

EFFICACY OF ISOTONIC SALINE SEAWATER IN THE TREATMENT AND PREVENTION OF RHINITIS IN CHILDREN

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BACKGROUND

The literature includes reports of the efficacy and safety of saline seawater solution in relieving sinonasal conditions and reducing the consumption of medication⁽¹⁾; however, little of this evidence results from well-designed trials, involving a significant number of patients using isotonic saline seawater as an adjunctive treatment for common rhinitis during the winter season in children⁽²⁾.

OBJECTIVES

- To demonstrate the efficacy of isotonic saline as an adjunctive treatment during non-complicated acute rhinitis to speed up the resolution of nasal symptoms.
- To evaluate its ability to prevent the reappearance of cold/flu and complications in children.

METHODS

We randomly (based on the order of attending for treatment by the physician) assigned 401 children (aged 6-10) with uncomplicated cold/flu to either:

- Standard medications (e.g. antipyretics, nasal decongestants, mucolytics, systemic antibiotics) for the "untreated" group.
- Nasal wash added-on to a standard treatment for the "treated" group.

The nasal solution used is a nasal wash product that contains sterile and preservative free undiluted seawater in which isotonicity is achieved by selective electro-dialysis, that adjusts tonicity while preserving the original mineral and trace element content.

The nasal wash was administered 6 times/day during acute illness and 3 times/day for prevention.

Follow-up lasted for a total of 12 weeks from January to April 2006. We evaluated:

- Acute illness at the first two visits (up to week 3)
- Prevention at the next two visits (at weeks 8 and 12).

The primary efficacy endpoints were :

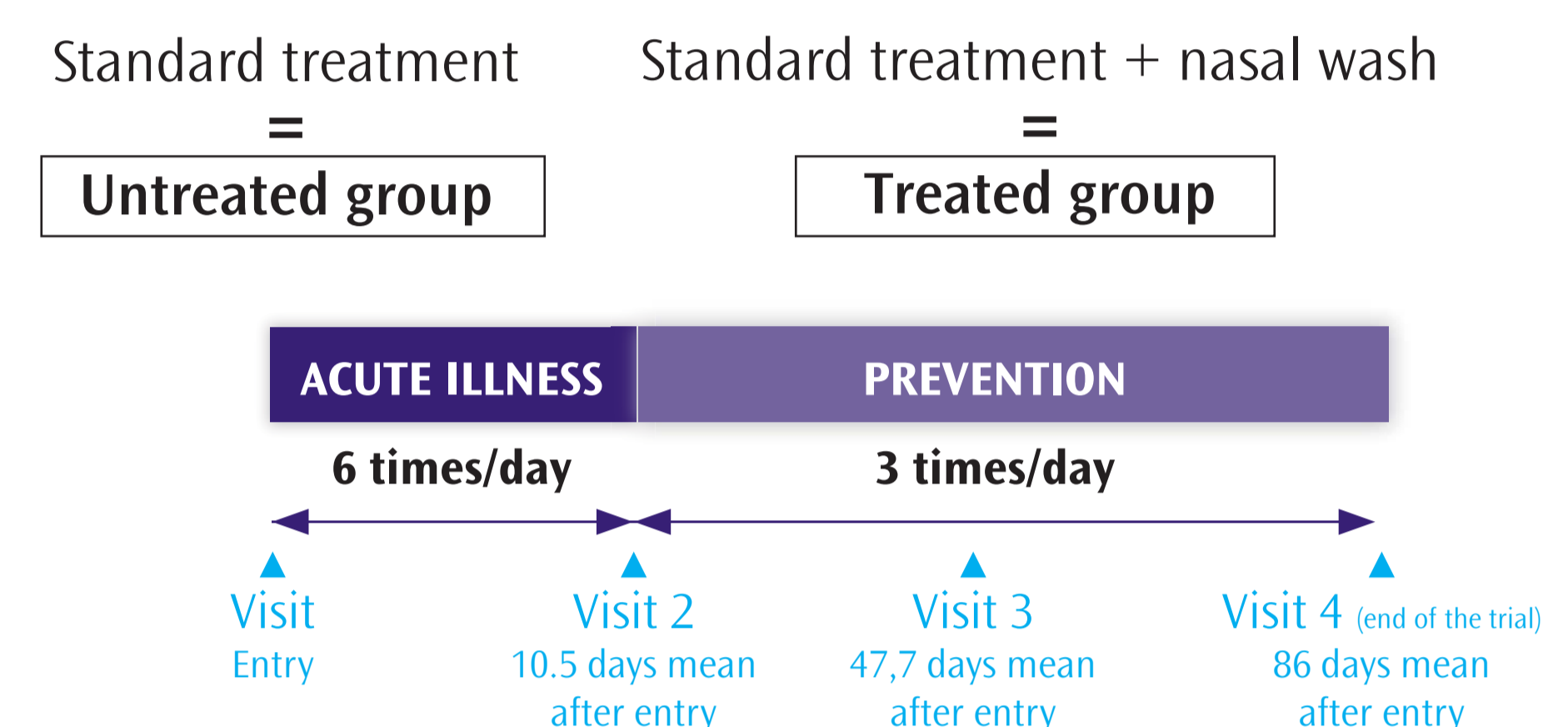
- resolution of nasal symptoms during acute illness (at visit 2)
- reappearance of cold/flu
- consumption of prescription medication

