Balloon Ostial Dilation for Treatment of Chronic Sinusitis

Description

Balloon ostial dilation (also known as balloon sinuplasty™) is proposed as an alternative to traditional endoscopic sinus surgery for patients with chronic sinusitis who fail medical management. The procedure involves placing a balloon in the sinus ostium and inflating the balloon to stretch the opening. It can be performed as a stand-alone procedure or an adjunctive procedure to functional endoscopic sinus surgery (FESS).

Background

Chronic rhinosinusitis (CRS) is characterized by purulent nasal discharge, usually without fever, that persists for weeks to months. Symptoms of congestion often accompany the nasal discharge. There also may be mild pain and/or headache. Thickening of mucosa may restrict or close natural openings between sinus cavities and the nasal fossae, although symptoms are variable because considerable variation exists in the location and shape of these sinus ostia.

Estimates are that approximately 30 million individuals in the U.S. suffer from chronic sinusitis. The majority of cases are treated with medical therapy, but surgical drainage is an option for patients who fail to respond to medical therapy. FESS has become an important aspect for surgical management of chronic sinusitis. For this procedure, a fiberoptic nasal endoscope is used to visualize the sinus ostia, and any obstruction found is corrected. This procedure restores patency and allows air and mucus transport through the natural ostium. Approximately 350,000 FESS procedures are done each year in the U.S. for chronic sinusitis.

A newer procedure, balloon ostial dilatation, can be used as an alternative to FESS or as an adjunct to FESS for those with chronic sinusitis. The goal of this technique, when used as an alternative to FESS, is to achieve improved sinus drainage using a less invasive approach. When used as an adjunct to FESS, it is intended to facilitate and/or increase access to the sinuses. The procedure involves placing a guide wire in the sinus ostium, advancing a balloon over the guide wire, and then stretching the opening by inflating the balloon. The guidewire location is confirmed with fluoroscopy or with direct transillumination of the targeted sinus cavity. General anesthesia may be needed for this procedure to minimize patient movement.
The maxillary sinus creates a unique challenge. The maxillary ostia, located within the ethmoid infundibulum, often cannot be accessed transnasally without excising a portion of the uncinate process. An alternate approach to the maxillary ostia is through the sinus, via the canine fossa. A guide wire can be advanced from within the maxillary sinus to the nasal fossa. The dilating balloon can enlarge the ostia while deflecting the uncinate process.

To quantify the severity of chronic sinusitis and to assess treatment response, various outcome measures can be used. The Lund-McKay scoring system utilizes radiologist-rated information derived from computed tomography (CT) scans regarding opacification of the sinus cavities. The Sino-Nasal Outcome Test (SNOT-20) is a validated questionnaire in which patients complete 20 symptom questions on a categorical scale (0=no bother to 5=worst symptoms can be). Average rankings can be reported over all 20 symptoms, as well as by 4 subclassified symptom domains.

Regulatory Status

In March 2008, the device “Relieva™ Sinus Balloon Catheter” (Acclarent, Menlo Park, CA) was cleared for marketing by FDA through the 510(k) process. FDA determined that this device was substantially equivalent to existing devices for use in dilating the sinus ostia and paranasal spaces in adults and maxillary sinus spaces in children. Subsequent devices developed by Acclarent have also been granted 510(k) marketing clearance. These include the Relieva Spin Sinus Dilation System® cleared in August 2011, and the Relieva Seeker Balloon Sinuplasty System® cleared in November 2012.

In June 2008, the device, FinESS Sinus Treatment (Entellus Medical, Inc, Maple Grove, MN) was cleared for marketing by the FDA through the 510(k) process. The indication noted is to access and treat the maxillary ostia/ethmoid infundibulum in adults using a transantral approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures. Two other balloon sinus ostial dilation devices by Entellus Medical, Inc. also received 510(k) approval in August, 2012. These are the ENTrigue® Sinus Dilation System, and the XprESS® Multi-Sinus Dilation Tool.

FDA product code: LRC

Related Policies

7.01.134 Implantable Sinus Stents for Postoperative Use Following Endoscopic Sinus Surgery

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Use of a catheter-based inflatable device (balloon ostial dilation) in the treatment of sinusitis is considered not medically necessary.
Rationale

Balloon sinus ostial dilation can be performed as a stand-alone procedure or as an adjunct to functional endoscopic sinus surgery (FESS). When performed in combination with FESS, it is sometimes referred to as a hybrid procedure, because there are elements of both balloon sinus ostial dilation and FESS.

