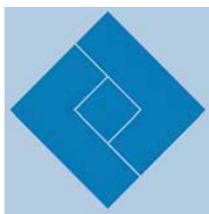


WOUND CARE



A 3-in-1 Perineal Care Washcloth Impregnated With Dimethicone 3% Versus Water and pH Neutral Soap to Prevent and Treat Incontinence-Associated Dermatitis

A Randomized, Controlled Clinical Trial

Dimitri Beeckman ■ Sofie Verhaeghe ■ Tom Defloor ■ Lisette Schoonhoven ■ Katrien Vanderwee

PURPOSE: We compared the effectiveness of a 3-in-1 perineal care washcloth versus standard of care (water and pH neutral soap) to prevent and treat incontinence-associated dermatitis (IAD). The product under study was a soft, premoistened washcloth, including a 3% dimethicone formula, with cleansing, moisturizing, and barrier protection properties.

DESIGN: Randomized, controlled clinical trial.

SUBJECTS AND SETTING: The study sample comprised a random sample of 11 nursing home wards (6 experimental and 5 control) in a convenience sample of 4 nursing homes in Belgium. The sample included nursing home residents at risk for and/or affected by IAD defined as incontinent of urine, feces, urine/feces, and/or having erythema of the perineal skin (not caused by pressure/shear), and/or having an edematous skin in the genital area.

METHODS: Participants in the experimental group were treated according to a standardized protocol, including the use of a 3-in-1 perineal care washcloth impregnated with a 3% dimethicone skin protectant. Participants in the control group received perineal skin care with water and pH neutral soap, the standard of care in Belgian nursing homes. The study period was 120 days. Data were collected between February and May 2010. Incontinence-associated dermatitis prevalence and severity were assessed using the IAD Skin Condition Assessment Tool. The surface (cm²), redness, and depth of the perineal lesion were assessed daily by the nurses. This tool generates a cumulative severity score (maximum score = 10) based on area of skin affected, degree of redness, and depth of erosion.

RESULTS: Four hundred sixty-four nursing home residents were assessed and 32.9% (n = 141) met the criteria for inclusion, including 73 subjects in the experimental group and 68 in the control group. Baseline IAD prevalence was comparable in both groups (experimental: 22.3% vs control: 22.8%, $P = .76$). Baseline IAD severity was 6.9/10 in the experimental group and 7.3/10 in the control group. A significant intervention effect on IAD prevalence was found (experimental: 8.1% vs control: 27.1%, $F = 3.1$,

$P = .003$). A nonsignificant effect on IAD severity could be determined (experimental: 3.8/10 vs control: 6.9/10, $F = 0.8$, $P = .06$).

CONCLUSION: The use of a 3-in-1 washcloth, impregnated with a 3% dimethicone formula, resulted in a significantly reduced prevalence of IAD and a trend toward less severe lesions. These findings provide indicative evidence for the use of 3-in-1 perineal care washcloth as an effective intervention against the use of water and a pH neutral soap to prevent and/or treat IAD.

■ **Dimitri Beeckman, PhD, RN**, Lecturer, Florence Nightingale School of Nursing & Midwifery, King's College London, United Kingdom; Assistant Professor, Nursing Science, Department of Public Health, Faculty of Medicine and Health Sciences, Ghent University, Belgium; and Visiting Lecturer, Department of Bachelor in Nursing, University College Arteveldehogeschool Ghent, Belgium.

■ **Sofie Verhaeghe, PhD, RN**, Professor, Nursing Science, Department of Public Health, Faculty of Medicine and Health Sciences, Ghent University, Belgium.

■ **Tom Defloor, PhD, RN**, Professor, Nursing Science, Department of Public Health, Faculty of Medicine and Health Sciences, Ghent University, Belgium.

■ **Lisette Schoonhoven, PhD, RN**, Assistant Professor, Scientific Institute for Quality of Healthcare, Radboud University Nijmegen Medical Centre, The Netherlands.

■ **Katrien Vanderwee, PhD, RN**, Professor, Nursing Science, Department of Public Health, Faculty of Medicine and Health Sciences, Ghent University, Belgium.

