

G. D'AMATO<sup>1</sup>, G. LICCARDI<sup>1</sup>, A. SALZILLO<sup>1</sup>, M. RUSSO<sup>1</sup>, P. NARCISO<sup>2</sup>, L. ALLEGRA<sup>3</sup>

## Nasal filters in prevention of seasonal rhinitis induced by allergenic pollen grains. Open Clinical Study

<sup>1</sup> Department of Chest Diseases, Division of Pneumology and Allergology, High Specialty "A. Cardarelli" Hospital, Naples, Italy - E-mail: gdamatomail@gmail.com

<sup>2</sup> Consultant, free professional

<sup>3</sup> Department of Respiratory Diseases – University of Milan

### KEY WORDS

*Aeroallergens, allergic rhinitis, atopic allergy, pollinosis, air-ways hypersensitivity, nasal filters, Parietaria pollen, pollen allergy, Sanispira®*

### Corresponding author

Dr. Gennaro D'Amato  
Department of Chest Diseases,  
Division of Pneumology and  
Allergology - High Speciality  
"A. Cardarelli" Hospital  
Via Rione Sirignano n°10,  
80121 Naples, Italy  
Phone: +390817473335-4-3  
Fax : + 39 081 7473331  
E-mail: gdamatomail@gmail.com

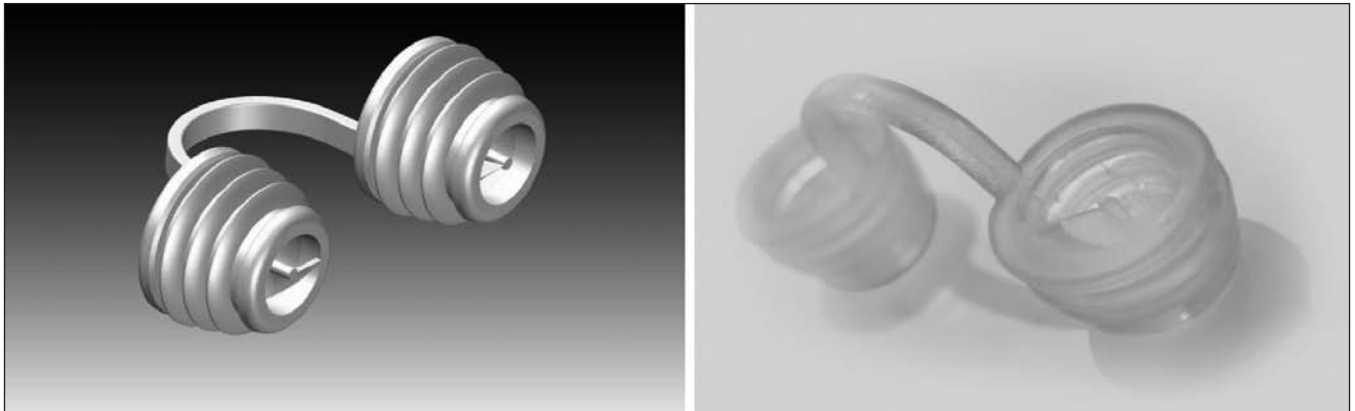
### SUMMARY

*Nasal filters (Sanispira®) might represent a novel approach in preventing exacerbations of symptoms of seasonal allergic rhinitis by reducing pollen access to nasal cavities. Female and male voluntary patients between the ages of 18 and 64 years living in Naples area and affected by allergic rhinitis were recruited in an open clinical study. All were allergic to Parietaria pollen as assessed by skin-prick and/or RAST test with or without associated sensitization to other pollens such as Gramineae and Olea europaea. A pollen count was also carried out from 10th April until 30th of June 2011. The results of our study show positive statistical differences between the scores of common nasal symptoms and the reduced use of antihistaminic drugs in patients using nasal filters in comparison to non users. Nasal filters constitute a useful mean to reduce symptoms of seasonal allergic rhinitis in patients suffering from pollen allergy.*

