

ORIGINAL ARTICLES

The Efficacy of Hypertonic Saline Nasal Irrigation for Chronic Sinonasal Symptoms

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OBJECTIVE: To assess quality of life (QOL) in patients with sinonasal symptoms in response to hypertonic saline nasal irrigation (HSNI), and to assess HSNI use patterns.

STUDY DESIGN AND SETTING: The study was an uncontrolled 12-month follow-up to a randomized controlled trial (RCT) and used HSNI in a community setting. We included 54 participants with recurrent or chronic sinonasal symptoms. Forty participants had been in the intervention group of a previous study; 14 had been control participants. Primary outcome measures were the Rhinosinusitis Disability Index (RSDI), a sinus-symptom severity assessment (SIA), and the Sino-Nasal Outcomes Test (SNOT-20). Secondary outcome measures were frequency and pattern of HSNI use, side effects and satisfaction.

RESULTS: Among participants using HSNI in the prior RCT, RSDI scores continued to improve, from 73.2 ± 2.6 points to 80.6 ± 2.4 points ($P < 0.001$). SIA and SNOT-20 scores remained stable. Former control participants reported QOL improvement similar to that of HSNI users in the prior RCT. RSDI scores improved from 62.0 ± 3.9 points to 79.7 ± 3.7 points ($P < 0.05$), SNOT-20 scores improved from 43.5 ± 5.7 points to 28.4 ± 4.8 points, and SIA scores improved from 4.2 ± 0.3 points to 2.6 ± 0.3 points ($P < 0.01$). Mean HSNI use for all participants was 2.4 irrigations per week; 33% of participants used HSNI regularly, 55% when symptomatic. Side effects were minor; satisfaction was high.

CONCLUSIONS: Participants with chronic sinonasal symptoms reported improved QOL and frequent, satisfying use of HSNI.

SIGNIFICANCE: HSNI is an effective adjunctive treatment of chronic sinonasal symptoms.

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Rhinosinusitis¹ is a common clinical problem with significant morbidity and often-refractory symptoms that accounted for approximately 26.7 million office and emergency visits and resulted in \$5.8 billion spent in direct costs in the United States in 1996.² Rhinosinusitis was the 5th most common diagnosis for which antibiotics were prescribed in the US from 1985-1992.³ The Centers for Disease Control has estimated that the number of US chronic rhinosinusitis cases in 1994 was 35 million, a prevalence of 134/1000.⁴ The impact on patients' quality of life is significant and can rate as high as back pain, congestive heart disease, and chronic obstructive pulmonary disease on some outcome measures.⁵

Originally part of the yogic and ayurvedic traditions, hypertonic saline nasal irrigation (HSNI) is an adjunctive therapy for sinusitis and sinus symptoms⁶⁻⁸ that flushes the nasal cavity, facilitating a wash of the structures within (Fig 1). Several randomized controlled trials (RCT) examining HSNI suggest that it is a safe, effective, and tolerable therapy for acute and chronic sinus symptoms.⁹⁻¹⁶ Previous studies have reported improvement of quality of life (QOL) scores^{9-11,16} and improvement of several surrogate measures.^{11-13,16} In a prior RCT (phase 1),¹⁶ our group tested the hypotheses that daily HSNI with 2% saline is associated

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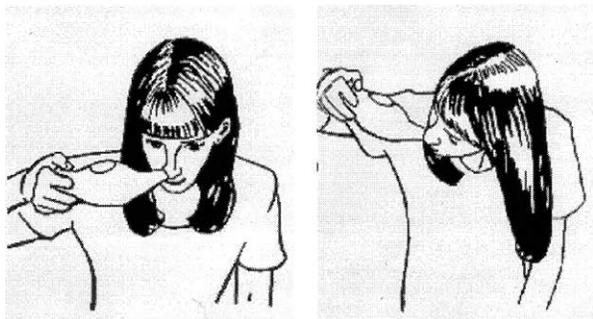


Figure 1 Position of nasal cup for nasal irrigation therapy.

with improved QOL, decreased antibiotic and nasal spray use, and improved sinus symptoms in adult participants with a history of frequent rhinosinusitis and chronic sinus complaints (Box 1). Briefly, of the 69 (91%) participants who completed the 6-month trial, adherence to daily HSNI averaged 87%. Compared with waitlisted control participants who used standard-of-care therapy for sinus complaints and rhinosinusitis, phase 1 intervention participants reported progressive, clinically meaningful improvement in overall QOL as assessed by 2 validated, disease-specific outcome measures ($P < 0.05$), used less antibiotics and nasal sprays ($P < 0.05$), and experienced fewer and less severe sinus symptoms ($P < 0.05$). We concluded that HSNI has the potential to be effective therapy for many patients with chronic sinonasal symptoms.

