No Infection Reduction Using Chlorhexidine Wipes in Total Joint Arthroplasty

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Abstract

Background Surgical site infection (SSI) after total joint arthroplasty (TJA) is a rare but devastating complication. Various skin antiseptic applications are used preoperatively to prevent SSI. Recent literature suggests 2% chlorhexidine gluconate (CHG) wipes reduce microbial content at surgical sites, but it is unclear whether they reduce rates of SSI.

Questions/purposes We compared the SSI rates between TJAs with and without CHG wipe use (1) with all TJAs in one group and (2) stratified by surgical subgroup (THA, TKA).

Methods We retrospectively reviewed all 3715 patients who underwent primary TJA from 2007 to 2009. CHG wipes were introduced at our facility on April 21, 2008. We compared SSI of patients before ($n = 1824$) and after ($n = 1891$) the introduction of CHG wipes. The wipes were applied 1 hour before surgery. There were 1660 patients

with THA (845 CHG, 815 no CHG) and 2055 patients with TKA (1046 CHG, 1009 no CHG). Infections were diagnosed based on the Musculoskeletal Infection Society Guidelines for periprosthetic joint infection. All patients were tracked for 1 year.

Results SSI incidences were similar in patients receiving (1.0%, 18 of 1891) and not receiving (1.3%, 24 of 1824) CHG wipes. In patients with THA, there was no difference in SSI between those receiving (1.2%, 10 of 845) and not receiving (1.5%, 12 of 815) CHG wipes. In patients with TKA, there also was no difference in SSI between those receiving (0.8%, eight of 1046) and not receiving (1.2%, 12 of 1009) CHG wipes.

Conclusions Introduction of CHG-impregnated wipes in the presurgical setting was not associated with a reduced SSI incidence. Our analysis suggests CHG wipes in TJA are unnecessary as an adjunct skin antiseptic, as suggested in previous smaller studies.

Each author certifies that he or she, or a member of his or her immediate family, has no funding or commercial associations (eg, consultancies, stock ownership, equity interest, patent/licensing arrangements, etc) that might pose a conflict of interest in connection with the submitted article.

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Introduction

Surgical site infection (SSI) after total joint arthroplasty (TJA) is a rare but devastating complication for patients. Approximately 230,000 THAs and 540,000 TKAs were performed in the United States in 2006, while the annual number of TJAs is increasing and is projected to reach a total of 4 million by 2030 [20, 33]. The rates of SSI after primary TKA and THA range from 0.39% to 2.9% and 0.2% to 2.2%, respectively, with SSI rates increasing annually [15, 21, 29, 32, 34]. Additionally, the incidence of SSI after TJA may be underestimated, as nearly ¼ of SSIs are late onset and occur after 2 years [31].

Complications associated with SSIs include increased risk of readmission [35], prolonged length of hospital stay [8, 12, 21, 23, 35], and increased risk of mortality [7, 18, 19]. Further, SSI is one of the most common reasons for TJA failure requiring revision [3, 4, 24]. SSI also increases healthcare costs, as patients with SSIs cost twice as much as noninfected patients [5] and costs range from USD 24,344 [35] to USD 43,970 [18]. Several studies [30, 31] have shown even a modest reduction in SSI rate (eg, 1.1%–1.5% reduction) through infection control initiatives may be cost-effective. Thus, a reduction in SSI rates can lead to both better clinical outcomes for patients and cost savings for hospitals.

Various strategies employed to prevent SSI include preoperative nasal decolonization of *Staphylococcus aureus* [2, 31], administration of perioperative antimicrobial prophylaxis [6], and the preoperative use of a variety of antiseptic surgical skin preparation solutions and scrubs [27]. One such antiseptic substance is chlorhexidine gluconate (CHG), which historically has a proven record of reducing healthcare-associated infections in a diverse number of roles: preoperative showering and bathing, impregnated devices, and skin decolonization, among others [22]. Recently, a new application for CHG has been suggested [11]: a 2% CHG wipe. When a skin incision is made during surgery, any microorganisms on the skin may infect the exposed tissue and cause an SSI; preoperative skin antiseptics are therefore a valuable tool for reducing skin microbes before surgery and may prevent subsequent SSI. A 2% CHG cloth reportedly reduces the microbial skin burden before shoulder surgery and on abdominal incision sites and therefore may be reasonable as a preoperative antiseptic scrub in TJA [10, 11, 25]. The antimicrobial activity of CHG is vast: broad activity against gram-positive and gram-negative bacteria, including *Escherichia coli* and methicillin-resistant *Staphylococcus aureus* (MRSA) [17, 22]. Several studies [1, 26, 28] have

