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Clinical Study and Literature Review of Nasal Irrigation

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Objectives/Hypothesis: **Nasal disease, including chronic rhinosinusitis and allergic rhinitis, is a significant source of morbidity. Nasal irrigation has been used as an adjunctive treatment of sinonasal disease. However, despite an abundance of anecdotal reports, there has been little statistical evidence to support its efficacy. The objective of this study was to determine the efficacy of the use of pulsatile hypertonic saline nasal irrigation in the treatment of sinonasal disease.** ***Study Design:*** **A prospective controlled clinical study.** ***Methods:*** **Two hundred eleven patients from the University of California, San Diego (San Diego, CA) Nasal Dysfunction Clinic with sinonasal disease (including allergic rhinitis, aging rhinitis, atrophic rhinitis, and postnasal drip) and 20 disease-free control subjects were enrolled. Patients irrigated their nasal cavities using hypertonic saline delivered by a Water Pik device using a commercially available nasal adapter twice daily for 3 to 6 weeks. Patients rated nasal disease–specific symptoms and completed a self-administered quality of well-being questionnaire before intervention and at follow-up.** ***Results:*** **Patients who used nasal irrigation for the treatment of sinonasal disease experienced statistically significant improvements in 23 of the 30 nasal symptoms queried. Improvement was also measured in the global assessment of health status using the Quality of Well-Being scale.** ***Conclusions:*** **Nasal irrigation is effective in improving symptoms and the health status of patients with sinonasal disease.** ***Key Words:*** **Nasal irrigation, rhinosinusitis, allergic rhinitis, aging rhinitis, nasal disease, Water Pik, alternative therapies.**
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INTRODUCTION

Nasal disease is a significant source of morbidity. Upper respiratory tract infections, rhinosinusitis, and allergic rhinitis are among the most frequent reasons for visits to primary care physicians and are the leading causes of absenteeism in the United States.[1,2] Sinusitis alone affects 15% of the population[3,4] with direct medical costs estimated at $2.4 billion[5] annually; allergic rhinitis affects 20% to 30% of the US population[6] with an estimated cost in the United States of $3.4 billion in 1993.[7]

Common alternative treatments for nasal disease are listed in Table I. Nasal irrigation was originally used at the University of California, San Diego (USCD, San Diego, CA) Nasal Dysfunction Clinic after endoscopic sinus surgery. Patients who used nasal irrigation after surgery reported tremendous benefits and often continued to irrigate well beyond the prescribed postoperative period. This observation led to the application of nasal irrigation in the treatment of nasal diseases including allergic rhinitis and chronic rhinosinusitis. Nasal irrigation has been used as an adjunctive treatment modality that has been recommended not only by the UCSD Nasal Dysfunction Clinic, but also by physicians around the world for the treatment of rhinosinusitis,[2,8–10] allergic rhinitis,[11,12] and other sinonasal disease.[13–16] Despite strong anecdotal evidence supporting its efficacy, statistical evidence has been lacking.

There has been little consensus regarding a uniform protocol for nasal irrigation. Recommendations include saline of varying tonicities, a multitude of delivery vehicles (including nasal sprayer, bulb syringe, cupped hand, and other commercially available systems), and a variety of additives. There is mounting evidence that hypertonic saline delivered via a standard Teledyne Water Pik (Fort Collins, CO) device has advantages over the alternatives. A recent study by Talbot et al.[13] demonstrated that hypertonic saline, but not normal saline, increased mucociliary saccharin transit times. In addition, it was shown that pediatric patients with chronic rhinosinusitis who had irrigation with hypertonic saline had better outcomes than those treated with normal saline.[17] It has also been shown that pulsatile saline delivery is more effective in removing bacteria than delivery via bulb syringe.[18] Furthermore, a study by Adam et al.[19] showed that saline delivered via nasal sprays such as Ocean or SeaMist is ineffective in improving symptoms of those with the common cold or rhinosinusitis.

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TABLE I.
Alternative Therapies Used for the Treatment of Nasal Disease.

Chicken soup
Humidifiers
Nasal hyperthermia
Hot tea
Iodides
Nasal irrigation

This study evaluated the efficacy of nasal irrigation using hypertonic saline delivered by a Water Pik dental device in the treatment of sinonasal disease. Patient outcomes were measured using a patient-reported nasal disease–specific questionnaire[20] and a standardized health outcomes measure, the Quality of Well-Being (QWB) scale.[21–24] The hypothesis was that there would be significant improvements in both nasal disease–specific measures and the global outcome measure for patients who used hypertonic saline irrigation.

