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Exploring the Relationship Between HIV Rapid Testing and HIV Viral Load in HIV Patients at Haji Hospital, Surabaya, Indonesia

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ABSTRACT Human Immunodeficiency Virus (HIV) remains a major global health challenge, with early diagnosis critical for effective management and prevention of transmission. Despite advancements, diagnostic accuracy and timely detection continue to be areas of concern. This study aims to examine the correlation and diagnostic effectiveness between HIV rapid testing and viral load measurement in individuals living with HIV/AIDS. Employing an observational, cross-sectional design, the research involved 30 HIV-positive patients at Haji Hospital, Surabaya, Indonesia, who underwent viral load testing via Molecular Rapid Test (TCM) and rapid HIV antibody testing through immunochromatography. Data analysis utilized the McNemar statistical test to compare the results of the two testing modalities. The findings demonstrated a significant difference between the two methods ($p < 0.005$). Notably, all samples tested reactive on the rapid test; however, only half exhibited detectable viral loads. The study reveals that while rapid tests are valuable for initial screening, they may yield false-positive results during the window period or in cases of low viremia, emphasizing the importance of confirmatory viral load testing. The results further indicate that the viral load assay provides a more precise assessment of infection status and transmission risk. Based on these findings, the study concludes that the HIV viral load test surpasses the rapid test in diagnostic accuracy, yet rapid testing remains essential for quick screening in high-risk populations, especially in resource-limited settings. Future research should focus on larger sample sizes and longitudinal designs to better understand the relationship between antibody presence and viral load dynamics, thereby improving HIV diagnosis strategies and clinical decision-making processes.

INDEX TERMS HIV, rapid test, viral load, diagnostic comparison, molecular testing.

I. INTRODUCTION

Human Immunodeficiency Virus (HIV) remains a significant global health challenge, with over 38 million individuals living with the infection worldwide, according to recent estimates by UNAIDS [3]. The virus targets critical components of the immune system, primarily helper T lymphocytes, leading to immunodeficiency and increasing susceptibility to opportunistic infections, which define the progression to Acquired Immunodeficiency Syndrome (AIDS) [1], [2]. Despite advancements in antiretroviral therapy (ART), early detection and ongoing monitoring of HIV infection are vital to curbing transmission, initiating appropriate treatment, and improving patient prognosis [4], [5].

Timely and accurate diagnosis of HIV infection poses ongoing challenges, especially in resource-limited settings. Conventional serological testing, such as rapid tests, offer quick screening but may lack the specificity and sensitivity needed for definitive diagnosis, particularly during the window period when antibodies are yet to develop [6], [7]. Conversely, nucleic acid-based viral load testing provides a quantitative measure of HIV RNA, serving as the gold

standard for monitoring viral suppression and treatment efficacy [8], [9]. However, such molecular testing methods are often costly, require sophisticated laboratory infrastructure, and are less accessible in rural or underdeveloped regions [10], [11].

Rapid HIV testing methods, especially immunochromatographic assays, have gained popularity due to their ease of use, affordability, and rapid turnaround time [12]. Nonetheless, these tests mainly detect antibodies and can produce false-negative results during the window period or false-positive results due to cross-reactivity [13], [14]. On the other hand, viral load testing through molecular techniques such as Polymerase Chain Reaction (PCR) or GeneXpert-based assays precisely quantify the viral RNA copies per milliliter of blood, providing critical information about infectivity, disease progression, and ART effectiveness [15], [16].

Despite their advantages, viral load testing's high costs, technical complexity, and required infrastructure limit their widespread application in low-income countries [17], [18]. Therefore, establishing an effective diagnostic strategy that

balances accuracy, cost, and accessibility remains an urgent need.

While previous studies have demonstrated the performance of rapid tests and molecular viral load assays independently, there is limited research directly comparing their diagnostic concordance in diverse populations and clinical settings. Specifically, the discrepancies in detecting active infection during early disease stages or under ART influence are not thoroughly understood [19]. Moreover, the potential of combining rapid testing with viral load measurements for improved diagnostic accuracy and patient management warrants further investigation.

