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Viral suppression following same-day initiation antiretroviral therapy among persons aware of their classification as recent or long-term infected with HIV per recent infection testing algorithm, Rwanda 2021–2022

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Abstract

Awareness of classification as recent or long-term HIV-infected, could potentially influence behavior that leads to differential ART outcomes. We examined whether persons aware of classification of their HIV infection as recent were more or less likely to initiate same-day antiretroviral therapy (ART) and have viral load suppression (VLS) 6-month post-ART initiation, compared to persons aware of classification of their HIV infection as long-term in a cohort of 1,238 adults newly diagnosed with HIV from August 2021 to October 2022 in Rwanda. All persons received a rapid test for recent infection (RTRI) at baseline and viral load (VL) testing at baseline and at follow-up (approximately 6-months post-ART initiation). Per study protocol recent infection testing algorithm (RITA), HIV infection was classified as RITA-recent (RTRI-recent and baseline VL $\geq$ 1000 copies/mL) or RITA-long-term (RTRI-long-term and baseline VL

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≥1000) and recency test results were returned per national guidelines; persons with baseline VL<1000 copies/mL were presumed previously diagnosed and on ART and excluded. Data were abstracted from Rwanda's case surveillance system. We calculated the proportion of persons with follow-up VLS (<1000 copies/mL). We estimated Risk Ratios (RRs) for follow-up VLS. Nearly all (99.6%) persons initiated same-day ART. Follow-up VLS did not differ between persons aware of classification of their HIV infection as RITA-recent (94%) versus RITA-long-term (94%). Awareness of RITA classification was not associated with follow-up VLS (RR=1.01 [95% confidence interval: 0.96–1.06]). In this setting where persons were aware of RITA-classification, the vast majority initiated same-day ART and achieved follow-up VLS, regardless of RITA-recent or -long-term infection.

Keywords

HIV recent infection; antiretroviral therapy; viral load suppression; Rwanda

BACKGROUND

Worldwide many countries have made substantial progress towards meeting Joint United Nations Programme on HIV/AIDS (UNAIDS) targets of 95% of people living with HIV knowing their status, 95% of people with known HIV status initiating antiretroviral therapy (ART), and 95% of persons on antiretroviral therapy with suppressed HIV viral load (VL). (1) Despite this progress, we observed ongoing HIV transmission with an estimated 1.3 million new HIV infections globally(1), but with effective and timely HIV case-finding, persons can be diagnosed and treated soon after HIV infection.

A recent infection testing algorithm (RITA) is a biomarker-based approach used among persons newly diagnosed to classify their HIV infection as either recent or long-term.(2) RITA includes a recency assay that measures a person's antibody avidity (or binding strength), which typically increases with time following seroconversion and classifies them as either recently or long-term infected based on a threshold value.(3, 4) The duration of infection for persons whose HIV infection was classified as recent varies across individuals and by type of recency assay used, but the mean for the currently commercially available Asante Rapid Recency assay (Sedia Biosciences, Beaverton, OR) is approximately 6 months and the maximum is 12 months.(5) Currently recency assays are used primarily in population surveys or studies to estimate HIV incidence and in clinical program-based surveillance to understand trends in recent infections among the population of persons newly diagnosed with HIV through routine testing programs.(2) These data provide opportunities to understand potential differences between persons with HIV infection classified by RITA as recent compared to persons with HIV infection classified by RITA as long-term.

One analysis of surveillance data on persons newly diagnosed with HIV from March to August 2021 in Zambia reported no statistical difference in baseline VL between persons with HIV infection classified as RITA-recent versus RITA-long-term.(6) To our knowledge, there are no studies to date examining differences in longitudinal outcomes following HIV

diagnosis (or enrollment) such as ART initiation or subsequent post-ART viral suppression, between persons with HIV infection classified as RITA-recent and RITA-long-term.

Global guidance recommends not returning RITA results to clients or providers, since these results are intended to be used for surveillance and not for clinical management.(2) Some countries, such as Rwanda, continue to return recent infection testing results as required by national guidelines. Client awareness of RITA classification status from return of results to clients could impact behavior. Similarly, client-perceived or clinician-disclosed stage of HIV infection based on symptoms or overall clinical status could impact behavior. Persons with HIV infection classified as RITA-recent (and in earlier stage of infection) may not feel the same urgency or imperativeness to start and stay on ART and may modify their behavior accordingly.(7–11) Alternatively, they may feel increased motivation for ART, as they may perceive that their HIV infection was diagnosed early, and the probability of successful treatment is high.(12)

To explore this hypothesis that client awareness of RITA classification may affect ART-related behavior and subsequent viral suppression, we examined ART initiation and post-ART viral suppression at 6-months among a cohort of persons in Rwanda who were newly diagnosed with HIV, had HIV infection classified by RITA as recent or long-term and were aware of their RITA results.

