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Efficacy of ethanol-based hand foams using clinically relevant amounts: a cross-over controlled study among healthy volunteers

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Abstract

Background: Foams based on 62% ethanol are offered for hand decontamination in some countries. A long drying time may reduce the compliance of healthcare workers to apply the recommended amount of foam.

Objective: We have investigated their drying times and efficacy.

Methods: Four foams all based on 62% ethanol (Alcare plus, Avagard Foam, Bode test foam, Purell Instant Hand Sanitizer) were applied in a total of seven variations to 14 volunteers. The drying time was measured. The efficacy of 1.6 g of two foams which are quite commonly used in the US was compared according to the EN 1500 to 2 x 3 mL of 2-propanol 60% (v/v), and to 1.6 g of water on hands artificially contaminated with *Escherichia coli* using a cross-over design with 15 volunteers.

Results: The mean weight of applied foam varied between 1.78 and 3.09 g, the mean duration to dry was between 37 s and 103 s. The correlation between the applied amount of foam and the time until hands felt dry was highly significant ($p < 0.001$; Pearson's correlation coefficient: 0.724; 95% confidence interval: 0.52 - 0.93). Based on the linear correlation, an amount of 1.6 g is an intercept of a 30 s application time. Application of 1.6 g of one foam coded as A (mean $\log_{10}$-reduction: 3.05 ± 0.45) and another foam coded as B (3.58 ± 0.71) was significantly less effective in comparison to the reference disinfection (4.83 ± 0.89 and 4.60 ± 0.59, respectively; $p \leq 0.001$). Application of 1.6 g of water revealed a mean $\log_{10}$-reduction of 2.39 ± 0.57.

Conclusions: When using foams based on 62% ethanol the time required for dryness quite often exceeds the recommended 30 s. It is therefore likely that only a small volume of such a foam will be applied in clinical practice. Such a small amount, however, failed to meet the efficacy requirements of EN 1500 and was only somewhat more effective than water.

Background

In the US hand foams based on 62% ethanol are quite popular among healthcare workers. User quite often mention that foams require more time to dry on hands. Therefore, we investigated 62% ethanol-based foams for correlation between the amount of foam applied, and the time required for drying. We also determined the efficacy of two foams using a standard amount that dried in 30 s.

Methods

Part 1: Four different 62% ethanol foams were applied as described in Table 1. Each foam was weighed. The subject spread and rubbed the foam over both hands. The time required until the hands felt dry again was noted. A linear correlation between the duration and the weighed of foam was evaluated for all variations, to identify the amount of foam likely to keep hands wet for 30 s.

Part 2: The efficacy of two foams coded as A and B was determined according to EN 1500 [1]. Hands were washed for one min, dried, immersed in the contamination fluid *(Escherichia coli)* for 5 s, and allowed to dry for 3 min [2]. Pre- and post-values were obtained by rubbing fingertips for one min in a petri dish containing liquid broth, the broth for post-values contained neutralisers (3% Tween 80, 0.3% lecithin, 0.1% histidine, 0.1% cysteine). Either 1.6 g of foam, 1.6 g of water, or 2 x 3 mL of reference alcohol were applied. Foams and water were rubbed into the hands for 30 seconds, and reference alcohol for 60 s. Log counts from the left and right hands of each subject were averaged separately, for both pre-values and post-values. The arithmetic means of all individual $\log_{10}$ reduction values were calculated. The Wilcoxon matched-pairs signed rank test (one-sided) was used for comparison (significance level, $p = 0.01$).

Results

Part 1: The correlation between the applied amount of foam and the time until hands felt dry was highly significant ($p < 0.001$; Pearson's correlation coefficient: 0.724; 95% confidence interval: 0.52 - 0.93) (Fig. 1). The linear correlation showed that an amount of 1.6 g gave an intercept of 30 s application time, which is the time necessary to ensure an adequate quality of hand coverage [3].

Part 2: Both foams were significantly less effective than the reference procedure of 2 x 3 mL applications of 60% isopropanol for 60 s (Table 2), and thus failed to meet the European efficacy requirements for hygienic hand disinfection.

