

Effectiveness of three surgical alcohol-based hand rubs on skin flora

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ABSTRACT

Background: It is proved that surgical hand disinfectant contains alcohol, and has favorable properties such as strong and rapid antibacterial effect, ease of application, and suitable effect on skin. Therefore, nowadays use of them has been gradually replacing traditional surgical hand scrub with antibacterial soap. Hence, several domestic and imported products are available to the healthcare facilities in Iran. This study was done in order to determine the antibacterial effect of Decosept, Sterillium, and Septicidine on skin flora.

Materials and Methods: This clinical trial was carried out on 20 volunteers. Subjects disinfected their hands with three test products. At first, subjects washed their hands with soap. Then pre-value sample was taken from the finger tips in Tryptic Soy Broth (TSB).¹ After that, the hands were disinfected with one of the surgical hand rubs with as much volume as necessary to keep the hands wet, at the recommended application time. Immediate post-value sample was taken from one hand and the other hand was gloved for 3 h. After removing the surgical glove, 3 h post-value sample (sustained effect) was taken from the hand.

Results: All products remarkably decreased the colony forming units (CFU) immediately ($P < 0.0001$) and 3 h ($P < 0.0001$) after disinfection. Analysis of variance (ANOVA) revealed significant differences among immediate post-values ($P < 0.005$). Septicidine was significantly the least effective than the others, whereas 3 h effect of the three products was similar ($P = 0.630$, ANOVA).

Conclusions: Our results confirm the effectiveness of the three alcohol-based hand rubs. Considering the short application time, less volume used, and more antibacterial effect, however, Sterillium seems to be a better choice.

Key words: Decosept, Septicidine, Sterillium, surgical hand disinfection

¹Tryptic Soy Broth

INTRODUCTION

Nowadays, surgery is one of the common treatments. This intervention has potential complications such as surgical site infection (SSI), one of the most frequent nosocomial infections,^[1] with a reported prevalence of 2–38.7%.^[2] These complications cause many problems to patients and healthcare facilities.^[2]

Prevention of SSI can be achieved by surgical hand disinfection, a standard and obligatory procedure used in all hospitals.^[3,4] The surgical hand antiseptics, performed

before donning sterile glove and gown, is defined as a process to remove transient microorganisms and reduce the resident skin flora.^[5]

Due to potential risk of surgical glove perforations occurring during surgery, it is necessary to reduce skin flora as high as possible, and use antibacterial solutions before gloves are worn.^[5]

Since Joseph Lister had shown the importance of hand washing in the control of postoperative SSI,^[6] researchers have been trying to introduce preparations that have maximum efficacy on the density of resident flora. Hence, a variety of formulations have been produced and presented to the pharmaceutical market.^[7] Up to now, based on the formulations produced, two main groups of surgical hand disinfectants have been presented: (a) Antibacterial soaps, used in traditional hand disinfection procedure, and (b) Alcohol-based hand solutions, which are used in surgical hand rub procedure, as a waterless and brushless method.

Alcohol-based hand rubs are known to be the most effective surgical hand antiseptics and are often preferred

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to antimicrobial soaps because they are broad-spectrum agents and have high antibacterial effect, act faster and in the shortest time, can be applied easily, and are better tolerated by skin.^[4] As Marchetti *et al.* reported, although antiseptic-based soap (Betadine) significantly reduced the skin flora, just Sterillium and Softaman (two alcohol-based hand rubs), and Hibiscrub (chlorhexidine) could meet the requirement of prEN 12791 (an European standard for evaluating the antibacterial efficacy of surgical hand antiseptics).^[8] Hsieh, in a systemic literature review, showed hand rubbing for 3 min with an alcoholic disinfectant was more effective than 6 min of hand scrubbing using chlorhexidine gluconate (CHG) 4%.^[5]

Alcohol-based hand disinfectants have been used in Europe for years.^[5] Recently, hand rubs have also been increasingly used in the Islamic Republic of Iran.^[9,10]

With the widespread use of alcoholic disinfectants, numerous formulations have been produced and are available for use in healthcare facilities. Health service managers are always trying to choose more efficient and cost-effective antiseptics. In addition, researchers around the world are constantly trying to compare the efficacy of these formulations to determine the effectiveness of them. For example, in a research conducted on 3 and 5 min hand disinfection with two hand rub products (ethanol- and isopropanol-based hand rubs), isopropanol hand rub caused better result in decreasing the skin flora.^[7] Kampf and Ostermeyer, in a controlled trial, compared the efficacy of two alcoholic disinfectants (Sterillium rub and Avagard); their results showed that based on prEN 12791, Sterillium rub was more effective than Avagard.^[11]

Iranian pharmaceutical market is mainly composed of a variety of imported and domestic surgical hand disinfectants of different prices. Today in Iran, economic sanctions have been led to sharp increases the price of imported products, therefore the Ministry of Health emphasizes the use of similar local products. Hence This study was conducted to compare the efficacy of two imported alcoholic hand rubs, Sterillium and Decosept, with that of domestic hand rub antiseptic, Septicidine. If the domestic product's effectiveness is similar to that of foreign products, its use is suggested as it is less expensive.

