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The Potential of the C-Reactive Protein-Albumin-Lymphocyte (CALLY) Index as a Prognostic Biomarker in Colorectal Cancer

SHUNSUKE FURUKAWA, MASATSUGU HIRAKI, NAOYA KIMURA, NAOHIKO KOHYA, MASASHI SAKAI, AKASHI IKUBO and RYUICHIRO SAMEJIMA

Department of Surgery, Japanese Red Cross Society Karatsu Red Cross Hospital, Karatsu, Japan

Abstract

Background/Aim: The C-reactive protein (CRP)-albumin-lymphocyte (CALLY) index is an innovative immunonutritional biomarker calculated from CRP, serum albumin, and lymphocyte count levels. This study aimed to determine the significance of the preoperative CALLY index as a prognostic biomarker in patients with stage II-III colorectal cancer who underwent colorectal surgery.

Patients and Methods: This retrospective study included 223 patients who underwent colorectal surgery for stage II-III colorectal cancer. The CALLY index was calculated as follows: (albumin × lymphocyte)/(CRP × 10^4). The patients were divided into CALLY-high group (n=112) and CALLY-low group (n=111) according to the preoperative CALLY index. The associations between the preoperative CALLY index and recurrence-free survival (RFS) and overall survival (OS) were evaluated.

Results: The cutoff value of the CALLY index was 3.41. The Kaplan–Meier survival curves for both RFS and OS in patients with stage II-III colorectal cancer demonstrated worse outcomes in the CALLY-low group than in the CALLY-high group (p=0.062 and p=0.008, respectively). A subgroup analysis of both stage II and stage III showed that patients in the CALLY-low group who did not receive postoperative adjuvant chemotherapy had the worst RFS and OS.

Conclusion: The preoperative CALLY index may serve as a prognostic biomarker in patients with colorectal cancer. Additionally, a low CALLY index may indicate a poorer prognosis, particularly in patients who did not receive postoperative adjuvant chemotherapy.

Keywords: CALLY index, colorectal cancer, recurrence.

Masatsugu Hiraki, Department of Surgery, Japanese Red Cross Society Karatsu Red Cross Hospital, 2430 Watada, Karatsu, Saga, 847-8588, Japan. Tel: +81 955725111, Fax: +81 955739530, e-mail: masatsuguhiraki@hotmail.com

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Introduction

Colorectal cancer is one of the most common malignant tumors worldwide, and its incidence has been increasing in recent years, presenting a serious threat to human health (1). Although there have been significant advancements in screening methods and treatments such as surgery, chemotherapy, and radiotherapy, the mortality rate of patients with colorectal cancer remains high (2). Identifying new biomarkers to predict recurrence and the prognosis following colorectal cancer surgery is essential to identify patients who may benefit from adjuvant chemotherapy and other additional treatments.

Recently, the usefulness of noninvasive prognostic biomarkers identified through various standard tests has been demonstrated (3). Several preoperative inflammation-based prognostic markers, including the neutrophil-to-lymphocyte ratio (NLR) (4-7), platelet-to-lymphocyte ratio (PLR) (8-10), Glasgow Prognostic Score (GPS) (11-13), and Prognostic Nutritional Index (PNI) (14-16) have been identified as prognostic factors in cancer patients. The C-reactive protein (CRP)-albumin-lymphocyte index (CALLY) that was the focus of this study is a comprehensive measure of the immune function, inflammation, and the nutritional status (17). There have been only three reports on the relationship between the CALLY index and the prognosis of patients with colorectal cancer (2, 18, 19). Additionally, for the first time, a subgroup analysis was conducted to examine the relationship between the CALLY index and prognosis based on the presence or absence of adjuvant chemotherapy. This study investigated the clinical outcomes of patients with stage II-III colorectal cancer who underwent surgical treatment, with outcomes assessed according to the preoperative CALLY index.

Patients and Methods

Patients. This retrospective study included 223 consecutive patients who underwent colorectal surgery for stage II-III colorectal cancer at the Department of Surgery, Karatsu Red Cross Hospital, Japanese Red Cross Society, between January 2013 and July 2019. The medical records of all the patients were thoroughly reviewed. The inclusion criterion was histologically confirmed stage II-III colorectal adenocarcinoma. Cases with missing data on the CALLY index were excluded from this study.

In this study, 223 patients were divided into the CALLY-high group (n=112) and the CALLY-low group (n=111) based on their preoperative CALLY index. All patients and their families were informed of the surgical procedures and provided their written informed consent. The study design was reviewed and approved by the Medical Ethics Committee of the Karatsu Red Cross Hospital, Japanese Red Cross Society (approval number: 23-I-17-01).

