International Journal of Public Health, Pharmacy and Pharmacology

Vol .2, No.2, pp.18-32, November 2017

Published by European Centre for Research Training and Development UK (www.eajournals.org)

EVALUATING THE EFFECT OF *MORINGA* (K FORMULA DIETARY SUPPLEMENT) ON RENAL FUNCTION AMONG HIV POSITIVE PATIENTS ON TDF REGIMEN: A LONGITUDINAL STUDY OF NIGERIANS

S. Akoko[1*], M. Siminialayi[1] and A.W. Obianime[1]

[1]Department of Pharmacology, College of Health Sciences, University of Port-Harcourt, Rivers State, Nigeria.

ABSTRACT: *This study evaluated the effect of Moringa on the renal function of HIV positive patients. It was a time dependent comparative pilot study involving 140 patients (53 (37.9 %) male and 87 (62.1%) female) in the sampled population, who attends ARV clinic at the University's Teaching Hospital, Port Harcourt. The study was a 3 phases design to include Visit 0, 1 and 2 which lasted for about 12weeks (3months). The subjects were divided into two experimental groups (those receiving tenofovir and moringa and those receiving tenofovir without moringa supplementation). For the moringa group at visit 0, 1 and 2 respectively, the following values were obtained (Urine phosphate was 16.37 ± 11.84, 12.79 ± 8.37 and 18.35±6.29; Urine Albumin was 2.00±1.41, 1.29±0.96 and 1.13±2.54; Urine Creatinine was 125.68 ± 2.01, 418.53 ± 225.54 and 766.21 ± 1030.82; Uric acid was 326.43 ± 87.45, 289.87±82.50 and 239.38±67.36; Urine Total Protein was 7.62±5.06; 19.85±42.94 and 8.45±3.85. Significant differences were seen in the measured parameters at Visit 0, 1 and 2. However in the non moringa group, Urine phosphate was 16.93±12.53, 17.49±9.33 and 18.94±6.77; Urine Albumin was 0.90±0.56, 1.36±0.89, and 1.36±0.94; Urine Creatinine was 479±1.90, 489.06±445.09 and 514.85±595.55; Uric acid was 317.81±72.78, 311.79±65.55 and 259.56±84.04; Urine Total Protein was 15.04±26.73 9.50±5.07 and 6.53±3.84; for Visit 0, 1 and 2. Significant difference was observed in the measured parameters across all Visits from baseline to end of study. However differences were generally higher in the control, compared to the experimental groups. Finding therefore shows that moringa improved renal function slightly in HIV positive subjects, while sex was also observed to play a role. The study is therefore recommended to Physicians and care givers in other to help improve the health and wellbeing of HIV patients, especially those on tenofovir (TDF) based ARV regimen.*

KEYWORDS: HIV, Renal Dysfunction, Tenofovir, Moringa

INTRODUCTION

The number one public health concern in the world with emphasis on Africa is HIV. Apart from cancer (with regards to management and cure), Human immune-deficiency syndrome (HIV) so far, is tipped to be the most challenging infection since the history of mankind, spanning through decades without a cure, with the hope of a possible cure being obscured by the ability of this virus to replicate and change its nature when attacked by agents (antiretroviral drugs) capable of blocking a stage in its life cycle. Hence frustrating even the hope of a vaccine. HIV accounts for 210,000 deaths in Nigeria as well as 220,000 new HIV infections are recorded annually (Avert, 2013). In hierarchy, Nigeria closely follows South Africa with the 2nd heaviest burden of HIV in Africa, with 3.4 million of its population estimated to be living with the virus (GARPR, 2015).

HIV infection has been linked to a number of chronic non communicable diseases such as renal failure, which have become a leading cause of "morbidity and mortality" within the infected population (Michelle *et al.*, 2010; Aidsmap, 2011; FIC 2014), when compared to the uninfected (Michelle *et al*, 2010; UNAID, 2011; Aidsmap, 2011; FIC 2014).

Though there may be no cure, certain drugs known as antiretroviral drugs (ARVs) have successfully being used to manage, control as well as prolong the lives of HIV infected individuals. Tenofovir (TDF) [a preferred nucleoside reverse transcriptase inhibitors (NRTI)] is one of such drugs, whose use cannot be overemphasized due to its potency. However renal toxicity has been attributed to its use (with incidence ranging from 0.3 to 2%) (Ketan *et al.*, 2010).

According to Krummel *et al.* (2005), mentioned in their hypothesis that the use of Tenofovir and related compounds such as, adefovir and cidofovir is associated with mitochondrial DNA depletion which may result to direct tubular toxicity.

No doubt there is a couple of other antiretroviral drugs; however, the use of Tenofovir has withnessed a dramatic upward movements on the drug charts for, following its approval by the United States Food and Drug Administration in 2001. This has also increased considerably the desire to study the seriousness and incidence of nephrotoxicity traceable to tenofovir and ways to reduces and/or reverse them and to explore the reno-protective effects of antioxidant nutritional supplementation.

However, Kidney disease is a serious and a substantive complications of HIV infection, as Kidney function is abnormal in almost 30% of HIV positive patients, AIDS-related kidney disease is now a fairly common cause of end-stage renal disease (ESRD) requiring dialysis, and may be associated with progression to AIDS and death eventually (Samir *et al*., 2005).

