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Efficacy of Tamsulosin as Compared to Placebo, in Reducing Post Operative Flank Pain during Voiding, in Patients with Ureteric Stent

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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Original Research Article

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ABSTRACT

Objective: To evaluate the efficacy of tamsulosin in reducing post operative flank pain during voiding, in patients with ureteric stent.
Study Design: This is a Randomized control trial (RCT) study.
Place and Duration: Study carried out at Department of Urology, Jinnah Post Graduate Medical Centre, Hospital, Karachi, Pakistan, from June 2016 to November 2016.
Methodology: 60 patients aged between 15 – 45years, undergone placement of ureteric stent to treat ureteric and renal calculi and have pain score >4, were included in the study. Divided into two groups 'group A' and 'group B'. In group 'A' and group 'B' Tamsulosin and Placebo was given

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respectively in patients with ureteric stent and reduction in post-operative flank pain was measured and compared. Tamsulosin was given post operatively when NPO is broken after 2 hours – 6 hours. Patients having uretral trauma, patients having BPH, patient underwent TURP or TURBT, patent having urinary tract infection and patients with pregnancy or lactating females were excluded. All patients were received intravenous antibiotic (Ceftrixone 1gr). Also all patients were receive oral analgesic (diclofenic sodium 50mg BID) and antispasmodics (Drotaverine 80mg BID). Patients were discharged after 24 hours. Postoperatively stent related flank pain during voiding was assessed via Pain Scale.

Results: 60 Patients who got operated for ureteric stent. In group 'A' there were 21 males (70%) and 9 females (30%), the mean age of group A was 35.67±5.99 as In group 'B' there were of 21 males (70%) and 9 females (30%) and mean age of group B was 35.04±6.42 (Table 1). Mean Pain score in 'Group A' (Tamsulosin) in week 1, 2, 3, 4, 5, 6 was 4.1, 3.5, 2.9, 2.3, 1.9, 1.3 respectively as shown in Table 2. Mean Pain score in 'group B' (Placebo) in week1, 2, 3, 4, 5, 6 was 6.9, 6.3, 5.9, 5.6, 5, 4.2 respectively as shown in Table 2. Average pain score in 'group A' and 'group B' came out to be 2.67 and 5.64 respectively (P value 0.005).

Conclusion: Alpha blockers reduces the post-operative flank pain and voiding complaints in patients with ureteric stent. Our study shows that the efficacy of Tamsulosin in reducing post-operatice flank pain in patients with uretercic stent is better than placebo.

Keywords: Ureteric stent; tamsulosin; flank pain; placebo.

1. INTRODUCTION

Ureteric stents were introduced 4 decades ago by Zimskind et al [1]. Ureteric stent is used in many of the urological procedures including management of renal and ureteric stones[2]. Available literature showed increased morbidities associated with use of ureteric stents particularly flank pain during voiding [3]. Moreover urinary symptoms has been reported in 78% of the patients whereas flank pain during voiding had been reported among 80% of the patients [4,5]. Around 45-80% of the patients with ureteric stent experienced deterioration in quality of life due to above-mentioned symptoms. In spite of various attempts ideal stent could not be developed which could reduce symptoms associated with it [6,7]. Several studies have been conducted to evaluate factors which cause morbidity associated with ureteric stent placement and its treatment. Some have suggested appropriate length and position of stent [8]. In contrast others have evaluated effect of intra-vesical instillation of chemical agents [9]. Some authors postulated that alpha blockers, by blocking alpha receptors located on ureteric orifice and trigone of the urinary bladder, getting effectiveness in reducing symptoms associated with ureteric stent [10,11].

After insertion of ureteric stent, due to mechanical irritation of bladder neck and trigone, can appear symptoms which resemble that of benign prostatic hyperplasia including flank pain during voiding [12]. This similarity of symptoms is because of the fact that in benign prostatic hyperplasia symptoms occur due to similar irritation of bladder neck and trigone. Due to the similar etiology of symptoms it was suggested that the medications which improve benign prostatic hyperplasia symptoms will also decrease stent related symptoms. For improvement of benign prostatic hyperplasia symptoms, role of selective alpha blockers is well proven [13]. It has been proposed that selective alpha blockers will also be helpful in reducing stent related flank pain. In a recent study by Beddingfeild R. et al, it was shown that only 53% of the patients taking tamsulosin experienced flank pain during voiding after insertion of ureteric stent as compared to 90% of the patients who were under placebo [14].