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Correspondence: Dimitri Beeckman, MSc, PGCert(Ed), PhD, RN, Florence Nightingale School of Nursing and Midwifery, Department of Adult Nursing, King's College London, James Clerk Maxwell Building, Room 3.17, 57 Waterloo Road, London SE1 8WA, United Kingdom (dimitri.beeckman@kcl.ac.uk).

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■ Introduction

Incontinence-associated dermatitis (IAD) is an inflammation of the skin in the genital, buttock, or upper leg areas that occurs when urine and/or feces come into contact with the skin.^{1,2} Clinical manifestations range from erythema (with or without loss of skin integrity) to cutaneous infections (such as candidiasis).²⁻⁵ Incontinence-associated dermatitis is often associated with redness, rash or vesiculation, and symptoms such as pain or itching.¹ Older people, and especially those in long-term care facilities, are at risk for urinary or fecal incontinence and IAD.^{4,6} Incontinence-associated dermatitis is reported to affect incontinent patients from 5.7% in nursing homes⁴ to more than 42% in acute geriatric care.⁷ Savik and colleagues¹ and Beekman and associates⁸ reported that IAD occurrence was significantly associated with (1) impairments in tissue tolerance, (2) problems of the perineal environment, and (3) altered toileting ability from daily use of restraints. Incontinence-associated dermatitis appears also to be strongly associated with age^{4,9} and this correlates with a more fragile epidermal barrier and a reduced capacity of the skin to regenerate and repair.^{10,11}

Prevention and Treatment of IAD

Incontinence-associated dermatitis prevention is based on avoiding or minimizing exposure to stool or urine.^{4,8} For IAD treatment, there should be an additional focus on the eradication of cutaneous infections and on the containment or diversion of urine and/or stool.⁴ Increasing evidence draws attention to the importance of a consistent, defined skin care regimen to prevent and treat IAD.¹²⁻¹⁵ Although studies on the effectiveness of different regimens show extensive variation in their components, all of them include (1) gentle perineal cleansing, (2) application of a moisturizer, and (3) use of a skin protectant.

Perineal skin cleansing should involve a product whose pH range reflects the acid mantle of healthy skin (pH between 5.4 and 5.9).¹⁶⁻¹⁸ Ananthapadmanabhan and associates¹⁹ demonstrated that high pH solutions (pH 10.0) can increase stratum corneum swelling and alter lipid rigidity, thereby suggesting that cleansers with neutral or acidic pH may be potentially less damaging to the skin. Skin cleansers provide an alternative for soap and water to perineal cleansing.²⁰ They may reduce some of the adverse effects of soap due to their chemical composition and help to maintain a pH level that minimizes barrier disruption.²¹ No-rinse skin cleansers combine detergents and surfactants to loosen and remove dirt or irritants; many also contain a moisturizing capacity to restore or preserve optimal barrier function.

Moisturization involves repairing the skin barrier, retaining and increasing water content, reducing transepidermal water loss, restoring the lipid barriers' ability to attract, and holding and redistributing water.²² Moisturizers contain varying combinations of emollients and humec-

tants to achieve their beneficial effects.²³

components of emollients and include fats, waxes, or oils.²⁴ Sources of lipids include animal products such as lanolin, petrolatum, and dimethicone (from mineral oils).^{21,24} According to Buraczewska and associates²⁵ and Crowther and coworkers,²⁶ the routine use of moisturizers is useful in replacing intercellular lipids and maintaining the barrier function of the skin.

Skin protectants, classified by dermatologists as occlusive moisturizers, contain petrolatum and dimethicone.²⁷ A skin protectant prevents skin breakdown due to moisture and biological irritants in urine and feces.²⁸ Currently used protectants are petrolatum-based ointments, dimethicone-based ointments, zinc oxide creams, oils, and liquid film-forming acrylates. Hoggarth and colleagues²⁸ reported that skin protectants containing petrolatum demonstrated protection against irritants and maceration and provided some skin hydration.²⁸ Products containing dimethicone varied in protection against irritants and have good skin hydration potential but lower barrier efficacy. Zinc oxide-based skin protectants showed protection against irritants but poor skin hydration and barrier properties to prevent maceration.

To effectively prevent and treat IAD, multiple products, involving different steps, should be used. Lewis-Byers and Thayer²⁹ and Bliss and colleagues³⁰ state that a defined skin care regimen that reduces steps or staff time should be encouraged. Multiple studies showed that a single-step intervention has the potential to maximize time efficiency and to encourage adherence to the skin care regimen.³¹⁻³⁵ These single-step products are disposable washcloths that incorporate cleansers, moisturizers, and skin protectants into a single product.

