

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

Bhveen H. Kapadia MD, Julio J. Jauregui MD, Daniel P. Murray BA,  
Michael A. Mont MD

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### Abstract

**Background** Periprosthetic hip infections are among the most catastrophic complications after total hip arthroplasty (THA). We had previously proven that the use of chlorhexidine cloths before surgery may help decrease these infections; hence, we increased the size of the previously reported cohort.

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

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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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B. H. Kapadia, J. J. Jauregui, D. P. Murray  
Department of Orthopaedic Surgery and Rehabilitation  
Medicine, SUNY Downstate Medical Center, Brooklyn, NY,  
USA

M. A. Mont (✉)  
Rubin Institute for Advanced Orthopedics, Center for Joint  
Preservation and Replacement, Sinai Hospital of Baltimore,  
2401 West Belvedere Avenue, Baltimore, MD 21215, USA  
e-mail: mmont@lifebridgehealth.org; rhondamont@aol.com

associated with risk reduction from the preadmission chlorhexidine preparation protocol?

**Methods** Between 2007 and 2013, a group of 998 patients used chlorhexidine cloths before surgery, whereas a group of 2846 patients did not use them and underwent standard perioperative disinfection only. Patient records were reviewed to determine the development of periprosthetic infection in both groups of patients.

**Results** Patients without the preoperative chlorhexidine gluconate disinfection protocol had a higher risk of infections (infections with protocol: six of 995 [0.6%]; infections in control: 46 of 2846 [1.62%]; relative risk: 2.68 [95% confidence interval {CI}, 1.15–0.26];  $p = 0.0226$ ). When stratified based on risk category, no differences were detected; preadmission chlorhexidine preparation was not associated with reduced infection risk for low, medium, and high NHSN risk categories ( $p = 0.386, 0.153, \text{ and } 0.196$ , respectively).

**Conclusions** The results of our study suggest that this cloth application appears to reduce the risk of infection in patients undergoing THA. When stratified by risk categories, we found no difference in the infection rate, but these findings were underpowered. Although future multi-center randomized trials will need to confirm these preliminary findings, the intervention is inexpensive and is unlikely to be risky and so might be considered on the basis of this retrospective, comparative study.

**Level of Evidence** Level III, therapeutic study.

### Introduction

Because the number of arthroplasties are only expected to increase, over the past 10 years, much has changed in the orthopaedic practice to decrease the odds for developing a

postoperative infection, especially in the arthroplasty world [15, 26]. Within these methods, laminar airflow, positive air pressure, and body exhaust suits have been proven to be effective [2, 9, 18, 22, 27, 28]; however, these steps cannot reduce infections from the patient's skin flora [12]. To reduce these infections, the Centers for Disease Control and Prevention has recommended bathing with an antiseptic agent the night before the index procedure [23]. Prior data have shown that preoperative chlorhexidine gluconate showers can effectively reduce surgical site infections when compared with patients who do not undergo preoperative showers [5, 6, 14, 21]. However, some data suggest that maintaining bactericidal chlorhexidine concentrations on the skin can be challenging when using baths, because the solution is often washed off [7]. Therefore, a simple 2% chlorhexidine gluconate no-rinse cloth product was developed that could have a better bactericidal effect at the surgical site and increase the patients' compliance.

On our previous study [17], by evaluating 2545 patients who underwent THA over a 4-year span, we determined that these cloths could effectively reduce the infection rate in these patients. Although we found that these cloths decreased the infection rate, our study was underpowered and it was over a specific timeframe. Since, the bacterial flora is constantly evolving and there is a continuous epidemiological transition, we evaluated 2 additional years.

We therefore asked: (1) Does a preadmission chlorhexidine cloth skin preparation protocol decrease the risk of surgical site infection in patients undergoing THA? (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?

