Review article

Preoperative chlorhexidine shower or bath for prevention of surgical site infection: A meta-analysis

Maciej Piotr Chlebicki MD a, Nasia Safdar MD, PhD b,c,d,* , John Charles O’Horo MD e, Dennis G. Maki MD b,c

a Department of Infectious Diseases, Singapore General Hospital, Singapore
b Section of Infectious Diseases, Department of Medicine, University of Wisconsin Medical School, Madison, WI
c Infection Control Department, University of Wisconsin Hospital and Clinics, Madison, WI
d William S. Middleton Memorial Veterans Hospital, Madison, WI
e Department of Graduate Medical Education, Aurora Healthcare, Milwaukee, WI

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Systematic review
Clean
Clean-contaminated

Background: Chlorhexidine showering is frequently recommended as an important preoperative measure to prevent surgical site infection (SSI). However, the efficacy of this approach is uncertain.

Methods: A search of electronic databases was undertaken to identify prospective controlled trials evaluating whole-body preoperative bathing with chlorhexidine versus placebo or no bath for prevention of SSI. Summary risk ratios were calculated using a DerSimonian-Laird random effects model and a Mantel-Haenszel dichotomous effects model.

Results: Sixteen trials met inclusion criteria with a total of 17,932 patients: 7,952 patients received a chlorhexidine bath, and 9,980 patients were allocated to various comparator groups. Overall, 6.8% of patients developed SSI in the chlorhexidine group compared with 7.2% of patients in the comparator groups. Chlorhexidine bathing did not significantly reduce overall incidence of SSI when compared with soap, placebo, or no shower or bath (relative risk, 0.90; 95% confidence interval: 0.77-1.05, P = .19).

Conclusions: Meta-analysis of available clinical trials suggests no appreciable benefit of preoperative whole-body chlorhexidine bathing for prevention of SSI. However, most studies omitted details of chlorhexidine application. Better designed trials with a specified duration and frequency of exposure to chlorhexidine are needed to determine whether preoperative whole-body chlorhexidine bathing reduces SSI.

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Approximately 25.2 million inpatient surgical procedures were performed in the United States in 2002. In the same year, almost 135,000 patients were discharged with a principal diagnosis of postoperative surgical site infection (SSI). The mean length of hospitalization for these patients was 7.5 days, and the mean hospital charges were $24,346, resulting in aggregate charges of almost $3.3 billion. 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 intensive care unit and twice as likely to die, and more than 5 times more likely to be readmitted to the hospital.

SSIs following clean surgery are caused in nearly all cases by endogenous organisms colonizing the patient’s skin and are introduced into the surgical wound intraoperatively. Most procedures for intraoperative surgical asepsis are designed to minimize cutaneous colonization of the surgical site and intraoperative contamination of the wound to prevent subsequent infection. Whole-body bathing or showering with an antiseptic agent, such as 2% to 4% chlorhexidine gluconate, has been shown to reduce bacterial colonization of the skin. Studies have shown that the antibacterial effect of chlorhexidine is cumulative and lasts longer than that produced by other antiseptic agents. Whereas some studies have shown that preoperative chlorhexidine showers reduce the incidence of SSI, others have found minimal or no clinically relevant benefit. We have undertaken a meta-analysis to systematically review published, controlled, clinical trials evaluating use of chlorhexidine baths or showers for prevention of SSI.

METHODS

We performed a search of MEDLINE, including PUBMED, and the COCHRANE NETWORK including the Cochrane Register of Clinical
Trials from inception until July 30, 2011, using the following keywords: chlorhexidine, bath, shower, wash, scrub, disinfection, preoperative care, perioperative care, surgical site infection, and surgical wound infection. No language restrictions were applied. References from articles were reviewed to identify other potentially relevant articles. Our search strategy and analysis complied with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.18

Prospective randomized controlled trials and quasirandomized trials—those that allocated treatment by day of the week or by ward—as well as before-after trials comparing a preoperative whole-body chlorhexidine shower or bath with nonantiseptic soap or no bath and reporting SSI as an outcome were included in our review. We chose to include quasirandomized trials because these are common study designs that may yield useful information. Case reports, abstract-only, review articles, letters, and editorials were excluded. All authors independently reviewed each report identified by the search strategy.

