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Key Points

Question

Is use of perioperative disposable jackets associated with the incidence of surgical site infections?

Findings

In this cohort study of 60 009 patients, implementation of a mandated policy for use of disposable perioperative jackets was not associated with significant reductions in the surgical site infection incidence in clean procedures in a large multicenter health care organization.

Meaning

Disposable perioperative jackets are not associated with surgical site infections in clean operative procedures.

Abstract

Importance

To help prevent surgical site infections (SSIs), recommendations by a national organization led to implementation of a mandatory operating room policy in a large multicenter health care organization of required use of disposable perioperative jackets.

Objective

To assess whether the use of perioperative disposable jackets is associated with the incidence of SSIs.

Design, Setting, and Participants

Surgical site infection data for patients undergoing clean surgical procedures were retrospectively reviewed from 12 hospitals in a large multicenter health care organization during a 55-month period from January 1, 2014, to July 31, 2018. The incidence of SSI was analyzed for all National Healthcare Safety Network monitored and reported procedures. The patient population was split into 2 groups; the preintervention group consisted of 29 098 patients within the 26 months before the policy starting March 1, 2016, and the postintervention group consisted of 30 911 patients within 26 months after the policy.

Main Outcome and Measures

Comparison of the incidence of SSIs before and after intervention periods underwent statistical analysis. The total number of disposable jackets purchased and total expenditures were also calculated.

Exposures

Implementation of the mandated perioperative attire policy.

Results

A total of 60 009 patients (mean [SD] age, 62.8 [13.9] years; 32 139 [53.6%] male) were included in the study. The overall SSI incidence for clean wounds was 0.87% before policy implementation and 0.83% after policy implementation, which was not found to be significant (odds ratio [OR], 0.96; 95% CI, 0.80-

1.14; $P = .61$). After accounting for possible confounding variables, a multivariable analysis demonstrated no significant reduction in SSIs (OR, 0.85; 95% CI, 0.71-1.01; $P = .07$). During the postintervention study period (26 months), a total of 2 010 040 jackets were purchased, which amounted to a cost of $1 709 898.46.

Conclusions and Relevance

The results of this study suggest that the use of perioperative disposable jackets is not associated with reductions in SSI for clean wounds in a large multicenter health care organization and presents a fiscal burden.

Introduction

A surgical site infection (SSI) is defined as a superficial or deep infection that occurs within 30 days after a surgical procedure or within 90 days if hardware is retained.[1,2] Surgical site infections occur in 2% to 5% of the 30 million patients undergoing inpatient surgery, and these surgical complications can have varying associations with clinical outcomes.[3,4,5] The range of associated morbidity includes additional office visits, return to the operating room for irrigation and debridement, and, in the most severe cases, amputation or death.[6] The associated SSI mortality rate is 1.5% to 3%, and 75% of SSI-associated deaths are directly attributable to the acquired SSI.[6,7]

In addition, SSIs are associated with a substantial financial burden for the patient, surgeon, and the health organization. Each year SSIs are estimated to account for approximately $10 billion in additional health care costs annually.[8] In 2009, it was estimated that an SSI extended the hospital length of stay by a mean of 9.7 days and increased costs by $20 842 per admission.[9] A study by Whitehouse et al[10] found that the mean costs of patient hospitalizations were $24 344 for patients with SSIs and $6636 for patients without SSIs.

Prevention of SSI is paramount, and various techniques are used to reduce this risk. Surgical site infections decrease with tight glycemic control, smoking cessation, preoperative antibiotic administration, reduction of operating room traffic, and proper skin antisepsis.[11,12,13,14,15,16,17] Increased risk of SSIs includes poor surgical technique, increased duration of the operation, postoperative blood transfusion, and inadequate sterilization of surgical instruments.[18,19,20] Evidence on perioperative attire for nonscrubbed members of the surgical team and the association with SSIs. On the basis of the 2015 Association for Perioperative Nurses (AORN) recommendations, our health care organization implemented a systemwide policy on March 1, 2016, in regard to perioperative attire. These recommendations required long sleeves (disposable jackets) be worn by all nonscrubbed personnel in operating rooms and perioperative areas, as well as use of mandatory disposable bouffant caps that cover the head and ears and beard covers (Box). This guideline and its ensuing policy (unofficially labeled the Blue Jacket Policy) were founded on the idea that long sleeves and other skin coverings capture skin squames that are theoretically harboring bacteria and can contaminate sterile areas.[21] Within the literature, however, little quality scientific evidence supports these claims.

