



Kansas City

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Balloon Ostial Dilation for Treatment of Chronic Sinusitis

Policy Number: 7.01.105

Last Review: 9/2014

Origination: 3/2007

Next Review: 3/2015

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for balloon sinuplasty. This is considered investigational.

When Policy Topic is covered

Not Applicable

When Policy Topic is not covered

Use of a catheter-based inflatable device (balloon sinuplasty) in the treatment of sinusitis is considered **investigational**.

Considerations

If balloon sinuplasty is performed in conjunction with cutting tools such as curettes and forceps, the balloon dilation would be considered inclusive/incidental to the procedure.

Description of Procedure or Service

Balloon sinuplasty is proposed as an alternative to 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.

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. 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. Functional endoscopic sinus surgery (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 mucous 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 sinuplasty™, 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 guidewire in the sinus ostium, advancing a balloon over the guidewire, 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 guidewire 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 outcomes 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 the FDA through the 510(k) process. The 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 infundibula 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.

Rationale

This policy was created in 2006 and updated regularly with searches of the MEDLINE database. The most recent literature search was performed for the period of March 2012 through August 31, 2013. The following is a summary of the key literature evidence to date:

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.

Literature Review

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-RCTs, 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 2 categories: (1) balloon ostial dilation as a stand-alone procedure, and (2) balloon ostial dilation as an adjunct to FESS.

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 evidence is insufficient to determine the effect of the technology on health outcomes. One randomized clinical trial comparing balloon sinus ostial dilation to FESS was inadequately powered and did not evaluate differences in outcomes between the two 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 two 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.

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.(2) 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 Sino-Nasal Outcome Test (SNOT-20) score at 6-month follow-up, and the mean number of débridements performed postoperatively. Secondary outcomes included recovery time, complication rates, and rates of revision surgery. Both superiority and noninferiority analyses were performed on these outcomes.

A total of 91 patients were available at 6-month 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 noninferiority). Postoperative débridements were more common in the FESS group compared with balloon dilation (1.2 ± 1.0 vs 0.1 ± 0.6 in the FESS 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 vs 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.

A small RCT from Turkey was published in 2011 that reported on physiologic outcomes.(3) Twenty patients were randomly assigned to removal of the uncinete process via FESS or balloon sinus ostial dilation as a stand-alone procedure. The main outcome measures were CO_2 concentration in the sinuses and maximum sinus pressure, both intended to be surrogate measures for sinus ventilation. The CO_2 concentration decreased in both study arms to a similar degree. The mean maxillary sinus pressure on inspiration 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.(4) 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 group compared to the FESS group on both the SNOT-20 score (43.8 ± 15.2 vs 29.7 ± 12.3 , $p<0.03$) and on the SCT score (7.5 ± 5.1 vs 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.(5) 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.

A nonrandomized comparison of balloon sinus ostial dilation with adenoidectomy in 49 children with chronic rhinosinusitis (CRS) who had failed medical management was published in 2010.(6) Thirty of the children had balloon sinus ostial dilation and 19 had adenoidectomy. Outcomes at 1 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 to 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 functional endoscopic surgery.(7) 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

	Balloon Sinus Ostial Dilation, mean (SD)	Endoscopic Surgery, mean (SD)	p
Baseline	2.80 (0.52)	2.70 (0.85)	NS
3 months postoperatively	0.78 (0.55)	1.29 (0.87)	0.006

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.(8) 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 to 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 nonrandomized comparative studies of balloon ostial dilation as a stand-alone procedure, compared to 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 1 RCT, the REMODEL study (n=105 patients randomized), was likely to have adequate power to detect group differences. This study reported noninferiority 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% vs 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.(9) 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-month 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(10) clarified that the difference reported in the results for endoscopic patency was not statistically significant. There were no major complications reported.

Systematic reviews

A Cochrane systematic review on balloon sinus ostial dilation for CRS was published in 2011.(11) This review concentrated on RCTs, and included the Plaza et al RCT(1) 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.(12) 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.”

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 below.

A prospective multicenter series of 71 subjects with CRS was published by Cutler et al.(13) 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.(14) In this study, 115 patients, for whom endoscopic sinus surgery 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.(15,16) These papers 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.(15) 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).(16) 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.(17) The primary outcome measure was patient-reported quality-of-life measure utilizing 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.(18) 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.

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.(19) 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.(13,20-22) These studies generally report high rates of success, with continued patency at the longest follow-up and low rates of adverse events.

Safety

In 2010, Tomazic et al reported on a case of ethmoid roof cerebrospinal fluid leak following frontal balloon sinus ostial dilation that was not recognized until 3 weeks' postprocedure.(23) 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.(24) 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.(25) 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 this side effect is uncertain. The most common treatment for postoperative 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 posttreatment. 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.

Clinical Input Received Through Physician Specialty Societies and Academic Medical Centers

In response to requests, input was received from 2 physician specialty societies and 2 academic medical centers while this policy was under review in 2008. While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted. Input from 1 specialty society did not specifically address the clinical aspects of this technique but made comments related to coding. Another specialty society noted concerns due to lack of controlled studies and also commented that the long-term objective follow-up (eg, CT scans) was on a limited number of patients. Input from 2 academic centers felt this treatment was not investigational but should be viewed as just another surgical tool for the treatment of chronic sinusitis. One comment received was that there are not adequate data in the peer-reviewed literature to sufficiently separate the benefits of balloon sinus ostial dilation from concurrent FESS. Another comment was that this may have a role in frontal and sphenoid sinus disease.

