

REVIEW ARTICLE

The predictive value of skin prick testing for challenge-proven food allergy: A systematic review

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Abstract

Immunoglobulin E-mediated (IgE) food allergy affects 6–8% of children, and the prevalence is believed to be increasing. The gold standard of food allergy diagnosis is oral food challenges (OFCs); however, they are resource-consuming and potentially dangerous. Skin prick tests (SPTs) are able to detect the presence of allergen-specific IgE antibodies (sensitization), but they have low specificity for clinically significant food allergy. To reduce the need for OFCs, it has been suggested that children forgo an OFC if their SPT wheal size exceeds a cutoff that has a high predictability for food allergy. Although data for these studies are almost always gathered from high-risk populations, the 95% positive predictive values (PPVs) vary substantially between studies. SPT thresholds with a high probability of food allergy generated from these studies may not be generalizable to other populations, because of highly selective samples and variability in participant's age, test allergens, and food challenge protocol. Standardization of SPT devices and allergens, OFC protocols including standardized cessation criteria, and population-based samples would all help to improve generalizability of PPVs of SPTs.

Immunoglobulin E-mediated (IgE) food allergy affects 6–8% of children, and the prevalence is believed to have been increasing over the last few decades (1–3). Whilst childhood allergy to egg and cow's milk tends to be transient, peanut allergy tends to persist with only 20% of children expected to outgrow it (4, 5). Food allergy can have a significant impact on the quality of life of children and their families. Restrictive diets are inconvenient, and potentially nutrient deficient and the risk of a severe reaction upon accidentally ingesting the food can cause significant anxiety and morbidity (6). Proper diagnosis is essential to ensure that a child is placed on an appropriate diet, and conversely, to avoid unnecessary dietary restrictions.

Diagnosis of food allergy utilizes a combination of clinical history, elimination diets, oral food challenges (OFCs), and

tests of sensitization to detect the presence of allergen-specific IgE, such as the skin prick test (SPT). OFCs are the gold standard of food allergy diagnosis, but they are expensive, time-consuming, and potentially dangerous. SPT on the other hand is cheap, safe, and easy to perform, but they have low specificity to food allergy. Sensitization may be present without a clinically significant reaction upon eating the food; that is, sensitization status from SPT is imperfectly correlated with the result of an OFC.

Skin prick test may be used in several ways in the assessment of food allergy. If a child presents with a clinical history suggestive of food allergy and subsequently records a positive SPT, the SPT confirms sensitization and that the reaction is likely due to IgE-mediated food allergy. An OFC may be unnecessary. If the history of reaction or exposure is unclear and the child records a positive SPT, then an OFC may be performed to diagnose food allergy. A previous episode of anaphylaxis (a severe and sometimes fatal allergic reaction) to any allergen may exclude the use of OFC. If the SPT wheal size exceeds a previously defined threshold

Abbreviations

SPT, skin prick test; OFC, oral food challenge; DBPCFC, double-blind placebo-controlled food challenge; PPV, positive predictive value; IgE, immunoglobulin E.

suggested to be highly predictive of food allergy, then the allergist may consider an OFC unnecessary (4). Depending on the source and reliability of this threshold the risk of misdiagnosis on the basis of SPT alone remains a possibility. In children who are yet to consume a particular food, SPT may be used as a screening tool to determine those at risk of food allergy. If SPT thresholds can be developed which have a high predictability to food allergy, it may prevent the need for OFCs in some individuals. Several researchers have addressed this question with varying results. In this paper, we review the results of previous studies and offer reasons for these discrepancies.

Methods

Search strategy

A search of PubMed was performed using the terms SPT or allergen skin test and ROC curves or predictive values and food allergy or food hypersensitivity. The reference lists for retrieved articles were also searched for potentially relevant studies.

