

Prognostic value of the postoperative CALLY index in T1/T2 clear cell renal cell carcinoma

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Abstract. Identifying patients with renal cell carcinoma (RCC) at risk of postoperative recurrence remains challenging, particularly in those with early-stage disease. The objective of the present study was to evaluate the prognostic utility of the C-reactive protein (CRP)-albumin-lymphocyte (CALLY) index and other haematological biomarkers in patients with pathologic T1/T2 clear-cell RCC (ccRCC). In total, data from 253 patients with pT1/T2 ccRCC who underwent nephrectomies were retrospectively analysed. Preoperative and postoperative levels of CRP, neutrophil-to-lymphocyte ratio (NLR) and CALLY index were assessed, and cut-off values were determined using receiver operating characteristic curves. Prognostic significance was evaluated using Kaplan-Meier and Cox regression analyses. A postoperative CALLY index of ≤ 2.163 was significantly associated with shorter progression-free survival [hazard ratio (HR)=3.64] and overall survival (HR=4.98). A preoperative NLR of ≥ 3.015 also predicted recurrence (HR=2.74). Furthermore, the postoperative CALLY index demonstrated the highest predictive accuracy for overall survival (area under the curve=0.8141). In conclusion, the postoperative CALLY index is a robust and accessible biomarker for recurrence and survival in patients with T1/T2 ccRCC, and may guide postoperative surveillance strategies.

Introduction

Renal cell carcinoma (RCC) accounts for approximately 2-3% of adult malignancies (1) and remains a notable cause of cancer-related mortality worldwide. Clear-cell RCC (ccRCC) has been identified as the predominant histological subtype,

accounting for approximately 75% of all RCC cases and the majority of RCC-specific deaths (2,3).

Surgical resection remains the mainstay treatment for localised RCC. Although patients with pT1 and pT2 tumours typically exhibit favourable outcomes, a subset experiences 'late recurrence' several years postoperatively, complicating follow-up strategies (4). Several inflammatory and nutritional blood biomarkers, including C-reactive protein (CRP) and the neutrophil-to-lymphocyte ratio (NLR), have been explored to improve risk stratification; however, none have gained widespread clinical adoption (5,6). These markers were selected based on their established relevance in reflecting systemic inflammation (CRP and NLR) and nutritional status (albumin and lymphocytes). As inflammation and immune suppression are known contributors to the progression of RCC, their integration into a composite index, such as the CRP-albumin-lymphocyte (CALLY) index, offers a biologically meaningful and clinically accessible prognostic tool.

The CALLY index has recently emerged as a novel composite biomarker that reflects systemic inflammation, nutritional status, and immune competence. Specifically, it has been highlighted that these markers capture distinct but interrelated aspects of cancer biology, inflammation (CRP, NLR), nutritional status (albumin), and immune competence (lymphocyte count), and that their composite use via the CALLY index may provide a more comprehensive risk assessment in RCC (5-12). We have previously demonstrated the prognostic value of the CALLY index in patients with advanced RCC (pT3) (7). Nevertheless, whether the CALLY index retains its clinical utility in lower-stage disease remains unknown.

In the current study, we aimed to evaluate the predictive relevance of the CALLY index for postoperative recurrence and survival in patients with pT1/pT2 ccRCC, with an emphasis on comparing preoperative and postoperative biomarker values.

Materials and methods

Study population. This retrospective study included 253 patients with pathologically confirmed ccRCC, staged as pT1 or pT2, who underwent partial or radical nephrectomy at Yamaguchi University Hospital between October 2005 and September 2023. Patient demographics, clinical characteristics, and pathological features were extracted from the

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institutional records. The median patient age was 67 years (range, 28-92 years; 172 male, 81 female). The median follow-up period was 37.9 months (range, 1-194 months). This study was approved by the Institutional Review Board of the Graduate School of Medicine, Yamaguchi University (IRB #2023-042), and all patients provided written informed consent.

Data collection and biomarker assessment. Data regarding clinical and laboratory parameters, including age, sex, body mass index, tumour stage, Fuhrman grade, and presence of sarcomatoid differentiation, were collected. Laboratory values included serum albumin (g/dl), CRP (mg/dl), absolute neutrophil count, and absolute lymphocyte count (cells/ μ l). The CALLY index is calculated as follows: CALLY index=(Albumin x Lymphocyte count)/CRP.

