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Research Article

Does Standardization of Surgical Preparation Decrease Infection Rate in Closed Fracture ORIF?

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Abstract

Objective: To evaluate the effect of standardization of surgical prep on the deep infection rate for ORIF of closed fractures.

Participants and Methods: As part of a quality improvement project, a total of 738 surgical cases were identified with discrete, new onset, closed fractures that were treated with surgery following standardization of practice for surgical prep from September of 2016 through November of 2017 at an ACS level I trauma center. A retrospective chart review included prep type, compliance with dry times of surgical preparation and the surgical procedure. Patients with multiple fractures were given separate entries for fractures that occurred at different anatomical sites. Adequate follow-up for patients to be included in the study group was 6 weeks minimum at our facility. The endpoint was return to the OR for deep infection prior to fracture healing. Data from 2 years prior to instituting the protocol served as the control group.

Results: Out of 738 patients, 25 patients (3.38%) returned to the OR for deep infection. The historical control infection rate for the previous 2 years was 5.7% (105/1827). Therefore, the standardization project led to a decrease of 2.32%. A Z-test showed a statistically significant decrease in infection risk with a z-score of 2.466 (P=.0068 95% CI .007-.04). 542/738 (73.4%) followed standardization procedures as described. 702/738 (95.1%) used chlorhexidine containing solution as the final step and complied with dry times before incision.

Conclusion: Standardization of surgical prep in the setting of ORIF of closed fractures significantly decreased the risk of post-operative infection requiring operative debridement. Standardizing the surgical prep minimizes confusion by staff who perform the prepping and increases consistency. These effects were seen in the setting of using an alcohol pre-prep followed by use of an alcohol-based chlorhexidine final prep.

Keywords: Surgical Preparation; Infection Rate; Closed Fracture; ORIF

Introduction

Surgical Site Infections (SSIs) are a major cause of financial burden and disability for patients. In the orthopedic trauma population, a number of proposed factors contribute to the rate of SSIs compared to elective surgery populations, including lack of pre-operative optimization due to the unexpected nature of the trauma, no preoperative decolonization and concomitant host factors. According to the CDC in their 2017 guidelines for the prevention of surgical site infections, SSI is defined as an infection of the incision, organ or space that occur after surgery [1]. The economic burden of SSIs is an estimated 1.5 billion dollars per year across all specialties [2].

Risk factors for developing SSIs include smoking and comorbid Diabetes Mellitus (DM) [3]. Lee, et al., identified additional risk factors for SSI in patients undergoing bone grafting procedures, including increased age, male gender, lower income, tuberculosis, DM and Acquired Immune Deficiency Syndrome (AIDS) [4]. For specific fractures, Yanbin, et al., identified a history

of smoking or open fracture as SSI risk factors in tibial plateau fractures [5].

Skin bacteria (*staphylococcus aureus* and coagulase negative staphylococcus) are the most common cause of SSIs, making surgical skin preparation a crucial issue [6,7]. Infection after Open Reduction and Internal Fixation (ORIF) of closed fractures leads to an average of two additional surgeries, 300% increase in average cost and increases the risk for fracture delayed union and nonunion [2,4,8].

Perioperative skin preparation using antimicrobial solutions remains a cornerstone of standard surgical care.1 Alcohol-based solutions containing Chlorhexidine Gluconate (CHG) are recommended for orthopaedic surgeries due their spectrum of antibiotic activity, duration of action and onset of effect [6,7,9,10]. Combination with fast acting alcohol further expands antimicrobial coverage to include gram negative and mycobacterial organisms [10]. The CDC in 1999 established guidelines for standardization of surgical preparation to prevent SSI, with subsequent updates in 2017 [1]. They made evidence-based recommendations including patient risk factors, definitions for surgical site infections, antimicrobial prophylaxis, sterile procedures in the OR and the use of antiseptic agents on the skin, but did not specify the type or technique given the paucity of data at the time [9]. However, given the broad range of agents available, a superior agent or combination of agents and technique has not been identified for orthopaedic surgery. A recent study by Schmitt, et al., standardized multiple aspects of fracture care including closure type, prep type and other factors and included open fractures in the study design and found a very low overall infection rate [11]. A recent Cochrane, review found weak evidence that chlorhexidine compounds in alcohol may provide a slight advantage of iodine containing solutions in all types of surgery [12]. The World Health Organization has a "strong" recommendation for chlorhexidine containing compounds over povidone-iodine aqueous solutions, but only a low to moderate level of evidence to support that recommendation [13].

