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HVDRS STUDY

Peripartum Virological Suppression and its Significant Implications for Elimination of Mother-To-Child Transmission of HIV in Resource-Constrained Settings of Eastern Cape, South Africa

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Background

South Africa – largest epidemic globally (1)

- 7.4 million people living with HIV
- 320,000 children

South Africa implemented the WHO Option B Plus in 2015

Over 95% of pregnant women are accessing antenatal care services – HIV test

All HIV-infected pregnant women are offered ART; EFV-based regimen

Early infant diagnosis reduced from 25-30% in 2001 to 2.6% in 2014

About 12,000 new paediatric infections occurred in SA in 2016

Concerns;

- Prevalence of 23.8% among reproductive age women (15 – 49 years) and
- 30.8% amongst women who attended antenatal care in 2015
- Intensified surveillance of **pregnant women on ART with high viral load** should be given greater priority

Data on the population impact for maternal and infant outcome are limited

This study addressed **two key objectives:**

1. Assessed the maternal virological suppression at delivery and early MTCT risks

2. Examined associated factors of virological failure at delivery and early MTCT risks

Methods

Design: Retrospective Cohort study

Setting: HIV-infected pregnant women who delivered at three maternity centres in the central region of Eastern Cape, South Africa between September 2015 and May 2016. The selected maternity services represent the three tiers of healthcare services in the Eastern Cape

Study sample

All HIV-infected parturient women who delivered their index infant at the study settings were included in the study. Participants were recruited serially within 24 hours of vaginal delivery and 72 hours of Caesarean section at the post-natal wards of the hospitals (N = 1709)

Independent variables

- Socio-demographics
- Lifestyle behaviours
- Clinical parameters including adherence to current ART

Outcome Measures

Peripartum virological suppression: VL < 1000 copies/ml

- Venous blood were sampled within 24 hours of vaginal and 72 hours of Caesarean section delivery

Virological suppression:

- Undetectable (VL < 20 copies/ml)
- Low level viraemia (VL = 20 – 999 copies/ml)

Early MTCT: Positive birth PCR results

All measures were assayed in line with established protocols through the National health Laboratory Services

Ethics approval: Walter Sisulu University Ethics Committee, ECDOH and respective clinical governance of each hospital. Written informed consent/assent were obtained

Statistical Analysis: Viral response to ART were compared with maternal demographics, lifestyle and clinical characteristics using the Pearson chi-square test and Fisher exact test for bivariate analysis. Using the adjusted and unadjusted multinomial logistic regression models, we identify the risk factors for undetectable viral load and low viraemia.