Discussion

The ability of foams based on 62% ethanol to provide sufficient patient safety is questionable. Healthcare workers are likely to apply an amount of foam that does not keep their hands moist for sufficient clinical efficacy. Compared to published data, even a simple hand wash has a similar or better antimicrobial

Foam (Manufacturer)	Label recommendation	Mode of application	Weight of the applied amount of foam (mean ± stdev)	Time to dry (mean ± stdev)
Alcare plus (Steris Corporation, St. Louis, MO, USA)	Dispense a palmful (golf ball) in one hand. Spread over both hands up to one-half inch above the wrists. Rub vigorously.	Apply a golf ball-sized amount of foam using a golf ball as reference, rub into both hands	3.09 ± 0.63 g	103 ± 34 s
		Apply a golf ball-sized amount of foam with no reference golf ball, rub into both hands	2.56 ± 0.81 g	78 ± 30 s
Avagard Foam (3M, St. Paul, MN, USA)	Apply sufficient amount to thoroughly wet all surfaces of hands and fingers. Rub onto hands until dry.	Apply a golf ball-sized amount of foam with no reference golf ball, rub into both hands	1.99 ± 0.93 g	60 ± 30 s
Bode test foam (Bode Chemie GmbH, Hamburg, Germany)	Not available.	Apply a golf ball-sized amount of foam with no reference golf ball, rub into both hands	2.16 ± 0.52 g	80 ± 34 s
Purell Instant Hand Sanitizer (Gojo Industries Inc., Akron, OH, USA)	Place enough product in your palm to thoroughly cover your hands. Rub hands together briskly until dry.	Apply a golf ball-sized amount of foam with no reference golf ball, rub into both hands	1.98 ± 0.42 g	57 ± 18 s
		Pump applicator three times and rub into both hands	1.78 ± 0.04 g	37 ± 10 s
		Pump applicator four times and rub into both hands	2.38 ± 0.05 g	63 ± 19 s

Table 1: Label recommendations for application of four different 62% ethanol foams, their mode of application in the study, and mean weight and mean drying time; each application was tested with 14 subjects.

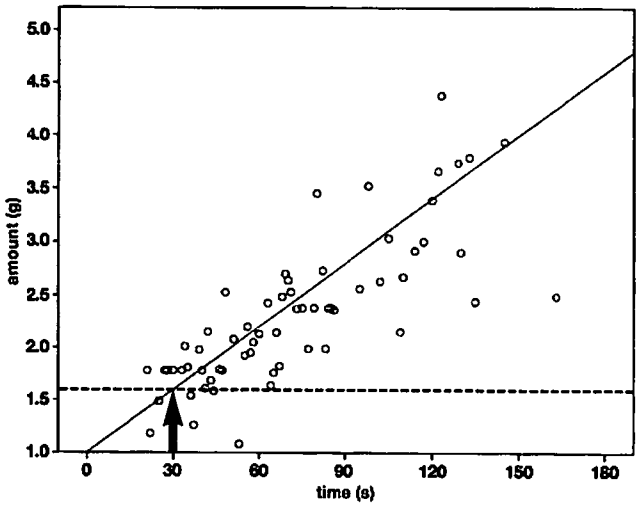

Figure 1: Correlation between the applied amount of 62% ethanol foam and the time required for hands to feel dry; the red arrow indicates the intercept between a drying time of 30 s and the corresponding weight of foam.

Product (all 1.6 g per application)	Product	EN 1500 reference treatment	p-value
Foam A	3.05 ± 0.45	4.83 ± 0.89	≤ 0.001
Foam B	3.58 ± 0.71	4.60 ± 0.59	≤ 0.001
Water (negative control)	2.39 ± 0.57	4.54 ± 1.01	≤ 0.001

Table 2: Efficacy expressed as mean log_{10}-reduction with stdev of two 62% ethanol foams or water, compared to EN 1500 reference disinfection of 2 x 3 mL 60 % isopropanol.

efficacy as 1.6 g of 62% ethanol foam [4]. As with gels, a higher concentration of ethanol might improve the efficacy of foams [5]. That is why other foams may reveal a better efficacy with a 1.6 g application.

A recent controlled prospective cross-over trial in intensive care units showed that introduction of a gel-based 62% ethanol product might improve compliance. The incidence of healthcare-associated infections, however, remained unchanged [6], suggesting that the concentration of ethanol in the gel may have been too low to prevent cross-transmission in clinical practice. This supports our concerns about the efficacy of foams based on 62% ethanol.

One of the foams was applied as three and four pumps of the applicator (Table 1), for mean amounts of 1.78 g, and 2.38 g, respectively. If healthcare workers pump only once, the dispensed amount could be as small as 0.6 g. Even two pumps would be less than 1.6 g per application. Based on these data, the amount of foam recommended on product labels for the post-contamination treatment of hands should be more precise, and address both the efficacy and a clinically acceptable time for drying after application. Otherwise, the use of the investigated 62% ethanol foams should be critically reviewed in hospitals, as they may jeopardize patient safety.

References

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