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THE EFFECT OF TENOFOVIR ON RENAL FUNCTION IN HIV-POSITIVE PATIENTS IN LESOTHO

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ABSTRACT

Lesotho introduced tenofovir disoproxil fumarate (TDF) for first-line antiretroviral treatment (ART) in 2008. The use of TDF has been associated with renal toxicity. The study utilised an analytical design to compare retrospective creatinine clearance (CrCl) data of 312 antiretroviral treatment naïve adults exposed to TDF and 173 unexposed patients. Impaired renal function was defined as CrCl < 50 ml/min calculated using the Cockcroft-Gault equation. In fifty-six patients (17.9%) TDF was found to be contraindicated. The use of TDF was marginally significant factor for renal toxicity ($p=0.054$) in univariate analysis, but was insignificant ($p=0.122$) in multivariate logistic analysis. Univariate ($p<0.1$) and multivariate logistic regression ($p<0.05$) were performed using STATA[®] 11. Female gender ($p=0.016$), hypertension ($p=0.009$), and age > 60 ($p=0.004$) were significantly associated with CrCl < 50 ml/min outcome. TDF is a weak contributing factor to renal impairment. Routine baseline renal function screening should be adopted to prevent patients with impaired renal function receiving TDF.

KEYWORDS

Tenofovir; TDF; Lesotho; renal impairment.

INTRODUCTION

The assessment of renal function in patients on tenofovir disoproxil fumarate (TDF) is important because TDF has been associated with renal toxicity^[1]. This is of particular importance in Lesotho because the success of ART programmes in Lesotho depends on the performance of the drug TDF which currently forms the backbone of first-line ART drugs.

The Government of Lesotho switched most of the patients on stavudine-based antiretroviral drug regimens to TDF-based regimens as recommended by the World Health Organisation (WHO) in 2008^[2,3]. Since then, TDF has become the preferred first line regimen for antiretroviral treatment of human immunodeficiency virus (HIV) infection in Lesotho. Renal function outcomes following the use of TDF had not been studied at Roma Health Service Area.

Numerous studies report that TDF is generally safe to use with respect to nephrotoxicity^[4-6]. The most common conclusions from the studies that justify the use of TDF, state that TDF-associated nephrotoxicity is a rare event and that nephrotoxicity on exposure to TDF may be linked to pre-existing renal disorders^[4-6]. Current international guidelines contraindicate use of TDF when creatinine clearance falls below 50 ml/min^[7].

In contrast, various studies have found evidence of renal proximal tubule injury and glomerular toxicity^[8-10] in non-predisposed patients. In Senegal, patients on TDF had higher rates of transition from mild to moderate renal insufficiency^[11]. In the USA^[1] and in Thailand,^[12] TDF-exposed groups had significantly higher incidences of renal disorder compared to TDF-unexposed groups. The use of TDF in HIV is therefore controversial because of the possible renal damage.

The aim of the study was to compare renal function outcomes between patients on TDF-based ART regimens and the patients

on non-TDF-based ART regimens and to determine the variables associated impaired renal function outcomes (CrCl < 50 ml/min).

METHODOLOGY

Study design and setting

This study utilised an analytical design to compare retrospective data for renal function outcomes of patients on TDF-based ART and patients on non-TDF-based ART.

The study was carried out at Roma Health Service Area (RHSA) that serves about 6% of Lesotho's population^[13]. Lesotho is a small landlocked country completely surrounded by South Africa. The RHSA is serviced by St Joseph's Mission Hospital and five satellite health centres. Patients at St Joseph's Mission Hospital and at Nazareth Health Centre made up 80% of the 4,116 HIV patients on ART in the entire RHSA. The study included adult HIV patients enrolled on ART between December 2006 and December 2012 at St Joseph's Mission Hospital and at Nazareth Health Centre.

Assuming an estimated odds ratio of 2 at 95% confidence level and a relative precision of 25%, a minimum sample size of 816 was required. However, only 485 patients met the set inclusion criteria from the two centres.

The study included non-pregnant adult patients who had at least one baseline creatinine value recorded while still ART-naïve, and had been on TDF or non-TDF based ART for at least six months.

Data collection and analysis

The study was approved on 13 of January 2012 by the Ministry of Health and Social Welfare of Lesotho.

