

Effect of Radiofrequency Neurolysis on the Symptoms of Chronic Rhinitis: A Randomized Controlled Trial

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Abstract

Objective. To determine the safety and efficacy of temperature-controlled radiofrequency (RF) neurolysis of the posterior nasal nerve (PNN) area for the treatment of chronic rhinitis.

Study Design. A multicenter, prospective, single-blinded, randomized controlled trial, in which the control arm underwent a sham procedure.

Setting. Sixteen otolaryngology centers.

Methods. Patients with 24-hour reflective Total Nasal Symptom Score (rTNSS) ≥ 6 , including moderate to severe rhinorrhea and mild to severe congestion, were randomized 2:1 to active treatment of the posterior nasal nerve area with a temperature-controlled RF device or a sham procedure, with no RF energy delivery. The stylus was applied bilaterally to nonoverlapping areas of the posterior middle meatus and posterior inferior turbinate in each nostril in the region of the PNN. The primary endpoint was responder rate at 3 months, where a response was defined as $\geq 30\%$ improvement (decrease) in rTNSS from baseline.

Results. Patients had a mean baseline rTNSS of 8.3 (95% CI, 7.9-8.7) and 8.2 (95% CI, 7.6-8.8) ($P = .797$) in the active treatment ($n = 77$) and sham control ($n = 39$) arms, respectively. At 3 months, responder rate was significantly higher in the active treatment arm: 67.5% (95% CI, 55.9%-77.8%) vs 41.0% (95% CI, 25.6%-57.9%) ($P = .009$). The active treatment arm had a significantly greater decrease in rTNSS (mean, -3.6 [95% CI, -4.2 to -3.0] vs -2.2 [95% CI, -3.2 to -1.3]) ($P = .013$). Three adverse events related to the device/procedure were reported, and all resolved.

Conclusion. This randomized controlled trial showed temperature-controlled neurolysis of the PNN area is free from significant adverse events and superior to a sham procedure in decreasing the symptom burden of chronic rhinitis.

Keywords

rhinitis, rhinorrhea, congestion, posterior nasal nerve, radiofrequency ablation, neurolysis

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Posterior nasal nerve (PNN) neurectomy is a surgical option for patients experiencing chronic rhinitis symptoms refractory to medical management such as antihistamines and corticosteroid or anticholinergic sprays.^{1,2} The PNN, composed of both sensory and autonomic nerves, provides parasympathetic innervation of the nasal mucosa. Due to its location distal to the pterygopalatine ganglion, neurolysis in the nasal cavity helps to minimize the dry eye side effects seen in other surgical procedures, such as a Vidian neurectomy. Developments in minimally invasive treatment options focused on the PNN area for the treatment of the symptoms of rhinitis include a handheld cryosurgical ablation device³⁻⁵ and endoscopic laser ablation.⁶

Radiofrequency (RF) energy-based devices are widely used in nasal therapies, including turbinate reduction and tonsil ablation.⁷⁻⁹ Temperature-controlled RF technology is different from most RF devices in that the device monitors tissue temperature and automatically adjusts the RF current to maintain a therapeutic treatment temperature, resulting in less adjacent tissue injury. A temperature-controlled RF device has demonstrated safety and efficacy when applied to the nasal valve for the treatment of nasal obstruction.^{10,11} The

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Table 1. The 24-Hour Reflective Total Nasal Symptom Score (rTNSS) Questionnaire Used in the Trial.

For each of the 4 symptoms listed below, check the box in the column that best describes how that symptom has impacted your quality of life in the **last 24 hours**.

	Rating 0: No symptoms	Rating 1: Mild symptoms (minimal awareness, easily tolerated)	Rating 2: Moderate symptoms (definite awareness, symptom is bothersome but tolerable)	Rating 3: Severe symptoms (hard to tolerate; interferes with daily activities or sleeping)
1. Runny nose	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Nasal congestion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Nasal itching	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Sneezing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

objective of the randomized controlled trial (RCT) reported here was to determine the safety and efficacy of temperature-controlled RF neurolysis of the PNN area on the symptoms of patients diagnosed with chronic rhinitis.

