Longitudinal Renal Safety of a Population-Level TDF-Based HIV PrEP Program in British Columbia, Canada

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BACKGROUND

- Since January 2018, publicly-funded oral HIV Pre-Exposure Prophylaxis (PrEP) with generic emtricitabine-tenofovir disoproxil fumarate (FTC-TDF) has been available to key populations in British Columbia (BC).
- We examined the renal safety, quantified the extent of reduced renal function, and determined associated characteristics in over 10,000 clients on FTC-TDF in BC's population-level PrEP program.

METHODS

- Retrospective observational cohort study.
- We included BC PrEP program clients, aged ≥ 19 with ≥ 1 FTC-TDF PrEP prescription dispensed between 1-Jan-2018 and 31-Dec-2023 and with ≥ 1 follow-up eGFR at least 7 days after the first PrEP dispense. Participants were followed to 30-Jun-2024.
- We quantified and described the baseline demographic and clinical characteristics for all clients, clients with reduced renal function after first PrEP dispense (defined as ≥2 consecutive follow-up eGFR <60mL/min, ≥30-days apart), and quantified clients with severely increased urine albumin/creatinine ratio after first PrEP dispense (uACR > 30mg/mmol).
- Clients with and without reduced renal function were also compared using Fisher's exact and Wilcoxon rank sum tests.
- Multivariate analysis was performed to determine adjusted hazard ratios, identifying key characteristics associated with time to reduced renal function.

RESULTS

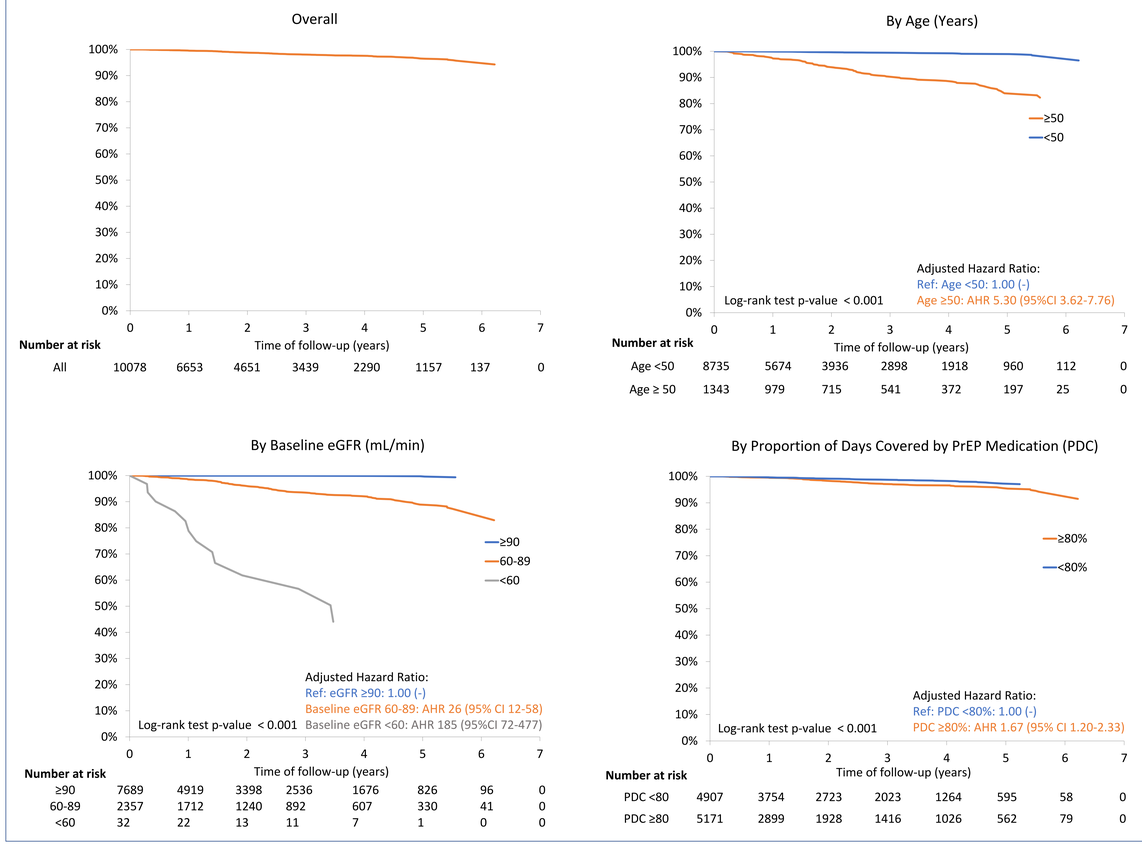
- A total of 10,078 participants were included, contributing 23,622 person-years (PY) of follow-up.
- Median follow-up time was 1.9 years (Q1-Q3, 0.7-3.9).

