Factors Associated With Intrapartum Detectable Viral Load Among Hiv Positive Parturients at Riley Mother and Baby Hospital, Eldoret-Kenya.

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Abstract

Background

Vertical transmission of Human Immuno-deficiency Virus (HIV) can occur during pregnancy, labour, and delivery, or in breastfeeding. Detectable viral load among pregnant women is the strongest predictor. Knowledge of factors associated with DVL could inform integrated prevention services both in prenatal and postnatal care.

Objective

To describe the patient characteristics, determine the prevalence of detectable viral load and assess factors associated with it among HIV infected women delivering at Riley Mother and Baby Hospital (RMBH), Eldoret Kenya.

Materials and methods

A cross-sectional study conducted among 140 HIV infected expectant women attending RMBH. Maternal sociodemographic and clinical characteristics were collected using structured interviewer administered questionnaire and viral load assay was done by the AMPATH Reference Laboratory with a detection threshold of 40 copies/ml. Descriptive statistics of means and proportions as well as bivariate tests of associations ($p \leq 0.05$) were conducted, followed by logistic regression for statistically significant variable.

Results

99 (70.9%) of the participants knew their HIV status prior to the pregnancy under review, 34 (24.3%) sero-discordant and 77 (55.0%) presented late (> 16weeks) for their first antenatal visit. TDF/3TC/EFV was the most common antiretroviral therapy (ART) regimen with an overall median ART duration of 20 (IQR: 6.0, 60.0) months. 25 (17.9%) had DVL, of whom 5/25 (20%) had Low level viremia (50-1000 copies/ ml) while 17/25 (68%), had > 1000 copies/ml. 16/17 (94%) of those with viral load of > 1000copies/ml delivered by spontaneous Vertex Delivery (SVD). Those with moderate or severe ART side effects were significantly more likely to have a detectable viral load at delivery (AOR = 6.189; 95% CI: 1.330, 28.797; p = 0.020).

Conclusion

The prevalence of DVL was 17.9% with moderate or severe ART related side effects being significant predictors. Adherence counselling in integrated PMTCT and antenatal care should focus on the

recognition of ART-related side effects and their management.

INTRODUCTION

Human Immunodeficiency Virus (HIV) affects approximately 1.4 million Kenyans[1,2], with a prevalence of 5.4% among women of reproductive age[3,4]. This high prevalence among women of reproductive age increases the risk of mother to child transmission (MTCT) which can occur during pregnancy, labour, and delivery or in breastfeeding[5]. The World Health Organization's (WHO) aim of eliminating mother to child transmission (eMTCT) - defined as fifty (50) new infections per 100,000 live births- can be achieved by initiating Antiretroviral Therapy (ART) prior to conception and maintaining a viral loads below detectable levels throughout pregnancy and at delivery[6]. Since 2016, Kenya adopted the test and treat for all people living with HIV (PLWHIV) including pregnant women[7–10]. In the same year, WHO strongly recommended HIV viral load testing for monitoring treatment progress by advising viral load testing three (3) months after ART initiation and every six months thereafter[5,11].To reduce perinatal transmission, HIV infected pregnant women eMTCT could be provided over the antenatal, delivery and postpartum phases. However, only about one-third adhere to the recommended eMTCT guidelines[12]. To maintain low viral load levels among infected expectant women, the Joint United Nations Programme on HIV/AIDS (UNAIDS) aims at 73% viral suppression[1,2,13].

The presence of a non-suppressed viral load during pregnancy could be multifactorial. Despite availability of evidence that Kenya is on the path to eliminating mother to child transmission, there are still high cases of new vertical transmissions[4,14]. However, there are limited local studies focusing on factors associated with detectable viral load. Lack of prompt viral load assessment and knowledge on detectable viral load counters global initiatives such as the 95-95-95 UNAIDS targets[13]. This study therefore addressed the knowledge gap on predictors of detectable HIV viral load at delivery. Furthermore, viral load monitoring is the best indicator of ART efficacy, early ART initiation and adherence to treatment. There is need to promptly determine the prevalence of detectable viral load at delivery and its associated factors among HIV infected women. Knowledge of this will inform HIV transmission prevention strategies by HIV care givers and policy makers, by providing evidence-based recommendations both in Kenya and the region. This study aimed to determine the patient characteristics, prevalence of detectable viral load and assess factors associated with it among HIV infected women delivering at RMBH, Eldoret Kenya.

MATERIALS AND METHODS

This was a cross-sectional study conducted among HIV-infected women delivering at Riley Mother Baby hospital, the maternity unit of Moi Teaching and Referral Hospital (MTRH) as well as the Post-natal Clinic. However, all confirmed or known HIV positive pregnant women with more than 28 weeks gestation or too ill to participate. Sample size of 140 participants was determined using the Cochran formula and potential participants were sampled consecutively until saturation.

