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ORIGINAL RESEARCH

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Treatment of sinus headache using a device that combines acoustic vibration with oscillating expiratory pressure

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Abstract

Objective: To determine if simultaneous administration of acoustic vibration and oscillating expiratory pressure affects the severity of facial pain among patients with complaint of "sinus headache".

Methods: This is a prospective single-arm observational study performed at a tertiary care medical center. Subjects with complaint of sinus headache without evidence of chronic rhinosinusitis on exam or computed tomography participated in a clinical study applying simultaneous acoustic vibrations and positive expiratory pressure to the nasal cavity twice daily over 4 weeks. Efficacy was assessed using three validated pain metrics—pain visual analog scale (VAS), brief pain inventory-short form (BPI-SF), and McGill pain questionnaire-short form (MPQ-SF). Device safety and patient satisfaction were also assessed using questionnaires.

Results: Twenty-nine patients (mean age 49 years, 55% female) completed the study without any major adverse events. At the 4 week follow-up, facial pain VAS improved from mean ± SD of 59.6 ± 15.7 to 34.6 ± 21.7 ($p < .001$), BPI mean pain (mean ± standard deviation) improved from 4.4 ± 2.0 to 2.9 ± 1.9 ($p = .007$), and MPQ-SF total improved from 12.2 ± 6.5 to 6.5 ± 5.2 ($p < .001$) with approximately 70% of patients achieving a minimal clinically important difference (MCID) across all metrics. Additionally, pain VAS was assessed 5 min after a single use at baseline with significant improvement ($p < .001$). Eighty-six percent of subjects would both use device again and recommend it to others.

Conclusions: Simultaneous administration of acoustic vibration and oscillating expiratory pressure appears to be a safe treatment for sinus headaches in patients without objective evidence of chronic sinusitis. Results from this initial study are promising with regard to efficacy in treatment of sinus headaches but will require further study.

Level of evidence: 2c.

KEYWORDS

facial pain, migraine headaches, sinogenic pain, sinus headaches, vibrational energy

1 | INTRODUCTION

Sinus headache is a frequently misused, but common presenting chief complaint in otolaryngology practices. Patients commonly use the term sinus headache to refer to the concept of facial pain/headache originating in the sinonasal or facial region. However, studies have demonstrated that most patients with a chief complaint of sinus headache present without objective evidence of sinonasal inflammation and that symptoms are often related to a primary headache disorder, with the majority having migraine headaches.[1–4]

Our understanding of the pathophysiology of migraine headaches has evolved. Previously thought of as a vascular phenomenon, it is now believed to be related to a primary neuronal dysfunction in which cortical-spreading depression, a self-propagating depolarizing wave, spreads across the cerebral cortex and ultimately activates trigeminal nerve afferents. When this occurs, pro-inflammatory mediators such as calcitonin-gene-related peptide and substance-p are released leading to mucosal inflammation and amplifying pain. This explains why many migraineurs experience rhinogenic symptoms of congestion and rhinorrhea.[1] Other primary headache disorders that can be misinterpreted as a sinus headache include cluster headaches, trigeminal neuralgias, autonomic cephalalgias, myofascial pain, and contact point headaches.[4] Regardless of diagnosis, the common final pathway seems to be a perturbation in trigeminal sensitivity and the feeling of achiness, pressure, and congestion in the face misinterpreted by patients to represent sinusitis.

Recently, a novel device employing simultaneous acoustic vibrations and positive expiratory pressure to the nasal cavity was found to improve measures of nasal congestion and objective peak nasal inspiratory flow levels after twice daily use.[5] Although the study was focused on patients with nasal congestion, subjects did report significant improvements in facial pressure. The question thus arose whether a device employing simultaneous acoustic vibrations and positive expiratory pressure to the nasal cavity could improve symptoms in patients with chief complaint of sinus headache. The aim of this study was to investigate the safety and utility of this device in patients with facial pain/pressure overlying the sinuses (also referred to as sinus headache) that lacked objective evidence of sinonasal inflammation.

