

Functional Endoscopic Sinus Surgery Versus Balloon Sinuplasty with Ethmoidectomy: A 2-year Analysis in Pediatric Chronic Rhinosinusitis

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Abstract To evaluate the 2-year post-operative outcomes of pediatric patients with chronic rhinosinusitis (CRS) treated with balloon catheter sinuplasty (BCS) and ethmoidectomy compared to functional endoscopic sinus surgery (FESS). Two-group, retrospective cohort study of 28 children with CRS was performed. Of these 28 participants, 15 were treated with traditional FESS (53.6 %) and 13 (46.4 %) underwent traditional ethmoidectomy with balloon sinuplasty. Pre-operative and 2-year postoperative total symptom scores and medications were compared. To examine the potential long-term differences in surgical outcomes and surgical procedure on symptom outcome, one-tailed Chi square analyses were employed. The mean age of the children examined was 9.3 (SD = SD = 4.1; range 3–18) and 61.9 % were male. Pre-operative

symptomatology, medication and Lund Mackay scores were evaluated for both groups and no significant differences were identified. Overall, 73.3 % of children that underwent traditional FESS and 76.9 % of those who had BCS with ethmoidectomy reported significant long-term improvement in at least one of their pre-operative sinus complaints. Our data suggests that both BCS with ethmoidectomy and traditional FESS are effective treatment options for uncomplicated CRS and result in long-term alleviation of core sinus complaints, as well as decreased sinus related medication use. Larger prospective studies are needed to further evaluate these procedures.

Keywords Balloon catheter sinuplasty · Pediatric chronic rhinosinusitis · Functional endoscopic sinus surgery

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Introduction

Chronic rhinosinusitis (CRS) is a common medical condition that affects patient quality of life and can hinder social function significantly. Estimated to be the second most common chronic medical condition in the United States, CRS has a predicted prevalence rate of 12.5–15 % [1, 2]. Previous literature has demonstrated that functional endoscopic sinus surgery (FESS) is an effective treatment for patients suffering from CRS refractory to medical therapy [3]. Balloon catheter sinuplasty (BCS) has been demonstrated as safe and effective as FESS in the treatment of frontal sinus disease [4]. In addition, the authors have shown that BCS patients require less antibiotic therapy post operatively in short-term evaluation [5].

A comprehensive knowledge of their anatomical relationship to other structures is essential to understanding

their functional implications. Their continuity with the nasal cavity, middle ear space, and nasopharynx can link the paranasal sinuses as a source of bacterial or viral spread to contiguous areas [6]. Anatomical variations from patient to patient can make susceptible individuals more prone to upper respiratory bacterial or viral infections [7].

FESS involves the physical removal of diseased and obstructive sinus tissue with the intention to restore sinus function. In this study, FESS describes total ethmoidectomy together with maxillary antrostomy and uncinctomy and/or frontal sinusotomy. Theoretically, BCS allows a less traumatic approach by utilizing sinus ostia dilation to restore sinus function [8].

When directly compared, BCS has been reported to be as effective as traditional FESS in the treatment of adult CRS [9]. Additionally, BCS has been demonstrated to be more effective than adenoidectomy in the pediatric population [10]. However, there is a lack of research available to more accurately compare both BCS with ethmoidectomy and FESS in a long-term pediatric cohort population [11].

The current investigation is a 2-year post-operative analysis and is a follow-up study based on previously published literature by the author examining short-term post-operative sinus complaints [5]. Specific core symptoms such as facial pain, headaches, post-nasal drip, rhinorrhea, and congestion were examined in a retrospective fashion. The above specific symptoms, are described in the Otolaryngology Head & Neck Surgery 2007 clinical guidelines on adult sinusitis and have been used for the development of SN-5 (Sinus and Nasal quality of life survey) and SNOT-20 (Sino-Nasal Outcome Test) quality of life questionnaires [12–14].

Medication requirements including steroids and antibiotic frequency were also investigated. We hypothesized that the children who received BCS with ethmoidectomy would experience similar long-term symptomatology and medication requirements as those who underwent FESS alone.

Methods

The protocol summary was reviewed by the Detroit Medical Center Institutional Review Boards (IRB), which granted full approval for the collection and reporting of data in this study.