- complications
- days off school
- reported days of illness during the following weeks (at visits 3 and 4).

The secondary efficacy endpoints were sensation during and after application, undesired side-effects, comfort of use and global satisfaction.

Parameters were evaluated at each visit for the nasal wash and control groups using the Mann-Whitney U test.

Fig. 1: Study schedule and design



All baseline parameters (e.g. average age, duration of illness, gender) were comparable in all groups.

Evolution of symptoms and use of medication

- At visit 2 (mean 10.5 days after initiation), patients receiving the isotonic seawater saline had reached the primary endpoints (using a 4 point scale; none=1 to severe=4) for the parameters nasal secretion and obstruction (1.79 vs 2.10; 1.25 vs 1.58; $p < 0.05$). (Fig. 2)

Fig. 2: Symptom score

(Symptom score: 1=none; 4=severe)

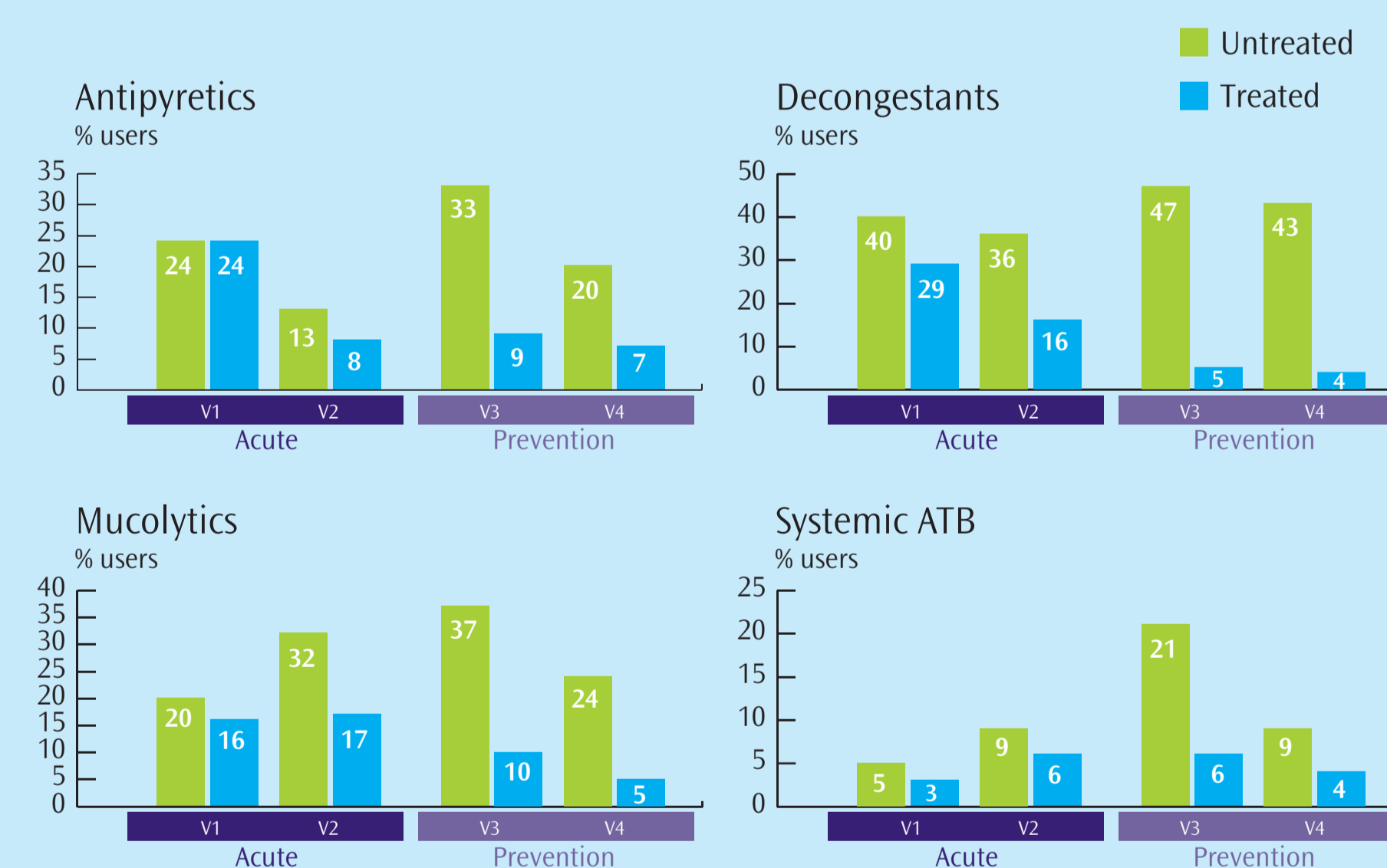
		ACUTE ILLNESS		PREVENTION	
		V1	V2	V3	V4
Sore throat	U	1.84	1.23	1.32	1.12
	T	1.69	1.09	1.07	1.05
Dry cough	U	1.60	1.14	1.40	1.04
	T	1.49	1.11	1.11	1.03
Productive cough	U	1.43	1.38	NA	1.13
	T	1.36	1.23	NA	1.02
Nasal secretion (NS)	U	2.70	2.10	1.86	1.55
