Journal of Molecular and Genetic Medicine

Faye et al., J Mol Genet Med 2019, 13:2

Research Article Open Access

Comparison of Roche COBAS®AmpliPrep/COBAS®TaqManHIV-1v2.0 and Abbott m2000sp/m2000rt for the Measurement of HIV-1 Viral Load in Senegal

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Abstract

Accurate quantification of HIV-1 viral load (VL) is crucial for assessing infection stage and efficacy of antiretroviral therapy (ART). Despite recommendations for measuring VL amongst people living with HIV, the accessibility and availability of this parameter remain low in resource-limited settings, primarily due to the lack of qualified human resources and necessary reagents. Solutions must be found to help developing countries attain the Joint United Nations Program on HIV/AIDS (UNAIDS) 90-90-90 targets for 2020. This study was designed to compare the quantification of HIV-1 VL between two reverse transcriptase real-time PCR techniques: RocheCOBAS® AmpliPrep/COBAS®TaqMan®HIV-1v2.0 and Abbott m2000sp/m2000rt. To conduct the comparison, 231 samples for VL were assessed. Samples were stratified according to the following VL intervals:<3 Log10; 3 Log10-4 Log10; 4 Log-5 Log10; 5 Log10-6 Log10 and > 6 Log10 copies/ml. The Bland-Altman method and the Bland-Altman plot were used for the comparison of the two techniques. The concordance varies from 92 to 98% depending on the VL interval studied. Our results showed that these two techniques give similar results and that all observed variations are under 0.5 Log10 copies/ml, which is considered a significant variation for treatment failure. This concordance was confirmed by the overall VL comparison obtained using linear regression. The linear regression shows a correlation with R^2 = 0.83 and a 95% agreement between the two techniques. Our results show that these techniques are interchangeable and thus, in some contexts, would improve the availability of VL to help achieve the UNAIDS third "90" target set for 2020.

Keywords: Comparison; Abbott; Roche; Viral load; HIV-1; Senegal

Introduction

HIV/AIDS remains a worldwide public health challenge, particularly in low and middle-income countries. According to the Joint United Nations Program on HIV/AIDS (UNAIDS) July 2018 report, in 2017 there were 36.9 million [31.1-43.9 million] people living with HIV worldwide, of which 35.1 million were adults and 1.8 million were children under the age of 15 [1]. In 2017, a total of 940,000 [670,000-1.3 million] people died of HIV/AIDS [1]. Among people living with HIV 21.7 million [19.1-22.6 million] have access to antiretroviral therapy (ART), or 59% of the treatment demand [1]. In Western and Central Africa, at the end of 2017 less than half (48%) of people living with HIV knew their HIV status, just two in five (40%) were accessing ART, and less than one third (29%) were virally suppressed [1]. Hence, addressing missed or delayed treatment is a priority in this region. The UNAIDS targets to end the HIV/AIDS epidemic by 2020 are as follows: that 90% of people living with HIV know their HIV status, that 90% of people living with HIV receive ART and that 90% of people receiving ART attain viral suppression [2]. Several countries, cities, and communities in different contexts have already achieved the 90-90-90 goals, which indicates that the global realization of the three 90s by 2020 is both achievable and accessible if we tackle with determination the gaps in the cascade of HIV testing and treatment [3,4]. However, the biggest gap remains in regard to the third 90 (undetectable viral load), which measures the success of ART in HIV patients. West and Central Africa are lagging behind in HIV detection, treatment, and viral suppression. For the third "90", West and Central Africa have an HIV VL coverage rate for all people living with HIV of 25% against 44% worldwide in 2017 [2]. In Senegal, the latest national evaluation shows that only 25% of patients on ART had access to VL in 2017 [5].

ART should make patient VL undetectable (< 50 copies/ml), promoting immune restoration, lowering the risk of viral drug resistance, and reducing clinical events associated with HIV [6]. Early initiation of ART produces a rapid decline in VL, reducing the risk of HIV transmission [7,8].

The implementation of HIV-1 VL testing is growing worldwide, but the availability is still problematic in resource-limited countries, despite international recommendations [9,10]. The evaluation of the suppression of plasma VL is extremely challenging in West and Central Africa as a result of the low availability of testing due to the high cost of equipment and the lack of human resources qualified in molecular biology. Even in settings where appropriate equipment and qualified personnel are present, an unstable supply chain threatens the availability of VL reagents and other supplies necessary for testing. Achievement of the UNAIDS goal to end the HIV epidemic by 2030 will be achieved first through the success of the three 90s by 2020, and particularly the third 90 of achieving undetectable VL through successful ART. Hence, the availability of an HIV VL testing platform, appropriate reagents

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Received April 23, 2019; **Accepted** May 17, 2019; **Published** May 24, 2019

Citation: Faye B, Dieng FB, Charlebois R, Sarr H, Diouf SG, et al. (2019) Comparison of Roche COBAS®AmpliPrep/COBAS®TaqManHIV-1v2.0 and Abbott m2000sp/m2000rt for the Measurement of HIV-1 Viral Load in Senegal. J Mol Genet Med 13: 424.

and supplies, and qualified personnel are necessary to assure high-quality, uninterrupted VL testing.

