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Performance and Cut-Off of Three Glomerular Filtration Rate Estimation Equations in a Population of Cameroonian Patients with Chronic Kidney Disease Stages 3 - 5 Non Dialyzed

Mahamat Maimouna[1,2*], Abdou Wouoliyou Nsounfon[1,3], Guy Sadeu Wafeu[4], Louis Marcel Bonga Ngapet[5], Aristide Nono[2], François Folefack Kaze[1,6], Gloria Ashuntantang[1,2]

[1]Department of Internal Medicine and Specialties, Faculty of Medicine and Biomedical Sciences, University of Yaoundé I, Yaoundé, Cameroon
[2]Nephrology Department, Yaoundé General Hospital, Yaoundé, Cameroon
[3]Internal Medicine Department, Central Hospital of Yaoundé, Yaoundé, Cameroon
[4]Centre for Research on Filariasis and Other Tropical Diseases, Yaoundé, Cameroon
[5]Subdivision Medical Center of Djebem, Demdeng, Cameroun
[6]Nephrology Department, University Teaching Hospital of Yaoundé, Yaoundé, Cameroon
Email: *m_mahamat@yahoo.fr

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Abstract

Background: Diagnosis of End-stage kidney disease (ESKD) is based on the glomerular filtration rate estimation equation. However, discrepancies have been observed in those formulas for the African population. We evaluated the performance of the Modification of Diet in Renal Disease (MDRD), Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI), and Cockcroft-Gault (CG) equations against measured glomerular filtration (mGFR) to diagnose end-stage renal disease in 27 patients with CKD stage 3 - 5. **Methods:** Consenting non-dialyzed chronic kidney disease patients consulting at the outpatient department in a nephrology referral center in Yaoundé were enrolled. We obtained mGFR from the average of Urea Clearance and Creatinine Clearance. These were obtained from validated 24-hour urine samples. Statistical comparison of the eGFR with measured GFR was performed using Bland-Altman analysis and Kappa statistics. The Receiver Operating Curve (ROC) was used to determine the best cut-off of eGFR to diagnose ESKD. **Results:** The three equations had a good accuracy for diagnosing ESKD with c-statistics ranging from 0.97 to 0.98. Best cut-offs of eGFR for diagnosis of ESKD were 16.25 ml/min/1.73m^2 for CKD-EPI, 18

ml/min/1.73m^2 for MDRD, and 16.8 ml/min/1.73m^2 for CG. Using these cut-offs, the agreement with mGFR was almost perfect for CKD-EPI (kappa = 0.852) and MDRD (kappa = 0.852), and moderate for CG (kappa = 0.78). **Conclusion:** The CKD-EPI equation seems to be slightly better than that of MDRD and CG in diagnosing ESKD in sub-Saharan Africans. The improvement of agreement while using a higher cut-off of more than 15 ml/min/1.73m^2 calls for revision for better accuracy.

Keywords

Performance, GFR Equations, Non-Dialyzed CKD, Sub-Saharan Africa

1. Introduction

Chronic Kidney Disease (CKD) is becoming a major public health problem worldwide, and its prevalence is constantly increasing in low and middle-income countries. It is estimated that by 2030, more than 70 percent of patients with End Stage Kidney Disease (ESKD) will be residents of developing countries [1] [2]. At this stage, kidney replacement therapy (KRT) is the major modality used for management. This therapy modality is expensive for African patients. In Nigeria, with the average yearly cost of hemodialysis treatment at about 3.3million naira (US $22,000), and about 50% of the Nigerian population living below the global poverty level, only very few individuals can afford hemodialysis treatment [3]. Then, efforts have to be directed toward screening and early diagnosis of kidney disease with non-expensive tools. Therefore, the accurate and unbiased estimation of glomerular filtration rate (GFR), the best indicator of overall kidney function, is important for making diagnoses and therapeutic decisions in clinical practice [4].