However, participants' responses in a highly structured and intensive RCT may not represent effects achievable in a general population. It is unclear whether participants in a less structured, more conventional setting will (1) continue to use HSNI and (2) experience similar efficacy. No study has rigorously assessed the natural history of HSNI use or patient outcomes over a longer period. We therefore tested the hypothesis that in a pragmatic, outcomes-based, 12-month follow-up trial (phase 2), participants with chronic sinonasal complaints would use HSNI, find it efficacious, and have similar use patterns, satisfaction, adherence, and side effects compared with intervention participants in our previous RCT (phase 1).

MATERIALS AND METHODS

The study protocol was approved by the University of Wisconsin Health Sciences Human Subjects Committee. Researchers informed all phase 1 participants about the outcomes-based project by letter and telephone call. Consent was obtained either at a face-to-face meeting or by mail. Researchers enrolled participants from January 2001 to June 2001 and exited them 12 months later, for a total assessment period of 18 months in phases 1 and 2.

Eligibility Criteria and Recruitment

Phase 1 inclusion criteria were clinically defined by 2 episodes of acute rhinosinusitis, or 1 episode of chronic rhino-

sinusitis per year, for 2 consecutive years that affected global quality of life. The operational definition for impaired QOL caused by sinus symptoms was a 4-7 score on a 7-point Likert scale. For phase 2, researchers invited all participants from the phase 1 trial. Additional testing, such as allergy tests or radiographic imaging, was not required for study entry because this was designed as a symptom-based, clinical outcomes study. The study was not intended to be limited to a specific diagnosis based upon radiographic or laboratory-based criteria but on a clinically defined symptom complex.

Subject Randomization and Intervention

Phase 1 control participants were trained in HSNI and crossed over into the HSNI intervention group; they are referred to as "phase 2 intervention" participants (Fig 2). They received in-person HSNI training identical to that of phase 1 intervention participants. This included viewing a 5-minute film, witnessing a live HSNI demonstration, and demonstrating proficiency with HSNI technique. All participants were advised to use HSNI using 2% buffered saline (1 heaping tsp of salt and ½ tsp of baking soda to 1 pint lukewarm tap water) in a SinuCleanse¹⁷ nasal cup "as needed" for sinus symptoms and to continue standard-of-care treatment for rhinosinusitis and sinus complaints.

Outcome Measures

Researchers collected all data by self-report by using 3 primary outcome QOL questionnaires, including 2 questionnaires from phase 1, the validated Rhinosinusitis Disability Index (RSDI)¹⁸ and a single-item sinus-symptom severity assessment (SIA; box 1). Use of The Medical Outcomes Survey Short Form (SF-12)¹⁹ was discontinued because it was judged to be too unresponsive for this small study. Researchers added the recently validated Sino-Nasal Outcomes Test (SNOT-20)²⁰ because it allowed participants to rate both the impact on QOL of 20 sinus-associated items and identify which of the 20 items were most important to them. As such, the SNOT-20 is both a health status measure and a QOL measure.

Secondary outcomes included frequency and pattern of nasal irrigation use, side effects (nasal burning, nasal irritation, epistaxis, tearing, postnasal drip, nasal discharge), overall sinus symptom severity and frequency, overall sinus medication use, and overall satisfaction with HSNI. Researchers assessed all secondary outcomes by single-item, nonvalidated questions. Primary and secondary outcome assessments were completed at 6, 10, 14, and 18 months. Because of a clerical error, a subset of 14 subjects did not receive the SNOT-20 at 10 months.

