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Prognostic Significance of Lymphocyte-to-Monocyte Ratio in Patients With Unresectable Biliary Tract Cancer Undergoing Systemic Chemotherapy

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Abstract. *Background/Aim: The incidence of biliary tract cancers (BTC), including cholangiocarcinoma and gallbladder cancer, has been increasing worldwide. Approximately 70% of BTC patients have advanced disease at diagnosis, leading to a poor survival rate. Recent clinical trials have demonstrated that the addition of immune checkpoint inhibitors, such as durvalumab or pembrolizumab, to gemcitabine plus cisplatin chemotherapy significantly improves survival rates, making triple therapy the current standard for first-line treatment of BTC. Few models with predictive value exist for BTC. Lymphocyte-to-monocyte ratio (LMR) is a relatively new inflammation-related score and translational biomarker and has prognostic value for survival of patients with other cancers. This study assessed the prognostic value of LMR in patients with advanced BTC and analyzed the risk factors associated with overall survival (OS). Patients and Methods: This prospective study enrolled 75 patients with advanced BTC who were treated with gemcitabine-based chemotherapies at Aso Iizuka Hospital, Japan. The cutoff value of LMR for predicting 6-month survival was 3.27. Results: OS was longer for patients with high LMR compared with low LMR (median 32.4 months and 8.6 months, respectively; p=0.0069). Multivariate analysis identified LMR >3.27 [hazard ratio (HR)=0.427, p=0.0339] and objective response rate (HR=0.210, p=0.0116) as independent factors associated with OS. Conclusion: Despite some limitations, such as the single-center design and small sample size, the results of this study suggest a potential role for LMR in predicting survival outcomes for BTC patients treated with gemcitabine-based chemotherapies.*

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Key Words: Biliary tract cancer, lymphocyte-to-monocyte ratio, gemcitabine, overall survival.

The incidence of biliary tract cancers (BTC), a group of malignancies that arise from the epithelium of the biliary tract and include cholangiocarcinoma, extrahepatic cholangiocarcinoma, and gallbladder cancer, has been increasing worldwide (1-3). Approximately 70% of patients with BTC already have advanced disease at the time of diagnosis, resulting in 5-year survival rates of just 5% to 15% (4, 5).

The ABC-02 trial published in 2010, established gemcitabine plus cisplatin (GC) as the standard first-line chemotherapy option for BTC (6). In the Japanese Phase III FUGA-BT trial, gemcitabine plus TS-1 (GS) was found to be non-inferior to GC (7). Based on the outcomes of these trials, gemcitabine-based therapy pairings are widely used to treat patients with advanced BTC. Two immune checkpoint inhibitors (ICIs), the anti-programmed death-1 (PD-1) antibody pembrolizumab and the anti-programmed cell death ligand 1 (PD-L1) antibody durvalumab, were recently evaluated in two large randomized trials in patients with advanced BTC (8, 9). These studies showed that adding durvalumab (TOPAZ-1) or pembrolizumab (KEYNOTE-966) to GC resulted in significantly higher survival rates compared with GC alone (8, 9). Consequently, triple therapy comprising GC plus anti-PD-1 or anti-PD-L1 agents has become the current standard in first-line treatment for BTC (10-12). Tumor location, PD-L1 combined positive score, microsatellite stability (MSI), and tumor mutational burden are biomarkers with demonstrated value in predicting response to ICIs (13). In the TOPAZ-1 and KEYNOTE-966 trials, the benefits of ICIs were seen regardless of PD-1 expression, and evaluation of tumor mutation burden or MSI as

Table I. *Baseline characteristics of patients*.

