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In-Office Stand-Alone Balloon Dilation of Maxillary Sinus Ostia and Ethmoid Infundibula in Adults With Chronic or Recurrent Acute Rhinosinusitis: A Prospective, Multi-institutional Study With 1-Year Follow-Up

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Objectives: This study evaluated in-office balloon dilation of maxillary sinus ostia and ethmoid infundibula to treat chronic rhinosinusitis (CRS) and recurrent acute rhinosinusitis (RARS).

Methods: Seventy-four patients with disease in the maxillary and anterior ethmoid sinuses on computed tomography were prospectively enrolled across 12 study centers. All procedures were performed in the office. The primary outcomes were clinical effectiveness and health-care utilization at 1 year, measured by the validated surveys Sino-Nasal Outcome Test (SNOT-20) and Rhinosinusitis Symptom Inventory (RSI).

Results: Dilation was successful in 69 patients (93.2%), and the average periprocedural pain level was 3.2 (scale of 0 to 10). The mean improvement on the SNOT-20 at 1 year was clinically and statistically significant ($p < 0.0001$), with no significant difference between the CRS and RARS patient outcomes. The treatment effect was the same in the CRS and RARS subgroups and was either "moderate" or "large" for 10 of 12 symptoms. The mean numbers of antibiotic courses ($p \leq 0.001$), sinus-related physician visits ($p < 0.0001$), and number of acute sinus infections ($p < 0.001$) decreased significantly in both subgroups. There were no serious device-related adverse events, and the rate of revision surgery was 5.8%.

Conclusions: Stand-alone balloon dilation of the maxillary sinus ostia and ethmoid infundibula performed in the office is well tolerated and effectively treats both CRS and RARS.

Key Words: balloon dilation, chronic rhinosinusitis, outpatient surgery, recurrent acute rhinosinusitis.

INTRODUCTION

Multiple clinical trials have confirmed that balloon devices are safe and effective in treating chronic rhinosinusitis (CRS).[1-4] Several recent prospective studies examined the feasibility and outcomes of balloon dilation procedures in an office setting.[5,6] Patients with CRS who failed medical management and were candidates for sinus surgery underwent ostial dilation rather than endoscopic sinus surgery (ESS). The published results through a minimum of 6 months showed that patients not only tolerated balloon dilation of the sinus ostia under local anesthesia in the office with little discomfort, but also experienced significant and sustained improvement in their sinus symptoms, similar in magnitude to that of patients who underwent ostial dilation in the operating room. The use of balloon dilation procedures to treat recurrent acute rhinosinusitis (RARS) has not yet been studied.

Sometimes referred to as chronic recurrent rhinosinusitis, since it is considered a type of CRS, RARS has a prevalence and disease burden about which less is known. Using medical claims data, one study estimated that 1 in 3,000 adults may suffer from RARS. The annual economic impact of diagnosis and treatment of RARS averaged $1,091 per patient, of which about 50% of the cost was due to prescription antibiotics and physician visits.[7] For comparison, earlier studies concluded that depending upon the severity of disease, between $921 and $1,220 per year were spent to treat each CRS patient.[8,9] Thus, although RARS has been studied less extensively than CRS, it appears to be no less costly to manage. The objectives of this study were to

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evaluate the postoperative health-care resource utilization and demonstrate the durability of symptom relief over time in patients with CRS or RARS and radiographic disease in the maxillary and anterior ethmoid sinuses who underwent stand-alone office balloon dilation. "Balloon dilation" as used throughout this report refers to balloon dilation of the maxillary sinus ostia and ethmoid infundibula.

PATIENTS AND METHODS

Study Overview and Statistical Analyses. The study (RELIEF: HealthcaRE UtiLization and Outcomes of FInESS Treatment in the OFfice; http://clinicaltrials.gov/show/NCT00986830) was a multicenter, prospectively enrolling clinical trial conducted under a common protocol and approved by Western Institutional Review Board (WIRB). Study data were collected according to Good Clinical Practices, and an independent statistician calculated standard summary statistics for all study end points. Categorical variables were summarized with frequency distributions, and continuous variables were summarized with means, standard deviations, and ranges. Continuous variables were compared by use of a 2-sample *t*-test with nonparametric methods when appropriate. All statistical tests were 2-sided, and p values of less than 0.05 were deemed statistically significant. All analyses were performed with SAS Version 9.2 (SAS Institute, Cary, North Carolina).

