THE REPORT FROM THE CONDUCTED STUDIES

The influence of Allergoff® Spray on house dust mite allergy

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Summary

House dust is well studied source of numerous airborne allergens such as allergens of mites and insects, mold spores as well as ingredients of saliva, epidermis and excrements of pet animals and others. The year round exposure of people with the features of atopy to house dust allergens promotes the development of bronchial asthma, atopic rhinitis, atopic eczema and year round allergic conjunctivitis.

Allergoff® Spray was used at homes of the selected group of patients with allergy in order to decrease the level of exposure to the inhalation of house dust allergens.

The results obtained shows:

- the significant reduction in the level of the main allergen *Dermatophagoides pteronyssinus* (Der p 1),
- significant reduction in the clinical symptoms of allergic rhinitis and conjunctivitis
- and the reduction in the need to use anti-allergic drugs and salbutamol compared to the base line.

Allergoff®

Introduction

The design of these studies has been accepted by the Bioethical Commission of the Silesian Medical University in Katowice.

House dust mites are a source of allergens causing airborne allergies in the form of allergic rhinitis, conjunctivitis and bronchial asthma. There is also evidence of significant influence of mite allergens on the occurrence of allergic skin inflammation. Allergens of these arachnids have a complex and compound structure known as components. The two most common species of mites, i.e. *Dermatophagoides pteronyssinus* and *D. farinae*, have approx. 20 such components. Some of them are crucial in inducing allergies, e.g. Der p 1, Der p 2, Der p 10, Der p 23, Der f 1 (2). These are mostly protein substances or their derivatives. Some components have the characteristics of enzymes.

Current medical documentation emphasizes the **very high health significance of exposure to Der p 1 allergen, which induces the development of allergic diseases. A high environmental concentration of this antigen may increase the severity of symptoms such as asthma attack, sneezing, nasal blockage and others in allergic patients.**

Attempts to eliminate mite allergens from the domestic environment influence the reduction of disease symptoms, which was confirmed in scientific studies and reflected in recommendations for the therapeutic management for the above-mentioned patients.

Recently, attention has been paid to the effect of the removal of the main allergen Der p 1 from the environment of the patient and the scale of clinical improvement of allergy.

Such research, including research with other allergenic components, is currently underway.

The aim of this study was to evaluate the efficacy of Der p 1 allergen removal from the environment of a patient allergic to dust with the evaluation of the degree of symptoms reduction by using Allergoff® for neutralization of house dust allergens from ICB Pharma company.

Objectives of the Study

The objective of this study is **to assess the value of the secondary prophylactic intervention with the use of Allergoff® Spray at homes** of patients sensitive to house dust allergens with particular reference to the possibility of reducing the level of house dust mite allergen *Dermatophagoides pteronyssinus* (Der p 1).

Research Method

In the first stage of research carried out during the heating season, between December 2016 and April 2017, the study included 42 people, 17 women and 25 men, including 14 people under the age of 18.

The second stage was carried out on a population of 64 patients between the ages of 18-75 years in the period from November 2017 to April 2018. The characteristics of patients participating in the second stage of the study are shown in Table 1.

Table No. 1. Characteristics of patients participating in the study, stage II

Patient's age:18-75 years old	N =64
Age +/- standard deviation	31,8 ± 6,17
Women (%)	29 (45,3)
year round allergic rhinitis	64 (100)
allergic bronchial asthma	19 (29,7)
place of residency: city	41 (64)
allergy to other allergens	8 (12,5)
allergy due to family history of the disease	36 (56,3)
smokers and former smokers	24 (37,5)

In total, the research group included 106 people, all of whom were residents of the Silesia province.

The criteria for including patients in the study were:

1. Symptoms of allergic rhinitis and/or conjunctivitis
2. Association of disease symptoms with exposure to house dust based on the patient's observation
3. Anti-allergic treatment

According to the study protocols, the procedure were performed on patients which consisted in one month observation of the symptoms of allergic disease and evaluation of the use of symptomatic drugs before and after the preventive intervention. At the same time, the presence and concentration of the main mite allergen *D. pteronyssinus* (Der p 1) was monitored in the samples of mattress dust collected and the allergen-specific level of IgE in the blood serum of the examined persons was assessed.