Controlled trials are essential in determining the efficacy of this procedure in relation to alternatives. Medical therapy is effective in reducing symptoms for most patients, and surgical drainage is an invasive procedure with its own set of risks and benefits. Therefore, while single-arm series can give some information on success rates and adverse events, they are not sufficient to determine comparative efficacy of balloon sinus ostial dilation.

The literature consists of a few small randomized, controlled trials (RCTs), a small number of non-randomized controlled trials, and a larger number of single-arm case series, the majority of which are retrospective. This evidence is reviewed below, with emphasis on the available controlled trials, in two categories: 1) balloon ostial dilation as a stand-alone procedure, and 2) balloon ostial dilation as an adjunct to FESS.

Systematic Reviews

A TEC Assessment was completed in 2012 titled “Balloon Ostial Dilation for Treatment of Chronic Rhinosinusitis”. (1) This Assessment reviewed evidence from 1 RCT, 3 nonrandomized comparative studies, and 9 case series. The following conclusions were made concerning the adequacy of this evidence for determining the effect of balloon sinus ostial dilation on outcomes.

The Assessment concluded that the evidence is insufficient to determine the effect of the technology on health outcomes. One RCT comparing balloon sinus ostial dilation to FESS was inadequately powered and did not evaluate differences in outcomes between the 2 treatments. While most nonrandomized comparative studies of balloon sinus ostial dilation and FESS show no difference in health outcomes between the two treatments, confounding factors may bias the comparison of the 2 treatments. Several case series show improvement in symptoms of rhinosinusitis over baseline measures, and such improvement appears durable up to 2 years. Case series do not allow conclusions regarding the comparative efficacy of balloon sinus ostial dilation to FESS.

A Cochrane systematic review on balloon sinus ostial dilation for chronic rhinosinusitis (CRS) was published in 2011. (2) This review concentrated on RCTs, and included the Plaza et al RCT3 as the sole controlled trial that met their selection criteria. The authors rated this study as having a low risk for bias for most parameters, but a high risk for bias in reporting of the outcomes. They noted that symptom scores were not presented systematically and that details of statistical testing were not reported. The overall conclusion of this review was that there is no convincing evidence supporting the use of balloon sinus ostial dilation in CRS.

In 2010, Batra et al performed a comprehensive review of the literature regarding balloon catheter technology (BCT) in rhinology. (4) Based on available evidence, they concluded:
“The accrued data attests to its safety, whereas the largest published observational cohort studies have demonstrated the ability to achieve ostia patency for up to 2 years. However, because the selection criteria for these studies were not clearly defined, it is unclear if this data can be extrapolated to the general population with chronic rhinosinusitis (CRS). Is BCT superior or equivalent to the existing devices employed in FESS for the management of CRS? Will the use of BCT translate into improvements in patient outcomes, overall health, and/or quality of life? The many unsettled questions will be best answered by prospective randomized trials that directly compare FESS to BCT, or directly compare medical to surgical treatment.”

**Controlled Trials of Balloon Ostial Dilation as a Stand-alone Procedure versus FESS**

The REMODEL study was an industry-sponsored study RCT that compared balloon ostial dilation as a stand-alone procedure with FESS. (5) A total of 105 patients with recurrent acute sinusitis or chronic sinusitis and failure of medical therapy were randomized to balloon ostial dilation or FESS. Balloon ostial dilation was performed with the Entellus device, which is labeled for a transantral approach. FESS consisted of maxillary antrostomy and uncinectomy with or without anterior ethmoidectomy. Thirteen patients withdrew consent prior to treatment, 11 in the FESS group (21%) and 2 in the balloon ostial dilation group (4%). The primary outcomes were the change in the SNOT-20 score at 6 month follow-up, and the mean number of debridements performed post-operatively. Secondary outcomes included recovery time, complication rates, and rates of revision surgery. Both superiority and non-inferiority analyses were performed on these outcomes.

