Literature Review: Use of 4% Chlorhexidine Gluconate Solution as a Surgical Hand Scrub and Healthcare Personal Handwash

Summary:
A search of PubMed and the Cochrane Library reveals that leading surgical guidelines\(^{1-3}\) and academic-and-peer-review published literature\(^{4-7}\) support the use of chlorhexidine gluconate solution as a surgical hand scrub or healthcare personal handwash.

Although the strong residual activity of chlorhexidine is described in the Centers for Disease Control and Prevention’s “Guideline for Hand Hygiene in Health-Care Settings”\(^1\), they do not specifically recommend one form of antimicrobial soap over another. The 2013 AORN “Perioperative Standards and Recommended Practices: Recommended Practices for Hand Hygiene in the Perioperative Setting” state that antimicrobial surgical hand hygiene products should have a persistent and cumulative effect, but again does not specifically recommend any antimicrobial over another.

Guidelines Supporting the Use of 4% Chlorhexidine Gluconate Solution as a Surgical Hand Scrub:

1. CDC Guideline for Hand Hygiene in Health-Care Settings, October 25, 2002
http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf

Although no randomized, controlled trials have been conducted to indicate that surgical-site infection rates are substantially lower when preoperative scrubbing is performed with an antiseptic agent rather than a non-antimicrobial soap, certain other factors provide a strong rationale for this practice. Bacteria on the hands of surgeons can cause wound infections if introduced into the operative field during surgery; rapid multiplication of bacteria occurs under surgical gloves if hands are washed with a non-antimicrobial soap. However, bacterial growth is slowed after preoperative scrubbing with an antiseptic agent. Reducing resident skin flora on the hands of the surgical team for the duration of a procedure reduces the risk of bacteria being released into the surgical field if gloves become punctured or torn during surgery.

Persistent antimicrobial activity of detergent-based surgical scrub formulations is greatest for those containing 2% or 4% chlorhexidine gluconate, followed by hexachlorophene, triclosan and iodophors. Because hexachlorophene is absorbed into the blood after repeated use, it is seldom used as a surgical scrub.

Several studies have demonstrated that scrubbing for 5 minutes reduces bacterial counts as effectively as a 10-minute scrub. In other studies, scrubbing for 2 or 3 minutes reduced bacterial counts to acceptable levels. Studies have indicated that a two-stage surgical scrub using an antiseptic detergent, followed by application of an alcohol containing preparation, is effective. For example, an initial 1- or 2-minute scrub with 4% chlorhexidine gluconate or povidone-iodine followed by application of an alcohol-based product has been as effective as a 5-minute scrub with an antiseptic detergent.

Recommendations (p. 32–33)
3. Surgical hand antisepsis
   C. Surgical hand antisepsis using either an antimicrobial soap or an alcohol-based hand rub with persistent activity is recommended before donning sterile gloves when performing surgical procedures (IB).
   D. When performing surgical hand antisepsis using an antimicrobial soap, scrub hands and forearms for the length of time recommended by the manufacturer, usually 2–6 minutes. Long scrub times (e.g., 10 minutes) are not necessary (IB).

Recommendation III

A surgical hand scrub should be performed by healthcare personnel before donning sterile gloves for surgical or other invasive procedures. Use of either an antimicrobial surgical scrub agent intended for surgical hand antisepsis or an alcohol-based antiseptic surgical hand rub with documented persistent and cumulative activity that has met U.S. Food and Drug Administration (FDA) regulatory requirements for surgical hand antisepsis is acceptable.

The objective of a surgical hand scrub is the reduction of transient and resident flora, which also may reduce healthcare-associated infections. Although the skin can never be rendered sterile, it can be made surgically clean by reducing the number of microorganisms. A surgical hand scrub will decrease transient and resident microorganisms on the hands and maintain the bacterial level below baseline. The mechanical action associated with hand scrubbing removes debris and microorganisms. This can be accomplished by rubbing the skin with or without a sponge to produce friction. With the addition of a healthcare organization–approved antiseptic soap, which acts as a surfactant, transient and some resident microorganisms can be lifted and flushed away under running water. Surgical hand antisepsis/hand scrubs are effective only if all surfaces are exposed to the mechanical cleaning and chemical antisepsis processes.

Recommendation IV

Surgical hand hygiene products should be selected following an analysis of product effectiveness, application requirements and user acceptance.

IV.b. Surgical hand hygiene products should be selected and used according to manufacturers’ written instructions.

