

Case Report

A Real-World User Survey On The Effectiveness, Safety And Performance Of A Hypertonic Seawater Nasal Spray In Patients With ENT Disorders

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Abstract

Hypertonic seawater nasal irrigation is a well-established, non-pharmacological measure for the management of sinonasal symptoms in Ear, Nose, and Throat (ENT) conditions. This prospective, real-world user survey evaluated the effectiveness, safety and performance of a hypertonic seawater nasal spray (HSS; 2.3% NaCl) in 96 patients presenting with a range of ENT disorders. Participants completed a structured questionnaire assessing sinonasal and quality-of-life (QoL) symptom severity before and after product use, together with usage patterns, overall satisfaction, ease of use, and safety. Following HSS use, statistically significant improvements were observed across all sinonasal symptoms (nasal congestion, rhinorrhea, sneezing, nasal itching, other nasal symptoms) and QoL parameters (fatigue, productivity, sleep quality, emotional state, overall feeling), with mean symptom-score reductions ranging from 48.3% to 63.2% ($p < 0.001$ for all comparisons). The safety profile was favorable: adverse events were infrequent and mild; no serious adverse events were reported. Overall, these real-world findings support the use of HSS as an effective, well-tolerated and easy-to-use option for the symptomatic management of sinonasal and QoL symptoms across common ENT conditions.

Keywords: Hypertonic saline; Nasal spray; Nasal irrigation; Seawater; Sinonasal symptoms; Nasal congestion; Quality of life; ENT.

INTRODUCTION

Ear, Nose, and Throat (ENT) disorders, including rhinitis, rhinosinusitis, and upper respiratory tract infections, are among the most common conditions in primary and specialist care, affecting large numbers of individuals annually and imposing a considerable burden in terms of symptom severity, quality of life, and productivity [1,2]. Nasal congestion, rhinorrhea, and related sinonasal symptoms frequently disturb sleep, reduce work performance, and impair emotional wellbeing, therefore effective symptom management is an important component of the clinical management of these conditions [2].

Saline nasal irrigation (SNI) is widely used in the management of sinonasal conditions. Its therapeutic effects are primarily mechanical, promoting the removal of mucus, allergens, pathogens, and inflammatory mediators while improving mucociliary clearance and supporting normal nasal mucosal function [3–5]. Hypertonic saline may additionally reduce mucosal

oedema through an osmotic effect, thereby improving nasal patency and facilitating mucus clearance [6,7]. Clinical studies have demonstrated that hypertonic seawater preparations are effective and well tolerated in several ENT conditions, including viral upper respiratory tract infections, rhinitis, and rhinosinusitis [8–13].

Although the clinical benefits of hypertonic seawater nasal irrigation have been demonstrated in controlled studies, evidence describing its use under routine clinical practice remains relatively limited. Patient-reported real-world data can provide complementary information on how hypertonic seawater preparations are used and experienced across a broader range of ENT conditions. Such data may also help characterize treatment satisfaction, ease of use, and the perceived effects on symptoms and quality of life.

Therefore, the present prospective, real-world user survey was conducted to evaluate the effectiveness, safety, and user experience of a 2.3% hypertonic seawater nasal spray

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in patients with a range of ENT disorders. The study assessed changes in sinonasal symptoms and quality of life (QoL) parameters, together with treatment satisfaction, ease of use, and tolerability under routine clinical practice conditions.

METHODS

Medical device

The product evaluated in this study is SINOMARIN MINI SPRAY, 30 mL; Gerolymatos International S.A (hereafter "HSS"), containing hypertonic seawater of 2.3% NaCl. HSS is intended for the cleansing and decongestion of the nasal cavities and may be used either as a standalone treatment or as an adjunct to prescribed therapies for the symptomatic management of sinonasal conditions.

Survey patients and design

This real-world, prospective user survey was conducted in Croatia between November 2025 and March 2026, and enrolled 96 adult and pediatric patients who sought advice or treatment for ENT-related symptoms in outpatient and pharmacy settings. Eligible patients were those experiencing symptoms associated with one or more ENT disorders, including rhinitis, rhinosinusitis, common cold and flu, and allergy, or requiring nasal hygiene and moisturization. Several patients presented with more than one concurrent condition. Patients were instructed to use the product according to its label. Each patient completed a structured questionnaire at two time points: before the first use of the nasal spray and after a period of use (typically 7–14 days).

Questionnaire and Outcome Measures

Sinonasal symptom severity (stuffy nose, runny nose, sneezing, itchy nose, and other nasal problems) and QoL symptoms (fatigue, reduced productivity, poor sleep, emotional state, and overall feeling) were assessed using a 0–6 Likert scale (0 = not troubled, 6 = extremely troubled), consistent with previously published user-survey methodologies [11,13,15,16]. Overall satisfaction and overall efficacy were captured on a six-point scale (extremely satisfied to extremely dissatisfied). Ease of use, willingness to recommend or repurchase, and willingness to use the product without medication were as-

sessed on a six-point scale from Absolutely Yes (1) to Absolutely Not (6). The questionnaire also recorded demographics, the ENT condition(s) for which the product was used, concomitant medications, usage patterns (duration, frequency), adverse events and device performance.

Data analysis

A total of 96 completed questionnaires with symptom-score data were included in the final analysis. Before analysis, the dataset was checked for completeness and internal consistency. For paired before–after comparisons, only participants with valid responses for both corresponding items were included; participants with a missing value for either item of a pair were excluded from that specific comparison only. Where participants simultaneously endorsed mutually exclusive usage-frequency categories, the variable was classified as indeterminate rather than excluded.