On the contrary, the world health organization (WHO) estimated that Eighty Percent of humans goes for traditional treatment with traditional preparations (concoctions) in several aspects of their health related issues (UNAIDS, 2007). The use of herbs is widespread in Africa and forms part of the way of life of the people as herbs have been used for many centuries globally as cosmetics and medicine (Korać *et al.*, 2011).

The herbal product chosen for this study (K formula) is a dietary supplement manufactured in Nigeria by formula 10 Herbal product; Bd 9 Rahama close, Kaduna; with NAFDAC registration number **A7-0799L**. K- Formula has been in the market for a while following approval by NAFDAC and is frequently bought off the shelves with no prescription commonly by patients with HIV attending ART outpatient clinic.

Each capsule of K formula is equal to 400mg/dose; it contains: 200mg of *Moringa Olifera* (main Ingredient with constitutes 50% of drug composition), 100mg *sorghum Bicolor* that is 25% in composition, 20mg *Oryza sativa* that is 5% in composition, 60mg of *Triticum Vulgare*, that is 15% in composition; 20mg of *Nigella Sativa*, that is 5% in composition in each *moringa* capsule.

In some African countries including Zimbabwe, South Africa, moringa is officially advocated for use in people who are HIV positive as nutritional supplement and immune booster (Peltzer *et al.*, 2008). The use of moringa by HIV positive patients has been stated to be as high as 68% in some cohorts (Monera, 2012). While an increasing number of HIV positive patients continue to use *moringa* as standalone therapy or as an adjunct to conventional ARV drugs, there are no

demonstrated clinical effects on the kidney as well as renal disease progression as far as we could determine.

This study therefore seek to determine if TDF regimen has effects on renal function of patient with HIV and to evaluate the significant effects of moringa (K formula dietary supplement) on renal function of HIV positive individuals on TDF regimen for at least six (6) months.

MATERIALS AND METHODS

Following ethical clearance issued by the University of Port Harcourt (UPH) ethics Committee, patients' eligibility was determined via a pre-randomization protocol; with an informed consent obtained in accordance with the Helsinki code.

One hundred and forty [140 (53 males and 87 females aged)] volunteer HIV patients visiting the outpatient clinic of the University of Port Harcourt Teaching Hospital ARV clinic were therefore included in the study.

It was a randomized comparative trial consisting of a pretreatment phase (visit 0), followed by Visit 1 (4 weeks after visit 0) and then Visit 2 (8 weeks after visit 1) making a total of 3 months (12weeks) treatment (interventional) protocol to test the effect of *moringa's* (K formula dietary supplement capsules).

At the end of pre-treatment phase (involving run in-visits scheduled to identify potential non-compliant patients and those no longer interested in the study), eligible participants were (those with more than 90% adherence) randomly grouped into two using a table of random numbers as hereunder:

1. Fifty Six (56) patients on Tenofovir ART regimen for a minimum of 6 months and also placed on 400mg of K formula dietary supplement capsules.
2. Eighty Four (84) patients also on Tenofovir ART regimen for a minimum of 6 months but not on moringa (K formula dietary supplement) capsules (used as control).

Sample collection for laboratory assessment was done on each visit. Questionnaires were used to obtain socio-demographic information.

Sample size determination

Sample size was determined using Li *et al*. (2007) and Zhong (2009);

$$N = 2 \times \left(\frac{Z_{1-\frac{\alpha}{2}} + z_{1-\beta}}{\delta} \right)^2 \times S^2$$

Where;

Z_α which is 0.05 at 95% confidence desired (two tailed test) = 1.96

Z_β which is the power to detect such a difference (set at 80%) with a 20% withdrawal rate = 0.84

δ is the difference to be detected in the percentage change = 5

S^2 becomes the Polled standard deviation of both comparison = $15^2 = 225$

Hence,

$$N = 2 \times \left(\frac{1.96 + 0.84}{5}\right)^2 \times 15^2$$

⇨ N = 140

Inclusion Criteria

i. Patient must have been on ART for at least 6 months.

ii. Patient must be 18 years old and above

iii. Patient should not be on any known medication capable of altering kidney and liver functions

Exclusion Criteria

Patients' exclusion criteria includes:

i. Inability to give consent (approval)

ii. Being bedridden

iii. Being on medications capable of altering kidney or liver function

iv. Patients preparing or already pregnant for at least 4 months

Study Procedure

Urine and blood samples were collected for the laboratory assessment of renal function during each visit and accessed for laboratory evidence of renal dysfunction.

Laboratory Sample Collection Methods

Morning spot urine samples were collected from patients using urine sample bottle. Urine analysis which was done within 4 hours of collection to avoid denaturing of protein parameters. WHO phlebotomy practices were followed in obtaining the blood samples using vacutena needle and syringe. Blood samples for haematological analyses were collected using the EDTA bottles, while those for clinical chemistry, were put in lithium heparin bottles. The blood and urine samples were eventually taken to the laboratory where standard laboratory protocol were employed for analyses. Blood samples [(Full blood count (CBC) and a 3-part white blood cell count (WBC) differential)] were analyzed using the Orphee Mythic 18 hematology auto analyzer (model 5.8.2), clinical chemistry variables (Levels of serum creatinine, Phosphate, total protein, and from Urine levels of Glucose, Phosphate, Albumin and creatinine) were analyzed using Vitro scient VS10 (a compact semi-automated clinical chemistry analyzer), while urine samples were analyzed using Medi- Test combi-9® manufactured in Germany by Macherey- Nagel. Urine variables analyzed includes creatinine, urobilinogen, blood, bilirubin, protein, Nitrites, Ketones, Ascorbic acid, Glucose and pH.

