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An Exploratory Study of Skin Problems Experienced by UK Nursing Home Residents Using Different Pad Designs

Sinead Clarke-O'Neill ■ Anne Farbrot ■ Marie-Louise Lagerstedt ■ Alan Cottenden ■ Mandy Fader

■ ABSTRACT

PURPOSE: The primary aim of this study was to determine whether the severity of incontinence-associated dermatitis (IAD) among nursing home–based incontinence pad users varies between pad designs. A second aim was to examine the utility of a simple method for reporting skin health problems in which healthcare assistants were asked to record basic observational data at each pad change.

STUDY DESIGN: Randomized, multiple crossover, observational, exploratory.

SUBJECTS AND SETTING: Twenty-one men and 57 women using absorbent continence products to contain urinary and/or fecal incontinence were recruited from 10 nursing homes in London and the south of England.

METHODS: A day-time variant and a night-time variant of each of the 4 main disposable pad designs on the market for moderate/heavy incontinence were tested: (1) insert pads with stretch pants; (2) 1-piece all-in-one diapers; (3) pull-up pants; and (4) belted/T-shape diapers. All pad variants for day-time use had an absorption capacity of 1900 mL ± 20% (measured using ISO 11948-1 International Standards Organization) while the capacity of night-time variants was 2400 mL ± 20%. Each resident used each of the 4 pad designs (day-time and night-time variants) for 2 weeks and the order of testing was randomized by nursing home. Skin health data were collected using 2 methods in parallel. Method 1 comprised visual observation by researchers (1 observation per pad design; 4 observations in total over 8 weeks). In method 2, healthcare assistants logged observational data on skin health at every pad change for the 8 weeks. The primary outcome variable was severity of the most severe skin problem noted by the researcher for each resident, and for each pad design (method 1). Descriptive data on skin care methods used in the nursing homes were also collected using short questionnaires and researcher observation.

RESULTS: No significant differences in the severity or incidence of skin problems were found between observations using the 4 pad designs. However, a wide range of skin conditions was recorded that made classification difficult; the skin was often marked with creases from absorbent products, temporary marks, and pink/purple discoloration. We observed few cases of the severe erythema, rashes, and vesicles that are commonly used descriptors in previous skin tools. Nevertheless, the collected data reflect an abundance of skin problems that were difficult to categorize neatly. Researcher observations (method 1) showed that nearly all the residents (96%) had at least 1 IAD skin problem recorded over the 8-week period and 64% of residents had at least 1 problem that was rated as maximum severity. Healthcare assistants logged skin problems on 6.1% of pad changes. The discrepancy between researcher and healthcare assistant data appears to be largely due to healthcare assistants sometimes discounting low-grade IAD as normal for that population.

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Conflict of interest: Two of the authors are employees of SCA Hygiene Products AB, which manufactured some of the products used in the study. SCA also provided funding for the manufacturing of the skin health labels using in method 2 and also for the preparation of the paper.

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CONCLUSION: Incontinence-associated dermatitis is common among nursing home residents who use incontinence pads, and it is often severe. No evidence was found that any design of pad was more likely than any others to be associated with skin problems. The method devised to enable healthcare assistants to record basic observational data on skin health in the diaper area at each pad change (Method 2) proved simple to use but still resulted in substantial underreporting of IAD, suggesting that further work is needed to develop a tool that more successfully encourages them to log and treat IAD problems.
KEY WORDS: incontinence-associated dermatitis, incontinence pads, incontinence, long-term care, skin health

Introduction

Incontinence in nursing homes is often successfully managed using disposable absorbent products to achieve social continence, bringing substantial benefits to residents' health-related quality of life.[1] Pad technology has developed considerably over recent years with the introduction of new design features and materials, but there is little published data to guide users and caregivers in making informed purchasing choices regarding efficacy and cost-effectiveness. In particular, little is known about the impact on skin health of using the different pad designs. The prevalence of incontinence-associated dermatitis (IAD) in long-term care facilities is thought to be about 5.7%, rising to 20% to 27% in acute care,[2] and it regularly affects incontinence pad users. Although sore or irritated skin can be an uncomfortable problem for any pad user, elderly and frail individuals (who often have reduced mobility, fecal incontinence, mental impairment, and a high risk of pressure ulcers) are particularly vulnerable to IAD.[3]

Manufacturers modify their products frequently and clinical trials are expensive and time-consuming. As a result, we have observed that few published trials include products that are still available, and many address research questions that are no longer relevant. In addition, the methodological quality of many studies is poor, further limiting their usefulness. A Cochrane review of absorbent products for the containment of urinary and/or fecal incontinence carried out in 2000 retrieved only 5 studies that proved eligible for inclusion.[4,5] Based on this review, the authors concluded that evidence was insufficient to provide a firm basis for incontinence pad users to make informed choices. There is a particular paucity of data on the performance of the newer pad designs—notably pull-up pants and belted/T-shape all-in-ones—compared with more traditional insert pads and all-in-ones. Pad performance data that were collected as part of the parent study were used to update the Cochrane review in 2008.[5]

Methodological challenges encountered when evaluating and comparing multiple products have been discussed by Fader and colleagues.[6] They suggest that a randomized control trial is often inappropriate because of the difficulty in determining a "control" pad. Instead, they favor a crossover design, particularly as incontinence is frequently a chronic condition and use of products does not affect underlying symptoms. They further stated that the participant's "overall opinion" rating is perhaps the most appropriate primary outcome variable because it synthesizes the various strengths and limitations of the product from a patient perspective. Fader and colleagues also discussed the problem of published data going out of date rapidly owing to the frequent introduction of new products, and they suggest evaluation of generic designs rather than specific products since the former evolve much more slowly than the latter.

