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Improvement of quality of life in allergic rhinoconjunctivitis patients using nasal filters, a preliminary study

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Key words

Allergic Rhinoconjunctivitis, SANISPIRA Nasal filters, Rhinoconjunctivitis quality of life questionnaire

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Summary

Background: *Allergic rhinoconjunctivitis is a clinical condition that impairs quality of life. The use of traditional drugs in many cases is not enough to improve quality of life in these patients.* ***Methods:*** *In this pilot study we used the Sanispira Nasal filters in 15 patients (mean age 34,7 years) affected by allergic rhinoconjunctivitis for 18 days. At each follow-up visit, patients were assessed with a specific quality of life questionnaire, a symptoms form and a drugs form that evaluates the use of antiallergic drugs in the last week. Patients sensitive to environmental allergens wore Sanispira nasal filters during the day, while patients sensitive to domestic allergens wore the device during the night.* ***Results:*** *Thirteen patients completed the study. We found an improvement significative (p=0,0241) of the total score of RQLQ of 23,10 points between baseline and 18 days (total score at baseline prior to nasal filter insertion= 60,60, at 1 week = 42, 28, at 18 days= 34, 10). A significative improvement in the nasal symptoms domain between baseline and 18 days (in particular stuffy nose p=0,047; runny nose p=0,012; sneezing p=0,0021;) and one item of practical problems domain, the need to repeatedly blow the nose(p=0,082). The total score of symptoms evaluated with the symptoms form improved significantly from baseline to 18 days. Total symptoms score at baseline was 9,7; at 1 week it was 8,1 and at 18 days it was 4,7. The improvement was statistically significant (p=0,0092). Three of the thirteen patients that completed the study eliminated completely the use of drugs during of the study.* ***Conclusions:*** *The use of SANISPIRA ®, has shown encouraging results, with an improvement in the quality of life in Rhinoconjunctivitis patients specially an improvement in nasal and ocular symptoms.*

Introduction

Asthma and allergic rhinitis are common medical conditions that cause serious disease and disability in the world. The prevalence of allergic rhinitis is about 10% to 20% in the United States and in Europe. Many factors contribute to the wide range of prevalence rates reported. These include the type of prevalence rate (current or cumulative), the selection criteria of study, age of participants, differences in survey methods, different geographic areas and socio-economic status, each of these factors is important to prevent a direct comparison between studies. In the majority of epidemiological studies a a standard set of diagnostic criteria For allergic rhinitis does not exist.

In most studies, the criteria for diagnosis are based on history of the subject, based solely on a questionnaire and rarely confirmed by skin tests. Furthermore, most of the studies focus on hay fever and less on perennial allergic rhinitis. A TC scan of the nasal and paranasal sinuses is generally not performed.

Epidemiological studies have consistently shown that asthma and rhinitis often coexist in the same patients. Asthma is <2% in subjects without rhinitis while it varies from 10% to 40% in patients with rhinitis. Moreover, the majority of patients have asthma associated with rhinitis; this data shows such as rhinitis constitutes a risk factor for the asthma.

The natural history of asthma and rhinitis is dependent on environmental exposure to inhaled allergens (pollen, mold, dust mites.), as well as on the genetic predisposition of the patient. Similarly also the symptoms reported by patients can often correlate to the concentration of pollen, which the patient is sensitive, at atmospheric level.

Allergic rhinoconjunctitis is a clinical condition that impairs quality of life of affected patients, specially nasal symptoms should be troublesome and embarrassing. In many cases the use of antiallergic drugs is not enough to improve significantly the quality of life of these patients.

The Sanispira nasal filter, a new device recently patented in Italy, is a new concept of filtering represented by a disposable nasal filter fully cost accessible, to be used for a limited time (in the order of hours), minimally invasive, reducing the exposure of patient allergic mucosa.

The device is able to simultaneously provide a high capture of particle and a low resistance to flow This new device, SANISPIRA®, is a single use nasal filter that reduces the exposure of the patient's nasal mucosa to allergens.