Data Analysis

Descriptive statistics was used to determine mean values with post hoc multiple comparison test used to compare group mean. ANOVA and students t-test was used to differences in mean values between the visits (0, 1 and 2) and sexual dimorphism respectively. Dunnetts multiple comparison test was used to determine group differences. Significance level was set at 95%, hence P< 0.05.
Changes were compared in summary statistics. All these was carried out using Statistical Package for the Social sciences (SPSS) version 23.0 and XLSTAT (4.0.1, 2015).

RESULTS AND DISCUSSION

Table 1: Descriptive statistics of urine samples of the tenofovir and non-moringa (T/NM) group and test of significance at Visit 0, 1 and 2

		Descriptive statistics						*ANOVA*		
Urine parameters	***Visit***	***N***	***Mean***	***S.D***	***S.E***	***95% C. I for Mean***		***F-value***	***P-value***	***Remarks***
						Lower Bound	***Upper Bound***			
Urine PO4	Visit 0	84	16.93	12.53	1.37	14.21	19.65	0.94	0.39	NS
	Visit 1	84	17.49	9.33	1.02	15.46	19.51			
	Visit 2	84	18.94	6.77	0.74	17.47	20.41			
	Total	252	17.79	9.83	0.62	16.57	19.01			
Urine Albumin	Visit 0	84	0.9	0.56	0.06	0.77	1.02	9.28	<0.01	S
	Visit 1	84	1.36	0.94	0.1	1.16	1.57			
	Visit 2	84	1.36	0.89	0.1	1.17	1.56			
	Total	252	1.21	0.84	0.05	1.1	1.31			
Urine Creatinine	Visit 0	84	514.85	595.55	64.98	385.61	644.1	37.64	<0.01	S
	Visit 1	84	489.06	445.09	48.56	392.47	585.65			
	Visit 2	84	479	419.7	0.21	4.38	521			
	Total	252	336.23	487.91	30.74	275.7	396.77			
Uric acid	Visit 0	84	317.81	72.78	7.94	302.02	333.6	15.52	<0.01	S
	Visit 1	84	311.79	65.55	7.15	297.56	326.01			
	Visit 2	84	259.56	84.04	9.17	241.32	277.8			
	Total	252	296.39	78.71	4.96	286.62	306.15			
Urine Total Protein	Visit 0	84	6.53	3.84	0.42	5.69	7.36	6.23	<0.01	S
	Visit 1	84	15.04	26.73	2.92	9.24	20.83			
	Visit 2	84	9.5	5.07	0.55	8.4	10.6			
	Total	252	10.35	16.19	1.02	8.34	12.36			
Total protein	Visit 0	84	97.76	62.87	6.86	84.12	111.41	3.98	0.02	S
	Visit 1	84	87.72	11.11	1.21	85.31	90.14			

Visit 2	84	81.67	10.3	1.12	79.44	83.91
Total	252	89.05	37.78	2.38	84.37	93.74

Note: ***N****=distribution,* ***S.D****=Standard deviation,* ***S.E****=Standard error of mean,* ***F-value*** *= fischer's value,* ***p-value*** *= propability value,* ***mini*** *= minimum,* ***maxi*** *= maximum,* ***S*** *= significant,* ***NS*** *= Not significant, P<0.05*

Table 2: Dunnett's multiple comparison test of urine samples of the tenofovir and non-moringa group and test of significance at Visit 0, 1 and 2

Urine parameters	*Visit (I)*	*Visit (J)*	*Mean Difference (I-J)*	*S.E*	*95% Confidence Interval*		*P-value*	*Remarks*
					Lower Bound	*Upper Bound*		
Urine PO4	Visit 0	Visit 1	-0.56	1.70	-4.67	3.55	0.98	NS
		Visit 2	-2.01	1.55	-5.77	1.75	0.48	NS
	Visit 1	Visit 0	0.56	1.70	-3.55	4.67	0.98	NS
		Visit 2	-1.45	1.26	-4.49	1.58	0.58	NS
Urine Albumin	Visit 0	Visit 1	0.00	0.14	-0.34	0.34	1.00	NS
		Visit 2	0.47	0.11	0.19	0.74	<0.01	S
	Visit 1	Visit 0	0.00	0.14	-0.34	0.34	1.00	NS
		Visit 2	0.47	0.12	0.18	0.76	<0.01	S
Urine Creatinine	Visit 0	Visit 1	-484.27	48.56	-602.53	-366.02	<0.01	S
		Visit 2	-510.07	64.98	-668.30	-351.84	<0.01	S
	Visit 1	Visit 0	484.27	48.56	366.02	602.53	<0.01	S
		Visit 2	-25.79	81.12	-221.55	169.97	0.98	NS
Uric acid	Visit 0	Visit 1	6.02	10.69	-19.75	31.79	0.92	NS
		Visit 2	58.25	12.13	28.99	87.50	<0.01	S
	Visit 1	Visit 0	-6.02	10.69	-31.79	19.75	0.92	NS
		Visit 2	52.22	11.63	24.17	80.28	<0.01	S
Urine Total Protein	Visit 0	Visit 1	-8.51	2.95	-15.68	-1.34	0.01	S
		Visit 2	-2.97	0.69	-4.65	-1.30	<0.01	S
	Visit 1	Visit 0	8.51	2.95	1.34	15.68	0.01	S
		Visit 2	5.54	2.97	-1.68	12.76	0.18	NS
T protein	Visit 0	Visit 1	10.04	6.97	-6.90	26.98	0.39	NS
		Visit 2	16.09	6.95	-0.82	33.00	0.07	NS
	Visit 1	Visit 0	-10.04	6.97	-26.98	6.90	0.39	NS
		Visit 2	6.05	1.65	2.06	10.03	<0.01	S

