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**Comprehensive complication index as a prognostic factor in minimally invasive
esophagectomy for esophageal squamous cell carcinoma**

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Conflict of Interest Statement

All of our authors declare that we have no conflict of interest.

Abstract

Introduction: Postoperative complications affect long-term prognosis in patients with esophageal squamous cell carcinoma (ESCC). Although a comprehensive estimator can predict long-term prognosis, the Clavien–Dindo classification system, a widely used approach to evaluate complications, assesses each complication individually. We aimed to clarify the utility of the comprehensive complication index (CCI) on predicting the overall survival (OS) of patients with ESCC following minimally invasive esophagectomy (MIE).

Methods: This was a retrospective study of patients undergoing MIE for ESCC in the prone position between January 2011 and December 2018. Univariate and multivariate analyses using the Cox proportional hazards model were performed to determine independent risk factors for OS.

Results: The study cohort included 229 patients who were categorized into patients with CCI values of ≥ 33.7 (CCI high) and < 33.7 (CCI low) by receiver-operating characteristic (ROC) curve analysis. There were no significant differences between the two groups according to clinicopathological factors such as sex, age, tumor location, tumor depth, lymph node metastasis, and neoadjuvant chemotherapy. The intraoperative transfusion rate in the CCI high group was significantly higher than in the CCI low group. The 5-year OS rate was significantly lower in the CCI high group than in the CCI low group (49.5% vs. 65.7%, $p = 0.030$). By multivariate analyses, lymph node metastasis, tumor depth, and the CCI were independent predictors of OS.

Conclusions: Comprehensive assessment of postoperative complications using the CCI was useful in predicting OS of patients undergoing MIE for the ESCC.

Key words: minimally invasive esophagectomy, esophageal squamous cell carcinoma, comprehensive complication index

1 **Introduction**

2 Surgery is the standard treatment for esophageal carcinoma, the seventh most common
3 cancer in the world [1, 2]. Minimally invasive esophagectomy (MIE), which has become a
4 popular surgical approach in the last decade, can reduce postoperative complications,
5 especially those involving the respiratory system; however, the incidence of complications
6 remain high, with pulmonary morbidity of 16.2% in patients undergoing MIE [3].

7 Several studies have reported that complications impact short- and long-term outcomes in
8 various cancers [4-9]. The Clavien–Dindo classification, commonly used to measure the
9 severity of surgical complications, evaluates each complication individually. A comprehensive
10 estimate is necessary to assess the impact of complications on survival because various
11 complications can simultaneously occur after esophagectomy [10]. The comprehensive
12 complication index (CCI) is a comprehensive assessment approach based on the Clavien–
13 Dindo classification [11, 12]. Several studies have reported a significant relationship between
14 the CCI and postoperative prognosis in other cancer [13-16]. Similarly, the CCI may
15 significantly impact long-term outcomes in patients with esophageal cancer treated with MIE.
16 In the present study, we evaluated the association of CCI with survival in patients with
17 esophageal squamous cell carcinoma (ESCC) who underwent MIE.

18 19 **Methods**

20 **Study population**

21 This study was a single-center, retrospective cohort including 295 patients with ESCC who
22 underwent MIE, also known as McKeown three-stage esophagectomy, in the prone position
23 between January 2011 and December 2018 [17]. In all patients, the ESCC diagnosis was
24 confirmed by esophagogastroduodenoscopy and biopsy. Computed tomography (CT)
25 (contrast-enhanced if possible) and/or positron emission tomography were used to examine
26 tumor depth as well as regional lymph node and distant metastases. Cancer staging was

performed according to the seventh Tumor–Node–Metastasis cancer staging system published by the Union for International Cancer Control [18]. All eligible patients met the following criteria: age > 20 years, ESCC confirmed by preoperative biopsy, pT1–4 pathological tumor stage, and pN0–3 lymph node metastasis stage. A total of sixty-six patients were excluded, including twenty-five patients whose tumor locations were not thoracic region, five patients who underwent MIE as salvage surgery, seven patients who underwent total pharyngolaryngeal dissection, and twenty-nine patients with incomplete resection. Patients with clinical stage II or III cancer received neoadjuvant chemotherapy with cisplatin and 5-fluorouracil. None of the patients in the present study received neoadjuvant radiotherapy.

