

DUST MITE CONTROLLER

Electronic Device against Mite Allergy

Scientific Documentation

CLINICAL TRIALS

The attached documentation is concerning the Clinical Trials, as follows:

A. Three studies conducted by the Allergy Centre of Mandic Merate Hospital, Italy.

B. Double blind placebo controlled trial performed by Pediatrician Dept. and Pediatric Allergy Centre of Macedonio Melloni Hospital in Milan, Italy.

(See separate document)

A

A. THREE WORKS ARE HERE REPORTED AS PERFORMED ON MITE'S ALLERGIC PATIENTS AT THE ALLERGY CENTRE OF MERATE HOSPITAL, ITALY.

These studies have been published at the European Congress of Allergology and Clinical Immunology.

Briefly the aim and the conclusions of the works:

Trial n° 1: "Ultrasonic waves as an environmental protection measure against house dust mites".

Aim: evaluation of electronic device's effectiveness in reducing both symptoms and drugs' use.

Patients: 20 patients using the electronic device for a 3 months period + 20 patients as control group.

Results: a 28% decrease in days with symptoms and a 22% decrease in drugs' intake, in the group of patients who used the electronic device.

Conclusions: the Authors explain the results, thanks to a possible action on mite's fecal pellet that is rich in allergens.

Trial n° 2: "A comparison between 2 means of environmental protection against mites: mattress cover vs. ultrasonic wave emitter".

Aim: comparison of electronic device's vs. cover mattress' effectiveness in reducing both symptoms and drugs' use.

Patients: 15 patients using the electronic device for a 6 months period + 15 patients using a cover mattress + 15 patients as control group.

Results: same decrease in days with symptoms (16%) in the group with the electronic device and in the group with the cover mattress, compared to the control group.

The decrease in drugs' consumption was also similar (about 10% compared to the control).

Conclusions: Both the cover mattress and the electronic device show their validity in reducing symptoms and drugs.

Trial n° 3: "A comparison between an ultrasonic wave emitter and a chemical acaricide in implementing environmental protection against mites".

Aim: comparison of electronic device's vs. acaricide's effectiveness in reducing both symptoms-drugs and mites' presence in houses.

Patients: 16 patients using the electronic device for a 5 months period + 16 patients using an acaricide + 16 patients as control group.

Results: similar decrease in days with symptoms (about 19%) in the group with the electronic device and in the group with the acaricide, compared to the control group.

The decrease in drugs' use was also similar (about 10% compared to the control).

About a 20% reduction in presence of mites inside patients' homes was observed, in the group using the electronic device or the acaricide, compared to the control group.

Conclusions: Both the acaricide and the electronic device show their validity in reducing symptoms and drugs. Both the methods are able to control mites' presence in houses.

ULTRASONIC WAVES AS AN ENVIRONMENTAL PROTECTION MEASURE AGAINST DUST MITES.

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Introduction

House dust mites are one of the major causes of allergy disorders. Numerous studies confirm that a reduction in the concentration of mites in the domestic environment produces an appreciable improvement in the symptoms of allergy sufferers. It follows that action, using the right methods, must be taken to secure such a reduction, especially in places where allergy sufferers spend prolonged periods of time.

Aim Of The Study

The aim of this study was to assess whether a device producing ultrasonic waves could bring about a reduction in the quantity of mites in the environment and, therefore, an abatement in the rhinitis and asthma symptoms suffered by patients allergic to dust mites.

Materials And Methods

The investigation concerned 40 patients who were allergic to Der.pter. and Der.far. and reacted with symptoms of rhinitis and/or asthma. No patient was currently undergoing SIT (Specific Immunotherapy) or had ever been so treated. Of the patients, 20 received a 40.000- Hz ultrasonic wave emitter. This device was sited in the patients bedrooms for a 3 month period (October – December) and during this period it emitted ultrasonic waves uninterruptedly.

No kind of environmental protection was prescribed for the other 20 patients (the control group).

All the patients made notes daily of any allergy symptoms they experienced (dyspnoea, coughing, rhinorrhoea) and their use of anti-allergy and/or anti-asthma medication.

Discussion

The effect of the ultrasonic waves on the dust mites is not entirely clear. It is scarcely plausible that the ultrasonic waves acted directly and immediately on the mites exerting, as it were, an action in the nature of a "disturbance".

