Overall agreement between eGFR estimates obtained with the CKD-EPI, MDRD and CG formulae in patients with advanced HIV diseases

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Abstract

Background: Traditional CKD risk factors as well as HIV-related factors are major determinants of the prevalence of renal diseases among HIV patients. Few equations have been used in clinical practice for calculating creatinine clearance, however, the accuracy of these formulae in HIV patients has been different. Our goal was to evaluate the reliability of all three equations (Chronic Kidney Disease Epidemiology Collaboration, Modification of Diet in Renal Disease, and Cockcroft-Gault) to estimate GFR in HIV-infected patients. **Materials and method:** We conduct a retrospective, observational cohort study of patients with HIV infection who are first time in care at selected HIV OPCs in Vietnam. **Results:** In 1108 patients eligible for analysis, a major patient was in HIV clinical stage 3 and 4 with a median age of 36, and median serum creatinine of 0.89 mg/dL. eGFR calculated by CG equation was lower than CKD-EPI formulae in overall except overweight patients ($p<0.05$, paired t-test) while the similar results were observed in both CKD-EPI and MRDR ($p=0.144$, paired t-test). **Conclusion:** There was a substantial agreement between CKD-EPI and MDRD eGFR, agreement percentage of 90.1 and MDRD was reliable as CKD-EPI to calculate eGFR in the HIV population.

Keywords*: HIV, eGFR, CKD-EPI, MRDR, CG.*

1. INTRODUCTION

Human Immunodeficiency Virus (HIV) has become a popular and serious health problem worldwide, as the number of people living and newly infected with HIV in 2021 are 38.4 million and 1.5 million people respectively [1]. Vietnam, as a part of Asia and the Pacific which was ranked as the 3rd of HIV-large scale epidemiology region, has also suffered from this disease of the century. According to data from The Joint United Nations Programme on HIV/AIDS (UNAIDS) in 2017, Vietnam had 250000 (220000-280000) people living with HIV and 8600 (6600 11000) cases of death-related AIDS in all ages [1]. One of the leading causes of mortality in HIV-positive patients is renal dysfunction, as many researchers have reported the high prevalence of this complication, ranging between 20.4% and 33.5% [2],[3].

Renal disease is common among HIV-infected individuals due to both direct (e.g., renal cell damaged by apoptosis, immuno-complex formation in HIV-associated nephropathy) and indirect causes (e.g., nephrotoxic antiretroviral therapy including tenofovir) in etiology [4],[5]. Guidelines for the management of patients with HIV/AIDS, including from the Vietnam Minister of Health, emphasize the importance of early recognition of renal insufficiency to prevent progression and limit complications [6] and adjusting the dose of the antiretroviral drug by creatinine clearance [7]. Numerous equations have been used in clinical to estimate creatinine clearance or Glomerular Filtration Rate (GFR) in clinical practice, such as Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI), Modification of Diet in Renal Disease (MDRD) and Cockcroft-Gault (CG) [8], [9], [10]. However, the accuracy of these equations among HIV-population has been different among studies, as CKD-EPI has shown to be the most precise calculation to evaluate renal function while the others have not been validated [6], [11], [12].

In Vietnam, there haven't had any research evaluate the reliability of all three formulae to estimate GFR in HIV-infected individuals, so we still haven't had any data of which formula is the most accurate. Additionally, there have been few studies looking specifically at impaired renal function and how it affects the outcome in Vietnamese HIV-infected populations [13]. Therefore, we established a study "Estimation of glomerular filtration rate in advanced HIV infected patients" to assess the overall agreement between eGFR estimates obtained with the CKD-EPI, MDRD and CG formulae.

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2. METHOD

2.1. Study design and selected criteria

This is a retrospective, observational cohort study of HIV-infected patients under a multicenter, prospective, cohort evaluation of a CrAg screening program among HIV-infected patients with CD4 ≤ 100 cells/µL who are newly enrolled in care at selected HIV OPCs in Vietnam.

