40 mg twice daily, bismuth tripotassium dicitrate 300 mg four times a day, tetracycline 500 mg four times a day, and metronidazole 500 mg three times a day, for 10 days. The primary end point was the eradication rate in the second-line treatment according to intention to treat (ITT) analysis. The minimum inhibitory concentrations were determined by agar dilution test.

Results The results were available for analysis in 398 patients up to Dec, 2017. The preliminary eradication rate in the EAML and BQ groups were 88.9% (169/190) and 91% (172/189), respectively ($p=0.505$) in the ITT analysis, and were 89.9% (169/188) and 96.1% (172/179) in the PP analyses, respectively ($p=0.021$) in the second line treatment. The efficacy of levofloxacin sequential therapy, but not bismuth quadruple therapy, appeared to be affected by levofloxacin resistance. In the third-line therapy, the eradication rate of EAML was 60% (3/5) for patients who failed after bismuth quadruple therapy. The eradication rate of BQ was 80% (12/15) for patients who failed after levofloxacin sequential therapy. The cumulative eradication rates were 95.3% (181/190) and 92.6% (175/189) in the EAML (2nd)-BQ(3rd) and the BQ(2nd)-EAML (3rd) groups ($p=0.276$). The frequencies of adverse effects were 42.8% (62/145) and 81.9% (118/144) in patients treated with EAML and BQ, respectively ($p<0.001$).

Conclusions Levofloxacin sequential therapy and bismuth quadruple therapy are similarly effective in the second-line treatment for *H. pylori* infection. (Trial registration number: NCT NCT03148366).

IDDF2018-ABS-0220 FAECAL MICROBIOTA TRANSPLANTATION FOR MAINTENANCE OF CLINICAL REMISSION IN PATIENTS WITH ACTIVE ULCERATIVE COLITIS: A RANDOMISED CONTROL TRIAL

Ramit Mahajan*, Vandana Midha, Varun Mehta, Arshdeep Singh, Husanpreet Khattar, Vikram Narang, Ajit Sood. *Dayanand Medical College, India*

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Background Though faecal microbiota transplantation (FMT) has been shown to be efficacious for induction of remission in patients with active UC, the long-term clinical outcomes after initial response have not been assessed.

Methods This single-blind, randomised, placebo-controlled trial was conducted at Dayanand Medical College and Hospital, India. Patients with active UC (Mayo score 4–10) who achieved clinical remission with multi-session FMT (0, 2, 6, 10, 14, 18 and 22 weeks) were randomly allocated in a 1:1 ratio to either maintenance FMT or placebo colonoscopic infusion every 8 weeks till 48 weeks. The primary endpoint was the maintenance of steroid-free clinical remission (Mayo score ≤ 2), and secondary endpoints were the achievement of deep remission (clinical and endoscopic remission, i.e. endoscopic Mayo score 0) and histological remission (Nancy grade 0, 1) at the end of 48 weeks. Clinical disease activity and adverse events were assessed at each visit or earlier in case of worsening of symptoms. The analysis was done by intention-to-treat and included all patients who underwent one session of FMT after initial clinical remission at week 22.

Results Forty-three of 78 patients treated with multi-session FMT achieved clinical remission, 22 of these were randomly

assigned to receive FMT and 21 received placebo, colonoscopically every 8 weeks. The primary outcome was achieved in 19/22 (86.4%) patients allocated FMT versus 14/21 (66.7%) patients assigned placebo ($p=0.126$). Secondary end-points of deep remission [18/22 (81.8%) with FMT versus 8/21 (38.1%) with placebo $p=0.003$] and histological remission [12/22 (54.5%) with FMT versus 3/21 (14.3%) with placebo $p=0.006$] were achieved in a significantly higher number of patients with FMT. Two patients receiving FMT and 5 patients on placebo relapsed. All relapses were treated with steroids. There were no serious adverse events necessitating discontinuation in patients on FMT, 1 patient who relapsed on placebo required colectomy.

Conclusions Maintenance therapy with FMT is required in patients who had earlier been treated with FMT for induction of remission. Moreover, FMT also enhances achievement of deep and histological remission.

