Prophylactic Antibiotic Choice and Risk of Surgical Site Infection After Hysterectomy

Shitanshu Uppal, MBBS, John Harris, MD, Ahmed Al-Niaimi, MD, Carolyn W. Swenson, MD, Mark D. Pearlman, MD, R. Kevin Reynolds, MD, Neil Kamdar, MS, Ali Bazzi, MS, Darrell A. Campbell, MD, and Daniel M. Morgan, MD

OBJECTIVE: To evaluate associations between prophylactic preoperative antibiotic choice and surgical site infection rates after hysterectomy.

METHODS: A retrospective cohort study was performed of patients in the Michigan Surgical Quality Collaborative undergoing hysterectomy from July 2012 to February 2015. The primary outcome was a composite outcome of any surgical site infection (superficial surgical site infections or combined deep organ space surgical site infections). Preoperative antibiotics were categorized based on the recommendations set forth by the American College of Obstetricians and Gynecologists and the Surgical Care Improvement Project. Patients receiving a recommended antibiotic regimen were categorized into those receiving β-lactam antibiotics and those receiving alternatives to β-lactam antibiotics. Patients receiving nonrecommended antibiotics were categorized into those receiving overtreatment (excluded from further analysis) and those receiving nonstandard antibiotics. Multivariable logistic regression models were developed to estimate the independent effect of antibiotic choice. Propensity score matching analysis was performed to validate the results.

RESULTS: The study included 21,358 hysterectomies. The overall rate of any surgical site infection was 2.06% (n=441). Unadjusted rates of "any surgical site infection" were 1.8%, 3.1%, and 3.7% for β-lactam, β-lactam alternatives, and nonstandard groups, respectively. After adjusting for patient and operative factors within clusters of hospitals, compared with the β-lactam antibiotics (reference group), the risk of "any surgical site infection" was higher for the group receiving β-lactam alternatives (odds ratio [OR] 1.7, confidence interval [CI] 1.27–2.07) or the nonstandard antibiotics (OR 2.0, CI 1.31–3.1).

CONCLUSION: Compared with women receiving β-lactam antibiotic regimens, there is a higher risk of surgical site infection after hysterectomy among those receiving a recommended β-lactam alternative or nonstandard regimen.

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Surgical site infections are associated with increased hospital length of stay and increased episode cost after surgery.[1,2] In addition, surgical site infections are the most common reason for readmission after a wide variety of operations.[3] The rate of overall surgical site infections (superficial, deep, and organ space) in hysterectomy has been reported to range between 1% and 4%.[4,5] Hysterectomy is among the most common major operation in the United States (600,000 performed annually) and may result in 6,000–24,000 surgical site infections each year. Consequently, beginning October 1, 2015, inpatient posthysterectomy surgical site infections were included in the Centers for Medicare & Medicaid Services calculations for Hospital-Acquired Condition Reduction Program metrics.[6]

Preoperative prophylactic antibiotic administration has been shown to consistently reduce the rate of

From the Department of Obstetrics and Gynecology, Gynecology Health Services Group, and the Department of Surgery, University of Michigan, Ann Arbor, Michigan; and the Department of Obstetrics and Gynecology, University of Wisconsin, Madison, Wisconsin.

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Corresponding author: Shitanshu Uppal, MBBS, Department of Obstetrics and Gynecology, Division of Gynecologic Oncology, University of Michigan, 1500 East Medical Center Drive, Ann Arbor, MI 48109; e-mail: Uppal@med.umich.edu.

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postoperative surgical site infections.[7] The American College of Obstetricians and Gynecologists (the College) has issued guidelines for choosing appropriate preoperative prophylactic antibiotics[8]; in addition, the Joint Commission's Surgical Care Improvement Project has issued a list of procedure-specific prophylactic antibiotics.[9] Studies have shown that compliance with these guidelines varies across institutions and procedures,[10] and regimens not in compliance have involved both undertreated and overtreated cohorts.

The objective of the current study is to quantify the effects of preoperative antibiotic choice on surgical site infection rates after hysterectomy using data from a statewide surgical collaborative.