shown *E coli* and MRSA are the pathogens most often associated with SSI, making CHG well-suited for reducing SSIs.

We therefore (1) determined whether CHG wipes reduced the rate of SSI after TJA in a single medical center over a 15-month intervention period compared to a 15-month historical period before CHG wipe use and (2) compared the SSI rate between those receiving and not receiving CHG wipes when stratified by surgical subgroup (THA and TKA).

Patients and Methods

We retrospectively reviewed the records of 3715 patients who underwent elective primary TJA surgery between January 1, 2007, and July 31, 2009. CHG wipes were introduced at our facility on April 21, 2008. A total of 1825 patients were included in the preintervention cohort, and 1891 patients were included in the intervention cohort. All patients undergoing unilateral primary THA or unilateral primary TKA were included in the study. We excluded patients who had either simultaneous or staged bilateral TJA, children (younger than 18 years), revision TJA, active joint infections, and nonelective (eg, trauma) TJA. No patients were lost to followup. Our followup for all patients at our institution was 1 year from the date of surgery. A centralized databank monitors and reports all infections tracked out to a year; after a year, the infection is assumed to be unrelated to the surgery and the institution does not track them. No patients were recalled specifically for this study; all data were obtained from medical records and radiographs.

We conducted an a priori power calculation showing a study of 1329 subjects per cohort group had 80% power to detect a reduction in SSI rate from 2.5% to 1.0% at 5% significance. With two cohort groups (CHG wipe and no CHG wipe), the minimum sample size for this study was therefore 2658 total subjects.

A nurse applied the CHG wipes to the surgical incision area approximately 1 hour before surgery in the preoperative holding area; thus, there was 100% compliance. Before TKA procedures, the leg was wiped circumferentially from mid-tibia to midfemur, while before THA procedures, the leg was wiped circumferentially from midfemur to the iliac crest, but not including the gluteal cleft or anus. Before both TKA and THA, the upper extremities were wiped circumferentially from distal hands to elbow.

During both the preintervention and intervention time periods, all patients received an identical standardized infection prevention protocol, with the only difference being those in the preintervention cohort did not receive preoperative CHG wipes. The protocol included preoperative

patient education, preoperative hair clipping at the surgical site, use of a preoperative antiseptic skin preparation solution that varied by surgeon (povidone iodine [Betadine®], iodophor-in-isopropyl alcohol [DuraPrep®], or CHG and isopropyl alcohol [ChloroPrep®]), and treatment with prophylactic perioperative antibiotics. All patients received standard postoperative followup care.

After surgery, patients were monitored for subsequent development of SSI, with followup visits at 2 weeks, 6 weeks, 3 months, 6 months, 1 year, and then yearly. Joint radiographs were taken at each followup appointment and the surgical site was evaluated for SSI at every visit. If infection was suspected, then the following were collected during the visit: serum erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP), joint aspirate with fluid analysis, and culture of the joint aspirate. SSI in this study was defined using the guidelines published by the Musculoskeletal Infection Society (MSIS) [36]. According to MSIS guidelines, periprosthetic joint infection exists when (1) there is a sinus tract communicating with the prosthesis, (2) a pathogen is isolated by culture from at least two separate tissue or fluid samples obtained from the affected prosthetic joint, or (3) four of the following six criteria exist: (1) elevated serum ESR and serum CRP concentration, (2) elevated synovial leukocyte count, (3) elevated synovial neutrophil percentage (PMN%), (4) presence of purulence in the affected joint, (5) isolation of a microorganism in one culture of periprosthetic tissue or fluid, and (6) greater than five neutrophils per high-power field in five high-power fields observed from histologic analysis of periprosthetic tissue at $\times 400$ magnification. We obtained information concerning SSIs from our infection prevention and control department.

