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Effectiveness of skin cleanser and protectant regimen on incontinence-associated dermatitis outcomes in acute care patients: A cluster randomised trial

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Abstract

Skin cleansers and protectants protect skin from incontinent matter to reduce the risk of incontinence-associated dermatitis (IAD), but their effectiveness treating established IAD in the tropics is unknown. We conducted an open-label cluster randomised trial to compare the effectiveness of a combined regimen of (1) specialised skin cleansers with disposable body wipes and (2) either an acrylic terpolymer (T1) or zinc oxide (T2) skin protectant against disposable body wipes and zinc oxide protectant (control) in promoting IAD healing and reducing the risk of deterioration. Eighty-four patients were recruited in a tertiary hospital in Singapore between April 2019 and January 2020 (T1: n = 23; T2: n = 37; Control: n = 24). Although not statistically significant, patients treated with T1 and T2 were 1.5 times as likely to experience IAD healing within seven days compared with the control ($P = .66$). Healing was more pronounced in participants with skin loss treated with T1 or T2. No treatment was superior in preventing IAD deterioration, the prevalence of which remained small (8%-14%). While skin cleaning and protectants reduced the overall risk of skin deterioration, the addition of skin cleansers enhanced IAD healing within a short period, an important consideration for future research examining IAD treatment in acute care.

KEYWORDS

dermatitis, dermatologic agents, incontinence-associated dermatitis, irritant, wound healing

1 | INTRODUCTION

Incontinence-associated dermatitis (IAD) is characterised by inflammation of skin on the sacral, gluteal, external genitalia, and upper thigh regions because of prolonged exposure to urine or faecal matter.[1,2]

This is a complex health care problem that contributes greatly towards poorer patient outcomes, higher health care costs, and prolonged hospitalisation.[3] Patients with IAD often experience itching, tingling, and excruciating pain.[4] The discomfort can affect sleep and impede mobility, which further predisposes them to urinary tract or chest infections.[5] IAD sites are also more prone to bacterial and/or fungal infections because of their close proximity to the gastrointestinal and urinary tracts.[1] In addition, IAD is an independent risk factor for the

development of pressure injury, causing further pain and decline in patients and incurring substantial health care costs for treatment.[6,7] Hence, if unaddressed, IAD can lead to a deleterious sequalae of deterioration.

There remains a pressing need to better understand IAD management strategies in the acute hospital environment. IAD is more widespread in acute hospital settings, present in 19% of incontinent patients in acute hospitals compared with 8.4% of incontinent patients in long-term care facilities.[8] This might be attributed to acutely ill patients being at higher risk of iatrogenic diarrhoea because of treatment ranging from multiple antibiotics to enteral feeding, subsequently developing IAD.[9] This underlines the need for better understanding of IAD treatment strategies that can be initiated and managed in an acute care environment.

The evidence to date on IAD management points towards a structured skin care regimen involving: (1) regular skin cleaning to remove urine and faecal matter and (2) application of a protectant layer to create a barrier between the skin and incontinence. Prompt and effective removal of urinary and faecal matter, followed by a protective layer to prevent their damaging effect on skin, contributes towards the restoration of the stratum corneum and overall skin integrity, leading to the healing of IAD.[10,11]

Typically, incontinent matter is cleaned off patients' skin using either soap and water or disposable body wipes—water-based cloth wipes designed for daily body cleaning as a "dry" bath.[12] However, current evidence points towards the addition of specialised (ie, pH-balanced, surfactant-containing, no-rinse, and hypoallergenic) skin cleansers as part of the cleaning process. They are applied on soiled skin, with their surfactant content making it easier to subsequently wipe off the incontinent matter using a body wipe or washcloth.[5,13] In addition, such cleansers have a pH close to that of healthy skin (pH 4-6), which do not degrade the skin's inherent acidity compared with traditional skin care media such as soap and water.[10,11,14] Compared with soap and water, these skin cleansers have been found to reduce the risk of developing IAD and increase the likelihood of IAD skin improvement.[15,16]

Skin protectants create a barrier between the stratum corneum and urine or faeces, reducing further irritation, and thus promoting skin recovery and IAD healing.[10] In addition, modern skin protectants often contain moisturisers as well, helping to replenish the lipid barrier on skin.[17,18] Two common types of such protectants are acrylate-based film barrier protectants that form a resilient transparent protective layer on the skin's surface, and zinc-oxide products which are typically formulated as pastes or creams.[11]

Key Messages

- This is the first study to evaluate the effectiveness of skin cleanser and protectant regimens in the treatment of incontinence-associated dermatitis conducted in a tropical climate.
- The combined use of skin cleansers, body wipes, and skin protectants may be more effective for IAD healing, compared with the use of body wipes and skin protectants alone.
- This effect of healing is more apparent in patients with skin loss.
- Improved IAD healing could be attributed to the properties of the skin cleanser—pH-balanced, surfactant-containing, no-rinse, and hypoallergenic.
- Health care professionals are encouraged to adopt skin cleansers and protectants as part of the recommended guidelines for IAD management to prevent further skin deterioration and promote healing