Characteristics	All	High LMR	Low LMR	*p*-Value
Number	75	38	37	
Age, years	74 (67-76)	75 (70-77.3)	72 (64-76)	0.0300
Sex, n (male/female)	43/32	22/16	21/16	0.9206
Primary tumor type				0.1064
iCCA	33	14	19	
eCCA	24	17	7	
Gallbladder carcinoma	18	7	11	
Stage II/III, IV	10/65	4/34	6/31	0.4675
Disease classification at start of systemic therapy				0.9068
Locally advanced	37	19	18	0.8406
Metastatic	38	19	19	
HBV or HCV infection	12	6	6	
Tumor marker				
CEA U/ml	5.1 (2.6-14.2)	4.2 (2.3-10.3)	6.2 (2.9-31)	0.1717
CA19-9 U/ml	76.4 (6.5-1022.8)	151.8 (23.9-1529.5)	13.6 (2.1-737)	0.3470
Treatment				0.4696
GEM	1	0	1	
GEM+CDDP	41	18	23	
GEM+CDDP+S-1	3	2	1	
Durvalumab+GEM+CDDP	17	10	7	
GEM+S-1	13	8	5	
FBC data WBC	6,380 (4,590-8,270)	5,585 (3,817.5-6,740)	7,660 (5,845-10,220)	0.0001
Neutrophil (/μl)	4,039.2 (2,638.4-5,769.8)	3,208.9 (2,316.2-4,536.9)	5,660.1 (3,693.5-7,626.3)	<0.0001
Lymphocyte (/μl)	1,335.5 (964.2-1,568.4)	1,470.1 (1,130.6-1,704.5)	1,125.8 (706.1-1,417.4)	0.0002
Monocyte (/μl)	344.9 (286.3-493.4)	298.4 (236.9-340.0)	438.4 (341.3-626.1)	<0.0001
Platelet ($\times 10^4$/μl)	22.1 (16.7-28.7)	20.9 (15.8-25.3)	24.6 (18.9-30.6)	0.0737
NLR	3.12 (2.15-5.40)	2.29 (1.67-2.62)	4.95 (3.55-7.655)	<0.0001
PLR	1.19 (0.65-1.84)	0.70 (0.52-1.03)	1.74 (1.16-2.48)	<0.0001
LMR	3.27 (2.33-4.67)	4.65 (3.98-5.90)	2.33 (1.82-2.82)	<0.0001
Observation months	8.6			

Data are expressed as median (interquartile range). LMR: Lymphocyte-to-monocyte ratio; eCCAs: extrahepatic cholangiocarcinomas; iCCAs: intrahepatic cholangiocarcinomas; HBV: hepatitis B virus; HCV: hepatitis C virus; CEA: carcinoembryonic antigen; CA19-9: carbohydrate antigen 19-9; GEM: gemcitabine; CDDP: cisplatin; S-1: TS-1; FBC: full blood count; SOT: start of treatment; NLR: neutrophil-to-lymphocyte ratio; PLR: platelet-to-lymphocyte ratio.

predictive markers was not feasible due to the rarity of MSI in BTC and/or lack of available mutational data (13).

Compared with biomarkers of response to treatment, less is known about biomarkers that predict long-term survival in patients with advanced BTC. Lymphocyte-to-monocyte ratio (LMR), a relatively recent inflammation-related score and translational biomarker, has prognostic value in patients with lymphoma, colorectal cancer, and lung cancer (14-16). Preoperative LMR has been shown to be a highly significant indicator of resectability in patients with BTC, and dynamic changes in LMR can accurately predict early recurrence in patients with advanced curable BTC (17). However, there has been no report on whether LMR is associated with prognosis or survival in patients with advanced BTC treated with systemic chemotherapy. In this study, we aimed to assess the prognostic value of LMR and analyze risk factors for overall survival (OS) in patients with advanced BTC.

Patients and Methods

Patients. This was a single-center prospective study of 75 patients with advanced BTC treated with gemcitabine-based systemic chemotherapies (GC, GS, GC plus TS-1, GC plus duruvalumab) at Aso Iizuka Hospital, Japan, between April 2014 and May 2024. The study was conducted in accordance with the guidelines of the Declaration of Helsinki and was approved by the Ethics Committee of Aso Iizuka Hospital (approval no. 24019). The opt-out method was used to obtain patient consent for the study.

LMR measurement. Peripheral blood (2 ml) was obtained from each patient at the start of treatment and a complete blood count with differential was performed. LMR was calculated as the absolute lymphocyte count divided by the absolute monocyte count in peripheral blood.

Evaluation of efficacy. Computed tomography or magnetic resonance imaging was conducted every 12–16 weeks after treatment initiation to determine the treatment response. The treating physician evaluated the antitumor response using the Response Evaluation Criteria in Solid Tumors (RECIST) criteria (18). The disease control rate (DCR) was defined as complete response (CR), partial response (PR), or stable disease (SD) lasting for at least four months. The objective response rate (ORR) was defined as PR+CR.

