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Immunovirological Profile of HIV1 Infection in Children and Adolescents Followed at the Bangui Pediatric University Hospital

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Abstract

History: Pediatric management of HIV infection in children in the Central African Republic began in 2004 with the use of fractionated adult antiretrovirals and Cotrimoxazole. It has evolved over the years with the use of pediatric forms, oral suspensions and dispersible tablets. The transition to Dolutegravir took place in 2020. The active file of our patients will grow from 78 to over 1900 today. Follow-up examinations are carried out to assess adherence to treatment. **Objective**: To determine the immunovirological profile and factors associated with treatment failure during follow-up of children on ART at the Bangui pediatric university hospital. **Patients and Method**: This was a cross-sectional, analytical study from May 30 to December 02, 2022. The study sample was drawn from a cohort of HIV-1-infected children followed up at the Bangui pediatric university hospital and on ART for three semesters who met the selection criteria. **Results**: The prevalence of treatment failure varied from one semester to the next. Thus, the prevalence of therapeutic failure was 20% in the first semester, 10% in the second semester and 7% in the third semester. The prevalence of virological failure was 10.28% in the first half of the year, 6.91% in the second half and 4.98% in the third. Secondly, immunological failure was 0.48% in the first half of the year, 0.32% in the second 0.64% in the third half. Finally, clinical failure was 8.82% in the first half, 4.82% in the second half, 1.92% in the third half. Socio-demographic and clinical factors associated with treatment failure were male gender ($p < 0.01$), deceased parents ($p < 0.001$) adherence < or = 95% ($p < 0.001$), WHO stage 3 or 4 at inclusion ($p < 0.001$) and viral load at initiation > 1000 copies/ml ($p <$

0.001). **Conclusion**: The occurrence of treatment failures in children is a major problem, especially in our resource-limited countries, given the challenges facing antiretroviral therapy. It is therefore necessary to carry out a study on resistance genotyping in order to propose correct management protocols, as the future of treatment programs depends on it.

Keywords

Profile, Immunovirological, HIV/AIDS, Children, Bangui

1. Introduction

Worldwide, in 2021, around 1.7 million children aged < 14 years were infected with HIV, 4% of the total number of cases worldwide [1]. Every year, around 160,000 more children are infected (10% of all new infections), and around 100,000 children die. Although these figures represent an impressive number of illnesses, new programs created to administer antiretroviral treatment to pregnant women and children have reduced the annual number of new infections and child deaths by between 33% and 50% in recent years [2]. However, infected children do not receive antiviral treatment as often as adults, despite the fact that interrupting vertical transmission or mother-to-child transmission and treating HIV-infected children remain the two most important global objectives of paediatric HIV medicine.

Antiretroviral treatment has considerably improved life expectancy and quality of life for HIV-infected children [3]. However, to remain effective, this treatment must be administered for life. It also requires continuous monitoring to diagnose and manage side effects and therapeutic failures at an early stage. In resource-limited countries such as the Central African Republic, despite the constant expansion of access to antiretrovirals (ARVs), including for children, access to the means of treatment is still limited of investigations for the biological monitoring of efficacy and tolerance of antiretroviral treatments is sorely lacking.

In the absence of viral load testing in certain areas, therapeutic changes based on clinical and immunological criteria alone are generally made at an advanced stage of the disease, increasing the risk of opportunistic infections and mortality. This is why it is so important to rapidly modify antiretroviral therapy after virological failure. This assertion was supported by a study which showed an accumulation of resistance mutations when the patient remains on the same therapy despite failure, even at relatively low viral load levels [4]. In our countries, access to genotypic resistance tests is even more limited, thus limiting the etiological diagnosis of ARV resistance occurring in our cohorts.

A study carried out among children followed up in Cameroon in 2011 reported that 80% of cases in virological failure were carriers of virus resistant to at least one antiretroviral agent [5].

Low blood concentrations of ARVs, disorders of ARV metabolism and the existence of primary ARV resistance have been cited as being associated with treatment failure [6]. Few data are available on resistance in children.