It could be hypothesised that the waves acted on the dust mites reproductive cycle or, alternatively or concurrently, on their faecal matter, deactivating it and transforming it into allergenically inert matter.

| SYMPTOMATIC DAYS | | |
|-------------------------|--------------------------------------|-----------------------------|
| | ULTRASONIC WAVES Group (20 patients) | CONTROL Group (20 patients) |
| - Dyspnoea | 56 | 79 |
| -Rhinorrhoea | 63 | 91 |
| -Nasal Cong | 78 | 102 |

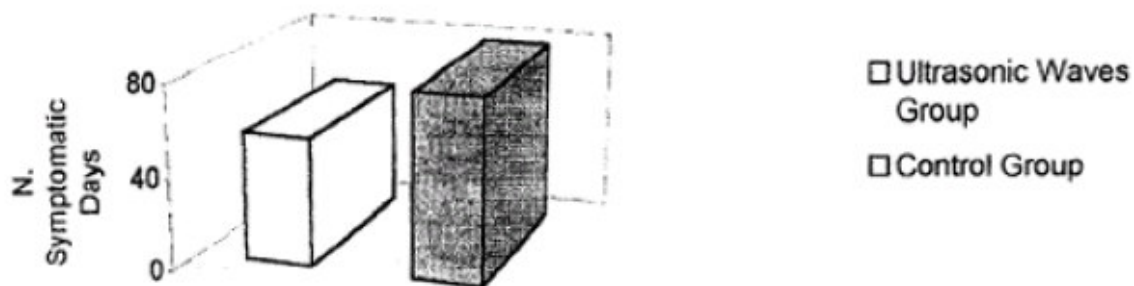
| DRUGS TAKEN DURING 3 MONTHS | | |
|------------------------------------|--------------------------------------|-----------------------------|
| | ULTRASONIC WAVES Group (20 patients) | CONTROL Group (20 patients) |
| | 108 | 139 |

Conclusions

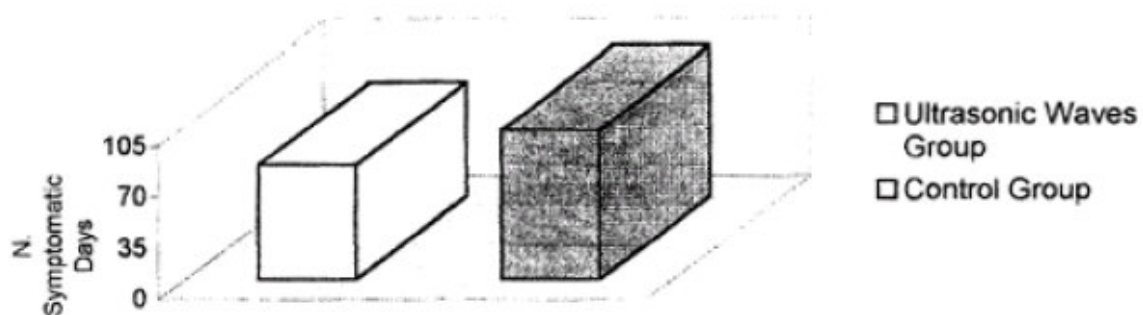
After 3 months the group of patients that had protected their environment with Ultrasonic Waves showed less allergy symptoms than the Control Group.

At the same time the group that had used the ultrasonic waves had had less recourse to medication.