The technique for site preparation is also important, however, there is a relative paucity of peer-reviewed evidence regarding comparative effectiveness of various methods. One study showed no significant differences between a vigorous scrub and the "paint" technique for SSI after abdominal surgery [14,15]. Because resident physicians, attending physicians, medical students, nurses, nursing students and other operating room personnel may participate in surgical site preparation in the orthopaedic trauma setting, antiseptic agent and preparation technique should be standardized based on best current evidence for prevention of SSI. The purpose of this study was to determine the effects of standardization of the components of surgical site preparation on SSI rate for patients undergoing closed fracture ORIF at an academic ACS level I trauma center.

Methods

With institutional review board approval (IRB # 2006501), patients that underwent closed fracture ORIF from October of 2016 through November of 2017 at an academic ACS level I trauma center were included for analysis. Exclusion criteria included open fractures, ORIF for any reason other than an acute closed fracture, previous nonunion or SSI in the same location, allergies to surgical site preparation components, noncompliance with the standardized surgical site preparation, and/or inadequate follow-up. Data collected for analysis included preparation type (solution(s)), compliance with dry times of surgical preparation and the surgical procedure(s) being performed. Patients with multiple fractures were assigned individual entries for fractures at separate anatomic locations. For example, a patient with tibia/fibula fracture was assigned one entry, while a patient with a distal radius fracture and a tibia/fibula was assigned two separate entries. Adequate follow-up for patients to be included in the study was 6 weeks to identify acute infections.

Standardization of surgical site preparation consisted of 3 primary components: preparation type, personnel and technique. For prep type, preliminary scrub to optimize mechanical debridement using 4% CHG solution applied with sponges, from the standard surgical preparation kit, for at least 30 seconds, immediately followed by 70% isopropyl alcohol using a paint technique with a foam applicator from the standard surgical preparation kit. Patients who were allergic to CHG were excluded. The alcohol was blotted dry using sterile towels and was allowed to dry completely. The final step in preparation used Chloraprep (3M, St. Paul, MN) solution applied using sterile technique and 3 minutes was allowed to pass per the manufacturer recommendations before final draping with an adhesive barrier, if used or surgical incision. The final step of sterile application of Chloraprep was performed by the circulating nurse. Compliance with standardization was evaluated. To assess the compliance, a thorough chart review was performed that characterized the combination of preparation solutions used, as well as compliance with dry times of prep.

The primary endpoint was defined by documented deep surgical site infection as determined by an infection requiring operative debridement denoted in the medical record. Patients with superficial infections treated nonoperatively were not considered SSIs for the analysis performed in this study.

Statistical Analysis

Data from the study population were compared to historical controls, which were compiled using the same inclusion and exclusion criteria applied to patients at our institution that underwent closed fracture ORIF from January 2014 through September of 2016 prior to the implementation of the surgical preparation standardization. Based on the nature of the study design which included continuous cases treated before and after an evidence-based shift in practice for orthopaedic trauma patient surgical preparation, case-control matching based on patient demographics, fracture type, operation or surgical time was not possible. To determine the effects of surgical site preparation method on SSI rate, a Z-test for the comparison of two proportions was used to compare the standardized protocol cohort to the historical control. The rejection region for our test was set zc=1.64 and our z-value was computed to 2.466. Our null hypothesis was rejected (z=2.466 > zc=1.64).

Results

For the 1,827 cases included in the historical control group, the deep SSI rate was 5.7% (n=105). For the 738 cases included following standardization of surgical preparation, the deep SSI rate was 3.4% (Table 1 and Fig. 1). As such, standardization of the surgical preparation protocol for patients undergoing closed fracture ORIF was associated with a statistically significant reduction in SSI (P=0.0068, 95% CI .007-.04) at our institution. The Absolute Risk Reduction (ARR) of SSI was 2.32% while the relative risk reduction (RRR) of SSI was 41%. Table 2 shows monthly breakdown by number of closed fracture ORIF cases and infections.

