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OUTCOME OF TRAIL WITHOUT CATHETER IN PATIENTS WITH BENIGN PROSTATIC ENLARGEMENT WITH RELATION TO DURATION OF CATHERIZATION

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Abstract:

Objective: *To observe the outcome of early and delayed catheter removal after acute urinary retention (AUR) due to benign prostatic enlargement (BPE)t with Alfuzosin treatment for success of trial without catheter (TWOC).*

Material and methods: *In this prospective randomized study, 60 men with AUR due to BPE, who fulfill the inclusion criteria were catheterized and included in the study. Two groups were formed of 30 patients each in one group, randomly assigned to receive 10 mg of alfuzosin for 4 days and 8 days, after that catheter was removed and voiding was observed.*

Results: *In the the group taking Alfuzosin for 4 days eighteen men and in group taking Alfuzosin for 8 days 21 men did not require recatheterization on the day of the TWOC (60% and 70%, respectively, P = 0.417). Complication as urinary tract infection, urine leakage, hematuria, or catheter obstruction occurred in five (16.7%) men who received Alfuzosin for 4 days and 13 (43.3%) men who received Alfuzosin for 8 days (P = 0.024).*

Conclusions: *Men catheterized for AUR can void successfully after catheter removal if treated with alpha-1 blockade (Alfuzosin), and success rate of TWOC is controversial regarding the duration of catheterization. However, the complications were increased with period of catheterization.*

Keywords: *Acute urinary retention, benign prostatic hyperplasia, Alfuzosin, trial without catheter.*

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INTRODUCTION:

Benign prostatic hyperplasia (BPH), a histologic diagnosis, is a condition that occurs with aging; the prevalence increases from 25% among men 40–49 years of age to >80% among men 70–79 years of age.[1]

Many complications may be developed from BPH such as increased postvoiding residual, bladder diverticula or calculi, vesicoureteral reflux, hydronephrosis, renal insufficiency, and urine retention.[2] Acute urine retention (AUR) is a common urological emergency that is characterized by sudden and painful inability to pass urine. The incidence of AUR in patients with BPH varies widely from 0.4% to 25%.[3] Management of AUR consists of immediate bladder decompression by catheterization usually followed by BPH-related surgery.[4]

A trial without catheter (TWOC) is considered preferable to leaving a catheter in place[5] alpha-1 (α-1) blockers decrease smooth muscle tone in the prostate, thereby rapidly improving urinary symptoms and flow.[6] Tamsulosin has a rapid onset of action and is effective in patients with moderate or severe symptoms. The drug is, therefore, a valuable therapeutic option, with both demonstrated and potential advantages over older nonselective agents, in the management of patients with lower urinary tract symptoms (LUTS) associated with BPH.[7]

The duration of catheterization before TWOC is controversial regarding the length of time a catheter should remain *in situ* during the initial therapeutic phase.[3],[8]

MATERIAL AND METHODS:

This study was conducted at Asian Institute of Medical sciences (AIMS), from July 2017 to June 2018. Total Sixty male patients with acute urinary retention (AUR), secondary to BPE having their first attack, were enrolled in a prospective randomized study. The study protocol had been approved from the local ethical committee at our hospitals. Patients having these : history of prior catheterization, urinary volume >1000 ml, Vesical Calculi, kidney failure, urethral stricture disease, neurogenic bladder, prostatic carcinoma, history of drugs causing urinary retention, previous history of use of Alpha Blockers, history of drug hypersensitivity or allergy to Alfuzosin, chronic retention were excluded from the study.

After informed consent from the patients, all patients were catheterized and the urine volume was assessed and sent for culture and sensitivity. After catheter insertion, the patients received prophylactic dose of ciprofloxacin 500 mg once and they divided randomly into two groups: Group I: 30 patients received Alfuzosin 10 mg at night and the catheter removed after 4 days and Group II: 30 patients received Alfuzosin 10 mg at night and the catheter removed after 8 days.

Patients who were enrolled in the study, complete history was noted with complete general physical examination including digital rectal examination, urine volume and color was recorded after putting catheter. Following investigation were performed complete blood count, urinalysis, urine culture and sensitivity, Serum creatinine, serum prostate specific antigen, ultrasound for renal collecting system and for prostatic size.

Complications related to drug (Alfuzosin) as well as related to catheter like bleeding, peri-catheter urinary leak, and urinary tract infection were in prescribed proforma in both groups.

