

ESTHER Rwanda-Luxembourg HAART program for patients with advanced-stage disease and limited resources

J Mugabo

Centre Hospitalier Universitaire de Kigali, Kigali, Rwanda

1. Summary

Setting up a large-scale comprehensive care programme for patients with advanced-stage disease and limited resources is a major challenge. This study describes the organization of a programme for patients with limited resources subsidised by ESTHER Luxembourg program (Ensemble de Solidarité Thérapeutique Hospitalière En Réseau), in the Central University Hospital of Kigali (CHUK) and difficulties encountered. The cohort includes 1603 patients under HAART and opportunistic infection (OI) prophylaxis since April 2003 in internal medicine and paediatrics at CHUK. Among patients under HAART, stage 3 and 4 represent 89,5%. The number of death under HAART amounts to 56/982 (5,7% with an average follow-up of xx months??). 99,5% of patients are treated on first line regimen and 4,6% changed treatment for intolerance. Medical staff of the hospital had to be reorganized, without increase in the number of doctors, but with a strong team of counsellors, nurses and social workers. 2057 outpatient visits were done by medical and psychosocial staff. Standardized tools were developed for follow up and home visits. Among major problems, care for OI was difficult, because of irregular procurement of drugs and reagents, lack of consensus workup flowcharts and treatment protocols and an insufficient number of doctors to cover proper care of hospitalised patients and outpatient ARV clinics, which contributes to a high intrahospital mortality rate before starting HAART.

Care for patients with limited financial resources is possible, including ARV therapy. It needs appropriate amounts of trained staff, drugs and reagents and reorganization of services, with reassignment of tasks for staff, empowerment of non-medical staff and standardized tools.

2. Introduction

In Rwanda, HIV/AIDS is a major health problem and seroprevalence is estimated at 9,8%. At CHUK, 69,8 % of patients hospitalised in internal medicine are HIV positive and 79,3 % of mortality in internal medicine is due to opportunistic infections. In 1998, the first patients have been put on HAART in Rwanda at CHUK, but they had to pay for the drugs and the laboratory exams. Patients with limited resources had no access to prophylaxis and HAART. They were either hospitalised again and again for the treatment of opportunistic infections, and others didn't even reach the hospital, knowing that hospitalisation was expensive and treatment was only symptomatic. In April 2003, the ESTHER Rwanda-Luxembourg program began to subsidise prophylactic treatment and HAART for 600 patients, including laboratory testing and since September 2003 the Global Fund contributed for scaling up to 19.000 patients in 5 districts.

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3. Materials and Methods

Since April 2003 to end of May 2004, the program followed up a cohort of 926 patients on both HAART and OI prophylaxis. The patients put on prophylaxis are in WHO stage 2, 3 or 4 or stage 1 with CD4<400. Children born to HIV positive mothers are put on Cotrimoxazole prophylaxis for one year starting at week 4. Between the ages of 1 to 5 years, prophylaxis is continued if the child is confirmed HIV positive and CD4 cell counts are below 750. Children above 5 years are kept on prophylaxis if CD4 cell counts are below 350.

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Selection criteria for HAART in adults are:

- ✓ HIV disease WHO stage IV, or stage III with CD4 cell counts below 350
- ✓ HIV disease WHO stage I or II with CD4 cell counts below 200
- ✓ Open Acceptability to share knowledge about HIV status with family or relatives
- ✓ Good adherence to a previous prophylaxis program, unless urgent need for antiretroviral treatment not permitting for a delay in treatment initiation.
- ✓ Residence in Kigali city or surrounding rural area

Selection criteria for HAART in children are:

- ✓ HIV disease CDC stage B or stage C
- ✓ HIV disease CDC stage A with CD4 < 750 with age less than 1 year, CD4 < 500 with age between 1 and 5 years and CD4 < 200 with age above 5 years
- ✓ Good adherence to a previous prophylaxis program, unless urgent need for antiretroviral treatment not permitting for a delay in treatment initiation
- ✓ Residence in Kigali city or surrounding rural area

Recommended first line HAART regimens consist of Lamivudine-Stavudine-Nevirapine, Lamivudine-Stavudine-Efavirenz, Lamivudine-Zidovudine-Nevirapine or Lamivudine-Zidovudine-Efavirenz. Recommended second-line regimens are Zidovudine-didanosine with either boosted lopinavir or indinavir.