Several studies showing the limitations of measuring CD4 in the management of HIV patients have made VL the main marker of prognosis for progression and therapeutic follow-up [11,12]. Measurement of plasma VL is used to evaluate the progression of infection, the efficacy of ART, and the occurrence of resistant HIV genotypes. Since inaccurate VL measurement can lead to inappropriate patient management, a comparison of the performance of the automated systems used to quantify HIV VL is essential. Discrepancies between commercial VL tests have been shown in the quantification of non-B subtypes which explains the recommendation of therapeutic groups to use a single technique to monitor patients VL [13-18].

Considering the variability between different VL tests and the geographical genomic diversity of HIV, a concordance study between the Abbott and Roche systems proved necessary to understand the impact of switching platform on VL results of people living with HIV in Senegal. In this study two different platforms for VL are used, Abbott m2000sp/m2000sp and Roche COBAS®AmpliPrep/COBAS®TaqMan® (CAP/CTM 96). Using these platforms interchangeability could improve the accessibility of VL testing, by allowing us to test patient based on the availability of inputs for one of the platforms, hence reducing delays.

The objective of this study is to compare two real-time PCR systems, Abbott (m2000sp/m2000rt) and Roche (COBAS®AmpliPrep/COBAS®TaqMan®HIV-1v2.0) for the determination of the HIV-1 VL in plasma at the molecular biology laboratory of the Military Hospital of Ouakam in Dakar, Senegal.

Materials and Methods

Study population

HIV positive plasma samples were collected at the Molecular Biology Laboratory of the Senegalese Armed Forces AIDS Program at the Military Hospital of Ouakam in Dakar from August 2, 2017 to February 2, 2018. All plasma samples are from patients positive for HIV-1. Consent was not required for these patients as plasma VL was done as part of their clinical follow-up for their ART. A total of 281 plasma samples were selected; however, 50 samples were excluded from this study as an undetectable result was obtained on at least one of the two platforms. Hence a total of 231 samples were used to conduct the study.

Sample collection and handling

Whole blood was collected in 7.2 mg BD K2E (EDTA) tubes (ref 368861) (Becton Dickinson, NJ, USA). After centrifugation at 6000 rpm for 20 minutes at 4°C, two plasma aliquots were prepared for each patient (one for Roche and the other for Abbott) and immediately frozen at -80°C until tested on the two platforms.

Quantification of HIV-1 RNA

Each plasma sample was processed on Abbott (m2000sp/m2000rt) and Roche (COBAS®AmpliPrep/COBAS®TaqMan®HIV-1 v2.0) for quantification of HIV-1 RNA.

Roche molecular technique

The COBAS®AmpliPrep/COBAS®TaqMan®HIV-1 v2.0 (Roche Molecular Systems, Inc, NJ, USA) is a real-time reverse transcriptase PCR assay. Extraction is done using the COBAS®AmpliPrep, using 1 ml of plasma. Then reverse transcriptase is initiated automatically followed by *in vitro* amplification and simultaneous detection of the highly conserved region of the gag gene and the LTR (long terminal repeat) region of the HIV-1 genome using a fluorescent TaqMan probe (COBAS®TaqMan®96). This test quantifies RNA over a range of 20 to 10,000,000 (1.3-7 log10) copies/ml [13,19]. Plasma samples are tested in the Roche CAP/CTM96 instrument according to the manufacturer's instructions. The CAP/CTM instrument is a closed automation system platform combining extraction, reverse transcriptase and real-time PCR, reducing the likelihood of contamination. Each test series includes three controls (one negative, one strong positive and one weak positive). The analyser automatically validates the manipulation and determines the presence or absence of HIV-1 nucleic acids according to a threshold cycle value (Ct value) which corresponds to the PCR cycle from which the detected signal indicates the presence of the amplicons.

VL quantification using the Roche system underwent external quality assessment with the College of American Pathologists (CAP) in 2018. All results were found to be within three standard deviations from the average of the peer group; hence the accuracy and reliability of results has been ensured.

Abbott molecular technique

The Abbott test (m2000sp/m2000sp) is a real-time reverse transcriptase PCR assay for the quantitative determination of HIV-1 RNA in HIV-1 positive plasma. The extraction is done using 0.6 ml of plasma, the reverse transcriptase is followed by an amplification and real-time detection of a fragment of the integrase region of the pol (pol/IN) gene of the HIV-1 genome with the m2000rt test kit fluorescent probe [20]. This test quantifies the RNA over a range of 1.6 to 7 log10 copies/ml (40 to 10,000,000 copies/ml) [21]. Plasma samples are tested in the m2000sp/m2000rt instrument according to the manufacturer's instructions.

The Abbott instrument is a closed automation system combining extraction, reverse transcriptase, and real-time PCR and detection, reducing the likelihood of contamination. Each test series includes three controls (one negative, one strong positive and one weak positive). The analyser automatically validates the manipulation and determines the presence or absence of HIV-1 nucleic acids according to a threshold cycle value (C_t value) which corresponds to the PCR cycle from which the detected signal indicates the presence of the amplicons.

Statistical analysis

The results obtained on both platforms are given in RNA copies/ml and were converted to log10 copies/ml before being analyzed. The 231 samples selected for the study were divided into five VL (log10 copies/ml) fractions: 1) 50 plasmas<3 log10; 50 plasmas between 3-4 log10; 50 plasmas between 4-5 log10; 50 plasmas between 5-6 log10 and 31 plasmas > 6 log10. The Bland-Altman method, the scatter plot and the linear regression were used to compare the two methods [21]. The statistical analysis was performed using GraphPad Prism version 8, GraphPad software (La Jolla, CA, USA) and p-value was considered significant if $P<0.05$. The discrepancy has been described in terms of bias with a 95% confidence interval.

