Comparing real-time adherence measurements to tenofovir blood concentrations in MSM and transwomen PrEP users in Cape Town, South Africa

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Background

Pre-exposure prophylaxis (PrEP) is an effective intervention to prevent HIV transmission in men who have sex with men (MSM) and transgender women (transwomen). With approval in South Africa (SA) late 2015, scale up is expected soon. Understanding optimal adherence measurements in implementation settings is critical to successfully scaling up PrEP.

Methods

The Sibanye Health Project:
 - One-year cohort study of MSM and transwomen in Cape Town, SA
 - HIV-negative, eligible participants were offered a combination HIV prevention package, including PrEP

PrEP adherence monitoring:
 - Participants on PrEP had visits one and two months after PrEP initiation, and every three months thereafter to identify suboptimal adherence and intervene with counseling
 - Collected self-reported missed doses in the last week and pill counts, used to assess adherence in real time
 - Dried blood spots (DBS) were collected, and tested for tenofovir concentrations. Tenofovir results were received in bulk and incorporated into counseling as available.

Analysis:
 - Compared identification of suboptimal adherence based on the three measures.
 - Receiver operating characteristic (ROC) curves to compare real-time measures of suboptimal adherence to the "gold standard" of tenofovir concentration

Comparisons of suboptimal adherence on PrEP using tenofovir blood concentrations, self-report, and pill counts
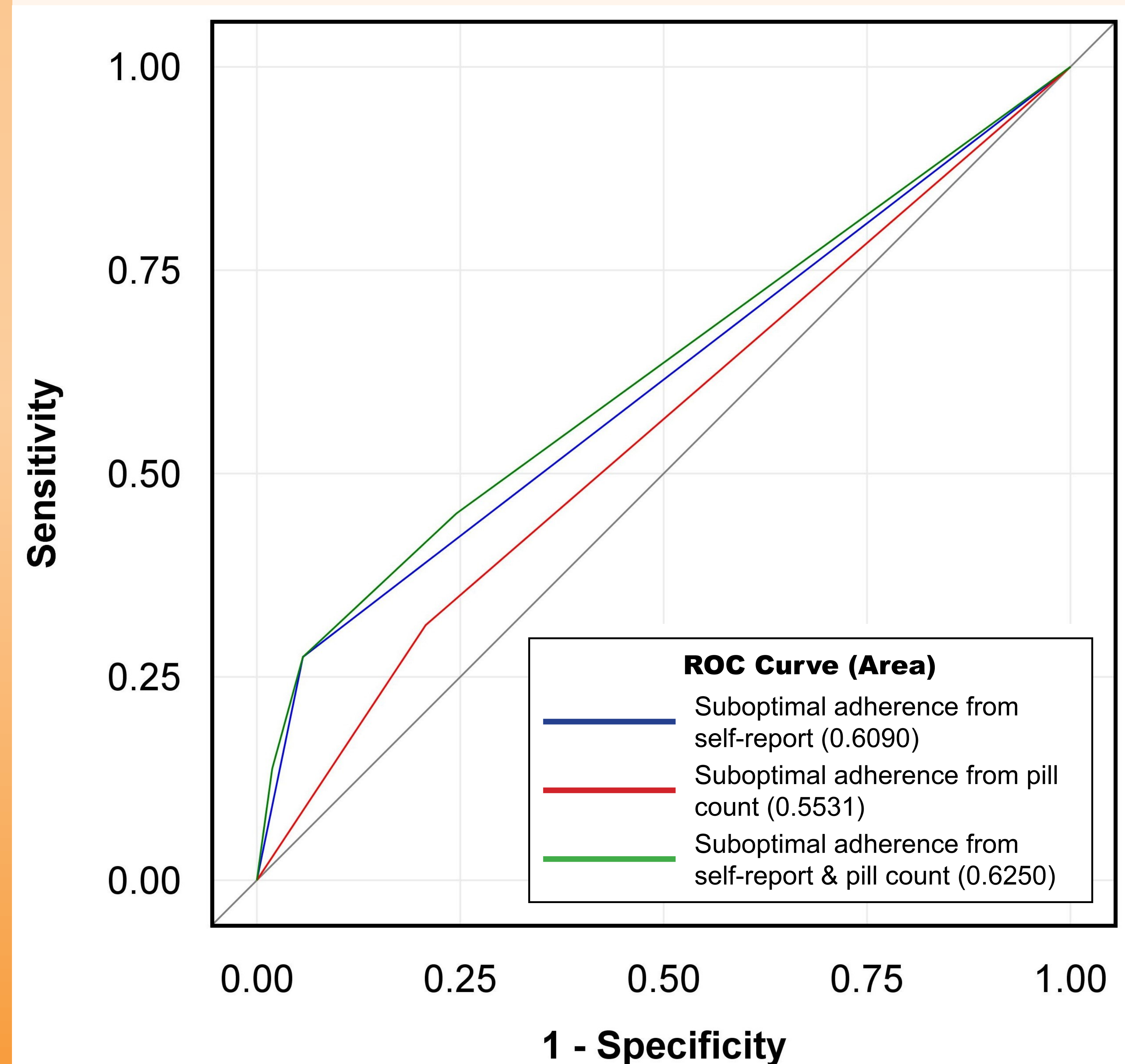
	Suboptimally adherent (tenofovir ≤ 40 ng/ml) n=48 patient-visits		Adherent (tenofovir > 40 ng/ml) n=53 patient-visits	
	n	%	n	%
Identified by self-report & pill count*	5	10%	40	75%
Identified by self-report only	6	13%	10	19%
Identified by pill count only	9	19%	2	4%
Identified by neither	28	58%	1	2%

