LONG-TERM OUTCOME OF ONCE DAILY SALINE IRRIGATION FOR THE TREATMENT OF PEDIATRIC CHRONIC RHINOSINUSITIS

BY

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Submitted to the graduate degree program in Clinical Research and the Graduate Faculty of the University of Kansas in partial fulfillment of the requirements for the degree of Master of Science.

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Date Defended: April 04, 2013

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Date approved: April 11, 2013

Abstract

Objectives: Chronic rhinosinusitis (CRS) results in significant morbidity and healthcare expenditure. The safety and effectiveness of nasal irrigation for the treatment of pediatric CRS has been demonstrated, but its long-term outcomes are unknown. This study's goals were to assess the effectiveness of nasal irrigation after first-time use for pediatric CRS and to determine the short- and long-term outcomes of treating nasal symptoms with irrigation.

Methods: This was a two-part study. First, we performed a retrospective cohort study on pediatric CRS patients who were treated by a single pediatric otolaryngologist between July 2003 and January 2012 and were prescribed a 6-week course of nasal irrigation. Demographics, presenting symptoms, Lund-Mackay scores, and treatment outcomes were summarized. Second, we surveyed parents from 1 to 9 years later to assess each patient's symptom recurrence, parent-initiated use of nasal irrigation for recurrent symptoms, and any subsequent surgical interventions.

Results: One hundred four patients were reviewed. The mean age was 8.0 years, and 65.4% were male. Presenting symptoms included congestion(95.2%), cough(79.8%), and rhinorrhea(60.6%). Comorbid conditions include asthma(57.3%) and positive allergy test(50.0%). After the initial 6 weeks of irrigation, 57.7% of patients reported complete resolution of symptoms, and 10.6% patients underwent FESS. Reductions in Lund-Mackay scores were 4.14 and 4.38 on the left and right sides, respectively ($p<0.001$). Fifty-four parents completed the follow-up survey with a median length of follow-up of 48 months(range 20-113). Of those surveyed, 53.7% reported using irrigation again in the last 12 months(median 1, IQR 0-3), and an additional 3 patients underwent FESS. There were no significant differences in age,

Lund-MacKay score changes, and symptom resolution proportions between those who completed the survey versus not.

Conclusion: Nasal irrigation may well be effective as a first line treatment for pediatric CRS as well as for recurring symptoms. Once nasal irrigation is used as a treatment modality for pediatric CRS, parents and caretakers are likely to utilize it again for recurrent symptoms. Patients with symptoms of CRS, even when refractory to other medical therapies, should utilize nasal irrigation before consideration for FESS.

Acknowledgements

I would like to thank Dr. Julie Wei for being my research mentor this year. She has been an absolute pleasure to work with. I would like to also thank Kevin Sykes for his guidance and encouragement this past year.

I am forever grateful to Frontiers: The Heartland Institute for Clinical and Translational Research, the University of Kansas Medical Center's CTSA. I am especially thankful to Dr. Theresa Shireman and Dr. Dianne Durham for their guidance this past year. I am also greatly appreciative of Dr. Edward Ellerbeck and Dr. Won Choi for guiding me in my early professional education. I would also like to recognize and thank Anita Macan for all her support.

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Introduction

Acute and chronic rhinosinusitis are a common cause of significant morbidity and healthcare expenditure. These conditions affect the quality of life (QoL) for both pediatric and adult populations. An analysis of the National Health Interview Survey between 1997 and 2006 found that sinusitis affects 15.2% of the United States' population annually.[1] The national healthcare costs due to chronic rhinosinusitis (CRS) are estimated to be $8.6 billion annually.[2] Rhinosinusitis is a common concern in the pediatric population. Children typically have six to eight respiratory viral infections per year. An estimated 0.5-5% of these cases proceed to acute rhinosinusitis, and an unknown number of these children will develop CRS.[3] If left untreated, these conditions could lead to long-term symptoms, such as nasal airway obstruction, congestion, rhinorrhea, cough, headache, and daytime fatigue. Rhinosinusitis can adversely affect the lives of children and their caretakers due to missed school and work days, respectively, and increase need to utilize the health care system. Children with CRS were perceived by their parents to have significantly more physical pain and debilitation compared to children with other chronic diseases, such as asthma and juvenile rheumatoid arthritis.[4]