Pakistan is located within the geographical distribution of stone disease. Urolithiasis is the commonest urological problem in Pakistan [15]. The aim of this study is to compare the efficacy of tamsulosin (Selective alpha blocker) versus placebo in patients with ureteric stent post operatively. This particular study has not been done in recent years in our population. In addition this study were emphasize in reducing the morbidity, hospital stay of patient & indirectly it will save the time, money (Government Budget) for other patient as well as will set guideline for others.

2. MATERIALS AND METHODS

The ethical review committee approved this research. 60 patients aged between 15 –

45years, undergone placement of ureteric stent to treat ureteric and renal calculi, have pain score >4, will be included in the study. Tamsulosin was given post operatively when NPO is broken after 2 hours – 6 hours. Patients having uretral trauma, patients having BPH, patient underwent TURP or TURBT, patient having urinary tract infection and patients with pregnancy or lactating females were excluded . Patients were informed about risk and benefits associated with this study and rights of participation. All those patients who fulfill the inclusion criteria were included in the study after taking informed consent.

After the placement of ureteric stent "BOSTON 4.8 Fr", all eligible patients who give the consent were randomized, by opaque envelops technique, into two equal groups A and B. The patients in both groups were kept admitted in ward after ureteric stenting for 24 hours. All patents were receive and intravenous antibiotic (Ceftrixone 1gm), one dose before the procedure and one dose afterward. Also all patients were receive oral analgesic (diclofenic sodium 50mg BID) and antispasmodics (Drotaverine 80mg BID).Patients were discharged after 24 hours. "Group A" were received tamsulosin 0.4mg once a day in postoperative period for 6 weeks. "Group B" were received placebo for 6 weeks duration. Postoperatively stent related flank pain during voiding was assessed via Pain Scale, a designed Performa was given to every patient and was asked to fill the scale on weekly basis and at the end of 6 weeks. The mean of the total scores was calculated and efficacy was labeled as significant if mean pain score is $\leq$4 in the patients who were previously labeled to have significant stent related flank pain during voiding.

3. RESULTS

All patients who got operated for ureteric stent were divided in two groups (group A and Group B). 30 Patients who were treated with tamsulosin were assigned to the 'group A', and 30 patients having placebo in their treatment were assigned to the 'group B'. In group 'A' there were 21 males (70%) and 9 females (30%), the mean age of group A was 35.67±5.99 years as In group 'B' there were of 21 males (70%) and 9 females (30%) and mean age of group A was 35.04±6.42 years (Table 1). Mean Pain score in 'Group A' (Tamsulosin) in week 1, 2, 3, 4, 5, 6 was 4.1, 3.5, 2.9, 2.3, 1.9, 1.3 respectively as shown in Table 2. Mean Pain score in 'group B' (Placebo) in week1, 2, 3, 4, 5, 6 was 6.9, 6.3, 5.9, 5.6, 5, 4.2 respectively as shown in Table 2. Average pain score in 'group A' and 'group B' came out to be 2.67 and 5.64 respectively (P value 0.005).

Table 1. Descritive statistics

Variable	Group A N=30		Group B N=30	
	No	**Percentage**	**No**	**Percentage**
Gender				
• Male	21	57.69%	23	65.38%
• Female	9	42.30%	7	34.61%
Age (means age Group A: 35.67±5.99, Group B: 35.04±6.42)				
• 25-32 years	10	84.61%	9	76.92%
• 33-39 years	12	61.53%	12	65.38%
• 40-45 years	8	53.84%	9	42.30%

Group A: Taking Tamsulosin, Group B: Taking Placebo

Table 2. Weekly pain score

Groups	Weekly Means Pain Score					
	1st week	**2nd week**	**3rd week**	**4th week**	**5th week**	**6th week**
• Group A	4.1	3.5	2.9	2.3	1.9	1.3
• Group B	6.9	6.3	5.9	5.6	5.0	4.2

Group A: Taking Tamsulosin, Group B: Taking Placebo
(Means Pain Score Group A: 2.67±1.09, Group B: 5.64±1.22)