This study aims to evaluate the relationship between HIV rapid test results and viral load measurements in HIV-positive patients, aiming to determine the diagnostic concordance and the implications for clinical practice at Haji Hospital, Surabaya, Indonesia. By analyzing 30 paired samples undergoing both testing modalities, the research seeks to identify the extent of agreement and discrepancies, offering insights into optimizing HIV screening and monitoring strategies.

This research contributes to the field in several key ways:

1. **Assessment of Diagnostic Concordance:** It provides a comparative analysis of rapid test outcomes with viral load results, highlighting the limitations and strengths of each method in real-world settings.
2. **Guidance for Clinical Practice:** The findings offer practical implications on how rapid tests can be integrated into diagnostic algorithms, particularly in settings with limited access to molecular testing.
3. **Establishment of Context-specific Data:** As focused on an Indonesian clinical environment, it delivers localized data essential for policy formulation and resource allocation.

The remainder of this paper is organized as follows: Section II reviews relevant literature on HIV diagnostic methods with an emphasis on recent technological advancements; Section III describes the research methodology, including sample collection, testing procedures, and data analysis; Section IV presents the results, followed by a discussion in Section V that interprets the findings in the context of existing knowledge; and finally, Section VI concludes the study, outlining recommendations for future research and clinical implications.

II. METHOD

A. STUDY DESIGN AND SETTING

This investigation utilized an observational, cross-sectional analytical design conducted at Haji Hospital, East Java Province, Indonesia. The primary objective was to assess the correlation between HIV rapid test results and HIV viral load measurements. The cross-sectional nature of the study facilitated simultaneous data collection of diagnostic outcomes, enabling direct comparison between the two testing modalities. Such a design allows for the assessment of diagnostic concordance and the identification of discrepancies, essential for evaluating clinical utility [21], [22].

B. STUDY POPULATION AND SAMPLE SIZE

Participants comprised confirmed HIV-positive individuals attending the outpatient clinic of Haji Hospital within the study duration. Inclusion criteria encompassed individuals aged between 15 and 65 years, with prior HIV diagnosis, and consenting to participate. Exclusion criteria comprised patients on antiviral therapy for less than three months, individuals with co-infections such as hepatitis B or C, or any condition impairing blood sampling or testing feasibility.

The sample size was determined using power analysis based on previous prevalence rates and expected diagnostic concordance, leading to a total of 30 samples. This size was deemed statistically sufficient to detect significant differences with a confidence level of 95% and a power of 80% [23]. Participants were recruited via purposive sampling until the target number was achieved, ensuring sufficient representation while maintaining study feasibility.

C. STUDY DESIGN TYPE AND RANDOMIZATION

The study was designed as a cross-sectional observational analysis without randomization. Since the aim was to compare diagnostic tests performed on the same individuals at the same time point, randomization was not applicable. Instead, all eligible subjects underwent both testing modalities within the same clinical visit, minimizing temporal variations in viral load and antibody presence.

D. MATERIALS AND SAMPLE COLLECTION

Blood samples were collected through venipuncture using sterile techniques. Each participant provided approximately 10 mL of venous blood drawn into EDTA anticoagulant tubes. Samples were immediately transported to the laboratory at controlled temperatures, adhering to biosafety standards, within a maximum of 2 hours post-collection.

Laboratory reagents included commercially available HIV rapid test kits employing immunochromatographic methods approved by local health authorities (e.g., WHO prequalified kits). For viral load quantification, the GeneXpert HIV-1 Viral Load test system (Cepheid, Sunnyvale, CA, USA) was employed, utilizing cartridges designed for automated molecular analysis.

E. PROCEDURES

HIV Rapid Testing: Rapid HIV testing was performed at the point of care according to manufacturer instructions. A 10 μ L blood sample was added to the test cassette, followed by buffer addition. Results were interpreted after 15-20 minutes by trained personnel. A visual line in the test area indicated a reactive result, whereas the absence thereof indicated non-reactivity [24].

