

Baseline Clinical and Laboratory Parameters of HIV Positive Pregnant Women: implication for Antiretroviral Drug Choice in PMTCT Programme

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Abstract: Our study aims to examine selected baseline clinical and laboratory parameters of PMTCT clients at the Federal Medical Centre (FMC), Makurdi for follow up of the success of the intervention. Data was obtained from the treatment centre's electronic data base. This one year retrospective review of 477 clients on the PMTCT programme from 1st January to 31st December, 2010 was conducted, studying some clinical and laboratory parameters. Results obtained were analysed using SPSS windows version 17 and significance was set at a P-value of <0.05. The mean age was 29.6 ± 5.3 (range 16-60years). Majority of clients 284 (68.9%) were in the age group 25-34years. Most 247 (63.6%) had at least secondary education with 57 (14.7%) being uneducated. Those married were 261 (67.4%) with singles making up 54 (14.0%). Farmers, students, traders and unemployed constituted 126 (32.6%), 40 (10.3%), 89 (23.0%), and 75 (19.4%) respectively. The mean weight was 63.0 ± 1163 (range 40-108Kg). Most clients 263 (83.0%) were continuing highly active antiretroviral therapy (HAART) with 12 (3.8%) not yet on HAART. At presentation 370 (77.6%) had no complaints. Common symptoms were cough 19 (4.0%), fever 17 (3.6%), abdominal pain 15 (3.1%) and vaginal discharge 13 (2.7%). The mean CD4 cell count was 421 (± 233) cells/ μ L. The mean viral load was 29780.7 (± 94770.7 copies/ml) and 173 (46.8%) clients had undetectable viral load. The mean haemoglobin was 10.4 (± 1.6 g/dL). Most clients were in their prime of life, had no symptoms with mean CD4 cell count and haemoglobin within normal limits. The mean viral load was high. Subsequent follow up of the mothers and their babies should give an indication of the success of the intervention.

Keywords: PMTCT, HAART, laboratory parameters, Makurdi

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I. Introduction

The role of Prevention of mother to child transmission of HIV (PMTCT) is unarguably a vital tool in the fight to curb the rise in prevalence of HIV and AIDS. The use of HAART has been shown to reduce the risk of transmission from about 25-40% where there is no intervention to less than 2% with antiretroviral therapy (ART) and other interventions^{1,2}. Despite strong evidence for the effectiveness of antiretroviral therapy for improving the health of women living with HIV and for the prevention of mother-to-child transmission (PMTCT), HIV persists as a major maternal and child health problem in sub-Saharan Africa³.

Over the years the World Health Organization (WHO) has brought out guidelines for ART use in PMTCT ranging from Option A, to Option B and more recently in 2013 the Option B+⁴. Most developing countries in Sub-Saharan Africa implemented option A or B; however, challenges with the provision of routine point of care CD4 cell count monitoring, as well as distances between healthcare facilities and ART centres have resulted in long waiting times and high transportation costs. Thus, the WHO has adopted the Option B+ (lifelong treatment irrespective of CD4 count)⁴. While this eliminates the use of CD4 cell count as a basis for initiating treatment, the need for routine monitoring of clinical and laboratory parameters is essential in assessing treatment success. Indeed it is recommended that an individual's history and baseline clinical and laboratory parameters should be taken into consideration when choosing the most appropriate antiretroviral regimen during pregnancy⁵.

Monitoring is essential to assess disease progression and success of treatment. This may be through the use of clinical parameters such as weight, symptoms, and laboratory parameters. Patient monitoring serves two main functions: first, it enables effective clinical management of patients; and secondly, it generates data used for programme monitoring and management. In this way it contributes to standardized indicators at the district, national and international levels for in-country and global reporting and planning⁶.

Weight loss, cough, diarrhoea, loss of function and opportunistic infections amongst other symptoms are useful in assessing treatment success or failure. A wide variety of tests are available to monitor HIV disease progression and the state of overall health. These aim to assess the viral activity (viral load), immune status (CD4 cell count), and side effects of treatment (complete blood count, liver function tests, and renal function tests)^{6,7}.

