Impact of Hair Removal on Surgical Site Infection Rates: A Prospective Randomized Noninferiority Trial

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BACKGROUND: Despite substantial prevention efforts, surgical site infections (SSIs) remain the most common health care-associated infection. It is unclear whether the Centers for Disease Control and Prevention recommendation to leave hair intact preoperatively reduces SSIs.

STUDY DESIGN: A single-center, prospective, randomized, clinical trial was conducted from October 2009 to February 2015 in a 325-bed multispecialty, tertiary care teaching hospital to test the noninferiority of clipping hair to no hair removal in the prevention of SSIs. A total of 4,908 adults scheduled for elective general surgical procedures were screened for study participation. Of these, 600 were approached but refused, and 2,630 were excluded. Patients were randomized 1:1 to either the clipped group (n = 834) or the not-clipped group (n = 844). The clipped group had hair at the surgical site removed using disposable electric clippers. Of the randomized patients, 1,543 (768 in the clipped group and 775 in the not-clipped group) completed follow-up. The primary endpoint was the proportion of patients who could be evaluated and who had no SSI, as defined by CDC criteria.

RESULTS: Baseline demographic, clinical, and surgical characteristics were similar between groups. The overall rate of SSI in the per-protocol analysis was 6.12% (47 of 768) in the clipped group and 6.32% (49 of 775) in the not-clipped group (absolute risk difference −0.20%; 95% CI −2.61% to 2.21%), p = 0.037). Because the absolute risk difference confidence interval included the prespecified noninferiority margin of 2%, we were unable to definitively demonstrate noninferiority for clipping hair.

CONCLUSIONS: Surgical site infection rates were similar whether hair was clipped or not in patients undergoing general surgical procedures. (J Am Coll Surg 2016;■:1−8. © 2016 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

Surgical site infections (SSIs) remain the most common health care-associated infection, despite widespread implementation of measures intended to prevent them. These infections have been shown to contribute to prolonged hospital stays or readmissions, ICU admissions, long-term wound complications, increased health care costs, and death.[1-4]

The impact of removing hair at the surgical site on the rate of SSIs remains unknown.[5,6] The CDC recommends that hair not be removed unless it is likely to interfere with the surgery, in which case it should be removed immediately before surgery, preferably with electric clippers.[5,7] Other advisory bodies, such as the Norwegian Centre for Health Technology Assessment, remain neutral on the issue, citing the lack of strong evidence for or against hair removal.[8] The United Kingdom's Hospital Infection Society Working Party advises against shaving whenever possible, but when hair removal is deemed necessary, it should be removed either the day before surgery using depilatory cream or immediately before surgery using clippers.[9] Results of a recent meta-analysis suggest that

Disclosure Information: Nothing to disclose.

Support: Portions of this study were funded by Gundersen Health Systems and the Gundersen Medical Foundation. Neither Gundersen Health System nor Gundersen Medical Foundation had any role in the study beyond the financial support of study personnel.

ClinicalTrials.gov number NCT00975377.

Presented at the Wisconsin Surgical Society Fall Meeting, Kohler, WI, November 2015, and at the American College of Surgeons 102nd Annual Clinical Congress, Washington, DC, October 2016.

Received February 18, 2016; Revised March 16, 2016; Accepted March 16, 2016.

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http://dx.doi.org/10.1016/j.jamcollsurg.2016.03.032
ISSN 1072-7515/16

hair removal has no statistically significant effect on SSI rates, but we acknowledge that the number of patients participating in the trials included in their analysis was insufficient to state their conclusion with confidence.[10]

Despite this longstanding debate, no peer-reviewed published reports have directly compared the effect of clipping hair vs no hair removal, the CDC's preferred hair management strategies. We aimed to compare the rate of SSI when hair at the surgical site was removed with electric clippers immediately before surgery with the rate of SSI when hair was left in place in a contemporaneous patient cohort. Even though the CDC recommends that hair not be removed, clipping is widely practiced—whether a product of historical practice patterns, personal comfort level, or real or perceived interference of hair with performing surgery. For this reason, we chose a noninferiority study design.[7,11]

METHODS

This prospective, randomized noninferiority clinical trial (ClinicalTrials.gov number NCT00975377) was conducted in accordance with the protocol, which was approved by the Gundersen Clinic, Ltd, Human Subjects Committee/Institutional Review Board. The study was conducted in a 325-bed multispecialty, tertiary care teaching hospital. The hospital is a part of Gundersen Health System, a fully integrated health care network headquartered in La Crosse, WI, serving 19 counties in western Wisconsin, northeastern Iowa, and southeastern Minnesota.