It differs from conventional filters because it is able to capture particles with a lower resistance to airflow. (Anovel multipotential air-filtering system; GIORN. IT. MAL. TOR., 63, 4, 000-000,2009, P.NARCISO1, E. CANTERA2, L.ALLEGRA3)

The conventional porous filters or cellulose filters do not have properties very similar to those presented by this device. The concept of "filtering" by the device employs an innovative patented mechanism of action, based on a coating of biocompatible material that has both the property of attracting the particles present in the air stream due to its electrostatic local charge and to trap them irreversibly thanks to its viscosity.

This material covers the inner surface of the filter substrate, which has been given the form of microchannels in order to increase the turbulence of the air, maximizing the probability of particle impact against the inner side of the filter, while minimizing the resistance to the air flow.

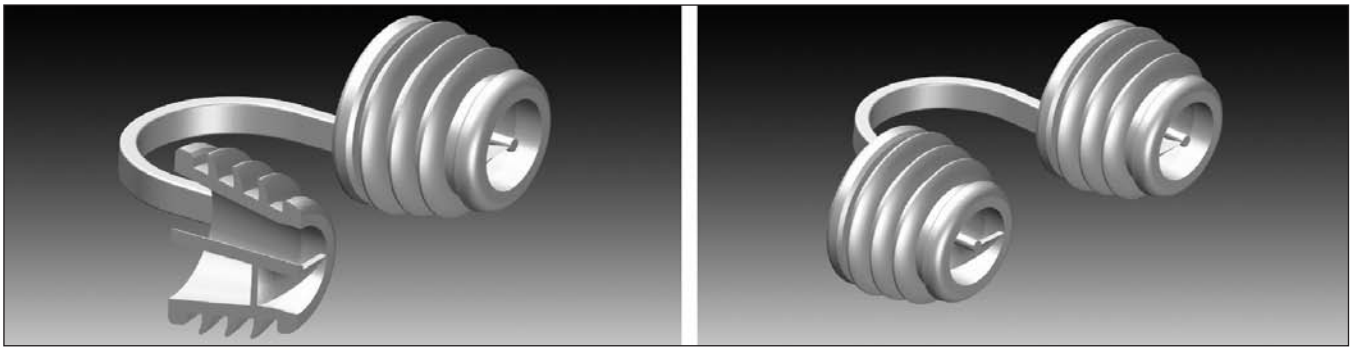
Compared to conventional porous filters or to the cellulose filters, the introduction of a coating capable of attracting and arresting the particles reduces the need of thin microchannels flow resistant. This concept described above shows a general validity and applicability, and can be applied to each filtering system, since it provides a unique "counterbalance" between the low air flowresistance and the high filter efficiency.

This concept has so far been primarily applied to a personal patented filtering device, called SANISPIRA ®, which can be used for all applications in which conventional filters are properly used, such as air conditioning, ventilation of buildings or vehicles, etc.

This innovative system is able to capture particles with a resistance to air flow that is lower than the one of a conventional filter by similar performance.

The aim of this study was to evaluated the quality of life and productivity of patients with persistent allergic rhinitis (PER) (symptoms lasting more than four days a week and more than four weeks a year) r intermittent allergic rhinitis (IAR) (symptoms lasting less than four days a week or less

Figure 1 - Sanispira Nasal filters



than four weeks a year) and with IgE-mediated hypersensitivity to aeroallergens using SANISPIRA® nasal filters.