Peripheral blood samples were obtained at two time points: Within two weeks prior to surgery (preoperative) and approximately one month after surgery (postoperative). To minimise the influence of perioperative physiological changes, only samples collected at least one month postoperatively were used for postoperative analysis.

Statistical analysis. Receiver operating characteristic (ROC) curve analysis was performed to evaluate the predictive ability of CRP, NLR, and CALLY index for progression-free survival (PFS) and overall survival (OS). The optimal cut-off values were determined using the Youden index. The sensitivity, specificity, positive predictive value, and negative predictive value were also calculated.

Kaplan-Meier survival analysis was used to estimate PFS and OS, and survival distributions were compared using the log-rank test. Univariate and multivariate Cox proportional hazards regression analyses were performed to identify independent predictors. Hazard ratios (HRs) with 95% confidence intervals (CIs) are reported. $P < 0.05$ was considered to indicate a statistically significant difference. Regarding association with clinical parameters, Wilcoxon rank-sum test was used. All statistical analyses were performed using the JMP Pro software (version 16.0; SAS Institute Inc., Cary, NC, USA).

Results

Patient characteristics. The patient characteristics are summarized in Table I. The median age was 67 years, with 67.98% males and 32.02% females. Among the 253 patients included in the study, 239 (94.5%) were classified as pT1, and 14 (5.5%) as pT2. Postoperative recurrence occurred in 21 (8.3%) patients. At the time of the last follow-up, 236 (90.9%) patients had survived (Table I).

ROC curve analysis. Figs. 1 and 2 showed that ROC analysis was used to evaluate the predictive ability of CRP, NLR, and CALLY index for PFS and OS. For PFS prediction using postoperative data, the CALLY index showed the highest specificity (82.8%), with an area under the curve (AUC) of 0.6525 and a cut-off value of 2.163. In contrast, preoperative CRP (cut-off: 0.2950) and NLR (cut-off: 3.015) had lower discriminative power (AUCs=0.6965 and 0.6089, respectively).

Likewise, the postoperative CALLY index exhibited the highest performance for OS prediction, with an AUC of 0.8141,

Table I. Patient characteristics (T1/T2N0M0, n=253).

Variable	Value
Sex, n (%)	
Male	172 (67.98)
Female	81 (32.02)
Age, years	
Median	67
Range	28-92
BMI, kg/m ²	
Median	23.64
Range	13.83-37.59
T stage, n (%)	
T1a	191 (75.49)
T1b	48 (18.97)
T2a	11 (4.35)
T2b	3 (1.19)
N stage, n (%)	
N0	253 (100)
N1	0 (0)
M stage, n (%)	
M0	253 (100)
M1	0 (0)
Fuhrman grade, n (%)	
G1	94 (37.15)
G2	140 (55.34)
G3	16 (6.32)
G4	3 (1.19)
Sarcomatoid feature, n (%)	
No	250 (98.8)
Yes	3 (1.2)
Outcome, n (%)	
Progression	
No	232 (91.70)
Yes	21 (8.3)
Overall survival	
Survival	236 (93.3)
Death	17 (6.7)

sensitivity of 76.5%, and specificity of 79.2% (cut-off: 3.399). Postoperative CRP level and NLR also exhibited notable performances, with AUCs of 0.8062 and 0.7682, respectively.

Kaplan-Meier survival analysis. Kaplan-Meier survival curves revealed that patients with a postoperative CALLY index ≤ 2.163 had significantly shorter PFS and OS than those with higher values (log-rank $P=0.0026$ and $P=0.002$, respectively) (Figs. 3 and 4). Similarly, high preoperative NLR (≥ 3.015) and high postoperative CRP (≥ 0.3850) were associated with significantly shorter PFS and OS.

