

FIVE YEARS RETROSPECTIVE ANALYSIS OF THE PATTERN OF VIRAL LOAD SUPPRESSION AMONG ADULTS ON ANTIRETROVIRAL THERAPY IN A TERTIARY HOSPITAL NORTH-CENTRAL, NIGERIA.

Abstract

Aim: The aim of this study was to determine the pattern of viral load suppression among adults on antiretroviral therapy for the past five years, since Human Immunodeficiency Virus (HIV) has claimed the lives of many people globally and impacted negatively on the health care system especially in Nigeria. The viral load detection on HIV patient is a good standard for checking compliance and effectiveness of antiretroviral drugs.

Purpose of the study: The main purpose of this study is to determine the viral load suppression, clinical characteristics and factors associated with viral load suppression.

Study Design: A retrospective cross-sectional study

Place and Duration of the Study: The study was carried out at Federal Medical Centre, Makurdi, Benue State, North Central-Nigeria from January 2020 to December 2024.

Methodology: A total of 9727 were retrieved and analyzed using Statistical Package for the Social Science (SPSS) Version 23 with their demographic characteristics, duration of antiretroviral therapy and first CD4 counts.

Results: The results showed that patients aged 38-47 had the highest proportion (38.7%) of viral load suppression. The female had better suppression (70.8%) when compared to the male. Patients with secondary education had viral load suppression (38.7%) when compared to the other levels of level of education. Patients with first line regimen had 93.4% suppression when compared to those on second line. Two thirds of the patients on antiretroviral therapy for at least ten years had more suppression (65%) when compared to those less than ten years on ART. About half (52.5%) of the patients who had first CD4 count <500 copies/ml, had better viral load suppression compared to those who had first CD4 count >500 copies/ml. The highest prevalence of viral load suppression (100%) was seen in those aged 78 years and above, and was statistically significant ($p < 0.001$). The female patients had higher prevalence (97.3%) of viral load suppression when compared to their male counterparts who had viral load suppression of 95.7%, which was statistically significant ($p < 0.001$).

Conclusion: The age, sex, first line regimen and duration on ART were independent predictors of viral load suppression.

Keywords: Antiretroviral therapy, CD4 counts, HIV-positive adults, Pattern, Viral Load Suppression, clinical characteristics, viral load

Comment [Ma2]: The grammatical omission of the word " had " takes clarity out of the context.

Comment [Ma3]: Limiting the duration on antiretroviral therapy to ten years in the write up for the results is in variance to what was actually done and captured in the table. Hence the need open it up to either " at least ten years" to include ten years and above.

1.0

INTRODUCTION

1.1 Background to the study

Human immunodeficiency Virus (HIV) remains a pandemic that has claimed many lives and impacted negatively on the healthcare system of many countries especially in low- and medium-income countries (Volberding, 2011). The advent of effective antiretroviral therapy (ART) has changed the landscape of medical intervention in HIV which was now considered a chronic illness (Groh *et al.*, 2011; Tougas *et al.*, 2015). One of the major strategies in the management of the HIV is ensuring patients are compliance to anti-retroviral therapy and monitoring of detectable viral loads. However, Human Immunodeficiency Syndrome remain one of the world's most significant public health challenges affecting about 38 million people globally especially in low- and medium-income countries of the world (Dedha *et al.*, 2017, WHO 2020; GBD, 2015). Therefore, Nigeria has a portion of these estimates with a recent national prevalence of 1.4 percent (1.9 percent among female and 0.9 percent among males) (NACA, 2020). The varying prevalence across Nigeria showed that Katsina State, North Western Nigeria have the lowest prevalence of 0.3 percent while Akwa Ibom South-South Nigeria and Benue States, North Central Nigeria have the highest prevalence of 5.6 percent and 5.3 percent respectively (UNAIDS, 2019; NACA, 2020). The 90%-90%-90% target by UNAIDS envisages that by 2020, 90 percent of people living with Human Immunodeficiency Virus (PLHIV) will know their HIV status, 90 percent of people who know their HIV positive status will be accessing treatment and 90 percent will have their viral load know and suppressed (UNAIDS, 2020). In 2018, Nigeria has only 67 percent of PLHIV know their status and only 42 percent have their viral load suppressed (WHO, 2017; NACA, 2020). However, Sub-Saharan Africa, especially Nigeria have transitioned from using CD4 count to viral load testing as way of assessing HIV disease progression, aiming