■ Study Aim

The aim of this study was to compare the effectiveness of a 3-in-1 perineal care washcloth versus standard of care (water and pH neutral soap) to prevent and treat IAD. The product we studied is a soft premoistened washcloth, including a 3% dimethicone formula, with cleansing, moisturizing, and barrier protection abilities (Comfort Shield Perineal Care Washcloth Dimethicone 3%, Sage Products Inc, Cary, Illinois).

■ Methods

A randomized, controlled clinical trial was conducted between February and May 2010. The prevalence and severity of IAD were the main outcome measures of this study. The study was performed in a random sample of 11 nursing home wards (6 experimental and 5 control) in a convenience sample of 4 nursing homes in Belgium. Simple randomization was used to assign the wards to the experimental and control groups (SPSS, Inc, Chicago, Illinois). The sample included nursing home residents at risk and/or affected by IAD.

Because of the lack of a definition and/or instrument to assess IAD risk in literature, nursing home residents were eligible to participate if they (1) were chronically incontinent of urine, stool, or double urinary and fecal incontinence and/or (2) had a discoloration of the perineal skin, caused by urine or stool and not caused by pressure/shear and/or (3) had hyperhydrated skin. Newly admitted residents were assessed and asked to participate within 48 hours after admission. Residents were excluded after being admitted to hospital or when being admitted from another ward in the nursing home.

Study procedures were approved by the ethical review board of Ghent University Hospital (Belgium) and by each of the participating nursing homes (B/67020097196). The residents were contacted by the senior nurse of the ward to request consent to participate. Permission from the resident's general practitioner was obtained before being included in the study. No eligible residents were excluded because of a physician's refusal. Written consent was obtained from residents who were conscious and communicative. Proxy consent was obtained for other residents.

Intervention

The experimental product is a cellulose fiber/polyester, premoistened washcloth, impregnated with a 3% dimethicone formula. The product was designed for cleansing, moisturizing, and application of a barrier protection. Its pH range is 3.5 to 5.0.

In the experimental group, the genital area, buttocks, and upper legs of residents at risk for IAD and/or affected by IAD were treated with the 3-in-1 washcloth. The washcloth was used (1) for daily routine perineal skin hygiene and (2) after each diaper/underpad change. Drying by evaporation was recommended and no towel rubbing/patting was allowed after applying the perineal washcloth. If the perineal skin of the resident was extremely soiled with urine/feces, the nurses were allowed to use (1) a soft washcloth and lukewarm water to remove soiling and (2) a soft towel and gentle rubbing technique to dry the skin (no patting was allowed). The nurses wiped the perineal area with the disposable cloths without rinsing or applying an additional barrier product. Additional cloths were used if needed. The experimental washcloths were kept ready for use at the bedside of the resident. If clinical signs of cutaneous bacterial or fungal infection occurred, the general practitioner of the resident was consulted. If antifungal products, steroidal topical anti-inflammatory products, and/or topical antibiotics were prescribed, these were combined with the perineal washcloth under study.

In the control group, a soft washcloth, water, and a pH neutral soap (pH range, 6.5–7.5) were used to treat the perineal skin of residents at risk for IAD and/or affected by IAD. This procedure was used (1) for routine perineal skin hygiene, (2) after each period of fecal/urinary incontinence, and (3) after each change of diaper/underpad. The nurses dried the perineal skin, using a soft towel rubbing

technique. No additional skin protectant was applied. An identical procedure was followed as in the experimental group when clinical signs of bacterial or fungal infection occurred. In both the groups, the diapers/underpads were used and the frequency of changing was based on the current protocol of the participating ward.

Procedure

The duration of data collection was 120 days. Prior to the study, all nurses and healthcare assistants in both groups were educated in depth using interactive, small-group educational sessions regarding (1) skin observation (use of a transparent disc/finger method to differ blanchable from nonblanchable erythema) and (2) the differentiation between IAD and pressure ulcers (according to the Pressure Ulcer Classification guidelines, <http://www.puclas.ugent.be/puclas/e/>).