The Ethics Committee of Kobe University and the institutional review board approved this study on April 27th, 2021. All patients who met the inclusion criteria provided written informed consent.

Surgical procedure

Thoracoscopic esophagectomy was conducted with the patient in the prone position. All surgeries were performed by one of the five surgeons who were qualified in Japanese endoscopic surgical skills and had done more than 30 MIEs before the study period [19]. Five ports were inserted in the ninth intercostal space (ICS) on the scapular angle line, the eighth ICS on the midaxillary line, the seventh and fifth ICS on the posterior axillary line, and third behind the midaxillary line, and the chest cavity was inflated via the ports with a CO₂ insufflation pressure of 8 mmHg. The endoscope was basically inserted through the ninth ICS. A new method (the "Bascule method") for lymphadenectomy along the left recurrent laryngeal nerve during prone esophagectomy for esophageal cancer [20].

Gastric conduit reconstruction via a posterior mediastinal route was performed in all cases. The neck was the site of anastomosis in all patients.

Outcomes

Postoperative clinical course

In the present study, CCI values were determined based on the severity of all postoperative complications within the first 30 days after surgery. The severity of all complications was classified according to the Clavien–Dindo classification system [11]. Postoperative complications were included recurrent laryngeal nerve (RLN) palsy, postoperative pneumonia, anastomotic leakage, pulmonary thrombosis, deep vein thrombosis, arrhythmia, ischemic stroke, subarachnoid hemorrhage, sepsis, surgical site infection, postoperative cholecystitis, enteritis, chylothorax, pneumothorax, mediastinal emphysema, tracheoesophageal fistula, gastric conduit necrosis, and delirium. For the diagnosis of RLN palsy, an otolaryngologist from the study institution routinely examined vocal cord mobility using a flexible laryngoscope on postoperative day seven in all patients undergoing MIE. The diagnosis of postoperative pneumonia was based on clinical manifestations of pneumonia or bronchopneumonia by radiological tests, including CT and positive sputum culture during the initial two weeks after surgery. Anastomotic leakage was diagnosed based on drainage characteristics, CT scan findings, and esophagogastroduodenoscopy results.

After discharge, all patients underwent periodic evaluation after surgery, including blood tests every three months, and CT scans and esophagogastroduodenoscopy every year. After the five-year follow-up, the patients could continue with continuous follow-up in the study institution or with their family physician.

CCI determination

The CCI, developed by Slankamenac *et al.*, is based on the severity of postoperative complications according to the Clavien–Dindo classification [11,12]. The CCI yields a scale from 0 (no complication) to 100 (death) based on the following formula: $CCI = \sqrt{(\sum (wC))}/2$. The weight of complication (wC) and the CCI calculator are freely available at

1 www.assessurgery.com.

3 Statistical analysis

4 All statistical analyses were performed using JMP 14 (SAS Institute, Cary, NC, USA).
5 Receiver-operating characteristic (ROC) curve analysis was used to determine the proper CCI
6 cutoff value [21]. The comparisons of patient characteristics were performed using Pearson's
7 chi-square and Student's *t* test, as appropriate. Each clinicopathological factor was classified
8 into a binary variable, and univariate and multivariate analyses were performed using the Cox
9 proportional hazards model. In univariate analyses, clinicopathological factors with *p* values
10 of < 0.05 were considered statistical significance and selected for multivariate analysis. Overall
11 survival (OS) rates were assessed using the Kaplan–Meier and the log-rank test, and *p* threshold
12 for statistical significance was set to < 0.05 .

14 Results

15 Postoperative complication

16 A total of 229 patients were included in the final analysis (Figure 1). Postoperative
17 complications with a Clavien–Dindo grade of $\geq$ I within 30 days after surgery developed in 162
18 (70.7%) patients, including 47, 72, 30, 23, 3, 3, and 1 case with Clavien–Dindo grade I, II, IIIa,
19 IIIb, IVa, IVb, and V complications, respectively. Multiple complications occurred in 48 (30%)
20 patients. The mean CCI was 15.8, and the range was 0 to 100.

