

Clinical Efficacy Exploration of Temperature-Sensitive Embolic Agent TACE Combined with HAIC and Targeted/Immunotherapy for Unresectable Primary Liver Cancer

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Objective: To evaluate the efficacy and safety of TEM-TACE combined with HAIC and targeted/immunotherapy for the treatment of unresectable primary liver cancer, and to clarify the clinical application potential of this multimodal therapeutic regimen.

Methods: This study was a small-sample retrospective case series. The clinical data of 4 patients with unresectable primary liver cancer who underwent TEM-TACE combined with HAIC and targeted/immunotherapy in our hospital from April 2025 to July 2025 were retrospectively analyzed. Tumor response was evaluated according to the mRECIST criteria, and the occurrence of adverse reactions was assessed on the basis of the Clavien–Dindo classification system. All patients included in this study provided written informed consent for the publication of their clinical details.

Results: Among the 4 patients, 2 were diagnosed with HCC, and the other 2 were diagnosed with ICC. All 4 patients achieved a PR after treatment with TEM-TACE combined with HAIC and targeted/immunotherapy, with a mean tumor reduction of 42.3%. The ORR and DCR both reached 100%. Among these patients, 2 successfully achieved treatment conversion and underwent radical surgical resection, while the remaining 2 refused surgery for personal reasons. During the perioperative period, only Clavien–Dindo grade I–II complications (mainly abdominal pain and nausea) occurred in the 4 patients, which improved after symptomatic treatment, and no severe adverse reactions were observed.

Conclusion: The multimodal therapeutic regimen of TEM-TACE combined with HAIC and targeted/immunotherapy is safe and effective for unresectable primary liver cancer. In particular, compared with conventional embolic agents, temperature-sensitive embolic agents enable precise peripheral embolization and sustained drug release, thereby significantly reducing tumor volume and improving the rate of conversion to surgical resection. Moreover, this regimen provides a novel approach for the conversion therapy of unresectable ICC. It is suitable for patients with primary liver cancer who have a tumor diameter >10 cm, liver function of Child-Pugh class A/B, and no severe comorbidities. However, further studies with larger sample sizes are still required to verify its long-term efficacy.

Keywords: unresectable primary liver cancer, temperature-sensitive embolic agent, transarterial chemoembolization, hepatic artery infusion chemotherapy, combined therapy

Introduction

Primary liver cancer is among the most common cancers in China and is also a major cause of cancer-related deaths in the country. On the basis of its pathological type, it is classified mainly into hepatocellular carcinoma (HCC) and intrahepatic cholangiocarcinoma (ICC).¹ Surgical resection offers a favorable prognosis for patients with early-stage primary liver cancer. However, the majority of patients in China have a background of hepatitis B virus (HBV) infection and consequent liver cirrhosis, and most of them are diagnosed at an advanced stage; thus, they lose the opportunity for

surgical resection. These patients usually have a poor prognosis, with a 5-year survival rate of less than 15%.^{2,3} Therefore, formulating effective therapeutic strategies for patients with advanced primary liver cancer is highly important.

Currently, the comprehensive efficacy of local and systemic therapy is widely recognized.⁴ Among them, transarterial chemoembolization (TACE) and hepatic arterial infusion chemotherapy (HAIC) are currently the most commonly used local treatment methods for patients with unresectable HCC. The combination of TACE and HAIC can result in a synergistic effect of tumor blood supply embolization and continuous infusion of chemotherapeutic drugs, thereby rapidly reducing tumor volume. Targeted therapy and immunotherapy are the preferred systemic antitumor methods for unresectable HCC. Studies have shown that targeted therapy (such as lenvatinib) inhibits tumor angiogenesis, reduces tumor vascular remodeling after TACE, and decreases tumor drug resistance. Moreover, immune checkpoint inhibitors (such as PD-1/PD-L1 inhibitors) can relieve immunosuppression, activate antitumor T-cell responses, convert “cold tumors” into “hot tumors”, and amplify the immunogenic cell death effect of local therapy.^{5,6}

