A high percentage of antiretroviral treatment-(ART) experienced patients enrolled in an HIV treatment program in Lagos, Nigeria: a comparison of the virological and immunological outcomes of ARV-naïve and ARV-experienced patients on 2003 WHO-recommended first-line ART

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Background

Lagos 2005:
- Population of 17 Million; 800,000 PLWHA
- Approximately 100,000 in need of ART; only 8,500 (8.5%) on ART

- Government Program is based on cost-recovery, and experienced antiretroviral drug (ART) stock rupture Nov 2003 - Jun 2004
- ARVs are available in the private sector

An increasing number of patients presenting to MSF HIV programs have previous ART experience

MSF-H Project Description

- Clinic opened November 2003 in Lagos General Hospital, Lagos, in collaboration with Ministry of Health.
- 2,000 patients were registered by July 2006.
- The clinic provides free medications, laboratory tests, consultations and care.
- In July 2004, the clinic placed its first patient on ART, using WHO prequalified generic fixed-dose combination ARVs
- All patients commence WHO recommended first-line ART:
  - d4T/3TC/NCV 49%, AZT/3TC/NCV 30%, d4T/3TC/EFV 15%

Objective

To compare the clinical, immunological and virological outcomes between ARV-experienced and ARV-naïve patients on 2003 WHO-recommended first-line ART

Methods

- A retrospective cohort study of patients commencing first-line ART using routine data collected via Fuchia software (Epipcentre, France)
- CD4 performed with FASCOUNT (Becton Dickinson)
- Viral load: Roche Ampliprep performed at Nigerian Institute of Medical Research (NIMR), Lagos

ART cohort Nov 2003-June 2006

Number of ART:
- 1,284
- ART Experienced: 233 (18%)
- Time on ART Prior to MSF: 15.7 months (IQR 10.3-20.3 Months)
- Regimens Prior to MSF:
  - AZT/3TC/NCV 49%
  - AZT/3TC/NCV 30%
  - AZT/3TC 15%

Characteristics at ART baseline

Parameter | ART-experienced (n=233) | ART-naive (n=1017) | p-value
--- | --- | --- | ---
Age (years) | 36 (30-42) | 35 (30-42) | 0.211
Female sex | 146 (60%) | 574 (56%) | 0.172
Median weight (kg) | 62 (55-75) | 67 (60-90) | <0.001
Median CD4 count (cell/mm³) | 280 (115-449) | ND | <0.001
Median Viral load copies/ml | 2,590 (760-60,000) | ND | <0.001
Median time on ART to start ART | 9.3 (5.2-14.1) | 14 | <0.001
High rebound (<50 copies/ml) | 85% (100%) | 105 (100%) | <0.001

Outcomes at 6-12 months of ART

Parameter | ART-experienced | ART-naive | p-value
--- | --- | --- | ---
Mortality (at 12 months) | 13.5% (95.1.5-6.5) | 18% (9.5-26.5) | 0.032
Liver failure (at 12 months) | 3.7% (2.6-5.1) | 5.9% (4.5-7.5) | 0.034
MACE weight change (kg) | 1.0 (1.5-6.5) | 0.5 (1.5-3.5) | <0.001
Weigh change on or off ART | 44 (48.4%) | 60 (55.3%) | <0.001
Median CD4 change (cell/mm³) | 18 (27-21) | 19 (25-28) | <0.001
CD4 change on or off baseline | 24 (16.2%) | 0.5 (18.4%) | <0.001

Virological outcomes after 6-12 months of ART

- Number of Patients with Treatment Interruption 122
- Number of Patients without Treatment Interruption

ART Interruption prior to MSF in ART-experienced patients (n=122)

- Number of Patients with Treatment Interruption
  - 122
  - 100% (95% CI)
  - 88 (72.1%)

- Number of Patients without Treatment Interruption
  - 122
  - 100% (95% CI)
  - 34 (27.8%)

Summary

- Significantly inferior clinical (weight gain) and immunological outcomes after 6-12 months of treatment in ART-experienced patients.
- Increased risk of high-level virological failure (>10,000 copies/ml) after 6-12 months of WHO first-line ART.
- Increased risk of progression to further AIDS-defining illness or death.

Conclusions

There is a high percentage of ART-experienced patients registered in MSF Lagos program, and most (72%) had experienced prior ART interruption.

Preliminary findings suggest that outcomes of ART-experienced patients on first-line ART are worse compared to ART-naïve patients.

There is a need for further investigation to determine if worse outcomes secondary to increased baseline ART resistance, possibly contributed to by frequent ART interruptions and inadequate ART regimens (2-drug).