Fader and colleagues[4] subsequently applied this philosophy in conducting trials of pads intended for 3 different user groups: (1) lightly incontinent women; (2) community-dwelling persons with moderate to heavy incontinence, and (3) nursing home residents with moderate to heavy incontinence. The purpose of the third evaluation was to evaluate the 4 generic disposable pad designs intended for moderate to heavily incontinent users. The test products included 2 traditional designs: a 2-piece or insert pad (worn with net pants) and an all-in-one or diaper design. They also evaluated 2 newer products: a T-shape or belted all-in-one and a pull-up pant (Table 1). Several brands were evaluated in an earlier trial conducted in community-dwelling persons with moderate/ heavy incontinence.[7] Based on their experiences in this study, Fader and colleagues[4] concluded that it would be impractical to test so many different brands in nursing homes. Instead, their experience provided a basis for selecting 1 suitable product (in a day-time variant and a night-time variant) to represent each of the 4 designs under consideration, purposely avoiding any products that performed atypically well or badly for that design. Furthermore, to strengthen the validity of comparisons between pad designs, all of the chosen products had similar absorption capacities, measured using ISO 11948-1[8] (1900 ml ± 20% for day-time pads and 2400 ml ± 20% for night-time pads). Since the nursing home residents were unable to self-report pad performance, products were evaluated via questionnaires filled out on each subject's behalf by his or her caregivers. Their

TABLE 1.
The Test Products

Design	Product Name (Supplier)
Insert (day)	Moliform plus (Hartmann)
Insert (night)	Attends Contour Super Plus (Paperpk)
All-in-one (day)	Euron Form Ultra (Ontex)
All-in-one (night)	Contifit (Shiloh)
Pull-ups (day)	Abri-flex Extra (Abena)
Pull-ups (night)	Tena Pants Super (SCA)
Belted/T-Shape (day)	Tena Flex Super (SCA)
Belted/T-Shape (night)	Tena Flex Super (SCA)

opinions on overall pad performance and various specific aspects of performance (eg, ease of putting on a pad) were measured in 2 ways: (1) acceptability for the individual nursing home resident was ranked using a 4-point rating scale (highly acceptable, acceptable, unacceptable, and totally unacceptable) and (2) a 10-point visual analogue scale that varied from 0 indicating worst possible design to 10 indicating best possible design.

The acceptability of the 4 pad designs as measured by the residents' caregivers is summarized in Table 2. For daytime use, the pull-up was rated significantly better than the insert and the T-shaped all-in-one, and significantly better than the diaper. Pull-ups were also rated as significantly better than each of the other 3 designs based on VAS scores ($P < .001$). There were no statistically significant differences between the other designs. For night-time use, the insert was significantly worse than each of the other 3 designs based on rankings and VAS scores ($P < .0005$), but there were no significant differences between the other designs; these study findings are published elsewhere.[4]

Skin Health

Incontinence pads have the potential to both increase and decrease the likelihood of IAD[9] and validated skin health tools are needed for use as outcome measures in intervention trials. Clinical tools that provide an objective measure of erythema or skin color are available and have been used in several nursing care studies.[10-12] Nevertheless, their use is limited because they sample a small area of skin and may fail to reflect the full extent of skin damage. Transepidermal water loss has also been used in a limited number of studies[11,12] to measure disruptions to the barrier function of the skin or the degree of overhydration of the skin, but measurements vary with air temperature, humidity, and air flow and are often impractical in uncontrolled environments such as nursing homes.[13] In addition, optimal methods for logging trans-epidermal water loss measurements and calculating skin wetness scores have not been determined.[14] As a result of these limitations, these instruments are infrequently used, or used only in combination with visual observations.

Erythema is the main clinical sign of IAD, and skin observation and grading of erythema by research or healthcare staff are commonly used in intervention trials. When data collection for this study began (September 2005), few published skin health tools were available and none had been validated widely. Three instruments were identified from the literature and were considered or piloted in the early stages of data collection.[15-18]

Brown and colleagues[15,18] developed and used the Perineal Dermatitis Grading Scale in studies of all-in-ones and underpads. This instrument incorporates a measure for erythema severity along with descriptions of skin integrity, the size of affected areas, and patient symptoms. However, our pilot work identified several limitations with its use. For example, the majority of our nursing home subjects were unable to accurately report on some of the symptoms included in the tool, such as tingling, itching, burning, or pain. In addition, the instrument required measurement of the overall size of the affected skin area. Unlike some wounds, the skin problems observed in many of our subjects involved several distinct but related lesions such as broken skin and discoloration, rendering measurement difficult. Further, the skin integrity category in the instrument included several classifications of skin integrity that proved unhelpful. Although we often saw macerated areas, we never observed bullae and vesicles, swollen or raised areas, or crusted or scaling areas.