	T	2.84	1.79	1.23	1.23
Character of NS	U	2.56	2.06	NA	1.53
	T	2.57	1.72	NA	1.21
Nasal breathing	U	2.16	1.58	1.64	1.39
	T	2.26	1.25	1.20	1.13
Sneezing	U	1.50	1.06	1.21	1.10
	T	1.51	1.04	1.06	1.06
Itching	U	1.27	1.06	1.08	1.11
	T	1.30	1.03	1.02	1.05
Loss smell/taste	U	1.38	1.09	1.19	1.11
	T	1.31	1.00	1.03	1.01

Black : $p < 0.05$

- During the prevention period at visit 3 (mean 37.2 days after visit 2) patients receiving the isotonic seawater saline had significant lower scores for sore throat, cough, nasal obstruction and secretion (all $p < 0.05$). Similar results were obtained at the final visit. (Fig. 2)

- Fewer children receiving the isotonic seawater saline used antipyretics (9 vs 33%), nasal decongestants (5 vs 47%), mucolytics (10 vs 37%) and systemic antibiotics (6 vs 21%) at visit 3. Results at the final visit were similar. (Fig. 3)

Fig. 3: Consumption of medication



Days of illness and absence from school

- During prevention (at visit 3) reduced illness (31 vs 75%), school absences (17 vs 35%) and complications (8 vs 32%) were reported in patients receiving isotonic seawater saline. Similar results were obtained at the final visit. (Fig. 4, 5)