Research procedure

1. Clinical evaluation of the patient's condition before the allergen elimination procedure.
2. Dust sampling from the patient's surrounding in accordance with Annex 1*.
3. The use of Allergoff® in the patient's environment (bed and its surroundings) in accordance with the manufacturer's instructions.
4. Evaluation of the patient's clinical condition after one month of the allergen elimination procedure.
5. Dust sampling from the patient's environment one month after Allergoff® use.

Stages of assessing the clinical condition of the patient before and after the allergen elimination procedure:

1. Physical examination.
2. Medical Questionnaire.
3. Blood collection to assess the level of IgE antibodies for house dust mites.

Diagnostic Procedures

1. Evaluation of Der p 1 allergen level in dust samples from the environment of the examined patients.

For the assessment, prepared dust samples from the patient's environment were taken according to the instructions before and one month after Allergoff® use. The samples were taken from the mattresses and the bed area (vacuuming an area of 1 m2 for 3 minutes). 100 milligram of dust sample was used. The sample was suspended in 1 ml of normal saline in propylene tubes. All samples were frozen in -20°C, until their determination.

After thawing, each sample was treated with 2 ml of buffered 0.05% Tween-20 solution and incubated for 120 minutes at room temperature and then centrifuged for 20 minutes at 3500 RMP at 6°C. Der p 1 allergen was determined in the obtained samples by using monoclonal antibodies in available ELISA kits (Indoor Biotechnologies, Charlottesville, USA). The reference level of Der p1 detection was (0.11 µg / g). The spectrophotometer and the bands of 387 and 390 nm were used for the assessment.

2. Evaluation of the concentration of IgE antibodies against Der p 1 allergen in the serum of the studied patients.

Antibodies were determined by immunoenzymatic method using the Immuno CAP method (ThermoFisher Scientific, Uppsala, Sweden) according to the manufacturer's instructions. The results were considered positive if the IgE value exceeded 0.35 IU / ml (as indicated by the manufacturer).

In order to reduce the level of exposure to inhalation allergens present in the home dust of patients, the product „Allergoff® allergen-neutralizing spray" has been applied to sleeping places including pillows and comforters, the floor area under the

Table No. 2. Assessment of Der p 1 concentration in the dust samples before and after use of Allergoff® Spray.

pacjent	przed	po	p
1	0,672	0	<0,05
2	0,098	0	<0,05
3	0,178	0,035	<0,05
4	0,411	0,321	NS
5	0,098	0	<0,05
6	0,056	0	<0,05
7	0,102	0,071	<0,05
8	0,075	0	<0,05
9	0,238	0,008	<0,05
10	0,278	0,076	<0,05
11	0,10	0	<0,05
12	0,437	0	<0,05
13	0,187	0	<0,05
14	0,138	0,161	NS
15	0,044	0,044	NS
16	0,101	0,036	<0,05
17	0,893	0	<0,05
18	1,461	0,156	<0,05
19	0,789	0	<0,05
20	0,009	0	<0,05
21	0,027	0,012	<0,05
22	0,802	0,456	<0,05
23	0,546	0	<0,05
24	0,117	0,099	NS
25	0,107	0	<0,05
26	0,32	0,018	<0,05
27	0,455	0	<0,05
28	0,298	0,032	<0,05
29	0,781	0	<0,05
30	1,141	0,056	<0,05
31	0,094	0	<0,05
32	0,335	0,079	<0,05
33	0,403	0	<0,05
34	0,211	0	<0,05
35	0,058	0	<0,05
36	0,094	0,045	<0,05
37	0,055	0	<0,05
38	0,012	0,034	NS
39	0,033	0,009	<0,05
40	0,921	0,067	<0,05
41	0,137	0,051	<0,05
42	0,102	0,033	<0,05
43	0,098	0,023	<0,05
44	0,561	0	<0,05
45	0,045	0,011	<0,05
46	0,428	0,101	<0,05
47	0,379	0,034	<0,05
48	0,362	0,022	<0,05
49	0,409	0,291	<0,05