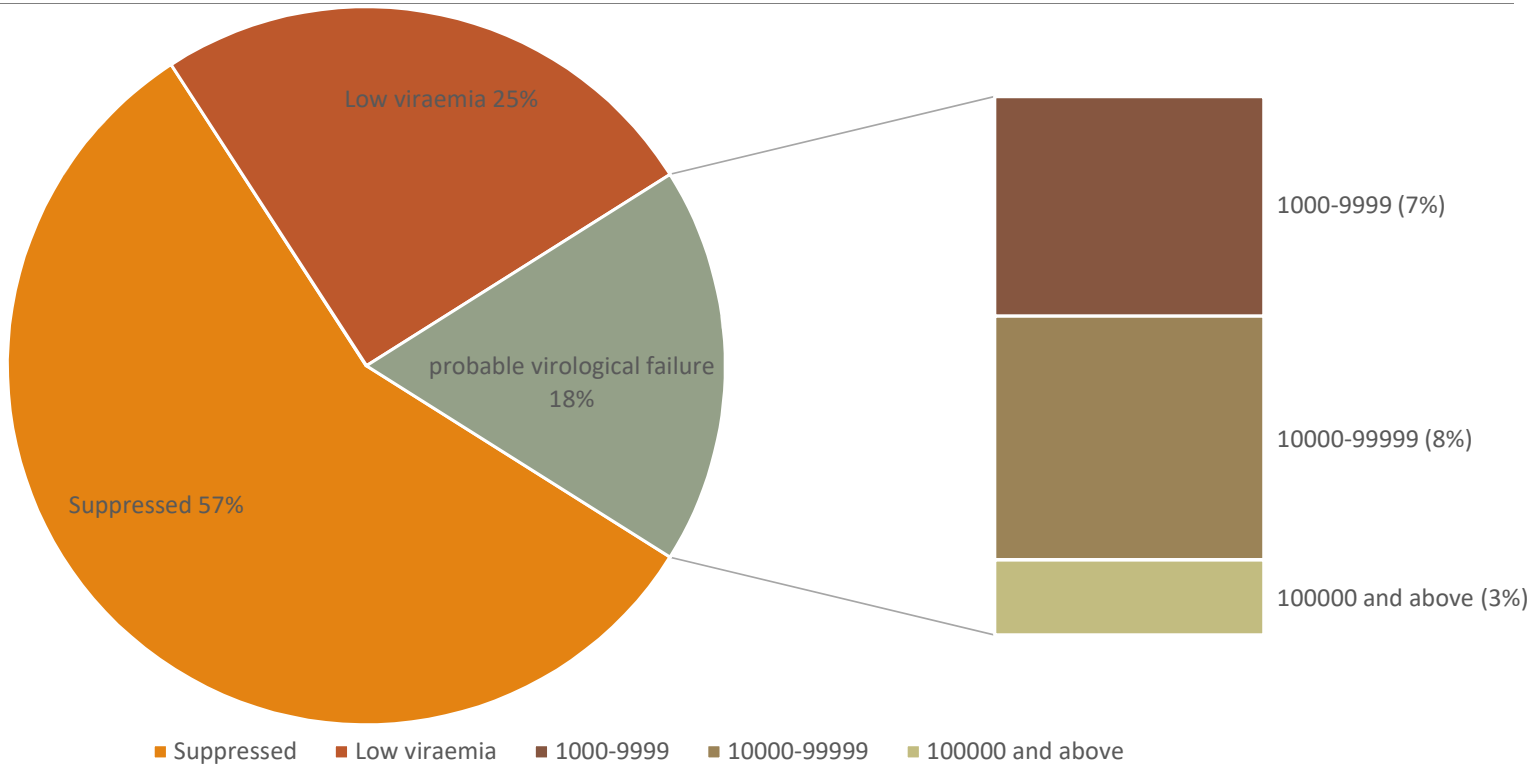
Results
Characteristics of participants

Ages: From 14 - 47 years

Variables	Frequency (n=1463)	Percentage
Marital status		
Married	274	18.7
Single	1003	68.6
Cohabiting	163	11.1
Divorce/separated	23	1.6
Place of residence		
Rural area	492	33.6
Semi-urban	680	46.5
Urban	291	19.9
Level of education		
No formal education	4	0.3
Grade 1-6	83	5.7
Grade 7-12	1276	87.2
Tertiary education	100	6.8
Employment status		
Unemployed	1085	74.2
Employed	378	25.8
Parity		
One	450	30.8
Two	520	35.5
Three	301	20.6
Four and more	192	13.1

Variables	Frequency (n=1463)	Percentage
Duration on ART treatment		
At least over 41 weeks on ART (Pre-conception ART)	850	58.1
27-40 weeks	86	5.9
13-26 weeks	430	29.4
Less than 13 weeks	97	6.6
Gestational age at booking		
First trimester	176	12.0
Second trimester	1061	72.5
Third trimester	226	15.4
ART regimen **		
First line regimen	1297	97.7
Second line regimen	30	2.3
Disclosed status to partner		
Yes	1089	25.1
No	365	74.9
Defaulted ARV		
No	1232	84.2
Yes	154	10.5
Not stated	77	5.3
HIV status at booking		
Positive	1182	80.8
Negative	79	5.4
Unknown	202	13.8

