

Impact of Patient-Reported Penicillin Allergy on Antibiotic Prophylaxis and Surgical Site Infection Among Patients Undergoing Colorectal Surgery

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BACKGROUND: Surgical site infections are a major preventable source of morbidity, mortality, and increased health care expenditures after colorectal surgery. Patients with penicillin allergy may not receive the recommended preoperative antibiotics, putting them at increased risk for surgical site infections.

OBJECTIVE: This study aimed to evaluate the impact of patient-reported penicillin allergy on preoperative antibiotic prophylaxis and surgical site infection rates among patients undergoing major colon and rectal procedures.

DESIGN: This is a retrospective observational study.

SETTING: This study was conducted at a tertiary teaching hospital in Dallas.

PATIENTS: Adults undergoing colectomy or proctectomy between July 2012 and July 2019 were included.

MAIN OUTCOME MEASURES: The primary outcomes measured were preoperative antibiotic choice and surgical site infection.

RESULTS: Among 2198 patients included in the study, 12.26% (n = 307) reported a penicillin allergy. Patients

with penicillin allergy were more likely to be white (82%) and female (54%; $p < 0.01$). The most common type of allergic reaction reported was rash (36.5%), whereas 7.2% of patients reported anaphylaxis. Patients with self-reported penicillin allergy were less likely to receive beta-lactam antibiotics than patients who did not report a penicillin allergy (79.8% vs 96.7%, $p < 0.001$). Overall, 143 (6.5%) patients had surgical site infections. On multivariable logistic regression, there was no difference in rates of surgical site infection between patients with penicillin allergy vs those without penicillin allergy (adjusted OR 1.14; 95% CI, 0.71–1.82).

LIMITATIONS: A limitation of this study was its retrospective study design.

CONCLUSIONS: Self-reported penicillin allergy among patients undergoing colorectal surgery is common; however, only a small number of these patients report any serious adverse reactions. Patients with self-reported penicillin allergy are less likely to receive beta-lactam antibiotics and more likely to receive non-beta-lactam antibiotics. However, this does not affect the rate of surgical site infection among these patients, and these patients can be safely prescribed non-beta-lactam antibiotics without negatively impacting surgical site infection rates. See **Video Abstract** at <http://links.lww.com/DCR/B838>.

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IMPACTO DE LA ALERGIA A LA PENICILINA INFORMADA POR EL PACIENTE EN LA PROFILAXIS ANTIBIÓTICA Y LA INFECCIÓN DEL SITIO OPERATORIO ENTRE PACIENTES DE CIRUGÍA COLORECTAL

ANTECEDENTES: Las infecciones del sitio operatorio son una de las principales fuentes prevenibles de morbilidad,



mortalidad y aumento del gasto sanitario después de cirugía colorrectal. Es posible que los pacientes con alergia a la penicilina no reciban los antibióticos preoperatorios recomendados, lo que los pone en mayor riesgo de infecciones en el sitio operatorio.

OBJETIVO: Este estudio tuvo como objetivo evaluar el impacto de la alergia a la penicilina informada por el paciente sobre la profilaxis antibiótica preoperatoria y las tasas de infección del sitio operatorio entre pacientes sometidos a procedimientos mayores de colon y recto.

DISEÑO: Estudio observacional retrospectivo.

AJUSTE: Hospital universitario terciario en Dallas.

PACIENTES: Adultos sometidos a colectomía o proctectomía entre julio de 2012 a julio de 2019.

PRINCIPALES MEDIDAS DE DESENLACE: Elección de antibióticos preoperatorios e infección del sitio operatorio.

RESULTADOS: Entre los 2198 pacientes incluidos en el estudio, el 12,26% ($n = 307$) informó alergia a la penicilina. Los pacientes con alergia a la penicilina tenían más probabilidades de ser blancos (82%) y mujeres (54%) ($p < 0,01$). El tipo más común de reacción alérgica notificada fue erupción cutánea (36,5%), mientras que el 7,2% de los pacientes notificó anafilaxia. Los pacientes con alergia a la penicilina autoinformada tenían menos probabilidades de recibir antibióticos betalactámicos en comparación con los pacientes que no informaron alergia a la penicilina (79,8% frente a 96,7%, $p < 0,001$). En general, hubo 143 (6,5%) pacientes con infecciones del sitio operatorio. En la regresión logística multivariable no hubo diferencias en las tasas de infección del sitio operatorio entre los pacientes con alergia a la penicilina frente a los que no tenían alergia a la penicilina (razón de probabilidades ajustada 1,14; intervalo de confianza del 95%, 0,71–1,82).

