



Preoperative decolonization to reduce infections in urgent lower extremity repairs

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Abstract

Purpose Medical implants and surgical site infections (SSIs) can be a burden on both patients and healthcare systems with a significant rise in morbidity, mortality and costs. Preoperatively, our practice of a chlorhexidine gluconate (CHG) washcloth bath or solution shower was supplemented with nasal painting using povidone-iodine skin and nasal antiseptic (PI-SNA). We sought to measure the effectiveness in reducing SSIs in patients undergoing repair of lower extremity fractures.

Methods A retrospective review of trauma patients undergoing orthopedic operations conducted at Conemaugh Memorial Medical Center from 10/1/2012 through 9/30/2016. The intervention period was 10/1/2014 to 9/30/2016 which included the addition of nasal painting with PI-SNA preoperatively. All patients were followed for 1 year prior to January 2013 and 30 or 90 days thereafter for the development of a SSI.

Results The pre-intervention group consisted of 930 cases with a 1.1% infection rate (10 SSIs). The intervention group consisted of 962 cases with a 0.2% infection rate (2 SSIs). This observed difference was statistically significant ($P=0.020$).

Conclusions This retrospective review of a methicillin-resistant *Staphylococcus aureus* decolonization protocol using CHG bath/shower and PI-SNA nasal painting revealed a significant decrease in the infection rate of patients undergoing lower extremity fracture repairs. We recommend its use without contraindications, but recognize that additional investigations are necessary.

Keywords MRSA · Fractures · Surgical site infection · Trauma · Povidone-iodine · Decolonization

Purpose

The Centers for Disease Control and Prevention (CDC) Healthcare-Associated Infection (HAI) Prevalence Survey estimated there were 722,000 HAIs in US acute care

hospitals in 2011, with 157,500 of these being surgical site infections (SSI) tied with pneumonia for the most common causes [1]. The Guideline for Prevention of SSI prior to 2013 defined SSI as infections that occur within 30 days post-operatively and up to 1 year after implantation of a medical device [2]. In January 2013, the CDC changed the surveillance period to 30 days for superficial SSI and 90 days for deep incisional or organ/space SSI following selected operative procedure categories including open reduction fracture. The term implant was no longer used as a criterion, rather specific operation categories as defined by the National Healthcare Safety Network (NHSN) [3, 4]. The most commonly reported source of SSIs is *Staphylococcus aureus* 30–33%, of these 49–53% are methicillin-resistant *S. aureus* (MRSA) [5–8]. SSIs carry a heavy burden on patients and the healthcare system, with costs of \$3.5 to \$10 billion annually [8]. There is also a higher risk of death as well as an increase of 7–11 additional postoperative hospital days in patients with SSIs [9].

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Schweizer et al. implemented a bundle protocol that successfully decreased *S. aureus* SSIs, using preoperative testing for colonization with eradication using mupirocin twice daily for 5 days and to bathe daily with chlorohexidine-glucanate (CHG) for 5 days. MRSA carriers were given vancomycin and cefazolin or cefuroxime for preoperative prophylaxis [10]. Bode et al. also decreased *S. aureus* SSI with screening and decolonization of nasal carriers of *S. aureus* in addition to CHG bath [11]. Gernaat-van der Sluis et al. in an unblinded study found that preoperative prophylactic treatment, without testing for colonization, of nasal *S. aureus* with intranasal mupirocin could reduce orthopedic wound infections [12]. Chimokowski et al. reduced overall sternal wound infections with prophylactic mupirocin intranasally also without testing for colonization [13]. The effectiveness of these regimens led us to implement our own protocol. In search for the best bundle we examined the costs and compliance of all options, as both were barriers to successful implementation and results in the literature [14, 15].

In our current study, we measured the effectiveness of PI-SNA the morning of surgery to decrease SSIs in patients undergoing lower extremity fracture repairs. Published studies using similar protocols have established a link between the decontamination and reduction in SSIs. We expanded the use of PI-SNA in surgical patients using this particular protocol in trauma patients undergoing urgent lower extremity fracture repair.

Methods

This is a single-institution, retrospective study at a rural community-based hospital. In keeping with the Cone-maugh Memorial Medical Center (CMMC) culture of continual improvement of patient care and outcomes, we have incorporated into the standard of care a preoperative PI-SNA nasal swab in patients undergoing operative repair of lower extremity fractures—with the main intent of decreasing infection rates of the most common organism in SSIs, *S. aureus*. The purpose of this project was to evaluate any change in the infection rate since the inception of nasal decolonization. Inclusion criteria were patients admitted to CMMC during October 2012 through September 2016, ≥ 18 years of age, having lower extremity fractures (i.e., hip/femur, knee, tibia/fibula and ankle) requiring surgical repair with hardware.

