

Predictors of rhinorrhea response after posterior nasal nerve cryoablation for chronic rhinitis

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Background: Posterior nasal nerve (PNN) cryoablation has shown promise in improving rhinorrhea due to allergic and nonallergic rhinitis (NAR). Early case series have shown meaningful clinical improvement in 75-80% of patients, but variables predicting PNN cryoablation success have not been studied. The purpose of this study was to evaluate whether disease features and ipratropium nasal spray response predicted rhinorrhea response after PNN cryoablation.

Methods: A multi-institutional retrospective case-control study of 55 patients who underwent PNN cryoablation for bilateral rhinorrhea due to allergic, nonallergic, or mixed rhinitis was conducted at 3 tertiary medical centers. Patients received a 1-month trial of ipratropium spray. Runny Nose Scores (RNSs) of 0-5 from the 22-item Sino-Nasal Outcome Test were collected prospectively, before and after PNN cryoablation.

Results: The mean age of subjects was 55.3 years and 54.6% were women. Mean follow-up was 170 days. NAR comprised 62% of patients. Of the 48 patients who trialed ipratropium spray, 33 (69%) had some response and 15 (31%) had no response. Mean overall preprocedural RNS was 4.2 ± 1.0 .

After PNN cryoablation, there was a ≥ 1 -point decrease in RNS in 39 patients (71%). Only ipratropium spray (INS) response predicted cryoablation success. For ipratropium spray responders, 28 of 33 (85%) had improved RNS after cryoablation, whereas 5 of 15 (33%) nonresponders improved ($p = 0.001$).

Conclusion: In chronic rhinitis patients, rhinorrhea response to ipratropium was predictive of rhinorrhea improvement after PNN cryoablation. This study has important implications for preoperative counseling and guiding patient expectations when considering PNN cryoablation. © 2020 ARS-AAOA, LLC.

Key Words:
rhinitis; chronic disease; therapeutics

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Chronic rhinitis is a common problem in the general population, affecting an estimated 60 million Americans.¹ Types of chronic rhinitis include allergic

rhinitis (AR), nonallergic rhinitis (NAR), and mixed rhinitis. AR is highly prevalent in 11-33% of the US population.² Although AR is roughly 3 times as prevalent as NAR, 60% of AR patients will actually have mixed rhinitis.³ Symptoms of rhinitis depend on the contributions from AR and NAR, but can include different combinations rhinorrhea, nasal obstruction, postnasal drip, nasal pruritis, and sneezing, each which can significantly impact quality of life.^{2,4} Chronic rhinitis can be treated medically with intranasal corticosteroids, antihistamines (oral and intranasal), leukotriene receptor inhibitors, mast cell stabilizers, intranasal anticholinergics, and decongestants.² These different medications can be employed based on type of rhinitis and symptoms associated with the rhinitis.

Rhinorrhea due to NAR or mixed rhinitis can cause significant impairment to one's daily activities, due to constant, periodic, or trigger-induced episodes of nasal drainage. Vasomotor rhinitis, a subtype of NAR, classically

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involves trigger-induced rhinorrhea with meals, alcohol, and temperature change, and may affect the elderly population at an increased rate.⁵⁻⁷ Ipratropium bromide nasal spray, an anticholinergic that blocks parasympathetic neurotransmission to secretory mucus glands of the nasal mucosa, has been shown in multiple randomized, controlled trials to significantly improve rhinitis-related rhinorrhea.⁸⁻¹⁰

Limited evidence exists on the success of various medical therapies for rhinitis-related rhinorrhea, but one study showed a 10-22% failure rate of medical therapy of chronic rhinitis.¹¹ Multiple surgical therapies have been described for rhinitis-related rhinorrhea to decrease or eliminate parasympathetic innervation to the intranasal mucus glands. These procedures have included inferior turbinate reduction, botulinum toxin injections, vidian neurectomy, posterior nasal neurectomy, and intranasal cryoablation,^{3,12} each demonstrating varying degrees of success. Intranasal cryoablation was first described in the 1970s,^{3,13-19} but there has been limited study of its efficacy until recently. A systematic review of 15 studies investigating cryotherapy in the treatment of chronic rhinitis showed general symptomatic improvement in 67-100% of patients, with rhinorrhea improvement in 77-100% of patients.¹ Recently, a new device, Clarifix (Stryker, Kalamazoo, MI), was developed to facilitate intranasal cryoablation of the posterior nasal nerve (PNN). Two prospective, noncontrolled studies of this device have shown significant improvement in subjective symptom scores, including rhinorrhea, at up to 365 days.^{11,20} Chang et al showed that 70-80% of patients achieved a minimal clinically important difference (MCID) in the Reflective Total Nasal Symptom Scale (rTNSS), but 20-30% of patients did not improve significantly.¹¹ It would be beneficial to determine whether certain factors could predict which patients may or may not respond to PNN cryoablation.

