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Safety of endoscopic sinus surgery in children with cystic fibrosis

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ABSTRACT

Introduction: Data on the safety of endoscopic sinus surgery (ESS) are limited in children with cystic fibrosis (CF). We used a multi-institutional surgical registry to examine ESS outcomes in children with CF.
Methods: The 2014–2015 American College of Surgeons' National Surgical Quality Improvement Program-Pediatric database was queried for patients age <18 years undergoing elective ESS. Prolonged hospital stay (>1 day), 30-day readmission, and 30-day unplanned reoperation were compared according to presence of CF diagnosis.
Results: The data included 213 children with CF (age 10 ± 5 years, 105/108 male/female) and 821 children without CF (age 10 ± 5 years, 504/317 male/female). CF patients were more likely than non-CF patients to require prolonged hospital stay (30% vs. 9%, $p < 0.001$), yet had similar rates of readmission (6% vs. 4%; $p = 0.189$) and reoperation (0 vs. 1%; $p = 0.133$). All readmissions but one among CF patients were unrelated to ESS. In the non-CF cohort, reasons for ESS-related readmissions included recurrence of sinusitis, postoperative pain, and bleeding.
Conclusions: We demonstrate the safety of ESS in the largest cohort of children with CF reviewed to date. Multi-institutional review of ESS safety may contribute to monitoring expansion of this intervention in children with CF.

1. Introduction

Chronic sinusitis is endemic in patients with cystic fibrosis (CF), an autosomal recessive disorder that impairs mucociliary clearance. Upwards of 90% of CF patients are reported to have sinus disease [1]. Endoscopic sinus surgery (ESS) is used to treat chronic sinusitis in patients with CF after exhausting medical management approaches [2]. The benefits of ESS in CF include improvements in subjective symptoms of sinusitis and self-reported quality of life [3–6]. Furthermore, improvements in pulmonary function test (PFT) performance and reduction in the need for inpatient hospitalization have been reported in some studies evaluating this surgical intervention [3–5]. Yet, the decision to perform ESS is controversial, due to inevitable progression of mucosal disease and the frequent need for surgical revision [2]. Particularly, high variability is seen in rates of sinus surgery among children with CF. Across pediatric hospitals with accredited CF care centers, rates of sinus surgery during inpatient encounters ranged from 1% to 24% [7]. With the initial ESS intervention typically delayed until young adulthood among patients with CF, the decision to perform ESS during childhood must weigh the expected benefits of this procedure against potential risks. Prior reviews have described ESS as generally safe [3,5], but noted the possibility of major complications, including hemorrhage, orbital injury, and brain injury [2]. Existing literature on the safety of ESS in CF is primarily limited to adult studies [3,4], or does not differentiate between adult and pediatric outcomes [1]. Therefore, the risk of pursuing surgical

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; CF, cystic fibrosis; CI, confidence interval; CPT, Current Procedural Terminology; ESS, endoscopic sinus surgery; NSQIP-Peds, National Surgical Quality Improvement Program – Pediatric; OR, odds ratio; PFT, pulmonary function test; PUF, participant use file.

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management of sinus disease in children with CF is unclear. We used a multi-institutional database to compare 30-day outcomes (prolonged hospital stay, readmission, unplanned reoperation) in children with CF and children without CF undergoing elective ESS.

2. Materials and methods

The study was deemed exempt from review by the local Institutional Review Board. The de-identified 2014 and 2015 Participant Use Files (PUFs) were obtained from the American College of Surgeons' National Surgical Quality Improvement Program – Pediatric (NSQIP-Peds) quality improvement database [8]. Primary data collection in the NSQIP-Peds has been previously described [9,10]. Briefly, participating hospitals performed systematic sampling of surgical cases involving patients age <18 years according to Current Procedural Terminology (CPT) codes. Trained raters extracted demographic, surgical, and postoperative data, and records were de-identified prior to dissemination in the PUF. For the present study, patients were evaluated for inclusion if they had undergone elective ESS (CPT codes 31254–31256, 31267, 31287). Exclusion criteria were lack of information on history of CF (due to this variable being discontinued in July 2015) [10], and a history of prior solid organ transplantation. In the primary analysis, patients were stratified according to whether they had a history of CF (marked by raters in a discrete variable).

