CLINICAL EFFECTIVENESS OF A STÉRIMAR Mn-ENRICHED ISOTONIC SEA WATER NASAL SPRAY IN ALLEVIATING CHRONIC ALLERGIC RHINITIS SYMPTOMS: A PATH FOR REDUCING ACUTE ALLERGIC EPISODES

M. Grasso, ENT Department, Head and Neck Surgery, University Sapienza, Rome
M. Bertini MD, PhD

OVERVIEW

Chronic Allergic Rhinitis (AR) represents a global pathology affecting between 10% and 40% of the world population with increasing prevalence despite the available treatments. This points to the need for safe methods for prevention/reduction of acute allergic rhinitis episodes (AARE) associated with the condition, especially in children. Daily nasal irrigation with isotonic saline solutions has been recognized as an efficient basic treatment for AR. The present study analyses the clinical effectiveness of Stérimar Nose Prone to Allergies (SNPA) nasal spray in a prospective randomized controlled 5-month clinical trial, conducted with 60 AR patients, showing a significant reduction in AARE rates and improvement in the quality of life (QoL).

INTRODUCTION

Allergic rhinitis (AR) is characterized by symptoms such as congestion, itching and sneezing. It has higher seasonal prevalence than perennial, is more common among children and young adults, and can frequently be undiagnosed[1-3]. The episodes mainly recur in spring time[4], exerting a big impact on the QoL, work/school performance, sleep and direct health expenditures (up to $5B/year) that highlight the need for alternative and cheaper approaches[5-8].

Nasal irrigation (NI) is a safe, inexpensive, easy to apply and well-tolerated approach[9,10], which improve nasal symptoms by 27%, increase mucociliary clearance time by 31% and QoL of AR patients by 27%. Used as an adjuvant to therapy, NI has been shown to reduce medicine intake in AR patients by 62%[9,11].

Stérimar Nose Prone to Allergies (SNPA) is a manganese (Mn)-enriched seawater based formulation. Mn has been shown to inhibit anaphylactic histamine release with antioxidant and inflammation response reduction effects[12-15].

The aim of the present study was to analyze the clinical effectiveness of SNPA in chronic AR patients.

METHODS

Sixty chronic AR adult patients (with more than 1 AARE and treated with drugs, as oral antihistaminic, nasal corticosteroids or nasal decongestants) were recruited for this prospective, randomized controlled, open-label clinical trial at the Department of Otorhinolaryngology, Hospital of Lamezia Terme, Italy. AR was diagnosed based on clinical symptoms and on skin or blood allergy testing. In spring 2013 (February-June), subjects were randomly assigned into 2 groups:

- **Group A:** 13 females, 17 males treated only with the standard care.
- **Group B:** 15 females, 15 males treated with the standard care plus SNPA (4 puffs/day).

The mean age was 39.63±1.96 and 46.63±1.46 in Group A and Group B, respectively (p=0.11). The primary endpoint was the number of AARE during the trial; and the secondary endpoint was the QoL improvements during the trial. Health-related QoL was measured using the visual analogue scale (VAS) questionnaire. All AARE were treated with the standard care (antihistaminic, nasal decongestants or/and corticosteroids) in both groups.

