

Effectiveness of ClariFix (Cryoablation) of the Posterior Nasal Nerve on Nasal Symptoms in Patients With Chronic Rhinitis: A Systematic Review and Meta-Analysis

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Background and Objectives: The present study evaluated the efficacy of cryoablation of the posterior nasal nerve in alleviating symptoms associated with chronic rhinitis.

Methods: A systematic review of pertinent literature sourced from PubMed, Scopus, Embase, Web of Science, and Cochrane databases was conducted through May 2024. The analysis focused on studies that appraised changes in quality of life and rhinitis-associated symptomatology before and after cryoablation treatment.

Results: A total of seven studies (495 patients) were included in the analysis. Significant improvements in rhinitis-related symptoms were observed in patients undergoing cryoablation, irrespective of etiology (allergic or nonallergic rhinitis). Furthermore, cryoablation yielded improvements in disease-specific quality of life, as measured by the Rhinoconjunctivitis Quality of Life Questionnaire. Notably, a clinically significant reduction ($\geq 30\%$ decrease from baseline) in total nasal symptomatology was noted in 71% of cases following cryoablation. Regarding the incidence of adverse effects, nasal dryness, epistaxis, ocular symptoms, and palatal numbness occurred in $< 5\%$ of patients, while postoperative pain occurred in 10% and headache in 20% of patients who underwent treatment. In subtype analysis, the total nasal symptom score in nonallergic rhinitis showed a significantly increasing pattern over time ($p=0.0017$).

Conclusion: Cryoablation of the posterior nasal nerve appears to yield a decrease in subjective nasal symptom scores and an improvement in disease-specific quality of life. Notably, these effects persisted for up to 12 months post-treatment, with marked improvements observed in both allergic and nonallergic rhinitis subtypes.

Keywords: Rhinitis; Quality of life; Nose; Cryotherapy; Meta-analysis.

INTRODUCTION

Chronic rhinitis impacts people worldwide and is charac-

terized by persistent inflammation of the nasal mucosa [1]. Additional subtypes of chronic rhinitis include hormone-induced rhinitis, infectious rhinitis, nonallergic rhinitis (NAR) with eosinophilia, and geriatric rhinitis [2]. Although it has been suggested that the cause of chronic rhinitis is an imbalance in sympathetic and parasympathetic activation, the precise mechanisms underpinning its pathogenesis remain elusive [2]. Notably, the clinical manifestations of chronic rhinitis, including chronic rhinosinusitis symptoms and olfactory dysfunction, impact patients' quality of life, prompting medical intervention [3]. Historically, vidian neurectomy was the favored surgical approach for chronic rhinitis. However, the recent emergence of alternative techniques, such as cryoablation with ClariFix (Stryker, Portage, MI, USA), that target distal posterior nasal nerves has mitigated vidian neurectomy-associated complications [3-9]. Cryoablation exhibits efficacy,

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particularly for specific chronic rhinitis symptoms. Thus, this meta-analysis aimed to assess the outcomes of posterior nasal nerve treatment with ClariFix for chronic rhinitis.

METHODS

Studies retrieved from PubMed, Scopus, Embase, Web of Science, and Cochrane databases up to May 2024 were analyzed. The search terms encompassed: 1) patients afflicted with chronic rhinitis, 2) cryoablation and posterior nasal nerve interventions, 3) intervention comparisons with sham procedures and pre-post comparisons, and 4) outcomes of interest including measures of quality of life, nasal congestion, nasal obstruction, sneezing, itching, total nasal symptom scores (TNSSs), and Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) scores.

Study abstracts and titles were independently screened by two authors, with a focus on studies of nasal surgery utilizing ClariFix (cryoablation). Studies not meeting this criterion were excluded. In cases where abstract and title screenings were inconclusive, the full texts were meticulously reviewed by the same two authors. The inclusion criteria encompassed cohort or controlled trials that involved patients seeking amelioration of rhinitis-related symptoms and improved quality

of life, particularly those experiencing severe rhinitis symptoms with or without nasal obstruction, as evidenced by high TNSSs. Studies involving patients who had undergone other nasal surgeries (e.g., turbinoplasty or sinus surgery) were excluded, as were duplicate studies and those lacking quantified data or presenting data that were challenging to compute. Studies utilizing cryoablation devices that were currently unavailable were also excluded. Consequently, a total of seven studies were selected for inclusion in this systematic review with meta-analysis. The selection process is delineated in Fig. 1.

