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Effects of Preoperative Skin Preparation on Postoperative Wound Infection Rates: A Prospective Study of 3 Skin Preparation Protocols

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Abstract

OBJECTIVE—To compare the effects of different skin preparation solutions on surgical-site infection rates.

DESIGN—Three skin preparations were compared by means of a sequential implementation design. Each agent was adopted as the preferred modality for a 6-month period for all general surgery cases. Period 1 used a povidone-iodine scrub-paint combination (Betadine) with an isopropyl alcohol application between these steps, period 2 used 2% chlorhexidine and 70% isopropyl alcohol (ChloraPrep), and period 3 used iodine povacrylex in isopropyl alcohol (DuraPrep). Surgical-site infections were tracked for 30 days as part of ongoing data collection for the National Surgical Quality Improvement Project initiative. The primary outcome was the overall rate of surgical-site infection by 6-month period performed in an intent-to-treat manner.

SETTING—Single large academic medical center.

PATIENTS—All adult general surgery patients.

RESULTS—The study comprised 3,209 operations. The lowest infection rate was seen in period 3, with iodine povacrylex in isopropyl alcohol as the preferred preparation method (3.9%, compared with 6.4% for period 1 and 7.1% for period 2; $P = .002$). In subgroup analysis, no difference in outcomes was seen between patients prepared with povidone-iodine scrub-paint and those prepared with iodine povacrylex in isopropyl alcohol, but patients in both these groups had significantly lower surgical-site infection rates, compared with rates for patients prepared with 2% chlorhexidine and 70% isopropyl alcohol (4.8% vs 8.2%; $P = .001$).

CONCLUSIONS—Skin preparation solution is an important factor in the prevention of surgical-site infections. Iodophor-based compounds may be superior to chlorhexidine for this purpose in general surgery patients.

Surgical-site infection (SSI) represents a major source of morbidity and mortality among surgical patients.[1,2] Infection of the surgical wound can prolong hospitalization,[3] increase the rate of intensive care unit admission,[4] and significantly increase the cost of treatment.[5,6]

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Integral to the prevention of SSI is the adherence to aseptic techniques, one of which is the preoperative preparation of the operative site. Several skin preparation modalities are approved by the Food and Drug Administration and are in use in operating rooms today. ChloraPrep (Cardinal Health) is a commercially available combination of 2% chlorhexidine and 70% isopropyl alcohol. The combination of chlorhexidine and isopropyl alcohol (or 70% isopropyl alcohol alone) has significantly better immediate antimicrobial activity than does 4% chlorhexidine. Also, the combination of chlorhexidine and isopropyl alcohol has demonstrated better residual antimicrobial activity than either 70% isopropyl alcohol alone or 4% chlorhexidine alone.[7] In other trials, 2% chlorhexidine and 70% isopropyl alcohol demonstrated better immediate and long-term residual antimicrobial activity than did povidone-iodine alone.[8] This finding has been observed clinically as well: Maki et al[9] observed that cutaneous disinfection with chlorhexidine before insertion of an intravascular device and for postinsertion site care can substantially reduce the incidence of device-related infection, compared with cutaneous disinfection with povidone-iodine.

Another skin disinfectant solution, consisting of iodine povacrylex in isopropyl alcohol (DuraPrep; 3M), is commercially available and has become popular for surgical disinfection.[10,11] Iodine povacrylex in isopropyl alcohol solution may provide longer-lasting antisepsis than other iodophor-based products because, when placed on skin, it dries to a film of disinfectant. It has been suggested that this film may resist being washed away by fluids and blood and thus may provide potential for longer-term protection than traditional povidone-iodine.[12,13]

Limited studies have been conducted that compare these 2 agents with SSI as the main outcome measure. The present study sought to test the hypothesis that a departmental initiative standardizing preoperative skin preparation modality would have a significant effect on SSI rates on the basis of the skin preparation used. On the basis of central venous catheter data, we hypothesized that the use of a chlorhexidine-based preparation would be associated with the lowest risk of SSI.

