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# Does Preadmission Cutaneous Chlorhexidine Preparation Reduce Surgical Site Infections After Total Knee Arthroplasty?

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**Abstract**

*Background* Many preventive methodologies seek to reduce the risk of surgical site infections after total knee arthroplasty (TKA), including the use of preoperative chlorhexidine baths and cloths. Although we have demonstrated in previous studies that this may be an efficacious method for infection prevention, our study was underpowered and we therefore set out to evaluate this with a larger sample size.

*Questions/purposes* (1) Does a preadmission chlorhexidine cloth skin preparation protocol decrease the risk of surgical site infection in patients undergoing TKA? (2) When stratified using the National Healthcare Safety Network (NHSN) risk categories, which categories are associated with risk reduction from the preadmission chlorhexidine preparation protocol?

*Methods* In our study, all patients (3717 total) who had undergone primary or revision TKA at a single institution between January 1, 2007, and December 31, 2013, were identified, of whom 991 patients used the chlorhexidine cloths before surgery and 2726 patients did not. All patients were provided cloths with instructions before surgery; however, as a result of a lack of compliance, we were able to substratify patients into treatment and control cohorts. Additionally, we substratified patients by NHSN risk category to determine differences in infection between the two cohorts (cloth versus no cloth). Patient medical records and an infection-tracking database were reviewed to determine the development of periprosthetic infection (patients who had superficial infections were excluded from our study) in both groups after 1 year surveillance. We then calculated relative risk reductions with use of chlorhexidine gluconate and stratified results based on NHSN risk category.

*Results* Use of a preoperative chlorhexidine cloth skin preparation protocol is associated with reduced relative risk of periprosthetic infection after TKA (infections with protocol: three of 991 [0.3%]; infections in control: 52 of 2726 [1.9%]; relative risk [RR]: 6.3 [95% confidence interval [CI], 1.9–20.1]; p = 0.002). When stratified by NHSN risk category, periprosthetic infection risk reduction was seen in the medium-risk category (protocol: one of 402 [0.3%]; control: 25 of 1218 [2.0%]; RR, 8.3 [CI, 1.1–60.7]; p = 0.038), but no significant difference was detected in the low- and medium-risk groups (RR, 2.1 [CI, 0.5–9.6; p = 0.33] and RR, 11.3 [CI, 0.7–186.7; p = 0.09]).

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Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.
This work was performed at the Rubin Institute for Advanced Orthopedics, Center for Joint Preservation and Replacement, Sinai Hospital of Baltimore, Baltimore, MD, USA.

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*Conclusions* A prehospital chlorhexidine gluconate wipe protocol appears to reduce the risk of periprosthetic infections after TKA, primarily in those patients with medium and high risk. Although future multicenter randomized trials will need to confirm these preliminary findings, the intervention is inexpensive and is unlikely to be risky and therefore might be considered on the basis of this retrospective, comparative study.
*Level of Evidence* Level III, therapeutic study.

## Introduction

The use of preoperative disinfection and antiseptics has long since been supported by the Centers for Disease Control and Prevention [5]. There are currently various cutaneous solutions being used, including antiseptic soaps, alcohol-based solutions, iodine-based solutions, and chlorhexidine agents [7]. Although there are conflicting data regarding the efficacy of these solutions, recent studies have shown improved efficacy of chlorhexidine gluconate when compared with povidone or iodine-based solutions after total joint arthroplasty [4–7]. Chlorhexidine has been demonstrated to be effective against a broad spectrum of organisms, including methicillin-resistant *Staphylococcus aureus* (MRSA) [7, 18]. This is important because it has been estimated that approximately 92% of periprosthetic infections were the result of Gram-positive organisms and 50% are purportedly the result of *S aureus*, of which 59% are MRSA infections [24].

Surgical site wound contaminations from the patients' native skin flora and operating room air are the most predominant proposed etiologies [4, 10, 23, 27], thus necessitating implementation of various preventive measures [1, 8, 25] as well as cleansing procedures such as wipes, washes, and bathing. Although baths have been shown to be successful in reducing surgical site infections, they have been reported to be less efficient as a result of improper bathing technique, maintaining an effective cutaneous concentration, and compliance issues [4, 6, 11, 17]. Other methods of skin preparation have included mixing solutions or using serial cleansing with antiseptic solutions for several days. However, many of these methods have been demonstrated to be used ineffectively as a result of decreased compliance with increased preparation, difficulty in comprehension of multiple steps, and improper bathing technique. Therefore, a more simple skin disinfection protocol such as the use of a preoperative chlorhexidine cloth application has the potential to increase compliance as a result of ease of use and reduced number of steps. Furthermore, this may confer higher cutaneous antiseptic concentration levels and thereby be more efficacious in preventing surgical site infections.

