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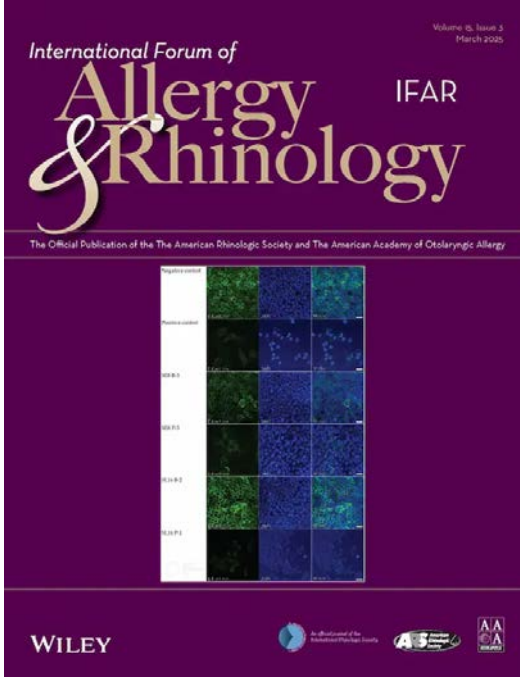

Acoustic resonance therapy is safe and effective for the treatment of nasal congestion in rhinitis : A randomized sham-controlled trial

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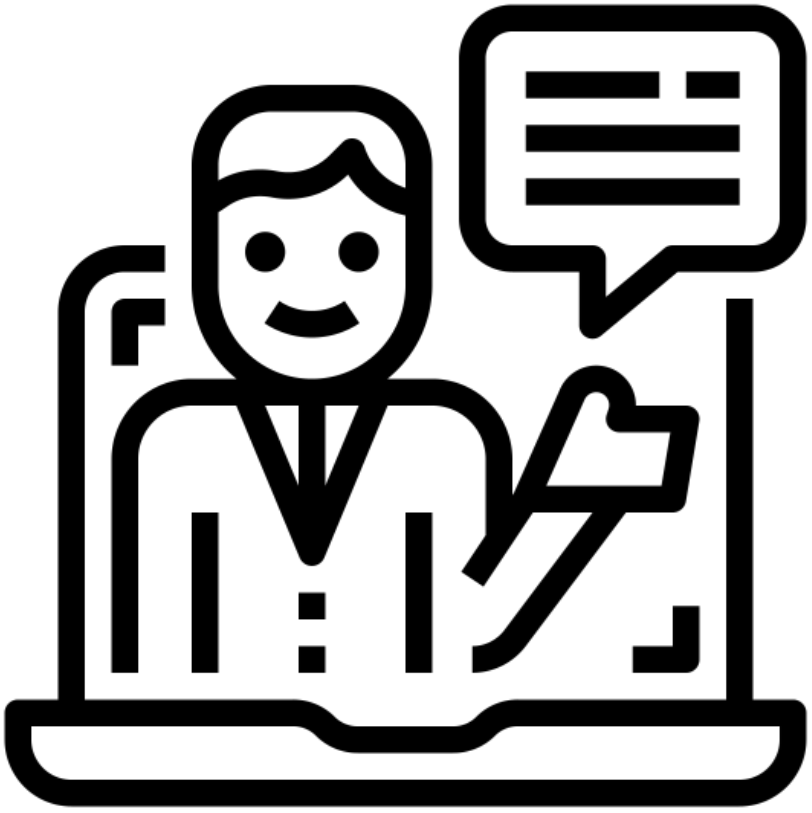
Introduction



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Background

- Nasal congestion affects roughly 20% of people worldwide.
- Significant implications for quality of life
  - Lowered productivity.
  - Impaired sleep quality.
- Substantial economic consequences

