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The art and science of surgery: Do the data support the banning of surgical skull caps?[☆]

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ABSTRACT

Background: Recommendations of the Joint Commission discourage the use of surgical skull caps in favor of bouffant or helmet headwear; however, data supporting such recommendations are limited and have been questioned in recent studies, as well as by our departmental and hospital leadership. At the end of December 2015, surgical caps were removed from our institution with the theoretic goal of decreasing surgical site infections. We aimed to assess the impact of this intervention on surgical site infection occurrence at our institution.

Methods: Using our institutional American College of Surgeons National Surgical Quality Improvement Program General and Vascular procedure-targeted data, we identified patients undergoing any surgical procedure classified as clean or clean-contaminated during a 12-month period before and after implementation of the surgical headwear policy. Patients without complete 30-day follow-up were excluded. Cases with active infection at the time of operation were excluded. Vascular surgery operations were excluded because of the implementation of a separate intervention to decrease surgical site infections during the study period. Patients were grouped according to timing of the operation in relation to the policy change (12 months before or after). Descriptive statistics focused on proportions and adjusted logistic regression models were used to investigate the association of alternative headwear use with any type of surgical site infection. Models were adjusted for potential confounders that included demographics and clinical characteristics (age, sex, race or ethnicity, obesity, diabetes, steroid use, smoking status, cancer, urgency of the operation, and wound classification).

Results: A total of 1,901 patients underwent 1,950 procedures during the study period, with 767 (40%) before and 1,183 (60%) after the headwear policy measure was adopted. The most common procedures overall were colectomy (18%), pancreatectomy (13.5%), and ventral hernia repair (8.9%). The overall rate of any surgical site infection was 5.4%, with no difference before and after policy implementation (5.3% versus 5.5%; $P = .81$). Multivariate analysis controlling for age, sex, race or ethnicity, obesity, diabetes, smoking status, steroid use, cancer diagnosis, and type of wound classification showed no association between implementation of this new policy and surgical site infections occurrence (odds ratio 1.12 [95% confidence interval 0.73–1.71]; $P = .59$).

Conclusion: In our institution, the strict implementation of bouffant or helmet headwear, with removal of skull caps from the operating room, was not associated with decreased surgical site infections for clean and clean-contaminated cases. Further evidence is required to assess the validity of this headwear guideline of the Joint Commission and support nationwide implementation of this policy.

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Introduction

It is estimated that up to 5% of patients undergoing inpatient surgery will develop a surgical site infection (SSI), accounting for up to 300,000 hospital-acquired infections per year.¹ SSIs are associated with increased morbidity, mortality, and cost across the surgical specialties, as well as with a negative impact on quality

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of life.^{2–5} SSIs can increase the cost of hospitalization by \$20,000 on average, and it is estimated that they are responsible for \$700 million in additional health care costs each year.¹ SSIs can be prevented through a variety of measures that include, but are not limited to, the implementation and use of proper surgical attire in the operating room (OR), such as gloves and other barrier devices.^{6,7} In 2012, the Association of periOperative Registered Nurses (AORN) released guidelines recommending against skull caps.⁸ Subsequently, the Joint Commission (JC) supported this measure, effectively banning the use of the traditional surgeon skull caps. The implementation of these guidelines led many institutions, including ours, to exclusively provide bouffant-style or helmet headwear for all ORs.

The effects on SSIs of the type of headwear worn by OR personnel, specifically bouffant caps as opposed to traditional skull caps, remain controversial. Studies have shown that human hair can be a site of pathogenic bacteria, such as methicillin-resistant *Staphylococcus aureus*.^{9,10} and, therefore intuitively, uncovered hair may increase the risk of SSI. In 1999, the US Centers for Disease Control (CDC) released the Guidelines for Prevention of Surgical Site Infection, recommending headwear, such as a cap or hood, be placed on before entering the OR to cover the head and facial hair.¹¹ The AORN-published guidelines for surgical attire specifically recommended against skull caps, with the rationale being that this type of headwear may not cover the entirety of hair and ears.⁸ The AORN based this recommendation on two studies from 1965 and 1973. The first study demonstrated that patients who were nasal and hair carriers of *Staphylococcus aureus* had greater rates of SSIs.¹² The second study described 2 series of SSI cases of 12 and 5 patients traced back to a resident and a nurse who cultured positive for the causative strains of *Staphylococcus aureus* in their hair.¹³