Cox proportional hazards regression. Univariate analysis identified preoperative NLR ≥ 3.015 (HR=2.74; 95% CI:

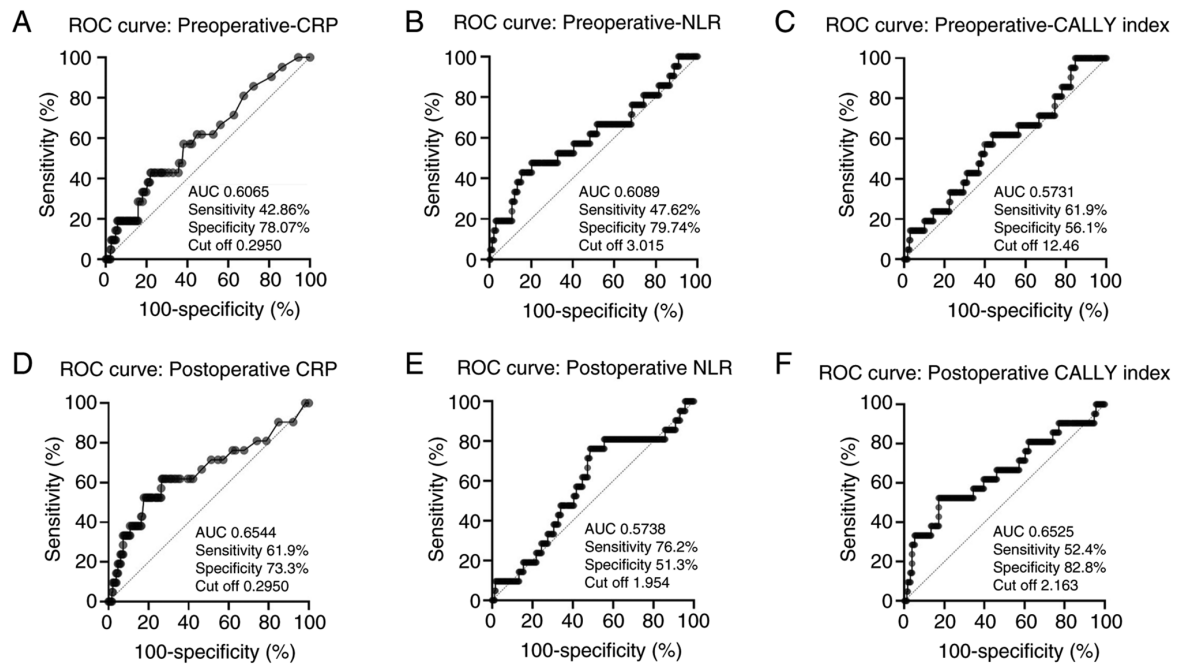


Figure 1. ROC curve analysis for progression-free survival using pre- and postoperative biomarkers: (A) Preoperative CRP, (B) preoperative NLR, (C) preoperative CALLY index, (D) postoperative CRP, (E) postoperative NLR, (F) postoperative CALLY index. ROC, receiver operating characteristic; CRP, C-reactive protein; NLR, neutrophil-to-lymphocyte ratio; CALLY, CRP-albumin-lymphocyte.