Statistical analysis

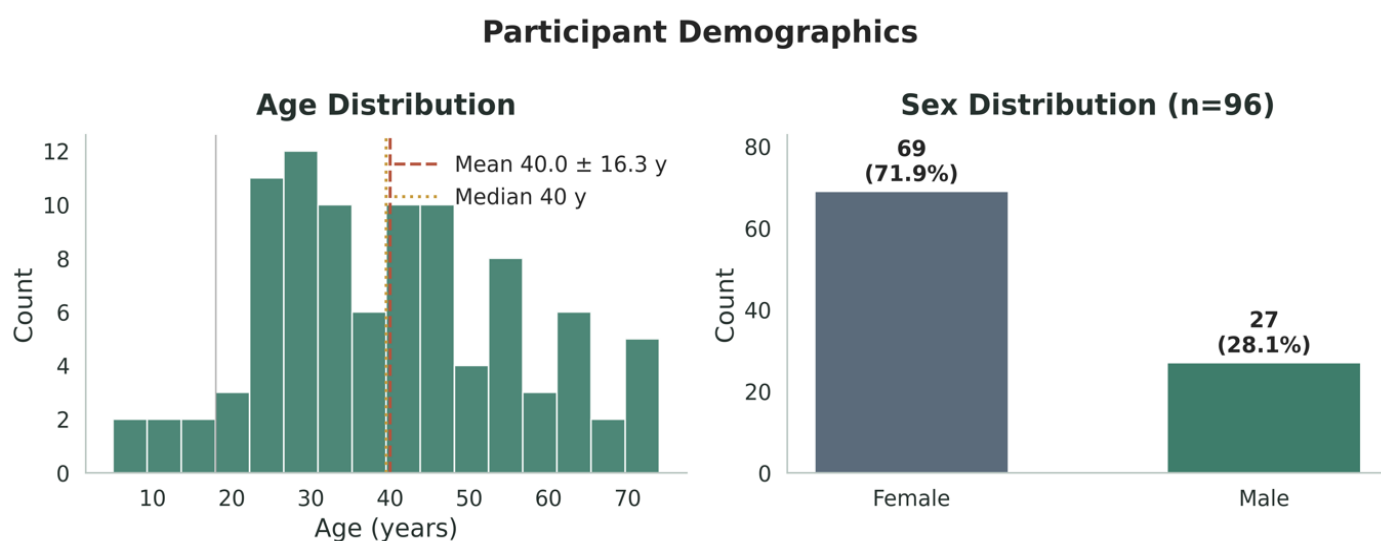
Data were analyzed using Python (version 3) in Jupyter Notebook (version 7.0.8) within the Anaconda distribution, together with standard statistical packages including NumPy and SciPy. Study variables were described using absolute and relative frequencies before and after treatment, and continuous variables were summarized as mean (standard deviation) and median (interquartile range). For each item, changes after treatment were classified as improvement, no change, or worsening. Percentage improvement was calculated as $(\text{mean score before} - \text{mean score after}) / \text{mean score before} \times 100$. Paired before–after comparisons were performed using the Wilcoxon signed-rank test and the paired t-test, as appropriate. The level of statistical significance was set at $\alpha = 0.05$.

RESULTS

Survey population and product use

Patients with a mean age of 40.0 ± 16.3 years (median 40; range 5–74 years) were included in the survey. The study population comprised 6 pediatric patients (< 18 years) and 90 adults. Of the cohort, 69 were female (71.9%) and 27 were male (28.1%) (**Figure 1**).

Figure 1. Participant demographics. Age distribution (left) and sex distribution (right) of the study population (n = 96). The cohort comprised 90 adults and 6 pediatric patients (<18 years).



Overall, 108 ENT-related conditions were reported, as some patients presented with more than one diagnosis. Rhinitis was the most frequent indication (50.0%; n = 54), followed by sinusitis (27.8%; n = 30), common cold and flu (16.7%; n = 18), allergy/allergic rhinitis (2.8%; n = 3), and single reports of snoring, nasal congestion, and COVID-19 (0.9% each) (**Figure 2**). Twelve patients (12.5%) presented with two or more concurrent conditions, the most frequent combination being rhinitis with sinusitis (n = 9; 9.4%) (**Figure 2**).

Figure 2. Presenting conditions. Distribution of reported ENT conditions (108 condition entries from the 94 patients with a recorded condition; multi-condition entries counted separately), expressed as a percentage of the total conditions (n = 108), and the most frequent multiple-condition combinations, expressed as a percentage of the total cohort (n = 96).

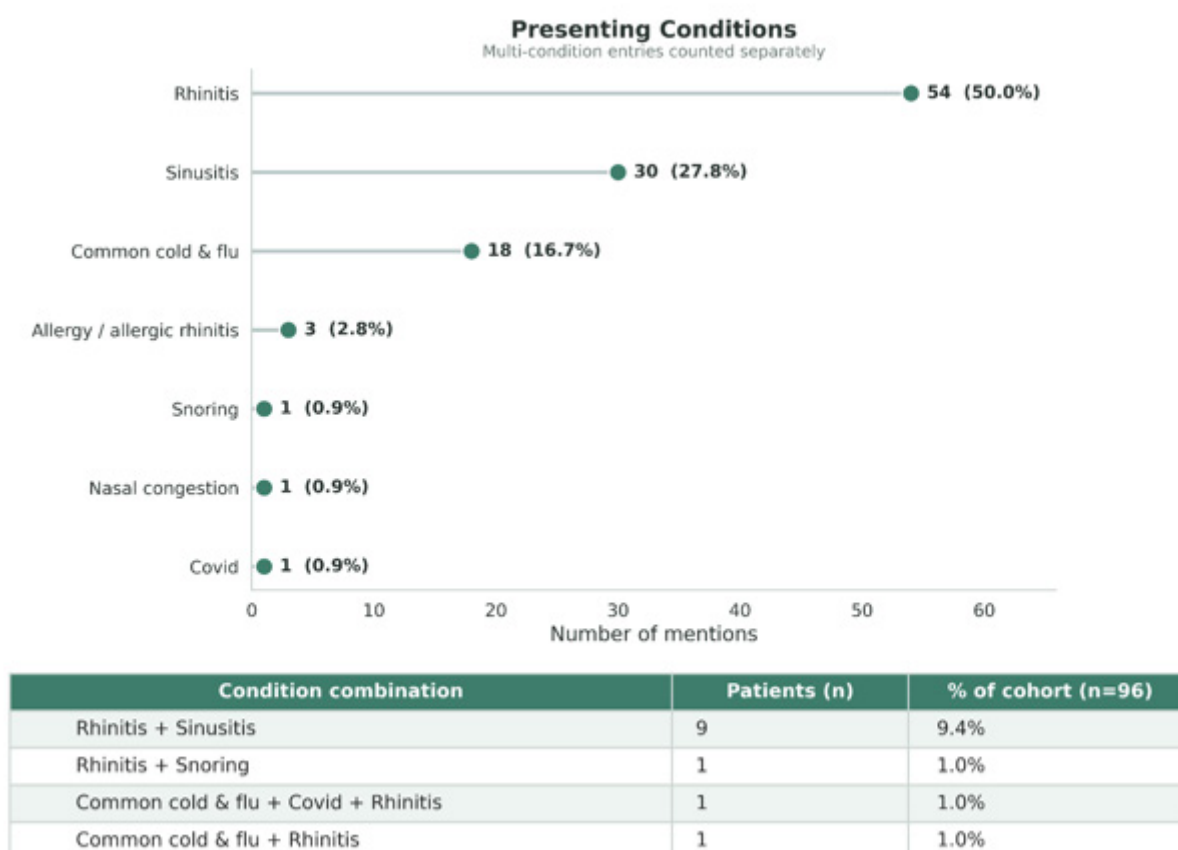
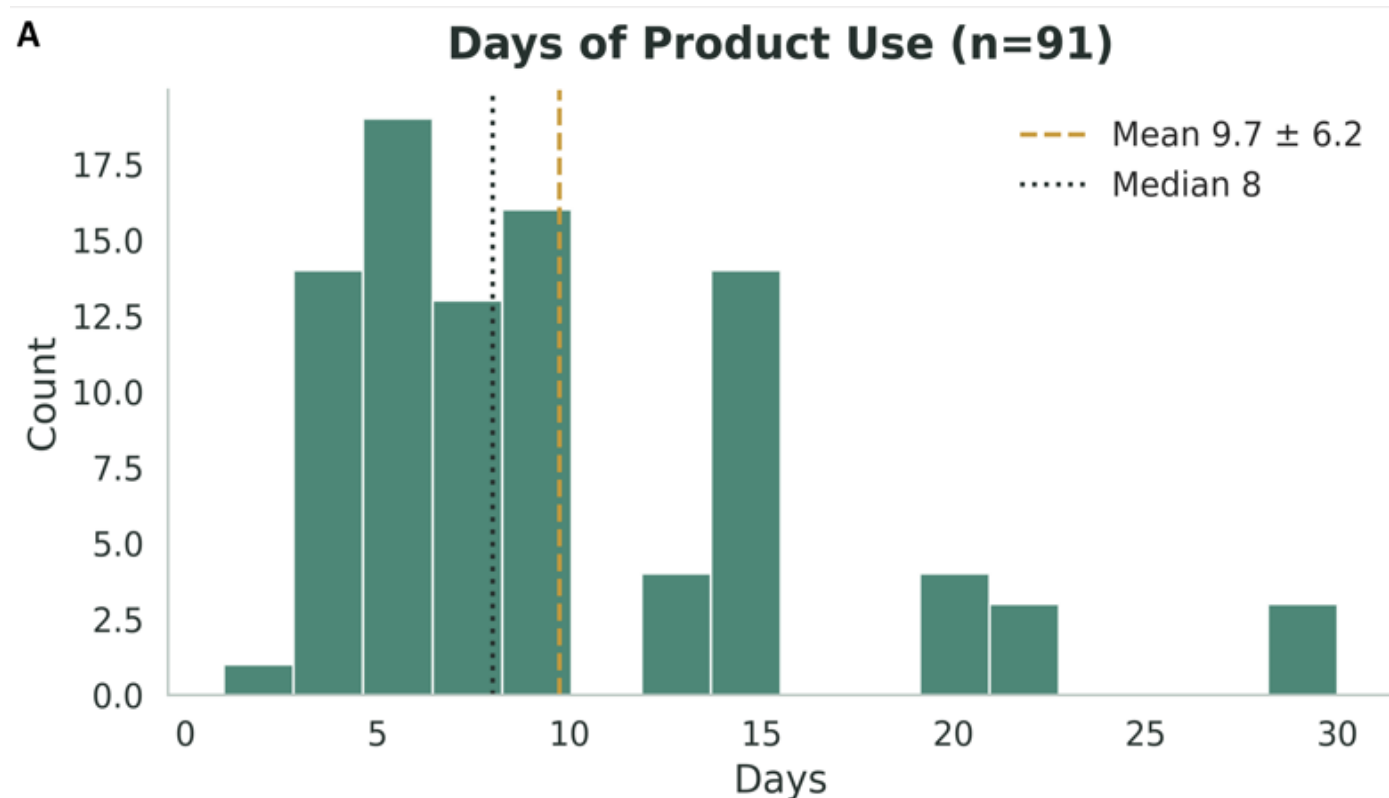