Fig. 4: Reported illness

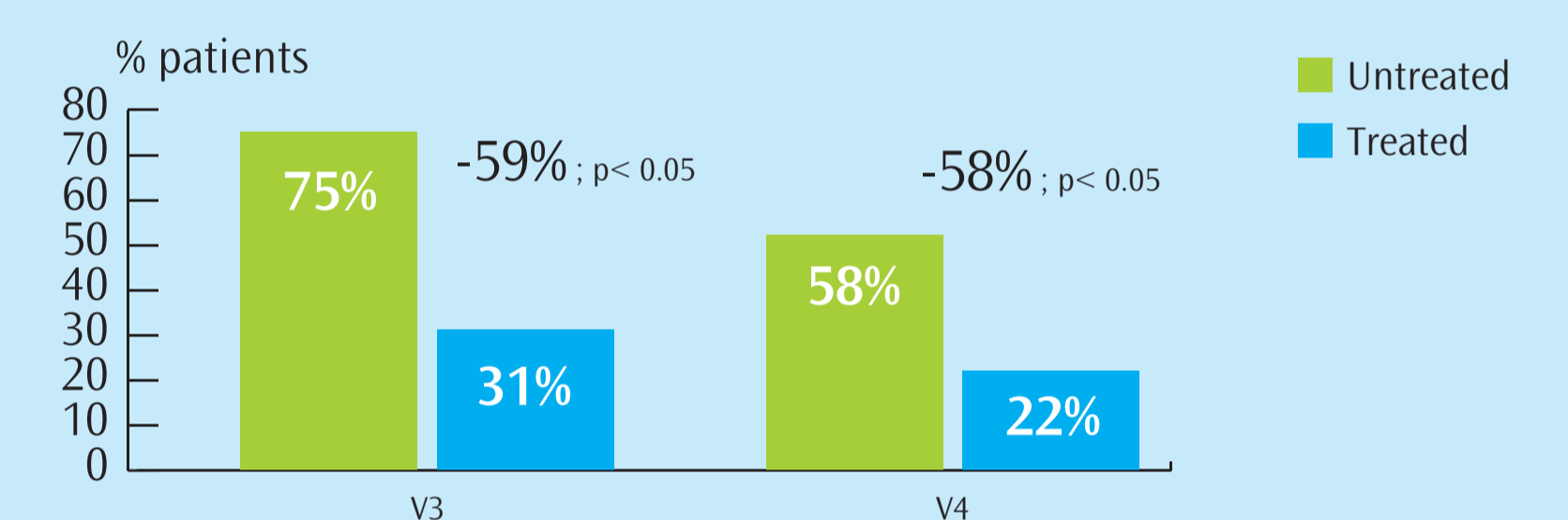
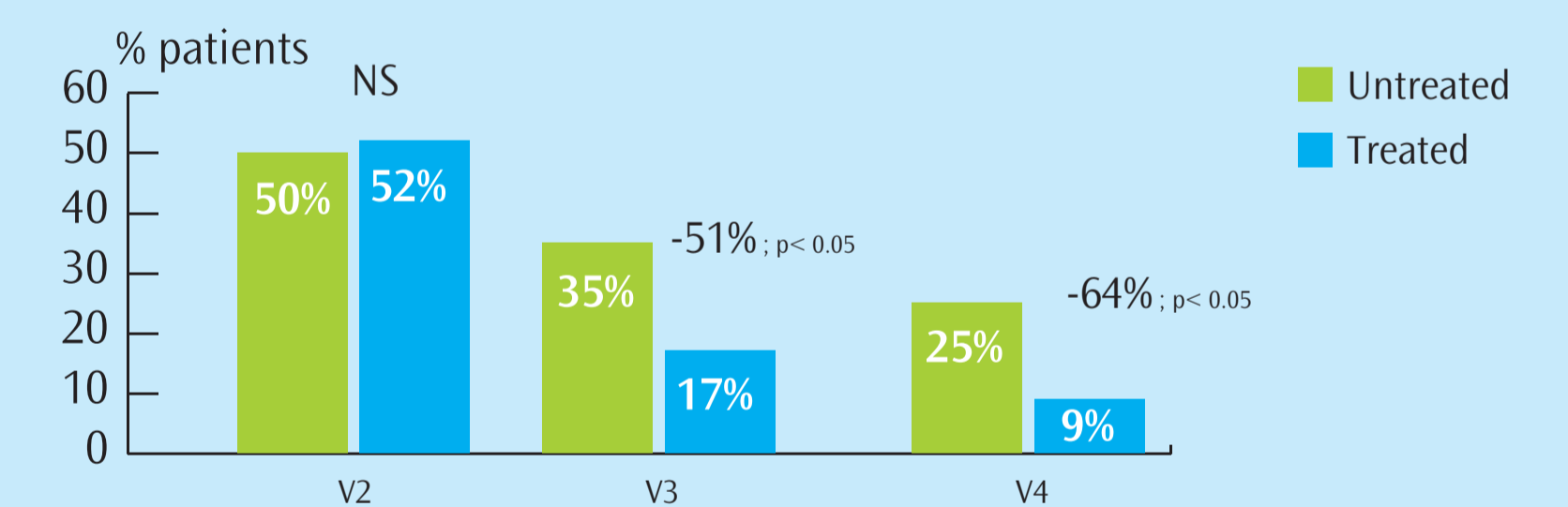
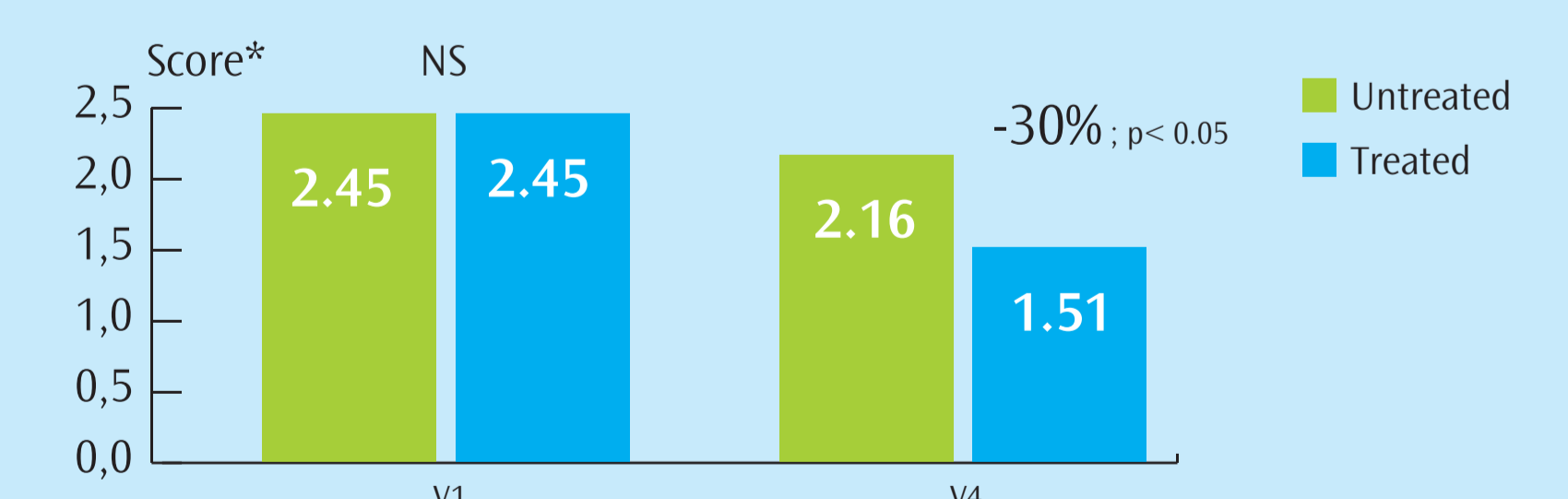


Fig. 5: Absence from school



- Overall health status assessed by parents was comparable at study entry, and significantly better for patients on isotonic seawater saline at study end (Fig. 6). The nasal wash was well tolerated, some children initially complained about the strong flow. Other complaints (burning sensations, nasal bleeding) were marginal.

Fig. 6: Overall health status assessment



*1=excellent; 4=unsatisfactory

CONCLUSIONS

Isotonic seawater saline used as an adjunctive treatment produced :

- Faster resolution of some nasal symptoms during common cold and flu
- Effective reduction of the recurrence of rhinitis if administered regularly (3 times/day), significantly lower consumption of medication (including systemic antibiotics), and reduced reported absence from school, illness days and complications
- Overall better health status (rated by parents) than the control group

These results lead us to consider isotonic saline seawater as of potential interest for both treatment and prevention.