2 | METHODS

2.1 | Patient enrollment

Subjects with persistent facial pain/pressure overlying the sinuses presenting to a tertiary rhinology clinic were recruited at the Medical University of South Carolina into a Phase I/II clinical trial. Inclusion criteria required adults ≥18 years of age complaining of facial pain or pressure for ≥3 months of symptom duration with a pain/pressure VAS score of ≥5. Exclusion criteria included sinonasal surgery within the last 3 months, nasal polyposis, purulence/edema or other signs of sinusitis on nasal endoscopy, upper respiratory illness within the last 2 weeks, topical decongestant use in the last week, nasal crusting or ulceration on nasal endoscopy, history of severe epistaxis, known pregnancy, allergic sensitivity to silicone or any other component of the device, inability to read and understand English, and inability to perform treatment due to underlying medical condition. All subjects provided written informed consent in accordance with the Medical University of South Carolina (MUSC) Institutional Review Board & Office of Research Integrity (Pro00100980) and the study was registered on www.clinicaltrials.gov (NCT04468204).

All subjects were evaluated at baseline by an otolaryngology provider who performed nasal endoscopy to screen for exclusion criteria and assess the subject's medical history, in order to determine medical comorbidities. The diagnosis of comorbidities (such as migraine and other headche disorders) in subjects were made based on the electronic medical record past medical history or patient reported history. Once negative endoscopy was confirmed, patients were offered imaging with neurology referral if appropriate or SinuSonic; the choice of management was left up to the patient. Patients were queried regarding duration of facial pain/pressure, demographics, current smoking, history of migraine disorder and prior/current treatments.

2.2 | Baseline assessments

Baseline patient-reported outcome metrics were collected on each subject, including facial pain visual analogue scale (VAS),[6] McGill Pain Questionnaire-Short Form (MPQ-SF),[7] and Brief Pain Inventory-Short Form (BPI-SF).[8] The facial pain VAS score is a scale from 0 to 100 mm and asks patients to rate the severity of their facial pain over a previous 1 week recall period with higher scores indicating greater pain intensity. Additionally, a current VAS pain score and an immediate 5-min post-use current VAS pain score was assessed. A prior study looking at orofacial pain reported a minimal clinically important difference (MCID) of 12 mm for VAS pain.[9] The MPQ-SF[7] consists of 15 descriptors (11 sensory; 4 affective) which are rated on an intensity scale as 0 = none, 1 = mild, 2 = moderate, 3 = severe. Three pain scores are derived from the sum of the intensity rank values of the words chosen for sensory, affective and total descriptors. Participants were also asked to rate their current pain (MPQ Now) and their overall intensity of pain (MPQ intensity) as the final two metrics of this instrument. Subjects also rated facial pain using the BPI-SF scale.[8] The BPI-SF assesses pain at its "worst", "least", "mean", and "now" (current pain). In clinical trials, the items "worst" and "mean" have been each used singly to represent the pain severity. Worst and mean pain were assessed over a previous 1 week recall period. BPI-SF also measures how much pain interferes (BPI interference) with seven daily activities including general activity, walking, work, mood, enjoyment of life, relations with others, and sleep. BPI pain interference is typically scored as the mean of the seven interference items. All items are rated on a 0–10 scale with 0 representing no pain/no interference and 10 representing pain as bad as you can imagine/interferes completely. A distribution-based approach using one-half the SD was used to determine MCID values for MPQ-SF and BPI-SF, as there is a paucity of research assessing the MCIDs for these pain measures for facial pain/headache.

FIGURE 1 SinuSonic® device. SinuSonic device combines acoustic vibration with oscillating expiratory pressure.

2.3 | Intervention

Subjects self-administered simultaneous nasal acoustic vibration and oscillating expiratory pressure using the SinuSonic device for 3 min twice daily (Healthy Humming LLC, Columbia, SC) according to the manufacturer's instructions (Figure 1). The SinuSonic device consists of a disposable medical grade silicone nosepiece mounted to a resin body. The device is equipped with a flutter valve located at the top of the device that creates self-guided oscillating expiratory resistance. Acoustic vibration is emitted via a single circuit board speaker at the base of the device at approximately 128 Hz. Subjects were instructed to inhale normally and then gently exhale through the nosepiece in order to activate the flutter valve for 3 min per session.