MATERIALS AND METHODS

The present study was a prospective Institutional Review Board–approved clinical trial involving patients recruited from the UCSD Nasal Dysfunction Clinic. The study period spanned 1 calendar year. All patients with sinonasal disease were eligible for the study, including those with allergic rhinitis, aging rhinitis (ICD-9 code 472.00, chronic rhinitis not otherwise specified), atrophic rhinitis, postnasal drip, and chronic rhinosinusitis. Patients who were not representative of the general patient population were excluded, such as those with head and neck cancer, patients with human immunodeficiency virus (HIV)–related nasal disease or cystic fibrosis, and postoperative nasal surgery patients. Control patients, who performed irrigation twice daily but did not have sinonasal disease, were either healthy subjects (patients' spouses, clinic employees) or patients seen at the clinic for reasons other than rhinological illness.

Patients were asked to rate nasal disease–specific symptoms (congestion, sleep disturbance, discharge, postnasal drip, seasonal and perennial allergies, anosmia, stress, cough, hoarseness, itchy nose, itchy eyes, sneezing, asthma, head and facial pain [both intensity and frequency], nasal cleanliness, and quantity of mucus) using a continuous scale ranging from 0 (no complaint or lowest severity) to 100 (maximum complaint, greatest severity). Duration of symptoms was assessed by asking patients to report the number of days during the past 8-week period in which they experienced a particular symptom. In addition, they were asked to complete a global health assessment measure, the self-administered QWB scale. All patients received a physical evaluation that included administration of the alcohol "sniff test" for evaluation of olfaction.[25] Patients were evaluated at the initial encounter and at follow-up 3 to 6 weeks later. Every effort was made to schedule all patients for a follow-up visit. Patients who did not return were contacted by telephone, and the reasons for their choosing not to return were queried and noted.

Patients were treated as the senior author (T.M.D.) deemed appropriate for each individual's history, physical examination, and laboratory data independent of enrollment status. For nasal irrigation, patients were instructed to use a store-bought adjustable Water Pik dental device with a nasal adapter, available from Anthony Products (Indianapolis, IN) and Ethicare Products (Fort Lauderdale, FL). The Grossan nasal adapter is available from HydroMed (Los Angeles, CA) and Kenwood Therapeutics (Fairfield, NJ).

Patients were instructed to irrigate each nostril with 250 mL of lukewarm tap water mixed with a half-teaspoon of table salt twice daily. The temperature of the water, the amount of salt added, and the pressure were individually adjusted by each patient to maximize comfort and convenience. The lowest pressure setting was recommended for initial uses.

The results were analyzed by comparing symptom scores at the initial evaluation with those from the follow-up visit (3–6 wk) using Student paired t tests. Several patient subsets based on diagnosis or treatment were compared using repeated-measures ANOVA with post hoc comparisons using the Bonferroni/Dunn procedure. $P < .05$ was defined as statistically significant.

RESULTS

Patients who used nasal irrigation for the treatment of sinonasal disease reported statistically significant improvements in 23 of the 30 symptoms queried after 6 weeks of use (Table II). These included nasal congestion, postnasal drip, seasonal/perennial allergies, and nasal discharge. There were improvements in severity and duration of symptoms. Improvements were also identified in a global assessment of health status (QWB scale). All improvements were also statistically significant when compared with changes in symptom scores reported by control patients. Compliance after 6 weeks was 92% among patients who returned for follow-up.

Because it was possible that concurrent nasal medications may have confounded the symptom scores, patients who used nasal irrigation alone were compared with patients who used nasal irrigation in addition to nasal medications including nasal steroids, antibiotics, and antihistamines. Although there was a trend toward greater improvement in patients who used additional medications, no statistically significant differences were identified between these two patient groups (Table II).

Adverse reactions included nasal irritation, nasal discomfort, otalgia, or pooling of saline in paranasal sinuses with subsequent drainage. A total of 114 patients did not have follow-up. The majority of these patients (109/114) were contacted by telephone and stated that they did not come in for a follow-up examination because of scheduling conflicts or because they believed follow-up was not necessary or would not be beneficial. Eighty-three of the 109 patients (76%) reported symptomatic improvement. Twenty-six patients (24%) reported adverse side effects or reported that they experienced no benefit from nasal irrigation.

DISCUSSION

This study has demonstrated that nasal irrigation using hypertonic saline delivered by a pulsatile Water Pik dental device is effective in the treatment of sinonasal disease, including chronic rhinosinusitis, allergic rhinitis, postnasal drip, aging rhinitis, and nasal congestion. Patients experienced improved sleep, decreased stress, and improvements in symptoms of nasal disease including postnasal drip, cough, headaches, and allergies. Patients also had symptoms for fewer days per week when using nasal irrigation.