Box.

Partial Association of Perioperative Registered Nurses Recommendations on Perioperative Attire

Head, hair, ears, facial hair, and nape of neck should be covered when entering the semirestricted and restricted areas.

Nondisposable head coverings should be covered with a disposable head cover.

Nondisposable head coverings should be laundered in a health care–accredited laundry facility.

All nonscrubbed personnel should have arms covered with long-sleeved jacket in restricted and semirestricted areas.

Scrub attire should be worn that covers arms when preparing the patient or when preparing and packaging sterile items in the clean assembly area of sterile processing.

Jewelry that cannot be contained or confined within the scrub attire should not be worn in the semirestricted or restricted areas.

We sought to investigate whether implementation of the Blue Jacket Policy would be associated with SSI incidence in our large multicenter health care organization. The financial ramifications of the policy were also investigated. We hypothesize that use of the disposable perioperative jackets and the associated policy would not be significantly associated with a decrease in the incidence of SSIs and the implementation would lead to unnecessary expenditures.

Methods

Records for clean surgical wounds and associated SSIs were reviewed during a 55-month period at 12 hospitals from January 1, 2014, to July 31, 2018. All clean cases were included, and laminectomy and spinal fusions with multiple procedures on the same day were counted as 1 procedure. A total of 714 records contained repeats (same facility, patient identification, date of procedure, and procedure code). Although most of these repeats were exact duplicates (identical on all factors recorded), several records had differences in 1 of more of the other variables. Therefore, for each of these repeats, 1 record was chosen at random for inclusion in the analysis. Because of reduced likelihood of exogenous contamination, only clean procedures were specifically used. Exclusion criteria included patients younger than 21 years, peripheral vascular bypass surgery, and duration of surgery less than 15 minutes. Peripheral vascular bypass surgery was excluded because the monitoring was not consistent between the preintervention and postintervention cohorts. On the basis of the National Healthcare Safety Network (NHSN) guidelines, the reported clean surgical procedures included abdominal hysterectomy, coronary artery bypass grafting (CABG) with chest and donor sites, CABG with chest site only, craniotomy, hip prosthesis, knee prosthesis, laminectomy, and spinal fusion. An SSI was defined by NHSN definitions, and these definitions did not change during the study period.[2] Surveillance for infections was performed by infection preventionists who reviewed all laboratory results, postsurgical readmissions, and return to the operating room. In addition, electronic *International Classification of Diseases, 10th Revision* review identified potential SSIs, followed by case review to categorize the event as an SSI and interfacility case reporting when admitted to another facility. During the study period, all hospitals included in the statistical analysis adhered to the recognized guidelines and Surgical Care Improvement Project (SCIP) protocols.[22] This study was determined to be exempt from institutional review board approval by the Feinstein Institute for Medical Research of Northwell Health. Informed patient consent was not required because the data collected were deidentified.

The SSI incidence for clean procedures was compared before and after policy implementation on March 1, 2016. The patient population was split into the preintervention cohort, which consisted of 29 098 surgical patients, and the postintervention cohort, which consisted of 30 911 surgical patients. The preintervention group included procedures performed 26 months before the policy (January 1, 2014, to February 28, 2016), and the postintervention group included procedures performed 26 months after the policy (June 1, 2016, to July 31, 2018). A 3-month washout period was incorporated after the start of policy implementation to allow for this policy adoption, and data from this period were subsequently omitted.