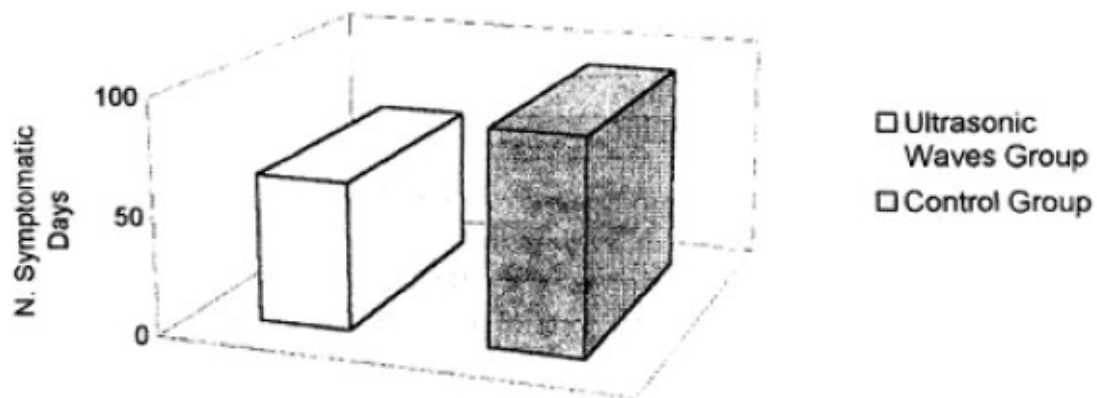
DYSPNOEA



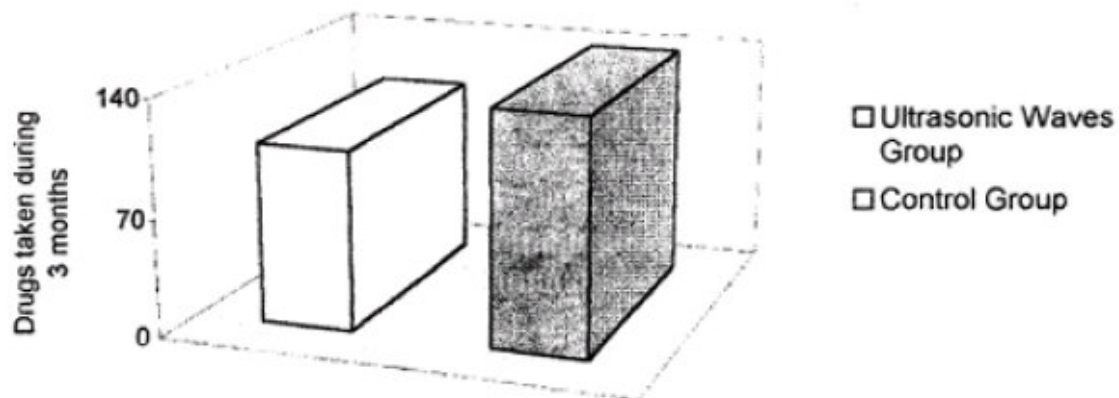
RHINORRHOEA



COUGHING



DRUGS



A COMPARISON BETWEEN 2 MEANS OF ENVIRONMENTAL PROTECTION AGAINST MITES: MATTRESS COVER VS ULTRASONIC WAVES EMITTER.

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Introduction:

The elimination of dust mites in the home (or at least a reduction in their concentration) is the method of choice for preventing symptoms in patients with al allergy to Dermatophagoides. (dust mites).

Over time numerous methods have been proposed as possible aids to extensively reducing mites and rendering the allergy-producing substances they release inactive.

Aim Of Trial:

The aim of the trial was to compare a method that has been in use for years, viz. cotton-made polyurethane-lined mattress covers, with ultrasonic wave emitters.

Clinical trials have demonstrated that ultrasonic wave at a frequency of 40,000 Hz disrupt the reproductive cycle and the development of mites.

Materials and Methods:

The trial was conducted on 45 patients allergic to mites and suffering from asthma and/or rhinitis. No patient had previously undergone Specific Immunotherapy, nor at the time was any patient undergoing it.

All patients were instructed in the rules for properly protecting the environment.

- 15 patients used mattress cover
- 15 patients used ultrasonic wave emitter
- 15 patients (the control group) relied exclusively on the general rules for protecting the quality of their environment.

All of the patients were subject to clinical observation over 6- month period (October-April).

During this period, using a diary on a daily basis, each patient recorded the presence of following symptoms: Dyspnoea, Rhinorrhoea and Nasal Congestion.

In addition, a record was kept by all patients of any anti-histamine and/or anti-allergy medication.

