

The Global Immune-Nutrition-Information Index (GINI) Is an Independent Prognostic Factor for Esophageal Cancer Patients Who Receive Curative Treatment

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Abstract. *Background/Aim:* The aim of the present study was to evaluate the clinical impact of the Global Immune-Nutrition-Information Index (GINI) in patients with esophageal cancer (EC) who received curative treatment and to clarify the potential of the GINI as a prognostic factor. *Patients and Methods:* Patients who underwent curative resection for EC at Yokohama City University between 2000 and 2020 were consecutively chosen based on their medical records. The GINI was defined as follows: $GINI = [C\text{-reactive protein} \times \text{platelet} \times \text{monocyte} \times \text{neutrophil}] / [\text{albumin} \times \text{lymphocyte}]$. *Results:* This study included 180 patients. Among them, 67 were categorized into the GINI-low group and 113 were categorized into the GINI-high group, with a cutoff value of 5000. The 3- and 5- year overall survival (OS) rates were 75.6% and 64.9%, respectively, in the GINI-low group and 55.3% and 48.1% in the GINI-high group ($p=0.005$). According to a multivariate analysis for OS, the GINI was identified as an independent prognostic factor [hazard ratio=2.106, 95% confidence interval=1.252-3.544, $p=0.005$]. Similar results were observed for RFS. In addition, the GINI

affects preoperative tube feeding and the induction rate of neoadjuvant chemotherapy (NAC). *Conclusion:* The GINI is a promising biomarker for the treatment and management of EC.

In 2020, 604,000 people were diagnosed with esophageal cancer (EC) worldwide, with an estimated 544,000 dying from the disease (1, 2). The standard treatment for locally advanced EC is chemoradiotherapy and surgical resection, but the prognosis after recurrence is extremely poor (3, 4). Therefore, the search for promising prognostic factors and more aggressive treatments using prognostic factors is necessary to improve outcomes.

Various prognostic factors have been reported for the treatment and management of EC (5-7). Recently, prognostic factors based on inflammation have included the neutrophil-to-lymphocyte ratio (NLR), platelet-to-lymphocyte ratio (PLR), lymphocyte-to-monocyte ratio (LMR), and systemic immune inflammation index (SII), including the prognostic nutritional index (PNI), Glasgow prognostic score (GPS), and modified Glasgow prognostic score (mGPS) (8-14). These prognostic factors are involved in tumor development and influence the clinical prognosis.

Recently, Topkan *et al.* reported that the GINI is a useful prognostic factor for stage IIIc non-small cell lung cancer patients treated with chemoradiotherapy (15). The GINI can assess the nutritional and inflammatory status simultaneously and it is very useful for predicting oncological outcomes. Considering these findings, we hypothesized that the GINI may be useful for EC. Because patients with EC receive chemotherapy before and after surgery, perioperative inflammation and the nutritional status are considered important. However, no reports have so far evaluated the clinical impact of the GINI in EC. The aim of the present study was to evaluate the clinical impact of the GINI in EC patients treated with curative therapy and to clarify the potential of the GINI as a prognostic factor in the treatment of EC.

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Table I. Patient characteristics.

Characteristics	No. of patients (%) (n=180)	Global immune and nutritional index <5,000 group (n=67)	Global immune and nutritional index ≥5,000 group (n=113)	p-Value
Age (years)				0.261
<70	52.8	39	56	
≥70	47.2	28	57	
Sex				0.757
Male	86.1	57	98	
Female	13.9	10	15	
Site of tumor				0.207
Upper	29.4	16	37	
Middle and lower	70.6	51	76	
T status				0.153
T1	43.9	34	45	
T2 to T4	56.1	33	68	
Lymph node metastasis				0.844
Negative	52.8	36	59	
Positive	47.2	31	54	
Lymph-vascular invasion				0.846
Negative	32.2	21	37	
Positive	67.8	46	76	
Postoperative complications				0.207
Yes	70.6	51	76	
No	29.4	16	37	

UICC: Union for International Cancer Control.