2.4 | Timeline

An immediate posttreatment assessment was performed 5 min after completion of the initial treatment session. Subjects were then instructed to perform twice daily treatment sessions (morning and night) at home using the SinuSonic device for 3 min each. Subjects filled out electronic surveys using the Research Data Capture (RedCAP) secure web application for follow-up assessment. An assessment with recall over the last week was performed at 2 weeks. Subjects continued twice-daily treatments in the home setting for an additional 2 weeks. A final assessment with recall over the last week was performed at 4 weeks via electronic survey.

TABLE 1 Demographics ($n = 29$).

	Mean (SD)/*n* (%)
Age	49.2 (14.4)
Gender	
Male	13 (44.8%)
Female	16 (55.2%)
Race	
White	23 (79.3%)
Non-white	6 (20.7%)
Ethnicity	
Hispanic or Latino	1 (3.4%)
Non-Hispanic/Latino	28 (96.6%)
BMI (units)	29.8 (8.4)
Allergic rhinitis by self-report	11 (37.9%)
Non-allergic rhinitis	2 (6.9%)
Migraine headache history	
None	16 (55.2%)
Resolved/past diagnosis	1 (3.4%)
Present/medicated	7 (24.1%)
Present/not medicated	5 (17.2%)
Asthma	6 (20.7%)
Current smoker	1 (3.4%)
Anxiety	6 (20.7%)
Depression	3 (10.3%)
Obstructive sleep apnea	
No	21 (72.4%)
Currently being treated	5 (17.2%)
History/no current treatment	3 (10.3%)
Current medication use	
Nasal steroid spray	16 (55.2%)
Nasal antihistamine	6 (20.7%)
Oral antihistamines	21 (72.4%)
Oral decongestant	5 (17.2%)
Mucolytic	6 (20.7%)
Leukotriene	5 (17.2%)
Rhinoscopic findings	
Septal deviation	10 (34.5%)
Nasal valve collapse	10 (34.5%)
Bleeding	0 (0%)
Crusting	0 (0%)
Otoscopy abnormal	0 (0%)
Facial pain duration	
<3 months	0 (0%)
3–6 months	4 (13.8%)
6–12 months	2 (6.9%)
1–3 years	2 (6.9%)
>3 years	21 (72.4%)

Abbreviation: BMI, body mass index.

TABLE 2 Intermediate (2 weeks) posttreatment assessments.

	n	Baseline, mean (SD)	Posttreatment, mean (SD)	*p* value
Facial pain VAS (past week)	29	60.3 (15.9)	41.7 (23.4)	*.001*
MPQ sensory	29	10.2 (4.6)	7.0 (4.9)	*.004*
MPQ affective	29	2.5 (2.4)	2.0 (2.2)	.174
MPQ total	29	12.6 (6.5)	9.0 (6.5)	*.002*
MPQ pain now	29	3.9 (2.4)	2.7 (2.4)	*.004*
MPQ pain intensity	28	2.2 (0.9)	1.8 (0.8)	.034
BPI worst pain	29	5.6 (1.7)	6.2 (2.3)	.201
BPI mean pain	29	4.4 (2.0)	3.7 (1.9)	.057
BPI current pain	29	3.9 (2.3)	2.9 (2.7)	.063
BPI activity	29	3.7 (2.2)	2.7 (2.6)	.070
BPI mood	29	4.6 (2.5)	4.0 (3.1)	.318
BPI walking	29	1.4 (2.0)	1.8 (2.4)	.311
BPI work	29	3.1 (2.7)	2.4 (3.0)	.225
BPI relations	29	3.0 (2.8)	2.6 (2.8)	.374
BPI sleep	29	4.7 (3.4)	3.2 (2.9)	*.022*
BPI enjoyment	29	3.8 (2.5)	3.3 (2.4)	.192

Note: Italic values indicates statistically significant.
Abbreviations: BPI, Brief Pain Inventory-Short Form; MPQ, McGill Pain Questionnaire-Short Form; VAS, Visual Analogue Scale.

