ALCOHOL BASED HAND RUB SKIN TOLERABILITY AND ACCEPTABILITY: FORMULATION & TEST METHODS MATTER

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ABSTRACT

Objective: Few environments are impacted more by topical product usage than Intensive Care Units. In this environment, healthcare workers may use alcohol-based hand sanitizer rub (ABHR) in excess of 120 times during a 12 hour shift, potentially exacerbating problem skin. This study assessed the skin performance of new high efficacy formulations (HE-ABHR) compared to existing ABHRs over four weeks in acute care hospitals.

Methods: Two acute care hospitals were studied during the winter; typically the worst season for skin condition. Baseline assessments were completed prior to introduction of HE-ABHR, followed by assessments at two and four weeks after intervention. Subjective questionnaires and objective skin hydration (Corneometer CM825) and skin desquamation (CuDerm D-Squame D-100) data was collected and analyzed using standard T-test statistics.

Results: HE-ABHR maintained skin hydration after four weeks, despite high frequency usage and harsh conditions. Multiple subjective skin care responses showed significant improvement ($p < 0.05$), including a perceived reduction of winter dryness by 2 points ($p < 0.001$). Combined with no net change in skin moisture or desquamation index ($p>0.05$), demonstrates skin's tolerance and acceptability for HE-ABHR over baseline ABHR formulations.

Conclusions: The new HE-ABHR formulations were effective at maintaining objective and improving subjective skin condition of healthcare workers in challenging clinical environments.

INTRODUCTION

The importance of ABHR (alcohol based hand rubs) to assist in infection prevention and control is well accepted and proven as a standard of care.[1, 2, 3] Specific formulations of ABHR are also known to have at least some impact on skin condition such as dryness, skin hydration, and Trans Epidermal Water Loss (TEWL).[4] This combined with regional climate and weather conditions can produce adverse skin condition which may negatively impact hand hygiene compliance. The Centers for Disease Control and Prevention (CDC) Hand Hygiene Guidelines[5] also recognizes this fact and recommends a lotion supplement.[2] ABHR with 62% alcohol and moisturizers have been available since 2005 to provide the combined benefits of an ABHR and a lotion. A newly developed Moisturizing High Efficacy (proprietary 70% alcohol) version of the ABHR (MHE-ABHR) has been formulated to provide both these benefits while meeting the greater efficacy needs of healthcare facilities. Under development and testing for several years, initial third party independent laboratory evaluations had proven the moisturizing benefits of the MHE-ABHR prototype. However, real-world Healthcare Worker (HCW) usage would validate final acceptance and confirmation of benefits MHE-ABHR in parallel to other skin friendly high efficacy versions of the ABHR (HE-ABHR). It is expected that an ABHR with greatest end-user acceptance and skin friendly characteristics should contribute to increased hand hygiene compliance.[6, 7, 8]

Two independent clinical studies were conducted to evaluate the seasonal impact of separate foam and gel MHE-ABHR in a high application ICU (Intensive Care Unit) environment. These studies were conducted in parallel to the HE-ABHR evaluations in acute care hospitals with a history and experience using reference 62% ABHR. Scientifically recognized objective skin measurements in combination with subjective evaluations of blinded end-user experience were executed to monitor both the physical skin condition and HCW perceptions of the multiple regimens over a four week period.

MATERIALS AND METHODS

Study protocols[9, 10] compliant with the Code of Federal Regulations and Good Clinical Practice (FDA Title 21) were independently submitted for IRB (Institutional Review Board) review and approval from the two hospitals. Following IRB approval, an onsite PI (Principal Investigator) targeted recruitment of 40 to 50 ICU staff participants in each intervention group. The targeted sample size or recruitment was developed to allow for participant attrition over the duration of the study while still yielding data capable of generating statistically valid ($P < 0.05$ or 95% confident) results. The PI was also responsible for validating inclusion / exclusion criteria in addition to administering Informed Consents to the volunteer participants. Overall timing of the clinical studies (February 15th to March 25th, 2011) was coordinated to coincide with a harsh seasonal environment which is most challenging to ICU staff due to the overall frequency of HHE (Hand Hygiene Events – handwashing and/or use of ABHR).

