

The Bladder-Button: a supra-pubic bladder insert combined with FES

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Abstract

Reynard's self-retaining balloon urinary catheter, introduced in 1853 and improved by Foley 80 years ago, has undergone little change in basic design and is still the most widely used for bladder drainage. Long-term indwelling catheterisation is associated with high morbidity. Bacterial infection often occurs within one month, recurrent catheter blockage in 50% and leakage of urine in over 30% of cases. Here we propose a new alternative and indicate the design issues. The new device combines suprapubic access to the bladder with FES - the Bladder-Button. The prototype provides a more cosmetic alternative, which may be less prone to blockage. The device also incorporates sensors that are used to provide; a trigger for conditional neuromodulation. In addition these sensors can provide feedback to the patient on bladder status, warning of high pressures and may provide ambulatory diagnostic information.

1. INTRODUCTION

Although intermittent self-catheterization has been shown to be the optimal method of bladder drainage, for many it is distasteful or difficult to perform routinely. Particularly in older women where atrophy of the pelvic organs may lead to the urethral meatus receding from view along the vaginal wall. In neurological disorders like SCI and MS adductor spasticity of the legs may impede urethral catheterization. Recent innovations include intraurethral inserts, such as the In-Flow system, and Neuromodulation. The In-Flow insert is suitable for women with areflexic bladders, good dexterity and able to sit on a toilet - complications include discomfort and migration of the device into the bladder. Neuromodulation, using electrical stimulation, is an exciting new drug-free treatment option for the overactive bladder – detrusor hyperreflexia (DH). This involves stimulation of the sacral or peripheral nerve afferents. For example, the applicants have demonstrated non-invasive surface electrode stimulation of the posterior tibial nerve to provide treatment for DH, Andrews & Reynard (2003). Neuromodulation appears to be most effective in the neurogenic bladder when applied in brief

bursts coinciding with the onset of each reflex bladder contraction Dalmose et al 2003. However, this “conditional modulation” technique has not yet been adopted clinically because of the lack of a practical trigger signal. Furthermore, electrical neuromodulation does not address the problem of detrusor-sphincter-dysnergia (DSD), which is common in neurogenic bladders. The indwelling Foley catheter and “Bladder Button” described below address DSD and the retaining balloon may be configured as a bladder pressure sensor to provide a trigger for conditional neuromodulation.

Long-term indwelling catheters (LTC) for many offer a drug-free option for a range of conditions ranging from prostatic retention to stress incontinence to both DH and DSD. In the UK approximately 9% of nursing home residents are managed with LTC, McNulty et al. 2003. LTC is associated with a high morbidity. The bladder will normally be colonised by bacteria within one month; recurrent catheter blockage will occur in 50% and leakage of urine around the catheter in over 30%. Over-distension of the bladder or a raised intravesical pressure, as occurs when a catheter blocks in the presence of infected urine, provokes a serious threat of systemic infection and septic complications. Bladder infection accounts for the majority of complications such as bladder stones, pyelonephritis, epididymitis, periurethral abscess and septicaemia. Catheter-associated urinary tract infections are the most common cause of nosocomial or hospital-acquired infection.

There are distinct advantages of the abdominal (suprapubic) over urethral access to the bladder, particularly for the older: where urinary retention or voiding problems due to prostatic obstruction or urethral stricture; for women with neuropathy who would otherwise be forced to sit on the catheter which can cause pressure sores or erosion of the bladder neck and urethra; for those or who have lack of mobility or restricted hip movements due to arthritis that prevents ease of achieving the required postural changes; those who are sexually active; many older women have difficulty with urethral catheters as indicated above. Furthermore, the supra-pubic approach

has an associated high level of satisfaction and improved quality of life (Sheriff et al. 1998).