Statistical analysis. JMP Pro version 11 software (SAS Institute Inc., Cary, NC, USA) was used for all statistical analyses. Data are presented as the median (interquartile range), and group medians were compared using Fisher's exact test or the Mann–Whitney *U*-test. OS was analyzed using the Kaplan–Meier method, log-rank test, receiver operating characteristic (ROC) curve analysis, and Cox proportional hazards analysis. Predictive factors for 6-month survival were evaluated by ROC curve and area under the curve (AUC) analysis. $p<0.05$ was considered to be statistically significant.

Results

Patient characteristics. Baseline characteristics of the 75 patients are shown in Table I. The median age at diagnosis was 74 years (range=67-76 years) and the median follow-up time was 8.6 months. The cut off value of LMR for predicting 6-month survival was calculated as 3.27 using ROC analysis (AUC=0.736, 1 – specificity 0.396, sensitivity 0.846). Patients were assigned to high (N=38) and low (N=37) LMR groups based on LMR >3.27 and ≤3.27, respectively.

The patients in the high LMR group were older than those in the low LMR group. In addition, white blood cell, neutrophil, and monocyte counts were higher and lymphocyte counts were lower in the high LMR group than in the low LMR group. Sex, primary tumor type, stage, treatment, carcinoembryonic antigen (CEA) levels, and carbohydrate antigen 19-9 (CA19-9) levels were similar between the two groups.

Anticancer response. ORR (CR+PR) was 23.7% (9/38) in the high LMR group and 18.9% (7/37) in the low LMR group (p=0.618). DCRs (CR+PR+SD) were 52.6% (20/38) and 37.8% (14/37) in the high and low LMR groups, respectively (p=0.418; Table II). Neither ORR nor DCR was significantly different between the high and low LMR groups.

OS. The median survival time (MST) for all patients was 16.0 months. Kaplan–Meier analysis revealed that the high LMR group had a longer MST than the low LMR group (16.3 months and 8.6 months, respectively, p=0.0108; Figure 1).

Factors associated with OS. Univariate analysis revealed that LMR >3.27 and ORR were both significantly associated with OS, whereas ICI was not. Multivariate analysis identified LMR >3.27 [hazard ratio (HR)=0.427; p=0.0339] and ORR (HR=0.210; p=0.0116) as independent factors associated with OS (Table III).

Table II. *Comparison of responses in the high and low lymphocyte-to-monocyte ratio (LMR) groups.*

	All n=75	High LMR n=38	Low LMR N=37	p-Value
Overall response				0.3590
CR	0	0	0	
PR	16	9	7	
SD	18	11	7	
PD	21	10	11	
NE	20	7	13	
ORR (CR+PR)	16	9	7	0.6178
DCR (CR+PR+SD)	34	20	14	0.4177

CR: Complete response; PR: partial response; SD: stable disease; PD: progressive disease; NE: not evaluated; ORR: objective response rate; DCR: disease control rate.

Discussion

The results of this study demonstrated that higher LMR (>3.27) was significantly associated with better OS in our cohort of 75 patients with advanced BTC treated with gemcitabine-based systemic chemotherapies.

A number of studies have shown that cancer progression can be influenced by the immune response, and both the development and progression of cancer are known to be characterized by inflammation (19). Proinflammatory cytokines and chemokines in the tumor microenvironment contribute to the survival and proliferation of tumor cells, metastasis, angiogenesis, and the destruction of adaptive immunity, thereby affecting survival and prognosis (20). Inflammation induces the accumulation of monocytes, platelets, and neutrophils, which produce cytokines and inflammatory factors to promote tumor growth and metastasis. Conversely, increased numbers of monocytes and lymphocytes can reduce tumor invasion (21). Previous studies have demonstrated the prognostic value of several inflammatory biomarkers, such as the ratios of neutrophils, lymphocytes, platelets, and C-reactive protein levels, in resectable BTC (22-26). Another study has reported that higher LMR was significantly associated with longer OS and better response in patients with advanced BTC treated with systemic chemotherapies, including ICIs (27). The prognostic value of inflammatory biomarkers in the response to gemcitabine-based systemic chemotherapies for advanced BTC has not been investigated.

