Urology Case Reports 26 (2019) 100947

Contents lists available at ScienceDirect

Urology Case Reports

journal homepage: www.elsevier.com/locate/eucr

Functional medicine

The Connected Catheter for management of Chronic Urinary Retention (CUR) in an adult male with Neurogenic Bladder – Case study

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ABSTRACT

Millions of adults suffer from chronic urinary retention or disorders that require catheterization for bladder management. The current standard of care for these patients consists of three different methods of catheterization, all of which present varying levels of infection, urethral trauma, and patient discomfort or inconvenience. We studied a 34 -year-old man with chronic urinary retention, frequent urinary tract infections and strictures, with a fully internal, extended use, wirelessly controlled catheter system. This new system was designed to improve overall Quality of Life and potentially decrease the rate of catheter associated clinical complications.

Introduction

Every year in the US, a total of roughly 30 million urinary catheters are used by over 5 million adults who suffer from urinary symptoms or disorders that require catheterization to empty the bladder.[1] As a result, the medical complication rates and corresponding costs associated with current standard-of-care urinary catheters are enormous. The CDC estimates that approximately 560,000 hospital-acquired urinary tract infections (UTIs) occur annually incurring an estimated $0.4 - $0.5 Billion in medical costs.[2–5] Furthermore, the need to manage the bladder via chronic catheterization imposes a dramatic burden on quality of life (QoL).

Case presentation

A 34-year-old man presented for screening with a history of a T6 ASIA-A spinal cord injury (SCI) requiring spinal surgery, who experienced urinary retention, frequent urinary tract infection, urethral strictures with an existing penicillin allergy. The subject was using intermittent catheters for bladder management for approximately 6 years since his injury. The subject was non-ambulatory and utilized a wheelchair for mobility. Urinalysis and urine culture tested negative for ongoing urinary tract infection. After use of an intermittent catheter, a baseline post-void residual volume (PVR) of 12 mL was measured using a portable ultrasound bladder scanner. On the Baseline Spinal Cord Injury Quality of Life measurement system (SCI-QOL), subject expressed his frustration and worries with bladder accidents. He stated that bladder accidents limited his independence and performing a bladder program in the restroom with intermittent catheters made him anxious and uneasy. The subject also communicated dissatisfaction associated with the burdensome routine of using Intermittent catheters.

A week after the screening visit, the subject underwent an Index Insertion with the Connected Catheter. The Connected Catheter System (Fig. 1) is a fully internal, wirelessly controlled urinary prosthesis designed to dramatically improve the quality of life (QoL) for males with urinary retention disorders, and to lower the incidence of catheter-associated medical complications such as urinary tract infections (UTIs) and genito-urinary trauma. The Connected Catheter resides fully internal to the male lower urinary tract (LUT), with its distal end in the mid-penile urethra. The distal Catheter tip incorporates a magnetic valve-pump which opens and closes via remote control and enables the bladder to fill naturally. The user controls voiding by using a hand-held wireless controller. The catheter enables users to empty their bladders comfortably and conveniently without frequent catheterization or an external drainage apparatus.

The insertion was reportedly easy compared to any standard catheter and was free of complications. No discomfort was experienced by the subject. The subject underwent acute assessment to evaluate the retention of the Connected Catheter in the lower urinary tract by performing a set of mobility maneuvers such as wheeling over ground, chair-to-bed transitions and seated to supine transitions. There were no instances of the catheter breaching during mobility maneuvers. Following the acute retention assessment, the subject remained at the study site and instructed to drink fluids until voiding urgency was felt. During this bladder filling period, the subject was encouraged to consume adequate fluids. The subject completed a single void cycle using the controller, and a post-void volume (PVR) of 52 mL was measured and recorded. During the void cycle, the subject was able to achieve and sustain the flow of urine. There was no visible presence of blood in the urine. Furthermore, the subject was free from significant urinary

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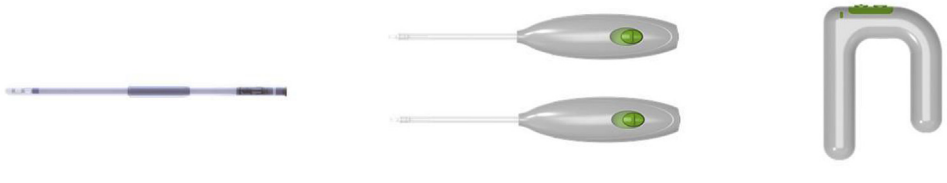
https://doi.org/10.1016/j.eucr.2019.100947
Received 21 May 2019; Accepted 14 June 2019
Available online 15 June 2019



a) b) c)

Fig. 1. a) Connected Catheter (1), Long flexible tube with magnetic valveb
b)Insertion/Removal Tool (2), Also known as "IR Tool", a single-use device used to insert or remove the Connected Catheterc
c)Controller (1/year), Controls unlocking and locking of the valve.

Table 1
Post-void residual volumes.

Post-void Residual Volume (PVR)	
Time	Volume (mL)
Baseline	12
Index	52
Month 1	26
Month 2	15
Month 3	11

incontinence 30 minutes after voiding. Prior to discharge, the subject completed the Connected Catheter User Experience Survey where he expressed confidence, ease and satisfaction in all areas of essential performance such as insertion, voiding and retention. He expressed satisfaction with the comfort, simplicity and convenience associated with the Connected Catheter.

The subject was discharged from the study site for an Extended Home Use Period with the Connected Catheter inserted and scheduled for the three-monthly office visits. During the Connected Catheter Home Use Period, the subject managed his bladder using the Connected Catheter (via controller) on an intermittent voiding strategy. At monthly office visits, post-void residual (PVR) was measured and the current Connected catheter was replaced with a new Connected Catheter. PVR recorded at month 1, month 2, and month 3 office visits were 26 mL, 15 mL and 11mL, respectively (Table 1). Visual and Tactile assessment during office visits revealed absence of catheter migration thereby indicating acceptable catheter retention and positioning. Urine cultures performed at months 2 and 3 detected bacterial colonization in the absence of clinical symptoms. Although the subject was diagnosed with asymptomatic bacteriuria, there were no symptoms that could be attributed to bacteria in the urine. During the 3rd office visit, the final Connected Catheter was removed, and the subject returned to his intermittent catheter routine. Follow-up phone calls were performed for an additional 2 weeks to inquire about the potential occurrence or persistence of lower urinary tract symptoms that may be related to the Connected Catheter usage. No signs or symptoms suggestive of UTI were reported by the subject.

Discussion

The subject expressed overall satisfaction and tolerance during the observation period. With the catheter residing fully within the body, the subject was able to empty his bladder comfortably and conveniently without frequent catheterization and without the need for an external drainage apparatus. Additionally, over time, the PVR values reduced suggesting the subject became more comfortable and confident utilizing this new bladder management system. A catheter designed in this manner holds the potential to both significantly improve urologic QoL for its users and to reduce the rates (and associated medical expenses) of common clinical complications, including UTI and trauma. Further, the Connected Catheter may significantly reduce the ongoing cost of supplies compared to clean intermittent catheterization. Finally, the subject reported a significant improvement in his quality of life for bladder management with Connected Catheter compared with his previous method of catheterization.

Conclusions

The Connected Catheter System use for bladder management in an adult male with neurogenic bladder produced acceptable post-void residual volumes and showed promise to improve the QoL. Additional studies are warranted to determine the long-term safety and effectiveness.

Acknowledgments

Funding for this research was provided by Spinal Singularity, Inc., San Clemente, California

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.eucr.2019.100947.

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