MATERIALS AND METHODS

A retrospective cohort study was performed of patients in the Michigan Surgical Quality Collaborative (herein also referred to as the collaborative) undergoing hysterectomy from July 2012 to February 2015. The collaborative is funded by the Blue Cross Blue Shield of Michigan/Blue Care Network, and it includes patients from all insurance payers (public and private). At each participating hospital, a trained, dedicated nurse abstractor collects patient characteristics, intraoperative processes of care (including the details of preoperative antibiotics administered), and 30-day postoperative outcomes from general and vascular surgery and hysterectomy cases. To ensure complete capture of the data, nurse abstractors make phone calls to the patients to determine whether they were admitted to a hospital other than the one in which the index surgery was performed. To reduce sampling error, a standardized data collection methodology is used whereby data abstraction is performed on only the first 25 cases of an 8-day cycle (alternating on different days of the week for each cycle). The standardized data collection methodology is routinely validated through scheduled site visits, conference calls, and internal audits.[11,12]

Patients were included in the study if they were older than 18 years of age and were undergoing abdominal, vaginal, laparoscopic, or robotic hysterectomy. Patients with gynecologic malignancy and those undergoing hysterectomy for benign indications were included in the study. Patients with no recorded antibiotic information and those with missing surgical site infection information were excluded from the analysis. Michigan Surgical Quality Collaborative data sets provided to the researchers contain no patient, hospital, or health care provider identifiers. Therefore, this study met the criteria for "exempt" status by the University of Michigan institutional review board–medical (HUM00073978).

The following information was available for analysis: age at the time of surgery, body mass index (calculated as weight (kg)/[height (m)]^2), covariates associated with performance status including American Society of Anesthesiologists (ASA) classification score (defined as a dichotomous variable ASA class less than 3 or 3 or greater),[13] and preoperative medical history including diabetes mellitus (defined as requiring oral hypoglycemic agents, insulin, or both), hypertension (defined as documentation in preoperative evaluation or of receiving antihypertension medications), and smoking status (defined as having smoked cigarettes, cigars, or pipe, chewed tobacco, or used marijuana within the past year). Preoperative transfusion was defined as having receiving a minimum of one unit of whole blood or packed red blood cells during the 72 hours before surgery. Patients with a final diagnosis coded as 179–184 based on the primary International Classification of Diseases, 9th Revision were defined as having the diagnosis of gynecologic cancer. All other International Classification of Diseases, 9th Revision diagnoses were defined as benign final pathology.

Approach to hysterectomy was categorized as open (all abdominal hysterectomy cases and all cases converted from laparoscopic or robotic cases) or minimally invasive, which encompassed laparoscopic (including robotic-assisted cases) and vaginal (including laparoscopic-assisted cases). Surgical complexity was calculated by adding the relative value units for each surgical procedure recorded for the patient. Operative times were reported in hours from the start of the surgery (incision) to the closing of the skin incision.

Surgical site infections within 30 days of surgery were defined by the Centers for Disease Control and Prevention criteria. A superficial surgical site infection involved only skin and the subcutaneous tissue of the incision. In this study, deep and organ space surgical site infections were both considered "deep surgical site infections" because the fascia and muscle layers of the vaginal cuff are contiguous with the organ space. The primary outcome of the study was a composite outcome of any surgical site infection. The term any surgical site infection indicates when there was either a superficial or deep surgical site infection.

Preoperative antibiotics were categorized based on the criteria set forth by the College[8] and the Surgical Care Improvement Project.[9] Patients receiving an antibiotic regimen recommended by the College or the Surgical Care Improvement Project were further categorized into those receiving β-lactam antibiotics (eg, cephalosporin, ampicillin–sulbactam, ertapenem) and those receiving alternatives to βlactam antibiotics (eg, combination of clindamycin with gentamicin or quinolone). Patients receiving antibiotic regimens not recommended by the College or the Surgical Care Improvement Project were categorized as those receiving overtreatment (eg, recommended antibiotic with additional antibiotic) and those receiving nonstandard antibiotics (eg, clindamycin alone). Patients who received overtreatment were excluded from the analysis because documented antibiotic resistance could account for such a decision. Figure 1 illustrates the development of the antibiotic categories.

For all included patients, descriptive and comparative statistics of demographics, comorbidities, operative details, and postoperative surgical site infections were analyzed. For bivariate analyses, χ^2 analysis or Fisher exact test was used. For continuous variables, parametric one-way analysis of variance or nonparametric Wilcoxon Mann-Whitney tests were used to assess significance in the bivariate relationship. To ascertain the independent effect of antibiotic categories included in the analysis, we constructed multivariate logistic regression models. Variables were excluded from model selection if they were not significant at a level of 0.1 in the bivariate analysis or if they were not related to the outcome in a clinically plausible manner.