Patients 18 years of age and older, undergoing nonemergent, elective general surgical procedures in a single center, were screened for participation in the study. Patients undergoing vascular, ano-rectal, orthopaedic, obstetric, or gynecologic procedures were excluded, as were those undergoing toe amputation. Patients who had received systemic antimicrobial therapy in the week before surgery, or who knew they would be unavailable for the study-required follow-up appointment, were also excluded.

On the day of surgery, preoperative nursing staff determined whether the enrolled patient had sufficient androgenic hair at the surgical site for participation in the study. If insufficient hair was present, the patient was excluded from further study participation. Randomization was performed in a block design with a block size of 100. A sealed envelope containing the randomized group assignment for each study patient determined to have sufficient hair for participation in the study was opened during preoperative preparations and before transport to the operating room. Patients were thereby randomly assigned in a 1:1 ratio to either the clipped group (hair removed from the surgical site with a single-use disposable electric clippers) or to the not-clipped group (no hair removal of any kind). Both the paper displaying the group assignment and the corresponding envelope were labeled with the same unique participant identification number. Opened envelopes were retained for the duration of the study.

Skin antisepsis was performed according to our institutional protocol at study onset: 7.5% povidone-iodine surgical scrub was applied around the incision line, ensuring 5 minutes of contact time, then rinsed with normal saline and dried; skin was then painted with 10% povidone-iodine solution, which was allowed to dry.[12] Patients allergic to povidone-iodine were prepared using chlorhexidine (without alcohol). Surgical procedures were performed by any of 19 attending surgeons from the health system's Department of General Surgery and additional surgical residents or fellows in training.

The primary endpoint was the proportion of patients who could be evaluated and who had no SSI of any type, as defined by CDC criteria,[5] at a postsurgical follow-up visit. Secondary endpoints were the development of specific types of SSI (superficial, deep, and organ space). Study nurses obtained baseline demographic information related to preoperative risk factors for SSI. The type of skin antisepsis used, preoperative antimicrobial use, and surgical procedure timing and duration were also recorded.

At the follow-up visit, each participant's surgical site was assessed by an independent study nurse not directly involved in the patient's care. The original study intent was for the assessor to be blinded to randomization status; however, it was not feasible for either the patient or the study nurses assessing the wounds to be blinded because whether hair had been recently clipped was obvious at follow-up. Study nurses recorded all clinical findings specific to the CDC definition of SSI. Additionally, study nurses attempted to contact patients approximately 30 days after surgery to confirm that no additional evidence of infection had developed since their follow-up visit. Patients who did not begin the follow-up process within 14 days $\pm$7 days after their surgery were considered lost to follow-up. Clinical management of SSI was directed by the study patient's surgeon. Surgeons were encouraged to obtain specimens for culture if signs or symptoms of SSI were present.

The study was designed to test the noninferiority of clipping to no hair removal with regard to the rate of SSI. We assumed an SSI rate of 2% in both groups based on historical institutional data. Therefore, using a 1-sided significance threshold of 0.025, a sample size of 770

patients per group (1,440 total) would be sufficient to establish the noninferiority of clipping with 80% power, for a noninferiority margin of +2%. We chose a noninferiority margin of 2% based on our baseline rates of infection and what we considered a minimal clinically relevant difference. The proportions of patients experiencing SSI and the associated 2-sided 95% CIs were calculated for each group. Additionally, the difference in the proportion of SSI between the 2 groups was calculated, along with the associated 2-sided 95% CI.

