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Clinical outcomes of single incision laparoscopic surgery for colorectal cancer: A propensity score-matched analysis between well-experienced and novice surgeons

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Abstract

Background: Single incision laparoscopic surgery (SILS) is a recent advancement in minimally invasive techniques for colorectal cancer (CRC). However, SILS is a technically challenging procedure for novice surgeons. The aim of this study was to evaluate clinical outcomes of SILS for CRC performed by novice surgeons compared with those performed by well-experienced surgeons.

Methods: We retrospectively analyzed 1004 consecutive patients with stage I-IV CRC who underwent SILS between May 2009 and December 2018, using propensity score-matched analysis.

Results: After propensity score-matching, we enrolled 344 patients (n = 172 in each group). Before matching, significant group-dependent differences were observed in terms of age (P = 0.034) and tumor location (P < 0.001). After matching, preoperative clinical factors were similar between groups, but operative time was longer in the Novice group (213 vs 171 min, P < 0.001). Other operative factors and morbidity rates did not differ significantly between groups. The number of harvested lymph nodes was smaller in the Novice group (23 vs 25, P = 0.040), and the number of patients with lymph node metastases was smaller in the Novice group (57 vs 86, P = 0.002). The 3-year disease-free survival rate was 85.8% in the Novice group and 89.9% in the Experienced group (P = 0.512). Three-year overall survival rate was 92.2% in the Novice group and 90.0% in the Experienced group (P = 0.899).

Conclusion: SILS for CRC was safely performed by novice surgeons under the guidance of well-experienced surgeons, and could provide satisfactory oncological outcomes.

KEYWORDS colorectal cancer, novice, single-incision laparoscopic surgery

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1 | INTRODUCTION

Single-incision laparoscopic surgery (SILS) is a recent advancement in minimally invasive techniques. The first case of SILS was described for right colectomy in 2008,¹ and the benefits included better cosmetic outcomes, less postoperative pain, faster postoperative recovery, and earlier discharge from the hospital.^{2–5} In addition, SILS is feasible and safe for colon cancer in terms of short-term^{5–10} and long-term oncological outcomes.^{5–7} However, SILS is technically limited owing to instrument crowding, inline positioning of the laparoscope, and insufficient triangulation, which can lead to unexpected intraoperative issues and thus increase the amount of stress experienced by surgeons.^{2,3} In meta-analyses of studies comparing SILS with multi-port laparoscopic surgery, SILS has shown safety, feasibility, and effectiveness when performed by highly skilled laparoscopic surgeons.^{11,12}

SILS is technically challenging, but educating novice surgeons in the specific skills needed is even more difficult. Although some reports have described resident training for traditional multi-port laparoscopic colorectal surgery,¹³⁻¹⁵ few have addressed resident training of SILS colorectal surgery.^{16,17} Moreover, no studies appear to have evaluated the clinical outcomes of SILS performed by novice surgeons. The aim of this study was thus to evaluate the clinical outcomes of SILS for colorectal cancer (CRC) performed by novice surgeons compared with those performed by well-experienced surgeons.

2 | PATIENTS AND METHODS

2.1 | Patient populations and surgeons

Consecutive patients who underwent SILS for CRC between May 2009 and December 2018 at Osaka Police Hospital were analyzed. Cases of obstruction or perforation that required emergent operation were excluded from this study.

In Osaka Police Hospital, the first case of SILS for CRC was carried out in May 2009. Since then, the indications for SILS have gradually been expanded to include advanced cancer. Since January 2010, patients have received a sheet describing the differences between conventional multi-port laparoscopic surgery and SILS. In addition, they received a thorough explanation of each operative procedure. All patients agreed to undergo SILS, and provided written informed consent. From January 2012, SILS has been considered a reasonable alternative approach for colon cancer and has been used for selected patients with rectal cancer.

This study involved two well-experienced surgeons who had completed fellowship training in advanced minimally invasive surgical techniques and had been performing SILS procedures for colorectal disease routinely, and four novice surgeons distributed among all graduate years from 5 to 10, who had no experience in single- or multi-port laparoscopic colorectal surgeries. All operations performed by novice surgeons were done under the guidance of one of the two fully trained, well-experienced surgeons.