## Patients and Methods

After obtaining proper institutional review board approval, we evaluated all patients who underwent primary or revision THA between January 1, 2007, and December 31, 2013, by using the infection-tracking database at our institution. We followed these patients to determine deep incisional or periprosthetic infections; all patients were followed for 1 year after surgery. In addition, a prospective database from the same time period tracked those who were compliant with the chlorhexidine protocol. We had reported in a previous study [17] the initial subset of patients ( $n = 2545$  patients) who are part of this study but were evaluated before December 2011. During this time period, surgeons at our institution were instructed to recommend the use of 2% chlorhexidine gluconate cloths with two applications (one the night before and one the morning

of surgery) to their patients. In the overall time interval, we identified a total of 3841 patients who underwent THA, with full preadmission protocol compliance by 995 patients. The remaining 2846 patients who were instructed to but did not use the preadmission protocol and therefore received only the standard in-hospital perioperative preparation for disinfection were our comparison cohort. During this time period, an additional parallel study was also performed to evaluate if this protocol benefitted patients undergoing TKA; however, in an attempt to be more specific and avoid increasing the confounding variables, we chose to publish it separately.

Patients in the chlorhexidine preparation group were given 2% chlorhexidine gluconate-impregnated cloths (500 mg chlorhexidine gluconate per cloth; Sage Products LLC, Cary, IL, USA) and were instructed to use them (rub the skin with the cloths) the evening before and morning of surgery. In addition, an instruction sheet detailing the at-home advance preoperative skin preparation was provided. 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. They were instructed to use these cloths in the sites described in our study evaluating knee arthroplasties.

Compliance was verified by having the patients remove adhesive stickers from the cloth packages at the time of application, attach them to the instruction sheet, and present them on the day of surgery. Patients were also questioned on the day of surgery about proper application of the cloths as an added level of verification. All patients, regardless of preadmission cloth use, received the same perioperative skin preparation. After anesthesia and positioning on the operating table, the surgical site was painted with alcohol only and subsequently with a combination of iodine povacrylex/alcohol (DuraPrep solution; 3M, St Paul, MN, USA). All patients also received postoperative and followup care according to their surgeon's standard protocol regardless of preadmission cloth use.

All patients were monitored for 1 year postoperatively to assess for infection based on the Musculoskeletal Infection Society definition; no patient was lost to followup or died within the 1-year followup period (Table 1) [24, 25]. In patients presenting with infections, they were characterized as either superficial or deep. A superficial infection was defined as an infection that occurred within 30 days of surgery and was confined to the skin or subcutaneous tissue of the incision. These infections were not considered periprosthetic infections for the purposes of this study. Deep infections were described as extending to the joint space or deep fascial layers and the definition of periprosthetic infection provided by the Musculoskeletal Infection Society was used [24]. According to these guidelines, a joint is considered positive for infection if

there is a sinus tract in communication with the prosthesis, if two separate tissue or fluid cultures from the joint demonstrate infection, or if three of the following five criteria are met: (1) an increased percentage of synovial polymorphonucleocytes; (2) an elevated erythrocyte sedimentation rate and C-reactive protein; (3) an elevated synovial leukocyte count or positive change on leukocyte esterase strip; (4) one fluid or tissue culture that grows a pathogen; or (5) frozen tissue sections display over five polymorphonucleocytes per high-powered field.

Patients were further stratified based on patient infection risk categories according to the surgical risk rating system from the NHSN [4, 23]. This classification consists of three components: American Society of Anesthesiologists risk category (less than or greater than 3), wound classification (clean or clean-contaminated or contaminated and dirty), and surgical incision time (less than or greater than 2 hours). Patients received a score of either 0 or 1 in each category with a maximum score of 3 and a minimum score of 0 for each patient. Patients receiving a total score of 0 were considered low risk, those with a total score of 1 were considered medium risk, and those with a score of either 2 or 3 were considered to be at high risk for infection at the surgical site (Table 2).

The patients in the study cohort had a mean age of  $58.4 \pm 12.6$  years and a mean body mass index (BMI) of  $30.3 \pm 7.04$  kg/m<sup>2</sup>, and 54% of these patients were women (539 women and 456 men). In the nonchlorhexidine cohort, the patients had a mean age of  $59.0 \pm 16.39$  years and a mean BMI of  $29.9 \pm 7.04$  kg/m<sup>2</sup>, and 55% of these patients were women (1581 women and 1265 men). There were no differences in age, BMI, or gender between both cohorts ( $p = 0.269$ ,  $0.229$ , and  $0.453$ , respectively).