Demographic, clinical, and surgical data were compared between study groups and between patients who experienced SSI and those who did not. For these comparisons, the chi-square or Fisher exact test was used to compare categorical data, and the Wilcoxon Rank Sum test was used to compare ordinal data.

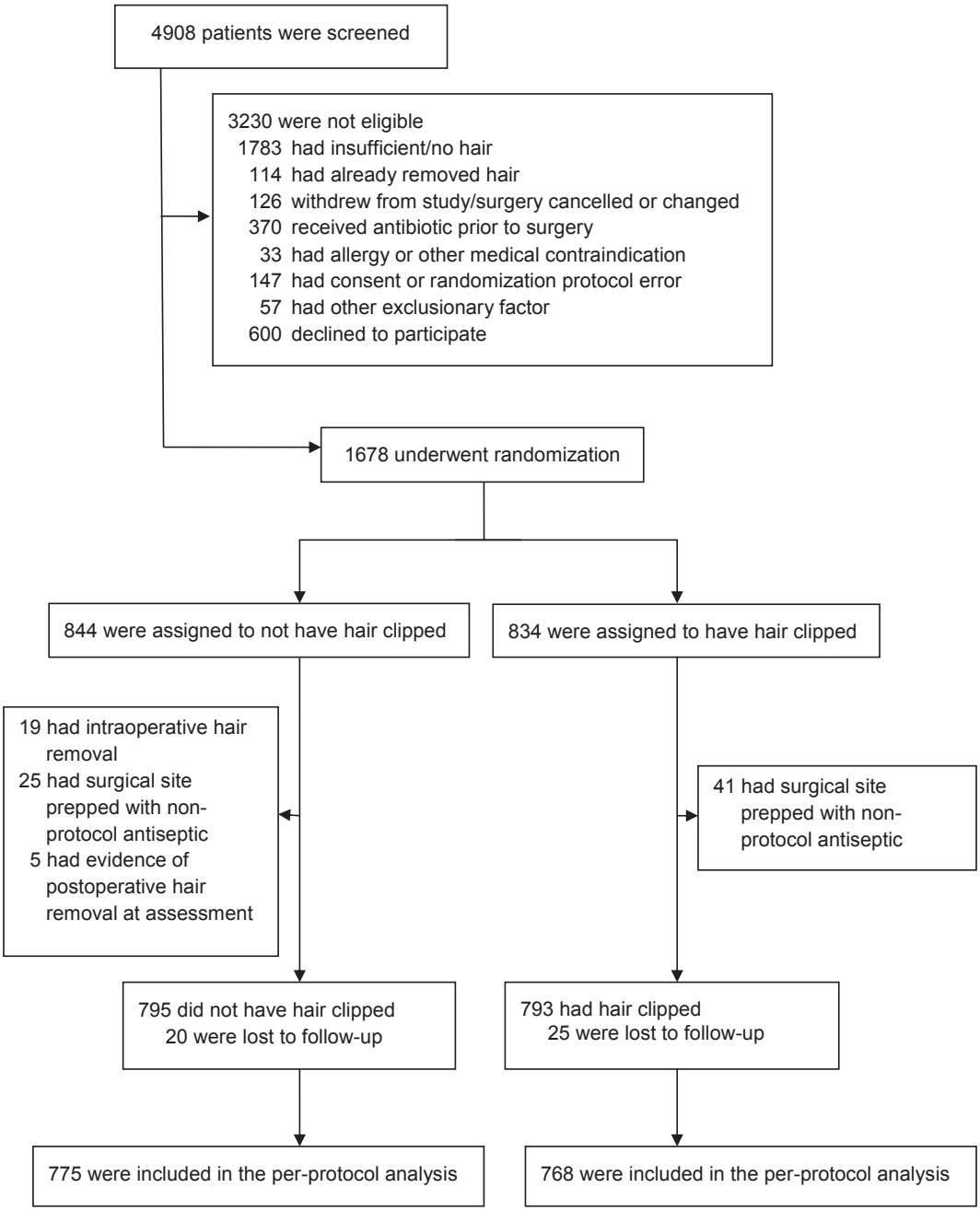

Figure 1. Study participant enrollment flow chart.