Statistical Methods

Paired *t* tests assessed changes in RSDI, SIA, and SNOT-20 total scores at each follow-up point compared with scores at the beginning of the study. Researchers analyzed all 54 participants who consented to participate in the study on an

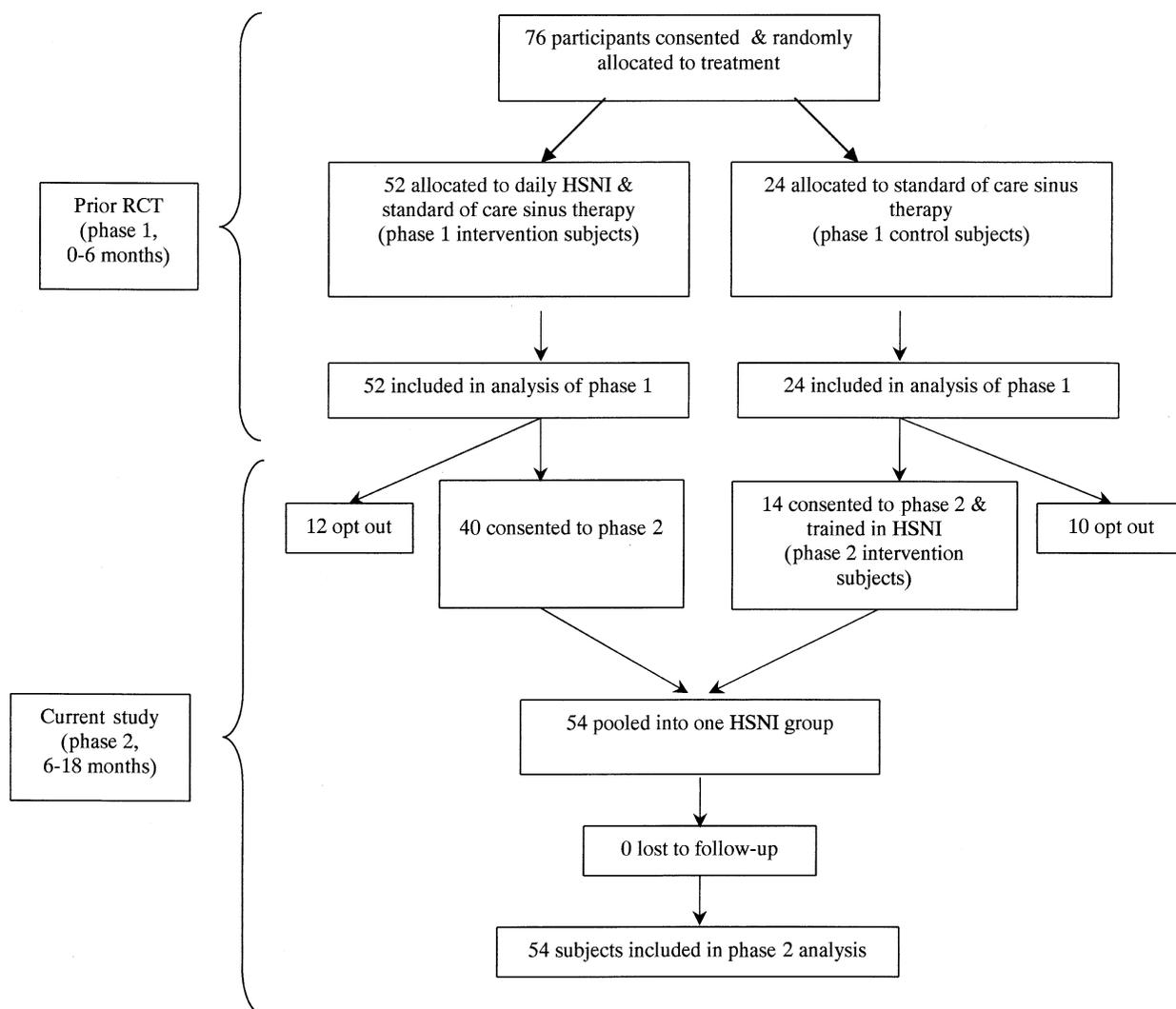


Figure 2 Subject participation in prior randomized controlled trial (phase 1) and current study (phase 2). *HSNI*, hypertonic saline nasal irrigation; *RCT*, randomized controlled trial.

intention-to-treat basis. They performed two-sample *t*-tests on score changes from the start of phase 2 (6 months) to test significance of group status. Statistical significance was defined as $P < 0.05$. Data are presented as mean values \pm standard error (SE), unless otherwise indicated.

