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Evaluation of the Effect of Anti-Mite Fabric on the Well-Being of Patients with a Mite Allergy

Abstract
House dust mites are a major allergen responsible for chronic year-long allergic rhinitis and bronchial asthma. The avoidance and elimination of allergens from the house environment is a causal activity; however, the effectiveness of many available methods of mite elimination as well as the reduction of their proliferation are still being analysed and discussed. The aim of the study was to evaluate the effect of anti-mite fabric on the well-being of patients with allergic rhinitis and/or asthma. The polypropylene fabric tested contained boric acid as an active agent vs. the fabric without an active agent (placebo). Thirty seven patients with a diagnosed mite allergy participated in the study. Clinical assessment, abrasion test, patch tests, and evaluation of the mite allergen concentration in the patient's bed were used in this research, as well as a questionnaire subjectively estimating the method of anti-mite prophylaxis and visual analogue scale of the general well-being applied. The fabric did not produce allergic reactions in patients allergic to house dust mites in neither the abrasive test nor the patch tests. When the active fabric was used, a statistically significant decrease in mite guanine was observed. In the total assessment of the patients (a single assessment on completion of the study), no clear differences were detected in the severity of symptoms during active fabric use vs. placebo. In the everyday score evaluation in the visual analogue scale, a significant improvement was found in the well-being of the active group.

Key words: *house dust mites, mite allergy, mite elimination, anti-mite fabric, effectiveness of mite elimination.*

Introduction

House dust mites are a major allergen responsible for chronic year-long allergic rhinitis and bronchial asthma. Exposure to mite allergens indoors is a key factor in the risk of sensitisation and occurrence of symptoms [1, 2]. Avoidance and elimination of allergens from the house environment is a causal activity; however, the effectiveness of many available methods of elimination as well as the reduction of mite proliferation is still being analysed, but it remains controversial or it is denied [3 - 7].

The most frequently applied methods of house dust mites elimination are: vacuum cleaning with the use of filters, the use of acaricides on upholstered surfaces, and the use of allergy-proof encasements over bedding and mattresses to prevent mites crawling in and out [7 - 12]. This article concerns investigations into the anti-mite activity of bedding inserts. The anti-mite activity of the test fabric was estimated earlier on the basis of *in vitro* tests. It was assumed that it might have a beneficial effect on the symptoms of patients allergic to mites by reducing the mite population in the patient's bed.

Aim

The major aim of the studies carried out was to assess the effect of anti-mite fabric vs. control fabric on the change in the severity of allergic complaints in patients sensitised to mite allergens. The study was carried out as a double-blind, placebo-controlled trial. The study was approved by the Bioethics Committee of the Medical University in Łódź.

Material and methods

The test fabric

Bedding inserts were used for the testing of anti-allergic properties of the textile material used for their manufacture. The bedding inserts were manufactured from a stitch nonwoven produced on a technological installation at the Textile Technic Enterprise (ITeE) in Łódź, with a surface density of 158 g/m^2 characterised by anti-mite activity, which is in accordance with French Standard NF G-33-011. The activity was tested in a acarologic laboratory at the Institute of Biopolymers and Chemical Fibres, Łódź, Poland [1, 2].

The raw-material blend was composed of the following two different kinds of fibre:

- Polyprpopylene bioactive staple fibres with a length of 32 mm and linear density of 5 dtex manufactured by the company PPH-U "Viola" at their "Multitex" branch in Mirsk, Poland. The content of the active substance Ceramite^{TM}, containing boric acid, was 1.0% wt. 2% of the AM 92223 masterbatch produced by Wells Plastic Ltd, which was used for producing the polypropylene fibres.
- Polyester staple filling fibres with a length of 76 mm and linear density of 6.6 dtex were produced by the company 'Elana' [13].

A stitch nonwoven composed of 50% modified polypropylene fibres and 50% polyester fibres was used for preparing the bedding inserts. A BTG–100 cotton net with a leno weave and mesh dimensions of 10 mm × 5 mm was used as a strengthening element in the nonwoven, which was an insert below the bed-sheet.

