Case Report: iMDT Corner

Complete response and long-term survival after short-course camrelizumab plus apatinib, hepatic arterial infusion chemotherapy, and transarterial chemoembolization in large and advanced hepatocellular carcinoma: a case report

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Background: In China, transarterial chemoembolization (TACE) and systemic therapy are the primary treatment for patients with advanced hepatocellular carcinoma (HCC). Hepatic arterial infusion chemotherapy (HAIC) is more effective than TACE in treating large HCC (largest diameter ≥7 cm) without macrovascular invasion or extrahepatic spread. Additionally, HAIC in combination with camrelizumab and apatinib has shown promising efficacy and safety in the Barcelona Clinic Liver Cancer stage C (BCLC-C) HCC. The efficacy and safety of the modality of HAIC followed by TACE combined with camrelizumab and apatinib for the treatment of large HCC remains unknown. We present the first case of long-term survival after short-course HAIC followed by TACE combined with camrelizumab and apatinib in large HCC.

Case Description: In April 2020, a 50-year-old Chinese woman was diagnosed with BCLC-C HCC. Magnetic resonance imaging (MRI) showed intrahepatic lesions involving the right and left lobes, with a total lesion size of 19 cm × 9 cm. After 3 cycles of HAIC with oxaliplatin, fluorouracil, and leucovorin (HAIC-FOLFOX) plus camrelizumab and apatinib, followed by 2 cycles of TACE plus camrelizumab and apatinib, the efficacy was evaluated as a partial response (PR), with a total lesion size of 6.7 cm × 4.6 cm. The patient continued to take apatinib orally for 1.5 months after the last cycle of TACE but discontinued any antitumor therapy for financial reasons. Subsequent imaging consultation showed an efficacy evaluation of complete response (CR) per the modified Response Evaluation Criteria in Solid Tumors (mRECIST). The patient did not experience any serious adverse events during treatment. As of September 2024, the patient's progression-free survival (PFS) has reached 53 months.

Conclusions: The treatment modality of short-course HAIC followed by TACE combined with camrelizumab and apatinib for large HCC is safe and effective, and long-term survival may be expected in patients who achieve a CR.

Keywords: Hepatocellular carcinoma (HCC); hepatic arterial infusion chemotherapy (HAIC); transarterial chemoembolization (TACE); immune checkpoint inhibitors (ICIs); case report

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Introduction

In 2020, primary liver cancer ranked as the sixth most common cancer in terms of incidence and the third most common in terms of mortality, and hepatocellular carcinoma (HCC) accounted for 75–85% of all primary liver cancers (1). Advanced HCC at diagnosis was reported in 55% of cases in China, 42% in North America, and 51% in Europe (2). Both transarterial chemoembolization (TACE) and systemic therapy are recommended in China for advanced HCC (3). Immune checkpoint inhibitors (ICIs) have changed the treatment paradigm for advanced HCC. In patients with unresectable HCC, camrelizumab plus apatinib has been shown to significantly prolong progression-free survival (PFS) and overall survival (OS) compared to sorafenib (4). For large HCC (largest diameter ≥7 cm) without macrovascular invasion or extrahepatic spread, hepatic arterial infusion chemotherapy (HAIC) with oxaliplatin, fluorouracil, and leucovorin (HAIC-FOLFOX) has a higher objective response rate (ORR), PFS, and OS than TACE (5). When HAIC-FOLFOX was combined with camrelizumab and apatinib to treat HCC at Barcelona Clinic Liver Cancer stage C (BCLC-C), the ORR per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 was 77.1% [95% confidence interval (CI): 59.9–89.6%], and the median PFS was 10.38 months (95% CI: 7.79–12.45) (6). However, the efficacy and safety of the modality of HAIC-FOLFOX combined with TACE plus camrelizumab and apatinib for the treatment of large HCC remains unknown, as does whether continued systemic therapy is necessary for large HCC that has achieved a complete response (CR). Herein, we present the first case of long-term survival after a short-course of HAIC-FOLFOX followed by TACE combined with camrelizumab and apatinib in large and advanced HCC. We present this case in accordance with the CARE reporting checklist (available at https://jgo.amegroups.com/article/view/10.21037/jgo-24-613/rc).

Highlight box

Key findings

- The authors have revised the conclusions as advised: hepatic arterial infusion chemotherapy (HAIC) combined with transarterial chemoembolization (TACE), camrelizumab, and apatinib may represent a viable treatment approach for large and advanced hepatocellular carcinoma, particularly in patients achieving complete response, which may indicate the potential for long-term survival.

