Evaluation of a new and simple classification for endoscopic sinus surgery

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ABSTRACT

Objective: *In 2013, the Japanese Rhinologic Society proposed a simple classification for endoscopic sinus surgery (ESS). This classification consists of five procedures (type I, fenestration of the ostiomeatal complex, with uncinectomy and widening of the natural ostium; type II, single-sinus procedure, with manipulating the inside of the sinus; type III, polysinus procedure; type IV, pansinus procedure; type V, extended procedure beyond the sinus wall). The clinical relevance of this classification in chronic rhinosinusitis (CRS) and paranasal sinus cyst was evaluated.*

Study Design: *A retrospective validation study.*

Methods: *A total of 122 patients (195 sinuses) who underwent ESS in Okayama University Hospital in 2012 were enrolled. The relationships between the ESS classification and the clinical course, including the operation time, bleeding amounts during surgery and postoperative changes of olfaction, the computed tomography (CT) score, and nasal airway resistance were analyzed.*

Results: *A total of 195 ESS procedures were classified into type I (n = 3), type II (n = 17), type III (n = 91), type IV (n = 82), and type V (n = 2). The major phenotypes of type II, III, and IV ESS were paranasal sinus cyst (68%), CRS without nasal polyps (77%), and CRS with nasal polyps (55%), respectively, and the difference was significant. The degree of ESS based on this classification was positively and significantly correlated with the operation time and bleeding amounts. As a whole, olfaction, CT score, and nasal airway resistance were significantly improved after surgery. The degree of improvement was similar between type III and type IV ESS.*

Conclusion: *This simple classification for ESS reflected the perioperative burden of the disease.*

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Endoscopic sinus surgery (ESS) is currently a standard surgical option for medically refractory chronic rhinosinusitis (CRS) and paranasal cyst. A recent study in the United States demonstrated that the incremental cost-effectiveness ratio for ESS versus medical therapy alone was approximately $14,000 per quality-adjusted life year in patients with CRS, which indicated that ESS is a cost-effective intervention.[1] ESS for such diseases includes various procedures, from simple uncinectomy to extended procedures beyond the sinus wall, such as the modified Lothrop procedure, and there is no universal classification of ESS.[2–4] Thus, it is difficult to compare and evaluate each surgical procedure both clinically and economically in the present circumstances.

In 2013, the Japanese Rhinologic Society proposed a new and simple surgical classification for ESS to aim for standardization of surgical procedures and the functional evaluation of the surgery.[5] This new classification consists of five types according to the extent of surgery as follows: type I, removal of the ostiomeatal complex; type II, the single-sinus procedure; type III, the polysinus procedure; type IV, the pansinus procedure (full-house ESS); and type V, the extended procedure beyond the sinus wall (*e.g.*, the modified Lothrop procedure). In 2014, the Japanese Health Insurance System set the flat surgical fee for each classification (type I, ¥ 36,000 (US $320); type II, ¥ 100,000 (US $880);

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type III, ¥ 245,000 (US $2,160); type IV, ¥ 319,900 (US $2,820); and type V, ¥ 400,000 (US $3,530)). A retrospective study was performed to evaluate whether this new classification was clinically relevant in patients who underwent ESS in Okayama University Hospital, the tertiary referral academic hospital in Okayama Prefecture, Japan.

METHODS

Subjects

A cohort of 122 patients (195 sinuses; age range, 8–80 years; mean age, 50.9 years; 70 males and 52 females) who underwent ESS in Okayama University Hospital in 2012 was enrolled. This cohort included 27 patients with CRS without nasal polyps (35 sinuses), 72 patients with CRS with nasal polyps (CRSwNP) (135 sinuses), and 23 patients with a paranasal sinus cyst (25 sinuses) defined by using the criteria reported in a European position paper on rhinosinusitis and nasal polyps.[6] All the patients were refractory to standard medical treatments, including long-term, low-dose macrolide therapy. All the patients underwent computed tomography (CT) examination within 1 month before surgery.

The ESS procedure was selected based on the presence of mucosal thickening in the ostium and/or inside the wall of each sinus on CT or the presence of inflammation, such as mucosal swelling and discharge, on endoscopic inspection during surgery. Concomitant septoplasty and turbinate surgery (submucosal turbinate bone dissection) was performed based on endoscopic inspection and coronal CT, which showed nasal cavity obstruction that might interfere with the ESS procedure. Primary and revision ESS procedures were performed in 111 and 11 patients, in 175 and 20 sinuses, respectively. Unilateral and bilateral ESS procedures were performed in 49 and 73 cases, respectively. All the surgeries were performed or supervised by a single surgeon (M.O.) with >20 years of experience with ESS. This study was approved by the human research committee of the Okayama University Graduate School of Medicine, Dentistry and Pharmaceutical Sciences, and all the patients provided their informed consent before surgery.