Although studies have confirmed the benefits of TACE combined with HAIC and targeted/immunotherapy, traditional embolic agents used in TACE, such as lipiodol, drug-eluting microspheres and gelatin sponge particles, are limited by their particle size and morphology, making the achievement of embolization of tumor peripheral blood vessels difficult and thus compromising therapeutic efficacy.⁷ Compared with traditional embolic agents, temperature-sensitive liquid embolic agents are a novel type of drug-loaded embolic material that have distinct physicochemical advantages. They are liquid at room temperature with high fluidity, enabling easy catheter-based delivery deep into the tumor vascular bed. When the ambient temperature exceeds their lower critical solution temperature (LCST), they undergo rapid phase transition and solidification to form stable solid embolic agents, achieving precise and long-lasting embolization of peripheral tumor blood vessels.^{8,9} In addition, their unique molecular structure enables the incorporation of contrast agents to achieve real-time intraoperative imaging. Moreover, the 3D network structure formed after phase transition enables the sustained release of chemotherapeutic drugs, avoiding drug burst release, enhancing bioavailability and reducing side effects.^{10–12} Animal experiments have confirmed that, compared with 40 μm embolic microspheres, temperature-sensitive embolic agents achieve more durable distal vascular embolization and a lower rate of vascular recanalization, with no significant systemic adverse reactions.¹³

By analyzing the clinical data of 4 patients with unresectable primary liver cancer who received TEM-TACE combined with HAIC and targeted/immunotherapy, this study preliminarily explored the clinical efficacy of this combined therapeutic regimen.

Case Presentation

Case 1

The patients' clinical baseline characteristics are presented in [Table 1](#). The patient was admitted to the hospital in April 2025 because of “detection of space-occupying liver lesions for more than 10 days”, Contrast-enhanced computed tomography (CTCT, [Figure 1A–C](#)) revealed a hepatocellular carcinoma (11×8 cm) in the left lobe of the liver, with possible invasion of the hepatic veins, leading to a high risk of liver failure if the patient was treated with direct surgical resection.

After multidisciplinary discussion within the department, a therapeutic regimen of TEM-TACE and HAIC combined with targeted/immunotherapy was adopted. During the operation, 5 mL of temperature-sensitive embolic agent mixed with 30 mg of epirubicin was injected via the tumor-feeding artery. Postoperatively, the FOLFOX regimen was administered for arterial infusion chemotherapy, 200 mg of camrelizumab was intravenously infused, and lenvatinib was orally administered (2 capsules once daily).

The patient was readmitted for reexamination three weeks later. The alpha-fetoprotein (AFP) concentration decreased to 11,448 ng/mL, and the protein concentration induced by vitamin K absence or antagonist-II (PIVKA-II) decreased to 2,653.43 mAU/mL ([Figure 1H](#)). CT ([Figure 1D–F](#)) revealed that the tumor shrank to 7.5×7 cm, a reduction of 30.7%. In accordance with the modified Response Evaluation Criteria in Solid Tumors (mRECIST) for hepatocellular carcinoma, the patient achieved a partial response (PR). A laparoscopic left hemihepatectomy was then performed as scheduled, and

Table 1 Baseline Characteristics of the Patients

	Case1	Case2	Case3	Case4
Sex	Male	Male	Female	Male
Age(years)	52	82	59	50
Diagnosis	HCC	HCC	ICC	ICC
Underlying Disease	Personal history of laryngeal cancer	Hypertension	–	–
Hepatitis B virus	+	–	+	+
HBV-DNA (IU/mL)	2.93*10 ⁵	–	8.05*10 ³	3.67*10 ²
Antiviral therapy	+	–	+	+
WBC (10 ⁹ /L)	7.72	6.59	4.51	4.65
NE (10 ⁹ /L)	5.97	4.76	2.84	2.78
PLT (10 ⁹ /L)	262	135	64	75
Hgb (g/L)	160	92	99	161
Alb (g/L)	41	38	29	45
TBil (μmol/L)	18.2	10.9	62.6	21.1
DBil (μmol/L)	7.6	6.2	25.2	3.7
ALT (U/L)	206	9	51	54
AST (U/L)	256	27	122	38
ALP (U/L)	132	62	314	89
GGT (U/L)	148	50	191	86
Crea (umol/L)	52	101	46	66
PT (s)	13.5	13.9	19.2	13.4
INR	1.01	1.06	1.61	1.01
PTA (%)	97	90	49	99
Ascites	–	–	Mild	–
Hepatic encephalopathy	–	–	–	–
Tumor size (cm)	11	10.4	Not measurable*	11.8
Cirrhosis	–	–	–	–
AFP (ng/mL)	121000	114.3	654.8	3.4
CA199 (U/mL)	–	–	130.2	35.9
PIVKA-II (mAU/mL)	30000	146.37	21761.68	21.79