Unfortunately, there remains a dearth of high-quality trials to guide the selection of products for clinical use.[10,11] Because of the lack of conclusive evidence, current clinical practices, like that of our hospital in Singapore, select IAD products based on their cost and availability, which risks being clouded by marketing and commercialisation efforts.[19]

In addition, to our knowledge, no study has investigated the combined effectiveness of skin cleaning and protection products in the prevention or treatment of IAD in tropical countries with warm temperatures and high humidity like Singapore.[10,11] In contrast, previous studies have typically been limited to the prevention of IAD and were conducted in temperate climates with lower humidity, such as Japan, Scotland, and the United States of America.[11,20] A higher humidity would increase the possibility of perspiration present on patients' skin. Perspiration was shown to reduce the adhesion force between the protectant and skin, possibly reducing the adherence of such products onto patients' skin.[21] This lowered adherence in turn could increase their risk of exposure to incontinent matter and the subsequent development or deterioration of IAD. As a result, findings from previous research in temperate climates might have limited generalisability to our local clinical settings.

Current gaps in evidence, combined with the worrying prevalence of IAD in the acute care environment,

reinforce the need to investigate the effectiveness of skin cleansing and protectant products in our acute care settings to ensure the provision of optimal care for persons with IAD.

1.1 | Aims

We sought to examine the effectiveness of two different skin cleansing and protectant regimes in promoting skin healing from IAD and the prevention of further skin deterioration, comparing it against our current model of IAD management.

2 | MATERIALS AND METHODS

2.1 | Study design

Our study was an open-label, three-arm, cluster randomised trial at a 1700-bedded tertiary hospital in Singapore (ClinicalTrials.gov number: NCT04625426).

2.2 | Participants

Participants were recruited from 49 critical care, general, and subacute wards between April 2019 and January 2020. Participant recruitment was originally planned to continue until September 2020 but was terminated earlier in January 2020 because of the COVID-19 pandemic in Singapore that led to restricted institutional access to reduce the risk of transmission.

Participants were eligible if they were aged 21 years and above, diagnosed with IAD, and at regular risk of exposure to urine and faeces over their hospitalisation. Patients were excluded if they had a known allergy to the treatment products, were haemodynamically unstable during recruitment, unable to tolerate lateral positioning for skin cleaning and treatment application, pregnant, or had an existing skin disease at the gluteal, perigenital or thigh regions that could cloud IAD assessment, such as herpes or scabies.

2.3 | Randomization

The 49 wards were first stratified into six groups by their level of patient acuity (critical care wards, general wards, and subacute wards) to ensure a balance of the different types of ward in each group. Each group was then randomly assigned to one of three treatment arms using the randomization software Research Randomizer.[22] This was performed by an independent study coordinator not involved in selecting products for the treatment arms, or training nurses in product application.

Participants received IAD treatment based on the wards they were admitted to. This approach allowed nurses to apply the treatment as indicated for their ward, preventing confusion over treatment regimens and contamination within the same ward.[23]

We decided for the administration of the treatment products to be open-label to allow immediate discontinuation of treatment if complications arose. Hence, ward nurses responsible for the application and maintenance of IAD treatment regimens were informed of their respective treatment arm allocation, but were unaware that there was an active comparison of the treatment regimens across the wards. True blinding might have been difficult as there is still a probability that nurses could have talked to one another. However, we tried to mitigate this from causing measurement bias by not involving them in the data collection and assessment process.

2.4 | Outcomes and measurements

Our primary outcome was the number of episodes of IAD healing over the first seven days of treatment. Secondary outcomes were (1) deterioration in skin condition and (2) development of skin loss.

Participants' photographs were used to assess their state of IAD, and if healing or deterioration occurred over follow-up. Healing was deemed to have occurred if there was a subsequent absence of visible skin impairment within the photograph, as this would have indicated the re-establishment of skin integrity. Photographs were taken by a trained data collector, after agreeing with the rest of the study team on the photograph angles and lighting required for assessment. The data collector used the same lighting environment (bedside and ceiling light) and camera to ensure a consistent quality of photographs. Two independent wound experts assessed the photographs. Any disagreements were resolved through discussion. Both experts were blinded to the treatment allocation of participants to reduce the risk of measurement bias.[24]

According to international clinical experts, improvement of the skin condition can be observed between two and four days after the introduction of a structured skin care routine.[25] We thus decided to examine if there was any skin deterioration within the first three days after the initiation of IAD treatment. Deterioration in skin condition was determined by a visual increase in the extent of skin redness, erosion, and maceration within the photograph, as these are the key clinical signs of IAD.[26]

