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Efficacy of an air-cleaning device equipped with a high efficiency particulate air filter in house dust mite respiratory allergy

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The efficacy of an air-cleaning device equipped with a high efficiency particulate air (HEPA) filter (without further avoidance measures) was studied in patients allergic to house dust mite. The effects of the air-cleaner on indoor *Dermatophagoides* sp. levels, symptom score and bronchial hyperresponsiveness in nine mite-allergic patients were assessed using a cross-over controlled study. No significant effect was demonstrated on indoor *Dermatophagoides* sp. levels when comparing the period of air-cleaner activity (2 months) with the control period (2 months). The *Dermatophagoides* sp. levels in the houses studied were lower than the risk level for asthmatic attacks, making it difficult to assess any effect on asthma; however, neither bronchial hyperresponsiveness nor rhinitis symptom score were changed by air-cleaner activity. During the trial period, however the mean level of *Dermatophagoides* sp. allergen in the houses changed spontaneously from 4.4 μg/g (mean level in the first 2 trial months) to 1. 75 μg/g of dust (second 2 months) ($P < 0.05$). Owing to this change, the mean rhinitis symptom score also decreased ($P < 0.05$), even if no significant correlation was demonstrated ($r = 0.4$ $P = 0.089$). HEPA filter air-cleaners appear insufficient as substitutes for standard avoidance measures in mite allergic patients.

Key words: air cleaning device, avoidance measures, bronchial hyperresponsiveness, HEPA filters, mite allergy,

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Since 1924, the influence of environmental factors on asthma has been noted and the "treatment" of the air breathed by these patients was proposed (24). The development of such observations has resulted in well-defined preventive measures, particularly for mite-allergic subjects (14, 16, 17).

Although some studies reported only minimal or no improvement in asthmatics following environmental prophylaxis (5, 8), the clinical efficacy of vigorous allergen avoidance measures appears to have been confirmed (3, 6, 7, 18). Efficacy is well-correlated to the aggressiv of the avoidance measures employed, for example, change of residence (3, 7, 18) or use of liquid nitrogen (6); however, serious problems are involved when adopting effective mite environmental prophylaxis in normal living and working conditions.

In an effort to increase the efficacy of avoidance measures, and to alleviate the hardships caused by their rigorous application, the use of acaricides (2, 12, 23) and air-cleaning devices (4, 21, 25) has been proposed. The clinical efficacy of the latter has not been properly defined. Studies done of air-cleaning devices have analysed changes in clinical symptoms without assessing the allergen environment (13).

In a randomized controlled study we have examined the effect on clinical symptoms and

Table 1

Characteristics of patients in the pretrial period

Age	
mean	16 years
range	10–28
Male/Female ratio	7/3
Prick test	
mean (SD) area of wheal	104 + 36 mm^2
skin positivity for other allergens absent from the environment in the study period	3/10
Mean FEV_1 (% pred)	
mean	93
range	70–110
Metacholine PD_{20} FEV_1	
geometric mean	115 µg
range	32–291 µg

indoor allergens of a commercial air-cleaning device equipped with a HEPA filter (Enviracaire), as well as normal house cleaning.

MATERIAL AND METHODS

Patients

Nine young subjects (non-smokers) affected by rhinitis and mild asthma (baseline FEV_1 > 70% of predicted values CECA) were studied between October 1988 and February 1989.

The patients were skin positive to *D. pteronyssinus* and *D. farinae* (Table 1). A positive skin prick test (Phazet Pharmacia) was defined as a weal 4 mm greater in diameter than the control. No subjects were undergoing long-term therapy with corticosteroids, theophylline, DSCG, specific immunotherapy, nor had a positive case history of viral infections in the month preceding the start of the study. The mean duration of the disorder was 7 years.

Study design

The study was designed as a cross-over trial. Patients were randomly divided into two groups of five and four subjects in each. There were no significant differences between the groups concerning the mean baseline FEV_1, area of cutaneous wheal, and PD_{20} FEV_1 metacholine. One group used Enviracaire (in the bedroom) 24 h/day for at least 8 weeks, as well as the routine house cleaning. The other group in the same test period, carried out only routine house cleaning. After the first period the placing of Enviracaire was reversed, the second group used the air-cleaning device, while the first only did routine house cleaning.

A bronchial metacholine test was performed before the beginning of the trial, and after 8 and 16 weeks. The second and third challenge was carried out by a person who was unaware of the previous baseline values or to which group the patient had been allocated. Before the beginning of the trial, and after each month, house dust samples were collected from the bedroom. Allergen quantitation was also performed by persons unaware of the placement of Enviracaire during sample collection.

