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TITLE

Association of HIV pre-exposure prophylaxis (PrEP) use and bacterial sexually transmitted infections (bSTI) among men with men (MSM) and transgender women (TGW) in HVTN 704/HPTN 085

PRESENTER

Jorge Antonio Gallardo-Cartagena

AUTHORS

J.A. Gallardo-Cartagena¹, P. Hunidzarira², K. Gillespie³, M. Juraska³, M. Neradilek³, P. Gilbert³, R. Cabello⁴, J.R. Lama⁵, J. Hinojosa⁶, J.J. Montenegro-Idrogo¹, V.G. Veloso⁷, B. Grinsztejn⁷, R. De La Grecca³, S. Karuna^{3,8}, S. Edupuganti⁹, K. Konda M. Cohen¹³, L. Corey³, J. Sanchez¹, HVTN 704/HPTN 085 Study Team

INSTITUTIONS

¹Universidad Nacional Mayor de San Marcos, Centro de Investigaciones Tecnológicas, Biomédicas y Medioambiental
²University of Zimbabwe, Clinical Trials Research Centre (UZ-CTRC), Harare, Zimbabwe, ³Fred Hutchinson Cancer Center Infectious Diseases Division, Seattle, United States, ⁴Asociación Civil Vía Libre, Lima, Peru, ⁵Asociación Civil Impacta Sc Lima, Peru, ⁶Asociación Civil Selva Amazónica, Lima, Peru, ⁷Instituto Nacional de Infectología Evandro Chagas, Fundaçã Cruz (INI/Fiocruz), Rio de Janeiro, Brazil, ⁸GreenLight Biosciences, Inc, Lexington, United States, ⁹Emory University, Department of Medicine, Division of Infectious Disease, Atlanta, United States, ¹⁰University of Southern California, Keck School of Medicine, Department of Population and Public Health Sciences, Los Angeles, United States, ¹¹University of Washington, Department of Medicine, Seattle, United States, ¹²University of Washington, Department of Global Health, Seattle, United States, ¹³University of North Carolina, Department of Medicine, Chapel Hill, United States

BACKGROUND: HIV prevention trials enroll participants with high vulnerability to HIV and provide access to an enhanced package, including PrEP. HVTN 704/HPTN 085 was a randomized clinical trial evaluating VRC01 for HIV prevention in Mexico, Central America, and Switzerland. We conducted a post-hoc analysis to characterize bSTI burden and evaluate the association of bSTI incidence among trial participants.

METHODS: We included trial participants who received at least one VRC01/placebo infusion and had bSTI results from at least one visit (baseline and every 6 months). Participants received education about oral PrEP and could opt to use it. Prevalence of bSTI was summarized at each visit and categorized by socio-demographics, geographic region, and PrEP use (a time-varying exposure based on self-reported PrEP use). We estimated incidence rates (for 100 person-years at risk [PYR]) of first bSTI occurrence among participants with negative at baseline, categorized by PrEP use. Cox proportional hazards models were used to evaluate the effect of PrEP on bSTI incidence, additionally adjusted for age, region, race, ethnicity, and VRC01/placebo.

RESULTS: The analysis included 2687 participants, of whom 31.8% initiated PrEP during follow-up. The table summarizes baseline prevalence by region and incidence rates by PrEP use. The baseline prevalence of any bSTI was highest among <20yo (32.4%), Hispanic/Latinx (32.4%), non-Black/non-Whites (32.1%), TGW (35.3%), and MSM (28.9%). Oropharyngeal (gonorrhea 6.5%) were more prevalent (chlamydia 9.0% and gonorrhea 5.8%) than genitourinary bSTI (chlamydia 3.0% and gonorrhea 2.5%). PrEP use was significantly associated with increased hazard of any bSTI (HR 1.7, 95%CI 1.4-2.1), chlamydia (HR 1.7, 95%CI 1.4-2.1), and syphilis (HR 1.9, 95%CI 1.3-2.8).

bSTI	Baseline prevalence summarized by n/N (%)				Incidence rates for 10C	
	Overall	Brazil	Peru	US/Switzerland	Overall	While on PrEP
Any bSTI	749/2687 (27.9%)	55/150 (36.7%)	392/1124 (34.9%)	302/1413 (21.4%)	28.6 (26.4-31.0)	37.2 (33.0-41.0)
Chlamydia	297/2687 (11.1%)	11/150 (7.3%)	158/1124 (14.1%)	128/1413 (9.1%)	16.1 (14.5-17.8)	20.4 (17.5-23.0)
Gonorrhea	273/2687 (10.2%)	22/150 (14.7%)	151/1124 (13.4%)	100/1413 (7.1%)	12.2 (10.9-13.7)	16.2 (13.7-19.0)
Syphilis	353/2687 (13.1%)	34/150 (22.7%)	194/1124 (17.3%)	125/1413 (8.8%)	6.7 (5.7-7.8)	8.8 (7.0-11.0)

CONCLUSIONS: HVTN 704/HPTN 085 engaged communities with significant HIV/STI vulnerability. While on PrEP, users had a lower risk of bSTI, suggesting risk compensation and underscoring the need for advancing bSTI testing and prevention measures in high-risk populations.

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