Published in final edited form as:

Neurol Urodyn. 2016 June ; 35(5): 630–635. doi:10.1002/nau.22770.

Safety and Efficacy of a Patient-Controlled Bladder Management System for Treating Urinary Retention in Men

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Abstract

Aims—The CymActive Bladder Management System (BMS) is a self-retaining, intraurethral catheter with a patient-controlled magnetic valve that allows cyclical bladder filling and emptying, without external appliances. We determined the safety and efficacy of the BMS in men with urinary retention who required catheterization for more than 7 days.

Methods—Men requiring continuous drainage, bladder capacity less than 300 mL, history of prostatic or urethral surgery, or urethral length outside of defined limits, were excluded. Data were collected from patient diaries and weekly visits during catheterization for up to 30 days. The primary composite endpoint assessed four outcomes: placement; post-void residual volume (PVR) of 75 mL or less; adverse device-related events requiring early removal; and removal.

Results—Nine of 23 patients met all four criteria: 8 of 18 non-neurogenic (7 / 11 prior Foley users and 1 / 7 without Foley experience), and 1 of 5 neurogenic (SCI) patients. Secondary outcomes in non-neurogenic patients included: 17 / 18 successful insertions; of these, 16 / 17 average PVR of 75 mL; successful valve openings and closings 95% of more than 1400 voids; minimal leakage. Four of five SCI patients discontinued within 7 days. Cystourethroscopy after removal revealed no marked inflammation or mucosal changes.

Conclusions—This pilot study demonstrated the BMS is potentially useful, convenient, and safe for appropriate patients. A follow-up study will better define the characteristics of patients who benefit from this device and examine whether the use of antimuscarinic agents improves outcomes.

INTRODUCTION

The invention of the Foley (indwelling) catheter in the 1930s permitted closed-bladder drainage and transformed bladder management in men with urinary retention. However, apart from improved materials and manufacturing standards, little has changed in catheter design, and the Foley catheter remains a compromise solution that is socially inconvenient¹, prone to encrustation², blockage¹, and urinary tract infections (UTI)³.

External catheter valves are an alternative to a leg bag for some patients with indwelling catheters. Several types are available in the UK, but their performance differs greatly. While patients generally prefer the valve to the leg bag, the incidence of discomfort, bladder spasm, and UTI is similar, and increased nocturnal frequency and urgency have been reported⁴.

Intermittent catheters, introduced in the 1970s, have reduced the need for long-term indwelling catheters⁵. However, these require acceptance and manual dexterity by the patient, require up to 20 minutes to complete a void, and are socially awkward to use away from home⁶. Additional complications reported with intermittent catheterization use after spinal cord injuries include epididymitis (28%), urethritis (18%), and prostatitis (33%)⁷.

Another option for long-term drainage is suprapubic catheterization. A recent review concluded that suprapubic catheters are associated with a low incidence of urethral injury and stricture, but have similar rates of upper tract damage, vesicoureteral reflux, renal or bladder calculi, and urinary tract infections compared to urethral catheters. No studies addressed stoma or skin care or health-related quality of life⁸. Additionally, no well-conducted randomized clinical trials have assessed different catheter types in management of neurogenic bladder⁹.

Several internally valved catheters have been patented during the last 30 years, but none has been approved for use by men to date¹⁰. A temporary prostatic stent is marketed in Europe for men with bladder outlet obstruction (BOO) to reduce elevated post void residual (PVR) and improve voiding symptoms, but it does not contain a valve and requires control of the external sphincter for control of urine flow¹¹.

The CymActive Intraurethral valved-Catheter is self-retaining and allows cyclical bladder filling and emptying, without an external appliance.

Ingenion Medical obtained European marketing approval (EC Certificate of Conformity) for the CymActive Bladder Management System (B.M.S.) in May 2014. Here, we report the results of a study assessing the clinical safety and effectiveness of this System.

METHODS

The institutional review board at each center approved the study. All patients gave written informed consent. Patient identities were kept confidential, and all data were de-identified for analysis and reporting.

