

Medical Policy Manual

Topic: Balloon Catheter Dilation for Treatment of Sinusitis

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Section: Surgery

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Balloon catheter dilation (also known as balloon sinuplasty) for the treatment of sinusitis involves placement and inflation of a balloon catheter within an obstructed frontal, sphenoid, or maxillary sinus ostium. The balloon catheter is placed using transnasal endoscopy, or a transantral approach may be used for direct access to the maxillary sinus. Inflation of the balloon is intended to enlarge the sinus ostium by compressing mucosa and displacing local bony structures. This technique has been used as an alternative or adjunct to conventional endoscopic sinus surgery which involves surgical excision of the mucosa and bone. When performed in combination with FESS, it is sometimes referred to as a hybrid procedure.

Regulatory Status

In March 2008, the device “Relieva Sinus Balloon Catheter” (Acclarent, Menlo Park, CA) was cleared for marketing by the U.S. Food and Drug Administration (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) approval. These include the Relieva Spin Sinus Dilation System®, approved in August 2011, and the Relieva Seeker Balloon Sinuplasty System®, approved 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 sinuplasty 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.

MEDICAL POLICY CRITERIA

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

SCIENTIFIC EVIDENCE

In order to determine the benefits and harms of balloon catheter dilation as a stand-alone procedure for the treatment of sinusitis, it must be compared with standard functional endoscopic sinus surgery (FESS) which involves excision of ostial tissues. Well-designed prospective comparative studies, preferably randomized controlled trials (RCTs), are needed to compare health outcomes between the two procedures and determine whether balloon dilation is as effective and durable as excision.

The most important clinical outcomes to compare for treatment of sinusitis are:

- Symptom relief
- Durability of any beneficial effects
- Adverse event rate and severity
- Rate and type of reoperations including repeat dilation procedures

Literature Appraisal

The focus of this evidence review is on systematic reviews, randomized controlled trials, and nonrandomized comparative trials.

Technology Assessment and Systematic Reviews

- A BlueCross BlueShield Association Technology Evaluation Center (TEC) Assessment was completed in 2012 titled “Balloon Ostial Dilation for Treatment of Chronic Rhinosinusitis”.^[1] This Assessment reviewed evidence from one RCT, three non-randomized comparative studies, and nine case series. The following conclusions were made concerning the adequacy of this evidence for determining the effect of balloon sinuplasty on health outcomes:
“The evidence is insufficient to determine the effect of the technology on health outcomes. One randomized clinical trial comparing balloon sinuplasty to FESS was inadequately powered and did not evaluate differences in outcomes between the two treatments. While most nonrandomized comparative studies of balloon sinuplasty 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 sinuplasty to FESS.”

- A 2011 Cochrane systematic review on balloon sinuplasty for chronic rhinosinusitis concentrated on RCTs.^[2] One small RCT^[3] met the inclusion criteria. Patients were randomized to a “hybrid approach” that included balloon sinuplasty of the affected frontal recess along with traditional FESS of other paranasal sinuses (n=16), or to traditional FESS (n=16). At 12 months follow-up, both groups reported improvements in symptoms, but there were no significant differences between the two groups. The authors of the Cochrane review rated this study as having a low risk for bias for most parameters, but a high risk for bias in reporting of the outcomes. Specifically, symptom scores were not presented systematically and 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 sinuplasty in chronic rhinosinusitis (CRS).
- In 2010, Batra and colleagues performed a comprehensive review of the literature regarding balloon catheter technology (BCT) in rhinology.^[4] The authors noted the following significant study design flaws that prevented the pooling of effectiveness data and precluded conclusions:
 - The lack of a comparator group significantly limited interpretation of the results or any efficacy claims relative to the FESS paradigm.
 - The single comparative study^[5] was a retrospective study in which the comparison group was not randomized or matched. In addition, the treatment modality was selected by the patients, which was likely to result in biased symptom and satisfaction scores.
 - It is unclear if the current data can be extrapolated to the general population with sinusitis because the selection criteria in most studies were not clearly defined.
 - The use of patient-reported symptom improvement was subject to recall bias and could not reliably quantify disease improvement after surgery.
 - Data on children was difficult to interpret because some patients also had adenoidectomy which is known to have a positive effect on sinusitis in children.

