


Clinical and Quality of Life Outcomes Following Temperature-Controlled Radiofrequency Neurolysis of the Posterior Nasal Nerve (RhinAer) for Treatment of Chronic Rhinitis



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Abstract

Background: Temperature-controlled radiofrequency (TCRF) neurolysis of the posterior nasal nerve (PNN; RhinAer) is a minimally invasive treatment option for patients with chronic rhinitis.

Objective: To determine clinical outcomes and quality of life (QoL) following TCRF neurolysis of the PNN.

Methods: A prospective single-arm study of 129 patients with chronic rhinitis at 16 medical centers in the United States and Germany.

Results: The mean 24-h reflective total nasal symptom score (rTNSS) improved from 7.8 (95% CI, 7.5-8.1) at baseline to 3.6 (95% CI, 3.2-4.0) at 3 months and continued to improve to 2.9 (95% CI, 2.5-3.3) at 6 months ($p < .001$ comparing follow-up to baseline and $p = .002$ comparing 3 and 6 months). This represents 53.8% improvement over baseline at 3 months and 62.8% improvement at 6 months. Rhinorrhea, congestion, sneezing, and itching subscores and postnasal drip and cough scores were all significantly improved over baseline at both timepoints. At 3 months, 76.2% (95% CI, 68.1%-82.8%) of patients achieved a minimal clinically important difference of $\geq 30\%$ improvement in rTNSS over baseline and the percentage was higher at 6 months (83.5% [95% CI, 75.8%-89.0%]). At 3 months, 80.3% (95% CI, 72.6%-86.3%) reported a minimal clinically important difference of ≥ 0.4 -point improvement in the mini rhinoconjunctivitis quality of life questionnaire score, and the percentage was higher at 6 months; 87.7% (95% CI, 80.7%-92.4%). There were no serious adverse events with a relationship to the device/procedure reported through 6 months.

Conclusion: In this large, multicenter study, TCRF neurolysis of the PNN was safe and resulted in a significant reduction in rhinitis symptom burden at 3 months that was sustained/improved through 6 months. The majority of patients reported a clinically relevant improvement in QoL at 3 and 6 months postprocedure.

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Keywords

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Introduction

Chronic rhinitis is a widespread disease with a significant effect on the quality of life (QoL) and work productivity.^{1,2} If pharmacological therapy does not offer adequate relief, patients may consider surgical interventions such as Vidian neurectomy³ or posterior nasal nerve (PNN) neurectomy.^{4,5} A minimally invasive temperature-controlled radiofrequency (TCRF) device designed to treat chronic rhinitis via PNN neurolysis exhibited superiority over a sham procedure at 3 months postprocedure in a randomized controlled trial (RCT).⁶ The treatment also showed a sustained effect through 12 months postprocedure in a separate, single-arm study.⁷ Interest in minimally invasive options (cryoablation and laser ablation) with potential for in-office application has increased in recent years.⁸⁻¹² Here, we report the safety and efficacy results of a large, pragmatic, single-arm study of TCRF neurolysis of the PNN for the treatment of chronic rhinitis. In addition to the standard reflective total nasal symptom score (rTNSS),¹³ this study included use of the mini rhinoconjunctivitis quality of life questionnaire (MiniRQLQ),¹⁴ which is the first time this QoL instrument has been used to report outcomes of the technology.

Methods

Study and Eligibility Criteria

This prospective single-arm study enrolled patients across 16 centers in the United States (13) and Germany (3). The study was approved by WCG Institutional Review Board for all centers in the United States (20202473), the Ethics Committee of Witten/Herdecke University (219/2020), and the Ethics Committee of the Technical University Dresden (BO-EK-463102020) for the centers in Germany. Patients gave written informed consent prior to the initiation of study procedures. The study was registered at clinicaltrials.gov; NCT04614324.