Results

For this study, 281 HIV-1 seropositive patients were collected at the Military Hospital of Ouakam laboratory as part of their immuno-virologic monitoring (VL and CD4). Out of 281 samples, 231 were included in the study; samples with an undetectable VL on one of

the platforms or both were excluded from the analysis. Of 281 HIV-1 patients, women accounted for 53% (148) and men 47% (133) presenting a sex ratio of 1.12. The median age was 32 years, ranging from 1 year to 80 years; where patient between 19-45 accounted for 49% (137), 29% (82), and (46-80) accounted for 22% (62) [1-20].

Comparison of Viral Load (VL) values between Abbott and Roche

Out of a total of 281 samples tested, 231 samples, or 82%, had detectable quantifiable VL when analyzed with Abbott, >1,6 log10 (>40 copies/ml) and Roche, >1,3 log10 (>20 copies/ml).

Samples were stratified into five VL intervals:

1. inferior to 3 log10 (1000 copies/ml), 50 samples.
2. between 3-4 log10 (1000 to 10,000 copies/ml), 50 samples.
3. between 4-5 log10 (10,000 to 100,000 copies/ml), 50 samples.
4. between 5-6 log10 (100000 to 1000000 copies/ml) 50 samples.
5. superior 6 log10 (1000000 copies/ml) is 31 samples.

The Bland-Altman method and the difference scatter plot were used for the comparison of the two techniques.

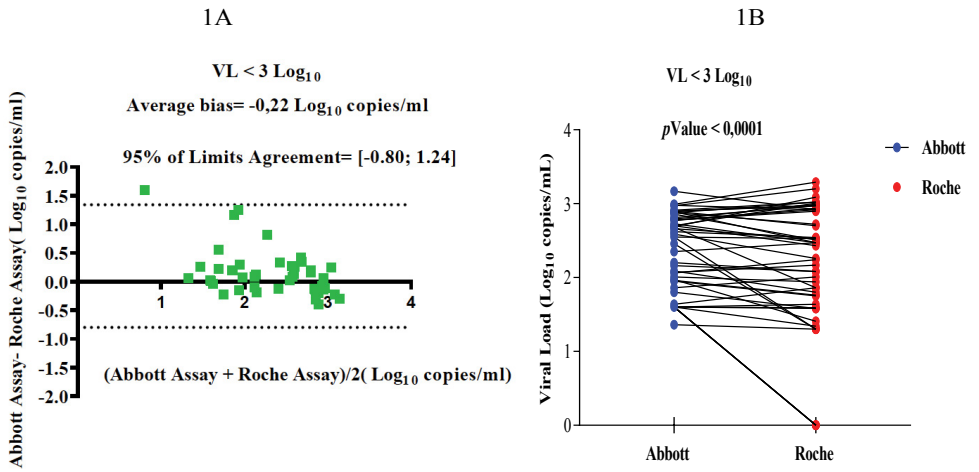

Figure 1: Analysis of the Viral Load (VL) less than 3 Log_{10} copies/ml with Bland-Altman Plot (A) and before-after scatter plot (B).

1A: The vertical axis represents the VL differences (Abbott method minus Roche method) per patient and the horizontal axis represents the mean of VL per patient (Abbott method+Roche method/2). Each data point represents one of the paired 50 quantifiable plasma samples. The solid line indicates the mean difference between the values and the dotted lines indicates the mean (95% limits of agreement). The number of samples within this range was 49 (98%).
1B: Analysis of the median VL between Abbott and Roche. The straight lines represent the VL correlation between Abbott method and Roche method. There is a concordance of 98%.

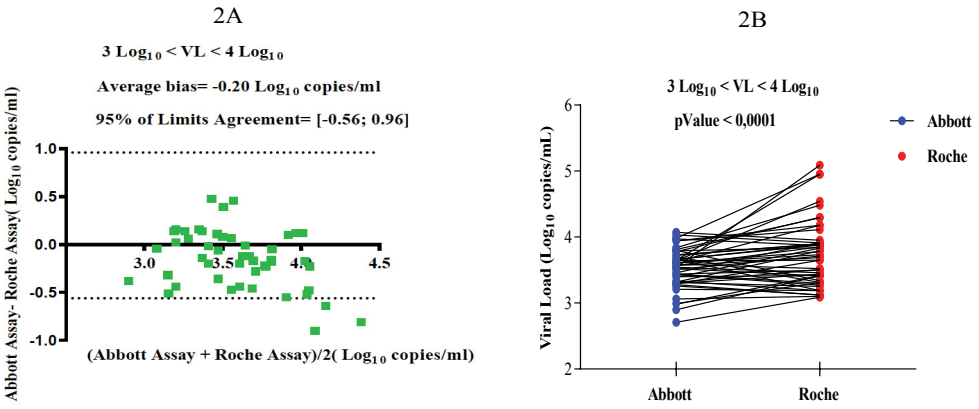

Figure 2: Analysis of the viral load (VL) when 3 Log_{10} <VL < 4 Log_{10} copies/ml with Bland-Altman Plot (A) and before-after scatter plot (B).