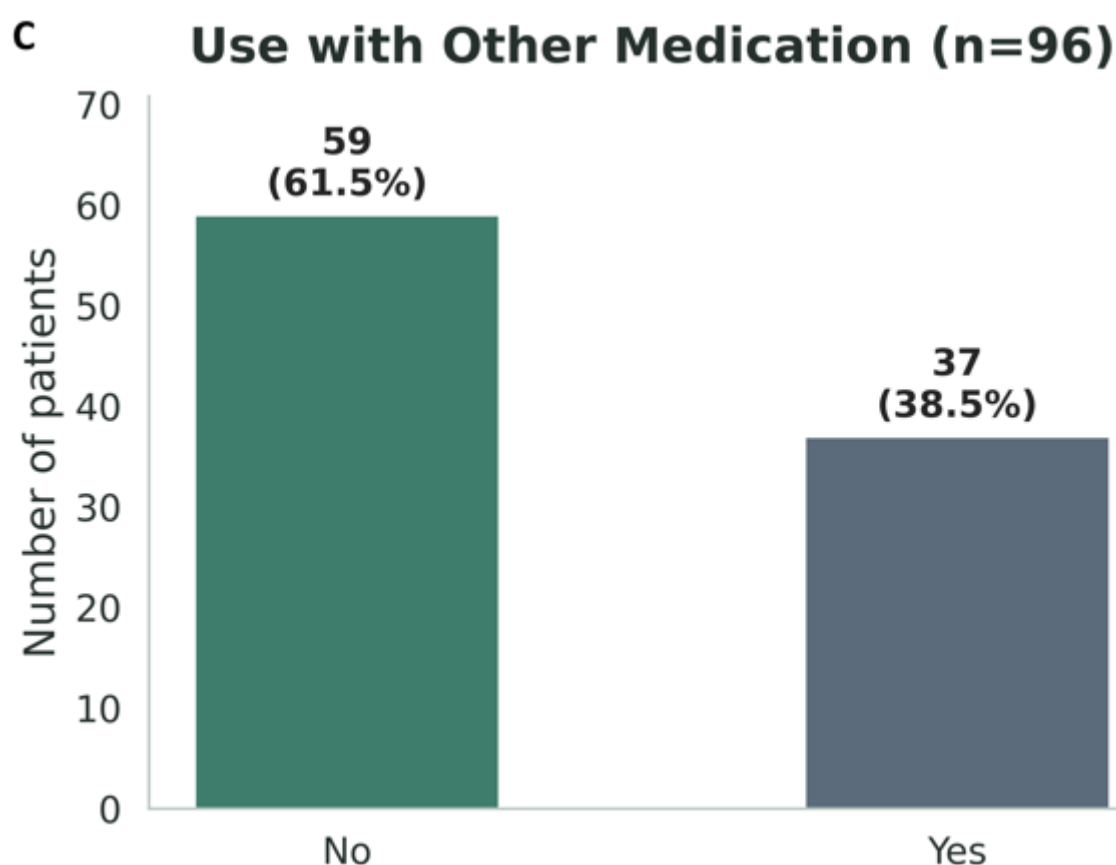
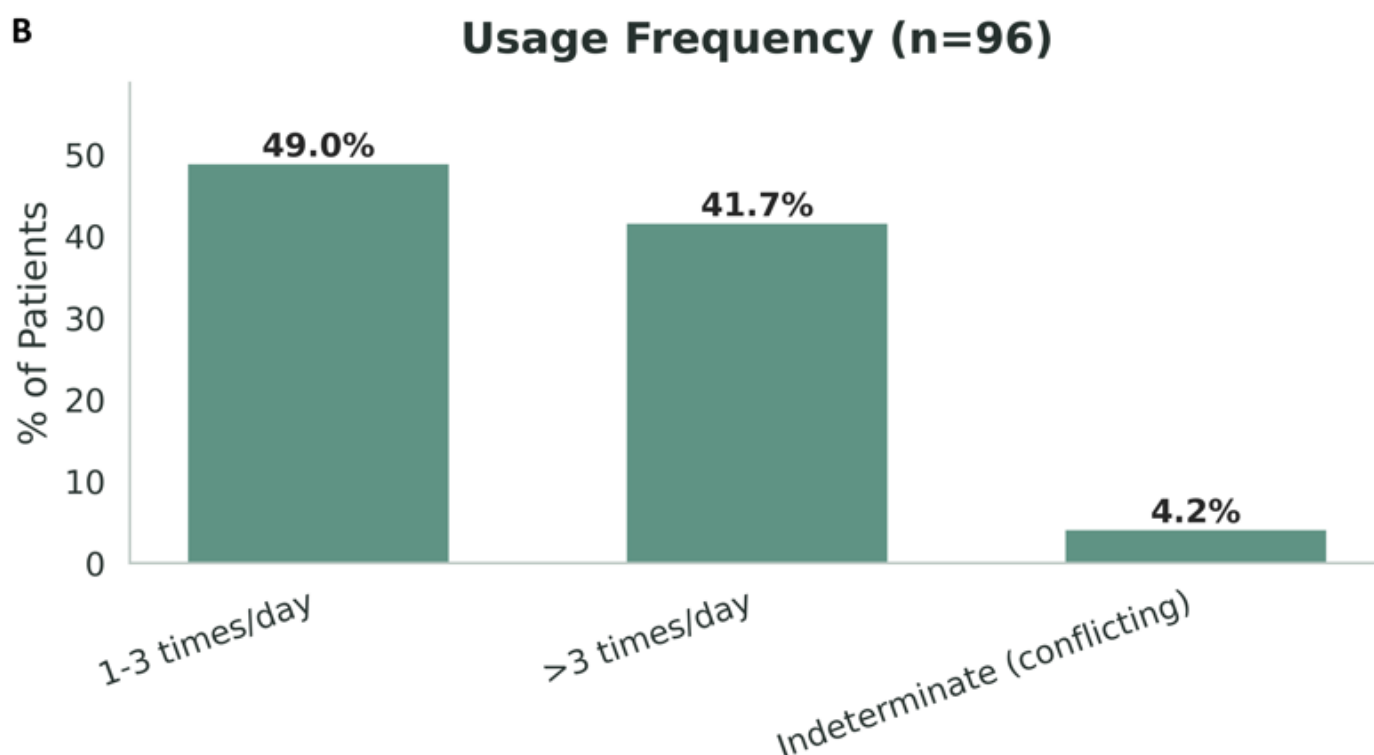
Table 1. Symptom score changes before and after product use. All comparisons were statistically significant ($p < 0.001$; Wilcoxon signed-rank test). Scores range from 0 (not troubled) to 6 (extremely troubled).

