

Sphenoid Case Study

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Relieva Balloon Sinuplasty™ Devices Used:

Relieva Sinus Balloon Catheter (5x16mm)
Relieva Sinus Guide Catheter (M-90)
 Standard *Relieva* Sinus Guidewire (0.035")
Relieva Sinus Lavage Catheter
Relieva Sinus Balloon Inflation Device

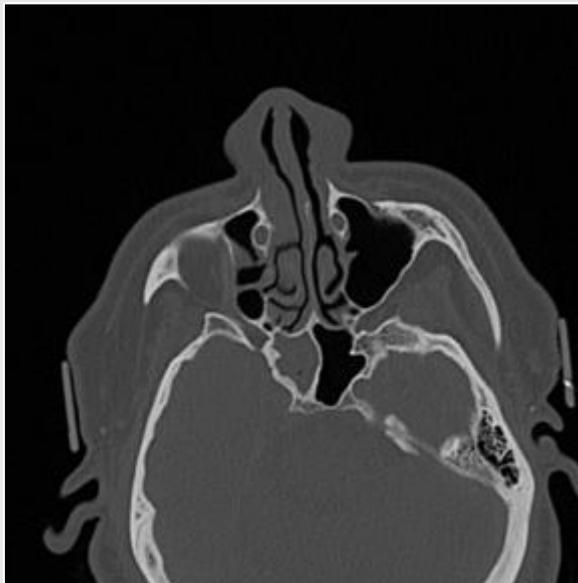


FIGURE 1

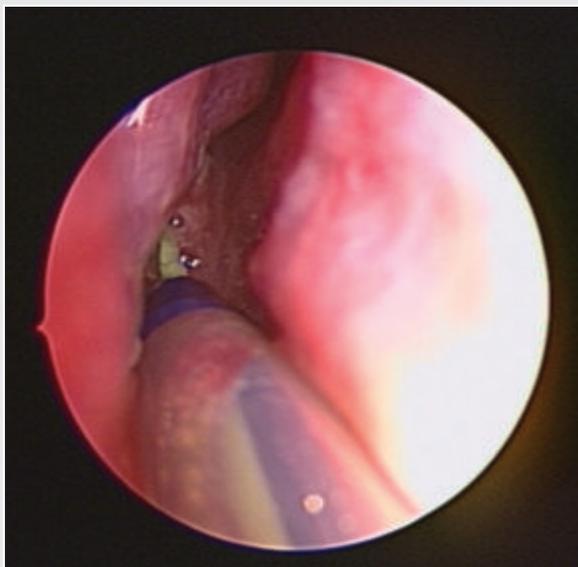


FIGURE 2

Background

The patient is a 57 year-old male who complained of constant postnasal drainage, throat clearing, and coughing. One and a half years ago, the patient had a coronary artery by-pass graft. In the post-operative period, the patient developed a CVA, left hemi-paresis, and had become largely aphasic. He communicated through his wife with a limited vocabulary and sign language. He also has insulin dependent diabetes mellitus and hypertension. Current medications included: baclofen, Coumadin®, folic acid, insulin 70/30, Lasix, NTG patch, ramipril, simvastatin, and Zoloft®.

Nasal endoscopy revealed no mucous, pus or polyps in either middle meatus. His sinus CT was clear except for an opaque right sphenoid sinus (Fig. 1). He was treated with 6 weeks of clindamycin and rescanned. The second scan did not clear. Because he was on Coumadin®, he was a poor surgical candidate and was treated with an additional 6 week course of clindamycin. The 12 week CT still demonstrated opacity in the lower half of the sinus. At this point of maximal medical therapy, it was decided that the least invasive/disruptive course would be a right sphenoid sinus surgery and irrigation using the *Relieva Balloon Sinuplasty™* devices. The patient and his wife agreed and surgery was scheduled. No change was made in his anticoagulation.