After removing catheter patients who voided at least 250 mls of urine comfortably without difficulty were discharged home with instructions to come on followup after 2 weeks for re-assessment with ultrasound with estimation of postvoid residual urine, urinalysis and uroflometry. While patients who were unable to pass urine were labelled as failure to trail without catheter were recatheterized and booked for Transurethral resection of Prostate.

STATISTICAL METHOD:

Data management and analysis were performed using Statistical Package for the Social Sciences (SPSS) version 20 for Windows comparisons between numerical variables of two groups were done by Student's unpaired *t*-test for parametric data and categorical variables were done by Chi-square test or Fisher exact test for small sample size, *P* value was considered significant when $P > 0.05$.

RESULTS:

The mean patients' age was 59.9 ± 8.9 years; prostatic volume ranged from 30 to 147 cc with mean of 59.7 ± 24 cc. Urine volume collected in the urine bag immediately after catheterization was recorded. Retained volume ranged from (450 to 1000 ml) with mean of 672.6 ± 153.6 ml. Screening serum PSA was done for all patients in the 2nd-week follow-up after catheter removal. median PSA level of the studied cases was 2.65 (interquartile range = 1.7–3.9) ng/ml. The IPSS was assessed for all patients during the first

clinical examination. Mean IPSS of the studied cases was 13.25 ± 3.56 (ranged from 6 to −22).

After catheter removal, 65% of patients voided successfully while 35% failed TWOC. the volume of residual urine was assessed in cases who voided by ultrasound and ranged from 0 to 182; median was 50 ml. Q_{max} was assessed in cases who voided by uroflowmetry and ranged from 10 to 22.6 with mean 17.56 ± 3.02 ml/s. The overall complication was 30%, included obstruction in 6.7%, UTI in 20%, hematuria in 10%, and urinary leakage in 3.3% of cases.

Bivariate analysis was carried out to identify factors that may affect the TWOC failure [Table 1]. The difference between mean age among failed and succeeded cases are significantly different (P = 0.04). Furthermore, the IPSS was P = 0.039. Age among cases with complications and those without were significantly different (P = 0.003) also was IPSS (P = 0.021).

Table 1: Bivariate analysis of factors related to trial without catheter outcome

	Success (n=39), n (%)	Failed (n=21), n (%)	P
Age			
Mean±SD	58.03±8.02	63.23±9.55	0.04
Range	45-72	49-87	
<60 years	29 (74.4)	8 (38.1)	0.3
60 years or more	10 (25.6)	13 (61.9)	
Prostate size			
Mean±SD	56.10±19.05	66.29±30.54	0.2
Range	30-120	30-147	
<60 cc	27 (69.2)	10 (47.6)	0.1
≥60 cc	12 (30.8)	11 (52.4)	
Retained urine volume			
Mean±SD	656.41±162.69	702.76±133.53	0.2
Range	450-1000	450-1000	
<650 ml	18 (46.15)	5 (23.8)	0.09
≥650 ml	21 (53.85)	16 (76.2)	
IPSS			
Mean±SD	12.56±3.5	14.52±3.3	0.04*
Range	6-19	10-22	
PSA			
Median	2.45	3.52	0.1
IQR	1.64-3.6	1.7-4.3	

*Statistically significant. SD: Standard deviation, IPSS: International Prostate Symptom Score, PSA: Prostatic-specific antigen

Table 2: Comparison between the studied groups

	Group I (*n*=30)	Group II (*n*=30)	*P*
Age (mean±SD)	59.2±8.00	60.5±9.74	0.6
Prostate size (mean±SD)	61.47±23.10	57.87±25.03	0.6
Retained urine volume (mean±SD)	683.3±160.45	661.93±148.35	0.6
IPSS (mean±SD)	13.30±3.89	13.2±3.25	0.9
PSA (median)	2.47	3.12	0.8
Success (%)	18 (60)	21 (70)	0.4
PVR urine (median)	47.5	60	0.4
Q_{max} (mean±SD)	18.43±2.59	16.82±3.21	0.1

SD: Standard deviation, PVR: Postvoid residual, IPSS: International Prostate Symptom Score, PSA: Prostatic-specific antigen

DISCUSSION:

Clinical BPH is one of the most common diseases in aging men which can lead to LUTS.[9] The prevalence of BPH rises markedly with increased age. Autopsy studies have observed a histological prevalence of 8%, 50%, and 80% in the fourth, sixth, and ninth decades of life, respectively.[10] As regarding age of the cases, our study demonstrated that there was significantly different in TWOC outcome with age as the mean age among succeeded cases was 58.03 ± 8.02, while among failed cases was 63.23 ± 9.55 (*P* = 0.03).