Schnelle and colleagues[16] undertook a large trial in which trained observers assessed the skin health of 100 nursing home residents at time intervals of not more than 3 weeks over a period of 60 days. Assessments were made using a specially designed data sheet that divided the "diaper area" into 4 major regions (front central; front peripheral; back central; and back peripheral); these areas were further divided into 40 subregions. Skin was monitored for 9 conditions: maceration; scaling/dry skin; papules; edema; macules; blanchable erythema; nonblanchable erythema; pressure ulcers; and non–pressure-induced ulceration. When piloting this data collection technique, we found it difficult to replicate the complex data sheet and

TABLE 2.

Visual Analogue Scale Scores and Acceptability Ratings for Day and Night Variants of the 4 Generic Pad Designs as Used by 100 Moderately/Heavily Incontinent Nursing Home Residents[a]

	Insert		All-in-One		T-Shape All-in-One		Pull-up	
	Day	Night	Day	Night	Day	Night	Day	Night
VAS mean (SD)	5.0	4.3	5.1	6.6	4.9	6.3	6.8	6.2
% highly acceptable	15.3	6.1	16.2	44.9	11.1	28.6	45.5	27.8
% acceptable	44.9	50.0	47.5	30.6	50.5	51.0	35.4	52.6
% unacceptable/totally unacceptable	39.8	43.8	36.4	24.5	37.4	20.4	19.2	19.6

[a]From Fader et al (2008).[4]

found a low incidence of skin conditions such as papules and edema.

Nix[7] developed the Perineal Assessment Tool to predict the risk of developing IAD rather than rating its severity. Although the Perineal Assessment Tool includes a category that rates perineal skin condition, the descriptors do not appear to be sensitive enough to detect the small changes in skin health of interest to us. For example, the instrument contains a single category of erythema while we posed to differentiate multiple degrees of erythema.

■ Methods

Although the skin health tools we piloted had useful elements, none of them proved suitable for use in our study. Therefore, we aimed to construct an instrument for use in this study; its development is described later. Because erythema (inflammation and redness of the skin) is one of the most common clinical indicators of IAD,[9] we focused on the rating of the severity of erythema. We drew on experience from an earlier study performed by members of the research team in which visual observation and grading of erythema had been undertaken on 81 patients in long-term care facilities.[2] This 5-point scale was adapted for use in this study by reducing the scale to 4 points (none, mild, moderate, severe); this modified scale was used in a more recent study of IAD in patients with fecal incontinence published in 2011.[19] Rather than creating highly precise categories and asking observers to fit their observations into these categories, the data collection form was left with an open structure with room to record observations/opinions about the appearance of the skin condition. A diagram of a torso was included to enable the data collector to document the position of skin problems (Figure 1). We adopted this approach to enable collection of in-depth information on the scope and nature of the skin problems commonly seen in nursing home residents with urinary or fecal incontinence.

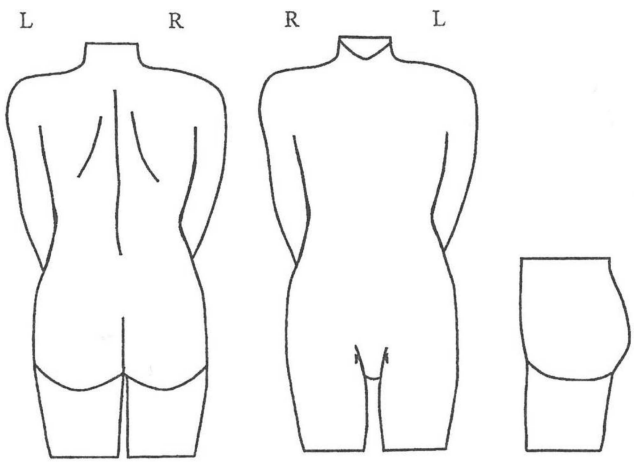

FIGURE 1. The torso diagram, included on the researcher observation form.

This skin health tool was completed by 2 research nurses biweekly (method 1). We acknowledge that more frequent observation of the skin is preferable, but this approach was not practical or affordable as part of our study. Therefore, a complementary method was devised (method 2) to enable nursing assistants to assess skin health with each pad change. The initial idea was that this system would capture skin health changes on a daily basis and act as an "alerting method," with healthcare staff contacting the research staff if a moderate or severe skin condition was observed. This "repeated carer-reported global skin health measure" was intended to be used as a secondary skin health outcome. However, experiences during the pilot study revealed that, although healthcare staff completed their observations regularly, they often failed to alert the research staff to relevant changes in skin condition. Thus, the method provided a useful daily overview of skin health, but it was not validated directly against the researchers' skin observations.

Skin Care Practices

In UK nursing homes, the core activities of bathing and dressing residents and changing pads are carried out by nursing assistants. Registered nurses do not directly supervise this activity and the responsibility lies with the care staff to use appropriate products and report problems or concerns to the nurse in charge. In order to collect data on the skin care regimen for individual participants, we piloted a questionnaire to be completed by the care staff. Initial findings suggested that the majority of care staff would apply some type of skin protectant to any erythematous areas and inform the nurse in charge. However, our initial experiences suggested that caregivers might be reporting findings based on nursing home policy rather than the individualized observations we sought. We therefore decided that researchers would observe skin care regimens during morning bathing to provide a more precise assessment of practice.