In a cohort study of 220 children at the Complexe Hospitalier Universitaire Pédiatrique de Bangui, 133 (60%) were in virological failure. Among children genotyped for HIV, a resistance mutation was identified in 45% of cases. More than half of children on 1st-line protocols had a major resistance mutation to first-generation non-nucleoside reverse transcriptase inhibitors (NNRTIs) (Nevirapine or Efavirenz), and 24% of children had a major mutation to protease inhibitors (PIs). Since June 2019, HIV genotyping has been subsidized with funding from the Global Fund and done through the Institut Pasteur in Bangui, which subcontracts with a laboratory in Europe. Up to the end of December 2019, 25 HIV antiretroviral resistance tests have been carried out. Sixteen (16) samples were amplified and all showed at least one major resistance mutation: 28 Nucleoside Reverse Transcriptase Inhibitor (NRTI) mutations, 24 NNRTI mutations and 12 PI resistance mutations [7]. However, this study only involved a small sample. The lack of statistics on the scale of this problem, and the identification of associated factors, limits the extent to which it can be taken into account in policies for the care of HIV-infected children in the Central African Republic. The WHO has therefore encouraged more research to evaluate the efficacy of long-term ARV treatment by measuring viral loads in children undergoing ARV treatment [8].

The main objective was to conduct a panoramic study of the immunovirological status of HIV-1-infected children and adolescents on antiretroviral therapy (ART) at the Bangui pediatric university hospital.

2. Patients and Methods

This was a cross-sectional, analytical study conducted over a period of six (06) months, from May 30 to December 02, 2022. The study sample was drawn from a cohort of HIV-1-infected children followed up at the Bangui pediatric university hospital. Selection criteria were:

- Children aged 18 months to 16 years.
- On antiretroviral treatment for more than 3 semesters.
- Follow-up examinations every 6 months: viral load, CD4 count.

Sociodemographic, clinical, biological and therapeutic data were collected using a survey form from the patient's file. The sample was drawn from 5 ml of whole blood on an Ethylene diamine tetraacetic acid (EDTA) tube taken from children and adolescents undergoing treatment at the Bangui paediatric hospital. Once completed, the blood was immediately sent to the LNBCSP for centrifugation at 2900 rpm for 14 minutes, and the plasmas frozen at −20˚C. For CD4 counts, the BD FACSC analyzer was used to automatically measure absolute CD4, CD8 and CD3 values, using whole blood to eliminate lysis and washing steps. For virological follow-up tests, the COBAS AmpliPrep/COBAS TaqMan 48® platform from Roche Diagnostics was used.The study was carried out in collaboration with the

Centre Hospitalier Universitaire Pédiatrique de Bangui (recruitment site), Laboratoire National de la Biologie Clinique et de la Santé Publique (reference center for immuno-virological tests) and Institut Pasteur de Bangui (institution with retrospective data).

Data were entered into Microsoft Excel 2007 and analyzed using Epi info7 software. The characteristics of the children included in the study are described by their numbers and percentages, surrounded by their confidence intervals. Quantitative variables were described by their means or medians and their dispersion parameters. Proportions were compared using Pearson's X2 test. The significance level of the tests was set at $p < 5\%$. The study was carried out in strict compliance with the Declaration of Helsinki, which states that no intervention likely to alter the dignity, integrity or privacy of a patient should be undertaken. the right to privacy of participants will not be implemented. Anonymity was respected. Informed consent was sought from parents after explanation.

Confidentiality is respected in our study by numbering the reports.

3. Results

A total of 622 children meeting our inclusion criteria were selected for this study. The age of our patients ranged from 18 months to 16 years at the time of initiation. The average age was 9 years. The most represented age group was 11 to 16 years. Males predominated, accounting for 65% (n = 402). The sex ratio was 1.82. Figure 1 below shows the distribution of patients by age group.

Rural patients accounted for 62 (10%).

For parental status, mothers were more infected than fathers.

The mean weight of patients at initiation was 14 kg, with extremes of 8.63 kg and 48.5 kg.

More than half our patients were in stage 1 or 2 at initiation, as shown in the following Table 1.