This study is a larger follow-up to a prior preliminary report that was published on earlier results of this procedure [13, 29]. Although we demonstrated a significant reduction in surgical site infections with the use of chlorhexidine, our study was underpowered and we therefore attempted to reevaluate the previous patient population with supplementation of new patients to improve the quality of our study. Furthermore, there are contrasting studies on the efficacy of this protocol after total joint arthroplasty. Additionally, some have purported that a longer duration of the protocol would yield superior results; however, we feel that this adds to the complexity and therefore reduces compliance and increases healthcare expenditures unnecessarily.

We therefore asked: (1) Does a preadmission chlorhexidine cloth skin preparation protocol decrease the risk of surgical site infection in patients undergoing TKA? (2) When stratified using the National Healthcare Safety Network (NHSN) risk categories, which categories are associated with risk reduction from the preadmission chlorhexidine preparation protocol?

## Materials and Methods

After obtaining proper institutional review board approval, we initially identified 3842 patients who underwent primary or revision TKA at a single institution (four surgeons) between January 1, 2007, and December 31, 2013. Then we excluded 125 patients who were lost to 1-year followup (3.23%) and obtained a total of 3717 patients (Fig. 1). An infection-tracking database was used to identify patients, which is maintained by the infection prevention definition. All patients are monitored, based on medical records, for readmissions or hospital visits, which would be indicative of an infection. Subsequently, radiographic, laboratory, and clinical data were reviewed to determine if there is an infection. If patients missed followup visits, they were contacted by telephone to evaluate their health status. If telephone contact failed, they were mailed a letter with return service requested.

All attempts were made to provide patients with the cloths during their preoperative clearance appointments; however, some patients who received medical clearance from outside institutions may not have been provided the cloths or patients just did not use them. Therefore, there was no preselection or screening of patients to be in either cohort; rather, our cohorts were a direct result of noncompliance. We are unable to conjecture why patients did not use the wipes, because all were provided the same instructions regarding the protocol. Of this total, 991 patients used the protocol and the remaining 2726 patients received only the standard in-hospital perioperative skin preparation. We have previously reported on 66% (2458 of 3717) of these patients, which also included 1-year followup. The patients in the chlorhexidine cohort had a mean age of 62 years (SD ± 10.7), a mean body mass index (BMI) of 34 kg/m$^2$ (SD ± 7.1), and 62% of these patients were women (612 women, 379 men). The patients in the control cohort had a mean age of 62 years (SD ± 11.7) and a mean BMI of 34 kg/m$^2$ (SD ± 8.0), and 62% of these patients were women (1666 women, 1060 men). There were no differences in age (p = 0.601), BMI (p = 0.345), or gender (p = 0.732) between the two treatment groups (Table 1).

Patients who were in the preoperative preparation group were provided with an instruction sheet detailing the at-home advance preoperative skin preparation protocol as well as 12 2% chlorhexidine gluconate-impregnated cloths (Sage Products, LLC, Cary, IL, USA). Each cloth contained 500 mg of chlorhexidine gluconate. The protocol did not require bathing or showering before their surgery; however, if patients did, they were instructed to wait at least 2 hours before applying the cloths. Patients were to use six cloths the evening before and the remaining six the morning of surgery at the following sites: (1) neck, chest, and abdomen; (2) back; (3) upper extremities; (4) left lower extremity; (5) right lower extremity; and (6) surgical site. After this application, patients were instructed to not shower, rinse, or apply any topical cream or powder. To verify compliance, the patients were informed to remove adhesive stickers from the cloth packages immediately after application and to append them to the protocol sheet that was presented on the day or surgery. Nursing records

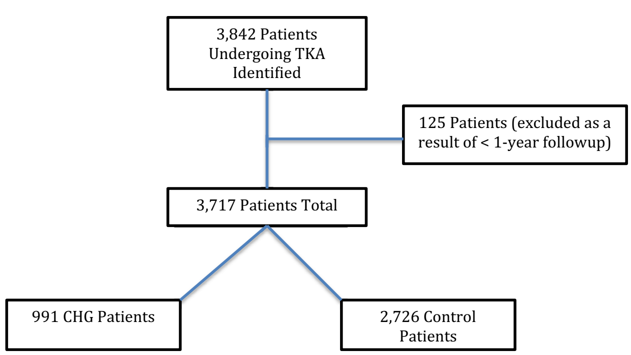


**Fig. 1** Flowchart depicting patients who were initially identified and subsequently included and excluded from our study.

in the preoperative holding area were reviewed as well to determine compliance with the cloth protocol. As an added measure of verification, all patients were questioned about proper cloth use the morning of surgery.