In the experimental wards, the indications and contraindications of the use of the perineal care washcloths (dimethicone 3%) were presented. Hands-on training and interactive education in small group sessions were provided for nurses so that they could learn about the proper application of the washcloths. Posters including guidelines regarding the application of the perineal care washcloth were developed and posted in the nursing staff room, allowing the nurses to have visibility to the proper application methods for the study. Pocket cards in user-friendly concise formats including recommendations about the skin care regimen were provided to all relevant healthcare staff.

In each of the control wards, the standard-of-care skin protocol (water, pH neutral soap, and drying with towel) was presented by the senior nurse in a 30-minute group lecture. No additional interventions were performed.

Baseline data were collected by the researchers in February 2010 and included (1) nursing home and ward characteristics, (2) basic resident characteristics, (3) incontinence status of each resident, (4) IAD risk assessment, (5) skin observation (genital area, buttocks, and upper leg), and (6) skin care interventions in each resident (products and procedure). Throughout the study, the perineal skin of the resident was observed each morning by the nurses and data on skin care (methods and products) were collected. The risk for IAD was reevaluated daily and prevention and treatment was started according to the protocol if a resident was found to be at risk for or had an IAD.

The interobserver reliability of IAD risk assessment and skin observation between the researcher and the nurses was checked by calculating the Cohen kappa (κ). In each ward, the researcher (D.B.) and the senior nurse had contact twice a week about the study progress.

Instrument

The Incontinence-Associated Dermatitis Skin Condition Assessment Tool³⁶ was used to observe the surface (cm²), redness, and depth of any perineal skin lesion. This tool generates a cumulative severity score (maximum score = 10) based on area of skin affected, degree of redness, and depth

of erosion. This tool is specifically designed to assess IAD severity. The items used in the instrument were designed based on literature describing the physiologic and clinical conditions that contribute to skin injury in incontinent persons and do not depend on descriptions that were originally intended to describe pressure ulcers.³⁷

Data Analysis

Descriptive data are presented in frequencies (percentages) and means (standard deviation). Chi-square test and independent sample *t* tests were performed to test for differences in outcomes between groups. A repeated-measures analysis of variance was performed to evaluate the effectiveness of the intervention. All data were analyzed at patient level because the outcome was measured at this level.

Time (day 1, day 21, day 42, day 63, day 91, and day 120) was entered as a within-subjects factor. Day 1 was defined as the baseline measure. Regular time intervals of 21 to 28 days were determined between the baseline measure and the final day of the intervention (day 120). These specific time intervals were determined to be able to evaluate the effectiveness over a relevant amount of time. Group (intervention vs control) was entered as a between-subjects factor. All analyses were performed using SPSS 15 software. A value of $P < .05$ was considered statistically significant.

Results

Four hundred sixty-four nursing home residents were observed in this trial (experimental = 239, control = 225) and 141 (32.9%) were included based on the inclusion criteria as described earlier (experimental = 73, control = 68). The mean age of the residents was 86.3 years in the experimental group and 85.9 years in the control group ($P = .57$). In both groups, approximately 60% of the residents were permanently incontinent for urine, 30% for feces, and 10% for urine/feces. A discoloration of the perineal skin was observed in approximately 1 in 4 residents (experimental = 27.9%, control = 25.0%, $P = .15$). A hyperhydrated appearance of the skin was reported in 17.7% of the participants in the experimental group (vs 14% in the control group, $P = .08$). No significant differences emerged between the other basic characteristics of the residents in both groups. An overview of the sample characteristics is provided in Table 1. The overall interobserver reliability regarding IAD risk assessment was $\kappa = 0.84$ (95% CI, 0.72-0.94) and $\kappa = 0.81$ (95% CI, 0.69-0.87) for skin observation.

Study Outcome: Prevalence and Severity of IAD

Baseline IAD prevalence was comparable in both groups (experimental = 22.3% vs control = 22.8%, $P = .76$). The prevalence of IAD significantly decreased in the experimental

TABLE 1.

