

Treatment with hypertonic saline versus normal saline nasal wash of pediatric chronic sinusitis

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Background: Chronic sinusitis (CS) is a common disease in children, especially those with allergies, that is caused by impaired drainage from the sinuses. Hypertonic NaCl solution has been shown to increase mucociliary clearance and ciliary beat frequency.

Objective: We performed a randomized double blind study to compare the effect of nasal wash with hypertonic saline (HS) (3.5%) versus normal saline (NS) (0.9%) on CS.

Methods: Thirty patients with CS aged 3 to 16 years were studied. They were randomly divided into two treatment groups matched by age and severity of the disease. Each individual was treated with either HS or NS for 4 weeks. All patients were evaluated by two clinical scores (cough and nasal secretions/postnasal drip [PND]) and by a radiology score at the beginning of the study and after 4 weeks.

Results: The HS group improved significantly in all scores (average \pm SD): cough score, from 3.6 ± 0.51 to 1.6 ± 0.74 ; nasal secretion/PND score, from 2.86 ± 0.35 to 1.6 ± 0.74 ; and radiology score, from 8.06 ± 1.28 to 2.66 ± 1.04 . The NS treatment group showed significant improvement only in the PND score (from 2.66 ± 0.49 to 1.53 ± 0.83) but no significant change in both the cough score (from 3.53 ± 0.52 to 3.33 ± 0.49) and the radiology score (from 8.13 ± 1.25 to 7.86 ± 0.91). Clinical observation 1 month after the end of the study showed no change compared with the end of the study in both groups.

Conclusion: HS nasal wash is an efficient treatment of CS. (J Allergy Clin Immunol 1998;101:602-5.)

Key words: Hypertonic saline, chronic sinusitis

Chronic cough and rhinitis are very common complaints among infants and children, especially those with asthma.¹⁻³ Usually these illnesses are the result of chronic inflammation of the maxillary sinuses, with increased secretions from the sinuses and postnasal drip (PND) caused by allergy or infection. The mucosa becomes swollen and hypertrophic, and the drainage from the sinuses is impaired. The impaired drainage of the secretion from the sinuses (especially from the maxillary sinuses) increases the likelihood of recurrent infections.^{1,2} The secretions are usually clear but may

Abbreviations used

CS:	Chronic sinusitis
HS:	Hypertonic saline
NS:	Normal saline
PND:	Postnasal drip

become purulent. The conventional medical approach to chronic sinusitis (CS) includes treatment with local and systemic antiinflammatory drugs with or without antibiotics.¹

Recently it has been demonstrated that hypertonic saline solution inhaled into the airways enhances mucociliary clearance in healthy subjects, as well as in patients with asthma and cystic fibrosis.⁴⁻⁶ The aim of this study was to investigate the effect of 4 weeks of nasal wash with hypertonic saline (HS) (3.5% wt/vol NaCl/H₂O) compared with normal saline (NS) (0.9% wt/vol NaCl/H₂O) as a treatment for CS in children.

METHODS

Thirty-four children 3 to 16 years of age were enrolled in the study. They were given a diagnosis of chronic maxillary sinusitis according to the criteria described by Shapiro and Rachlefsky^{4,7} during the summer seasons (June to September) of the years 1993 and 1994. They had been treated in the past with antibiotics for 3 weeks or more (seven patients in the HS group and three in the NS group), β_2 -agonists (eight in the HS group and 12 in the NS group), nasal steroids (two in the HS group and five in the NS group), and systemic steroids (13 in the HS group and seven in the NS group). Treatment was stopped for more than 1 month before the beginning of the study. Only 30 of the patients completed the study. The study was approved by the Institutional Review Board of Bikur Cholim Hospital, and informed consent was obtained from all the parents of the children before entering the study.

The severity of the disease was measured by two clinical scores and a radiology score. Cough score and nasal secretions/PND scores were measured at the beginning of the study, once a week for 4 weeks, and 1 month after the end of the study in the clinic. Waters' projection for the radiologic score was performed only at the beginning of the study and after 4 weeks at the end of the treatment period. Clinical cough score was rated on the following scale: 1 = no symptoms, 2 = mild cough only at night, 3 = moderate cough at night and day, and 4 = severe cough during the day also disturbing sleep. The PND/nasal secretion score was rated on the following scale: 1 = no secretions, 2 = clear secretions, and 3 = purulent secretions. The radiology score for each of the maxillary sinuses was rated on the following scale: 1 = normal maxillary sinus, 2 = mild

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Received for publication Aug. 15, 1997; revised Jan. 12, 1998; accepted for publication Jan. 14, 1998.

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0091-6749/98 \$5.00 + 0 1/1/88926

thickening of the maxillary mucosa, 4 = significant thickening of the mucosa of greater than 4 mm, and 5 = complete opacification of the maxillary sinus (each sinus was scored separately and the two scores were summarized).