For all logistic regression models, to account for violations in model assumptions resulting from nonindependence of observations within clusters of data (hospital level), we used Huber-Eicker-White robust standard errors. These robust standard errors and the hospital-level clustering allowed the model to better reflect the collected data characteristics.[13–15] We used STATA 14.0 SE for Macintosh for all analyses. Results of the logistic regression models were confirmed

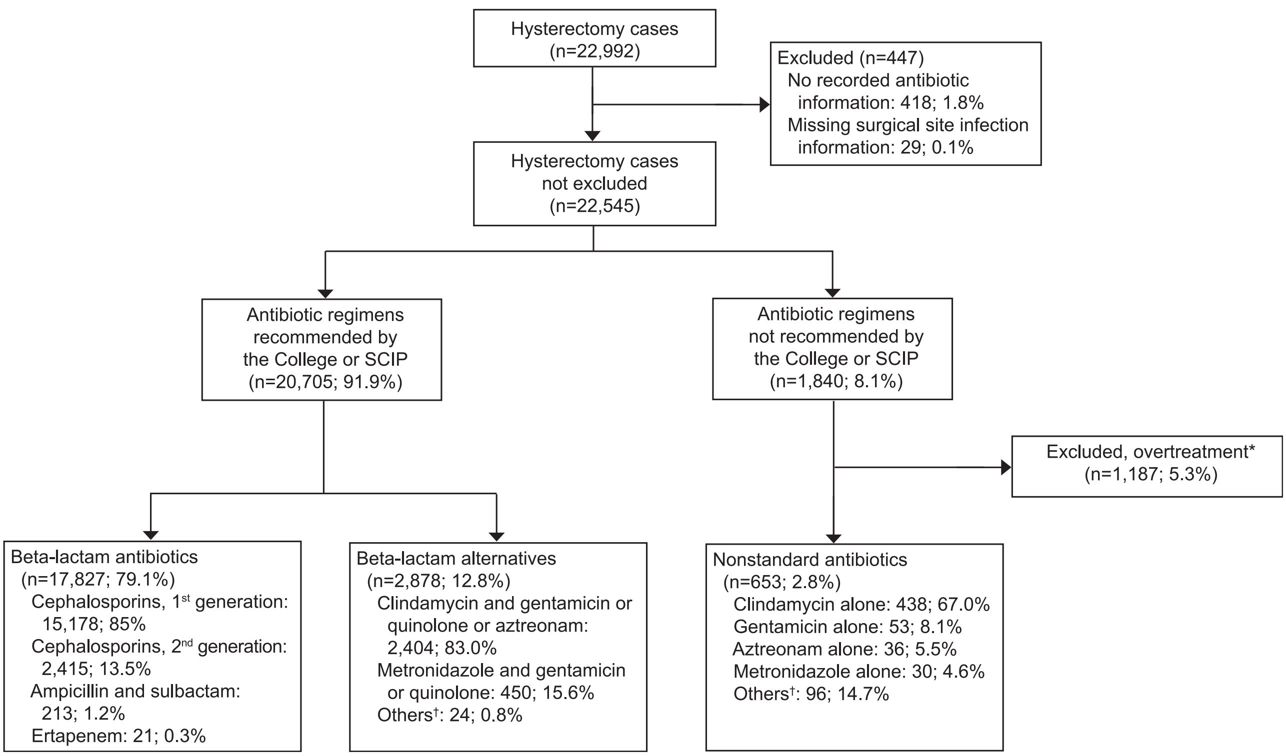

Fig. 1. Breakdown of the antibiotic categories based on the American College of Obstetricians and Gynecologists (the College) use guidelines and the Surgical Care Improvement Project use guidelines. Antibiotic regimen details available in Appendix 2, available online at http://links.lww.com/AOG/A754. *Patients receiving additional antibiotics to those recommended by the College and the Surgical Care Improvement Project guidelines were categorized as overtreatment.

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using propensity score matching (Appendix 1, available online at http://links.lww.com/AOG/A753).