Inclusion and Exclusion Criteria. Patients were eligible to participate if they were at least 18 years of age and met the American Academy of Otolaryngology–Head and Neck Surgery Adult Sinusitis Clinical Practice Guidelines (2007) for either CRS or RARS.[10] Specifically, CRS was defined as at least 12 weeks of sinus symptoms and documentation of inflammation in the middle meatus or paranasal sinuses, whereas RARS was defined as 4 or more episodes of acute bacterial rhinosinusitis per year without signs or symptoms between occurrences. Patients also had to have undergone a failure of medical management including a minimum of 3 weeks of treatment with antibiotics and either a nasal or oral steroid drug before enrollment. Radiographic (computed tomography; CT) imaging was performed within the 4 months prior to enrollment, but image acquisition relative to failed medical therapy was not prespecified by the protocol. Each patient scan had to show mucosal inflammation in one or both maxillary sinuses, and opacification of the anterior ethmoid sinuses was also permitted. For a diagnosis of RARS, patients had to have documented endoscopic evidence of edema or purulence in the middle meatus region during at least 1 of the 4 RARS episodes.

Patients were excluded from the study if they had radiographic evidence of sinus disease in the frontal, posterior ethmoid, or sphenoid sinuses. Fungal sinusitis, the presence of thickened polypoidal mucosa, ciliary dyskinesia, cystic fibrosis, Samter's triad, and hemophilia were also exclusion criteria. Patients who were known to have immunosuppression or who were unable to stop use of anticoagulant or antiplatelet medications were not eligible, nor were those who had a severe septal deviation causing complete nasal obstruction, a history of midfacial or orthognathic surgery, or a history of any sinonasal surgery within the 3 months prior to enrollment.

Study Procedures and Outcome Measures. Within the 60 days prior to the procedure, the patients underwent an otolaryngological examination that included nasal endoscopy to assess their eligibility and to document their baseline symptoms. They also completed the validated Sino-Nasal Outcome Test 20 (SNOT-20)[11] and the Rhinosinusitis Symptom Inventory (RSI; developed by Neil Bhattacharyya, MD, Boston, Massachusetts, copyright 1999).[8] Both surveys score patient-reported symptom severity on a numeric scale of 0 to 5, where 0 indicates that the symptom is absent or not a problem and 5 indicates that it is severe or as bad as it can be. The patients also reported resource utilization data and missed workdays related to their sinus problems on the RSI.

Patients who consented to participate and met all eligibility criteria were required to undergo the stand-alone balloon dilation procedure in an office setting. Preprocedure benzodiazepines were administered at the discretion of the surgeon, but the procedure anesthesia was limited to topical decongestants, topical anesthesia, and local injections. The balloon dilation was confined to the maxillary sinus ostia and ethmoid infundibula and was performed with the commercially available FinESS™ Sinus Treatment system (Entellus Medical, Inc; Plymouth, Minnesota). This system uses a flexible-tipped balloon catheter, a micro-trocar, an access sheath, and a proprietary endoscope to pass through the canine fossa and traverse the maxillary antrum to access and dilate the maxillary sinus ostium and ethmoid infundibulum.[12] Concomitant sinonasal surgeries and tissue removal with traditional ESS instruments were prohibited. The rate of technical success (number of successful dilations per number of attempted dilations) and intraoperative complications were documented. Postoperative nasal dressing and medications were administered at the discretion of the surgeon. Procedural discomfort was self-reported on a scale from 0 (no pain) to 10 (severe pain). After discharge, the patients were contacted at 1 week