Symptom	n	Before (mean)	After (mean)	% improvement
Stuffy nose	91	4.11	1.85	55.1
Runny nose	84	3.04	1.39	54.1
Sneezing	85	2.46	0.98	60.3
Itchy nose	82	2.59	0.95	63.2
Other nasal	87	2.67	1.07	59.9
Fatigue	88	2.91	1.39	52.3
Reduced productivity	88	2.57	1.10	57.1
Poor sleep quality	87	3.08	1.32	57.1
Emotional state	88	1.80	0.88	51.3
Overall feeling	86	2.79	1.44	48.3

The mean duration of HSS reported use was 9.7 ± 6.2 days (median 8; range 1–30 days). The product was used 1–3 times daily by 49.0% of participants, while 41.7% reported using it more than three times daily (**Figures 3A and 3B**). Overall, 37 patients (38.5%) reported concomitant use of HSS with prescribed medication, whereas the remaining participants used HSS as a standalone treatment (**Figure 3C**). Among patients receiving concomitant medication, the most frequently reported therapeutic classes were corticosteroids/inhaled corticosteroids (40%), other saline or seawater nasal products (20%), and nasal decongestant sprays, combination cold/sinus preparations, and antihistamines (9% each) (data not shown).

Figure 3. HSS use. (A) Duration of use ($n = 91$) and (B) usage frequency of HSS ($n = 96$: 47 patients 1–3 times/day, 40 patients >3 times/day, 5 not specified, 4 indeterminate). (C) Patients using the product with ($n = 37$) versus without ($n = 59$) concomitant medication.





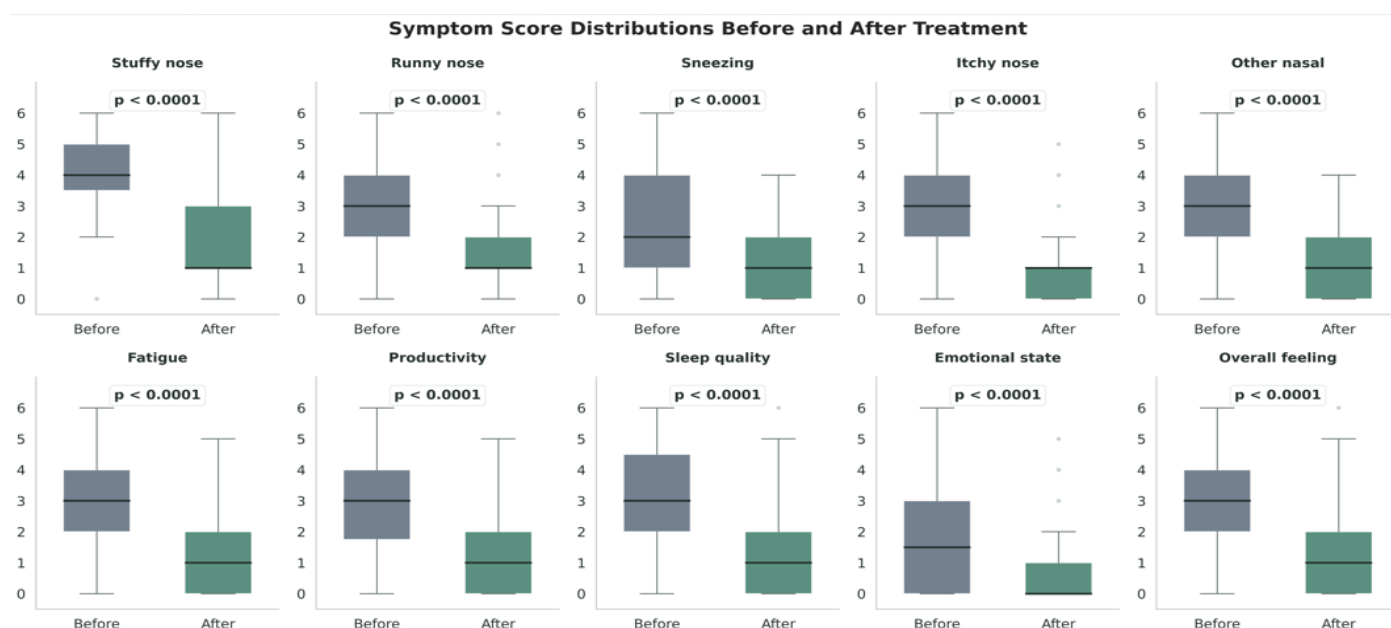
Sinonasal and Quality-of-Life Symptom Improvement

Changes in sinonasal symptoms and QoL parameters were evaluated by comparing patient-reported scores before and after HSS use. A statistically significant improvement was observed for all assessed sinonasal symptoms and QoL domains following HSS use ($p < 0.001$ for all outcomes), with improvements reported across the different ENT conditions included in the study (Figure 4; Table 1).

