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Predictive factors for the success of trial without catheter for men with urinary retention

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Abstract

Objective: To investigate the trial of spontaneous urination without catheter (TWOC) outcomes for men with acute urinary retention, determine successful TWOC predictors, and evaluate the impact of add-on medication therapy on TWOC.

Methods: This retrospective study included men with acute urinary retention and post-void residual (PVR) >250 mL who underwent TWOC between July 2009 and July 2019. Patients were divided into a medicated group who received alpha1 blocker on urinary retention diagnosis and a naïve group who did not. The trial was defined as unsuccessful if the PVR was >150 mL or if the patient experienced difficulty emptying their bladder with abdominal discomfort or pain, and a transurethral catheter was reinserted.

Results: Among 576 men with urinary retention, 269 (46.7%) constituted the medicated group and 307 (53.3%) the naïve. The naïve group comprised more elderly patients ($P = 0.010$) with higher Eastern Cooperative Oncology Group performance status (PS) ($P = 0.001$) and smaller prostate volume ($P = 0.028$) than the other. In the medicated group, 153 men received additional oral medication before TWOC to increase the success rate. There were significant age differences ($P = 0.041$) in the medicated group and significant median PS differences ($P = 0.010$) in the naïve group between the successful and unsuccessful outcomes of TWOC. The multivariate logistic regression model demonstrated that age <80 years in medicated patients ($P = 0.042$, odds ratio [OR] 1.701) and PS <2 in naïve patients ($P = 0.001$, OR 2.710) were significant independent predictors of successful TWOC outcomes.

Conclusions: This is the first study classifying patients with urinary retention according to medication status. Both medicated and naïve groups had different patient backgrounds and TWOC outcome predictors, suggesting a discrepant etiology behind urinary retention. Hence, acute urinary retention management in men should vary based on medication status for male lower urinary tract symptoms when urinary retention is diagnosed.

KEYWORDS
catheters, male LUTS, urinary retention

1 | INTRODUCTION

Acute urinary retention is defined as a painful, palpable, or percussive bladder when the patient is unable to pass any urine.[1,2] Bladder outlet obstruction (BOO) is considered the most prevalent cause of urinary retention.[3] Several clinical guidelines indicate that the general management of acute urinary retention is immediate decompression of the bladder with a catheter, followed by a trial without a catheter (TWOC) or prostate surgery. TWOC is a trial to determine whether a patient with urinary retention can obtain a catheter-free status. Immediate prostate surgery after acute urinary retention results in higher perioperative surgical complications;[4] thus, TWOC is considered a feasible and valuable treatment which prevents the long-term implantation of urinary catheters.

Administration of alpha1-adrenoceptor antagonists (α1-blockers) before TWOC is the most popular treatment option[5] for medication-naïve patients owing to a higher success rate of TWOC than placebo.[6–9] However, predictors of successful outcomes of TWOC in medication-naïve male patients with acute urinary retention have not yet been elucidated. The add-on medication therapy includes phosphodiesterase 5 (PDE5) inhibitors, 5 alpha reductase inhibitors, herbal extract medications, or parasympathomimetics in male patients who received α1-blockers at diagnosis of urinary retention and those utilities were not fully investigated. Currently, only one randomized controlled trial was available showing that addition of tadalafil to α-blockers has no significant advantage in improving benign prostatic hyperplasia-related acute urinary retention vs tamsulosin alone.[10]

The primary purpose of this study was to investigate the outcomes of TWOC in men with acute urinary retention and determine

TABLE 1 Characteristics of patients divided into medicated and naïve groups.

		Medicated	Naïve	*P* value
Number of patients		269	307	
Age		75.8 ± 8.2	77.3 ± 8.7	0.010
ECOG performance status	0	73	53	0.001
	1	171	194	
	2	13	24	
	3	12	34	
	4	0	2	
Prostate volume (mL)		54.5 ± 35.7	47.3 ± 25.8	0.028
Past history	Diabetes mellitus	64	70	0.779
	Neurogenic disorders	51	65	0.509
	Dementia	19	28	0.368
	Intra-pelvic surgery	13	21	0.308
Blood test	Alb (g/dL)	3.3 ± 0.7	3.4 ± 0.7	0.475
	Cre (mg/dL)	1.2 ± 1.0	1.1 ± 0.9	0.329
	CRP (mg/dL)	2.9 ± 4.4	2.2 ± 3.4	0.093
	WBC (10^3/μL)	7.2 ± 3.3	7.2 ± 2.8	0.974
	Neutrophil (/μL)	67.4 ± 10.9	67.1 ± 10.6	0.779
	Hb (g/dL)	11.9 ± 2.3	12.1 ± 2.2	0.400
	Plt (10^3/μL)	237.6 ± 91.1	251.5 ± 109.0	0.153
	BS (mg/dL)	138.2 ± 59.3	124.0 ± 41.9	0.065
	PSA (μg/dL)	23.1 ± 17.2	20.5 ± 35.3	0.292
Administration of add-on medicine before TWOC		153	N.A.	
Details of add-on medication	Alpha-1 blocker (changed the type or increased volume)	72	N.A.	
	PDE5 inhibitors	3	N.A.	
	5α reductase inhibitors	20	N.A.	
	Parasympathomimetics	42	N.A.	
	Herbal extract medications	16	N.A.	
Outcome of TWOC	Successful	159	183	0.903
	Non-successful	110	124	

