



Clinical Science

The impact of surgical hand antisepsis technique on surgical site infection

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ABSTRACT

Background: Limited evidence exists regarding the effect on superficial and deep incisional surgical site infections (SDSSIs) of alcohol-based hand rubs (ABR) versus traditional aqueous surgical scrubs (TSS). User preferences and practice are unknown.

Methods: A retrospective cohort study examining SDSSIs using VA Surgical Quality Improvement Program cases before ABR implementation (2007–2009, TSS group) and after (2013–2014, ABR group). A descriptive survey.

Results: SDSSI rates were 1.8% and 1.5% for TSS (n=4051) and ABR (n=2293), respectively (p=0.31). The adjusted odds of SDSSI using ABR was not significant (OR 0.82; 95% CI, 0.51–1.32). Greatest SDSSI risk was from preoperative radiotherapy (OR, 2.78; 95% CI, 1.14–6.78), general surgery (OR, 2.39; 95% CI, 1.30–4.39) and preoperative smoking (OR, 1.58; 95% CI, 1.02–2.44). Of 95 surveys included, 52% favored ABR. Although 95% self-reported correct product application, improper duration was revealed in both groups (TSS 18% and ABR 10%).

Conclusions: Implementation of an ABR for use in surgical hand antisepsis did not alter SDSSI rates. Improving product knowledge and compliance may improve SSI rates.

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1. Introduction

Surgical Site Infection (SSI)-related morbidity, mortality and cost have been targeted by healthcare systems since the Deficit Reduction Act of 2005.^{1,2} These infections account for over 20% of all healthcare-associated infections which affect 4% of hospitalized patients annually.^{3,4} Factors which contribute to SSIs involve the patient, the operating room environment, equipment sterilization, surgical and aseptic technique and hand hygiene.^{5,6}

To focus on hand hygiene, surgical hand antisepsis targets both transient and resident skin flora.^{7,8} By reducing the microbial inoculum, it is assumed that SSI rates will be reduced. Although evidence exists that the degree of microbial inoculum correlates

with clinical outcomes, the precise relationship between the two remains elusive.^{9–11} Most of the available literature uses surrogate endpoints rather than clinical outcomes to evaluate product effectiveness.^{6,7,11–15} Studies evaluating SSI rates have, thus far, shown equivalence between alcohol-based hand rubs (ABR) and traditional aqueous surgical scrubs (TSS).^{16–19} While the most recently published Centers for Disease Control and Prevention (CDC) guidelines for prevention of SSIs in 1999 do not recommend any agent over another, the World Health Organization renders preference to ABRs.^{6,7}

From 2012 to 2014, the period following the addition of an ABR option for surgical hand antisepsis at our institution, we observed an increase in SSIs. This prompted us to remove the ABR from the operating room and to scientifically evaluate this relationship. We hypothesized that compared to TSS products alone, adding an ABR increases SSIs. In addition, we also sought to understand best practice techniques and preferences among personnel who practice surgical hand antisepsis.

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2. Material and methods

2.1. Study design

This is a local Veterans Affairs (VA) retrospective cohort study using prospectively collected data. The study was approved and granted waiver of consent by the VA Boston Healthcare System (VABHS) institutional review board and local VA Research and Development Committee.

2.2. Study population

All patients identified in the VA Surgical Quality Improvement Program (VASQIP) database who underwent surgery at VABHS between January 1, 2007 and December 31, 2009 and between January 1, 2013 and December 31, 2014. All ophthalmic surgery and oral and maxillofacial surgery cases along with any case designated as contaminated or dirty were excluded. The earlier time period served as the baseline period and was naturally limited to only TSS (e.g., chlorhexidine gluconate 4% and povidone-iodine 13%). The later time period corresponded to the study group during which an ABR (ethyl alcohol 70%) was incorporated as an alternative to TSS. The exclusion of the interval spanning January 1, 2010 to December 31, 2012 is explained by the intermittent availability of an ABR beginning in 2010 at VABHS with full institution occurring in February 1, 2012. This eliminated the unpredictable availability of an ABR between January 1, 2010 and February 1, 2012 and allowed through the end of December 2012 for users to acclimate to the new product.