What is known and what is new?

- HAIC in combination with camrelizumab and apatinib showed promising efficacy and safety in the Barcelona Clinic Liver Cancer stage C hepatocellular carcinoma (HCC).
- This is the first case presenting long-term survival after short-course HAIC followed by TACE combined camrelizumab and apatinib in large HCC.

What is the implication, and what should change now?

- Clinical trials are warranted to explore whether there is a difference in survival between patients who continue systemic therapy after achieving a complete response (CR) to short-course HAIC followed by TACE combined camrelizumab and apatinib in large HCC versus discontinuing any antitumour comparator after achieving a CR.

Case presentation

In March 2020, a 50-year-old Chinese woman consulted Central Hospital of Chang-Tu County due to upper abdominal discomfort that was aggravated by eating. Magnetic resonance imaging (MRI) showed that the lesions involved the right and left lobes of the liver, with a high probability of HCC and a small amount of ascites. Personal history: 20-year history of hepatitis B (already received antiviral treatment), no smoking or drinking habits. She had lost about 5 kilograms in the past 3 months. Physical examination: no positive signs. Routine blood test and urine test: no abnormality (white blood cells and platelets were normal). Blood biochemistry and coagulation tests: alanine aminotransferase (ALT) 65 U/L, aspartate aminotransferase (AST) 36 U/L, total bilirubin 19.6 μmol/L, albumin 45.3 g/L, and prothrombin time 12.9 seconds. Tumor biomarker: alpha-fetoprotein (AFP) 8,342 ng/mL (*Figure 1*). Hepatitis B surface antigen (+), hepatitis B surface antibody (–), hepatitis B core antibody (+), and HBV-DNA: 2.46E+04. Chest computed tomography (CT) ruled out thoracic tumor metastasis, and no additional evidence of extrahepatic disease was identified. The patient was diagnosed with primary HCC in accordance with the 2017 Edition of the Guidelines for Diagnosis and Treatment of Primary Liver Cancer in China (7), with the presence of tumor thrombus in both the portal and middle hepatic veins, liver function Child-Pugh classification grade A (6 points), Eastern Cooperative Oncology Group performance status (ECOG-PS) score 1, BCLC-C, China Liver Cancer (CNLC) stage IIIa, and tumor-node-metastasis (TNM) stage IIIB. The patient's baseline albumin of 40 g/L and total bilirubin of 27.95 μmol/L