Methods

Design

This was a prospective, multicenter, single-blinded, RCT with a sham procedure control arm. The trial was a superiority design with 1-way crossover available to the patients randomized to the sham control arm after their 3-month follow-up visit, if still eligible. Data from crossover patients will be available for future publications. Patients were enrolled at 16 centers across the United States. The trial was approved by Western Institutional Review Board (IRB) or center-specific IRBs (Rush University Medical Center IRB, Vanderbilt University IRB, Houston Methodist IRB). The trial was registered at clinicaltrials.gov as NCT04533438. All enrolling site principal investigators were board-certified otolaryngologists.

Eligibility Criteria

A complete list of eligibility criteria is available in the supplemental material (in the online version of the article). Key inclusion criteria were patients aged 18 to 85 years, seeking treatment for chronic rhinitis symptoms of at least 6 months duration, moderate to severe symptoms of rhinorrhea (24-hour reflective Total Nasal Symptom Score [rTNSS] rhinorrhea subscore 2-3), mild to severe symptoms of nasal congestion (rTNSS congestion subscore 1-3), and total rTNSS ≥ 6 . The rTNSS questionnaire is shown in **Table 1**. Key exclusion criteria were anatomic obstructions limiting access to the posterior nasal passage; altered anatomy of the posterior nose as a result of prior sinus or nasal surgery or injury; active nasal or sinus infection; history of significant dry eye, chronic epistaxis, rhinitis medicamentosa, or head or neck irradiation; seasonal allergic rhinitis; a predisposition to excessive bleeding; anticoagulation therapy that could not be discontinued before the trial procedure; prior procedure or surgery for chronic rhinitis; and a predisposition to poor wound healing (in the opinion of the investigator) as the RF stylus creates a lesion at the site of application (when active), as outlined below. All

patients gave written informed consent prior to undergoing any study-specific procedures.

Randomization and Blinding

A 2:1 site-stratified block randomization scheme was used. After enrollment, assignment was determined via a web-based database. Patients were blinded to their assignment and blindfolded during the treatment.

Interventions

The RhinAer System (Aerin Medical) consists of the Aerin Console and the RhinAer Stylus. The single-use disposable stylus delivers bipolar RF energy to tissue. The RhinAer device controls energy delivery by monitoring tissue temperature and automatically adjusting the RF current to maintain a therapeutic treatment temperature of $\sim 60^{\circ}\text{C}$. The target tissue was the posterior middle meatus and superior portion of the posterior inferior turbinate, in the region of the PNN. Patients were treated in-office, were seated, and received topical anesthesia. Lidocaine (with or without epinephrine, per investigator preference) was administered by submucosal infiltration in the target area in both arms. The protocol allowed treatment at 1 to 5 nonoverlapping positions in each nostril, based on target anatomy size. Treatment settings per lesion were temperature, 60°C ; power, 4 W; treatment time, 12 seconds. In the sham procedure, the stylus was identically applied to the tissue, but sounds mimicking treatment were played and no RF energy was delivered. No repeat (touch-up) procedures were permitted throughout the follow-up period. Patients marked a 10-cm visual analog scale (VAS) to capture their pain level immediately postprocedure.

Clinical Endpoints and Sample Size

The primary endpoint was the responder rate at 3 months, where a responder was defined as $\geq 30\%$ improvement (decrease) in rTNSS from baseline. Patients will be followed through 2 years in the trial. Secondary endpoints were the mean change in rTNSS from baseline through 3 months and the rate of device- and procedure-related serious adverse events through 3 months.

A pain VAS score was also collected at 1 and 3 months. A physical and endoscopic nasal exam was completed prior to

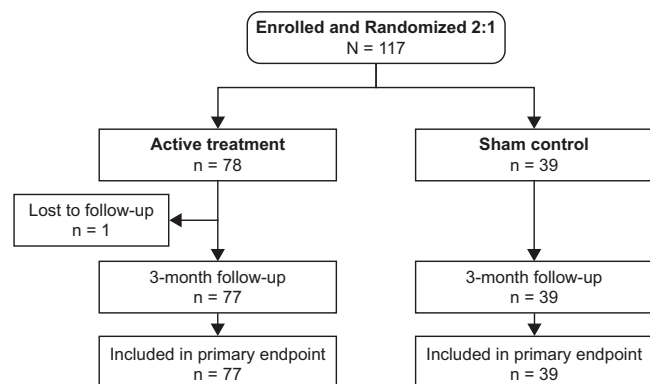


Figure 1. Enrollment, treatment arm allocations, and follow-up through 3 months postprocedure.

the procedure and during follow-up. Adverse events were recorded throughout the follow-up period.