Study population this study was conducted in 22 outpatient clinics throughout Vietnam participating in the Vietnam Cryptococcal Retention in Care Study. We included all patients who have met the folowing criteria: 1) Aged ≥ 18 years (having passed 18th birthday using Western calendar), 2) Confirmed HIV infection HIV diagnostic testing algorithm with three tests using different HIV assays, 3) CD4 ≤ 100 cells/µL, 4) Able to provide written informed consent, 5) Enrolled at and plan to receive ongoing outpatient care at one of the selected study OPCs. We excluded the following patients: 1) Receipt of ART for more than 4 consecutive weeks within the past year.

2.2. Procedures and Sampling size

A convenience sampling method was used to include all patients with HIV infection and serum creatinine tests during the study period.

Firstly, a list of all patients with HIV infection was obtained from Microbiology Unit, Laboratory Department in 22 outpatient clinics. Afterward, information including the patient's name, age, blood collection date, and the department was extracted from the microbiology records to match with outpatient clinics identification, address, date of admission, and discharge from clinical department data. This information was then used to identify patients' full medical records. Patients' statuses were updated after 6 months and 12 months. Records that were lost to follow-up, misplaced, or did not have serum creatinine tests were not included in the study process. A clearly instructed case report form was used to collect data.

Regarding clinical and laboratory characteristics of HIV-positive patients, the following information was recorded after hospitalization: demographics (including age, gender, height and weight at baseline), clinical stage, CD4 cell counts, HBsAg, anti-HCV, serum urea and serum creatinine. The clinical outcomes were evaluated at 6 months and 12 months after enrolment.

2.3. Glomerular filtration rate definition: is the volume of fluid filtered from the renal (kidney) glomerular capillaries into Bowman's capsule per unit time

$$\text{GFR (ml/min)} = \frac{\text{Urine Concentration x Urine Flow}}{\text{Plasma Concentration}} \text{ (mL/min)}$$

Cockcroft-Gault (CG) formulae

$$\text{GFR (ml/min)} = \frac{(140 - \text{age}) \text{ x Lean Body Weight (kg)}}{\text{Serum creatinine (mg/dL) x 72}} \text{ [x 0.85 (female)]}$$

$$\text{BSA } (m^2) = \sqrt{\frac{\text{height (cm)} \times \text{weight (kg)}}{3600 \text{ (cm kg/m}^4\text{)}}}$$

$$\text{GFR CG–BSA} = (1.73 \text{ m}^2 \times \text{GFR})/\text{BSA}$$

Modification of Diet in Renal Disease (MDRD) formulae

$$\text{GFR} = 186.3 \text{ x [creatinine (mg/dL)]}^{-1.154} \text{ x [age (years)]}^{-0.203} \text{ x [0.742 (female)]}$$

$$\text{x [1.21 (black)]}$$

Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formulae: GFR estimated with serum creatinine (mg/dL)

1. Female, creatinine ≤ 0.7: GFR = 144 x $(\text{creatinine}/0.7)^{-0.329}$ x $(0.993)^{\text{age}}$
2. Female, creatinine > 0.7: GFR = 144 x $(\text{creatinine}/0.7)^{-1.209}$ x $(0.993)^{\text{age}}$
3. Male, creatinine ≤ 0.9: GFR = 141 x $(\text{creatinine}/0.9)^{-0.411}$ x $(0.993)^{\text{age}}$
4. Male, creatinine > 0.9: GFR = 141 x $(\text{creatinine}/0.9)^{-1.209}$ x $(0.993)^{\text{age}}$