TABLE 1. BASELINE DEMOGRAPHICS OF 69 PATIENTS

Age at time of consent (y)	47.1 ± 14.4
Gender	
Male	25 (36.2%)
Female	44 (63.8%)
Ethnicity	
Caucasian	61 (88.4%)
Hispanic	4 (5.8%)
Asian	2 (2.9%)
African American	1 (1.4%)
Other	1 (1.4%)
Smoking history	
Never smoked	49 (71.0%)
Former smoker	18 (26.1%)
Current smoker	2 (2.9%)
Allergies	
None	17 (24.6%)
All year	35 (50.7%)
Seasonal	17 (24.6%)
Previous sinus surgery	7 (10.1%)
Septal deviation	47 (68.1%)
Rhinosinusitis diagnosis	
Chronic (CRS)	52 (75.4%)
Recurrent acute (RARS)	17 (24.6%)
Sinuses affected	
Maxillary only	55 (79.7%)
Maxillary and anterior ethmoid	14 (20.3%)
Lund-Mackay score (n = 51)	4.5 ± 3.6

Data for age and for Lund-Mackay score are mean ± SD. Other data are numbers of patients.

CRS — chronic rhinosinusitis; RARS — recurrent acute rhinosinusitis.

and monthly thereafter through 1 year of follow-up to assess for possible adverse events and occurrence of revision surgery. The patients also completed the SNOT-20 and RSI questionnaires at 6 months and 1 year. A preprocedure-postprocedure comparison was made of sinus symptoms, medication use, workdays missed, homebound days, physician visits, and acute sinus infections. An aggregate analysis of all patients was performed, and descriptive statistics were computed for patient subgroups by location of sinus disease and rhinosinusitis diagnosis.

RESULTS

Patient Accountability and Demographics. A total of 74 subjects were enrolled at 12 study centers. No study center contributed more than 20% of the patient enrollments. Balloon dilation was attempted but was unsuccessful in 5 patients (4 unilateral cases and 1 bilateral case), leaving an evaluable sample size of 69 patients. These attempts were included in the analysis of procedure technical success, procedure pain, and adverse events, but were excluded from the 1-year outcomes analyses. Sixty-six of the 69 evaluable patients completed the required follow-up through 1 year, for a per-protocol compliance rate of 95.7%. The baseline demographics are shown in Table 1. There were no statistically significant differences in baseline demographics when the population was stratified by rhinosinusitis diagnosis (CRS versus RARS) or radiographic location of sinus disease (maxillary only versus maxillary and anterior ethmoid).

Office Procedure Outcomes. The overall technical success rate was 91.9% (124 of 135 ostia). There was a learning curve observed in which as physicians gained experience, the success rate increased. In the first 30 patients the technical success rate was 85.5% (47 of 55 ostia), whereas in the next 44 patients the success rate improved to 96.3% (77 of 80 ostia). The reasons for unsuccessful attempts included inability to visualize the natural ostium, procedure intolerance, and inability to cannulate the sinus. On a scale of 0 to 10, the average level of pain experienced by patients during the procedure was 3.2. None of the patients were sent home with nasal packing, and no postoperative debridements were performed.

Symptom Improvement. The baseline mean SNOT-20 score for all patients who completed the baseline and follow-up surveys was 2.3. The mean SNOT-20 score improved to 1.1 at 6 months, and this improvement was sustained through 1 year. At each time point, the mean decrease of 1.2 was not only highly significant ($p < 0.0001$), but was also greater than the mean threshold ($\Delta \geq 0.8$) that represented clinically meaningful improvement. Table 2 and Table 3 show the 6-month and 1-year SNOT-20 symptom improvement by rhinosinusitis diagnosis (CRS versus RARS) and by sinus disease location (maxil-

TABLE 2. SNOT-20 SYMPTOM IMPROVEMENT BY RHINOSINUSITIS DIAGNOSIS AND TIME PERIOD

	CRS					*RARS*					
Follow-Up	*N*	*Baseline*	*Follow-Up*	*Δ*	*p**	*N*	*Baseline*	*Follow-Up*	*Δ*	*p**	p†
6 mo	46	2.2 ± 0.9	1.0 ± 1.1	–1.1	<0.0001	15	2.6 ± 0.8	1.5 ± 0.9	–1.1	0.005	NS
1 y	48	2.2 ± 0.9	1.0 ± 1.0	–1.1	<0.0001	16	2.5 ± 0.8	1.3 ± 0.9	–1.2	<0.001	NS

SNOT-20 — Sino-Nasal Outcome Test; NS — not significant.

