Evaluating the Efficacy of a Uniquely Delivered Skin Protectant and Its Effect on the Formation of Sacral/Buttock Pressure Ulcers

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Skin breakdown is a common adverse occurrence in healthcare facilities; effective management of related risk factors is critical for prevention. Measures focusing on the skin care of patients with incontinence are recommended to reduce the incidence of pressure ulcers on the sacrum and ischium. However, little research exists to support these recommendations. A retrospective study was conducted to determine if the use of a skin cleansing/protectant product on residents with incontinence decreased the incidence of nosocomial pressure ulcers in the sacral/buttock area. Chart data from all residents with incontinence of a 57-bed, long-term care, skilled nursing home that employs a comprehensive approach to pressure ulcer prevention were collected for a period of 3 months before use of the new product and for 3 months following introduction of the new product .

During the first 3 months, five (14.7%) of the 34 incontinent residents developed superficial pressure ulcers (20% were Stage I, 80% were Stage II). Following the change in skin care, no pressure ulcers occurred in the 30 residents with incontinence. The observed decrease (McNemar's chi-square = 4.786, df = 1, Phi = -.273, P = .015) suggests a significant association between the consistent application of a skin protectant and the prevention of skin breakdown. The results of this study demonstrate that, in this population, and in the presence of a comprehensive pressure ulcer prevention program, use of this skin protectant can significantly reduce the incidence of nosocomial sacral/buttocks pressure ulcers.

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The development of pressure ulcers is a common adverse occurrence in healthcare, affecting 2.3% to 28% of patients in long-term care (LTC) facilities.[1] Although the highest prevalence (total number of people affected within the population at any time) is seen in LTC facilities, the highest incidence (number of people with new ulcers formed within a specific period of time) is in acute care.[1] The perception that all pressure ulcers are a marker of poor care and neglect provokes litigation that mostly affects nursing homes.[2,3] More than 75% of pressure ulcers represent superficial tissue damage (Stage I - 37% and Stage II - 39%).[4] Almost half of all pressure ulcers form on the sacrum or ischium; patients over the age of 70 are affected the majority of the time.[4]

Once a pressure ulcer develops, longer hospitalization and more nursing time are required, resulting in higher costs.[5] Pressure ulcers tracked across multiple healthcare settings cost, on average, between $1,119 and $10,185 to treat[6] while the management of severe wounds may cost as much as $55,000.[7] In the current decade, pressure ulcer prevention has become a national goal, as healthcare facilities seek to reduce pressure ulcer prevalence in nursing home residents from 16 per 1,000 residents (1997 baseline National Nursing Home Survey to 8 per 1,000 residents.[8] More recently, the Centers for Medicare and Medicaid Services (CMS) have designated pressure ulcers as a quality measure in the Nursing Home Quality Initiative.

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Risk factors that may compromise the ability of tissue to tolerate the forces of pressure, friction, or shear include: Age, mobility, nutrition, continence, concurrent disease, medication, and a history of previous pressure ulcer formation.[5,10-12] Unfortunately, none of these risk factors operates independently. The presence of one factor often accompanies at least two others, making pressure ulcer prevention strategies complex and interrelated.[9,11,13] Efforts to prevent pressure ulcers focus on managing the risk factors that are amiable to manipulation.

Urinary and fecal incontinence have been cited as risk factors, with fecal incontinence the better predictor of ulcer formation.[9-13] Fecal incontinence provides an environment where physical and chemical trauma compromise the skin's normal barrier function, which compromises tissue integrity and increases a patient's chance of developing a pressure ulcer up to 22 times higher than continent patients.[12] In addition, patients with incontinence require frequent cleansing of the perineal and buttock areas, which can dry the skin and alter its pH, especially when soap and water are used; thus, compromising the skin's ability to withstand physical and chemical trauma.[14-20]

Products designed to cleanse, moisturize, and protect the skin abound on the market in the form of sprays, foams, lotions, creams, and ointments. The Agency for Healthcare Research and Quality (AHRQ) developed a guideline in 1992 that advocates the use of protectant moisture barriers. However, the guideline was derived from usual practice and standards developed by professional organizations, not on research evidence.[21] The Wound Ostomy and Continence Nurses Society (WOCN) has formed a Clinical Practice Committee that is currently developing four evidence-based wound guidelines; the second in the series will address pressure ulcers. This guideline is expected to be completed in 2003.