METHODS

Adults aged at least 18 years who were undergoing general surgical procedures (gastrointestinal, colorectal, breast, oncologic, hepatobiliary, transplant, or endocrine surgery) at the University of Virginia Health System from January 1, 2006, to June 30, 2007, were included. These cases included elective and emergent cases and inpatients, outpatients, and patients admitted immediately following their procedure. Patients who did not receive the assigned preparation because of a personal history of allergy to the solution or one of its components or who for any other reason did not receive the assigned preparation were also followed up.

Before the initiation of the 18-month study, the following accepted infection control measures were standardized and implemented as part of a health system–wide SSI reduction program. These measures were based to a large extent on recommendations from the Surgical Infection Prevention and Surgical Care Improvement Project initiatives.[14]

1. Identification and treatment of infections remote to the surgical site before elective surgery.
2. Clipping of hair (if necessary) immediately before the operation, rather than shaving.
3. Use of established preoperative hand and/or forearm antisepsis by the surgical team with either iodophor- or chlorhexidine-based products.

4. Appropriate surgical attire and drapes.
5. Appropriate surgical antimicrobial prophylaxis. Specifically, 1 dose was given within 1 hour before incision, except for vancomycin, which was given 2 hours before incision; patients who were undergoing endocrine, breast, small bowel, or stomach procedures received cefazolin or, if allergic, clindamycin or vancomycin; patients who were undergoing colorectal surgery received cefoxitin or ertapenem or, if allergic, metronidazole and ciprofloxacin; antibiotics were re-dosed intraoperatively as needed; antimicrobial prophylaxis was not continued beyond 24 hours.
6. Preoperative mechanical bowel preparation with Phosphosoda (Fleet) and enemas for colorectal surgery patients.
7. Maintenance of normothermia (temperature more than 36.0° C) during the perioperative period.
8. Meticulous aseptic technique and appropriate tissue handling and surgical technique.
9. Adequate intraoperative and postoperative serum glucose control in diabetic patients (target, less than 150 mg/dL).
10. Maintenance of the postoperative dressing for 24–48 hours.

The efficacy of these measures in the reduction of SSI rates in our institution is reported elsewhere.[15,16] Standardization of these measures resulted in a 3.6% absolute risk reduction in SSI incidence for all general surgery patients[15] and a 9.7% absolute risk reduction among colorectal surgery patients.[16] The current project was undertaken in an effort to reduce SSI rates beyond the rates achievable by means of the previously mentioned evidence-based interventions. Three skin preparation solutions were compared. Each skin preparation solution was adopted as the preferred modality for a 6-month period for all included patients.

Period 1: Povidone-Iodine (January 1–June 30, 2006)

The first period used our baseline institutional standard preparation. When applicable, the umbilicus was prepared using 2 cotton swabs soaked in povidone-iodine soap (povidone-iodine 7.5%). Foam sponges or sterile gauze was then used to apply 3 consecutive applications of povidone-iodine soap in concentric circles, starting at the incision and moving outward. The surgical site was washed with a single application of 70% isopropyl alcohol in the same manner, and a sterile towel was placed over the surgical site and patted dry. The process was then completed with 3 consecutive applications of a 10% povidone-iodine paint that was allowed to dry before the application of sterile drapes. At the conclusion of the procedure, visible solution was washed from the patient with sterile warm water or saline before application of the surgical dressing.

Period 2: 2% Chlorhexidine and 70% Isopropyl Alcohol (July 1, 2006–December 31, 2007)

In preparation for period 2, surgical staff members were trained in the proper use of the 2% chlorhexidine and 70% isopropyl alcohol product by manufacturer representatives. When applicable, the umbilicus was prepared using 2 cotton swabs soaked in solution from the applicator. The applicator was then used to scrub the incision site in a back-and-forth manner for 30 seconds. Staff were instructed to continue the scrub for 2 minutes in moist areas. The solution was given adequate time to dry completely before the application of surgical drapes. Postoperatively, the dried solution was left in place for at least 24 hours before active removal.

