

Comparative Efficacy of Alcohol-Based Surgical Scrubs: The Importance of Formulation



DAVID R. MACINGA, PhD; SARAH L. EDMONDS, MS, CCRP; ESTHER CAMPBELL, BS;
ROBERT R. McCORMACK, BS

ABSTRACT

Alcohol-based surgical scrubs (ABSSs) are used to prevent surgical site infections. Chlorhexidine gluconate (CHG) often is added to enhance persistent germicidal activity. The aim of this study was to determine the influence of ABSS product formulation on efficacy. We evaluated three commercially available ABSS formulations and one control alcohol formulation according to the surgical scrub methodology specified by the US Food and Drug Administration (FDA). Only one ABSS formulation met FDA efficacy requirements when tested at the manufacturer's recommended dosage. In contrast, two ABSS formulations, one of which contained CHG, failed to meet the FDA acceptance criteria for a 3- \log_{10} reduction on day 5, meaning the formulations did not sufficiently reduce bacteria levels on hands on the fifth day of product application. The data suggest that recommendations to include CHG in ABSS formulations should be reconsidered, and product efficacy, skin tolerability, and user acceptability should be evaluated on a case-by-case basis. *AORN J* 100 (December 2014) 641-650. © AORN, Inc, 2014. <http://dx.doi.org/10.1016/j.aorn.2014.03.013>

Key words: *surgical scrub, alcohol-based hand rub, chlorhexidine gluconate, antimicrobial.*

The purpose of preoperative hand disinfection is to eliminate transient microorganisms, reduce resident microorganisms from the hands, and maintain microorganism levels below baseline for the duration of surgery.¹ In the United States, surgical scrubs must meet both immediate kill and persistence requirements, according to the *Tentative Final Monograph for Healthcare Antiseptic Drug Products* published by the US Food and Drug Administration (FDA).²

The objective of this study was to evaluate the effect of the active ingredient and product

formulation on the antimicrobial efficacy of surgical scrubs. We asked three research questions:

- What are the relative contributions of ethanol and chlorhexidine gluconate (CHG) to both the immediate and persistent activity of surgical scrub preparations?
- Does the inclusion of CHG provide a microbiological benefit to alcohol-based surgical scrubs (ABSSs)?
- What influence does overall ABSS product formulation have on surgical scrub efficacy?

NURSING SIGNIFICANCE

The results of this study will help perioperative nurses make more informed choices for hand disinfection before donning sterile gloves prior to entering the OR or procedure room. These choices may affect patient safety as well as the risk of adverse skin reactions among nurses and other perioperative personnel.

LITERATURE REVIEW

The World Health Organization (WHO),³ Centers for Disease Control and Prevention,⁴ and AORN^{1,5} recommend using either an antimicrobial hand wash or an alcohol-based hand rub before donning sterile gloves to perform surgical procedures. Because the activity of alcohol-containing products is demonstrated to be superior to antimicrobial hand washes, the WHO guidelines state a preference for alcohol-based products.³

There is debate regarding the need for additional antimicrobial ingredients to provide added persistence activity to ABSSs. Although alcohol does not have true persistent activity, because of the extent of its immediate kill activity, regrowth of the resident microflora to baseline typically takes more than six hours.³ The WHO³ has concluded that because alcohol maintains microbial hand flora below baseline for that period, the need for a sustained effect of a product is “superfluous.” In contrast, the Centers for Disease Control and Prevention⁴ and AORN⁵ emphasize the need to use hand hygiene products with demonstrated persistent activity. The AORN “Recommended practices for hand hygiene in the perioperative setting,” last updated in 2009, states,

A standardized surgical hand scrub using an alcohol-based surgical hand rub product with demonstrated persistence and cumulative activity should be performed according to the manufacturer’s written directions for use. An alcohol and chlorhexidine product that is fast drying and has residual effect is preferred.^{5(p64)}

Recent studies suggest that the overall product formulation may be a more important determinant of efficacy than the inclusion of CHG. Kampf and Ostermeyer⁶ compared the efficacy of two waterless surgical hand scrubs and found that an 80% ethanol-only product met European efficacy requirements for presurgical hand antisepsis when tested according to the EN 12791 standard,⁷ whereas a product composed of 61% ethanol and 1% CHG did not. Rotter et al⁸ compared the activity of three ABSS formulations, attributing an immediate “fast and strong” effect entirely to the alcohol content of one of the products. In the same study, a preparation containing CHG provided some persistent effect, but the investigators noted that it was not significant and concluded that the contribution of CHG to delaying bacterial regrowth on gloved hands was “minor.”⁷ In contrast, Olson et al⁹ showed superior persistence of an ABSS containing 1% CHG after five days of use when tested according to the FDA-recommended method (ASTM E1115).¹⁰ However, the investigators failed to mention that none of the products in the study met FDA efficacy requirements for a 3-log₁₀ reduction immediately after use on day 5; thus, legitimate conclusions regarding the superiority of one product versus the others cannot be made.⁸

METHODS

The Gallatin Institutional Review Board in Bozeman, Montana, approved our protocol before subject enrollment. Using nonspecific advertising, we recruited participants from the general population who were healthy adults. We asked them to sign an informed consent form before participation, and we compensated those who completed the entire study with \$300 for their time.

Study Design

We conducted the study as described in the FDA *Tentative Final Monograph for Healthcare Antiseptic Drug Products*.² We calculated sample

Download English Version:

<https://daneshyari.com/en/article/2641465>

Download Persian Version:

<https://daneshyari.com/article/2641465>

[Daneshyari.com](https://daneshyari.com)