Directly observed anti-retroviral therapy amongst female inmates

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ABSTRACT

Objectives: It is considered that the gold standard for success in HAART is adherence. To improve adherence amongst inmates with HIV-AIDS, the use of directly observed treatment (DOT) is proposed using the tuberculosis treatment model.

Material and methods: HIV positive female patients with ARVT criteria who voluntarily participated were used for the study. The initial and final CD4 cell count and HIV viral load were the principal data used for assessment purposes.

Results: 52 women with an average age of 34 years were studied, with an average HIV infection time span of between 1 and 20 years. Initial CD4 cell count of <100 copies/ml in 16 patients (30.7%) and an equivalent final count in 4 patients (7.6%) were found. Initial undetectable viral loads were not found in any patient, while final undetectable viral loads were found in 33 (63.4%). 21% of patients had opportunistic infections. The most important of these was tuberculosis, followed by HCV co-infection. The most frequently used ARVT schedule was two NRTI with one NNTRI.

Conclusions: The application of DOT strategy to ARVT was effective amongst our patients, as shown by the increase in CD4 counts and the increased number of patients with reductions in viral loads to undetectable levels. While it is a tool that is not easy to use for cases of chronic treatment, we do consider it to be useful for prison inmates.

Key words: HIV Seroprevalence; Antiretroviral Therapy, Highly Active; Prisons; Women; Anti-HIV Agents.

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INTRODUCTION

Currently, the treatment of HIV or AIDS implies a lifelong handling of the disease, and adherence is therefore of paramount importance with regard to the evolution and the reduction of morbidity and mortality. Throughout the last years we have come across the extraordinary advantages of the antiretroviral therapy (ART). Nevertheless the enthusiasm created by this recent success has been blurred by biologic, clinical, social and economic issues that restrain access to such treatments and their therapeutic success.

Nowadays we accept that adherence is as important as the treatment's power itself.

Therefore an array of measures has been implemented to promote such adherence to ART, amongst which we highlight the following:

Interventions with the patient, which entail creating routines that include their medication in their daily activities. Within this context the DOT strategy is included, which has been successfully used with imprisoned populations and other groups but which is difficult to implement amongst other types of population.

Interventions towards the health team, which entail continuing interviews with the patient in order to establish an appropriate environment to determine the moment in which the patient is ready to take up the treatment. From that moment on, the relevant physician will regularly assess adherence, in order to keep up with the performance and identify possible obstacles to overcome. None of these interventions is enough by itself.

DOTS is the internationally recommended strategy to ensure the healing of tuberculosis. Its five key components are shared with disease control strategies and support early case detection and effective management of infectious cases in order to restrain the transmission of tuberculosis. This last strategy was outlined by Crofton at the beginning of 1960 to control tuberculosis.

This is how the term "directly observed treatment" is created, which was broadly used during many years until WHO changed it to "directly observed therapy-short course" in 1995 and was then used to describe a comprehensive TB control strategy.

Directly observed treatment basically involves "a trained and supervised person who observes the patient while he/she takes the pills" and is essential in ensuring treatment adherence. The first WHO documents highlighted the importance of direct observation by health professionals. Later experience achieved with DOTS programs throughout the world proved that laypeople specifically trained were, at least, equally suitable for the observation.

Nevertheless, applying DOTS to ART entails some differences depending on the pathologies themselves, such as:

- Tuberculosis (TB) generally is a curable disease, HIV infection can only be controlled.
- In TB, the treatment has a limited duration, while in HIV it is a lifelong treatment.
- Compliance of TB treatment is regarded as a public health issue and patients can be therefore persuaded in doing so, but ART is voluntary and a personal decision of the patient.

MATERIAL AND METHODS

Female inmates with HIV infection from the Female Correctional Institute, Unit 3 from Servicio Penitenciario Federal (the Federal Penitentiary System) who were suitable for ART in accordance to national guidelines, were included in the study.

So that ART could begin, patients underwent medical consultation with the relevant physician, psychological support sessions on demand and training sessions on the daily delivery of medicines and how these should be taken in front of the health team staff.

The staff in charge of providing medicines was chosen amongst the staff from the health team, nurses, and belonging to security staff, because they were the only ones authorized to doing so.

Such staff was previously trained on HIV-AIDS infection, the relevance of treatment adherence and the DOTS scheme.

The following information was assessed: age, HIV infection time, comorbidity, ART scheme, and initial and final CD4 cell count and HIV viral load.

RESULTS

The aforementioned Unit currently counts with 461female inmates, 27 of whom are HIV positive (5.85%). Throughout the study 91 HIV positive women participated, 52 of whom fulfilled the criteria to be treated and agreed with doing so and with the DOT.

The age span was among 21 and 54 years, with an average of 34 +/- 7 years.

The year the diagnosis was made was between 1988 and 2007, this is between 21 and 1 years of diagnosis time; 78% had 10 or less years or diagnosis time.

The initial CD4 cell count was between 19 and 868 cells/mm^3. The higher values of some patients (over 500 cells/mm^3) was due to prior diagnosis and treatment to their entrance in prison, but nevertheless were included in the DOT.

Initial CD4 cell count was less than 16cells/mm^3 in 16 patients (30.7%), while such result only appeared in 4 patients by the end of the study (7.6%).

Final results for CD4 cell counts were under 100cells/mm^3 in 4 patients, between 99 and 199 cells/mm^3 in 14 patients, and over 300 cells in 30 patients. (Graphic 1).

