

## ABSTRACT

**Background:** Minimizing the bioburden of cutaneous microflora on the surgical site prior to surgery is fundamental to prevention of surgical site infection (SSI). Few studies have prospectively evaluated the adjunctive value of a *continuum* of advance preoperative antiseptic prepping and the efficacy of differing antiseptic agents for preoperative disinfection of the surgical site in the operating room.

**Purpose:** To ascertain the relative efficacy of an advance preoperative antiseptic skin preparation with a rinse-free 2% chlorhexidine gluconate (CHG)-impregnated washcloth (Sage) combined with 3 different antiseptic regimens for final preoperative disinfection of the surgical site in the operating room.

**Methods:** 126 healthy adult subjects underwent quantitative sampling of the aerobic cutaneous microflora on the anterior chest and inguinal areas prior to an advance antiseptic skin preparation with a 2% CHG washcloth or triclosan soap (Dial) (control). Subjects were randomized to 6 regimens in a crossover design, with ~40 subjects per group: 2 advance preoperative applications using the 2% CHG cloth, without rinsing, or showering with triclosan soap, followed ~12 hours later by a final OR skin preparation of the subclavian and inguinal areas with the 2% CHG washcloth, 0.7% alcoholic tincture of povidone-iodine (PI) (DuraPrep, 3M) or 10% aqueous PI (Scrubcare Prep Skin Prep, Cardinal Health). Subjects underwent 5 quantitative sampling of each site using the standard scrub cup method: prior to the first advance skin preparation (baseline), following the 1st and 2nd application, and 10 minutes and 6 hours after the final skin prep in the operating room; appropriate neutralizers were employed.

**Results:** All of the regimens were well tolerated. Use of the 2 advance preoperative rinse-free skin preps with 2% CHG significantly lowered the number of microorganisms on both potential surgical sites as compared with control triclosan soap showering ( $>1 \log$ ,  $P < 0.001$ ). Although not consistently significant, the reductions following the final surgical site prep prep with all 3 surgical site skin prep products were  $-0.5 \log$  to  $1.0 \log$  greater for subjects who had had an advance rinse-free 2% CHG prep than those who showered with triclosan.

**Conclusions:** This study shows that advance preoperative skin preparation with 2% CHG done twice, ~12 and ~3 hours prior to anticipated surgery, without rinsing, significantly reduces the number of microorganisms on the surgical site at the time the incision is made, regardless of the agent used in the final surgical site prep in the operating room.

There is an urgent need for a large multicenter trial to determine with clinical outcome data whether advance preparation of the site with multiple rinse-free applications of 2% CHG prior to elective surgery, with prolonged exposure to the antiseptic, significantly reduces the rate of SSI and, also, whether 2% CHG might be superior to iodophores for the final prep of the surgical site in the OR, which has been the standard of care in North America for nearly 50 years.

## INTRODUCTION

More than 25 million inpatient surgical procedures were reported in 2002.<sup>1</sup> In that year almost 135 thousand patients were discharged with a diagnosis of postoperative surgical site infection (SSI); the average length of hospitalization for these patients was 7.5 days and mean hospital charges were \$24,346, resulting in aggregate charges of almost 3.3 billion dollars.<sup>2</sup> Kirkland et al reported that patients who develop SSI have longer and costlier hospitalizations than patients who do not develop such infections, are 60% more likely to spend time in an ICU and twice as likely to die, and more than five times more likely to be readmitted to the hospital.<sup>3</sup> Patients with orthopedic SSIs suffer major physical limitations and reductions in health-related quality of life.<sup>4</sup>

The incidence of SSI is much higher after clean-contaminated, contaminated, or dirty operations than clean surgeries, because the surgical wound in non-clean surgeries are exposed to a much larger number and variety of organisms originating from mucous membranes, colonized hollow viscera or infected tissues.<sup>5</sup> In contrast, SSIs following clean surgery are caused in nearly all cases by endogenous organisms colonizing the patient's skin and introduced into the surgical wound during operation.<sup>6-8</sup>

Most of the ritual of intraoperative surgical asepsis – including preoperative hair removal, the antiseptic scrub of the surgical team, sterile surgical gowns and drapes, the antiseptic preparation of the surgical site in the operating room, and the use of perioperative antimicrobial prophylaxis<sup>9</sup> – is designed to minimize cutaneous colonization of the surgical site and intra-operative contamination of the wound in order to prevent subsequent infection.

