Received: 31 July 2023 | Revised: 16 September 2023 | Accepted: 23 September 2023

DOI: 10.1002/alr.23284

IFAR: International Forum of Allergy & Rhinology

ORIGINAL ARTICLE

Acoustic resonance therapy is safe and effective for the treatment of nasal congestion in rhinitis: A randomized sham-controlled trial

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Abstract

Background: Acoustic resonance therapy (ART) is a novel vibrational treatment that delivers patient-specific resonant frequency acoustic energy to the sinonasal cavities. In a pilot study, ART was effective for the acute treatment of nasal congestion. We conducted a sham-controlled randomized trial to validate the efficacy of ART when administered daily for 2 weeks.

Methods: A total of 52 adult patients were enrolled in a multi-center, randomized, double-blinded, sham-controlled, interventional study evaluating ART administered by a vibrational headband. Patients received either active treatment or a non-therapeutic sham treatment twice daily over 2 weeks. Clinical endpoints were the average change in nasal congestion sub-score of the Total Nasal Symptom Score (TNSS) and the average change in composite TNSS.

Results: ART resulted in a significantly greater mean change in the nasal congestion sub-score compared to sham (−0.87 [95% confidence interval [CI] −1.11,

Abbreviations: ART, acoustic resonance therapy; MCID, minimal clinically important difference; TNSS, Total Nasal Symptom Score.

−0.62] vs. −0.44 [95% CI −0.64, −0.23], $p = 0.008$). ART also resulted in a significantly greater reduction in the composite TNSS versus sham, (−2.85 [95% CI −3.85, −1.85], vs. −1.32 [95% CI −2.27, −0.36], $p = 0.027$). The response rate, determined by a nasal congestion sub-score minimal clinically important difference of 0.23, was 80.8% for ART and 46.2% for sham, with an adjusted risk ratio of 1.95 (95% CI 1.26, 3.02, $p = 0.003$) in favor of ART. Safety endpoints showed no adverse events.

Conclusion: ART is a safe and effective non-pharmacologic alternative for the treatment of nasal congestion.

KEYWORDS

acoustic resonance, allergic rhinitis, humming, nasal congestion, non-allergic rhinitis, randomized trial, vibration

1 | INTRODUCTION

Nasal congestion is a highly prevalent symptom that is estimated to affect roughly 20% of the world population.[1] It is a key symptom in a number of common conditions such as allergic rhinitis and can lead to a variety of related quality of life disturbances including impairments in daytime productivity and lower quality of sleep. As a result, the economic burden associated with nasal congestion and its related causes is substantial. The global sale of over-the-counter allergy medications for the treatment of allergic rhinitis was projected to reach $14.8 billion in 2021.[2] Moreover, productivity-related losses secondary to allergic rhinitis were estimated in 2003 to range from $2 to $5 billion in the United States alone.[3] Overall, patients experience a significant detriment of quality of life as a result of nasal congestion, impairing physical, mental, and social functioning.

Clinical studies have demonstrated that acoustic energy or vibration applied to the sinonasal cavities results in quantifiable nasal decongestion and thereby present an underexplored non-pharmacologic treatment option for nasal congestion.[4–7] Acoustic resonance therapy (ART) is a novel method of delivering acoustic energy to the nasal cavity and paranasal sinuses. ART is differentiated from non-resonant acoustic vibrational therapies because ART delivers vibrations at the specific resonant frequency of the sinonasal cavities to achieve maximum transfer of energy. Because the resonant frequency is directly dependent on the volume of the airspaces being vibrated (as with a musical instrument) based on the Helmholz equation, the calculation of nasal cavity and paranasal sinus volumes is critical to "tuning" the vibration to the optimal resonant frequency, which, like all aspects of anatomy, is variable and patient specific. Resonant frequency vibration energy has been shown in previous literature to improve delivery of nebulized topical medications and, more recently, to reduce nasal congestion when applied externally to the face.[8,9]

A single-arm non-randomized pilot study evaluated the efficacy of ART as delivered via a sound-emitting headband worn by the patient.[9] In a cohort of 50 participants, there were statistically significant decreases in nasal congestion after two treatment cycles of 10 min each, with 90% of subjects overall reporting an improvement.[9] The present study seeks to further validate the safety and effectiveness of ART for nasal congestion via a 2-week, randomized sham-controlled trial.

