

Assessment of adherence by healthcare providers to WHO Tenofovir guidelines at Levy Mwanawasa General Hospital

Samwalumilupi*, Sakala Christopher*Phd*, Yassa Pierre,Phd**, DR Gustave Banza,MD**

*Lusaka Apex Medical University Of Lusaka**University Of Kamina In Congo DRC.

ABSTRACT Introduction:-

The use of tenofovir in HIV/AIDS patients has been associated with nephrotoxicity, which is exacerbated by irregular monitoring of renal function by healthcare providers. This is despite the World Health Organization introducing treatment guidelines on the use of tenofovir. The study is aimed at assessing adherence by healthcare providers on WHO Tenofovir guidelines.

General objectives: The study assessed if healthcare providers adhered to the WHO treatment protocols of requesting for renal function tests in HIV/AIDS patients on tenofovir based regimen, at 2 weeks before initiating treatment, at 3 months and 6 months after initiating treatment.

Methodology: The study was a retrospective cross-sectional survey which involved a review of patient files of 322 study patients who were on tenofovir based regimen at Levy Mwanawasa General Hospital. The variables of the study were analyzed using statistical package for social sciences (SPSS) Version 16.0.

Results: The study reviewed adherence by healthcare providers to treatment protocols. At baseline 92.5% of patients had their creatinine results available in their files while 7.5% did not have creatinine results at baseline. A follow-up at 3 months after initiating treatment revealed that 68% had their creatinine results in their files while 32% did not have their creatinine results on their files. This showed a gradual decrease in the level of adherence to treatment protocols. Another follow-up at 6 months after treatment revealed a steady increase in adherence levels where 82% had their creatinine results on their files and results were available on their files.

I. CONCLUSION

The study showed non-adherence by healthcare providers to treatment protocols. Although clinicians were requesting for creatinine tests, some patients did not have creatinine results in their files. This meant that these patients were being given medication without a close renal monitoring. This posed a great risk to these patients as they could develop renal injury due to nephrotoxicity that is caused by tenofovir. Although the study was a success, and the institution where this study was being carried out was committed to providing quality patient care in the midst of limited resources, manpower and other challenges, the importance of renal creatinine clearance monitoring in patients on tenofovir based regimen should be emphasized. Introduction of the antiretroviral drug has greatly improved the quality of life and the life expectancy of many people who are living with HIV virus. Much as these drugs are saving lives of people, they also cause many adverse effects and toxicities that demand regular renal monitoring especially in patients taking tenofovir based regimen who require routine renal monitoring (Mulenga et al, 2014). The use of tenofovir has been associated with the development of renal impairment, (Hall, 2012; Judda, 2010). As such baseline renal functioning tests are required to be conducted prior to commencement of treatment and thereafter regular monitoring is required at specified intervals (Cooper, 2010). A study done in Australia revealed that HIV infected individuals have a higher risk of developing both acute and chronic renal failure than the general population, especially those on tenofovir based therapy (Holt, 2014). Since the introduction of tenofovir in 2002 in Australia, a series of case reports and large population studies have viewed its nephrotoxic potential in HIV/AIDS patients, (Holt, 2014). With the increased use of ART, clinicians must routinely screen patients for the development of renal disease especially if the regimen employed increases the risk of renal injury. (Perazella, 2011). Studies done in review that most patients on tenofovir based regimen tend to develop renal damage within the first 36 months of treatment. Hence the need for regular renal creatinine clearance monitoring (WHO, 2010), (MOH, 2014). In 2007 the ministry of health in Zambia introduced the use of tenofovir based regimen as the first line of treatment in HIV. Tenofovir was being widely used in many developed countries and also in resource limited countries because of its proven efficacy on HIV viral suppression, its tolerability,

Safety, Its ability to be formulated with other drugs and it has also associated with delayed development of drug resistance. (Mulenga et al., 2014; Chabala, 2015). According to the Ministry of Health HIV treatment Protocols, Once a patient was diagnosed with HIV, Renal Function test is supposed to be conducted 2 weeks before commencing treatment, Then at 3 months, 6 months and Then Annually (WHO, 2014). Many studies done on tenofovir have only focused on its associated nephrotoxic potential in HIV/AIDS patients (Peyrière, 2004; Isabelle, 2013; Horberg, 2010). A number of researchers have recommended the need for clinicians to routinely perform baseline renal monitoring in these patients. Therefore, this research study will assess the adherence of healthcare providers in monitoring renal creatinine clearance in HIV/AIDS adult patients on tenofovir based regimen. Findings of this study would help in mitigating the development of early renal injury.

