Efficacy and Safety of Cluster Immunotherapy with Highly Polymerized Mite Allergen Extracts

J. Uhlig[1]; V. Agababov[2], B. Hofmann[3], J. Niemeyer[4], R. Sempell[5]

[1] Roxall Medizin, Hamburg; [2] ENT-Centre, Hannover; [3] ENT-centre, Stralsund; [4] Dermatologist, Nordhausen; [5] Dermatologist, Itzehoe
Germany

BACKGROUND

Mites are the most important triggers for perennial allergic rhinitis and allergic asthma with increasing tendency.
For now specific immunotherapy (SIT) is the only causal treatment for IgE-mediated diseases with the option to induce immunological tolerance and to prevent the onset of allergic asthma.
Cluster immunotherapy offers the possibility to achieve the maintenance dose with just few injections and is therefore more and more accepted by patients and doctors.
In a multicentre cohort study safety and efficacy of cluster immuno-therapy with highly polymerized mite allergen extracts in patients with clinical sensitazation to house dust mites were evaluated after an observation period of one year.

METHODS

Patients

53 patients between 7- 79 years of age (median:12.8 years; 28 female, 25 male) with a history of allergic rhinitis, conjunctivitis and/or allergic asthma bronchiale received specific immunotherapy with highly polymerized allergen extracts of D.pteronyssinus/ D.farinae (CLUSTOID®, ROXALL Medizin, Hamburg) according to their clinical history, positive skin test results to mites and to the standard inclusion criteria that are applied for specific immunotherapy.
Characteristics of patients are summarized in Tab.1.

Tab. 1 Characteristics of Patients

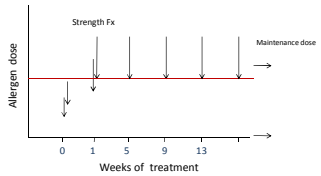
	CLUSTOID®
Number of patients (n)	53
Female	28
Male	25
Age (years)	7-79

Schedule of treatment

The up dosing followed a cluster schedule:

- 0.1 mL + 0.2 mL on the first treatment day, subcutaneously in one and the other arm with an interval of 30 minutes.
- 0.3 mL + 0.5 mL on the next treatment day one week later from the same vial, again sub-cutaneously in one and the other arm with an interval of 30 minutes.
- 0.5 mL as maintenance dose for perennial continuation course once a month (Fig.1).

Fig. 1 Cluster-Schedule



The data were analyzed during the pollen season before and after starting of treatment. The patient's general condition was analyzed based on a visual analog scale (VAS) graded from 1 to 5:

1 = very good, 2 = good,
3 = satisfying,
4 = bad, 5 = very bad.

To evaluate the safety of cluster therapy the tolerance as well as any side effects related to the injections were documented. Adverse events (local and systemic reactions) were categorized according to their severity.
Local reactions were classified according to the diameter of the wheal.

RESULTS

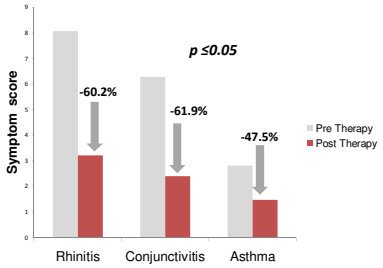
Efficacy

The overall study period was one year. Safety and efficacy data from 53 patients with 607 injections were analyzed.

Symptom Score

The overall symptom score was significantly reduced by 56.5% ($p<0.05$). Rhinitis symptoms were reduced by 60.2%, conjunctival symptoms were reduced by 61.9% and the average asthma symptom score by 47.5% (Fig. 2).

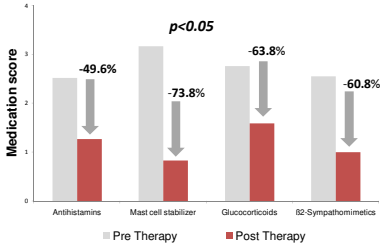
Fig. 2 Symptom Score



Medication Score

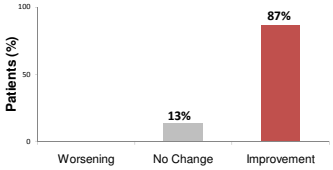
The overall medication score was significantly reduced by 62% ($p<0.05$):
The use of antihistamines decreased significantly by 49.6%, intake of mast cell stabilizers by 73.8% the use of glucocorticoids by 63.8% and of β2-sympathomimetics by 60.8 %, Fig. 3.

Fig. 3 Medication Score



Forty-six out of 53 patients (87%) described an improvement in their general conditions after having started specific immunotherapy with the clustoids. No patient reported worsening, 7 patients (13%) did not notice any change (Fig. 4).

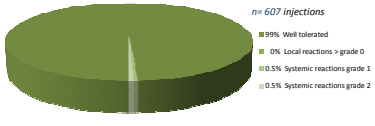
Fig. 4 Improvement of Patients' General Conditions



Safety

In total 607 injections were analyzed, 601 (99%) were well tolerated. No injection resulted in local reactions larger than grade 0 (wheal diameter 0-5 cm). Systemic reactions of grade 1 (0.5%) consisted of pruritus, light feeling of sickness, sneezing. Three injections (0.5%) resulted in systemic side effects of grade 2 with bronchial obstruction, asthmatic reactions two days after the injection or a light hypotensive episode (Fig.5). No severe systemic reactions were recorded.

Fig. 5 Safety Profile



CONCLUSION

Cluster immunotherapy with highly polymerized mite allergen extracts is safe and effective.
Symptom score and medication score were significantly reduced.