Note: Continuous values were represented as mean ± SD.
Abbreviations: Alb, albumin; BS, blood sugar; Cre, creatinine; CRP, C-reactive protein; ECOG, Eastern Cooperative Oncology Group; Hb, hemoglobin; PDE5, phosphodiesterase 5; Plt, platelet; PSA, prostate specific antigen; TWOC, trial of spontaneous urination without catheter; WBC, white blood cell.

the predictors of successful TWOC. Patients were divided according to medication status at the point of urinary retention as medicated and non-medicated (naïve) groups and may have different etiologies leading to urinary retention. Thus, the predictors of TWOC outcome may vary and necessitate different treatment strategies depending on medication status. The secondary purpose of this study was to evaluate the impact of add-on medication therapy on TWOC outcomes for urinary retention in men.[11]

2 | METHODS

2.1 | Study population

The inclusion criteria were male patients with acute urinary retention, defined as a painful, palpable, or percussible bladder, and unable to pass any urine.[2] This was accompanied by post-void residual (PVR) > 250 mL[11] measured by ultrasound or computed tomography

TABLE 2 Characteristics of medicated patients divided into successful and unsuccessful outcomes of TWOC.

		Successful	Unsuccessful	*P* value
Number of patients		159	110	
Age		75.0 ± 8.2	77.0 ± 8.2	0.041
ECOG performance status	0	44	29	0.326
	1	103	68	
	2	8	5	
	3	4	8	
	4	0	0	
Prostate volume (mL)		53.1 ± 36.6	56.6 ± 34.5	0.508
Past history	Diabetes mellitus	35	29	0.410
	Neurogenic disorders	29	22	0.717
	Dementia	9	10	0.280
	Intra-pelvic surgery	8	5	0.855
Identifiable cause of urinary retention	Presence/absence	93/66	54/56	0.128
Details of identifiable causes	Post-operation (urological operation)	52 (43)	17 (12)	0.009
	Cardiovascular event	3	6	
	Infection	5	4	
	Cerebrovascular event	3	1	
	Drinking alcohol	15	5	
	Taking cold medicine	5	4	
	Acute medical illness	10	17	
Blood test	Alb (g/dL)	3.4 ± 0.8	3.2 ± 0.7	0.179
	Cre (mg/dL)	1.1 ± 0.8	1.4 ± 1.3	0.065
	CRP (mg/dL)	2.5 ± 3.7	3.4 ± 5.2	0.165
	WBC (10^3/μL)	6.7 ± 2.4	7.9 ± 4.3	0.013
	Neutrophil (/μL)	67.1 ± 10.6	67.9 ± 11.4	0.667
	Hb (g/dL)	12.0 ± 2.3	11.7 ± 2.3	0.331
	Plt (10^3/μL)	237.1 ± 90.3	238.4 ± 92.9	0.918
	BS (mg/dL)	144.0 ± 67.5	131.7 ± 48.5	0.352
	PSA (μg/dL)	23.9 ± 20.5	21.4 ± 45.0	0.535
Administration of add-on medicine before TWOC		85	68	0.174
Details of add-on medication	Alpha-1 blocker (changed the type or increased volume)	38	34	0.098
	PDE5 inhibitors	3	0	
	5α reductase inhibitors	9	11	
	Parasympathomimetics	23	19	
	Herbal extract medications	12	4	

Note: Continuous values were represented as mean ± SD.