Baseline Characteristics of the Residents

	Experimental % (n)	Control % (n)	χ^2 ^a	<i>P</i> ^b
Residents	100 (73)	100 (68)		
Gender				
Female	82.0 (60)	78.6 (53)	1.36	0.35
Male	18.0 (13)	21.4 (15)		
Incontinence				
Urine	61.0 (45)	57.4 (39)	2.03	0.22
Feces	29.3 (21)	30.9 (21)	0.98	0.57
Urine/feces	9.7 (7)	11.7 (8)	1.37	0.63
Perineal skin status				
Discoloration	27.9 (22)	25.0 (17)	2.10	0.15
Hyperhydrated	17.7 (12.9)	14.0 (10)	3.14	0.08
Weight, kg				
<55	45.3 (33)	41.4 (28)	1.78	0.49
55–94	26.3 (19)	28.3 (19)		
>94	28.4 (21)	30.3 (21)		
IAD prevention according to protocol, ^c yes	5.1 (4)	7.9 (5)	2.94	0.07
Pressure ulcer risk, ^d at risk	69.3 (51)	70.3 (48)	0.06	0.84

^aChi-square test.

^bStatistical significance.

^cCleansing with water/pH neutral soap, application of barrier zinc oxide paste.

^dBraden Scale score < 17 and/or pressure ulcer (categories I-IV).

group (day 1: 22.3%; day 120: 8.1%, $P < .001$). In contrast, IAD prevalence increased in the control group (day 1: 22.8%; day 120: 27.1). Overall, a significant Time \times Group intervention effect on IAD prevalence was found ($F = 3.1$, $P = .003$).

The baseline IAD severity score was 6.9/10 in the experimental group and 7.3/10 in the control group ($P = .99$). The IAD severity score significantly decreased in the experimental group (day 1: 6.9/10; day 120: 3.9/10, $P < .001$). There was no change in IAD severity in the control group (day 1: 7.3/10; day 120: 6.4/10). Overall, a nonsignificant Time \times Group effect on IAD severity score could be determined (day 120: experimental = 3.8/10 vs control: 6.9/10, $F = 0.8$, $P = .06$).

Scores on the Incontinence-Associated Dermatitis Skin Condition Assessment Tool significantly improved between day 1 and day 120 in the experimental group: (1) surface (day 1: 1.9/3 vs day 120: 1.2/3, $P < .001$), (2) redness (day 1: 2.7/3 vs day 120: 1.3/3, $P < .001$), and (3) depth (day 1: 2.3/4; day 120: 1.4/4, $P = .05$). No significant improvement on none of the items of the instrument was observed in the control group.

No patient in either group developed clinical signs of bacterial or fungal infection. An overview of the results regarding the IAD prevalence and IAD severity scores over time is presented in Table 2 and Figure 1.

Discussion

The primary aim of this clinical trial was to study the efficacy of a premoistened washcloth, impregnated with a 3% dimethicone formula to prevent and treat IAD. Results were compared to cleansing via tap water and a pH neutral

soap (pH range: 6.5-7.5), which is the standard of care in Belgian nursing homes. In-depth education was provided for all healthcare professionals involved in daily skin care. During the study, a significant reduction of IAD prevalence was observed in the experimental group. No significant effects were observed in the counterintervention. A decrease in IAD severity was found in the experimental group, while no improvement could be observed in the control group. This discussion will consider (1) the characteristics and formula of the experimental product and (2) regimen compliance as the key to IAD prevention and treatment. To conclude this "Discussion" section, study limitations of this trial will be depicted.

Characteristics and Formula of the Experimental Product

The effect of the experimental intervention may be linked to the characteristics and formula of the product under study. The capacity of the experimental product to cleanse the perineal skin (without using water and soap) is based on the impregnation of the washcloth with a low amount of purified water, combined with surfactant ingredients to loosen and remove dirt, thus reducing the risk of skin dryness and loss of skin integrity. These characteristics may have reduced rubbing over the perineal skin to remove urine/feces, which may have caused a reduction in friction damage. Frequent washing in the control group (using water and soap) may have increased friction damage, resulting in a decrease in skin integrity.³⁸ Furthermore, the pH of the experimental washcloth reflects the acid mantle of the skin (range: 3.5-5.0), which may prevent the invasion of bacteria/fungi³⁸ and reduce the risk of stratum corneum swelling and lipid rigidity alterations.¹⁹ The latter

TABLE 2.
Evolution of Incontinence-Associated Dermatitis Prevalence and Severity Over Time