2.2 | Data collection

Patient age, sex, body mass index (BMI), Eastern Cooperative Oncology Group performance status (ECOG-PS), American Society of Anesthesiologists (ASA) score, previous abdominal surgery, tumor location, clinical TNM classification, and comorbidities were obtained from the medical records. Categorization of the primary tumor localization was performed according to the surgical records and pathological reports. Primary tumors located from the cecum to the splenic flexure were coded as right-sided. Tumors located either at the splenic flexure or from the splenic flexure to the rectosigmoid colon were categorized as left-sided. As listed in Table 1, cardiac disease consisted of ischemic disease, chronic heart failure, or cardiomyopathy. Pulmonary disease consisted of asthma, chronic obstructive pulmonary disease, or interstitial pneumonia. Cerebrovascular disease consisted of history of transient ischemic attacks or cerebrovascular events with or without neurological deficit. As listed in Table 2, postoperative complications were classified according to the Clavien-Dindo classification.¹⁸ As listed in Table 3, infectious complications consisted of abscess, colitis, urinary tract infection, nephritis, catheter-related infection, or cholecystitis. Operative mortality was defined as death during the same admission or within 30 days of surgery. All patients were followed for at least 30 days after surgery. This study was approved by the institutional review board of Osaka Police Hospital.

2.3 | Statistical methods

Prior to propensity score-matching, the t test or Wilcoxon rank-sum test was used for continuous variables, and the χ^2 test or Fisher's exact test was applied for categorical variables. Propensity scorematching was then applied to minimize the possibility of selection bias and to adjust for significant differences in the baseline characteristics of patients (Figure 1). The first step in the matching process was to complete a multivariate logistic regression analysis to obtain propensity scores. Nine covariates that might affect short- and longterm outcomes for SILS were included in the model for calculating the propensity score, as follows: age, sex, BMI, ECOG-PS, ASA score, tumor location, previous abdominal surgery, comorbidities, and clinical TNM classification. The next step was the 1:1 matching process, using calipers set at 0.2. This propensity score-matching was used to evaluate the effect of SILS on surgical and pathological outcomes. After propensity score-matching, baseline characteristics, including covariates not entered into the propensity score model, were compared between groups using bivariate analyses.

Data are presented as the median and interquartile range (IQR) for continuous variables and as the frequency and percentage for categorical variables. The χ^2 test was used for comparisons of categorical variables. Student's *t* test was used to determine the significance of differences between continuous variables. Survival curves were calculated using the Kaplan-Meier method and were then compared by log-rank testing. Values of *P*<0.05 were considered

TABLE 1 Demographic characteristics of patients

	Overall (n = 1004)			Propensity score-m		
	Well experienced (n = 829)	Novice (n = 175)	P value	Well experienced (n = 172)	Novice (n = 172)	P value
Age, years, median (IQR)	70 (63-78)	73 (65-80)	0.034	72 (64-79)	73 (65-80)	0.524
Gender, male, n (%)	413 (49.8)	85 (48.6)	0.803	77 (44.8)	82 (47.7)	0.665
BMI, kg/m ² , median (IQR)	22.4 (19.9-24.5)	22.1 (20.0-24.4)	0.948	21.5 (19.8-23.7)	22.1 (20.1-24.4)	0.150
ECOG-PS, 0 or 1, n (%)	777 (93.7)	169 (96.6)	0.158	170 (98.8)	167 (97.1)	0.448
ASA score, 3>, n (%)	160 (19.3)	42 (24.0)	0.177	30 (17.4)	41 (23.8)	0.183
Previous abdominal surgery, n (%)	554 (66.8)	113 (64.6)	0.597	60 (34.9)	62 (36.1)	0.910
Tumor location, n (%)			<0.001			0.877
Right-sided colon	353 (42.6)	125 (71.4)		121 (70.4)	123 (71.5)	
Left-sided colon	301 (36.3)	31 (17.7)		30	31	
Rectum	175 (21.1)	19 (10.9)		21 (12.2)	18 (10.5)	
Tumor invasion, n (%)			0.062			0.121
cT1	157 (18.9)	27 (15.4)		33 (19.2)	26 (15.1)	
cT2	122 (14.7)	35 (20)		35 (20.4)	35 (20.4)	
cT3	267 (32.2)	68 (38.9)		49 (28.5)	67 (39.0)	
cT4a	253 (30.5)	34 (19.4)		48 (27.9)	33 (19.2)	
cT4b	30 (3.6)	11 (6.3)		7 (4.1)	11 (6.4)	
Clinical TNM stage, n (%)			0.116			0.513
I	252 (30.4)	56 (32.0)		64 (37.2)	55 (32.0)	
II	245 (29.6)	38 (21.7)		29 (16.9)	37 (21.5)	
III	243 (29.3)	64 (36.6)		59 (34.3)	64 (37.2)	
IV	89 (10.7)	17 (9.7)		20 (11.6)	16 (9.3)	
Comorbidities ^a , n (%)						
Cardiac	155 (18.7)	36 (20.6)	0.596	24 (14.0)	35 (20.4)	0.152
Pulmonary	83 (10.0)	11 (6.3)	0.153	8 (4.7)	10 (5.8)	0.810
Diabetes	144 (17.4)	27 (15.4)	0.581	26 (15.1)	27 (15.7)	1
Cerebrovascular	97 (11.7)	26 (14.9)	0.254	20 (11.6)	25 (14.5)	0.523
Other cancer-bearing	56 (6.8)	15 (8.6)	0.417	17 (9.9)	15 (8.7)	0.853