Prior to commencing the study, a written informed consent was obtained privately by trained research assistants. Following this, a semi-structured questionnaire was used to obtain participants' sociodemographic and clinical characteristics from both interviews and review of medical records. After enrolment, a viral load sample from whole blood was collected by a trained phlebotomist while adhering to Good Clinical Laboratory Practices (GCLP). The samples were taken to the Academic Model Providing Access to Healthcare (AMPATH) reference lab within the first hour of collection for processing using the Abbott real time PCR analyser (at a detection threshold 40 copies/ml). Adherence was measured using self-reporting at enrolment, (delivery). Women were considered non-adherent if they reported missing Highly Active Antiretroviral Therapy (HAART) at the 7-day recall. Data analysis was done using the statistical package for social sciences (SPSS) Version 24. Continuous variables such as age, viral load among others were summarized using mean and the corresponding standard deviation. Pearson Chi-Square test of association between patient characteristics and the occurrence of detectable viral load at the time of delivery was conducted, where a $p \leq 0.05$ was considered statistically significant. Odds ratios were computed at 95% confidence interval. A multivariate logistic regression was conducted to control for the probable confounders. Ethical approval was obtained from the Institutional Research and Ethics Committee (IREC) of Moi University School of Medicine and MTRH (Approval number: 0002060).

RESULTS

We enrolled 140 expectant and seropositive women with a mean age of 29.42 years. More than two-thirds (67.9%) of them were married, 40.7% had a primary level of education, less than half were either unemployed (42.9%) or self-employed at 44.2% (Table 1).

Table 1: Sociodemographic Characteristics (N=140)

Sociodemographic Characteristic		n (%)
Maternal age (years)	Mean (SD)	29.42 (±7.07)
	Median (IQR)	29.0 (17.0, 45.0)
Marital Status	Single	31 (22.1)
	Married	95 (67.9)
	Separated	13 (9.3)
	Widowed	1 (0.7)
Highest Level of Education attained	None	7 (5.0)
	Primary	57 (40.7)
	Secondary	47 (33.6)
	Tertiary	29 (20.7)
Religion	Christian	139 (99.3)
	Muslim	1 (0.7)
Occupation	Employed	18 (12.9)
	Unemployed	60 (42.9)
	Self-employed	62 (44.2)

Participants median gravidity was 3.0 (IQR: 1.0, 8.0), 55% presented late (>16 weeks) for their first antenatal visit with a median of 4 (IQR: 1.0, 5.0) antenatal visits. 123 (87.1%) were Rhesus positive, 62 (44.3%) had blood group O, 13 (9.3%) were reactive to venereal disease research laboratory (VDRL) serum tests, 23 (16.3%) reported an illness in the current pregnancy while 15 (10.7%) were hospitalized during their pregnancy (Table 2).

Table 2: Reproductive and Clinical Characteristics

Reproductive Characteristic		Mean (SD)/ n (%)
Gravidity	Mean (SD)	3.22 (±1.62)
Gestation at first ANC Visit (weeks)	Late (>16)	77 (55.0)
	Early (≤16)	63 (45.0)
ANC Visits	Mean (SD)	4.15 (±1.44)
VDRL Status	Non-reactive	122 (87.1)
	Reactive	13 (9.3)
	Missing VDRL	5 (3.6)
Blood Group	A	38 (27.1)
	AB	7 (5.0)
	B	33 (23.6)
	O	62 (44.3)
Illness in Pregnancy	Anaemia	9 (6.4)
	Asthma	1 (0.7)
	Hypertension	7 (5.0)
	Lower Back Pain	1 (0.7)
	Opportunistic infections	2 (1.4)
	Other illness	3 (2.1)
Diagnosed in current pregnancy	Yes	15 (10.7%)
Gestation at Delivery (weeks)	Mean (SD)	38.24 (±3.29)
Weight (Kgs)	Mean (SD)	67.53 (± 11.8)
Height (cm)	Mean (SD)	160.8 (± 6.23)
BMI (kg/m^2)	Mean (SD)	26.64 (± 4.23)
Current HAART Regimen	Protease Inhibitors	6 (4.3)
	Integrase Inhibitors	10 (7.1)
	NNRTI-based	124 (88.6)
Duration of HAART (months)	Median (IQR)	20 (6.0, 60.0)