A multivariate model of SSI was constructed using a 2-step logistic regression method, with an overall effect significance of $p < 0.15$ used as the threshold for inclusion of potential predictive factors in each model iteration. All calculations were performed using SAS software, Version 9.3 (SAS Institute Inc).

RESULTS

Participants

A total of 1,678 patients were randomized to the clipped (n = 834) or not-clipped (n = 844) group and included in the modified intention-to-treat analysis (Fig. 1). Of the randomized patients, 1,543 (768 in the clipped group and 775 in the not-clipped group) completed follow-up and were included in the per-protocol analysis. Seventy-three percent (66 of 90) of the patients who were excluded after randomization were excluded owing to use of nonprotocol antiseptic pursuant to an unanticipated change in surgical practice. Baseline demographic, clinical, and surgical characteristics were similar between groups (Table 1). The clipped group had a lower mean BMI (weight in kilograms divided by the square of the height in meters) than patients in the not-clipped group (30.5 ± 7.1 kg/m^2 and 31.6 ± 7.9 kg/m^2, respectively; $p = 0.01$).

For the modified intention-to-treat analysis, all patients excluded after randomization or lost to follow-up were assumed to have an SSI. In this analysis, the overall rate of SSI was 13.55% (113 of 834) in the clipped group and 13.98% (118 of 844) in the not-clipped group (risk difference, −0.43%; 95% CI, −3.73 to 2.86), $p = 0.074$ for the noninferiority test, with a noninferiority limit of +2.0%.

The overall rate of SSI in the per-protocol analysis was 6.12% (47 of 768) in the clipped group and 6.32% (49 of 775) in the not-clipped group (risk difference, −0.20%; 95% CI, −2.61 to 2.21), $p = 0.037$ for the noninferiority test, with a noninferiority limit of +2.0%. Although the SSI rates in the study groups were nearly identical, they did not meet the prespecified criteria for noninferiority because the limit was set at 2% for a meaningful difference, and the 95% CI for the risk difference includes 2%. Additional per-protocol analysis SSI data are shown in Table 2 (type of infection: any, superficial incisional, deep incisional, organ space) and Table 3 (type of surgery: foregut, hernia, biliary, colon/intestinal, other). In Table 2, note that patients with clipped hair were found to have an absolute, although not statistically significant, increase in the rate of deep SSI. The clinical implications of this finding are unclear. The median complete follow-up time (defined as a clinic visit with the surgeon or subsequent completed contact assessing additional evidence of wound infection) was 37 days (interquartile range 34 to 41 days).

Table 1. Baseline Demographic, Preoperative, and Intraoperative Patient Characteristics (Per-Protocol Analysis)

Variable	Clipped	Not clipped	p Value
n	768	775	
Demographic characteristic			
Age, y, mean ± SD	57.1 ± 14.8	57.4 ± 15.1	0.50
Men, n (%)	721 (93.9)	713 ± 92.0	0.15
White race, n (%)	758 (98.7)	768 (99.1)	0.45
BMI, kg/m^2, mean ± SD	30.5 ± 7.1	31.6 ± 7.9	0.01
Clinical characteristic, n (%)			
Active malignancy	48 (6.3)	55 (7.1)	0.51
Recent unintentional weight loss	23 (3.0)	22 (2.8)	0.86
History of diabetes	100 (13.0)	86 (11.1)	0.25
Use of tobacco	130 (16.9)	122 (15.7)	0.53
History of MRSA colonization	5 (0.7)	7 (0.9)	0.77
Corticosteroid use	35 (4.6)	45 (5.8)	0.27
Anticoagulation before surgery	174 (22.7)	208 (26.8)	0.06
Preoperative prophylactic antimicrobial agent given, n (%)	678 (88.3)	694 (89.6)	0.43
Time from initiation of preoperative antibiotics to surgical incision, min (SD)*	23.5 (19.1)	23.3 (15.0)	0.07
Surgical characteristic			
Laparoscopic, n (%)	327 (42.6)	345 (44.5)	0.44
Type, n (%)			0.14
Hernia	482 (62.8)	462 (59.6)	
Biliary	125 (16.3)	109 (14.1)	
Foregut	91 (11.9)	113 (14.6)	
Colon/intestinal	64 (8.3)	85 (11.0)	
Other	6 (0.8)	6 (0.8)	
Operative time, min (SD)	96.4 (62.2)	105.5 (76.1)	0.070

*In the clipped group, 3 patients infused after incision and 90 patients not infused were excluded from calculations (n = 675); in the not clipped group, 3 patients infused after incision and 81 patients not infused were excluded from calculations (n = 691).

