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An interdisciplinary approach for immediate ART initiation in patients with acute HIV infection in Mexico City

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Abstract

Background: Early initiation of antiretroviral therapy (ART) during acute HIV infection is associated with favorable clinical and epidemiological outcomes. Barriers to prompt treatment initiation limit the benefits of universal access to ART in Mexico.

Methods: A nationwide cohort of patients with acute HIV infection was created in 2015. In order to identify cases and treat them promptly in our center, an interdisciplinary group coordinated through an instant-messaging tool using smart-phones was established. When a probable case was detected, a discussion was initiated to confirm the diagnosis and facilitate the administrative processes to initiate ART as soon as possible. We compared time to ART initiation with a comparison group of patients with chronic HIV infection enrolled during the same period (May 2015 to February 2017) through routine care, using survival analysis estimators and log-rank tests.

Results: We recruited 29 patients with acute HIV-infection. The median time to ART initiation was of 2 days in these patients, in contrast to 21 days for patients with chronic infection. There were no significant differences in the percentage of patients engaged in care, on treatment or virologically suppressed at one year of follow-up.

Conclusions: Implementing immediate ART initiation programs is feasible in Mexico, in spite of the extensive administrative barriers that exist in the country. More extensive replication of this model in other centers and in patients with chronic infection is warranted to evaluate its effect on the continuum of care.

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Keywords

Acute HIV-infection; tertiary healthcare; antiretroviral therapy

Introduction

Recent studies have proven that immediate initiation of ART in patients with chronic HIV infection is associated with significant benefits in time to viral suppression and engagement in care^{1–3}. In theory, this translates into reduced HIV transmission in the community⁴ and an improved continuum of care³. Additionally, several studies have demonstrated that initiating antiretroviral therapy (ART) during acute HIV infection results in patients having a lower probability of clinical progression to advanced CDC stages, lower viral reservoir and RNA set-point, and several other significant immunological benefits^{5–7}. This should also hypothetically, result in improved clinical outcomes⁷. For all these reasons, strategies for early identification of HIV infections and their immediate treatment have become priority targets in implementation science research in the fight against HIV.

In Mexico, although universal access to ART has been the standard since 2003⁸, numerous administrative and operational barriers exist in the public health system, which hamper the implementation of immediate ART initiation programs on a large-scale basis. For example, patients cannot receive benefits from most of the specialized healthcare programs (including access to ART) before they complete the necessary registration paperwork. This entails a lengthy multi-step process that requires the patient to physically provide a number of personal documents (birth certificate, photographic ID, proof of address), obtain a certificate of affiliation, and finally enroll in care in the nearest HIV clinic initiation^{10,11}; effectively delaying ART initiation.

On the other hand, acute HIV infection remains an underdiagnosed condition due to lack of awareness, absence of specialized staff in areas where patients present with symptoms, poor communication channels amongst the personnel involved in the care of these patients and suboptimal pre-designed processes for HIV care¹². In México, ART is rarely initiated when patients are in the acute phase of the infection, with up to 79% of all patients initiating ART with CD4 counts of <200 cells/ml.¹³ Furthermore, there are no national guidelines designed to effectively detect acute HIV infection. Most diagnostic guidelines only recommend the repetition of the screening test after a designated period of time in the context of a negative screening test in a patient with a probable acute HIV infection.¹⁴

In order to improve detection and treatment of patients with acute HIV infection, in the year 2015 we established VIHIA (from its name in Spanish “*Virus de la Inmunodeficiencia Humana Infección Aguda*”), a multicenter cohort of such patients in Mexico. In our center, we implemented a clinical procedure based on communications by instant messaging tools openly available with the use of smart phones, involving key personnel in all the areas related to HIV care. This strategy intends to detect probable cases, readily diagnose and provide same-day ART to this population of patients. The aim of this report is to describe the implementation of this program and to show the resulting trend in the time from first clinical contact until treatment initiation, by comparing it to the usual practice in place for

patients with chronic infection. Additionally, we evaluated the impact of same day ART on retention in care, and viral suppression in both groups of patients

Materials and Methods

Study settings and study design

The immediate ART initiation program was implemented at the Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán (INCMNSZ); a public, university-affiliated, tertiary-care center in Mexico City. The HIV Clinic at INCMNSZ provides care to approximately 2,100 adults. As a tertiary care, referral hospital, it does not offer any primary care interventions for the general population, including HIV screening. This intervention was designed for all patients diagnosed and enrolled in care with acute HIV infection. Acute HIV infection was defined as a Fiebig stage of 5 or lower, or as a Fiebig stage of 6 with a negative 4th generation ELISA for HIV in the previous three months. All patients were enrolled for participation in the VIHIA observational cohort.

