

## Complication Rates After Functional Endoscopic Sinus Surgery: Analysis of 50,734 Japanese Patients

Sayaka Suzuki, MD; Hideo Yasunaga, MD, PhD; Hiroki Matsui, MPH; Kiyohide Fushimi, MD, PhD;  
Kenji Kondo, MD, PhD; Tatsuya Yamasoba, MD, PhD

**Objective:** The complication rates associated with different types of functional endoscopic sinus surgery (FESS) remain to be fully examined.

**Study Design:** Retrospective cohort study.

**Methods:** We extracted data from the Japanese Diagnosis Procedure Combination database on 50,734 patients (aged  $\geq 16$  years) who underwent FESS for chronic rhinosinusitis between 2007 and 2013. We focused on specific types of surgery and stratified the patients into three groups: group 1 (single sinus surgery), group 2 (multiple sinus surgery), and group 3 (whole sinus surgery). Patient characteristics and early postoperative complications including cerebrospinal fluid (CSF) leakage, orbital injury, severe hemorrhage, and toxic shock syndrome (TSS) that occurred during 1 to 2 weeks of each hospitalization were compared. Multivariable logistic regression analysis was performed to assess the association between overall complication rate and background characteristics, with adjustment for within-hospital clustering.

**Results:** The overall complication rate was 0.50%; the rates of CSF leakage, orbital injury, hemorrhage requiring surgery, blood transfusion, and TSS were 0.09%, 0.09%, 0.10%, 0.18%, and 0.02%, respectively. Ethmoidectomy combined with sphenoidotomy was associated with higher overall complication rates (1.40%). The rate of orbital injury was highest in group 2, whereas that of other complications did not differ significantly among the groups. Extent of FESS showed no significant association with overall complication rate.

**Conclusion:** More extensive FESS was not associated with increased rates of postoperative CSF leakage, hemorrhage, or TSS. Multiple sinus surgery was associated with a higher rate of orbital injury. The extent of surgery did not significantly affect the overall complication rate.

**Key Words:** Chronic rhinosinusitis, functional endoscopic sinus surgery, intraoperative complication, postoperative complication, nationwide study, types of surgery.

**Level of Evidence:** 2b.

*Laryngoscope*, 125:1785–1791, 2015

### INTRODUCTION

Functional endoscopic sinus surgery (FESS) for chronic rhinosinusitis (CRS) was introduced in the 1980s and is now one of the most commonly performed otorhinolaryngological procedures.<sup>1,2</sup> The term describes many different procedures, such as maxillary antrostomy, ethmoidectomy, and a combination of two or more surgeries, but classification of FESS procedures according to the extent of surgery has not been well standardized.

From the Department of Clinical Epidemiology and Health Economics, School of Public Health (S.S., H.Y., H.M.); the Department of Otolaryngology and Head and Neck Surgery, Faculty of Medicine (S.S., K.K., T.Y.), The University of Tokyo; and the Department of Health Policy and Informatics, Tokyo Medical and Dental University Graduate School of Medicine (K.F.), Tokyo, Japan

Editor's Note: This Manuscript was accepted for publication March 24, 2015.

This study was funded by the Ministry of Health, Labour and Welfare of Japan (grant: Research on Policy Planning and Evaluation; grant number: H26-Policy-011). The authors have no other funding, financial relationships, or conflicts of interest to disclose.

Send correspondence to Sayaka Suzuki, MD, Department of Clinical Epidemiology and Health Economics, School of Public Health, The University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 1130033, Japan. E-mail: sayasuzuki-ty@umin.ac.jp

DOI: 10.1002/lary.25334

Functional endoscopic sinus surgery is generally a safe procedure, but serious complications may occur. Reported complication rates vary widely because of differences in study populations and study periods, with cerebrospinal fluid (CSF) leakage reported in 0.004% to 0.55% of cases, orbital hematoma or injury reported in 0.02% to 6.6% of cases, severe hemorrhage reported in 0.19% to 3.9% of cases,<sup>3–14</sup> and toxic shock syndrome (TSS) reported in 0.017% of cases.<sup>15</sup> Because complications are rare, a large sample size is needed to determine complication rates. The sample sizes of most previous studies were too small to accurately assess postoperative morbidity after FESS, which limits the usefulness of the conclusions.<sup>16</sup> To our knowledge, the largest study reporting complications after FESS was conducted in the United States ( $n = 62,823$ ),<sup>4</sup> but that study did not evaluate outcomes according to the specific type of surgery performed.

The aim of this retrospective observational study was to investigate the rates of early postoperative complications (CSF leakage, meningitis, orbital injury, orbital hematoma, binocular movement disorder, hemorrhage requiring surgery or blood transfusion, and TSS) recorded during each hospitalization (hereafter referred to as *complication rates*) using a nationwide inpatient

database in Japan. First, we described the complication rates according to the specific types of surgery, including maxillary antrostomy, ethmoidectomy, sphenoidotomy, and surgeries for two or more sinuses. Next, we compared the complication rates according to the type of FESS performed (single, multiple, or whole sinus surgery). Finally, we analyzed the association between overall complication rate and background characteristics.

