

Multicenter Registry of Balloon Catheter Sinusotomy Outcomes for 1,036 Patients

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Overview

The PatiENT Registry Study analyzes outcomes for more than 1,000 patients who underwent sinus surgery using the *Relieva Balloon Sinuplasty*[™] system across 27 US otolaryngology practices, validating previously published results in a “real world” setting.

Methodology

All consecutive endoscopic sinus surgery cases that included use of sinus balloon catheters between December 2005 and May 2007 across 27 physician practices in the US were subjected to retrospective chart review.

All patients in the study had been diagnosed with chronic sinusitis and underwent endoscopic sinus surgery on the basis of the clinical judgement of the operating surgeon. The only exclusion criteria were that the patient could not be younger than 18 years old at the time of surgery, and could not have previously recorded outcomes data in literature.

Summary of Results

Of the 1,036 patients in this study, sinus balloon catheters were used in 3,276 peripheral sinuses for an average of 3.2 sinuses treated per patient. The average follow-up was 40.2 weeks.

Safety:

- No major adverse events attributable to use of sinus balloon catheters; compares favorably to 1.1% incidence of serious adverse events during traditional sinus surgery as reported in published FESS literature

Effectiveness:

- 2.4% of patients required a revision surgery
- 1.3% of sinuses treated with *Balloon Sinuplasty*[™] instruments required a revision surgery

Patient Outcomes:

- Sinus symptoms improved for 95.2% of patients
- 73.8% of patients were completely free of sinus infections post-surgery

The results of this study confirm other published peer-reviewed studies showing that use of *Relieva Balloon Sinuplasty*[™] instruments in sinus surgery is safe and effective and improves patients' quality of life. The data show that revision rates and patient symptom improvement rates are comparable with previously reported results of functional endoscopic sinus surgery, and that complication rates compare favorably. These results are consistent across a wide range of sinusitis patients and physician practices.