During the trial period,the patients were given a diary card and asked to record the best of three peak expiratory flow (PEF) recordings, morning and evening, using an Assess peak flow meter. In addition, they made daily recordings of their symptom score, and of the number of terfenadine tablets and of salbutamol inhalations used for symptomatic relief (the only permitted medications). Subjective severity of their symptoms was scored on an analogue scale from 0 (asymptomatic) to 3 (maximum symptoms). These symptoms included rhinitis, cough, dyspnoea. The mean severity of each symptom was calculated according to the following formula:

Total of symptomatic days/number of trial days × total of symptom score /number of symptomatic days.

With this formula each mean symptom score ranged from 0 to 3. The days on which drugs were used were totalled and divided by the number of trial days to obtain each medication score.

Metacholine bronchial provocation test

The metacholine PD_{20} FEV_1 was evaluated according to the method (20) summarized below.

A jet nebulizer connected to a dosimeter driven by compressed air (Mefar MB3, Italy) generated aerosols. With 1.5 kg/cm^2 inlet pressure and 1.5 s duration of nebulization an ampule output of 10 mg of solution was obtained. A pneumotachograph (Altair 1000 COSMED, Italy) was used to measure ventilatory function.

Wearing a noseclip, each patient inhaled via a mouthpiece from a dosimeter, using tidal breathing, first phosphate buffered saline, followed by, at 5-min intervals, increasing doses of metacholine aerosol (20, 40, 80, 120, 200, 400, 800, 1600, 3200 µg). The response measurement was performed 3 min after the onset of each inhalation. Baseline FEV_1 was taken as the best of three measurements after five phosphate buffered saline inhalations. Metacholine inhalations were continued until the decrease in FEV_1 was $> 20\%$ below the post-diluent value; the log-cumulative dose of metacholine producing this change, was considered a measure of bronchial responsiveness.

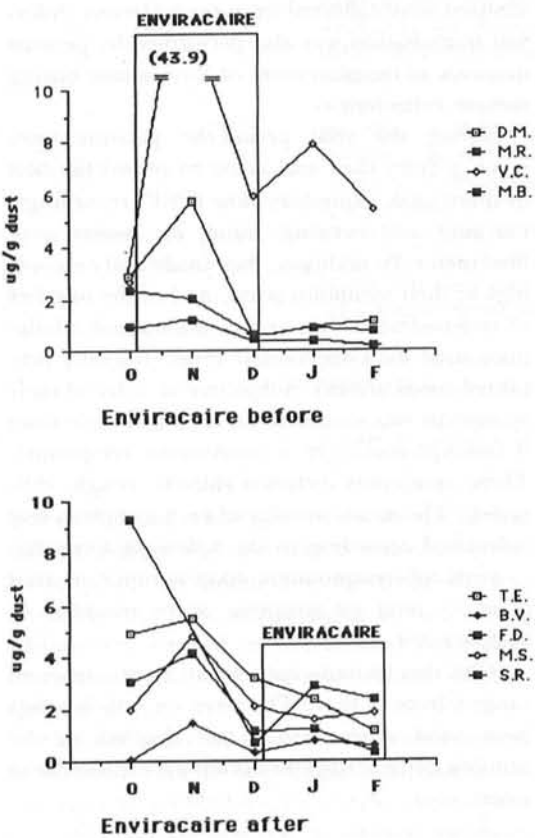


Fig. 1. Changes in the Der p I + Der f I + Der m I content (µg/g) of serial dust samples obtained from each house, related to the month and the presence of Enviracaire.

Collection of samples and allergen quantitation

Monthly dust samples were collected from the bedroom floor the day after usual room cleaning. Collection time was 30 min, always using the same vacuum-cleaner with a fresh disposable bag each time.

The dust was emptied into a sealable plastic bag and stored at -20°. When all the samples were collected they were sent (refrigerated by dry ice) by air to the laboratory in Copenaghen (ALK Laboratories).

Quantitation of the major fecal allergen of *D. pteronyssinus* (Der p I), *D. farinae* (Der f I) and *D. microceras* (Der m I) was performed by ELISA. Monoclonal antibodies were used as capture layer for Der p I and Der f I; rabbit antibody was used for Der m I. The assay was performed essentially as described in (9, 10, 11). The results are stated as µg allergen/g dust.

Statistical analysis

The Student t test for paired observations was used. The correlation coefficent was obtained by use of linear regression analysis. All probabilities < 0.05 were considered significant.

RESULTS

All patients completed the study; the only complaint (by one patient) concerned excessive nighttime noise produced by the Enviracaire in the bedroom.

