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## Utility of beta-lactam allergy assessment in patients receiving vancomycin for surgical prophylaxis

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### Abstract

**Background:** Beta-lactam antibiotics are first-line agents for most patients receiving antimicrobial prophylaxis in surgical procedures. Despite evidence showing low cross-reactivity between penicillins and cephalosporins, patients with beta-lactam allergies commonly receive vancomycin as an alternative to avoid allergic reaction.

**Methods:** Adult patients receiving vancomycin for surgical prophylaxis with a reported beta-lactam allergy at our institution between August 2017 to July 2018 were retrospectively evaluated for potential eligibility for penicillin allergy testing and/or receipt of standard prophylaxis.

**Results:** Among 830 patients who received vancomycin for surgical prophylaxis, 196 reported beta-lactam allergy and were included in the analysis. Approximately 40 % of surgeries were orthopedic. Of patients receiving vancomycin as first-line therapy, 189 (96.4 %) were potentially eligible for beta-lactam prophylaxis.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

**Conclusions:** Patients with beta-lactam allergies often qualify for receipt of a first-line antibiotic. An opportunity exists for improved allergy assessment as an antimicrobial stewardship intervention in surgical prophylaxis.

### Keywords

Antibiotic allergy; Surgical prophylaxis; Allergy evaluation; Antimicrobial stewardship

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## 1. Introduction

Penicillin allergies are the most commonly reported allergy in the United States, with 10–15 % of the population reporting a penicillin allergy, yet greater than 95 % of patients with a reported allergy can in fact tolerate penicillins [1]. Inaccurate labels of allergy (i.e., patients inaccurately noted to have an allergy in their medical record) may occur because of miscommunication of side effects or family history. In addition, sensitivity wanes over time (80 % of IgE-mediated allergies to penicillin disappear after 10 years) [2,3].

Surgical site infections (SSI) are a key contributor to morbidity and mortality in patients undergoing surgical procedures. All-cause mortality risk in patients with SSIs has been found to be approximately 2 to 11 times higher than in patients without SSI [4,5]. As the most common adverse event affecting patients undergoing surgery, SSIs are associated with increased cost of care, extended length of hospital stay and higher rates of hospital readmissions [6]. A previous study evaluating the impact of documented beta-lactam allergies on perioperative antibiotic selection found that patients with beta-lactam allergies had a 9-fold lower odds of receiving first-line antimicrobial prophylaxis compared to those without documented allergy [7]. In addition, penicillin allergic patients have been shown to have 1.5 increased odds to develop SSI as patients without a penicillin allergy label, a risk almost entirely mediated by their receipt of second-line antibiotics for surgical prophylaxis [8,9].

The presence of documented antibiotic allergies can limit the ability to initiate appropriate antibiotic therapy, however there is an opportunity to avoid alternative antibiotic use in patients undergoing surgical procedures [10,11]. It is unnecessary to avoid all beta-lactam therapy in all patients with allergies due to low cross-reactivity between and across classes of beta-lactams and for patients with misclassified allergies [12, 13]. Second, patients with low risk or IgE-mediated allergies may be safely administered an oral challenge with the offending agent for the purpose of allergy de-labeling.

Penicillin skin testing and direct challenges can be utilized as tools to determine whether a patient truly has a penicillin allergy. Such screening tests can be used pre-operatively to identify patients with clinically relevant allergies and thus limit use of alternative antibiotics only to these patients, rather than those who are able to tolerate penicillins [14]. Previous studies have shown that over 95 % of patients who are labeled penicillin allergic can be delabeled following evaluation and testing. The objective of this study was to evaluate inappropriate use of vancomycin surgical prophylaxis among patients reporting beta-lactam allergies. We accomplished this by evaluating documented allergies in those who may have

been eligible to receive first line therapy had they met institutional criteria for allergy de-labeling or receipt of primary antimicrobial prophylaxis.