TABLE II.
Net Changes in Symptom Scores of Patients Before and After Intervention ($t_1 - t_2$).

	All Patients Treated With Nasal Irrigation (n = 108)		Nasal Irrigation Alone (n = 62)		Nasal Irrigation Plus Another Treatment (n = 46)		Control (n = 20)	
	Net Change	*P* Value	Net Change	*P* Value	Net Change	*P* Value	Net Change	*P* Value
Global Health Status Measure (0–1)								
QWB	*0.036	.0015	*0.037	.0067	0.036	.0627	0.0013	.9705
Nasal Disease–Specific Measures, Severity (0–100)								
Nasal congestion	*23.6	<.0001	*16.7	.0010	*32.6	<.0001	1.3	.7724
Nasal discharge	*16.3	<.0001	*16.9	.0002	*14.1	.0120	−0.8	.8763
Postnasal drip	*23.4	<.0001	*19.5	<.0001	*28.0	<.0001	−4.4	.4758
Nasal cleanliness	*17.3	<.0001	*13.7	.0008	*22.6	<.0001	7.4	.0763
Mucus	*10.6	0.0003	*6.8	.6990	*16.1	.0006	−2.0	.5078
Itchy nose	*9.4	0.0009	*6.8	.0698	14.1	.0015	7.8	.0445
Itchy eyes	*11.1	<.0001	*7.7	.0233	*17.0	.0001	8.4	.0079
Sneezing	*8.9	0.0004	*5.3	.0776	*14.7	.0007	9.8	.0459
Seasonal allergies	*18.4	<.0001	*13.1	.0022	*27.2	<.0001	5.5	.0206
Perennial allergies	*14.0	<.0001	*6.5	.0757	*26.2	<.0001	0.3	.3299
Head and facial pain, frequency	*11.4	<.0001	*11.6	.0050	*10.5	.0083	−4.9	.2076
Head and facial pain, intensity	*7.6	0.0153	*6.8	.0583	*9.2	.0988	−2.5	.6058
Smell loss	*9.8	0.0002	*3.6	.2473	*18.6	<.0001	0.5	.3299
Taste loss	*4.3	.0042	1.7	.2385	8.9	.0043	0	
Dysgeusia	*9.7	.0003	6.8	.0319	*15.0	.002	3.3	.2918
Hoarseness	*9.2	.0006	*9.2	.0219	*8.2	.0138	−1.0	.3299
Sleep disturbance	*20.0	<.0001	19.0	<.0001	21.0	.0004	4.8	.2300
Stress	*11.4	.0010	*9.2	.0494	14.5	.0043	0.8	.8474
Cough	*13.1	<.0001	*11.4	.0060	*15.1	.0034	1.3	.7610
Nasal Disease–Specific Measures, Duration (weeks)								
Sinus headaches and pain, duration	*0.63	.0211	*0.71	.0256	*0.38	.4552	0.278	.3160
Nasal drainage and postnasal drip, duration	*1.86	<.0001	*1.49	.0044	*2.18	.0001	(−.25)	.2690
Congestion, duration	*1.33	.0002	*0.80	.0958	*1.92	.0004	0	N/A

Positive values represent improvements and negative values represent worsening of symptoms. Data were analyzed using Student's paired *t* test and repeated measure ANOVA. There were no significant changes for phantosmia, asthma, burning mouth, alcohol sniff test, or parosmia for any of the groups. A significance level of $P < .05$ was used. Asterisk indicates changes in symptom scores that were found to be statistically significantly different from control values by repeated measures ANOVA with the Bonferroni/Dunn post hoc procedure with a significance level of $P < .05$.

Clinical Applications

Nasal irrigation plays a major role in the treatment of nasal disease at the UCSD Nasal Dysfunction Clinic. The usual instructions are twice-daily pulsatile nasal irrigation with 500 mL of warm hypertonic saline. Allergic rhinitis is treated with nasal irrigations, nasal steroids, and environmental control. In aging rhinitis, as patients age and sex hormones decrease, the nasal mucus membranes undergo changes. The changes in mucus membranes include 1) a decrease in height and 2) a decrease in water secretion. Thus nasal secretions are more mucoid and tenacious. Whereas more watery, less viscous secretion is swallowed, the thickened secretion is less easily swallowed and ultimately becomes annoying by its presence and associated cough. This chronic, annoying condition is cured by twice-daily nasal irrigations. Troublesome septal perforations with symptoms of crusting and bleeding are greatly ameliorated by nasal irrigation. Postoperative care of endoscopic sinus surgery includes 6 weeks of nasal irrigation; suction and cleaning are not required. Adhesions occur rarely. Sinusitis in the cystic fibrosis patient is treated with endoscopic sinus surgery followed by twice-daily nasal irrigation and once-daily tobramycin 20 mg in the last 50 mL of nasal irrigation, irrigated evenly in both nostrils.[26] The thick, tenacious secretion and rhinosinusitis of HIV illness is treated with endoscopic sinus surgery followed by twice-daily nasal irrigation.

