Incidence of renal Fanconi syndrome in patients taking antiretroviral therapy including tenofovir disoproxil fumarate.

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ABSTRACT

The objective of this study was to measure the incidence and predictors of Fanconi syndrome in patients taking TDF in a large patient cohort.

METHODS

The study was approved by the Alfred Human Ethics Committee (approval number 600/15). Patients were included in the study if they were taking a TDF-containing regimen for at least three months, had a serum creatinine below 150 μmol/L at the commencement of their TDF exposure and had remained on TDF for at least one year. Of the 2047 patient years represented in TDF-exposed patients, 278 patient years of exposure were examined in the comparator group not taking TDF. Logistic regression analysis was used to examine the predictors of FS in patients exposed to TDF.

RESULTS

Ten F-S cases were identified. Cases were identified before ART exposure was stopped. All cases of FS were identified in patients taking TDF as the total of which 85% was identified, of whom nine patients were in a TDF regimen with tenofovir (Table 2A). Reversal of renal dysfunction was observed in eight of these cases (cases 2, 3, 5, 6, 7, 8, 9, and 11) (Table 2B). Diabetes was present in those with declined renal function (in all cases the second, published by Gupta et al in 2014, found that FS was associated with lower baseline renal function and an impaired renal safety profile. Ten patients (cases 1, 4, 5, and 10) had a history of chronic kidney disease (CKD) or its risk factors or who had been on treatment for many years.

CONCLUSIONS

Fanconi renal syndrome is associated with TDF exposure and is not rare. The incidence of FS in patients taking TDF without ritonavir was 1.09/1000PYs (95% confidence interval 0.54-1.63) and increases to 5.50/1000PYs (3.66-7.33) with ritonavir co-administration. Sex, comorbidity, pre-existing renal impairment, country of birth and CD4 nadir were not association with an increased risk of FS.

Incresing TDF based ART in lower and middle income countries and TDF based PrEP in higher income countries reinforces the need to ongoing surveillance and research into this condition.