Initial viral load ranged between 101 and 14,000 and none presented an undetectable viral load. The lower values (between 50 and 5000 copies) belonged to 11 patients (21.1%), while 20 of them (38.4%) had over 500,000 copies.

The last control showed that 33 patients (63.4%) had an undetectable viral load (< 50 copies/ml); 7 had less than 5,000 copies and the rest presented higher levels than he aforementioned. (Graphic 2). Amongst the undetectable patients, 20 (60%) had been diagnosed 5 or less years ago.

Opportunistic infections affected 11 patients (21%), amongst which tuberculosis was the most important; it affected 8 out of the 11 symptomatic patients (81%).

Co-infection by HCV appeared in 9 patients.

The treatment schedule included 2 NRTI + 1 NNRTI in 40 patients, 2 NRTI +1 PI in 2 cases; rPI + 2 NTRI (or 1 NuTRI + 1 NTRI or 3 NTRI or 1 NNTRI + 2 NTRI) in 10 cases and 3 NTRI in 1 case.

Treatment time ranged between 1 and 4 years.

DISCUSSION

Directly observed treatment (DOT) is another strategy to improve treatment adherence. It has been successfully used in TB treatment and efforts have been made to adapt it to the special features of ART.

Several studies have achieved positive initial results regarding short and medium-time DOT in ART, but programs which better adapt to it are still not well defined and the optimal duration, the best candidates for the programs and the relation cost-affectivity still need to be clarified.

Personalized intervention strategies, based on psychological, education and personal counseling strategies, enable the adaptation of ART regimes to the patients' lifestyles and they provide a tool to overcome difficulties. These strategies have also proven to be useful in improving treatment adherence and response.

Directly observed treatment (DOT) cannot be generally recommended.

Nevertheless, it can be interesting and useful in patients with specific features (imprisoned population, extreme social isolation and methadone maintenance programs).

Recently, great advanced have been achieved with ART implying the possibility of taking easy and powerful treatment regimes that specifically improve treatment adherence. Such advances include co formulation of several active principles in a sole dosage, the availability of medicines that can be taken once a day and thus the possibility of daily dosage combinations.

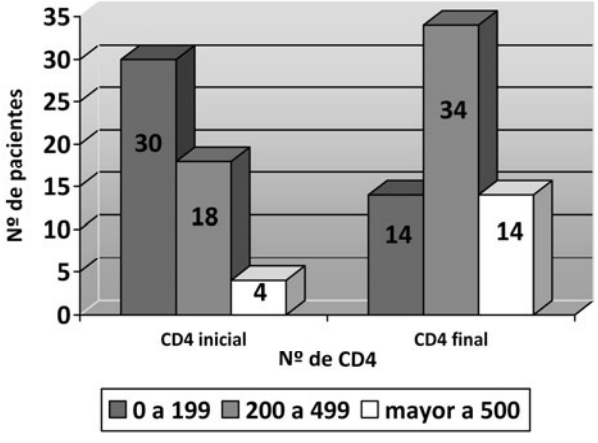

Gráfico 1: comparación entre el recuento de cd4 antes de iniciado y después de finalizado el período de tdo.

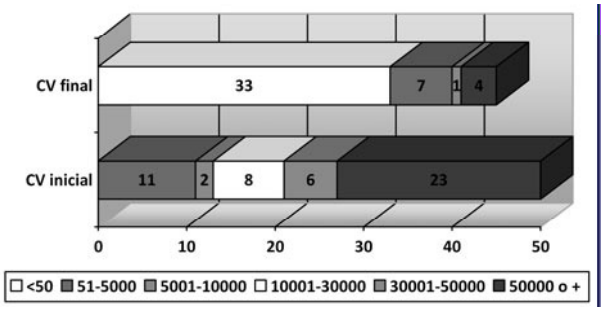

Gráfico 2: Comparación entre las cargas virales antes de iniciar y al finalizar el tdo.

CONCLUSIONS

ART adherence plays a major role in the decision of up taking ART and in the duration of the viral response. It has been proven that non-compliance is the main reason of therapeutic failure. It is also related to the increase of hospital admissions, the evolution of AIDS and the mortality of AIDS patients, as well as a cause of public resource inefficiency due to its high costs.

ART must be personalized and adapted to the needs and preferences of each patient. The simplest guidelines are recommended as far as the number of pills and daily doses are concerned.

In patients with continuous viral suppression, achieved with a complicated guideline, ART can be simplified to other guidelines that have proven the same or better efficiency and safety.

The major issues that have proven to be related to adherence include the treatment's complexity, secondary effects, psychological problems, active addiction to drugs or alcohol, lack of social and family support and the behavior and beliefs of the patient towards the treatment.

Several associated methods have to be used in estimating adherence. Within regular monitoring of adherence, reasonable methods need to be used, adapted to the hospital's reality and as universally applicable as possible. The minimum accepted can be a validated questionnaire and the dispensation record from the Pharmacy Service.

With those patients with whom appropriate adherence or compliance levels are not achieved, multi-disciplinary intervention strategies based on education, psychological and social features must be attempted with personal counseling and so that the ART regime schedule can be adjusted to the patient's lifestyle with problem solving strategies.

Currently simpler regimes with regard to the number of pills and daily dosage can be considered a tool in simplifying ART.

Within such background DOT applied to ART is found. Although the experience in doing so is still not enough because of the variety of pathologies with which it is used (TB and HIV), its implementation in specific contexts, such as prisons, can entail an useful tool for better evolution and quality of life of HIV positive imprisoned populations.

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