2.4. Statistical analysis

Data were entered into an electronic database using Epidata. All analyses were performed using STATA version 13.0. The quantitative variables with normal distribution were presented as mean (95% confidence interval (95% CI)), and those with non-normal distribution were presented as median (interquartile range IQR). The categorical variables were presented as percentages. To compare the difference between two and over independent groups, the t-test, and Man-Whitney test was used for the continuous variable, and Chi-squared and Fisher's exact test were used for the categorical variable as appropriate. The kappa statistic was used to assess the agreement between eGFR stages defined by CG, MDRD, and CKD-EPI. The Bland-Altman test was used to graphically illustrate the limits of agreements between three formulas, although the data were not normally distributed. The standard deviation (SD) of the difference between the three values was used to estimate the limit of agreement. All statistical tests are two-sided and associations with P-value ≤ 0.05 were considered statistically different. The association between renal function estimations and 6-month and 12-month mortality was assessed by logistic regression and receiver operating curve with statistical comparisons of the area under the curve (AUC). Models were adjusted for age, gender, BMI, clinical stage at baseline, CD4 cell counts at baseline, HBsAg and anti-HCV results.

2.5. Ethical issue

All patient information was kept confidential and anonymous. The inform consent was waived due to the retrospective nature of the study.

3. RESULT

3.1. Study population characteristics

Table 1. Baseline characteristics of study population

Characteristic	n	%
All	1108	100%
Gender		
Female	286	25.8%
Male	822	74.2%
BMI		
Underweight	544	49.1%
Normal weight	547	49.4%
Overweight	17	1.5%
Clinical stage at baseline	365	32.9%
Stage 1 and 2	743	67.1%
Stage 3 and 4		
CD4 cell counts at baseline	828	74.3%
< 50	280	25.7%
50-100		
HBsAg status		
Positve	123	11.1%
Negative/Not performed	985	88.9%
Anti-HCV status		
Positve	278	25.1%
Negative/Not performed	830	74.9%
	Median	IQR
Age (year)	36	30-41
BMI (kg/m^2)	18.8	16.9-20.4
Serum creatinine (mg/dL)	0.89	0.74-1.01

Table 1 showed that the median age of the study population was 36 (IQR 30-41), median BMI was 18.8 kg/m^2 (IQR 16.9-20.4) and median serum creatinine was 0.89 mg/dL (IQR 0.74-1.01). Patients were commonly male (74.2%), underweight or normal weight (49.1% and 49.4%, respectively). At baseline, 67.1% of the study group was in HIV clinical stage 3 and 4, 74.3% had CD4 cell counts lower than 50 compared to 25.7% counts between 50 and 100. Also, the proportion of patients had positive HBV and HCV results were 11.1% and 25.1% respectively.

Comparison of estimated GFR calculated by three equations

According to table 2, the mean eGFR of the study population calculated by both CKD-EPI and MDRD equation was approximately the same overall (103, p=0.144, paired t-test) and in most subgroups. eGFR calculated by MDRD was statistically higher than CKD-EPI in subgroups male, underweight, clinical stage 3-4, and HCV-positive result (p<0.05, paired t-test). Female patients had higher eGFR calculated by the CKD-EPI equation than the MDRD equation (p=0.002, paired t-test). In contrast, the mean eGFR defined by the CG equation was statistically lower than the CKD-EPI equation in overall and most subgroups except overweight patients (p<0.05, paired t-test)

