Research Article

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No Clear Benefit of Chlorhexidine Use at Home Before Surgical Preparation

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Abstract

Introduction: Several studies have evaluated the efficacy of home use of chlorhexidine before surgery to reduce bacterial colonization. However, these studies have provided conflicting evidence about the potential efficacy of this strategy in decreasing bacterial loads and infection rates across surgical populations, and no prior study has analyzed the benefit of this intervention before spine surgery. We prospectively analyzed the effectiveness of chlorhexidine gluconate wipes for decreasing bacterial counts on the posterior neck.

Methods: Sixteen healthy adults participated in this prospective study. The right side of each participant's neck was wiped twice (the night before and the morning of the experiment) with chlorhexidine gluconate wipes. The left side was used as the control region. Bacterial swabs were obtained as a baseline upon enrollment in the study, then upon arrival at the hospital, and, finally, after both sides of the neck had received standard preoperative scrubbing.

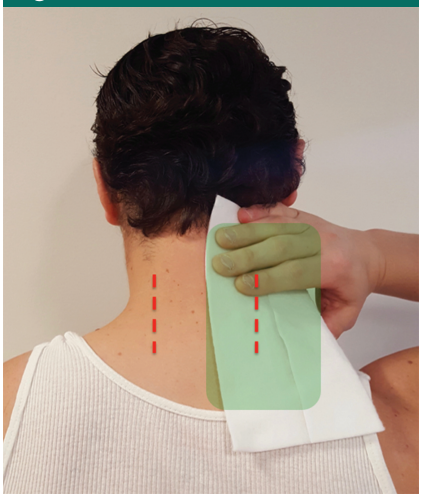
Results: All patients had positive baseline bacterial growth (median >1,000 colonies/mL). When chlorhexidine gluconate wipes were used, decreased bacterial counts were noted before the preoperative scrub, but this finding was not statistically significant ($P = 0.059$). All patients had zero bacteria identified on either side of their neck after completion of the preoperative scrub.

Conclusion: At-home use of chlorhexidine gluconate wipes did not decrease the topical bacterial burden. Therefore, using chlorhexidine gluconate wipes at home before surgery may offer no added benefit.

Surgical site infections (SSIs) can cause substantial morbidity and mortality and lead to severe clinical, economic, and social burdens across surgical disciplines.[1] These complications can be especially harmful in spine surgery, where the sequelae of infection and extensive revision can include neurologic compromise or even death.[2]

Substantial effort has been made by surgeons to decrease SSI rates.[1-6] One intervention has been the use of chlorhexidine gluconate (CHG) wipes by the patient at home preoperatively.[7-13] Prior work has shown the possibility of achieving substantial CHG concentration on the skin through repeated topical application.[14-16] However, prior studies have provided conflicting evidence about the potential efficacy of this strategy in decreasing bacterial loads and infection rates across surgical populations.[10,11,17-22] Preadmission cleansing has been studied in numerous trials and reviews; however, to our knowledge, no prior

Figure 1



Photograph showing how the study participants were instructed to cleanse the right side of their posterior neck with the chlorhexidine gluconate wipe. The dashed lines indicate the locations where the cutaneous samples were obtained.

study has analyzed the benefit of such an intervention in the field of spine surgery. Further, many prior studies assessed bacterial counts when patients arrived at the hospital, instead of at the clinically relevant time point, after the standard surgical scrub had occurred.

We sought to perform a prospective, case-controlled cohort investigation to assess the efficacy of CHG-impregnated wipes in reducing cutaneous bacterial loads. We hypothesized that skin cleansing at home would decrease the overall bacterial burden, although we thought that after participants received the standard preoperative surgical scrub, similar bacterial counts would be present regardless of CHG wipe usage.

Methods

The protocol for CHG wipe usage, bacterial sampling, and data analysis was determined via consensus among the coauthors, representing the fields of orthopaedic surgery, microbiology, infectious disease, and statistics. We performed an a priori power analysis to determine the necessary sample size to establish statistical equivalence (defined as zero or one bacterial colony per milliliter difference between groups) between the use or nonuse of CHG wipes at home. On the basis of the power analysis, 16 participants were deemed necessary, with the contralateral side of each participant's neck serving as the control site for that participant (for a total of 32 sites of sampling). After Institutional Review Board approval was obtained, volunteers (consisting of medical staff and practitioners) at a single institution were prospectively enrolled. Oral and written informed consent was obtained from each participant.