Clinical Hepatology

IDDF2018-ABS-0058 EARLY NORMALISATION OF ALANINE AMINOTRANSFERASE (ALT) AFTER NUCLEOS(T)IDE ANALOGUE TREATMENT REDUCES THE RISK OF HEPATOCELLULAR CARCINOMA (HCC) IN PATIENTS WITH CHRONIC HEPATITIS B – A TERRITORY-WIDE STUDY OF 21,182 SUBJECTS

¹Terry Cheuk-Fung Yip*, ²Grace Lai-Hung Wong, ¹Yee-Kit Tse, ²Henry Lik-Yuen Chan, ²Vincent Wai-Sun Wong. ¹*Institute of Digestive Disease, Department of Medicine and Therapeutics, The Chinese University of Hong Kong, Hong Kong;* ²*Institute of Digestive Disease, Department of Medicine and Therapeutics, and State Key Laboratory of Digestive Disease, The Chinese University of Hong Kong, Hong Kong*

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Background We aimed to evaluate the impact of alanine aminotransferase (ALT) normalisation (ALTN) achieved at different time after the start of antiviral treatment on the risk of hepatocellular carcinoma (HCC) in patients with chronic hepatitis B (CHB).

Methods We identified a territory-wide cohort of CHB patients who received entecavir and/or tenofovir disoproxil fumarate (TDF) for ≥ 1 year between 2005 and 2016 in Hong Kong. Serial on-treatment ALT levels were analysed. ALTN referred to ALT level lower than the upper limit of normal (ULN) (30 U/L in males and 19 U/L in females). Early ALTN was defined as ALTN within 12 months. The primary outcome was HCC based on ICD-9-CM diagnosis codes. Patients with cancers previously or during the first year of treatment were excluded.

Results 21,182 CHB patients (10 437 with and 10 745 without ALTN at 12 months after antiviral treatment) were identified and followed for a median (interquartile range) of 4.1 (2.4–6.0) years. Patients with or without ALTN at 12 months differed in gender distribution (76.9% vs. 58.4% male), baseline ALT (58 vs. 61 U/L), baseline serum HBV DNA (4.9 vs. 5.1 log₁₀IU/mL), proportion of positive hepatitis B e antigen (31.5% vs. 37.1%), and presence of cirrhosis (8.8% vs. 10.5%) and diabetes mellitus (8.1% vs. 9.1%); 509 (2.4%) patients developed HCC. ALTN at 3, 6, 9 and 12 months

were associated with a reduced risk of HCC (Figure 1), with adjusted hazard ratios (aHR) (95% confidence interval [CI]) of 0.55 (0.42,0.71), 0.52 (0.41,0.64), 0.47 (0.38,0.58) and 0.46 (0.37,0.56), respectively (all $p < 0.001$). In contrast, ALT 1 to 2 times the ULN and ALT greater than 2 times the ULN at 12 months were associated with a higher risk of HCC as compared to ALTn at 12 months, with aHR (95% CI) of 2.07 (1.67,2.56) and 3.21 (2.32,4.44), respectively, after adjustment for baseline ALT and important covariates.

Conclusions Early on-treatment ALTn reduces the risk of HCC in CHB patients having entecavir/TDF treatment. On-treatment ALT above 1 and 2 times the ULN at 12 months were associated with higher risk of HCC.

IDDF2018-ABS-0067

EFFICACY AND SAFETY OF GLECAPREVIR/PIBRENTASVIR IN PATIENTS WITH HCV GENOTYPE 5 OR 6 INFECTION: THE ENDURANCE-5, 6 STUDY

¹Tarik Asselah*, ²Tram Tran, ³Katia Alves, ⁴Tuan Nguyen, ⁵Florence Wong, ⁶Adam Mahomed, ⁷Seng Gee Lim, ⁸Samuel S Lee, ⁹Armand Aberger, ¹⁰Joe Sasadeusz, ³Preethi Krishnan, ³Zhenzhen Zhang, ³Ariel Porcalla, ³Roger Trinh, ¹¹Edward Gane. ¹Centre de Recherche sur l'Inflammation, INSERM UMR 1149, Université Paris Diderot, Department of Hepatology, AP-HP Hôpital Beaujon, Clichy, France; ²Cedars Sinai Medical Center, Los Angeles, California, USA; ³AbbVie Inc., North Chicago, Illinois, USA; ⁴Research and Education, Inc., San Diego, California, USA; ⁵Toronto General Hospital, University of Toronto, Toronto, Ontario, Canada; ⁶Faculty of Health Sciences, University of Witwatersrand, Charlotte Maxeke Johannesburg Academic Hospital, Department of Gastroenterology and Hepatology, South Africa; ⁷Division of Gastroenterology and Hepatology, National University Health System, Singapore; ⁸University of Calgary, Calgary, AB, Canada; ⁹CHU Estaing, Clermont Ferrand, France; ¹⁰Royal Melbourne Hospital, Melbourne, Australia; ¹¹Auckland Clinical Studies, Auckland, New Zealand

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Background The pangenotypic direct-acting antivirals (DAAs) glecaprevir (developed by AbbVie and Enanta)/pibrentasvir (G/P) are approved to treat chronic HCV genotype (GT)1–6 infection. In Phase 2 and 3 studies, G/P achieved high SVR12 rates with no virologic failures in 80 patients with GT5 or 6 infection. To increase the body of data for these genotypes, ENDURANCE-5,6 evaluates patients from countries where GT5 and GT6 are endemic, such as South Africa (GT5), Myanmar and Vietnam (GT6). This study evaluates the efficacy and safety of G/P in patients with chronic HCV GT5 or GT6 infection.

