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Use of isotonic seawater solutions in patients with ENT symptoms: Real world efficacy, safety and performance evaluation

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Abstract

Limited real-world data exist on the efficacy, user satisfaction, and usage patterns of medical devices used for nasal rinsing in patients with ENT conditions. This study aimed to evaluate a natural Isotonic Seawater nasal Spray (ISS). Over a 1-2 week period, 101 patients were studied for effectiveness, safety, and performance of ISS in alleviating symptoms and improving well-being. Results showed that 82.2% of patients found ISS effective in managing symptoms; 87.1% were satisfied with its usage. A notable decrease in nasal congestion, rhinorrhea, sneezing, itching, dryness, and other related issues, was noted (P<0.0001). Improvements in Quality-of-Life symptoms, such as fatigue, productivity levels, sleep quality, emotional well-being, and overall feelings, were also evident (P<0.0001). Perceived improvement occurred rapidly, with 84% of patients reporting benefits within 30 min, and 28% in 5 min. When ISS was used adjunctively to medication, 63.0% of users reported decreased prescribed medication consumption post-ISS use, and 78.2% considered using ISS alone without medication. 93.0% expressed their intent to purchase ISS in the future, and 95.0% would recommend it to others. These findings support the usefulness of ISS in managing sinonasal and QoL symptoms, indicating its potential in routine care.

Keywords: Nasal spray; User survey; Isotonic seawater solutions; Sinonasal symptoms; Nasal congestion; Quality of life symptoms.

Abbreviations: ISS: Isotonic Seawater nasal Spray; SNI: Saline Nasal Irrigation; ENT: Ear, Nose, and Throat; QoL: Quality of Life.

Introduction

Saline Nasal Irrigation (SNI) is a multifaceted treatment for sinonasal conditions. It works by mechanically cleansing the nasal passages from mucus, allergens, inflammatory mediators, pathogens and pollutants, thereby increasing mucociliary clearance and facilitating nasal mucosa function [1-3]. Many studies have consistently demonstrated the benefits of SNI across various conditions such as acute and chronic rhinosinusitis, allergic and nonallergic rhinitis, and postoperative care [1,4-6]. Incorporating SNI into treatment plans often reduces prescribed medication need [7,8] and may lessen the necessity for surgical intervention in chronic sinusitis cases [9].

Saline irrigation is recommended for individuals of all ages and is considered safe, affordable, and easy to use. Isotonic solutions, matching the osmolarity of nasal tissues, are ideal for nasal irrigation due to their hydrating properties and compat-

ibility with mucosal health and physiological balance. Overall, these solutions are well tolerated and safe for regular nasal use, promoting gentle and effective irrigation without adverse effects [10].

While nasal irrigation is praised for its efficacy, there is a shortage of real-world user feedback. Additionally, there is a lack of understanding on how consumers view medical devices for nasal rinsing and whether they consider these treatments effective and easy to use. This user survey aimed to investigate the satisfaction levels and effectiveness of using ISS, an isotonic seawater nasal spray, in improving symptoms related to ENT conditions, as well as its impact on the overall quality of life of patients.

Methods

Medical device

ISS (Sinomarin® Isotonic, Gerolymatos International S.A.) is a natural isotonic (0.9% NaCl) seawater nasal spray product line used for nasal cleansing and for the relief of sinonasal symptoms. There are three product forms: Adults (aluminum can, 125 mL), Children (aluminum can, 100 mL) and Mini (plastic container, 50 mL). ISS can also be used with medicated treatments.

Survey patients and design

Participants of this prospective user survey were recruited from 24 pharmacies in the United Arab Emirates between September and December 2023. The questionnaire was distributed to adult patients who visited the pharmacy to seek advice on treating symptoms associated with ENT conditions, e.g. rhinitis, cold, sinusitis, etc. or after endonasal surgery. The pharmacist presented the nasal spray and explained the product benefits. The patient was instructed to use the nasal spray according to its instructions. The patient filled the same questionnaire before the initial use of the nasal spray and a few days later, when symptoms have improved (e.g. 7 or 10 days later).

