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Research Article

Cryoablation of the Posterior Nasal Nerves in Pediatric Patients with Chronic Rhinitis: A 5-Year Experience

Nisreen Al-Musaileem, Yusuf Gulleth and Peter Catalano*

Department of Otolaryngology Head and Neck Surgery, St. Elizabeth's Medical Center, Boston, MA, USA

***Corresponding Author:** Peter Catalano, Department of Otolaryngology Head and Neck Surgery, St. Elizabeth's Medical Center, Boston, MA, USA.

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Abstract

Background: Chronic rhinitis, including allergic rhinitis (AR) and non-allergic rhinitis (NAR), affects millions of individuals, with a significant burden in pediatric populations. Vasomotor rhinitis (VMR), a subtype of NAR, is characterized by nasal symptoms of congestion and watery discharge. Cryoablation (CA) of the posterior nasal nerves (PNN) using the Clarifix™ device has shown efficacy in adults, but data on its application in pediatric patients is lacking.

Objective: This study aimed to evaluate the safety, tolerability, feasibility, and effectiveness of cryoablation of the PNN in pediatric patients with AR and VMR.

Methods: A retrospective cohort study was conducted on 97 pediatric patients aged 4-12 years who underwent cryoablation using the Clarifix™ device between January 2018 and December 2022. Patients included in the study were diagnosed with AR or VMR and underwent cryoablation during nasal surgeries such as septoplasty, endoscopic sinus surgery (ESS), turbinate reduction, or adenoidectomy. Collected data included demographic information, preoperative and postoperative medical treatments, intraoperative and postoperative complications/side effects, and symptomatic improvement measured by the Total Nasal Symptom Score (TNSS).

Results: The study population consisted of 65 males (67%) and 32 females (33%), with a mean age of 7.5 years. Indications for surgery were VMR (70%) and AR (30%). A majority of our patients complained of nasal obstruction due to Grade 4 inferior hypertrophy (68%), middle turbinate concha bullosa (65%) and paradoxical middle turbinate (29%). Only 3 cases (3%) aborted due to inability to access the PNN region, primarily in younger children at age 4 years. There were no intra-operative complications and postoperative side effects were rare. Mild pain was reported in 1% of patients immediately post-op; bleeding and sinusitis, which occurred in 2%, was unrelated to the cryotherapy procedure. No other complications were reported postoperatively. Significant reduction in TNSS scores post-op showed effectiveness of the procedure (mean TNSS reduction from 7.03 to 2.23; $p < 0.001$, with VMR patients experiencing the greatest benefit (6.33 to 0.61; $p < 0.001$. Post-operative use of nasal steroid spray (20% of VMR patients) was not required for any patient with VMR.

Conclusion: Cryoablation of the posterior nasal nerves under general anesthesia is a safe, well-tolerated, and effective treatment for pediatric patients with chronic rhinitis. The procedure demonstrates a high success rate in improving symptoms, particularly in patients with VMR and AR, making it a viable option for managing chronic rhinitis in children.

Keywords: Chronic Rhinitis (CR); Allergic Rhinitis (AR); Vasomotor Rhinitis (VMR)

Introduction

Chronic rhinitis (CR), a condition marked by persistent nasal symptoms such as congestion, rhinorrhea, and sneezing, significantly impacts the quality of life for millions of individuals worldwide. In the United States alone, it affects over 60 million people, contributing to a substantial burden on healthcare resource [1-3]. The condition can be broadly categorized into allergic rhinitis (AR) and non-allergic rhinitis (VMR), with vasomotor rhinitis (VMR) being a prevalent subtype of VMR. VMR is best described as unbalanced autonomic control of the nasal tissues that is often triggered by environmental factors such as weather changes, strong odors, and emotional stress, and it is primarily diagnosed based on clinical symptoms rather than allergen exposure [4,5].

Traditionally, the management of CR has relied on pharmacological interventions, including antihistamines, intranasal corticosteroids, decongestants, and anticholinergics. However, these treatments are not very effective because some patients are refractory to medical management, experience significant side effects, or are non-compliant [6,7]. Consequently, there has been growing interest in minimally invasive surgical options, such as cryoablation (CA), which targets the posterior nasal nerve (PNN) to reduce nasal hyperreactivity and tissue inflammation [8,9].