2 | MATERIALS AND METHODS

The study was designed as a multi-center, randomized, double-blinded, sham-controlled evaluation of the safety and effectiveness of an ART headband as a treatment for moderate to severe nasal congestion (Sonu by Sound Health Systems, Los Altos, CA). The study protocol received approval from the Western Institutional Review Board. Subjects were recruited from the patient population served by three geographically distinct practices (San Francisco, CA, otolaryngology; Bethlehem, PA, otolaryngology and allergy; Fresno, CA, allergy). Patients with nasal congestion were identified and screened by the treating physician, and enrolled subjects received a modest remuneration ($125) for participation in the trial.

2.1 | Device description

ART was delivered through an adjustable headband that houses two bone conduction transducers and is worn circumferentially at the level of the forehead (Figure 1). The

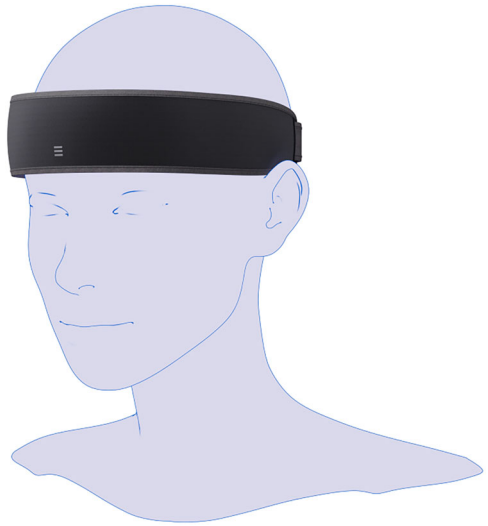

FIGURE 1 Schematic of treatment headband as worn on participant during treatment.

headband has a Bluetooth connection to a smartphone app, enabling controlled delivery of ART to the sinonasal cavities. To calculate the resonant frequency unique to a given subject, the app utilized the smartphone's self-facing camera to capture multiple surface anatomic landmarks, which served as proxies for the boundaries of the nasal cavity, ethmoid sinuses, and maxillary sinuses. These collected points (>1000) were then used to create a virtual mesh surface, from which sinonasal volume was calculated using a machine-learning predictive model based on correlative CT-derived data sets. The initial algorithm for calculation of maxillary sinus volume was based on a data set of 28 CT scans and corresponding facial mesh surfaces.[10] The algorithm employed in our study was further enhanced with 75 additional patient CT scans and corresponding facial mesh data, which allowed for calculation of maxillary sinus, ethmoid sinus, and nasal cavity volumes (sphenoid and frontal sinuses excluded). The subject's unique resonant frequency and associated harmonics were calculated using a proprietary algorithm (unpublished). These resonant frequencies fall in the audible range of 100 Hz–1 kHz.

Patients in the therapeutic treatment arm received continual sound transmission of the calculated resonant frequency and harmonics played through the headband for 15 min twice daily. The sham treatment, delivered through a physically identical device, entailed delivery of a non-resonant acoustic tone (2 kHz) delivered at 50% volume for 2 s, followed by an 8-s period of silence, cycled for 15 min. Developed in conjunction with and approved by the FDA, the sham treatment protocol using 2 kHz was chosen, as the frequency falls outside the highest resonant range of the treatment group while still allowing the patient to feel and hear the acoustic vibrations.

2.2 | Eligibility criteria

Patients were 18 years of age or older, presenting with symptoms of moderate to severe nasal congestion for at least 1 month. Moderate to severe nasal congestion was defined as having a 24-h reflective nasal congestion subscore of the Total Nasal Symptoms Score (TNSS) of 2 or more at the time of screening. The TNSS is a validated patient-reported outcome measure for nasal disease, measuring four symptom subdomains accounting for rhinorrhea, nasal congestion, nasal itching, and sneezing, each self-rated on a scale of 0–3 with a total possible score of 12.[11]

Patients with head or sinonasal surgery within the past 3 months, sinus infection within the last month, rhinitis medicamentosa, or a history of nasal polyposis or mass were excluded. No physical exam/nasal endoscopy findings or radiologic criteria were used for either inclusion or exclusion.

