392

Homan H[1], Dmochowski R[2], Cochran J[3], Karsh L[4], Sherman N[5], Yalla S V[6]
1. *Ingenion Medical Limited,* ***2.*** *Vanderbilt University School of Medicine,* ***3.*** *Urology Clinics of North Texas,* ***4.*** *The Urology Clinics of Colorado,* ***5.*** *Premier Urology Group,* ***6.*** *Harvard Medical School*

SAFETY AND EFFICACY OF A PATIENT-CONTROLLED BLADDER MANAGEMENT SYSTEM FOR TREATING URINARY RETENTION IN MEN

Hypothesis / aims of study:
A novel intra-urethral catheter (IUC) has been developed that is self-retaining and employs a patient-controlled magnetic valve that allows the bladder to fill normally and to be emptied on demand, without external appliances. The sterile and disposable catheter can remain in the lower urinary tract for up to 30 days. It is inserted through the urethra and held in place in the bladder by a self-retaining Malecot. To void, the patient holds a small "actuator magnet" near the base of the penis, allowing urine flow (Figure 1). Withdrawing the actuator magnet allows the valve to close. Several of the design features of the IUC were demonstrated to be effective in an earlier study (1). This study evaluated the current improved version of the IUC in men with acute urinary retention.

Study design, materials, and methods:
We enrolled18 men, at least 18 years old, who had acute urinary retention from nonneurogenic causes in a multicenter, prospective, non-randomized, open-label study. Men who required continuous bladder drainage or had a documented bladder capacity of less than 300 mL were excluded. Data were collected from patient diaries and from weekly follow-up visits during catheterization for up to 30 days. The primary endpoint was success in all of four conditions: proper placement of the catheter, uneventful removal, a post-void residual volume of 75 mL or less, and no adverse device-related events. Secondary outcome measures included Quality of Life assessment (2).

Results:
Of 18 men were enrolled (median [range] age 72 [53 to 91] years; weight, 78.5 [51 to 97.5 kg]). Summary results are shown in Table1. Cystoscopy after catheter removal showed no clinically important inflammation or other mucosal changes. Patient satisfaction was self-evaluated as "excellent".
Interpretation of results: The catheter is safe, effective, and well tolerated in men with acute urinary retention from non-neurogenic causes.

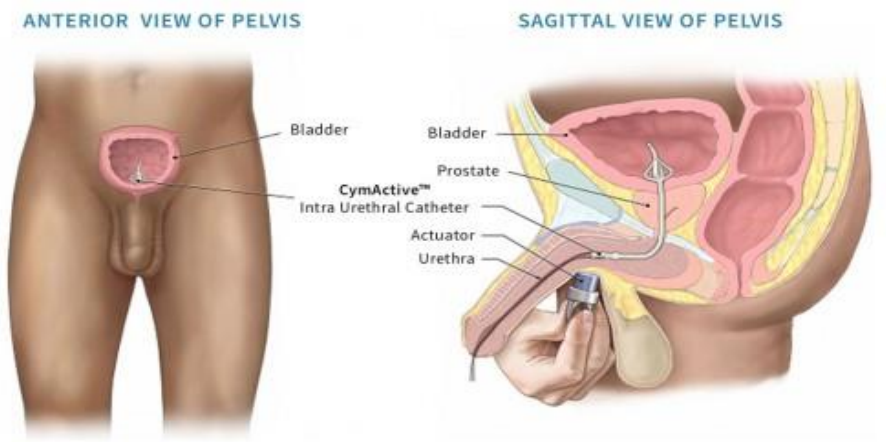
Concluding message:
This novel IUC is an attractive alternative to Foley catheters and intermittent catheterization. Its use is not complicated by encrustation, infection, or blockage, and it does not require fastidious hygiene. Its simplicity of use, comfort, social acceptability, and ease of replacement all favor patient acceptance and adherence.

Table 1. Safety and Efficacy Outcomes of a New Bladder Management System in 18 Men with Non-Neurogenic Acute Urinary Retention

Variable	Value [a]
Enrolled, n/N	18
Completed the protocol, n/N	8/18
Discontinued, n/N	10/18
Unable to insert	1/18
Catheter not functioning	0
Adverse event	8/18
Consent withdrawn	0
Success in all 4 parts of the primary endpoint, n/N	8/17
Proper placement of the catheter	17/18
Post-void residual volume ≤ 75 mL	16/17
Freedom from adverse events	9/17
Successful removal of catheter	17/17
Catheter position adequately maintained, n/N	17/17
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) [b]
Valve closing success rates, No. successes/No. attempts (%)	1378/1434 (96) [b]

[a] Catheterization was unsuccessful in 1 patient, so the sample size is 17, unless otherwise indicated
[b] The discrepancy between the number of valve actuations and closing is the result of missing data.

Figure 1. The Intra Urethral Catheter is held in place in the bladder by the malecot and a magnetic valve in the distal end blocks urinary flow until it is opened by the patient holding an actuator magnet near to the scrotum.



References
1. Orris BG, Jahoda AE, Walter JS, et al. 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
2. Bonniaud V1, Bryant D, Parratte B, Guyatt G. Development and validation of the short form of a urinary quality of life questionnaire: SF-Qualiveen. J Urol. 2008 Dec;180(6):2592-8

Disclosures
Funding: This study was funded by Urovalve, Inc., with partial funding from NIH Grant #5R44HD039566-3 **Clinical Trial:** Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Western Institutional Review Board (WIRB) **Helsinki:** Yes **Informed Consent:** Yes