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Long-term Outcome of Once Daily Nasal Irrigation for the Treatment of Pediatric Chronic Rhinosinusitis

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Abstract

Objectives—Chronic rhinosinusitis(CRS) results in significant morbidity and healthcare expenditure. Safety and efficacy of nasal irrigation use in the treatment of pediatric CRS has been demonstrated but long-term outcomes are unknown. We reviewed characteristics and treatment outcomes after 6 weeks of once daily nasal irrigation in pediatric CRS based on CT scan, and summarize parental reports of subsequent use of nasal irrigation for recurring symptoms.

Study Design—Retrospective cohort study and cross-sectional survey.

Methods—Review and survey of 144 pediatric CRS patients diagnosed between July 2003 and January 2012.

Results—One hundred four patients were reviewed. Mean age was 8.0 years, and 65.4% were male. Presenting symptoms included congestion(95.2%), cough(79.8%), rhinorrhea(60.6%), headache(48.1%), and fatigue(40.4%). Comorbidities include positive allergy test(50%), asthma(57.3%), and GERD(28.2%). After 6 weeks 57.7% of patients reported complete resolution of symptoms. Reductions in Lund-Mackay CT scores were 4.14 and 4.38 on the left and right sides, respectively ($p<0.001$). Of the 54 parents who completed the prospective surveys, 53.7% reported using irrigation again in the last 12 months(median 1, IQR 3). Only 9 patients underwent FESS after the initial 6 weeks. Patients requiring FESS were, on average, 3.6 years of age older than those that did not receive FESS($p=0.0005$). Median length of follow-up was 48 months(range 20–113). 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 is effective as a first-line treatment for pediatric CRS and subsequent nasal symptoms, and reduces need for FESS and CT imaging.

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Keywords

nasal irrigation; saline irrigation; chronic rhinosinusitis; outcome studies

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, but in fact, while frequently prescribed they are usually ineffective as CRS is not an acute bacterial infection but reflective of chronic inflammation as seen by circumferential mucosal thickening on computed tomography.⁵ These drugs have weak evidence in effectively treating CRS.⁶ Based on a meta-analysis, oral steroids can be effective in treating CRS associated with nasal polyps, but its use has insufficient evidence for treating CRS without nasal polyps.⁷

Several studies have examined the efficacy of nasal irrigations in alleviating sinus symptoms in pediatric patients. An randomized controlled trial 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.⁵ 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.⁸ Most commonly reported minor adverse events include post-irrigation nasal drainage and initial discomfort.⁹ Rare cases of nosebleeds and stinging have been reported.¹⁰ A meta-analysis on the use of nasal irrigation for the treatment of CRS concluded that its benefits outweighed its adverse effects.¹¹

Approximately 52.5% of patients with CRS report symptoms refractory to medical treatment and consider surgical options.¹² The reported success rate for adenoidectomies in the treatment of pediatric CRS is estimated to be 50–70%, with functional endoscopic sinus surgery (FESS) reported to have an estimated success rate of 88%.¹³ Functional endoscopic sinus surgery has been reported to significantly improve quality of life for patients.¹⁴ However, 3% of patients that undergo FESS experience major complications, such as uncontrolled bleeding and periorbital bruising.¹⁵ 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 with need for general anesthesia as well as those associated with 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 once daily nasal irrigation was recommended. Second, we surveyed parents whose children were seen from 2003 to 2012 to assess self-initiated use and outcomes of nasal irrigation for nasal symptoms. Parents or primary caretakers were contacted prospectively from October through January 2012 to participate in a cross-sectional survey on the subsequent use of nasal irrigations after initial experience with nasal irrigation at the time of meeting the treating pediatric otolaryngologist. The patients were identified using ICD-9 code for chronic sinusitis (including any and all sinuses, frontal, ethmoid, sphenoid, and/or maxillary) from the clinic of the senior author at KU Medwest, a satellite clinic of the University of Kansas Medical Center. Patients were included if they were diagnosed and treated between July 2003 and January 2012. This study proposal was approved by the KUMC Institutional Review Board, after which a list of pediatric CRS patients was obtained. We excluded patients who did not have CT evidence of sinus disease, those who were not prescribed daily nasal irrigations as the primary modality of treatment for their symptoms, and those who were unable to tolerate once daily irrigation for at least 6 week duration.

Data extracted from the medical record included patient demographics, referring physicians, past medical and surgical histories, medications tried prior to otolaryngology 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. All patients were prescribed 6 weeks of once daily nasal irrigation using the NeilMed Sinus Irrigation kit (squeeze bottle and buffered salt packets). Follow-up CT

scans were generally performed 6 weeks after the irrigation period. We reviewed clinical outcomes reported by patients and families after the initial irrigation period, 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 cohort were contacted between October 2012 and January 2013. The survey was administered by telephone, and the survey assessed the subsequent use of nasal irrigation after initial experience at the time of meeting treating pediatric otolaryngologist. It also assessed symptom recurrence, parent self-initiated use of nasal irrigation for child's nasal symptoms, duration of irrigation if used, and any subsequent surgical intervention including adenoidectomy and/or FESS. 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.