Presence of allergens in the bedroom

A dose of major allergen of *Dermatophagoides* sp > 10 µg/g floor dust was found in only one of the 49 samples examined; 39 samples had an

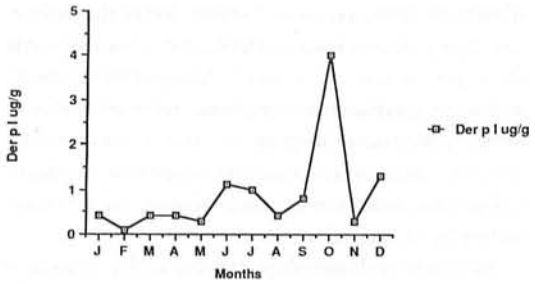


Fig. 2. Variation of the mean mite contamination level in 12 houses in the city of Ancona during 1986. The monthly mean was based on 60 dust samples (1).

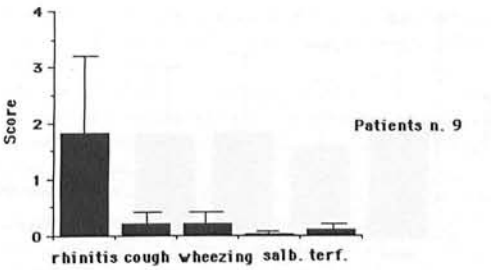


Fig. 3. Symptom and medication scores recorded during the study (mean ± SD).

allergen level between 0.5 and 10 μg and the remaining nine had values between 0 and 0.5 μg. Referring to the dose/effect relationship described by other authors (17), the degree of contamination in the houses studied appeared low.

A comparison of the floor allergen levels with and without Enviracaire showed no significant differences. Instead, a spontaneous decrease in allergen levels was observed between the first and the second study period (Fig. 1). This finding was in agreement with the seasonal variations of house dust mite contamination observed by other authors (17) and also confirmed in our geographic area (1) (Fig. 2). A significant difference ($P < 0.05$) in mean allergen quantity between October-December (4.4 μg/g of dust)and January-February) (1.75 μg/g of dust) was documented.

Symptom analysis

The symptom mainly observed was rhinitis (Fig. 3). Because of the large spontaneous variations in house dust mite contamination, the symptom score analysis not only evaluated the effects of Enviracaire but also the role of the higher (first 2 months) and lower (subsequent 2 months) allergen levels, independent of its presence in the house. There was a significant decrease ($P < 0.05$) in the mean of rhinitic symptoms linked to the spontaneous reduction of mite contamination, while the presence of Enviracaire had no significant influence (Fig. 4).

We observed evident rhinitic symptoms with mild involvement of the lower airways at a mean environmental dose of *Dermatophagoides* sp. major allergen of 4.4 μg/g of dust (October-December). During January-February, the lowering of the mean contamination to 1.75 μg/g of dust with a significant decrease in the rhinitis symptom score ($P < 0.05$) was documented; however, no significant correlation was demonstrated ($r = 0.4$ $P = 0.089$). The scores obtained for the other symptoms were too small to allow a statistical evaluation. No significant change was found in mean baseline FEV_1, PEF analysis and PD_{20} FEV_1, either in relation to the presence of Enviracaire or to spontaneous mite contamination levels (Table 2).

DISCUSSION

The study indicates that Enviracaire, without other avoidance measures, did not significantly change the degree of mite allergen contamination nor influence allergic symptoms caused by mite allergens. The levels of allergen contamination in the houses studied were almost always lower than the risk level for asthmatic attacks, making it difficult to assess any effect on asthma: however, neither bronchial hyperresponsiveness nor the rhinitis symptom score were changed by air-cleaner activity.

Another study found no clinical benefit following the combined use, for 2 weeks, of air cleaning devices (electronic and HEPA filter equipped) and avoidance measures in house dust mite allergic patients (4). Fifteen days was

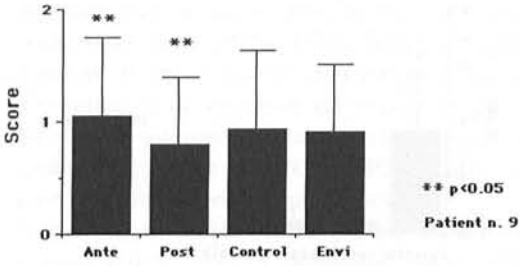


Fig. 4. Analysis of the rhinitis symptom score (mean±SD) in relation to the spontaneous evolution of the degree of mite contamination (ante/post) and to the presence of Enviracaire (control/Envi).

probably too short a test period to evaluate any possible positive effect on symptoms (16).