CA, a procedure that involves the application of extreme cold to ablate tissue, has gained popularity due to its efficacy and minimally invasive nature [10]. The ClariFix™ device, introduced in 2016, allows for office-based CA of the PNN and has shown promising results in adult populations [11]. Initial clinical trials demonstrated significant reductions in symptoms such as rhinorrhea and nasal congestion, with minimal side effects and a high rate of patient satisfaction [12]. Despite these advances, its application in pediatric populations remains underexplored, with limited data available on its safety and efficacy.

The PNN, a branch of the greater petrosal nerve that supplies parasympathetic innervation to the nasal mucosa, plays a crucial role in the pathophysiology of rhinitis. Ablation of the PNN has been shown to reduce nasal secretions and congestion by disrupting the parasympathetic innervation that drives these symptoms [13,14]. Previous surgical approaches, such as vidian neurectomy, have been effective but are associated with significant risks, including dry eye and palatal numbness, which have limited their widespread acceptance [15,16]. CA offers a safer alternative by targeting the PNN directly while preserving the lacrimal gland's innervation, thereby reducing the risk of dry eye [14].

Studies have shown that CA of the PNN is effective in both allergic and non-allergic rhinitis, with significant improvements in symptom scores observed as early as seven days post-procedure and sustained for up to a year [12,17]. However, the optimal evaluation and selection of candidates for this procedure remain areas of ongoing research. Recent evidence suggests that preoperative assessments, including nasal endoscopy, allergy testing, and computed tomography (CT) scans are crucial in identifying patients who are likely to benefit from the procedure and in ruling out other conditions, such as chronic rhinosinusitis (CRS), which may mimic or coexist with CR [18].

This study aims to address the gap in knowledge regarding the application of CA in pediatric patients with CR. Specifically, it seeks to evaluate the safety, tolerability, and effectiveness of CA of the PNN in a pediatric cohort. By conducting a comprehensive review of patient records over a five-year period, this study aims to provide valuable insights into the potential benefits and limitations of this emerging treatment modality for pediatric CR.

Methods

Study design

This retrospective cohort study was conducted at a tertiary care hospital and included pediatric patients who underwent CA of PNN for CR treatment from January 2018 to December 2022. The institutional review board (IRB) approved the study, ensuring compliance with ethical standards for human subject's research.

Patient selection

Patients eligible for the study were aged 4 to 12 years with CR, including AR and VMR, diagnosed clinically by history, endoscopic examination, allergy testing, and CT sinus. For inclusion in the study, patients must have had chronic symptoms for six months or more, characterized by moderate-to-severe rhinorrhea (symptom rating at least 2 on TNSS score) and mild-to-severe nasal congestion (symptom rating at least 1 on TNSS). A minimum total TNSS score of 4 out of 12 at the time of the treatment visit was also required. Patients with endoscopic/CT finding of bilateral inferior turbinate hypertrophy, deviated nasal septum, swell bodies, and concha bullosa were included.

All participants underwent comprehensive allergy testing (skin or blood or both) to confirm the diagnosis of AR or VMR. Patients discontinued the use of all nasal sprays and medications two weeks pre-operatively.

Patients with nasal polyps, cryoglobulinemia, paroxysmal cold hemoglobinuria, cold urticaria, or Raynaud's disease were excluded.

A total of 97 patient charts met these inclusion criteria and were analyzed in the study.

Data collection

Data collection involved a comprehensive review of electronic medical records, covering demographic information (age, gender, ethnicity); indications - (i.e. AR, and VMR), trials of medical treat-

ment, allergy testing results, history of asthma and atopic dermatitis; technical feasibility - number of aborted cases, CT sinus findings, intra-operative challenges and complications; safety/tolerability - complications/side effects (immediate, 3 weeks postoperative, 3 months postoperative); and effectiveness – need for medical therapy post cryoablation and the TNSS score. TNSS was used to measure the symptomatic improvement of patients after cryoablations of PNN at 3 months post op compared to their baseline score pre-operatively.