A complete list of eligibility criteria is available in Supplemental information. Key inclusion criteria were 18 to 85 years of age, chronic rhinitis symptoms (≥ 6 months), total 24-h rTNSS ≥ 6 , moderate to severe rhinorrhea (rTNSS rhinorrhea subscore 2-3), and mild to severe nasal congestion (rTNSS congestion subscore 1-3). The main exclusion criteria were anatomic obstructions limiting access to the posterior nasal passage; altered anatomy of the posterior nose via prior sinus or nasal surgery/injury; active nasal/sinus infection; history of significant dry eye, chronic epistaxis, nose bleeds, rhinitis medicamentosa, head/neck irradiation; seasonal allergic rhinitis; a predisposition to excessive bleeding; anticoagulation therapy that could

not be discontinued prior to the procedure; and prior procedure/surgery for chronic rhinitis.

Study Procedure

Patients were treated with the RhinAer Stylus (Aerin Medical), a single-use, disposable device. The target tissue was the posterior middle meatus and superior portion of the posterior inferior turbinate, in the region of the PNN. The protocol dictated treatment at 1-5 nonoverlapping regions on each side, where the number of treatment areas was based on target anatomy size. Patients were treated in-office and received topical anesthesia followed by lidocaine (with or without epinephrine) administered by submucosal infiltration in the treatment area. Treatment settings were: temperature, 60 °C; power, 4 W; treatment time, 12 s. No repeat (touch-up) procedures were allowed during follow-up.

Primary and Secondary Endpoints

The primary endpoint was the mean change in 24-h rTNSS from baseline to 3 months. Secondary efficacy endpoints were responder rate (defined as the minimal clinically important difference [MCID] of $\geq 30\%$ improvement [decrease] in rTNSS¹⁵) and the mean change in the MiniRQLQ¹⁴ score from baseline to 3 months. The validated MiniRQLQ instrument consists of 14 questions across 5 domains: activity limitations, practical problems, nose symptoms, eye symptoms, and other symptoms, based on a 1-week recall. The safety endpoint was the frequency of device-related and procedure-related serious adverse events over 3 months. These data were also collected through 6 months.

Additional Outcome Measures

Responder rate based on the MCID of ≥ 1 point improvement in rTNSS from baseline was also determined.¹³ Postnasal drip and cough symptoms were recorded on a 4-point scale (0-3) at baseline and all follow-up timepoints. MiniRQLQ domain scores were also determined at baseline and all follow-up timepoints. The MCID for MiniRQLQ score is a 0.4-point improvement from baseline.¹⁶ The proportion of patients achieving the MiniRQLQ MCID was determined at 3 and 6 months. Nasal pain was recorded on a 100-point visual analog scale immediately after the procedure and at 3 months; with 0 being no pain and 100 indicating the worst pain imaginable.¹⁷ Medication use was not dictated by the protocol, however, medication classes (antihistamines, decongestants, oral leukotriene inhibitors, intranasal steroid sprays, and intranasal anticholinergic sprays) were recorded

from baseline through 6 months. Patients were asked about their satisfaction with the treatment and whether they were likely to recommend the treatment to a friend suffering from chronic rhinitis at 3 and 6 months postprocedure. Responses were provided on a 5-point scale (0–4, with 4 being “very satisfied” for satisfaction or “yes, absolutely” for a recommendation). Patients will contribute data over 3 years and the results presented in this report represent the data available at the time of submission for publication.

Statistical Analysis

Continuous data are presented as mean and 95% confidence intervals (CI), and categorical data as numbers and percentages of the total, unless stated otherwise. Primary and secondary endpoints were defined by the protocol at 3 months postprocedure; unadjusted means are presented and a *t*-test was used to compare follow-up to baseline. Missing data were not imputed (including some baseline data); population sizes are reported with the result and in Supplemental information. All other outcomes were assessed using a

linear mixed effect model to test for an overall change over time; adjusted (least squares) means are presented, with Tukey–Kramer comparisons between baseline and follow-up visits and between follow-up visits. Generalized estimating equations were used to assess repeated binomial outcome measures and repeated multinomial ordered categorical distributions. Responses to the questions on satisfaction and likelihood to recommend are presented as median (interquartile range [IQR]). SAS/STAT version 15.2 (SAS Institute) was used for analyses.