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Entry points for selection are hospitalisation in internal medicine and paediatrics and outpatient clinic. Doctors present patients to a selection committee after a pre-treatment visit to the counsellor and after exclusion of hepatic and renal disorders. The committee, composed of doctors, counsellors and nurses, meets every week. The follow up is organised by the counsellor team, programming counselling visits, medical visits and laboratory testing.

The doctors are in charge of clinical and biological evaluation of the patients, prescription of drugs and care of hospitalised patients. Counsellors are responsible for preparing patients to HIV testing, do pre-HAART counselling, drug distribution and psychosocial follow-up. In addition, the counsellor team puts a special emphasis on adherence to treatment and patient motivation.

Nurses provide care to patients in the hospitalisation wards and outpatient clinic.

CD4 testing is done at the hospital on Cyflow Counter and viral loads are done at the national reference laboratory using Amplicor Monitor HIV 1.5.

Patient information are collected on paper in a special HAART file and encoded in the FUCHIA (Follow-Up of Clinical HIV Infection and AIDS) database.

4. Results

As of 27 May 2004, the cohort is composed of 1603 patients alive, 183 children (0 to 13 years) and 1420 adults (above 13 years). All children are on cotrimoxazole prophylaxis and 102 children are on HAART. 1336 adults are on cotrimoxazole prophylaxis and 84 are on both fluconazole and cotrimoxazole prophylaxis. 824 adults are on HAART and prophylaxis.

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Since the beginning of the program 2057 outpatient visits were done by medical and psychosocial staff.

A. Patients above 13 years on HAART (Adults)

Since the beginning of the program 875 adults have begun treatment, from which 51 patients have died all of opportunistic infections (5,8%) despite a short follow-up period average follow-up of??.

Among adults on HAART, 69,8 % of the patients are female and 30,2 % are male. The 824 adults alive and on HAART are classified as WHO stage 3 in 51,9 % and WHO stage 4 in 37,6 %.

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98,5 % of the patients are on first line schemes and 1,5 % of the patients are on second line schemes. The most current therapeutic first line schemes are 3TC, D4T, NEV (Fixed-dose combination FDC) - 71,8% ; 3TC, AZT, EFA - 14,3% and 3TC, D4T, EFA - 9,2%.

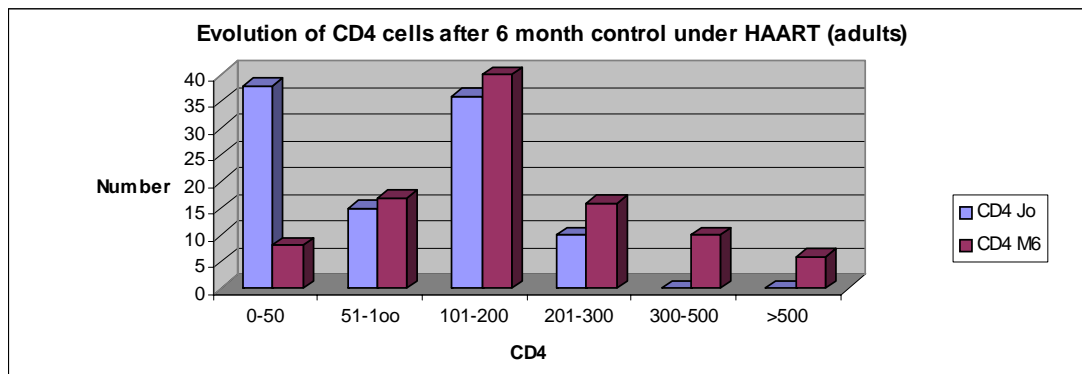
Hospitalisation has occurred for 33 patients on HAART (4,2%). Among major diagnosis of hospitalisation are tuberculosis (24 %), diarrhoea (21 %), cryptococcal meningitis (9 %) and oral candidosis (9 %).

Intolerance has been described for 41 patients (4,6 %) leading to stopping at least one drug.

Among major side effects are cutaneous rash and vomiting due to NVP, peripheral neuropathy due to D4T and DDI and anaemia due to AZT. 1 female patient had to change EFV to NVP due to pregnancy.