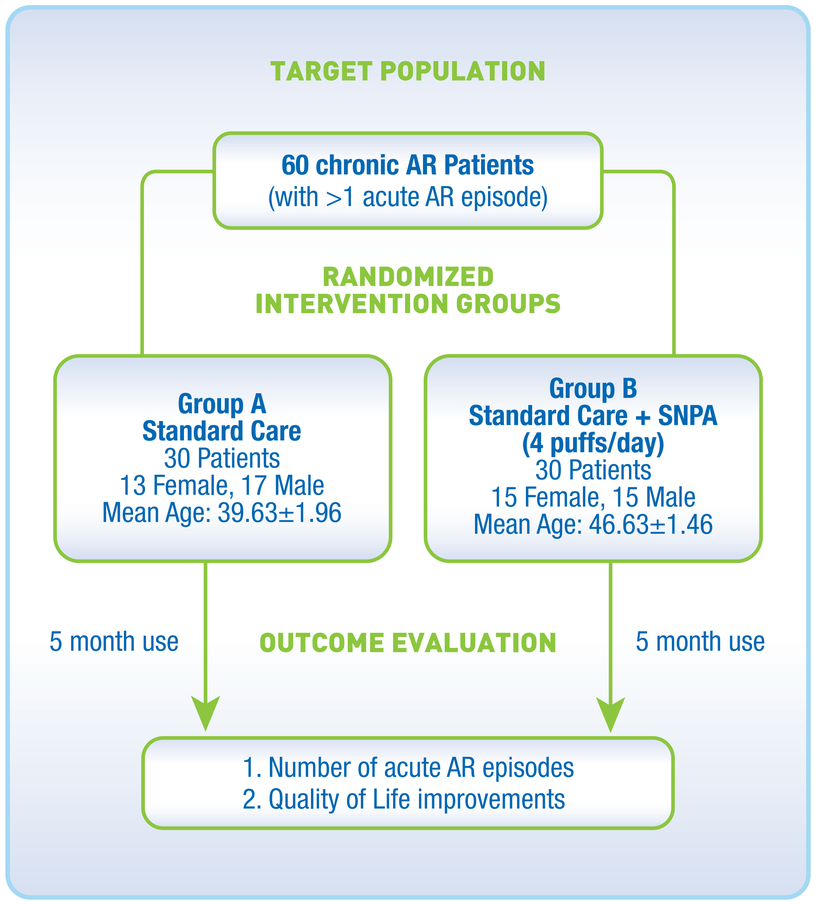

Figure 1: Clinical study design, evaluating the efficiency of Stérimar Nose prone to allergies nasal spray in chronic allergic rhinitis patients.

RESULTS

1. SNPA DECREASES THE NUMBER OF EPISODES IN CHRONIC AR PATIENTS

Prior to treatment, the mean number of AARE was comparable between groups (Group A: 9.50±2.64 vs. Group B: 10.67±3.14). However, at the end of the trial, mean number of AARE in Group B decreased significantly compared to Group A (Group A: 9.33 vs. Group B: 6.33, p<0.001) (Figure 2).

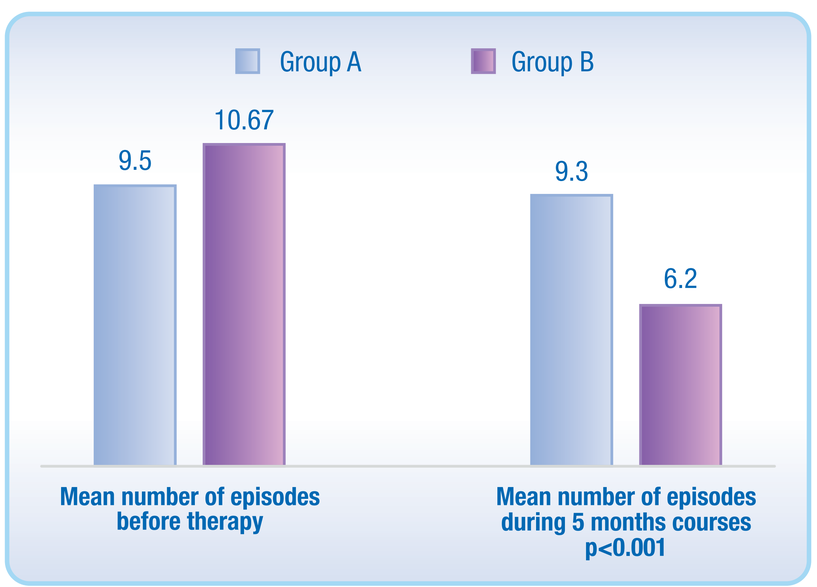

Figure 2: Number of episodes of acute allergic rhinitis during the 5-month randomized trial. Group A: standard care; Group B: Standard care + SNPA (4 puffs/day)

2. SNPA TREATMENT IMPROVES QUALITY OF LIFE OF CHRONIC AR PATIENTS

According to the QoL VAS score, a statistically significant improvement was observed in Group B during the 3rd, 4th and 5th month of treatment compared to Group A (p<0.001) without observing the typical adverse events of standard therapies (Figure 3).

