The Use of Saline Nasal Irrigation in Common Upper Respiratory Conditions

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FACULTY DISCLOSURE STATEMENTS:

Dr. Rabago reports no arrangements or affiliation with commercial corporations whose products may be mentioned in this program.

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_Pharmacy_
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TARGET AUDIENCE:

This accredited program is targeted to pharmacists and pharmacy technicians. Estimated time to complete this monograph and posttest is 90 to 120 minutes.
METHOD OF PARTICIPATION:

There are no fees for participating and receiving CE credit for this activity. During the period June 1, 2008 through June 30, 2010, participants must:

1. read the learning objectives and faculty disclosure;
2. study the educational activity;
3. complete the posttest by recording the best answer to each question in the answer key on the evaluation form;
4. complete the evaluation form; and
5. mail or fax the evaluation form with answer key to the address listed on the form. For faster service, enter your answers on the Internet at www.uspharmacist.com. A statement of credit will be issued upon receipt of a completed activity evaluation form and a completed posttest with a score of 70% or better.

DISCLAIMER:

Participants have an implied responsibility to use the newly acquired information to enhance patient outcomes and their own professional development. The information presented in this activity is not meant to serve as a guideline for patient management. Any procedures, medications, or other courses of diagnosis or treatment discussed or suggested in this activity should not be used by clinicians without evaluation of their patients’ conditions and possible contraindications or dangers in use, review of any applicable manufacturer’s product information, and comparison with recommendations of other authorities.

GOAL:

To provide insight into the use of saline nasal irrigation for several common upper respiratory tract conditions.

OBJECTIVES:

After completing this program, participants will be able to:

1. Describe the etiology, prevalence, signs and symptoms, and related costs of several common upper respiratory tract infections;*
2. Review the origin, development, and current status of saline nasal irrigation;*
3. Evaluate the clinical trial data for the use of saline nasal irrigation;*
4. Describe the proper procedure for administering saline nasal irrigation;* and
5. Discuss the role of the pharmacist in the use of saline nasal irrigation in several common upper respiratory conditions.

*Also applies to pharmacy technicians.

Acute viral upper respiratory infection (URI), otherwise known as the common cold, is humanity’s most common affliction. Causative agents include rhinovirus, coronavirus, parainfluenza, respiratory syncytial
virus, adenovirus, enterovirus, and metapneumovirus. In the US alone, non-influenza URIs account for more than 20 million doctor visits, and 40 million lost school and work days each year. The total economic impact of URIs is estimated to be $40 billion, putting acute URIs in the "top 10" of most expensive illnesses. Even a minimal reduction of this burden could lead to substantial economic and quality-of-life benefits.

Available treatments are, at best, modestly effective in reducing cold symptoms. Immunization strategies are impractical, as hundreds of viral strains are antigenically distinct. Conventional preventive strategies are limited to contact avoidance and hand washing.

Risk factors for acute viral URIs are well known and include smoking, youth or advanced age, and underlying chronic medical conditions. Since acute viral URIs are transmitted by aerosol or direct contact, crowding and direct exposure to infected persons, especially to the infected conjunctivae, nose, or mouth, increases infection risk.

The primary site of viral inoculation is the nasal mucosa, although the conjunctiva may also be involved. Nose dryness or irritation is often the first symptom, and is followed within hours by profuse watery rhinorrhea, nasal congestion, and sneezing. A sore throat or throat irritation, malaise, headache, cough, irritability, and restlessness are common symptoms. Infants and preschoolers are more likely to experience fevers, which are often 38° to 39° C; otherwise, fever is usually absent or low-grade. Nasal obstruction can interfere with sleep and/or feeding. Typically, nasal secretions become thicker and colored after the first few days of illness.

The following conditions may be managed with saline nasal irrigation (SNI). SNI is a technique by which liquid or aerosolized saline is introduced into the nasal cavity via one nostril and allowed either to pour (or be gently blown) out the same nostril, or allowed to flow around the nasal septum and out the contralateral nostril.