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

Data Analysis

Data were collected in a Microsoft Access database. The Wilcoxon rank sum test was used for comparisons of continuous or ordinal variables, and the χ^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).

Terminology

Acute rhinosinusitis is defined as nasal symptoms lasting up to 4 weeks, while subacute symptoms last 4–12 weeks. This study focuses on CRS and children who report 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.

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. The mean age at first visit to the pediatric otolaryngologist was 8.0 years (IQR: 5.00–9.88). Presenting symptoms, atopic history, and medications used are summarized in Table II. 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). Most common medications tried prior to pediatric otolaryngology referral include nasal or oral steroids, antihistamines, and montelukast

sodium. Titers for *Streptococcus pneumoniae* had been checked by patient's allergist 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 exam findings by the senior author included strands of thin, clear, stringy mucus found to span from the inferior turbinate to the septum in 31 patients (30.1%). Rhinorrhea during the exam was documented in only 17 patients (16.5%).

Baseline CT scans were performed in 97 patients, and the mean Lund-Mackay scores before use of 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 III). After 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 have reviewed the follow-up CT scan and 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. Of the 54 patients we were able to contact for the long-term follow-up, an additional 3 patients underwent FESS. Patients who underwent FESS were, on average, 3.6 years of age older than those that did not receive FESS ($p=0.0005$).

Long term follow-up and parental surveys are summarized in Table IV. 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. From this group, 30/54 (55.6%) parents reported that their child experienced recurrence of symptoms suggestive of CRS during the long term follow-up period. Overall, 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 3), and median duration of irrigation was 1 week (IQR 2). Median length of follow-up for this cohort was 48 months (range 20–113).

DISCUSSION

The goal of this study was to report 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. Our previous randomized clinical trial using saline versus saline plus gentamycin showed a 94% compliance rate as well as statistically significant reduction in both Lund-Mackay CT scores and improvement in QoL using the Sinonasal 5 (SN-5) questionnaire after 6 weeks of once daily irrigation.⁵

Our previous report also demonstrated that underlying atopy is the most common medical comorbidity associated with children who develop CRS, with 50% of the patient in this study having positive skin testing for common aeroallergens. The current follow-up study is the first to report the likelihood of parent/caretaker-initiated use of once daily nasal irrigation for subsequent or recurrent nasal symptoms after initial experience with nasal irrigation.

We report similar patient characteristics when comparing this larger cohort group to our smaller group of 40 patients in the previous clinical trial, with a mean age of approximately 8 years for children diagnosed with CRS. In this group, the most commonly presenting symptoms are nasal congestion, cough, and rhinorrhea as was previously reported. The senior author rarely sees rhinorrhea despite the chief complaints of nasal stuffiness and congestion, and even if there is actual rhinorrhea during the office exam, even with consistent 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.¹⁶ 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, even prolonged course of 21 days or more of broad-spectrum antibiotics which are often prescribed especially when there is CT evidence of sinus opacification.

Clarifications must be made to the readership regarding the use of CT imaging for children with suspected CRS as indications and use have changed for the senior author over the course of the past decade. First, majority these patients have been and continue to be referred to the senior author by allergists or primary physicians, and almost all of them have had a CT scan ordered by the referring physician prior to otolaryngology consultation. This led to the senior author’s observation in the early years, of the consistent correlation between clinical symptoms and CT evidence of paranasal sinus mucosal thickening, specifically the circumferential thickening of maxillary sinuses reflective inflammatory changes rather than acute rhinosinusitis. As the senior author started prescribing once daily nasal irrigation as the first line treatment for these patients, she ordered post-irrigation CT imaging to ensure complete reversal of mucosal thickening as objective evidence that nasal irrigation is indeed efficacious and correlates to resolution of clinical symptoms according to patients and caretakers. Once such correlation was observed, we performed a clinical trial in which recorded changes in the Lund-MacKay scores on pre and post-irrigation CT scans were used

to serve as objective evidence demonstrating the efficacy of nasal irrigation. Based on the findings of our clinical trial, the senior author made significant changes to her clinical practice, specifically no longer ordering CT scans post irrigation to assess mucosal disease.