The gold standard for evaluating GFR is the measured clearance of such exogenous markers as inulin. However, because of difficulty in use, expense, radiation exposure, and radionuclide regulatory requirements, these methods have limited use in the routine laboratory and are typically confined to the research setting. GFR is often estimated clinically from serum concentrations of endogenous creatinine [4]. In 2002, Guidelines developed by the National Kidney Foundation recommended the use of creatinine-based equations to estimate the level of GFR, such as the Modification of Diet in Renal Disease (MDRD) Study and Cockcroft-Gault (CG) equations [5]. Recently, the Kidney Diseases Improving Global Outcomes (KDIGO) organization recommended that creatinine-based eGFR should be reported using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation [6]. In practice, these equations are preferred as GFR determination is a simple, non-expensive, and internationally standardized test. Nonetheless, these equations have originally been developed and evaluated in North American patient cohorts with mild CKD and therefore might not simply be applicable to Sub-Saharan African (SSA) cohorts. Furthermore, discrepancies in their performances have been reported in sub-Saharan Africa [7] [8].

The CKD-EPI and MDRD equations performed better without the race coefficient in participants with GFR ≥ 60 mL/min/1.73m^2, and cystatin C did not improve the performance of the equations. Bukabau *et al.* have suggested that MDRD and CKD-EPI equations without ethnic factors had better performance than the same equations with ethnic factors; the equations using Cystatine C (alone or combined with SCr) performed better than the creatinine-based equations [9]. But this study was performed in the Congolese healthy population.

According to the K/DOQI CKD guidelines, the stage of kidney disease should be determined for each CKD patient, and the clinical action plan should be developed on the basis of the stage of disease [5]. Thus, inaccurate estimation of the GFR may lead to misclassification of patients and lead to inappropriate evaluation or treatment of these patients [10] [11], particularly ESKD patients.

We aim to evaluate the performance of the MDRD study, CKD-EPI, and CG equations against measured glomerular filtration rate (mGFR) to diagnose end-stage kidney disease in patients with CKD stage 3 - 5.

2. Methods

2.1. Study Setting and Population

We conducted a 5-month cross-sectional study at the outpatient department in a nephrology referral center in Yaoundé, Cameroon. We consecutively enrolled 27 non-dialysed patients aged more than 21 years, with CKD stages 3 to 5 (K/DOQI classification). Patients who had undergone an amputation or had a prosthesis, those who had the following comorbidities: Cancer, severe infection, heart or liver failure, and those with incomplete 24-hour urine collection, were excluded.

Before inclusion, we obtained a written consent from each participant after an explanation of the objectives, procedure, advantages, and disadvantages of the study. The ethical clearance was obtained from the ethical committee of Yaoundé General Hospital.

2.2. Data Collection

After informed consent, a standardized questionnaire was administered to collect data on age, gender, and comorbidities. Blood pressure (in mmHg) was measured in a sitting position on the left arm after at least 10 min of rest, using an electronic device (OMRON HEM-7222-Z intellisense). Two measures were taken 5 min apart, and the mean value was considered. We used a stadiometer (SECA®) to measure the height to the nearest 0.5 cm in the standing position. Weight was obtained at the nearest 0.1 kg with an electronic device (SECA®), the patient standing without shoes. BMI was calculated using the formula $\frac{\text{Weight}}{(\text{Height})^2}$ in kg/m^2.

The procedure of 24-hour urine sample collection was explained to participants, and they received the urine collection form and written instructions. The sample was obtained after an initial voiding in the morning upon awaking; thereafter, all urines were collected until the next morning upon awaking. This sample was im-

mediately transported to the laboratory at ambient temperature for volume (to the nearest 10 ml), urinary urea, and creatinine measurements. A fasting venous blood sample was collected into a 5 ml dry tube and was immediately transported to the laboratory, where it was centrifuged and serum analysed for serum urea and creatinine. Serum and urine creatinine and urea were measured using an automated instrument according to standards using the enzymatic method (Roche/Hitachi/Cobas C 311).