Approach. Colorectal cancer was diagnosed preoperatively *via* colonoscopy and a pathological examination. Patient characteristics as well as preoperative, operative, and postoperative parameters were carefully analyzed. The following data were obtained from the medical records: sex, age, body mass index, American Society of Anesthesiologists Physical Status (ASA-PS), blood test results, preoperative chemotherapy, tumor location (tumors located from the cecum to the transverse colon were classified as right-sided cancers, while those found from the left colonic flexure to the rectum were classified as left-sided cancers), TNM stage, histological type, operative time, intraoperative bleeding, blood transfusion, postoperative complications, postoperative stay, and postoperative chemotherapy. The CALLY index was calculated as follows: (albumin × lymphocyte)/(CRP × 10^4). The median value of 3.41 was used as the cutoff for the CALLY index.

Surgical procedure and patient management. All the patients underwent either open or laparoscopic surgery with appropriate lymphadenectomy. Complete mesocolic excision was performed for colon cancer, whereas tumor-specific mesorectal excision or total mesorectal excision was performed for rectal cancer. The pathological tumor stage was classified based on the eighth edition of the Union for UICC-TNM classification. Postoperative complications

were assessed using the Clavien–Dindo (CD) classification (20, 21). Postoperatively, the levels of carcinoembryonic antigen (CEA) and carbohydrate antigen 19-9 (CA19-9) tumor markers were assessed at least every three months, computed tomography was performed every 6 months, and colonoscopy was conducted annually for cancer surveillance. The primary endpoints of the study were recurrence-free survival (RFS) and overall survival (OS) based on the preoperative CALLY index. The follow-up duration was determined from the time of surgery to the most recent clinical note in the medical records.

Statistical analyses. Continuous variables are presented as the median and interquartile range (IQR), and categorical variables are presented as numbers. In the univariate analysis, Wilcoxon's rank-sum test was applied for continuous variables, and Fisher's exact test was used for binary variables. RFS and OS during the follow-up period were evaluated using the Kaplan–Meier method. $p<0.05$ was considered for statistical significance. All analyses were performed using SPSS (version 25; IBM Japan, Tokyo, Japan).

Results

Among 223 patients (males, n=121; females, n=102) with colorectal cancer who underwent curative surgery, 112 were classified into the CALLY-high group and 111 were classified into the CALLY-low group. Table I shows the results of the univariate analysis of the patient background factors and characteristics. The univariate analyses showed that age ($p=0.042$), ASA-PS ($p<0.001$), hemoglobin level ($p<0.001$), white blood cell count ($p=0.048$), lymphocyte count ($p=0.047$), albumin level ($p<0.001$), CRP level ($p<0.001$), CALLY index ($p<0.001$), NLR index ($p=0.023$), PNI index ($p<0.001$), histological type ($p<0.005$), intraoperative bleeding ($p=0.016$), and blood transfusion ($p=0.006$) were significantly different between the two groups. In contrast, sex, body mass index, PLR index, CEA and CA19-9 levels, preoperative chemotherapy, tumor location, T category, N category, surgical procedure, operative time, anastomotic leakage (CD ≥2), any complication (CD ≥2), postoperative stay, and postoperative chemotherapy were not significantly different between the two groups.

The RFS for stage II-III colorectal cancer, analyzed using the Kaplan–Meier method, showed a decrease in the CALLY-low group relative to the CALLY-high group, without statistical significance ($p=0.062$, Figure 1A). However, Kaplan–Meier analysis of OS showed a significant decrease in the CALLY-low group relative to the CALLY-high group ($p=0.008$, Figure 1B).

A subgroup analysis of stage II cases showed that patients who did not receive postoperative adjuvant chemotherapy had significantly worse RFS and OS, with a particularly pronounced decline in the CALLY-low group ($p=0.022$ and $p=0.028$, Figure 2A and B). Similarly, a subgroup analysis of stage III cases showed that patients who did not receive postoperative adjuvant chemotherapy had significantly worse RFS and OS, with a particularly pronounced decline in the CALLY-low group relative to the CALLY-high group. Additionally, the results for stage III showed a more significant decline relative to stage II ($p<0.001$ and $p<0.001$, Figure 3A and B).