The nonwoven was characterised by the following physical-mechanical properties:

- Surface density of the stitched nonwoven 158 g/m^2
- Stitching number 6 -7/cm^2
- Stitching depth 7 mm
- Relative breaking force in the longitudinal direction 4,040 N/m
- Relative breaking force in the transversal direction 854 N/m

- Surface density of the BTG-100 net 40 g/m^2
- Type of sewing weave tricot
- Wale density 25/100 mm.

The final bedding inserts were manufactured by sewing. The inserting set was composed of

- An insert dedicated to use under a bed-sheet with dimensions of 2,000 × 1,400 mm.
- An insert dedicated to use with a quilt coverlet with dimensions of 2,000 × 1,400 mm.
- An insert dedicated to use with a pillow with dimensions of 700 × 800 mm [14].

The inserts made of the test fibres were prepared to be interposed between the bed-clothes used thus far.

The bedding inserts of anti-mite fabric (for 28 patients), and of a fabric without the addition of an anti-mite substance (for 9 subjects – the control group) were alloted to the patients by the double-blind trial method. The Bedding inserts were used for 6 weeks. Each patient received a set of inserts: under the bed sheet, in the pillow case and in the quilt case. The patients used all the bedding inserts in their own homes.

Material

The study comprised 37 patients of both genders, aged 5-54 (mean age: 24.6 years) with an earlier diagnosed allergy to mites and with characteristic symptoms of allergic rhinoconjunctivitis and/or atopic asthma during natural exposure. All subjects (or their legal guardians) gave their consent for participation in the study.

Study group A included 28 patients (15 females and 13 males), aged 6-54 (mean age: 22.8 years). Control group P included 9 subjects (5 females and 4 males), aged 5-52 (mean age: 26.4 years). During the study, the patients were asked to use the prepared bed-clothes every night, to apply the prescribed pharmacotherapy without changing the doses and without having any breaks during the observation to avoid greater than usual exposure to dust (e.g. thorough cleaning).

Methodology

Preliminary examinations (qualifying)

A qualifying medical visit (with history)

During the first visit, the patient's health condition was assessed. It was also checked whether the patient had a documented allergy to mites (positive skin tests for *Dermatophagoides pteronyssinus* and *Dermatophagoides farinae*) confirmed by medical interview, and whether the patient felt symptoms of the disease at that moment. The medical therapy was administerd at the same level during the trial.

Abrasion test performed for each qualified patient using the test and control fabrics

An abrasion test was performed using fragments of the test fabrics on the inside part of the forearm,which was read after 1, 5 and 10 minutes.

Patch tests with the test and control fabrics

Finn Chambers (Epitest Ltd, Finland) were used to perform patch epidermal tests. The reading was made in accordance with current guidelines laid down by a Group of Experts of the Polish Allergological Society and Allergological Section of the Polish Dermatological Society. The tests were performed on the inside part of the patient's forearm. Readings were made after 48 h and 72 h.

An acarex test (*Allergopharma* Nexter, Germany) was performed twice to demonstrate guanine concentration, which signals the presence of mite allergens in dust collected from a patient's bedclothes before and 6 weeks after the use of anti-mite fabrics. The acarex test is a semi-quantitative method of assessing the level of guanine in the test material. Dust was collected from the patients' beds in accordance with the recommendations of the test producer. The concentration of mite allergens was assessed indirectly in the following scale: 0, low, medium, high, very high. If mites were not detected in the tested samples, these patients were not qualified for further tests.

A questionnaire subjectively subjectively the applied method of anti-mite prophylaxis was filled in by the patient after completing the period of utilisation. In general, the questionnaire estimated any noticeable improvement in well-being or its lack or deterioration, as well as additional remarks related to the application of the fabric.

Visual analogue scale of general well-being – a 24-hour questionnaire filled in every day by patients. A questionnaire evaluating the severity of allergic symptoms with the help of a visual scale of 0 - 10 in a 24-hour evaluation.

The final examination was after 4 - 6 weeks. The current severity of the patients' allergic symptoms was assessed again with the help of an interview and physical examination. Skin tests and spirometry were not performed irrespective of the detailed daily scales.

All diagnostic methods applied belong to allergological clinical diagnostics.