MATERIALS AND METHODS

This quasi-experimental study was a clinical trial consisting of one group, with before and after design. This study was approved by the research ethics committee of Hamadan University of Medical Sciences. The study was conducted on 20 healthy volunteers who were students or personnel of the university. Inclusion criteria were: (a) Age more than

18 years, (b) having clean and short nails, and (c) not having used any substance with antibacterial activity 1 week before the study. Exclusion criteria were: (a) Pregnancy, (b) afflicted with any skin diseases, and (c) presence of any cuts or abrasion on hands.^[12]

All subjects signed written informed consent before enrolling in the experiments.

The sample size was estimated to be 20 subjects for each treatment (paired sample), considering the Kamp fetal article data^[13] and using the following equation for $\alpha = 0.05$ and $\beta = 0.2$:

$$n = \frac{(\sigma_1^2 + \sigma_2^2)(Z_{1-\beta})^2}{(\mu_1 - \mu_2)^2}$$

Test products

The following surgical hand rubs were used:

Sterillium (45% 2-propanol, 30% 1-propanol, 0.2% mecetronium etilsulfate; Bode chemie, Hamburg, Germany), Septicidine pc (50% ethanol, 25% isopropanol, 0.5% CHG; Behban Shimi, Tehran, Iran), Decosept HA (44.7% 2-propanol, 21.9% 1-propanol, 0.1% benzalkonium chloride; Borer Chemie, Zuchwil, Switzerland).

Treatment

Each subject applied all the hand rubs under investigation. For recovering of skin flora, at least 1 week interval had been elapsed before every intervention. Before treatment, subjects washed their hands with soft soap (sapokalinus²). After rinsing and drying of hands with non-sterile paper towel, bacterial culture samples of finger tips of both hands were taken (pre-value count). Then both hands were rubbed with one of the products under test.^[12] After disinfecting, to assess the immediate antibacterial effect, a sample as well as pre-value was taken from one randomly selected hand and the unsampled hand was gloved for 3 h. To evaluate the 3 h antibacterial effect, after removing the glove, sampling was performed similar to that of the immediate sample.

Wash phase

Washing hands up to wrist was achieved according to the method recommended by the World Health Organization (WHO)^[14] and EN12791 with 10 ml of sapokalinus for 1 min.^[12]

Sampling method and microbial culture determination

Distal phalanges of each hand were rubbed in 9-cm diameter Petri dish containing 10 ml of Tryptic Soy

²sapokalinus is a standard soft soap described in EN12791 and contains linseed oil, potassium hydroxide, and ethanol.

Broth (TSB). For pre-value, dilutions of 10^{-1} and 10^{-2} of sampling fluid were prepared in TSB. For each dilution, 0.1 ml was spread over the surface of a Tryptic Soy Agar (TSA) plate. For post-value sampling, 1 and 0.1 ml of undiluted sampling fluid and 0.1 ml from its 10^{-1} dilution were spread over TSA plates. All plates were incubated aerobically at $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for 24–48 h. The interval between sampling and incubating was less than 30 min.^[12]

Disinfection phase

The hand rubbing was practiced in accordance with the instruction of manufacturer as follows: For all hand antiseptics, the procedure was the same as that for standard hand rub, up to wrist. During the procedure, if hands nearly dried, additional volume of the product was applied to hands so they were being kept moist during disinfection phase. But the duration of application and, consequently, the volume of product were different for each product: For Decosept, they were 3 min and 8–12 ml, for Septicidine 6 min and 10–14 ml, and for Sterillium 1.5 min and 4–7 ml, respectively. The three hand rubs were dispensed sterilely into the hollow of subjects' palm.

In order to normalize the data, pre and post treatment colony counts per milliliter of sampling fluid (CFU/ml) were inverted to 10 logarithmic values.^[12] Data analysis was performed using SPSS 16. Based on normalized data, paired *t*-test and ANOVA test were used. Significance level was set at $P < 0.05$.

Calculating of bacterial population

The number of colony forming units (CFU) per plate for each dilution was recorded, and then the number of CFU per milliliter was calculated. The plate counts between 15 and 300 were chosen in order to calculate the CFU/ml. If the CFU of post-value plates were less than 15, these values were counted.^[12] If values in the range that could be entered into calculations were obtained from more than one dilution, their mean was used as the final logarithmic value.