Abbreviations: Alb, albumin; BS, blood sugar; Cre, creatinine; CRP, C-reactive protein; ECOG, Eastern Cooperative Oncology Group; Hb, hemoglobin; PDE5, phosphodiesterase 5; Plt, platelet; PSA, prostate specific antigen.; TWOC, trial of spontaneous urination without catheter; WBC, white blood cell.

imaging. Consecutive patients who underwent the TWOC between July 2009 and July 2019 were enrolled and retrospectively analyzed. Exclusion criteria were patients without any medication therapy before TWOC for certain reasons (mainly reluctant or unable to take medications) and patients with urological malignancies including prostate and bladder cancers. The study protocol (institutional review board number YKH20-73) waiving the requirement for written informed consent was approved by the institutional ethics committee of Yokosuka Kyosai Hospital. Informed consent was obtained as an opt-out on the Yokosuka Kyosai Hospital website. The study was conducted in accordance with the principles of the Declaration of Helsinki and all local regulations.

The indications for TWOC in our hospital were as follows. After the diagnosis of urinary retention, a transurethral catheter was inserted to drain residual urine from the bladder. The patients were divided into two groups depending on medication status when diagnosed with urinary retention: Medicated groups (treated with α1 blocker upon diagnosis of urinary retention) and naïve groups (not receiving medication for lower urinary tract symptoms [LUTS] at diagnosis of urinary retention). At least 1 week after transurethral catheter implantation, TWOC was performed. In general, add-on medications including PDE5 inhibitors, herbal extract medications (Eviprostat or Cernitin), or parasympathomimetics (bethanechol or distigmine bromide) along with α1 blocker administration were administered to the medicated groups, while an α1 blocker was administered to the naïve groups before TWOC. Thus, the different etiologies may vary the predictors of TWOC outcome and require different treatment strategies depending on medication status.

In TWOC, after the instillation of warm saline (200–300 mL or until the first desire to void), the urinary catheter was removed and residual urine was measured after the first void or 6 hours later. The trial was defined as unsuccessful if the PVR was >150 mL or if the patient experienced difficulty emptying their bladder with abdominal discomfort or pain, and a transurethral catheter was reinserted.[12]

Patient characteristics, including age, Eastern Cooperative Oncology Group performance status (PS), body mass index, blood test parameters, and comorbidities, were retrospectively compared according to the outcome of the trial catheter removal. Multivariate regression models were used to identify the predictors of successful trial outcomes and to evaluate the impact of any medication on trial outcomes.

2.2 | Statistical analysis

Statistical analysis was performed using SPSS software (SPSS version 22, IBM, Armonk, NY, USA). Paired and unpaired Student's *t* tests were used, as appropriate, to compare continuous clinical variables. The Chi-square test was employed to compare qualitative variables. Continuous variables were presented as the mean, the SD, and qualitative variables as percentages. Statistical significance was set at $P < .05$. For the multivariate analysis, a logistic regression model with stepwise analysis was used.

3 | RESULTS

A total of 723 men were diagnosed with acute urinary retention and underwent TWOC over 10 years (between 2009 and 2019) at the Yokosuka Kyosai Hospital. Among them, 576 men were treated with medications (initial or add-on therapy) before TWOC, of which 269 (46.7%) already received α1 blockers for LUTS at the time of diagnosis of urinary retention (medicated group). The remaining 307 (53.3%) did not receive LUTS medications before urinary retention (naïve group).

The success rate of the TWOC was equivalent between the medicated (59.1%) and naïve groups (59.6%, $P = 0.903$). A majority of the naïve group consisted of elderly patients ($P = .010$) with lower PS

TABLE 3 Multivariate logistic regression model predicting the successful outcome of TWOC in medicated patients.

				95% CI of Exp (B)	
		P value	Exp (B)	Lower limit	Upper limit
Initial model	Diabetes mellitus	0.522	1.220	0.664	2.241
	Neurogenic disorders	0.613	0.838	0.423	1.660
	Dementia	0.542	1.353	0.512	3.572
	Intra-pelvic surgery	0.800	0.859	0.265	2.784
	ECOG-PS (0, 1 vs ≥2)	0.205	1.778	0.730	4.328
	Age (<80 vs. ≥80)	0.024	1.037	1.005	1.071
	Add-on medication before TWOC	0.294	0.757	0.450	1.273
	Identifiable cause of urinary retention	0.100	1.538	0.920	2.571
	Constant	0.006	0.014		
Final model	Age (<80 vs ≥80)	0.021	1.037	1.006	1.069
	Constant	0.010	0.037		

Abbreviation: ECOG-PS: Eastern Cooperative Oncology Group performance status; TWOC, trial of spontaneous urination without catheter.

TABLE 4 Characteristics of naïve patients divided into successful and unsuccessful outcomes of TWOC.