Standardization Measures

In total, 542 of the 738 cases (73.4%) used chlorhexidine/alcohol paint in combination with a final Chloraprep and complied with the standardized protocol for use of both products. Overall, 95.1% (702/738) cases used a CHG containing solution with compliance with final dry time. In total, 90.7% (669/738) of the cases used alcohol paint as the part of the first scrub of the skin preparation. For the remaining cases (n=69), a combination of agents including betadine scrub, Dial soap or chlorhexidine/alcohol, Chloraprep or CHG as a standalone aseptic preparation agent was used (Table 3).

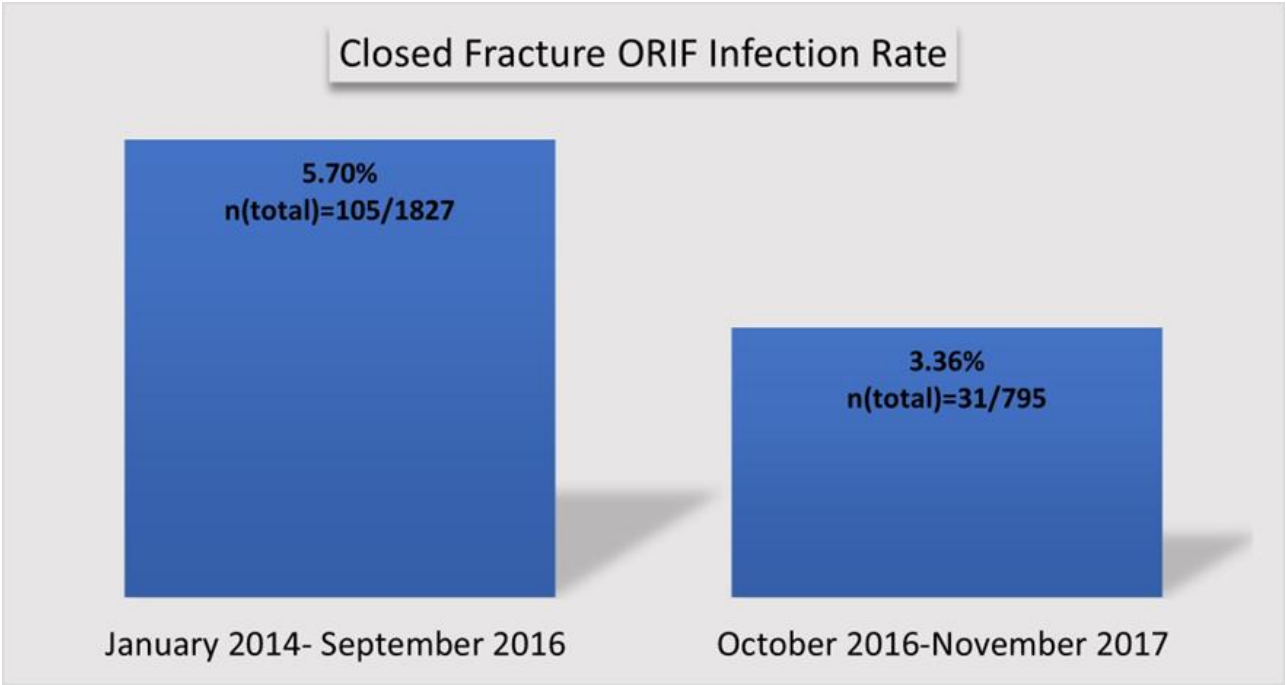

Figure 1: Closed fracture ORIF pre- and post-intervention. Z-test was performed for comparison of two means with a p-value = .0068.

Patients Category	No Infection	Deep Infection	P-value
Pre-Standardization	1722 (94.3%)	105 (5.7%)	
Post-Standardization	713 (96.64%)	25 (3.38%)	.0068

Table 1: Deep infection.