to prevent treatment delays and drug resistance (Shako *et al.*, 2019). The Viral load monitoring that defines the amount of HIV viral particles in blood per milliliter was a critical tool in evaluating ART effectiveness (JUNP,2016). Therefore, the primary treatment goal was to achieve viral load suppression (VLS), where viral replication was reduced to undetectable levels (below 400 copies/ml) (Cardoso *et al.*, 2014, Prepstra *et al.*, 2020, Deeks *et al.*, 2015, Rangarajan *et al.*, 2014). However, viral load measurement is the gold stand for monitoring treatment success (Ornel *et al.*, 2017; Evans *et al.*, 2015; Sangede *et al.*, 2014) and it yields numerous benefits, such as reduced transmission risk, improved health outcomes, lower mortality, and a boosted immune system. As a result, viral load monitoring is pivotal in assessing ART success and enhancing the quality of life for PLWHIV (Byrd *et al.*, 2020). Viral load monitoring can be conducted through fresh plasma specimens with nucleic acid quantification or dried blood spots on filter paper cards, the latter being more cost-effective and suitable for resource-constrained settings (Vubil *et al.*, 2020). Successful viral suppression is typically defined as maintaining a viral load below 400 RNA copies/ml of blood plasma, while virological failure is marked by a viral load exceeding 1000 copies/ml (WHO,2016) Therefore numerous factors influences the Viral Load Suppression which include sociodemographic such as age, sex, marital status, employment, settlement type, social support, and clinical characteristics including WHO staging, pre-ART counselling, adherence, and TB history (Langwenya *et al.*,2018, Wakooko *et al.*,2020). Also, ART initiation and differentiated care models have contributed to improving viral suppression rates (Bessong *et al.*, 2021), non-adherence, lack of awareness, and inadequate knowledge about the benefits of viral load suppression hinder progress (Waju *et al.*, 2021). Nigeria has thus adopted a universal test and treatment strategies, aligning with the 90-90-90 UNAIDS targets, focusing on testing, initiating treatment, and achieving viral suppression

(WHO, 2015). Despite all the progress made in ensuring that viral load was suppressed, Nigeria still remain with varied viral suppression rates. Against this backdrop that this study aimed to determine the pattern of viral load suppression among adults on antiretroviral therapy for the past five years in Tertiary Hospital North Central Nigeria. to address the persisting challenge of achieving VLS among PLWHIV. By comprehensively understanding the factors contributing to VLS, the research seeks to inform interventions that will significantly enhance retention and adherence to treatment, ultimately improving health outcomes and substantially reducing HIV transmission.

2. Materials and Methods

2.1 Study Area

This study was carried out at the Federal Medical Centre Makurdi, Benue State. The Benue State is situated in the North Central part of Nigeria. It is bounded on the South by Cross River, Ebonyi and Enugu States, West by Kogi state, North by Taraba State. Benue State also shares an international boundary with Cameroon on the east. Benue state had a population of 5,741,800 during the 2016 population census and a total of 50.4 percent males and 49.6 percent females. Makurdi as at 2016 population census had a population of 405,500 and most of the people are Tiv, Idoma, Igbo and Iggede. Most of the people, 75 percent are local farmers while few others, 6 percent are civil servants and 19 percent are small and medium businessmen and women. Federal Medical Centre has five sites as follows: Permanent site, National Health Insurance Scheme (NHIS) Complex, Staff Clinic, Ward Site, and the Mission. The study was conducted in the mission ward at the sexually transmitted infections clinic (STIC). There are over 9000 non-pregnant HIV positive patients on antiretroviral therapy seen on the clinic every week. The patients are seen on Mondays, Wednesdays, and Fridays every week. The antiretroviral drugs and screening maternal for viral load and CD4 counts are supplied to the clinic by the National

Agency for the Control of AIDs (NACA) through the AIDs Prevention Initiative in Nigeria (APIN) and these items are distributed to the clinic free of charge.

Clinical Protocol: At every Clinic Day, patients arrive at the waiting/triaging area and are given numbers starting from the first to have come. They were addressed on health issues by nurses or any other persons in charge. Their weight, height, temperature, pulse rate and blood pressure are taken by the nurses and recorded in the book. Those that needed routine investigations such as the viral load and CD4 Count are investigated for at least every 12 months and 6 months respectively and recorded accordingly.

