

CLINICAL EVALUATION OF DAILY NASAL IRRIGATION WITH STÉRIMAR HYPERTONIC SEAWATER SOLUTION IN CHRONIC RHINOSINUSITIS

Josip Culig^{1,2}, Andrijana Vceva³, Davorin Djanic^{3,4}

¹ Department of Pharmacoepidemiology, Andrija Štampar Institute of Public Health, Zagreb, Croatia

² Department of Pharmacology, School of Medicine, Josip Juraj Strossmayer University, Osijek, Croatia

³ Department of Otorhinolaryngology, School of Medicine, Josip Juraj Strossmayer University, Osijek, Croatia

⁴ Department of Otorhinolaryngology and Cervicofacial Surgery, General Hospital Dr. Josip Benčević, Slavonski Brod, Croatia

OVERVIEW

The present randomized controlled, parallel group clinical study evaluated the effect of Stérimar hypertonic seawater solution (SHSS) and Stérimar isotonic seawater solution (SIS) in 60 patients with chronic rhinosinusitis during a 14-day treatment. The use of both products was associated with a reduction of medication intake. The hypertonic solution was significantly more efficient in alleviating symptoms such as nasal congestion, cough and waking during the night, as well as in improving patient quality of life (QoL) from day 1 to day 15.

INTRODUCTION

Nasal congestion is a common symptom of chronic rhinosinusitis and can negatively affect work performance and quality of life^{1,2}.

Seawater contains many minerals essential to the body and it has been suggested that it is superior to normal saline solution in symptom alleviation and QoL improvement in chronic rhinosinusitis patients³. The aim of the present study was to assess the clinical efficacy of SHSS ($\approx 2.12\%$ NaCl) enriched with Mn and Cu salts in comparison to SIS ($\approx 0.9\%$ NaCl) in chronic rhinosinusitis patients.

METHODS

The study enrolled 60 patients with clinically established signs of chronic rhinosinusitis, such as nasal discharge, nasal obstruction, headaches, pain in the facial region and high body temperature. Sinus endoscopy and X-ray had previously been performed and recorded in patients' histories. Patients were randomly assigned to use either an isotonic or hypertonic sea water solution 3-6 times daily over a 15-day study period (Figure 1). Information about the symptoms was collected in a test list, completed by a physician during 3 visits, a Patient LogBook filled out by patients daily and a previously validated QoL questionnaire⁴.