RESULTS

A total of 22,992 patients undergoing hysterectomy were available in the collaborative database. Excluded from the analysis were cases with no recorded antibiotic information (n=418 [1.8%]) and those with missing surgical site infection information (n=29 [0.1%]). Patients who received overtreatment were excluded from the analysis (n=1,187 [5.1%]). A total of 21,358 (93%) were included in the analysis (Fig. 1).

Most of these patients received β-lactam antibiotics (n=17,827 [79.1%]) followed by the β-lactam alternatives (n=2,878 [12.8%]). The nonstandard regimens were administered in 2.8% (n=653) of cases (Fig. 1). The majority of patients in the nonstandard group received single-agent antibiotics (clindamycin alone 67%; gentamicin only 8%) Details of the 15 regimens included in this group are provided in Appendix 2, available online at http://links.lww.com/AOG/A754.

The overall rate of any surgical site infection was 2.06% (n=441). Patients with any surgical site infection were older, had higher body mass index, were more likely to have diabetes, were more likely to report tobacco use, received a preoperative transfusion, and had gynecologic cancer as a surgical indication. In addition, patients with any surgical site infection had higher use of open abdominal approach, higher median blood loss, higher complexity of surgery (measured by mean relative value units), and longer operative times (Table 1).

Table 1. Predictors of Surgical Site Infection (Unadjusted)

		Surgical Site Infection (Any)		
Variable	Overall (N=21,358)	Absent (n=20,917)	Present (n=441)	*P*
Demographics and comorbidities				
Age (y)	48.1±11.7	48.1±11.7	47.9±11.8	.8
BMI (kg/m^2)				
30 or greater, obese	10,150 (47.5)	9,879 (97.3)	271 (2.7)	<.001
Less than 30, nonobese	11,208 (52.5)	11,038 (98.5)	170 (1.5)	
Diabetes				
Present	1,984 (8.8)	1,911 (96.3)	73 (3.7)	<.001
Absent	20,561 (91.2)	20,169 (98.1)	392 (1.9)	
Smoker				
Yes	4,991 (23.4)	4,864 (97.5)	127 (2.5)	.006
No	16,367 (76.6)	16,053 (98.1)	314 (1.9)	
ASA class				
2 or less	16,812 (78.7)	16,514 (98.2)	298 (1.8)	<.001
3 or greater	4,546 (21.2)	4,403 (96.8)	143 (3.2)	
History of hypertension				
Present	6,358 (30)	6,209 (97.2)	176 (2.8)	<.001
Absent	14,973 (70)	14,708 (98.2)	265 (1.8)	
Preoperative transfusion				
Yes	146 (0.7)	139 (95.2)	7 (4.8)	.02
No	21,212 (99.3)	20,778 (98)	434 (2)	
Final pathology				
Cancer	1,997 (9.3)	1,911 (95.7)	86 (4.3)	<.001
Benign	19,261 (90.7)	19,006 (98.2)	355 (1.8)	
Surgical factors				
Surgical approach				
Open	5,797 (27.1)	5,569 (96.1)	228 (3.9)	<.001
Minimally invasive*	15,561 (72.9)	15,348 (98.6)	213 (1.4)	
Estimated blood loss (mL)	100 (50–200)	100 (50–200)	200 (100–350)	<.001
Mean surgical complexity (total RVU)	26.7±14.1	26.5±13.9	31.8±21.7	<.001
Operative time (h)	2.2±1.3	2.1±1	2.5±1.3	<.001
Antibiotic type				
Beta-lactam antibiotics	17,827 (83.5)	17,498 (98.2)	329 (1.8)	<.001
Beta-lactam alternatives	2,878 (13.5)	2,790 (96.9)	88 (3.1)	
Nonstandard	653 (3)	629 (96.3)	24 (3.7)	

BMI, body mass index; ASA, american Society of Anesthesiologists; RVU, relative value units.
Data are median±standard deviation, n (%), or median (interquartile range) unless otherwise specified.
* Laparoscopic, vaginal, and robotic hysterectomy.

Baseline comparison among the three groups of antibiotic categories is provided in Table 2. Patients receiving β-lactam antibiotics had lower incidence of tobacco use, ASA class 3 or greater, a history of hypertension, and a history of diabetes. The three groups did not differ in the operative time, blood loss, surgical complexity, and proportion of patients with malignancy. The β-lactam antibiotics group had a higher proportion of patients undergoing open surgery than the other two groups. Unadjusted surgical site infection rates were 1.8% for β-lactam antibiotics, 3.1% for β-lactam alternatives, and 3.75% for nonstandard antibiotics. Details of the unadjusted rates of any surgical site infection, superficial surgical site infections, and deep surgical site infections are provided in Table 2.