Patients and Methods

Patients. Patients who underwent curative resection for EC at Yokohama City University between 2000 and 2020 were selected based on their medical records. Patients who met the following criteria were included in the study: 1) histologically confirmed squamous cell carcinoma; 2) clinical stage 0-III disease, defined according to the 12th edition of the general rules of the Japanese Esophageal Cancer Association for EC (16); 3) curative esophagectomy as the primary treatment and esophagectomy after preoperative chemoradiotherapy or chemotherapy for EC; and 4) complete (R0) resection of EC.

The same dataset used in this study was also used in the study conducted by Aoyama *et al.* (17).

Surgery and adjuvant treatment. All the patients in the present study underwent esophagectomy with either 2- or 3-field lymph node dissection. Patients with pathological stage II or III disease also received adjuvant chemotherapy (18).

Determination of the Global Immune-Nutrition-Information Index (GINI). The GINI was defined as follows: $GINI = [C\text{-reactive protein} \times \text{platelets} \times \text{monocytes} \times \text{neutrophils}] / [\text{albumin} \times \text{lymphocytes}]$ (15).

Follow-up. Follow-up evaluations were carried out at outpatient clinics, where patients underwent hematological tests (including tumor marker measurements) and physical examinations at least every three months for a duration of five years. Furthermore, within the initial three months, semiannual CT examinations were performed up to the fifth year after surgery.

Statistical analysis. The significance of the differences between GINI and clinicopathological factors was evaluated using the chi-square test. The Kaplan-Meier method was used to generate curves for overall and recurrence-free survival. A Cox proportional hazards model was used for the univariate and multivariate survival analyses. Statistical significance was set at $p < 0.05$. The SPSS software program (v27.0 Win; IBM, Armonk, NY, USA) was used to perform all the statistical analyses.

Ethical approval. Approval for the present study was obtained from the Institutional Review Board of Yokohama City University (F220500064).

Results

Patient background. This study included 180 patients (male, $n=155$; female, $n=25$; median age, 70 years). The comparison of overall survival (OS) according to the patients' clinicopathological factors revealed statistically significant differences in age, tumor site, T status, lymph node metastasis status, GINI, lymphovascular invasion status, and postoperative surgical complications. In the present study, we set the cutoff value of the GINI at 5000 based on previous studies and the 3- and 5- year OS (Table I). The patients in the present study were categorized into GINI-low ($n=67$) and GINI-high ($n=113$) groups. When comparing these groups, significant differences were found in NAC and preoperative tube feeding. The GINI

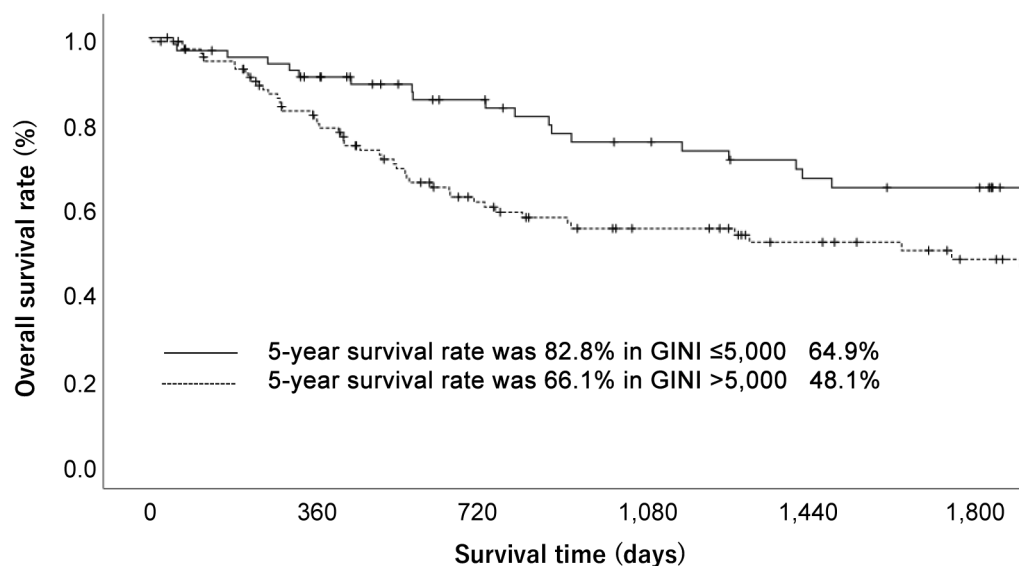


Figure 1. Overall survival of esophageal cancer patients in the global immune and nutritional index (GINI)-high and GINI-low groups.