The purpose of this study was to determine whether certain demographics, disease characteristics, and/or procedure-related factors were associated with subjective improvement in rhinorrhea after undergoing PNN cryoablation with the Clarifix device. Identifying such factors could facilitate patient selection and management of patient expectations when consenting for the cryoablation procedure.

Patients and methods

A multi-institutional retrospective case-control study was performed, and institutional review board approval was obtained at each site individually. Patients who underwent PNN cryoablation using the Clarifix device between October 2017 and September 2019 at the Henry Ford Health System (Detroit, MI) facility, the University of California Irvine (Irvine, CA), and Rush University (Chicago, IL) were identified. Data were collected prospectively as part of each surgeon's clinical practice and obtained for analysis through retrospective review.

All patients failed at least a 1-month trial of 0.06% ipratropium nasal spray, used as often as patients felt necessary to control their rhinorrhea. If patients had an inadequate response to the ipratropium spray, they were offered intranasal cryoablation via the Clarifix device. Intranasal cryoablation was performed according to previous publications and company information, either in the office or operating room.²⁰ After topical anesthesia and decongestion, all patients underwent cryoablation with the Clarifix device along the posterior aspect of the lateral wall of the middle meatus, just anterior to the middle turbinate's posterior insertion. Cryogen was applied to each site for 30-60 seconds, according to surgeon discretion. Only 2 patients underwent cryoablation treatment in both the middle meatus and the inferior meatus.

The following demographics and disease characteristics were collected: age, gender, smoking status, rhinitis type (AR, NAR, or mixed rhinitis), presence or absence of rhinorrhea triggers, and ipratropium spray use and response. Rhinitis types were defined based on allergy testing and clinical history. Mixed rhinitis was diagnosed when patients had positive allergy tests along with clinical histories of nonallergic symptom triggers such as food, alcohol, temperature changes, or others. Ipratropium response was defined as any improvement vs no improvement in rhinorrhea as reported by patients. The following procedure-specific information was also collected: location of procedure (clinic or operating room), primary vs revision procedure, concurrent septoplasty, number of cryoablative applications per side, and complications. Patient-reported outcomes regarding runny nose were determined using the Runny Nose Score (RNS) from the 22-item Sino-Nasal Outcomes Test (SNOT-22), and were collected before and after cryoablation. After cryoablation, the RNS was collected at each follow-up visit. All patients required a minimum of 4 weeks of follow-up for inclusion.

Statistical analysis was performed using SAS version 9.4 (SAS Institute, Cary, NC). Descriptive statistics for patients were tabulated. Comparisons of categorical variables were conducted utilizing chi-square and Fisher's exact tests. Continuous variable comparisons were conducted using the Wilcoxon matched pairs signed rank test. Regression analysis was performed to trend SNOT-22 RNS scores over time. Significance was set at $p < 0.05$.

Results

A total of 55 patients were included in this study. Demographics, patient characteristics, and procedure-related data are presented in Table 1. Women represented 54.5% of the study patients, and the mean age was 55.3 ± 17.2 years. Of the rhinitis types, AR was most common (61.8%), followed by mixed rhinitis (23.6%) and AR (14.6%). The vast majority of patients were nonsmokers (92.7%). Only 37.0% of patients reported specific triggers for their rhinorrhea. Of the 55 patients, 48 had a trial of ipratropium