Multivariate logistic regression models were constructed for any surgical site infection, superficial surgical site infections, and deep surgical site infections. Table 3 summarizes the independent effect of factors included in the regression models. Compared with the β-lactam antibiotics (reference group), patients receiving the β-lactam alternatives had increased risk of any surgical site infection (odds ratio [OR] 1.62, 95% confidence interval [CI] 1.27–2.07, $P<.001$), superficial surgical site infections (OR 1.5, 95% CI 1.04–2.09, $P=.03$), and deep organ space surgical site infections (OR 1.7, 95% CI 1.27–2.4, $P<.001$). Similarly, compared with the β-lactam antibiotics (reference group), patients receiving any nonstandard regimen had at least twice the risk of any surgical site infection (OR 2.0 95% CI 1.31–3.1, $P<.001$), superficial surgical site infections (OR 2.5, 95% CI 1.46–4.34, $P<.001$), but did not differ significantly in the rate of deep organ space (Table 3). The adjusted rate of any surgical site infection with respect to the antibiotic categories is shown in Figure 2. Results of the logistic regression were validated using propensity score matching (Appendix 1, http://links.lww.com/AOG/A753).

The overall rate of nonstandard antibiotics uses in the collaborative dropped from 5.2% to 2.5% over the study time period (Fig. 3).

DISCUSSION

In this retrospective analysis of patients undergoing hysterectomy in the Michigan Surgical Quality Collaborative, we found that the choice of antibiotic regimen given before hysterectomy independently predicts the rate of any surgical site infection. Beta-lactam antibiotics (cephalosporins, ampicillin–sulbactam, ertapenem) are associated with the lowest rates of surgical site infections. Recommended β-lactam alternatives (eg, clindamycin plus gentamicin or quinolone or aztreonam) and patients receiving nonstandard regimens (eg, gentamicin only, clindamycin only) have a significantly higher risk of surgical site infections. One possible explanation is that β-lactam antibiotics are highly effective against skin flora (*Streptococcus* species, *Staphylococcus aureus*, and coagulase-negative staphylococci), which are the predominant organisms

Table 2. Baseline Comparison of Characteristics Among the Antibiotic Groups

Variable	Beta-Lactam Antibiotics (n=17,827)	Beta-Lactam Alternatives (n=2,878)	Nonstandard (n=653)	*P*
Demographics and comorbidities				
Median age (y)	48±11.4	48.5±12.3	48±12.2	.09
BMI (kg/m^2)	30.8±8	31.6±8	31.7±9	.001
Diabetes present	1,461 (8.2)	305 (10.6)	68 (10.4)	.001
Tobacco user	4,088 (22.9)	730 (25.4)	173 (26.5)	.003
ASA class 3 or greater	3,632 (20.4)	744 (25.9)	170 (26)	<.001
History of hypertension	5,245 (29.4)	931 (32.3)	209 (32)	.03
Preoperative transfusion	122 (0.7)	23 (0.8)	1 (0.2)	.1
Gynecologic cancer	1,624 (9.1)	310 (10.8)	63 (9.6)	<.001
Perioperative factors				
Surgical approach, open	4,880 (27.4)	757 (26.3)	160 (24.5)	<.001
Estimated blood loss (mL)	100 (50–200)	100 (50–200)	100 (50–199)	.6
Surgical complexity, total RVU	25.9±12.8	26.8±13.4	25.4±13.4	<.001
Operative time (h)	2.2 (1)	2.2 (1)	2 (1)	.2
Surgical site infection (unadjusted)				
Any	329 (1.8)	88 (3.1)	24 (3.7)	<.001
Superficial	165 (0.9)	41 (1.4)	15 (2.3)	<.001
Deep organ	167 (0.9)	47 (1.6)	10 (1.5)	.003

BMI, body mass index; ASA, American Society of Anesthesiologists; RVU, relative value units.
Data are mean±standard deviation, n (%), or median (interquartile range) unless otherwise specified.