Participant Criteria

Inclusion criteria for study participants included men and women aged ≥18 years. Each enrolled participant agreed to perform a CHG cleansing at home per the protocol and was appropriately coached on the proper technique. Exclusion criteria included open skin wounds at the time of enrollment or the inability to adequately conform to protocol requirements because of physical limitations. Enrolled participants who failed to perform the necessary home protocol were excluded from data analysis. Participants were advised to terminate the study protocol if they experienced adverse reactions to the wipes.

Intervention

For the purposes of this study, the term CHG wipes refers to the prepackaged and self-administrable CHG wipes that are given to patients to use at home the night before and morning of surgery. The term scrub refers to the standard preoperative scrubbing technique that would be performed in the operating room immediately before surgery. Each participant was provided with the standard preoperative CHG wipes used at our institution (2% CHG cloth; Styrker). The right side of each participant's posterior neck served as the surface of experimental intervention in this study and was cleansed with CHG wipes (Figure 1). The left side of the posterior neck served as the control surface. Participants were instructed not to cleanse the control region with the wipes. Participants were instructed to shower at night and then, after drying the neck, apply the CHG wipe to the back of the neck on the right side. They were asked to apply

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Figure 2

Photograph showing the posterior aspect of a participant's neck isolated with the use of nonsterile plastic drapes before the standard preoperative cleansing regimen was performed.

Figure 3

Photograph showing the process of obtaining cutaneous cultures from the posterior neck. The dashed line indicates the region in which the sample was obtained.

Figure 4

Photograph showing the chlorhexidine scrub of the posterior neck.

a new wipe to the right side of the neck again the following morning. Participants were instructed to wipe only the right side of the neck and to forgo use of lotions or other skin treatment after wiping. Participants who used the morning wipe at least 1 hour before sterile skin preparation were included in this study.

Subsequent skin preparation included a standardized preoperative cleansing regimen performed equally on both the experimental and control regions. The posterior aspect of each participant's neck was isolated with nonsterile plastic drapes (Figure 2). Both the control and experimental areas were cleansed with alcohol foam solution and then allowed to dry for 1 minute. Next, a chlorhexidine paint solution (2% CHG and 70% isopropyl alcohol) was applied in a sterile manner. The solution was allowed to dry for 1 minute. A second application of chlorhexidine paint solution was applied and allowed to dry for 5 minutes to ensure complete drying (the estimated drying time, according to the manufacturer's package insert, is 3 minutes).

Specimen Sampling

Cutaneous samples were obtained by swabbing the posterior cervical sites of each participant at three specific time points. Samples were obtained to assess for the presence of aerobic and anaerobic bacteria. The first skin swabs of each side of the neck (referred to as R1 and L1) were obtained on the day of enrollment and served as baseline specimens before intervention. The following day, after participants had used the CHG wipes as directed on the right side of the neck at night and that morning, each side of the neck was again individually sampled (R2 and L2). The third set of samples was obtained after the alcohol and chlorhexidine surgical scrub regimen was performed (R3 and L3; Figures 3 and 4).

All specimens were collected using a sterile specimen collection and transport system (BD ESwab system; BD). The swab, which was premoistened in the contained sterile solution included in its packaging, was swiped 10 strokes over a 3-cm × 3-cm region on the right or left side of the posterior aspect of each participant's neck. All samples were sent immediately after acquisition to the microbiology laboratory for expedient analysis. The microbiologist who performed the plating and evaluation of samples was blinded to the experimental or control nature of each specimen.

Data Analysis

Data collected on the study participants included age, sex, and compliance with cleansing protocol (ie, wiped once, twice, or not at all). As noted, power analysis was performed before the start of the trial to ensure

adequate power to determine equivalence between the use or nonuse of the CHG wipes. Equivalence between was defined as an absolute difference of zero or one bacterial colony per sample, with each sample at a given time point consisting of 1 mL. A paired Student *t*-test with $\alpha = 0.05$ indicated that for the study to achieve 83% power, 16 participants were required, with the contralateral side of each participant's neck serving as the control site for that participant. Matched-paired Student *t*-testing was used to determine statistical significance.

