HAART can be provided safely in African HIV positive children: analysis of patients in 2 urban health centres in Kigali (Rwanda)

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BACKGROUND AND METHODS

MSF started in 2002 in Kigali with a comprehensive care for PLWHA and in 2003 with HAART. From the start we opted for a family approach, hence the large cohort of children on treatment.

We describe the treatment outcomes in children (< 15 years of age) and assess the safety of HAART.

Data were routinely collected using a monitoring software (Access®). Treatment and safety outcomes were analysed by Excel® and SPSS®.

PATIENT CHARACTERISTICS

As of mid July 2006, 2596 patients were initiated on ARV of whom 7% have died or are lost to follow-up. 11,3 % (n=293) of our active cohort constitute of children. More than a quarter are younger than 5 years. Half are female (compared to 70% for the adult cohort) and two thirds (67%) are more than 1 year on treatment. Inclusion criteria for ART are based on old and new WHO guidelines (2003 and African region version 2005).

Distribution of WHO stages 1, 2, 3 and 4 (new classification of 2005) at start of ARV are depicted in Fig.1. Main reason for entering stage 2 are dermatological manifestations followed by recurrent respiratory tract infections. In stage 3, children presented mainly with persistent diarrhoea, persistent fever, moderate malnutrition and/or oral candidiosis. Seven TB cases were recorded.

The majority (n=260,89%) started on d4T/3TC/NVP in line with WHO and MSF recommendations (see fig. 2). Once able to swallow tablets (from 2 to 3 years onwards), fixed dose combinations were prescribed based on a simplified dosing table with 4 weight categories. No quarters were used, only whole or half tablets (table 2).

TABLE 1. PATIENT CHARACTERISTICS OF PEDIATRIC COHORT (<15 years)

Adults	2303	(88,7%)	
Children on ART	293	(11,3%)	
< 5 years	81	(28%)	
5 to 14 yr	212	(72%)	
Mean age	7.3		
Female (%)	52 %		
Median time ART (IQR)	16.9 months	(10-23)	(397 patient years FU)
Baseline CD4 %			
< 5 years (IQR)	15 %	(10.5-19)	
5-14 years (IQR)	12 %	(9-16)	
in absolute count	292	(179-404)	
Baseline SGPT	25.3	(19-35)	
Baseline Hb	11.1	(10.4-11.8)	

Fig 1: WHO stage (at start HAART)

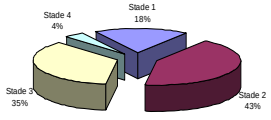

Fig 2: Regimen at start HAART

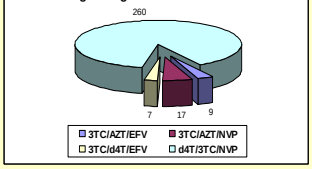

Table 2: dosing scheme (> 14 d.)

< 10 kg	Syrups
10 to 13 kg	Triviro 30 ½ tab bid
14 to 17 kg	Triviro 30 ½ tab bid + NVP ½ tab od
18 to 20 kg	Triviro 40 ½ tab bid + NVP ½ tab od
21 to 30 kg	Triviro 30 1 tab bid

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TREATMENT CHARACTERISTICS AND OUTCOME

Overall treatment outcomes in July 2006 were: 261 (89%) alive and followed, 7 died and 19 transferred out. Only 2% was lost to follow-up (see Table 3).

After 5 months, 85% increased their weight. The ones not gaining had a mean loss of 1 kg. Haemoglobin levels raised with a mean of 1,5mg/dl to 12,6.

Mean CD4% increases can be seen in Figure 3. Viral loads were routinely performed after 1 year treatment (mean time 19 months, 101 results available). Eighty eight percent had less than 400 copies while only 8% were above > 5000 copies.

Fig 3a: CD4% evolution (< 5 years of age)

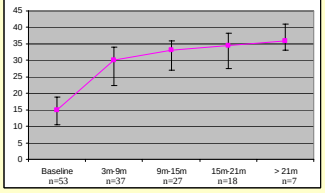

Fig 3b: CD4 evolution (>= 5 to 14 yrs)

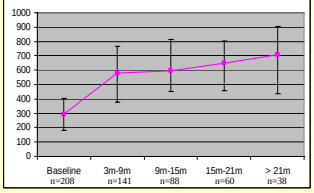

TABLE 2. Viral loads (n=101)

< 40 copies	81	(80%)
< 400 copies	89	(88%)
> 400 copies	12	(12%)
> 5000 c.	8	(8%)

TABLE 3. Treatment OUTCOMES

Mortality	7 patients	(2,4%)
Transfer out	19 patients	(6,5%)
Lost to follow-up	6 patients	(2%)

SAFETY

Liver function tests were performed at baseline, 2, 4, 8 weeks and then every 6 months and on clinical grounds. Severe hepatic abnormalities (grade 2-4 and symptomatic grade 1) appeared in 12 cases (4,5%). Median time of onset was 43 days (IQR 30-122) with two thirds presenting before 2 months. Seven symptomatic (fatigue, nausea, fever, jaundice, RUQ pain and/or hepatomegaly) children changed to EFV. Four of the eight patients with grade 2-3 levels continued NVP with spontaneous recovery.

Another 11 (4%) switched to EFV because of skin manifestations (allergy/dermatitis). Median time of onset was 24 days (82% within 1 month) and none had ALAT levels > 2,5 UNL.

Five changed to EFV due to start TB treatment.

TABLE 4. Side Effects

Livertoxicity (PACTG 1994)		
• grade I (moderate: 50-100)	42 patients	(16%)
• grade I (severe: 100-200)	14 patients	(5%)
switch to EFV	4 patients	
• grade II	7 patients	(2,5%)
switch to EFV	3 patients	
• grade III/IV	1 patient	
SGPT follow-up (> 3 months)		
Mean (IQR)	28 (20-40)	
Skin reactions		
with switch to EFV	11 patients (3%)	
Peripheral neuropathy	0	
Lactic acidosis	0	

CONCLUSION

Our results show that it is feasible to initiate HAART in a large group of children in urban health centres. Side effects due to HAART are less common in children than in adults and none was life threatening. Follow-up with liver function tests may not be necessary since all treatment changes were in patients with symptomatic disease. Rural health centres starting access to HAART might consider focussing on children instead of adults given the fewer side effects (with less biochemical follow-up needed) and given the better response to treatment in terms of morbidity and mortality.