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ORIGINAL RESEARCH

Appropriate adherence to antiretroviral therapy in the Alto Paranaiba, Minas Gerais, Brazil

Gabriela de Oliveira Souza[I], Aline Andréia Caixeta Magalhães Tibúrcio[II], Márcia Kiyomi Koike[I,III]

[I] Instituto de Assistência Médica dos Servidores Públicos do Estado, IAMSPE, São Paulo, SP, Brazil.
[II] Centro Universitário de Patos de Minas, UNIPAM, Patos de Minas, MG, Brazil.
[III] Universidade Anhembi-Morumbi, São Paulo, SP, Brazil.

OBJECTIVE: This study aimed to assess the adherence to antiretroviral treatment of HIV-infected patients at the *Centro de Referência Viva Vida in Patos de Minas, Minas Gerais, Brazil*.
METHODS: As a descriptive and quantitative retrospective cross-sectional study, we enlisted HIV-infected patients, over 18 years old, users of highly active antiretroviral therapy (HAART) from June 2011 to July 2012. Data on withdrawal of medication and viral load were collected from the drug logistics management information system and from the medical records, respectively. Sociodemographic and data regarding HAART use were collected manually, using appropriate forms. The CEAT-HIV questionnaire was filled out by140 patients who were using HAART. For data analysis, we used ANOVA and Kruskal-Wallis Rank Sum tests, complemented with Dunn's test, when necessary. $P < 0.05$ was adopted as the limit for significance.
RESULTS: The age group 18-30 years presented lower adherence compared with the group aged over 60 years ($p = 0.047$). Regarding the HAART usage time, there was no difference between groups ($p = 0.515$). For the number of pills taken per day, there was greater adherence for patients taking up to 4 pills compared to those taking 5-10 pills daily ($p = 0.037$). Concerning adherence measured by the CEAT-HIV questionnaire, there was strict/rigorous adherence in 57.8% of patients, with 21.4% of the patients classified as having adequate adherence, according to the data on dispensation of medicines.
CONCLUSION: Patients participating in HAART and taking up to 4 pills had good adherence to treatment.

KEYWORDS: Adherence, Compliance, HAART, HIV/AIDS.

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E-mail: souzagabriela@hotmail.com

INTRODUCTION

Acquired Immunodeficiency Syndrome (AIDS) is one of today's biggest health problems due to its pandemic character and severity.[1]

In Brazil, 608,230 AIDS cases were reported from 1980 to June 2011, and 34,218 new cases were recorded in 2010 (incidence of 17.9/100,000 inhabitants), according to the latest Epidemiological Bulletin of the Brazilian Ministry of Health.[2]

According to Blath,[3] the incidence of AIDS tended to stabilize in the south, southeast and midwest of the country; however, in the north and northeast, the incidence of AIDS increased.

In Brazil, the universal access program to highly active antiretroviral therapy (HAART) began in 1996, ensuring the availability of drugs for the treatment of individuals with HIV/AIDS. Due to the establishment of HAART, there was an increase in survival, quality of life and maintenance of productivity. Moreover, there was a decreased frequency of hospitalizations because of a reduction in the viral load and of a reconstitution

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of the immune system.[1,4,5] Thus, the mortality rate of AIDS in Brazil reduced 35% (9.7/100,000 inhabitants in 1995 to 6.3/100,000 inhabitants in 2010). Nevertheless, approximately 12,000 people died in Brazil because of AIDS in 2010.[2]

Despite efforts to prevent the disease, infection with the HIV virus continues to expand.[4] Full compliance/adherence to treatment is needed to achieve the treatment benefits. Currently, 17 types of antiretroviral drugs are distributed in Brazil, and according to the Ministry of Health, approximately 200,000 people infected with HIV/AIDS were undergoing treatment in 2008.[6]

Adherence to HAART is a dynamic process influenced by the sociocultural context, the quality of the relationship between patients and the health professional team and the coping mechanisms of infected individuals to achieve therapeutic success and better quality of life.[7]

Antiretroviral therapy requires a complex integration of acceptance, knowledge, skills and factors related to the environment and general health care from patients.[8] The number of pills, frequency of use, amount of side effects, social support and relationship with the health team appear to influence adherence to treatment.[9]

To ensure therapeutic success, the World Health Organization[10] noted that an adherence greater than or equal to 95% is required to achieve satisfactory levels of suppression of viral load due to the high potential of mutation and replication of the HIV virus. Low adherence to HAART quickly leads to resistance, which could be transmitted to others, making it more difficult to contain the epidemic.