Table II. Uni- and multi-variate Cox proportional hazards analysis of clinicopathological factors for overall survival.

Factors	No	Univariate analysis			Multivariate analysis		
		OR	95%CI	p-Value	OR	95%CI	p-Value
Age (years)				0.535			
<70	95	1.000					
≥70	85	1.160	0.727-1.851				
Sex				0.279			
Female	25	1.000					
Male	155	1.539	0.705-3.358				
T status				<0.001			0.007
T1	79	1.000			1.000		
T2 or T3	101	3.473	2.012-5.995		2.327	1.260-4.298	
Lymph node metastasis				<0.001			0.024
Negative	95	1.000			1.000		
Positive	85	2.644	1.625-4.302		1.793	1.081-2.975	
GINI				0.006			0.005
<5,000	67	1.000			1.000		
≥5,000	113	2.074	1.235-3.481		2.106	1.252-3.544	
Lymph-vascular invasion				<0.001			0.100
Negative	58	1.000			1.000		
Positive	122	3.243	1.742-6.037		1.794	0.895-3.596	
Tumor location				0.848			
Upper	53	1.000					
Middle, lower	127	1.051	0.631-1.750				
Postoperative complications				0.611			
No	53	1.000					
Yes	127	1.137	0.692-1.869				

GINI: Global immune and nutritional index.

high-group had a higher percentage of patients who received preoperative tube feeding. NAC was performed more frequently in the GINI-high group than in the GINI-low group.

Survival analysis. The 3- and 5- year OS rates were 75.6% and 64.9%, respectively, in the GINI-low group and 55.3% and 48.1% in the GINI-high group ($p=0.005$) (Figure 1). The

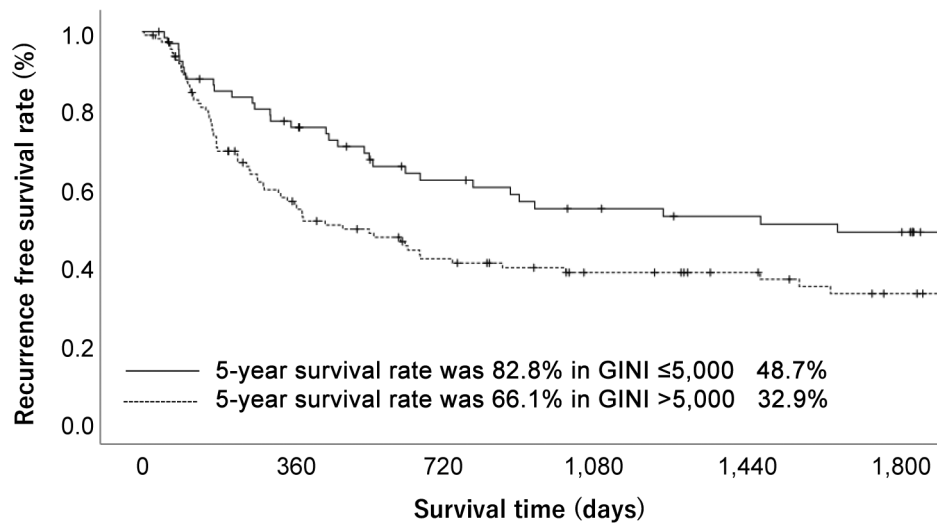


Figure 2. Recurrence-free survival of esophageal cancer patients in the global immune and nutritional index (GINI)-high and GINI-low groups.

following prognostic factors were identified in a univariate analysis for OS: age, T status, lymph node metastasis status, GINI, lymphovascular invasion status, tumor location, and postoperative surgical complications (Table II). In a multivariate analysis for OS, the GINI was identified as an independent prognostic factor [hazard ratio (HR)=2.106, 95% confidence interval (CI)=1.252-3.544, $p=0.005$]. The 3- and 5-year recurrence-free survival (RFS) rates were 54.7% and 48.7%, respectively, in the GINI-low group and 38.3% and 32.9% in the GINI-high group ($p=0.019$) (Figure 2). A univariate analysis for RFS identified the following prognostic factors: T status, lymph node metastasis status, GINI, lymphovascular invasion, tumor location, and postoperative surgical complications (Table III). In a multivariate analysis for RFS, the GINI was identified as a significant prognostic factor (HR=1.692, 95%CI=1.100-2.602, $p=0.017$).