2A: The vertical axis represents the VL differences (the Abbott method minus the Roche method) per patient and the horizontal axis represents the means of VL per patient (Abbott method+Roche method/2). Each data point represents one of the paired 50 quantifiable plasma samples. The solid line indicates the mean difference between the values and the dotted lines indicates the mean (95% limits of agreement). The number of samples within this rang was 46 (92%).
2B: Analysis of the median VL between Abbott and Roche. The straight lines represent the VL correlation between Abbott method and Roche method. There is a concordance of 92%.

Comparison of VL inferior to 3 Log10 copies/ml (< 1000 copies/ml)

Comparative evaluation between both methods for values<3 log10 copies/ml showed that there is 49/50 (98%) VL values which are in concordance and 1/50 (2%) VL values are divergent (Figures 1A and 1B). The Altman Bland method shows a negative bias in favor of Abbott of -0.22 log10 copies/ml with 95% limits of -0.80 to 1.24 (Figure 1A).

Comparison of VL between 3 and 4 Log10 copies/ml (1000 to 10,000 copies/ml)

Comparative evaluation between both methods for values between 3 log10 and 4 log10 copies/ml showed that there is 46/50 (92%) VL values which are in concordance and 4/50 (8%) VL values are divergent (Figures 2A and 2B). The Altman Bland method shows a negative bias in favor of Abbott of -0.20 log10 copies/ml with 95% limits of -0.56 to 0.96 (Figure 2A).

Comparison of VL between 4 and 5 Log10 copies/ml (10,000 to 100,000 copies/ml)

Comparative evaluation between both methods for values between 4 log10 and 5 log10 copies/ml showed that there is 47/50 (94%) VL values which are in concordance and 3/50 (6%) VL values are divergent (Figures 3A and 3B). The Altman Bland method shows a negative bias in favor of Abbott of -0.05 log10 copies/ml with 95% limits of -0.80 to 1.02 (Figure 3A).

Comparison of VL between 5 and 6 Log10 copies/ml (100,000 to 1,000 000 copies/ml)

Comparative evaluation between both methods for values between

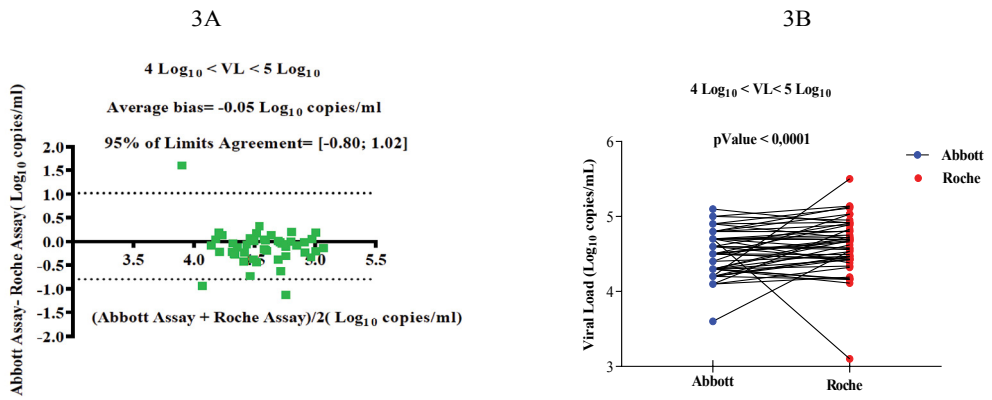

Figure 3: Analysis of the viral load (VL) when 4 Log10 < VL < 5 Log10 copies/ml with Bland-Altman Plot (A) and before-after scatter plot (B).

3A: The vertical axis represents the VL differences (the Abbott method minus the Roche method) per patient and the horizontal axis represents the means of VL per patient (Abbott method+Roche method/2). Each data point represents one of the paired 50 quantifiable plasma samples. The solid line indicates the mean difference between the values and the dotted lines indicates the mean (95% limits of agreement). The number of samples within this rang was 47 (94%).
3B: Analysis of the median VL between Abbott and Roche. The straight lines represent the VL correlation between Abbott method and Roche method. There is a concordance of 94%.

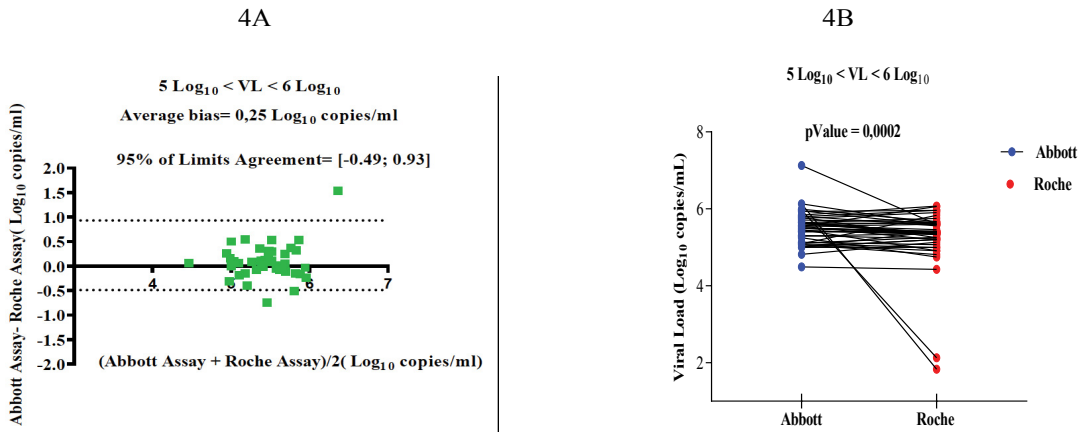

Figure 4: Analysis of the viral load (VL) when 5 Log_{10} < VL < 6 Log_{10} copies/mL with Bland-Altman Plot (A) and before-after scatter plot (B).