## 2. Methods

### 2.1. Study setting

We conducted a cross-sectional study of adult inpatients (≥ 18 years) receiving vancomycin for surgical prophylaxis with a reported penicillin and/or cephalosporin allergy at Oregon Health & Science University (OHSU) between August 2017 to July 2018 as a secondary analysis of a larger cohort assembled for a prior study. OHSU is a 500-bed academic medical center with fifteen independent surgical subspecialties (abdominal organ transplantation, bariatric, cardiothoracic, otolaryngology, general, pediatric, plastic and reconstructive, neurosurgery, obstetrics and gynecology, orthopedic surgery, otolaryngology, surgical oncology, trauma, urology and vascular). OHSU performed approximately 13,500 inpatient surgeries during the study period.

### 2.2. Study design

The cohort for the prior study was identified using the Centers for Disease Control and Prevention's (CDC) National Healthcare safety network (NHSN) definition for antibacterial agents predominantly used for resistant Gram-positive infections and patients were included for this analysis based on receipt of vancomycin for surgical prophylaxis with a reported penicillin and/or cephalosporin allergy. Determination of eligibility for receipt of beta-lactam prophylaxis or allergy testing was performed by a single infectious disease trained pharmacist (KJT) who also serves as a member of the antimicrobial stewardship program and provides routine evaluation and assessment of antibiotic surgical prophylaxis regimens and referral for allergy de-labeling with determinations being guided by an inpatient protocol which was developed and reviewed by the antimicrobial stewardship team in coordination with surgeons at our institution. Electronic medical records were retrospectively evaluated for potential to receive beta-lactam therapy utilizing the institutional protocol developed in May 2020 (Fig. 1.) which makes recommendations for surgical prophylaxis in patients with beta-lactam allergies. Patients with mild beta-lactam allergies were determined to be eligible for beta-lactam prophylaxis if the reported beta-lactam allergy did not have a similar side chain to the recommended prophylactic agent of choice per institutional guidelines, which recommends cefazolin as 1st line for the majority of surgical procedures at our institution. Eligible patients with an IgE-mediated allergy due to a penicillin antibiotic were evaluated for potential penicillin allergy testing based on our penicillin allergy testing protocol (Fig. 2.) which allows for de-labeling of eligible patients per protocol. Study subjects were identified using the Pharmacy Research Repository (PHARR), a repository from the OHSU electronic medical record (EMR) system that includes encounter, allergy, culture, laboratory, and pharmacy data. Subjects receiving vancomycin were identified utilizing the CDC's NHSN standardized antimicrobial administration ratio (SAAR) for antibacterial agents predominantly used for resistant Gram-positive infections. Manual EMR review was performed by a single reviewer to capture demographics, surgical type, detailed allergy history, previous receipt of a beta-lactam antibiotic and if the surgery was an elective procedure. The surgery was

deemed to be an elective procedure if the patient was admitted for non-emergent surgical diagnosis or outpatient pre-surgical consultation was documented within the EMR. History of methicillin-resistant *Staphylococcus aureus* (MRSA) and number of patients not receiving combination prophylaxis with vancomycin and a beta-lactam were captured for descriptive purposes.

### 2.3. Data analysis

The primary endpoint for this study was to evaluate the percentage of patients who unnecessarily received vancomycin for surgical prophylaxis due to a documented beta-lactam allergy. Secondary endpoints sought to characterize the types of beta-lactam allergies and the potential for penicillin allergy testing via direct amoxicillin challenge or penicillin skin testing. Descriptive analyses were performed to characterize the study population. Categorical variables were described using frequencies and percentages. Continuous variables were reported using medians and interquartile ranges. Data management and statistical analysis was performed using Microsoft Excel (Microsoft Corporation, 2018). The study protocol was approved under IRB study protocol 00019104.