Results:

| SYMPTOMATIC DAYS | | | |
|------------------------------------|---------------|----------------------|------------------------|
| | CONTROL Group | COVER MATTRESS Group | ULTRASONIC WAVES Group |
| Dyspnoea | 384 | 282 | 294 |
| Rhinorrhoea | 1056 | 852 | 828 |
| Nasal Obstruction | 1116 | 1008 | 1032 |
| DRUGS TAKEN DURING 6 MONTHS | | | |
| | CONTROL Group | COVER MATTRESS Group | ULTRASONIC WAVES Group |
| | 1470 | 1305 | 1325 |

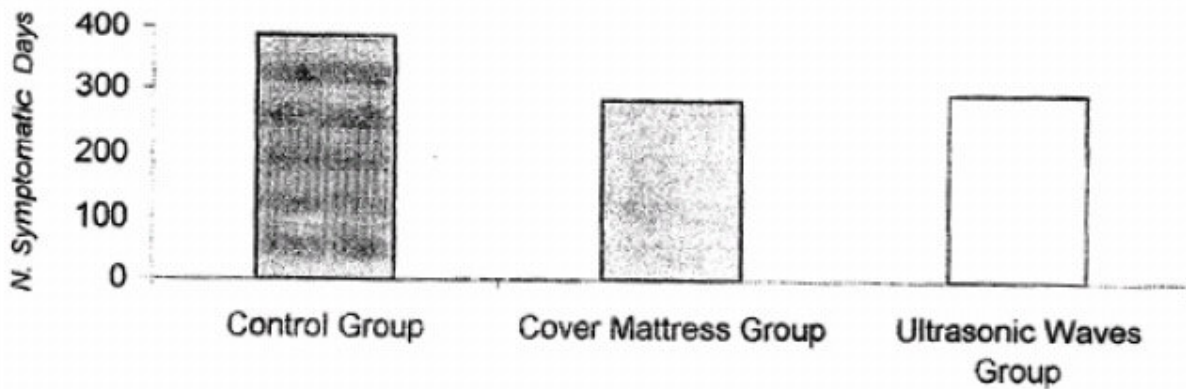
Conclusions:

The trial demonstrates that those patients who used either the mattress covers or the ultrasonic wave emitters displayed less symptoms and made less use of their medication than those in the control group.

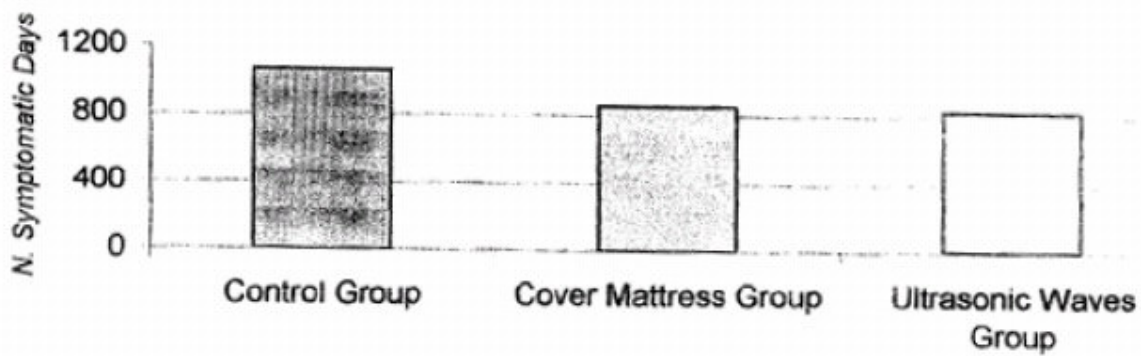
No significant differences (as to symptoms and/or use of medication) were noted between the patients using the mattress covers and those using the ultrasound wave emitters.

Accordingly, the trial demonstrates that both the mattress covers and the ultrasound wave emitter improve the quality of life for patients with an allergy to dust mites.