Major advances in immunotherapy-based treatment of solid tumors have occurred in recent years, and ICIs are now among the first-line therapeutic options for patients with advanced BTC (8, 9). In the present study, ICI treatment was not a significant factor associated with OS; this may be due to the relatively short observation period and/or the small number of

Table III. *Factors associated with overall survival.*

	Univariate			Multivariate		
	HR	95%CI	*p*-Value	HR	95%CI	*p*-Value
Sex	1.526	0.754-3.086	0.2393			
Age ≥70	1.118	0.564-2.216	0.7513			
Stage	1.749	0.609-5.023	0.2986			
LMR >3.27	0.393	0.194-0.793	0.0091	0.427	0.195-0.937	0.0339
ICI	0.634	0.330-1.822	0.3721			
ORR	0.220	0.066-0.737	0.0141	0.210	0.062-0.705	0.0116
CEA	1.005	0.997-1.012	0.1195			
CA19-9	1.000	0.999-1.000	0.1478			

LMR: Lymphocyte-to-monocyte ratio; ICI: immune checkpoint inhibitor; ORR: objective response rate; CEA: carcinoembryonic antigen; CA19-9: carbohydrate antigen 19-9.

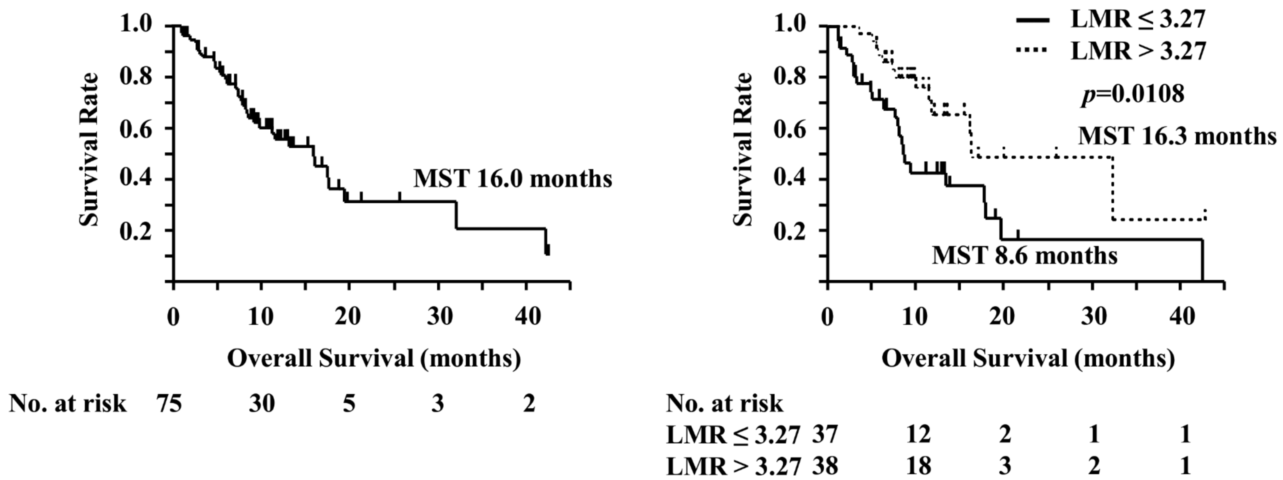

Figure 1. *Kaplan–Meier analysis of overall survival (OS) in patients with biliary tract cancer treated with gemcitabine-based systemic chemotherapies. OS of all patients (left) and of patients stratified by high and low lymphocyte-to-monocyte ratio (LMR) (right). MST: Median survival time; No.: number.*

patients treated with ICI. Nevertheless, LMR may be a prognostic biomarker for immunotherapy-based treatment in BTC.

Limitations of this study included the small number of BTC patients, due mainly to the single-center study design. In addition, the study included advanced BTC cases with different tumor types and stages.

In conclusion, this study identified a potential role for LMR in predicting the outcomes for BTC patients treated with gemcitabine-based chemotherapies.

Conflicts of Interest

The Authors declare that they have no competing interests in relation to this study.

Authors' Contributions

HS, AK, KT, MY, and KM designed the study. HS, AK, JT, and KT assisted with data analyses. HS wrote the initial draft of the manuscript. AK and MY contributed to the analysis and interpretation of the data. KT and KM assisted in the preparation and critical review of the manuscript. HS and AK confirmed the authenticity of all raw data. All Authors approved the final version of the manuscript and agreed to be accountable for all aspects of the work.

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