Managing urinary incontinence with BioDerm® external continence device

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Urinary incontinence (UI) is a common problem, experienced by both men and women, and has a significant impact on quality of life. For male patients, UI can be caused by a number of conditions, including post-prostatectomy, neurogenic problems (such as Parkinson’s disease, multiple sclerosis and spinal cord injury), dementia, and an overactive bladder. One way of managing male UI is through the use of urinary sheaths – containment devices which capture the urine that is voided involuntarily. This article discusses male UI and its management, looking at common problems encountered when using urinary sheaths. It goes on to describe BioDerm®, a new type of continence device that could meet the needs of some groups of men, and is an alternative to the previously used external condom catheter-based system of urinary drainage.

Key words: BioDerm ■ Continence ■ Urinary incontinence ■ Urinary sheath

Male UI

Unlike female UI, male UI has not, as yet, been formally appraised by the National Institute for Health and Clinical Excellence, although there is likely to be guidance in the near future.

Epidemiological studies on UI in males are scarce when compared with the large number of studies in women. A large study (Diokno et al, 2007) describes the prevalence of UI among community dwelling men in the United States. The study found that 12.7% of men with a mean age of 50 years (+/-15.2 years) reported symptoms of UI in the previous 30 days, which correlates with earlier prevalence described by the Royal College of Physicians (RCP, 1995) in the UK of 7–10% of men over the age of 65 years experiencing UI. These problems increase with age with urinary urge incontinence being the predominant form. In another study, Umlauf and Sherman (1996) reported that up to 29% of older community-dwelling men report uncontrolled urine leakage.

These statistics highlight the large number of men who can suffer from UI and who may benefit from the use of urinary containment devices. Whereas for women a sheath system is inappropriate, and they have to resort to pads, for men a sheath collection system is far more likely to be the appropriate containment device.

Male patients can suffer from UI for a number of reasons. In males, these include:

- Radical prostatectomy
- Neurogenic problems, such as Parkinson’s, MS, stroke and spinal cord injury
- Dementia
- An overactive bladder.

UI post-prostatectomy

Radical prostatectomy results in greater persistence of urinary dysfunction than other forms of prostate cancer treatment due to bladder neck sphincter incompetence caused by the surgery, and can create high levels of bother associated with treatment outcomes (Weber et al, 2007). However, following any form of prostate surgery, patients can have varying degrees of UI that can affect their life both physically and socially (Hampel et al, 2004).

Although pelvic floor exercises can be used in the treatment of post-surgical UI their effect has not been proved to be greatly beneficial, with the studies investigating the effect of pelvic floor exercises being of poor or moderate quality (Hunter et al, 2007).

Although Hunter et al (2007) found from their systematic review that external penile clamps may be the most effective method of treatment, for men with problems with the external urethral meatus, such as stenosis, the BioDerm® system may offer an alternative.
beneficial management option for the post-prostatectomy patient, there is also a place for a well fitting urinary sheath, especially as there are problems associated with using clamps, such as necrosis of the penis.

Neurogenic UI
Patients with MS, Parkinson's disease and those who have strokes or spinal cord lesions can suffer high levels of UI due to the neural and spinal control inherent in maintaining continence. The prevalence of lower urinary tract symptoms in patients with Parkinson's ranges from 27% to 42% (Araki et al, 1996; Hennessey et al, 1999; DasGupta and Fowler, 2003); in patients who have had spinal cord injuries over 50% (Pagliacci et al, 2007), and in strokes 40%, with 10% still having symptoms at 2 years after the event (Patel et al, 2001).

In all these conditions the patient can have spontaneous UI and detrusor hyperreflexia concurrently. This means that although they might suffer from UI, their bladder does not empty to completion and they either have to undergo intermittent catheterization or wear a permanent indwelling catheter. As yet it has been difficult to source a urinary sheath that allows for the easy insertion of a catheter for intermittent catheterization.

Incontinence with dementia
Incontinence in older people is a huge problem, with the majority of patients residing in care homes, and who have dementia, suffering UI. This is difficult to manage and treat, and in the majority of cases, unless staffing numbers are sufficient to allow for toileting regimens, management comes in the form of containment devices. In the author's experience, most men with dementia will not tolerate a urinary sheath and will often pull it off; thus, using a sheath with this patient group is often not an option.

Overactive bladder
The symptoms of an overactive bladder include: voiding frequency more than 6–7 times during the daytime, urgency of micturition, urge incontinence and nocturia (more than once a night). It can be related to a neurological disability, obstruction due to an enlarged prostate and can also present in men with dementia; however, it can be idiopathic in nature.