According to Barbosa,[11] there are approximately 16,000 reported cases of HIV/AIDS in the State of *Minas Gerais*, of which 72% are males. The highest incidence rates are concentrated in the *Triangulo Mineiro* and *Alto Paranaíba* regions, as well as in the Metropolitan area of *Belo Horizonte*, the state capital and largest city (currently 1.5 million inhabitants). According to the Brazilian Institute of Geography and Statistics (Instituto Brasileiro de Geografia e Estatística - IBGE), (a) the *Triângulo Mineiro* region is one of the ten planning regions of State of Minas Gerais, has an estimated population of 2 million and is constituted of following cities: *Uberaba, Uberlândia, Araguari, Patos de Minas, Ituiutaba, Patrocínio*; (b) the *Alto Paranaíba* region is another one of the ten planning regions of State of Minas Gerais, has an estimated population of 250.000 and is constituted of following cities: *Patos de Minas, Araxá, Patrocínio, Monte Carmelo, São Gotardo, Carmo do Paranaíba, Coromandel, Sacramento, Ibiá* and *Lagoa Formosa*.

In spite of a high incidence of HIV/AIDS cases in the *Alto Paranaíba* region, there is a lack of studies of patients' treatment adherence. The *Patos de Minas* estimated population is 125.000 and its health center offers a Specialized Care Service for sexually transmitted disease, including HIV/AIDS for the entire *Alto Paranaíba* region.

The objective of this study was to assess the level of adherence to HIV antiretroviral treatment in patients assisted in *Patos de Minas, Minas Gerais.*

METHODS

The study was authorized by the City Health Department and approved by the Ethics Committee of the Research Center of the University of *Patos de Minas* - UNIPAM (case # 23/12), according ethical principles defined by Resolution #196/96 of the Brazilian National Health Council.

To determine the adherence to antiretroviral treatment, a retrospective cross-sectional study of descriptive and quantitative characterization was performed in HIV-infected adult patients (> 18 years old), both genders, treated at the *Patos de Minas* Health Center (this is named C*entro de Referência Viva Vida Dona Francisca Escolástica Pereira*); all included patients agreed to participate in the study. The operation logistics establishes that the pharmacy unit of the *Centro* dispenses antiretroviral drugs approximately every 30 days to patients infected with the HIV.

The exclusion criteria were: patients on antiretroviral treatment for less than twelve months, patients who were transferred and/or deceased during the study period, patients receiving antiretroviral drugs as a prophylactic measure (occupational exposure, sexual exposure), pregnant women, recent mothers, and those who did not agree to participate.

At the time of signing the consent form all the volunteers were instructed about the research objectives, and given a guarantee of anonymity and the right to quit participation at any time. It is important to note that the volunteers were able to request assistance from researchers to fill out the questionnaire, even though this was intended to be filled out by the volunteers.

Data on medication withdrawal and viral loads were collected in the System of Drug Logistics Management and from the medical records. Sociodemographic data were collected, such as gender and age, as well as data on the HAART used, such as drug name(s), time of treatment and regimen. The collection of these data was performed manually, using an appropriate form.

A questionnaire created by Remor[12] and translated, adapted and validated for the Brazilian population by Remor et al[4] entitled *"Cuestionario para la Evaluación de la adhesion al Tratamiento Antiretrovirala" - CEAT-HIV* (Assessment of Adherence to Antiretroviral Therapy Questionnaire) was used for collection of patient data of 91 patients using HAART. This questionnaire was applied after patients consulted the infectious disease physician or at the time they picked up drugs from the pharmacy unit.

