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Original Article

Comparison of the Efficacy of Tamsulosin and Placebo in the Management of Acute Urinary Retention Secondary to Benign Prostatic Hyperplasia Undergoing Trial without Catheter until Definitive Therapy

V Chandramohan, N Narayanamoorthy

Assistant Professor, Department of Urology, Government Vellore Medical College, Vellore, Tamil Nadu, India

Abstract

Introduction: Acute urinary retention (AUR) is one of the most significant, uncomfortable and inconvenient events in the natural history of benign prostatic hyperplasia (BPH). The immediate treatment is bladder decompression using urethral or suprapubic catheterization.

Aim: In this study, the effect of tamsulosin has been evaluated in the temporary management of AUR by increasing the rate of successful trial without catheter (TWOC) until definitive therapy.

Materials and Methods: This prospective randomized study was conducted in tamsulosin Group A/placebo Group B. Patients with AUR after catheterization were given once daily dose of tamsulosin 0.4 mg for 4 days. Placebo group, patients with AUR after catheterizations were given 4 days of vitamin tablets. Success criteria for TWOC; trial without the catheter is considered successful if the patient passes urine more than 100 ml with a PVR of <200 ml either in ultrasonography or actually measured by inserting an interferential therapy.

Results: In Group A, the total success rate of TWOC is 59.5% and the failure rate is 40.5%. In Grade 1 prostate, 11 of 12 had successful TWOC (91.66%) with tamsulosin. The success rate of TWOC in Group B is 32.4%, and TWOC is more successful in patients with Grade 1 prostate (6 of 10).

Conclusion: Prostate size has the statistically significant influence on trial without the catheter. Patients with larger prostate have more chances of failure in the trial without the catheter in both groups. However, tamsulosin increases the success rate of trial without the catheter in patients with the larger prostate.

Key words: Acute urinary retention, Benign prostatic hyperplasia, Management, Tamsulosin, Trial without catheter

INTRODUCTION

Acute urinary retention (AUR) is the most common urological emergency in patients with benign prostatic hyperplasia (BPH). AUR is defined as the sudden and complete inability to void urine voluntarily despite the presence of urine in the bladder and the desire to urinate. 10% of men in 61–70 years age group and 30% in 71–80 years age group would have AUR in the next 5 years (Curtis *et al.* 2001). AUR is the main indication for 25–30% of the patients undergoing prostatic surgery. The event triggering AUR is not identified in most cases. It is the natural history of BPH that progresses to spontaneous AUR. Sudden sympathetic stimulation causes an acute rise in the smooth muscle tone resulting in urinary retention. Alpha blockers aid in voiding by relaxing the smooth

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Corresponding Author: Dr. N Narayanamoorthy, Department of Urology, Government Vellore Medical College, Vellore, Tamil Nadu, India. E-mail: drvchandramohan@gmail.com

muscle tone and relieving obstruction.[1] Patient quality of life is affected by AUR to the extent that it can be comparable to quality of life impaired by acute renal colic.[2] AUR is usually managed by immediate catheterization and emptying the bladder followed by trial without catheter (TWOC) with medical therapy or immediate surgery for benign prostatic hypertrophy. Immediate surgery (within few days after AUR) with urinary catheter *in situ* is associated with more complications in the post-operative period. Patients on prolonged catheterization without undergoing surgery have to undergo potential morbidity in the form of bacterial colonization the urinary tract, bacteriuria, fever, and urosepsis with involvement of upper urinary tracts. To date, the first line of treatment in these patients is giving TWOC with a prior administration of an alpha-blocker that should increase the likelihood of success. An initial drained volume of urine <1 L following catheterization of AUR, patients with <60–65 years of age, a precipitated AUR and catheterization for more than 3 days would increase the chance of successful TWOC. Patients undergoing TWOC are later subjected to elective transurethral resection of prostate (TURP) or continue drug therapy in the form of alpha-blockers alone or in combination with 5 α reductase inhibitors (5 α RI). 5 α RIs like dutasteride are added to alpha-blockers if the gland size is above 30 cc to reduce the gland size and risk of AUR.[3]

Aim

In this study, the effect of tamsulosin has been evaluated in the temporary management of AUR by increasing the rate of successful TWOC until definitive therapy. Successful TWOC helps patient to undergo elective TURP without an indwelling urinary catheter or may continue medical therapy if he opts for medical therapy over surgery depending on the indication.

