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Assessment of Renal Function and Predictive Performances of GFR Estimating Equations among Nigerian Diabetic Patients

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Authors' contributions

This work was carried out in collaboration between all authors. Author STS designed the study, performed the statistical analysis, wrote the protocol, and wrote the first draft of the manuscript under the supervision of author AAF. Author SOJ assisted in calculation of the predictive equations and managed the analyses of the study. All authors read and approved the final manuscript.

Original Research Article

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ABSTRACT

Aims: To assess the renal functions in Nigerian diabetic patients and to examine the predictive performances of Glomerular Filtration Rate (GFR) estimating equations.
Study Design: A case-control study.
Place and Duration of Study: Department of Physiology and University College Hospital, University of Ibadan, Ibadan, Nigeria. May-August, 2009.
Methodology: One hundred and nine volunteers comprising 58 diabetic patients receiving treatments and 51 healthy individuals. Measured GFR (mGFR) was by creatinine clearance and the equations includes Cockcroft and Gault, CG; Modification of Diet in Renal Disease, MDRD study equation; Chronic Kidney Disease and Epidemiological study group, CKD-EPI and Mayo Clinic Quadratic, Q equation. Ethnicity factor was administered as appropriate. Performances were determined by mean bias, precision and accuracy.
Results: mGFR was significantly (P=.05) reduced among the diabetic when compared with the non-diabetic though within the recommended range for normal renal function. Among the diabetics, CG equation has the least bias when compared with the mGFR but

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overestimated the GFR by 2.42ml/min/1.73m^2 while Q has the highest bias. When the bias of other equations where compared with that of CG, the CKD/EPI formula significantly underestimated the GFR (P=.05) and the Q significantly overestimated GFR (P=.05). The highest precision was by CG and the least was found in the CKD/EPI though not significantly. The highest accuracy in this group was by CKD/EPI. In the non-diabetics, the least bias was recorded in the MDRD when compared with the mGFR while the highest was recorded in the CKD/EPI, the bias when compared with that of CG, the CKD significantly underestimated GFR by up to 7.54ml/min/1.73m^2 (P=.001). Precision was highest in the Q though, not significant while its accuracy was significantly lower (P=.05) when compared with the CG. Adjustment for the ethnicity factor significantly overestimated GFR in our two study groups.

Conclusion: Creatinine-based predictive equations are useful in estimating renal functions but the CG as well as the MDRD equations are more superior in their predictive ability among Nigerians and the use of the ethnicity factor is not recommended in Nigerian African as there is overestimation when used with the relevant equations.

Keywords: Renal function; GFR, cockcroft and gault; MDRD, CKD/EPI; mayo quadratic; diabetic patients; Nigeria.

1. INTRODUCTION

Diabetes is a disease of epidemic proportion and the number of people developing the disease is growing every year [1]. Rapid growth of diabetes worldwide had been reported and that the number of new cases of diabetes may triple by the year 2030 [2]. In Africa, 19.8 million adults suffer from diabetes with regional prevalence of 4.9%, Nigeria has 3.9 million peoples with diabetes and is ranked the highest in Africa, followed by 2.6 million in South Africa, 1.9 million in Ethiopia and 1.7 million in United Republic of Tanzania [3]. In 2011 alone, 63340 Nigerians died of diabetes related complications [4] and with the incidence of diabetes in African population on the rise, the incidence of late complications is also expected to increase accordingly [5].

Renal disease affects approximately 40% of type 1 and type 2 diabetic patients; and diabetic nephropathy is the leading cause of kidney disease in patients starting renal replacement therapy [6]. Epidemiological studies had shown a genetic predisposition that contributes to diabetic kidney disease [7,8]. Diabetic nephropathy is typically defined by either macroalbuminuria or by abnormal renal function as represented by an abnormality in serum creatinine, calculated by creatinine clearance or Glomerular Filtration Rate, GFR [9]. In Sub-Sahara Africa, diabetic nephropathy is emerging as a major cause of End Stage Renal Disease [10] and Nigerian patients with diabetic nephropathy has been identified as high risk group for excessive cardiovascular morbidity [11,12].