2.5 | Analytic plan

Statistical analysis was conducted using SPSS version 25 (IBM Corp, Armonk, NY). Descriptive statistics such as means, range, SDs, frequencies, and percentages were generated in order to present the baseline characteristics of the study population. All continuous variables were tested for normal distribution as determined by the Shapiro–Wilk test. To evaluate differences in outcome metrics across time, paired *t*-tests were used for normally distributed variables. Wilcoxon signed rank tests were used for non-normally distributed or ordinal variables. To correct for making two comparisons of the same variable over multiple time points, the Holm test was used and a value of $p \leq .025$ was considered statistically significant. For all other tests, a value of $p \leq .05$ was considered statistically significant. The amount of change between baseline and follow-up variables of interest was calculated and measured against previously reported MCID thresholds when available or by using one-half of the baseline SD if not previously reported.

3 | RESULTS

A total of 30 patients were enrolled, with 28 patients completing all survey questionnaires at all time points. The study cohort had a mean age of 49.2 years (±14.4, range: 23–82 years), just over half were women (55%), and 21% reporting non-White race (Table 1). All patients had negative endoscopies without evidence CRS and 55% had imaging completed, which was normal without evidence of CRS on either CT or MRI. All patients with imaging available, with the exception of a single patient with a mucous retention cyst, had clear imaging without any sinus opacification. The average Lund–Mackay CT score was 0.1 (± 0.25). Seventy two percent of patients reported facial pain symptoms for >3 years. Thirty-eight percent of patients reported a history of allergic rhinitis and 45% had a formal diagnosis of migraine headache disorder. Nasal endoscopy revealed that that 35% had a septal deviation and 35% had nasal valve collapse. Seventy-two percent of patients were on oral antihistamines and 55% were on topical steroid sprays. Remaining current medication usage and comorbidity information is detailed in Table 1.

3.1 | Pain location

The most common regions of pain localization included over the maxillary sinuses (right maxillary: 82.8%; left maxillary: 69.0%), ethmoid sinuses (51.7%), and frontal sinuses (right frontal: 51.7%; left frontal: 48.3%). The sphenoid sinuses (localizing over the temporal region), the occipital region, and vertex were less common locations of pain.

3.2 | Immediate (5-min) assessment

After initial treatment with SinuSonic for 3 min, mean ± SD current VAS scores decreased from 44.8 ± 22.6 to 34.8 ± 21.7 ($p < .001$).

3.3 | Intermediate (2-week) assessment

After 2 weeks of twice daily treatments with SinuSonic, mean ± SD VAS scores decreased from 60.3 ± 15.9 to 41.7 ± 23.4, a 31% relative decrease compared to baseline (Table 2, Figure 2). Similarly, mean ± SD