A total of 91 patients were available at 6 months of follow-up. The improvement in the SNOT-20 score was 1.67±1.10 in the balloon dilation group and 1.60±0.96 in the FESS arm (p=0.001 for non-inferiority). Postoperative debridements were more common in the FESS group compared with balloon dilation (1.2±1.0 in the FESS arm versus 0.1±0.6 in the Balloon Dilation arm, p<0.001 for superiority). Patients in the balloon dilation arm returned to normal daily activities earlier (1.6 days vs 4.8 days, p=0.002 for superiority), and required fewer days of prescription pain medications (0.9 days versus 2.8 days, p=0.002 for superiority). There were no major complications in either group, and 1 patient in each group required revision surgery.

Bikhazi et al reported 1-year follow-up from the REMODEL study in 2014. (6) A total of 89 subjects (96.7%) were available for follow up to 1 year. The improvement in the SNOT-20 score was 1.64 in the balloon dilation arm and 1.65 in the FESS arm (p<0.001 for noninferiority). During 1-year postprocedure, both the balloon dilation and FESS groups had fewer self-reported rhinosinusitis episodes (reduction in 4.2 episodes in the balloon arm and reduction in 3.5 episodes in the FESS; not significantly different between groups).

Marzetti et al reported results from a small RCT that compared balloon ostial dilation with an unspecified device (or devices) with FESS in the treatment of sinus headache. (7) The study included 83 patients with sinus headache, based on American Academy of Otolaryngology–Head and Neck Surgery, 44 randomized to conventional endoscopic sinus surgery (ESS) and 35 to balloon ostial dilation. In the balloon dilation group, 23 patients were “only frontal sinus balloon” patients, in which balloon catheters were the only tools used for frontal sinus sinusotomy, and 12 were “hybrid,” in which
balloon catheters and traditional ESS were used concurrently. It is not specified how patients were selected for these groups. At 6-month follow-up, scores on the SNOT-22 improved from 28.6 at baseline to 7.8 in the ESS group and from 27.3 at baseline to 5.3 in the balloon ostial dilation group, with a statistically significant reduction in both groups (p<0.001). At 6-month follow-up, headache scores based on visual analog score improved from 6.5 at baseline to 5.4 in the ESS group and from 7.1 at baseline to 1.2 in the balloon ostial dilation group (p<0.001).

A small RCT from Turkey was published in 2011 that reported on physiologic outcomes. (8) Twenty patients were randomly assigned to removal of the uncinate process via FESS or balloon sinus ostial dilation as a stand-alone procedure. The main outcome measures were CO2 concentration in the sinuses and maximum sinus pressure, both intended to be surrogate measures for sinus ventilation. The CO2 concentration decreased in both study arms to a similar degree. The maximum sinus pressure decreased in the FESS group but did not change in the balloon sinus ostial dilation group.

Another small RCT was published by Achar et al in 2012. (9) This trial enrolled 24 patients with chronic sinusitis who had failed medical therapy and were scheduled for surgery. Patients were randomized to balloon dilation or FESS and followed for a total of 24 weeks. The primary outcome measures were changes in the SNOT-20 score and the saccharine clearance time (SCT) test. Both groups improved significantly on both outcome measures. The degree of improvement was greater for the functional endoscopic dilatation sinus surgery (FEDS) group compared to the FESS group on both the SNOT-20 score (43.8±15.2 versus 29.7±12.3, p<0.03) and on the SCT score (7.5±5.1 versus 3.5±4.3, p=0.03). Adverse events were not reported.

Bozdemir et al published a small study of 10 patients with nasal polyposis, in which one side was treated with FESS and the other with balloon sinus ostial dilation. (10) All procedures were performed by the same surgeon, and polypectomy was performed prior to FESS or balloon sinus ostial dilation in all patients. Outcome measures included sinus patency, as measured by computed tomography (CT) scan (Lund-McKay classification) or repeat endoscopy (McKay grading). At 10 days following the procedure, there were improvements in both groups on measures of patency, but there were no differences between groups.

Nonrandomized Comparative Studies

A nonrandomized comparison of balloon sinus ostial dilation with adenoidectomy in 49 children with CRS who had failed medical management was published in 2010. (11) Thirty of the children had balloon sinus ostial dilation and 19 had adenoidectomy. Outcomes at one year included change in the SN-5 scores and the need for revision surgery. There were significantly more patients in the balloon sinus ostial dilation group that had significant improvement in symptoms (24/30 [80%]) compared with the adenoidectomy group (10/19 [53%]; p<0.05). There was no difference in the need for revision surgery between the 2 groups.

