Evaluation Of A Rapid Test Algorithm To Estimate HIV Incidence: HPTN 071/PopART

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HPTN
HIV Prevention Trials Network

Purpose and Methods

Purpose

- To evaluate the performance of the Sedia Asante HIV-1 Rapid Recency Assay (Rapid assay) for estimating population level incidence
- To compare the performance of the Rapid assay to the Sedia HIV-1 LAg-Avidity Enzyme Immuno Assay (LAg assay)

Study Methods

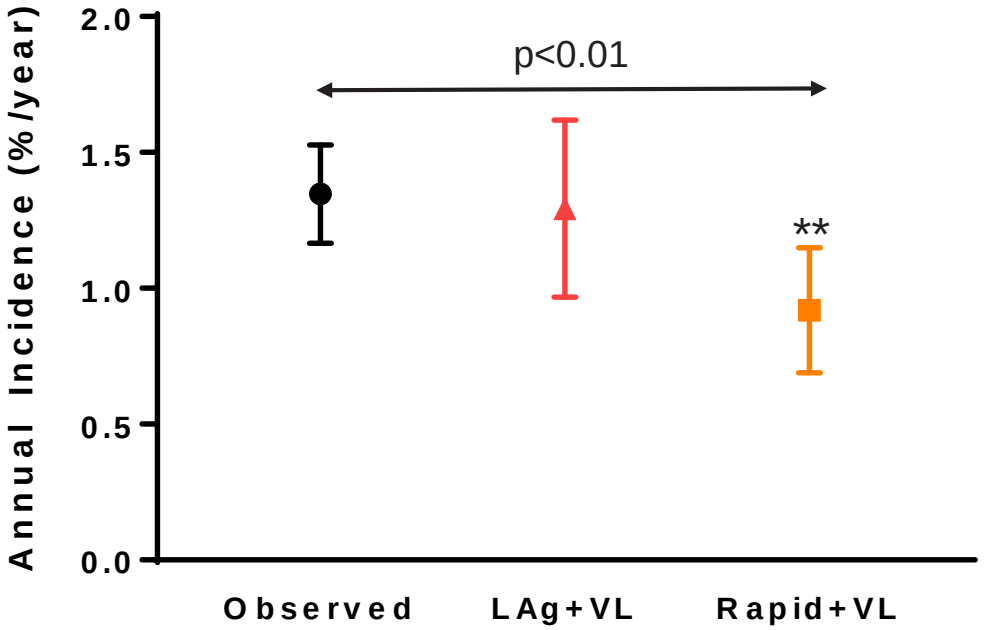
- Samples were obtained from the HPTN 071 trial for participants who had known HIV status 1 and 2 years after the start of the study (samples from Zambia and South Africa)
- 20,472 participants: 15,845 HIV- both visits; 4,406 HIV+ both visits
- 221 seroconverted between visits

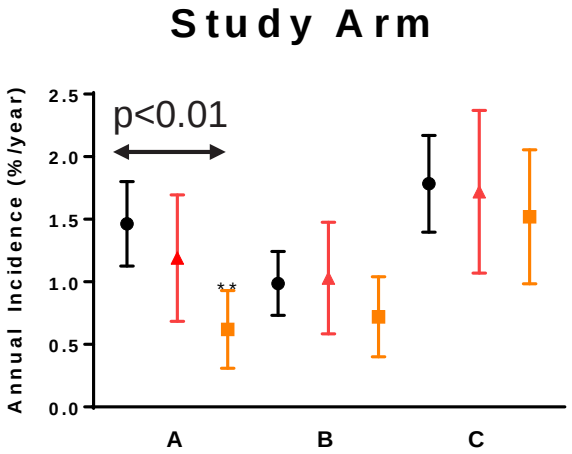
	Arm A Prevention interventions + universal ART	**Arm B** Prevention inteventions + ART according to local guidelines	**Arm C** Standard of care	**Overall**
# Participants	6724	7534	6214	20472
Zambia	3912	4304	3658	11874
South Africa	2812	3230	2556	8598
Male	1685	1928	174	5335
Female	5039	5606	4472	15117
18-24	1951	2142	1775	5868
25+	4773	5392	4439	14604