A skin protectant, or moisture barrier, is defined as "a drug which protects injured or exposed skin or mucous membrane surface from harmful or annoying stimuli."[22] Research supports the ability of these products to protect the skin and maintain skin integrity in both *in vitro*[23] and *in vivo* environments.[24] The Food and Drug Administration (FDA) categorizes 13 different ingredients, in varying concentrations, as "generally regarded as safe and effective" over-the-counter skin protectants for incontinence use. Clinically, a protectant moisture barrier has been shown to improve tissue integrity as evidenced by a significant reduction in transepidermal water loss (TEWL) and erythema.[14] One study incorporated the application of skin protectant as part of a comprehensive pressure ulcer prevention program that decreased the incidence of pressure ulcer formation.[25] However, few published studies have isolated and evaluated the efficacy of these products and their potential as a preventive measure in reducing the incidence of pressure ulcers.[26,27]

Background

Early in 2001, a Quality Improvement (QI) team at Fulton County Medical Center's Long-Term Care Unit identified the prevention of sacral/buttock pressure ulcers as an area that needed improvement. Pressure ulcer preventive strategies already in place included: a) daily skin assessment, b) use of a standardized pressure-reducing support surface consisting of an 8-inch foam mattress with an egg-crate surface, c) a consistent, documented repositioning program for immobile and inactive residents, maintained through adequate staffing, that exceeds state requirements for staff ratios, d) dietary monitoring of all residents with an individualized care plan for malnourished or overweight residents, e) treatment and maintenance of concurrent disease conditions, and f) use of pads and briefs that absorb moisture and have a quick-drying surface on

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KEY POINTS

- Expert opinion and common sense suggest that protecting patients' skin against the effects of urine and/or feces may help prevent pressure ulcers.
- However, as observed by the authors, time constraints and real (or perceived) cost considerations may result in less-than-optimal incontinence care procedures in every day practice.
- The results of this retrospective study suggest that, when used in conjunction with other pressure ulcer prevention strategies, optimal skin care following incontinence episodes reduces the incidence of skin breakdown.
- The results of prospective, controlled clinical studies may confirm these findings and contribute much needed evidence to support current opinions about the need to protect patients' skin.

patients with incontinence. Residents with incontinence are cleaned at soiling and checked at least every 2 hours for wetness.

The protocol for incontinence care involved large disposable wipes (Tena® Skin-Caring® Washcloths, SCA Hygiene Products, Bowling Green, Ky.) and moisturizing lotion to remove stubborn fecal matter as needed. The protocol also included use of a skin protectant (Restore™ Barrier Cream Skin Protectant, Hollister, Libertyville, Ill.; active ingredient: 1.5% dimethicone) for the treatment of damaged skin, but it was not recommended for preventive care because it was perceived as cost-prohibitive. In fact, product utilization data revealed that the protectant was almost never applied. According to a staff survey, the time and inconvenience associated with use of the barrier cream often inhibited the application.

This information resulted in the decision to purchase a skin protectant that is incorporated into a thick disposable washcloth that cleanses and moisturizes the skin while applying the skin protectant (Comfort Shield® Perineal Care Washcloths, Sage Products, Inc., Cary, Ill.; active ingredient: 3% dimethicone). It was hoped that this all-in-one product would control process variation by removing the inhibitors of time and inconvenience associated with application of a separate product; thus, ensuring greater consistency of skin protectant application.

Before March 1, 2001, the Minimum Data Set (MDS) Facility Quality Indicator Profile, which provides summary and feedback information submitted to the state, provided the only pressure ulcer tracking data available. The MDS section M, which addresses skin condition, classifies ulcers as follows:

Stage I: A persistent area of skin redness (without a break in the skin) that does not disappear when pressure is relieved

Stage II: A partial-thickness loss of skin layers that presents clinically as an abrasion, blister, or shallow crater

Stage III: A full-thickness of skin is lost, exposing the subcutaneous tissues. It presents as a deep crater with or without undermining adjacent tissue

Stage IV: A full-thickness of skin and subcutaneous tissue is lost, exposing muscle or bone.

Ulcer type is also categorized by its cause: pressure or stasis.

