Point-of-Care CD4 (Pima) Impact on Linkage to Care with Home-Based HIV Testing, Kenya

#632LB

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Background

Referral lab-based CD4 testing has been cited as a key barrier in the HIV care cascade, leading to delays in antiretroviral treatment (ART) initiation. Point-of-care (POC) CD4 testing has been demonstrated to improve linkage to care (LTC) among HIV-seropositive persons, but its impact has not been assessed with a randomized, controlled trial (RCT) in the context of home-based HIV counseling and testing (HBCT). We evaluated whether providing POC CD4 count, integrated with HBCT and referral for HIV care, would improve LTC and ART initiation when compared to standard-of-care (SOC) lab-based CD4 measurement.

Methods

RCT participants were enrolled July 2013-February 2014 in two rural districts of Western Kenya with an ongoing HBCT campaign. Compounds were randomized 1:1 to POC CD4 (Alere PIMA) or SOC CD4 testing at one of three referral labs. Participants in both arms received HBCT, post-test counseling, and referral for HIV care. All newly diagnosed HIV+ individuals and those not engaged in care in the prior six months were invited to participate. Intervention arm participants received additional counseling on the POC CD4 result, including their ART eligibility based on CD4 criteria at that time (<350cells/μL). Enrolled participants gave informed consent. Participants were interviewed six months after enrollment to ascertain whether and where they sought care, which was verified with charts at any of 23 clinics serving the study area. Verified LTC (a HIV clinic visit) was the primary outcome, with protocol-specified analysis of time to linkage and ART initiation comparing SOC to intervention using a Cox proportional hazards model. Predictors of linkage to care and ART initiation were identified using multivariate logistic regression in a Cox proportional hazards model.

Figure 1: Flow of HIV-infected study participants

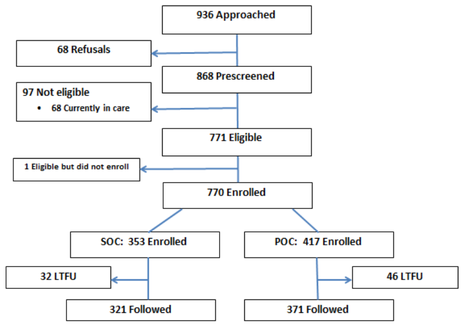


Table 1: Demographic characteristics by study arm at baseline

Variable	Overall (n = 692)	SOC (n = 321)	POC (n = 371)	p-value
Gender, n(%)				0.93
Male	235 (34.0)	108 (33.6)	127 (34.2)	
Female	457 (66.0)	213 (66.4)	244 (65.8)	
Age, n(%)				0.46
<18years	50 (7.2)	24 (7.5)	26 (7.0)	
18-24	92 (13.3)	49 (15.3)	43 (11.6)	
25-34	229 (33.1)	107 (33.3)	122 (32.9)	
35-80	321 (46.4)	141 (43.9)	180 (48.5)	
Education (Adults), n(%)				0.97
Primary	557 (87.3)	256 (87.1)	301 (87.5)	
Secondary	81 (12.7)	38 (12.9)	43 (12.5)	
Marital Status (Adults), n(%)				0.95
Married	433 (68.0)	198 (67.6)	235 (68.3)	
Single	49 (7.7)	22 (7.5)	27 (7.8)	
Other	155 (24.3)	73 (24.9)	82 (23.8)	
Employment (Adults), n(%)				0.14
No	172 (27.0)	88 (29.9)	84 (24.4)	
Yes	466 (73.0)	206 (70.1)	260 (75.6)	

Table 2: Primary outcome results: Linkage to care and ART status

Outcome	Overall (n=692)	SOC (n=321)	POC (n=371)	p-value
Linkage to Care, n (%)				<0.001
No	369 (53.3)	213 (66.4)	156 (42.0)	
Yes	323 (46.7)	108 (33.6)	215 (58.0)	
On ART, n(%)				0.01
No	596 (86.1)	288 (89.7)	308 (83.0)	
Yes	96 (13.9)	33 (10.3)	63 (17.0)	
On ART among Linked, n(%)				0.92
No	227 (70.3)	75 (69.4)	152 (70.7)	
Yes	96 (29.7)	33 (30.6)	63 (29.3)	