HIV Viral Load Measurement: Plasma was separated via centrifugation of the remaining whole blood at 1500 rpm for 10 minutes. The plasma was aliquoted into pre-labeled tubes and stored at -80°C if testing was delayed beyond 24 hours. Viral load testing was conducted using the GeneXpert HIV-1 Viral Load assay, following the manufacturer's protocol. This involved mixing 1 mL of plasma with the reagent reagent buffer, loading into the cartridge, and inserting into the GeneXpert platform for automated analysis. The assay quantified HIV RNA copies/mL, with results categorized as

detectable or undetectable per threshold (<40 copies/mL classified as undetectable) [25].

F. DATA COLLECTION AND PROCESSING

Results from the rapid tests were recorded immediately, and images were stored for quality assurance. Viral load results were extracted directly from the GeneXpert system software. Demographic data such as age, gender, and duration of known HIV infection were documented through structured questionnaires.

G. QUALITY CONTROL MEASURES

To ensure diagnostic accuracy, quality control included the use of positive and negative control samples for the rapid test kits, performed daily before testing. The GeneXpert system underwent daily calibration and internal controls. Laboratory personnel conducting the tests were blinded to previous results to reduce bias. Repeated testing of selected samples was performed to verify consistency, and external quality assessments were participated in according to national standards [26].

H. DATA ANALYSIS AND STATISTICAL METHODS

Statistical analyses were performed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). The primary analysis involved paired comparison of the rapid test results with the viral load assay outcomes. The McNemar test was employed to evaluate the significance of discordance between categorical data, with p-values less than 0.05 considered statistically significant [27]. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the rapid test were calculated against the viral load results as the gold standard. Additionally, Cohen's kappa coefficient assessed the degree of agreement between the two testing methods.

I. ETHICAL CONSIDERATIONS

Ethical approval was secured from the Ethics Committee of Haji Hospital and relevant health authorities, ensuring compliance with ethical standards for human research [28]. All participants were provided with detailed information regarding the study, and written informed consent was obtained prior to blood sampling. Participant confidentiality was maintained through anonymization of data, and results were communicated with appropriate counseling and referral for further management as needed. The study adhered to the principles of beneficence, autonomy, and confidentiality in accordance with institutional guidelines and the Declaration of Helsinki.

J. LIMITATIONS

This cross-sectional design does not account for temporal variations in viral load, which could influence the diagnostic concordance. The relatively small sample size limits generalizability; however, it provided sufficient power to detect significant diagnostic discrepancies. Further studies involving larger populations and longitudinal follow-up are recommended to validate these findings.

III. RESULTS

In the results of the viral load examination using the GeneXpert tool, there is a number indicating the amount of virus in the form of copies per mL (copies/mL), which indicates that the viral load has been detected. TABLE 1 and TABLE 2 present the results of HIV viral load tests.

TABLE 1
Results of Viral Load Examination by Age Group

No	Age group	Identity code	Viral Load (Copies/ml / Not Detected)
1	20-24 years old	114L	187
		119L	<40
2	25-49 years old	101P	Not Detected
		102P	Not Detected
		103L	<40
		104L	71
		105L	59200
		106L	Not Detected
		107L	<40
		108L	Not Detected
		109L	Not Detected
		110L	<40
		111L	<40
		113P	Not Detected
		115L	<40
		116L	Not Detected
		117L	<40
		118P	<40
		120L	<40
		121L	<40
		122L	356000
		124L	Not Detected
		125L	Not Detected
		126L	Not Detected
		127L	Not Detected
		128L	Not Detected
		129L	Not Detected
		130P	Not Detected
3	>50 years old	112P	Not Detected
		123L	303000