Several treatment options for pediatric CRS currently exist with varying efficacies and risk. Treatments for CRS may also depend on addressing underlying co-morbidities such as allergies. Therapies for CRS are divided into medical and surgical options. Medical therapies have traditionally included antibiotics, corticosteroid and antihistamine nasal sprays, and nasal irrigation. Traditionally, antibiotics have been considered the first-line medical treatment for CRS. However, while they are frequently prescribed, antibiotics do not have any Level 1 evidence in effectively treating this disease.[5] Their ineffectiveness is believed to be because CRS is not due to an acute bacterial infection. The circumferential mucosal thickening on computed

tomography is reflective of chronic inflammation.[6] Any bacterial infection associated with CRS is considered secondary to the pathophysiology of CRS, so antibiotics alone would not improve this condition.

Given the underlying inflammatory mechanism, the use of oral corticosteroids has shown to reduce the size of nasal polyps to improve drainage and symptoms. A meta-analysis of the use of oral corticosteroids for the treatment of CRS concluded that oral steroids can be effective in treating CRS associated with nasal polyps.[7] However, its use has insufficient evidence for treating CRS without nasal polyps because they have not been shown to directly reduce the chronic inflammation within the blocked sinuses. No other medications were included in the meta-analysis.[7]

An alternative approach is the use of nasal irrigation, which has been shown to directly cleanse the nasal mucosa and promote mucus excretion.[8,9] It also removes inflammatory mediators[10,11] and improves ciliary beat frequencies.[12,13] Several studies have examined the efficacy of nasal irrigations in alleviating sinus symptoms in pediatric patients. An RCT comparing saline or saline with gentamycin showed that nasal irrigation was well-tolerated, with over 95% compliance during a 6 week treatment course, and significantly improved the quality of life as measured by the Sinonasal 5 (SN-5) survey.[6] The most commonly reported minor adverse events include post-irrigation nasal drainage and initial discomfort,[14] though rare cases of nosebleeds and stinging have been reported.[15] Other studies have also reported the safety of irrigation without any serious adverse effects, while minor adverse events can be avoided by modifying one's technique.[16] A meta-analysis on the use of nasal irrigation for the treatment of CRS concluded that its benefits outweighed its adverse effects.[12] Several systematic reviews have since recognized nasal irrigation as a treatment for CRS symptoms.[17-19]

In a small study of adults with CRS, 52.5% of them were reported to be refractory to medical treatment and needed to consider surgical procedures.[20] Although the refractory rate in the pediatric CRS population remains unknown, surgical procedures are still considered for those that fail medical therapies. The reported success rate for adenoidectomies in the treatment of pediatric CRS is estimated to be 60-70% in multiple small single site studies.[21,22] Functional endoscopic sinus surgery (FESS) reported to have an estimated success rate of 88% based on a meta-analysis of over 800 pediatric CRS patients.[23] FESS has also been reported to significantly improve quality of life for patients.[24] However, 3% of patients that undergo FESS experience major complications, such as uncontrolled bleeding and periorbital bruising.[25]

Although surgical treatments have been reported to have high success rates in treating CRS, avoidance of surgical intervention in children would eliminate any inherent risk associated with general anesthesia as well as sinus surgery. Parents and physicians alike would likely agree that non-surgical treatment options should be exhausted before considering FESS. The use of nasal irrigation for the treatment of pediatric CRS has been studied but not extensively. Based on clinical experience, it remains underutilized in the pediatric population. This project sought to address the use of nasal irrigation across several years in an active practice with long-term follow-up of parental acceptance. This study's goals were to assess the effectiveness of nasal irrigation after first-time use for pediatric CRS and to determine the short- and long-term outcomes of treating nasal symptoms using irrigation.

Materials and Methods

Study Design

This was a two-part study. First, we performed a retrospective cohort study on patients under 18 years of age with an established diagnosis of CRS based on history and CT imaging by

a single pediatric otolaryngologist and for whom a 6-week course of nasal irrigation was recommended. Second, we surveyed parents from 1 to 9 years later to assess sustained use and outcomes of nasal irrigation for recurrent symptoms.

The patients were identified using ICD-9 code from an EMR for chronic sinusitis (including any and all sinuses, frontal, ethmoid, sphenoid, and/or maxillary) from the otolaryngology clinic at KU Medwest, a satellite clinic of the University of Kansas Medical Center (KUMC).