Participant characteristics

- Baseline characteristics varied between participants with and without reduced renal function (Table).
- Overall, the median age was 32 (Q1-Q3, 27-40) years; 96.5% were cis-men, 1.5% trans-women (TGW), 0.7% cis-women, 0.5% trans-men, and 0.5% non-binary.
- Median eGFR at baseline was 104 mL/min (Q1-Q3, 90-116).

Incident reduced renal function was infrequently observed amongst participants of a TDF-based HIV PrEP program (rate: 0.62 per 100 PY). Participants aged ≥50 at baseline and those with lower baseline eGFR were disproportionately affected by incident reduced renal function.

Figure: Probability of Maintaining Consecutive eGFR ≥60mL/min



Participants with reduced renal function (≥2 consecutive follow-up eGFR <60mL/min, ≥30-days apart)

- Of 10,078 PrEP participants, 146 (1.4%) had incident eGFR <60mL/min at least twice consecutively, at median 24 (range 4-76) months.
- The rate of reduced renal function was 0.62 per 100 PY.
- Participants aged 50 and older accounted for 74% of the reduced renal function group despite making up 13% of the total study population.

Urine Albumin/Creatinine Ratio (uACR)

- Of 2468 (24%) participants with ≥1 uACR result available, 31 (1.3%) had ≥1 value >30mg/mmol reported.

Table: Participant demographics: Bivariate results comparing participants with and without reduced renal function.

Variable	eGFR <60 mL/min at least twice consecutively (≥30-days apart)		
	Yes (N=146)	No (N=9932)	p-value
Age at baseline (years) n (%)			<0.001
<30	5 (3)	3867 (39)	
30-39	11 (8)	3539 (36)	
40-49	22 (15)	1291 (13)	
≥50	108 (74)	1235 (12)	
Gender identity at baseline*, n (%)			0.590
Cis-Man	141 (97)	9587 (97)	
Cis-Woman	<5 (<5)	69 (1)	
Trans-Woman	<5 (<5)	150 (2)	
Trans-Man	0 (0)	45 (0)	
Other	0 (0)	68 (1)	
Participants' residence at baseline*, n (%)			0.018
Vancouver	76 (52)	5401 (54)	
Greater Vancouver	27 (18)	2483 (25)	
Outside of Greater Vancouver	42 (29)	1965 (20)	
eGFR at baseline (mL/min), n (%)			<0.001
<60	13 (9)	19 (0)	
60-89	126 (86)	2231 (22)	
≥90	7 (5)	7682 (77)	
PDC, Median % (Q1-Q3)[a]			0.743
	84.4 (61.7-95.5)	81.4 (50.6-97.4)	

*Individuals of unknown status excluded from table and analysis
[a]PDC: Estimated maximum proportion of days covered by PrEP medication. Total number of pills dispensed from first dispense to the end of follow-up divided by the participant follow-up time in days x 100.

Multivariate Analysis : modeling time to the first of two consecutive eGFR <60 mL/min (≥ 30-days apart)

- Age at baseline ≥50 years, baseline eGFR <60mL/min, baseline eGFR 60-89mL/min, and higher proportion of days covered by PrEP medication (PDC) were associated with earlier time to reduced renal function (Figure).

CONCLUSIONS

- Over 6 years of BC's population-level FTC-TDF-based HIV PrEP program, we found that incident reduced renal function was infrequent amongst clients.
- Due to the overall safety of FTC-TDF, the quarterly recommended frequency of renal monitoring may be re-evaluated in young PrEP users with normal baseline renal function.
- For individuals experiencing renal adverse effects, novel PrEP agents may offer an alternative.

Note: Numbers from original abstract submission have been updated

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BC Centre for Excellence in HIV/AIDS www.bccfe.ca/hiv-pre-exposure-prophylaxis-prep

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