EE71

Budget Impact Analysis of a Non-invasive Temperature-controlled Radiofrequency Device for the Treatment of Nasal Airway Obstruction

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Background and Objectives

- Nasal airway obstruction (NAO) is a common condition affecting approximately 1/3 of the population[1] in which patients present with congestion and feeling of fullness in the nasal cavity and complaints of sleep problems, fatigue and headaches. NAO is often caused by structural abnormalities of the nasal airway that lead to narrowing or collapse of the nasal valve area.
- The American Academy of Otolaryngology-Head and Neck Surgery issued a position statement on nasal valve repair (March 2023) recognizing non-invasive office-based radiofrequency treatments as treatment option for nasal valve stabilization.
- Patients with severe or extreme NAO may be offered functional rhinoplasty surgery which is known to be complex, costly, and carry a risk of further functional and cosmetic changes.[2]
- Temperature-controlled radiofrequency (TCRF) treatment of the nasal valve using the VivAer® device (Aerin Medical, Mountain View, CA) is a non-invasive, in-office alternative to surgical treatment of nasal valve collapse with efficacy shown to be effective in several clinical studies showing a sustained improvement in nasal breathing for up to 4 years with treatment effects similar to surgical nasal valve repair.[3-7]
- The objective of this study is to determine the budget impact in the US market of the introduction of an office-based, minimally-invasive temperature-controlled radiofrequency (TCRF) device (VivAer®) for the treatment of patients with NAO due to nasal valve collapse (NVC).
- A 4-year time horizon was used assuming treatment for a hypothetical health plan with a member population of 1 million and member growth rate equivalent to that of the US population.
- The eligible population includes patients with severe/extreme NAO, defined as a Nasal Obstruction Symptom Evaluation (NOSE) score of ≥ 55 indicating severe to extreme NAO, for which NVC is the primary cause or a significant contributor.

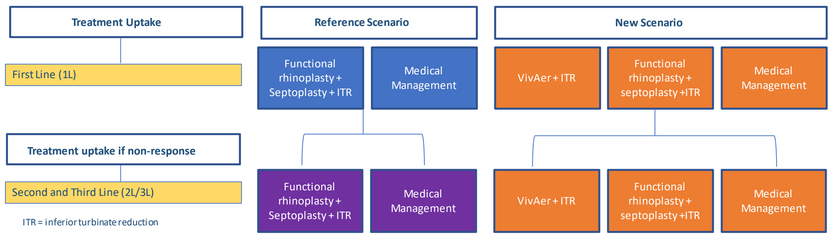
METHODS

- The budget impact model was developed using Excel Software (Microsoft, WA). The budget impact was calculated by comparing annual health care costs using two scenarios: 1) a reference scenario of reflecting surgical correction of the nasal valve (functional rhinoplasty with inferior turbinate reduction [ITR]) performed in the hospital outpatient surgery department, which reflects current clinical practice without TCRF as an available treatment option; 2) a new scenario reflecting minimally-invasive nasal valve treatment (VivAer TCRF with ITR) performed in an office setting.
- Uncertainty within the model structure and input parameters was assessed using one-way sensitivity analysis and scenario analysis.

Table 1: Total Budget Impact of VivAer*

Patient Numbers	Values Used in Model	Year 1	Year 2	Year 3	Year 4
Plan Population*		1,000,000	1,005,000	1,010,025	1,015,075
Prevalence of NAO[1]	30.0%	300,000	301,500	303,008	304,523
% of patients with NAO who seek treatment/visit ENT Physician[1]	21.0%	63,000	63,315	63,632	63,950
% of patients with severe/extreme NAO[8]	63.0%	39,690	39,888	40,088	40,288
% of patients with severe/extreme NAO for which NVC is a significant contributor[8]	73.0%	28,974	29,119	29,264	29,410
% of patients who receive 1L treatment (Eligible Population)**	**25.0%**	**7,243**	**7,280**	**7,316**	**7,353**
* Incorporates 0.5 annual population growth rate each year; **Not all eligible patients will pursue surgery					

Figure 1: Treatment Pathway Framework



Key Assumptions and Considerations:

- A time constant proportion of eligible patients are assumed to initiate 1L treatment to account for payor conditions encountered in practice where not all eligible patients will immediately consider VivAer as a treatment option.
- Patients are retained in the model following the year of entry, if patient incurs costs beyond entry year, they are attributed to the relevant calendar year
- If patients do not respond to initial treatment and receive subsequent treatment, subsequent treatment costs are applied in subsequent year to reflect time delay for receiving further treatment.
- Costs are assumed to be zero upon achievement of treatment response; post-treatment resource use is assumed to be equivalent between response and non-response health states
- Only adverse event costs requiring further treatment are included, out of pocket expenses are excluded.
- Treatment response is defined as ≥20% decrease in NOSE Scale score or 1 category improvement in NOSE Scale severity category; treatment response is considered permanent; 12-month response rate is used to determine resource use/monitoring in post-treatment period
- Efficacy of subsequent treatments are assumed independent of the prior treatment received.
- Adverse events from subsequent treatments (repeat treatments) are assumed equivalent to incident rates for adverse events resulting from initial treatment
- Incidence rates for VivAer with turbinate reduction and functional rhinoplasty with septoplasty with turbinate reduction are assumed equivalent regardless of any additional procedures that are conducted.
- Procedure and adverse event costs were derived from 2023 Medicare reimbursement rates for relevant CPT codes; Adverse event incidence was derived from the literature.