METHODS

The Rwanda HIV Recency Evaluation Study was conducted from August 2021 to October 2022 and enrolled all adults (≥ 15 years) newly diagnosed with HIV and consenting to participate in HIV case surveillance and recent infection surveillance across 60 health facilities. Health facilities were sampled across all five provinces in Rwanda using probability sampling proportional to the number of infections classified as RITA-recent during the preceding two years. Additional consent was obtained for study specific interviews, use of biomarker testing results, and abstraction of data from HIV case surveillance and electronic medical records at baseline (time of diagnosis) and monthly through 6 months follow-up. At HIV diagnosis, all participants underwent a rapid test for recent infection (RTRI) with the Asante Rapid Recency assay (Sedia Biosciences, Beaverton, OR), which is routinely done as a part of recent infection surveillance in Rwanda and a baseline VL measurement which is not routinely done as a part of program or surveillance in Rwanda but was additionally done under the study protocol. Per a study-specific RITA, a person's HIV infection was classified as RITA-recent (RTRI-recent and baseline VL ≥ 1000 copies/mL) or RITA-long-term (RTRI-long-term and baseline VL ≥ 1000 copies/mL); persons with a baseline VL < 1000 copies/mL were presumed previously diagnosed and on ART and were excluded from analyses. RITA results were returned to persons per Rwanda national guidelines. The study was reviewed and approved by institutional review boards at the Rwanda National Ethics Committee, and the Columbia University Medical Center.¹

¹§ See 45 C.F.R. part 46.101(c); 21 C.F.R. part 56

We limited our analysis to participants who were newly diagnosed (VL ≥ 1000 copies/mL), initiated ART, and had a follow-up VL result. Per Rwanda national guidelines, all persons initiating ART should have a follow-up VL done by approximately 6-months post-ART initiation. We included the first VL result post-ART initiation as the 6-month VL. We calculated the median and interquartile range of time from ART initiation to follow-up VL. As the primary outcome, we calculated the proportion of persons with VL suppression (VLS) (< 1000 copies/mL) based on the 6-month VL. The median and interquartile VL were calculated for persons with unsuppressed VL (≥ 1000 copies/mL) at follow-up. All analyses are presented overall, and by the primary exposure variable, categorized as either RITA-recent (a person whose infection is classified on RITA as recent) or RITA-long-term (a person whose infection is classified on RITA as long-term). Other variables of interest included age, categorized using a cut-point of 30 years; World Health Organization (WHO) HIV clinical stage classification; baseline VL (which by definition was ≥ 1000 copies/mL for all persons in the cohort), categorized using a cut-point of $4.0 \log_{10}$ copies/mL which was selected based on the median value in the cohort; initial ART regimen; employment status; sex; pregnancy status; and marital status.

Bivariate statistical analysis was conducted to understand differences in covariates of interest that may impact viral suppression status at 6-months follow-up between persons with HIV infection classified as RITA-recent and RITA-long-term. Kruskal-Wallis rank sum tests were used to assess differences in the medians for continuous covariates. Chi-squared or Fisher's exact test (if the number in any cells was ≤ 5) was used to assess differences in proportions for categorical variables, respectively. A threshold of < 0.05 for alpha was used to determine statistically significant differences. Poisson regression models with robust variance estimators were used to estimate risk ratios (RRs) with 95% confidence intervals (CIs) for the primary outcome of VLS during follow-up. We created a separate model for each exposure variable and assessed other covariates as potential confounders to adjust for in the model. We examined RITA-classification as the primary exposure of interest. We examined WHO clinical stage, baseline VL, ART regimen, employment status, marital status, sex, and age separately as secondary exposures of interest. For variable selection for each of these models, we used a backwards elimination process that accounted for the change in the estimate of our exposure by sequentially assessing covariates with least statistical significance first. In assessing each covariate, if dropping it from the model did not result in $> 10\%$ change in estimate of the RR between the exposure and outcome, the covariate was eliminated from the model. In all models, all covariates that were assessed as potential confounders were eliminated, leaving only the exposure; age, sex, baseline VL, and ART regimen were empirically added back in and adjusted for in all models. Pregnancy status was not included in this modeling process as it was colinear with sex. Analyses were conducted using SAS version 9.4 (SAS Institute, Cary, NC) and statistical packages in R version 4.3.1 (R Core Team, 2024).