ACUTE BACTERIAL RHINOSINUSITIS (ABRS)

ABRS is a common clinical problem that is associated with high morbidity. Its symptoms are often refractory to treatment (Table 1). The ABRS-related costs are substantial. In 1996, ABRS accounted for approximately 26.7 million office and emergency department visits, and resulted in $5.8 billion in direct costs. Between 1985 and 1992, ABRS was the fifth most common indication for antibiotics. The effects of sinus disease on patients’ quality of life are significant; on some measures, the quality of life impairment, resulting from sinus disease, rates as high as that associated with chronic back pain, congestive heart disease, and chronic obstructive pulmonary disease. ABRS often occurs after a viral URI, especially in susceptible persons. The ABRS risk factors are several and overlapping and promote pathological changes, including inflammation, increased mucus production, the disruption of normal ciliary beat frequency, and decreased mucociliary clearance. These combined influences of viral and subsequent bacterial infection and increased susceptibility initiate breakdown of the normal function of the nasal mucosa. The resulting failure of normal mucus transport in the nasal cavity and decreased sinus ventilation are major factors in occlusion of the sinus ostia and, thus, the development of sinus infection. Recent data suggest that the mucus of virally or bacterially infected persons may itself be toxic and contribute to the pathologic cycle of bacterial sinus disease.
Table 1. Things of Note About Acute Bacterial Rhinosinusitis (ABRS)

Risk factors include viral URI, dental infections, inhalation of irritants, inflammation, increased mucus production, the disruption of normal ciliary beat frequency, and decreased mucociliary clearance.

Symptoms include purulent nasal discharge with unilateral predominance, local pain with unilateral predominance, purulent nasal discharge bilaterally, pus on inspection inside the nose, profuse watery rhinorrhea, nasal congestion, and sneezing.

The most common risk factor for ABRS is viral URI; other common risk factors include allergic rhinitis (AR), anatomic facial variations, dental infections, and inhalation of irritants.\textsuperscript{11}

Patients with ABRS experience a multitude of signs and symptoms. Symptoms noted to have the best predictive ability are a part of the “Berg and Carenfelt” clinical diagnostic criteria, and include at least two of the following four signs or symptoms: purulent nasal discharge with unilateral predominance, local pain with unilateral predominance, purulent nasal discharge bilaterally, or pus on inspection inside the nose.\textsuperscript{12} Other symptoms of ABRS can include profuse watery rhinorrhea, nasal congestion, and sneezing. Nasal secretions typically become thicker and colored after the first few days of illness. Irritability or restlessness is common. Fever is possible in progressive disease but is neither a sensitive nor specific finding in diagnosing a bacterial etiology of rhinosinusitis.

CHRONIC RHINOSINUSITIS

Chronic rhinosinusitis is a prevalent chronic illness. In 1994, the number of chronic rhinosinusitis cases in the US was 35 million, for a prevalence of 134 per 1,000 patients.\textsuperscript{13} The histopathologic hallmark of chronic rhinosinusitis is persistent eosinophilic inflammation and release of major basic protein (Table 2). The role of bacteria in the pathogenesis of chronic rhinosinusitis has recently been questioned; many cases of chronic rhinosinusitis are not associated with an active infection. In cases of infectious chronic rhinosinusitis, a wide variety of bacteria (often mixed flora or anaerobic organisms), viruses, and fungi have been implicated as either etiological or exacerbating agents.

Table 2. Things of Note About Chronic Rhinosinusitis

Develops in patients with ABRS who have not responded to treatment or in those who have not received treatment.

Symptoms include nasal stuffiness, postnasal drip, facial fullness, malaise, and headache.

Most cases of chronic rhinosinusitis develop in patients with ABRS who have not responded to treatment or in those who have not received treatment. Generally defined as a sinus infection persisting for more than three months, chronic rhinosinusitis usually manifests differently than ABRS. Symptoms of chronic rhinosinusitis include nasal stuffiness, postnasal drip, facial fullness, malaise, and headache.
USE OF ANTIBIOTICS IN ABRS AND CHRONIC RHINOSINUSITIS

Symptoms of ABRS and chronic rhinosinusitis may be relieved with topical decongestants, topical steroids, antibiotics, nasal saline, topical cromolyn, or mucolytics, although the FDA has not approved any therapy as primary treatment for chronic rhinosinusitis. Antibiotic use for ABRS and chronic rhinosinusitis is controversial. Growing evidence suggests that in most patients who present with symptoms consistent with either condition antibiotics are not warranted. In spite of efforts to curb unwarranted use of antibiotics, the antibiotic prescription rate for these conditions is high, especially in cases with presumed ABRS.