Results

Preliminary examinations (qualifying)

A qualifying medical visit – history taking

In the active group atopic asthma was diagnosed in 64.3% of patients, and allergic rhinoconjunctivitis in 35.7%. In the control group atopic asthma was diagnosed in 88.9% of cases, and allergic rhinoconjunctivitis in 11.1%. All patients (37/37) from both groups had positive skin prick tests for *Dermatophagoides pteronyssinus* (Dp) and *Dermatophagoides farinae* (Df) mites.

Abrasion test

The abrasion test performed during the qualifying visit for both the active and control fabrics was negative in all patients (37 subjects).

Patch tests

Patch test with the test fibres gave negative results in all patients from groups A and P (37 subjects).

Due to negative results of the above tests, the whole group of patients qualified for a double-blind, placebo-controlled trial using the test fabrics.

The fabric without the addition of an acaricide substance was placebo.

Proper tests

Results of the Acarex test

In the active group, high or medium mite concentration was found before the use of fabrics in 17/28 (60.7%) patients, whereas in the remaining 11/28 (39.3%) patients the concentration was low. After testing, high or medium concentration was observed in 8/28 (28.6%) of patients, whereas in the remaining 20/28 (60.7%) the concentration was low. There was also a lack of mite allergens in 3/28 (10.7%) patients.

In 50% of patients (14/28) a decrease in the level of mite allergens was detected, in 13/28 (46.4%) – the same level, and in one patient (36%) - an increase in the concentration. It was estimated that the decrease in the concentration of mites in the dust from the beds of patients from group A was statistically significant (chi 2 test = 0.003) (***Figure 1***).

In the control group, high or medium concentration of allergens was initially observed in 7/9 patients, whereas for the remaining 2/9, it was low. After testing, high and medium concentration was found in 3/9 patients, while for the remaining 6/9, it was low.

In 4/9 patients the same mite concentration was maintained, whereas in 5/9 it decreased. Due to the small number of patients in the group, no statistical analysis was performed .

Final questionnaire of the patient's subjective feelings (single, after completion of the study).

In group A 42.9% (12/28) of patients noticed an improvement in their general well-being compared to the previous visit, whereas 57.1% (16/28) did not notice any significant difference. None of the patients observed any intensification of allergic symptoms.

78.3% (18/23) of patients found the test fabric pleasant in use and warm. The remaining subjects (5/23), 21.7%, had remarks concerning mainly the smell of the fabric and its functional quality (no buttons, zip, or the size).

In the control group 3/9 patients estimated that the allergic symptoms decreased when the fabric was used. In over half of the patients, 5/9, the symptoms remained at the same level, but in one patient exacerbation of allergic symptoms was

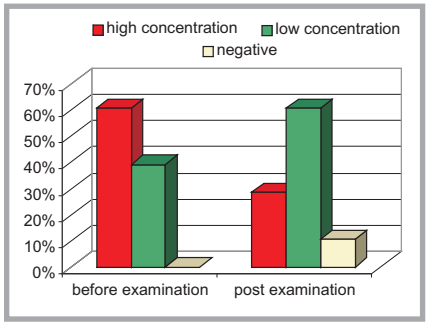

Figure 1. *Concentration of mite allergens in dust from the bed-clothes of group A.*