2.3 | Randomization and blinding

Patients were asked to discontinue all as-needed allergy medications and decongestants prior to enrollment, but were allowed to continue all other regularly taken nasal and oral allergy medications. After informed consent, participants were then randomized 1:1 to active therapy (ART) versus placebo. Patients received the device (either active therapy or sham) at an initial clinic visit and self-administered treatments for a 2-week study duration, according to device use instructions included with the product.

2.4 | Outcome measurement

The primary effectiveness endpoint was defined as a statistically significant improvement in the nasal congestion sub-score of the TNSS averaged over the 2-week treatment period compared to baseline screening. The secondary effectiveness endpoint was defined as a statistically significant improvement in 24-h reflective TNSS averaged over the 2-week treatment period compared to baseline screening.

The safety endpoint was defined as a lack of serious adverse events. Adverse events that were measured included inpatient hospitalization, necessity of medical or surgical intervention as a result of device use,

permanent impairment of a body structure or function, or life-threatening illness or injury.

2.5 | Statistical analysis

Sample size calculations were based upon the prior pilot study demonstrating greater than 25% mean percent improvement in the nasal congestion sub-score as a result of ART.[9] Assuming an estimated baseline nasal congestion sub-score of 2.1 with standard deviation of 0.30 and a 10% attrition rate, 20 subjects were needed to achieve a 90% power to detect a primary endpoint of 25% difference in nasal congestion sub-score between groups. A total sample size of 50 was chosen to ensure >90% power to measure the primary endpoint but also a >90% power to detect the secondary endpoint of >30% difference in overall TNSS between groups.

Descriptive statistics and graphs were used to summarize the data. For categorical variables, counts and percentages were calculated. For continuous variables, means, standard deviations, standard errors, and 95% confidence intervals were calculated. Statistical analysis was conducted on an intent-to-treat basis. Changes in TNSS and nasal congestion sub-scores from baseline to 2-week study period were evaluated using a paired *t*-test, and the distributions of within-subject changes from baseline over the 2-week study period were examined. Changes in TNSS and nasal congestion sub-scores between ART and sham groups were compared using linear mixed effect models with repeated measures. The models further controlled for subjects' demographic factors and allergic or non-allergic rhinitis to estimate the adjusted treatment effect. Two tailed *t*-tests were used and a *p*-value of 0.05 or less was considered statistically significant.

A clinically meaningful change in TNSS from baseline was defined as the minimal clinically important difference (MCID) of 0.23, identified using anchor-based methods in allergic rhinitis.[12,13] Due to the lack of MCID being described in the literature for the nasal congestion sub-score, 0.23 was assumed to be the MCID of this sub-score as well. Univariable and multivariable Poisson regression models with robust variance were created to estimate the crude and adjusted risk ratio of the MCID.[14]

Overall responder rate was further defined as the proportion of patients who reported improvement in nasal congestion greater than the MCID of 0.23 in TNSS. This analysis was performed by comparing the reduction in TNSS after the 2-week period to baseline for ART and sham groups.

The success of blinding was assessed by Bang's blinding index, a statistical instrument that is used to evaluate the adequacy of blinding in a randomized controlled trial,

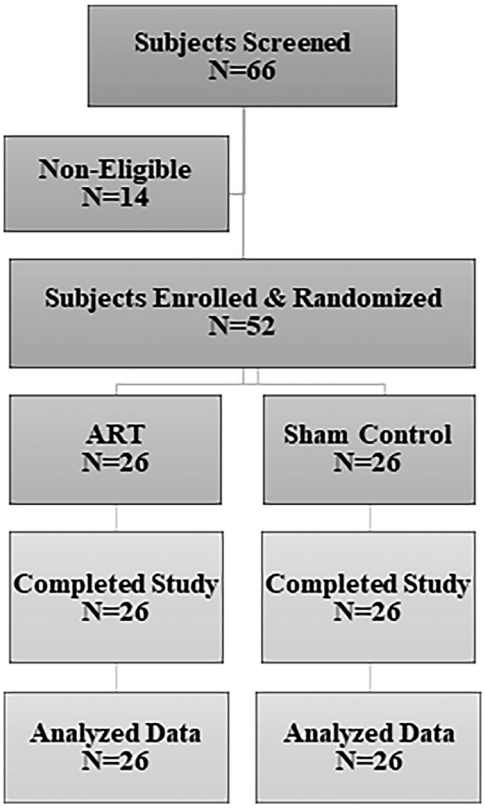

FIGURE 2 Flowchart of randomization.

based on responses to a standard set of questions. In our study, subjects were asked after completing the final day of the study period whether they could guess which arm of the study they were randomized to. The trial was registered on clinicaltrials.gov (ID NCT05821842).

