Conclusions ALT/ALP ratio, Bilirubin >100, and high MELD scores are useful in differentiating diagnosis of acute AIH vs. DILI. Furthermore, the higher ALT/ALP ratio indicates AIH is predominately a hepatitic process, whereas DILI more commonly has a mixed hepatitis/biliary profile.

P213 OBETICHOLIC ACID IMPROVES HEPATIC FIBROINFLAMMATION ASSESSED BY MULTIPARAMETRIC MRI: INTERIM RESULTS OF THE REGENERATE TRIAL

Rohit Loomba, Quentin Anstee, Stephen Harrison, Arun Sanyal, Vlad Ratziu, Zobair Younossi, Zachary Goodman, Rajeshri Banerjee, Michael Stenklstrom, Shrema Shingapure, Luna Zarri, Aditya Venugopal, Leigh MacConell, Mary Rinella, Perspectum Diagnostics, Intercept Pharmaceuticals, University of California, San Diego, USA; Institute of Clinical and Translational Research, Newcastle University, UK; Virginia Commonwealth University, USA; Pinnacle Clinical Research Center, USA; Hôpital Pitié-Salpêtrière, France; Inova Health System, USA; Hôpital Beaujon, France; Intercept Pharmaceuticals, USA; Feinberg School of Medicine, Northwestern University, USA; Hull University Teaching Hospitals NHS Trust, UK, UK

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Introduction A Month 18 interim analysis of REGENERATE showed that treatment with obeticholic acid (OCA) improved fibrosis and steatohepatitis based on liver histology in patients with nonalcoholic steatohepatitis (NASH). However, liver biopsy has several limitations and development of noninvasive tools for diagnosis and monitoring of NASH is warranted. Here, we evaluate the effects of OCA on multiparametric MRI-derived, iron-corrected T1 (cT1) mapping.

Methods Multiparametric MRI by LiverMultiScan was performed in a subset of REGENERATE patients with fibrosis stage 2–3 (N=20) randomised 1:1:1 to placebo (n=7), OCA 10 mg (n=6), or OCA 25 mg (n=7). Changes in cT1 and liver fat content were evaluated after 18 months of treatment.

Results At baseline, mean (SD) cT1 was similar across all groups (856.7 [106.8] ms; 943.2 [116.1] ms; and 882.1 [94.7] ms in placebo, OCA 10-mg, and OCA 25-mg groups, respectively); elevated values reflect definite steatohepatitis and significant fibrosis. After 18 months of treatment, a dose-dependent reduction in cT1 was observed with a mean change from baseline of -91.7 ms in the OCA 25-mg group and -59.6 ms in the OCA 10-mg group, compared to -1.4 ms in the placebo group. Mean liver fat content at baseline was 16.29% (placebo), 19.27% (OCA 10 mg), and 15.3% (OCA 25 mg). Modest reduction (~7.9%) in fat content was noted with OCA 25-mg as early as 6 months and was generally sustained through Month 18 (figure 1).

Conclusions Treatment with OCA resulted in dose-dependent improvements in cT1 and liver fat content by multiparametric MRI, which may be consistent with histologic improvements in steatohepatitis and fibrosis, and in serum-based noninvasive markers of steatohepatitis and fibrosis (Anstee 2019). The REGENERATE study remains ongoing and will continue through clinical outcomes for verification and description of clinical benefit.

P214 PREDICTED RISK OF END STAGE LIVER DISEASE UTILIZING THE UK-PBC RISK SCORE IN PBC PATIENTS

David Jones, Marco Carbone, George Mells, Alexander Liberman, Elizabeth Smoot Malecha, Leigh MacConell, Kuldip Digpal*. Institute of Cellular Medicine-Newcastle University, UK; Academic Department of Medical Genetics-University of Cambridge, UK; Academic Department of Medical Genetics-University of Cambridge, UK; Intercept Pharmaceuticals, USA; Intercept Pharmaceuticals, UK

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Introduction The UK-PBC Study group developed and validated a long-term prognostic model of primary biliary cholangitis (PBC) based on data from ~3000 patients (pts) with PBC. The model uses albumin, platelets, alanine transaminase, gamma-glutamyl transferase, alkaline phosphatase, and total bilirubin as serum-based predictors. The aim of this study was to validate the model in PBC patients from Intercept Pharmaceuticals’ studies and to assess the prediction of end stage liver disease (ESLD) risk.

Methods The model was developed using data from the UK-PBC Study, and validated using data from Intercept Pharmaceuticals’ studies. The prediction of ESLD was assessed using the UK-PBC Risk Score calculated for each study participant and compared to the observed outcome of ESLD (cirrhosis or death). The model performance was evaluated using the area under the receiver operating characteristic curve (AUC).

Results The UK-PBC Risk Score was calculated for 340 study patients from Intercept Pharmaceuticals’ studies. The AUC for the model’s prediction of ESLD was 0.91 (95% CI 0.87–0.95). The model showed good calibration, with a Hosmer-Lemeshow test p-value of 0.81. The model was able to identify patients at high risk of ESLD with a sensitivity of 90% and a specificity of 84%.

Conclusions The UK-PBC Risk Score has good predictive performance for ESLD in PBC patients from Intercept Pharmaceuticals’ studies. The model can be used to identify patients at high risk of ESLD and inform clinical decision-making.

Abstract P213 Figure 1 Fibroinflammatory disease and fat content by multiparametric MRI