Period 3: Iodine Povacrylex in Isopropyl Alcohol (January 1–June 30, 2007)

In preparation for period 3, surgical staff members were trained in the proper use of the iodine povacrylex in isopropyl alcohol product by manufacturer representatives. When applicable, the umbilicus was prepared using 2 cotton swabs soaked in solution from the applicator. The applicator was then used to paint the abdomen, starting at the incision site, in a single uniform application. The solution was given adequate time to dry completely before the application of surgical drapes. Postoperatively, the dried solution was left in place indefinitely without active removal.

The primary outcome measured was the occurrence of SSI conditioned on skin preparation assignment period. SSI was defined using established criteria from the Centers for Disease Control and Prevention/National Nosocomial Infections Surveillance system guideline for prevention of SSI.[17] We recorded patient demographic and past medical information as well as perioperative details, including procedure performed, wound classification, operative time, skin preparation solution used, estimated blood loss, and need for perioperative blood transfusion. Data were gathered by dedicated research nurses in a prospective fashion by means of the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) database. Our site's surgical clinical nurse reviewers used a variety of methods, including medical chart abstraction, physician interview, clinic visits, and calls to patients, to capture all demographic and outcome data.

Statistical Analysis

During the study design, a power analysis was performed. Using unpublished historical data from our ACS NSQIP database, we estimated a baseline SSI rate of approximately 6.5%. A hypothetical reduction to 4.0% with $\alpha = .02$ (adjusted for multiple comparisons) and $\beta = .30$ would require 1,060 patients per period, for a total of 3,180 patients. Approximately 2,300 general surgical procedures were performed at our institution in 2005. If one assumes a continuation of that operating rate, 18 months (6 months per period) would yield approximately 3,450 patients for analysis.

After data collection, preoperative patient characteristics, demographic characteristics, operative details, and outcomes for each of the 3 periods were compared using χ^2 analysis and analysis of variance, where appropriate. Patients were analyzed in the period corresponding to their surgery, regardless of the preparation actually received. Similar methodology was then used to compare the same characteristics for patients who were diagnosed with or without SSI.

A second analysis was then performed, examining outcomes on the basis of the preoperative skin preparation solution actually used. Logistic regression analysis examining the occurrence of SSI was performed. Variables included in the model were those that were found to have significant associations with SSI on univariate analysis ($P \leq .05$). Data organization and computation were accomplished using SAS, version 9.1.3 (SAS Institute).

RESULTS

From January 1, 2006, to June 30, 2007, at the University of Virginia Health System, 3,209 operative cases meeting inclusion criteria were followed up (period 1, $n = 987$; period 2, $n = 994$; and period 3, $n = 1,228$). The increase in cases during the third period may be attributed to an expansion of the number of available operating rooms. We identified 182 cases of SSI.

Patient demographic characteristics for each of the 3 periods are listed in Table 1. The 3 groups were not statistically different in terms of age, race, American Society of Anesthesiologists score for physical status, or distribution of wound classification.

Preoperative medical history distribution was also similar. No differences were observed in the frequency of diabetes, dialysis dependence, cancer, open wounds, steroid use, or preoperative weight loss. Minor variations were observed in the frequency of patients with a smoking history or preoperative sepsis and in sex. Mean operating room times were 13–14 minutes shorter in period 3, compared with the times in the other 2 periods ($P = .002$). Table 1 also includes preparation solutions actually used.

Table 2 lists SSI outcomes by period. The lowest SSI incidence (3.9%) was observed in period 3, compared with 6.4% in period 1 and 7.1% in period 2 ($P = .002$). Most of this difference was observed in the superficial SSI category. No differences were observed in the incidence of deep or organ/space SSI. When stratified by wound classification, similar statistically significant differences were seen in clean-contaminated wounds, with lower SSI incidence observed in period 3 (5.9%), compared with the SSI incidence in period 1 (8.7%) or period 2 (10.7%) ($P = .021$). Some patients had more than one type of infection, leading to a total number of infections that is higher than the number of subjects with infections.

