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Brief Communication

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The Incidence and Risk Factors of Renal Insufficiency among Korean HIV infected Patients: The Korea HIV/AIDS Cohort Study

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ABSTRACT

Renal insufficiency is one of the common issues in people living with human immunodeficiency virus (PLHIV). We studied the incidence and risk factors for renal insufficiency in male PLHIV using the Korea HIV/acquired immunodeficiency syndrome (AIDS) Cohort Study. Among the 830 enrolled patients, 32 (3.9%) cases of renal insufficiency occurred over 9576 patient-years of follow-up. The incidence of renal insufficiency in HIV-infected men in this study was 3.3 per 1000 patient-years. Diabetes mellitus, dyslipidemia, tenofovir or non-nucleoside reverse transcriptase inhibitor exposure for >1 year, and AIDS-defining illness were risk factors for renal insufficiency.

Keywords: HIV/AIDS; Renal insufficiency; Cohort study

Renal insufficiency is one of the common issues among people living with human immunodeficiency virus (PLHIV) infections [1, 2]. HIV patients have a higher risk for renal insufficiency than healthy people [3] due to their exposure to several factors that can result in decreased renal function. Renal dysfunction in HIV patients is attributable to the direct viral renal cell injury caused by HIV infection, chronic inflammation, and drugs, in addition to traditional risk factors such as diabetes, hypertension, and aging [1].

Advancements in combination active antiretroviral therapy (cART) have resulted in longer life expectancies in HIV patients [4, 5]. However, the incidence of non-communicable diseases (NCDs) in PLHIV has continued to increase concurrently [6]. Among the causes of death in PLHIV, the proportion of acquired immunodeficiency syndrome (AIDS)-related causes are

Infection & Chemotherapy

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Ethics Statement

This study was approved by the Institutional Review Board (IRB) of the Severance hospital (IRB approval number: 4-2019-0419), and written informed consent was obtained from all participants.

Conflict of Interest

JYS is editorial board of Infect Chemother. However, he did not involve in the peer reviewer selection, evaluation, and decision process of this article. The other authors have no conflicts of interest to declare.

Author Contributions

Conceptualization: JHK, JYC. Formal analysis: JHK, HJ, JYC. Investigation: JHK, HJ, JHK, JYS, SWK, SIK, BYC, JYC. Methodology: JHK, HJ, JYC. Writing - original draft: JHK. Writing - review & editing: HJ, JHK, JYS, SWK, SIK, BYC, JYC.

decreasing while non-AIDS causes are increasing [7]. The incidence of renal dysfunction caused by NCDs like diabetes and hypertension is also increasing in PLHIV [3, 7].

Although several studies have evaluated the incidence of renal dysfunction in PLHIV, only a few have examined the incidence in Korean patients. In addition, the factors influencing the occurrence of renal dysfunction have been studied inadequately. Therefore, the purpose of our study is to describe the incidence of renal insufficiency and investigate the risk factors of renal insufficiency in this population by using data from the Korea HIV/AIDS cohort study.

The Korea HIV/AIDS cohort study is an ongoing prospective cohort study that has been conducted in Korea since 2006 with 21 participating hospitals [8]. Among Korean HIV-infected patients over 18 years old, those who were diagnosed with HIV infection by Western blotting and who agreed to participate in the cohort study were included in the study [8]. At the time of registration, a trained clinical researcher interviewed all enrolled participants and documented baseline clinical and epidemiological data [8]. The prospective cohort study recorded questionnaire assessments that included medical history, body measurements, laboratory tests with immunological status, and HIV viral load. The investigation was performed every six months [8]. This study was conducted on male patients aged more than 18 years who were enrolled in this cohort study between December 2006 and December 2018. Patients with an initial estimated glomerular filtration rate (eGFR) <60 mL/min per 1.73 m^2 at baseline were excluded from the study. We investigated the incidence of renal insufficiency by following up with patients who were included in the cohort until December 2018.

We defined renal insufficiency as two eGFR ≤60 mL/min per 1.73 m^2 consecutively (≥3 months apart). The simplified modification of diet in renal disease (MDRD) equation was used to assess eGFR measurements based on serum creatinine levels. We analyzed data on the date of diagnosis of HIV infection, age, sex, height, weight, mode of transmission, diabetes mellitus (DM), hypertension (HTN), dyslipidemia, CD4 T-cell count, HIV viral load, AIDS-defining illness, Years on ART, and laboratory test at study enrollment. Patients without sufficient data and non-Korean patients were excluded from the analysis.

