Analysis Of Prevalence Of Patients Living With The HIV Vírus (PLHIN) With Undetectable Viral Load After Genotyping Realized By Previous Therapeutic Failure

Análise Da Prevalência De Pacientes Que Vivem Com HIV Indetectáveis Pós-genotipagem Realizada Por Falha Terapêutica Prévia

Análisis De La Prevalencia de Pacientes Que Viven Con VIH Indetectable Postgenotipación Realizada Por Falla Terapéutica Previa

RESUMO

A genotipagem é um exame utilizado para detectar mutações específicas que eram resistência aos antirretrovirais do tratamento padrão dos pacientes vivendo com o vírus HIV (PVHIV) após a confirmação da carga viral maior que 500 cópias/mL após 6 meses de correta aderência à TARV. Objetivo: Avaliar a prevalência de pacientes que vivem com HIV indetectáveis após a realização de genotipagem feita por falha virológica prévia. Método: Trata-se de um estudo transversal, de abordagem quantitativa,totalizando 691 prontuários de PVHIV. Resultados e Discussão: De toda a amostra analisada (n=691), 160 pacientes tiveram a indicação formal de realização de genotipagem por falha terapêutica prévia, no entanto, apenas 69 realizaram-na, dos quais 13 pacientes obtiveram indetectabilidade de carga após a mudança farmacológica indicada pelo exame. A principal indicação de genotipagem pós-tratamento em PVHIV é a falha terapêutica. Esta, por sua vez, advém – em sua maioria – da má adesão terapêutica dos pacientes. A importância da genotipagemem PVHIV detectáveis centra-se além do paciente per se, mas tem uma notória relevância epidemiológica, relacionando-se com a instransmissibilidade em pacientes indetectáveis.

DESCRITORES: HIV; Genotipagem; Indetectável; Falha; Terapêutica.

ABSTRACT

Genotyping is a test used to detect specific mutations that were resistant to antiretrovirals in the standard treatment of patients living with HIV (PLHIV) after confirmation of a viral load greater than 500 copies/mL after 6 months of correct adherence to ART. Objective: To assess the prevalence of patients living with undetectable HIV after genotyping due to previous virological failure. Method: This is a cross-sectional study with a quantitative approach, totaling 691 medical records of PLHIV. Results and Discussion: Of the entire sample analyzed (n=691), 160 patients had a formal indication for genotyping due to previous treatment failure; however, only 69 underwent it, of which 13 patients achieved undetectable load after the pharmacological change indicated by the test. The main indication for post-treatment genotyping in PLHIV is treatment failure. This, in turn, comes – in most cases – from poor therapeutic adherence of patients. The importance of genotyping in detectable PLHIV focuses beyond the patient per se, but has a notable epidemiological relevance, relating to non-transmissibility in undetectable patients.

DESCRIPTORS: HIV; Genotyping; Undetectable; Failure; Therapy.

RESUMEM

El genotipado es un examen utilizado para detectar mutaciones específicas resistentes a los antirretrovirales en el tratamiento estándar de pacientes que viven con el virus VIH (PVVIH) después la confirmación de una carga viral superior a 500 copias/mL después de 6 meses de correcta adherencia al TARV. Objetivo: Evaluar la prevalencia de los pacientes que viven con VIH indetectable después de un genotipado realizado por falla virológica previa. Método: Se trata de un estudio transversal, con enfoque cuantitativo, con un total de 691 historias clínicas de PVVIH. Resultados y Discusión: De toda la muestra analizada (n=691), 160 pacientes tuvieron indicación formal de genotipado por fracaso terapéutico previo, sin embargo, sólo 69 lo realizaron, de los cuales 13 pacientes alcanzaron carga indetectable luego del cambio de valoración farmacológica indicado por el examen. La principal indicación para el genotipado postratamiento en personas que viven con el VIH es el fracaso del tratamiento. Esto, a su vez, surge –en su mayor parte– de la mala adherencia terapéutica de los pacientes. La importancia del genotipado en personas que viven con el VIH detectables va más allá del paciente per se, pero tiene una relevancia epidemiológica notable, relacionada con la no transmisibilidad en pacientes indetectables.

DESCRIPTORES: VIH; Genotipado; Indetectable; Falla; Terapia.

