

Relationship between the Conservation of Medications and Virological Failure in HIV Positive Patients in a Health Care Institution at the Colombian Orinoquia and Amazonia

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Abstract

Introduction: The HIV-AIDS pandemic remains a scientific and political challenge worldwide. Antiretroviral treatment has decreased the development of AIDS among those who are HIV+. However, psychosocial barriers may impair proper treatment for HIV+ patients. Psychosocial barriers are related to treatment, patient, health system access and health team characteristics.

Objective: Establish the relationship between the medication storage and psychosocial barriers in HIV positive patients with virological failure in a health provider institution in the Colombian Orinoquia and Amazonia.

Materials and Methods: Cross-sectional study with descriptive analysis was carried out for the relationship between the preservation of medications: chi-square or Fisher. Subjects were patients treated in a health care institution.

Results: Virological failure prevalence is 31.6%: 47.95% poor medication storage, 20.55% do not have electricity, 49.32% did not use or did not have a refrigerator. A relationship of all psychosocial barriers was found to be related to poor medication storage; significant: "exhaustion, having to take the medication very often" 89.47%; "barriers to transportation to the healthcare institution" 42.11%. For those who conserved medication, the median hours of energy was: 4 hours ($p = 0.000$).

Conclusion: A relationship was found between medications storage and available hours of electrical power, psychosocial barriers are related to poor medication storage in these patients with virological failure. It is important to explore the prevalence of virological failure and characteristics related to these barriers, nationally and internationally.

Keywords: Virological Failure; HIV-AIDS Pandemic; HIV+ Patients

Abbreviations

HIV: Human Immunodeficiency Virus; AIDS: Acquired Immunodeficiency Syndrome; IPS: Health Provider Institution; Gp120: Glycoprotein 120; Gp41: Glycoprotein 41; CD4: Cluster of Differentiation 4; DNA: Deoxyribonucleic Acid; RNA: Ribonucleic Acid; Gag: Gen-Specific Antigen; Pol: Pol Gene (Polymerase); Env: Gen Env (Envelope); Tat: Trans-Activator of Transcription; rev: Regulator of Virion; vif: Viral Infectivity Factor; vpr: Viral Protein R; vpu: Virus Protein U; vpx: Virus Protein for HIV-2; UN: United Nations; ART: Anti-Retroviral Treatment; CV: Viral Load

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Introduction

The human immunodeficiency virus (HIV) is a retrovirus that infects humans and is responsible for acquired immunodeficiency syndrome (AIDS), which is a condition in which the immune system is weakened, leaving it prone to opportunistic infectious diseases. HIV disease is caused by infection with HIV-1 or HIV-2, which are retroviruses of the Retroviridae family, genus *Lentivirus* [1,2].

Lentivirus (from Latin *lentus* "slow") is a genus of the Retroviridae family that has the essential characteristics of having a long incubation period and being cytopathogenic; causing slow progression of the disease, an ultimately killing the cells it infects [1]. They are enveloped viruses that require sexual contact between infected organisms for transmission to occur, or can also cause infection through other routes such as: blood, semen, breast milk, vaginal secretions, and vaginal canal contact. Spherical in shape, they have a diameter that ranges between 80 and 100 nanometres. They are composed of: of various proteins (60%) that mainly form its structure, lipids (35%), carbohydrates (3%), nucleic acid that constitutes the genome (2%). Generally, four structural genes are present in the lentivirus genome: *gag*, *pro*, *pol*, *env* [3]. Lentiviruses mainly infect cells of the immune system and have the particularity of being able to cross the species barrier.

HIV-1 is a spherical virus with an average diameter of 145 nanometres [4]. Like many viruses that infect animals, it has an envelope made up of a fragment of the infected cell's membrane. Envelope glycoprotein trimers (*Env*) are inserted into this lipid envelope. Each *Env* protein is composed of 2 subunits: a *gp120* surface subunit and a *gp41* transmembrane subunit. On the cell membrane, the *Env* protein *gp120* binds to a CD4 receptor found on the surface of CD4 + cells [5]. It is for this reason that HIV only infects cells with this receptor on its surface, which are overwhelmingly CD4 + lymphocytes.

Inside the envelope there is a protein matrix (*MA*) made up of *p17* proteins and the capsid (*CA*) made up of *p24* proteins. It is the latter type of protein that, together with *gp41* and *gp120*, are used in HIV Western blot tests. The *p7* nucleocapsid (*NC*) proteins protect the viral RNA by covering it. The *p6* protein is excluded from the capsid and is located between the matrix and the capsid, it allows the budding of newly formed viruses in the cell [6]. The HIV genome, contained in the capsid, consists of a single duplicate strand of RNA, accompanied by enzymes that are essential for its infection and replication [7]. For example, reverse transcriptase catalyses the passage of RNA and DNA, integrase is important for integrating viral DNA with the cell's genome, and protease is related to virion maturation. These three enzymes are the main targets of antiretroviral therapy because they are specific to retroviruses.