The MDS data reflect ulcers and other skin conditions present within 7 days of the MDS assessment and include conditions present on admission and nosocomial status. Because the MDS data were not sensitive enough to differentiate ulcers based on body site or whether they were nosocomial or present on admission, the tracking of all new pressure ulcers in the sacral/buttock area began in March 2001.

Although the ultimate goal of changing incontinence care protocols was to reduce the number of nosocomial pressure ulcers in the sacral/buttock area, the observed reduction — ie, no new pressure ulcers during the months of May, June, and July — was unexpected. To ascertain if this observation was real or subjective, a study was designed to determine if the decreased incidence of nosocomial pressure ulcers in the sacral/buttock area could be related to the use of the new skin protectant.

Methods

Study design. After obtaining appropriate Internal Review Board approval, a quasi-experimental, retrospective study, using data from the medical record chart, was developed to look at the study population (90-day period when the product was exclusively used) and a historical control population (90-day period before new product introduction) to determine if differences in patient risk may have accounted for the 3-month absence of pressure ulcer formation in the sacral/buttock area.

Preventive strategies that were already in place, including policy, procedures, equipment and staffing (turnover and ratio), were scrutinized to determine if changes were made during the study period that could have affected the outcome. Practice, equipment, and staffing were found to be consistent over the study time period selected.

The study time period was defined as May 1, 2001 through July 29, 2001, and the control time period was defined as January 1, 2001 to March 31, 2001. Selection of the control period was based on the rationale that staffing and practice would be the most similar immediately before the test period. April was not included because the product was introduced in the facility during this month, other products were still available for use, and a transition time for staff to become familiar with the product would have taken place.

In addition to the detailed retrospective chart audit, patient medical record charts were reviewed back to July 2000 to define the facility's historical monthly incidence of pressure ulcers in the sacral/buttock area in residents with incontinence.

Setting and participants. The study was conducted in a 57-bed long-term care (LTC) skilled nursing home attached to a 25-bed acute care hospital in a rural area. Average daily census is between 55 and 57 residents with an average length of stay of 1.3 years. Residents of the LTC units are 70% female, 30% male, and 100% Caucasian, which reflects the demographics of the surrounding community. Ages range from 65 years to more than 100 years; almost half of the residents are between the ages of 75 and 84; 42% are 85+ years old. Historically, 60% to 62% of the residents are incontinent of urine, stool, or both. A majority of the residents (73%) are discharged due to death, 18% return home, and the remaining 9% move to another facility.

Inclusion criteria. For both time periods, all current and newly admitted residents who were incontinent of urine, stool, or both (as identified through MDS Quality Indicator Summary) and resided in the facility's LTC unit for at least 30 consecutive days during the study or control study period participated.

The Nursing Assessment Coordinator (RNAC) was responsible for MDS completion. In addition, the registered nurse who has overseen the diagnosis, staging, and treatment of pressure ulcers in this facility since 1993 worked with the RNAC to ensure consistent application of definitions and documentation of the variables collected.

Data collection. To define the facility's historical monthly incidence of sacral/buttock pressure ulcers on residents with incontinence, the medical record charts for all such residents from July 2000 to March 2001 were reviewed. Location of the ulcer, stage, date of diagnosis, and date of resolution were recorded.

To assess patient risk during the control and test periods, a medical record abstraction was conducted. Variables collected to assess pressure ulcer risk and population characteristics included:

- Age (calculated in years for first day of study period)
- Gender
- Length of stay (LOS) during study period (calculated as total days of residency during 90-day study period)
- Mobility/Activity indicators. These were rated on a scale of 0 (independent) to 4 (total dependence) or 4 if the activity did not occur per MDS Section G1a-e, I, G2
- Incontinence status. This was rated on a scale of 0 (continent) to 4 (incontinent) per MDS Section H1a and b and H2c (diarrhea)
- Concurrent diseases that were noted as absent or present per MDS Section I1 and 2. Patient records were reviewed to ensure no new diagnosis was missed
- Body mass index (BMI), calculated from MDS Section K2
- Albumin level (dietary summary record, confirmed by laboratory report)
- Pressure ulcers formed during study period (nursing notes, wound treatment record)
- History of pressure ulcers in the sacral/buttocks area (nursing notes, wound treatment record).