**Table 1.** Demographic characteristics for patients undergoing THA

Metric	CHG (n = 995)	No CHG (n = 2846)	p value
Age (years; mean $\pm$ SD)	$58.4 \pm 12.6$	$59.0 \pm 16.39$	0.269
BMI (kg/m <sup>2</sup> ; mean $\pm$ SD)	$30.3 \pm 7.04$	$29.9 \pm 7.04$	0.229
Number of women (%)	539 (54%)	1581 (55%)	0.453

CHG = chlorhexidine; BMI = body mass index.

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

Wound class	American Society of Anesthesiologists score		Surgical cut time (hours)	
	Contaminated, dirty	<3 $\geq$ 3	$\leq$ 2	>2
Clean or clean-contaminated	1	0	0	1

Total score: 0 = low risk; 1 = medium risk; 2 or 3 = high risk; NHSN = National Healthcare Safety Network; CHG = chlorhexidine.

All data collected were imputed into an electronic spreadsheet (Excel version 2010; Microsoft Corporation, Redmond, WA, USA) and then comparison and calculations were performed with the same software. Statistical analyses were performed with the aid of statistical software (MedCalc; MedCalc Software bvba, Ostend, Belgium). Fisher's exact tests were performed to compare infection rates, age, gender, BMI, and the NHSN risk category between the group of patients using the chlorhexidine protocol and the group of patients who did not use the protocol. Within the NHSN risk category cohorts, a post hoc power analysis was also performed.

## Results

Patients without the preoperative chlorhexidine gluconate disinfection protocol had a higher risk of infections (infections with protocol: six of 995 [0.6%]; infections in control: 46 of 2846 [1.62%]; relative risk: 2.68 [95% confidence interval {CI}, 1.15–0.26];  $p = 0.0226$ ).

When stratified based on risk category, no differences were detected between the patients treated with the chlorhexidine protocol and those who were not; preadmission chlorhexidine preparation was not associated with reduced infection risk for low, medium, and high NHSN risk categories. Within the patients in the low-risk category without the disinfection protocol, similar infection rates were observed (infections with protocol: three of 579 [0.5%]; infections in control: 13 of 1437 [0.9%]; relative risk: 1.74 [95% CI, 0.50–6.08];  $p = 0.386$ ; Table 3). Patients in the medium-risk category without the disinfection protocol also had similar infection rates (infections with protocol: two of 317 [0.6%]; infections in control: 19 of 1051 [1.8%]; relative risk: 2.88 [95% CI, 0.68–12.31];  $p = 0.153$ ; Table 4). Similarly, patients in the high-risk category without the disinfection protocol also had equivalent infection rates

**Table 3.** Low-risk category stratified by cohort and infection

Preparation	No CHG (n = 1450)	CHG (n = 582)	p value
Number of infected joints	13 (0.9%)	3 (0.5%)	0.386

CHG = chlorhexidine.

(infections with protocol: one of 96 [1%]; infections in control: 14 of 331 [4.1%]; relative risk: 3.78 [95% CI, 0.50–28.41];  $p = 0.196$ ; Table 5). However, within the low-, medium-, and high-risk cohorts, the findings were underpowered (power of 0.136, 0.100, and 0.069, respectively; Fig. 1).

Other findings of our study were that patients with higher risk categories had overall higher risk for developing an infection. By just evaluating the relative risk of

developing an infection in our conventional nonchlorhexidine gluconate cohort, we found that high-risk patients had a relative risk 4.53 higher (95% CI, 2.15–9.54;  $p < 0.001$ ) than the low-risk patients and a relative risk 2.4 higher (95% CI, 1.14–4.43;  $p = 0.019$ ) than low-risk patients. Also, when compared with low-risk patients, medium-risk patients had a relative risk of 2.02 (95% CI, 1.01–4.06;  $p = 0.049$ ) for developing an infection (Table 6). In addition, these high-risk patients had the greatest reduction of 3% in contrast to the 1.2% reduction for the moderate risk and 0.4% reduction for the low risk.