Outcomes

The perioperative outcomes of operation time, bleeding amounts during surgery, and surgical complications were observed for each patient. The bleeding amount was calculated based on suction traps. A very small amount of bleeding was calculated as 10 mL. To evaluate radiologic improvement by ESS, the examination was performed again 6 months after the surgery in 69 patients with CRS who agreed to undergo a repeated examination. The radiologic severity of CRS was graded by using the Lund-Mackay system.[6] Preoperative and 3-month postoperative anterior rhinomanometry findings were evaluated in 45 patients with bilateral CRS (90 sinuses) who had had moderate-to-severe nasal congestion. Inspiratory nasal airway resistance at 100 Pa was determined.[7]

When the nasal airway resistance was unmeasurable due to complete nasal obstruction, it was defined as 5 $Pa/cm^3/s$. Similarly, preoperative and 3-month postoperative olfactory tests (T&T olfactory test) were performed in 47 patients with subjective moderate-to-severe hyposmia or anosmia.[8] Evaluation of improvement in olfaction was determined by the criteria of the Olfactory Review Committee of the Japanese Rhinologic Society as follows: cure, postoperative average perception threshold improved ≤2.0; improvement, postoperative average perception threshold improved by ≥1.0; impairment, postoperative average perception threshold deteriorated by ≥1.0; and no change, <1.0 improvement or deterioration. None of the participants received systemic corticosteroids for a period of <4 weeks at the time of postoperative evaluation.

To evaluate the relationship between the degree of ESS classified by the new operative criteria and perioperative outcomes, an ESS score and the total endonasal surgery score were used. The ESS score is the sum of the proposed classification number of both sides (*e.g.*, type III ESS on the right side and type IV ESS on the left side results in a score of 7). The score for concomitant septoplasty and unilateral turbinate surgery was set to one point (*e.g.*, septoplasty and bilateral inferior turbinate surgery results in a score of 3). The total endonasal surgery score was set as the sum of the ESS score and the concomitant surgery score.

Statistical Analysis

Values are given as medians. The χ^2 test was used for comparisons of two factors. The nonparametric Mann-Whitney *U* test and the one-way analysis of variance (ANOVA), followed by *post hoc* testing were used to compare data between two and multiple groups, respectively. The Wilcoxon signed rank test was used to analyze the data within each group. Correlation analyses were performed by using the Spearman rank correlation. The *p* values of <0.05 were considered significant. Statistical analyses were performed with GraphPad Prism software (version 6.04; GraphPad Software, Inc., La Jolla, CA).

RESULTS

Classification of Patients Who Received ESS

In 2012, 195 ESS procedures were performed in 122 patients. According to the new proposed criteria,

Table 1 **Patient characteristics based on the new ESS classification**

	Type I (n = 3)	Type II (n = 17)	Type III (n = 91)	Type IV (n = 82)	Type V (n = 2)	p Value
Age, mean ± SD, y	52.2 ± 12.1	50.8 ± 17.7	50.7 ± 14.1	50.8 ± 13.2	63.0	0.681*
Male/female patients, no.	3/0	5/12	52/39	53/29	0/2	0.016#
CRSwNP/CRSsNP/cyst, no.	3/0/0	0/0/17	56/27/8	74/8/0	2/0/0	<0.001#
Primary/revision, no.	3/0	17/0	87/4	68/14	0/2	<0.001#
Unilateral/bilateral, no.	1/2	15/2	33/58	0/82	0/2	<0.001#

ESS = Endoscopic sinus surgery; SD = standard deviation; CRSwNP = chronic rhinosinusitis without nasal polyps; CRSsNP = chronic rhinosinusitis with nasal polyps.
**Determined by the Kruskal-Wallis test.*
#Determined by the χ^2 test.

