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RESEARCH NOTE

Resonant vibration of the sinonasal cavities for the treatment of nasal congestion

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INTRODUCTION

Nasal congestion contributes to significant global disease burden, with chronic nasal congestion impacting roughly 20% of the world population.[1] Patients experience a significant detriment to quality of life and many are dissatisfied with the current treatment options.[1]

The acoustic vibration associated with humming has been shown to decrease symptoms of nasal congestion, possibly through modulation of autonomic inputs to the nasal mucosa or through nitric oxide activity, which may in turn exert a decongestant and anti-inflammatory effect.[2–4] This study evaluates the safety and efficacy of acoustic resonance therapy (ART) to simulate these beneficial effects, using a novel device that provides an acoustic vibratory intervention calibrated to an individual's sinonasal resonance frequencies in patients suffering from nasal congestion.

PATIENTS AND METHODS

Design

This was a prospective, nonrandomized, interventional cohort study of patients over 18 years of age suffering from active nasal congestion, defined as a score of 2 or 3 out of a possible 3 on the nasal congestion subdomain of the Total Nasal Symptom Score (TNSS). The minimal clinically important difference (MCID) has been reported to be 0.28 points using anchor-based methods in allergic rhinitis.[5] The study was done at Stanford University and San Francisco Otolaryngology Medical Group.

Intervention

Participants were provided the SoniFlow vibrational headband device (Third Wave Therapeutics, Los Altos, CA,

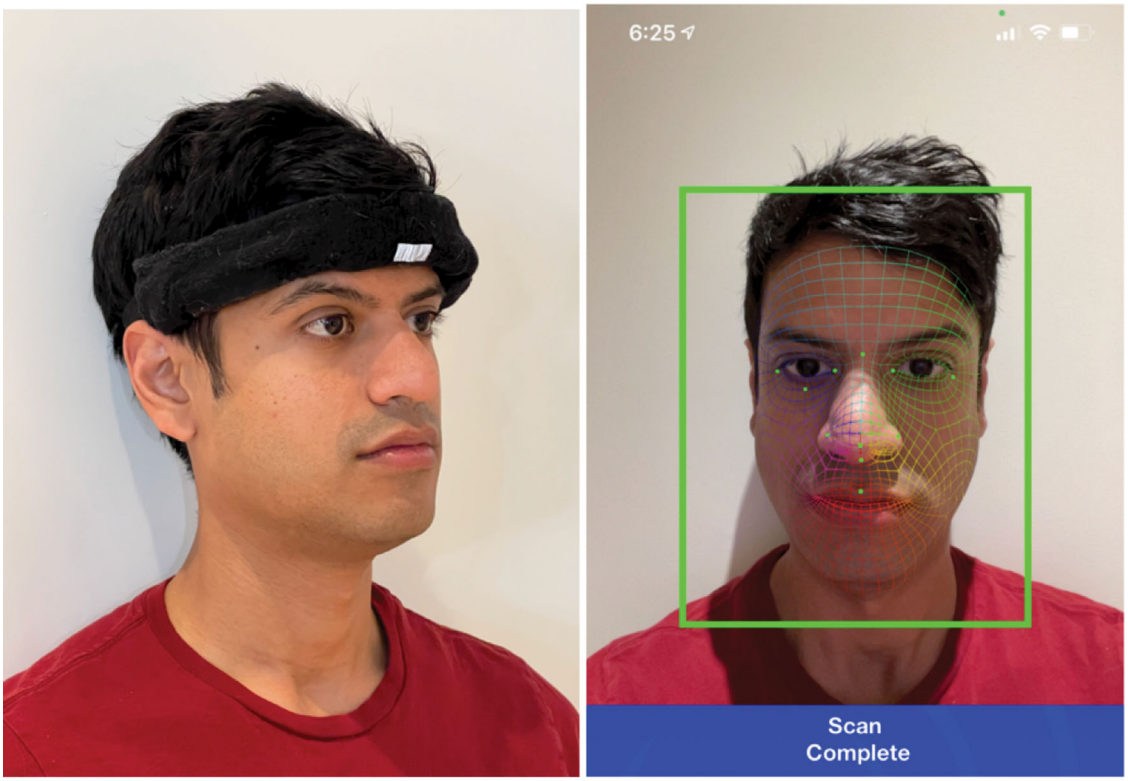

FIGURE 1 (A) SoniFlow headband device as worn by subject. Smartphone app is downloaded separately. The device is paired with the smartphone via Bluetooth to transmit the calibrated frequency data. (B) Facial landmarks are registered using the smartphone app to estimate sinonasal cavity volume. An algorithm uses these measurements to calculate an associated resonant frequency to optimize the efficacy of intervention

USA) and accompanying smartphone app, which uses the phone's self-facing camera to capture a facial scan and measure facial surface landmarks (Figure 1). An algorithm derived from cadaver studies and machine learning processes calibrated to facial landmarks was used to estimate sinonasal volume and thereby determine the resonant frequency and harmonics of the sinonasal cavities. The app generates an individualized sound file played through the wearable headband's vibrational transducers, with frequencies in the audible acoustic range.

The intervention consisted of two sequential 10-min treatment cycles, with treatment time automatically tracked by the app, allowing for a brief pause between treatment cycles to allow completion of response surveys (~2 min). Patients were given a gift card of nominal value upon completion of the study.

Evaluation

Subjects reported their baseline TNSS, including subscores for each of the four subdomains, as well as visual analogue scales (VASs) for headache and facial pain prior to any intervention and immediately after each of the two 10-min treatment cycles.