Note: *The patient's tumor presented with an irregular shape and diffuse distribution, with unmeasurable size.

Abbreviations: WBC, White Blood Cell; NE, Neutrophil; PLT, Platelet; Hgb, Hemoglobin; Alb, Albumin; TBil, Total Bilirubin; DBil, Direct Bilirubin; ALT, Alanine Aminotransferase; AST, Aspartate Aminotransferase; ALP, Alkaline Phosphatase; GGT, Gamma-Glutamyl Transferase; Crea, Creatinine; PT, Prothrombin Time; INR, International Normalized Ratio; PTA, Prothrombin Time Activity; AFP, Alpha-fetoprotein; CA199, Carbohydrate Antigen 19–9; PIVKA-II, Protein Induced by Vitamin K Absence or Antagonism-II.

postoperative pathological examination confirmed the presence of HCC (Figure 1G). No recurrence or metastasis was observed as of September 2025, with a 5-month follow-up period.

Case 2

The patients' clinical baseline characteristics are presented in Table 1. The patient presented to the hospital in June 2025 with complaints of exertional dyspnea and fatigue for 3 months and bilateral lower extremity edema for 2 weeks, and a space-occupying liver lesion was identified upon examination. CT (Figure 2A–C) revealed a large hepatocellular carcinoma measuring 10.4×8.4 cm in the right hepatic lobe, accompanied by multiple retroperitoneal lymph node metastases and potential invasion of adjacent blood vessels, for which no surgical indication was determined.

Therefore, the therapeutic regimen of TEM-TACE and HAIC combined with immunotherapy was adopted. During the operation, 5 mL of temperature-sensitive embolic agent mixed with 30 mg of epirubicin was infused via the tumor-feeding artery. Postoperatively, arterial infusion chemotherapy with a regimen of 150 mg oxaliplatin and 4 mg raltitrexed was administered, combined with intravenous infusion of 200 mg camrelizumab, with one treatment cycle every 3 weeks.

