1815. Prevalence of Systemic Hypertension Among HIV-Infected and HIV-Uninfected Young Adults

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Background. Advances in HIV care and treatment have resulted in perinatally infected children aging into adulthood. These patients may be at higher risk of HIV-associated non-AIDS conditions, including systemic hypertension (HTN). This study examined the association between HIV infection and the prevalence of HTN among young adults receiving care in West Baltimore.

Methods. We conducted a cross-sectional study of young adults with perinatally-acquired (PA) HIV frequency matched on race and sex to a stratified random sample of young adults with non perinatally-acquired (NPA) HIV and HIV-uninfected young adults (UI). All subjects were aged 18–29 years of age as of September 1, 2014. The outcome of HTN was ascertained through chart review (two systolic blood pressure measurements > = 140 mmHg or diastolic > = 90 mmHg at least three months apart; and/ or physician prescription for an antihypertensive mediation). Logistic regression was used to estimate adjusted prevalence odds ratios (aPOR) and 95% confidence intervals (CI) for the association between HIV infection and HTN. All data were collected from clinics within the University of Marvland Medical System.

Results. Three hundred and twenty-four patients were included in the study, 108 per exposure group. The prevalence of HTN was 23% among PA patients, 10% among NPA patients, and 9% among UI patients. The median age was 24 (IQR 22 - 26), 95% were African American, and 42% were male. PA patients had the highest prevalence of chronic kidney disease (CKD) and dyslipidemia (19% and 13% respectively) compared with NPA (1% and 3%) and UI (0% and 5%). PA patients had 3 (95% CI 1.4 - 6.6) times the base odds (controlling for matching variables) of prevalent HTN compared with UI patients and NPA had 1.1 times the base odds (95% CI 0.5 - 2.7) compared with UI patients. After controlling for race, gender, family history of HTN, and CKD, the prevalence odds ratio for HTN was 2.7 (95% CI 1.06 - 7.0) times higher for PA compared with UI, and 1.3 (95% CI 0.5 - 3.4) times higher for NPA compared with UI.

Conclusion. Our findings suggest that the prevalence of HTN among young adults with PA HIV is significantly higher than sex and race matched UI patients of similar age. HIV providers should carefully monitor these patients for the development of HTN, particularly as they enter adulthood.

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1816. Effect of Macrolide Prophylactic Therapy on AIDS-Defining Conditions and HIV-Related Mortality

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Background. Mycobacterium avium–intracelllulare complex (MAC) prophylaxis is recommended for patients with CD4 counts of < 50 cells/mm 3 . With the significant decrease in incidence of disseminated MAC infection and the effective immune recovery due to the availability of combination antiretroviral therapy (ART), the benefits of giving MAC prophylaxis were investigated. This study examined the impact of

macrolide prophylaxis on AIDS-defining conditions and HIV-associated mortality in a cohort of HIV-infected patients on ART.

Methods. TREAT Asia HIV Observational Database (TAHOD) patients aged ≥18 years with a CD4 count < 50 cells/mm³ at ART initiation were included. The effect of macrolide prohylaxis on HIV-associated mortality or an AIDS event (as a combined outcome) and HIV-associated mortality alone were evaluated using competing risk regression. Sensitivity analysis was conducted to assess whether results were consistent in patients with a CD4 < 100 cells/mm³ at ART initiation.

Results. Of 1,345 eligible patients (78% male with median age at ART initiation of 34.8 years), 10.6% received macrolide prophylaxis. The rates of the combined outcome and HIV-associated mortality per 100 patient years were 7.35 [95% confidence interval (CI): 6.04-8.95] and 3.14 (95% CI: 2.35-4.19), respectively. After adjusting for possible confounders, macrolide use was associated with a significantly decreased risk of HIV-associated mortality (HR 0.10, 95% CI: 0.01-0.80, P=0.031) but not the combined outcome (HR 0.86, 95% CI: 0.32-2.229, P=0.764). Sensitivity analyses showed that, among patients with a CD4 < 100 cells/ mm³ at ART initiation, these results were consistent.

