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Six month incidence of major adverse cardiovascular events among adults with HIV in northern Tanzania: a prospective observational study

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ABSTRACT

Objectives We aimed to prospectively describe incident cardiovascular events among people living with HIV (PLWH) in northern Tanzania. Secondary aims of this study were to understand non-communicable disease care-seeking behaviour and patient preferences for cardiovascular care and education.

Design A prospective observational study.

Setting This study was conducted at the Majengo HIV Care and Treatment Clinic, an outpatient government-funded clinic in Moshi, Tanzania

Participants Adult patients presenting to an HIV clinic for routine care in northern Tanzania were enrolled from 1 September 2020 to 1 March 2021.

Interventions At enrolment, participants completed a survey and a resting 12-lead ECG was obtained. At 6 month follow-up, a repeat survey regarding interim health events and repeat ECG was obtained.

Primary and secondary outcome measures Interim major adverse cardiovascular events (MACE) were defined by: self-reported interim stroke, self-reported hospitalisation for heart failure, self-reported interim myocardial infarction, interim myocardial infarction by ECG criteria (new pathologic Q waves in two contiguous leads) or death due to cardiovascular disease (CVD).

Results Of 500 enrolled participants, 477 (95.4%) completed 6 month follow-up and 3 (0.6%) died. Over the 6 month follow-up period, 11 MACE occurred (3 strokes, 6 myocardial infarctions, 1 heart failure hospitalisation and 1 cardiovascular death), resulting in an incidence rate of 4.58 MACE per 100 person-years. Of participants completing 6 month follow-up, 31 (6.5%) reported a new non-communicable disease diagnosis, including 23 (4.8%) with a new hypertension diagnosis.

Conclusions The incidence of MACE among PLWH in Tanzania is high. These findings are an important preliminary step in understanding the landscape of CVD among PLWH in Tanzania and highlight the need for interventions to reduce cardiovascular risk in this population.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ One of the first prospective studies of cardiovascular events among people with HIV in sub-Saharan Africa.
⇒ Only patients engaged in HIV care were enrolled, therefore findings may not reflect the incidence of major adverse cardiovascular events among those with undiagnosed or uncontrolled HIV.
⇒ We relied on patient self-report for stroke and heart failure hospitalisation, which may have resulted in inaccurate estimation of the event rate.
⇒ We used patient self-report and ECG criteria for interim myocardial infarction (MI), which have modest sensitivity and specificity for interim MI.
⇒ This study was conducted at a single centre, which limits generalisability.

INTRODUCTION

People living with HIV (PLWH) are at greater risk of developing cardiovascular disease (CVD) compared with people without HIV. HIV-associated inflammation and immune activation is thought to contribute to an approximately twofold increase in the risk of myocardial infarction (MI) in patients with HIV, compared with the general population.[1 2] In recent years, there have been an increasing number of studies on the importance of reducing CVDs among people with HIV in high-income countries.[3]

While it is well documented that PLWH in high-income settings have greater risk of CVD compared with people without HIV,[4 5] there is a paucity of data describing cardiovascular events among PLWH in sub-Saharan Africa (SSA). Indeed, a recent systematic review of the global burden of CVD among PLWH noted that there was much less published data describing CVD burden among PLWH from SSA specifically.[6] As PLWH in SSA are living

longer,[5] the prevalence of cardiovascular risk factors such as hypertension and diabetes among this population is increasing.[7 8] A recent systematic review of CVD among PLWH in SSA found that many studies have described the prevalence of CVD risk factors like hypertension,[9] which occurs in one of every four adults in Tanzania,[10] but few studies have reported the incidence of cardiovascular events such as MI and other major adverse cardiovascular events (MACE).

As the burden of cardiovascular risk factors among PLWH in SSA has grown,[11] a number of studies in the region have explored integration of non-communicable disease (NCD) care with HIV care.[12 13] In Tanzania, integrated HIV and NCD care is not currently standard of care, so PLWH typically receive care for HIV and NCDs in separate facilities.[7] Little is known about how Tanzanians with HIV currently seek CVD and NCD care in the current system or whether patients in Tanzania would be interested integrated care.

In this study, we aimed to prospectively describe incident CVD events among PLWH in northern Tanzania. Secondary aims of this study were to understand NCD care-seeking behaviour and patient preferences for CVD care and education. These aims will be essential for informing future clinical care, medical research and policy in the region.

