Medical Policy Manual Surgery, Policy No. 209

Minimally Invasive Treatments of Nasal Valve Collapse or Obstruction

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Next Review: November 2024
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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

Minimally invasive treatments (e.g., absorbable nasal implants or radiofrequency ablation) have been proposed as alternative procedures to more invasive grafting procedures in patients with severe nasal obstruction.

MEDICAL POLICY CRITERIA

Minimally invasive treatments, including but not limited to the insertion of an absorbable lateral nasal implant or radiofrequency ablation (e.g., Vivaer), for the treatment of symptomatic nasal valve collapse or obstruction is considered **investigational**.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Rhinoplasty, Surgery, Policy No. 12.28
2. Surgeries for Snoring, Obstructive Sleep Apnea Syndrome, and Upper Airway Resistance Syndrome, Surgery, Policy No. 166
3. Hypoglossal Nerve Stimulation, Surgery, Policy No. 215
4. Cryoablation for Chronic Rhinitis, Surgery, Policy No. 224

BACKGROUND

NASAL OBSTRUCTION

Nasal obstruction is defined clinically as a patient symptom that presents as a sensation of reduced or insufficient airflow through the nose. Commonly, patients will feel that they have nasal congestion or stuffiness. In adults, clinicians focus the evaluation of important features of the history provided by the patient such as whether symptoms are unilateral or bilateral. Unilateral symptoms are more suggestive of structural causes of nasal obstruction. A history of trauma or previous nasal surgery, especially septoplasty or rhinoplasty, is also important. Diurnal or seasonal variation in symptoms is associated with allergic conditions.

Etiology

Nasal obstruction associated with the external nasal valve is commonly associated with post-rhinoplasty or traumatic sequelae and may require functional rhinoplasty procedures. A common cause of internal nasal valve collapse is septal deviation. Prior nasal surgery, nasal trauma, and congenital anomaly are additional causes.

Pathophysiology

The internal nasal valve, bordered by the collapsible soft tissue between the upper and lower lateral cartilages, anterior end of the inferior turbinate, and the nasal septum, forms the narrowest part of the nasal airway. During inspiration, the lateral wall cartilage is dynamic and draws inward toward the septum and the internal nasal valve narrows providing protection to the upper airways. Given that the internal nasal valve accounts for at least half of the nasal airway resistance; even minor further narrowing of this area can lead to symptomatic obstruction for a patient. Damaged or weakened lateral nasal cartilage will further decrease airway capacity of the internal nasal valve area, increasing airflow resistance and symptoms of congestion.[1]

Physical Examination

A thorough physical examination of the nose, nasal cavity, and the nasopharynx is generally sufficient to identify the most likely etiology for the nasal obstruction. Both the external and internal nasal valve areas should be examined. The external nasal valve is at the level of the internal nostril. It is formed by the caudal portion of the lower lateral cartilage, surrounding soft tissue and the membranous septum.

The Cottle maneuver is an examination in which the cheek on the symptomatic side is gently pulled laterally with one to two fingers. If the patient is less symptomatic with inspiration during the maneuver, the assumption is that the nasal valve has been widened from a collapsed state or dynamic nasal valve collapse. An individual can perform the maneuver on themselves, and it is subjective. A clinician performs the modified Cottle maneuver. A cotton swab or curette is inserted into the nasal cavity to support the nasal cartilage and the patient reports whether there is an improvement in the symptoms with inspiration. In both instances, a change in the external contour of the lateral nose may be apparent to both the patient and the examiner.

Measuring Nasal Obstruction

Stewart (2004) proposed the Nasal Obstruction Symptom Evaluation as a validated sinonasal-specific health status instrument that is used to assess the impact of nasal obstruction on the

quality of life of affected persons.[2] It is a five-item questionnaire on breathing problems: nasal congestion or stuffiness, nasal blockage or obstruction, trouble breathing through the nose, trouble sleeping, and inability to get enough air through the nose during exercise or exertion. The responses are made on a Likert-type scale ranging from zero (not a problem) to four (severe problem). The range of raw scores is 0 to 20. The score is then scaled to a potential total score of 0 to 100 by multiplying the raw score by five. A score of 100 means the worst possible problem with nasal obstruction.

Lipan and Most (2013) developed a Nasal Obstruction Symptom Evaluation scale–based nasal obstruction severity classification system.[3] The system is proposed as a means to classify patients for clinical management as well as to better define study populations and describe treatment or intervention responses (see Table 1).

