had concomitant upper respiratory symptoms identified as shortness of breath, sore throat, or cough (n = 54). Patients presenting with GI symptoms had no underlying chronic digestive diseases. Admission laboratory tests of interests included AST (n = 96), ALT (n = 96), Ferritin (n = 73), Procalcitonin (68), LDH (64) and CRP (n = 65) (Figure 2). Patients with GI symptoms were found to have non-statistically significant levels of elevated transaminases, Ferritin, and LDH on admission in those without GI symptoms. These presenting with GI symptoms were more likely to be hospitalized (n = 42, 61%) versus those without (n = 34, 44%). Length of stay was greater in those presenting with GI symptoms (M1 = 5.43 days) versus those without (M2 = 4.42 days); (P = 0.273, Mann-Whitney test.) No difference in mortality was seen.

CONCLUSION: Preliminary data supports studies from China that GI symptoms are rather common secondary to COVID19. The initial trends from the ALCO database support that GI symptoms are indicative of severe disease characterized by increased inflammation, elevated transaminases and longer hospitalizations. Our hope is continued investigation during the current outbreak will lead to more information to clarify the role of GI manifestations in COVID19.

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Effect of Alcoholism on Outcomes of Patients With COVID-19 Infection: A Retrospective Analysis
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INTRODUCTION: The United States has rapidly emerged as the epicenter for the novel coronavirus (COVID-19) pandemic. Chronic alcohol use (CAU) is associated with worsening outcomes in disorders such as pneumonitis, ARDS, and gastrointestinal bleeds. Studies indicate chronic alcohol use may increase the susceptibility to respiratory infections, including potentially COVID-19. However, the effect of chronic alcohol use on outcomes in patients with COVID-19 viral infection is currently unknown. This study aims to assess the effect of chronic alcohol use (CAU) on the outcomes of patients admitted with COVID-19 infection in a suburban safety-net hospital in New York.

METHODS: A retrospective single-center study of 640 patients (age ≥ 18 y) admitted to our facility from March 9, 2020 to April 20, 2020 with the diagnosis of COVID-19 infection. Presence of current or past alcohol use was documented in all COVID-19 patients able to provide history. The primary outcome was all-cause in-hospital mortality; other hospitalization outcomes including cardiac arrests, ARDS, arrhythmia, shock, and intubation rate were measured. Chi-square tests and independent T-tests were used to compare the primary outcome and other factors of morbidity between groups who did or did not report a history of alcohol use. Analyses were descriptive.

RESULTS: Of total 640 patients, 88 (13.0%) reported a history of chronic alcohol use (CAU), 460 (67%) denied and 91 (13.4%) were unable to provide history. Patients with CAU did not have a statistically elevated risk of mortality than those without alcohol use (25.0% vs. 31.5%, P = 0.013), lower rates of acute kidney injury (14.8% vs. 26.6%, P = 0.027) and higher rates of arterial fibrillation (5.7% vs. 3.3%, P = 0.006). No statistical difference was seen between groups on other factors of morbidity including ICU admission, intubation, cardiac arrest or septic shock. Patients with alcohol use had higher rates of diabetes, and concurrent tobacco and illicit drug use. Mean age in CAU was 55.8 vs. 58.9 in no alcohol use (SD 14.9, P = 0.068). There was no statistical difference between two groups in hospital or ICU length of stay.

CONCLUSION: Chronic immunosuppression from alcohol use and associated liver dysfunction may not be a significant contributing factor to worsening outcomes in patients with concomitant COVID-19 infection.

S1169

Twelve Month Interim Analysis of Efficacy and Safety of Givosiran, an Investigational RNAi Therapeutic for Acute Hepatic Porphyria, in the ENVISION Open Label Extension Study
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INTRODUCTION: Acute hepatic porphyria (AHP) is a family of rare genetic diseases due to enzymatic defects in hepatic heme biosynthesis. Induction of 5-aminolevulinic acid synthase 1 (ALAS1), the rate-limiting step in heme biosynthesis, can lead to accumulation of toxic heme intermediates 5-aminolevulinic acid (ALA) and porphobilinogen (PBG), causing neurovisceral attacks and chronic manifestations. Givosiran, an investigational RNAi therapeutic, targets liver ALAS1 to reduce ALA/PBG and ameliorate attacks and clinical manifestations.

METHODS: ENVISION (NCT03338816) is an ongoing Phase 3 global, multicenter, randomized, placebo-controlled trial, evaluating the efficacy and safety of subcutaneous monthly doses of 2.5 mg/kg givosiran in AHP patients in a 6-month double-blind (DB) period and an open label extension (OLE) period up to 30 months. Using the OLE, patients received either 2.5 mg/kg or 1.25 mg/kg monthly givosiran. Outcome measures included composite annualized attack rate (AAR) requiring hospitalization, urgent care, or IV-hemoin at home, ALA/PBG levels, heme use, daily worst symptoms, and quality of life (QoL). Analyses were descriptive.

Table 1. Demographic and clinical outcomes of alcohol dependence vs. no alcohol dependence based on documented history
RESULTS: As of July 23, 2019, 93 patients entered the OLE. 56 (placebo/givosiran = 29; givosiran/givosiran = 27) received 2.5 mg/kg monthly givosiran, and 37 (placebo/givosiran = 17; givosiran/givosiran = 20) received 1.25 mg/kg. In givosiran patients (both doses), median AAR was 1.1 (range: 0.0-20.5) through Month 12. In placebo patients who crossed over to givosiran in the OLE, median AAR (DB = 10.6; OLE = 1.81) and proportion of attack-free patients (DB = 17.4%; OLE = 42.2%) were similar to the givosiran group in the DB period (median AAR = 1.04; attack-free patients = 48.9%). In addition, sustained lowering of ALA/PBG in the OLE was accompanied by reductions in hemin use, daily worst pain and analgesic use, and improvements in QoL. Among patients on givosiran from Day 1 through Month 12, 62% had ≤1 drug-related adverse event (AE) and 3% had ≥2 drug-related serious AE. There were no new AEs leading to discontinuation and no deaths. No new safety concerns occurred in the OLE. There was a trend toward increased efficacy with the 2.5 mg/kg dose compared to 1.25 mg/kg dose, and safety was acceptable at both doses.