Data extraction and assessment of the risk of bias were conducted independently by two authors. Standardized forms were utilized to analyze the data extracted from the included studies [10]. Disease-specific symptoms and quality of life scores were assessed prior to cryoablation treatment and again within a 12-month post-treatment period. The review protocol was registered with the Open Science Framework (<https://osf.io/8fdpu/>). Comparisons between the cryoablation treatment group and the sham treatment group were conducted during the follow-up period or before and after cryoablation treatment, with a particular focus on TNSSs. The TNSS is a well-established scoring system for symptom severity assessment that encompasses four individual subject-assessed symptom scores for rhinorrhea, nasal congestion,

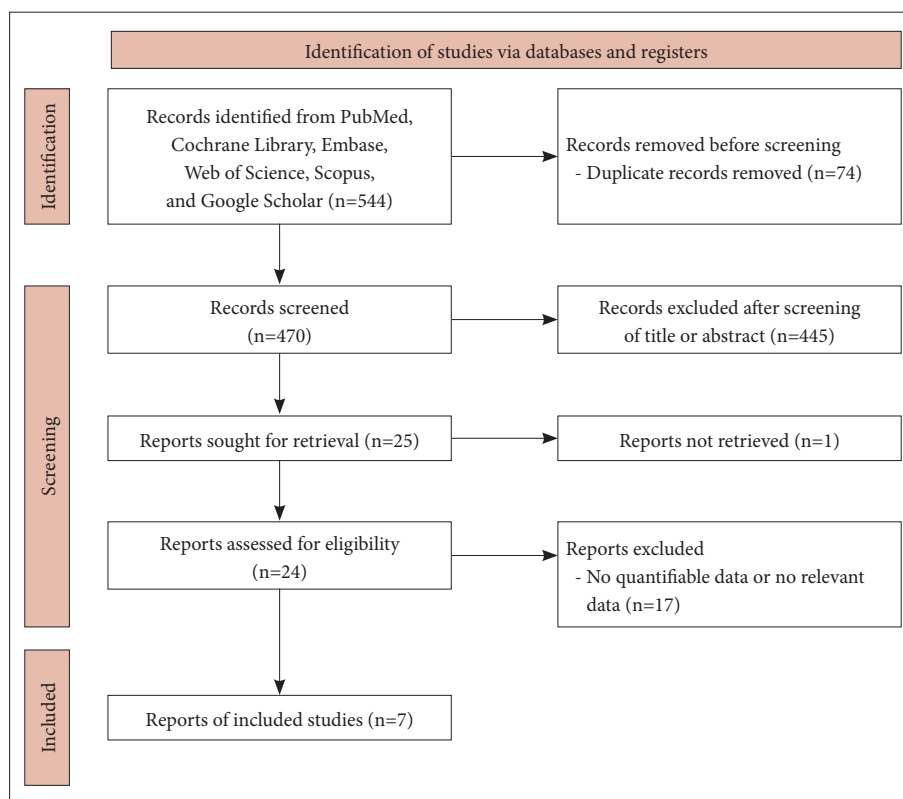


Fig. 1. Flowchart depicting the article search process and selection of studies for analysis.

Table 1. Study characteristics in a selective review and meta-analysis of cryoablation efficacy in chronic rhinitis

Study	Study design	Number of patients	Age (yr)	Sex (male/female)	Nation	NAR/AR	Comparison	Device	Outcomes
Hwang 2017 [7]	Prospective cohort	27	53.3±3.3	10/17	USA	14/13	Pre-post	ClariFix device	Total nasal symptom score (regardless of AR or NAR subtype), TNSS subdomain, reflective TNSS (AR, NAR)
Chang 2020 [4]	Prospective cohort	98	58.6±16.2	35/63	USA	70/28	Pre-post	ClariFix device	Total nasal symptom score (regardless of AR or NAR subtype), RQLQ, TNSS subdomain, reflective TNSS (AR, NAR)
Yen 2020 [5]	Prospective cohort	30	60.0±15.8	14/16	USA	14/16	Pre-post	ClariFix device	Total nasal symptom score (regardless of AR or NAR subtype), RQLQ, TNSS subdomain
Ow 2021 [8]	Prospective cohort (multicenter)	62	57.1±13.4	22/40	USA	43/19	Pre-post	ClariFix device	Total nasal symptom score (regardless of AR or NAR subtype)
Gerka Stuyt 2021 [6]	Prospective cohort	24	60.04±16.7	12/12	USA	16/8	Pre-post	ClariFix device	Total nasal symptom score (regardless of AR or NAR subtype), TNSS subdomain, reflective TNSS (AR, NAR)
Del Signore 2022 [3]	Randomized, single-blinded trial, sham-controlled (multicenter)	133	55.2±16.3	77/56	USA	76/57	Pre-post/ comparison with sham	ClariFix device	Total nasal symptom score (regardless of AR or NAR subtype), RQLQ, TNSS subdomain, reflective TNSS (AR), comparison with sham control (respondent rate, TNSS, RQLQ)
Rosi-Schumacher 2023 [9]	Prospective cohort	127	52.4 (49.4–55.3)	50/77	USA	64/63	Pre-post	ClariFix device	Total nasal symptom score (regardless of AR or NAR subtype), RQLQ, TNSS subdomain