Table 3. Logistic Regression Model: Independent Predictors of Surgical Site Infection

Variable Adjusted for in Logistic Regression Model	Any Surgical Site Infections			
	Unadjusted OR	Adjusted OR	95% CI	*P*
Antibiotic category				
Beta-lactam antibiotics	Ref	Ref	Ref	Ref
Beta-lactam alternatives	1.7	1.62	1.27–2.07	<.001
Nonstandard	2.1	2.02	1.31–3.1	<.001
Surgical time (per h)	1.3	1.23	1.14–1.33	<.001
BMI (kg/m^2)				
Less than 30, nonobese	Ref	Ref	Ref	Ref
30 or greater, obese	1.8	1.5	1.2–1.9	<.001
Smoking status				
Nonsmoker	Ref	Ref	Ref	Ref
Smoker	1.33	1.46	1.18–1.8	<.001
ASA category				
Less than 3	Ref	Ref	Ref	Ref
3 or greater	1.8	1.12	0.9–1.4	.3
Surgical complexity (per RVU)	1.02	1.01	0.9–1.01	.13
Diabetes				
Absent	Ref	Ref	Ref	Ref
Present	1.8	1.36	1.05–1.76	.02
Final pathology				
Benign	Ref	Ref	Ref	Ref
Cancer	2.4	1.7	1.3–2.2	<.001
Surgical route				
MIS	Ref	Ref	Ref	Ref
Open	3	2.6	2.1–3.1	<.001

OR, odds ratio; CI, confidence interval; Ref, referent; BMI, body mass index; ASA, American Society of Anesthesiologists; RVU, relative value units; MIS, minimally invasive surgery (vaginal, laparoscopic, and robotic hysterectomies).

that cause surgical site infections.[16–18] Regimens that do not contain a β-lactam antibiotic are inferior in controlling these organisms.[7]

Given this increased risk, patient-reported allergy to penicillin should be thoroughly investigated to ascertain its validity and severity. Previous studies have shown that because of the fear of penicillin anaphylaxis, clinicians frequently accept a diagnosis of penicillin allergy without obtaining a detailed history of the reaction.[19] In our study, approximately 12% of the patients received a β-lactam alternative antibiotic regimen, a prevalence consistent with the self-reported penicillin allergy described in the literature.[20] It is important to remember that cephalosporin crossreactivity shown in skin testing is present in only 10% of patients with a true penicillin allergy.[19,21] Patients with negative results on penicillin skin testing and those without a history of an anaphylactic reaction to penicillin can safely receive cephalosporin.[19,22,23] Routine use of penicillin skin testing could potentially increase the use of cephalosporins and therefore reduce the use of alternative antibiotics in perioperative settings.[24,25]

The current analysis quantifies the association of administering antibiotics not recommended by the College or by Surgical Care Improvement Project guidelines before hysterectomy. Wright et al[10] reported that 2.3% of patients undergoing gynecologic surgery received antibiotics not recommended by the guidelines. However, the authors did not report the effect of nonadherence to guidelines on surgical site infection rates. In our study, the majority of patients who received a nonstandard regimen received a single-agent antibiotic (clindamycin, gentamicin, or metronidazole). Previous studies have shown these single agents are inferior to cephalosporins.[26] Studies have also shown that adherence to Surgical Care Improvement Project's surgical site infection reduction bundle into surgical safety checklists can significantly improve antibiotic infusion timing and antibiotic selection.[27] In our study, for each quarter starting in July 2012, the percentage of patients in the collaborative who received nonstandard antibiotics has consistently decreased (Fig. 3). Although precise reasons of this improvement are likely multifactorial, the participation of hospitals in a functional collaborative encouraging