Through a retrospective data extraction from the trauma, operating room services, and infection control databases, common patients were correlated and combined into one dataset that was used for our evaluation. The decolonization protocol consisted of bathing patients with 2% CHG washcloths or Dynahex 4% CHG solution. One of these methods is completed the night before surgery, if possible, and the

morning of surgery. On occasion, the night bath/shower was omitted because the patients were admitted late in the evening or very early in the morning for urgent procedures, but the morning bath is always performed. PI-SNA preoperatively within 1 h of incision completed the decolonization protocol. Patients were administered standard preoperative antibiotics based on indications, the procedure, and allergy history. All patients were followed according to NHSN definitions for the development of a SSI (1 year postoperatively prior to January 2013 at which point after this date these patients were followed for 30 days for superficial SSI and 90 days for deep incisional or organ/space SSI). The patient information extracted and compared included presence of SSIs, American Society of Anesthesiologist (ASA) score, duration of surgery (DOS), sex, age, and ethnicity, see Table 1. The data also included history of autoimmune disease, cancer, cardiac disease, chronic obstructive pulmonary disease (COPD), dementia, diabetes mellitus (DM), hypertension, known previous infection, liver disease, obesity, peripheral vascular disease (PVD), and chronic kidney disease (CKD), see Table 2.

Statistical analysis and methodology included descriptive demographic statistics using the stated patient information. Homogeneity was tested between pre-intervention and intervention groups as well as no SSI and SSI groups. Potential risk factors were investigated using univariate analyses. Logistic regression was used to investigate the influence of appropriate predictors found during the univariate analysis on the development of a SSI postoperatively. Chi-squared test, Fisher's exact test, and the Mann–Whitney *U* test were used where appropriate. SPSS version 24 was used with an overall alpha set at 0.05.

Results

From October 1, 2012 to September 30, 2016 a total of 1746 unique trauma patients underwent a total of 1892 orthopedic operations to repair fractures of the lower extremities using hardware. In our pre-intervention period, October 1, 2012 to September 30, 2014, 862 patients were identified as the pre-intervention group. After the decolonization protocol was instituted on October 1, 2014, 884 patients were identified as having an orthopedic operation over the next 2 years and formed the intervention group. In the entire study population ($N = 1746$) every patient was involved in a traumatic injury resulting in a fracture of the lower extremity. The mean age of all patients was 67 years, 617 males and 1125 (65%) females. These 1,746 unique patients had 1892 surgeries in which the following clinical characteristics were recorded: 961 (51%) hypertension, 587 (31%) had known cardiac disease [i.e., coronary artery disease (CAD), heart failure (HF), myocardial infarction (MI), and atrial fibrillation (A-fib)],

Table 1 Demographics of patients in the pre-intervention and intervention groups

	Pre-inter- vention		Intervention		<i>P</i> value
	Count	%	Count	%	
Sample size, all surgeries	930		962		
SSI	10	1.1	2	0.2	0.020
MSSA	2		2		
MRSA	8		0		
ASA score					
1	47	5	35	4	0.231
2	267	29	316	33	
3	308	33	322	34	
4	303	33	284	30	
5	2	0	4	0	
Missing	3	0	1	0	
Duration of surgery, minutes					
< 150 min	877	94	897	93	0.336
≥ 150 min	51	40	63	45	
Missing	2	0	2	0	
Sample size, unique patients	862		884		
Sex					
Female	548	64	577	65	0.459
Male	312	36	305	35	
Missing	2	0	2	0	
Age, years					
< 65 years	350	41	391	44	0.125
≥ 65 years	512	59	493	56	
Missing	0	0	0	0	
Ethnicity					
White	841	98	858	97	0.534
Black	11	1	17	1	
Hispanic	1	0	0	0	
Am-Ind-Als	1	0	0	0	
Other	3	0	5	1	
Unknown	2	0	1	0	
Missing	3	0	3	0	

SSI surgical site infections; SA, *Staphylococcus aureus*; MRSA methicillin-resistant *Staphylococcus aureus*; ASA American Society of Anesthesiologist; AM-IND-ALS American Indian Alaskan

401 (21%) DM, 285 (15%) CKD, 258 (14%) had COPD, and 269 (14%) a history of dementia. Of the comorbidities from Table 2, 69% of the pre-intervention group had one or more comorbidities per case/operation with 19% having zero comorbidities. In the intervention group, 68% had one or more comorbidities per case/operation and 18% had none. There was an average of 3.53 comorbidities per case/operation for the pre-intervention group and 3.51 comorbidities per case/operation for the intervention group.