The questionnaire contained 20 items assessing compliance with treatment over the previous week, general adherence from the beginning of treatment, adherence to medication time, patient appreciation of their degree of adherence and level of memorization of drug names used in the treatment. The questionnaire also assessed other factors including the patient-physician relationship and the strategies used by patients to remember how to use the medication. The total score was the sum of all items (minimum value 17, maximum 89).[13]

The response options were presented in a Likert scale of five points, and the highest score indicated greater adherence. According to the score, it was possible to classify the adherence at three levels: low/insufficient (≤ 74 points), good/adequate (75-79 points), and strict/rigorous (≥ 80 points).[4]

For data analysis, the following parameters were considered: gender, age group (18-30, 31-60, > 60 years old), HAART time (60, 60-120, > 120 months), and the use of the three most frequent antiretroviral therapy strategies (1 = Zidovudine (AZT) + Lamivudine (3TC) + Efavirenz (EFV), 2 = AZT + 3TC + Neverapine (NVP), 3 = other). One Way ANOVA or Kruskal-Wallis Rank Sum tests were used, complemented with Dunn's test, when necessary. $P < 0.05$ was adopted as the limit for significance.

RESULTS

During period from July 2011 to June 2012, 140 HIV/AIDS patients using HAART were studied. The average age of participants was 45 ± 12 years, and 58% were males. Table 1 shows the sample distribution of patients according to age and gender.

Table 1 - Distribution of patients, according to sociodemographic data

SOCIODEMOGRAPHIC DATA	%	N
GENDER		
female	42	59
male	58	81
AGE		
≤ 30 years old	10.7	15
30-60 years old	77.9	109
> 60 years old	11.4	16

The average time of HAART use was 56 ± 43 months, ranging from 2 to 195 months. We found that 82% (115/140) of the participants maintained an undetectable viral load (< 50 copies/mL) throughout the study period. Moreover, 19% of the patients (26/140) had their viral load reduced to undetectable levels over the period.

There were 22 different types of treatment regimens observed. The most common were combination 1 (AZT + 3TC + EFV) and 2 (AZT + 3TC + NVP), used by 49% and 11% of participants, respectively (Table 2).

Table 2 - Frequency distribution of the therapeutic schemes used by patients of the *Centro de Referência Viva Vida "Dona Francisca Escolástica Pereira"*

THERAPEUTIC SCHEME	# ofusers	%
AZT + 3TC + EFZ	69	49.3
AZT + 3TC + NVP	16	11.4
3TC + TDF + EFZ	15	10.7
3TC + NVP + TDF	6	4.3
AZT + 3TC + ATV + RTV + TDF	6	4.3
3TC + ATV + RTV + TDF	4	2.8
3TC + TDF + LPV/r	5	3.6
3TC + AVT + TDF + LVP/r	2	1.4
AZT + 3TC + ATV + RTV	2	1.4
AZT + 3TC + LVP/r	2	1.4
AZT + 3TC + TDF + EFZ	2	1.4
3TC + ATV + RTV + TDF + EFZ	1	0.7
3TC + ATV + RTV + TDF + LPV/r	1	0.7
3TC + RAL + EFZ + MVQ	1	0.7
3TC + RAL + RTV + DRV + MVQ	1	0.7
3TC + TDF + EFZ + DRV + RTV	1	0.7
3TC + TDF + NVP + LPV/r	1	0.7
AZT + 3TC + ATV + RTV + EFZ	1	0.7
AZT + ATV + RTV + TDF	1	0.7
AZT + TDF + EFZ	1	0.7
AZT + TDF + NVP	1	0.7
DRV + RVT + T-20 + RAL	1	0.7
TOTAL	140	

3TC: Lamivudine; ATV: Atazanavir; AZT: Zidovudine; DRV: Darunavir; LPV/r: Lopinavir; + Ritonavir; NVP: Nevirapine; MVQ: Maraviroc; RAL: Raltegravir; RTV: Ritonavir; T-20: Enfuvirtide; TDF: Tenofovir.

According to Figure 1, the number of pills per day varied between 3 and 10, with an average of 4 ± 1.7 pills per day. In the period when the study was conducted, there were changes in the therapeutic regimens of nine participants (6.4%).

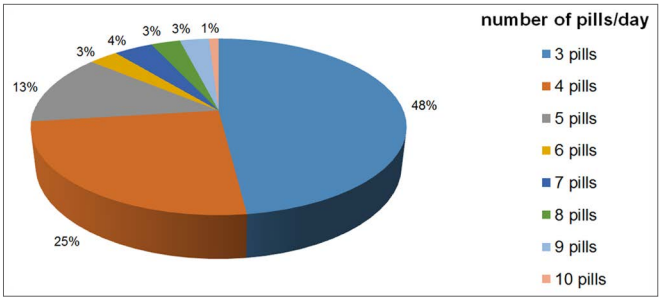

Figure 1 - Sample distribution by number of daily ingested pills used by participants.