All patients underwent the same perioperative skin preparation procedure after admission. Induction of anesthesia was followed by application of a solution of 0.7% iodine povacrylex and 74% isopropyl alcohol (DuraPrep solution; 3M, St Paul, MN, USA). If patients reported allergies to iodine, a chlorhexidine based solution was used. The perioperative skin preparation was done by nursing staff in the hospital and was therefore standardized. All patients underwent postoperative and followup care as per the surgeon's standard protocol.

Using the NHSN surgical risk rating system, patients were stratified based on infection risk (Table 2) [3, 20]. Three categories were evaluated under the classification system: surgical time (less than or greater than 2 hours), American Society of Anesthesiologists risk category (less than or greater than 3), and wound classification (clean or clean-contaminated or contaminated and dirty). Each category was assigned a score 0 or 1 with a minimum score of 0 and a maximum score of 3. A total score of 0 was considered low risk, a total score of 1 was considered intermediate risk, and a total score of either 2 or 3 was considered high risk for infections. Patients were further stratified by the NHSN risk category of low, medium, or high between the two groups.

Patients were monitored for 1 year from the date of the operation as per the Musculoskeletal Infection Society guidelines. Any infections occurring after 1 year were excluded from our analysis. Infections were categorized as either deep or superficial with deep infections being defined as extending to either the joint space or deep fascial layers and superficial infections being defined as one that occurred within 30 days postoperatively and affecting only the skin or subcutaneous tissue at the surgical site. Diagnosis of a deep infection was based on the guidelines by the International Consensus Group on Periprosthetic Infections, which considered a joint to be positive for infection if one of the following major criteria were met: (1) there was a sinus tract in communication with the joint; or (2) if there were two separate positive periprosthetic cultures with phenotypically identical organisms [21]. Additionally, a joint is considered positive for an infection if three of five

**Table 1.** Demographic characteristics

| Demographic | Chlorhexidine | Control | p value |
|---|---|---|---|
| Age, mean (years) | 62 | 62 | 0.601 |
| Body mass index, mean (kg/m$^2$) | 34 | 34 | 0.345 |
| Number of women (%) | 612 (62%) | 1666 (61%) | 0.732 |

of the following minor criteria are met: (1) elevated serum C-reactive protein and erythrocyte sedimentation rate; (2) elevated synovial fluid white blood cell count or a positive change on leukocyte esterase test strip; (3) elevated synovial fluid polymorphonuclear neutrophil percentage; (4) positive histological analysis of periprosthetic tissue; and (5) a single positive culture [21]. Superficial wound infections were not considered periprosthetic infections for this study and were excluded.

Excel spreadsheet software (Version 2011; Microsoft Corporation, Redmond, WA, USA) was used for data collection, comparison, and calculations. Statistical software MedCalc (MedCalc Software bvba, Ostend, Belgium) and GraphPad Prism software (Version 5.0; GraphPad Software, San Diego, CA, USA) were used for analysis of data. Fisher's exact test was used to compare infection rates, gender distribution, and the NHSN risk category between the two groups. A t-test was used to compare age and BMI between the two groups. A 95% confidence interval of a proportion was calculated to compare the incidence of surgical site infection between the groups.

## Results

Use of a preoperative chlorhexidine cloth skin preparation protocol is associated with reduced risk of infection after TKA (infections with protocol: three of 991 [0.3%]; infections in control: 52 of 2726 [1.9%]; relative risk [RR], 6.3 [95% confidence interval {CI}, 1.9–20.1]; p = 0.002; Table 3). When stratified by NHSN risk category, infection risk reduction was seen in the medium-risk group (protocol: one of 402 [0.3%]; control: 25 of 1218 [2.0%]; RR, 8.3 [CI, 1.1–60.7]; p = 0.003, but no difference was detected in the low- (protocol: two of 431 [0.4%]; control: 10 of 1016 [1.0%]; RR, 2.1 [CI, 0.5–9.6]; p = 0.33) and high-risk groups (protocol: zero of 158 [0%]; control: 17 of 492 [3.5%]; RR, 11.3 [CI, 0.7–186.6]; p = 0.09; Fig. 2; Table 4).