The analysis population includes all patients treated, including 5 patients who were determined to be ineligible due to an inadequate rTNSS at screening.

Results

A total of 129 patients were treated with TCRF neurolysis of the PNN between October 2020 and March 2021. Patient disposition is shown in Supplemental information. A total of 128 patients reached 3 months (1 lost to follow-up) and 123 patients reached 6 months (2 lost to follow-up, 3 withdrew). Baseline demographics and characteristics of the 129 patients treated with the TCRF device are shown in Table 1. The majority of patients had been suffering from rhinitis for >1 year ($n = 124$, 96.1%).

In the 126 patients with an rTNSS at baseline and 3 months, the mean change in rTNSS at 3 months (primary endpoint) was -4.2 (95% CI, -4.6 to -3.7 ; $p < .001$), a 53.8% improvement from baseline. At 6 months ($n = 121$), the adjusted mean change in rTNSS was -4.9 (95% CI, -5.5 to -4.3), a 62.8% improvement from baseline, $p < .001$ comparing 3 and 6 months to baseline and $p = .002$ comparing 3 and 6 months (Figure 1).

At 3 months, 76.2% (95% CI, 68.1%–82.8%) of patients were responders (secondary endpoint); they had achieved an MCID of $\geq 30\%$ improvement in rTNSS over baseline.

Table 1. Baseline Demographics and Characteristics of Patients Treated with the TCRF Device.*

Characteristic	N = 129	
Female sex	69	(53.5)
Age, years	57.9	± 13.4
BMI, kg/m ²	27.2	± 5.7
Race		
Asian	4	(3.1)
Black or African American	5	(3.9)
White	117	(90.7)
Other	3	(2.3)
Nasal exam (1 or both sides)		
Turbinate enlargement	30	(23.3)
Nasal polyps	3	(2.3)
Prior nasal surgery	44	(34.1)
Rhinitis type ^a		
Allergic	10	(7.8)
Nonallergic	93	(72.1)
Mixed allergic and nonallergic	1	(0.8)
Not known	25	(19.4)
Medication use ^b		
Antihistamines	64	(50.0)
Decongestants	32	(25.0)
Oral leukotriene inhibitors	14	(10.9)
Intranasal steroid sprays	82	(64.1)
Intranasal anticholinergic sprays	33	(25.8)

Abbreviations: TCRF, temperature-controlled radiofrequency neurolysis; BMI, body mass index; rTNSS, 24-h reflective total nasal symptom score. Notes. *Continuous variables are presented as mean \pm standard deviation. Categorical variables are presented as number (% of total).

^aBased on prior knowledge (patient report or physician assessment).

^b $n = 128$.

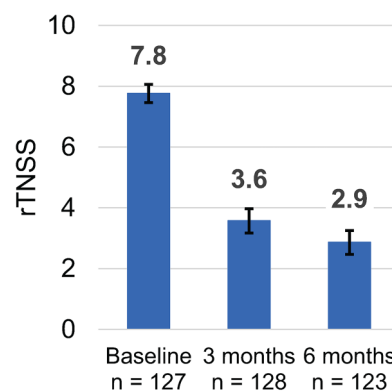


Figure 1. Adjusted mean rTNSS at baseline and follow-up. Bars indicate the 95% confidence interval, $p < .001$ comparing each follow-up timepoint to baseline and $p = .002$ comparing 3 and 6 months. rTNSS = 24-h reflective total nasal symptom score.