The suggestion of "some benefit" from the use of HEPA filters was reported in one double-blind study which was designed to compare 4 weeks of Enviracaire with active filter and 4 weeks of Enviracaire with blank filter in alleviating respiratory symptoms and reducing particulate matter in the bedroom (21). An average 70% reduction in the particulate matter with active HEPA filters was demonstrated, but there was no difference in total symptom/medication scores or individual symptom scores during the placebo and the active filter periods. To eliminate any carry-over effect from the previous time, an analysis of the last 2 weeks of each filter period was evaluated. Active filter benefit was suggested by the significant improvement of some symptoms (nighttime nasal congestion, eye, ear, nose and throat irritation) but asthma symptoms and medication scores were unaffected by active filter use.

No clear relationship between the absolute particle count and clinical response could be documented.

In accordance with other authors (13, 21) we believe that some general factors influence the effectiveness of air-cleaning devices, putting into question the real value of such units. In addition to the clinical effects of exposure to mites, other than in the room where air cleaning was in use, the rapid settling out of airborne fecal mite pellets carrying class I allergen (30–45 min) induces us to believe that very little airborne allergen exists apart from domestic activities (13, 15, 19). However, it has recently been indicated (22) that class II allergen (primarily associated with body fragments) has longer airborne permanence. Thus, for mite-allergic patients to remove allergen from the air without attending to the most important phase of exposure (e.g., contact with the mattress during sleep) appears to be insufficient. The best clini-

Table 2

Changes in respiratory functional parameters studied (mean ± SD) over a period of 2 months in nine mite allergen patients.

PD_{20} FEV_1 (μg)*		
ante - post	117.2±2.2	97.2±3.1
control - Enviracaire	123.8±1.9	108.6±3
FEV_1 (l)		
ante - post	3.21±84	3.29±87
control - Enviracaire	3.13±82	3.27±73
PEF (l/min)		
	Control	Enviracaire
morning	445±117	443±106
evening	444±116	442±105
	Ante	Post
morning	445±107	442±116
evening	445±109	441±113

P = NS

The Ante/Post analysis is related to the spontaneous change of the mite contamination level.
Control/Enviracaire is related to the phases of Enviracaire use. *Geometric mean.

cal improvements have been demonstrated by a laminar flow of HEPA-filtered air over the sleeper's head (13, 25).

While we were unable to demonstrate the effectiveness of Enviracaire on symptoms, the spontaneous decrease of *Dermatophagoides* sp. allergen from 4.4 µg to 1.75 µg/g dust, during the study period, did elicit a positive effect on rhinitic symptoms. This observation confirms the role of a larger allergen dose ($\geq$ 10 µg Der p I/g of dust) as a threshold dose for asthmatic attacks in mite-allergic patients (14, 17, 19) but also emphasizes the role of small allergen doses in eliciting nasal symptoms and the clinical efficacy resulting from the reduction of mite allergen levels. On the contrary, this change in allergen dose was insufficient to modify the level of bronchial hyperresponsiveness. This is consistent with the level of indoor mite allergen ($\geq$ 2 µg Der p I/g of dust) which has been suggested to be the provisional standard level of risk to increase bronchial reactivity (17, 19).

The most convincing studies on changed bronchial hyperresponsiveness following avoidance measures were carried out in environments in which the absence ($\leq$ 0.4 µg Der p I/g of dust), more than the reduction of house dust contamination was assumed (3, 6, 7, 18).

In conclusion, the authors believe that in normal living and working conditions the decrease in the indoor mite allergen level improves nasal and/or bronchial symptoms but, rarely affects bronchial hyperresponsiveness. The authors consider that the use of Enviracaire as an alternative to standard mite avoidance measures is not advisable. However, further studies are needed in order to evaluate the effect of an air-cleaning device in relation to dose and type of allergens so as to better define its clinical role.