The charts and contact information of otherwise healthy children (ages 3–18) who underwent FESS or balloon sinuplasty with ethmoidectomy for persistent CRS, despite maximal medical therapy, were reviewed. All prospective subjects had to be free of other documented medical conditions prior to and following surgery with the exception of

complaints of seasonal allergies. For example, children with immunodeficiencies or mucociliary diseases like Kartagener's syndrome and cystic fibrosis were not included in this study. Additionally, eligibility for participation required that each possible subject had experienced intractable sinus symptoms, despite trials of nasal steroids, nasal saline, oral antihistamines, decongestants, and/or intravenous antibiotics and documented bilateral sinus disease on computed tomography (CT) scan with a Lund-Mackay score greater than 5. Any child with complicated rhinosinusitis as described by the 2007 Sinusitis guidelines, with sino-nasal polyps, hypoplastic sinuses or unilateral sinus disease were excluded [12]. To maintain the goal of examining these two different sinus surgery techniques, children who underwent intra-operative septoplasty, adenoidectomy, sinus irrigations and/or combined FESS and BCS treatments directed at the maxillary or frontal sinuses at the same time of the investigated procedure were excluded as well.

Pre-operative CT evidence of paranasal sinus disease was also recorded. All patients' had documented bilateral anterior and posterior ethmoidal disease along with bilateral maxillary and/or bilateral frontal disease on CT examination. Lund-Mackay scores were determined by 2-blinded pediatric radiologists in this study.

Charts of potential subjects were examined for demographic data, including age and gender. Reports of persistent complaints of facial pain, sinus congestion, post-nasal drip, rhinorrhea, headaches and low-grade fever related to sinus disease were also recorded in detail. These particular symptoms were only recorded as positive findings if they were (1) present for at least 6 h a day and (2) persisted for >90 days despite maximal medical therapy. The types and doses of oral antihistamines, nasal steroids, nasal saline and antibiotics used by the subject were also recorded. These data were analyzed for the pre-operative period, at 2–4 weeks and 4-months post-surgery as well as two or more years post-operatively. At discharge subject self-perceived symptom improvement data was also gathered.

Both pre- and post-operative total symptom scores were constructed (one point for each symptom meeting criteria) for the following complaints: facial pain, sinus congestion, post-nasal drip, rhinorrhea, headaches and low-grade fever. The scores were obtained at the 2–4 week, 4-month and 2-year post-operative periods. Success and improvement were defined as a decrease in the total complaint score of 1 or more points at the latter most data set. Total improvement was defined as resolution of all complaints (i.e. symptom score of 0).

Pre-operative data were obtained from clinic charts and operating room records from the Department of Pediatric Otolaryngology in association with procedures employed for our previous investigation of short-term efficacy of

BCS with ethmoidectomy vs traditional FESS in the treatment of CRS. [5] Subjects who met the aforementioned eligibility requirements were then contacted and scheduled for a long-term evaluation (i.e. >2 year follow-up). Upon evaluation, the presence or absence of individual sinus symptom complaints and medication use were recorded by an independent, blinded pediatric otolaryngologist. These data were then randomly assigned numbers to track type of surgical treatment, symptom improvements and long-term gains. Two-blinded otolaryngologists gathered and recorded the entire data set for each subject without access to each other's impressions. The results were interpreted to evaluate long-term efficacy of balloon sinuplasty with ethmoidectomy versus traditional FESS in the treatment of pediatric CRS.

Descriptive statistics including frequency distributions, measures of central tendency (mean, median, mode), and dispersion were conducted on all study variables. Independent sample t-tests were performed on pre-operative data to identify differences in total symptom score by gender and prior adenoidectomy. Pearson correlation coefficient evaluated the relation between age of child and total symptom score. Individual t-tests and Chi square analysis were utilized to examine pre-surgical differences in symptoms and Lund-Mackay scores by procedure type. To examine the potential long-term differences in surgical outcome by procedure, one-tailed Chi square analyses were employed. A one-tailed test was performed as the direction of the effect was identified a priori.

Results

Of the original 31 patients identified, 28 were available for 2-year post-operative evaluation. Of these 28 participants, 15 were treated with traditional FESS (53.6 %) and 13 (46.4 %) underwent traditional ethmoidectomy with balloon sinuplasty. The mean age of the children examined was 9.3 (SD = 4.1; range 3–18) and 60.7 % were male. Pre-operative symptomatology, medication and Lund Mackay scores were evaluated for both groups and no significant differences were identified (Table 1).