		Successful	Unsuccessful	*P* value
Number of patients		183	124	
Age		76.7 ± 8.2	78.3 ± 9.4	0.341
ECOG performance status	0	35	18	0.010
	1	124	70	
	2	10	14	
	3	14	20	
	4	0	2	
Prostate volume (mL)		48.6 ± 28.2	45.1 ± 21.4	0.387
Past history	Diabetes mellitus	46	24	0.236
	Neurogenic disorders	34	31	0.177
	Dementia	12	16	0.058
	Intra-pelvic surgery	11	10	0.484
Identifiable cause of urinary retention	Presence/absence	127/56	62/62	<0.001
Details of identifiable causes	Post-operation (urological operation)	57 (30)	16 (5)	<0.001
	Cardiovascular event	9	9	
	Infection	23	12	
	Cerebrovascular event	1	7	
	Drinking alcohol	8	1	
	Taking cold medicine	6	0	
	Acute medical illness	26	17	
Blood test	Alb (g/dL)	3.4 ± 0.7	3.4 ± 0.8	0.456
	Cre (mg/dL)	1.2 ± 0.9	1.1 ± 0.7	0.513
	CRP (mg/dL)	2.4 ± 3.8	2.0 ± 2.7	0.376
	WBC (10^3/μL)	7.3 ± 3.0	7.1 ± 2.5	0.642
	Neutrophil (/μL)	67.2 ± 11.0	67.1 ± 10.1	0.962
	Hb (g/dL)	12.0 ± 2.2	12.2 ± 2.2	0.490
	Plt (10^3/μL)	256.1 ± 116.6	245.2 ± 97.7	0.446
	BS (mg/dL)	126.8 ± 44.4	120.7 ± 38.9	0.488
	PSA (μg/dL)	22.9 ± 38.1	16.0 ± 29.5	0.420

Note: Continuous values were represented as mean ± SD.

Abbreviations: Alb, albumin; BS, blood sugar; Cre, creatinine; CRP, C-reactive protein; ECOG, Eastern Cooperative Oncology Group; Hb, hemoglobin; Plt, platelet; PSA, prostate specific antigen; TWOC, trial of spontaneous urination without catheter; WBC, white blood cell.

TABLE 5 Multivariate logistic regression model predicts successful outcomes of TWOC in naïve patients.

				95% CI of Exp (B)	
		P value	Exp (B)	Lower limit	Upper limit
Initial model	Diabetes mellitus	0.438	0.79	0.435	1.433
	Neurogenic disorders	0.611	1.17	0.639	2.142
	Dementia	0.645	1.225	0.517	2.903
	Intra-pelvic surgery	0.292	1.664	0.646	4.288
	ECOG-PS (0, 1 vs ≥2)	<0.001	3.593	1.855	6.957
	Age (<80 vs ≥80)	0.395	1.013	0.983	1.043
	Identifiable cause of urinary retention	<0.001	2.997	1.775	5.059
	Constant	<0.001	0.01		
Final model	PS (0, 1 vs ≥2)	<0.001	3.941	2.110	7.360
	Identifiable cause of urinary retention	<0.001	3.094	1.852	5.168
	Constant	<0.001	0.027		

Abbreviation: ECOG-PS, Eastern Cooperative Oncology Group performance status; TWOC, trial of spontaneous urination without catheter.

($P = .028$) than the medicated group, and the prostate volume was larger in the medicated group (54.5 ± 35.7 mL) than in the naïve group (47.3 ± 25.8 mL) ($P = 0.028$, Table 1).

In the medicated group, 153 patients received add-on medicine before the TWOC (Table 1). In the successful TWOC, younger age ($P = 0.041$) and lower serum white blood cell value ($P = 0.013$) were observed than those in the non-successful TWOC (Table 2). The multivariate logistic regression model demonstrated that age <80 years was a significant independent predictor of successful TWOC in the medicated patients ($P = .021$, odds ratio [OR] 1.037, 95% confidence interval [CI] of OR 1.006–1.069) (Table 3).

In the naïve group, a lower PS ($P = 0.010$) and presence of identifiable cause of urinary retention ($P < 0.001$) were found in the successful TWOC group than in the unsuccessful TWOC (Table 4). The multivariate logistic regression model demonstrated that a PS <2 ($P < .001$, OR 3.941, 95% CI of OR 2.110–7.360) and presence of identifiable cause of urinary retention ($P < 0.001$, OR 3.094, 95% CI of OR 1.852–5.168) were a significant independent predictors of successful outcomes of TWOC in naïve patients (Table 5).