Among control patients who did not receive preadmission chlorhexidine, patients in the NHSN medium- and high-risk categories had a higher risk of infection compared with those with low risk (low: 10 of 1016 [1.0%]; medium 25 of 1218 [2.1%]; RR, 2.1 [CI, 1.0–4.3]; p = 0.048; high: 17 of 492 [3.5%]; RR, 3.5 [CI, 1.6–7.6]; p = 0.001). Interestingly, among patients who received chlorhexidine pretreatment, although those with low NHSN had two of 431 (0.5%) infections, increased NHSN risk category designation seemed to be irrelevant (medium: one of 402 [0.2%], RR compared with low, 0.5 [CI, 0.0–5.9], p = 0.610; high: zero of 158 [0%], RR compared with low, 0.5 [CI, 0.0–11.3], p = 0.693).

**Table 2.** NHSN surgical wound infection risk classification

| Classification | Score |
|---|---|
| Wound class | |
| Clean or clean-contaminated | 0 |
| Contaminated, dirty | 1 |
| American Society of Anesthesiologists score | |
| $< 3$ | 0 |
| $\geq 3$ | 1 |
| Surgical cut time (hours) | |
| $\leq 2$ | 0 |
| $> 2$ | 1 |
| Total score | 0: Low risk |
| | 1: Medium risk |
| | 2, 3: High risk |

NHSN = National Healthcare Safety Network.

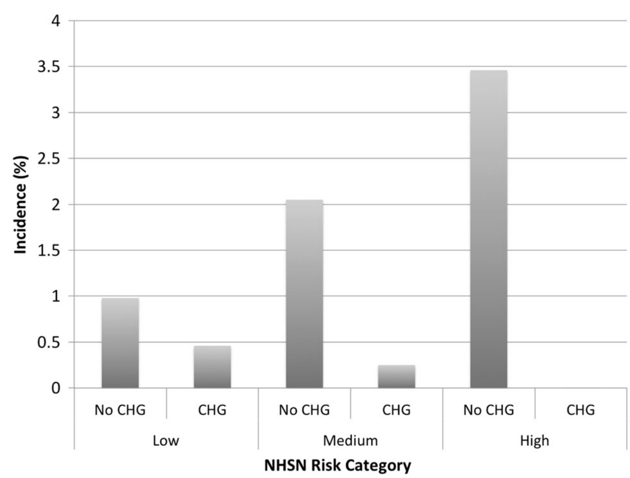


**Fig. 2** Bar graph representing the incidence of infection for both cohorts when substratified by NHSH risk category.

**Table 3.** Infection risk

| Control (n = 2726) | CHG pretreatment (n = 991) | Relative risk (95% CI) | p value |
|---|---|---|---|
| 52 (1.9%) | 3 (0.3%) | 6.3 (1.9–20.1) | 0.002 |

CHG = chlorhexidine gluconate; CI = confidence interval.

**Table 4.** NHSN risk stratification, proportion infected

| Group | Low | Medium | RR versus low | p value | High | RR versus low | p value |
|---|---|---|---|---|---|---|---|
| Control | 10/1016 (1.0%) | 25/1218 (2.1%) | 2.1 [1.0–4.3] | 0.048 | 17/492 (3.5%) | 3.5 [1.6–7.6] | 0.001 |
| CHG | 2/431 (0.5%) | 1/402 (0.2%) | 0.5 [0.0–5.9] | 0.610 | 0/158 (0.0%) | 0.5 [0.0–11,3] | 0.693 |

Values in brackets are 95% confidence intervals; NHSN = National Healthcare Safety Network; CHG = chlorhexidine gluconate.

## Discussion

The Centers for Disease Control and Prevention have suggested the inclusion of preoperative antiseptic baths, antibiotic prophylaxis, and maintaining appropriate serum glucose levels among other methods in surgical patient sterilization protocols [20]. Antiseptic baths, although shown to be beneficial, may be difficult to use effectively as a result of decreased compliance with increasing preparation, improper bathing technique, and reduced bactericidal duration and concentration [11]. In previous studies, we evaluated the incidence of infections in patients who used a chlorhexidine protocol; however, our study was underpowered and in this study we attempted to reevaluate a larger patient population [13, 29]. We therefore aimed to elucidate the effectiveness of a preoperative 2% chlorhexidine gluconate applicator cloth as a substitute to chlorhexidine bathing as an infection prevention measure after TKA.