We employed a randomized, multiple crossover design during which each of 4 different pad designs was tested. Each design was tested for a 2-week period; the order of product testing was randomized by nursing home using Latin squares.

Residents were deemed suitable for inclusion in the study if they were currently using absorbent products for moderate to heavy urinary incontinence. They were excluded from the study if they had a urethral catheter or were at the end stage of a terminal illness. Nursing home staff identified all potential participants who met inclusion/exclusion criteria, and the research staff were introduced to the participants and a systematic consenting procedure was then followed. Researchers met with potential participants and contacted the next of kin if they believed that the resident was unable to give informed consent. The study was discussed with next of kin and residents were included in the trial only if the next of

kin believed that it was something that the residents would desire to participate in. This consenting procedure was reviewed by the Camden and Islington local research ethics committee.

Sample Size and Power Calculation

The main aim of the parent study was to compare the performance of different pad designs, and the primary outcome variable was caregiver overall opinion. This outcome was assessed using a 4-point acceptability scale and a 10-point visual analogue scale. The researcher-observed maximum severity of skin problem for each subject when they were using each of the pad designs was used as the primary outcome variable for skin health. Power calculations revealed that a minimum of 80 participants were required to allow the detection with 90% power of a difference of 30% in overall opinion scores in any pairwise comparison of pad designs based on an overall significance level of 5% or less for any pairwise comparisons.

Skin Health Outcome Measures

Method 1

Researchers carried out detailed skin observations on each subject once during the second week of testing for each of the 4 products. Skin was graded for erythema based on the 4-point scale described previously. Any erythema identified was further categorized as blanching, nonblanching, or a mixture of these conditions. The approximate area of any lesion was classified as small, medium, or large. There was also space on the form for recording the presence of a rash (discrete satellite regions indicating a cutaneous fungal rash) and areas of eroded skin. The presence of any full-thickness (grade/stage 3 or more) pressure ulcer was documented. A line drawing of a torso (Figure 1) was included so that the location of any skin problem could be recorded easily, and space was left for additional notes describing the skin problem. If residents were in the supine position when the researcher entered the room, they were repositioned onto their side and left for 20 minutes before observations commenced. Initially, information was also collected on the participants' position before the observation along with an estimate of how long they had been in this position. This assessment was abandoned when it became evident that it was not possible to accurately record how long the resident had been in a particular position.

Method 2

During each pad change throughout the test period, healthcare assistants (HCAs) were asked to log their skin health observations on a specially designed label that was attached to a plastic bag where pads were placed for subsequent weighing (pad weighing was conducted as part of the parent study).[4] Each label queried, "Does the resident have a skin problem in the pad area?) Yes / No" and "If yes—is the skin problem mild, moderate, or severe?" In the interests of simplicity, HCAs were not asked to log the location of any skin problems. The researchers visited the nursing home daily to weigh the used pads and transfer labels into a log book.

In 2 of the 10 nursing homes, staff were asked to complete a short questionnaire about skin cleansing and use of skin protectants A researcher also observed morning bathing routines of 27 residents including the time required, along with the types of cleansers and skin protectants.

Prior to data collection, the researchers visited each nursing home and held an introductory meeting to describe the aim of the study and explain what the staff would need to do. A short talk was given describing common skin problems experienced by nursing home residents. The 4 product designs were shown and the correct method of application based on the manufacturers' guidelines was demonstrated. The labels for logging skin health observations were introduced, and the importance of their completion at every pad change was emphasized. The research staff visited daily during the study and provided encouragement to adhere to the protocol.

■ Data Analysis

Ordinal outcome variables were analyzed using cumulative logit modeling and quantitative outcome variables were analyzed by linear modeling, allowing for repeated observations by each subject. Bonferroni adjustments[19] were made in significance tests and to confidence intervals for multiple comparisons between designs. Data were analyzed using Excel (2003 version, Microsoft, Redmond, Washington) and SPSS (Statistical Package for Social Sciences, version 11.5, Chicago, Illinois).

■ Results

The key characteristics of the 78 subjects are summarized in Table 3. The sample comprised 21 men and 57 women with a mean age 82.7 ± 12.7 years (mean ± SD), and body build was classified on a 3-point scale subjectively by the researcher as underweight, normal, or overweight. The majority of participants (68.1%) were classified as having a normal body build. Participants were a frail group, as evidenced by their poor mobility and low Norton, Braden, Barthel, and Hodkinson Mental test scores. More than three-quarters had fecal incontinence (as well as urinary incontinence) and, for most of them, fecal leakage was severe.

Skin Health

The researcher observation data (Method 1) were used to identify the worst skin problem across all skin sites observed. Figure 2 shows that for each pad design, a skin problem occurred in 80% to 90% of the subjects (mean 85.7%) but when the data were dichotomized for analysis

TABLE 3.

