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New method for assessing hand disinfection shows that pre-operative alcohol/chlorhexidine rub is as effective as a traditional surgical scrub

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SUMMARY

**Background:** Several studies have shown that rubbing hands with an alcohol/chlorhexidine solution provides equivalent microbial decontamination to a conventional surgical scrub using aqueous chlorhexidine. However, the authors believe that these studies have methodological flaws which limit their applicability to the operating theatre environment. As such, a method was developed to compare products in an everyday operating theatre environment using working operating theatre personnel.

**Aim:** To determine whether or not an alcohol/chlorhexidine rub is as efficacious as a traditional surgical scrub using a novel method.

**Methods:** Bacterial counts at baseline were collected from 20 anaesthetists using the glove juice method. Subsequently, with sequential exchange of sterile gloves, one hand underwent a 3-min scrub using 4% aqueous chlorhexidine, and the other hand underwent a 60-s rub with a 70% isopropyl alcohol/0.5% chlorhexidine solution. The residual bacterial count was collected for each hand after 30 min using the glove juice method. These counts were converted to log\(_{10}\) values to compare the baseline counts of right and left hands, and efficacy between the treatment groups.

**Findings:** Mean [+/- standard deviation (SD)] bacterial counts at baseline were (log\(_{10}\)) 4.42+/-0.81 for left hands and 4.64+/-0.60 for right hands \((P>0.05)\). The mean (+/- SD) reduction from baseline was (log\(_{10}\)) 1.45+/-0.50 for 4% chlorhexidine and 2.01+/-0.98 for alcohol/chlorhexidine \((P>0.05)\).

**Conclusion:** An alcohol/chlorhexidine hand rub was found to be as efficacious as a traditional scrub after 30 min; this study differs from previous work as it was undertaken in a population of practising anaesthetists in their working environment. The McKenzie method allows baseline and study evaluations to be performed.
contemporaneously on the same individual. The subject is their own control. This method offers a more clinically relevant way to compare disinfectant solutions than standard methods.

*Keywords:*

Alcohol/chlorhexidine solution
Surgical scrub
Pre-operative hand disinfection
McKenzie method
**Introduction**

Could an alcohol-based hand rub replace a conventional surgical scrub for hand disinfection for sterile procedures associated with anaesthesia? Alcohol rubs have been shown to reduce hand preparation time by two-thirds,¹ and several studies have shown an alcohol chlorhexidine-based preparation to be equivalent or superior to aqueous chlorhexidine in terms of ability to reduce skin bacterial counts.²,³,⁴

However, these studies, as well as current US⁵ and European⁶ hand disinfection guidelines, have potential methodological flaws that may limit their applicability to a working operating theatre environment. These include the need for test subjects to adhere to stringent conditions for days before the studies,³,⁵,⁶ performing baseline studies on a different occasion from the test studies,²–⁵ and testing the products for comparison on a different occasion in each subject.²–⁶

As such, a novel method – the McKenzie method – was developed to compare the products in an everyday operating theatre environment using working operating theatre personnel. With this method, subjects have no special preparation, the test solutions are compared at the same time using sequential glove changes, and the subjects act as their own control.

**Methods**

The study received approval from the Princess Alexandra Hospital Ethics Committee.

**Participants**

Twenty volunteers who were either anaesthetic consultants or registrars gave consent to participate in the trial. Exclusion criteria were the use of antibiotics in the
preceding seven days or significant skin damage on the hands, such that the use of alcohol-based products would be considered painful.

\textbf{<B>Handwashing technique – the McKenzie method}

No hand preparation was required prior to baseline collection, except for the removal of wristwatches and rings. Baseline microbial counts were taken from each hand using the glove juice method. This involved placing sterile gloves over each hand and adding 20 mL of sterile nutrient broth solution aseptically to each glove. The gloves were sealed at the wrist with adhesive tape, the hands were massaged uniformly for 1 min (timed) by a trained operator (CJ), and the volunteer was asked to open and close their hands five times. Subsequently, the broth was extracted aseptically and placed in a sterile container for processing in the microbiology laboratory.

A random number table was used to select which hand would undergo the surgical scrub and which hand would undergo the alcohol rub. The glove on one hand (Hand 1) was removed and that hand underwent a conventional 3-min surgical scrub up to the wrists using 4% aqueous chlorhexidine (Microshield 4, Johnson and Johnson, North Ryde, Australia). The other hand (Hand 2) remained sealed in the glove to avoid contamination, but participated in washing Hand 1 as normal. After washing, Hand 1 was patted dry using a sterile towel and placed in a new sterile glove that was sealed at the wrist. Next, the glove was removed from Hand 2 and that hand underwent an alcohol hand rub up to the wrist using 70% isopropyl alcohol with 0.5% chlorhexidine (Debug, Orion Laboratories, Balcatta, Australia). Sufficient product was applied to wet all areas of the hand and rubbed for 60 s, assisted by Hand 1 which was still protected by a sterile glove. Once air dried, Hand 2 was placed in a new sterile glove and sealed at the wrist. The anaesthetist then continued with their duties.
using both hands which were sealed in the sterile gloves. After 30 min, sterile nutrient broth solution was added to each gloved hand and massaged for 1 min, as described previously. The solution was extracted aseptically into a labelled sterile container, and delivered to the microbiology laboratory for processing.