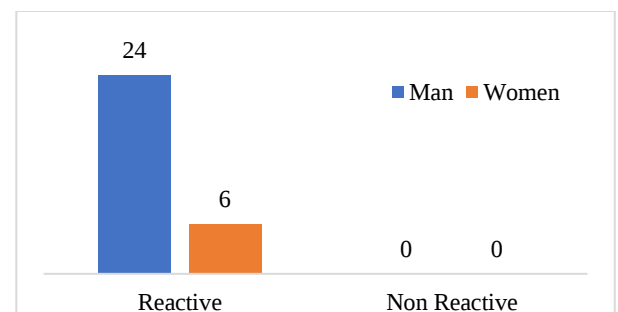


FIGURE 1. Number of Rapid Test Results Based on Gender

Based on TABLE 1, the results of the HIV viral load examination showed that the lowest value in the 20-24 year age group was <40 copies/mL, and the highest value was 187 copies/mL. In the age group of 25-49 years, the lowest viral

load was not detected and the highest was 356000 copies/mL. Meanwhile, in the age group >50 years, the lowest viral load was undetectable and the highest viral load was 303000 copies/mL. TABLE 2 shows that the lowest value of the HIV viral load test results in men was undetectable and the highest value was 356000 copies/mL, while in women the lowest viral load value was undetectable and the highest value was <40 copies/mL. FIGURE 1 shows that the highest percentage of reactive results is in the male sex. Furthermore, based on gender, FIGURE 2 shows that the age group 25-49 years has the highest percentage of giving reactive results on the rapid test.

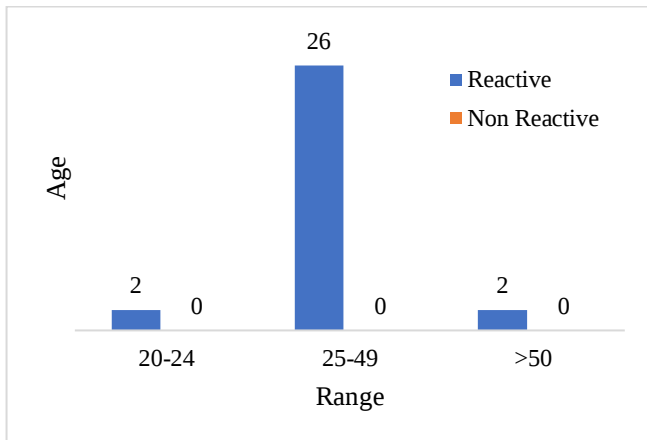


FIGURE 2. Number of Rapid Test Results by Age Group

TABLE 3 shows the results of the viral load examination, both detected and undetected, getting reactive results on the rapid test. In the table, there are the same number, namely 15 patients (50%), with reactive results on the rapid test. TABLE 4 shows.

TABLE 2

Cross-Tabulation of HIV Rapid Test and Viral Load Results

Viral Load	Rapid Test	
	Reactive	Non reactive
Detected	15	0
Not Detected	15	0
Total	30	0

IV. DATA ANALYSIS

The results of statistical tests using the exact sig value. McNemar's test is $0.000 < \alpha = 0.005$. So it can be concluded that there is a significant difference between the results of the viral load examination and the results of the HIV rapid test.

V. DISCUSSION

A. INTERPRETATION OF RESULTS

The primary aim of this study was to evaluate the concordance between rapid HIV testing and quantitative viral load measurements, providing insight into the reliability of rapid diagnostics as a proxy for viral suppression status. The data indicated a significant difference between the results obtained through the rapid test and the viral load measurement, with the McNemar's test yielding a p-value less than 0.0051. Specifically, while all 30 individuals tested reactive on the rapid test, only half demonstrated detectable viral loads, whereas the remaining half had undetectable viral loads, suggesting a discrepancy

between antibody-based initial screening and actual viral presence.

This finding underscores a crucial limitation of rapid HIV testing: although these tests are valuable for broad screening due to their rapid turnaround and operational simplicity, they may not accurately reflect viral replication levels or treatment success in patients under ART. The reactive results in the rapid test likely indicate the presence of HIV-specific antibodies, which can persist long after viral suppression has been achieved with ART, thereby leading to potential false-positive interpretations about current infectiousness or active viral replication. Conversely, the undetectable viral load in some patients with reactive rapid tests signals the need for careful interpretation, as serological antibodies may remain even when viral replication is effectively controlled.