AR, allergic rhinitis; NAR, nonallergic rhinitis; TNSS, total nasal symptom score; RQLQ, Rhinoconjunctivitis Quality of Life Questionnaire; NR, not reported; SD, standard deviation; Pre-post, before and after cryoablation treatment

nasal itching, and sneezing and is rated on a scale from 0 (no symptoms) to 3 (severe symptoms). The reflective TNSS, a 12-point scale, captures the subject's evaluation of symptom severity over the preceding 12 or 24 hours, with the minimal clinically important difference (MCID) defined as a decrease of at least 1.0 point. A favorable treatment response was defined as an improvement in TNSS class evidenced by a $\geq 30\%$ decrease in total TNSS. Efficacy outcomes also included alterations from baseline in the RQLQ scores. The RQLQ is comprised of 14 items that assess impairments across five domains. Each item is rated on a 7-point scale, with the overall RQLQ score calculated as the mean of these items. The MCID for the abbreviated RQLQ was determined to be either 0.4 or 0.5 points.

Data pertaining to p-values, patient numbers, and grading scale data were extracted from the included studies before and after ClariFix treatment. The quality assessment of non-randomized controlled studies was conducted utilizing the Newcastle-Ottawa Scale, which evaluates study quality on a scale of 0 to 9 based on selection, comparability, and outcome assessment. Meanwhile, the risk of bias in randomized controlled studies was assessed using the Cochrane Risk of Bias tool.

Statistical analyses were performed through a meta-analysis of the included studies utilizing R statistical software version 4.3.0 (R Foundation for Statistical Computing, Vienna, Austria). Mean and standard deviation values of the control and cryoablation treatment groups were compared using continuous measures, with the mean difference serving as the effect size when all studies yielded identical results and shared units of measurement on the TNSS and RQLQ scales. Heterogeneity was evaluated via the Cochran Q test and the I^2 test. Publication bias was assessed using a funnel plot and the Egger test, with the trim and fill method of Duval and Tweedie employed to address any identified publication bias.

RESULTS

As depicted in Fig. 1, the final review incorporated data from 495 patients across seven studies. The pertinent characteristics of each study are summarized in Table 1. However, an aggregate overview of patient characteristics could not be derived due to incomplete reporting of patient information in the included studies. Summaries of study biases are presented in Supplementary Tables 1 and 2 (in the online-only Data Supplement).

Alterations in rhinitis-related measurements following ClariFix treatment

The rates of respondents exhibiting $\geq 30\%$ reduction in to-

tal TNSS after cryoablation treatment at 1 and 3 months were 69.1% (95% confidence interval [CI], 0.5406–0.8096; $I^2=89.0$) and 73.7% (95% CI, 0.6639–0.7998; $I^2=0.0\%$), respectively. While the rates appeared to increase over time, the difference between the two follow-up periods was not statistically significant ($p=0.5422$) (Fig. 2A). Decreases in the TNSS from baseline following cryoablation treatment were observed at 1 month (mean difference 3.2584; 95% CI, 2.8556–3.6611; $I^2=59.0\%$), 3 months (mean difference 3.5067; 95% CI, 3.2990–3.7144; $I^2=17.4\%$), 6 months (mean difference 3.5388; 95% CI, 2.7585–4.3191; $I^2=83.7\%$), and 12 months (mean difference 3.7650; 95% CI, 2.9171–4.6129; $I^2=85.6\%$) (Fig. 2B). Notably, no significant difference was discerned across the period from 1 to 12 months post-treatment ($p=0.6425$). The TNSS exhibited a propensity to increase from 1 to 12 months following cryoablation treatment, suggesting a trend of increasing severity over time. Nonetheless, since the changes from baseline in the TNSSs across all follow-up periods surpassed the MCID threshold (1.0), substantial symptom amelioration was evident after cryoablation treatment (Fig. 2B). Reductions in RQLQ from baseline following cryoablation were observed at 1 month (mean difference 1.2973; 95% CI, 1.0782–1.5164; $I^2=0.0\%$) and 3 months (mean difference 1.5155; 95% CI, 1.3018–1.7293; $I^2=0.0\%$) (Fig. 2C). No significant difference was noted across the period from 1 to 3 months post-treatment ($p=0.1623$). Since changes from baseline in the RQLQ across all follow-up periods exceeded the MCID threshold (0.4), substantial enhancement in quality of life was evident after cryoablation treatment (Fig. 2C).