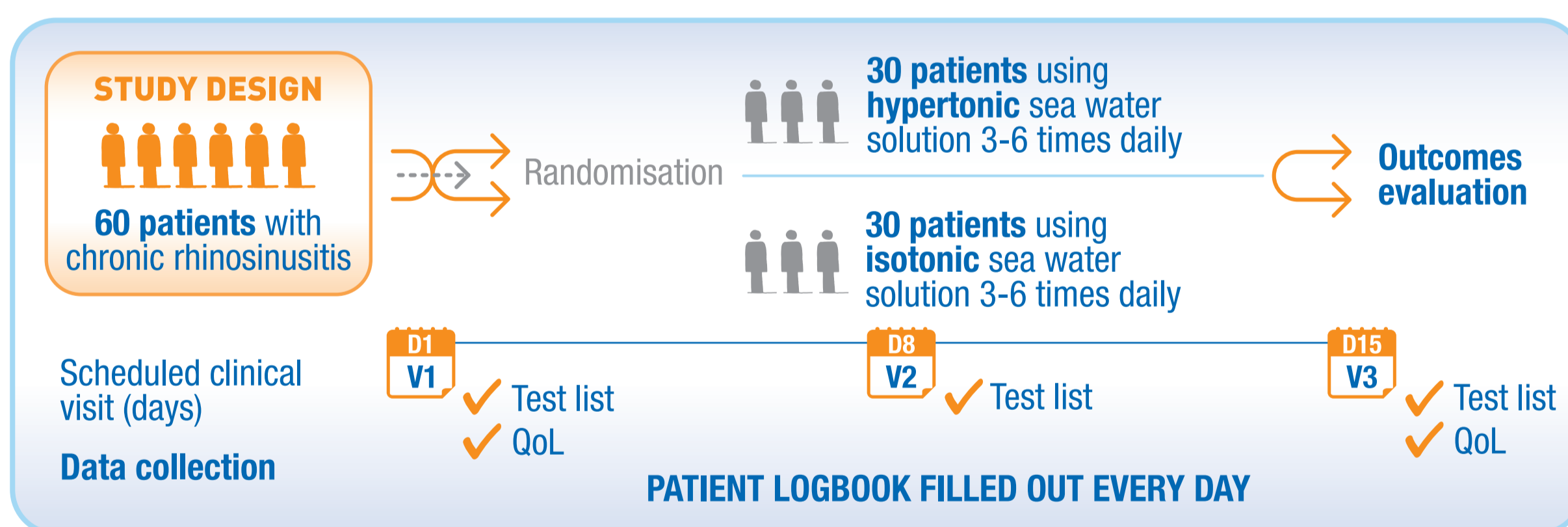


Figure 1: Schematic representation of the clinical study design, evaluating the efficiency of SHSS and SIS nasal spray in chronic rhinosinusitis.

RESULTS

1. BOTH STÉRIMAR FORMULATIONS REDUCE MEDICATION INTAKE

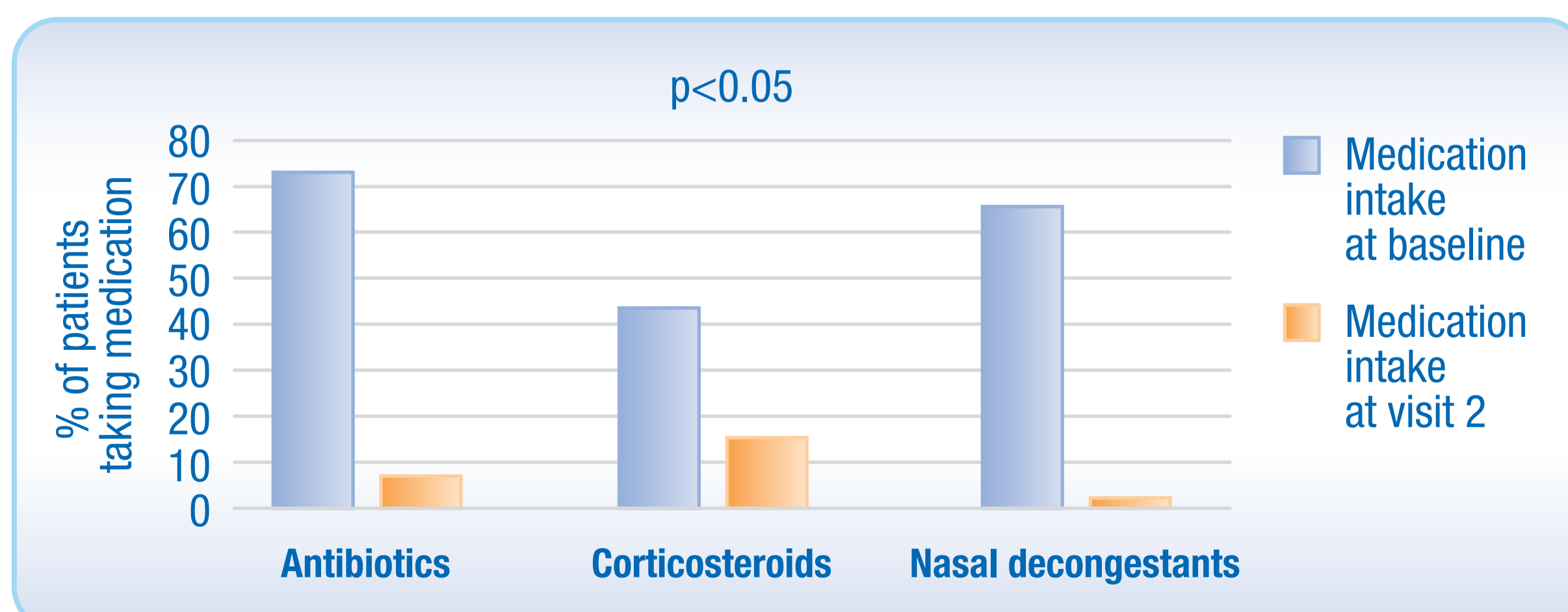


Figure 2: Percentage of patients taking medication at baseline and at visit 2. No distinction is made on whether patients were using isotonic or hypertonic solutions.

2. STÉRIMAR HYPERTONIC SOLUTION HELPS ALLEVIATE CHRONIC RHINOSINUSITIS SYMPTOMS

According to physician evaluation and patient self-recorded data, there was a significantly higher number of patients with improved symptoms in the SHSS group (Figure 3).

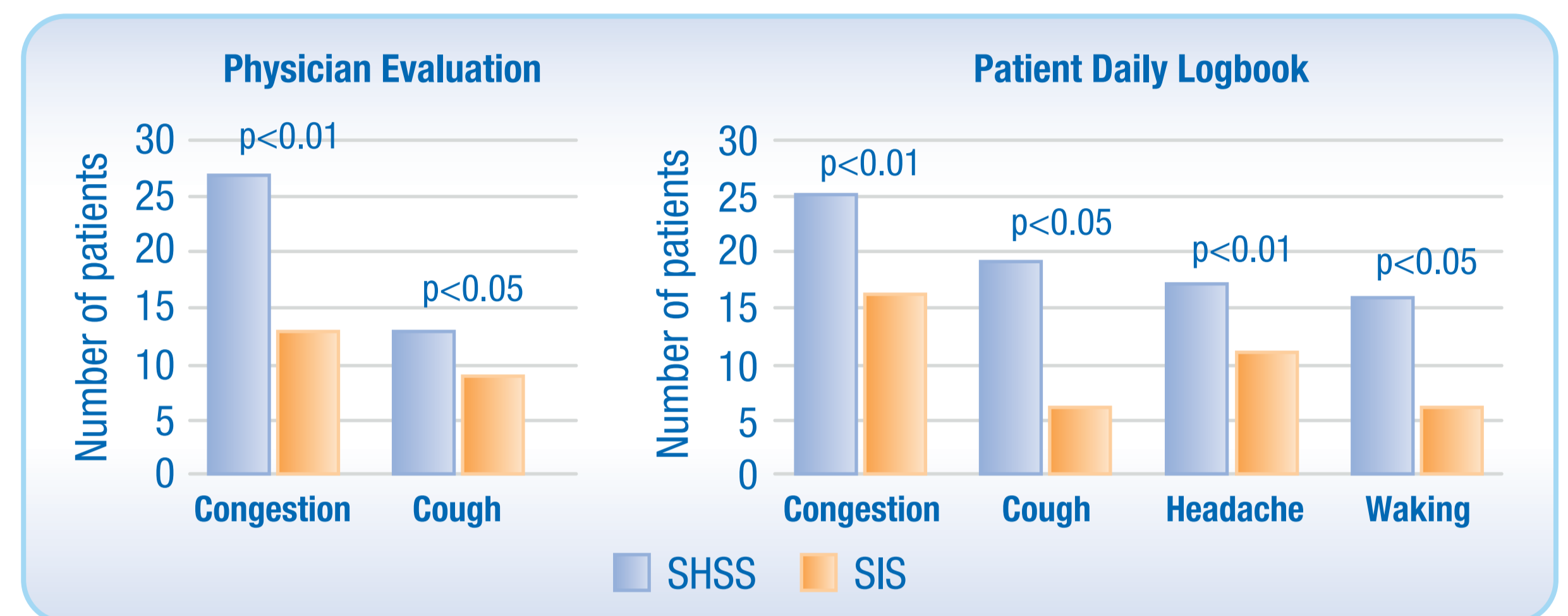


Figure 3: Number of patients with improved symptoms on Day 15 as per physician evaluation and patient self-evaluation.

3. STÉRIMAR HYPERTONIC SEAWATER SOLUTION IMPROVES QoL

According to the QoL questionnaires completed by the patients, the severity of almost all symptoms was reduced by around 70% in the SHSS group (Figure 4). In the SIS group, the severity of only 3 symptoms was reduced and by less than 50%. In the QoL questionnaire, patients graded their symptoms on the visual analog scale 0-10, in which 10 indicated severe and very frequent symptoms and 0 indicated a symptom free condition.