## MATERIALS AND METHODS

### Data Source

Data were obtained from the Diagnosis Procedure Combination (DPC) database, which is a national inpatient database in Japan that includes administrative claims data and discharge abstract data. This study was approved by the institutional review board of The University of Tokyo, Japan. Because of the anonymous nature of the data, informed consent was not required.

For each patient, the database includes: 1) the main diagnoses, comorbidities at admission, and complications after admission, coded by International Statistical Classification of Diseases (ICD)-10 codes; 2) surgical interventions, coded by original Japanese codes; 3) age, sex, and patient characteristics; 4) procedure costs; and 5) type of hospital (academic or nonacademic). The database includes the dates of all surgical procedures and blood transfusions. Codes for procedures, medication, blood transfusion, surgery, and anesthesia are almost complete because they are compulsory for health care cost reimbursement. To maximize accuracy of the data, the physicians in charge are required to record the information about diagnoses, comorbidities, and therapies from patients' medical charts. In the DPC database, the diagnoses of comorbidities after admission can be clearly distinguished from those of comorbidities at admission. The duration of data collection in the database was 6 months (July 1 to December 31) each year from 2007 to 2010, and it was extended to the entire year from 2011. All 82 academic hospitals across Japan are obliged to participate in the DPC database, whereas the participation of community hospitals is voluntary. The number of patients included in 2012 was 6.8 million, which represents more than 50% of all inpatient admissions to acute care hospitals in Japan.<sup>17</sup> A more detailed description has previously been published.<sup>18</sup>

### Patient Selection

Data were extracted for patients who underwent sinus surgery from July 2007 to March 2013 (51 months in total). Patients were included if they had a diagnosis of chronic sinusitis (ICD-10 code: J32x) or nasal polyps (J33x) at the time of admission and underwent sinus surgery during the admission. The exclusion criteria were: 1) meningitis (G00x to G03x), meningoencephalitis (G04x, G05x), abscess of orbit (H050), abscess of face (i.e., frontal abscess in patients with frontal sinusitis, and buccal abscess in those with maxillary sinusitis; L020), or intra-/extracranial abscess (G060, G062) at the time of admission; 2) malignant neoplasm (Cxx); 3) papilloma or other benign neoplasm of the paranasal or nasal cavities (D14.0); 4) benign neoplasm of the meninges (D32x); 5) benign neoplasm of the brain or another part of the central nervous system (D33x); 6) neoplasm of uncertain or unknown behavior of the brain or another part of the central nervous system (D43x); 7) neoplasm of the pituitary gland (D44.3); 8) age  $\leq$  15 years; and 9) Caldwell-Luc operation, Killian operation, or surgery for organic hematoma.

We focused on the following surgeries: maxillary antrostomy; ethmoidectomy; sphenoidotomy; frontal sinusotomy com-

bined with/without ethmoidectomy (FE); ethmoidectomy and sphenoidotomy (ES); ethmoidectomy and maxillary antrostomy (EM); ethmoidectomy and maxillary antrostomy with frontal sinusotomy (EMF); ethmoidectomy and maxillary antrostomy with sphenoidotomy (EMS); and surgery for all the sinuses on one side (EMFS). Patients were divided into three groups according to the extent of surgery performed: group 1, single sinus surgery (maxillary antrostomy, ethmoidectomy, sphenoidotomy); group 2, multiple sinus surgery (procedure for two or more sinuses, including FE, ES, EM, EMF, and EMS); and group 3, whole sinus surgery (EMFS). Because frontal sinusotomy is usually combined with ethmoidectomy, we classified it as group 2. The number of patients who underwent turbinectomy was counted. We excluded patients who received two or more types of sinus surgery during a single hospitalization and included patients who underwent only one type of the above-mentioned surgery in each hospitalization.

### Patient Background Characteristics and Outcomes

The patient background characteristics assessed were age, sex, Charlson Comorbidity Index (CCI),<sup>19,20</sup> smoking status (nonsmoker/current or ex-smoker), allergic rhinitis, asthma, aspirin-induced asthma (AIA), and image-guided surgery (IGS) (yes/no).

