

Inert Cellulose Powder in the Treatment of Seasonal Allergic Rhinitis

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Abstract

Objective: To assess efficacy and safety of inert cellulose powder (ICP) in the treatment of mild seasonal allergic rhinitis (SAR).

Methods: An observational, non-randomized, open study including 74 examinees suffering from mild SAR was conducted. The study subjects were divided in two groups, Group 1 (G1) and Group 2 (G2). The study subjects from G1 were treated 10 days with oral cetirizine and ICP, while the study subjects from G2 were treated 10 days only with oral cetirizine. The treatment outcomes were evaluated after five and 10 days by self-assessment of the symptoms on a five-point scale.

Results: In both groups improvement of the symptoms five and 10 days after the treatment was registered. There was significantly higher prevalence of the G1 study subjects in the point 4 ("major relief, casual sneezing") five days after beginning of the treatment (43.2% vs. 18.9%; $P < 0.05$), as well as in the point 5 ("complete relief, without symptoms") at the end of the treatment (56.7% vs. 27.0%; $P < 0.05$). A low frequency of adverse effects was registered among examinees of both groups.

Conclusion: The results obtained indicated high efficacy and safety of ICP in the treatment of mild SAR.

Keywords: Efficacy; Inert cellulose powder; Seasonal allergic rhinitis; Safety; Cethirizine

Introduction

Allergic rhinitis (AR) became a global public health problem in the last decades due to the direct and indirect costs associated with its diagnostics, treatment, and rehabilitation. The global prevalence of AR worldwide is estimated to be 10%-20%, i.e., from AR suffer approximately 500 million people worldwide [1]. According to the results of the survey conducted in R. Macedonia in 2003, the AR prevalence was 23.1% in adults and 15.6% in children [2].

For a period of time AR has been classified into seasonal and perennial AR based on the time of exposure. Seasonal AR (SAR) is defined as an inflammation of the nasal mucosa characterized by seasonal nasal symptoms that occur in sensitized subjects following exposure to outdoor allergens (pollens and certain moulds). Perennial AR (PAR) is defined as an inflammation and hypertrophy of the nasal mucosa characterized by nasal symptoms persisting round-year. According to the new classification, based on duration of symptoms, AR is subdivided into intermittent and persistent AR. Intermittent AR is characterized by symptoms occurrence in less than four days per week or in less than four weeks per year. Persistent AR is characterized by symptoms occurrence in a longer period (e.g. in more than four days per week or in more than four weeks per year). According to the classification based on severity AR is divided into mild and moderate-severe depending on symptoms and quality of life [3].

The management of AR consists of environmental control measures, pharmacological treatment, allergen-specific immunotherapy, and other types of therapy. Environmental control measures involve the avoidance of allergen (allergens) to which the patient is sensitized, as well as the avoidance of nonspecific triggers. Pharmacological treatment includes antihistamines, decongestants, anticholinergics, and anti-inflammatory medications (cromones, leukotriene antagonists, and corticosteroids) [1].

The ICP is a micronised powder composed of fine particles of chemically inert cellulose of vegetable origin used as a monotherapy

or combined with other medications in the treatment of SAR and PAR. The preparation based on ICP is registered as a Class 1 Medical Device under EU Directive 93/42/EEC and is currently on sale in many countries, including R. Macedonia. The ICP as a spray applied to the inside of nose via appropriate delivery system reacts with moisture within the airway producing a protective barrier over the nasal mucosa. This barrier prevents airborne allergens from binding with receptor sites and avoids mast cell degradation. It can be considered not only as an effective measure to prevent the initial immunologic response but also as a management strategy for reducing the symptoms of the AR once triggered [4]. According to the actual guidelines, the ICP is not on the list of medications recommended for treatment of AR. There is also no recommendation not to be used in its treatment because of suspect efficacy or possibility of adverse effects like homeopathic preparation, acupuncture, phototherapy and other physical techniques, as well as like butterbur (*Petasites hybridus*) and other herbal preparations [1].

Methods

An observational, non-randomized, open study (a real life study) was conducted in the Institute for Occupational Health of R. Macedonia, Skopje-WHO Collaborating Center and GA²LEN Collaborating Center in the period March-August, 2016. The study on

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the efficacy and safety of the ICP in the treatment of AR carried out by Vlahitis et al. [5]. was used as a model.

Including criterion was mild SAR caused by sensitization to pollens (hay fever). SAR and its severity were defined according to the recommendations of the actual AR guidelines [1,3].