Recently, the catheter valve (Figure 1 (b)) has been shown to be an alternative to the conventional leg bag (Figure 1(a)). The catheter valve is a small device, similar to a leg bag tap that connects to the catheter outlet. Potential advantages are: they offer a more discreet arrangement; may help to retain bladder tone; allows the bladder to fill and empty normally; the intermittent flushing action can help reduce/delay the build-up of encrustation in Foley catheters (Sabbuba et al. 2005). However, in prescribing these valves it is essential that the user have good manual dexterity, as the valve must be released regularly to prevent over distension of the bladder – this will also require good cognitive function to comply with the timing schedule. These devices are inappropriate for people with inadequate bladder capacity or uncontrolled detrusor overactivity. In a group of 100 older male and female subjects the authors reported that catheter valves were extremely acceptable to the patients with no increased infection rate when compared in a randomised controlled trial (RCT) with leg bags Lewington et al. 1989. In another RCT, Rowley et al 1995 found the valve to be more comfortable when walking and enabled “more natural voiding”. However the valve gave rise to more nocturnal frequency and episodes of urge incontinence, concluding the optimal management would be the valve by day and the bag by night.

2. METHODS - design

The Bard gastrostomy button has been used to allow urodynamic evaluation prior to vesicostomy closure in three children aged 2.5 – 10years, one boy with prune belly syndrome and two girls with cloacal anomalies, Badiola et al. (1996). The devices were used for periods up to 4 weeks without any encrustation or lithiasis or urinary infection. The same device was also used to provide intermittent bladder drainage in a group of 19 spinal cord injury patients with areflexic bladders for periods up to one year. In 10 cases the device failed and required removal mainly due to inadequate fit to the stoma length; the distance from skin to bladder was too long for the range of devices available. In the other 9 there was an improvement in the quality of life and although the infection rate was 100% the rate of symptomatic infection was low with a low incidence of encrustation and absence of

bladder stone. In our opinion, the Bard Button could be improved if it were available in an extended range of sizes, although ideally this should be customisable.

However, since the shape of the bladder insert needs to be small, to allow insertion through the stoma into the bladder, its surface area, in contact with the bladder, may lead to high interface pressure and mucosal erosion. Furthermore, the one-way access flap-valve is situated at the end of the 3-4 cm stoma tube, which may act as a nidus for infection.

3. RESULTS

We have based our design on a type of gastrostomy insert that features an inflatable retaining balloon as shown in figure 1(c). This provides a better low-pressure seal at the bladder balloon interface, in a similar way to the Foley balloon. The size of the balloon can be adjusted to obtain a reliable leak-free seal with correct sizing to the stoma length and diameter. Furthermore, the access valve is located on the outside thus eliminating the potential nidus for infection in the Bard design and is more accessible for routinely cleansing. The only reported urological application for this type of device was to provide temporary occlusion for vesicostomy in 9 children with non-neuropathic bladders for periods up to 28 months (Cobussen-Boekhorst et al). 2003. Interestingly, no blockages were reported and only two cases of symptomatic urinary tract infection occurred, which were quickly resolved with antibiotic treatment.



Figure 1(a)



Figure 1(b)



Figure 1(c)

Figure 1: (a) Indwelling catheter with leg bag
(b) Foley catheter and valve (c) Bladder Button

4. DISCUSSION AND CONCLUSIONS

The low-profile, self retaining balloon gastrostomy button offers an alternative to the suprapubic indwelling Foley catheters for areflexic bladders that is worth further investigation. The water filled retaining balloon also provides a convenient environment for a pressure transducer. This pressure signal closely correlates with the intravesical pressure measured directly. This signal can be wirelessly transmitted and used in a number of ways, for example, to warn of unsafe high pressures,

particularly in cases involving bladders with poor compliance or over activity. The device is more discreet and appears to be less prone to blockage. In the neurogenic bladder the problem of DSD difficult to control using FES but is avoided in the proposed approach. The problem of DH can be reduced using either Botulinum or neuromodulation. In our presentation we outline preliminary findings using a version of the Bladder-Button that provides a trigger source for conditional neuromodulation for detrusor hyperreflexia.

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