Table 1. NOSE Severity Classification

Severity Class	NOSE Score Range
Mild	5-25
Moderate	30-50
Severe	55-75
Extreme	80-100

NOSE: Nasal Obstruction Symptom Evaluation.

Treatment

Treatment of symptomatic nasal valve collapse includes the use of nonsurgical interventions such as the adhesive strips applied externally across the nose (applying the principle of the Cottle maneuver) or use of nasal dilators, cones, or other devices that support the lateral nasal wall internally (applying the principle of the modified Cottle maneuver).

Severe cases of obstruction result from nasal valve deformities are treated with surgical grafting to widen and/or strengthen the valve. Common materials include cartilaginous autografts and allografts, as well as permanent synthetic grafts. Cartilage grafts are most commonly harvested from the patient's nasal septum or ear.

Nasal Implants

The placement of an absorbable implant to support the lateral nasal cartilages has been proposed as an alternative to more invasive grafting procedures in patients with severe nasal obstruction.

REGULATORY STATUS

In May 2016, LATERA® (Spirox) was cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process (Food and Drug Administration product code: NHB).[4] LATERA® is the only commercially available absorbable nasal implant for treatment of nasal valve collapse. It is a class II device and regulatory details are summarized in Table 2.

Table 2. Absorbable Nasal Implant Cleared by the Food and Drug Administration

Product	Manufacturer	Date Cleared	510(k) No.	Indication
LATERA® absorbable nasal implant	Spirox (part of Stryker)	2016	K161191	Supporting nasal upper and lower lateral cartilage

The VivAer® device (Aerin Medical) first received 510(k) Premarket Notification FDA clearance (K172529) for the VivAer ARC stylus in December 2017. In April 2020, a second clearance (K200300) was issued for the VivAer Stylus, as substantially equivalent in function, design, and intended use as the predicate device. The VivAer Stylus was approved for the intended use of coagulation of soft tissue in the nasal airway, to treat nasal airway obstruction by shrinking submucosal tissue, including cartilage in the internal nasal valve area.

EVIDENCE SUMMARY

The purpose of these treatment is to provide an alternative to or an improvement on existing therapies. Existing therapies include nonsurgical treatments such as the use of externally applied adhesive strips or intranasal insertion of nasal cones. The basic mechanism of action of these treatments is to widen the nasal valve and permit increased airflow. Surgical grafting using either autologous cartilage (typically from the nasal septum, ear, or homologous irradiated rib cartilage) or a permanent synthetic implant may be performed to provide structural support to the lateral wall support defect.

The question addressed in this evidence review is: Do these minimally invasive therapies, including radiofrequency treatment and absorbable nasal valve implants, improve the net health outcome in patients who have symptomatic nasal valve obstruction due to nasal valve collapse? The general outcomes of interest are change in symptoms and disease status, treatment-related morbidity, functional status, and change in quality of life. The Nasal Obstruction Symptom Evaluation (NOSE) score is an accepted symptom questionnaire for research purposes. The score can also be stratified to indicate the degree of severity of the nasal obstruction symptoms.

Study Selection Criteria

To determine efficacy outcomes, published randomized controlled trials (RCTs) were considered. Given the limited availability of RCTs, available single-arm or non-controlled studies also were considered to assess longer-term outcomes and adverse effects of the treatments.

ABSORBABLE LATERAL NASAL VALVE IMPLANT

The insertion of the absorbable implant is performed under local anesthesia and the adverse event profile includes mild pain, irritation, bruising and inflammation, awareness of the presence of the implant, infection, and the need for device retrieval prior to complete absorption.

Randomized Controlled Trials

In an RCT by Stolovitzky (2019), 137 patients from 10 clinics were randomized into either treatment (n=70) or sham control (n=67).[5] Patients in the active treatment arm received the implant (Latera®), delivered using a cannula inserted into the nasal lateral wall. Patients in the sham control arm had an identical cannula inserted into the nasal lateral wall but received no implant. Follow-up visits including collection of NOSE scores, visual analogue scale (VAS) for nasal airway obstruction, and adverse event assessment were at seven days, 30 days, and three months after the procedure. The primary endpoint was the responder rate (defined as at least one NOSE class improvement or a NOSE score reduction of at least 20% from baseline) at three months after the procedure. The authors reported that at three months follow-up,

