Long-term treatment of decompensated cirrhosis with human albumin improves survival

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Results from the ANSWER study presented today showed that long-term administration of human albumin improves the survival rate of patients with decompensated cirrhosis (the symptomatic stage of chronic liver disease). The study, presented at The International Liver Congress 2017 in Amsterdam, The Netherlands, demonstrated that treatment with human albumin also improved the management of ascites (accumulation of fluid in the abdominal cavity) and quality of life, and reduced the incidence of severe complications of the disease and the need for hospitalisation.

Decompensated cirrhosis occurs after severe fibrosis deposition (scarring) and a mass reduction in liver cells, as a consequence of long-lasting liver injury, and when the circulation and function of the organ are compromised (portal hypertension and liver insufficiency).1 Following decompensation, cirrhosis becomes a systemic disease, with multi-organ dysfunction and, ultimately, failure. As a result, patients with decompensated cirrhosis have a poor prognosis with the one-year probability of mortality being 20%.2 The only curative therapy currently available is liver transplantation.3 Therapies which improve survival in decompensated cirrhosis are an important unmet need in hepatology.

Human albumin is a relatively small protein synthesised by liver cells that plays a vital role in regulating fluid distribution in the body. Moreover, the albumin molecule is a potent scavenger of reactive

oxygen and nitrogen species, and binds and transports exogenous and endogenous toxic substances.4 Due to the reduced function of the liver, patients with cirrhosis often have low albumin levels in the blood.4 Human albumin has been used for many years to treat some of the most severe complications of cirrhosis in the acute setting.5

"There has been a lack of scientific evidence proving that long-term human albumin can treat cirrhosis with ascites," said Prof Mauro Bernardi, University of Bologna, Italy, and author of the study. "The ANSWER study has now clarified this issue, showing that human albumin extends survival and helps better manage ascites, as well as reducing the incidence of severe complications of this very serious disease."

The ANSWER study was a randomised, controlled trial of 440 patients with cirrhosis and uncomplicated ascites that compared standard diuretic therapy with standard diuretic therapy plus human albumin (40 g intravenously twice weekly in the first two weeks and then once weekly). The primary endpoint was overall survival and patients were followed for up to 18 months.

The rate of survival was significantly higher in patients receiving human albumin plus to standard therapy, compared with those receiving standard therapy only. Treatment with human albumin reduced the risk of death by 38%. Statistically significant benefits of administering human albumin rather than standard therapy alone were demonstrated for the management of ascites, complications of cirrhosis, quality of life and hospital admissions.

"The reduction in mortality observed in the albumin-treated arm of this randomised controlled study is a novel and important piece of information. Based on this data, weekly administration of albumin should be considered in patients with cirrhosis and ascites to prevent life-

threatening complications," said Prof Annalisa Berzigotti, University Clinic for Visceral Surgery and Medicine, University of Berne, Switzerland, and EASL Governing Board Member.

More information: Abstract: Long-term albumin administration improves survival in patients with decompensated cirrhosis: final results of the "ANSWER" study (LBO-08), The International Liver Congress 2017.

References:

1 British Liver Trust. Cirrhosis of the liver. Available from: www.britishlivertrust.org.uk/l … onditions/cirrhosis/. Last accessed: April 2017.
2 Zipprich A, Garcia-Tsao G, Rogowski S, et al. Prognostic indicators of survival in patients with compensated and decompensated cirrhosis. Liver Int. 2012 Oct;32(9):1407-1414.
3 European Association for the Study of Liver. The burden of liver disease in Europe. A review of epidemiological data. Available from: www.easl.eu/medias/EASLimg/Dis … 845caec619f_file.pdf. Last accessed: April 2017.
4 Bernardi M et al. Role of human albumin in the management of complications of liver cirrhosis. J Clin Exp Hepatol. 2014;4(4):302-11.
5 Arroyo V, Garcia-Martinez R, Salvatella X. Human serum albumin, systemic inflammation, and cirrhosis. J Hepatol. 2014;61(2):396-40.

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