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Cottenden A[1], Fader M[1], Pettersson L[1], Brooks R[1]
1. University College London

HOW USEFUL IS LABORATORY TEST ISO 11948-1 (THE ROTHWELL METHOD) FOR PREDICTING THE LEAKAGE PERFORMANCE OF INCONTINENCE PADS IN REAL USE?

Aims of Study

Although disposable bodyworn pads are the most commonly used products for managing intractable heavy incontinence, the plethora of alternative products and the frequency with which manufacturers modify them make informed purchasing difficult. Accordingly, laboratory tests – quicker and easier to perform than clinical evaluations – are often used to compare competing products before purchase. This study aimed to measure how well data from a commonly used international standard test (ISO 11948-1, the Rothwell method) correlates with the leakage performance of pads in real use. A secondary aim was to measure the impact on pad leakage performance of product features like elastication at the legs.

Methods

Technical: All 20 ranges of shaped disposable inserts and stretch pants (20 products, each at 3 or 4 absorbencies = 74 products) and the large and medium sizes of all 34 disposable diapers (67 products in all: one came in only one size) on the UK market in 1997 were tested using ISO11948-1 [1]. This involved measuring the total absorption capacity of a pad by immersing it in normal saline then draining it under gravity. Five repeat measurements were made and the mean and coefficient of variation (standard deviation as a percentage of the mean) calculated. Linear logistic regression models [2] were then created by fitting to the clinical data (see below) models based on the technical data, including variables describing the presence/absence of the various product design features.

Clinical: The inserts were evaluated by 228 women (mean age 85y) and the diapers by 192 subjects (60 men; 132 women; mean age 80y) recruited via a total of 70 nursing/residential homes and hospitals Subjects in each centre tested between four and eight of the product ranges in random order. Each used pad was weighed by care staff who also judged whether it had leaked *a lot*, *a little* or *not at all*. Linear logistic regression modelling [2] was then used to estimate the probability of products leaking as a function of the urine mass in them.

Finally, correlations were sought between the models based on the technical data and on the clinical data in order to determine (i) how well the Rothwell method predicts pad performance and (ii) the impact of product design features on pad performance.

Results

The Rothwell absorption capacities of all 141 products are shown in Fig 1.

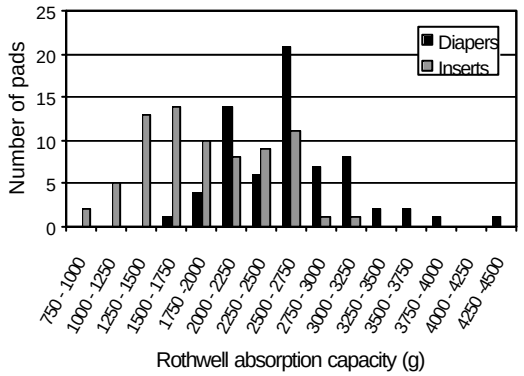

Fig 1: Rothwell absorption capacity for the 141 diapers and inserts.

Coefficients of variation were less than 5% for three-quarters of the products and only one exceeded 10%. In general the diapers were more absorbent than the inserts (ie contained more absorbent material). Almost 24,000 used pads were saved and weighed (Fig 2). Diapers generally contained more urine than inserts, presumably because they were changed less

frequently. Leakage data were used to construct performance curves for each product and an example is given in Fig 3.

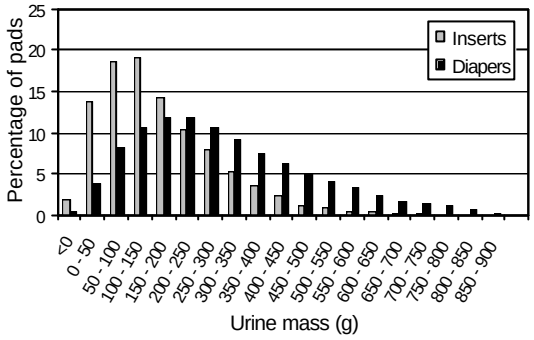

Fig 2: Urine mass distribution for weighed pads.

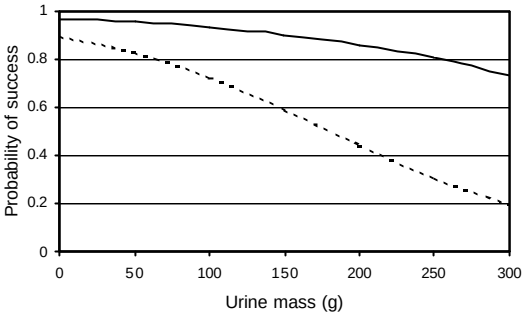

Fig 3: Pad leakage performance curves for a product showing the probability of it not leaking at all (broken line) and of not leaking a lot (solid line) as a function of urine mass.

The only technical parameters to have a significant impact on pad leakage performance were: urine mass, Rothwell absorption capacity, coefficient of variation of Rothwell absorption capacity, and whether the product was an insert or a diaper. For a given Rothwell absorption capacity diapers leaked much less than inserts. Correlation coefficients between technical models based on these parameters and clinical models based on pad weighing / leakage data are shown in the table for the lower quartile, median, upper quartile and 90 percentile urine masses for the data set (Fig 2). No evidence was found for any of the other product features investigated (presence / absence of (and number of elastic strands in) standing elasticated cuffs); number of strands in leg elastication; and (for diapers only) the presence / absence of waist elastic and landing strip to facilitate refastening adhesive tabs) affecting pad leakage performance.

Urine mass (g)	Correlation coefficients between technical and clinical models for:	
	Prob. of pads not leaking at all	Prob. of pads not leaking a lot
100 (lower quartile)	0.784	0.624
200 (median)	0.870	0.802
300 (upper quartile)	0.819	0.848
450 (90 percentile)	0.757	0.782

Conclusions

Models based on the Rothwell absorption capacity (along with the design of the pad - diaper or insert - and the coffeicient of variation of the Rothwell absorption capacity) provide sufficiently accurate predictions of the leakage performance of pads in real use to assist with buying decisions. However, they should be used with caution. It is tempting for busy purchasers to ignore the imprecision of the models and use them to generate a rigid ranking of products in which even the smallest differences are assumed to be significant. For a given Rothwell absorption capacity, the leakage performance of diapers was superior to inserts, suggesting that the former should be more widely used. No evidence was found for any of the other product features investigated having an impact on pad leakage performance. However, such features may benefit other aspects of pad performance like comfort and fit.

References

[1] International Standards Organisation. 'Urine absorbing aids – Part 1: Whole product testing'; ISO 11948-1; 1996.

[2] Hosmer DW and Lemeshow S. Applied Logistic Regression. New York: Wiley, second edition, 2000.