A total of 74 maxillary and/or frontal sinuses underwent surgical intervention along with total ethmoidectomy (BCS = 34; FESS = 40) (Fig. 1). BCS was performed on 26 maxillary and 8 frontal sinuses, all were performed with uncinete sparing technique. Thirty maxillary and 10 frontal sinuses were addressed using traditional maxillary antrostomy with uncinectomy and Draf I/IIA frontal sinusotomy surgical techniques. Individuals without developed frontal sinuses or disease did not receive frontal surgery.

When analyzing pre-operative mean symptom scores and post-operative short and long-term reports of symptom

Table 1 Patient characteristic, symptoms (averages and total individual number) and medication use by surgical group pre-operatively

	Mean or %		t or χ^2	p
	FESS	Balloon		
Child age	9.3	9.5	-0.12	0.45
Gender (% male)	66.7 %	53.8 %	0.48	0.24
Adenoidectomy (% yes)	26.7 %	53.8 %	1.68	0.07
Lund-Mackay total score	9.7	11.5	-0.97	0.17
Symptoms				
Facial pain	20.0 %	53.8 %	3.48	0.03
Sinus congestion	53.3 %	53.8 %	0.00	0.49
Post nasal drip	66.7 %	38.5 %	2.23	0.07
Rhinorrhea	66.7 %	53.8 %	0.48	0.24
Headache	53.3 %	46.4 %	1.45	0.11
Low grade fever	13.3 %	0.0 %	1.87	0.09
Total	4.5	4.7	-0.33	0.37
Antibiotics (total)	0.9	1.5	-1.27	0.11
Allergy medications (total)	0.5	0.8	-1.00	0.16
Nasal steroid spray (total)	0.7	1.1	-2.35	0.01

relief, total number of complaints on average improved in both groups throughout the post-operative period (Fig. 2).

As demonstrated in Table 2, at 2-year follow-up, both groups reported improvements in all examination categories regardless of procedure. These improvements were defined as symptoms being absent and/or not affecting daily life when compared to pre-operational complaint. Overall, 73.3 % of children that underwent traditional FESS and 76.9 % of those who had BCS with ethmoidectomy reported significant long-term improvement in at least one of their pre-operative sinus complaints. Patient's who underwent FESS did report a significant improvement with headache relief when compared to BCS with ethmoidectomy. While, both groups reported a similar antibiotic use long-term. While 69.2 % of those who underwent BCS with ethmoidectomy and 92.3 % who underwent traditional FESS reported a generalized self-perceived improvement ($\chi^2 = 2.23$; $p = 0.07$).

The two groups are further illustrated in Fig. 3a, b and demonstrate similar long-term outcomes. Nine people who underwent traditional FESS and 6 BCS patients had total improvement of their sinus complaints. One FESS patient and 4 BCS patients reported the absence of at least 1 pre-operative symptom, while both groups had 2 individuals that reported no improvement of the symptoms measured. One patient from the BCS and 2 from the FESS group complained of additional sinus symptoms long-term after surgery. With the one patient whom underwent BCS originally, undergoing traditional FESS revision and still having worsening of symptoms.

Fig. 1 Breakdown of patients’ treated with either BCS + Ethmoidectomy or Traditional FESS and associated paranasal sinuses that were addressed