Among the sinonasal symptoms, the greatest reduction was observed for nasal congestion (stuffy nose), with the mean score decreasing from 4.11 to 1.85 (55.1% improvement), followed by runny nose, which decreased from 3.04 to 1.39 (54.1% improvement). Marked improvements were also observed for sneezing (60.3%), nasal itching (63.2%), and other nasal symptoms (59.9%) (**Figure 4; Table 1**).

Improvements were also consistently observed across all assessed QoL-related parameters. Sleep quality and productivity showed the largest relative improvements, both decreasing by 57.1% (sleep quality: 3.08 to 1.32; productivity: 2.57 to 1.10). Reductions were also observed for fatigue (2.91 to 1.39; 52.3%), emotional state (1.80 to 0.88; 51.3%), and overall feeling (2.79 to 1.44; 48.3%), which represented the smallest but still clinically relevant improvement among the QoL parameters assessed (**Figure 4; Table 1**).

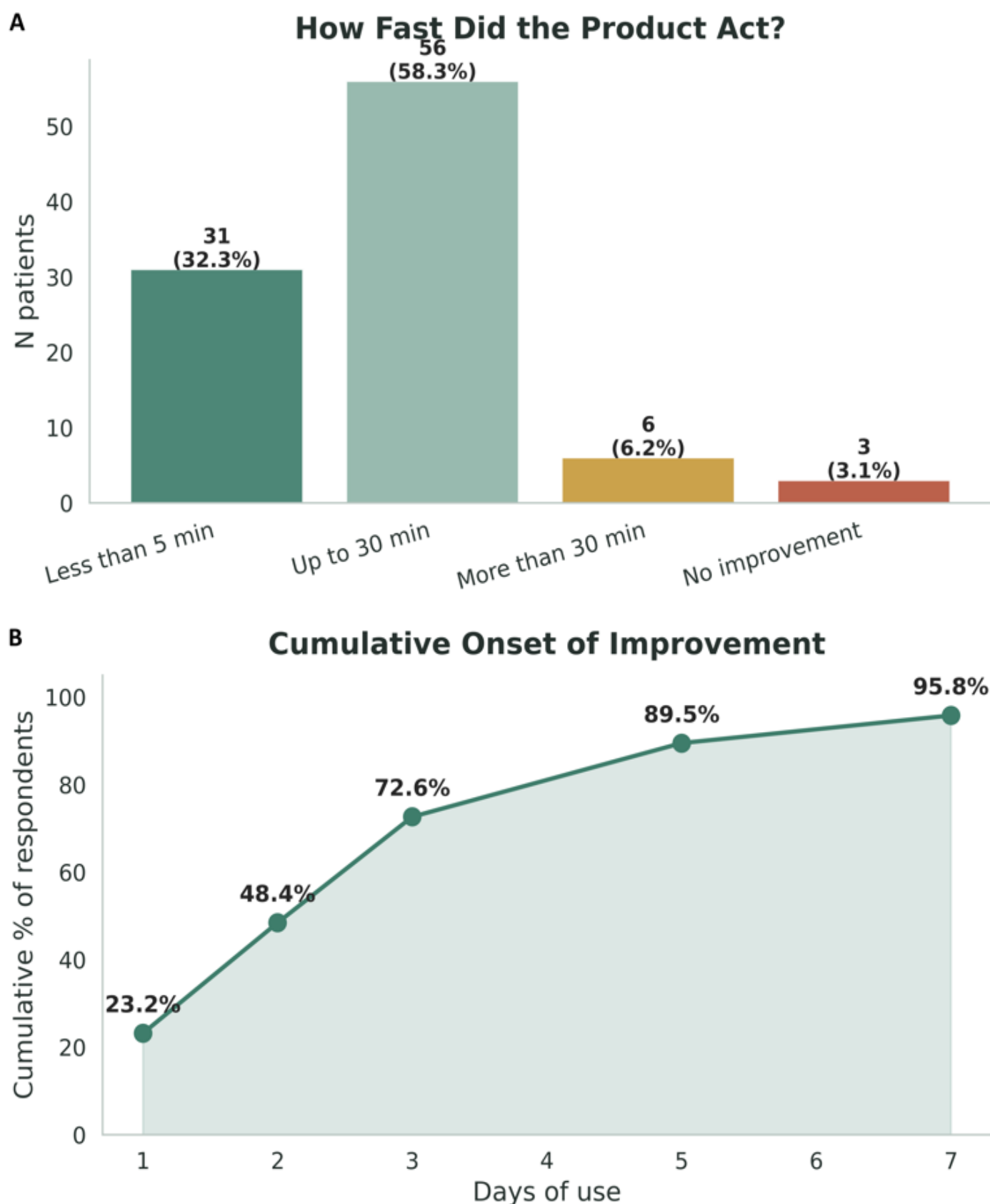
Figure 4. Symptom score distributions before and after treatment. Boxplots of sinonasal and quality-of-life symptom scores (0–6 scale) before and after product use (Wilcoxon signed-rank test, $p < 0.0001$ for all items). Paired data were available for 82–91 patients per item, as detailed in **Table 1**.



Reported Onset of Symptom Relief

The timing of perceived symptom improvement following HSS application was assessed using patient-reported responses. Improvement was reported within 5 minutes by 32.3% of patients, while 58.3% reported improvement between 5 and 30 minutes. Overall, 90.6% of patients reported symptom relief within the first 30 minutes after application (**Figure 5A**). Only 3.1% of participants reported no improvement (**Figure 5A**). The cumulative proportion of patients reporting improvement increased progressively over the first week of use, from 23% on Day 1 to 48% on Day 2 and 73% on Day 3, reaching 96% by Day 7 (**Figure 5B**). These findings indicate that patients perceived both an early onset of symptom relief shortly after application and continued improvement during the initial days of use ($n = 96$ for speed of action; $n = 95$ for day of first improvement).

Figure 5. Symptom onset of relief. (A) Speed of action (time to first perceived improvement after application; n = 96) and (B) cumulative onset of improvement over days of use (n = 95).