Alterations in TNSS subdomains and rhinitis type (allergic rhinitis and nonallergic rhinitis) following cryoablation treatment

Some of the included studies delineated changes in individual TNSS subdomain scores; thus, changes in these subdomains were also scrutinized in our review. All subdomains changed significantly from the baseline during all follow-up periods (Fig. 3): congestion scores at 1 month (mean difference [95% CI]: 1.0372 [0.8890–1.1855]; $I^2=38.9\%$), 3 months (1.0680 [0.9123–1.2237], $I^2=43.8\%$), 6 months (1.2192 [0.9734–1.4651]; $I^2=78.5\%$), and 12 months (1.3865 [1.2644–1.5086]; $I^2=0.0\%$) ($p=0.0009$); itching scores at 1 month (0.4660 [0.3356–0.5965]; $I^2=54.7\%$), 3 months (0.4320 [0.2963–0.5678]; $I^2=60.7\%$), 6 months (0.4361 [0.2744–0.5979]; $I^2=81.0\%$), and 12 months (0.5000 [0.2171–0.7829]; $I^2=NA$) ($p=0.9649$); rhinorrhea scores at 1 month (1.1634 [0.8904–1.4364]; $I^2=76.1\%$), 3 months (1.2632 [1.1338–1.3927]; $I^2=0.0\%$), 6 months (1.3000 [1.1589–1.4411]; $I^2=0.0\%$), and 12 months (0.9560 [0.4204–1.4915]; $I^2=71.3\%$); and sneezing scores at 1 month (0.4563 [0.3218–0.5908]; $I^2=62.5\%$), 3 months (0.6701 [0.5276–0.8127];

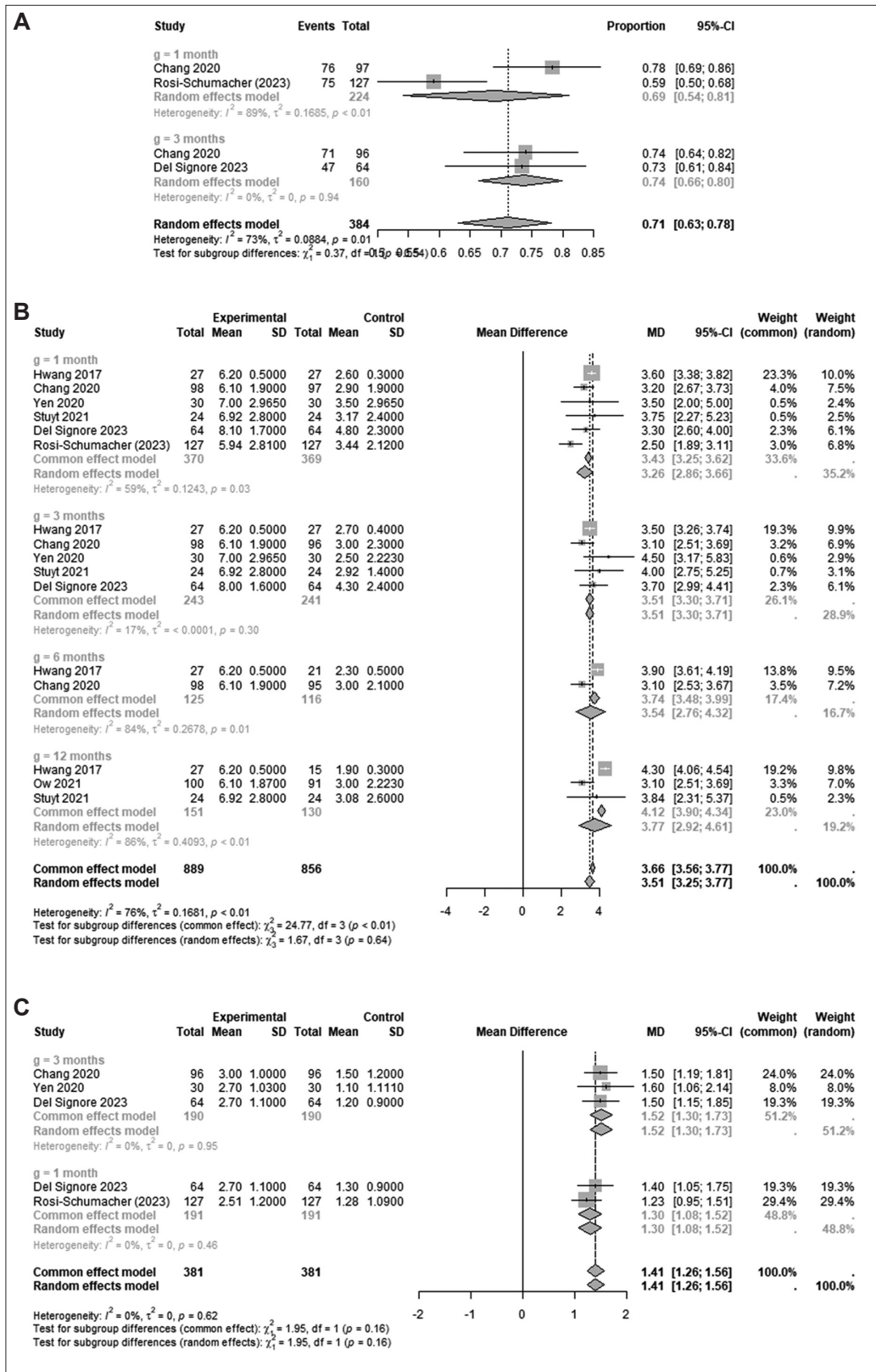


Fig. 2. Response rates after cryotherapy treatment (A), change of TNSs from baseline after cryotherapy treatment (B), and change of RQLQ scores from baseline after cryotherapy treatment (C) [3-9]. TNSs, total nasal symptom score; RQLQ, Rhinoconjunctivitis Quality of Life Questionnaire.