MATERIALS AND METHODS

This prospective randomized study was conducted in the Department of Urology at tertiary care hospital. Tamsulosin Group A; patients with AUR after catheterization were given once daily dose of tamsulosin 0.4 mg for 4 days. Placebo Group B, patients with AUR after catheterizations were given 4 days of vitamin tablets. Success criteria for TWOC; TWOC is considered successful if the patient passes urine more than 100 ml with a PVR of <200 ml either in ultrasonography (USG) or actually measured by inserting an interferential therapy (IFT).

Inclusion Criteria

Patients with AUR due to benign prostatic enlargement were included in this study.

Exclusion Criteria

AUR due to stricture, carcinoma prostate, carcinoma bladder, hematuria with clot retention, neurogenic causes, in immediate post-operative period (any surgery) and TURP (due to early or late complications of TURP), any other previous surgery in bladder neck or urethra or prostate, AUR due to stone disease, drug-induced AUR, AUR due to trauma, or spinal cord diseases were excluded from the study.

Follow-Up

After 4 doses of tamsulosin/placebo, urinary catheter removed, after patient passing urine. Actual urine passed is measured, and post-void residual is measured using USG or IFT. The patient would be planned for TURP and sent to operation theater without an indwelling catheter or would be given alpha-blockers with or without 5 α RIs depending on the indication.

RESULTS

About 74 patients were selected for the study and randomly allocated in two groups, Group A and Group B, each comprising 37 patients. Following catheterization patients in Group A were given 4 doses tamsulosin 0.4 mg in once daily and 8–12 h after the 4th dose, TWOC given. Group B patients were given vitamin tablets for 4 days, and TWOC given same like Group A. Patients selected for both groups were comparable in terms of age group and prostate size. In age Group 1 comprising patients within 51–60 years, there were 18 patients in total (24.3%). In this group, there were 7 patients in Group A (18.9% within group and 9.5% of total) and 11 patients in Group B (29.7% within group and 14.9% of total). Age Group 2 comprises patients with 61–70 years of age. In this age group, there were 35 patients in total 47.3%. In this age group, there were 16 patients in Group A (43.2% within group and 21.6% of total) and 19 patients in Group B (51.4 % within group and 25.7% of total). In age Group 3 comprising patients within 71–80 years, there were 21 patients (28.4%). In this age group, there were 14 patients in Group A (37.8% within group and 18.9% of total). Age group wise both Groups A and B, patients were comparable and statistically no significant difference among both groups. Of the total 74 patients in the study, 22 patients had Grade 1 prostate (29.7% of total), and 12 patients were in Group A (32.4% within group and 16.2% of total), and 10 patients were in Group B (27% within group and 13.5% of total). 38 patients had Grade 2 prostate (51.4% of total), of which 16 were in Group A (43.2% within group and 21.6% of total) and 22 were in Group B (59.5% within group and 29.7% of total). 14 patients had Grade 3 prostate (18.9% of total), of which 9 were in Group A (24.3% within group

and 12.2% of total) and 5 were in Group B (13.5% within group and 6.8% of total) [Table 3].

There exists a statistical significance between both groups with respect to TWOC. Among the failure patients ($n = 40$), 37.5% ($n = 15$) patients are in Group A. This indicates that the Group A significantly differ from Group B with respect to TWOC [Table 2].

In Group A, the total success rate of TWOC is 59.5%, and the failure rate is 40.5%. Age Group 1 (between 51 and 60 years), 6 of 7 patients had successful TWOC (85.7%). Age Group 2 (between 61 and 70 years), 10 of 16 patients had successful TWOC (62.5%). Age Group 3 (between 71 and 80 years), only 6 of 14 patients had successful TWOC (42.9%) and failure (57.1%) is more (8 out of 14) in this age group.