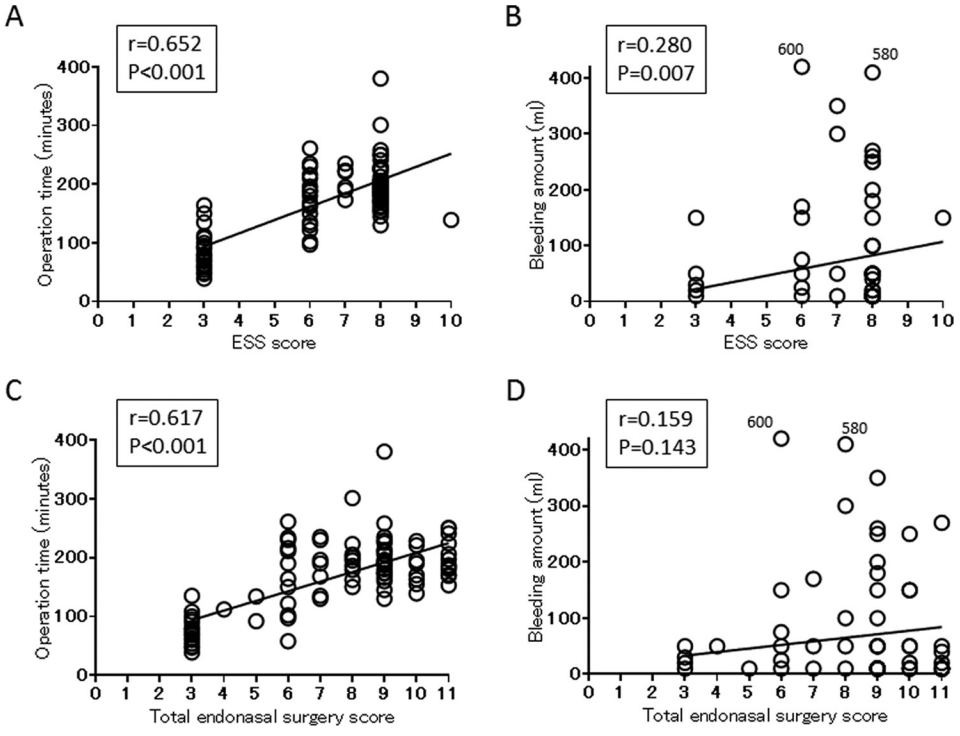

Figure 1. *The relationships between the endoscopic sinus surgery (ESS) score (A and B) or the total endonasal surgery score (C and D) and operation time (A and C) or bleeding amount (B and D).*

3, 17, 91, 82, and 2 ESS procedures were classified as type I (1.5%), type II (8.7%), type III (46.7%), type IV (42.1%), and type V (1.0%), respectively. As shown in Table 1, no significant differences were seen in age (p = 0.681, ANOVA). However, sex differences were seen according to the criteria (p = 0.016, χ^2 test) in which type I, III, and IV ESS were male predominant, whereas type II and type V ESS were female predominant. Disease phenotype was significantly different ($p < 0.001$, χ^2 test), in which the majority of type IV ESS procedures were performed for patients with CRSwNP, and the majority of type II ESS procedures were performed for those with paranasal sinus cyst.

Of the 195 sinuses, revision ESS was performed for 20 sinuses. Significant differences in the proportion of revision ESS procedures were seen with the new criteria, in which type IV ESS contained more revision ESS procedures (n = 14 [17.1%]) than the other types ($p < 0.001$, χ^2 test). Fifty-seven septoplasties were concomitantly performed in 51 bilateral (38 in type III and 64 in type IV) and 6 unilateral ESS (all type III), which indicated that the septoplasty was independently correlated with the type of procedure ($p < 0.001$, χ^2 test). Similarly, 35 patients received 59 turbinate reduction surgeries. Among these, 5 surgeries were performed without ipsilateral ESS; the other 54 surgeries were concomitantly performed in type I (n = 2), type III (n = 17), and type IV (n = 35) ipsilateral ESS, which indicated that the turbinate reduction surgery was also independently correlated with the type of procedure ($p < 0.001$, χ^2 test).