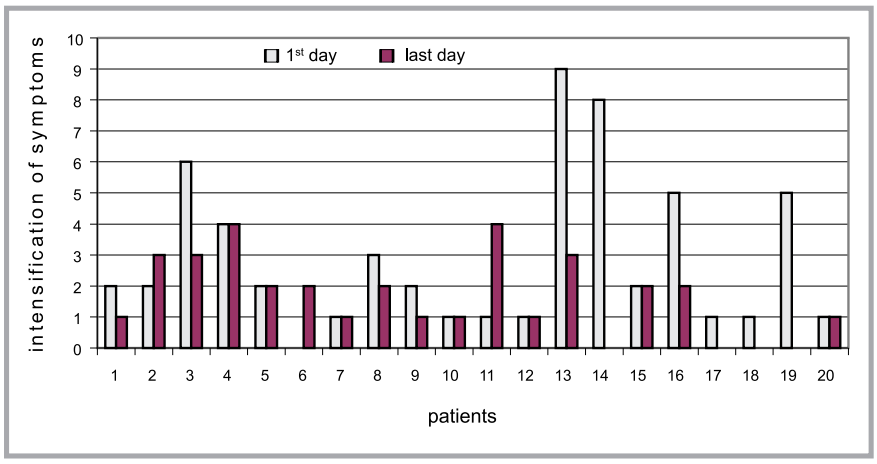

Figure 2. *Intensification of allergic symptoms in particular patients from the active group. Visible significant differentiation of initial symptoms and more distinct improvement in more affected patients before mite control.*

observed. The majority of patients, 5/9, found the fabric pleasant and warm.

Visual analogue scale (VAS)

The analysis of the patients' well-being was measured with the visual scale of well-being during the qualifying visit. The result obtained on the first day was considered as the initial value (before the use of the fabric). The value after using the fabric was obtained on the last day (after 6 weeks). The patients who had an infection in the final stage, or whose symptoms intensified due to other non-allergic reasons, were excluded from the analysis.

The mean of symptoms before using the fabric in group A was 2.71 score. Intensification of symptoms oscillated from 1 to 9 scores. After application of the fabric, the mean score value of the intensification of symptoms was 1.57 score. In 50% (10/20) of the subjects tested, the severity of symptoms decreased after the period of fabric application. In 35% (7/20) of patients the severity of symptoms remained at the same level; however, this group consisted exclusively of patients with insignificant intensification of symptoms: initially from 1 to 4 scores. In 15% (3/20) of patients the severity of symptoms increased (on average by 2 scores/person), which is from 2 to 3 scores in one patient, from 0 to 2 scores in the second patient, and in the third from 1 to 4 scores (***Figure 2***).

In Group P were patients with initially weaker symptoms. The mean score value of the severity of symptoms before application of the fabric was 1.33 score, whereas after application of the fabric it was 1 score. After 6 weeks 75% of group P subjects (6/8) estimated the severity of their symptoms as the same as before. For 1 patient the severity of symptoms decreased (by 1 score), while in another it increased from 3 to 6 scores (***Figure 3***).

Discussion

The beneficial results presented should be interpreted cautiously because they are not in agreement with Cochrane meta-analyses published in the years 2001, 2004 and 2007 [5, 6]. The reports quoted, based on reliable methodology have permanently negated the value of any attempts at mite control as an effective method of combating mite asthma. Therefore, should the search for new strategies of fighting against the causes of the worldwide epidemic of mite asthma through controlling harmful arachnids, be abandoned? Will it be enough to focus efforts on pharmacological techniques of suppressing inflammation caused by their

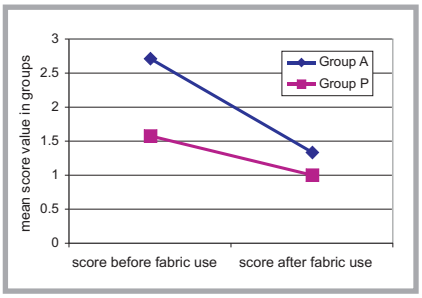

Figure 3. *Application of the test fabric resulted in patients with a mite allergy showing significant improvement in their well-being, which was measured with a visual analogue scale before and after testing (the score being 2.7 before testing, 1.5 after testing vs. 1.3 and 1.1 in the placebo group).*

antigens? These questions require urgent comment with respect to the results presented here.

In the observations carried out in this study using the double-blind trial method, a statistically significant advantage was obtained of the effectiveness of active acaricide fabric over placebo. Also, in our previous study the effectiveness of modern aerosol acaricides appeared to be significant [11]; similar opinions are given by others. The results obtained are confirmed by the most recent, reliable reports. In randomised intervention studies, important indications for domestic allergen elimination in children at high risk of atopy were demostrated for the first time. Using the double-blind trial, Halken [15] demonstrated that the Allergy Control Program for children, involving semi-permeable polyurethane mattresses and tight pillow case use, resulted in a considerable reduction in exposure to dust mites.

