100

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A RANDOMISED CROSSOVER STUDY OF DISPOSABLE PADS FOR INCONTINENT CHILDREN

Hypothesis / aims of study

Children with delayed acquisition of continence require an absorbent product, which has traditionally meant diapers (Figure 1a). Pull-up style pads (pull-ups) (Figure 1b), a more recent innovation, may have advantages and are increasingly demanded by parents. However, pull-ups cost around 50% more than diapers and no study has compared their performance with diapers.

Figure 1a: Diaper

Figure 1b: Pull-up

This study aimed to:

- Evaluate all disposable pull-ups for children available in the UK in 2002 (n=5)
- Compare this design group as a whole with a representative sample of five disposable diapers
- Establish parent / child preference for these design groups

Study design, materials and methods

Design: a randomised crossover trial – every subject tested all products.

Subjects: 61 children with learning / physical disability (age range: 3-15 years) were recruited who had been assessed as requiring a pad for heavy daily incontinence supplied by the UK health service and had parents/guardians (carers) willing to assist. Exclusion criteria were acute or terminal illness, or an inability to wear either one of the designs.

Products: The products, selected in consultation with manufacturers and the UK national health purchasing agency, were grouped as follows:
Group 1 – Pull-up design (all five disposable pull-ups available in the UK)
Group 2 – Diaper design (a representative sample of five disposable diapers)

Group 1: Pull-ups

Manufacturer	Product
First Quality International	Prevail All Nites
Paul Hartmann Ltd.	Fixies Unisex
Kimberly-Clarke	Huggies Drinite
Procter & Gamble	Pampers Easy Up
SCA Hygiene	Libero Up & Go

Group 2: Pull-ups

Manufacturer	Product
Abena UK Ltd.	Bambolina
Paul Hartmann Ltd.	Fixies Ultra Dry
Ontex UK Ltd.	Moltex Elastic Extra Dry
Procter & Gamble	Pampers Baby-Dry
SCA Hygiene	Libero

Methods: Group order was randomised and individual products were randomised within their group. Each product was tested for up to one week. Aspects of product performance which subjects/carers had indicated to be important e.g. leakage/absorbency, fit and comfort were rated in a validated product *performance questionnaire* using a 3-point rating scale of 'good', 'okay' or 'poor'. Wet product weights and amount of leakage were recorded in a *pad leakage diary* on a 3-point scale of 'a lot', 'a little' or 'none'. At completion of testing, qualitative data were collected by asking carers to state and comment on their design preference for both day and night use.

Results

- A significant difference ($p<0.005$) was found for parent preference for diapers for night use (65% preferred diapers; 27% preferred pull-ups)
- No significant differences were found for design preference for day use (57% preferred diapers; 38% preferred pull-ups)
- Almost all parents did state a clear preference for one or other design (95% for day use; 92% for night use) and qualitative data showed that their decisions were based on the individual needs of their children
- The pad diaries showed that leakage performance was similar for the two designs although the diapers were perceived to be more absorbent than the pull-ups. This was substantiated by measurement of Rothwell capacity[1] of both diapers and pull-ups which established the mean capacity of the diapers as 181g greater than the pull-ups
- There were significant differences between the performance of the individual pull-ups: for the primary outcome indicator 'overall opinion', Pampers Easy Up Pants performed significantly better than two other products in the group ($p<0.005$)

Interpretation of results

- Each design has a place in the containment of leakage for this group of children and the appropriateness of either for day time use is dependent on a range of factors
- Pull-ups are more suitable for children who:
  - are able to assist with pad changing
  - are developing independence in toileting e.g. starting to remove and replace underwear themselves
  - do not wear callipers or adapted footwear
  - are not faecally incontinent
  - require a more discrete product for day use
- Diapers are more suitable for children who:
  - cannot assist with pad changing
  - use callipers, adapted footwear and or wear trousers and require a discreet pad change
  - require a more absorbent product where discreteness is less of an issue e.g. night use
  - have faecal incontinence
- Although most pull-ups and diapers performed similarly to the other products within their design group, significant differences did exist, either as a result of problems achieving a good fit or indirectly related to fit e.g. the product was too small or too large and leaked more than the other products.
- The parents made design preference choices based on practical issues and the specific needs of their children rather than the desire to have a novel or more aesthetically acceptable product.

Concluding message

Our findings indicate that both pull-ups and diapers have a place in the management of incontinence for disabled children. Diapers are preferable for night use and for most children during the day but the additional cost of pull-ups for day use can be justified for selected children by a thorough assessment of the child and family circumstances and both designs should be made available to these children.

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