Inclusion criteria

Studies were included if they assessed the association between the SPT wheal size and risk of egg or peanut allergy confirmed by OFC. OFCs were either open challenges (where the child and parent knew that the food was being consumed) or double-blind placebo-controlled challenges (the child consumes the target food and a placebo vehicle without the target food on separate occasions, without knowing on which occasion the target food was consumed). Studies that diagnosed some cases of food allergy only on the basis of SPT wheal size without conducting a food challenge were excluded. Studies were included if the investigators reported a SPT wheal size with at least 90% positive predictive value (PPV) of challenge-proven food allergy, or a SPT wheal size with 100% specificity to challenge-proven food allergy.

Data collection

Information on study characteristics, food challenge protocol, and study quality was extracted from each article. The quality of the studies was assessed by examining sample size, subject selection, and protocols of the SPT and food challenges and definition of a positive OFC.

Results

The search of the electronic database produced 71 results. Sixty were immediately excluded because they tested for allergens other than egg or peanut or did not quantify the association between SPT wheal size and the risk of food allergy; one article was not available in English. The remaining 11 articles were retrieved and assessed as to whether they met the inclusion criteria. A manual search of the references in these articles revealed a further ten studies that were

retrieved. Eleven studies were identified which met the inclusion criteria, which included five studies retrieved from references (see Figure 1).

The characteristics and results of these studies are presented in Tables 1 and 2. The results of these studies vary considerably – for egg allergy, wheal size thresholds highly likely of predicting food allergy ranged from 3 to 14 mm, and for peanut allergy, the thresholds ranged from 4 to 16 mm. The PPVs in the studies considered in this review tended to cluster in the mid-range (egg ≥ 6 –9 mm, peanut ≥ 7 –8 mm) or be large (egg ≥ 13 mm, peanut ≥ 15 mm). When the samples were restricted to children under 2 yrs of age, the thresholds were smaller (egg ≥ 3 –5 mm, peanut ≥ 4 mm).

The populations differed between these studies. With the exception of one study that included children from a birth cohort with positive SPT, all of these reports used study populations where there is high prevalence of food allergy and therefore high pre-test probability, i.e., clinic populations attending for allergy assessment. The prevalence of egg allergy ranged from 43% to 79% (median 67%) and peanut allergy 37–83% (median 57%). Participants in these studies were either suspected to have food allergy or previously diagnosed with food allergy, and most studies prospectively assessed the participants. An exception to this was one study that restricted their sample to children with atopic dermatitis, a known risk factor for egg allergy, who had not previously ingested egg (7). Four of the studies excluded children with a history of severe reactions or anaphylaxis (8–11). The remaining seven studies did not specify any exclusion criteria. The ages of the subjects in the samples differed. Three studies restricted their samples to children under 2 yrs of age (7, 12, 13), whereas the remaining studies included both infants, children and adolescents without stratifying the results.

There were several methodological differences between the studies. SPT devices and techniques are not universal, and different commercial allergens were used in the studies. The definition of a positive SPT was not consistent across the studies. Most studies defined a positive SPT as wheal size ≥ 3 mm, whereas two studies challenged all children, including those with small wheal sizes (≤ 2 mm) (7, 13). As demonstrated in these two studies, it is possible that children with small wheal sizes may subsequently fail an OFC. Two studies chose to use raw foods for the SPT rather than commercial extracts (11, 14). One paper examined end-point titration, a method where serial dilutions of the allergen extract are used to identify the lowest concentration with a mean wheal size of 3 mm. The investigators found that an end-point dilution of 1:256 successfully discriminated between positive and negative OFC and that this method demonstrated excellent performance in terms of sensitivity, specificity, PPV, negative predictive value, and positive likelihood ratio (LR) (15). Several studies used double-blinded placebo-controlled food challenges (8, 11) whereas the remaining used open-food challenges. Challenge protocol and the criteria for a positive challenge differed between the studies. In the egg challenges, two studies used raw egg white, three raw whole egg, and one cooked egg white, and one used a combination of raw

Table 1. Published skin prick test (SPT) cutoffs in egg allergic children, stratified by age (<2 and ≥2 yrs)