RESULTS

Among 1,238 persons newly diagnosed with HIV (VL ≥ 1000 copies/mL), nearly all (99.6%) initiated ART (Figure 1). Among these persons who initiated ART, 29 (2.4%) were documented to have died before having a follow-up VL test; of these, all were RITA-long

term. Additionally, 153 (12.4%) persons without documented death did not have a follow up VL test; of these, 142 (92.8%) were RITA-long-term. We included the remaining 1,051 persons who were newly diagnosed with HIV, initiated ART, and had a follow-up VL, in our analysis.

The median age was 31 years (IQR: 26–38). The proportion of younger persons (age <30 years) was 40% overall, and higher among those RITA-recent (56%) compared to those RITA-long-term (38%) ($p=0.001$). The overall proportion female was 65%, and higher among those RITA-recent (78%) compared to those RITA-long-term (64%) ($p=0.01$). Among female participants, 29% were pregnant at baseline with no significant difference among those RITA-recent and those RITA-long term. Over half of persons self-reported being married or cohabiting with a partner (52%), and marital status did not differ by RITA-classification. Median time to ART initiation after HIV diagnosis was 0 days (same day ART initiation) overall, and among those RITA-recent versus RITA-long-term. Nearly all persons (96%) were prescribed TDF+3TC+DTG as their ART regimen. Median VL at baseline was 4.4 log₁₀ copies/mL overall, and among those RITA-recent and RITA-long term (Table 1).

The proportion with viral suppression during follow-up was 94% overall, and (the same) among those RITA-recent and those RITA-long-term (Figure 2). Median time from ART initiation to follow-up VL was 6.0 months (IQR: 5.8–6.4 months). Among those with unsuppressed VL ($n = 66$), the distribution of VL and change from baseline in VL at follow-up by RITA-classification is displayed in Figure 3. Median VL at follow-up was 4.3 log₁₀ copies/mL (IQR: 3.6–4.9 log₁₀ copies/mL) and did not differ ($p=0.4$) between those RITA-recent (4.0 log₁₀ copies/mL [IQR: 3.8–4.0 log₁₀ copies/mL]) and those RITA-long-term (4.4 log₁₀ copies/mL [IQR: 3.6–5.0 log₁₀ copies/mL]). Median change (from baseline) in VL among those unsuppressed at follow-up was -0.2 log₁₀ copies/mL (IQR: -1.2 – 0.5 log₁₀ copies/mL) and did not differ ($p=0.67$) between those RITA-recent (-0.5 log₁₀ copies/mL [IQR: -1.0 – 0.2 log₁₀ copies/mL]) and those RITA-long-term (-0.2 log₁₀ copies/mL [IQR: -1.2 – 0.5 log₁₀ copies/mL]).

RITA-classification was not associated with viral suppression during a six-month follow-up period (RR=1.01 [95% CI: 0.96–1.06]). Being less than 30 years (RR=0.95 [95% CI: 0.92–0.99]) was associated with being less likely to be virally suppressed during follow-up; baseline VL < 4 log₁₀ copies/mL was associated with being more likely to be virally suppressed during follow-up (RR=1.04 [95% CI: 1.01–1.07]). No other variables were significantly associated with viral suppression during follow-up (Figure 4).

DISCUSSION:

In this study of 1,238 persons newly diagnosed with HIV whose infection was classified by RITA as recent or long-term infected and had their recency results returned to them, nearly all (99.6%) initiated same-day ART. Similar to what has been reported from other studies and routine surveillance data, those RITA-recent were predominately younger and female and may reflect higher risk for HIV acquisition and/or enhanced case-finding HIV efforts in these sub-populations.(13–15) Of note, baseline VL did not differ between those

RITA-recent and those RITA-long-term, which is similar to what has been reported from Zambia.(6) Among those with documented follow-up VL results post-ART initiation (85%), viral suppression was high overall (94%) in this cohort, and among those RITA-recent (94%) or those RITA-long-term (94%); likely contributed to by near-universal same-day ART initiation. Among those with a non-suppressed VL during follow-up, median VL (and change in VL from baseline) did not differ by RITA classification status. Other than baseline VL, the only variable associated with viral suppression during follow-up was age, with those <30 years being less likely to suppress, which is consistent with other studies (16); however, the magnitude and strength of association was relatively small.