RESULTS

Primary Outcomes

Fifty-four (71%) participants (14 from the phase 1 control group and 40 from the phase 1 intervention group) consented to participate in the phase 2 outcomes study. Twenty-two (29%) participants from phase 1 identified lack of time and lack of interest as reasons for not participating. There were no significant baseline differences in QOL scores or sinus-related medical histories between phase 1 and phase 2 participants (Table 1). Participant retention over 12 months was 100%. Participants completed surveys at a rate of 93% (150/162).

Table 1
Baseline QOL scores and demographic and medical characteristics of participants in phase 1 and phase 2 studies

Characteristic	Phase 1 (N = 76)	Phase 2 (N = 54)
Age in y (mean \pm SE)	42.1 \pm 1.2	42.8 \pm 1.5
Female, n (%)	55 (72)	39 (72)
Baseline RSDI (mean \pm SE)	58.8 \pm 1.6	58.8 \pm 2.0
Baseline SIA (mean \pm SE)	3.96 \pm 0.1	3.92 \pm 0.2
Seasonal allergies, n (%)	51 (67)	37 (69)
Asthma, n (%)	18 (24)	13 (24)
Nasal surgery, n (%)	26 (34)	20 (37)
Nasal polyps, n (%)	12 (16)	9 (17)
Deviated septum, n (%)	19 (25)	15 (28)

RSDI, rhinosinusitis disability index; *SIA*, single-item assessment; *SE*, standard error.

BOX 1: METHODS AND RESULTS OF PHASE 1

Enrollment: Participants were enrolled from May to August 2000 and were exited after a study period of six months.

Randomization: Participants were randomized using a two-block design. A 2:1 intervention:control scheme was selected due to resource limitations.

Eligibility Criteria and Subject Recruitment: The billing databases of a large university-associated health group were screened for potential participants with acute or chronic sinusitis (ICD-9 codes 461 and 473, respectively). Inclusion criteria were: age, 18–65 years old and either two episodes of acute sinusitis or one episode of chronic sinusitis per year for 2 consecutive years. Inclusion also required a ‘moderate to severe’ overall burden of sinus disease on a 7-point Likert scale.

Intervention: Seventy-six participants consented and were randomized to intervention or control groups. Intervention participants saw a brief instructional film, witnessed HSNI, and demonstrated proficiency with HSNI prior to departure. Both control and intervention participants continued standard of care therapy for sinus disease. Intervention participants were asked to irrigate the nose (150 ml through each nostril) daily for 6 months using a SinuCleanse™ nasal cup containing 2.0% saline buffered with baking soda.

Outcome Measures: The primary outcomes were quality of life (QOL) scores from the validated Rhinosinusitis Disability Index (RSDI) and from a single-item sinus symptom severity assessment (SIA) using a 7-point Likert scale (“Please evaluate the overall severity of your sinus symptoms since you enrolled in the study”). Each was completed at baseline, 1.5, 3, and 6 months. Secondary outcomes included adherence, sinus symptom frequency (headache, congestion, facial pressure, facial pain, nasal discharge), antibiotic and nasal-spray use, satisfaction with HSNI, and side effects.

Statistical Methods: Intention to treat analysis involved all 76 randomized participants. Repeated measures analysis of variance contrasted quality of life scores within each group at baseline and subsequent periods. Statistical significance was assessed using two-tailed tests.

Results: Primary Outcomes Sixty-nine participants (91%) completed the study. Randomization was effective. Intervention participants showed significant improvement in RSDI scores: from 58.4 ± 2.0 at baseline to 72.8 ± 2.2 points at 6 months ($P < 0.05$). SIA scores for intervention participants improved ($P < 0.05$) at all follow-up points compared to controls.

Results: Secondary Outcomes Intervention participants reported using HSNI on 87% of days of the study. The survey completion rate was 96%. Compared to control participants, intervention participants spent less time with nasal congestion, sinus headache and frontal pain and pressure, and used less antibiotics and nasal sprays ($P < 0.05$). Ten (23%) intervention participants experienced side effects i.e., eight identified nasal irritation, burning, tearing, nosebleeds, headache, or nasal drainage as occurring but “not significant” and two subjects identified irritation and headache as “significant,” but this did not change their high satisfaction rating.