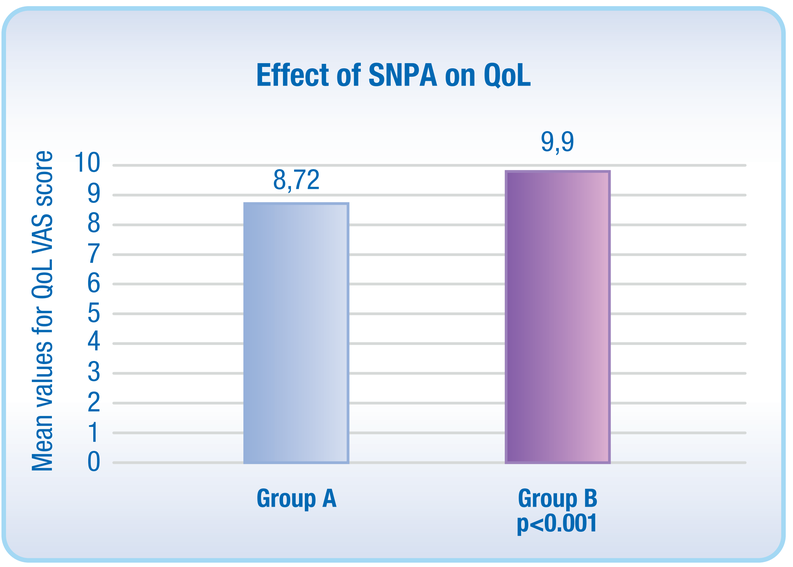

Figure 3: Effect of SNPA on QoL according to QoL VAS score at the end of the 5-month treatment. Group A: standard care; Group B: Standard care + SNPA (4 puffs/day)

CONCLUSIONS

These preliminary results demonstrate the effectiveness of SNPA (4 puffs/day) in both reducing the number of AARE and increasing the QoL of patients. The sea water solution enriched with manganese seems to be a good tool in the management of the AARE in patients affected by CAR, without the typical side effects of common therapies. These results, if confirmed in double-blind, randomized, controlled clinical trials, would present a new, safe and affordable approach for managing CAR in adults and children.

BIBLIOGRAPHY

1. Bauchau, V. and S.R. Durham, Prevalence and rate of diagnosis of allergic rhinitis in Europe. Eur Respir J, 2004. 24(5): p. 758-64.
2. Bernstein, J.A., Allergic and mixed rhinitis: Epidemiology and natural history. Allergy Asthma Proc, 2010. 31(5): p. 365-9.
3. Meltzer, E.O. and D.A. Bukstein, The economic impact of allergic rhinitis and current guidelines for treatment. Ann Allergy Asthma Immunol, 2011. 106(2 Suppl): p. S12-6.
4. Cingi, C., et al., Seawater gel in allergic rhinitis: entrapment effect and mucociliary clearance compared with saline. Ther Adv Respir Dis, 2010. 4(1): p. 13-8.
5. Fireman, P., Treatment of allergic rhinitis: effect on occupation productivity and work force costs. Allergy Asthma Proc, 1997. 18(2): p. 63-7.
6. Jauregui, I., et al., Allergic rhinitis and school performance. J Investig Allergol Clin Immunol, 2009. 19 Suppl 1: p. 32-9.
7. Meltzer, E.O., et al., Allergic rhinitis substantially impacts patient quality of life: findings from the Nasal Allergy Survey Assessing Limitations. J Fam Pract, 2012. 61(2 Suppl): p. S5-10.
8. Seidman, M.D., et al., Clinical practice guideline: Allergic rhinitis. Otolaryngol Head Neck Surg, 2015. 152(1 Suppl): p. S1-43.
9. Hermelingmeier, K.E., et al., Nasal irrigation as an adjunctive treatment in allergic rhinitis: a systematic review and meta-analysis. Am J Rhinol Allergy, 2012. 26(5): p. e119-25.
10. Rabago, D., et al., The efficacy of hypertonic saline nasal irrigation for chronic sinonasal symptoms. Otolaryngol Head Neck Surg, 2005. 133(1): p. 3-8.
11. Garavello, W., et al., Nasal rinsing with hypertonic solution: an adjunctive treatment for pediatric seasonal allergic rhinoconjunctivitis. Int Arch Allergy Immunol, 2005. 137(4): p. 310-4.
12. Foreman, J.C. and J.L. Mongar, The action of lanthanum and manganese on anaphylactic histamine secretion. Br J Pharmacol, 1973. 48(3): p. 527-37.
13. Tagen, M., et al., Mitochondrial uncoupling protein 2 inhibits mast cell activation and reduces histamine content. J Immunol, 2009. 183(10): p. 6313-9.
14. Kannus, P., Structure of the tendon connective tissue. Scand J Med Sci Sports, 2000. 10(6): p. 312-20.
15. Coassin, M., F. Ursini, and A. Bindoli, Antioxidant effect of manganese. Arch Biochem Biophys, 1992. 299(2): p. 330-3.