Associations between demographic characteristics and SSI incidence are shown in Table 3. Factors associated with a higher incidence of SSI by univariate analysis included female sex (risk ratio [RR], 1.80; $P < .001$), diabetes mellitus (RR, 1.67; $P = .002$), cancer diagnosis (RR, 1.84; $P = .033$), preoperative sepsis (RR, 1.73; $P = .013$), and preoperative weight loss (RR, 2.17; $P = .003$). Operative times in patients with subsequent SSI were longer by a mean of 80 minutes ($P < .001$). Other factors with statistically significant associations with SSI included wound classification ($P < .001$) and preparation solution actually used ($P = .004$).

The relationship between preparation solution received and SSI outcome is further explored in Table 4. Lower SSI rates overall were seen in the povidone-iodine preparation group (4.8%) and the iodine povacrylex in isopropyl alcohol group (4.8%), compared with the SSI rates in the 2% chlorhexidine and 70% isopropyl alcohol group (8.2%) ($P < .05$). No difference was seen between the povidone-iodine group and the iodine povacrylex in isopropyl alcohol group ($P = .97$). The same findings were observed for superficial SSI, with lower rates seen with the use of povidone-iodine (3.2%) and iodine povacrylex in isopropyl alcohol (3.3%), compared with the use of 2% chlorhexidine and 70% isopropyl alcohol (5.4%) ($P < .05$). No differences were seen in the incidence of deep SSI and organ/space SSI subgroups when stratified by preparation solution used. When stratified by wound classification, no statistically significant differences were identified; however, a trend exists toward lower SSI rates in the clean-contaminated cases for iodine-based preparations (both iodine-based preparations, 6.5%), compared with SSI rates in the clean-contaminated cases for the chlorhexidine preparation (10.1%) ($P = .15$).

Given that no significant differences were found between the povidone-iodine preparation group and the iodine povacrylex in isopropyl alcohol group, the patient preparation variable was dichotomized to iodophor-based preparations (ie, the povidone-iodine and the iodine povacrylex in isopropyl alcohol) and the chlorhexidine-based preparation (2% chlorhexidine and 70% isopropyl alcohol). An analysis of rates for all SSIs as well as for superficial SSI, deep SSI, and organ/space SSI that compared iodophor-based preparations with 2% chlorhexidine and 70% isopropyl alcohol, stratified by wound classification, was performed. Lower infection rates were noted after the use of iodophor-based preparations for superficial SSI following clean procedures (infection in 4 [0.4%] of 930 patients for iodophor-based preparations and in 4 [1.8%] of 224 patients for 2% chlorhexidine and 70% isopropyl alcohol; $P = .028$) and for all SSI following dirty procedures (in 15 [7.5%] of 201 patients for iodophor-based preparations and in 12 [15.6%] of 77 patients for 2% chlorhexidine and 70% isopropyl alcohol; $P = .041$).

Table 5 presents the results of a logistic regression analysis predicting all SSI, including factors associated with SSI in Table 3. Because there was no difference between the povidone-iodine preparation group and the iodine povacrylex in isopropyl alcohol group by univariate analysis, these 2 preparations were again combined before analysis. Significant independent predictors of SSI in this model included female sex, clean-contaminated wound classification (compared with clean wounds), contaminated wound classification, dirty wound classification, and operating room time. The use of an iodophor-based preparation was associated with a lower incidence of SSI, but this difference did not reach statistical significance.

