

Evidence table

Clinical Area: Balloon Sinuplasty

References: Bolger WE, Brown CL, Church CA, et al. Safety and outcomes of balloon catheter sinusotomy. A multicenter 24-week analysis in 115 patients *Otolaryngol Head Neck Surg.* 2006;137:10-20.

Kuhn FA, Church CA, Goldberg AN, et al. Balloon catheter sinusotomy; One-year follow-up. Outcomes and role in functional endoscopic sinus surgery. *Otolaryngol Head Neck Surg.* 2008;139:S27-S37

Weiss RL, Church CA, Kuhn FA, et al. Long-term outcome analysis of balloon catheter sinusotomy: Two-year follow-up. *Otolaryngol Head Neck Surg.* 2008;139:S38-S46

Study Type: Case Series

Study Aim: To evaluate the safety, effectiveness, and long term outcomes of balloon catheter Devices to dilate obstructed sinus ostia/perform sinusotomy

Outcomes

- *Primary:* Ostial patency
- *Secondary:* Symptom improvement and final ostial size.

Design

- *Number of subjects:* = 115 patients (342 sinuses) were enrolled, 109 (304 sinuses) were treated with balloon catheters sinusotomy with or without traditional endoscopic surgery and followed for 24 weeks. 66 patients (202 sinuses) were followed for 1 year, and 65 (195 sinuses) were followed for 2 years.
- *Description of study population:* The study enrolled patients from 9 centers in different states in the US from April to December 2005. Their mean age at enrollment was 47.8 years (range 21-76), 35.7% men, 18.3% with history of previous endoscopic sinus surgery.
- *Inclusion criteria:* Age ≥ 18 years, chronic sinusitis unresponsive to medical treatment, planned endoscopic sinus surgery.
- *Exclusion criteria:* Extensive sinonasal polyps, previous extensive sinonasal surgery, extensive sinonasal osteoneogenesis, cystic fibrosis, sinonasal tumors, history of facial trauma and distorted sinus anatomy, ciliary dysfunction, or pregnancy.
- *Consecutive patients?* Yes for those who met the inclusion criteria.
- *Exposure/Intervention:* The patients underwent an initial preoperative evaluation for sinusitis they included a physical exam, sinonasal endoscopy, paranasal CT scan, and a Sino-Nasal Outcome Test (SNOT 20). The investigators selected patients for the balloon sinuplasty procedure based on their disease pattern. Preparation of the patients for the procedure was similar to that used for endoscopic sinus surgery. Using sinus guiding catheters, sinus guide wires, and 5, 6, or 7 mm sinus balloon catheters (Acclarent Inc, Menlo Park, CA), the sinuses were catheterized and dilated under fluoroscopic control. If the investigator was unable to cannulize the ostium, or if the balloon catheter failed to sufficiently open the ostium, the standard endoscopic surgical technique was performed. Balloon catheter was used in the

maxillary, sphenoid, and frontal sinuses. Patients with significant ethmoid sinus disease were treated with standard endoscopic surgery.

- *Source of outcome data (e.g. patient self-report, doctor report, lab results):* Postoperative visits at 1-2, 12, 24 weeks, 1 year, and 2 years after the procedure
- *Length of follow-up:* 2 years in the last report.
- *Completeness of follow-up:* Follow-up was complete for 84% of the patients at 12 weeks, 82.6% at 24 weeks, 57.4% at one year, and 56.5% at two years (two centers did not participate in the 1 and 2-year follow-up).

Validity

- *Is the study type appropriate for the question(s) being asked?* No a randomized controlled study comparing the procedure to the standard surgery would be more appropriate.
 - *Were patients similar with respect to baseline characteristics?* Apparently not; there was a wide variation in age, and an 18.3% had undergone a previous endoscopic sinus surgery.
 - *Were the intervention and other aspects of patient care similar for all patients (or for all patients in a defined subgroup)?* Yes.
 - *Was the process of observation likely to affect the outcome?* Yes, for the subjective outcomes.
 - *Was follow-up duration appropriate?* Relatively.
 - *Was follow-up rate sufficient?* No
 - *Industry funded?* Yes.
- **Conclusions regarding validity of methods:**

This was a case series with no comparison or control group. Patients were selected for the procedure and the outcomes were mainly subjective, which are potential sources of selection and observation bias.