The survey questionnaire (Figure 1) consisted of questions regarding general personal information, nasal condition/disease, standalone use or adjunct to medication, user satisfaction, use frequency and safety. The questionnaire was structured with "yes/no", multiple-choice and free-text answers. Providing multiple answers was permitted. For nasal and quality-of-life symptom severity assessment, Likert score scales were used. Regarding safety parameters, the users had four choices to report potential adverse events (nasal irritation/discomfort, nasal dryness, bleeding, headache). They also had the option to add free text ("other") to describe any additional adverse event they had experienced.

Statistical analysis

Data was analyzed using R version 4.3.2. All tests were two-sided, and the significance level was set at α=5%. Statistical analysis was based on descriptive statistics. Each item was described as categorical variable by absolute and relative frequencies before and after treatment. A shift table was used to present the change after treatment for each item. Improvement, no change, worsening of each item after treatment was presented in a frequency table. Percentages were based on the total number of patients. Missing categories were considered for the calculation of the summary percentages. Average score was calculated for each item based on the rating scale 0-6: Not troubled -> Extremely troubled. Score summaries were based on the number of patients with non-missing data, mean, standard deviation, median, minimum and maximum before and after treatment. Comparisons between the two time points were assessed by paired samples t-test.

Results

One hundred and one patients were interviewed for this user survey. The majority of patients (74%) were between 26-45 years old and the male/female ratio was 1.2:1 (men: 54, women: 45). Patient conditions included sinusitis (36%), cold (28%), allergy (24%), post-surgery discomfort (1%), allergy with cold (3%), sinusitis with cold (3%), sinusitis with allergy (2%), and sinusitis with allergy and cold (1%) (Table 1). Most of the participants (90.1%) used the Adult product form (ISS-Adults) whereas 5.9% used the Mini product (ISS-Mini). No patient used the Children product (ISS-Children). The participants used the spray several times during the day, with or without medication treatment (Table 2).

Nasal spray performance and consumer satisfaction

Eightythree users (82.2%) judged ISS as effective for symptom management, whereas 88 individuals (87.1%) were satisfied with its use (Table 3). As far as sinonasal symptoms were concerned, before ISS use, most users experienced mild to moderate symptoms with symptom scores ranging from 1.99 to 3.24 for sinonasal symptoms and 2.12 to 2.97 for quality-of-life symptoms. Following ISS use, significant score reductions in all individual symptoms were observed ($P<0.001$), with symptom scores ranging from 0.49 to 1.07 for sinonasal symptoms and 0.31 to 0.62 for QoL symptoms (Figure 2).

Figure 3 shows the percentage of patients expressing favorable, unfavorable or no changes in symptom scores. Overall, most of the participants reported improvement in both sinonasal and QoL symptoms. Briefly, 85.2% reported improvement in stuffy nose, 82.0% in runny nose, 82.6% in sneezing, 80.0% in itchy nose, and 64.3% in other problems. For what concerns QoL, 75.0% of the participants experienced less fatigue, 68.8% less reduced productivity, 73.3% less poor sleep, 73.6% felt less emotionally tired, and collectively the overall feeling was improved in 79.5% of users (Figure 3). 84% of the patients perceived symptom improvement in less than 30 min (56% in less than 30 min and 28% in less than 5 min) and only 14% experienced late effects manifesting in more than 30 min (Figure 4).

In relation to use of the spray in combination with medication, 46% replied positively, 50% negatively and 4 (4%) gave no answer. Among the drug prescriptions used, 83% consisted of only one medicated product, predominantly (41%) an antihistamine (Figure 5). The overall efficacy of the combined treatment of ISS plus medication was evaluated as good, very good and extremely good in 34.8%, 56.5% and 4.3% of users, respectively (Table 3). 63.0% of patients responded positively (maybe yes/yes/absolutely yes) in ISS assisting in reducing overall medicated product use. Among these patients, 78.2% would consider using ISS alone, without medication (Table 4).