The most significant requirement is to repeat mite elimination procedures. Swinnen and Vroom [14 conducted a study aimed at the evaluation of benzyl benzoate efficacy in 60 dogs allergic to dust mites. Acaricide was used until negative results of guanine Acarex tests were obtained, in order to evaluate the effects of dust mites elimination on the state of animals. Moderate and significant results were obtained in 82% of allergic dogs. The clinical trial presented clearly demonstrates the usefulness of mite control in the case of allergic dogs [16].

Hubert et al. demonstrated the efficacy of the most important acaricides in the eradication of warehouse mites (*Acarus siro)*. The authors included substances containing a single active component or ready mixtures available on the market (deltamethrin, chloropyfifos, beta-cyfluthin and combinations). None of the pesticides examined by the author was able to provide complete eradication of the most resistant types of mites. The most effective was Allergoff 175CS, composed of nanocapsules containing a suspension of permethrin, pyriproxiphen and benzyl benzolate [17, 18].

Experts in the problem of controlling of food warehouse mites know both success and failure [1], but there are no doubts regarding mite control [3]. Thus, where does the contradiction concerning asthma result from?

A precise analysis of the previously mentioned meta-analyses reveals that for years they have been using the established, classic technique of spirometry (FEV1 index) and grading of the treatment applied (the amount of drugs used, including those purely symptomatic). Thus, they treat asthma as a disease in which mainly the component of a bronchospasm is assessed, because it causes airflow limitation and coughing fits or dyspnoea. This index of forced expiratory volume in one second (FEV1) only seems to be an objective trait. Those who perform bronchial function tests are aware of their limited value. That is why other diagnostic methods are continuously searched for [19]. Current GINA 2008 guidelines suggest anti-inflammatory treatment inhalatory glycocorticosteroids, antileukotriene agents) which would prevent secondary bronchospasm, the narrowing of bronchial lumen, and thus the need for rescue administration of beta-2-mimetics. The same guidelines point to the significant role of environmental allergens in the development of an inflammatory condition in sensitive subjects, but they still suggest a reduction in the causes of asthma as an important element of the patient's health-promoting education as compared to dietary recommendations for diabetic patients [19].

In the latest publications, where drug efficacy is also discussed, quality of life scales, depending on the disease, were used (Health Related Quality of Life – HQOL) [15]. They also included details of measurements of expirated nitric acid, bronchial washing cytology and the estimation of markers of inflammation in induced sputum [19] etc. It seems that only consistent use of similar tools will allow to decide explicitly on the usefulness of mite control as it happens in cases of the elimination of other factors causing asthmatic inflammation – animal hair (fur), food or pollen.

Furthermore, it seems that the degree of allergy and effectiveness of mite control can be diametrically different. Such a possibility has been illustrated in the material studied. It will be of great satisfaction to the authors of this report if the promising results presented here inspire other researchers to persist in their efforts to aid technically, particularly chemically, at least a part of asthmatic patients in their long battle with pathogenic mites.

Conclusions

The test fabric did not produce allergic reactions in patients strongly allergic to house dust mites in neither the abrasion test nor the patch tests. This points to the possibility of allergic individuals safely using this product. The majority of patients judged the fabric to be warm and pleasant in use. 1/5 of patients had remarks concerning the technical side of product preparation, which were linked to the producers of bedding inserts.

During active fabric utilisation, a statistically significant decrease in mite guanine concentration was observed, which points to an actual decrease in allergen exposure.

In a single general assessment, according to the subjective feelings of the patients, no clear differences were detected during utilisation of the active fabric vs. placebo. In one patient (placebo group) exacerbation of symptoms was observed.

The application of the test fabric in patients with a mite allergy resulted in a significant improvement in their well-being, measured before and on completion of the testa using the visual analogue scale (the score being 2.7 before the test, 1.5 after the testing vs. 1.3 and 1.1 in the placebo group). Further clinical studies are planned for the future.

Improvement was observed in half of the patients who completed the tests with full documentation, using the visual scale of symptoms method vs. 1 subject showing improvement in the control group.

From the point of view of textile fabric manufacture, the bedding inserts were evaluated as satisfactory.

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