Study	Sample size	Population	Outcome	Median age (range)	Allergy prevalence (%)	Method	SPT cutoff (mm)
Boyano Martinez (12)	81	Children with history of egg allergy or suspected egg allergy	64 positive OFC*	Under 2 yrs	79	93% PPV ROC curves	3
Monti (7)	107	Children with atopic dermatitis who had never ingested egg	72 positive OFCs	5 months (1–19 months)	67	94% PPV	4
Sporik (13)	39	Children referred to allergy clinic with suspected food allergy or retested after positive challenge at least 12 months prior	29 positive OFC (subgroup of below)	Under 2 yrs	74	100% specificity ROC curves	5
Tripodi (15)	47	Children attending allergy clinic with suspected egg allergy (39) or recent positive OFC to egg (8)	20 positive OFC	Mean 6.2 yr (1.1–15.7 yr)	43	100% PPV ROC curves 2 × 2 tables	6
Sporik (13)	121	Children referred to allergy clinic with suspected food allergy or retested after positive challenge at least 12 months prior	93 positive OFC	36 months (1–154 months)	77	100% specificity ROC curves	7
Dieguez (8)	157	Children previously diagnosed egg allergic, examining persistence of allergy	100 positive DBPCFC	2.5 yr (15 months–16 yr)	63	95% PPV ROC curves	9
Verstege (14)	160	Children referred to hospital with suspected food allergy (SPT fresh food allergens)	101 positive OFC (75% DBPCFC and 25% open OFC)	22 months (3 months–14.5 yr)	63	95% PPV Logistic regression	13
Mehl (9)	193	Children with suspected food allergy	128 positive OFC	13 months (3 months–14 yr)	66	95% PPV Logistic regression	14

*OFC was not conducted, but considered positive, in children who had history of anaphylaxis or history of multiple episodes of urticaria and angioedema within 2 h of egg ingestion and last episode within 3 months of doctors visit and positive SPT (n = 7). OFC, oral food challenge; PPV, positive predictive value.

and cooked egg. Whilst there were commonalities shared in the criteria for a positive challenge, such as urticaria, vomiting, and evidence of anaphylaxis, four studies included subjective symptoms of abdominal pain, five included exacerbation of eczema, and six included rhinitis. Six studies included late reactions in their analysis. Statistical methods differed among the studies. PPVs can be obtained using either ROC curves or logistic regression. It is possible that results from the studies may differ if an alternative statistical method was applied to the same data.

Discussion

Skin prick tests are able to detect sensitization; however, the quandary remains that some sensitized children will not react when consuming the food. Data from a population sample showed that only 33% of infants sensitized to peanut, and 55% of infants sensitized to egg where challenge-proven allergic (16). The 95% PPVs in the studies considered in this review tended to cluster in the mid-range (egg ≥ 6–9 mm,

peanut ≥ 7–8 mm) or be large (egg ≥ 13 mm, peanut ≥ 15 mm). When the samples were restricted to children under 2 yrs of age, the thresholds were smaller (egg ≥ 3–5 mm, peanut ≥ 4 mm).

Published data confirms the assertion that thresholds differed between infants and older children, sensitivity and specificity are modest at best, and a variety of scenarios and risk profiles contributed data to the summary table. Despite thresholds in the mid-range (≥6–9 mm) demonstrating 95% probability of food allergy, their specificity may still be low. Children may record wheal sizes greater than these thresholds yet not react to the food. In Wainstein's sample, an 8-mm cutoff would have incorrectly diagnosed one-third of the children as allergic. Conversely, large SPT cutoffs (≥13 mm) that have 100% specificity to food allergy may not be clinically useful as few children may reach that threshold (4). Using Wainstein's study as an example, whilst they found a wheal size of 15 mm to be 100% predictive of peanut allergy, only three patients of 52 positive challenges reached that threshold. These larger thresholds may be difficult to extrapolate to

Table 2. Published skin prick test (SPT) cutoffs in peanut allergic children, stratified by age (<2 and ≥2 yrs)

