**Abstract**

**Objective**

* To compare performance of three continence management devices and absorbent pads used by men with persistent urinary incontinence (> 1yr) post treatment for prostate cancer.

**Patients and Methods**

* Randomised, cross-over trial of 56 men with one year follow up.
* Three devices were tested for three weeks each: sheath drainage system, body-worn urinal, penile clamp. Device and pad performance were assessed.
* Quality of life (QOL) was measured at baseline and follow-up with the King’s Health Questionnaire.
* Stated (intended use) and revealed (actual use) preference for products was assessed.
* Value-for-money was gathered.

**Results**

Substantial and significant differences in performance were found:

* Sheath: good for extended use (e.g. golf and travel) when pad changing is difficult

Good for keeping skin dry, not leaking, not smelling and convenient for storage and travel

* Body-worn urinal: generally rated worse than the sheath and was mainly used for similar activities but by men who could not use a sheath (e.g. retracted penis); not good for seated activities
* Clamp: good for short vigorous activities like swimming/exercise. Most secure, least likely to leak, most discreet but almost all men described it as uncomfortable or painful
* Pads: good for everyday activities and best for night-time use. Most easy to use, comfortable when dry but most likely to leak and most uncomfortable when wet
* A preference for having a mixture of products to meet daytime needs; 3 months after testing 58% of men were using a combination of pads and devices compared to 9% at baseline

**Conclusions**

* This is the first trial to systematically compare different continence management devices for men
* Pads and devices have different strengths which make them particularly suited to certain circumstances and activities
* Most men prefer to use only pads at night but around half would choose a mixture of pads and devices during the day as opposed to a single product
* Device limitations were important but may be overcome by better design

Key words: penile compression device; body worn urinal; sheath drainage system; King’s Health Questionnaire; quality of life.

**Introduction**

Prostate cancer is the commonest male cancer in the UK.1 Around 10-15% of men who undergo surgical or non-surgical treatment for prostate cancer will suffer lifelong urinary incontinence (UI).2-4 UI has major negative effects on quality of life and social interactions5-11 and is associated with long term morbidities such as skin injury, urinary tract infection, falls, and increased hospital stays.12 For those who do not regain continence, absorbent pads or alternative products and devices are required to maintain social continence.

In addition to the usual choice of absorbent pads, other continence products include penile compression devices (clamp), sheath/condom drainage systems (sheath), and body-worn urinals (BWU). In the UK the latter two are available on NHS prescription. However their market share is low compared to the use of absorbent products despite recommendations that men should be offered male devices as well as pads12-14 and evidence that men may prefer sheaths to pads.15 The limited research on the comparative efficacy, strengths and limitations, is an important barrier to alternate device use. Thus, the objective of this study was to compare the performance of three continence management devices (sheath, BWU and penile clamp) and absorbent pads used by men with on-going incontinence (UI) following prostate cancer treatment. The relative costs of providing the different products, and participants’ views on value-for-money were also investigated.

**Participants & methods**

Community dwelling men living in the Southern Counties in England who had been treated for prostate cancer, had persistent UI > 1 year, currently used at least one absorbent pad per day, and had satisfactory manual dexterity to apply and remove the devices. Exclusion criteria were: faecal incontinence and problems that might make the use of male devices unsafe i.e. a known latex allergy, reduced genital sensation and impaired cognitive function (MMSE < 27). Ethics approval was given by Southampton and South West Hampshire REC; NHS governance approval was obtained from each of the NHS Trusts. Written informed consent was obtained from each participant.

**Trial Design**

The study was a randomised cross-over trial using Latin Squares method16 with each participant testing the three devices in random order day and night for up to three weeks (except the clamp, which is not suitable for night use). A registered nurse expert in continence care visited participants in their homes at data collection points. Baseline data included demographics, continence status, measures of independence (Barthel Index17), cognitive function (Folstein Mini-mental test exam18) and quality of life (King’s Health Questionnaire19). **Figure 1** shows trial design.