Note: ***N****=distribution,* ***S.E****=Standard error of mean,* ***p-value*** *= probability value,* ***mini*** *= minimum,* ***maxi*** *= maximum,* ***S*** *= significant,* ***NS*** *= Not significant, P<0.05.*

Table 3: Descriptive statistics of urine samples of the tenofovir and moringa (T/M) group and test of significance at Visit 0, 1 and 2

		Descriptive statistics						*ANOVA*		
Urine parameter	***Visit***	***N***	***Mean***	***S.D***	***S.E***	***95% Confidence Interval for Mean***		***F-value***	***P-value***	***Remarks***
						Lower Bound	***Upper Bound***			
Urine PO4	Visit 0	56	16.37	11.84	1.58	13.19	19.54			
	Visit 1	56	12.79	8.37	1.12	10.55	15.03	5.35	0.01	S
	Visit 2	56	18.35	6.29	0.84	16.67	20.03			
	Total	168	15.83	9.36	0.72	14.41	17.26			
Urine Albumin	Visit 0	56	2.00	1.41	0.19	1.63	2.38			
	Visit 1	56	1.29	0.96	0.13	1.03	1.54	3.92	0.02	S
	Visit 2	56	1.13	2.54	0.34	0.45	1.81			
	Total	168	1.47	1.79	0.14	1.20	1.75			
Urine Creatinine	Visit 0	56	125.68	2.01	0.27	5.14	6.22			
	Visit 1	56	418.53	225.54	30.14	358.13	478.93	21.87	<0.01	S
	Visit 2	56	766.21	1030.82	137.75	490.15	1042.27			
	Total	168	396.81	681.12	52.55	293.06	500.55			
Uric acid	Visit 0	56	326.43	87.45	11.69	303.01	349.84			
	Visit 1	56	289.87	82.50	11.02	267.77	311.96	16.90	<0.01	S
	Visit 2	56	239.38	67.36	9.00	221.34	257.42			
	Total	**168**	**285.23**	**86.81**	**6.70**	**272.00**	**298.45**			
Urine Total Protein	Visit 0	56	7.62	5.06	0.68	6.26	8.97			
	Visit 1	56	19.85	42.94	5.74	8.35	31.35	4.17	0.02	S
	Visit 2	56	8.45	3.85	0.51	7.42	9.48			
	Total	**168**	**11.97**	**25.53**	**1.97**	**8.08**	**15.86**			

Note: ***N****=distribution,* ***S.D****=Standard deviation,* ***S.E****=Standard error of mean,* ***F-value*** *= fischer's value,* ***p-value*** *= propability value,* ***mini*** *= minimum,* ***maxi*** *= maximum,* ***S*** *= significant,* ***NS*** *= Not significant, P<0.05.*

Table 4: Dunnett's multiple comparison test of urine samples of the tenofovir and moringa group and test of significance at Visit 0, 1 and 2

Urine parameter	*Visit (I)*	*Visit (j)*	*Mean Difference (I-J)*	*95% Confidence Interval*		*S.E*	*P-value*	*Remarks*
				Lower Bound	*Upper Bound*			
Urine PO4	Visit 0	Visit 1	3.58	-1.12	8.28	1.94	0.19	NS
		Visit 2	-1.99	-6.35	2.38	1.79	0.61	NS
	Visit 1	Visit 0	-3.58	-8.28	1.12	1.94	0.19	NS
		Visit 2	-5.56	-8.96	-2.17	1.40	<0.01	S
Urine Albumin	Visit 0	Visit 1	0.72	0.16	1.27	0.23	0.01	S
		Visit 2	0.88	-0.07	1.82	0.39	0.08	NS
	Visit 1	Visit 0	-0.72	-1.27	-0.16	0.23	0.01	S
		Visit 2	0.16	-0.73	1.04	0.36	0.96	NS
Urine Creatinine	Visit 0	Visit 1	-412.86	-486.99	-338.72	30.14	<0.01	S
		Visit 2	-760.53	-1,099.36	-421.71	137.75	<0.01	S
	Visit 1	Visit 0	412.86	338.72	486.99	30.14	<0.01	S
		Visit 2	-347.68	-693.62	-1.74	141.01	0.05	S
Uric acid	Visit 0	Visit 1	36.56	-2.38	75.49	16.07	0.07	NS
		Visit 2	87.04	51.26	122.82	14.75	<0.01	S
	Visit 1	Visit 0	-36.56	-75.49	2.38	16.07	0.07	NS
		Visit 2	50.49	15.97	85.00	14.23	<0.01	S
Urine Total Protein	Visit 0	Visit 1	-12.23	-26.43	1.96	5.78	0.11	NS
		Visit 2	-0.84	-2.90	1.22	0.85	0.69	NS
	Visit 1	Visit 0	12.23	-1.96	26.43	5.78	0.11	NS
		Visit 2	11.40	-2.76	25.56	5.76	0.15	NS
Total protein	Visit 0	Visit 1	9.69	4.23	15.16	2.25	<0.01	S
		Visit 2	12.50	7.15	17.84	2.20	<0.01	S
	Visit 1	Visit 0	-9.69	-15.16	-4.23	2.25	<0.01	S

