CLINICAL SUMMARY

The VivAer® Procedure for Treatment of Nasal Airway Obstruction – A ProspecTive, Multicenter Randomized Controlled TriAl Comparing VivAer to Sham Control (VATRAC)

VATRAC RCT 2-year Analysis

Published Title

Two-year outcomes of radiofrequency device treatment of the nasal valve for nasal airway obstruction

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Study Overview

This publication reports the long-term outcomes of a prospective, single-blinded (patient), randomized controlled trial (RCT) with a sham procedure control arm. Eligible patients were originally enrolled at 16 US centers and randomized 2:1 to either the VivAer index active treatment arm or the index sham control arm. After 3-month follow-up demonstrated that the responder rate^ was significantly higher in the active treatment arm than in the sham control arm ($p<0.001$), eligible patients from the sham control arm elected to undergo cross-over treatment to receive active treatment, forming a new active treatment group consisting of 108 patients. At 2 years, 73 active treatment patients were analyzed based on responder rate^, mean change in Nasal Obstruction Symptom Evaluation (NOSE) Scale score, Epworth Sleepiness Scale (ESS), concomitant medication and nasal dilator use, and frequency of new adverse or serious adverse events related to the trial device/procedure. The responder rate at 2 years was 90.4%, and the mean change in NOSE Scale score was -41.7, representing a 54.7% symptom reduction vs. baseline. There were no serious adverse events with relationship to the device or procedure reported throughout the 2 years. The outcomes of this long-term follow-up demonstrated that VivAer treatment of the nasal valve was safe and resulted in significant and sustained improvements in the symptoms of nasal airway obstruction (NAO) at 2 years, accompanied by a reduction in medication and nasal dilator use.

^Responder rate defined as the percentage of patients with 20% or greater improvement (decrease) in NOSE Scale score or 1 or greater NOSE Scale severity category improvement from baseline

Objective

To determine treatment effect durability and changes in medication and nasal dilator use for NAO patients receiving active VivAer treatment of the nasal valve.

Outcome measures

Primary endpoint	Other endpooints
• Responder rate at 3-month post-treatment, where a responder was defined as ≥20% improvement (decrease) in NOSE Scale score or ≥1 NOSE Scale severity category improvement from baseline	• Responder rate at 6-month and 1- and 2-year • Mean change in NOSE Scale score from baseline at 3- and 6-month and 1- and 2-year post-treatment • Mean change in ESS score from baseline at 3- and 6-month and 1- and 2-year post-treatment • Change in medication and nasal dilator class use from baseline to 2 years post-treatment • Frequency of device- and/or procedure-related adverse and serious adverse events through 2 years post-treatment

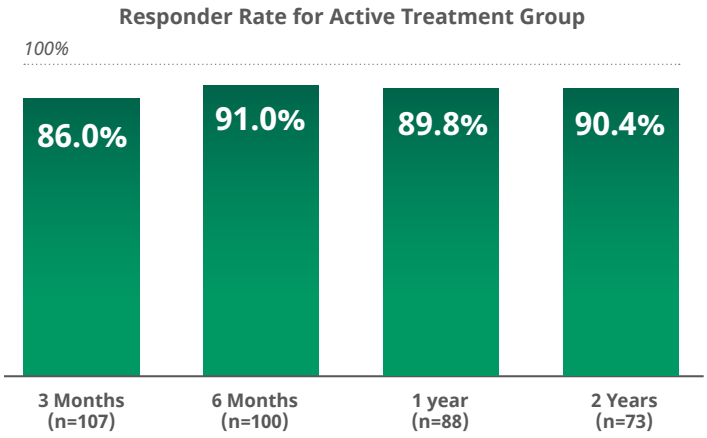
Patient selection

All patients enrolled in this trial previously completed participation in the original 3-month follow-up*, which adhered to the following eligibility criteria:

Key inclusion criteria	Key exclusion criteria
• Age 18-85 years • Baseline NOSE Scale score ≥55 • Nasal valve collapse as primary or a significant contributor to nasal obstruction • Positive response to a temporary nasal dilation measure such as the Modified Cottle Maneuver • Patient dissatisfaction with medical management	• Prior surgery of lateral nasal wall • Severe case of septal deviation • Turbinate hypertrophy, polyps, or ptotic nose tip believed to be the primary contributor to the nasal obstruction symptoms and warranting surgical intervention

* Silvers, SL, Rosenthal, JN, McDuffie, CM, Yen, DM, Han, JK. Temperature-controlled radiofrequency device treatment of the nasal valve for nasal airway obstruction: A randomized controlled trial. Int Forum Allergy Rhinol. 2021; 11: 1676– 1684. https://doi.org/10.1002/alr.22861

KEY FINDINGS



VivAer was effective in relieving NAO symptoms caused by nasal valve dysfunction (NVD)