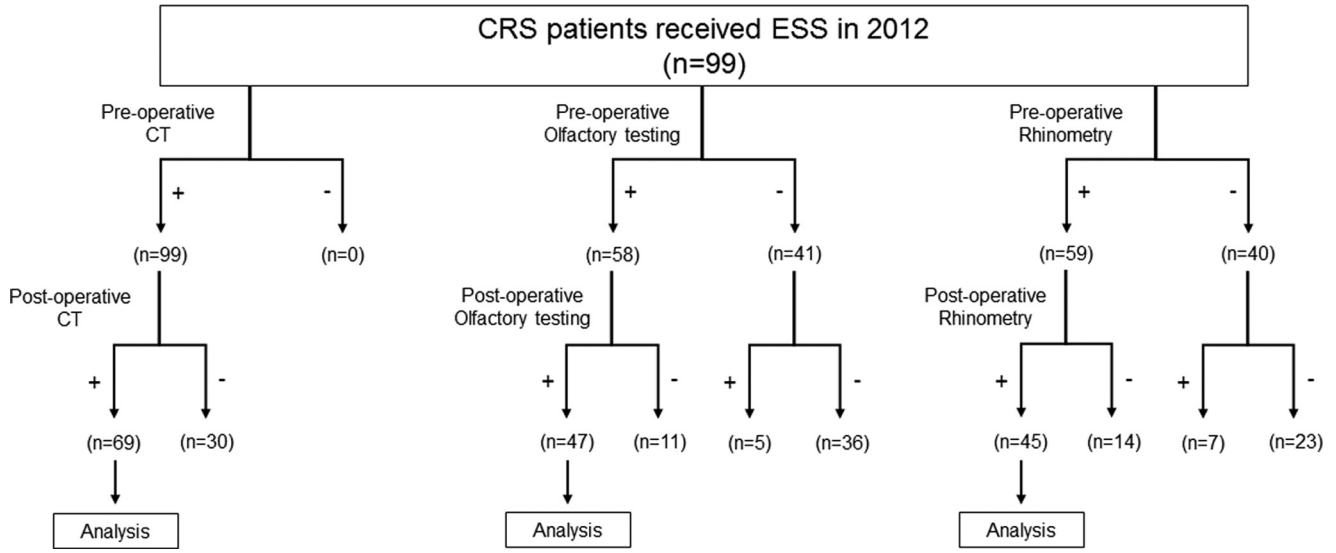

Figure 2. *A flow chart diagram of patients enrolled in the study.*

Relationship Between the New Classification of ESS and Perioperative Outcomes in Patients with CRS

Of the 99 patients with CRS (170 sinuses), the operation time was recorded in 96. A significant positive correlation between the ESS score and operation time was seen ($r = 0.652$; $p < 0.001$, Spearman rank correlation test) (Fig. 1 *A*). Bleeding amounts during surgery were carefully recorded in 90 patients. A weak though significant positive correlation between the ESS score and bleeding amount during surgery was also seen ($r = 0.280$; $p = 0.007$) (Fig. 1 *B*). A total of 57 septoplasty and 59 turbinate surgeries were performed in 57 and 35 patients, respectively. A significant correlation was seen between the total endonasal surgery score and the operation time ($r = 0.617$, $p < 0.001$) (Fig. 1 *C*) but not between the total endonasal surgery score and the bleeding amount ($r = 0.159$, $p = 0.143$) (Fig. 1 *D*). Postoperative bleeding was a major complication, as seen in six cases. No significant differences in the rate of this complication among the new classification types were detected ($p = 0.255$, χ^2 test). No other major complications, such as CSF leaks and visual disturbance, were seen.

Relationship Between the New Operative Classification of ESS and Physiologic Characterizations of Patients with CRS

The number of patients with CRS enrolled; the number of patients who underwent preoperative and 3-month postoperative testing, including rhinometry and olfactory testing; and the number of patients who received a 6-month postoperative CT examination are shown in Fig. 2. Results of ANOVA indicated significant differences in the preoperative CT score among the classification types ($p < 0.001$), in which type V showed the highest score (median, 12.0), followed by type IV (median, 8.4), type III (median, 5.2), and type I (median, 4.3) in patients with CRS. *Post hoc* testing further showed a significant difference between type III ESS and type IV ESS ($p < 0.001$) and between type III ESS and type V ESS ($p = 0.016$) (Fig. 3 *A*). A significant positive correlation between the degree of ESS and the preoperative CT score was also seen ($r = 0.547$; $p < 0.001$, Spearman test). A postoperative CT examination was performed in 69 patients (121 sinuses: type I, $n = 1$; type III, $n = 56$; type IV, $n = 62$; and type V, $n = 2$). As a whole, significant improvement was seen ($p < 0.001$, Wilcoxon signed rank test). Results of the ANOVA indicated a significant difference in the degree of improvement among type III, type IV, and type V ESS ($p = 0.005$). *Post hoc* testing showed a significantly greater improvement in type V ESS than in type III ESS ($p = 0.035$) (Fig. 3 *B*).