Adherence to treatment was measured in two ways: through the score obtained in the CEAT-HIV questionnaire and by analyzing the data concerning the dispensing of antiretroviral drugs in the Medicine Dispenser Unit at Health Center.

The score of CEAT-HIV to adherence level was strict/rigorous adherence for 58% of patients, low/insufficient adherence for 21%, and good/proper adherence for 21% (Figure 2).

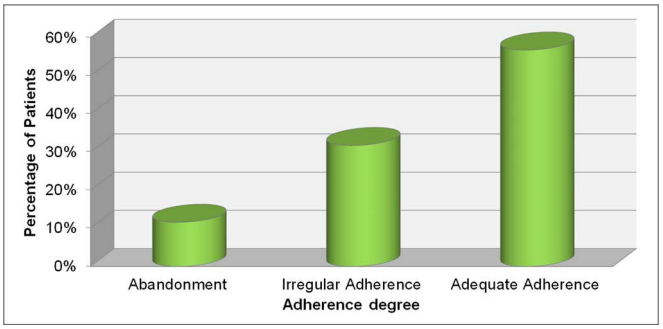

Figure 2 - Adherence degree to antiretroviral treatment from the score obtained in the CEAT-HIV.

The minimum and maximum total CEAT-HIV score of values recorded in the sample were 52 and 87, respectively, with a global average score of 79 ± 6.5. There were no floor or ceiling effects. The results of the responses of the questionnaire items are listed in Table 3.

Table 3 - Results of responses to CEAT-HIV questionnaire items

Item (answerchoices)	Mean	Standard deviation	Median	Variation (min.-max.)
Item 01 (1-5)	4.6	0.9	5	5 (1-5)
Item 02 (1-5)	4.9	0.4	5	4 (2-5)
Item 03 (1-5)	4.9	0.3	5	3 (3-5)
Item 04 (1-5)	4.9	0.3	5	3 (3-5)
Item 05 (0-2)	0.5	0.8	0	3 (0-2)
Item 06 (1-5)	4.9	0.4	5	4 (2-5)
Item 07 (1-5)	4.5	0.8	5	5 (1-5)
Item 08 (1-5)	3.7	1.2	4	5 (1-5)
Item 09 (1-5)	4.7	0.7	5	4 (2-5)
Item 10 (1-5)	4.6	0.8	5	5 (1-5)
Item 11 (1-5)	4.7	0.7	5	4 (2-5)
Item 12 (1-5)	4.3	1.0	5	5 (1-5)
Item 13 (1-5)	4.6	0.8	5	5 (1-5)
Item 14 (1-5)	4.4	0.7	4	4 (2-5)
Item 15 (1-5)	4.1	1.3	5	5 (1-5)

In the CEAT-HIV survey results, 69% patients forgot medications' name, 14% remembered partially, and only 16% remembered all antiretroviral medications' name.

The amount of information exhibited by the patients about the antiretroviral drugs was considered adequate or large for 57% of patients, medium for 26% and little or absent for 16%.

A total of 92% reported daily medication intake during the immediately previous week, 36% related missed intake for a full day or more since they began treatment, with a mean of eight missed days. Regarding the medication schedule, 97% of the patients reported good adherence to the schedule, whereas 3% reported that they never followed the schedule prescribed by the physician.

The use of strategies to remember the schedule of medication intake was described by 14% of the patients. These strategies included putting drugs in a visible place, setting alarm clocks or other alarms for medication time or linking the use of drugs to some task of a daily routine. Patients who did not use any strategy to remember taking the medication stated that taking medicine was already part of their daily routine; 39% of the patients reported to be quite/very adherent to the treatment, while 3.6% reported to have some/a lot of trouble to take medication.

The intensity of side effects of drugs for treating HIV was considered insignificant for 56% of participants, light for 22%, standard for 10% and intense or very intense for 12%.

A total of 95% of patients reported a good relationship with the medical doctor, and 92% were satisfied or very satisfied with treatment. Furthermore, 94% perceived health improvement since their treatment began.

