

# Nasal Saline for Chronic Sinonasal Symptoms

## A Randomized Controlled Trial

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**Objective:** To determine if isotonic sodium chloride (hereinafter “saline”) nasal irrigations performed with large volume and delivered with low positive pressure are more effective than saline sprays at improving quality of life and decreasing medication use.

**Design:** A prospective, randomized controlled trial.

**Setting:** Community.

**Participants:** A total of 127 adults with chronic nasal and sinus symptoms.

**Interventions:** Patients were randomly assigned to irrigation performed with large volume and delivered with low positive pressure (n=64) or spray (n=63) for 8 weeks.

**Main Outcome Measures:** Change in symptom severity measured by mean 20-Item Sino-Nasal Outcome Test (SNOT-20) score; change in symptom frequency measured with a global question; and change in medication use.

**Results:** A total of 121 patients were evaluable. The irrigation group achieved lower SNOT-20 scores than the spray group at all 3 time points: 4.4 points lower at 2 weeks ( $P=.02$ ); 8.2 points lower at 4 weeks ( $P<.001$ ); and 6.4 points lower at 8 weeks ( $P=.002$ ). When symptom frequency was analyzed, 40% of subjects in the irrigation group reported symptoms “often or always” at 8 weeks compared with 61% in the spray group (absolute risk reduction, 0.2; 95% confidence interval, 0.02-0.38 ( $P=.01$ ). No significant differences in sinus medication use were seen between groups.

**Conclusion:** Nasal irrigations performed with large volume and delivered with low positive pressure are more effective than saline sprays for treatment of chronic nasal and sinus symptoms in a community-based population.

**Trial Registration:** clinicaltrials.gov Identifier: NCT00318006

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**C**HRONIC NASAL AND SINUS conditions are extremely common in the general population. Chronic rhinosinusitis (CRS) alone reportedly affects 36 million Americans each year.<sup>1,2</sup> Allergic and nonallergic types of rhinitis afflict millions more. Medications for these conditions abound, and therapy is usually directed at the underlying disease process: antibiotics for rhinosinusitis and antihistamine or anti-inflammatory drugs for allergy and rhinosinusitis. Persistent symptoms may be owing to a failure of therapy, inability to treat disease process, or failure of accurate diagnosis. For example, nonallergic rhinitis frequently coexists with allergic rhinitis. Yet if the nonallergic component of the patient’s rhinitis is untreated, symptoms often persist, and the antihistamine therapy may be deemed a “failure.” Additional treatment may be prescribed, including leukotriene inhibitors, topical corticosteroids, mast cell stabilizers, decongestants, and/or anticholinergics,

yet many patients remain symptomatic. Isotonic sodium chloride (hereinafter “saline”) irrigations may be useful adjunctive therapy for patients with such chronic sinonasal symptoms.

Otolaryngologists recommend the use of nasal irrigations following sinus surgery to cleanse the nasal passages and promote mucosal healing. Clinical experience and anecdotal reports of symptom improvement have resulted in extension of the use of nasal irrigations beyond postoperative debridement. Many otolaryngologists recommend use of irrigations for a wide array of sinonasal conditions. Until recently, evidence of their benefit remained anecdotal. However, 2 recent clinical trials have demonstrated the clinical efficacy of nasal irrigations in nonsurgical patients, and nasal saline treatment is becoming increasingly common.<sup>3,4</sup>

Nasal saline sprays are often used as an alternative to saline irrigations because saline spray is often perceived to be equivalent to and better tolerated than irriga-

tion.<sup>5</sup> The clinical efficacy of saline sprays is unproven.<sup>6</sup> The present study was designed to compare the efficacy of saline spray with saline irrigation with respect to disease-specific quality of life change in a general population of patients with chronic nasal and sinus complaints.