Device and procedure

The cryoablation procedure was performed by a handheld, single-use disposable cryoablation device from Stryker Corporation, Kalamazoo, MI. This device employs nitrous oxide as the cryogen to freeze mucosal tissue in a targeted fashion within the nasal cavity. The target tissue lies at the posterior aspect of the middle meatus (Figure 1), adjacent to the sphenopalatine foramen and corresponding to the trajectory of the posterior nasal nerve as it emerges from the pterygopalatine fossa. The cryoprobe's surface reaches −60 to −80°C, and treatment is estimated to achieve −20°C cryoablation to a depth of 3 millimeters. All procedures were done by 2 senior attending rhinologists under general anesthesia using Clarifix during nasal surgery that included one or a combination of the following: septoplasty, ESS, turbinate reduction, swell body reduction, and adenoidectomy. The tip of the cryodevice was applied endoscopically to the posterior middle meatus at two sites to cover all branches of the posterior nasal nerve. The surgeon then activated the cryogen to perform cryoablation in the region of the PNN for 30 sec at each site. The contralateral side was treated in identical fashion.

As part of our protocol, we instruct patients to stop all nasal sprays 2 weeks before surgery and do not use any nasal medication in post op period unless advised otherwise. All patients were instructed to do saline nasal rinses twice daily for first 3 weeks post op.

Patients were assessed immediately after the surgery and again three weeks postoperatively in the clinic for any complications, side effects, complaints, or recovery issues. A follow-up visit three months post-operation allowed for a reassessment of any complications, side effects, or complaints and to evaluate clinical improvement and the need for medical treatment. The TNSS was also recorded at this time to measure the effectiveness of the cryoablation.

Outcome measures

Primary outcomes focused on the safety, tolerability, and effectiveness of the procedure. Safety and tolerability were assessed by documenting intraoperative and postoperative complications. Effectiveness was evaluated using the TNSS for specific symptoms (rhinorrhea, congestion, itching, sneezing) and for overall clinical improvement from baseline to follow-up.

Statistical analysis

Data analysis was performed using SPSS software version 25.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as means ± standard deviation (SD) or median, and categorical variables as frequencies and percentages. The effectiveness of CA was assessed by comparing preoperative and postoperative TNSS using paired t-tests, with a p-value of less than 0.05 indicating statistical significance. Subgroup analyses evaluated the impact of variables like ethnicity, asthma presence, and positive allergy testing on postoperative outcomes using Chi Square and Fisher exact tests.

Results

Patient demographics

A total of 97 pediatric patients who underwent CA of the PNN for CR during the study period (Table 1). The study group consisted of 65 males (67%) and 32 females (33%), with a mean age of 7.5 years (SD = 2) and a median age of 8 years. Regarding ethnicity, 49.5% of patients identified as White, 39.2% did not respond, 10.3% identified as Puerto Rican, and 1% as Asian.

Table 1: Demographic Characteristics of the Study Population.

Variable	Value
Total Patients	97
Age (Mean ± SD)	7.5 ± 2 years
Median Age	8
Male	65 (67%)
Female	32 (33%)
White	48 (49.5%)
Asian	1 (1%)
Puerto Rican	10 (10.3%)
Not reported	38 (39.2%)

Clinical characteristics

The clinical diagnoses among the patients were 70% VMR and 30% AR (Figure 1). Preoperatively, 28.9% of patients were on intranasal corticosteroids (INCS), 39.6% were on oral antihistamines, and 3% were using nasal Atrovent. A history of bronchial asthma was present in 12.4% of the patients while 4% had atopic dermatitis.