**Primary Outcome: Overall Opinion Questionnaire**

The Overall Opinion Questionnaire was completed after all products had been tested; it was designed to illicit:

* overall opinion (rated on a 10 point visual analogue scale) for day or night use
* product acceptability ( not acceptable /poor/ acceptable / good)
* advantages and disadvantages of the test products and the absorbent pad in regular use by the participant
* stated preferences (which products men planned to use post-test)

**Secondary outcomes**:

* Product Performance Questionnaire responses
* stated and revealed preference 3 and 12 months following product testing
* QOL
* economic analysis

1. Product Performance Questionnaires were based on a previously tested tool used in a study of sheath use20 and were piloted by seven men (5 using sheath or BWU; 2 using clamp) to ensure questions captured all relevant aspects of product performance. These were administered at the end of each product testing.
2. At 3 and 12 months post testing, data on revealed preferences was obtained (which products participants had actually been using vs planned use) and views about what the NHS should provide based on estimated cost to the NHS of each device, including pads.
3. Quality of life was measured with the validated King’s Health Questionnaire (KHQ). KHQ has weighted scores for nine dimensions ranging from 0 (best)-100 (worst). The lower the score the better the reported QOL.
4. Simplified questions on value-for-money were used following piloting of more complex versions. The costs of products (derived from the NHS Supply Chain catalogue21 and from online formulary data22) were disclosed to participants to see if awareness of relative costs affected their stated preferences.

**Study Products (Figure 2)**

Pads: Participants used their current product supplied by the NHS.

Sheaths: The three most commonly used brands, based on prescription analysis data23 and design (one piece) 20  were selected, and participants were randomised to one of the three brands. Men with very light leakage had the option of connecting a valve to their sheath, rather than wearing a drainage bag.

BWUs: These were fitted by representatives from the only two UK suppliers of these products (SG&P Payne and Jade Euro Med Ltd.) as is normal practice.

Clamps: The Cunningham clamp was selected because there is evidence that it is the most effective.24

**Sample size:** Target sample was 80 men to allow for the detection, with about 80% power, of a difference of 30% in *Overall Opinion* scores for any pair-wise comparison of products with an overall significance level, of at most, 5% for all such comparisons.

**Randomisation:** Randomisation was determined using a computer generated list into random block sizes of 6. Participant assignments were given by the central study administrator to the local research nurse after consent and baseline data were obtained. Because of packaging, it was not possible to blind participants or research staff to products.

**Statistical Methods:** Background characteristics were described using summary statistics. Product performance (after testing each device) and overall opinion and acceptability of products (after all products had been tested) were compared using appropriate statistical tests. Preferences in different situations and reported use 3 and 12 months post-testing were analysed using frequencies and percentages.

**Results**

**Participants**

Data collection occurred between December 2010 and April 2012. 3547 men living in South East England were contacted by mail via Continence Advisory Services, Urology outpatients and prostate cancer charities (an unknown number were invited via email and face to face by these organisations). 302 were screened for eligibility and 74 recruited; 18 either withdrew or were withdrawn (Figure 3); 56 had complete data at the end product testing. Baseline characteristics are summarised in Table 1. The participants were predominantly retired, independent men whose quality of life was adversely affected by incontinence. Most had received surgical treatment for prostate cancer and reported stress urinary incontinence (SUI). Eighteen did not use continence products at night. At study entry, more than half had previously tried out sheaths, but few had used BWUs and clamps.

**Products**

(Table 2 shows summary of product performance (daytime))

*Overall opinion*

Pads were rated significantly higher than the other products on a visual analogue scale in all situations. Comparisons of the acceptability of the products (not acceptable / poor *vs.* acceptable / good) showed that pads were: significantly more acceptable than all the other products for day use at home; significantly more acceptable than BWU and clamps (but not sheaths) for day use away from home; sheath was more acceptable than BWU for day home and day away use. At night, pads were significantly more acceptable than sheaths and BWU, and sheaths were preferred to BWU.

