

Intra-Vaginal Practices Reported by Participants: HPTN 035

Investigators/Team Members

Jane Matambo¹ Margaret Kasaro¹, Cheri Reid¹, Bonus Makanani²
Connie Cellum³, Jeanne Marrasso³

1. Centre for Infectious Disease Research in Zambia
2. College of medicine, John Hopkins Project, Malawi.
3. Departments of Global Health, Medicine, and Epidemiology,
University of Washington, Seattle, Washington, USA



Background

- HPTN 035 was a double-blinded four arm Phase 2/2b randomized controlled trial of two topical microbicides, PRO 2000 and Buffergel, with two control arms, Placebo Gel and No Gel (condoms only).
- 3101 sexually active women were enrolled in the study at a ratio 1:1:1:1

Background

- Intra-vaginal practices (cleansing, douching or other culturally-prescribed vaginal inserts) cause discrete changes in the vaginal microenvironment
 - Bacterial changes
 - Epithelial integrity
- These Practices have long been suspected to be associated with increased HIV-1 susceptibility, and are widespread in different regions and populations (Scott McClelland).

background

- Changes in Lactobacilli and epithelial integrity has shown to increase risk of HIV acquisition (Myer et al 2005, Atashili et al 2008).
- Reasons for intra-vaginal practices are to take care of sexual, hygiene and health needs (van der Straten et al 2010, Cottrell B H 2010).

Objectives

- To describe the intra-vaginal practices as practiced by HPTN 035 participants.
- To understand participant characteristics associated with intra-vaginal practices across sites.

Hypotheses

- Intra-vaginal practices were common at sites that participated in the HPTN 035 trial.

- Intra-vaginal practices will be associated with
 - Reported genital symptoms
 - Demographic characteristics

Study Design

- Observational analysis of prospective cohort study data.
- Demographic characteristics (women and sex partners) at screening.
- Self-report of intra-vaginal practices was collected at Baseline and Quarterly visits
 - use of water
 - water with vinegar
 - water with soap
 - use of paper, cloth, cotton or cotton wool
 - tampons
 - fingers without anything else
- 10 follow-up Quarterly visits over 30 months



Analysis Plan

Exposure of Interest

- The dependent variables are the demographic characteristics of the cohort of women.
- Analysis for the association of demographic characteristics with the intra-vaginal practices will be assessed by multivariate analysis.

Primary Outcomes

- Self-reported intra-vaginal practices.
- Frequencies of intra-vaginal practices by categories.

Implications

- Emphasizes need to understand reasons for intra-vaginal practices.
- Contribution to development of counseling messages to avoid potentially harmful practices.



Thank you!