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REFERENCES

1. Antonicelli L, Pucci S, Bilò MB, Boner AL, Bonifazi F. Dosi di allergene ed efficacia clinica dell'immunoterapia (IT) con D. pteronyssinus: studio in doppio cieco randomizzato. 18° Congresso della Società Italiana di Allergologia ed Immunologia Clinica Firenze 8-12/12/1987, Riassunti p. 119.
2. Bischoff E, Fischer A. Control of house dust: a new method of counting mites to establish the efficacy of water-based acaricides and their application. J Allergy Clin Immunol *79*, 194 (abstract), 1987.
3. Boner AL, Niero E, Antolini I, Valletta EA, Gaburro D. Pulmonary function and bronchial hyperreactivity in asthmatic children with house dust mite allergy during prolonged stay in the Italian Alps. (Misurina 1756 m) Ann Allergy *54*, 42-45, 1985.
4. Bowler SD, Mitchell CA, Miles J. House dust control and asthma: a placebo-control trial of cleaning air filtration. Ann Allergy *55*, 498-500, 1985.
5. Burr ML, St Leger AS, Neale E. Anti-mite measures in mite-sensitive adult asthma. A controlled trial. Lancet *1*, 333-335, 1976.
6. Dorward AJ, Colloff MJ, MacKay NS, McSharry C, Thomson NC. Effect of house dust mite avoidance measures on adult atopic asthma. Thorax *43*, 98-102, 1988.
7. Kerrebijn KF. Endogenous factors in childhood CNSLD: methodological aspects in population studies. In: Orie NMG, Van der Lende R. (eds.): Bronchitis III. pp. 38-48. Royal Vangorcum Assen, The Netherlands, 1970.
8. Korsgaard J. Preventive measures in mite asthma. A controlled trial. Allergy *38*, 93-102, 1983.
9. Lind P. Enzyme-linked immunosorbent assay for determination of major excrement allergens of house dust mite species *D. pteronyssinus D. farinae* and *D. microceras*. Allergy *41*, 442-451, 1986.
10. Lind P. Demonstration of close physicochemical similarity and partial immunochemical identity between the major allergen, Dp42, of the house dust mite, *D. pteronyssinus* and corresponding antigens of *D. farinae* (Df 6) and *D. microceras* (Dm 6). Int Arch Allergy Appl Immunol *79*, 60-65, 1986.
11. Lind P, Norman PS, Newton M, Löwenstein H, Schwartz B. The prevalence of indoor allergens in the Baltimore area: house dust-mite and animal-dander antigens measured by immunochemical techniques. J Allergy Clin Immunol *80*, 541-547, 1987.
12. Mitchell EB, Wilckens S, Deighton JM, Platts-Mills TEA. Reduction of the house dust mite allergen levels in the home; use of acaricide pirimophos methyl. Clin Allergy *15*, 235-240, 1985.
13. Nelson HS, Hirsch SR, Ohman JL, Platts-Mills TEA, Reed CE, Solomon WR. Recommendations for the use of residential air-cleaning devices in the treatment of allergic respiratory diseases. J Allergy Clin Immunol *82*, 661-669, 1988.
14. Platts-Mills TEA, De Weck AL. Dust mite allergens and asthma - A worldwide problem. J Allergy Clin Immunol *83*, 416-427, 1989.
15. Platts-Mills TEA, Heymann PW, Longbottom JL, Wilkins SR. Airborne allergens associated with asthma:particle size carryng dust mite and rat allergens measured with a cascade impactor. J Allergy Clin Immunol *77*, 850-857, 1986.

16. Platts-Mills TEA. Dust mite avoidance in the treatment of asthma. Ann Allergy *55*, 419–420, 1985.
17. Platts-Mills TEA, Chapman MD. Dust mites:Immunology, allergic disease, and environmental control. J Allergy Clin Immunol *80*, 755–775, 1987.
18. Platts-Mills TEA, Tovei ER, Mitchell EB, Moszoro H, Nock P, Reduction of bronchial hyperreactivity during prolonged allergen avoidance. Lancet *2*, 675-678, 1982.
19. Platts-Mills TEA, Pollart SM, Luczynska CM, Chapman MD, Heymann PW. Indoor-allergens, quantification and characterization in relation to asthma. Allergologie- Proceedings XIV Congress EAACI 63–67, 1989.
20. Protocollo per l'esecuzione del test di provocazione bronchiale aspecifico del Gruppo di Lavoro per la normalizzazione dei tests di provocazione bronchiali aspecifici. Fisiopat Resp *3*, 3–15, 1982.
21. Reisman RE, Mauriello PM, Davis GB, Georgitis JW, DeMasi JM. A double-blind study of the effectiveness of a high efficiency particulate air filter (HEPA) in the treatment of patients with perennial allergic rhinitis and asthma. J Allergy Clin Immunol *85*, 1050–1057, 1990.
22. Swanson MC, Campbell AR, Klauck MJ, Reed CE. Correlation between levels of mite and cat allergens in settled and airborne dust. J Allergy Clin Immunol *83*, 776–783, 1989.
23. Van de Maele B. A new strategy in the control of house dust mite allergy. Pharmatherapeutica *3*, 441–449, 1983.
24. Van Leeuwen WS. Bronchial asthma in relation to climate. Proc R Soc Med *19*, 19, 1924.
25. Villaveces JW, Rosengren H, Evan J. Use of laminar flow portable filter in asthmatic children. Ann Allergy *38*, 400–404, 1977.

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