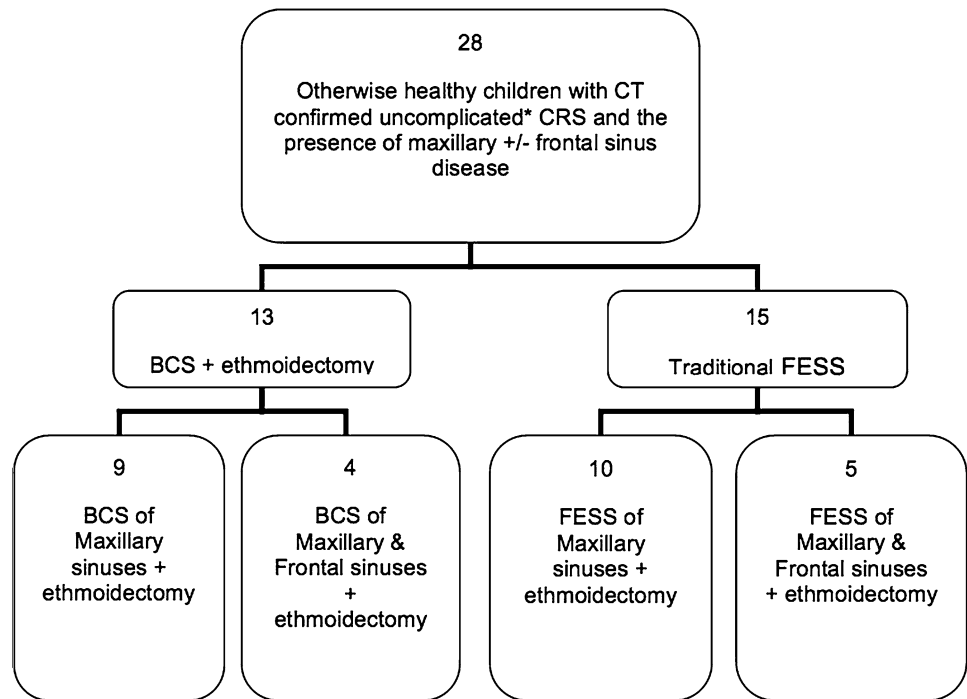
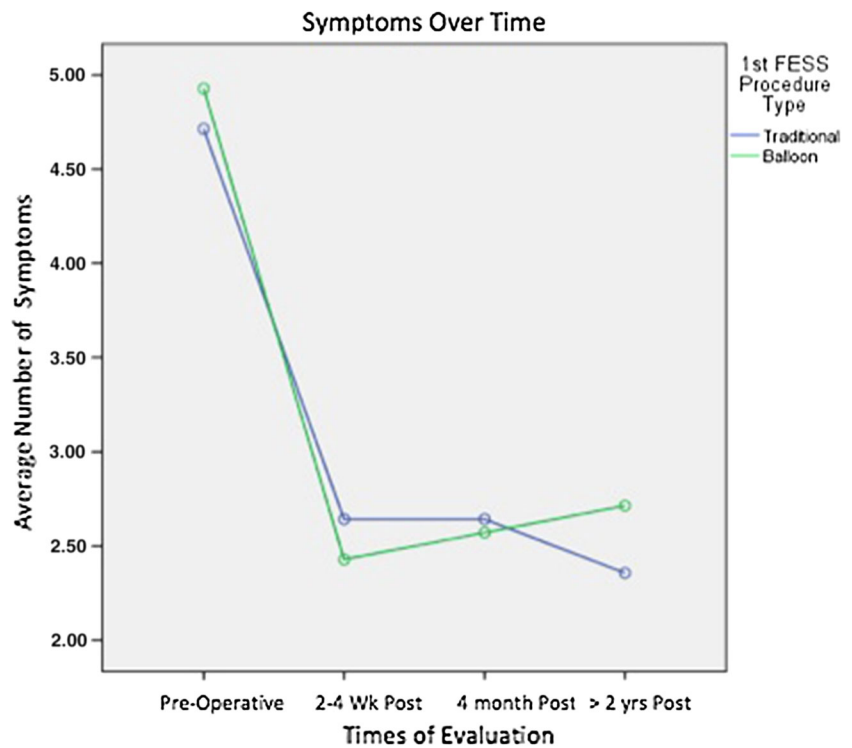


Fig. 2 Examination of symptoms mean over time. Preoperative (BCS: mean = 4.92, SD = 1.27; FESS: mean = 4.71, SD = 2.23); 2–4 week postoperative (BCS: mean = 2.42, SD = 1.40; FESS: mean = 2.64, SD = 1.33); 4-months postoperative (BCS: mean = 2.57, SD = 1.65; FESS: mean = 2.64, SD = 1.78); >2 years postoperative (BCS: mean 2.71, SD = 1.85; FESS: mean = 2.35, SD = 2.16)



Discussion

The surgical management of pediatric CRS has traditionally been viewed as a last resort, and has been limited thus far to adenoidectomy and traditional FESS procedures [11]. In recent years BCS technology has been added as a

potentially less traumatic and mucosal sparing option for the treatment of CRS; numerous studies have demonstrated this alternative to be safe in both adults and children [15–17]. While data has been published comparing BCS to adenoidectomy in pediatric CRS treatment, investigations comparing BCS with ethmoidectomy to FESS has been