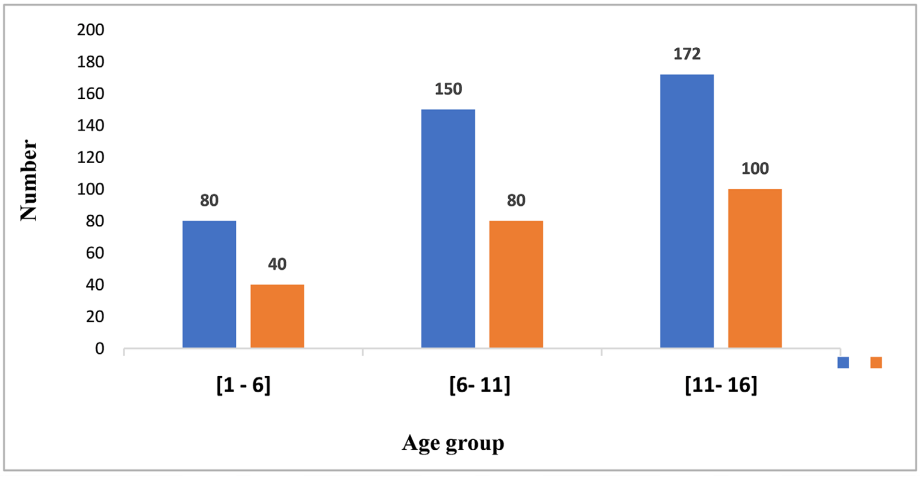

Figure 1. Age distribution of patients.

At initiation, CD4 testing was not the preferred option, with only 89 patients (14.3%) having it performed. Of those who did, 49 (7.8%) had a CD4 count of less than 200 cells/mm^3.

At the start of treatment, only 89 (14, 30) patients had their CD4 count measured (Table 2).

At treatment initiation, 524 (84.3%) had achieved viral load (Table 3).

In semester 1, few patients (64) had a viral load above 1000 copies per milliliter.

In semester 2, few of these patients had a viral load greater than 1000 copies/Ml.

In semester 3, only 31 (4.9%) patients had a viral load above 1000 copies/Ml.

At initiation, AZT/3TC/NVP is the most widely used combination therapy. As at initiation, in semester 1, AZT/3TC/NVP is the most frequently used combination therapy. From semester 2 to semester 3, ABC/3TC/DTG is the most frequently used combination therapy. All children had received cotrimoxazole prophylaxis at some point during follow-up. The prevalence of treatment failure was 20% in the first half of the year, 10% in the second and 7% in the third. Table 4 below shows the factors associated with treatment failure in these patients.

Table 1. Distribution of patients according to WHO stage since initiation of treatment.

Period	Stage 1	Stage 2	Stage 3	Stage 4	NR	Total
Initiation	**200**	**180**	100	15	127	622
Semester 1	360	200	43	10	9	622
Semester 2	380	200	25	5	12	622
Semester 3	400	200	10	2	10	622

Table 2. Breakdown of patients by CD4 count at treatment initiation, by age group.

CD4 count at initiation (cellule/mm^3)	[1-6]	[6-11]	[11-16]	Total
<200	5	20	**24**	49
200 - 350	10	**5**	10	25
>350	5	5	5	15
NR	100	200	233	533
Total	120	230	272	622

Table 3. Distribution of patients by viral load at initiation, by age group.

Viral load (copie/Ml)	[1-6]	[6-11]	[11-16]	Total
<40	100	50	**150**	**300**
40 - 1000	10	40	50	100
>1000	5	100	19	124
NR	5	40	53	98
Total	**120**	**230**	**272**	**622**

Table 4. Socio-demographic and clinical factors associated with treatment failure.

	Therapeutic Failure	Therapeutic Success	[P]	[IC]
Gender				
Male	20	382	0.01	[0.24 - 0.83]
Female	23	197		
Father'survival				
Alive	20	480	0.00	[0.094 - 0.33]
Deceased	23	99		
Mother'survival				
Alive	15	435	0.00	[0.09 - 0.34]
Deceased	28	144		
Compliance				
>95%	20	508	0.00	[0.06 - 0.23]
<Ou = 95%	23	71		
WHO Stage				
Stage 1 et 2	23	357	0.000015	[0.16 - 0.58]
Stage 3 et 4	20	95		
CD4 Count				
>200	3	37	0.135	[0.09 - 1.43]
<Ou = 200	9	40		
Plasma C V				
<1000	3	397	0.00	[0.010 - 0.05]
>ou = 1000	40	182		

Sociodemographic and clinical factors associated with treatment failure were male gender, deceased parents, adherence ≤ 95%, WHO stage 3 or 4 at inclusion and viral load at initiation > 1000 copies/ml.

4. Discussions

This study is, however, limited by the difficulties encountered, such as the lack of data from certain patients, which, when they do exist, may be incomplete.

Despite these relatively marginal limitations, this study has given us an overview of the prevalence and factors associated with virological, immunological and clinical failure.