sleeping place, carpets and rugs, upholstered furniture, curtains , bedspreads, plush toys, etc. In addition, to neutralize and remove allergens present in fabrics, during the washing of bedding and clothes, a product called „Allergoff® Wash has been used. In the first stage of the study before and after the use of Allergoff®, the level of concentration of mite allergens in the mattress dust tests was evaluated using the „Acarex test" by Allergopharma.

Product Evaluation

Allergoff® is a new solution based on microencapsulation, which provides dual protective action:

1. It glues dust particles together thus reducing the risk of contact with airborne allergens
2. It neutralizes the main allergens of house dust mites

The microencapsulation technology provides a slow release of the applied active ingredient (benzyl benzoate), thus ensuring the long-term protective action.

The results

1. Before taking preventive measures by using Allergoff® Spray, it was found that the concentration level of the main mite *D. pteronyssinus* (Der p 1) allergen in the dust samples from the mattress was high in most cases (the highest value is 0.802 µg / g) or medium from 0.2 – 0.4 µg / g. Only in individual cases the concentration of Der p 1 allergen has been found low as 1 µg / g or at the borderline of detection of 0.009 µg / g.
2. After Allergoff® Spray has been used, the test has been repeated. The results showed the absence of the main Der p 1 allergen in the samples of collected mattress dust, which was analyzed using colored test called „Acarex test" in all patients (100%). On the other hand, based on the detailed allergen detection in the second stage of the study, the average concentration of Der p 1 in 1 gram of the examined dust decreased significantly to 0.176 ± 0.066 µg (Table 2 – the table does not include samples that do not allow to determine the level of allergen in collected dust samples).
3. The demonstrated decrease in the content of the main allergen of D. pteronyssinus mite was correlated with the patients' subjective assessment during the medical questionnaire. In the first stage, the patients indicated a significant reduction in disease symptoms by an average of 5.4 ± 0.8 (± standard deviation) points on a 10 point scale in relation to the baseline

test, where full symptom score was 10 points and 0 indicated complete resolution. This result was statistically significant ($p < 0.05$).

The second stage showed a correlation between decrease in the Der p 1 allergen concentration and the improvement of the patients' well-being (improvement of the clinical picture expressed by the reduction of nasal symptoms): $R = -0.7$ for $p < 0.05$ (graph 1).

4. A significant improvement expressed as the significant reduction in pathological symptoms and reduction in drugs used within a month following the application of the preparation Allergoff® Spray was observed in 64.1% patients, while a moderate effect was achieved in further 14.1% patients. 21.8% did not report any significant difference following the application of the preparation.
5. Reduction in the symptoms of allergic rhinitis was reported in 60.9% patients, and in the symptoms of asthma in 63.2% patients, including nocturnal symptoms in 26.8% patients.
6. In addition, a significant reduction by approximately 42%, was observed in the amount of symptomatic drugs used.
7. In the group of patients with the symptoms of bronchial asthma, 18% reduction in the rescue use of salbutamol was observed as compared to the month preceding the application of Allergoff® Spray.
8. Average IgE Der p 1 concentrations decreased slightly but it was not statistically significant. A similar analysis carried out in mite allergic patients, but not included in the eradication procedure, showed a slight increase in the mean IgE concentration for Der p 1. However, the increase was also statistically insignificant.