The incidence of renal insufficiency was evaluated by dividing the number of cases in which renal insufficiency was defined by the total observation period. We conducted Chi-square's tests for categorical variables and paired *t*-tests for continuous variables to investigate the differences in characteristics between patients with renal insufficiency and those without. Cox proportional hazard regression was used to identify predictive variables for the incidence of renal insufficiency. A two-tailed test with a P <0.05 was set as statistical significance. All of the statistical analyses were conducted using SAS version 9.4 (SAS Institute, Cary, NC, USA).

A total of 1,515 HIV-infected men were enrolled from December 2006 to December 2018, of which 685 patients were excluded from the analyses owing to missing data and the exclusion criteria. Among the 830 enrolled patients, 32 (3.9%) cases of renal insufficiency occurred over 9,576 patient-years of follow-up. A comparison of the baseline characteristics during the window period (**Table 1**) showed that more patients in the renal insufficiency group had DM, dyslipidemia, and a high HIV viral load at enrollment. 13 (40.6%), 25 (78.1%), and 18 (56.3%) of the patients took tenofovir, nucleoside reverse transcriptase inhibitor (NRTI), and protease inhibitor (PI), respectively, for >1 year in the renal insufficiency group. Renal insufficiency occurred in 32 patients at a rate of 3.3 events per 1,000 patient-years, while the incidence rate of renal insufficiency in men aged >60 years was 9.91 events per 1,000 patient-years. HIV-infected

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patients with DM showed renal insufficiency at an incidence rate of 11.96 events per 1,000 patient-years, while those with dyslipidemia showed renal insufficiency at an incidence rate of 10.13 events per 1,000 patient-years (**Table 2**). In multivariate analyses, the risk factors for renal insufficiency were DM (hazard ratio [HR]: 13.72, 95% confidence interval [CI]: 4.39 - 42.91; P <0.001), dyslipidemia (HR: 3.10, 95% CI: 1.25 – 7.69; P = 0.01), and AIDS-defining illness (HR: 2.48, 95% CI: 1.05 – 5.84; P = 0.04). Among the cART-related risk factors for the development of renal insufficiency, tenofovir exposure for more than 1 year (HR: 2.41, 95% CI: 1.01 – 5.77; P = 0.047) and non-nucleoside reverse transcriptase inhibitor (NNRTI) exposure for more than 1 year (HR: 3.88, 95% CI: 1.30 – 11.59; P = 0.01) were statistically significant risk factors (**Table 3**).

The incidence of renal insufficiency in PLHIV varies according to definition of renal insufficiency, type of calculation equation, income level, regions, race composition, ART status and average age ranging from 1.9 to 29.2 per 1,000 patient-year [9-11]. The incidence of renal insufficiency in our cohort study was 3.3 per 1,000 person-years. This result is similar to the incidence rate of 3.4 per 1,000 persons in a study among populations in Asia [12]. The age and sex standardized incidence of end stage kidney disease (ESKD) was 24.0 per 100,000 people using the Korean National Health Insurance Service-National Sample cohort database in 2015 [13].