Dear Customer,

This is a survey to record user satisfaction with ISS. Thank you for taking the time to respond as precisely as possible.

Part #1: Before Using ISS

1. **Please indicate your age range:**
A) 18-25 ☐ **B)** 26-35 ☐ **C)** 36-45 ☐ **D)** 46-55 ☐ **E)** Above 55 ☐

2. **Please indicate your sex:**
A) Male ☐ **B)** Female ☐

3. **Please indicate the name of the Product you will use:**
A) ISS Adults 125ml ☐ **B)** ISS Mini 30ml ☐ **C)** ISS Children 100ml ☐

4. **Please indicate the condition for which you will use ISS:**
A) Allergy ☐ **B)** Cold ☐ **C)** Sinusitis ☐ **D)** After nasal surgery ☐ **E)** Other ☐ *Please indicate* .....

Symptoms before using the product

5. **Nasal symptoms before treatment: how troubled have you been?** *Please circle the extent to which you agree with the following statements:*

	Not troubled	Hardly troubled at all	Somewhat troubled	Moderately troubled	Quite a bit troubled	Very troubled	Extremely troubled
Stuffy / blocked nose	0	1	2	3	4	5	6
Runny nose	0	1	2	3	4	5	6
Sneezing	0	1	2	3	4	5	6
Itchy / Dry Nose	0	1	2	3	4	5	6
Other problems (eyes, throat, etc.)*	0	1	2	3	4	5	6

*(i.e. watery eyes, sore throat, reduced smell or taste)

6. **Other symptoms before treatment: how troubled have you been?** *Please circle the extent to which you agree with the following statements:*

	Not troubled	Hardly troubled at all	Somewhat troubled	Moderately troubled	Quite a bit troubled	Very troubled	Extremely troubled
Fatigue	0	1	2	3	4	5	6
Reduced productivity	0	1	2	3	4	5	6
Poor sleep quality	0	1	2	3	4	5	6
Emotionally tired	0	1	2	3	4	5	6
Your overall feeling	0	1	2	3	4	5	6

Part #2: After Using ISS, a few days later e.g. 7 or 10 days

7. **Please provide your opinion on the ISS used.** *Please circle the extent to which you agree with the following statements:*

	Extremely dissatisfied	Very dissatisfied	Somewhat dissatisfied	Somewhat satisfied	Very satisfied	Extremely satisfied
Overall satisfaction with the use of ISS	1	2	3	4	5	6
Overall efficacy of ISS	1	2	3	4	5	6

8. **How fast did ISS act in relieving your nasal symptoms when you used it?** *Please circle the appropriate answer.*
A) Improvement in less than 5 minutes ☐ **C)** Improvement in more than 30 minutes ☐
B) Improvement in up to 30 minutes ☐ **D)** No improvement ☐

9. **Did you use ISS together with other prescribed medication?** *Please tick the appropriate answer.*
A) yes ☐ **If yes, please answer questions 10-12**
B) no ☐ **If no, please go to question 13**

10. **Please name the prescribed medication you used:**
_____

11. **Please score the overall efficacy of the combined treatment** (*circle the appropriate answer*)

	Extremely bad	Very bad	Bad	Good	Very good	Extremely good
Overall efficacy of the combined treatment	1	2	3	4	5	6

12. **Please answer to the following** (*circle the appropriate answer*)

	Absolutely not	Not	Maybe not	Maybe yes	Yes	Absolutely yes
Did the use of ISS allow you to reduce the overall medicated product intake?	1	2	3	4	5	6
Would you consider using ISS alone, without medication?	1	2	3	4	5	6