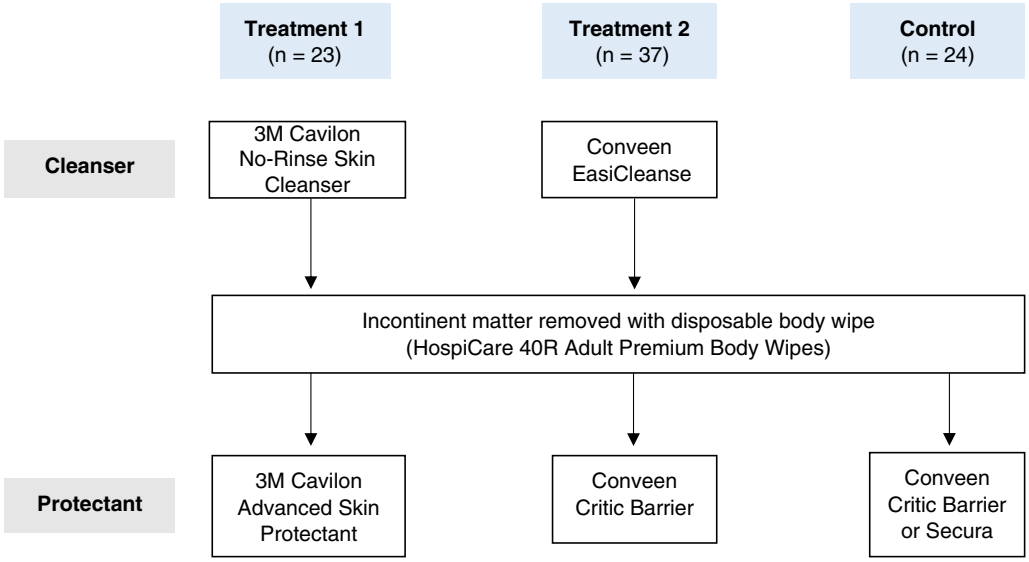

FIGURE 1 Summary of treatment received in arms

The Ghent Global IAD Categorisation tool (GLOBIAD), an internationally validated and reliable tool, was used to characterise the severity of IAD at recruitment according to the presence or absence of skin loss (category 1 vs 2) and the presence or absence of infection (category A vs B).[25] This tool was also used to determine if participants experienced skin loss over the course of follow-up, a sign of IAD deterioration. The GLOBIAD tool was found to have good inter-rater reliability (Fleiss kappa = 0.32) and intra-rater reliability (Cohen's kappa = 0.76) when distinguishing between intact skin and skin loss in IAD photographic assessments.[25]

Demographic and care-related information—participants' age, gender, ethnicity, body mass index (BMI), history of type 2 diabetes mellitus, ward type, and presence of an indwelling urinary catheter—were captured. Participants' risk of pressure injury at point of recruitment, a proxy for the level of mobility restriction and nutritional status, was determined using the Braden Scale.[27] The presence of urinary, faecal, or dual incontinence at the point of recruitment was recorded, with the consistency of faecal matter measured using the Bristol Stool Chart.[28]

2.5 | Intervention

A summary of the treatments received by participants according to their treatment arms is reported in Figure 1. As all three arms necessitated the removal of incontinent matter from skin as part of the cleaning regimen, we established that participants in all arms would receive the same type of body wipe (HospiCare 40R Adult Premium Body Wipes). This body wipe is a water-based disposable wipe used in our hospital's standard clinical care for daily body cleaning and the removal of incontinent matter. Such body wipes have been applied for body cleaning in other studies examining the effectiveness of skin cleanser.[29,30]

Participants in the treatment arms received a skin cleanser to aid in the removal of incontinence, with a body wipe applied to remove incontinent matter from skin. This was followed by the application of a moisturiser-containing skin protectant.

A panel of seven wound experts across five different institutions in Singapore chose the skin cleanser and skin protectant products for the two intervention arms based on their ease of application, clinical benefits, and cost effectiveness. Both skin cleansers selected for this study's intervention arms were pH-balanced, surfactant-containing, no-rinse, and hypoallergenic.

Treatment 1 (T1) consisted of the skin cleanser (3M Cavilon No-Rinse Skin Cleanser) and a moisturiser-containing liquid acrylic terpolymer skin protectant layer (3M Cavilon Advanced Skin Protectant). On the first day of treatment, the skin cleanser was first sprayed onto skin and incontinence was removed using a body wipe, followed by application of the skin protectant. During each episode of incontinence, the skin cleanser was first sprayed onto the incontinent matter on skin and residual soiling removed with the body wipe. The protectant was reapplied on the third day of treatment as recommended by the manufacturer.[31]

Treatment 2 (T2) consisted of the skin cleanser (Conveen EasiCleanse) and a moisturiser-containing zinc oxide-based barrier cream (Conveen Critic Barrier). On the first day of treatment, the skin cleanser was first

sprayed onto skin and incontinence was removed using a body wipe, followed by application of the skin protectant. During each episode of incontinence, the skin cleanser was first sprayed onto the incontinent matter on skin and residual soiling removed with the body wipe. The barrier cream was re-applied after every episode of skin cleansing.

