CLINICAL SUMMARY

VivAer® Breathe Better.

Study Title

Twelve-month Outcomes Following Temperature-Controlled Radiofrequency Treatment of the Septal Swell Body for Nasal Airway Obstruction

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Study Overview

This publication reports the 12 month outcomes of a prospective, multicenter, open-label, long-term study in subjects with nasal airway obstruction (NAO) with septal swell body (SSB) hypertrophy. Eligible patients were originally at 9 US centers. At 12 months, 62 patients were analyzed based on responder rate,[1] mean change in Nasal Obstruction Symptoms Evaluation (NOSE) Scale vs. baseline, Numeric Rating Scale (NRS) – Breathing Score vs baseline, patient satisfaction, and frequency of new adverse or serious adverse events related to the trial device/procedure. The responder rate at 12 months was 95.2%, and the adjusted mean change at 12 months was -48.1, representing a 65.4% improvement from baseline. The adjusted mean change in NRS- Ease of Breathing score was -4.0, representing a 62.5% improvement from baseline. At 12 months, the mean satisfaction score was 4.2 out of a total of 5.0. The outcomes of this long-term follow-up demonstrated that the VivAer® procedure was safe and resulted in a significant and sustained reduction in NAO symptoms at 12 months, accompanied by a reduction in concomitant medication burden. There were no serious adverse events with a relationship to the device or procedure reported throughout the 12 months.

[1]Responder was defined as ≥1 NOSE scale severity category improvement or ≥ 20% improvement (decrease) in NOSE scale score at follow-up when compared to the baseline score

Objective

To assess the long-term safety and efficacy of temperature-controlled radiofrequency (TCRF) treatment of the septal swell bodies (SSB) at 12-months post-treatment.

Secondary Outcome Measures

- NOSE Scale scores and responder rates at 3, 6 and 12 months post-treatment
  - Change in number of patients in each NOSE symptom severity category over time
- Other outcome measures assessed at baseline and at 3, 6, and 12 months
  - Device- and procedure-related adverse events
  - Numeric Rating Scale (NRS) – ease of breathing
  - Patient satisfaction

Key Eligibility Criteria:

- Seeking treatment for nasal obstruction and willing to undergo an office-based procedure
- Baseline NOSE score ≥ 55
- Endoscopic confirmation of SSB hypertrophy limiting visualization of the middle turbinate by more than 50%
- SSB assessed prior to and after application of topical decongestant

Methods:

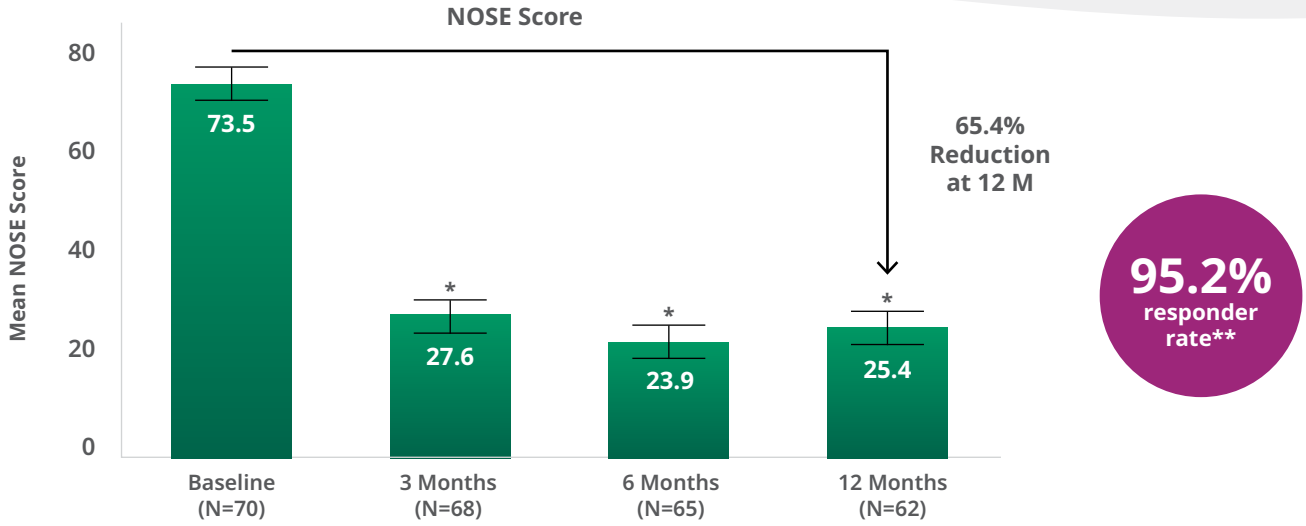
A total of 70 patients with severe/extreme NAO attributed to SSB hypertrophy as primary contributor were enrolled at 9 US centers. Patients underwent in-office bilateral TCRF treatment of the SSB using the VivAer Stylus and Aerin® Console in up to 6 non-overlapping applications. Sixty-two subjects completed the 12-month follow-up visit.