22 Distribution and ROC analysis of the CCI

23 The patients divided by each CCI score were distributed as Figure 2. By the ROC analysis, the
24 CCI cutoff value of 33.7 had the highest sensitivity and specificity for OS, with an AUC of
25 0.56. Therefore, the study patients were categorized into those with CCI values of ≥ 33.7 (CCI
26 high) and < 33.7 (CCI low).

Comparison of the patients with the CCI values of ≥ 33.7 (CCI high) and < 33.7 (CCI low)

The characteristics of the CCI high group and the CCI low group are shown in Table 1. We determined the CCI cutoff value as 33.7 by the ROC analysis. There were no significant differences between the two groups regarding preoperative factors, including age, tumor location, tumor depth, regional lymph node metastasis, distant metastasis, neoadjuvant chemotherapy, the rate of three-field lymphadenectomy, and total and thoracic procedure time. The number of patients with blood loss (≥ 200 mL) and the intraoperative transfusion rate were significantly higher in the CCI high group than in the CCI low group (66% vs. 46%, $p = 0.03$) (46% vs. 20%, $p = 0.001$). The state and distributions of each complication in each group was shown (Figure 3)

Survival analysis

In the overall cohort of 229 patients, the median OS was 49.4 months, and the 5-year OS rate was 62.3% by the Kaplan–Meier analysis. Comparison of the Kaplan–Meier survival curves using the log-rank test (Figure 4) revealed that the 5-year OS rate of the CCI high group was significantly lower than the CCI low group (49.5% vs. 65.7%, $p = 0.030$).

Univariate and multivariate analyses of OS

Table 2 shows the results of univariate and multivariate analyses performed using the Cox proportional hazards model to determine independent factors associated with OS. In univariate analyses, pT3–4 stage ($p < 0.0001$), pN+ status ($p < 0.0001$), neoadjuvant chemotherapy (yes, $p < 0.0001$), intraoperative transfusion (yes, $p = 0.007$), and CCI high ($p = 0.04$) were significantly associated with OS. The multivariate analysis including these factors revealed that pT3–4 stage ($p < 0.0001$), pN+ status ($p = 0.001$), and CCI high ($p = 0.003$) were significantly associated with poor prognosis.

Discussion

In this single-center, retrospective study of 229 patients, the CCI was an independent predictor of OS in patients with ESCC treated with MIE. The intraoperative blood loss and transfusion rate in the CCI high group were significantly greater than in the CCI low group. This suggests that a high CCI might be associated with operative factors related to tumor invasiveness. Longer operation time, increased intraoperative blood loss, and additional regions for lymph node dissection are associated with surgical invasion [13-16]. During esophagectomy, more extensive surgical invasion is associated with postoperative complications such as pneumonia, RLN palsy, and anastomotic leakage. Oshikiri *et al.* reported that three-field lymph node dissection was associated with a significantly higher risk of postoperative pneumonia, which resulted in increased CCI values [22]. The CCI is a comprehensive postoperative estimator of the severity of complications based on the Clavien–Dindo classification. Although the Clavien–Dindo classification is a commonly used estimator of postoperative complications, it is not a comprehensive indicator and can be inappropriate for estimation in patients with multiple complications. For example, using the Clavien–Dindo classification, it is challenging to compare a patient with two grade II complications to another patient with one grade I and one grade IIIa complication. In the present study, 30% of the patients with postoperative complications had multiple complications. Our ROC analysis using a specific cutoff value revealed that the CCI was an independent risk factor of OS. We also examined the relationship between the CCI and disease-specific survival, and there was no significance (data not shown). These results suggest that the high CCI is related to poor prognosis, not from esophageal cancer.

Several studies previously reported the association between the CCI and prognosis in patients with cancer [13-16]. For example, a CCI cutoff value of 26.2, which was equivalent to one grade IIIa complication, was used in several studies [12, 23]. Shimizu *et al.* utilized a cutoff CCI value of 32.15 based on the ROC analysis of patients with Clavien–Dindo grade II-IV

1 complications after surgery for gastric cancer [15]. A higher CCI was reported to be associated
2 with age, sex, Charlson comorbidity score, combined resection, open surgery, and total
3 gastrectomy in patients with gastric cancer [13, 14]. Other investigators reported that the CCI
4 correlated with neutrophil/lymphocyte ratio and poor long-term prognosis after resection [15,
5 16]. A high CCI was associated with increasing neutrophil/lymphocyte ratio, an indicator of
6 systemic inflammation before and after surgery related to poor prognosis. Nakagawa *et al.*
7 reported the correlation between surgical Apgar score and long-term prognosis after
8 esophagectomy. 24 The authors found that surgical factors influenced surgical Apgar score and
9 postoperative complications. These results support our findings showing that a high CCI was
10 associated with operative factors. However, few reports examined the association between the
11 CCI and prognosis of esophageal cancer after surgery. To our knowledge, this is the first report
12 elucidating the relationship between the CCI and long-term prognosis after MIE for ESCC.