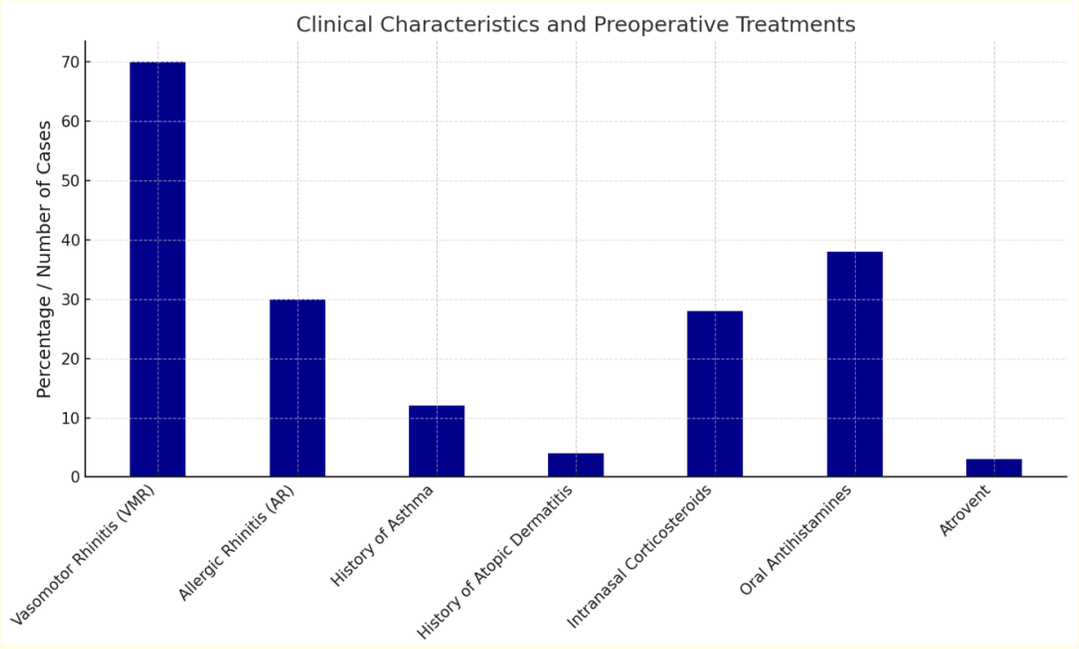

Figure 1: Clinical Characteristics and Preoperative Treatments.

Surgical feasibility

Out of the 97 cases, 3 (3%) were aborted intraoperatively due to the inability to properly access the PNN region (Table 2). These aborted cases occurred exclusively in younger children with a mean age of 4 years. Table 2 shows the frequency and degree of inferior turbinate hypertrophy, paradoxical middle turbinates and concha bullosa with each being potentially responsible for limiting access to the PNN treatment area. Septoplasty was done in 45% of patient who underwent CA. As independent factors, the need to perform a septoplasty, or the presence of grossly hypertrophic inferior turbinates, concha bullosa of middle turbinate, or paradoxical middle turbinates were not clinically or statistically relevant in terms of our ability to complete the procedure. However, as shown in Table 2, when several of these factors are present simultaneously in a small child, the ability to safely and accurately access the region of the PNN may be compromised.

Table 2: Relationship of Anatomical Variations and Septoplasty.

Factor	Completed Cases (n = 94)	Aborted Cases (n = 3)	Total (n = 97)
CT Grade of IT			
Grade 2	1 (1.1%)	0 (0%)	1 (1.0%)
Grade 3	29 (30.9%)	1 (33.3%)	30 (30.9%)
Grade 4	64 (68.1%)	2 (66.7%)	66 (68.0%)
CT Sinus Anatomical Variation			
Concha Bullosa	61 (64.9%)	2 (66.7%)	63 (64.9%)
Paradoxical Middle Turbinate (Type 2)	27 (28.7%)	1 (33.3%)	28 (28.9%)
Normal middle turbinate	6 (6.4%)	0 (0%)	6 (6.2%)
Septoplasty			
No	52 (55.3%)	3 (100%)	55 (56.7%)
Yes	42 (44.7%)	0 (0%)	42 (43.3%)

Postoperative safety and tolerability

There were no reported intraoperative complications (n = 94) such as excessive bleeding, mucosal lacerations, or injury to other nasal structures. Postoperative side effects were extremely rare. In the immediate postoperative period, only 1 patient reported mild pain (3/10) according to visual analogue scale, which was managed effectively with perioperative paracetamol. At the 3-week follow-up, 2 patients reported a complication—one case of sinusitis and one case of bleeding, both of which were associated with patients who underwent septoplasty and inferior turbinate reduction and swell body ablation. Bleeding was managed with silver nitrate cautery of the inferior turbinate in office and sinusitis resolve with antibiotics and normal saline sinus rises. By the 3-month follow-up, no complications were reported, and all patients had fully recovered without any long-term adverse effects. Healing was excellent in all patients, with no infectious complications, evidence of scarring, mucosal atrophy, or bone exposure at the treatment sites as assessed by endoscopic examination.