responder rate was significantly higher for the treatment arm compared to the control arm although over half of the control group also were considered responders. The authors also reported a significantly greater decrease in NOSE score and significantly lower VAS scores for patients in the treatment arm than those in the sham control arm. Although patients were blinded to treatment group, the nasal examinations were performed by the treating physicians which introduces risk of bias. Six patients (8.6% of 70) had the implant removed within three months of the procedure. Other adverse events included pain (n=4), foreign body sensation (n=3), localized swelling (n=2), inflammation (n=1), skin puncture (n=1), and vasovagal response (n=2). Follow-up of the implant group will continue through 24 months.

Bikhazi (2021) reported results from a 24-month uncontrolled follow-up phase of the RCT.[6] Participants randomized to the control group were given the option to crossover to the treatment group following the three-month randomized phase and 40 of the 66 elected to do so. Of the 111 patients in the trial who received the active treatment (including crossover patients), 90 completed the 12-month follow-up and 70 completed the 24-month follow-up. There were statistically significant improvements from baseline in the NOSE score (mean change -38.4 [standard deviation 25.8], p<0.001) and the Epworth Sleepiness Scale (mean change -2.6 [standard deviation 4.1], p<0.001). There were 34 adverse events in 26 patients, none of which were severe, including 10 patients who experienced implant migration or retrieval.

Nonrandomized Studies

The characteristics and results of nonrandomized studies are summarized in Tables 3, 4, and 5.

Table 3. Summary of Key Nonrandomized Study Characteristics

Study	Study Type	Country	Dates	Participants[a]	Treatment, n	Follow-Up
Sidle (2020)[7, 8]	Two prospective single cohorts	U.S. (19 clinical sites)	2016-2019	277 patients with severe to extreme nasal obstruction (NOSE score > 55) and a positive Cottle maneuver	• Insertion of implant[b] alone: 109 • Insertion of implant[b] plus inferior turbinate reduction: 67 • Insertion of implant[b] plus septoplasty plus inferior turbinate reduction: 101	1, 3, 6, 12, 18, 24 months
San Nicoló (2017 and 2018)[9, 10]	Prospective single cohort	Germany (3 clinical sites)	NR	30	• Insertion of 56 lateral wall implant[b]: • Bilateral: 26 • Unilateral: 4	1 week and 1, 3, 6, 12, 24 months

NOSE: Nasal Obstruction Symptom Evaluation; NR: not reported.
[a] Inclusion criteria: NOSE score ≥55. Exclusion criteria: septoplasty or turbinate reduction within six months, rhinoplasty within 12 months, recurrent nasal infection, intranasal steroids, permanent nasal implants or dilators, precancerous or cancerous lesions, radiation or chemotherapy within 24 months.
[b] Absorbable polylactide implant marketed in the United States as Latera.

Table 4. Summary of Key Nonrandomized Study NOSE Score Results

Study	1 Month	3 Months	6 Months	12 Months	18 Months	24 Months
Sidle (2020)[7, 8]						
N	276	267	258	232	185	177
Baseline (SD)	77.8 (13.6)	77.7 (13.5)	77.6 (13.6)	77.0 (13.5)	77.6 (13.2)	78.0 (13.1)
Mean score (SD)	33.7 (23.0)	27.8 (23.4)	27.5 (24.0)	26.0 (23.9)	25.4 (24.0)	24.2 (23.6)
Mean change from baseline (95% CI)	-43.9 (-46.7 to 41.2)	-49.9 (-52.7 to -47.1)	-50.2 (-53.0 to -47.3)	-51.5 (-54.5 to -48.4)	-52.2 (-55.6 to -48.8)	-53.6 (-57.0 to -50.1)
Response rate[b]	90.9%	93.3%	91.9%	91.4%	93.5%	93.2%
Response rate[b] for implant alone group[c]	90.8% (99/109)	92.5% (98/106)	92.0% (92/100)	88.3% (83/94)	94.5% (69/73)	89.9% (62/69)
San Nicoló (2017 and 2018)[9, 10]						
N	30		29	30	29	25
Mean score (SD)	76.7 (14.8)	NR	28.4	33.3	35.2	32.0 (29.3)
Mean change from baseline (SD)			-48.4 (26.9)	-43.3 (29.7)	-40.9 (29.2)	-44.0 (31.1)
p[d]			<0.001	<0.001	<0.001	<0.001
Response rate, n (%)[b]			25 (86.2)	24 (80)	22 (75.9)	