II. RESEARCH METHODS

Research methods were used to meet the objectives of the study.

2.1 STUDY

DESIGN

The study was a cross-sectional survey which aimed at assessing adherence by health care providers on requesting for renal creatinine clearance test in HIV/AIDS adult patients on tenofovir based regimen at Levymwanawasahospital.

2.2. STUDY POPULATION

The study population was the HIV/AIDS patients on tenofovir based regimen.

2.3. STUDY SITE/LOCATION

The study was conducted at Levymwanawasahospital In Lusaka.

2.4. SAMPLE SIZE DETERMINATION

The sample size of the patient files was calculated using the equation below

$$N = Z^2 p (100 - P) / E^2$$

Where n = Sample size

P = The prevalence which is 30%

E = Magnitude of tolerable error (5%)

Z = Significance level (1.96 at 95%)

$$N = 1.96^2 \cdot 30 (100 - 30) / 5^2$$

$$N = 322 \text{ Files}$$

2.5. Sampling Technique

The patient's files were sampled using a simple random sampling method. The list of file numbers was entered into an excel spreadsheet for all the files that meet the inclusion criteria for the period under review. Then, in the column right next to the list, the function =RAND() was pasted. This is an excel's way of putting a random number in the cells. Then, sorted the column with list of file numbers. This rearranged the list in random order from the lowest to the highest random number. Then, the first 322 files were isolated for review.

2.6. Exclusion and inclusion criteria

Inclusion criteria

The eligible patients were:

- i). HIV/AIDS patients on tenofovir based regimen at Levymwanawasahospital.
- ii). Patients who have been on ART treatment from at least 6 to 18 months.

Exclusion criteria

- i). HIV/AIDS patients who are not on tenofovir based regimen

2.7. Procedure

Data was collected from the patient files to determine whether creatinine clearance was done according to the protocols.

2.8. Data Collection

Data was collected from the patient record files by using a data collection sheet.

Table 1: Variables With Their Associated Definitions And Scales Of measurements

Type	Definition	Of	Scale Of measurement	Descriptive	Graphical Presentati
Creatinine	Creatinine	Clearance	Categorical	Percentage	Barcharts
Gender	Male and Female	According	1=0 Months 2=3 Months		
Age	Age				

Age Defined As age group Categorical

1=18-25yrs
2=25yrs and Above

Percentage Barcharts

Gender Defined as male and Female

Nominal

1=Male, 2=Female

Percentage Barcharts Foot Notes: The Table Shows 4 Variables That were used In The study

2.9. Data analysis

The data to be collected was analyzed using the statistical package for social sciences (SPSS) Version 16.0.

2.10. Ethical Consideration

Clearance was obtained from the national health research authority. Confidentiality

was assured for all information that

was collected and no reference was made to individual

patients and no patient file was taken away from the hospital premise. The computer was protected with a password

to avoid unauthorized access to information.

RESULTS

This chapter gives the results of the following objectives of the study:

1. To assess if clinicians requested for serum creatinine clearance tests on the patient at 2 weeks before initiating treatment.
2. To assess if clinicians requested for serum creatinine clearance tests after 3 months of commencing treatment.
3. To assess if clinicians requested for serum creatinine clearance tests after 6 months of treatment. In this study 322 participants were included and met the inclusion criteria. The number of female participants was higher than that of male participants, of the total participants in the study 172 (53.4%) were females and 150 (46.6%) were males.