Study	Sample size	Population	Outcome	Median age (range)	Allergy prevalence (%)	Method	SPT cutoff (mm)
Sporik (13)	18	Children referred to allergy clinic with suspected food allergy or retested after positive challenge at least 12 months prior	15 positive OFC (subgroup of below)	Under 2 yrs	83	100% specificity ROC curves	4
Nolan (10)	54	Children recruited from an allergy clinic with previous reaction or positive SPT but no ingestion	19 positive OFC	6.3 yr (3.7–14.8 yr)	37	93% PPV ROC curves	7
Sporik (13)	95	Children referred to allergy clinic with suspected food allergy or retested after positive challenge at least 12 months prior	69 positive OFC	58 months (1.5–168 months)	73	100% specificity ROC curves	8
Roberts (22)	161	Children previously investigated for nut allergy or children from a birth cohort with positive peanut SPT	83 positive OFC	Mean 7.0 yr (1.0–16.4 yr)	52	95% PPV Logistic regression	8
Wainstein 2007 (4)	84	Children recruited from allergy clinic	52 positive OFC*	4.5 yr (11 months–17 y)	61	100% specificity Logistic regression	15
Rance (11)	363	Children referred for suspected food allergy. (SPT raw food extract)	177 positive DBPCFC	4 yr (0.1–15.9 yr)	49	100% PPV ROC curves	16

*OFC was not conducted, but child considered allergic, if reported a reaction to peanut in 3 months prior to OFC or had previous episode of anaphylaxis. OFC, oral food challenge; PPV, positive predictive value.

other populations, and whilst the specificity is high, the sensitivity tends to be low. There may be a large proportion of allergic children below these thresholds requiring an OFC to confirm the diagnosis.

The 95% PPV provides additional diagnostic value beyond that of considering sensitivity and specificity of SPT alone. Sensitivity and specificity are inherent qualities of a test although they may vary according to techniques, devices, or allergens used. However, PPV is dependent on the prevalence of disease in the population; the lower the prevalence, the lower will be the proportion of true positives among test positives and will result in a lower PPV (17). PPVs derived from high-risk groups with high allergy prevalence, such as the samples considered in this review, will be higher than those derived from the population with lower allergy prevalence. PPVs reported from high-risk settings are not generalizable to the population. Other statistical methods may be employed to overcome this limitation, such as the use of the likelihood ratio, as its interpretation is not dependent on the underlying disease prevalence. The likelihood ratio may be used to transfer the results of a study to the allergists own population, providing they have a reliable estimate of the patients pre-test probability (18, 19). One might also consider setting thresholds at points which have 95% sensitivity or 95% specificity, but this requires determination of whether it

is more important to avoid false negatives or false positives (20).

Patient selection is not adequately characterized in all allergy studies, most classifying the patients as suspected allergic and/or high risk. Several studies recruited children who were already diagnosed with food allergy, and two studies included children already diagnosed as allergic and rechallenged to investigate the persistence of allergy (8, 13). The prevalence of allergy is likely to be greater than that of the population in these samples. Some studies selected participants to confirm food allergy on the basis of highly suggestive clinical histories, whereas others selected participants on the basis of SPT results without prior ingestion of the food. One study recruited children on the basis of atopic dermatitis, a known risk factor for food allergy, who had not ingested the allergen. Exclusion criteria were not consistent in all studies; six studies did not state exclusion criteria, and the remaining four excluded children with a history of severe reaction or anaphylaxis. These mixed populations are likely to influence the PPVs.

Studies that relied on open-food challenges in older children may have been subject to observer bias, although this is not usually an issue in young children and infants. The variations in challenge protocol and the lack of standardized cessation criteria of OFC influence the reported prevalence of

