

Cancer of the Liver Italian Program score helps identify potential candidates for transarterial chemoembolization in patients with Barcelona Clinic Liver Cancer stage C

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BACKGROUND: The Barcelona Clinic Liver Cancer (BCLC) staging system for hepatocellular carcinoma (HCC) recommends transarterial chemoembolization (TACE) as the first line therapy for stage B patients and sorafenib treatment for stage C patients. However, stage C patients exhibit variations in terms of tumor burden, liver function, and extrahepatic metastasis, which could potentially affect disease outcome. Here, we assessed whether the Cancer of the Liver Italian Program (CLIP) scores can help identify stage C patients likely to benefit from TACE.

METHODS: Out of 295 BCLC stage C HCC patients enrolled between January 2009 and December 2011, those with platelet counts $>30 \times 10^9$ cells/L, total bilirubin $<51 \mu\text{mol/L}$, and an unobstructed main portal vein were scheduled for TACE ($n=195$). The remaining patients received best supportive care (BSC, $n=100$). All the patients were followed up for symptoms, performance status, and Child-Pugh classification scores every 4 weeks until death or December 2013. The prognosis of each group was evaluated by using the log-rank test and Cox-Mantel test.

RESULTS: The median overall survival (OS) was 6 months [95% confidence interval (CI): 4.64-7.36]. The OS was 9 months for the TACE group and 4 months for the BSC group. The TACE group had a longer OS than the BSC subgroup for CLIP scores 0-2 [13 months (95% CI: 8.55-17.45) vs 4 months (95% CI: 0.00-10.96), $P=0.001$]. No significant differences were found between the TACE and BSC groups for CLIP scores 3-5. The CLIP score and treatment methods were found to be independent prognostic factors.

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CONCLUSIONS: BCLC stage C HCC patients exhibit definite disease heterogeneity and can be reclassified by using the CLIP scoring system. Moreover, patients with CLIP scores 0-2 are likely to benefit from TACE. However, additional studies with long-term follow-up will be required to validate these findings.

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KEY WORDS: hepatocellular carcinoma;
BCLC staging system;
CLIP scoring system;
transarterial chemoembolization

Introduction

Hepatocellular carcinoma (HCC) is the fifth most common cancer and the third leading cause of cancer-related deaths worldwide.^[1, 2] According to the practice guidelines of the American Association for the Study of Liver Diseases (AASLD) for HCC, the Barcelona Clinic Liver Cancer (BCLC) system is the only staging system that can match patient groups to therapies across the continuum of disease heterogeneity seen with HCC.^[3, 4] Based on the BCLC staging system, transarterial chemoembolization (TACE) is recommended as the first line non-curative therapy for patients with large or multifocal HCC without vascular invasion or extrahepatic metastasis (BCLC stage B), whereas sorafenib is recommended as first line therapy for advanced (BCLC stage C) HCC patients requiring liver function protection who are less likely to benefit from curative therapy or TACE.^[5-7]

However, sorafenib is not always available for some HCC patients due to financial limitations, especially in developing countries. In Asian countries, TACE has been widely used for patients with unresectable HCC, including those with portal vein thrombosis and extrahepatic metastasis, because of its good survival benefit and over-

all safety for selected patients.^[8-13] Tumor burden, liver function, portal vein invasion, and extrahepatic metastasis vary among BCLC stage C patients. This heterogeneity suggests different prognostic outcomes in these patients and the possibility that there are different strata of BCLC stage C patients with variable prognosis and requiring different optimal therapies.

In this study, we analyzed the overall survival (OS) and prognostic factors of BCLC stage C patients with HCC and found that the Cancer of the Liver Italian Program (CLIP) scoring system could more accurately stratify the patients with different outcomes.^[15]

Methods

Patients

We enrolled 295 HCC patients who were initially classified into BCLC stage C between January 2009 and December 2011. The diagnosis of HCC was made according to the AASLD guidelines.^[5]

The inclusion criteria were: (1) Eastern Cooperative Oncology Group (ECOG) performance status of 1-2; (2) liver function reserve of class A-B on Child-Pugh classification; (3) Okuda stage 1-2; (4) portal vein tumor thrombosis and/or extrahepatic metastasis; and (5) patients treated with TACE or supportive treatment. Patients with a secondary malignancy or with severe organ function failure were excluded. OS was calculated from the date of enrollment till the date of death or December 31, 2013. Gender, age, etiology, Child-Pugh class, CLIP score, tumor size, type, and extent, portal vein tumor thrombosis, extrahepatic metastasis, platelet count, serum aspartate aminotransferase (AST), and serum alpha-fetoprotein (AFP) level were included as baseline variables.

The study protocol was approved by the Ethics Committee of Beijing You'an Hospital, Capital Medical University and adhered to the *Declaration of Helsinki*. Because of the retrospective nature of the study, written informed consent was waived off by the approval of the institutional review board.

Treatment

On the basis of our experience, patients with platelet count $>30 \times 10^9$ cells/L, total bilirubin $<51 \mu\text{mol/L}$, and a main portal vein that was not completely obstructed by tumor thrombosis were scheduled for TACE. The patients were reevaluated after 3 to 4 weeks; in the interim, they were given symptomatic treatment as required. TACE would be repeated in the event of a residual tumor or if tumor recurrence was confirmed by computed tomography (CT) or magnetic resonance imaging (MRI)

during follow-up. Patients who refused to undergo TACE or those who were not considered as suitable candidates for TACE were given symptomatic treatment or best supportive care (BSC).

TACE

Overall, 195 patients underwent TACE. First, angiography was performed to identify the targeted feeding arteries of the tumor. The catheter was advanced to the hepatic artery and then to the lobar and segmental branches to facilitate maximum selectivity. A combination of chemotherapeutic agents and iodized oil was injected into the arteries, and a gelatin sponge was used to embolize the feeding artery. Doxorubicin (50 mg/m^2) or 5-fluorouracil (500 mg/m^2) was used as chemotherapeutic agent. The quantities of the iodized oil and sizes of the gelatin sponges used to embolize the tumors were decided by two senior interventional physicians at our center based on the tumor sizes.

Follow-up

The patients were followed up for symptoms, ECOG performance status, and Child-Pugh classification with a physical examination every 4 weeks. They underwent enhanced MRI and CT scanning every 4 to 8 weeks until death or the end point of follow-up, December 31, 2013.

Statistical analysis

All data were analyzed with the SPSS statistical software (IBM SPSS Statistics 21). Disease-specific survival was analyzed using the Kaplan-Meier method. The log-rank test was used to analyze differences in survival. Multivariate analysis was performed using the Cox proportional hazards model with forward stepwise selection. A P value of <0.05 was considered statistically significant.

Results

Baseline characteristics of TACE and no-TACE patient

Of the 295 patients, 195 (66.1%) received TACE (TACE group) and 100 (33.9%) received symptomatic treatment or BSC (BSC group). TACE was repeated in 91 of the 195 patients; the median session of TACE procedures per patient was 2 (range 1-8). Baseline characteristics of the patients are shown in Table 1. Gender, age, etiology, tumor size, extent, metastasis, platelet count, and the levels of AST and AFP were not significantly different between the two groups (Table 1). The baseline Child-Pugh class, CLIP score, portosystemic shunt, and portal vein invasion status were significantly different between the two groups, with patients in the BSC group having a more

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