Because each study period covered 90 days, each resident was ensured of having an MDS assessment performed during the study period — ie, for admission, quarterly, or as part of the annual assessment. Because data for concurrent diseases and BMI are collected annually, these data were collected from the MDS annual assessment closest to the study period.

Concurrent diseases were recorded as present or absent under the categories of diabetes mellitus, cardiac, neurological, respiratory, anemia, and renal failure. A value of 1 was assigned to each disease category if present and 0 if not present. A concurrent diseases scale was calculated by using the sum of the disease category values for each resident. This resulted in a concurrent disease scale that ranged from 0 to 6.

Data analysis. Statistical analyses were performed using SPSS System (SPSS, Inc., Chicago, Ill.). Because all subjects did not match identically in both groups, independent samples *t*-tests were conducted to demonstrate that the groups did not differ significantly in terms of risk factors for skin breakdown (pressure ulcer formation). Independent sample *t*-tests were used rather than dependent samples *t*-tests because the authors wanted to test whether the control and study groups were dependent. In other words, if such an analysis demonstrated that the groups did not differ significantly regarding risk factors for developing pressure ulcers, the groups presumably were matched (ie, the same).

A chi-square test of independence was performed for gender and history of pressure ulcers. A McNemar's chi-square test was used to discern whether an association existed between the study and control groups with regard to history of pressure ulcers and to examine the relationship between treatment with skin protectant and the development of pressure ulcers. Such a test of significance is used for situations when samples are matched (ie, samples are not independent).

TABLE 1
GROUP CHARACTERISTICS

Variable	Study Mean	Control Mean	t	P
Age (years)	82.2	83.56	-0.732	0.467
Length of stay (days during study period)	86.17	81.24	1.33	0.188
Mobility in bed*	3.10	2.94	0.641	0.524
Transfer between surfaces*	2.97	3.09	-0.521	0.604
Incontinent of bowel†	1.80	2.09	-0.635	0.528
Incontinent of urine†	3.57	3.44	0.777	0.44
Body mass index: weight (kg)/height (cm)	24.79	23.84	0.764	0.448
Albumin (nutritional status; mg/dL)	3.12	3.06	0.866	0.39
Concurrent disease scale‡	2.23	2.24	-0.008	0.993

** Scale= 0-independent, 1-supervision, 2-limited assistance, 3-extensive assistance, 4-total dependence, 4-activity did not occur*

† Scale= 0-continent, 1-usually continent, 2-occasionally incontinent, 3-frequently incontinent, 4-incontinent

Results

Over the 9-month review of historical incidence, 28 to 35 residents were incontinent each month (average = 31). The number of residents who formed new sacral/buttock pressure ulcers each month ranged from 0 to 3; 12 residents with incontinence developed 15 sacral/buttock ulcers. All pressure ulcers were superficial (13% were Stage I and 87% were Stage II) and usually were due to moisture and enzymatic damage. Monthly incidence was calculated by dividing the number of residents who formed new ulcers by the total number of residents with incontinence each month, for an average monthly incidence for the 9-month period of 4.7%.

Of the residents in the control group, 34 met inclusion criteria; in the study group, 30 met the inclusion criteria. Twenty-six residents were members of both the control and study groups. Two residents in the control time period died before completing their quarterly assessment, so data were obtained through their assessment completed in December of 2000. Albumin levels could not be located for two of the residents of the control group.

Of the residents in both study populations, 94% had five or more of the nine possible pressure ulcer risk factors. Given the parameters of assessment, it can be assumed that both populations in the study were at high-risk.

The study and control groups were not significantly different in age, length of stay during study (in days), mobility in bed, ability to transfer between surfaces, incontinence of bowel or urine, body mass index (BMI), albumin (nutritional status), and concurrent diseases (see Table 1). For example, the treatment group averaged 2.23 on the concurrent disease scale while the non-treatment group averaged 2.24. This difference is not statistically significant (t = -.008, df = 62, P = .993). No significant association was evident between gender and the formation of pressure ulcers (chi-square = .267, df = 1, P = .599) or between the study and control groups with regard to history of pressure ulcers (McNemar's chi-square = .758, df = 1, P = .384).