**Table 4.** Medium-risk category stratified by cohort and infection

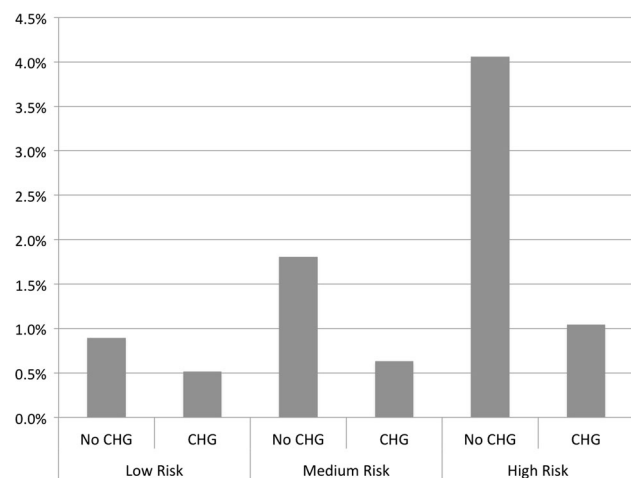
Preparation	No CHG (n = 1051)	CHG (n = 317)	p value
Number of infected joints	19 (1.8%)	2 (0.6%)	0.153

CHG = chlorhexidine.

**Table 5.** High-risk category stratified by cohort and infection

Preparation	No CHG (n = 345)	CHG (n = 96)	p value
Number of infected joints	14 (4.1%)	1 (1.0%)	0.196

CHG = chlorhexidine.



**Fig. 1** Bar graph representing the incidence of infection stratified by risk classification. CHG = chlorhexidine gluconate.

## Discussion

There are various measures aimed at preventing periprosthetic infections such as antibiotic prophylaxis, sterilization of operating room air, and antiseptic skin preparations. Specifically, preoperative measures have inconclusive information beyond standard bathing before surgery [23]. In previous studies, we evaluated the reduction of infections with chlorhexidine gluconate skin preparation [16, 17]. Because the skin is normally colonized with bacteria that can potentially cause infections, we corroborated the efficacy of a simple and inexpensive preadmission protocol using a 2% chlorhexidine gluconate-impregnated cloth in preventing periprosthetic infection. However, we were unable to demonstrate this efficacy when stratifying by risk category.

This study has several limitations, most notably the potential for self-selection bias, the lack of prospective design, randomization, and the lack of stratification by primary versus revision surgery. In regard to the self-selection bias, the more health-conscious patients might have chosen to use the wipes, whereas less health-conscious patients did not; the result of this could have been the inflation of the appearance of a benefit from treatment. However, because the patients come from an equivalent patient population, we believe that our findings are still relevant and this is not a disqualifying limitation. In addition, compliance with a proper application technique often varies depending on the patient. However, all patients were instructed to provide proof of compliance by affixing the adhesive stickers from the packaging of the cloths to their instruction sheets and bringing them on the day

**Table 6.** Relative risk for developing and infection comparing risk categories

Risk category	Both cohorts			No CHG			CHG		
	RR	95% CI	p value	RR	95% CI	p value	RR	95% CI	p value
Medium versus low	1.95	1.02–3.72	0.043	2.02	1.00–4.06	0.050	1.22	0.21–7.29	0.824
High versus low	4.32	2.15–8.67	<0.001	4.53	2.15–9.54	<0.001	2.02	0.21–19.23	0.541
High versus medium	2.22	1.15–4.26	0.017	2.24	1.14–4.43	0.020	1.65	0.15–18.01	0.681

CHG = chlorhexidine; RR = relative risk; CI = confidence interval.

of surgery. As an added measure of verification, all patients were questioned by staff regarding application of the cloths. Additionally, surgeons and staff were regularly reminded and encouraged to distribute the instruction packets with the chlorhexidine cloths. Furthermore, various comorbidities and demographic factors may have been confounding factors that could have affected clinical outcomes. However, given the power of our study for answering our first question, we feel that our main finding is valid.

