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SEXUAL HEALTH

Renal impairment risk in Indigenous and non-Indigenous people who take HIV pre-exposure prophylaxis (PrEP): a retrospective cohort study

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ABSTRACT

Background. Tenofovir disoproxil-containing HIV pre-exposure prophylaxis (PrEP) is associated with a small risk of renal impairment. How this risk may differ in Aboriginal and Torres Strait Islander peoples (hereafter, respectfully, 'Indigenous') who have higher rates of chronic kidney disease and associated risk factors than non-Indigenous Australians, has yet to be described. **Methods.** A retrospective longitudinal open cohort study of adults with a baseline estimated glomerular filtration rate (eGFR) ≥60 mL/min/1.73 m^2 commencing tenofovir disoproxil-containing PrEP as part of routine care was conducted. Client data were collected from 67 clinics participating in the Australian Collaboration for Coordinated Enhanced Sentinel Surveillance of Sexually Transmissible Infections and Blood Borne Viruses network between January 2012 and December 2019. The primary outcome was the rate of new renal impairment, defined as an eGFR of <60 mL/min/1.73 m^2 or >25% decline of eGFR from baseline. **Results.** Of the 8696 adults, 203 identified as Indigenous and were eligible for inclusion. The median age was 34 years (IQR 28–44), 96.8% were men who have sex with men and 90.1% resided in major cities. Indigenous clients were less likely to have a baseline eGFR 60–90 mL/min/1.73 m^2 (15.8% vs 24.1%; $P = 0.006$). Over a median follow-up period of 1.7 years (IQR 1.1–2.4), rates of renal impairment were similar for Indigenous and non-Indigenous clients: 5.6 events/1000 person-years (95% CI 1.4–22.8) and 4.8 events/1000 person-years (95% CI 3.9–6.1) respectively ($P = 0.83$). **Conclusions.** Renal impairment was rare among Australians commencing PrEP as part of usual care. We observed no difference in the development of renal impairment among Indigenous and non-Indigenous Australians.

Keywords: Aboriginal and Torres Strait Islander health, chronic kidney disease, HIV, kidney, men who have sex with men (MSM), pre-exposure prophylaxis, renal impairment, sexual health, tenofovir disoproxil.

Introduction

The efficacy of pre-exposure prophylaxis (PrEP) has made it a key component of Australian HIV-prevention strategies.[1–3] Since gaining approval for government subsidy in 2016, over 50,000 individuals have had PrEP dispensed in Australia.[4]

All currently subsidised PrEP regimens in Australia contain tenofovir disoproxil, co-formulated with emtricitabine.[5] Although generally well tolerated, tenofovir disoproxil is associated with a risk of renal injury via direct toxicity to the renal tubules.[6–9] The Australian Expanded PrEP Implementation in Communities-New South Wales (EPIC-NSW) study, found this risk is largely confined to older individuals and those with pre-existing renal disease, but it did not comment on the risk in Aboriginal and Torres Strait Islander peoples (hereafter, respectfully, 'Indigenous'), a priority population for HIV-prevention.[3,8]

The renal safety of PrEP in Indigenous Australians warrants further consideration due to higher rates of chronic kidney disease (CKD), and concurrent co-morbid health conditions that may be additive to CKD risk, than in non-Indigenous Australians.[10,11] Some CKD risk factors, including diabetes and hypertension, are common in Indigenous and non-Indigenous

Australians.[7,8,12] Other risk factors, including low birthweight, infant malnutrition and post-infectious glomerulonephritis disproportionately contribute to the lifetime CKD risk in Indigenous Australians.[3,13,14]

An understanding of renal impairment risk related to PrEP use for Indigenous people would help inform clinical guidelines. Current Australian guidelines recommend 6-monthly renal function testing when taking PrEP and more frequently if risk factors for renal disease are present.[3] It may also support clinical decision-making regarding alternative PrEP strategies, such as on-demand dosing, which can reduce tenofovir disoproxil exposure.[3]

Here, we report a retrospective analysis of a large national dataset of Indigenous and non-Indigenous adults who commenced PrEP to determine the incidence of new renal impairment and explore potential risk factors.

Methods

Study population

We conducted a retrospective longitudinal open cohort study. Individuals were included from the date they were first prescribed PrEP at a participating clinic, between January 2012 and December 2019.