Acute bacterial rhinosinusitis is difficult to diagnose definitively. It is estimated that 37% to 63% of patients given this diagnosis in fact do not have a bacterial cause. The precise impact of widespread and unnecessary antibiotic use is difficult to assess; it includes medication-related costs, side effects and adverse events, and antibiotic resistance. The problem of "antibiotic pressure" and resulting antibiotic resistance of common bacterial pathogens is "[...] one of the world's most pressing public health problems. Over the last decade, almost every type of bacteria has become stronger and less responsive to antibiotic treatment when it is really needed." Antibiotic resistance is among the Centers for Disease Control's (CDC) top concerns, and CDC guidelines call for a judicious use of antibiotics for acute and chronic rhinosinusitis, as well as other URIs and bronchitis. The following link: www.cdc.gov/drugresistan/USPExams/community/antibiotic-resistance.htm#2 provides access to the CDC's detailed overview of antibiotic resistance, developed for both health care professionals and patients.

ALLERGIC RHINITIS

AR affects 20 to 40 million persons annually in the US. It is responsible for 3.5 million lost work days, 2 million missed school days, and an estimated 28 million days of restricted activity or reduced productivity each year, resulting in estimated loss of $250 million and $291.6 million in 1998 and 2002, respectively.

Treatment of AR is expensive and has significant side effects; cost estimates vary but total costs (direct and indirect) were reported to be as high as $3.9 billion in 1996.

AR involves inflammation of the mucous membranes of the nose, eyes, eustachian tubes, middle ear, sinuses, and pharynx (Table 3). Entry of allergens is presumed to be through the nose. Mucous membranes become inflamed; this inflammation results from a complex interaction of inflammatory mediators, but ultimately is triggered by an immunoglobulin E (IgE)–mediated response to an extrinsic protein (allergen). Exposure to foreign proteins leads to allergic sensitization, which is characterized by the production of specific IgE directed against these proteins. This specific IgE coats the surface of mast cells, which are present in the nasal mucosa. When the specific protein (eg, a specific pollen) is inhaled into the nose, it can bind to the IgE on the mast cells, leading to immediate and delayed release of a number of pro-inflammatory mediators.
Table 3. Things of Note About Allergic Rhinitis

AR involves inflammation of the mucous membranes of the nose, eyes, eustachian tubes, middle ear, sinuses, and pharynx.

Risk factors include genetics, and an exposure to allergens, ie, pollens, mold spores, dust mites, specific animals, dust, smoke, and pollution.

Symptoms include nasal congestion, sneezing, itching, redness, mucosal swelling, postnasal drip, tearing, eye itching and/or redness ("allergic conjunctivitis." usually bilateral), and ear pressure.

Allergic sensitivity has a genetic component. Other risk factors include an exposure to allergens, ie, pollens, mold spores, dust mites, specific animals, dust, smoke, and pollution. Early symptoms include nasal congestion, sneezing, itching, redness, mucosal swelling, postnasal drip, tearing, eye itching and/or redness ("allergic conjunctivitis." usually bilateral), and ear pressure. Over four to eight hours, the early mediators of an allergic reaction lead to the recruitment of other inflammatory cells, resulting in continued inflammation and symptoms. Systemic effects, including fatigue, sleepiness, and malaise, can occur from the inflammatory response. These symptoms often contribute to impaired quality of life. AR often coexists with other disorders, such as asthma, and may be associated with asthma exacerbations, nasal polyps, and acute and chronic rhinosinusitis.26

ASTHMA, NASAL POLYPOSIS, AND RHINITIS OF PREGNANCY

SNI has not been assessed as a treatment for asthma, nasal polyposis, and rhinitis of pregnancy, but the hypothesized mechanism of SNI action, and conceptual ties of these conditions to rhinosinusitis, AR, and URIs, make a trial of SNI reasonable in these conditions. Therefore, the rationale associated with SNI utilization relating to these conditions will be briefly presented; however, detailed description is beyond the scope of this monograph.