RESULTS

The pre-value and immediate post-value \log_{10} of the three

products were: Sterillium: 4.3 ± 0.44 and 0.32 ± 0.57 , Decosept: 4.07 ± 0.53 and 0.81 ± 0.84 , and Septicidine: 3.95 ± 0.94 and 1.28 ± 1.14 , respectively. *t*-Test showed the differences were significant, that is, the three hand rubs had immediate effect. Using ANOVA test for comparison of immediate effect revealed significant difference among them, that is, the effects of products were not similar. Sterillium had the most and Septicidine had the least immediate effect [Table 1].

After 3 h, the bacterial density of hands increased, but these counts (3 h post-value) were significantly lower than the pre-value: Sterillium: 3.92 ± 0.63 and 1.80 ± 1.14 , Decosept: 3.86 ± 1.44 and 1.94 ± 1.10 , and Septicidine: 3.98 ± 1.02 and 1.58 ± 1.23 (*t*-test; $P < 0.0001$). ANOVA test revealed no significant difference among the three alcohol-based hand rubs. This means the 3 h effect of the antiseptics was the same [Table 1]. Septicidine did not cause fast and immediate effect as the other products, but comparison of \log_{10} immediate value and \log_{10} after 3 h of the products using *t*-test showed that only Septicidine could retain the antibacterial effect after 3 h under the glove [Table 2].

DISCUSSION

The skin flora consists of microorganisms which reside on the skin. The density and composition of the skin normal flora may be influenced by various factors, including anatomical locale, age, sex, moisture, pH, and immune system. It has been estimated that about 10^2 – 10^6 CFU/cm² inhabit on the skin of a human adult.^[5]

The skin microbes found in the most superficial layers of the epidermis are Gram-positive cocci (*Staphylococcus epidermidis* and *Micrococcus* sp.) and corynebacteria such as *Propionibacterium* sp. These are generally nonpathogenic or commensal; even some of them are mutualistic (offer a benefit). Sometimes potentially pathogenic *Staphylococcus aureus* is found on the face and hands in individuals who are nasal carriers.^[15] Nevertheless, these flora do not cause infection, if the skin is intact. In patients undergoing surgery, surgical incision may result in SSI, a common nosocomial infection.

Table 1: Comparison of the bacterial effect (immediate and 3 h) of the three surgical alcohol-based hand rubs

Effect products	Immediate effect			3 h effect		
	M±SD		P value	M±SD		P value
	Log ₁₀ pre-value	Log ₁₀ immediate		Log ₁₀ pre-value	Log ₁₀ 3 h	
Sterillium	4.03=0.44	0.32=0.57	<i>t</i> -test: $P < 0.0001$	3.92=0.63	1.80=1.14	<i>t</i> -test: $P < 0.0001$
Decosept	4.07=0.53	0.81=0.84	<i>t</i> -test: $P < 0.0001$	3.86=1.44	1.94=1.10	<i>t</i> -test: $P < 0.0001$
Septicidine	3.95=0.94	1.28=1.14	<i>t</i> -test: $P < 0.0001$	3.98=1.02	1.58=1.23	<i>t</i> -test: $P < 0.0001$
ANOVA	$F=0.001$ 0.99	$F=5.872$ 0.005		$F=0.001$ 0.99	$F=0.466$ 0.630	

ANOVA: Analysis of variance

Table 2: Comparison of immediate effect and 3 h effect of the three surgical alcohol-based hand rubs

Products	Value		
	Log ₁₀ immediate	Log ₁₀ 3 h	P value t-test
Sterillium	0.32±0.57	1.80±11.14	0.001
Decosept	0.81±0.84	1.94±1.10	0.001
Septicidine	1.28±1.14	1.58±1.23	0.24

S. aureus and *S. epidermidis* were reported to be the two most common organisms causing SSI.^[16]

One predisposing factor of SSI is the microorganisms carried by the hands of surgical team in case of using perforated surgical gloves; hence, surgical hand antisepsis is carried out to eliminate the transient flora and diminish the resident skin flora as much as possible.

In this study, we found that all three alcoholic hand rubs were able to significantly reduce the skin colony count immediately and 3 h after disinfection. This result is similar to previously reported results.^[6,8,10,13,17] Despite the fact that these clinical trials used different methods, their results showed significant reduction in skin flora after the interventions. It demonstrates the general effectiveness of the antiseptics used.