**Microbiology protocol**

A sterile nutrient broth solution, containing neutralizers to deactivate the ongoing bactericidal effect of chlorhexidine, was used for the glove juice technique (Tween 80, phosphatidyl choline, sodium thiosulphate, nutrient broth no. 2). The effectiveness of the neutralizer was validated during a pilot study. The same solution was used for both baseline and test sample collections to allow direct comparison of results. Both 10-µL and 1-µL loops were used to inoculate each sample on to separate trypticase soy agar plates. These were incubated at 30°C in air for 48 h before examination. Colony counts were determined from plates with a range from 0 to >300 to determine colony count/mL of glove juice solution. If no growth was detected, a count of 99/mL was assigned to allow statistical analysis. Similarly, if >300 colonies were counted on a 1-µL plate, a count of 300,000/mL was assigned for analysis. Colony counts were converted to a log_{10} value prior to analysis.

**Statistical analysis**

The sample size determined by the US and European guidelines differs in methodology, but similar numbers are required. European guidelines require 18–20 volunteers and US guidelines require \( N \geq \frac{(S^2)(Z_{\alpha/2} + Z_\beta)^2}{\delta^2} \) volunteers. Variance \( (S^2) \) from the pilot study was 0.34, although it has been set at 0.6 in previous studies. Using the larger number and setting a type 1 error of 0.05 and power of 0.95 whilst
considering a clinically significant difference (δ) between means to be 0.4log₁₀, the US method required at least 17 volunteers. The baseline microbial counts on the right and left hands were compared using Wilcoxon signed ranks test. Wilcoxon rank sum test was used to compare the reduction in bacterial count for each treatment arm.

**Results**

The distribution of participants by time since last sterile scrub is shown in Table I. Although not shown, there was no significant difference between the bacterial counts at baseline of participants who had performed a sterile scrub recently and participants who had not.

**<insert Table I near here>**

Table II shows the bacterial loads on hands at baseline. Wilcoxon signed ranks test showed that there was no significant difference between bacterial counts of an individual’s right and left hands at baseline (P>0.05). Three left-hand-dominant volunteers were included in the study.

**<insert Table II near here>**

The efficacy (or reduction factor) of hand disinfection was determined as the reduction in microbial number below baseline. Table III shows there was no significant difference between treatment efficacy of the gold standard and the alcohol rub. On two occasions in the scrub group and on one occasion in the hand rub group,
the microbial count was not reduce below baseline. These results were excluded from the final analysis, but possible causes are mentioned in the Discussion.

**Discussion**

This study demonstrates that, in a functioning operating theatre environment, an alcohol-based hand rub (chlorhexidine 0.5%/ isopropyl alcohol 70%) is not inferior to a conventional 3-min scrub with 4% aqueous chlorhexidine for hand disinfection after 30 min in sterile gloves.

The McKenzie method was introduced for testing hand disinfection products contemporaneously using individuals as their own experimental control, in an attempt to address the shortcomings of the conventional US and European methods. A common, standardized method for testing hand disinfection is desirable to prevent the scenario of a product passing one method but not another.\(^9,10\) The methods are compared in Table IV.

**Table IV**

The authors believe that the baseline status used to evaluate a product should reflect the actual working conditions of the users. In the operating theatre, anaesthetists frequently wash their hands with both soap and antibacterial solutions, and the baseline status should reflect this. The McKenzie method does not preclude the use of these preparations in the days before the study, unlike the US and European methods. Furthermore, the restrictions placed on subjects before the baseline studies...
could result in bacterial skin flora that differs from that of an anaesthetist in the operating theatre.

The US and European methods require handwashing with soap before a baseline study. This decimates the bacterial count and considerably reduces the bacterial burden that the test solution has to overcome. However, an anaesthetist would not normally wash their hands with soap before applying an alcohol-based solution; to do both would negate any time saving and convenience over a conventional surgical scrub. Alcohol-based rubs (and chlorhexidine) have limited effect on bacterial spores or when there is visible skin contamination; in these instances, handwashing with soap and water is recommended.

The European method uses the finger tip plating technique. Critics argue that although glove perforations commonly occur at the finger tips, the bacterial count at the finger tips may not be representative of the whole hand, and that glove perforations can occur anywhere on the hand. The incidence of glove perforation during surgery is 7.5–20%, with a high percentage (but not all) occurring on the fingers.