2.3. Calculations

Estimated GFR in ml/min/1.73m^2 was calculated using the following equations:

- Cockcroft-Gault (CG) equation [12]:

$$\text{eGFR} = \frac{(140 - \text{age}) \times \text{weight} \times 0.85[\text{if female}]}{72 \times \text{SCr}}$$

where SCr represents serum creatinine in mg/dl, age is measured in years, and weight in kg.

- Modification of Diet in Renal Disease (MDRD) equation [13]:

$$\text{GFR} = 175 \times (\text{SCr})^{-1.154} \times (\text{age})^{-0.203} \times 1.212 \times 0.742[\text{if female}]$$

where SCr represents serum creatinine in mg/dl, and age is measured in years.

- Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation [14]:

$$\text{eGFR} = 141 \times \min(\text{SCr}/\text{k},1)^{\alpha} \times \max(\text{SCr}/\text{k},1)^{-1.209} \times 0.993^{\text{Age}} \times 1.018[\text{if female}] \times 1.159$$

where SCr is serum creatinine in mg/dl, k is 0.7 for females and 0.9 for males, α is −0.329 for females and −0.411 for males, min indicates the minimum of SCr/k or 1, and max indicates the maximum of SCr/k or 1. Race or ethnicity coefficient for "Black" individuals in the MDRD and CKD-EPI equations was not applied.

Urea clearance (UCl) was calculated using the following formula:

$$\text{UCl} = (\text{urinary Urea} \times \text{urine flow}) / \text{plasma Urea}$$

Creatinine clearance (CrCl) was calculated using the standard formula:

$$\text{CrCl} = (\text{urinary creatinine} \times \text{urine flow}) / \text{plasma creatinine}$$

The result was adjusted for body surface area (BSA) using Dubois' formula [15].

$$\text{BSA} = 0.007184 \times \text{Weight}(\text{kg})^{0.425} \times \text{Height}(\text{cm})^{0.725}$$

Measured glomerular filtration rate (mGFR) was obtained using this formula:

$$(\text{Creatinine Clearance} + \text{Urea Clearance})/2$$

As creatinine clearance (CrCl) significantly overestimates the measured glomerular filtration rate and urea clearance (UCl) significantly underestimates mGFR, some authors have proposed calculating the average of CrCl and UCl [16]. The 2005 European Best Practices Guidelines for stages 4 - 5 CKD also propose this method when GFR is less than 15 ml/min/1.73m^2. In this study, we used the average urinary clearances of creatinine and urea as the gold standard measurement of GFR.

2.4. Statistical Analysis

Characteristics of the population were described using mean (standard deviation) and median (interquartile range) for quantitative variables, and number (percentage) for qualitative variables. Agreement between eGFR and mGFR was assessed using Bland-Altman's analysis. Bias was calculated as the mean difference between mGFR and eGFR. Precision was considered as one standard deviation (SD) of bias. Agreement limits were calculated (bias ± 1.96 SD) and presented on the graph with bias and corresponding 95% confidence intervals. We used c-statistics to assess the mGFR-based ESKD (mGFR < 15 ml/min/1.73m^2) diagnostic accuracy of eGFR from each of the equations. The Receiver Operating Curve (ROC) was used to determine the best eGFR cut-off from each of the equations for the diagnosis of mGFR-based ESKD. The agreement of each of the eGFR equations (using the best cut-off) with mGFR for assessing ESKD (GFR < 15 ml/min/1.73m^2) was tested using Cohen's kappa statistics. Data analysis was done using IBM SPSS Statistics 23.0 software, and graphs were represented using Microsoft Excel 2013 and GraphPad Prism 6.0 for Windows.

2.5. Ethical Considerations

Administrative authorization to carry out the study was obtained from the authorities of the Yaoundé General Hospital.