Each center recruited patients according to the protocol (available from the corresponding author). Patients were compensated only for travel and incidental expenses. Payment to each

center was limited to usual fees and professional time with no incentives for recruitment. The principal investigator at each center was responsible for overseeing the study.

The study was funded by Urovalve, Inc. (a predecessor of Ingenion Medical Ltd), which received partial funding from NIH (Grant #R44HD039566).

The Bladder Management System

The CymActive B.M.S. consists of the CymActive Intraurethral Catheter (I.U.C.), pre-assembled on the CymActive Insertor (Figure 1), the CymActive Actuator magnet, and the magnetic UroValve. This second-generation system, developed by Urovalve, Inc., was formerly called Surinate¹².

The insertor enables the I.U.C. to be placed non-surgically (like a Foley catheter), through the urethra and into the bladder. The roughly diamond-shaped cage (self-retaining Malecot) engages the bladder neck to resist distal migration and creates a seal. The distal end of the catheter remains in the bulbous urethra, leaving a substantial portion of the distal urethra unaffected (Figure 2).

Research Design

In this prospective, non-randomized, open-label study, the I.U.C. was inserted and removed by trained investigators at each center. Prior to insertion of the I.U.C., a cystoscopic exam of the urethra and bladder was performed and the length of the urethra from the bladder neck sphincter to the junction of the bulbous and pendulous urethra was assessed using the cystoscope or by palpation during removal of an indwelling or intermittent catheter, following which the appropriate length I.U.C. (100 mm, 120 mm, or 140 mm) was selected and inserted. Men who had a history of prostatic or urethral surgery, required a continuously drained bladder, had bladder capacity less than 300 mL, or whose urethra from bladder neck sphincter to beginning of pendulous urethra was less than 101 mm or greater than 160 mm were excluded.

The study ran from the date of insertion until the date of removal at the end of the 30th day or earlier, if the system was no longer clinically necessary, the patient requested removal, or the system malfunctioned. The planned duration of catheterization was from 7 to 30 days.

Patients

The study planned to enroll 10 to 25 men at least 18 years old, who had acute urinary retention and needed catheterization. Two cohorts were to be enrolled: at least five men with urinary retention from non-neurogenic causes and at least five men with urinary retention from spinal cord injury (SCI) below C6.

Immediately after insertion of the I.U.C., the patient and his companion or aide were taught how to open the valve with the actuator magnet. After demonstrating this ability, the patient was sent home with two actuator magnets, an instruction guide, and an emergency phone number card. Anticholinergic or other spasmolytic agents were not recommended in the protocol. Patients returned for weekly follow-up visits as long as they used the I.U.C. Data collected at each office visit, in addition to those for the primary and secondary endpoints,

included vital signs, a urine dipstick test, a urine culture, and medication use. Patients also underwent a cystourethroscopic examination after the catheter was removed.

Patients were instructed to record in a daily diary how often and how well the valve worked and how much leakage, if any, they experienced, as well as any symptoms or difficulties with the use of the I.U.C.

Effectiveness and Safety Endpoints

The primary endpoint was a composite outcome of success with four parts:

1. **Proper initial placement of the I.U.C.** The UroValve is intended to be positioned in the bulbous urethra, close to the junction with the pendulous urethra (Figure 2). Proper placement was confirmed by one successful patient-controlled drainage during the office visit.
2. Successful emptying of the bladder at every follow-up visit. Defined as a post-void residual volume (PVR) of 75 mL or less, as estimated by bladder ultrasound (using a bladder scan).
3. Freedom from any adverse, device-related events that required premature removal of the I.U.C. Defined as removal because the I.U.C. was no longer clinically necessary or completion of 30 days.
4. **Successful removal of the I.U.C.** Defined as removal of the I.U.C. that was not associated with any adverse events.

The following secondary endpoints were evaluated at each office visit:

- Maintenance of adequate catheter position;
- Total PVR, as measured at each weekly visit by ultrasound;
- Maximum flow rates and time to peak flow;
- Diary records of whether the valve “opened well” and “closed well” at each valve actuation.
- Incidents of leakage, as recorded in patient diaries as “a little,” “a lot,” or “none,” assessed before and after each time the patient actuated the valve.

