Randomized Controlled Trial Examining the Effects of Balloon Catheter Dilation on “Sinus Pressure” / Barometric Headaches

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Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

Abstract

Objective. To determine if balloon catheter dilation of sinus ostia affects the severity or frequency of headache among patients who have barometric pressure–related “sinus” headache.

Study Design. Prospective single-blinded randomized controlled trial.

Setting. Tertiary care medical center.

Subjects and Methods. Subjects with a diagnosis of sinus pressure headache without evidence of mucosal thickening on computed tomography were recruited. Subjects were blinded and randomized to undergo balloon dilation of affected sinus ostia (active treatment) or balloon dilation in the nasal cavity (placebo). Two balloon devices were utilized (Acclarent and Entellus) and outcomes compared. Subjects were followed with pre- and postprocedure SNOT-22 scores (Sinonasal Outcome Test–22), HIT-6 scores (Headache Impact Test–6), and medication utilization logs for 6 months.

Results. There was no statistically significant difference in SNOT-22 or HIT-6 scores between the arms at any time point. However, both arms experienced statistically and clinically significant decreases in SNOT-22 and HIT-6 scores from preprocedure to 6 months postprocedure. There was no statistically significant difference in SNOT-22 or HIT-6 score reductions between the Entellus and Acclarent devices. There was no statistically significant difference in medication utilization between the groups at any time point.

Conclusions. Subjects with sinus pressure headache without evidence of mucosal thickening on computed tomography had no significant difference in outcomes between active treatment (balloon dilation of sinus ostia) and placebo (nasal dilation). Further study on the etiology and effective treatment of barometric pressure / “sinus” headache is needed.

Keywords
sinus pressure headache, barometric pressure headache, balloon catheter dilation

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A long-standing debate exists regarding the role of weather and barometric pressure in causing “sinus pressure” headaches (SPHs). Temperature, pressure, moon phase, pollutants, allergens, and humidity have all been implicated, but definitive data regarding this entity are lacking.1,2 SPHs are generally described as the sensation of pressure or pain in the head and/or face overlying the paranasal sinuses, which is exacerbated by changes in barometric pressure or weather patterns. Patients with this pathophysiology regularly report that they can sense drops in atmospheric pressure or when it will rain or that flying is an unpleasant experience.

Since patients with SPHs frequently note pressure over their sinuses, it is plausible that obstruction of the narrow ostia of the paranasal sinuses is the underlying anatomic cause. Indeed, sinus ostia have an average diameter of only 1.7 mm.3 Therefore, even small amounts of inflammation could obstruct the ostia and prevent pressure equalization with the environment, leading to a sensation of pressure.

The American Academy of Otolaryngology—Head and Neck Surgery website suggests conservative measures for

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treated sinus headaches, including pain medications, decongestants, and saline irrigations. However, few data support these measures. For patients suffering from sinus barotrauma—a condition on the extreme end of a continuum including SPH—prior studies suggested that relieving obstruction of the affected sinuses (with radiographic evidence of damage) with endoscopic sinus surgery can be beneficial.

The advent of balloon sinus ostial dilation (BSOD) has provided otolaryngologists with a tool to use in the office setting to widen the narrow sinus ostia in patients with chronic or recurrent acute rhinosinusitis. Ostial dilation results in less tissue trauma, bleeding, and postoperative pain medicine usage when compared with traditional endoscopic sinus surgery. Previous reports indicated that balloon technology is already being used for SPH in addition to sinusitis. In fact, several websites claim to resolve SPH with BSOD. However, there are scant published data regarding the role of sinus dilation for SPH. The purpose of this study is to determine if balloon catheter dilation of sinus ostia affects the severity or frequency of headache among patients who have barometric pressure–related “sinus” headache.

**Methods**

**Participant Recruitment**

A single-blinded prospective randomized controlled trial was conducted at the San Antonio Military Medical Center, with subjects presenting to the otolaryngology clinic with the chief complaint of “sinus pressure”–or barometric pressure–related headaches. Prior to initiation of recruitment, Institutional Review Board approval was obtained from the office of Clinical Research Administration at the 59th Medical Wing (protocol FWH20150103H). Subjects were screened on initial intake with the Headache Study Inclusion Survey (in the online version of the article). For inclusion, subjects were required to have headache onset associated with barometric pressure or weather changes. Additionally, their headaches had to begin in the face in an area corresponding with ≥1 of their sinuses amenable to balloon sinus dilation (ie, maxillary or frontal). Subjects were then evaluated for the potential diagnosis of other common headache disorders based on the International Classification of Headache Disorders (ICHD) definitions of migraine, cluster, medication overuse, and tension headaches (see Headache Study Inclusion Survey). Subjects with other identifiable causes for headache were excluded from the study and referred to neurology. Finally, subjects were required to have computed tomography of their sinuses performed within the past year, which documented sinuses that were completely free of mucosal thickening (Lund-Mackay score of 0). Recruited subjects included active duty military, family members, and military retirees. Potential subjects from vulnerable populations (ie, <18 years of age, pregnant women, prisoners, trainees) and those who had undergone previous sinus surgery were excluded from the study.