Because the two groups were not statistically different on risk factors for developing pressure ulcers, the groups were treated as matched pairs for the chi-square analysis. McNemar's chi-square test found a significant association between being treated with skin protectant and not developing pressure ulcers (McNemar's chi-square = 4.786, df = 1, P = .015). Because one of the cells had less than five cases, a Fisher's Exact Test, a more accurate measure of level of significance in such a case, was conducted to test the level of significance for this association (P = .036).[28]

None of the 30 residents in the study group developed pressure ulcers; whereas, five (14.7%) of the 34

residents in the control group developed 10 pressure ulcers (20% Stage I and 80% Stage II). The significance of the association between study group and the development of pressure ulcers was weak to moderate (Phi = -.273, $P = .015$).

Discussion

Although this study demonstrated a 100% reduction in the incidence of sacral/buttock pressure ulcers between the control and study periods/groups, it is questionable if this reduction can be maintained over time. For a more practical representation of the long-term implications, the average monthly incidence of pressure ulcers for the 9-month historical baseline (4.7%) was compared with the incidence of pressure ulcers when the skin protectant was used as a preventive measure with an additional 3 months of data (0.5%) extracted from the medical charts. This represents an 89% reduction in the average monthly incidence of sacral/buttock pressure ulcers when the skin protectant was applied to residents with incontinence.

The results of this study demonstrate a direct association between the use of a skin protectant and a decrease in the incidence of superficial pressure ulcers. Logically, application of any FDA-identified skin protectant could achieve similar results, providing the product is consistently applied. In this study, delivering the skin protectant with a disposable washcloth simplified the process considerably and led to its adoption as the new standard of care for use in continence cleanup. Because many of the supplies needed to treat Stage I and Stage II pressure ulcers are stocked on the unit, estimating the cost of treating the ulcers formed in the control group was not possible.

During the months when the new product was used exclusively, utilization of large disposable wipes previously used for incontinence cleansing procedures decreased by half, resulting in an estimated cost savings of $3,700 annually. Based on diaper and pad usage in this facility, the number of incontinent episodes per day was estimated to be around 107 for the 29 to 31 residents with incontinence. The cost of providing the new product is estimated at $1.07 to $1.15 per incontinent resident/day. Assuming the same level of compliance and the same number of incontinent episodes, costs would have been $1.56 to $1.67 per resident per day using the pre-study skin protectant (16 uses per 4-ounce tube).

Stage I pressure ulcers and perineal dermatitis are clearly delineated at this facility. As part of the study, an attempt was made to measure incidence and qualify perineal dermatitis from existing medical record documentation using the Perineal Dermatitis Grading Scale, developed by Brown in 1993.[29] Skin color was usually noted, but skin integrity assessments usually consisted of subjective terms (eg, excoriated) that were not clearly defined or standardized. The surface area affected was not quantified and usually no patient symptoms were noted. Additionally, ensuring that every case of perineal dermatitis was accounted for in the chart was not realistic. Given the challenges presented above, no analysis was performed on the data collected.

Retrospective studies have the limitation of relying on existing data in the medical record. For those variables obtained from the MDS, each resident's condition was reliant in data collected once during a 90-day period, with the exception of BMI and albumin, which were collected once annually. Concurrent diseases were evaluated as either present or absent, making it impossible to account for the disease severity that would lower or raise patient risk. However, any "significant change" would have prompted the completion of a new assessment, so some level of stability in patient condition can be assumed.

Of course, potential changes in staff time and attention as a result of the new product trial may have affected the results obtained. Variability in the incidence of pressure ulcers is not uncommon,[30] and the variability observed during the control time period in the study is a limitation. Unfortunately, resources and time constraints prevented a review residents' charts over a longer time period, which would have been desirable and might have yielded somewhat different results.

Conclusion

Results of this study indicate that, in the presence of a comprehensive pressure ulcer prevention program, the preventive use of the skin protectant significantly reduced the incidence of nosocomial sacral/buttocks pressure ulcers. This finding adds to the body of evidence-based strategies for the prevention of pressure ulcers. It also supports the AHRQ guideline recommendations related to the use of a protectant moisture barrier to protect skin from the effects of prolonged exposure to moisture.

Additional research is needed to investigate the efficacy and cost-effectiveness of this intervention in different patient populations. - OWM

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