Comparison of the postoperative clinical course. When the sites of recurrence were compared between the two groups, the GINI-high group had a significantly higher lymph node recurrence rate than the GINI-low group (34.5% vs. 16.4%, $p=0.009$) (Table IV).

Discussion

The aim of the present study was to evaluate the clinical impact of the GINI in EC patients treated with curative therapy and to clarify the potential of the GINI as a prognostic factor in the treatment of EC. The major finding of the present study was that the GINI affected OS and RFS, and thus could be a useful prognostic factor. Furthermore,

the GINI has been found to influence postoperative lymph node recurrence and to be associated with local disease control. Our results suggest that the GINI may be a useful prognostic biomarker for EC.

The CONUT method is a screening nutritional assessment method that evaluates nutritional levels by scoring blood parameters, such as albumin, total lymphocyte count, and total cholesterol (19). Several studies have reported the clinical significance of the CONUT score as a prognostic factor in gastrointestinal cancer (20, 21). Similar results have been reported in previous studies, and Topkan *et al.* reported the prognostic value of the GINI in patients with stage III non-small cell lung cancer (NSCLC) treated with radiation chemotherapy (15). The patients were divided into two groups: GINI-low ($n=364$) and GINI-high ($n=438$), using a cutoff value of 1562. There were significant differences in the median OS and 5-year OS between the two groups. The median OS was 37.8 months in the GINI-low group, and 19.1 months in the GINI-high group ($p<0.001$). Moreover, the 5-year OS was 32.1% in the GINI-low group and 7.9% in the GINI-high group ($p<0.001$). The 5-year locoregional failure (LRF) rate was 60% in the GINI-high group and 45.9% in the GINI-low group ($p=0.003$). The rate of distant metastasis was also worse in the GINI-high group than in the GINI-low group (89.9% vs. 76.6%; $p=0.001$). Aoyama *et al.* also reported that the GINI is a useful prognostic factor in patients with gastric cancer who received curative treatment (17). Their patients were divided into two groups: GINI-low ($n=169$) and GINI-high ($n=89$), using a cutoff value of 1,730. There were significant differences in the 3- and 5- year OS rates between the two groups. The 3- and 5- year OS rates were 86.4% and 78.4%, respectively, in the GINI-

Table III. Uni and Multivariate Cox proportional hazards analysis of clinicopathological factors for recurrence-free survival.

Factors	No	Univariate analysis			Multivariate analysis		
		OR	95%CI	p-Value	OR	95%CI	p-Value
Age (years)				0.885			
<70	95	1.000					
≥70	75	1.030	0.689-1.539				
Sex				0.291			
Female	25	1.000					
Male	155	1.403	0.749-2.628				
T status				<0.001			<0.001
T1	79	1.000			1.000		
T2 or T3	101	4.434	2.744-7.165		2.885	1.698-4.901	
Lymph node metastasis				<0.001			0.060
Negative	95	1.000			1.000		
Positive	85	2.420	1.606-3.647		1.503	0.983-2.298	
GINI				0.019			0.017
<5,000	67	1.000			1.000		
≥5,000	113	1.669	1.087-2.562		1.692	1.100-2.602	
Lymph-vascular invasion				<0.001			0.010
Negative	58	1.000			1.000		
Positive	122	4.021	2.313-6.990		2.225	1.213-4.083	
Tumor location				0.840			
Upper	53	1.000					
Middle, lower	127	1.047	0.671-1.632				
Postoperative complications				0.785			
No	53	1.000					
Yes	127	1.062	0.690-1.634				

GINI: Global immune and nutritional index.

Table IV. Patterns of recurrence according to global immune and nutritional index.