QOL scores remained stable or improved among phase 1 intervention participants (Table 2). Mean RSDI scores improved from 73.2 ± 2.6 points at month 6 to 80.6 ± 2.4 points at month 18 ($P < 0.001$); SIA scores remained stable, 2.3 ± 0.1 points at 6 months and 2.1 ± 0.2 points at 18 months ($P = 0.3$); SNOT-20 scores also remained stable, 24.0 ± 4.0 points at baseline and 25.5 ± 2.9 points at 18 months ($P = 0.8$).

Phase 2 intervention participants reported pre- and post-HSNI QOL scores similar to those of phase 1 intervention participants. RSDI scores improved from 62.0 ± 3.9 points at the start of phase 2 to 79.7 ± 3.7 points ($P < 0.05$) at 18 months; SIA scores improved from 4.2 ± 0.3 points to 2.6 ± 0.3 points ($P < 0.01$). SNOT-20 scores improved from 43.5 ± 5.7 points to 28.4 ± 4.8 points. In both groups, participants identified the following sinus-related survey items as being most responsive to HSNI on the SNOT-20: facial pain, ear fullness, sense of sadness and frustration, and postnasal drip.

Secondary Outcomes

Overall, 47 (87%) participants reported using HSNI in any 4-month period. Frequency of HSNI use for all

participants averaged 2.4 irrigations per week (± 0.7 ; range 2.3–3.6) at 18 months. Participants who had not used HSNI previously reported 3.6 (± 0.6) irrigations per week at 4 months and decreased to 2.3 (± 0.8) irrigations per week at 18 months. Participants who had used HSNI previously reported 2.3 (± 0.3) irrigations per week at 4 months and 2.4 (± 0.4) irrigations per week at 18 months. Scheduling of HSNI use was also consistent. On average, during any given 4-month period, 33% of all participants reported using HSNI regularly, whereas 55% of all participants reported using HSNI only when symptomatic; 13% of all participants reported not using nasal irrigation during any given 4-month period.

Subjective responses to HSNI were positive. On average, 52% of participants reported “feeling better overall,” 72% reported “fewer sinus infections,” 58% reported “using less sinus medication” and 69% reported “overall easier breathing.” Among all participants, 83.2% reported fewer nasal symptoms during any given 4-month period, and 84% reported that nasal symptoms were less severe. Ninety-five percent of all participants reported that they would continue to use HSNI while 98.5% of all participants would recommend HSNI.

Table 2
Baseline primary outcome scores for phase 1 and RSDI, SiA, and SNOT-20 scores \pm SE for all time points in phase 2

Status	N	Initial RCT T = 0, begin phase 1	Score at 6 months, begin phase 2	Score at 10 months, phase 2	Score at 14 months, phase 2	Score at 18 months, phase 2
RSDI						
Phase 1 intervention	40	58.3 \pm 2.3	73.2 \pm 2.6 (<i>P</i> < 0.001)	75.7 \pm 2.5 NS	78.2 \pm 2.4 (<i>P</i> < 0.01)	80.6 \pm 2.4 (<i>P</i> < 0.001)
Phase 2 intervention	14	60.5 \pm 4.2	62.0 \pm 3.9 (NS)	80.9 \pm 3.8 (<i>P</i> < 0.01)	70.5 \pm 3.8 (<i>P</i> < 0.01)	79.7 \pm 3.7 (<i>P</i> < 0.05)
SiA						
Phase 1 intervention	40	3.8 \pm 0.2	2.3 \pm 0.1 (<i>P</i> < 0.01)	2.2 \pm 0.1 NS	2.0 \pm 0.2 NS	2.1 \pm 0.2 NS
Phase 2 intervention	14	4.1 \pm 0.3	4.2 \pm 0.3 (NS)	2.5 \pm 0.3 (<i>P</i> < 0.01)	3.4 \pm 0.3 NS	2.6 \pm 0.3 (<i>P</i> < 0.01)
SNOT-20						
Phase 1 intervention	40	NA	24.0 \pm 4.0	MD	24.3 \pm 3.1 NS	25.5 \pm 2.9 NS
Phase 2 intervention	14	NA	43.5 \pm 5.7	23.0 \pm 4.3 (<i>P</i> < 0.01)	41.1 \pm 3.3 NS	28.4 \pm 4.8 NS

Phase 1 intervention subjects used nasal irrigation from month 0 to month 18; phase 2 intervention subjects used nasal irrigation from month 6 to month 18. NA, not applicable (SNOT-20 was not administered in phase 1); NS, not significant; MD, missing data.