The HIV genome is made up of nine genes. The main three are *gag*, *pol* and *env*, which define the structure of the virus and are common to all retroviruses. The other six genes are *tat*, *rev*, *nef*, *vif*, *vpr*, and *vpu* (or *vpx* for HIV-2), which encode regulatory proteins [8]. The AIDS pandemic has caused the death of approximately 32 million people between 1981 and 2018. It is estimated that around 1% of people aged 15 to 49 are infected with HIV, predominantly sub-Saharan Africa [9].

Regarding Colombia, according to UNAIDS, prevalence for an HIV+ diagnosis remains at 160,000 people, with 1.2% being sex workers, 17% being men who have sex with men, of which 26.3% knew of their diagnosis. This seroprevalence data was taken in 7 cities of the country. In 2014 a prevalence of 2.8% was found in IV drug users, and 21% in transgender people [9]. Colombia is a very unique country with several different topographical regions, each separate region displaying significant cultural and socio-anthropological differences. First hand experience as healthcare providers serving the people of the Colombian plains or Llanos, as well as the people of the Amazon has allowed us a unique understanding of some of the cultural beliefs of this population. A large amount of these local populations live encapsulated, and culturally isolated from mainstream culture, with widespread ignorance in regards to how medical treatments work, or how to properly store medication. A common finding has been improper storage of therapeutic agents, which when paired with the extreme temperatures that are frequent in these regions may lead to premature degradation of medication. Likewise, other psychosocial barriers may also play a role as a barrier for proper drug storage, and as a barrier to treatment compliance for these patients. Our objective is to understand such barriers and to try to quantify how many patients have suffered virological failure related to these factors. There is

no current data on these variables for these populations. However, it is worth highlighting the work of Robbins., *et al.* 2010, where in their intention to validate a predictive instrument of virological failure, they took variables such as: suboptimal adherence, CD4 count < 100/μL, drug and alcohol abuse, unpleasant experience with ART, absent ≥ 1 medical appointment, history of virological failure [10]. A study in 2018 in Ethiopia found a prevalence of virological failure in 14.7%, and these looked for the association with variables such as: age, marital status, reason for drug change, CD4 count [11]. Another study from the same year and the same country studied virological failure (prevalence found 10.5%) versus variables such as: low income, absence of social support, interruption of ART, adherence, dysfunctional work status, WHO stage III and IV, con- infection with tuberculosis [12]. The Colombian guideline for the management of AIDS establishes that there is a greater risk of suffering virological failure when the viral load is above 10,000 copies. Regarding these numbers, we did not find the association of factors versus virological failure, but rather related it to compliance with treatment. The variables were: depression, use of alcohol and psychoactive drugs, young age, having a household with many members, female sex, knowledge and limited educational level, unstable home and homelessness, doctor's visits, ability to name their medicines [13].

Objectives of the Study

General objective

Establish the relationship between storage/conservation of medications and psychosocial barriers in HIV-positive patients with virological failure in a health care institution in the Colombian Amazonia and Orinoquia between January 2018 and December 2019.

Specific objectives:

- a) Identify HIV-positive patients with virological failure who were treated at the healthcare institution.
- b) Characterize the population of HIV positive patients with virological failure treated at the healthcare institution.
- c) Determine the relationship between medications storage and the psychosocial barriers for treatment, for the patient, for the health system and for the healthcare team.

Materials and Methods

Research design

The research design corresponds to a cross-sectional study of patients treated in a health provider institution in the Orinoquia and Colombian Amazon treated between January 2018 and December 2019.

HIV positive patients in a healthcare institution in the Colombian Orinoquia and Amazonia between January 2018 and December 2019.

Data collection

The data were taken retrospectively, looking for patients with virological failure (if in the period analysed, the patient has a failure twice, the first case of failure will be counted), taking patients with a viral load ≥ 1000 copies/mL.

We searched the clinical history for data on psychosocial barriers present (defined below) at the time of virological failure.

