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Hypersaline nasal irrigation in children with symptomatic seasonal allergic rhinitis: A randomized study

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Recent evidence suggests that nasal irrigation with hypertonic saline may be useful as an adjunctive treatment modality in the management of many sinonasal diseases. However, no previous studies have investigated the efficacy of this regimen in the prevention of seasonal allergic rhinitis-related symptoms in the pediatric patient. Twenty children with seasonal allergic rhinitis to Parietaria were enrolled in the study. Ten children were randomized to receive three-times daily nasal irrigation with hypertonic saline for the entire pollen season, which had lasted 6 weeks. Ten patients were allocated to receive no nasal irrigation and were used as controls. A mean daily rhinitis score based on the presence of nasal itching, rhinorrea, nasal obstruction and sneezing was calculated for each week of the pollen season. Moreover, patients were allowed to use oral antihistamines when required and the mean number of drug assumption per week was also calculated. In patients allocated to nasal irrigation, the mean daily rhinitis score was reduced during 5 weeks of the study period. This reduction was statistically significantly different in the 3th, 4th and 5th week of therapy. Moreover, a decreased consumption of oral antihistamines was observed in these patients. This effect became evident after the second week of treatment and resulted in statistically significant differences during the 3th, 4th and 6th week. This study supports the use of nasal irrigation with hypertonic saline in the pediatric patient with seasonal allergic rhinitis during the pollen season. This treatment was tolerable, inexpensive and effective.

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Allergic rhinitis is a disease characterized by the classic symptoms of rhinorrhea, obstruction of the nasal passage, sneezing and itching, all occurring in a temporal relationship to allergen exposure (1). Treatment options include antihistamines, decongestants, anticholinergics and corticosteroids (1–3). At present, H_1-antagonistic drugs are the most frequently used medication. However, adequate management of the disease is a major and still largely unsolved topic in this field (1). Recent studies have documented interesting results using nasal irrigation as an adjunctive treatment modality in many sinonasal diseases including allergic rhinitis (1, 4–6). In this regard, it has also been reported that an increased efficacy could be effected using hypertonic saline instead of normal saline (6–9). However, statistical evidence to justify a widespread clinical use of nasal irrigation is still poor (4). More specifically, to the best of our knowledge, no previous studies have investigated the efficacy of nasal irrigation using hypertonic saline in the prevention of seasonal allergic rhinitis symptoms in the pediatric patient. This issue is herein addressed in a randomized study in which patients treated with nasal irrigation during the pollen season were compared with patients who did not receive the therapy.

Materials and methods

Twenty children (8 boys) 6–12 years of age with seasonal allergic rhinitis who attended the Rhinological Service of the Department of Otolaryngology of the San Gerardo Hospital entered the study. Specifically, patients with seasonal allergic rhinitis to Parietaria were enrolled, as this plant is known to be the most important hay fever-provoking plant in Italy (10). The study was performed during the pollen season when the patients were symptomatic.

The diagnosis of seasonal allergic rhinitis to Parietaria was based on (1) typical anamnesis for seasonal allergic rhinitis for at least 2 years; (2) positive prick tests to Parietaria pollen extracts in a hydroglyceric solution titrated at 20.00 biological units (BU)/ml (SARM allergeni, Guidonia-Rome, Italy); (3) positive RAST to Parietaria pollens of at least class 2 (Pharmacia Diagnostics, Uppsala, Sweden; CAP system – FEIA). Exclusion criteria were the presence of symptoms of asthma, urticaria or eczema, a clinically relevant sensitization to other allergens and the use of specific immunotherapy within the past 2 years. All patients were under the care of two of the authors (MR, CD). The study was approved by the Institutional Review Board of San Gerardo Hospital, and informed consent was obtained from all the parents of the children before study entry.

Parietaria pollen count per m^3 of air was continuously taken with a volumetric pollen trap (Burkard Manufacturing, Rickmansworth, UK) placed in our area at a height of approximately 20 m. Although the concentration of Parietaria tended to be below 50 grains/m^3 during the first and the last week of treatment, a concentration of Parietaria persistently over 50 grains/m^3 was documented during the other 4 weeks. These data confirmed that the study period was largely coincident with the pollen season, when recruited patients were expected to be symptomatic.