Evolution of CD4 cells during HAART

97 patients had CD4 control at month 6 in the file. Among these at baseline, 38 patients had CD4 cells under 50/μl and only 10 patients above 200/μl. At month 6, only 8 patients remained under 50/μl and CD4 cell counts of 32 patients was above 200/μl. Give the mean CD4 increase!!



Viral load has been done for 59 patients, for which 42 (71,2 %) were undetectable.

B. Patients under 13 years on HAART (Children)

Since the beginning of the program 107 children have begun treatment, from which only 5 have died of opportunistic infections (4,7%) despite a short follow-up period.

Among children on HAART, 57,9 % are female and 42,1 % are male. The 105 children alive and on HAART are classified as CDC stage 2 in 12 %, CDC stage 3 in 68 % and CDC stage 4 in 11 %.

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All the children are on first line schemes. The most common therapeutic first line schemes are 3TC, D4T, NEV - 57,8% ; 3TC, AZT, EFA - 35,3% and 3TC, D4T, EFA - 4,9%.

Hospitalisation has occurred for 3 children on HAART (2,9%). Among diagnosis of hospitalisation are tuberculosis (1), cryptococcal meningitis (1) and cachexis (1).

There has been no case of stopping a drug for intolerance.

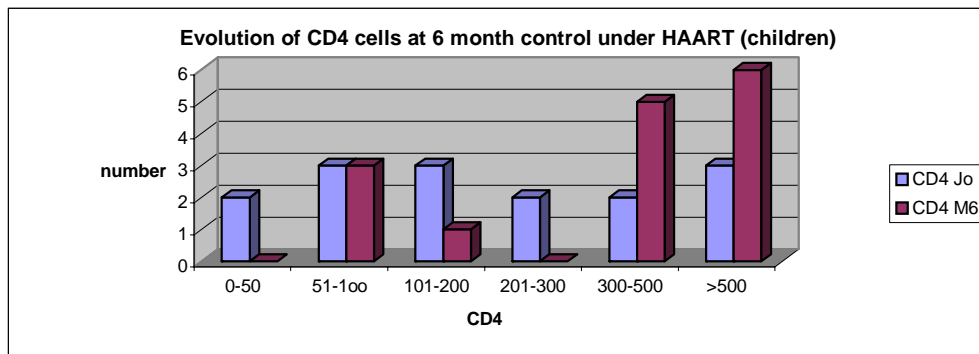
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Evolution of CD4 cells during HAART

15 children had CD4 control at month 6 in the file. Among these at baseline, 5 children had CD4 cells under 100/ μ l and only 5 children above 300/ μ l. At month 6, 3 children remained under 100/ μ l and CD4 cell counts of 11 children was above 300/ μ l. give mean increase



Organisation of services

Medical staff of the hospital had to be reorganized, without increase in the number of doctors (13 doctors for internal medicine and 4 doctors for paediatrics), but with a strong team of counsellors, nurses and social workers (13 persons). 2057 (à changer encore) outpatient visits were done by medical and psychosocial staff.

Standardized tools were developed for follow up as for example workup flowcharts and treatment protocols for IO treatment or management of ARV side effects. Home visits were organised for evaluating patient's socio-economic situation and track "lost for follow up".

Among major problems, care for opportunistic infections was difficult, because of irregular procurement of drugs and reagents for the diagnosis of OI, lack of consensus workup flowcharts and treatment protocols and an insufficient number of doctors to cover proper care of hospitalised patients and outpatient ARV clinics. This contributes to a high intrahospital mortality rate before starting HAART.

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5. Conclusions

Care for late stage patients with limited financial resources is possible, including HAART. Even patients with CD4 cell under 50/ μ l when closely followed up showed a good evolution under HAART. But it needs appropriate amounts of trained staff, drugs and reagents and reorganization of services, with reassignment of tasks for staff, empowerment of non-medical staff and standardized tools.

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Recommendations: For comprehensive care for patients with limited financial resources, prerequisites are necessary: consensus on global OI care and HAART, a well trained, multi-disciplinary team, reorganization of in- and outpatient services and increased responsibilities to paramedical staff.

6. References

UNAIDS, annual report 2003
FUCHIA