Patient-Reported Outcomes

After device removal, patients completed the Qualiveen-30 Quality of Life Questionnaire, a self-administered instrument validated for measuring health-related quality-of-life specifically in patients with neurogenic urinary disorders¹³.

Patients also indicated on 100-mm visual analog scales their overall satisfaction with the ease, comfort, and convenience of voiding with the catheter.

Statistical Methods

The study was not powered to detect a given difference in any endpoint. However, a sample of 25 had at least an 80% probability of detecting a serious adverse event if the incidence of the event was 7% or higher.

RESULTS

Of the 6 study sites, 5 enrolled a total of 23 patients. The first patient entered the study on May 4, 2010, and the last patient finished on July 7, 2011. Eighteen patients (17 non-Hispanic white and 1 Hispanic) were in the non-neurogenic cohort, and 5 (4 non-Hispanic white and 1 non-Hispanic black) were in the neurogenic cohort. Of the 18 non-neurogenic patients, 11 had used an indwelling catheter and 7 had used an intermittent or no previous catheter. All 5 of the neurogenic patients used intermittent catheters.

Median age for the 15 patients reporting it was 72 (range, 53 to 91) years. Median weight was 78.5 (range, 51 to 97.5) kg.

Results for the Primary Endpoint

Nine of the 23 patients were overall treatment successes, having met all four criteria for the primary endpoint: 8 of 18 non-neurogenic patients (7 prior Foley users and 1 without Foley experience), and 1 of 5 neurogenic (SCI) patients (Table I).

The I.U.C. was inserted successfully in 17 of 18 non-neurogenic patients and 5 of 5 SCI patients. It remained in the correct anatomical position for the duration of usage in 16 of 17 nonneurogenic and 3 of the 5 SCI patients. Distal migration that made valve actuation difficult occurred within the first week in 2 of 5 SCI patients and one non-neurogenic patient who had had a prior TURP and should have been excluded..

Sixteen of 17 successfully catheterized non-neurogenic patients, and the one SCI patient who continued for at least 7 days, had PVR of 75 mL or less throughout catheterization (Table I).

Seven of the eleven non-neurogenic patients who had experienced Foley catheters completed 4 weeks of catheterization without adverse events (AE). Two more used the I.U.C. successfully for at least 7 days. One of the seven non-neurogenic patients who did not have experience with Foley catheters completed 4 weeks without adverse events, and two more completed at least 7 days. One SCI patient completed 4 weeks of catheterization without AE. The other four discontinued before day 7 (two because of migration; one leakage; one bladder spasms).

There were a total of 33 adverse events reported. Fifteen patients reported at least one adverse event (11 non-neurogenic and 4 neurogenic). Thirteen patients were discontinued and had the IUC removed as a result of the adverse event. Two AEs (hyperkalemia and congestive heart failure) were recorded as serious. Both occurred in the same non-neurogenic patient, and were determined to be unrelated to the use of the I.U.C. Six adverse events were deemed to be definitely related to the I.U.C (leakage, bladder spasms, bladder

encrustation, migration – 3 times). No Serious AEs were determined to be possibly, probably, or definitely related to the I.U.C., and no unanticipated adverse device effects were reported (Table II).

The I.U.C. was removed uneventfully from all 23 patients. Cystourethroscopic evaluation of the urethra and bladder after I.U.C. removal showed only minimal inflammation.

Results for the Secondary Endpoints

Only one of the five SCI patients used the I.U.C. for more than 3 days. There were not enough data on secondary endpoints to allow meaningful analysis.

Results for the secondary endpoints in the non-neurogenic patients were largely positive (Table I). Median PVR was 17 mL (range, 0 to 178). Median peak urine flow rate, measured at catheter placement for 16 of the 18 patients, was 5.7 mL/second (range, 2 to 35 mL/second). Patients had little trouble opening and closing the valve and reported success at least 95% of the 1434 attempts. Patients reported leaking before opening as “a little” 8%, and “a lot” 1% of recordings; after closing as “a little” 31%, and “a lot, 1% of recordings (Table I).