Study quality

We assessed study quality and assessed for potential bias using the recommendations of the Cochrane collaboration.19 Selection bias was assessed by evaluations of subject allocation and blinding, especially relevant for nonrandomized studies. Performance bias—systematic differences in care provided apart from the intervention being evaluated—was evaluated by comparing the different bathing protocols and other interventions employed to reduce SSI in each study. Detection bias was evaluated by examining the operational definition for SSI. Reporting bias was analyzed using Egger’s statistical test and a funnel plot to specifically examine publication bias.19

Statistical analysis

Summary risk ratios (RR) and their 95% confidence intervals (CI) were calculated using the DerSimonian and Laird random-effects model.20 Heterogeneity was assessed with an I² statistic, where 0% indicates no heterogeneity, and 100% indicates the highest level of heterogeneity.21 Sensitivity and subgroup analyses were performed to analyze sources of heterogeneity. Data analysis was performed using Cochrane Database’s Review Manager 5.1.0 software.19

RESULTS

Study selection

The literature search strategy yielded 857 potential articles. After screening and reviewing articles, 16 studies met our inclusion criteria.9,10,12-17,22-29 The search strategy and reasons for exclusion are detailed in a PRISMA flow diagram in Figure 1.30

In one of these trials,26 the chlorhexidine group was compared with 2 control groups: 1 group that received only a limited, partial chlorhexidine body wash and another group that received no shower. We only included the chlorhexidine treatment group and the control group that received no shower in our statistical analysis.

Study characteristics

Eight randomized control trials and 8 quasirandomized trials were identified. The 16 included trials enrolled 17,932 patients.6,10,12-17,22-29; 7,952 patients received a chlorhexidine shower or bath, and 9,980 patients were allocated to various comparator groups of a preoperative shower or bath with nongermicidal soap (n = 5,696) or placebo (n = 2,207) or no preoperative shower/noncompliance with regimen (n = 2,077). Six studies10,14,15,27-29 had patients bathe as outpatients prior to procedure, nine11-13,16,17,22,24-26 had baths or showers as inpatients, and one9 did not specify where the washes took place. There was considerable interstudy variation in the volume, timing, and/or number of applications as summarized in Table 1.

In 7 trials12-14,16,17,22,26 patients had a single preoperative bath. Two baths were used in 5 trials,10,15,27-29 and 3 trials9,11,24 evaluated the effect of 3 or more preoperative chlorhexidine baths or showers. One did not specify the regimen.25

In all trials using a liquid formulation of chlorhexidine, patients were required to apply the chlorhexidine solution or comparator...
and then thoroughly rinse it off, without specifying the duration of continuous exposure of the skin to 4% chlorhexidine. Trials using chlorhexidine cloths instructed patients to use the product once the night before and once the morning of surgery without rinsing the wash off. Sponges or brushes were not used in any of the trials.

Preoperative antibiotic prophylaxis was routinely administered in 6 trials but was given to only 12% of patients in the trial conducted by Rotter et al. In both studies, randomization was carried out in each participating surgical unit by means of computer-generated patient trial numbers, which were attached by manufacturer to the bottles containing either chlorhexidine or placebo.

The trial by Lynch et al was also prospective, randomized, double-blind, and placebo-controlled trial by Rotter et al and a single center, randomized controlled trial by Veiga et al. In both studies, randomization was carried out by Veiga et al.16. In both studies, randomization was carried out in each participating surgical unit by means of computer-generated patient trial numbers, which were attached by manufacturer to the bottles containing either chlorhexidine or placebo.

The trial by Lynch et al was also prospective, randomized, double-blind, and placebo controlled, but no details of the randomization procedure were provided. Similarly, Randall et al and Lynch et al did not provide any details of the randomization scheme. Murray et al was randomized and used masked allocation but did not use an identical placebo.

