Original Article

Efficacy of a Protective Hand Cream versus a Conventional Cream to Improve Skin Barrier Function among Pediatric Intensive Care Unit Healthcare Workers: A Pilot Study

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Background: Hand hygiene is one of the most effective procedures for preventing health care-associated infection. Barrier creams are used to prevent the irritant effect caused by occupational exposure.

Objective: To compare an aluminum chlorohydrate-containing hand cream and a conventional cream in health-care workers (HCWs) by using clinical assessment score and quantitative measurement of transepidermal water loss (TEWL).

Materials and Methods: A double-blinded, randomized, placebo-controlled trial was performed in pediatric intensive care unit HCWs. The subjects were assigned to regularly use the given cream (one fingertip unit per time, equal to 0.5 gram) after washing their hands with either 4% chlorhexidine gluconate or alcohol hand rub, which is 70% alcohol, glycerin, D-panthenol. The clinical assessment score, ranging from 0 to 3 points per item, were performed by the investigator evaluating for erythema, dryness, scaling, vesicles, fissuring and lichenification, and by the subject evaluating the redness, itching, tightness, dryness and sweating, together with TEWL assessment in a controlled environmental condition at day 0, 7, and 14.

Results: Sixty HCWs were equally divided for each product. Barrier cream and conventional cream, amount used were 32.20 g and 26.43 g, respectively. At day 14, the clinical assessment score by the investigator and by the subject were reduced by 40.02% and 43.38% in the barrier cream group, and 35.5% and 47.83% in the conventional cream group ($p<0.001$. However, the TEWL in both groups was not significantly different from the baseline. Both products were well tolerated.

Conclusion: The amount of cream applied by HCWs was lower than assigned. Both barrier cream and conventional cream can clinically improve the clinical score. Frequent and regular use of hand creams should be encouraged to decrease or prevent skin irritation and hand dermatitis.

Keywords: Protective hand cream, Transepidermal water loss, Healthcare workers, Hand hygiene practices, Pediatric intensive care unit

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Hand hygiene is one of the most effective procedures for preventing health care-associated infection. According to the Centers for Disease Control and Prevention (CDC) guideline for hand hygiene in health care settings in 2002, healthcare workers (HCWs) who provide direct patient care are encouraged to wash their hands frequently, however, the compliance rates are only 30% to 57%[1,2]. The proposed primary reason for hand hygiene compliance failure was skin irritation[3]. One study found that 55% of inpatient nurses and 65% of intensive care unit nurses had observable hand dermatitis[4].

In King Chulalongkorn Memorial Hospital, one cross-sectional study that surveyed hand hygiene compliance and attitudes of HCWs and visitors in the medical intensive care units and the neurosurgical intensive care unit revealed that hand hygiene compliance rates were less than 50%, and of these, 15.5% were from skin irritation[5].

Barrier creams are introduced to inhibit or delay cutaneous penetration of substances that could have deleterious effects when in contact with the skin or to induce systemic effects due to percutaneous absorption[6]. Therefore, it is used to prevent irritant effects caused by occupational exposure and is recommended for application before and during work[7-9].

The authors hypothesized that newly-introduced barrier cream would minimize the damage from hand hygiene procedures and maintain an effective skin

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barrier function. The aim of the present study was to compare the efficacy of protective hand cream and conventional cream to improve skin barrier function among pediatric intensive care unit (PICU) HCWs.

Materials and Methods

The present study was approved by the Institutional Review Board, Faculty of Medicine, Chulalongkorn University (IRB 164/60). The study was also registered in the Thai Clinical Trial Registry (TCTR20190128005). Written informed consents were obtained from all study participants. The subjects were recruited from August to November 2017.

Study design

A double-blinded, randomized, placebo-controlled trial study was performed to randomly assign subjects to Group A (conventional cream) or Group B (Nutraplus® protect hand cream) by sequential pack numbers. Conventional cream contains cetyl alcohol, stearic acid, glyceryl monosterate, propylene glycol and is supplied from the Department of Pharmacy, King Chulalongkorn Memorial Hospital, Bangkok, Thailand. Nutraplus® protect hand cream is supplied from Galderma, Lausanne, Switzerland and contains aqua, paraffinum liquidum, behenyl alcohol, aluminum chlorohydrate, glycerin, ethylhexyl palmitate, Simmondsia Chinensis seed oil, ceteth-10, steareth-20, and dimethicone. The Nutraplus® protect hand cream was repacked in tubes identical to conventional cream.