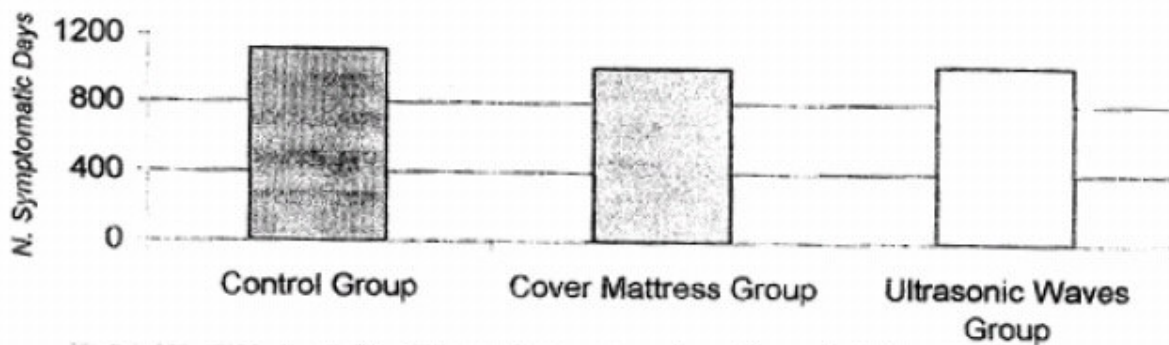
DYSPNOEA



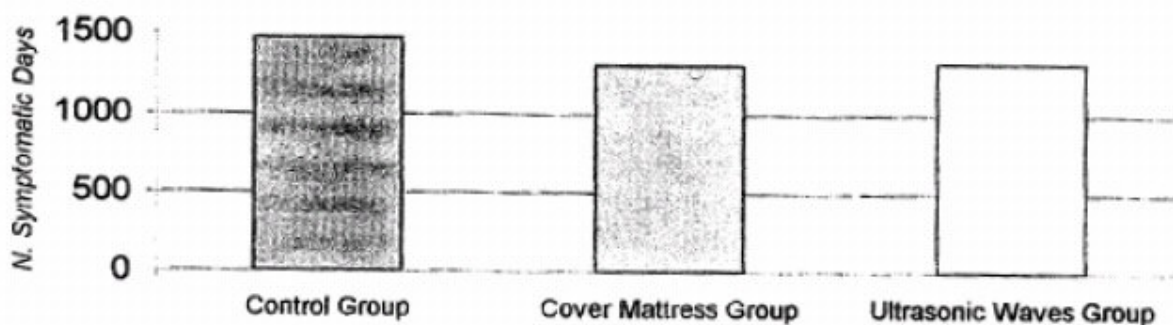
RHINORRHEA



NASAL OBSTRUCTION



DRUGS TAKEN DURING 6 MONTHS



A COMPARISON BETWEEN AN ULTRASONIC WAVE EMITTER AND A CHEMICAL ACARICIDE IN IMPLEMENTING ENVIRONMENTAL PROTECTION AGAINST DUST MITES.

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Introduction

In cases of respiratory allergy disorders caused by Dermatophagoides it is important to raise the level of hygiene in the home. The quantity of mites present may be reduced by adopting environmental control arrangements and employing aids to this end.

Of the latter the most commonly used to date are mattress covers and chemical acaricides.

Recently an ultrasonic wave emitter device was made available for sale. A number of trials have demonstrated that the continuous emission of ultrasonic waves can relieve the symptoms of patients who are suffering from mite-related allergy.

Aim of the Study

The aim of this study was to effect a comparison between a 40,000 Hz ultrasonic wave emitter and a traditional chemical mean of protection, such as benzyl benzoate in powder form in implementing environmental protection against mites.

Materials and methods

The patients in the study numbered 48, were suffering from allergy to mites, and had symptoms of rhinitis and/or asthma. None of the patients had previously undergone Specific Immunotherapy and nor was any undergoing such treatment at the time. All the patients in the study adopted general, non-specific, measures for environmental protection.

16 patients (control group) relied solely on the normal measures involved in environmental protection.

16 patients used the chemical Acaricide.

16 patients used the ultrasonic wave emitter.

The study lasted 5 months (October-February).

Throughout the entire period of observation the following symptoms were assessed for each patient by means of clinical diary that was written up daily: Dyspnoea, Rhinorrhoea, and Nasal Congestion.

In addition each patient made a daily note of any anti-allergy and/or ant-asthma medication that they used.

In addition, applying the "Acarex test" method, an assessment was made of the environmental concentration of mites at times T0 (October), T1 (December), T2 (February).

The "Acarex test" provides a semi-quantitative determination of guanine in the dust in a given environment. It works through comparison with a colour chart and records the quantity of nitrogenous products excreted by mites.