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Letícia Fernanda da Silva
Medical student State. University of Ponta Grossa, Brazil
ORCID: https://orcid.org/0009-0003-3470-6458

Felício de Freitas Netto
Medical Graduate. State University of Ponta Grossa, Brazil
ORCID: https://orcid.org/0000-0002-1274-1979

Fabiana Postiglione Mansani
PhD in Biochemical Sciences. State University of Ponta Grossa, Brazil
ORCID: https://orcid.org/0000-0002-2156-1953

Thiago Martins Figueiredo
Medical Graduate. State University of Ponta Grossa, Brazil
ORCID: https://orcid.org/0000-0002-1718-2352

Eduardo Machado Dechandt
Medical Graduate. State University of Ponta Grossa, Brazil
ORCID: https://orcid.org/0009-0008-6253-8902

INTRODUCTION

In 2022, according to UNAIDS, the estimated number of people living with HIV (PLHIV) in the world is 39 million, of which 29.8 million are on antiretroviral treatment (ART); 1.3 million of them correspond to new cases of HIV infection and approximately 630 thousand died from Acquired Immunodeficiency Syndrome (AIDS), an advanced stage of the disease. Within this same data analysis, in Brazil, the estimate in 2022 would be 990 thousand Brazilians living with HIV; of these, 723 thousand would be on ART; 51 thousand Brazilians were newly diagnosed with HIV infection and 13 thousand of them died from AIDS-related diseases. (UNAIDS, 2022).

In view of this public health problem, UNAIDS has been setting targets to reduce new HIV infections in conjunction with the United Nations Sustainable Development Goals. Currently, UNAIDS has titled the report "The Path to Ending AIDS", in which the objective is for countries that are part of the United Nations (UN) to achieve the 95-95-95 target by 2030, through financial investments, gender equality, non-discriminatory laws and by encouraging community care and support networks. The 95-95-95 target aims for 95% of people living with HIV to know their diagnosis, 95% of people diagnosed with HIV to be on ART and, finally, for 95% of PLHIV on ART to have an undetectable viral load. (UNAIDS, 2022)

In Brazil, ART – since 1996 – has been guaranteed by the Unified Health System (SUS - Sistema Único de Saúde) under Law No. 9,313 (ADRIANO, 2008). The diagnosis and treatment of PLHIV are covered by the Specialized Care Service (SCS), an outpatient care unit with a multidisciplinary team that offers the recommended testing for sexually transmitted infections (STIs), including HIV, and performs the recommended diagnostic-therapeutic follow-up for the respective disease, in addition to providing longitudinal care to patients. (MINISTRY OF HEALTH, 2018)

HIV is a public health problem that requires specific and continuous treatment with antiretrovirals, which, according to the Clinical Protocol and Therapeutic Guidelines for the Management of HIV Infection, should be initiated in all patients diagnosed with the disease and aims to reduce the viral load to undetectability within six months after starting ART.

Currently, for the general Brazilian population, ART consists of three medications: tenofovir (TDF) and lamivudine (3TC) in 1 fixed-dose combination tablet (DFC); and dolutegravir (DTG), totaling two tablets taken continuously daily. After six months of starting treatment, the goal is for the patient to become undetectable, that is, with no evidence of the virus in

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the viral load test performed by the polymerase chain reaction (PCR) methodology. When, after this period, the viral load is still detected in the patient's serum sample, virological failure is defined, the main cause of which is poor medication adherence. Post-treatment genotyping is then indicated for PLHIV with a detectable viral load and quantified at at least 500 copies/mL after six months of starting ART, according to the guidelines of the Ministry of Health. (MINISTRY OF HEALTH, 2018)

In this sense, the present study is justified given the importance of recognizing virological failure in PLHIV, since its main cause is poor adherence to the proposed treatment, such that detectable patients are transmissible, perpetuating the transmissibility cycle of a virus with notorious harmful capacity to human beings.

In view of this, with the data collected such as age, gender, sexual orientation, type of transmission, viral load before genotyping and new therapeutic method, the study aims to evaluate the prevalence of HIV genotyping in the Campos Gerais region, as well as the reasons why genotyping is performed, such as therapeutic failure and the prevalence of undetectable patients after a therapeutic change that motivated genotyping.

MATERIALS AND METHODS

This is a cross-sectional, observational study with a quantitative approach, carried out based on data collected from medical records and the Notification Form of PLHIV treated at the Specialized Assistance Service in the city of Ponta Grossa - Paraná, with a diagnosis of infection between January 2015 and December 2021. The work was approved by the Research Ethics Committee (CEP) of the State University of Ponta Grossa (UEPG) under number 5,475,114 and CAAE 58774422.9.0000.0105.

Data collection took place between August and October 2022 from the AIDS Report System of the Ministry of Health (MS), totaling 691 medical records and from these, a survey of sociodemographic variables, year of diagnosis of HIV infection, current ART regimen, CV and LTCD4+ exams and co-infections was carried out. The data were tabulated in a Microsoft Excel 2016 spreadsheet.

For statistical analysis, a descriptive analysis of the data was first performed with simple and relative frequency, estimates of mean, median, standard deviation and interquartile range.