Results

Seventeen participants initially consented and were enrolled in the study; however, one participant withdrew before any intervention because of subsequent awareness of an allergy to an ingredient in CHG wipes. Sixteen healthy participants underwent the study protocol and were analyzed. The cohort's mean age was 37 years. The study population included 10 men and 6 women. All participants reported full adherence to the protocol for self-administration of the CHG wipes at home. All participants were found to have bacterial growth on both the right and left sides of the neck in baseline sampling (median >1,000 colonies/mL on each side).

We then compared these baseline samples (R1 and L1) with samples obtained after CHG wipes were used on the right side (R2) and no intervention was performed on the left side (L2). Thirteen participants had no bacterial growth on the right side of their necks, where they had used CHG, whereas only six participants had no bacterial growth on the control side. The bacterial burdens were reported as the number of colonies per milliliter (Table 1). The mean decrease in bacterial counts from L1 to L2 (control side) was 536 colonies, and the mean decrease from R1 to R2 (interventional side) was 790 colonies; however, this difference between the two sides was not statistically significant ($P = 0.059$). Five minutes after the surgical scrub was performed on both sides, all patients had zero bacteria isolated from each side of the neck (R3 and L3).

Subjective speciation performed by the lead microbiology director at our institution (S.W.) showed that all patients had coagulase-negative *Staphylococcus* on both the right and left sides of their necks at the initial time point (R1 and L1). *Micrococcus* was the second most common species isolated. At the second time point, coagulase-negative *Staphylococcus* species and *Micrococcus* were the most common other colonies isolated. A single sample contained gram-negative rods. One plate contained bacillus (Table 2).

Because we noted that some of the L2 samples showed no bacterial growth, we performed a follow-up trial of three control participants to see if these findings could have been attributable to the CHG wipe having been mistakenly used not only on the right side, but partially on the left side of the neck, as well. These participants were sampled at baseline (sample 1) and again the following day (sample 2), without any use of CHG wipes. Then, the necks of these participants were surgically prepared with the standard alcohol and chlorhexidine regimen, allowed to fully dry for 5 minutes, and sampled again (sample 3). All three samples had positive bacterial growth at the first and second sampling time points, and negative growth at the third.

Discussion

To our knowledge, no prior study has definitively evaluated the effects of preoperative skin cleansing on the cutaneous bacterial burden before spine surgery. Although some studies have examined the potential efficacy of cleansing at home before surgery, multiple studies have demonstrated geographic variation in skin bacterial flora and colony counts.[8-13,23,24] We therefore decided to look at the value of preoperative cleansing in posterior cervical spine surgery, where rates of infection as high as 17% or 18% have been reported in the literature.[25] Surgeons use numerous methods to decrease the risk of infection in patients perioperatively. Validating the efficacy of these methods will allow the design of optimal protocols that contribute to improved outcomes without undue physical or financial burden on patients.

Our study showed no added benefit of using CHG wipes at home before the standard surgical scrub. Home CHG wipes are used with the goal of decreasing SSI rates. The mechanism through which infection rates are thought to be reduced is by decreasing cutaneous bacterial loads. However, our study showed that the use of CHG wipes at home did not decrease the ultimate bacterial burden on the skin after a surgical scrub, compared with control sites that underwent the standard surgical cleansing without home use of CHG wipes. Therefore, one can deduce that CHG wipes do not play a clear role in reducing rates of SSI.