The total patient population during the study period was 60 009 patients. The overall incidence of SSIs was determined by dividing the total number of SSIs during the period by the total number of surgical procedures. This calculation was used for each procedure.

Logistic regression was used to examine the association between period (before vs after intervention) and SSI. In addition, a multivariable model, including possible confounders, was also examined. Confounders used in this multivariable model included facility, procedure type, American Society of Anesthesiologists class, emergency procedure, endoscopic approach, trauma, diabetes, age, and duration of surgery. Closure technique was considered a possible confounder but could not be included in the multivariable model because of the low number of patients undergoing operations with a closure technique other than primary.

Because of patients being nested within facilities, the preferred approach would be to use a generalized linear mixed model (GLMM) for binary clustered (ie, hierarchical) data to account for the hierarchical structure of multiple patients within a facility. However, the multivariable GLMM model did not converge using the a priori risk covariates. Therefore, logistic regression was used for all analyses for consistency.

A secondary analysis was performed using separate logistic regression models to examine whether, for each of the 8 procedures, there was an association between period and SSI. For these comparisons, to be conservative because of multiple hypothesis testing, a 2-sided $P < .01$ was considered statistically significant. For some of the individual procedures, it was not feasible to examine the possible confounders because of the small number of SSIs. Results are given as odds ratios (ORs) with associated 95% CIs. In addition, for the univariable analyses, the difference in SSI rates (postintervention rates minus preintervention rates) with associated 95% CIs are given.

The total number of perioperative jackets purchased at each hospital was calculated by reviewing purchase records and inventory. These data were used to calculate the total cost of all jackets during the study period and the total cost, including the disposable jackets, beard covers, and bouffant caps.

Results

A total of 60 009 patients (mean [SD] age, 62.8 [13.9] years; 32 139 [53.6%] male) were included in the study. Baseline characteristics of the 2 cohorts are given in Table 1, with statistical differences for all measures except for endoscopic approach and primary closure technique. The overall incidence of SSIs for clean wounds was 0.87% before policy implementation and 0.83% after policy implementation, which was not significant (OR, 0.96; 95% CI, 0.80-1.14; $P = .61$) (Table 2). An adjusted multivariable analysis for possible confounding variables further demonstrated no statistical significance in SSI reduction (OR, 0.85; 95% CI, 0.71-1.01; $P = .07$) (Table 2). Before the intervention policy, CABG with chest and donor sites had the highest incidence of SSI at 2.15%, and CABG with chest site only had the lowest incidence at 0.44% (Table 1). After the intervention policy, CABG with chest site only had the highest incidence of SSI at 1.89%, and knee prosthesis had the lowest incidence at 0.45% (Table 2). Overall, the SSI incidence was highly variable (Table 2).

During policy implementation, a total of 2 010 040 jackets were purchased in the health care organization, amounting to a cost of $1 709 898.46. Including disposable jackets, beard covers, and bouffant caps, the total cost equaled $2 103 729.63.

Discussion

In this study, we found that mandatory implementation of the AORN policy in our health care system was not significant in reducing SSIs for clean procedures. These findings support the current literature on surgical attire and SSI incidence, and to our knowledge, this is the largest cohort analyzed on the subject.[23,24] Within the data, there were some specific results that necessitated further review. Specifically, CABG with chest and donor sites had significant SSI reductions in the crude and adjusted analyses. In the preintervention period, an infection cluster was identified within 2 of the 4 facilities that performed this type of procedure, which necessitated additional hospital-level interventions. These interventions included nasal screening and treatment with mupirocin ointment when patients tested positive for *Staphylococcus aureus* or methicillin-resistant *S aureus*, initial antibiotic administration with intraoperative redosing, use of separate surgical instruments for graft harvest, and as strict adherence to presurgical skin preparation. These interventions returned the incidence of SSIs back to baseline shortly before the implementation of the Blue Jacket Policy.

