

Do environmental measures improve quality of life in mite-induced allergic rhinitis?

Gli interventi ambientali migliorano la qualità della vita nei pazienti con rinite allergica da acari?

C. INCORVAIA, M.R. YACOB^{*}, A. RAPETTI^{**}, I. ZAPPELLI^{***}, R. QUALIZZA, B. BRAMÈ, G.G. RIARIO-SFORZA
Allergy/Pulmonary Rehabilitation Unit, Istituti Clinici di Perfezionamento, Milan; ^{*} Allergy and Rheumatology Unit, IRCCS "San Raffaele" Hospital, Milan; ^{**} Blood Center, Tradate Hospital, Tradate; ^{***} Department of Biology, University of Milan, Italy

Key words

House dust mite • Rhinitis • Bedding covers • Acaricide • Quality of life

Parole chiave

Acari della polvere • Rinite • Coprimaterassi • Acaricidi • Qualità della vita

Summary

Background

The effectiveness on mite allergy of environmental measures is still discussed. We evaluated the effects of such measures on quality of life in patients with mite-induced allergic rhinitis.

Methods

Subjects with mite-induced allergic rhinitis were randomized to use for six months: 1) a polypropylen bed cover and a benzyl-benzoate acaricide aerosol, or 2) a cotton bed cover and a placebo aerosol. At baseline, the concentration of mites allergens was measured in dust to evaluate possible differences between the two groups. Quality of life was assessed at baseline and at the end of the study by the specific Juniper's RQLQ questionnaire.

Results

25/29 (86.2%) of the participants completed the study, 13 in the placebo arm, and 12 in the actively treated one. There was no difference in mite allergens exposure and quality of life between the two groups at baseline. After six months, a significant difference in quality of life score improvement occurred (0.63 ± 0.23 in actively treated versus 0.36 ± 0.39 in placebo treated, $p = 0.006$), but compared to baseline, it did not achieve the significance neither in placebo nor in actively treated patients.

Conclusion

The evaluation of quality of life does not allow to assess the effectiveness of environmental measures in patients with mite-induced allergic rhinitis.

Riassunto

Introduzione

L'efficacia degli interventi ambientali nell'allergia agli acari della polvere è tuttora oggetto di discussione. Noi abbiamo valutato gli effetti di tali interventi sulla qualità della vita in pazienti con rinite allergica da acari.

Metodi

Soggetti con rinite allergica da acari sono stati randomizzati a ricevere un intervento della durata di sei mesi con: 1) coprimaterasso in polipropilene e spray acaricida a base di benzil-benzoato, oppure 2) coprimaterasso in cotone e spray placebo. All'inizio dello studio è stata misurata la concentrazione allergenica degli acari per valutare possibili differenze tra i due gruppi. La qualità della vita è stata valutata all'inizio e al termine dello studio mediante il questionario specifico RQLQ di Juniper.

Risultati

25/29 (86,2%) dei partecipanti hanno completato lo studio, 13 nel braccio placebo e 12 nel braccio attivo. Non si sono osservate differenze tra i due gruppi nell'esposizione allergenica e nella qualità della vita all'inizio dello studio. Dopo sei mesi è stata riscontrata una differenza significativa nel punteggio di qualità della vita tra i due gruppi ($0,63 \pm 0,23$ nei trattati attivamente, $0,36 \pm 0,39$ nei trattati con placebo, $p = 0,006$), ma rispetto alle condizioni basali non c'erano differenze significative in nessun gruppo.

Conclusione

La valutazione della qualità della vita non consente di stabilire l'efficacia degli interventi ambientali in pazienti con rinite allergica da acari.

Introduction

The importance of allergen avoidance in house dust mite allergy is well established when measures such

as staying at high altitude^{1,2} or in a mite-free environment³ are taken. Internationally accepted clinical guidelines now recommend that house dust mite avoidance measures to apply at home (such as vacuum

cleaning, using acaricides, bedding covers, and high-efficiency particulate air filters) must be considered in people with house dust mite-provoked rhinitis^{4,5}. However, the real effectiveness on mite-allergy obtained by these simple measures is very controversial. Recent Cochrane reviews on such issue concerning patients with asthma⁶ and rhinitis⁷ are available. In particular, the review on rhinitis included the results of seven randomized controlled trials involving subjects with clinician diagnosed allergic rhinitis and demonstrated sensitization to house dust mite. Among the three main interventions (bedding covers, acaricides, filters), acaricides use seems to be the most effective to reduce house dust mite load, but the important methodological limitations of the few selected studies make uncertain the results interpretations⁷.

