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Radiofrequency device as an alternative therapy for refractory nasal valve collapse

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ABSTRACT A clinical decision report using:

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 Dec;11(12):1676-1684.
<http://doi.org/10.1002/alr.22861>

for a patient with nasal valve collapse.

Keywords: *temperature-controlled radiofrequency device treatment, nasal valve collapse*

Clinical-Social Context

Ms. Nancy Smith (pseudonym) is a 64-year-old woman (she/her/hers) with a past medical history significant for hypertension, breast cancer, and seasonal allergies. She was once a cocaine user for several years but quit 27 years ago and has not used it since. Her chief complaint deals with a long history of unilateral nasal valve obstruction, which has been getting worse. Concerns including difficulty breathing and a persistent feeling of nasal congestion. She has had difficulty breathing due to this obstruction for as long as she can remember but has delayed focusing on its treatment for various reasons, including personal circumstances and other health concerns. As a single mother to three children, one of whom has a neurodevelopmental disability, she had little time to focus on her own healthcare needs. However, she feels as if her breathing has been more hindered lately. She was also drawn away from receiving care for fear of costs, but at her most recent primary care appointment (done after a several-year hiatus), her physician mentioned the potential for sleep apnea which scared her and thus prompted her to seek further help with an otolaryngologist.

Ms. Smith has tried a few management options. Nasal strips applied bilaterally around the nose at bedtime helped for some time but are now inadequate. She has also tried a few nasal congestion sprays with propylhexedrine and oxymetazoline which seemed to treat the congestion surrounding her seasonal allergies more than the valve collapse. Recently, she tried an internal dilator which helped at first, but she is seeking a solution that does not involve having to worry about a device.

Flexible nasolaryngoscopy revealed an obstructed nasal valve, possibly due to accumulated injury from previous cocaine use. Pulling skin adjacent to the nose relieves nasal obstruction as well. No other abnormalities are noted on physical examination. The care team's primary concern for Ms. Smith was finding a solution for her refractory difficulty breathing secondary to an obstructed nasal valve that puts her at risk of sleep apnea.

SARA FAROOQUI is a 3rd-year medical student at Wayne State University School of Medicine. DOO HEE KIM is a student at Wayne State University School of Medicine and a student editor of this journal.



Clinical Question

What alternative treatments exist for refractory nasal valve collapse that offer enduring benefits, minimal complications, and require infrequent follow-ups?

Research Article

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 Dec;11(12):1676-1684.
<http://doi.org/10.1002/alr.22861>¹

Description of Related Literature

A PubMed search using key terms “nasal valve collapse” and “treatment” was conducted yielding 270 results. Applying a filter to include only clinical trials narrowed the results down to 18. Studies with focuses on treatments for nasal valve collapse that are other than nasal strips, nasal sprays, and dilators were focused on to emphasize the point of refractory nasal valve collapse.

Studies in the paper include a NOSE score, which is an assessment tool used to survey how a patients’ breathing symptoms are affecting their quality of life. Five questions are answered by the patient on a scale from 0 to 4 with 0 being “Not a problem” and with 4 being “Severe problem” over the past month. The score from the five questions is added and multiplied by 5 giving the nasal obstruction severity classification. 5-25 is considered mild, 30-50 is considered moderate, 55-75 is considered severe, and 80-100 is considered extreme.²

Stolovitzky et al. performed a clinical trial assessing the viability of bioabsorbable implants for patients with nasal valve collapse. In this single-blinded study, approximately half of the subjects received the treatment and the other half a sham control.³ The results showed that this treatment was safe and effective based on valid measures of Nasal Obstruction Symptom Evaluation (NOSE) scores. However, this study was not chosen for appraisal because the study showed efficacy for only up to 3 months post-implant, which fails to answer whether it has enduring benefits for Ms. Smith since making clinic appointments are difficult for her.

Vaiman et al. had an interesting approach in their randomized clinical trial by examining muscle-building therapy’s effectiveness in nasal valve collapse.⁴ They questioned whether nasal muscle-building through a home-exercise program would be effective in patients with the affliction and saw that such a complex therapy has potential benefits as symptoms were diminished especially compared to those whose muscles were electrically stimulated. Despite the “subjective improvement” that patients reported, the study did not include a control group, so it is hard to know whether the improvements were due to the placebo effect or not. Therefore, this study was not chosen for appraisal.

A separate study from Vaiman et al. looked at the use of biofeedback therapy for training nasal muscles.⁵ The researchers used surface electromyography for measurement, and they found that every patient in the trial showed improvement. However, they failed to include a control group, and the study was not chosen for appraisal.

Sufyan et al. conducted a prospective study to see whether autologous alar batten grafts may have any merit in managing patients with nasal obstruction due to nasal valve collapse.⁶ This was an interesting piece as the intervention discussed is surgical in nature, a more invasive option which lent to curiosity in its effectiveness. The researchers learned that not only was this treatment beneficial for the purposes of nasal valve collapse and helping patients breathe better, but nasal allergy symptoms were also improved, and patients’ nasal steroid use was also diminished subsequently. However, this study was not selected for appraisal because it focused on an invasive method that used a graft that may not be available everywhere. In addition, the cost of the operation and the graft were not mentioned, but it must be considered considering she has previously avoided doctor’s appointments due to fear of costs.