WHO Clinical Staging	Stage I	132 (94.3)
	Stage II	8 (5.7)
HIV Diagnosis	New	41 (29.3)
	Known	99 (70.7)
Partner's HIV Status	Positive	77 (55.0)
	Sero-discordant	34 (24.3)
	Unsure	29 (20.7)
Side Effects	Moderate/Severe	10 (7.1)
	Mild	130 (92.9)
Mode of Delivery	ELCS	12 (8.6)
	EMCS	31 (22.1)
	Vaginal	97 (69.3)

This study determined that 25 (17.9%) of all the expectant women diagnosed with HIV and enrolled into the study had detectable viral load at the time of delivery. Among the 25 participants with a detectable viral load (>40 copies/ml) at delivery, 3/25 (12%) were between 41-50copies/ml, 5/25 (20%) had low level viremia (51-1000copies/ml), while 17/25 (68%) had more than 1000 copies/ml. 94.1% of women with viral load copies of >1000copies/ml delivered via vaginal delivery. Women who reported moderate or severe antiretroviral use side effects were significantly more likely to have detectable viral load compared to those with mild side effects (OR=3.250; 95% CI: 1.552, 6.808; p=0.017). Despite lack of adherence to HAART medication or regimen change, shorter duration of HAART use (less than 3 years), being married and having a lower level of education (primary education or less) increased the likelihood of a detectable viral load, the relationship between these predictors and detectable viral load was not statistically significant. Although 99 (70.9%) of the participants already knew their HIV status (known positives), there was a greater likelihood (OR = 1.610; 95% CI: 0.789, 3.283) of those diagnosed in the current pregnancy to have a detectable viral load. Most women were on NNRTI-based (Tenofovir, Lamivudine and Efavirenz) highly active antiretroviral therapy (HAART) regimen while those on protease inhibitors were more likely (OR=0.780; 95% CI: 0.369, 1.648; p=0.639) to have a detectable viral load compared to those on other form of HAART. Women who had a late first ANC visit (of more than 16 weeks gestation) were more likely to have detectable viral load compared to those who came earlier (OR= 2.104; 95% CI: 0.939, 4.715; p=0.076).

Table 3: Factor associated with detectable viral load.

Factor associated with detectable viral load	OR (95% CI:) / p-value
Side Effects (Moderate/Severe vs Mild)	3.250 (1.552, 6.808) **p=0.017**
HIV Diagnosis (Current pregnancy vs known positive)	1.610 (0.789, 3.283) p=0.227
HAART Regimen (Integrase inhibitors vs NNRTI-based)	0.780 (0.369, 1.648) p=0.639
Protease Inhibitors use	1.913 (0.581, 6.294) p=0.298
Gestation at first ANC (Late vs Early)	2.1044 (0.939, 4.715) p=0.076
Lack of HAART Adherence	1.214 (0.595, 2.478) p=0.654
Gravidity (High vs Low)	1.263 (0.557, 2.865) p=0.587
Lack of Partner's Disclosure	1.310 (0.618, 2.772) p=0.617

When a multivariate logistic regression statistical analysis was conducted, (controlling for HAART regimen, no HAART regimen change, Protease inhibitor use, lack of treatment adherence, partner use of HAART and Partner disclosure); these confounders did not affect the statistically significant association between HAART related side effects and patient presenting with a detectable viral load at the time of delivery, (AOR=6.189; 95% CI: 1.330, 28.797; p=0.020).

DISCUSSION

This study presents a detectable viral load (> 40 copies per ml) rate of 17.9%. This proportion is higher than the set limit of 5% by the Joint United Nations Programme on HIV/AIDS (UNAIDS), which aims to end the consequences of HIV infection including transmission and deaths from Acquired Immune Deficiency Syndrome (AIDS) by 2030. Lack of prompt viral load assessment and knowledge on detectable viral load counters global initiatives such as the UNAIDS 95-95-95 targets; where 95% of those who are HIV positive should know their status, 95% of those who know they are HIV infected should be on treatment and 95% of those on treatment should be virally suppressed. From the most recent national survey on HIV findings in Kenya[15], 82.7% of Kenyan women aged between 15 to 64 years

who tested positive to HIV already knew their status. Among these 96.6% were already on treatment while 90.4% of those on treatment had achieved viral load suppression. This implies that despite Kenya being on the path to achieving the UNAIDS 95-95-95 targets, it is yet to achieve it. This study documents higher rates of detectable viral load at delivery on pregnant HIV infected women compared to NASCOPs finding on all women (irrespective of pregnancy status) as well as the 95-95-95 UNAIDS target.