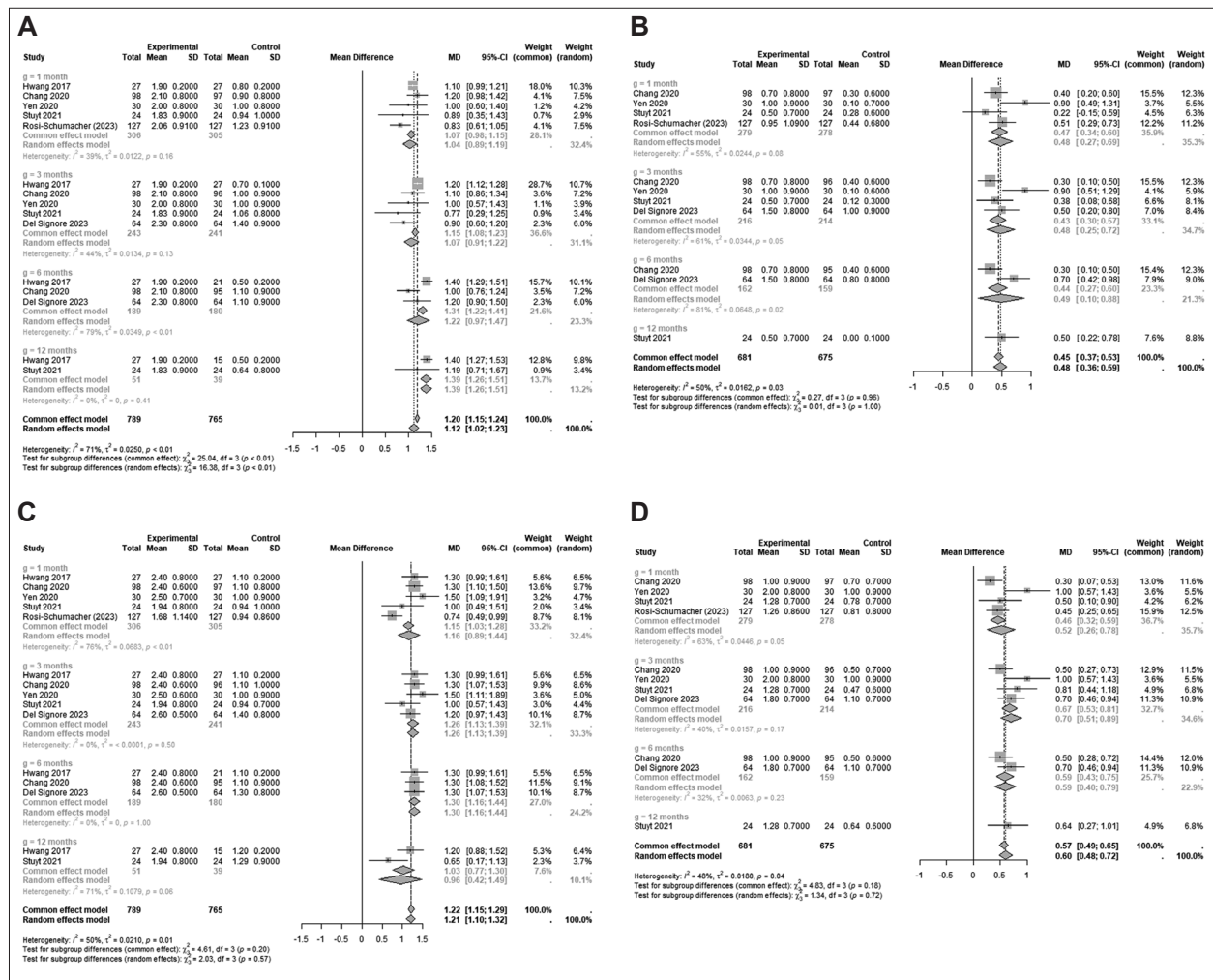


Fig. 3. Changes in the TNSS subdomain after cryotherapy treatment for congestion (A), itching (B), rhinorrhea (C), and sneezing (D) [3-7,9]. TNSS, total nasal symptom score.