Generally, CD4 cells should be above 500 cells/ μ L indicating a good immune status while an undetectable viral load (of less than 50 copies/ml) is the goal⁸. It is not uncommon to find anaemia in HIV infected patients as a consequence of infection as well as side effect of some antiretroviral agents⁶. Derangement in liver function may inform the decision to either withhold treatment or change antiretroviral drugs^{6,7}. It is against this background that our study sought to examine some clinical and laboratory parameters of clients on the PMTCT programme at the FMC, Makurdi.

II. Materials And Methods

This was a one year retrospective study conducted between 1st January and 31st December, 2010. Data of all clients who accessed the PMTCT programme at the Riverside Clinic of the FMC, Makurdi was examined. The hospital is a tertiary institution located in Makurdi, the capital of Benue State which is itself situated in the North Central zone of Nigeria. It caters for not only Benue State but also the neighbouring states of Enugu, Kogi, Nassarawa and Taraba. The FMC, Makurdi was a site supported by the President's Emergency Plan for AIDS Relief (PEPFAR) for HIV/AIDS diagnosis, referral and treatment. The programme for adults commenced at the hospital in July 2007. The PMTCT programme was introduced on 1st April, 2008. As of 31st October, 2011 a total of 13,707 clients were on adult antiretroviral therapy, while 1965 were accessing the PMTCT programme. All 477 clients seen during the year 2010 were recruited into the study using the HIV/AIDS programme electronic data base.

At their first visit, all clients had their blood samples taken for baseline investigations of complete blood count, CD4 cell count, viral load, renal function tests as well as liver function tests. The laboratory dedicated solely to HIV/AIDS care had both internal and external quality control measures in place under the close supervision of the PEPFAR. Ethical approval was obtained from the institution's Ethics committee before the study was commenced.

Information obtained was of the socio-demographic characteristics of clients namely their age, marital status and level of education. Other information sought was of the HIV risk factors and clinical symptoms which they presented with. The CD4 cell count, the viral load as well as the haemoglobin concentration were also documented.

Statistical analysis

Data was analysed using (SPSS Inc., Chicago, IL). Descriptive statistics was used to summarise the data. Frequency tables were generated and Chi Square (χ^2) was used to test for association between categorical variables while Pearson Correlation Coefficient (r) was used as a measure of relationship between variables. Significance was set at a P -value of < 0.05 .

III. Results

Four hundred and seventy seven clients were recruited into the PMTCT programme during the period under review.

Table 1 shows the socio-demographic characteristics of the study population. Two thirds of the clients were in the age group 25 – 34 years 284 (68.9%), and 261 (67.4%) were married. Most had at least secondary education 247 (63.6%). A large number of clients were farmers 126 (32.6%).

Table no 1: Frequency table showing socio-demographic variables

Variable	Frequency	Percentage (%)
Age group		
15-24 years	59	14.3
25-34 years	284	68.9
35-44 years	66	16.0
≥ 45	3	0.7
Education status		
None	57	14.7
Primary	84	21.6
Secondary	155	39.9
Tertiary	92	23.7
Marital status		
Divorced	1	0.3

Married	261	67.4
Separated	26	6.7
Single	54	14.0
Widowed	45	11.6
Occupation		
Civil Servant	57	14.7
Farming	126	32.6
Student	40	10.3
Trading	89	23.0
Unemployed	75	19.4

Table 2 shows the symptoms of the clients at presentation. Majority of the clients (77.6%) had no symptoms. Of those with symptoms, the commonest were cough 19 (4.0%), followed by fever 17 (3.6%), abdominal pain 15 (3.2%) and vaginal discharge 13 (2.7%) respectively.

Table no 2: Presenting Symptoms

Symptom	N (%)
None	370 (77.6)
Fever	17 (3.6)
Headache	10 (2.1)
Cough	19 (4.0)
Abdominal Pain	15 (3.2)
Vaginal Discharge	13 (2.7)
Diarrhoea	2 (0.4)
PV bleeding	2 (0.4)
Body rash	4 (0.8)
Others	25 (5.2)
Total	477 (100)

Majority 263 (83.0%) were continuing highly active antiretroviral therapy (HAART) with 12 (3.8%) not yet on HAART; 336 (85.9%) were heterosexual. Only one client (0.3%) was an intravenous drug user (IVDU). A total of 239 (56.6%) had CD4 cell count ≥ 350 cells/ μ L while 306 (75.9%) had haemoglobin concentration ≥ 10 g/dL.