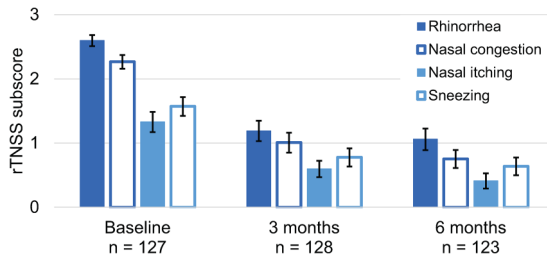


Figure 2. Adjusted mean rTNSS subscores at baseline and follow-up. Bars indicate the 95% confidence interval, $p < .001$ comparing each follow-up timepoint to the baseline for each subscore. Comparing 3 and 6 months, congestion ($p = .005$) and itching ($p = .019$) were significantly further improved at 6 months, sneezing ($p = .066$) and rhinorrhea ($p = .261$) were not significantly different. rTNSS = 24-h reflective total nasal symptom score.

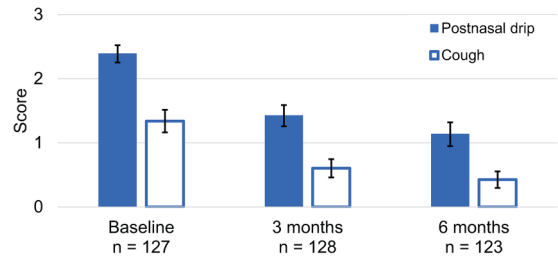


Figure 4. Adjusted mean postnasal drip and cough scores at baseline and follow-up. Bars indicate the 95% confidence interval, $p < .001$ comparing each follow-up timepoint to the baseline for each score. Comparing 3 and 6 months, both postnasal drip ($p = .002$) and cough ($p = .019$) were significantly further improved at 6 months.

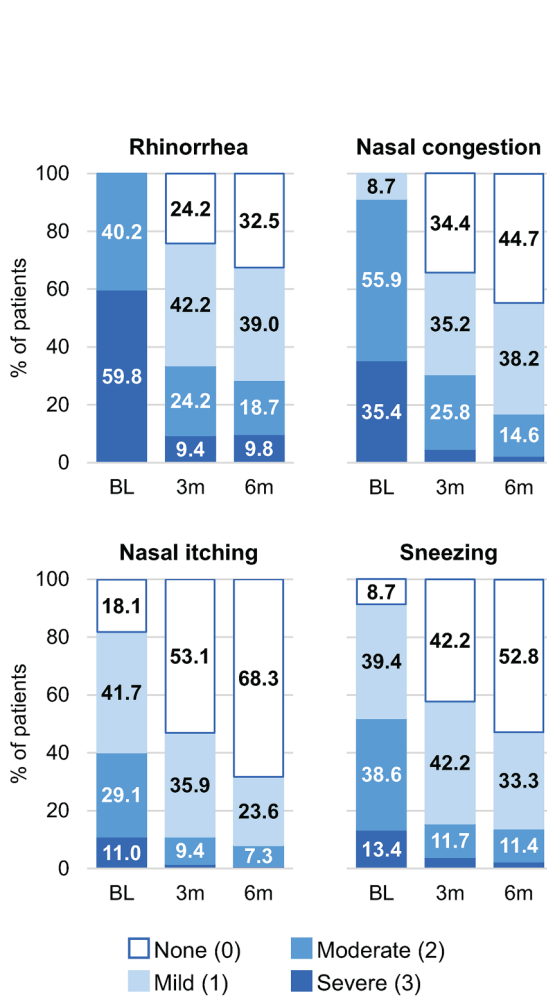


Figure 3. The percentage of patients reporting each rTNSS subscore at baseline and follow-up. $p < .001$ comparing each follow-up timepoint to baseline. Comparing 3 and 6 months, congestion ($p = .002$), itching ($p = .002$), and sneezing ($p = .021$) were significantly further improved at 6 months, and rhinorrhea ($p = .084$) was not significantly different. $n = 127$ at baseline, $n = 128$ at 3 months, and $n = 123$ at 6 months. rTNSS = 24-h reflective total nasal symptom score.