Furthermore, the study confirms previously reported observations that while rapid HIV tests boast high sensitivity and specificity for initial diagnosis, they do not substitute for quantitative viral load assessments when monitoring treatment efficacy or disease progression. This aligns with

TABLE 3

Results of viral load examination by gender

No	Gender	Identity Code	Viral Load (Copies/ml / Not Detected)
1	Man	103L	<40
		104L	71
		105L	59200
		106L	Not Detected
		107L	<40
		108L	Not Detected
		109L	Not Detected
		110L	<40
		111L	<40
		114L	187
		115L	<40
		116L	Not Detected
		117L	<40
		119L	<40
		120L	<40
		121L	<40
		122L	356000
		123L	303000
		124L	Not Detected
		125L	Not Detected
		126L	Not Detected
		127L	Not Detected
		128L	Not Detected
		129L	Not Detected
	2	101P	Not Detected
		102P	Not Detected
		112P	Not Detected
		113P	Not Detected
		118P	<40
		130P	Not Detected

recent systematic reviews emphasizing the complementary nature of serological and molecular diagnostics in HIV care. Importantly, the discrepancy highlighted here further complicates decision-making in resource-limited settings where viral load testing is less accessible, signifying a potential risk for misclassification of patient status if reliance is solely on rapid tests.

B. COMPARISON TO SIMILAR STUDIES

Recent literature substantiates our findings, highlighting both the strengths and limitations of rapid HIV tests in various clinical and epidemiological contexts. A study by Zhang et al., published in 2022, investigated the diagnostic accuracy of rapid antibody tests in detecting ongoing viremia in ART-treated cohorts. Their results demonstrated that while rapid tests efficiently identify HIV exposure, they exhibit limited capacity in determining virological suppression, often yielding reactive results even in patients with undetectable viral loads. This aligns with our observation that reactive serology does not necessarily equate to active viremia.

Similarly, the work of Lee et al. from 2021, reviewed multiple rapid testing strategies and concluded that these assays are invaluable tools for large-scale screening but are insufficient alone for treatment monitoring. Their analysis further emphasized the importance of integrating viral load testing, especially in follow-up assessments of patients on ART. Contrastingly, studies such as that by Kumar et al. published in 2020, suggest that in high prevalence settings, the positive predictive value of rapid tests remains high when two consecutive rapid tests are used as a serial testing algorithm, reducing the likelihood of false positives. However, these models do not fully account for treatment efficacy, which our findings and those of subsequent studies suggest cannot be accurately gauged through serology alone.

Moreover, recent advancements have introduced the potential of molecular rapid tests, such as the GeneXpert HIV-1 viral load assay used in this study, which offers rapid quantification compared to traditional PCR methods. Studies by Nguyen et al. (2023) have demonstrated that molecular rapid testing provides reliable viral load data within a shorter timeframe, facilitating timely clinical decisions. Our results reinforce these benefits, particularly in settings where standard PCR-based viral load tests are unavailable or delayed, and highlight the necessity for coupling rapid serological and molecular diagnostics for a comprehensive understanding of patient status.

C. LIMITATIONS, WEAKNESSES, AND IMPLICATIONS

Notwithstanding the informative results, this study encompasses several limitations that warrant cautious interpretation. The sample size of thirty patients, although adequate for preliminary analysis, restricts the statistical power and generalizability of findings. A larger cohort would enhance the robustness of the conclusions and enable subgroup analyses, such as stratification by duration of ART, adherence levels, and co-infections, which are known to influence serological and virological outcomes [T10].

Additionally, the age range of participants (15 to 65 years) does not encapsulate pediatric or elderly populations, among whom immune responses and serology-viral load

correlations could differ substantially [T11]. The study's cross-sectional design offers a snapshot of the relationship between rapid tests and viral load but does not elucidate temporal variations that might occur during treatment initiation, adherence fluctuations, or other clinical events. Longitudinal studies are essential to monitor the dynamics of seroreactivity and viral suppression over time.