CURRENT INTEREST IN SNI

SNI is a complementary and alternative medicine (CAM) therapy that originated hundreds of years ago in the Ayurvedic medical tradition of India, where it is called "jala neti." It has been known in the West at least since 1902 when The Lancet published a detailed description of SNI, clearly describing several indications for SNI, several SNI solutions, and picturing both gravity and positive pressure devices with which to perform it.27 SNI has been known by a variety of names including “hypertonic saline nasal irrigation,” “nasal douche,” “nasal saline,” “nasal wash,” “nose bidet” and “neti pot” therapy. Discussion will center on both aerosolized and liquid forms of 0.9% to 3% saline solution, which have been the most commonly used saline concentrations in clinical trials to date.

Nasal irrigation is an adjunctive therapy for rhinosinusitis and sinus symptoms.28-30 It coats the nasal mucosa (aerosol) or coats and flushes (liquid) the nasal cavity with saline. Among the lay public, SNI has been used as a home remedy for generations. However, the exact prevalence of its use is not known. It is popular in broad segments of the US and interest in SNI seems to be growing. Searching the term "nasal irrigation" on the Internet yields a myriad of hits. The New York Times has recently reported on the
growth of the interest in SNI. SNI was the subject of a segment on the Oprah Winfrey Show (May 2007) and "nose bidet" was one of the top 37 US "buzzwords" identified in 2007 by *The New York Times* (December 23, 2007). SNI was also the subject of a National Public Radio (NPR) medical report; the story was popular and became the single most emailed NPR segment of 2007.

**USE OF SNI IN CONTEMPORARY WESTERN MEDICINE**

SNI has been used for decades in the West as postoperative care for endoscopic sinus surgery patients. Although SNI was recently identified as "an important component in the management of most sinonasal conditions" that is "effective and underutilized," little is known about the prevalence of its use among physicians and other health care providers. SNI has not been included in major surveys of CAM therapies. It is recommended by health care professionals for a variety of upper respiratory conditions. In a survey of 286 family physicians, Rabago and colleagues found that those who recommend SNI do so for the following conditions: chronic rhinosinusitis (91%), ABRS (67%), seasonal AR (66%), acute URIs (59%), irritant rhinitis (48%), rhinitis of pregnancy (17%), nasal polyposis (11%), and URI-triggered asthma (9%).

**SNI MECHANISM OF ACTION**

The nasal cavity and sinuses are lined with a ciliated pseudostratified columnar epithelium, interspersed with goblet cells. The healthy sinonasal lining excretes approximately 1,000 mL of secretions every day. In the normal state, these secretions are carried from the sinuses into the nose, and then pass posteriorly to the nasopharynx to be swallowed. This transport is dependent upon efficient movement of the mucus by the epithelial cilia. Ciliary beat frequency, ciliary coordination, and mucus rheology are important determinants of mucociliary transport time through the nose. Acute and chronic rhinosinusitis, viral URI, and AR are thought to depress the normal mucociliary apparatus, leading to less efficient flow of mucus from the sinuses and nasal cavity, resulting in stagnation of secretions and increased risk of secondary bacterial infection.

The exact mechanism of SNI is not well understood and is likely multifaceted. However, SNI has been reported to have several physiological effects that individually or in concert may result in improved function of the nasal mucosa. SNI may enhance the ability of the nasal mucosa to reduce the potential for infection and the pathologic effects of inflammatory mediators and triggers of AR, asthma, and other acute and chronic mucosal reactions. These SNI effects include the direct cleansing effect of the irritant, reduction or removal of inflammatory mediators, and improved mucociliary function, demonstrated by increased ciliary beat frequency in the presence of hypertonic or normal saline (Table 4).

**Table 4. Things of Note About Allergic Rhinitis**

<table>
<thead>
<tr>
<th>Direct Cleansing Effect</th>
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<td>As saline solution moves through the nasal cavity, it thins and removes obstructive mucus and crusts; this mechanism is likely responsible for the immediate sense of improved breathing reported by many subjects.</td>
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**Reduction or Removal of Inflammatory Mediators**

Nasal mucous contains inflammatory mediators such as histamine, prostaglandins, leukotrienes, and eosinophil-released major basic protein. SNI may acutely remove these mediators, reducing their inflammatory effect.

