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P-581. Racial/Ethnic Disparities of Renal Outcomes in People with HIV (PWH) on Tenofovir Alafenamide (TAF) Based Antiretroviral Treatment (ART) Regimens in the Real World

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Background. The risk of chronic kidney disease (CKD) is higher in PWH than HIV-negative persons. Black communities are not only disproportionately affected by HIV but also more at risk for kidney disease than other races. Despite Black PWH generally being underrepresented in clinical trials, the BRAAVE trial showed switching to bictegravir/emtricitabine/TAF demonstrated non-inferior efficacy and similar tolerability, including renal safety, compared to prior ART regimens in this group. With this analysis, we aim to assess whether these trial results translate to the real-world setting among Black PWH using a retrospective cohort analysis.

Table 1. Patient characteristics at ART initiation by exposure group

	TAF among Black PWH (n=4,562)	TAF among non-Black PWH (n=5,946)	P-value
Age, years	45.1 (14.4)	48.0 (13.8)	<0.0001
Sex at birth			
Male	3,054 (67.0)	5,165 (86.9)	<0.0001
Female	1,508 (33.0)	7,81 (13.2)	
Baseline comorbidities#			
HBV	29 (0.6)	60 (1.1)	0.0384
HCV	210 (4.6)	386 (6.5)	<0.0001
Diabetes	680 (14.9)	654 (11.0)	<0.0001
Hypertension	1,774 (38.9)	1,661 (27.9)	<0.0001
Chronic liver disease	161 (3.5)	216 (3.6)	NS
Substance use disorder			
Alcohol	816 (17.9)	1073 (18.0)	NS
Illicit drug use	671 (14.7)	1105 (18.6)	<0.0001
Renal function at ART initiation			
Serum creatinine, mg/dl	1.0 (0.4)	1.0 (0.3)	NS
eGFR at ART initiation, mL/min/1.73 m^2 (MDRD-4)*	80.1 (33)	90.0 (37)	<0.0001
eGFR at ART initiation, mL/min/1.73 m^2 (CKD-EPI)	89.9 (25)	92.4 (23)	<0.0001
During follow-up:			
Current CD4 cell counts, cells/μL	643.8 (376.4)	701.0 (328.5)	<0.0001
Current HIV RNA < 50 copies/mL	Yes	Yes	
Follow-up time, months	22.0 (21.0)	22.0 (21.0)	NS

#Diagnosed before index date.
* Calculated using four variable MDRD equation.
Data presented as n (%) or as mean (SD).
NS = nonsignificant

Methods. The descriptive analysis was conducted using IQVIA ambulatory electronic medical record (EMR) database (November 2015 – July 2023). The study population included PWH (≥ 18 years) who were newly prescribed with ART regimens. Study endpoints evaluated the incidence of azotemia, Fanconi syndrome, renal tubular acidosis (RTA), renal toxicity, acute kidney injury (AKI), and CKD stages using diagnosis codes, stratified by racial group (Black and non-Black) and treatment with TAF-based regimens using prescription codes. Incidence rates were reported. The analysis was conducted using ATLAS Version 2.12.1.

Table 2. Incidence rate of renal outcomes

	TAF among Black PWH (n = 4,562)			TAF among non-Black PWH (n = 5,946)		
	Time at risk (years)	No. of cases	Incidence rate#	Time at risk (years)	No. of cases	Incidence rate#
Azotemia	7875	6	0.76 (0.32, 1.57)	10051	9	0.90 (0.44, 1.63)
Renal toxicity	6505	184	28.29 (24.42, 32.60)	8739	204	23.34 (20.30, 26.72)
Acute kidney injury	7843	9	1.15 (0.57, 1.57)	10138	9	0.89 (0.44, 1.63)
Advanced CKD Stages						
Stage 4	7860	15	1.91 (1.11, 3.07)	10167	5	0.49 (0.19, 1.08)
Stage 5	7820	20	2.56 (1.61, 3.87)	10173	7	0.69 (0.31, 1.35)
Renal tubular acidosis*	7828	17	2.17 (1.31, 3.40)	10113	15	1.48 (0.87, 2.38)
Fanconi Syndrome	7933	0	0	10198	0	0

Incidence rate reported per 1,000 person-years
* Includes all subtypes of renal tubular acidosis
The confidence intervals follow Poisson distribution.
Renal diseases were identified by the following ICD-9/10 codes:
Azotemia: 790.6, R79.89.
Renal toxicity codes verified by: List of greater than 150 ICD codes used by Gilead safety team.
Acute kidney injury: 584, 584.5, 584.6, 584.7, 584.8, 584.9, N17.0-9.
CKD stage 4 or 5: 585.4, 585.5, 585.6, 403.01, 403.11, 403.91, I12.0, N18.4, N18.5, N18.6, or eGFR less than 30 or dialysis procedure.
Renal tubular acidosis: 588.89, N25.89.

Results. Overall, 4,562 Black and 5,946 non-Black PWH were identified on TAF-containing regimen, with 7,933 and 10,198 person-years of follow-up, respectively (Table 1). Compared to non-Black PWH, Black PWH were more likely to be female, have diabetes and hypertension. Black PWH on TAF had a higher incidence of advanced CKD and similar incidence rates of azotemia, renal toxicity, AKI, and RTA compared to non-Black PWH on TAF (Table 2). When stratified by baseline hypertension, no significant differences in the incidence of renal disease were observed between Black and non-Black PWH. There were no cases of Fanconi syndrome in the study cohort.

Conclusion. Despite the inherent limitations of real-world data, this analysis included a large cohort of Black PWH on TAF-containing ART and showed a low incidence of RTA and AKI, despite predisposition to increased rates of renal decline or safety outcomes in Black PWH starting ART.

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