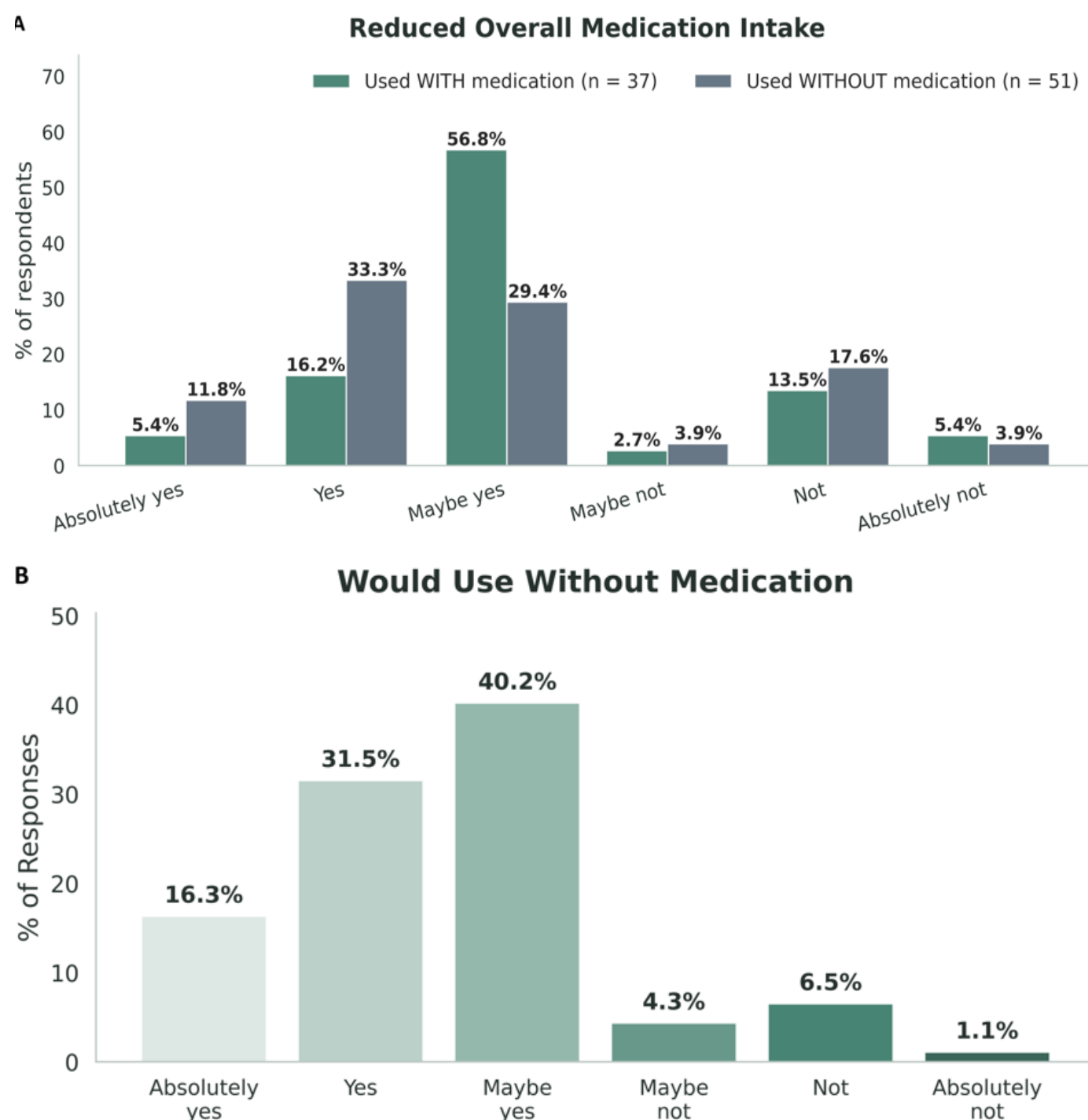
Reported Medication Reduction and Standalone Use

As reported previously (Figure 3C), 37 participants (38.5%) used HSS with prescribed medication, while 59 (61.5%) used HSS without concomitant medication. All participants were asked whether HSS use was associated with a reduction in their intake

of medicated products. Among respondents ($n = 88$), 76.1% reported a perceived reduction (9.1% “absolutely yes,” 26.1% “yes,” and 40.9% “maybe yes”). The proportion of affirmative responses was similar between the two subgroups (29/37, 78.4% vs 38/51, 74.5%). However, responses were less definite among participants using concomitant medication, with “maybe yes” being the most frequent response (56.8% vs 29.4%) (**Figure 6A**). Of note, for the participants using HSS without concomitant medication, the responses did not reflect a reduction in ongoing medication use, but rather their perception that HSS use could reduce the need for medicated products for symptom relief.

Willingness to use HSS as a standalone option was also high, with 88.0% of respondents giving a positive response and 47.8% selecting “absolutely yes” or “yes” ($n = 92$; **Figure 6B**). These responses indicate that most participants were willing to use HSS as a standalone option for symptomatic management.

Figure 6. Reported reduced medication. **(A)** Patient-reported reduction in overall medication intake, shown as the percentage of respondents within each group (used with medication, 37/37 respondents; used without medication, 51/59 respondents) and **(B)** willingness to use the product without medication ($n = 92$).