Visit 2	2.80	-2.03	7.63	1.99	0.41	NS

Note: ***N****=distribution,* ***S.E****=Standard error of mean,* ***p-value*** *= probability value,* ***mini*** *= minimum,* ***maxi*** *= maximum,* ***S*** *= significant,* ***NS*** *= Not significant, P<0.05.*

Table 5a: Descriptive statistics of Male urine samples between the experimental groups and test of significance at Visit 0

		Descriptive statistics						***T – test***		
Urine parameters	***Experimental group***	***N***	***Mean***	***S.D***	***S.E***	***Mini***	***Maxi***	***F-value***	***T-value***	***Remarks***
Urine PO4	T/M	21	17.15	13.24	2.89	3.09	50.50	-0.37	0.71	NS
	T/NM	32	18.61	14.26	2.52	2.91	53.80			
	Total	53	18.03	13.75	1.89	2.91	53.80			
Urine Albumin	**T/M**	**21**	**2.10**	**1.43**	**0.31**	**0.47**	**6.49**	**2.57**	**0.02**	**S**
	T/NM	**32**	**1.24**	**0.70**	**0.12**	**0.36**	**2.72**			
	Total	**53**	**1.58**	**1.12**	**0.15**	**0.36**	**6.49**			
Urine Creatinine	T/M	21	550	2.13	0.47	234	936	1.44	0.16	NS
	T/NM	32	471	1.64	0.29	256	891			
	Total	53	502	1.87	0.26	234	936			
Uric acid	T/M	21	350.37	61.39	13.40	146.70	420.00	-0.07	0.95	NS
	T/NM	32	351.45	48.37	8.55	241.70	435.60			
	Total	53	351.02	53.34	7.33	146.70	435.60			
Urine Total Protein	T/M	21	7.55	3.90	0.85	0.56	13.40	1.46	0.15	NS
	T/NM	32	6.02	3.61	0.64	0.81	15.00			
	Total	53	6.63	3.77	0.52	0.56	15.00			
T protein	**T/M**	**21**	**99.48**	**10.80**	**2.36**	**78.40**	**117.40**	**1.97**	**0.05**	**S**
	T/NM	**32**	**92.87**	**12.66**	**2.24**	**67.20**	**114.10**			
	Total	**53**	**95.48**	**12.29**	**1.69**	**67.20**	**117.40**			

Note: ***N****=distribution,* ***S.D****=Standard deviation,* ***S.E****=Standard error of mean,* ***T-value*** *= fischer's value,* ***p-value*** *= propability value,* ***mini*** *= minimum,* ***maxi*** *= maximum,* ***S*** *= significant,* ***NS*** *= Not significant, P<0.05.*

Table 5b: Descriptive statistics of Female urine samples between the experimental groups and test of significance at Visit 0

		Descriptive statistics						T – test		
Urine parameters	***Experimental group***	***N***	***Mean***	***S.D***	***S.E***	***Mini***	***Maxi***	***F-value***	***T-value***	***Remarks***
Urine PO4	T/M	35	15.89	11.10	1.88	0.64	40.60	0.00	1.00	NS
	T/NM	52	15.90	11.36	1.58	2.48	53.50			
	Total	87	15.89	11.19	1.20	0.64	53.50			
Urine Albumin	T/M	35	1.95	1.41	0.24	0.06	5.72	1.84	0.07	NS
	T/NM	52	1.44	0.98	0.14	0.39	4.06			
	Total	87	1.65	1.19	0.13	0.06	5.72			
Urine Creatinine	T/M	35	578	196	0.33	256	9.88	2.15	0.03	S
	T/NM	52	484	205	0.28	210	9.96			
	Total	87	522	206	0.22	210	9.96			
Uric acid	T/M	35	312.06	97.92	16.55	121.60	575.60	0.79	0.43	NS
	T/NM	52	297.11	77.78	10.79	132.20	441.20			
	Total	87	303.12	86.21	9.24	121.60	575.60			
Urine Total Protein	T/M	35	7.65	5.70	0.96	0.96	26.30	0.74	0.46	NS
	T/NM	52	6.84	3.97	0.55	0.92	22.20			
	Total	87	7.16	4.73	0.51	0.92	26.30			
T protein	T/M	35	94.82	13.89	2.35	59.20	116.30	-0.44	0.66	NS
	T/NM	52	100.78	79.44	11.02	64.90	655.00			
	Total	87	98.38	61.87	6.63	59.20	655.00			

