10 mg (n=73), OCA 5–10 mg (n=70, 33 patients titrated from 5 to 10 mg at Month 6), or PBO (n=73) groups during DB treatment. In the OLE, all patients were initially treated with 5 mg OCA with the option to increase to 10 mg (or later decrease) based on response and tolerability every 3 months. Non-invasive measures of liver fibrosis that were assessed were APRI and liver stiffness measurements (LSM) by transient elastography.

Results APRI was significantly reduced from baseline to DB Month 12 in both OCA–treated groups compared to PBO ($p<0.01$). PBO patients who initiated OCA during the OLE phase and patients randomised to OCA 5–10 mg had significant reductions from baseline to OLE Month 12 in mean APRI score ($p<0.05$). The mean APRI score in OCA 10 mg was reduced, but not significant at OLE Month 12 compared to baseline. During DB and OLE phases, while not significant, the OCA 10 mg group had mean reductions in LSM, while both OCA 5–10 mg and PBO groups had mean increases in LSM (Table).

Mean (SD)	Placebo ± UDCA	OCA 5-10 mg ± UDCA	OCA 10 mg ± UDCA
Baseline APRI	1.1 (1.0) n=73	1.1 (0.9) n=70	1.0 (0.8) n=72
Δ DB Month 12	0.1 (0.6) n=68	-0.2 (0.5)** n=60	-0.2 (0.5)** n=59
Baseline APRI > 0.54, Month 12 APRIs ≤ 0.54 n (%)	6 (9)	16 (27)	15 (25)
Δ OLE Month 12	-0.1 (0.5)* n=58	-0.2 (0.6)* n=59	-0.1 (0.7) n=55
Baseline TE (kPa)	12.7 (10.7) n=39	10.7 (8.6) n=35	11.4 (8.2) n=32
Δ DB Month 12	0.5 (3.0) n=34	0.6 (2.5) n=32	-0.3 (8.9) n=26
Δ OLE Month 12	0.9 (4.4) n=27	0.8 (6.9) n=29	-0.9 (7.4) n=26

*p<0.05, **p<0.01. P-value during DB for comparing active treatments to Placebo is obtained using an ANCOVA model with baseline value as a covariate and fixed effects for treatment and randomization strata factor. P-value during OLE for within group comparison was determined using a paired t-test. Values are Mean (SD) unless otherwise specified. 97% of patients completing the study enrolled in the OLE.

Abstract PTU-097 Figure 1

Conclusion Both LSM and APRI, as non-invasive measures of liver fibrosis, have been found to be effective in predicting outcome in patients with PBC. DB and OLE treatment with OCA resulted in a mean reduction in liver stiffness and significant improvements in APRI suggesting that with long-term use, OCA has the potential to improve long term outcomes for patients.

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PTU-098 TACE FOR HCC: LONG TERM OUTCOME IN A REGIONAL CENTRE

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Introduction The incidence of hepatocellular carcinoma (HCC) is rising.[1,2] Transarterial chemoembolisation (TACE) is frequently used as a palliative treatment or as a bridge to surgery. TACE can be offered alone, or together with radiofrequency ablation (RFA) or Sorafenib. Child-Pugh grade and Barcelona Clinic Liver aim was to assess outcome for patients receiving TACE over a 6 year period in our regional centre.

Method Patients with HCC were prospectively entered onto a regional HCC database between 01.01.09–01.01.15. Patients who underwent TACE (in addition to other therapies) were identified and clinical data obtained from electronic records. Child-Pugh grade and BCLC were calculated at time of diagnosis, with survival our primary outcome.

Results 497 patients were diagnosed with HCC during this period. 121 (99 male, 22 females; mean age 68 years) underwent TACE. 20, 47 and 54 patients had TACE during the periods 2009–10, 2011–12 and 2013–14 respectively. 102 (84%) had TACE alone, 6 (5%) each had TACE with RFA and TACE with Sorafenib, 5 (4%) had TACE then transplant, and two TACE then resection. 87 (72%), 31 (26%) and 3 (2%) had Child-Pugh grade A, B and C disease respectively and 38 (31%), 61 (50%), 20 (17%) and 2 (2%) BCLC stage A, B, C and D.

Of the 102 patients having TACE alone, survival is shown in table:

		Overall	Child-Pugh			BCLC	
			A	B	C	A/B	C/D
number		*102*	*70*	*29*	*3*	*81*	*21*
Survival	1 year	77%	78%	76%	67%	77%	71%
	2 year	43%	50%	30%	0	46%	29%

Two year survival for patients having TACE and RFA was 80%; for TACE and Sorafenib 17% and for TACE then transplant/resection 100%.