In addition, to investigate the effectiveness of our rapid ART initiation program, we conducted an observational, retrospective cohort study comparing two different cohorts of patients enrolled in our center. The intervention group was composed of all patients enrolled in the VIHIA cohort from May 2015 to February 2016 in our Institution. The comparison group comprised all ART-naïve, chronically HIV-infected patients enrolled in our site during the same time period. These patients underwent the regular enrollment process. VIHIA cohort data were collected in real time, while demographic and clinical data of chronic HIV patients were retrieved from the HIV Clinic database. This database prospectively collects information on all patients receiving care in our clinic as part of our collaboration with the CCASAnet group¹⁵ We excluded patients in whom according to guidelines prompt initiation of ART was not recommended (for example Central Nervous System Cryptococcosis). In order to exclusively perform an intention to treat analysis, we did not exclude patients that rejected the immediate initiation of ART.

Description of the intervention to start ART immediately

Personnel from the key areas involved in the care of HIV patients in our hospital (infectious diseases fellows, attending physicians, social workers, nurses, and laboratory and administrative staff) were sensitized to the importance of prompt ART for acute HIV and taught an algorithm for immediate treatment initiation (Figure 1). To facilitate a coordinated response, we created an encrypted instant-messaging group using software available to smart phone users that included the aforementioned staff. The main purpose of sharing information in this group was to elicit an alert when any participating member became aware of a patient with probable acute HIV-infection.

When any of the members of the group identified a probable case of acute HIV-infection (outpatient referrals with discordant HIV tests, screening in blood bank and in the outpatient clinic, or a suggestive clinical presentation in the emergency room or hospitalization areas), a conversation was initiated in the group to discuss the likelihood of the diagnosis with the attending physicians. If the scenario was deemed a possible case, an infectious disease

specialist performed a directed clinical evaluation, and blood samples were taken to run confirmatory tests as soon as possible.

The laboratory personnel prioritized execution of the tests (4th generation ELISA, Western Blot, viral load, and CD4 lymphocyte count) in order to obtain the results as soon as possible and share them immediately with the group. Patients with a confirmed diagnosis of acute HIV infection, received a prescription for ART, as well as an additional evaluation that included HIV counseling, adherence counseling and standard HIV care. Immediately afterwards, the administrative personnel processed the paperwork to enroll the patient in the Mexican HIV drug program and provided the patient with ART. Patients received treatment even if their administrative process was incomplete and the necessary admission paperwork was completed in subsequent visits if needed. Routine laboratory testing was available for some patients as part of their work up. HIV-negative patients received post-test counseling and were referred to the appropriate care and follow up. Patients with chronic HIV infection followed standard clinic procedures, and thus were scheduled for a later visit with all the necessary paperwork to enroll to the clinic and undergo a complete clinical evaluation.

Assessment of effectiveness of the intervention to reduce time to ART initiation and its impact on retention in care, treatment acceptability and viral suppression

The primary outcome was the time from the patient's first medical contact with the HIV clinic to the initiation of ART. The first medical contact was defined as the day of the patient's first visit to the clinic when referred from another center, the blood bank or the outpatient clinic, or the day that the first screening HIV test was made in case the patient was hospitalized in our center. ART initiation was defined as the day of ART provision, since patients were instructed to start treatment the same day. Secondary outcomes were the proportion of patients with complete viral suppression (defined as an HIV RNA <40 copies/ml), and sustained engagement in care (defined as attendance to a follow-up visit at the HIV clinic or laboratory in the assigned time period or a following time period) in the patient's first year of follow-up. Due to the heterogeneity of the follow-up amongst both cohorts, the secondary outcomes were analyzed in three different time-bins (1–4 months, 5–8 months and 9–12 months). To further characterize the impact of immediate ART initiation on the secondary outcomes, we also compared all patients that started ART after the first 48 hours of their first clinical contact with those who started earlier (regardless of their status as acutely or chronically infected).