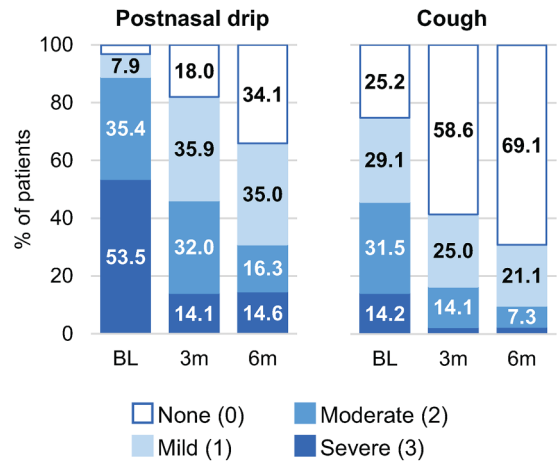


Figure 5. The percentage of patients reporting each postnasal drip and cough score at baseline and follow-up, $p < .001$ comparing each follow-up timepoint to baseline for each score. Comparing 3 and 6 months, both postnasal drip ($p < .001$) and cough ($p = .011$) were significantly further improved at 6 months. $n = 127$ at baseline, $n = 128$ at 3 months, and $n = 123$ at 6 months.

The responder rate was significantly higher at 6 months (83.5% [95% CI, 75.8%-89.0%]; $p = .039$).

Mean rTNSS subscores (rhinorrhea, nasal congestion, itching, and sneezing) were significantly improved from baseline at both timepoints, $p < .001$ comparing each follow-up timepoint to baseline for each subscore (Figure 2). Comparing 3 and 6 months, congestion and itching were significantly further improved at 6 months ($p < .05$); rhinorrhea and sneezing were not significantly different ($p > .05$).

The distributions of the rTNSS subscores further illustrate the significant decrease in symptom burden postprocedure, $p < .001$ comparing each follow-up timepoint to baseline for each subscore (Figure 3; tabulated data in Supplemental information). Comparing 3 and 6 months, congestion, itching, and sneezing were significantly further improved at 6 months ($p < .05$), but rhinorrhea was not significantly different ($p > .05$).

Mean postnasal drip and cough scores were significantly improved at both timepoints, $p < .001$ comparing each follow-up timepoint to baseline for each score, and both further improved between 3 and 6 months ($p < .05$) (Figure 4).

The distributions of the postnasal drip and cough scores also illustrate a significant decrease in symptom burden post-procedure, $p < .001$ comparing each follow-up timepoint to baseline for each score, and both further improved between 3 and 6 months ($p < .05$) (Figure 5, tabulated data in Supplemental information).

Patient reports of periprocedural pain, assessed immediately after completion of the procedure, as well as nasal pain at 3 months, were low on the 100-point scale. The mean periprocedural pain score was 19.0 (95% CI, 14.7-23.2; $n = 129$) and at 3 months, the mean pain score was significantly lower at 4.4 (95% CI, 2.1-6.7]; $p < .001$ by Wilcoxon signed ranks test). There were no serious adverse events related to the study device/procedure through 6 months. A total of 10 adverse events with at least a possible relationship to the study device or procedure were reported in 8 patients with all but 1 reported as mild to moderate in severity (tabulated data in Supplemental information). Single occurrences of vasovagal reaction, dry eye, nasal mucosa changes, ear discomfort, eye pressure, and two events each of sinusitis and nasal soreness were reported during the 6-month follow-up period. One patient developed a late severe nasal adhesion at 96 days postprocedure.

