Medical Policy Manual

Topic: Balloon Ostial Dilation for Treatment of Sinusitis  Date of Origin: August 8, 2006
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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 ostial dilation (also known as balloon sinusplasty, balloon catheter dilation or sinus ostial dilation) 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 functional endoscopic sinus surgery (FESS) 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.

In 2013, a sinus dilation system (Medtronic Xomed, Jacksonville, FL), later named the NuVent™ EM Balloon Sinus Dilation System, was cleared for marketing by the FDA through the 510(k) process for use in conjunction with a Medtronic computer-assisted surgery system when surgical navigation or image-guided surgery may be necessary to locate and move tissue, bone, or cartilaginous tissue surrounding the drainage pathways of the frontal, maxillary, or sphenoid sinuses.

Also in 2013, a sinus dilation system (ArthroCare, San Antonio, TX), later named the Ventera™ Sinus Dilation System, was cleared for marketing through the 510(k) process to access and treat the frontal recesses, sphenoid sinus ostia, and maxillary ostia/ethmoid infundibula in adults using a transnasal approach.

**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 ostial 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.

**Adult Patients**

**Systematic Reviews**
In 2015, Levy et al. reported on a systematic review and meta-analysis of studies of paranasal balloon ostial dilation for chronic rhinosinusitis.\[^{1}\] The review included 17 studies, only two of which were RCTs.\[^{2,3}\] The two RCTs reported on differences in the change in 20-Item Sinonasal Outcome Test (SNOT-20) scores between patients treated with balloon ostial dilation or FESS (n=110; standard mean difference [SMD] -0.42, 95% CI -1.39 to 0.55, I²=76%). However, the reviewers found no significant differences in outcome in patients treated with balloon ostial dilation compared to those treated with conventional FESS (p = 0.07). The reviewers did report improvements in SNOT-20 score and sinus opacification after balloon ostial dilation, but these conclusions were not drawn from comparative studies, but from five cohort studies.

A BlueCross BlueShield Association Technology Evaluation Center (TEC) Assessment was completed in 2012 titled “Balloon Ostial Dilation for Treatment of Chronic Rhinosinusitis”.\[^{4}\] 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.\[^{5}\] One small RCT\[^{6}\] 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.\[^{7}\] 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\[^{8}\] 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 (RCTs)

The REMODEL Study

Bikhazi et al. has recently published two additional follow-up publications of the REMODEL study. One follow up publication reported on nasal airway resistance and sinus symptoms between FESS- and balloon ostial dilation-treated groups.\(^9\) For this analysis, 62 patients were included (32 from the FESS group and 30 from the balloon ostial dilation group). Patients in the balloon ostial dilation group had significant improvements in nasal volume from pre- to post-operative measurements, but there were no significant differences between groups pre- or postoperatively in nasal volume.

An additional follow-up of the REMODEL study by Bizaki et al. reported on an RCT that compared balloon ostial dilation with FESS, with a focus on mucociliary clearance.\(^10\) It was conducted at the same institution as the previously-reported Bizaki et al. RCTs; however, it is not specified that it was the same set of patients. This study enrolled 36 patients who were randomized to balloon ostial dilation (n=17) or FESS (n=19); however, 7 patients dropped out (n=3 in the FESS group and n=4 in the balloon ostial dilation group) and were not included in analyses. SNOT-22 scores improved in both group from pre- to post-operative analyses. However, change in total SNOT-22 score did not differ significantly between groups. There was no significant change in mucociliary clearance before and after either treatment, and no significant between-group difference in mucociliary clearance.

Chandra and colleagues published final results of the REMODEL (randomized evaluation of maxillary antrostomy versus ostial dilation efficacy through long-term follow-up) study\(^11\), which compared the outcomes of standalone balloon sinus dilation in an outpatient office setting with conventional FESS performed in an operating room. Patients in the balloon sinus dilation groups experienced significantly faster recovery (1.7 vs. 5.0 days; p<0.0001), less nasal bleeding (32% vs. 56%; p=0.009), and less need for prescription pain medication (1.0 vs. 2.8 days; p=0.0001). Study authors also reported results of a meta-analyses of several stand-alone balloon sinus dilation studies. The meta-analysis was based on five studies that included non-randomized studies. Three studies were published and summarized below and two studies were reportedly not unpublished. Based on results of the meta-analyses, FESS and balloon dilation were not significantly different for mean SNOT-20 symptom scores and revisions rates assessed at 12 months.

As a follow-up of the REMODEL study described below, Bikhazi et al. compared 1-year outcomes between office balloon dilation and FESS. A total of 92 patients (balloon dilation, n=50; FESS, n=42)
were treated and 89 (96.7%) completed 1-year follow-up. Both groups showed clinically meaningful and statistically significant (p<0.0001) improvement in mean overall SNOT-20 scores and in all 4 SNOT-20 subscales. Ostial patency was 96.7 and 98.7% after balloon dilation and FESS, respectively, and each group reported significant reductions (p<0.0001) in rhinosinusitis episodes (mean decrease, 4.2 for balloon dilation and 3.5 for FESS) during the follow-up period of 1 year. Overall work productivity and daily activity impairment due to chronic sinusitis were significantly improved (p<0.001) in both groups. There were no complications, and the revision surgery rate was 2% in each arm through 1 year. The authors concluded that stand-alone balloon dilation was as effective as FESS in the treatment of CRS in patients with maxillary sinus disease, with or without anterior ethmoid disease, who failed medical therapy, and met the criteria for medically necessary FESS. The study included the use of self-reported quality of life (QOL) questionnaires, which are subject to recall bias.

