Subcutaneous immunotherapy: safety of modified and unmodified allergen extracts

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Background

Subcutaneous allergen immunotherapy is an efficacious treatment for allergic respiratory diseases such as rhinoconjunctivitis and asthma. Several studies have demonstrated that this route of administration is safe.

Objective

To evaluate the safety of immunotherapy, in an Allergy Clinic in Madrid (Spain) using therapeutic vaccines containing modified and unmodified allergen extracts adsorbed onto aluminium hydroxide from the same company (Inmunotek, S.L., Spain).

Material and Methods

The period analyzed was from 28/12/2000 to 28/12/2009. All injections were administered in the immunotherapy unit of the Clinic and recorded using specific software (Inmunowin®). Unmodified vaccines (Alutek®) were administered following a conventional build-up schedule, whereas rush or cluster was used for the modified preparations (Clustoid®). The concentration of more than the half of the modified preparations was 3 times than the usual (Clustoid® Forte). Patients were instructed to wait 30 min after injections. Systemic reactions related to immunotherapy were recorded and classified according to the criteria of the EAACI in 1993 (1). Immediate local reactions below 5 cm of diameter and delayed below 10 cm were considered irrelevant. The number and the grade of reactions between both groups was analyzed by means of a contingency table.

Conclusions

Subcutaneous immunotherapy is safe to treat patients with allergic respiratory diseases in the daily clinical praxis in an immunotherapy unit. The administration of modified preparations, even at higher doses (3X) using rush or cluster schedules is as safe as the administration of the unmodified using the conventional build-up schedule. This fact allows the administration of higher doses in a short period of time and could accelerate the appearance of clinical benefit.

Results

The total number of injections administered during this period was 146526. From these, 126085 (86.05%) corresponds to unmodified allergen preparations and 20441 (13.95%) to modified (Figure 1). Unmodified allergen extracts induced 278 systemic reactions (150 immediate and 128 delayed), whereas modified induced 52 (30 immediate and 26 delayed). Local reactions were 223 (118 immediate and 105 delayed) for the unmodified extracts and 37 (13 immediate and 24 delayed) for the modified. Table I shows the local and systemic reactions related to immunotherapy. Table II shows the grade of the immediate systemic reactions. The contingency table analysis showed that there was not significant differences between both groups (P>0.05).

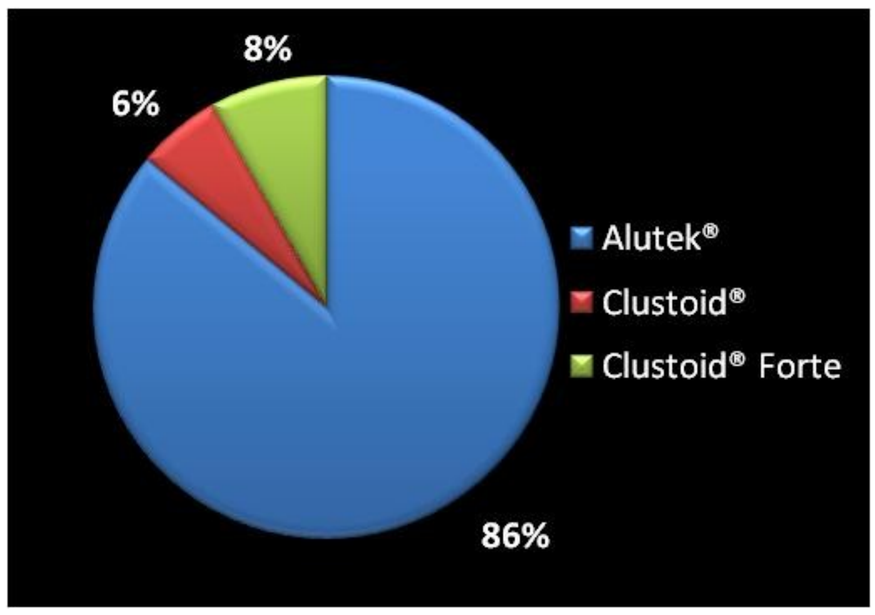

Figure 1. Percentage of injections administered by preparation

Table I. Local and systemic reactions related to immunotherapy

		Systemic				Local			
Product	Number of injections	I*	%	D*	%	I*	%	D*	%
Alutek®	126085	150	0.119	128	0.102	118	0.094	105	0.083
Clustoid®	8629	16	0.185	14	0.162	7	0.081	9	0.104
Clustoid® Forte	11812	14	0.119	12	0.102	6	0.051	15	0.127

I*: Immediate

D*: Delayed

Table II. Grade of the immediate systemic reactions

		Immediate systemic reactions							
Product	Number of injections	Grade 1	%	Grade 2	%	Grade 3	%	Grade 4	%
Alutek®	126085	73	0.058	54	0.043	23	0.018	0	0
Clustoid®	8629	6	0.070	8	0.093	2	0.023	0	0
Clustoid® Forte	11812	5	0.042	6	0.051	3	0.025	0	0

References

1.- Dreborg, S., Frew, A. Position paper: Allergen standardization and skin tests. The European Academy of Allergology and Clinical Immunology. Allergy 1993; 48 (Suppl 14):48-82.