Participants in the control arm received the hospital's standard care for IAD management. Any incontinence present on skin was removed using the body wipe. Thereafter, skin protection was provided using hospital-issued moisturiser-containing zinc-oxide barrier creams (either Conveen Critic Barrier or Secura).

Identified researchers trained the nurses in the allocated wards on how to apply their allocated skin cleansers and protectants as per the respective manufacturer's instructions.

2.6 | Data collection

When the ward nurses identified a patient with IAD, our study team was contacted to evaluate the patient's suitability for the study. Eligible participants were then recruited to the study after providing consent.

Following recruitment, an initial baseline assessment (day 0) was done by the trained data collector before the nurse-in-charge of the participant applied the allocated treatment. The participant's buttocks, posterior aspect of thigh, and perineal region were inspected for IAD—amount and extent of denudement, exudate level, redness, and signs of infection—before a baseline photograph was taken.

After the baseline assessment, the nurse-in-charge of the participant was given the treatment products as per treatment allocation to apply onto the patient. Subsequent reviews were made on days 1, 3, 5, and 7 of treatment. During each review, photographs were taken by the trained data collector to document the extent of IAD over the buttocks and/or thighs and/or perineal region. The patients were followed up for seven days of treatment or until discharge, whichever was earlier.

2.7 | Sample calculation

Fleiss' table was used to estimate the minimum sample size for the treatment arms, comparing the proportion of participants expected to experience IAD healing in the control arm to the treatment arms.[32] Although there has been limited research available on the effectiveness of IAD treatment regimens, one study recorded a 13% incidence rate of healing amongst participants given 'standard treatment'.[33] Hence, we estimated that 20% of participants in the control arm would have experienced IAD healing over the 7-day period. Factoring the products chosen for the treatment arms, we then estimated 50% of participants in our treatment arms would have experienced IAD healing over the 7-day period. The difference in proportion of participants experiencing healing is hence 30%. Applying Fleiss' table, we sought to recruit a minimum of 45 patients in each arm, or a total of 135 participants.

2.8 | Statistical analysis

Descriptive statistics and survival analysis was carried out using R Version 3.6.1.[34,35] Categorical variables were reported with their absolute numbers and percentages, and continuous variables were reported with their mean values and their standard deviations (SD). Participants who dropped out of the study or whose IAD did not heal by the end of seven days were censored in analysis.

The intra-class correlation coefficient (ICC) was calculated to examine the extent to which the primary outcome of interest, IAD healing, was likely to be similar within each of the six clusters. ICC was calculated using the First-order Model Linearized Estimate.[36] We established a target ICC of 0.10 or below to indicate negligible effects of clustering on the independence of the observed outcome of IAD healing.[29,37,38]

A Kaplan-Meier survival curve with the log-rank (Mantel-Cox) test was applied to compare the time to healing between the treatment arms. Survival analysis was conducted using Cox proportional hazards modelling to examine the likelihood of IAD healing by treatment arm, using the control group as the reference value. Based on feedback from expert wound clinicians, we planned for sensitivity analysis to examine the effectiveness of treatment on participants whose IAD had skin loss at the point of recruitment.

Pearson's chi-squared test was applied to compare both the proportion of individuals whose IAD had deteriorated at the 3-day mark and the proportion of individuals who had developed skin loss as measured using the GLOBIAD scale.[39] Statistical significance for all tests was established at .05.

2.9 | Ethics

This study was approved by the Domain Specific Review Board of the National Healthcare Group (Reference: 2018/01208). Written informed consent was sought from eligible participants or their named decision makers if they lacked decision-making capacity. Written study information and a copy of their signed consent form were provided to all participants.

