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COMPARATIVE EVALUATION OF SILODOSIN, TAMSULOSIN AND ALFUZOSIN FOR A SUCCESSFUL CATHETER FREE TRIAL IN ACUTE URINARY RETENTION SECONDARY TO BENIGN PROSTATIC HYPERPLASIA

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Abstract

Background: Acute urinary retention (AUR) due to benign prostatic hyperplasia (BPH) is a urological emergency requiring immediate catheterization, historically followed by surgical intervention. However, an alpha-blocker increases the probability of spontaneous voiding after catheter removal. This study compared the efficacy of silodosin, tamsulosin and alfuzosin for successful catheter-free trial in patients with AUR secondary to BPH. Materials and Methods: From April 2023 to December 2023, 45 patients with AUR secondary to BPH were enrolled prospectively and randomized into three groups: Group 1: tamsulosin 0.4 mg once daily (15 patients), Group 2: silodosin 8 mg once daily (15 patients) and Group 3: alfuzosin 10 mg once daily (15 patients). Catheter-free trial was performed after 3 days. Patients unable to void or with a post-void residual urine (PVRU) exceeding 150 ml were classified as failed trial without catheterization (TWOC). Descriptive analysis, independent t-test, one-way analysis of variance (ANOVA) and Chi-square test were used for data analysis. Results: 29 out of total 45 patients (64.44%) had successful TWOC. Frequency of successful TWOC was similar in all the groups without any statistically significant difference (Group 1: 10 (66.67%) patients, Group 2: 9 (60%) patients and Group 3: 10 (66.7%) patients, p-value: 0.388). Also there was no statistically significant difference in mean peak flow rate at TWOC (Group 1: 10.5 \pm 1.3 ml/sec, Group 2: 11.3 \pm 2.5 ml/sec and Group 3: 11.9 \pm 2.1 ml/sec, p-value: 0.178) and mean improvement in International Prostate Symptom Score (IPSS) after 2 months (Group 1: 3.98 ± 1.2 , Group 2: 2.79 ± 0.9 and Group 3: 3.11 ± 2.2 , p-value: 0.102). Conclusion: No significant differences were observed in the effectiveness of tamsulosin, silodosin, and alfuzosin in patients with AUR due to BPH in regard to successful catheter-free trial and improvement in peak flow rate or IPSS after 2 months.

INTRODUCTION

Acute urinary retention (AUR) is a common urologic emergency defined by the International Continence Society as, "a painful, palpable or percussable bladder, when the patient is unable to pass any urine".^[1] Benign prostatic hyperplasia (BPH) represents a predominant etiology of AUR.^[2] The initial approach to managing AUR due to BPH involves the prompt insertion of a urethral catheter.^[3] A trial without catheter (TWOC) is defined as, when a catheter which has been inserted per urethra into the bladder for drainage purpose is removed after a trial period to determine whether the patient is able to pass urine spontaneously without the need for further catheterization. TWOC is usually recommended after 2–7 days, however the optimal time has not yet been established.^[4]

An alpha-blocker significantly increases the rate of successful TWOC if the AUR is caused by increased sympathetic activity at the level of the prostatic smooth muscles.^[5] Various alpha-blockers have been used and compared for efficacy in TWOC. Failure of TWOC is reported in up to 40% of patients treated with an alpha blocker.^[6]

This study aims to compare the efficacy of silodosin, tamsulosin and alfuzosin in catheter-free trial after AUR due to BPH.

MATERIALS AND METHODS

A total of 45 patients presenting in our department with AUR secondary to BPH from April 2023 to December 2023 were catheterized per urethra and prospectively enrolled in the study. Patients with age less than 45 years or more than 80 years, recurrent urinary retention, a retention volume of more than 1 liter, previous urethral, prostatic or bladder neck surgery, renal failure, liver disease, known case of urethral stricture or neurogenic bladder were excluded from the study. A comprehensive medical history was obtained, followed by a thorough systemic and general examination. A digital rectal examination was performed to evaluate the size, of the prostate. and consistency texture. Transabdominal ultrasonography was utilized to measure the prostate size, assess residual urine, and evaluate the intravesical bulge of the median lobe of the prostate.

Using a computer-generated algorithm, patients were randomized in a 1:1:1 ratio to either of the three groups:

Group 1: tamsulosin 0.4 mg once daily (15 patients), Group 2: silodosin 8 mg once daily (15 patients) and Group 3: alfuzosin 10 mg once daily (15 patients). All patients took the medication at bedtime daily for 3 days. The catheter-free trial was performed after 3 days. Patients who were able to void underwent uroflowmetry and measurement of post-void residual urine (PVRU). Patients unable to void or with a PVRU exceeding 150 ml were classified as failed TWOC. These patients were re-catheterized and planned for transurethral resection of prostate. All patients were followed up at 2 weeks, 1 month and 2 months after successful TWOC. None of the patients were lost on follow up. The International Prostate Symptom Score (IPSS) was calculated at the initial presentation and again after two months following TWOC. Descriptive analysis, independent t-test, oneway analysis of variance (ANOVA) and Chi square test were used for data analysis.