In 2008, Friedman et al reported a retrospective chart review that compared results in 35 consecutive patients who received balloon sinus ostial dilation and 35 consecutive patients who received FESS. (12) During the time period under consideration, patients with Lund-McKay scores of under 13 (scores
can range from 0 to 24) without polyps had been given the choice of either procedure. Patients generally had a history of recurrent rhinosinusitis despite medical management, but there were no consistent eligibility criteria. Individuals who received a combination of the 2 procedures, or who were missing preoperative SNOT-20 scores, were excluded from the analysis. The SNOT-20 score 3 months after the operation was significantly higher (more symptoms) in the endoscopic surgery group (see Table 1).

**Table 1. SNOT-20 Scores in Friedman et al**

<table>
<thead>
<tr>
<th></th>
<th>Balloon sinus ostial dilation</th>
<th>Endoscopic surgery</th>
<th>p-value</th>
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</thead>
<tbody>
<tr>
<td>Baseline, mean (SD)</td>
<td>2.80 + 0.52</td>
<td>2.70 + 0.85</td>
<td>NS</td>
</tr>
<tr>
<td>3-months postoperatively, mean (SD)</td>
<td>0.78 + 0.55</td>
<td>1.29 + 0.87</td>
<td>0.006</td>
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Postoperative pain, as measured by the number of days patients used a narcotic, was significantly lower in the group of patients who underwent balloon sinus ostial dilation (0.8 ± 0.7 days) compared to endoscopic sinus surgery (1.3 ± 1.0; p=0.011). The patient satisfaction measure also favored the balloon sinus ostial dilation group. The primary complications reported were turbinate lateralization, or scarring, which occurred in 8 patients who underwent balloon sinus ostial dilation and in 3 patients who had endoscopic surgery. One or more sinus infections occurred in 6 balloon sinus ostial dilation patients and 9 endoscopic surgery patients during the 3-month follow-up; 1 patient in the balloon sinus ostial dilation group required revision surgery due to persistent infection.

Another retrospective comparative study was published in 2012 by Koskinen et al. (13) This trial identified 208 patients who underwent either balloon sinus ostial dilation or FESS. Of the 208 patients, 85 (41%) met inclusion criteria for the study and 53 (25%) responded to the mailed questionnaire. These 53 patients, 29 in the FESS group and 24 in the balloon sinus ostial dilation group, comprised the final study groups. The mailed questionnaires contained items on symptoms, exacerbations of chronic sinusitis, medication use, work exposure, and the Lund-Mackay score. The mean symptom score was worse in the balloon sinus ostial dilation group compared to the FESS group (4.37 vs 3.22, p=0.04). Patients in the balloon sinus ostial dilation group reported a greater number of exacerbations compared with the FESS group. The majority of other outcome measures were similar between groups, and there were no measures on which the balloon sinus ostial dilation group showed superior outcomes compared to the FESS group.

**Section Summary:** There are a number of small randomized and non-randomized comparative studies of balloon ostial dilation as a stand-alone procedure, compared with FESS. These studies generally report that short-term outcomes of balloon ostial dilation are similar to those of FESS. However, there remains a lack of high-quality evidence on the comparative efficacy of the 2 procedures. Only one RCT, the REMODEL study (n=105 patients randomized), was likely to have adequate power to detect group differences. This study reported non-inferiority for the change in the SNOT-20 scores and superiority for balloon ostial dilation on postoperative recovery and pain medication use. The trial had some methodologic limitations. It was unblinded and did not have blinded outcome assessment for the
symptom-based outcomes or the secondary clinical outcomes. There was also some evidence of differential dropout, with larger numbers of patients withdrawing from the FESS group following randomization (21% versus 4%). The other trials were either very small RCTs, or nonrandomized comparative studies.

This evidence shows some support for balloon ostial dilation as an alternative to FESS in patients with CRS, but it is not definitive because of the small quantity of evidence and the limitations in the available trials. Further high-quality evidence is required to determine whether outcomes of balloon ostial dilation are equivalent to FESS.

