

Glutaraldehyde modified allergen extract immunotherapy are able to cause anaphylaxis as an adverse reaction?

Kilimajer J.¹, García F.², Córdoba P.², Barjau C.², Casanovas M.¹, Subiza J.²

Inmunotek S.L., Clínica Subiza, Madrid, Spain



INTRODUCTION

Several studies have demonstrated that subcutaneous allergen immunotherapy is an efficacious and safe approach to treat allergic diseases.

Glutaraldehyde-modified allergen extracts offer several benefits compare to native allergen extract vaccines.

The principal objective was to evaluate the safety of immunotherapy, in an Allergy Clinic in Madrid (Spain) in the last 18 years using therapeutic vaccines comparing modified and unmodified allergen extracts.

MATERIAL AND METHODS

The 19 years period analyzed was from 01/01/2000 to 28/02/2019.

All injections were administered in the immunotherapy unit of the Clinic and recorded using specific software (Inmunowin®).

Patients received therapeutic modified and unmodified vaccines. Safety was assessed by recording all side reactions related to immunotherapy.

RESULTS

The total number of injections administered during this period was **236,259**.

From these, **132,769 (56.2%)** correspond to unmodified allergen preparations and **103,490 (43.8%)** to modified.

In the last 8 years this proportion had change (**79,366 injections**), observing **68,368 (86.1%)** for modified and **10,998 (13.9%)** for unmodified vaccines.

The total immediate systemic reactions in 19 years was **338 (0.14% from total)**, **136 (40.2%)** for modified and **202 (59.8%)** for unmodified (p = 0.189).

However, we detected **2 severe adversereactions (anaphylaxis: 1/70,000 injections)** related with unmodified immunotherapy.

On the contrary within 103,490 modified injections we didn't observed any anaphylaxis.

236,259 injections (01/2000- 02/2019)



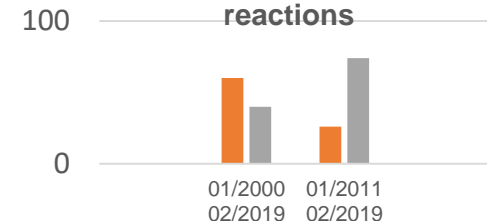
Unmodified 56.2%

79,366 injections (01/2000- 02/2019)



Unmodified 13.9%
Modified 86.1%

338 immediate systemic reactions



Unmodified % Modified %

The total immediate systemic reactions in 19 years was **338 (0.14% from total)**, **136 (40.2%)** for modified and **202 (59.8%)** for unmodified (p = 0.189).

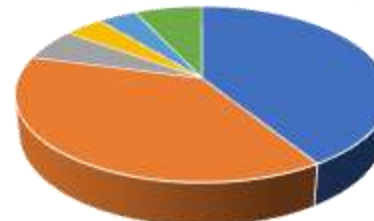
In the last 8 years the total immediate systemic reactions was **119 (0.14% from total)**, **88 (73.9%)** for modified and **31 (25.1%)** for unmodified.

2 SEVERE ADVERSE REACTIONS ANAPHYLAXIA

(Hymenoptera vaccines were discarded)

1st – Mites UNMODIFIED – Build up
2nd – Cat UNMODIFIED - Build up

Percentage of injections based on producers (AIT > 9500 doses)

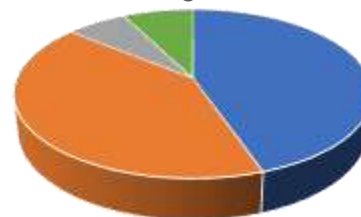


ALUTEK 40.9 %
ALUSTAL 6.3 %
EH RETARD 4%
CLUSTOID 38%
DEPIGROID 4.45 %
Others 7%

Injections by brands (only those with > 9500 doses)

Unmodified vaccines : Alutek® (INMUNOTEK S.L.), Alustal®(STALLERGENES S.L.), Retard/EH®(LETI S.L)
Modified extracts (alergoids) : Clustoid® (Clustoid, Clustoid Max, Clustoid Forte , INMUNOTEK S.L.) and Depigoid® (LETI S.L.)

Percentage of injections based on Allergens



Pollens 79%
Mites 12%
Dander 7 %
Others 7%

CONCLUSIONS

Anaphylaxis was detected only with unmodified immunotherapy but not with modified immunotherapy.

In this last decade the use of modified allergen extracts has triplicate its use.

Allergen immunotherapy using modified extracts is safer