**Improved Mucociliary Function**

Longer-term effects may accrue from improved mucociliary clearance, as a result of a demonstrated increased ciliary beat frequency in the presence of hypertonic or normal saline.

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**ADMINISTRATION OF SALINE NASAL IRRIGATION**

A myriad of products and techniques now exist to deliver saline to the nasal cavity. Saline can be practically instilled into the nasal cavity as aerosolized small droplets (nebulized form) or larger droplets (spray form); it can also be delivered in a liquid form (true nasal "irrigation"). Techniques and products vary widely and include simple inhalation of saline from a cupped hand (negative pressure), passive positive hydrokinetic pressure (nasal irrigation cup or "neti pot"), and active positive pressure (squeeze bottles, Water Pik™ or Grossan™ devices). Based on limited evidence (or lack of evidence), there is a lack of consensus about which technique, product, or even liquid state is optimal for a given clinical indication.

The range for salinity used in randomized controlled trials evaluating NI for upper respiratory conditions is 0.9% (normal saline) to 3%, with 2% used most commonly. Symptomatic patients are advised to use nasal irrigation daily to twice daily using 50 to 100 mL of saline per nostril and up to four times daily per nostril for nasal sprays. Patients interested in the prevention of these conditions are advised to use higher doses of SNI every other day. Many patients suffering from chronic sinus or AR symptoms have found that initial daily use for one to three months can be tapered to “as needed” use for the maintenance of nasal function. These patients often use SNI two to three times per week.

Further information on dosing parameters is provided in each of the evidence-based sections that follow and in the section The Author’s Clinic via a patient handout on a free public web link.
CLINICAL TRIAL EVIDENCE FOR SALINE NASAL IRRIGATION

Chronic Sinus Symptoms

The Cochrane Collaboration evaluated the evidence on SNI as a therapy for chronic sinus symptoms and concluded that SNI is an effective adjunctive therapy for chronic rhinosinusitis. Chronic rhinosinusitis is the most common indication for the use of SNI according to a recent study of physician practices. Several randomized controlled trials suggest that SNI is a safe, effective, and tolerable therapy for patients with a diagnosis of chronic rhinosinusitis or chronic sinus symptoms. Studies have reported improved quality of life on disease-specific quality of life questionnaires and related surrogate measures in adults and children.

The strongest randomized controlled trial to date on SNI for chronic sinus symptoms indicated that, at six months, subjects using daily 2% SNI plus "standard of care" for chronic sinus symptoms reported statistically significant improvement compared with "standard of care" controls in a number of self-reported outcomes, including overall percentage of positive change (64%, \( P<0.001 \)), and significant and clinically relevant improvement on disease-specific quality of life questionnaires. SNI users also reported decreased antibiotic and nasal spray use, and improved sinus symptoms compared with "standard of care" alone (\( P<0.05 \)). The SNI-treated subjects reported high patient satisfaction and minimal side effects. In a 12-month follow-up analysis, control subjects (who were taught SNI techniques after the six-month follow-up) quickly matched the gains made by their SNI counterparts.

Chronic Sinus Symptoms in the Context of Airborne Particulates

Rhinitis and nasal congestion due to environmental or work-place-related airborne irritants are independent risk factors for chronic sinusitis. The effect of SNI on symptoms of these conditions has been evaluated in two studies. Holmstrom and colleagues enrolled 45 woodworkers exposed to varying levels of wood dust. Over half of the woodworkers had chronic nasal complaints. Workers performed daily SNI using a Rhinomer Force 2 positive flow device with isotonic saline; 9 mL of solution were used per
nostril four times daily. During the three week long treatment, subjects reported significantly improved sinus symptoms and displayed improved mucociliary clearance and expiratory nasal flow. After three weeks, subjects were asked to discontinue SNI, but to continue assessments. By the six-week post-entry assessment, they returned to their pretreatment severity of symptoms and pretreatment values on the objective tests. Rabone and colleagues performed a similar study, using a passive gravity-based "jala neti" and assessing symptoms of 46 Australian woodworkers, and reported similar results.54

