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ORIGINAL ARTICLE

Safety of immunotherapy in patients with rhinitis, asthma or atopic dermatitis using an ultra-rush buildup. A retrospective study

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Abstract
Background: Allergen-specific immunotherapy is a proven, highly effective treatment for IgE–mediated diseases. However, ultra-rush immunotherapy is prescribed infrequently because of the perception that accelerated immunotherapy buildup leads to a higher rate of systemic reactions.
Objective: To evaluate the frequency of adverse reactions in patients with IgE–mediated diseases receiving house dust mite (HDM) ultra-rush immunotherapy.
Methods: A retrospective, observational study was conducted for patients with IgE–mediated diseases receiving allergen-specific immunotherapy. Subcutaneous immunotherapy with depigmented polymerized mites extract was administered in two refracted doses of 0.2 and 0.3 ml at first injection, and in single 0.5 ml doses in subsequent monthly injections. A 30 min observation time was required after each injection. Systemic reactions were graded using the World Allergy Organisation grading system.
Results: 575 patients were included. The age range was 1–83 years. Most patients had respiratory diseases (544) and 101 patients had atopic dermatitis. A total of 27 patients (4.6%) experienced 139 reactions (reactions/injections: 1.9%); 22 patients (3.8%) experienced 134 local reactions (local reactions/injections: 1.8%). Eight patients (1.3%) experienced eight systemic reactions (systemic reactions/injections: 0.1%). Five systemic reactions were grade 2 and three grade 1. Two systemic reactions were reported during buildup. There were no fatalities.
Conclusion: Taking into account the possible bias for the retrospective design of this study we observed that immunotherapy for patients with IgE–mediated diseases using a depigmented polymerized mites extract, with an ultra-rush buildup, has similar frequency of systemic reactions than that seen in slower buildup immunotherapy in other studies. Accelerated buildup could improve patients' adherence and reduce dropout rates.

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Introduction

One of the principal factors cited against the widespread adoption of subcutaneous immunotherapy (SCIT) for asthma and other allergic diseases is the risk of serious adverse reactions.[1] In the 1980s a review study reported incidence of systemic reactions in patients receiving SIT for asthma over 30%[2] but in the last 20 years the prevalence of systemic reactions has been reported from 0.25% to 4%.[3–6] When differential risks exist between therapies, the more risky therapy can only be justified if that therapy offers substantial additional benefit over the safer therapy. Allergen immunotherapy is the only treatment that controls clinical symptoms and simultaneously modified the course of allergic diseases like asthma, rhinitis, conjunctivitis and atopic dermatitis.

The Word Allergy Organisation (WAO) has been making an effort to unify the definition and classification of systemic reactions using five steps according to the system affected and the severity of the reaction;[3] this could be useful for a homogeneous classification between studies and to evaluate possible risk factors such as the type of extract,[7–9] immunotherapy schedule,[10] and atopic disease treated.[11,12]

Slow buildups with several injections per week for two or three months are frequently used to avoid systemic reactions and some articles support a reduction of incidence with slow buildups compared with accelerated buildups when aqueous extracts are used.[13,14] However, slow buildups have a higher drop-out rate and there are no studies evaluating if slow buildups are better than accelerated buildups when depigmented and polymerized extract are used. Here we present the results of a retrospective study with 575 patients evaluating the safety of IT with a depigmented and polymerized mites extract with a buildup phase of two injections in one day.

Methodology

This retrospective study was designed to evaluate local and systemic reactions after immunotherapy with house dust mites (HDM) during the buildup and/or maintenance dosing. The study was conducted in a single allergy centre with six allergists associated at the University of Antioquia and was approved by the University Institutional Review Board.

Patients receiving SCIT for the period of May 2007–September 2011, were included. Subcutaneous Immunotherapy with depigmented polymerized mites extract (Leti, Madrid Spain) was administered monthly. Mite allergen extracts were administered in two refracted doses of 0.2 and 0.3 ml during buildup, and in single 0.5 ml doses (50 DPP) in subsequent monthly injections (Table 1). A 30 min observation time was required after each injection, for observing and counteracting possible side effects.

Table 2 Demographic features.

Demographics	Finding
Total patients	575 (100%)
Females	294 (51%)
Age	15 (1–83)
Diagnosis	
Asthma	313 (54.4%)
Rhinitis	505 (87.8%)
Conjunctivitis	251 (43.6%)
Atopic Dermatitis	101 (17.5%)
Premedication before immunotherapy	478 (82.6%)

Patients or patients' parents were instructed to identify and report any delayed reaction.

In our population we usually do immunotherapy against a single source of allergens, principally dust mite. In polysensitized patients with two or more sources that prove to be clinically relevant, we vaccinated with those extracts separately, however this is very infrequently and only nine patients of this group needed it.

To classify systemic reactions, the World Allergy Organisation subcutaneous immunotherapy grading system was used. The reactions of patients and the treatment provided were recorded at the time of the reaction taking into account the type of reaction (local, systemic), symptoms, time, organ systems affected.[15]

The clinical history of patients was reviewed for pertinent historical information. Particular attention was focused on sensitisation pattern (monosensitized, polysensitized) and allergic diseases.

Results

Patient characteristics

Five hundred and seventy-five patients received ultra-rush mite immunotherapy. Patients with HDM immunotherapy had a mean age of 15 years with a mode of 10 and ranged from 1 to 83 years of age. Two hundred and ninety-four (51%) patients were female; all patients had an IgE-mediated disease diagnostic by an allergist (Table 2). Five hundred and forty-four (94.6%) patients had a respiratory disease; allergic asthma (313 = 54.4%) or rhinitis (505 = 87.8%). Two hundred and fifty-one (43.6%) had allergic conjunctivitis and 101 (17.5%) atopic dermatitis.

Three patients with HDM immunotherapy received dog dander immunotherapy too. Among the patients receiving mites, 541 were vaccinated with a combination of *Der f*/*Der p*; 13 with *Blo t*/*Der f*/*Der p*; 4 with only *Der f*; 10 with only *Der p*, and 7 with only *Blo t*.

Table 1 Ultra rush immunotherapy protocol.

Face	Day	# Injection	Volume	Concentration
Buildup	1 day	1	0.2 ml	50 DPP
		1	0.3 ml	50 DPP
Maintenance	Monthly	1	0.5 ml	50 DPP