4A: The vertical axis represents the VL differences (the Abbott method minus the Roche method) per patient and the horizontal axis represents the means of VL per patient (Abbott method+Roche method/2). Each data point represents one of the paired 50 quantifiable plasma samples. The solid line indicates the mean difference between the values and the dotted lines indicates the mean (95% limits of agreement). The number of samples within this rang was 47 (94%).
4B: Analysis of the median VL between Abbott and Roche. The straight lines represent the VL correlation between Abbott method and Roche method. There is a concordance of 94%.

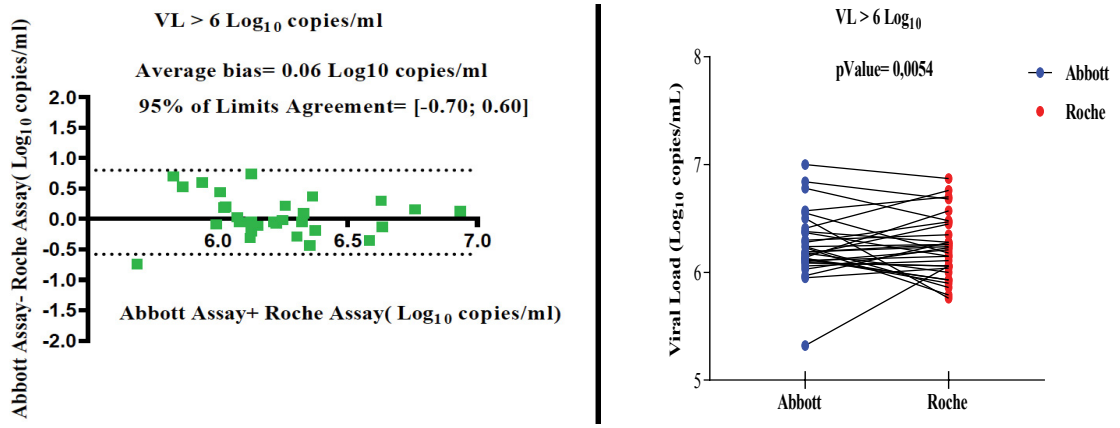

Figure 5: Analysis of the viral load (VL) greater than 6 Log_{10} copies/ml with Bland-Altman Plot (A) and before-after scatter plot (B).

5A: The vertical axis represents the VL differences (the Abbott method minus the Roche method) per patient and the horizontal axis represents the means of VL per patient (Abbott method+Roche method/2). Each data point represents one of the paired 31 quantifiable plasma samples. The solid line indicates the mean difference between the values and the dotted lines indicates the mean (95% limits of agreement). The number of samples within this rang was 30 (97%).
5B: Analysis of the median VL between Abbott and Roche. The straight lines represent the VL correlation between Abbott method and Roche method. There is a concordance of 97%.

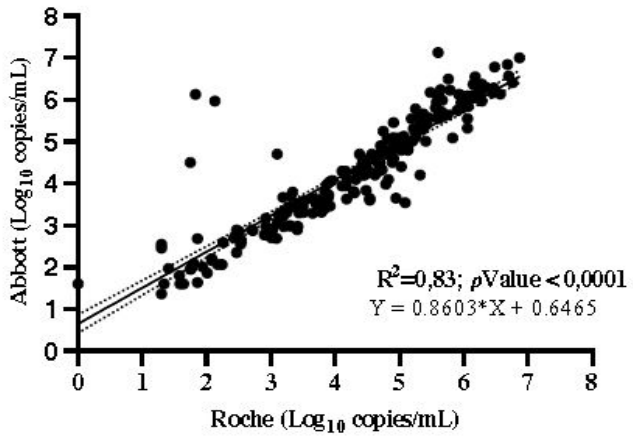

Figure 6: Regression analysis of the quantitative results of the plasma HIV-1 RNA Viral Load measured by the Abbott method (y-axis) and the Roche method (x-axis).

Each data point represents one of the paired 231 quantifiable plasma samples. The best fit for the regression analysis is indicated by the solid line. The equation of the fitted line and the Pearson coefficient of determination are presented on the plot. Two methods have 95% concordance; (R^2 = 0,83; *p* value < 0.0001); There is a dispersion of 5% (12/231).

5 log10 and 6 log10 copies/ml showed that there is 47/50 (94%) VL values which are in concordance and 3/50 (6%) VL values are divergent (Figures 4A and 4B). The Altman Bland method shows a positive bias in favor of Abbott of 0.25 log10 copies/ml with 95% limits of -0.49 to 0.93 (Figure 4A).