## METHODS

### STUDY PARTICIPANTS

Potential study participants were recruited from the general population between December 2005 and May 2006 through several mechanisms: (1) an electronic posting at the Engage bulletin board, which is sponsored by the University of Michigan Center for the Advancement of Clinical Research to advertise active clinical trials at the University of Michigan Health System; (2) an electronic posting at [clinicaltrials.gov](http://clinicaltrials.gov); (3) flyers posted in the public corridors of the University of Michigan Hospital; (4) study brochures distributed to local allergists, pulmonologists, and primary care physicians; and (5) flyers posted in public places throughout the local community, such as libraries, grocery stores, pharmacies, housing complexes, and other sites. Eligible participants were adults 18 years or older who self-reported 1 or more of the following symptoms 4 or more days each week in the preceding 2 weeks: nasal stuffiness (blocked sensation in the nose), nasal dryness or crusting, nasal congestion (this term was left open to the individual patient's interpretation), discolored nasal discharge, or thick nasal discharge (including postnasal discharge). In addition to the presence of symptoms at least 4 days each week, the symptoms must have been present at least 15 of the preceding 30 days. Participants were excluded if they had recent sinus surgery, respiratory infection within the preceding 2 weeks, or had used either of the study interventions within the preceding month. Subjects with recent (2 week) upper respiratory tract infections, whether viral or bacterial, were excluded. However, subjects with at least 4 weeks of symptoms were included. As a result, our subjects may have had acute rhinosinusitis or CRS.

### STUDY DESIGN

The study was a randomized controlled trial comparing 2 methods of nasal saline use: nasal irrigation and nasal spray. The study protocol was reviewed and approved by the University of Michigan Health System institutional review board and the General Clinical Research Center (GCRC). Financial support for the study was provided by NeilMed Pharmaceuticals, Santa Rosa, California, who is the manufacturer of the saline product, Sinus Rinse.

A brief telephone survey was used to screen subjects and to confirm eligibility of potential study participants. Eligible study participants met with the study coordinator at 1 of 3 outpatient clinical research GCRC sites: University of Michigan Hospital, Ann Arbor; Domino's Farms, Ann Arbor; and Ypsilanti Health Center, Ypsilanti, Michigan. Written informed consent was obtained from all study participants at the time of meeting with the study coordinator prior to the conduct of any study-related procedures.

### SURVEY INSTRUMENTS

Baseline and follow-up surveys consisted of the 20-Item Sino-Nasal Outcome Test (SNOT-20)<sup>7</sup> measure of symptom severity, a global question regarding symptom frequency, and a medication diary. The SNOT-20 is a validated, self-administered, quality of life instrument specific for patients with symptoms of rhinosinusitis. The instrument measures physical problems, functional limitations, and emotional consequences of sinusitis by asking subjects to score 20 items, including the need to blow the

nose, sneezing, runny nose, cough, postnasal discharge, thick nasal discharge, ear fullness, dizziness, ear pain, facial pain/pressure, difficulty falling asleep, waking up at night, lack of a good night's sleep, waking up tired, fatigue, reduced productivity, reduced concentration, frustrated/restless/irritable, and being sad and embarrassed. The SNOT-20 gives a summary measure that is usually scored from 0 to 5. For ease of interpretation, we have used a multiple of 20, giving a summary score ranging from 0 to 100, with 100 indicating worse symptoms.

Symptom frequency was measured with the question "Over the past 2 weeks, how much have you been bothered by your nasal and/or sinus symptoms?" offering the following 5-point multiple-choice Likert response scale: "never," "rarely," "sometimes," "often," or "always." Symptom chronicity was measured with the questions: "Of the preceding 12 months, how many months have you had these symptoms?"

A medication diary was used to document treatment compliance and use of prescription or nonprescription medications for nasal and sinus-related symptoms (including but not limited to antihistamines, nasal steroid sprays, decongestants, and antibiotics).

### RANDOMIZATION

Randomization was stratified by GCRC site; and within each stratum, blocked randomization with random block size was performed to further enhance the balancing of the patients. The biostatistician (H.M.K.) generated the computerized randomization codes, and sequentially numbered, opaque envelopes with random assignments were prepared beforehand and given to site coordinators at each site.

### INTERVENTION

A study visit was scheduled on day 0. On day 0, according to randomization, subjects were instructed in the technique of nasal lavage (*irrigation group*) or nasal saline spray (*spray group*) and were asked to do the assigned treatment twice daily for 8 weeks. They were provided with an 8-week supply of materials (Sinus Rinse irrigations from NeilMed Products Inc, and Deep Sea nasal saline spray distributed by Major Pharmaceuticals, Livonia, Michigan). Both the saline solution (irrigation) and saline spray used in our study were isotonic sodium chloride solutions. Subjects were allowed to continue their usual medications.

