Feasibility of in-office endoscopic sinus surgery with balloon sinus dilation

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ABSTRACT

Background: Balloon sinus dilation (BSD) tools are increasingly used in endoscopic sinus surgery (ESS) and may cause less tissue trauma/bleeding, potentially enabling office-based ESS. We evaluate the feasibility of ESS performed in-office using BSD instrumentation.

Methods: All patients had a diagnosis with chronic rhinosinusitis. Because of symptom resolution failure post maximal medical therapy (prolonged antibiotics, corticosteroids, and other adjuvant therapies), all patients were candidates for ESS. In-office ESS using BSD tools was performed on 37 subjects at nine sites. Procedure feasibility was assessed prospectively through technical success rate, procedure tolerability, quality of life, and radiographic outcomes. Subjects were followed at 1, 4, 24, and 52 weeks.

Results: In-office technical success by subject was 89% (33/37). There was one nonserious adverse event. In-office BSD was tolerable, with 93% (27/29) of patients reporting the procedure as tolerable or highly tolerable. Two in-office subjects (7%) indicated poor procedure tolerability. Intraprocedure pain was also well managed during in-office BSD, with 66% (24/36) of patients reporting no pain or pain of low intensity. While 33% (12/36) reported higher-scale pain, usually during balloon inflation, only 2 patients experienced intense pain. At 52 weeks, 95% of the subjects stated they would have procedure again. Sino-Nasal Outcome Test-20 scores revealed clinically and statistically significant treatment effects at all time points, comparable to previous balloon dilation studies conducted in an operating room setting. Lund-Mackay scores revealed a statistically significant reduction at 24 weeks.

Conclusion: Office-based ESS with BSD is feasible with demonstration of high technical success rate, meaningful patient symptom improvement, and high patient satisfaction.

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Rhinosinusitis afflicts ~14% of the U.S. adult population annually and ranks among the costliest health conditions.^{1,2} The economic burden of chronic rhinosinusitis (CRS) is estimated at \$4.3 billion to \$5.8 billion annually.^{3,4}

Of 31 million people in the United States with sinusitis, ~500,000 undergo sinus surgery in the U.S. annually for medically refractory disease.⁵ Since their introduction to the U.S. market in 2005, balloon sinus dilation (BSD) tools are increasingly used in endoscopic sinus surgery (ESS) and have been shown to be efficacious and safe, with evidence of successful treatment outcomes comparable with “conventional” ESS.^{6,7}

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Surgery in office settings has proven safe and effective in various surgical specialties.^{8,9} In-office procedures avoid general anesthesia complications and costs (pharmacy, anesthesiologist, postanesthesia care unit).^{10,11,12} Patient convenience and return-to-work advantages also exist.^{11,13}

ESS with BSD tools may allow for less tissue trauma than ESS with traditional tools, thus enabling ESS under local anesthesia for selected patients. The concept of in-office ESS has been described previously in the literature with preliminary reports of safety and patient acceptance.^{13,14,15} However, to date there are no studies available that demonstrate the feasibility of transnasal balloon dilation in the office setting.

The primary objective was a prospective evaluation of the feasibility of ESS using BSD tools under local anesthesia in the office. Feasibility was defined by technical success, patient tolerance, as well as quality of life and radiographic clinical outcome reporting.

METHODS

Study Design

This was a prospective, nonrandomized, multicenter evaluation of ESS performed in the office setting with BSD tools.

Institutional review board approval was obtained for each location. All subject data were maintained according to human subject research standards and good clinical practice, and informed consent was obtained from all patients prior to study enrollment.

Patient Selection

Subjects aged 18 or older were offered study participation. All subjects had standard indications for ESS: a strictly defined CRS diagnosis per Rhinosinusitis Task Force criteria (more than 12 weeks of symptoms including but not restricted to nasal obstruction, sinus/facial pressure, nasal discharge, and congestion) that was unresponsive to maximal medical management.^{16,17} Maximal medical management included three to six weeks of antibiotic therapy, inhaled and/or systemic corticosteroids, decongestants as appropriate, and saline irrigations. Subjects with cystic fibrosis, Samter's triad, sinonasal tumors, ciliary dysfunction, pregnancy, or history of facial trauma

were excluded from study enrollment. CRS patients with nasal polypoidosis were not excluded because this was a feasibility study intended to determine procedure feasibility across a broadly representative population, which would include patients with polyp disease.

