



Clinical Summary Series

HAI Therapy for Unresectable Intrahepatic Cholangiocarcinoma

Hepatic disease control in patients with intrahepatic cholangiocarcinoma correlates with overall survival.

Soares KC, Jolissaint JS, McIntyre SM, Seier KP, Gonen M, Sigel C, Nasar N, Cercek A, Harding JJ, Kemeny N, Connell LC, Groot Koerkamp B, Balachandran VP, D'Angelica MI, Drebin JA, Kingham TP, Wei AC, Jarnagin WR.

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BACKGROUND

The purpose of this study was to investigate the impact of hepatic disease control in intrahepatic cholangiocarcinoma (iCCA) and its implications for overall survival (OS).

METHODS

This single-institution retrospective analysis of a prospectively maintained database evaluated outcomes in a total of 714 patients with biopsy-proven iCCA. Of these patients, 250 were treated with curative intent resection (24.8% of these receiving adjuvant chemotherapy), 176 were treated with hepatic artery infusion (HAI) therapy (+/-) systemic chemotherapy, and 288 were treated with systemic therapy alone.

Overall survival and hepatic progression-free survival were assessed using Kaplan–Meier methods and Cox proportional hazards modeling. To reduce treatment-selection bias, a propensity score–matched (PSM) analysis was performed in patients with unresectable, liver-limited disease, comparing outcomes between those treated with HAI and those receiving systemic chemotherapy alone. Additional analyses examined patterns of recurrence and the impact of locoregional salvage therapies in patients with isolated hepatic recurrence following resection.

RESULTS

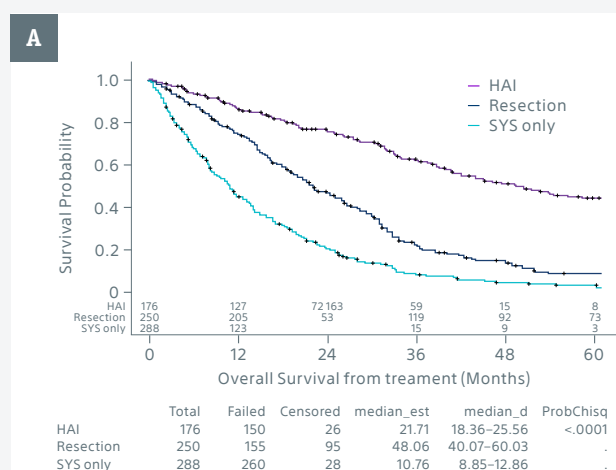
Resection was associated with an improved median OS (48.1 months) compared with both HAI (21.7 months) and systemic chemotherapy alone (10.8 months; $p < 0.001$) (Figure 1A). In addition, resected patients were significantly less likely to recur/progress in the liver compared with HAI and systemic chemotherapy patients (2-year CIF: 0.41 vs. 0.58 vs. 0.63; $p < 0.001$).

These data demonstrate both the adverse impact of intrahepatic recurrence or progression on survival, as well as the ability of HAI to provide better hepatic disease control and improved survival compared to treatment with systemic chemotherapy alone in patients with unresectable advanced iCCA.

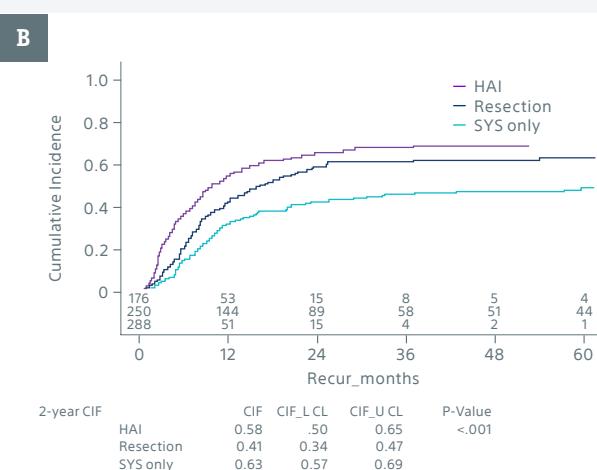


Full Cohort

Overall survival according to treatment modality (upfront resection, hepatic artery infusion [HAI], or systemic chemotherapy alone [SYS]) (N=714).