2.3. Study database

VASQIP has been previously described.²⁰ In brief, it analyzes risk-adjusted 30-day morbidity and mortality data within the VA. It tracks demographic, preoperative risk and laboratory data, operative data and 30-day postoperative mortality and defined morbidity outcomes in select patients undergoing major surgery. The information is prospectively abstracted by a nurse reviewer trained in clinical medicine and quality assurance. The reviewer uses standard CDC National Healthcare Safety Network definitions of operative procedure category and SSIs to ensure data reliability.

2.4. Statistical analysis

The cases (ABR + TSS group) and controls (TSS group) were compared between categories of patient characteristics, intra-operative and outcomes variables using either the *t*- or χ^2 -test. A composite SSI outcome variable, "SDSSI," was created by combining superficial and deep incisional SSIs.

The unadjusted odds of developing an SDSSI related to patient and operative characteristics known to be predictive of SSI including ABR, sex, age, body mass index (BMI), race, diabetes, chronic obstructive pulmonary disease (COPD), dyspnea, congestive heart failure, alcohol use, preoperative smoking status, acute renal failure, dialysis, preoperative radiotherapy, steroid use, preoperative serum albumin, preoperative serum total bilirubin, preoperative transfusion >4 units packed red blood cells (PRBC), preoperative open wound, preoperative sepsis, surgical specialty, American Society of Anesthesiologists (ASA) classification, emergent surgery, wound classification, intraoperative transfusion, operation duration, work relative value unit (RVU) and total hospital length of stay were calculated.²¹ Compliance with SSI Surgical Care Improvement Project measures during both time periods as evaluated on a quarterly basis by the Veteran Health Administration External Peer Review Program varied between 97% and 100% for VABHS.

The adjusted odds of developing an SDSSI related to ABR implementation was subsequently calculated using a multivariate regression model, adjusting for significant covariates from our univariate analysis. Additionally, ABR implementation and ASA classification 3 were forced into the model secondary to clinical relevance.

Quarterly SDSSI rates over time were compared. Also, a within-group analysis was performed for the ABR + TSS period comparing quarters of high versus low SDSSI rates based on patient, intra-operative and postoperative characteristics. Lastly, patients from both TSS and ABR + TSS were selected using significant variables obtained from the within-group analysis and SDSSI rates were compared. All comparisons utilized either the *t*- or χ^2 -test. All analyses were completed using SAS v9.2 (SAS Institute Inc) with $\alpha = .05$.

2.5. Survey

One-hundred thirty-one anonymous paper surveys were distributed to all surgical and operating room personnel who perform surgical hand antisepsis at either of two campuses within VABHS. Participants represented all surgical specialties. The survey assessed product preference, product-specific patterns of use, surgical hand antisepsis education and product knowledge. Descriptive statistics were utilized as well as the χ^2 -test for user-specific comparisons.

3. Results

3.1. Retrospective cohort

Of 6,754 VASQIP cases transmitted within the pre-defined time periods, 6,344 (93.9%) met inclusion criteria: 4,051 TSS and 2,293 ABR + TSS (Figure 1). The characteristics of patients before (TSS period) and after the introduction of ABR (ABR + TSS period) are shown in Table 1. SDSSI rates for TSS and ABR + TSS were 1.8% and 1.5%, respectively ($P = 0.31$; Table 2).