Excluding criteria were moderate to severe SAR, PAR, non-allergic rhinitis and other forms of rhinitis, as well as inadequate collaboration of the study subjects, worsening of the disease and serious adverse effects during the treatment.

The study population included 74 subjects, 39 males and 35 females, aged 22 to 46 years, who were informed about the study and their written consent was obtained. The study subjects were divided in two groups: Group 1 (G1) and Group 2 (G2). The study subjects from G1 were treated with oral cetirizine 10 mg once daily at the evening and ICP one application per each nostril at the morning, while the study subjects from G2 were treated only with oral cetirizine 10 mg once daily at the evening. All study subjects were followed up for 10 days with an intermediate visit at 5 days at which they were asked about their symptoms and the side effects of the treatment.

The treatment outcomes were evaluated by self-assessment of the symptoms on a five-point scale:

1. AR with complete symptoms
2. Allergy symptoms apparent with periodic flare ups
3. Light, but noticeable allergic symptoms
4. Major relief, casual sneezing
5. Complete relief, without symptoms

The data obtained were statistically processed by descriptive and inferential methods using the Statistical Package for the Social Sciences (SPSS) version 11.0 for Windows. Analyses of the data included testing the differences in frequencies and comparison of the means by chi-square test (or Fisher's exact test where appropriate) and independent-samples T-test. A P-value less than 0.05 were considered as statistically significant.

Results and Discussion

Examined groups included subjects with similar characteristics (Table 1). Runny nose was dominant symptom in both examined groups. In addition, the frequency of study subjects sensitized to grass pollen was higher than the frequency of sensitization to tree and weed pollens in both examined groups.

As it is mentioned above, all study subjects were symptomatic at the beginning of the study (a point 1 of the five-point scale). Improvement of the symptoms five days after the beginning of the treatment was registered in all participants of both examined groups. The frequency of the study subjects who assessed their symptoms as a point 2, 3 or 5 was similar in both examined groups, whereas the frequency of the study subjects who assessed their symptoms as a point 4 improvement was significantly higher in G1 than in G2 (43.2% vs. 18.9%; $P < 0.05$) (Figure 1).

The treatment outcome 10 days after its beginning is shown Figure 2. The frequency of the study subjects who assessed their symptoms as a point 3 or 4 did not differ significantly between two examined groups. We found significantly higher frequency of the study subjects who assessed their symptoms as a point 5 in the G1 than in the G2 (56.7% vs. 27.0%; $P < 0.05$).

Characteristic	Group 1 (n=37)	Group 2 (n=37)
M/F ratio	1.1	1.1
Mean age (years)	33.4 ± 5.9	32.6 ± 7.8
Employment status		
Administrative workers	9 (24.3%)	10 (27.0%)
Industrial/service workers	14 (37.8%)	12 (32.4%)
Unemployed	14 (37.8%)	15 (40.5%)
Smoking status		
Active smoker	15 (40.5%)	13 (35.1%)
Ex-smoker	3 (8.1%)	5 (13.5%)
Passive smoker	8 (21.6%)	10 (27.0%)
Never smoker	11 (29.7%)	9 (24.3%)
Mean duration of the disease (years)	10.8 ± 5.2	11.6 ± 4.6
Symptoms before treatment		
Sneezing	23 (62.2%)	25 (67.6%)
Itching	21 (56.8%)	20 (54.1%)
Runny nose	37 (100%)	37 (100%)
Blocked nose	10 (27.0%)	8 (21.6%)
Ocular symptoms	19 (51.4%)	21 (56.8%)
Sensitization to pollen allergens		
Grass pollens	32 (86.5%)	30 (81.1%)
Tree pollens	17 (45.9%)	18 (48.6%)
Weed pollens	22 (59.4%)	20 (54.1%)

Numerical data are expressed as mean value with standard deviation; frequencies as number and percentage of the study subjects with certain variable.
M: males; F: females.

Table 1: Characteristics of the study subjects.