Maternal Virological Suppression at Delivery



Correlates of Virological Suppression

In the **adjusted binary logistic regression,**

Undetectable VL

- Age 24 years and below
- Being unemployment
- History of defaulting ART
- Short duration on ART (0 – 13 weeks) and
- Lower CD4 counts (<200 cells/ml) were associated with a lower likelihood of having an undetectable viral load

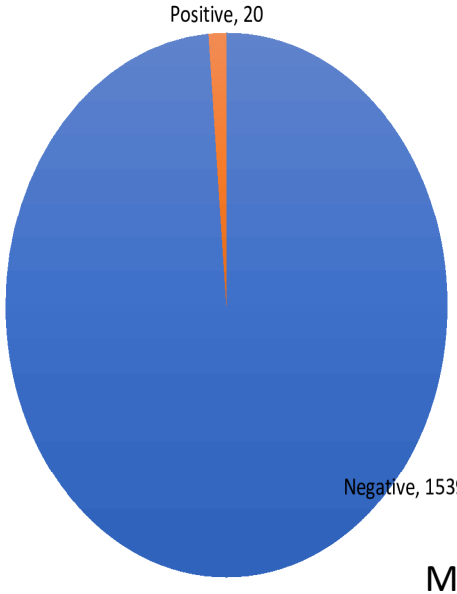
Virological suppression (**VL>1000 copies/ml**)

- Age less than 25 years
- Being unemployed
- Smoked during pregnancy
- Low peripartum CD4 counts and
- History of defaulting ART

Correlates of virological suppression

Variable	Undetectable viral load (VL<20 copies/ml)		Viral load < 1000 copies/ml	
	UOR	AOR	UOR	AOR
History of defaulting in using ARV				
Never defaulted in use of ARV	2.95 (2.07-4.20)***	2.50 (1.70-3.68)***	4.08 (2.85-5.8)***	2.92 (1.93-4.40)***
Unknown	3.74 (2.10-6.65)***	3.69 (1.95-6.95)***	2.94 (1.54-5.62)*	2.62 (1.24-5.54)***
Defaulted in using ARV in the past (ref)	1	1	1	1
Duration on treatment				
Less than 13 weeks	0.48 (0.31-0.72)***	0.49 (0.30-0.79)*	0.81 (0.48-1.37)	0.93 (0.51-1.69)
13-26 weeks	0.77 (0.61-0.97)*	0.86 (0.63-1.16)	1.14 (0.83-1.57)	1.42 (0.94-2.13)
27-40 weeks	0.48 (0.31-0.75)*	0.46 (0.27-0.78)*	0.46 (0.28-0.75)*	0.50 (0.28-0.91)*
At least over 41 weeks on ART (Pre-conception ART)	1	1	1	1
Age				
24 and below	0.61 (0.47-0.77)***	0.63 (0.48-0.83)*	0.63 (0.47-0.85)***	0.59 (0.42-0.83)*
25 and above (ref)	1	1	1	1
Employment status				
Unemployed	0.69 (0.54-0.88)*	0.69 (0.53-0.89)*	0.56 (0.40-0.79)*	0.60 (0.41-0.86)*
Employed (ref)	1	1	1	1
Smoking status				
Smoked during pregnancy	0.57 (0.36-0.89)*	0.67 (0.39-1.15)	0.35 (0.22-0.56)***	0.48 (0.26-0.87)*
Quit smoking during pregnancy	1.38 (0.84-2.25)	1.73 (1.00-2.98)	1.16 (0.60-2.25)	1.54 (0.73-3.23)
Never smoked (ref)	1	1	1	1
Alcohol use				
Drank during pregnancy	0.68 (0.50-0.93)*	0.94 (0.66-1.36)	0.56 (0.39-0.80)*	0.87 (0.55-1.36)
Quit drinking during pregnancy	0.95 (0.74-1.21)	1.01 (0.77-1.33)	0.99 (0.72-1.36)	1.09 (0.76-1.57)
Never drank alcohol (ref)	1	1	1	1
Disclosure to partner				
No	0.73 (0.57-0.92)*	1.12 (0.86-1.45)	1.49 (1.11-2.00)*	1.18 (0.85-1.64)
Yes (ref)	1	1	1	1
Year diagnosed with HIV				
1 year or less	0.71 (0.54-0.95)*	0.89 (0.63-1.25)	0.89 (0.61-1.32)	0.93(0.59-1.47)
2 years	0.83 (0.55-1.26)	0.79 (0.50-1.22)	0.65 (0.39-1.10)	0.56 (0.32-0.99)*
Not available	0.60 (0.45-0.80)***	0.79 (0.55-1.14)	0.60 (0.41-0.87)*	0.58 (0.36-0.94)*
3 -17 years	1	1	1	1
Peripartum CD4 counts				
1-199	0.17 (0.12-0.25)***	0.18 (0.12-0.27)***	0.14 (0.09-0.22)***	0.15 (0.09-0.23)***
200-349	0.47 (0.36-0.63)***	0.49 (0.36-0.65)***	0.42 (0.29-0.63)***	0.44 (0.30-0.67)***
350-499	0.35 (0.22-0.56)***	0.37 (0.21-0.55)***	0.24 (0.14-0.41)***	0.21 (0.12-0.38)***
Not available	0.77 (0.58-1.02)	0.77 (0.57-1.04)	0.64 (0.42-0.98)*	0.67 (0.43-1.04)
500-3200 (ref)	1	1	1	1