**Controlled Trials of Balloon Ostial Dilation as an Adjunct to FESS versus FESS Alone**

A small double-blinded, RCT of balloon sinus ostial dilation as an adjunct to FESS versus FESS alone was published by Plaza et al. in 2011. (3) This study enrolled 34 patients with CRS who were refractory to intensive medical management. Patients were randomized to a “hybrid approach” that included balloon sinus ostial dilation of the affected frontal recess along with traditional FESS of other paranasal sinuses, or to traditional FESS with the Draf I procedure. In both groups, an anterior ethmoidectomy was performed. A posterior ethmoidectomy and/or sphenoidotomy was performed as required by intraoperative assessment in both groups. Outcome measures at 12-months follow-up included were symptoms, the rhinosinusitis disability index, CT results of sinus patency, and the permeability of the frontal recess, as assessed by office endoscopy. There was one dropout in each group, leaving a total of 16 patients per group for analysis. For both groups, there were improvements in symptoms and standardized rhinosinusitis scoring indices, but there were no differences between groups. There were also improvements in CT patency in both groups but no differences between groups. The outcome of endoscopic patency at 12 months was achieved by 73% of the balloon sinus ostial dilation patients versus 63% of the FESS patients. The published study contained contradictory statements on whether this difference was statistically significant. Personal communication with the first author (14) clarified that the difference reported in the results for endoscopic patency was not statistically significant. There were no major complications reported.

**Single-Arm Studies**

There are numerous single-arm series of balloon sinus ostial dilation. A representative sample of these studies, focusing on studies that are prospective, multicenter, large in number, or with extended follow-up, is presented next.

A prospective multicenter series of 71 subjects with CRS was published by Cutler et al. (15) Successful dilatation was achieved in 129 of 132 (98%) of maxillary sinuses. Half of the procedures were performed in the operating room and half performed in the clinic setting. Tolerance of the procedure was good, with patients discharged within 2 hours after the procedure was completed. There were statistically significant improvements in symptoms at 3, 6, and 12 months postprocedure, with no difference in efficacy by site of procedure.
Bolger and Vaughan reported on outcomes at 24 weeks from a prospective, multicenter study of balloon sinus ostial dilation of 115 patients. In this study, 115 patients, for whom ESS was recommended, received treatment with the balloon catheter. Sinusotomy was attempted in 358 sinuses, and cannulation was successful in 347. Ostia patency rates were assessed at weeks 1, 12, and 24; at 24 weeks, 304 of the 347 sinuses were evaluated (88%). While only 5 were nonpatent, the status of 18% was reported as indeterminate. Patients’ symptoms as measured by the SNOT-20 also improved posttreatment. The device malfunctioned in 12 of 358 cases (3.4%), the balloon ruptured in 7 cases, and the catheter tip malfunctioned in 4 cases. The authors indicated that there were no serious adverse events.

Additional follow-up, up to 2 years, to this study has been published. These articles report on the 1- and 2-year follow-up on a subset of the 115 patients studied. In the 1-year follow-up, there were a total of 70 of 115 patients (61%) remaining in the study. Of the 66 patients who had follow-up nasal endoscopy, 85% of sinus ostia were patent; however, by adding results of CT scans showing improvement, 92% were judged to have functional patency. The report on clinical symptoms with the 2-year follow-up involved a similar subset of patients (N=65). In this longer term study, in which 34 patients had only balloon treatment, 85% of patients had improved symptoms. Revision treatment was required in 3.6% of sinuses involving 6 of 65 patients (9%).

A second prospective multicenter, single-arm study of balloon sinus ostial dilation in refractory rhinosinusitis was published by Stankiewicz et al in 2010. This study reported 1-year follow-up data of the Balloon Remodeling Antrostomy Therapy (BREATHE I) study. In this study, 30 patients received balloon dilation of the ethmoid infundibulum using the FinESS system, a transantral dilation approach via the canine fossa. The primary outcome measure was patient-reported quality-of-life measure using the SNOT-20. Average overall symptom scores at baseline were 2.9±1.0. At 3, 6, and 12 months following the intervention, average overall symptom scores were 0.7±0.8, 0.8±0.9, and 0.8±0.9, respectively. Additional subjects are continued to be enrolled, and follow-up data will continue to be collected at 2 years for the cohort.