Other studies that reported higher rates of detectable viral load levels at delivery were conducted in countries within the East African Community. In a cross-sectional baseline assessment was conducted in 35 provincial health zones within Kinshasa- the Democratic Republic of Congo (DRC), the proportion of detectable viral load at delivery was 52%[16]. Although both studies used a similar viral load cut-off (> 40 copies/ml), the study conducted in Kinshasa enrolled more participants (N = 1623) from multiple (n = 35) study sites compared to the 140 enrolled in a single site in the current study. This difference in study population and sample size could have a direct effect in the overall proportion of detectable viral load eventually reported, as the relationship could be confounded by more factors than those that could be witnessed in a single national referral hospital setting. In Rwanda, the authors[17], reported a proportion of 47.8% which is higher than the current study. The difference between these two studies could be attributed to methodological variance. Our study collected samples at delivery, which is at the tail end of a pregnancy journey while in Rwanda[17] it was from the beginning of third trimester (28 weeks) to delivery. Many women with detectable viral load at 28 weeks would have a lower or undetectable viral load if tested at delivery assuming satisfactory adherence to ART. Labor and delivery carries the highest risk of mother to child transmission, which advised the timing of viral load testing in this study. Secondly, the study in Rwanda used a lower threshold for detectable viral load of 20 copies per ml compared to our study of 40 copies per ml. In South Africa[18], 22% of the 574 women enrolled and were on HAART, were found to have a detectable viral load a relatively comparable finding to our study. Higher proportions (36.4%) of detectable viral load at delivery were reported in a second study from South Africa[19] conducted among 2769 HIV infected women delivering at four tertiary obstetric units in Gauteng –South Africa between June 2018 to March 2019. The study[19] adopted a relatively higher viral load cut-off (> 50 copies/ml) compared to this current study (> 40 copies/ml). When a sub-analysis on the distribution of detectable viral loads in this study was done, of the 25/140 (17.9 %) who had etectable viral load, 3/25 (12%) of them had viral loads of between 41–50 copies/ml, hence were virally suppressed. Viral suppression has been defined by the World Health Organization currently as having less than 50 copies per ml[20]. 5/25 (20%) had low level viremia (between 51-1000 copies/ml), and the majority 17/25 (68%) had more than 1000 copies/ml. Focusing on viral copies of more than 1000/ml, studies[21,22] have shown a reduction in mother to child transmission of HIV if delivery is done through pre labour caesarean section (Elective Caesarean) for women with a viral loads of more than 1000 copies/ml. This study found that almost all 16/17 (94%) of the participants who had a detectable viral load of more than 1000 copies/ml had a vaginal delivery. According to the Kenya ART guidelines[14] at the time of this study, where available a pre labour caesarean delivery was recommended for women with viral load of > 1000 copies/ml. From the findings in this study, these women 16/17 (94%) had their infants exposed to an

increased risk of intrapartum HIV vertical transmission that would have been reduced by Elective caesarean section.

The second major finding in this study was a statistically significant association between women presenting with a moderate or severe HAART related side effects and intrapartum detectable viral load. These women had a six-fold increased likelihood of presenting with detectable viral load at delivery. These findings suggests that there is need for additional effort to improve adherence counselling focusing on side effects to ART in this special sub-population of pregnant women who experience unique challenges of pregnancy, especially in clinical settings where both PMTCT and antenatal care services are integrated, as in our case at MTRH. The counselling offered should include ways of how to manage the side effects. It has been previously documented that ART related side effects have a negative effect on patient adherence to medications[23,24]. This finding is close to that reported in Rwanda[17] where women who reported side effects had a higher likelihood of detectable viral load (OR = 2.63; 95% CI: 1.72, 4.03, p < 0.0001). Late diagnosis of HIV status and immunosuppression associated with pregnancy could explain the higher plasma viral load among this group of women.[17,24,25] Many programs have been put in place to encourage HIV surveillance, early detection and prevention of mother to child transmission of HIV.[3,26,27] Furthermore, women enrolled in this study presented with either stage I or II clinical staging of HIV according to the World Health Organization guidelines [20]. Women who had stage II of the disease had a two-fold (OR = 2.400; 95% CI: 0.900, 6.401; p = 0.152) increased likelihood of having a detectable viral load compared to those with the first stage. Although this relationship was not statistically significant, a higher stage of the disease is often a result of the immune system's inability to regulate viral replication, hence a higher plasma viral load finding.[1,28]

Women who are consistent with their overall HIV comprehensive care will have their regimen promptly changed when indicated to improve the clinical outcome, in the event of a treatment failure due to drug resistance. In this study, women who had never had a HAART regimen change, had an increased likelihood (OR = 1.583; 95% CI: 0.579, 4.330) of presenting with a detectable viral load compared to those who had their regimen changed at any point of their HIV treatment period. This lack of change could be attributed to either recent treatment initiation or hence a short duration of HAART use to warrant any change.[29–31]