A total of 47 patients with CRS completed both preoperative and 3-month postoperative olfactory tests. Because all the patients underwent bilateral ESS, the more-severe type of ESS in each patient was recorded (type III, $n = 14$; type IV, $n = 32$; type V, $n = 1$) (Fig. 4 *A*). No significant difference in the preoperative average perception threshold on the T&T olfactory test was seen between type III and type IV ESS ($p = 0.666$, Mann-Whitney *U* test). As a whole, the average perception threshold 3 months after surgery was significantly lower ($p < 0.001$, Wilcoxon signed rank test). Both type III ($p = 0.004$) and type IV ($p = 0.006$) ESS showed significant improvements in the average perception threshold. Improvement of olfaction was seen in 28 of 47 patients (59.6%). No significant difference in the degree of improvement was seen among type III, IV, and V ESS ($p = 0.376$, χ^2 test) (Fig. 4 *B*).

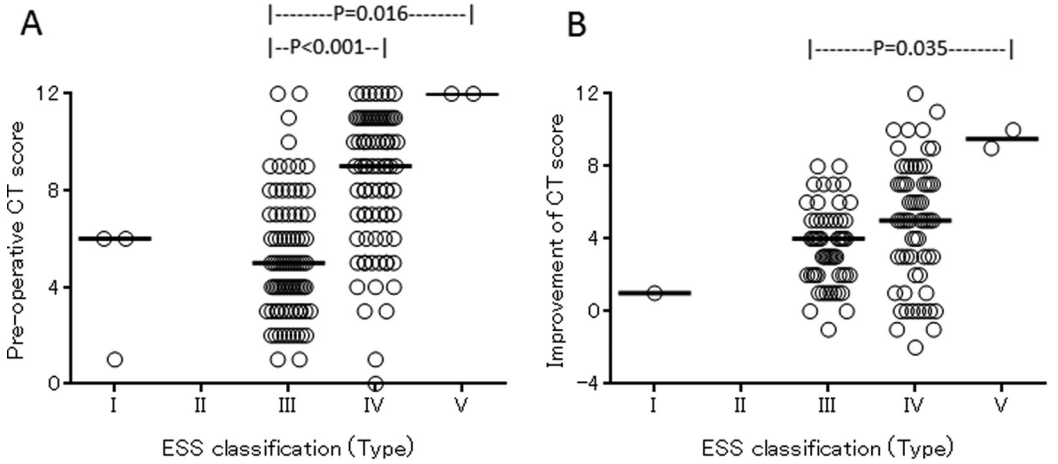

Figure 3. The relationship between the new classification of endoscopic sinus surgery (ESS) and the computed tomography (CT) score. (A) Comparison of the preoperative CT score among the classification types. (B) Comparison of the improvement of the CT score 6 months after surgery among the classification types. The bar indicates the median; the p values were determined by using the post hoc test.