Cerebrospinal fluid leakage was identified by the ICD-10 code for CSF leakage (G960) or by surgery to repair CSF leakage. Postoperative meningitis and meningoencephalitis were identified by the ICD-10 codes G00x to G05x. Total cranial complications included CSF leakage with/without surgery and postoperative meningitis/meningoencephalitis. Orbital injury was identified by the ICD-10 codes for orbital hematoma (H052), disorder of binocular movement (H519), fracture of the orbital floor (S023), other orbital parts (S028), or by surgery to repair orbital fractures. Total orbital injury included orbital injury with/without surgery, orbital hematoma, and disorders of binocular movement. Severe bleeding was identified by the use of blood transfusion or surgery for hemostasis after sinus surgery. Toxic shock syndrome was identified by the ICD-10 codes for streptococcal sepsis (A40x) or other sepsis (A41x) after admission and by the Japanese text data for "toxic shock."

### Statistical Analysis

Patient characteristics and complications were compared among the three groups of patients using the *t* test or  $\chi^2$  test, as appropriate. Multivariable logistic regression analysis was performed to analyze the association between each type of complication and patient background characteristics, including age, sex, smoking status, CCI, allergic rhinitis, asthma, IGS, extent of surgery, and type of hospital (academic or nonacademic), with adjustment for within-hospital clustering using a generalized estimating equation.<sup>21</sup> To assess the multicollinearity between the independent variables, we checked variance inflation factors for each independent variable. A variance inflation factor of more than 10 was considered to show multicollinearity. A *P* value  $<$  0.05 was considered statistically significant. All analyses were performed using the Statistical Package for Social Sciences 20.0 (IBM SPSS Corp., Armonk, NY).

## RESULTS

Among 80,152 patients who underwent sinus surgery during the study period, 64,466 had a diagnosis of chronic sinusitis or nasal polyps at the time of

TABLE I.  
Patient Characteristics According to the Extent of Surgery.

	All (n = 50,734)	Group 1 (n = 3,616)	Group 2 (n = 29,034)	Group 3 (n = 18,084)	P Value
Age (years), mean ± SD	54.0 ± 15.4	56.1 ± 16.5	54.0 ± 15.7	53.5 ± 14.7	< 0.001
Sex (male), n (%)	33,191 (65.4)	2,186 (60.4)	18,452 (63.6)	12,553 (69.4)	< 0.001
CCI, n (%)					
0	49,181 (96.9)	3,504 (96.9)	28,171 (97.0)	17,506 (96.8)	0.387
≥ 1	1,553 (3.1)	112 (3.1)	863 (3.0)	578 (3.2)	
Smoking, n (%)					
current or ex-smoker	12,642 (24.9)	756 (20.9)	7,070 (24.4)	4,816 (26.6)	< 0.001
nonsmoker	26,088 (51.4)	1,974 (54.6)	15,182 (52.3)	8,932 (49.4)	
unspecified	12,004 (23.7)	886 (24.5)	6,782 (23.4)	4,336 (24.0)	
Allergic rhinitis, n (%)	1,865 (3.7)	113 (3.2)	1,069 (3.7)	683 (3.8)	0.163
Asthma, n (%)	3,861 (7.6)	163 (4.5)	1,559 (5.4)	2,139 (11.8)	< 0.001
AIA, n (%)	293 (0.6)	15 (0.4)	111 (0.4)	167 (0.9)	< 0.001
Image-guided surgery, n (%)	3,867 (7.6)	193 (5.3)	1,897 (6.5)	1,777 (9.8)	< 0.001
Academic hospitals, n (%)	16,119 (31.8)	1,110 (30.7)	7,707 (26.5)	7,302 (40.4)	< 0.001

Group 1, single sinus surgery; group 2, multiple sinus surgery; group 3, whole sinus surgery.  
AIA = aspirin-induced asthma; CCI = Charlson Comorbidity Index; SD = standard deviation.

admission. Of these, 2,550 patients were excluded for the following reasons: meningitis or meningoencephalitis (n = 52); orbital abscess (n = 58), facial abscess (n = 4) or intra-/extracranial abscess (n = 4) at the time of admission; malignant neoplasm (n = 366); papilloma or other benign neoplasm of the paranasal or nasal cavities (n = 2,105); benign neoplasm of the meninges (n = 32); benign neoplasm of the brain or another part of the central nervous system (n = 12); neoplasm of uncertain or unknown behavior of the brain or another part of the central nervous system (n = 55); neoplasms of the pituitary gland (n = 40); or age ≤ 15 years (n = 1,377). A total of 57,588 patients who underwent endoscopic sinus surgery were identified. Of those, 2,226 were excluded because they underwent the Caldwell-Luc operation, Killian operation, or surgery for organic hematoma. We also excluded 4,628 patients who received two or more types of sinus surgery during hospitalization. The remaining 50,734 eligible patients from 706 hospitals were divided into three groups: group 1 (single sinus surgery), group 2 (multiple sinus surgery), and group 3 (whole sinus surgery).