This study focuses on children who reported symptoms for longer than 12 weeks. All subjects were diagnosed as having medically refractory CRS, defined as the persistence of chronic symptoms despite the use of oral antibiotics, nasal and/or oral corticosteroids, nasal and/or oral antihistamines, decongestants, and/or other medications. Patients were included if they were diagnosed and treated with nasal irrigation between July 2003 and January 2012. Patients were prescribed the NeilMed Sinus Irrigation kit (squeeze bottle and buffered salt packets).Patients were excluded if they did not have CT evidence of sinus disease, were not prescribed daily nasal irrigations as the primary modality of treatment for their symptoms, or were unable to tolerate once daily irrigation for at least a 6 week duration.

Data extracted from the medical record included patient demographics, referring physician, past medical and surgical histories, medications tried prior to referral, presenting symptoms, and Lund-Mackay scores. Lund-Mackay scores were calculated for the patient's baseline pre-irrigation computed tomography (CT) scan as well as post-treatment CT scan. Lund-Mackay scores are a validated assessment tool to measure the severity of CRS by evaluating mucosal thickening on CT scans. Each paranasal sinus is evaluated for mucosal thickening on a point system: 0 for no thickening, 1 for partial thickening, and 2 for complete

opacification of the sinus. The ethmoids are divided into posterior and anterior portions, each receiving an individual score. Along with frontal, maxillary, and sphenoid sinuses, a score of 2 is also given in the case of osteomeatal obstruction.[26] A cumulative score of 5 or higher provides a sensitivity and specificity of 86% and 85%, respectively.[27] We reviewed symptoms resolution rates as reported by patients and families as well as need for adenoidectomy and/or FESS after the initial irrigation period.

For the follow-up survey, parents or primary caretakers from the specified patient population were contacted between October 2012 and January 2013. The survey was administered by telephone, using numbers available in the medical record. The survey assessed the subsequent use of nasal irrigations after initial experience with nasal irrigation at the time of meeting the treating pediatric otolaryngologist. It also assessed symptom recurrence, parent-initiated use of nasal irrigation for recurrent symptoms, duration of irrigation if used, and any subsequent surgical interventions. To reduce recall bias, parents and caretakers were requested to report on irrigation use only in the previous 12 months. The long-term follow-up period was defined as the duration between the last known follow-up time pertaining to CRS and the time of survey administration.

Data Analysis

Data were entered into a Microsoft Access database. The Wilcoxon rank sum test was used for comparisons of continuous or ordinal variables, and the X^2 test was used for comparisons of categorical variables. Changes in Lund-Mackay scores for individual sinus as well as total scores for each side were summarized. Statistical significance was established *a priori* at 0.05. Statistical analysis was performed with SPSS, version 20.0 (SPSS Inc, Chicago, IL, USA).

This study proposal was approved by the KUMC Institutional Review Board, after which a list of pediatric CRS patients was obtained.

Results

We identified 144 potential subjects during the study period. Forty patients were excluded for the following reasons: 12 did not tolerate irrigation, 2 did not have a confirmed CRS diagnosis, 3 were not prescribed nasal irrigation, and 23 were lost to short-term follow-up.

A total of 104 patients were included in this study, with 65.4% being males. All patients underwent at least 6 weeks of daily nasal irrigation. In Table 1, the distribution of baseline characteristics were compared between the two groups (long-term follow-up versus no long-term follow-up). The mean age at first visit to the pediatric otolaryngologist was 8.0 years (IQR: 5.00-9.88). The most commonly reported symptoms include chronic nasal congestion, intermittent or persistent cough, and rhinorrhea. Comorbid conditions include positive allergy tests, asthma, and previous diagnosis of gastroesophageal reflux disease (GERD).

TABLE I.
Baseline Characteristics.

	Total (n=104)	Surveyed (n=54)	Not Surveyed (n=50)
Age (yr)	8.02 ± 3.60	8.11 ± 3.75	7.92 ± 3.46
Gender, no. (%)			
Male	68 (65.4)	35 (64.8)	33 (66.0)
Female	36 (34.6)	19 (35.2)	17 (34.0)
Referral, no. (%)			
Asthma/allergy	59 (56.7)	34 (63.0)	25 (50.0)
Pediatrician	26 (25.0)	12 (22.2)	14 (28.0)
Self	11 (10.6)	4 (7.4)	7 (14.0)
Other	8 (7.7)	4 (7.4)	4 (8.0)
Reported Symptoms, no. (%)			
Congestion	99 (95.2)	53 (98.1)	46 (92.0)
Cough	83 (79.8)	43 (79.6)	40 (80.0)
Rhinorrhea	63 (60.6)	35 (64.8)	28 (56.0)
Headache	50 (48.1)	29 (53.7)	21 (42.0)
Fatigue	42 (40.4)	26 (48.1)	16 (32.0)