We collected the following demographic and procedural data from the electronic medical records of all patients: age, sex, American Society of Anesthesiologists (ASA) score [9], preoperative diagnosis, type of procedure, type of anesthesia, surgeon, laterality of procedure, operative time, and hardware removal. We found no differences in associated microorganisms ($p = 0.467$), age ($p = 0.380$), sex ($p = 0.953$), ASA score ($p = 0.806$), diagnosis ($p = 0.698$), type of procedure ($p = 0.364$), type of anesthesia ($p = 0.309$), and laterality ($p = 0.497$) between patients receiving and not receiving CHG wipes (Table 1).

We determined whether CHG wipes reduced the rate of SSI after TJA in a single medical center over a 15-month intervention period compared to a 15-month historical period before CHG wipe use using unpaired t-tests. We also compared the SSI rate between those receiving and not receiving CHG wipes when stratified by surgical subgroup (THA and TKA) with unpaired t-tests. The association with the use of CHG wipes and type of microorganism, ASA score, type of anesthesia, sex, age, and diagnosis was determined using

Table 1. Demographic and operative data

Variable	CHG wipe	No CHG wipe	p value
Number of patients	1891	1824	
Age (years)*	64.2 $\pm$ 12.4	64.6 $\pm$ 12.5	0.380
Sex (number of patients)			0.953
Male	798 (42.2%)	768 (42.1%)	
Female	1093 (57.8%)	1056 (57.9%)	
ASA class (number of patients)			0.806
1	30 (1.6%)	24 (1.3%)	
2	716 (37.9%)	687 (37.7%)	
3	1072 (56.7%)	1034 (56.7%)	
4	73 (3.9%)	79 (4.3%)	
Procedure (number of patients)			0.364
THA	845 (44.7%)	815 (44.6%)	
TKA	1046 (55.3%)	1009 (55.3%)	
Anesthesia (number of patients)			0.309
Spinal	1457 (77.0%)	1370 (75.1%)	
General	434 (23.0%)	451 (24.7%)	
Regional	0 (0%)	1 (0.1%)	
MAC	0 (0%)	1 (0.1%)	
Epidural	0 (0%)	1 (0.1%)	
Laterality (number of patients)			0.497
Right	941 (49.8%)	928 (50.9%)	
Left	950 (50.2%)	896 (49.1%)	
Diagnosis (number of patients)			0.698
DJD	1756 (92.9%)	1704 (93.4%)	
RA	15 (0.8%)	11 (0.6%)	
AVN	63 (3.3%)	60 (3.3%)	
Posttraumatic arthritis	17 (0.9%)	11 (0.6%)	
Tumor	7 (0.4%)	8 (0.4%)	
Dysplasia	7 (0.4%)	4 (0.2%)	
Fusion	2 (0.1%)	2 (0.1%)	
Psoriatic arthritis	1 (0.1%)	0 (0.0%)	
Failed previous implant	9 (0.5%)	4 (0.2%)	
Acute fracture	14 (0.7%)	20 (1.1%)	
Surgical site infection (number of patients)			
All	18 (1.0%)	24 (1.3%)	0.294
THA	10 (1.2%)	12 (1.5%)	0.607
TKA	8 (0.8%)	12 (1.2%)	0.327
Organisms (number of patients)			0.450
Culture negative	0 (0.0%)	2 (8.3%)	
MRSA	3 (16.7%)	1 (4.2%)	