Abbreviations: ECOG-PS, Eastern Cooperative Oncology Group Performance Status Scale; ASA score, American Society of Anesthesiologists Score; BMI, body mass index.

^aComorbidities: Cardiac = ischemic disease, chronic heart failure and cardiomyopathy, excluded hypertension; Pulmonary = asthma, chronic

obstructive pulmonary disease, and interstitial pneumonia Cerebrovascular = history of transient ischemic attacks and cerebrovascular event with or without neurological deficit.

statistically significant. All statistical analyses were performed using JMP version 14.0 software (SAS Institute).

3 | RESULTS

3.1 | Baseline patient profiles

An overview of our study is shown in Figure 1. Between May 2009 and December 2018, a total of 1844 patients underwent surgery for CRC, of whom 1018 underwent SILS for CRC. Fourteen of these 1018 patients were excluded, as six patients did not undergo primary tumor resection and eight patients underwent simultaneous resection of another cancer (gastric cancer in six; hepatocellular carcinoma in two). The total sample size was thus 1004 patients who underwent SILS for CRC. Among these 1004 patients, SILS was performed by well-experienced surgeons for 829 patients (Experienced group; 82.6%) and by novice surgeons for 175 patients (Novice group; 17.4%). Table 1 lists the demographic characteristics of the overall cohort and for propensity score-matched patients. The overall cohort included 498 males (49.6%), and median age was 71 years (IQR, 63-80 years). A history of previous abdominal surgery was present in 667 patients (66.4%). The Experienced group comprised 84 patients with cecal cancer, 169 patients with cancer of the ascending colon, 100 patients with transverse colon cancer, 41 patients with cancer of the descending colon, 260 patients with

TABLE 2 Operative findings

	Overall (n = 1004)		Propensity score-matched pairs (n = 34			44)
	Well experienced (n = 829)	Novice (n = 175)	P value	Well experienced (n = 172)	Novice (n = 172)	P value
Procedures			<0.001			0.296
lleocecal resection	180 (21.7)	83 (47.4)		64 (37.2)	81 (47.1)	
Right hemicolectomy	115 (13.9)	30 (17.1)		40 (23.3)	30 (17.4)	
Partial resection	112 (13.5)	23 (13.1)		22 (12.8)	23 (13.4)	
Left hemicolectomy	14 (1.7)	3 (1.7)		1 (0.6)	3 (1.7)	
Sigmoidectomy	231 (27.9)	16 (9.1)		24 (14.0)	16 (9.3)	
Subtotal colectomy	2 (0.2)	1 (0.6)		0	1 (0.6)	
Rectal resection	175 (21.1)	19 (10.9)		21 (12.2)	18 (10.5)	
Blood loss, mL, median (IQR)	5 (5-50)	5 (5-50)	0.359	5 (5-50)	5 (5-50)	0.635
Operative time, min, median (IQR)	175 (135-217)	213 (175-259)	<0.001	171 (130-213)	213 (177-259)	<0.001
Extent of lymph node dissection, D3, n (%)	632 (76.2)	142 (81.1)	0.167	132 (76.7)	139 (80.8)	0.429
Multivisceral resection, n (%)	39 (4.7)	10 (5.7)	0.563	10 (5.8)	10 (5.8)	1
SPS completion, n (%)	771 (93.0)	165 (94.3)	0.739	159 (92.4)	162 (94.2)	0.667
Conversion to open surgery, n (%)	6 (0.7)	5 (2.9)	0.029	2 (1.2)	5 (2.9)	0.448
Conversion to multi-port surgery, n (%)	12 (1.5)	3 (1.7)	0.734	3 (1.7)	3 (1.7)	1
Required an additional port, n (%)	40 (4.8)	2 (1.1)	0.022	8 (6.4)	2 (1.2)	0.104