Evidence for the discontinuation of skull caps has been overall lacking. In fact, more recent data suggest that there may be no association between SSIs and type of surgical headwear. Rosen et al¹⁴ demonstrated that occurrences of SSIs were comparable in ventral hernia repair regardless of the type of hats worn by surgeons. In agreement, another recent study examining a large cohort of a variety of clean operative cases in a single institution did not show any difference in SSI rates before and after the implementation of bouffant caps in the OR.¹⁵ The paucity of further evidence has led to persistent disagreement between the AORN guidelines and recommendations from other organizations, such as the American College of Surgeons (ACS), regarding the most appropriate form of surgical headwear.

To comply with JC guidelines, our institution banned the use of surgical skull caps in the OR, favoring bouffant caps or helmet headwear in late December 2015. This allowed us the opportunity to assess SSI rates before and after this new policy was implemented. We hypothesized that this measure would not be associated with a decrease in the incidence of SSIs at our institution.

Methods

Data source

The current retrospective study relies on the procedure-targeted data of ACS National Surgical Quality Improvement Program (NSQIP) corresponding to our institution. Trained surgical clinical reviewers prospectively extract the ACS-NSQIP data from patients' medical charts and, if necessary, sent letters to or telephoned patients.¹⁶ The NSQIP data allow the quantification of 30-day, risk-adjusted surgical outcomes, including post-discharge information.

Study population

We identified all patients at our institution undergoing any operative procedures classified as clean or clean-contaminated, who had a complete 30-day follow-up within our NSQIP data set 12 months before and after the headwear policy was adopted in our institution (late December 2015). Patients undergoing vascular procedures were excluded because of the implementation of a separate intervention to attempt to decrease SSIs during the study period. Also, patients who were lost during the 30-day follow-up or who presented with sepsis or active infection at the time of operation were excluded from this analysis. Patients were grouped according to study period: before (January 1, 2015 to December 31, 2015) and after (January 1, 2016 to December 31, 2016).

Patient and procedure characteristics

Variables extracted included age, sex, race or ethnicity (white, black, Hispanic, Asian, other), obesity [body mass index] > 30 kg/m², diabetes, use of steroids or immunosuppression, smoking status, cancer diagnosis, elective status of procedure (versus emergent), and wound classification (clean, clean-contaminated).

Outcome measures

The primary outcome was any type of SSI, which included superficial, deep, and organ or space infections per the National Nosocomial Infections Surveillance system of the CDC.¹⁷ Patients who underwent two or more procedures and had an SSI were counted as one.

Statistical analysis

Categorical variables were compared between group categories using χ^2 tests and non-normally distributed continuous variables, using the Kruskal-Wallis one-way analysis of variance. Multivariate logistic regression models were used to investigate the risk-adjusted association of the headwear policy adoption with SSIs. Models were adjusted for potential confounders (age, sex, race or ethnicity, obesity, diabetes, steroid use, smoking status, cancer diagnosis, procedure urgency, and wound classification). These models used robust standard errors. All statistical analyses were performed using Stata 13.0 (StataCorp, College Station, TX). This project was undertaken as a quality improvement initiative at Thomas Jefferson University Hospital (Philadelphia, PA), and, as such, it was not formally supervised by the institutional review board per their policies.

Sensitivity analysis

During part of study period affecting the postintervention cohort, the colorectal surgery division implemented a bundle of measures aimed to decrease the incidence of SSIs. A sensitivity analysis was performed, excluding surgeons who adopted this measure to investigate whether this bundle had an overall effect in the post-intervention cohort SSI rates.

Results

A total of 1,901 patients underwent 1,950 surgical procedures during the study period, 760 (40%) patients before and 1,141 (60%) patients after the headwear policy was adopted in our institution. The 3 most common procedures in both cohorts were colectomy (18%), pancreatectomy (13.5%) and ventral hernia repair (8.9%). Together, they accounted for 42% of all procedures captured in our institutional NSQIP database. Overall, patients had a median age

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