ASCO 50th ANNUAL MEETING SCIENCE & SOCIETY

Meeting Abstracts

# Standardized radiofrequency ablation (sRFA) ≥ 45 minutes (m) plus lyso-thermosensitive liposomal doxorubicin (LTLD) for solitary hepatocellular carcinoma (HCC) lesions 3-7 cm: A retrospective analysis of phase III HEAT study.



Sub-category:
Hepatobiliary Cancer

Category:
Gastrointestinal (Noncolorectal) Cancer

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**Abstract Disclosures**

Abstract:

**Background:** The outcome of RFA for HCC tumors >3cm remains unsatisfactory, with high recurrence rates suggesting that RFA alone often fails to eradicate all disease. We previously conducted a double-blind randomized controlled trial (DBRCT) of RFA ± LTLD, the HEAT Study. LTLD is given by iv infusion. The liposomes selectively localize in and around tumors due to the enhanced permeability and retention properties of tumors. When these areas are heated to >40°C, the liposomes quickly break down and release a high concentration (conc) of the heat-enhanced cytotoxic doxorubicin (dox). We randomized 701 patients (pts) who had <4 unresectable HCC lesions, with at least one ≥3cm and none >7cm. No minimum RFA heating time was required. The primary and a key secondary endpoint were progression-free survival (PFS) and overall survival (OS). RFA + LTLD was safe, with reversible myelotoxicity similar to dox. Median PFS was about 14 months in both arms and median OS was about 53 months in both arms. Pts with multiple lesions did not benefit from adding LTLD to RFA. A computational modeling study of LTLD and mild (43ºC) heat found that the conc of dox in liver tumor tissue increases with duration of heating, but it takes 45m to deliver 75% of maximum conc. Also, a preclinical study of LTLD in healthy pigs confirmed that longer RFA heat time results in higher dox liver conc. **Methods:** Post hoc multivariate Cox regression analysis was performed on the HEAT study subgroup of 446 pts with a solitary lesion, with 7 prognostic factors (RFA heat time >45m or <45m, age, etiology, lesion diameter, Child-Pugh class, region, RFA device) considered in the model. **Results:** Both univariate and multivariate analyses suggest that the efficacy of RFA + LTLD is optimized by standardizing RFA to provide ≥ 45m heat time. Among the 285 pts with a solitary lesion who received sRFA, the OS hazard ratio is 0.64 (95% CI: 0.41 - 1.00, P = 0.0495); medians have not yet been reached based on the 86 deaths to date. **Conclusions:** A DBRCT of sRFA ± LTLD is warranted. We will soon initiate the 550-pt OPTIMA study to evaluate ≥ 45m RFA ± LTLD in pts with a single 3-7cm lesion. Clinical trial information: NCT00617981.

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1. ABC-03: A randomized phase II trial of cediranib (AZD2171) or placebo in combination with cisplatin/gemcitabine (CisGem) chemotherapy for patients (pts) with advanced biliary tract cancer (ABC).

Meeting: 2014 ASCO Annual Meeting Abstract No: 4002 First Author: Juan W. Valle
Category: Gastrointestinal (Noncolorectal) Cancer - Hepatobiliary Cancer

2. STORM: A phase III randomized, double-blind, placebo-controlled trial of adjuvant sorafenib after resection or ablation to prevent recurrence of hepatocellular carcinoma (HCC)

Meeting: 2014 ASCO Annual Meeting Abstract No: 4006^ First Author: Jordi Bruix
Category: Gastrointestinal (Noncolorectal) Cancer - Hepatobiliary Cancer

3. Biomarker analyses and association with clinical outcomes in patients with advanced hepatocellular carcinoma (HCC) treated with sorafenib with or without erlotinib in the phase III SEARCH trial.

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