First HIV Viral Load Remains Strong Predictor of Treatment Success in South Africa

#4118

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BACKGROUND

> Globally, <50% of people living with HIV (PLHIV) are virally suppressed [1]

> World Health Organization (WHO) guidelines recommend routine viral load (VL) testing for ART monitoring [2]

> Point-of-care (POC) VL monitoring can improve viral suppression by providing real-time feedback to providers and patients [3]

> Even in the context of POC VL monitoring, patients still face challenges achieving viral suppression and staying retained in HIV care

- Aimed to assess risk factors associated with not achieving viral suppression and/or not being retained in HIV care

METHODS

> Simplifying HIV TREAtment and Monitoring (STREAM) trial was a randomized controlled trial in Durban, South Africa [4]

> 390 PLHIV who were clinically stable on ART for approximately 6 months were randomized to receive either:

- POC VL testing (Xpert HIV-1 VL, Cepheid, Sunnyvale, CA) with task-shifting to an enrolled nurse (n=195)
- Standard laboratory-based VL monitoring (n=195)



> Composite outcome 18 months after ART initiation: viral suppression (<200 copies/mL) and retained in care at the study clinic

> Estimated relative risks using modified Poisson models with robust standard errors to evaluate association between participant characteristics at study baseline and:

- Not achieving composite outcome
- 18-month VL ≥50 copies/mL

> Analyses were performed using SAS 9.4. Significant covariates ($p<0.3$ for Table 3, $p<0.2$ for Table 4) from the univariate analyses, plus study randomization arm, were included in the final adjusted models

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RESULTS

Table 1. Demographic and behavioral characteristics of STREAM participants at study baseline, N=390

	n (%)
Age – median [IQR]	32 [27-38]
Female gender	235 (60.3)
Did not pass secondary school	193 (49.5)
Does not report a regular/stable partner	79 (20.3)
Traveled ≤5 kilometers to the study clinic	86 (22.1)
Positive depression screen (PHQ-2)	37 (9.5)
High alcohol use (AUDIT C)	96 (24.6)
Current tobacco smoker	64 (16.4)
Any recreational drug use in previous six months	28 (7.2)

Table 2. Clinical characteristics of STREAM participants at study baseline, N=390

	n (%)
>12 months since HIV diagnosis	128 (32.8)
Missed 1 or more ART doses in last 4 days	74 (19.0)
HIV plasma viral load ≥200 copies/mL	27 (6.9)
CD4 count (cells/mL) – median [IQR]	N=389 468 [309-666]

> 17.2% (67/390) failed to achieve the composite outcome

> Baseline VL ≥200 copies/mL (aRR=3.82, $p<0.01$) and younger age (per 5-year decreases, aRR=1.18, $p=0.04$) were significantly associated with failure to achieve the composite outcome after adjusting for CD4 count at baseline, distance traveled to the study clinic, and study arm

> Among the 367 with a VL18 months after ART initiation, baseline VL ≥200 copies/mL (aRR=2.51, $p<0.01$) and lower CD4 count (per 100 cell/mL decreases, aRR=1.12, $p<0.01$) were significantly associated with detectable VL ≥50 copies/mL

Table 3. Baseline characteristics associated with failure to achieve the composite primary outcome of retention in care and viral suppression (<200 copies/mL) after 12 months of follow-up in the STREAM study, N=390