The REMODEL study was an industry-sponsored RCT that compared balloon ostial dilation as a stand-alone procedure with FESS. 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 uncinection 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%).

Other RCTs

Marzetti et al. reported results of a small RCT that compared balloon ostial dilation with an unspecified device (or devices) with FESS in the treatment of sinus headache. The study included 83 patients with sinus headache, based on the American Academy of Otolaryngology-Head and Neck Surgery criteria, 44 of whom were randomized to conventional 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 endoscopic sinus surgery were used concurrently. It was not specified how patients were selected for these groups. FESS treatment was administered on participants in both groups, but specific data was not reported by study authors. At 6 months of follow up, scores on the SNOT-22 improved from 28.6 at baseline to 7.8 in the ESS group and 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 months of follow up, headache scores based on the visual analog score (VAS) improved from 6.5 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). Study authors did not report other patient-relevant outcomes, such as the number of headache days or use of pain medications following treatment. Limitations of this study included the small number of patients who received balloon ostial dilation, which limits the generalizability of study results, and the lack of blinding of both patients and clinical assessors. In addition, there were various concurrent surgical procedures conducted in both treatment and control groups, which made it difficult to properly assess the treatment effects of balloon ostial dilation.

Another small RCT was published by Achar et al in 2012.[2] 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.

A small RCT was published in 2011 that reported on physiologic outcomes.[14] 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.

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.[15] 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 Studies

In 2014, Gould et al. published a large nonrandomized study and assessed the 1-year changes in sinonasal symptoms and health care use after office-based multi-sinus balloon dilation in an industry-sponsored prospective, multicenter study.[16] A total of 313 ostial dilations were attempted and 307 were successfully completed (98.1%) in 81 subjects. Seventy-six of the 81 patients completed the 1-year follow-up. Mean procedure tolerance was 2.8 ± 2.2 (0 = no pain; 10 = severe pain). SNOT-20 symptom improvement was observed at 1 and 6 months and sustained through 1 year. The RSI questionnaire that rates 5 major and 7 minor rhinosinusitis symptoms measured a treatment effect for all major rhinosinusitis symptoms. Compared with the previous 1-year period, patients reported an average of 2.3 fewer acute sinus infections (p < 0.0001), 2.4 fewer antibiotic courses taken (p < 0.0001), and 3.0 fewer sinus-related physician visits (p < 0.0001) after balloon dilation. No serious device or procedure-related adverse events occurred. One subject (1.3%) underwent revision surgery. The authors reported that patients reported significant reductions in both sinonasal symptoms and health care use after balloon dilation. Methodological limitations included the implementation of self-reported SNOT-20 and RSI
questionnaires which may lead to recall bias, lack of a comparison group which precludes the ability to isolate any reported treatment effects, and the timing between the preoperative CT scan and failure of medical management was not known.

Brodner et al reported a prospective, multi-center 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.[17] The criteria for previously-scheduled conventional ESS are not specified. There were a mean 2.7 sinuses per patient treated; of the targeted sinuses, 479/497 (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, 76/83 (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<0.0001 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 who were enrolled in the ORIOS trial.[18] The study included 37 subjects (59 sinuses) who had a diagnosis of chronic rhinosinusitis (>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 33/37 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 post-procedure, 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% 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 post-procedure, respectively. For the 29 subjects who had CT scans available at baseline and 24 weeks of follow up, Lund-Mackay score improved from 6.62 pre procedure to 2.79 post procedure (p<0.0001).

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.[19] 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 twenty-four week follow up was available for 112 patients, who demonstrated a mean improvement in SNOT-20 scores of -1.1 (p<0.0001). In the 110 patients with 24 week CT scans available, Lund-Mackay score improved by -4.3 compared with baseline (p<0.0001 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 chronic rhinosinusitis (N=52) or recurrent acute sinusitis (N=17).[20] Balloon dilation was successful in 69 patients, and analyses are reported per protocol. The overall technical success rate in patients was 91.9% (124 of 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<0.0001). There were no significant differences in improvements reported between the chronic rhinosinusitis and recurrent acute sinusitis patients.
A number of additional 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, a heterogeneous study population, no primary health outcomes reported, limited follow-up, retrospective study design, or implementation of self-reported questionnaires. The exception is a single-arm study reported by Tomazic et al, in which the authors planned to evaluate a cohort of 200 patients with balloon ostial dilation or a hybrid procedure, but ended the study early after 45 patients after a high technical failure rate was noted, with 44/68 sinuses in a planned balloon ostial dilation group and 29/44 sinuses in a planned hybrid procedure group failing.

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.