A prospective non-blinded randomized trial was performed. Randomization was achieved in March 2001 before the onset of the pollen season. This randomization was performed according to a computer-generated list unknown to the physicians. Six out of 26 children who were eligible for randomization refused to enter the study. Ten children were randomized to receive three-times daily nasal irrigation with hypertonic saline for 6 weeks. Treatment began on April 30, 2001 and lasted for 6 weeks. Ten patients were allocated to receive no nasal irrigation treatment and were used as controls. Nasal irrigation was administered using a disposable syringe filled with 5 ml (2.5 ml in each nostril) sterile, room-temperature 3.0% hypertonic saline. The solution was prepared in the laboratory of our Institute.

Patients and their parents were instructed to record their daily symptoms on diary card. Nasal symptoms included: (1) nasal itching, (2) rhinorrea, (3) nasal obstruction and, (4) sneezing. Intensity of these four symptoms was rated according to a 5 grade scale: 0 = no symptom, 1 = slight, 2 = mild, 3 = moderate, 4 = severe. Total scores ranged from 0 to 16 and represented the sum of scores of these four symptoms. These data were used to calculate a mean daily rhinitis score for each week of the pollen season. Furthermore, patients were allowed to use oral antihistamines to control rhinitis symptoms when required. The daily oral intake of these drugs was also recorded on the same diary card and the mean number of drug assumption per week for each week of the pollen season was calculated.

Statistical analysis was performed using the Student's *t*-test for independent samples and χ^2 analysis to compare basal characteristics of the two groups. Mean daily rhinitis score and mean number of antihistamine assumptions were compared using a non-parametric test (Wilcoxon's test) adjusting for multiple comparisons. $p < 0.05$ was considered significant in all comparisons.

Results

No significant differences were found between the two groups (active treatment and controls) in terms of age, gender, years of clinically relevant rhinitis, sensitization to other allergens and results of allergic diagnostic tests (data not shown).

No patients were lost to follow-up and no adverse effects were reported. Significant clinical benefits were observed in children with seasonal allergic rhinitis to Parietaria who received a regimen of three-times daily nasal irrigation with hypertonic saline during the pollen season (Fig. 1). Indeed, the mean daily rhinitis score was reduced during 5 weeks of the study treatment period. More specifically, this difference resulted in statistical significance in the 3th, 4th and 5th week of therapy. Conversely, the mean daily rhinitis score during the first week of treatment resulted similar in the two groups (Fig. 1). In regard to the use of oral antihistamines, a reduced assumption of this drug in patients allocated to nasal irrigation with hypertonic saline was observed (Fig. 2). This

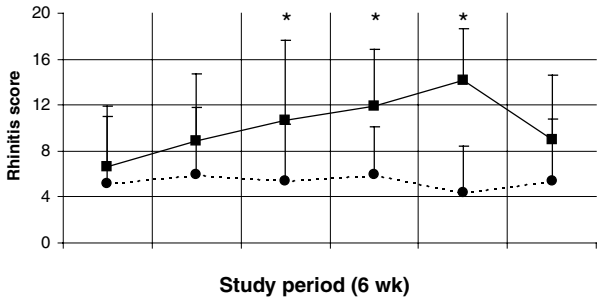

Fig. 1. Mean ± SD of the rhinitis score during the 6-week period of the pollen season for both patients treated with nasal irrigation (dotted line) and controls (solid line). Scores represent the sum of scores of four different symptoms: nasal itching, rhinorrea, nasal obstruction and sneezing. Intensity of these four symptoms was rated according to a 5-grade scale: 0 = no symptom, 1 = slight, 2 = mild, 3 = moderate, 4 = severe and a mean daily rhinitis score for each week of the pollen season was calculated. The mean daily rhinitis score for each week of the pollen season was reduced during 5 weeks of the study treatment period in patients who were prescribed nasal irrigation. This difference resulted in statistical significance (*) in the 3th, 4th and 5th week of therapy.