Note: ***N****=distribution,* ***S.D****=Standard deviation,* ***S.E****=Standard error of mean,* ***T-value*** *= fischer's value,* ***p-value*** *= propability value,* ***mini*** *= minimum,* ***maxi*** *= maximum,* ***S*** *= significant,* ***NS*** *= Not significant, P<0.05.*

Table 6a: Descriptive statistics of Male urine samples between the experimental groups and test of significance at Visit 1

		Descriptive statistics						T – test		
Urine parameters	***Experimental group***	***N***	***Mean***	***S.D***	***S.E***	***Mini***	***Maxi***	***T-value***	***P-value***	***Remarks***
Urine PO4	T/M	21	13.56	8.69	1.90	1.62	41.00	-1.56	0.13	NS
	T/NM	32	17.81	10.32	1.82	4.11	41.00			
	Total	53	16.12	9.84	1.35	1.62	41.00			
	T/M	21	1.21	0.99	0.22	0.45	4.11	-0.34	0.74	NS

Urine Albumin	T/NM	32	1.31	1.01	0.18	0.41	5.01			
	Total	53	1.27	0.99	0.14	0.41	5.01			
Urine Creatinine	T/M	21	476.97	257.04	56.09	3.99	909.20	0.33	0.75	NS
	T/NM	32	456.12	206.78	36.55	5.80	889.00			
	Total	53	464.38	225.85	31.02	3.99	909.20			
Uric acid	T/M	21	318.29	71.67	15.64	124.20	412.80	-0.26	0.80	NS
	T/NM	32	322.87	57.24	10.12	236.10	418.60			
	Total	53	321.05	62.72	8.62	124.20	418.60			
Urine Total Protein	T/M	21	24.53	51.10	11.15	1.68	182.80	0.76	0.45	NS
	T/NM	32	16.14	29.19	5.16	0.00	172.50			
	Total	53	19.47	39.11	5.37	0.00	182.80			
T protein	T/M	21	92.35	11.59	2.53	66.00	112.80	0.61	0.55	NS
	T/NM	32	90.35	11.79	2.08	66.30	115.50			
	Total	53	91.14	11.64	1.60	66.00	115.50			

***Note: N**=distribution, **S.D**=Standard deviation, **S.E**=Standard error of mean, **T-value** = Fischer's value, **p-value** = probability value, **mini** = minimum, **maxi** = maximum, **S** = significant, **NS** = Not significant, P<0.05.*

Table 6b: Descriptive statistics of Female urine samples between the experimental groups and test of significance at Visit 1

		Descriptive statistics						***T – test***		
Urine parameters	***Experimental group***	***N***	***Mean***	***S.D***	***S.E***	***Mini***	***Maxi***	***T-value***	***P-value***	***Remarks***
Urine PO4	**T/M**	**35**	**12.32**	**8.26**	**1.40**	**2.14**	**32.70**	**-2.65**	**0.01**	**S**
	T/NM	**52**	**17.29**	**8.77**	**1.22**	**3.71**	**36.70**			
	Total	**87**	**15.29**	**8.87**	**0.95**	**2.14**	**36.70**			
Urine Albumin	T/M	35	1.33	0.96	0.16	0.42	4.01	-0.32	0.75	NS
	T/NM	52	1.40	0.90	0.13	0.42	4.09			
	Total	87	1.37	0.92	0.10	0.42	4.09			
Urine Creatinine	T/M	35	383.47	200.12	33.83	3.55	909.20	-1.31	0.19	NS
	T/NM	52	509.33	543.43	75.36	5.80	4162.00			
	Total	87	458.70	441.38	47.32	3.55	4162.00			
Uric acid	T/M	35	272.82	84.80	14.33	108.40	412.80	-1.93	0.06	NS
	T/NM	52	304.97	69.84	9.68	124.50	402.80			

	Total	87	292.03	77.37	8.30	108.40	412.80			
Urine Total Protein	T/M	35	17.04	37.75	6.38	1.00	167.00	0.40	0.69	NS
	T/NM	52	14.35	25.36	3.52	2.34	188.00			
	Total	87	15.44	30.76	3.30	1.00	188.00			
T protein	T/M	35	83.59	9.02	1.52	59.20	100.20	-1.17	0.25	NS
	T/NM	52	86.11	10.46	1.45	62.90	117.20			
	Total	87	85.09	9.93	1.06	59.20	117.20			

***Note: N**=distribution, **S.D**=Standard deviation, **S.E**=Standard error of mean, **T-value** = Fischer's value, **p-value** = probability value, **mini** = minimum, **maxi** = maximum, **S** = significant, **NS** = Not significant, P<0.05.*

Table 7a: Descriptive statistics of Male urine samples between the experimental groups and test of significance at Visit 2