Identifying and stratifying patients at risk for renal disease are integral parts of clinical nephrology. These tasks are performed in part by measuring the GFR, which is generally considered to be the best marker of renal function in healthy and diseased states [13]. The GFR can be precisely measured by using the filtration markers inulin, [^{125}I] iothalamate, ^{51}Cr-ethylenediaminetetraacetic acid, 99mTc-diethylenetriaminopentaacetic acid, and iohexol [14]. However, because these markers are, to varying degrees, costly and cumbersome to use and may involve radioactivity, which necessitates special handling, disposal and limits use, they are not typically used in clinical practice [13].

A far more common method has been to estimate renal function by using specifically designed predictive equations based on demographic characteristics, such as age, gender, race, and weight, and biochemical indices, including serum creatinine, urea, and albumin levels [14]. Such equations includes that of Jelliffe [15], Cockcroft and Gault [16], Baracskay et al. [17], Hull et al. [18], Schwartz et al. [19], Salzar & Corcoran [20], Modification of Diet in Renal Disease, MDRD [21], Mayo Quadratic [22], CKD-EPI [23] etc. Of these, probably the most frequently applied formula is that proposed by Cockroft and Gault [14]. Regardless of whether these equations were derived to predict creatinine clearance or GFR, they all use and are influenced by the serum creatinine level [13].

Predictive performances of some of these equations had been evaluated among Nigerians with chronic kidney diseases [24-27] however, not in patients with type 2 diabetes, similarly, the ethnicity factor of 1.212 used in adjusting for African Americans in some of the equations had not been examined among Nigerians. Therefore, this study assess the GFR of Nigerian diabetic patients and the predictive performances of Cockcroft and Gault, CG equation; Modification of Diet in Renal Disease, MDRD equation; Chronic Kidney Disease and Epidemiological study group (CKD-EPI) equation and the Mayo Quadratic (Q) equation in Nigerian diabetic patients. Also, the ethnicity factor in two of the equations was examined.

2. MATERIALS AND METHODS

2.1 Study Design

The study is a case control study involving volunteered patients with diabetes mellitus at the University College Hospital Ibadan and volunteered controls who were non diabetic individuals recruited from residents of Agbowo area, Ibadan; staff of Abadina Senior secondary school, and staff of Abadina Junior Schools 1 and 2 ,University of Ibadan, Ibadan. Ethical issues were considered and approval was issued by UI/UCH Ethics committee (UI/UCH/EC/09/0101).

A study population n= 109 was used, of which 58 (28 male, 30 female) were diabetic and 51 (26 male, 25 female) were non diabetic (control) volunteers. Diabetes Mellitus was ruled out in the control using Fasting Plasma Glucose (FPG). Those with FPG<110mg/dl were included if they were not on any hypoglycemic medication. All the subjects were not hypertensive and were not on any diuretics.

2.2 Measurements

The consent of the volunteers was sought evidenced by a signed informed consent form. The procedure involved and rationale behind the study was explained to them. The subjects were given a code by which they were referred to in the course of the study. The ages as at the last birthday of the participating volunteers were sought and recorded in years; heights were measured in meter, and; weight in kilogram. Fasting Plasma Glucose was measured using a ONE TOUCH® ultra-glucometer (LifeScan Inc., USA).

GFR was measured by creatinine clearance using a 24 hours urinary sample. Urine collection commenced from 7am of the previous day to 7am of the day blood sample was taken. The total volume of urine was noted and an aliquot was taken for the estimation of creatinine.

5mls of blood was collected after an overnight fast into sterile plastic syringe by venepuncture with minimum venous constriction. Out of which 2mls was gently dispensed into commercially prepared specimen tube containing lithium-EDTA (for plasma) and the remaining 3mls was dispensed into a plain tube (for serum). Plasma and serum concentration of creatinine were estimated from the blood sample. The kinetic Jaffe method was used to estimate blood and urine creatinine level.

Creatinine clearance was then calculated as Urine creatinine level U_{cr}x24 hr Urine vol/plasma creatinine, P_{cr} x24x60 minute.