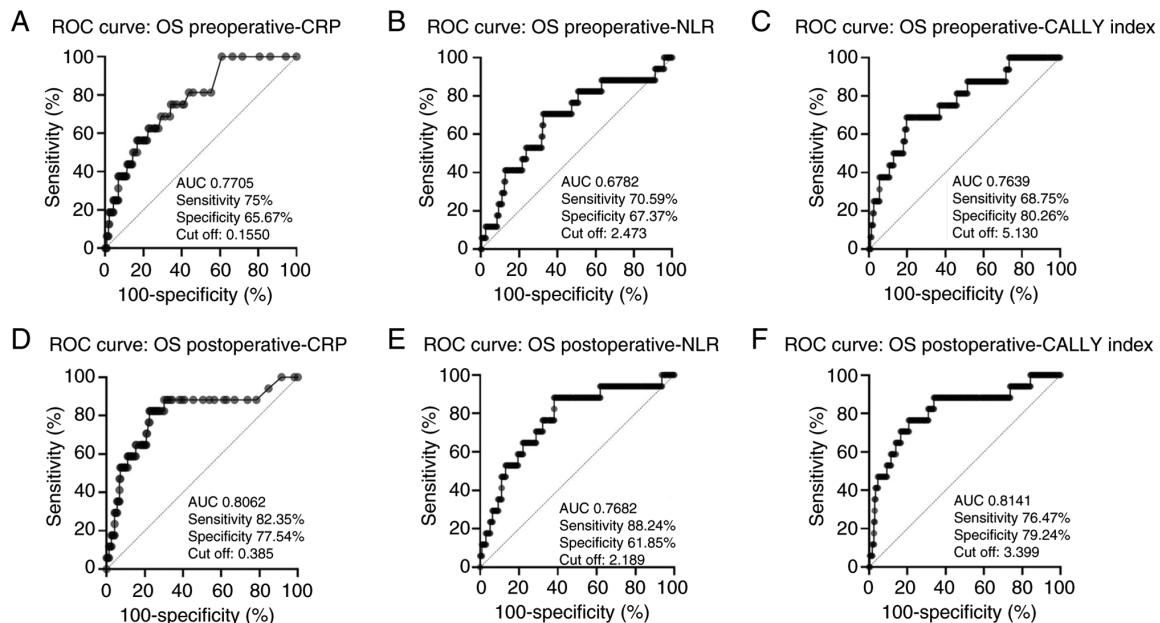


Figure 2. ROC curve analysis for OS using pre- and postoperative biomarkers: (A) Preoperative CRP, (B) preoperative NLR, (C) preoperative CALLY index, (D) postoperative CRP, (E) postoperative NLR, (F) postoperative CALLY index. ROC, receiver operating characteristic; CRP, C-reactive protein; NLR, neutrophil-to-lymphocyte ratio; CALLY, CRP-albumin-lymphocyte; OS, overall survival.

1.16-6.47; $P=0.0208$) and postoperative CALLY index ≤ 2.163 ($HR=3.64$; 95% CI: 1.45-8.25; $P=0.005$) as significant predictors of recurrence (Table II). For OS, postoperative Fuhrman grade ≥ 3 ($HR=6.07$; 95% CI: 1.28-28.79; $P=0.023$) and postoperative CALLY index ≤ 2.163 ($HR=4.98$; 95% CI: 1.59-15.56; $P=0.0057$) were identified as significant predictors associated with recurrence (Table IIIA).

In multivariate analysis, a low postoperative CALLY index (≤ 2.163) and high Fuhrman grade remained independent

predictors of poor OS. In contrast, the CALLY index showed the strongest association with both recurrence and survival outcomes.

Association with clinical parameters. Subgroup analysis revealed that the CALLY index was significantly lower in patients with pT2 tumours and higher Fuhrman grades ($P<0.05$) (Table IVA). Although similar trends were observed postoperatively, they did not reach statistical significance (Table IVB).

Table II. Univariate analysis to predict progression-free survival in pT1/pT2 patients.

Variable	Cut-off	Comparison	HR (95% CI)	P-value
Sex	-	Male vs. Female	1.292572 (0.973913-1.715494)	0.0756
Age, years	67 ^a	Older vs. Younger	1.321941 (0.544308-3.21055)	0.5376
BMI, kg/m ²	23.64 ^a	High vs. Low	1.064536 (0.822657-1.378381)	0.6312
Stage	-	T2 vs. T1	3.00129 (0.881974-10.21316)	0.0786
Fuhrman grade	-	34 vs. 1 + 2	1.473568 (0.194606-11.15796)	0.7074
Preoperative CRP	0.295	High vs. Low	1.919245 (0.807844-4.559671)	0.1398
Preoperative NLR	3.015	High vs. Low	2.748875 (1.166315-6.478798)	0.0208
Preoperative CALLY index	12.46	Low vs. High	1.79135 (0.741854-4.325562)	0.1949
Postoperative CRP	0.2950	High vs. Low	1.919245 (0.807844-4.559671)	0.1398
Postoperative NLR	1.954	High vs. Low	2.690201 (0.985032-7.347159)	0.0535
Postoperative CALLY index	2.163	Low vs. High	3.461179 (1.454691-8.235263)	0.005

^aMedian. CRP, C-reactive protein; NLR, neutrophil-to-lymphocyte ratio; CALLY, CRP-albumin-lymphocyte.