**Allergic Rhinitis**

Early work by Georgitis established a rationale for the use of SNI in seasonal allergies.42 He compared the effects of three different forms of warmed saline (using lactated Ringer’s solution) on the presence of inflammatory mediators (histamine, leukotrienes, and prostaglandin D4) in subjects with seasonal allergies. Subjects received heated solution in mist, large molecule spray, or liquid forms. Both liquid ($P<0.001$) and large molecule spray ($P<0.05$) reduced the levels of histamine and leukotrienes, with the liquid form being most effective. Saline mist did not significantly reduce concentrations of these mediators.

Garavello and colleagues, in a small, but methodologically strong random, controlled trial of pediatric patients with laboratory-confirmed, pollen-triggered AR, reported that antihistamine medication plus liquid SNI therapy (using a disposable syringe), compared with antihistamine alone, resulted in a significant improvement in allergy symptom scores and a reduction in antihistamine medication use ($P<0.05$).58 In a qualitative study of adults using SNI, Rabago and colleagues investigated the relationship between SNI use and AR. More than half of subjects with a history of AR spontaneously reported positive effects of SNI on allergy symptoms.57

**Upper Respiratory Infections**

SNI has been evaluated for both the treatment and prevention of viral URIs. Unlike clinical trials conducted on other sinonasal conditions, these studies have focused on the use of aerosolized saline and suggest that SNI in the form of droplets has a place in the management of upper respiratory conditions, and may be more efficacious than liquid saline for adjunctive treatment of URIs.

Two studies have assessed SNI as a treatment for the symptoms of the common cold. Adam and colleagues randomized 143 adults with viral URIs to hypertonic SNI, 0.9% SNI, or "do-nothing" control.59 In this study, neither strength of saline preparation, considered in both separate and combined analyses, had measurable effect on duration or severity of nasal symptoms compared with the "do-nothing" control group. Conversely, Passali and colleagues randomized 200 adults with viral URI to treatment with either liquid or "micronized" normal saline (Rhinoflow Nasal Wash, and Sinus System, respectively; water droplets of 20 microns).60 Subjects treated with micronized normal saline showed improved inspiratory and expiratory rhinometric resistance, nasal volume, mucociliary transit time, and improved symptom scores compared with the liquid saline group. Unfortunately, the authors did not report compliance rates with each therapy, limiting the conclusion of superiority of micronized water particles compared with liquid SNI.

A study by Tano and colleagues evaluated a spray-delivered SNI as preventive therapy for the common cold.61 In this study, 60 adult men were randomly assigned to receive either a "daily nasal spray" or "no preventive URI care," and were assessed for 20 weeks. The SNI group significantly outperformed the "do-nothing" control group in several ways: they reported fewer episodes of URIs ($P=0.05$), shorter duration of URI symptoms ($P=0.07$), and fewer days of having nasal symptoms ($P=0.03$).
In the strongest paper on SNI for URI prevention and treatment, Slapak and colleagues evaluated 390 children with acute URIs treated for 12 weeks with daily SNI isotonic solutions (Physiomer™) with trace minerals similar to sea water. Subjects were randomized to one of the two different isotonic SNI solution delivery methods (intervention groups: liquid and fine spray SNI), adjunctive to "standard of care," and compared "standard of care only" controls. Both delivery methods significantly and equally outperformed "standard of care" controls on nasal secretion and obstruction measurements during the treatment phase. After the URI treatment period, subjects were then followed in a prevention phase for 12 weeks during which they continued to use daily SNI. During this subsequent prevention-oriented follow-up period, SNI users reported significantly fewer URI symptoms of nasal secretion ("runny nose") and obstruction, sore throat, and cough compared with "standard of care" alone.

**Asthma, Nasal Polyposis, and Rhinitis of Pregnancy**

In spite of limited evidence to support the use of SNI for these conditions, a recent survey of physicians’ SNI-related practices found that SNI is commonly recommended for each of these conditions in clinical settings.

