Allergy Testing in Children With Low-Risk Penicillin Allergy Symptoms

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abstract

BACKGROUND: Penicillin allergy is commonly reported in the pediatric emergency department (ED). True penicillin allergy is rare, yet the diagnosis results from the denial of first-line antibiotics. We hypothesize that all children presenting to the pediatric ED with symptoms deemed to be low-risk for immunoglobulin E-mediated hypersensitivity will return negative results for true penicillin allergy.

METHODS: Parents of children aged 4 to 18 years old presenting to the pediatric ED with a history of parent-reported penicillin allergy completed an allergy questionnaire. A prespecified 100 children categorized as low-risk on the basis of reported symptoms completed penicillin allergy testing by using a standard 3-tier testing process. The percent of children with negative allergy testing results was calculated with a 95% confidence interval.

RESULTS: Five hundred ninety-seven parents completed the questionnaire describing their child's reported allergy symptoms. Three hundred two (51%) children had low-risk symptoms and were eligible for testing. Of those, 100 children were tested for penicillin allergy. The median (interquartile range) age at testing was 9 years (5–12). The median (interquartile range) age at allergy diagnosis was 1 year (9 months–3 years). Rash (97 [97%]) and itching (63 [63%]) were the most commonly reported allergy symptoms. Overall, 100 children (100%; 95% confidence interval 96.4%–100%) were found to have negative results for penicillin allergy and had their labeled penicillin allergy removed from their medical record.

CONCLUSIONS: All children categorized as low-risk by our penicillin allergy questionnaire were found to have negative results for true penicillin allergy. The utilization of this questionnaire in the pediatric ED may facilitate increased use of first-line penicillin antibiotics.

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Dr Vyles conceptualized and designed the study, analyzed and interpreted the collected data, drafted the initial manuscript, and critically reviewed the manuscript; Drs Adams, Chiu, Brousseau, and Mr Nimmer designed the study, analyzed and interpreted the collected data, and critically reviewed the manuscript; Dr Simpson analyzed and interpreted the collected data and critically reviewed the manuscript; and all authors approved the final manuscript as submitted.

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WHAT'S KNOWN ON THIS SUBJECT: Many children present to the pediatric emergency department (ED) with a reported penicillin allergy. The majority of reported penicillin allergy symptoms are low-risk for true reaction. Children are not receiving optimal antibiotics because of a misdiagnosed penicillin allergy.

WHAT THIS STUDY ADDS: Of children tested for penicillin allergy after being categorized as low-risk on the basis of a pediatric ED questionnaire, 100% had negative results for penicillin allergy. Low-risk allergy symptoms likely do not represent true allergy in the pediatric ED.

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Children who present for care in the pediatric emergency department (ED) often are reported to have a penicillin allergy. Penicillin is the most commonly reported medication allergy, and the reported allergy alters antibiotic prescribing by the treating physicians.[1–6] A recent study in the pediatric ED revealed that the majority of the symptoms of penicillin allergy reported by families are low-risk for true allergy.[7] These symptoms are often adverse reactions such as maculopapular rash, vomiting, diarrhea, or other benign symptoms.[8,9] Hives are frequently reported as a symptom of penicillin allergy; however, in young children, hives can be the result of a bacterial or viral infection and misinterpreted as an allergy when a penicillin agent is being administered for treatment.[7,10] Because there is no process to safely and rapidly diagnose true penicillin allergy in an acute care setting, providers in the pediatric ED are reluctant to prescribe penicillin antibiotics to children with a reported penicillin allergy.

Penicillin allergy testing utilizes a standard 3-tier testing process, which involves first performing a percutaneous skin test, followed by more sensitive intracutaneous testing, and finally an oral drug challenge that ultimately determines if the drug hypersensitivity exists.[11] This process is the gold standard for diagnosing penicillin allergy, yet it is time-consuming and may be painful. Researchers utilizing percutaneous and intracutaneous testing in an adult ED found that 91.3% of patients who presented with a report of penicillin allergy received negative results after skin testing.[12] Although this study was promising, it is impractical in the pediatric ED because of time constraints and invasiveness.