A retrospective study conducted by Bansal and Aditi Arora[11] of 2188 patients presenting with first episode of AUR between January 2009 and July 2016 showed that age was an independent predicting factor of successful TWOC for AUR and that patients older than 65 years were at a 1.84 times higher risk of failure of TWOC than were those younger than 65 years.

Our results showed that prostate volume is an insignificant predicting factor of successful TWOC for AUR where mean prostate size among succeeded cases was 56.10 ± 19.05 while mean size in failed cases was 66.29 ± 30.54 (*P* = 0.175), this may be due to the small number of patients in our study (*n* = 60). Our study statistically showed that patients with prostate volume ≥50 cc were at 1.62 times higher risk of failure of TWOC than those with >50 cc (61.9% vs. 38.1) and those with volume ≥60 cc were at 1.1 times (52.4% vs 47.6%).

Previous studies by Kumar *et al.*[13] in 2000 and Zeif *et al.* in 2010[14] also demonstrated that failure of TWOC was associated with larger prostate size. However, studies by Tan and Foo in 2003[15]and Djavan *et al.* in 1997[16]showed contradictory negative results.

Taube and Gajraj in 1989[17]found that the successful outcome of TWOC is associated with retained volume >900 ml. Similarly, our data showed that retained volume of ≥650 ml is associated with increased failure rate of TWOC but it was statistically insignificant (*P* = 0. 09). This may be because of prolonged bladder distension due to large volume of residual urine which may result in ischemia and axonal degeneration leading to loss of bladder tone.[14]

Our results are consistent with those of Bhomi and Bhattachan in 2011[18]who also confirmed that patients with low AUA score had significantly higher chances of successful TWOC. However, Djavan *et al.* in 1997 showed no correlation of AUA score with outcome of TWOC. Lim *et al.* in 1999[19] studied the association of serum PSA with outcome of TWOC and showed that serum PSA is significantly higher in patients in whom TWOC failed and assumed that it is due to prostatic

infarction or infection giving rise to AUR. However, Zeif *et al.*in 2010[14] found no impact of serum PSA level on the outcome of TWOC.

Our study demonstrated that 65% of cases who received Alfuzosin before catheter removal succeeded TWOC while 35% failed. McNeill *et al*. in 2004 found in their study that the use of α-blockers increases the TWOC success rate compared to placebo, 61.9% versus 47.9%, which approximate our study success rate. Similar findings are reported by Reten-World Study Group where the prevalent use of α-blockers (86%) worldwide is noted with the result doubling success rate of TWOC.[20]

In controversy, Desgrandchamps *et al*. in 2006[21] found that the success rate of a TWOC was also higher when the catheter was removed after 1–3 days than for a longer duration of catheterization. In their survey, the TWOC success rates were greater for short catheter duration (63.2%, 52.7%, and 52.5% after 1, 2, and 3 days, respectively) than longer catheter duration (41.5% and 46.9% for 4–7 and >7 days, respectively). The study was not randomized and this may reflect differences in the clinical profile of patients.

As regarding complications of catheterization, our study showed that the overall complications rate was 30% and the complication rate was statistically significantly higher in the group who catheterized for 8 days (43.3%) (more than one complication occurred in one patient) than the group who catheterized for 4 days (16.7%) (P = 0.024).

Our study showed that people with catheter for 8 days had UTI significantly higher than those with catheter for 4 days (33.3% vs. 6.7%, P = 010). Furthermore, Stensballe *et al*. in 2007 found that people with catheters acquire bacteriuria at different rates. Incidence of conversion from sterile urine to bacteriuria occurs at the rate of 3%–10% per day in agreement with our study that showed increases the risk of UTI 6.65% per day with prolonged duration of the catheter.

CONCLUSION:

Urethral catheterization followed by a TWOC is the standard practice worldwide and that alpha-1 blockade before TWOC increase the chances of success, success rate of TWOC was controversial regarding early catheter removal compared to late catheter removal. Late catheter removal was observed to be accompanied by significant increased prevalence of adverse effects such as catheter blockage, hematuria, UTI, and urinary leakage. Finally, to get more data and more valuable statistics, more studies on a larger number of cases should be done.

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