The age group between 18-30 years had lower adherence compared to the > 60 years old group (p = 0.047). Regarding the analysis based on the use of HAART time, there were no significant differences between age groups (p = 0.515). The relationship between adherence and types of treatment was similar among groups (0.904).

Concerning adherence measured from medication dispensing data: 12% of patients were listed as "Abandonment of Treatment", i.e., without collecting/receiving medication for 60 consecutive days or more; 32% had irregular medication withdrawals or at some point lacked monthly adherence ("Irregular Adherence"); and 57% had a steady behavior during the study period and were therefore classified as "Adequate Adherence".

DISCUSSION

In this study, the level of adherence to HIV antiretroviral treatment in patients assisted in *Patos de Minas, Minas Gerais* was considered adequate. Adherence to AIDS treatment involves taking prescribed medicines at the correct times, maintaining a good level of nutrition, practicing regular physical activities, and attending the health service on the planned dates, among other concerns. Non-adherence, in particular, can lead to viral resistance to antiretroviral drugs, which reduces treatment alternatives.[14]

HAART is one of the most celebrated advancements in the history of the treatment of HIV/AIDS. Nucleoside reverse transcriptase inhibitors, when combined with non-nucleoside reverse transcriptase and protease inhibitors, are highly effective at reducing viral replication; consequently, they improve clinical outcomes. Although remarkably effective, these multidrug regimens result in one of the most complicated therapeutic regimens for diseases that require continuous treatment.[10] In this study, patients were included who consumed up to 10 pills per day, thereby embarking upon complex treatment regimens.

Factors that hinder treatment adherence relate (a) to the number of pills per dose and doses per day; (b) fasting or water drinking restrictions; (c) amount of side effects such as diarrhea, nausea, lipodystrophy, neuropathy, etc.; (d) possible incompatibilities between drugs. Patient related factors include (i) the difficulty in understanding the goals of therapy and the implications of its misuse; (ii) patient's beliefs about the disease and drugs, (iii) confusion and forgetfulness; (iv) the doctor-patient relationship, (v) psychosocial aspects, such as emotional support, (vi) routine adaptation capability and understanding that poor adherence leads to resistance.[10,15]

Regarding data obtained through the dispensing of antiretroviral drugs, only 57% of patients showed adherence. Higher values of adherence were found in different studies that also studied adult (> 18 years old) patients on antiretroviral treatment. In a survey conducted by Blatt et al,[3] approximately 70% to 80% of patients claimed adherence. In contrast, the adherence according to the dates of drug collection was approximately 50%, which possibly indicates self-report overestimation.

In the patients included in this research, adherence measured by the CEAT-HIV questionnaire was considered Strict/Rigorous for 60%, a higher number than described in other studies where this type of evaluation was applied.[4,13]

The wide distribution of antiretroviral drugs by the National Health System, the increase in the number of specialized care services (SAE) for people living with HIV/AIDS and the implementation in the last decade of the National Genotyping Network to perform genotypic resistance testing has led to a significant increase in viral suppression levels in patients with 12 months of treatment: 63.8% in 2006 to 73.3% in 2010.[16] As found within the national Brazilian framework, the studied sample had a high level of viral suppression: 82.5% of patients had a viral load lower than 50 copies/mL for 12 months.

The CEAT-HIV questionnaire was also applied to 41 patients with HIV/AIDS treated at *Centro Médico Naval "Cirurgião Major Santiago Távara"* in Lima, Peru during the months of December 2005 and January 2006 by Tafur-Valderrama and colleagues. Only 24% of these patients claimed Strict Adherence.[13]

According to Colombrini et al,[8] it is of fundamental importance that health professionals recognize that non-adherence should be discussed with the patient in a systematic way, with a corresponding development of actions to support the effective performance of these professionals and with a plan of treatment for the patient. For this, it is necessary to be aware of the factors that may interfere with adherence and of the need to recognize the specificities of each particular patient.

We suggest that the development of a booklet containing information on HAART should be distributed at the dispensing unit at the first medication dispensation. Patients must know why they are using antiretroviral drugs, how drugs act against HIV, care about conservation and recommendations to avoid adverse effects, drug and food interactions, what to do when they forget to take their medicine, and other information the teams may deem to be necessary. Although patients reported having openness and confidence in the team to answer their questions, such a booklet would increase and facilitate patient access to important information for their treatment.