RESULTS

The sample (n=691) of the present study is composed of patients diagnosed with HIV registered at the Specialized Assistance Service/Testing and Counseling Center (SAE/CTA) of Ponta Grossa - PR between January 2015 and December 2021. The analysis began through two sociodemographic variables: sexual orientation and gender identity. Of those affected by the disease, 59.04% had heterosexuality as their sexual orientation, 26.48% were homosexual, followed by 5.35% bisexual. Regarding gender identity, the majority of the sample was male (58.61%), while the percentage of infected women was 31.84%, while 0.14% of those infected did not identify with any gender and 9.41% did not inform their identity. These data are illustrated for better visualization in Table 1.

Table 1 – Descriptive analysis of sociodemographic variables. Ponta Grossa/PR – BR – 2015 to 2021

Variable		N	%	CI (95%)	
				Inf	Sup
Sexual OR	*Bissexual*	*37*	*5,35*	*3,91*	*7,29*
	Heterosexual	*408*	*59,04*	*55,34*	*62,65*
	Homosexual	*183*	*26,48*	*23,33*	*29,90*
	Uninformed	*63*	*9,12*	*7,19*	*11,50*
Gender ID	*Man*	*405*	*58,61*	*54,90*	*62,23*
	Woman	*220*	*31,84*	*28,47*	*35,40*
	No	*1*	*0,14*	*0,026*	*0,82*
	Uninformed	*65*	*9,41*	*7,45*	*11,81*

OR: Sexual orientation; ID: Gender identity; CI: confidence interval
SOURCE: Silva, Vaccari, Netto, Marcondes, Mansani, Donatoni (2023).

Table 2 shows the percentage analysis of patients who underwent genotyping (9.99%). It also includes the percentage of patients who underwent specific analyses in this test. Of the total number of PLHIV who underwent the aforementioned test (9.99% of the total), 4.49% underwent analysis for mutations in the protease and 2.46% were analyzed for mutations in the reverse transcriptase enzyme. Table 2 also shows the percentage of these patients who changed ART after genotyping, with 149 (21.56%) patients undergoing the change, while 524 (75.83%) did not undergo this change.

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Table 2 – Descriptive analysis of exams. Ponta Grossa/PR – BR – 2015 to 2021

Variable		N	%	CI (95%)	
				Inf	Sup
Medication change	*No*	*524*	*75,83*	*72,50*	*78,88*
	Yes	*149*	*21,56*	*18,66*	*24,78*
	Uninformed	*18*	*2,60*	*1,65*	*4,08*
Genotyping	*No*	*601*	*86,98*	*84,26*	*89,28*
	Yes	*69*	*9,99*	*7,97*	*12,45*
	Uninformed	*21*	*3,04*	*2*	*4,60*
Genotyping type	*Protease: no*	*632*	*91,46*	*89,14*	*93,32*
	Protease: yes	*31*	*4,49*	*3,18*	*6,30*
	Protease: NI	*28*	*4,05*	*2,82*	*5,79*
	RT: no	*632*	*91,46*	*89,14*	*93,32*
	RT: yes	*17*	*2,46*	*1,54*	*3,90*
	RT: NI	*42*	*6,08*	*4,53*	*8,11*
TCD4 last test	*Detectable*	*423*	*61,22*	*57,53*	*64,78*
	Undetected	*203*	*29,38*	*26,10*	*32,88*
	Not carried out	*1*	*0,14*	*0,026*	*0,82*
	Uninformed	*64*	*9,26*	*7,32*	*11,65*

SOURCE: Silva, Vaccari, Netto, Marcondes, Mansani, Donatoni(2023).

Table 3 shows the descriptive analysis of the viral load test in two periods: pre- and post-genotyping. Of the 691 patients analyzed, 160 (23.15%) were included in the pre-genotyping detectability group, 454 (65.70%) had an undetectable viral load, 76 (10.99%) did not have their viral load reported in the analyzed medical records and, finally, 1 patient (0.14%) did not perform the test in the period studied. Of the 160 detectable PLHIV patients, 69 (9.99%) underwent the genotyping test and 39 of them (56.52% in relation to the total genotyping tests performed) underwent the viral load test, of which 13 patients (33.34% in relation to the total viral load tests) obtained a detectable viral load and 26 (66.66%) achieved undetect-

Table 3 – Descriptive analysis of viral load pre and post-genotyping. Ponta Grossa/PR – BR – 2015 to 2021

Variable		N	%	CI (95%)	
				Inf	Sup
Pre-genotyping viral load	*Detectable*	*160*	*23,15*	*20,16*	*26,44*
	Undetected	*454*	*65,70*	*62,08*	*69,15*
	Not carried out	*1*	*0,14*	*0,026*	*0,82*
	Uninformed	*76*	*11*	*8,88*	*13,55*
Post-genotyping viral load	*Detectable*	*13*	*1,88*	*1,10*	*3,19*
	Undetected	*26*	*3,76*	*2,58*	*5,46*
	Undetected	*652*	*94,36*	*92,38*	*95,84*

SOURCE: Silva, Vaccari, Netto, Marcondes, Mansani, Donatoni(2023).