TABLE 1. Demographics, patient characteristics, and procedure data

	Total cohort (N = 55)
Gender	
Male	25 (45.4%)
Female	30 (54.5%)
Age, in years (mean $\pm$ SD)	55.3 $\pm$ 17.2
Diagnosis (%)	
Allergic rhinitis	8 (14.6%)
Nonallergic rhinitis	34 (61.8%)
Mixed rhinitis	13 (23.6%)
Smoking status	
Nonsmoker	51 (92.7%)
Smoker	4 (7.3%)
Rhinitis symptom triggers	
None	20 (37.0%)
Food	19 (35.2%)
Alcohol	3 (5.6%)
Temperature changes	19 (35.2%)
Fragrances	2 (3.7%)
Exercise	4 (7.4%)
Other	4 (7.4%)
Ipratropium response	
No improvement	15 (27.3%)
Any improvement	33 (60.0%)
Never tried	7 (12.7%)
Preprocedure SNOT-22 RNS (mean $\pm$ SD)	4.2 $\pm$ 1.0
Preprocedure ipratropium use	
0 times per day	1 (1.8%)
1 time per day	4 (7.3%)
2 times per day	13 (23.6%)
3 times per day	20 (36.4%)
4 times per day	7 (12.7%)
5 times per day	2 (3.6%)
6 times per day	1 (1.8%)
Not used	7 (12.7%)
Location of procedure	
Clinic	34 (61.8%)
OR	21 (38.2%)

(Continued)

TABLE 1. Continued

	Total cohort (N = 55)
Primary vs revision procedure	
Primary	51 (92.7%)
Revision	4 (7.3%)
Concurrent septoplasty	8 (14.6%)
Number of treatments per side (mean $\pm$ SD)	1.55 $\pm$ 0.50
Complications	
None	42 (79.3%)
Headache	4 (7.5%)
Facial pain	6 (11.3%)
Palate numbness	3 (5.7%)
Mean follow-up (days)	169.7 $\pm$ 159.4

OR = operating room; RNS = Runny Nose Score; SD = standard deviation.

bromide nasal spray, where they used the spray at various frequencies as needed for their rhinorrhea. Patients utilized ipratropium spray anywhere from 1 to 6 times a day as needed to control their rhinorrhea.

The mean preprocedural RNS was 4.2 (standard deviation [SD], 1.0). The majority of cryoablation procedures were performed in the office (61.8%). Only 4 patients undergoing cryoablation had received the procedure previously (7.3%). Concurrent septoplasty was required in 8 patients (14.6%). Complications occurred in only 13 patients, with temporary facial pain being the most common, seen in 11.3% of patients. Mean postprocedural follow-up was 169.7 $\pm$ 159 (range, 30-655) days.

Postprocedural RNS was significantly improved at the first (n = 50; RNS, 2.30 $\pm$ 1.84; p = 0.001), second (n = 38; RNS, 1.95 $\pm$ 1.79; p = 0.001), and third (n = 15; RNS, 2.60 $\pm$ 1.68; p = 0.002) postprocedure visits. Cryoablation success and factors associated with improvement in RNS are presented in Table 2. Success analysis was performed based on both any improvement of RNS by ≥ 1 point, as well as for RNS improvement of ≥ 2 points. Overall, 33 of 48 (68.8%) patients had at least some improvement in RNS, whereas 28 of 48 (58.3%) patients had a ≥ 2 -point improvement in RNS. Ipratropium spray response was the only factor significantly associated with improvement in RNS. Ipratropium responders had ≥ 1 -point improvement in RNS in 84.9% of cases and ≥ 2 -point improvement in 75.8% of cases, whereas ipratropium nonresponders had these improvements in 33.3% and 20%, respectively (p = 0.001). None of the other factors, including gender, age, diagnosis, smoking status, primary vs revision procedure, presence of rhinorrhea triggers, office vs operating room setting, or concurrent septoplasty, affected cryoablation response. Interestingly, RNS improvement approached

TABLE 2. Cryoablation success and factors associated with improvement in SNOT-22 RNS