Table 2 Percentages of patients reporting improvement in sinus symptoms at >2 years post-operatively as well as medication use

	% Improvement		χ^2
	FESS	Balloon	
<i>Symptoms Overall Complaints</i>			
>2 year Post-Surgical	73.3 %	76.9 %	0.05
<i>Individual Complaints</i>			
<i>Facial Pain</i>			
>2 year Post-Surgical	100 %	85.7 %	0.01
<i>Sinus Congestion</i>			
>2 year Post-Surgical	75.0 %	28.6 %	1.69
<i>Post Nasal Drip</i>			
>2 year Post-Surgical	70.0 %	80.0 %	0.53
<i>Rhinorrhea</i>			
>2 year Post-Surgical	80.0 %	71.4 %	0.11
<i>Headaches</i>			
>2 year Post-Surgical	75.0 %	50.0 %	3.43*
<i>Low Grade Fever</i>			
>2 year Post-Surgical	100 %	0.0 %	0.08
<i>Antibiotic Use</i>			
>2 year Post-Surgical	28.5 %	35.3 %	0.29
<i>Allergy Medication Use</i>			
>2 year Post-Surgical	37.5 %	37.5 %	–
<i>Nasal Steroid Spray Use</i>			
>2 year Post-Surgical	72.7 %	46.6 %	0.10

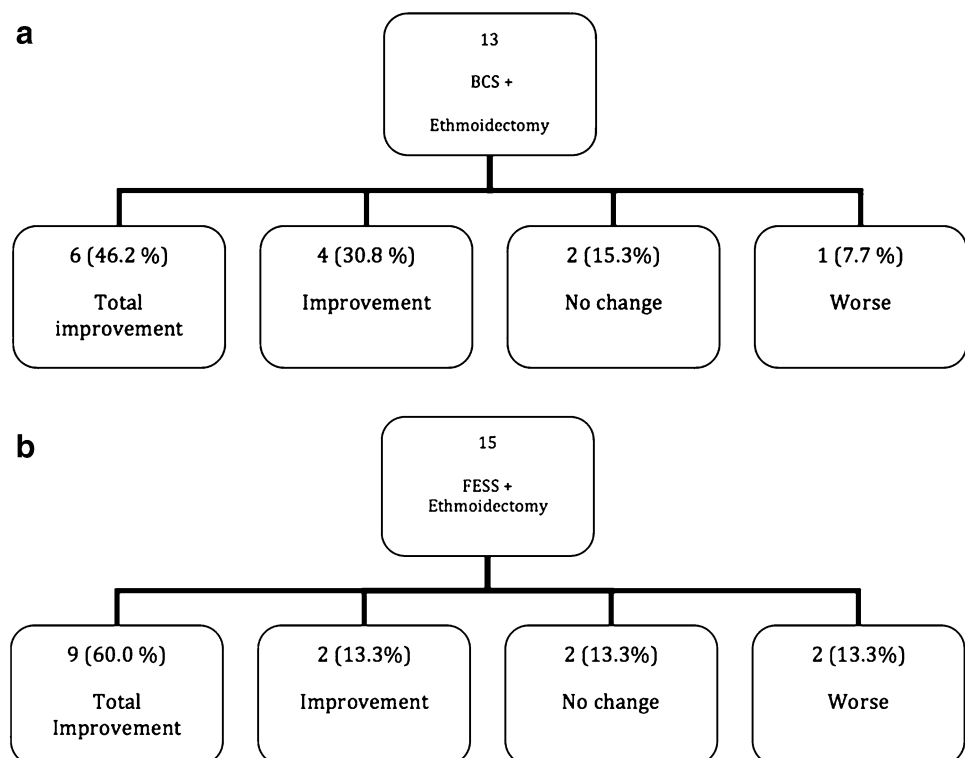
* $p < 0.05$, ** $p < 0.01$, One-tail tests

sparse [5, 10]. Moreover, long-term data examining these two techniques in a side-by-side comparison has not been reported [11].