Only 3 of 13 non-neurogenic patients who used the I.U.C. for 7 days or longer had bacteriuria that was possibly or probably related to the device. All three had used an indwelling Foley catheter before, and none were discontinued from the study because of UTI. None of the non-neurogenic patients who were not catheterized previously developed bacteriuria.

Patient-Reported Outcomes

Sixteen patients completed the Quality of Life assessment (zero [best] to 4 scale). The highest averaged median score was 1.4 (for bothered by limitations) and the highest maximum averaged value was only 2.6 (the frequency of limitations), indicating good acceptance of the I.U.C. (Table III).

Twelve of 16 patients would recommend the catheter to a friend, and 9 of 16 would use it again. The I.U.C. was preferred by 6 of the 11 patients who had experienced a Foley and by 8 of the 12 who had not.

Among the 15 patients who answered the overall satisfaction questions, the 9 who had experienced a Foley had median scores above 90 on all three questions. Among the 6 who had not experienced a Foley, median scores ranged from a low of 34 for overall satisfaction to 85 for comfort.

Examination of I.U.C's Post-Removal

Inspection of 24 devices revealed no encrustation that affected function of the valve. A kidney stone was found in the shaft of one I.U.C., but it did not affect function. The silicone coating on the valve seat of one I.U.C. was damaged and associated with leakage that resulted in early removal.

DISCUSSION

In this pilot study, 8 of 18 non-neurogenic patients met all four criteria for treatment success, indicating that the CymActive Bladder Management System can be functional, effective, and safe in helping men manage acute urinary retention from non-neurogenic causes. The one unsuccessful insertion was with the patient in the lateral position, rather than in the supine position, which may have contributed. The catheter remained in the correct anatomical position in all 17 of the patients catheterized successfully.

The limited data from the neurogenic cohort restricts the ability to draw conclusions about the I.U.C. for this patient population.

Factors Associated with Early Catheter Removal

The most common reason for not achieving treatment success was early removal of the I.U.C. Most patients who requested that the I.U.C. be removed early had never had an indwelling catheter and may have had unrealistic expectations. Similar reports of discomfort are also common among first-time Foley users. Patient education and pretreatment with antimuscarinic agents, such as oxybutynin and tolterodine¹⁴, should reduce this discomfort.

Problems with Catheters

Bladder discomfort related to catheterization occurs in about 58% of patients¹⁵. Patients with bladder outlet obstruction may be subject to neurologic denervation of the smooth muscles of the bladder because of prolonged increased intravesical pressure, which may lead to increased stimulation of afferent receptors, resulting in marked irritation¹⁶. Changes in the urethra and bladder found on cystourethroscopy in our patients were considered minimal.

Leaking around the I.U.C was not reported in any non-neurogenic patient, probably because of the integrity of the urethral sphincters. In one patient previously treated with intermittent catheterization, the catheter was removed on Day 8 because of leaking through the valve, which proved to be defective. The valve worked as designed in 95% of more than 1,400 voids, and leaks reported in diary entries were few and minor.

The mean PVR in patients with Foley catheters is 96 mL in intensive care units and 136 mL in hospital ward patients¹⁷. The mean PVR for our patients was 32 mL for those who had used a Foley catheter and 11 mL for those who had not. Foley catheters place the drainage orifice near the apical tip, above the balloon, and away from the bladder neck. Consequently, residual urine accumulates below the orifice. Tubing segments of the Foley can also coil and form air locks¹⁶. The reduced length of the CymActive I.U.C. makes coiling unlikely, and the Malecot, with the drainage orifice at the level of the bladder neck, enables more efficient passive drainage of the bladder.

Catheter-Associated Urinary Tract Infections

A major concern with any form of catheterization is the risk of CAUTI. There were 40,429 hospitalizations from indwelling urinary catheters alone in the USA in 2010, creating a “national bill” of \$1.3 billion, excluding costs for secondary diseases associated with the hospital stay; a 7-fold increase since 2001¹⁸. In the UK, UTI have been reported to

represent 40% of all hospital-acquired infections. Foley catheter use was associated with 80-90% of UTI, costing the NHS £110M in 1999¹⁹. A recent, large, randomized controlled clinical trial reported the incidence of symptomatic antibiotic-treated UTI was 12.6% after 1–3 days of indwelling catheterization and did not differ significantly with catheters coated with nitrofurantoin or silver alloy. Longer duration catheterization was associated with increased rate of CAUTI²⁰. CAUTI rates in SCI patients using intermittent catheterization for 5 years ranged from 1 UTI per year in 81% to 4 UTI per year in 12%⁷.