Univariate analysis found the following variables to be significantly associated with a higher SDSSI rate: preoperative smoking (odds ratio [OR], 1.89; 95% confidence interval [CI], 1.29–2.76), preoperative radiotherapy (OR, 7.48; 95% CI, 3.50–15.99), preoperative transfusion (OR, 13.06; 95% CI, 2.79–61.15), preoperative open wound (OR, 2.63; 95% CI, 1.39–4.96), general surgery (OR, 1.95; 95% CI, 1.31–2.91), otolaryngology (2.46; 95% CI, 1.30–4.64), vascular (OR, 1.90; 95% CI, 1.21–2.99), ASA classification > 3 (OR, 2.86; 95% CI, 1.83–4.48), emergent surgery (OR, 3.18; 95% CI, 1.52–6.65), clean contaminated wound classification (OR, 2.31; 95% CI, 1.58–3.39), intraoperative PRBC transfusion (OR, 1.08; 95% CI, 1.03–1.13), operative duration (OR, 1.34; 95% CI, 1.27–1.42), work RVU (OR, 1.07; 95%

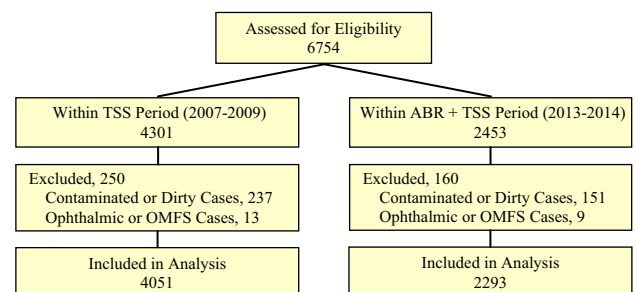


Fig. 1. Study Population (n) in Two Time Periods. Abbreviations: TSS traditional aqueous surgical scrub, ABR alcohol-based hand rub, OMFS oral and maxillofacial surgery.

Table 1
Characteristics of patients before and after implementation of an alcohol-based hand rub.

Characteristic	TSS (n = 4051)	ABR + TSS (n = 2293)	P Value
Patient Variables			
Male Sex (%)	91.7	90.7	0.16
Age, mean (SD), y	62.3 (13.4)	62.6 (12.9)	0.44
Body Mass Index, mean (SD)	29.0 (7.0)	29.3 (6.1)	0.14
Race (%)			
Hispanic, White	0.1	0.0	<0.001*
American Indian or Alaska Native	0.5	0.6	
Black, Not of Hispanic Origin	5.4	5.8	
Asian or Pacific Islander	0.9	0.5	
White, Not of Hispanic Origin	86.8	90.4	
Unknown	6.3	2.7	
Diabetic (%)	19.7	20.9	0.24
Chronic Obstructive Pulmonary Disease (%)	17.6	18.6	0.29
Dyspnea (%)	13.2	11.5	0.04*
Congestive Heart Failure (%)	0.5	0.5	0.77
Consumption >2 Drinks/Day, Within 2 Weeks (%)	6.6	7.1	0.45
Smoker, Within 1 Year (%)	35.4	34.0	0.25
Preoperative Acute Renal Failure (%)	0.1	0.1	0.89
Preoperative Dialysis, Within 2 Weeks (%)	0.9	0.6	0.19
Preoperative Radiotherapy for Malignancy, Within 90 Days (%)	1.4	0.7	0.02*
Preoperative Steroid Use for Chronic Condition, Within 30 Days (%)	1.4	1.5	0.87
Preoperative Serum Albumin, mean (SD), g/dl	3.8 (0.5)	3.7 (0.5)	<0.001*
Preoperative Total Bilirubin, mean (SD), mg/dl	0.6 (0.4)	0.6 (0.7)	<0.001*
Preoperative Transfusion, >4 units PRBCs Within 72 Hours (%)	0.3	0.0	0.01*
Preoperative Open Wound (%)	4.7	3.4	0.01*
Preoperative Sepsis (%)	0.4	0.2	0.13
Intraoperative Variables			
Surgical Specialty (%)			
Cardiac Surgery	0.7	0.4	<0.001*
General Surgery	20.3	25.0	
Gynecology	2.3	3.1	
Neurosurgery	9.5	7.6	
Orthopedic Surgery	26.0	22.6	
Otolaryngology	4.1	5.2	
Plastic Surgery	1.6	1.0	
Thoracic Surgery	8.5	8.9	
Urology	11.7	13.3	
Podiatry	0.6	0.7	
Vascular	14.7	12.3	
ASA Physical Status Classification (%)			
1	2.4	1.8	
2	23.4	25.4	
3	61.5	67.0	
4	12.4	5.6	
5	0.3	0.1	
Emergency Surgery (%)	2.8	2.1	0.06
Surgical Wound Classification (%)			
Clean	67.0	62.6	<0.001*
Clean Contaminated	33.0	37.4	
Intraoperative PRBCs, mean (SD), n	0.3 (1.6)	0.2 (1.5)	0.41
Total Operation Time, mean (SD), h	2.5 (1.9)	2.6 (2.0)	0.09
Work Relative Value Units, mean (SD), n	15.6 (9.3)	16.4 (9.3)	<0.01*