Whole body bathing or showering with an antiseptic agent, such as 2-4% chlorhexidine gluconate, has been reported to reduce bacterial colonization of the skin.<sup>9,10</sup> Studies have shown that the antibacterial effect of chlorhexidine is cumulative<sup>11,12</sup> and lasts longer than that produced by other antiseptic agents.<sup>13-15</sup> In the first comparative clinical (non-randomized) trial, Brandberg et al showed that multiple preoperative chlorhexidine showers significantly reduced the incidence of SSI.<sup>16</sup> In a large prospective randomized trial conducted by Hayek et al, preoperative chlorhexidine baths markedly reduced the incidence of SSI, especially those caused by *Staphylococcus aureus*,<sup>17</sup> and chlorhexidine showers were also effective in another Swedish study.<sup>18</sup> However other studies showed either minimal (and statistically insignificant) benefit<sup>19,20</sup> or no measurable impact of preoperative chlorhexidine showers or baths on the incidence of SSI.<sup>21-25</sup>

We report a prospective study undertaken in volunteers to evaluate the adjunctive value for disinfection of the surgical site of employing a *continuum* of preoperative antiseptic prepping, including with a novel chlorhexidine-impregnated washcloth *without* rinsing, combined with use of differing antiseptics for preoperative disinfection of the surgical site in the operating room.

# EVALUATION OF 6 PREOPERATIVE CUTANEOUS PREP PROCEDURES FOR PREVENTION OF SURGICAL SITE INFECTIONS

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## METHODS

### PURPOSE OF THE STUDY

This study evaluated the antimicrobial effectiveness of a full body presurgical antiseptic skin preparation performed in a shower with triclosan-containing soap vs. continuous preparation of the skin for 3-5 minutes, without rinsing or showering, using 2% CHG-impregnated wash cloth (Sage) over the course of two applications: one -12 hours prior to preoperative skin prepping, and one -3 hours prior to preoperative skin prepping in the operating room, assessing subclavicular and inguinal test sites.

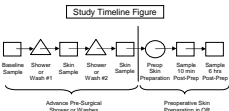
Three different agents were assessed for the final OR surgical antiseptic site prep: 0.7% tincture of povidone iodine (DuraPrep™, 3M), 10% aqueous povidone iodine (Scrub Care®, Cardinal Health), or the 2% CHG washcloths (Sage).

### STUDY DESIGN

The compensated test subjects, 126 healthy volunteers aged 18-70 without preexistent skin disease or allergies to any of the test agents, underwent a wash-out period of 14 days, followed by baseline quantitative sampling of aerobic microbial flora on the skin of the test sites. Subjects were instructed how to perform the advance presurgical shower with triclosan soap or continuous application of 2% chlorhexidine using the washcloth, without showering or rinsing, in their own home, as randomly assigned.

Samples of bacterial populations at the test sites were taken approxi-

mately 2 hours following each of the Advance Skin Prep procedures. The OR Preoperative Skin Prep, assigned randomly in a crossover design, was then applied to the test sites on the skin of the subclavicular and inguinal regions, and bacterial population samples were taken 10 minutes and 6 hours following the application:



### MICROBIOLOGIC METHODS

Sites were sampled using the standard scrub-cup method (ASTM), using neutralizers in the sampling fluid (SSF++/BBP++), which was tested and shown to effectively quench the antimicrobial properties of the test antiseptics (ASTM E 1054-02, Standard Test Methods for Evaluation of Inactivators of Antimicrobial Agents). The number of organisms in each sample was quantified by culturing serial dilutions on solid media in duplicate, incubating plates at 37C for 48 hours.