In patients with Grade 1 prostate, 11 of 12 had successful TWOC (91.66%). In patients with Grade 2 prostate, 9 of 16 had successful TWOC (56.25%). In patients with Grade 3 prostate, only 2 of 9 had successful TWOC (22.22%), i.e., TWOC failure (77.78%) is more in these patients.

The success rate of TWOC in Group B is 32.4%, and TWOC success is uniformly less across all age groups in Group B. Group B patients, TWOC is more successful in patients with Grade 1 prostate (6 of 10). TWOC failure rate is more in patients with Grade 2 prostate (16 of 22) and most in Grade 3 prostate (0 of 5) [Table 3].

Table 1: Prostate size grade

Prostate size grade	Group A	Group B
Grade 1	12	10
Grade 2	16	22
Grade 3	9	5

Table 2: TWOC success comparison between Groups A and B

TWOC	Group A	Group B	*P*
Success	22	12	0.020
Failure	15	25	

TWOC: Trial without catheter

Table 3: Per-rectal prostate size grade and TWOC success

Prostate size grade	Group A	Group B
Grade 1	11	6
Grade 2	9	6
Grade 3	2	0

TWOC: Trial without catheter

DISCUSSION

Management of AUR in patients with BPH is TWOC. After successful TWOC, as the subsequent risk of AUR is high, the patient may undergo TURP immediately or selectively at a later date. In patients without undergoing any treatment, recurrence of AUR is 70% within 1 week of the first episode.[4] In the past, AUR was an immediate indication for surgery constituting about 25–30% of TURPs.[5] For deciding management, spontaneous AUR needs to be differentiated from precipitated AUR. Precipitated AUR is the inability to urinate following a trigger cause. These triggering events may be surgery, anesthesia, or usage of drugs with sympathomimetic or anticholinergic effects, antihistamines. AUR without a trigger factor is categorized as spontaneous. Following an episode of spontaneous AUR, 15% of patients had recurrent AUR, and 75% of these patients underwent surgery. Following an episode of precipitated AUR, only 9% had recurrent AUR, and 26% underwent surgery.[6] Patients undergoing TURP immediately following AUR had significantly higher rates of complications such as re-catheterization (13.8%), septicemia (1.1%), and shock (0.3%).[7] They also had more urinary tract infections (UTIs), lower tract symptoms, and higher medical expenses. The morbidity like catheter-associated UTI increased by the presence of an indwelling urinary catheter.[8] Hence, a trial without the catheter is given to the patient. When TWOC is successful, the patient may undergo surgery electively without catheter-associated morbidity. Alpha-blockers like tamsulosin increase the TWOC success rate. Although alpha-blockers increase the success rate of trial without the catheter, they would not prevent progression of the disease. Patients with significant symptoms of frequency, urgency, voiding symptoms, and a prostate size of more than 30 cc on transrectal US or a PSA level more than 1.5 ng/ml are at high risk of progression of the disease.[9] For preventing progression of the disease, 5 5 α RIs are added to alpha blockers. If after taking combination therapy for 3 months there are persistent symptoms of frequency and urgency, antimuscarinics may be added to treat symptoms of overactive bladder.[9] After a period when 5 α RIs have maximal effect (9 months), alpha-blockers can be withdrawn and patient may be monitored clinically.[9] If patient is symptomatically better, anticholinergics dose reduction or discontinuation may be attempted and patient may be continued on 5 α RI monotherapy.[9] If the patient still has frequency, urgency or other voiding symptoms as well as erectile dysfunction, the addition of a daily phosphodiesterase Type 5 inhibitor may be considered.[9] If medical therapy is not tolerated or does not improve symptoms, surgery is considered. According to AUA guidelines surgery is recommended in patients who complain recurrent gross hematuria of prostatic origin, recurrent UTIs, renal dysfunction secondary to