DISCUSSION

We report a single-center, prospective, phase 4, unblinded, protocol implementation comparison of the influence of 2% chlorhexidine and 70% isopropyl alcohol, iodine povacrylex in isopropyl alcohol, and our previous institution standard of povidone-iodine and isopropyl alcohol preoperative skin preparation on the incidence of SSI in patients who were undergoing general surgical procedures. The comparison was designed to answer, in a very pragmatic manner, the following question: which method of skin preparation, when applied as the recommended technique for all general surgery procedures, would be associated with the lowest risk of SSI? These comparisons were performed with the background of a fully evolved SSI risk–reduction initiative that had already yielded beneficial results[15,16] in a hospital where the reduction of SSI had already been identified as an institutional priority.

In our primary goal of lowering SSI rates by changing the standard preferred preoperative surgical skin preparation method, we were successful. We observed an absolute risk reduction of at least 2.5% for all SSI and at least 1.8% for superficial SSI in period 3 (iodine povacrylex in isopropyl alcohol), compared with the prior 2 periods, for all SSI. In the analysis of preparation actually received, no difference in the primary outcome was observed between the traditional povidone-iodine with alcohol preparation and the iodine povacrylex in isopropyl alcohol preparation; however, SSI infection rates were more than 3% higher with the use of 2% chlorhexidine and 70% isopropyl alcohol, compared with rates with the use of the 2 iodophor-based preparations. A strong trend in this direction was also observed in the multivariate analysis. These results suggest that preoperative skin preparation with iodophor compounds may be superior to 2% chlorhexidine and 70% isopropyl alcohol in preventing SSI following general surgical procedures.

The majority of studies of skin preparation solutions during the past several decades have focused on unvalidated surrogate end points. These include in vitro studies as well as studies that use skin surface and/or wound culture counts before and after the application of preparation solutions as end points.[7,10,11,18,19] For example, Jeng and Severin[12] exposed test solutions to inguinal and abdominal skin sites of human subjects and measured the log reductions in skin flora for each formulation. Ostrander et al[19] performed a randomized study of 3 skin preparation solutions for patients who were undergoing foot and ankle surgery, including the same chlorhexidine and iodine povacrylex preparations used in the present study. Quantitative culture results were used as the outcome. They found 2% chlorhexidine and 70% isopropyl alcohol to be the most effective agent for bacterial elimination. Although it is logical that skin flora reduction might translate unto reduced SSI rates, we could find no studies that validate this assertion.

Although no large studies in general surgical procedures examine SSI outcomes as they relate to the method of skin preparation, a number of studies examining the effect of skin preparation on catheter-associated bloodstream infections have been reported. When a

benefit is demonstrated, these studies tend to favor chlorhexidine over povidone-iodine solutions. In 2002, Chaiyakunapruk et al[20] performed a meta-analysis of 8 randomized clinical trials that examined catheter-associated bloodstream infection rates after assigned skin preparation. They found the summary RR for infection to be 0.49 for chlorhexidine, compared with povidone-iodine. More recently, Mimoz et al[21] published a randomized clinical trial that compared 5% povidone-iodine in 70% ethanol to a combination of 0.24% chlorhexidine gluconate, 0.025% benzalkonium chloride, and 4% benzylic alcohol for skin cleansing before catheter insertion and at subsequent dressing changes. Catheters in the chlorhexidine group had a lower incidence of bacterial colonization (11.6%, compared with 22.2%) and a statistically nonsignificant trend toward lower infection rates.

The finding of a lack of superiority of chlorhexidine in our study, compared with the findings of studies of central venous catheter insertion and care, was a surprise and probably relates to intrinsic differences in the procedures studied. Central venous catheter insertion is a procedure that is brief, creates a small defect in the skin, and is relatively clean in terms of contamination with bodily fluids. Open surgical procedures, on the other hand, generally take hours to perform, create much more extensive skin defects (even when performed laparoscopically), and may involve extensive contact of the wound with blood, serum, irrigation solutions, and not infrequently contaminated luminal contents from the gastrointestinal, genitourinary, or oropharyngeal tracts.

