Is an HIV Antibody Rapid Test Sufficient to Monitor PrEP Efficacy?

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Background: Pre-exposure prophylaxis (PrEP) significantly reduces HIV infection by up to 92% in people who are at high risk of infection. Frequent HIV testing is required to ensure absence of breakthrough infections during PrEP. Conclusions: Stronger Together Study

Objective

We evaluated the strategy of using the INSTI HIV-1/2 rapid antibody (INSTI) test with fingerstick whole blood (FSWB) as a monitoring test for patients on PrEP. We compared results of the INSTI with plasma (INSTI) test with fingerstick whole blood (FSWB) as a monitoring test.

Methods

• 130 INSTI (FSWB)-negative plasma specimens from 35 participants with 3 to 5 longitudinal samples were available
• Each specimen was tested with:
  » HIV immunoassay blood test
  » BRC HIV-1/2 Ag/Ab (BRC) test
  » All 130 samples were target not detected on the APT-Quant
• All initially reactive test results were repeated
  » BRC repeatedly reactive samples were tested with Genius HIV-1/2 supplemental test
  » The presence of tenofovir (TFV) and emtricitabine (FTC) was measured by tandem liquid chromatography-mass spectrometry (limit of quantification (LOQ)= 10 ng/mL)
  » For each participant, the average drug level for each drug was calculated (5 ng/mL was used when the drug level was <LOQ)
  » The mean was calculated of the drug averages for participants that had non-reactive or reactive HIV tests and compared

Results

• All 130 samples were target not detected on the APT-Quant (LOQ=30 copies/ml)
• Three participants (A, B, C) had seroreactivity at one time point (Fig)
  » All three had detectable levels of at least one PrEP drug at each time point, except for participant A at 18 months
  » All three samples remained negative at all subsequent follow-ups up to 24 months
• HIV test specificities:
  » BRC: 97.7% (95% CI 92.94% - 99.41%)
  » INSTI and DC: 99.24% (95% CI 95.19% - 99.96%)
  » 20% of participants had at least one instance of low adherence to PrEP (drug level <10 ng/mL)

Figure: Timeline of testing for reactive specimens including molecular and serological testing and drug levels (ng/ml)

Conclusions

• Our results indicate that PrEP in combination with HIV risk reduction counseling protecting a high-risk population from HIV-1 infection
• The ease of INSTI use with FSWB makes it a good option for monitoring infection status
• The absence of detectable breakthrough infections in our cohort and lack of longer term follow-up are limitations in this study
• Seroreactivity in three persons may indicate rare false-reactivity, but seroreactivity due to HIV exposure under potent chemoprophylaxis cannot be discounted
• Cases of rare, possible false-immunoreactivity and reports of ambiguous HIV test results suggest that diagnostic performance with PrEP use requires further investigation.

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References

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2. Smith D et al OFID 2018