Nasal septal deviation is common in patients diagnosed with rhinosinusitis and has been shown to correlate with an increased prevalence of the disease.¹ Septoplasty is often performed to manage symptoms related to nasal airway obstruction and facilitate access during endoscopic sinus surgery (ESS).² Balloon sinus dilation is a prevalent treatment option for appropriate chronic and recurrent acute rhinosinusitis patients, but existing clinical trials evaluating the safety and effectiveness of balloon sinus dilation have not evaluated the effect of septal deviation on procedure success or sinonasal symptom improvement.

This retrospective study of balloon sinus dilation procedures performed in the physician’s office without concomitant septoplasty analyzed the impact of mild to moderately deviated septums on:

- Technical success of balloon sinus dilation procedure
- Procedure tolerability in awake patients
- Symptom improvement

All patients suffered from chronic or recurrent acute rhinosinusitis.

**KEY FINDINGS**

**High Technical Success**
There were no significant differences in either percent balloon dilation successfully performed in the sinus ostia (98%).

**High Patient Comfort**
Using a 0 (no pain) to 10 (severe pain) discomfort scale, patients mean procedure pain level were low (2.4 ± 2.2) for both mild and moderate septal deviation groups.

**Similar Symptom Improvement for Mild and Moderate Septal Deviation Groups**
At 6-month follow-up, overall mean symptom improvement as measured by SNOT-20 was clinically meaningful and statistically significant in both septal degree groups and there was no significant difference between groups.

**EXECUTIVE SUMMARY**

Septoplasty is not required with balloon sinus dilation to achieve a high technical success rate, high patient comfort and statistically significant symptom improvement.
BACKGROUND

Septal deviation is common among patients with rhinosinusitis, and septoplasty is one of the most common sinonasal procedures performed annually in the United States. In over 600,000 patients who underwent ambulatory sinonasal procedures, over 56% of procedures included a septoplasty and/or turbinate surgery. Although the safety and effectiveness of balloon sinus dilation procedures have been previously reported across clinical trials, none of the studies have evaluated the effect of septal deviation on procedure success or sinonasal symptom improvement. A deviated septum could potentially impede access to the maxillary, sphenoid, or frontal sinuses during standalone balloon dilation, depending on location and angle of deviation.

This retrospective study of procedures performed in the physician's office analyzed the impact of septal deviation on balloon dilation success, procedure comfort in awake patients, and symptom improvement in patients with rhinosinusitis and mild to moderately deviated septums.

METHODS

A retrospective analysis of prospectively collected data from patients undergoing balloon dilation of the sinus ostia and ethmoid infundibula with or without turbinectomy between 2007 and 2012 was performed. All participants consented to participation prior to enrollment and the studies were approved by an Institutional Review Board.

All patients underwent balloon dilation of the sinus ostia and ethmoid infundibula under local anesthesia using balloon devices manufactured by Entellus Medical, Inc. (Plymouth, MN). Prior to discharge, patients rated procedure discomfort on a scale of 0 (no pain) to 10 (severe pain). Technical success was calculated as the number of successful ostial dilations divided by the number of attempts. The 20-item Sino-Nasal Outcome Test (SNOT-20) and Rhinosinusitis Symptom Inventory (RSI; developed by Neil Bhattacharyya, M.D., Boston, MA, copyright 1999) validated surveys were used to assess disease-specific symptom changes between pre-procedure (baseline) and 6-month post-procedure visits. An Independent Statistician performed all statistical analyses using SAS Version 9.3 (SAS Institute, Cary, NC).

Baseline computed tomography (CT) scans were analyzed to quantify the septal deviation angle. A coronal CT image at the level of the ostiomeatal complex (OMC) and the area of the most severe deviation was used to calculate the degree of septal deviation (Figure 4). The deviation angle was defined as the angle between one line drawn from the superior insertion of the septum at the crista galli to the premaxilla and another line from the superior insertion of the septum at the crista galli to the apex of the septal deviation at the most prominent point of bony tissue of the deviation. Scans were magnified to achieve a lesser degree of variability and all measurements were performed by the same reviewer. These techniques were similar to the methods used in previous studies designed to assess the impact of septal deviation in patients with rhinosinusitis. Synedra View Personal 3 (version 3.2.0.2) DICOM (Digital Imaging and Communications in Medicine) software was used to measure each septal deviation angle and patients were divided into two subgroups: “mild” (septal deviation <10°) and “moderate” (septal deviation ≥10°).