Subjects who required adjunctive treatments (*e.g.*, septoplasty) poorly suited for the in-office setting were not recommended nor selected as in-office subjects. However, adjunctive procedures (such as turbinoplasty) were permitted in the office per surgeon discretion.

Preoperative assessment included physical examination, sinonasal endoscopy, computed tomographic (CT) scan, and baseline Sino-Nasal Outcome Test (SNOT-20).^{19,20} CT imaging of the paranasal sinuses was obtained preoperatively except when patients brought satisfactory CT sinus imaging studies from referring physicians.

Once the determination was made for ESS, in-office location decision was made together by the patient and surgeon after thorough discussions of the potential benefits and risks, including cerebrospinal fluid leak, orbital injury, possibility of poor tolerance, and possibility of unsuccessful access requiring general anesthetic in separate procedure.

Statistics

All statistical analyses were performed by using SAS 9.2 (SAS Institute, Inc., Cary, NC). Continuous data are displayed as mean (SD). The paired Student's *t* test was used to compare preoperative versus postoperative mean values within the study group. Statistical significance was accepted when *p* < .05.

Treatment

All physician investigators were experienced BSD device users. In-office procedures were performed using transnasal BSD tools (Accurant, Inc., Menlo Park, CA) and local anesthesia per surgeon preference. Because this was a feasibility study, attempts to standardize the local anesthesia were not made. The preferred local anesthesia technique for each investigator was, however, recorded.

During the procedure, the ability to access and dilate the sinus was assessed. Access success was defined by a positive transillumination of the lighted guide-wire (maxillary and frontal sinuses) or direct endoscopic visualization of the wire entering the sinus (sphenoid sinus). Successful dilation was determined by endoscopic visualization of the inflated balloon in a targeted transition space followed by inspection of the dilated space upon balloon removal. Sinuses requiring irrigation or adjunctive procedures, such as turbinoplasty, were performed in their appropriate sequence per surgeon preference.

Upon procedure completion, patients were asked to rate procedure tolerability and pain levels. Pain was quantified along a scale of 0 to 5 (0 was "no pain," and 5 was "severe pain"). Pain was further stratified by the procedure step at which maximal pain occurred (*e.g.*, wire placement, balloon insertion, or balloon dilation) Tolerability was rated on a scale of 0 to 5 (0 was "not tolerated/procedure aborted," and 5 was "highly tolerable").

All observed and subject-reported perioperative and postoperative adverse events were recorded. Adverse events were classified as serious or nonserious and evaluated to determine whether they were related to the procedure or devices used.

Follow-up

Subjects were followed at 1, 4, 24, and 52 weeks postprocedure. Physical examination, assessment for adverse events, and SNOT-20 were reviewed at each visit. A 0.8-point decrease in SNOT-20 was determined to represent a clinically significant change as demonstrated by Piccirillo *et al.*¹⁹ At 24 weeks, a repeat CT exam was performed, with scoring based on the scale described by Lund and Mackay.¹⁸ At 52 weeks, subjects were asked to rate their overall experience (procedure, recovery, follow-up) on a scale from 5 to -5 (5 was the best possible experience; -5 was the worst possible experience). Subjects were also asked "Would you have the procedure again?" and "Would you recommend the procedure to a family member or friend?"

Table 1 Baseline patient characteristics (*n* = 37)

Age, mean ± SD (95% confidence interval*)	54.6 ± 12.5 (50.41–58.77)
Male/female (%)	16/21 (43.2/56.8)
Prior ESS, <i>n</i> (%)	17 (46)
Lund-Mackay CT, mean (95% confidence interval*)	6.38 (5.13–7.63)
SNOT-20§, mean ± SD (95% confidence interval*)	2.24 ± 0.98 (1.90–2.57)
Polyp disease, <i>n</i> (%) (95% confidence interval#)	8 (21.6) (9.8–38.2)

*By normal approximation.

#Clopper-Pearson exact confidence interval.

§(*n* = 36).

Table 2 Sinuses treated

Sinus Type	(<i>N</i> = 59)
Maxillary, <i>n</i> (%)	28 (47.5)
Sphenoid, <i>n</i> (%)	10 (16.9)
Frontal, <i>n</i> (%)	21 (35.6)
Ethmoid, <i>n</i> (%)	0
No. sinuses treated per patient, mean ± SD*	1.7 ± 1.1

*Does not include the 2 maxillaries that could not be successfully treated in office and were subsequently treated in the operating room.

The number of debridements performed was also recorded.