Two-year results of the BREATHE study were reported in 2012. At this time point, a total of 59 patients were treated with balloon sinus ostial dilation with a mean follow-up of 27±3.6 months. Mean SNOT-20 scores improved from 2.65±0.97 at baseline to 0.79±0.71 at the longest follow-up. This report also included measures of functional impairment by the Work Limitation Questionnaire (WLQ) and the Work Productivity and Activity Impairment Questionnaire (WPAI). Mean scores on the WLQ for overall productivity loss decreased from 8% at baseline to 2.5% at longest follow-up (estimates from graphical representation), and this pre- and postchange was statistically significant (p<0.001). Similar improvements were reported on other parameters of the WLQ and WPAI scales.

In 2014, Gould et al reported results of a prospective, single-arm study of balloon dilation of the maxillary sinuses and ethmoid infundibula with or without frontal or sphenoid ostial dilation with the XprESS device. The study enrolled 82 adult patients with CRS (n=73 [89%]) or recurrent acute sinusitis (n=9 [11%]), who had, at minimum, maxillary sinus disease, but who could also have frontal, sphenoid, and/or ethmoid disease. Three hundred thirteen ostial dilations were attempted in 82 subjects, and 307 were completed in 81 subjects. Follow-up to 1 year was available for 75 subjects.
(91.4%), at which point the SNOT-20 score improved to 0.75 from 2.27 at baseline (absolute reduction, -1.57; p<0.000). Patient-reported rates of sinus-related physician visits and antibiotic courses also improved.

Brodner et al reported a prospective, multicenter study to evaluate outcomes for the XprESS device for the treatment of the frontal recesses, maxillary ostia, and/or sphenoid sinus ostia in 175 adults who had previously been scheduled for conventional ESS.22 The criteria for previously-scheduled conventional ESS are not specified. There were a mean 2.7 sinuses per patient treated; of the targeted sinuses, 479 of 497 (96.4%) were successfully accessed and treated. One-year follow-up was planned in the first 50 subjects, who only underwent dilation of frontal recesses and sphenoid ostia; at 1 year, in the 41 subjects with 1-year follow-up available, 76 of 83 (91.6%) of the ostia dilated with the study device were patent. At 1 year, in 44 subjects who completed follow-up, the average overall SNOT-20 score was 0.8 (vs 1.9 at baseline; p<0.000 for change), which was considered a clinically meaningful improvement (change, ≥0.8).

Albritton et al reported results of a prospective, nonrandomized evaluation of the feasibility of in-office balloon sinus dilation with the Relieva device in patients who were enrolled in the ORIOS trial. (23) The study included 37 subjects (59 sinuses) who had a diagnosis of CRS (>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. Successful access and dilation of all targeted sinuses occurred in 33 of 37 subjects (89%). Follow-up was available for 32 (86.5%), 31 (83.8%), 26 (70.2%), and 21 (56.8%) at 1, 4, 24, and 52 weeks postprocedure, respectively. Symptoms were assessed based on the change in SNOT-20 score from baseline to follow-up, with a mean reduction from baseline of -0.98 (95% confidence interval [CI], -1.27 to -0.70), -1.32 (95% CI, -1.65 to -1.00), -1.25 (95% CI, -1.65 to -0.85), and -1.42 (95% CI, -1.87 to -0.90) at 1, 4, 24, and 52 weeks postprocedure, respectively. For the 29 subjects who had CT scans available at baseline and at 24-week follow-up, Lund-Mackay score improved from 6.62 preprocedure to 2.79 postprocedure (p<0.000).

In the ORIOS2 study, Karanfilov et al reported results of a prospective, nonrandomized, multicenter evaluation of office-based balloon sinus dilation with the Relieva device in 203 patients who required ESS for medically refractory chronic sinusitis. (24) Three cohorts were enrolled, a lead-in cohort, which consisted of each investigator’s first cases where all targeted sinuses were successfully dilated (N=36), a standard enrollment cohort, which consisted of up to approximately 15 cases (N=84), and an extended enrollment cohort, which included subjects after the first 15 cases (N=83). Dilation technically successful in 552 of 592 attempted sinuses (93.2%). Matched baseline and 24-week follow-up was available for 112 patients, who demonstrated a mean improvement in SNOT-20 scores of -1.1 (p<0.000). In the 110 patients with 24-week CT scans available, Lund-Mackay score improved by -4.3 compared with baseline (p<0.000 for change).