LIMITACIONES: Diseño de estudio retrospectivo.

CONCLUSIONES: La alergia a la penicilina autoinformada entre los pacientes de cirugía colorrectal es común, sin embargo, solo un pequeño número de estos pacientes informan reacciones adversas graves. Los pacientes con alergia a la penicilina autoinformada tienen menos probabilidades de recibir antibióticos betalactámicos y más probabilidades de recibir antibióticos no betalactámicos. Sin embargo, esto no afecta la tasa de infección del sitio quirúrgico entre estos pacientes y se les puede recetar de forma segura con antibióticos no betalactámicos sin afectar negativamente las tasas de infección del sitio quirúrgico.

Consulte **Video Resumen** en <http://links.lww.com/DCR/B838>. (Traducción—Dr. Juan Carlos Reyes)

KEY WORDS: Colorectal surgery; Penicillin allergy; Preoperative antibiotics; Surgical site infection.

Surgical site infections (SSIs) are a major source of morbidity, mortality, and increased health care expenditure, with an estimated \$25,000 in additional charges per occurrence.^{1–5} Patients undergoing colorectal surgery are subject to SSI rates ranging from 5.2% to 26%.^{6–9} The role of properly selected preoperative antibiotics in reducing SSI rates following colorectal surgery is well established and has been widely adopted as a quality metric for health care systems.¹⁰ Beta-lactam antibiotics are considered the first line for prophylaxis because of their effectiveness, reduced cost, and wider availability.^{11–13} Both the 2011 “Surgical Care Improvement Project (SCIP)” and the 2013 “Clinical Practice Guidelines for Antimicrobial Prophylaxis in Surgery” recommend beta-lactam antibiotics, either by themselves or in combination with metronidazole.

On the basis of these guidelines, first-line preoperative antibiotics for colorectal procedures include single doses of second-generation cephalosporins, like cefoxitin or cefotetan, versus cefazolin or ceftriaxone in combination with metronidazole, or a single dose of ampicillin-sulbactam.^{10,14} However, penicillin allergies are reported by 10% to 35% of the population,^{15–17} and these allergies have been reported to have a high cross-reactivity with cephalosporins. These factors, when combined, may result in patients not receiving the established first-line preoperative prophylactic antibiotics, which puts these patients at an assumed increased risk for SSIs.

In reality, only a small fraction (<10%) of self-reported penicillin-allergic patients are found to have a true allergic reaction to penicillin.^{15,18–20} Furthermore, less than 1% of patients with true penicillin allergy have cross-reactivity with cephalosporins.²¹ Yet, prior studies have shown that patients with self-reported penicillin allergy are less likely to receive beta-lactam antibiotics and more likely to receive non-beta-lactam antibiotics, like vancomycin, clindamycin, and gentamycin.^{22,23} Prior studies have also shown increased SSI rates among patients with penicillin allergy undergoing major surgical procedures.^{22–24} However, there is a paucity of data to assess the impact of penicillin allergies on patients undergoing colorectal surgery. The purpose of this study is to determine the impact of self-reported penicillin allergies on 1) the type of antibiotic administered before surgery and 2) the SSI rates among patients undergoing major abdominal colorectal procedures.

MATERIALS AND METHODS

Study Population

Patients undergoing elective colectomy or proctectomy surgical procedures at our institution from July 2012 to July 2019 were identified using the following specific Current Procedural Terminology (CPT) codes: 44140 to



44144, 44160, and 45550 (open partial colectomy); 44204 to 44206 and 45402 (laparoscopic partial colectomy); 44150 to 44153 (open total abdominal colectomy); 44210 (laparoscopic total abdominal colectomy); 44155 to 44158 (open total abdominal proctocolectomy); 44211 and 44212 (laparoscopic total abdominal proctocolectomy); 44145 to 44147, 45111 to 45116, and 45119 (open low anterior resection); 45397, 44207, and 44208 (laparoscopic low anterior resection); 45110 (open abdominoperineal resection); and 45395 (laparoscopic abdominoperineal resection). Patients undergoing emergency or revisional surgeries were excluded. Additional exclusion criteria included ASA class V, ventilator dependence, systemic inflammatory response syndrome, sepsis, septic shock, and open wound present at the time of surgery. Patients with additional CPT codes were excluded to avoid any SSI risk attributable to the resection of other organs. However, patients with CPT codes 44213 (laparoscopic mobilization of splenic flexure), 44139 (mobilization of the splenic flexure in conjunction with partial colectomy), and 15860 (intravenous injection of agent [eg, fluorescein]) were not excluded because these are integral parts of colorectal surgeries.

