International Journal of Pediatric Otorhinolaryngology 76 (2012) 1355–1360

Contents lists available at SciVerse ScienceDirect

International Journal of Pediatric Otorhinolaryngology

journal homepage: www.elsevier.com/locate/ijporl

Functional endoscopic sinus surgery (FESS) alone versus balloon catheter sinuplasty (BCS) and ethmoidectomy: A comparative outcome analysis in pediatric chronic rhinosinusitis☆

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ARTICLE INFO

Article history:
Received 24 March 2012
Received in revised form 11 June 2012
Accepted 15 June 2012
Available online 6 July 2012

Keywords:
Pediatric
Balloon sinuplasty
Balloon catheter sinuplasty
BCS
Sinusitis
Sinus disease
Sinus surgery
Chronic sinusitis
Chronic rhinosinusitis
Pediatric chronic rhinosinusitis
FESS
Functional endoscopic sinus surgery

ABSTRACT

Objective: To evaluate whether the addition of BCS (balloon catheter sinuplasty) would improve the treatment outcome in children with chronic rhinosinusitis (CRS) compared to FESS (functional endoscopic sinus surgery).
Study design: Two-group, retrospective cohort with blinded chart review comparison.
Setting: Children's Hospital of Michigan, Detroit, MI.
Subjects and methods: Chart review of 15 pediatric patients who underwent BCS with ethmoidectomy and 16 who underwent FESS from 2008 to 2011 for treatment of CRS in a tertiary care, university affiliated, pediatric institution. Pre-operative CT-scans as well as pre and post-operative sinus symptoms and medications were compared. Post-surgical outcome was examined using chi square analysis.
Results: Mean age of children at the time of the procedure was 9.3 (SD = 4.19; range = 3–17). Both groups had similar pre-surgical Lund–Mackay CT CRS scores (FESS: mean = 9.33 and $t = 0.67$; balloon: mean = 10.58, $t = 0.68$, and $p = 0.51$). Analyses identified significant post-treatment reductions in overall symptoms and needed interventions in both treatment groups. Side-by-side post-operative comparison of patients who underwent balloon sinuplasty to FESS demonstrated statistically significant post-operative difference between the two groups in antibiotic requirement, sinus congestion and headaches. Though not statistically significant, 62.5% of FESS patients and 80.0% of BCS patients ($\chi^2 = 1.15$) reported improvement in their overall sinus symptoms post-operatively.
Conclusion: Both BCS and FESS are suitable treatments for CRS in children. Both treatments significantly reduced CRS complaints post-operatively and had similar overall results. BCS patients required significantly fewer antibiotics post-operatively for CRS related disease when compared to FESS. Larger prospective studies with long-term data are needed to further evaluate.

1. Introduction

Chronic rhinosinusitis (CRS) is a common disease afflicting both adults and children. Approximately 15% of the population in the United States suffer from this condition, and more than five billion dollars per year is spent treating this disease [1]. For children with CRS refractory to medical treatment, conventional functional endoscopic sinus surgery (FESS) is an effective treatment, but associated morbidities, complications and results are variable. There has been recent inquiry regarding whether the addition of balloon catheter sinuplasty (BCS) techniques would significantly improve the treatment outcome in children who undergo surgery for CRS [2]. Preliminary reports suggest that when FESS is combined with balloon dilation, initial symptoms of facial pain, sinus congestion, post-nasal-drip, rhinorrhea and headaches are substantially less severe [3]. This treatment outcome has not been extensively corroborated in the scientific literature. Moreover, there is a paucity of research investigation comparing combined BCS + ethmoidectomy versus FESS alone, relative to overall treatment outcomes in a cohort pediatric sample population.

☆ Research results were presented as an oral presentation on September 13, 2011 in the Rhinology section at AAO-HNS Annual Meeting in San Francisco, CA.

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http://dx.doi.org/10.1016/j.ijporl.2012.06.006

The paranasal sinuses (frontal, ethmoid, maxillary and sphenoid) are mucosa-lined compartments that are physically contiguous with the nasal cavity [4]. The exact function of the paranasal sinuses is unknown, but it has been theorized that they assist in moistening and humidifying ambient air, act as resonant chambers for voice, and serve to dampen and protect the brain from trauma [4]. The anatomical continuity of the sinuses with the nasal cavity, nasopharynx, and middle ear space helps explain the propensity of bacterial and viral spread to and from these interconnected structures [5]. CRS due to infectious processes or gross anatomical abnormalities adversely affects normal drainage and cavity aeration [6].

The FESS procedure works by physically removing, altering and opening sinus air cells or drainage pathways to create greater continuity, mucous flow and sinus aeration. For this study, traditional FESS will be used to describe total ethmoidectomy together with maxillary antrostomy with uncinectomy and/or frontal sinusotomy. Theoretically, BCS is a less traumatic procedure that works directly on the natural openings of the various sinuses. This technique involves the placement of a balloon tipped catheter into the openings of the sinus followed by balloon inflation. The natural ostia are radially widened as a consequence. At our institution, BCS is used to treat the maxillary and frontal sinus ostia in combination with traditional FESS ethmoidectomy.