4 | DISCUSSION

This is the first study to distinguish patients with urinary retention according to their medication status prior to events and identify the predictor of TWOC outcome in each group. The medicated group received medication for relieving LUTS prior to the diagnosis of urinary retention, and the naïve group did not. This study suggested that predictors of successful TWOC outcome were different between medicated and naïve patients, namely age <80 years in the medicated group and PS <2 and presence of identifiable cause of urinary retention in the naïve group. Both groups had different backgrounds: younger age, lower PS, and larger prostate volume in the medicated group than in the naïve group, indicating that the etiology of urinary retention varied between the two groups. Thus, the management of urinary retention should be modified and different treatment strategies should be employed for both groups.

This study also established that add-on medication for male LUTS in the medicated group showed no clinical efficacy in retaining a catheter-free status. Few studies have investigated TWOC outcomes in patients with urinary retention under medicated conditions, and the preventative role of oral α1-blockers for recurrent acute urinary retention has not yet been established.[13] Another clinical question was sufficient administration period for add-on medications was not yet elucidated. We treated patients with 1-week administration of add-on drugs in our hospital and at least 1-week treatment showed no remarkable efficiency.

In the medicated group, prostate volume was larger than that in the naïve group, and age (>80 years) was significantly associated with TWOC failure outcome, indicating that exacerbation of male LUTS and progression of benign prostatic enlargement (BPE) with aging may possibly cause urinary retention in the medicated group. Meanwhile, in the naïve group, the etiology of urinary retention is considered more complicated and heterogenic than that in the medicated group, not being simple BPE progression with aging. The finding that TWOC failure was strongly associated with higher PS in the naïve group, suggested that urinary retention was mainly caused by a deteriorated general condition. Furthermore, no identifiable (unknown) cause of urinary retention was also determined as an unfavorable predictor, indicating possible cause of urinary retention (especially, drinking or taking cold medicine) should be assessed before TWOC in naïve patients. To the best of our knowledge, no study has investigated the relationship between TWOC and either PS or identifiable cause of urinary retention.

The successful TWOC rate in this study was approximately 60% irrespective of medication status, and a few previous reports showed varied results (39.0%–61.4%),[5,14,15] possibly because of the huge heterogenic backgrounds of patients. A few previous studies have investigated the predictors of TWOC outcome and stated that smaller prostate volumes[14,15] and younger ages[14] were associated with successful TWOC outcomes. Another multivariate regression analysis confirmed that α1-blockers before TWOC, older age (≥70 years), prostate size (≥50 g), severe LUTS, drained volume at catheterization (≥1000 mL), and spontaneous acute urinary retention (AUR) led to TWOC failure.[5] Our previous study showed that TWOC outcome in female patients with AUR was significantly associated with serum albumin value;[12] however, this study indicated that this was not true in male patients.

This study had a few limitations, including its retrospective nature and single-center design. Additionally, there was heterogeneity in the study cohort. However, this study reflected real-world clinical data and a randomized study with a larger cohort is necessary to confirm the efficacy of add-on or initial oral medication on TWOC outcomes. Another limitation of this study was missing urodynamics information and we were unbale to identify the exact cases of detrusor underactivity (DU) and BOO in this cohort. However, recent studies indicated routine urodynamics did not contribute to avoiding unnecessary prostate surgery for patients with male LUTS[16,17] and we believed that the role of urodynamics would also be limited in prediction of TWOC outcome.

In conclusion, the medicated and naïve groups had different predictors of TWOC outcome with different patient backgrounds, suggesting a discrepant etiology behind urinary retention between the two groups. These findings suggest that the management of AUR in men should vary depending on the medication status for male LUTS at the point of diagnosed urinary retention.

AUTHOR CONTRIBUTIONS

Hiroki Ito, Masato Takanashi, Takeshi Fukazawa, Risa Shinoki, and Hiroki Takizawa and Mari Hioki conceived and designed the experiments. Masato Takanashi, Hiroki Ito, Takeshi Fukazawa, Masato Takanashi, Risa Shinoki, and Hiroki Takizawa and Mari Hioki collected the data. Analyzed the data: Hiroki Ito, Masato Takanashi, Takashi

Kawahara, and Kazuki Kobayashi. Interpreted the data: Hiroki Ito, Masato Takanashi, Hiroki Takizawa and Mari Hioki, Takashi Kawahara, and Kazuki Kobayashi. Masato Takanashi, Hiroki Ito, and Kazuki Kobayashi wrote the manuscript. All authors have read and approved the final manuscript.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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