Wells et al used a quasirandomized design in which patients were assigned to a chlorhexidine or soap bath by month. In a study conducted by Wihlborg, participating patients were allocated to different wards by the chief surgeon. Finally, the 3 remaining trials used a design in which all patients admitted to selected surgical wards were allocated to a chlorhexidine bath or shower group, and patients admitted to other wards constituted the control group.

The investigators used varying definitions of SSI in their trials (Table 1). Six studies used clinical criteria, such as wound inflammation, breakdown, or discharge, to define SSI. Although the trials did not explicitly state so, these criteria are similar to the CDC definition for deep incisional SSI as follows: “Meet[ing] one of the following criteria: infection occurs . . . after the operative procedure . . . and infection appears to be related to the operative procedure and involves deep soft tissues (e.g., fascial and muscle layers) of the incision and patient has at least 1 of the following: (1) purulent drainage from the deep incision but not from the organ/space component of the surgical site, (2) a deep incision spontaneously dehisces or is deliberately opened by a surgeon and is culture positive or not cultured and has 1 of the following signs or symptoms: fever, or localized pain, or tenderness. A culture negative finding does not meet this criterion. (3) An abscess or other evidence of infection involving the deep incision is found on direct examination during reoperation or by histopathologic or radiologic examination. (4) Diagnosis of a deep incisional SSI by a surgeon or attending physician.”

Details of randomization

The highest quality trials performed were a multicenter center, prospective, randomized, double-blind, and placebo-controlled trial by Rotter et al and a single center, randomized controlled trial by Veiga et al. In both studies, randomization was carried out in each participating surgical unit by means of computer-generated patient trial numbers, which were attached by manufacturer to the bottles containing either chlorhexidine or placebo.

The trial by Lynch et al was also prospective, randomized, double-blind, and placebo controlled, but no details of the randomization procedure were provided. Similarly, Randall et al and Lynch et al did not provide any details of the randomization scheme. Murray et al was randomized and used masked allocation but did not use an identical placebo.

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Subgroup and sensitivity analysis

Sensitivity analysis was performed, excluding studies sequentially to determine whether any individual study or subgroup had a disproportional impact on the outcome. Sensitivity analyses did not show significant impact from any study or subgroup.

To determine whether there was a differential effect of chlorhexidine in patients undergoing clean surgery, we analyzed the findings in the studies reporting the efficacy of preoperative chlorhexidine showers or baths for prevention of SSI in patients undergoing clean surgery. This subgroup failed to reach the threshold for statistical significance, with whole-body preoperative chlorhexidine showering or shower demonstrating no clear benefit (RR, 0.88; 95% CI: 0.71-1.09, P = .24). I² value was 38%, indicating moderate heterogeneity. The lack of benefit was seen also in contaminated and clean contaminated surgery (RR, 0.94; 95% CI: 0.76-1.16, P = .55), with low heterogeneity (I² = 0%).

We conducted an analysis restricted to the high-quality, randomized controlled trials. In these, no benefit of preoperative chlorhexidine washing or showering could be demonstrated (RR, 0.99; 95% CI: 0.85-1.16, P = .90). Heterogeneity of these results was low with I² = 0%.