13. **How did you use ISS?** *You may tick more than one of the below.*

A. More than 3 times a day	Yes ☐	No ☐
B. 1-3 times per day	Yes ☐	No ☐
C. Together with medication, immediately prior to the medicated product (e.g. 5-10 minutes prior)	Yes ☐	No ☐
D. Together with medication, between medicated product doses	Yes ☐	No ☐
E. I did not pay special attention to how I used medication and ISS	Yes ☐	No ☐
F. Other ☐	*Please indicate:* _____	

Symptoms after using the product

14. **Nasal symptoms after treatment: how troubled are you now?** *Please circle the extent to which you agree with the following statements:*

	Not troubled	Hardly troubled at all	Somewhat troubled	Moderately troubled	Quite a bit troubled	Very troubled	Extremely troubled
Stuffy / blocked nose	0	1	2	3	4	5	6
Runny nose	0	1	2	3	4	5	6
Sneezing	0	1	2	3	4	5	6
Itchy / Dry Nose	0	1	2	3	4	5	6
Other problems (eyes, throat etc) *	0	1	2	3	4	5	6

*(i.e. watery eyes, sore throat, reduced smell or taste)

15. **Other symptoms after treatment: how troubled are you now?** *Please circle the extent to which you agree with the following statements:*

	Not troubled	Hardly troubled at all	Somewhat troubled	Moderately troubled	Quite a bit troubled	Very troubled	Extremely troubled
Fatigue	0	1	2	3	4	5	6
Reduced productivity	0	1	2	3	4	5	6
Poor sleep quality	0	1	2	3	4	5	6
Emotionally tired	0	1	2	3	4	5	6
Your overall feeling	0	1	2	3	4	5	6

16. **Did you experience any of the adverse events below?**

If you answer yes, please indicate how troubling each symptom was based on a scale of 0-6 (0: not troubling: 6: extremely troubling*)

			*Score 0-6
A. Nasal irritation or discomfort	No ☐	Yes ☐	
B. Nasal dryness	No ☐	Yes ☐	
C. Bleeding (epistaxis)	No ☐	Yes ☐	
D. Headache	No ☐	Yes ☐	
E. Other (please provide additional information):	No ☐	Yes ☐	

_____

17. **Do you believe these events were caused by the product or by your condition?** *Please tick the appropriate answer.*
A) Product ☐ **B)** Condition ☐

18. **Did you experience any technical problem with the device (e.g. malfunction?)** *Please tick the appropriate answer.*
A) Yes ☐ **B)** No ☐

If yes, please describe (e.g. the product did not spray at all):
_____

19. **Intent to recommend and/or purchase ISS?** *Please circle the appropriate answers below.*

	Absolutely not	Not	Maybe not	Maybe yes	Yes	Absolutely yes
Would you recommend ISS?	1	2	3	4	5	6
Would you purchase ISS in the future?	1	2	3	4	5	6

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Figure 1: ISS user survey questionnaire.

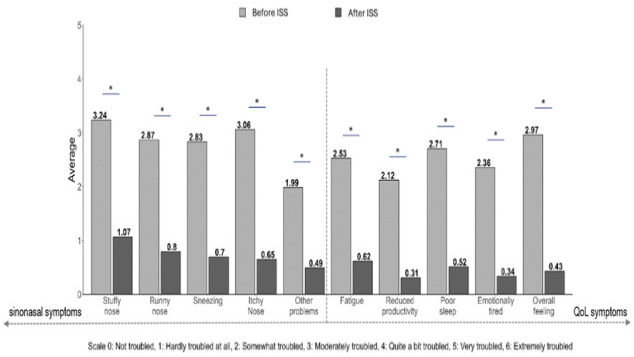

Figure 2: Sinonasal and quality-of-life (QoL) symptoms severity before and after ISS use *P<0.001.