In this study, we used a 3-tier penicillin testing process to assess the utility of a parent-reported penicillin allergy questionnaire in identifying children likely to be at low risk for penicillin allergy. The allergy questionnaire included 17 items assessing allergy history and was developed in consultation with a pediatric allergist. This questionnaire was used in our previous study in which 500 children completed the questionnaire, and 76% of children were found to have exclusively low-risk allergy symptoms.[7] Allergy-related questions included: age of child when allergy was diagnosed, name of the antibiotic the child was taking when the allergy was diagnosed, indication of antibiotic prescription for the child, and symptoms of allergic reaction. We hypothesized that children presenting to the pediatric ED with low-risk symptoms of allergy would test as negative for true penicillin allergy.

METHODS

Study Design

The study took place in an urban pediatric ED with an annual volume of 65 000 visits per year between April 1, 2015 and November 10, 2016. The study was approved by the hospital's institutional review board.

A convenience sample of children, aged 3.5 to 18 years with a history of reported allergy to penicillin by parents or guardians (hereafter termed parent[s]) were identified. Research staff approached parents and children for consent and assent, respectively, and administered a penicillin allergy questionnaire[7] via an electronic tablet. Results were then uploaded to a secure, online database. If 2 parents were present in the ED, only 1 parent completed the survey; thus, 1 survey was completed per child. Research staff abstracted age, recorded in years (or months if <1 year old), and sex from the medical record (Table 1).

TABLE 1 Characteristics of Questionnaire Participants

	Overall
Child Age, y (Median, IQR)	
Testing completion	9 (5–12)
Allergy diagnosis	1 (9 mo–3 y)
Race, *n* (%)	
White	59 (59.0)
African American	20 (20.0)
Hispanic	11 (11.0)
Multiracial	7 (7.0)
American Indian	2 (2.0)
Asian American	1 (1.0)
Girl, *n* (%)	35 (35.0)

The questionnaire included a "yes/no" option about interest in receiving penicillin allergy testing if a child was deemed eligible by study inclusion and exclusion criteria. To be eligible for testing, children had to be 4 years of age at the time of testing and have a low-risk symptom of allergy to penicillin. The term "low-risk" referred to reactions that were not likely to represent a severe immunoglobulin E (IgE)-mediated or T-cell–driven process. Low-risk symptoms of allergy include rash, itching, diarrhea, vomiting, runny nose, nausea, cough, or a reported family history of allergy. Children were excluded from testing if they had a high-risk symptom of allergy to penicillin. They were also excluded from being tested for penicillin allergy if they had a history of developmental delay or an inability to tell providers that they were having an allergic reaction during the penicillin testing process. The term "high-risk" was used to refer to reported reactions, either IgE-mediated or T-cell–driven, which bore high clinical risk for readministration of penicillin by any route. For potentially IgE-mediated symptoms, respiratory or cardiovascular involvement was deemed to be high-risk (ie, wheezing, difficulty breathing, airway swelling, syncope, drop in blood pressure, etc). Cutaneous involvement with a severe reaction was also deemed to be high-risk

(ie, orofacial or limb angioedema). Any report of anaphylaxis was also classified as high-risk. For potentially T-cell–mediated symptoms, any report consistent with a bullous cutaneous reaction was classified as high-risk; this is in consideration of Stevens-Johnson syndrome and toxic epidermal necrolysis. Additionally, diffuse erythema that could represent drug reaction with eosinophilia and systemic symptoms was also classified as high-risk. Charts for children with a complex past medical history were reviewed by a pediatric emergency medicine fellow and discussed with an allergist before inviting them back for allergy testing. If parents expressed an interest, a phone call was made to each child's current medical provider's office to verify that the reported allergy was low-risk by designated inclusion criteria. Medical providers were also asked who diagnosed the child's allergy on the basis of their medical record. If no high-risk symptoms were noted, the chart was reviewed by a physician, who then invited the family to return to the Translational Research Unit for standard 3-tier penicillin allergy testing.