For comparison with renal estimates of the formulas, the measured GFR (mGFR) was normalized to 1.73m^2 of body surface area (BSA) by multiplying the mGFR by 1.73/BSA. The BSA was calculated according to Du Bois and Du Bois [28]: 71.84xWeight$^{0.425}$xHeight$^{0.725}$/10000.

2.3 Predictive Formulas

The prediction of GFR (ml/min) by the Cockcroft-Gault formula [16] was calculated as (140 – age) xbody weight/plasma creatininex72 (x0.85 if female). For comparison with the prediction of other formulas, the predicted creatinine clearance by Cockcroft-Gault was normalized per 1.73m^2 of BSA using the formula of Du Bois and Du Bois [28] identical to the normalization of the GFR measurement.

The abbreviated MDRD estimate [21] of kidney function was calculated as 175xplasma creatinine$^{-1.154}$xage$^{-0.203}$ (x 0.742 if female;x1.21 if black). The CKD-EPI estimate [23] of renal function was calculated as recommended: For women with a plasma creatinine ≤0.7, (plasma creatinine/0.7)$^{-0.329}$ x (0.993)^{age} (x166 if black; x144 if white or other); for women with a plasma creatinine >0.7, (plasma creatinine/0.7)$^{-1.209}$ x (0.993)^{age} (x166 if black; x144 if white or other); for men with a plasma creatinine ≤0.9; (plasma creatinine/0.9)$^{-0.411}$x (0.993)^{age} (x163 if black; x141 if white or other); for men with a plasma creatinine >0.9, (plasma creatinine/0.9)$^{-1.209}$ x (0.993)^{age} (x166 if black; x144 if white or other). The Mayo clinic quadratic equation [22] was calculated as: exp [1.911+5.249/SCr–2.114/SCr^2–0.00686xage (years)–0.205 if female].

The estimated renal functions using the (abbreviated) MDRD and the CKD-EPI equations are expressed as GFR in ml/min per 1.73m^2. Age was expressed in years, body weight in kg, and plasma creatinine in mg/dl.

2.4 Statistical Analysis

Data were presented as means±SEM. Relations between various parameters were tested using linear regression. To compare the performance of the formulas, bias, precision, and accuracy were calculated as recommended [29]. Bias was defined as the mean difference between estimated and measured kidney function, whereas precision was expressed as the SD of this difference. To define the best formula, the accuracy was used because it is a combination of bias and precision [30]. Accuracy was calculated as the percentage of patients who had an estimated kidney function within 30% limits of the measured GFR. Differences in bias and accuracy between the formulas were tested with a paired *t* test or McNemar test, respectively.

Furthermore, the relationship between the GFR and measurement error was studied by applying the method as proposed by Bland and Altman [31]. We assessed the bias as well as the limits of agreement, which were calculated as the bias plus or minus two times the precision. Because the GFR measurements are far more likely to be closer to the real GFR than the predicted estimates by the formulas, we used the measured GFR on the *x* axes instead of the mean of both methods. This procedure was performed using Analyse-it® version 2.22 Excel 12+ (Analyse-it Software, Ltd) which was specifically designed to test performance of different methods.

3. RESULTS

The characteristics of the study groups are presented in Table 1, there is no significant difference in the BMI and BSA however there is significant difference in Age (P=.001) and the measured Glomerular Filtration Rate (P=.05) between the control and the diabetic patients used in this study as shown in Fig. 1.

Table 1. Characteristics of the study population

	Diabetic n= 58	Non diabetic n= 51
Male gender (%)	48.3	51
Age (Years; Mean±SEM)	58.2±1.41	43.1±1.19**
BMI(Kg/m^2; Mean±SEM)	26±0.68	25.04±0.70
BSA (m^2;Mean ± SEM))	1.80±0.03	1.77±0.02
Measured GFR corrected for BSA (ml/min/1.73m^2; Mean±SEM)	91.65± 4.16	110.34±5.70*