Patient QoL was significantly improved at 3 months post-procedure. In the 127 patients with MiniRQLQ scores at baseline and 3 months, the mean change in MiniRQLQ score at 3 months (secondary endpoint) was -1.6 (95% CI, -1.8 to -1.4 ; $p < .001$), a 53.3% improvement from baseline. At 6 months, the adjusted mean change in MiniRQLQ score was -1.8 (95% CI, -2.1 to -1.5), a 60.0% improvement

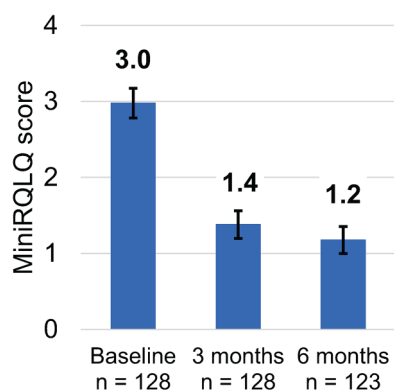


Figure 6. Adjusted mean mini rhinoconjunctivitis quality of life questionnaire (MiniRQLQ) score at baseline and follow-up. Bars indicate the 95% confidence interval, $p < .001$ comparing each follow-up timepoint to baseline and $p = .022$ comparing 3 and 6 months.

from baseline, $p < .001$ comparing 3 and 6 months to baseline and $p = .022$ comparing 3 and 6 months (Figure 6).

At 3 months, 80.3% (95% CI, 72.6%-86.3%) of patients had achieved an MCID of ≥ 0.4 -point improvement in MiniRQLQ score over baseline. The percentage at 6 months had significantly increased to 87.7% (95% CI, 80.7%-92.4%; $p = .022$).

Mean MiniRQLQ domain scores (activity limitations, practical problems, nose symptoms, eye symptoms, and other symptoms) were all significantly improved from baseline, $p < .001$ comparing each follow-up timepoint to baseline for each domain score (Figure 7). Comparing 3 and 6 months, nose and eye symptoms were further improved at 6 months ($p < .05$); activity and practical limitations and other symptoms were not significantly different ($p > .05$).

Medication use was not dictated by the protocol. To ensure medication use was not substantially affecting the treatment effect size, the changes in rTNSS and rTNSS-based responder rate were determined after imputing the data of any patients with an increase in at least 1 medication class (antihistamines, decongestants, oral leukotriene inhibitors, intranasal steroid sprays, and intranasal anticholinergic sprays) from the timepoint of increase onwards; the change in rTNSS was imputed as zero and a responder was imputed as a nonresponder if not already a nonresponder. Baseline medication use is shown in Table 1. Seven patients had an increase in at least 1 medication class from baseline at some point in the study and the results of the data imputation for these patients are shown in Table 2, illustrating the minimal change in result. The same imputation methods were applied to evaluate the change in MiniRQLQ score and the percentage of patients achieving the MiniRQLQ ≥ 0.4 -point improvement MCID. Table 3 shows the results of these analyses, again illustrating the minimal difference in the results obtained after data imputation.

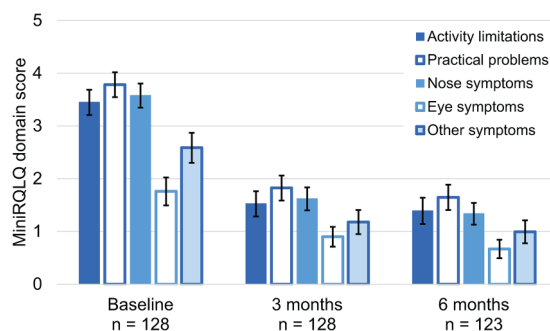


Figure 7. Adjusted mean mini rhinoconjunctivitis quality of life questionnaire (MiniRQLQ) domain scores at baseline and follow-up. Bars indicate the 95% confidence interval, $p < .001$ comparing each follow-up timepoint to the baseline for each domain score. Comparing 3 and 6 months, nose and eye symptoms were improved at 6 months ($p < .05$); activity and practical limitations and other symptoms were not significantly different ($p > .05$).

Table 2. Adjusted Mean Change in rTNSS and Percentage of Patients Achieving an rTNSS MCID (Responder Rate): (i) With no Data Imputation and (ii) With Data Imputation for Increased Medication Use.