History, no. (%)			
Asthma	59 (57.3)	32 (59.3)	27 (54.0)
Positive Allergy Test	52 (50.0)	30 (55.6)	22 (44.0)
Adenoidectomy	39 (37.5)	20 (37.0)	19 (38.0)
GERD	29 (28.2)	10 (18.5)	19 (38.0)
Medications Tried, no. (%)			
Nasal steroid spray	79 (75.0)	41 (75.9)	38 (76.0)
Oral antihistamine	51 (49.0)	24 (44.4)	27 (54.0)
Oral steroids	49 (47.1)	26 (48.1)	23 (46.0)
Leukotriene Antagonist	44 (42.3)	24 (44.4)	20 (40.0)
Albuterol	41 (39.4)	25 (46.3)	16 (32.0)
OTC decongestant	13 (12.5)	8 (14.8)	5 (10.0)
None/Not Reported	7 (6.7)	3 (5.6)	4 (8.0)

All study subjects had tried antibiotics prior to referral to the pediatric otolaryngologist. The mean number of courses of antibiotic therapy completed in the previous 6 months (n=37) was 3.59 ± 1.99 and in the previous 12 months (n=26) was 5.46 ± 2.49. The number of antibiotic therapies tried was inconsistently reported in the medical record. Other common medications tried prior to pediatric otolaryngology referral include nasal or oral steroids, antihistamines, and leukotriene antagonists. Titers for *Streptococcus pneumoniae* had been checked by the referring allergist in 23 patients (22.1%), from which 15 patients were found to have low titers and were given booster shots. In this cohort, 39 patients (37.5%) had already undergone adenoidectomy earlier in childhood. Documentation on physical exam included strands of thin, clear, stringy mucus found to span from the inferior turbinate to the septum in 31 patients (30.1%). On physical exam, rhinorrhea was observed in only 17 patients (16.5%) though 60% of parents reported it.

Baseline CT scans were available in 97 patients prior to irrigating. The mean Lund-Mackay scores before nasal irrigation were 5.56 (IQR 4.00-7.00) on the left side and 5.84 (IQR 4.00-7.50) on the right for all sinuses (Table II). After the initial 6 weeks of once daily irrigation, 91 patients (87.5%) returned to clinic for the scheduled follow-up visit. Of the 97 patients with

baseline CT scans, 70 underwent a follow-up scan after 6 weeks of once daily irrigation. The mean reduction of Lund-Mackay scores was 4.14 (IQR 2.00-6.25) and 4.38 (IQR 2.00-7.00) for all sinuses on the left and right sides, respectively. There were 13 families who did not have an actual follow-up clinic visit. Often, this was because the otolaryngologists having reviewed the follow-up CT scan, found complete reversal of CT disease post-irrigation, and informed families by phone. If parents reported complete or near-complete symptom resolution then office visit was deemed unnecessary. A few simply did not return. Overall, 60/91 patients (65.9%) and their families reported complete resolution of symptoms. After the 6 weeks of once daily irrigation, 11/91 (12.1%) patients were recommended by the pediatric otolaryngologist to undergo limited FESS (bilateral middle meatal antrostomy with anterior ethmoidectomy) surgery due to persistent clinical symptoms and post irrigation CT demonstrating persistence or worsening of mucosal thickening. Patients who underwent FESS were, on average, 3.6 years of age older than those that did not receive FESS (p=0.0005).

TABLE II.
Computed Tomography Scoring (Lund-Mackay) at Baseline and After 6 Weeks of Irrigation, Mean ± SD

	Pre-irrigation	Post-irrigation	Change	p value
Left Sinuses	5.56 ± 2.61	1.96 ± 2.16	-4.14 ± 3.07	<0.001
Right Sinuses	5.84 ± 2.56	2.00 ± 2.13	-4.38 ± 3.15	<0.001

