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High rate of early cancer recurrence following direct-acting antiviral treatment for hep C virus

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A new study fast-tracked for publication today in the *Journal of Hepatology* has shown that patients with a prior history of hepatocellular carcinoma (HCC) and who have been treated with direct-acting antivirals (DAAs) for Hepatitis C (HCV) infection have a higher than expected early recurrence rate of their liver cancer than previously thought - with the rate in some subgroups exceeding 40%. The study authors posit that the recurrences could be a result of a weakened immune system following DAA therapy.

The publication coincides with similar data from a study group in Italy also being presented today at The International Liver Congress in Barcelona, Spain.

HCC is the most common form of liver cancer worldwide.[1] According to the World Health Organization, liver cancer accounts for 662,000 deaths and is the third leading cause of cancer-related death, exceeded only by cancer of the lung and stomach.[2] Approximately 75% to 80% of cases of HCC occur in Asia, however, there is considerable variation within continents.2 The overwhelming majority of HCC cases occur in patients with chronic liver disease, where approximately 80% to 90% have cirrhosis (scarring of liver tissue), and most of the remainder have moderate to advanced fibrosis (an accumulation of scar tissue in the liver).2

"Direct-acting antivirals have made a huge impact on the treatment of Hepatitis C and have made viral clearance possible for many types of patients," said Professor Jordi Bruix of the Barcelona Clinic Liver Cancer (BCLC) Group, Hospital Clinic Barcelona, CIBEREHD, and University of Barcelona, Spain and joint lead author of the study. "Interferon-free regimens in particular are now being studied in many patient cohorts including those with other pre-existing disease such as HCC. Our data, even though from a relatively small number of patients, are so striking that it clearly signals we must exercise caution in the use of these agents in such patients, at least until data from further large-scale assessments are available."

The study included 103 patients across four hospitals who had HCV infection and a prior history of HCC. Of these, 58 patients had achieved complete response after treatment of their cancer and met inclusion criteria for the study. Baseline characteristics, laboratory and radiologic tumor response were registered in all patients before starting antiviral therapy and during the follow-up, according to the clinical practice policy.

After a median follow-up of 57 months, three patients died and 16 developed radiologic tumor recurrence (27.6%). The pattern of recurrence was: intrahepatic growth (three patients), new intrahepatic lesion (one nodule in five patients, up to three nodules less or equal to 3 cm in four cases and multifocal in one patient) and infiltrative ill-defined HCC and/or extra-hepatic lesions in three patients. Interestingly, median time between antiviral treatment and detection of recurrence was 3.5 months.

"This study adds to the data presented today at The International Liver Congress by Federica Buonfiglioli from an Italian study group. It is important that hepatologists continue to weigh up the risks and the benefits of DAA treatment for each individual patient, as these drugs are

still relatively new. Meanwhile we look forward to further data examining the mechanisms of metastatic awakening and the immune system so that we can accordingly tailor treatment for our patients," said Professor Massimo Colombo, Professor of Gastroenterology at the University of Milan, Italy and former Editor-in-Chief of the *Journal of Hepatology*.

More information: María Reig et al. Unexpected early tumor recurrence in patients with hepatitis C virus -related hepatocellular carcinoma undergoing interferon-free therapy: a note of caution, *Journal of Hepatology* (2016). DOI: 10.1016/j.jhep.2016.04.008

References:

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2 US National Library of Medicine National Institutes of Health. Hepatocellular carcinoma: management of an increasingly common problem. Available from: www.ncbi.nlm.nih.gov/pmc/articles/PMC2446418/. Last accessed: April 2016.

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