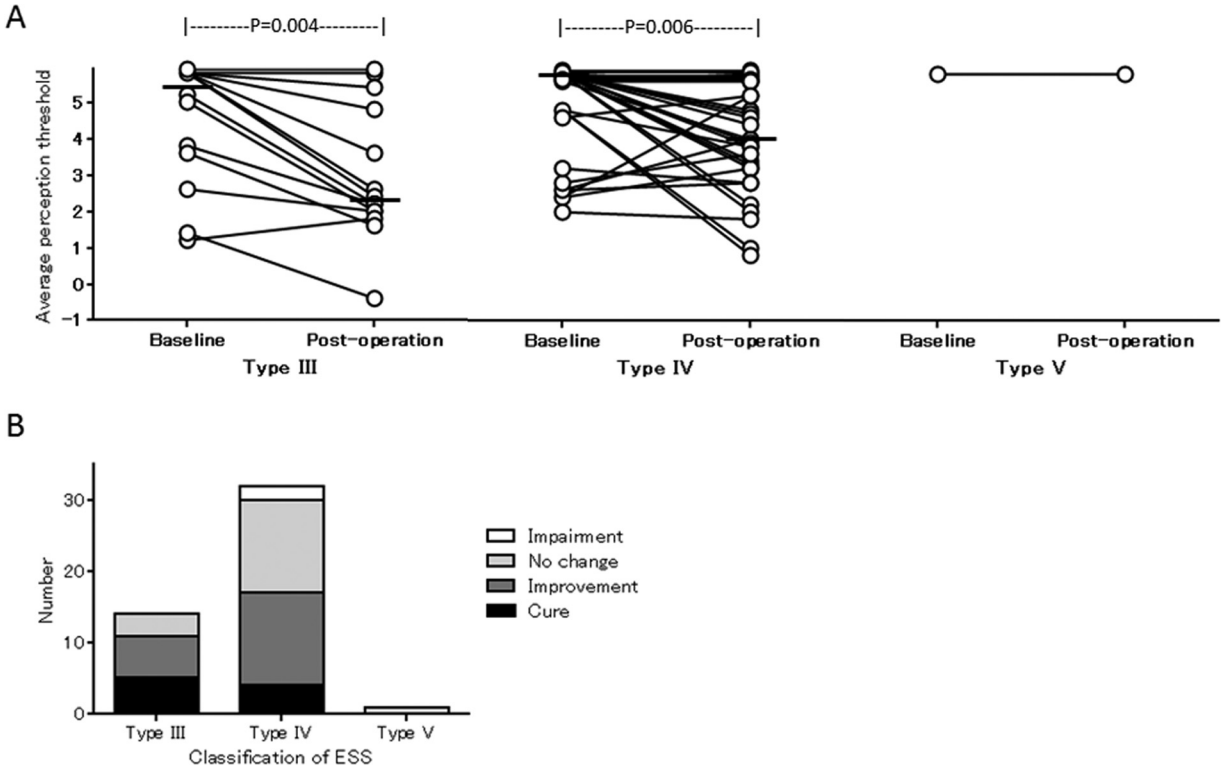

Figure 4. The relationship between the new classification of endoscopic sinus surgery (ESS) and olfaction. (A) Comparison of preoperative and 3-month postoperative average perception thresholds determined by the T&T olfactory test among the classification types. (B) A comparison of improvement of olfaction after surgery among the classification types. The bar indicates the median; the p values were determined by the Wilcoxon signed rank test.

Nasal airway resistance was examined both before and 3 months after surgery in 45 patients with CRS (90 sinuses: type III, $n = 28$; type IV, $n = 60$; type V, $n = 2$). Results of an ANOVA indicated no significant difference in the preoperative resistance among the groups ($p = 0.121$) (Fig. 5 *A*). As a whole, a significant reduction in the resistance was seen 3 months after surgery compared with before surgery ($p < 0.001$, Wilcoxon signed rank test); both type III and type IV ESS showed significantly decreased resistance (both $p < 0.001$) (Fig. 5 *B*). Similar to before surgery, no significant difference in postoperative resistance was seen among the groups ($p = 0.653$). A significant decrease in nasal resistance was seen even in patients who did not undergo septo-