The psychosocial barriers analysed will be related to:

1. Barriers related to treatment:

- a. Difficulty taking pills
 - b. Side effects
 - c. Unpleasant sensation from the medication
 - d. Restrictions during treatment
 - e. Exhaustion due to medication use
 - f. Forgetfulness in taking medications
 - g. Medication need
 - h. Non-existence of disease.
2. Factors related to the patient:
- a. Clinic Control attendance
 - b. Limitation when sharing with others (patient's trustworthiness???)
 - c. Feelings of anger towards the disease
 - d. Diagnosis denial
 - e. Patient's support system
 - f. do not care about the improvement of the disease (lack of desire to get better).
3. Factors related to the provider (healthcare system and team):
- a. Explanation by the attending physicians
 - b. Medication management information
 - c. Supply of antiretroviral drugs
 - d. Vulnerability of information in diagnosis and reservation of clinical history
 - e. Knowledge of clinical controls dates
 - f. Information through simple words
 - g. Treatment by healthcare staff
 - h. Transportation from home to healthcare institution
 - i. Difficulty in taking exams.

In the same way, the poor preservation of medicines was studied taking into account the patient’s conditions in terms of access to electrical power, absence of a refrigerator or the non-use of it, and available hours of electrical power per day.

Statistical analysis

Univariate analysis was performed with absolute frequencies and relative frequencies for the nominal qualitative variables and measures of central tendency and dispersion for the quantitative variables. The chi-square or Fisher test was used to analyse the relationship between drug preservation. Median CD4, CV and hours of electrical energy of patients with and without medication conversation were compared with the Mann-Whitney test. Statistically significant tests were considered if the p-value was less than 0.05.

Results

Virological failure prevalence

The total number of patients enrolled in the program in the time investigated was 231 patients, of which 73 cases of virological failure were found; equivalent to a prevalence of 31.60% (Table 1).

		Virological failure prevalence
Number of cases	73	
Total N	231	31.60%

Table 1: Virological failure prevalence.

General characteristics of patients with virological failure.

It was found that 49.32% of the causes of virological failure were due to the absence of cold chain preservation, followed by 47.95% of the reported failures due to poor medication conservation; furthermore, the storage of medicines in general with 50.68% is carried out in the refrigerator, followed by 12.33% in the room and, to a lesser extent, 10.95% in the Styrofoam refrigerator. Shown in table 2.

Virological failure patients	Total (n = 73)
	% (n)
Poor conservation of medications	47,95 (35)
No access to electricity	20,55 (15)
No use or no fridge	49,32 (36)
CD4 at the date of virologic failure, median (Quartile 1 - quartile 3)	292 (178 - 467)
Viral Load at the date of virologic failure, median (Quartile 1 - quartile 3)	10336 (4197 - 36873)
Hours per day with electricity	24 (4 - 24)
Medication storage	
Fridge	50,68 (37)
Room	12,33 (9)
Styrofoam icebox	10,95 (8)
Clay pot	9,59 (7)
Drawer	1,44 (3)

Bedside table	2,74 (2)
Purse	1,37 (1)
Wardrobe	1,37 (1)
Freezer	1,37 (1)
Under the bed	1,37 (1)
Inside a pot	1,37 (1)
In a jar underground	1,37 (1)
Personal suitcase or bag	1,37 (1)

Table 2: General characteristics of patients with virological failure, n = 73.

Psychosocial barriers to medication

Described barriers were difficulty taking medicine, side effects, unpleasant taste, restriction during treatment, exhaustion, forgetting or stopping the medicine, belief that the medicine is not necessary, belief that there is no virus.

In relation to the psychosocial barriers of the medication with medication storage, we found a statistically significant result (p = 0.048) for “feeling exhausted, due to having to take the medication very frequently” with a frequency of 89.47%, followed by but without a significant p “Considering that the medicine has an unpleasant taste or smell” (Table 3).

Medication psychosocial barriers	Conservation of medications				p Value
	Total	Yes	No	OR (IC)	
	n= 73	n = 35	n = 38		
% (n)	% (n)	% (n)			
It has been difficult for you to take the pills or you have had trouble opening the bottles to get the medicine.	16,44 (12)	14,29 (5)	18,42 (7)	0,73 (0,21;2,58)	0,43*
You have experienced side effects at some point during the treatment	53,42 (39)	57,14 (20)	50 (19)	0,93 (0,37;2,35)	0,54*
You think the medicine has an unpleasant taste or smell	42,47 (31)	31,43 (11)	52,6 (20)	0,41 (0,15; 1,07)	0,055*
You have had to undergo restrictions of some kind during the course of treatment.	23,29 (17)	28,57 (10)	18,42 (7)	1,42 (0,47;4,28)	0,306*
You have felt exhausted from having to take your medication too often	80,82 (59)	71,43 (25)	89,47 (34)	0,29 (0,08; 1,04)	0,047*
Occasionally you have forgotten to take the medicine or by your own decision you have decided to take breaks	82,19 (60)	80 (28)	88,21 (32)	0,75 (0,22; 2,49)	0,43†
At some point during the treatment, you have considered that the medicine is not necessary and does not help	26,03 (19)	20(7)	31,58 (12)	0,54 (0,18; 1,58)	0,26†
At some point you have thought that the virus has disappeared because there is no longer a fever or because there is no increase in Viral Load	12,33 (9)	8,57 (3)	15,79 (6)	0,5 (0,11; 2,17)	0,28†
*: Fisher test					