Penicillin Allergy Testing

Penicillin allergy testing, utilizing the standard 3-tier testing process for penicillin, occurred in the Translational Research Unit at the Children's Hospital of Wisconsin. Tests were performed by pediatric emergency medicine or allergy and/or immunology fellows who were trained in allergy testing by a board-certified allergist. Percutaneous skin tests utilizing the Multi-Test PC device (Lincoln Diagnostics, Decatur, IL) were placed on the upper back. Tests included the major determinant (PRE-PEN; ALK-Abello, Pflugerville, TX) mixture reagent and minor determinant (Penicillin G; Pfizer, New York, NY), a normal saline solution negative control (Greer Laboratories, Lenoir, NC), and a positive histamine hydrochloride control (Greer Laboratories, Lenoir, NC).

If the penicillin percutaneous test results were negative at 15 minutes, intracutaneous tests were conducted. Intracutaneous testing was completed in the child's upper left or right arm and it was conducted in duplicate, after product insert, with 0.02 mL of PRE-PEN and penicillin G, along with a single saline solution control. These intracutaneous injections were then evaluated after 15 minutes, and if their results were negative, the patient was allowed to proceed to an oral challenge. Percutaneous and intracutaneous test results were measured with a ruler and were considered positive if either the major determinant or the minor determinant resulted in a wheal diameter $\geq$3 mm larger than the negative control with a flare, consistent with standard allergy testing guidelines.

In the event of a positive percutaneous or intracutaneous test result, children were allowed to proceed to a graduated oral challenge. They could only proceed to a graduated oral challenge if no high-risk symptoms of allergy occurred during this portion of testing. In the initial portion of the study, 2 children were found to have positive percutaneous testing results to penicillin. An article published during the study by Mill et al[13] highlighted the safety of a graduated oral challenge with penicillin in children. This study was taken into account with the known low positive predictive value (PPV) of penicillin skin tests[14–16], and subsequently our study protocol was amended to allow for this graduated oral challenge in children whose skin test results were positive.

For the oral challenge, the child was given a 500 mg tablet of amoxicillin, or if the child was unable to tolerate pills, then 520 mg of liquid amoxicillin was given (dose difference was because of rounding necessary with the syringe used).

After the completion of penicillin allergy testing, a note describing the encounter was placed in the electronic medical record and the allergy designation was removed from the child's chart if testing results were negative.

Data Management

Data were collected and managed by using REDCap (Research Electronic Data Capture), hosted at the Medical College of Wisconsin.[17]

Data Analysis

Descriptive statistics were used to summarize baseline patient characteristics, allergy questionnaires, and testing data. The reasons for which a child was ineligible for testing were summarized. The frequency of positive and negative penicillin allergy test results was analyzed by using a binomial exact calculation with a 95% confidence interval (CI). A prespecified sample size of 100 children was determined before allergy testing to satisfy an upper CI of 97%. The frequency of low-risk allergy symptoms was analyzed and reported by using a 95% CI. SPSS version 22 was used to perform all analyses.

RESULTS

During the study period, 744 parents were approached for participation, and 597 (80.2%) questionnaires were completed (Fig 1). Four hundred thirty-four (72.6%) children were found to have low-risk symptoms of allergy to penicillin, and 163 (27.3%) children had at least 1 high-risk symptom of allergy. Three hundred fifty-two (81.1%) low-risk children's families indicated an interest in allergy testing, 305 (70.3%) were eligible for testing