Discussion

This report investigated the association between the preoperative CALLY index and stage II-III colorectal cancer. This study showed that patients with stage II-III colorectal cancer who underwent curative resection with a low CALLY index score demonstrated a significantly worse prognosis. The CALLY index has been reported to be a useful prognostic factor for various types of cancers. Hashimoto *et al.* reported that a low CALLY index in gastric cancer is associated with worse RFS and OS (22), while Aoyama *et al.* suggested that a low CALLY index in gastric cancer may lead to worse OS as well as an increase in postoperative surgical complications and the use of adjuvant chemotherapy (23). In addition, a low CALLY index in esophageal cancer has been associated with RFS and OS (24, 25) and is associated with an increased risk of postoperative surgical site infections (24) and

Table I. *Results of the univariate analyses of the patients.*

	CALLY		
	Low (n=111)	High (n=112)	*p*-Value
Patient factors			
Sex (male: female)	58:53	63:49	0.592
Age (years.; median [IQR])	74 [65-81]	69 [63-79]	**0.042**
Body mass index (kg/m^2; median [IQR])	22.1 [19.3-24.4]	22.6 [20.9-25.0]	0.063
ASA-PS (1, 2: 3)	92:19	108:4	**<0.001**
Hemoglobin (g/dl; median [IQR])	11.3 [9.2-12.6]	12.3 [10.3-13.9]	**<0.001**
White blood cell (×10^3/µl; median [IQR])	6.08 [4.98-7.70]	5.68 [4.54-8.76]	**0.048**
Lymphocyte (×10^3/µl; median [IQR])	1.79 [1.47-2.27]	1.68 [1.34-1.99]	**0.047**
Albumin (g/dl; median [IQR])	3.5 [3.0-3.9]	4.1 [3.9-4.4]	**<0.001**
C-reactive protein	0.6 [0.3-1.4]	0.1 [0.04-0.11]	**<0.001**
CALLY	1.09 [0.38-2.08]	7.58 [5.20-17.76]	**<0.001**
NLR	2.47 [1.85-3.79]	2.17 [1.61-3.08]	**0.023**
PLR	192 [126-256]	158 [124-226]	0.055
PNI	42.6 [37.5-46.6]	49.7 [45.9-52.8]	**<0.001**
CEA (median [IQR])	3.8 [2.2-7.8]	3.9 [2.4-8.2]	0.659
CA19-9 (median [IQR])	8.6 [3.3-20.1]	10.5 [4.2-24.7]	0.451
Preoperative chemotherapy (yes: no)	7:104	6:106	0.784
Tumor factors			
Tumor location (right: left)	45:66	44:68	0.892
T category (T0-T3: T4)	40:71	54:58	0.078
N category (negative: positive)	55:56	46:66	0.227
Histological type (tub1, tub2: por, sig, muc)	95:16	108:4	**<0.005**
Operative factors			
Surgical procedure (open: laparoscopic)	7:104	2:110	0.102
Operative time (min; median [IQR])	284 [210-400]	299 [214-407]	0.827
Intraoperative bleeding (ml; median [IQR])	50 [10-146]	24 [10-113]	**0.016**
Blood transfusion (yes: no)	12:99	2:110	**0.006**
Postoperative factors			
Anastomotic leakage ≥CD2 (yes: no)	3:108	1:111	0.369
Any complication ≥CD2 (yes: no)	31:80	20:92	0.081
Postoperative stay (days; median [IQR])	15 [11-24]	12 [11-18]	0.051
Postoperative chemotherapy (yes: no)	51:60	65:47	0.082

IQR: Interquartile range; CD: Clavien-Dindo classification; CALLY: C-reactive protein (CRP)-albumin-lymphocyte index; NLR: neutrophil-to-lymphocyte ratio; PLR: platelet-to-lymphocyte ratio; PNI: Prognostic Nutritional Index; CEA: carcinoembryonic antigen; CA19-9: carbohydrate antigen 19-9. Numbers in bold represent statistically significant findings.

anastomotic leakage (25). Furthermore, Iida *et al.* reported that a low CALLY index in hepatocellular carcinoma (HCC) after hepatectomy is associated with worse OS (3). However, existing studies on the relationship between colorectal cancer and the CALLY index are limited (2, 18, 19), and the subgroup analysis in this study was the first to examine the association between the CALLY index and the presence or absence of adjuvant chemotherapy in patients with colorectal cancer.

The CALLY index combines CRP, albumin, and lymphocyte levels (26). CRP is an acute-phase protein that is produced in response to inflammation-related cytokines such as vascular endothelial growth factor and interleukin-6 (27). Serum albumin, a key protein in blood, is an effective marker of the nutritional status (28). The lymphocyte count is a conventional biomarker that reflects the immune function (29). The CALLY index is thus regarded as a biomarker for evaluating a patient's immuno-nutritional status and systemic inflammation (30).