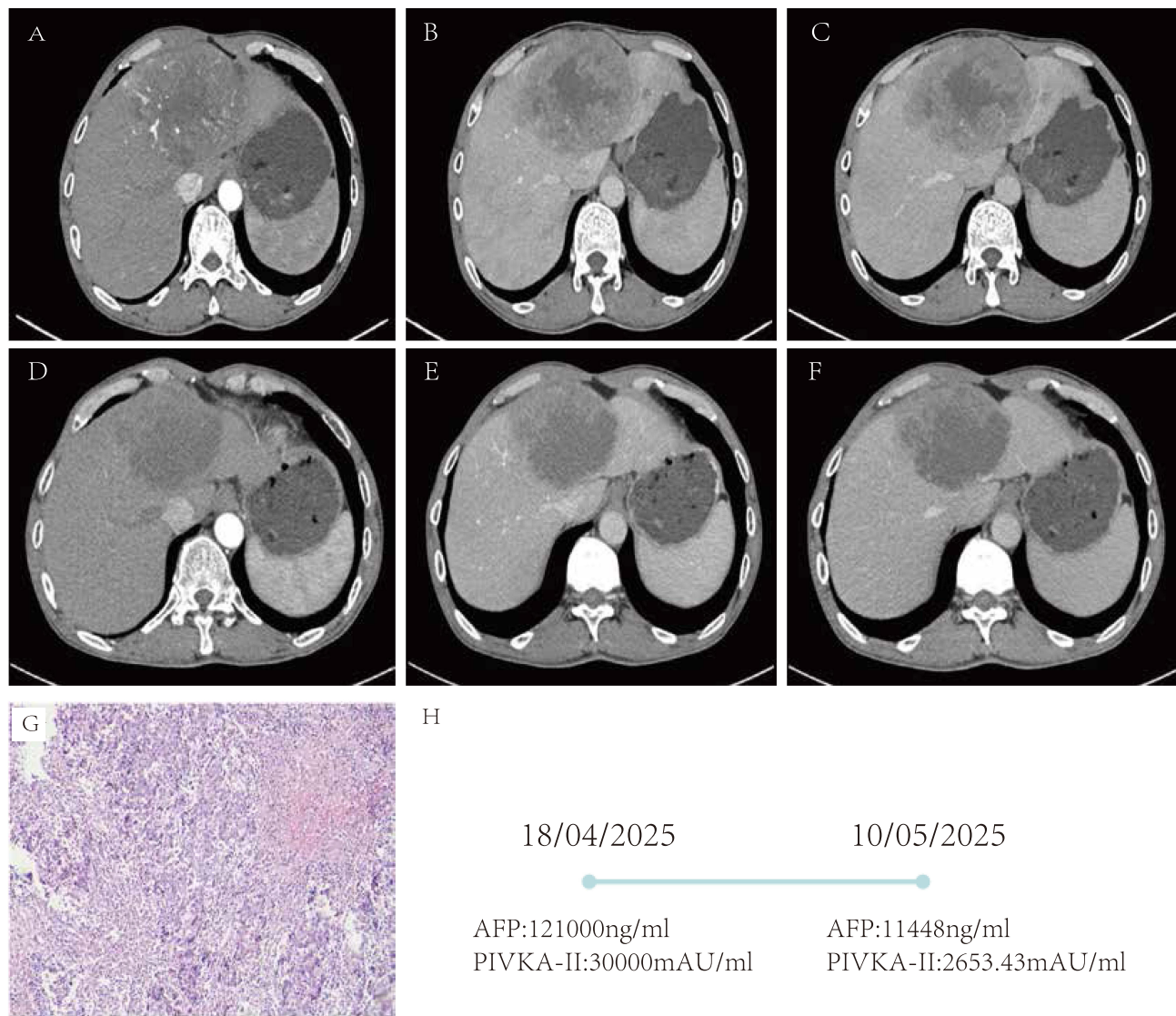


Figure 1 Clinical images of Patient 1. (A–C) Contrast-enhanced computed tomography (CT) images before interventional therapy, showing an 11 cm × 8 cm space-occupying lesion in the left hepatic lobe; (D–F) CT images after the first interventional therapy, with the tumor reduced to 7.5 cm × 7 cm; (G) postoperative pathology: extensive necrosis was observed in the submitted tissue, with a small amount of residual moderately differentiated hepatocellular carcinoma (HCC); and (H) changes in tumor markers during treatment, with both alpha-fetoprotein (AFP) and protein induced by vitamin K absence or antagonist-II (PIVKA-II) significantly decreased.

As of September 2025, the patient had undergone a total of 3 interventional therapy sessions. Follow-up CT revealed that the tumor had shrunk to 4×3.6 cm, a reduction of 56.7%; the enlarged lymph nodes had significantly decreased in size; and the tumor markers had also decreased markedly (Figure 2M). In accordance with the mRECIST criteria, the patient achieved PR. However, the patient’s family declined surgical treatment because of concerns about the patient’s age.

Case 3

The patients’ clinical baseline characteristics are presented in Table 1. The patient was admitted to the hospital in July 2025 because of “detection of a liver space-occupying lesion for more than 3 days”. Contrast-enhanced abdominal magnetic resonance imaging (CE-MRI, Figure 3A) revealed masses in the left hepatic lobe and hilar region, which were suspected to be cholangiocarcinoma, accompanied by hepatic artery-portal vein fistula and tumor thrombus in the left branch of the portal vein. The patient’s preoperative liver function was classified as Child–Pugh grade B, resulting in a relatively high risk of liver failure following surgical resection.

