



**ABSTRACT**

**Background:** Controversy still exists regarding virologic response in HIV-infected women. Most of the data are coming from trials with underrepresentation of women showing lower virologic suppression by up to 50% in women when compared to men. The objective of this study was to assess the response to treatment of HIV-infected women after antiretroviral initiation.

**Methods:** This was a retrospective, observational study of treatment-naïve HIV-infected women managed at the 550 clinic who started antiretroviral therapy (ART) between January 1st, 2006 and December 31, 2013. Patients with available CD4 counts and viral load before initiating ART and one year after treatment were included in this study. Virologic success was defined as a viral below the limit of detection of laboratory test. Immunological recovery was defined as a CD4 count increase of at least 150 cells/mm<sup>3</sup>. Dichotomous variables were reported in number and percentage. Continuous variables were reported as mean and standard deviation (SD).

**Results:** A total of 120 women were included in the study. At the time of diagnosis mean age was 39 years old (SD 10), AIDS was documented in 33% of the patients, and viral load above 100,000 copies/mL in 27%. Virologic success at one year of ART initiation was documented in 50% of the women. Immunological recovery was documented in 51% of the patients.

**Conclusion:** The virologic response rate found in our study is in agreement with already published literature. Future studies assessing particular barriers and needs affecting HIV-infected women are needed in order to improve care in this population.

**INTRODUCTION**

**Women and HIV**

HIV infection has become a chronic condition particularly for those patients compliant with treatment. In 2007, adult and adolescent women represented 27% of people living with HIV (1), that percentage is on the rise in the US and around the world (2). HIV-positive women face different challenges to remain in care and have successful outcomes. Published data shows that HIV-infected women have poorer virologic responses when compared to men who have sex with men (3). HIV + women have more no show rates to appointments, which is likely due to gender roles, lower levels of education, pregnancies and higher rates of mental illnesses such as depression. Women living with HIV are also likely to be more non-compliant or to have a higher rate of discontinuation in therapy due to adverse events and intolerance (2).

**HIV Women and ART response**

Even with improved techniques in diagnosis and many options available for antiretroviral treatment (ART), many of the HIV infected population is not receiving care. CDC recent data reports 41% of the 1.2 million people living with the disease in the US are aware of their diagnosis and are not receiving the appropriate treatment (1). Controversy still exists regarding virologic response in HIV-infected women.

Most of the data are coming from registration trials with an underrepresentation of women. These studies showed a lower virologic suppression in women when compared to men. It has been reported that 1 in 4 women are not receiving ART (4). Providers were more likely to report self-discontinuation of treatment in women and the rate of lack of therapy was higher in African American women (2).

The primary objective of this study was to assess the response to treatment of HIV-infected women after antiretroviral initiation. The secondary objectives were to assess immunological recovery at one year and rate of modifications during that first year of antiretroviral treatment.

**METHODS**

**Study design and study population**

This was a retrospective, observational study of treatment-naïve HIV-infected women managed at the 550 Clinic – University of Louisville Hospital. Data was collected between January 1, 2006 and December 31, 2013. Non-consecutive medical records of female patients with the diagnosis of HIV who were treatment naïve and started treatment and were followed up for at least 1 year in the clinic were reviewed. Validation of data quality was performed at the study center before the case was entered into the database. Institutional Review Board approval was obtained.

**Study definitions**

*Inclusion criteria*

ART initiated between January 1st, 2006 and December 31, 2013. Patients with available CD4 counts and viral load before initiating ART and one year after treatment were included in this study.

*Study outcomes*

Virologic success: defined as a viral below the limit of detection of laboratory test.

Immunological recovery was defined as a CD4 count increase of at least 150 cells/mm<sup>3</sup>.

ART modification was defined as any modification in the initial regimen over the first year. Reasons for this modification were recorded if available in the record.

**Statistical analysis**

Dichotomous variables were reported in number and percentage. Continuous variables were reported as mean and standard deviation (SD).

**RESULTS**

- A total of 120 women were included in the study.
- Patients' characteristics are shown in Table 1.
- At the time of diagnosis, mean age was 39 years old (SD 10), AIDS was documented in 33% of the patients, and viral load above 100,000 copies/mL in 27%.
- Virologic success at one year of ART initiation was documented in 50% of the women.
- Immunological recovery was documented in 51% of the patients.
- A total of 15% patients had at least one modification in the ART within the first year of treatment.
- Percentages of initial ART are shown in Table 2.
- Reasons for modifications in ART within the first year are shown in Figure 1.

**RESULTS**

Table 1 Patients' characteristics

<b>Total population</b>	<b>120</b>
Mean age (SD)	39
White	30%
AA	62%
Other race	8%
<b>Ethnicity</b>	
Non Hispanic	89%
Hispanic	11%
<b>Risk factors for HIV acquisition</b>	
Heterosexual contact	76%
Homosexual contact	24%
IV drug use	6%
Other	0%
<b>Social history</b>	
Alcohol	48%
Tobacco	67%
Non IV drug use	31%
<b>HIV status at diagnosis</b>	
VL > 100 000	22%
CD4 <200	25%
CD 4 < 15%	21%

Table 2 Percentages of initial ART

<b>First ART used</b>	
NNRTI based	20%
PI based	57%
INSTI based	22%
Other	1%

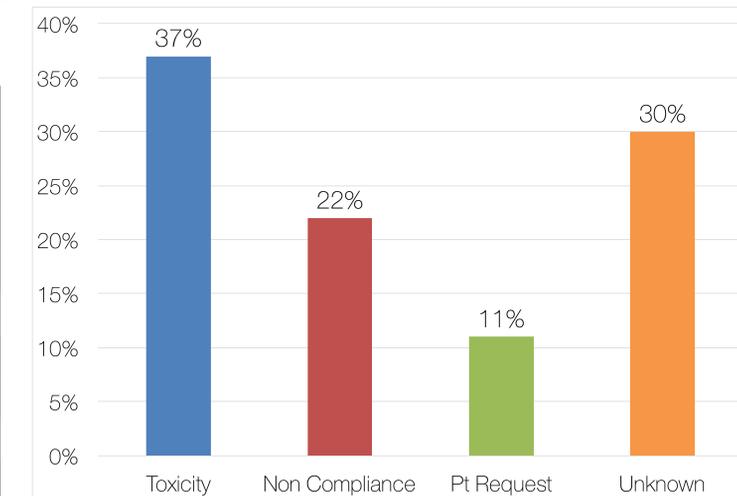


Figure 1 Reasons for modifications in ART within the first year

**CONCLUSIONS**

- Our study showed a virologic response rate of 51%. This rate found in our study is in agreement with the limited information available on this topic in the published literature.
- Women seem to delay ART initiation more than men, they have more side effects from the medication. Data showed that women are more likely to experience neurologic, dermatologic or constitutional toxicities or more specific symptoms and females appear to metabolize the drugs on a different way. Other factors include mental illnesses, reluctance to take medication at home and socio-economic status. (2)
- Studies assessing particular barriers and needs affecting HIV-infected women are needed in order to improve care in this population.

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