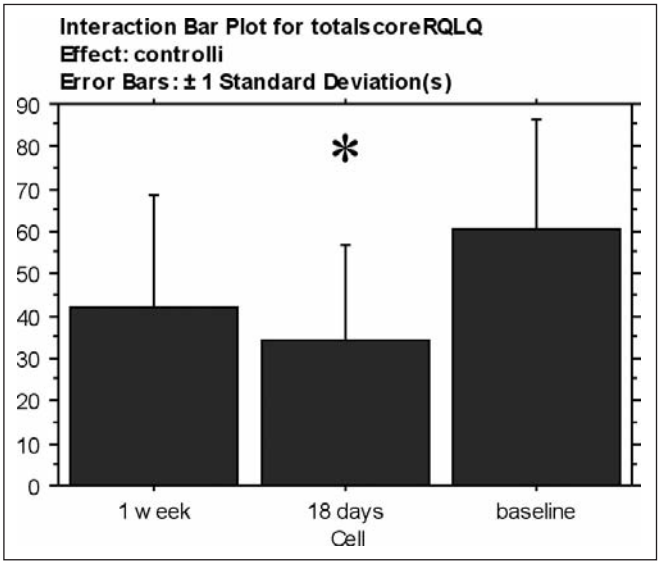
Materials and methods

The study was carried out in Rome from February till September of 2012. volunteers patients (8 males and 7 females) , mean age 34,7 years were enrolled in this open non controlled study. All patients signed informed consent for the study. All the patients suffered from rhinoconjunctivitis, 6 of them also suffered from bronchial asthma. Patient were enrolled in the study at the beginning of their pollination period symptoms for patient who suffered from allergic rhinitis.
Patients had positive prick tests or specif Ig E for different allergenic pollen grains (parietaria, graminacee, olive, alternaria) or dermatophagoids.
All patients were instructed how to wear Sanispira nasal filters. A clinician show how to wear device at the first visit, helping the patient in improving his confidence with this new type of filters. Those nasal filters have three standard measure, the clinician and the patient choose together the best fitting device. Every filter has a sterile box.
Patients sensitive to environmental allergens wore Sanispira nasal filters during the day (10 patients), while patients sensitive to domestic allergens wore the device during the night. In polysensitized patients the filters were worn in the period of the day in which the patient has more severe symptoms. In both cases nasal filters were worn for 8 hours a day for 18 days.
Each patient was assessed by the RQLQ (Rhinoconjunctivitis quality of life questionnaire) at three different timepoints: at baseline, and at two follow up visits (after seven days of Sanispira use, and after 18 days of Sanispira use).
The baseline is placed at the beginning of the pollen season for patients sensitive to environmental allergens or at the first visit for the remaining patients. The RQLQ is composed of specific questions designed to measure the functional problems (physical, emotional, social and occupational) that are most troublesome to adults (17-70 years) with either seasonal or perennial rhinoconjunctivitis of either allergic or non-allergic origin, and thus to quantify the impact of the rhinoconjunctivitis condition on the quality of life of the individual patient.
The RQLQ has 28 questions in 7 domains. At the beginning of the questionnaire patients are asked to select three activities in which they are most limited by their rhinoconjunctivitis. Once the activities are identified patients are asked to recall how bothered they have been by their nasal / ocular symptoms during the previous week and respond to each question on a 10-point scale (0= not impaired at all; 9= impossibility to do the activity). To score the other domains: sleep problems, other general symptoms, practical problems, emotional problems, nose symptoms and eye symptoms, a 7 point scale is used (0= no discomfort; 6= very high discomfort).
The overall RQLQ score is the mean of all 28 responses and the individual domain scores are the means of the items in those domains.
The RQLQ has excellent measurement properties and has been used extensively throughout the world both in clinical practice and clinical trials.
Moreover, at baseline visit and at each follow up visit patients were asked to complete other two forms: the symptoms form that evaluates the presence or absence of ocular, nasal and respiratory symptoms in a 4 point scale (0= absence of symptoms; 3= severe symptoms), and the drugs form that evaluates the use of antiallergic drugs (antihistamines, antileucotriens, nasal spray, eye drops, bronchial spray) in the last week.

Results

Thirteen patients completed the study. Two patients didn't complete the study because they were unable to comfortably wear the nasal filters. Actually both patients were

Figure 2 - Rhinoconjunctivitis Quality of Life Questionnaire Total Score: significative improvement after 18 days of Sanispira use



then submitted to septoplasty due to a serious deviation of the nasal septum. .
Overall differences between baseline scores and time points scores were analyzed by one-way analysis of variance (ANOVA) and t-test with the Stat view program. Statistical significance was defined as p<0,05.
There were not differences between the use of Sanispira during the night hours or during the day hours. Nasal filters were well tolerated.and useful during day hours and also during night hours.
Any adverse event was reported.