Table 3 shows a cross tabulation of CD4 cell count and haemoglobin concentration. In 49 (28.2%) clients their CD4 cell count was less than 350 cells/ μ L while their haemoglobin was less than 10g/dL. For 177 (78.7%) of clients whose CD4 cell count was greater than 350 cells/ μ L their haemoglobin concentration was greater than 10g/dL. However, this was not statistically significant.

One hundred and ninety seven clients (41.3%) had viral load of above 200 copies/ml while 173 (46.8%) had undetectable viral load.

Table no 3: Cross tabulation of CD4 count and Haemoglobin

CD4 Count groups	Haemoglobin Groups		Total N (%)
	<10g/dl N (%)	≥ 10 g/dl N (%)	
<350 cells/ μ L	49 (28.2)	125 (71.8)	174 (100)
≥ 350 cells/ μ L	48 (21.3)	177 (78.7)	225 (100)
Total	97 (24.3)	302 (75.7)	399 (100)

$\chi^2 = 2.486, P = 0.115$

Table 4 shows the socio-biological and laboratory parameters. When correlated with CD4 cell count only viral load and haemoglobin were significantly correlated with CD4 cell count. The viral load was negatively and weakly correlated to CD4 cell count ($r = -0.221, P < 0.001$) while haemoglobin was positively correlated to CD4 cell count ($r = 0.167, P = 0.001$). Age, creatinine and alanine transaminase had weak negative and insignificant correlation with CD4 cell count.

Table no 4: Correlation between CD4 count and some socio-biological and laboratory variables

Variables	CD4 Count	
	Pearson Correlation Coefficient (r)	P value
Age	-0.051	0.305
Viral Load	-0.221	<0.001
Hemoglobin	0.167	0.001
Creatinine	-0.086	0.117
ALT	-0.022	0.691

IV. Discussion

In this study, 431 (95.7%) clients were aged between 20-39 years and this is the peak of the reproductive age. One hundred and fifty-five of them had secondary education while 261 (67.4%) were married.

Benue state being an agrarian society, it was not surprising that farmers constituted a significant proportion, 126 (32.6%) of the study population. Several studies have been conducted to assess clinical and laboratory parameters in HIV positive patients with variations. A study by Adefemi et al⁹ at Federal Medical Centre, Bida reviewed 1100 HIV positive adults (724 females, 376 males) in contrast with this study which focused only on the PMTCT clients. Parameters assessed in their study were weight, CD4 cell count, haemoglobin estimation, serum creatinine and serum alanine transaminase (ALT). The mean age was 34 years as opposed to 29.6 years in our study. While 39.5% of patients were uneducated in their study, 14.7% of patients in our study were uneducated. Similar to our study most of the patients were married. Their study showed that majority of people with HIV/AIDS belong to the low socio-demographic and economic strata namely, female gender, uneducated, not in paid employment.

Most clients in our study had no symptoms at presentation raising the possibility that they may not have even been aware of their HIV status and so risked spreading the disease. This confirms the finding that many people living with HIV in Nigeria are unaware of their status¹⁰. Where there were symptoms, these consisted of cough, fever, abdominal pain and vaginal discharge. Majority of the clients, 336 (85.9%) were heterosexual with only one (0.3%) being an intravenous drug user. Intravenous drug use therefore did not appear to be a common risk factor for HIV transmission in our environment.

It is common knowledge that pre-treatment CD4 cell count predicts subsequent counts even many years later. Thus, both CD4 cell counts and viral load are important tools used in monitoring of virologic response. Almost 50% of the study population of Adefemi et al⁹ had CD4 cell counts less than 200 cells/ μ L which was similar to a study by Ajayi et al¹¹ but far less than our findings of a mean CD4 cell count of 421 cells/ μ L. In a study by Nwokedi et al¹² the mean baseline CD4 cell count was 302 cells/ μ L and majority of the patients (72%) had CD4 cell counts less than 350 cells/ μ L in contrast to 43.4% clients in our study.