3.1. CREATININE RESULTS AT BASELINE

In this study 92.5% (298/322) of patients had their creatinine test done 2 weeks before they commenced their treatment on a Tenofovir based regimen.

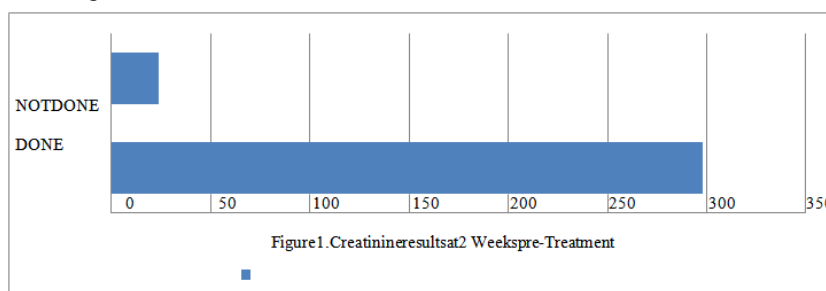
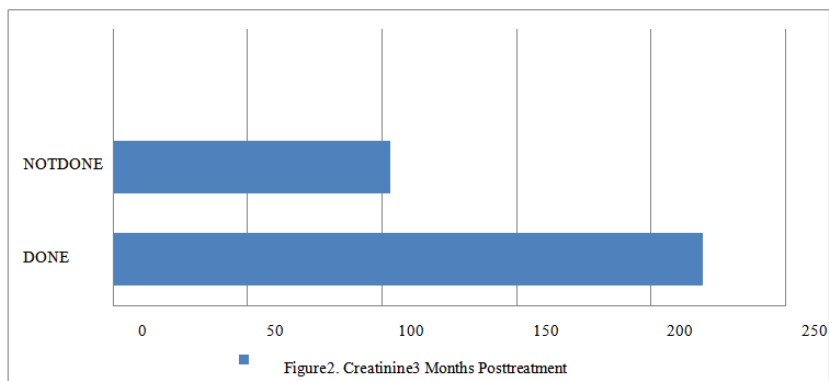


Figure 1. Shows creatinine results at 2 weeks before commencement of treatment.

3.2. CREATININE RESULTS 3 MONTHS POST TREATMENT

In this study 68.3% (219/322) of patients had their creatinine test done 3 months after they had initiated treatment on a Tenofovir based regimen.



2.3. CREATININE RESULTS 6 MONTHS POST TREATMENT

In this study 82% (264/322) of patients had their creatinine test done 6 months after they had initiated treatment on an Atenofovir based regimen.

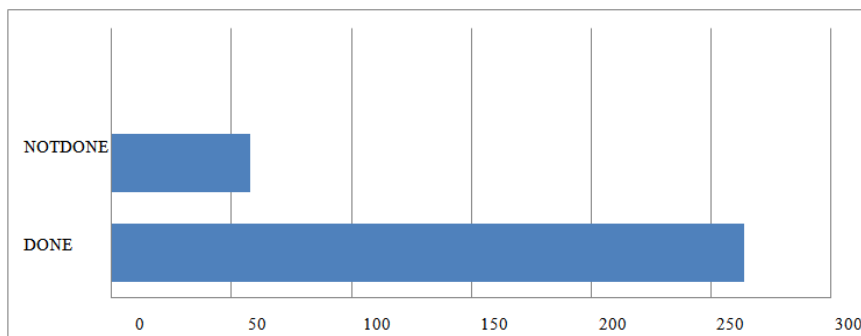


Figure 3. Shows Creatinine results 6 Months Post Treatment DEMOGRAPHICS AND CHARACTERISTICS OF PARTICIPANTS