RESULTS

Nine sites enrolled 37 subjects throughout 14 months. Sixteen male subjects and 21 females were studied, with a mean age of 54.6 years (SD: 12.5). Twenty subjects had in-office BSD as a primary ESS procedure, and 46% (17/37) were revisions of prior conventional ESS. Approximately 22% (8/37) patients presented with polyp disease. Baseline disease burden, as assessed by validated SNOT-20 questionnaires, was 2.24 (0.98). In Table 1 baseline subject characteristics are provided.

A total of 59 sinuses were successfully accessed and dilated in 37 subjects. Of successful dilations, 48% (28/59) were performed on maxillary sinuses (Table 2). There were 21 frontal sinuses and 10 sphenoid sinuses successfully dilated. On average, 1.7 (1.1) sinuses per subject were successfully dilated in-office. No ethmoid sinuses were treated in-office during this feasibility study. Adjunctive procedures, such as turbinate reduction or excision of synechia, were performed in 24% (9/37) of the subjects during their in-office sinus interventions.

All but four subjects had successful access and dilation of all targeted sinuses, giving a subject specific success rate of 89% (33/37). When analyzing all targeted sinuses as a whole, success (accessed and dilated) rate was 91% (59/65).

Access with BSD tools could not be achieved in 2 of 37 subjects due to discomfort related to scarring from previous ESS (bilateral frontal sinuses) or anatomic issues (bilateral maxillary sinuses). In two additional subjects, partial success was achieved (not all planned sinuses were successfully dilated). Two of the four subjects who could not be fully treated in the office completed treatment in a subsequent operating room (OR) procedure. For the other two subjects, the operating surgeon determined a substantial component of the disease had been addressed and monitored the subjects for recurrence of symptoms over time.

At all sites, topical anesthesia was followed by an injection of epinephrine and lidocaine solution. Topical anesthesia generally consisted of pontocaine or lidocaine sprays. At some sites, cottonoids or

Figure 1. Injection sites for local anesthesia. In all in-office cases, local anesthesia consisted of topical anesthetic with decongestant.

Figure 2. Procedure tolerability.

pledgets were also used, soaked with pontocaine or cocaine, and inserted into the middle meatus for additional topical effect. For example, 2% pontocaine with phenylephrine or oxymetazoline was used. After topicalization, all sites submucosally injected between 3 and 6 cc of 1% lidocaine with epinephrine 1:100,000 into the anterior and posterior attachments of the middle turbinate as well as the medial inferior middle turbinate (Fig. 1). No cardiovascular issues resulted from the injection of epinephrine. Heart rate, blood pressure, pulse oximetry, and other monitoring were performed at surgeon discretion.

There were 29 of 37 (78%) subjects who completed procedure-tolerability questionnaires, and 36 of 37 (97%) completed a postprocedure pain assessment. Ninety-three percent (27/29) of patients reported the procedure as tolerable, while two subjects (2/29; 7%) indicated poor procedure tolerability (Fig. 2). Although eight subjects did not have a tolerability data recorded, their post procedure pain scores were of a low intensity and did not require termination of the procedure.

Pain was reported as low intensity (0 to 2 on the scale) by 24 of 36 (67%) subjects, while 12 of 36 (33%) reported more intense pain (3 to 5 on the scale). Of the 12 subjects who reported higher-scale pain, two reported intense pain (Fig. 3). Balloon inflation was most frequently reported as the discomfort cause (five of the 12 subjects with higher pain [41.7%]).

One nonserious, procedure-related adverse event occurred when a subject swallowed a plectet, which passed uneventfully. There were no serious adverse events and no device-related adverse events. The

average debridement rate was 0.42 debridements per patient through the follow-up period. One patient of the 37 enrolled required a revision treatment.

Patient symptoms improved postoperatively at all study time points as demonstrated by SNOT-20 scores (Table 3). The mean reduction (SD) from baseline was -0.98 (0.79), -1.32 (0.89), -1.25 (0.99), and -1.43 (0.96) for subjects with matched pairs at 1 week, 4 weeks, 24 weeks, and 52 weeks, respectively. SNOT-20 revealed a statistical and clinically significant reduction in symptom severity at all time points relative to baseline ($p < .0001$). SNOT-20 symptom score improvements (as measured from baseline to 52 weeks) were similar regardless of the presence or absence of nasal polyps ($p = .66$).