TABLE 3 Postoperative complications

	Overall (n = 1004)			Propensity score-matched pairs (n = 344)		
Clavien-Dindo classification (grade ≥2), n (%)	Well experienced (n = 829)	Novice (n = 175)	P value	Well experienced (n = 172)	Novice (n = 172)	P value
Bleeding	13 (1.6)	6 (3.4)	0.121	4 (2.3)	6 (3.5)	0.750
Anastomotic leakage	23 (2.8)	3 (1.7)	0.602	2 (1.2)	2 (1.2)	1
Wound infection	47 (5.7)	13 (7.4)	0.380	8 (4.7)	13 (7.6)	0.368
Bowel obstruction	29 (3.59	7 (4.0)	0.661	7 (4.1)	7 (4.1)	1
Pneumonia	11 (1.3)	3 (1.7)	0.739	3 (1.7)	3 (1.7)	1
Infectious complications ^a	51 (6.2)	17 (9.7)	0.097	12 (7.0)	17 (9.9)	0.438
Perioperative death	2 (0.2)	1 (0.6)	0.437	1 (0.6)	1(0.6)	1
Overall complication	164 (19.8)	41 (23.4)	0.302	33 (19.2)	39 (22.7)	0.508
Postoperative hospital stay,	9 (7-12)	9 (8-14)	0.025	9 (7-12)	9 (8-14)	0.216

^aInfectious complications = abscess, colitis, urinary tract infection, nephritis, catheter-related infection, cholecystitis.

cancer of the sigmoid colon, and 175 patients with rectal cancer. On the other hand, the Novice group comprised 34 patients with cecal cancer, 58 patients with cancer of the ascending colon, 33 patients with cancer of the transverse colon, 14 patients with cancer of the descending colon, 17 patients with cancer of the sigmoid colon, and 19 patients with rectal cancer. Before matching, significant groupdependent differences were observed in terms of age (P = 0.034) and tumor location (right-sided, P < 0.001; rectum, P = 0.002). After matching, 172 matched pairs were selected. Baseline characteristics of patients were conserved between the two matched groups.

3.2 | Comparison of short-term outcomes between groups

Table 2 summarizes the details of operative findings between groups after matching. Operative time was significantly longer in the Novice group (213 min) than in the Experienced group (171 min; P < 0.001). No relevant differences were found between groups in terms of blood loss, extent of lymph node dissection, multivisceral resection rate, or SILS completion rate. In the Experienced group, two patients were converted to open surgery and 11 patients required additional



FIGURE 1 Flowchart of patients who underwent SILS for colorectal cancer

ports. In the Novice group, five patients were converted to open surgery and five patients required additional ports, which was comparable to the results in the Experienced group.

Table 3 depicts the postoperative complications that occurred in each group. The rate of Clavien-Dindo grade ≥ 2 did not differ between groups (P = 0.508), and no significant differences in rates of postoperative complications (bleeding, anastomotic leakage, wound infection, bowel obstruction, pneumonia, or infectious complications) were observed. Perioperative death was recorded in one patient in each group, due to pneumonia in the Experienced group and sepsis in the Novice group. Median duration of hospital stay was 9 days in each group.

The pathological features and oncologic outcomes are summarized in Table 4. Median number of harvested lymph nodes was significantly higher in the Experienced group (25 nodes) than in the Novice group (23 nodes, P = 0.040). The rate of positive lymph node metastases was also significantly higher in the Experienced group than in the Novice group (P = 0.018). Radial margin positivity was not found in any patients. Tumor size and pathological T4 rate were similar in both groups.

3.3 | Comparison of long-term oncological outcomes between groups

Median follow-up was 53.8 months in the Experienced group and 48.5 months in the Novice group (P = 0.091). The 3-year disease-free survival rate was 85.8% in the Novice group and 89.9% in the Experienced group (Figure 2), and the 3-year overall survival rate

was 92.2% in the Novice group and 90.0% in the Experienced group (Figure 3), showing no significant differences between groups.