Table 2. Comparison of eGFR by MDRD and CG to CKD-EPI equation

Characteristic		CKD-EPI eGFR (mL/min/1.73m²)	MDRD eGFR (mL/ min/1.73m²)	p value	CG eGFR (mL/min /1.73m²)
Overall		103 (89-117)	103 (84-117)	0.144[a]	94 (78-107)
Gender	Female	100 (84-117)	98 (77-114)	0.002[a]	93 (76-108)
	Male	103 (91-117)	105 (86-118)	0.001[a]	95 (79-106)
BMI	Underweight	104 (90-119)	106 (86-122)	0.012[a]	92 (76-105)
	Normal	101 (88-115)	101 (84-114)	0.377[a]	96 (81-109)
	Overweight	96 (81-117)	96 (77-119)	0.948[a]	105 (82-125)
Clinical stage at baseline	Stage 1 and 2	101 (88-115)	100 (84-113)	0.120[a]	94 (79-106)
	Stage 3 and 4	103 (90-118)	105 (85-120)	0.011[a]	94 (78-108)
CD4 cell counts classification	< 50	103 (90-117)	104 (85-118)	0.163[a]	94 (78-106)
	50-100	102 (88-116)	102 (82-116)	0.620[a]	95 (79-108)
HBsAg status	Positve	103 (90-117)	103 (85-117)	0.897[a]	94 (78-105)
	Negative/Not performed	103 (89-117)	103 (84-117)	0.112[a]	94 (78-108)
Anti-HCV status	Positve	104 (93-117)	106 (87-120)	0.019[a]	96 (79-108)
	Negative/Not performed	102 (89-117)	102 (84-117)	0.753[a]	94 (78-107)

[a]paired t-test

Table 3. Agreement of eGFR calculated by CKD-EPI and MDRD equations

eGFR classification		eGFR–CKD-EPI (mL/min/1.73 m²)					Total
		≥ 90	60-90	30-60	15-30	< 15	
eGFR-MDRD (mL/min/1.73 m²)	≥ 90	719 (88.0%)	1 (0.4%)	0	0	0	720 (65.0%)
	60 - 90	98 (12.0%)	255 (95.5%)	0	0	0	353 (31.8%)
	30 - 60	0	11 (4.1%)	21 (100%)	0	0	32 (2.9%)
	15 - 30	0	0	0	3 (100%)	0	3 (0.3%)
	< 15	0	0	0	0	0	0
Total		817 (73.7%)	267 (24.1%)	21 (1.9%)	3 (0.3%)	0	1108 (100%)

Bold numbers in table 3 indicated the number of patients classified to the same CKD stage according to both compared methods. Chronic kidney disease as eGFR < 60 was present at baseline in 2.2% (CKD-EPI) and 3.2% (MDRD). Substantial agreement was observed between CKD-EPI and MDRD- derived eGFR band, as the agreement percentage was 90.1% and kappa = 0.7762 (p < 0.001, kappa statistic). The best agreement was observed for those with eGFR < 90.

Table 4. Agreement of eGFR calculated by CKD-EPI and CG equations

eGFR classification		eGFR CKD-EPI (mL/min/1.73 m2)					Total
		≥ 90	60 - 90	30 - 60	15 - 30	< 15	
eGFR CG (mL/min/1.73 m2)	≥ 90	589 (72.1%)	0	0	0	0	589 (53.2%)
	60 - 90	228 (27.9%)	237 (88.8%)	1 (4.8%)	0	0	466 (42.0%)
	30 - 60	0	30 (11.2%)	19 (90.4%)	0	0	49 (4.4%)
	15 - 30	0	0	1 (4.8%)	3 (100%)	0	4 (0.4%)
	< 15	0	0	0	0	0	0
Total		817 (73.7%)	267 (24.1%)	21 (1.9%)	3 (0.3%)	0	1108 (100%)

Bold numbers in table 4 indicated the number of patients classified to the same CKD stage according to both compared methods. Chronic kidney disease as eGFR < 60 was present at baseline in 2.2% (CKD-EPI) and 4.8% (CG). Moderate agreement was observed between CKD-EPI and CG derived eGFR band, as agreement percentage was 76.53% and kappa = 0.536 (p < 0.001, kappa statistic). The best agreement observed for those with eGFR < 90. Nearly 28% of patients with stage 1 eGFR measurements by CKD-EPI had stage 2 measurements by CG.