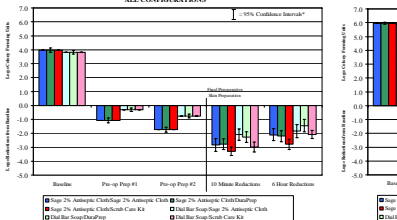
## RESULTS

All of the regimens were well tolerated; 3 subjects showed mild irritation at the site following advance prepping with 2% chlorhexidine; none showed evidence of hypersensitivity.

Use of the advance multiple preoperative skin preps with 2% CHG significantly lowered the number of microorganisms on both potential surgical sites as compared with control triclosan soap (>1 log<sub>10</sub>, P<0.001).

Although not consistently significant statistically, the reductions following the final prep surgical site prep with all 3 products were -0.5 log<sub>10</sub> greater for subjects who had had an advance 2% CHG washcloth rinse-free prep than those who had showered with triclosan.

RESULTS ON SUBCLAVIAN TEST SITES  
ALL CONFIGURATIONS



# CUTANEOUS ANTISEPTIC REGIMENS FOR SURGICAL INFECTION

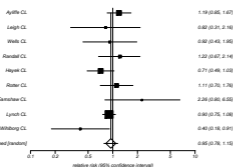
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## DISCUSSION

This study shows that advance preoperative skin preparation with 2% CHG done twice, -12 and -3 hours prior to anticipated surgery, without rinsing, significantly reduces the number of microorganisms on the surgical site at the time the incision is made, regardless of the agent used in the final surgical site prep.

We have recently undertaken a meta-analysis of published, prospective controlled trials in order to evaluate the value of preoperative showering or bathing with chlorhexidine for prevention of SSI (Chlebicki, Crnich and Maki, Submitted for Publication). Advance showering or bathing with chlorhexidine did not significantly reduce the incidence of surgical site infection:

Relative risk meta-analysis plot (random effects)



We find it difficult to believe that preoperative showering or bathing with chlorhexidine has no benefit, whatsoever. Chlorhexidine was developed in the 1940s as an antiseptic

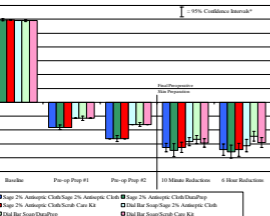
for skin wounds.<sup>26</sup> Fifty years later, we have a great deal of scientific evidence attesting to the effectiveness and safety<sup>27-33</sup> of chlorhexidine cutaneous antiseptics for prevention of healthcare-acquired infections in a very wide range of clinical settings.

Chlorhexidine is a highly effective topical antiseptic, and prospective trials have shown its effectiveness as a surgical hand scrub.<sup>34,35</sup> For antiseptic preparation of the surgical site in the operating theatre,<sup>36</sup> for cutaneous antiseptics prior to placement of vascular catheters<sup>37,38</sup> or as an active agent in impregnated vascular catheter dressings<sup>39,40</sup>. Trials have shown that chlorhexidine is more efficacious than povidone-iodine whether used as a surgical hand scrub<sup>14,41</sup>, a preoperative shower<sup>13,42</sup>, or skin preparation solution.<sup>36, 43</sup> Oral chlorhexidine rinse has been shown in randomized trials to significantly reduce the incidence of ventilator-associated pneumonia after elective cardiothoracic surgery.<sup>44,45</sup> It has also been shown to decrease the occurrence of alveolar osteitis following dental extraction.<sup>46</sup> Several prospective randomized trials have shown that incorporating chlorhexidine with silver-sulfadiazine as an antiseptic coating on central venous catheters significantly reduces the risk of catheter-associated bloodstream infection.<sup>47-49</sup> Chlorhexidine's effectiveness for prevention of vascular catheter-associated bloodstream-associated infection has been endorsed by multiple professional societies in their evidence-based guidelines.<sup>5,50,51</sup> Moreover, in an recent large cohort time-sequence trial in 1787 hospitalized medical patients, daily bathing or washing with the 2% chlorhexidine-impregnated washcloth studied in our trial resulted in a marked reduction in cutaneous colonization of patients by vancomycin-resistant enterococci, from 26 to 9 per 1000 hospital days (P<0.01).<sup>52</sup>