Although Yoo et al.’s clinical trial focused on post-rhinoplasty outcomes, their analysis of use of auto spreader flap relates to nasal obstruction.⁷ They found that use of this technique had merit especially in patients with pre-existing mid-vault collapse. This study focused more on patients undergoing a rhinoplasty for cosmetic reasons and was unrelated to Ms. Smith’s situation; therefore, it was not selected for appraisal.



The study done by Silvers et al. was selected as the paper for appraisal. They performed a single-blinded randomized control trial with patients from multiple facilities assessing the efficacy of radiofrequency therapy for nasal valve collapse.¹ Although the study is relatively new, the study is well designed with data showing evidence that the outcomes are overwhelmingly positive. Based on the SORT criteria, the Level of Evidence for this study is Level 1.⁸

Critical Appraisal

The randomized clinical trial conducted by Silvers et al. has many strengths.¹ Being a single-blinded (from patient's perspective) randomized control trial with patients from multiple facilities, the study was well-designed. Inclusion criteria for this study include age between 18 and 85, being a patient specifically seeking treatment for their nasal valve collapse, a NOSE score of at least 55, positive Cottle maneuver (lateral cheek pull relieving symptoms), patient not being satisfied with medical treatment thus far, and the main source of nasal obstruction being valve collapse. Exclusion criteria included previous surgical intervention for this purpose, polyps, turbinate hypertrophy, or severe septal deviation. Of note, the study was not double-blinded as the researchers could not practically perform either task without knowing what the subjects were receiving; the technicalities were completely different.

According to the above inclusion and exclusion criteria, Ms. Smith checked all the boxes in being a candidate for the randomized control trial. Using an exact test, a sample size minimum of 99 patients, with two-thirds in the experimental group and one-third in the control group, was given. Ultimately, 117 eligible patients were selected. The demographics of the experimental group and the control group were compared using a t-test for continuous data and Fisher exact test for categorical data. The study failed to mention the effects of selection/attrition bias on the outcome.

The 117 subjects were randomized and split into the two groups: 77 patients were experimental group to receive the active treatment, and 40 were in the sham-control arm. Both groups received identical patient preparation, for example topical anesthesia administration. All patients were blindfolded during the procedure. The experimental group received bilateral Vivaer treatment in four areas of the nasal mucosa at the interface between the lower and upper lateral cartilage of the wall. Treatment settings were standardized in terms of temperature, power, treatment time, and cooling time.

Patients had a baseline mean NOSE score of 76.⁹ Participants who underwent radiofrequency Vivaer treatment reported a mean decrease in NOSE score of 42.3 vs a mean decrease in NOSE score of 16.8 in the sham control group. The results were statistically significant with a $p < 0.001$. Ultimately, the researchers concluded that the radiofrequency Vivaer treatment is effective in relieving symptoms caused by nasal valve obstruction due to nasal valve collapse. Not only that, but the safety profile was also deemed outstanding with little to no treatment-related adverse events.

This randomized controlled trial was very effective in portraying the point that radiofrequency therapy is an effective treatment for nasal valve collapse, especially given the strict inclusion criteria and need for patients to have refractory symptoms. Minimum sample size determination was also an added strength to this study which was there to ensure that results are as applicable as possible.

Clinical Application

Ms. Smith has been struggling with nasal valve collapse for many years now. She has tried many methods of management including but not necessarily limited to nasal strips, internal dilator, and nasal congestion sprays. They did help to an extent, but she noticed her breathing was becoming harder and her primary physician told her of the possibility of apnea which prompted her to seek care from an otolaryngologist regarding the issue. Ms. Smith was presented with the option to try Vivaer radiofrequency therapy for her nasal valve collapse. She was told that it is a newer management tool but with years of research behind it. She was told of the benefits, potential risks, and potential lack of efficacy.

After long discussion and answering any questions she had, Ms. Smith opted to try Vivaer radiofrequency therapy. She felt as if she had exhausted all other options which even led her to the point of seeing a specialist. Although she was a bit skeptical at the novelty of the therapy, she was amenable to the therapy to improve her quality of life and to subdue any fears she had regarding apnea. She demonstrated understanding that the therapy may not have

the desired effects she wants. A few weeks later, she was scheduled for the in-office procedure and handled it well with no complications. Although her follow-up was just a few weeks following the procedure, she had already noticed a difference in her breathing, and she did not feel the need to always stretch the skin beside her nose to open the nasal passageway.

New Knowledge Related to Clinical Decision Science

Ms. Smith's situation regarding refractory nasal valve collapse allowed the medical team an opportunity to dig further into its management and provided an opportunity to explore newer management options. The use of a large, randomized control trial using valid measurement tools was important in addressing Ms. Smith's concerns. Despite the limited data currently available, a well-designed clinical trial still allowed for the application to a patient. Also considering the early nature of Vivaer therapy, having more data points for future patients is an additional beneficial aspect. With hopes of more research in this area, the adequate clinical data allowed a decision for Ms. Smith to be made.¹⁰

Conflict Of Interest Statement

The authors declare no conflicts of interest.

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