## 3. Results

Out of 1626 surgeries, there were 830 patients who received vancomycin for surgical prophylaxis. Among 830 patients who received vancomycin for surgical prophylaxis, there were 196 unique patients who reported beta-lactam allergy and were included in the analysis. Baseline characteristics of patients who reported a beta-lactam allergy are provided in Table 1. The median age of patients was 57 years old (range 33–81 years). The majority (78 %) were female. Of surgical procedures conducted, 77 % were deemed to be non-urgent. Approximately 40 % of all surgeries were performed by an orthopedic surgical subspecialty (see Table 1). There were 22 patients with a history of MRSA of which only one patient received vancomycin and a B-lactam agent as part of their prophylactic regimen. Table 2 presents patient allergy stratified by type and beta-lactam. There were 155 patients (80 %) with a penicillin allergy alone, 20 patients (10 %) with a cephalosporin allergy, and 21 (10 %) patients with both cephalosporin and penicillin allergies. Only four (2 %) patients were ineligible for first-line beta-lactam prophylaxis due to a cefazolin allergy reported as anaphylaxis. The most commonly reported allergy was severe IgE-mediated (32.6 %) followed by mild non-IgE mediated (23.5 %) allergy, with anaphylaxis being the most common severe IgE-mediated allergy (25 % of all allergies). There was a total of 105 (12.7 %) IgE-mediated allergies. Of these, 10 occurred greater than 10 years ago with three of them being anaphylaxis. There were 153 of 155 patients who may have qualified for a pre-procedural penicillin allergy testing either through graded oral amoxicillin challenge or penicillin skin testing. Eighty-two of these patients (53.6 %) may have received direct amoxicillin challenge, while 71 (46.4 %) may have received penicillin skin testing for potential removal of penicillin allergy labels prior to surgery. There were two patients overall (0.2 %) ineligible for any penicillin allergy testing due to severe non-IgE mediated allergy, reported as drug fever and hemolytic anemia. Of the 196 patients included, 189 may have potentially received prophylaxis with a preferred beta-lactam antibiotic due to lack of cross-reactivity or receiving pre-operative allergy evaluation.

## 4. Discussion

In our study, 96.4 % of all patients with beta-lactam allergies who received vancomycin for surgical prophylaxis could have been safely evaluated and/or challenged in order to receive recommended first-line prophylaxis with a beta-lactam antibiotic. Antibiotics are an important component of surgical practice and there exists a need for increased focus on antimicrobial stewardship [15]. Our study supports antimicrobial stewardship efforts in this area as there exists an opportunity for improved beta-lactam allergy assessments in patients undergoing surgery.

Sacco and colleagues evaluated perioperative antibiotic use by performing penicillin skin testing in patients with allergies as part of a preoperative evaluation process and found that 91.6 % of all patients referred for testing had negative penicillin skin testing. They also found that use of vancomycin, clindamycin and levofloxacin were significantly reduced in patients who underwent allergy testing [16]. Plager, et al. found that 92 % of patients undergoing preoperative penicillin allergy evaluation received first-line perioperative antibiotics compared to 38 % of patients who did not [14]. In their study, penicillin skin testing was the method of choice for allergy de-labeling, however, penicillin skin testing is not without limitations. Resource limitations such as cost, and time-constraints have been identified as barriers to implementation within many hospital systems [17]. Despite this, studies have shown that patient interview and direct oral challenges may help alleviate these barriers when implemented as part of a systematic process. For patients requiring scheduled surgical procedures, outpatient delabeling may be helpful prior to the scheduled procedure. However, delabeling can still be done in some instances while the patient is inpatient while waiting for a procedure, provided that the hospital has an inpatient delabeling program. A study conducted at our institution, following this data collection period, evaluated pharmacist-driven allergy evaluation in medical patients, we were able to de-label approximately 40 % of patients using interview alone [18]. Another 60 % of patients were able to be de-labeled using direct oral amoxicillin challenge by pharmacist intervention with only one patient requiring penicillin skin testing prior to challenge. Furthermore, only two patients developed signs of an allergic reaction, one reported as mild lip tingling requiring diphenhydramine while the other developed gastrointestinal upset. No patients developed an allergic reaction following delabeling. Cefazolin is the drug of choice for the majority of surgeries, in this study only 2 % of patients had a cefazolin allergy. Because cefazolin does not cross react with any other B-lactam antibiotics, the vast majority of patients identified could have received first-line prophylaxis regardless of allergy history. In this study, we identified that approximately 54 % of patients may have been de-labeled through oral amoxicillin challenge which would avoid time delays associated with penicillin skin testing. The findings of this study support stewardship efforts by highlighting the potential of an institutional guideline focused on avoiding second-line agents in combination with an allergy evaluation protocol regardless of financial and personnel resources devoted to allergy testing. Approximately 10 to 15 % of patients admitted to the hospital will have a penicillin allergy [1]. The problem of penicillin allergies is simply too vast for every patient with a labeled penicillin allergy to be evaluated by an allergist in the timeframe needed prior to surgery. Various strategies may be utilized to avoid unnecessary delays in surgery while