Table 3: Medication psychosocial barriers and the relationship with medication preservation.

Psychosocial barriers of the patient

These refer to difficulties in attending a consultation, suffers from limitations to express or share dialogue regarding their diagnosis, feelings of anger or rage, denial of the diagnosis, there is no good family support network, does not give importance to whether there is improvement or not of his condition.

Regarding the patient’s psychosocial barriers of the relationship with the storage of medications, no statistically significant results were found. The highest frequencies in psychosocial barriers were Support networks, diagnosis denial, clinic appointment attendance, the last six months (Table 4).

Patient psychosocial barriers	Preservation of medications				p Value
	Total	Yes	No	OR (IC)	
	n= 73 % (n)	n = 35 % (n)	n = 38 % (n)		
Has strictly complied with attendance at clinic controls, the last six months	45,21 (33)	42,86 (15)	47,37 (18)	0,83 (0,33;2,09)	0,44*
You have experienced at some point that the disease has limited sharing with other people	34,25 (25)	25,71 (9)	42,11 (16)	0,47 (0,17; 1,28)	0,10*
You have felt angry (rage) with the disease because of the discomfort it causes you	38,36 (28)	31,43 (11)	44,74 (17)	0,56 (0,21; 1,47)	0,17*
You have had to deny or suppress your diagnosis to close people	61,64 (45)	65,71 (23)	57,89 (22)	1,39 (0,53; 3,60)	0,32*
Has the support of family or close people	72,6 (53)	77,14 (27)	68,42 (26)	1,55 (0,54; 4,42)	0,21*
At one time, you have not minded that your illness improves.	13,7 (10)	14,29 (5)	13,16 (5)	0,88 (0,24; 3,22)	0,57*
OR: Odss Ratio; IC. Confidential interval *: Fisher test					

Table 4: Patient psychosocial barriers of the and the relationship with the preservation of medications.

Provider-related psychosocial barriers

These refer to whether the doctor explained the patient’s condition, medication management information, difficulty in providing antiretroviral drugs, was the information violated, knowledge of the date of their control consultation, simple language approach, treatment by the staff assistance, relocation of housing that impacts access to the health care institution, difficulties with taking exams.

In terms of the psychosocial barriers related to the provider (service provider clinic) in relation to medication storage, we found statistically significant “Transportation difficulties to the healthcare institution where he is treated” with a frequency of 42.11% p = 0.02. Followed by “Treating doctors have clearly explained all the aspects related to his condition” but without being statistically significant, p = 0.13 (Table 5).

Provider psychosocial barriers	Preservation of medications				p Value
	Total	Yes	No	OR (IC)	
	n = 73 % (n)	n = 35 % (n)	n = 38 % (n)		
Your attending physicians have clearly explained all the aspects related to your condition	95,89 (70)	100 (35)	92,1 (35)	ns	0,13*
You have been clearly informed about how to handle the medications, how to take them, at what times, and how to store them	97,26 (71)	97,1 (34)	97,3 (37)	0,91 (0,05;15,27)	0,73*
Have had any difficulty with the provision of antiretroviral medications	10,96 (8)	14,29 (5)	7,89 (3)	1,94 (0,42;8,82)	0,30*
You consider that the information about your Diagnosis and the reservation of clinical history by the healthcare institution has been violated	4,11 (3)	5,71 (2)	2,63 (1)	2,24 (0,19; 25,88)	0,46*
You have clear knowledge regarding the date of your clinical controls	64,38 (47)	62,86 (22)	65,79 (25)	0,88 (0,33; 2,29)	0,49*
The information is provided in simple words	97,26 (71)	100 (35)	94,74 (36)	0,64 (0,10; 4,11)	0,33*
You consider that the treatment you receive from the healthcare personnel encourages you to return to clinical controls	100 (73)	100 (35)	100 (38)		N/A
You have had difficulties with transportation from your home to the healthcare institution where you are treated	54,79 (40)	68,57 (24)	42,11 (16)	3 (1,14; 7,84)	0,02*
You have presented difficulties to undertake tests (CD4 Count and Viral Load) and their reading	6,85 (5)	8,57 (3)	5,26 (2)	1,68 (0,26; 10,75)	0,46*
OR: Odds Ratio; IC. Confidential interval *: Fisher test					

Table 5: Provider psychosocial barriers and the relationship with medication conservation.