Currently, the senior author identifies children at risk for CRS based on the triad of symptoms, chronic nasal congestion, cough, and rhinorrhea, lasting over 3 months. Since our previous trial demonstrated that saline was equally effective in symptom resolution and reversal of mucosal thickening on CT scan when compared to saline plus gentamycin, gentamycin in saline was no longer prescribed as an irrigation solution. Secondly, based on consistent and statistically significant reduction in Lund-Mackay scores on pre-treatment and post-treatment CT scans demonstrating reversal of mucosal thickening after once daily nasal irrigation for 6 weeks, the senior author no longer orders any CT imaging pre-irrigation to diagnose CRS if patients have not already had one ordered by the referring physician, nor is CT imaging routinely ordered after 6 weeks of irrigation treatment. Once daily saline irrigation for 6 weeks is always the recommended initial treatment for children suspected to have CRS. Based on our prior study results, CT imaging is no longer ordered except for patients who do not experience moderate or complete symptom resolution after a trial of once daily nasal saline irrigation, regardless of whether there has been a prior CT scan. Despite communicating the rationale for avoiding CT imaging to referring physicians as it no longer alters her clinical recommendations and treatment plans, many children continue to receive a CT scan prior to otolaryngology consultation. With increase in awareness and education by the Image Gently Campaign, as well as what our findings have shown, we hope there will continue to be an avoidance of unnecessary radiation exposure to children as well as the cost associated with CT imaging.

The routine recommendation of a trial of once daily nasal saline irrigation by the senior author when CRS is suspected has led to elimination of any CT imaging ordered on pediatric patients from our practice, and CT is now only ordered for rare patients who “fail” nasal irrigation as defined by lack of moderate to complete resolution of symptoms. It has been the senior author’s experience that in such patients, which is only approximately 10% of all patients seen for suspected CRS, CT imaging will likely demonstrate moderate to significant mucosal thickening with obstruction of bilateral ostiomeatal complexes. We believe CT imaging ordered in this context is appropriate and necessary for planning of limited FESS as the definitive treatment. Whenever CT imaging is necessary, we utilize a low-dose radiation protocol which scans at an equivalent of almost 1/7th the standard dose of radiation received from prior protocols for CT sinus imaging.¹⁷

The clinical diagnosis of CRS is not easy to make, as children typically do not have nasal polyposis nor have significant exam findings other than perhaps some hypertrophy of inferior turbinate mucosa, which may be a subjective observation. Cough and nasal congestion may be appreciated during the office visit. While a thorough history and symptoms are easy to obtain, confirmation of presence of mucosal thickening are only obtained at the cost of giving radiation exposure to children. Since modifying her clinical practice protocol in children with suspected CRS based on symptoms only without CT scans, the senior author has continued to find that nasal irrigation continues to be a highly effective treatment. The avoidance of radiation exposure and additional healthcare

expenditure when outcomes are favorable has supported the decision to utilize this clinical protocol. Gastroesophageal reflux, asthma, and allergies 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 the most common comorbidities.

We report atopy as the most common medical-comorbidity in this group of children, with approximately two-thirds of the patients having positive skin allergy tests to common aeroallergens, and over half having been diagnosed and treated for asthma. 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. The senior author consistently asks parents/caretakers regarding history of skin allergy testing as well as results of testing if performed. She also asks in children who are old enough, whether diagnosis of asthma has been made based on objective testing such as spirometry, 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”. The senior author explains to all families that 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 completely 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.

Our previous study emphasized the point that CT findings of opacification in paranasal sinuses represent mucosal thickening and not acute bacterial sinusitis as there are no air-fluid levels. Unless there is complete opacification in the maxillary sinuses, one will almost unanimously see that the opacification is circumferential again reflecting that the “gray” we see in the sinus is in fact 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, increase in presence of goblet cells and subsequent secretion of mucoid effusion. It seems logical that when nasal mucosa becomes congested and hypertrophic, leading to obstruction of the natural ostia and ostiomeatal complex, this leads to subsequent hypoxia and lack of oxygenation in the paranasal sinuses leading to change in paranasal sinus mucosa as well as chronic inflammation. The author continues to meet patients daily in whom a CT scan was already ordered and the child has been prescribed generally at least 21 days of oral systemic antibiotics for the treatment of “sinus” infection. While these symptoms undoubtedly are troublesome, parents/caretakers always 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.

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 ostiomeatal obstruction.¹⁸ A cumulative score of 5 or higher provides a sensitivity and specificity of 86% and 85%, respectively.¹⁹ Again, the statistically significant reductions in Lund-Mackay scores in our group of patients after once daily nasal irrigation reflects the reversal of mucosal thickening and return to sinonasal health from nasal irrigation alone without additional medical therapies. High compliance with 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 to help their child experience any improvement from such chronic symptoms which does lead to significant impairment in their QoL as reported in our previous study.