Diagnosis and Treatment of Adult Nasal Congestion According to EPOS 2020

Diagnosis Methods

1. **Symptom Assessment**
    1. Associated symptoms such as nasal discharge, olfactory dysfunction, headache, and facial pain help differentiate causes.
2. **Clinical Classification**
    1. Acute vs. chronic rhinosinusitis (CRS) based on duration
    2. Presence or absence of nasal polyps may influence treatment strategies
3. **Imaging and Endoscopy**
    1. **Nasal endoscopy**: Used to confirm structural abnormalities or nasal polyps
    2. **CT scan**: Recommended for assessing CRS severity, especially if symptoms persist or a tumor is suspected

Diagnosis and Treatment of Adult Nasal Congestion According to EPOS 2020

Pharmacological Treatment

1. **Nasal Corticosteroids**
2. **Antihistamines**
3. **Decongestants (Oral/Nasal)**
4. **Leukotriene Receptor Antagonists (e.g., Montelukast)**

   -May benefit patients with **allergic rhinitis or coexisting asthma**.
5. **Antibiotics**

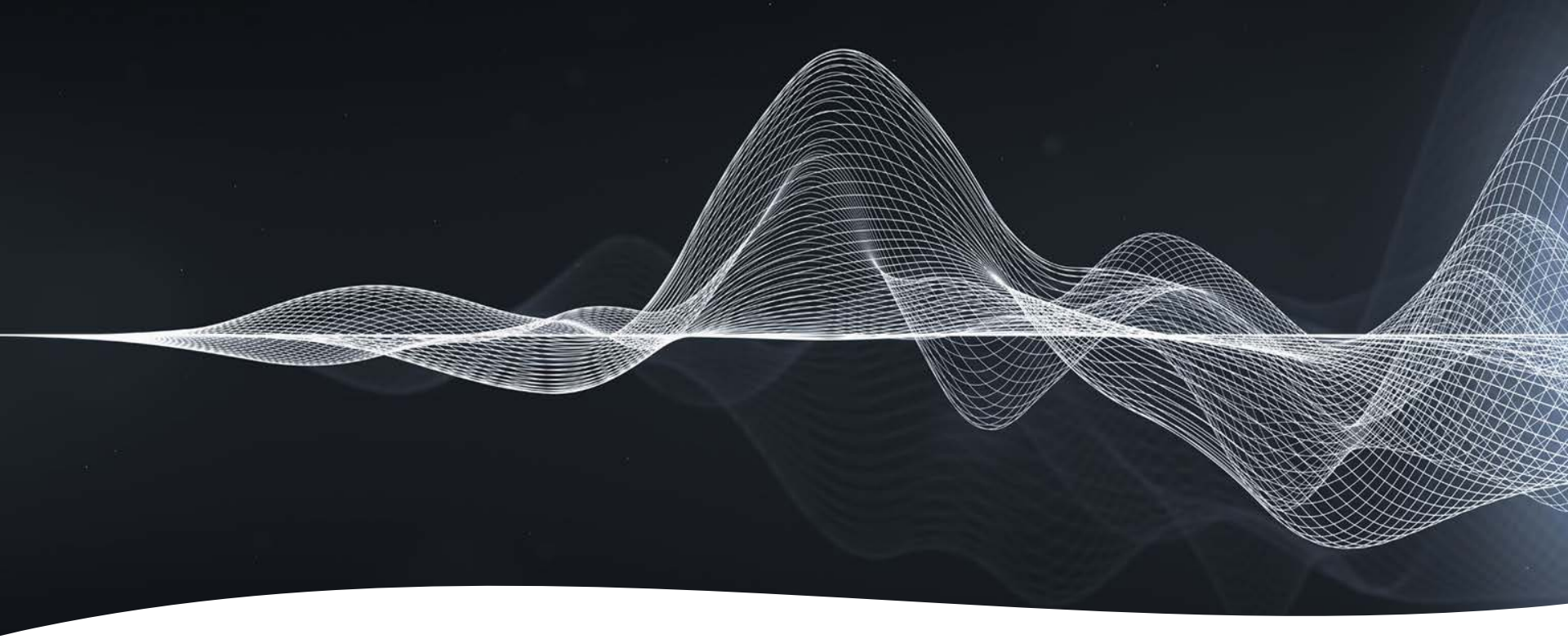
   -Not routinely recommended for viral rhinosinusitis due to lack of efficacy and risk of antimicrobial resistance
6. **Biologic Therapy (e.g., Dupilumab)**

   -Used for **severe CRSwNP**, improving **nasal congestion and sense of smell**.