Rhinoconjunctivitis quality of life questionnaire

In the Rhinoconjunctivitis Quality of Life Questionnaire the patients were asked to identify the most important daily activities affected by their pathologies. The activities most identified were training and working, eating and social living. We found an improvement of the total score of QOLQ of 23,10 points between baseline and 18 days (total score at baseline prior to nasal filter insertion= 60,60, at 1 week = 42, 28, at 18 days= 34, 10). The improvement is already present at 1 week of Sanispira use with 15,86 points difference, and it is significative between baseline and 18 days (p=0,0241).

Figure 3 - Rhinoconjunctivitis Quality of Life Questionnaire: Significative improvement of different nasal symptoms after 18 days of Sanispira use.

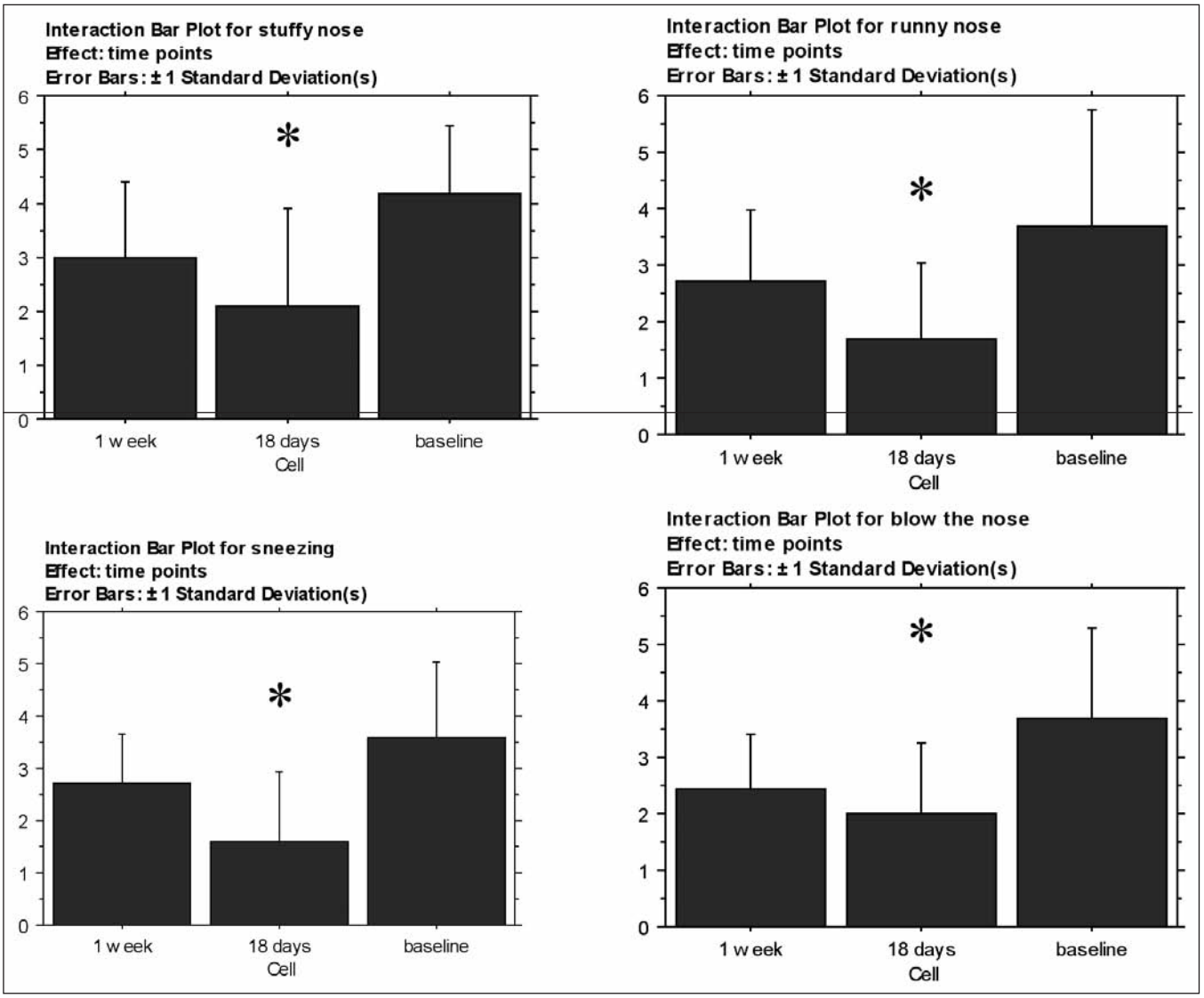


Figure 4 - Symptoms form Total score: significative improvement after 18 days of Sanispira use.

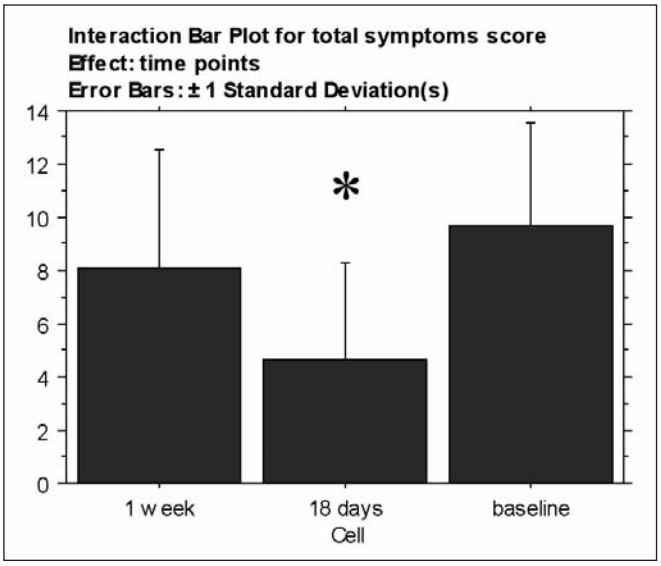
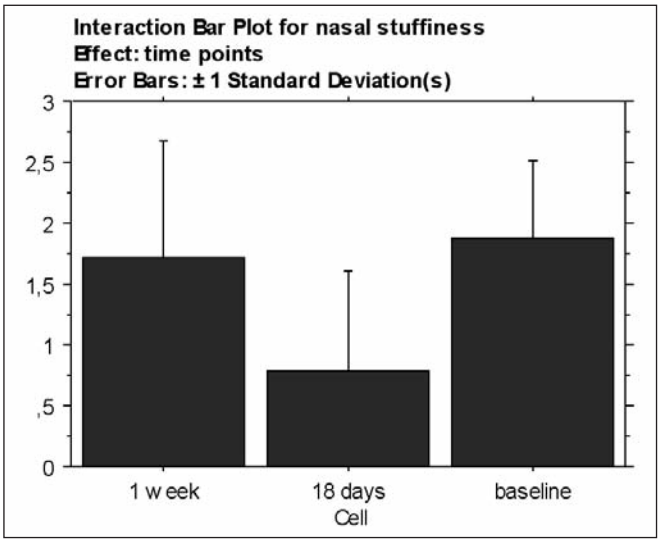
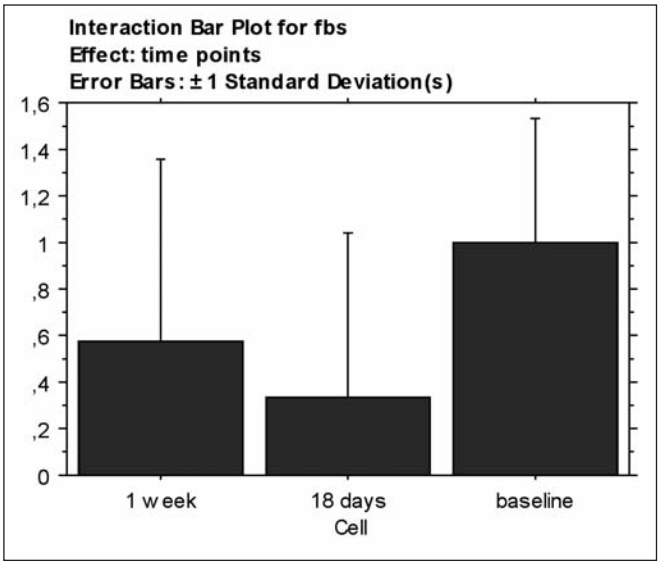


Figure 5 - Symptoms form Nasal stuffiness: significative improvement after 18 days of Sanispira use.