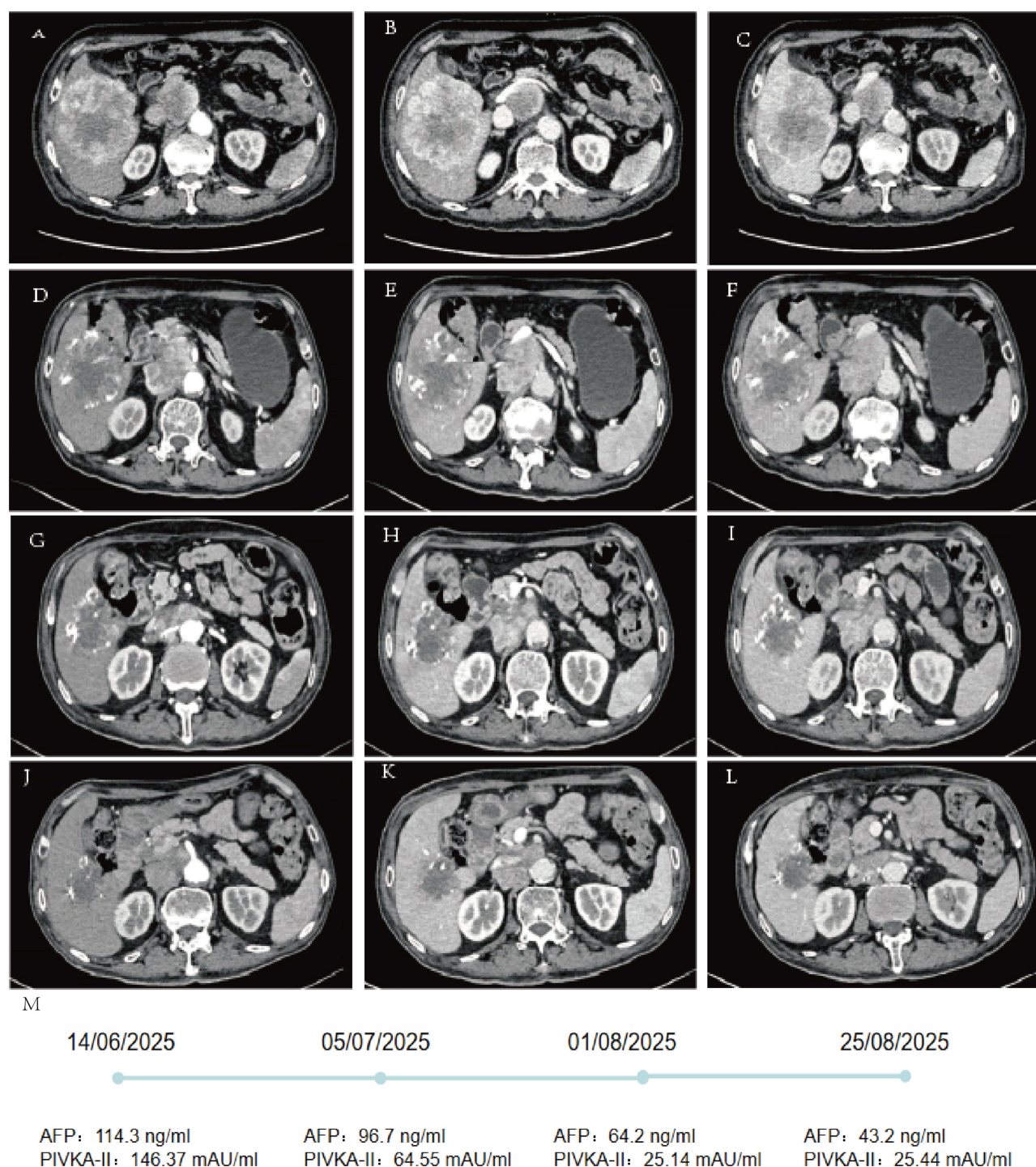


Figure 2 Clinical images of Patient 2. (A–C) CT images before interventional therapy, revealing a large 10.4 cm × 8.4 cm mass in the right hepatic lobe; (D–F) CT images after the first interventional therapy, showing a slight reduction in tumor volume; (G–I) CT images after the second interventional therapy, with further shrinkage of the tumor and lymph nodes; (J–L) CT images after the third interventional therapy, with the tumor reduced to 4 cm × 3.6 cm; and (M) changes in tumor markers during treatment, with AFP and PIVKA-II showing a continuous downward trend.