Comparison of VL greater than 6 Log10 copies/ml (>1,000 000 copies/ml)

A comparative evaluation between both methods for values > 6 log10 copies/ml showed that there is 30/31 (96.8%) VL values which are in concordance and 1/31 (3.2%) VL values are divergent not within the 95% confidence interval [-0,70; 0.60], with a positive bias for Abbott of 0.06 (Figures 5A and 5B).

Viral Load (VL) (Log_{10} copies/ml)	Concordance between the two methods		Bias (Log_{10} copies/ml)	IC %	*P* value
	n	%			
< 3 (N = 50)	49	98	-0.22	[-0.80; 1.24]	< 0.0001
3 – 4 (N = 50)	46	92	-0.20	[-0.56; 0 ;96]	< 0.0001
4 – 5 (N = 50)	47	94	-0.05	[-0.80; 1.02]	< 0.0001
5 – 6 (N = 50)	47	94	0.25	[-0.49; 0.93]	= 0.0002
> 6 (N = 31)	30	96.8	0.06	[-0.70; 0.60]	= 0.0054
Total (N = 231)	223	96.5	-0.05	[-1.11; 1.22]	< 0.0001

Table 1: Summary table of the comparison between Abbott m2000sp/m2000rt and Roche COBAS®Ampliprep/COBAS®Taqman® HIV-1 v2.0 for HIV-1 Viral Load (VL) measurement.

It should be noted that no clinically significant variation (0.5 Log10 copies/ml) was observed on any of the two platforms on the quantification ranges indicated (Bland-Altman analysis) and the scatter plot was confirmed before and after.

Overall comparison of VL by linear regression method

A dispersion of 3.5% (8/231) or 96.5% agreement between Abbott (m2000sp/m2000rt) and Roche (COBAS®AmpliPrep/COBAS®TaqMan®HIV-1v2.0) is found for all the VL values covering linearity from 1.6 to 7 Log10 copies/ml (40 to 10,000 000 copies/ml) (Table 1). In addition, the linear regression method shows that there is a strong correlation (R^2 = 0.83, P<0.0001) between the two methods for VL between 1.6 log10 to 7log10 copies/ml (Figure 6).

Discussion

More than 90% of new HIV infections occur in resource-limited

countries [21]. Hence, reaching the UNAIDS 90-90-90 target in these regions is critical to ending the HIV epidemics. Good availability of VL is a necessity in order to ensure appropriate treatment regimens. Incorrect or delayed VL measurement can lead to poor patient management. The evaluation of available VL techniques and their comparison is essential to implement appropriate and timely protocols in place. Indeed, the genetic diversity of HIV-1, PCR primers, amplicon revelation probes and the difference of the genomic regions of HIV target amplification are sources of discrepancies between different VL tests and must be taken into account when choosing a technique [22]. For these reasons, it is important to compare VL tests in order to better understand the impacts of different techniques to ensure appropriate patient management. Statistically significant concordance and linearity of results between two existing methods in a laboratory would allow the interchange of these techniques permitting a better VL availability. This is especially true in resource-limited countries where reagent and input failures jeopardize testing availability when relying on a single technique. Our study aimed to compare two reverse transcriptase real-time PCR assay for the quantification of HIV-1 RNA, namely the Roche COBAS®AmpliPrep/COBAS®TaqMan HIV-1 v2.0 and the Abbott m2000sp/m2000rt in real-time HIV-1.

Comparison of Viral Load Measurement Techniques

The comparison between the two techniques used 231 samples with detectable VL on both platforms. We also evaluated inter-assay comparability and linearity at variable VL thresholds (< 3 Log10, 3-4 Log10, 4-5 Log10, 5-6 Log10 and > 6 Log10 copies/ml). For VL <3 Log10 copies/ml, our results show a 98% concordance between Abbott (m2000sp/m2000rt) and Roche COBAS®AmpliPrep/COBAS®TaqMan®HIV-1v2.0. Further studies described a lower concordance than ours (95% concordance) when comparing the two platforms for samples<3 Log10 copies/ml in 14 sites in Europe, North America, and Africa [23]. Our comparison data using Bland Altman plots shows a negative bias of -0.22 Log10 in favor of Abbott (m2000sp/m2000rt). Another study has shown similar results with a positive bias of 0.2 in favour of Roche COBAS®AmpliPrep/COBAS®TaqMan®HI-1v2.0 (22). Biases of 0.3 and 0.33 Log10 copies/ml have been described for a comparison of the two platforms on subtypes B and C of HIV-1 [19,22]. The comparison of low VL<3 Log10 copies/ml is of clinical interest for HIV-1+ patients on ART. International recommendations for ART define viral suppression as a VL<1.7 Log10 (50) copies/ml. Virologic failure is defined by WHO as a VL > to 3 Log10 copies/ml after two consecutive measurements at three intervals after 6 months of ART [17]. Other groups set virologic failure as a VL > 2.6 Log10 copies/ml; > 2.3 Log10 copies/ml; > 1.7 Log10 copies/ml; > 1.68 Log10 copies/ml after viral suppression was achieved [18,24]. Thus, it is generally accepted that the increase in VL from<1.7 to 3 Log10 copies/ml in a patient with a prior undetectable VL corresponds to virologic failure.