	RNS improvement ≥ 1 point	<i>p</i> value	RNS improvement ≥ 2 points	<i>p</i> value
Gender				
Male	18 of 25 (72.0%)	0.871	15 of 25 (60.0%)	1.000
Female	21 of 30 (70.0%)		18 of 30 (60.0%)	
Age				
Unsuccessful	54.1 $\pm$ 19.3	0.745	56.5 $\pm$ 19.2	0.679
Successful	55.8 $\pm$ 16.5		54.5 $\pm$ 15.9	
Diagnosis				
Allergic rhinitis	7 of 8 (87.5%)	0.407	6 of 8 (75.0%)	0.168
Nonallergic rhinitis	22 of 34 (67.7%)		17 of 34 (50.0%)	
Mixed rhinitis	10 of 13 (76.9%)		10 of 13 (76.9%)	
Smoking status				
Nonsmoker	35 of 51 (68.6%)	0.241	30 of 51 (58.8%)	0.241
Smoker	4 of 4 (100.0%)		3 of 4 (75%)	
Ipratropium response				
Nonresponders	5 of 15 (33.3%)	0.001 ^a	3 of 15 (20%)	0.001 ^a
Responders	28 of 33 (84.9%)		25 of 33 (75.8%)	
Primary vs revision				
Primary	36 of 51 (70.6%)	0.852	31 of 51 (60.8%)	0.674
Revision	3 of 4 (75.0%)		2 of 4 (50%)	
Triggers				
No	17 of 20 (85.0%)	0.118	14 of 20 (70.0%)	0.307
Yes	22 of 34 (64.7%)		19 of 34 (55.9%)	
Setting of procedure				
Clinic	21 of 34 (61.8%)	0.067	17 of 34 (50.0%)	0.059
Operating room	18 of 21 (85.7%)		16 of 21 (76.2%)	
Concurrent septoplasty				
No	32 of 47 (68.1%)	0.286	27 of 47 (57.5%)	0.358
Yes	7 of 8 (87.5%)		6 of 8 (75.0%)	

RNS = Runny Nose Score; SD = standard deviation; SNOT-22 = 22-item Sino-Nasal Outcome Test.

^aStatistically significant.

significance when cryoablation was performed in the operating room for both the ≥ 1 - and ≥ 2 -point improvement groups ($p = 0.067$ and $p = 0.059$, respectively). Figure 1 shows regression lines for scatterplots of RNS over time for ipratropium nonresponders and responders, with an interaction p value of 0.001, indicating that there was a significant difference between the 2 groups. Comparison of demographics and patient characteristics between ipratropium responders and nonresponders revealed no statistically significant differences between the 2 groups (Table 3).

Discussion

Surgical management for chronic rhinitis and the symptom of rhinorrhea has been utilized for decades with some success, as noted previously. When described by Principato in 1978, the cryotherapy procedure for chronic rhinitis was performed in the outpatient clinic setting with local anesthesia, utilizing nitrous oxide as the freezing agent, and using a “freezing probe” for “successive applications along the entire length of each inferior turbinate.” In this case series of 350 patients, 84% had either “good” or “excellent” overall results, with 70% reporting “good” or “excellent”

