

PERFORMANCE AND COST-EFFECTIVENESS OF ABSORBENT PRODUCTS FOR WOMEN WITH LIGHT URINARY INCONTINENCE: A RANDOMIZED CROSS-OVER CLINICAL TRIAL

Hypothesis / aims of study

Absorbent products are essential for maintaining the quality of life of many women with incontinence, but costs to individuals and health services are high (1). There have been no clinical trials comparing washable and disposable absorbent products for women with light urinary incontinence. The aim of this study was to compare the performance and cost-effectiveness of the four main designs (disposable pads (DPad), menstrual pads (MPad); washable pants with integral pad (WPants); and washable pads (WPad).

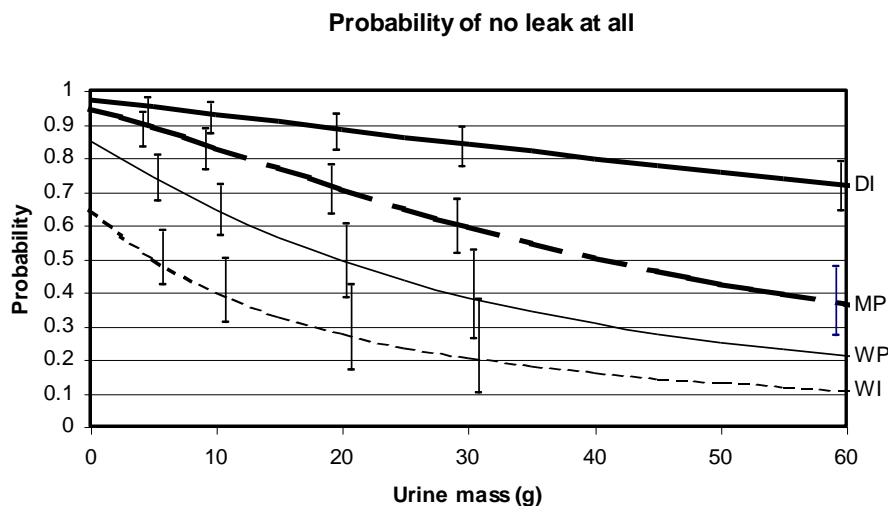
Study design, materials and methods

Randomized cross-over clinical trial. Women with light urinary incontinence (> x 5 per week) tested three products from each of the four main design available (total of 12 test products). Products were selected systematically based on published data for DPads and WPants or availability of products (only 3 WPad on market); the 3 MPads were commonly available brands for heavy nighttime use from large manufacturers. The testing order of the three products within each design and between the designs was randomised. Sample size was calculated to require 80 participants to detect, with 90% power a difference of 30% in 'overall acceptability' scores (primary outcome variable) in pairwise comparison of design groups, with a 5% overall significance level. Product performance was characterised using a validated questionnaire to evaluate pad performance (leakage, discretion etc) with a 5 point scale (very good – very poor) at the end of each week of product testing. A pad change and leakage diary was used to record severity of leakage from pads (three-point scale none, a little a lot), and numbers of laundry items and pads used were recorded to estimate costs. Skin health changes were recorded weekly. At a final interview preferences were ranked (with and without costs), acceptability of the design recorded (highly acceptable – totally unacceptable) and overall opinion marked on a visual analogue scale (VAS) of 0-100 points (worst design – best design). This VAS score was used to estimate cost-effectiveness.

Results

85 women (mean age 60) completed the study. Most had good mobility and independence in activities of daily living. Mean ICIQ was 12.5(SD 3.8). A total of 8402 used products were saved and weighed. Leakage performance was modelled for each design, based on the binarised leakage data (none) versus (a little + a lot) and urine weights. The figure below shows the plots of the probabilities of no leak at all for increasing urine masses.

Figure 1 Estimated probabilities of 'no leak' at different urine masses by design (with CI)



There were significant differences ($P < 0.005$) between all the designs in their ability to prevent leakage, in the order: DPad better than MPad, MPad better than WPant, WPant better than WPad, for all urine masses. Pad consumption rates were similar for all designs. The MPad produced nearly twice as much laundry as the DPad (ratio of means 1.97 CI: 1.02, 3.66) and both washable designs produced around 8-10 times more washing (including the washable products themselves) than the disposables. Product performance variables showed that the DPad was significantly better than the other three designs for most variables except discretion which was better for the MPad (OR 1.69 CI: 1.01, 2.82). The WPad was significantly ($P < 0.0001$) worse than the other designs for 'staying in place'. Skin health problems were reported by 12-20% of women over the test period, were generally mild and occurred least with the DPad. More skin health problems were recorded with the washables but not significantly more than the MPad.

At the final interview DPads were significantly more acceptable and more frequently preferred ($P < 0.0001$) than the other designs, but some preferred the WPant (13/85) or the MPad (6/85). The WPad was significantly less acceptable than all other designs (72/85 found unacceptable). In social situations (e.g. going out) the MPads and WPants were acceptable for less than half of women (MPads 46%; WPants 21%), but were more acceptable in the home (87% and 67% respectively). Considerably more practical problems were experienced with washables than with disposables, particularly management of wet products when outside the home (>60% found this a big or insurmountable problem). Cost-effectiveness was calculated using the mean monthly costs (UK retail prices September 2004) and VAS scores. There was no dominant (i.e. cheaper and better) design. The washable products were better value-for-money, even when the incontinence associated laundry (including the products themselves) were included

but were less acceptable. The WPad was the cheapest but was unacceptable to most (>80%); the DPad was the most expensive but was acceptable to almost all participants.

Interpretation of results

This clinical trial has shown that there are substantial differences between the different designs of absorbent products for women with light urinary incontinence. For the primary outcome variables of overall acceptability, and for mean VAS, preference and leakage performance, DPads were better than MPads, which were better than WPants, which were better than WPads. The superior leakage performance of DPads is evident at both low and high urine masses and washable designs performed relatively poorly in this respect. Even at very low urine masses washable designs are likely to leak, indicating that the ability of the washable materials to allow fast penetration or 'strike through' of urine is poor. Discreetness and price are the main drawbacks of DPads which performed best but at almost twice the cost of the MPads which are the second most effective. A significant minority of women prefer WPants or MPads, both of which are cheaper. Where absorbent products are provided by health services, savings could be made if all designs were offered (rather than only DPads) and if women were given choice and allowed to 'mix and match' the products they used according to their daily activities or circumstances.

Concluding message

This trial demonstrated that DPads were better than the other designs for most aspects of performance (including leakage), and were the most acceptable and preferred design, but were the most expensive. The Washable designs had relatively poor leakage performance and low acceptability compared to disposable designs (particularly WPads). Not all women chose the DPad as their first choice and the alternative, cheaper, washable and disposable designs were preferred by nearly a quarter of women and many more would find them acceptable in certain situations. Cost-effective management may be achieved by offering the range of designs and allowing women to select combinations (within a limited budget) to suit their own circumstances. Further research should focus on improving the leakage performance of washable designs.

References

(1) BJU Int (2004) 93(9); 1246-52

<i>Specify source of funding or grant</i>	Health Technology Assessment Programme Research Grant
<i>Is this a clinical trial?</i>	Yes
<i>Is this study registered in a public clinical trials registry?</i>	Yes
<i>Specify Name of Public Registry, Registration Number</i>	National Research Register N0484114805
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	North London MREC
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes