

EFFICACY OF HYPERTONIC SEAWATER SALINE IN THE TREATMENT OF PERSISTENT RHINITIS/RHINOSINUSITIS

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BACKGROUND

The literature includes reports that the adjunctive use of hypertonic saline solutions in intermittent or chronic rhinosinusitis improves symptoms and reduces the need for medication^(1,2), but there has been insufficient investigation of its ability to reduce intranasal steroid (ICS) consumption.

OBJECTIVES

Primary objective

To demonstrate the efficacy of a hypertonic seawater nasal spray (2.2%) in chronic or intermittent rhinosinusitis of allergic or non-allergic origin.

Secondary objectives

- To compare the efficacy of a 2.2% hypertonic seawater saline nasal spray versus control group of standard treatments (inhaled corticosteroids, antihistaminics and/or leucotrien antagonists).
- To evaluate the impact in reducing ICS use among long-term users.

METHODS

A total of 256 patients were randomized to one of the three treatment groups listed below and followed-up for 6 weeks:

- **Group 1:** standard treatment including ICS. No hypertonic nasal spray.

- **Group 2:** hypertonic nasal spray added-on to standard treatment from study entry; ICS discontinued from week 2.
- **Group 3:** hypertonic nasal spray and standard medication; ICS discontinued from study entry.

The nasal spray used contains 2.2% hypertonic, sterile and preservative free seawater obtained by selective electro-dialysis, that adjusts tonicity while preserving the original mineral and trace element content.

Inclusion criteria:

Age above 12 years, rhinitis/sinusitis for at least 2 years, ICS used for at least 4 weeks prior to trial initiation, signed informed consent, cooperative patient.

Exclusion criteria:

Nasal polyps or anatomic abnormalities.

Medication:

Patients were allowed to use oral antiallergy medication, however they were not allowed to change oral medication or initiate treatment during the trial course. Topical nasal mastocyte stabilizers were contraindicated. Groups 2 and 3 could use nasal corticosteroids as rescue medication (this had to be recorded). Assessment after 2 and 6 weeks.

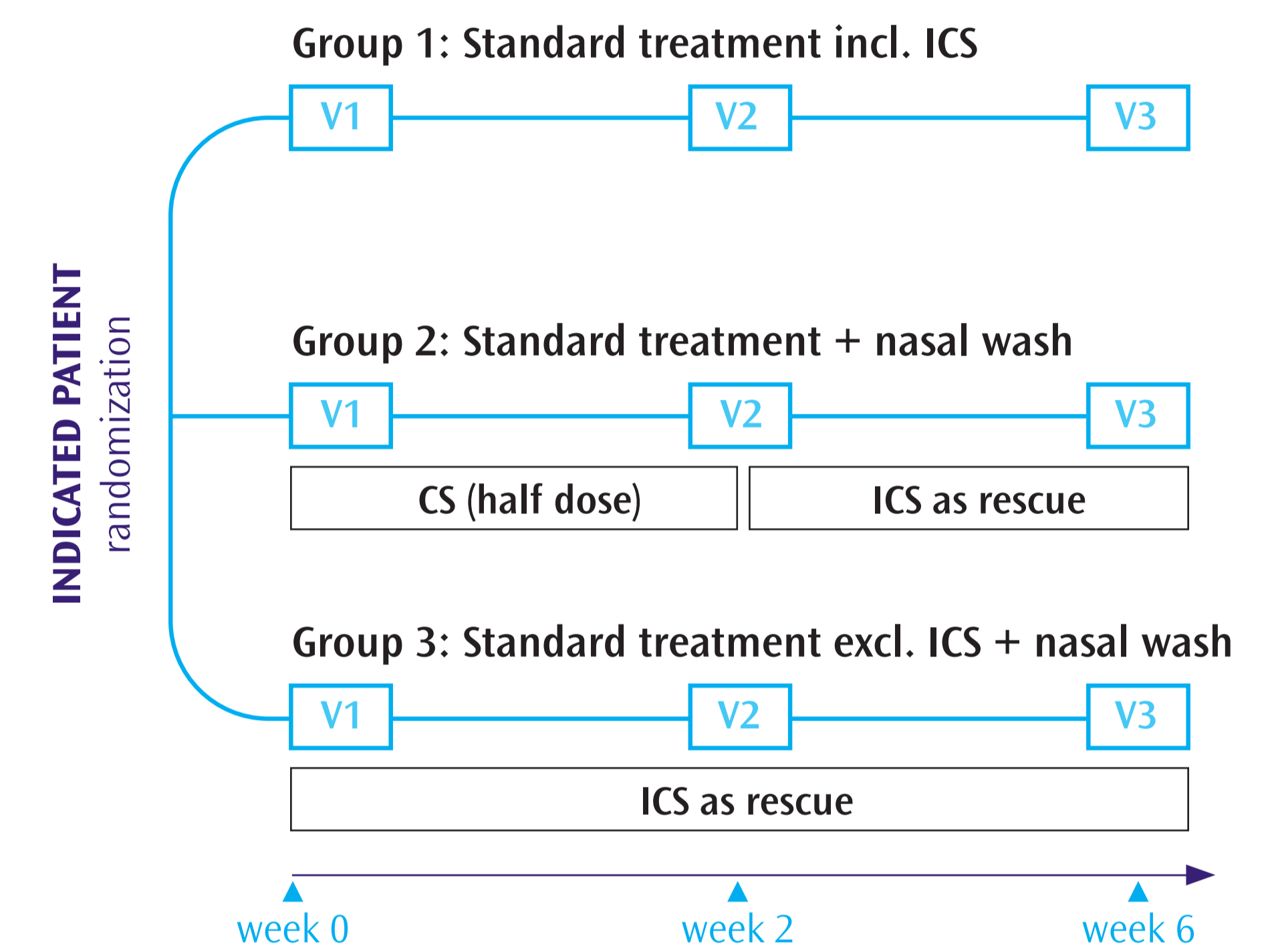
Efficacy endpoints:

Nasal symptoms (rhinorrhea, congestion, sneezing, itching and nasal index score (NIS) using a qualitative scale (none to severe), number of ICS applications/day and health status evaluated by patient.

Statistical analysis:

Comparison of treatments - Cochran-Mantel-Haenszel test. Efficacy parameters (e.g. NIS) - ANOVA. The Bonferroni method for multiple comparisons; Tukey for wise comparisons.

Fig. 1: Study schedule and design



RESULTS

All baseline parameters other than gender were comparable in all groups at study entry.

- After 14 days, significantly greater improvement in groups 2 and 3 than in group 1 for the following parameters: itching, sneezing, congestion and NIS. Rhinorrhea significantly improved in group 3 but not in group 2.
- At final visit (mean of 42 days after study entry), all nasal parameters significantly improved in both groups of nasal wash vs control ($p < 0.05$).

- Number of ICS applications remained unchanged in group 1 (1.7 dose/day) and decreased in both groups with nasal wash (1.9 to 0.07; $p < 0.05$ and 1.7 to 0.04; $p < 0.05$).

- Health status (rated by patients on a scale from excellent to not satisfactory) significantly improved in nasal spray groups vs group 1 during the study ($p < 0.05$).

- At study entry, around one third of patients in all groups reported very good to excellent health status; at study end, the percentage remained stable in group 1 (32% vs 33%); in both other groups it had improved significantly (68% vs 27%; 71% vs 27%; $p < 0.05$).

Fig. 2: Nasal Index Score (NIS)

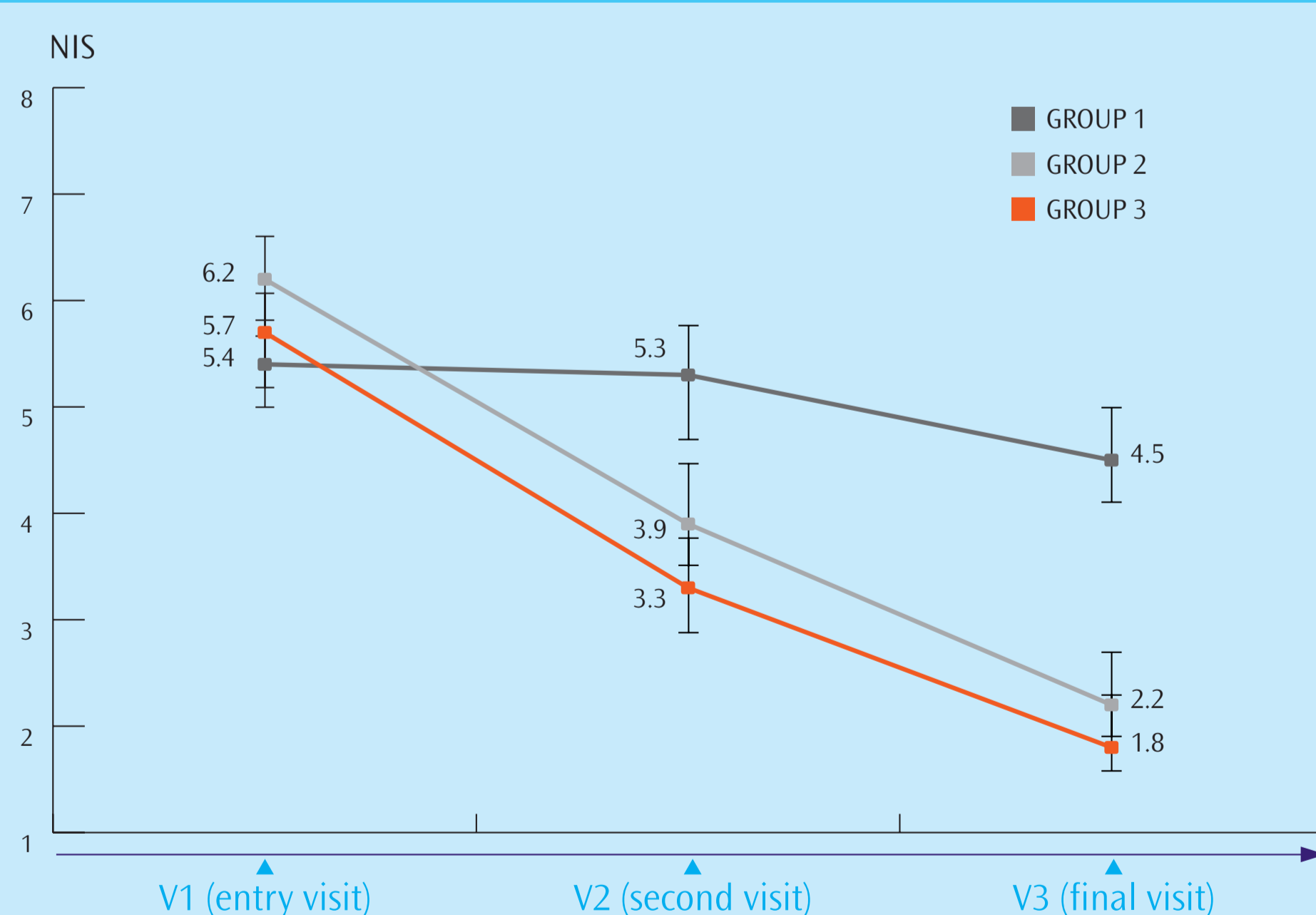


Fig. 3: Mean nasal ICS dose

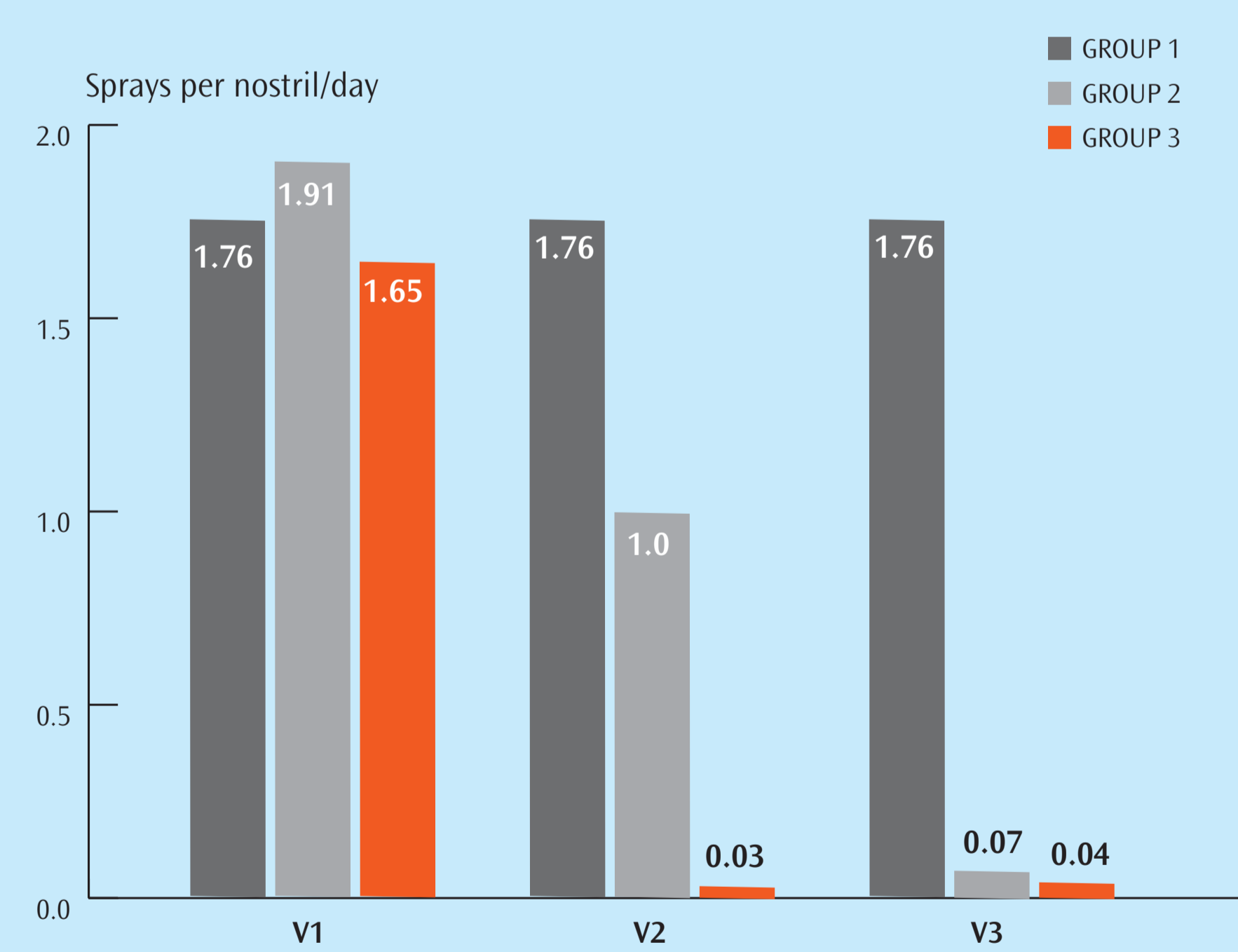
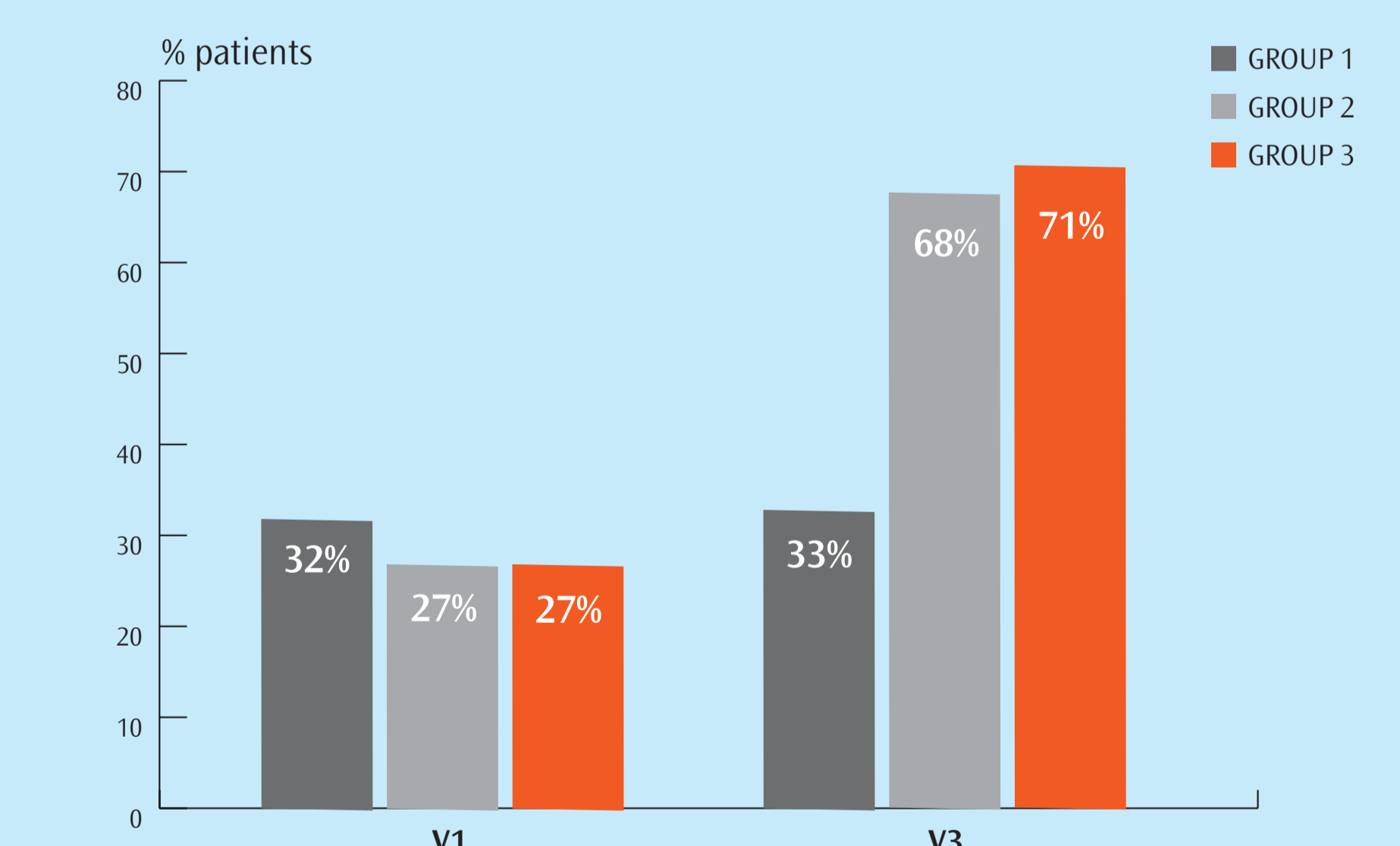


Fig. 4: Health status rating



CONCLUSIONS

- Hypertonic 2.2% hypertonic seawater saline nasal spray significantly improved nasal symptoms and decreased frequency of ICS use.
- During the course of the study, the results were robust for all parameters (regardless of whether assessed by physician or patient).
- Health status assessment in all three groups was in line with other results.

Our results show that concomitant nasal spray application of hypertonic seawater saline provides effective and safe adjunctive treatment to standard medication. It is an interesting finding that hypertonic seawater saline can contribute to ICS dose reduction or even permit intermittent dosing among long-term ICS users.