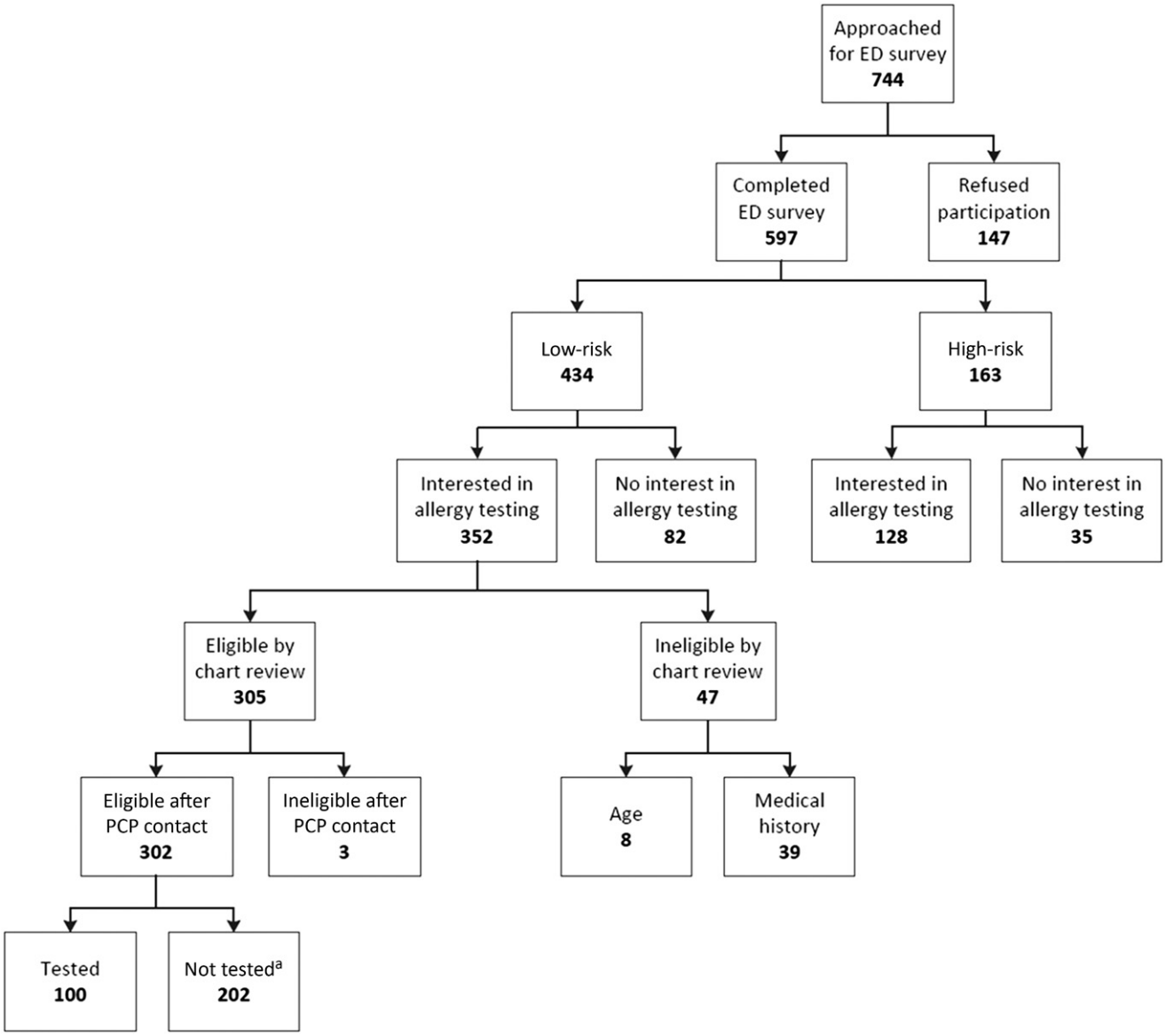

FIGURE 1
CONSORT. [a] Unable to test because of scheduling conflicts or inability to reach family. PCP, primary care provider.

after initial chart review, and 302 (69.6%) were eligible after symptom verification with the child's primary medical provider. Families were then called in order of questionnaire administration date and offered the opportunity to undergo penicillin allergy testing. We tested these patients on the basis of family availability for testing; overall, 100 (33.1%) eligible children underwent penicillin allergy testing consistent with our prespecified sample size. Of the 47 children found to be ineligible for testing, 39 (82.9%) were ineligible because of medical history, and 8 (17.1%) were ineligible because of age.

