COVID-19 Evidence Digest 03/26/21

Convalescent plasma in patients admitted to hospital with COVID-19 (RECOVERY): a randomised, controlled, open-label, platform trial (MedRxIV)

Bottom Line: In a large clinical trial of hospitalized patients with COVID-19, high-titer convalescent plasma did not improve 28-day survival, hospital discharge, or prevent a composite end point of mortality or progression to invasive mechanical ventilation.

Details: In this study, 81% (N = 13,127) of patients enrolled in the Randomized Evaluation of COVID-19 Therapy (RECOVERY, a randomized, controlled, open-label trial of hospitalized patients with suspected or laboratory-confirmed COVID-19 in the UK), were eligible to receive either usual care or usual care plus high-titer convalescent plasma. During May 20, 2020–January 15, 2021, 5,795 patients were allocated to receive two units (275mls ± 156 75mls) of high-titer (EUROIMMUN S/CO of ≥6) convalescent plasma–first doses were given soon after the randomization and second dose were given the following day and at least 12 hours apart; 5,763 patients received usual care alone. For the study's primary outcome–all-cause 28-day mortality, 24% (N = 1,398) of the patients in the convalescent plasma group and 24% (N = 1,408) of patients in the usual care group died, which suggested no statistically significant difference (rate ratio [RR]: 1.00; p value = 0.93). For subgroup (age, sex, ethnicity, duration of symptoms, level of respiratory support, and use of corticosteroids) analyses, similar 28-day mortality rate ratios were observed, including in those patients without detectable SARS-CoV-2 antibodies at baseline. The RR of patients discharged from hospital within 28-days was 0.98, and was not statistically significant (66% vs 67%; p value = 0.50). Among patients not needing invasive mechanical ventilation at baseline, no significant difference in RR regarding a composite endpoint of requiring invasive mechanical ventilation or death was observed (28% vs 29%; RR = 0.99; p value = 0.79).

Key Takeaways:

- In the RECOVERY trial, convalescent plasma was not found to be associated with improving patient survival or other clinical outcomes among hospitalized patients with COVID-19.

Efficacy of the ChAdOx1 nCoV-19 COVID-19 Vaccine against the B.1.351 Variant (NEJM)

Bottom Line: The two-dose AstraZeneca vaccine may not be very effective against mild to moderate COVID-19 due to the South African variant.

Details: This study was a multicenter, randomized, controlled trial assessing the safety and efficacy of the ChAdOx1 nCoV-19 (AstraZeneca) vaccine against the SARS-CoV-2 B.1.351 (South African) variant from June 24, 2020 and November 9, 2020. The study included 2,026 participants between the ages of 18 and 65 years old who are human immunodeficiency virus (HIV) negative in South Africa. Participants were assigned to receive either two doses of the vaccine or a placebo between 21 to 35 days apart. There were 1,011 participants in the vaccine group (received at least one dose) while 1,010 participants received at least one dose of the placebo. The median age of all participants was 30 years old with 56% being male. The analysis included 1,467 participants with 750 receiving the vaccine and 717 receiving the placebo. Among those who received the vaccine, 2.5% (N = 19) of them developed mild to moderate

COVID-19 compared to 3.2% (N = 23) of the placebo group, making the vaccine 21.9% effective (95% CI, -49.9–59.8). Among the 42 cases of COVID-19, 92.9% were due to the B.1.351 (South African) variant, making the vaccine against this variant 10.4% effective (95% CI, -76.8–54.8). None of these patients were hospitalized and had mild to moderate COVID-19.

Key Takeaways:

- It was found that the AstraZeneca vaccine was only 10% effective against the B.1.351 variant of COVID-19 in mild to moderate cases.
- The efficacy of the vaccine against severe COVID-19 could not be determined due to the lack of severe cases in the study, likely because of the young age of participants (median of 30 years old).
- A second-generation of COVID-19 vaccines against newer strains like this are beginning to be developed.

Progesterone in Addition to Standard of Care Versus Standard of Care Alone in the Treatment of Men Hospitalized with Moderate to Severe COVID-19: A Randomized, Controlled Pilot Trial (CHEST)

Bottom Line: In a small pilot study of men hospitalized with COVID-19, receiving subcutaneous progesterone was associated with greater clinical improvement by day 7.

Details: In an open label randomized trial of subcutaneous (SC) progesterone, patients dosed at 100mg twice daily for 5 days versus standard of care (SOC) alone was evaluated in men hospitalized with moderate or severe COVID-19. Patients requiring invasive or noninvasive mechanical ventilation at baseline were excluded. There were 22 men randomized to the control group and 20 to the progesterone group, and clinical improvement was measured using a 7 point ordinal scale. Men who received SC progesterone had greater clinical improvement (1.5 point difference on the ordinal scale) by day 7, and had fewer days where they required supplemental oxygen as well as shorter hospitalization time compared to men who received SOC alone. No safety concerns were noted.

Key Takeaways: Subcutaneous progesterone given for 5 days to men hospitalized with moderate or severe COVID-19 was associated with improved clinical status, reduced need for supplemental oxygen and shorter hospital stay as compared to SOC alone.