4 | DISCUSSION

The present study appears to be the first to compare clinical outcomes between well-experienced surgeons and novice surgeons for CRC patients. The results suggest that, in selected patients, SILS for CRC can be performed safely by novice surgeons (as per the 94.2% SILS completion rate) and yields adequate short-term surgical outcomes (e.g. morbidity 22.7%, mortality 0.6%). In terms of oncological outcomes, we achieved a 100% R0 resection rate regardless of SILS experience, and satisfactory 3-year disease-free and overall survival rates in patients with CRC who underwent SILS by novice surgeons.

In this study, SILS was successfully performed by novice surgeons in 94.2% of their patients, including 62 patients (36.1%) who had a history of prior abdominal surgery. In a previous systematic review of SILS for CRC,¹⁹ the rate of conversion to open surgery was 0.92% and 13.3% of patients who underwent SILS procedures required insertion of an additional port to allow completion of the operation, comparable with our results. In patients with rectal cancer, surgeons sometimes encounter technical difficulties, including mobilization and division of the rectum, which might be overcome by adding a port.²⁰⁻²² In this study, 11 cases required an additional port for division of the rectum, and all cases were able to be completed with SILS plus one port. TABLE 4 Pathological features and oncological outcomes

	Overall (n = 1004)			Propensity score-matched pairs ($n = 344$)		
	Well experienced (n = 829)	Novice (n = 175)	P value	Well experienced (n = 172)	Novice (n = 172)	P value
Tumor size, mm, median (IQR)	40 (25-55)	40 (25-50)	0.859	40 (25-60)	40 (25-50)	0.403
Number of harvested lymph nodes, median (IQR)	23 (15-32)	22 (16-30)	0.404	25 (16-36)	23 (16-30)	0.040
Tumor invasion, n (%)			0.869			0.770
pT1	157 (18.9)	37 (21.1)		30 (17.4)	36 (20.9)	
pT2	105 (12.7)	23 (13.1)		24 (14.0)	23 (13.4)	
pT3	366 (44.2)	78 (44.6)		73 (42.4)	77 (44.8)	
pT4a	180 (21.7)	32 (18.3)		40 (23.3)	31 (18.0)	
pT4b	21 (2.5)	5 (2.9)		5 (2.9)	5 (2.9)	
Lymph node metastasis, n (%)			0.009			0.006
pN0	451 (54.4)	117 (66.9)		86 (50)	115 (66.9)	
pN1	232 (28.0)	33 (18.9)		50 (29.1)	32 (18.6)	
pN2	146 (17.6)	25 (14.3)		36 (20.9)	25 (14.5)	
Positive radial margin, n (%)	6 (0.7)	1 (0.6)	1	0	0	-
pTNM stage, n (%)			0.022			0.010
L	229 (27.6)	53 (30.1)		46 (26.7)	52 (30.2)	
II	216 (26.1)	61 (34.9)		38 (22.1)	61 (35.5)	
III	300 (36.2)	44 (25.1)		71 (41.3)	43 (25)	
IV	84 (10.0)	17 (9.7)		17 (9.9)	16 (9.3)	
Adjuvant chemotherapy (stage II or III), n (%)	174 (33.7)	27 (25.7)	0.137	37 (33.9)	26 (25)	0.177
Recurrence (stage I-III)						
Liver	48	9		7	8	
Lung	17	5		2	6	
Peritoneal	20	4		5	4	
Distant lymph node	14	2		3	1	
Other	9	2		2	2	
Total	108 (14.6)	22 (14.4)		18 (11.8)	20 (13.3)	

In this study, operative time was significantly longer in the Novice group than in the Experienced group (P < 0.001). Operative time in the Experienced group was comparable with those in results from several previous studies.^{3-6,8-10} On the other hand, mean operative time of SILS performed by residents was reported as 164-214 minutes.^{13,14} However, 80.8% of cases in the Novice group in this study underwent D3 lymphadenectomy, which has been associated with longer operative time. Other perioperative outcomes, including blood loss, multivisceral resection rate, and postoperative complications, did not differ between groups, and were comparable with findings from previous studies.⁵⁻¹⁰ Although this study analyzed only 172 patients and was retrospective in nature, our results with SILS performed by novice surgeons showed high reliability in terms of operative time and successful completion rate in patients with CRC.