		Descriptive statistics						***T – test***		
Parameters	***Experimental group***	***N***	***Mean***	***S.D***	***S.E***	***Mini***	***Maxi***	***F-value***	***T-value***	***Remarks***
Urine PO4	T/M	21	17.56	7.60	1.66	4.11	36.70	-0.39	0.70	NS
	T/NM	32	18.31	6.38	1.13	10.11	36.70			
	Total	53	18.02	6.83	0.94	4.11	36.70			
Urine Albumin	T/M	21	0.84	0.56	0.12	0.04	2.79	-0.07	0.95	NS
	T/NM	32	0.85	0.56	0.10	0.02	2.09			
	Total	53	0.84	0.55	0.08	0.02	2.79			
Urine Creatinine	T/M	21	789.86	1074.66	234.51	287.20	4011.22	1.15	0.26	NS
	T/NM	32	518.43	645.33	114.08	290.30	4010.87			
	Total	53	625.97	842.87	115.78	287.20	4011.22			
Uric acid	T/M	21	256.13	66.58	14.53	136.30	349.40	-0.15	0.88	NS
	T/NM	32	258.95	64.28	11.36	140.00	388.20			
	Total	53	257.83	64.58	8.87	136.30	388.20			
Urine Total Protein	T/M	21	8.24	3.71	0.81	3.07	16.00	-1.32	0.19	NS
	T/NM	32	9.85	4.68	0.83	2.80	21.20			
	Total	53	9.21	4.35	0.60	2.80	21.20			
T protein	T/M	21	85.15	9.18	2.00	61.00	100.20	1.48	0.15	NS
	T/NM	32	81.22	9.69	1.71	61.00	94.20			
	Total	53	82.78	9.60	1.32	61.00	100.20			

Note: ***N****=distribution,* ***S.D****=Standard deviation,* ***S.E****=Standard error of mean,* ***T-value*** *= fischer's value,* ***p-value*** *= propability value,* ***mini*** *= minimum,* ***maxi*** *= maximum,* ***S*** *= significant,* ***NS*** *= Not significant, P<0.05.*

Table 7b: Descriptive statistics of Female urine samples between the experimental groups and test of significance at Visit 2

		Descriptive statistics						T-test		
Urine Parameters	***Experimental group***	***N***	***Mean***	***S.D***	***S.E***	***Mini***	***Maxi***	***F-value***	***T-value***	***Remarks***
Urine PO4	T/M	35	18.82	5.41	0.91	10.14	36.00	-0.36	0.72	NS
	T/NM	52	19.33	7.03	0.97	10.77	36.70			
	Total	87	19.13	6.40	0.69	10.14	36.70			
Urine Albumin	T/M	35	1.30	3.18	0.54	0.16	19.49	0.84	0.40	NS
	T/NM	52	0.93	0.57	0.08	0.02	3.09			
	Total	87	1.08	2.06	0.22	0.02	19.49			
Urine Creatinine	T/M	35	752.02	1019.32	172.30	116.09	4011.07	1.40	0.16	NS
	T/NM	52	512.66	569.28	78.94	235.60	4011.07			
	Total	87	608.95	785.43	84.21	116.09	4011.07			
Uric acid	T/M	35	229.33	66.75	11.28	111.70	350.20	-1.65	0.10	NS
	T/NM	52	259.94	94.78	13.14	136.30	675.70			
	Total	87	247.63	85.54	9.17	111.70	675.70			
Urine Total Protein	T/M	35	8.58	3.98	0.67	1.01	15.50	-0.71	0.48	NS
	T/NM	52	9.28	5.33	0.74	2.80	21.20			
	Total	87	9.00	4.82	0.52	1.01	21.20			
T protein	T/M	34	83.40	10.79	1.85	49.19	100.19	0.61	0.54	NS
	T/NM	52	81.96	10.74	1.49	60.70	96.00			
	Total	86	82.53	10.72	1.16	49.19	100.19			

Note: ***N****=distribution,* ***S.D****=Standard deviation,* ***S.E****=Standard error of mean,* ***T-value*** *= Fischer's value,* ***p-value*** *= probability value,* ***mini*** *= minimum,* ***maxi*** *= maximum,* ***S*** *= significant,* ***NS*** *= Not significant, P<0.05.*

Laboratory samples (urine) were collected from Tenofovir dependent HIV patients placed on *moringa* (K formula supplementation) who have been on the regimen for a minimum of 6 months. Samples were also collected from a control group who were not placed on *moringa* (K formula supplementation). After laboratory analysis, statistical analysis were carried out and results were presented as hereunder. Descriptive statistics of the measured samples was presented in Table 1, 3, 5a, 5b, 6a, 6b, 7a and 7b; Analysis of Variance [(ANOVA) (Table 1 and 3)] to determine statistical significance between mean values at the 3 visits, while Dunnett's multiple comparison test (Table 2 and 4) was used to determine which visit(s) differed from the other. Differences between the experimental and control groups according to sex was determined using independent sample T-test (Table 5a, 5b, 6a, 6b, 7a and 7b).

Mean values were generally higher for the Non moringa group compared to the moringa, and these values on the average increased from Visit 0 through visit 2 in the Non moringa group (Table 1), but decreased across from visit 1 to 2 in the moringa group (Table 2).

In visit 0, mean values were generally higher in females except for uric and urine total protein (Table 5a and b).