BPH, vesical stones, lower urinary tract symptoms (LUTS) refractory to other therapies and refractory or recurrent urinary retention. Hence, alpha-blockers are used to increase the TWOC success rate and continued to keep the patient catheter free until he undergoes surgery. The patient may continue alpha-blockers in combination with 5 α RIs or anticholinergics depending on indications or his option for medical therapy. In Lucas *et al.* study, the success rate of TWOC has been increased to 52% and recurrence of AUR significantly reduced by administration of alpha-blocker tamsulosin, when compared with the success rate of 34% in placebo.[10] In our study, success rate of tamsulosin group is 59.5% when compared with that of placebo group 32.4%. Patients in the placebo group had 3 times more risk for failure of trial without the catheter. In another study by Madhu.S.Agarwal *et al.* in India, following AUR in BPH, TWOC success rate is 70% in patients given tamsulosin, when same is compared with placebo 36%.[11] This success rate with tamsulosin is high when compared with our study (59.5%). In their study by Hua *et al.*, the success rate of TWOC with tamsulosin following an AUR is 61% when compared with control group 28%.[12] However, in their study efficacy of treatment was not influenced by the volume of the prostate. In our study, size of the prostate significantly influenced the success rate of TWOC both in tamsulosin and placebo group. In our study, there is the statistically significant difference in TWOC success in patients given tamsulosin concerning prostate size. In patients with Grade 1 prostate, 11 of 12 had successful TWOC (91.66%). In patients with Grade 2 prostate, 9 of 16 had successful TWOC (56.25%). In patients with Grade 3 prostate, only 2 of 9 had successful TWOC (22.22%), i.e., TWOC failure (77.78%) is more in these patients (*P*-value = 0.005). In MTOPS study also, it was established that efficacy of alpha-blockers was less effective in men with large prostate.[13] In their study, Fitzpatrick *et al.* found that age more than 70 years, prostate size more than 50 cc, severe LUTS, drained volume at catheterization more than 1000 mL, and spontaneous AUR favored TWOC failure whereas catheterization for more than 3 days and α 1 blockade before TWOC increased success of TWOC.[14] In our study, in patients given tamsulosin, TWOC success rate in 51–60 years group is (85.7%) more when compared with same (42.9%) in 71–80 years age group, but it is not statistically significant. However, prostate size influenced the TWOC success in both tamsulosin and placebo group, and that is statistically significant. Patients with Grade 3 prostate, TWOC failure is more in both tamsulosin and placebo group, when compared with Grade 1 prostate. These patients had higher TWOC success when given tamsulosin (22.22% vs. 0%). In our study tamsulosin showed a higher success rate of TWOC in patients with larger prostate like Grades 2 and 3 prostates. TWOC success rate in the placebo group is significantly less in these patients. Hence, use of tamsulosin in patients presenting with AUR, and large prostate increases TWOC success rate. In our study average post-void residual urine after TWOC in patients treated with tamsulosin is 163.51 ml (standard deviation of 103.93) and in the placebo group, post-void residual urine is 212.97 ml (standard deviation of 90.49 ml). This is statistically significant observation. Hence, this study demonstrated that prior administration of tamsulosin significantly reduces post-void residual urine in the trial without the catheter.

CONCLUSION

Tamsulosin increases the success rate of trial without the catheter in patients with AUR. There are 3.056 times odds (risk) for placebo Group B comparative to tamsulosin Group A concerning the failure of trial without the catheter. Prostate size has the statistically significant influence on trial without the catheter. Patients with larger prostate have more chances of failure in the trial without the catheter in both groups. However, tamsulosin increases the success rate of trial without the catheter in patients with the larger prostate. Post-void residual urine is significantly reduced by addition of tamsulosin in patients with AUR undergoing trial without the catheter. Tamsulosin increases the success rate of TWOC in older age group patients with AUR due to BPH compared with placebo. However, this is not statistically significant in our study.

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