### END POINTS AND FOLLOW-UP

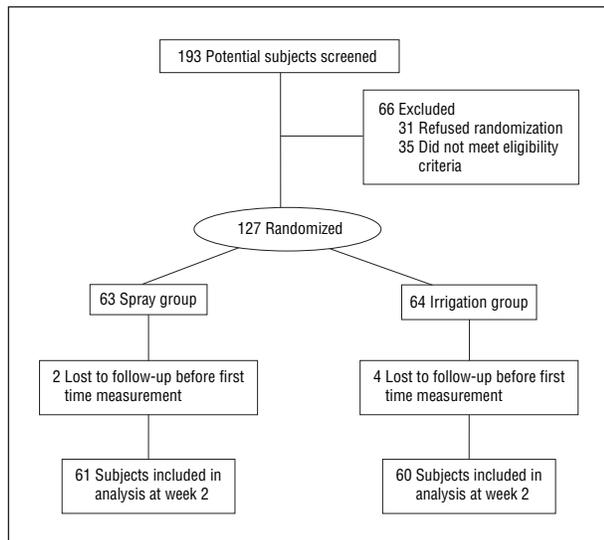
Outcomes were measured at 2, 4, and 8 weeks after randomization using a mail-in survey composed of the SNOT-20, the global question of symptom frequency, and the medication diary. Data on adverse effects were collected prospectively with an open-ended question. The study coordinator, who was not blinded to treatment group, telephoned each subject 1 week after enrollment to answer any participant questions and encourage compliance. Telephone calls thereafter were used to collect missing survey data.

### DEMOGRAPHIC MEASURES

Demographic measures consisted of age, sex, race, and highest educational status attained. Subjects self-reported their race/ethnicity, and options were defined according to the 2-tier question used by the US Census Bureau.<sup>8</sup>

### STATISTICAL ANALYSIS

Baseline characteristics, including baseline values of the outcome measures, were compared between the 2 study groups using



**Figure 1.** Randomization of the study cohort.

a  $\chi^2$  test for categorical variables and a 2-sample *t* test for continuous variables. The SNOT-20 mean scores and mean change scores relative to baseline were calculated by group at each follow-up point. Trends over time and between groups were first graphically explored. The analysis was done to test for significant improvement in outcome after randomization within each study group using paired *t* tests. Between-group outcome differences at each follow-up time were done using 2-sample *t* tests. Finally, we compared outcomes between 2 study groups averaged over the follow-up times using mixed-effect model analysis.<sup>9</sup> The global symptom question was dichotomized to compare frequent symptoms (often or always) with infrequent symptoms (seldom, rarely, or never), and between-group comparisons were made using  $\chi^2$  tests. Symptom frequency during follow-up was compared between the 2 groups using a logistic regression model with robust standard error estimates to adjust for within-patient correlation from having repeated measures of symptom severity data. Odds ratios were used as a summary measure comparing differences in symptom burden between groups.

## RESULTS

### PARTICIPANTS

A total of 193 potential subjects were screened, of whom 127 eligible patients were enrolled and randomized to either the irrigation or spray group (**Figure 1**). Of those randomized, 6 patients withdrew before they reached the first follow-up measurement time (4.7%), and thus were not included in the analysis. A total of 121 subjects were observed for at least 2 weeks (60 in the irrigation group and 61 in the spray group), and 113 subjects had complete data (93%) at all 4 planned measurement times. Demographic and baseline characteristics of study participants were similar between the 2 groups (**Table 1**).