3. Results

3.1. General Characteristics of the Study Population

A total of 27 (16 Males) out of the 91 eligible patients were enrolled in the study (**Figure 1**). The mean (standard deviation) age was 57 (12.17) years. Hypertension and diabetes were the most prevalent comorbidities, concerning 92.6% (n = 25) and 37% (n = 10) of patients, respectively. The median (interquartile range) evolution time of CKD was 5 (1 - 13) years. The main aetiologies of CKD were diabetes, hypertension, chronic glomerulonephritis, and chronic interstitial nephritis, affecting respectively 25.9% (n = 7), 25.9% (n = 7), 14.8% (n = 4), and 14.8% (n = 4) of patients. Other clinical characteristics are shown in **Table 1**.

3.2. Performance of CKD-EPI, MDRD, and CG Equations in Estimating GFR

Overall, the three equations had an almost excellent accuracy in the diagnosis of end-stage kidney disease; the c-statistics were 0.97 for CKD-EPI and CG, and 0.98 for MDRD (**Table 2**).

Bland-Altman plots for CKD-EPI, MDRD, and CG vs mGFR are shown in **Figure 2**. Bias (95% confidence interval) was significantly different from zero for all three equations; it was lower for CKD-EPI [3.24 (1.5 - 4.9) ml/min/1.73m^2] than for MDRD and CG [respectively 5.17 (2.9 - 7.4) and 5.76 (3.4 - 8.2) ml/min/1.73m^2]. The limits of agreement were wide for all three equations, although these limits were narrower for the CKD-EPI equation. The ROC curves of equations to assess the best

cut-off in the diagnosis of eGFR-based ESKD are shown in Figure 3. CKD-EPI equation had the lowest cut-off value (16.25 ml/min/1.73m^2), with sensitivity (Se) = 0.93 and specificity (Sp) = 0.92 (Figure 3(a)). For MDRD and CG equations, cut-offs (sensitivity and specificity) were respectively 18 ml/min/1.73m^2 (Se = 0.93; Sp = 0.92) (Figure 3(b)) and 16.8 ml/min/1.73m^2 (Se = 0.93; Sp = 0.85) (Figure 3(c)). Using these cut-offs, the agreement with mGFR was almost perfect for CKD-EPI (kappa = 0.852) and MDRD (kappa = 0.852), and moderate for CG (kappa = 0.78). Other details on the performances of equations are shown in Table 2.

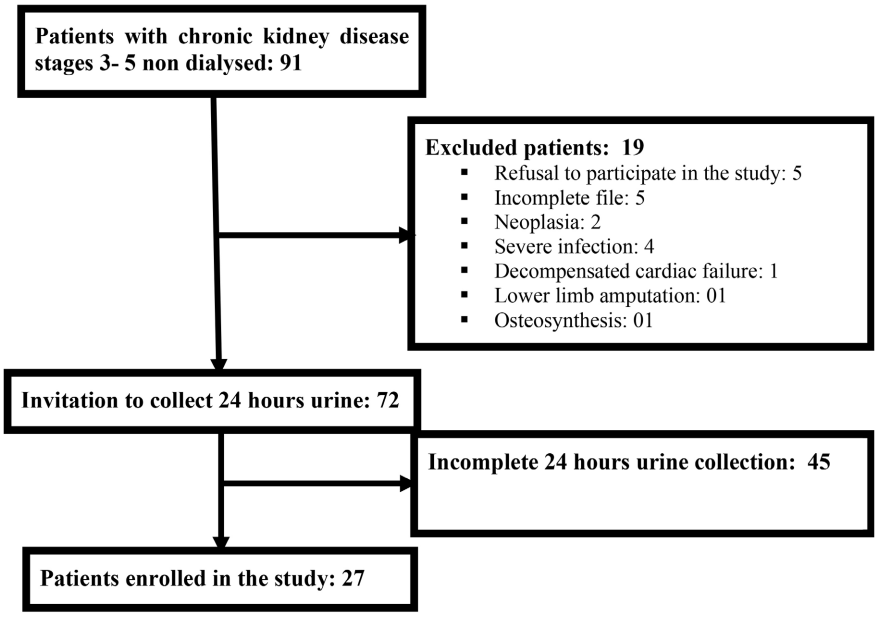


Figure 1. Flowchart of the inclusion of participants.