13 Several studies reported the correlation between complications and postoperative
14 prognosis in patients with ESCC. Respiratory complications, such as pneumonia and other
15 complications, were associated with worse long-term survival [9, 10, 24, 25]. These studies
16 used the Clavien–Dindo classification system or the presence of complications. However, the
17 contribution of relatively mild or multiple complications was not considered in previous studies.
18 For example, in the present study, the CCI threshold of 33.7 is similar to one C-D grade IIIb
19 complication. However, in our study, some of the CCI high cases consisted of multiple
20 complications those were lower than C-D grade IIIb.

21 The present study has several limitations that should be acknowledged. First, this single-
22 center retrospective study might have a more significant surgical bias compared with
23 multicenter studies. Second, only three major complications were used to calculate the CCI and
24 further investigation is necessary to confirm factors associated with increased CCI. Third,
25 although the CCI cutoff value of 33.7 used in the present study was similar to the previous
26 research, optimal CCI cutoff values for OS estimation remain unclear [14,15]. Previous studies

1 investigated their utility in small cohorts of patients with various types of cancer. Large-scale
2 trials are warranted to address this issue.

3

4 **Conclusions**

5 CCI should be considered as a predictive factor for survival in patients undergoing MIE for
6 ESCC.

7

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Figure legends

Figure 1. Flowchart of this study.

Figure 2. Distribution of the CCI

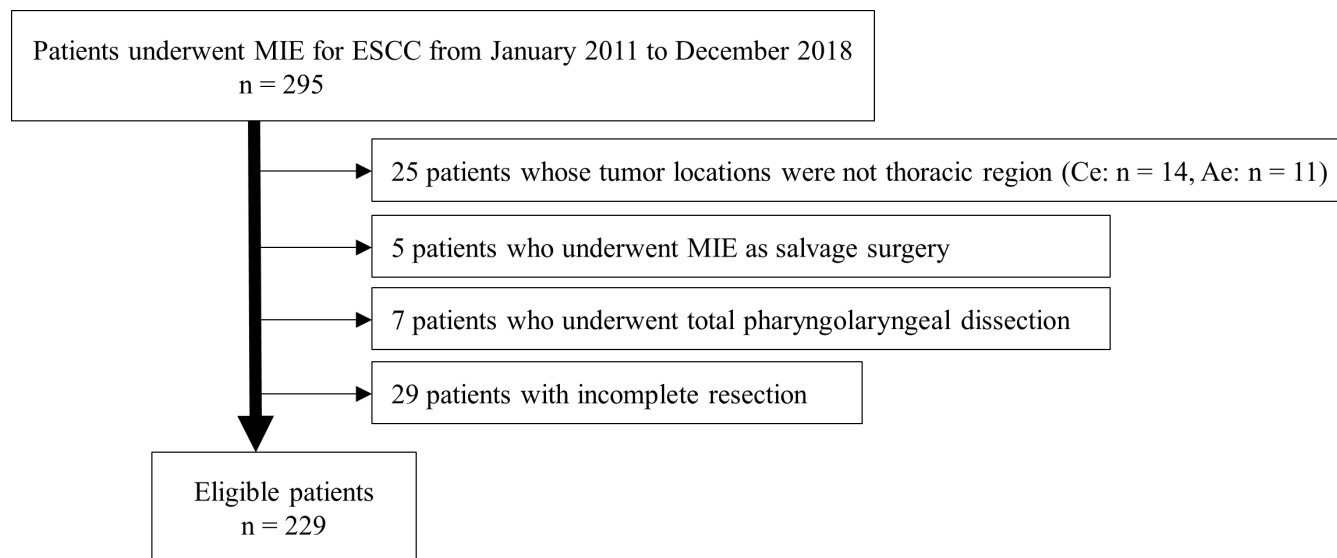
The vertical dashed line showed that the patients were divided into two groups by CCI score of 33.7.