Reduction and prevention of SSIs include intrinsic and extrinsic factors as well as modifiable and nonmodifiable risk factors. A multifaceted approach for SSI reduction produced a 27% decrease in SSIs during 1 year with a regimented protocol of antibiotic administration, hair removal, glucose management, and proper thermoregulation.[25] In most case of SSIs, the responsible pathogens originate from intrinsic factors (such as the patient's endogenous flora) but can originate from various exogenous sources as well.[18,26] A review by Dominioni et al[19] concluded that most SSIs are attributable to intrinsic patient-related factors rather than factors that are extrinsic.

To supplement infection prevention policy, practice guidelines from various organizations, including The Joint Commission, Centers for Disease Control and Prevention, AORN, and Occupational Safety and Health Administration, are adopted by hospitals and policy makers.[18,21,23,27,28] Before the AORN recommendation guidelines in 2015, there was no protocol for perioperative attire. In regard to arm cover-up, the AORN support for its policies is based on archaic scientific evidence that postulates that increased shedding of skin squames leads to an increase in colony-forming unit (CFUs) in the air, which in turn correlates with an increase in SSIs.[29,30] Despite these claims and the current policy, the AORN agrees that there is little evidence of any difference in SSI incidence with perioperative surgical attire, but they refer to the theoretical risk of increasing the number of airborne bacteria without their use.[21]

To address the concept of CFUs, air quality, and SSIs, Nelson et al[31] found that despite laminar flow in operating rooms (which are designed to improve sterility and reduce SSIs), the expected reduction in airborne CFUs did not correspond to a substantial decrease in infection incidence. In addition, Hooper et al[32] looked at the use of laminar flow and exhaust system suits in orthopedic joint replacement surgery and surprisingly found an increase in SSIs with their use. Lastly, a systematic review[33] that looked at laminar airflow in joint replacement surgery found that its use might increase SSIs, pointing to the fact that air quality may have little effect on SSIs.

Regarding clothing and skin cover-up, other various operating room techniques have been evaluated for their associations with SSIs. With regard to the CFU levels in different areas of the body, CFUs were higher in persons wearing scrubs than their naked counterparts, and it was hypothesized that friction caused by clothing on the skin triggers shedding of skin squames.[34] The contamination of scrubs worn in and out of the operating room has also been evaluated, and no significant difference was found in the levels of CFUs. The highest level of contamination occurred when the scrubs were initially donned, possibly because of irritation of skin flora.[35] These aforementioned studies[34,35] refute the AORN concept for exposed skin cover-up because they suggest that increased skin coverings may actually lead to increased skin shedding.

This policy has been met with mixed reviews because it is seen by some personnel as being unnecessary and a misuse of hospital resources. Moreover, concerns have been voiced by various medical team members about the additional layer of clothing worn by nonscrubbed personnel. A survey by Moalem et al[36] looked to evaluate the climate among physicians after implementation of the AORN guidelines and found that most respondents (96%) believed the guidelines had no association with SSIs and decreased overall morale of the surgical team.

During the 26-month policy implementation period, the hospital organization spent $1 709 898.46 on 2 010 040 disposable jackets. This amount equaled $854 949.23 spent annually and more than $71 000 a month on disposable perioperative jackets. The policy, which includes disposable jackets, disposable bouffant caps, and beard covers, totaled $2 103 729.63.

Limitations

This study has a few limitations. Evaluation of SSIs across multiple hospitals can have additional confounding variables that are not possible to eliminate; notably, the cohorts could be confounded by the study period. The SCIP protocol is another reported variable that occurred during the study period. However, the SCIP measures were discontinued January 2015; therefore, SCIP data were not available throughout the entire study. As a result, SCIP could not be assessed as an additional variable in the logistic regression model. Of note, before discontinuation of SCIP reporting, adherence was reported at 95% or greater. Surgical skin preparation used before incision was based on surgeon preference and was either a 1-step preparation with chlorhexidine gluconate with alcohol or povidone iodine with alcohol as the preferred surgical skin preparation or a scrub with paint with povidone iodine. The difference in skin preparation was not captured in the NHSN guidelines; therefore, we were unable to adjust for method of skin preparation.