	Did not achieve primary outcome N (%)	Unadjusted RR [a] (95% CI)	p-value	Adjusted RR [b] (95% CI)	p-value
Study arm					
Laboratory-based VL (standard of care)	47 (24.1)	2.35 (1.45-3.81)	**<0.01**	2.49 (1.56-3.97)	**<0.01**
POC VL monitoring and task shifting (intervention)	20 (10.3)	REF	-	REF	-
Younger age (years) – median [IQR] [c]	31 [26-35]	1.15 (0.99-1.33)	**0.06**	1.18 (1.01-1.38)	0.04
Education					
Did not pass secondary school	36 (18.7)	1.19 (0.77-1.84)	0.45		
Passed secondary school	31 (15.7)	REF	-		
Regular or stable partner					
No partner	16 (20.3)	1.24 (0.75-2.05)	0.41		
Does report a partner	51 (16.4)	REF	-		
Travel distance to the study clinic					
≤5km	18 (20.9)	1.30 (0.80-2.11)	**0.29**	1.28 (0.80-2.05)	0.31
>5km	49 (16.1)	REF	-	REF	-
Self-reported ART adherence in past 4 days					
≥1 missed dose	15 (20.3)	1.23 (0.74-2.06)	0.43		
No missed doses	52 (16.5)	REF	-		
HIV plasma viral load [d]					
≥200 copies/mL	14 (51.9)	3.55 (2.29-5.52)	**<0.01**	3.82 (2.42-6.02)	**<0.01**
<200 copies/mL	53 (14.6)	REF	-	REF	-
Lower CD4 count (cells/mL)– median [IQR] [e,f]	436 [286-633]	1.05 (0.96-1.15)	**0.29**	1.02 (0.94-1.11)	0.64

[a] Female gender (RR=1.11, p=0.66), >12 months since HIV diagnosis (RR=1.14, p=0.56), current tobacco smoking (RR=1.23, p=0.46), positive depression screen (RR=0.94, p=0.87), high alcohol use (RR=1.13, p=0.64), and recreational drug use in previous six months (RR=1.04, p=0.92) were also assessed in univariate analyses. [b] Adjusted for age, distance traveled to study clinic, HIV viral load at study baseline, CD4 count at study baseline, and study randomization arm. [c] Age in univariate and multivariate analyses is per 5-year decreases. [d] Viral loads at enrollment measured per protocol by study arm. Laboratory measured via Abbott m2000 RealTime and POC measured via Cepheid Xpert HIV-1 viral load assay. [e] CD4 count in univariate and multivariate analyses is per 100 cell/mL decreases. [f] Missing 1 observation of CD4 count at study baseline.

Table 4. Baseline characteristics associated with viral load ≥50 copies/mL among participants with a viral load obtained after 12 months of follow-up in the STREAM study, N=367

	VL ≥50 at study exit N (%)	Unadjusted RR (95% CI)	p-value	Adjusted RR [a] (95% CI)	p-value
Study arm					
Standard of care	47 (26.4)	1.25 (0.86-1.80)	0.24	1.31 (0.93-1.86)	0.13
Intervention	40 (21.2)	REF	-	REF	-
Gender					
Female	44 (19.8)	0.67 (0.46-0.96)	**0.03**	0.78 (0.54-1.12)	0.18
Male	43 (29.7)	REF	-	REF	-
HIV viral load [b]					
≥200 copies/mL	15 (68.2)	3.27 (2.30-4.64)	**<.01**	2.51 (1.70-3.70)	**<.01**
<200 copies/mL	72 (20.9)	REF	-	REF	-
Lower CD4 count (cells/mL)– median [IQR] [c, d]	360 [263-501]	1.16 (1.07-1.26)	**<.01**	1.12 (1.03-1.21)	**<.01**

[a] Adjusted for gender, HIV viral load at study baseline, CD4 count at study baseline, and study randomization arm. [b] Viral loads at enrollment measured per protocol by study arm. [c] CD4 count in univariate and multivariate analyses is per 100 cell/mL decreases. [d] Missing 1 observation of CD4 count at study baseline.

CONCLUSIONS

> Six month VL after ART initiation strongly predicts poor HIV outcomes including viral suppression & retention in HIV care

> Identifying PLHIV with high VLs early & focusing on viral suppression should be a priority to improve health outcomes

> Using POC VL tests can serve as an important ART monitoring tool to target patients with persistent viremia, especially shortly after ART initiation

LIMITATIONS

> Participants were stable on ART for ~6 months at enrollment, so findings are not generalizable to those initiating ART

> Questionnaires were verbally administered by a research or clinic nurse, which may have resulted in under reporting of stigmatized behaviors

1. Joint United Nations Programme on HIV/AIDS (UNAIDS) 2018
2. World Health Organization 2016
3. Drain P et al. *Lancet HIV* 2020
4. Dorward J et al. *BMJ Open* 2017

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