

The Senegalese government HAART initiative: an 18-month follow-up study of feasibility, effectiveness, adherence, toxicity and viral resistance

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Study design

Prospective observational cohort study to assess the feasibility, effectiveness, adherence, toxicity and viral resistance of HAART in an African government initiative
Performed in Dakar from 1998 to 2000
Initial treatment included 2 NRTI + 1 PI
Available drugs were d4T, ddI, ZDV, 3TC, IDV
Government-sponsored treatment
34 US\$ per month paid by 90% of patients

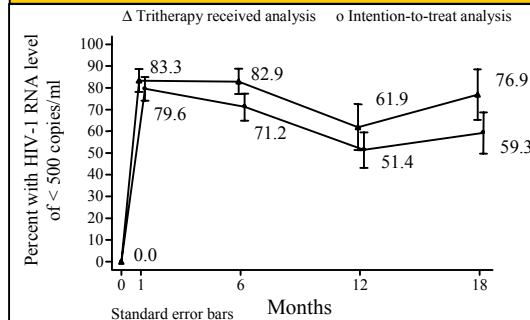
Inclusion criteria

HIV-1 infected patients
Asymptomatic (class A)
HIV-1 RNA > 100 000 copies/ml
CD4 < 350/mm³
Mildly symptomatic (class B)
HIV-1 RNA > 10 000 copies/ml
CD4 < 350/mm³
Symptomatic (class C)
Karnofsky score ≥ 70%
free of major opportunistic infections
Naive to antiretroviral therapy

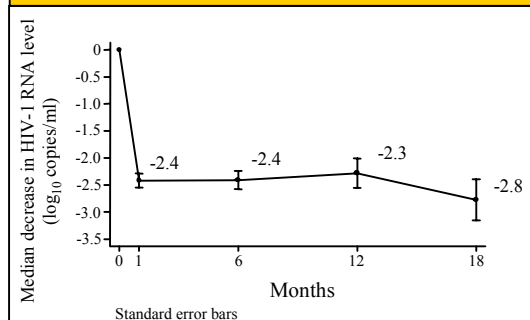
Baseline characteristics of the 58 patients

Male – no. (%)	32 (55.2)
Median age (IQR) – years	41.5 (30-46)
HIV 1+2 – no. (%)	3 (5.2)
HIV-1 genotypes – no. (%)	
Group O	2 (3.4)
Group M subtype A	9 (15.5)
" " " B	3 (5.2)
" " " C	5 (8.6)
" " " D	2 (3.4)
" " " G	4 (6.9)
CRF02-AG	31 (53.4)
CDC class – no. (%)	
Class B	16 (27.6)
Class C	42 (72.4)
Median CD4 count (IQR) /mm ³	108.5 (34-217)
Median HIV-1 RNA (IQR) – copies/ml	107 650 (28 255-217 655)
Median body mass index (IQR)	20.3 (18.4-22.5)
Karnofsky score – no. (%)	
70	2 (3.4)
80	7 (12.1)
90	34 (58.6)
100	15 (25.9)
Antiretroviral treatment	
d4T+ddI+IDV	47 (81.0)
ZDV+3TC+IDV	8 (13.8)
ZDV+ddI+IDV	3 (5.2)
Cotrimoxazole prophylaxis	47 (81.0)

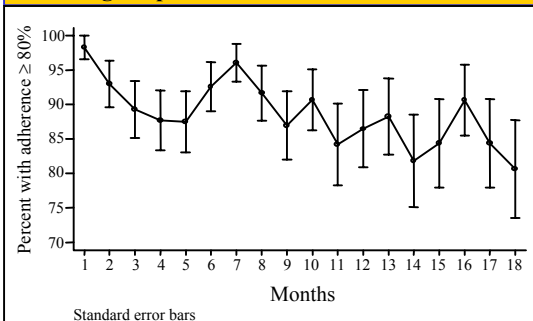
Percentage of patients with HIV-1 RNA < 500 copies/ml



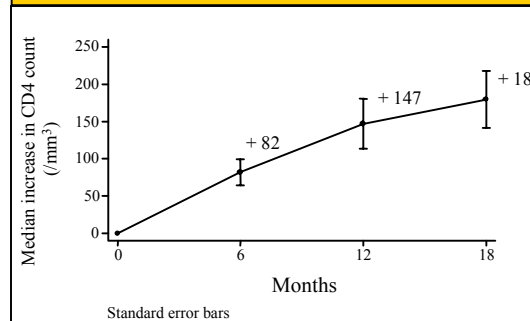
Median decrease from baseline in HIV-1 RNA level



Percentage of patients with adherence ≥ 80%



Median increase from baseline in CD4 cell count



Clinical outcome

Body mass index increases only the first year
Karnofsky score increases non significantly
7 clinical AIDS-defining events (oesophageal candidiasis, tuberculosis, *Mycobacterium avium complex* infection)
6 patients (out of 7) died of HIV-related infections
AIDS-stage at baseline
treatment was interrupted
CD4 < 100/mm³ in 5 patients
HIV-1 RNA < 500 copies/ml in 4 patients

Adverse effects

47 adverse effects in 30 patients (51.7%)
Gastrointestinal disorders predominated (24/47, 51.1%)
80.8% of adverse effects were mild or moderate
12.8% were severe (hepatitis (n=3), urinary lithiasis, jaundice, vomiting)
4.3% were life-threatening (anemia)
None patient died of adverse effect
4 adverse effects (8.5%) led to short hospital stay (less than 7 days)

Drug resistance

Natural resistance to NNRTI for 2 group O viruses
No major mutations associated with resistance to NRTI or PI at baseline
Wide variety of minor mutations at baseline (Vergne L, et al. J Clin Microbiol 2000,3913-25.)
2 cases of drugs resistance occurred during follow-up (d4T and ZDV+3TC+PI)

Conclusion

This study shows that HAART is feasible and well tolerated in African patients. Clinical and biological results were comparable to those seen in western cohorts, despite differences in the HIV-1 subtype distribution and an advanced disease stage when the treatment was initiated. Contrary to other recent studies in Africa, viral resistance rarely emerged.



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