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Safety and predictors of adverse events during oral immunotherapy with raw egg white

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Background

Oral immunotherapy (OIT) for food allergy has shown promising efficacy results. However, safety is still concerning. Objectives. To evaluate safety of egg-OIT. To identify clinical/immunological predictors of adverse events.

Methods

Prospective longitudinal epidemiological intervention study. Egg-allergic children aged 5–18 underwent a Spanish-approved egg-OIT protocol without premedication.

Clinical data, skin prick test (SPT) and specific IgE (sIgE) at baseline and 9 months after OIT were registered. All dose-related reactions, treatments needed and cofactors involved were recorded. Through survival analysis, we studied the cumulative probability of reactions resolution over time and clinical/immunological risk factors of reactions persistence.

Results

51 children were recruited. Mean follow-up was 16 months. 74% reached desensitization to one raw egg. 90% of children suffered reactions, 88% of which affected a single organ. Reactions occurred in 7% of doses, being mainly grade 1 (30%) or 2 (32%). Gastrointestinal (37%) and cutaneous (35%) were the most frequent symptoms. Reactions were heterogeneously distributed: (a) 23 children (45%) had occasional symptoms which ceased over time; (b) 28 (65%) children had more frequent and intense symptoms (71% of total reactions). 11 of them, the most difficult cases, had to interrupt the treatment early, whereas in 17 children reactions decreased in frequency but persisted overtime. Reactions persistence was associated with a higher frequency and severity. Kaplan–Meier estimate revealed a cumulative probability of reactions resolution of 25% at 6 months (95% CI: 2.95-9.05) and 50% (95% CI: 7.2-18.8) at 13 months. Cox proportional hazards multivariate regression model identified 2 variables (egg white-sIgE and Sampson's severity grades 3 or 4 at baseline egg challenge) as independent risk factors of reactions persistence, with hazard ratios of 1.15 (95% CI: 1.05-1.27; p=0.002) and 4.39 (95% CI: 1.78–10.87; p=0.01), respectively. Early withdrawal was associated to pre-existing asthma and higher sIgE levels ($p<0.05$).

Conclusion

OIT with raw egg white led to early withdrawal due to adverse events in 21% of children. An additional 33% had persistent reactions over follow-up. Egg white-sIgE, reaction severity at baseline challenge and pre-existing asthma would help clinicians to identify highly reactive patients before egg-OIT. Further research is needed to improve safety before egg-OIT can be extended to routine practice.

Disclosure of interest

None declared.

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