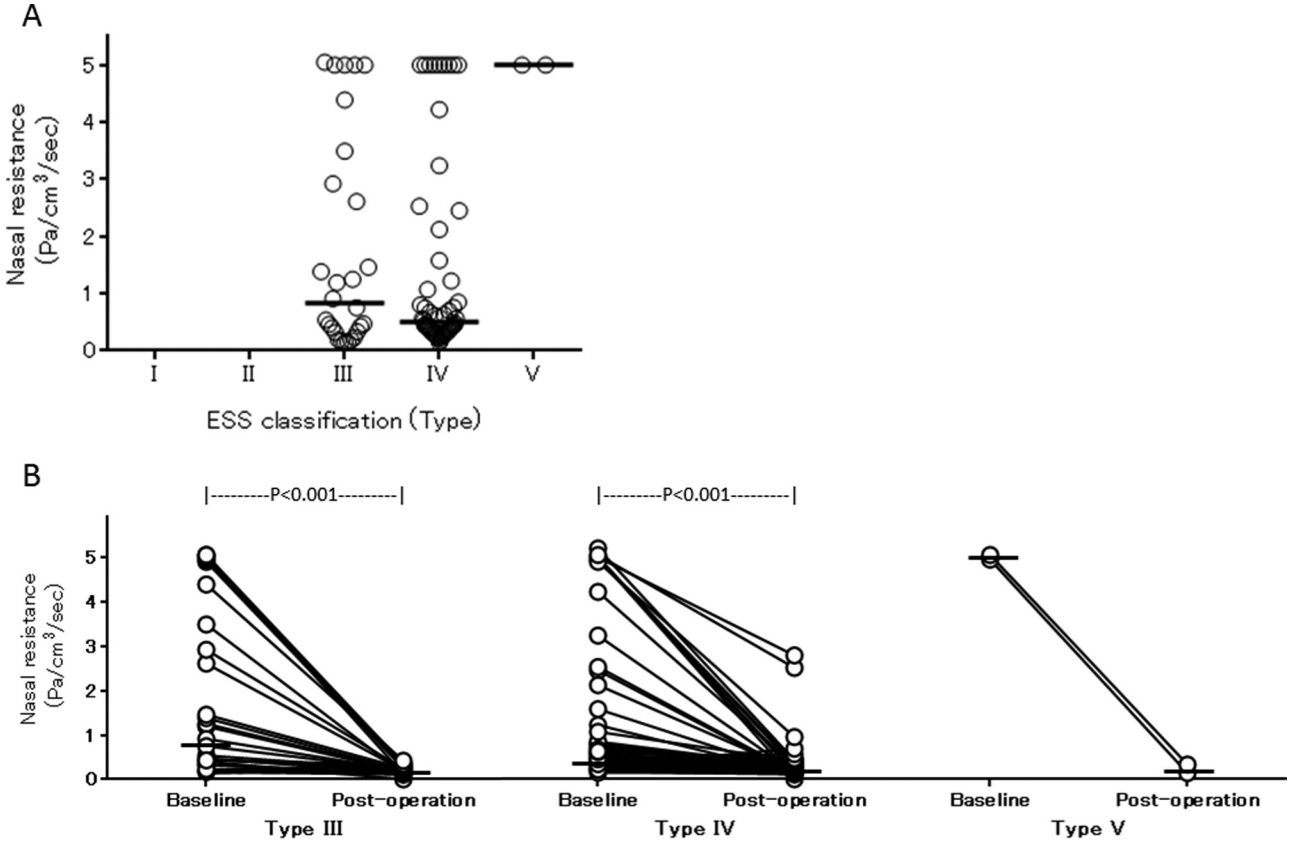

Figure 5. The relationship between the new classification of endoscopic sinus surgery (ESS) and nasal resistance. (A) A comparison of preoperative inspiratory nasal resistance at 100 Pa among the classification types. (B) A comparison of improvement of nasal resistance after surgery among the classification types. The bar indicates the median; the p values were determined by the Wilcoxon signed rank test.

plasty or inferior turbinate surgery ($p < 0.001$, Wilcoxon signed rank test) ($n = 22$).

DISCUSSION

The present study was a pilot analysis to validate the proposed classification system in patients with CRS and paranasal sinus cyst. ESS is regarded as standard surgery for these diseases and is widely performed in each facility. For example, the Japanese Diagnosis Procedure Combination data base showed that 50,734 patients with CRS and/or nasal polyposis from 706 hospitals underwent ESS over 51 months in Japan.[9] However, unlike the Wulstain classification of otologic surgery, classification, in other words, grading, of ESS has not been fully standardized.[10] In the present study, discussed as a pilot analysis to validate the proposed classification system, it was found that this new classification reflected the surgeon's burden in terms of operation time and bleeding amounts. In addition, significant improvements in radiologic severity, olfaction, and nasal airflow resistance were achieved after surgery regardless of the grade of ESS, which indicated that proper selection of the ESS procedure led to an acceptable postoperative course.

Most patients with CRS underwent type III or type IV ESS among the five types. This reflected that CRS usually involves multiple sinuses.[11] Furthermore, the majority of type IV ESS cases were performed for CRSwNP. This may be due to the increase of intractable eosinophilic rhinosinusitis (ECRS), an endotype of CRSwNP, in Japan, which may progress from ethmoid-dominant inflammation to pansinus inflammation.[12] A recent report by Snidvongs *et al.*[13] recommended type IV ESS to provide a single sinus cavity in which the frontal, ethmoid, maxillary, and sphenoid sinuses are in communication, followed by nasal irrigation with or without corticosteroids for ECRS. Thus, type IV ESS may become the major procedure in which the proportion of ECRS is high.

Significant differences in sex but not age were seen among the five types, in which types I, III, and IV ESS cases were male predominant. Because type I, III, and IV ESS were mainly performed in patients with CRS but not paranasal sinus cysts, male predominance may be due to the sex difference in patients with CRS who underwent ESS. Although heterogeneous results were

seen for the sex difference in the prevalence of CRS, several reports showed a male predominance in patients with CRSwNP who underwent ESS.[11–15] For example, the Japanese Epidemiologic Survey of Refractory Eosinophilic Rhinosinusitis study demonstrated that the male-to-female ratio was 2.2:1 in patients with CRS who underwent ESS.[12] A similar difference was also seen in the Japanese Diagnosis Procedure Combination data base, in which 65.4% of the subjects who underwent ESS were male.[9] In fact, when patients with paranasal cysts were excluded, significant sex differences among the ESS classification types were lost ($p = 0.119$, χ^2 test).