The adequate measurement of VL<3 log10 copies/ml is a necessity to make good clinical decisions to limit resistance to ARVs. In view of our results, it is possible to follow on both platform patients with low viral load (< 3 log10).

Our comparison of the other intervals of VL showed a 92% concordance for VL ranging from 3 to 4 Log10; 96.8% for VL of 4 to 6 Log10 copies/ml; 94% for VL of 4 to 5 Log10; and 94% for VL of 5 to 6 Log10 copies/ml. The Bland Altman's analysis shows biases of -0.20; -005; 0.25 and 0.06 Log10 copies/ml respectively for the following VL intervals; 3 to 4 Log10, 4 to 5 Log10, 5 to 6 Log10 and > 6 Log10 copies/ml. Other studies found a concordance (difference<0.5 Log10) of 85% and a bias of 0.2 between Roche COBAS®AmpliPrep/COBAS®TaqMan®HIV-1v2.0 and Abbott m2000sp/m200rt [22,25]. Similar biases of 0.04 and -0.26 have been reported in samples from Luxembourg, Rwanda and Senegal [26]. Our results show a discrepancy ranging from 2 to 8% which are lower to than other results (14.9%) previously reported in the literature [27].

An overall comparison by linear regression showed us a correlation coefficient of $R^2 = 0.83$ for all VL between 1.6 to 7 Log10 copies/ml. This confirms the results described above and demonstrates that both methods interchangeable. Other studies obtained coefficients of 0.728 and 0.90 between the two methods for global VL values [19,28]. This correlation is variable according to the VL level, effectively, lower VL have a lower correlation between values [23]. Given these results, our study showed similar results between the two techniques. Based on this data we believe that both techniques are interchangeable. Allowing, a better follow-up of patients living with HIV-1 when only one of the platforms assess is functional.

However, there are a number of factors that may contribute to results discrepancy for viral loads, i.e., sample handling, contamination, or difference in PCR primers used [29]. In addition, intrinsic factors such as the target gene are involved in the sensitivity of these types of assays. Abbott technology is a real-time quantitative RT-PCR with a target located at the Pol/IN gene level and Roche technology is a real-time quantitative RT-PCR targeted at the Gag/LTR region of HIV-1. The volume of the test sample (0.6 ml for Abbott and 1.020 ml for Roche), the difference in precision of methods and variations in HIV-1 subtypes could potentially explain some of the discordant results. Studies have shown that the variability of HIV-1 subtypes and low VL levels contribute to the discordance between VL test results [19,22,28,30]. A recent comparison of Roche COBAS®AmpliPrep/COBAS®TaqMan®HIV-1 and Abbott m2000sp/m200rt on the quantification of A, B, and non-A/non-B genotypes yielded respective 0.089 biases; -0.262 and -0.298 [25]. The perspectives of our study would be to make a comparison between these methods on different HIV-1 subtypes and in particular on the genotype CRF02-AG highly represented in Senegal to have an idea on the concordance according to the genotype.

Conclusion

Our results demonstrate reproducibility and correlation between Roche COBAS®AmpliPrep/COBAS®TaqMan®HIV-1V.2.0 and Abbott m2000sp/m200rt; allowing interchangeability method for the VL quantification in people living with HIV. This information will improve the management of people living with HIV in Senegal through greater availability of plasma viral load testing. Further studies will be needed to evaluate the interchangeability of the two methods according to the circulating HIV-1 genotypes. Further studies would enable the selection of techniques according to a geographical region and its subtypes.

Acknowledgement

We would like to extend our acknowledgement to the US Department of Defense HIV/AIDS Prevention Program (DHAPP), GSSHealth and Africare for their precious collaboration to the AIDS Program of the Senegalese Armed Forces and the inscription of the laboratory in the Competency Assessment program for HIV Viral load.