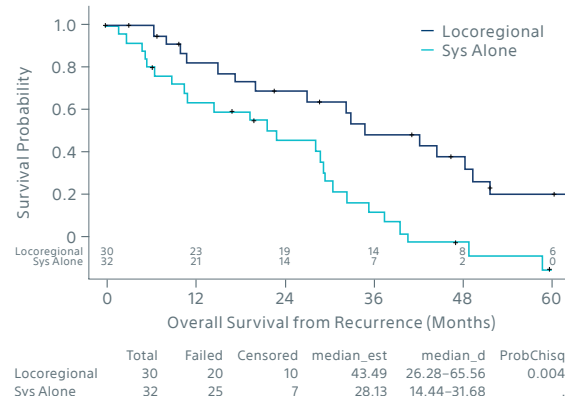


Cumulative incidence curve of time to progression or recurrence in the liver according to treatment modality (upfront resection, hepatic artery infusion [HAI], or systemic chemotherapy alone [SYS]) (N=714).



A total of 161 patients (64.4%) recurred after resection. Of the 65 patients with isolated liver recurrence, 46.2% were treated with locoregional liver-directed therapies: resection 36.7%, HAI 30.0%, transarterial chemoembolization (TACE) 13.3%, and ablation 20.0%. The median OS was significantly longer in patients whose post-resection recurrence was treated with locoregional therapy versus systemic chemotherapy alone (43.5 months vs. 28.1 months; $p = 0.004$). On multivariable analysis, locoregional therapy after recurrence was associated with a significant improvement in OS (HR 0.46, $p = 0.002$) while recurrence within 12 months of resection was associated with significantly decreased OS after controlling for recurrence location (HR 2.1; $p < 0.001$).

Overall survival of resected patients with liver recurrence treated with locoregional therapy versus systemic chemotherapy alone. (Three patients were lost to follow-up at the time of recurrence, therefore $n = 62$. SYS, systemic chemotherapy.)





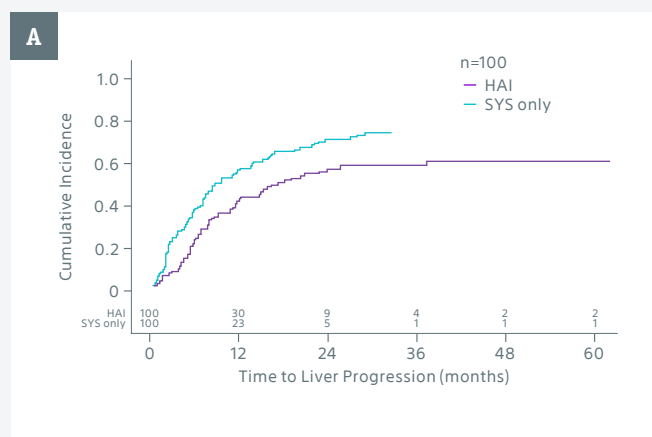
Propensity Matched Cohort

After PSM adjusting for age, sex, race, lymph node metastasis, multifocal liver disease, and tumor grade, HAI was associated with a 35% improvement in hepatic PFS (HR 0.65; $p = 0.012$) and a 41% improvement in OS (HR 0.59; $p < 0.001$). Within the PSM sample, progression in the liver – either alone or in combination with extrahepatic recurrence or progression – was associated with a 10-fold increased risk in mortality (HR 10.239; $p < 0.0001$), extrahepatic recurrence or progression was associated with a nearly 9-fold increased risk in mortality (HR 8.931; $p < 0.0001$), and HAI treatment was associated with a one-third reduction in mortality risk (HR 0.673; $p = 0.0134$).