Month	Cases	Deep Infection
Sep-16	47	1
Oct-16	50	0
Nov-16	49	2
Dec-16	70	4
Jan-17	40	0
Feb-17	32	1
Mar-17	55	1
Apr-17	30	1
May-17	45	3
Jun-17	53	5
Jul-17	69	2
Aug-17	52	1
Sep-17	64	2
Oct-17	50	2
Nov-17	32	0
Totals	738	25

Table 2: Monthly breakdown of closed fracture ORIF cases and subsequent infection.

Agent Used	First Scrub			Second Scrub		
	Dry Time Compliant			Dry Time Compliant		
	Yes	No	Total (Agent Used)	Yes	No	Total (Agent Used)
Alcohol	62	4	66	0	0	0
Alcohol/CHG*	553	97	650	6	1	7
CHG*	2	0	2	11	0	11
Chloraprep	3	0	3	685	32	717
Betadine/Iodine	5	0	5	2	0	2
Dial Soap	0	0	0	1	0	1
Totals (Dry Time)	625	101	726	705	33	738
*CHG= Chlorhexidine Gluconate						

Table 3: Compliance with standardization of various agents.

Discussion

In this study, standardization of surgical site preparation consisting of 3 primary components related to preparation type, personnel and technique for patients undergoing closed fracture ORIF was associated with a 41% relative risk reduction in deep surgical site infection when compared to a control population of similar patients who did not undergo the standardized surgical site preparation. These data highlight the potential for standardizing patient care protocols to benefit outcomes after orthopaedic trauma and can be used to inform further optimization of surgical site preparation protocols. Given the dramatic reduction in deep infection rate for closed fracture ORIF cases in the present study, the protocol has been implemented for surgical site preparation for open fractures and polytrauma cases as an evidence-based shift in practice at our institution.

Compliance with dry times of various agents as well as technique in application remains an important component in determining the success of reducing surgical site infections requiring return to the OR. As seen in our study, changes such as type and technique of agent application may represent a crucial component of reducing infections. At the time of this study, it was not

known whether the circulating nurse was performing the final preparation, although it was part of the initial education regarding this intervention. It is well understood in the orthopedic traumatology department at this institution that this is the formal responsibility of the circulating nurse.

The PREP-IT trial is the largest study to date evaluating skin preparation in lower extremity trauma for both open and closed fractures [16]. This was a cluster-randomized crossover trial that compared iodine combined with alcohol (iodine povacrylex) and chlorhexidine in alcohol for skin preparation. They compared superficial (30 days) and deep infection (90 days) infection rates. There were 6785 closed fracture and 1700 open fracture patients from 25 hospitals. Of note, specific preparation technique and compliance with drying time was not recorded. In the closed fracture group, similar to ours, there was a 2.4% (77/3205) SSI rate in the iodine group and 3.3% (108/3272) in the CHG group. Our study only looked at return to OR for deep infection. In the PREP-IT trial rates for deep infection was 0.9% (29/3205) with an unplanned reoperation rate for infection of 3.3% (98/2982) in the iodine group compared to 1.7% (54/3272) with an unplanned reoperation rate for infection of 3.8% (117/3047). We defined deep infection as return to OR for debridement. Our study with Chloraprep with CHG and alcohol pre-prep had a deep infection rate of 3.38% (25/738). By standardizing the protocol, our relative risk reduction was 44% compared to the historical control group.