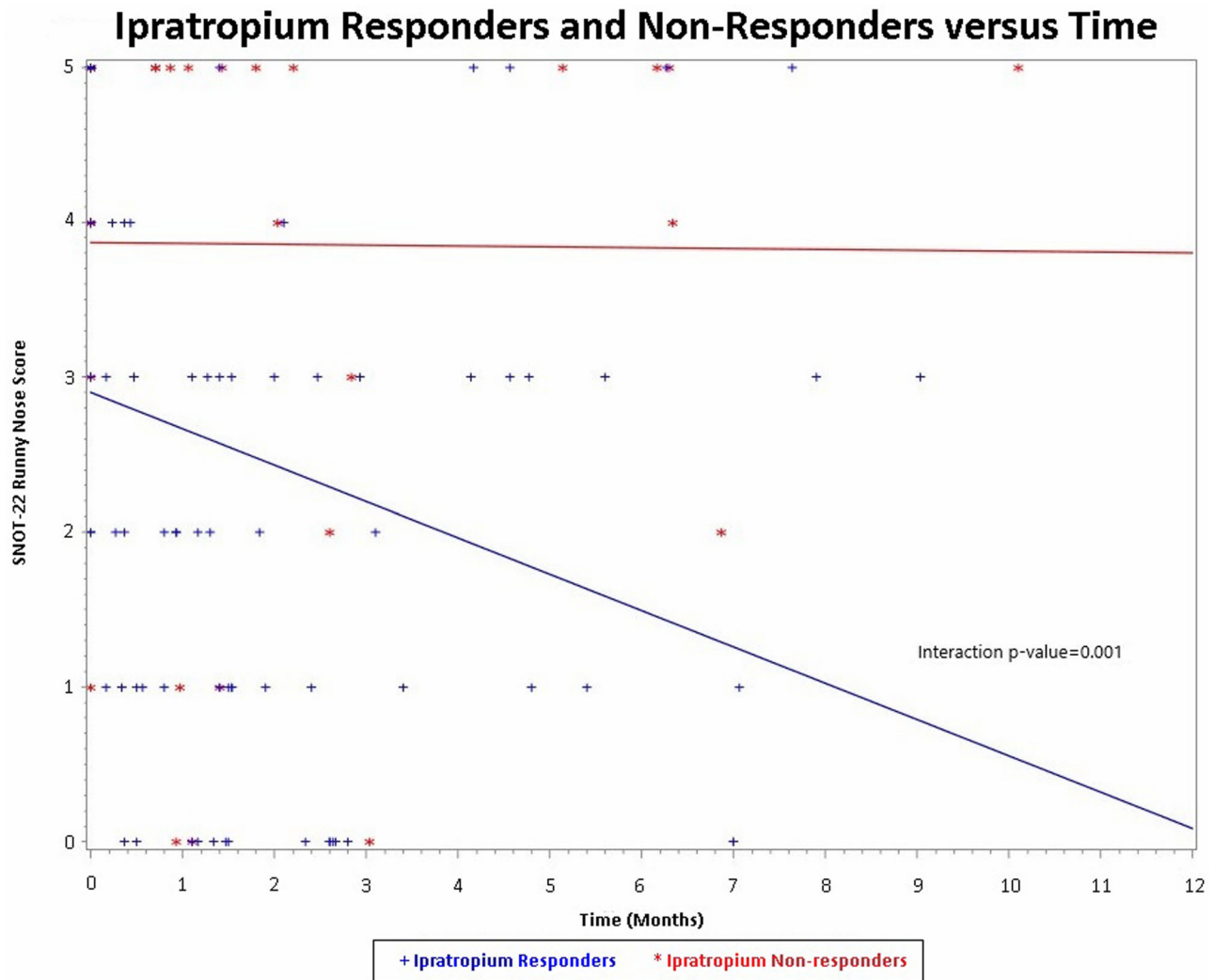


FIGURE 1. Scatterplot of SNOT-22 Runny Nose Scores over time with trend lines for ipratropium responders and nonresponders. Blue plus signs = ipratropium responders; red asterisks = ipratropium nonresponders. The significant interaction indicated the response was statistically different between the 2 groups. SNOT-22 = 22-item Sino-Nasal Outcome Test.

awareness of decreased nasal drainage.¹⁷ As described by Hwang et al, the targeted treatment area for the Clarifex device is along the lateral wall of the posterior middle meatus.²⁰ The mucosa in this region overlies the palatine bone, and contains multiple parasympathetic nerve fibers that course through the bone to supply the mucus-secreting glands.²¹ By focally cryoablating this region, one avoids the potential for temporary or permanent dry eye that can occur after vidian neurectomy in up to 60% of cases.³ Although Clarifex PNN cryoablation has been shown to be efficacious in a majority of patients with chronic rhinitis with a low side-effect profile, there are still possible side effects. Similar to the current study, other studies have reported side effects, such as headache/facial pain, epistaxis, aural fullness/pain, and palatal numbness.^{11,20} Identifying factors that predict cryoablation success will help when counseling patients, as surgeons can weigh their chance for success against the low but known risks of PNN cryoablation.

In this study, 68.8% of patients had at least some improvement in RNS with cryoablation, with 58.3% having an RNS improvement of ≥ 2 points. This result is similar to, although slightly lower than, the previously published 70-80% of patients achieving MCID on the rTNSS in the Chang et al study.¹¹ Although an MCID for the individual “Runny Nose” item on the SNOT-22 has not been determined, previous investigations have determined the average MCID to be 3.8 points for the 6-item rhinologic domain of the SNOT-22.^{22,23} Extrapolating from this, in the current study we considered any improvement in the RNS of ≥ 1 point to be clinically significant, but a separate analysis was also conducted to assess for more robust responses by analyzing RNS improvements of ≥ 2 points.