The US method uses the glove juice technique, which was adopted in this study. The present authors believe that the glove juice technique gives a more accurate representation of the bacterial population of the whole hand.

A criticism of the US method is the importance of showing a sustained effect on hand bacterial growth over two weeks, at the expense of demanding an initial reduction in bacterial number that can be achieved by household soap alone. This implies a difference in the standard acceptable for a patient having a procedure on Day 1 compared with Day 13.
There was an initial concern that handedness may have led to a difference in baseline counts. However, the results support the pilot study which found no significant difference associated with hand dominance. As such, either hand can be used during treatment comparisons. Bacterial counts at baseline may have been slightly lower than anticipated in this study because the study population consisted of volunteers who were actively involved in patient care at the time of the experiment; however, numbers were in keeping with previous studies. The decision to use 4% chlorhexidine as the gold standard for comparison was based on current local antiseptic handwashing practices.

In this study, there was no reduction in bacterial count from baseline on two occasions in the chlorhexidine group and one occasion in the hand rub group. These results were included in calculations for baseline, but not for efficacy of hand disinfection. This finding was unexpected and may have been due to contamination at any point from sample collection to plating and incubation. Comparable studies only published mean bacterial counts, so it is not possible to ascertain whether there were similar failures of efficacy in these studies. Alternatively, the failure in both groups may be an accurate reflection of handwashing efficacy in the clinical setting, whereby the handwashing technique of the individual is at fault. It is also possible that gloves may have had small perforations as the volunteers continued with their clinical duties. Determining microbiological counts by serial dilution can be a source of error, which if it occurs, will be magnified due to the large numbers involved. As the counts were performed manually, it could only be reasonably expected to count <300 colonies per plate. As only two dilutions were performed, a true number was not derived if the count was more than 300,000/ml (5.477log\text{10}), which may have altered mean values. The baseline counts were in the range of previous work performed in healthcare
workers, and were acceptable in terms of minimum number for both the US and European guidelines; however, they were slightly lower than results published by Rotter, Mulberry et al. and Kampf et al.²,⁸,⁹

The results of this study were compared with those from existing studies involving similar products in order to validate the McKenzie method. The efficacy results for the present study (baseline reduction 1.45) fall between those of Rotter (0.9) and Mulberry et al. (1.8) for 4% aqueous chlorhexidine, and were similar for the alcohol/chlorhexidine combination (2.01 vs 2.1 vs 2.5).²,⁸ Kampf et al. achieved a better immediate baseline reduction for alcohol-based rubs, and reported 2.8–2.9 when using the US protocol and 2.35–2.97 when using the European protocol.⁹ The difference in reduction factor in their experiment, which used the same products but different international guidelines, highlights the need for a unified testing protocol.

The number of subjects in this study was modest; the technique obviously requires further evaluation and validation. The authors intend to undertake further studies to evaluate the technique, and study these and other preparations over longer time frames, making the results more applicable in operating theatres. Modification of retrieval of the nutrient broth solution may also be examined in order to reduce the possibility of contamination. Running samples in duplicate or triplicate would strengthen the results, although this would increase the costs associated with the study.

Some form of hand disinfection before applying gloves for a sterile procedure is axiomatic. This study and others have shown that validated alcohol solutions provide equivalent or better hand disinfection compared with a conventional surgical scrub. Waterless alcohol rubs are already commonly used pre-operatively in Scandinavia, and are accepted in the UK for subsequent procedures following an
initial handwash. Waterless hand disinfection is also advantageous in cases of roadside trauma or in remote locations where water is unavailable or in limited supply.

Changing to an alcohol-based hand rub will save precious theatre time and allow hand disinfection to occur in the operating theatre. An anaesthetist will no longer have to leave the vicinity of the patient, which has safety implications during sedation and general anaesthesia. Resistance to change may be due to concern over increasing surgical site infections. A study by Parienti et al. involving over 2000 subjects showed that there was no change in surgical infection rate when surgeons changed to using alcohol rubs alone for hand disinfection.

Conclusion

Using the McKenzie method, this study found that an alcohol/chlorhexidine hand rub (70% isopropyl alcohol/0.5% chlorhexidine) is an acceptable alternative to a conventional surgical scrub with aqueous chlorhexidine for procedures lasting less than 30 min. Additional handwashing only needs to be performed if the hands are visibly soiled. This is consistent with the findings of other studies, but validates them in a functioning clinical setting.