Some patients have reported that sometimes they stopped using the medication to prevent people close to them from knowing about the use of HAART. Furthermore, they reported that some bottles of antiretroviral drugs indicated on the label that it was AIDS medication. To prevent such potentially embarrassing scenarios, many patients remove the labels, which leads to later confusion about the time of use of the medication. There were also complaints that pill size sometimes made them difficult to swallow.

In such cases, some strategies can facilitate patient adherence to treatment, such as using "pill-boxes", which serve to organize daily doses for a certain period and are helpful in cases of travel and when patients want to maintain the confidentiality regarding the treatment. The use of alarms and a diary helps to prevent forgetting doses and helps to establish a routine for the correct use of medicines. Diaries are also useful to control the appearance of side effects and to remind the patients about the difficulties and doubts regarding the drugs, which may be clarified by the team in due course.[14]

Adherence is an essential factor for therapeutic success, and both the patient and the multidisciplinary team should assume their roles for successful treatment. The adhesion reported in this study is considered adequate, because 90% patients say they took medication over the one-week period immediately preceding the interview. Factors such as drug numbers, medication time did not seem to interfere with successful treatment. However, some interviewees complained about the size of drugs and about drug reactions.

Part of this sutdy was based in information from questionnaire responses and this can be an important

limitation, due to the possibility of untruthful responses to some questions or because responders might not remember or might have been even ashamed of any noncompliance with treatment.

In conclusion, the patients participating in high active antiretroviral therapy taking up to 4 pills/day had adequate adherence to treatment in a health center in the city of *Patos de Minas,* in the Brazilian state of Minas Gerais.

AUTHOR CONTRIBUTION

Souza GO: Conception, intellectual and scientific content of the study, technical procedures, acquisition of data, manuscript writing. Tibúrcio AACM: Conception of the study, technical procedures, acquisition of data. Koike MK: Conception, design, intellectual and scientific content of the study; critical revision; final approval of the manuscript.

CONFLICT OF INTEREST

Authors report no conflict of interest regarding this project

ADERÊNCIA ADEQUADA AO TRATAMENTO ANTI-RETROVIRAL NO ALTO PARANAÍBA, MINAS GERAIS, BRASIL

OBJETIVO: Este estudo teve como objetivo avaliar a adesão ao tratamento antirretroviral de pacientes infectados pelo HIV no Centro de Referência Viva Vida em Patos de Minas, Minas Gerais, Brasil.

MÉTODOS: Neste estudo transversal retrospectivo, descritivo e quantitativo, alistamos pacientes infectados pelo HIV, maiores de 18 anos, usuários de terapia antirretroviral altamente ativa (HAART), de junho de 2011 a julho de 2012. Os dados sobre a retirada da medicação e da carga viral foram coletados a partir do sistema de informação de gestão logística de drogas e dos registros médicos, respectivamente. Dados sociodemográficos e dados sobre o uso da HAART foram colhidas manualmente, usando formulários apropriados. O questionário CEAT-HIV foi preenchido by140 pacientes que estavam usando HAART. Para análise dos dados, foram utilizados os testes ANOVA e Kruskal--Wallis Rank Sum, complementados com o teste de Dunn, quando necessário. Foi adotado um valor de $P < 0,05$ como o limite para significância.

RESULTADOS: O grupo etário 18-30 anos apresentou menor adesão em comparação com o grupo com idade superior a 60 anos ($p = 0,047$). Em relação ao tempo de uso da HAART, não houve diferença entre os grupos ($p = 0,515$). Para o número de comprimidos tomados por dia, houve maior adesão por parte dos doentes medicados com até 4 comprimidos em comparação com aqueles que tomam 5-10 comprimidos por dia ($p = 0,037$). No que diz respeito a aderência, medida pelo questionário CEAT-VIH, houve a adesão estrita/rigorosa em 57,8% dos pacientes, com 21,4% dos pacientes classificados como tendo a aderência adequada, de acordo com os dados relativos à dispensação de medicamentos.

CONCLUSÃO: Os pacientes participantes de HAART e tomando até 4 comprimidos/dia apresentaram boa adesão ao tratamento.

PALAVRAS-CHAVE: Adesão; Conformidade; HAART; HIV/AIDS.

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