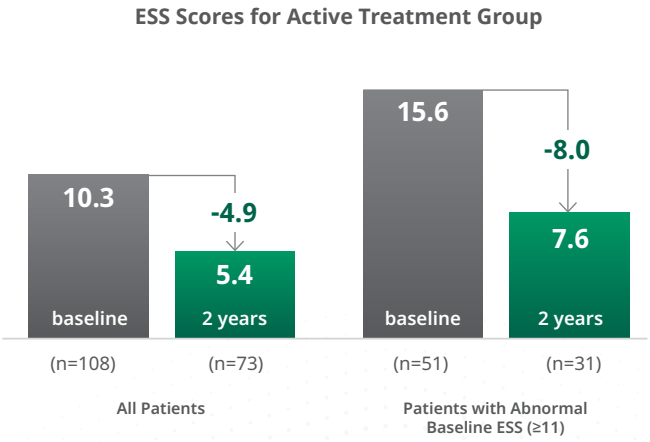
- The responder rate of 86.0% at 3 months was sustained through two years (90.4%), representing a mean NAO symptom reduction of 53.6% and 54.7% from baseline at 3 months and 2 years, respectively
- The adjusted mean change in NOSE Scale score and all its components (nasal congestion/stuffiness, nasal blockage/congestion, trouble breathing through the nose, trouble sleeping, and unable to get enough air through the nose during exercise or exertion) was significantly improved over baseline at all follow-up timepoints ($p<0.001$)
- The adjusted mean changes in the NOSE scale score reflected significant and sustained improvements in NAO symptom burden for all subpopulations at all follow-up timepoints ($p<0.001$). The subpopulations analyzed include: severe or extreme NAO severity class, prior/no prior nasal surgery, with/without septal deviation, with/without septal swell body, and with/without turbinate enlargement

Reduction in Medication/Nasal Dilator Use for Active Treatment Group

Medication/Nasal Dilator Class	Medication/Nasal Dilator Use at Baseline (No.)	Decreased or Stopped at 2 Years (No.)	Decreased or Stopped at 2 Years (%)
Antihistamines	37	21	56.8%
Decongestants	22	14	63.6%
Leukotriene inhibitors	9	3	33.3%
Corticosteroid sprays	38	25	65.8%
Anticholinergics	2	2	100.0%
Nasal strips/cones	20	19	95.0%

VivAer delivered reduction in overall NAO medication and nasal dilator use

- At baseline, 78.1% of patients were using ≥1 medication/nasal dilator class, but by 2 years post-treatment, 33.3% had stopped all medications/nasal dilators, 45.6% had stopped or decreased use in ≥1 medication/nasal dilator class, and 10.5% had the same level of medication/nasal dilator use as baseline
- A substantial number of patients had either stopped or decreased use of medication/nasal dilators at 2 years: 56.8% for antihistamines, 63.6% for decongestants, 33.3% for leukotriene inhibitors, 65.8% for corticosteroid sprays, 100.0% for anticholinergics, and 95.0% for nasal strips/cones



VivAer was demonstrated to have a positive impact (decrease) on daytime sleepiness

- Epworth Sleepiness Scale (ESS) is a self-administered questionnaire that measures a person's general level of daytime sleepiness based on their likelihood of dozing off or falling asleep while engaged in eight different activities (source: https://epworthsleepinessscale.com/)
  - 0-5 Lower Normal Daytime Sleepiness
  - 6-10 Higher Normal Daytime Sleepiness
  - 11-12 Mild Excessive Daytime Sleepiness
  - 13-15 Moderate Excessive Daytime Sleepiness
  - 16-24 Severe Excessive Daytime Sleepiness
- The active treatment group had a mean ESS score of 10.3 at baseline, indicating higher normal daytime sleepiness, which improved (decreased) by 4.9 points at 2 years post-treatment to reach 5.4, representing lower normal daytime sleepiness
- The cohort of patients with mild, moderate, or severe excessive daytime sleepiness (n=51, ESS≥11) had a baseline mean ESS score of 15.6, which improved (decreased) by 8.0 points at 2 years post-treatment to reach 7.6, representing higher daytime sleepiness

VivAer was demonstrated to be a safe nasal valve dysfunction treatment for addressing NAO

- No new or serious adverse events related to the device/procedure were reported through 2 years

VATRAC will continue patient follow-up through three years

Citation: Silvers SL, McDuffie CM, Yen DM, Rosenthal JN, Davis SE, Han JK. Two-year outcomes of radiofrequency device treatment of the nasal valve for nasal airway obstruction. Rhinology. 2024 Jan 13. doi: 10.4193/RhinRhin23.377. Epub ahead of print. PMID: 38217847.

Rhinology Journal: https://www.rhinologyjournal.com/Abstract.php?id=3153

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Indication for use: The VivAer ARC 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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