3 | RESULTS

A total of 52 subjects were recruited and randomized (Figure 2). As shown in Table 1, the study population consisted of 22 males (42.3%) and 30 females (57.7%), with a broad range of ages, race, and ethnicities. Twenty-eight (54.9%) participants had self-reported allergic rhinitis and 23 (45.1%) participants had non-allergic rhinitis, with one not responding. Baseline nasal congestion sub-scores and TNSS were well matched between the ART and sham control arms. Overall, about 44% of the subjects continued their daily allergy medications or saline rinses (which they were previously taking) during the study and the remaining 56% did not take allergy medications during the study; there were no significant differences between the two groups.

The primary effectiveness analysis showed that at the 2-week follow-up, the ART group showed a greater clinically and statistically significant mean reduction in the nasal congestion sub-score versus sham (−0.87 [95% confidence

TABLE 1 Demographics of study subjects.

	ART	Sham	Total	*p*-value
Sex				
Male (%)	16 (61.5%)	6 (23.1%)	22 (42.3%)	0.005[b]
Female (%)	10 (38.5%)	20 (76.9%)	30 (57.7%)	
Age				
Mean ± standard deviation	45.3 ± 17.7	48.8 ± 14.9	47.1 ± 16.3	0.38[a]
Median (minimum–maximum)	43.5 (18-76)	48 (18-72)	45 (18-76)	
Ethnicity				
Hispanic/Latino	6 (23.1%)	4 (15.4%)	10 (19.2%)	0.48[b]
Not-Hispanic/Latino	20 (76.9%)	22 (84.6%)	42 (80.8%)	
Race[d]				
Asian	6 (28.6%)	4 (18.2%)	10 (23.3%)	0.48[c]
Unknown	0 (0.0%)	1 (4.5%)	1 (2.3%)	
White	14 (66.7%)	17 (77.3%)	31 (72.1%)	
White/Asian	1 (4.8%)	0 (0.0%)	1 (2.3%)	
Allergic vs. non-allergic rhinitis[e]				
Allergic (%)	12 (48.0%)	16 (61.5%)	28 (54.9%)	0.33[b]
Non-allergic (%)	13 (52.0%)	10 (38.5%)	23 (45.1%)	
Baseline nasal congestion sub-score				
Mean ± SD	2.27 ± 0.45	2.12 ± 0.33	2.20 ± 0.39	0.17[b]
Baseline TNSS				
Mean ± SD	6.65 ± 2.37	6.58 ± 2.10	6.62 ± 2.24	0.90[b]
Medication				
Subjects on daily allergy meds during treatment	10 (38.5%)	13 (50.0%)	23 (44.2%)	0.40[b]

Abbreviations: ART, acoustic resonance therapy; TNSS, Total Nasal Symptom Score.

[a]Based on Mann–Whitney test.

[b]Based on chi-squared test.

[c]Based on Fisher's exact test.

[d]A total of nine patients did not report race (five in ART and four in Sham).

[e]One patient did not report allergic or non-allergic rhinitis.

