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Adverse drug reactions in patients with cirrhosis

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primary end point compared to non-HCC patients though their baseline PC was similar.

Conclusion: AVA was superior to PBO in increasing PC and reducing both the proportion of patients with CLD who required a PT or rescue procedure for bleeding, and the proportion of patients who achieved a $PC \geq 50 \times 10^9/L$ by Procedure Day. Efficacy was similar for both end points regardless of HCC status, supporting the consistent efficacy of AVA.

SAT-137

Adverse drug reactions in patients with cirrhosis: analysis of spontaneous reports from the Dutch Pharmacovigilance Centre Lareb

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Background and aims: Patients with cirrhosis are susceptible for certain adverse drug reactions (ADRs), such as renal impairment and hepatic encephalopathy. However, not much is known. To obtain more ADR information, data from pharmacovigilance centers could be useful. We aim to describe the content of ADR reports from a pharmacovigilance center on patients with cirrhosis.

Method: We extracted all reports that mentioned "cirrhosis" from the database of the Dutch Pharmacovigilance Center Lareb. We excluded double reports, reports with cirrhosis as ADR and reports with an uncertain diagnosis of cirrhosis. The content of the included reports was quantitatively described.

Results: We retrieved 50 reports from the Lareb database. Twelve reports were excluded: two were double, in two others cirrhosis was the ADR and eight reports had an uncertain diagnosis of cirrhosis. Of the 38 included reports, 12 (32%) described the severity of cirrhosis of the patient. The reporter expressed this severity in a Child-Pugh class in seven and the other five reports mentioned severity in terms of decompensated or severe cirrhosis. The 38 reports concerned 49 suspected ADRs (median 1; range 1-3). These ADRs most often involved the following organ classes: "skin and subcutaneous tissue disorders" (n = 8; 21%), "nervous system disorders" (n = 6; 16%) and "gastrointestinal disorders" (n = 5; 13%). The most reported individual ADRs were: thrombocytopenia, a rash and an insult (all reported thrice). Two reports involved hepatotoxic events (one cholestatic hepatitis and one acute hepatitis). The pharmacovigilance assessor considered more than half (61%) of ADRs serious. In three, a death was reported. The medicines most frequently suspected for causing the ADR were: pegylated interferon-alpha-2a (n = 3), meropenem and norfloxacin (both n = 2). In one-fifth (21%) of reports the causality was evaluated as "probable" and in the remaining the causality was "possible".

Conclusion: The frequency of ADR reports on patients with cirrhosis is low in the Dutch Pharmacovigilance database. This suggests underreporting or inadequate documentation of cirrhosis as (co) morbidity. To indicate ADR risks in patients with cirrhosis, we advise to use a worldwide pharmacovigilance database.

SAT-138

Cirrhotic cardiomyopathy: A 2-year longitudinal follow-up study using advanced cardiac imaging

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Background and aims: Cardiac dysfunction is an established complication in cirrhosis, but the temporal relationship between progression of liver dysfunction, cardiac impairment and survival is unknown. The study aim was to investigate the development of

structural and functional cardiac changes over time with the progression of cirrhosis and outcome

Method: In a prospective 2-year longitudinal follow-up study, we included 63 cirrhotic outpatients (Child class: A = 9, B = 46, C = 8) and 14 healthy controls. We assessed advanced cardiac characteristics such as cardiac MRI with extracellular volume (ECV) quantification, speckle tracking echocardiography, ECG and biomarkers at 0/6/12/18/24 months. Patients were followed-up for a median of 30 months with registration of acute decompensations (AD), liver transplantation (LT), and death.

Results: In the 34 patients who remained stable or improved in cirrhosis during the 2-year study period limited cardiac deterioration was seen. Conversely, patients who progressed, underwent LT, or died had more pronounced cardiac dysfunction with structural myocardial changes, and left atrial enlargement. During follow-up 25 patients developed AD, 4 underwent LT, and 20 died. Mean arterial pressure was the only cardiovascular parameter associated with death in a univariate analysis ($p = 0.037$), and the main predictors were MELD and age. However, last visit myocardial ECV was independently associated with the combined end point of LT/death ($p = 0.001$), and in AD patients a low cardiac index was independently associated with death ($p = 0.01$).

Conclusion: Patients with stable cirrhosis have limited progression in cardiac dysfunction over a 2-year period with modest impact on survival. However, cardiac function seems to deteriorate in relation to progression in cirrhosis and may influence survival in AD patients. Our results encourage careful cardiac monitoring in patients with advanced cirrhosis.

SAT-139

Predictive factors for the development of acute-on-chronic liver failure in a North American cohort of hospitalized patients with cirrhosis and decompensation

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Background and aims: Acute-on-chronic liver failure (ACLF), irrespective of definition, is often precipitated by an event that disturbs systemic or regional homeostasis, leading to failure of one of more extra-hepatic organs, associated with high morbidity and short-term mortality. The aim of the study was to characterize cirrhotic inpatients with ACLF and to identify admission predictors of development of ACLF, as defined by the North American Consortium for the Study of End-stage Liver Disease (NACSELD) in hospitalized patients with cirrhosis.

Method: NACSELD, a consortium of 14 hepatology centers, prospectively enrolled non-electively admitted cirrhotic inpatients. We compared those who developed ACLF (≥ 2 organ failures) ≥ 48 hours after admission (ACLF+, n = 125) to those who did not (ACLF-, n = 2516). We excluded 416 patients with ACLF within the 1st 48 hrs of