Sixty 60 HCWs including physicians, nurses, and nurse assistants, aged between 20 to 60 years old, working in the PICU, King Chulalongkorn Memorial Hospital, Bangkok, Thailand were recruited. The inclusion criteria were HCWs who having hand washing frequency of more than 10 times per 8-hours shift, working time of more than eight shifts per two weeks, willingness to stop using any other hand lotions or creams except those dispensed for the study and stopping the use of current hand lotions or creams for two weeks (wash out period). The authors excluded HCWs having active skin diseases of their hands, using of anti-inflammatory or immunosuppressive drugs, regularly using high dose antihistamines, or having history of allergies to any substances contained in the study products.

The subjects were assigned to regularly use the given cream (one fingertip unit each time, equal to 0.5 gram) after washing their hands with either 4% chlorhexidine gluconate or alcohol hand rub that included 70% alcohol, glycerin, and D-panthenol. All the subjects must have completed the case the record forms to record the number of hand washings, number of gloves worn in each shift, number of wet-work at home, and refrain from the use of any other products on their hands during the 2-week study period.

The assessments composed of clinical evaluation were as follows:

1. Self-assessment score for subjects was a composite score (range 0 to 15) of clinical presentation of dryness, redness, itching, tightness and sweating; each of which were evaluated on a score of 0 to 3 points per item (0=none, 1=mild, 2=moderate, 3=severe)[10].

2. Investigator-assessment score was performed by only one physician for the entire study, observing dryness, erythema, scaling, vesicles, fissuring, lichenification), which was rated from 0 to 3 points per item (0=none, 1=mild, 2=moderate, 3=severe)[10].

3. Transepidermal water loss (TEWL) measurement by using Cutometer MPA 580 Tewameter™ 300 in a temperature-controlled and humidity-controlled room.

At the end of second week, the cream tubes were weighed to evaluate the amount of cream used by the subjects.

Sample size calculation

The present study was a two independent samples, comparing means $\mu 1$ and $\mu 2$, with a clinically significant difference in means of clinical score between the two groups of 20%, a pooled standard deviation=20%, α error=5%, β error=10%, variance (δ)=20%. The study would require a sample size of 26 for each group to achieve a power of 90% and a level of significant of 5%. About 10% drops out was estimated, therefore, the authors enrolled 30 patients per group.

Statistical analysis

Statistical analysis was conducted using IBM SPSS Statistics software, version 22.0 (IBM Corp., Armonk, NY, USA). Differences between means of the assessed parameters of both groups were evaluated by using independent t-test, paired t-test, and chi-square test. The level of significance was set at a 5% probability of error (p-value less than 0.05).

Results

Participants was randomly assigned according to the flow in Figure 1.

In both groups, there were 29 females and one male. Average age was 32.5±8.6 years in the