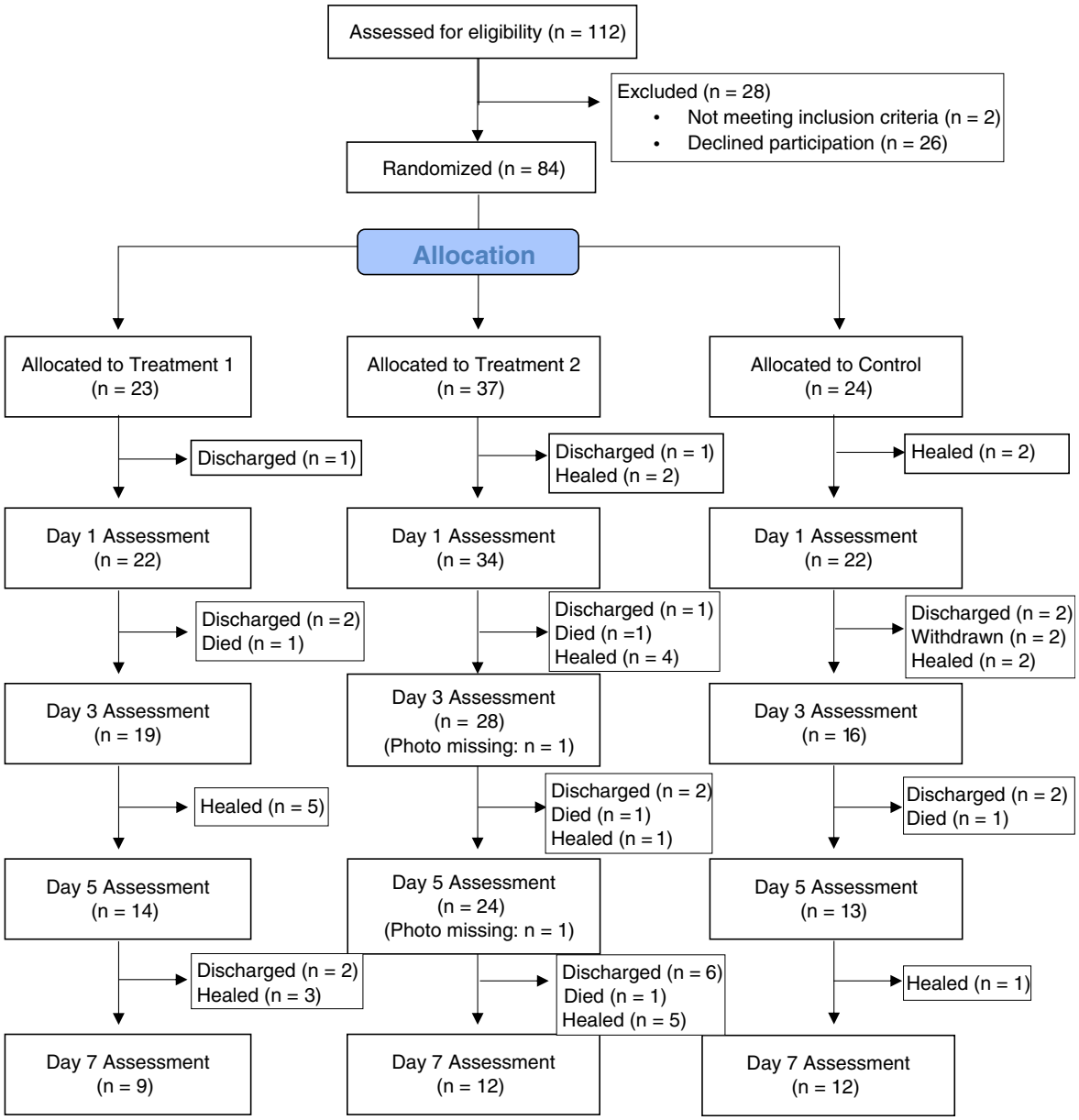

FIGURE 2 CONSORT flow chart of study participants

3 | RESULTS

3.1 | Participant flow

The flow of participants is illustrated in Figure 2. Because of the early termination of participant recruitment following the COVID-19 outbreak in Singapore, we assessed a total of 112 patients for eligibility for this study. Eighty-four patients (75%) were found to be eligible and consented to participate, 2 (2%) were excluded as they did not meet our inclusion criteria, and 26 (23%) declined participation.

Based on the ward the 84 participants were admitted to, 23 were allocated to Treatment 1, 37 to Treatment 2, and 24 to the control group.

3.2 | Baseline demographics

Participants' demographic characteristics are reported in Table 1. All three groups were found to have similar demographic characteristics. There was an equal distribution of males and females within the groups. The participants in each group were predominantly Chinese, with the mean age of each group being above 75 years of age. Most participants had dual incontinence.

Amongst those with faecal incontinence, the majority had loose or poorly formed stool—Bristol stool values 5, 6, or 7.[28] Participants across three groups were in the normal BMI weight range (mean BMI: 13.3-14.2) and were at moderate risk of developing

TABLE 1 Baseline demographic profile of participants

Variable	Treatment 1 (n = 23)		Treatment 2 (n = 37)		Control (n = 24)	
	n (%)	Mean (SD)	n (%)	Mean (SD)	n (%)	Mean (SD)
Gender						
Male	9 (39)		17 (46)		12 (50)	
Female	14 (61)		20 (54)		12 (50)	
Age (years)		77.22 (10.6)		80.19 (9.56)		80.67 (8.03)
Ethnicity						
Chinese	22 (96)		35 (95)		22 (92)	
Malay	0 (0)		2 (5)		0 (0)	
Indian	1 (4)		0 (0)		2 (8)	
Body mass index (kg/m^2)		20.31 (3.81)		21.02 (5.19)		20.43 (3.42)
History of diabetes mellitus	10 (44)		7 (19)		6 (25)	
Incontinence						
Urinary	17 (74)		24 (65)		21 (88)	
Faecal	22 (96)		37 (100)		24 (100)	
Dual	16 (70)		24 (65)		21 (88)	
Faecal frequency		3.25 (1.65)		3.52 (2.01)		3.43 (2.31)
Presence of indwelling urinary catheter	7 (30)		12 (32)		3 (13)	
Braden score		14.20 (2.47)		13.90 (2.17)		13.30 (2.54)
Stool consistency						
Type 4	0 (0)		2 (5)		3 (13)	
Type 5	4 (17)		8 (22)		4 (17)	
Type 6	6 (26)		12 (32)		8 (33)	
Type 7	6 (26)		9 (24)		6 (25)	
Missing	7 (30)		6 (16)		3 (13)	
GLOBIAD scale						
Skin loss	13 (54)		18 (49)		11 (46)	
Infection	4 (17)		3 (8)		2 (8)	
Level of patient care						
Critical care	1 (4)		0 (0)		3 (13)	
General ward	16 (70)		25 (68)		14 (58)	
Subacute	6 (26)		12 (32)		7 (29)	