Table I shows the patient characteristics in each group. Patients in group 1 were older (mean age 56.1 years) than those in group 2 (mean age 54.0 years) and group 3 (mean age 53.5 years). The proportions of patients with CCI and allergic rhinitis were similar among the three groups. Of the 3,861 asthma patients, 293 patients had AIA. The proportions of current/ex-smokers and patients with asthma were greater in groups 2 and 3 than in group 1, and those with AIA were greater in group 3 than in group 1 or 2, suggesting that current/ex-smokers and patients with asthma or AIA received more extensive sinus surgery. There was a linear relationship between the frequency of IGS and the extent of sinus surgery. The proportion of patients treated at academic hospitals was lower in

group 2 (26.5%) than in group 3 (40.4%) and group 1 (30.7%).

Table II details the overall complication rates in each type of surgery. More than one-third of patients had EM (n = 17,291) or EMFS (n = 18,084), followed by EMF (n = 7,358) and EMS (n = 2,818). The overall complication rate was highest in ES (1.40%), whereas those in other surgeries were all < 1%. The rate of CSF leakage was highest in FE (0.23%), followed by EMF (0.20%). The rate of orbital injury was highest in EM (0.15%), followed by FE (0.12%). The rates of postoperative hemorrhage requiring surgery, blood transfusion, and TSS were highest in ES and were 0.28%, 0.70%, and 0.28%, respectively. No patient had a postoperative brain abscess.

Table III shows the overall complication rates in all of the groups and complication rates according to the extent of FESS. The overall complication rate was 0.50% (254/50,734). The rate of CSF leakage with or without surgery was not significantly different among groups 1, 2, and 3 ( $\chi^2$  test). However, the rate of total orbital injury was significantly higher in group 2 than in the other groups (0.03%, 0.15%, and 0.13% in groups 1, 2, and 3, respectively;  $P = 0.016$ ). The rate of postoperative hemorrhage requiring surgery or blood transfusion was not significantly different among the three groups. A wider extent of sinus surgery was associated with a longer duration of anesthesia ( $P < 0.001$ ), longer length of postoperative hospital stay ( $P < 0.001$ ), and higher total cost ( $P < 0.001$ ). Among all patients, the mean duration of anaesthesia was significantly longer in patients with any complication than in patients with no complication ( $226 \pm 113$  minutes vs.  $162 \pm 65$  minutes;  $P < 0.001$ ). Postoperative length of stay (days, mean ± standard deviation [SD]) for patients with any complication (n = 254) was significantly longer than for patients with no complication (n = 50,480) ( $15.3 \pm 19.2$  days vs.  $7.2 \pm 2.9$  days,  $P < 0.001$ ).

TABLE II.  
Complication Rates According to Specific Type of Surgery.

n (%)	Group 1			Group 2					Group 3
	Maxillary Antrostomy	Ethmoidectomy	Sphenoidotomy	FE	ES	EM	EMF	EMS	EMFS
Total	1,501	1,695	420	853	714	17,291	7,358	2,818	18,084
Overall complications	6 (0.40%)	4 (0.25%)	1 (0.24%)	6 (0.70%)	10 (1.40%)	75 (0.43%)	41 (0.56%)	15 (0.53%)	96 (0.53%)
Total cranial complications*	0	2 (0.12%)	0	2 (0.23%)	2 (0.28%)	11 (0.06%)	15 (0.20%)	2 (0.07%)	18 (0.10%)
CSF leakage in total	0	1 (0.06%)	0	2 (0.23%)	1 (0.14%)	11 (0.06%)	15 (0.20%)	2 (0.07%)	14 (0.08%)
CSF leakage requiring surgery	0	0	0	0	0	1 (0.01%)	3 (0.04%)	1 (0.04%)	1 (0.01%)
Meningitis	0	1 (0.06%)	0	0	1 (0.14%)	0	0	0	4 (0.02%)
Total orbital injury <sup>†</sup>	0	1 (0.06%)	0	2 (0.23%)	0	29 (0.17%)	11 (0.15%)	1 (0.04%)	13 (0.07%)
orbital injury requiring surgery	0	0	0	0	0	2 (0.01%)	0	0	0
Hemorrhage requiring surgery	2 (0.13%)	0	0	1 (0.12%)	2 (0.28%)	13 (0.08%)	4 (0.05%)	5 (0.18%)	25 (0.14%)
Blood transfusion	3 (0.20%)	1 (0.06%)	1 (0.24%)	1 (0.12%)	5 (0.70%)	21 (0.12%)	12 (0.16%)	8 (0.28%)	39 (0.22%)
Toxic shock syndrome	1 (0.07%)	0	0	0	2 (0.28%)	2 (0.01%)	2 (0.03%)	0	3 (0.02%)

\*Included CSF leakage with/without surgery and postoperative meningitis.

<sup>†</sup>Included orbital injury with/without surgery, orbital hematoma, and binocular movement disorders.