Table 1. Clinical characteristics of the study population.

Characteristics	n (%)	Mean ± SD	Median (IQR)
Age, Years		57 ± 12.17	56 (51 - 65)
Sex			
Male	16 (59.3)		
Female	11 (40.7)		
Comorbidities			
Hypertension	25 (92.6)		
Diabetes	10 (37)		
Obesity	3 (11)		
HIV	2 (7.4)		
HBV	1 (3.7)		
HCV	2 (7.4)		
Hyperuricemia	7 (25.9)		

Continued

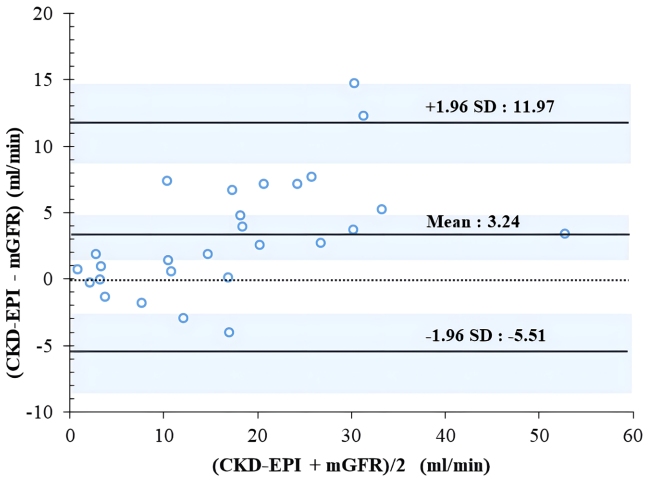
Duration of CKD, Years			**5 (1 - 13)**
Stage of CKD			
Stage 3	8 (29.6)		
Stage 4	9 (33.3)		
Stage 5	10 (37)		
Hemodynamic and Anthropometric Parameters			
Systolic BP, mmHg		150.48 ± 24.58	149 (135 - 170)
Diastolic BP, mmHg		89.44 ± 13.96	89 (70 - 86)
Weight, kg		70.68 ± 13.49	70 (61 - 76)
BMI, kg/m^2		25.87 ± 4.14	24.7 (22.3 - 30)
Biologic Parameters			
CrCl, ml/min/1.73m^2		21.2 ± 14.4	22.6 (10.3 - 29.2)
UCl, ml/min/1.73m^2		10.1 ± 8.5	9.2 (3.7 - 14.7)
Measured GFR, ml/min/1.73m^2		15.6 ± 11.1	15.8 (6.7 - 21.9)

IQR: Interquartile Range; SD: Standard Deviation; CKD: Chronic Kidney Disease; BMI: Body Mass Index; CrCl: Creatinine Clearance; UCl: Urea Clearance; GFR: Glomerular Filtration Rate; BP: Blood Pressure; HBC: Hepatitis B Virus; HCV: Hepatitis B Virus; HIV: Human Immunodeficiency Virus.

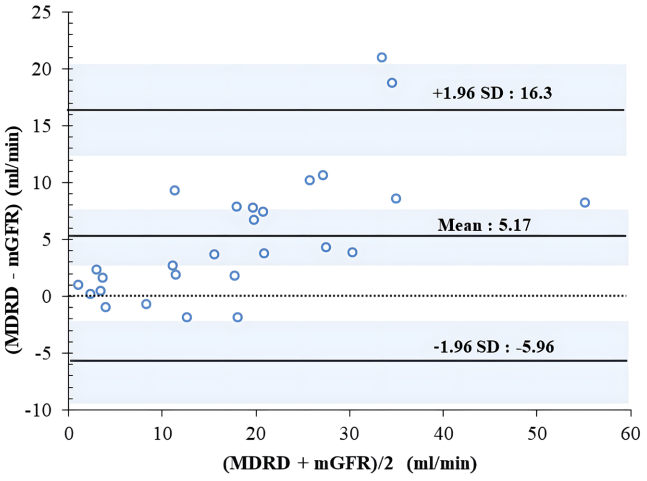
Table 2. Performance of CKD-EPI, MDRD, and CG equations in estimating GFR.