Data was collected using pre-designed Microsoft Access[®] 2007 (Microsoft Corporation, Redmond, USA) data collection tool

which was piloted at St Joseph’s Mission Hospital. No personal information was captured into the data collection tool. Demographic data, diagnoses, treatments and laboratory values of HIV-positive patients were extracted from patient medical records. Baseline data included weight, age and gender; baseline ART regimen, WHO clinical stage, blood pressure, CD4 count, serum creatinine, blood urea nitrogen, full blood count, differential count, and liver function test. Hypertension was defined according to standard guidelines^[14].

Data was analysed using STATA® version 11 (StataCorp, Texas, USA). Sub-optimal renal function outcome was defined as serum creatinine clearance below 50 ml/min^[7]. Creatinine clearance was calculated using the Cockcroft-Gault equation^[10]. For analysis of baseline renal function and renal function outcomes, CrCl values were also categorised according to Chronic Kidney Disease (CKD)^[15] stages. Unfortunately, patient height was not collected. Therefore the body mass index (BMI) could not be calculated and was not used as a distinguishing factor in the study.

Summary statistics which included mean, median and inter-quartile ranges of the patients’ clinical profiles at baseline and at six-month intervals were analysed for significance of the differences between the TDF and the non-TDF groups using the t-test and Fisher’s exact test.

Univariate and multivariate logistic regression analyses were done to determine significant variables associated with creatinine clearance less than 50 ml/min. Predictors with *p*-values less than 0.1 in the univariate analysis were included in multivariate logistic regression analysis. Significant variables (*p*<0.05) were selected to remain in the final regression model.

RESULTS

Out of the 485 patients, 173 (36%) fell in the control group (non-TDF), while 312 (64%) fell in test group (TDF group).

The ages of the study population ranged from 20 to 78. Age was normally distributed both in the TDF and the non-TDF groups. The median age was not statistically different between the two groups (*p*=0.235). However, the 30-39 age group was the largest. There were no statistically significant differences in gender distribution (Table 1) between the TDF and the non-TDF group (*p*=0.258).

The baseline weight in the TDF group was significantly (*p*<0.001) lower than the baseline weight in the non-TDF group (Table 1). Baseline CD4 count of patients in the TDF group was significantly higher than the baseline CD4 counts in the non-TDF group (*p*=0.029). Tuberculosis was significantly (*p*=0.006) more common in the TDF group than in the non-TDF group.

When the baseline CrCl values were categorised according to CKD stages, there were no significant differences in baseline renal function between the TDF and the non-TDF group.

Variables associated with impaired renal function at baseline and during follow up

The baseline renal function did not differ between sexes (*p*=0.078). There was no association with decreased baseline CD4 counts (<50 cells/mm³) and WHO clinical stage and baseline renal function (*p*=0.575; and *p*=0.913 respectively). Patient age of 60 and above (*p*<0.001), as well as hypertension^[14] (*p*<0.001), were strongly associated with impaired baseline renal function (CrCl<50 ml/min).

From a baseline median of 69 ml/min (IQR 55-84), renal function improved by a median change of +4 ml/min at 12 months to a median of 73 ml/min (IQR 57-92) and by another median change of +2 ml/min at 24 months. However, 10 patients (2.1%) had severe impairment; and three patients had end-stage renal disease.

The number of patients who had impaired renal function (CrCl<50 ml/min) outcome (19.3%, *n*=312) in the TDF group

Table 1: Clinical profile of the study population

| Baseline (BL) characteristic | Non-TDF Group (n=173) | TDF Group (n=312) | P-value |
|------------------------------|-----------------------|-------------------|-----------|
| Age, median + (IQR) | 42 + (17) | 38 + (16) | 0.235 |
| Gender | | | |
| male | 63 (36.4%) | 130 (41.7%) | 0.258 |
| female | 110 (63.6%) | 182 (58.3%) | 0.258 |
| Weight (kg) + (IQR) | 56.1+ (15.6) | 54.0 + (12.0) | < 0.001** |
| WHO stage | | | |
| Stage I – III | 165 (95.4%) | 299 (95.8%) | 0.819 |
| Stage IV | 8 (4.6%) | 13 (4.2%) | - |
| CD4 count: median (IQR) | 142+ (133.0) | 167 + (180.5) | 0.029** |
| Hypertension stage I or II | 24 (17.5%) | 53 (20.4%) | 0.593 |
| Tuberculosis | 12 (6.9%) | 49 (15.7%) | 0.006** |
| Creatinine Clearance | | | |
| Median CrCl (IQR) | 70.0 + (35.0) | 70.0 + (28.0) | 0.318 |
| CrCl < 50 ml/min | 32 (18.5%) | 56 (17.95%) | 0.902 |

CrCl = serum creatinine clearance; IQR = inter-quartile range; CD4 count is in cells/mm³; ** = Significant *p*-value.