*Comparison of mean change (Δ) from baseline to follow-up within subgroup; p value from paired *t*-test.

†Comparison of difference (Δ) between CRS and RARS subgroups; p value from generalized linear models comparing groups.

TABLE 3. SNOT-20 SYMPTOM IMPROVEMENT BY SINUS DISEASE LOCATION AND TIME PERIOD

	Maxillary Only					*Maxillary + Anterior Ethmoid*					
Follow-Up	*N*	*Baseline*	*Follow-Up*	*Δ*	*p**	*N*	*Baseline*	*Follow-Up*	*Δ*	*p**	p†
6 mo	48	2.3 ± 0.8	1.1 ± 1.1	–1.1	<0.0001	13	2.3 ± 1.1	1.1 ± 1.0	–1.2	0.010	NS
1 y	52	2.3 ± 0.8	1.1 ± 1.0	–1.1	<0.0001	12	2.3 ± 1.2	1.0 ± 1.0	–1.3	0.004	NS

*Comparison of mean change (Δ) from baseline to follow-up within subgroup; p value from paired *t*-test.

†Comparison of difference (Δ) between sinus disease location subgroups; p value from generalized linear models comparing groups.

lary only versus maxillary and anterior ethmoid), respectively. The improvement in both subgroups was not only similar to that of the overall population, but was also similar between the subgroups. In addition, the results at 6 months were nearly identical to those obtained at 1 year for both rhinosinusitis diagnosis subgroups and for both sinus disease location subgroups.

A total of 49 CRS patients and 16 RARS patients had RSI symptom data at baseline and 1-year follow-up. The mean sinonasal symptom score at baseline, the net change from baseline at 1 year, and the effect size for each of the 5 major and 7 minor sinus symptoms are shown in Table 4. Congestion and nasal obstruction were the highest-scored (ie, most symptomatic) major sinus symptoms in both subgroups before treatment. Both CRS and RARS patients experienced "large" treatment effects and significant improvement ($p < 0.001$) at 1 year of follow-up for the following major symptoms: facial pressure, congestion, nasal obstruction, and hyposmia. For 10 of the 12 RSI symptoms, the treatment effects in the CRS and RARS subgroups were in the same category of either "moderate" or "large". There was no evidence of a statistical difference in symptom improvement for any of the 12 symptom scores between the CRS and RARS subgroups.

A total of 52 "maxillary only" and 12 "maxillary and anterior ethmoid" patients had RSI data at baseline and 1 year. There was concordance in the treatment effect size between the two subgroups for 11 of the 12 symptoms, and the effect size was moderate or large for all 12 symptoms for both subgroups.

Health-Care Utilization and Work Status. The preprocedure and postprocedure RSI results for the CRS and RARS subgroups are summarized in Table 5. Before balloon dilation, a larger percentage of RARS patients were using nasal steroids and antihistamines. In the year after balloon dilation, the percentage of patients using a nasal steroid decreased from 87.5% to 68.8% in the RARS subgroup ($p = 0.065$) and decreased significantly, from 67.3% to 51.0%, in the CRS subgroup ($p = 0.036$). The number of antibiotics courses decreased significantly in both subgroups in the year after ostial dilation ($p \leq 0.001$).

