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High Mortality Rates for SARS-CoV-2 infection in Patients with Pre-existing Chronic Liver Disease and Cirrhosis: Preliminary Results from an International Registry.

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Title: High Mortality Rates for SARS-CoV-2 Infection in Patients with Pre-existing Chronic Liver Disease and Cirrhosis: Preliminary Results from an International Registry.

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Tables 1

Figures 1

Abbreviations:

CLD – chronic liver disease

COVID-19 – coronavirus disease 2019

CTP – Child-Turcotte-Pugh

MELD – Model for end-stage liver disease

SARS-CoV-2 – Severe acute respiratory syndrome coronavirus 2

To the Editor: Chronic liver disease (CLD) and cirrhosis are common conditions[1] associated with immune dysregulation[2] leading to concerns that these patients are at increased risk for complications of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and resulting coronavirus disease 2019 (COVID-19).[3] However, the effects of COVID-19 among patients with pre-existing liver disease are currently undefined.

We report the outcomes of the first 152 consecutive submissions of clinician-reported cases of laboratory-confirmed COVID-19 in patients with CLD to two international reporting registries (COVID-Hep.net and COVIDCirrhosis.org) between 25 March 2020 and 20 April 2020. Our combined database includes 103 patients with cirrhosis and 49 with non-cirrhotic CLD from 21 countries across 4 continents (59.9% male, median age 61 years, aetiology 22.4% non-alcoholic fatty liver disease, 19.7% alcohol, 11.8% hepatitis B, 10.5% hepatitis C, 35.6% other/combination).

Contributors were encouraged to enter data at the end of the patient's disease course. For patients admitted to hospital, cases were only included in the analysis if a definitive outcome of death or discharge was reported. 95.2% of patients with cirrhosis were hospitalised with a median length of hospital stay until discharge or death of 10 days (IQR 5-14 days). Outcomes for patients with cirrhosis included admission to intensive care unit (ICU) in 23.3%, invasive ventilation in 17.5%, non-invasive ventilatory support in 18.6%, renal replacement therapy 4.9% and death in 39.8%. Mortality far exceeded that reported in unselected populations[4], hospitalised patients with cirrhosis in the era preceding COVID-19[5], and in patients with cirrhosis admitted with influenza.[6] In patients not admitted to ICU, 59.5 % had non-severe disease, 27.8% had severe disease but escalation of care was deemed inappropriate, and 3.7% were considered to require ICU but were not admitted due to lack of availability. Targeted antiviral therapy was used in 38.1% of total cases. The most frequently used treatments were chloroquine/hydroxychloroquine (23.0%), lopinovir/ritonavir (6.6%), tocilizumab (3.3%), and interferon-alpha (3.3%).

Cause of death in patients with cirrhosis was reported as COVID-19 lung disease in 78.7%, cardiac-related in 4.3%, and liver-related in 12.2%. Risk factors for poor COVID-19 outcomes in the general population including advanced age, obesity, renal impairment, heart disease, and diabetes mellitus were over-represented among those who died, although male sex and non-white ethnicity were not.[7] Mortality correlated strongly with baseline Child-Turcotte-Pugh (CTP) class and model for end-stage liver disease (MELD) score **(Table 1)**. Deaths occurred in 12.2% of CLD without cirrhosis, 23.9% CTP-A cirrhosis, 43.3% CTP-B cirrhosis, and 63.0% CTP-C cirrhosis **(Fig. 1A)**. CTP-B and CTP-C cirrhosis remained associated with death after adjusting for baseline characteristics including comorbidities **(Table 1)**. CTP-B and CTP-C cirrhosis remained significant predictors of mortality even when analysis was restricted to those with cirrhosis.

Hepatic decompensation occurred in 36.9% and was associated with baseline CTP class **(Fig. 1B).** Decompensation events included worsening ascites (27.2%), spontaneous bacterial peritonitis (2.9%), hepatic encephalopathy (16.5%), and variceal haemorrhage (1%). Hepatic decompensation during COVID-19 was strongly associated with a subsequent risk of death: 63.2% of those with new decompensation died compared to 26.2% of those without new decompensation. Notably, 24.3% of those with new hepatic decompensation had no respiratory symptoms of COVID-19 at the time of diagnosis.