	3 months		6 months	
Change in rTNSS ^a				
No imputation ^b	-4.2	(-4.7 to -3.7)	-4.9	(-5.5 to -4.3)
Medication increase imputation ^c	-4.1	(-4.7 to -3.6)	-4.6	(-5.3 to -4.0)
Responder rate ^d				
No imputation ^b	76.2%	(68.1% to 82.8%)	83.5%	(75.8% to 89.0%)
Medication increase imputation ^c	74.6%	(66.4% to 81.4%)	78.5%	(70.4% to 84.9%)

Abbreviations: MCID, minimal clinically important difference; rTNSS, 24-h reflective total nasal symptom score.

Notes. rTNSS presented as mean (95% confidence intervals). MCIDs presented as percentages (95% confidence intervals).

^aChange in rTNSS from baseline.

^b $n = 126$ at 3 months and $n = 121$ at 6 months.

^cImputing data from the 7 patients with an increase in at least 1 class of medication class (antihistamines, decongestants, oral leukotriene inhibitors, intranasal steroid sprays, intranasal anticholinergic sprays) from the timepoint of increase onwards to a change in rTNSS of zero or to nonresponder status (not achieving MCID) if not already a nonresponder. Three data points were imputed at 3 months, and 7 data points were imputed at 6 months.

^dPercentage of patients that achieved a decrease in rTNSS of $\geq 30\%$ from baseline (responder rate).

Table 3. Adjusted Mean Change in MiniRQLQ Score and Percentage of Patients Achieving the MiniRQLQ MCID, (i) With no Data Imputation and (ii) With Data Imputation for Increased Medication Use.

	3 months		6 months	
Change in MiniRQLQ score ^a				
No imputation ^b	-1.6	(-1.9 to -1.3)	-1.8	(-2.1 to -1.5)
Medication increase imputation ^c	-1.6	(-1.9 to -1.3)	-1.7	(-2.0 to -1.4)
Achieved MiniRQLQ MCID ^d				
No imputation ^b	80.3%	(72.6%-86.3%)	87.7%	(80.7%-92.4%)
Medication increase imputation ^c	78.7%	(70.8%-85.0%)	82.8%	(75.1%-88.5%)

Abbreviations: MCID: minimal clinically important difference; MiniRQLQ: mini rhinoconjunctivitis quality of life questionnaire.

Notes. MiniRQLQ score presented as mean (95% confidence intervals). MCIDs presented as percentages (95% confidence intervals).

^aChange in MiniRQLQ score from baseline.

^b $n = 127$ at 3 months and $n = 122$ at 6 months.

^cImputing data from the 7 patients with an increase in at least 1 class of medication class (antihistamines, decongestants, oral leukotriene inhibitors, intranasal steroid sprays, and intranasal anticholinergic sprays) from the timepoint of increase onwards to a change in MiniRQLQ score of zero or to below the MCID if not already below the MCID. Three data points were imputed at 3 months, and 7 data points were imputed at 6 months.

^dPercentage of patients that achieved a decrease in MiniRQLQ score of ≥ 0.4 points from baseline.

In response to a question on satisfaction with the treatment, the median score was 3 (IQR, 2-4) at both 3 and 6 months. In response to a question on whether patients were likely to recommend the treatment to a friend who suffered from chronic rhinitis, the median score was 4 (IQR, 2-4) at 3 months and 4 (IQR, 3-4) at 6 months.

Discussion

The results of this study contribute to the increasing amount of data demonstrating a significant and clinically important reduction in symptom burden from minimally invasive TCRF neurolysis of the PNN.⁷ A high percentage of patients achieved the MCID of $\geq 30\%$ improvement in rTNSS over baseline (76.2% and 83.5% at 3 and 6 months, respectively). This MCID is a more stringent test than ≥ 1 -point

improvement,¹³ which has previously been used to evaluate the TCRF device⁷ and other technologies targeting the PNN area (cryoablation).^{18,19} The responder rate based on ≥ 1 point improvement in this study was $>90\%$ at both timepoints (96.0% [95% CI, 91.1%-98.3%] at 3 months and 95.0% [95% CI, 89.6%-97.7%] at 6 months). The 3-month results of this single-arm study are on par with the results of an RCT, in which active TCRF device treatment was demonstrated to be superior to a sham procedure at 3 months.⁶

The results of the postnasal drip and cough assessments are interesting as these symptoms are not assessed by the widely used rTNSS instrument but are commonly associated with chronic rhinitis; both showed significant improvement at 3 and 6 months.