Data Sources

Data on patient demographics, comorbidities, operative details, postoperative complications, and mortality were collected using the institutional American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) database. The ACS-NSQIP database is composed of prospectively collected validated data on more than 130 variables for each patient encounter. These variables pertain to patient demographics, preoperative comorbidities, operative information, and postoperative outcomes for up to 30 days postoperatively. This database is validated and has been used extensively for outcomes research. At our institution, colectomy and proctectomy are targeted NSQIP procedures, and they are all abstracted and reported.

Penicillin allergy status was established via individual patient medical record review. The type of allergic reaction, as well as the antibiotic administered before surgery, were also noted. These 2 datasets were combined for analysis.

Outcomes of Interest

Patients were divided into penicillin allergy and no penicillin allergy cohorts. Primary outcomes were the type of antibiotic administered to patients before surgery and the SSI rate in patients with self-reported penicillin allergies. At our institution, preoperative antibiotics administration is protocolized with a clear alternative antibiotics recommendation (ciprofloxacin + Flagyl) in case of penicillin allergy.

Surgical site infections are categorized in NSQIP as one of the following: 1) superficial SSI, 2) deep SSI, and

3) organ space SSI. For this study, all 3 SSI variables were combined into a single variable as “any SSI.” We also studied the impact of penicillin allergy on each category of SSI individually.

Secondary outcomes of interest included the prevalence of self-reported penicillin allergy among patients undergoing colorectal surgery, the frequency of different types of allergic reactions, and the impact of penicillin allergy on length of hospital stay, unplanned readmissions, and return to the operating room.

Statistical Analysis

Differences in demographic data and operative details between the 2 patient cohorts (penicillin allergy versus no penicillin allergy) were compared using means and SDs for continuous variables and frequency and percent for categorical variables. An independent sample *t* test and χ^2 /Fisher exact test were used for continuous and categorical variables.

Propensity score risk adjustment was used to assess the adjusted effect of penicillin allergy on outcomes. First, the indicator for penicillin allergy was modeled as a dependent variable in a multivariable logistic regression model, and we obtained the conditional probability/likelihood of experiencing penicillin allergy given the patient's characteristics. The patient characteristics considered included age, sex, race, ethnicity, BMI, diabetes, type of surgery, steroid immunosuppressant use for chronic pain, chronic obstructive pulmonary disease, congestive heart failure, smoking history, ASA class, preoperative mechanical bowel preparation, and oral antibiotic preparation.

The derived conditional probabilities (also known as the propensity scores) were then used in multivariable logistic regression models to obtain the risk-adjusted effect of penicillin allergy on the outcomes. These models considered outcomes such as SSI, wound dehiscence, *Clostridium difficile* infection, unplanned readmission, or return to the operating room as dependent variables, and indicator of penicillin allergy and propensity scores derived in step 1 were considered as independent variables. Length of stay was modeled in a similar fashion using a multivariable linear regression model.

Statistical analysis was performed using the SAS software (SAS Institute Inc, Cary, NC). A *p* value of <0.05 was considered statistically significant. The research was exempt from individual patient consent. The flow chart (Fig. 1) breaks down the process utilized for patient selection and data gathering.

RESULTS

Patient Characteristics

Of the 2198 patients who met our inclusion criteria, 307 (12.26%) had a self-reported penicillin allergy. Most of the