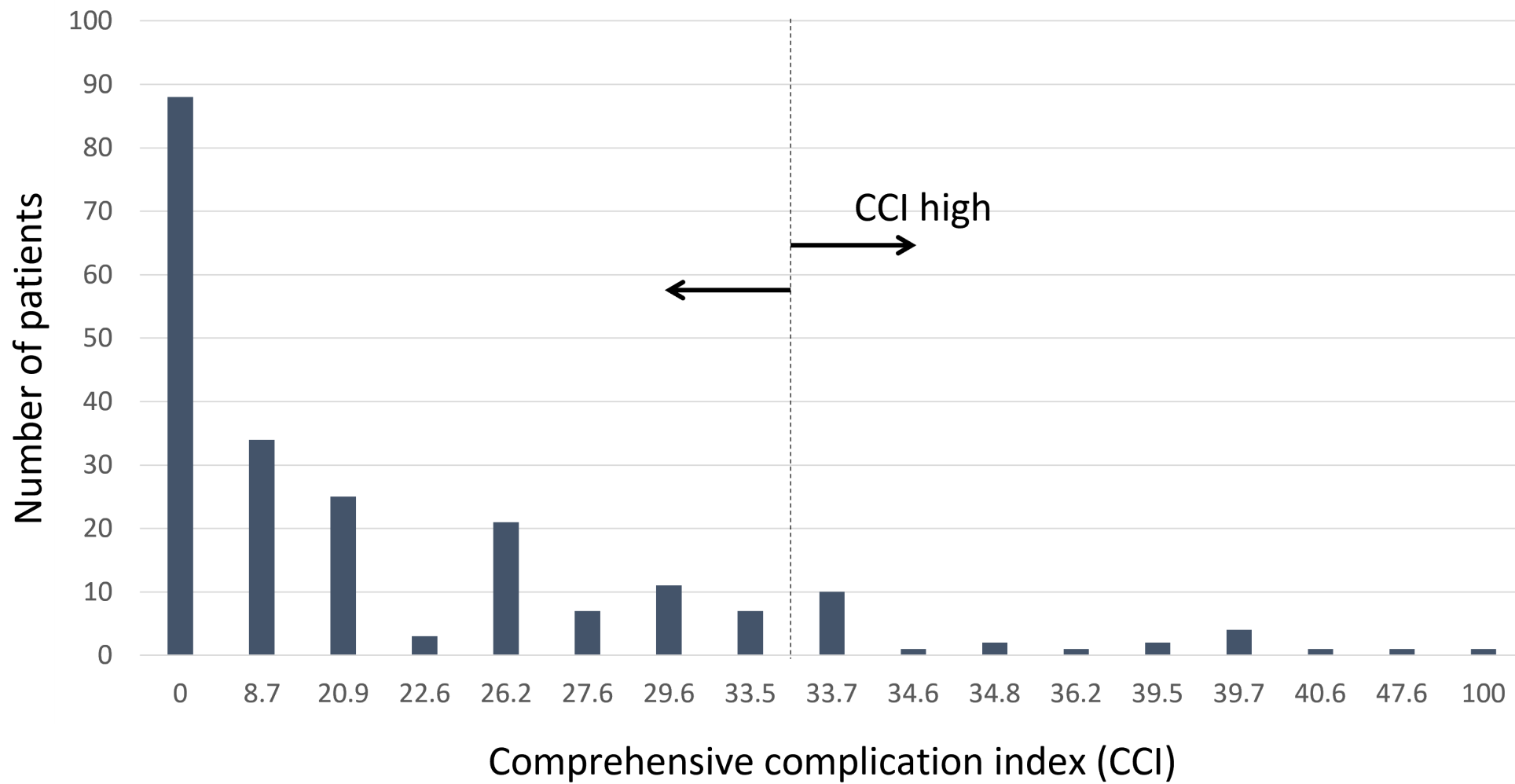
Figure 3. State of each complication in each group

Horizontal line shows each grade of Clavien-Dindo classification. The vertical line shows the number of patients occurred each complication.