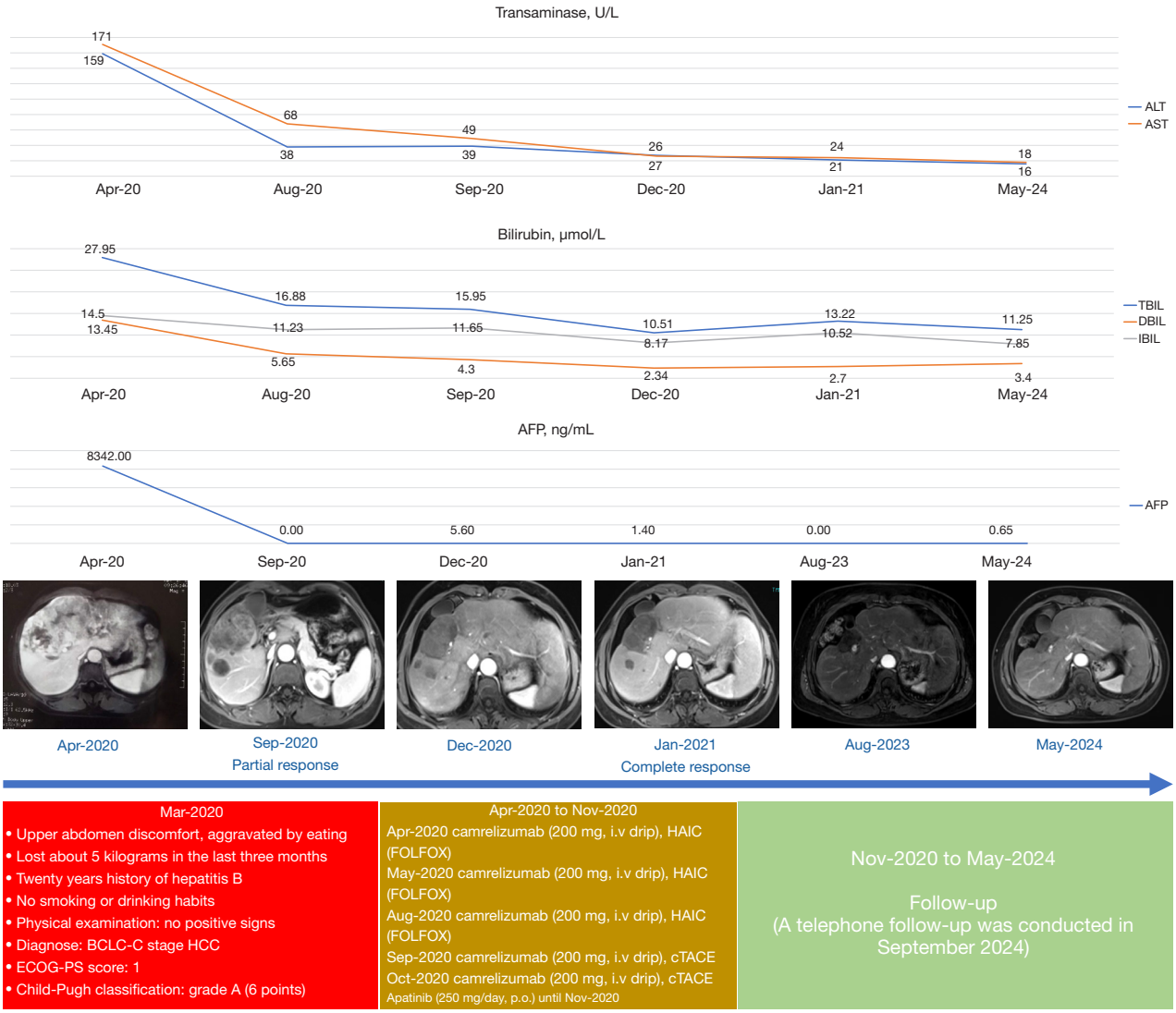

Figure 1 Timeline of laboratory findings, treatments, and imaging. ALT, alanine aminotransferase; AST, aspartate aminotransferase; TBIL, total bilirubin; DBIL, direct bilirubin; IBIL, indirect bilirubin; AFP, alpha fetoprotein; BCLC, Barcelona Clinic Liver Cancer; HCC, hepatocellular carcinoma; ECOG-PS, Eastern Cooperative Oncology Group performance status; HAIC, hepatic arterial infusion chemotherapy; FOLFOX, oxaliplatin, fluorouracil, and leucovorin; cTACE, conventional transarterial chemoembolization.

resulted in a calculated albumin-bilirubin (ALBI) score of −2.45, grade 2. In April 2020, an MRI showed intrahepatic lesions involving the right and left lobes, with a total lesion size of 19 cm × 9 cm meeting the definition of large HCC (5). Due to the presence of a fistula between the hepatic artery and the middle hepatic vein at baseline, TACE could not be administered in accordance with clinical guidelines (7). Based on a thorough literature review and obtaining informed consent from the patient, we selected HAIC-FOLFOX as the interventional treatment regimen with the aim of achieving tumor response and additional clinical benefits for the patient (8). To enhance the efficacy of tumor reduction, with the patient's consent, we added camrelizumab (200 mg, every 21 days) and apatinib (250 mg, everyday) to the HAIC-FOLFOX regimen (9). After 3 cycles of HAIC-FOLFOX plus camrelizumab and apatinib, the patient achieved partial response (PR) according to the modified RECIST (mRECIST) criteria, with a total lesion size of 7.8 cm × 5.9 cm. The fistula between the hepatic artery and middle hepatic vein that

was present at baseline had decreased, hence, 2 cycles of conventional TACE (cTACE) plus camrelizumab and apatinib were performed. The patient's efficacy was evaluated as a PR, with a total lesion size of 6.7 cm × 4.6 cm. The patient continued to take apatinib orally for 1.5 months after the last cycle of TACE but discontinued any antitumor therapy for financial reasons. Subsequent imaging consultation showed an efficacy evaluation of CR per the modified RECIST, with a total lesion size of 6.3 cm × 4.5 cm. We recommended an evaluation of the patient's eligibility for surgical resection, however, the patient declined due to financial constraints. The patient did not experience any serious adverse events during treatment. Gastric distension, acid reflux, nausea, and hepatic discomfort had been experienced only after HAIC/TACE, which resolved after acid-suppressing, hepatoprotective, and anticoagulant treatments. In September 2024, we conducted a telephone follow-up with the patient, who had achieved a PFS of 53 months. All procedures performed in this study were in accordance with the ethical standards of the institutional and national research committee(s) and with the Helsinki Declaration (as revised in 2013). Written informed consent for publication of this case report and accompanying images was provided by the patient. A copy of the written consent is available for review by the editorial office of this journal.