optimizing antibiotic use. Penicillin allergy evaluation and testing can be done via a protocol by various disciplines [18,19]. Different programs in different healthcare settings utilize physicians, pharmacists, nurses, allergists or others for allergy evaluation. Most penicillin allergies are low risk and can be managed by protocol. Our recommendation is that each institution utilize available expertise to develop a program with input from a board-certified allergist to meet their needs.

We did not evaluate clinical outcomes in our study; however, the presence of beta-lactam allergies is a key contributor to SSI rates. A study conducted by Wilhelm *et al.* which evaluated 2676 surgical procedures found that the odds of developing a surgical site infection in patients with reported beta-lactam allergies was 2 times the odds in patients without beta-lactam allergies [9]. This suggests that de-labeling patients with allergies has potential to modify the incidence of surgical site infections in patients undergoing surgical procedures. Furthermore, although this has not yet been demonstrated in a prospective study of patients undergoing surgery, data from the general population supports improved clinical outcomes in patients who have had allergies de-labeled.

There are several limitations to our study. As a retrospective study, these results are subject to observation bias due to the retrospective nature. To account for this, a single reviewer reviewed all cases of reported allergies using a standardized protocol as described in Figs. 1 and 2. The majority of patients in this study were from orthopedic and neurosurgery, and the findings of this study may not be representative of the impact of delabeling patients across all surgeries [20]. As a small, single-center study, a larger sample may have potential to demonstrate a larger impact and these results may not translate to other centers which might report varying rates of penicillin allergies, however we note that our findings where applicable are in-line with other published works. Previous studies have shown that hypersensitivity to penicillin antibiotics wanes over time, with 80 % of IgE mediated reactions resolving after 10 years [2,3,21]. Within our cohort, only 11 patients had an allergy documented more than 10 years ago. Due to EMR limitations, we reported these numbers based on documentation period. It is possible that patients with recently documented allergies actually had the reaction greater than 10 years ago and may have been safely de-labeled using direct amoxicillin challenge. A preoperative consultation may serve as an opportunity for identifying patients with recently documented allergies that could undergo allergy evaluation and de-labeling. Thirty-three percent of the included patients required urgent surgery, which would preclude a preoperative consultation for allergy de-labeling. Even so, 96 % of patients with a beta-lactam allergy were not allergic to standard therapy and may have received a first-line agent which highlights the importance of implementing institutional guidelines focused on administering first-line agents. Although this study did not evaluate patient outcomes previous data have shown that de-labeling anywhere between 112 and 124 patients with reported allergy would prevent 1 SSI [8]. Our institution performs approximately 13,500 surgeries annually; given that 10–15 % of admitted patients will have a penicillin allergy, implementation of a pre-surgical evaluation process might prevent approximately 10 to 18 SSIs per year [8]. This could result in a length of stay decrease ranging from 90 to 162 days and potential cost-savings to the institution ranging from \$200,000 to \$360, 000 per year based on an average increased length of hospital stay of 9 days and increased hospital cost association of \$20,000 [22,23].