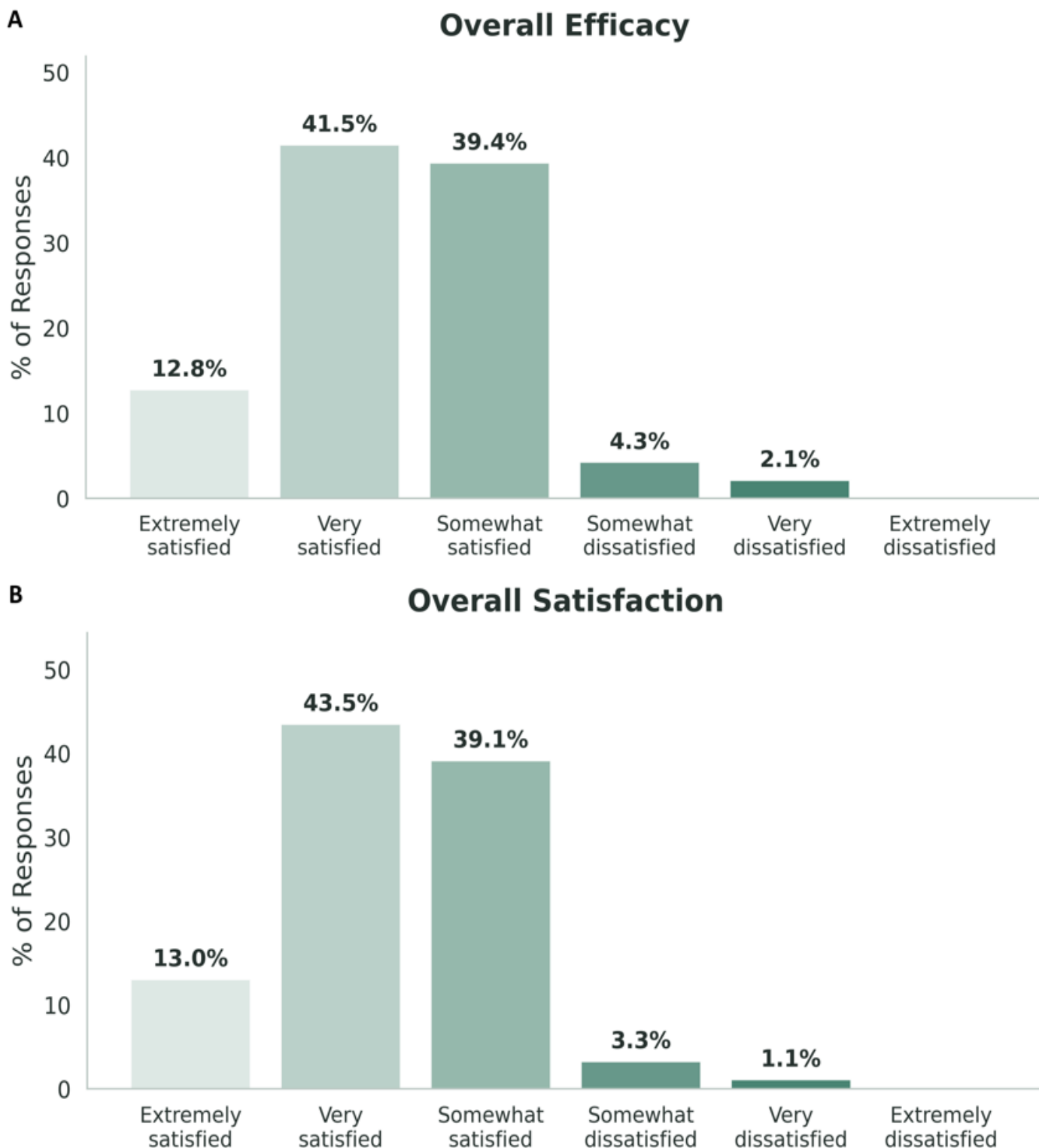


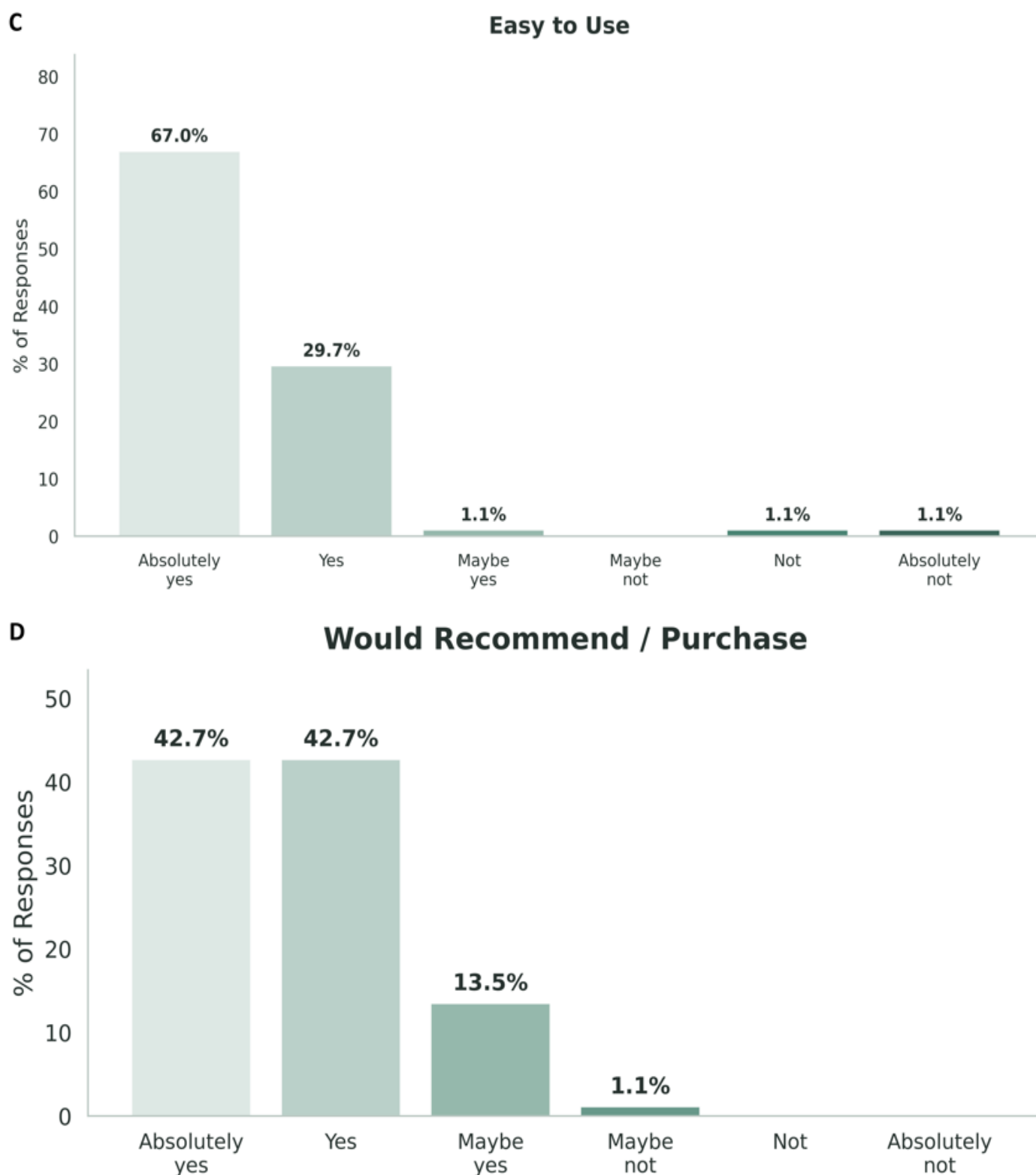
User Satisfaction and Ease of Use

In addition to evaluating symptom improvement, the survey assessed patient-reported satisfaction, perceived efficacy, ease of use, and willingness to continue using or recommending the product.

Overall, consumer satisfaction and perceived efficacy were high. Specifically, positive ratings (top three response categories) were reported by 95.7% of respondents for overall satisfaction and by 93.6% for overall efficacy, with more than half of patients rating each as very or extremely satisfied (**Figure 7A, 7B**). The product was rated as easy to use by 96.7% of participants, including 67.0% who selected “absolutely yes” and 29.7% who selected “yes” (**Figure 7C**). In addition, willingness to recommend or repurchase the product was also high, with 98.9% of respondents providing a positive rating (n = 89).

Figure 7. User satisfaction and usability. Distribution of responses for (A) overall efficacy (n = 94), (B) overall satisfaction (n = 92), (C) ease of use (n = 91), and (D) willingness to recommend or repurchase the product (n = 89).