Although a GLMM approach was not used, as discussed in the Methods section, additional analyses for the main outcome (all procedures) were performed to examine how the use of logistic regression instead of GLMM was associated with the results. The univariable GLMM model (which converged) and the logistic regression model were similar. A multivariable GLMM model fit using a subset of the explanatory variables (which converged) was similar to the logistic regression model fit on the same subset. However, the proportion of facility variation compared with the total variation was low (intraclass correlation = 0.037).

Surgical site infections in the preintervention and postintervention periods were low within a large population (0.87 vs 0.83), with a 15% reduction in odds with $P = .07$. Because of this conclusion on the association between the intervention and a decreased rate, this may or may not be clinically significant. Detection of an SSI is not a straightforward event. and an unknown number of SSIs could have been missed during routine surveillance because of follow-up at other facilities outside the organization and even because of death. However, by adhering to the NHSN requirements and additional monitoring methods described above, hospitals have likely reduced the number of missed SSIs. Despite hospital policy, there is some variability with jacket use and adherence to AORN policy across different hospitals, and this limitation cannot be avoided. Periodic visits by the US Department of Health assessed adherence and reinforced policy implementation, with consequences for failure of adherence, such as possible hospital operating privilege suspension. Continuous monitoring by the nursing administration from each individual hospital helped to enforce policy adherence. In addition, after implementation of the policy, there was likely a time delay for full policy adherence that could have varied among hospitals. Finally, we could not feasibly calculate actual jacket use per procedure, and we therefore extrapolated jacket purchases as an indicator of jacket use.

Conclusions

A recent body of evidence reports that use of the AORN guidelines is not associated with reductions in SSI incidence, which suggests that surgical attire is not associated with SSIs.[37,38,39,40,41] These results decrease the likelihood that disposable perioperative jackets are significant in reducing SSIs and are in turn a financial burden. Despite adjusting for several confounding variables in such a large cohort, statistical models were unable to obtain significance for overall SSI reduction. Variability of results among surgical specialties, notably in the various orthopedic procedures in which there were actual increases in SSIs, questions the benefit of such policy implementation. Readers are free to interpret these results as they see fit and determine whether the results are clinically significant and fiscally warranted.

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Figures and Tables

Table 1.

Baseline Characteristics Between the Preintervention and Postintervention Groups[a]

Characteristic	Study Period[b]		*P* Value
	Preintervention (n = 29 098)	Postintervention (n = 30 911)	
Age at procedure, mean (SD), y	62.4 (14.4)	63.5 (13.5)	<.001[c]
Duration of procedure, mean (SD), y	2.4 (1.5)	2.5 (1.5)	<.001[c]
Procedure			
CABG-CD	2512 (8.6)	2661 (8.6)	<.001[d]
CABG-C	458 (1.6)	529 (1.7)	
Craniotomy	1771 (6.1)	2230 (7.2)	
Spinal fusion	4514 (15.5)	5233 (16.9)	
Hip prosthesis	6569 (22.6)	7189 (23.3)	
Abdominal hysterectomy	220 (0.8)	340 (1.1)	
Knee prosthesis	7787 (26.8)	9013 (29.2)	
Laminectomy	5267 (18.1)	3716 (12.0)	
ASA class			
1	1082 (3.7)	789 (2.6)	<.001[d]
2	13 460 (46.3)	12 953 (41.9)	
3	10 852 (37.3)	13 156 (42.6)	
4	3623 (12.5)	3919 (12.7)	
5	81 (0.3)	94 (0.3)	
Emergency procedure	1687 (5.8)	1508 (4.9)	<.001[d]
Endoscopic approach	1860 (6.4)	1858 (6.0)	.053[d]
Trauma	1150 (4.0)	1047 (3.4)	<.001[d]
PRI closure technique	29 080 (99.9)	30 899 (99.9)	.21[d]
Diabetes	4291 (14.8)	6614 (21.4)	<.001[c]

Abbreviations: ASA, American Society of Anesthesiologists; CABG-CD, coronary artery bypass graft with chest and donor site incisions; CAGB-C, coronary artery bypass graft with chest incision only; PRI, primary closure technique.