Group 1, single sinus surgery; group 2, multiple sinus surgery; group 3, whole sinus surgery

CSF = cerebrospinal fluid; ES = ethmoidectomy and sphenoidotomy; EM = ethmoidectomy and maxillary antrostomy; EMF = ethmoidectomy and maxillary antrostomy with frontal sinusotomy; EMS = ethmoidectomy and maxillary antrostomy with sphenoidotomy; EMFS = surgery for all the sinuses on one side; FE = frontal sinusotomy combined with/without ethmoidectomy.

The overall complication rate was not significantly different between patients with asthma (0.34%, 13/3,861) and patients without asthma (0.48%, 226/46,873) ( $P = 0.216$ ), between patients with AIA (0.68%, 2/293) and patients without AIA (0.47%, 237/50,441) ( $P = 0.595$ ), or between current/ex-smokers (0.45%, 57/12,642) and nonsmokers (0.44%, 116/26,088) ( $P = 0.352$ ). The overall complication rates in patients with and without IGS were 0.7% (26/3,867) and 0.5% (228/46,867), respectively ( $P = 0.073$ ). The postoperative length of stay (days, mean  $\pm$  SD) was  $7.8 \pm 4.4$  and  $7.1 \pm 3.1$  ( $P < 0.001$ ), respectively; and total costs (USD) were  $\$7,853 \pm \$2,621$  and  $\$6,423 \pm \$2,262$  ( $P < 0.001$ ), respectively, in the groups with or without IGS.

Table IV details the results of multivariable regression analysis. Variance inflation factors were all less than 1.5, indicating no multicollinearity. Charlson Comorbidity Index  $\geq 1$  was associated with a higher overall complication rate, and comorbid asthma with a smaller rate. No significant association with overall complication rate was seen for age, sex, smoking status, allergic rhinitis, extent of surgery, IGS, or type of hospital.

Turbinectomy was performed in 2,193 patients. Among these, only three patients received surgery for hemostasis, and none required blood transfusion. Of the three patients, two underwent turbinectomy combined

with EMFS, and one underwent turbinectomy combined with EM.

## DISCUSSION

The results of this study show that the overall complication rate after FESS in Japan is low at 0.50% (254/50,734). This figure is comparable to those reported in previously studies (0.23% to 11.7%).<sup>3-14</sup> Higher proportions of complications were found in specific types of surgery, including ES, FE, and EMF. Each complication rate was not associated with the extent of sinus surgery, except for total orbital injuries. Charlson Comorbidity Index  $\geq 1$  was independently associated with the overall occurrence of complication, whereas other factors including extent of surgery, IGS, and type of hospital were not.

Functional endoscopic sinus surgery is widely accepted as a safe and standard treatment in Japan and other countries for CRS that is refractory to nonsurgical treatment. Although rare, major complications such as CSF leakage, orbital injury, and severe hemorrhage requiring surgical intervention may occur even in experienced hands because of the anatomical proximity of the sinuses to the orbit and the anterior skull base. CSF leakage and orbital injury may have a negative impact on the patient's life. Toxic shock syndrome is a rare acute

TABLE III.  
Complication Rates According to Surgical Type.

	All (n = 50,734)	Group 1 (n = 3,616)	Group 2 (n = 29,034)	Group 3 (n = 18,084)	P Value
Overall complications, n (%)	254 (0.50)	11 (0.30)	147 (0.51)	96 (0.53)	0.207
Total cranial complications*, n (%)	50 (0.10)	2 (0.06)	32 (0.11)	18 (0.10)	0.685
CSF leak in total, n (%)	46 (0.09)	1 (0.03)	31 (0.11)	14 (0.08)	0.251
CSF leak requiring surgery, n (%)	6 (0.01)	0	5 (0.02)	1 (0.01)	0.417
Meningitis, n (%)	6 (0.01)	1 (0.03)	1 (0.00)	4 (0.02)	0.128
Total orbital injury †, n (%)	57 (0.09)	1 (0.03)	43 (0.15)	13 (0.13)	0.016
Orbital injury requiring surgery, n (%)	2 (0.00)	0	2 (0.00)	0	0.474
Hemorrhage requiring surgery, n (%)	52 (0.10)	2 (0.06)	25 (0.09)	25 (0.14)	0.149
Blood transfusion, n (%)	91 (0.18)	5 (0.14)	47 (0.16)	39 (0.22)	0.338
Toxic shock syndrome, n (%)	10 (0.02)	1 (0.03)	6 (0.02)	3 (0.02)	0.896
Duration of anesthesia (minute, mean ± SD)	161 ± 66	124 ± 59	149 ± 60	185 ± 67	< 0.001
Postoperative length of stay (day, mean ± SD)	7.2 ± 3.2	6.9 ± 4.0	7.2 ± 3.0	7.3 ± 3.4	< 0.001
Total cost (USD, mean ± SD)	6535 ± 2324	4271 ± 1940	5931 ± 1851	7958 ± 2293	< 0.001

Group 1, single sinus surgery; group 2, multiple sinus surgery; group 3, whole sinus surgery.