Statistical Analysis

The sample size estimation was based on comparison of 2 proportions using a Fisher exact test, assuming 80% responder rate in the active treatment arm, 50% in the sham control arm, treatment allocation 2:1, significance level of .05 (2-sided), and 80% power. This resulted in a minimum of 99 patients (66 active treatment/33 sham control). After adjustment to allow for unevaluable patients and a distribution across the sites, 120 was the enrollment target.

Demographic and baseline characteristics of the active treatment and sham control arms were compared using *t* tests for continuous data and Fisher exact tests for categorical measures. Mean rTNSS and rTNSS subscores (on a scale of 0-3 for each subscore) and 95% CIs were calculated at baseline and 3 months. The within-arm changes in rTNSS total scores were calculated as the mean of the follow-up visit score minus the baseline score, compared using paired *t* tests, and the between-arm changes compared using *t* tests. Due to data not meeting the normality assumption necessary for *t* tests, the within-arm changes in rTNSS subscores were compared using Wilcoxon signed rank tests and the between-arm changes compared using Wilcoxon-Mann-Whitney tests. A negative change is indicative of a decrease (improvement) in rTNSS total scores and subscores. Change from baseline in longitudinal pain VAS data was analyzed using a restricted maximum likelihood-based mixed-model repeated-measures analysis to account for both 1-month and 3-month time points. The primary and secondary endpoint analyses were predefined, and other analyses were post hoc. Statistical analysis was performed using SAS version 9.4 and SAS/STAT version 14.1 (SAS Institute).

Results

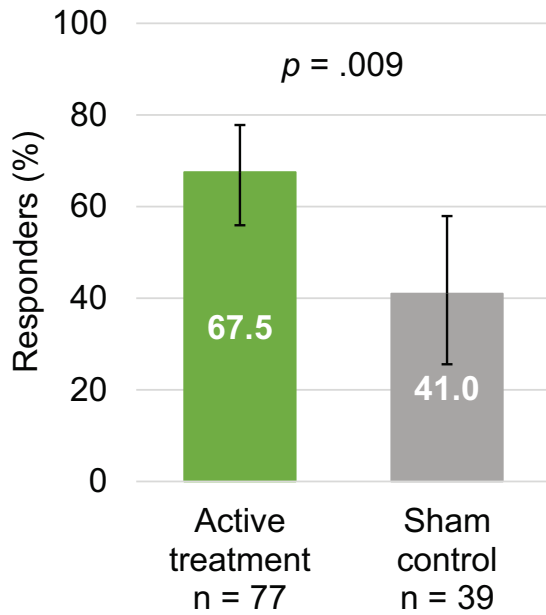
A total of 117 patients were enrolled, randomized, and treated between July 2020 and December 2020, with 78 assigned to active treatment and 39 patients assigned to the sham

Table 2. Patient Demographics and Baseline Characteristics by Treatment Group.^a

Characteristic	Active treatment (n = 77)	Sham control (n = 39)	P value
Female sex	49 (63.6)	26 (66.7)	.838
Age, y	57.3 ± 14.8	57.8 ± 14.4	.864
BMI, kg/m ²	27.8 ± 5.6	28.3 ± 6.3	.651
Race			
Asian	1 (1.3)	0 (0)	
Asian, white	0 (0)	1 (2.6)	
Black or African American	5 (6.5)	1 (2.6)	
Black or African American, white	0 (0)	1 (2.6)	
White	69 (89.6)	36 (92.3)	
Declined choices	2 (2.6)	0 (0)	
Nasal exam			
Turbinate enlargement	16 (20.8)	8 (20.5)	>.999
Nasal polyps	3 (3.9)	0 (0)	.550
Prior nasal surgery	27 (35.1)	13 (33.3)	>.999
rTNSS	8.3 ± 1.9	8.2 ± 1.8	.797
Medication use			
Antihistamines	56 (72.7)	28 (71.8)	>.999
Decongestants	22 (28.6)	10 (25.6)	.828
Oral leukotriene inhibitors	4 (5.2)	3 (7.7)	.686
Intranasal steroid sprays	34 (44.2)	26 (66.7)	.030
Intranasal anticholinergic sprays	19 (24.7)	8 (20.5)	.816

Abbreviations: BMI, body mass index; rTNSS, reflective Total Nasal Symptom Score.