This large study also showed an improvement in QoL as early as 3 months postprocedure, reported using a validated

instrument, and the effect was maintained through 6 months. The MiniRQLQ was selected for this study based on ease of use, with 14 questions in 5 domains. Again, a large percentage of patients achieved the MCID of ≥ 0.4 -point improvement at 3 and 6 months. This MCID has been used in reports on other technologies targeting the PNN area for the treatment of chronic rhinitis.^{18,19} There does not appear to be any domain of the MiniRQLQ that was dominating the overall outcome, as all domains showed significant improvement at each follow-up timepoint.

The safety profile of the device/procedure was excellent during this study and no safety concerns arose. The in-office procedure utilizes a combination of topical anesthesia followed by submucosal infiltration with lidocaine (with or without epinephrine) at the treatment sites. Patients reported minimal periprocedural pain, which may be a consequence of the controlled temperature feature of the device. The advantage of TCRF over radiofrequency (RF), in general, is that a therapeutic treatment temperature of $\sim 60^{\circ}\text{C}$ is maintained as the stylus delivers bipolar RF energy to tissue and monitors tissue temperature, and automatically adjusts the RF current. The controlled temperature allows neurolysis to occur but limits the damage to overlying mucosa and adjacent tissues. Importantly, no headaches or other significant pain-related adverse events were reported. In comparison with other technologies targeting the PNN area for the treatment of chronic rhinitis, headache, and postprocedural pain at the treatment site are among the most commonly reported pain-related symptoms after cryoablation of the PNN.^{9,11,20} A report on diode laser ablation included patients treated under sedation in the operating room (21 of 31) and in the office (10 of 31), where the postprocedural pain score was 1.8 out of 10 for patients treated in the office.¹²

The data imputation methods used in this study to evaluate the potential that an increase in medication use confounds the treatment effect delivered by the device were similar to that used in the RCT evaluating the technology.⁶ Medications are widely used to manage the symptoms of chronic rhinitis and it was therefore considered pragmatic not to dictate medication use in the protocol, thereby enabling the results to more closely reflect real-world outcomes. Considering that changes in rTNSS responder rate, MiniRQLQ score, and the number of patients achieving the MiniRQLQ MCID were minimally affected when imputing the data of patients with an increase in medication use, supports the hypothesis that the treatment effect is primarily from the device.

Patient satisfaction with the procedure was high and the majority of patients were likely to recommend the procedure to a friend suffering from chronic rhinitis, based on responses to questions at both 3 and 6 months.

The limitations of this study were the lack of a control arm and the limited follow-up to date. The effect sizes of the primary and secondary efficacy endpoints were large; although unlikely, it is possible that placebo effects may

have contributed to the overall observed effect. Medication use was not limited by the protocol, but the study was pragmatically designed to collect real-world outcomes. While the current study shows the efficacy of this technology, future research is needed to determine cost-benefit analysis.

Conclusion

In this large, pragmatic study in the United States and Europe, TCRF neurolysis of the PNN resulted in a significant improvement in both chronic rhinitis symptom burden and disease-specific QoL at 3 and 6 months postprocedure. Patients reported a significant reduction in rhinorrhea, nasal congestion, itching, and sneezing, in addition to a significant reduction in postnasal drip and cough symptoms. No serious adverse events with a relationship to the device/procedure were reported through 6 months. Continued follow-up will confirm that treatment effects are consistent with previously published long-term evidence.

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Declaration of Conflicting Interests

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Supplemental material

Supplemental material for this article is available online.

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