Early MTCT and its Correlates



MTCT rate = 1.3%

Figure 2: Rate of Early Mother-To-Child Transmission

Dose-response effect between maternal VL and MTCT;

- undetectable viral load = 0.5%
- Low level viraemia = 0.6%
- High viral load (3.3%)

In the **unadjusted logistic regression**;

- History of defaulting ART
- High peripartum viral load

The direction of effect remains after controlling for important covariates

- Parturient women who **failed to achieve virological suppression at delivery** were about **nine times more likely** to transmit HIV virus to their babies
- Likewise, women who **reported non-adherence** to ART were over **four times more likely** to transmit HIV to their infants

Discussion and Recommendations

Findings demonstrate the significant progress of PMTCT programme and population-effectiveness of lifelong ART in the study area

Universal access to ART and viral load monitoring are the game-changers in the effort to eliminate new paediatric HIV infections

There are evidence suggesting significant risk of transmission with low level viraemia (VL < 1000 copies/ml) [21, 29]; hence, VL < 50 copies/ml would be ideal.

Rate of virological suppression at delivery in the present study fell short of the last 90% target [1]

Significant association between socio-behavioural factors and high peripartum viral load suggest the need for clinicians to screen for these factors during clinic visits

Finding of 1.3% MTCT is comparable to reports from the non-breastfeeding population in Europe and America as well as reports from clinical trials [21, 22, 37].

Maternal viral load is the key driver for MTCT of HIV, which has been described in previous studies [13,19-22, 37].

Conclusion

Over half of the women achieved undetectable viral load and over three-quarter achieved viral suppression at delivery, and very low (in-utero) MTCT in the resource-constrained Eastern Cape.

Undetectable viral load and virological suppression were significantly associated with lifestyle behaviours and adherence challenges.

Intervention strategies focusing on addressing maternal lifestyle behaviours and ART adherence challenges require targeted research.

Also, retention in care of the mother-infant pair post-delivery will provide insightful understanding of postpartum viral suppression and breastfeeding transmission in the context of lifelong ART.

Future studies should explore the impact of implementing a **point-of-care viral load test** at delivery in the study setting.

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