Inclusion criteria were (1) history of chronic cough for at least 4 months, which may have increased during sleep; (2) PND or nasal secretion on physical examination; (3) confirmation of sinusitis by Waters' projection with significant thickening of the mucosa (≥ 4 mm) or complete opacification of the sinuses; and (4) severity of the disease as measured by two clinical scores (cough score ≥ 3 and nasal secretion score ≥ 2) and by radiology score (≥ 5).

The nasal secretion score was performed by one of the investigators, the patients or their parents performed the cough score, and the radiology score was given separately to each sinus film, which was marked with a number by two investigators. All the investigators and the patients were blinded to the treatments.

Exclusion criteria were (1) mucocele, previously known anatomic defect, or both that obstruct the maxillary sinuses; (2) signs of bronchial obstruction at the beginning and during the study; (3) fever during the study; and (4) treatment with steroids or antibiotics during the study.

Patients were randomly divided into two groups matched by age and severity of the disease. NS 0.9% (0.9 gm NaCl in 100 ml H₂O) sterile solutions and HS 3.5% sterile solutions were prepared and placed in a blinded fashion into randomized numbered bottles by the hospital pharmacy. The patients of one group instilled 10 drops (about 1 ml) of HS three times a day, and the patients of the second group instilled 10 drops of NS three times a day for 4 weeks. The drops were instilled fast upward in a sitting or standing position, with the head pulled back to allow the secretions to flow downward from the nose without the patient breathing them in. They were immediately removed from the nose in order to minimize the salty or burning feeling of the saline solutions. Instillation of drops was chosen over nasal spray to avoid breathing in the solution.

Statistics

The differences of the scores between the HS and the NS groups as measured before and at the end of the study (after 4 weeks and after 8 weeks) were calculated by the Mann-Whitney U Test. Probability (*p*) values of 0.05 or less were considered significant. The differences within the groups of the scores before and at the end of the treatment were calculated by the Wilcoxon signed-rank test, and *p* values of 0.05 or less were considered significant.

RESULTS

Thirty-four patients began the study, but four patients (three from the HS group and one from the NS group) could not tolerate the treatment because of the burning feeling in the nose and throat and left the study after 1 to 4 days.

The clinical and radiology scores were calculated as means \pm SD. There was no significant difference between the readings of the radiology scores of the two investigators.

Fifteen patients (eight boys and seven girls, age 3 to 16 years old [median age, 9 years]) were treated with HS, and 15 patients (nine boys and six girls, age 3 to 16 years old [median age, 9.5 years]) were treated with NS. The HS treatment group reported an increase in clear nasal

secretions during the first 2 weeks, and all but one had complete freedom from nasal secretion by the third week of treatment. Most of them had improved clinical cough scores (13 of 15) from 3.6 ± 0.51 to 1.6 ± 0.74 , improved PND/nasal secretion scores (13 of 15) from 2.86 ± 0.35 to 1.6 ± 0.74 , and improved sinus radiology scores (14 of 15) from 8.06 ± 1.28 at the beginning to 2.66 ± 1.04 at the end of the study (Table I).

The fifteen patients who were treated with NS did not report any significant improvement in their coughs (from 3.53 ± 0.52 to 3.33 ± 0.49) and had no significant change in their radiologic scores at the end of the study (from 8.13 ± 1.25 to 7.86 ± 0.91). However, a significant improvement in the nasal secretion score was observed (from 2.66 ± 0.49 to 1.53 ± 0.83) as PND/nasal secretions disappeared or became clear in most of the patients (13 of 15) (Table I).

The difference in both the clinical and radiologic scores between the groups at the beginning of the study was not significant. At the end of the study, however, the differences were very significant in both the radiology (HS = 2.13 ± 1.76 vs NS = 7.86 ± 1.4) and the cough scores (HS = 1.6 ± 0.74 vs NS = 3.33 ± 0.49) but not the PND/nasal secretions score (Table I).

Regarding tolerability of the treatment, the patients in the HS group reported burning and itching in the nose more than those in the NS group, but only during the first 3 to 4 days. After that period, there was no difference between the groups and no problem was reported.

DISCUSSION

Sinusitis is an increasingly recognized common and important cause of morbidity.² Many patients with sinusitis experience chronic cough, fatigue, and lassitude characteristic of the disease. The prevalence of CS among patients with respiratory complaints is estimated to be as high as 73% of children 2 to 6 years of age, 74% of children 6 to 10 years of age, and 38% of children older than 10 years of age.³ CS also complicates 5% to 10% of the upper respiratory infections of young children.⁸ New evidence points to a pathophysiologic link between sinusitis, allergic rhinitis, and asthma.^{9, 10}

Three key elements are important to the normal physiologic functioning of paranasal sinuses: (1) the patency of the ostium, (2) the function of the ciliary apparatus, and (3) the quality of secretions.^{10, 11} Impaired drainage and retention of secretions in the paranasal sinuses is usually caused by one or more of the following factors: obstruction of the ostium, reduction in the number of cilia or an impairment of their function, and overproduction of secretions or a change in the viscosity of secretions.