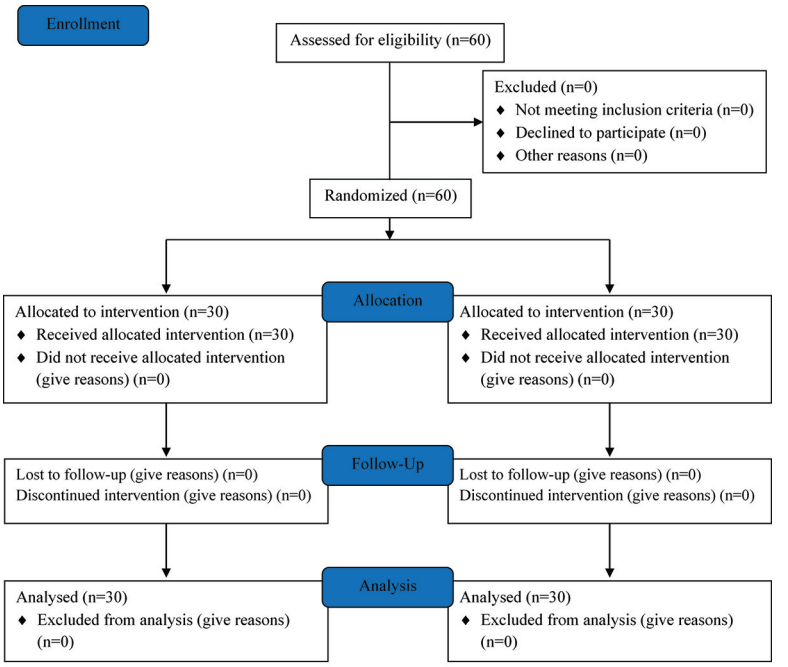

Figure 1. Participant flow.

Table 1. Demographic data

	Conventional cream (n=30); n (%)	Barrier cream (n=30); n (%)	p-value
Sex			1
Male	1 (3.3)	1 (3.3)	
Female	29 (96.7)	29 (96.7)	0.963
Age (year); mean±SD	32.53±8.63	32.43±8.17	
Previous hand cream			0.592
Yes	10 (33.3)	12 (40.0)	
No	20 (66.7)	18 (60.0)	
Previous hand eczema			0.448
Yes	3 (10.0)	5 (16.7)	
No	27 (90.0)	25 (83.3)	

SD=standard deviation

p-value corresponds to independent t-test and chi-square test

conventional cream group, and 32.4±8.1 years in the barrier cream group, respectively (p=0.96). History of previous hand cream used, and previous hand eczema were comparable between both groups (Table 1).

There was no difference in number of hand washing in both groups. The average number of hand washing with 4% chlorhexidine were 130.6±41.65 in the conventional cream group, and 145.97±41.29 in the barrier cream group (p=0.157). The average number of hand washing with alcohol hand rub were 73.33±34.87 and 70.03±42.21, respectively (p=0.743).

The number of gloves worn during working hours in two weeks were comparable between the two groups. The average number of one-handed glove wearing in the conventional cream group and the barrier cream group were 13.4±23.71 and 14.77±20.5, respectively (p=0.812), and for two-handed glove wearing was 71.07±31.47 and 74.3±40.11, respectively (p=0.73).

The number of wet-work at home during the two weeks was not significantly different between the two groups (p=0.855). The average number of wet-work at home in the conventional cream group and the barrier cream group was 12.33±16.81 and 13.17±18.21, respectively.

Amount of used cream

In the conventional cream group, the average amount of used cream in one week and two weeks were 13.6 g and 26.43 g, and in the barrier cream group were 13.9 g and 32.2 g, respectively. There was no statistically significant difference between the two groups (p=0.897 and p=0.162 at week 1 and 2, respectively).

Table 2. Clinical assessment scores by the subjects

	Conventional cream (n=30); mean (95% CI)	Barrier cream (n=30); mean (95% CI)	Mean difference (95% CI)	p-value* between groups
Average total score				
At baseline	3.8 (2.89, 4.71)	4.27 (3.4, 5.13)	−0.47 (−1.69, 0.76)	0.449
At 1 week	2.7 (1.78, 3.62)	2.6 (1.99, 3.21)	0.1 (−0.98, 1.18)	0.854
At 2 weeks	1.83 (1, 2.67)	2.13 (1.46, 2.81)	−0.3 (−1.35, 0.75)	0.570
% change at 1 week compare to baseline	−23.98 (−41.77, −6.19)	−26.53 (−50.67, −2.39)		0.862
% change at 2 weeks compare to baseline	−47.83 (−66.29, −29.38)	−43.38 (−61, −25.76)		0.722
p-value** at 1 week compare to baseline	0.002*	<0.001*		
p-value** at 2 weeks compare to baseline	<0.001*	<0.001*		