Data for the primary outcomes in this study were coded by NSQIP-Peds raters and covered a 30-day follow-up period. Hospital length of stay was recorded as days between the dates of admission and discharge. Hospital stays >1 day were considered prolonged in this analysis. Raters recorded hospital readmissions and unplanned reoperations within 30 days of the index surgical procedure. Categorical data were summarized as counts with percentages, and compared between groups using Chi-square tests or Fisher's exact tests for rare events (cell sizes <5 cases). Continuous data were summarized as means with standard deviations, and compared among groups using unpaired t-tests. Multivariable logistic regression was used to compare outcomes between CF and non-CF groups while accounting for observed confounding characteristics. A forward selection algorithm was used to include covariates which were associated with each outcome a $p < 0.2$. Covariates evaluated for inclusion were age (years), gender, race/ethnicity (non-Hispanic White vs. all others), weight status (determined according to body mass index [BMI] for age; normal weight: <85th percentile; overweight: ≥85th percentile), American Society of Anesthesiologists (ASA) physical classification (1–2 vs. 3–4), presence of any neuromuscular comorbidities or cardiac risk factors, as determined by NSQIP-Peds raters [10], primary surgical procedure (ethmoidectomy, CPT codes 31254, 31255; maxillary antrostomy, CPT codes 31256, 31267; or sphenoidotomy, CPT code 31287), operative time, and whether polypectomy was performed in addition to ESS. Due to the rarity of underweight (<5th BMI-for-age percentile; <1% of the CF group and <4% of the non-CF group), this category was combined with normal weight for analysis. Cases with missing data on covariates were excluded from multivariable analysis. Analyses were performed in Stata/13.1 IC (College Station, TX: StataCorp LP), and two-tailed $p < 0.05$ was considered statistically significant.

3. Results

The 2014–2015 NSQIP-Peds PUFs contained data on 1481 children undergoing elective ESS. After excluding 440 patients for whom history of CF was not ascertained, and 7 patients who had received a solid organ transplant, there remained 213 patients with CF (age 10 ± 5 years, 105/108 male/female) and 821 patients without CF (age 10 ± 5 years, 504/317 male/female) in the analytic sample. The characteristics of the CF and non-CF cohorts are compared in Table 1. CF patients were assigned higher ASA classification, had lower body mass for age, and were more likely to undergo ethmoidectomy rather than maxillary antrostomy. Polypectomy was recorded as a separate procedure for 11 (5%) patients with CF. Although CF patients were significantly more likely than non-CF patients to require prolonged hospital stay during the index admission (30% vs. 9%, $p < 0.001$), there were no significant differences between the CF and non-CF cohorts in readmission (6% in CF vs. 4% in non-CF; $p = 0.189$) or unplanned reoperation (none in CF, 1% in non-CF; 0.133).

The most common reason for readmission among CF patients was pulmonary exacerbation, and one CF patient was readmitted for recurring sinusitis. No other readmissions in the CF cohort were deemed related to ESS. In the non-CF cohort, reasons for ESS-related readmissions included recurrence of sinusitis, postoperative pain, and bleeding. To further examine differences between CF and non-CF patients in prolonged hospital stay, a multivariable logit model was constructed for this outcome, using forward stepwise selection of covariates described above. The model was limited to 925 cases with complete data on study variables. After multivariable adjustment, CF patients remained more likely to require prolonged hospitalization (OR = 2.8; 95% CI: 1.8, 4.4; $p < 0.001$) compared to children without CF undergoing elective ESS (Table 2). Other factors predicting prolonged hospitalization in the multivariable model included ASA status ≥3 and prolonged operative time.

4. Discussion

ESS is often performed in patients with CF to alleviate chronic sinusitis [1–4]. Yet, the persistence of underlying CF disease (and,

Table 1
Characteristics and 30-day outcomes of children undergoing elective endoscopic sinus surgery, according to history of cystic fibrosis (n = 1034).

Variable	Missing data (n)	Non-CF (n = 821)	CF (n = 213)	P[a]
		N (%) or mean (SD)	N (%) or mean (SD)	
Age (years)	0	9.6 (4.6)	10.4 (4.7)	0.025
Male	0	504 (61%)	105 (49%)	0.001
Non-Hispanic White[b]	0	552 (67%)	194 (91%)	<0.001
Weight status	139			<0.001
Normal weight		432 (60%)	160 (79%)	
Overweight		290 (40%)	43 (21%)	
ASA physical classification	0			<0.001
1-2		660 (80%)	70 (33%)	
3-4		161 (20%)	143 (67%)	
Neuromuscular comorbidity	0	19 (2%)	2 (1%)	0.280
Cardiac risk factors present	0	47 (6%)	4 (2%)	0.020
Surgical procedure	0			0.001
Ethmoidectomy		430 (52%)	141 (66%)	
Maxillary antrostomy		368 (45%)	65 (31%)	
Sphenoidotomy		23 (3%)	7 (3%)	
Operative time (m)	0	83 (60)	97 (51)	0.003
Polypectomy performed	0	28 (3%)	11 (5%)	0.231
Surgical outcomes[c]				
Hospital stay >1 day	0	72 (9%)	63 (30%)	<0.001
Readmission	0	33 (4%)	13 (6%)	0.189
Unplanned reoperation	0	11 (1%)	0	0.133

ASA = American Society of Anesthesiologists; CF = cystic fibrosis; SD = standard deviation.

[a] P-values calculated by unpaired *t*-test for continuous variables, Chi-square test for categorical variables, or Fisher's exact test for categorical variables with one or more cells including <5 cases.

[b] Comparison group includes all other race/ethnicity categories.

[c] Assessed within 30 days of the index procedure.