From the families whom we were able to contact for prospective follow-up, we found that approximately half report 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. It is important to clarify that subsequent self-initiated irrigation use for symptoms of nasal congestion, cough, and/or rhinorrhea are likely treating symptoms from an acute viral upper respiratory illness, exacerbation of underlying allergies, or even acute rhinosinusitis after a viral URI as opposed to true CRS. Once patients and caretakers have experienced the benefit of nasal irrigation, they are likely to initiate its use again for onset of symptoms without waiting for symptoms to persist for over 12 weeks and the return of CRS diagnosis. Nonetheless, it is conceivable that any benefit in symptoms resolution, which likely correlate with early reversal of mucosal thickening of the paranasal sinuses, will also minimize persistent symptoms and development of true CRS.

This study has several limitations. First, all patient subjects were taken from a single clinic setting. 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 are 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 support 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, however, this was not possible due to similar improvements among the majority of the subjects.

Despite all the limitations described, our results strongly support the use of once daily saline nasal irrigation using the NeilMed Sinus Rinse system as the first line treatment for pediatric CRS and confirms the our previously reported common triad of symptoms which are highly diagnostic of CRS as proven by CT imaging. Our limited long-term follow-up data suggest that once nasal irrigation is used as a treatment modality for treating pediatric CRS, parents/caretakers are likely to utilize it again for recurrent symptoms, which may lead to less utilization of the health care system including physician visits and use of multiple medications. Most importantly, saline nasal irrigation is a cost-effective and clinically efficacious treatment for pediatric CRS, improves the quality of life of children who suffer from chronic symptoms, and eliminates the need for routine CT scan for the diagnosis of CRS as well as reversal of mucosal disease after irrigation when there is symptom resolution

Clinical Importance

CT scans and 21 day course or longer of oral systemic antibiotics continue to be the primary diagnostic and treatment approach to the management of CRS. Given that parents/caretakers always 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 should 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 1/7th the standard dose of radiation received from prior protocols for CT sinus imaging.¹⁷ 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 should 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, as well as 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 for recurring nasal symptoms. Use of once daily nasal irrigation for a 6-week period is effective and leads to symptom resolution as well as minimize the need for sinus surgery. Patients with symptoms of CRS, even when refractory to other medical therapies with or without adenoidectomy, should consider nasal irrigation before consideration for FESS. Routine use of CT scan for diagnosis and documentation of reversal of mucosal thickening after irrigation should be avoided.

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TABLE I

Baseline Characteristics.

	Contacted (n=54)	Not Contacted (n=50)	Total (n=104)
Age (yr)	8.11 ± 3.75	7.92 ± 3.46	8.02 ± 3.60
Gender, no. (%)			
Male	35 (64.8)	33 (66.0)	68 (65.4)
Female	19 (35.2)	17 (34.0)	36 (34.6)
Referral, no. (%)			
Asthma/allergy	34 (63.0)	25 (50.0)	59 (56.7)
Pediatrician	12 (22.2)	14 (28.0)	26 (25.0)
Self	4 (7.4)	7 (14.0)	11 (10.6)
Other	4 (7.4)	4 (8.0)	8 (7.7)

TABLE II

Presenting Symptoms, Atopic History, and Medications Used. (n=104)

Symptoms, no. (%)	
Congestion	99 (95.2)
Cough	83 (79.8)
Rhinorrhea	63 (60.6)
Headache	50 (48.1)
Fatigue	42 (40.4)
No. of courses of antibiotic therapy completed in previous	
12 months (n=26)	5.46 ± 2.49
6 months (n=37)	3.59 ± 1.99
History, no. (%)	
Asthma	59 (57.3)
Adenoidectomy	39 (37.5)
GERD	29 (28.2)
Positive Allergy Skin Test	52 (50.0)
Medications Tried, no. (%)	
Nasal steroid spray	79 (75.0)
Oral antihistamine	51 (49.0)
Oral steroids	49 (47.1)
Montelukast (leukotriene receptor antagonist)	44 (42.3)
Albuterol	41 (39.4)
OTC decongestant	13 (12.5)
None/Not Reported	7 (6.7)

TABLE III
Computed Tomography Scoring (Lund-Mackay) at Baseline and After 6 Weeks of Irrigation

	Left Sinuses				Right Sinuses			
	Baseline	Postirrigation	Change	p value	Baseline	Postirrigation	Change	p value
	Mean	St. Dev			Mean	St. Dev		
	5.56	1.96	-4.14	<0.001	5.84	2	-4.38	<0.001
	2.61	2.16	3.07		2.56	2.13	3.15	

TABLE IV

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
	None of the above	9	16.7
	Other	5	9.3
Did irrigation help your child each time he/she used it?	Every time	25	46.3
	Sometimes	18	33.3
	Not sure	9	16.7
	No	2	3.7
	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	3
	Duration, weeks	1	2

* Interquartile Range