Patients in the pre-intervention and intervention groups were found to be homogeneous on ASA score, duration of

surgery (categorized into < 150 min and ≥ 150 min), sex, age [categorized into non-geriatrics (< 65 years) and geriatrics (≥ 65 years)], ethnicity (aggregated), and all clinical characteristics (Tables 1, 2). The change in SSI rate from 1.1% (10/930, pre-intervention) to 0.2% (2/962, intervention) was statistically significant (*P* value = 0.020). Based on our study time period, the annualized infection rates are found in Table 3. The univariate analysis between the SSI group and no SSI group (Table 4) showed homogeneity on ASA score, duration of surgery (categorized into < 150 min and ≥ 150 min), sex, age [categorized into non-geriatrics (< 65 years) and geriatrics (≥ 65 years)], ethnicity (aggregated), and all clinical characteristics except for cancer (*P* value = 0.045) and decolonization (*P* value = 0.020) using Fisher's exact test. These results were used to establish potential risk factors (*P* ≥ 0.05) for developing a SSI. Only cancer and decolonization were identified as possible risk factors and, therefore, were included as predictors in the multivariate logistic regression analysis. Both cancer [odds ratio (OR), 5.17 (95% CI, 1.37–19.53), *P* value = 0.015] and preoperative decolonization [odds ratio (OR), 0.18 (95% CI, 0.039–0.822), *P* value = 0.027] were shown to be statistically significant independent risk factors for developing a SSI postoperatively within the defined criteria per CDC.

Among the ten SSIs in the pre-intervention group, eight were MRSA and two were MSSA. Thirty percent (3/10) of these had a previous bacterial infection with all three being MRSA (> 2 years from surgery date). Both of the infections observed during the intervention period were MSSA. One of these patients was screened for nasal MRSA colonization over 1 year before surgery and was negative. The other patient had an open fracture initially repaired with external fixation and was positive at the second surgery. The clinical characteristics and demographics of these 12 are found in Tables 4 and 5, respectively.

Conclusions

In 2013, our hospital had a working team that included the infection prevention department and the operating room staff that monitored internal data for SSIs. Rates of SSIs at the end of 2012 were 1.21 per 100 procedures for the combined operations of coronary artery bypass graft, craniotomies, spinal fusions, fracture repairs, and hip and knee arthroplasty. The SSIs in all fracture repairs as a single category were 2.01 per 100 procedures at the end of 2012. At the end of 2013 the rates had dropped for fracture repairs to 0.78 per 100 procedures; however, throughout 2014, this rate increased to 1.69 by the end of that year. SSI rate is a high-profile measure that is continuously scrutinized and as such, ongoing efforts are actively pursued to drive the SSI rate to zero. This substantial increase prompted implementation

Table 2 Clinical characteristics for pre-intervention and intervention groups

	Pre-intervention		Intervention		Diff. (%)	P value
	Count	%	Count	%		
Sample size, all surgeries	930		962			
Clinical characteristics by documented ICD 9/10 codes						
Autoimmune dis.	20	2.2	33	3.4	1.3	0.0960
Cancer	55	5.9	76	7.9	2.0	0.1030
Cardiac	287	30.9	300	31.2	0.3	0.8820
COPD	126	13.5	132	13.7	0.2	0.9470
Dementia	128	13.8	141	14.7	0.9	0.5990
DM	214	23.0	187	19.4	−3.6	0.0630
Hypertension	491	52.8	470	48.9	−3.9	0.0890
Previous infection	18	1.9	27	2.8	0.9	0.2300
Liver disease	6	0.6	10	1.0	0.4	0.4540
Obesity	42	4.5	55	5.7	1.2	0.2520
PVD	27	2.9	32	3.3	0.4	0.6920
CKD	144	15.5	141	14.7	−0.8	0.6530

COPD chronic obstructive pulmonary disease, DM diabetes mellitus, PVD peripheral vascular disease, CKD chronic kidney disease

Table 3 Annualized infection rate for study period

Pre-intervention	
1.5% (7/476)	October 1, 2012 through September 30, 2013
0.7% (3/454)	October 1, 2013 through September 30, 2014
10 total infections from Oct 1, 2012 through Sep 30, 2014	
Total <i>S. aureus</i> is 0.42 infections/month or 5/year (8 total MRSA, 0.33/month)	
Intervention	
0.2% (1/484)	October 1, 2014 through September 30, 2015
0.2% (1/478)	October 2, 2015 through September 30, 2016
2 infections from Oct 1, 2014 through Sep 30, 2016	
Total <i>S. aureus</i> is 0.083 infections/month or 1/year (0 MRSA)	