[a]Data are presented as number (percentage) of patients unless otherwise indicated.
[b]The preintervention period is from January 1, 2014, through February 29, 2016, and the postintervention period is from June 1, 2016, through July 31, 2018.
[c]Statistical analysis using 2-sample *t* test.
[d]Statistical analysis using χ^2 test.

Table 2.

Multivariable Analysis for Possible Confounding Variables

Procedure	No. of SSIs/No. of Procedures (%)		Difference (95% CI)	Unadjusted Odds Ratio (95% CI)[b]	*P* Value	Adjusted Odds Ratio (95% CI)[b]	*P* Value
	Preintervention (n = 29 098)[a]	Postintervention (n = 30 911)[a]					
All procedures and SSIs	252 (0.87)	256 (0.83)	−0.04 (−0.18 to 0.11)	0.96 (0.80 to 1.14)	.61	0.85 (0.71 to 1.01)[c]	.07
CABG-CD	54/2512 (2.15)	26/2661 (0.98)	−1.17 (−1.85 to −0.49)	0.45 (0.28 to 0.72)	<.001	0.36 (0.22 to 0.60)[d]	<.001
CABG-C	2/458 (0.44)	10/529 (1.89)	1.45 (0.15 to 2.76)	4.39 (0.96 to 20.15)	.06	NE	NA
Craniotomy	24/1771 (1.36)	37/2230 (1.66)	0.30 (−0.45 to 1.06)	1.23 (0.73 to 2.06)	.43	NE	NA
Spinal fusion	41/4514 (0.91)	61/5233 (1.17)	0.26 (−0.14 to 0.66)	1.29 (0.86 to 1.92)	.21	1.05 (0.69 to 1.60)[e]	.82
Hip prosthesis	46/6569 (0.70)	60/7189 (0.83)	0.13 (−0.16 to 0.43)	1.19 (0.81 to 1.76)	.37	1.17 (0.80 to 1.73)[e]	.42
Abdominal hysterectomy	2/220 (0.91)	3/340 (0.88)	−0.03 (−1.63 to 1.57)	0.97 (0.16 to 5.85)	.97	NE	NA
Knee prosthesis	49/7787 (0.63)	41/9013 (0.45)	−0.17 (−0.40 to 0.05)	0.72 (0.48 to 1.09)	.12	0.68 (0.44 to 1.03)[f]	.07
Laminectomy	34/5267 (0.65)	18/3716 (0.48)	−0.16 (−0.47 to 0.15)	0.75 (0.42 to 1.33)	.32	NE	NA

Abbreviations: CABG-CD, coronary artery bypass graft with chest and donor site incisions; CABG-C, coronary artery bypass graft with chest incision only; NA, not applicable; NE, not examined (because of low SSI rate); SSI, surgical site infection.

[a]The preintervention period is from January 1, 2014, through February 29, 2016, and the postintervention period is from June 1, 2016, through July 31, 2018.
[b]Reference for odds ratio is preintervention group.
[c]Confounders in the multivariable model included facility, procedure type, American Society of Anesthesiologists class, emergency procedure, endoscopic approach, trauma, diabetes, age, and duration of surgery.
[d]Confounders in the multivariable model included facility, emergency procedure, endoscopic approach, diabetes, age, and duration of surgery.

[e]Confounders in the multivariable model included facility, American Society of Anesthesiologists class, emergency procedure, endoscopic approach, trauma, diabetes, age, and duration of surgery.
[f]Confounders in the multivariable model included facility, American Society of Anesthesiologists class, emergency procedure, trauma, diabetes, age, and duration of surgery.