*Product performance*

Feedback on product performance immediately after testing each product indicated some important differences between the four designs (Table 3). Although pads were rated highest for overall opinion, they were reported to leak the most but were the easiest product to apply and remove, and scored highly for comfort when dry (but not when wet). The sheath was generally rated better than the pad for leakage, odour, comfort when wet, ease of carrying and disposal, and better than the BWU for comfort when dry, comfort when wet, visibility, odour, ease of putting on and ease of carrying. The BWU was rated as being better than pads for comfort when wet, but worse than the sheath in all other aspects. It was also significantly worse than the sheath and clamp for impact on self-image. The clamp was rated better than the other three products for security, leakage and low impact on clothing choice, ease of application, better than the BWU and sheath for keeping the skin dry, and superior to pads for odour control. However the clamp caused the most pain.

*Stated and revealed preferences*

With respect to planned future use of products, most men selected combinations for day use, but only pads for night. The proportion of men opting for a combination of products in the day was higher at three months after testing compared with baseline (n= 32/55, 58.1% v 5/56, 8.9%)) and one year later (19/37, 51.3% v 5/56, 8.9%).

**Qualitative data**

Qualitative data reinforced the results showing preference for a mix and the value of having a selection available.

“If I am at home and not engaged in anything too physical I just have underpants on. Maybe in the evening particularly if I have a drink I may wear some padded underpants...If I play golf I wear the sheath system….I have found that if I go out for the evening for a meal or maybe a couple of drinks at a gathering….I do tend to wear the sheath.”

“None of the three appliances in the trial are as comfortable or convenient to use as pads; it is always pleasant to use a fresh pad; none of these appliances has this feeling. However, they do have advantages, in particular the potential to enable me to go for longer periods without having to change something such as a pad, e.g. a reasonably long walk or shopping, or several hours working in the garden. Even the two hours of the clamp can provide this to a small extent when I am being active, but the two hour limit means using some kind of timer to avoid over-running by too long…….in summary, I need a reason to use one of these devices over and above simply using a pad.”

**Quality of Life**

Quality of life was measured at baseline, after each test period and at 3 months post testing. There was a significant initial improvement in QOL after trying the sheath and the BWU but no overall difference in quality of life scores at 3 months compared to baseline.

**Overview of health economic analysis**

*Views about value-for-money of products* (Table 4*)*

First men were asked about use of pads and sheaths in various combinations for day use. Forty percent stated that the NHS should only provide pads (the cheapest option). Immediately after testing all products and when the relative costs were not known by participants, less than a quarter would select just pads and higher proportions chose more expensive combinations of pads and sheaths.

When the costs were disclosed, over 70% thought the NHS should offer BWU and clamps to men, although much smaller proportions had reported using these products post testing or stated they would use them in the future.

**Adverse Events**

Reported adverse events were: skin reddening from the sheath, BWU and clamp (each n=1); blister from BWU straps and sheath removal (each n=1); and pain (most or all of the time) from penile clamp (n=22), BWU (n=15), sheath (n=3) and pad (n=4).

**Discussion**

This is the first clinical trial comparing the performance of three male-specific devices for continence management and absorbent pads, and the first to examine user preferences for each product design. It is also the first published trial of body worn urinals (there have been clinical trials of urinary sheaths,15, 20 absorbent pads,25 and penile clamps.24, 26 Substantial differences were found in the performance of the products and an important finding was the extent to which men found benefit from using a mix of products, often for different activities or circumstances. Around two thirds continued to use at least one device in addition to absorbent pads 3 months after testing (A full research report with additional diagrams is available on the Prostate Cancer UK website27).