Results:

VivAer was an effective and durable treatment for reducing the overall symptom burden of NAO

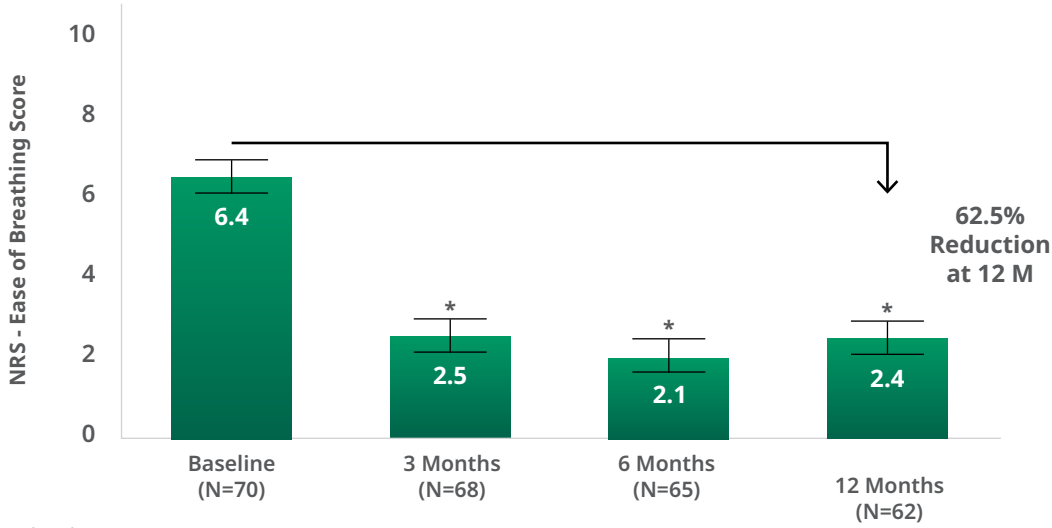
- The responder rate of 95.6% at 3 months was sustained through 12 months (95.2%)

KEY FINDINGS



p<0.001 vs. baseline score
***Responder was defined as ≥1 NOSE scale severity category improvement or ≥ 20% improvement (decrease) in NOSE scale score at follow-up when compared to the baseline score*

- Patients showed a significant improvement (decrease) in mean score for all NOSE scale components (congestion, nose blockage, trouble breathing, trouble sleeping, and less air during exercise) at each time point when compared to the baseline (p<0.001).



p<0.001 vs. baseline score

VivAer delivered an overall decrease in NAO medication use

- At baseline, the most common medications classes used were Antihistamines (52.4%) and nasal steroid sprays (39.7%)
- At 12 months, 33.3% of patients had decreased or stopped usage of antihistamines and 32% decreased or stopped nasal steroid sprays. The majority of the patients remained the same and few patients started new nasal medications

Patients were satisfied with their VivAer Treatment

- Patient satisfaction remained high at each follow-up visit with a mean score of 4.2 out of a possible 5.0 at 3 months and 12 months

VivAer treatment of the SSB was demonstrated to be a safe for reducing the symptoms of NAO

- No new or serious adverse events related to the device/procedure were reported through 12 months

Citation: Pritikin, J., Silvers, S., Rosenbloom, J., Davis, B., Del Signore, A., Sedaghat, A., Tajudeen, B., Schmale, I., & Chandra, R. (2024). Twelve-month Outcomes Following Temperature-Controlled Radiofrequency Treatment of the Septal Swell Body for Nasal Airway Obstruction. International Forum of Allergy & Rhinology.

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Indication for use: the VivAer® Stylus is indicated for use in otorhinolaryngology (ENT) surgery for the 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

To learn more about VivAer, please visit VivAer.com

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