It is believed that the McKenzie method offers a novel and efficient means of evaluating skin preparation solutions in a working theatre environment using practising clinicians. It allows the normal bacterial population of a working anaesthetist to be used as a control, and the control, test and reference evaluations to be performed on the same occasion. The subject is their own control. The McKenzie method has the potential to replace the more laborious and time-consuming US and European standard methods.
References


Table I
Demographic data

<table>
<thead>
<tr>
<th>Time since last scrub (days)</th>
<th>Participants (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;3</td>
<td>4</td>
</tr>
<tr>
<td>3–7</td>
<td>7</td>
</tr>
<tr>
<td>&gt;7</td>
<td>9</td>
</tr>
</tbody>
</table>
**Table II**
Bacterial loads on hands at baseline (colonies/mL)

<table>
<thead>
<tr>
<th>Mean load on right hands (log₁₀) +/- SD (range)</th>
<th>Mean load on left hands (log₁₀) +/- SD (range)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.42 +/- 0.81 (3–5.48)</td>
<td>4.64 +/- 0.60 (3.60–5.48)</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

SD, standard deviation.
### Table III
Treatment efficacy (log$_{10}$ baseline – log$_{10}$ residual count)

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean reduction from baseline (log$_{10}$) +/- SD (range)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>4% chlorhexidine</td>
<td>1.45 +/- 0.50 (0.80–2.52)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Alcohol/chlorhexidine rub</td>
<td>2.01 +/- 0.98 (0.35–3.48)</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

SD, standard deviation.
### Table IV

Comparison of hand disinfection methods

<table>
<thead>
<tr>
<th>Main criterion</th>
<th>Current trial</th>
<th>US method</th>
<th>European method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design</td>
<td>Randomized, self-controlled design</td>
<td>Randomized, blinded parallel arm design</td>
<td>Randomized, reference controlled crossover design</td>
</tr>
<tr>
<td>Test organism</td>
<td>Resident flora</td>
<td>Resident flora</td>
<td>Resident flora</td>
</tr>
<tr>
<td>Prerequisites</td>
<td>Sample size</td>
<td>( N \geq [(S^2)(Z_{\alpha/2} + Z_\beta)^2] / \bar{d}^2 )</td>
<td>18–20</td>
</tr>
<tr>
<td>Treatment of hands before baseline</td>
<td>None</td>
<td>Wash with non-antibacterial liquid soap for 30 s</td>
<td>Wash with sapo kalinus for 1 min</td>
</tr>
<tr>
<td>Sampling</td>
<td>Method</td>
<td>Glove juice method for 1 min using broth containing neutralizers</td>
<td>Glove juice method for 1 min</td>
</tr>
<tr>
<td>No. of samples</td>
<td>Two baseline, two treatment (at 30 min)</td>
<td>Three baseline (collected in week prior to study), nine treatment (0, 3 h, 6 h on days 1, 2 and 5)</td>
<td>One baseline, two treatment (0 and 3 h) per patient (repeated during crossover)</td>
</tr>
<tr>
<td>Antiseptic hand treatment</td>
<td>Reference treatment</td>
<td>4% chlorhexidine for 3 min</td>
<td>Positive control recommended, not required</td>
</tr>
<tr>
<td>Test product</td>
<td>As recommended by manufacturer</td>
<td>As recommended by manufacturer, or 10 min</td>
<td>As recommended by manufacturer</td>
</tr>
<tr>
<td>Number of treatments</td>
<td>One per subject</td>
<td>Eleven per subject</td>
<td>One per subject per experiment</td>
</tr>
<tr>
<td>Treated skin area</td>
<td>Hands up to wrists</td>
<td>Hands and lower two-thirds of forearm</td>
<td>Hands up to wrists</td>
</tr>
<tr>
<td>Study duration per participant</td>
<td>45 min</td>
<td>19 days (one week pre-test, one week baseline, five days testing)</td>
<td>14 days (one week pre-test, one week crossover)</td>
</tr>
<tr>
<td>Requirement</td>
<td>Baseline</td>
<td>No minimum</td>
<td>Minimum $1.5 \times 10^5$ $(5.17\log_{10})$</td>
</tr>
<tr>
<td>----------------------</td>
<td>----------------</td>
<td>-----------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>Immediate effect</td>
<td>Not tested</td>
<td>Day 1 ≥ $1\log_{10}$ reduction from baseline, Day 2 ≥ $2\log_{10}$ reduction and Day 5 ≥ $3\log_{10}$ reduction</td>
<td>Not less effective than reference (Wilcoxon matched pairs signed rank test)</td>
</tr>
<tr>
<td>Sustained efficacy</td>
<td>Not less effective than 4% chlorhexidine at 30 min</td>
<td>At 6 h on Days 1, 2 and 5, count must not exceed baseline</td>
<td>Not less effective than reference at 3 h (Wilcoxon matched pairs signed rank test)</td>
</tr>
</tbody>
</table>
Baseline testing using glove juice method

Sequentially isolating hand

Perform normal duties for 30 min, then collect sample using glove juice method

**Figure 1.** McKenzie method.