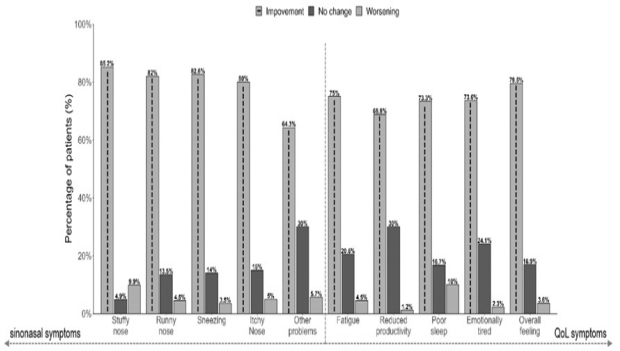

Figure 3: Percentage of patients expressing favorable, unfavorable or no changes in symptom scores as recorded during the survey.

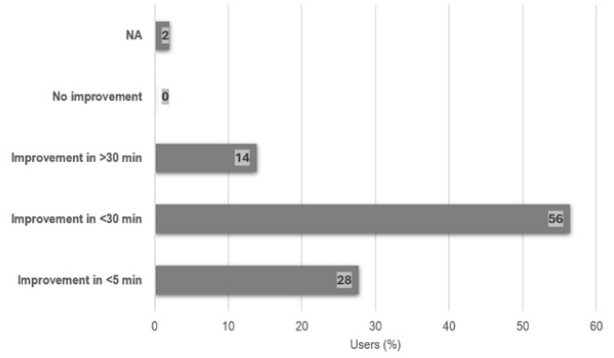

Figure 4: Time to perceived symptom relief.
NA: non-applicable.

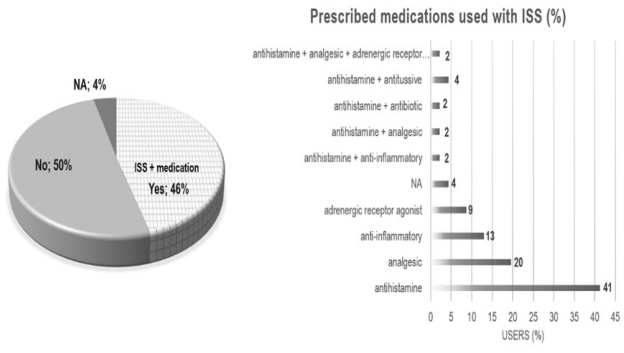

Figure 5: Additional use with prescribed medication. Categories of the prescribed medication treatments.
NA: non-applicable.

Table 1: Survey participants demographics and condition for which the nasal spray was used.

Age distribution	No of users	Responses
18 to 25	10	10
26 to 35	38	37
36 to 45	37	37
46 to 55	11	11
56+	3	3
NA	2	2
Total	*101*	*100%*
Sex distribution		
Males	54	53
Females	45	45
NA	2	2
Total	*101*	*100%*
Condition for which ISS was used		
allergy	24	24
cold	28	28
sinusitis	37	36
after nasal surgery	1	1
allergy & cold	3	3
sinusitis & cold	3	3
sinusitis & allergy	2	2
sinusitis & allergy & cold	2	2
other	1	1
Total	*101*	*100%*

Table 2: Nasal spray used and usage patterns.

Medical device used	No of users	Responses
ISS Adults 125 mL	91	90.1
ISS Children 100 mL	0	0.0
ISS Mini 50 mL	6	5.9
NA	4	4.0
Total	*101*	*100%*

NA: non-applicable data

Time and frequency of ISS use	Counts
>3 times/day	22
1-3 times/day	25
Prior to the medication	29
Between medicated doses	17
I did not pay special attention	9
Other	0

Consumer attitudes

The vast majority of the survey participants (93.0%) replied that they would purchase ISS in the future and 95.0% would recommend ISS to other counterparts (Table 4).

Medical device safety and technical quality

Out of the 101 survey participants, 15 (14.9%) reported a product-related adverse event. However, no information was provided on the nature of the problem. Two users reported a technical problem with the device. However, only one user specified the cause of the malfunction that involved a device not expelling properly.

Table 3: Nasal spray performance and consumer satisfaction after use.