Abbreviations: TSS traditional aqueous surgical scrub, ABR alcohol-based hand rub, PRBC packed red blood cell, ASA American Society of Anesthesiologists.

*Indicates significance to $P < 0.05$.

CI, 1.06–1.09) and total hospital length of stay (OR, 1.01; 95% CI, 1.00–1.01). On the other hand, preoperative serum albumin (OR, 0.62; 95% CI, 0.44–0.88), orthopedic surgery (OR, 0.27; 95% CI, 0.14–0.54) and urology (OR, 0.20; 95% CI, 0.06–0.64) were significantly

associated with a lower SDSSI rate.

The c statistic for the multivariate regression model was 0.787 (Table 3). After adjusting for significant covariates from our univariate analysis along with ASA classification 3, ABR was not

Table 2
Outcomes of patients before and after implementation of an alcohol-based hand rub.

Characteristic	TSS (n = 4051)	ABR + TSS (n = 2293)	P Value
Any Surgical Site Infection (%)	2.6	2.3	0.39
Superficial Incisional Surgical Site Infections (%)	1.5	1.1	0.13
Deep Incisional Surgical Site Infections (%)	0.3	0.4	0.46
Superficial and Deep Incisional Surgical Site Infections (%)	1.8	1.5	0.31
Organ/Space Surgical Site Infections (%)	0.8	0.8	0.98
Length of Total Hospital Length of Stay, mean (SD), d	7.1 (18.7)	6.1 (13.1)	<0.01*

Abbreviations: TSS traditional aqueous surgical scrub, ABR alcohol-based hand rub.

*Indicates significance to $P < 0.05$.

associated with SDSSI rate (OR, 0.82; 95% CI, 0.51–1.32). Variables associated with a significantly higher SDSSI rate were preoperative smoking (OR, 1.58; 95% CI, 1.02–2.44), preoperative radiotherapy (OR, 2.78; 95% CI, 1.14–6.78), general surgery (OR, 2.39; 95% CI, 1.30–4.39), operative duration (OR, 1.13; 95% CI, 1.04–1.23) and work RVU (OR 1.03; 95% CI, 1.01–1.06).

The secular trend of SDSSI rates was examined between TSS and ABR + TSS as well as within the ABR + TSS period (Figure 2). The ABR + TSS period fluctuated between calendar quarters of high (Periods A—Q2 2013 and C—Q3 2014 to Q4 2014) and low (Period B—Q3 2013 to Q1 2014) SDSSI rates. Compared to TSS, no significant difference in SDSSI rates was noted in periods A and C ($P = 0.08$),

but rates in period B were significantly lower ($P < 0.01$). Within ABR + TSS, periods A and C combined demonstrated significantly higher SDSSI rates compared to period B (2.8% vs 0.6%, $P < 0.001$). Patients in periods A and C had higher rates of COPD (20.5% vs 16.4%, $P = 0.03$), higher ASA classifications ($P = 0.01$) and underwent procedures with higher work RVUs (mean $\pm$ SD; 17.2 ± 9.7 vs 15.9 ± 9.2 , $P < 0.01$) compared to period B (eTable 1 in the Supplement). Comparing TSS and ABR + TSS patients (total $n = 517$) with COPD, ASA classification >3 and work RVU > 21.6 (75th percentile) revealed no significant difference in SDSSI rates (3.43% vs 2.99%, $P = 0.8$; respectively).