Although the incidence of CKD tends to decrease in HIV patients, the incidence is still higher than the general population [14]. In this study, we observed that the tenofovir-based regimen was related to a risk factor of renal insufficiency. Tenofovir is a widely known factor that increases the risk of CKD, which may lead to renal tubular damage [15]. Several reports have documented a higher incidence of CKD with tenovovir-based regimens [12, 16]. We performed the analysis about tenofovir without distinguishing between tenofovir disoproxil fumarate (TDF) and tenofovir alafenamide (TAF). TAF is a prodrug of tenofovir and is known to have low nephrotoxicity due to the low concentration of tenofovir in plasma [17]. Therefore, there is a possibility that the incidence of renal insufficiency in patients taking TAF would be lowered. In our study, taking NNRTIs for >1 year was considered a risk factor for renal insufficiency. The reason for this finding remains unclear. However, the possibility that renal insufficiency occurred in patients diagnosed HIV long time age who maintain NNRTIs or cannot change NNRTIs to other drug due to poor compliance should be considered, rather than the possibility of drug toxicity. Further research is required to evaluate this finding. The CD4 T-cell count and HIV viral load at the time of enrollment were not statistically significant risk factors. However, the presence of AIDS-defining illness was a statistically significant risk factor. Thus, well-controlled HIV infection can reduce the incidence of renal insufficiency. In our study, the risk factors for renal insufficiency among patients with NCDs were DM and dyslipidemia. DM and dyslipidemia are an underlying disease that often accompanies HIV infections [18]. Especially, dyslipidemia may be induced by a kind of cART and natural course of HIV infection involves characteristic changes in lipid levels [19, 20]. In advanced HIV stages, triglyceride and very low density lipoprotein cholesterol are elevated [20]. DM and dyslipidemia are important risk factors for CKD and should be carefully managed. Our study had several limitations. First, the study was conducted with a small sample size and included only men due to the small number of women. Among female PWHIV, only 59 people were available for analysis, and none of them developed renal insufficiency. A further large study would be performed involving women. Second, we performed the analysis about tenofovir without distinguishing between TDF and TAF. However, considering the time when TAF was started in Korea since 2017, it is unlikely that many patients taking TAF were included. The incidence of renal insufficiency in HIV-infected men in this study was 3.3 per 1,000 patient-years. DM, dyslipidemia, Tenofovir or NNRTI exposure for >1 year, and AIDS-defining illness were risk factors for renal insufficiency.

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Table 1. Demographic and clinical characteristic of patients with and without renal insufficiency at baseline

Characteristics	Overall (n = 830)	Incident renal insufficiency		*P*-value[a]
		Yes (n = 32)	No (n = 798)	
Age (years) [n (%)]				<0.0001
<40	410 (49.4)	2 (6.2)	408 (51.1)	
40 - 49	227 (27.4)	14 (43.8)	213 (26.7)	
50 - 59	138 (16.6)	10 (31.3)	128 (16.0)	
>60	55 (6.63)	6 (18.8)	49 (6.1)	
BMI (kg/m^2) [n (%)]				0.469
<18.5	62 (7.5)	1 (3.1)	61 (7.6)	
18.5 - 22	442 (53.3)	17 (53.1)	425 (53.3)	
23 - 25	152 (18.3)	9 (28.1)	143 (17.9)	
>25	174 (21.0)	5 (15.6)	169 (21.2)	
Mode of transmission [n (%)]				0.440
Homosexual	310 (37.4)	11 (34.3)	299 (37.5)	
Heterosexual	271 (32.7)	13 (40.6)	258 (32.3)	
Bisexual	219 (26.4)	6 (18.8)	213 (26.7)	
Unknown	30 (3.6)	2 (6.2)	28 (3.5)	
Diabetes mellitus [n (%)]				0.002
Yes	49 (5.9)	7 (21.9)	42 (5.3)	
No	781 (94.1)	25 (78.1)	756 (94.7)	
Hypertension [n (%)]				0.060
Yes	75 (9.0)	6 (18.8)	69 (8.6)	
No	755 (91.0)	26 (81.3)	729 (91.4)	
Dyslipidemia [n (%)]				0.001
Yes	96 (11.6)	11 (34.3)	85 (10.7)	
No	734 (88.4)	21 (65.6)	713 (89.3)	
eGFR, mL/min/1.73 m^2 [mean (SD)]	105.5 (130.7)	79.3 (13.1)	106.6 (133.1)	<0.0001
CD4 [n (%)]				0.146
≤100	65 (7.8)	5 (15.6)	60 (7.5)	
101 - 200	98 (11.8)	6 (18.8)	92 (11.5)	
201 - 350	195 (23.5)	5 (15.6)	190 (23.8)	
>351	472 (56.9)	16 (50.0)	456 (57.2)	
HIV viral load [n (%)]				0.047
<400 copies/mL	486 (58.6)	20 (62.5)	466 (58.4)	
400 - 50,000 copies/mL	231 (27.8)	4 (12.5)	227 (28.4)	
>50,000 copies/mL	113 (13.6)	8 (25.0)	105 (13.2)	
AIDS-defining illness [n (%)]				0.108
Yes	162 (19.5)	10 (31.3)	153 (19.2)	
No	668 (80.5)	22 (68.8)	645 (80.8)	
Years on antiretroviral treatment [n (%)]				0.663
<2	530 (63.9)	19 (59.4)	511 (64.0)	
2 - 5	226 (27.2)	9 (28.1)	217 (27.2)	
>5	74 (8.9)	4 (12.5)	70 (8.8)	
Tenofovir exposure [n (%)]				0.174
Never	438 (52.8)	12 (37.5)	426 (53.4)	
Less than 1 year	138 (16.6)	7 (21.9)	131 (16.4)	
1 year or more	254 (30.6)	13 (40.6)	241 (30.2)	
NRTI exposure [n (%)]				0.041
Never	153 (18.4)	1 (3.1)	152 (19.0)	
Less than 1 year	148 (17.8)	6 (18.8)	142 (17.8)	
1 year or more	529 (63.7)	25 (78.1)	504 (63.2)	
NNRTI exposure [n (%)]				0.268
Never	572 (68.9)	19 (59.4)	553 (69.3)	
Less than 1 year	72 (8.7)	2 (6.2)	70 (8.8)	
1 year or more	186 (22.4)	11 (34.4)	175 (21.9)	
Protease inhibitor exposure [n (%)]				0.009
Never	362 (43.6)	6 (18.8)	356 (44.6)	
Less than 1 year	132 (15.9)	8 (25.0)	124 (15.5)	
1 year or more	336 (40.5)	18 (56.3)	318 (39.8)	

