Allergol Immunopathol (Madr). 2016;44(1):54–58

Allergologia et immunopathologia

Sociedad Española de Inmunología Clínica, Alergología y Asma Pediátrica

www.elsevier.es/ai

ORIGINAL ARTICLE

Prevalence of adverse reactions following a passed oral food challenge and factors affecting successful re-introduction of foods. A retrospective study of a cohort of 199 children

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Received 29 December 2014; accepted 29 April 2015
Available online 1 August 2015

KEYWORDS
Adverse reaction;
Food tolerance;
Food allergy;
Oral food challenge

Abstract
Background: After a passed oral food challenge (OFC), regular and normal food consumption is attended. The main objective of this study is to assess the safety of tested food dietary re-introduction after a passed OFC.
Patients and methods: In 2014, a telephone survey was submitted to patients who passed OFC and those who failed it only presenting with contact urticaria (we consider these OFC as passed), between 2009 and 2013. Questionnaire items included demographic data, food allergy details, food consumption after the OFC was performed, recurring symptoms and life style changes.
Results: 249 OFC questionnaires were collected from 199 children, 228 OFC were passed, 21 were failed exclusively due to contact urticaria. The most tested food was cows' milk. In 71% of cases target food was re-introduced in patients diet in normal amounts. We found children >2 years introduced less frequently tested food than infants. In 2% of cases adverse reactions to offending food were reported, but severe reactions never occurred.
Discussion: The majority of children of this study ate target food regularly and their family's quality of life improved. In our study, adverse reactions frequency in patients who passed OFC was very low and never serious. We highlight the importance of re-assessing proper food consumption in every patient who passed OFC.

Introduction

Food allergy (FA) plays an important role in children and their family's quality of life. If FA is diagnosed, then strict allergen avoidance is officially recommended. Oral food

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http://dx.doi.org/10.1016/j.aller.2015.04.010
0301-0546/

challenge (OFC) is the gold standard for FA diagnosis; moreover, it helps to find out if a patient has outgrown a food allergy.[1,2] A passed OFC demonstrates that tested food is tolerated and it can be safely included in patients' diet. Inappropriate or overly long food elimination diets should be avoided as they may cause several disadvantages. First of all, they may reduce the children's and their family's quality of life; secondly they could induce patient's improper growth[3]; and lastly they may have negative effects on health expenditure. However, tested food dietary re-introduction does not always follow from a passed OFC. In fact, many patients prolonged their elimination diet even if they passed the OFC, as well as some parents fear to give their children the offending food at home; in fact, there are some reports about adverse reactions occurring even after a passed OFC.[4,5,7–9] Therefore, it would seem that OFC can have false negative; this fact could be due to daily life cofactors such as infections or physical exercise, which may increase allergic reactivity.[10]

Moreover, there is scant literature[4,5] regarding whether re-introducing the offending food is adhered to, and, when some patients prolonged the elimination diet, what type of dietary advice these children received, and who gives this advice and why.

The main objective of this study was to assess if, after a passed traditional OFC or a failed one exclusively due to contact urticaria, food re-introduction is safe. We considered the latter a passed test as we allowed patients to include tested food in their diet. For instance, we evaluated if any adverse reaction occurred when food was taken in different situations of daily life. In other words, basing on our population, we rated how many times traditional OFC ended up with a false negative result. Moreover, we wanted to assess: (a) level of parents' adherence to given instructions (strict or not) and (b) presence of any children/patient characteristic which could influence the adherence to a re-introduction diet.

Patients and methods

At the paediatric allergy clinic of Agostino Gemelli Hospital in Rome, during the years 2009–2013, patients with a passed OFC or with a failed one due to exclusively contact urticaria were retrospectively identified and included in the study. Among those patients, IgE-mediated FA or Food Protein Induced Enterocolitis Syndrome (FPIES) were previously suspected basing on symptoms and IgE tests.

Final diagnosis was issued from a failed OFC, except those cases of IgE-mediated FA in which anaphylaxis occurred within 12 months, as well as patients affected by FPIES who experienced at least two episodes of repeated vomiting, pallor and lethargy. In all children, skin prick tests (SPT) were performed. They were conducted at the time of diagnosis and prior to each OFC, using fresh food (prick-by-prick with raw and cooked suspected food) and if available, using commercial allergen extracts (Lofarma, Milan, Italy). SPT results were considered positive if the mean wheal size was >3 mm than negative control.

With the aim of testing a possible gain of tolerance, many OFCs were performed 1 year after the last adverse reaction to culprit food had occurred. We conducted open OFCs feeding patients suspect food in measured doses. We started with very small doses and increased food amounts every 20 min. In the last three doses total food amount was almost equal to the patients' average daily intake (one egg, 200 ml of cow's milk). When the last dose was given, patients remained under clinical observation for 2 h. OFC was interrupted and considered failed in case of objective symptoms and/or serious and/or persistent and/or reproducible ones.[11] Patients presenting exclusively with contact urticaria during the OFC were able to tolerate a full dose of tested food. After a passed OFC or a failed one due to limited contact urticaria, all families were told to start a normal diet containing the offending food in normal amounts.

In 2014, parents of enrolled patients were contacted and underwent a telephone interview based on a questionnaire; all parents gave informed consent. Questions included demographic data, food consumption after the OFC, adverse reactions recurrence, and a request for explanation of any food avoidance.

The study was approved by the local Ethics Committee (protocol P/68/CE/2011).

Statistical analysis

All data were entered into an Excel spreadsheet and analysed using Excel 2010 (Microsoft, Redmond, WA, USA). Fisher exact test (two tailed) was used to analyse the significance of the association between variables ($p < 0.05$).

Results

Patients' characteristics

During the study period, 297 OFC with the required characteristics were recorded. 48 families (16%) were not reached by telephone, therefore the interviews focused on 249 OFC in 199 children. 228 OFC were passed, and 21 were failed due to the presence of exclusively contact urticaria. Tested foods were cows' milk (CM, 112), hens' egg (77), fish and shellfish (18), fruit or vegetables (15), grains (8), peanuts (5), nuts (3), hazelnut (2), pistachio (1), soy (3), beef (4), and chicken (1). 53/199 children (26%) were also affected by respiratory allergies. Median age at diagnosis was 19 months (range 0–13 years) and tolerance OFC was performed at a median age of 30 months (3 months–13 years).

At the time of diagnosis, clinical manifestations were urticaria and angio-oedema (121 children), vomiting and abdominal pain (51 children), generalised non-anaphylactic allergic reaction (26 children), anaphylaxis (16 children), FPIES (14 children). Median time length between OFC and data collection was 2.5 years (6 months–5 years).

Adherence to dietary advice

In 71% of cases (176/249) tested food was re-introduced regularly and in normal amounts (i.e. doses were appropriate to children age and food type), while in 21% (52/249) food was given occasionally and in small amounts. In 8% of cases (21/249) food was not given at all and parents' motivations were: fear of an adverse reaction,[6] doubts regarding the