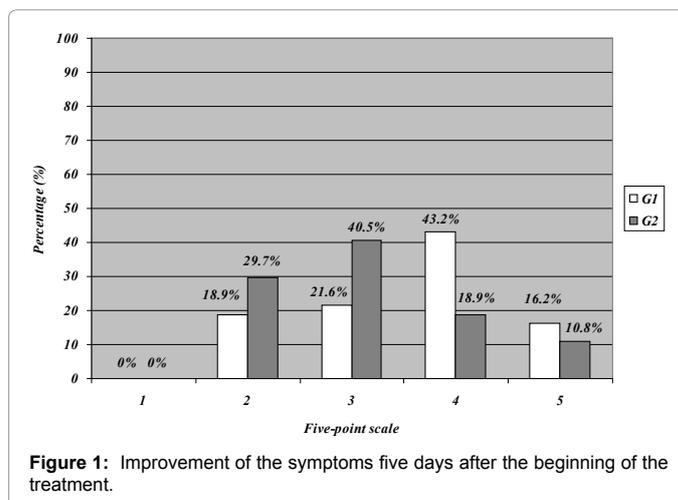
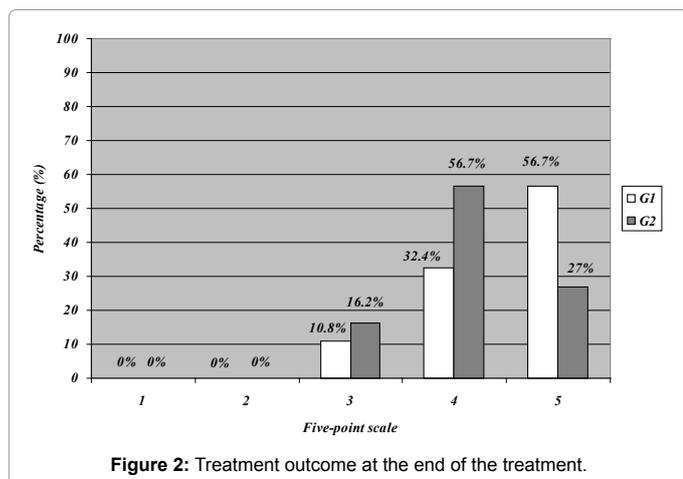


Figure 1: Improvement of the symptoms five days after the beginning of the treatment.

Side-effects during the treatment were reported by two subjects from the G1 (9.4%) and by four subjects from the G2 (12.5%). In all cases mild sleepiness at the beginning of the treatment which did not require discontinuation of the treatment was reported. The sleepiness is due to the well-known central effects of antihistamines. Additional side-effects among study participants from the Group 1 were not reported.

Similar findings are reported in several trials which investigated efficacy and safety of the ICP in the treatment of AR [6]. In the double-blinded, placebo-controlled study including SAR patients, Emberlin et al. [7] reported high efficacy of the ICP used as monotherapy. Similar results are obtained in the study conducted by Josling et al. [7] also including SAR patients. According to the results of the double-blinded, placebo-controlled study conducted by Emberlin et al. [9] the ICP use reduces the nasal response expressed by symptom/score, as well as by the



results of the nasal challenge (i.e., the values of maximal inspiratory and expiratory nasal flow) with Der p 1 and Der p 2 allergens in the patients with PAR sensitized to house dust mite. In a Swedish study including children and adolescents with SAR, Aberg et al. [10] demonstrated that an ICP caused a significant alleviation of nasal symptoms showing the best efficacy after a low-moderate birch pollen load (a concentration representing major parts of the Swedish pollen season).

The present study had some limitations. The results should be viewed with caution, since the study was neither blinded nor randomized and, therefore, can be a subject to possible selection bias. On the other hand, the study design may be its strength, as it is documented by other real life studies. In addition, relatively small number of the subjects in the examined groups could have certain implications on the data obtained and its interpretation.

Conclusion

In conclusion, in an observational, non-randomized, open-label study of efficacy and safety of the ICP in the treatment of mild SAR we found high efficacy and safety of the examined medication that is complementary to the results of several similar clinical trials suggesting that its use may be beneficial in the treatment of this entity. Further investigations, as well as comparisons to the other therapeutic modalities, are needed for more precise determination of the eventual place of the ICP in the treatment of AR.

Ethical Approval

The Ethical Committee of the Institute of Occupational Health of R. Macedonia, Skopje-WHO Collaborating Center and GA2LEN Collaborating Center gave approval for performing the study and publishing the results obtained (02-34/1).

Competing Interests

All authors hereby have declared that no competing interests exist.

Authors Participations

JM participated in the study design, data collection, managing the analyses of the study, and writing all versions of the manuscript. JKB

and TP participated in the study design, managing the analyses of the study, as well as writing all versions of the manuscript. KV performed the statistical analysis and participated in the managing of the analyses of the study. SS and DM participated in the data collection and in the managing of the analyses of the study. All authors read and approved the final manuscript.

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