Levine et al reported results of a prospective, nonrandomized, multicenter evaluation of office-based balloon sinus dilation with the FinESS device in 74 patients with CRS (n=52) or recurrent acute sinusitis (n=17). (25) Balloon dilation was successful in 69 patients, and analyses are reported per protocol. The overall technical success rate in patients was 91.9% (124/135 ostia; not specified if this
was in overall sample of 74 patients or in analysis sample of 69 patients). Mean SNOT-20 scores improved from a mean 2.3 at baseline to 1.1 at 6 months and 12 months in the 66 patients with follow-up data available (mean change, -1.2; p<0.000). There were not significant differences in improvements reported between the CRS and recurrent acute sinusitis patients.

A large retrospective single-arm series published by Levine et al reported on results from a registry study of 1036 patients who received a balloon sinus ostial dilation procedure at 27 sites from December 2005 to May 2007. (26) This registry was developed through retrospective chart review of consecutive cases at these institutions. All but 2 patients in this study had treatments while under general anesthesia. An average of 3.2 sinuses was treated per patient. Symptom improvement was reported at 95%. With average follow-up of 40 weeks, the revision rate was 1.3%

There are numerous other published single-arm studies. These are mostly small, retrospective, and from a single center. (15,27-31) These studies generally report high rates of success, with continued patency at the longest follow-up and low rates of adverse events. The exception is a single-arm study reported by Tomazic et al, (31) in which the authors planned to evaluate a cohort of 200 patients with balloon ostial dilation or a hybrid procedure, but halted the study early after a high technical failure rate in 45 patients was noted, with 44 of 68 sinuses in a planned balloon ostial dilation group and 29 of 44 sinuses in a planned hybrid procedure group failing.

Safety

In 2010, Tomazic et la reported on a case of ethmoid roof cerebrospinal fluid (CSF)-leak following frontal balloon sinus ostial dilation that was not recognized until 3 weeks’ postprocedure. (32) This is a known risk factor of any ethmoid manipulation, including endoscopic sinus surgery. The bony defect matched the tip of a standard sinus balloon catheter device. The patient underwent subsequent repair and is reportedly symptom-free. The authors commented that although relatively safe, complications can occur.

Chandra discussed questions about potential radiation damage to the lens (lenticular opacity) from the fluoroscopic guidance used to position the guide wire. (33) By extrapolating information from other procedures, the authors suggested that the threshold for lenticular opacity would be attained in the left eye after approximately 29 minutes of fluoroscopy. In a recent review, Vaughan comments that in bilateral cases, less than 5 minutes of fluoroscopy is generally used. (34) In that review, Vaughan also comments on the question of whether balloon sinus ostial dilation represents an exciting and minimally invasive set of devices or a premature attempt to transfer balloon dilation into the field of otolaryngology.

Posttreatment swelling and inflammation can occur following balloon sinus ostial dilation, as well as with endoscopic surgery, and this can lead to temporary sinus obstruction. The comparative rates of this complication with balloon sinus ostial dilation versus endoscopic surgery are not known. Also, the optimal treatment to reduce or prevent temporary sinus obstruction is uncertain. The most common treatment for post-operative swelling and obstruction are nasal packs and anti-inflammatory medications such as local or systemic steroids. Implantable spacers or stents are also available to
maintain patency post-treatment. Repeat balloon sinus ostial dilation has also been used for this purpose, but no empiric evidence was identified in the literature on its use for this indication.

**Ongoing Clinical Trials**

An online search of ClinicalTrials.gov on September 9, 2014, identified the following ongoing studies evaluating balloon ostial dilation for chronic sinusitis:

- **Comparison of Balloon Sinuplasty In-Office Versus Medical Management for Recurrent Acute Sinusitis Patients (CABERNET) (NCT01714687):** CABERNET is a randomized, single-blinded trial to compare balloon sinus dilation with medical therapy for the treatment of recurrent acute sinusitis. The primary outcome is change in disease-specific patient-reported quality of life from baseline to 24 weeks posttreatment. Enrollment is planned for 400 subjects; the estimated study completion date is January 2016.

- **Medical Therapy Versus Balloon Sinus Dilation for Patients With Chronic Rhinosinusitis (MERLOT) (NCT01685229):** MERLOT is an observational cohort study to evaluate the use of balloon sinus dilation in patients with CRS refractory to medical management. The primary outcome is change in disease-specific patient-reported quality of life from baseline to 24 weeks posttreatment. Enrollment is planned for 250 subjects; the estimated study completion date is July 2015.