CI: confidence interval; NOSE: Nasal Obstruction Symptom Evaluation; NR: not reported; SD: standard deviation.
[a] Paired t tests were used to compare the mean baseline value with each of the follow-up time points to determine whether there was evidence of significant reductions in NOSE scores. Cis not reported.
[b] Response rate was defined as an improvement of at least 1 NOSE score category or a 20% reduction in NOSE score.
[d] Paired t tests comparing the mean preoperative NOSE score to the mean score at each follow-up time point. Cis not reported.

Table 5. Summary of Key Nonrandomized Study Safety and Adverse Event Results

Study	1 Month	3 Months	6 Months	12 Months	24 Months
Sidle (2020 and 2021)[7, 8]					
Device related[a]			19 events in 17 patients[b,c]	41 events in 31 patients[d,c]	54 events in 45 patients
Device removals				17 out of 319 implants (5.3%)	22 out of 543 implants (4.0%)
San Nicoló (2017 and 2018)[9, 10]					
N or n	30	29	30	29	25
Device tolerability, % (n)					
None/mild pain	30 (100)	29(100)	29 (96.7)	29(100)	25 (100)
Not assessed			1 (3.3)		
No cosmetic changes[d]	26 (86.7)	27 (93.1)	27 (90.0)	26 (89.7)	17 of 19 (89.5)
Device-related adverse events[e]	5	0	0	0	

[a] Defined as implant- or procedure-related.

[b] Reported in sample size of 101.
[c] Total number only reported for inflammation, foreign body sensation, skin irritation, hematoma, infection, and implant retrievals.
[d] reported in sample size of 166
[d] Photographic review.
[e] Three device retrievals, 1 hematoma, and 1 inflammation.

Sidle (2020, 2021) published two post-marketing studies that enrolled a total of 277 patients with severe-to-extreme NOSE scores at 19 U.S. clinics between September 2016 and July 2017[7, 8], which was an expansion of a previous study by the same group.[11] One trial was conducted in an office setting and enrolled 166 patients. Patients were treated with a bioabsorbable implant (Latera®) to support the lateral wall, with (n=61) or without (n=105) concurrent inferior turbinate reduction (ITR). NOSE scores were measured at baseline and one-, three-, six-, and 12 months post-procedure. A Lateral Wall Insufficiency (LWI) score was determined by independent physicians observing the lateral wall motion video at baseline and six months post-procedure. The second study implanted the device in the operating room and included 113 patients. An additional publication from these studies included data from 177 patients who were followed for 24 months under a protocol extension. Patients were enrolled as implants only (n=69), implants with inferior turbinate reduction (n=39), and implants with septoplasty and ITR (n=69). NOSE scores were reported as 30.4 (24.6) for implant alone, 27.6 (23.1) for implant plus inferior turbinate reduction, and 16.0 (20.7) for an implant combined with septoplasty and inferior turbinate reduction. The mean changes in NOSE scores and VAS scores were statistically significant ($p<0.001$) at all follow-up periods compared to control. A summation of outcomes from these studies are outlined in Tables 3, 4, and 5.

San Nicoló (2017) reported on outcomes up to 12 months following implantation of 56 implants in 30 subjects.[9] All implanted patients had NOSE score ≥55. San Nicoló (2018) reported 24-month outcomes for the patients with initial results reported in.[10] This study reported that there were no device-related adverse events in the period of 12 to 24 months.

RADIOFREQUENCY TREATMENT OF NASAL VALVE COLLAPSE

Randomized Controlled Trials

Silvers (2021) published an industry-sponsored, single-blind, sham-controlled RCT of radiofrequency treatment using the Vivaer Stylus device.[12] Patients with nasal airway obstruction (NOSE score ≥55) and nasal valve collapse, who had shown a positive response to temporary nasal dilation were included. Patients with previous surgery of the lateral nasal wall and those with a severe case of septal deviation, turbinate hypertrophy, polyps, or ptotic nose tip were excluded. The primary endpoint was “response,” defined as a ≥20% improvement in NOSE-scale score or ≥1 NOSE-scale severity category improvement after three months. A total of 119 patients were randomized 2:1 to radiofrequency treatment or a sham treatment, in which the stylus was applied in the same manner but without RF energy delivery. After three months, the response rate in the active treatment group was significantly higher than in the control group (88.3%, 95% CI 79.2% to 93.7%, vs. 42.5%, 95% CI 28.5% to 57.8%, respectively, $p<0.001$). The ease-of-breathing VAS score also showed greater improvement in the active treatment group than in the control group (−31.4, 95% CI −38.5 to −24.2, vs. −16.1, 95% CI −26.3 to −6.0, respectively, $p=0.015$).