METHODS

Setting and recruitment

This study was conducted at the Majengo HIV Care and Treatment Clinic (MCTC), an outpatient government-funded clinic in Moshi, Tanzania. MCTC serves a population of approximately 1200 PLWH (75% of whom are female)[14] and provides free HIV-related care. In 2014, the prevalence of hypertension and diabetes mellitus among the adult population in Moshi was 28% and 6%, respectively.[15 16] Currently, no screening for NCDs are provided at MCTC as part of routine care, similar to most HIV clinics in Tanzania; at MCTC, NCD care is provided at a separate clinic directly adjacent to MCTC. Recent qualitative research in Tanzania found that patients with HIV and their providers had positive attitudes towards integrating HIV and cardiovascular care but also revealed multiple barriers to cardiovascular care in the HIV clinic setting, including lack of provider training, high cost of care for cardiovascular risk factors such as hypertension for uninsured patients and lack of medications and supplies for cardiovascular care in the HIV clinic.[17 18] Although basic hypertension and diabetes care is fully covered by the national health insurance plan, only one-third of adults with HIV in northern Tanzania have health insurance.[19]

All adult patients (age≥18 years) who presented to MCTC for routine HIV care were eligible for enrolment, which took place from 1 September 2020 to 1 March 2021. There were no exclusion criteria. Trained research assistants approached patients at the clinic during check in to offer enrolment and obtain written informed consent. Screening and enrolment was conducted during normal HIV clinic hours (8 AM to 5 PM on Mondays, Wednesdays and Thursdays).

Patient and public involvement

Our research team in Tanzania is supported by a local Community Advisory Board (CAB) in Moshi, Tanzania. The CAB reviewed this study protocol and gave input prior to study initiation, and the research questions were developed with our clinician partners at MCTC and Kilimanjaro Christian Medical Centre. The results of this study were shared with the CAB and the MCTC staff and patients prior to formal publication.

Study procedures

Research assistants administered a standardised survey, based on the WHO STEPS tool for NCD risk factor surveillance,[20] to each participant. This survey gathered information on sociodemographic background, health status, preventative practices and medical history. Information regarding HIV care was collected from participants' medical records including date of initial diagnosis, viral load, CD4 count and current antiretroviral therapy. If CD4 count or HIV viral load was not available from the medical record, a blood sample was collected by a research clinical officer, and testing was performed at the Kilimanjaro Christian Research Institute Biotechnology Laboratory. Viral load assays were performed using the Abbott m2000 Reverse Transcriptase instrument (Abbott Laboratories, Chicago, Illinois) and CD4 count assays were performed using the BD FACSCount and BD FACSCalibur instruments (BD Biosciences, Franklin Lakes, New Jersey). At the time of initial enrollment, participant weight and height were measured. Additionally, a resting 12-lead ECG was obtained for all participants using the tablet-based PADECG (Edan Instruments, Shenzhen, China).

Six month follow-up

Participants were asked to return to MCTC 6 months after initial enrolment for a follow-up visit, and a repeat ECG was obtained at this visit. Participants also completed a survey about new medication use, new NCD diagnoses and any healthcare encounters within the preceding 6 months. These follow-up visits were scheduled to coincide with routine HIV clinic visits and reimbursement was provided for transportation. Participants were also asked several additional questions about their healthcare utilisation during the past 6 months, their interest in any further education about cardiovascular health and if they would prefer to obtain cardiovascular healthcare at the HIV clinic or a different facility. Participants who did not show-up for their follow-up visit were contacted via telephone to encourage follow-up. If participants were unreachable by telephone or did not present to clinic despite receiving a phone call, a research assistant visited their home in-person to encourage follow-up.

In cases of participant death and absence of an official recording of cause of death, a verbal autopsy was performed with a first-degree relative of the participant, using the WHO verbal autopsy instrument.[21] Verbal autopsies were performed 6 months following enrolment or whenever the study team learnt of the participant's death. Verbal autopsy data were reviewed by a committee of physicians and clinical officers from Tanzania and the USA to assign one of the following primary causes of death to each case: CVD, non-CVD and indeterminant. All disagreements among committee members were resolved by consensus.

ECG interpretation

Initial and 6 month ECGs were interpreted side-by-side and by two independent physician adjudicators. In accordance with guidelines from the Fourth Universal Definition of MI,[22] incident MI was defined by the presence of pathologic Q waves in at least two contiguous leads on follow-up ECG that were not present on baseline ECG. Participants with baseline Q waves were not excluded from the study, but only cases of new Q waves in a new distribution were counted as evidence of incident MI. In cases of disagreement among adjudicators regarding presence of interim MI, a third physician adjudicator served as a tiebreaker. Overall, agreement among physician adjudicators was excellent regarding interim MI (97.9% agreement).