RESULTS

- The budget impact of introducing VivAer as a treatment option for NAO compared to functional rhinoplasty with septoplasty and ITR is negative in each year of the model reflecting cost savings from the introduction of VivAer. The magnitude of cost savings increases in each year of the model, reflecting the increase in uptake of VivAer (via market shares).
- The primary driver of cost savings is the higher unit cost for the surgical comparator.

Table 2: Total Budget Impact of VivAer*

	Year 1	Year 2	Year 3	Year 4
Reference Scenario (without VivAer)	$82,301,235	$82,712,741	$83,126,305	$83,541,936
New Scenario (with VivAer)	$70,129,105	$64,363,255	$58,537,993	$52,652,870
Budget Impact of VivAer	**-$12,172,130**	**-$18,349,486**	**-$24,588,312**	**-$30,889,067**
* Market share estimates used in scenario for years 1-4 are 20%, 30%, 40%, and 50%, respectively as proportions of total number of surgeries performed annually estimated using data from the Definitive Healthcare claims database				

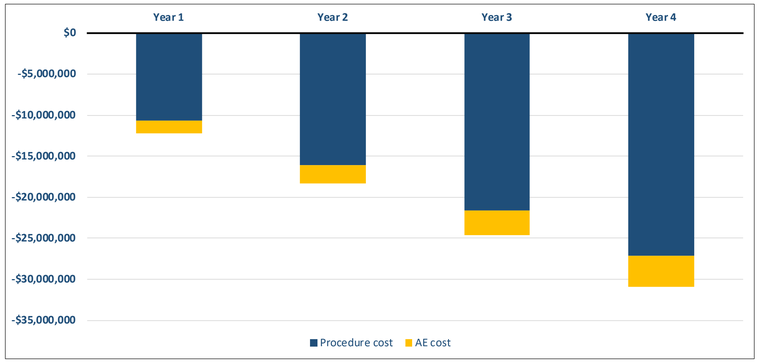
- The total number of overall surgeries decreased through the 4-year time horizon reflecting the hypothetical increase in the uptake of VivAer replacing surgical procedures. For the number of surgeries in the subsequent lines this is 0 as currently the model assumes that all patients who require additional lines of treatment are treated with medical management.

Table 3: Total Surgical Procedures Performed Per Year by Scenario

		Year 1	Year 2	Year 3	Year 4
Reference Scenario (Without VivAer)	Functional rhinoplasty + septoplasty + ITR	7,243	7,280	7,316	7,353
New Scenario (With VivAer)	Functional rhinoplasty + septoplasty + ITR	5,795	5,096	4,390	3,676
Change in number of surgeries in all treatment lines		**-1,449**	**-2,184**	**-2,926**	**-3,676**
Change in number of subsequent surgeries*		0	0	0	0
*assumes all patients requiring subsequent treatment receive medical management					

- Over the 4-year time-horizon, the introduction of VivAer results in overall decreased procedure and adverse event costs.
- Introducing VivAer, a non-invasive procedure, offers the potential added benefit for patient health outcomes by reducing exposures to the risks of adverse events associated the invasive functional rhinoplasty + Septoplasty + ITR surgeries.

Figure 2: Budget Impact by Cost Type for All Patients



CONCLUSIONS

- Over the 4-year time-horizon, the net budget impact showed that the use of an in-office, non-invasive TCRF device treatment for NAO due to NVC is likely to provide cost-savings due to reductions in the number of surgeries, costs avoided from resolving complications and the lower overall procedure cost of the device relative to surgical comparators.
- Cost savings estimated when standard of care represented a mix of surgical interventions and medical management remained robust when varying parameter values in sensitivity analyses.

REFERENCES

1. Wever C. C. (2016). The Nasal Airway: A Critical Review. Facial plastic surgery: FPS, 32(1), 17–21. https://doi.org/10.1055/s-0035-1570323
2. Sharif-Askary B, Carlson AR, Van Noord MG, Marcus JR. Incidence of Post-Operative Adverse Events After Rhinoplasty: A Systematic Review. Plastic and Reconstructive Surgery. 2019.
3. Jacobowitz O, Driver M, Ephrat M. In-office treatment of nasal valve obstruction using a novel, bipolar radiofrequency device. Laryngoscope Investigative Otolaryngology. 2019; 4(2):211-217.
4. 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. International Focum of Allergy and Rhinology. 2021; 11(12):1676-1684.
5. Ephrat M, Jacobowitz O, Driver M. Quality-of-life impact after in-office treatment of nasal valve obstruction with a radiofrequency device: 2-year results from a multicenter, prospective, clinical trial. International Forum of Allergy and Rhinology. 2021; 11(4);755-765.
6. Jacobowitz O, Ehmer D, Lanier B, Scurry W, Davis B. Long-term outcomes following repair of nasal valve collapse with temperature-controlled radiofrequency treatment for patients with nasal obstruction.
7. Kandathil CK, Spataro EA, Laimi K, Moubayad SP, Most SP, Saltychev M. Repair of the lateral nasal wall in nasal airway obstruction: a systematic review and meta-analysis. JAMA Facial Plastic Surgery. 2018. Jul-Aug; 20(4):307-313.
8. Clark DW, Del Signore AG, Raithatha R, Senior BA. Nasal Airway Obstruction: Prevalence and Anatomic Contributors. Ear, Nose & Throat Journal. 2018;97(6):173-176.
9. Schuman, T. A., & Senior, B. A. (2018). Treatment Paradigm for Nasal Airway Obstruction. Otolaryngologic clinics of North America, 51(5), 873–882. https://doi.org/10.1016/j.otc.2018.05.003

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