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**Shabir Ahmad Mir**

Department of Surgery,  
Government Medical College  
Srinagar, Jammu and Kashmir,  
India

**Waseem Dar**

Department of Surgery,  
Government Medical College  
Srinagar, Jammu and Kashmir,  
India

**Saleem Javaid**

Department of Surgery,  
Government Medical College  
Srinagar, Jammu and Kashmir,  
India

**Mumtazdin Wani**

Department of Surgery,  
Government Medical College  
Srinagar, Jammu and Kashmir,  
India

## Assessment of efficacy of silodosin in the management of acute urinary retention: A prospective study at a tertiary care hospital of northern India

**Shabir Ahmad Mir, Waseem Dar, Saleem Javaid and Mumtazdin Wani**

### Abstract

**Background:** AUR in BPH (benign prostatic hyperplasia) patients is not an uncommon presentation in our tertiary care hospital. Most of the studies regarding the use of alpha blockers have been conducted using alfuzosin and other older alpha blockers. Under this background present study was carried out to assess the efficacy of silodosin (a highly selective alpha blocker) in the management of these AUR patients. **Materials and Methods:** This prospective study was conducted over a period of 4 years in the unit-II of the Postgraduate Department of General Surgery of SMHS (Shri Maharaja Harisingh) hospital, an associated hospital of Govt. medical college Srinagar, from January 2014 to December 2017). Patients were randomized to two groups- 1 and 2. Each group comprised of thirty-one patients with similar clinical and demographic variables.

**Objective:** The aim of the present study was to assess the efficacy of silodosin in the management of AUR in BPH (benign prostatic hyperplasia) patients.

**Results:** Age of patients ranged from 57 to 87 years with a mean age of 68.54 years. Equal number of patients were included in both the groups (group 1 and group 2). Baseline patient demographic and clinical characteristics were similar in the two groups. Successful TWOC was observed in 74.2% of the patients in group 1 and in 41.9% of the patients in group 2 (p value =0.010). Thus Group 1 has statistically significant higher success rate of TWOC as compared to group 2.

**Conclusion:** Silodosin appears to be effective treatment modality for managing the first time AUR in patients with BPH (benign prostatic hyperplasia).

**Keywords:** Acute, urinary, retention, silodosin, trial, catheter

### Introduction

Acute urinary retention (AUR) is uncomfortable, stressful, and even painful (palpable or percussible bladder). Consequently, the patient is unable to pass any urine [1]. Acute urinary retention (AUR), which is characterized by a sudden painful inability to void, affects about 10% of men in their eighth decade and about 33% of men by the age of 89 years [2]. AUR is classified as spontaneous or precipitated. Spontaneous AUR is considered when no evidence of stimulating factors exists except benign prostatic hyperplasia (BPH). Conversely, precipitated AUR is considered when stimulating factors including BPH and others (e.g., preceding surgery, stroke, urinary tract infection, and some anticholinergic medicaments; the Proscar Long-Term Efficacy and Safety Study) are present [3-5]. When compared to elective surgery for symptoms alone, emergency surgery after AUR has a higher risk of intraoperative and postoperative complications [6]. Under the AUA recommendation, patients with AUR due to BPH should undergo TWOC at least once before being considered for surgery [7]. The decrease in the rates of surgical interventions was beneficial for patients [8, 9]. Benign prostatic hyperplasia (BPH) is the main cause of AUR in men [10]. Trial without catheter (TWOC) is now the standard of care for AUR [11]. TWOC involves removing the catheter after 3 days, which allows 23%-40% of patients to void successfully [11, 12]. Most of the studies regarding the use of alpha blockers have been conducted using alfuzosin and other older alpha blockers. Because BPH is an age-related problem and the incidence of cardiac comorbidities increases with age, less selective alpha blockers can have intolerable side effects. Silodosin is a highly selective alpha blocker with less cardiac side effects and can be safely used [13].

### Material and methods

This prospective study was conducted over a period of 4 years in the unit-II of the Postgraduate

### Correspondence

**Shabir Ahmad Mir**

Department of Surgery,  
Government Medical College  
Srinagar, Jammu and Kashmir,  
India

Department of General Surgery of SMHS (Shri Maharaja Harisingh) hospital, an associated hospital of Govt. medical college Srinagar, from January 2014 to December 2017.

**Aim:** The aim of the present study was to assess the efficacy of silodosin in the management of AUR in BPH (benign prostatic hyperplasia) patients.

Patients (age >50 years) with complaints of first time acute urinary retention (AUR) and with retained urinary volume measuring 400-1000 ml (collected in urobag immediately after catheterization) were included in the study. The exclusion criteria were: suprapubic catheterization; large residual volume(>1 litre) of urine; serum creatinine more than 1.5 mg/dl; hematuria; prostate < 40 grams; history of lower urinary tract surgery, neurological disease, urethral stricture disease, carcinoma prostate, orthostatic hypotension, and allergy to silodosin; and patients already on alpha blockers.