In response to requests, input was received from 2 physician specialty societies and 6 academic medical centers while this policy was under review in 2011. As noted above, while the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted. Input was mixed. A number of reviewers agreed that this technique was investigational. These reviewers commented about the need for additional trials to compare outcomes to standard approaches. There were also comments about the lack of selection criteria for use of the balloon catheter. Reviewers also noted that the current studies do not permit separating the results for use of the balloon from concurrent FESS, since most studies used both techniques.

In response to requests, input was received from 2 specialty societies and 6 academic medical centers while this policy was under review in 2013. The overall input was mixed on whether balloon ostial dilation should be medically necessary, either as a stand-alone procedure or as an adjunct to FESS. There was no consensus on subpopulations of patients with CRS that might benefit from balloon ostial dilation. There was consensus that RCTs should be performed comparing balloon ostial dilation to standard care in order to determine efficacy.

Ongoing Clinical Trials

A search of online site ClinicalTrials.gov using the term “balloon sinuplasty” returned 8 studies. One of these was an active RCT, and the remainder were either inactive or observational studies.

- [NCT01714687](https://clinicaltrials.gov/ct2/show/study/NCT01714687). Comparison of Balloon Sinuplasty In-Office Versus Medical Management for Recurrent Acute Sinusitis Patients (CABERNET). This is an RCT comparing balloon sinuplasty to medical therapy in patients with recurrent acute rhinosinusitis. The outcome measures are changes in quality of life, medication usage, missed days of work or school, medical visits due to sinusitis, number of sinus infections, and number of sinus procedures. The planned enrollment is 400 patients with an estimated completion date of October 2015.

Summary

Balloon sinus ostial dilation is a minimally invasive alternative to functional endoscopic sinus surgery (FESS), or can be used as an adjunct to endoscopic sinus surgery. There is evidence that this technique can be performed successfully and safely in patients with chronic rhinosinusitis. However, there is still insufficient evidence on the impact of balloon sinus ostial dilation on health outcomes. Small, randomized controlled trials, including the largest study (REMODEL) of 105 patients, report short-term improvement in symptoms that are similar to FESS, and potential advantages for balloon ostial dilation on postoperative recovery time and pain medication use. These trials have limitations, which for 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 (prior to publication of REMODEL study) was 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 endoscopic sinus surgery, and which patients should get 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 considered investigational.

Practice Guidelines and Position Statements

National Institute for Health and Clinical Evidence (UK): “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.”(26) Therefore, this procedure can be used provided that normal arrangements are in place for clinical governance, consent and audit

In June 2010, the American Academy of Otolaryngology– Head and Neck Surgery offered a statement on balloon ostial dilation. They stated that “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...”(27)

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.(28)

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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Billing Coding/Physician Documentation Information

31295	Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or via canine fossa
31296	Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (eg, balloon dilation)
31297	Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (eg, balloon dilation)
31299	Unlisted procedure, accessory sinuses
C1726	Catheter, balloon dilatation, nonvascular

Beginning in 2011, there are specific category I CPT codes for these procedures (31295-31297). These codes may be used to describe balloon sinuplasty when no other surgical intervention has been performed on the same sinus site.

Prior to 2011, and perhaps in the future, this procedure might be coded as an unlisted sinus procedure (31299). It could be submitted alone or along with other nasal/sinus endoscopy codes.

If balloon sinuplasty is performed in conjunction with cutting tools such as curettes and forceps, the procedure might be coded using the CPT codes for nasal/sinus endoscopy with maxillary antrostomy (31256), nasal/sinus endoscopy with frontal sinus exploration (31276), or nasal/sinus endoscopy with sphenoidectomy (31287). Plans should be aware of this possibility. In this instance, the balloon dilation would be considered inclusive/incidental to the procedure.

In the Medicare outpatient hospital setting, HCPCS code C1726 may be used for the device.

Between 2007 and 2011, a specific HCPCS S code for the procedure was available – S2344 Nasal/sinus endoscopy, surgical; with enlargement of sinus ostium opening using inflatable device (i.e., balloon sinuplasty)

Additional Policy Key Words

N/A

Policy Implementation/Update Information

3/1/06	New policy; considered investigational.
3/1/07	No policy statement changes.
9/1/07	No policy statement changes.
3/1/08	No policy statement changes.
9/1/08	No policy statement changes.
3/1/09	No policy statement changes.
9/1/09	No policy statement changes.
3/1/10	No policy statement changes.
9/1/10	No policy statement changes.
1/1/11	Coding updated.
3/1/11	No policy statement changes.
9/1/11	No policy statement changes.
3/1/12	No policy statement changes.
9/1/12	No policy statement changes.
3/1/13	No policy statement changes.
9/1/13	No policy statement changes.
3/1/14	No policy statement changes. Changed title to Balloon Ostial Dilation for Treatment of Chronic Sinusitis
9/1/14	No policy statement changes.

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