Long term follow-up and parental surveys are summarized in Table III. For the 54 patient families who completed long-term follow-up surveys, 38/54 (70.4%) of parents recalled that nasal irrigation providing complete resolution of symptoms. Over half, 30/54 (55.6%), of parents reported that their child experienced recurrence of symptoms suggestive of CRS during the long term follow-up period. From this subgroup of 30 patients, 11 (36.7%) reported that using irrigation helped every time it was utilized for recurrent symptom, 16 (53.3%) reported it helped “some of the time”, 2 (6.7%) reported “not at all” helpful, and 1 (3.3%) was unsure if

irrigation helped or not. For the past 12 months, 29 families (53.7%) reported their child had used nasal irrigation again for recurring symptoms. For families who reported using irrigation for recurrent symptoms, 58.6% report irrigation was typically used once daily for less than 3 weeks. Median number of times irrigation was used during long-term follow-up was 1(IQR 0-3), and median duration of irrigation was 1 week (IQR 0-2). Of the 54 patients we were able to contact for the long-term follow-up, an additional 3 patients underwent FESS that did not receive it following the initial 6 week regimen of nasal irrigation. Median length of follow-up for this cohort was 48 months (range 20-113).

TABLE III.
Long-term Follow Up and Parental Report of Outcome. (n=54)

		No.	%
Were your child's problems successfully treated using irrigation?	Completely	38	70.4
	Partially	13	24.1
	No	2	3.7
	Not sure	1	1.9
When symptoms recurred, did you start your child on irrigation, medications, go to the doctor, or try other remedies?	Irrigation	33	61.1
	Medication	25	46.3
	Went to Doctor	20	37.0
	Other	5	9.3
	None of the above	9	16.7
Did irrigation help your child each time he/she used it? (n=30)	Every time	11	36.7
	Sometimes	16	53.3
	No	2	6.7
	Not sure	1	3.3
		Median	IQR*
Please estimate the number of occasions your child has used irrigation in the last 12 months and the duration of each occasion.	Number	1	0-3
	Duration, weeks	1	0-2

*Interquartile Range

Discussion

The goals of this study were to report on the efficacy of daily nasal irrigation after first-time use for pediatric CRS and to determine the short- and long-term outcomes of treating nasal

symptoms using irrigation. Of the patients that had short-term follow-up after the initial use of irrigation, 65.9% of patients reported complete resolution of symptoms, and 12.1% patients underwent limited FESS due to persistent clinical symptoms. On long-term follow-up, 61.1% of families that completed the survey reported self-initiated use of nasal irrigation for recurring symptoms, and an additional 3 patients were found to have undergone FESS during the follow-up period of up to almost 4 years.

Based on reported resolution of symptoms, reduction of Lund-Mackay Scores on CT imaging, and minimal need for sinus surgery, once daily saline irrigation is an effective treatment for pediatric CRS. Parents and caretakers are likely to use nasal irrigation for subsequent or recurrent nasal symptoms after initial experience with nasal irrigation. Despite using a wide variety of medications, our study population continued to have chronic symptoms until nasal irrigation was used. Therefore, irrigation might well be a suitable first line treatment for pediatric CRS.

The statistically significant reductions in Lund-Mackay scores in our study population after once daily nasal irrigation reflects the reversal of mucosal thickening and return to sinonasal health from nasal irrigation alone without additional medical therapies. A previous randomized clinical trial of nasal irrigation compared saline versus saline plus gentamycin and showed statistically significant reductions of about 4 points in Lund-Mackay CT scores of sinuses on either side. This reduction was shown to be correlated with improvements in QoL as measured by the sinonasal 5 (SN-5) questionnaires before and after treatment.[6] Our study also found statistically significant reductions of over 4 points of Lund-Mackay scores on each the left sinuses and right sinuses. Unfortunately, the patients' medical records did not contain any information on them having completed the SN-5 surveys, so it was not reported in our study.

Our previous trial emphasized that CT findings of opacification in paranasal sinuses represent mucosal thickening and not acute bacterial sinusitis since there are no air-fluid levels.[6] Unless there is complete opacification in the maxillary sinuses, one will almost always see that the opacification is circumferential, reflecting the thickened mucosa. It would appear that the paranasal sinus system parallels the human middle ear and mastoid system. In the latter, we know that lack of aeration/oxygenation through the normal functioning of Eustachian tubes often leads to middle ear mucosal metaplasia and hypertrophy, increased goblet cells, and subsequent secretion of mucoid effusion. It seems logical that when the nasal mucosa becomes congested and hypertrophic, the natural ostia and ostiomeatal complex are obstructed, leading to subsequent hypoxia and lack of oxygenation in the paranasal sinuses. This change in the paranasal sinuses ultimately leads chronic mucosal inflammation.