IV.b.1. Antimicrobial surgical hand hygiene products should

- significantly reduce microorganisms on intact skin
- contain emollients and humectants to prevent skin irritation
- be broad-spectrum
- be fast-acting, and
- have a persistent and cumulative effect

3. APIC Text: Chapter 19 – Hand Hygiene – BASIC PRINCIPLES
Janet P. Haas, DNsc, RN, CIC, Director, Infection Prevention and Control, Westchester Medical Center, Valhalla, New York

Surgical Hand Antisepsis

Product Selection

Either an antimicrobial soap or an alcohol-based surgical hand rub with persistent activity may be used. Alcohol-based formulations are the most effective at immediately lowering bacterial counts. The next most effective agents, in order of decreasing activity, are CHG, iodophors, triclosan and plain soap. Persistent antimicrobial activity is another important characteristic for a surgical scrub, and the most effective are CHG (2% or 4%), triclosan and iodophors.

References Supporting the Use of 4% Chlorhexidine Gluconate Solution as a Surgical Hand Scrub:

4. Comparative Evaluation of Five Surgical Hand Scrub Preparations

This article describes the antimicrobial characteristics of five products so OR personnel may better choose the appropriate product, based on their specific needs. The study was performed at Bio-Science Laboratories, Inc., Bozeman, Mont., without outside funding from any manufacturer whose products were tested. The investigators have
no financial interests in any of the companies whose products were evaluated.

We designed this study to evaluate these three parameters (i.e., immediate, persistent and residual antimicrobial properties) in five representative surgical scrub products (i.e., 4% CHG, 2% CHG, PVP-I, PCMX, alcohol). We used the study design that the FDA recognizes for formal efficacy studies of surgical scrub products.

Thirty healthy adults (i.e., six subjects assigned to each of the five product groups) participated voluntarily in the study. The sample consisted of 21 women and nine men, ranging in age from 18 to 58 years. We selected five representative surgical scrub products from the four main categories of topical antimicrobials. Test product one was a 4% CHG impregnated brush. Test product two was a 2% CHG solution used with a dry sterile brush. Test product three was a PVP-I-impregnated brush. Test product four was a PCMX-impregnated brush. Test product five was an alcohol detergent–impregnated brush. We chose the 2-minute hand scrub procedure for all hand scrubs in this study, because this procedure is used commonly in surgical settings.

The 4% CHG product demonstrated a significant immediate antimicrobial effect (i.e., decrease in microbial counts from baseline) (p < .0001). It also demonstrated significant persistent antimicrobial effects. For each of the three sampling days (i.e., days one, two and five) of the five-day test period, the microbial counts remained at least 1 log, below the baseline value (p < .0001). The 4% CHG product also demonstrated a significant residual effect. As the study progressed during the five-day test period, the microbial counts declined at both the immediate (i.e., time zero) sample as well as during the three- and six-hour post-scrub samples; these results confirm the product’s residual effects (p < .001). In this study, the two CHG preparations were the only products that achieved a 3 log, reduction in microorganisms from the baseline counts. These two scrub preparations also were the only products that kept the microbial rebound growth significantly below the baseline counts during the six-hour post-scrub period and were the only products to demonstrate significant residual properties.

These findings are consistent with other published reports that state that the 4% CHG products are the most favorable surgical hand scrub products (i.e., the products that demonstrate significant immediate, persistent, residual antimicrobial properties). Based on the results of this study and other studies that we have performed at BioScience Laboratories, Inc, we believe the 2% and 4% CHG products are equivalent in antimicrobial effectiveness when used on a regular basis. In other studies that we have conducted, the 2% CHG products consistently have demonstrated less irritation potential to the hands than the 4% CHG formulations.

5. Surgical hand antisepsis to reduce surgical site infection

Surgical hand antisepsis, to destroy transient micro-organisms and inhibit the growth of resident micro-organisms, is routinely carried out before undertaking invasive procedures. Antisepsis may reduce the risk of surgical site infections in patients. The objective of this review is to determine the effects of surgical hand antisepsis on the number of surgical site infections (SSIs) in patients. The secondary objective is to determine the effects of surgical hand antisepsis on the numbers of colony-forming units (CFUs) of bacteria on the hands of the surgical team. We searched the Cochrane Wounds Group Specialized Register (June 2007), the Cochrane Central Register of Controlled Trials (Issue 2, 2007), MEDLINE (Week 5, 2007), CINAHL (June 2007), EMBASE (Week 23, 2007) and ZETOC (2005).