Table 5. Agreement of eGFR calculated by CKD-EPI and CG equations in patient with CD4 cell counts classification <50

eGFR classification		eGFR CKD-EPI (mL/min/1.73 m²)				Total
		≥ 90	60 - 90	30 - 60	15 - 30	
eGFR CG (mL/min/1.73 m²)	≥ 90	443 (71.6%)	0	0	0	443 (53.5%)
	60 - 90	176 (28.3%)	169 (88.9%)	1 (6.3%)	0	346 (41.8%)
	30 - 60	0	21 (11.1%)	14 (87.4%)	0	35 (4.2%)
	15 - 30	0	0	1 (6.3%)	3 (100%)	4 (0.5%)
Total		619 (73.7%)	190 (24.1%)	16 (1.9%)	3 (0.3%)	828 (100%)

Table 6. Areement of eGFR calculated by CKD-EPI and CG equations in patient with CD4 cell counts classification > 50

eGFR classification		eGFR CKD-EPI (mL/min/1.73 m²)			Total
		≥ 90	60 - 90	30 - 60	
eGFR CG (mL/min/1.73 m2)	≥ 90	**146 (73.7%)**	0	0	146 (52.1%)
	60–90	52 (26.3%)	**68 (88.3%)**	0	120 (42.9%)
	30–60	0	9 (11.7%)	**5 (100%)**	14 (5.0%)
Total		198 (70.8%)	77 (27.5%)	5 (1.8%)	280 (100%)

According to table 5 and 6, the subgroup with CD4 cell counts classification > 50 witnessed moderate agreements between CKD-EPI and CG derived eGFR band, as agreement percentage was 76.0% and kappa = 0.523 (p < 0.001, kappa statistic). Similar results were found in CD4 cell counts classification < 50 subgroup (78.2%, kappa = 0.575).

Table 7. Agreement of eGFR calculated by three equations in subgroups

Characteristic		MDRD vs CKD-EPI kappa	p	CG vs CKD-EPI kappa	p	CG vs MDRD kappa	p
Gender	Female	0.773	0.001	0.627	0.001	0.783	0.001
	Male	0.775	0.001	0.501	0.001	0.641	0.001
BMI	Underweight	0.755	0.001	0.398	0.001	0.594	0.001
	Normal	0.795	0.001	0.679	0.001	0.774	0.001
	Overweight	0.790	0.001	0.884	0.001	0.677	0.001
Clinical stage at baseline	Stage 1 and 2	0.764	0.001	0.592	0.001	0.701	0.001
	Stage 3 and 4	0.781	0.001	0.501	0.001	0.651	0.001
CD4 cell counts classification	< 50	0.780	0.001	0.523	0.001	0.664	0.001
	50-100	0.765	0.001	0.575	0.001	0.728	0.001
HBsAg status	Positve	0.783	0.001	0.556	0.001	0.688	0.001
	Negative/Not performed	0.775	0.001	0.554	0.001	0.679	0.001
Anti-HCV status	Positve	0.758	0.001	0.527	0.001	0.675	0.001
	Negative/Not performed	0.782	0.001	0.538	0.001	0.681	0.001

Overall, the kappa values of agreement of eGFR calculated by MDRD vs CKD-EPI equations were approximately similar between the study population (0.77) and all the patient subgroups (p<0.001). Although there was substantial agreement between eGFR measured by CG vs MDRD in most subgroups, the same agreements of eGFR calculated by CG vs CKD-EPI equations were only seen when patients were female, with normal BMI, and overweight, whereas all other subgroups witnessed moderate agreement with kappa indexes between 0.5 to 0.6 (p<0.001).

4. DISCUSSION

Some studies of the general population have typically compared CG, MDRD and CKD-EPI equations, and found the CKD-EPI equation to be closer to the gold standard GFR measurements (using creatinine in 24 hours, inulin, etc). However, majority of epidemiological studies in HIV-infected populations and also our study did not have a gold standard eGFR measurement. As CKD-EPI has shown to be the most precise calculation to evaluate renal function while the others have not been validated [6], [11], [12], we evaluated the level of accuracy in calculating eGFR by CG and MDRD equations by comparing them to eGFR by CKD-EPI.