We did observe decreased bacterial counts before the surgical scrub in the regions where the wipes were used, compared with those where the wipes were not used, but the finding was not statistically significant. Furthermore, even though several studies have examined bacterial counts at this stage as their ultimate point of analysis, bacterial burdens at this time are clinically meaningless because the skin has yet to be cleansed thoroughly with standard preparation in the

Table 1

Bacterial Colony Counts at Each Time Point[a]

	Bacterial Counts (Colonies/mL)					
	Day 0 (Baseline)		Day 1, After Wipe/Before Scrub		Day 1, After Scrub	
Participant No.	L1	R1	L2	R2	L3	R3
1	200	300	0	0	0	0
2	>1,000	>1,000	0	0	0	0
3	300	>1,000	0	0	0	0
4	>1,000	>1,000	>1,000	0	0	0
5	100	500	0	0	0	0
6	>1,000	>1,000	300	400	0	0
7	>1,000	>1,000	>1,000	0	0	0
8	150	200	0	0	0	0
9	>1,000	>1,000	500	0	0	0
10	>1,000	>1,000	100	0	0	0
11	>1,000	>1,000	500	0	0	0
12	>1,000	>1,000	0	0	0	0
13	>1,000	>1,000	400	500	0	0
14	>1,000	>1,000	400	0	0	0
15	700	1,000	260	0	0	0
16	2,000	640	420	100	0	0

[a] "R" refers to the intervention (chlorhexidine gluconate wipe) region of the neck (right); "L" refers to the control region of the neck (left).

operating room, and thus the bacterial count at this time point does not represent the bacterial count on the skin at the time of incision. We noticed that some participants had no bacterial growth even on the side of the neck that they did not wipe. It is unlikely that they had gathered no bacteria since the time of their shower the previous night. A more likely reason is that they had mistakenly partially wiped the left side of their neck in addition to applying the wipes to the right side of their neck. Our follow-up control trial of three participants supports this claim: When these participants did not use CHG wipes at all, all samples obtained before the surgical scrub were found to be heavily colonized (and after the scrub, all had no bacterial colonization).

Several trials have examined the effects of preoperative cleansing with chlorhexidine with mixed results. Murray et al[26] performed a prospective, randomized study examining the effect of CHG cloth treatment at home preoperatively. This industry-sponsored investigation concluded that this cleansing led to decreased bacterial presence preoperatively. However, they reported only the results of samples obtained in the preoperative holding area. Arguably, the bacterial burden after preoperative preparation is of more relevance. Accordingly, a more targeted investigation would be required to determine whether the level equalizes in both groups after a formal scrubbing process because no surgeon routinely operates without a scrub. Murray et al[26] also reported a significant increase in side effects (defined as mild itching or dry skin) associated with the chlorhexidine group, compared with the control group (24% versus zero, $P < 0.0002$). Other studies in plastic surgery have analyzed skin colonization after the use of wipes but before preoperative skin cleansing.[27,28] These studies also show decreased bacterial colony counts with no reported differences in SSIs.

Ng et al[29] prospectively studied the effect of CHG foot washes on patients before foot and ankle surgery and found reductions in the bacterial burden after washing. They analyzed bacterial flora qualitatively rather than quantitatively, reporting only culture positivity rather than bacterial colony counts. They stated that CHG decreased flora intraoperatively; however, their so-called intraoperative sample was obtained after washing and before the surgical preparation and drape. This sample would be more precisely labeled a preoperative sample. It was obtained approximately 20 minutes after washing, so the decreased bacterial burden in this sample is not surprising. They noted a reduction in bacteria postoperatively in the CHG footbath group; however, this

Table 2

Bacterial Species Found at Each Time Point[a,b]

	Bacterial Species					
	Day 0 (Baseline)		Day 1, After Wipe/Before Scrub		Day 1, After Scrub	
Participant No.	L1	R1	L2	R2	L3	R3
1	CoNS	CoNS, MC, AS	—	—	—	—
2	CoNS	CoNS, MC	—	—	—	—
3	CoNS2	CoNS2, MC	—	—	—	—
4	CoNS2	CoNS2, MC, AS	CoNS	—	—	—
5	CoNS, MC, AS	CoNS, MC	—	—	—	—
6	CoNS	CoNS	CoNS2, MC	CoNS, MC, AS	—	—
7	CoNS2	CoNS	CoNS	—	—	—
8	CoNS2, MC	CoNS, MC	—	—	—	—
9	CoNS2	CoNS, MC, AS	CoNS, bacillus	—	—	—
10	CoNS, MC, AS	CoNS2, MC, AS	CoNS, MC	—	—	—
11	CoNS, MC	CoNS, MC, AS	CoNS, MC	—	—	—
12	CoNS2	CoNS2	—	—	—	—
13	CoNS	CoNS	CoNS	CoNS2	—	—
14	CoNS, AS	CoNS	CoNS, MC	—	—	—
15	CoNS2	CoNS2	CoNS3	—	—	—
16	CoNS2, gram-negative rods	CoNS2	CoNS2	CoNS	—	—