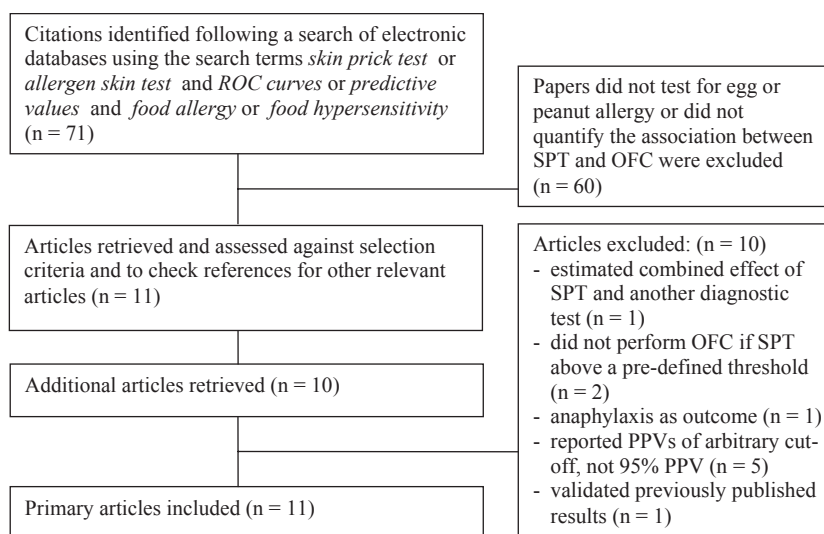


Figure 1 Articles assessed in systematic review.

allergy and do not allow for direct comparison between some studies. Furthermore, in most studies in this review, children with wheal sizes < 3 mm were not challenged. Two studies did challenge children with small wheal sizes (≤ 2 mm), and some children with negative SPT (0 mm) tested positive in an OFC. This potentially explains some of the discrepancies seen in this review.

The variations in thresholds may also be due to several other factors that affect SPT and OFC results such as different skin test devices and techniques, different sources of allergen, and ages of the children. The median age of the children in these studies vary, and the predictive value of wheal sizes changed within studies when the samples were stratified by age (< 2 and ≥ 2 yrs) (13, 14). Skin reactivity varies with age and children may outgrow a food allergy in the first few years of life (19).

The source of allergen used for the SPT may influence the wheal size. Processing of allergens to produce the standardized commercial extracts reduces its protein and allergenic content, and commercial extracts may therefore vary in allergenicity and potency (4). Raw extracts tend to produce larger wheal sizes than commercial extracts and have higher sensitivity and specificity. Verstege et al. and Rance et al. chose to use raw extracts as they believed fresh foods were superior to commercial extracts in that they mimic the real-life allergen exposure. Both these studies presented large wheal sizes with 95% PPV to food allergy. Tripodi et al. concluded that end-point titration was more efficient than standard (undiluted) SPT at discriminating between degrees of atopic sensitivity, including between positive and negative OFC. The 1:256 dilution was able to accurately predict a positive OFC in both older and younger children; this is not always the case with standard SPT thresholds (15).

The type of food used in the OFC may also account for some variation in the results. In the egg challenges, two studies used raw egg white, three raw whole egg, one cooked egg

white and one used a combination of raw and cooked egg. Raw egg white is more allergenic than cooked egg and may have led to a higher rate of allergy diagnosis in these studies.

In the diagnosis of food allergy in children, there is a need for standardized diagnostic procedures. The disagreement between the predictive values SPT wheal size to challenge-proven food allergy is most likely influenced by both patient selection and outcome definition and to a lesser degree, statistical methods, SPT device and allergen. Allergists should be aware of their chosen device's and allergen's sensitivity and specificity, and their patient's pre-test probability before choosing a threshold. Ninety-five percent PPVs generated from a population sample using standardized OFC cessation criteria may help overcome some of the issues identified. The prevalence of food allergy at the population level may reduce the predictive value calculated from high-risk and highly selective populations, but it would increase generalizability and usefulness of the thresholds. There has been a recent interest in developing mathematical equations to facilitate predictive diagnostic points and using skin test end-point titration as this has shown better diagnostic performance than conventional SPT (15, 21). These endeavors are likely to significantly improve the decision-making process for clinicians in this field provided international standardization of skin prick testing, and food challenge protocols are achieved.

Conclusion

Several cutoffs for SPT thresholds that highly predict food allergy have been reported with varying results. Owing to the highly selective nature of the study samples and variations in statistical methods, outcome definition, SPT devices, and allergens, these thresholds may not be generalizable to other clinical settings. 95% PPVs developed from population-based studies using standardized skin prick testing and OFC cessation criteria may overcome these limitations.

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