Clients were eligible for inclusion if they had an available baseline estimated glomerular filtration rate (eGFR), defined as the eGFR measured closest to PrEP commencement (from 180 days before to 30 days after) and had at least two further eGFR measurements after PrEP commencement. Clients were excluded if Indigenous identity was not disclosed or if these data were missing. Clients were also excluded if they had an eGFR <60 mL/min/1.73 m^2 before starting PrEP, as contemporaneous guidelines did not recommend PrEP use in such individuals.

Data source

Data were extracted from 67 clinics Australia wide who were participating in a sentinel surveillance program known as the 'Australian Collaboration for Coordinated Enhanced Sentinel Surveillance of Sexually Transmissible Infections and Blood Borne Viruses' (ACCESS – https://accessproject.org.au). These clinics include sexual health clinics, general practice clinics, hospitals and community health services.[15,16] Data were initially collected as part of routine care and then securely extracted via GRHANITE software (The University of Melbourne, Australia). De-identified probabilistic linkage was applied to the dataset to unify client records across multiple clinics.

Demographic variables of interest included sex, age group (16–39, 40–49 and ≥50 years), Australian Statistical Geography Standard-Remoteness Area (major cities, inner regional, outer regional/remote) and men who have sex with men (MSM) status. Clinical variables extracted from the ACCESS dataset included, history of intravenous drug use and diabetes diagnosis. Extracted laboratory findings included eGFR and hepatitis C antibody status.

Outcome measures

Clients were followed from PrEP commencement until developing renal impairment or until the study end date 31 December 2019. Clients were censored earlier if more than 365 days elapsed without eGFR testing, with censoring effective from 182 days after the last eGFR measurement. Follow-up time was truncated at 3 years due to low client numbers. Comparison of median follow-up durations was by Pearson chi-squared test.

Renal impairment was defined as an eGFR <60 mL/min/1.73 m^2 or >25% decline in eGFR from baseline. To account for transient fluctuations, and confounders like creatine supplementation or high dietary protein intake this needed to be followed by a subsequent eGFR measure, with the average of the two measures meeting the definition of renal impairment. Where a clients's baseline eGFR was reported as '>90' mL/min/1.73 m^2, a subsequent eGFR <70 mL/min/1.73 m^2 was taken as new renal impairment.

Statistical analysis

Baseline characteristics were tabulated separately for Indigenous and non-Indigenous clients. Chi-squared tests were used to assess differences in the distributions of categorical variables.

Rates of renal impairment per 1000 person-years were calculated for Indigenous and non-Indigenous clients and differences assessed using log rank tests. Cumulative probability of renal impairment over time was estimated using the Kaplan–Meier method, with differences between survivor curves measured using log rank tests. Univariate Cox proportional hazards models, stratified by treatment clinic centre, were used to assess potential predictors of renal impairment. Self-identified Indigenous status was included in the multivariate model as independent variable in addition to those variables that were significant in univariate analyses at $P < 0.1$ level. Potential collinearity in multivariate models were assessed based on pairwise assessment of model covariates and condition index in conjunction with covariate variance decomposition proportions. All analyses were conducted using Stata ver. 15.1, (StataCorp LLC, College Station, TX, USA).

Sensitivity analysis

A sensitivity analysis was performed in which renal impairment was defined as two consecutive eGFR results <60 mL/min/1.73 m^2, with those results being collected at least 85 days apart. This definition was chosen to correspond to the Kidney Disease Improving Global Outcomes (KDIGO)

definition of at least Stage 3 CKD.[17] All subsequent analyses were performed as described for the primary endpoint.

Ethics

Aboriginal and Torres Strait Islander community representatives participated in the design of this research project and reporting of its findings. Academic co-investigators also included members of the Indigenous community. The manuscript was reviewed and approved by the Aboriginal Health and Medical Research Council prior to submission.

Ethics approval was provided by the Human Research Ethics Committees at Alfred Hospital (248/17), Central Australia Human Research Ethics Committee at Flinders University. (CA-19-3355), Northern Territory Department of Health and Menzies School of Health (08/47), University of Tasmania (H0016971), Aboriginal Health and Medical Research Council (1099/15), AIDS Council of New South Wales (2015/14), Victorian AIDS Council/Thorne Harbour Health (VAC REP 15/003), Western Australian Aboriginal Health Ethics Committee (885), and St. Vincent's Hospital (08/051). As our analyses involved de-identified data collected under the auspices of public health surveillance, individual client consent was not required. Individuals were able to initially opt-out of the surveillance network.