Specimens for bacterial culture were collected for 51 of the 96 patients with any type of SSI. Fifty of the 51 patients had cultures positive for at least 1 organism. Microbiologic findings for the study groups are provided in Table 4. No differences in the microbiology of infections were apparent by group.

Near the end of the study period, a questionnaire was sent to participating surgeons to gather impressions of the impact that the presence of hair or its removal had on their practice. Questionnaires were distributed to

Table 2. Proportion of Patients with Surgical Site Infection (Per-Protocol Analysis)

Type of infection, n (%)	Clipped	Not clipped	Risk difference*	p Value (noninferiority)
Any surgical site	47 (6.1)	49 (6.3)	−0.20 (−2.6−2.2)	0.037
Superficial incisional	36 (4.7)	39 (5.0)	−0.3 (−2.5−1.8)	N/A†
Deep incisional	6 (0.8)	1 (0.1)	0.7 (−0.0−1.3)	N/A†
Organ space	5 (0.7)	9 (1.2)	−0.5 (−1.5−0.4)	N/A†

*Data are risk difference, clipped vs not clipped (95% CI).
†The test for noninferiority was not performed because no prespecified noninferiority margins were established for the comparison of infection subtype prevalence.
N/A, not applicable.

30 surgeons and residents, all of whom participated in the study for at least 6 months. Of the 24 who responded, 22 reported that closure of the wound was either significantly or moderately more difficult in the not-clipped group. More than 80% (20 of 24) believed that the overall quality of patient care was not compromised by participation in the study.

Table 5 shows the univariate and multivariate logistic regression models used to evaluate the association between selected risk factors and the subsequent development of SSI. Preoperative anticoagulation, morbid obesity, and colon surgery were independently associated with increased risk of SSI in the multivariate model.

DISCUSSION

Despite substantial effort and targeted interventions for improvement, SSI remains the most common health care-associated infection in the United States.[13] The CDC recommends that to reduce the risk of SSI, hair not be removed preoperatively. In this large randomized clinical trial, we found that infection rates were similar between patients who did not have hair removed preoperatively and those who had hair removed with single-use electric clippers. Furthermore, although the optimal preoperative skin antiseptic agent remains controversial,[14] chlorhexidine-alcohol may be superior to povidone-iodine for SSI prevention.[15] This is relevant because current CDC guidelines strongly recommend no hair removal unless the hair will interfere with the surgery.[5] However, chlorhexidine-alcohol is not to be used in hairy areas of the body because the extended dry time—up to 1 hour—may pose a fire hazard in the operating room. A more contemporary analysis of risk factors for SSI after colorectal surgery identified no removal of hair from the surgical site as an independent risk factor for postoperative SSIs.[16] Therefore, our results in conjunction with those of Darouiche and colleagues[15] and Itani and associates[16] suggest that clipping hair immediately before surgery and using chlorhexidine-alcohol skin antisepsis may be a preferred SSI prevention strategy.

We were unable to demonstrate that hair clipping was not inferior to leaving hair in place because we set a strict clinical limit of noninferiority (±2%), and because observed SSI rates were higher than predicted. Although our findings fell short of statistical significance for noninferiority, the 95% CI for the difference in infection rates between groups was −2.61% to 2.21%. The inability to declare statistical significance despite the marked similarity in SSI rates between groups can be attributed to the fact that the study was initially powered to test noninferiority at an assumed SSI rate of 2% rather than the approximate 6% rate actually observed in the study population. Accordingly, it is highly unlikely that a clinically significant difference in SSI rates between hair management strategies exists. The reason our SSI rate was higher than predicted is unclear.