The relevant improvement in total score of QOLQ was principally due to a significative improvement in the nasal symptoms domain between baseline and 18 days (in particular stuffy nose p=0,047; runny nose p=0,012; sneezing p=0,0021;) and one item of practical problems domain, the need to repeatedly blow the nose(p=0,082).
The results obtained from the other assessments made by the QOLQ (activities, sleep problems, other general symptoms, practical problems, emotional problems, and eye symptoms) had an improving trend but without reaching any statistically relevant value.
Any of the evaluated symptoms worsened during the study.

Figure 6 - Symptoms form foreign body sensation or redness or itching: significative improvement after 18 days of Sanispira use.



Symptoms form

The total score of symptoms evaluated with the symptoms form improved significantly from baseline to 18 days. Total symptoms score at baseline was 9,7; at 1 week it was 8,1 and at 18 days it was 4,7. The improvement was statistically significant (p=0,0092).
In particular there was a significative improvement in nasal stuffiness from baseline and 18 days (p= 0,032) and from 1 week and 18 days (p= 0,0143).
The improvement in ocular symptoms (foreign body sensation, or redness or itching) was also significative (p=0,049).
The other symptoms assessed with the symptoms form (rhinorrhea, sneezing, itch, tearing) slightly improved but with not statiscally significative results were found.

Drugs form

Drugs form evaluated the use of antiallergic drugs in the last week. We found a trend to diminish the consumption of drugs. In particular three of the thirteen patients that

completed the study eliminated completely the use of drugs at the end of the study.

Discussion and Conclusions

In our study the majority of patients interviewed were enthusiastic about the presence of a new device on the market which help to reduce the symptoms of allergic rhinitis.

Our results are in line and follow statistically with those of D'Amato and O Meara. In fact patients had a great improvement in their nasal symptoms, and thus in their quality of life. Actually the questionnaire used in this study was not specifically designed for this study but we used a validated questionnaire for the quality of life in rhinoconjunctivitis patients. The use of a validated questionnaire strengthens the validity of our results. Like in the study of O' Meara, patients in our study had also an significative improvement in ocular symptoms after 18 days of nasal

Rhinoconjunctivitis quality of life questionnaire

Table 1 - ACTIVITIES

	No discomfort	Almost no discomfort	A slight discomfort	Little discomfort	Enough discomfort	High discomfort	A very high discomfort	I have not done this activity
	0	1	2	3	4	5	6	9
Activities 1	☐	☐	☐	☐	☐	☐	☐	☐
Activities 2	☐	☐	☐	☐	☐	☐	☐	☐
Activities 3	☐	☐	☐	☐	☐	☐	☐	☐

Table 2 - SLEEP

	No discomfort	Almost no discomfort	A slight discomfort	Little discomfort	Enough discomfort	High discomfort	A very high discomfort
	0	1	2	3	4	5	6
Difficulty while getting to sleep	☐	☐	☐	☐	☐	☐	☐
Waking up during the night	☐	☐	☐	☐	☐	☐	☐
Absence of good sleep	☐	☐	☐	☐	☐	☐	☐

Table 3 - GENERAL ISSUES

	No discomfort	Almost no discomfort	A slight discomfort	Little discomfort	Enough discomfort	High discomfort	A very high discomfort
	0	1	2	3	4	5	6
Fatigue	☐	☐	☐	☐	☐	☐	☐
Thirst	☐	☐	☐	☐	☐	☐	☐
Reduced productivity	☐	☐	☐	☐	☐	☐	☐
Feeling sleepy	☐	☐	☐	☐	☐	☐	☐
Low concentration	☐	☐	☐	☐	☐	☐	☐
Headache	☐	☐	☐	☐	☐	☐	☐
Prostration	☐	☐	☐	☐	☐	☐	☐