The proportion of persons initiating same-day ART in our study was comparable or higher than what has been reported in the literature from studies in Rwanda and other countries and did not vary by RITA classification status. In a study of 2,542 persons living with HIV enrolling in care at 10 facilities in Kigali, Rwanda between July 1, 2016 and December 31, 2018, 860 (34%) initiated same-day ART.(17) In recent studies from other countries the proportion varied: 98.1% in a study in Blantyre, Malawi from 2018–2021(18), 64% in a study of International epidemiology Databases to Evaluate AIDS (IeDEA) sites in sub-Saharan Africa from country-specific Treat-All adoption dates to January 2019(19), and 66% in KwaZulu-Natal, South Africa from June to November 2020 (20). In the Rwandan setting where RITA results are returned to clients, RITA classification status was not associated with time to ART initiation, and suggesting that knowledge of recent infection status by clients or providers does not impact willingness to initiate ART. These findings are encouraging and demonstrate that it is programmatically feasible to have same-day ART initiation (per national and global guidance) in nearly all newly diagnosed clients.

Similarly, VLS in our study population was comparable or higher than those previously described from Rwanda and other countries (and nearly at the 95% UNAIDS target) and did not vary by RITA classification. Globally, UNAIDS estimates that 93% of all persons on ART are virally suppressed.(1) In a study of 10,200 persons living with HIV on ART in 10 facilities in Rwanda, 91% had viral suppression, based on their most recent VL test result within the preceding year.(21) In our study, the proportion virally suppressed, as well as the median VL and change in VL from baseline among the subset unsuppressed, did not vary by RITA status, suggesting that with timely and effective ART, it is feasible for persons to suppress virus at 6-months, regardless of whether their HIV infection was classified as recent or long-term. Furthermore, this suggests that client awareness of RITA-recent or RITA-long-term infection classification may not influence behavior that would result in any differences in 6-month VLS.

There are at least three limitations to consider in our study that should be considered when interpreting the findings. First, we limited our analysis to the subset of persons alive and with a documented VL at 6-months follow-up. There is some potential bias in this approach, as persons who did not have a VL test done or documented may have been less likely to be virally suppressed. If we recalculated viral suppression at 6 months among all persons initiating ART (and assume that all persons who did not have a VL done were unsuppressed), viral suppression would be 79.9% overall and not statistically different ($p=0.36$) between those RITA-recent (83.7%) and those RITA-long term (79.6%).

We created and compared Table 1 for persons missing VL (not presented), with Table 1 for the overall cohort included in our analysis, which suggests that missingness of VL was non-differential across the baseline demographic and clinical variables we captured in our study. Additionally, the study follow-up period was limited and did not allow us to analyze potential differences in longer term ART outcomes beyond 6-months. Second, we were limited to clients enrolled in and data routinely captured through HIV case surveillance and electronic medical records. Therefore, we could not account for all potential variables that could be associated with HIV VL, which may have resulted in residual confounding. Additionally, we were limited to the number of clients newly diagnosed with HIV during the study period and a sample size that was powered for the primary outcomes of the study, not for the outcome of follow-up viral suppression; therefore, we may have been potentially underpowered to detect a potential difference by RITA-classification. Third, due to individual variation in antibody avidity, there may be some classification of persons with recent infection as RITA-long-term and some classification of persons with long-term infection as RITA-recent. For example, in our study, we observed that 8 (9.2%) persons classified as RITA-recent were also WHO stage II or III, which may suggest long-term infection. Similarly, because antibody avidity declines in people with advanced HIV disease, there may be some persons with long-term infection who present for diagnosis with advanced HIV disease who are classified as RITA-recent. Accordingly, global guidance recommends that RITA-results only be used for surveillance and does not recommend that RITA-results be returned to clients or used at the individual-level for clinical management. Study procedures that included additional clinical information from HIV case surveillance and electronic medical records systems, as well as baseline VL testing on all persons, were utilized to help minimize this potential error.