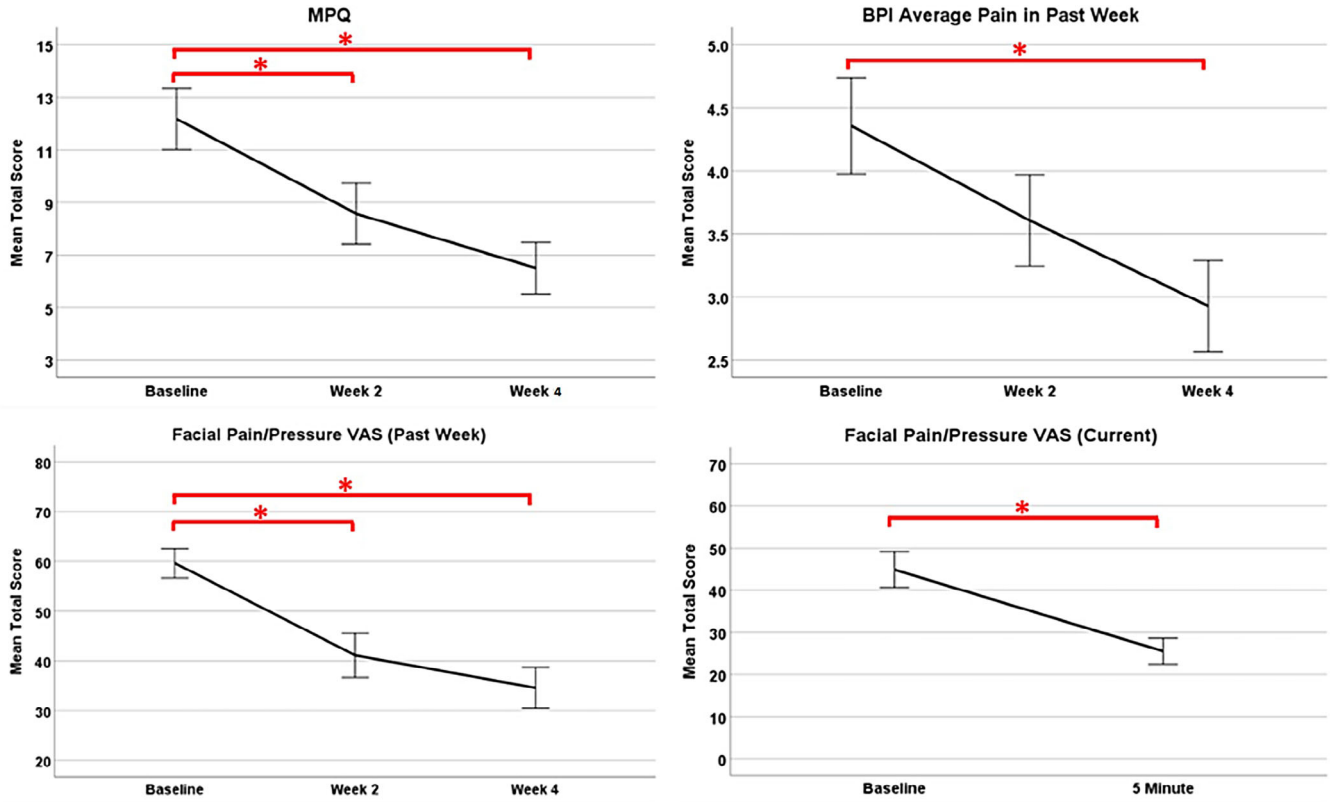

FIGURE 2 Mean patient-reported outcome measure over time. *Statistically significant. BPI, Brief Pain Inventory-Short Form; MPQ, McGill Pain Questionnaire-Short Form; VAS, Visual Analogue Scale.

TABLE 3 Final (4 weeks) posttreatment assessments.

	n	Baseline, mean (SD)	Posttreatment, mean (SD)	% Relative improvement over baseline	*p* value
Facial pain VAS (past week)	28	59.6 (15.7)	34.6 (21.7)	41.9%	*<.001*
MPQ sensory	28	9.9 (4.5)	5.1 (3.6)	48.5%	*.003*
MPQ affective	28	2.3 (2.2)	1.4 (2.0)	39.1%	.034
MPQ total	28	12.2 (6.5)	6.5 (5.2)	46.7%	*<.001*
MPQ pain now	28	3.8 (2.3)	2.2 (2.0)	42.1%	*.001*
MPQ pain intensity	27	2.2 (1.0)	1.3 (0.9)	40.9%	*.004*
BPI worst pain	28	5.5 (1.6)	4.9 (1.8)	10.9%	.174
BPI mean pain	28	4.4 (2.0)	2.9 (1.9)	34.1%	*.007*
BPI current pain	28	3.8 (2.2)	2.0 (2.2)	47.4%	*.002*
BPI activity	28	3.6 (2.2)	1.8 (2.1)	50.0%	*.003*
BPI mood	28	4.4 (2.4)	2.4 (2.1)	45.5%	*.003*
BPI walking	28	1.4 (2.0)	1.2 (1.7)	14.3%	.787
BPI work	28	2.9 (2.5)	1.6 (2.0)	44.8%	.040
BPI relations	28	2.8 (2.5)	1.5 (2.2)	46.4%	.052
BPI sleep	28	4.6 (3.4)	2.0 (2.3)	56.5%	*.001*
BPI enjoyment	28	3.6 (2.3)	1.9 (2.3)	47.2%	*.005*

Note: Italic values indicates statistically significant.
Abbreviations: BPI, Brief Pain Inventory-Short Form; MPQ, McGill Pain Questionnaire-Short Form; VAS, Visual Analogue Scale.