Conclusion. Macrolide prophylaxis is associated with significantly improved survival among Asian HIV-infected patients with very low CD4 cell counts. The benefits of giving macrolide prophylaxis remain despite the availability of effective ART.

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1817. Analysis of a Phase 2b Study of GEN-003, a Genital Herpes Immunotherapy, Showed Significant Reductions in Viral Shedding and Lesion Rate Vs Placebo Thomas C. Heineman, MD, PhD¹; David Bernstein, MD, FIDSA²; Anna Wald, MD, MPH, FIDSA³; Nicholas Van Wagoner, MD, PhD⁴; Peter Leone, MD⁵; Kenneth Mayer, MD⁶; Gregg Lucksinger, MDʔ; Sandra Win, MD, MS³; William Koltun, MD⁰; Nisha Desai, MD¹⁰; Thomas Oliphant, MS, PhD¹¹; Andrew Natenshon, MA¹; Lisa K. McNeil, PhD¹; Jessica B. Flechtner, PhD¹ and Seth Hetherington, MD¹; ¹Genocea Biosciences, Cambridge, MA; ²Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio; ³Department of Medicine, University of Washington, Seattle, Washington; ⁴Division of Infectious Diseases, University of Alabama at Birmingham, Birmingham, Alabama; ⁵Department of Medicine, University of North Carolina, Chapel Hill, North Carolina; ⁶The Fenway Institute, Boston, Massachusetts; ¹Tekton Research, Austin, Texas; ²eStudy Site, San Francisco, California; ¹Medical Center for Clinical Research, San Diego, California; ¹Planders Center, Portland, Oregon; ¹¹Innovative Analytics, Kalamazoo, Michigan

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Background. GEN-003 is an investigational genital herpes immunotherapy comprising gD2 Δ TMR, an HSV-2 antigen that induces neutralizing antibody and T cell responses, ICP4.2, an HSV-2 T cell antigen selected through human T cell screens, and Matrix-M2", a saponin-based adjuvant. This Phase 2b study was designed to evaluate efficacy and safety of GEN-003 vs. placebo.

Methods. Healthy persons, age 18–50 years, with 3–9 HSV-2 genital herpes outbreaks annually were randomized to 3 groups: placebo, or 60 μg of each antigen combined with 50 μg (60/50 group) or 75 μg (60/75 group) of adjuvant, administered 3 times 21 days apart. Study endpoints included safety, immunogenicity, HSV-2 shedding frequency, lesion rate and recurrence frequency. Viral shedding was measured from anogenital swabs by PCR. Swabs were collected for 28 days at baseline, and after the third dose, 6 months and 1 year. The presence of herpes lesions was recorded daily by electronic diary.

Results. One hundred and thirty-one participants enrolled and >90% received all 3 doses. In the 28-day post-treatment period, viral shedding was reduced by 40% and 27% in the 60/50 and 60/75 groups, respectively, compared with a 5% increase in the placebo group. At 6 months post-treatment, median lesion rates were significantly lower in the 60/50 and 60/75 groups (2.7% and 1.9%, respectively) vs. the placebo group (5.6%, p < 0.05), resulting in median reductions of 52% and 66%. In participants not receiving suppressive antivirals, the median recurrence frequency was 1.0/6 months in the 60/50 group vs. 2.0 in the placebo group (p = 0.08). The median recurrence duration in the 60/50 group was lower than in the placebo group (2.8 vs. 4.2 days; p < 0.05). The most commonly reported adverse events (AEs) following GEN-003 vaccination were nijection site pain/tenderness (97%), fatigue (82%), headache (82%) and myalgia (80%). No vaccine-related serious AEs, autoimmune events or other AEs of special interest were reported.

Conclusion. In adults with recurrent genital herpes, GEN-003 reduced HSV-2 shedding frequency, genital herpes lesion rate, recurrence frequency and recurrence duration through 6 months after the last dose. Local and systemic symptoms were common in GEN-003 recipients, but treatment completion was high with few discontinuations due to AEs.

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