Range of satisfaction/efficacy	Efficacy with ISS use N (percentage)	Satisfaction with ISS use N (percentage)	Range of efficacy	Overall efficacy with the combined treatment N (percentage)
Extremely satisfied	18(17.8%)	12(11.9%)	Extremely good	2(4.3%)
Very satisfied	50(49.5%)	48(47.5%)	Very good	26(56.5%)
Somewhat satisfied	15(14.9%)	28(27.7%)	Good	16(34.8%)
Total satisfied	*83(82.2%)*	88(87.1%)	Total "good"	44(95.6%)
Somewhat dissatisfied	4(4.0%)	1(1.0%)	Bad	0
Very dissatisfied	7(6.9%)	8(7.9%)	Very bad	0
Extremely dissatisfied	1(1.0%)	2(2.0%)	Extremely bad	0
Total dissatisfied	12(11.9%)	11(10.9%)	Total "bad"	0
NA	6(5.9%)	2(2.0%)	NA	2(4.4%)

Table 4: Medication intake and consumer attitudes following ISS use.

Score	Did the use of ISS allow you to reduce the overall medicated product intake? N (percentage)	Would you consider using ISS alone, without medication? N (percentage)	Would you recommend ISS? N (percentage)	Would you purchase ISS in the future? N (percentage)
Absolutely yes	7(15.2%)	6(13.0%)	32(31.7%)	34(33.7%)
Yes	14(30.4%)	19(41.3%)	54(53.4%)	51(50.5%)
Maybe yes	8(17.4%)	11(23.9%)	10(9.9%)	9(8.8%)
Total positive	29(63.0%)	36(78.2%)	96(95.0%)	94(93.0%)
Absolutely not	2(4.3%)	0	0	0
No	9(19.6%)	4(8.7%)	0	0
Maybe not	5(10.9%)	3(6.5%)	3(3.0%)	2(2.0%)
Total negative	16(34.8%)	7(15.2%)	3(3.0%)	2(2.0%)
NA	1(2.2%)	3(6.6%)	2(2.0%)	5(5.0%)

Discussion

Nasal irrigation is crucial for ENT disease management, clearing mucus, allergens and infectious agents [2,3] and improving mucociliary clearance [4,11]. As such, isotonic saline solutions are recommended for relieving nasal symptoms and enhancing overall nasal health in ENT diseases [10,12]. However, little is known in relation to their usage patterns, user satisfaction, and perceived effectiveness in real-world settings. This prospective, questionnaire-based, user survey study evaluated the safety and performance of ISS nasal sprays in participants who used the device for copying with their ENT symptoms.

The survey cohort gathered 101 patients with sinonasal symptoms resulting from a variety of ENT conditions. Following ISS use, participants experiencing allergy, cold, sinusitis or after endonasal surgery felt relief from nasal congestion, rhinorrhea, and sneezing compared to before use. Effective symptom control is the therapeutic advantage of nasal irrigations as noted by a plethora of studies in ENT diseases [7,10,13-14].

Improvement of symptom severity was also reported in all quality-of-life symptoms assessed, indicating an alleviation of patients' discomfort. These included perceived fatigue, compromised sleep and productivity, and poor overall feeling. Enhanced efficacy in both sinonasal and quality-of-life symptoms resolution was noted when ISS was combined with medicated treatments. More importantly, the respondents emphasized that they managed to reduce prescribed drugs upon ISS use.

The convenience of using a nasal spray daily was highly valued among the participants of this survey. Initiation of nasal spraying with ISS yielded high consumer satisfaction. Consumers were highly satisfied with the spray's performance and with the combined efficacy with medicated treatments. The natural nasal spray's high consumer satisfaction is also evident in their inclination towards future purchases. These results support published results collected in another real-world study [8].

Conclusion

Overall, nasal irrigation with isotonic seawater solutions is a comprehensive modality, promoting nasal health by providing optimal sinonasal and quality of life symptom management in individuals with sinonasal conditions.

Conflicts of interest: No conflict of interest was declared by the authors.

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