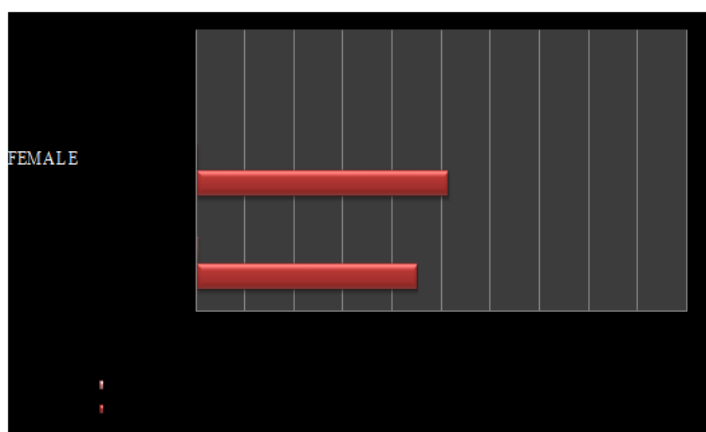


Figure 4. Shows percentage of participants by gender

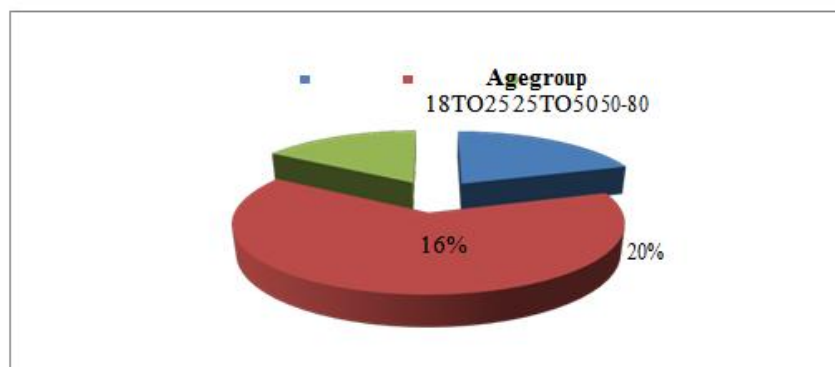


Figure 5. Shows Percentage Of Participants By Age

III. DISCUSSION

The Discussion section focuses on the results of the three objectives of this study which assessed if clinicians were requesting for renal creatinine clearances in HIV/AIDS patients on Tenofovir-based regimen at 2 weeks (baseline) before initiation of treatment, then at 3 months and at 6 months post-treatment.

This study reviewed 322 HIV/AIDS patients who were on tenofovir-based regimen at Levy Mwanawasa General Hospital in Lusaka.

IV. CREATININE RESULTS AT BASELINE (2 WEEKS PRE-TREATMENT)

The result of this study shows that clinicians requested for renal creatinine tests on the patient at weeks before initiating treatment. In this study, 92.5% of the patients had their renal creatinine test done before they could commence treatment on tenofovir-based regimen. These findings are in conformity with the 2014 Zambia HIV Consolidated Guidelines and also the WHO HIV treatment protocols on tenofovir, which recommend that renal creatinine test should be a prerequisite before a patient can commence treatment on tenofovir. This reflects a moderate adherence by healthcare providers on the treatment protocols. However, 7.5% of the patients did not have their creatinine results in the files, therefore this meant that these patients had commenced treatment on tenofovir without renal monitoring, hence risking the patients' quality of life. The baseline renal monitoring is of great significance as it determines the choice of the treatment depending on the creatinine results, thus a complete adherence to treatment protocols is required. Lack of adherence to treatment guidelines could result in the development of renal injuries. This is evidenced by a study which was done in Zambia at the Centre for Infectious Disease Control by Chabala (2015) which aimed at determining whether patients on treatment with TDF-based regimen develop renal dysfunction after one year of therapy compared to those on non-TDF-based regimen. The study concluded that adults with HIV/AIDS on treatment with TDF-based regimen were 8.7 times more likely to develop renal dysfunction after one year of therapy from having no renal dysfunction at the beginning of therapy compared to those on non-TDF-based regimen. A number of challenges could have affected the findings of this study, these range from limited resources, lack of creatinine reagents, lack of manpower, etc.