Table 2: Logistic regression analysis of variables associated with impaired renal function outcomes.

| Variable | CrCl>50 (n=403) | CrCl<50 (n=82) | Unadjusted OR (95% CI) | P-value | Adjusted OR (95% CI) | P-value |
|-----------------------------|-----------------|----------------|------------------------|----------|----------------------|---------|
| Non-TDF | 152 (87.6) | 21 (12.4) | 1 | - | 1 | - |
| TDF group | 251 (80.7) | 61 (19.3) | 1.7 (1.0-2.9) | 0.054* | 1.7 (0.9-3.2) | 0.122 |
| Age 20-29 | 61 (14.8) | 3 (3.2) | 1 | - | 1 | - |
| Age 30-39 | 145 (37) | 25 (31) | 3.5 (1.0-12.0) | 0.046** | 3.2 (0.9-11.6) | 0.077 |
| Age 40-49 | 176 (43.7) | 40 (48.8) | 4.0 (1.1-13.9) | 0.029** | 3.5 (1.0-12.9) | 0.060* |
| Age 50-59 | 176 (43.7) | 40 (48.8) | 5.6 (1.6-20.0) | 0.008** | 3.8 (1.0-14.9) | 0.053* |
| Age 60-78 | 21 (5.2) | 14 (17.1) | 14.2 (3.7-54.6) | <0.001** | 9.1 (2.0-41.2) | 0.004** |
| Male | 232 (57.8) | 60 (73.2) | 1 | - | 1 | - |
| Female | 171 (42.4) | 22 (26.8) | 2.1 (1.2-3.6) | 0.005** | 2.2 (1.2-4.1) | 0.016** |
| No HTN | 267 (79.0) | 39 (57.3) | 1 | - | 1 | - |
| HTN I or II | 71 (21.0) | 29 (42.7) | 2.8 (1.6-4.8) | <0.001** | 2.2 (1.2-4.0) | 0.009** |
| ^a CrCl>50 ml/min | 347 (86.1) | 50 (60.9) | 1 | - | 1 | - |
| ^a CrCl<50 ml/min | 56 (13.9) | 32 (39.0) | 4.2 (2.5-7.1) | <0.001** | 1.6 (0.8-3.2) | 0.218 |

HTN = Hypertension; CrCl = serum creatinine clearance in ml/min; ^aCrCl = baseline serum creatinine; OR= odds ratio; ** significant; * marginally significant.

was significantly higher (p=0.043) than the number of patients with impaired renal function outcome (12.4%, n=173) in the non-TDF group. When baseline renal function was controlled by excluding patients with impaired baseline renal function (CrCl<50 ml/min), the number of patients with impaired renal function outcome in the TDF group (12.5%, n=312) remained significantly higher (p=0.030) than the number of patients with impaired renal function outcome (5.8%, n=173) in the non-TDF group.

When improved renal function outcome was considered (CrCl>50 ml/min), 12.1% of the patients in the non-TDF group had an improved renal function outcome compared to 10.9% in the TDF group. When changes decrease in CrCl were compared between the groups, the TDF group had a marginally significant proportion of patients whose mean CrCl values dropped by 25% or more from the baseline (p=0.069).

Overall, more patients in the TDF group had a impaired baseline renal function outcome (40 or 12.5%) compared to the improved outcome (34 or 10.9%). In the non-TDF group, more patients had an improved renal function outcome (21 or 12.1%) compared to impaired renal function outcome (11 or 5.8%). Although improved and impaired outcomes occurred in both groups, the TDF group had a higher inclination towards the negative outcome.

Table 2 presents results for univariate (Unadjusted Odds Ratio) and multivariate (Adjusted Odds Ratio) logistic regression analysis. In the univariate logistic regression analysis, the variables that had higher odds of predicting impaired renal function outcomes were: (1) use of TDF (OR=1.7); (2) age of 60 or higher (OR=14.2); (3) female gender (OR=2.1); (4) hypertension (OR=2.8); and (5) baseline renal insufficiency (OR=4.2).