Statistical analysis

Demographic, clinical, and laboratory data from the electronic database in the HIV clinic and VIHIA cohort were de-identified and exported into Stata v12 software (StataCorp, 2012, College Station, Texas) for analysis. The time to ART initiation was imported to and analyzed in GraphPad Prism v6 (GraphPad Inc., 2012, San Diego, California), represented using a Nelson-Aalen cumulative hazards curve and compared with the log-rank test. The secondary outcomes were compared using the Chi-squared test.

Ethical considerations

Patients with acute HIV infection provided informed consent to participate in the VIHIA cohort. Our Institutional Review Board evaluated and approved separately both the VIHIA study and the use of de-identified data for research purposes as part of our CCASAnet collaboration.

Results

During the study period, we identified 29 adults that met the inclusion criteria for the intervention group and 115 ART-naïve chronically infected adults in the comparison group. The intervention group consisted of 29 adults with acute HIV infection (8 patients diagnosed in Fiebig stage 6, 5 in stage 5, 10 in stage 4, 1 in stage 3 and 5 in stage 2). The baseline characteristics of both groups are described in Table 1. The sociodemographic characteristics of patients with acute HIV infection were similar to their counterparts. Most patients with acute HIV infection sought care due to symptoms attributed to acute retroviral syndrome. As expected, patients with acute HIV infection had higher median CD4 count at enrollment (407.28 cells/ml vs 189.08 cells/ml, $p < 0.001$), higher median CD4/CD8 ratio (0.92 vs 0.59, $p < 0.001$) and higher median HIV viral load (3.07×10^6 copies/ml vs 0.68×10^6 copies/ml, $p < 0.001$). More patients in the acute and recent HIV infection group received INSTI based regimes (39.28% vs 17.39%, $p = 0.007$).

Time to ART initiation

In the acute infection group, of all the 27 patients that accepted the intervention; 14 initiated ART on the day of their first visit, 6 more by the end of week one, and the remaining 4 by day 35. Two patients rejected the immediate initiation of ART and started their treatment until day 129 and day 189 after enrollment. The median time to ART initiation was of two days in the intervention group, and 21 days in the comparison group ($p < 0.001$) (Figure 2).

The main reasons for not initiating ART in the first 48 hours in the intervention group were: delay in the processing of the confirmatory or routine laboratory tests, patient preference for receiving HIV care in another center, and patient's refusal of HIV care.

Secondary outcomes

3 patients in the chronic group and 1 patient in the acute group died during the first two months of ART, leaving only 112 patients and 28 patients for the analyzes of the 5–8 month and the 9–12 month time-bins. The proportion of patients engaged in care, receiving ART, or in virological suppression at 4, 8 and 12 months of enrollment did not differ significantly between groups (Figure 3).

Comparison of immediate initiators vs. non-immediate initiators

15 patients from the acute group (52%) and 9 patients from the chronic group (8%) started ART in less than 48 hours. When comparing the immediate ART initiation group with the non-immediate ART group, there were no significant differences in engagement in care, ART initiation, or viral suppression at any of the time-bins (Figure 4).

Discussion

We describe our experience implementing a immediate ART initiation strategy in adults with acute HIV infection based on a multidisciplinary approach supported by instant communications tools for smartphones. The inclusion of medical, laboratory and administrative staff in an instant communications group improved the coordination and execution needed to confirm the diagnosis of patients with acute HIV infection and ensure rapid provision of ART. The median time to ART initiation was significantly reduced in these patients compared to the standard of care for patients enrolled in our center during the study period, from 21 days to 2 days. Patients with acute HIV infection enrolled through this approach had similar rates of engagement in care, ART initiation and complete viral suppression when compared to those with chronic HIV-infection. The lack of significant observed differences in these parameters amongst both intervention and comparison groups and immediate and non-immediate groups, shows that the intervention does not have a negative impact in the cascade of care of HIV patients in our center. There were no other statistically significant differences in treatment acceptability, mortality and loss to follow-up between both groups in their first year of follow-up after enrollment (data not shown).

Our study has several similarities with other early ART initiation studies. The different appointments and clinical and laboratory examinations are all compressed into one day, we initiate ART on most patients with INSTI, and we enroll the patient in care the same day we initiate treatment³⁻⁵. As opposed to other same day ART studies, we exclusively included acutely infected HIV patients. As shown in other studies that implemented immediate ART initiation in settings with a high rate of engagement in care, our study showed no modification of engagement rates^{2,3}. The absence of an observable difference in the time to achieve viral suppression could be attributed to the lack of earlier and more frequent viral load measurements, like those carried out in those studies^{2,3}.