Most men in this study had light incontinence (determined by usual pad size) and all had had treatment for prostate cancer. This population differs from that reported by Chartier-Kastler15 who studied men with moderate/heavy incontinence (any cause) when wearing a sheath drainage system compared to their usual pads. Participants in that study reported significantly better quality of life with sheaths and around two thirds preferred sheaths to pads. We also found that men had significantly better quality of life initially following sheath testing (and BWU ) and around a third stated that they preferred to use a sheath but almost always in combination with pads and/or other devices. Our study supports the provision of sheaths but usually as part of a mix with other pads and devices rather than as an alternative.

At study entry, 55% had used at least one of the devices (usually a sheath). Most who had tried devices had done so with apparently little, if any, support from HCPs; 97% reported fitting their own devices unaided. Study participants received several visits to ensure maximum success with each device and the acceptability of devices probably indicates the importance of good fitting and support.12

Currently men do not usually have to pay for their pads or devices as they are supplied freely within the tax-funded NHS. However, cost sensitivity was shown by some men in the study. Having stated immediately after the end of product testing, when relative prices were not known to them, that they would prefer the more expensive containment option of a mix of disposable devices (sheath) and pads, they agreed that the NHS should provide only the cheaper 'pad only' option or a mix of pads and reusable devices (BWU and clamp) when the relative costs were disclosed to them three months later.

Important short-comings of device designs were revealed. The BWU design was generally less successful than the sheath and most men who could use a sheath would do so in preference to the BWU. Sheaths are difficult to use for men with a short or retracted penis and, although the BWU is designed for this purpose, men experienced difficulty in keeping the BWU in place. The BWU design was also considered the most unappealing design with the worst impact on self-image. The clamp had important strengths in continence control but also caused discomfort and pain. A substantial proportion of men may not receive good information and advice about products. To help provide men with fitting information our team produced a video on successful sheath application.25

**Limitations**

Despite the extensive mail-out, the recruitment target was not achieved in the time available. Not all continence pad delivery services were able to identify men who had prostate cancer and some men did not participate because of fear of jeopardizing their pad supply. Not all urology services routinely asked men whether they experienced continence problems and thus were unable to assist with recruitment.

A small number of men volunteered for the study who were using sheaths in addition to absorbent pads, and may have been pad ‘rejectors’, and this may have influenced our findings. Most men had light incontinence. A study focusing on men with moderate/heavy incontinence may show that the product combinations preferred are different.

No validated tool for assessing quality of life of pad or device users is available and although we carried out a brief validation of our questionnaire and based it on one that had been previously tested for reliability in another study, our questions may not have included all the items of importance to pad/device users.

**Recommendations for research**

* Improved products for non-surgical approaches to the management of urinary incontinence in men. Taking advantage of modern materials and technologies conducted in partnership with users to ensure their needs and preferences are accommodated.
* Development and validation of a reliable instrument for measuring the performance and quality of life implications of different designs.

**Recommendations for practice**

The findings have several implications for clinical practice. Better information and advice about male devices is needed to inform and support health care professionals and patients. During routine follow-up of prostate cancer treatment, men should be asked about the presence of urinary incontinence, and how it affects their daily life. Containment products can be tailored to men’s needs depending on the the sport/leisure/work and social activities that they do, or would like to do. Men should be offered information about all types of absorbent pads and male devices and how to obtain products to try. In general, a sheath system might be tried before a BWU, but individual advice on fitting is required to maximise chances of success. Clamps can be recommended, but for short periods only (we recommended release the clamp after no more than two hours wear time), and provided cognitive ability, manual dexterity and bladder and genital sensation enable safe and reliable release and removal.

**Conclusion**

The three devices and absorbent pads compared in this study have different strengths and limitations that make them more (or less) suitable for particular activities. Although pads are the most preferred night time product, most men prefer to use a **combination** of devices and pads during the day in order to meet their lifestyle needs and, therefore, men should be offered a range of products. The devices currently available have limitations which may be overcome by better design.

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