Preservation of medications and CD 4 relationship

The median CD4 score in patients without drug storage was 320 (quartile 1: 149 and quartile 2: 549) and in patients who maintained drug storage it was 226 (quartile 1: 178 and quartile 2: 415), respectively. When comparing the medians, no significant differences were found ($p = 0.320$).

Preservation of medications and viral load relationship

In relation to the median Viral Load in patients without medication preservation, it was 8971 (Quartile 1: 3432 and quartile 2: 38909) and the response of patients who retained their medications was 12463 (Quartile 1: 4197 and quartile 2: 36873). There were no significant differences when comparing the medians in both groups ($p = 0.7656$).

Conservation of medications and hours of electric power relationship

The median hours of available electrical power in the group of patients without medication conservation was 24 hours (quartile 1:24 and quartile 2:24). In the group that conserved the drugs, the median hours of electrical energy was 4 hours (quartile 1: 0 and quartile 2:24); in this case, there are significant differences ($p = 0.000$).

Discussion

According to De La Hoz, *et al.* in 2014, the prevalence of virological failure is 20.9% [14], somewhat far from the African studies discussed in the introduction to this document with values of 14.7% and 10.5% [11,12] but also far from what was found in the present investigation where in this HIV positive population living in the Colombian Orinoquia and Amazonia a prevalence of virological failure of 31.6% was found. Something that was suspected from the clinical perception but had not been published in previous studies.

Furthermore, it was important to search for characteristics related to the prevalence of virological failure reported in the results of the study and its tables, statistically significant findings are highlighted. Our findings are significant, and although our current sample is small, we would like to explore these variables across bigger population samples, perhaps for the whole country of Colombia, or even at a global level.

Medications have evolved over time with specific guidelines for storage. We are aware of the inhospitable climate that these patients face living in the described remote regions. These regions are frequently beyond the reach of local government, and have less access to basic services and healthcare. Geographical characteristics as well as sociocultural beliefs may lead to poor treatment compliance. This investigation was motivated by a desire to understand these barriers in the hopes of improving outcomes in these patients.

There is a dearth of data regarding psychosocial barriers and medication storage as a barrier for treatment in HIV+ patients. Almost half of these patients stored their medication improperly, due to a lack of access to refrigeration. It is striking that some who did have access to electricity did not have a refrigerator and even some who did failed to store medication properly. In some cases, patients froze the antiretrovirals.

The taking of various frequencies of medications was statistically significant as a psychosocial barrier to medication and others, although odor and taste were not significant. This shows that it is vitally important to provide patient-friendly treatment frequencies and providing more palatable drug presentations.

Regarding psychosocial barriers for the patient: the support network that the patient has, denial or self-denial regarding their diagnosis, responsibility to comply and go to their medical appointments.

According to Colombian legislation “health provider institution - IPS (institución prestadora de salud)”. Regarding the psychosocial barriers related to the provider (IPS) versus the preservation of medicines, we see that patients present difficulties in terms of geography, topography, security and communication routes; these circumstances in a country like Colombia and in the Orinoquia and Amazonia, will have an enormous impact to access the IPS where they are provides of the service. This goes hand in hand with what was found in terms of the conservation of medications and the hours of electricity, significant differences were presented ($p = 0.000$).

Conclusion

In general terms, a relationship was found between medication storage/conservation and available hours of electricity, all psychosocial barriers are related to poor medications storage in these patients with virological failure.

Those that were statistically significant of the medication psychosocial barriers with the preservation of the medications, we found a statistically significant result ($p = 0.048$) for “exhaustion due to medication use” with a frequency of 89.47%. Of the psychosocial barriers related to the provider (service provider clinic) in relation to the preservation of medications, we find statistically significant “He has had difficulties with the transfer from his home to the clinic where he is treated” with a frequency of 42.11% $p = 0.02$.

It is important to explore the prevalence of virological failure and the characteristics related to these barriers in the rest of the nation, as well as in other countries with the potential or existence of virological failure prevalence.

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There was no funding.

Conflict of Interest

There is no conflict of interest

Ethics Approval

By the design of the study and the Colombia law, no ethical approval was needed for this study.

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