Type IV and type V ESS procedures contain more revision surgeries, 17.1 and 100%, respectively, than other ESS types (0–3.3%). To the best of our knowledge, little is known about the comparison of procedures between primary and revision ESS. Although a recent report from the United States showed that the proportion of type IV ESS was 16.4% in primary ESS, the proportion was not clear in revision ESS.[16] Along with the finding described above that ECRS is increasing in Japan, it is likely to require extended surgery to create a single sinus cavity for patients refractory to primary ESS.

The ESS score was significantly positively correlated with the operation time and bleeding amounts, which indicated that, if the procedure of the new operative classification was more advanced, then operation times and bleeding amounts were greater. The surgical fee for ESS is not well-known worldwide. A recent systematic review reported that the overall procedural cost of ESS, including not only the surgical fee but also other fees, such as anesthetist fees and surgical supplies, ranged from U.S. $1,000 to U.S. $10,500 per adult patient and differed by country.[17] In Japan, there is a universal public health care system, and the surgical fee for ESS is based on the severity according to the operative classification. Thus, the setting of the flat surgical fee based on the new classification seems to be reasonable. However, the total endonasal surgery score was significantly and positively correlated with operation time but not by bleeding amount. This may be due to the low risk of intraoperative bleeding in septoplasty and/or submucosal turbinate bone resection compared with ESS.[18]

A significant and positive correlation between the ESS type and the preoperative CT score was also seen in patients with CRS, which indicated that selection of the ESS procedure was principally based on radiologic findings in the present cases. Although a significant radiologic improvement was seen as whole, more improvement was achieved in type V ESS than with type III ESS. This may be due to the high preoperative CT score in type V ESS (12 points), in which more radiologic improvement can be achieved compared with cases with a low baseline CT score. Nevertheless, the present results indicated that appropriate selection of the new operative procedure led to satisfactory results on radiologic examination.

Preoperative olfaction was not different between type III and type IV ESS. This may be due to the basis of procedure selection in that a particular type of ESS was not chosen based on the olfaction level. A significant decrease in the average perception threshold on the T&T olfactory test was achieved 3 months after surgery, and improvement of olfaction was seen in 59.6% of patients. Previous reports demonstrated that the improvement of olfaction after ESS ranged from 23 to 100%, depending on evaluation conditions (*e.g.*, observation period, method of monitoring olfaction) and patient characteristics, such as nasal polyp formation and concomitant asthma.[19–21] However, no significant difference in the degree of improvement was seen among types III, IV, and V ESS, which may be because the new classification of ESS does not mention the procedure for the olfactory cleft. Olfactory cleft opacification on CT is known to be a predictive factor of smell recovery after ESS.[22]

Consistent with previous reports that used rhinomanometry, a significant improvement in nasal airway resistance was seen 3 months after surgery.[23,24] Because the nasal valve region primarily determines nasal resistance, it may be argued that concomitant surgery for the nasal cavity is a confounding factor that affects the changes in nasal resistance.[25] However, a significant decrease in nasal resistance was seen even in patients who underwent ESS alone. One of the reasons why ESS improves nasal airflow is that alleviation of sinus inflammation by ESS leads to a reduction of nasal mucosal edema and mucus in the nose.[23,24] Together with the finding that significant improvement in nasal airway resistance was seen regardless of ESS type, the present results indicated that appropriate selection of the ESS procedure led to an improvement of nasal airflow by controlling sinus inflammation. One major weakness in this study was that there were no subjective outcomes used. Objective nasal resistance measures do not always reflect patient's subjective nasal obstruction.

CONCLUSION

The current results indicated that the new proposed criteria for ESS were simple and useful both clinically and economically. Because the numbers of type I, II, and V ESS procedures were relatively small in the present study, a future prospective, multicenter analysis with a large number of patients will provide a basis for determining the usefulness of these criteria in the clinical setting for treatment with ESS. In addition, the current payment scheme in Japan may encourage sur-

geons to perform a type IV sinus surgery when not indicated by the extent of disease. Future research will look at how the classification of surgeries changed before and after 2014 when the payment scheme went into effect.

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