Therefore, a therapeutic regimen of TEM-TACE and HAIC combined with targeted/immunotherapy was adopted. During the operation, 5 mL of temperature-sensitive embolic agent mixed with 30 mg of epirubicin was infused via the tumor-feeding artery. Postoperatively, arterial infusion chemotherapy with 150 mg oxaliplatin and 4 mg raltitrexed was administered, combined with intravenous infusion of 200 mg tislelizumab and oral administration of lenvatinib (2 capsules once daily).



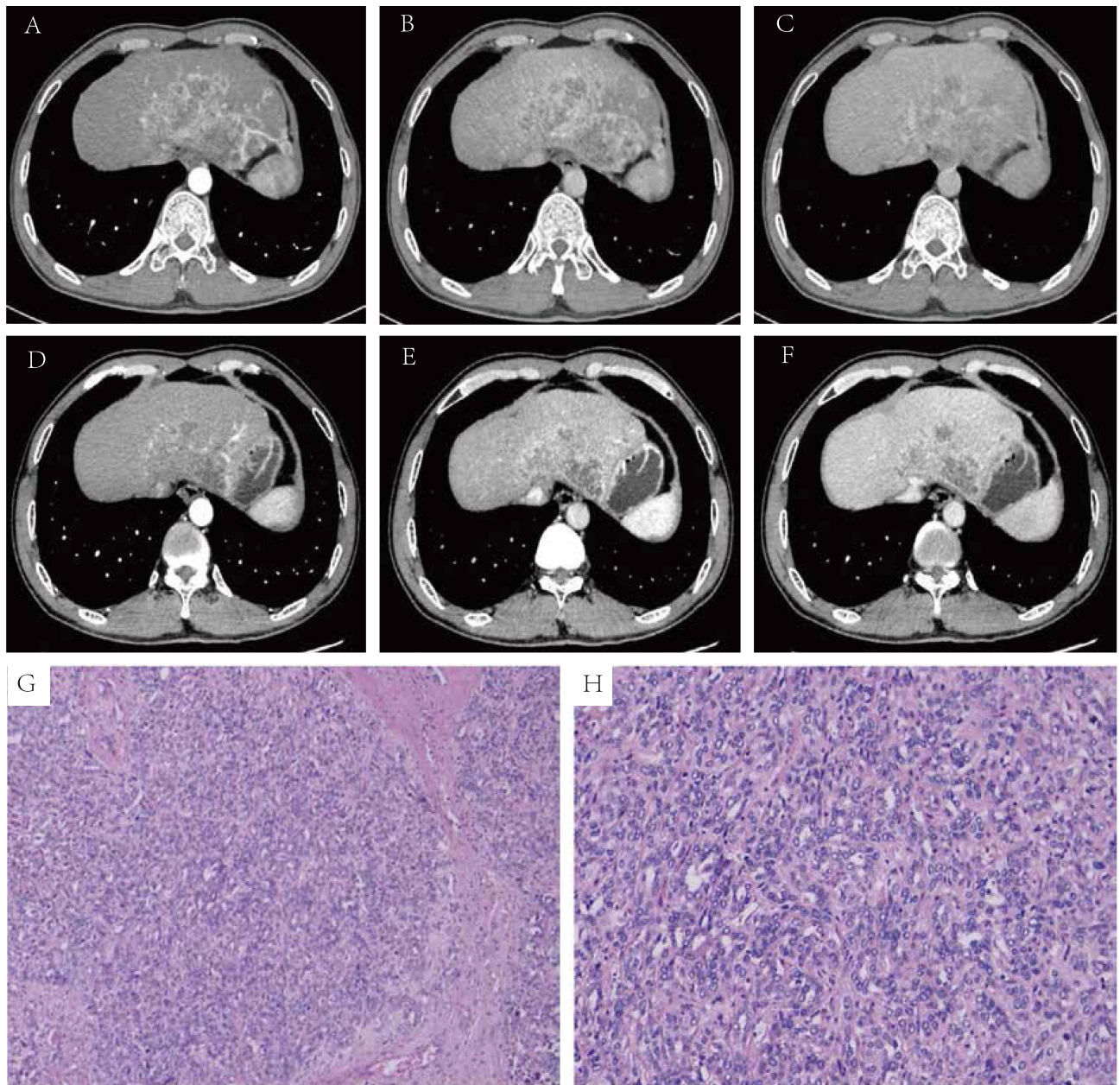
Figure 3 Clinical images of Patient 3. (A) Magnetic resonance imaging (MRI) image before interventional therapy, demonstrating malignant space-occupying lesions in the left hepatic lobe and hilar region; (B–D) CT images after the first interventional therapy, with reduced tumor volume; and (E) changes in tumor markers during treatment, with AFP, PIVKA-II and carbohydrate antigen 199 (CA199) all significantly decreased.