Our study does have limitations. We used a historical case control to establish a baseline for our infection rate and used retrospective data to evaluate the change. We did not do cohort matching for this retrospective cohort study, however, having this at a single center with a similar patient population during both time periods makes it more pragmatic and mimics clinical practice. For example, if we separated out closed tibia fractures and closed distal radius fractures, the results would not be generalizable for such a common practice of surgical site preparation. Data from the study population were compared to historical controls, which were compiled using the same inclusion and exclusion criteria applied to patients at our institution that underwent closed fracture ORIF from January 2014 through September of 2016 prior to the implementation of the surgical preparation standardization. Based on the nature of the study design which included continuous cases treated before and after an evidence-based shift in practice for orthopaedic trauma patient surgical preparation, case-control matching based on patient demographics, fracture type, operation or surgical time was not possible. Limited data regarding follow-up time, fracture type, patient and demographics inhibited meaningful comparison of these points between control and intervention groups. However, given the patient population and the time span covering multiple seasons, there is likely to be low variability between these groups, although we cannot say definitively making this a limitation of our study. Ideally, we should have collected this data prospectively to increase the accuracy. The study was performed at a single center over a several year period for each group and therefore the risk of inter-group variability is likely to be low, although this cannot be confirmed with the available data. Alternatively, some may consider a single center study a limitation to its generalizability. But this data is generalizable for American College of Surgeons-verified Midwestern United States Level One trauma centers. Although there was over 95% compliance with using Chloraprep, dry time and use of alcohol for skin pre-preparation, prospective compliance documentation would improve accuracy. This was also similar to the compliance documented in the PREP-IT trial [16]. We did, however, use the electronic medical record which requires documentation of skin preparation. Furthermore, having different people do skin preparation doesn't equal same technique, etc., but having a standard protocol for something that all of those involved are trained to do makes it more generalizable. This is similar to the PREP-IT trial that only controlled the specific agent used [16]. Another weakness that may be noted is that there may be inadequate follow-up to establish patients as having deep infection. However, the time to deep infection was unknown in the historical control, making this an impractical point of comparison for our study. Since we started a new standardization, we did not set a fixed time that the initial chlorhexidine scrub/alcohol paint was supposed to dry before the application of the Chloraprep which may have affected the documentation of these findings. This does provide an opportunity for further standardization of the process in the future to assure accurate charting. In addition, several instances were noted of use of only alcohol prior to Chloraprep, which may represent inadequate space for charting of the initial pre-scrub using CHG solution. In relation to the use of Chloraprep, another data point which was not available is the surface area covered by each Chloraprep applicator and the compliance with this recommendation. Additionally, the ability of the staff member applying the prep to estimate surface area and determine adequate coverage of the area is unknown. This represents another area for future study.

Another point which must be raised is the effect of simple standardization of a process versus the agents used in the actual standardization. In other words, standardization using another regimen may result in similar results of lowering infection rates.

A prospective study would have to be undertaken which compared different regimens while controlling for confounding variables including patient demographics, comorbidities and fracture location. However, the PREP-IT trial, the best study to date for orthopaedic trauma did not do this because controlling these number of variables makes it less generalizable and furthermore, the study just evaluated the use of the agents, not specific techniques [16]. Standard surgical preparation techniques were assumed. Whereas our study raised the power of a standardization process with a more complex surgical site preparation technique that had a lower incidence of unplanned surgeries for infection compared to PREP-IT for closed fractures and a 44% relative risk reduction for deep infection-related surgeries compared to our historical controls. Although our data is retrospective, it can be used as a baseline for future studies looking at standardization for surgical site preparation protocols.

Another component of standardization that was not addressed in our study was presurgical scrubs preceding the day of operation. There are mixed results regarding the number of days for chlorhexidine scrubs before and after surgery, but there is one study to suggest whole body scrub with chlorhexidine was more effective than surgical area preparation by the patient. The CDC recommends implementing this cleansing at the latest the night before surgery.

Surgical prep agents can be divided into either water-based (povidine iodine, safe on mucous membranes) or alcohol-based. The 3 criteria for an effective skin prep agent include its immediate, persistent (residual) and cumulative antimicrobial efficacy. Optimization of these three characteristics remains the goal of skin preparation. The PREP-IT trial did use iodine povacrylex that allows the iodine compound to be combined with alcohol [16]. The ability to potentially combine these 3 criteria was the basis for using this iodine compound as opposed to povidine iodine. Other considerations include patient comfort and ease of removal following the operation, although these remain secondary concerns. Patient allergies to antiseptic agents as well as skin irritation are also important components to consider and patient allergies to these agents were not considered when analyzing the final compliance with the standardization efforts. Standardizing the process of surgical site preparation in patients undergoing closed fracture ORIF significantly reduced the risk of deep infection in our patient population.

Conflict of Interests

The authors declare that they have no conflict of interest in this paper.

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