Results

| | Symptomatic Days (5 months) | | |
|-------------------|------------------------------|-----------|--------------|
| | Control group | Acaricide | Ultra. Waves |
| Dyspnoea | 370 | 281 | 308 |
| Rhinorrhoea | 631013 | 814 | 825 |
| Nasl Cong | 1044 | 879 | 904 |
| Drugs (5 months) | | | |
| | 1416 | 1278 | 1301 |

| | Environmental Concentration of Mites (Acarex Test – Reference colour chart. H:high; L: low) | | |
|-------|--|--------------|--------------|
| | Control group | Acaricide | Ultra. Waves |
| - T 0 | H:86%; L:14% | H:88%; L:12% | H:86%; L:14% |
| - T 1 | H:85%; L:15% | H:62%; L:38% | H:66%; L:34% |
| - T 2 | H:86%; L:14% | H:67%; L:33% | H:64%; L:36% |

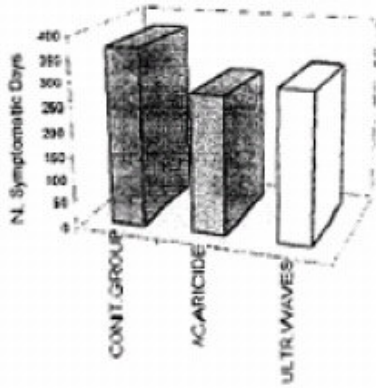
Conclusions

The patients who used either the ultrasonic wave emitter or the chemical acaricide displayed fewer symptoms and resorted less to medication as compared with the control group.

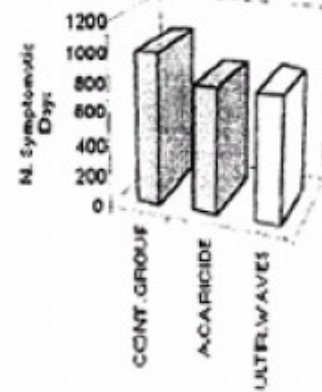
Moreover, the period T0-T2, the concentration of mites in the environment was significantly reduced.

As to comparatively evaluating the use of the ultrasonic wave device and that of the chemical acaricide, no significant differences were noted.

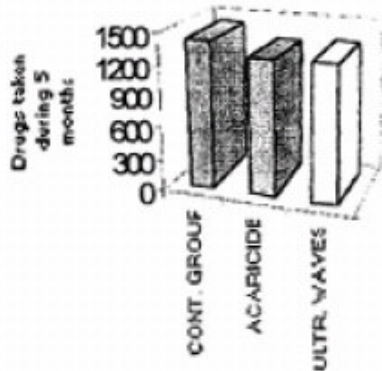
D Y S P N O E A



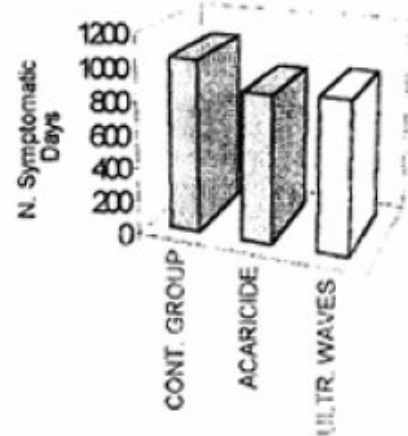
R H I N O R R H O E A



D R U G S T A K E N D U R I N G 5 M O N T H S



N A S A L C O N G E S T I O N



B. DOUBLE BLIND PLACEBO CONTROLLED TRIAL PERFORMED AT THE PEDIATRICIAN AND ALLERGY DEPARTMENT OF MACEDONIO MELLONI HOSPITAL IN MILAN - ITALY.

The study has been presented at the 5^o Congress of the Italian Society of Pediatric Allergology and Immunology at Riva del Garda – Italy. April 1 – 4 2003.

Briefly, 40 patients have been enrolled and later split into 2 groups.

40 devices have been distributed to the patients. 20 devices were properly working while the remaining 20, even if identical to the other ones, were not working.

The distribution of patients and devices into the two groups has occurred according to a random scheme, so to design and perform a double blind placebo controlled trial.

The patients (range: 4 to 15.5 years old) were allergic to mites and suffering from asthma. Each patient has received a diary for reporting symptoms and the related data have been analysed from a statistical point of view at the end of the study. The attached original paper lets to see the details concerning the inclusion criteria, the clinical monitoring, the therapies, the results of the study.