Recurrence site	GINI				p-Value
	<5,000 (n=67)		≥5,000 (n=113)		
	Number	%	Number	%	
Hematological recurrence	18	26.9	39	34.5	0.286
Lymph node recurrence	11	16.4	39	34.5	0.009
Local site	7	10.4	19	16.8	0.240

GINI: Global immune and nutritional index.

low group and 66.4% and 58.3%, respectively, in the GINI-high group ($p<0.0001$). Moreover, the GINI-low group had 3- and 5- year RFS rates of 81.4% and 76.3%, respectively. In contrast, the GINI-high group had 3- and 5- year RFS rates of 63.7% and 54.5%, respectively ($p<0.001$). The peritoneal recurrence rate was significantly higher in the GINI-high group than in the GINI-low group (21.3% vs. 7.1%, $p<0.001$).

The induction rate of NAC was significantly higher in the GINI-low group than in the GINI-high group. The GINI-low group had a significantly lower incidence of lymph node

recurrence than the GINI-high group. This may have been influenced by the introduction of NAC, which suppresses the mitogenic potential of the tumor and the spread of tumor cells by surgery, thereby preventing distant metastasis and recurrence (22). The introduction of NAC and the prevention of recurrence were considered to be responsible for the significantly higher OS and lower RFS in the GINI-low group relative to the GINI-high group. Aoyama *et al.* (17) reported similar results, noting that postoperative adjuvant chemotherapy was required in 31.4% of the patients in the GINI-low group and 56.2% of the patients in the GINI-high

group ($p < 0.001$). Nevertheless, the percentages of patients who received postoperative adjuvant chemotherapy in the GINI-low and GINI-high groups were 64.1% and 52.0%, respectively. The rate of introducing postoperative adjuvant chemotherapy was higher in the GINI-low group than in the GINI-high group. They also reported significant differences in OS, RFS, and peritoneal recurrence between the GINI-low and GINI-high groups, thus suggesting that the rate of induction of adjuvant chemotherapy may have contributed to these differences. These results suggest that the GINI may be involved in the initiation of chemotherapy and may affect the patient prognosis. The GINI is also an indicator of the preoperative nutritional status. In this study, the preoperative tube-feeding rate was higher in the GINI-high group than in the GINI-low group.

This suggests that more patients with a poor nutritional status requiring preoperative tube feeding were in the GINI-high group. The ESPEN (European Society for Clinical Nutrition and Metabolism (ESPEN) guidelines recommend 7-14 days of preoperative nutritional therapy for patients undergoing cancer surgery who are at risk for severe nutritional problems (23). The GINI-high group was more likely to have poor preoperative nutritional status and lower OS than the GINI-low group. Topkan *et al.* noted that the GINI incorporates CRP and albumin, two nutritional indicators that are also recognized as indicators of cancer cachexia, and that the GINI may have influenced the patients' nutritional status and susceptibility to developing cancer cachexia during CCRT treatment or subsequent follow-up periods. They reported that the GINI-high group probably had a pre-cachectic health status, which may have later transformed into cancer cachexia, with a significant negative impact on survival. These findings suggest that the GINI reflects the pretreatment nutritional status of patients and has an impact on their prognosis.

The present study was associated with some limitations. First, it was a retrospective study conducted at a single institution. Therefore, the possibility of a selection bias cannot be ruled out. Second, our study included patients treated between 2000 and 2020. The treatment guidelines for EC changed significantly during this period, which may have affected OS and RFS. Third, the optimal cutoff value of the GINI is unclear. Establishing an optimal cutoff value for the use of GINI in clinical practice is important for effective treatment and management. We set the cutoff value of the GINI at 5000 according to the 3- and 5- year survival rates. In contrast, Aoyama *et al.* set the cutoff value of the GINI at 1,730. These differences might be due to differences in patient background factors, the number of patients, and treatment methods. Therefore, further studies are needed to determine the optimal cutoff value of the GINI. Given these findings, our study needs to be validated in a larger cohort.

In conclusion, the GINI is a useful prognostic factor for EC. The GINI status is also related to the patient's preoperative nutritional status and the rate of NAC induction. Therefore, the GINI may be a promising biomarker for the treatment and management of EC.

Conflicts of Interest

The Authors declare no conflicts of interest in association with the present study.

Authors' Contributions

TA and SY contributed substantially to the concept and study design. TA, YM, IH, SY, RE, KK, AT, MU, and KN made substantial contributions to the data acquisition, analysis, and interpretation. TA, MN, AS, and NY were involved in drafting and critically revising the manuscript for important intellectual content. TA and YM approved the final version of the manuscript.

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