MPQ and BPI scores decreased from 12.6 ± 6.5 to 9.0 ± 6.5 ($p = .002$) and 4.4 ± 2.0 to 3.7 ± 1.9 ($p = .057$), respectively (Table 2, Figure 2).

3.4 | Final (4-week) assessment

After 4 weeks of twice-daily treatments with SinuSonic, mean ± SD VAS scores decreased from 59.6 ± 15.7 to 34.6 ± 21.7, a 42% relative decrease compared to baseline (Table 3, Figure 2). Similarly, mean ± SD MPQ and BPI scores decreased from 12.2 ± 6.5 to 6.5 ± 5.2 ($p < .001$) and 4.4 ± 2.0 to 2.9 ± 1.9 ($p = .007$), respectively (Table 3, Figure 2). Across these three measurements, approximately 70% of patients achieved an MCID.

Regarding safety, 89% reported no pain or discomfort after 4 weeks of twice-daily treatments. There was one mild instance of epistaxis reported that resolved with conservative measures but no other instances of bleeding. throughout the study period. At study completion, 86% of subjects expressed willingness to recommend device to a family member/friend and use device again.

4 | DISCUSSION

Sinus headache is a common presenting complaint at otolaryngology practices. The majority of patients with sinus headache lack objective evidence of chronic sinusitis and suffer from migraines or other form of non-rhinogenic headache disorders.[2–4] Headache disorders are very prevalent affecting nearly 50% of the world's population and a third of these are patients with migraine headaches.[10] Despite regional variations, headache disorders are exceedingly common affecting people of all ages, races, income levels and geographic regions. The activation of the trigeminal system with development of rhinogenic symptoms such as rhinorrhea and congestion in migraineurs contributes to the confusion in migraine patients who believe their symptoms are related to sinusitis.[1] Furthermore, a significant portion of patients with headache disorder can suffer from comorbid chronic rhinitis given the large prevalence of both conditions further confounding their clinical picture.[2] In our cohort, no patients demonstrated objective evidence of chronic sinusitis on endoscopy or computed tomography, but 72% of patients were on antihistamines and 44% reported a diagnosis of chronic rhinitis.

A previous study looking at use of SinuSonic in the treatment of nasal congestion found significant improvements in objective and subjective metric of nasal congestion/obstruction with an MCID being achieved in 62%–80% of patients suggesting that there may be physiologic changes occurring within the nasal cavity in response to device use.[5] What these changes are and how they modulate the trigeminal system to lessen pain is still unknown. Prior studies looking at acoustic energy applied to the nasal cavity have demonstrated increases in nasal nitric oxide which may also modulate the pain pathway via anti-inflammatory effects, but further research in this space is needed.[11]

There are nearly 300 classifications of headache disorders according to the International Classification of Headache Disorders (ICHD-3) with a large portion of headaches relying on the same anatomical basis involving the trigeminal neurovascular system.[12] The current treatment landscape for complaint of sinus headaches is not well defined as it is likely heterogenous group of patients with multiple forms of primary headache disorders some of which are less defined entities with fewer treatment options. In general, management of headache disorders often includes non-pharmacologic strategies (such as dietary modification), treatment for acute attacks, and preventative measures all of which are underutilized.[13,14] A similarly designed study performed by Del Gaudio et al enrolled patients with sinus headaches without objective evidence of CRS and empirically treated them with triptans.[15] In this study, approximately 80% of patients noted significant improvement in facial pain on a VAS scale following treatment. An additional study looking at balloon sinuplasty for sinus pain/pressure (without objective evidence of sinusitis) also noted significant improvements in pain metrics, however there was no statistically significant difference compared to the control arm which involved ballooning the nasal cavity. SNOT22 scores experienced a relative reduction of approximately 30% in both groups.[16] In our study using SinuSonic, approximately 70% of patients improved and achieved an MCID on the VAS facial pain score—comparable to other studies utilizing pharmacologic interventions for sinus pressure/pain.[15]

Daily SinuSonic use appears to improve mean pain scores over time suggesting efficacy as a maintenance/preventative form of therapy. Additionally, we also measured pain scores 5-min after use with significant improvements, suggesting that SinuSonic may also be useful in acute settings of facial pain/pressure. Ultimately, this study will help inform appropriate power calculation to develop and design a randomized controlled trial to further assess efficacy of the acoustic vibration with oscillating expiratory pressure on sinus headache.