*Suboptimal adherence defined via self-report as missing 3 or more pills in the last week and via pill count as having a raw adherence score based on pill count of less than 0.80 (pills dispensed-pills returned /days since last refill)

Results

Of 115 enrolled participants, 80 were HIV-uninfected, 60 were PrEP-eligible, and 45 initiated PrEP. Data on all three adherence measures were available for 40 participants during 101 patient-visits (Table). Self-report and pill counts have low sensitivity in identifying suboptimal adherence (Figure). Tenofovir concentrations identified 28 additional patient-visits requiring increased counseling.

Receiver operating characteristic (ROC) curves for detecting suboptimal adherence based on "gold standard" tenofovir blood concentrations

ROC Curve (Area)
- Suboptimal adherence from self-report (0.6090)
- Suboptimal adherence from pill count (0.5531)
- Suboptimal adherence from self-report & pill count (0.6250)

Conclusions

 - While viral load is an accepted measure of treatment adherence, there is limited consensus on appropriate PrEP adherence measures.
 - These data suggest that drug concentrations are useful in measuring PrEP adherence for MSM in South Africa, at least early after initiation.
 - In this setting of a comprehensive intervention program, self-report and pill count alone are likely not sufficient for identifying suboptimal adherence to PrEP
 - Tenofovir-diphosphate testing will be conducted to clarify the utility of biomedical measures.
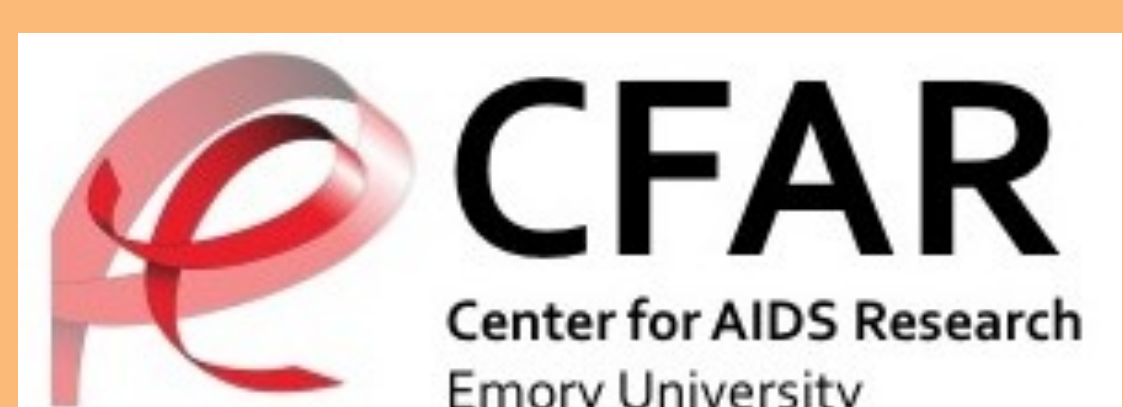
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