The mean eGFRs and kappa values were approximately similar between the study population and all patient subgroups (by age, gender, BMI, clinical stage at baseline, CD4 cell counts at baseline, HbsAg status, Anti-HCV status), although mean eGFR calculated by CKD-EPI was somewhat higher than by MDRD, resulting in smaller numbers of patients with eGFR < 90 mL/min/1.73 m^2 (24.1% vs 31.8% respectively). The mean eGFR difference overall between these two equations was just 0.6 mL/min/1.73 m^2. Also in our study chronic kidney disease as eGFR < 60 was present at baseline in 2.2% (CKD-EPI) and 3.2% (MDRD), respectively. This finding correlated favorably with study by Fowzia Ibrahim et al (2.0% and 2.3% respectively). Nonetheless, l substantial agreement was observed between CKD-EPI and MDRD derived estimated GFR band, as agreement percentage was 90.1%, kappa index = 0.7762 and best agreement observed for those with eGFR < 90. These finding coincided exactly with the previous studies of M. P. Cristelli (91.2%, kappa = 0.803) [11] and Fowzia Ibrahim et al (kappa = 0.701) [13].

As our results stated that the highest agreement

was in the subgroup with GFR < 90 ml/min/1.73 m^2, A.S. Levey et al [8] concluded that the CKD-EPI equation was as accurate as the MDRD equation in the subgroup with estimated GFR < 60 and substantially more accurate in the subgroup with estimated GFR > 60. Whereas in Fowzia Ibrahim et al [13], the best agreements were observed for those with eGFR < 30 or > 90. The reason for our different results might be our study populations were smaller than the populations in the two studies. Although the study in the general population comparing CKD-EPI and MDRD against gold standard GFR will provide less bias, we can conclude that MDRD and CKD-EPI equations showed a high degree of agreement in stratifying CKD patients by baseline estimated GFR, therefore MDRD can be a reliable tool to calculate eGFR in HIV population.

The proportion of chronic kidney disease as GFR < 60 estimated by CGBSA in our study was 4.8%. This finding correlated favorably with Daisuke Mizushima et al (7.3%) [14] and A Mocroft et al (5.2%) [15]. The mean eGFR defined by the CG equation was statistically lower than the CKD-EPI equation in overall and most subgroups, as the mean difference between the estimates from CG-BSA and CKD-EPI was 8.4 ml/min/1.73m^2, higher than the value reported by A Mocroft et al (0.5 ml/min/1.73 m^2). We also found that lower values of kappa score and moderate agreement between these equations were seen in our study than those by A Mocroft et al (0.536 and 76.53% vs 0.75 and 85.7% respectively) [15]. The reason for these differences might be due to the study population in A Mocroft et al study being higher (133873 eGFRs) than in our study. Consistent with G Ravasi et al [16], we observed that substantial agreement was observed between CG and MDRD-derived estimated GFR band, as kappa indexes were around 0.7 in most subgroups. As nearly 28% of patients with stage 1 eGFR measurements by CKD-EPI had stage 2 measurements by CG, we believe that CG may overestimate the severity of renal impairment in the HIV-infected population, therefore reclassifying more patients into worse renal function categories. Our data are consistent with observations in the general population and some other studies on the HIV population like Daniel Yilma et al [17] and Aghogho A Okparavero et al [18].

5. CONCLUSION

5.1. Chronic kidney disease as eGFR < 60 was present at baseline in 2.2% (CKD-EPI), 3.2% (MDRD) and 4.8% (CG) patients.

5.2. Substantial agreement was observed between CKD-EPI and MDRD eGFR, as agreement percentage was 90.1%, kappa value = 0.7762. MDRD was reliable as CKD-EPI to calculate eGFR in HIV population.

5.3. Moderate agreement was observed between CKD-EPI and CG eGFR, as agreement percentage was 76.53%, kappa value = 0.536.

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