AS = α-hemolytic *Streptococcus*, CoNS = coagulase-negative *Staphylococcus*, MC = *Micrococcus*
[a] "R" refers to the intervention (chlorhexidine gluconate wipe) region of the neck (right); "L" refers to the control region of the neck (left).
[b] The notation "2" or "3" indicates additional species of the specified type of bacteria.

finding was not statistically significant. Further, their methodology included preoperative povidone-iodine skin preparation for all patients. In the foot and ankle literature, Keblish et al[11] suggested that chlorhexidine and alcohol preparation is more effective than povidone-iodine preparation. Therefore, preoperative CHG washing in the study by Ng et al[29] may have equalized the postoperative results between the groups even further. Additionally, neither researchers nor patients were blinded in that study, which could potentially bias the results.

Arthroplasty literature from a single institution has suggested that infection rates are decreased after preoperative home CHG cleansing.[30,31] The cohort data were prospectively collected in a nonrandomized manner. Patient grouping was dependent on compliance with the CHG protocol. All patients were told to do CHG preoperative cleansing. Those who were compliant were placed in the intervention group, whereas the noncompliant patients were placed in the control group. Potential confounding can be seen in the significantly higher numbers of patients who smoked and had coronary artery disease in the control group, compared with the intervention group ($P < 0.0001$, $P < 0.0001$). Moreover, the control group also had a higher average body mass index. Assigning patients to groups by their ability to comply with a preoperative protocol may potentially raise larger issues of overall patient compliance. Because of the significantly higher rates of comorbidities in the control group, these factors could likely have contributed to their relatively worse outcomes. Based on these outcomes and theoretic assumptions, economic data would suggest that home CHG cleansing is effective.[7,32] However, other economic models based on findings of similar SSI rates regardless of preadmission CHG use suggest the opposing view.[33] These evaluations cannot be substantiated without more reliable data as inputs into the economic model.

Daily inpatient decontamination regimens have also been examined in large inpatient populations. Bode et al[34] enrolled *Staphylococcus aureus* carriers across a variety of inpatient medicine and surgical wards from 2005 to 2007 in a randomized controlled trial (RCT) to assess the benefit of repetitive nasal mupirocin administration and CHG skin cleansing. They concluded that the decolonization protocols reduced *S aureus* infections among inpatients.[34] A similar finding was

reported in a study analyzing daily bathing of patients in intensive care units.[35] These findings suggest that peri-incisional decolonization protocols—not before the routine cleansing that occurs in the operating room, but instead postoperatively, before the wound has healed—could possibly be beneficial for hospitalized surgical patients.

Rotter et al[17] reached opposing conclusions, stating that preoperative chlorhexidine bathing did not decrease bacterial burdens or the rate of SSI. They performed a prospective randomized double-blinded, multicenter trial of 2,813 patients across multiple European countries. They reported similar rates of SSI at 21 days and found no difference in culture data between the patients who bathed twice preoperatively with a specific detergent that included chlorhexidine and the patients who used the detergent without it. These patients were from several surgical specialties, including general surgery, orthopaedic surgery, and vascular surgery. The authors of the study acknowledged that these specialties had varying infection rates, with some procedures in the trial having four times the infection rates of others. Wound infections were noted by a nurse or surgeon in the hospital. The authors stated that an attempt was made to contact each patient up to 21 days postoperatively, which may be insufficient to track infections comprehensively in joint arthroplasty and spine surgery patients. In addition, of the 70 infections they encountered, only 25 had bacterial culture results, which provides insufficient power to detect differences in bacterial results. These results were qualitative, not quantitative, and the methods of microbiologic sampling and processing were not standardized across sites. Furthermore, the use of antibiotic and infection prophylaxis varied. Only 12% of patients in the trial received preoperative antibiotics, which may have confounded the results. Two other meta-analyses, including a recent Cochrane review, have not been able to show a definitive benefit of preoperative CHG cleansing at home.[36,37] The Cochrane meta-analysis reviewed 7 RCTs, whereas the other meta-analysis reviewed 16 trials, of which 8 were RCTs.[36]