The RARS and CRS patients on average missed between 5.1 and 6.2 fewer workdays, respectively, in the year after treatment, and also reported significantly fewer homebound days ($p = 0.047$; $p = 0.024$). In both subgroups there was a significant reduction

TABLE 4. BASELINE AND ONE-YEAR CHANGES IN SINONASAL SYMPTOM SCORES BY RHINOSINUSITIS DIAGNOSIS

	CRS				*RARS*				
Symptom	*Baseline*	*Δ*	*Effect Size*	*p**	*Baseline*	*Δ*	*Effect Size*	*p**	*p†*
Major									
Facial pressure	2.9	–1.8	–1.29 (large)	<0.0001	3.3	–1.8	–1.05 (large)	<0.001	NS
Congestion	3.2	–2.0	–1.24 (large)	<0.0001	3.6	–1.8	–1.03 (large)	<0.001	NS
Nasal obstruction	3.1	–1.9	–1.11 (large)	<0.0001	3.4	–1.9	–1.12 (large)	<0.001	NS
Rhinorrhea	2.9	–1.7	–0.89 (large)	<0.0001	2.4	–1.1	–0.49 (small)	0.070	NS
Hyposmia	2.1	–1.5	–0.81 (large)	<0.0001	2.2	–1.5	–0.81 (large)	0.007	NS
Minor									
Headache	2.9	–2.0	–1.26 (large)	<0.0001	3.1	–1.4	–0.84 (large)	0.004	NS
Fever	0.9	–0.7	–0.61 (moderate)	<0.0001	0.8	–0.6	–0.51 (moderate)	0.058	NS
Halitosis	1.7	–1.2	–0.85 (large)	<0.0001	2.0	–1.4	–0.99 (large)	0.001	NS
Fatigue	3.1	–1.9	–1.11 (large)	<0.0001	3.5	–1.8	–1.16 (large)	<0.001	NS
Dental pain	1.6	–1.0	–0.78 (moderate)	<0.0001	2.1	–1.6	–0.98 (large)	0.002	NS
Cough	2.0	–1.1	–0.69 (moderate)	<0.0001	2.1	–1.1	–0.59 (moderate)	0.033	NS
Ear pain	2.4	–1.5	–1.01 (large)	<0.0001	2.9	–1.9	–1.29 (large)	<0.001	NS

Effect size: small — less than 0.5; moderate — 0.5 to less than 0.8; large — at least 0.8.

*Comparison of mean change (Δ) from baseline to 1-year follow-up within subgroup; p value from paired *t*-test.

†Comparison of difference (Δ) between CRS and RARS subgroups; p value from generalized linear models comparing groups.

TABLE 5. BASELINE AND ONE-YEAR CHANGES IN HEALTH-CARE UTILIZATION AND MISSED WORKDAYS BY RHINOSINUSITIS DIAGNOSIS

	CRS				*RARS*				
Clinical or Resource Variable	*Baseline*	*1 Year*	*Δ*	*p**	*Baseline*	*1 Year*	*Δ*	*p**	*p†*
Patients using nasal steroids	67.3%	51.0%	–16.3%	0.036	87.5%	68.8%	–18.7%	0.065	NS
Patients using antihistamines	42.9%	38.8%	–4.1%	0.536	75.0%	56.3%	–18.7%	0.365	NS
No. of antibiotic courses	5.1 ± 2.4	2.1 ± 2.1	–3.0	<0.0001	6.6 ± 2.5	2.8 ± 3.2	–3.8	0.001	NS
No. of workdays missed	8.8 ± 15.4	2.5 ± 9.0	–6.2	<0.0001	6.4 ± 9.8	1.3 ± 2.2	–5.1	0.061	NS
No. of homebound days	10.9 ± 18.0	4.1 ± 12.3	–6.8	0.024	6.8 ± 7.7	2.3 ± 3.6	–4.5	0.047	NS
No. of physician visits	6.9 ± 4.0	2.2 ± 3.1	–4.7	<0.0001	7.9 ± 2.7	3.3 ± 3.4	–4.7	<0.0001	NS
No. of acute infections	5.2 ± 4.3	1.8 ± 2.1	–3.4	<0.0001	7.3 ± 2.6	2.9 ± 2.6	–4.4	<0.001	NS

*Comparison of mean change (Δ) from baseline to 1-year follow-up within subgroup; p value from paired *t*-test.