CI=confidence interval

Self-assessment score for subjects was a composite score (range 0 to 15) of clinical presentation of dryness, redness, itching, tightness and sweating each of which were evaluated on a score of 0 to 3 from 0-3 points/item (0=none, 1=mild, 2=moderate, 3=severe)

p-value corresponds to * independent t-test and ** paired t-test

Table 3. Clinical assessment scores by the investigator

	Conventional cream (n=30); mean (95% CI)	Barrier cream (n=30); mean (95% CI)	Mean difference (95% CI)	p-value* between groups
Average total score				
At baseline	2.13 (1.73, 2.53)	2.47 (1.91, 3.03)	−0.33 (−1.01, 0.34)	0.327
At 1 week	1.53 (1.23, 1.84)	1.7 (1.18, 2.22)	−0.17 (−0.76, 0.42)	0.574
At 2 weeks	1.17 (0.97, 1.36)	1.43 (0.8, 2.07)	−0.27 (−0.92, 0.38)	0.414
% change at 1 week compare to baseline	−19.67 (−34.87, −4.47)	−24.17 (−42.74, −5.6)		0.703
% change at 2 weeks compare to baseline	−35.5 (−46.24, −24.76)	−40.02 (−51.75, −28.28)		0.564
p-value** at 1 week compare to baseline	<0.001*	<0.001*		
p-value** at 2 weeks compare to baseline	<0.001*	<0.001*		

CI=confidence interval

Investigator-assessment score (dryness, erythema, scaling, vesicles, fissuring, lichenification), which rating from 0 to 3 points/item (0=none, 1=mild, 2=moderate, 3=severe)

p-value corresponds to * independent t-test and **paired t-test

Clinical assessment scores by the investigator and by the subjects

Clinical assessment scores by the subjects: The average clinical scores by the subjects in the conventional cream group and the barrier cream group were comparable at baseline, week 1, and week 2. Clinical scores by the subjects at week 1 and week 2 statistically significant decreased from baseline scores (Table 2).

Clinical assessment scores by the investigator: The average clinical scores by the investigator were comparable between groups at baseline, week 1, and week 2. Clinical scores by the investigator at week 1 and week 2 statistically significantly decreased from baseline scores (Table 3).

The percentage of change of the average total clinical score by the subjects and investigator were comparable as shown in Figure 2.

TEWL measurement before and after treatment with conventional cream and barrier cream

The average TEWL were comparable in the conventional cream group and the barrier cream group at baseline, week 1, and week 2. There was no statistically significant difference among the average TEWL at baseline, week 1, and week 2 (Figure 3).

Tolerance

Both creams were well tolerated. No serious adverse reaction was reported in the study.

Discussion

The present study showed that in real working situations, subjects used less cream than assigned

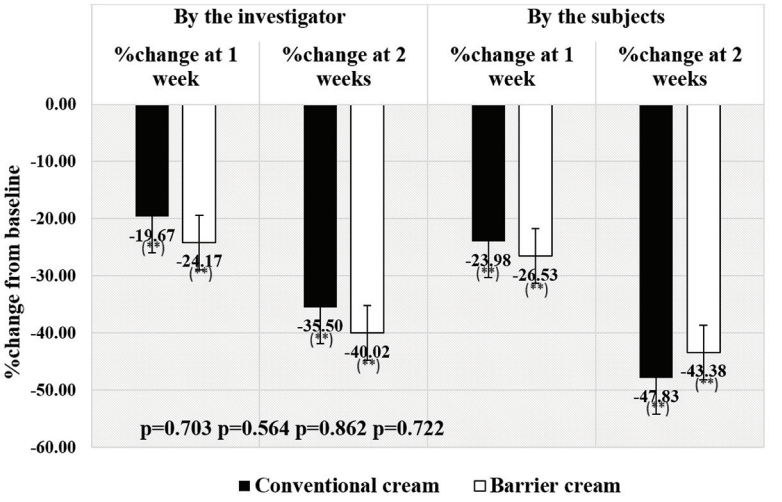

Figure 2. The percentage of change of average total clinical scores by the investigator and by the subjects.