This larger cohort had similar patient characteristics compared to the smaller group of 40 patients in the previous clinical trial with a mean age of approximately 8 years for children diagnosed with CRS.[6] In our study, the most commonly presenting symptoms are nasal congestion, cough, and rhinorrhea and match the most common symptoms in prior studies.[3,6] Despite the chief complaints of nasal stuffiness and congestion, upon physical exam, rhinorrhea is inconsistently observed, even with flexible fiberoptic nasal endoscopy and nasopharyngoscopy in the office setting. Parents, caretakers, and patients typically report either a white or cloudy and rarely yellowish rhinorrhea or purulent. As rigid nasal endoscopy in pediatric patients is oftentimes difficult, purulent drainage from the middle meatus is rarely visualized.[28] The lack of purulent rhinorrhea emphasizes our assertion that pediatric CRS is an inflammatory process and not active “bacterial” infection. Hence, clinical symptoms are rarely responsive to systemic

antibiotic therapy and even prolonged courses of 21 days of broad-spectrum antibiotics, which are often prescribed when there is CT evidence of sinus opacification.

Asthma, allergies, and gastroesophageal reflux disease (GERD) have been reported to be the most common co-morbidities associated with CRS, with most patients report having been prescribed systemic and nasal steroids and antihistamines prior to visiting to otolaryngology.[16] Our study population also demonstrated that allergies, asthma, and GERD are common comorbidities. We report asthma as the most common medical-comorbidity in this group of children, with over half having been diagnosed and treated for asthma. Approximately 50% of the patients had positive skin allergy tests to common aeroallergens. A previous trial had reported asthma in about half of the study population, and atopy, in about 73%.[6] These differences may simply reflect the minor dissimilarities. Parental/caretaker report of previously diagnosed and/or treated GERD was lower in this larger group, at only 27% compared to the previously reported 45% in only 40 children.[6]

As such, it is important to ask parents/caretakers regarding history of skin allergy testing as well as results of testing if performed and, in children who are old enough, whether diagnosis of asthma has been made based on objective testing such as spirometry or pulmonary function test with methacholine challenge. Many otherwise healthy school-aged children are now prescribed bronchodilator therapy for symptoms of chronic cough, perhaps, for the presumed diagnosis of "cough-variant asthma." If there is mucosal thickening representative of inflammation in the paranasal sinuses, then the sinopulmonary reflex may be responsible for the cough and reversal of mucosal inflammation is likely necessary for complete resolution of chronic cough. For those patients presenting with symptoms suggestive of CRS who have not had allergy evaluation, evaluation and testing is strongly recommended. If the testing is negative

for allergies, it is important to counsel families on the opportunity for their children not to consume medications unnecessarily. A previous trial demonstrated a 94% compliance rate with the 6 week daily nasal irrigation regimen.[6] The high compliance with and self-initiated use of nasal irrigation reflects the high motivation on the part of the parents/caretakers in hopes of avoiding any need for FESS as well as desire for improvements from chronic symptoms. Resolution rates have been shown to lead to significant improvements in QoL as reported in a previous trial.[6]

This follow-up study is the first to report on the long term use and outcome of nasal irrigation. From the families whom we were able to contact for prospective follow-up, we found that more than half reported self-initiated use of saline nasal irrigation for recurrent symptoms even without making another appointment to see otolaryngology or any other physicians. Most families report that they find it useful at least some of the times whenever their child is able to irrigate. Our data suggest that once nasal irrigation is used as a treatment modality for pediatric CRS, parents and caretakers are likely to utilize it again for recurrent symptoms.

Limitations

This study has several limitations. First, all patient subjects were taken from a single clinic setting. Second, our phone follow-up survey was achieved in about 60% of all patients and families in this cohort. Despite multiple attempts to contact families based on the home and/or cell phone numbers available to us, and leaving messages, many calls were unreturned and some numbers were either disconnected or no longer in service. Parents who had a favorable experience may have been more likely to respond to the survey request.