RESULTS

29 out of total 45 patients (64.44%) had successful TWOC. All the three groups were similar in regard to patient age, prostate size and volume of urinary retention [Table 1]. Successful TWOC was seen in 10 (66.67%), 9 (60%) and 10 (66.67%) patients of group 1 (Tamsulosin), group 2 (Silodosin) and group 3 (Alfuzosin) respectively [Table 2]. Frequency of successful TWOC was comparable in all the three groups with no statistically significant difference (p=0.388). The groups showed no statistically significant difference when compared for mean peak flow rate at TWOC (p=0.178) and mean improvement in IPSS score at 2 months (p=0.102) [Table 3].

Parameter	Group 1 (Tamsulosin)	Group 2 (Silodosin)	Group 3 (Alfuzosin)	p-value
Number of patients (n)	15	15	15	-
Age (years)	63.1 ± 7.2	60.9 ± 8.6	61.7 ± 6.5	0.719
Prostate size (grams)	44.3 ± 8.3	47.1 ± 7.9	43.6 ± 9.2	0.495
Retained urine volume (ml)	720 ± 170	740 ± 150	810 ± 160	0.282

Table 2: Comparison of successful trial without catheter among the groups.

Group	Total number of patients (n)	Patients with Successful TWOC (%)	Patients with Failed TWOC (%)	p-value
Group 1 (Tamsulosin)	15	10 (66.67%)	5 (33.33%)	0.388
Group 2 (Silodosin)	15	9 (60%)	6 (40%)	
Group 3 (Alfuzosin)	15	10 (66.7%)	5 (33.3%)	

TWOC Trial without catheter

Table 3: Comparison of mean peak flow rate at TWOC and mean improvement in IPSS score at 2 months among the groups

Parameter	Group 1 (Tamsulosin)	Group 2 (Silodosin)	Group 3 (Alfuzosin)	p-value
Mean peak flow rate at TWOC (ml/sec)	10.5 ± 1.3	11.3 ± 2.5	11.9 ± 2.1	0.178
Mean improvement in IPSS score at 2 months	3.98 ± 1.2	2.79 ± 0.9	3.11 ± 2.2	0.102

IPSS International Prostate Symptom Score, TWOC Trial without catheter

DISCUSSION

BPH is characterized by the nonmalignant enlargement of the prostate, a condition frequently observed in older males. BPH is a progressive condition marked by a gradual worsening of symptoms. This progression can result in severe complications, including AUR, which may necessitate surgical intervention.^[7] AUR is defined by the International Continence Society as, "a painful, palpable or percussable bladder, when the patient is unable to pass any urine".^[1] AUR can

present in 0.4 to 25% of patients with BPH.^[8] AUR requires prompt bladder decompression via catheterization.^[3]

Immediate surgical intervention after AUR is associated with higher morbidity and mortality due to the increased risk of sepsis and bleeding. Hence, TWOC has been advocated which has enabled some patients to avoid surgery entirely. A TWOC is defined as, when a catheter which has been inserted per urethra into the bladder for drainage purpose is removed after a trial period to determine whether the patient is able to pass urine spontaneously without the need for further catheterization. TWOC is usually recommended after 2–7 days, however the optimal time has not yet been established.^[4]

In 23-40% cases, patients void successfully after a TWOC of up to 3 days.^[8,9] Alpha-1 blockers are considered as first line therapy for alleviating lower urinary tract symptoms associated with BPH. By decreasing sympathetic nervous system activity, these agents lower bladder outlet resistance and improve urinary flow in symptomatic BPH.^[10] Several studies indicate that alpha-1 blockers enhance the success rate of TWOC and hence these are routinely used before TWOC.^[6,11,12] This study aims to compare the efficacy of silodosin, tamsulosin and alfuzosin in catheter-free trials after AUR due to BPH.

In our study, 64.44% patients had successful TWOC, while 35.56% patients failed TWOC. Fisher et al. noted that the failure rate of TWOC can be as high as 40% in patients treated with an alpha blocker.^[6] Hua et al. showed 61% successful TWOC with tamsulosin which is slightly lower than our study (66.67%).^[13] Kumar et al. demonstrated 76.7% successful TWOC with silodosin which is higher than our study (60%).^[14] Also, Gopi et al. showed 61.3% successful TWOC with alfuzosin which is slightly lower than our study (66.67%).^[15]

In our study, we found no statistically significant difference (p=0.388) between patients receiving either tamsulosin, silodosin or alfuzosin in regard to frequency of successful TWOC. Patil et al. found that efficacy with tamsulosin (67.5%) was slightly higher than with silodosin (60%) but comparable.^[16]

Parikh et al. compared tamsulosin, silodosin or alfuzosin and found no difference in the efficacy of tamsulosin (61.11%), silodosin (62.5%), and alfuzosin (60%) in catheter-free trial. They also showed an improvement in IPSS in the range of 2.9–3.2 points with no statistically significant difference comparing tamsulosin, silodosin or alfuzosin.^[17] Our study demonstrated improvement in IPSS ranging from 1.89–5.18 points at 2 months interval. Furthermore, no statistically significant difference was found between the groups while comparing for either mean improvement in IPSS score at 2 months (p=0.102) or mean peak flow rate at TWOC (p=0.178).

However, small study population is a major limitation of our study and further studies with larger groups are required.

CONCLUSION

The administration of three doses of alpha-blockers demonstrated beneficial outcomes in the majority of patients with AUR secondary to BPH. Moreover, tamsulosin, silodosin, and alfuzosin were found equally effective for successful catheter-free trial in patients with AUR due to BPH.

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