**Pediatric Patients**

**Nonrandomized Studies**

In 2015, Wang et al. reported on a perspective nonrandomized controlled study of 79 pediatric patients (age 7-12) with chronic sinusitis resistant to medical therapy, including 42 patients treated with sinus balloon catheter dilation balloon (SBCD) and 37 control patients treated conservatively (including oral antibiotics, local nasal steroid spray, and nasal saline irrigation). At 1-year post-treatment the SN-5 scores were significantly better in the SBCD group (22 patients [52%] had marked improvement, 11 [26%] had moderate improvement, and six [14%] had mild improvement) than in the control group (five [14%], seven [19%], and four [11%], respectively) (p < 0.05 for all comparisons).

In a 2012 retrospective comparative study, Thottam et al. evaluated the incremental value of Relieva balloon catheter sinuplasty when combined with FESS in 31 children (mean age 9.3 years) who had persistent chronic sinusitis despite standard maximal medical therapy. The authors performed a blinded chart review of 15 children who underwent balloon catheter sinuplasty with ethmoidectomy and 16 children who underwent FESS. Thirteen children had prior adenoidectomy. A total symptom score was constructed for the number of complaints presurgery, postsurgery, and at the final postsurgical examination (> four months) including facial pain, sinus congestion, postnasal drip, rhinorrhea, headache, and low-grade fever. Success and improvement were defined as a decrease in the total complaint score of ≥ 1 point at the last visit, while total improvement was defined as total resolution of all complaints (i.e., symptom score of 0). Compared with baseline values, significant posttreatment reductions in overall sinusitis symptoms and needed interventions were observed in both treatment groups. In the Relieva balloon catheter sinuplasty group, 80% of the patients reported improvements in their overall sinus symptoms at an average of 37 weeks, versus 62.5% of the FESS patients. This difference between groups was not significant. No serious complications occurred.

In a 2010 prospective, nonrandomized controlled study, Ramadan and Terrell compared the efficacy and safety of Relieva balloon sinuplasty combined with adenoidectomy (n=30) with that of adenoidectomy alone (n=19) in 49 children (mean age 6.6 years, range 2-11) with chronic sinusitis that was refractory to medical therapy for ≥ 6 months. The patients were followed at regular intervals for up to one year. Twenty-four of the 30 (80%) patients in the Relieva + adenoidectomy group showed symptom improvement at one year compared with 10 of 19 (52.6%) children in the adenoidectomy alone group. Two (6%) patients with hypoplastic sinuses failed balloon sinuplasty and required revision FESS. One patient was lost to follow-up, and another had no improvement in SN-5 scores. Three (15%) children
who did not improve after adenoidectomy had balloon sinusplasty. Overall, the mean SN-5 score for all of the children decreased from a baseline value of 4.1 to 2.9 after surgery. In the Relieva + adenoidectomy group, the mean SN-5 score decreased from 4.2 to 3.0 while in the adenoidectomy alone group, the score decreased from 3.8 to 2.9. No major complications occurred in either treatment group.

In 2010 Ramadan et al. evaluated the safety and efficacy of balloon sinusplasty in a prospective, multicenter, nonrandomized evaluation of 32 children.[31] Of the 32 children enrolled, 24 were studied at 1-year follow-up. No adverse procedure-related events were reported. Significant improvements in quality of life outcomes were reported using the SN-5 score (p < 0.0001). Twelve (50%) children had a significant improvement of their SN-5 score, seven children (29%) had moderate improvement, two (8%) had mild improvement, one (4%) remained the same, and two children (8%) had worsening scores. Although the investigators felt that balloon catheter dilation in children was safe and a significant number showed improvement of their SN-5 at 1 year follow-up, additional studies comparing balloon sinusplasty to other modalities of treatment in children were needed to determine its efficacy in the treatment of chronic sinusitis in pediatric patients.

Clinical Practice Guidelines and Position Statements

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

In 2015, the AAO-HNS published clinical practice guidelines for adult sinusitis, which included diagnostic criteria for chronic sinusitis but did not provide recommendations on treatment.[32] In addition, the AAO-HNS published a position statement in 2014 addressing sinus ostial dilation. However, the position statement was not based on a systematic review of the evidence and is not a clinical practice guideline.[33]

Summary

There is insufficient evidence to determine the impact on health outcomes of balloon ostial dilation as a minimally invasive alternative to functional endoscopic sinus surgery (FESS). The role of this technique as a stand-alone procedure in patients with chronic sinus disease remains uncertain. Prospective, well-designed 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. In addition, there are no published evidence-based clinical practice guidelines that recommend the use of balloon ostial dilation either as a stand-alone procedure or in conjunction with functional endoscopic sinus surgery (FESS) for the treatment of sinusitis. Therefore, balloon ostial dilation either as a stand-alone procedure or in conjunction with functional endoscopic sinus surgery (FESS) for the treatment of sinusitis is considered investigational.

REFERENCES


### CROSS REFERENCES

**Implantable Sinus Stents for Postoperative Use Following Endoscopic Sinus Surgery and for Recurrent Sinonasal Polyposis**, Surgery, Policy No. 198

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