2.2 Study Site

The study was carried out at the sexually transmitted infections clinic (STIC), Federal Medical Centre. This clinic serves over 10,000 HIV positive patients, including adolescents on antiretroviral therapy (ART). The clinic operates four days a week, with adolescents seen on Wednesdays and Fridays.

2.3 Study Design

The study is a cross-sectional study.

2.4 Study Population

The population includes all HIV-positive adults attending the STIC at the Federal Medical Centre, Makurdi.

2.4.1 Sampling method

Purposive sampling method was used in the study

2.4.2 Selection criteria

2.4.2.1 The inclusion criteria:

- a. All HIV positive adult patients that were non pregnant and had been on antiretroviral therapy for at least six months.

b. All HIV positive adults that are 18 years and above, and had been on antiretroviral therapy for more than six months.

2.4.2.2 Exclusion criteria:

- a. All HIV positive adults that were pregnant.
- b. All HIV positive patients without informed consent

2.5 Data Collections

The data was obtained from data base of HIV positive patients attending clinic at sexually transmitted infection clinic Federal Medical Centre Makurdi, North Central Nigeria from January 2020 to December 2024. A total of 10,000 clients were registered within this period. The data base provided information on socio-demographic, clinical immunological, virological, and other related parameters of the patients. Data on viral load was collected from those who had being on HAART for at least six months; the viral load was measured in terms of viral RNA copies/ml of blood. Before 2017, virological monitoring was carried out only in those clients with clinical suspicion of failure or poor adherence. Following the policy change and update of National guideline in 2018, all enrolled PLHIV had a minimum of yearly viral load monitoring. However, where the viral load was above the threshold of 1000 copies/ml intensified adherence counselling was carried out and viral load assays repeated within three (3) and six (6) months.

2.6 Data Analysis

The data collected were analyzed using statistical package for social sciences (SPSS) version 23.0. The basic descriptive summaries of the participant's characteristics and the outcome interest were computed. The Frequencies and percentages were used to determine prevalence and determinants of viral load suppression. Prevalence of viral load suppression was represented on a

pie chart. Continuous variables were presented as means and standard deviation, while categorical variables were presented as proportions and analyzed using chi square, Multivariate logistic analysis was used to identify determinants of viral load suppression. Only variables that had p value < 0.10 in bivariate analysis were considered eligible for multiple logistic regression analysis. Adjusted odds ratio estimated from logistic regression together with 95% confidence interval also measured the strength of association. The level of statistical significance was set at P-value of ≤ 0.05 in all analysis.

2.7 Duration of the Study

The study was a retrospective study on positive HIV adults on antiretroviral for a period of five (5) years

2.8 Ethical Approval

Ethical approval was obtained from the Research and Ethics Committee of the Federal Medical Centre Makurdi with reference number: FMH/ FMC/HREC/108/VOL.1

2.9 Funding

The cost of this research work was funded by the researchers.

Authors' contributions

This work was carried out in collaboration among all authors. Author TB designed the study, performed the statistical analysis, wrote the protocol. Author NAN wrote the first draft of the manuscript; Author N.K managed the analyses study and Author O.C.C managed the literature searches. All authors read and approved the final manuscript

3 Result and Discussion

Table 1: shows socio-demographic characteristics of participants.

The age range of participants was 18 to 92 years. The mean age was 46.69 ± 10.89 years. Participants aged 38-47 years had the highest frequency (38.2%). Over two-third (71.4%) were

females. About one-third of the participants (32.3%) had secondary education. Majority (50.6%) were married. These results are similar to a study carried out in northwestern Nigeria (Abdullahi et al., 2021).

Figure 1: Shows Pie Chart of viral load suppression rate.

