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The Incidence of Virological Success and Its Independent Predictors Following A Short Course of HAART among HAART Naïve HIV Positive Pregnant Women in Nnewi

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Abstract: Background*: Highly active anti-retroviral therapy (HAART) is introduced to HIV pregnant women to reduce their viral load and increase their CD4 count; this reduces the risk of mother to child transmission of HIV. Viral load is use to monitor the success of HAART.*

Aim: To study the incidence of Virological Success, and its independent predictors following a short course of HAART among HAART naïve HIV positive pregnant women.

Study Design and Setting: This is prospective longitudinal study carried out at Nnamdi Azikiwe University Teaching Hospital, Nnewi, South East, Nigeria between January 1st, 2017 and December 31st, 2017.

Methodology

This is a prospective longitudinal study in which HAART naive HIV positive pregnant women, who presented to the Antenatal clinic of NAUTH, Nnewi were recruited and followed up till delivery.

Baseline viral load prior to initiation of HARRT were obtained, and recorded. During labour, (at least after 4 weeks of HARRT therapy) another sample of blood was collected for a repeat viral load.

Univariate analysis (Odds ratio and chi-square) was used to analyse the factors associated with virological success and P-value of <0.05 was considered statistically significant. Logistic regression was used to identify the independent predictors of virological success.

Result :Forty-two (52.5%) had virological success. Adherence (Adj OD= 7.198, P=0.014), long therapy (Adj OD = 9.018, P=0.008) and immunological success (Adj OD = 6.413, P =0.018) were independent predictors for virological success.

Conclusion: The virological success is fairly high among HAART naïve HIV positive pregnant women following a short period of HAART. Adherence, long period of therapy, and immunological success were independent predictors of virological success.

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I. Introduction

In the third world countries, HIV infection in pregnancy has become the most common medical complications of pregnancy. Over 90% of HIV infections in children are as a result of MTCT, and annually about 600.000 children are infected through this route. This represents over 1600 infections every day[1].

High level of maternal viraemia is a risk factor for transmission of HIV from the mother to the child[2]. A high viral load is a risk factor to transmission of the virus from mother to child. It was noted that 12% transmission occurred in those with less than 1000 copies/ml compared with 29% in those with more than 10 000 copies/ml[2]

Measurement of the virus with quantitative PCR DNA and RNA has made it easy to measure the viral load in HIV patients. The use of HAART is employed to reduce the viral load; hence, increase the CD4 count to stem down the rate of transmission. Vaginal delivery has been advocated when the viral load is undetectable and a cesarean section (C/S) whenever it is detectable[3] while others employ C/S when the viral load is more than 1000 copies/ml.[4,5]

This study aims to determine the incidence and the predictors of virological success among HAART naïve HIV positive pregnant women following a short course of HAART.

II. Methodology

This is a prospective longitudinal study carried out at Nnamdi Azikiwe University Teaching Hospital, Nnewi, South East, Nigeria. The ethical committee of the hospital approved the study.

HARRT naïve HIV positive pregnant women, who presented to the Antenatal clinic of NAUTH, Nnewi were asked for consent. Those who consented, were interviewed and examined; and eligibility criteria were applied to screen the patients. All the patients were managed according to departmental protocol without discrimination. **The following pregnant women were excluded-those whose pregnancy is less than 13 weeks gestation, those whose gestational age is above 36weeks and those already on HAART.**

Information on age, parity, gestational age and HIV status were obtained and recorded in the proforma. The viral load before the initiation of HARRT were obtained, and recorded in the proforma. The patients were evaluated every 4weeks till delivery to check the level of adherence to her drugs. During labour (after a minimum 4weeks of HARRT therapy) another sample of blood were collected for repeat of viral load.

Laboratory tests

Blood samples (10mls) were collected from each patient's vein using sterile hypodermic needle and syringe, and put into clean EDTA bottle, centrifuged at 800 – 1000 RBM for 20 mins to get plasma . The plasma was aliquot into 3 cryoval tubes and stored at -20'C for a maximium of 6 weeks. Viral loads were done using quantitative polymerase chain reaction equipment (RochCobastampliprep and Taqman instruments, 3.3 versions). These tests were done by a laboratory scientist.

