Conclusion. SOT group was younger, had longer LOS, and more COVID-related modalities. The 30-d survival estimate for SOT group is 92.9% and for NTP group is 86.5%, but the survival curve for NTP was worse likely secondary to age. Use of REM & DEX in SOT recipients is a valid recommendation.

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546. Therapeutic Effect of Regdanvimab in Patients with Mild to Moderate COVID-19: Day 28 Results from a Multicentre, Randomised, Controlled Pivotal Trial

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547. Risk Factors Associated with 30-Day Mortality in a Large Cohort of Patients who Received Remdesivir and Corticosteroids for Severe COVID-19

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Session: P-24. COVID-19 Treatment

Background. Regdanvimab is a monoclonal antibody with activity against SARS-CoV-2. A Phase 2/3 study with two parts is currently ongoing and data up to Day 28 of Part 1 is available while the data from 1315 patients enrolled in Part 2 are expected in June 2021.

Methods. This phase 2/3, randomized, parallel-group, placebo-controlled, double-blind study with 2 parts is aimed to assess the therapeutic efficacy of regdanvimab in outpatients with mild to moderate COVID-19, not requiring supplemental oxygen therapy. Patients aged >18 with the onset of symptoms within 7 days were eligible to be enrolled.

Results. In Part 1, 307 patients (101, 103, and 103 patients in the regdanvimab 40 mg/kg, regdanvimab 80 mg/kg, and placebo groups, respectively) were confirmed to have COVID-19 by RT-qPCR at Day 1 (or Day 2). Regdanvimab significantly reduced the proportion of patients who required hospitalization or supplemental oxygen therapy compared to placebo (8.7% in the placebo vs. 4.0% in the regdanvimab 40 mg/kg). The difference in event rates was even larger in patients who met the high-risk criteria and confirmed a 66.1% reduction in patients receiving regdanvimab 40 mg/kg (Table 1). The median time to clinical recovery was shorter by 2.9 days for regdanvimab 40 mg/kg and 10.03 days for placebo (high-risk).

548. Risk Factors Associated with 30-Day Mortality in a Large Cohort of Patients who Received Remdesivir and Corticosteroids for Severe COVID-19

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Session: P-24. COVID-19 Treatment

Background. Remdesivir (RDV), an antiviral agent, is approved by Food and Drug Administration (FDA) for the treatment of patients (pts) admitted with SARS-CoV-2 infection (COVID-19). Earlier RDV studies (such as ACCT-1) prior to widespread use of corticosteroids (CS), showed a 30-day mortality of 11%. Advanced age, obesity, and certain comorbidities are known risk factors for death in COVID-19, but whether these risks vary in pts treated with RDV and CS is unknown. As of March 20, 2020 pts were the most important risk factors (Figure 2).

Results. A total of 1,591 pts received RDV and were included in the study; median age 67 years, 56% male and 18% Black. RDV use increased after emergency use authorization and FDA approval (Fig 1). Death within 30 days occurred in 15.3%. Patients who died were older males with higher rates of hypertension, kidney disease, diabetes, smoking, and more likely to have qSOFA ≥2 on admission (Table 1). A multi-variable logistic model, advanced age, male gender, pulmonary disease, CKD, obesity, and qSOFA≥2 were independent predictors of death (Figure 2). Among these, age and qSOFA≥2 were the most important risk factors (Figure 2).

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Patients receiving remdesivir (red) were included in the study. Routine use of corticosteroids was avoided on all patients in our health system beginning March 20, 2020. Systemic use of remdesivir increased following Food and Drug Administration approval in fall 2020.

On both logistic regression and time-to-event analysis, advanced age and qSOFA ≥ 2 had the highest predictive value for mortality. Others comorbidities were similar and comparable in importance.

Conclusion. The population in our Real-world study was older with more comorbidities as compared to ACCT-1, and the 30-day mortality was 15%. Despite the use of CS and EVD advanced age and qSOFA were the most important drivers of mortality. Future, therapeutic strategies need to focus on this group which is at the highest risk of dying from COVID-19 infection.

Disclosures. All Authors: No reported disclosures

54. Convalescent Plasma in Hospitalized Pediatric and Obstetric patients with COVID-19

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Session: P-24. COVID-19 Treatment

Background. Published data on COVID-19 convalescent plasma (CCP) use in children and obstetric patients is limited. We describe a single-center experience of hospitalized patients who received CCP for acute COVID-19.

Methods. We performed a retrospective review of children 0-18-years-old and pregnant patients hospitalized with laboratory-confirmed acute COVID-19 who received CCP from March 1st, 2020 to March 1st, 2021. Clinical and laboratory data were collected to assess the safety of CCP administration. Antibodies to SARS-CoV-2 were measured before and at various time points post CCP transfusion. Correlation between SARS-CoV-2 immunoglobulin administered versus the SARS-CoV-2 anti-Spike immunoglobulin response in patient serum was assessed.

Results. Twenty-two children and 10 obstetric patients were eligible. 12 pediatric and 8 obstetric patients had moderate disease and 10 pediatric and 2 obstetric patients had severe disease. 5 pediatric patients died. 18/37 (48.6%) CCP units that were measured met FDA criteria for a high IgG titer. There were no complications with transfusion based on CDC, NHSN Biovigilance Component: Hemovigilance Module Surveillance Protocol. Two pediatric patients had fevers a few hours after CCP with low suspicion for a transfusion reaction. Median SARS-CoV-2 anti-spike antibody levels of pediatric patients post-transfusion for 0-7 days was 80.6AU/mL (range: 2-1070), 8-21 days was 180AU/mL (range: 12-661) and >21 days was 210AU/mL (range: 4.1-1220). For obstetric patients, post-transfusion antibody levels were only obtained 0-7 days post-transfusion with median 45AU/mL (range: 9.5-100). High-titer CCP showed a positive correlation with rise in patient immunoglobulin levels only in the obstetric patients but not in pediatric patients.

Conclusion. CCP was administered safely to our moderately to severely ill pediatric and obstetric patients. Among pediatric patients, the median serum antibody level increased over time after transfusion and suggested that CCP did not interfere with the endogenous antibody production. Antibody dose of high-titer CCP correlated with post-transfusion response in only obstetric patients. Randomized trials in pediatric and obstetric patients are needed to further understand how to dose CCP and evaluate efficacy.

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54.5 Monoclonal Antibody Therapy for COVID-19 Infection in Michigan: The Flint Experience

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Session: P-24. COVID-19 Treatment

Background. Bamlanivimab (BAM), a neutralizing IgG1 monoclonal antibody (mAb), received emergency use authorization (EUA) by the U.S. Food and Drug Administration (FDA) for treatment of mild to moderate COVID-19 infection in patients 12 years of age and older weighing at least 40 kg at high risk for progressive and severe disease on Nov 10, 2020. The purpose of this study is to describe our experience with this treatment modality.

Methods. Hurley Medical Center (HMC), a 443-bed inner city teaching hospital in Flint, MI. HMC administered its first BAM infusion on Nov 19, 2020. Through April 30, 2021, 407 patients with confirmed SARS-CoV-2 infection, received a mAb infusion. 62/407 patients received the combination mAb therapy of BAM + Etesevimab, as the EUA for BAM monotherapy was revoked on 04/16/21. We retrospectively collected basic demographic data and hospitalization to our facility within 14 days of receiving mAb therapy of these patients.