Although accurate data recording and collection were maintained as much as possible, there were limitations to this study, including its retrospective nature, which can introduce biases. Another limitation of our study is that there may have been self-selection bias resulting from the fact that patients who tend to be more hygienic may also be more compliant with the applicator protocol and may also be less likely to have an infection. This may have made the treatment appear more efficacious. However, all patients were selected from an equivalent patient population. Furthermore, there are various other factors that have been implicated as risk factors for periprosthetic joint infection such as smoking status, socioeconomic status, diagnosis at the time of surgery, etc, which have not been evaluated that may be confounding factors. Another limitation in this study was the reliance on patient cooperation and compliance, because some of the data are self-reported, which can introduce further biases into our data set. To minimize this, patients were informed to remove specific stickers from the cloth package and apply them to the instruction packet. Furthermore, patients were asked about cloth use to verify compliance. Additionally, the long period of inclusion may induce bias because other factors may have been modified over a 6-year period. All surgeons were encouraged to promote the use of the cloths; however, it is possible that proper distribution of the instruction sheet and cloth packets may not have occurred for all patients who used the cloths. Additionally, although all patients were offered the cloths; some patients did not use them, which is how we were able to formulate our two cohorts. There were no changes to the pre- or postoperative practices for the duration of the study to patient prophylaxis or operative room sterilization. Additionally, all patients in this study were followed for 1 year postoperatively; any patients for which this data were not available were excluded from the analysis.

Other reports have demonstrated a reduction in infections after surgery with the use of preoperative chlorhexidine cleansing [7, 12–14, 19, 28, 29]. In a randomized, prospective study done by Murray et al., 100 patients were evaluated for the effectiveness of chlorhexidine cloths compared with that of a shower with soap and water the morning of surgery [19]. The chlorhexidine protocol required one application the evening before and another one the morning of surgery, similar to that of patients in this study. No patients in either the control or experimental group developed infections (zero of 50 for both groups); however, cultures revealed that there was a threefold decrease in the colony count for patients who received chlorhexidine, which has been demonstrated in additional studies [2, 19, 28]. Although the results of our study are supportive of the use of chlorhexidine cloths for preoperative sterilization, other studies have reported findings in opposition to ours. Farber et al. reported an infection rate of 1.0% (18 of 1891) in patients who received chlorhexidine cloths preoperatively compared with 1.3% (24 of 1824) who did not [9]. These results may have differed from ours as a result of the use of only one application of the chlorhexidine cloth 1 hour before surgery compared with our patients who used two applications, the night before and the morning of surgery. The application of chlorhexidine was limited to areas around the surgical site as opposed to our study, which involved wiping the entire body. Edmiston et al. reported that the use of chlorhexidine the evening before and the morning of surgery yielded a higher cutaneous concentration compared with that of one application either in the evening before or the morning of surgery [6]. Higher cutaneous concentrations of chlorhexidine led to increased bactericidal activity as a result of increased binding to bacterial cell walls, whereas lower concentrations are more bacteriostatic in nature [6].

Patients who used a 2% chlorhexidine cloth have also been shown to have higher mean cutaneous concentrations at all skin sites compared with patients who used a 4% chlorhexidine wash before surgery [5]. Furthermore, increased exposure times to chlorhexidine resulted in an increased reduction in cutaneous bacterial load [26].

Use of chlorhexidine pretreatment seems effective in risk reduction for those designated as NHSN high and medium risk. The NHSN is a useful resource in both tracking and analyzing surgical site infections and can be used to identify and treat patient-related risk factors for infection, thereby potentially decreasing the rate of infections. The risk models for joint replacements have been validated in a single institutional study of 21,941 joints by Lewallen et al., which demonstrated that a higher NHSN risk score was predictive of a higher risk of developing periprosthetic joint infections [16].

In conclusion, this study demonstrated a reduction in surgical site infections after TKA with the use of a preoperative 2% chlorhexidine gluconate when used the evening before and the morning of surgery, especially in those with higher NHSN risk categories. The need for enhanced infection prevention methods in orthopaedic procedures is imperative as the number of procedures continues to increase [15, 22]. We believe that the use of an advanced 2% chlorhexidine gluconate cloth protocol the evening before and morning of surgery may be effective in reducing infection rates after TKA. Additionally, the use of a quick risk screen might be efficacious to identify those patients at higher risk of infection (higher NHSN categories) and to provide them with the cloths. Larger, prospective studies are necessary to evaluate various chlorhexidine-based preparations, the efficacy of additional surveillance methods as well as the compliance for these practices.

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