The results of our study are in agreement with previous studies, which evaluated the use of 2% chlorhexidine gluconate cloths over standard bathing in patients undergoing total joint arthroplasty [8, 16, 30]. In our previous study by Johnson et al. [16], we evaluated 2213 patients undergoing TKA and assessed the effectiveness of this chlorhexidine cloth protocol in preventing periprosthetic infections. We found that 478 patients used the preadmission cloths and 1735 patients did not use them. After a 1-year followup period, only three patients who used the cloths reported with infection, whereas 38 of the patients in the control group reported with infection. After a 1-year followup period, the risk of infection was found to be much lower in the group treated with cloths than in the control group (2.19% versus 0.62%). Similarly, Lamplot et al. [20] prospectively evaluated a cohort of 1224 patients who underwent TKA with a modified protocol to decrease surgical site infections, which included 0.4% chlorhexidine surgical wipes. They compared the infection with an historical cohort and found less infections (0.49% versus 2.24%;  $p < 0.001$ ). Various other studies have also reported reductions in cutaneous bacterial colonization and subsequent infection when using 2% chlorhexidine cloths compared with washing with soap and water [1, 29, 30].

Chlorhexidine gluconate has been shown to be effective in reducing the risk of infection compared with standard washes and other antiseptic methods in a variety of medical specialties when applied after invasive procedures [3]. As such, a retrospective study by Farber et al. [10] evaluated a total of 3715 patients using a similar chlorhexidine cloth protocol and showed contrasting results. All patients undergoing lower extremity total joint arthroplasty were evaluated and were substratified into a chlorhexidine cohort (1891 patients) and a control cohort (1824 patients). The authors found that at 1-year followup, there was no difference in the infection rate between the two groups. However, the difference that we found and was not observed by Faber et al. may be explained by a methodological difference between the studies. Those authors used a single application the morning of surgery, whereas our study used two applications, one the morning of and the second the evening before surgery. The potential benefit of the two-part application could have been demonstrated to be the result of a cumulative effect whereby there was a

higher bactericidal cutaneous concentration [3]. Additionally, the superior protection against infection could have also been attributed to the rapid and residual bactericidal effects of chlorhexidine [13]. Additionally, chlorhexidine has been shown to maintain persistent bactericidal activity after exposure to bodily fluids, which may explain its superior efficacy over other preoperative antiseptics in patients undergoing total joint arthroplasty [5].

Additionally, as described by Florschütz et al. [11], patients who have higher NHSN classification scores have a higher incidence of infection. This is consistent with our findings, because we found a higher proportion of infected patients in those with higher risk status. In addition, it is important to acknowledge that the proportion of patients is not equal between the study and comparison cohort in each risk cohort; however, because we have independently compared these cohorts and none of these were significantly different, we believe that this does not skew our results.

This study showed that application of an advanced preoperative 2% chlorhexidine gluconate cloth on the night before and the morning of surgery is associated with reduced risk of periprosthetic infections after THA when compared to patients who received standard perioperative antiseptic measures only. However, when stratifying our patients by NHSN classification, we did not find a reduction in the risk of developing an infection. An effective chlorhexidine cloth protocol could reduce the periprosthetic infection rate in this patient population, which is projected to increase dramatically in the near future [19]. By minimizing these infection rates, we can help reduce the economic burden to the patients, institutions, and overall healthcare system as well as the risks of marked morbidity and mortality associated with these infections. Although future multicenter randomized trials will need to confirm these preliminary findings, the intervention is inexpensive and is unlikely to be risky, and might be considered on the basis of this retrospective, comparative study. These studies can also determine the factors that influence patient compliance. In addition of confirming our findings, with a larger cohort studies, the effect of potential confounding factors on the incidence of infections such as comorbidities and operative time can be clarified.

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