Radiofrequency ablation for nasal valve collapse

Clinical Policy ID: CCP.1539

Recent review date: 4/2024

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Policy contains: Nasal blockage, nasal valve collapse; nasal obstruction; radiofrequency ablation; temperature-controlled radiofrequency devices.

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Coverage policy

Radiofrequency ablation as a treatment to repair nasal valve collapse are investigational/not clinically proven, and therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

No alternative covered services were identified during the writing of this policy.

Background

Nasal obstruction, also known as nasal congestion or blockage, is a common condition that affects many people in the United States. It can be caused by various factors, including anatomical issues like septal deviation, inferior

turbinate hypertrophy, nasal valve collapse, and conditions like allergies and viral infections (Clark, 2018). A study involving patients with sinonasal complaints (n = 1,906) found that the prevalence of nasal valve collapse was 67%, septal deviation was 76%, and inferior turbinate hypertrophy was 72% (Clark, 2018). Another study found that nearly one in four Americans with nasal congestion experience symptoms almost every day (Harris on Demand, 2021).

Nasal obstruction can significantly impact a person's quality of life, leading to symptoms such as difficulty breathing, persistent nasal congestion, and disrupted sleep patterns (García-Chabur, 2023). It can also be associated with sleep-disordered breathing, including conditions like sleep apnea. Treatment options for nasal obstruction range from home remedies and medications to surgical interventions, depending on the severity and cause of the obstruction (García-Chabur, 2023).

Common surgical approaches known as rhinoplasty techniques aim to address nasal valve compromise (Ng, 2013). These involve placing grafts or splints to widen and open the cross-sectional nasal valve area to improve airflow dynamics. Functional rhinoplasty approaches attempt to decrease nasal airway resistance and improve nasal breathing capacity by structurally modifying the nasal valve region (Ng, 2013).

Temperature-controlled radiofrequency devices offer an alternative treatment option for nasal obstruction, particularly for conditions like nasal valve collapse (Silvers, 2021). The treatment works by delivering controlled energy to the nasal valve area, which heats the tissue in a controlled manner. This process aims to cause tissue remodeling and tightening, thereby reducing the symptoms of nasal obstruction (Silvers, 2021).

Radiofrequency ablation is viewed as a minimally invasive approach to heat the nasal submucosa while protecting the overlying mucous layers (Neiderman, 2023). The controlled damage elicits healing responses such as fibrosis and volume reduction capable of remodeling tissues triggering obstructive symptoms (Neiderman, 2023). Compared to more invasive interventions, radiofrequency ablation offers simpler and less disruptive correction of obstructed airways through its outpatient application under local anesthesia (Neiderman, 2023).

Findings

The American Academy of Otolaryngology-Head and Neck Surgery issued a position statement that listed radiofrequency treatment as one of several potential office-based treatments that can be used to stabilize the nasal valve, along with implants. However, it goes on to say that for patients requiring anatomic widening and definitive stabilization, surgical treatment is needed to optimize outcomes (American Academy of Otolaryngology-Head and Neck Surgery, 2023).

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In a systematic review and meta-analysis, data across eight studies (n = 451) was analyzed to evaluate the efficacy of temperature-controlled radiofrequency treatment for nasal valve collapse causing nasal obstruction. The studies showed statistically significant improvement in disease-specific quality of life scores (measured by NOSE scores) from baseline to 12-24 months post-radiofrequency treatment. The mean difference in NOSE scores ranged from 41.75 points at one month to 56.35 points at 24 months across the studies (p=0.0107). The NOSE score is a standardized scoring system used to quantify patients' subjective symptoms related to nasal obstruction and its impact on disease-specific quality of life. Additionally, the rates of clinically improved status after treatment ranged from 78% at 1 month to 86% at 24 months (p=0.3661). Responder rates (defined as ≥20% decrease in NOSE score or ≥1 severity level improvement) ranged from 87-98% from 3 to 24 months. The sham

control group showed less improvement in scores and responder rates. This evidence supports coverage for radiofrequency ablation under appropriate indications. Additional randomized controlled trials are still warranted to confirm treatment efficacy (Kang, 2024).

A systematic review of four studies (n = 218) evaluating temperature-controlled radiofrequency treatment for nasal valve collapse causing nasal obstruction. The meta-analysis found a significant improvement in the mean NOSE score from 76.16 pre-treatment to 31.2 at three months post-treatment (mean difference of 46.13 points, P <0.05). In the one randomized sham-controlled trial, the temperature-controlled radiofrequency treatment group improved significantly more than sham control on the NOSE score at three months (34.4 vs 62.0, P <0.05). Minor adverse events like nasal congestion and pain occurred in a small number of patients and resolved (Casale, 2023). Silvers (2021) was analyzed in the Casale study.

A systematic review of 26 studies (n = 1,476) patients comparing radiofrequency (RF) turbinoplasty to microdebrider-assisted turbinoplasty (MAT) for inferior turbinate reduction. Meta-analysis found both procedures significantly improved subjective (visual analog scale score improved by 4.53 points for RF and 3.81 points for MAT) and objective nasal airflow metrics through a median follow-up of six months. There was no significant difference between RF and MAT on these outcomes. Minor complications occurred (Acevedo, 2015).

A 12-month follow-up of a randomized controlled trial evaluating temperature-controlled radiofrequency (TCRF) treatment in n=108 patients with nasal obstruction primarily due to nasal valve collapse. Patients treated with TCRF showed a significant improvement in nasal obstruction symptoms compared to sham control at three months in the initial trial. In this longer-term follow-up study, the responder rate (defined as ≥20% improvement on the NOSE score or ≥1 severity level improvement) was 89.8% at 12 months. The mean NOSE score improved by -44.9 points from baseline (58.8% improvement). There were no device-related serious adverse events (Han, 2022).

A second randomized controlled trial (n = 117) compared temperature-controlled radiofrequency (TCRF) treatment of the nasal valve versus sham control in patients with nasal obstruction primarily due to nasal valve collapse. At three months, the responder rate (defined as ≥20% improvement on the NOSE score or ≥1 severity level improvement) was 88.3% in the TCRF group compared to 42.5% in the sham control group (p<0.001). The mean NOSE score improved by -42.3 points in the TCRF group versus only -16.8 points in the control group (p<0.001). This represents a 55.1% improvement for TCRF patients. There were no serious adverse events related to the TCRF device/procedure (Silvers, 2021).

References

On February 2, 2024, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “nasal valve collapse” and “radio frequency ablation”, “nasal blockage and ““radio frequency ablation,” and “temperature-controlled radiofrequency devices.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

2/2024: initial review date and clinical policy effective date: 3/2024