Another limitation is recall bias, an inherent concern for any long-term follow-up. To address this we asked the parents/caretakers to estimate the frequency and duration of irrigation

regimens in the past 12 months. Parents and caretakers who responded were keenly aware of their children's medical history and interventions in the previous 12 months and were able to provide answers to the best of their recall. Approximately 70% of parents recalled successful reversal of symptoms after initial experience using nasal irrigation, similar to the 65% who reported complete resolution of symptoms at the initial follow-up after 6 weeks of once daily irrigation. The consistency in parental report of treatment "success" after use of nasal irrigation supports the long term efficacy of nasal irrigation in symptoms resolution. We acknowledge the limitations inherent to the retrospective part of reviewing this cohort. One example is the information on frequency of prescribed and use of oral antibiotics by other providers, which when recorded by the pediatric otolaryngologist during the office visit is entirely dependent on what was reported by parents and caretakers. As we have moved to electronic medical record in the outpatient setting in the past 22 months, we anticipate that in the future we can better capture relevant data prospectively and continue to gain insights into patterns of medication prescription and utilization. We found no statistically significant differences in baseline characteristics, Lund-Mackay scores pre and post-irrigation, symptoms resolution after the initial 6 weeks of nasal irrigation between those who completed the long-term follow-up versus those we were unable to contact.

One of the greatest limitations of this current study is that we did not prospectively collect sinonasal-5 (SN-5) quality of life surveys in this entire group pre and post irrigation treatment. However, based on our previous published results and the senior authors experience from parental reports at follow-up visit, we believe that if such data were available, it would likely demonstrate significant improvement in overall quality of life after 6 weeks of once daily irrigation.

The sample size of the study may not be high enough to detect any differences when comparing those that we contacted to those we were unable to contact. While the results of a 6 week treatment period could be confounded by natural resolution or use of other treatments, due to consistent follow-up after 6 weeks of irrigation, the senior author confirms in each case that no other medications or treatment methods were likely responsible for the resolution of symptoms and post irrigation CT scan findings in these patients. While not all patients had a post-treatment CT scan report, the statistically significant reduction in Lund Mackay scores based on the 70 patients who did have pre- and post-treatment scans supports our experience and conclusions that nasal irrigation is highly effective for treating pediatric CRS. We had hoped to determine predictive factors of treatment outcomes based on irrigation, but this was not possible due to high rates of improvement among the majority of the subjects.

Clinical Importance

CT scans and 21 days of oral systemic antibiotics for the treatment of "sinus" infection continue to be the primary approaches to management of CRS. . Given that parents/caretakers usually state that these children are not febrile, nor do they miss school or other activities, and their children continue to function despite the quality of life impairments due to these symptoms, once daily saline irrigation for 6 weeks should be the recommended initial treatment for children with suspected CRS. CT imaging can be reserved for only those who do not experience moderate or complete symptom resolution. CT scans may also be necessary for planning of limited FESS as the definitive treatment in cases of exhausting all medical therapies.[3] Whenever CT imaging is necessary, a low-dose radiation protocol can be used, which scans at an equivalent of almost $1/7^{th}$ the standard dose of radiation received from prior protocols for CT sinus imaging.[29] These changes are important to minimize radiation exposure in children.

It is also important to counsel families on this opportunity for their otherwise healthy children not to consume medications unnecessarily. This follow-up study is the first to report on the long term use and outcome of nasal irrigation. Our data suggest that once nasal irrigation is used as a treatment modality for pediatric CRS, parents and caretakers are likely to utilize it again for recurrent symptoms. This is important to empower patients and families to treat symptoms without overutilization of the health care system and use of multiple medications.

As CRS remains a source of significant medical expenditure, an undoubtedly important aspect of these clinical implications is cost-effectiveness. The NeilMed Sinus Rinse Kit is available at local drug stores and costs $13.79 on CVS.com. Routine CT scans and unnecessary sinus surgeries may be sources of avoidable medical expenses. However, further studies are warranted to analyze the actual cost savings associated with using nasal irrigation in this patient population. The results of these studies can impact insurance coverage of nasal irrigation kits for the treatment of CRS.

Future research of studying the use of nasal irrigation for the treatment of pediatric CRS will include a randomized, controlled trial to prospectively analyze the rates of resolution and subsequent need for sinus surgery in the nasal irrigation arm compared to a control group. Further studies could also be performed to address the cost-effectiveness of using sinus irrigation compared to sinus surgery.

Conclusion

Nasal irrigation is effective as a first line treatment for pediatric CRS and also useful for recurring symptoms. Use of once daily nasal irrigation for a 6 week-period is effective and leads to symptom resolution as well as minimizes need for sinus surgery. Patients with symptoms of

CRS, even when refractory to other medical therapies, should consider nasal irrigation before consideration for FESS.

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