Regarding trial's results, it has been observed that at the end of the study (at 4th month) the difference in score symptoms between the two groups was in favour of the use of the electronic device. The difference was significant from a statistical point of view concerning rhinorrhea, nocturnal cough, nasal obstruction, sneezes.

Both Italian original paper and the translation into English are here attached.

5° CONGRESSO NAZIONALE SIAIP
Società Italiana di Allergologia
e Immunologia Pediatrica



RIVA DEL GARDA (TN)
1-4 APRILE 2003

Riassunti dei posters

PERCORSI INTERATTIVI



PER IL PEDIATRA



IN ALLERGOLOGIA

E IMMUNOLOGIA



CLINIC EFFICACY OF A DEVICE OF ULTRASONIC REVULSION IN THE THERAPY CONNECTED TO CHILDREN WITH PERSISTENT ASTHMA DUE TO ALLERGY TO ACARI

EFFICACIA CLINICA DI UN DISPOSITIVO DI REVULSIONE ULTRASONICO NELLA TERAPIA DI BAMBINI AFFETTI DA ASMA PERSISTENTE DA ALLERGIA AD ACARI

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ABSTRACT

INTRODUCTION. The house dust mite allergy represents the most frequent cause of first breathing sensitivity in children under 6 years and one of the main reasons till 18 years. In the field of the allergy to dust mites, after the specific immunotherapy (SIT), at the moment the most effective way to prevent and/or lessen the severity of this disease is reducing the house dust mite allergen levels by environmental reclamation. For this reason the application of devices of revulsion based on the use of ultrasounds has been recently proposed, but there are no scientific proves of its efficacy in paediatrics. We intend evaluate its efficacy, in terms of subjective symptomatology, in children with intermittent asthma or mild persistent, allergic to dust mites.

MATERIALS AND METHODS. Fourty children (27 M, 13 F, average age 6.5 years, range 4-15.5 years), of our allergologic surgery who corresponded to the criteria of inclusion/exclusion, have become part of a prospective, randomized, double blind study of an expected 6 months lenght, having received undistinguishable devices, working or disactivated. The devices have been supplied by: Kem-o-Tek Italia s.r.l., Caronno Pertusella (MI). Daily clinic diaries, returned at the monthly checks, revealed the number of episodes of dyspnoea, wheezing, nasal obstruction, itchiness, rhinorrea, sneezes, night and exercise-induced cough. Every check included also an examination of the clinical status, compliance to the protocol, the taken therapy, the right filling in of the returned diary, handing over the new diary, efficacy and integrity of the device. The collected data have been submitted to statistic analysis by Student test.

RESULTS. The survey has been suspended at the fourth month having reached a significant statistics. All the patients have completed the survey. The first month of the treatment didn't show any significant statistics differences. In the second month significant differences related to 4/8 symptoms (nasal obstruction, sneezes, itchiness and rhinorrea) have been revealed. Only 2 symptoms (nasal obstruction and wheezing) were different between the 2 groups in the third month, while in the fourth all the symptoms except dyspnoea displayed relevant statistics values. The whole evaluation of the 4 months revealed a significant reduction of the subjective symptomatology concerning wheezing, nasal obstruction, sneezes, rhinorrea and night cough. The mirror-like check by counting the days without symptomatology confirmed what had been found.

CONCLUSIONS. The results demonstrate the clinical efficacy of this ultrasound device, but we can't tie up the results, even if it can be perceived by intuition, to the reduction of the house dust mite allergen level, as a direct measurement hasn't been conducted. Besides the reduction of the number of mites has been introduced in a previous work by a nother Author'. The most relevant benefits are connected to rhinorrea, nasal obstruction, sneezes, night cough and wheezing, with a lighter effect on the reduction of other symptoms such as itchiness, exercise-induced cough and dyspnoea. The efficacy grows day by day. The results look promising and it would be interesting to extend the evaluation to a wider paediatric population, including the measurement of the dust mite allergen levels. The acceptance of the device by the patients has been good and no collateral effect has been reported.

Key words: dust mite, allergy, prevention, childhood, ear, ultrasound, exposure

A comparison between an ultrasonic waver emitter and a chemical acaricide in implementing environmental protection against mites.

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