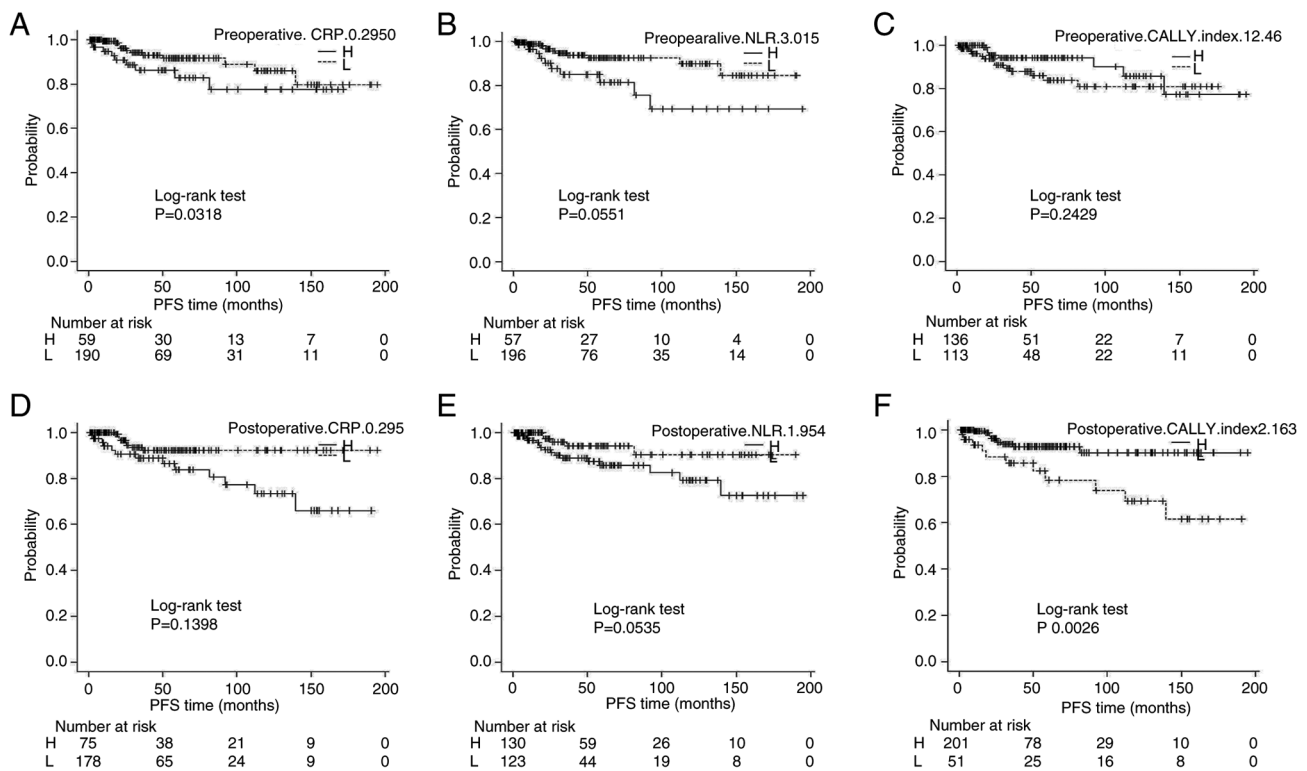


Figure 3. Kaplan-Meier survival analysis for PFS stratified by biomarker cut-offs: (A) Preoperative CRP, (B) preoperative NLR, (C) preoperative CALLY index, (D) postoperative CRP, (E) postoperative NLR, (F) postoperative CALLY index. Patients were divided into H and L groups according to the cut-off value determined by receiver operating characteristic curve analysis. CRP, C-reactive protein; NLR, neutrophil-to-lymphocyte ratio; CALLY, CRP-albumin-lymphocyte; PFS, progression-free survival; H, high; L, low.

Discussion

In this study, we evaluated the prognostic relevance of the CALLY index in patients with pathological T1/T2 ccRCC, focusing on its ability to predict postoperative recurrence and OS.