Lack of partner disclosure of HIV status increased the likelihood of a woman presenting with a detectable viral load at the point of delivery, however, this relationship was not statistically significant. Contrasting findings were reported in Rwanda[17] where women who had not disclosed their HIV status to their sexual partners were two times (OR = 2.11; 95% CI: 1.51, 2.95) significantly (p < 0.001) more likely to have a detectable viral load. Similarly, lack of HIV disclosure significantly increased the likelihood of detectable viral load in a study conducted in Kinshasa- Democratic Republic of Congo.[32] Partner disclosure has a direct impact on HAART compliance which by extension increases the risk of treatment failure[33].

In a study conducted in Kenya's Busia County[34], majority of the patients with treatment resistance were on TDF + 3TC + EFV regimen. Although majority of the patients on HAART in both this study and in the country were on this regimen, both the current study and the one conducted in Busia still reported a higher treatment failure rate for this cohort of HIV infected patients. This creates a need for routine HAART resistance testing to improve treatment outcomes. Additionally, there is need to initiate women on HAART prior to conception because of its multiple benefits. The HAART regimen should be chosen based on the woman's pregnancy related issues, treatment tolerance as well as prior information on adherence to treatment so as to ensure continuity between pre-conception and prenatal care[33,35] These medications provide additional benefit by protecting male partner in the conception attempt. The authors[6] reported no perinatal transmissions in women who received preconception ART, continued throughout pregnancy and delivered with viral load of < 50 copies/ml.

In this study, when duration of HAART use was stratified, women who had been on HAART for not more than three years had an increased likelihood (OR = 1.773; 95% CI: 0.712, 4.413; p = 0.239) of presenting with detectable viral load compared to those who had been on treatment of more than three years. Although the current study did not find any statistically significant association between duration of HAART use and presenting with a detectable viral load at the time of delivery, this finding matches a retrospective study conducted among 707 women in Brazil[36] enrolled between 1996 to 2006 where there was a significantly increased likelihood of detectable viral load among the women who had been on HAART for less than 12 weeks and presenting with a detectable viral load (OR = 2.51; 95% 1.72, 3.65). In Gauteng-South Africa[19], there was a four-fold (OR = 4.11; 95% CI: 2.20, 7.66) increased likelihood of detectable viral load among expectant women who had a shorter duration (< 3 months) of HAART use compared to their counterparts who had been on HAART for 3 or more months. In Kinshasa- Congo[32], women who had been on HAART for at least 12 months were more likely to have viral load suppression compared to their counterparts who had used antiretroviral for a shorter duration. The longer the duration of HAART use the greater the likelihood of viral suppression. However, prolonged HAART use (greater than 3 years) predisposes the women to HAART resistance, which could counter the intended benefit of viral suppression. These women have been reported to have a detectable late pregnancy (> 28 weeks) viral load[17]. In Benin[37], women who did not have impaired HAART adherence were less likely to have a detectable viral load. The authors further noted that the probability of an undetectable plasma viral load was four times higher among those who had been on treatment for 8 weeks or more. These long durations could only be feasible if the treatment was initiated before 28 weeks of gestational[37]. In the United Kingdom, the authors[38] reported that women with viral loads above 10,000 copies/ml at initiation of treatment, the probability of achieving undetectable viral loads (< 50copies/ml) was reduced by initiating HAART after 20.4 weeks gestation. Finally, this was a hospital-based study and findings may not be generalized to the entire population

CONCLUSIONS AND RECOMMENDATIONS

This is the first local study assessing detectable viral load status at delivery and its associated factors among HIV infected pregnant women; to inform prevention of mother to child transmission strategies. It ensured consistency in viral load detection by processing all the plasma samples in a single laboratory. The prevalence of detectable viral load at delivery reported among HIV infected women is 17.9% with 94% of those with detectable viral load of more than 1000 copies/ml delivering vaginally. The significant predictor of detectable viral load was having moderate or severe HAART related side effects.

To eliminate HIV mother-to-child transmission, there is need for sustained suppression of plasma viral load during pregnancy, delivery and breastfeeding among women living with HIV. From the findings of this study, we recommend institution of facility-based mechanisms for checking viral load ahead of delivery; and ensuring that HIV infected pregnant women have delivery plans at late Antenatal Clinic visits in line with their viral load status. Additionally, there is need to adequately counsel HIV positive pregnant women on possible side effects of HAART and how to manage those side effects; especially in view of the unique challenges that pregnancy physiology brings along.

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Supplementary Files

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