We also analyzed the 7 studies in which patients underwent 2 or 3 preoperative showers or baths. The use of multiple chlorhexidine baths did not reach statistical significance, although there was a trend toward reduction of SSI (RR, 0.79; 95% CI: 0.60-1.03, P = .08).
<table>
<thead>
<tr>
<th>Authors, year</th>
<th>Study design</th>
<th>Type of surgery</th>
<th>Exclusion criteria</th>
<th>Definition of SSI</th>
<th>Chlorhexidine dosing schedule</th>
<th>Comparator group (s)</th>
<th>Risk of bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brandberg et al, 1979</td>
<td>Prospective nonrandomized</td>
<td>Clean (vascular surgery)</td>
<td>Not specified</td>
<td>Pus collection at surgical wound site</td>
<td>Three to 8 chlorhexidine shower-baths prior to procedure</td>
<td>Soap and water wash</td>
<td>High</td>
</tr>
<tr>
<td>Ayliffe et al, 1983</td>
<td>Before/after, two 30-week periods</td>
<td>Clean, CL/CONT, contaminated</td>
<td>Trauma and emergency surgery</td>
<td>Inflammation, breakdown or discharge from wound</td>
<td>Single bath or shower with undiluted 4% chlorhexidine (25 mL) on the day of or before operation</td>
<td>Nonmedicated bar soap</td>
<td>High</td>
</tr>
<tr>
<td>Leigh et al, 1983</td>
<td>Before/after, 2 wards, 4 months</td>
<td>Clean, CL/CONT, contaminated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Single bath or shower with undiluted 4% chlorhexidine (supplied in 250-mL bottle) a few hours before operation.</td>
<td>Non-medicated soap</td>
<td>High</td>
</tr>
<tr>
<td>Wells et al, 1983</td>
<td>Quasirandomization (by month)</td>
<td>Clean (cardiothoracic surgery)</td>
<td>Emergency surgery</td>
<td>Not stated</td>
<td>Single scrub with undiluted 4% chlorhexidine (30 mL) 1 day before operation</td>
<td>Nonmedicated bar soap</td>
<td>High</td>
</tr>
<tr>
<td>Randall et al, 1983</td>
<td>Randomized, (no details) controlled trial, 3 groups</td>
<td>Clean (vasectomy only)</td>
<td>Not stated</td>
<td>Discharge or wound breakdown</td>
<td>Single bath or shower 1 hour before surgery (no other details provided)</td>
<td>Two groups: nonmedicated bar soap and no shower</td>
<td>Low</td>
</tr>
<tr>
<td>Hayek et al, 1987</td>
<td>Before/after, 2-month periods</td>
<td>Clean, CL/CONT, contaminated</td>
<td>Emergency surgery, concurrent infection</td>
<td>Inflammation, breakdown or discharge from wound</td>
<td>Two baths or showers with undiluted 4% chlorhexidine (supplied in two 25-mL sachets) 1 day before and on the morning of operation</td>
<td>Two groups: placebo and nonmedicated bar soap</td>
<td>High</td>
</tr>
<tr>
<td>Dimitrov et al, 1984</td>
<td>Prospective study, method of allocation not specified</td>
<td>CL/CONT (gastrointestinal and genitourinary surgeries)</td>
<td>Not stated</td>
<td>Suppuraton at surgical site</td>
<td>Patients instructed to bath with chlorhexidine prior to surgery, regimen and concentration not specified</td>
<td>Bar soap</td>
<td>High</td>
</tr>
<tr>
<td>Wihlborg, 1987</td>
<td>Quasirandomization (by ward)</td>
<td>Clean, CL/CONT (only biliary, hernia or breast surgery)</td>
<td>Not stated</td>
<td>Definite collection of pus.</td>
<td>Single shower (double application) on the afternoon of the day before surgery.</td>
<td>No shower</td>
<td>High</td>
</tr>
<tr>
<td>Rotter et al, 1988</td>
<td>Randomized, multicenter, double-blind, placebo controlled</td>
<td>Clean (various procedures)</td>
<td>Fever, concurrent infection, recent antibiotics (7 days), incarcerated inguinal hernia or radical mastectomy</td>
<td>Inflammation, or discharge from wound</td>
<td>Two baths or showers (2 applications each time) with undiluted 4% chlorhexidine (supplied in one 100-mL bottle) 1 day before and on the morning of operation</td>
<td>Identical placebo</td>
<td>Low</td>
</tr>
<tr>
<td>Earnshaw et al, 1989</td>
<td>Randomized (no details), controlled trial</td>
<td>Clean (vascular surgery)</td>
<td>Not stated</td>
<td>Purulent (but not serous) wound discharge</td>
<td>Single bath or shower with 2 applications of undiluted 4% chlorhexidine (no other details provided)</td>
<td>Nonmedicated soap</td>
<td>Low</td>
</tr>
<tr>
<td>Byrne et al, 1991</td>
<td>Randomized controlled trial</td>
<td>Clean (hernia surgery)</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Three showers with 4% chlorhexidine prior to surgery</td>
<td>Identical placebo</td>
<td>Low</td>
</tr>
<tr>
<td>Lynch et al, 1992</td>
<td>Randomized (no details), double-blind, placebo controlled</td>
<td>Clean, CL/CONT, contaminated</td>
<td>Not stated</td>
<td>Purulent discharge or ASEPSIS score &gt; 10</td>
<td>Three baths or showers with undiluted 4% chlorhexidine on admission, before going to bed and on the morning of operation</td>
<td>Nonmedicated liquid soap</td>
<td>Low</td>
</tr>
</tbody>
</table>
Three studies used a 2% chlorhexidine impregnated cloth product rather than a liquid preparation used in the other studies. Analysis restricted to studies that used the cloth product (n = 3) did not show a reduction (P = .29) in incidence of SSI.