Results

A total of 11,184 clients were prescribed PrEP at an ACCESS clinic within the study period. Clients were excluded from the analysis if they did not to state whether or not they identified as Aboriginal and/or Torres Strait Islander (n = 314) or if these data were missing (n = 1377). A further 79 clients were excluded, as they had an eGFR <60 mL/min/1.73 m^2 before commencing PrEP. An additional 718 clients were excluded due to insufficient follow-up data.

A total of 203 Indigenous and 8493 non-Indigenous clients were eligible for inclusion in this study. Baseline characteristics of the two cohorts are shown in Table 1. Nearly all clients identified as male (98.1%). Median age was similar between Indigenous (31 years; IQR 25–39) and non-Indigenous clients (34 years; IQR 28–44; P = 0.17). However, there were significantly fewer Indigenous clients aged ≥50 years (8.9 vs 14.5%; P = 0.024). Indigenous clients were approximately three-fold more likely to reside in inner and outer regional areas (P < 0.001), although the majority of all clients (90.1%) were from major cities. Indigenous clients were less likely to have a baseline eGFR <90 mL/min/1.73 m^2 (15.8 vs 24.1%; P = 0.006), whereas diabetes prevalence was similar between Indigenous and non-Indigenous clients (2.5 vs 1.4%; P = 0.22).

Median follow-up duration was 1.7 years (IQR 1.1–2.4) for both Indigenous and non-Indigenous clients, with a similar drop-off rate between the two cohorts (20.7 vs 24.2% respectively, P = 0.25). Renal impairment was noted in two Indigenous and 71 non-Indigenous clients, corresponding to event rates of 5.7 (95% CI 1.4–22.8) and 4.9 (95% CI 3.9–6.1) per 1000 person-years, respectively. These did not significantly differ (P = 0.83). The cummulative risk of renal impairment over time for both groups is shown in Fig. 1.

Potential risk factors for new renal impairment were assessed by Cox regression (Table 2). A multivariable analysis demonstrated that Indigenous clients as a group did not experience higher risk of renal impairment than non-Indigenous clients (P = 0.39). Clients aged ≥50 years had more than an eight-fold higher risk than those aged <40 years (Hazard ratio (HR) 8.21; 95% CI 4.17–16.14; P < 0.001). Those with a baseline eGFR 60–90 mL/min/1.73 m^2 had a 5.61-fold (95% CI 3.15–9.99; P < 0.001) higher risk of renal impairment than those with a baseline eGFR >90 mL/min/1.73 m^2. As no episodes of new renal impairment occurred in female clients or those with evidence of previous hepatitis C infection, these could not be assessed as potential risk factors.

Table 1. Baseline characteristics of Indigenous (n = 203) and non-Indigenous clients (n = 8493) attending 67 clinics for PrEP between January 2012 and December 2019.

Characteristics	Indigenous *n* (%)	Non-Indigenous *n* (%)	*P*-value
Gender			0.054
Male	195 (96.1)	8337 (98.2)	
Female	5 (12.5)	81 (1.0)	
Trans/intersex/other	0 (0.0)	13 (0.2)	
Missing	3 (1.5)	62 (0.7)	
Age (years) – median (IQR)	31 (25–39)	34 (28–44)	0.17
Age (years)			0.012
16–39	154 (75.9)	5624 (66.2)	
40–49	31 (15.3)	1639 (19.3)	
≥50	18 (8.9)	1230 (14.5)	
Exposure risk			
MSM	188 (92.6)	8227 (96.9)	<0.001
IVDU	20 (9.9)	359 (4.2)	<0.001
Renal risk factors			
Baseline eGFR <90 mL/min/1.73 m^2	32 (15.8)	2047 (24.1)	0.006
Diabetes mellitus	5 (2.5)	121 (1.4)	0.22
Prior HCV infection	8 (3.9)	92 (1.1)	<0.001
Remoteness			<0.001
Major cities	154 (75.9)	7678 (90.4)	
Inner regional	33 (16.3)	477 (5.6)	
Outer regional/remote	13 (6.4)	162 (1.9)	
Not specified	3 (1.5)	176 (2.1)	

eGFR, estimated glomerular filtration rate; HCV, hepatitis C virus; IVDU, intravenous drug use; MSM, men who have sex with men.