Conclusion There has been a steady rise in the number of patients with HCC undergoing TACE procedures in our unit. Survival following TACE compares favourably to other studies.[3,4]

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Disclosure of Interest None Declared

PTU-099 A NOVEL FUNCTIONAL BIOASSAY PREDICTS 90-DAY SURVIVAL IN PATIENTS WITH SEVERE ALCOHOLIC HEPATITIS

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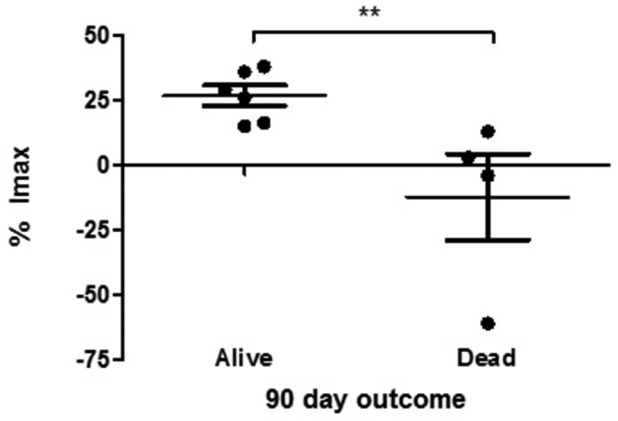
Introduction Severe alcoholic hepatitis (SAH) has a high mortality and only corticosteroids have a proven short term benefit. Early prediction of treatment response would allow selection of appropriate patients who would benefit from corticosteroids. We

have previously reported that a functional bioassay measuring *in vitro* corticosteroid sensitivity, DILPA, accurately predicts 6 month survival in patients with SAH[1]. However, due to its requirement for radiation it lacked clinical translatability and a second generation assay, bromodeoxyuridine (BrdU) incorporation in lymphocyte steroid sensitivity assay (BLISS) assay, has been developed and validated in healthy controls[2]. In this study we aimed to generate preliminary data to determine whether the BLISS assay can be used to predict clinical outcome in patients with SAH.

Method Peripheral blood was drawn from patients with a clinical diagnosis of SAH (discriminant function [DF] >32). All participants gave informed consent and ethical approval was obtained from the NHS Health Research Authority. All patients were treated with corticosteroids for 28 days. The primary outcome measure was 90 day survival. Peripheral blood mononuclear cells, isolated by density gradient centrifugation, were stimulated with lymphocyte mitogen in the absence or presence of dexamethasone and cultured for 48 hours per previously described protocol[2]. Proliferation was determined by measuring BrdU incorporation using a commercial kit. The maximum suppression of proliferation by corticosteroids (Imax) was determined.

Results 10 patients were recruited (7 female, median age 50) with mean DF 75. 6 patients survived to 90 days and had a significantly higher Imax than non-survivors (27% v −12%; p=0.01) with clear separation between groups (figure 1). Survivors also had lower Lille score than non-survivors (0.20 v 0.79; p=0.02) but in applying the established threshold of 0.45, 1 patient was misclassified as a steroid non-responder. However, Imax did not correlate with Lille score (r^2=0.21) or percentage change in bilirubin from day 0 to day 7 (r^2=0.10).



Abstract PTU-099 Figure 1

Conclusion The BLISS assay clearly differentiates survivors from non-survivors at 90 days and shows potential for use as a stratification tool in the initial management of patients with SAH. Further validation in a larger multicentre cohort is planned.

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Disclosure of Interest None Declared

PTU-100 EFFICACY OF OBETICHOLIC ACID TREATMENT IN PATIENTS WITH PRIMARY BILIARY CHOLANGITIS WITH CIRRHOSIS

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Introduction Obeticholic acid (OCA) is a potent and selective farnesoid X receptor (FXR) agonist under investigation for treatment of primary biliary cholangitis (PBC) and other chronic liver diseases. POISE was a double-blind, placebo-controlled, randomised Phase 3 study examining the efficacy of OCA in PBC. The objective of this post-hoc analysis was to assess the efficacy of OCA in the subset of patients with cirrhosis who were at higher risk of progression to liver-related outcomes or death.

Method We randomised and dosed 216 patients 1:1:1 with placebo (PBO) (n=73), OCA 5–10 mg (n=70, titrated to 10 mg after 6 months based on response and tolerability) or OCA 10 mg (n=73). Inclusion criteria included PBC diagnosis, ALP≥1.67x ULN and/or total bilirubin (BILI) >ULN to <2x ULN, stable UDCA dose or intolerance to UDCA. Patients were considered to have cirrhosis if they met one of the following criteria: biopsy-proven cirrhosis, transient elastography of ≥16.9 kPa, or history of cirrhosis. The primary composite endpoint was an ALP<1.67x ULN with ≥15% reduction in ALP and BILI ≤ULN after 12 months.

Results Cirrhosis was present in approximately 17% of patients in POISE: PBO, n=13; OCA 5–10 mg, n=13; OCA 10 mg, n=10. At month 12, 54% (p<0.05) of patients in the OCA 5–10 mg group and 40% (p=0.06) in the OCA 10 mg group met the primary composite endpoint compared to 8% of PBO patients with cirrhosis. The table shows significant differences in ALP and BILI between PBO and both OCA groups after 12 months. BILI increased on PBO; however, it remained stable in both OCA groups after 12 months of treatment. Pruritus was the most common adverse event in patients with cirrhosis, affecting 23%, 69%, and 80% of patients in the PBO, OCA 5–10 mg, and OCA 10 mg groups, respectively.

Conclusion In this post-hoc analysis, no additional safety concerns due to OCA were observed in the subgroup of OCA-treated patients with cirrhosis, and OCA treatment resulted in significant improvements in biochemical markers associated with disease progression. The percentage of patients achieving the primary composite endpoint on OCA was comparable in patients with cirrhosis and non-cirrhotic patients. These results suggest that OCA may play a beneficial role in preservation of the functional capacity of residual liver tissue in cirrhotic patients.

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