International Multidisciplinary Team (iMDT) discussion

Discussion among physicians from Liaoning Cancer Hospital & Institute

To our knowledge, this is the first case reporting CR and long-term survival after short-course HAIC-FOLFOX followed by TACE combined camrelizumab and apatinib in large HCC. In the FOHAIC-1 study (NCT03164382), the HAIC-FOLFOX responder had longer PFS than the non-responder (14.3 months, 95% CI: 10.4–18.2 *vs.* 6.2 months, 95% CI: 4.6–7.8, P=0.001) (10). In the CARES-310 study (NCT03764293), the median duration of response was 14.8 months [95% CI: 8.4–not reached (NR)] with camrelizumab and rivoceranib which was numerically higher than the 9.2 months (95% CI: 5.3–NR) achieved with sorafenib. PFS by baseline ALBI Grade 2 (*post-hoc*) was 5.5 months (95% CI: 4.4–6.3) in the camrelizumab plus apatinib group and 3.5 months (95% CI: 1.9–3.7) in the sorafenib group [hazard ratio (HR) 0.54, 95% CI: 0.39–0.74] (4). The median PFS was 10.38 months (95% CI: 7.79–12.45) in the TRIPLET study (NCT04191889) and 10.4 months (95% CI: 5.8–15.0) for HAIC-FOLFOX plus lenvatinib and toripalimab in patients with high-risk advanced HCC (NCT04044313), both of which were numerically higher than those of HAIC-FOLFOX alone (7.8 months, 95% CI: 6.0–9.6) or camrelizumab plus apatinib (5.6 months, 95% CI: 5.5–7.4) (4,6,10,11). This case report demonstrated a numerically longer PFS compared to the TRIPLET study regimen. One possible explanation is the addition of TACE, which may have enhanced local tumor control. The CHANCE 2211 study (NCT04975932) showed that the median OS, PFS, and ORR in TACE plus camrelizumab and apatinib group were significantly higher than those in the TACE monotherapy group [median OS, 24.1 *vs.* 15.7 months, P=0.008; median PFS, 13.5 *vs.* 7.7 months, P=0.003; ORR, 59.5% (50/84) *vs.* 37.4% (55/147), P=0.002] (12). The results of the EMERALD-1 study (NCT03778957) further support the PFS benefit of combining TACE with ICI and anti-angiogenic agents in the treatment of HCC (13). As illustrated in *Figure 1*, the patient's serum transaminase levels gradually decreased to within the normal range following cTACE. This result suggests that when using transaminase levels post-TACE to predict ORRs, it may be necessary to also consider the potential impact of systemic therapy and/or other interventional treatments (14). HAIC can rapidly reduce the tumor burden to avoid an immunosuppressive environment that reduces the efficacy of ICI and can subsequently release many tumor-associated antigens for antigen-presenting cells to present to cytotoxic T cells (15,16). Following TACE, the tumor microenvironment exhibits a significant enrichment of triggering receptor expressed on myeloid cells 2^+ tumor-associated macrophages ($TREM2^+$ TAMs), which secrete galectin-1 to promote the expression of programmed cell death ligand 1 (PD-L1) in endothelial cells (16,17). In addition to inhibiting tumor cell proliferation and angiogenesis, low-dose apatinib also alleviated hypoxia, increased infiltration of $CD8^+$ T cells, reduced recruitment of TAMs in the tumor, and decreased transforming growth factor-β (TGF-β) amounts in both tumor and serum (18). Camrelizumab can further deregulate the inhibition of cytotoxic T-cells by programmed cell death 1 (PD-1) and improve anti-tumor efficacy (4). Taking all the above evidence together, it is reasonable to hypothesize that HAIC-FOLFOX plus camrelizumab and apatinib to reduce tumor size, and sequential TACE plus camrelizumab and apatinib to consolidate further the efficacy of the treatment

in patients with large HCC, would be an effective and safe treatment modality and that patients who achieve an objective response would be expected to have a greater survival benefit. In patients who achieve a CR, tumor-specific T cells are capable of controlling the tumor from recurrence without the necessity for continued systemic therapy due to the significant reduction in tumor-associated suppressors. Currently, there are no reliable predictive biomarkers for assessing the efficacy of HAIC combined with ICI, tyrosine kinase inhibitor (TKI), and TACE in the treatment of advanced large HCC (10,19). Based on the results and hypotheses presented in this study, monitoring immune cell populations and PD-L1 expression within the immune microenvironment before and after treatment may represent a potential direction for future research. Clinical trials will be warranted to explore whether there is a difference in survival between patients who continue systemic therapy after achieving a CR to short-course camrelizumab and apatinib plus HAIC and TACE in large HCC versus discontinuing any antitumor comparator after achieving a CR. Furthermore, clinical trials are needed to explore the impact of various combinations of TKIs, ICIs, HAIC and TACE on patient ORRs and survival benefits (19).