The patient was readmitted for reexamination three weeks later. The AFP concentration decreased to 117 ng/mL, the PIVKA-II concentration decreased to 67.31 mAU/mL, and the carbohydrate antigen 199 (CA 19–9) concentration decreased to 53.3 U/mL (Figure 3E). CT (Figure 3B–D) revealed that the tumor volume was reduced compared with that at baseline, with a reduction of 38.1%. According to mRECIST, the patient achieved PR. However, the patient’s family declined surgical treatment because of concerns about surgical risks, and no further reexamination was conducted as of September 2025, with a 2-month follow-up period.

Case 4

The patients’ clinical baseline characteristics are presented in Table 1. The patient was admitted to the hospital in July 2025 because of “detection of liver space-occupying lesions for more than 5 days”. CT (Figure 4A–C) revealed multiple intrahepatic nodules (predominantly in the left hepatic lobe, with the largest lesion measuring approximately 11.8×8.0 cm), which were suspected to be ICCs complicated by multiple intrahepatic metastases; thus, no surgical indication was identified.

Therefore, a therapeutic regimen of TEM-TACE and HAIC combined with targeted therapy was administered. During the operation, 5 mL of temperature-sensitive embolic agent mixed with 30 mg of epirubicin was injected.



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AFP:3.4ng/ml

PIVKA-II:21.79mAU/ml

CA199:35.9U/ml

AFP:3.3ng/ml

PIVKA-II:25.04mAU/ml

CA199:20.5U/ml

Figure 4 Clinical images of Patient 4. (A–C) Images before interventional therapy, showing multiple nodules sized 11.8 cm × 8.0 cm in the left hepatic lobe; (D–F) CT images after interventional therapy, with the tumor reduced to 8.0 cm × 4.5 cm; (G–H) postoperative pathology: intrahepatic cholangiocarcinoma (small duct type, moderately differentiated), with no cancer tissue detected at the surgical margin; and (I) changes in tumor markers during treatment, with CA199 significantly decreased, while AFP and PIVKA-II showed no obvious fluctuation.

Postoperatively, arterial infusion chemotherapy with the FOLFOX regimen was performed, combined with oral administration of lenvatinib (2 capsules once daily).

The patient was readmitted for reexamination three weeks later. The AFP concentration was 3.3 ng/mL, the PIVKA-II concentration was 25.04 mAU/mL, and the CA 19-9 concentration was 20.5 U/mL (Figure 4I). CT (Figure 4D-F) revealed that the tumor had shrunk to 8×4.5 cm, a reduction of 46.2%. According to mRECIST, the patient achieved PR. A laparoscopic left hemihepatectomy was then performed as scheduled, and postoperative pathological examination confirmed the ICC (Figure 4G and H). No recurrence or metastasis was observed as of September 2025, with a 2-month follow-up period.