Han (2022) published the uncontrolled 12-month follow-up results of this trial, which allowed patients who originally received sham treatment to crossover to active treatment after three months.[13] Sham-treated patients who did not opt to crossover were removed from the study;

thus only actively treated patients (n=108) were included. The outcomes assessed were the NOSE score and the Epworth Sleepiness Scale. The response rate of the combined active treatment group was 86.0% (95% CI 78.2% to 91.3%), 91.0% (95% CI 83.8% to 95.2%), and 89.8% (95% CI 81.7% to 94.5%) at three, six, and 12 months, respectively. No adverse events were reported.

Nonrandomized Studies

Torabi (2023) reported on adverse events related to intranasal radiofrequency devices from the Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) registry.[14] In this registry, there were 24 device-related AEs: 11 for Celon® (Olympus), eight for Rhinaer® (Aerin), three for Vivaer® (Aerin), and two for Neuromark® (Neurent). These adverse events included tissue necrosis, synechiae formation, mucosal perforation, empty nose syndrome, and an episode of pediatric ocular palsy. For the posterior nasal nerve ablating devices, most (9/10) adverse events were epistaxes, of which seven required reoperation.

Jacobowitz (2019) published a multicenter cohort study of radiofrequency treatment in 50 patients seeking treatment for nasal obstruction due to nasal valve collapse.[15] Patients were excluded if they had any of the following: prior nasal surgery within the past 12 months; severe or chronic sinusitis; allergies leading to nasal obstruction and currently requiring oral corticosteroids; severe case of septal deviation, turbinate hypertrophy, polyps, or ptotic nasal tip; pre-disposition to poor wound healing; or increased surgical risk. Patients were followed for 26 weeks after the procedure, with one patient lost to follow-up. The mean NOSE score declined from 80 to 25 at 26 weeks ($p<0.001$), and there was no significant difference in this score between patients who had previously had nasal surgery and those who had not. Survey results also indicated that patients were generally satisfied with the procedure. Additional 24- and 48-month follow-up results were published for this cohort, which indicated the potential for long-term improvement, however there was substantial loss to follow-up in these studies.[16, 17]

Brehmer (2019) published an observational study of 31 patients who received radiofrequency treatment for chronic nasal obstruction with sleep-disordered breathing.[18] At 30 and 60 days following the treatment, the patients completed the NOSE survey and Snore Outcomes Survey. Both outcomes showed statistically significant improvements from baseline over the course of the study.

PRACTICE GUIDELINE SUMMARY

There are no evidence-based clinical practice guidelines that recommend the use of an absorbable lateral nasal implant or radiofrequency treatment for nasal valve collapse or obstruction.

SUMMARY

There is not enough research to show that minimally invasive treatments, including insertion of an absorbable lateral nasal implant or radiofrequency (e.g., VivAer®) improves health outcomes for people with symptomatic nasal valve collapse or obstruction. No clinical guidelines based on research recommend the use of an absorbable lateral nasal implant or radiofrequency treatment (e.g., Vivaer®) for nasal valve collapse. Therefore, minimally

invasive treatments, including insertion of an absorbable lateral nasal implant or radiofrequency (e.g., Vivaer®) treatment are considered investigational for these indications.

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CODES

NOTE: The physician work for the nasal implant placement would be billed with the unlisted CPT code 30999 - Unlisted procedure, nose. Some providers may use CPT 30465 for this service, Repair of nasal vestibular stenosis (e.g., spreader grafting, lateral nasal wall reconstruction); however the unlisted code is the appropriate code.

Codes	Number	Description
CPT	30468	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)
	30469	Repair of nasal valve collapse with low energy, temperature-controlled (ie, radiofrequency) subcutaneous/submucosal remodeling
	30999	Unlisted procedure, nose
HCPCS	None	

Date of Origin: *November 2018*