Measurement techniques were chosen to evaluate both objective non-invasive skin condition in combination with subjective feedback to measure both physical impact and end-user experience with the regimens. The Courage+Khazaka CM825 Corneometer was used according to standard methods[11] to measure stratum corneum hydration of the participants. This instrument was specifically chosen due to its sensitivity to the drier skin condition[12] typically found in ICU workers hands. The CuDerm D-Squame D-100 Discs were used to measure skin desquamation[13] as an additional non-invasive objective assessment of the regimens. However since skin performance of an ABHR alone may not be sufficient to drive HHC6 (Hand Hygiene Compliance), subjective questionnaires were used to evaluate both the participants experience with the ABHR regimens in addition to perceived impact on skin.

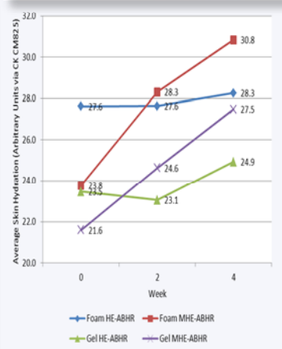
Initial baseline assessments were executed to assess the impact and perception of the reference 62% ABHR products used at the respective hospitals. Following these measures, blinded test ABHR regimens known as "The Pink Product" or "The Green Product" were installed in the respective ICU units. Table 1 shows details regarding the installation and participation. Additional measures were conducted following two weeks and four weeks experience and interaction with the ABHR regimens. The two week cycle was chosen to coincide with a known biological turnover of the stratum corneum. Once the comprehensive data packages were complete, SPSS Version 16 consisting of Paired Sample T-test was used to evaluate statistical differences between ABHR regimens and time intervals.

RESULTS

Table 1: ABHR Installations and Participation Summaries

Study	Group/Unit	Baseline Product	Participation	Two Week Product	Participation	Four Week Product	Participation	Three Visit Total
Gel ABHR Acute Care Hospital	ICU Unit #1	Reference Gel 62% ABHR	33	Gel MHE-ABHR	32	Gel MHE-ABHR	28	23
	ICU Unit #2		26	Gel HE-ABHR	24	Gel HE-ABHR	25	27
	Regimen Total		59		56		53	50
Foam ABHR Acute Care Hospital	ICU Unit #3	Reference Foam 62% ABHR	21	Foam MHE-ABHR	20	Foam MHE-ABHR	21	20
	ICU Unit #4		16		15		15	14
	ICU Unit #5		4		3		4	3
	Group Total		41		38		40	37
	ICU Unit #6		9	Foam HE-ABHR	8	Foam HE-ABHR	8	8
	ICU Unit #7		19		18		16	16
	Group Total		28		26		24	24
	Regimen Total		69		64		64	61
	Combined Final Study Total		128		120		117	111

Figure 1: Skin Hydration by Regimen



The Foam HE-ABHR results (Figure 1) showed no statistically valid change from the baseline 62% ABHR to two week ($p < 0.99$); two week to four week ($p < 0.12$); or overall from baseline to four week ($p < 0.35$) demonstrating no measured impact of a Foam HE-ABHR over the reference Foam 62% ABHR product formulation. Likewise, the Gel HE-ABHR indicated no initial change from baseline to two week ($p < 0.92$), the two week to four week did show a statistically significant change ($P < 0.0049$), but overall demonstrated a near statistical improvement from baseline to four week ($p < 0.057$). This indicates that both the Foam and Gel HE-ABHR have no impact in skin moisture over respective baseline 62% ABHR over the four week period. However, the Foam MHE-ABHR Regimen demonstrates an improvement in baseline to two week moisture ($P < 0.00$), a two week to four week improvement ($P < 0.0005$) and an overall improvement (baseline to four week $P < 0.00$). Similar to the Foam MHE-ABHR, the Gel MHE-ABHR shows a baseline to two week moisture improvement ($P < 0.00$), a two week to four week improvement ($P < 0.00$) and overall improvement (baseline to four week at $P < 0.00$) thus improving skin moisture even under the challenging work and environmental conditions.