**P=.05; **P=.001*

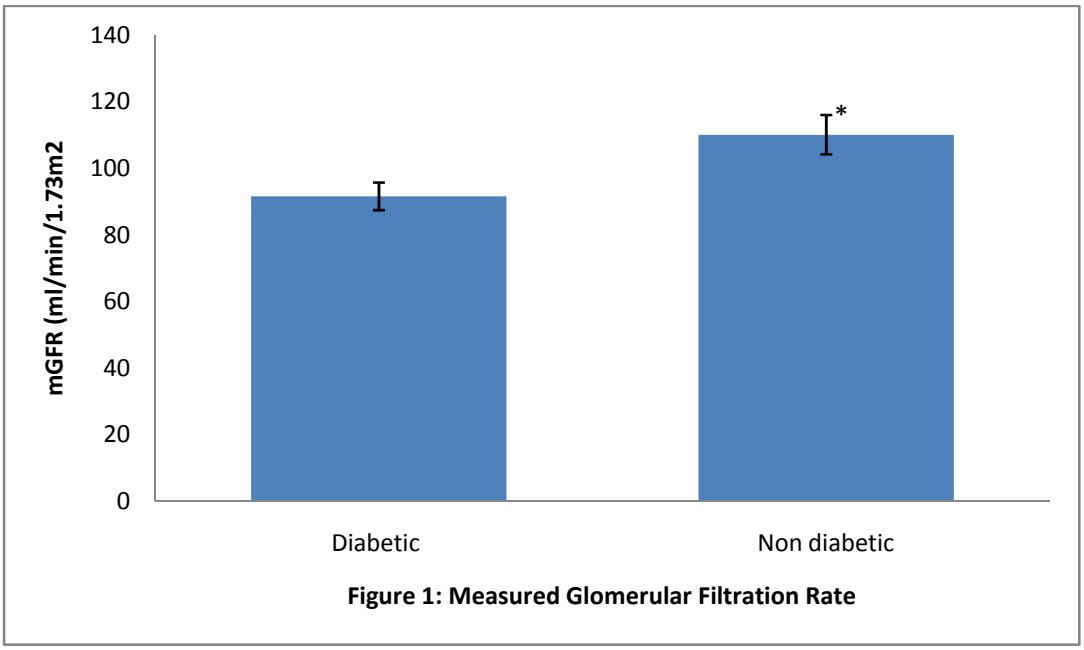


Fig. 1. Measured glomerular filtration rate among the two groups
**P=.05*

3.1 Performance of Estimating Equations among the Non Diabetic Group

The performances of the equations in the non diabetic group are shown in Table 2, the least bias was recorded in the MDRD equation when compared with the measured GFR while the highest was recorded in the CKD, the bias where compared with that of CG, the CKD significantly underestimated GFR by up to 7.54 ml/min/1.73m^2 (P=.001). Precision was highest in the Mayo quadratic though, not significant (P>0.05) while its accuracy was significantly lower (P=.05) when compared with the CG.

Figs. 2 (A-D) are Bland-Altman difference plots showing the bias of the different estimating equations to the measured GFR and their various limits of agreements among the non diabetic group.

Table 2. Performances of the estimating equations in the non diabetic group

	CG	MDRD	CKD	Q
Estimate (ml/min/1.73m^2; Mean±SEM	115.30±5.27	111.17±5.89	102±3.39	108±3.14
Bias (ml/min/1.73m^2)	4.21	-0.29	-7.54**	-2.37
Precision	24.72	23.05	26.99	35.76
Accuracy within 30%, P_{30} (%)	84	88	80	65*

*See the materials and method section for definition of bias, precision and accuracy; *P=.05 when compared with the Cockcroft and Gault; **P=.001 when compared with the Cockcroft and Gault; -the negative sign suggests an underestimation*

3.2 Performance of Estimating Equations among the Diabetic Group

Table 3 shows the performance of the estimating equations among the diabetic group, CG equation has the least bias of all the equations when compared with the measured GFR, it overestimated the GFR by 2.42ml/min/1.73m^2, and the Mayo quadratic has the highest bias. When the bias of other equations where compared with that of CG, the CKD/EPI formula significantly underestimated the GFR (P=.05) and the Mayo quadratic significantly overestimated the GFR (P=.05). The highest precision was by CG and the least was found in the CKD however, they were not significantly different. Accuracy was highest in the CKD though when compared with the accuracy in CG was not significantly different (P>0.05).