The efficacy of alcohol-based hand formulation is influenced by (a) the type, concentration, and volume of alcohol used, (b) duration of application, and (c) other disinfectant or auxiliary agent.^[6] In our study, Sterillium, containing 1-propanol 30%, the best effective alcohol, and 2-propanol 45% (total 75%), led to the immediate decrease of resident hand flora. Similar to this, in some studies, it was found to be the most effective alcoholic hand rub among others with different alcohol types and longer application time.^[6,7] Among the short chain alcohols, 1-propanol is better than 2-propanol, and it is better than ethanol.^[6,18] Comparison of an 80% ethanol-based hand rub, irrespective of the application time (1.5, 3, and 5 min), with propan-1-ol 60% (3 min) showed less significant effect than that of propane-based rub, and comparison of 1.5 and 3 min disinfection with propan-2-ol 75% and propan-1-ol 60% (3 min) demonstrated less significant effect of isopropanol-based hand rub.^[7] The 6 min hand rub with Septicidine (contains ethanol 50%, 2-propanol 25%, and CHG 0.5%) caused the least immediate effect; but after 3 h disinfection, any significant increase in resident flora did not reduce. It was concluded that Septicidine could retain the antibacterial effect during 3 h; in other words, its effect persisted better, which may be related to the ingredient in Septicidine (CHG). Although reduction in resident flora after 3 h in comparison to the pre-value was significant

for the two other formulations, skin flora increased after 3 h in comparison to the immediate value. To the best of our knowledge, there is no study concerning the effectiveness of Septicidine. One minute application of a hand rub (Hibistat containing CHG 0.5%, isopropanol 70%; its formulation is nearly similar to Septicidine), in comparison to 3 min disinfection with propan-1-ol 60%, caused significantly less immediate and 3 h effect.^[19] It may be related to the short time of application (1 min).

Effectiveness of each alcohol-based solution must be considered with time span. In this study, Decosept, Sterillium, and Septicidine, respectively, within 3, 1.5, and 6 min, could achieve effective results. Very short application time may fail to show antibacterial efficacy or long application may not result in any further effect. Hence, it is an important factor to determine how long should be the contact time. Suchemel *et al.* reported that hand rubbing within 1.5 and 3 min with Sterillium and 1.5 min with Sensiva (containing propan-1-ol 45%, propan-2-ol 28%, and lactic acid 3%) showed similar results, whereas 1.5 min disinfection with Desderman (ethanol 78.2%, 2-biphenylol 0.1%) did not show acceptable results.^[6] In another study, two WHO formulations, ethanol 80% and isopropanol 75%, with 5 min application time were as effective as applying them for 1.5 and 3 min.^[7] Even when the most powerful alcohol, propan-1-ol 70%, plus CHG 0.5% and ethanol 78% plus biphenyl-2-ol 0.1% were used for 1 min, they could not produce suitable effect.^[19] For each hand rub, the best antibacterial efficacy can be achieved by a certain application time that is recommended by the manufacturer.^[12] In clinic, this cannot be practiced. Some study reported surgical team disinfected their hand for shorter application time,^[9] which certainly resulted in less efficacy; therefore, it is necessary that surveillances are frequently undertaken and the importance of this influencing factor must be emphasized to surgeons and surgical technologists.

Short application time of hand disinfectants is certainly accompanied with less volume of antiseptic products used. Because of saving time and applied volume, short application of disinfectant without any decrease in the quality of antiseptic effect is a known favorable clinical condition, which makes healthcare facilities use such products.

Antiseptic dose is also a factor influencing their efficacy. In our study, the applied volume for total disinfection time was: 4–7, 8–12, and 10–14 ml, respectively, for Sterillium, Decosept, and Septicidine. Kampf and Ostermyer studied the efficacy of 3 min disinfection with different doses of propan-1-ol. Based on the applied volume of the product under test, which was necessary keep the hand moist, they designated volunteers to three groups (6, 9, and 12 ml). As no

significant differences were found among interventions, they concluded that the required volume of alcoholic hand rubs is the volume necessary to keep the hand wet,^[20] which varied according to the size, temperature, and activity of hands.^[21]

To conclude, in this experiment, the alcohol concentrations of products were somewhat equal. The alcohol concentrations of Sterillium, Septicidine and Decosept are 75, 75 and 66.6 percent respectively, that their concentrations were in range of effective alcohol concentration.^[18,22] In a study, Sterillium rub containing ethanol 80% at 3 min disinfection led to better significantly effect on skin flora than Avagard (ethanol 61% plus CHG 1%). The authors concluded that the difference between the two disinfectants was related to the high concentration of ethanol in Sterillium rub, whereas CHG 1% could not enhance the antibacterial efficacy of Avagard.^[11]

CONCLUSION

Based on the results of the study, although Decosept and Septicidine had significant effect on skin flora, considering the factors that influence the antibacterial efficacy of alcohol-based hand rub (type, concentration, applied volume, and duration of contact with antiseptic), Sterillium was the best product.

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