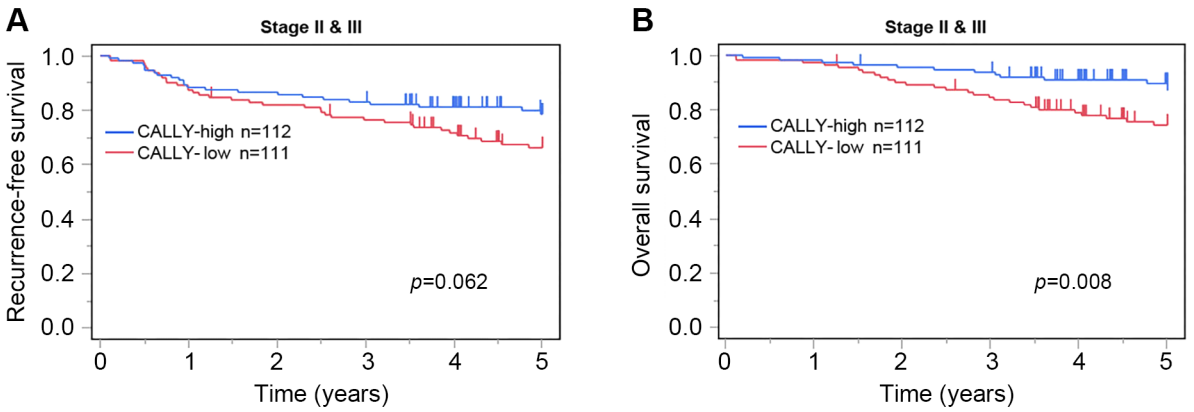

Figure 1. *Comparison of patients with stage II-III colorectal cancer in the C-reactive protein (CRP)-albumin-lymphocyte index (CALLY)-high and CALLY-low groups. Correlation between the preoperative CALLY index and recurrence-free survival (RFS) (A). Correlation between the preoperative CALLY index and overall survival (OS) (B).*

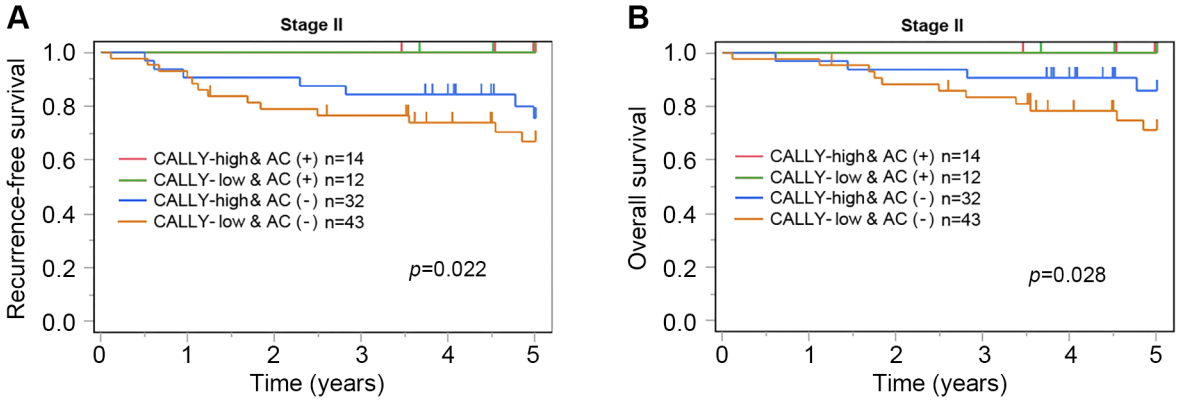

Figure 2. *Comparison among the four groups of patients with stage II colorectal cancer: C-reactive protein (CRP)-albumin-lymphocyte index (CALLY)-high with adjuvant chemotherapy (AC), CALLY-low with AC, CALLY-high without AC, and CALLY-low without AC. Correlation of the preoperative CALLY index with progression free survival (RFS) (A). Correlation of preoperative CALLY index with OS (B).*