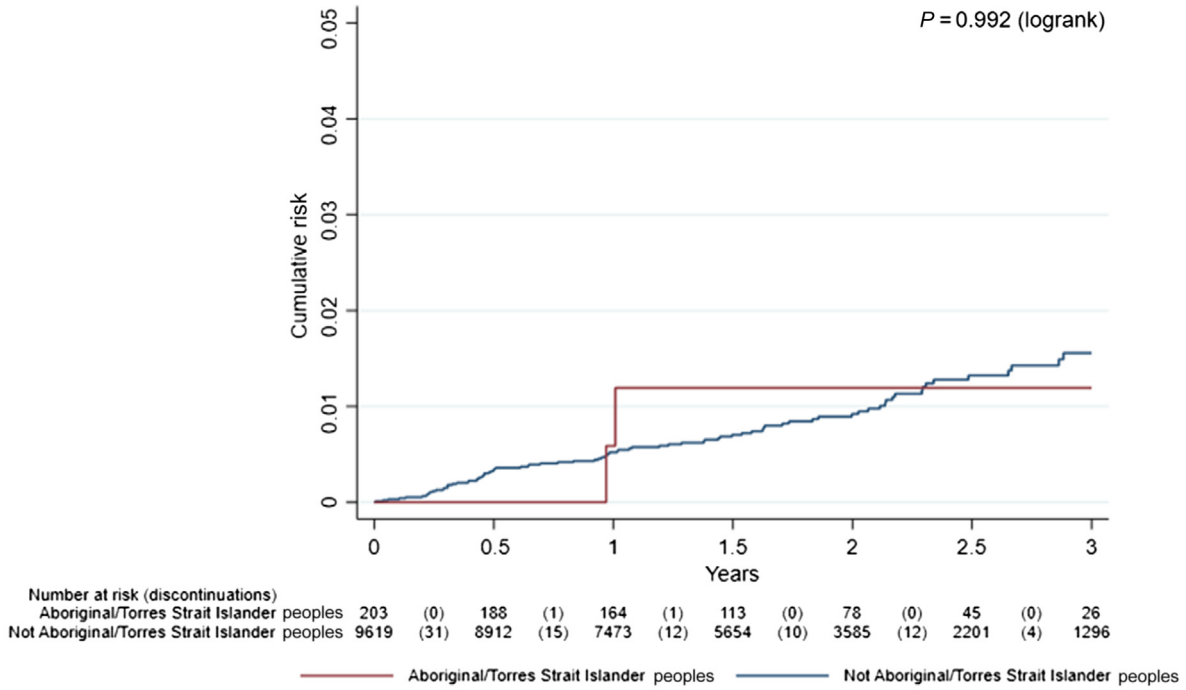

Fig. 1. Cumulative risk renal impairment by Indigenous status in clients attending 67 clinics for PrEP between January 2012 and December 2019.

Table 2. Potential predictors of new renal impairment in clients (n = 8696) attending 67 clinics for PrEP between January 2012 and December 2019.

	Single variable		Multivariable	
	HR (95% CI)	*P*-value	HR (95% CI)	*P*-value
Indigenous status				
Indigenous	1 (ref)	–	1 (ref)	–
Non-indigenous	0.88 (0.21–3.70)	0.87	0.52 (0.12–2.27)	0.72
Age group (years)				
16–39	1 (ref)	–	1 (ref)	–
40–49	4.06 (1.93–8.53)	<0.001	2.71 (1.28–5.75)	0.001
≥50	16.55 (8.74–31.34)	<0.001	8.21 (4.17–16.14)	<0.001
IVDU	0.68 (0.16–2.79)	0.60	–	–
Baseline eGFR <90 mL/min/1.73 m^2	10.28 (5.99–17.65)	<0.001	5.61 (3.15–9.99)	<0.001
Diabetes	5.87 (2.03–16.93)	0.001	1.78 (0.60–5.25)	0.30
Remoteness			–	–
Major cities	1 (ref)	–		
Inner regional	1.96 (0.82–4.67)	0.13		
Outer regional/remote	[A]	[A]		

eGFR, estimated glomerular filtration rate; IVDU, intravenous drug use.
[A]No events occurred in this subgroup and so values could not be calculated.

A sensitivity analysis was performed where renal impairment was defined as the development of at least Stage 3 CKD. Of the 44 clients who developed CKD, nearly half (47.7%) had a baseline eGFR between 60 and 69 mL/min/1.73 m^2. None had an eGFR >90 mL/min/1.73 m^2. In multivariable Cox regression analysis, commencing PrEP at age ≥50 years (HR 8.09; 95% CI 3.02–21.69; P < 0.001) and having a baseline eGFR <90 mL/min/1.73 m^2 (HR 78.07 95% CI 10.50–580.86, P < 0.001) were associated with a higher risk of developing at least Stage 3 CKD.