Evidence from four studies suggests that chlorhexidine-based aqueous scrubs are significantly more effective than povidone-iodine-based scrubs in terms of the reduction in the number of colony-formed units (CFUs) on the hands both immediately after scrubbing, two hours after scrubbing and at the end of the surgical procedure. In the absence of information regarding the clinical impact of CFUs on surgical site infection (SSI), it is tentatively suggested that aqueous scrub solutions of chlorhexidine should be used in preference to aqueous povidone-iodine scrubs for surgical hand antisepsis.
References Supporting the Use of 4% Chlorhexidine Gluconate Solution as a Surgical Hand Scrub:

6. Comparative Efficacy of Alternative Handwashing Agents in Reducing Nosocomial Infections in Intensive Care Units

R. P. Wenzel, NEJM, July 9, 1992, 88–92

Nosocomial infections represent major sources of morbidity and mortality for patients in the intensive care unit. Chlorhexidine gluconate is frequently recommended because of its broad antimicrobial spectrum, low toxicity and residual activity. Isopropyl alcohol, also effective in removing nontransient bacterial flora from the hands, is relatively inexpensive and is widely used in Europe. We report the results of an eight-month crossover study comparing the effects of these two agents on nosocomial-infection rates in the ICUs at our hospital.

The University of Iowa Hospital is a 902-bed teaching facility providing tertiary care to residents of Iowa and the surrounding region. An eight-month clinical trial was performed from July 3, 1988, through February 28, 1989, to compare the effect of the two handwashing systems on nosocomial-infection rates on the three adult ICUs. A study design involving a monthly crossover was used.

During the eight-month study, 1894 patients were admitted to the three ICUs and were cared for by 577 healthcare workers. The mean stay in the ICU was 3.4 days. Four hundred and twenty patients (22 percent) were in the ICUs at the time of the crossover between treatments. There were 932 in the chlorhexidine group and 962 patients in the alcohol-soap group, who were in the ICU at a time when only one agent was used. As a result, 1,352 patients were included in the chlorhexidine group and 1,382 in the alcohol-soap group for the comparison of baseline characteristics. It is important to note that the two treatment groups did not differ appreciably with respect to age, sex, length of stay in the ICU, nursing Unit Acuity Scores, major diagnostic categories, American Society of Anesthesiology scores (for those undergoing an operative procedure) or surgical rates.

Overall, 152 nosocomial infections occurred in the chlorhexidine group, as compared to 202 in the alcohol-soap group (IDR, 0.73; 95% CI, 0.59 to 0.90). Although the present study was neither randomized nor blinded, we have shown that a monthly crossover clinical trial is efficient and statistically powerful for the study of alternative handwashing systems. Using this approach, we have shown statistically lower rates of nosocomial infection when ICUs have a system that used chlorhexidine as opposed to one that used alcohol and soap.

7. Comparison of Four Antiseptic Products Containing Chlorhexidine Gluconate


The purpose of this study was to compare the antimicrobial effectiveness of several formulations of a single antiseptic ingredient and to answer the question “Are there differences in antimicrobial activity of several different formulations of CHG?” This work was funded by Amsco, Erie, Pa.

A convenience sample of 50 healthy adult volunteers with no history of allergies or sensitivity to topical soaps or detergents, psoriasis, eczema or other skin diseases was recruited primarily from among employees and students at the study institution. Subjects were assigned by block randomization to one of five treatment groups: one of two formulations of detergent-based liquid containing 4% CHG (Bacto-Shield liquid [CHG4; Amsco, Erie, Pa.] or Hibiclens [CHG4a; Stuart Pharmaceuticals, Wilmington, Del.]), a detergent-based foam containing 4% CHG (Bacto-Foam; Amsco), a detergent-based liquid containing 2% CHG (Bacto-Shield 2 [CHG2]; Amsco), and the nonmedicated control soap.

For five days, subjects washed their hands 15 times per day with the assigned product, using the standardized technique under supervision in a laboratory. Hands were dried after each wash with a paper towel. All 50 subjects
completed the five days of testing. There were 42 women (84%) and 8 men (16%) with ages ranging from 20 to 54 years (mean, 30.6 ± 7.7). Mean base-line log10 CFU counts ranged from 5.67 to 6.28.

There were no significant differences in CFU counts between any of the antiseptic soaps and the control soap after a single handwash (P = 0.92) or after eight washes (P = 0.43), but after 15 washes, reductions were significantly greater for all four antiseptic groups when compared with controls (P < 0.05). By day five, subjects in all four antiseptic groups had statistically lower CFU counts than controls (P < 0.001) and counts that were significantly lower than at baseline (P < 0.001). There were no significant differences in mean log CFU counts between the four antiseptic products (P > 0.30). In the five treatment groups, there were no significant differences in subject assessment of skin condition after the testing period (P = 0.78) or in product ratings (P = 0.69); all products were rated acceptable.

Analysis of our data suggested that the formulas tested were comparable in effectiveness; all four CHG-containing products were significantly better than control soap and effected significant, sustained reductions in colonizing flora over baseline measurements. Although not significantly different, the reductions in flora among those using the 2% CHG product were less than those with any of the three 4% products.