\*Included CSF leakage with/without surgery and postoperative meningitis.

†Included orbital injury with/without surgery, orbital hematoma, and binocular movement disorders.

CSF = cerebrospinal fluid; SD = standard deviation; USD = United States dollar.

multisystem disorder, caused by toxins produced by *Staphylococcus aureus* or group A streptococcus. Early diagnosis and immediate therapy including removal of nasal packing, drainage of pus, and antibiotics are essential for the treatment of TSS.<sup>22–25</sup> Physicians should provide patients with adequate information regarding these potential complications prior to FESS.<sup>26–29</sup> Knowledge of the risks associated with the different types of surgery is useful for providing information to patients undergoing FESS.

Only a few previous studies reported on associations between the extent of surgery and surgical outcomes.<sup>6,9,13</sup> One study found that complication rates were higher in patients who underwent more extensive sinus surgery.<sup>9</sup> Intra- and postoperative hemorrhage (1.3%), CSF leakage (1.1%), and orbital hematoma (0.6%) were the most common complications in 3,402 patients who underwent FESS by a single surgeon, and extensive disease status was associated with a higher risk of complications. A prospective study in the United Kingdom (n = 3,128)<sup>13</sup> found that the complication rate was associated with the extent of disease measured in terms of symptom severity and health-related quality of life but not with surgical characteristics including the extent of surgery (simple polypectomy/antral washout vs. inferior meatus/middle meatus/anterior ethmoid surgery vs. distal sinus surgery). A recent retrospective study (n = 2,596) also did not find an association between complications and the extent of surgery.<sup>6</sup> It should be noted, however, that these studies were limited by small sample sizes.

In the current large-scale nationwide study, FESS procedures were categorized into three groups according to the extent of surgery. The results show that a wider extent of surgery was not necessarily associated with a higher rate of each complication. The extent of surgery

itself was not significantly associated with the overall complication rate after adjustment for other background factors. More extensive sinusitis and polyps could have resulted in absence of surgical landmarks because of the long duration of mucosal inflammation or increased pressure on the surrounding structures, and absence of surgical landmarks could have made the procedures more difficult and impacted negatively on surgical outcomes. Another view exists, however, that the occurrence of any intraoperative complication may have impeded

TABLE IV.  
Multivariable Logistic Regression Analysis.

Factors	Odds Ratio	95% Confidence Interval	P Value
Age, by 10-year increase	0.98	0.88–1.08	0.639
Sex (female)	0.73	0.52–1.02	0.065
Smoking category (vs. nonsmoker)			
Current/ex-smoker	0.91	0.63–1.34	0.644
Unspecified	1.12	0.80–1.56	0.506
CCI (≥ 1 vs. 0)	4.56	3.01–6.91	<0.001
Asthma	0.50	0.25–0.99	0.046
Allergic rhinitis	1.01	0.54–1.89	0.985
Extent of surgery (vs. group 1)			
Group 2	1.68	0.88–3.22	0.117
Group 3	1.69	0.90–3.20	0.105
Image-guided surgery	1.31	0.84–2.04	0.232
Academic hospital	1.40	0.92–2.13	0.119

Group 1, single sinus surgery; group 2, multiple sinus surgery; group 3, whole sinus surgery.

CCI = Charlson Comorbidity Index.

continuation of the planned surgery, resulting in a lower rate of complications in more extensive sinus surgery.

In this study, none of the rates of CSF leakage, meningitis, orbital hematoma, binocular movement disorder, postoperative hemorrhage requiring surgery/blood transfusion, or TSS was associated with the extent of sinus surgery. However, the rate of total orbital injury was associated with the extent of sinus surgery and was highest in group 2. Most cases of orbital injury were treated conservatively. Complete removal of the diseased mucosa, reopening of the sinus, and drainage of effusion could have contributed to the safety of procedures in group 3.

Regarding specific types of surgery, ES had the highest overall complication rate (1.40%), followed by FE and EMF. The association between surgery for ethmoid sinus and a higher rate of complications would be inevitable due to the anatomical location of the ethmoid sinus adjacent to the orbit and anterior skull base and because it contains the anterior ethmoidal artery. Additional frontal sinusotomy or sphenoidotomy for EM showed only a slight increase in the overall complication rate. Taking into consideration the higher complication rate in ES than in EMS, additional maxillary antrostomy could have allowed a better understanding of the anatomical landmarks. However, because of the difference in the sample sizes between ES and EMS, the results should be interpreted cautiously.

Considering that the development of paranasal sinuses is almost complete by the age of 15 years,<sup>30,31</sup> the insignificant association between age and overall complication rate is plausible.