Data analysis

All the data obtained were analyzed using statistical package SPSS version 20. Univariate analysis (Odd ratio and chi-square) were used to analyse the predictors of virological success and P-value of <0.05 were considered statistically significant. In this study, Virological success was taken as VL < 1000copies/ml at the time of delivery while Virological failure taken as viral load ≥1000copies/ml at delivery[6,7]

III. Result

The women studied had age range between 19 and 36 years with the mean age of 27.83± 5.92yrs while their parities ranged from 0 to 5, with mean of 2.53± 3.00. The gestational age at booking ranged from 14 to 34 weeks, mean of 22.39±6.34 weeks while the GA at delivery ranged from 34 to 41 weeks, mean of 37.5± 1.90 weeks.

Viral load at booking ranged from 83 to 9421copies/ml and mean value of 2746.91±2531.12 copies/ml while viral load at delivery ranged from 40 to 2678 copies/ml, mean value of 1130.13±637.66 copies/ml, the duration of therapy ranged from 4 to 25 weeks with a mean of 15.11± 6.63 weeks as shown in table I.

Table II, showed the demographic features- frequency table. Sixty-three (78.8%) of the studied women were married, while 17(21.2%) were unmarried. Fifty-one (63.8%) of their husbands had RVD status positive while 29(36.2) either unknown or negative. Those who had Zidovudine based combination were 45(56.3%) where 35(43.8%) were on Tenofovir based combination therapy. Those who adhere to their drugs were 45(56.3%) while 31(38.8%) were non adherent. Forty-two (52.5%) had virological success while 38(47.5) had virological failure. Those who received long duration of therapy (of at least 8 weeks duration) were 62(77.5%) while 18(22.5%) had short duration of therapy. The young women (<25 yrs) were 39(48.8%) while 41(51.3%) were not young.

Those with low parity (0-2) were 52(65%) while high parity women (3-5) were 28(35%). Those with high CD4 at booking were 42(52.5) while 38(47.5%) had low CD4 at booking. Sixty-one (76.3%) of the studied women had low viral load at booking while 19(23.8%) had high viral load at booking.

Table III demonstrated the potential predictors of virological success using univariate analysis with the following findings: Adherence (x^2=22.30, P-value=0.000), long duration of therapy (x^2=15.95, P-value=0.000), high CD4 count at booking (x^2=24.10, P-value=0.000), immunological success (x^2=11.84, P-value=0.001), and low viral load at booking (x^2=9.88, P-value=0.002) were found to be significantly predictors of virological success. While type of HAART (x^2=2.32 P-value=0.128), age (x^2=1.28, P-value=0.26) and parity (x^2=0.64, P-value=0.425) were not significantly associated with virological success.

When the significant predictors were subjected to logistic regression, only adherence (Adj OD= 7.198, P=0.014), long therapy (Adj OD = 9.018, P=0.008) and immunological success (Adj OD = 6.413, P =0.018) were found be independent predictors of virological success while CD4 count and viral load at booking were not, as demonstrated in table IV.

Table I : The socio-demographical features

Features	Ranges	Mean± SD
Age (yrs)	19 – 36	27,83±5,92
Parity	0 – 5	2.53 ±1.58
GAb (wks)	14 – 34	22.39 ±6.34
GAd (wks)	34 – 41	37.50 ±1.90
VLb (copies/ml)	83 – 9421	2746.91 ± 2531.12
VLd (copies/ml)	40 – 2678	1130,13 ± 637.66
Drug duration(wks)	4 – 25	15.11 ± 6.63

Definitions.
GAb….gestational age at booking , GAd ..gestational age at delivery.
VLb..viral load at booking. VLd..viral load at delivery

Table II: demographical features- frequency table

NO	FACTORS	FREQ	PERCENTAGE
1	MARRIED……YES	63	78.8
	NO	17	21.2
2	HUS STATUS …POS	51	63.8
	NEG	29	36.2
3	ZIDOVUDINE BASE	45	56.2
	TENOFOVIR BASE	35	43.8
4.	ADHERENCE ….YES	49	61.3
	NO	31	38.7
5.	VIRAL SUCCESS… YES	42	52.5
	NO	38	47.5
6.	LONG THERPY…..YES	62	77.5
	NO	18	22.5
7.	AGE……..YOUNG <25YRS	39	48.8
	NO. ≥25	41	51.2
8.	PARITY…..0 – 2	52	65
	3 – 5	28	35
9	HIGH CD4b …YES	42	52.5
	NO	38	47.5
10	IMMUNOLOGICAL SUCCESS..YES	55	68.8
	NO	25	31.2
11.	LOW VLb…. YES	61	76.2
	NO	19	23.8

