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Hepatic arterial infusion chemotherapy (HAIC) with oxaliplatin, fluorouracil, and leucovorin (FOLFOX) versus transarterial chemoembolization (TACE) for unresectable hepatocellular carcinoma (HCC): A randomised phase III trial

M. Shi, Q. Li, M. He, R. Guo

Background

TACE is the current standard of care for patients with unresectable intermediate-stage HCC. In a previous phase II study we found HAIC with FOLFOX yielded a higher treatment response versus TACE in patients with large unresectable HCC. Here we report results from a phase III trial of HAIC with FOLFOX versus TACE.

Methods

In this randomised, multi-centre, open-label trial, adults (≥18 years) with a primary unresectable HCC tumour with a largest diameter ≥7 cm, without macrovascular invasion or extrahepatic spread were randomised 1:1 to HAIC (oxaliplatin 130 mg/m^2, leucovorin 400 mg/m^2, fluorouracil bolus 400 mg/m^2 on day 1, and fluorouracil infusion 2400 mg/m^2 for 24 hours, every 3 weeks via repeated catheterization) or TACE (50 mg of epirubicin, 50 mg of lobaplatin, and lipiodol and polyvinyl alcohol particles). The primary endpoint was overall survival (OS) and secondary endpoints were objective response rate (ORR) using RECIST, progression-free survival (PFS) and safety. Treatment response was also assessed using mRECIST. Treatment outcomes were evaluated in an intention-to-treat population and safety was assessed in patients who received ≥1 cycle of study treatment.

Results

A total of 315 patients were randomised to HAIC (n=159) or TACE (n=156). The cut-off for the present analysis was April 2020 and patient follow-up is on-going. Median OS was higher for patients receiving HAIC versus TACE: 23.1 months (95% CI, 18.23–27.97) versus 16.07 months (95% CI, 14.26–17.88); hazard ratio (HR), 0.58 (95% CI, 0.45–0.75; P <0.001). Compared with the TACE group, patients in the HAIC group had a higher ORR (RECIST: 45.9 [73] vs. 17.9% [28], P <0.001; mRECIST: 48.4 [77] vs. 32.7% [51], P=0.004), and a longer median PFS (9.63 [95% CI, 7.40–11.86] vs. 5.40 [95% CI, 3.82–6.98] months; P <0.001). More patients in the HAIC group underwent subsequent resection compared with the TACE group (23.8 [38] vs. 11.5% [18], P=0.004). The incidence of serious adverse events was higher in the TACE group versus the HAIC group (30 vs 19%, P=0.03).

Conclusions

HAIC with FOLFOX significantly improved OS compared with TACE in patients with unresectable HCC.

Clinical trial identification

NCT02973685.

Legal entity responsible for the study

Shi Ming.

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Disclosure

All authors have declared no conflicts of interest.