Propensity Score Matched Analyses

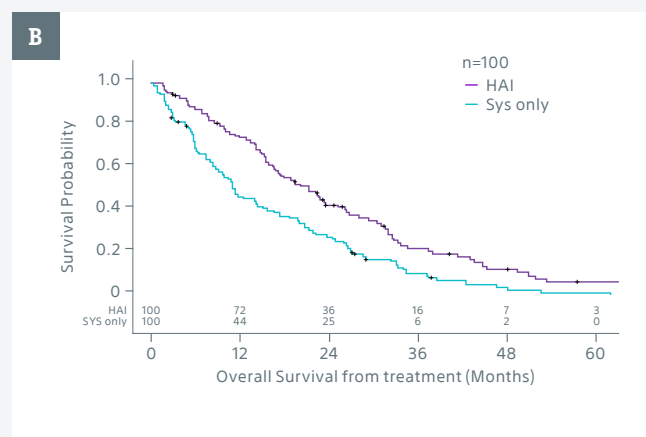
A: TIME TO ANY LIVER PROGRESSION

Propensity score matched analysis of cumulative incidence of time to any liver progression for patients receiving hepatic artery infusion pump versus systemic chemotherapy alone.

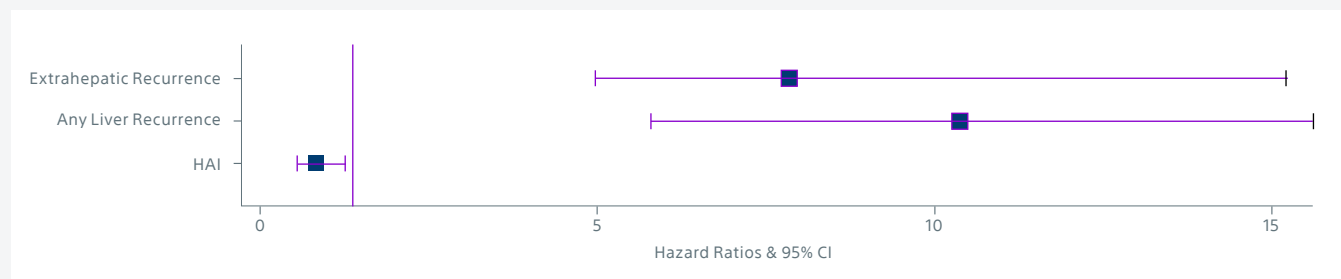


B: OVERALL SURVIVAL

Propensity score matched analysis of overall survival of patients receiving hepatic artery infusion pump versus systemic chemotherapy alone.



Hazard Ratios for Mortality





INTERA 3000™ Hepatic Artery Infusion Pump

Takeaways, Conclusions, Limitations

This study demonstrated the importance of hepatic disease control to outcomes in patients with advanced iCCA. For those eligible, curative-intent resection provided the best hepatic disease control and survival. In resected patients with isolated liver recurrence, treatment with locoregional therapy was associated with superior disease control compared with systemic chemotherapy alone.

For patients with unresectable disease, HAI was associated with a survival advantage compared with systemic chemotherapy alone. After PSM, patients with liver-limited disease who were treated with HAI had a 35% lower risk of any liver progression and a 41% reduction in risk of mortality.

Takeaways

- Patients who were able to undergo resection were least likely to recur or progress in the liver compared with those who received HAI or systemic chemotherapy.
- In patients with unresectable liver-limited iCCA, hepatic disease progression was associated with a 10-fold increase in risk of mortality.
- In propensity-matched patients with unresectable, liver-limited iCCA, HAI was associated with improved hepatic progression-free survival (HR=0.65) and reduced risk of mortality (HR=0.59) compared with systemic chemotherapy alone.

Limitations

- Retrospective, single center study
- Chemotherapy regimens not standardized across study
- Possible selection bias, despite propensity matching



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