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Presentation Title: Renal Function after Use of Tenofovir as Part of the Initial ART Regimen

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Background: Tenofovir DF (TDF) has demonstrated renal safety in clinical trials in ART-naive individuals. However, observational studies suggest that TDF is associated with renal toxicity, principally in patients who are ART-experienced at time of TDF start. We wished to determine if TDF is associated with renal dysfunction when part of an initial ART regimen in ART-naïve patients in clinical practice. **Methods**: We analyzed data from an observational clinical cohort, comparing all ART-naïve patients with an estimated GFR > 50 ml/min/1.73m^2 (MDRD equation) who initiated either TDF (n=201) or any alternative NRTI (n=231) after Jan 1, 2002. We analyzed the time to a 25% and 50% decline in GFR (confirmed by 2 measures) to maximum of 2 years using Kaplan-Meier methods. Multivariate analyses were performed using Cox regression. **Results**: There was no difference in baseline GFR (TDF=101 vs. NRTI=105; p=0.17); time on initial regimen (TDF=438, NRTI=410 days; p=0.27); 25% decline in renal function by 1 year (TDF=23.4%, NRTI=20.2%, p=0.51) or 2 years of follow-up (TDF=30.1%, NRTI=28.4%, p=0.59); or 50% decline in renal function by 1 year (TDF=4.7%, NRTI=5.5%, p=0.49) or 2 years of follow-up (TDF=5.1%, NRTI=6.9%, p=0.65). There was no difference between the TDF and NRTI groups in 25% (p=0.39) or 50% decline (p=0.56) adjusting for age, race, baseline GFR and CD4, use of a ritonavir-boosted PI (PI/r) vs NNRTI, concomitant diabetes or hypertension. However, older age, lower CD4, and hypertension were each associated with GFR decline (p<0.05) independent of TDF use. There was a statistical interaction between TDF and PI/r use, i.e., 2.1-fold greater risk of a 50% decline in GFR compared to NRTI + PI/r use. No interactions were found for other risk factors. **Conclusion**: Our results emphasize the importance of having a control group who receive an alternative NRTI, since a modest decline in rGFR was observed among patients taking both TDF and NRTI. Our results support use of TDF within the initial ART regimen, although the GFR should be monitored more closely when TDF is used with a PI/r.

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