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In vivo comparative efficacy of three surgical hand preparation agents in reducing bacterial count

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SUMMARY

Background: Besides objective efficacy, the choice between an antiseptic-based liquid soap, or an alcohol-based hand rub for surgical hand preparation technique is based on personal preference. Glycerol is often added to the formulations in order to enhance tolerability; however, it has been recently reported as a factor reducing the sustained effect of surgical hand rubs.

Aim: To compare the efficacies of three commercial products for hand decontamination.

Methods: The *in vivo* efficacy of an alcohol-based hand rub (isopropyl alcohol 40%; N-propyl alcohol 25%; glycerin 1.74%; triethanolamine salt of carbomer <1%) was compared with other widely used products in surgical hand antisepsis (chlorhexidine and povidone-iodine). All products were used according to the manufacturers' instructions.

Findings: The best results were achieved with the alcohol-based hand rub and these were sustained for a period of 3 h. Some volunteers experienced skin peeling off the hands when using alcohol-based hand rub; in this group of participants, the bacterial count was reduced only by 0.91 ± 1.67 $\log_{10}$ compared with 2.86 ± 1.22 $\log_{10}$ in the group who did not show this phenomenon.

Conclusion: Besides confirming the importance of alcohol-based hand rubs for surgical hand decontamination, the results suggest the value of assessing the characteristics, and response of healthcare workers' skin, that may contribute to the development of skin peeling, and the subsequent possibility of a paradoxical overcolonization of hands after surgical preparation with alcohol-based hand rub.

Introduction

Surgical site infections (SSIs) are still among the most common hospital-acquired infections worldwide despite significant developments in surgical technique.[1,2] Disinfection can be performed using a surgical hand wash with an antiseptic liquid soap, or with an alcohol-based hand rub.[3,4] Products for surgical hand disinfection should pass two European standards for bactericidal efficacy: European Norm (EN) 12054, which is a suspension test using four different test bacteria to determine a general bactericidal activity; and EN 12791, which is a test used to determine the bactericidal efficacy *in vivo*.[5–7] However, recently there has been a growing interest in challenging surgical handwashing procedure in real working settings, and

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the formulations recommended by the World Health Organization have been discussed.[8–10] Moreover, the glycerol component of alcohol-based hand rub has been recently evaluated as a factor reducing the sustained effect of surgical hand rubs.[11]

The objective of this work was to compare the *in vivo* efficacy of an alcohol formulation with respect to other widely used products in surgical hand antisepsis.

Methods

Products tested

The tested products were based on the following formulations: (i) chlorhexidine (chlorhexidine gluconate 4%; propan-2-ol 1–5%; lauryldimethylamine oxide 1–5%; glycerol 1–5%); (ii) povidone-iodine (7.5%); and (iii) an alcohol formulation (isopropyl alcohol 40%; N-propyl alcohol 25%; glycerin 1.74%; triethanolamine salt of carbomer <1%). The following neutralizers were used: polysorbate 80 (3%), saponin (0.3%), histidine (0.1%) and cysteine (0.1%). The *in vivo* bactericidal efficacy of the three products was assessed in 20 healthy volunteers aged 27–50 years. The skin of the volunteers was free from cuts or abrasions and no other skin disorders were present. Nails were short and clean. In three distinct cross-over experiments, each formulation containing one of the three products was tested. A washout period of one week was allowed between each test run. At the end of the four experiments, each volunteer had used each formulation once. Volunteers participated after having expressed a written informed consent.

Wash phase (pre-values)

To remove transient bacterial flora and foreign agents, volunteers' hands were washed with a plain soap with the following procedure: 10 mL of the soap was poured into the cupped dry hands and rubbed vigorously on to the skin up to the wrists in accordance with the standard procedure to ensure total coverage of the hands, which were then rinsed in running tap water and dried with a sterile paper towel.