Our patients ranged in age from 16 months to 16 years at initiation. Our results corroborate those of Zoufaly *et al.* in Cameroon, who had a mean age of 107 months. Tigist in Ethiopia and Barth in the Netherlands, who reported younger cohorts with mean ages of 74.64 months and 72 months respectively [4] [9] [10]. Male children predominated, accounting for 65% (n = 402). The sex ratio was 1.82. Our results are similar to those found by Petros in Cambodia 52% [11], and contrary to those of Tigist in Ethiopia 49% and Torsac in Thailand 48% [10] [12]. In terms of parental status, mothers are more infected than fathers.

This difference in proportion between fathers and mothers could be explained by the fact that women are in the forefront of monitoring their children in our cohort, and therefore more accessible to screening programs. This suggests that the transmission pathway is essentially vertical.

The majority of patients (90%) came from Bangui, where the treatment facility was located. Sangaré reported the same result for adults in Bobo in 2009 [13]. On the other hand, Cissoko in Dakar noted that only 60% of patients in his study were from the same commune as the care facility [14].

Depending on the WHO clinical stage at inclusion, different results are found in the literature, with 43.5% at stage C (CDC) according to Barbara in Peru [15], Torsac 22% at stage C (CDC) [10] and Niklaus in Lesotho 12% at stages 3 and 4 [16]. These results differ from those found in adults, where stages 3 and 4 accounted for a total of 68% to 85% of patients in Africa, while there were no stage 4 cases in Europe. Thus, Sangaré had 68.6% of patients at WHO stage 3 and 4 in Bobo Dioulasso [13], Akondé had 85% of patients at stage 3 and 4 at inclusion in Ségou, Mali [17], Ouédraogo counted 79% of patients at stage 3 and 4 at inclusion in Ouagadougou [18], Egger had 82% of patients at stage 3 and 4 in South Africa, 23% at stage 3 and 0% at stage 4 in Europe [19]. The difference between the results for children and adults could be explained by the fact that children are followed up earlier in the Prevention of Mother-to-Child Transmission (PMTCT) program and puton ARV treatment as soon as the first opportunistic infections appear.

At initiation, CD4 testing was not preferred, with only 89 out of 622 patients having a CD4 test performed. Our results are comparable to those of Zoufaly in Cameroon, who found 12% of children with CD4 T-cell counts below 200 cells/ml. Our results could be explained by the fact that our population was included early and put rapidly on ARV treatment in line with the new WHO "Test-Treat" recommendations. These results may be explained by the increasingly early detection of HIV infection in health facilities and HIV/AIDS associations, PMTCT, and the prevention and early management of opportunistic infections.

At initiation, 300 patients had a viral load of less than 40 copies/ml. In our cohort, 48.23% of cases had a viral load of less than 40 copies/ml. It is for this reason that the WHO has proposed two viral loads per year as part of the therapeutic follow-up of people receiving ARVs. In line with WHO recommendations, all patients were on the 2INTI + 1INNTI regimen, and at the start of our study, patients on the 2INTI + 1INNTI regimen accounted for 83.92%, compared with 16.08% on the regimen including a Protease Inhibitor (PI). Several studies found comparable results. These include Sangaré in Bobo-Dioulasso 93%, Dieng in Senegal 72% and Akondé in Niger 94% for combinations combining 2INTI + lINNTI.

With regard to transition, 320 (51.8%) were on ABC/3TC/DTG.

In our cohort as a whole, around 40% of patients still had adherence levels < or = 95% in the first half of the year. One hundred and twenty-four (20%) of patients were in treatment failure at the first semester. Our results are comparable

to those reported by Niklaus in Lesotho (17%).

The occurrence of clinical failure in our cohort could be explained by the fact that some patients do not always benefit from measurements of CV and CD4 T lymphocytes in accordance with WHO recommendations, enabling adherence to be reinforced or a change of treatment line to be made in time.

Therapeutic failure was frequently encountered in patients at initiation already in advanced stages, orphaned of at least one parent and from rural areas. Compliance: less than or equal to 95%, a deceased mother and advanced WHO stage were also associated factors. Several factors may contribute to ARV treatment failure in 0 - 19 year-olds: late initiation of treatment; unavailability of medicines suitable for children; compliance problems, i.e. failure to follow instructions on how to take medicines correctly; limited access to virological monitoring, which enables us to judge the effectiveness of treatment; precariousness of families and fear of stigmatization, which delay treatment or aggravate compliance problems; lack of training and experience of healthcare providers in paediatric treatment.