†Comparison of difference (Δ) between CRS and RARS subgroups; p value from generalized linear models comparing groups.

in the number of physician visits ($p < 0.0001$) and in the number of acute infections of the nose or sinuses ($p < 0.001$).

Safety and Revision Rate. One serious adverse event (arrhythmic death), unrelated to either the study device or the procedure, was reported after a patient underwent surgery to treat a necrotizing hemorrhagic ileitis with perforation. The most common nonserious adverse event (persistent mild numbness of the tissue in the region of the canine fossa) was reported in 5 patients (6.8%). In 3 of these patients, the procedure was performed by the same surgeon. After balloon dilation, 4 patients went on to have ESS to treat ongoing sinus symptoms coupled with radiographic evidence of disease in the maxillary and/or ethmoid sinuses, for a surgical revision rate of 5.8%.

DISCUSSION

This study evaluated sinus symptom severity and health-care utilization in CRS and RARS patients before and after balloon dilation and assessed the durability of this office-based procedure through 1 year. The aggregate RELIEF data complement recently published data from office-based studies and literature reviews[13] by also showing a high rate of technical success, a high degree of patient comfort, and significant, sustained symptom improvement with a low rate of revision surgery. However, it was recently suggested that more work was necessary to evaluate possible indications for office-based balloon dilation in the treatment of various disease types and patient groups, including RARS.[14] RELIEF is the first balloon study to prospectively evaluate in-office stand-alone balloon dilation procedures in RARS patients.

Bhattacharyya and Lee[15] characterized RARS patients and compared the severity of their disease to that shown in a database of CRS patients. The RARS patients were on average 40.9 years old and female (3:1), with an average Lund-MacKay score of 3.8 and a significant degree of sinus symptoms, similar in magnitude to that of CRS patients. The RARS patients missed significantly more workdays and took significantly more courses of antibiotics than did their CRS counterparts. Similarly, the RELIEF RARS patients were on average 41.9 years old, were primarily female, had a sinus symptom severity comparable to that of RELIEF CRS patients, and had an average Lund-Mackay score of 4.2. However, the RARS patients of Bhattacharyya and Lee[15] reported less utilization of sinus-related medications than did the RELIEF RARS subgroup at baseline; eg, fewer patients were on nasal steroids (69% versus 88%) or antihistamines (54% versus 75%). Greater preprocedure medication use by the RARS patients in RELIEF may be in part attributed to the study criterion that required each patient to have a failure of medical management before enrollment. In addition, more patients in this study had histories of allergy (82%) and asthma (41%), which may have increased the utilization of sinus-related medications.

After characterizing RARS, Bhattacharyya[16] conducted a follow-up study in which 19 adult patients with RARS underwent ESS. In the year following surgery, patients saw "large" treatment effects and statistically significant improvement in rhinosinusitis symptoms. In addition, statistically significant decreases in antihistamine use, number of workdays missed, and number of acute infections were reported. The RELIEF RARS subgroup saw similar symptom improvement after stand-alone balloon dilation. Unlike the ESS study on RARS patients, RELIEF also found significant reductions in the numbers of physician visits and courses of antibiotics in the year after surgery. The similarities in eligibility criteria, sample sizes, baseline demographics, and symptom scores between these two studies suggest that there was not a significant disparity between the RARS patient populations.

Although the specificity of RELIEF eligibility criteria and procedure limitations resulted in significant patient screening activity, confounding variables such as tissue removal and concomitant nasal surgery were avoided, thus allowing more accurate assessment of the treatment effect of balloon dilation when mucosal inflammation of the maxillary and anterior ethmoid sinuses was present on CT. Understanding the treatment effect of stand-alone balloon dilation on patients with maxillary and anterior ethmoid disease is important because research has suggested a potential relationship between the ostiomeatal complex and RARS. In their experience with RARS, Poetker et al[17] observed that disease was centered around the ostiomeatal complex and the patients were therefore candidates for maxillary and anterior ethmoid surgery. Alkire and Bhattacharyya[18] evaluated CT scans of RARS patients and found a greater prevalence of Haller cells and significantly smaller infundibular widths relative to a control. Although the sample sizes were small and more research is necessary to further correlate ostiomeatal complex disease patterns, infundibular widths, and other anatomic variables to rhinosinusitis diagnoses and treatment, there is anatomic and empirical evidence to support stand-alone balloon dilation as a procedural alternative to ESS in RARS patients.