Table 1. continued

Variable	CHG wipe	No CHG wipe	p value
MSSA	7 (38.9%)	11 (45.8%)	
<i>Enterobacter</i>	1 (5.6%)	1 (4.2%)	
Coagulase-negative <i>Staphylococcus</i>	0 (0.0%)	3 (12.5%)	
<i>Pseudomonas</i>	1 (5.6%)	0 (0.0%)	
<i>Enterococcus faecalis</i>	2 (11.1%)	1 (4.2%)	
<i>Klebsiella</i>	0 (0.0%)	1 (4.2%)	
<i>Diphtheroids</i>	1 (5.6%)	2 (8.3%)	
Group B <i>Streptococcus</i>	1 (5.6%)	0 (0.0%)	
<i>Peptostreptococcus</i>	1 (5.6%)	0 (0.0%)	
<i>Serratia marcescens</i>	1 (5.6%)	0 (0.0%)	
<i>Escherichia coli</i>	0 (0.0%)	1 (4.2%)	
No cultures	0 (0.0%)	1 (4.2%)	

* Values are expressed as mean $\pm$ SD, with range in parentheses; CHG = chlorhexidine gluconate; ASA = American Society of Anesthesiologists; MAC = monitored anesthesia care; DJD = degenerative joint disease; RA = rheumatoid arthritis; AVN = avascular necrosis; MRSA = methicillin-resistant *Staphylococcus aureus*; MSSA methicillin-sensitive *Staphylococcus aureus*.

chi-square tests. We performed all statistical analyses using PASW[®] Version 19.0 (SPSS, Inc, Chicago, IL, USA).

Results

The incidence of SSI between patients receiving CHG wipes preoperatively (1.0%, 18 of 1891) and patients not receiving CHG wipes (1.3%, 24 of 1824) was not different ($p = 0.294$; odds ratio [OR], 0.69; 95% CI, 0.38–1.27) (Table 1).

When stratified by type of surgical procedure (THA or TKA), we found no difference in incidence of SSI in patients receiving CHG wipes preoperatively compared to those not receiving CHG wipes in either the THA subgroup ($p = 0.607$; OR, 0.80; 95% CI, 0.34–1.87) or TKA subgroup ($p = 0.327$; OR, 0.59; 95% CI, 0.24–1.43) (Table 1). In the THA subgroup, there were 10 SSIs among 845 patients (1.2%) receiving CHG wipes preoperatively compared to 12 SSIs among 815 patients (1.5%) not receiving the wipes. Similarly, in the TKA subgroup, there were eight SSIs among 1046 patients (0.8%) receiving CHG wipes preoperatively compared to 12 SSIs among 1009 (1.2%) patients not receiving the wipes.

Discussion

The mortality and morbidity associated with SSI after TJA make its prevention important. A recent approach to SSI

reduction after primary TJA is the use of 2% CHG-impregnated cloths. Our institution added a 2% CHG cloth intervention to the preoperative prevention protocol with the goal of reducing SSIs. We compared the SSI rate of those receiving and not receiving CHG wipes before TJA (1) with all TJAs in one group and (2) stratified by surgical subgroup (THA and TKA).

We note several limitations of our study. First, we lacked a standard intraoperative antiseptic skin preparation solution. However, the choice of antiseptic skin preparation solution remained constant for each surgeon throughout the study and did not vary between cohorts. Second, we could not collect patient comorbidity data (eg, diabetes mellitus, coronary artery disease, etc) from the electronic medical record, making the conclusions of this study susceptible to selection bias. However, the large sample size of each cohort helps to reduce the risk of this bias. Third, the study was retrospective and comes with the inherent drawback that definitive conclusions cannot be drawn from this type of statistical analysis. However, the conclusions drawn can be used to generate hypotheses for future randomized, prospective studies. Fourth, our study was powered only to detect a difference in SSI of 1.5% between groups. Since we did not find a difference in SSI incidence between the CHG wipe group and non-CHG wipe group, the results may indeed represent a true-negative finding or may indicate the study was underpowered to detect a difference in SSI incidence reduction and represents a false-negative finding. The effect size of 1.5% was based on the previous literature, where 2% CHG wipes demonstrated a reduction in SSI incidence ranging from 1.6% to 3.0% [13, 14, 16, 37]. We included all consecutive patients meeting inclusion and exclusion criteria, and our sample size of 3715 was as large as possible given the data available at our institution at the time of the study. Fifth, our followup was limited to 1 year. As noted earlier, nearly 1/4 of SSIs are late onset and occur after 2 years [31]. Therefore, our incidence of infection may be underestimated, but we believe it speculative to presume infections beyond 1 year would be related to the surgery.