Results:

- 56/115 (48.7%) patients underwent balloon catheter sinusotomy alone, and 59 (51.3%) underwent the procedure with a concurrent endoscopic surgery at different sinuses (hybrid).
- Median fluoroscopy time 0.81minutes/sinus
- Average radiation dose approximately 730 mrem/patient
- 109 patients were followed up for 24 weeks
- 66 (57.4%) patients were followed up for 1 year, after withdrawal of patients and participating centers.
- 65 (56.5%) patients were followed up for 2 years.
- An adjunct septoplasty was performed in 21% of the patients treated with balloon catheter only, and 41% in hybrid patients. Turbinectomy was also performed in 51% of hybrid patients.

Ostial patency on sinonasal endoscopy**at 24 week, N=109 patients (304 sinuses)*

	Maxillary	Sphenoid	Frontal
No of sinuses	N=124	N=66	N=114
Patent	113 (91%)	40 (61%)	94 (82%)
Non patent	1 (1%)	0	1 (1%)
Indeterminate	10 (8%)	26 (39%)	19 (17%)

Ostial patency on sinonasal endoscopy* at 1 year, N=66 patients (202 sinuses)*

	N=36	N=74	
N= 92			
Patent	83 (92%)	26 (72%)	63 (85%)
Non patent	0	0	2 (3%)
Indeterminate	9 (10%)	10 (28%)	9 (12%)

Ostial patency on sinonasal endoscopy* at 2 years,*

No data were provided

* Including hybrid and balloon sinuplasty

**Based on the investigator assessment. Indeterminate was used if the ostium could not be viewed in the post-procedure setting with rigid endoscopy, or if the patient did not tolerate a complete endoscopic examination

Mean SNOT 20 scores before and after sinusotomy using balloon catheter devices*

	Balloon catheter with concurrent endoscopic surgery (Hybrid)			Balloon catheter sinusotomy only		
	Mean	Difference from baseline	P	Mean	Difference from baseline	P
Preoperative baseline	2.42	-	-	2.14	-	-
Postoperative week 12	0.98	-1.44	<0.0001	1.08	-1.06	<0.0001
Postoperative week 24 (n=84) **	1.02	-1.40	<0.0001	1.27	-0.87	<0.0001
Postoperative 1-year (n=66) ***	0.87	-1.39	0.0001	0.95	-1.06	0.0001
Postoperative 2-year (n=65) †						
Primary surgery	0.58	-1.58	<0.001	1.05	-0.98	< 0. 001
Revision surgery††	0.96	-1.84	0.120	1.35	-1.16	0.150

* Patients asked to rate severity of 20 symptoms in over the preceding 2 weeks, on a 6-point scale from 0=no problem, to 5= problem as bad as can be. This can be reported as mean score (maximum 5.0) or as a sum score (maximum of 100) or as s

**N=48 for balloon catheter with concurrent endoscopic surgery, and N=36 for balloon catheter sinusotomy only

***N =34 for balloon catheter with concurrent endoscopic surgery, and N=31 for balloon catheter sinusotomy only

(The 24 w mean and difference from baseline for the patients with 1 year follow-up were 1.22 and -1.04 respectively for hybrid patients, and 0.97 and -1.04 respectively for balloon catheter only patients

† n=61 with available data, 32 in balloon only patients and 29 hybrid patients

†† four (21%) patients in the balloon only patients, and 5 hybrid patients underwent a revision surgery

Adverse events:

Devices malfunction* 12/358 (3.4%) applications/sinuses

No serious adverse events were reported. There were no incidents of cerebrospinal fluid leak, diplopia, visual loss or significant intraoperative bleeding

* Balloon deflated/ruptured or catheter tip malfunctioned.