Figure 4. Kaplan-Meier curves of OS

The markers on the curves show censored data. The 5-year OS rate of the CCI high group is significantly lower than the CCI low group (49.5% vs. 65.7%, $p = 0.030$).

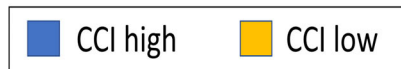




Number of complications



Claven-Dindo classification



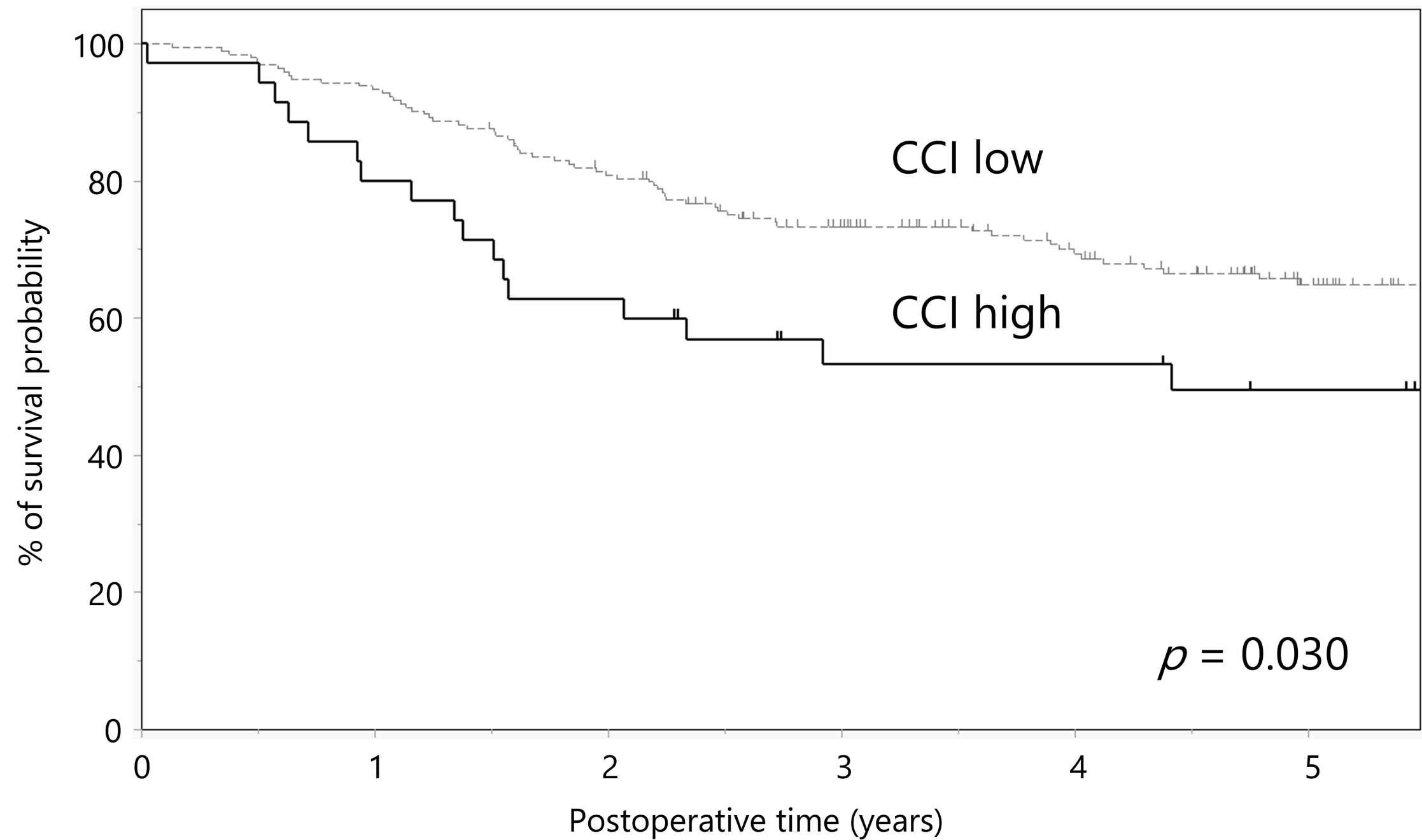


Table 1. Clinicopathological characteristics of the study cohort based on CCI

Factors	CCI ≥ 33.7 ($n = 35$)	CCI < 33.7 ($n = 194$)	<i>p</i>
Sex, Male/Female	30/5 (86%/14%)	164/30 (85%/15%)	0.86 [†]
Age, years*	67 [42–81]	69 [55–79]	0.14 [‡]
<73/ ≥ 73 years	27/8 (77%/23%)	153/41 (79%/21%)	0.81 [†]
BMI, kg/m ² *	19.38 [14.05–26.47]	20.845 [12.77–28.04]	0.03 [‡]
≤ 19.72 / > 19.72 kg/m ²	19/16 (54%/46%)	68/126 (35%/65%)	0.03 [†]
Comorbidity, n (%)			
Hypertension	13 (37%)	63 (35%)	0.59 [†]
Diabetes mellitus	8 (23%)	14 (7%)	0.004 [†]
COPD	1 (3%)	9 (5%)	0.63 [†]
Anticoagulants use	1 (3%)	7 (4%)	0.82 [†]
ASA-PS 1/2/3/4	5/26/4/0 (14%/74%/11%/0)	36/150/6/2 (19%/77%/3%/1%)	0.14 [†]
ASA-PS 1-2/3-4	31/4 (89%/11%)	186/8 (96%/4%)	0.07 [†]
Location, Ut/ Mt/ Lt	2/22/11 (6%/63%/31%)	32/105/57 (17%/54%/29%)	0.19 [†]
Tumor depth, pT1–2/3–4	28/7 (80%/20%)	130/64 (67%/33%)	0.11 [†]
Lymph node metastasis, pN0/1-3	20/15 (57%/43%)	99/95 (51%/49%)	0.50 [†]
Neoadjuvant chemotherapy, no/yes	11/24 (31%/69%)	59/135 (30%/70%)	0.90 [†]
Lymph node dissection, two-field/three-field	20/15 (43%/57%)	133/61 (69%/31%)	0.19 [†]
