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Original Article

Efficacy of Tamsulosin in Relieving Double-J Stent-related Symptoms: a Randomized Controlled Study

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Abstract

Introduction: Ureteral stent placement is an increasingly common procedure in urological practice. They are used for both prevention and treatment of ureteral obstruction. Despite improved design and materials, many patients still develop stent-related symptoms which commonly affect quality of life and sometimes necessitate early removal. Tamsulosin improves stent-related symptoms and quality of life. But such study has not been conducted in Nepalese context. In the present study, the effect of Tamsulosin in improving double-J stent-related symptoms and quality of life following ureteral stent placement was studied.

Methods: This study was carried out in the Department of Urology and Kidney Transplant Surgery, Tribhuvan University Teaching Hospital, Kathmandu, Nepal from February 2015 to January 2016. Forty six patients were included in the study and randomized into Tamsulosin (T) group and Control (C) group each having 23 patients. In addition to standard postoperative care, Tamsulosin group received 0.4 mg Tamsulosin daily for 2 weeks and Paracetamol on demand and control group received only Paracetamol (1gram/dose). Stent related symptoms and quality of life was assessed by International prostate symptom score (IPSS) at discharge (day2) and at the time of DJ stent removal (2 weeks). Pain was evaluated by visual analog scale (VAS) and analgesic requirement was documented. Data were analysed using Statistical Package for the Social Sciences (SPSS) 20, chi-square test and Student's t- test was used. A p-value of <0.05 was considered significant.

Results: Mean age in Tamsulosin group was 37.96±12.98 years and Control group 36.43± 10.99 years ($p=0.67$).There was no significant difference in IPSS ($p=0.141$), QoL index ($p=0.089$) and VAS ($p=0.59$) in the two groups at the time of discharge. At the time of DJ stent removal, IPSS ($p<0.001$), QoL index($p<0.001$),VAS($p=0.004$) and analgesic needed($p<0.001$) was significantly lower in T group than in C group.

Conclusion: Tamsulosin lowers stent related symptoms, pain and improves quality of life in patients with indwelling DJ stent though the effect is not immediate.

Key words: DJ stent; IPSS; Tamsulosin; VAS.

Introduction

Ureteral stent placement is an increasingly common procedure in urological practice. Expanding endourological surgery and ESWL have made ureteral stent an integral part of urology.[1]They are used for both prevention and treatment of ureteral obstruction. Despite improved design and materials, many patients still develop stent-related symptoms.[2,3]The degree of complications varies among patients ranging from stent-related symptoms, migration and encrustation, but commonly affect quality of life and sometimes stent related symptoms necessitate early removal.[4-6] Tamsulosin is a selective α1A and α1D-adrenoceptor antagonist, relaxing smooth muscle in the prostate, bladder neck and distal ureter.[7] It improves

stent-related symptoms and quality of life, and can be applied in routine clinical practice.[8,9] But no such study has been conducted in Nepalese context. The objective of this study was to evaluate the effect of Tamsulosin in improving double-J stent-related symptoms and quality of life following ureteral stent placement.

Methods

This RCT was carried out in the Department of Surgery, Tribhuvan University Teaching Hospital, Kathmandu, Nepal from February 2015 to January 2016. After approval from the Institutional Review Board, forty eight patients who underwent double J stenting following percutaneous nephrolithotomy and ureterolithotripsy were included in the study. With the mean outcome in control group at 8.8 and the expected mean outcome in study group at 5.1 and standard deviation of 3.7, the sample size calculated was 24 in each group. (Sample Size[10]: $N = f(\alpha/2, \beta) \times 2 \times \sigma 2 / (\mu 1 - \mu 2)2,$)

After confirming the correct position of the DJ stent with intraoperative fluoroscopy and postoperative KUB (kidney-ureter-bladder) x-ray patients were randomized in Tamsulosin (T) group and Control (C) group each having 23 patients by computer generated random numbers. In addition to standard postoperative care, Tamsulosin group received 0.4mg Tamsulosin with analgesic (Paracetamol) on demand orally for 2 weeks and control group received analgesic (Paracetamol) only (1gram/dose). Stent related symptoms and QoL was assessed by IPSS at discharge and at the time of DJ stent removal. Pain was evaluated by VAS and analgesic requirement was documented.

Data were analysed using SPSS 20, chi-square test and Student's t test was used where appropriate. A p-value of <0.05 was considered significant.