Symptomatic improvement

Results showed statistically significant improvement in all symptoms particularly congestion, rhinorrhea, nasal itching, and sneezing (Table 3 and Figure 2).

Table 3: Symptom Scores: Pre-CA (Baseline), and Post- CA.

Symptom	Pre (Baseline) (Mean ± SD)	Post (Mean ± SD)	P value†
Congestion	2.19 ± 0.592	0.55 ± 1.074	<0.001
Rhinorrhea	2.49 ± 0.503	0.54 ± 1.074	<0.001
Sneezing	1.34 ± 0.811	0.47 ± 0.786	<0.001
Itching	1.05 ± 0.872	0.69 ± 0.790	<0.001

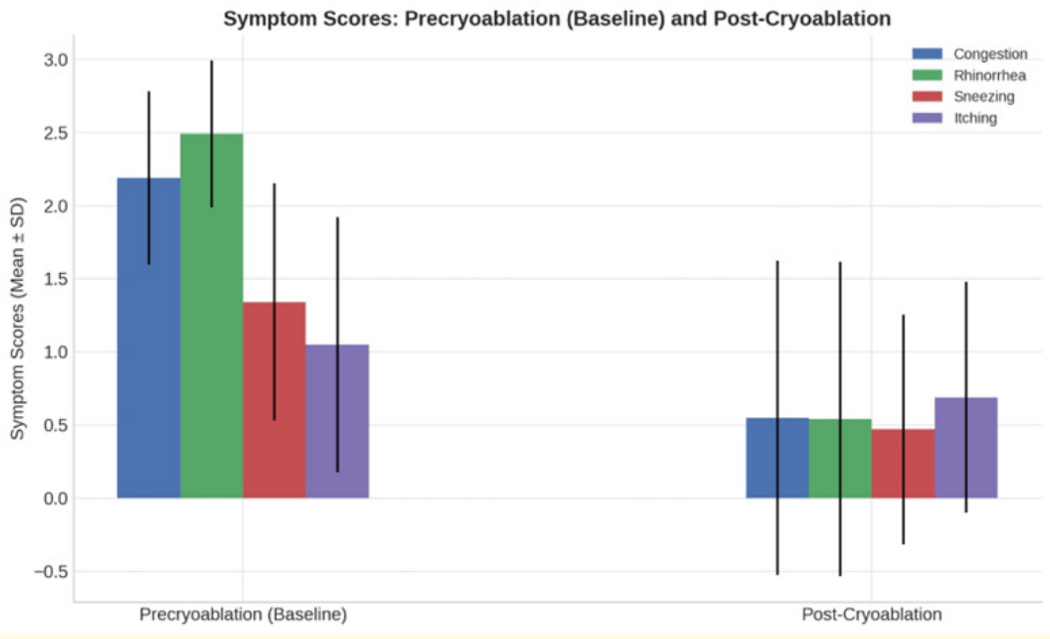

Figure 2: Symptom Scores at Different Time Points.

The bar and whisker chart in Figure 2 illustrates the mean symptom scores (± SD) for congestion, rhinorrhea, sneezing, and itching at two different time points: pre- CA (baseline) and 3 months post- CA.

TNSS in all patients and subgroup analysis: (AR vs. VMR)

The primary outcome measure for effectiveness was the TNSS, which was assessed preoperatively (at baseline), and at 3 months postoperatively (Table 4 and Figure 3). The results demonstrated a statistically significant improvement in TNSS across both patient groups, AR and VMR. However, a subgroup analysis revealed much greater improvement in the patients with VMR.

Table 4: TNSS Scores in AR and VMR Patients.