^aContinuous variables are presented as mean ± SD. Categorical measures are presented as number (% of total). Characteristics of the arms were compared using *t* tests for continuous data (after finding insufficient evidence of nonnormality in the measures) and Fisher exact tests for categorical measures.



Responder is $\geq 30\%$ improvement in rTNSS from baseline

Figure 2. Primary endpoint at 3 months, defined as $\geq 30\%$ improvement in reflective Total Nasal Symptom Score (rTNSS) from baseline. Active treatment was superior to the sham procedure control ($P = .009$). Bars represent 95% CIs.

procedure control (**Figure 1**). One patient was lost to follow-up in the active treatment arm, resulting in 77 in the active treatment arm and 39 in the sham control arm available for primary endpoint analysis at 3 months. Basic demographics and baseline characteristics of the patients in each arm are shown in **Table 2**.

Primary endpoint analysis demonstrated a significantly higher responder rate in the active treatment arm than in the sham control arm: 67.5% (95% CI, 55.9%-77.8%) vs 41.0% (95% CI, 25.6%-57.9%), $P = .009$ (**Figure 2**). The primary endpoint was also determined by imputing the patient lost to follow-up in the active treatment arm as a nonresponder, but the superior outcome in the active treatment arm over the sham control arm was unchanged: 66.7% (95% CI, 55.1%-76.9%) vs 41.0% (95% CI, 25.6%-57.9%), $P = .010$. The overall mean rTNSSs in each arm were not significantly different at baseline: 8.3 (95% CI, 7.9-8.7) for active treatment vs 8.2 (95% CI, 7.6-8.8) for sham control, $P = .797$. Secondary endpoint analysis showed the reduction in symptom burden was significantly greater in the active treatment arm at 3 months, as shown by a significantly greater decrease in mean rTNSS: -3.6 (95% CI, -4.2 to -3.0) vs -2.2 (95% CI, -3.2 to -1.3), $P = .013$ (**Figure 3**). This represents a 43.5% improvement in score from baseline in the active treatment arm vs a 26.9% improvement in the sham control arm.

The decrease in rTNSS rhinorrhea and congestion subscores from baseline through 3 months was significantly

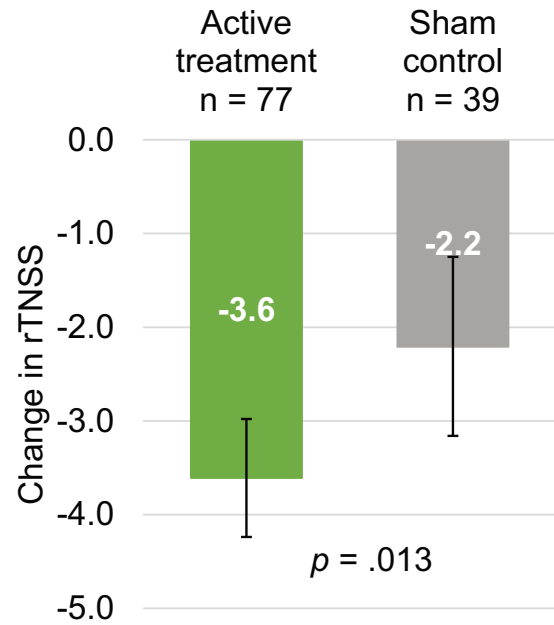


Figure 3. Secondary endpoint at 3 months, change in reflective Total Nasal Symptom Score (rTNSS) from baseline. Change in active treatment arm was significantly greater than in sham control ($P = .013$). Bars represent 95% CIs.

greater in the active treatment arm than in the sham control arm (**Table 3**). The difference in decrease in rTNSS itching subscore from baseline through 3 months between arms did not reach statistical significance (**Table 3**). The distribution of the percentage of patients reporting each subscore clearly shows the significantly larger shift toward lower subscores for rhinorrhea and congestion following active treatment (**Figure 4**; equivalent baseline data are available in the supplemental material in the online version of the article).