The median (interquartile range [IQR]) age at allergy testing was 9 years (5–12). The median (IQR) age at allergy diagnosis was 1 year (9 months–3 years). Of those tested, 60 (60%) were white, 20 (20%) were African American, and 11 (11%) were Hispanic (Table 1). Rash (97 [97%]) and itching (63 [63%]) were the most commonly reported allergy symptoms (Table 2). 75 (75%) were given the antibiotic for which they reported the allergy for an ear infection (Table 3). Families identified their primary care physician as the person who diagnosed the allergy in 92 (92%) children. All 100 primary care physicians were called for allergy verification, and after discussion with primary care physician and/or chart review, 14 (14%) were found to have had their reaction witnessed by a medical provider; all others were a simple parent report of symptoms.

TABLE 2 Allergy Symptoms as Reported by Parents

Low-Risk Symptoms	N[a] (%)
Nonhive rash	73 (73.0)
Itching	63 (63.0)
Hive rash	17 (17.0)
Diarrhea	7 (7.0)
Other	4 (4.0)
Vomiting	2 (2.0)
Nausea	2 (2.0)
Runny nose	1 (1.0)
Cough	1 (1.0)
Headache	1 (1.0)
Dizziness	1 (1.0)
Cannot remember	7 (7.0)

[a] Not mutually exclusive.

TABLE 3 Indication for Antibiotic as Reported by Parents

Indication for Antibiotic	N[a]	%
Ear infection	75	75
Throat infection	12	12
Other infection	4	4
Skin infection	2	2
Urine infection	2	2
Chest infection	1	1
Cannot remember	7	7

[a] Not mutually exclusive.

Overall, 100 children (100%; 95% CI, 96.4%–100%) were found to have negative results for penicillin allergy after oral challenge. Of those tested, 3 (3%) children were found to have positive results on the percutaneous portion of penicillin testing (Table 4).

DISCUSSION

In this study, we used a penicillin allergy questionnaire that stratified children with reported penicillin allergy into high- and low-risk groups on the basis of symptoms.[7] Our results showed that the majority of children had rash and itching as their primary reported symptom of allergy. Consistent with our hypothesis, all children with symptoms deemed to be low-risk for true IgE-mediated drug hypersensitivity ultimately had negative results for true penicillin allergy after the standard 3-tier testing process.

Our results in the current study highlight that the high percentage of patients reporting a penicillin allergy to medical providers are likely inconsistent with true allergy, as the true incidence of penicillin allergy is reported to be between 0.004% and 0.015%.[1–6,17–19] In this study, each child's current medical provider was contacted to verify that the reported allergy symptom was low-risk. After completing these calls, 302 of 305 (99%) families reported low-risk symptoms were in agreement with the primary care physician record. Of note, the 3 (1%) children who would have been deemed high-risk by our criteria were never seen by a medical provider and had their allergy diagnosis labeled over the phone. These family members identified low-risk symptoms of allergy when presented with our questionnaire. We believe this indicates that there may have been incorrect transmission of information over the phone, and that in subsequent studies a phone call to a child's medical provider before testing may be unnecessary. Our aim in this study was to test the practical application of a risk-stratification allergy questionnaire to determine if we could identify a low-risk population of children who could tolerate a penicillin antibiotic without an IgE-mediated allergic reaction by using the standard 3-tier testing process.