Table 4 - PRATICAL ISSUES

	No discomfort	Almost no discomfort	A slight discomfort	Little discomfort	Enough discomfort	High discomfort	A very high discomfort
	0	1	2	3	4	5	6
The inconvenience of having to take along towels or paper towels	☐	☐	☐	☐	☐	☐	☐
The need to rub your nose or eyes	☐	☐	☐	☐	☐	☐	☐
The need to repeatedly blow the nose	☐	☐	☐	☐	☐	☐	☐

Table 5 - EMOTIONAL ISSUES

	Never	Almost never	Once in a while	Sometimes	Often	Almost always	Always
	0	1	2	3	4	5	6
Felt annoyed and disappointed	☐	☐	☐	☐	☐	☐	☐
Impatience and restlessness	☐	☐	☐	☐	☐	☐	☐
Irritability	☐	☐	☐	☐	☐	☐	☐
Embarrassment due to illness	☐	☐	☐	☐	☐	☐	☐

Table 6 - NASAL ILLNESS

	No discomfort	Almost no discomfort	A slight discomfort	Little discomfort	Enough discomfort	High discomfort	A very high of discomfort
	0	1	2	3	4	5	6
Stuffy nose	☐	☐	☐	☐	☐	☐	☐
Runny nose	☐	☐	☐	☐	☐	☐	☐
Sneezing Phlegm in the throat	☐	☐	☐	☐	☐	☐	☐

Table 7 - OCULAR ILLNESS

	No discomfort	Almost no discomfort	A slight discomfort	Little discomfort	Enough discomfort	High discomfort	A very high of discomfort
	0	1	2	3	4	5	6
Itchy eyes	☐	☐	☐	☐	☐	☐	☐
Watery eyes	☐	☐	☐	☐	☐	☐	☐
Irritated eyes	☐	☐	☐	☐	☐	☐	☐
Swollen eyes	☐	☐	☐	☐	☐	☐	☐

Table 8 - SYMPTOMS FORM

	0	1	2	3
	No symptoms	Mild symptoms	Moderate symptoms	Severe symptoms
Rhinorrhea	☐	☐	☐	☐
Nasal stuffiness	☐	☐	☐	☐
Sneezing	☐	☐	☐	☐
Itch	☐	☐	☐	☐
Foreign body sensation or redness / itching	☐	☐	☐	☐
Tearing	☐	☐	☐	☐
Cough	☐	☐	☐	☐
Dyspnea	☐	☐	☐	☐
Exercise-induced bronchospasm	☐	☐	☐	☐

Table 9 - DRUGS FORM

Days of use in the last week							
	1	2	3	4	5	6	7
Antihistamine	☐	☐	☐	☐	☐	☐	☐
Antileucotrieni	☐	☐	☐	☐	☐	☐	☐
Nasal spray	☐	☐	☐	☐	☐	☐	☐
Eye drops	☐	☐	☐	☐	☐	☐	☐
Bronchial spray	☐	☐	☐	☐	☐	☐	☐

filters use. The relationship between nasal allergens and ocular symptoms has extensively been demonstraded.

In our study Sanispira nasal filters showed to be effective for environmental and domestic allergens, and thus for seasonnal and perennial rhinoconjunctivitis. More studies are necessary to verify the compliance of filters use for longer periods of time

The use of SANISPIRA ®, even if it involves a time horizon so limited, has shown encouraging results, with an improvement in the quality of life in rhinoconjuctivitis patients specially an improvement in nasal and ocular symptoms.

Regarding the consumption of drugs: although there has been a short period of time, at the end of the study 3 patients (20%) reduced to zero the use of antiallergic drugs; for the remaining, we should hypothize that with a longer period of time of Sanispira use the reduction of antiallergic drugs use should significantly decrease, and be in line with the results of D'amato (reduction of antihistamines drugs).

More studies are need to confirm these preliminary results, specially the use of Sanispira nasal filters during longer periods of time and during the night hours should be deepen.

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