DISCUSSION

The first case of HIV infection in Brazil was recorded in the 1980s. In 1996, Brazil was the first developing country to offer free ART to the population with HIV and low CD4+ T cell counts, so much so that since 2015, ART has been offered to all people living with HIV, regardless of lymphocyte quantification. Antiretroviral treatment is provided and guaranteed by the SUS, with access assured by Law No. 9,313, associated with the Brazilian HIV/AIDS Program. (BENZAKENet al, 2019)

Due to national strategies to address this public health problem, Brazil is among the developing countries progressing towards meeting the UNAIDS 90-90-90 target, which in 2023 was changed to the 95-95-95 target, to be achieved by 2030 (UNAIDS, 2023). Currently, Brazil has reached the following percentage numbers: 88% of people with HIV know their diagnosis; 83% of diagnosed PLHIV are on ART; and 95% of these have an undetectable viral load; according to the global report released by UNAIDS in July 2023. (UNAIDS, 2023)

In this sense, the present study identified that of the 691 PLHIV analyzed, 160 would need to undergo genotyping due to previous treatment failure; however, a minority of these patients were, in fact, subjected to the test. Of the patients who underwent post-treatment genotyping due to virological failure, it was found that the majority of them continued to have a detectable viral load.

This can be explained by the persistence of the habit of non-adherence to medication, the main cause of virological failure in PLHIV in Brazil. This habit is closely related to psychosocial factors that determine the withdrawal of medications from dispensing pharmacies, causing patients not to do so due to feelings of shame, regret and irrelevance in the face of their diagnosis. (GUTIÉRREZ et al, 2019)

From this perspective, stigma towards PLHIV directly influences adherence to ART. Since 1996, the Brazilian Constitution has ensured that these patients have their rights guaranteed through the publication of the Declaration of Fundamental Rights of Persons Living with the HIV Virus. In this

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document, patients living with HIV are assured of having exact and specific knowledge about their diagnosis and access to ART. In addition, these patients cannot suffer isolation due to discriminatory causes and have the right to participate in all aspects of social life, among other points of biopsychosocial relevance. However, few PLHIV are aware of this excerpt from the Brazilian Constitution, a factor that reflects the inequality and inequity of these patients compared to the general population. (MINISTRY OF HEALTH, 2022)

In 2016, a randomized controlled trial was conducted in PLHIV in seven sites supported by the Health Management and Development HIV Care and Treatment Program in Tanzania. The sample consisted of 3,418 non-pregnant and non-lactating PLHIV, aged over 18 years, with a mean age of 37 years, 70% female and 30% male. These patients underwent monthly viral load collection, considering a cut-off of over 1,000 copies/mL as virological failure, a group to which 14.9% of the patients analyzed were allocated (HAWKINS et al, 2016).

It is possible to observe a discrepancy in the parameters used between this study and the research carried out in Tanzania, justifying the need for further studies on genotyping in patients with HIV, as well as their post-genotyping follow-up. In addition, it is worth highlighting that, in Brazil, detectable PLHIV will only undergo genotyping, in the SUS, if the load quantification is greater than 500 copies/mL. (MINISTRY OF HEALTH, 2018) In a recent study carried out by Henerico et al, and published in 2022, 326 people living with HIV treated at the Bugando Medical Center were analyzed.

Virological failure was considered to be a viral load greater than 1,000 copies/mL, a parameter distinct from this study. Of the total number, 97.5% had their viral load analyzed, of which 20.2% presented a result greater than 1,000 copies/mL, of which 87.5% of those detectable underwent genotyping and more than 80% had some mutation found. It is emphasized that 57.4% of these patients had been on ART for more than 5 years. (HENERICO et al, 2022)

Between 2011 and 2012, in Kenya, an analytical study was carried out on virological failure and subsequent genotyping in PLHIV, which – in this case – was indicated for detectable patients, whose viral quantification was greater than 1,000 copies/mL, a criterion contrasting with that of this study. The sample of Kantor et al included 394 people, aged over 18 years, with an average age of 42 years, 60% women and 40% men. Of the total number, 189 had a detectable viral load according to the stipulated parameters. A total of 105 patients underwent genotyping, that is, 84 detectable patients did not have their possible mutational pathways of antiretrovirals analyzed. Of the genotyped patients, 79% had identified pharmacological resistance. (KANTOR et al, 2018)

From the above, it is possible to perceive the scarcity and non-uniformity of the parameters evaluated to define detectable and undetectable patients in the international literature regarding the care of PLHIV. In Brazil, there is a lack of consolidated data for a solid comparative analysis on this topic, justifying the importance of this research carried out in the Campos Gerais region, since the initiation of studies on this topic tends to motivate other researchers to deepen their knowledge, thus contributing to the better care of patients living with HIV.

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