pressure injuries (mean Braden score: 20-21).[27] According to the GLOBIAD categorisation, about half of the participants in each group had IAD with skin loss.[40]

3.3 | Outcome measures

The calculated ICC for each outcome was below 0.10. The highest ICC observed was for the outcome 'Development of skin loss on Day 3 of treatment', with a value of 0.03. This reflected cluster independence of our observed outcomes in each of the three treatment arms.

3.4 | IAD healing

Over the seven day follow-up period, there were 8 (34%) episodes of IAD healing in the T1 group, 12 (34%) in T2, and 5 (21%) in the control group.

Kaplan-Meier survival curves were plotted to examine the survival time of participants' IAD healing by the treatment they received. These are reported in Figure 3. Examination of the curves revealed that there was no evidence of a difference between treatment arm and healing within the seven days of follow-up ($P = .70$).

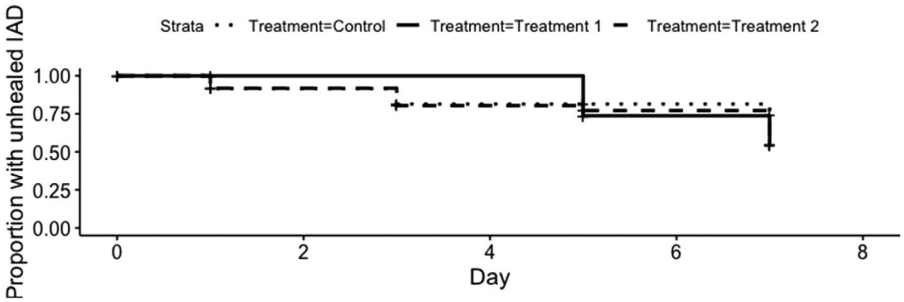

FIGURE 3 Kaplan-Meier distribution curve of incontinence-associated dermatitis (IAD) healing by treatment arm

TABLE 2 Summary of effect of treatment on likelihood of healing

Category	Overall healed	Overall not healed	b (SE)	HR (95% CI)	Likelihood ratio value	*P*
Treatment regimen					$\chi^2_2 = 0.82$	.66
Treatment 1	8	15	0.43 (0.57)	1.54 (0.50-4.70)		
Treatment 2	12	25	0.44 (0.53)	1.55 (0.55-4.41)		
Control	5	19	[a]			

[a]Referent value.

TABLE 3 Summary of effect of treatment on likelihood of healing of participants who started with skin loss

Category	Overall healed	Overall not healed	b (SE)	HR (95% CI)	Likelihood ratio value	*P*
Treatment regimen					$\chi^2_2 = 1.69$	.40
Treatment 1	4	9	1.11 (1.12)	3.03 (0.34-29.17)		
Treatment 2	5	13	1.22 (1.10)	3.40 (0.39-29.27)		
Control	1	10	[a]			

[a]Referent value.

TABLE 4 Distribution of incontinence-associated dermatitis (IAD) deterioration by days after initiation of treatment

	Treatment 1 (%) (n = 23)	Treatment 2 (%) (n = 37)	Control (%) (n = 24)	χ^2 value	*P*
Skin deterioration					
1 day	1 (4)	4 (11)	2 (8)	0.82	.67
3 days	1 (4)	4 (11)	0	2.95	.23
Development of skin loss					
1 day	0	2 (5)	2 (8)	1.78	.41
3 days	0	3 (8)	1 (4)	2.00	.37

Cox proportional hazards modelling was applied to examine the effect of treatment on healing on all patients, regardless of their skin condition at the beginning of treatment. The results are shown in Table 2. Patients who received T1 and T2 were 1.54 and 1.55 times as likely to have their IAD healed within seven days compared with patients who received the control treatment (T1: 95% confidence interval [CI]: 0.50-4.70, $P = .66$; T2: 95% CI: 0.55-4.41, $P = .66$). Hence, both treatments appear to increase the possibility of IAD healing within seven days compared with the control.