[a]Significance of difference between patient with and without renal insufficiency; Chi-square test for categorical variables and paired *t*-test for continuous variables were used.
BMI, body mass index; eGFR, estimated glomerular filtration rate; SD, standard deviation; CD4, cluster of differentiation 4; HIV, human immunodeficiency virus; AIDS, acquired immunodeficiency syndrome; NRTI, nucleoside reverse transcriptase inhibitor except tenofovir; NNRTI, non-nucleoside reverse transcriptase inhibitor.

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Table 2. Crude incidence rates of renal insufficiency per 1,000 person-years during the 12-year follow-up period

Characteristics	No. of total case	No. of events (%)	Person-year	Incidence rate
Overall	830	32 (3.9)	9,684	3.30
Age (years)				
<40	410	2 (0.5)	4,903	0.41
40 - 49	227	14 (6.2)	2,611	5.36
50 - 59	138	10 (7.3)	1,564	6.39
>60	55	6 (10.9)	605	9.91
BMI (kg/m^2)				
<18.5	62	1 (1.6)	734	1.36
18.5 - 22	442	17 (3.9)	5,163	3.29
23 - 25	152	9 (5.9)	1,751	5.14
>25	174	5 (2.9)	2,035	2.46
Mode of transmission				
Homosexual	310	11 (3.6)	3,613	3.04
Heterosexual	271	13 (4.8)	3,138	4.14
Bisexual	219	6 (2.7)	2,588	2.32
Unknown	30	2 (6.7)	345	5.80
Diabetes mellitus				
Yes	49	7 (14.3)	585	11.96
No	781	25 (3.2)	9,099	2.75
Hypertension				
Yes	75	6 (8.0)	911	6.59
No	755	26 (3.4)	8,773	2.96
Dyslipidemia				
Yes	96	11 (11.5)	1,086	10.13
No	734	21 (2.9)	8,598	2.44
CD4 (cells/mm^3)				
≤100	65	5 (7.7)	731	6.84
101 - 200	98	6 (6.1)	1,127	5.32
201 - 350	195	5 (2.6)	2,300	2.17
>351	472	16 (3.4)	5,525	2.90
HIV viral load				
<400 copies/mL	486	20 (4.1)	5,665	3.53
400 - 50,000 copies/mL	231	4 (1.7)	2,741	1.46
>50,000 copies/mL	113	8 (7.1)	1,277	6.26
Years on antiretroviral treatment				
<2	530	19 (3.6)	6,196	3.07
2 - 5	226	9 (4.0)	2,622	3.43
>5	74	4 (5.4)	866	4.62
AIDS-defining illness				
Yes	162	10 (6.2)	1,925	5.20
No	668	22 (3.3)	7,759	2.84
Tenofovir exposure				
Never	438	12 (2.7)	5,153	2.33
Less than 1 year	138	7 (5.1)	1,590	4.40
1 year or more	254	13 (5.1)	2,941	4.42
NRTI exposure				
Never	153	1 (0.6)	1,825	0.55
Less than 1 year	148	6 (4.1)	1,728	3.47
1 year or more	529	25 (4.7)	6,131	4.08
NNRTI exposure				
Never	572	19 (3.3)	6,693	2.84
Less than 1 year	72	2 (2.8)	848	2.36
1 year or more	186	11 (5.9)	2,143	5.13
Protease inhibitor exposure				
Never	362	6 (1.7)	4,299	1.40
Less than 1 year	132	8 (6.1)	1,522	5.26
1 year or more	336	18 (5.4)	3,863	4.66