RESULTS

The study concluded that balloon dilation in patients with mild to moderate nasal septal deviation can be completed comfortably with a high rate of success and do not require concomitant septoplasty. In addition, patients experience clinically meaningful and statistically significant improvement in sinonasal symptoms through 6 months post-balloon dilation. Specific results were:

Thirty-two physicians across 22 study centers treated 171 patients and no physician enrolled more than 25% of patients. The mean age of the population was 49.3 ± 15.7 with a majority female (63.7%). Non-smokers (69.7%) and patients with allergies (67.9%) were common while only 26.1% of the patients had asthma. Baseline characteristics were similar between subgroups. The mean septal deviation angle was 5.1° ± 3.3° (N=122) and 13.5° ± 3.3° (N=49) in the “mild” and “moderate” subgroups respectively.

High Technical Success - Overall technical success was 98.8% (417/422) and there was no significant difference in technical success between the septal deviation subgroups (p=0.671; Figure 1). Stand-alone balloon dilation was performed in 144 patients while 27 underwent balloon dilation with turbinectomy. A total of 323 maxillary, 70 frontal, and 24 sphenoid sinus ostial dilations were completed.
High Patient Comfort - The overall mean patient discomfort was 2.4 ± 2.2. Subgroup analyses of mean pain score revealed discomfort at 2.4 ± 2.1 in patients with "mild" septal deviations versus 2.5 ± 2.4 in patients with "moderate" septal deviations, and the difference was not statistically significant (p=0.628; Figure 2).

Similar Symptoms Improvement with Mild and Moderate Septal Deviation - Both subgroups had similar sinonasal symptom scores before treatment (baseline mean SNOT-20: 2.4 vs 2.6; p=0.290) and both groups experienced statistically significant (p<0.001) and clinically meaningful symptom improvement (SNOT-20 ≥0.8) through 6 months post-procedure. The average reduction (i.e. improvement) in mean SNOT-20 score was almost double the margin required to be clinically meaningful (-1.4; Figure 3) and neither the “mild” nor “moderate” subgroup experienced more significant improvement compared to the other (p=0.837); thus demonstrating that patients saw similar, significant improvement in their sinonasal symptoms regardless of the septal deviation angle.

Improvement was also statistically significant within each group and similar between the two populations for 11 of 12 major and minor rhinosinusitis symptoms. Before treatment, symptom severity in patients with "mild" septal deviations was greatest for congestion and nasal obstruction (RSI; Table 1). Congestive and obstructive symptoms, along with facial pressure, headache and fatigue were greatest in patients with "moderate" septal deviations. Six months after balloon dilation, all five (5/5) of the major sinus symptoms improved significantly in both subgroups. Among the 5 major symptoms, the treatment effect size was greatest for symptoms of congestion and nasal obstruction. For major and minor symptoms combined, the effect size of the treatment was large in 11/12 symptoms in the “mild” subgroup and 10/12 symptoms in the “moderate” subgroup.

Using endoscopy or transillumination to confirm cannulation/dilation success, this study demonstrated a very high rate (98%) of procedure success in patients with "mild" or "moderate" septal deviations. Concerns that a narrowed space in the nasal cavity either due to structural abnormalities or inflammation could cause more patient discomfort because of frequent contact between the balloon device and sinonasal tissue were unfounded. Patients treated under local anesthesia experienced low levels of pain irrespective of the severity of the septal deviation.