Operation time			
– Total (min)*	693 [443–891]	684.5 [302–1061]	0.96 [§]
– Thoracic procedure (min)*	297 [180–523]	311.5 [150–600]	0.23 [§]
Blood loss, < 235 / ≥ 235 mL	15/20 (43%/57%)	120/74 (62%/38%)	0.03 [†]
Intraoperative transfusion, no/yes	19/16 (54%/46%)	154/39 (80%/20%)	0.001 [†]

Abbreviation: CCI, comprehensive complication index; BMI, body mass index; COPD, chronic obstructive pulmonary disease; ASA-PS, American Society of Anesthesiologists

Physical Status; Lt, lower thoracic; Mt, middle thoracic; Ut, upper thoracic,

*: median [range], †: Pearson's chi-square test, ‡: Student's *t* test, §: Mann–Whitney *U* test

Table 2. Multivariate analyses of prognostic factors

Factors		<i>n</i>		Multivariate analysis		
				OR	95% CI	<i>p</i>
Sex						
	Female	35	(15%)			
	Male	194	(85%)	1.72	0.84-3.80	0.13
Age						
	<73 years	180	(79%)			
	≥73 years	49	(21%)	1.72	1.05-2.81	0.03
BMI						
	>19.72 kg/m ²	142	(62%)			
	≤19.72 kg/m ²	87	(38%)	1.32	0.83-2.10	0.24
ASA-PS						
	1, 2	217	(95%)			
	3, 4	12	(5%)	1.08	0.42-2.78	0.87
pT						
	1, 2	158	(69%)			
	3, 4	71	(31%)	3.33	2.04-5.44	<0.0001
pN						
	0	119	(52%)			
	1-3	110	(48%)	2.47	1.50-4.08	0.0004
Intraoperative transfusion						
	No	174	(76%)			
	Yes	55	(24%)	1.37	0.84-2.24	0.21
Comprehensive complication index						
	< 33.7	194	(85%)			
	≥ 33.7	35	(15%)	2.67	1.46-4.87	0.001

CI, confidence interval; OR, odds ratio; Lt, lower thoracic; Mt, middle thoracic; Ut, upper thoracic