### PRIMARY OUTCOMES

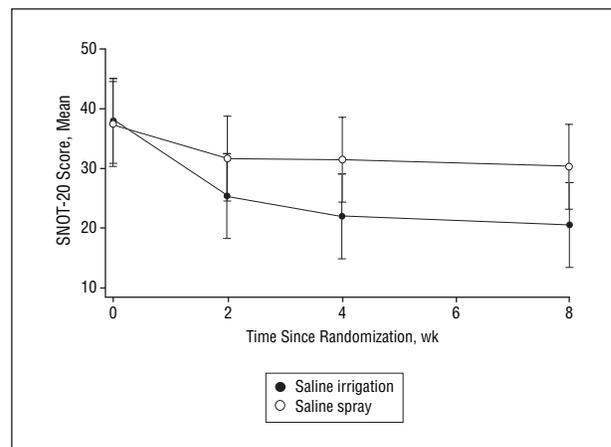
Baseline mean SNOT-20 scores (35.5 for spray, 37.6 for irrigation) were similar in the 2 groups and comparable to the mean SNOT-20 scores reported in patients with CRS.<sup>7</sup> Both study groups showed significant improvement in

**Table 1. Baseline Characteristics of Study Groups After Randomization<sup>a</sup>**

Characteristic	Spray (n=63)	Irrigation (n=64)	P Value
Age, mean (SD), y	48.1 (17.1)	45.1 (14.6)	.29
Men	18 (29)	24 (38)	.29
≥ College degree	52 (83)	51 (80)	.68
White	47 (75)	48 (75)	.72
Smoking status			.61
Current smoker	7 (11)	11 (17)	
Quit smoking	22 (35)	20 (31)	
Never smoked	34 (54)	33 (52)	
Symptom burden			.77
Rarely	0	1 (2)	
Seldom	3 (5)	4 (6)	
Often	29 (46)	29 (45)	
Always	31 (49)	30 (47)	
Symptom duration, mo			> .99
1-2	0	0	
3-6	5 (8)	5 (8)	
7-12	58 (92)	57 (92) <sup>b</sup>	

<sup>a</sup>Unless otherwise indicated, data are reported as number (percentage) of subjects.

<sup>b</sup>Missing data for 2 subjects in the irrigation group.



**Figure 2.** Scores from the 20-Item Sino-Nasal Outcome Test (SNOT-20)<sup>7</sup> determined at baseline and weeks 2, 4, and 8 after randomization by irrigation and spray study group.

SNOT-20 scores after randomization (**Figure 2**) at each of weeks 2, 4, and 8 ( $P < .001$  for each week, paired *t* test). However, the SNOT-20 scores were consistently lower (better) in the irrigation group than in the spray group.

The change in mean SNOT-20 scores over the study period in both groups is summarized in **Table 2**. When SNOT-20 scores over the 8-week period were modeled, the time-averaged decrease (improvement) in SNOT-20 scores from baseline was 6.7 ( $P < .001$ ) for the spray group, and the irrigation group had additional decreases of 4.4 ( $P = .02$ ) at week 2, 8.2 ( $P < .001$ ) at week 4, and 6.4 ( $P = .002$ ) at week 8 (data not shown). The analysis was adjusted for baseline scores of SNOT-20, smoking status, baseline symptom frequency, and age.

The frequency of sinus or nasal symptoms in the preceding 2 weeks at each measurement time as assessed with the global question is summarized in **Table 3**. At base-

**Table 2. Change From Baseline in SNOT-20 Scores at 2, 4, and 8 Weeks After Randomization<sup>a</sup>**

Week	Spray		Irrigation		P Value <sup>b</sup>
	Subjects, No.	SNOT-20 Score	Subjects, No.	SNOT-20 Score	
2	61	6.7 (14.5)	59	12.2 (16.1)	.05
4	60	7.4 (14.3)	57	16.2 (16.4)	.002
8	59	8.5 (15.2)	55	15.0 (17.6)	.04

Abbreviation: SNOT-20, 20-Item Sino-Nasal Outcome Test.<sup>7</sup>

<sup>a</sup>Unless otherwise indicated, data are reported as mean (SD) SNOT-20 scores. Within spray and irrigation groups, the changes were statistically significantly greater than 0 based on paired *t* test at *P* < .001 for every week.

<sup>b</sup>For comparison of irrigation with spray group using the 2-sample *t* test.