## 5. Conclusion

A clear opportunity exists for improved beta-lactam allergy assessments in patients undergoing surgical procedures. Patients with reported beta-lactam allergies often qualify for receipt of a recommended first-line agent and increased efforts should be placed on safely evaluating and challenging allergies. Implementation of pre-surgical protocols focused on allergy assessment will contribute to antimicrobial stewardship efforts in the surgical population and reduce SSIs, however further data is needed to assess other patient-specific outcomes.

## Funding source

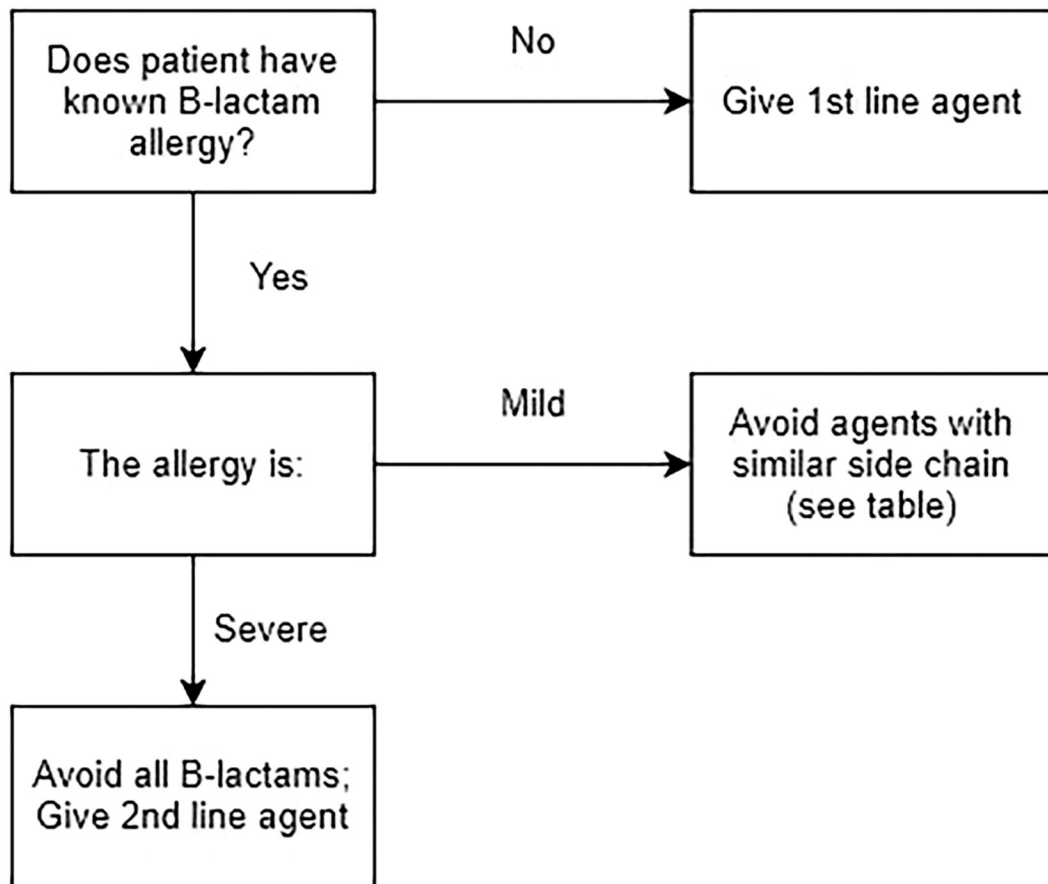
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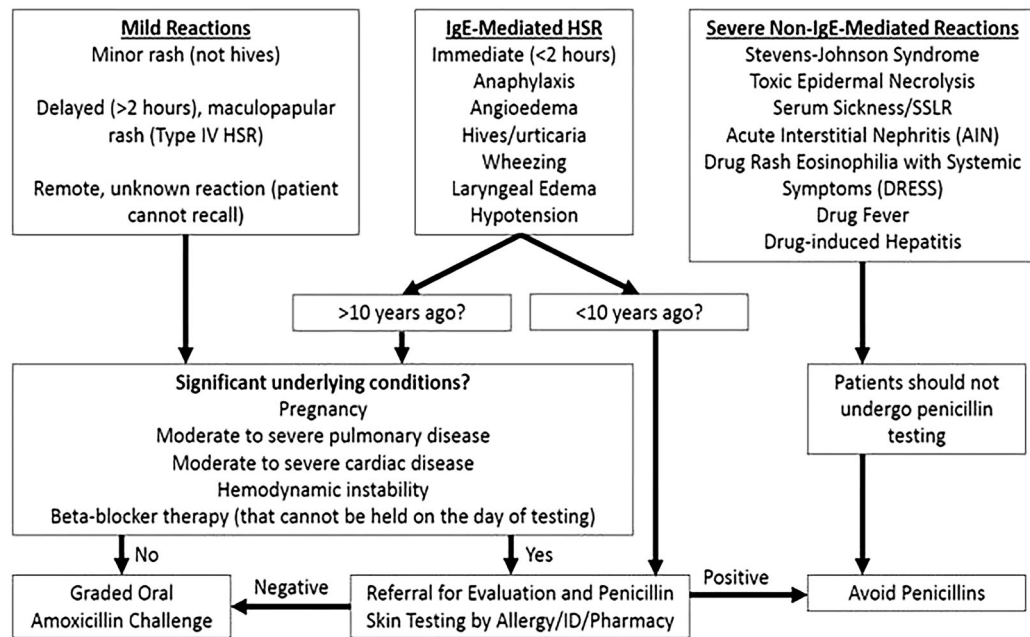
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**Fig. 1.** Institutional perioperative surgical prophylaxis guideline recommendations for patients with B-lactam allergies.