In a previous study, Raja et al[12] found that when penicillin skin testing was performed in an adult ED population, the majority of patients lacked drug hypersensitivity. This study proved effective in ruling out drug hypersensitivity; however,

TABLE 4 Description of Children Who Are Percutaneous Positive

Child	Description
Child 1	• Tested positive before IRB amendment • Age at diagnosis, and testing completion within the median IQR age of children who were tested • Girl • "Rash" listed as symptom of allergy • During initial testing a wheal diameter >3 mm larger than the negative control for both PRE-PEN and penicillin G was recorded as positive reaction • Retested on later date and had negative percutaneous, intracutaneous and oral challenge results
Child 2	• Tested positive before IRB amendment • Age at diagnosis, and testing completion within the median IQR age of children who were tested • Girl • "Rash" listed as symptom of allergy • During initial testing a wheal diameter >3 mm larger than the negative control for penicillin G was recorded as positive reaction • Retested on later date and had negative percutaneous, intracutaneous and oral challenge results
Child 3	• Tested positive after IRB amendment • Age at allergy diagnosis within the median IQR of children who were tested • Below the 25% IQR in the testing population • Boy • "Rash" and "Itching" listed as symptoms of allergy • During initial testing a wheal diameter >3 mm larger than the negative control for penicillin G was recorded as positive reaction • Subsequent negative results for intracutaneous and graduated oral challenge

IRB, institutional review board.

the utilization of penicillin skin testing in a pediatric ED would be time-consuming, costly, and labor-intensive, rendering it impractical for real-world application. Additionally, the low PPV of penicillin skin tests leads to the overdiagnosis of allergy, especially in children with low-risk symptoms of true allergy.[13–16] In this study, we completed an oral challenge in every patient regardless of skin test findings. The utility and safety of providing a direct oral challenge to patients reporting allergy was supported by Mill et al.[13] They provided a graduated oral challenge to 818 children in an allergy clinic, and only 48 (5.8%) had true allergy; no serious adverse reactions occurred after oral drug challenge. Dissimilar to our study, the previous study included children with a history of symptoms of anaphylaxis, which supports the safety and utility of the questionnaire in effectively identifying children who are at low risk for true IgE-mediated penicillin hypersensitivity.

The ability of the questionnaire to successfully identify a population likely to be at low risk for penicillin allergy was validated by subsequent gold standard allergy testing. It identified a group of low-risk children who successfully passed an oral drug challenge. This highlights the questionnaire's potential as a safe alternative to time-consuming, costly, and labor-prohibitive penicillin skin testing in the ED setting for select patients. Furthermore, each of the 3 children with positive percutaneous skin test results passed a subsequent oral drug challenge. This points to the safety of our study, which is backed by Mill et al[13] and underscores the low PPV of penicillin allergy skin testing.[17–19]

This study is limited in that not all participants agreed to testing, and thus a selection bias could exist. The study also enrolled a convenience sample of children with parent-reported allergy; however there was no way for the study team to know which symptoms would be reported or the results of allergy testing in advance, thus making selection bias less likely. This study is also limited in that the survey relies on the classification of allergies by parent-reported symptoms, and that the misclassification of a potential major and/or anaphylactic reaction as a minor reaction could result. Therefore, providers should ensure the accuracy of a low-risk symptom of allergy through discussion with the family before the consideration of an oral challenge. Additionally, the study was also insufficiently powered to make definitive conclusions pertaining to the ability to bypass penicillin allergy skin testing entirely for all ED patients. However, future research could examine the possibility of administering the questionnaire in the pediatric ED and performing an oral challenge at that time in children with low-risk symptoms.

CONCLUSIONS

All children categorized as low-risk by our penicillin allergy questionnaire were found to be negative for true penicillin allergy. Our results suggest that low-risk symptoms of parent-reported penicillin allergy in the pediatric ED do not correspond to true allergy when evaluated by the standard 3-tier testing process. Utilization of this questionnaire in the pediatric ED may facilitate increased use of first-line penicillin antibiotics.

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ABBREVIATIONS

ED: emergency department
IgE: immunoglobulin E
PPV: positive predictive value

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