For the determination of the pre-values of colony-forming units (cfu), the distal phalanges of the right and left hand were rubbed separately, including thumbs, for 1 min on to two 9 cm Petri dishes containing 10 mL tryptic soy broth (TSB). A 0.1 mL aliquot, as well as the same volume of 1:10 and 1:100 dilutions, were seeded in TSB. Sampling fluids were spread over tryptic soy agar dishes with a sterile glass spatula. Two dishes were used for each dilution. No more than 5 min elapsed between sampling and seeding. Dishes were incubated for 24 h at 37 ± 2 °C. After an initial count of the cfu, Petri dishes were incubated for another 24 h to detect slow-growing colonies.[5]

Surgical preparation phase

Each volunteer used the test products at least on a weekly basis, in order to allow reconstitution of participants' skin flora. All products were used according to the manufacturers' instructions. After surgical hygiene, hands were rinsed with running tap water for 15 s and dried with a sterile cotton towel.

Determination of post values

After hand preparation, one hand was randomly selected to obtain the post-value (immediate effect). The other hand was allowed to dry and thereafter gloved (sterile surgical glove) for 3 h for assessment of the sustained effect, obtained after removal of the glove. In order to obtain the post-value, TSB with neutralizers was used. The neutralizers were 3% Tween-80, 3% saponin, 0.1% histidine and 0.1% cysteine. Sampling was done in a similar way to the immediate effect.

Moreover, participants were asked to report eventual personal notation about the effects of the different products on their skin (such as: dusty, sticky sensations).

Data analysis

For each dilution the mean number of cfu scored in duplicate dishes was calculated. This was multiplied by the dilution factor in order to obtain the number of cfu per millilitre of sampling liquid. Pre- and post-values were expressed as $\log_{10}$ values. For calculation purposes values of 0 were reset to 1, whereas values uncountable in the Petri dish were considered as 1,000,000 cfu (with $\log_{10} = 6$). If countable values of cfu were obtained from more than one dilution their mean was used to calculate the final logarithm value. For each volunteer the reduction factor (RF) was obtained as the difference between $\log_{10}$ post-values and the $\log_{10}$ pre-value. The mean of the $\log_{10}$ values (RF) of each product were compared with the corresponding values for a paired analysis of the immediate and sustained effect. Paired *t*-test was used to compare immediate and sustained effect globally for each product. Difference between mean RFs of different products was performed with analysis of variance (ANOVA) with Bonferroni correction for multiple comparisons; a post-hoc analysis was performed with Tukey's honestly significant difference (HSD) test. All analysis were two-tailed, with level of significance set at $P < 0.05$. Analyses were performed by using Stata 9.0 software (Stata Corp., College Station, TX, USA).

Results

Alcohol-based product had an immediate mean RF significantly higher than the other agents (Figure 1); in particular, the alcohol formulation showed a mean 2.27 ± 1.64 $\log_{10}$ reduction, followed by chlorhexidine, with 0.94 ± 1.11 $\log_{10}$ reduction, and povidone-iodine 0.16 ± 0.42.

Comparison of mean RFs using an ANOVA model revealed a significant difference between the products ($F = 17.03$; $P < 0.0001$). In order to clarify the results, we report pair-wise comparisons between each couple of tested products (Table I). The post-hoc analysis revealed that the alcohol-based product was significantly more effective compared with the other tested products ($P < 0.0001$; Tukey's HSD). After 3 h (Figure 2) the situation was similar to that registered immediately. In particular, after 3 h the alcohol formulation showed a mean 1.91 ± 1.52 $\log_{10}$ reduction, followed by chlorhexidine, with 0.82 ± 1.16 $\log_{10}$ reduction, and povidone iodine 0.52 ± 0.92.

ANOVA tests showed a significant difference between sustained effects for all the products ($F = 7.12$; $P < 0.01$); details for pairwise comparisons of product are reported in Table II. The *post hoc* analysis revealed that the alcohol-based product was significantly more effective compared with the other tested products ($P < 0.0001$; Tukey's HSD).