Our sensitivity analysis to determine the effectiveness of treatment on participants whose IAD had skin loss at the point of recruitment is reported in Table 3. Patients who received T1 and T2 were approximately 3 and 3.4 times as likely to have IAD healing within seven days compared with patients who received the control treatment (T1: 95% CI: 0.34-29.17, $P = .40$; T2: 95% CI: 0.39-29.27, $P = .40$).

3.5 | IAD deterioration

The distribution of IAD deterioration by treatment arm over the first three days of treatment is reported in Table 4.

There was no evidence of a difference in the proportion of participants who had deterioration in skin condition at the first ($P = .67$) and third day ($P = .23$) after initiation of treatment. Similarly, there was no evidence of a difference in the proportion of participants who developed skin loss as identified using the GLOBIAD scale at the first ($P = .41$) and third day ($P = .37$) after initiation of treatment.

We also observed that the overall prevalence of such indicators of IAD deterioration remained low across our study. For example, overall skin deterioration at the third day of follow-up was observed in only five (6%) of participants, and skin loss as assessed using the GLOBIAD scale was observed in only four (5%) participants.

4 | DISCUSSION

Our study examined the effectiveness of two treatment regimens against our current clinical practice in enhancing IAD healing and preventing skin deterioration.

Both intervention arms demonstrated a greater potential for healing within seven days as compared to the control arm. This effect was especially apparent amongst patients with skin loss when they commenced treatment. Although the early discontinuation of our study prevented the results from being sufficiently powered to reach statistical significance, they suggest that the addition of specialised skin cleansers on incontinent matter before removal with body wipes is more beneficial for skin healing than the use of body wipes without a cleanser. In addition, we found no evidence of any treatment being superior in preventing skin deterioration. Instead, the low prevalence of deterioration in each arm suggests that the combination of skin cleansers and protectants is important to prevent skin breakdown.

4.1 | IAD healing

Our study has the novel finding that introducing specialised skin cleansers into the management of patients with IAD increased the likelihood of IAD healing by approximately 50%, with the effect increased threefold in IAD patients with skin loss. To our knowledge, no published studies have examined the combined use of skin cleansers with body wipes and protectants in IAD healing, with the majority of research based around IAD prevention and not IAD treatment to produce healing.[11] Our findings are aligned with current research which points towards the benefit of skin cleansers over other cleansing media, such as soap and water or body wipes alone, in improving IAD outcomes.[11,17] The combination of a skin cleanser and protectant reduced the risk of IAD development by approximately 30%.[15,16]

The addition of such skin cleansers could have contributed towards more effective removal of urine and faeces on the skin, reducing the risk of dermal irritation and improving the conditions for skin healing.[5,41] The formulation of these cleansers, being pH-balanced, potentially improved skin conditions by preserving the natural acidity of the stratum corneum. This could have provided the optimum environment for lipid synthesis and enzyme regulation to maintain tissue integrity and repair damage caused by prolonged exposure to irritants, leading to IAD healing.[17,29,42]

In addition, the surfactant content in the cleansers reduces surface tension and loosen urine and faecal debris, allowing them to be easily removed from the skin when applying body wipes. The no-rinse formula eliminates the need for an excessive application of water or friction to remove such debris. In turn, these may have reduced the risk of both skin overhydration, which disrupts skin barrier integrity, and frictional skin damage, which frequently causes inflammation and worsens IAD.[17,29,42] Moreover, the hypoallergenic nature of skin cleansers minimises the risk of vulnerable skin developing hypersensitivity reactions and further irritation, producing a conducive environment for IAD healing.[11,43]

In contrast, nurses who used body wipes alone in removing urine and faecal matter anecdotally reported to our data collectors that they had difficulty in removing such debris at times, leading to the need for rinsing with water or applying gentle friction. The resultant risk of overhydration and frictional skin damage in persons with IAD who were cleaned with body wipes alone could have reduced their chances for skin healing.

4.2 | IAD deterioration

Our study highlights the necessity of a structured skin care regimen in preventing skin deterioration, corroborating findings from past studies and current practice recommendations.[42,44,45] Skin protectants form a barrier between the stratum corneum from irritants such as urine and faeces. This reduces exposure to caustic agents that disrupt skin integrity, thereby lowering the risk of skin deterioration and IAD development.[5,11] The overall proportion of participants who experienced skin deterioration across the treatment arms in our study, 8% to 14%, is similar to the reported 12% of intensive care patients who experienced IAD deterioration when undergoing a skin protectant regimen.[44]

Although only the intervention arms received skin cleansers, all three arms used the same body wipes to remove incontinent matter and received skin protectants,

either using zinc oxide or acrylic terpolymer. This was because of our hospital's current clinical practice of using a moist cloth to remove incontinent matter and applying a protective layer over skin with signs of IAD. The overall low proportion of deterioration might reflect the capability of such skin protectants in preventing further deterioration.

4.3 | Implications for practice

Our study underlines two important findings: (1) the benefit of combining specialised skin cleansers with body wipes when cleaning skin instead of body wipes alone to promote IAD healing, and (2) adhering to a structured skin care regimen of skin cleansing and protecting to prevent IAD skin deterioration.