Presentation of some research results

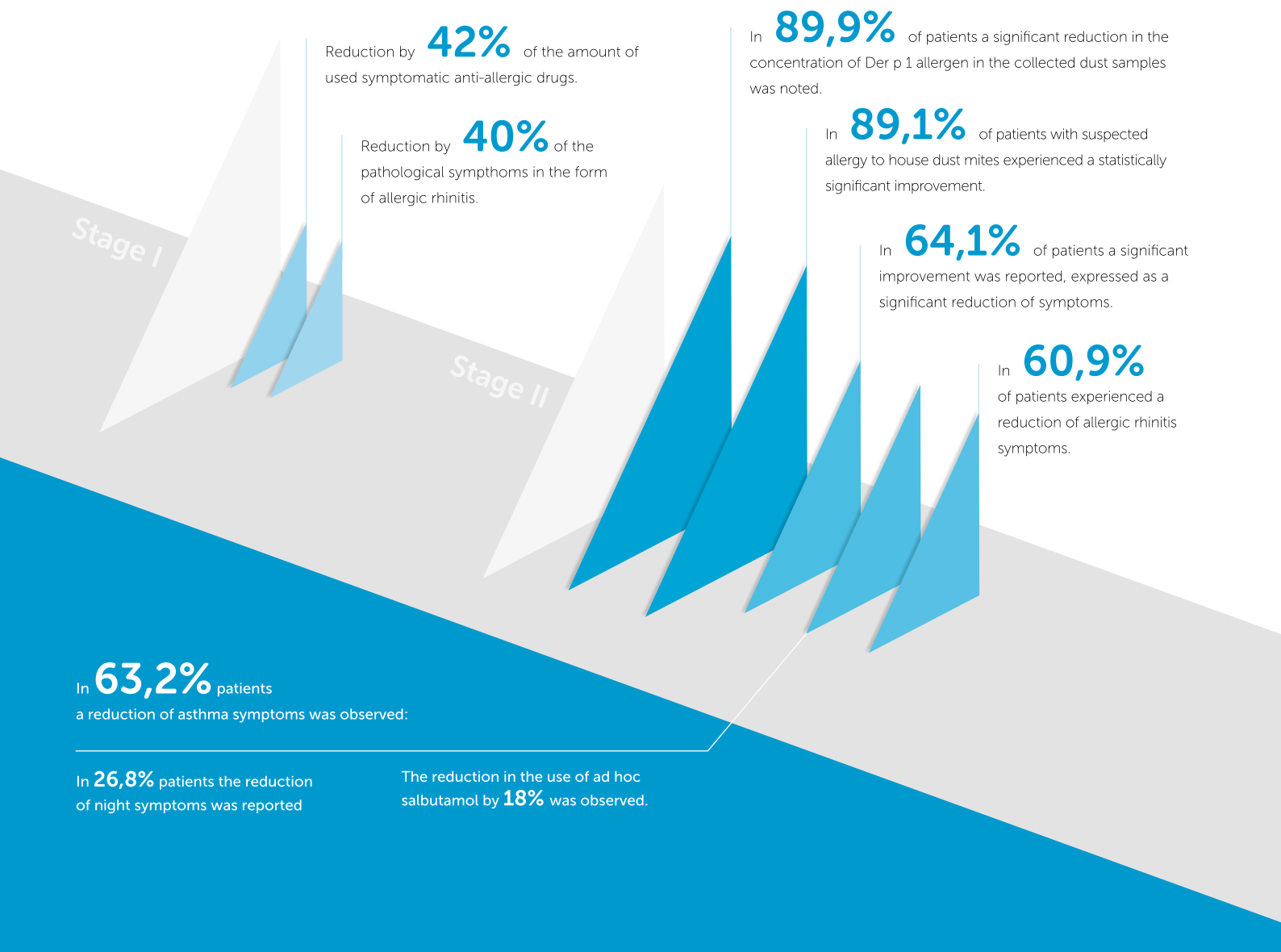
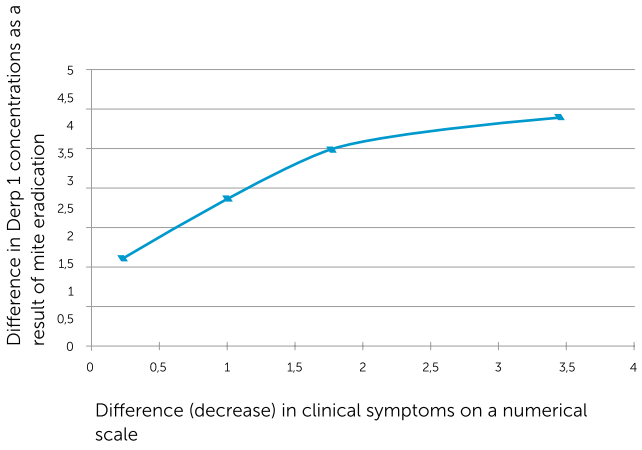
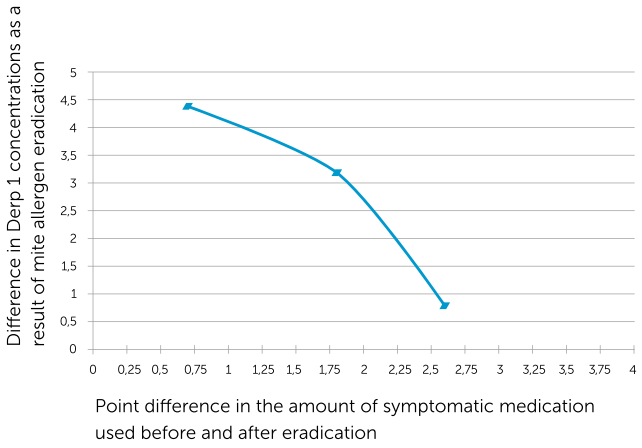