**Table 3. Study Participants Who Reported Symptoms Often or Always<sup>a</sup>**

Week	Spray	Irrigation	P Value <sup>b</sup>
0	58 (95)	56 (93)	.68
2	42 (69)	32 (53)	.08
4	38 (62)	28 (47)	.08
8	37 (61)	24 (40)	.02

<sup>a</sup>Unless otherwise indicated, data are reported as number (percentage) of subjects.

<sup>b</sup>Based on  $\chi^2$  test.

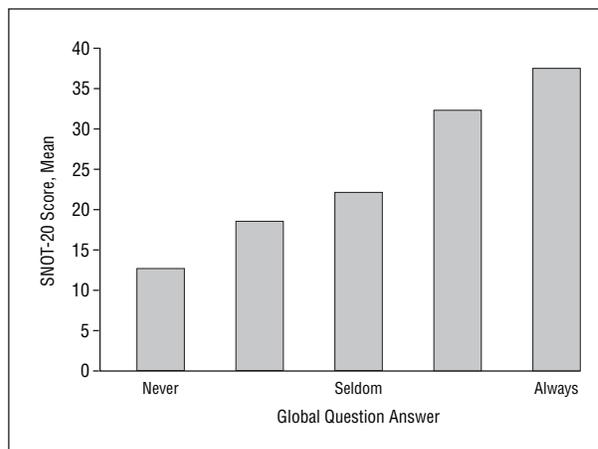
line, 95% of the spray group (n=58) and 93% of the irrigation group (n=56) reported having been bothered by frequent nasal or sinus symptoms. However, at week 8, 40% of the irrigation group (n=24) vs 61% of the spray group (n=37) reported having frequent symptoms. When symptom frequency was dichotomized and modeled, frequent symptoms (often or always vs seldom, rarely, or never) were significantly less likely among the irrigation group. During the follow-up period, the odds of frequent symptoms for the irrigation group relative to the spray group were 0.49 (*P* = .01) after adjusting for smoking status, patient age, and baseline SNOT-20 score.

The absolute risk reduction in symptom frequency with saline irrigations was 0.2 (95% confidence interval 0.02-0.38) (*P* = .01) with the number needed to treat equal to 5. The absolute risk reduction of symptom severity, measured by a clinically significant improvement in SNOT-20 scores (corresponding to  $\geq 16$  points), was 15% with the number needed to treat equal to 7.

As depicted in **Figure 3** using data from both groups, there was good correlation between mean SNOT-20 scores (symptom severity) and global question (symptom frequency) answers.

## SECONDARY OUTCOMES

The numbers and percentages of participants who reported medication use for treatment of their nasal or sinus symptoms are summarized in **Table 4**. Participants in both groups were more likely to use oral medications than nasal medications at all time points. Within each group, over the duration of the study, there was no difference in the number of participants who reported medication usage. Since there was no within-group difference, we combined the 2 groups to assess any change in medication use



**Figure 3.** Relationship between mean 20-Item Sino-Nasal Outcome Test (SNOT-20)<sup>7</sup> scores and global question scores.

over time. When data across time and groups were combined, the number of participants reporting any medication use was found to be significantly less, both for oral medications (*P* = .002) and nasal medications (*P* = .04), relative to baseline. However, the duration of medication use (measured in days) did not differ significantly from baseline (*P* = .39 for oral medication duration; *P* = .57 for nasal medication duration). When the analysis of SNOT-20 was further adjusted for the duration of nasal medication use in the past 2 weeks, the irrigation group still showed greater symptom reduction at each of the 3 follow-up times compared with the spray group, and each additional day of nasal medication use was associated with a 0.54-point lower SNOT-20 score (*P* = .01).

Compliance (defined as using the assigned intervention for at least 11 days in the past 2 weeks) was higher in the spray group (97%, 93%, and 93%) than in the irrigation group (92%, 81%, and 79%) at weeks 2, 4, and 8, respectively (*P* = .03).

Adverse effects were common in both groups (25% in the spray group, 43% in the irrigation group). Forty-one subjects reported a total of 67 occurrences of adverse effects over the duration of the study (32%). Post-treatment nasal drainage (an expected adverse effect) was the most common adverse effect (n=14) in each group. There was no statistically significant difference (*P* = .21) in the overall rate of adverse effects reported between the 2 groups, and no participants discontinued treatment owing to adverse effects.

