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ORIGINAL ARTICLE

Diagnostic accuracy of atopy patch tests for food allergy in children with atopic dermatitis aged less than two years

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Abstract
Background: Atopy patch tests (APT) have been introduced as a valuable tool for the diagnosis of food allergy. However, interpretation of the readout of APT requires further clarification.
Objective: To investigate the accuracy of APT in identifying atopic sensitisation to hen's eggs (HE), cow's milk (CM), soybean and wheat in Chinese children with atopic dermatitis (AD) aged less than two years and to evaluate skin signs of APT for accurate diagnosis of food allergy.
Methods: APT was performed and food allergy confirmed by open oral food challenges with HE, CM, soybean and wheat in 150 Chinese AD children aged less than two years. The sensitivity, specificity, positive (PPV) and negative (NPV) predictive values, positive (LR+) and negative likelihood ratio (LR−) of APT were calculated.
Results: Erythema and infiltration were not sufficiently indicative of a positive APT. The PPV increased with the appearance of indurations and the number of papules. The true positive APT rate increased from scores of + to +++. The PPV and specificity were 100% while APT scores of +++ were obtained with HE, CM and wheat. The sensitivity of APT with HE, CM, soybean and wheat allergy ranged from 59.6% to 90.5%, while the specificity ranged from 82.1% to 92.4%.
Conclusion: The APT is a suitable method for the diagnosis of AD in Chinese children aged less than two years with food allergies. Erythema and infiltration are not sufficient indicators of APT positivity. The PPV increases with indurations and the number of papules.
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Introduction

Atopic dermatitis (AD) is a T-cell-mediated chronic inflammatory skin disease, associated with hyperreactivity to environmental antigens, such as food allergens and aeroallergens.[1] Moreover, food allergy occurs in the early years of life, up to three years of age, when tolerance to food is established and sensitisation to aeroallergens occurs.[2] Up to 40% of children with AD also have clinically relevant food allergy,[3] with the most commonly involved foods being milk, egg, fish, wheat, soy and peanut, which account for 90% of positive clinical responses.[4] Therefore, accurate and timely

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identification and avoidance of the relevant allergens are critical for the effective treatment of AD in infancy and early childhood and prevention of relapse.

It is generally accepted that oral food challenges (OFC) are the gold standard for the diagnosis of food allergy. However, such tests are time-consuming, difficult to perform in the clinic, troublesome for the patient and can be associated with the risk of severe allergic symptoms. Therefore, laboratory-based diagnostic tools are required to minimise the frequency of double-blind placebo-controlled food challenges (DBPCFC). Skin prick tests (SPT) and the measurement of specific serum IgE (sIgE) are considered to be good tests for the diagnosis of immediate food hypersensitivity, although these techniques are not suitable for the identification of allergens in delayed-onset reactions.[5] There are no standardised diagnostic levels for sIgE, which has different diagnostic criteria for various foodstuffs and are age-dependent.[6] The SPT, which is simple to conduct, with no requirement for blood sampling, is an inexpensive and widely used method for the assessment of IgE-mediated food allergy. However, positive SPT results are based on allergen binding to specific IgE antibodies attached to mast cells, leading to the release of inflammatory factors. Therefore, positive SPT responses indicate only the presence of allergen-bound antibodies attached to mast cells. In other words, these tests reflect sensitisation, but not clinical allergy.

Recently, atopy patch tests (APTs), which are devoid of any side-effects were introduced as part of the diagnostic work-up for the diagnosis of non-IgE-mediated food allergy, seen in conditions like AD or digestive disorders.[7–10] Atopy patch tests may aid in the early diagnosis of food allergy in preterm, while SPT and sIgE tests are negative.[8,11] Furthermore, the detection rate is increased when APT are used in parallel with an SPT or sIgE tests.

For a long time, the use of APTs in clinical practice was limited by subjective interpretation and intra-observer variation and differences in the diagnostic accuracy of these tests between studies. Eventually, in 2006, the European Task Force on Atopic Dermatitis (ETFAD) proposed a standardised method for the interpretation of APTs in children with AD, based on graded qualitative measures (−, +, ++, +++ and ++++) recorded following the manifestation of erythema, vesicles and the number of papules.[12] Subsequently, research into the diagnostic accuracy of APTs designated reactions graded as + and above as positive APT results. However, the clinical relevance of different grades of positive APT reactions is unclear. Moreover, data describing the effect of the severity of skin signs on APTs are scarce.

In this study, APTs were performed with hen's egg (HE), cow's milk (CM), soybean and wheat in Chinese AD children aged less than two years and food allergy was confirmed by OFC. The diagnostic properties of the different classifications of APT results were prospectively evaluated in relation to the outcome of controlled food challenges in order to validate the clinical relevance of different grades of APT reactions. Consequently, the influence of the severity of skin signs on the diagnostic accuracy of APTs was evaluated in children with AD. Furthermore, the value of APT skin signs in the diagnosis of food allergy without OFC was investigated.

Materials and methods

Patients

From November 2008 to July 2011, 150 children (56 females and 94 males) with suspected food allergy and AD and fulfilling the criteria of Hanifin and Rajka,[13] were enrolled in this study. The ages of these patients ranged from 3 to 24 months (mean 9 months). Severity scoring of AD (SCORAD), reflecting the severity of eczema, ranged from 32 to 81 (mean SCORAD $\pm$ SD = 47.7 $\pm$ 15.0). SCORAD includes topography items (affected skin area), intensity criteria (erythema, oedema, crusts, excoriations, lichenification and xerosis) and subjective evaluations (intensity of itch and loss of sleep).[14] Seventy-seven children had moderate AD (SCORAD 25–50) and 73 children had severe AD (SCORAD > 50). In addition, 20 healthy children without eczema, asthma, allergic rhinitis and AD (10 males and 10 females) aged 3–24 months (mean $\pm$ SD = 8 $\pm$ 5 months) were enrolled as the control group.

All of the patients and the healthy children were referred to the Paediatric Dermatology Outpatient clinic of the Children's Hospital of Chongqing Medical University. During the study, each child was evaluated by the same investigator. Patients with systemic diseases, acute infectious diseases and autoimmune diseases were excluded from the study. Children did not take oral immunosuppressive drugs, including oral corticosteroids, for at least one month before the test. Oral antihistamine drugs and topical treatment of the back with corticosteroids were discontinued for at least seven days before the test. The study was reviewed and approved by the Institutional Review Board of The Children's Hospital of Chongqing Medical University and informed consent was obtained from the parents of the children.

Study design

On an in-patient basis, the children with the symptoms suggesting food allergy were challenged in an open manner. APT were performed in all AD patients and 20 healthy children before the oral food challenges with the identical native fresh allergens, including CM, HE, soybean and wheat.

Atopy patch test

Atopy patch tests were performed according to the ETFAD protocol.[12] The patch test formulation was prepared fresh each day with one part of petrolatum and two parts allergen powder: cow's milk (milk powder containing 3.5% fat), fresh egg (white and yolk), soybean (raw soybean, crushed and mixed as a powder) or wheat powder. The formulations were then placed in 12 mm Finn Chambers (Epitest Ltd., Oy, Tuusula, Finland) on uninvolved areas of the patient's upper back, which was prepared to ensure that the area was free of ointments and excessive sebum. Petrolatum was used as a negative control. The occlusion time was 48 h and the result was read 24 h after the removal of the Finn Chambers. The APT results were graded according to ETFAD standards: no reaction or erythema without infiltration (−), erythema and infiltration (+), erythema and few papules (++), erythema

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