Fig. 1. Correlation between the degree of reduction of Der p 1 concentration in dust samples after eradication and **the degree of improvement of clinical symptoms.**



At the same time, a correlation between the decrease in Der p 1 concentration and the reduction in the use of symptomatic medication R = -0.56 for p < 0.05 (Fig. 2) was found.

Fig. 2. Correlation between the degree of reduction of Der p 1 concentration in dust samples after eradication and the **degree of use of symptomatic drugs.**



Conclusions

The use of allergen neutralising spray in the home environment of patients resulted in a decrease in the level of the main mite allergen, *Dermatophagoides pteronyssinus* (Der p 1).

As a result of preventive measures, a significant reduction in clinical symptoms of allergic rhinitis and conjunctivitis as well as asthma symptoms, including night symptoms, was observed in the patients studied.

In the patients studied, a 42% decrease in the need for anti-allergic drugs was observed compared to the initial assessment.

In a group of patients with allergic bronchial asthma symptoms, the reduction in the use of ad hoc salbutamol by 18% was observed in relation to the month preceding the preventive intervention.

No statistically significant differences in IgE antibody levels were found prior to the preventive intervention and in final studies.

The use of Allergoff® did not cause any adverse effects in the patients studied.

The improvement of the clinical picture in the study group occurred already within 30 days after the use of Allergoff® Spray.

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* Załącznik nr 1 dostępny u Autorów badań.

Final remarks

The most important goal of asthma treatment is to get control over the disease. That includes normal lung ventilation, a complete absence of night symptoms, reduce activity, the onset of symptoms or the need to use antihistamine medication twice a week at most.

Early results obtained in the group of patients with allergic bronchial asthma shows significant improvement of patients quality of life. There was a reduction in night symptoms and a reduction in the amount of used medication.

The improvement of the clinical picture in the study group occurred already within 30 days after the use of Allergoff® Spray.

Due to the surprisingly short time in which the quality of patients life was improved and the medication used by the patients was reduced, the study of the effectiveness of prophylactic interventions with the use of Allergoff® Spray will be continued on a larger group of patients.

The desirable clinical effect in the bronchial asthma treatment can be accomplished by combining immunotherapy, which increase the allergens sensitivity treshold and by using effective methods of the secondary prophylaxis whichrole is to lower the concentration of the airborne allergens.

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