The incidence of UTI in 57 men originally treated with indwelling catheters for chronic urinary retention, who all had UTI, and were treated with antibiotics when their catheters replaced with intra-urethral stents for 3 to 16 months dropped to 16%²¹. Similarly, the CymActive catheter may reduce UTI risk because it is entirely contained within the urethra, thus preventing an ascending passage for pathogens.

Limitations of the Study

Major limitations of this study are due to sample size and the heterogeneity of the patients in terms of causality of urinary retention and previous experience with catheters. Four of the five SCI patients, all of whom were using intermittent catheterization, withdrew during the first week. This study could not accommodate the marked differences between these men and the 18 non-neurogenic men, 11 of whom had experience with indwelling catheters.

Another limitation was that urine cultures were obtained only if dipsticks were positive. A recent study suggests the dipstick sensitivity of leukocyte esterase and nitrate may be suboptimal²².

Conclusions

This pilot study demonstrated that the patient-controlled CymActive Bladder Management System is a potentially useful, convenient, and safe technology for managing urinary drainage in appropriate patients, particularly non-neurogenic patients who have had a positive experience with an indwelling catheter. A post-marketing clinical follow-up study is planned to better define the characteristics of patients who benefit from this device and to examine whether the use of antimuscarinic agents increases positive outcomes in patients who have not had experience with indwelling catheters. The incidence of urinary tract infections compared to SOC will be assessed in a RCCT.

References

1. Aaronson DS, Wu AK, Blaschko SD, McAninch JW, Garcia M. National incidence and impact of noninfectious urethral catheter related complications on the Surgical Care Improvement Project. *J Urol*. May. 2011; 185(5):1756–60. [PubMed: 21420117]
2. Stickler DJ, Young R, Jones G, Sabbuba N, Morris N. Why are Foley catheters so vulnerable to encrustation and blockage by crystalline bacterial biofilm? *Urol Res*. 2003; 31:306–11. [PubMed: 14574534]
3. Clec'h C, Schwebel C, Français A, Toledano D, Fosse JP, Garrouste-Orgeas M, et al. Does catheter-associated urinary tract infection increase mortality in critically ill patients? *Infect Control Hosp Epidemiol*. 2007; 28(12):1367–73. [PubMed: 17994517]
4. van den Eijkel E, Griffiths P. Catheter valves for indwelling urinary catheters: a systemic review. *Br J Community Nurs*. 2006; 11(3):111–4. [PubMed: 16607246]