Endpoints and data analysis

To detect a difference of 1 on the TNSS with 90% power, 50 subjects were required. The primary outcome of the study was change in TNSS versus baseline, and secondary outcomes were changes in VAS versus baseline for headache and for facial pain.

Statistical analyses were performed using GraphPad Prism 9 (GraphPad Software, Inc., La Jolla, CA, USA). Paired *t* test was used to compare the continuous outcome variables before and after each intervention.

RESULTS

Fifty patients were enrolled. Thirty-five subjects completed the study in clinic, whereas the remaining 15 were shipped the device and completed the study via teleconference because of the coronavirus disease 2019

TABLE 1 Outcomes

	Baseline	Treatment 1	Treatment 2
TNSS, mean (95% CI)			
Nasal congestion	2.2 (2.1–2.3)	1.6 (1.4–1.8)*	1.2 (1.0–1.4)*
Sneezing	0.6 (0.4–0.8)	0.3 (0.1–0.4)*	0.2 (0.1–0.4)*
Nasal itching	0.5 (0.3–0.7)	0.3 (0.1–0.4)*	0.2 (0.1–0.3)*
Rhinorrhea	0.9 (0.6–1.2)	0.7 (0.3–1.2)	0.4 (0.2–0.5)*
Total	4.1 (3.5–4.6)	2.9 (2.2–3.6)*	2.0 (1.6–2.5)*
Headache VAS, mean (95% CI)	1.2 (0.6–1.7)	1.1 (0.6–1.6)	0.9 (0.4–1.4)
Facial pain VAS, mean (95% CI)	1.3 (0.7–1.9)	1.3 (0.7–1.9)	0.9 (0.5–1.4)*

Abbreviations: CI, confidence interval; TNSS, total nasal symptom score; VAS, visual analogue scale.
*Statistically significant findings compared to baseline.

(COVID19) pandemic. The aggregate TNSS was 4.1 at baseline, which dropped to 2.9 after the first treatment cycle ($p < 0.001$), and further dropped to 2.0 after the second cycle ($p < 0.001$). After two treatment cycles, 90% of subjects demonstrated an improvement in TNSS and none reported worsening. Improvements were noted to occur independently of sex, ethnicity, and age. The mean nasal congestion subscore at baseline was 2.2, which dropped to 1.6 after one treatment cycle ($p < 0.001$), and further dropped to 1.2 after the second cycle ($p < 0.001$). Significant reductions compared with baseline were noted in all individual subdomains of the TNSS upon completion of the second treatment cycle (Table 1).

Mean facial pain VAS among all patients decreased significantly from 1.3 at baseline to 0.9 after the second treatment cycle ($p = 0.01$). Among the 20 subjects with baseline facial pain VAS ≥ 1, 16 demonstrated improvement after the second cycle. Mean headache VAS did not change significantly with intervention across the entire cohort ($p = 0.2$), but this included 18 of 35 patients who reported no headache at baseline. Among the 17 patients who reported a headache VAS ≥ 1 at baseline, 13 patients demonstrated a significant reduction in headache VAS, from a baseline mean of 3.3 to 2.4 after two treatment cycles ($p = 0.03$).

All enrolled patients successfully completed two cycles of treatment without incident. There were no adverse events reported.

DISCUSSION

ART offers promise as a nonpharmacological therapeutic option for nasal congestion. Although the precise mechanism of action has not been fully elucidated, vibration has been shown to modulate the autonomic nervous system toward enhanced sympathetic tone, and additionally may increase nitric oxide production, thereby influencing vasomodulatory mechanisms and ciliary function.[6–9] The theoretical advantage of patient-specific ART versus nonspecific, uncalibrated vibration is based on our group's cadaver studies, which demonstrated that application of resonant frequencies generated the maximum vibrational effect within the sinus cavities (our unpublished data).

Based on the MCID of 0.28 for the TNSS in allergic rhinitis, we found clinically meaningful and statistically significant improvements in both the nasal congestion subscore as well as the total symptom score with ART. The symptom score improvements exceeded the MCID after a single 10-min cycle as well as after a subsequent 10-min cycle. We also observed clinically meaningful and statistically significant improvements in all individual subdomains of the TNSS after two treatment cycles.

Although we initially chose to measure pain and headache scores to ensure that patients were not experiencing adverse effects of ART, we found that patients not only did not worsen, but also that patients who had some baseline pain and headache (VAS ≥ 1) experienced a notable improvement. Again, the mechanisms of action are not clear but may be related to vibration-induced modulation of pain receptors or inhibition of the parasympathetic system.[10]

As with many pilot studies, there are limitations of this study. First, given that patients were not randomized or blinded, a placebo effect is possible. Second, although the efficacy of the device presupposes the importance of delivering resonant frequencies, the study was not designed to evaluate this hypothesis. Future studies may elaborate the optimal duration, durability, and interval of treatments with ART, which remain to be determined. Longitudinal studies with daily use may reveal longer-term benefits that were not assessed by this study. Finally, although our data suggest that ART may be beneficial for other symptoms in addition to nasal congestion—such as rhinorrhea, headache, and facial pain—additional study is necessary to characterize the efficacy of ART for these associated conditions.

CONFLICT OF INTEREST

Peter H. Hwang and Bryant Lin have equity stake in Third Wave Therapeutics. No other authors have relevant financial or personal conflicts of interest.

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