References

1. https://www.unaids.org/en/resources/documents/2018/knowledge-is-power-report

2. https://www.unaids.org/en/resources/documents/2017/20170720_Global_AIDS_update_2017
3. Granich R, Williams B, Montaner J, Zuniga JM (2017) 90-90-90 and ending AIDS: Necessary and feasible. Lancet 390: 341-343.
4. Lepère P, Milleliri JM (2017) VIH: Rattraper le retard thérapeutique est une priorité en Afrique de l'Ouest et du Centre. Med Sante Trop 1: 1-2.
5. Batista G (2018) Enquete Nationale pour la determination des taux de retention aux soins des personnes vivant avec le VIH et autres indicateurs du programme VIH/SIDA. Dakar, Senegal.
6. Peeters M, Jung M, Ayouba A (2013) The origin and molecular epidemiology of HIV. Expert Rev Anti Infect Ther 11: 885-896.
7. Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, et al. (2011) Prevention of HIV-1 Infection with early antiretroviral therapy. N Engl J Med 365: 493-505.
8. Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, et al. (2016) Antiretroviral therapy for the prevention of HIV-1 transmission. N Engl J Med 375: 830-839.
9. Rouet F, Rouzioux C (2007) The measurement of HIV-1 viral load in resource-limited settings: how and where? Clin Lab 53: 135-148.
10. Fiscus SA, Cheng B, Crowe SM, Demeter L, Jennings C, et al. (2006) Forum for Collaborative HIV Research Alternative Viral Load Assay Working Group. HIV-1 Viral Load Assays for Resource-Limited Settings. PLoS Med 3: e417.
11. Chaiwarith R, Wachirakaphan C, Kotarathititum W, Praparatanaphan J, Sirisanthana T, et al. (2007) Sensitivity and specificity of using CD4+ measurement and clinical evaluation to determine antiretroviral treatment failure in Thailand. Int J Infect Dis 11: 413-416.
12. Reynolds SJ, Nakigozi G, Newell K, Ndyanabo A, Galiwongo R, et al. (2009) Failure of immunologic criteria to appropriately identify antiretroviral treatment failure in Uganda. AIDS 23: 697-700.
13. De Bel A, Marissens D, Debaisieux L, Liesnard C, Van den Wijngaert S, et al. (2010) Correction of underquantification of human immunodeficiency virus type 1 load with the second version of the Roche Cobas AmpliPrep/Cobas TaqMan assay. J Clin Microbiol 48: 1337-1342.
14. Gueudin M, Plantier JC, Lemée V, Schmitt MP, Chartier L, et al. (2007) Evaluation of the Roche Cobas TaqMan and Abbott RealTime extraction-quantification systems for HIV-1 subtypes. J Acquir Immune Defic Syndr 44: 500-505.
15. Swanson P, De Mendoza C, Joshi Y, Golden A, Hodinka RL, et al. (2005) Impact of human immunodeficiency virus type 1 (HIV-1) genetic diversity on performance of four commercial viral load assays: LCx HIV RNA Quantitative, Amplicor HIV-1 Monitor v1.5, Versant HIV-1 RNA 3.0, and NucliSens HIV-1 QT. J Clin Microbiol 43: 3860-3868.
16. Damond F, Roquebert B, Benard A, Collin G, Miceli M, et al. (2007) Human Immunodeficiency Virus Type 1 (HIV-1) Plasma Load Discrepancies between the Roche Cobas Amplicor HIV-1 Monitor Version 1.5 and the Roche COBAS AmpliPrep/Cobas TaqMan HIV-1 Assays. J Clin Microbiol 45: 3436-3438.
17. https://www.who.int/hiv/pub/arv/arv-2016/en/
18. https://aidsinfo.nih.gov/contentfiles/AdultandAdolescentGL003510.pdf
19. Scott L, Carmona S, Stevens W (2009) Performance of the New Roche Cobas AmpliPrep-Cobas TaqMan Version 2.0 human immunodeficiency virus type 1 assay. J Clin Microbiol 47: 3400-3402.
20. Huang S, Salituro J, Tang N, Luk KC, Hackett J, et al. (2007) Thermodynamically modulated partially double-stranded linear DNA probe design for homogeneous real-time PCR. Nucleic Acids Res 35: e101.
21. Altman DG, Bland JM (1983) Measurement in medicine: The analysis of method comparison studies. Stat 32: 307.
22. Bourlet T, Signori-Schmuck A, Roche L, Icard V, Saoudin H, et al. (2011) HIV-1 load comparison using four commercial real-time assays. J Clin Microbiol 49: 292-297.
23. Swenson LC, Cobb B, Geretti AM, Harrigan PR, Poljak M, et al. (2014) Comparative performances of HIV-1 RNA load assays at low viral load levels: Results of an international collaboration. J Clin Microbiol 52: 517-523.
24. Churchill D, Waters L, Ahmed N, Angus B, Boffito M, et al. (2016) British HIV Association guidelines for the treatment of HIV-1-positive adults with antiretroviral therapy 2015. HIV Med 17: S2-S104.
25. Katsoulidou A, Rokka C, Issaris C, Haida C, Tzannis K, et al. (2011) Comparative evaluation of the performance of the Abbott RealTime HIV-1 assay for measurement of HIV-1 plasma viral load on genetically diverse samples from Greece. Virol J 8: 10.
26. Karasi JC, Dziezuk F, Quennery L, Förster S, Reischl U, et al. (2011) High correlation between the Roche COBAS® AmpliPrep/COBAS® TaqMan® HIV-1, v2.0 and the Abbott m2000 RealTime HIV-1 assays for quantification of viral load in HIV-1 B and non-B subtypes. J Clin Virol 52: 181-186.
27. Liang DJN, Richard Y, Zhao HA, Adkins H, Zhao RY (2010) Comparison of HIV-1 Viral Load between Abbott m2000 and Roche COBAS TaqMan Methods. J Antivir Antiretrovir 2: 1-4.
28. Amendola A, Marsella P, Bloisi M, Forbici F, Angeletti C, et al. (2014) Ability of two commercially available assays (Abbott RealTime HIV-1 and Roche Cobas AmpliPrep/Cobas TaqMan HIV-1 Version 2.0) to quantify low HIV-1 RNA levels. J Clin Microbiol 52: 2019-2026.
29. Gatanaga H, Tsukada K, Honda H, Tanuma J, Yazaki H, et al. (2009) Detection of HIV type 1 load by the Roche Cobas TaqMan assay in patients with viral loads previously undetectable by the Roche Cobas Amplicor Monitor. Clin Infect Dis 48: 260-262.
30. Wirden M, Tubiana R, Marguet F, Leroy I, Simon A, et al. (2009) Impact of discrepancies between the Abbott realtime and cobas TaqMan assays for quantification of human immunodeficiency virus type 1 group M non-B subtypes. J Clin Microbiol 47: 1543-1545.