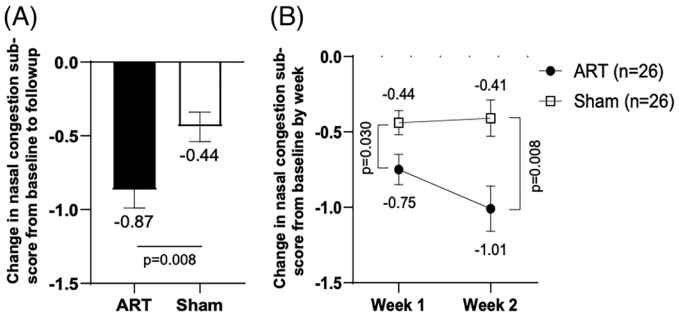

FIGURE 3 Nasal congestion sub-score improves with acoustic resonance therapy. (A) Mean change in nasal congestion sub-score of Total Nasal Symptom Score (TNSS) was calculated from baseline to after 2-week daily treatments with either acoustic resonance therapy (ART) or sham and (B) mean change in nasal congestion sub-score of TNSS from baseline was calculated after Weeks 1 and 2 of treatment with either ART or sham. Error bars depict standard error.

interval [CI] −1.11, −0.62] vs. −0.44 [95% CI −0.64, −0.23], $p = 0.008$). Figure 3A shows the average change in the nasal congestion sub-score for the ART and sham groups. After adjustment for age, gender, and allergic/non-allergic rhinitis, the difference in change of the nasal congestion sub-score between the two groups increased from 0.43 to 0.47 (95% CI 0.15, 0.79), remaining statistically significant ($p = 0.005$).

Additionally, a time-based analysis showed that average weekly nasal congestion sub-score for ART was further reduced in Week 2 compared to Week 1. At Week 1, the reduction in nasal congestion sub-score was −0.75 for ART versus −0.44 for sham ($p = 0.03$), whereas in Week 2, the reduction in nasal congestion sub-score was −1.01 for ART versus −0.41 for sham ($p = 0.008$) (Figure 3B). Using repeated measures analysis, the between-group difference

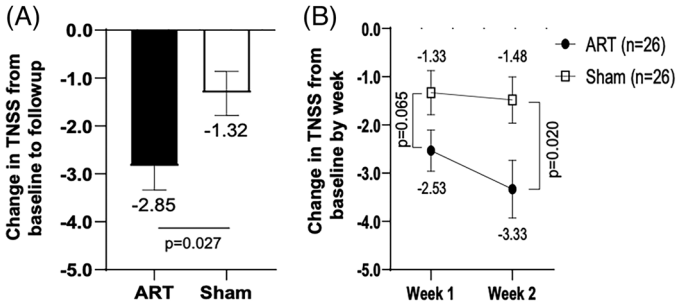

FIGURE 4 Total Nasal Symptom Score (TNSS) improves with acoustic resonance therapy. (A) Mean change in TNSS was calculated from baseline to after 2-week daily treatments with either acoustic resonance therapy (ART) or sham and (B) mean change in TNSS from baseline was calculated after Weeks 1 and 2 of treatment with either ART or sham. Error bars depict standard error.

in reduction in the nasal congestion sub-score was 0.49 (95% CI 0.06, 0.92; $p = 0.026$) at Day 14, exceeding the difference obtained using the 14-day average (0.43, 95% CI −0.12, 0.74; $p = 0.008$).

The secondary effectiveness analysis also demonstrated clinically and statistically significant reductions in the composite TNSS for ART versus sham (−2.85 vs. −1.32, $p = 0.027$) (Figure 4A). After adjustment for age, gender, and allergic/non-allergic rhinitis, the difference in change of the TNSS between the two groups increased from 1.53 to 1.80 (95% CI 0.46, 3.13) and remained statistically significant ($p = 0.009$). Using repeated measures analysis at Day 14, the unadjusted difference between groups for the reduction in TNSS was 1.77 (95% CI 0.45, 3.09; $p = 0.009$) and the adjusted difference was 2.16 (95% CI 0.80, 3.53; $p = 0.002$). Both measures exceeded the difference obtained using the 14-day average.

As with the nasal congestion sub-score, the weekly average TNSS for ART demonstrated progressive reduction between Weeks 1 and 2 of treatment (Figure 4B). At Week 1, the reduction in TNSS was −2.53 for ART versus −1.33 for sham ($p = 0.065$); for Week 2, the reduction in TNSS was −3.33 for ART versus −1.48 for sham ($p = 0.02$).