The diagnosis of sinusitis in the young is difficult and should be based on a combination of the patient's symptoms, physical examination, radiographic results,^{11, 12} and computed tomography.¹³

The treatment as described in the medical literature includes antibiotics, usually a β -lactamase-resistant an-

TABLE I. Results of cough scores, PND/nasal secretion scores, and radiology scores: Number of patients with each score at the beginning and at the end of the study and means \pm SD

Group	Score	Before treatment		After treatment	
		No. of patients	Mean \pm SD	No. of patients	Mean \pm SD
Cough score					
HS	1	—	3.6 \pm 0.51	8	1.6 \pm 0.74*†
	2	—		5	
	3	6		2	
	4	9		—	
NS	1	—	3.53 \pm 0.52	—	3.33 \pm 0.49†
	2	—		—	
	3	7		10	
	4	8		5	
PND score					
HS	1	—	2.86 \pm 0.35	8	1.6 \pm 0.74*
	2	2		5	
	3	13		2	
NS	1	—		10	
	2	5	2.66 \pm 0.49	2	1.53 \pm 0.83*
	3	10		3	
Radiology score					
HS	2	—		8	
	3	—		6	
	4	—		—	
	5	1	8.06 \pm 1.28	—	2.66 \pm 1.04*†
	6	—		1	
	7	4		—	
	8	3		—	
	9	6		—	
	10	1		—	
	NS	2	—	8.13 \pm 1.25	—
3		—		—	
4		—		—	
5		—		—	
6		1		1	
7		4		4	
8		3		6	
9		6		4	
10		1		—	

*Difference within the groups of scores before and at the end of the treatment, $p \leq 0.05$.

†Difference between HS and NS groups, $p \leq 0.001$.

tibiotic,¹⁴⁻¹⁶ and promotion of drainage, including fluids, expectorants, decongestants (both oral and topical), and topical steroids.^{9, 10, 17} It has been recommended by some authors that if medical treatment fails to resolve the disease within 3 months, surgical intervention may be necessary.^{15, 17}

It has been shown that the tonicity of the HS solution enhanced mucociliary clearance in asthmatic patients, healthy subjects, and patients with cystic fibrosis.⁴⁻⁶ Despite this data, there was no evidence regarding the effect of HS on CS. The data that support the improvement of mucociliary clearance after hypertonic inhalation directed us to investigate the effect of HS on CS.

In various studies, different concentrations of hypertonic NaCl solutions were used. In one publication a 7% HS solution was used,⁴ and a concentration of 6% HS was tested in another study. The concentration of 3.5% saline solution was chosen because it is about the seawater concentration and was considered to be harmless and better tolerated by the patients. To avoid aerosol deposition in the lower airways, HS was instilled as nasal drops.

In our study we showed the beneficial effect of HS on CS. There was improvement of both clinical scores and plain Waters' projection radiology scores. There were few side effects among patients in the HS-treated group, and these related mainly to local irritation of the swollen and inflamed mucosa, such as a burning and itching feeling of the nose during the first 4 days. These sensations vanished over time or after discontinuation of the treatment.

The nasal secretion/PND score improved in both the HS and NS groups and was not helpful in distinguishing the difference between the two groups. NS nasal wash was shown to be effective for cleaning the nose and facilitating mechanical removal of intranasal crusts, thereby improving patient comfort and improving drainage.¹⁴ It is possible that the washing of the secretion was enough to change the nasal secretion/PND score observed by the investigators. We conclude that this score had no significant value in the follow-up of patients with CS in our study.

It is not yet clear how HS improved CS. The morphologic changes of the respiratory mucosa in CS show ciliary disorientation; loss of ciliated cells; an increasing number of nonciliated cells, metaplasia, extrusion of epithelial cells; and short cilia that indicate ciliogenesis.¹⁸ Hyperosmolarity of the airway fluids causes an increase in Ca^{2+} release from intracellular stores,^{19, 20} and the increase in Ca^{2+} may stimulate the ciliary beat frequency, possibly by regulating the use or availability of adenosine triphosphate by the ciliary axoneme. The histologic pattern in chronic maxillary sinusitis that shows disorientation of the cilia of the mucosal epithelia¹⁸ obviates the possibility that the main effect of HS in CS is achieved through the improvement of ciliary beat frequency. A recent study on the effect of HS on the function of the pulmonary epithelial barrier showed that after instillation of hyperosmolar seawater, there is a rapid influx of water from the plasma into the bronchoalveolar space.²¹ The osmotic equilibrium was reached within 3 minutes. Furthermore, there was no injury to the epithelial or endothelial barriers of the lung. In this study of HS administration, we were unable to examine its effect on reducing the infectious process that can take place in CS. The topical antibacterial effect of hypertonic saline solution is well established in wound dressing and washing of open wounds.^{22, 23}

In conclusion, instillation of 1 ml HS three times a day for 1 month improves the clinical and radiologic status among children with CS. The treatment is tolerable, inexpensive, and effective.

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