This study has several limitations. Selection of study centers was based in part upon referral patterns and the types of patients in their practices in an attempt to achieve similar numbers of CRS and RARS enrollments. However, because of the specificity and number of eligibility criteria and the diagnosis requirement that at least 1 RARS episode had to be confirmed by a physician, fewer RARS patients were enrolled in the study, and this discrepancy is a potential source of bias. Acquisition of CT scans for eligibility assessment was not timed to a prespecified interval after completion of medical therapy. Although standardizing the interval between sinus medication use and CT scanning would have added greater control to the design, this study was conducted within community-based practices, and the physician investigators often relied on patient medical histories, including previous CT scanning and medication use, rather than restarting medical therapy and performing repeat CT scanning when it did not appear to be medically necessary to confirm an accurate diagnosis of rhinosinusitis. Although Lund-Mackay scoring was not an initial requirement of the study design, the baseline CT scans were retrospectively collected and scored by an independent physician expert to further characterize the study population.

To reduce the likelihood that significant changes in patient symptoms occurred before treatment, all SNOT-20 surveys were completed within 2 weeks of the study procedure and all RSI surveys were completed upon arrival at the clinic on the day of the study procedure, before use of topical or injection anesthesia. Both quality-of-life surveys were also completed after failure of a minimum of 3 weeks of antibiotics and use of either a nasal or oral steroid to further reduce the likelihood for treatment bias. Postoperative medication use was at the discretion of each physician and was neither mandated nor controlled. Although sinus-related medication use generally decreased after the study procedure, the pharmacologic influence on balloon dilation effectiveness cannot be determined. In addition, health-care utilization data were based upon patient-reported events and were thus subject to recall bias.

One of the attributes of the SNOT-20 survey that increases its clinical utility is the inclusion of a mean change score (≥0.8) that is considered clinically meaningful. In RELIEF, 42 of the 64 patients (65.3%) had individual SNOT-20 change scores (Δ) of at least 0.8 at the 1-year follow-up. Earlier, ESS studies using other quality-of-life surveys with prespecified minimum clinically important difference thresholds showed similar results, with 64.4% to 70.9% of patients experiencing meaningful improvement between 6 months and 20 months after surgery.[19] However, no claims can be made based on our research to suggest that balloon dilation is either equivalent or superior to ESS in the treatment of rhinosinusitis. Hopkins et al[20] validated an updated version of the SNOT-20 instrument (SNOT-22) that also assesses nasal blockage and the loss of sense of taste and smell, and use of this updated questionnaire should be considered in future studies. Furthermore, randomized studies to compare balloon dilation to standard-of-care treatments for rhinosinusitis, including medical management and traditional ESS, continue to be necessary.

CONCLUSIONS

Balloon dilation to treat either CRS or RARS can be performed in the office with a high rate of technical success and minimal discomfort to patients. The severity of sinus symptoms and the utilization of sinus-related health-care resources are comparable for both rhinosinusitis diagnoses, and both RARS and CRS patients experience similar and significant improvement in their sinus symptoms through 1 year after balloon dilation. Patients with RARS also report significantly less postoperative antibiotic use, fewer physician visits for sinus-related problems, and fewer acute sinus infections after ostial dila-

tion. Stand-alone balloon dilation of the maxillary ostia and ethmoid infundibula to treat disease that CT shows as limited to the maxillary and anterior ethmoid sinuses is associated with improved healthcare utilization and is an effective procedure to treat CRS and RARS in an office setting.

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