Whereas FESS and BCS have each been separately investigated in children with intractable CRS, the efficacy of combining the two techniques for synergistic treatment effects and individual comparative outcomes has not been extensively studied [1,3,7]. Both FESS and BCS have shown to be more effective then adenoidectomy, and other known treatments for pediatric CRS [1,7,8]. Furthermore, when compared to FESS, BCS has been shown to result in fewer complications in both children and adults with CRS (0.01% per patient) [3,9].

The current investigation was designed to examine otherwise healthy children who were treated for CRS with FESS alone or BCS with ethmoidectomy. Improvements in core presenting sinus symptoms of facial pain, post-nasal-drip, rhinorrhea, headaches and sinus congestion were examined in detail. These specific symptoms, along with other complaints, have been 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-21 (Sino-Nasal Outcome Test) quality of life questionnaires [10–12]. Use of antibiotics and topical nasal steroids prior to, and following surgery was also investigated for comparative purposes, as were overall complication factors and rates associated with each surgical approach. We hypothesized that children who underwent combined BCS and ethmoidectomy would experience similar outcomes relative to sinus symptoms, medication requirements, and complications post-operatively to those who submitted to FESS alone.

2. Methods and materials

2.1. Subjects

The charts of 106 patients (ages 3–17) with the diagnosis of CRS and who underwent sinus surgery were reviewed from the clinical database within the department of pediatric otolaryngology at The Children's Hospital of Michigan from 2008 to 2011. From this database, children diagnosed with craniofacial abnormalities, immunodeficiency disorders, or mucociliary diseases were excluded from this study. Furthermore, any child with complicated rhinosinusitis as described by the 2007 Sinusitis guidelines, with sino-nasal polyps or unilateral sinus disease were excluded [10]. In order to maintain the goal of examining these two different sinus surgery techniques, children who underwent intra-operative sinus irrigations and/or combined FESS and BCS treatments directed at the maxillary or frontal sinuses were excluded as well.

From this pool, 31 children in whom CRS persisted despite standard maximal medical therapy met the inclusion criteria for this investigation [5]. All subjects had no other documented medical conditions, besides complaints of seasonal allergies. These children had two or more symptoms related to sinus disease preoperatively despite trials of nasal steroids, nasal saline, oral antihistamines, decongestants, oral antibiotic and sometimes IV antibiotic therapy. These individuals experienced intractable symptoms for at least 90 days. 13 children (8 BCS; 5 FESS) did undergo adenoidectomy at a previous date for obstructive sleep apnea ± rhinitis symptoms, but were still having persistent CRS complaints. For these specific children, traditional FESS or BCS with ethmoidectomy were employed, with no patients receiving adenoidectomy at the time of surgery. Each subject had to have completed at least pre-surgical, and final post-surgical examinations.

2.2. Measures

Charts were examined for various demographic data points including age and gender. Charts were also assessed for CRS diagnosis with minimal improvement despite standard maximal medical therapy, history of previous sinus surgery. Patient's charts were examined for reports of cough, headache, rhinorrhea, facial pain, postnasal drip, and/or congestion refractory to medical therapy and affecting daily life. All sinus symptoms and medical therapy were assessed pre-, 2–4 weeks post- and final post-surgical exam (>4 months, average of 37 weeks). CT evidence of paranasal sinus disease was obtained and a Lund–Mackay score was completed for each subject pre-operatively.

2.2.1. Surgical outcomes

A total symptom score was constructed (1 point for each symptom if reported as being present for at least 6 h a day and affecting daily life and no points if symptom did not affect daily life or was absent) for the number of complaints pre-surgery, post-surgery, and at the final post-surgical exam for the following: facial pain, sinus congestion, post nasal drip, rhinorrhea, headache, and low-grade fever. Success and improvement were defined as a decrease in the total complaint score of 1 or more points at last visit. While total improvement was defined as total resolution of all complaints (i.e., symptom score of 0).

All data were obtained from clinic charts and operating room records of patients cared for by four board certified pediatric otolaryngologists and three pediatric radiologists. Charts reviewed were randomly assigned a number regardless of treatment process. Each chart was appraised for history of sinus complaints, clinical and laboratory examinations conducted, treatments rendered both pharmacologically and surgically, and outcomes obtained. Data for each subject were independently coded on a standardized record form by two separate blinded otolaryngologists to control for inter-rater reliability level of agreement. In the final analysis, inter rater reliability for the entire study population was 90%. No patients of the above mentioned coding physicians' were used in this study to control for bias.

2.3. Design and data analysis

The investigation employed a two-group, retrospective cohort, blinded chart review methodology. Descriptive statistics including frequency distributions, measures of central tendency (mean, median, and mode), and dispersion were conducted on all study variables. To examine pre-surgical differences between groups, independent *t*-tests and chi square analyses were employed. To