Subjects were not compensated in any way for their participation in this study.

**Subject Enrollment and Study Design**

Subjects meeting the inclusion criteria were voluntarily enrolled in the study. Informed consent and Health Insurance Portability and Accountability Act consents were obtained for all subjects prior to data collection. To evaluate baseline symptoms, SNOT-22 (Sinonasal Outcome Test–22) and HIT-6 (Headache Impact Test–6) questionnaires were collected from all subjects prior to any intervention. The SNOT-22 is a validated patient symptom–based tool used to evaluate the severity of a patient’s rhinosinusitis symptoms. The HIT-6 is a 6-question validated tool that objectively evaluates the impact of a person’s headaches on one’s daily life. Additionally, subjects were asked to document their medication utilization for their SPHs, using a daily medication diary for at least 1 month prior to intervention. Medications that were specifically tracked included pain medications, such as acetaminophen, ibuprofen, and narcotics (eg, oxycodone, tramadol), as well as any medications containing pseudoephedrine.

All subjects were randomized to 1 of 2 treatment arms via a random number generator. All patients with even numbers underwent balloon sinus dilation of the symptomatic sinus ostia, while those with odd numbers underwent placebo dilation—specifically, deployment of the balloon within only the nasal cavity and without manipulation of the ostia (balloon nasal dilation). Subjects were blinded throughout the study with regard to the treatment arm to which they were assigned.

**Intervention and Follow-up**

On the day of the office-based procedure, subjects were consented for balloon dilation of sinus/nasal cavities. Subjects then reconfirmed the location of the sinus headache (ie, right maxillary and right frontal, bilateral frontal, etc). Subjects were instructed to utilize 5 sprays per naris of oxymetazoline to decongest their nasal cavities. Following this, subjects were given 1:1000 epinephrine. The injection of oxymetazoline with a Freer elevator. The balloon was then used to dilate the appropriate sinuses on the basis of the patient’s symptoms. This included between 1 and 4 sinuses per subject.

For subjects undergoing balloon dilation of sinus ostia, pledget placement was removed, and the middle turbinate was medialized with a Freer elevator. The balloon was then used to dilate the appropriate sinuses on the basis of the patient’s symptoms. This included between 1 and 4 sinuses per subject.
medialized with a Freer elevator. For patients reporting maxillary or frontal pressure, the balloon was placed in the middle meatus and dilated without entering the ethmoid infundibulum or sinus ostia. This was performed unilaterally or bilaterally depending on the patient’s symptoms.

Following the procedure, subjects were monitored for 5 minutes to ensure hemostasis. All subjects were discharged with a 1-week course of antibiotics (ie, Augmentin or doxycycline for penicillin-allergic patients), a 5-day Medrol Dosepak, nasal saline irrigations, and 20 hydrocodone/acetaminophen tablets for pain. Subjects were asked to continue to keep a medication log, and all were seen in the clinic at 2 weeks, 3 months, and 6 months. At each interval, subjects were given the SNOT-22 and HIT-6 questionnaires, and medication logs were collected. Subjects were blinded to the procedure performed throughout the duration of the study.

**Statistics**

Statistical analysis was performed with SPSS (IBM, Chicago, Illinois). Prior to initiation of the study, a power analysis was performed with an effect size of 1.032, a significance level of 0.05, and a power of 0.8, resulting in a sample size calculation of 32 participants (16 per group). This analysis was based on the average effect size of the rhinologic and extranasal rhinologic subdomains of the SNOT-22 as noted by DeConde et al in a study examining patients who elected to undergo surgical intervention for their rhinosinusitis. For the SNOT-22 and subdomains, the HIT-6, and medication use, means were calculated with standard errors, and a repeated-measures analysis of variance was used to make comparisons between the types of procedure performed (sinus vs nasal dilation). Additionally, comparisons were made between the types of device utilized (Acclarent vs Entellus) to determine any statistically significant difference.