A vast majority of the participants (96.8%) had viral load suppression. The level of viral suppression in this study was high and it falls within the global target of 95% viral suppression

Among people living with human immune deficiency syndrome (PHIV) on HAART (USAID, 2020). This level is higher compared with the national level of viral suppression of 44.4% in the north-western part of Nigeria (NACA, 2020, WHO, 2020). The value of viral suppression in this study was also higher compared to 79% reported in a multi-center Nigerian study (Stafford *et al.*, 2019), and 84% in Borno state, north-eastern Nigeria (Sunkanmi *et al.*, 2020), 69% in Ghana (Ofori *et al.*, 2020) and 73% in northern Ethiopia (Desta *et al.*, 2020). High level of viral suppression in this study are comparable with the reports from Uganda where a level of 95% was observed for viral suppression after 12 months of HAART among PLHIV (Ssemwanga *et al.*, 2020). Similarly, the level of viral non-suppression obtained in this study is comparable to 9.0% and 7.0% reported in the African cohort study (Kiweewa *et al.*, 2019), and Vietnam (Rangarajan *et al.*, 2016) respectively. The high levels of viral suppression observed in this study compared to the other studies may be due to several reasons such as; the cut off value used for VL suppression in this study was $VL < 1000$ compared with a low value of 400 used in the earlier Nigerian studies that evaluated viral suppression after test and treat protocols (Stafford *et al.*, 2019) and after 6 months of initiation of first-line of HAART in a Moroccan study (Ababe *et al.*, 2017). Furthermore, our centre is a tertiary health care centre with a dedicated unit for PLHIV and patients routinely undergo adherence counselling during their clinic visits which

could have enhanced their compliance with their medications leading to viral suppression (Mainaa *et al.*, 2020). Our findings also suggest that the goal of achieving a 90% level of viral suppression is achievable in a resource-limited country like ours if the current approach in the management of HIV is sustained.

Table 2: Shows Clinical Characteristics of participants.

A vast majority of the participants, (93.0%) were on first line regimen. About two-third (64.7%) of the participants were on ART for equal or greater than ten years. Above half, (52.7%) of the participants had their first CD4 Count <500 copies/ml. Similar to a study carried out in northwestern Nigeria (Abdullahi et al 2021), most of the participants (93.0%) were on first line regimen. Almost two-third (n=6294, 64.7%) of the participants were on ART for ten years or more. Above half (52.7%) of the participants had their first CD4 Count <500 copies/ml.

Table 3: Median and interquartile range of viral load

The median viral load in 2019 was 20.0 (IQR: 20-51), in 2020 the median was 20 (IQR: 20-20), in 2021 median was 20 (IQR: 0-40), in 2022 the median was 0 (IQR: 0-19) and in 2023 the median was 0 (IQR: 0-19).

Table 4: Shows the Factors associated with viral load suppression.

The results show that participants aged 78 years and above have the highest prevalence (100%) of viral load suppression, while the least prevalence (90.3%) was seen in those aged 18-27 years. This was statistically significant ($p<0.001$). On the contrary, Abdullahi et al, observed a higher viral load suppression among those between 36 and 45 years (Abdullahi et al 2021). In contrast, the study in Borno State, north-eastern Nigeria found that the female participants had higher prevalence of viral load suppression when compared to males, this was statistically significant (97.3% vs 95.7%, $p<0.001$). This agrees with Abdullahi and colleagues (Abdullahi et al, 2021).

According to level of education, participants with primary education had slightly higher prevalence (97.7%) of viral load suppression, while the least prevalence (96.5%) was seen in those with secondary education. This was not statistically significant ($p=0.001$). Concerning marital status, divorced participants had the highest prevalence (99.1%) of viral load suppression while the least prevalence (96.6%) was seen in those who were single. This was not statistically significant ($p<0.459$). In another study, those who were married had higher viral load suppression (Abdullahi et al, 2021). Similar to another study (Abdullahi et al, 2021), participants who were on first line regimen had higher prevalence of viral load suppression when compared to those on second line regimen, this was statistically significant (97.2% vs 91.6%, $p<0.001$). Participants who were on ART for equal or greater than ten years had higher prevalence of viral load suppression when compared to those who were on ART for less than ten years, this was statistically significant (97.3% vs 95.9%, $p<0.001$). On the other hand, in a study conducted by Abdullahi et al, those who had been on ART for over 5 years were better suppressed virologically compared with those who were less than 5 years on therapy (Abdullahi et al, 2021). In terms of first CD4 count, participants who had their first CD4 count ≥ 500 copies/ml had a higher prevalence of viral load suppression compared to participants who had first CD4 count < 500 copies/ml, this was statistically significant (97.3% vs 96.4%, $p<0.001$). This also agrees with the study by Abdullahi et al (Abudullahi et al, 2021)

Table 5: Shows logistic regression model of independent variables predicting viral load suppression.