$I^2=40.3%$, 6 months (0.5881 [0.4271–0.7491]; $I^2=31.6%$), and 12 months (0.6400 [0.2711–1.0089]; $I^2=NA$) ($p=0.1850$). In particular, the mean difference of congestion scores from baseline increased significantly over time (from 1 month to 12 months after treatment; $p=0.0009$). These results showed that cryoablation would be beneficial for all subdomains of nasal symptoms, especially congestion, in chronic rhinitis. Because some included studies measured changes in outcomes by rhinitis type (allergic rhinitis [AR] or NAR), we also evaluated changes based on the type of rhinitis. The TNSS in both types of rhinitis changed significantly from the baseline during all follow-up periods (Fig. 4): AR at 1 month (mean difference [95% CI]: 3.4981 [3.1207–3.8755]; $I^2=0.0%$), 3 months (3.1253 [2.7004–3.5501]; $I^2=0.0%$), 6 months (3.3284 [2.7670–3.8898]; $I^2=9.5%$), and 12 months (3.7090 [3.1356–4.2823]; $I^2=0.0%$) ($p=0.3853$) and NAR at 1 month (3.2365 [2.3941–4.0789]; $I^2=84.1%$), 3 months (3.6008 [2.8051–4.3965];

$I^2=71.4%$, 6 months (3.9654 [2.2997–5.6311]; $I^2=94.5%$), and 12 months (4.8577 [4.4067–5.3087]; $I^2=0.0%$) ($p=0.0017$). Therefore, cryoablation would be effective in both types of rhinitis and have better long-term efficacy in NAR.

Incidence of adverse effects from ClariFix after cryoablation treatment

There were no major or irreversible adverse effects (e.g., neurovascular injuries) reported in the included studies. The minor or reversible effects included nasal dryness (proportion=0.0467 [95% CI: 0.0089–0.2106]; $I^2=85.9%$), epistaxis (0.0280 [0.0134–0.0576]; $I^2=0.0%$), ocular symptoms (dry or watery eyes) (0.0140 [0.0038–0.0496]; $I^2=0.0%$), and palatal numbness (0.0267 [0.0037–0.1696]; $I^2=83.0%$) and occurred in <5% of patients who underwent ClariFix cryoablation. By

contrast, the incidence of postoperative pain and headache were reported to be 0.2122 (0.0896–0.4245; $I^2=89.4\%$) and 0.1028 (0.0398–0.2405; $I^2=88.8\%$), respectively (Fig. 5).