CONCLUSION: In an ongoing Phase 3 study, givosiran 2.5 mg/kg monthly demonstrated maintenance or enhancement of clinical efficacy and an acceptable safety profile consistent with that observed in the 6-month DB period.

Observations of Patients With Cirrhosis Admitted With an Upper GI Bleed and Areas for Improvement

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INTRODUCTION: Cirrhosis, a major cause of morbidity and mortality in the United States, is annually responsible for more than 200,000 admissions and billions of dollars to the healthcare system. Upper GI Bleed (UGIB), a potentially fatal complication of cirrhosis, is associated with significant readmission rates and high mortality. In this study, we describe the utilization of various quality metrics in a sample of patients with cirrhosis admitted with an UGIB.

METHODS: We performed a retrospective chart review of patients admitted with cirrhosis and UGIB to two academic hospitals, University of Miami Hospital and Jackson Memorial Hospital, between 10/1/2017 to 10/1/2018. Patients were excluded if they did not have cirrhosis or qualifying admissions (Figure 1). We performed univariate analysis to describe patient demographics and specific patient-care practices pertaining to UGIB.

RESULTS: Overall, there were 52 total eligible admissions admitted with a primary diagnosis of UGIB. In 24 patients, the index admission was for UGIB. Of these 24 patients, their underlying liver disease etiology included 54% with Alcohol-related Liver Disease, 20.8% Non-alcoholic liver disease, and 20.8% with Hepatitis C. One patient died during their index admission, 42%, and two were discharged to hospice, 8.4%. Of all those with bleeding during their index admission, 63% had an upper endoscopy (EGD); 4 patients did not receive an EGD for non-specific reasons. Only 2 patients were discharged with an outpatient EGD scheduled. Twelve patients with an index admission for UGIB were readmitted. In 50%, the subsequent admission was due to UGIB. Of all 52 eligible UGIB admissions, 45 had an EGD and 82.2% were found to have esophageal varices (EV); in 59.4% cases this was felt to be the etiology of the UGIB. Of 37 with EVs, only 40.3% patients were discharged with an outpatient EGD scheduled. Twelve patients with an index admission for UGIB received 1.25 mg/kg. In givosiran patients (both doses), median AAR was 1.1 (range: 0.0-20.5) through Month 12. In placebo patients who crossed over to givosiran in the OLE, median AAR (DB = 10.6; OLE = 1.81) and proportion of attack-free patients (DB = 17.4%; OLE = 42.2%) were similar to the givosiran group in the DB period (median AAR = 1.04; attack-free patients = 48.9%). In addition, sustained lowering of ALA/PBG in the OLE was accompanied by reductions in hemin use, daily worst pain and analgesic use, and improvements in QoL. Among patients on givosiran from Day 1 through Month 12, 62% had ≤1 drug-related adverse event (AE) and 3% had ≥2 drug-related serious AE. There were no new AEs leading to discontinuation and no deaths. No new safety concerns occurred in the OLE. There was a trend toward increased efficacy with the 2.5 mg/kg dose compared to 1.25 mg/kg dose, and safety was acceptable at both doses.

CONCLUSION: In an ongoing Phase 3 study, givosiran 2.5 mg/kg monthly demonstrated maintenance or enhancement of clinical efficacy and an acceptable safety profile consistent with that observed in the 6-month DB period.

MELD-Na Score Is Prognostic of Illness Severity in COVID-19 Patients

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INTRODUCTION: Prognostic markers are needed to understand the disease course and severity in patients with Covid-19, a viral respiratory illness that causes systemic symptoms. However, there is no model to date that evaluates the complexity of this illness. We hypothesized that the MELD-Na score would be associated with disease severity in patients with Covid-19.

METHODS: This is an IRB approved, retrospective, single institution, cohort study that analyzed patients admitted to a community academic hospital with the diagnosis of Covid-19 between March 1st 2020 and June 11th, 2020. The primary outcome was mortality at 30 days based on MELD-Na score calculated at the time of admission. Secondary outcomes included the development of an Acute Kidney Injury (AKI), need for hemodialysis (HD), need for vasopressor hemodynamic support, need for intubation and hospital stay lasting longer than 7 days.

RESULTS: The sample size consisted of 99 patients: admission data to calculate a MELD-Na score was available for 63 patients (63%). The MELD-Na score was found to be significantly higher in those who died at 30 days (14.38 ± 6.92) after discharge relative to those who survived (9.68 ± 5.66; p = 0.03). The odds of death at 30 days with a MELD-Na score greater than 10 was 9.00 (95% CI: 2.29, 35.50; P = 0.001). Patients with a MELD-Na score greater than 10 were more likely to have an AKI by an odds ratio (OR) of 3.31 (95% CI: 1.08, 10.17; P = 0.03), need HD by an OR of 9.69 (95% CI: 1.74, 53.96; P = 0.007), need vasopressor support by an OR of 4.55 (95% CI: 1.22, 16.99; P = 0.02) and stay in the hospital longer than 7 days by an OR of 4.17 (95% CI: 1.05, 16.47; P = 0.03).

CONCLUSION: The MELD-Na score was found to be higher in patients with Covid-19 who died relative to those who survived at 30 days after discharge. A MELD-Na score greater than 10 was