Diagnosis and Treatment of Adult Nasal Congestion According to EPOS 2020

- **Non-Pharmacological Treatment**

1. **Nasal Irrigation**
    1. **Hypertonic saline irrigation** provides symptom relief for **acute upper respiratory infections and CRS**.
2. **Surgical Treatment (FESS, Functional Endoscopic Sinus Surgery)**
    1. Recommended for **severe CRS or CRSwNP** that is **unresponsive to medical therapy**.
3. **Other Adjunct Therapies**
    1. **Steam inhalation or honey-based ointments** may provide some relief, but evidence is limited.



Introduction to Acoustic Resonance Therapy (ART)

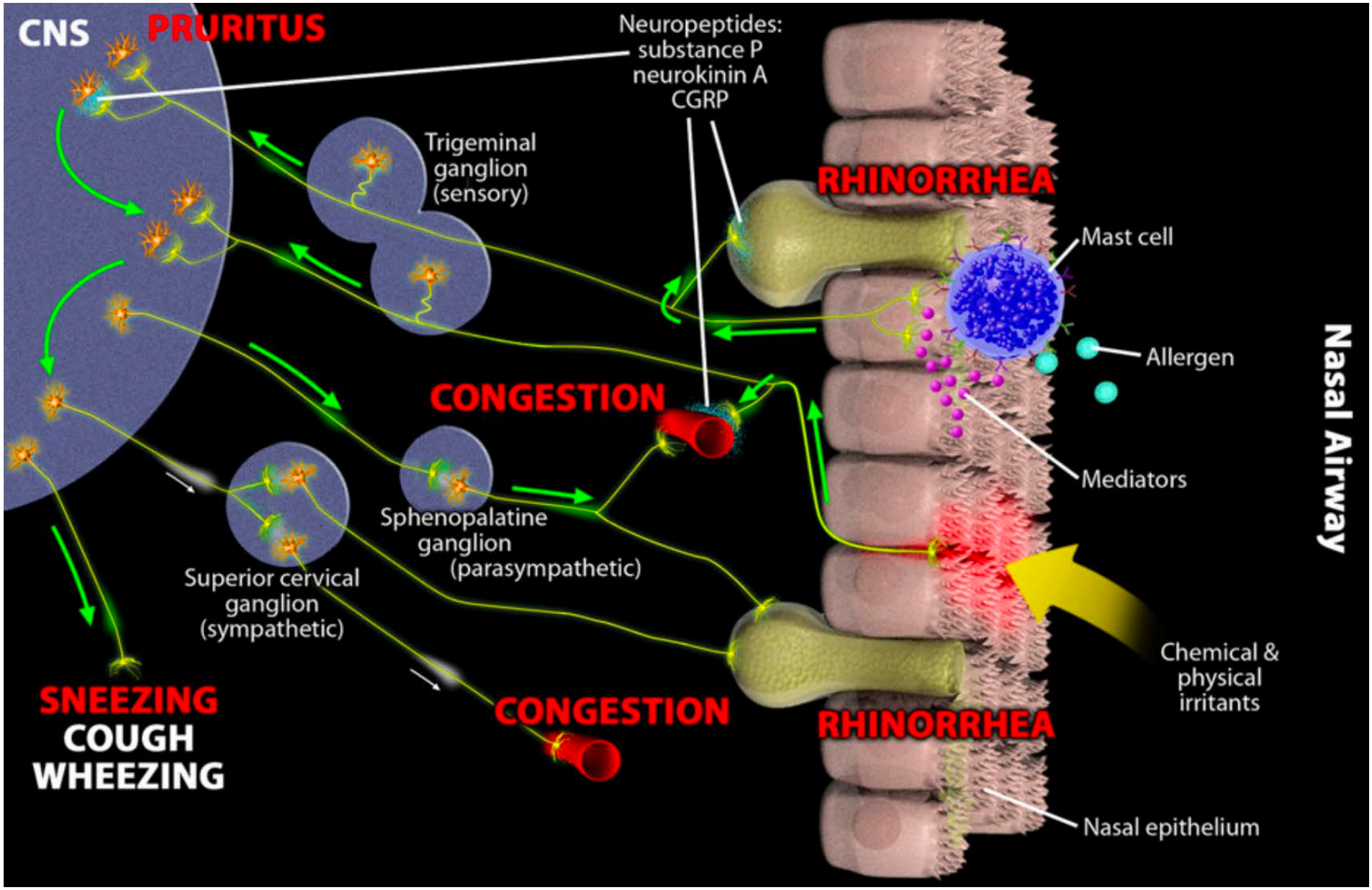
- Innovative non-pharmacological method
- Utilizes patient-specific resonant acoustic frequencies
- Targeted delivery to nasal cavity and sinuses