Discussion

Primary liver cancer is highly occult in its early stage. Most patients are diagnosed at an advanced stage, have lost the opportunity for surgical resection, and thus have an extremely poor prognosis.¹⁴ Currently, multimodal therapeutic strategies have yielded encouraging outcomes in the management of unresectable HCC. Previous studies have demonstrated that the surgical conversion and resection rates of TACE combined with HAIC are significantly greater than those of TACE alone (48.8% vs 9.5%, $P < 0.001$).¹⁵ Another retrospective cohort study confirmed that compared with targeted/immunotherapy alone, the quadruple therapy regimen of TACE-HAIC combined with targeted/immunotherapy significantly improved overall survival (OS, 29.4 months [95% CI: 23.9–NA] vs 18.0 months [14.7–31.8]; $P = 0.041$), progression-free survival (PFS, 16.4 months [95% CI: 12.7–NA] vs 10.0 months [3.32–31.8]; $P = 0.012$), objective response rate (ORR, 68.4% vs 28.0%; $P = 0.001$) and disease control rate (DCR, 92.3% vs 63.1%; $P < 0.001$) in patients with Barcelona Clinic Liver Cancer (BCLC) stage C HCC.¹⁶ These studies have demonstrated the advantages of multimodal therapy. However, no clear and effective conversion therapy regimen for unresectable ICC currently exists.

Moreover, a wide variety of embolic agents are available for TACE, and no unified consensus on their selection currently exists. Compared with traditional embolic agents, temperature-sensitive embolic agents are a novel type of drug-loaded embolic material that have been developed in recent years: they can achieve distal vascular cast embolization in the liquid state; once solidified, they provide durable and nonmigratory embolization. Moreover, they possess real-time imaging and sustained drug-release capacities, which not only improve the precision of embolization but also reduce the side effects of chemotherapy.^{8–12} Existing studies have shown that among 11 patients with unresectable HCC who received TEM-TACE, 1 achieved a complete response (CR), 9 achieved a PR, 1 had stable disease (SD), and 0 had disease progression. The ORR reached 90.91%, and the DCR was 100%. No serious embolic agent-related complications occurred in any of the patients during or after the operation.¹¹

In this study, all 4 patients were diagnosed with unresectable primary liver cancer at the initial visit, including 2 patients with HCC and 2 patients with ICC. Among them, one patient was classified as Child–Pugh grade B in terms of liver function. All patients received a multimodal therapeutic regimen consisting of TEM-TACE combined with HAIC and targeted/immunotherapy. After treatment, all 4 patients achieved PR according to mRECIST. The average tumor reduction percentage reached 42.3%, with both the ORR and the DCR reaching 100%. Specifically, 2 patients successfully underwent conversion surgery, while the remaining 2 were also eligible for surgical resection. In terms of safety, on the basis of the Clavien–Dindo classification, only grade I–II complications (mainly abdominal pain and nausea) were observed in the 4 patients after interventional therapy. These complications improved significantly following symptomatic treatment, and no severe intervention-related adverse reactions were reported. Compared with previous studies on traditional TACE combined with HAIC, the conversion efficacy in ICC patients in this study provides a new direction for the treatment of this specific type of liver cancer. Moreover, the DCR, ORR, and tumor reduction rate of unresectable liver cancer patients in this study are not inferior to those reported in previous studies, which fully demonstrates the technical advantages of temperature-sensitive embolic agents.

Limit

However, this study still has certain limitations. First, it is a small-sample case report with only 4 patients, which may lead to selection bias. Second, the follow-up period for patients was relatively short (with an average follow-up of 2.75

months), so long-term efficacy indicators such as PFS and OS were not obtained. In the future, we will extend the follow-up period to supplement and improve the relevant data.

Conclusion

In conclusion, the multimodal therapeutic regimen of TEM-TACE combined with HAIC and targeted/immunotherapy is safe and effective for unresectable primary liver cancer (including HCC and ICC) with a tumor diameter > 10 cm and Child–Pugh grade A/B liver function. It can significantly reduce tumor volume and achieve surgical conversion. Moreover, this regimen provides a new idea for the conversion therapy of ICC, but its long-term efficacy needs to be further verified by multicenter, large-sample, and long-term follow-up randomized controlled trials.

Data Sharing Statement

The original data related to this study are available from the corresponding author upon reasonable request, who will provide data support for eligible applicants in accordance with relevant regulations.

Ethics Statement

In accordance with the requirements of the Ethics Committee of the First Affiliated Hospital of Chongqing Medical University, case reports are not classified as research and do not require ethical review. All medical record materials were obtained with the patient's informed consent.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Disclosure

The authors have no conflicts of interest to declare for this work.

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