Our findings demonstrate that the postoperative CALLY index is a superior prognostic marker compared with individual haematologic biomarkers, such as CRP and NLR. Notably, a

low postoperative CALLY index (≤ 2.163) was independently associated with disease recurrence and poor OS, underscoring its clinical relevance in postoperative risk stratification.

Previous studies primarily examined the prognostic value of the CALLY index in advanced RCC (7) and other malignancies (8-10). Our previous study highlighted the significance of this index in patients with pT3 RCC (7). By extending this study to a lower-risk cohort, we demonstrated that the CALLY index remained a robust indicator of prognosis, suggesting

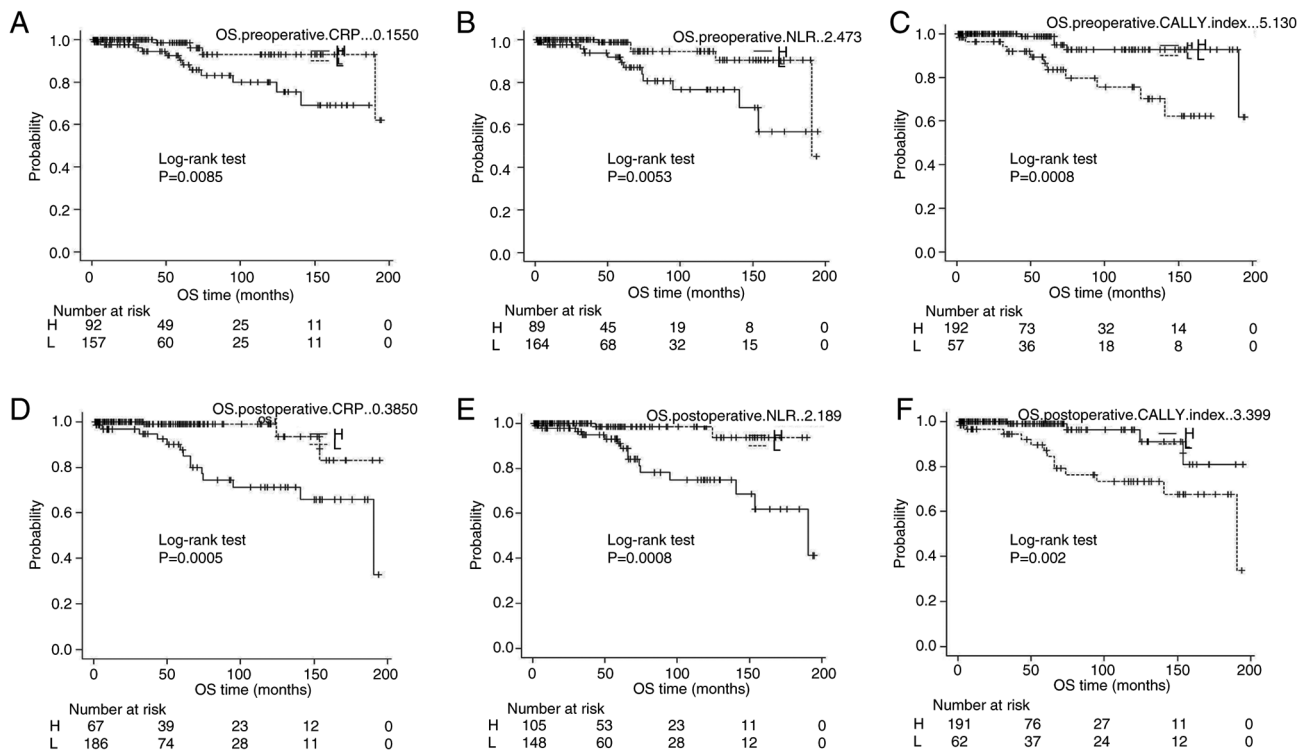


Figure 4. Kaplan-Meier survival analysis for OS stratified by biomarker cut-offs: (A) Preoperative CRP, (B) preoperative NLR, (C) preoperative CALLY index, (D) postoperative CRP, (E) postoperative NLR, (F) postoperative CALLY index. Patients were divided into H and L groups according to the cut-off value determined by receiver operating characteristic curve analysis. CRP, C-reactive protein; NLR, neutrophil-to-lymphocyte ratio; CALLY, CRP-albumin-lymphocyte; OS, overall survival; H, high; L, low.

broader applicability across disease stages. Importantly, the enhanced prognostic accuracy of postoperative values, compared with preoperative measures, indicates that the resolution of perioperative inflammation may be necessary to reveal the true baseline immune and nutritional status.