The current study has limitations that will prevent widespread application of its findings. First, the study was not randomized, although there were several scientific reasons for this. By means of a pragmatic study, we wished to analyze the effects of a widespread implementation of a protocol as is commonly seen in hospital practice. In addition, we wanted to maximize the consistency of preparation application and use (which would not occur if 3 different techniques were in use simultaneously) and keep the overall time frame short, to minimize the risk of other prevention measures being sequentially added and altering our results. Second, only a single center was studied, and local variation in patient populations, compliance, and other standards related to SSI prevention might have influenced the results. Clearly, reproduction of these results in multiple other centers would be needed before widespread recommendation of one skin preparation method over another. Third, the study was performed in a hospital where the minimization of SSI was seen as a priority and a stringent program had already been enacted to achieve this goal. A similar study in a hospital where other accepted prevention measures had not already been rigorously applied might yield different results. Fourth, only general surgery patients were studied. Whether similar results would be found for other subspecialties is not clear. Orthopedic surgery, for example, usually involves more soft-tissue destruction than does general surgery but rarely enters contaminated areas and might benefit from a different method of skin preparation. Fifth, compliance with use of both the 2% chlorhexidine and 70% isopropyl alcohol and iodine povacrylex in isopropyl alcohol preparations was only in the 70% range. These rates probably reflect what can be expected if similar protocols are implemented in other hospitals, perhaps increasing the clinical relevance of the findings.

Finally, the opening of additional operating rooms during the iodine povacrylex in isopropyl alcohol period may have altered the patient population seen, including more cases of decreased complexity that had previously been treated at our outpatient surgery center. This change might also explain the decreased operative time seen during the third period. This heterogeneity may account for the initial difference in infection rates seen between the povidone-iodine period and the iodine povacrylex and isopropyl alcohol period. Our further analysis and our multivariate analysis found no difference in our primary outcome between these 2 iodophor-based modalities.

Despite these limitations, the present report represents a large-scale study that examines clinically relevant interventions and end points in a real-world general surgery population. On the basis of the results of this study and surgeon preference, our institutional practice has changed, and iodine povacrylex in isopropyl alcohol is now used as the preferred preparation modality in general surgery cases. We suggest that adoption of this approach in other centers or other populations should be done only if SSI outcomes are consistently followed and analyzed.

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TABLE 1

Demographic Characteristics of Patients for 3 Periods of Prospective Study of Skin Preparation Protocols

Characteristic	Period 1 (*n* = 987 procedures)	Period 2 (*n* = 994 procedures)	Period 3 (*n* = 1,228 procedures)	*P*
Female sex	631 (63.9)	612 (61.6)	721 (58.7)	.042
Age, mean ± SD, years	53.0 ± 16.2	53.2 ± 15.6	52.9 ± 15.9	.91
Race				
White	825 (83.6)	824 (82.9)	973 (79.2)	.05
Black	123 (12.5)	136 (13.7)	193 (15.7)	
Other	39 (4.0)	34 (3.4)	62 (5.0)	
Medical history[a]				
Diabetes	146 (14.8)	177 (17.8)	160/962 (16.6)	.19
Smoking	739 (74.9)	780 (78.5)	762/962 (79.2)	.048
Dialysis dependence	22 (2.2)	17 (1.7)	15/962 (1.7)	.51
Cancer	34 (3.4)	33 (3.3)	42/962 (4.4)	.41
Open wound	38 (3.9)	37 (3.7)	30/962 (3.1)	.65
Sepsis	73 (7.4)	86 (8.7)	47/962 (4.9)	.004
Steroid use	67 (6.8)	59 (5.9)	72/962 (7.5)	.39
Weight loss	35 (3.5)	45 (4.5)	29/962 (3.0)	.20
ASA class ≥ 3	406 (41.1)	424 (42.7)	476/962 (40.1)	.48
NIH weight class[b]				
Underweight	27/962 (2.8)	25/961 (2.6)	27/937 (2.9)	.91
Normal	252/962 (26.2)	265/961 (27.6)	246/937 (26.3)	
Overweight	268/962 (27.9)	257/961 (26.8)	250/937 (26.7)	
Obese	254/962 (26.4)	232/961 (24.2)	243/937 (25.9)	
Morbidly obese	161/962 (16.7)	182/961 (18.9)	171/937 (18.2)	
Wound classification[c]				
Clean	376 (38.4)	355 (35.7)	438/1,138 (38.5)	.24
Clean-contaminated	460 (46.6)	469 (47.2)	530/1,138 (46.6)	
Contaminated	63 (6.4)	62 (6.2)	82/1,138 (7.2)	
Dirty	88 (8.9)	108 (10.9)	88/1,138 (7.7)	
OR time, mean ± SD, min	139 ± 103	140 ± 116	126 ± 97	.002
Preparation solution used				
Povidone-iodine base	970 (98.3)	261 (26.3)	283 (23.0)	<.001
Chlorhexidine	2 (0.2)	699 (70.3)	126 (10.3)	
Iodine povacrylex	0 (0)	0 (0)	794 (64.7)	
Other	15 (1.5)	34 (3.4)	25 (2.0)	