DISCUSSION

Pharmaceutical interventions, including corticosteroids,

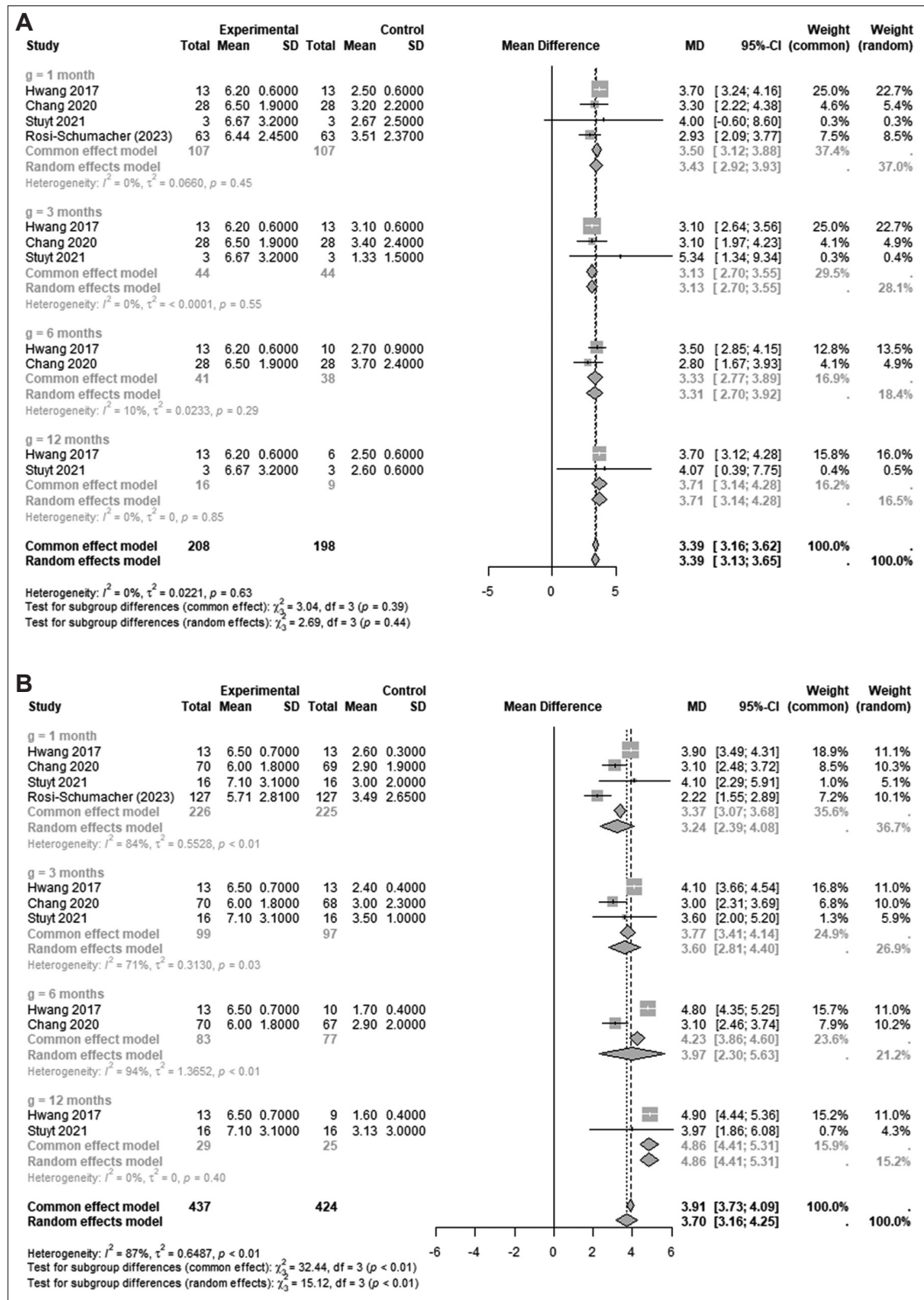


Fig. 4. Changes in TNSSs after cryotherapy treatment for AR (A) and NAR (B) [4,6,7,9]. TNSS, total nasal symptom score; AR, allergic rhinitis; NAR, nonallergic rhinitis.

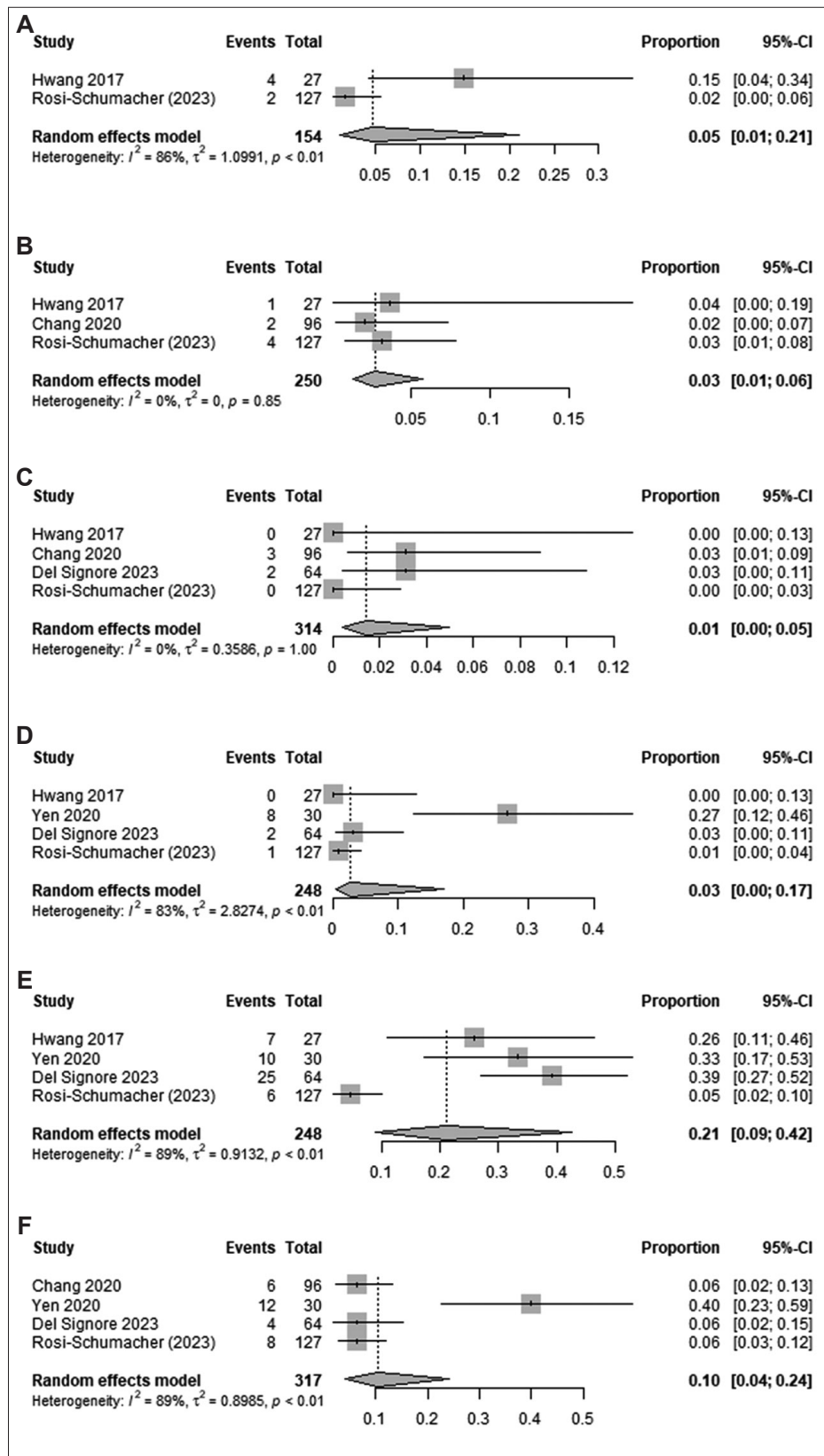


Fig. 5. Incidence of nasal dryness (A), epistaxis (B), ocular symptoms (C), palatal numbness (D), postoperative pain (E), and headache (F) after cryotherapy treatment for chronic rhinitis [3-5,7,9].