Seasonal allergic rhinitis induced by allergenic pollen grains constitutes a widely common clinical condition (1-6). Parietaria is an Urticacea with very strong allergenic properties that is widespread in Naples area with a spring and summer pollen season in part contemporaneous with that of other common weeds such as grasses and oleaceae (*Olea europaea* tree). Commonly available antiallergic drugs (anti H1 antihistaminic agents and inhaled corticosteroids) are sometimes poorly effective in highly sensitized individuals. Endonasal filters might represent a novel approach to prevent exacerbations of symptoms by reducing pollen access to nasal cavities. Sanispira®, recently patented in Italy, is a new

filtering system characterized by a conical trunk of medical silicone containing an elicoid coated by biocompatible viscous substance which has minimum invasivity and a high particle capturing ability (Fig. 1) (7). The biogel which is made of a certified biocompatible material, coats the inner surface of filter which inserted inside the nostrils; the filter can be shaped into different geometries, with the aim of increasing the air turbulence in order to maximise the impact probability of the particles with the inner walls of the filter, while minimising the air flow resistance.

The filter is capable of trapping particulate matter including allergenic pollen grains.

*Figure 1* - Nasal filters

The aim of our study is to verify the efficacy of nasal filters in reducing nasal symptoms in patients suffering from seasonal allergic rhinitis induced by pollen allergens.

Fifty female and male volunteers between the ages of 18 and 64 (mean age 29.3 years, 28 females and 22 males) all living in Naples area and affected by allergic rhinitis have been recruited in an open clinical study. All patients were allergic to *Parietaria* pollen as assessed by skin-prick and/or RAST test with or without associated sensitization to other pollens such as Gramineae and *Olea europaea*. All patients needed in previous years (almost two years) antihistaminic drugs and nasal corticosteroids and they were not in treatment with specific immunotherapy. They were subdivided in two groups, each containing 25 subjects:

- 1) group A patients using the filters for at least four hours a day, consecutively, especially outdoors.
- 2) group B patients not using the filters.

A case report form (CRF) containing all information for each patient was completed during the enrollment phase of study. The standardized form reported: demographic data, type and duration of respiratory symptoms, pets ownership, results of the skin prick tests (SPTs), results of specific IgE evaluation (when performed). The forms had to be filled by the allergist, who also verified the consistency of clinical history and SPT results. Then, the same doctor confirmed the diagnosis of seasonal allergic rhinitis according to the International Guidelines (6).

A questionnaire, including symptom scores, specifically designed for this study was also distributed to all patients before and after the open clinical study. The score of symptoms are scheduled as follows: 0= no symptoms; 1= slight symptoms; 2= moderate symptoms and 3= severe symp-

toms. Also the use of antihistaminic drugs was scored as yes or not use.

We have selected only patients with comparable symptom scores before the beginning of the trial in order to homogenize clinical and sensitization characteristics.

The collection of airborne allergenic pollen grains has been carried out in the Naples area from 10th April until 30th of June 2011 by using a volumetric pollen trap (Lanzoni volumetric pollen trap Bologna, Italy). The concentrations of airborne pollen grains were calculated by using a standardized procedure (1-3) and the results expressed as n° of pollen/cubic meter of air (Fig. 2).

Twenty-one patients of Group A and 22 of group B completed the study.