Superficial Surgical Site Infections				Deep Surgical Site Infections			
Unadjusted OR	Adjusted OR	95% CI	*P*	Unadjusted OR	Adjusted OR	95% CI	*P*
Ref	Ref	Ref	Ref	Ref	Ref	Ref	Ref
1.6	1.5	1.04–2.09	.03	1.8	1.7	1.2–2.4	<.001
2.5	2.5	1.46–4.34	.001	1.7	1.6	0.8–3.1	.1
1.3	1.14	0.98–1.3	.08	1.3	1.26	1.14–1.39	<.001
Ref	Ref	Ref	Ref	Ref	Ref	Ref	Ref
2.3	1.8	1.2–2.7	<.001	1.4	1.2	0.8–1.6	.2
Ref	Ref	Ref	Ref	Ref	Ref	Ref	Ref
1.5	1.7	1.2–2.2	<.001	1.2	1.27	0.9–1.7	.14
Ref	Ref	Ref	Ref	Ref	Ref	Ref	Ref
2.2	1.2	0.8–1.7	.5	1.4	1.1	0.8–1.5	.5
1.02	1.01	0.9–1.02	.1	1.01	1.002	0.9–1.01	.9
Ref	Ref	Ref	Ref	Ref	Ref	Ref	Ref
2.2	1.5	1.04–2.2	.03	1.4	1.3	0.8–1.8	.24
Ref	Ref	Ref	Ref	Ref	Ref	Ref	Ref
3	1.8	1.3–2.6	.01	1.8	1.5	0.9–2.5	.08
Ref	Ref	Ref	Ref	Ref	Ref	Ref	Ref
4.2	3.5	2.6–5	<.001	2	1.9	1.37–2.6	<.001

evidence-based practices seems to improve the quality of surgical care across the hospitals.[28]

This study has several strengths. The Michigan Surgical Quality Collaborative is a statewide collaborative that uses standardized data collection methods and dedicated nurse abstractors who are regularly audited for interrater reliability. Although the collaborative is limited to a single state, it includes a mix of academic and community hospitals, making the data more generalizable. In addition, our logistic regression modeling accounted for the clustering effect from

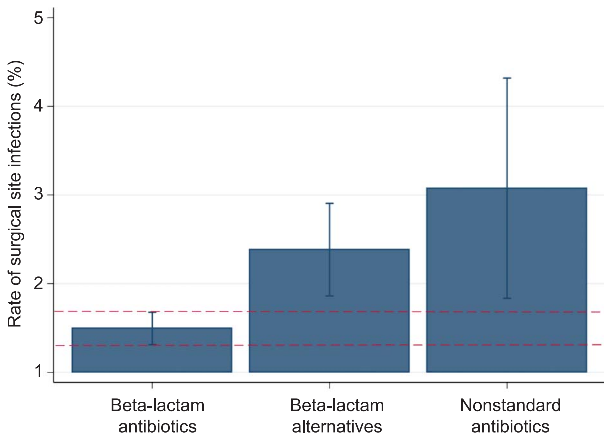

Fig. 2. Adjusted rates of overall surgical site infection by antibiotic category. Rates adjusted for patient factors (age, body mass index, American Society of Anesthesiologists category, history of diabetes, gynecologic malignancy, and tobacco use) and operative factors (surgical time, blood loss, and surgical complexity). *Red dashed lines* indicate 95% confidence interval bounds for referent category.

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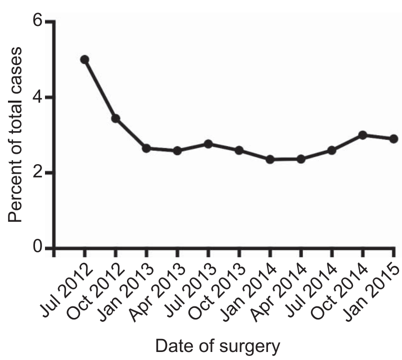

Fig. 3. Proportion of patients over time enrolled in the Michigan Surgical Quality Collaborative receiving nonstandard antibiotic regimens per the American College of Obstetricians and Gynecologists use guidelines and the Surgical Care Improvement Project use guidelines.

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physician and facility preferences. Studies have shown that the quality of data from collaboratives such as the Michigan Surgical Quality Collaborative and the National Surgical Quality Improvement Project is similar to that of chart review and much better than that of administrative claims-based databases.[29]

Limitations of our study include reported heterogeneity in surgical site infection reporting in the literature; however, collaborative abstractors are trained to reduce variations in reporting. Moreover, the Centers for Disease Control and Prevention criteria for surgical site infection diagnosis may underestimate the true incidence of surgical site infections by excluding cases of cellulitis by as much as threefold.[30] Although the nurse abstractors follow up with patients by phone within the 30-day period to avoid missing capturing complications if patients seek care in another hospital, potential for underreporting surgical site infections remains. Lastly, data on the appropriate timing and dosage of antibiotics were not available, and variations in these could have affected the conclusions of this study.

In summary, efforts to decrease surgical site infections could focus on adherence to recommended preoperative antibiotic guidelines and thorough evaluation of patient-reported penicillin allergies to increase the number of patients receiving β-lactam antibiotics.

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