AB068. P-39. Comparison of selective internal radiation therapy (SIRT) versus sorafenib in patients with locally advanced hepatocellular carcinoma in Mongolia: a subgroup analysis of SIRveNIB study

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Background: Mongolia has one the highest hepatocellular carcinoma (HCC) incidence in the world due to widespread hepatitis B and C endemic along with high alcohol consumption rate. However, local data on optimal therapeutic regime for these patients is scarce. The objective of this study is to evaluate the efficacy of selective internal radiation therapy (SIRT) using SIR-Spheres yttrium-90 microspheres versus sorafenib in Mongolian patients with locally advanced HCC patients at Barcelona Clinic Liver Cancer (BCLC) stage B and C patients without extra-hepatic metastasis.

Methods: It was a subgroup analysis based on patients enrolled from the National Cancer Center, Mongolia in the SIRveNIB study. SIRveNIB was a multi-center, randomized trial in which eligible patients with locally advanced inoperable HCC was randomized (1:1) to either single injection of SIRT or sorafenib (oral 400 mg BD) and patients were followed up till progressive disease or unacceptable toxicity. Key endpoints were overall survival (OS) (primary endpoint), tumor response rate, time-to-tumor progression, progression-free survival and toxicity.

Results: Thirty-nine patients (20 SIRT, 19 sorafenib) were enrolled from Mongolia. BCLC C patients without extra-hepatic metastasis comprised 62% of patients, 18% had portal vein thrombosis, 85% were Child-Pugh A, 45% were hepatitis B and 30% were hepatitis C. Altogether 4 of 20 patients (20%) in the SIRT arm failed to receive the study therapy. Intention-to-treat analysis was carried out with the OS in the SIRT and sorafenib arms being 9.2 and 15.6 months, respectively [hazard ratio (HR) 0.95, P=0.889]. Tumor response rate (TRR) was 10% and 0% (P=0.487) respectively. Time-to-tumor progression (TTP) was 6.2 *vs*. 8.5 months (HR 1.01, P=0.971) and progression-free survival (PFS) 5.9 *vs*. 8.5 months (HR 1.07, P=0.842 for SIRT and sorafenib, respectively. At least one severe adverse event (≥3 grade) was found in 56% and 47% of patients in the SIRT and sorafenib arms, respectively.

Conclusions: In this subgroup analysis of a single center which is part of a larger multi-center, randomized controlled trial, 20% of the patients assigned to the SIRT arm failed to receive SIRT. On intention-to-treat analysis, there was no significant difference in OS, TRR, TTP and PFS between the SIRT and sorafenib arms.

Keywords: RECIST; selective internal radiation therapy (SIRT); alanine aminotransferase; aspartate aminotransferase

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