Radiographic improvement was evaluated at postoperative week 24 compared to baseline. For the 29 subjects who completed the 24-week follow-up for which matched pair CT scans were available, Lund-Mackay score improvement from a mean score (SD) of 6.62 (3.80) before the procedure to 2.79 (2.70) at 24 weeks postprocedure was observed (Fig. 4). The reduction in Lund-Mackay score from preop to 24 weeks was statistically significant ($p < .0001$). There was no difference in Lund-Mackay score reduction from baseline to 24 weeks for patients with or without polyps ($p = .27$).

Twenty-one of 37 patients completed 52-week follow-up. Ranking their overall experience at 52 weeks, 20 of 21 subjects (95%) reported a score of 3 or higher (5 was best possible experience; -5 was worst possible experience). Of the subjects, 95% (20/21) indicated a willingness to have the procedure again, and 100% (21/21) would recommend to family or close friends.

Figure 3. Pain rating.

Table 3 SNOT-20 symptom scores

Time	N	Preoperative mean (SD)	95% Confidence interval	Postoperative mean (SD)	95% Confidence interval	Δ from baseline (SD)	95% Confidence interval	p
Postoperative 1 week	32	2.11 (0.93)	[1.77–2.45]	1.13 (0.76)	[0.85–1.40]	−0.98 (0.79)	[−1.27–−0.70]	<.001
Postoperative 4 weeks	31	2.13 (0.94)	[1.79–2.48]	0.81 (0.65)	[0.57–1.05]	−1.32 (0.89)	[−1.65–−1.00]	<.001
Postoperative 24 weeks	26	2.09 (0.81)	[1.76–2.42]	0.84 (0.80)	[0.52–1.16]	−1.25 (0.99)	[−1.65–−0.85]	<.001
Postoperative 52 weeks	21	2.14 (0.86)	[1.75–2.52]	0.70 (0.67)	[0.40–1.01]	−1.43 (0.96)	[−1.87–−0.99]	<.001

Figure 4. Matched-pair CT scores for subjects with six-month follow-up. (Note: baseline CT scores differ from Table 1 as a consequence of including only matched pairs in the analysis).

DISCUSSION

There are 10 million office-based procedures performed annually in the United States.²⁰ The plastic surgery, oral surgery, and gynecologic literature describe efficiencies when performing certain procedures in the office versus the OR.^{8,9} In otolaryngology, anesthesia avoidance and eliminated physician travel time are identified advantages of office-based procedures.¹³

Office-based rhinologic procedures have precedents. Powered instrumentation for in-office polypectomy was described as early as 1996,²¹ while laser turbinectomy performed under local anesthesia was described in 2007.²² Transnasal balloon sinus dilation in the office setting has been described in a preliminary report, including six subjects with frontal stenosis.²³ Despite this, office-based ESS is not currently commonplace in modern otolaryngologic practice.

This study was designed to determine the feasibility of office-based ESS using balloon dilation as a first step in determining in-office BSD

viability for patients and physicians. Feasibility was assessed primarily through technical success, patient-reported tolerability/pain, and clinical outcomes as measured by quality of life and radiographic outcomes.

In-office ESS with BSD tools seems to be safe. No serious adverse events such as cerebrospinal fluid leak occurred, although the study was likely not sufficiently large to discern the rate of such events, given the generally low rate of serious adverse events for ESS. One minor adverse event, a patient swallowing a pledget, can be prevented in the future by not trimming attached strings in awake patients. No device-related adverse events occurred.

Whether patients could be adequately anesthetized with local techniques and create a tolerable procedure was a major question entering the study. Because this was a feasibility study, a standardized optimal local anesthetic technique was not known a priori. Investigators were permitted to choose their preferred technique. Small sample size

limited the ability to test for interactions between anesthetic technique and patient tolerability/pain. No single technique appeared obviously superior or inferior to others.

When asked of their pain experiences immediately post procedure, 12 of 36 (33%) respondents indicated pain scores of 3 or higher. Two subjects gave a score of 5, indicating severe pain. While reported pain incidence was greater than desired, tolerability appeared high: 93% of subjects reporting their experience as "tolerable" or "highly tolerable."

Taken in context, the results suggest the level of pain did not directly correlate with tolerability scores. We hypothesize that patients may have a similar pain/tolerability experience as in-office dental procedures or office myringotomy tubes, but we cannot draw definitive conclusions with this data set.

The application of BSD tools in-office is still in its infancy. Additional study should focus on technical refinement, anesthesia optimization, and patient selection in effort to increase in-office ESS tolerability.

No major logistical issues occurred in the in-office setting. The most common challenge occurred during sinus irrigation, which was successfully managed by adjusting the subject to sitting position.