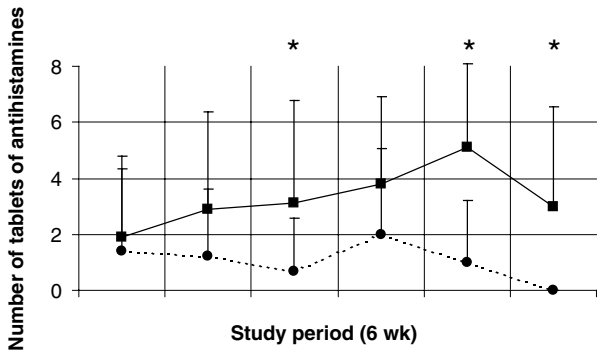

Fig. 2. Mean ± SD number of oral intake of antihistamines per week for each week of the pollen season in both patients treated with nasal irrigation (dotted line) and controls (solid line). The assumption of this drug was reduced among patients allocated to nasal irrigation. This reduction resulted in statistical significance (*) during the 3th, 4th and 6th week of the study period.

reduction became evident after the second week of treatment and resulted in statistical significance during the 3th, 4th and 6th week of the study period (Fig. 2).

Discussion

The results of this comparative study demonstrate that nasal irrigation using hypertonic saline is effective in controlling allergic rhinitis-related symptoms in the pediatric patient during the pollen season. The efficacy and the interest of this local management is also supported by the significant decrease of the use of antihistamine drugs reported by the patients treated with this local therapy compared with controls and by the absence of relevant side-effects.

The use of nasal irrigation is currently recommended as an adjunctive treatment modality in many sinonasal diseases such as rhinosinusitis, allergic rhinitis and other sinonasal diseases (1, 4–6). In particular, Tamooka et al. have previously reported that nasal wash is efficient in the treatment of seasonal allergic rhinitis in adults (4). These authors, employing a patient-reported nasal disease-specific questionnaire, documented a significant improvement in symptoms score after nasal irrigation with hypertonic saline. The results of our trial are in line with this previous report. More specifically, to the best of our knowledge, our study represents the first comparative report clearly documenting the benefits of this therapeutic regimen in the pediatric patient with seasonal allergic rhinitis.

A controversy in our study may be related to the study design because our trial was not blinded and we did not use placebo. However, it should be noted that none of the available studies have conducted a true double-blinded placebo-controlled trial; although such study design would have been preferable, the extreme specificity of the way of administration hampers its application. At present, we are unable to assess the importance of the placebo effect in determining the nasal symptoms control observed in our study. Nevertheless, considering the marked beneficial effect in lowering symptoms intensity, it is unlikely that this bias may exclusively explain the results observed in this trial. Moreover, no differences in both symptoms score and antihistamine drug use between patients treated with nasal irrigation and controls could be observed during the first week of the study period when the placebo effect is expected to be more relevant. Finally, in our study, compliance with the study protocol was complete, patients were under the care of only two experienced physicians and the two study groups were comparable in terms of age and allergic rhinitis-related symptoms. Therefore, we estimate that other important sources of bias in our trial can be excluded.

In this study, hypertonic saline was chosen as several *in vitro* and *in vivo* studies have demonstrated that an increased efficacy could be effected using hypertonic saline instead of normal saline (6, 8–10). However, further studies are required to assess the most effective preparation to prescribe. The possibility of using a twice or even a once daily nasal irrigation has also to be investigated as such a simpler protocol might be

as effective as the longer one whereas patient adherence could be further increased.

In conclusion, this study supports the use of a three-times daily regimen of nasal irrigation with hypertonic saline in the pediatric patient with seasonal allergic rhinitis. The treatment is tolerable, inexpensive and effective. Further trials are required to identify the most appropriate protocol of treatment and to evaluate whether similar results could be obtained also in patients with other forms of allergic rhinitis.

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