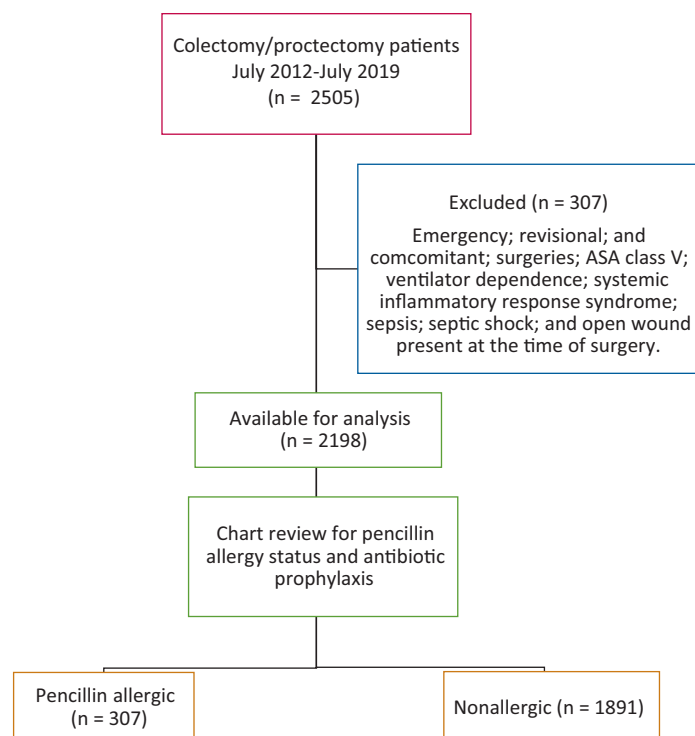


FIGURE 1. Study design with inclusion and exclusion criteria.

patients reporting penicillin allergies were white (82%) and female (54%; $p < 0.01$). No additional significant differences were identified between baseline demographics, comorbidities, and intraoperative characteristics for patients who reported penicillin allergy vs those who did not (Table 1).

Prevalence of Self-Reported Penicillin Allergy

The 307 self-reported penicillin-allergic patients reported a total of 334 different types of allergic reactions. The types of allergic reactions were classified into 3 major categories, including allergic reactions and hypersensitivities, side effects, and other. The most common category of self-reported allergic reaction was hypersensitivity reactions (70.1%), and rashes were the most common type of hypersensitivity reaction, reported by 36.5% of all self-reported allergic patients. Twenty-four patients (7.2%) reported anaphylaxis. Classification and prevalence of different types of allergic reaction are listed in Table 2.

Impact of Penicillin Allergy on Type of Antibiotics Administered

Analysis of preoperative antibiotic administration data showed that ceftriaxone plus metronidazole was the most commonly administered antibiotic combination overall, with 49.5% of all patients receiving it before surgery. The most common non-beta-lactam antibiotic combination administered was a quinolone (either levofloxacin or ciprofloxacin) plus metronidazole, received by only 3% of all

patients. Patients with self-reported penicillin allergy were less likely to receive beta-lactam antibiotics (79.8% of penicillin-allergic vs 96.7% of non-penicillin-allergic patients, $p < 0.001$) and more likely to receive non-beta-lactam antibiotics (18.2% of penicillin-allergic vs 2.1% of non-penicillin-allergic patients, $p < 0.00$). Figure 2 shows the antibiotic prescription patterns between penicillin-allergic and non-penicillin-allergic groups.

Impact of Penicillin Allergy on SSI

Among the 2198 patients included in this study, 143 (6.5%) had an SSI. Of these, 59 patients had a superficial SSI, 19 patients had a deep SSI, and 72 patients had an organ space SSI. On univariate analysis, no difference was noted in rates of SSI between patients with a penicillin allergy vs those without. Length of stay, unplanned readmission, and return to the operating room were not significantly different between the 2 cohorts (Table 3).

On multivariate logistic regression, after adjusting for age, sex, race, ethnicity, BMI, diabetes, type of surgery, steroid use, chronic obstructive pulmonary disease, congestive heart failure, smoking history, ASA class, operative time, and intraoperative or postoperative blood transfusion requirements, preoperative mechanical bowel preparation, and oral antibiotic preparation, there was no significant difference in the rates of SSI, wound dehiscence, unplanned readmission or return to the operating room between patients with penicillin allergy vs those without penicillin allergy (adjusted OR, 1.14; 95% CI, 0.71–1.82; Fig. 3).