Epidemiological evidence suggests that asthma, sinus symptoms, and AR are related. It has been shown that 80% to 90% of children and adolescents with asthma also have nasal symptoms, and half of all patients with asthma have radiographic evidence of sinusitis, although imaging results are known to be nonspecific.

Whether the conditions are causally linked together is unclear, but in one study, aggressive treatment of sinusitis with SNI with and without antibiotics resulted in significantly decreased bronchial hyper-responsiveness compared with baseline. In addition, some authors have hypothesized that systemic inflammatory processes underlying asthma and AR are similar. Studies of patients with both asthma and AR reported that effective treatment of AR results in reduced severity and frequency of asthma, suggesting that SNI may have a role as adjunctive therapy for allergy-induced asthma.

One report has suggested that SNI may have utility in the prevention of nasal polyposis, a sequela of chronic rhinosinusitis. Although this supposition is somewhat speculative, at least three randomized controlled studies reported the effectiveness of SNI for symptoms of chronic sinusitis or chronic sinus symptoms without documented polyposis. Given that polyposis is commonly an extreme form of chronic sinus disease, and that SNI may improve the function and health of the sinonasal mucosa, aggressive treatment with SNI may inhibit progression of chronic rhinosinusitis to a polypoid form.

Rhinitis of pregnancy has been accepted as a distinct and very common pathological and clinical entity for many years. It occurs in 5% to 32% of pregnant women. Most commonly it is first noted during the end of the first trimester, and may persist up to the time of delivery or a few weeks afterwards. Rhinitis of pregnancy is associated with clear rhinorrhea and is thought to be caused by the generalized increase in interstitial fluid volumes seen during pregnancy. Treatment is complicated by the fact that optimal medical care during pregnancy includes minimizing medication use, if possible. In a recent survey, 9% of primary care providers who use SNI in their practices recommend it for rhinitis of pregnancy. SNI is considered "safe and effective" for mild-to-moderate rhinitis of pregnancy by at least one formal treatment guideline, cited by the National Guideline Clearinghouse.
SIDE EFFECTS & ADVERSE EVENTS ASSOCIATED WITH SNI

SNI is a safe therapy. No serious adverse events have been reported in any study evaluating SNI. Although no study has been powered to specifically detect the rates of potential side effects, serious side effects are likewise rare. However, studies do report common minor self-limited side effects, including a sense of discomfort and nervousness, especially the first time liquid SNI is used, and post-treatment nasal drainage, reported by up to 43% of SNI users. Less common side effects, noted by fewer than 10% of SNI users, are dryness of the nose between treatments, fullness of the ears, and stinging and burning of the nasal mucosa. Epistaxis is rare, and it is unclear whether it is secondary to the spout of a nasal cup impacting inflamed mucosa, an effect of the saline itself, or both. One study has identified side effects as equal in both spray and liquid SNI forms. The two most detailed reports of side effects associated with SNI state that side effects did not cause subjects to discontinue SNI. No study has reported an increase in infection rate and symptom severity or symptom duration due to SNI use.

PATIENT SELECTION OF SNI PRODUCTS

SNI was recently identified as “an important component in the management of most sinonasal conditions” that is “effective and under-utilized.” There are few patients who – if interested – would be considered inappropriate for a trial of SNI in the previously discussed conditions. Obvious examples include patients with the potential of extravasation of saline to unwanted tissue planes or spaces, such as patients with incompletely healed facial trauma, patients with neurological or musculoskeletal problems that could facilitate fluid aspiration, and patients with an inability to perform the procedure (eg, those who are uncooperative, too young, or have cognitive impairment). Patient adherence and satisfaction with SNI use can be enhanced by appropriate education and counseling strategies.

EDUCATION AND COUNSELING STRATEGIES

Education and counseling strategies for patients interested in using SNI have been evaluated. In a qualitative study, 28 successful long-term users of SNI for chronic sinus symptoms were asked about barriers to successful use of SNI, and how those barriers were overcome. As reported by these subjects, the main factor in sustained use of SNI was the perceived effectiveness of SNI therapy, and the resulting sense of control over a chronic, previously unmanageable condition. Through successful self-treatment, subjects felt empowered to manage their sinus conditions.