Results

Forty eight patients were included in the study, 24 patients in each arm. One patient from each group was excluded due to various reasons. (Figure 1) Ratio of male and female in T group was 10:13 and 12:11 in C group. Mean age was 37.96 ±12.98 years and 36.43± 10.99 years in T and C group respectively (p=0.67). IPSS at discharge in T was 8.96±4.21 and C 11.00±4.99 (p=0.141). QoL index in each group was 4.35±0.93 and 4.74±0.54 (p=0.089) respectively. VAS in T group was 1.65±0.83 and C group 3.30±0.76 (p=0.59). These results show that baseline characteristics were comparable in two groups and there was no difference in symptom score, QoL index, VAS and analgesic requirements at the time of discharge (Table 1).

At the time of DJ stent removal, IPSS was 4.70±3.89 and 14.74±5.25 (p<0.001),QoL index 2.87±1.14 and 5.43±0.59 (p<0.001) in each group. Similarly VAS was 0.48±0.59 and 2.57±1.23 (p=0.004) in T and C group respectively. Analgesic needed was 13.78±4.91grams in T group and 27.87±7.66 grams (p<0.001) in C group. It indicates all parameters improved significantly in study group compared to control (Table 2).

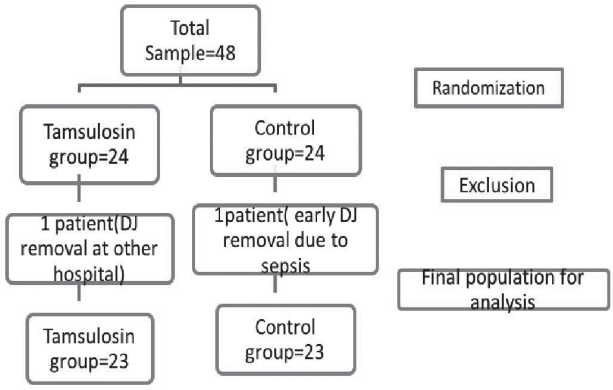

Figure 1: Consort diagram

Table 1: Variables at the time of discharge

Variables @ Discharge	Tamsulosin group	Control group	P-value
IPSS (Mean±SD)	8.96±4.21	11.00±4.99	0.141
QoL (Mean±SD)	4.35±0.93	4.74±0.54	0.089
VAS (Mean±SD)	1.65±0.83	3.30±0.76	0.59

Table 2: Variables at the time of DJ removal

Variables @ DJ removal	Tamsulosin group	Control group	P-value
IPSS (Mean±SD)	4.70±3.89	14.74±5.25	<0.001
QoL (Mean±SD)	2.87±1.14	5.43±0.59	<0.001
Alagesics reqd (Mean±SD)	13.78±4.91	27.87±7.66	<0.001
VAS (Mean±SD)	0.48±0.59	2.57±1.23	0.004

Discussion

The double-J stent is a common tool used in urological surgery.[1] It has been observed that that stent diameter and composition does not affect double-J stent-related symptoms.[11] Stent-related symptoms can be explained by multiple factors such as trigone, ureteral and renal irritation, and pressure between the bladder and renal pelvis.[2,3,11,12] Alfa1D receptors are present in the ureter and that α-blockers relieve double-J stent related symptoms by decreasing ureteral spasm, trigone sensitivity and urine reflux during voiding.[13]

A prospective randomized trial including 146 patients found that Tamsulosin improved stent-related symptoms and quality of life (p=<0.0001).[8] In our study, Tamsulosin improved stent related symptoms and QoL(p=<0.001). A study with 75 patients demonstrated that Tamsulosin 0.4 mg once daily was helpful in improving stent-related urinary symptoms and pain (p=<0.001).[9] Similar was the result in this study where stent-related symptoms and pain improved significantly in Tamsulosin group(p=0.004). A prospective study with 100 patients using alfa blocker (Alfuzosin) proved that it improves stent-related symptoms (p=<0.001) and pain (p=0.027).[13] A prospective randomized controlled trial with 150 participants also proved that α-blockers, reduce stent-related symptoms and the negative impact on quality of life(p=<0.01).[14] Results of both these studies are similar to our study.

Symptoms and pain did not improve significantly at the time of discharge (2nd postoperative day) in our study. This could be due to pharmacokinetics of Tamsulosin which achieves steady-state concentration after 4 day of once daily preparation.[15] No patient developed side effects of Tamsulosin in our study whereas Tamsulosin related side effects developed in 2 of 21(9.52%) patients in study published in 2010 that included 42 patients.[16] This may be due to the fact that they used Tamsulosin for 4 weeks. One patient (2%) developed stent related sepsis requiring early removal in control group, which is less than that observed by Damiano and colleagues who reported incidence of stent related sepsis in 12.3% of the patients.[17]

We do have some limitations in the study. We could use ureteral stent symptoms questionnaire (USSQ) as symptom assessment tool and placebo in control group.

Conclusion

Tamsulosin lowers stent related symptoms, pain and improves quality of life in patients with indwelling DJ stent though the effect is not immediate.

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