The trial was pragmatic in that the protocol did not limit or otherwise prescribe medication use or changes in medication, and the results, therefore, are likely to reflect real-world device effect outcomes. However, medication use, based on a number of classes (antihistamines, decongestants, oral leukotriene inhibitors, intranasal steroid sprays, intranasal anticholinergic sprays), was tracked over time. Medication use between the arms was not significantly different at baseline, except for slightly higher intranasal steroid spray use in the sham control arm (**Table 2**). During follow-up, 12 patients increased use in at least 1 of the medication classes. Of the total of 12 patients with an increase in medication use during follow-up, 7 (9.1%) were in the active treatment arm and 5 (12.8%) were in the sham control arm. Of these 12 patients, a total of 2 patients increased their use of anticholinergic sprays, one in each arm—the patient in the active treatment arm was a responder and the patient in the sham arm was a nonresponder. Notably, the patients who increased anticholinergic spray use also decreased antihistamine and decongestant use. To determine the potential effect of an increase in medication use on the trial outcome, patients with an increase in medication use in both arms were assigned to nonresponder

Table 3. Reflective Total Nasal Symptom Score Subscore at Baseline and the Change From Baseline Through 3 Months in the Active Treatment and Sham Control Arms.

Characteristic	Active treatment (n = 77)				Sham control (n = 39)				P value ^a
	Mean	95% CI	Median	IQR	Mean	95% CI	Median	IQR	
At baseline									
Rhinorrhea	2.7	2.6 to 2.8	3	2 to 3	2.7	2.5 to 2.8	3	2 to 3	.810
Congestion	2.4	2.3 to 2.6	3	2 to 3	2.4	2.2 to 2.6	3	2 to 3	.769
Itching	1.5	1.2 to 1.7	2	1 to 2	1.4	1.1 to 1.7	1	1 to 2	.552
Sneezing	1.7	1.5 to 1.9	2	1 to 2	1.8	1.5 to 2.1	2	1 to 3	.609
Change from baseline									
Rhinorrhea	-1.1	-1.3 to -0.9	-1	-2 to 0	-0.7	-1.1 to -0.3	0	-2 to 0	.029
Congestion	-1.0	-1.2 to -0.8	-1	-2 to 0	-0.5	-0.8 to -0.2	0	-1 to 0	.001
Itching	-0.8	-1.0 to -0.5	-1	-1 to 0	-0.5	-0.8 to -0.1	0	-1 to 0	.279
Sneezing	-0.8	-1.0 to -0.5	-1	-1 to 0	-0.6	-0.9 to -0.3	-1	-1 to 0	.561

Abbreviation: IQR, interquartile range.

^aCompared by Wilcoxon-Mann-Whitney test.

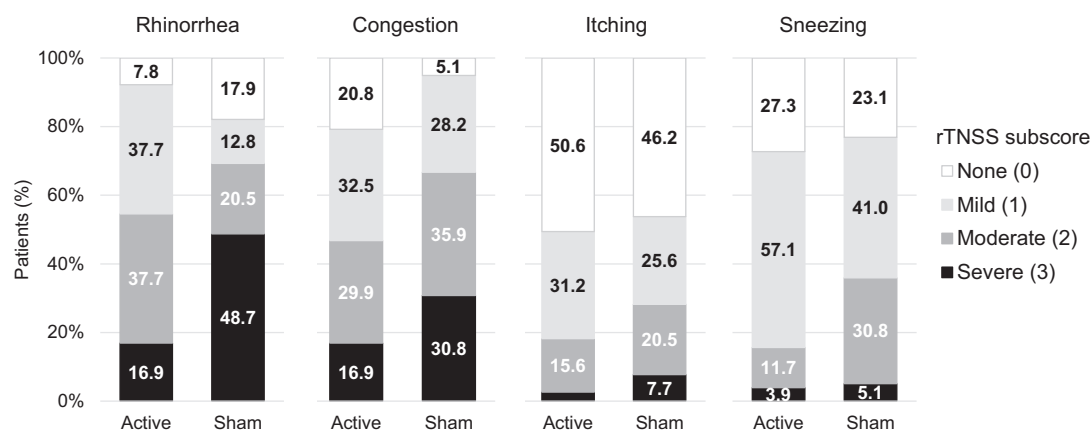


Figure 4. The distribution of patients with the different reflective Total Nasal Symptom Score (rTNSS) subscores at 3 months in the active treatment and sham control arms. Itching severe (active) = 2.6%.