antihistamines, leukotriene receptor antagonists, anticholinergics, and decongestants, represent primary therapeutic approaches for managing chronic rhinitis. Immunotherapy is selectively employed in certain AR cases, while ongoing research into biologic treatments is in progress [11]. Nonetheless, compared to AR, there remains a paucity of research and development dedicated to medications for chronic rhinitis including NAR [12]. Consequently, medications prescribed for AR patients are often administered to patients with chronic rhinitis based on symptomatic presentations. This study elucidated the efficacy of cryoablation targeting the posterior nasal nerve in chronic rhinitis cohorts, demonstrating notable effectiveness, particularly in chronic rhinitis cases. Furthermore, cryoablation proves efficacious in alleviating prevalent rhinitis symptoms such as rhinorrhea and congestion, which commonly prompt outpatient consultations. Therefore, the finding that cryoablation of the posterior nasal nerve offers heightened efficacy in chronic rhinitis treatment holds significant implications for future therapeutic strategies.

Chronic rhinitis involves complex interactions between sensory and autonomic nerve pathways, with sensory pathways detecting allergens and irritants that elicit a parasympathetic response via the vidian nerve [13]. Procedures such as vidian neurectomy aim to alleviate chronic rhinitis symptoms; however, they may engender side effects like dry eyes due to the ablation of parasympathetic innervation to the lacrimal glands [14,15]. Ablation of the posterior nasal nerve presents a viable strategy to mitigate such side effects [16]. Therefore, targeted therapies focusing on this region offer symptom relief while minimizing associated adverse effects. Cryoablation, a simple office-based procedure, utilizes liquid nitrogen to ablate posterior nasal tissue, inducing ice crystal formation and cellular contraction, ultimately leading to cellular lysis [17]. Cryoablation has advantages such as precise soft tissue and nerve ablation, a predictable depth of penetration, preserved arterial vascular supply, and reduced risk of necrosis. In contrast to endoscopic vidian neurectomy, cryoablation eliminates the need for general anesthesia and mitigates the risk of postoperative dry eye, a complication observed in half of vidian neurectomy patients [16]. Nonetheless, cryoablation is associated with adverse events in a subset of patients, with post-procedural pain or discomfort being the most common. Other reported events include headache, nasal synechia, palatal numbness, sinusitis, sinus pain, epistaxis, eye dryness, eye pressure, ear discomfort, and vasovagal reaction, although the majority are transient and mild. It is imperative to acknowledge that a recent randomized, sham-controlled trial highlighted a notable incidence of adverse events in the treatment group, underscoring the importance of vigilant monitoring and patient counseling. Recent studies have explored postnasal nerve ab-

lation for chronic rhinitis treatment, albeit with an ambiguous definition of “chronic rhinitis.” Notably, diverse outcome measures across studies introduce heterogeneity in findings integration, which necessitates standardized assessments. Moreover, studies sponsored by the device manufacturer warrant scrutiny for potential conflicts of interest, necessitating independent verification of findings.

Overcoming these limitations requires long-term, high-quality randomized controlled trials to definitively establish cryoablation’s safety and efficacy. Furthermore, meticulous examination of patients with chronic rhinitis to discern treatment effects across subtypes and symptomatic classifications is warranted to inform tailored therapeutic strategies.

CONCLUSION

Intranasal cryoablation directed at the posterior nasal nerve demonstrates favorable outcomes in managing chronic rhinitis. The enduring impacts were particularly discernible up to 12 months after treatment, and significant enhancements were evident across both allergic and nonallergic rhinitis.

Supplementary Materials

The online-only Data Supplement is available with this article at <https://doi.org/10.18787/jr.2024.00015>.

Ethics Statement

Not applicable

Availability of Data and Material

All data generated or analyzed during the study are included in this published article and its supplementary information files.

Conflicts of Interest

Se Hwan Hwang and Do Hyun Kim who are on the editorial board of the *Journal of Rhinology* were not involved in the editorial evaluation or decision to publish this article. The remaining author has declared no conflicts of interest.

Author Contributions

Conceptualization: Se Hwan Hwang, Do Hyun Kim. **Data curation:** all authors. **Formal analysis:** Se Hwan Hwang. **Funding acquisition:** Se Hwan Hwang. **Investigation:** Se Hwan Hwang, Do Hyun Kim. **Methodology:** Do Hyun Kim. **Project administration:** Se Hwan Hwang, Do Hyun Kim. **Resources:** Se Hwan Hwang. **Software:** Se Hwan Hwang. **Supervision:** all authors. **Validation:** Se Hwan Hwang, Do Hyun Kim. **Writing—original draft:** Bo Yun Choi. **Writing—review & editing:** all authors.

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