The responder analysis showed that for the nasal congestion sub-score of the TNSS, the ART group had an 80.8% treatment responder rate compared to a 46.2% responder rate in the sham group ($p = 0.02$). The ART group had a 75% higher probability of achieving or exceeding the MCID of 0.23 compared to the sham group (risk ratio = 1.75, 95% CI 1.11, 2.76; $p = 0.016$). After adjusting for demographics and allergic/non-allergic rhinitis, the risk ratio increased to 1.95 (95% CI 1.26, 3.02; $p = 0.003$). When examining overall TNSS, the ART group response rate was 84.6% compared to 65.4% for the sham group ($p = 0.11$). The ART group had a 29% higher probability of achieving or exceeding the MCID of TNSS compared to the sham group (risk ratio = 1.29, 95% CI 0.94, 1.79; $p = 0.12$). However, the risk ratio was improved and became statistically significant after adjustment for demographics and allergic/non-allergic rhinitis (risk ratio = 1.51, 95% CI 1.10, 2.08; $p = 0.011$).

Participants were adherent to 84.8% of possible treatments (1234 doses out of a total possible of 1456 doses), with adherence being similar between ART (81.0%, 95% CI 71.1, 91.0) and sham groups (88.5%, 95% CI 83.3, 93.6).

The success of blinding was assessed using Bang's blinding index, separately for the two groups. Bang's index for the sham group was −0.08 (95% CI −0.34, 0.18), indicating that 8% of sham participants mistakenly named ART beyond random chance. Bang's index of the ART group was 0.36 (95% CI 0.09, 0.63), indicating that about 36% of participants correctly guessed their treatment devices beyond random chance.

The safety analysis showed that there were no intervention-related severe or non-severe adverse events.

4 | DISCUSSION

ART builds on the previously demonstrated benefits of vibrational energy for the treatment of upper and lower airway disease. Specific breathing exercises that incorporate humming have been practiced for centuries and have recently been shown to reduce symptoms of chronic rhinosinusitis including nasal congestion.[15,16] Vibration systems have now been used extensively in respiratory therapy for patients with chronic lower respiratory disorders.[17] Vibration is thought to decrease congestion through three possible mechanisms: (1) sinonasal mucosal vasoconstriction, (2) increased muco-ciliary clearance, and (3) decreased mucus viscosity.[6–8,16,18] Vibration has also been shown to result in vasoconstriction in vivo.[18–20] Furthermore, in patients with chronic pulmonary disease, techniques using vibration have been shown to increase muco-ciliary clearance by aiding in mucus expectoration, decreasing airway collapsibility, and facilitating airflow.[18,21,22]

In the upper airway, other forms of vibrational therapy for the treatment of nasal congestion have demonstrated similar effects. A single-frequency vibrational device with positive pressure increased peak inspiratory nasal airflow and improved nasal-related quality of life in patients without fixed anatomic obstruction who suffer from nasal congestion.[23,24] However, current treatment options lack the delivery of vibrations at sinonasal resonant

frequencies, which are matched to individual patient anatomy. Delivery of energy at the correct resonant frequency and intensity has previously been demonstrated to be important in optimizing drug deposition in nebulization of topical sinonasal medications.[8]

Many patients are unsatisfied with the range of current treatment options for chronic nasal congestion, presenting opportunities for innovation.[1] Intranasal corticosteroid sprays have been associated with nasal dryness and bleeding.[25] Nasal decongestant sprays risk the development of rhinitis medicamentosa,[26] and oral decongestants can be associated with cardiovascular side effects including hypertension and tachycardia.[27] Some patients wish to avoid pharmacologic treatments altogether and are seeking additional options using non-pharmacologic strategies. Furthermore, surgical treatments for chronic congestion can be associated with suboptimal efficacy, relapse of symptoms, or surgical complications.

Based on this double blinded, sham-controlled study, ART appears to be a safe and effective non-pharmacologic treatment for nasal congestion. Both primary and secondary endpoints were achieved, with ART showing a statistically significant reduction in the nasal congestion sub-score of the TNSS and composite TNSS using the 2-week average when compared to sham. Additionally, the repeated measures analysis and time analysis supported these findings, demonstrating that clinical improvement in nasal congestion and composite TNSS from ART is rapid in onset and sustained without tachyphylaxis, with even greater improvements seen in the second week of treatment.