This large, multicentre, international cohort of patients with chronic liver disease and cirrhosis allows for in depth assessment of the clinical factors associated with poor outcomes from COVID-19. Accepting that data from registries are subject to selection bias, preliminary findings suggest that baseline liver disease severity is strongly associated with COVID-19-related morbidity and mortality. Furthermore, many SARS-CoV-2-infected patients with cirrhosis experienced hepatic decompensation even in the absence of respiratory symptoms. These findings have important implications for clinicians regarding risk stratification and prognostication for patients with

cirrhosis and COVID-19 and suggest the need to maintain a low threshold for SARS-CoV-2 testing in the presence of new hepatic decompensation.

	Univariable analysis							Multivariable analysis	
	Total; n = 152		Survived; n = 105		Died; n = 47				
Variable	**Median or n**	**IQR or %**	**Median or n**	**IQR or %**	**Median or n**	**IQR or %**	**p value†**	**OR (95%CI) for death**	**p value§**
Age (years)	61	48-71	60	46-70	64	57-73	**0.025**	1.04 (1.00-1.09)	**0.048**
Sex (male)	91	59.9%	61	58.1%	30	63.8%	0.666	-	-
White ethnicity	86	56.6%	56	53.3%	30	63.8%	0.228	-	-
Smoker	9	5.9%	7	6.7%	2	4.3%	0.560	-	-
Obese (BMI >30 kg/m2)	33	21.7%	18	17.1%	15	31.9%	**0.017**	3.59 (1.10-10.47)	**0.033**
Cardiovascular disease	33	21.7%	18	17.1%	15	31.9%	**0.041**	1.87 (0.57-6.15)	0.303
Diabetes mellitus	54	35.5%	30	28.6%	24	51.1%	**0.007**	2.86 (1.00-8.20)	0.051
Hypertension	60	39.5%	35	33.3%	25	53.2%	**0.021**	0.71 (0.22-2.24)	0.555
Liver disease severity									
CLD without cirrhosis	49	32.2%	43	41.0%	6	12.8%	**<0.001**	1.00	-
CTP A cirrhosis	46	30.3%	35	33.3%	11	23.4%		1.21 (0.30-4.90)	0.789
CTP B cirrhosis	30	19.7%	17	16.2%	13	27.7%		4.90 (1.16-20.61)	**0.030**
CTP C cirrhosis	27	17.8%	10	9.5%	17	36.2%		28.07 (4.42-178.46)	**<0.001**
MELD score*	10	7-17	9	7-17	13	9-17	**0.014**	-	-
Laboratory (baseline)									
Sodium (mmol/L)	138	135-141	139	136-141	137	134-140	0.058	1.06 (0.93-1.22)	0.377
Prothrombin time (s)	13	12-17	13	12-15	15	13-18	**0.011**	-	-
Bilirubin (mg/dL)	1.1	0.6-1.9	0.9	0.5-1.5	1.4	0.8-2.0	**0.013**	-	-
Albumin (g/dL)	3.4	2.8-4	3.8	3.0-4.0	2.9	2.4-3.3	**<0.001**	-	-
Creatinine (mg/dL)	0.9	0.6-1.1	0.8	0.6-1.0	0.9	0.7-1.1	**0.010**	0.88 (0.53-1.47)	0.634
Events after diagnosis									
Any decompensation	39	25.7%	15	14.3%	24	51.1%	**<0.001**	-	-
New jaundice	27	17.8%	14	13.3%	13	27.7%	0.067	-	-