TABLE 1. Comparison of baseline characteristics and intraoperative factors between penicillin-allergic and non-penicillin-allergic patients

Variable	All patients (n = 2198)	Penicillin allergy (n = 307)	No penicillin allergy (n = 1891)	p value
Age, y, mean (SD)	59.9 (14.9)	60.8 (15.3)	59.8 (14.8)	0.27
Sex (female), n (%)	1186 (54.0)	188 (61.2)	998 (52.8)	<0.01
Race, n (%)				<0.01
White	1802 (82.0)	276 (89.9)	1526 (80.7)	
Black	334 (15.2)	27 (8.8)	307 (16.2)	
Other	62 (2.8)	4 (1.3)	58 (3.1)	
Hispanic ethnicity, n (%)	205 (9.3)	26 (8.5)	179 (9.5)	0.58
BMI, n (%)	27.9 (6.7)	27.9 (6.7)	27.9 (6.7)	0.98
Diabetes, n (%)	352 (16.0)	45 (14.7)	307 (16.2)	0.48
COPD, n (%)	67 (3.0)	16 (5.2)	51 (2.7)	0.02
CHF, n (%)	31 (1.4)	5 (1.6)	26 (1.4)	0.73
Current smoker, n (%)	321 (14.6)	53 (17.3)	268 (14.2)	0.15
Acute renal failure, n (%)	7 (0.3)	1 (0.3)	6 (0.3)	0.98
Preoperative oral antibiotic preparation, n (%)	668 (30.4)	103 (33.6)	565 (29.9)	0.19
Preoperative mechanical bowel preparation, n (%)	850 (38.7)	137 (44.6)	713 (37.7)	0.02
ASA classification, n (%)				0.57
ASA I, no disturbance	25 (1.1)	2 (0.7)	23 (1.2)	
ASA II, mild disturbance	775 (35.3)	100 (32.6)	675 (35.7)	
ASA III, severe disturbance	1316 (59.9)	193 (62.9)	1123 (59.4)	
ASA IV, life threatening	82 (3.7)	12 (3.9)	70 (3.7)	
Operative duration, min, n (%)	198.2 (113.0)	199.0 (101.8)	198.0 (114.7)	0.89
Blood transfusion, n (%)	247 (11.2)	34 (11.1)	213 (11.3)	0.94
Type of surgery, n (%)				0.94
Open	513 (23.3)	68 (22.1)	445 (23.5)	
MIS	835 (38.0)	116 (37.8)	719 (38.0)	
MIS converted to open	142 (6.5)	21 (6.8)	121 (6.4)	
Not specified	708 (32.2)	102 (33.2)	606 (32.0)	
Wound class, n (%)				0.28
Clean	3 (0.1)	0 (0.0)	3 (0.2)	
Clean/contaminated	1097 (49.9)	140 (45.6)	957 (50.6)	
Contaminated	960 (43.7)	149 (48.5)	811 (42.9)	
Dirty/infected	138 (6.3)	18 (5.9)	120 (6.3)	

CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; MIS = minimally invasive surgery.

DISCUSSION

Studies have shown that a patient's penicillin allergy status can adversely impact the administration of first-line

TABLE 2. Documented self-reported penicillin allergic reactions by type

Type of self-reported allergic reaction	n (%)
Total	334 (100)
Allergic reactions and hypersensitivities	234 (70.1)
Rash	122 (36.5)
Hives	46 (13.8)
Swelling, angioedema	32 (9.6)
Anaphylaxis	24 (7.2)
Respiratory distress	9 (2.7)
Blisters	1 (0.3)
Side effects	19 (5.9)
GI symptoms (nausea, vomiting, diarrhea)	9 (2.7)
Neurologic symptoms (headache, hallucination)	6 (1.8)
Fever	2 (0.6)
Musculoskeletal symptoms	1 (0.3)
Oral thrush	1 (0.3)
Other	81 (24.3)
Unknown	71 (21.3)
Childhood reaction	10 (3.0)

preoperative antibiotics, putting them at an increased risk of SSIs.^{22,24} Despite the increased risk of SSI associated with colorectal surgery at baseline, the prevalence and impact of penicillin allergy in this population has not been studied.^{22–24} Using the NSQIP institutional database, we found that even though a patient's self-reported penicillin allergy impacts the administration of the type of antibiotic, this does not translate into higher rates of SSI for these patients.