Previous studies suggested that IGS in FESS for CRS accurately confirmed the paranasal anatomy, especially in patients with poor surgical landmarks because of CRS itself, individual anatomical distortion, or previous surgery, and possibly contributed to favorable surgical outcomes.<sup>32,33</sup> However, a reduction in clinical complications with IGS has not been statistically confirmed. The current study also showed no significant association between IGS and overall complication rate. However, no definitive conclusions could be drawn because the data on revision surgery or paranasal anatomy was not available in the current study. Selection bias by physicians for IGS cannot be eliminated because of the retrospective nature of this study; that is, patients with more complex paranasal anatomy may have been more likely to have received IGS.

The reduced risk of overall complications in patients with asthma was shown in the multivariable regression analysis in our study, in contrast to the results of a previous study from Japan.<sup>14</sup> The possible explanation for this may be that asthma patients were more likely to receive early surgery because FESS in asthma patients may improve clinical outcomes of asthma.<sup>34</sup>

The proportion of sinus surgeries performed in academic hospitals in Japan may be higher than that in Western countries. This may be related to differences in clinical practices and health care systems between countries. Postoperative intranasal packing is routinely per-

formed in most Japanese hospitals. In Japan, patients usually stay in hospital for several days after sinus surgery for follow-up medical care and in case of severe bleeding after the removal of nasal packing. Furthermore, FESS is widely performed both by trainees or ear, nose, and throat specialists (in Japan, qualified as board-certified otorhinolaryngologists), and in academic hospitals and nonacademic hospitals.

Several limitations of this study should be acknowledged. First, this was a retrospective observational study, without random treatment assignment. Unrecorded confounding factors such as preoperative Lund-Mackay CT score, revision surgery, each surgeon's experience, synechia formation, and individual anatomical distortions may have affected complication rates and the duration of anesthesia. Second, comorbidities are generally recorded less accurately in an administrative claims database than in planned prospective studies. The relatively low complication rate in our study could be explained by differences in the definition of each complication between studies. Symptoms and signs are generally less likely to be reported in administrative databases, and recorded complications are considered to be underestimated. Additionally, delayed complications, which were reported in a previous study,<sup>4</sup> were not identified in the current study and would likely lead to an underestimation of the complication rates.

## CONCLUSION

This study used a nationwide Japanese inpatient database to evaluate the current complication rates after FESS for CRS, according to the specific types of surgery and the extent of surgery (single sinus surgery, multiple sinus surgery, or whole sinus surgery). The overall complication rate was low (0.50%). ES was associated with the highest overall complication rate (1.40%). Whole sinus surgery was not associated with higher rates of CSF leakage, orbital injury requiring surgery, or postoperative hemorrhage requiring surgery or blood transfusion than less extensive sinus surgery. The extent of surgery was not independently associated with the overall occurrence of complications.

## BIBLIOGRAPHY

1. Stammberger H. Endoscopic surgery for mycotic and chronic recurring sinusitis. *Ann Otol Rhinol Laryngol Suppl* 1985;119:1–11.
2. Kennedy DW, Zinreich SJ, Rosenbaum AE, Johns ME. Functional endoscopic sinus surgery. Theory and diagnostic evaluation. *Arch Otolaryngol* 1985;111:576–582.
3. May M, Levine HL, Mester SJ, Schaitkin B. Complications of endoscopic sinus surgery: analysis of 2108 patients—incidence and prevention. *Laryngoscope* 1994;104:1080–1083.
4. Ramakrishnan VR, Kingdom TT, Nayak J V, Hwang PH, Orlandi RR. Nationwide incidence of major complications in endoscopic sinus surgery. *Int Forum Allergy Rhinol* 2012;2:34–39.
5. Tschopp KP, Thomaser EG. Outcome of functional endonasal sinus surgery with and without CT-navigation. *Rhinology* 2008;46:116–120.
6. Siedek V, Pilzweiger E, Betz C, Berghaus A, Leunig A. Complications in endonasal sinus surgery: a 5-year retrospective study of 2,596 patients. *Eur Arch Otorhinolaryngol* 2013;270:141–148.
7. Castillo L, Verschuur HP, Poissonnet G, Vaille G, Santini J. Complications of endoscopically guided sinus surgery. *Rhinology* 1996;34:215–218.
8. Dursun E, Bayiz U, Korkmaz H, Akmansu H, Uygur K. Follow-up results of 415 patients after endoscopic sinus surgery. *Eur Arch Otorhinolaryngol* 1998;255:504–510.