Mechanism of ART

- Resonant frequency acoustic energy matched to individual anatomy
- Potential mechanisms:
  - Sinonasal mucosal vasoconstriction
  - Enhanced mucociliary clearance
  - Reduced mucus viscosity

How ART Induces Vasoconstriction?

1. **Sound wave vibrations may influence sympathetic nervous activity**
    1. High-frequency sound waves or mechanical vibrations can activate the **sympathetic nervous system**, promoting the release of **norepinephrine**, which induces **vasoconstriction**.
2. **Similar effects to "humming" (Humming-induced NO release)**
    1. Studies have shown that **humming** significantly increases **nasal NO levels**, which affects nasal vascular tone.
    2. **Supporting study:**
        1. **Weitzberg & Lundberg, 2002**: *"Humming increases nasal NO concentration by 15 times compared to quiet breathing, potentially influencing nasal vascular regulation."*



Source: Sarin et al., J Allergy Clin Immunol, 2006;118:999-1014. DOI: 10.1016/j.jaci.2006.09.013.

ART Device Description

- Wearable adjustable headband
- Integrated bone conduction transducers
- Controlled via smartphone app
- Facial landmarks captured for individualized frequency calibration

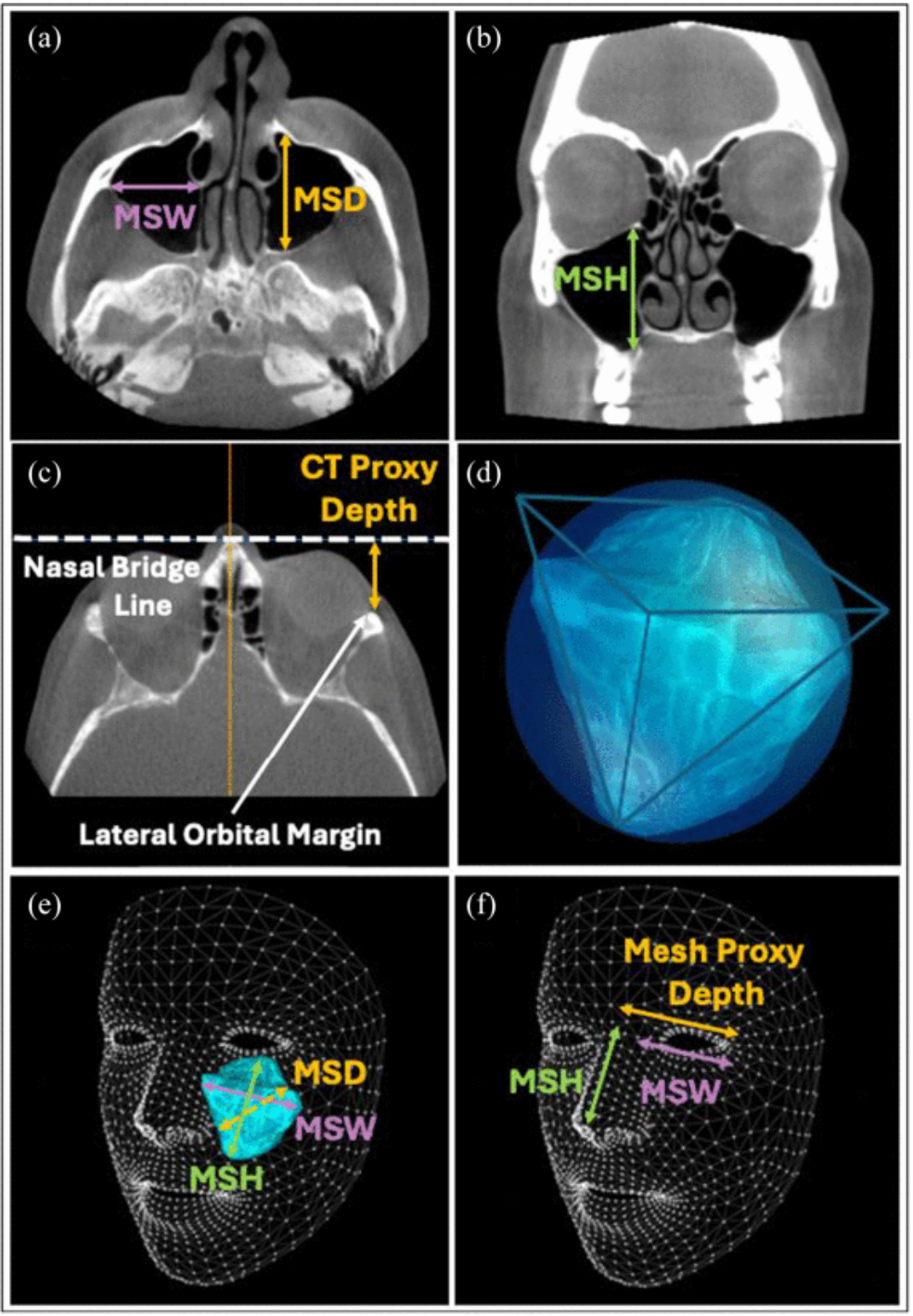
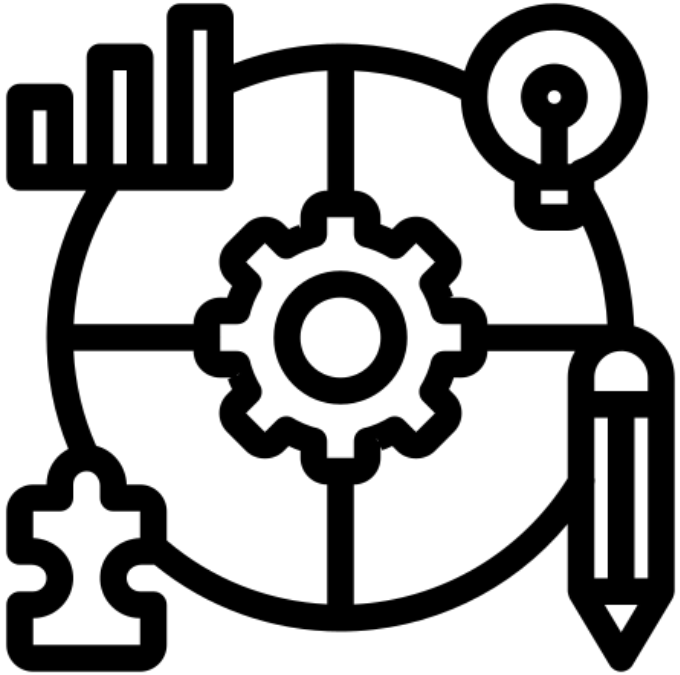


Fig. 1. Maxillary sinus measurements. Axial (a) and coronal (b) views of the maxillary sinus were used to calculate its maximal width (MSW), height (MSH) and depth (MSD). Axial view (c) showing the CT proxy depth measured from the lateral orbital margin to the line crossing the nasal bridge. Schematic (d) illustrating the maxillary sinus shape as an intermediate form between a sphere and a pyramid. 3D representation of the left maxillary sinus (e) on Apple's face mesh showing the three actual dimensions of the sinus. Measurements of the maxillary sinus width (MSW), height (MSH) and mesh proxy depth on Apple's face mesh. MSW: Maxillary sinus width, MSH: Maxillary sinus height, MSD: Maxillary sinus depth.