Publication bias

Publication bias was assessed with a funnel plot (Fig 3). This is consistent with some degree of publication bias.

Adverse effects of chlorhexidine

In only 1 trial were adverse effects of preoperative showering or bathing with chlorhexidine reported. In that trial, itching or reddening of skin occurred in 5 patients (0.36%) of the placebo group and 5 (0.36%) in chlorhexidine group. No adverse effects attributed to the chlorhexidine shower or bath were mentioned in the remaining 15 trials.

DISCUSSION

Our analyses show that preoperative whole-body showering or bathing with chlorhexidine, in its current nonspecified manner, is of no benefit for prevention of postoperative SSI. Our findings agree with and extend those of a Cochrane systematic review that included data from 9 trials from 1983 through 2005 and failed to show a benefit for chlorhexidine bathing or showering. Our review extends the literature search to July 2011 and identified 4 additional trials since the Cochrane review, thus increasing the statistical power of the analysis to detect a clinically relevant reduction in SSI if one exists. Our study also included quasieperimental designs that were excluded in Cochrane’s methodology.

Given the known efficacy of chlorhexidine in reducing bacterial burden, it is somewhat surprising that this meta-analysis demonstrated no clinical benefit. Several factors may have contributed to this. Many of the trials 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. Also, the authors of most of the studies did not provide specific data on the proportion of patients in each group that received perioperative antimicrobial prophylaxis. Major disparities between study groups in frequency of antimicrobial prophylaxis are unlikely in randomized studies; however, it is very possible that significant disparities in the use of antimicrobial prophylaxis could have occurred in studies using a time-sequence, before-after design and masked a true beneficial effect of preoperative chlorhexidine showering or bathing.

It is also worth noting that chlorhexidine may have been employed in a less than optimal fashion in several studies. In all the trials, patients were simply instructed to bathe or shower with the study agent in the usual fashion, not specifically instructed to keep the 4% chlorhexidine on their skin for several minutes before rinsing. Moreover, the application of chlorhexidine was not supervised in the majority of trials. It is possible that the duration of chlorhexidine application was considerably less than adequate, effective cutaneous antisepsis.

Studies evaluating the optimal duration of chlorhexidine hand scrubs provide insights into this potentially very important issue. Pereira et al showed that a 5-minute initial hand scrub followed by consecutive 3-minute scrubs resulted in far lower bacterial counts on hands than a 3-minute initial scrub followed by consecutive 30-second scrubs suggesting that application of 4% chlorhexidine to the skin for 3 to 5 minutes provides optimal antibacterial effect on the cutaneous microflora. It is very plausible that the patients enrolled in the analyzed trials received far too brief application of
4% chlorhexidine, which might well explain the failure to detect any benefit in the pooled data.

The antibacterial effect of chlorhexidine is cumulative and greatly enhanced by repeated applications. Paulson evaluated the antibacterial effect of chlorhexidine showers daily over 5 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 multiple applications of chlorhexidine over several