TNSS (Patients)	Pre-CA (Baseline) (Mean ± SD)	Post (Mean ± SD)	P value
TNSS (All Patients)	7.03 ± 2.034	2.23 ± 3.406	<0.001
TNSS (AR Patients)	8.68 ± 2.262	6.07 ± 4.118	<0.001
TNSS (VMR Patients)	6.33 ± 1.461	0.61 ± 0.721	<0.001

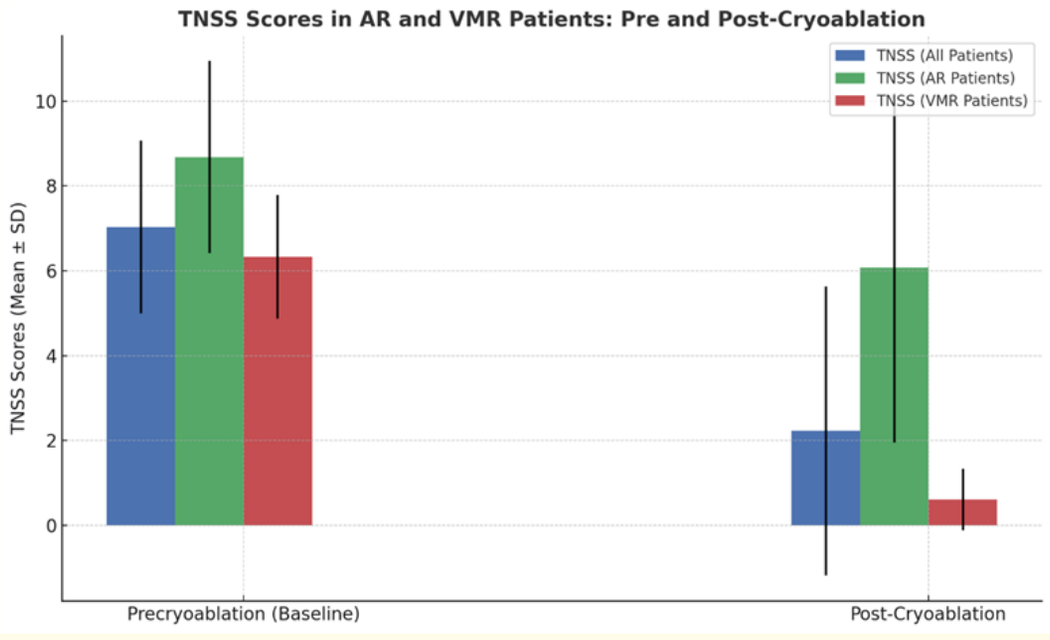

Figure 3: TNSS Scores at Different Time Points.

The bar and whisker chart in Figure 3 illustrates the TNSS for all, AR, and VMR patients at two different time points: pre- CA baseline, and post- CA.

There was an overall decrease in the use of intranasal corticosteroid spray (INCS) post-CA for the entire study group, from 27.7% pre-op down to 21.3% post-op. In patients with VMR, 20% used INCS pre-op and no one required them post-op. However, the use of INCS increased in AR group (46% pre-CA to 71% post-CA), which was highly significant ($p < 0.000$) (Table 5).

Table 5: Impact of Allergy Test Results on Post-Cryoablation Need for INCS.

Allergy Test Result (Type)	Patients (n)	Not Using INCS Pre-Op (%)	Using INCS Pre-Op (%)	Not Using INCS Post-Op (%)	Using INCS Post-Op (%)
Negative (VMR)	66	80.3% (53/66)	19.7% (13/66)	100% (66/66)	0% (0/66)
Positive (AR)	28	53.6% (15/28)	46.4% (13/28)	28.6% (8/28)	71.4% (20/28)
Total	94	72.3% (68/94)	27.7% (26/94)	78.7% (74/94)	21.3% (20/94)

Effect of asthma, atopic dermatitis and ethnicity

There was no statistically significant difference in improvement of TNSS scores between patients with/without atopic dermatitis or asthma, or between different ethnicities (Fisher Exact and Chi Square values > 0.05).

