

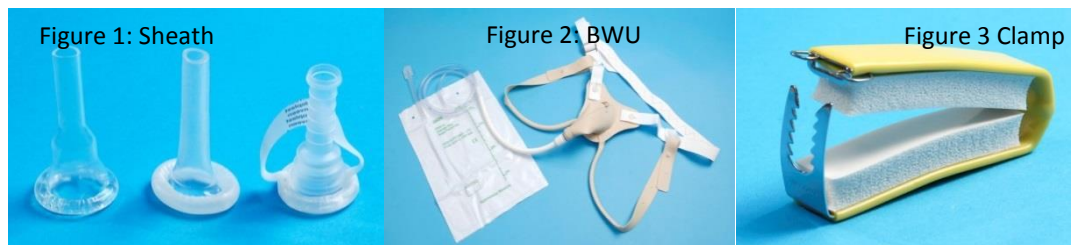
A TRIAL OF DEVICES FOR THE MANAGEMENT OF URINARY INCONTINENCE FOLLOWING TREATMENT FOR PROSTATE CANCER

Hypothesis / aims of study

Around 10-15% of men who have had surgery for prostate cancer will suffer lifelong urinary incontinence (UI) (1). Most men will use absorbent pads in the short term but there are alternative products. Male devices include penile compression devices (clamp), sheath drainage systems (sheath), and body-worn urinals (BWU) Figures 1 -3. There is some evidence to show that men with heavy incontinence may prefer sheaths to pads (2) but there have been no published clinical trials of BWUs or clamps and therefore little evidence to guide practice.

The study aimed to:

- Compare the performance of three continence management devices and absorbent pads when used by men with intractable urinary leakage following prostate cancer surgery
- Identify and explore the strengths and limitations of these devices and the patient characteristics, circumstances or situations in which they are likely to be of benefit.
- Provide recommendations and guidance to health care professionals and users regarding advice and provision of these products to men



Study design, materials and methods

We did a clinical trial using a cross-over design. We recruited men who were experiencing incontinence more than a year after prostate cancer treatment and were currently using absorbent pads to test the three different male devices in random order. Devices were tested for three weeks each and men completed questionnaires on device performance (and also on their usual pads) including their strengths and limitations. Having tested each of the devices, men were asked to state which products they preferred to use. Three months later they were asked to state which products they were actually using and for what activities and circumstances.

The 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.

Results

Seventy-four men were recruited and 56 men completed testing of all the devices. For overall opinion (primary outcome variable) pads were the most highly rated compared with sheaths ($p=0.31$), clamps ($p<0.001$) and BWUs ($p<0.001$) and sheaths were more highly rated than BWUs ($p=0.014$). There were substantial and significant differences between products in terms of their performance characteristics and differences in the circumstances and activities under which they were found to be useful. Sheaths were found to be good for using over extended periods (e.g. golf and travel) when pad changing is difficult. The body-worn urinal was mainly used for similar activities but by men who could not use a sheath (e.g. retracted penis) and was generally rated worse than the sheath (significantly so for pain and self-image, $p<0.02$). The clamp was rated as significantly more secure, less leaky and was less restrictive of clothing choice than the other devices and pads ($p<0.05$) but was also significantly more painful than all of them ($p<0.002$). Both the sheath and the clamp were better than the BWU and pad for ease of storage, carrying and for odour ($p<0.01$). The clamp was good for short vigorous activities like swimming, exercise or dancing.

The pads were found to be significantly easier to put on and take off ($p<0.003$) than all the other devices and were rated as most comfortable when dry but were also most leaky and most uncomfortable when wet ($p<0.01$). Pads were good for everyday activities and were the best product for night-time use. Pad use decreased significantly from a mean of 16.7 to 13.3 pads per week (95% CI -5.9, -.82) but there were no changes in quality of life scores compared to baseline. More than half of men (30/56) were using a combination of pads and devices three months after testing was completed.

Interpretation of results

This is the first study that has compared the three main male devices for incontinence with absorbent pads. The devices tested and absorbent pads were found to have different strengths and limitations that make them more (or less) suitable for particular activities. Our recruitment shortfall affected the power of our study and although we found many statistically significant differences between products some differences did not achieve significance which may have done so if the recruitment target had been reached.

Around half of the men in this study had tested a device before (usually a sheath) but only one had had any help with fitting. Almost all of the men were unfamiliar with clamps or BWUs. To make best use of alternatives to absorbent pads men need skilled advice about how to use them and better information about what they are best used for, and how to obtain them.

Concluding message

Male devices can enable men with long-term bladder leakage following prostate cancer treatment to undertake many social, leisure and travel activities that would be difficult or impossible using pads only. Most men prefer to use a combination of devices and pads in order to meet their lifestyle needs.

References

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Disclosures

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