<table>
<thead>
<tr>
<th>Authors, year</th>
<th>Duration of follow up for determination of SSI</th>
<th>Number of patients in chlorhexidine arm</th>
<th>Number of SSI in chlorhexidine arm (%)</th>
<th>Number of patients in comparator arm</th>
<th>Number of SSI in comparator arm (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brandberg et al, 1979</td>
<td>Not specified</td>
<td>171</td>
<td>13 (7.6)</td>
<td>170</td>
<td>30 (17.6)</td>
</tr>
<tr>
<td>Ayliffe et al, 1983</td>
<td>Through hospital discharge</td>
<td>2,703</td>
<td>147 (5.4)</td>
<td>2,833</td>
<td>140 (4.9)</td>
</tr>
<tr>
<td>Leigh et al, 1983</td>
<td>Through hospital discharge</td>
<td>109</td>
<td>12 (11.0)</td>
<td>115</td>
<td>13 (11.3)</td>
</tr>
<tr>
<td>Wells et al, 1983</td>
<td>Through postoperative day 10 or hospital discharge</td>
<td>209</td>
<td>11 (5.3)</td>
<td>245</td>
<td>14 (6.7)</td>
</tr>
<tr>
<td>Randall et al, 1983</td>
<td>Seven days</td>
<td>32</td>
<td>12 (37.5)</td>
<td>62</td>
<td>19 (30.6)</td>
</tr>
<tr>
<td>Hayek et al, 1987</td>
<td>Six-week follow-up</td>
<td>689</td>
<td>62 (9.0)</td>
<td>1,326</td>
<td>163 (12.3)</td>
</tr>
<tr>
<td>Dimitrov et al, 1984</td>
<td>Not specified</td>
<td>57</td>
<td>0 (0)</td>
<td>46</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Wiborg, 1987</td>
<td>Not specified</td>
<td>541</td>
<td>9 (1.7)</td>
<td>437</td>
<td>20 (4.6)</td>
</tr>
<tr>
<td>Rotter et al, 1988</td>
<td>Three weeks</td>
<td>1,413</td>
<td>37 (2.6)</td>
<td>1,400</td>
<td>33 (2.4)</td>
</tr>
<tr>
<td>Earnshaw et al, 1989</td>
<td>Through hospital discharge</td>
<td>31</td>
<td>8 (25.8)</td>
<td>35</td>
<td>4 (11.4)</td>
</tr>
<tr>
<td>Byrne et al, 1991</td>
<td>Six-week follow-up</td>
<td>29</td>
<td>2 (6.9)</td>
<td>27</td>
<td>2 (7.4)</td>
</tr>
<tr>
<td>Lynch et al, 1992</td>
<td>Not specified</td>
<td>1,575</td>
<td>225 (14.3)</td>
<td>1,576</td>
<td>241 (15.3)</td>
</tr>
<tr>
<td>Veiga et al, 2009</td>
<td>Thirty days follow-up</td>
<td>50</td>
<td>1 (2)</td>
<td>50</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Johnson et al, 2010</td>
<td>Not specified</td>
<td>157</td>
<td>0 (0)</td>
<td>897</td>
<td>14 (1.6)</td>
</tr>
<tr>
<td>Murray et al, 2011</td>
<td>Two months</td>
<td>50</td>
<td>0 (0)</td>
<td>50</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Zywiec et al, 2011</td>
<td>Not specified</td>
<td>136</td>
<td>0 (0)</td>
<td>711</td>
<td>21 (3.0)</td>
</tr>
</tbody>
</table>

**Table 2**

Results of the included studies

**Figure 2.** Number of infections in clean surgery and clean contaminated/contaminated subgroups. When excluding higher risk of bias studies, OR, 0.98 (95% CI: 0.83-1.16)

Figure generated with Review Manager 5 software.
days prior to anticipated surgery may be far more efficacious than a single preoperative chlorhexidine shower or bath. There was a trend toward fewer infections in individuals receiving multiple applications compared with single applications in our study, although this failed to reach statistical significance.

In conclusion, our analysis does not support routine use of preoperative, whole-body chlorhexidine showering or bathing for prevention ofSSI. However, many of the trials done were suboptimal in design, and the manner in which the chlorhexidine solutions were used in the trials was not clearly described. Although chlorhexidine bathing preoperatively is a low risk and relatively low cost intervention that may be employed even if the magnitude of benefit is marginal, it is nonetheless important to definitively answer this question, given constrained resources for infection control. A cluster randomized trial to provide adequate statistical power in patients undergoing clean surgery that employs standardized application techniques and a prolonged duration of chlorhexidine with rigorous blinded assessment of SSI outcomes is needed.

References