



OLDER LIVER CANCER PATIENTS RESPOND TO RADIOEMBOLISATION USING SIR-SPHERES EQUALLY AS WELL AS YOUNGER PATIENTS, NEW STUDY IN *JOURNAL OF HEPATOLOGY* SAYS

Based on New Data from Multi-Centre ENRY Evaluation of 325 Patients, Authors Suggest that Radioembolisation May Be a Well-Tolerated and Effective Option for an Increasing Population of Older Patients

Bologna, Italy (20 June 2013) – Results of a new analysis by members of the multi-centre European Network on Radioembolisation with Yttrium-90 Resin Microspheres (ENRY), published on-line in the *Journal of Hepatology*, the peer-reviewed official journal of the European Association for the Study of the Liver¹, may have important implications for older patients with inoperable primary liver cancer (hepatocellular carcinoma, or HCC).

The analysis found essentially identical long-term treatment outcomes following radioembolisation using SIR-Spheres in 128 elderly (age 70 years or older) compared to 197 younger (less than 70 years of age) patients with otherwise similar demographics. “Our findings suggest that age alone should not be a discriminating factor for the management of HCC patients. This is important because there is a trend towards increased age in patients diagnosed with HCC, particularly in developed countries,” said the article’s lead author, Rita Golfieri, MD, Professor of Radiology in the Department of Digestive Diseases and Internal Medicine of The University of Bologna.

Prof. Golfieri also stated that “While age should not be a barrier to the management of older patients with HCC, physicians should definitely take age and frailty into account when deciding which treatments to use.

“For example, the relative mildness of procedure-related events after radioembolisation with SIR-Spheres compared with transarterial chemoembolisation, or TACE, suggests that an effective single radioembolisation procedure may be more acceptable to elderly patients than the multiple courses of treatment required with TACE.

“In addition, while the tyrosine kinase inhibitor, sorafenib, represents a good treatment option for many elderly patients with HCC, the increased frequency of adverse events associated with its use in patients over 75 years old may require dose-modification,” Prof. Golfieri said.

The new study is the most recent report based on an extensive evaluation of 325 HCC patients treated by teams of liver specialists, oncologists, interventional radiologists and nuclear medicine physicians at eight centres in Germany, Italy and Spain, and coordinated by Bruno Sangro, MD, PhD, Director of the Liver Unit at Clinica Universidad de Navarra, Pamplona, Spain, and chair of the ENRY group.

About Hepatocellular Carcinoma

Hepatocellular carcinoma (HCC) occurs in people whose livers have become severely damaged or cirrhotic, due to conditions such as hepatitis and alcoholism. It is one of the ten most-common cancers in the world, with nearly 750,000 cases diagnosed annually, and the third-leading cause of cancer deaths.² It occurs with greatest frequency in regions where hepatitis is most often diagnosed, such as in Asia Pacific and Southern Europe.

Hepatocellular cancer can be cured only by surgery, either by resecting the diseased parts of the liver, or by transplantation with a liver from a healthy donor. These interventions, however, are inappropriate for the great majority of patients, whose survival may range from a few months to two or more years depending largely on the state of their liver at the time of their diagnosis and the extent of tumour invasion.

Key Findings of the Age-based ENRY Evaluation

The new analysis compared HCC treatment outcomes among 128 patients age 70 or older (mean age 74) with those for 197 younger patients (mean age 58). The authors also performed an additional sub-analysis of 49 very elderly patients ranging from 75–87 years (mean age 78).

The elderly and younger age groups had similar baseline characteristics, with many having multi-nodular, advanced-stage HCC which was present in both lobes of the liver and had reasonably-well compensated (Child-Pugh class A) underlying cirrhosis. Elderly patients had a significantly lower tumour burden, smaller liver volume – both overall and the amount targeted by radioembolisation – and were less likely to have had hepatitis B viral infection.

The difference in overall survival of patients in the study was not statistically significant between elderly (median 14.5 months) and younger (12.8 months) patients. There was also no significant difference in survival between very elderly patients (75 years or older) and those under that age (median 14.9 vs. 12.8 months).

Radioembolisation with SIR-Spheres was equally well-tolerated in both age groups. Common procedure-related events, such as fatigue, nausea and/or vomiting, abdominal pain, fever and raised bilirubin, were predominantly mild-to-moderate in severity and short in duration. Almost none of these events were rated at grade 3 or above, the exceptions being one reported case of grade 3 fatigue and two grade 4 elevations in bilirubin. Gastrointestinal (GI) ulceration (caused by the inadvertent deposition of microspheres in the GI tract) was similarly infrequent and of mild-to-moderate intensity in the two age groups. Severe GI ulcers (grade 3 and above) were actually almost three times less common among older patients (0.8% vs. 2.7%).

When the consolidated ENRY data were first published in 2011,³ Professor Sangro noted that: “As ENRY was not a prospective study, our findings must be interpreted conservatively. What we can say, based on our evaluation of a broad range of patients with HCC treated in routine clinical practice, is that radioembolisation using SIR-Spheres directly targets tumours and spares viable liver tissue, which enables us to reduce the burden of disease and potentially increase both the patient’s survival