While in visit 1, mean values were generally higher in males except for urine albumin. (Table 6a and 6b).

However in visit 2, mean values were observed to be generally higher in males, except for urine PO4 and albumin (Table 7a and b).

In other to evaluate the effect of *moringa* (K formula dietary supplement) on Kidney function in HIV infected patients on TDF regimen for 6months and longer, mean values and statistical differences between the groups were considered.

In both groups, there was significant difference between the *moringa* group and the non *moringa* group for Urine albumin at Visit 0 (Table 1). Significant difference was observed between the male population in the *moringa* group, compared to their non *moringa* counterparts (Table 5a) and no significance was observed in the female population between the groups (Table 5b).

Urine creatinine was not significant between the two groups at $p < 0.05$. Significant difference was observed in the female population (Table 5b) but not in the males (Table 5a). While Uric acid, was not significant in both study groups and between sex (Table 5a and b).

At visit 1, urine phosphate showed statistical significance (Table 6a). These differences where significant in the female and male populations respectively (Table 6a and b), while other parameters were not significant.

In visit 2, no statistical significant difference was observed between the males and females of the two groups (Table 7a and b).

However, at visit 0, the mean values of both groups were much higher and close to each other, with no significant difference between them except for urine albumin and total protein in males and urine creatinine in females.

While with intervention, it was observed that the mean values of the moringa (treated) group were generally much lower compared to the no moringa (non-treated) group at visit 1 as well as visit 2, hence suggesting that moringa (K-formula) has a role to play in the renal function of HIV patients placed on tenofovir regimen.

CONCLUSION

Findings made in this study has suggested that *moringa* (K-formula) supplementation plays a role in balancing the renal function of HIV patients managed with Tenofovir regimen. This was evident as blood and urine levels of various parameters whose presence suggests renal dysfunction were high in the experimental group, as compared to the control. Hence it can be concluded that k-formula (*moringa olifera*) plays in role in restoring renal function in HIV

positive patients placed on Tenofovir regimen. The findings of this study is therefore recommended to physicians and care givers managing HIV patients to recommend moringa (K-formula) supplementation as an adjunct in the general management of HIV patients.

REFERENCES

Aidsmap (2016). HIV and non-communicable disease (NCD). Accessed from http://mobile.aidsmap.com/HIV-and-non-communicable-diseases-NCDs/page/2094965, accessed April, 2016.

Avert. (2013). Accesed online http://www.avert.org/professionals/hiv-around-world/sub-saharan-africa/nigeria. Accessed April 2016.

FIC (2014). Advancing science for global health. Chronic Disease Threatens Progress against HIV/AIDS: Scientist propose urgent NCD research agenda; September /October 2014, Vol 13, Issues 5 accessed from http://www. fic.nih.gov/News/GlobalHealthMatters/september-october-2014/Pages/hiv-comorbidities.aspx in March, 2016

GARPR (2015). Global Aids Response Country Report. Nigeria.

Ketan K.P., Atul K.P., and Jagdish K.P. (2010) .Tenofovir-associated renal dysfunction in clinical practice: An observational cohort from western India. Indian Journal of Sexually Transmitted Diseases 2010 Jan-Jun; 31(1): 30–34. doi: 10.4103/0253-7184.68998.PMCID:PMC3140146. Medknow Publications.

Korać R, Kapil M. (2011). The potential of herb in skin protection from ultraviolet radiation. Pharmacognosy Reviews.Jul-Dec, 5 (10): 164-173. Doi: 10.4103/0973-7847.91114.Medknow Publications.

Krummel T, Parvez-Braun L, Frantzen L, Lalanne H, Marcellin L, Hannedouche T, Moulin B. (2005).Tenofovir-induced acute renal failure in an HIV patient with normal renal function. Nephrol Dial Transplant; 20:473-4.

Michelle M., Derek M., Mohamed G. (2010). Recent development in HIV related kidney disease. NIH Public Access; 4(5): 589–603. doi:10.2217/hiv.10.42.

Monera, T. G., Maponga, C. C. (2012). Prevalence and patterns of Moringa Oleifera use among HIV positive patients in Zimbabwe: a cross sectional survey. J Pub Health in Africa; 3; eb, 22 -24.

Peltzer K, Preez N, Ramlagan S, Fomundam H. (2008). Use bof Traditional Complementary and Alternative medicine for HIV patients in Kwazulu –Natal, South Africa. BMC Public Health; 8:255.

Samir K. Gupta, Joseph A. Eustace, Jonathan A. Winston, Ivy I. Boydstun, Tejinder S. Ahuja, Lynda A. Szczech (2005). Guidelines for the Management of Chronic Kidney Disease in HIV-Infected Patients: Recommendations of the HIV Medicine Association of the Infectious Diseases Society of America. Clin Infect Dis. 40 (11): 1559-1585. doi: 10.1086/430257.

UNAIDS (2007). Collaborating with Traditional Healers for HIV prevention and care in Subsaharan Africa; suggestions for programme managers and field workers. World Health Organization.

UNAIDS report (2011).Chronic care of HIV and noncommunicable diseases:How to leverage the HIV experience. UNAIDS / JC2145E (English original, May 2011) ISBN 978-92-9173-949-3.