In our study, 12.26% of patients had some form of self-reported penicillin allergy. This is in concordance with previously conducted studies evaluating the prevalence of self-reported penicillin allergy among surgical patients in the United States. Studies have reported penicillin allergy rates of 11% to 21.6% among their surgical patients.^{22–24} A similar prevalence rate (11.2%) was also found among a large cohort of individuals (representing about 1% of the US population) who received care at Kaiser Foundation hospitals.²⁵ Despite this high percentage of patients reporting a penicillin allergy, less than 10% actually have a penicillin allergy barring them from receiving beta-lactam antibiotics.^{18–20} A skin-testing study of patients in acute care facilities discovered that 96% patients with self-reported allergy had a negative skin test.²⁶ Although we

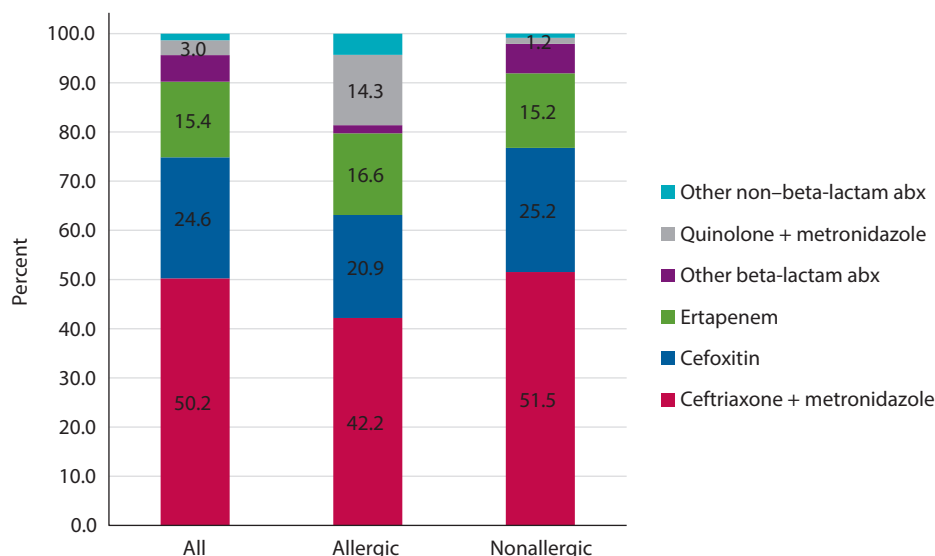


FIGURE 2. Prescription patterns of antibiotics before surgery among penicillin-allergic and non-penicillin-allergic populations. abx = antibiotics.

TABLE 3. Association of self-reported penicillin allergy with surgical infections and postoperative outcomes

Postoperative outcomes	Total (n = 2198)	Penicillin allergy (n = 307)	No penicillin allergy (n = 1891)	p value
Superficial surgical site infection, n (%)	59 (2.7)	6 (2.0)	53 (2.8)	0.39
Deep surgical site infection, n (%)	19 (0.9)	2 (0.7)	17 (0.9)	0.66
Organ space surgical site infection, n (%)	72 (3.3)	15 (4.9)	57 (3.0)	0.09
Any surgical site infection, n (%)	143 (6.5)	23 (7.5)	120 (6.3)	0.45
Length of stay, d, mean (SD)	6.4 (5.4)	6.2 (4.6)	6.4 (5.5)	0.61
Unplanned readmission, n (%)	202 (9.2)	38 (12.4)	164 (8.7)	0.04
Return to operating room, n (%)	99 (4.5)	19 (6.2)	80 (4.2)	0.12

did not test for penicillin allergy in our study, only 7.2% of patients with penicillin allergy listed anaphylaxis as their allergic reaction, which is similar to previously reported rates of 5%.²²

We found that patients with penicillin allergy are much more likely to receive non-beta-lactam antibiotics than patients who did not report a penicillin allergy

(18.2% vs 2.1%). This finding is in concordance with previous studies in which patients undergoing general, orthopedic, and cardiac surgery procedures were less likely to receive a beta-lactam antibiotic if they reported a penicillin allergy.^{22–24} Surprisingly, despite the predilection for non-beta-lactam antibiotics in the penicillin allergy group, beta-lactam antibiotics were still the most common