5. Lapides J, Diokno AC, Silber SM, Lowe BS. Clean intermittent self-catheterization in the treatment of urinary tract disease. *J Urol.* 2002; 167:1584–6. [PubMed: 11912368]
6. Jamil F. Towards a catheter free status in neurogenic bladder dysfunction: a review of bladder management options in spinal cord injury (SCI). *Spinal Cord.* 2001; 39:355–61. [PubMed: 11464308]
7. Biering-Sørensen F, Nielans HM, Dørflinger T, Sørensen B. Urological situation five years after spinal cord injury. *Scand J Urol Nephrol.* 1999; 33:157–61. [PubMed: 10452290]
8. Hunter K, Bharmal A, Moore KN. Long-term bladder drainage: suprapubic catheter versus other methods: a scoping review. *Neurourol Urodyn.* 2013; 32:944–51. [PubMed: 23192860]
9. Jamison J, Maguire S, McCann J. Catheter policies for management of long term voiding problems in adults with neurogenic bladder disorders. *Cochrane Database Syst Rev.* 2011; 12:004375.
10. Davis, PJ.; Winegar, TW.; Homan, HD.; Leopold, AR. "System and method for implanting a catheter".. U.S. Patent Application No. 11/993,356 (Publication No. 2009/0157053)
11. Shore ND, Dineen MK, Saslawsky MJ, Lumerman JH, Corica AJ. A temporary intraurethral prostatic stent relieves prostatic obstruction following transurethral microwave thermotherapy. *J Urol.* 2007; 177:1040–46. [PubMed: 17296408]
12. Orris BG, Jahoda AE, Walter JS, Nemchausky BN, Wurzel R, Homan HD, Melloy S, Wheeler JS. A 24-hour feasibility study of intraurethral valved catheter for bladder management in males with spinal cord injury. *J Rehabil R&D.* 2008; 45(4):639–646.
13. Costa P, Perrouin-Verbe B, Colvez A, Didier J, Marquis P, Marrel A, et al. Quality of life in spinal cord injury patients with urinary tract difficulties. Development and validation of Qualiveen. *Eur Urol.* 2001; 39:107–113. [PubMed: 11173948]
14. Agarwal A, Dhiraaj S, Singhal V, Kapoor R, Tandon M. Comparison of efficacy of oxybutynin and tolterodine for prevention of catheter related bladder discomfort: a perspective, randomized, placebo-controlled, double blind study. *BR J Anesth.* 2006; 96:377–80.
15. Wein AJ, Rackley RR. Overactive bladder: a better understanding of pathophysiology, diagnosis and management. *J Urol.* 2006; 175:S5–S10. [PubMed: 16458739]
16. Garcia MM, Gulati S, Liepmann D, Stackhouse GB, Greene K, Stoller ML. Traditional Foley drainage systems--do they drain the bladder? *J Urol.* 2007; 177(1):203–7. [PubMed: 17162043]
17. May M, Brookman-Anissah S, Hoschke B, Gilfrich C, Braun K-P, Kendel F. Post-void residual urine as a predictor of urinary tract infection – is there a cutoff value in asymptomatic men? *J Urol.* 2009; 181:2540–4. [PubMed: 19375097]
18. Colli, J.; Walls, K.; Dunn, E.; Tojuola, B.; Aranmolate, S. *J Urol.* Vol. 189. 4 Supplement: 2013. WakeR. Hospitalizations due to indwelling urinary catheters, 2001-2010.; p. e56
19. Plowman, R.; Graves, N.; Griffin, N.; Roberts, JA.; Swan, A.; Cookson, BD., et al. Socioeconomic burden of hospital-acquired infection. Public Health Laboratory Service; London: 2000.
20. Pickard R, Lam T, MacLennan G, Starr K, Kilonzo M, McPherson G, et al. Antimicrobial catheters for reduction of symptomatic urinary tract infection in adults requiring short-term catheterisation in hospital: a multicentre randomised controlled trial. *Lancet.* 2012; 380:1927–35. [PubMed: 23134837]
21. Nissenkorn I, Lobik L. An intraurethral mini-catheter for prevention of indwelling catheter-induced morbidity and mortality in aging male. *Curr Urol.* 2009; 3:185–9.
22. Khasriya R, Khan S, Lunawat R, Bishara S, Bignall J, Malone-Lee M, et al. The inadequacy of urine dipstick and microscopy as surrogate markers of urinary tract infection in urological outpatients with lower urinary tract symptoms without frequency and dysuria. *J Urol.* 2010; 183:1843–7. [PubMed: 20303096]

Figure 1.

A. The CymActive™ I.U.C. is a soft, thin walled, silicone intraurethral catheter with a relatively large lumen. Laboratory tests of the I.U.C. (hydrostatic pressure of 40 cm water) measured a flow rate of about 6.4 mL/sec, a rate similar to those measured under identical conditions for commercial intermittent catheters (Mentor Self-Cath 12 Fr = 7.3 mL/sec; Kendall Dover red rubber 16 Fr = 6.31 mL/sec).

Figure 1B. The CymActive™ I.U.C. is packaged locked onto an integrated **Inserter** that mirrors the process for inserting a Foley catheter. When the I.U.C. is in place, the Inserter is disengaged and removed.

Figure 2.