In the majority of instances patients can be managed with conservative treatments, such as bladder retraining and drug treatment. However, if the patients have marked UI, a urinary sheath is often the preferred option, rather than wearing a pad.

Assessing the use of urinary sheaths
Urinary sheaths are under-used by health professionals in the management of male UI. There are a number of reasons for this, but they include the fact that nurses are not routinely taught about them when training, and that their knowledge, once trained, remains poor. In addition, urinary sheaths are associated with a number of common problems, such as that they are found to be difficult to fit and have a propensity to leak and fall off (Table 1).

Like the vast majority of medical devices, there is scant evidence on the effectiveness of the majority of urinary sheaths due to lack of research being undertaken/financed by product companies and a dearth of interest in financing such research by government agencies. This has led to the problem that there is a multiplicity of products on the market with little or no evidence to help the clinician evaluate and choose the one most suitable for their patient group, or even one that is effective.

Two studies show the glaring difference in the types of research that have been carried out. Pemberton et al (2006) undertook a study, financed by the manufacturer, comparing the company's new urinary sheath and the long-established product. This found the new variety to be more effective than the older product. However, this was an intrinsically-biased study that would only shift use of one make of company product to a newer, more expensive one.

A far more robust crossover study (Fader et al, 2001) was carried out by a group of researchers from what used to be the Medical Devices Agency research consortium (long-disestablished). The study evaluated six different self-adhesive urinary sheaths that were available on prescription within the UK in September 1998. The researchers found substantial differences between products in their general performance and ergonomics, and for the frequency of detachment, which was recorded by a diary. One sheath was particularly successful while another was particularly unsuccessful when compared with the other sheaths. Sheaths with no applicators were preferred to those with applicators. Applicators are mainly designed to make sheaths easier to put on, especially for carers; however, the researchers found no evidence that...
carers preferred applicators. The researchers made a comment that this evidence on applicators might have implications for manufacturers – it did, and the sheath that used an applicator was quickly withdrawn from the UK market and newer sheath systems have not been manufactured with applicators.

Unfortunately there have not been any other studies carried out since the Fader study evaluating different types of urinary sheaths. The means that the evidence base for nursing staff to use when choosing a sheath is distinctly lacking.

**Education and training**

There has generally been a lack of systematic education of the nursing workforce on how to select the appropriate urinary sheath for a patient, and even more importantly on how to fit a sheath. It is not unusual to walk into a ward or into a patient’s home, having been asked to see the patient because his urinary sheath keeps falling off, only to find out that he has the largest one feasible fitted to his penis. This often results from an inaccurate assumption that ‘one size fits all’, a totally inaccurate assumption by a number of nursing staff, and because the patient has not been fitted for size using a sizing device.

Another reason for a urinary sheath not being sized accurately and then falling off is the situation where a student or newly qualified nurse is sent off with no instructions or training to ‘… just fit Mr X with a sheath will you’, often resulting in the patient being fitted with the first one that they can find.

The lack of high quality training on fitting is an issue that has recently been recognized by the continence Skills for Health working group. National competencies have now been developed on the care of individuals using containment products, which include collection devices such as urinary sheaths (Skills for Health, 2008).

The ten competencies for performance criteria by Skills for Health (2008) (Table 2) make it clear that the fitting of a urinary sheath requires thinking about in a structured way, and that there is no ‘one size fits all’ when it comes to the use of this device. These competencies need to be included in all continence training programmes, be part of all continence policies, and should be fundamental to the delivery of nursing care to males with UI.

Skills for Health (2008) also detail health knowledge and understanding criteria (Table 3). Ten of these criteria are pertinent to the use of urinary sheath devices, including an in-depth knowledge of how to use a device properly and how to provide information to patients so that they know how to use them and to obtain support for themselves if problems arise – another area that tends to be forgotten when fitting a product.

**BioDerm® external continence device (ECD)**

BioDerm is a new type of continence device that could meet the needs of some groups of males and is an alternative to the previously used condom catheter-based system of urinary drainage.

**Advantages**

BioDerm uses only a very small area of the glans penis around the meatus. This makes it ideal for patients with a retracted penis (Webb, 2006). It is also easy to catheterize through the aperture, making it ideal for patients who have to self-catheterize but who leak between catheterization episodes. It also requires no sizing as it fits all lengths of penis; therefore, raising the feasibility that it might be useful in some ward situations where staff have a lack of access to sizing guides. Additionally, cost in the ward situation will be outweighed by the fact that unsized sheaths have a tendency to fall off regularly, whereas BioDerm can remain in place for up to 3 days.