Method



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Study Objective

- To assess the safety and effectiveness of ART
- Compare ART against sham (placebo)
- Evaluate outcomes over 2 weeks of treatment

Patient Selection and Characteristics:

- **Inclusion Criteria**

1. **Age**: ≥18 years
2. **Symptoms**: Moderate to severe nasal congestion for ≥1 month
3. **Total Nasal Symptom Score (TNSS):** Nasal congestion sub-score ≥2 at screening

- **Exclusion Criteria**

1. **Recent Surgery**: Head or sinonasal surgery within the past 3 months
2. **Recent Infection**: Sinus infection within the last month
3. **Medication-Induced Rhinitis**: History of rhinitis medicamentosa
4. **Structural Abnormalities**: History of nasal polyposis or nasal mass

Study Design

- Multi-center, randomized, double-blinded, sham-controlled
- Total subjects: 52 adults
- Twice daily treatments for 2 weeks
- Treatment duration: 15 minutes per session

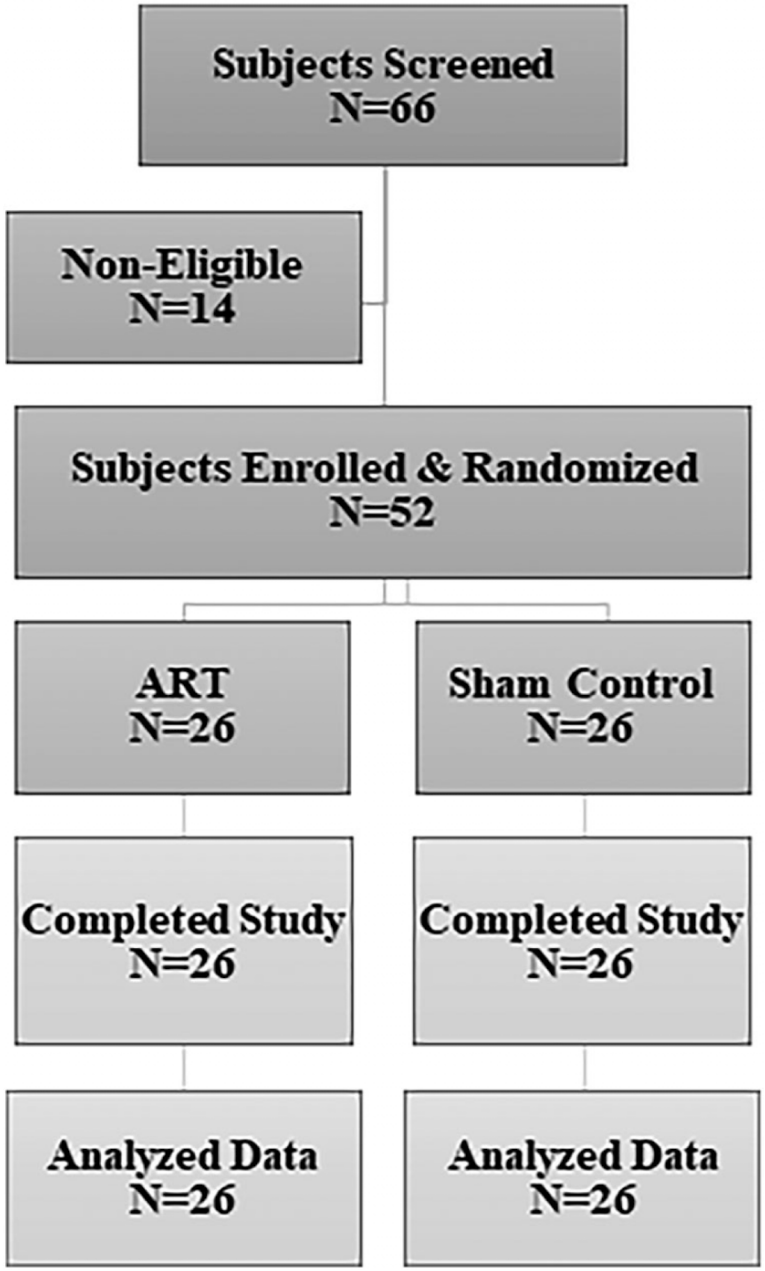

FIGURE 2 Flowchart of randomization.

Primary and Secondary Endpoints

- Primary: Nasal congestion sub-score of Total Nasal Symptom Score (TNSS)
- Secondary: Total TNSS improvement

Result

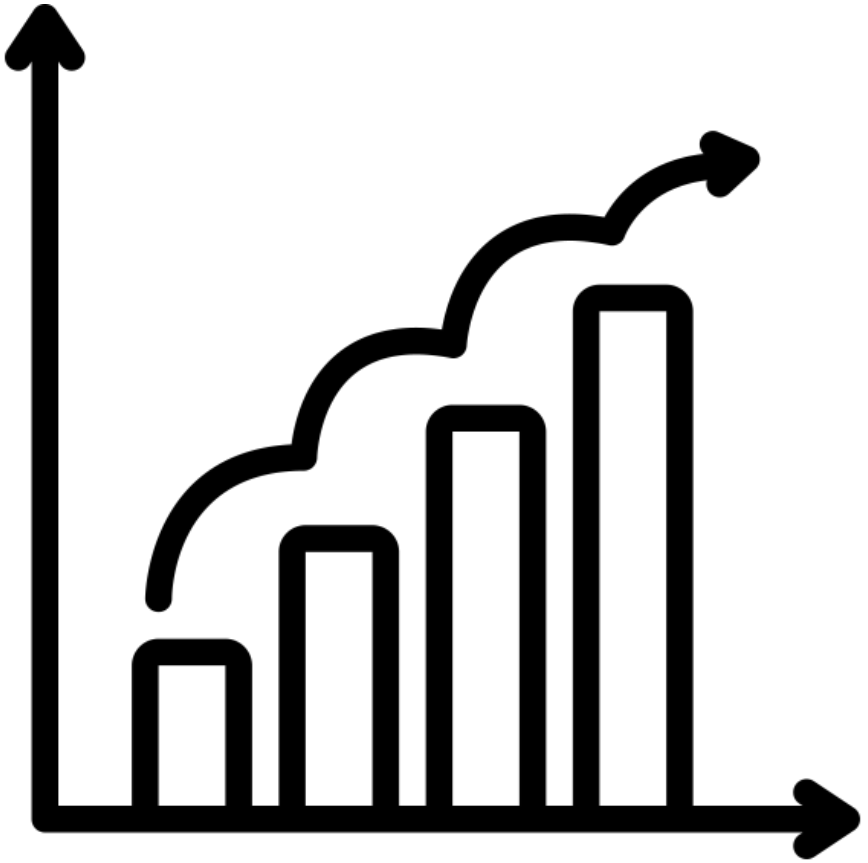

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TABLE 1 Demographics of study subjects.

	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.

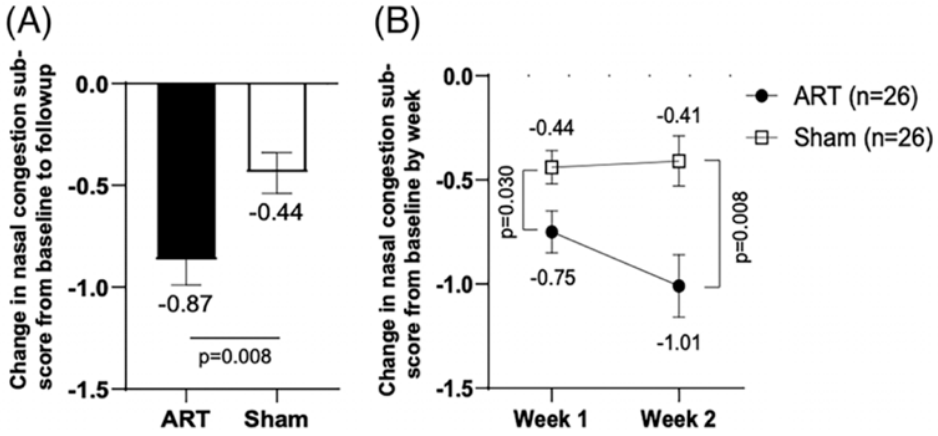
[d]A total of nine patients did not report race (five in ART and four in Sham).