Despite these limitations, our findings have several potential key implications for HIV programs. First, in this setting of return of recency results, the lack of association between RITA classification and time to ART initiation and viral suppression (both baseline and follow-up) underscores global recommendations that RITA results not be used to differentiate clinical management of persons.(2) Program services designed to support same-day ART initiation, retention, and adherence may help all clients (regardless of RITA-status), attain viral suppression. Efforts to diagnose and treat persons living with HIV early in the course of infection are important to prevent HIV transmission, however, our findings suggest that regardless of RITA-classification, same-day ART initiation and viral suppression at 6-months was relatively high. Second, despite these overall positive findings, there were still some clients who remained virally unsuppressed at 6-month follow-up and others who did not have documented follow-up VL. Other than younger age (for which the magnitude and significance of association was limited), no other variables included in our analysis appeared predictive of viral suppression. Additional data sources or a longer timeframe may need to be explored to more comprehensively understand the extent and factors associated with viral suppression in Rwanda, to continue progress toward the global target of 95%.

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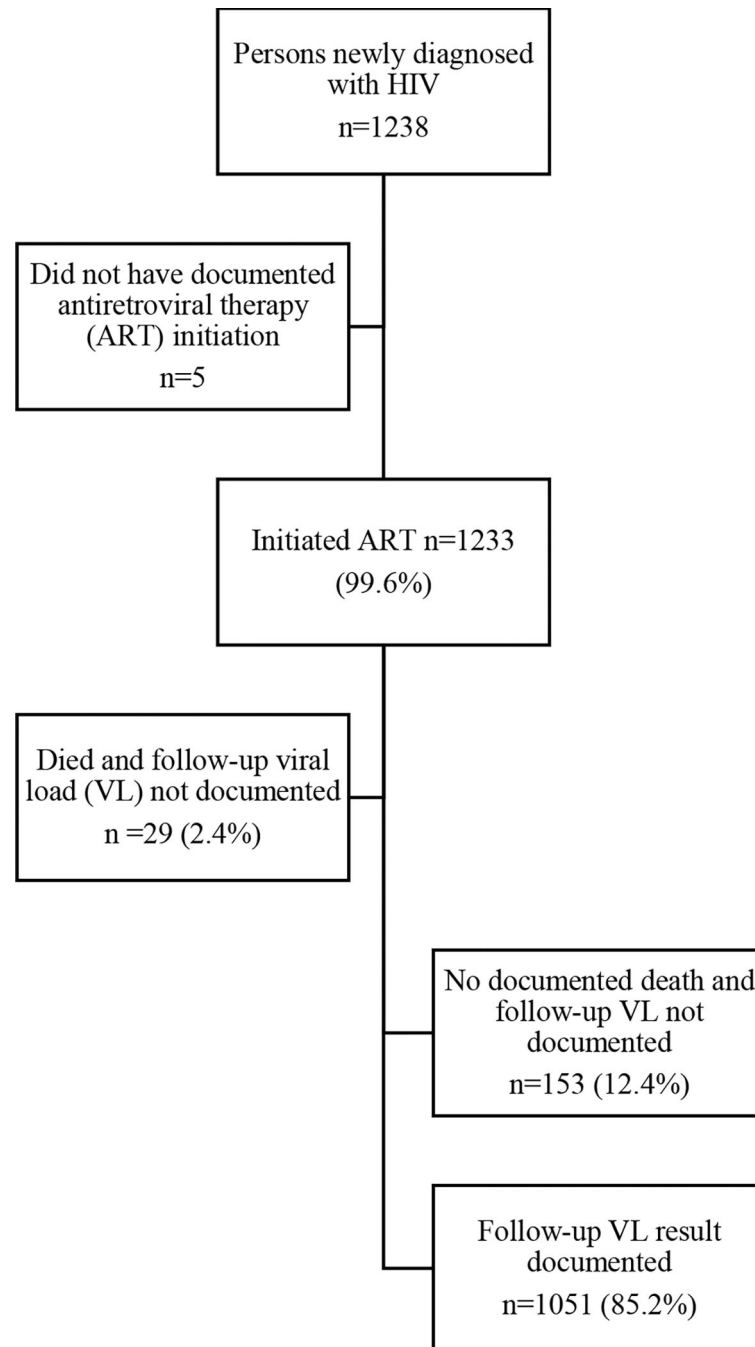