status if not already nonresponders (5 patients in the active treatment arm and 2 in the sham control arm were changed). Primary endpoint analysis with the data imputed in this way did not change the outcome: 61.0% (95% CI, 49.3%-72.0%) vs 35.9% (95% CI, 21.2%-52.8%), $P = .018$.

Nasal pain was recorded on a 10-cm VAS immediately postprocedure and at 1 month and 3 months. The nasal pain was not statistically significantly different between the active treatment and sham control arms immediately postprocedure: active treatment mean, 2.1 (95% CI, 1.6-2.6) vs sham control, 1.4 (95% CI, 0.7-2.0), $P = .078$. At 1 month and 3 months postprocedure, the pain was also not statistically significantly different between the active treatment and sham control arms: 1-month active treatment mean, 0.8 (95% CI, 0.4-1.2) vs sham control, 0.3 (95% CI, 0.0-0.5), $P = .227$; 3-month active treatment mean, 0.6 (95% CI, 0.2-0.9) vs sham control, 0.6 (95% CI, 0.1-1.1), $P = .595$.

No serious adverse events with any potential relationship to the device and/or procedure occurred during the trial. Three

adverse events designated at least possibly related to the device and/or procedure occurred. One patient in the active treatment arm had severe nasal soreness/pain the night after the procedure, accompanied by earache and headache. The event was managed with medications and resolved by the next day. Another patient in the active treatment arm complained of increased nasal congestion at 1 month postprocedure. Mucopurulent discharge consistent with sinusitis was noted on nasal exam. The patient had no further complaint at 3-month follow-up and was a responder. A patient in the sham control arm experienced mild nasal bleeding immediately postprocedure that became severe during the night. Nasal packing resolved the event.

The results of the physical and endoscopic nasal assessment were unremarkable in most patients. Significant dry eye was noted in 1 active treatment patient at 1 month postprocedure but had resolved by 3 months. Severe findings in a total of 7 nostrils were noted postprocedure: 3 in the active treatment arm (1-month swelling/edema, 1-month nasal obstruction from

tissue edema, and immediately postprocedure soreness—there were no severe findings noted at 3 months) and 4 in the sham control arm (3-month swelling/edema, 1-month disruption of mucosal flow [there was no severe finding at 3 months], 1-month and 3-month numbness).

Discussion

The results of this RCT showed that RF neurolysis is superior to sham control in reducing the overall symptom burden, as measured by rTNSS, experienced by patients with chronic rhinitis. The criterion used to define a responder in the primary endpoint ($\geq 30\%$ improvement [decrease] in rTNSS from baseline) corresponds to a 2- to 4-point improvement based on inclusion criteria, which is in line with literature values¹² and is more rigorous than a ≥ 1 -point minimal clinically important difference used in a single-arm study targeting PNN neurectomy via cryosurgical ablation for the treatment of chronic rhinitis.⁵

The efficacy of Vidian and PNN neurectomy is believed to result from interruption of efferent parasympathetic stimulation of the nasal mucosa. Blocking parasympathetic innervation has been shown to reduce submucosal glands secretion, blood flow in the submucosa, and stromal edema.¹³ Furthermore, intranasal botulinum toxin A administration has shown some efficacy in decreasing rhinitis symptoms.^{14,15} The effect of botulinum toxin A on the mucosal lining of the nose is suspected to result from suppression of parasympathetic nerves in the nasal mucosa. The improvement in rTNSS subscores (rhinorrhea, congestion, itching, and sneezing) observed in the active treatment arm of this RCT is consistent with that observed in studies using cryosurgical ablation of PNN (ie, a significant change in each subscore from baseline at 3 months).⁴ When controlled (ie, comparing the change in subscores between arms), rhinorrhea and congestion subscores showed a significantly greater improvement in the active treatment arm. We expected to see an improvement in rhinorrhea symptoms based on the neurolysis mechanism that underlies the device and procedure. Furthermore, reduction in the blood flow in the submucosa and stromal edema may be contributing to the reduction in congestion symptoms observed in the active treatment arm.