To our knowledge, ours is the first peer-reviewed study comparing the impact of hair clipping with that of no hair removal on the rate of SSI. This study is also the largest

Table 3. Proportion of Patients with Surgical Site Infection by Study Group and Surgery Type (Per-Protocol Analysis)

Characteristic	Clipped	Clipped, with infection	Not clipped	Not clipped, with infection
n	768	47	775	49
Surgery type, n (%)				
Foregut	91 (11.8)	3 (3.3)	113 (14.6)	4 (3.5)
Hernia	482 (62.8)	19 (3.9)	462 (59.6)	17 (3.7)
Biliary	125 (16.3)	8 (6.4)	109 (14.1)	4 (3.7)
Colon/intestinal	64 (8.3)	16 (25.0)	85 (11.0)	24 (28.2)
Other	6 (.7)	1 (16.7)	6 (.7)	0 (0.0)

Table 4. Microbiologic Findings of 50 Patients with Surgical Site Infection and Positive Bacterial Cultures

	Clipped, n (n = 28)				Not clipped, n (n = 22)				p Value
Organism	**Superficial**	**Deep**	**Organ space**	**Any**	**Superficial**	**Deep**	**Organ space**	**Any**	**Any vs Any**
Gram-positive aerobic bacteria									
Staphylococcus aureus	5	3	0	8	7	0	1	8	0.99
Staphylococcus, coagulase negative	7	1	0	8	6	0	0	6	0.99
Enterococci	1	0	2	3	2	0	3	5	0.26
Streptococci	4	0	2	6	5	0	0	5	0.99
Corynebacteria	5	0	0	5	0	0	1	1	0.22
Gram-negative aerobic bacteria									
Enterobacter species	4	1	1	6	1	0	1	2	0.44
Pseudomonas aeruginosa	2	0	0	2	3	0	1	4	0.38
Escherichia coli	1	0	2	3	0	0	3	3	0.99
Other gram-negative aerobes*	1	0	1	2	0	0	1	1	0.99
Anaerobic gram-negative rods	3	1	1	5	1	0	3	4	0.99
Anaerobic gram-positive rods	3	1	3	7	3	0	3	6	0.99

**Proteus* species, *Klebsiella* species, *Hafnia* species.

and most rigorously designed to assess the impact of preoperative hair removal on SSI. The results of previous studies inconclusively suggest that preoperative shaving vs either no hair removal or clipping is associated with increased rates of SSI.[17-21] Previous studies comparing hair removal by shaving vs depilatory creams also demonstrated either no difference or a higher rate of SSI in the groups in which hair was shaved.[17,22-27] Earlier studies assessing preoperative hair removal suffered from significant limitations, including small, underpowered sample sizes and nonstandardized follow-up and assessment of patients. Additionally, these studies were noncontemporaneous studies published before the incorporation of modern multidisciplinary SSI prevention efforts, such as those included in the Surgical Care Improvement Project (SCIP).[15,28]

More than 157,000 SSIs are believed to have occurred in the United States in 2011[13] at an estimated annual cost of $1.6 billion.[4] The Agency for Healthcare Research and Quality has developed patient safety indicators to measure hospital complications, including postoperative wound dehiscence and sepsis. Patient safety indicator data are

Table 5. Univariate and Multivariate Logistic Regression Analysis of the Association Between Risk Factors for and Development of Surgical Site Infections