BioDerm only attaches to the glans penis, and the hypoallergenic hydrocolloid strips are malleable (thus making them better able to accommodate changes in penile size). Therefore, it is suitable for patients who experience frequent erections (Pomfret, 2006; Woodward, 2007), including early wakening erections which are common in patients with neurological disease. Patients who have experienced ulceration or allergy with other urinary sheaths may also find the product useful (Vaidyanathan et al, 2005).

BioDerm is made of a unique hydrocolloid ‘petal’ style, which allows adherence to the glans penis to ensure a comfortable and secure fit for most men. A thin hydrocolloid ‘butterfly’ completes the seal. BioDerm is available with two apertures:

- ECD (circular) for a regular shaped meatus
- XLS (oval) for enlarged or regular meatus (i.e. catheter damaged).

Like most urinary sheaths there is no robust research to underpin its use or some of its claims, e.g. stretching to accommodate changes in penile size. However, two authors (Kyle, 2007; Woodward, 2007) describe how initial patient feedback appears positive.

Woodward (2007) states that patients who have been using the device in the UK include those with Parkinson’s, MS...
and spinal cord injury, as described previously. These patients have reported that it is easy to apply, comfortable and easy to remove. Patients have reported a benefit from a feeling of increased security and this has led to a return to social activities for some. Woodward (2007) also points out that although costs savings have been demonstrated in a number of cases owing to increased wear times and reduction in the number of changes required as a result of devices falling off, there is a need for large scale comparative clinical trials to be undertaken.

Instructions for use

1. Clean the glans (head of the penis), retracting the foreskin if present, and then dry thoroughly.
2. Remove the backing paper and position the wafer over the urinary opening so that the smallest petal is at the bottom.
3. Avoiding wrinkles, smooth the petals, starting with bottom one, Press gently for 20 seconds, the heat of the hand helping to activate adhesion.
4. Remove backing paper and place the ‘butterfly’ seal around the petals with the notch over the frenulum (ridge of the skin under the glans if uncircumcised). Gently smooth the ‘butterfly’ seal around the glans. Do not stretch it. Press gently for a further 20 seconds.
5. Insert the tube into the stem of the wafer. It is important to return the foreskin to its natural position over the ‘butterfly’ seal. The tube connects directly to most urine collection systems.

Removal

To remove BioDerm simply wrap a warm, wet cloth around the adhesive area (or soak in warm water) until the wafer is white. It will then gently slide off. BioDerm can be changed when the wafer and seal becomes white or opaque, or if there are any signs of leakage.

Disadvantages

Like all other continence devices, with BioDerm there are certain disadvantages with its use. Patients must have reasonable manual dexterity and eyesight in order to be able to attach it to the glans penis. In addition, it is a little more involved than the majority of penile sheath systems to fit (Woodward, 2007) and patients may therefore be more reliant on carers to achieve a good fit. This is especially important as if it is not applied correctly it has more of a propensity to fall off. If application is generally not good and it does fall off regularly this can lead to a lack of confidence by both the patient and the carer (professional and non-professional) into its efficacy and reliability.

Woodward (2007) describes how, on occasions, patients wearing this device and who have a sudden large diuresis may experience a feeling of suction on the tip of the penis, which tends to be more noticeable in patients who experience this sensation when wearing a more traditional form of sheath. As this device is applied directly to the glans penis, Vaidyanathan et al (2005) suggest that it is not suitable for patients who have phimosis, catheter-induced hypospadias, ulceration of the external urethral meatus or infection of the glans penis or prepuce.

Conclusion

Management of UI should only involve continence products following a thorough continence assessment. Urinary sheaths are a useful device for men with UI, and are not used often enough by nursing staff. However, they need to be fitted accurately and the patient assessed for the right kind of sheath.

BioDerm is new to the UK market and comments from patients who have used it are favourable, and it should be considered as an option for certain groups of patients. These include patients who have a retracted penis, who get spontaneous erections or have received ulceration or allergies from other urinary sheaths.

There might also be a case for BioDerm to be used in some acute settings where the options for measuring and selecting the correctly sized urinary sheath are limited.


KEY POINTS

- Male urinary incontinence (UI) is a commonly experienced problem by men, with causes including radical prostatectomy, neurogenic problems, dementia and overactive bladder.
- Until recently, patients with UI have had to rely on the use of either pads or wearing a condom catheter-based urinary sheath
- There are a number of problems associated with wearing a urinary sheath, including twisting or kinking; the sheath falling off; potential allergies and reduced independence.
- While a thorough assessment is essential before implementing the use of any continence product, BioDerm is an alternative to the external condom catheter-based urinary drainage system.