Three previous studies concluded CHG wipes reduce SSI incidence in patients with TJA (Table 2). However, these studies had multiple limitations. Eiselt [13], comparing CHG wipes to povidone-iodine scrubs, noted the institution had poor compliance with povidone-iodine scrubs. Thus, it is not surprising a compliant CHG wipe group had a lower SSI incidence than a noncompliant povidone-iodine group [13]. Johnson et al. [14, 16] and Zywiell et al. [37] had only 14% and 15%, respectively, comply with the CHG protocol. In addition, Johnson et al. [14, 16] published an erratum with an updated table that lists 67 patients as receiving the CHG wipes while the text reports 157 patients. This inconsistency makes accurate

Table 2. Comparison of preoperative CHG wipe studies within the literature

Study	Year	Type of surgery	Number of patients in CHG cohort	Number of patients in non-CHG cohort	Time of CHG wipe application	Application site	Limitations	Number of SSIs	p value
Eiselt [13]	2009	Primary and revision TJA	727	736	Night before and morning of surgery	Surgical site	No operative or demographic data, mixed primary and revision TJA data	CHG: 1.59%* Non-CHG: 3.19%*	None
Johnson et al. [14, 16]	2010	Primary and revision THA	157	897	Night before and morning of surgery	Head, neck, UE, LE, surgical site	Small sample size, mixed primary and revision THA data, CHG cohort in higher surgical risk category	CHG: 0 (0%) Non-CHG: 14 (1.6%)	0.231
Zywił et al. [37]	2010	Primary and revision TKA	136	711	Night before and morning of surgery	Neck, chest, back, abdomen, UE, LE, surgical site	Small sample size, mixed primary and revision TKA data	CHG: 0 (0.0%) Non-CHG: 21 (3.0%)	None
Current study	2012	Primary TJA	1891	1824	Morning of surgery	UE, surgical site, area surrounding surgical site	No comorbidity data	CHG: 18 (1.0%) Non-CHG: 24 (1.3%)	0.294

* Absolute number of SSIs was not provided, only the SSI rate; CHG = chlorhexidine gluconate; SSI = surgical site infection; TJA = total joint arthroplasty; UE = upper extremities; LE = lower extremities.

interpretation of this study difficult. Finally, all three studies grouped primary and revision TJA together, despite the fact that revision TJA has higher SSIs [21, 24]. In contrast, our study had the benefit of a much larger sample size, inclusion of only primary TJA surgeries, and perfect compliance with the protocol. One methodologic difference that may explain the difference in results between our study and the previous three is the number of wipe applications. Our study had a single application the morning of the surgery by a nurse, while other studies wiped the night before and the morning of surgery. A study by Edmiston et al. [10] indicated application both the night before and morning of surgery delivered a CHG concentration to the skin 349.1 times the concentration required to kill *Staphylococci* isolates, compared to a concentration of 198.3 and 87.2 for only morning of surgery application and only evening before surgery application, respectively. Therefore, the dual application may have contributed to the reduction in SSI rate if SSI rate correlates with skin CHG concentration. Another variable to consider is the area of CHG application (Table 2). The additional microbial burden removed during the full-body disinfection in the studies of Zywił et al. [37] and Johnson et al. [14, 16], as opposed to our more limited sites of application, could have contributed to the lower SSI incidence.

Our findings call into question the previous reports [13, 14, 16, 37] that suggest using 2% CHG wipes leads to a reduction in SSI after primary TJA. Possible explanations for the difference in SSI incidence between our study and previous reports lie in the dual application of CHG in previous studies versus single application in our study and full-body application of wipes in previous studies versus more limited site application in our study (Table 2). Based on our findings, we do not recommend a single-use 2% CHG wipe on the day of surgery, as it may not be an efficacious or cost-effective infection prevention control measure. However, both the previous literature [13, 14, 16, 37] and our study are retrospective in design so further randomized, prospective study is needed to definitively answer the question of whether 2% CHG wipes reduce SSI incidence in a TJA population.

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