Undisclosed ART use found by urine LFA is common in South Africa, not associated with lower TB risk

Poster no. 1202

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Background

- People with HIV (PWH) not on ART are at high risk for low CD4 counts and tuberculosis (TB). ART use is associated with a decreased risk of TB
- Undiagnosed TB prevalence in South Africa is 5-10% in PWH not on ART. The DROP-TB cohort study identified a lower 1% TB prevalence in self-reported ART initiators
- South Africa ART initiation procedures include CD4 testing and Xpert MTB/RIF Ultra testing for TB
- Previous studies have shown that up to 30% of initiators may have undisclosed ART use for unknown reasons[2]
- We used a urine tenofovir (TFV) assay to evaluate the rate of undisclosed ART use as a potential explanation for the low TB prevalence in the cohort

Methods

- **Study setting**: Two public health clinics in uMkhanyakude district, KwaZulu-Natal, South Africa
- **Participants**: Adults aged >=18 with confirmed positive HIV test, no ART use within 90 days (self-report), presenting to initiate ART
- **Time Period:** December 2021-August 2023
- **Baseline testing**: CD4 count, sputum TB culture, sputum Xpert Ultra, urine TB-LAM. Remaining urine frozen and archived.
- Thawed urine samples tested for TFV (Aug-Sep 2023) using a novel lateral-flow antibody-based urine immunoassay (96% sensitive, 100% specific vs. LC-MS/MS)[1]. A positive urine TFV assay (>1500 ng/ml) indicates TFV use in the prior 4 days
- **Undisclosed ART**[2] defined as a positive urine TFV lateral flow assay (LFA) result with self-reported ART use negative
- **TB positive** defined as a positive Xpert Ultra or culture, or initiation of TB treatment within 3 months
- Logistic regression assessed predictors of ART nondisclosure; relationship between ART nondisclosure and positive TB status at enrollment.

Results

- N=315 PWH presenting for ART initiation had urine samples available for testing
- N=63/315 (20%) PWH had TFV detected in urine using the LFA→ undisclosed ART use
- N=15/315 (5%) tested positive for TB. 11/15 were male, 15/15 reported at least one TB symptom.
- Undisclosed ART not significantly associated with having TB: aOR 2.70 (95% CI 0.91-8.03), adjusting for gender.
- Undisclosed ART use associated with older age, higher CD4 counts and rural clinic site

20% of PWH presenting to initiate ART **have undisclosed current ART use**

Conclusions

- High prevalence of undisclosed ART use in PWH reporting no current ART
- Undisclosed ART use was not associated with risk of TB
- Use of urine TFV-LFA to assess recent ART use at initiation could triage costly CD4 testing; TB testing should continue regardless of ART use

Table 1. Characteristics of ART "initiators" reporting no ART use at 2 clinics in South Africa

Characteristics of PWH	ART present on LFA (n=63)	ART not present on LFA (n=252)	P value
Gender, N (%): Female	35 (56%)	154 (61%)	
Male	28 (44%)	98 (39%)	0.42
Age, N (%); median (IQR)	37 (32-42)	31 (26-38)	
18-29	8 (13%)	97 (39%)	
30-29	47 (77%)	139 (56%)	
>50	6 (10%)	11 (5%)	<0.001
Facility location, N (%)			
Peri urban clinic	26 (42%)	182 (73%)	
Rural clinic	36 (58%)	67 (27%)	<0.001
CD4 count, N (%); median (IQR)	503 (280-637)	336 (178-510)	
0-99	6 (10%)	22 (9%)	
100-499	22 (35%)	157 (62%)	
500-999	25 (40%)	60 (24%)	
>=1000	10 (15%)	13 (5%)	<0.001
Highest education, N (%)			
Primary	16 (26%)	25 (10%)	
Secondary	42 (68%)	217 (86%)	
Tertiary	0 (0%)	2 (1%)	
Unknown	4 (6%)	8 (3%)	0.004
Smoking status, N (%)			
Current	23 (37%)	57 (23%)	
Declined to answer	0 (0%)	1 (0%)	
Former	0 (0%)	2 (1%)	
Never	40 (63%)	192 (76%)	0.13
TB Positive	6 (10%)	9 (4%)	0.04

Table 2. Predictors of undisclosed ART use in PWH initiating ART

Predictor	n/N (%)	Adjusted OR (95% CI) for undisclosed ART	P value
Gender: male (vs. female ref)	126/315 (40)	0.74 (0.38-1.44)	0.38
Age: 30-49 (vs.18-29 ref)	**188/315 (60)**	**4.79 (2.02-11.36)**	**<0.001**
>=50 (vs.18-29 ref)	**19/315 (6)**	**8.95 (2.53-31.65)**	**0.001**
CD4: 100-499 (vs. 0-99 ref)	179/315 (57)	*0.59* (0.20-1.74)	0.35
500-999 (vs. 0-99 ref)	85/315 (27)	*1.67* (0.56-5.01)	0.36
>=1000 (vs. 0-99 ref)	23/315 (7)	*3.09* (0.78-12.27)	0.11
Clinic location: Peri-urban (vs. Rural ref)	**208/315 (66)**	**0.35 (0.19-0.66)**	**0.001**

References:
1. Gandhi M et al. J Acquir Immune Defic Syndr. 2019;81(1):72-7. PMID 30664078
2. Sithole N et al. AIDS Behav. 2021;25(11):3695-703. PMID: 34097208

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