This study identified age, sex, level of education, first line regimen, duration on ART and first CD4 count as being independent factors that affected viral load suppression. Age, between 58 and 67 years, being female, being on first line medication, and duration on ART for more than 10

years were all statistically significant; On the contrary, Abdullahi et al in their study, identified that high baseline CD4 count, being employed, uneducated and being on first-line highly active antiretroviral therapy (HAART) were the determinants of viral load suppression (Abdullahi et al, 2021). There was high level of viral suppression (96.8%) among participants, while the unsuppressed viral load was 3.2%. The high viral load suppression compares to a study in northwestern Nigeria (Abdullahi et al 2021) that reported a viral suppression of 95%. On the other hand, the viral suppression in this present study is higher than those of Stafford et al that reported a viral suppression of 79% (Stafford et al, 2019), and Sunkanmi et al that documented a suppression of 84% (Sunkanmi et al, 2020). The study has a low viral un-suppression, is similar to those documented by Kiweewa et al in their study as 9.0% (Kiweewa et al, 2019) and Rangaran et al as 7.0% (Rangaran et al, 2016). The very high viral load suppression and low viral load un-suppression documented in this study could be as a result astute client monitoring, which include among others continues phone call reminders on the dos and don'ts concerning their management.

A logistic regression analysis was done to determine the independent predictors of viral load suppression among the study participants. Independent variables that were eligible to be entered into the logistic regression model were those that were significant at 0.1% on bivariate analysis. They included age, sex, level of education, current regimen line, duration on ART and first CD4 count. Regarding age with reference to those aged 18-17 years, participants with aged 58-67 years were more likely to have viral load suppression. This association was statistically significant ($p < 0.05$). With reference to males, female participants were more likely to have viral load suppression. This association was statistically significant ($p < 0.001$). Participants who were on first line regimen were more likely to have viral load suppression. This was statistically

significant ($p < 0.001$). Participants who were on ART for ten years, and above were more likely to have viral load suppression. This was statistically significant ($p < 0.05$).

In summary, age, sex, first line regimen and duration on ART were the independent predictors of viral load suppression.

4.0 The Strengths and Limitations of the study

The strength of this study was that it had large data, and however, it is limited because it was a retrospective and hospital-based study.

Comment [Ma4]: Just for clarity

5.0 Conclusion/Recommendation

This study concluded that age, sex, first line regimen and duration on ART were the independent predictors of viral load suppression. It is therefore pertinent to consider these variables when managing clients in the centre.

Table 1: Socio-demographic characteristics of participants (n=9282)

Socio-demographic	Frequency	Percent
Age (in years)		
18-27	386	4.2
28-37	1209	13.0
38-47	3544	38.2
48-57	2677	28.3
58-67	1232	13.3
68 and above	284	3.1
Mean=46.69±10.89		
Sex		
Male	2657	28.6
Female	6625	71.4
Educational level		
Informal Education	1336	14.4
Primary	1630	17.6
Secondary	3002	32.3
Tertiary	2402	25.9
Missing	912	9.8
Marital Status		
Married	4697	50.6
Single	1362	14.7
Divorced/Separated	1492	16.1
Widowed	833	9.0
Missing	898	9.7

Table 2: Clinical Characteristics of participants (n=9282)

Current Regimen Line	Frequency	Percent
1st Line Regimen	8759	94.4
2nd Line Regimen	523	5.6
Duration on ART		
<10 years	2374	25.6
≥10 years	6908	74.4
First CD4 Count		
<200	1010	10.9
≥200	7320	78.9
Missing	952	10.2

Table 3: Median and interquartile range of viral load

Year	Median	Interquartile range
2019	20.0	20 – 51
2020	20.0	20 – 20
2021	20.0	0 – 40
2022	0.0	0 – 19
2023	0.0	0 – 19

The median viral load in 2019 was 20.0 (IQR: 20-51), in 2020 the median was 20 (IQR: 20-20), in 2021 median was 20 (IQR: 0-40), in 2022 the median was 0 (IQR: 0-19) and in 2023 the median was 0 (IQR: 0-19).