Discussion

The results of our study found that CA led to significant reductions in TNSS across all patient groups, with particularly pronounced effects in patients in the VMR subgroup. The mean TNSS for all patients decreased from 7.03 at baseline to 2.23 postoperatively ($p < 0.001$). This finding is consistent with previous studies that have reported substantial reductions in TNSS following this procedure. For instance, a multicenter study demonstrated a reduction in TNSS from 6.2 to 1.9 at 365 days post-procedure, indicating sustained symptomatic relief [14]. The significant decrease in TNSS observed in our study reinforces the utility of CA as an effective intervention for managing CR, particularly in pediatric patients where long-term medication compliance can be challenging.

Subgroup analysis revealed that VMR patients benefited the most from CA, with TNSS scores dropping from 6.33 to 0.61 ($p < 0.001$). This is consistent with previous research showing that the procedure is particularly effective in treating VMR, likely due to its ability to target the overactive parasympathetic nerves responsible for symptoms in these patients [19]. In contrast, AR patients, while still showing statistically significant improvement, had higher post-treatment TNSS scores (mean = 6.07), which could be attributed to the persistent presence of allergen-driven inflammation that CA alone may not fully address [20].

The marked improvement in symptom scores, particularly in VMR patients, highlights the potential of CA as an excellent treatment option in cases where traditional pharmacotherapy has been ineffective, poorly tolerated, or patients are less compliant. This is especially relevant in pediatric patients who may experience significant side effects from long-term use of intranasal corticosteroids and antihistamines and are less compliant with long-term medication regimens [14].

CA was well-tolerated in our study. There were no reported intraoperative complications (n = 94) such as excessive bleeding, mucosal lacerations, or injury to other nasal structures. Postoperative side effects were extremely rare. In the immediate postoperative period, only 1% of patients reported mild pain which was managed effectively with non-narcotic perioperative analgesia. At the 3-week follow-up, 2 patients reported complications—one case of sinusitis and one case of localized bleeding, both of which were associated with the other procedures that were done in combination with CA. These findings are consistent with existing literature that highlights the procedure's favorable safety profile [12]. In a study by Hwang., *et al*. the procedure was associated with minimal discomfort and no serious adverse events, supporting our findings [21].

Our results also align with the study by Moore., *et al*. which emphasized the importance of patient selection to minimize procedural complications. The three cases in our study that were aborted intraoperatively due to an inability to access the PNN region underscore the need for careful preoperative assessment, particularly in younger children with a small nasal cavity and the presence of inferior turbinate hypertrophy and/or a paradoxical middle turbinate or concha bulla. The use of computed tomography (CT) and nasal endoscopy in preoperative planning, as recommended by Schmale., *et al*. can help identify anatomical variations that may pose challenges during the procedure [19]. We did use a sinus CT scan preoperatively but did not appreciate the limitations imposed by a combination of these space occupying anatomic variations.

The results of this study are in line with previously published data on the effectiveness and safety of CA in treating CR. The significant reduction in TNSS observed in our study mirrors findings from adult populations, where the procedure has been shown to provide long-term relief from symptoms such as rhinorrhea, congestion, sneezing, and itching [22]. Moreover, our findings contribute to the growing body of evidence supporting CA as a viable treatment option in pediatric patients, a population in which this procedure has not been reported previously.

The clinical implications of this study are significant, particularly for pediatric otolaryngologists and allergists. The procedure offers a minimally invasive option for managing CR in children, reducing the need for long-term pharmacotherapy and its associated risks. Given the procedure's efficacy, particularly in VMR patients, it could be considered as a first-line treatment in pediatric patients.

While this study provides valuable insights into the effectiveness and safety of this procedure in pediatric patients, it is not without limitations, namely the retrospective nature of the study and the relatively short follow-up period of 3 months, which may not reflect the long-term outcomes and potential for recurrence of symptoms. There is also no control group of medically managed

children for us to compare against our reported outcomes. Future research should be prospective, include a control group and provide longer follow-up periods to confirm and compare our findings and to evaluate the long-term outcomes of CA in children.

Conclusion

Cryoablation of the PNN is a safe, well-tolerated, and effective treatment for chronic rhinitis in pediatric patients. The procedure significantly reduces nasal symptoms, particularly in patients with non-allergic rhinitis, and offers a promising alternative to long-term pharmacotherapy. These findings support the integration of the procedure into the treatment paradigm for pediatric chronic rhinitis, particularly for patients who have not responded to conventional medical treatments.

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