Parameter	CDK-EPI	MDRD	CG
mGFR < 15 ml/min/1.73m^2, n (%)	11 (40.7)	10 (37)	9 (33.3)
Mean ± SD	18.84 ± 13.43	20.78 ± 14.7	21.37 ± 15.8
Median (IQR)	16.9 (6.8 - 28.1)	18.6 (7.9 - 30.8)	18.1 (9.2 -29.4)
Min-Max	1.2 - 54.5	1.5 - 59.3	3.1 - 79.4
Bias (95% CI)	3.24 (1.5-4.9)	5.17 (2.9 - 7.4)	5.76 (3.4 - 8.2)
Precision	4.37	5.68	6.09
Limit of Agreement	[−5.51 - 11.97]	[−5.96 - 16.3]	[−6.18 - 17.69]
c-Statistics	0.97	0.98	0.97
Best Cut-off, ml/min/1.73m^2	16.25	18	16.8
Kappa Statistics			
Kappa (95% CI)	0.85 (0.65 - 1.04)	0.85 (0.65 - 1.04)	0.78 (0.54 -1.02)
p-value	< 0.001	< 0.001	< 0.001

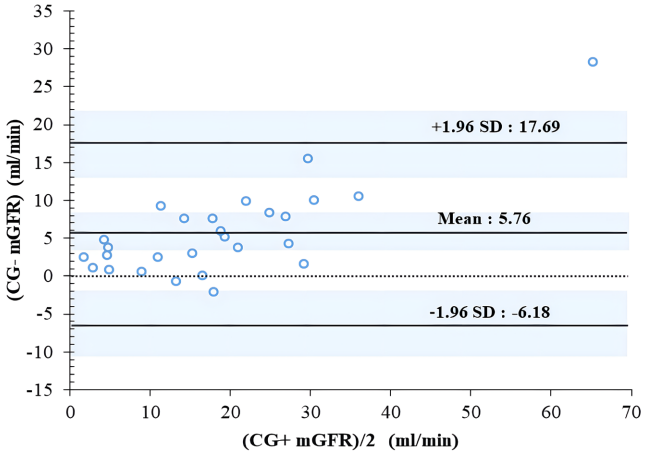
IQR: Interquartile Range; SD: Standard Deviation; mGFR: measured Glomerular Filtration Rate; CI: Confidence Interval; MDRD: Modification of Diet in Renal Disease; CKD-EPI: Chronic Kidney Disease Epidemiology Collaboration; CG: Cockcroft-Gault.



(a)



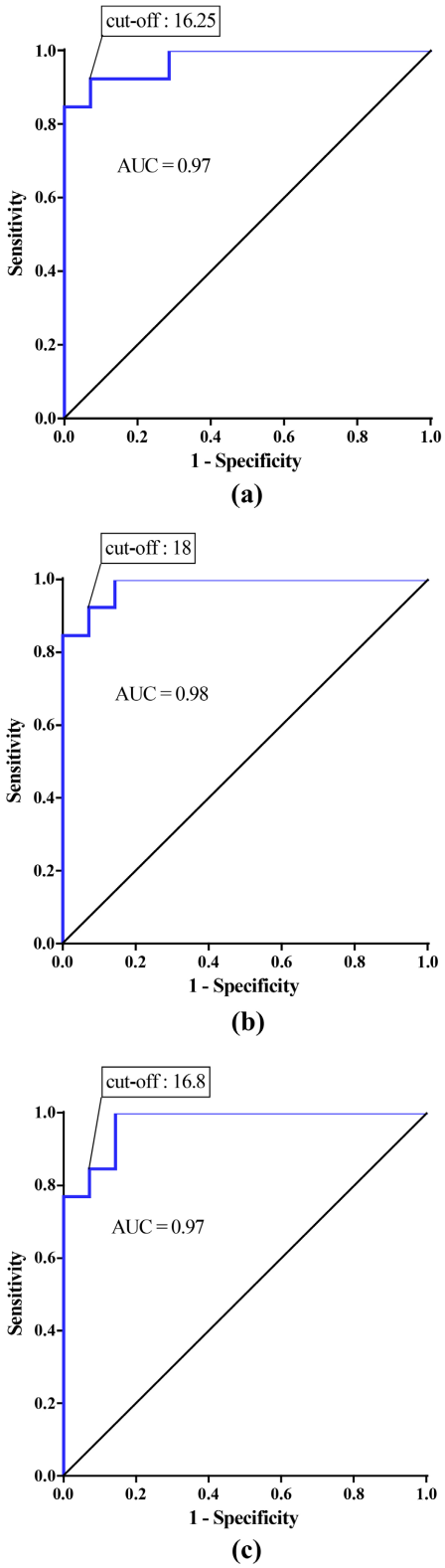
(b)