The components of the CALLY index, serum albumin level, CRP level, and lymphocyte count have been individually recognised for their prognostic relevance. Hypoalbuminaemia reflects poor nutritional status and systemic inflammation (11,12), CRP is a marker of the acute-phase response and tumour-related inflammation, and lymphopenia indicates impaired immune surveillance (13-15). The integration of these variables into a composite index allows for a more holistic assessment of host-tumour interactions. Our data reinforce the utility of the CALLY index as a composite measure, particularly when assessed in a stable postoperative setting.

The postoperative CALLY index demonstrated stronger predictive power for OS (AUC=0.8141) than either CRP or NLR alone. This supports previous findings observed in patients with gastrointestinal and hepatocellular cancers, in which postoperative inflammatory indices provided improved prognostic resolution (8-10). In RCC, systemic inflammation is associated with disease progression and resistance to therapies such as immune checkpoint inhibitors (ICIs) (16-18). A persistently low postoperative CALLY index may signal sustained inflammation or immune dysfunction, making patients less likely to benefit from ICI monotherapy (19).

Our findings have several important clinical implications. First, the postoperative CALLY index may serve as a

cost-effective and non-invasive tool to guide surveillance intensity. Second, patients with low postoperative CALLY index values may benefit from closer follow-up or earlier introduction of adjuvant therapy. Third, this index may aid in the selection of patients for combined ICI and tyrosine kinase inhibitor regimens in future prospective trials.

Nevertheless, the limitations of this study need to be addressed. The retrospective design and single-institution cohort may have introduced selection bias. Additionally, the limited number of recurrence events restricts the statistical power, particularly in multivariate models. Although the Fuhrman grade and tumour stage were included in the analysis, other molecular or genomic features were not assessed. Future studies should incorporate molecular profiling to enhance prognostic modelling and validate our findings in independent cohorts. Furthermore, the retrospective design, single-centre setting, and lack of external validation may limit the generalisability of our findings. In addition, the absence of dynamic postoperative biomarker trends or radiological confirmation of the timing of recurrence warrants cautious interpretation. Future prospective studies incorporating multicentre data and longer follow-up periods are necessary.

To further validate the prognostic role of the CALLY index, future multicentre prospective studies incorporating diverse populations and standardised postoperative sampling protocols are warranted.

Overall, the postoperative CALLY index is a valuable biomarker for identifying patients with T1/T2 ccRCC who have an increased risk of recurrence and mortality. Its incorporation into clinical decision-making may improve individualised

Table III. Univariate and multivariate analyses to predict overall survival in pT1/pT2 patients.