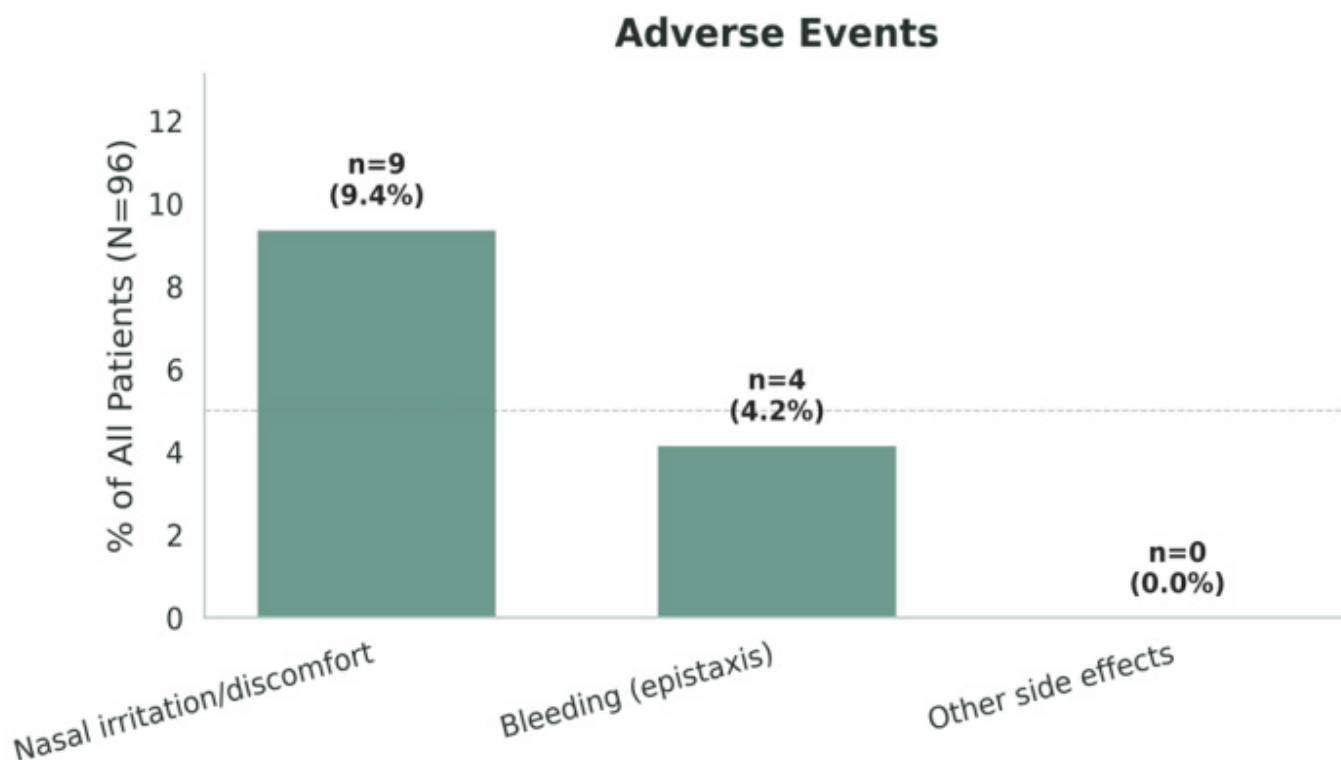
Safety and Device Performance

Safety and device performance were assessed based on participants' reports of adverse events, product-related complaints, and tolerability during HSS use. Data showed that HSS demonstrated a favorable safety and tolerability profile. Specifically, the most commonly reported adverse event was nasal irritation/discomfort in 9 patients (9.4%; 8/90 adults and 1/6 pediatric patients), followed by epistaxis in 4 patients (4.2%), all in adults; no other side effects were reported (**Figure 8**). All adverse events were mild in nature, and no serious adverse events were recorded during the observation period.

Considering device performance, a single device malfunction was reported (1.0%). Specifically, the user reported that the product was not spraying when the pump spray was tilted as described in the instructions for use (not shown).

Overall, the reported findings indicate good tolerability, with no serious safety concerns and a low frequency of reported device-related issues during HSS use.

Figure 8. HSS safety profile. Adverse events reported as a percentage of all patients (n = 96).



DISCUSSION

This prospective, real-world user survey evaluated the effectiveness, safety, and consumer satisfaction of a hypertonic seawater nasal spray (2.3% NaCl) in 96 patients with a range of ENT disorders. Statistically significant improvements were observed across all sinonasal and QoL symptoms following product use, with reductions ranging from 48.3% to 63.2% ($p < 0.001$ for all). These findings are consistent with the established evidence for hypertonic saline nasal irrigation and with previous real-world evaluations of 2.3% seawater products in ENT patients [8,9,11,12,16].

The cohort reflected the heterogeneity of routine practice, with rhinitis and sinusitis representing the predominant conditions and a proportion of patients presenting with concurrent ENT conditions. The largest improvements were seen for nasal obstruction and rhinorrhea, in line with the established mechanical and osmotic effects of hypertonic saline solution which may contribute to enhanced mucociliary clearance, reduced mucosal oedema, and improved nasal patency [6]. In addition, parallel improvements across QoL parameters, including fatigue, productivity, sleep quality, emotional state, and overall well-being were also observed, suggesting a broader positive impact of improved sinonasal symptom control on daily functioning.

Symptom improvement was perceived rapidly, with more

than 90% of users reporting relief within 30 minutes of application. Furthermore, many participants indicated that HSS could contribute to reducing the need for medicated products and expressed willingness to use the product as a stand-alone option. High levels of satisfaction, perceived efficacy, and ease of use may support user acceptance and continued use, particularly in self-care settings [13,15].

The safety profile was favorable, with infrequent and mild adverse events consistent with the established tolerability of hypertonic seawater-based nasal solutions and no serious adverse events reported [8,9,14].

Taken together, these findings support the use of HSS as a well-tolerated option for the symptomatic management of common sinonasal complaints in routine practice. The results from this real-world cohort complement existing evidence on hypertonic saline irrigation and provide additional insights into patient-reported benefits, usability, and acceptability in everyday use. Further prospective, controlled studies incorporating objective endpoints would help to confirm these patient-reported benefits and to define the optimal place of HSS within integrated ENT symptom-management pathways.

Study limitations

This study has limitations inherent to its observational, uncontrolled survey design, which limits causal inference. All outcomes were patient-reported and therefore reflect sub-

jective perception rather than objective clinical assessment, and are subject to reporting bias. Despite these limitations, the consistency of improvement across multiple parameters and the low rate of adverse events support the favorable real-world performance of the product in this population.

CONCLUSION

In this real-world user survey, a hypertonic seawater nasal spray (2.3% NaCl) was associated with significant improvements in sinonasal and QoL symptoms among patients with a range of ENT disorders. HSS was also associated with rapid perceived symptom relief, high user satisfaction, good tolerability, and a favorable safety profile. These findings support the potential role of hypertonic seawater nasal spray as a well-tolerated non-pharmacological option for the symptomatic management of sinonasal conditions in routine practice.

Conflicts of Interest

SG and KA are employees of Gerolymatos-International.

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