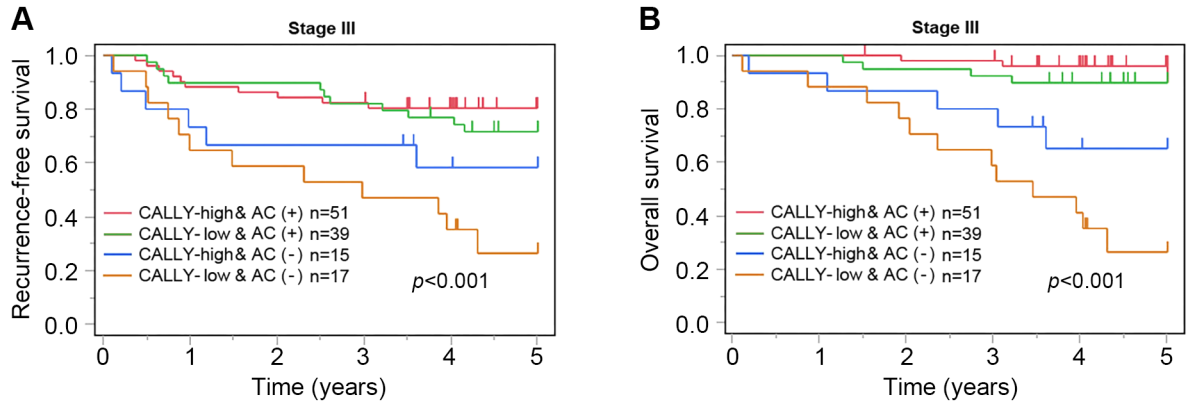

Figure 3. *Comparison among the four groups of stage III colorectal cancer patients: C-reactive protein (CRP)-albumin-lymphocyte index (CALLY)-high with adjuvant chemotherapy (AC), CALLY-low with AC, CALLY-high without AC, and CALLY-low without AC. Correlation of the preoperative CALLY index with recurrence-free survival (RFS) (A). Correlation of the preoperative CALLY index with overall survival (OS) (B).*

The CALLY index is associated with cell differentiation and the types of colorectal polyps and colorectal cancer (2, 31). Ciftel *et al.* reported that patients with a low CALLY index have a higher prevalence of high-grade dysplasia than those with no dysplasia or low-grade dysplasia, and that the CALLY index has potential utility in early detection and risk stratification of colorectal polyps (31). Additionally, in colorectal cancer, a low CALLY index has been reported to be associated with undifferentiated carcinoma, rather than differentiated carcinoma (2). In this study, patients with a low CALLY index exhibited a significantly higher prevalence of poorly differentiated adenocarcinomas, suggesting that a low CALLY index may indicate a higher degree of histological malignancy.

There have been only three previous reports related to colorectal cancer and the CALLY index. Takeda *et al.* reported that a decline in the CALLY index was associated with a significant reduction in both RFS and OS in stage II-III colorectal cancer (2). According to Yang *et al.*, a decrease in the CALLY index was linked to a noteworthy decrease in OS across all stages of colorectal cancer (18). Moreover, Furukawa *et al.* reported that a low CALLY index was associated with a decrease in OS and an increase in postoperative complications in patients who underwent liver resection for colorectal liver metastasis (19). Previous reports have cited cutoff values for the CALLY index as 2.0 (2), 1.47 (18), and 4.0 (19), while this study used 3.41. A clear cutoff value has not yet been established. In this study, similar to previous reports, a decline in the CALLY index was associated with a reduction in RFS and OS. Interestingly, in the subgroup analysis, a lower CALLY index, combined with the absence of postoperative adjuvant chemotherapy, was associated with a particularly significant decline in both RFS and OS. The CALLY index is a useful indicator that can be calculated from preoperative blood tests in patients with colorectal cancer and can easily predict a poor prognosis. In patients with a low CALLY index, aggressive nutritional therapy and postoperative adjuvant chemotherapy may lead to an improved prognosis.

The present study was associated with several limitations, including its retrospective design and the fact that it was conducted at a single institution with a relatively small sample size. In addition, the standardized cutoff values for the CALLY index are controversial. Moreover, as the CALLY index was only measured preoperatively, the postoperative measurements may have had an impact on the results. Therefore, further studies are required to verify the association between the preoperative CALLY index and the prognosis in colorectal cancer.

Conclusion

The preoperative CALLY index may function as an independent prognostic biomarker for patients diagnosed with stage II-III cancer. Specifically, in colorectal cancer patients with a low preoperative CALLY index who did not undergo postoperative adjuvant chemotherapy, these findings may indicate a high risk for cancer recurrence. The CALLY index may serve as a new biomarker for determining the suitability of postoperative adjuvant chemotherapy in colorectal cancer.

Conflicts of Interest

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

Authors' Contributions

S Furukawa and M Hiraki designed the study. S Furukawa, M Hiraki, N Kimura, N Kohya, M Sakai, A Ikubo and R Samejima treated patients. S Furukawa, M Hiraki, and N Kimura collected data. M Hiraki analyzed the data. S Furukawa and M Hiraki interpreted the results and wrote the manuscript. All the Authors have edited the manuscript. R Samejima supervised the study and approved the final manuscript. All Authors have read and approved the final manuscript.

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