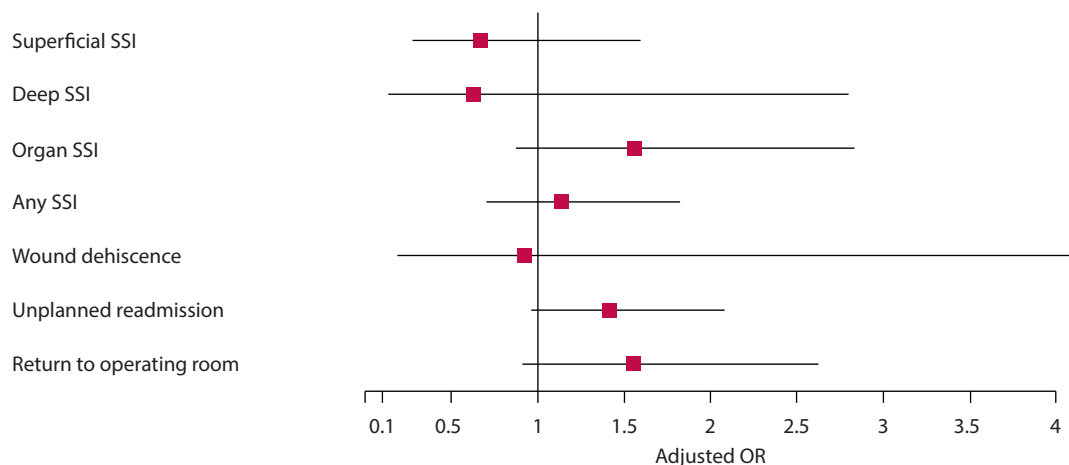


FIGURE 3. Forrest plot of adjusted impact of penicillin allergy on SSI and other outcomes. SSI = surgical site infection.

class of antibiotics given to both patients with and without self-reported penicillin allergy (79.8% vs 96.7%), further demonstrating the faux nature of these allergies. In a 2017 systemic review of patients with penicillin allergy, 95% of patients who report penicillin allergy are ultimately able to tolerate penicillin administration.²⁷ The most common non-beta-lactam antibiotic our patients received was metronidazole plus quinolone, which is different from other studies reporting that clindamycin and vancomycin were the antibiotics most commonly used in patients with penicillin allergies.^{22,23} This difference is likely due to a different spectrum of coverage needed for colorectal compared with noncolorectal cases.

Prior studies have shown penicillin allergy increasing the risk of SSI.^{22,24} Blumenthal et al²² reported increased odds of SSI (adjusted OR, 1.51; 95% CI, 1.02–2.22) in patients with self-reported penicillin allergy. In contrast, penicillin allergy was not associated with increased risk of SSI in our study. This difference in main outcomes in our study can be the result of several factors. First, most of our patients with penicillin allergy received the first-line SCIP-recommended antibiotics in accordance with our hospital antibiotic protocol: ceftriaxone plus metronidazole, cefoxitin, and ertapenem. The next most common antibiotic administered to these patients was a quinolone in combination with metronidazole. Although not first line, they are recommended by SCIP in patients with penicillin allergies. All these antibiotics have been shown to be as effective in reducing the risk of SSIs as certain beta-lactam antibiotics. A study of 4331 patients undergoing colectomy from Michigan surgical collaborative showed that even though the use of SCIP-compliant antibiotics was associated with a lower rate of SSI,²⁸ among these antibiotics, 3 specific antibiotic choices that were associated with the greatest decrease in SSI were ciprofloxacin plus metronidazole, cefazolin plus metronidazole, and ertapenem. It is possible that penicillin-allergic patients in the Blumenthal et al²² study did not receive the recommended alternative antibiotic, leading to increased SSI rates. Second, Blumenthal et al evaluated 8385 patients to assess the impact of penicillin allergy on SSI compared with only 2198 patients in our study. It is possible that our study was underpowered to assess the impact of penicillin allergy on SSI given the low rate of postoperative SSI in our study.

We acknowledge several limitations of our study, including its retrospective nature, limited numbers, and single institutional design. We addressed these issues by using data over a long period of time from more than 15 individual surgeons.

CONCLUSION

Self-reported penicillin allergy is common among patients undergoing colorectal surgery. Most of the allergic reactions listed are either side effects or benign allergic

reactions, with only 7.2% eliciting anaphylaxis. Patients with self-reported penicillin allergy are less likely to receive beta-lactam antibiotics preoperatively, but most patients still receive some form of SCIP-compliant first-line beta-lactam antibiotics despite self-report of allergy, and the remainder receive the recommended second-line antibiotic prophylaxis. As such, the rate of SSI or other short-term outcomes among these patients remain comparably low. Patients with penicillin allergy can be safely prescribed recommended non-beta-lactam antibiotics without increased risk of SSI.

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