**Table 4. Medication Use by Study Groups**

Week	Spray		Irrigation	
	Participants, No. (%)	Days Used, Mean (SD) <sup>a</sup>	Participants, No. (%)	Days Used, Mean (SD) <sup>a</sup>
	<b>Oral</b>			
0	29 (48)	8.7 (8.9)	30 (50)	5.4 (6.3)
2	18 (30)	6.3 (5.1)	19 (32)	6.3 (5.1)
4	19 (31)	7.8 (5.4)	21 (35)	9.9 (5.1)
8	19 (31)	8.6 (5.0)	17 (28)	9.9 (5.3)
	<b>Nasal</b>			
0	13 (21)	6.5 (5.5)	11 (18)	8.5 (5.6)
2	6 (10)	4.8 (3.4)	9 (15)	8.9 (6.1)
4	7 (11)	3.3 (1.8)	6 (10)	7.3 (6.0)
8	12 (20)	5.9 (4.1)	10 (17)	10.3 (5.3)

<sup>a</sup>In the past 2 weeks.

**COMMENT**

To our knowledge, this is the first randomized controlled trial showing greater efficacy of saline irrigation vs saline spray for providing short-term (8 week) relief for chronic nasal symptoms. The result demonstrated substantially greater benefit with irrigation than with spray, both in terms of symptom severity (SNOT-20) and symptom frequency. The irrigation group achieved a clinically significant improvement in quality of life as measured by the SNOT-20 instrument, whereas the spray group did not. Furthermore, the irrigation group experienced 50% lower odds of frequent nasal symptoms compared with the spray group.

The baseline severity of nasal and sinus symptoms of the subjects enrolled in this study and the magnitude of symptom improvement achieved with irrigation can best be appreciated when compared with other studies that have used the SNOT-20. In the study by Piccirillo et al,<sup>7</sup> the work that validated the instrument, comparable SNOT-20 scores for subjects with presumed CRS and healthy subjects, were 38 and 12, respectively.<sup>7</sup> Although the patients in our study did not undergo clinical evaluation to discern the underlying cause of their chronic nasal and sinus complaints, the severity of their symptoms, as measured by baseline mean SNOT-20 scores (35.5, spray group; 37.6, irrigation group), and the chronicity of their symptoms (>6 months for most subjects), were comparable to those with presumed CRS.

As for the magnitude of symptom improvement, Piccirillo et al<sup>7</sup> suggested a clinically meaningful SNOT-20 change score that would correspond to 16 in our current study. For comparison, SNOT-20 scores of patients who undergo sinus surgery have improved 19 to 22 points,<sup>10</sup> and patients with severe nasal polyposis treated with oral prednisone improved 10 points.<sup>11</sup> Our mean SNOT-20 improvement (range, 12.2-16.2 points) over the 8-week study is similar to a clinically meaningful threshold. This finding is even more remarkable given the nominal cost and minimal risk of this saline intervention.

The benefits derived from nasal saline use are likely due to 1 or more local effects,<sup>12,13</sup> including decreased viscosity of nasal secretions,<sup>14</sup> decreased edema of the nasal mucosa, and removal of debris, bacteria, allergens, and inflammatory mediators by the mechanical “lavage” ac-

tion of saline irrigation.<sup>15</sup> Enhanced mucociliary clearance has also been hypothesized as a possible mechanism of action, although the data are conflicting.<sup>16,17</sup> The greater efficacy of irrigation over saline spray may be due to greater volume, increased delivery pressure, and mechanical debridement achieved with irrigations. (A demonstration of nasal irrigation can be viewed at <http://www.salineirrigation.com/instructions.html>.)

In the present study, although overall compliance in both groups was high, participants in the spray group were more compliant than those in the irrigation group ( $P = .04$ ). Nonetheless, the compliance of patients in the irrigation group (79%) was still quite high and comparable to the 87% compliance rate at 6 months reported by Rabago et al.<sup>4</sup> It also suggests that our results are a conservative estimate of the true benefit of irrigation therapy.