Established barriers to headache therapy include failure to consult an appropriate prescribing healthcare professional, failure to arrive at a specific diagnosis, and lack of use of appropriate acute and preventative therapy.[17] Despite efforts within the otolaryngology community to educate providers on appropriate diagnosis and treatment of these headache patients, significant challenges remain. Frequently, there are long wait times for patients to see neurology consultants. From an otolaryngology provider's perspective, many are unfamiliar prescribing neuroactive medications. And from a patient's perspective, there is significant stigma associated with a diagnosis of headache disorders making it difficult for patients to accept this reality.[18,19] Depending on the medication, there are several side effects that patients can experience with medical management of headache disorders. Side effects associated with triptans include dizziness, sleepiness, dry mouth, and muscle weakness. In very rare instances triptans have been linked to heart attack and stroke and are contraindicated in patients with these diagnoses.[20,21] There are several preventative medications for primary headache disorders which have their own side-effect risk profiles that can often present bigger quality-of-life impairments than the condition itself. In this phase I/II study, we present important data on the safety and efficacy of simultaneous administration of nasal acoustic vibration and oscillating expiratory pressure delivered through the SinuSonic device. There was only one instance of mild bleeding in

the first 2 weeks of device use. Over 95% of participants reported no pain/minimal discomfort with use suggesting that SinuSonic carries minimal risk in appropriately selected patients.

There are several considerations that must be kept in mind when interpreting results from this study. First, this study specifically excluded patients with objective evidence of chronic rhinosinusitis. Therefore, one cannot say whether similar efficacy would be seen in patients with comorbid chronic rhinosinusitis. This phase I/II study was limited to a single arm; therefore, placebo effects and regression to the mean cannot be excluded as influencing results. The next logical step in evaluating this treatment is to conduct further research incorporating appropriate control groups. Furthermore, it should be noted that two patients did not complete the trial, and the reasons for their discontinuation remain unknown. Among the patients who successfully completed the study ($n = 28$), it was found that 71% of them achieved the MCID on the VAS pain scale. If we assume that the two participants who dropped out did not achieve an MCID, then taking into account all the patients initially enrolled ($n = 30$), the proportion of individuals who achieved an MCID would be 67%. Additionally, the study population is a heterogenous cohort with 45% of patients with a history of migraine headaches and many others with likely an undiagnosed primary headache disorder. While this cohort likely reflects a real-world population of patients presenting to otolaryngologists with sinus headaches, future studies may consider including neurologic evaluation and determining strict diagnostic criteria which might allow subgroup analysis by specific headache types. Lastly, follow-up was limited to 4-week data. Future studies might explore efficacy over a longer period and/or explore whether alternative regimens might be efficacious, such as use on an as-needed basis.

5 | CONCLUSION

In patients with sinus headaches lacking objective sinonasal inflammation, acoustic vibration and oscillating expiratory pressure to the nasal cavity appears to result in significant improvements of multiple patient reported outcome measures of facial pain (VAS & MPQ-SF) after 2 weeks of twice-daily treatments. Further significant improvement was noted after 4 weeks of use across all three pain metrics—VAS, MPQ-SF, & BPI-SF. Assessment of 5-min post-use VAS pain scores reveal significant immediate improvements, highlighting the device's ability to provide quick-onset relief. SinuSonic device had only one instance of mild epistaxis and minimal discomfort. This study will help inform future sham-controlled trials targeting specific facial pain/headache diagnoses.

CONFLICT OF INTEREST STATEMENT

None.

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