	Univariate analysis		Final multivariate model	
Risk factor	**Odds ratio (95% CI)**	**p Value**	**Adjusted odds ratio (95% CI)**	**p Value**
Hair clipped	1.04 (0.69–1.57)	0.87	NS	
Body mass index, kg/m^2				
<25	Reference	—	Reference	—
≥25 to <30	0.85 (0.26–1.58)	0.61	0.97 (0.50–1.88)	0.93
≥30 to <40	1.00 (0.54–1.85)	0.99	1.20 (0.62–2.34)	0.59
≥40	1.90 (0.97–3.69)	0.06	5.79 (2.53–13.28)	<0.001
Tobacco use	1.78 (1.10–2.89)	0.02	NS	
Recent unintentional weight loss	4.06 (1.89–8.69)	<0.001	NS	
Anticoagulation before surgery	5.05 (3.30–7.72)	<0.001	3.99 (2.08–7.66)	<0.001
History of MRSA colonization	5.16 (1.37–19.37)	0.02	NS	
Active malignancy	7.06 (4.28–11.66)	<0.001	1.81 (0.92–3.57)	0.08
Surgery type				
Biliary	1.34 (0.69–2.62)	0.39	0.89 (0.44–1.81)	0.75
Colon/intestine	9.11 (5.59–14.86)	<0.001	2.55 (1.20–5.41)	0.01
Foregut	0.88 (0.39–2.01)	0.77	0.08 (0.03–0.25)	<0.001
Hernia/other	Reference	—	Reference	—

then used by the Centers for Medicare and Medicaid Services Value-Based Purchasing program to determine payment. However, quality improvement efforts to reduce SSI rates have had mixed results, best demonstrated by the lack of association between adherence to SCIP infection prevention guidelines and reduction of SSI rates.[29,30] Our study findings further highlight the need for additional high-quality research to identify novel modifiable factors by which SSI rates can be reduced, including potential postoperative factors,[31] before widespread incorporation of such reimbursement penalties.

The vast majority of patients in our study had skin antisepsis with povidone-iodine. Midway though the study period, evidence was published suggesting that chlorhexidine-alcohol may be superior to povidone-iodine for SSI prevention.[15] This unanticipated circumstance presented a challenge in ongoing participant recruitment and implementation of the study, primarily because surgeons were increasingly interested in using chlorhexidine-alcohol skin antisepsis. Ongoing education of our surgical teams was implemented to reinforce the importance of not using chlorhexidine-alcohol in patients in whom abundant hair at the surgical site could lead to delayed drying times, posing a fire hazard.

Our study has limitations. It is slightly underpowered to demonstrate definitively that clipping is noninferior to no hair removal, primarily because SSI rates during the study were higher than had been predicted. Povidone-iodine was the standard skin antisepsis used in the study, but midway through the study evidence emerged that chlorhexidine-alcohol may be superior to povidone-iodine. Our study population was from a single center and was overwhelmingly white. We did not collect data about patient feedback or any adverse events that may have been related to study group assignment other than SSIs, although study nurses noted complaints of unclipped hair impeding dressing adherence and clipped hair resulting in excessive pruritis. Finally, our study was limited to general surgical procedures, so extrapolation of these findings to other procedure types cannot be assumed.

Study strengths include the fact that it is a large, contemporaneous, rigorously implemented clinical trial. The pragmatic design and implementation of the study closely mirror real-world practice, thereby enhancing generalizability to other general surgical populations.

CONCLUSIONS

The SSI rates in the study groups were nearly identical. Therefore, we conclude that surgeon preference ought to drive decisions about hair removal before surgery.

Author Contributions

Study conception and design: Kowalski, Kothari, Mathiason

Acquisition of data: Kowalski, Kothari, Mathiason, Borgert

Analysis and interpretation of data: Kowalski, Kothari, Mathiason, Borgert

Drafting of manuscript: Kowalski, Borgert

Critical revision: Kowalski, Kothari, Mathiason, Borgert

Acknowledgment: Todd J Kowalski, MD, had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. The authors thank the Department of General Surgery at Gundersen Health System for their willing participation in this study. We also thank Gundersen Medical Foundation, which funded our study nurses, Phyllis R Schneider, RN, BSW, Linda K Peterson, RN, MSN, Jonean E Thorsen, RN, BS, Tracey S Coleman, RN, BSN, and Mary B Knutson, RN, MSN. Dawn M Scallon, RN, Gundersen Health System, also provided study assistance. Foundation personnel from the Department of Medical Research further assisted in patient recruitment: Kara J Kallies, MS, Brook M de Maiffe, BA, Rochelle M Clements, Erica S Osley, BS, and Heather M Bushman. The Foundation also funded the biostatistical support of Andrew J Borgert, PhD, and the editorial support of Cathy Mikkelson Fischer, MA, ELS.

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