A, Analyses based on postoperative data						
Variable	Cut-off	Comparison	Univariate HR (95% CI)	Univariate P-value	Multivariate HR (95% CI)	Multivariate P-value
Sex	-	Male vs. Female	1.863947 (0.597746-5.812336)	0.2832	-	-
Age, years	67 ^a	Older vs. Younger	1.725438 (0.638896-4.65981)	0.2819	-	-
BMI, kg/m ²	23.64 ^a	High vs. Low	2.207195 (0.775425-6.282635)	0.138	-	-
Stage	-	T2 vs. T1	5.324408 (1.84181-15.3921)	0.002	3.225972 (1.019327-10.20957)	0.0463
Fuhrman grade	-	34 vs. 1+2	6.075185 (1.281854-28.79258)	0.023	3.657307 (0.708305-18.88436)	0.1216
CRP	0.385	High vs. Low	6.889604 (1.951844-24.31887)	0.0027	5.828419 (0.570453-59.54996)	0.1371
NLR	2.189	High vs. Low	8.108854 (1.840612-35.72372)	0.0057	4.462875 (0.910259-21.88086)	0.0652
CALLY index	3.399	Low vs. High	4.981984 (1.594653-15.56462)	0.0057	1.771683 (0.217442-14.43542)	0.5931
B, Analyses based on preoperative data						
Variable	Cut-off	Comparison	Univariate HR (95% CI)	Univariate P-value	Multivariate HR (95% CI)	Multivariate P-value
Sex	-	Male vs. Female	1.863947 (0.597746-5.812336)	0.2832	-	-
Age, years	67 ^a	Older vs. Younger	1.725438 (0.638896-4.65981)	0.2819	-	-
BMI, kg/m ²	23.64 ^a	High vs. Low	2.207195 (0.775425-6.282635)	0.138	-	-
Stage	-	T2 vs. T1	5.324408 (1.84181-15.3921)	0.002	2.46747 (0.753225-8.083124)	0.1357
Fuhrman grade	-	34 vs. 1+2	6.075185 (1.281854-28.79258)	0.023	3.878816 (0.769975-19.53987)	0.1004
CRP	0.155	High vs. Low	4.698866 (1.321837-16.70353)	0.0168	1.033698 (0.105675-10.11152)	0.9773
NLR	2.473	High vs. Low	3.957946 (1.392138-11.25272)	0.0099	2.330853 (0.754118-7.204278)	0.1416
CALLY index	5.130	Low vs. High	5.675808 (1.799224-17.90483)	0.0031	3.058945 (0.367179-25.48385)	0.3013

^aMedian. CRP, C-reactive protein; NLR, neutrophil-to-lymphocyte ratio; CALLY, CRP-albumin-lymphocyte.

follow-up strategies and support the selection of appropriate therapeutic interventions.

In conclusion, the postoperative CALLY index is a reliable and accessible biomarker for predicting recurrence and survival in patients with pathological T1/T2 ccRCC. This index provides superior prognostic accuracy compared with individual haematologic markers and may enhance current risk stratification protocols. Incorporating the CALLY index into postoperative

monitoring could improve individualised patient management and inform clinical decision-making regarding adjuvant therapy. The postoperative CALLY index may assist in identifying patients who require close surveillance or early systemic therapy.

Acknowledgements

Not applicable.

Table IV. Association of CALLY index with several clinical factors.

A, Preoperative (n=249)				
Parameter	Group	n	CALLY index (mean)	P-value ^a
Sex	Male	169	120.698	0.1707
	Female	80	134.088	Reference
Age (median, 67 years)	Low	125	121.344	Reference
	High	124	128.685	0.4213
BMI (median, 23.64 kg/m ²)	Low	125	128.688	Reference
	High	124	121.282	0.4172
TNM	T1	235	129.017	Reference
	T2	14	57.571	0.0003
Fuhrman grade	G1 + G2	232	127.563	Reference
	G3 + G4	17	90.029	0.0381
B, Postoperative (n=253)				
Parameter	Group	n	CALLY index (mean)	P-value ^a
Sex	Male	172	123.267	0.2311
	Female	81	134.926	Reference
Age (median, 67 years)	Low	127	118.386	0.0601
	High	126	135.683	Reference
BMI (median, 23.64 kg/m ²)	Low	126	134.992	Reference
	High	127	119.071	0.0836
TNM	T1	239	128.264	Reference
	T2	14	105.429	0.2565
Fuhrman grade	G1 + G2	235	128.815	Reference
	G3 + G4	18	103.306	0.1541

^aWilcoxon rank-sum test.

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Availability of data and materials

The data generated in the present study may be requested from the corresponding author.

Authors' contributions

HH conceived the study and wrote the manuscript. KosS and TT contributed to the data acquisition. NF and KK conducted the statistical analyses. KojS contributed to the analysis of data. HH and TT confirm the authenticity of all the raw data. All authors read and approved the final manuscript.

Ethics approval and consent to participate

This study was approved by the Institutional Review Board of the Graduate School of Medicine, Yamaguchi University (IRB #2023-042), and written informed consent was obtained from all participants.

Patient consent for publication

Written informed consent for publication was obtained from all patients prior to inclusion in the study.

Competing interests

The authors declare that they have no competing interests.

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