**Fig. 2.**  
Penicillin Allergy Assessment Algorithm.

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**Table 1**Patients receiving vancomycin for surgical prophylaxis ( $n = 830$ ).

Characteristics	N (% or median [IQR])
Patients with B-lactam allergy	196(%)
Surgery type	
Cardiac	8 (4 %)
Gastrointestinal/Genitourinary	11 (6 %)
Neurosurgery	76 (39 %)
Obstetrics/Gynecology	4 (2 %)
Orthopedic	79 (40 %)
Otolaryngology	3 (1.5 %)
Thoracic	6 (3 %)
Transplant	8 (4 %)
Vascular	1 (0.5 %)
Age (yrs)	57 (IQR 33 – 81)
Female	129 (78 %)
Race – White	177 (90 %)
Beta-lactam allergy type	
Penicillin	155 (80 %)
Cephalosporin	20 (10 %)
Penicillin and Cephalosporin	21 (10 %)
History of methicillin-resistant <i>Staphylococcus aureus</i>	22 (11 %)

**Table 2**

Patient Allergy by type and antibiotic.

Allergy type	Penicillin <i>N</i> = 155	Cephalosporin <i>N</i> = 21	Penicillin and cephalosporin* <i>N</i> = 20
Mild non-IgE	37 (23.8 %)	6 (28.6 %)	3 (15 %)
Severe non-IgE	2 (1.3 %)	0	0
Mild IgE	32 (20.6 %)	6 (28.6 %)	4 (20 %)
Severe IgE	50 (32.3 %)	5 (23.8 %)	9 (45 %)
Adverse effect	12 (7.7 %)	3 (14.2 %)	1 (5 %)
Unknown	22 (14.2 %)	1 (4.8 %)	3 (15 %)

\* Most severe allergy reported when multiples noted.

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