We sought to evaluate the effects of bed covering and acaricidal treatment on rhinitic symptoms by a different approach, represented by quality of life (QoL), which was previously studied in patients with asthma but not in those with rhinitis.

To this aim a group of patients with rhinitis due to hypersensitivity to dust mites was investigated in a double-blind placebo-controlled fashion.

Methods

PATIENTS

Patients were enrolled from those referring for respiratory symptoms to the Allergy/Pulmonary rehabilitation Unit of the ICP Hospital in Milan. To be included in the study they had to present persistent rhinitis from at least two years, and a positive skin prick test (SPT) with *Dermatophagoides pteronyssinus* and/or *Dermatophagoides farinae* allergen extracts. Patients with other sensitizations, namely to animal hair and dander, moulds, and pollens, were excluded to avoid interference with QoL during the study.

All patients gave their written consent to participate to the study, which was approved by the ethical committee of the ICP Hospital in Milan.

METHODS

SPT were done with extracts by Stallerg enes (Antony, France), and were considered positive when a weal with a diameter equal or greater than that elicited by histamine hydrochloride was observed.

The subjects were randomized to receive active materials, represented by a polypropylen bed cover (Aclobed[®], Lofarma, Milan, Italy) and by an acaricide consisting of a spray foam aerosol having 2.5% benzyl-benzoate as active principle (Aclocid[®], Lofarma, Milan, Italy), or placebo, represented by a cotton bed cover and by an aerosol similar to the active one but with only the eccipients.

Immediately before the beginning of the study dust samples were obtained by vacuuming the surfaces of

the mattress covers in the bedroom and of the sofas in the living room. This was made to assess possible differences in allergen exposure between placebo and actively treated patients able to bias the results.

Each patient had two samplings, one in the mattress and one in the sofa. Such samples were examined for the presence and identification of dust mites by microscopy and analysed for their content in major allergen Der f 1 (this was chosen because of the prevalence of *Dermatophagoides farinae* in the samples) by an ELISA method as previously described⁸; the results were expressed in µg/g of dust.

QoL was assessed by the RQLQ questionnaire on rhinitis introduced by E.F. Juniper, with higher scores indicating worse QoL⁹. The questionnaire was submitted immediately before the randomisation and after six months, i.e. at the end of the study.

STATISTICAL ANALYSIS

The difference in quality of life scores was analyzed by non-parametric tests, namely the Wilcoxon test for intra-group comparison and Mann-Whitney U test for inter-group comparison. The level of statistical significance was set at $p < 0.05$.

Results

A group of 29 subjects with mite-induced rhinitis and asthma were enrolled. They were divided in four groups: 1) both active mattress encasement and acaricide, 2) active encasement and placebo acaricide, 3) placebo encasement and active acaricide, and 4) both placebo treatments. Four patients did not complete the study: two because moved to another house, one for unspecified reasons and one who refused to continue, thus 25 patients were evaluated for changes in quality of life, 12 allocated in active treatment and 13 in placebo treatment.

Table I reports the number of mites identified in dust samples, with *Dermatophagoides farinae* as the mite most frequently found, and Table II shows the level of Der f 1 measurement in dust samples before the beginning of the study.

The QoL scores obtained by RQLQ at baseline and at the end of the study are showed in Table III. There were no differences by the Mann-Whitney U test in baseline score between the actively and placebo treated subjects. In both groups there was an improvement in QoL score at the end of the study, but with no statistical significance with the Wilcoxon test. Eight of the 12 actively treated subjects (67%) compared to three of the 13 placebo treated subjects (23%) had a score reduction of at least 0.50, which is considered the minimal significant change with the RQLQ¹⁵.

The difference in QoL score reduction at the end of the study -0.63 ± 0.23 in actively treated versus 0.36 ± 0.39 in placebo treated – was significant, with a $p = 0.006$.

Tab. I. Identification of house dust mites in dust samples at baseline.

House dust mite	Number of mites identified	Rate of identification in samples
Dermatophagoides farinae	423	77.8%
Dermatophagoides pteronyssinus	240	52.3%
Euroglyphus maynei	32	8.9%
Acarus siro	70	14.4%
Tyrophagus putrescentiae	39	14.4%
Glycyphagus domesticus	41	8.8%

Tab. II. Levels of Der f 1 at baseline.