MRSA methicillin-resistant *Staphylococcus aureus*

of our decolonization protocol in October 2014. The surgeries were targeted individually with the decolonization protocol to decrease SSI rates. In May 2013 hip and knee arthroplasty, March 2014 coronary artery bypass graft, craniotomies, and spinal fusions and in October 2014 all patients undergoing fracture repairs underwent implementation of the decolonization protocol. The trauma department took this opportunity to investigate the effectiveness of the decolonization protocol in a group of patients that were not represented in the current body of literature. A patient population due to the nature of the disease, in this case a traumatic accident, required admission to the hospital, thus the CHG bathe will be performed by nursing staff. Our patients were being operated on within 24 h, thus mupirocin would not be an option in these patients as it is needed to be applied for 5 days, so PI-SNA was the better option. We

took advantage of an opportunity to control compliance with this group of patients.

Our practice had previously consisted of washing patients with 2% CHG washcloths or a Dynahex 4% CHG solution shower, the night before surgery, if possible, and always the morning of surgery. In addition to the CHG wash, we chose PI-SNA over mupirocin, as mupirocin is required to be applied multiple times per day for up to 5 days before surgery for effectiveness. The work by Phillips et al. in a randomized trial compared nasal mupirocin ointment and PI-SNA, and found PI-SNA to be as effective as mupirocin and may be considered as an alternative to mupirocin. In the per protocol analysis, *S. aureus* deep SSI was seen in 5 of 763 surgical procedures in the mupirocin group and 0 of 776 procedures in the PI-SNA group ($P=0.03$) [15]. We also searched the literature for the efficacy of PI-SNA and found it was tested by Anderson et al. on porcine mucosa (PM) and human subjects. The infected tissue was treated with PI-SNA and resulted in a >2.0 log₁₀ CFU reduction in MRSA. The anterior nares of human subjects were swabbed with PI-SNA which significantly reduced resident *S. aureus* compared to saline at 1, 6, and 12 h post-prep. In addition, pretreatment of PM explants with PI-SNA prevented MRSA infection [16]. Bebeko et al. also examined the effectiveness in a preoperative decontamination protocol and they found a significant reduction in MRSA nasal carrier status in patients that received PI-SNA (2.2%) compared to (5.5%) in placebo group [17]. Also, we elected not to undergo preoperative colonization testing due to costs of the test and the low risks associated with prophylactic PI-SNA use. An important factor in creating our bundle was choosing a specifically manufactured PI-SNA product to use for the nasal swab versus an

Table 4 Univariate analysis of clinical characteristics for patients without and with a SSI

	No SSI		SSI		Diff. (%)	P value
	Count	%	Count	%		
Sample size, all surgeries	1880		12			
Clinical characteristics by documented ICD 9/10 codes						
Autoimmune dis.	53	2.8	0	0.0	−2.8	0.1000
Cancer	128	6.8	3	25.0	18.2	0.0450
Cardiac	584	31.1	3	25.0	−6.1	0.7640
COPD	256	13.6	2	16.7	3.0	0.6730
Dementia	267	14.2	2	16.7	2.5	0.6840
DM	396	21.1	5	41.7	20.6	0.1460
Hypertension	952	50.6	9	75.0	24.4	0.1450
Previous infection	44	2.3	1	8.3	6.0	0.2520
Liver disease	16	0.9	0	0.0	−0.9	1.0000
Obesity	96	5.1	1	8.3	3.2	0.4690
PVD	58	3.1	1	8.3	5.2	0.3170
CKD	283	15.1	2	16.7	1.6	0.7000

COPD chronic obstructive pulmonary disease, *DM* diabetes mellitus, *PVD* peripheral vascular disease, *CKD* chronic kidney disease

off-the-shelf PI product. Rezapoor compared off-the-shelf PI swabs to a specifically manufactured product and found that off-the-shelf PI swabs were not as effective at 4 h as the specifically manufactured product for *S. aureus* decolonization [18]. We used a specifically manufactured 3M™ skin and nasal antiseptic (5% povidone-iodine) PI-SNA product that is stated by the manufacturer to decrease nasal bacteria by 99.5%, including *S. aureus*. In the preoperative holding area, the patients were instructed to clean the inside of both nostrils with a tissue. A nurse opened the sterile package and dipped the swab in the PI solution stirring vigorously for 10 s. The swab was inserted into one nostril and rotated for 15 s covering all surfaces and then an additional 15 s focusing on the inside tip of the nostril. This was repeated three additional times with three new swabs for a total of two applications in each nostril.