V. CREATININE RESULTS AT 3 MONTHS POST TREATMENT

In this study, we provide evidence that clinicians requested for renal creatinine clearances on patients after 3 months of commencing treatment. We found that 68% of patients had their renal creatinine results done 3 months after they had commenced treatment on tenofovir. This showed a decline in the level of adherence to treatment protocols as compared to 92.5% adherence recorded at baseline. In this study, 32% of the patients did not have renal creatinine results in their files, this entails that patients continued receiving medication without a review of their renal performance after exposure to tenofovir. A reduction in the adherence of renal creatinine monitoring can result in the emergency of nephrotoxicities which could culminate in high mortality rates. Similar findings are evidenced in studies which were done by (Hall, 2012), (Isabelle, 2013), (Horberg, 2010) and (Nelson, 2007), which consensually concluded that tenofovir use decreases renal performance, thus where it recommends a complete adherence to treatment protocols. The reduction in adherence to protocols by healthcare providers could be attributed to the limited resources in most health facilities such as creatinine reagents, lack of manpower among other challenges.

VI. CREATININE RESULTS AT 6 MONTHS POST TREATMENT

Our results indicate that clinicians requested for renal creatinine tests on patients after 6 months of treatment. We found that 82% of the patients had their creatinine test done after 6 months of being on treatment. This showed a slight increase in the levels of adherence by Health Care providers As Compared To 68% Which Was Scored At 3 Months. Despite the Increase in the levels of adherence 6 months after commencing Treatment, About 18% Of These patients did not have their creatinine results in their treatment files, This means that The patients were being given medication without a closer renal monitoring. As Such, This Posed a greater risk on these patients of developing renal injury due to the nephrotoxicity That is caused by tenofovir. The findings of this study Are in line with other studies which were Done by (Horberg 2010; Holt et al., 2014; Pate et al., 2010) Which emphasize on the need to Monitor Renal Creatinine clearance regularly, Especially to Patients On Tenofovir In order to effectively Manage these patients on tenofovir based regimen. A robust system of monitoring renal performances should be put in Place And clinicians should Adhere to it, This Can Help mitigate the occurrence of renal injuries resulting From tenofovir use. Apart from Clinicians, Pharmacists also Should Play An Active Role In Ensuring That Drugs Are Not Dispensed Without availability of Creatinine results especially if the patient Is Due For laboratory Check Up. The fluctuations in the levels of adherence by Healthcare providers may be due to a number of reasons that range from limited resources, Inadequate creatinine reagents, Lack of Man Power and many More. Any Improvement on these challenges will help in elevating the Adherence levels, This ultimately help improve the quality of life for the patient, Including Early Diagnosis of renal Injury and Reduction In mortality resulting from Renal Toxicity.

VII. CONCLUSION

In this study 92.5% (298/322) of patients had their creatinine test done 2 weeks (Baseline) before they commenced their treatment on tenofovir based regimen, While 7.5% of patients did not have creatinine results on their files, Considering The Nephrotoxic Nature Of Tenofovir, It Was Risky For The 7.5% Patients Who Started Treatment Without creatinine results in their files. In this study 68.3% (219/322) of patients had their creatinine test done 3 months after they had initiated treatment on tenofovir based regimen, While 32% of the patients had no creatinine results on their files. This was quiet low as most patients continued taking medication without monitoring the renal performance, This was unsafe for the patients. The follow up at 6 months post treatment showed that 82% (264/322) of patients had creatinine results in their files, However 18% of patients did not have creatinine results in their files, This is so posed a risk to patients because their renal performance was not known despite them taking a nephrotoxic drug. Although the study was a success, and the institution where this study was being carried out was committed to providing quality patient care in the midst of limited resources, Manpower and other challenges, The importance of renal creatinine clearance monitoring in patients on Tenofovir based regimens should be emphasized.

VIII. RECOMMENDATIONS

- 1) We recommend that similar studies should be carried out at a large scale so as to bring out on a national scale so as to bring out a true picture of the many challenges and lacunas faced in the implementations of treatment protocols.
- 2) There is need for the government to employ more specialized staffs and train them in key areas of need so as to scale up in the provision of quality patient care.
- 3) There is need to procure more laboratory equipments and also train more staff in art management.
- 4) Need to employ more medical records clerks so as to improve on patient record keeping

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