Table 4: Factors associated with viral load suppression

Variables	Viral load suppression		Test statistic χ^2	df	p-value
	Suppressed n (%) n=8937	Unsuppressed n(%) n=345			
Age (in years)			32.18	2	<0.01*
18-35	1101(93.8)	73(6.2)			
36-45	3182(95.9)	136(4.1)			
46 and above	4654(97.2)	136(2.8)			
Sex			25.06	1	<0.01*
Male	2517(94.7)	140(5.3)			
Female	6420(97.0)	205(3.1)			
Educational level			1.27	1	0.259
Informal Education	1295(96.9)	41(3.1)			
Formal Education	6774(96.3)	260(3.7)			
Marital Status			0.23	1	0.630
Currently married	4526(96.4)	171(3.6)			

Currently not married	3560(96.6)	127(3.4)			
Current Regimen Line			49.47	1	<0.01*
1st Line Regimen	8463(96.6)	296(3.4)			
2nd Line Regimen	474(90.6)	49(9.4)			
Duration on ART			8.19	1	<0.01*
<10 years	2263(95.3)	111(4.7)			
≥10 years	6674(96.6)	234(3.4)			
First CD4 Count			48.75	1	<0.01*
<200	938(92.8)	72(7.1)			
≥200	7109(97.1)	211(2.9)			

Table 5: Logistic regression model of independent variable predicting viral load suppression

Variables	Adjusted odds ratio (aOR)	95% confidence interval (CI)	P-value
Socio-demographic			
Age (in years)			
18-27	Reference		
28-37	1.26	0.51 – 2.46	0.767
38-47	1.58	0.73 – 3.39	0.240
48-57	1.78	0.81 – 3.93	0.148
58-67	2.55	1.06 – 6.11	0.036*

68-77	1.61	0.55 – 4.75	0.381
78 and above	69835861.40	-	-
Sex			
Male	Reference		
Female	1.67	1.25 – 2.22	<0.001**
Educational level			
Informal Education	0.83	0.54 -1.28	0.404
Primary	1.14	0.76 – 1.72	0.501
Secondary	0.84	0.61 – 1.15	0.298
Tertiary	Reference		
Current Regimen Line			
1st Line Regimen	3.76	2.67 – 5.24	<0.001**
2nd Line Regimen	Reference		
Duration on ART			
<10 years	Reference		
≥10 years	1.39	1.05 – 1.84	0.019*
First CD4 Count			
<500	Reference		
≥500	1.31	0.99 – 1.73	0.051

Note: *p<0.05, **p<0.001, Hosmer-Lemeshow goodness of fit test: $\chi^2 = 5.41$, df = 8, p =0.712, Nagelkerke R²=0.047

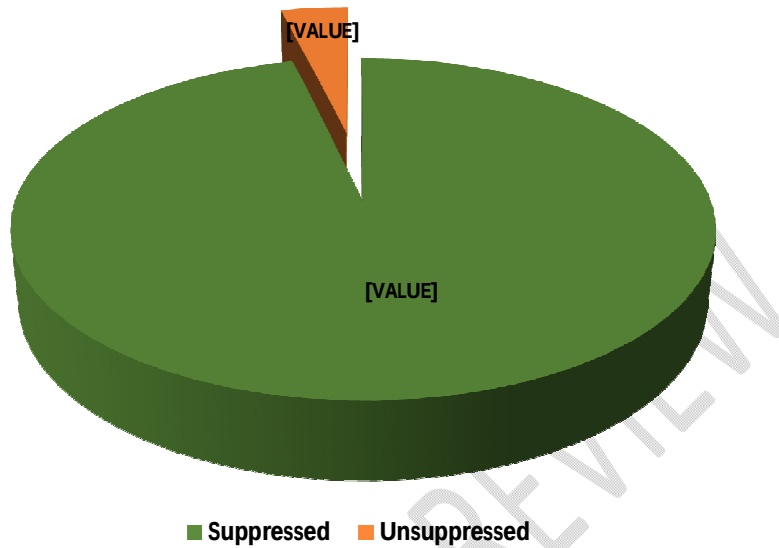


Figure 1: Show prevalence of viral load suppression.

A vast majority of the participants had viral load suppression (96.8%).

COMPETING INTERESTS DISCLAIMER:

Authors have declared that they have no known competing financial interests OR non-financial interests OR personal relationships that could have appeared to influence the work reported in this paper.

Comment [Ma5]: In summary, this is a good and useful work done with only minor review comments.

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