Authors' Conclusions:

The authors concluded that that balloon catheter sinusotomy appears safe and effective in relieving ostial obstruction and improving symptoms in patients with moderate chronic sinusitis. They also concluded that the 2-year follow-up indicates that the clinical results are durable. They noted however, that the procedure is not appropriate for all sinusitis patients, and that those with sinonasal polyps or extensive previous surgery with significant osteogenesis are not appropriate candidates.

Reviewer's Conclusions:

The study was a multicenter case series with no comparison group or control group. It was sponsored and funded by the manufacturer of the balloon catheter device. The aim of the study was to evaluate the safety and effectiveness of the device in relieving sinus obstruction, and maintaining its patency. Patients were highly selected for the procedure, and had some baseline differences. The study centers did not use a standardized definition for chronic sinusitis. Determining the stage of the disease was based on CT scan staging systems which have not been validated for chronic sinusitis, and correlates poorly with the symptoms. Patients with ethmoid sinus disease underwent the standard endoscopic surgery, and more than half the patients had were treated concurrently with the balloon catheters and traditional endoscopic surgery. After withdrawal of two centers, and a number of patients from the study, the 1 year, and 2-year follow up data were complete for only 57% of the patients, and data on the ostial patency, the primary outcome, were not provided in the 2-year results. Ostial patency was not assessed in the ethmoid sinuses and could not be determined in 22% of the maxillary, sphenoid, and frontal sinuses. Moreover, postoperative medical therapy including antibiotic use differed between providers, and any variation may influence the outcomes and severity of the symptoms, which in this study were rated by subjective measures.

Table 1
SNOT-20 symptom scores

Time	N	Pre-op mean	95% CI	Post-op mean	95% CI	Δ from baseline	95% CI	P value
All patients								
Postoperative 24 weeks*	60	2.17	(1.86, 2.48)	0.99	(0.73, 1.26)	-1.18	(-1.54, -0.82)	<0.001
Postoperative 1 year†	55	2.13	(1.80, 2.48)	0.84	(0.61, 1.07)	-1.29	(-1.63, -0.95)	<0.001
Postoperative 2 years*†	61	2.17	(1.86, 2.48)	0.87	(0.64, 1.11)	-1.30	(-1.64, -0.95)	<0.001
Balloon-only patients								
Postoperative 24 weeks‡	31	2.09	(1.72, 2.46)	1.07	(0.71, 1.42)	-1.02	(-1.41, -0.65)	<0.001
Postoperative 1 year§	28	2.07	(1.66, 2.47)	0.99	(0.62, 1.36)	-1.08	(-1.45, -0.70)	<0.001
Postoperative 2 years‡§	32	2.09	(1.71, 2.46)	1.09	(0.73, 1.44)	-1.00	(-1.37, -0.63)	<0.001
Hybrid patients								
Postoperative 24 weeks	29	2.27	(1.73, 2.80)	0.92	(0.51, 1.32)	-1.35	(-1.99, -0.71)	<0.001
Postoperative 1 year**	27	2.26	(1.64, 2.75)	0.68	(0.39, 0.98)	-1.58	(-2.10, -0.93)	<0.001
Postoperative 2 years **	29	2.26	(1.73, 2.80)	0.64	(0.33, 0.96)	-1.62	(-2.23, -1.01)	<0.001

*Matched-pairs difference between 24-week and two-year scores not statistically significant ($P = 0.496$).

†Matched-pairs difference between one-year and two-year scores not statistically significant ($P = 0.841$).

‡Matched-pairs difference between 24-week and two-year scores not statistically significant ($P = 0.942$).

§Matched-pairs difference between one-year and two-year scores not statistically significant ($P = 0.712$).

||Matched-pairs difference between 24-week and two-year scores not statistically significant ($P = 0.274$).

**Matched-pairs difference between one-year and two-year scores not statistically significant ($P = 0.843$).