

Short communication

Importance of Madagascar's HIV/AIDS reference laboratory

Importance du laboratoire malgache de référence pour le VIH/SIDA

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Abstract

Objective. – We aimed to describe the challenge faced by the national reference laboratory to support the national HIV/AIDS response in Madagascar.

Methods. – Collaboration between the National Reference Laboratory of Madagascar (NRLM) and foreign partners (a laboratory and an international organization) on the basis of a tripartite agreement. The aim was to offer virological analysis to 259 HIV-infected patients.

Results. – An alarming proportion (13.9%) of drug resistance among HIV-infected patients was observed.

Conclusion. – The NRLM contributed to improving the fight against HIV in Madagascar and led to the revision of national therapeutic guidelines. Strengthening reference laboratories has to be a priority in developing countries.

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Keywords: HIV; Reference laboratory; Madagascar

Résumé

Objectif. – Décrire le défi auquel fait face le laboratoire national de référence afin de soutenir la réponse nationale à l'épidémie de VIH/SIDA à Madagascar.

Méthodes. – Collaboration entre le Laboratoire national de référence de Madagascar (LNRM) et certains partenaires internationaux (un laboratoire et une organisation internationale) sur la base d'une convention tripartite. L'objectif était de réaliser les analyses virologiques de 259 patients infectés par le VIH.

Résultats. – Une proportion alarmante de résistance aux antirétroviraux (13,9 %) a été observée.

Conclusion. – Le LNRM a permis une amélioration de la lutte contre le VIH avec une révision des directives thérapeutiques nationales. Le renforcement de ce type de laboratoires devrait être une priorité dans les pays en développement.

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Mots clés : VIH ; Laboratoire de référence ; Madagascar

1. Introduction

The role of reference laboratories is to support the follow-up of HIV-infected patients. However, most laboratories of developing countries do not have the means to perform virological

analyses. Yet, the emergence of drug-resistant viruses is currently threatening the global therapeutic response to HIV infection. Drug resistance results from specific mutations selected by drug exposure to the three main antiretroviral drug classes. Resistance to nucleoside/nucleotide reverse transcriptase inhibitors (NRTI), non-nucleoside/nucleotide reverse transcriptase inhibitors (NNRTI), and protease inhibitors (PI) was indeed observed in both resource-rich settings and resource-limited areas after the large scaling-up of antiretroviral therapy (ART) [1]. Appropriate therapeutic management of

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HIV-1-infected patients has thus become a challenge for low-resource countries. Poor settings in developing countries have limited resources to support antiretroviral therapy, i.e., limited number of clinical sites, lack of treatments and laboratory testing for biological follow-up.

In 2013, prevalence of HIV infection in Madagascar was still low among adults aged 15 to 49 years: 0.4% [0.3–0.5] [2]. Access to ART in Madagascar has increased since 2005, as recommended by the World Health Organization (WHO) [3]. Until 2009 only four CD4 counters by flow cytometry were available in four main cities (Antananarivo, Antsiranana, Mahajanga, and Toamasina). A total of 32 CD4 counters are now available since 2009 in the 47 clinical settings for HIV-infected patients. One of these flow cytometers is available at the National Reference Laboratory of Madagascar (NRLM), which is part of the Ministry of Health. Renovation works were carried out in the NRLM from 2007 to 2010 to provide effective and improved biological follow-up for patients receiving ART. The works included the provision of new infrastructure, equipment, and technical staff. Biological follow-up of HIV-infected patients performed at the national level used to be only based on CD4 counts until 2009. Viral load measurement was not available. During this period national recommendations for treatment included zidovudine (AZT) + lamivudine (3TC) + nevirapine (NVP) as a first choice or tenofovir (TDF) + 3TC + efavirenz (EFV) as a second choice for the first-line regimen, and abacavir (ABC) + didanosine (DDI) + lopinavir (LPV) as the second-line regimen.

2. Patients and methods

The NRLM entered into a tripartite agreement with the virology laboratory of the French Necker Hospital (Paris) and the international non-governmental organization Solthis (Therapeutic Solidarity and Initiatives for Health) to introduce virological analyses into the biological follow-up of HIV-infected patients. The technical support provided consisted in offering viral load measurement and genotyping analysis for determination of drug resistance using the algorithm of the French National agency for AIDS and viral hepatitis research (French acronym ANRS) and for the HIV-1 subtyping according to the HIV procedures of the ANRS [4]. The genotyping analysis was performed by the virological laboratory of the Necker Hospital with the help of a biologist from the NRLM. The viral load analysis was performed at the Necker Hospital in 2008–2009. Following the renovation of the NRLM's technical platform in 2010, the above-mentioned biologist was able to teach the technical skills learned in Paris to the technical team of the NRLM. The viral load analysis could thus be performed locally. This was the first and only virological investigation on HIV subtypes and drug resistance performed at a national level in Madagascar among HIV-infected patients managed at referral clinical settings from 2008 to 2012. Patients were recruited throughout the year by referral physicians during routine visits, without any exclusion criteria.

A total of 10 out of the 22 regions of Madagascar (Analamanga, Analanjirofo, Anosy, Atsimo-Andrefana, Atsinanana, Boeny, Diana, Menabe, Sava, Sofia) were included in the

study. This corresponds to locations where 93% (594/641, 2011 national HIV/AIDS data) of HIV-infected patients across the country were reported.

3. Results

Table 1 details the percentage of drug resistance (to NRTIs, NNRTIs, or PIs) according to the algorithm of the ANRS in the 10 regions of Madagascar as well as the patients' general characteristics. Overall, 259 patients were included in the study. Resistance mutations to NRTIs and NNRTIs were observed in 36 (13.9%) of them but resistance mutations to PIs was observed in less than 2%. Overall, 52.1% of patients were aged between 26 and 40 years; 17.4% of patients infected with NRTI-resistant HIV strains were men. Overall, 22% of treated patients were infected with mutated HIV resistant to NRTIs and/or NNRTIs and three with mutated HIV resistant to PIs. Less than 10% of treatment naïve patients were infected with mutated HIV resistant to NRTIs and NNRTIs and two with mutated HIV resistant to PIs. Drug resistance mutations were observed among treatment-naïve and treated patients. Drug resistance was mainly observed in three regions (Analamanga, Boeny, and Diana).

4. Discussion

The results of our study revealed an alarming proportion (13.9%) of drug resistance among HIV-infected patients in Madagascar. Only one study conducted in 2006 reported a virus harboring resistance mutations to PIs [5]. Indeed, our investigation was the first national virological investigation to be conducted over a five-year period among HIV-infected patients.

We also observed, for the first time, that drug resistance could be transmitted to treatment naïve patients. However, the existence of primary resistance has also been reported in other African countries [6,7] in patients presenting with similar therapeutic history and receiving similar types of regimen. Further investigation needs to be carried out at the national level on the basis of the HIV drug resistance threshold survey method recommended by WHO for the surveillance of transmitted HIV drug resistance [8]. However, conducting such study would be very difficult in a country with a low HIV prevalence such as Madagascar.

The tripartite agreement enabled the NRLM to communicate these alarming findings to healthcare providers, policy makers, and all stakeholders involved in the response to HIV/AIDS.

Healthcare providers were trained to adequately analyze resistance mutations and assess associated outcomes for patients receiving ART. The therapeutic management of HIV-infected patients enrolled in the study was therefore made possible by the active collaboration of their respective physicians.

The NRLM also shared these findings with decision makers at the Ministry of Health and with other partners involved in the national fight against HIV/AIDS. The transmitted drug resistance to NRTIs observed in the study (data not shown) led to the revision of the first-line regimen mentioned in

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