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

Results – Primary Outcomes

- Significant nasal congestion reduction:
- ART group: −0.87 vs Sham group: −0.44 (p=0.008)
- Statistically and clinically significant outcome

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.



Results – Secondary Outcomes

- Composite TNSS significantly improved:
- ART: −2.85 vs Sham: −1.32 (p=0.027)
- Progressive improvement observed during treatment weeks

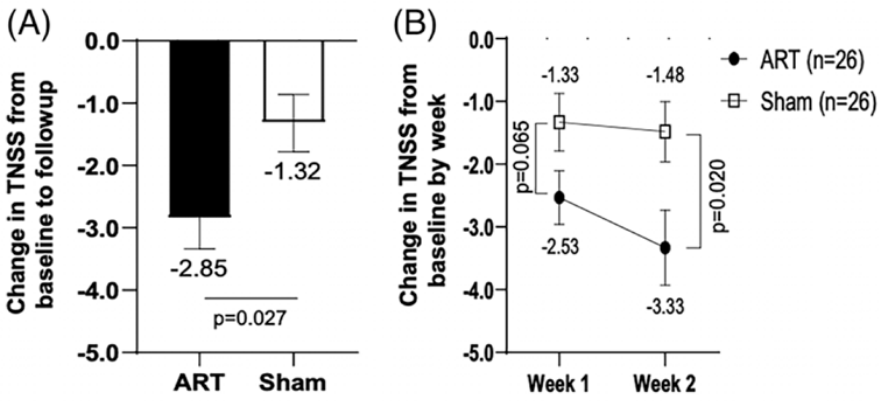


FIGURE 4 Total Nasal Symptom Score (TNSS) improves with acoustic resonance therapy. (A) Mean change in TNSS was calculated from baseline to after 2-week daily treatments with either acoustic resonance therapy (ART) or sham and (B) mean change in TNSS from baseline was calculated after Weeks 1 and 2 of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

Responder Analysis

- Minimal clinically important difference (MCID) set at 0.23 in TNSS
- ART responder rate: 80.8%, Sham responder rate: 46.2%
- Adjusted Risk Ratio (ART vs Sham): 1.95 (95% CI 1.26, 3.02; p=0.003)

Safety and Compliance

- High adherence (~85%)
- No ART-related adverse events recorded
- ART confirmed as safe treatment modality

Discussion

Discussion – Advantages of ART

- Effective and safe alternative to pharmacologic treatments
- Avoids common pharmacologic side effects:

  - Nasal dryness, bleeding, medication-induced rhinitis

  - Cardiovascular side effects from oral decongestants
- Improved patient adherence potential

Broader Applications and Future Directions

- Possible use in chronic rhinosinusitis and other nasal disorders
- Potential for upper airway resistance syndrome treatment
- Encourages further research and innovation

Limitations

- MCID for nasal congestion sub-score undefined in existing literature
- Moderate success in maintaining blinding
- Real-world adherence still unclear

Future Directions

- Larger-scale studies needed for broader generalizability
- Explore effectiveness in chronic rhinosinusitis
- Evaluate long-term adherence and effectiveness

Conclusion

Conclusion

- ART is confirmed safe and effective for treating nasal congestion in rhinitis
- Promising non-pharmacologic treatment option
- Beneficial for both allergic and non-allergic rhinitis patients

Thank You