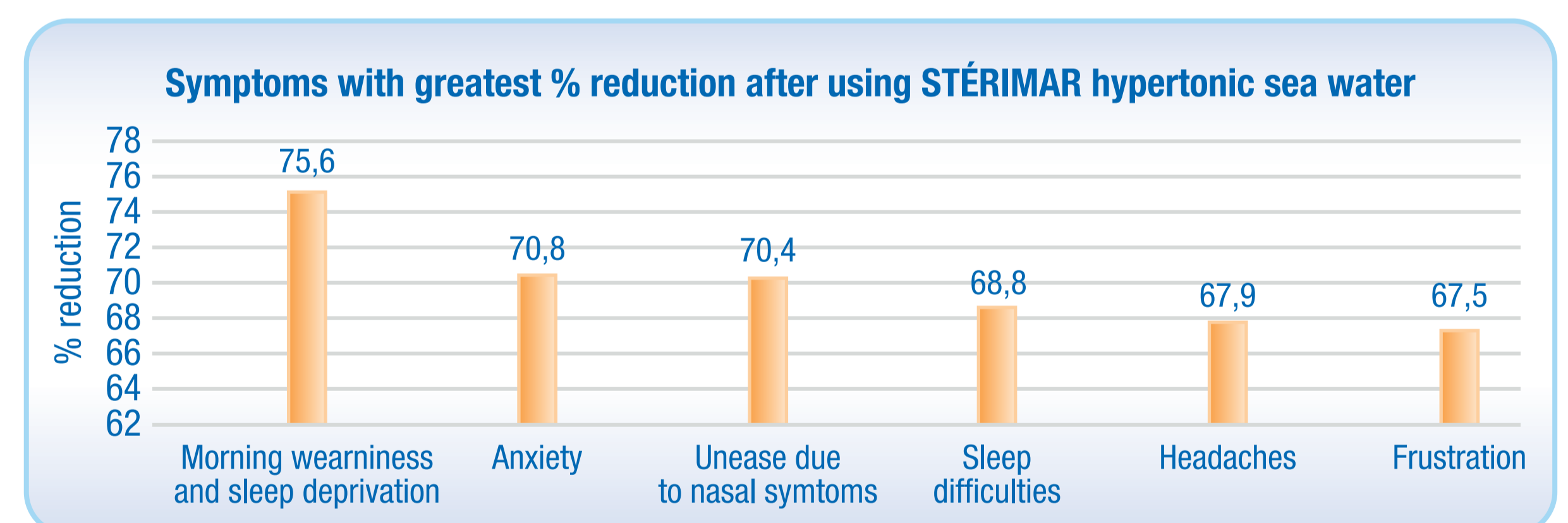


Figure 4: Percentage of reduction in chronic rhinosinusitis symptoms upon SHSS treatment as assessed by QoL questionnaires.

CONCLUSIONS

The aim of this clinical study was to assess efficacy and symptom alleviation of two solutions, hypertonic (SHSS) and isotonic (SIS), in chronic rhinosinusitis. The results confirmed that both solutions were effective in reducing prescribed medication. Additionally, based on physicians' and self-patients observation, Hypertonic Seawater Solution was more effective in alleviating chronic rhinosinusitis symptoms such as nasal congestion, cough, headache and waking up during the night. Both solutions had a beneficial effect on QoL with SHSS causing a reduction of symptom severity by around 70%.

BIBLIOGRAPHY

1. Pessey, J.J., C. Reitz, and F. Los, [Acute rhinosinusitis in the adult: national survey of general practice management]. *Rev Laryngol Otol Rhinol (Bord)*, 2000. 121(4): p. 237-41.
2. Ferrand, P.A., et al., [Acute sinusitis in adults. Management by general practitioners]. *Presse Med*, 2001. 30(21): p. 1049-54.
3. Bastier, P.L., et al., Nasal irrigation: From empiricism to evidence-based medicine. A review. *Eur Ann Otorhinolaryngol Head Neck Dis*, 2015. 132(5): p. 281-5.
4. Včeva A, Djanic D, Kotromanovic Z, Pajic-Penavic I. Comparison of isotonic and hypertonic seawater solution in the treatment of chronic rhinosinusitis. In: Abstract of the 6th Congress of Croatian Society for Otorhinolaryngology and Head and Neck Surgery with International Participation, Dubrovnik, Croatia, 2009. Abstract 104, str. 119. Croatian Society for Otorhinolaryngology and Head and Neck Surgery, Zagreb, Croatia.