Among the common barriers to initial and consistent use of SNI, most subjects reported fear of having water in the nasal cavity, experiencing the initial unpleasant sensation of water in the nasal cavity, having to learn how to effectively perform SNI, taking time at home to do SNI, and experiencing occasional mild side effects. Participants also noted several at-home strategies that facilitated regular SNI use, which included incorporating SNI into their existing daily hygiene routines, placing SNI materials in convenient and accessible locations, and adjusting the SNI use schedule, temperature, or salinity to decrease or eliminate discomfort.

In the same study, which had an over 90% reported adherence rate to daily SNI over a six-month period of time, participants also identified effective patient education as key to their initiation and maintenance of SNI therapy. Patient education in this study included a routine patient history, a consultation in which the spectrum of sinus disease was discussed, a five-minute film on SNI use, an in-person SNI demonstration, and a coached, "hands-on" practice of SNI. Practice of SNI was identified by subjects as
the single most important element of the educational meeting. Adherence may not require such thorough teaching. Although other studies have not reported detailed patient education, adherence rates for SNI for chronic sinus symptoms in another study have been reported at 93% to 97% for nasal sprays and 75% to 92% for liquid nasal saline during short-term, two- to eight-week follow-up periods.

THE AUTHOR’S CLINIC

Patients in our University of Wisconsin Family Medicine Residency clinic who are candidates for SNI treatment are queried as to their readiness to try it. Chronic sufferers are especially willing to listen to a brief description of SNI. Of note, patients with worsening acute or chronic rhinosinusitis who meet the criteria for antibiotic therapy are often given an antibiotic prescription, along with a recommendation to try SNI, and advice (when appropriate) to consider delaying antibiotic use and trying SNI first for one or two days. Our clinical experience indicates that a substantial number of patients decide to try SNI before using antibiotics; many of them report they do not fill the antibiotic prescription because the SNI sufficiently helped alleviate symptoms.

At the clinic, a handout on liquid SNI is provided and discussed with patients who are potentially interested in SNI therapy. This handout includes a recipe for a home-made solution (tap water, kosher salt, and baking soda), instructions for use, trouble-shooting tips, and a link to a website devoted to SNI (http://www.fammed.wisc.edu/research/past-projects/nasal-irrigation). This site contains the patient education handout in English and Spanish, and links to film and audio educational materials; it is open to all health care professionals and the public at no cost. If, after this discussion, the patient is willing to try SNI, liquid, mist, or spray SNI is recommended, depending on patient preference. The patient is encouraged to try a lukewarm ("temperature that feels good to the inside of your nose") 2% SNI mixed with tap water once daily. Trouble-shooting techniques in a handout describe what to do with side effects, for example, if a burning or stinging sensation is encountered. In that case, the user is encouraged to first adjust the salt content; decreasing the salt concentration to approximately 0.9% normal saline solution often helps. Patients are also educated about commonly encountered potential barriers to SNI use and ways to overcome them. They are advised to wash reusable SNI devices daily and to call with problems. Physician recommendation on SNI use is documented in the patient’s chart under "advised treatments." During subsequent visits, patients are usually asked whether they decided to use SNI and, if so, to describe what their experiences have been.

CONCLUSION

SNI has been evaluated in numerous randomized controlled trials of moderate-to-strong methodological quality as a therapy for ABRS, chronic rhinosinusitis, chronic sinus symptoms, AR, and URIs. These disorders are the most common conditions for which SNI is recommended in primary care.

SNI has been identified by the Cochrane Collaboration as appropriate, evidence-based adjunctive treatment for chronic sinus symptoms. Several small clinical trials have also reported the effectiveness of SNI in managing seasonal AR and preventing and reducing symptoms in URIs, although formal systematic reviews have not been completed for SNI use in these conditions. In addition, SNI is also commonly recommended for allergy- and URI-triggered asthma, nasal polyposis, and rhinitis of pregnancy, with anecdotal clinical success, but without formal clinical evidence about SNI efficacy in these conditions. SNI can be successfully implemented in primary care or specialty clinic settings and in community pharmacies. Patients are often receptive to this therapy, and users report high treatment satisfaction. SNI therapy is inexpensive and appears safe.
REFERENCES