Table III : Potential Predictors of virological success using univariate analysis

Variables	X^2	p-value
Type of HAART	2.32	0.128
Adherence	22.30	0.000
Long duration of therapy	15.95	0.000
age	1.28	0.26
Parity	0.64	0.425
High CD4b	24.10	0.000
CD4 success	11.84	0.001
low VLb	9.88	0.002

Definitions:
Virological success = Vld ≤ 1000 copies/ ml
Immunological Success= CD4(d) – CD4(b) ≥50 cells/ul
Adherence= ≥95% compliant
Long therapy≥ 8weeks therapy
High CD4 >250cells/ul
Low viral load<2000 copies/ml.

Table IV: The independent predictors of virological success using logistic regression analysis

Factors	OR	Adj OR	p value
Adherence	8.087	7.194	0.014
Long therapy	14.545	9.018	0.008

High CD4b	11.815	2.144	0.284
Low VLb	6.196	4,566	0,086
CD4 success	6.000	6.413	0.018

IV. Discussion

In this study, the incidence of virological success was 52.5%, this was lower than that obtained in a study in Maiduguri [8](83%). This difference may be because the Maiduguri study used non pregnant women and the viral load was repeated after 6 months. While in our study, it was repeated at an average of 3.5 months; hence, the longer period of therapy may have accounted for the difference. Lehtoirta[9] used pregnant women and obtained viral success of 90% using <1000 copies/ml, this is far higher than what is obtained in the current study. In the Lehtoirta study, the women were on drugs before pregnancy; hence, very difficult to state how long they have been on a therapy.

This study revealed that immunology success, adherence to treatment, and longer duration on HAART were found to be independent predictors of virological success, while parity, age, booking CD4 count and viral load were not, although high CD4 count and low viral load were associated with virological success.

` Adherence to drug (HARRT) treatment is an independent predictor of virological success in HAART naive HIV pregnant women, and this is in keeping with findings of Mark oetta et al[10] and Belete et al [11]. Invariably, non adherence is a risk factor for viral failure in this study; this is in agreement with the findings from other studies in China[12] and Mozambique[13] where poor adherence was a major risk factor for viral failure. This may be ascribed to lower plasma concentration of the drug, increased risk of resistance and reduced immunity leading to viral failure. Non adherence to therapy is an independent risk factor as documented by other studies[14,15]. This is due to low RVD drug plasma concentration which in turn results in suboptimal virological response and suppression, but those with adherence to drug maintain high plasma concentration of the drug which in turn keeps the viral level suppressed.

Long duration of HAART in our study, is an independent predictor of virological success, although this is at variance with the finding by Belete et al[11] who found that long duration of therapy is an independent factor for virological failure, the difference in these two studies is that long duration of therapy was over 2 years in Belete's study, while in this study, it is just 2 months. This may be explained by the fact that there is a period of time required for the drugs to have effect on the viral load and after a longer period, adherence may drop, resistance may develop with manifestation of opportunistic infections resulting in a rise in viral load and a drop in CD4 count.

Immunological success is an independent predictor of virological success in HAART naive HIV pregnant women on HAART, this is because when there issuppression of viral load, the CD4 count improves leading to immunological success. This is to say that, virological success is associated with immunological success while the virological failure is associated with Immunological failure. Immunological failure was a risk factor for viral failure in our study; this is in consonance with study by Ballah Denue [8] et al.

Age was not associated with virological success in this study, unlike that of studies in Nyanza, Kenya[16] where the study showed that age <35 years is associated with viral failure. The difference with our study may be that most of our patients were below 35 years.

V. In conclusion

Following a short period of HAART among the HAART naïve, HIV positive pregnant women , the incidence of virological success is 52.5%. The independent predictors of virological success were immunological success, adherence to drugs and therapy of at least 8 weeks before delivery.

HIV positive pregnant women should be encouraged to start HAART and comply/adhere with the medications for at least in the last 8 weeks of pregnancy.

Limitation of the study: It was difficult to measure accurately the level of drug adherence, as it was not directly observed therapy. We relied on their words.

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