A Malecot retains the CymActive I.U.C. in the bladder and a magnetic valve (**UroValve™**) at the distal end controls urinary flow. The one moveable piece in the valve is a samarium cobalt magnetic sphere that is held to the valve seat by attraction to a ferrous ring. The patient holds the Actuator magnet near the scrotum to open the valve, and moves the actuator magnet away to allow the valve to close. Extraction tethers at the distal end of the catheter may be allowed to extend beyond the tip of the penis for easy removal or may be trimmed to end inside the penile meatus. (Image © 2010 Golgeon Group, Inc.).

Table I

Primary and Secondary Outcomes of the CymActive Bladder Management System in 18 Men with Non-Neurogenic Acute Urinary Retention

Outcomes	Values
The primary endpoint	
Success in all 4 parts of the primary composite endpoint, n/N	8/18
Proper placement of the catheter	17/18
Post-void residual volume ≤ 75 mL	16/17
Removal unrelated to adverse events	9/17
Successful removal of catheter	17/17
The secondary endpoints	
Post-void residual volume, median (range), mL	17 (0 to 178)
Peak flow rates (Qmax), median (range), mL/sec	5.7 (2 to 35)
Valve activation success rates, No. successes/No. attempts (%)	1367/1434 (95)
Valve closing success rates, No. successes/No. attempts (%)	1378/1434 (96)
Incidence of leakage before actuation, No. leaks/No. voids (%)	
“a little” (14 patients)	114/1434 (8)
“a lot” (14 patients)	15/1434 (1)
Incidence of leakage after actuation, No. leaks/No. voids (%)	
“a little” (14 patients)	439/1434 (31)
“a lot” (14 patients)	17/1434 (1.2)

Table II

Adverse Events in 18 Men with Non-Neurogenic and 5 Men with Neurogenic Acute Urine Retention Using the CymActive Bladder

Adverse event	Number of Occurrences	AE / SAE*	Relationship to Device				Removed because of AE
			Unrelated	Possible	Probable	Definite	
Hyperkalemia	1	SAE	1				0
Congestive Heart Failure	1	SAE	1				0
Device Migration - Patient unable to actuate valve	2	SAE				2	2
Full thickness wound deterioration (left ischial area)	1	AE	1				0
Bladder spasms	3	AE			3	0	3
Frequency and Urgency	3	AE		1	2	0	2
Clinically significant UTI	4	AE	1	2	1		0
Bacteriuria	1	AE		1			0
Dysuria	2	AE		1	1		0
Urethral irritation	1	AE			1		0
Hematuria	3	AE		1	2		0
Penile pain	1	AE			1		0
Penoscrotal pain	1	AE			1		1
Perineal discomfort	1	AE			1		1
Catheter discomfort	1	AE			1		1
Penile tip irritation	1	AE		1			0
Anemia	1	AE	1				0
Elevated blood pressure	1	AE	1				0
Constipation	1	AE		1			0

Table III

Patient-Reported Outcomes in 18 Men with Non-Neurogenic and 5 Men with Neurogenic Acute Urine Retention Using the CymActive Bladder Management System

Outcome	History of Foley use	No history of Foley use
Qualiveen-30 quality of Life score, median (range)^a (n=16)		
Overall	0.8 (0.2 to 1.4)	1.2 (0.9 to 1.7)
Bothered with limitations	1.0 (0 to 2)	1.4 (0.5 to 1.9)
Frequency of limitations	1.2 (0 to 2.6)	1.2 (0.7 to 2.6)
Fears	0.5 (0 to 1.25)	0.9 (0.1 to 1.9)
Feeling	0.6 (0 to 1.4)	1.3 (0 to 1.6)
Overall satisfaction Score, median (range), mm^b (n=15)		
Overall satisfaction	69 (13 to 99)	31 (0 to 65)
Ease of emptying	75 (24 to 100)	63 (18 to 98)
Comfort	85 (24 to 100)	65 (13 to 94)
Convenient	80 (25 to 100)	70 (22 to 100)

^aScores range from zero to 4. Lower scores indicate better quality of life.

^bMeasured on a 100-mm visual analog scale. Higher scores indicate greater satisfaction.