Characteristics of the 78 Subjects Whose Incontinence-Associated Skin Health Was Studied Here[a]

	N	Mean (SD)	Range				
Age (y)	72	82.7 (12.7)	47-102	<70	70-79	80-89	≥90
				8	13	27	24
Gender	78	NA	NA	Male	Female		
				26.9	73.1		
Body build	72	NA	NA	Underweight	Normal	Overweight	
				19.4	68.1	12.5	
Mobility	72	NA	NA	Independent	Uses aid	Wheelchair/ chair-bound	Bed-bound
				6.9	25.0	52.8	15.3
Norton score	70	10.1 (2.8)	5-16	≤14 (at greatest risk)	15-17 (not at risk but observe)	18-20 (minimal risk)	
				91.4	8.6	0.0	
Braden scale score pressure ulcer risk assessment	71	14.9 (3.5)	7-22	6-10 (very high)	11-15 (High)	16-19 (Medium)	20-23 (Low)
				12.7	39.4	36.6	11.3
Barthel score	73	20.4 (19.4)	0-60	0-20	25-40	45-60	
				60.3	21.9	17.8	
Hodkinson mental test score	68	2.4 (3.2) (for the 64 able to answer)	0-10	unable to answer	0	1-6	7-10
				5.9	50.0	33.8	10.3
Faecal incontinence	71	NA	NA	No	Yes: small amounts	Yes: large amounts	
				22.5	12.7	64.8	

[a]They were a subset of the 100 who produced the data summarized in Table 2.

(no skin problem vs skin problem) no significant differences were found between the 4 designs (the Fisher exact test: P = .48-.90). The severity of skin problems was divided roughly equally between mild and moderate and relatively few observations were ranked as severe (1.6%-7.1% of observations). Of the 78 subjects, only 3 (4%) remained free from IAD during the 8-week observation period.

Figure 3 illustrates the researchers' skin health observations based on skin location (buttocks, sacrum, groins,

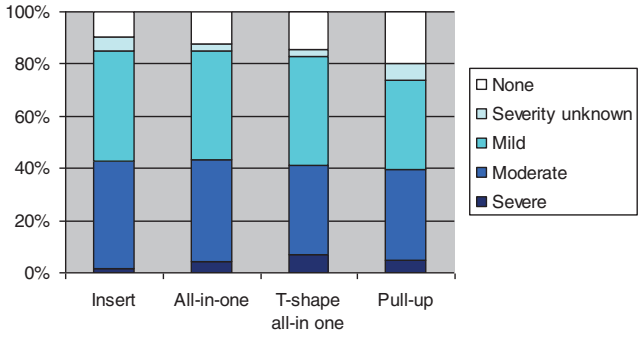

FIGURE 2. Summary of the most severe incontinence-associated skin problem logged by researchers for each subject, by product design. Data are available on between 61 and 74 subjects per product design. "Severity unknown" refers to occasions when a skin problem was logged but the severity (severe, moderate, or mild) was not.

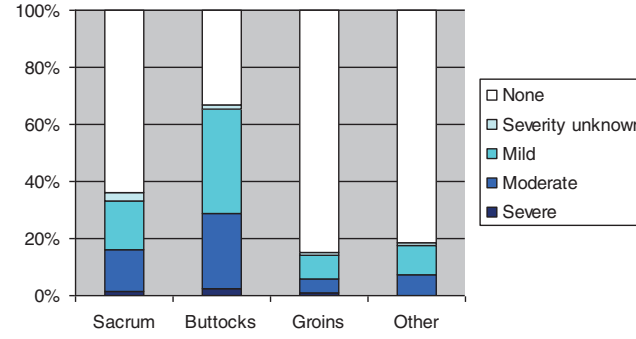

FIGURE 3. Summary of the proportion of researcher observations for all subjects and all 4 product designs for which the different severities of skin problem were logged at the various body locations. Data are for a total of 267 observations at each location. "Severity unknown" refers to occasions when a skin problem was logged but the severity (severe, moderate, or mild) was not.

TABLE 4.

Percentages of the 267 Researcher Observations at Which Skin Problems Were Logged at Different Numbers of Skin Sites (Sacrum and/or Buttocks and/or Groins and/or "Other")

	Number of Skin Sites Affected				
	0	1	2	3	4
% observations	13.9	46.4	30.0	8.2	1.5

or other); data are combined over the 4 product designs together. It shows that the buttocks were most commonly affected (67% of observations), followed by the sacrum (36% of observations). The groin (15%) and other skin locations (19%) were affected less often. No skin problems were observed during 13.9% of observations. A skin problem was found in just 1 location for almost half, and at 2 or more locations for almost 40% of observations (Table 4). Skin problems at sites other than the buttocks occurred less often alone as compared to problems involving the buttocks and 1 or more additional sites (Table 5).

The longevity of skin problems was not studied specifically, but Figure 4 gives some insights into their persistence by summarizing data on the proportion of the researcher observations of individual subjects at which a skin problem was identified for the various locations. For 36% of subjects, a skin problem was recorded on the buttocks for all of their observations (either buttock) while only 7% had no buttocks skin problems recorded at all.

