Several cohort studies have found low risk of renal dysfunction with the use of TDF, whereas a recent large longitudinal cohort study demonstrated that TDF may be an independent risk factor for mild to moderate renal impairment. The aim of this study is to assess changes in glomerular filtration rate (GFR) in patients receiving TDF containing highly active retroviral therapy (HAART) compared to patients on non-TDF HAART.

METHODS: Retrospective cohort data comparison of HIV infected patients attending to our clinic that were initiated on TDF containing HAART during 2002-2005. Patients who continued on HAART for at least three months had serum creatinine measurements at initiation and during therapy were eligible. GFR was estimated using the simplified modified diet and renal disease (MDRD) equation. Any decline in GFR greater than 25% from baseline was considered for renal impairment analysis ( mild 25-49%, moderate 50-74%, and severe 75-100% ).

RESULTS: 500 patients met the criteria for the study. 250 patients received TDF containing HAART and 250 patients received an alternative NRTI containing highly active antiretroviral therapy (HAART). The study occurred in an average of 298 and 418 days, respectively ( p <0.001). 3/250 (1.2%) patients in the TDF group vs. 0 in the NRTI stopped therapy in association with an increase of serum creatinine (Cr) in a median of 9.8 months. The median baseline creatinine was 0.9 mg/dl with no difference between groups. The mean baseline GFR was lower in the TDF than the NRTI group; this difference is statistically but not clinically significant, 101.65 ± 20.80 ml/min/1.73 m² (p<0.001). The median GFR change over the duration of the study was -0.6% (±14%), 12% in the TDF and -0.5% (±13%) in the NRTI group (p=0.9). A sustained decrease in the GFR was observed in 14/250 (5.6%) and 10/250 (4%) patients in the TDF and NRTI groups respectively.

CONCLUSIONS: Retrospective Evaluation of Changes in the Renal Function of HIV Patients Receiving Tenofovir Disoproxil Fumarate Containing Highly Active Antiretroviral Therapy

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Retrospective Study to Evaluate Changes in the Renal Function of HIV Patients Receiving Tenofovir Disoproxil Fumarate Containing Highly Active Antiretroviral Therapy

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RESULTS: 500 patients met the criteria for the study, 250 patients received TDF containing HAART and 250 received an alternative NRTI containing HAART. A mild decrease in the GFR was observed in 60 and 52 patients while a moderate decrease was recorded in 6 and 3 patients respectively for the TDF and NRTI groups ( p<0.04 for trend). This occurred in an average of 298 and 418 days, respectively ( p<0.001). 3/250 (1.2%) patients in the TDF group vs. 0 in the NRTI stopped therapy in association with an increase of serum creatinine (Cr) in a median of 9.8 months. The median baseline creatinine was 0.9 mg/dl with no difference between groups. The mean baseline GFR was lower in the TDF than the NRTI group; this difference is statistically but not clinically significant, 101.65 ± 20.80 ml/min/1.73 m² (p<0.001). The median GFR change over the duration of the study was -0.6% (±14%), 12% in the TDF and -0.5% (±13%) in the NRTI group (p=0.9). A sustained decrease in the GFR was observed in 14/250 (5.6%) and 10/250 (4%) patients in the TDF and NRTI groups respectively.

CONCLUSIONS: There was no difference in the number of patients who had a mild or moderate decrease in the GFR from baseline among both groups. The GFR changes in the TDF group occurred earlier in time than the NRTI. Although 20-24% of the patients in both group had a mild decrease in the GFR compared to baseline, only 5.6% versus 4% patients in the TDF and NRTI groups respectively, had a sustained decrease in the GFR over time and only 1% stopped therapy from association with increase in serum Cr in the TDF group. These observations were not statistically significant. Even though the mean baseline GFR was lower in the TDF than the NRTI group, this difference was of uncertain clinical significance given the no difference in the frequency of GFR changes among both groups.

BACKGROUND: Tenofovir disoproxil fumarate (TDF) is the first and only nucleoside reverse-transcriptase inhibitor (NRTI) to be approved for the treatment of HIV infection. Since its approval in October 2001, TDF has been widely prescribed for its simple dosing schedule with a favorable resistance profile without serious adverse effects. TDF renal safety profile has been proved in several clinical trials. Several case reports and case series have suggested that TDF may be associated with renal dysfunction. Although several cohort studies have found low risk of renal dysfunction with the use of TDF, others have reported mild to moderate renal failure. The most of the cases have occurred in patients with underlying renal disease or in patients taking nephrotoxic agents however some without any risk factor. The aim of this study is to assess changes in glomerular filtration rate (GFR) in patients receiving TDF containing highly active antiretroviral therapy (HAART) compared to patients receiving an alternative NRTI containing HAART.

METHODS: Retrospective cohort data comparison of HIV infected patients attending to our clinic that were initiated on TDF containing HAART during 2002-2005. Patients who continued on HAART for at least three months had serum creatinine measurements at initiation and during therapy were eligible. GFR was estimated using the simplified modified diet and renal disease (MDRD) equation. Any decline in GFR greater than 25% from baseline was considered for renal impairment analysis ( mild 25-49%, moderate 50-74%, and severe 75-100% ).

RESULTS: 500 patients met the criteria for the study, 250 patients received TDF containing HAART and 250 received an alternative NRTI containing HAART. A mild decrease in the GFR was observed in 60 and 52 patients while a moderate decrease was recorded in 6 and 3 patients respectively for the TDF and NRTI groups ( p<0.04 for trend). This occurred in an average of 298 and 418 days, respectively ( p<0.001). 3/250 (1.2%) patients in the TDF group vs. 0 in the NRTI stopped therapy in association with an increase of serum creatinine (Cr) in a median of 9.8 months. The median baseline creatinine was 0.9 mg/dl with no difference between groups. The mean baseline GFR was lower in the TDF than the NRTI group; this difference is statistically but not clinically significant, 101.65 ± 20.80 ml/min/1.73 m² (p<0.001). The median GFR change over the duration of the study was -0.6% (±14%), 12% in the TDF and -0.5% (±13%) in the NRTI group (p=0.9). A sustained decrease in the GFR was observed in 14/250 (5.6%) and 10/250 (4%) patients in the TDF and NRTI groups respectively.

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