Our study has limitations. We analyzed bacterial counts and culture results as our primary outcomes, rather than analyzing rates of SSI. The proposed mechanism of action of CHG wipes is through cutaneous bacterial reduction, rather than systemic therapy. If CHG wipes do not decrease the bacterial burden, one can logically infer that the use of these wipes cannot directly lead to a decrease in SSIs. Although we had a relatively small sample size, the study was adequately powered to determine statistical equivalence between groups. The decreased bacterial count in the control region before the surgical scrub, compared with the baseline count in that region, was likely attributable to mistaken partial wiping of that side of the neck. Measurement at this time point was not clinically relevant, and the final bacterial counts all ultimately decreased to zero regardless of whether the preoperative home cleansing occurred. Our prospective, case-controlled cohort design allowed for a feasible and efficient way to compare bacterial burdens after an intervention. However, prospective RCTs of patients undergoing spine surgery, rather than healthy volunteers, will be needed to validate these findings.

Conclusion

The main purpose of this study was to assess bacterial growth after drying of the alcohol and chlorhexidine preparation that would be used immediately before skin incision. All samples at this time point exhibited zero bacterial growth, supporting the conclusion that CHG wipe use at home adds no additional benefit to the standard procedure.

There is a paucity of level I data supporting the efficacy of preadmission chlorhexidine cleansing despite its widespread use. Even if preadmission chlorhexidine cleansing decreases the cutaneous bacterial burden, patients become contaminated with a plethora of bacteria en route to the sterile operating room. This contamination occurs in the patients' homes, in transportation vehicles, and even in preoperative holding areas. One could argue that the financial cost of using chlorhexidine wipes at home is minimal and that their use has few negatives. However, if a regimen, no matter how inexpensive, does not add a scientifically proven benefit, one cannot easily argue for its widespread use. Surgeons often use techniques based on personal preference or dogma rather than scientific evidence. Evidence has disproven the benefits of several trends, such as soap irrigation, high-pressure irrigation, urgent surgical débridement of open fractures within 6 hours, and even widespread home use of antibacterial soap.[38-40] This study reinforces the concept that thorough skin preparation, consisting of cleansing with alcohol followed by two sequential cleansings with chlorhexidine paint solution, allowed to dry at least 1 minute between applications, is essential in decreasing the bacterial load and minimizing infection rates after posterior cervical surgery.[3] Continued attention to the efficacy of interventions is warranted to focus efforts on the truly beneficial strategies.

Supplemental home chlorhexidine use is not without long-term

population-based risk. Chlorhexidine currently has tremendous bactericidal capability (as does mupirocin for nasal mucosa *S aureus*). With its increasingly widespread use in the community setting, consideration should be paid toward minimizing the risk of bacterial resistance.[34]

Because of the morbidity, mortality, and cost of SSIs, continued efforts must be focused on optimizing protocols to decrease the risk of infection. We have shown that although skin cleansing may decrease the bacterial burden preoperatively, this effect becomes irrelevant after the chlorhexidine preparation is performed in the operating room. Therefore, the use of CHG wipes at home may not offer any additional benefit over the current standard preoperative surgical scrub. Patients and physicians could focus on the methods that have been shown to decrease bacterial counts and SSIs, without the need to expend time and resources to have patients perform preoperative skin cleansing at home.

References

Evidence-based Medicine: Levels of evidence are described in the table of contents. In this article, references 6, 14, 15, and 38 are level I studies. Reference 8 is a level II study. References 4 and 22 are level III studies. References 2, 3, and 32 are level IV studies. References 1 and 40 are level V expert opinion.

References printed in **bold type** are those published within the past 5 years.

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