Collazos et al¹² compared the clinical, virological and immunological parameters of men and women at baseline and during antiretroviral treatment and concluded that women have more favourable clinical and viro-immunological patterns than men both at baseline and during antiretroviral treatment thus inferring that sex has a small but significant influence on the clinical and laboratory outcomes of HIV infection. Our study only looked at baseline clinical and laboratory parameters.

Abdulqadir et al¹⁴ reviewed haematological parameters of HIV positive and negative pregnant women and concluded that pregnant women with HIV had statistically significant lower haematocrit and white blood cell (WBC) and higher ESR than pregnant women without HIV. Our study also found lower haemoglobin concentration but relatively normal white cell counts. We did not look at the ESR in our population.

Marazzi et al¹⁵ conducted a retrospective study to evaluate pregnancy outcomes in a cohort of HIV-infected women receiving triple antiretroviral therapy (ART) for prevention of mother-to-child-transmission (PMTCT). Main outcome measures were maternal mortality, abortion/stillbirth, prematurity, and low birth weight. The conclusion was that antenatal triple ART reduces adverse pregnancy outcomes in HIV-infected women. Their finding underscores the WHO's most recent guideline for use of option B+⁴.

Benue State of Nigeria where this study was conducted currently ranks second in the prevalence of HIV in the country at 4.9%. This was part of the findings of the largest population based HIV survey known as the Nigeria HIV/AIDS indicator and impact survey (NAIIS)¹⁶. The survey also shows the current national HIV prevalence as 1.4% (down from 2.8% in 2017) among adults aged 15-49years. It gave a total estimated 1.9million persons living with HIV in Nigeria. The prevalence among females is significantly higher at an estimated 1.9% with male prevalence of 0.9%. Akwa Ibom State was noted to have the highest prevalence rate of 5.6%. Mother-to-Child transmission (MTCT) of HIV accounts for 90% of HIV infections in children in Nigeria¹⁶. To tackle this high prevalence the Government of Nigeria has set in place several strategies encapsulated in the revised national HIV and AIDS strategic framework 2019-2021¹⁶.

In high income countries, the MTCT rate is less than 1% through perinatal PMTCT interventions. In low and middle income countries, Nigeria inclusive, PMTCT programme coverage remains low and consequently, transmission rate is high. The NAIIS has identified several reasons for this low coverage. They found that PMTCT programmes at all levels are still concentrated in public health facilities. They are also characterized by poor ownership with funding gaps and dwindling donor funding. These challenges are further compounded by weak referral systems, linkages and follow-up of positive pregnant women¹⁶. Our study in this context provides findings from a PMTCT programme in Benue State confronted with all the above challenges and so should be useful in any intervention to combat the epidemic not only in the state but Nigeria as well.

As the number of HIV infected women continues to increase world-wide, the impact of PMTCT programmes on maternal health care in resource-poor settings should look beyond the PMTCT programme.

The launching of the revised national HIV and AIDS strategic framework 2019-2021¹⁶ by the Government of Nigeria is therefore a step in the right direction as it takes into consideration, the realities of today.

Since the study was a retrospective one conducted in the early phase of the PMTCT programme at FMC, Makurdi one major challenge was that of missing data. This may affect the conclusions that can be drawn from the study. Being a hospital based study also, the findings cannot be extrapolated to the general population.

We recommend that the programme managers of PMTCT at the FMC Makurdi, should continue to monitor the programme closely, to ensure sustained improvements in coverage, referrals, linkages, records keeping and service delivery. Further studies will need to be done to evaluate the effect of therapy on clinical and laboratory parameters on this cohort of clients and their babies.

V. Conclusion

It is recommended that an individual's history, baseline clinical and laboratory parameters should be taken into consideration when choosing the most appropriate anti-retroviral regimen to use during pregnancy. Our data suggested that, women accessing PMTCT were at the peak of their reproductive and productive careers. They were likely to be married and symptom-free at presentation. They had CD4 cell counts greater than 350 cells/ μ L, their viral loads were greater than 200 copies/ml and their haemoglobin concentration was greater than 10g/dL. Developing interventional programmes to target the age groups 25-44 years and married couples may contribute to the reduction of HIV transmission in our environment.

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