As such, it would be sound for healthcare institutions to introduce a structured skin care regimen of skin cleaning and protecting for any patients at risk of direct skin exposure to urinary, faecal, or dual incontinence. This would greatly aid in the prevention and treatment of IAD. These regimens could be stated in hospital skin care guidelines to standardise practices.

One potential concern was an increase in the time taken for skin cleaning because of the additional step of using a skin cleanser. However, feedback gathered from nurses who used the skin cleansers elicited that they appreciated having the skin cleansers, likening them to 'window cleaning solutions' in the resultant ease of removing dried urine and faecal matter. As reported, patients also appeared to be in less discomfort when treated with the cleansers compared to the use of body wipes alone, possibly due to easier spoilage removal from tender skin with the cleansers. These led to some departments requesting for the hospital to procure skin cleansers for continued patient care use after the study's completion. Such feedback reflects the value of including a skin cleanser into the cleaning regimen to remove incontinent matter in persons with IAD.

We found that the usage of skin cleansers (either 3M Cavilon or Conveen EasiCleanse) in addition to body wipes is more efficacious for IAD healing than the current practice of skin cleaning with body wipes alone. In addition, we found that either a zinc oxide or acrylic terpolymer moisturiser-containing skin protectant would be beneficial to prevent further skin deterioration.

Because both types of cleansers and protectants show potential, institutions might consider product selection based on cost or ease of availability, factoring in the number of applications expected over the patient's course of stay. For example, over the course of our study, we found the average regimen cost using T1 (SGD $51.00 or USD $38.48) was much higher than that of T2 (SGD $15.00 or USD $11.32), which could lead to clinicians opting for T2 because of its lower price. Upon discussion with clinicians who trained nurses in the use of both T1 and T2, we found that both regimens took a similar amount of time for cleanser and protectant application. While the acrylic terpolymer was only applied up to two times per patient, the greater ease of applying zinc oxide resulted in a negligible difference in the time taken. Hence, from our experience of both T1 and T2 regimens, T2 would be more affordable in an our setting, despite their similarity in time taken for application.

4.4 | Strengths and limitations of the study

To our knowledge, this is the first study that examined the effectiveness of a combination of skin cleaning and protection products in a tropical climate. As a result, these findings would be highly valuable to health care professionals caring for patients in a similar climate of high humidity and warm temperatures that could increase the risk of poor skin healing because of a poorer adherence of skin product to dampened skin.[20,21] Our randomization process was effective as well because it led to an equal distribution of potential confounders such as age and BMI across the three arms, ensuring that the main exposure that differed over the course of the study was the treatment regimen patients received. In addition, our low ICC value in each of the outcomes demonstrates that there was no clustering effect in the outcomes that could have biased our results within our cluster randomised trial.[37]

The manufacturers' instructions for the skin cleansers specified for a moist cloth to be used to remove incontinent matter. Hence, we chose to use body wipes as this is part of clinical practice, both locally and in other trials examining the use of such cleansers.[29,30] This was done to standardise the type of body wipe used across all three arms, preventing it from becoming a confounder in the study.

A limitation we faced was our inability to achieve the planned sample size for an adequately powered analysis. In response to the COVID-19 outbreak in Singapore, institutional access to patients was restricted in order to curb the risk of transmission. Participant recruitment thus had to be terminated prematurely. As such, we were unable to achieve our intended sample size. Moreover, as this study was conducted in a tertiary hospital instead of a long-term care facility, it was difficult to achieve long-term follow-up to study the effects of the IAD treatment because patients are quickly discharged once medically fit, preventing follow-up for a full seven days for all participants. Nevertheless, our findings are still important

given the higher prevalence of IAD in this setting and the demonstrated benefit for skin healing within a short period if a skin cleanser and skin protectant regimen is initiated during the acute hospitalisation period.[8]

4.5 | Future research

Our findings point towards the generation of the hypothesis that the combined use of pH-balanced, surfactant-containing, no-rinse, and hypoallergenic skin cleansers with body wipes in a skin cleaning regimen are superior to body wipes alone for IAD healing. However, this should be confirmed in a larger-scale study that is sufficiently powered. While our research points towards the potential of skin cleansers for effective removal of urine and faecal matter without residual damage to the skin, and hence better skin healing than the use of body wipes alone, the mechanics behind skin cleansing are beyond the scope of our study, and could be explored in the future. Future research would be necessary to better understand the physical attributes of skin cleansers products to develop more effective products.

5 | CONCLUSION

The use of specialised skin cleansers and body wipes in combination with a skin protectant may be more effective for IAD healing, compared with the use of body wipes alone in combination with a skin protectant. In particular, this effect is amplified in IAD patients with skin loss. Hence, the implementation of a structured skin care regimen emphasising on effective cleaning and skin protection can aid in IAD healing and prevent further deterioration in skin integrity.

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CONFLICT OF INTEREST

The authors declared no potential conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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