± 8.92	0.001*
Mean global QOL score with stent in situ	4.7	4.2	0.696

p-value <0.05 significant* = independent sample t test

Table 3: Comparison of adverse effects among two groups

Side effect	Once daily tamsulosin (n = 30) n (%)	Twice a day tamsulosin (n = 30) n (%)	p-value
Dizziness	14 (40)	21 (70)	<0.001†
Retrograde ejaculation	15 (50%)	18 (60%)	0.029
Orthostatic hypotension	6 (20%)	9 (30%)	0.227
Headache	15 (50)	21 (70)	0.085

p-value <0.05 significant †= Chi-square test

Overall, Tamsulosin was well tolerated at doses of 0.4 mg and 0.8 mg. Dizziness was clinically significant side effect when the dosage was increased; whereas retrograde ejaculation, headache, and orthostatic hypotension were not significant. This data was similar to study done by Osman et al.[14] None of the side effects required cessation of the medication.

The authors acknowledge the potential limitations of this study. Only a single stent, design, and material were evaluated; however, it has been demonstrated that the degree of stent-related symptoms is not associated with the stent characteristics (composition, style, length) or placement techniques. Another drawback was that in all patients the only indication for stent insertion was after surgery. Also, the authors followed up the patients for only four weeks until they completed the USSQ and terminated medication. Future randomised prospective studies of a larger sample of consecutive patients with a longer follow-up might potentially overcome current study limitations and compare the morbidity of stents with different characteristics and insertion indications.

CONCLUSION

The administration of twice a day tamsulosin improves stent-related urinary symptoms as compared to once daily dosage without much increment in side effects.

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