Table 3

Univariate analysis and multivariate regression of superficial and deep surgical site infections.

Characteristic	Odds ratio (95% CI)	Adjusted Odds ratio (95% CI)
Patient Variables		
ABR	0.81 (0.54–1.22)	0.82 (0.51–1.32)
Male Sex	2.48 (0.91–6.77)	
Age	1.01 (1.00–1.03)	
Body Mass Index	0.98 (0.95–1.01)	
Race		
Hispanic, White	1.01 (0.14–7.38)	
American Indian or Alaska Native	—	
Black, Not of Hispanic Origin	0.877 (0.32–2.40)	
Asian or Pacific Islander	—	
White, Not of Hispanic Origin	1.05 (0.69–1.59)	
Unknown	1.51 (0.76–3.01)	
Diabetic	1.02 (0.63–1.63)	
Chronic Obstructive Pulmonary Disease	1.39 (0.88–2.18)	
Dyspnea	1.30 (0.77–2.20)	
Congestive Heart Failure	—	
Consumption >2 Drinks/Day, Within 2 Weeks	1.10 (0.53–2.27)	
Smoker, Within 1 Year	1.89 (1.29–2.76)*	1.58 (1.02–2.44)*
Preoperative Acute Renal Failure	—	
Preoperative Dialysis, Within 2 Weeks	2.54 (0.61–10.60)	
Preoperative Radiotherapy for Malignancy, Within 90 Days	7.48 (3.50–15.99)*	2.78 (1.14–6.78)*
Preoperative Steroid Use for Chronic Condition, Within 30 Days	—	
Preoperative Serum Albumin	0.62 (0.44–0.88)*	1.16 (0.75–1.79)
Preoperative Total Bilirubin	1.09 (0.86–1.37)	
Preoperative Transfusion, >4 units PRBCs Within 72 Hours	13.06 (2.79–61.15)*	5.80 (0.99–34.03)
Preoperative Open Wound	2.63 (1.39–4.96)*	1.60 (0.72–3.53)
Preoperative Sepsis	3.06 (0.41–23.05)	
Intraoperative Variables		
Surgical Specialty		
Cardiac Surgery	1.71 (0.23–12.57)	
General Surgery	1.95 (1.31–2.91)*	2.39 (1.30–4.39)*
Gynecology	0.35 (0.05–2.51)	
Neurosurgery	0.40 (0.15–1.08)	
Orthopedic Surgery	0.27 (0.14–0.54)*	0.32 (0.09–1.14)
Otolaryngology	2.46 (1.30–4.64)*	2.25 (0.93–5.43)
Plastic Surgery	—	
Thoracic Surgery	1.73 (1.00–3.01)	
Urology	0.20 (0.06–0.64)*	0.32 (0.07–1.46)
Podiatry	1.45 (0.20–10.63)	
Vascular	1.90 (1.21–2.99)*	1.42 (0.71–2.85)
ASA Physical Status Class		
1	0.35 (0.19–0.63)	
2		
3	1.06 (0.71–1.58)	1.27 (0.58–2.78)
4	2.86 (1.83–4.48)*	1.76 (0.71–4.37)
5		
Emergency Surgery	3.18 (1.52–6.65)*	1.67 (0.70–4.00)
Surgical Wound Classification		
Clean Contaminated	2.31 (1.58–3.39)*	1.41 (0.81–2.43)
Intraoperative PRBCs	1.08 (1.03–1.13)*	0.98 (0.90–1.06)
Total Operation Time	1.34 (1.27–1.42)*	1.13 (1.04–1.23)*
Work Relative Value Units	1.07 (1.06–1.09)*	1.03 (1.01–1.06)*
Postoperative Variable		
Length of Total Hospital Length of Stay	1.01 (1.00–1.01)*	1.01 (1.00–1.01)

Abbreviations: TSS traditional aqueous surgical scrub, ABR alcohol-based hand rub, PRBC packed red blood cell, ASA American Society of Anesthesiologists.