The goal of our previous study was to examine the efficacy of both traditional FESS and BCS with ethmoidectomy as treatment options for pediatric CRS in otherwise healthy children refractory to maximal medical management [5]. In the previous study 62.5 % of those who underwent traditional FESS and 80.0 % of who submitted to BCS with ethmoidectomy experienced significant improvements in sinus symptoms at >4 months post respective procedure [5]. Whereas these results demonstrated the effectiveness of both procedures in short term sinus treatment, long-term evaluation is needed. The current investigation sought to re-evaluate the same patient population at >2 years post sinus surgery, examining and comparing the long-term effectiveness of traditional FESS to BCS with ethmoidectomy.

In the treatment of adult CRS, the long-term efficacy of BCS alone and with ethmoidectomy in the reduction of sinus related complaints has been documented [15]. Recently, Weiss et al. surveyed 61 adults who underwent BCS or BCS with ethmoidectomy using Sino-nasal Outcome Test (SNOT) 20 questionnaires and at 2 years post-procedure 84 % reported improvement of their symptoms [18]. In a retrospective analysis of 73 children and adolescents with CRS, Seidek et al. reported that 77 % reported improvement at long-term evaluation [19]. Results of the

Fig. 3 a Overall percentage of patients who underwent BCS with ethmoidectomy reporting the absence of all previous symptoms (*Total Improvement*), absence of at least one pre-operative complaint (*Improvement*), presence of same pre-operative complaint (*No change*) or presence of new sinus symptoms (*Worse*) at >2 year post-operative visit. **b** Patients who underwent FESS reporting the absence of all previous symptoms (*Total Improvement*), absence of at least one pre-operative complaint (*Improvement*), presence of same pre-operative complaint (*No Change*) or presence of new sinus symptoms (*Worse*) at >2 year post-operative visit



current study are closely aligned with such findings wherein 76.9 % of children who underwent BCS with ethmoidectomy and 73.3 % of those treated with traditional FESS experienced improvement of at least one symptom post-operatively (Table 2). Furthermore, both of our study groups reported overall decreases in individual symptoms and medication use when compared to pre-operative data (Table 2) and on average these improvements were demonstrated in short-term examination as well (Fig. 2). Our data further corroborated the existing database that both BCS with ethmoidectomy and traditional FESS are effective long-term treatment options for CRS.

Interestingly, 92.3 % of those who underwent traditional FESS and 69.2 % of those who underwent BCS with ethmoidectomy reported a generalized self-perceived improvement. This may be due to still present symptoms not meeting our criteria for reporting or other sinus complaints not evaluated by this study having a compounding affect.

To our knowledge, this investigation is the first to examine long-term outcome differences between BCS with ethmoidectomy and traditional FESS in the pediatric population. The subjects were selected from our previous set of subjects; both groups were similar pre-operatively, underwent bilateral surgical treatment for bilateral disease, and met strict inclusion criteria for participation (Table 1) [5].

The methods employed in this study were not without limitations. The strict inclusion criteria and the long follow-up time both contributed to a small sample population. Although the symptoms evaluated were not completed in a validated format, all symptoms investigated were described in proven tools such as the SN-5, SNOT-21 and the adult sinusitis clinical practice guidelines. The data on antibiotic use both pre and post-surgery did add a level of objective measurement to this study. The sample examined represented a well-organized, homogenous pre-operative population with uncomplicated CRS refractory to maximal medical therapy that underwent either BCS with ethmoidectomy or FESS (Table 1). This allowed for a comparison of the instrumentation and technique focused directly at the frontal and maxillary sinuses while providing control for bias secondary to severity of disease, patient characteristics and surgical selection.

Conclusion

Surgical treatment as an option for pediatric CRS is relatively controversial and generally only utilized as a last resort for those refractory to maximal medical management [20]. Both BCS with ethmoidectomy and traditional FESS have been utilized for these populations and currently there is a paucity of long-term data analyzing the utility of these

techniques alone or comparatively. Results of the current investigation suggest that both BCS with ethmoidectomy and traditional FESS are effective treatment options for uncomplicated CRS. They each may result in long-term alleviation of core sinus complaints, as well as decreased sinus-related medication use. Furthermore, with healthcare cost becoming an ever-growing concern, both techniques should be investigated for cost-effectiveness in future studies while larger prospective studies are needed for more comprehensive analyses of treatment outcomes.