Methods ENDURANCE-5,6 is an ongoing phase 3b, non-randomised, open-label, multicenter study conducted in adults with chronic HCV GT 5 or 6 infections with or without compensated cirrhosis who are HCV treatment-naïve or experienced with interferon (IFN) or pegIFN with or without ribavirin (RBV) or sofosbuvir and RBV with or without pegIFN. G/P (300 mg/120 mg) was orally dosed once-daily for 8 or 12 weeks in patients without or with compensated cirrhosis, respectively. The primary efficacy endpoint was SVR12. Secondary endpoints were on-treatment virologic failure or relapse. Adverse events and clinical laboratory abnormalities were monitored in all patients.

Results Seventy patients have enrolled to date, 61 and 9 in the 8- and 12 week treatment arms, respectively; 66 have completed treatment. Baseline demographics are shown in table 1. The SVR4 among patients with available data is 61/62 (98%). One HCV GT6c-l-infected patient with

compensated cirrhosis experienced virologic breakthrough at treatment week 12, and one HCV GT5a-infected patient without compensated cirrhosis who achieved SVR4 relapsed at post-treatment week 12. To date, three patients (4%) have experienced treatment-emergent serious adverse events, none of which were related to G/P or led to discontinuation; no Grade 3 alanine aminotransferase elevations have occurred.

Abstract IDDF2018-ABS-0067 Table 1 Baseline Demographics and Disease Characteristics

Characteristics	8 week G/P No Cirrhosis n= 61	12 week G/P Cirrhosis n= 9
Female, n (%)	36 (59)	4 (44)
Asian, n (%)	38 (62)	5 (56)
Age, median years (range)	57 (24–79)	65 (32–75)
Genotype 5, n (%)	20 (33)	3 (33)
Genotype 6, n (%)	41 (67)	6 (67)
GT6a/6b	19 (31)	1 (11)
GT6c-l	22 (36)	5 (56)
HCV treatment-naïve, n (%)	55 (90)	8 (89)
Baseline HCV RNA, median log ₁₀ IU/	6.85 (4.6–7.5)	6.29 (4.9–7.2)
ML (range)		

Conclusions In this ongoing dedicated study, HCV genotype 5- and 6-infected patients without and with compensated cirrhosis treated with G/P for 8 and 12 weeks, respectively, achieved high rates of SVR4. Complete SVR4 and available SVR12 data will be presented.

IDDF2018-ABS-0082

QUANTIFICATION OF CIRCULATING MIR-125B-5P PREDICTS SURVIVAL IN CHRONIC HEPATITIS B PATIENTS WITH ACUTE-ON-CHRONIC LIVER FAILURE

Enqiang Chen*, Yachao Tao, Juan Liao, Duoduo Lv, Yonghong Wang, Dongbo Wu, Dongmei Zhang, Hong Tang, Menglan Wang. West China Hospital of Sichuan University, China

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Background This study aimed to analyse serum levels of miR-125b-5p in CHB patients with varying degrees of liver damage and evaluate its value in predicting the short-term outcome of acute-on-chronic liver failure (ACLF).

Methods CHB patients with normal hepatic function (n=100), moderate-to-severe liver damage (n=90) and ACLF (n=86) were included. Serum levels of miR-125b-5p and miR-122 were measured by quantitative real-time PCR.

Results Serum miR-125b-5p levels were increased along with disease progression, and lower in survival than in death among HBV-ACLF patients. Among HBV-ACLF patients, serum miR125b-5p were positively correlated with total bilirubin (TBil) ($r=0.214$, $p<0.05$) and MELD score ($r=0.382$, $p<0.01$), and negatively correlated with prothrombin activity (PTA) ($r=-0.215$, $p<0.05$). Interesting, serum miR-122 showed a completely opposite performance as compared to that of serum miR-125b-5p. Cox Regression Analysis showed that serum miR-125b-5p, miR122 and PTA were all independent survival predictors of HBV-ACLF; and low miR125b-5p and high miR122 may predict