Time ^a	IAD Prevalence (%)		IAD Severity Score (max. 10)	
	Experimental	Control	Experimental	Control
1	22.3	22.8	6.9/10	7.3/10
	$t = 1.7^b$, $P = .76^c$		$t = 1.7$, $P = .99$	
2	20.3	29.5	5.2/10	6.2/10
	$t = 3.9$, $P = .003$		$t = 1.9$, $P = .56$	
3	18.4	28.3	3.1/10	6.4/10
	$t = 4.3$, $P < .001$		$t = 2.3$, $P = .09$	
4	16.3	28.4	3.7/10	6.1/10
	$t = 5.1$, $P < .001$		$t = 2.4$, $P = .07$	
5	11.3	26.9	3.2/10	6.3/10
	$t = 5.9$, $P < .001$		$t = 2.9$, $P = .04$	
6	8.1	27.1	3.8/10	6.4/10
	$t = 6.3$, $P < .001$		$t = 3.1$, $P = .03$	

^a1 = day 1, 2 = day 21, 3 = day 42, 4 = day 63, 5 = day 91, 6 = day 119.

^b t test of the equality of 2 variances.

^cStatistical significance.

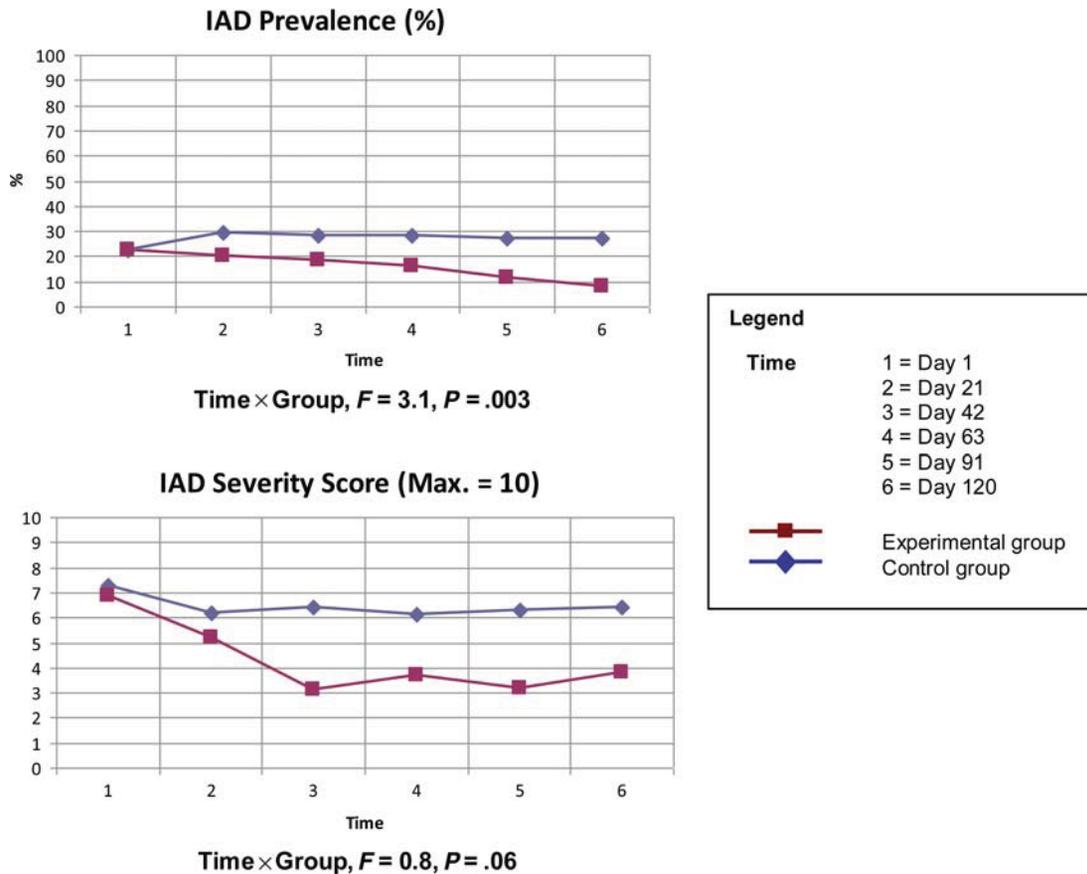


FIGURE 1. Graphic representation of the evolution of incontinence-associated dermatitis (IAD) prevalence and severity over time.