FIGURE 1. Analytic population of persons newly diagnosed with HIV and initiated on antiretroviral therapy (ART) with 6-month follow-up VL, Rwanda 2021–2022

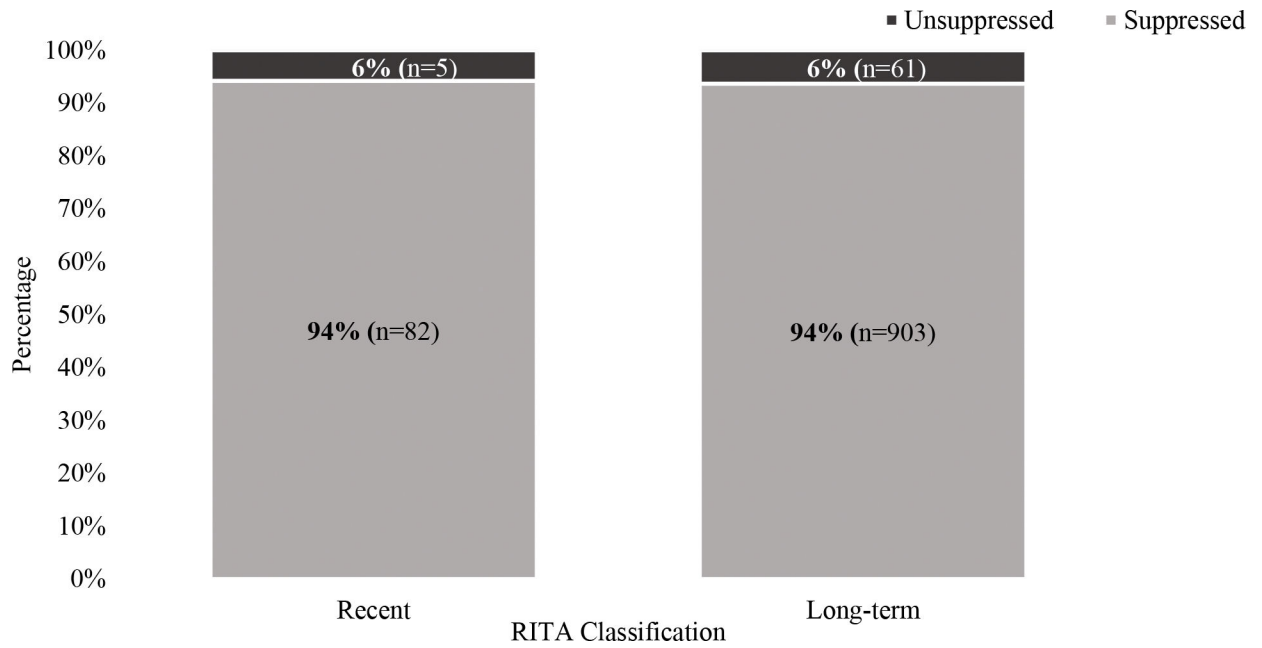


FIGURE 2. VL suppression at 6-months follow-up by recent infection testing algorithm (RITA) classification status (n=1051), Rwanda 2021–2022