NOTE. Data are no. (%) or proportion (%) of surgical procedures, unless otherwise indicated. ASA, American Society of Anesthesiologists; NIH, National Institutes of Health; OR, operating room.

[a] Medical history data were not available for all patients in period 3.

[b] Data on weight class were not available for all patients in any period.

[c] Wound classification data were not available for all patients in period 3.

TABLE 2

Surgical-Site Infections (SSIs) and Wound Classifications, by Study Period

Variable	No. of SSIs	No. of surgical procedures	Period 1 (*n* = 987 procedures)	Period 2 (*n* = 994 procedures)	Period 3 (*n* = 1,228 procedures)	*P*[a]
SSIs						
All	182	…	63 (6.4)	71 (7.1)	48 (3.9)	.002
Superficial	123	…	43 (4.4)	48 (4.8)	32 (2.6)	.015
Deep	11	…	6 (0.6)	4 (0.4)	1 (0.1)	.088
Organ/space	50	…	14 (1.4)	19 (1.9)	17 (1.4)	.56
Wound classification						
Clean	…	1,169	5 (1.3)	5 (1.4)	4 (0.9)	.79
Clean-contaminated	…	1,459	40 (8.7)	50 (10.7)	31 (5.9)	.021
Contaminated	…	207	9 (14.3)	4 (6.5)	7 (8.5)	.30
Dirty	…	284	9 (10.2)	12 (11.1)	6 (8.8)	.57

NOTE. A single patient may have had more than 1 type of SSI.

[a]For pairwise comparisons with period 3.

TABLE 3

Associations Between Demographic Characteristics and Surgical-Site Infection (SSI)