4. DISCUSSION

Ureteral stents are considered to be an integral part of endoscopic surgery, but the resulting discomfort and pain can affect the quality of life, and many patients report that this is the worst part of surgery. 80% of patients reported painful symptoms and pain related to stents, and 32% and 58% of patients reported sexual dysfunction and decreased work efficiency, respectively [16,17]. The most common symptoms include flank pain, haematuria, dysuria, frequency, and urgency. Stent pain and LUTS are attributed to local irritation of the bladder and urinary tract mucosa, which can lead to smooth muscle strain and pain caused by high-pressure ureteral reflux [18]. A device that combines these symptoms has been developed to evaluate the symptoms of the stent. The USSQ examines six areas of urinary system symptoms, body pain, general health, work performance, sexual problems, and other problems, and summarizes the scores for each section. A high score indicates a poor result.

The Arabic version of USSQ has been validated and is considered a reliable tool for assessing the symptoms and healthy QoL of patients with ureteral stents, so it was used in this study [19]. The stent can make meaningful comparisons of various interventions in ongoing work to improve tolerance. Monotherapy studies using selected alpha 1 blockers (such as tamsulosin) reported improved urinary symptoms, flank pain, pain during voiding, visual analogue pain scale (VAPS), and QoL [20]. Although urinary stents are widely used in urological surgery, they are related to diseases, including urinary tract symptoms, pain and impact on the quality of life of patients [21]. The etiologies of stent-related symptoms are not fully understood and it is thought that involuntary bladder contraction caused by trigone irritation contributes to urinary bothersome. Some researchers reported that alpha-blockers including tamsulosin and terazosin have been shown to have a positive effect on stent-related discomfort . However the study conducted by Kuyumcuoglu, reported There was no change in stent pain even after taking tamsulosin [22,23]. He believes that new strategies and stent designs are needed to reduce stent-related complications. However, a recent study found that the new stent did not improve stent-related symptoms. In view of the current research and two recently published meta-analyses, alpha blockers have been shown to be effective in reducing stent-related symptoms [23-25].

Compared with placebo users, patients treated with tamsulosin had significantly lower overall international prostate symptom score (IPSS), flank and voiding pains, analgesic counts, and QoL. Recently, two studies have been conducted about the effects of alpha blockers/ anticholinergics on stent-related symptoms. One study found that stent positioning was more important than drug therapy, and another study found that combined therapy improved urinary system symptoms and quality of life, but did not improve pain [26,27]. In randomization more patients were observed in combined-therapy as compared with placebo group (33% vs. 12%) in PCNL procedure [28].

However, regardless of whether the patient has underwent TUL or PCNL, they have all undergone ureteroscopy or cystoscopic stent placement. Therefore, flank pain might be the only different symptom between both procedure, and the lower urinary tract symptoms might be the same for those. [29]. We concluded that the significant improvement in pain caused by tamsulosin treatment compared to the placebo group can be explained by this concept. In addition, we excluded PCNL patients and only analyzed TUL cohorts that showed similar results except voiding pain. Some studies of the position of the stent suggest that the stent passes away from the midline of the bladder through the distal end of the stent and this is significantly related to the discomfort of the ureteral stent. [30].

This study has some limitations. First, we used stents of the same size and length; However, some studies have shown that stent length is related to stent-related symptoms, while other studies have shown that it has no effect on stent discomfort.In view of this, we used the same stent, although we can also use stents of different sizes that are proportional to the length of the patient's body. Second, the timing of stent implantation varied between groups, but was not significant ($p = 0.06$). However, Irani et al. It turns out that the symptoms associated with the stent have not changed even after a few days. Third, we use IPSS to diagnose urinary tract symptoms, but Joshi et al. A special tool for evaluating stent-related symptoms, called the Ureteral Stent Symptom Questionnaire (USSQ). Although it has been implemented in the past, we have not been able to implement it due to the lack of local language translation and its accuracy and reliability [5].

5. CONCLUSION

Alpha blockers reduce postoperative flank pain and voiding problems in patients with ureteral stents. Our research observed that tamsulosin is better than placebo in reducing postoperative flank pain in patients with ureteral stents.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

CONSENT

Informed and written consent was taken from patients.

ETHICAL APPROVAL

As per international standard or university standard written ethical approval has been collected and preserved by the author(s).

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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