(c)

CKD-EPI: Chronic Kidney Disease Epidemiology Collaboration; mGFR: measured Glomerular Filtration; MDRD: Modification of Diet in Renal Disease; CG: Cockcroft-Gault.

Figure 2. Bland-Altman plots for CKD-EPI versus mGFR (a), for MDRD versus mGFR (b), and for CG versus mGFR (c).



CKD-EPI: Chronic Kidney Disease Epidemiology Collaboration; mGFR: measured Glomerular Filtration; MDRD: Modification of Diet in Renal Disease; CG: Cockcroft-Gault.

Figure 3. ROC curve for CKD-EPI in diagnosis of GFR-based ESKD (a), for MDRD in diagnosis of GFR-based ESKD (b), and for CG in diagnosis of GFR-based ESKD (c).

4. Discussion

Equations for estimating glomerular filtration rate (eGFR) have not been validated in Sub-Saharan African populations, and data on GFR are scarce [17]. We aimed to determine the most useful eGFR equation for the diagnosis of end-stage kidney disease in patients with stage 3 - 5 CKD. Our results suggested that the diagnosis of ESKD was accurate with the 3 creatinine-based equations. Similarly, a study conducted in Ghana showed that GFR calculated from 24-hour urine collection was most comparable to eGFR, either by MDRD-4 or CKD-EPI, omitting the factor for black Americans [17]. Omuse *et al.* found that the CKD-EPI equation could be a more ideal equation when estimating GFR in an asymptomatic population not known to have risk factors for CKD [18].

In some studies, the CKD-EPI equation and the MDRD Study equation were equally accurate in a subgroup with eGFR less than 60 mL/min/1.73m^2. Here, like for Stevens *et al.*, the bias was lower for CKD-EPI with a stronger agreement compared to MDRD and Cockroft and Gault equations [19]. Our results suggest that the CKD-EPI equation classified more participants as having a reduced eGFR compared to the MDRD equation. For Rule *et al.*, the MDRD equation underestimated GFR by 6.2% in patients with chronic kidney disease [20]. Our cohort included subjects whose characteristics are similar to those of one European cohort in terms of age, weight, and BMI, and who found that the MDRD equation had greater precision and accuracy than the Cockcroft-Gault formula in CKD patients (GFR < 60 mL/min/1.73m^2) [21].

The Cockroft and Gault equation is easily used in our conditions (access to a computer is not always available), but this study shows the substantial agreement for the diagnosis of ESKD. This has to be interpreted with caution because Agarwal *et al.* in the Chinese population found that this equation's performance is relevant when multiplying the result by 0.84 to correct for overestimation of GFR [22].

Despite advances in GFR estimation, no equation can be considered perfectly accurate. A threshold of 16 ml/min/1.73m^2 could, in practice, overestimate the number of patients with advanced kidney disease. However, this would be an advantage in the African context, which is characterised by a lack of screening and late referrals.