When multivariate regression analysis was performed, a number of significant variables remained in the final model (Table 2). The significant variables included old age, especially ages over 60 (p=0.004), female gender (p=0.016), and hypertension (p=0.009). Although the use of TDF had higher odds ratio of de-

veloping impaired CrCl outcome (adjusted OR=1.5) compared to the non-TDF group, the use of TDF became insignificant in the final adjusted model (p=0.122). When odds ratios (OR) were considered, older ages above 60 had the highest odds ratio (adjusted OR=9.1) of having CrCl<50 ml/min.

DISCUSSION

Although there was no significant difference between the TDF and the non-TDF group with respect to age (p=0.235), the 30-39 age group constituted more than one-third of the study population. The high frequency of this age group might mean that there is a higher risk of HIV infection in this age group. The results were similar to the results of another study conducted in Lesotho^[16], which reported that the 30-39 age group constituted up to 43.7% (n=255) of the study population.

The baseline variables of this study concurred with those of Bygrave *et al.*^[17] at another site in Lesotho with respect to the effect of gender and age, but differed with respect to CD4 counts. The results of this study did not show that low baseline CD4 count was a significant predictor for development of impaired renal function outcome. The reason could be that the wider range of baseline CD4 counts in this study when compared to those of Bygraves *et al.*^[17]

Tuberculosis was the most common infection at baseline. This was in line with the national TB statistics^[18]. According to a report by the Government of Lesotho^[18], about three-quarters (76%) of TB patients in Lesotho are co-infected with HIV.

Although the current guidelines do not indicate an upper age limit at which patients may not be given TDF, some patients older than 70 were put on TDF-containing regimens. Older patients are at a higher risk of having an impaired renal function outcome than younger patients because GFR decreases with age^[19].

In this study, the four patients that developed severe renal impairment were taking ARVs and anti-TB drugs such as rifampicin concurrently. Rifampicin is associated with interstitial

nephritis^[20]. Impaired renal function outcomes cannot therefore be attributed to TDF alone. Rifampicin was however used in almost equal proportions between the TDF (35.6%, n=312) and non-TDF group (33.5%, n=173).

The proportion of patients with impaired (CrCl<50 ml/min) baseline renal namely was (56 or 18.0%). However, about twice as many patients (40 or 12.8%) developed impaired renal function outcomes in this study compared to those of Bygrave *et al.*^[17] where 31 or 5.5% of patients with baseline CrCl>50 ml/min developed renal function impairment. In the study of Bygrave *et al.*^[17] only one patient (0.2%) developed severe impairment and none developed end-stage renal disease. In this study, five patients (1.6%) in the TDF group developed severe renal impairment, and one patient in the TDF group developed end-stage renal disease.

The use of ARVs containing TDF emerged as a marginally significant factor associated with impaired renal function outcomes in the univariate logistic regression analysis (p=0.054) but was an insignificant factor (p=0.122) when adjusted for age (p<0.05), gender (p=0.005), high blood pressure (p=0.009), and body weight (p<0.05). The results indicated that TDF may not contribute significantly towards the development of renal impairment when compared to other variables such as female gender, high blood pressure, older age, or TDF may only worsen a pre-existing renal disorder as reported in South Africa^[6].

The reported incidence of severe renal impairment following the use of TDF ranges from below 0.5% to just above 2%. The results of this study showed that 1.6% (n=312) of the patients developed severe renal impairment. The proportion with severe renal impairment was comparable to proportions reported in other studies. For example, a proportion of 1% was reported in the USA^[1], 0.5% in the UK^[21]; and 0.4% in India^[22].

The major source of bias in this study included confounding variables, limited clinical data of the patients, and failure to account for the patients' BMI data. Baseline CD4 counts and tuberculosis infection differed significantly between the TDF and the non-TDF groups at baseline. These two variables may have influenced the results of this study. Data on patients' height, which is required for the calculation of body mass index (BMI), was not available. Lesotho does not measure patients' heights as part of the ART programme. Therefore, the effect of BMI on kidney function which was not assessed in the study is another potential source of bias.

Differing methodologies used in various studies may explain why the results of some studies differed. For example, a study in Italy^[24] only included infants and adolescents but not adults. The impasse over TDF nephrotoxicity is likely to continue unless more studies are undertaken.

CONCLUSION

The results of this study indicate that there is a weak association between use of TDF and the development of renal impairment (p=0.054) before controlling for other variables and no association when the results were controlled for other variables (p=0.122). The use of TDF does not contribute as much to renal impairment outcomes when compared to other variables such as hypertension, older age, and female gender. More research on the long term effects of TDF is recommended. Routine base-

line renal function screening should be adopted to prevent patients with impaired renal function receiving TDF.

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