Patients with chronic rhinosinusitis (CRS) and septal deviations often present with similar symptoms including nasal obstruction, facial pressure, facial congestion, and headache while symptom causes due to CRS versus septal deviation based on facial symptoms may be difficult. Harill et. al. found that treating patients who have both a septal deviation and inferior turbinate hypertrophy, with an inferior turbinate reduction alone, can relieve symptomatic nasal obstruction. In our study, patients with non-obstructive “mild” to “moderate” septal deviations experienced similar improvement in their sinonasal symptoms that was not only statistically significant but also nearly twice the threshold for clinically meaningful improvement. All major and most minor sinonasal symptoms also improved significantly in both groups with nasal obstructive symptoms showing large treatment effects after standalone balloon dilation without any surgical correction to the deviated septums. Our results are supplemental to earlier work by Rudmik et al. that concluded septoplasty performed concurrently during ESS does not affect CRS-specific quality of life or symptom outcomes. Together, these findings suggest concomitant septoplasty during balloon dilation in patients with rhinosinusitis and non-obstructive “mild” to “moderate” septal deviations is not necessary to significantly improve sinonasal symptoms.

Table 1: Baseline and 6-Month Changes (Δ) in Mean RSI Major and Minor Sinonasal Symptom Scores

<table>
<thead>
<tr>
<th>Symptom</th>
<th>&quot;Mild&quot; Septal Deviation (&lt;10°)</th>
<th>&quot;Moderate&quot; Septal Deviation (≥10°)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Δ1</td>
</tr>
<tr>
<td><strong>MAJOR</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facial pressure</td>
<td>3.0</td>
<td>-1.9</td>
</tr>
<tr>
<td>Congestion</td>
<td>3.8</td>
<td>-2.6</td>
</tr>
<tr>
<td>Nasal obstruction</td>
<td>3.6</td>
<td>-2.2</td>
</tr>
<tr>
<td>Rhinorrhea</td>
<td>3.3</td>
<td>-2.1</td>
</tr>
<tr>
<td>Hyposmia</td>
<td>2.3</td>
<td>-2.0</td>
</tr>
<tr>
<td><strong>MINOR</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>3.1</td>
<td>-2.1</td>
</tr>
<tr>
<td>Fever</td>
<td>0.8</td>
<td>-0.7</td>
</tr>
<tr>
<td>Halitosis</td>
<td>1.9</td>
<td>-1.3</td>
</tr>
<tr>
<td>Fatigue</td>
<td>3.3</td>
<td>-2.0</td>
</tr>
<tr>
<td>Dental pain</td>
<td>2.0</td>
<td>-1.4</td>
</tr>
<tr>
<td>Cough</td>
<td>2.3</td>
<td>-1.4</td>
</tr>
<tr>
<td>Ear pain/pressure</td>
<td>2.7</td>
<td>-1.7</td>
</tr>
</tbody>
</table>

1 The RSI survey was not used in all studies and therefore the sample size for these analysis is 38 ("mild"=23; "moderate"=15).
2 Effect size: small - less than 0.5; moderate - 0.5 to less than 0.8; large - at least 0.8
3 Comparison of mean change from baseline to 6-month follow-up within subgroup; p-value from paired t-test.
4 Comparison of difference (Δ) between "mild" and "moderate" septal deviation subgroups; p-value from generalized linear models comparing groups.
About the Author
Dr. Brodner is board certified in Otolaryngology-Head and Neck Surgery and in Sleep Medicine. He received his M.D. degree from the University of Florida School of Medicine, followed by an internship and residency at the Tulane University School of Medicine. Dr. Brodner was raised in Palm Beach County and, after completing his residency, returned in 2001 to start his Private Practice. Although proficient in managing all maladies of the ear, nose and throat, his interests have focused on the evaluation and treatment of sleep disorders and sinus/allergy complaints. In 2010, Dr. Brodner was among the first sinus surgeons to utilize malleable sinus balloon technology in the operating room and has since become a pioneer in the use of minimally-invasive balloon sinus dilation in the office. Dr. Brodner has created The Center for Sinus, Allergy, and Sleep Wellness to continue his commitment to evidence-based medicine and personalized attention to his patients.

REFERENCES