This RCT was not designed to demonstrate a reduction in medication use with active treatment and did not dictate medication use. The trial was pragmatic in its design and reflects real-world practice, where medications are an integral part of the management of chronic rhinitis. The review of 12 patients (7 in the active treatment arm and 5 in the sham control arm) that increased medication use demonstrated that increases in medication use at some point in the study were not likely to have affected the overall conclusion of a significant device treatment effect.

It was interesting to note that 3 patients with nasal polyps were treated in the active treatment arm. Two of the 3 patients were responders at 3 months, indicating patients with polyps may be treated with the device as long as the polyps do not prevent access to the target area. Further research is needed in this area.

In our experience, the technique is relatively easy with a quick learning curve, safe, and well tolerated by patients under local anesthesia in the office. Few adverse events were noted in this trial. Furthermore, the pain experienced by patients in the active treatment arm was low and never significantly different from that reported by sham control arm patients from immediately postprocedure through 3 months.

There are a few limitations of this study. The results reported to date are through 3 months, and longer-term follow-up will report on the durability of the effect. Patients with a predisposition to poor wound healing (in the opinion of the investigator) were excluded from this trial, and therefore, the results may not be applicable to this patient population. Investigators were not blinded. However, the rTNSS used in endpoint evaluation was reported by the blinded patient, mitigating the risk of bias. Furthermore, the pain VAS was completed by the blinded patients. Allergy testing was not required, so the relative efficacy by rhinitis subtype could not be compared. Medication use was not controlled and could potentially have had some confounding effect on symptom relief as measured by the rTNSS. However, analysis of the results when assigning all patients in the active treatment arm who reported an increase in medication use to nonresponders did not change the superiority of active treatment over sham control.

Conclusions

The results of this RCT demonstrated that temperature-controlled neurolysis of the PNN area is free from significant adverse events, is effective in reducing the overall symptom burden of chronic rhinitis, and primarily results from significant decreases in rhinorrhea and congestion. The active treatment was superior to a sham procedure control in both responder rate and degree of overall symptom improvement. Long-term follow-up is needed to demonstrate the durability of the treatment effect.

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Author Contributions

J. Pablo Stolovitzky, conception and design, data acquisition, data analysis/interpretation, drafting article, revision for important intellectual content, final approval of version to be published, agreement to be accountable for all aspects of the work; **Randall A. Ow**, data acquisition, revision for important intellectual content, final approval of version to be published, agreement to be accountable for all aspects of the work; **Stacey L. Silvers**, data acquisition, revision for important intellectual content, final approval of version to be published, agreement to be accountable for all aspects of the work; **Nadim B. Bikhazi**, data acquisition, revision for important intellectual content, final approval of version to be

published, agreement to be accountable for all aspects of the work; **Curtis D. Johnson**, data acquisition, revision for important intellectual content, final approval of version to be published, agreement to be accountable for all aspects of the work; **Masayoshi Takashima**, conception and design, data acquisition, data analysis/interpretation, drafting article, revision for important intellectual content, final approval of version to be published, agreement to be accountable for all aspects of the work.

Disclosures

Competing interests: J. Pablo Stolovitzky, consultant for Aerin Medical, Intersect ENT, and Cryosa; Randall A. Ow, consultant for Aerin Medical, Intersect ENT, Lyra Therapeutics, Optinose, and Genentech; Stacey L. Silvers, consultant for Aerin Medical and Intersect ENT; Nadim B. Bikhazi, none; Curtis D. Johnson, consultant for Aerin Medical; Masayoshi Takashima, consultant for Aerin Medical.

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Supplemental Material

Additional supporting information is available at <http://journals.sagepub.com/doi/suppl/10.1177/2473974X2111041124>

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