Results

Final results from 770 enrolled participants are presented here. Seventy-eight participants were lost to followup; 692 had LTC status verified by chart abstraction. Baseline characteristics including sex, age, education, marital and employment status were similar in the two arms (Table 1). Of 321 SOC participants, 108 (33.6%) had chart-verified LTC within six months after enrollment, whereas of 371 in the intervention arm, 215 (58.0%) were linked to care (Table 2). The risk ratio for linkage to care was 1.73 times higher in the POC arm (p<0.001). Overall, the risk ratio for ART Initiation overall was 1.65 times higher in the POC arm (p=0.01), but the ART initiation rate among the linked was similarly low (p=0.92) in both study arms,.

Kaplan-Meier analysis of time to LTC (Fig. 2) produced a log-rank p<0.0001 for the difference in proportions linked to HIV care in two arms, and revealed a significant, early and durable impact of POC CD4 testing compared to referral lab CD4 testing, on proportion linked to care after home-based HIV testing. Multivariate logistic regression on predictors of time to linkage to care (Table 3) produced Cox proportional hazard ratio of 2.14 (95%CI: 1.69-2.70).

Figure 2: Kaplan-Meier analysis of time to linkage to care

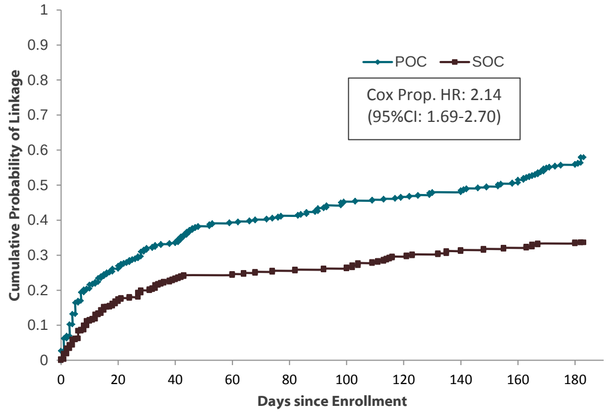


Table 3: Multivariate logistic regression on time to linkage to care

	Hazard Ratio (95%CI)	p-value
Study Arm		
SOC (ref)	-	-
POC	2.135 (1.688-2.700)	<0.001
Gender		
Male (ref)	-	-
Female	1.002 (0.775-0.297)	0.99
Age		
<18 (ref)	-	-
18-24	0.504 (0.273-0.932)	0.029
25-34	0.629 (0.343-1.153)	0.13
35-80	0.551 (0.294-1.034)	0.063
Education		
Primary (ref)	-	-
Secondary	1.174 (0.845-1.630)	0.34
Marital Status		
Married (ref)	-	-
Other	0.932 (0.699-1.243)	0.63
Single	0.756 (0.468-1.223)	0.25
Employment		
No (ref)	-	-
Yes	1.290 (0.993-1.675)	0.057

Discussion

Final results of the first RCT on the impact of POC CD4 testing in a resource-limited HBCT setting revealed significant improvements in rate of LTC and ART initiation. The effect of POC CD4 appears to be in primarily facilitating an earlier and higher rate of linkage to care but not in improving the rate of ART initiation after linkage to care occurs. More in-depth analyses on the time to linkage to care and ART initiation among the linked subpopulation by important clinical predictors such as CD4 count, and demographic factors are ongoing. The lack of availability of baseline CD4 count among the SOC arm participants is a limitation of our study. Nonetheless, our trial findings support further costing and cost-effectiveness analyses on incorporating POC CD4 in ongoing home- and community-based HIV outreach programs.

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