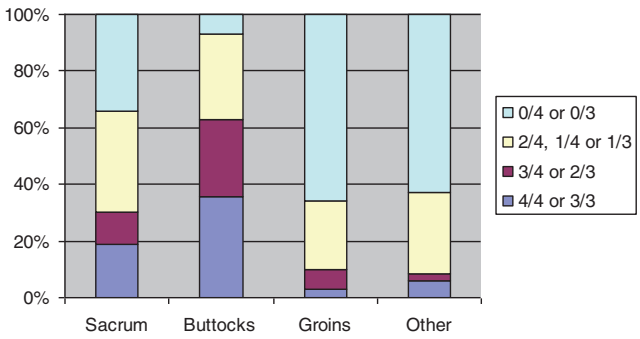

FIGURE 4. Summary of the relative frequency with which researchers logged IAD (of any severity) for different proportions of their observations, for the various skin locations. Data relate just to those 70 subjects for whom either 4 (46 subjects) or 3 (24 subjects) observations were made.

If the skin was found to be eroded, a description was collected as an open question by the researcher. These data were coded during analysis of the data and 5 categories emerged from the data that described both the break and the surrounding skin (i) eroded only, (ii) eroded and rash, (iii) eroded and red (moderate-severe erythema) and (iv) eroded and pink (mild erythema), and (v) eroded and discolored. All lesions were partial thickness, and no full-thickness wounds or pressure ulcers were observed during data collection. Fifteen subjects had at least 1 observation of any category of eroded skin on the sacrum and for 3 of these subjects the damaged skin was present on 3 consecutive observations. Seven subjects experienced a single occurrence of eroded skin that was not present on the next observation, indicating that it had healed. Eight subjects had at least 1 observation of eroded skin on the right buttock, and 12 on the left buttock; 4 had damage on both right and left buttock at the same time. One subject had persistent eroded skin on all 4 observations and for 2 of these observations eroded skin was observed on the right and left buttock at the same time.

Skin marks from pad edges and creases caused some difficulties in classification because they often persisted long after residents were rolled on to their side, making it difficult to judge whether the effect on the skin was transient or longer lasting. Purple discoloration to the skin also posed challenges since it seemed to be normal for some subjects, even though this finding could be mistaken for a suspected deep tissue injury. All of these observations will be helpful in work to further develop a skin health tool.

Estimating the area of skin damage (small, medium, and large) proved unhelpful because the location of the IAD appeared to exert a greater influence on the size ranking (small, medium, and large) than did assessment of the severity of skin damage. For example, no occurrences observed in the groin were categorized as large and only 3.2% of problems observed in the sacral area were categorized as large. In contrast, 58.9% to 62.8% of skin damage that occurred on the right and left buttocks was categorized as medium or large.

TABLE 5.

Percentages of the 267 Researcher Observations at Which Skin Problems Were Logged (or Not) at Each Site—Alone, and in Combination With 1 or More Other Sites

Skin Site	This Site Not Affected	This Site Alone Affected	This Site + 1 Other Affected	This Site + 2 Others Affected	All 4 Sites Affected
Sacrum	64.0	7.9	19.1	7.5	1.5
Buttocks	33.0	31.8	25.8	7.9	1.5
Groin	84.6	1.5	8.6	3.7	1.5
Other	81.3	5.2	6.4	5.6	1.5

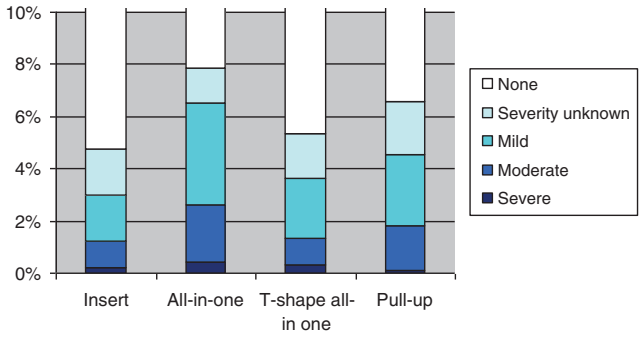

FIGURE 5. Summary of the most severe IAD logged by healthcare assistants at any skin location at each pad change, by product design, for all subjects. Data are available on between 1654 and 2157 pad changes for each product design. "Severity unknown" refers to occasions when a skin problem was logged but the severity (severe, moderate, or mild) was not.

Observations by the HCAs (Method 2) were collected at 7758 pad changes (Figure 5). Data analysis revealed that they logged skin problems at only 6.1% of pad changes, varying from 4.7% to 7.8% between product designs. Although the observation methodologies of researchers and assistants differed, the same rating scale for skin problems was used in each. Data from the 2 kinds of observers are displayed differently in Table 6, which is based on the most severe skin problem (any location) which each observed for each subject, taking all products together. Researchers and HCAs agreed on their maximum scores for 31% of subjects, while researcher grades exceeded those of HCAs by a single category on the rating scale (eg, moderate rather than mild) in an additional 31%, and the reverse was true for 26%. Although correlation between researchers' and HCAs' grading for individual subjects was weak, their distributions across the severity grades were similar. For example, both assigned a rating of moderate to the worst skin problem for about 50% of the subjects (40/78 for researchers and 39/78 for HCAs), but for only 18 subjects did researchers and HCAs agree on a moderate rating.