Decreasing morbidity and mortality is an ongoing goal of hospital quality improvement programs. With SSIs accounting for the bulk of HAIs, minimization of SSIs can dramatically impact improvement of patient outcomes. The health-care costs associated with SSIs range from a mean of \$2,200 to \$73,533 per incident and result in a case fatality rate of 2.8% [19, 20].

Many bundles exist that include some combination of CHG bathing, CHG oral rinse, mupirocin or PI-SNA for decontamination and standard preoperative prophylactic antibiotics. These regimens have been well studied. Patient populations have varied from orthopedic, cardiothoracic, vascular, gastrointestinal, general surgical procedures as well as nonsurgical patients. Our study population was derived from all trauma patients with urgent lower extremity orthopedic repairs with hardware. With the addition of PI-SNA,

we created our own decolonization bundle and helped decrease SSIs from 1.1 to 0.2%. We found no other risk factor to be associated with development of SSI in trauma patients undergoing urgent repair of lower extremity fractures except for the presence of cancer and when PI-SNA was not used preoperatively.

The generalizability of our results may be limited due to its retrospective design, the focused population (trauma patients with lower extremity fractures undergoing urgent repairs), lack of ethnic diversity (98% Caucasian), and location (a rural community hospital). We also recognize that our protocol itself has some limitations, such as no post-nasal decontamination culture to test the efficacy of the PI-SNA. We elected not to undertake any screening cultures pre or post because we were sufficiently confident in the effectiveness of the PI-SNA, given the evidence in the current body of literature. The costs associated with universal decontamination are far more advantageous at \$16 per package compared to greater than \$60 for a MSSA/MRSA nasal culture. At our facility, we do not have hospital-wide data for screening nasal cultures pre- or post-protocol change. We do, however, obtain screening nasal cultures for *S. aureus* on all patients admitted to the intensive care unit and the step down unit. Although the results of these cultures are not representative of our population, these results nevertheless can help give insight into the prevalence of positive nasal *S. aureus* colonization. Since 2012, 1.8 positive screenings per month were recorded for the same time period as our study, pre- and post-protocol, on all patients admitted or transferred into these units.

The decrease in SSI rate among our trauma patients requiring lower extremity fracture repairs with hardware can be attributed to the use of PI-SNA as part of a decolonization

Table 5 Univariate analysis of demographics for patients without and with a SSI

	No SSI		SSI		P value
	Count	%	Count	%	
Sample size, all surgeries	1880		12		
ASA score					
1	82	4	0	0	0.807
2	581	31	2	17	
3	622	33	8	67	
4	585	31	2	17	
5	6	0	0	0	
Missing	4	0	0	0	
Duration of surgery, minutes					
< 150 min	1763	94	11	92	0.527
≥ 150 min	113	6	1	8	
Missing	4	0	0	0	
Sample size, unique patients	1734		12		
Sex					
Female	1116	64	9	75	0.556
Male	614	35	3	25	
Missing	4	0	0	0	
Age, years					
< 65 years	350	41	391	44	0.125
≥ 65 years	512	59	493	56	
Missing	0	0	0	0	
Ethnicity					
White	1687	98	12	100	0.869
Black	28	1	0	0	
Hispanic	13	1	0	0	
Am-Ind-Als					
Other					
Unknown					
Missing	6	0	3	0	

SSI surgical site infections; ASA American Society of Anesthesiologist; AM-IND-ALS American Indian Alaskan

protocol with CHG bath/shower and preoperative antibiotics. These results have not only met statistical significance, but the protocol is cost effective and simple to use, the products are widely available and familiar to medical professionals, plus the implementation is not complex. Multi-center studies are encouraged to test the effectiveness of decolonization protocols as well as broadening the protocol to other specialties and surgical procedures with implants. This protocol is currently being employed in our institution and has been expanded to other surgical specialties.

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Compliance with ethical standards

Conflict of interest Daniel S. Urias, Merin Varghese, Thomas Simunich, Shawna Morrissey and Russell Dumire have no conflict of interest to declare.

Informed consent Informed consent was not obtained as this was a retrospective study and only minimal personal health information (PHI) was collected. Following completion of data extraction, the data were de-identified with no link remaining to any PHI, and each case was randomly assigned a randomly generated study subject identification number.

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