**Results**

**Subjects**

A total of 63 subjects were screened for the study, and 35 were enrolled between January 2016 and April 2017 (Figure 1). Thirty-four subjects completed the follow-up visits and questionnaires through 6 months, with only 1 being lost to follow-up prior to the 2-week postprocedure visit. Data from this subject were excluded from final analysis. Demographic data for both arms (sinus ostia dilation and nasal dilation) are included in Table 1. There were no statistically significant differences between groups in age, sex, or baseline data (SNOT-22, HIT-6, medication usage). Only 2 subjects reported pain overlying 1 sinus; 20 subjects, 2 sinuses (ie, bilateral frontal or right frontal and maxillary, etc); 1 subject, 3 sinuses; and 12 subjects, all 4 sinuses (bilateral frontal and maxillary sinuses). The number of balloon dilations for each subject corresponded with the number of sinuses along which one felt pain. Eighteen subjects were randomized into the balloon sinus ostia dilation group, of whom 17 completed the study; 17 were randomized into the control nasal dilation group. With regard to complications, 4 patients experienced postprocedure infections, documented by symptoms and purulence on nasal endoscopy at the 2 weeks postoperative visit, which required treatment with additional antibiotics and sinus...
Saline rinses. Two of these subjects were in the sinus dilation group, and 2 were in the nasal dilation group. No other complications occurred.

**SNOT-22 Changes**

SNOT-22 scores were evaluated preoperatively and at 2 weeks, 3 months, and 6 months postprocedure. There was no statistically significant difference in SNOT-22 scores between groups at any time point (Figure 2). Overall, SNOT-22 scores improved between initial evaluation and 2 weeks, 3 months, and 6 months for both arms—active treatment and placebo ($P < .001$). Improvement in SNOT-22 scores persisted at 6 months, with an average improvement of 16.1 points in the sinus dilation arm and 19.7 points in the nasal dilation arm. Subjects in both arms reported improvements that exceeded the minimally important difference of −8.9 points. Additionally, SNOT-22 scores were analyzed per subdomain (sleep, nasal, otologic/facial, and emotional), and no statistically significant difference between treatment and placebo was identified at any time point (Table 2).

**HIT-6 Changes**

Regardless of treatment arm, HIT-6 scores also significantly improved between initial evaluation and each postprocedural time point ($P < .001$). For HIT-6 scores, there was no statistically significant difference in scores between the sinus dilation group (active treatment) and nasal dilation group (placebo control) at any time point (Figure 3). At 6 months, improvement persisted for both arms above the minimally important change of −6 points (9.7 points, sinus dilation arm; 13.6 points, nasal dilation arm).

Subgroup analysis was performed for subjects with HIT-6 scores $>65$ and SNOT-22 scores $>45$ to evaluate if there was any difference in outcomes with patients with more severe headache or sinonasal symptoms. There was no statistically significant difference between treatment arms at any time point.

**Devices**

During the study, Acclarent and Entellus balloon devices were both utilized to evaluate any difference in results based on device. The Entellus Xpress dilation device was
utilized in 14 patients (7 sinus dilation and 7 nasal dilation), and the Acclarent Relieva Spin device was utilized in 21 patients, including the 1 patient lost to follow-up (11 sinus dilation and 10 nasal dilation). No statistically significant difference in SNOT-22 or HIT-6 scores were demonstrated between the devices at any time point (Figures 4 and 5). Regardless of device and whether sinus dilation or nasal dilation was performed, subjects experienced statistically significant improvements between initial baseline scores and 2 weeks, 3 months, and 6 months scores for SNOT-22 ($P < .001$) and HIT-6 ($P < .001$).

**Medication**

Finally, medication utilization was monitored prior to the procedure and for 6 months postprocedure. Medication usage was averaged over a 30-day period for comparison. There was no statistically significant difference in medication utilization between the sinus ostia dilation group and the nasal dilation group at any time point (Figure 6).

**Discussion**

An estimated 47% of the world’s population suffers from a headache disorder.\textsuperscript{15} SPH is not a diagnosis listed in the ICHD, and it is best categorized under classification 11.9: headache or facial pain attributed to other disorder of cranium, neck, eyes, ears, nose, sinuses, teeth, mouth, or other facial or cervical structures.\textsuperscript{16} This lack of standardized diagnostic criteria is the primary reason why the incidence of this condition is currently unknown. However, patients meeting our definition of SPH who do not meet criteria for the most common ICHD headache disorders are frequently seen in otolaryngology clinics. As an option to treat patients with this complaint, the favorable safety profile and in-office option make BSOD an appealing treatment possibility. This is consistent with a review of BSOD in a hospital system without financial incentive, which identified that BSOD had been performed for patients with clinical pictures consistent with SPH, despite the lack of evidence to support its use.\textsuperscript{11}

Some evidence exists supporting the surgical opening of narrow sinus passages in select patients with severe barotrauma\textsuperscript{5,6}; however, the subjects in these studies were high-
performance pilots rather than people in the general public. Additionally, nearly all these patients had imaging findings consistent with acute sinus barotrauma and underwent formal endoscopic sinus surgery. Thus, these data may not be applicable to the general population.