SNOT-20 scores showed statistically significant improvement, consistent with published findings for OR-based BSD procedures. The SNOT-20 change (preoperative to 52 weeks) in this study was -1.43 ($n = 21$), compared with -1.06 ($n = 31$) in the balloon-only group from the CLEAR study.²⁴ The preoperative SNOT-20 score in our study population of 2.24 is similar to the preop SNOT-20 score of 2.25 reported for OR-based balloon dilation,²⁵ and it is also similar to the 2.17 reported in a traditional OR-based ESS study.²⁶ Similarity in preoperative SNOT-20 scores suggests a quality of life disease burden for the study patient population reflected that which was reported in the literature for OR-based procedures. As such, patient selection for this office-based feasibility study was not biased toward less symptomatic patients.

Comparing patients with polyps to patients without polyps demonstrated no difference in SNOT-20 or Lund-Mackay score change; however, it must be recognized that the study was not designed nor powered to detect such a difference. In a side-by-side randomized study comparing balloon catheter dilation plus polypectomy to ESS plus polypectomy, Bozdemir *et al.*²⁷ demonstrated that balloon dilation plus polypectomy was as effective as ESS at 12-month follow-up. It is not the goal of this paper to draw any conclusions of balloon instrumentation efficacy in polyposis, but sufficient data exists that makes the inclusion of these patients worthwhile in this feasibility study.

Feasibility of office-based balloon dilation appears to have been confirmed. In addition to high levels of procedural technical success and patient tolerance, a validated quality of life measure demonstrates that clinical outcomes similar to OR-based balloon dilation procedures may be anticipated in additional studies.

The study had several limitations. The follow-up rate to 52 weeks was 57% (21/37), which is not unexpected, given the observational nature of this feasibility study and the recognized challenges with the CRS patient population returning for long-term follow-up.⁵ To assess whether bias was introduced into the results from incomplete follow-up, a comparison was made between the patients who completed 52-week follow-up and the patients who did not complete full follow-up. There was no statistical difference between these two groups in baseline SNOT-20, Lund-Mackay score, polyp presence, or prior surgery rate, which suggests that the patients who achieved 52-week follow-up were representative of the population. Future, larger population studies would strengthen the power of this study's conclusions.

Although all patients were required to have documented CRS and failure of maximal medical therapy, the specific medical therapy during the trial was not controlled. As in Smith *et al.*, medical therapy was determined by the treating physician and customized to the

patients' symptoms and disease process.⁵ The study outcome cannot exclude patient benefit from postoperative medical management, although it should be emphasized that all patients were refractory to medication when entering the study.

Migrating procedures safely and effectively from OR to an office-based site is attractive from a societal cost perspective. In addition to anesthesia-related costs, the specialized personnel and equipment in the OR make OR-based procedures more costly.^{28,29} Reduced costs in-office have been demonstrated.^{11,12,30,31} For instance, in-office microlaparoscopic tubal ligation has had high patient acceptance and tolerability, with a reported cost savings of 66% in the office setting.³¹ In otolaryngology, in-office bone-anchored hearing aid implantation revealed a 31% reduction in patient fees and a 73% reduction in patient time investment with equal procedural efficacy and no increased morbidity.¹¹ Unsedated, office-based laryngeal laser surgery for laryngeal papillomata has also been well tolerated, with an average cost savings reported to exceed \$5,000 per case.¹²

Just as CRS is a spectrum of disease etiology and severity, surgical treatment varies in intervention invasiveness. When considering procedure venue, the surgeon considers disease severity and therapeutic invasiveness. The in-office setting appears to offer potential resource use advantages and lessened patient anesthetic risks.

It must be clearly stated that in-office location was used only for those patients clinically indicated for ESS who would have otherwise been selected for the OR under current practice paradigms. In-office BSD is not described nor advocated as a method of extending surgical indication to more patients. However, in-office location may extend access to those needing surgical intervention, especially in patients who are medically infirm or otherwise poor candidates for general anesthetic.

CONCLUSION

ESS with BSD in the office is feasible as demonstrated by procedural technical success, patient tolerability, and clinical outcomes. Subject satisfaction was high in patients who completed 52 weeks of follow-up. Although early in implementation, technical success is acceptable. Additional studies should better refine patient selection, comfort via optimized anesthesia, and confirm safety.

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Erratum

Dietary polyphenols affect MUC5AC expression and ciliary movement in respiratory cells and nasal mucosa

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