Study definitions

Comorbidities such as hypertension and diabetes were defined by participant self-report. A sedentary lifestyle was determined, in accordance with WHO guidelines,[23] by participant self-report of <150 min of moderately vigorous exercise per week. Body mass index was calculated directly from baseline measured weight and height and categorised as underweight (<18.5 kg/m^2), healthy weight (18.5–24.9 kg/m^2), overweight (25.0–29.9 kg/m^2) or obese (≥30.0 kg/m^2).[24] Daily fruit and vegetable consumption was defined by participant self-report of eating any quantity of fruit or vegetables on a daily basis. Virologic suppression was defined as most recent viral load <200 copies/mL. MACE was defined by any of the following occurring between enrolment and follow-up: interim MI by ECG or self-report, self-report of interval stroke between initial enrolment and 6 month follow-up, self-report of hospitalisation for heart failure or death due to cardiovascular disease.

Statistical analysis

Statistical analyses were performed in R Suite (RStudio, V.2022.12.0+353). Continuous variables were presented as medians (IQR) and categorical variables were presented as proportions. Body mass index was calculated directly from measured height and weight. For purposes of MACE incidence calculation, only participants who completed 6 month follow-up or participants who died were included in the analysis. Participants who were lost to follow-up were excluded from the analysis. Six month incidence rate was calculated by dividing the number of observed MACE by the number of participants who died or completed 6 month follow-up. The 6 month incidence rate was then multiplied by 200 (2 x 100) to report an incidence rate in units of MACE per 100 person-years. Sensitivity analyses were also performed to determine the incidence rate if all or none of those lost to follow-up had a MACE outcome. Sample size calculations for this study have been reported elsewhere.[25]

Ethics

This study was approved by ethical review committees at the Tanzania National Institute for Medical Research, Kilimanjaro Christian Medical Centre and Duke Health. Research assistants obtained written informed consent from all patients prior to enrollment.

RESULTS

Selection of participants

Of 501 MCTC patients who were approached for study inclusion, 500 (99.8%) consented to participate and were enrolled. Of enrolled participants, 477 (95.4%) completed 6 month follow-up and 3 (0.6%) died during the 6 month follow-up period and verbal autopsies were performed. Twenty participants (4.0%) were lost to follow-up and were excluded from the final analysis (figure 1).

Patient characteristics

The baseline characteristics of study participants are summarised in table 1. The median (IQR) age of participants was 45 (38, 52) years and 361 (72.2%) identified as female. Hypertension was the most common self-reported comorbidity (n=57, 11.4%), and no patients self-reported a history of prior MI. The majority of participants reported a history of alcohol use (n=392, 78.2%) and about half reported current alcohol use (n=244, 48.8%). Fewer participants reported a history of tobacco use (n=123, 24.6%) or current tobacco use (n=49, 9.8%).

Cardiac events

Six months following enrolment, 20 (4%) of participants were lost to follow-up and were excluded from the analysis. Of the remaining 480 participants, 3 (0.6%) had died and 477 (99.4%) were alive at 6 months. A summary of MACE among participants is presented in table 2. In total, 11 (2.3%) participants experienced a MACE during the 6 month follow-up period, corresponding to an incidence rate of 4.58 MACE per 100 person-years: 6 (1.25%) participants had evidence of interim MI on ECG, 3 (0.6%) participants reported an interim stroke, 1 (0.2%) participant reported a hospitalisation for heart failure during the follow-up period, and of the three participant deaths, 1 (0.2%) was deemed due to a MACE by the adjudication committee. Of the three cases of interim stroke, two occurred in participants without