Skin Care Practices

Self-completing questionnaires were used to obtain data on skin care practice from 31 nursing home staff in 2 of the London nursing homes. Most of the staff (84%) said that when a resident had red skin they either applied a skin protectant (Sudocrem, Forest Laboratories UK, Dartford, Kent) or reported it to the nurse in charge. Eleven of the 18 caregivers (61%) who responded stated that they used a skin protectant, and 2 reported that they would use it in combination with a zinc and castor oil cream (a ready-made preparation used to moisturize skin and protect against exposure to irritants). Seventeen of the 30 caregivers (45%) who responded to the question reported that they would use "cream" (a generic term used by HCAs to describe any skin protectant) routinely to prevent red skin. The majority were not concerned that their application might affect pad performance, and only 2 of the 31 caregivers (6%) who responded to the question indicated that they avoided the use of skin protectants due to concerns over pad leakage. Soap and water was the most commonly used cleanser (81%).

One researcher directly observed skin care practices in 27 residents in 2 nursing. Particular attention was paid to the type of skin cleansers that were used and whether skin protectants were used routinely or to treat specific conditions, like erythema (Table 7). The amount of time spent on the morning wash ranged from 5 to 85 minutes (median = 20 minutes). They noted that caregivers appeared to spend adequate time with residents to complete this task. Although soap and water was the most commonly used cleansing agent, one of the notable results from the observation was the use of a commercially available bubble bath as a skin cleanser, either diluted in a bowl of water (n = 7) and applied undiluted directly to the skin (n = 3). This practice was not reported in the questionnaire. Based on their observations, observers concluded that caregivers liked the liquid nature of the bubble bath and its pleasant fragrance; nevertheless, bubble bath products are not intended for use as skin cleansers. Researchers did not observe staff using no-rinse perineal or incontinence skin cleansers.

Discussion

The primary aim of the work was to compare the prevalence of IAD problems between product designs in a population of elder nursing home residents who were regularly using incontinent pads for incontinence. Analysis of findings revealed no significant differences based on comparisons of the 4 product types evaluated. Incontinence-associated dermatitis was recorded by HCAs at 6.1% of pad changes; this finding is similar to the range of values reported in a comprehensive review published in 2012.[2] However, research nurses logged the much higher point prevalence figure of 85.7% during the 2-weekly skin observations on the same test subjects. Even if skin problems classified as mild are discounted (leaving only those

TABLE 6.

(Non)-concordance Between the Most Severe Incontinence-Associated Skin Problem Logged by Researchers and by Healthcare Assistants, by Subject, Across All 4 Products Designs

Most Severe Skin Problem By Subject (Researcher)	None	Mild	Moderate	Severe	All
None	0	1	1	0	2
Mild	2	5	17	3	27
Moderate	1	14	18	6	39
Severe	0	5	4	1	10
All	3	25	40	10	78

TABLE 7.

Observations on the Washing of 27 Subjects (a Subset of the 78 Whose Skin Health Was Studied) – 8 Men and 19 Women

Washing Product Category	Washing Product Variant Used		
Washing agent	Soap and water	Bubble bath diluted with water	Bubble bath
	63.0	25.9	11.1
Type of wash cloth: face a body	Cotton toweling	Disposable	Sponge
	55.6	40.7	3.7
Type of wash cloth: bottom	Cotton toweling	Disposable	Sponge
	3.7	92.6	3.7
Type of skin protectant	zinc oxide-based ointment	Other skin protectant	None
	55.6	3.7	40.7

classified as moderate or severe), we found a point prevalence of 45.5%, which is approximately 7 times higher than the occurrence rate recorded by HCAs. Subsequent dialogue between researchers and HCAs suggested that some of the explanation might be in HCAs assuming low-grade IAD as normal for that population and failing to record it. Nevertheless, while this tendency would be expected to result in HCAs documenting fewer skin problems than nurse researchers, it does not account for the fact that HCAs tended to assign less severe grades to skin problems (Table 6). This finding suggests that HCAs tend to underreport skin problems at all levels of severity. Alternatively, it may indicate that HCAs tend to classify these problems as transient and unlikely to lead to more severe skin damage.

Care must be exercised when comparing HCA and nurse research assessments because the researcher observations were undertaken at 1 point (point prevalence) during the second week of product testing and the various care assistant ratings were documented repeatedly over the whole product test period. They were not clinically validated against each other as it was not possible to identify skin observations that occurred on the same day. Nevertheless as the primary outcome variable was maximum severity of IAD, we would expect moderate to severe IAD to have been detected using both methods (researcher observation and HCA observation).

Other relevant results emerged from the study. For example, the buttocks were the most common site for IAD development (Figure 3). In addition, 40% of research observations revealed that skin problems were present at more than 1 skin site (Tables 4 and 5), and they persisted or recurred at the same skin site. Specifically, less than 10% of subjects experienced no skin damage during the observation period, whereas 36% had buttock skin problems at every researcher observation. The etiology of the erythema on the buttocks was frequently unclear. Erythema is a sign of inflammation that may be attributable to ischemic tissue damage or exposure to an irritant such as stool or urine. Skin damage also may be caused by a combination of these issues.[2] We assessed whether areas of erythema were blanchable or nonblanchable, but none progressed to a pressure ulcer, perhaps suggesting that the observed problems were irritant in nature. Three percent of subjects had skin problems in the groin that persisted during every observation. Groin skin problems were more likely to be a form of moisture-associated skin damage because they are not traditionally subjected to prolonged pressure and deformation when the individual is lying in a bed or sitting.

