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GENDER DIFFERENCES IN PERFORMANCE OF AND PREFERENCES FOR ABSORBENT PRODUCTS FOR MEN AND WOMEN WITH MODERATE-HEAVY URINARY INCONTINENCE: A RANDOMIZED CROSS-OVER CLINICAL TRIAL

Hypothesis / aims of study
Men and women with moderate-heavy incontinence often need large and frequently bulky absorbent products to maintain their quality of life, yet little is known about the comparative performance of these products. New designs have been introduced: Pull-ups (like toddler training-pants) and T-shape diapers (diapers with waistband) which may have advantages over conventional, more common designs: Pads and Diapers. Washable designs are alternatives that may also have potential for cost-savings. Designs are not gender-specific and there have been no previous trials which have included community-dwelling men and women and therefore little evidence to guide selection. The aim of this study was to compare the performance of the main disposable and washable designs.

Study design, materials and methods
Randomized cross-over clinical trial. Men and women with moderate-heavy incontinence, who were able to complete self-report questionnaires/diaries tested two/three products from each of the four main disposable designs and one washable design (total of 14 test products): disposable Pads (with mesh pants), Diapers, T-shaped diapers, Pull-ups and Washable diapers. Products were selected systematically based on pilot studies. Two of the three washables were similar, were made of terry-towelling cotton and were worn with plastic pants; the third was substantially different and was a more typical washable design with waterproof backing; results for this product were analysed separately. The testing order was randomized within and between the designs. Sample size was calculated to require 85 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, discreetness 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 with product costs to estimate cost-effectiveness.

Results
85 participants (mean age 53; 49 men, 36 women) completed the study. Most had good mobility and independence in activities of daily living. Mean ICIQ was 14.2(SD 3.4). A total of 13661 used products were saved and weighed. Substantial differences between results from men and women were found. Mean urine weights showed that the men's pads contained substantially more urine than the women's pads: mean daytime urine mass for men: 375.4 g, women: 215.3 g (difference 148.7 g CI 79.8, 217.7); but men used similar numbers of pads to women (mean 2.4 /day; 1.5 /night). Leakage performance scores by gender showed men's pads leaked around 10% more than women's pads (depending on design) during the day and 20% at night. For both sexes Pads leaked significantly more than Diapers (OR 0.50 CI: 0.3, 0.9). Significantly more Pads were used ($P<0.05$) and they produced about twice as much laundry as the other disposable designs. The Washable diaper was the best design for leakage performance at night and was significantly better than the disposables ($P<0.002$) with 85% of products not leaking compared to 55% for Pads and around 60-65% for the other disposable designs; however the Washables produced 2-3 times more laundry (including the Washable products themselves) than the disposables (except the Pad).
For overall acceptability both men and women rated Pull-ups significantly better than Pads both day and night (day OR 0.21 CI: 0.09, 0.52), but for most other design comparisons results for men and women were opposed (Table 1). Division of the sample for analysis by gender resulted in smaller numbers in each group and interpretation of results should therefore be cautious. Men significantly preferred ($P<0.0001$) Diapers (41/49) to Pads (8/49), but women did not ((25/36 preferred Pads NS). For women the Pull-up was the best design and was significantly preferred to all other designs for both day and night ($P<0.03$). Despite superior leakage performance the Washable was 'unacceptable' to almost all women during the day and three-quarters of women at night, but was more acceptable to men for whom it was the most popular first choice at night. Overall the new T-shape was not significantly preferred to the Diaper by men or women.

Men = 49 Women =36	**Pad**	**Diaper**	**Pull-up**	**T-shape**	**Washable**

	Day	Night	Day	Night	Day	Night	Day	Night	Day	Night
Men	36.6	22.4	85.7	85.7	79.6	48.9	83.7	61.2	51.0	81.7
Women	82.3	66.7	55.5	63.9	94.5	91.6	41.7	52.7	11.1	24.0

Table 1: % rating design as 'acceptable' or 'highly acceptable' for overall opinion

Interpretation of results

This study showed that men and women have different preferences for absorbent products and designs perform differently for them. This may partly be explained by the substantial difference in the severity of their incontinence, but also by anatomical differences. In women the urethra is 'fixed' and urine loss occurs from a predictable position. For men, the orientation of the penis may vary considerably, particularly at night when lying on the side. Men commented that the absorbent areas for some designs (particularly T-shape diaper and Pull-up) were not well-placed or did not cover a wide enough area at the front. Pads were also criticised for not staying in place, particularly at night. Comments about the Washables indicated that the presence of absorbent areas at the sides (for side-lying at night) was good for leakage prevention. Diapers were the preferred design for men during the day and Diapers or Washables at night. Overall these findings indicate that men may need more absorbent products than women. Women preferred Pull-ups (the most expensive design) and (more surprisingly given their poor leakage performance) Pads (the cheapest during the day) rather than Diapers, and women generally found Washables unacceptable. For both men and women, Washables incurred many practical problems when outside the home, were generally unappealing and unacceptable for going out. Current designs are not gender-specific and participants' comments suggest that they are considered either babyish (Diapers and Washables) or feminine (Pads and Pull-ups). Products designed to meet the performance and aesthetic needs of men would be welcomed.

Concluding message

There are gender differences in the performance of and preferences for absorbent products for community-dwelling men and women with moderate-heavy urinary incontinence. Diapers (day and night) and Washables (night) are preferred by men; women strongly prefer Pull-ups to all other designs but these are expensive and Pads may be a cheaper option. Urine mass is substantially higher for men than women and they may therefore require more absorbent products. This study shows that there is a need for services to provide a range of designs to meet the needs of men and women. Enabling choice of combinations of designs for day and night and for different circumstances (e.g. for women, Inserts at home, Pull-ups when out), is likely to increase both patient satisfaction and cost-effectiveness. The development of better disposable designs for men and more appealing washable designs is recommended.

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