According to Bernard Taverne, analysis of the stories and observations revealed a range of structural and social factors, some of which have already been highlighted in Senegal or in other contexts, for people living with HIV adults and/or children and adolescents. The strengths of this study are to objectivize the respective influences of these factors in their contribution to the success or failure of therapy; to show how their interactions potentiate or attenuate the effects of these factors by comparing the situation of children in successful versus unsuccessful therapy, and by establishing these comparisons for Children and adolescents followed for HIV/AIDS in different types of structures [20].

5. Conclusions

At the end of this study, it appears necessary to maintain the efforts made in the clinical follow-up of children living with HIV, but also and above all to improve the technical platform in order to make routine follow-up examinations accessible.

In view of the challenges facing antiretroviral therapy in our context, a study of resistance genotyping is needed in order to propose appropriate therapeutic protocols.

Author Contributions

Simplice Cyriaque Kango: Conception and design development, data analysis and interpretation.

Critical reading: Synthia Ningatoloum Nazita, Marie Colette Nganda-Bangue.

Data collection: Michaël Dan-Houron.

Verification of statistical work: A. MANIRAKIZA.

Supervision: Pr Jean Chrysostome Gody.

All authors have read and approved the handwritten version.

Conflicts of Interest

The authors declare no conflict of interest.

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Data Collection Form

Survey form n°/_____/

Date : /___/____/_____/

I. Identity

Unique code :

Date of birth: /____/____/____/

Age: year /____/ month /_____/

Residence :

Nationality: Central African /__/ Other /__/

Addresses :

Parents' status

Father: Living /___/ Deceased /___/

HIV status: HIV+ /___/ HIV- /___/

Occupation: Employed /___/ unemployed /___/

Mother : Living /___/ Deceased /___/

HIV status: HIV+ /__/ HIV- /__/

Profession: Employed /___/ unemployed /___/

II. Clinical data at inclusion

1 = Presence of clinical signs

2 = No clinical signs

Weight in Kg: /_____/

WHO stage: Stage 1 /__/ Stage 2 /__/ Stage 3 /__/ Stage 4 /__/

1st half-year

Weight in kg: /___/

Therapeutic compliance :

Occurrence of opportunistic infections :

Extra pulmonary tuberculosis /__/

Pulmonary tuberculosis: /__/

Chronic diarrhea: /__/

Oropharyngeal candidiasis /__/

Unexplained weight loss: /__/

Cerebral toxoplasmosis: /__/

Others to report: .....

WHO clinical stage: /__/

2nd semester

Weight in kg: /___/

Therapeutic compliance :

Occurrence of opportunistic infections :

Extra pulmonary tuberculosis /__/

Pulmonary tuberculosis: /__/

Chronic diarrhea: /__/

Oropharyngeal candidiasis /__/

Unexplained weight loss: /__/

Cerebral toxoplasmosis: /__/

Others to report: .....

WHO clinical stage: /__/

3rd semester

Weight in kg: /___/

Therapeutic compliance :

Occurrence of opportunistic infections :

Extra pulmonary tuberculosis /__/

Pulmonary tuberculosis: /__/

Chronic diarrhea: /__/

Oropharyngeal candidiasis /__/

Unexplained weight loss: /__/

Cerebral toxoplasmosis: /__/

Others to report: .....

WHO clinical stage: /__/

III. Biological data

1st semester

Viral load in copies: .....

CD4 count :

Specific tests for opportunistic infections: .....

2nd semester

Viral load in copies: .....

CD4 count:

Specific work-up for opportunistic infection: .....

In the 3rd semester

Viral load in copy: .....

CD4 count:

Specific assessment in relation to opportunistic infection:.....

IV. Treatment

Initial treatment regimen: .....

Current treatment regimen: .....

V. Trends

1st semester:

Therapeutic success: Yes /__/ No /__/

Therapeutic failure: Yes /__/ No /__/

- Virological failure: Yes /__/ No /__/
- Immunological failure: Yes /__/ No /__/
- Clinical failure: Yes /__/ No /__/

2nd semester

Therapeutic success: Yes /__/ No /__/

Therapeutic failure: Yes /__/ No /__/

- Virological failure: Yes /__/ No /__/
- Immunological failure: Yes /__/ No /__/
- Clinical failure: Yes /__/ No /__/

3rd semester

Therapeutic success: Yes /__/ No /__/

Therapeutic failure: Yes /__/ No /__/

- Virological failure: Yes /__/ No /__/
- Immunological failure: Yes /__/ No /__/
- Clinical failure: Yes /__/ No /__/