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References

1. Adams PF, Hendershot GE, Marano MA (1996) Current estimates from the National Health Interview Survey, 1996. *Vital Health Stat 10* 1999:1–203. Data from the National Health Survey
2. Collins JG (1997) Prevalence of selected chronic conditions: United States, 1990–1992. *Vital Health Stat 10* 194:1–89 Data from the National Health Survey
3. Humayun MP, Alam MM, Ahmed S, Salam S, Tarafder KH, Biswas AK (2013) Comparative study of outcome of the endoscopic sinus surgery and conventional surgery for nasal polypsis. *Mymensingh Med J* 22:84–92
4. Plaza G, Eisenberg G, Montojo J, Onrubia T, Urbasos M, O'Connor C (2011) Balloon dilation of the frontal recess: a randomized clinical trial. *Ann Otol Rhinol Laryngol* 120:511–518
5. Thottam PJ, Hauptert M, Saraiya S, Dworkin J, Sirigiri R, Belenky WM (2012) Functional endoscopic sinus surgery (FESS) alone versus balloon catheter sinuplasty (BCS) and ethmoidectomy: a comparative outcome analysis in pediatric chronic rhinosinusitis. *Int J Pediatr Otorhinolaryngol* 76:1355–1360
6. Hengerer AS (1984) Surgical anatomy of the paranasal sinuses. *Ear Nose Throat J* 63:137–143
7. Laine FJ, Smoker WR (1992) The ostiomeatal unit and endoscopic surgery: anatomy, variations, and imaging findings in inflammatory diseases. *AJR Am J Roentgenol* 159:849–857
8. Catalano PJ (2013) Balloon dilation technology: let the truth be told. *Curr Allergy Asthma Rep* 13:250–254
9. Achar P, Duvvi S, Kumar BN (2012) Endoscopic dilatation sinus surgery (FEDS) versus functional endoscopic sinus surgery (FESS) for treatment of chronic rhinosinusitis: a pilot study. *Acta otorhinolaryngol Ital* 32:314–319
10. Ramadan HH, Terrell AM (2010) Balloon catheter sinuplasty and adenoidectomy in children with chronic rhinosinusitis. *Ann Otol Rhinol Laryngol* 119:578–582

11. Sedaghat AR, Cunningham MJ (2011) Does balloon catheter sinuplasty have a role in the surgical management of pediatric sinus disease? *Laryngoscope* 121:2053–2054
12. Rosenfeld RM, Andes D, Bhattacharyya N et al (2007) Clinical practice guideline: adult sinusitis. *Otolaryngol Head Neck Surg* 137:S1–31
13. Kay DJ, Rosenfeld RM (2003) Quality of life for children with persistent sinonasal symptoms. *Otolaryngol Head Neck Surg* 128:17–26
14. Browne JP, Hopkins C, Slack R, Cano SJ (2007) The Sino-Nasal Outcome Test (SNOT): can we make it more clinically meaningful? *Otolaryngology–head and neck surgery : official journal of American Academy of Otolaryngology-Head and Neck Surgery* 136:736–741
15. Bolger WE, Brown CL, Church CA et al (2007) Safety and outcomes of balloon catheter sinusotomy: a multicenter 24-week analysis in 115 patients. *Otolaryngology–head and neck surgery : official journal of American Academy of Otolaryngology-Head and Neck Surgery* 137:10–20
16. Kutluhan A, Bozdemir K, Cetin H et al (2009) Endoscopic balloon dilation sinuplasty including ethmoidal air cells in chronic rhinosinusitis. *Ann Otol Rhinol Laryngol* 118:881–886
17. Ramadan HH (2009) Safety and feasibility of balloon sinuplasty for treatment of chronic rhinosinusitis in children. *Ann Otol Rhinol Laryngol* 118:161–165
18. Weiss RL, Church CA, Kuhn FA, Levine HL, Sillers MJ, Vaughan WC (2008) Long-term outcome analysis of balloon catheter sinusotomy: two-year follow-up. *Otolaryngol Head Neck Surg* 139:S38–S46
19. Siedek V, Stelter K, Betz CS, Berghaus A, Leunig A (2009) Functional endoscopic sinus surgery—a retrospective analysis of 115 children and adolescents with chronic rhinosinusitis. *Int J Pediatr Otorhinolaryngol* 73:741–745
20. Clinical practice guideline (2001) Management of sinusitis. *Pediatrics* 108:798–808