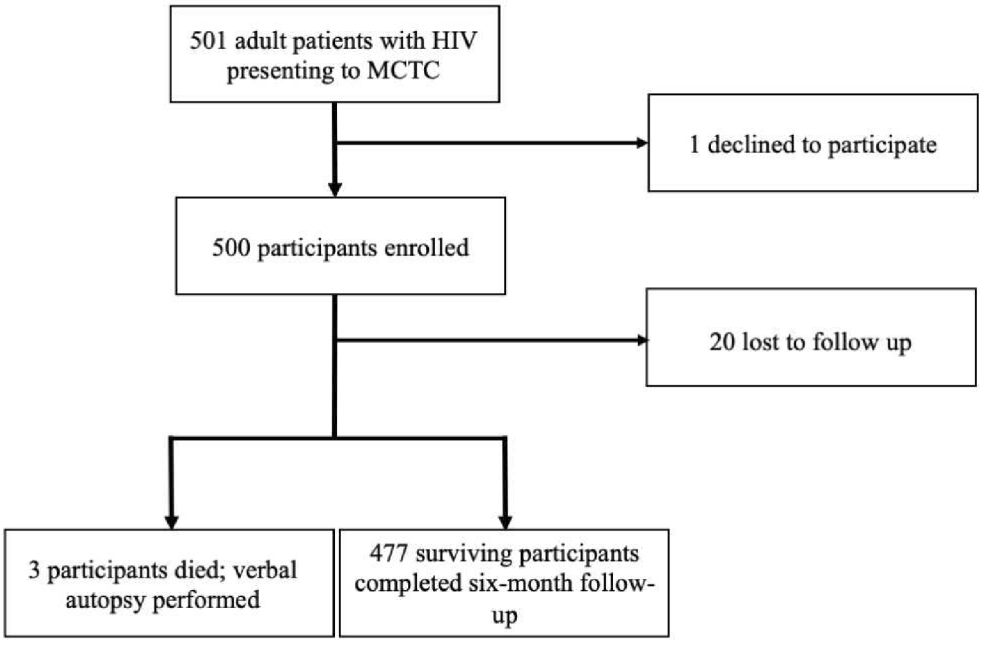

Figure 1 Study participant flow diagram.

prior history of stroke. The single participant who was hospitalised for heart failure did not have a known history of heart failure prior to hospitalisation. No participant experienced multiple MACE outcomes during the follow-up period.

Sensitivity analyses

Assuming all 20 participants lost to follow-up had a MACE outcome would yield an incidence rate of 12.40 MACE per 100 person-years. Conversely, assuming none of the lost patients had a MACE outcome would yield an incidence rate of 4.40 MACE per 100 person-years.

Table 3 presents healthcare seeking behaviour and preferences for cardiovascular care among the 477 participants who completed the 6 month follow-up visit. Of these, 97 (20.3%) reported receiving a new medication prescription during the 6 month follow-up period; the most common newly prescribed medication was an antibacterial (n=39, 8.2%). Four (0.9%) reported receiving a new prescription for an antihypertensive medication during the 6 month follow-up period. Thirty-one (6.5%) participants reported being diagnosed with a new NCD during the 6 month follow-up period, including 23 (4.8%) with a new diagnosis of hypertension. Most participants (n=320, 67.1%) reported owning a personal non-smartphone; 35 (7.3%) reported no mobile phone access. Nearly all participants (n=469, 98.3%) reported an interest in receiving education about ways to improve one's cardiovascular health; the most-preferred method of education was pamphlets (n=223, 46.8%). The majority of participants (n=362, 75.7%) preferred receiving outpatient cardiovascular care at their HIV clinic, rather than in another facility.

DISCUSSION

This study is among the first to prospectively describe MACE among PLWH in SSA, which is critical to address the paucity of data describing cardiovascular events in this population. Our study found a relatively high incidence of MACE over a brief 6 month follow-up period. Furthermore, we found that participants had a strong desire for more cardiovascular health education and preferred integration of NCD and HIV care in a single facility. Together, these findings call attention to the need for better CVD screening, treatment and education among PLWH in Tanzania.

The incidence of MACE we observed among PLWH in Tanzania is higher than what has been reported in studies conducted in high-income and middle-income settings outside of SSA (0.32–1.11 events per 100 person-years among PLWH in North America, Europe and Asia).[1 26–29] In these comparative studies from higher income settings, the median age of participants was similar, but the prevalence of diagnosed hypertension and diabetes was higher.[1 26–29] Our study population also had a higher prevalence of alcohol use and obesity than participants with HIV in the comparative studies from other settings.[1 26–29] The substantially higher incidence of MACE in our study could be due to a multitude of reasons, including higher rates of undiagnosed and uncontrolled cardiovascular risk factors like hypertension and diabetes,[7 19] higher prevalence of obesity (among PLWH),[30] widespread use of integrase inhibitor-based regimens (which have been associated with increased risk for MACE),[31] unmeasured genetic risk factors, socioeconomic factors and access to care. Prior studies from Tanzania demonstrated a high burden of undiagnosed and untreated NCDs such as hypertension and diabetes among PLWH.[7 19] Another

Table 1 Characteristics of participants presenting for routine HIV care, northern Tanzania, 2020–2021 (n=500)