may also be associated with a reduced risk for skin dryness, contact dermatitis, and eczema.³⁸

In the experimental group, perineal skin drying by evaporation was recommended to reduce friction damage associated with rubbing with a towel.²⁰ In the control group, the standard rubbing technique is a part of the protocol, which may have caused further friction damage to the skin. This friction damage may have had a disrupting effect on the skin's barrier function, resulting in a reduction of the capability of the stratum corneum to regulate loss of water from the skin.³⁸ In the actual trial however, it is unclear whether drying of the perineal skin by evaporation offered an advantage to conventional rubbing as this technique may leave the skin wetter and at greater risk of frictional damage.²⁰ Further research and subsequent guidance are required to elucidate the drying procedure when using the premoistened washcloth.

The experimental product also contains a moisturizing and a barrier capacity based on the addition of a dimethicone 3% formula. Multiple moisturizers are based on occlusive substances, such as dimethicone²⁷; they are labeled skin protectants in the United States. The dimethicone in the washcloth used by the intervention group is based on the addition of silicone oil with a low surface tension that contains creeping and spreading properties.³⁶ Hoggarth and colleagues²⁸ reported that the effectiveness

of dimethicone may be more related to the good ability of skin hydration/moisturizing and less to its barrier function. Whether the effects in this trial are related to the hydration/moisturizing and/or the barrier function of dimethicone could not be determined. Further evidence from an in vitro trial is recommended.

The washcloth used by the intervention group is based on a 3% dimethicone formulation. The Nair & Cosmetic Ingredients Review Expert Panel³⁹ reported that dimethicone concentrations of up to 15% are used in some moisturizing products. Evidence about the effectiveness of the 3% concentration in the experimental washcloth is lacking as no benchmark for measuring a product's ability to block exposure to a specific irritant is available. Further research regarding the validation of such a benchmark is suggested.

■ Regimen Compliance

Adherence to a defined or structured skin care regimen is advocated as a key to effective IAD prevention and treatment.^{3,4} Adherence was not measured in this study. However, we hypothesize that the results found in this trial may have been influenced by an increased adherence to the skin care regimen. This effect may be attributable to

a combination of (1) in-depth education of the professionals involved in daily skin care and (2) the 1-step characteristic of the product. Furthermore, the fact that the experimental washcloths were kept ready for use at the bedside of the resident may have had a positive effect on the compliance to follow the skin care regimen.

According to the American Professional Wound Care Association,⁴⁰ compliance is significantly related to effective and high-quality education of professionals. We used interactive education, delivered in small group sessions, including hands-on training and interactive discussions, because this technique has been found to exert a positive influence on adherence to a protocol.⁴¹ Designing online Web-based learning as part of an educational plan is suggested to enhance adherence in the clinical setting, but this task may involve more extensive resources and planning.⁴²

■ Limitations

Several limitations need to be addressed in this study. A prospective power analysis was not completed. However, a post hoc power analysis (based on the sample size in both groups and the effect size in this study) revealed a statistical power of 85% ($\alpha = .05$). A second limitation is the use of the Incontinence-Associated Dermatitis Skin Condition Assessment Tool³⁶ to measure the severity of the IAD. Adequate reliability testing of the instrument had not been completed when we selected the instrument. By introducing the evaluation of the interobserver reliability, the researchers made an important attempt to reduce the effect of this limitation.

In both groups, the use of adult containment briefs and underpads was not standardized; rather, the frequency of brief or pad changes and the product selected were based on the current protocol of the participating ward. Also, the use of pH neutral soaps in the control group was not standardized, resulting in a variety of different products. This lack of standardizing reflects the situation in clinical practice. However, for this study, it did not allow us to make appropriate statistical corrections.

■ Conclusion

A defined (structured) skin care regimen, including the use of a soft premoistened washcloth impregnated with a 3% dimethicone skin protectant, resulted in a significantly reduced prevalence of IAD and a trend toward less-severe lesions. This study provides evidence supporting the use of a 3-in-1 perineal care washcloth as more effective than standard care including water and a pH neutral soap from IAD prevention and treatment.

■ ACKNOWLEDGMENTS

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