There were two limitations associated with this case report. First, the long survival result comes from only one case, and we cannot confirm whether it is attributable to antitumor therapy or individual differences in patients. Second, we did not test for biomarkers, so we do not know the molecular biology or immunologic characteristics of the patients.

Questions to be further discussed by international experts as follows

(I) According to mRECIST1.1, the patient has sustained a CR for an extended duration. Should additional interventions, such as surgery or stereotactic body radiation therapy (SBRT), be considered?

Expert opinion 1: Ju Dong Yang

In the absence of any viable tumor for an extended duration, I don't think additional HCC treatment would be indicated.

Expert opinion 2: Nobuyuki Takemura

There is a paucity of reports on the percentage of patients with advanced HCC who achieve pathologic CR after treatment with ICIs. Therefore, especially since I am a liver surgeon, I may opt for hepatic resection in this case to confirm the efficacy of multidisciplinary therapy in addition to the therapeutic goals. However, since surgical resection is invasive, additional therapeutic intervention may not be necessary if CR persists on imaging and there are no elevations in tumor markers. This remains a controversial issue.

(II) Is there a method available to forecast the advancement of a patient's illness in advance?

Expert opinion 1: Ju Dong Yang

I often monitor HCC tumor marker panel to detect minimal residual diseases. Imaging is not highly sensitive in detecting minimal residual diseases. For example, patients who have increased tumor marker [AFP, AFP L3, or des-gamma-carboxy prothrombin (DCP)] have high chance of having minimal residual diseases despite negative imaging, particularly after locoregional treatment (20).

Expert opinion 2: Nobuyuki Takemura

Compared to other cancer types, the relationship between genetic mutations and prognosis in HCC remains unclear. At present, imaging vascular invasion and tumor markers are the only limited methods to predict a patient's progression in advance.

(III) In patients with HCC, what is the optimal duration for administering ICIs to achieve a balance between manageable adverse reactions and disease progression?

Expert opinion 1: Ju Dong Yang

There is no clear consensus on it. Most people continue with ICIs as long as patient tolerate treatment without side effect. I typically consider stopping treatment about 12 months after achieving CR, especially when I am considering a liver transplant.

Expert opinion 2: Nobuyuki Takemura

The optimal balance of manageable adverse reactions and disease progression in patients with HCC depends on the efficacy of chemotherapy. As discussed below, withdrawal may be considered when CR and tumor markers have been normalized for at least 3 to 6 months on imaging. On the other hand, if CR is not achieved on imaging or tumor markers have not normalized, ICIs should be continued while managing side effects.

(IV) Can CR serve as an indicator for discontinuing ICIs?

Expert opinion 1: Ju Dong Yang

Yes, but achieving deep remission is important and I start consider discontinuing ICIs at least 1 year after achieving

remission.

Expert opinion 2: Nobuyuki Takemura

CR alone on images cannot be an indicator for discontinuing ICIs. In my opinion, normalization of CR and tumor markers on imaging for at least 3 to 6 months is an indicator for discontinuing ICIs.

Conclusions

HAIC combined with TACE, camrelizumab, and apatinib may represent a viable treatment approach for large and advanced HCC, particularly in patients achieving complete response, which may indicate the potential for long-term survival. More clinical studies need to be initiated to explore and validate the efficacy and safety of this treatment modality.

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Footnote

Reporting Checklist: The authors have completed the CARE reporting checklist. Available at https://jgo.amegroups.com/article/view/10.21037/jgo-24-613/rc

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jgo.amegroups.com/article/view/10.21037/jgo-24-613/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All procedures performed in this study were in accordance with the ethical standards of the institutional and national research committee(s) and with the Helsinki Declaration (as revised in 2013). Written informed consent for publication of this case report and accompanying images was provided by the patient. A copy of the written consent is available for review by the editorial office of this journal.

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