Demographic and clinical variables of the patients were recorded. Clinical details included lower urinary tract symptoms (LUTS) in the month before AUR, medical history, history of constipation, date and time of catheterization, digital rectal examination (DRE) findings (done by a single physician), serum creatinine, and serum prostate-specific antigen (PSA). Transabdominal ultrasound was obtained in all patients before trial without catheter (TWOC). Patients were randomized to two groups- 1 and 2. Each group comprised of thirty-one patients with similar clinical and demographic variables. Group 1 patients received 8 mg silodosin capsule from the day of catheterization for a total of 3 days. Group 2 patients did not receive any alpha blocker medication for these initial three days. On the third day of catheterization, patients were given trial without catheterization (at least two hours after the third dose of silodosin in case of group 1 patients). If the patient voided successfully, a postvoid ultrasound was performed to measure his residual urine volume. If there was < 150 mL postvoid residual urine volume after voiding at least more than 100 mL of urine, he was considered to have a successful TWOC. However, if the patient re-experienced painful AUR or if the PVR urine volume was >150 mL, he was re-catheterized and considered to have a failed TWOC.

All patients with a successful TWOC were started on silodosin on day 4 regardless of which arm they were in, and followed up at 2 weeks with uroflowmetry, PVR volume, and IPSS. Patients who failed TWOC were offered the surgical option of a TURP or other forms of minimally invasive therapy for BPH.

**Statistical Methods:** The recorded data was compiled and entered in a spreadsheet (Microsoft Excel) and then exported to data editor of SPSS Version 20.0 (SPSS Inc., Chicago, Illinois, USA). Continuous variables were expressed as Mean  $\pm$ SD and categorical variables were summarized as frequencies and percentages. Chi-square test or Fisher's exact test, whichever appropriate, was applied for comparing categorical variables. A P-value of less than 0.05 was considered statistically significant. All P-values were two tailed.

## Results

Age of patients ranged from 57 to 87 years with a mean age of 68.54 years. Equal number of patients were included in both the groups (group 1 and group 2). Baseline patient demographic and clinical characteristics were similar in the two groups. Successful TWOC was observed in 74.2% of the patients in group 1 and in 41.9% of the patients in group 2 (p value =0.010). Thus Group 1 has statistically significant higher success rate of TWOC as compared to group 2.

Results of the TWOC after three days of catheterization are depicted in table 1 to 3.

**Table 1:** Group 1 Characteristics

Age group(years)	Trial without catheter (TWOC)		Total
	Successful	Failed	
50-59	4	1	5
60-69	8	3	11
$\geq 70$	11	4	15
Total	23	8	31

**Table 2:** Group 2 Characteristics

Age group(years)	Trial without catheter (TWOC)		Total
	Successful	Failed	
50-59	3	2	5
60-69	4	7	11
$\geq 70$	6	9	15
Total	13	18	31

**Table 3:** Group 1 versus Group 2

Category	Trial without catheter (TWOC)		Total	Chi-square=6.624 P value=0.010
	Successful	Failed		
Group 1	23	8	31	
Group 2	13	18	31	

## Discussion

In our study, patients were randomized to two groups- 1 and 2. Each group comprised of thirty-one patients with similar clinical and demographic variables. Group 1 patients received 8 mg silodosin capsule from the day of catheterization for a total of 3 days. Group 2 patients did not receive any alpha blocker medication for these initial three days. On the third day of catheterization, patients were given trial without catheterization (at least two hours after the third dose of silodosin in case of group 1 patients). Successful TWOC was observed in 74.2% of the patients in group 1 and in 41.9% of the patients in group 2 (p value =0.010). Thus Group 1 has statistically significant higher success rate of TWOC as compared to group 2. Kumar S *et al.*,<sup>[13]</sup> in their study showed that patients receiving silodosin for 3 days after catheterization for AUR were about 2 times more likely to void successfully than those who received placebo. Similar results were achieved in our study.

Silodosin is a new alpha-adrenergic antagonist with a high selectivity for  $\alpha$ -1A receptors, which predominate in the male bladder outflow tract relative to  $\alpha$ -1B receptors. Silodosin's  $\alpha$ -1A:  $\alpha$ -1B binding ratio is extremely high (162:1), leading to its selective action in the lower urinary tract with minimal side effects on blood pressure regulation<sup>[14]</sup>. Silodosin has a good URO selectivity when compared with that of tamsulosin and prazosin *in vivo*<sup>[15, 16]</sup>. Fitzpatrick *et al.*,<sup>[17]</sup> reported successful TWOC in 61% of their population. Among them, 86.7% and 5.6% were treated with  $\alpha$ -blockers and underwent TURP, respectively. According to Hagiwara *et al.*<sup>[18]</sup> and Zhengyong *et al.*,<sup>[19]</sup> the successful TWOC rates were 88.8% and 66.9%, respectively. These results agree with the results of the present study (74.2% patients in group 1 and in 41.9% patients in group 2). It is expected that the second or third TWOC could succeed after the failure of the first TWOC. However, Oelke *et al.*<sup>[20]</sup> demonstrated that successful TWOC rate for the second or third time was not high, and most patients with TWOC failures required surgical interventions. The volume of urine collected at the time of first catheterization (ie, retention urine volume) had been reported to affect the chance of successful voiding<sup>[12]</sup>. We

excluded the patients with 1 liter of retention volume at time of catheterization from our study because they were likely to have chronic urinary retention. It has been shown in a previous study that retention volumes lower than 900 mL is associated with better success at TWOC [12]. Similarly, Djavan *et al.* [21] found that less than 1 liter of retention volume was associated with a good chance of successful voiding after catheter removal, but recommended a period of prolonged catheterization if the volume was more than 1.3 liters.

### Conclusion

Silodosin appears to be effective treatment modality for managing the first time AUR in patients with BPH (benign prostatic hyperplasia).

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