Table 1. Characteristics of patients with laboratory-confirmed chronic liver disease and COVID-19 submitted to COVIDCirrhosis.org and COVID-Hep.net reporting registries between 25th March 2020 and 20th April 2020. † = p values for univariable analyses calculated using chi-squared or Wilcoxon ranksum tests as appropriate; § = p values for multivariable analysis calculated by multiple logistic regression with the dependent variable as death and the following independent variables: age, obesity, cardiovascular disease, diabetes mellitus, hypertension, chronic liver disease status as Child-Turcotte-Pugh class, baseline serum sodium, and baseline serum creatinine. Pseudo r^2 = 0.256. * = MELD score presented is as calculated for all patients; when restricted to patients with cirrhosis, MELD was 11 (IQR 7-19) in those who survived and 14 (9-17) in those who died, p = 0.136. To explore the relationship of MELD with death, multiple logistic regression was repeated with death as the dependent variable and age, baseline MELD, obesity, cardiovascular disease, diabetes mellitus, hypertension, and baseline albumin as independent variables; here the OR for death for MELD was 1.05 (0.98-1.11) p = 0.204; other variables with p < 0.05 were age 1.05 (1.00-1.08) p = 0.038, obesity 3.61 (1.36-9.60) p = 0.010, and baseline albumin 0.97 (0.93-1.00) p = 0.029. Any decompensation defined as one or more of worsening ascites, spontaneous bacterial peritonitis, hepatic encephalopathy, or variceal haemorrhage. BMI = body mass index; CI = confidence interval; CLD = chronic liver disease; CTP = Child-Turcotte-Pugh grade; IQR = interquartile range; MELD = model for end-stage liver disease (2016 revision); OR = odds ratio.

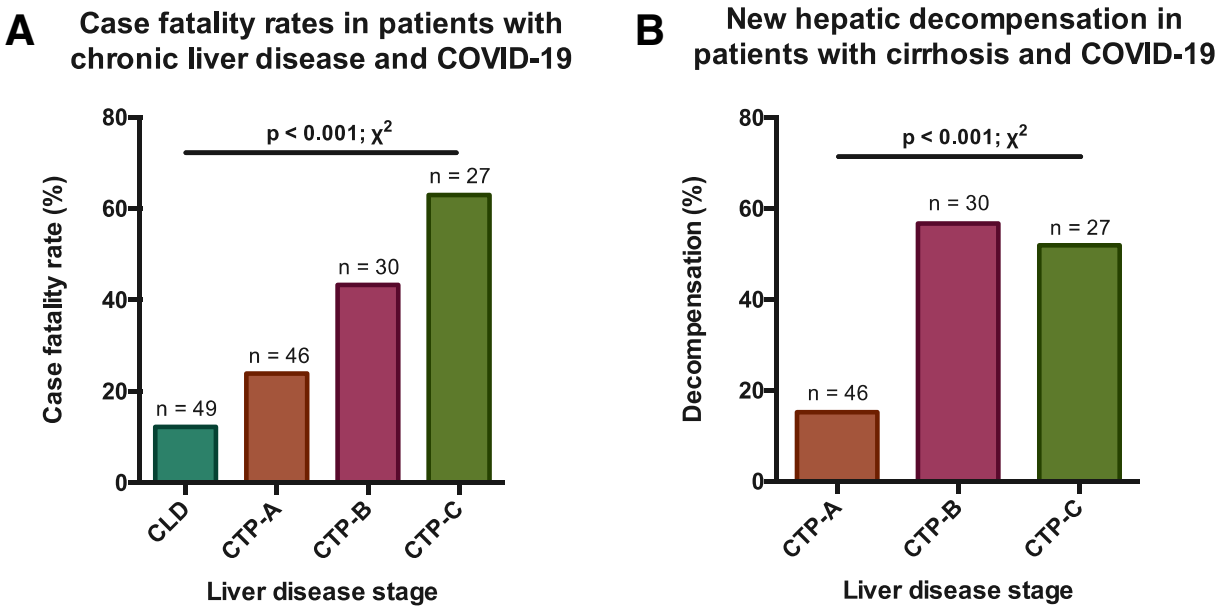

Fig. 1: Outcome in patients with non-cirrhotic chronic liver disease or cirrhosis with COVID-19. Graphs depict data from 152 submissions to COVID-Hep.net and SECURE-Cirrhosis registries submitted between 25th March 2020 and 20th April 2020. (A) Case fatality rate by liver disease stage. (B) Rates of hepatic decompensation by stage of cirrhosis (defined as one or more of new or worsened ascites, spontaneous bacterial peritonitis, new or worsened hepatic encephalopathy, or variceal haemorrhage). p values derived using chi-squared test. CLD = Chronic liver disease without cirrhosis; CTP = Child-Turcotte-Pugh stage of cirrhosis.

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Supplementary appendix

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