Adverse effects are given as a percentage of participants who reported the presence of an adverse effect in any given 4-month period. Nasal irritation and burning were the most common, with up to 5 participants (9%) identifying either effect as a problem during any given 4-month period. Of those who experienced an adverse effect, 1 or 2 participants reported that it was serious enough to reduce or modify, but not eliminate, their use of HSNI. Some participants reduced the salinity of the irrigant, or reduced the frequency of HSNI use. These techniques were successful for approximately half the participants with adverse effects. The adverse effect profile of phase 2 is consistent with that of phase 1.

DISCUSSION

In phase 1,¹⁶ among participants with chronic sinonasal symptoms, we found statistically significant, clinically meaningful improvement in QOL, decreased overall sinus symptom severity, reduced antibiotic and nasal spray medication use, infrequent adverse effects, frequent HSNI use, and high participant satisfaction. These results were consistent with other reports of QOL improvement using HSNI over a short period of time.⁹⁻¹¹

In phase 2, an outcomes study designed to assess the effectiveness of HSNI in a standard clinical setting, we report long-term improvement in QOL scores on 3 disease-specific outcomes instruments. These findings are consistent with those of a single study involving woodworkers, a population at high risk for chronic sinus symptoms; in that study, on nonvalidated outcome instruments, sinonasal

symptom improvement and satisfaction with HSNI was high for many participants for 12 months.¹⁴

No RCT has rigorously assessed QOL change in the setting of HSNI use over an extended period. Significant improvement in phase 2 intervention QOL scores demonstrates that minimal training and intervention are sufficient to facilitate use of HSNI and provide clinical improvement equal to that of phase 1 intervention participants. QOL scores on the RSDI, SiA, and SNOT-20 for phase 2 intervention participants statistically match those of their phase 1 intervention counterparts. Considering all subjects, frequency of HSNI use, after peaking at 4 months, stabilized at 2.3 irrigations per week. That 87% of participants reported using HSNI in any 4-month period attests both to the chronic nature of their sinus symptoms and to the relative success of HSNI therapy. Finally, analysis of the number-needed-to-treat to show a clinically meaningful change of 10% on the RSDI for phase 2 intervention participants is very favorable: 1.1-1.8 (confidence interval 1.1-3.5).

The current study is limited by its relatively small sample size, lack of phase 2 control group, and the participants' potential bias toward using HSNI because they had been in phase 1. Methodologic strengths of this study include patient-centered primary and secondary outcomes, intention-to-treat analysis, low missing data rates, high compliance rate and low drop-out rate. Particularly intriguing is the reported decreased use of sinus medication among HSNI users in both phase 1 and phase 2.

Questions about the basic science, clinical protocol (eg, irrigation schedule, irrigant concentration, buffering, and irrigant delivery system) and specific indications remain. Our inclusion criteria were intended to capture patients with

recurrent or chronic sinonasal symptoms that affected their health-related quality of life. Consequently, we did not obtain or require allergy testing or radiographic imaging for study entry. By implication, physicians can recommend HSNI on clinical grounds, based upon a patient's symptom complex, without a specific requirement for further testing. Although this limits the discussion of HSNI as a treatment of specific diagnosis, the study design allows for meaningful outcomes-based discussion using validated instruments in the management of recurrent and acute sinonasal symptoms. These issues require further study in a larger patient population including identified subgroups, such as patients with chronic rhinitis alone, patients with polypoid change, and patients who have had previous sinonasal surgery.

This study strengthens the argument that HSNI is a safe, well-tolerated, inexpensive (nasal pot, \$15; daily therapy, <\$1/mo), effective, long term therapy that patients with chronic sinonasal complaints can and will use at home with minimal training and follow-up.

CONCLUSION

In this long-term outcomes study, participants already using HSNI continued to report QOL gains seen in a prior study. Participants new to HSNI who received brief instruction and minimal monitoring reported QOL gains that matched those of prior-study counterparts. Use of HSNI was frequent, well-tolerated, and met with high participant satisfaction. Clinicians should consider HSNI to be an effective adjunctive treatment for symptoms associated with chronic sinonasal symptoms.

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