- **Study for the Management of Pediatric Chronic Rhinosinusitis With or Without Balloon Sinuplasty (NCT01990820):** This is a randomized, single-blinded trial to compare balloon sinuplasty with the Acclarent Relieva system with adenoidectomy and maxillary sinus irrigation in children with sinonasal symptoms of at least 12 weeks in duration or recurrent sinusitis at least 3 times per year. The primary outcome is change in quality of life. Enrollment is planned for 48 subjects; the estimated study completion date is March 2016.

**Practice Guidelines and Position Statements**

A 2008 practice guideline on balloon catheter dilation of paranasal sinus ostia from the National Institute for Health and Clinical Evidence (UK) states: "Current evidence on the short-term efficacy of balloon catheter dilation of paranasal sinus ostia for chronic sinusitis is adequate and raises no major safety concerns. Therefore, this procedure can be used provided that normal arrangements are in place for clinical governance, consent and audit." (35)

In 2012 the American Academy of Otolaryngology– Head and Neck Surgery offered a statement on balloon ostial dilation reaffirmed their 2010 position statement which states: “sinus ostial dilation is an appropriate therapeutic option for selected patient with sinusitis. This approach may be used alone or in conjunction with other instruments...." (36)

The American Rhinologic Society has offered a statement that endoscopic balloon catheter sinus dilation technology is acceptable and safe in the management of sinus disease. (37)
U.S. Preventive Services Task Force Recommendations

Balloon ostial dilation is not a preventive service.

Summary

The evidence related to the use of balloon ostial dilation, as a stand-alone procedure or an adjunct to functional endoscopic sinus surgery (FESS), has been reviewed in several systematic reviews, including a Cochrane review and a Blue Cross and Blue Shield Association TEC Assessment. These reviews have concluded that, although nonrandomized evidence suggests that balloon ostial dilation has similar outcomes to endoscopic sinus surgery (ESS), evidence from randomized trials is needed to demonstrate an improvement in outcomes for patients treated with balloon ostial dilation. Since the publication of the systematic reviews, an additional randomized controlled trial has been published, the REMODEL study. This study, which included 105 patients, reported short-term improvement in symptoms that are similar to those seen with FESS, and potential advantages for balloon ostial dilation on postoperative recovery time and pain medication use. Limitations of the REMODEL study include the unblinded design, lack of blinded outcome assessment across the range of outcome measures, and differential dropout between groups. Other trials are either very small, or nonrandomized comparisons. The results of clinical vetting in 2013 (before publication of REMODEL study) were mixed, and did not show consistent support for the medical necessity of balloon dilation. Further high-quality trials are needed to determine the comparative efficacy of balloon ostial dilation and FESS.

In addition, more information is needed to determine which patients and which sinuses benefit from the balloon technique as an adjunct to traditional ESS, and which patients should receive standard approaches. Given the limitations of the available data, the uncertain impact on clinical outcomes, and questions about which patients might be candidates for this procedure, this approach is not medically necessary.

Medicare National Coverage

There is no national coverage determination.

References

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Balloon Ostial Dilation for Treatment of Chronic Rhinosinusitis. TEC Assessments 2012; Volume 27, Tab 9. PMID


14. Plaza G. Personal Communication with primary author (G Plaza). 4/12/12 April 12, 2012. PMID


### Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>June 2012</td>
<td>New Policy</td>
<td></td>
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<tr>
<td>March 2014</td>
<td>Update Policy</td>
<td>Policy updated with literature review. Policy title changed to balloon ostial dilation. Numerous references added and removed. No change to policy statement.</td>
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<tr>
<td>March 2015</td>
<td>Update Policy</td>
<td>Policy updated with literature review; References 6, 7, 21-25, and 30-31 added. Rationale section reorganized. Policy statement edited to remove trademarked name, but otherwise unchanged.</td>
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### Keywords

Balloon Sinuplasty  
Sinuplasty, Balloon  
Acclarent  
Relieva  
Sinus  
Sinusitis  
Entellus  
FinESS

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 20, 2015 and is effective April 15, 2015.

*Signature on file*

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