Adverse effects were frequent in both groups, although most were minor, and none resulted in discontinuation of therapy. The most commonly reported adverse effect in each group was posttreatment drainage. Others occurred more sporadically, and included symptoms common to patients with chronic nasal and sinus conditions (eg, dryness in the nose and pressure in the ears). Overall, the types and rates of these effects were comparable to those reported in other clinical trials.<sup>4,13</sup> Although subjects in the irrigation group were more likely to have these adverse effects, no subject in the study found the adverse effects severe enough to stop treatment. A 2006 study by Rabago et al<sup>18</sup> reports that patients not only continue to use irrigation long term but also are able to self-adjust their irrigation schedule and technique to minimize any possible adverse effects.<sup>18</sup> The positive sense of satisfaction among irrigation users is associated with clinical improvement as well as improvement in quality of life.

We did not find decreased medication use with adjunctive saline treatments. This was somewhat surprising and contrasts with findings from other prospective studies of saline irrigation, which have shown decreased medication use overall<sup>12</sup> and specifically less antibiotic use.<sup>3</sup> There are several possible explanations for our negative result. Rabago et al<sup>3</sup> required a prior diagnosis of recurrent acute rhinosinusitis or CRS and thus may have selected for subjects with greater antibiotic or other medication use. Since our study was designed to recruit patients without any spe-

cific diagnosis or cause for their symptoms, differences in inclusion criteria may have contributed to the inability to demonstrate a reduction in medication use with initiation of nasal irrigations. Heatley et al<sup>12</sup> reported decreased medication use, but it is not clear whether they found fewer subjects using any medication or fewer medication days among all subjects. Finally, our study was slightly underpowered to detect change in medication use (the study had 78% power to detect reduction in medication use compared with 99% to detect a clinically significant change in SNOT-20 score). Further studies focused on recruiting subjects with high rates of antibiotic use for sinusitis could be designed to evaluate the potential cost savings of this intervention.

The generalizability of this study is one of its greatest strengths. The results of this study are applicable to the large number of patients with assorted nasal and sinusitislike symptoms seen by primary care providers on a daily basis. This study was specifically designed to recruit subjects from the general community with self-reported chronic nasal and sinus symptoms. Other strengths of our study design include prospective recruitment, patient-oriented primary and secondary outcomes, an intention-to-treat analysis, and a very low dropout rate. However, this study was not blinded and did not have adequate power to evaluate the potential heterogeneous subgroups of patients with nasal symptoms, such as those patients with allergic rhinitis, nasal polyps, cystic fibrosis, or those with nasal congestion that complicates nasal continuous positive airway pressure use. In addition, the nature of our study did not allow blinding, although we were diligent in our efforts to prevent any experimenter bias. Finally, despite efforts to document compliance through the use of self-report diaries, there is the possibility for patient overreport of compliance. However, given the positive findings of our study, we do not believe this was a notable problem.

In conclusion, our study suggests that nasal irrigations performed with a large volume and delivered with low positive pressure are more effective than saline sprays over an 8-week period for treatment of chronic nasal and sinus symptoms among a community-based population with self-reported symptoms. Our findings also suggest that the benefit of saline irrigations as adjunctive therapy for chronic nasal and sinus-related symptoms could be expanded beyond the otolaryngologist's armamentarium and incorporated into the general practice of other clinical health care providers who frequently evaluate patients with such symptoms. Primary care physicians and physician extenders may prove to be essential in explaining the benefits and usefulness of saline irrigations to patients in the community.

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**Author Contributions:** Dr Pynnonen had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Pynnonen, Mukerji, Kim, Adams, and Terrell. *Acquisition of data:* Pynnonen,

Mukerji, and Terrell. *Analysis and interpretation of data:* Pynnonen, Mukerji, Kim, and Terrell. *Drafting of the manuscript:* Pynnonen, Mukerji, Kim, and Terrell. *Critical revision of the manuscript for important intellectual content:* Pynnonen, Mukerji, Kim, Adams, and Terrell. *Statistical analysis:* Mukerji, Kim, and Terrell. *Obtained funding:* Pynnonen, Kim, and Terrell. *Administrative, technical, and material support:* Pynnonen, Mukerji, and Terrell. *Study supervision:* Pynnonen, Mukerji, and Terrell. **Financial Disclosure:** None reported.

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