In cancer treatment, oncological clearance must take precedence over cosmetic advantages or reduced invasiveness. Although no significant differences were found in terms of tumor location, clinical TNM classification, or operative procedures, more lymph nodes were harvested and a higher proportion of patients with pathological lymph node metastases were seen in the Experienced group. However, the oncological outcomes, regardless of surgeon experience, were comparable to those of randomized control trials comparing open and multi-port laparoscopic surgery for CRC,²³⁻²⁶ as well as those comparing multi-port laparoscopic surgery and SILS for colon cancer.⁸⁻¹⁰ Although these results may have been affected by the proficiency of the individual surgeons, we consider the oncological outcomes of our study, including for novice surgeons, to be valid.

For the present study, the number of pathological Stage III patients was greater in the Experienced group, but no significant differences were found in terms of the 3-year disease-free survival rate, 3-year overall survival rate, or recurrence pattern. We examined survival rates for each stage, but no significant differences were found between groups in each stage (data not shown). Several studies have reported long-term outcomes of SILS for colon cancer equivalent to those of multi-port laparoscopic surgery using propensity

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FIGURE 2 Kaplan-Meier analysis of the 3-year disease-free survival rate between groups



FIGURE 3 Kaplan-Meier analysis of the 3-year overall survival rate between groups

score-matching analysis,^{6,27,28} comparable to our results regardless of surgeon experience. Our oncological results may have been due to the small number of patients in each stage.

Optimal methods for teaching novice surgeons to safely perform SILS colorectal surgery remain unclear. A few studies have examined the effects of training SILS tasks²⁹⁻³¹; however, to the best of our knowledge, there have not been any clinical evaluations of SILS training. In this study, there was a significantly higher rate of right-sided colon (P < 0.001) among the patients that underwent SILS performed by novice surgeons compared to the overall cohort. In our institute, SILS ileocecal resection has been adopted as a training procedure for novice surgeons. Moreover, advanced SILS colorectal surgeries, such as right hemicolectomy, transverse colectomy, and anterior resection, are indicated according to the proficiency level of each surgeon. We believe that novice surgeons, if properly taught the necessary steps, can safely perform SILS colorectal surgery.

Our study has several limitations warranting consideration. First, data were obtained retrospectively from a single, high-volume

center. To overcome this limitation, we matched cases using several clinical variables, balancing the groups and reducing selection bias. However, potential for selection bias remains, despite the propensity score-matching. Second, BMI in our cohort was typical of a Japanese population, and the generalizability of our results to the higher-BMI populations of Western countries is thus questionable, and BMI may significantly affect the feasibility of SILS performed by novice surgeons. Third, follow-up was short in both groups. The long-term oncological outcomes or rates of later complications such as umbilical incisional hernia thus could not be assessed. Fourth, we did not analyze the learning curve of novices because there were individual differences in the surgical proficiency and the number of cases among the four novice surgeons. We plan to analyze the learning curve of novice surgeons in the future, if a greater number of cases can be accumulated. Despite these limitations, we consider that this analysis of about 1000 cases using propensity scorematching demonstrated that SILS performed by novice surgeons for CRC is safe and feasible. Further analysis is needed to validate our results, and to evaluate long-term oncological outcomes in future randomized clinical trials.

5 | CONCLUSIONS

Although SILS is an advanced, minimally invasive technique, SILS for CRC was safely performed by novice surgeons under the guidance of experienced surgeons, and could provide satisfactory oncological outcomes regardless of the surgeons' experience.

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DISCLOSURE

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Conflict of Interest: Tsunekazu Mizushima is an editorial board member.

Author Contribution: MT and YS conceived and designed the study. MT, YS, MO, KI, AN, MI, TM, and HA acquired the data. MT and YS analyzed and interpreted the data. MT drafted the manuscript. YS, MO, KI, AN, MI, TM, and HA critically revised the article. MT, YS, MO, KI, AN, MI, TM, and HA approved the final version of the manuscript to be published.

Ethics: The study protocol was approved by a suitably constituted Ethics Committee of the institution and it conforms to the provisions of the Declaration of Helsinki. It was approved by the Ethics Committee of Osaka Police Hospital (Osaka, Japan), Approval No. 2021-1350.

Informed consent was obtained from all patients before the surgery. This research was not preregistered in an independent, institutional registry (N/A).

This research was not an animal study (N/A).

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