Characteristics	n	%
Female sex	361	72.2
Age, median, years	45	IQR: 38–52
Self-reported comorbidities	68	13.6
Hypertension	57	11.4
Diabetes	9	1.8
Hyperlipidaemia	0	0
Prior MI	0	0
Prior stroke	5	1.0
Heart failure	1	0.2
Highest level of education		
None	30	6.0
Primary	351	70.2
Secondary	92	18.4
University	27	5.4
Sedentary lifestyle	337	67.4
Body mass index		
Underweight (18.5 kg/m^2)	24	4.8
Healthy weight (18.5–24.9 kg/m^2)	245	49.0
Overweight (25.0–29.9 kg/m^2)	131	26.2
Obese (30.0 kg/m^2)	98	19.6
Daily fruit consumption	101	20.2
Daily vegetable consumption	124	24.8
History of tobacco use	123	24.6
Current tobacco use	49	9.8
History of alcohol use	391	78.2
Current alcohol use	244	48.8
Current antiretroviral therapy		
TDF/lamivudine/dolutegravir	471	94.2
Other	27	5.4
None	1	0.2
HIV virologic suppression* (<200 copies/mL)	476	95.6
Years since HIV diagnosis, median, years	4	IQR: 2–9
Most recent CD4 count, median, cells/mm^3	460	IQR: 290–638

*Viral load data were missing for two participants; virologic suppression defined by most recent recorded viral load (within the past 12 months).
MI, myocardial infarction; TDF, tenofovir disoproxil fumarate.

potential explanation for the substantially higher incidence of MACE observed in our study may be our reliance on ECG criteria to identify interim MI. Although the presence of new Q waves on a resting 12-lead ECG is highly suggestive of interim MI, this finding is neither extremely sensitive nor specific for MI (with sensitivity 66%–90% and specificity 85%–90%).[32 33] Nonetheless, the high incidence of MACE observed in our study necessitates additional studies in SSA, and interventions to reduce cardiovascular risk among this population with enhanced education, screening and treatment of CVD risk factors. Importantly, to the best of our knowledge,

Table 2 Summary of major adverse cardiovascular events among participants during 6 month follow-up period (n=480)

Cardiovascular event	n	%
Interim MI by ECG	6	1.3
Self-reported interim MI	0	0.0
Self-reported stroke	3	0.6
Self-reported hospitalisation for heart failure	1	0.2
CVD death	1	0.2
Total events	11	2.3

CVD, cardiovascular disease; MI, myocardial infarction.

Table 3 Healthcare-seeking behaviour and preferences for cardiovascular care among Tanzanians with HIV surviving to 6 month follow-up, northern Tanzania, (n=477)

Variable	n	%
New non-communicable diagnoses during 6 month follow-up period (self-reported)	31	6.5
Hypertension	23	4.8
Diabetes	12	2.5
Heart failure	1	0.2
Mobile phone access		
Personal smart phone	109	22.9
Personal non-smart phone	320	67.1
Shared smart phone	4	0.8
Shared non-smart phone	9	1.9
None	35	7.3
Interested in receiving education about how to improve cardiovascular health	469	98.3
Preferred method of cardiovascular health education		
Pamphlet	223	46.8
Private face-to-face counselling	126	26.4
Counselling via phone call	123	25.8
SMS messages	100	21.0
Group sessions	89	18.7
Preferred location for outpatient cardiovascular care		
HIV clinic	362	75.7
Other facility	95	19.9
Not sure	20	4.2

SMS, short message service.

there are currently no published data regarding the incidence of MACE among adults without HIV in Tanzania, so it is unknown how the incidence of MACE observed among PLWH in our study compares to the general population.

Our follow-up survey data illuminated other opportunities to potentially improve cardiovascular risk factor management among PLWH. Specifically, our findings demonstrated a need for regular screening of hypertension, diabetes and heart disease among PLWH. Of our participants, 6.5% were diagnosed with new hypertension, diabetes or heart failure by another provider during the relatively brief 6 month follow-up period. This finding suggests that regular screening for comorbidities among this population in the HIV clinic would be beneficial for early identification and treatment of NCD comorbidities. Additionally, most participants agreed with integrated NCD and HIV care, a model that has been evaluated in other settings in SSA and has generally been found to be feasible,[12 34] and accepted by patients. However, integrated care is not yet standard of care in Tanzania.[12 34 35] Further studies are needed in Tanzania to determine if integrated NCD care improves health outcomes among PLWH.