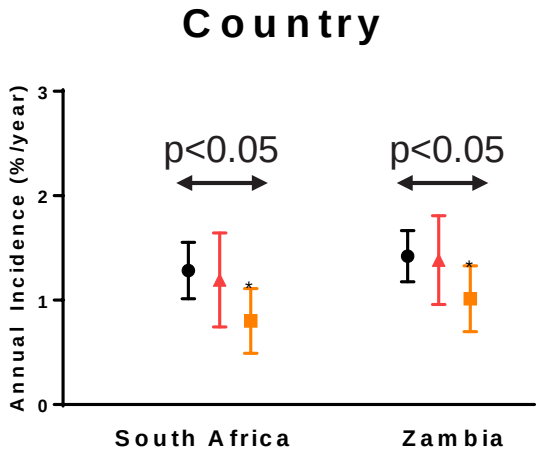
Methods

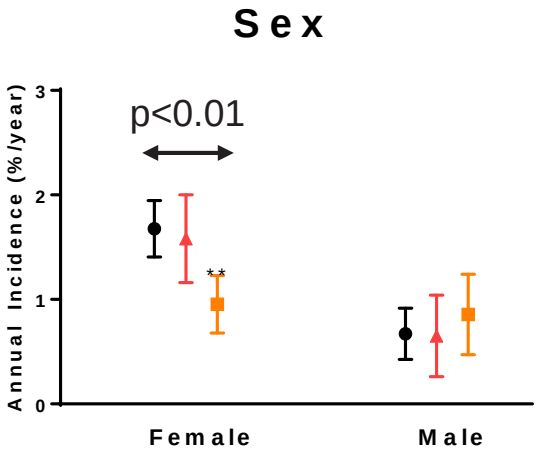
- HIV+ samples from year 2 visit were tested with both incidence assays
- Asante HIV-1 Rapid Recency Assay + Viral Load (Rapid+VL)
  - No long-term band + viral load > 1000 → recent infection
  - Mean duration of recent infection = 180 days
- HIV-1 LAg-Avidity Enzyme Immuno Assay + Viral Load (LAg+VL)
  - Normalized optical density <1.5 + viral load >1000 → recent infection
  - Mean duration of recent infection = 130 days
- Incidence estimates were calculated with the ABIE v3 incidence calculator by CEPHIA (Kassanjee, et al. ARHR 2014; 30:45-49)
- Sub-analyses were performed by country, study arm, sex, and young persons by sex (age 24 & under)

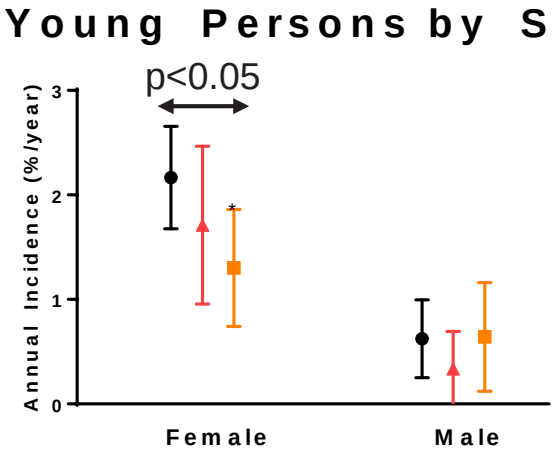
Results











Incidence Estimate ● Observed ▲ LAg+VL ■ Rapid+VL

Conclusions

The Rapid+VL algorithm underestimated HIV incidence in a large population-based cohort from South Africa and Zambia

- **This algorithm was less accurate for estimating incidence compared to the LAg+VL algorithm**

Possible explanations:

- **The mean duration of recent infection (180 days) suggested by the manufacturer may be too long**
- **The Rapid assay is not accurately detecting recent infections**

Additional studies are needed to determine the correct MDRI for the Rapid+VL algorithm

Acknowledgments

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