Treatment

The patient was put in the supine position and administered general anesthesia. Under sterile prep and drape, the *Relieva* Sinus Guide Catheter (S-30) was passed into the sphenoethmoidal recess to the sphenoid ostium. Marked edema of the right sphenoid sinus ostium was noted. The standard *Relieva* Sinus Guidewire (0.035") was passed through the Sinus Guide Catheter to the sphenoid sinus (Fig. 2). Fluoroscopy was used to confirm proper positioning of the Sinus Guidewire in the sphenoid sinus. Next, a *Relieva* Sinus Balloon Catheter (5x16mm) was passed over the Sinus Guidewire, across the ostium and into the sphenoid sinus. Sinus balloon placement was confirmed with fluoroscopy. The sinus balloon was inflated to 2-3 atm. This pushed yellow debris out of the sinus into the sphenoethmoidal recess, where it was aspirated into a Leukin's trap to be submitted for aerobic/anaerobic bacterial and fungal culture. Then the sinus balloon was deflated, repositioned across the ostium and re-inflated to 16 atm (Fig. 3, on back page). Inflation was monitored using fluoroscopy. The sinus balloon was deflated and the Sinus Balloon Catheter removed, leaving the Sinus Guidewire in place. Finally, the *Relieva* Sinus Lavage Catheter was passed over the Sinus Guidewire into the sphenoid sinus.

Sphenoid Case Study

Continued

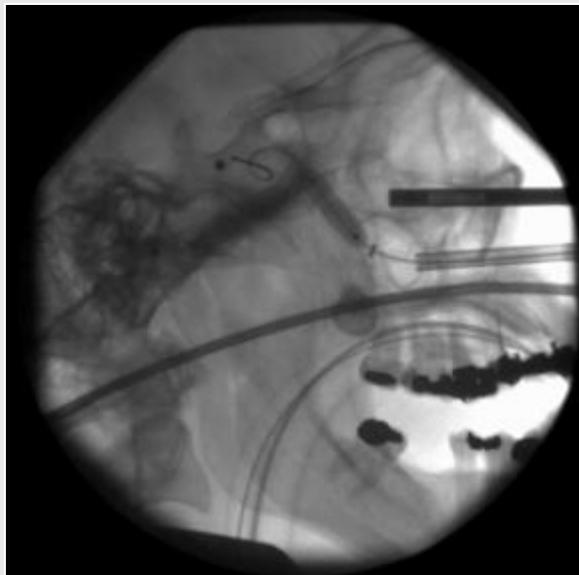


FIGURE 3



FIGURE 4

The Sinus Guidewire was removed and irrigation was performed with normal saline. The irrigant was removed via suction before the Sinus Lavage and Sinus Guide Catheter were removed. Fluoroscopy was used to confirm removal of all instruments. There was no bleeding. The patient was extubated and returned to recovery in satisfactory postoperative condition. The entire sinus surgery required 30 minutes. No tissue was removed and no bleeding was induced. The sinus contents yielded fungal hyphae on smear and multiple bacteria (alpha-strep & Neisseria sp.) on culture

Discussion

The patient was seen in the office postoperatively at days 8 and 16; as well as weeks 5, 8, 12, 24, and 57. His symptoms steadily improved. At 5 weeks, on the RSOM-31¹, he did not indicate post nasal drainage was a problem. He continued to note symptoms of cough and the need to rub the nose or eyes. He saw his primary care physician for the cough and was treated for bronchitis vs. pneumonia with antibiotics and albuterol. The cough improved at subsequent visits.

Nasal endoscopy at 5 weeks revealed that the sphenothmoidal recess edema was gone and that the sphenoid ostium was patent and measured 2 x 3 mm at 5 and 57 weeks. In addition, the CT scan demonstrated that the right sphenoid sinus was clear at 12 (Fig. 4), 24, and 57 weeks, and all other sinuses remained clear.

In summary, this patient had a complicated medical history, which made him a poor surgical candidate. He had persistent annoying symptoms associated with his chronic sphenoid sinusitis from which he wanted relief. After failure to respond to prolonged medical therapy, it was determined that sphenoid sinus surgery and irrigation with the *Relieva Balloon Sinuplasty*[™] devices was the most appropriate next course for this patient. After patient approval, endoscopic sinus surgery was performed. The patient experienced no surgical complications or bleeding, the anesthesia time was short, and there was minimal post op care required. Five weeks after surgery, the patient reported a marked improvement in his symptoms, which has persisted for 57 weeks.

1. Piccirillo et al. Psychotric and clinimetric validity of the 31-item Rhinosinitis Outcome Measure (RSOM-31). *Am J Rhinology* 1995;9:297-306.

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