We would, therefore, have expected to see some measurable effect of chlorhexidine in the prospective comparative surgical trials done, but did not. Why? First of all, most of the available prospective comparative trials were flawed, several quite severely.<sup>18,20</sup> Only two were truly randomized and double-blinded,<sup>19,24</sup> in two trials details of randomization were not provided<sup>23,25</sup> and another two had questionable schemes for allocation of patients to the treatment groups.<sup>19,20</sup> Definitions of SSI were not given in two studies.<sup>20,22</sup> Several of the trials mainly studied patients undergoing clean-contaminated or contaminated types of surgery, where the patient's cutaneous flora contributes negligibly if at all to the incidence of SSI.<sup>5,53,54</sup> Finally, the authors of most of the studies did not provide specific data on the proportion of patients in each group which received perioperative antimicrobial prophylaxis, to be able to be confident that the two treatment groups in the study were comparable for this very important factor which influences the risk of SSI.<sup>5,55</sup>

Notwithstanding shortcomings in the design and execution of most of the trials, we suspect that it is more likely that the failure to find a significant benefit of preoperative chlorhexidine showering or bathing, if there is indeed a true benefit, derives from *inadequate application* of the agent. In all the trials, patients were simply instructed to bathe or shower with the study agent in the usual fashion, vis-à-vis, to apply the chlorhexidine solution or comparator to their body and then rinse it off. They were not instructed to use sponges or brushes, and they were not specifically instructed to keep the undiluted chlorhexidine on their skin for several minutes before rinsing. Moreover, the application of chlorhexidine was not supervised in the majority of trials. We can only surmise that the duration of chlorhexidine application was considerably less than one minute in the majority of enrolled patients. This is far shorter than any infection control practitioner would consider sufficient for the surgical scrub by members of the operating team,<sup>5</sup> for final prep of surgical

### RESULTS ON INGUINAL TEST SITES ALL CONFIGURATIONS





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sites in the operating room<sup>36</sup> or for antiseptic preparation of a central venous catheter insertion site.<sup>50</sup>

Studies evaluating the optimal duration of chlorhexidine hand scrubs provide insights into this potentially very important issue.<sup>34,35,56,57</sup> It is very plausible that the patients enrolled in the nine analyzed trials received far too brief (and suboptimal) application of undiluted chlorhexidine, which might well explain the failure to detect any benefit in the pooled data. It is also well known that the antibacterial effect of chlorhexidine is cumulative and greatly enhanced by repeated applications.<sup>11-13</sup> Paulson et al<sup>12</sup> evaluated the effect of chlorhexidine showers daily over five days and found that, as the study progressed, ever greater microbial reductions from the baseline were achieved, vis-à-vis, a cumulative effect. It is very plausible that that *multiple* applications of chlorhexidine over several days prior to anticipated surgery may be far more more efficacious than a single preoperative chlorhexidine application, especially in a shower or bath.

In conclusion, the currently available studies do not support routine use of preoperative, whole body chlorhexidine showering or bathing for prevention of SSI. However, most of the trials done were suboptimal in design, and the manner in which the chlorhexidine solutions were used in the trials was very likely suboptimal.

We believe that better designed and adequately powered prospective, randomized, double-blind placebo-controlled trials – ideally, a multicenter trial -- done exclusively in clean surgery, with at least two consecutive showers or bathings 6 to 12 hours apart – ideally, the night prior and the morning of surgery -- and application of undiluted chlorhexidine to patients' skin without rinsing, are needed to determine with certainty whether an advance preoperative, whole-body chlorhexidine antiseptic skin preparation is of benefit for prevention of postoperative SSI, and, also, whether 2% CHG might be superior to iodophores for the final prep of the surgical site in the OR, which has been the standard of care in North America for nearly 50 years.

## ACKNOWLEDGEMENTS

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