When examining RNS improvement by patient, disease, and procedure-related factors, only ipratropium nasal spray response was significantly associated with RNS improvement, both in the ≥ 1 - and ≥ 2 -point improvement

TABLE 3. Demographics, characteristics, and pre- and post-RNS by ipratropium responders and nonresponders

	Ipratropium responders (N = 33)	Ipratropium nonresponders (N = 15)	p value
Gender			
Male	15	7	0.938
Female	18	8	
Age (mean $\pm$ SD)	56.2 $\pm$ 15.7	53.3 $\pm$ 19.6	0.497
Diagnosis (%)			
Allergic rhinitis	5	1	0.543
Nonallergic rhinitis	19	11	
Mixed rhinitis	9	3	
Smoking status			
Nonsmoker	30	15	0.542
Smoker	3	0	
Primary vs revision procedure			
Primary	31	13	0.579
Revision	2	2	
Rhinitis symptom triggers			
None	15	4	0.117
Food	12	6	0.809
Alcohol	3	0	0.542
Temperature changes	11	3	0.746
Fragrances	2	0	0.100
Exercise	1	3	0.084
Other	2	1	
Preprocedure SNOT-22 RNS (mean $\pm$ SD)	4.30 $\pm$ 0.92	4.40 $\pm$ 1.12	0.5334
Postprocedure SNOT-22 RNS ^a			
First follow-up	2 (1.50); N = 30	3.57 (2.06); N = 14	0.006 ^b
Second follow-up	2 (1.53); N = 25	3 (1.95); N = 10	0.010 ^b
Third follow-up	3 (1.56); N = 12	5 (NA); N = 1	0.174
Fourth follow-up	3 (0.89); N = 5	NA	NA
Fifth follow-up	4 (2.12); N = 2	NA	NA

NA = Not applicable; RNS = Runny Nose Score; SD = standard deviation; SNOT-22 = 22-item Sino-Nasal Outcome Test.

^aData in parentheses are SDs.

^bStatistically significant.

groups. Therefore, ipratropium responders had a significantly greater likelihood of reduced rhinorrhea after PNN cryoablation compared with nonresponders. These findings would corroborate the purported pathophysiology that rhinitis-related rhinorrhea can be due to autonomic dysfunction with enhanced parasympathetic tone.¹⁷ Ipratropium is an anticholinergic agent that blocks postsynaptic muscarinic receptors in parasympathetic nerve ending

synapses at mucus glands. Because ipratropium response predicted success of cryoablation, it would suggest that success of cryoablation depends upon parasympathetic nerve damage. A lack of response to ipratropium spray could indicate that a patient's rhinitis symptoms are due to a different pathophysiologic mechanism.

Another noteworthy observation from this study is the trend toward increased success of the cryoablation proce-

dures in the operating room as compared with the office setting. Patients underwent cryoablation in the operating room either for concurrent septoplasty for access or patient preference. Concurrent septoplasty was necessary in only 8 patients who underwent the cryoablation procedure in the operating room and was not associated with increased success of cryoablation. Although septoplasty is often combined with inferior turbinate reduction when surgically treating rhinitis, the septoplasty portion has generally been utilized for addressing septal deviations for access or for nasal obstruction, but not for rhinorrhea.²⁴ Although the reasons for the trend toward increased success of cryoablation in the operating room will require further study, it is possible that placement of the Clarifix device was easier with patients under general anesthesia. Surgeons could be more comfortable placing the device into the most optimal position, as patient-perceived pain is no longer a factor. This would especially be true in patients with challenging intranasal anatomy causing narrow access to the treatment site. Further investigation with a larger sample size will be necessary to determine whether PNN cryoablation is more successful under general as opposed to local anesthesia.

The main limitations of this study include the relatively small sample size and reliance on the RNS from the SNOT-22, which has not been specifically validated to

rhinitis treatment outcomes. In addition, although the study was multi-institutional and data were collected prospectively, the design was retrospective with inconsistent timing of follow-up visits between the 4 different surgeons. To address this, RNS from the SNOT-22 was evaluated at each postprocedural follow-up visit, as well as over time (Fig. 1). Also of note, total follow-up durations varied significantly from 4 weeks to 23 months, and therefore, it was difficult to assess the average duration of clinical response to PNN cryoablation procedure, as it may be affected by patient and disease factors. Another possible limitation of the study is that ipratropium spray use and response was based on subjective patient reports, which could have introduced bias. Future prospective studies with larger sample sizes, consistent follow-up schedules, and use of disease-specific patient-reported outcome measures will be useful for confirming the findings from the present study.

Conclusion

In chronic rhinitis patients, rhinorrhea response to ipratropium was predictive of rhinorrhea improvement after PNN cryoablation. Although further investigation is warranted, the findings of this study may help guide clinicians in patient selection as well as patient counseling before performing PNN cryoablation. 

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