The authors reached the following conclusions:

“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.”

Randomized Controlled Trials

- The REMODEL study was an industry-sponsored RCT that compared balloon ostial dilation as a stand-alone procedure with FESS.^[6] 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 uncinctomy 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.

This study was likely to have adequate power to detect group differences; however there were some methodologic limitations. The study 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%).

- A small RCT was published in 2011 that reported on physiologic outcomes.^[7] 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 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.^[8] 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.^[9] 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 Trials

A number of nonrandomized studies have been identified which do not allow conclusions concerning the impact of BSD on primary health outcomes compared with FESS. These studies have methodological limitations such as a limited number of patients,^[10,11] a heterogeneous study population,^[12] no primary health outcomes reported,^[13] limited follow-up,^[10-12,14] retrospective study design^[14,15,16], or implementation of self-reported questionnaires.^[13,15]

Retrospective studies are limited by the accuracy of the medical records reviewed or the recall ability of patients when filling out a study questionnaire. In addition there is no randomization or blinding in a retrospective study design and therefore it is difficult to control for bias and confounders.

Clinical Practice Guidelines and Position Statements

The published position statements noted below are not evidence-based and did not involve systematic reviews and critical appraisals of the scientific literature. Both statements are based on opinion and consensus.

- **American Rhinologic Society (ARS)**

The current opinion of the ARS is as follows:

- Endoscopic balloon dilation technology, alone or in combination with conventional endoscopic techniques, is acceptable and safe for use in the management of sinus disease.
- Endoscopic balloon dilation technology is a tool, not a procedure.
- As a tool, balloon catheter technology should not be viewed as investigational or experimental.

This position was not based on a systematic review of the published evidence. Three references were provided to support this change in the ARS position. One study was a preclinical cadaver study. One was the preliminary study by Brown and colleagues which included only ten patients.^[18] The third was the six-month data from the “CLEAR” study.^[19] The opinion that the procedure is “acceptable and safe” appears to be based primarily on the ARS’ position that this technique is not a distinct procedure.

- **American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)**

The AAO-HNS states that “sinus ostial dilation (e.g. balloon ostial dilation) is an appropriate therapeutic option for selected patients with sinusitis. This approach may be used alone to dilate a sinus ostium (frontal, maxillary, or sphenoid) or in conjunction with other instruments...” No references are cited to support this opinion.

Summary

There is insufficient evidence to determine the impact on health outcomes of balloon sinuplasty as a minimally invasive alternative to functional endoscopic sinus surgery. The role of this technique as a stand-alone procedure in patients with chronic sinus disease remains uncertain. Prospective comparative studies with larger patient populations that include relevant outcomes with sufficient follow-up duration are needed to determine the outcomes for this treatment compared with surgical alternatives. Relevant outcomes data include symptom improvement, the durability of any treatment effects, and the need for subsequent revision. In addition, more information is needed to determine which patients might be

treated with the balloon technique and which require the more standard approaches. Therefore, balloon sinuplasty as a stand-alone treatment of any sinus is considered investigational.

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CROSS REFERENCES

None

CODES	NUMBER	DESCRIPTION
CPT	31295	Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or via canine fossa (Do not report 31295 in conjunction with 31233, 31256, and 31267 when performed on the same sinus)
	31296	Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (eg, balloon dilation) (Do not report 31296 in conjunction with 31233, 31256, and 31267 when performed on the same sinus)
	31297	Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (eg, balloon dilation) (Do not report 31297 in conjunction with 31233, 31256, and 31267 when performed on the same sinus)
HCPCS	None	