BMI, body mass index; CD4, cluster of differentiation 4; HIV, human immunodeficiency virus; AIDS, acquired immunodeficiency syndrome; NRTI, nucleoside reverse transcriptase inhibitor except tenofovir; NNRTI, non-nucleoside reverse transcriptase inhibitor.

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Table 3. Multivariate analysis of risk factors for incident renal insufficiency

Variables	HR (95% CI)	*P*-value[a]
Age (years)	1.05 (1.01 – 1.09)	0.03
BMI (kg/m^2)		
<18.5	0.43 (0.04 – 4.19)	0.47
18.5 - 22	1.00 (Ref)	
23 - 25	0.66 (0.24 – 1.81)	0.42
>25	0.42 (0.13 – 1.37)	0.15
Mode of transmission		
Homosexual	1.24 (0.50 – 3.08)	0.64
Heterosexual	1.00 (Ref)	
Bisexual	0.31 (0.10 – 0.94)	0.04
Unknown	2.91 (0.58 – 14.50)	0.19
Diabetes mellitus		
Yes	13.72 (4.39 – 42.91)	<0.0001
No	1.00 (Ref)	
Hypertension		
Yes	0.59 (0.18 – 1.97)	0.39
No	1.00 (Ref)	
Dyslipidemia		
Yes	3.10 (1.25 – 7.69)	0.01
No	1.00 (Ref)	
Baseline eGFR, mL/min/1.73 m^2	0.91 (0.88 – 0.94)	<0.0001
CD4 at enrollment		
>350	1.00 (Ref)	
201 - 350	0.47 (0.15 – 1.52)	0.21
101 - 200	1.38 (0.42 – 4.530)	0.60
≤100	2.78 (0.73 – 10.65)	0.14
HIV viral load at enrollment		
≤400 copies/mL	1.00 (Ref)	
>400 copies/mL	1.23 (0.49 – 3.10)	0.65
AIDS-defining illness		
Yes	2.48 (1.05 – 5.84)	0.04
No	1.00 (Ref)	
Years on antiretroviral treatment		
<2	1.00 (Ref)	
2 - 5	0.49 (0.18 – 1.31)	0.15
>5	1.38 (0.40 – 4.84)	0.61
Tenofovir exposure		
Never	1.00 (Ref)	
Less than 1 year	1.45 (0.47 – 4.46)	0.52
1 year or more	2.41 (1.01 – 5.77)	0.047
NRTI exposure		
Never	1.00 (Ref)	
Less than 1 year	0.96 (0.08 – 11.96)	0.98
1 year or more	1.68 (0.15 – 18.31)	0.67
NNRTI exposure		
Never	1.00 (Ref)	
Less than 1 year	1.73 (0.32 – 9.27)	0.52
1 year or more	3.88 (1.30 – 11.59)	0.01
Protease inhibitor exposure		
Never	1.00 (Ref)	
Less than 1 year	3.40 (0.79 – 14.61)	0.10
1 year or more	2.81 (0.73 – 10.85)	0.13

[a]Cox proportional hazards regression model was adjusted for age, body mass index, mode of transmission, history of diseases (diabetes mellitus, hypertension, and dyslipidemia), level of eGFR, CD4, HIV viral load, AIDS-defining illness, Years on antiretroviral treatment, tenofovir exposure, NRTI exposure, NNRTI exposure, and protease inhibitor exposure.
HR, hazard ratio; CI, confidence interval, BMI, body mass index; eGFR, estimated glomerular filtration rate; CD4, cluster of differentiation 4; HIV, human immunodeficiency virus; AIDS, acquired immunodeficiency syndrome; NRTI, nucleoside reverse transcriptase inhibitor except tenofovir; NNRTI, non-nucleoside reverse transcriptase inhibitor.

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