Sample source	Mean Der f 1 level (µg/gm of dust)
Mattresses	
Active bed cover	2.62
Placebo bed cover	1.82
Sofas	
Active acaricide	1.18
Placebo acaricide	1.20

Discussion

The clinical effectiveness of house dust mite avoidance measures is still a matter of discussion. Though a number of studies have stressed the role of dust mite avoidance measures and specifically the use of mattress impermeable covers in reducing the levels of house dust mite allergens^{6 7 10-16}, evidences of clinical effectiveness of these measures are very poor when considering meta-analysis results⁶⁷. Recent studies on patients with mite-induced asthma undergoing active or placebo mattress covers introduced the approach of measuring quality of life, an issue of increasing importance in medicine. Woodcock et al. used the St. George's Respiratory Questionnaire¹⁰ and Rijssenbeeck et al. used the QoL-RIQ questionnaire¹¹: both studies failed to detect significant differences in QoL scores between actively and placebo treated groups. We evaluated the effects of mattress encasement in the bedroom and acaricidal treatment in the living room in patients with mite-induced rhinitis in a double-blind, placebo-controlled fashion by analysing the

changes in QoL measured by the specific questionnaire RQLQ by Juniper⁹. At baseline there was no difference in QoL scores between actively and placebo treated patients, neither was in the level of mite-allergen exposure, measured to assess possible different allergen loads able to bias the results. The levels of mite allergen in mattresses and sofas we found were in a range from 1.82 to 2.62 µg/gm of dust, generally considered as associated to allergic sensitisation, but not to asthma¹⁷, as actually observed in our patients who had only rhinitis, however there are no clear-cut rules defining the relationship between the allergen concentrations and the clinical expression of allergy. For example in the Melbourne House Dust Mite Study also levels of Der p 1 lower than 1 µg/gm of dust were found in dwellings, including mattresses, of children with mite-induced asthma¹⁸. We chose not to repeat measurement of mite-allergen levels at patient's homes to minimize the interference with patient's life with its possible bias on QoL. In addition, it has been reported that home visits may be a potent stimulus for a change in behaviour, with a resulting increase in cleaning and a reduction in allergen levels also in control groups¹⁹. On the other hand, in both studies which evaluated QoL in mite-asthmatic subjects significant reductions in concentration of Der p 1 were found only in actively treated patients, but this was not associated to better results in QoL measurements^{10 12}.

In our study actively treated patients had after six months a significantly lower mean QoL score than placebo treated patients ($p = 0.006$), indicating a better QoL in relation to their mite-induced allergic rhinitis. However, this is counterbalanced by the observation that the mean QoL score decrease in actively treated subjects, and

Tab. III. Difference in quality of life (QoL) scores before (T0) and at the end of the study (T1).

Device	QoL mean score		Mean difference	Significance (p)
	T0	T1		
Active bed cover and placebo acaricide	1.01 ± 0.29	0.50 ± 0.05	0.54 ± 0.27	n.s.
Placebo bed cover and active acaricide	1.08 ± 0.27	0.39 ± 0.15	0.69 ± 0.28	n.s.
Overall active treatment	1.18 ± 0.38	0.56 ± 0.28	0.63 ± 0.23	0.006
Placebo bed cover and placebo acaricide	1.51 ± 0.37	1.09 ± 0.39	0.36 ± 0.39	n.s.

in placebo treated as well, did not reach the statistical significance, though a decrease of the score of at least 0.50, which is considered indicative of an effective improvement in QoL, was found in two thirds of the actively compared to less than one fourth of the placebo treated, and this cannot be disregarded when transferred to routine clinical application of mite allergen control measures in patients with rhinitis.

In conclusion, we introduced the approach of measuring QoL, which explores the patient's feeling and thus the final effect of a medical treatment, to analyse the effectiveness of house dust mite control measures in mite-allergic rhinitic patients. Some beneficial effects on QoL, with a significant difference in QoL score in favour of the actively treated patients, were found, and

this suggests a more positive response in rhinitis than in asthma, where thus far no difference between active and placebo treatment was reported. However, studies on high number of patients, as available for mite-induced asthma, are needed to definitely state the role of home environmental control in mite-induced rhinitis.

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Correspondence: Cristoforo Incorvaia, ICP Hospital, via Bignami 1, 20126 Milano, Italy - Tel. +39 02 57993289 - Fax +39 02 57993315 - E-mail: cristoforo.incorvaia@fastwebnet.it