Results represent the overall cohort. The multivariate model incorporates all significant covariates from the univariate analysis as well as ABR and ASA Class 3.

— No patient in this category with a superficial or deep incisional surgical site infection.

*Indicates significance to $p < 0.05$

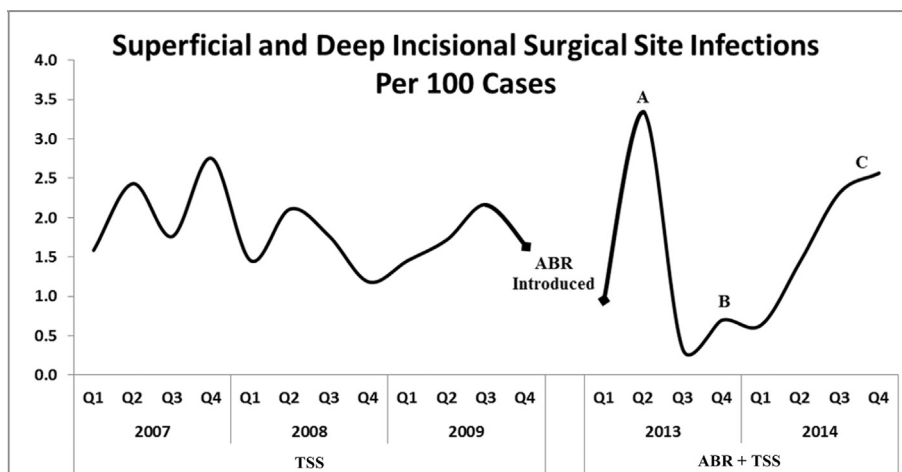


Fig. 2. Superficial and Deep Surgical Site Infection Rate by Calendar Quarter TSS traditional aqueous surgical scrub, ABR alcohol-based hand rub, Q Calendar Quarter.

3.2. Survey

A total of 97 (74%) surveys were returned; two were incomplete and excluded. The remaining 95 surveys consisted of 47% women, 37 staff surgeons (39%), 29 residents and fellows (31%), and 29 nursing staff (30%). Ninety-five percent confirmed prior use and proper application of both product types; however, improper application times of less than 3–6 minutes for TSS and less than 1 minute for ABR were reported by 18% and 10% of participants, respectively. Among all users, 64% supported an ABR option while only 52% favored this product-type. Preference did not differ between physicians and non-physicians ($P = 0.67$). Product preference for ABR was driven by its ease of use (79%) while those who preferred TSS favored its side effect profile (54%). Of the respondents who altered their application behaviors (39%), case-specific wound classification (13.7%), soiled hands (11.6%) and emergency/trauma cases (8.4%) were cited as the most common triggers.

Forty-eight percent had not read the manufacturer's instructions for either product, and over 80% had never received formal in-person training. While 73% of physicians reported familiarity with each product's active ingredients, less than one-third correctly identified alcohol's concentration of greatest anti-microbial activity or its mechanism of action, and only two-thirds correctly identified chlorhexidine's mechanism of action. Lastly, only 3 of 64 physician-respondents reported any familiarity with the U.S. Food and Drug Administration's Tentative Final Monograph for over-the-counter topical antimicrobial drug products, the evolving standard by which surgical hand antisepsis products are evaluated.

4. Discussion

Our study assessed SDSSI rates following the implementation of an ABR option for use in surgical hand antisepsis. While this did not influence the risk of developing an SDSSI as compared to TSS alone, preoperative smoking and radiotherapy as well as general surgery specialty, operative duration and work RVU all had significantly increased odds of developing an SDSSI. These variables have been previously identified as independent risk factors for SSI development.^{21–24} SDSSI rates differed between calendar quarters within the ABR + TSS period between which significantly different patient and intraoperative variables were identified. After controlling for these variables, however, SDSSI rates across ABR + TSS and TSS periods were not significantly different.