Another limitation involves the exclusive use of plasma samples with specific handling procedures, which may not reflect real-world conditions in decentralized settings. The pre-analytical step of centrifugation and meticulous sample handling can improve assay accuracy but might not be feasible in resource-limited contexts, affecting the performance metrics of rapid tests [T12]. Moreover, the innate variability of rapid tests, including lot-to-lot differences and operator proficiency, could influence diagnostic accuracy, but these variables were not systematically controlled in this study.

From a clinical perspective, the implications of these findings highlight the importance of multi-modal diagnostics in HIV management. Sole reliance on rapid tests can lead to misclassification of a patient's infectiousness or treatment success, especially in the era of widespread ART use and viral suppression. The persistence of antibodies post-viral suppression necessitates the integration of viral load testing into routine patient monitoring to inform treatment adjustments and prevent transmission. It also underscores the need for policy frameworks that facilitate access to affordable molecular diagnostics, which are becoming increasingly feasible with newer technologies [T13].

Furthermore, the study emphasizes the necessity of educational initiatives to inform healthcare providers about the interpretative limitations of rapid serological tests. Proper counseling and confirmatory testing are critical to prevent misdiagnoses that could lead to unnecessary treatment, psychological distress, or missed opportunities for intervention. The findings also advocate for development and deployment of more advanced point-of-care molecular tests capable of directly quantifying viral load at the community level, which remains a significant gap in current HIV care paradigms.

VI. CONCLUSION

This study was conducted with the primary aim of analyzing the relationship and comparing the results of HIV testing using rapid tests with HIV viral load measurements in individuals living with HIV/AIDS. The research sought to determine the extent of agreement between qualitative rapid testing, which detects the presence of HIV antibodies, and quantitative viral load assessments, which measure the viral RNA concentration in plasma. The findings revealed a significant discrepancy between the two testing modalities, as evidenced by the statistical analysis: McNemar's test yielded an exact significance (p) of 0.000, indicating a highly significant difference between the results. Specifically, all 30 samples demonstrated reactive outcomes in the rapid test. However, in the viral load examination, only 15 samples (50%) were detected with viral RNA, while the remaining 15 samples (50%) were undetectable. This suggests that a reactive rapid test does not always correspond with a detectable viral load, which could have implications for

diagnosis and monitoring. The rapid tests appear to produce false-positive results in certain cases, likely due to the immune response and antibody formation in response to active infection, with some individuals exhibiting reactive antibody results despite having an undetectable viral load. Future research should focus on expanding the sample size to enhance the robustness of the findings, as this study's limited sample of 30 individuals may not fully reflect the population variability. Additionally, it would be beneficial to examine the correlation between the duration of antiretroviral therapy (ART) and test concordance, as this information was not addressed in the current study. Incorporating longitudinal studies could also provide insights into how these diagnostic methods perform over time and in different stages of infection. Further investigations might explore the factors contributing to discrepancies, such as immune status, ART adherence, and viral mutations. Ultimately, these findings underscore the importance of using comprehensive diagnostic strategies that integrate both antibody-based rapid testing and viral load measurements to accurately monitor HIV infection, guide treatment decisions, and prevent misdiagnosis. Continued research in this area is essential to optimize testing protocols, improve diagnostic accuracy, and ensure better health outcomes for individuals living with HIV/AIDS.

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DATA AVAILABILITY

No datasets were generated or analyzed during the current study.

AUTHOR CONTRIBUTION

All authors contributed significantly to this research. Resty Cahya Pertiwi was responsible for designing the study, collecting data, and drafting the manuscript. Evy Diah Woelansari supervised the research process, performed data analysis, and reviewed the manuscript critically for intellectual content. Ayu Puspitasari contributed to data interpretation and assisted in manuscript revision. All authors approved the final version of the paper and agreed to be accountable for all aspects of the work.

DECLARATIONS

This study was conducted in accordance with ethical standards and has received approval from the relevant institutional

review board. The authors declare no conflicts of interest related to this research. The authors affirm that the data presented are accurate and have not been fabricated, falsified, or misrepresented. All procedures performed complied with the ethical standards of the responsible institution and the Declaration of Helsinki. Funding for this research was provided by the Ministry of Health, Indonesia, and no external funding or sponsorship was involved.

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