Table 2: Desquamation by Regimen

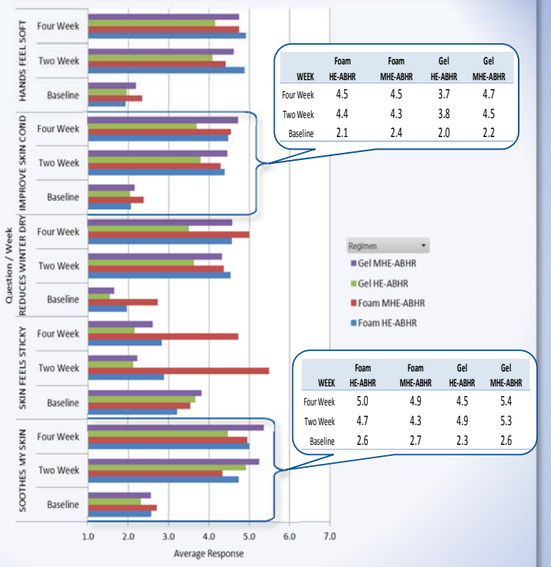
Week	Regimen: Foam HE-ABHR	Foam MHE-ABHR	Gel HE-ABHR	Gel MHE-ABHR
Baseline	20.0	24.5	21.3	19.9
Two Week	28.7	27.5	25.0	22.0
Four Week	26.9	24.3	24.3	21.4

Mean Desquamation Index

Table 2 shows the change in Desquamation Index from baseline 62% Foam ABHR to two week for the Foam MHE-ABHR was not significant ($p < 0.17$). In comparison, the change in Desquamation Index from baseline 62% Foam ABHR to two week for the Foam HE-ABHR indicated a significant change ($P < 0.0022$). Similar differences were observed between baseline 62% Foam ABHR and four week for the Foam MHE-ABHR ($p < 0.98$) vs. the Foam HE-ABHR ($P < 0.0022$). The differences however between the Foam MHE-ABHR and the Foam HE-ABHR are not statistically different at two week ($p < 0.07$) whereas the difference becomes significant at four week ($P < 0.025$). It is hypothesized that cold, dry, winter weather caused the Foam HE-ABHR to increase in dryness, whereas Foam MHE-ABHR was able to reduce the harsh effects of winter and working conditions associated with the skin of healthcare workers.

Table 2 also shows the change in Desquamation Index from baseline 62% Gel ABHR to two week for both Gel MHE-ABHR ($p < 0.15$) and the Gel HE-ABHR ($p < 0.059$) indicated no significant change. Similar observations continued between baseline 62% Gel ABHR and four week for the Gel MHE-ABHR ($p < 0.21$) and the Gel HE-ABHR ($p < 0.24$). In addition the Gel MHE-ABHR and the Gel HE-ABHR are not statistically different at either two week ($p < 0.72$) or four week ($p < 0.81$). Therefore both the Gel MHE-ABHR and the Gel HE-ABHR are effective at maintaining skin condition even under the dry, winter weather and working conditions of healthcare workers.

Figure 2: Survey Summary by Regimen



WEEK	Foam HE-ABHR	Foam MHE-ABHR	Gel HE-ABHR	Gel MHE-ABHR
Four Week	4.5	4.5	3.7	4.7
Two Week	4.4	4.3	3.8	4.5
Baseline	2.1	2.4	2.0	2.2

WEEK	Foam HE-ABHR	Foam MHE-ABHR	Gel HE-ABHR	Gel MHE-ABHR
Four Week	5.0	4.9	4.5	5.4
Two Week	4.7	4.3	4.9	5.3
Baseline	2.6	2.7	2.3	2.6

Figure 2 shows both HE-ABHR Foam products were positive over the previous Foam Control 62% ABHR representing many significant improvements. However there is exception with Sticky and Residue associated specifically with the Foam MHE-ABHR product. The change for these two attributes from the 62% Foam is statistically significant in the negative direction ($P < 0.0002$ for sticky and $P < 0.0004$ for residue). Perception of both Gel HE-ABHR products was very positive over the previous Gel Control 62% ABHR. MHE-ABHR Gel is trending to have an advantage or practical significance (80% confidence) at two weeks over HE-ABHR Gel as less drying, more soft, more improved skin condition, more moisturizing, and more likely to reduce the effects of winter dryness.

CONCLUSIONS

- ***Properly formulated Foam and Gel HE-ABHR do not impact skin condition in worst case winter weather and high use environments of Clinical ICUs.***
- **HE-ABHR products are preferred over the reference 62% ABHR.**
- **Both Foam and Gel MHE-ABHRs are effective at improving skin moisture levels within two weeks of healthcare workers.**
- **Properly formulated Gel and Foam MHE-ABHRs are recognized to condition, soften, and soothe HCWs skin.**
- **Properly designed clinical studies in challenging environments are successful in validating statistically significant objective and subjective performance of topical products.**

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