The limitation of this study was that the measured GFR was based on the 24-hour urine collection that was done at home, and therefore, could bias this collection. In addition, although these creatinine-based estimation equations of GFR are widely used, they have been shown to be less effective than an equation for estimating glomerular filtration rate, which uses both creatinine and cystatin C [23]. Also, our results must be analyzed carefully because of the small number of participants. However, this local pilot study helps us to understand different equations usually used to evaluate glomerular filtration rate in our setting.

5. Conclusion

The CKD-EPI equation seems to be slightly better than MDRD and CG in diag-

nosing ESKD in sub-Saharan Africans with stages 3 - 5 CKD. The improvement of agreement while using a higher cut-off than 15 suggests that it has to be revised for better accuracy.

What Is Already Known on This Topic

- The performance of equations estimating the glomerular filtration rate is known in the population with chronic kidney disease in other settings.
- The performance of equations estimating the glomerular filtration rate is known in certain groups of patients in sub-Saharan Africa, for example, type II diabetes.

What This Study Adds

This study shows that:

- The CKD-EPI equation seems to be slightly better than MDRD and CG in diagnosing ESKD in sub-Saharan Africans with stages 3 - 5 CKD.
- These findings highlight the improvement of agreement while using a higher cut-off of more than 15 ml/min/1.73m^2, calling for revision for better accuracy.

Availability of Data and Materials

The materials described in the manuscript, including all relevant raw data, will be freely available to any scientist wishing to use them for non-commercial purposes. The data that support the findings of this study are then available from the corresponding author.

Authors' Contributions

- Conception and study design: AWN, MM, GSW, and GA.
- Data collection: AWN.
- Data analysis and interpretation: AWN, GSW, and GA.
- Manuscript drafting: AWN.
- Manuscript revision: AWN, MM, GSW, LMBN, AN, FFK, and GA.
- Guarantor of the study: GA.
- All the authors have read and agreed to the final manuscript.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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STROBE Statement

Checklist of items that should be included in reports of cross-sectional studies.

	Item No	Recommendation	Page No
Title and Abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done, and what was found	2
Introduction			
Background/Rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State-specific objectives, including any prespecified hypotheses	4
Methods			
Study Design	4	Present key elements of the study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4, 5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	5
Variables	7	Clearly define all outcomes, exposures, predictors, and potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4 - 6
Data Sources/Measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe the comparability of the assessment methods if there is more than one group	4 - 6
Bias	9	Describe any efforts to address potential sources of bias	4 - 6
Study Size	10	Explain how the study size was arrived at	
Quantitative Variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5, 6
Statistical Methods	12	(a) Describe all statistical methods, including those used to control for confounding	6
		(b) Describe any methods used to examine subgroups and interactions	6
		(c) Explain how missing data were addressed	
		(d) If applicable, describe analytical methods taking account of the sampling strategy	
		(e) Describe any sensitivity analyses	6

Continued

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—e.g., numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyzing	7
		(b) Give reasons for non-participation at each stage	
		(c) Consider the use of a flow diagram	
Descriptive Data	14*	(a) Give characteristics of study participants (e.g., demographic, clinical, social) and information on exposures and potential confounders	7
		(b) Indicate the number of participants with missing data for each variable of interest	13 - 14
Outcome Data	15*	Report numbers of outcome events or summary measures	4, 5
Main Results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for, and why they were included	7
		(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other Analyses	17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	7
Discussion			
Key Results	18	Summarise key results with reference to study objectives	8
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both the direction and magnitude of any potential bias	8, 9
Interpretation	20	Give a cautious overall interpretation of results, considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	8, 9
Generalisability	21	Discuss the generalisability (external validity) of the study results	8, 9
Other Information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	

*Give information separately for exposed and unexposed groups. **Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at https://journals.lww.com/epidem/pages/default.aspx). Information on the STROBE Initiative is available at https://www.strobe-statement.org/.