Discussion

This retrospective analysis examined the emergence of renal impairment among Australian adults receiving tenofovir disoproxil-containing PrEP to prevent HIV as part of routine care. Our main finding is that the incidence of new renal impairment was low and was not significantly or differentially experienced in Indigenous men, as compared to non-Indigenous men.

The result showing Indigenous clients were less likely to have a low eGFR (60–90 mL/min/1.73 m^2) at baseline than non-Indigenous clients was unexpected. Fewer Indigenous clients being aged ≥50 years may account for some of this discrepancy; however, as noted in the 2015 Australia survey, CKD was still 1.4-fold greater in young Indigenous adults than young non-Indigenous adults nationwide.[11] Diabetes prevalence was also lower among Indigenous PrEP users than expected among similarly aged Indigenous Australians. In this cohort, diabetes prevalance was statistically equivalent between

Indigenous and non-Indigenous clients in our cohort, as compared to three to four times more common in Indigenous adults than non-Indigenous adults nationally.[18,19]

In our cohort, a large majority of both Indigenous and non-Indigenous clients resided in major cities and more than 93% identified as MSM. These factors combined may have resulted in better overall health status, likely attributable to greater healthcare access and health literacy than the general population.[11,19] Similar demographic trends and lower rates of non-communicable diseases than respective population averages have been noted in other PrEP cohorts internationally.[7,12]

The proportion of Indigenous clients accessing PrEP at inner regional and particularly outer regional clinics/remote was less than expected given overall population trends.[19] These discrepancies may stem from additional barriers to healthcare access and health promotion for Indigenous persons, which are particularly pronounced in regional areas.[20] We note that remote areas have been the focus of much Indigenous health research. Its generalisability to Indigenous people in urban areas is unclear, and the need for Indigenous led health research in urban areas has been identified.[21]

The overall risk of new or worsening renal impairment in our study was similar to that reported in EPIC-NSW (4.9 vs 5.8 events per 1000 person-years).[8] Older age and low baseline eGFR were predictors of renal impairment in both studies, with the smaller hazard ratios in our study likely reflecting better estimations of risk from a larger sample size.[8] The similar risk of renal impairment in Indigenous and non-Indigenous clients suggests that no additional monitoring is required for Indigenous PrEP users is warranted under current guidelines.[3]

Our sensitivity analysis demonstrated that approximately half of the episodes of new renal impairment in our cohort met the KDIGO definition of at least Stage 3 CKD.[17] Although rare overall, half of those who developed CKD had baseline eGFR values 70–90 mL/min/1.73 m^2. This emphasises the importance of regular monitoring of renal function in those with even mild baseline renal impairment, while on PrEP.

The main limitation of our study is the short duration of follow-up. This is common among PrEP studies published to date and warrants further consideration, given longer-term studies in people living with HIV demonstrating increasing renal impairment risk with cumulative tenofovir disoproxil exposure.[6,8,12,22] However, given high rates of discontinuation of daily dosing PrEP regimens and guidelines now incorporating alternative on-demand dosing strategies, any potential consequences of long-term daily PrEP use are likely to be of concern to a minority of PrEP users.[3,23]

The extent to which on-demand dosing may have occurred in our study is unknown, but suspected to be limited given our study window of 2012 to 2019. Although the efficacy of on-demand demand dosing was demonstrated in the findings of IPERGAY, published in late 2015, this dosing strategy was not incorporated into local guidelines until mid-2018.[24,25]

Proteinuria data are not collected in the ACCESS database and so we are unable to comment on the development of tubular proteinuria in the cohort. While previous data have demonstrated that substantial proteinuria can occur before reductions in the eGFR, the long-term consequences for renal function remain unclear.[9,26] Both proteinuria and reductions in eGFR have been shown to be largely reversible with prompt discontinuation of tenofovir disoproxil.[27,28] However, how these renal injuries may impact lifetime CKD risk has yet to be described.

This retrospective audit of routine PrEP use throughout 67 centres in Australia confirmed a low incidence of renal impairment after commencing PrEP and no difference in renal impairment risk between Indigenous and non-Indigenous clients. These findings support the safety of current prescribing guidelines and suggest that alternative PrEP guidelines for Aboriginal and Torres Strait Islander individuals are not warranted.

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Data availability. The data that support this study cannot be publicly shared, as we do not have ethics approval to do so.

Conflicts of interest. Darren Russell is an Associate Editor for *Sexual Health*, but was not involved in the peer review or decision-making process for this paper. The authors declare no other conflicts of interest.

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