We also found that most participants desired more education about CVD. Prior studies from Tanzania and elsewhere in SSA have found that adults engaged in HIV care tend to have limited knowledge of CVD and poor understanding of CVD risk factors.[6 14 36 37] Among our participants there was little consensus about which educational strategy would be most desirable.[38] There have been few studies on effective educational interventions regarding cardiovascular health among PLWH in SSA.[37 39] A small pilot study found that an educational intervention on hypertension delivered by a community health worker was feasible and acceptable among Tanzanians with HIV and comorbid hypertension,[40] but larger studies are needed to evaluate the effect of such strategies on disease control and risk reduction. Although telephone-based educational interventions have been studied in the general population in SSA,[41–43] most of our participants did not have access to a smart phone, and only 21% expressed interested in short message service-based education. Given the lack of consensus regarding preferred educational modalities in our cohort, an educational strategy offering multiple approaches may be necessary for maximal impact in Tanzania.

This study has several limitations. First, only patients engaged in HIV care were enrolled and therefore our findings may not reflect the incidence of MACE among those with undiagnosed or uncontrolled HIV. Men with HIV, who are much less likely to be engaged with HIV care,[44] were under-represented in our study, which may have biased our results. Second, we relied on patient self-report for stroke and heart failure hospitalisation, which may have resulted in inaccurate estimation of the event rate due to recall bias. Additionally, as discussed above, diagnosis of interim MI based on ECG criteria of newly developed Q waves without other confirmatory tests such as coronary angiography or cardiac magnetic resonanace imaging likely had limited accuracy;[45] such testing is currently unavailable in northern Tanzania. Although MI was defined by a composite of ECG criteria and self-report, no participants in our study self-reported an interim MI. Prior study has demonstrated that MI is substantially underdiagnosed in northern Tanzania;[46] therefore, partial reliance on self-report likely resulted in underestimation of interim MI. Third, the follow-up period for this study was relatively short; future studies with longer follow-up periods are needed to confirm our estimates of MACE incidence. Additionally, as discussed above, we used ECG criteria for interim MI, which have modest sensitivity and specificity for interim MI. More advanced modalities, such as echocardiography, coronary angiography, cardiac biomarkers such as troponins and cardiac MRI, might have provided a more accurate estimate, however such testing is currently unavailable in northern Tanzania. Furthermore, a small number of participants were lost to follow-up, which may have biased our incidence calculations. However, as our sensitivity analyses demonstrate, even if none of those lost to follow-up had a MACE outcome, the overall conclusion of our study would be remain the same: the MACE rate among PLWH in Tanzania is quite high and substantially greater than what has been reported among PLWH in high-income settings. Finally, we relied on participant self-report for their interest in cardiovascular health education and integration of care, and therefore their responses may have been subject to social desirability bias.

In conclusion, this study is among the first to report the incidence of MACE among PLWH in SSA. Our findings reveal a high incidence of MACE among adults engaged in HIV care in Tanzania. Furthermore, we found that multimodal education about cardiovascular health is an unmet need and that there is strong interest in integrated HIV and NCD care among this population. These findings are an important preliminary step in understanding the landscape of CVD among PLWH in Tanzania and highlight the need for interventions to reduce cardiovascular risk in this population.

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Contributors KS analysed the data, conducted data quality assurance and edited the manuscript. PO wrote the manuscript and edited the manuscript. FMS conceptualised the study, supervised data collection, conducted data quality assurance and edited the manuscript. JSF enrolled participants, collected data and contributed to the manuscript editing. BM conceptualised the study, supervised data collection and edited the manuscript. BB, KG, LAC, AR, and AG all contributed to manuscript editing, PM helped develop the study methodology assisted with data analysis and manuscript writing. GSB conceptualised the study and contributed to manuscript editing. JTH conceptualised the study, developed the study methodology, contributed to data analysis, EGC interpretation, study supervision, manuscript writing and obtained funding for this study. JTH is the guarantor of the study, accepting full responsibility for the work.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Consent obtained directly from patient(s).

Ethics approval This study involves human participants. This study was approved by ethical review committees at the Tanzania National Institute for Medical Research (NIMR/HQ/R.8a/Vol IX/3437), Kilimanjaro Christian Medical Centre (Proposal No. 893) and Duke Health (Pro00090902). Research assistants obtained written informed consent from all patients prior to enrolment. Participants gave informed consent to participate in the study before taking part.

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Data availability statement Data are available upon reasonable request. The data sets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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