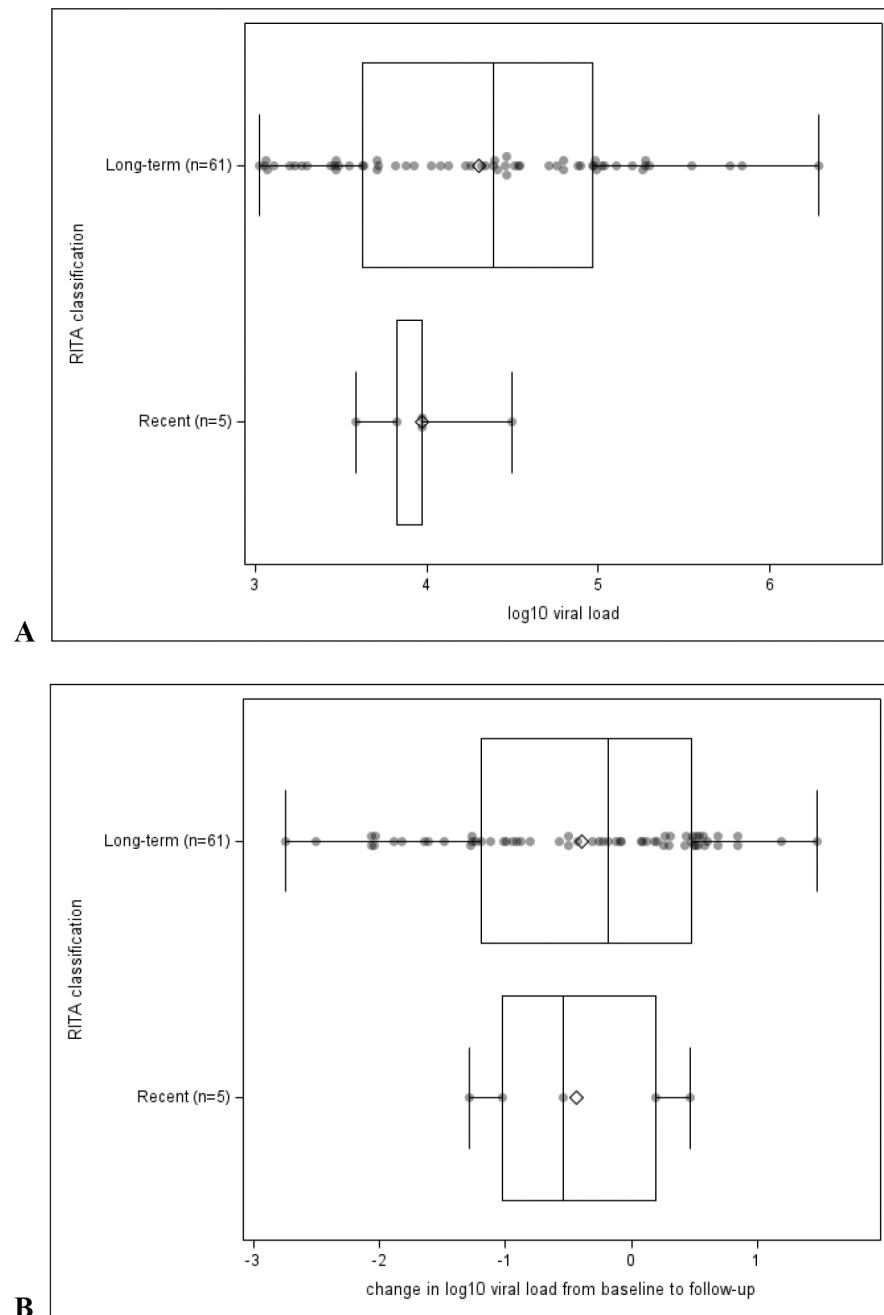


FIGURE 3: Boxplot* of distribution log₁₀VL (A) and change in log₁₀VL (B), among newly diagnosed persons with unsuppressed VL at 6-months follow-up by recent infection testing algorithm (RITA) classification (n=66), Rwanda 2021–2022

*The box edges represent the first quartile (left edge) and third quartile (right edge) of the VL (VL) values; the line within the box represents the median of the VL values; the lines extending from the box represent the minimum and maximum values; the diamond represents the mean of the VL values; the individual shaded circles represent individual VL values