There are important limitations in our study. Most importantly, the lack of randomization in the intervention diminishes the control over the confounding factors, and although most sociodemographic characteristics between both groups did not differ significantly, the chronic HIV group had a lower socioeconomic status. This in part reflects the fact that patients in Mexico tend to get linked to care late¹³, and shows that patients that seek care in the acute phase of HIV infection tend to have a higher socioeconomic status. Finally, our treatment strategy requires more time and effort from all the involved personnel, as well as a controlled deviation from standard ART protocol, which might not be a possibility in some settings. However, the study demonstrates that implementation of a same-day treatment initiation strategy is feasible in our setting, which may translate to others with similar highly regulated ART programs and complicated administrative processes that pose important challenges for implementation of early ART.

Another aspect of our study is the coordinated approach to detect acutely HIV infected patients in a tertiary care center. Most of the efforts destined towards timely detection of new infections in Mexico are performed at the first level of care, with up to 86.4% of HIV tests applied in non-specialized centers in 2016.¹⁶ We have shown that specialized care centers represent areas of opportunity for HIV diagnosis¹⁷ that also happen to possess the necessary

tools for the identification of acute HIV-infection and immediate ART initiation¹⁸. Even more, the creation of multidisciplinary task-forces and specialized instant action algorithms have been successfully implemented for the attention of other medical conditions in these settings, such as cerebrovascular disease^{19,20}. Our results demonstrate that an optimized utilization of these resources could have a positive impact in the care of adults with HIV infection in similar settings, allowing tertiary care hospitals and other primary HIV care centers that identify HIV infections in very early stages and make significant progress towards the national goals in HIV care.

Conclusion

As evidence supporting immediate ART initiation accumulates, implementation of this strategy in different settings should be explored. By creating a multidisciplinary approach using instant communication technology we have demonstrated that this strategy is feasible in patients with acute HIV infection in the setting of a mid-income country challenged by strong administrative and bureaucratic hurdles. Immediate ART should be evaluated in selected groups of chronically infected patients in similar settings.

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Figure1:
Detection and treatment algorithm, ARV, antiretroviral; ASAP, as soon as possible; ER, emergency room.

Figure2:
Time to ART initiation, ART, antiretroviral therapy.

Figure3:
Evaluation of continuum of care - Acute HIV infection vs. Chronic HIV infection.

Figure4:
Evaluation of continuum of care - Immediate ART initiation vs. Non-immediate ART initiation

Table1

Patients' baseline characteristics

Baseline characteristics	Acute HIV (N= 29)	Non-acute HIV (N = 115)	P value
Age in years, mean (SD)	35.54 (± 10.30)	36.9 (± 9.98)	0.520
Male	26 (92.86%)	110 (92.44%)	0.939
More than 9 years of schooling	28 (100%)	98 (85.21%)	0.108
Socioeconomic status			0.001
Low	4 (13.79%)	49 (42.61%)	0.004
Mid	21 (72.41%)	64 (55.65%)	0.101
Hgh	4 (13.79%)	2 (1.74%)	0.004
Risk factor for HIV-transmission *			0.189
MSM	22 (78.57%)	75 (63.56%)	0.118
Heterosexual	3 (10.71%)	29 (24.58%)	0.115
Bisexual	0 (0%)	10 (8.47%)	0.112
Other	3 (10.71%)	4 (3.39%)	0.100
Reason to seek care and HIV-testing *			-
Risk behavior	2 (7.14%)	No data	-
Screening	4 (14.29%)	No data	-
Acute Retroviral Syndrome	22 (78.57%)	No data	-
Third component in Initial treatment			0.047
NNRTI	15 (53.57%)	86 (72.27%)	0.077
IP	1 (3.57%)	12 (10.43%)	0.289
INSTI	11 (39.28%)	20 (17.39%)	0.007
Immune-virologic status, mean (SD)			
CD4+ Lymphocyte count (cells/ml)	407.28 (± 200.90)	189.08 (± 191.51)	<0.001
CD4/CD8 ratio	0.92 (± 1.3)	0.59 (± 0.14)	<0.001
Viral Load (copies/ml)	3.07×10^6 ($\pm 4.57 \times 10^6$)	0.68×10^6 ($\pm 1.46 \times 10^6$)	<0.001

* Self reported