p-value corresponds to * independent t-test and ** paired t-test

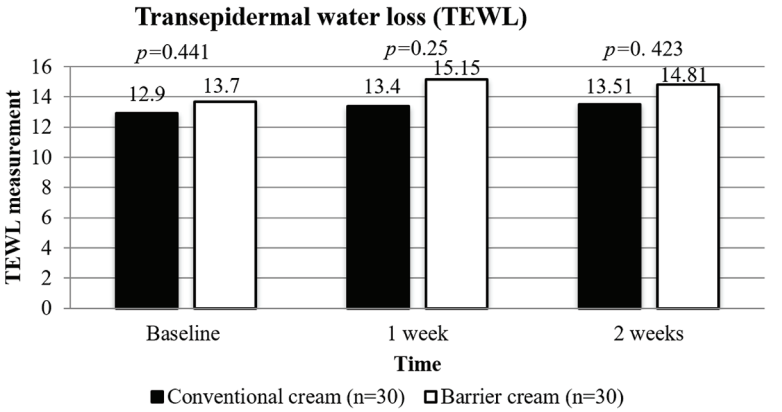

Figure 3. TEWL measurement before and after treatment with conventional cream and barrier cream.

despite an effort to encourage the proper amount. According to the recommendation, subjects should have used one fingertip unit or 0.5 g after hand washing with 4% chlorhexidine gluconate. With the average number of hand washings with 4% chlorhexidine in two weeks, the exact amount of used cream was only 40.1% in the conventional cream group and 44.1% in the barrier cream group. This might have affected the clinical outcome. Previous studies showed that the amount of cream applied in the workplace situations was significantly lower in experimental studies[9,11], and higher doses of barrier cream provided significant protection against irritation[11]. Hand cream products should be tested in the amount of normal use in the workplace. The authors need to encourage the use of a sufficient amount of cream to protect skin barrier function of the hand to avoid irritant contact dermatitis.

Clinical assessment score by the investigator and by the subjects were concordant at baseline, week 1, and week 2. Clinical assessment scores by the investigator and by the subjects at week 1 and week 2 in both groups were statistically significantly decreased from the baseline, but there was no statistically significant difference between the two groups. TEWL was not significantly different with baseline in both groups even though the clinical scores were decreased. The present study result was similar to the previous study, which compared the efficacy of barrier cream containing aluminum chlorohydrate and its vehicle in 50 nurses with mild clinical diagnosed hand eczema in one month. They found that clinical

scores by the investigator and by the subjects were significantly decreased and related with the duration of hand cream use with no significant difference between the two groups. TEWL was not significantly different with the baseline[10]. Another study was conducted in 54 HCWs with severe hand eczema using barrier cream or oil-containing lotion. They found that both barrier cream and oil-containing lotion could protect hands of HCWs from frequent hand washing. Clinical scores by the investigator and by the subjects were statistically significantly decreased at one week and stable until four weeks in both groups, but the clinical score in the oil-containing group were more statistically significantly decreased than in the barrier cream group[12]. In contrast, Williams et al. compared five different moisturizers with a control group in healthy subjects. They found that at two weeks, the control group had a significantly increased clinical score, while five other groups found no significant difference with baseline. For TEWL, only one product had statistically significant decreased at two weeks[13].

Besides hand washing, the use alcohol hand rub can cause hand irritation. In the present study, the number of alcohol hand rub usage was not significantly different in both groups. Compliance and preference of hand cream are also important. Greasy residue after use of all creams on the hand may affect and limit the amount of usage.

Conclusion

In real working situations, the amount of cream applied by HCWs was lower than recommended. Both conventional cream and barrier cream significantly decreased clinical score after one and two weeks of treatment. TEWL was not significantly different from baseline. Frequent and regular use of hand creams should be encouraged in HCWs to decrease or prevent skin irritation and hand dermatitis to achieve hand hygiene for preventing health care-associated infection.

What is already known for this topic?

Hand hygiene is one of the most effective procedures for preventing health care-associated infection. Barrier creams are used to prevent the irritant effect caused by occupational exposure.

What this study adds?

Either conventional cream or barrier cream can alleviate the dryness and irritation from frequent hand washing.

What are the implications for public health practice?

Frequent and regular use of hand creams should be encouraged in HCWs to decrease or prevent skin irritation and hand dermatitis to achieve hand hygiene for preventing health care-associated infection especially in the era of COVID-19 pandemic.

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Conflicts of interest

The authors declare no conflict of interest.

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