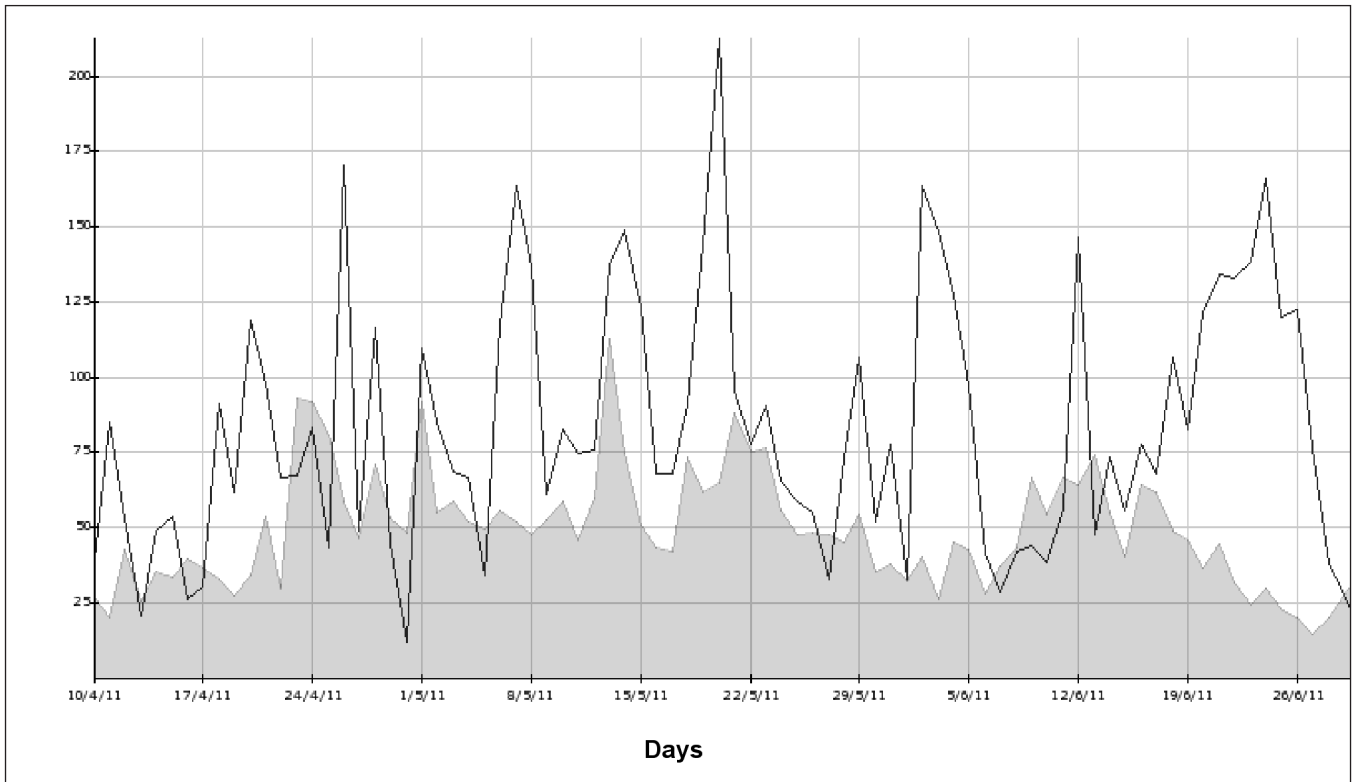
The data was analyzed by one-way analysis of variance (ANOVA) followed by a Bonferroni's test.

The results of our open study show positive statistical differences ( $F=28,52$ ;  $P<0.001$ ) of common nasal symptoms scores (runny nose, nasal congestion, nasal pruritus, and sneezing) in patients using Sanispira® compared to those who did not. There was also a statistically significant reduction of use of antihistaminic drugs in Group A ( $F=559,37$ ;  $P<0,001$ ). None of the patients reported the onset of side effects such as sneezing, bleeding etc. during the use of Sanispira®.

It is important to stress that these positive clinical results have been obtained even in the presence of concentrations of airborne *Parietaria* pollen grains significantly higher than the average of the period 1995-2010 (Fig. 2).

The results of our study are similar to those of O'Meara et al. (8) who studied the effects of a prototype nasal filter in reducing nasal symptoms during natural exposure to ragweed and grass pollen. Both studies showed a significant

**Figure 1** - Urticaceae pollen grains (Parietaria) for m<sup>3</sup> of air as daily mean concentration from 10 April to 30 June 2011



reduction in the score of some typical symptoms such as number of sneeze, runny nose, itchy nose. Nasal blockage was significantly reduced in our study whereas in the study of O'Meara et al. there was a trend to improvement but the difference was not significant.

In conclusion, nasal filters (Sanispira®) constitute a useful mean to reduce symptoms of seasonal allergic rhinitis in patients suffering from pollen allergy in addition to usual anti-allergic drugs (anti-h1 agents and nasal corticosteroids). Nasal filters might represent a novel approach in preventing allergic symptoms by reducing pollen access to the nasal cavities. It is likely that these nasal filters could be used also in reducing the inhalation of other allergens in already sensitized individuals (for example before entering indoor environments containing high amounts of mites etc.).

Further studies are needed to confirm these preliminary results.

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