9. Stankiewicz JA, Lal D, Connor M, Welch K. Complications in endoscopic sinus surgery for chronic rhinosinusitis: a 25-year experience. *Laryngoscope* 2011;121:2684–2701.
10. Mueller SA, Caversaccio M. Outcome of computer-assisted surgery in patients with chronic rhinosinusitis. *J Laryngol Otol* 2010;124:500–504.
11. Cumberworth VL, Sudderick RM, Mackay IS. Major complications of functional endoscopic sinus surgery. *Clin Otolaryngol Allied Sci* 1994;19:248–253.
12. Vleming M, Middelweerd RJ, de Vries N. Complications of endoscopic sinus surgery. *Arch Otolaryngol Head Neck Surg* 1992;118:617–623.
13. Hopkins C, Browne JP, Slack R, et al. Complications of surgery for nasal polyposis and chronic rhinosinusitis: the results of a national audit in England and Wales. *Laryngoscope* 2006;116:1494–1499.
14. Asaka D, Nakayama T, Hama T, et al. Risk factors for complications of endoscopic sinus surgery for chronic rhinosinusitis. *Am J Rhinol Allergy* 2012;26:61–64.
15. Jacobson JA, Kasworm EM. Toxic shock syndrome after nasal surgery. Case reports and analysis of risk factors. *Arch Otolaryngol Head Neck Surg* 1986;112:329–332.
16. Dalziel K, Stein K, Round A, Garside R, Royle P. Endoscopic sinus surgery for the excision of nasal polyps: A systematic review of safety and effectiveness. *Am J Rhinol* 2006;2:506–519.
17. Nakamura M, Yasunaga H, Shimada T, Horiguchi H, Matsuda S, Fushimi K. Body mass index and in-hospital mortality in anorexia nervosa: data from the Japanese Diagnosis Procedure Combination database. *Eat Weight Disord* 2013;18:437–439.
18. Matsuda S, Fujimori K, Kuwabara K, et al. Diagnosis procedure combination as an infrastructure for the clinical study. *Asian Pac J Dis Manage* 2011;5:81–87.
19. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis* 1987;40:373–383.
20. Quan H, Sundararajan V, Halfon P, et al. Coding algorithms for defining comorbidities in ICD-9-CM and ICD-10 administrative data. *Med Care* 2005;43:1130–1139.
21. Hubbard AE, Ahern J, Fleischer NL, et al. To GEE or not to GEE: comparing population average and mixed models for estimating the associations between neighborhood risk factors and health. *Epidemiology* 2010;21:467–474.
22. Younis RT, Lazar RH. Delayed toxic shock syndrome after functional endonasal sinus surgery. *Arch Otolaryngol Head Neck Surg* 1996;122:83–85.
23. Abram AC, Bellian KT, Giles WJ, Gross CW. Toxic shock syndrome after functional endonasal sinus surgery: an all or none phenomenon? *Laryngoscope* 1994;104:927–931.
24. Weber R, Hochapfel F, Draf W. Packing and stents in endonasal surgery. *Rhinology* 2000;38:49–62.
25. Gallo UE, Fontanarosa PB. Toxic streptococcal syndrome. *Ann Emerg Med* 1990;19:1332–1334.
26. Wolf JS, Malekzadeh S, Berry JA, O'Malley BW. Informed consent in functional endoscopic sinus surgery. *Laryngoscope* 2002;112:774–778.
27. Wolf JS, Chiu AG, Palmer JN, O'Malley BW, Schofield K, Taylor RJ. Informed consent in endoscopic sinus surgery: the patient perspective. *Laryngoscope* 2005;115:4992–4994.
28. Sharp HR, Crutchfield L, Rowe-Jones JM, Mitchell DB. Major complications and consent prior to endoscopic sinus surgery. *Clin Otolaryngol Allied Sci* 2001;26:33–38.
29. Patel AM, Still TE, Vaughan W. Medicolegal issues in endoscopic sinus surgery. *Otolaryngol Clin North Am* 2010;43:905–914.
30. Spaeth J, Krugelstein U, Schlondorff G. The paranasal sinuses in CT-imaging: development from birth to age 25. *Int J Pediatr Otorhinolaryngol* 1997;39:25–40.
31. Park I-H, Song JS, Choi H, et al. Volumetric study in the development of paranasal sinuses by CT imaging in Asian: a pilot study. *Int J Pediatr Otorhinolaryngol* 2010;74:1347–1350.
32. Smith TL, Stewart MG, Orlandi RR, et al. Indications for image-guided sinus surgery: the current evidence. *Am J Rhinol* 2007;21:80–83.
33. Ramakrishnan VR, Orlandi RR, Citardi MJ, et al. The use of image-guided surgery in endoscopic sinus surgery: an evidence-based review with recommendations. *Int Forum Allergy Rhinol* 2013;3:236–241.
34. Vashishta R1, Soler ZM, Nguyen SA, Schlosser RJ. A systematic review and meta-analysis of asthma outcomes following endoscopic sinus surgery for chronic rhinosinusitis. *Int Forum Allergy Rhinol* 2013;3:788–794.