834. Characterization of Heavy Treatment Experienced HIV-1 Infected Clinical Trial Participants Infected with SARS-CoV-2 COVID 19: Fortsasvir BRIGHTE

Phase 3 Clinical Trial
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Session: P-46 HIV: Complications and Co-infections

Background. BRIGHTE is an ongoing global study evaluating the gp120 attachment inhibitor fostemsavir (FTI) in heavily treatment-experienced (HTE) adults with multidrug resistant (MDR) HIV-1 unable to form a viable antiretroviral (ARV) regimen. An estimated 2 million people living with HIV-1 have been infected with SARS-CoV-2. Those with HIV viremia and/or low CD4+ counts are at increased risk of serious adverse outcome. We described the reported COVID cases in a clinical trial population of people living with MDR HIV and immune suppression.

Methods. At the start of the COVID pandemic, all ongoing BRIGHTE subjects had achieved ≥ 192 weeks on FTI and optimized background ARVs; results through Week 96 were presented previously. Investigators used WHO guidelines for COVID diagnosis and reported exposure, testing results and symptom presence.

Results. 371 subjects [272 Randomized Cohort (RC), 99 Non-Randomized Cohort (NC)] were enrolled; 44% were ≥ 50 years of age and 86% had an AIDS history. Median CD4+ count at study start was 80 cells/mm³ (IQR 11–202); 30% with ≥ 20 cells/mm³. 250 subjects remained in BRIGHTE at pandemic start. By April 2021, 17 subjects (14 RC, 3 NC) had confirmed COVID-19 (positive PCR test); all were ≥ 25 years of age. By May 2021, 31 COVID cases were confirmed (20 RC, 11 NC). Median age was Grade 1-3, all cases resolved with no deaths. Six subjects were hospitalized (Table 1); most recent CD4+ count prior to COVID were 293-1641 cells/mm³ and 5/6 subjects were virologically suppressed. Treatments often included prophylactic anticoagulants and supplemental oxygen; no CART changes were made. The remaining 11/17 confirmed cases were managed outpatient. Five more subjects had suspect COVID not confirmed by PCR and 2 subjects had negative PCR tests.

Conclusion. A total of 22/250 COVID-19 cases (17 confirmed, 5 unconfirmed) have been reported in BRIGHTE. Outcomes were reassuring with no deaths or known persistent sequelae, despite having advanced HIV and comorbid diseases at baseline associated with poorer COVID outcomes. Outcomes may have benefited from immunomodulatory improvement during the trial.

Disclosures. Shiven Chabria, MD, Viiv Healthcare (Employee) Stephanie De Wit, MD, Gilead (Grant/Research Support) Janssen (Grant/Research Support) Merck Sharpe & Dohme (Grant/Research Support) Viiv Healthcare (Grant/Research Support) Amy Pierce, BS, Mark Lustberg, MD, PhD, Carlos Malvestuto, M.D.; "The Ohio State University Wexner Medical Center, Columbus, Ohio; "The Ohio State University College of Medicine, Columbus, Ohio; "The Ohio State University, Columbus, Ohio

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Background. Weight gain among PWH on ART is a growing clinical concern. We explore factors associated with weight gain at The Ohio State University Wexner Medical Center Infectious Diseases Clinic.

Methods. This was a single site, retrospective, cohort study of adult PWH on ART for at least 3 months seen at our clinic from 1/1/2015 to 1/1/2019. Patients with CD4+ T cell < 200 cells/mm³, viral load >200 copies/mL, history of malignancy, or pregnancy were excluded. 870 patients met criteria. Patient demographics, lifestyle factors, medical co-morbidities, concurrent medications, and ART regimens were documented during the study period. The primary outcome was percent weight change over the follow up period. Secondary outcome was the odds of > 5 kg weight gain over the study period. The effects of concurrent medications, medical comorbidities, ART combinations, and self-reported lifestyle behaviors on these outcomes were modeled using mixed effect linear and logistic regression analysis.

Results. At baseline, 83.6% were male, 29.2% were African American, and 65.6% had a body mass index ≥ 25 kg/m². Over a mean follow up of 1.86 years, the study population gained a mean percent weight of 2.12 ± 0.21% (p< 0.001) with an odds of weight gain >5kg of 0.293 (p< 0.001). Male sex and increasing age were significantly associated with a decrease in percent weight change over the study period as reflected in the table below. Diet was also significantly associated with a decrease in percent weight change over the study period of -1.99 ± 0.47 %, p= < 0.001 and a lower odds of > 5kg of weight gain (OR: 0.70, 95% CI: 0.50 – 0.97, p=0.03). In regression models, combination therapy with tenofovir alafenamide (TAF) and integrase strand transfer inhibitor (INSTI) containing regimens were significantly associated with an increase in percent weight over the study period. Other significant factors including demographics and ART regimens are noted in Table 1.

Conclusion. "The Ohio State University Wexner Medical Center Infectious Diseases Clinic.

Disclosures. Shiven Chabria, MD, Viiv Healthcare (Shareholder) GlaxoSmithKline (Employee, Shareholder) Andrew Clark, MD, GlaxoSmithKline (Shareholder) Viiv Healthcare (Employee) Bronagh M. Shepherd, PhD, GlaxoSmithKline (Employee, Shareholder) Michael Warwick-Sanders, BM BSc DPM MFPM, GSK (Employee) Marcia Wang, PhD, GlaxoSmithKline (Employee, Shareholder) Andrew Clark, MD, GlaxoSmithKline (Shareholder) Viiv Healthcare (Employee) Peter Ackerman, MD, GlaxoSmithKline (Employee, Shareholder)

835. Improvement in Diet Attenuates Antiretroviral Therapy (ART) Associated Weight Gain in Persons with Human Immunodeficiency Virus (PWH)

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