In a study by Marzetti et al, frontal sinus balloon dilation was performed among patients with a condition the authors termed “vacuum rhinogenic headache.”17 Numerous subjects in the study also had inferior turbinate reduction, which potentially confounded their results. The authors indicated that patients reported improvements with headaches per visual analog scale scores. By contrast, subjects in the present study did not have any ancillary procedures like turbinate reduction. Additionally, in our study, while subjects with sinus ostial dilation improved symptomatically, these improvements were not significantly different from those experienced by subjects in the control arm.

Subjects in both arms reported similar improvements on the validated surveys, SNOT-22 and HIT-6, as well as decreased medication usage. Interestingly, the same degree of clinically meaningful decreases in SNOT-22 was noted in the BSOD group and the control arm. Subjects in both groups also reported equal and clinically significant decreases in the HIT-6—from a starting score of approximately 65 to a postintervention score of closer to 50, which represents persistent quality-of-life impairment (P < .05). Thus, there was no significant difference between active treatment and placebo. Additionally, while subjects in both groups improved, they were still symptomatic, requiring self-treatment with medications. The BSOD group showed an increase from baseline in pain medicine utilization at the 2-week time point. However, the overall reported use of medication was lower in both groups after intervention, and the amount used was the same between cohorts. In this study, there was no difference in symptom reduction among subjects in the BSOD arm, regardless of device used. The findings of this study show no significant difference between BSOD and nasal dilation (placebo) for treatment of SPH.

One explanation for the lack of additional benefit in the BSOD group is that SPH may be triggered by a more complex mechanism than obstruction of sinus ostia. Other environmental factors appear to have an effect on patients suffering from multiple headache classifications. Barometric pressure is accompanied by multiple environmental changes, such as increases in wind speed, cloud cover, rain/storms, and changes in temperature—all of which have been implicated as headache triggers.18-22 Self-reporting by migraineurs suggests that weather is a trigger for 7% to 82%, with most reporting low pressure as the instigator.22-25 Approximately half of patients suffering with tension headaches also report weather as a trigger.19,20 Additionally, patients with temporomandibular joint dysfunction note worsening pain with drops in barometric pressure.20

It can be challenging to differentiate patients suffering from sinusitis versus primary headache. Many of the symptoms, such as facial pressure, dental pain, rhinorrhea, facial edema, and nasal obstruction, overlap among etiologies. Thorough history, examination with nasal endoscopy, and radiographic workup are often paramount in differentiating among causes.27,28 Despite being a validated instrument for rhinosinusitis symptoms, the SNOT-22 is not specific and can be elevated among those without objective evidence of chronic sinusitis. Lal et al identified high SNOT-22 scores for patients with primary headache disorder and normal imaging results.29 In the current study, potential subjects were specifically excluded if they met criteria for known primary headache disorders or if they had computed tomographic evidence of sinusitis.

One cannot definitively state why the nasal dilation group noted clinically meaningful effects from intranasal balloon dilation. One explanation is that all patients had medialization of the middle turbinate. While this maneuver does not manipulate or widen sinus ostia, it could alter airflow patterns in the nose, altering other characteristics of weather change. Of course, the placebo effect from having any procedure performed is also highly possible.

There are several limitations to the study. First, SPH is not clearly defined in the ICHD, despite being recognized by the AAO-HNS as a distinct pathophysiology on its website. We attempted to address this problem by excluding those who met criteria for an alternative primary headache disorder. Second, 34 patients may not be sufficient to detect small variations between treatment arms. Differential effects between these prospectively randomized blinded groups with low attrition did not approach significance. This minimizes the likelihood of a small effect being missed. A final limitation is that there is no validated objective method to evaluate SPH specifically. In light of this, we utilized the SNOT-22 and HIT-6, tools that address overlapping symptoms of chronic sinusitis and migraine. Additional research is needed to better understand this condition and validate measures to properly diagnose and eventually treat it.

Conclusion

Subjects with SPH without evidence of sinusitis on computed tomography had no significant difference in outcomes when treated with balloon sinus dilation versus placebo nasal dilation. This result held regardless of balloon dilation device used. SPH may have multiple etiologies and is likely more complex than an inability to equilibrate pressure between the sinuses and the nasal cavity. Additional studies on the etiology and effective treatment of this condition are needed.

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Author Contributions

Adrienne M. Laury, study design, implementation, data collection, analysis, and manuscript preparation; Philip G. Chen, study design and manuscript preparation; Kevin C. McMains, study
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Supplemental Material

Additional supporting information is available in the online version of the article.

References