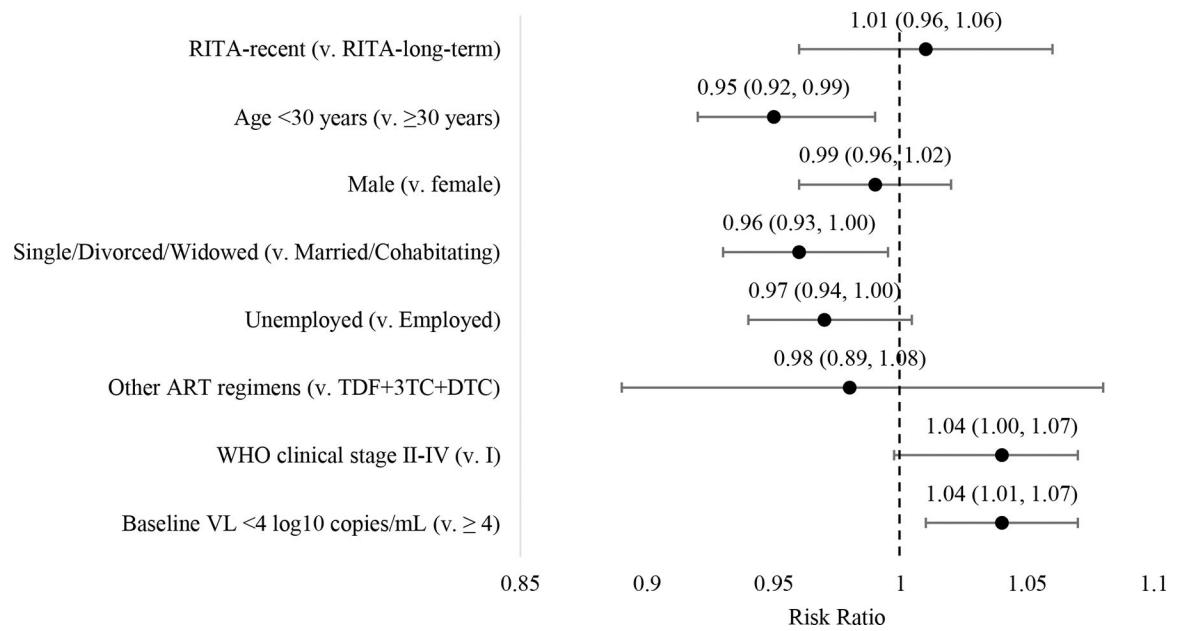


FIGURE 4. Forest plot of adjusted* risk ratios and 95% confidence intervals for viral suppression at 6-months follow-up (n=1051), Rwanda 2021–2022

*Models for each variable as an exposure were adjusted for age, sex, baseline VL, and ART regimen.

TABLE 1.

Baseline characteristics of newly diagnosed persons initiating antiretroviral therapy (ART), overall and by recent infection testing algorithm (RITA) classification (n=1051), Rwanda 2021–2022

	Overall N = 1051	RITA-recent N = 87 (8%)	RITA-long term N = 964 (92%)	p-value
Age (years), median (interquartile range [IQR])	31 (26–38)	29 (23–35)	32 (26–39)	0.002
Age < 30	417 (40%)	49 (56%)	368 (38%)	0.001
Age ≥ 30	634 (60%)	38 (44%)	596 (62%)	0.001
Sex, n (%)				
Female	685 (65%)	68 (78%)	617 (64%)	0.01
Male	366 (35%)	19 (22%)	347 (36%)	0.01
Marital status, n, (%)				
Single	302 (29%)	31 (36%)	271 (28%)	0.14
Married/cohabiting	551 (52%)	41 (47%)	510 (53%)	0.30
Widowed	48 (5%)	2 (2%)	46 (5%)	0.42
Divorced/separated	150 (14%)	13 (15%)	137 (14%)	0.85
Pregnancy status, n (%) *				
Yes	199 (29%)	23 (34%)	176 (29%)	0.4
No	484 (71%)	45 (66%)	439 (71%)	0.4
Employment status, n (%)				
Employed	587 (56%)	45 (52%)	542 (56%)	0.5
Unemployed	464 (44%)	42 (48%)	422 (44%)	0.5
Time to ART initiation (in days), median (IQR)	0 (0, 1.0)	0 (0, 0.5)	0 (0, 1.0)	0.1
Initial ART regimen, n (%)				
ABC+3TC+DTG	36 (3%)	1 (1.1%)	35 (3.6%)	0.3
TDF+3TC+DTG	1014 (96%)	86 (99%)	928 (96%)	0.4
Other	1 (0.1%)	0 (0%)	1 (0.1%)	1.0
VL (VL) (log ₁₀ copies / mL), median (IQR)	4.4 (3.8, 5.1)	4.4 (3.8, 5.4)	4.4 (3.8, 5.0)	0.9
<4 log ₁₀ copies/mL	342 (33%)	31 (36%)	311 (32%)	0.6
≥4 log ₁₀ copies/mL	709 (67%)	56 (64%)	653 (68%)	0.6
World Health Organization (WHO) clinical stage, n (%)				
Stage I	919 (87%)	79 (91%)	840 (87%)	0.4
Stage II	92 (9%)	4 (4.6%)	88 (9.1%)	0.2
Stage III	34 (3%)	4 (4.6%)	30 (3.1%)	0.7
Stage IV	6 (1%)	0 (0%)	6 (0.6%)	1.0

* Pregnancy status was limited to female participants and was missing for two participants