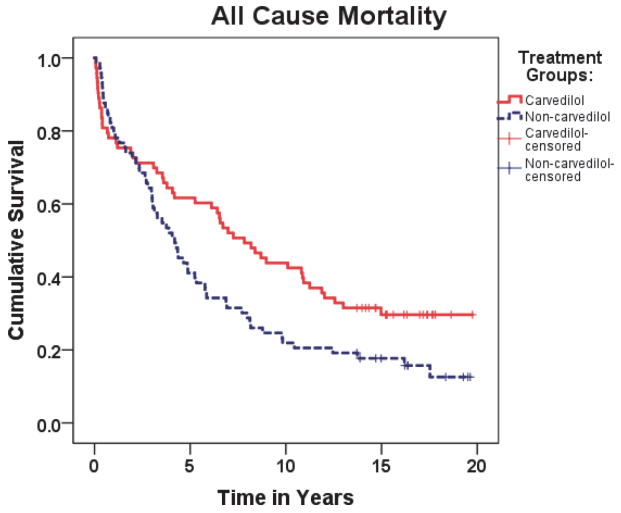


Abstract O23 Figure 1

hypertension. The difference in all-cause and liver-related mortality suggests that this survival benefit may not be entirely liver related.

REFERENCES

1. Sinha R, Lockman KA, Mallawaarachchi N, Robertson M, Plevris JN, Hayes PC. Carvedilol use is associated with improved survival in patients with liver cirrhosis and ascites. *J Hepatol* 2017 Jul;**67**(1):40–46
2. Facciorusso, A., Roy, S., Livadas, S. *et al*. Nonselective Beta-Blockers Do Not Affect Survival in Cirrhotic Patients with Ascites. *Dig Dis Sci* 2018;**63**:1737–1746
3. Tripathi D, Ferguson JW, Kochar N, *et al*. Randomized controlled trial of carvedilol versus variceal band ligation for the prevention of first variceal bleed. *Hepatology* 2009 Sep;**50**(3):825–33

O24 DURABILITY OF OBETICHOLIC ACID RESPONSE IN PBC PATIENTS WHO DID NOT ACHIEVE POISE TRIAL CRITERIA

[1]Gideon Hirschfield, [2,3]Marco Carbone, [4]David Jones, [1,5]Bettina Hansen, [6]Andreas Kremer, [7]Michael Trauner, [8]Alexander Liberman, [8]Elizabeth Smott Malecha, [8]Leigh MacConell, [9]Jonty Manuja*. *[1]Toronto Centre for Liver Disease, Canada; [2]University of Cambridge, UK; [3]University of Milan Bicocca, Italy; [4]Newcastle University, UK; [5]IHPME, University of Toronto, Canada; [6]Friedrich-Alexander-University Erlangen-Nürnberg, Germany; [7]Medical University of Vienna, UK; [8]Intercept Pharmaceuticals, USA; [9]Intercept Pharmaceuticals, UK*

10.1136/gutjnl-2020-bsgcampus.24

Introduction In clinical studies and in clinical practice, response to primary biliary cholangitis (PBC) treatment has been assessed using dichotomous biochemical response criteria. Although achieving these criteria may be associated with improved clinical outcomes, the benefit in patients (pts) with an incomplete response to treatment may be underestimated. This analysis assessed the extent and durability of obeticholic acid (OCA) response in pts with PBC not achieving the dichotomous primary endpoint in the phase 3 POISE study through 72 months of OCA treatment.

Methods Key inclusion criteria included PBC diagnosis, alkaline phosphatase (ALP) ≥1.67× upper limit of normal (ULN) and/or total bilirubin >ULN to <2× ULN, and on a stable dose of—or intolerant of—ursodeoxycholic acid (UDCA). During the 12-month double-blind (DB) phase, 216 pts were randomised to daily placebo, OCA 5–10 mg, or OCA 10 mg. This analysis pooled DB placebo (OCA baseline [BL] was open-label extension [OLE] day 0) and DB OCA pts to evaluate the efficacy and safety of up to 72 months of OCA treatment. Pts who achieved the POISE primary endpoint (ALP<1.67×ULN, with a ≥15% reduction from BL, and total bilirubin ≤ULN) 12 months from OCA BL were excluded. Values shown are mean (SD) unless otherwise specified. P values were based on paired t-tests.

Results Of the 193 pts enrolled in the OLE, 107 (55%) did not achieve the POISE criteria after 12 months of OCA treatment. Pts were 93% female, 91% Caucasian, 56 (10) years old at BL, and 91% received UDCA (15 [4] mg/kg/day). At BL, ALP was 356 (138) U/L and total bilirubin was 13 (8) µmol/L (>ULN in 18 pts [17%]). Despite not achieving the POISE criteria after 12 months of OCA, a significant and durable reduction was observed in ALP (p<0.01 at all time points) through 72 months of treatment (figure 1). Total bilirubin levels remained stable and near BL values within the normal range through the duration of treatment. Throughout the 6-year study period, the most common adverse events were pruritus (92 pts [86%]) and fatigue (33 pts [31%]), consistent with previous reports from POISE and expected PBC symptoms.

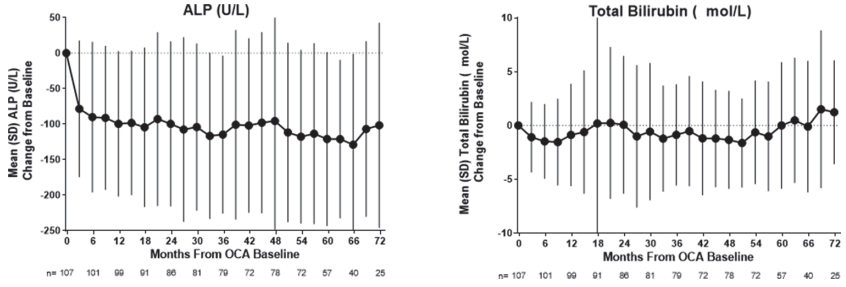
Conclusions Despite not achieving the POISE primary endpoint, these pts showed significant and sustained biochemical improvements.

O25 ALCOHOL RELATED LIVER DISEASE: DELAYED DIAGNOSIS AND MISSED OPPORTUNITIES FOR INTERVENTION

[1]Miss Rebecca Elleray*, [2,3]Mohsen Subhani, [2,3]Stephen Ryder, [4]Jane Bethea. *[1]Public Health England, Nottingham, UK; [2]University of Nottingham, Nottingham, UK; [3]NIHR Nottingham Biomedical Research Centre at Nottingham University Hospitals NHS Trust, Nottingham, UK; [4]Nottingham City Council, Nottingham, UK*

10.1136/gutjnl-2020-bsgcampus.25

Introduction Death from alcohol related liver disease (ARLD) is preventable and increasing. Effective identification and brief



Abstract O24 Figure 1 Change from baseline in ALP and total bilirubin through 72 months of OCA treatment

Gut: first published as 10.1136/gutjnl-2020-bsgcampus.24 on 21 January 2021. Downloaded from http://gut.bmj.com/ on February 2, 2021 by guest. Protected by copyright.