Patient characteristic	No SSI (*n* = 3,027 patients)	SSI present (*n* = 182 patients)	*P*
Female sex	1,148 (37.9)	97 (53.3)	<.001
Age, mean ± SD, years	53.0 ± 15.9	53.1 ± 15.7	.94
Race			
White	2,467 (81.5)	155 (85.9)	.44
Black	432 (14.3)	20 (10.1)	
Other	128 (4.2)	7 (3.9)	
Medical history			
Diabetes	438/2,761 (15.9)	45 (9.3)	.002
Smoking	2,150/2,761 (77.9)	131 (72.0)	.065
Dialysis dependence	51/2,761 (1.9)	3 (1.7)	>.99
Cancer	97/2,761 (3.5)	12 (6.6)	.033
Open wound	100/2,761 (3.6)	5 (2.8)	.54
Sepsis	185/2,761 (6.7)	21 (11.5)	.013
Steroid use	183/2,761 (6.6)	15 (7.6)	.40
Weight loss	95/2,761 (3.4)	14 (7.7)	.003
ASA class ≥ 3	1,221/2,986 (40.9)	85 (46.7)	.12
NIH weight class			
Underweight	77/2,680 (2.9)	2/180 (1.1)	.50
Normal	709/2,680 (26.5)	54/180 (30.0)	
Overweight	725/2,680 (27.1)	50/180 (27.8)	
Obese	683/2,680 (25.5)	46/180 (25.6)	
Morbidly obese	486/2,680 (18.1)	28/180 (15.6)	
Wound classification			
Clean	1,155/2,937 (39.3)	14 (7.7)	<.001
Clean-contaminated	1,338/2,937 (45.6)	121 (66.5)	
Contaminated	1,87/2,937 (6.4)	20 (9.7)	
Dirty	257/2,937 (8.8)	27 (14.8)	
OR time, mean ± SD, min	130 ± 100	210 ± 161	<.001
Preparation solution used			
Povidone-iodine	1,442 (47.6)	72 (39.6)	.004
Chlorhexidine	759 (25.1)	68 (37.4)	
Iodine povacrylex	756 (25.0)	38 (20.9)	
Other	70 (2.3)	4 (2.2)	

NOTE. Data are no. (%) or proportion (%) of patients, unless otherwise indicated. Data were not available on all patients. ASA, American Society of Anesthesiologists; NIH, National Institutes of Health; OR, operating room; SD, standard deviation.

TABLE 4

Surgical-Site Infections (SSIs) and Wound Classifications, by Preparation Solution Actually Received

Variable	No. of SSIs	No. of surgical procedures	Povidone-iodine (*n* = 1,514 procedures)	Chlorhexidine (*n* = 827 procedures)	Iodine povacrylex (*n* = 794 procedures)	*P*[a]
SSIs						
All[b]	178	…	72 (4.8)	68 (8.2)	38 (4.8)	.001
Superficial	120	…	49 (3.2)	45 (5.4)	26 (3.3)	.019
Deep	11	…	6 (0.4)	4 (0.5)	1 (0.1)	.49
Organ/space	49	…	18 (1.2)	19 (2.3)	12 (1.5)	.12
Wound classification						
Clean	…	1,154	6/714 (0.84)	5/224 (2.2)	3/216 (1.4)	.21
Clean-contaminated	…	1,409	44/541 (8.1)	46/454 (10.1)	27/414 (6.5)	.15
Contaminated	…	204	9/82 (11.0)	5/65 (7.7)	6/57 (10.5)	.78
Dirty	…	278	13/150 (8.7)	12/77 (15.6)	2/51 (3.9)	.076

NOTE. Data are no. (%) or proportion (%) of surgical procedures, unless otherwise indicated. Data were not available on all surgical procedures.

[a]For pairwise comparison with chlorhexidine.

[b]Of the 182 SSIs in the study, 4 involved surgical procedures that did not use any of the defined preparation solutions, so the total here is 178.

TABLE 5

Logistic Regression Model Predicting Surgical-Site Infection (SSI) Occurrence by Means of Variables with Statistically Significant Univariate Associations

Variable	Odds ratio (95% CI)	*P*
Female sex	1.56 (1.14–2.15)	.006
Medical history		
Diabetes	1.46 (0.99–2.12)	.051
Cancer	1.39 (0.73–2.65)	.32
Sepsis	1.35 (0.78–2.34)	.28
Weight loss	1.28 (0.68–2.41)	.44
NIH wound classification		
Clean	Reference	
Clean-contaminated	5.35 (3.03–9.47)	<.001
Contaminated	6.84 (3.31–14.1)	<.001
Dirty	6.59 (3.25–13.4)	<.001
OR time, per minute	1.003 (1.002–1.004)	<.001
Preparation solution used		
Iodophor-based	Reference	
Chlorhexidine	1.35 (0.97–1.87)	.073

NOTE. R^2, 0.049; c statistic, 0.76. CI, confidence interval; NIH, National Institutes of Health; OR, operating room.