The effect size for ART in our study compares favorably with that of nasal corticosteroid sprays as reported in randomized placebo-controlled trials for allergic rhinitis.[28] Vasar et al. showed that fluticasone furoate, used as monotherapy for the treatment of perennial allergic rhinitis, was superior to placebo, resulting in a −0.97 reduction in the nasal congestion sub-score of the TNSS versus −0.69 for placebo (difference of −0.277). The composite TNSS was reduced by −3.82, compared to −2.36 for placebo (difference of −1.459).[28] Placebo effect sizes in the Vasar study and our study were notable but were exceeded significantly in both studies by the active treatment arm, and in our study the responder rate of the treatment arm also significantly exceeded sham. These findings speak to the importance of evaluating new therapies through rigorous controlled trials.

ART may serve as an effective non-pharmacologic alternative to standard medical therapies for the treatment of rhinitis. There has been recognition of a multitude of barriers which result in poor adherence to pharmacologic management of rhinitis, including fear of adverse effects, perceived lack of efficacy, poor health literacy, and forgetfulness, among others.[29,30] Recent literature has shown that medication adherence to intranasal corticosteroid treatment in allergic rhinitis is as poor as 58.9%.[29] In addition, nasal topical therapies, although traditionally regarded as having a low side effect profile, can be bothersome to patients due to irritation, epistaxis, and bad taste.[29,31,32] Based on the results of this study, which showed that patients were successful at self-administering ART at home, non-pharmacologic self-administered devices for the treatment of rhinitis may be an attractive alternative for those patients who have difficulty adhering to pharmacologic management.

Although the focus of this study was the symptom of nasal congestion, the broader improvements seen in the composite TNSS score suggest that conditions other than rhinitis may possibly be worthy of study. Future trials for ART may include indications such as chronic rhinosinusitis and upper airway resistance syndrome.

5 | LIMITATIONS

Although the MCID for the overall TNSS is defined as >0.23, the MCID for the nasal congestion sub-score is not defined in the literature. Because 0.23 was used as the MCID of the nasal sub-score in this analysis, this is likely an overestimate of the real MCID given that this is only one sub-score of the total TNSS. This may indicate that the true responder rate for the nasal congestion sub-score of both the ART and sham groups are higher than the data in this analysis reflects.

While the assessment of blinding indicated that both groups had some ability to correctly identify their assigned treatment, better blinding was achieved in the sham group than the ART group. This limitation may reflect the inherent difficulty of blinding in ART, as differences in frequency of acoustic therapy are directly perceived by the patient.

Lastly, while adherence rates were high in this study with participants completing 85% of possible treatments and 84% of participants recording data for at least 10 days, real-world adherence to ART has not been studied. This may influence effectiveness of treatment if actual patient adherence rates are substantially lower.

6 | CONCLUSION

ART was safe and effective compared to sham control in a 2-week, multi-center, randomized, double-blind, sham-controlled interventional study of 52 patients suffering from moderate to severe nasal congestion secondary to allergic and non-allergic rhinitis.

CONFLICT OF INTEREST STATEMENT

Amber U. Luong serves as a consultant for Lyra Therapeutics, Medtronic, Neurent Medical, Sanofi, and Stryker. Amber U. Luong also serves on the scientific advisory board for ENTvantage Dx, Maxwell Biosciences, and Sound Health Systems. Michael Yong is a consultant for Sound Health Systems. Peter H. Hwang is a consultant for Slate Therapeutics, Stryker, Medtronic, and has equity ownership in Sound Health Systems. Bryant Y. Lin, Paramesh Gopi, and Vivek Mohan have equity ownership in Sound Health Systems. Yifei Ma is a consultant for Sound Health Systems. Jacob Johnson has no disclosures. David M. Yen is a consultant for Sound Health Systems. Richard S. DeMera is a member of the speakers bureau for GSK and Regeneron. Benjamin S. Bleier is a consultant for Olympus, Karl Storz, Medtronic, Sound Health Systems, Stryker, Diceros Therapeutics, and receives royalties from Thieme.

FUNDING INFORMATION

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How to cite this article: Luong AU, Yong M, Hwang PH, et al. Acoustic resonance therapy is safe and effective for the treatment of nasal congestion in rhinitis: A randomized sham-controlled trial. *Int Forum Allergy Rhinol*. 2023;1-9. https://doi.org/10.1002/alr.23284