Partial-thickness skin loss or eroded skin was also a relatively infrequent occurrence; even when noted, it was present for only 1 observation in approximately 50% of cases. However, it was clearly more problematic and persistent, particularly in the sacral area where 22.9% of observations were categorized by the researchers as eroded skin. There were no observations of eroded skin in the groin area; erosion was observed in 7.1% and 11.5% of observations of the right and left buttocks, respectively. Because of the relatively short follow-up period, it was not possible to monitor persistent skin conditions to determine progression. Researchers alerted HCAs and nursing staff to a missed occurrence of eroded skin on several occasions; each prompt led to treatment that may have prevented additional skin damage.

We estimated the size of skin lesions as small, medium, or large rather than attempting to objectively measure the frequently diffuse areas of damage or inflammation. Analysis of these findings showed that the size of the problem was influenced by the location itself. For example, problems on the sacrum were almost always rated as small or medium; however, the sacrum represents a smaller total skin area than the buttocks and the lesions were more likely to be ranked as large. Size of the problem is considered useful as a marker of change to see if a problem has become bigger/smaller. However, this measurement is complicated with IAD because the approximate size of the damaged skin may decrease, even though the severity of erythema or skin integrity may worsen. An alternative approach may be to consider a "global opinion

of severity" based on the observers' overall impression, which is able to assimilate the complexity of the situation.

Skin observations revealed considerable complexity; the skin of our elderly participant was almost permanently covered in an absorbent pad, and it rarely appeared to be entirely normal. Instead, it was often wet, marked by creases and pad marks, and it appeared mottled with indentations and markings. Healed pressure ulcers and eroded areas often left marks and areas of depigmentation, and we observed frequent occurrences of purple discoloration. It is possible that some of the mild problems were partially explained by this complicated presentation and the actual clinical significance of these findings remains unclear. More than one-third of residents had problems recorded on all of their observations indicating ongoing problems. This may reflect the vulnerable nature of the population or it may indicate that skin problems were not being adequately identified and treated. There was no use of specialized skin cleansers in any of the homes and the most frequent skin cleansing routine observed was soap and water and a skin protectant (either routinely or for treatment). This may influence the persistence of problems that were observed. However, care must be taken when interpreting these findings because observations were completed at 2-week intervals and we do not know what happened to the skin during the intervening periods. Nevertheless, our observations provided detailed descriptive data on the nature of skin problems and IAD and these categories were useful in forming the foundations for a new IAD specific skin health tool.[21]

Since this study was completed, Borchert and colleagues[22] have published a validated instrument called the Incontinence-Associated Dermatitis and its Severity instrument. The instrument rates IAD in 13 skin locations and a score is calculated from 0 to 52. A 4-point scale is used (1 = pink in color, 2 = red without rash or skin loss, 3 = fungal rash, 4 = any degree of skin loss). The authors tested interrater reliability, using 4 case scenarios showing different levels of IAD with 247 WOC nurses and 100 nursing staff and showed high levels of agreement. This instrument has been subsequently validated by WOC nurses for use with people with dark and lighter skin tones[23] and has been amended so that there are now 14 areas and a maximum score of 56. It has also been used as an outcome measure in a recent study of the effect of a structured skin care regimen for patients with fecal incontinence.[24] Because the Incontinence-Associated Dermatitis and its Severity focuses primarily on erythema, it would be unlikely to capture the range and variability of skin problems that were observed during the study in the UK nursing homes, many of which were transient and nonprogressive.

Limitations

At the time the study commenced, there was no suitable validated instrument to measure IAD. The instrument developed by the authors was based on an instrument we used in an earlier study. Nevertheless, it had not been previously validated. There was no defined skin care routine used throughout the study, and the HCAs were asked to follow their "usual" skin care routine, which predominantly consisted of soap and water and application of a skin protectant, when deemed necessary. This lack of consistency may have influenced study findings. The HCAs and the researchers did not look at the same skin conditions at the same time, which also may have influenced findings. Concurrent observation was not possible because of limited observers and the design of the study. We were, therefore, unable to determine whether differences existed between researcher and HCA ratings of IAD.

Conclusion

We found no statistically significant differences in the occurrence of IAD when different pad designs were used. Incontinence-associated dermatitis, as identified by the researchers, was found on 85.7% of observations, it was often persistent and frequently present at more than one site. The buttocks were most commonly affected. The occurrence of IAD as reported by the HCAs was much lower at 6.1%. The reason for this difference is unclear; we hypothesize that this difference may have occurred because HCAs considered low grades of IAD as normal for this population and ceased to notice or document it. We believe that research into the prevalence and natural history of IAD is hampered by the lack of a validated instrument. Finding from our study suggests that a simple instrument that would enable HCAs to identify IAD is practicable but more work is needed to investigate why researchers and HCAs recorded such different occurrence rates.

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