Mechanism of Action

This study has shown that nasal irrigation is effective in decreasing symptoms of nasal disease. The mechanism by

which this improvement is effected is unclear. It has been hypothesized that nasal irrigation promotes improvement of nasal symptoms via 1) improving mucociliary function,[13] 2) decreasing mucosal edema, 3) decreasing inflammatory mediators,[27] and 4) mechanically clearing inspissated mucus.[28]

Mucociliary clearance (MCC) is important in the development of sinonasal disease. Scanning electron microscopy has shown that there is ciliary disorientation, loss of ciliated cells, an increasing number of nonciliated cells, metaplasia, and extrusion of epithelial cells in patients with chronic rhinosinusitis.[29] It is damage to the mucociliary transport system that leads to mucosal stasis, infection, and thickening of secretions. MCC is impaired in patients who have chronic sinonasal disease but may return to normal after removal of inspissated mucus and other debris.[30] In a study involving patients with chronic rhinosinusitis, MCC increased at least twofold in 13 patients after daily nasal irrigation with normal saline, 11 of whom had complete disappearance of visible pus.[31] In addition, Parsons et al.[9] found that nasal irrigation using hypertonic saline improved mucociliary transport time in patients with acute and chronic rhinosinusitis.

A study comparing changes in inflammatory mediators in patients with perennial rhinitis treated with nasal hyperthermia or hypertonic nasal irrigation via Water Pik demonstrated that the greatest decline in histamine levels occurred in the group using hypertonic saline nasal irrigation, with declines in leukotriene C_4 levels occurring exclusively in this group.

Other Treatment Modalities

Nasal hyperthermia. A modality that has recently gained attention has been nasal hyperthermia for treatment of nasal disease. This method involves the delivery of heated mist of varying particle sizes to the nasal mucosa and is a treatment modality that has been recommended for years to treat nasal symptoms attributable to various causes and origins including chronic rhinosinusitis, allergic rhinitis, and the common cold.[19,32–35] Georgitis[27] demonstrated that in patients with perennial allergic rhinitis, local hyperthermia, but not nasal irrigation, significantly reduced nasal symptom scores and increased nasal airflow. The salt concentration was not reported. In addition, patients in this group were required to perform irrigation for a total of 15 minutes, far above the 2 to 3 minutes usually required in our current protocol. This may have accounted for the large preference of patients for nasal hyperthermia over irrigation. Past studies have shown significant symptomatic improvement in patients with allergic rhinitis[21] and the common cold[36] who were treated with nasal hyperthermia. Other authors have found no beneficial effects of steam inhalation on common cold symptoms.[23] Given the current evidence, further inquiry regarding nasal hyperthermia is indicated.

Additives. Several additives to the saline used in nasal irrigation have been used, including aminoglycosides, vasoconstrictors, and buffers. Shaikh[37] compared patients with allergic rhinitis who were treated with nasal irrigation delivered via a bulb syringe with normal saline or without added 1% ephedrine. It was found that the use of the ephedrine-saline nasal wash resulted in significantly greater improvement as measured by symptom scores and nasal inspiratory flow rates. Aminoglycosides have been used as an additive in nasal irrigation protocols, especially in the management of chronic rhinosinusitis in patients with cystic fibrosis to prevent the colonization and growth of *Pseudomonas* organisms.[25] Several authors have recommended buffered hypertonic saline using sodium bicarbonate to a pH of approximately 7.6.[11,13] Other additives that have been recommended include white corn syrup[11] and alkalol,[10] although the effects of such additives have not been reported

Other products. A number of products have been developed to using gravity to deliver saline for nasal irrigation. Among these are the Neti pot (http://www.zeta.org.au/nunyara/neti/medical) and SinuCleanse (http://www.sinucleanse.com).

CONCLUSION

Nasal irrigation is an effective tool in improving symptoms in patients with nasal disease. Nasal irrigation represents a cost-effective method of alleviating symptoms of nasal disease. This method has no documented serious adverse effects and is well tolerated by most patients. Given the large number of patients with sinonasal disease, this nasal irrigation has enormous potential in improving quality of life in a cost-efficient manner for millions of patients.

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