The rates of SSI in this study are consistent with the nationally estimated burden.^{1,25,26} Furthermore, other studies confirm our findings.^{16–19} Parienti et al demonstrated in 4,387 patients SSI rates of 2.48% versus 2.44% (Relative Risk [RR], 1.02; 95% CI, 0.70–1.48) for TSS and ABR, respectively.¹⁶ Al-Naami et al randomized 500 patients and found SSI rates of 5.3% and 2.9% (OR 1.83; 95% CI, 0.68–5.01) for TSS and ABR, respectively.¹⁷ In a smaller study of 100 randomized patients, Vergara-Fernandez et al showed an SSI rate of 2% for the TSS group and 4% in the ABR group (RR, 0.5; 95% CI, 0.05–5.34).¹⁹ A cluster-randomized crossover trial of 3,133 patients in rural Kenya by Nthumba et al demonstrated higher SSI rates compared to those of developed nations but equivalence in rates between a plain soap and water group and an ABR group (8.0% versus 8.3%, respectively; OR, 1.03; 95% CI, 0.80–1.33).¹⁸

Based on our survey, users welcomed the institution of an ABR to our healthcare system. Other survey-based studies have shown success of ABR-implementation with at least half of users preferentially choosing to perform surgical hand antisepsis with an ABR while rating it higher in terms of ease of application and efficacy.^{27,28} Issues involving improper application are likely attributable to unfamiliarity with product instructions or lack of formal training and have been shown to affect outcomes.²⁹ Also, proper hand hygiene has been shown to have poor correlation with self-reporting.^{30,31} With equivalent SDSSI rates despite 10% of users applying the ABR too quickly, one could question whether improper product application yields any negative effect on clinical outcome. However, while studies have shown no consequence to reducing ABR application time to 1.5 minutes using surrogate markers, to our knowledge, outcomes of less than 1 minute duration have not been studied and there is evidence that a 1 minute application time results in decreased efficacy.^{32–34}

Our study is unique as it allows for patient level risk adjustment in a large observational cohort of consecutive patients over two well defined time periods. However, this design also has limitations such as procedural variables that could not be identified such as a regular hand wash prior to scrubbing or rubbing and each user's specific product selection. TSS was also available during the ABR period which potentially confounds our results. Lastly, there were unaccounted intraoperative variables such as double-gloving, glove, gown or drape changes and personnel changeovers and foot traffic. Altogether, given our findings, an ABR was re-introduced into our institution in 2016 following in-service on the various products as reviewed and summarized in a recent publication³⁵

5. Conclusions

Performing surgical hand antisepsis either before or after ABR implementation shows equivalent SDSSI rates. However, improved protocol compliance and product knowledge may improve rates by limiting any effect of behavior. The correlation of bacterial inoculum with SSIs while comparing both product-types in future prospective trials is warranted.

Author contributions

Dr. Oriel and Dr. Chen had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design.* All authors. *Acquisition, analysis, or interpretation of data.* All authors. *Drafting of the manuscript.* Oriel, Itani. *Critical revision of the manuscript for important intellectual content.* All authors. *Statistical analysis.* Chen. *Administrative, technical or material support.* All authors. *Study supervision.* Itani.

Conflict of interest disclosures

Drs. Brad S. Oriel and Qi Chen have no conflicts of interest. Dr. Kamal M.F. Itani has received research funds to his institution from Merck, Sanofi, and Dr. Reddy's laboratories. He was a research consultant for Irrimax.

Disclaimer

The opinions expressed are those of the authors and do not necessarily reflect those of the US Department of Veterans Affairs.

Appendix A. Supplementary data

Supplementary data related to this article can be found at <http://dx.doi.org/10.1016/j.amjsurg.2016.09.058>.

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