Table 3. Performances of the estimating equations in the diabetic group

	CG	MDRD	CKD	Q
Estimate (ml/min/1.73m^2; Mean±SEM	95.20±3.67	97.19±3.50	89.24±2.40	102±2.77
Bias (ml/min/1.73m^2)	2.42	4.03	-3.03*	9.20*
Precision	32.43	31.38	28.21	31.03
Accuracy within 30% , P_{30} (%)	66	68	74	60

*See the materials and method section for definition of bias, precision and accuracy; *P=.05 when compared with the Cockcroft and Gault; -the negative sign suggests an underestimation*

Figs. 3 (A-D) are Bland-Altman difference plots showing the bias of the different estimating equations to the measured GFR and their various limits of agreements among the diabetic group.

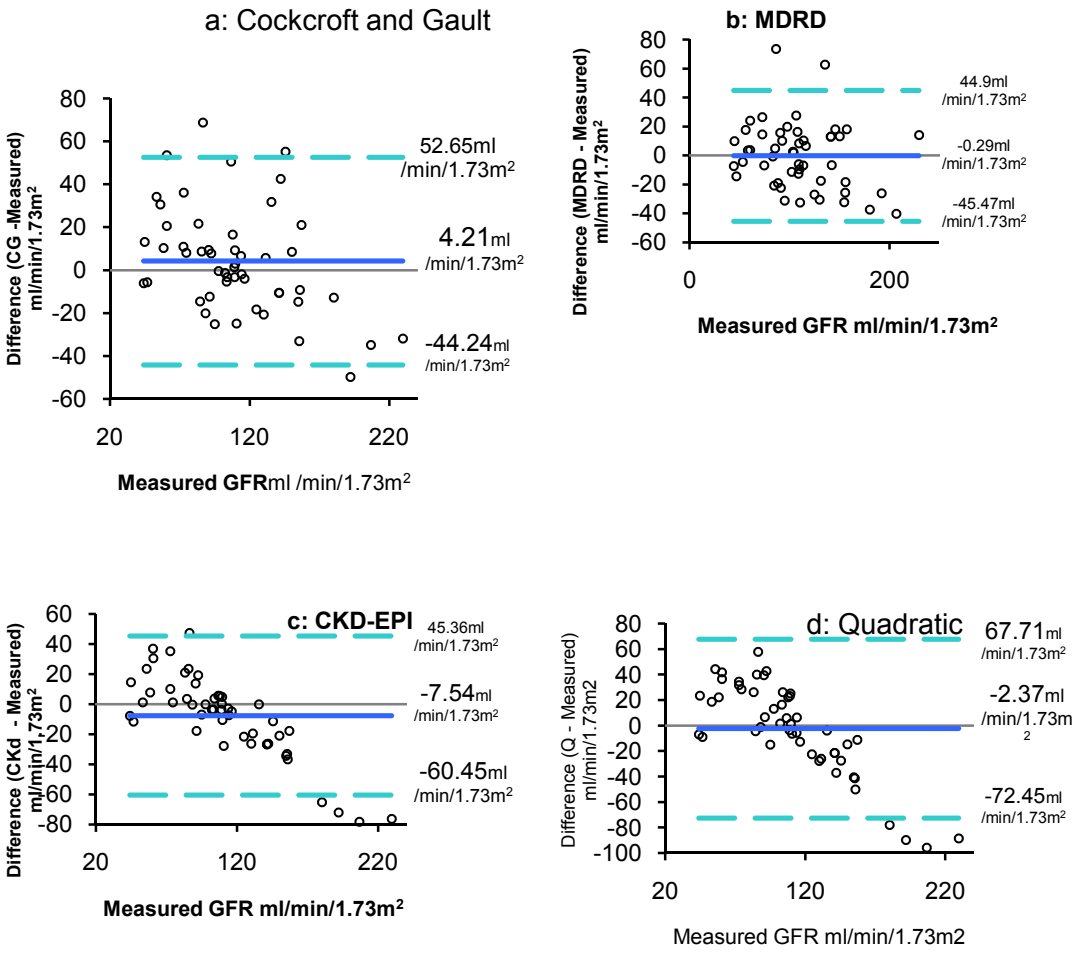
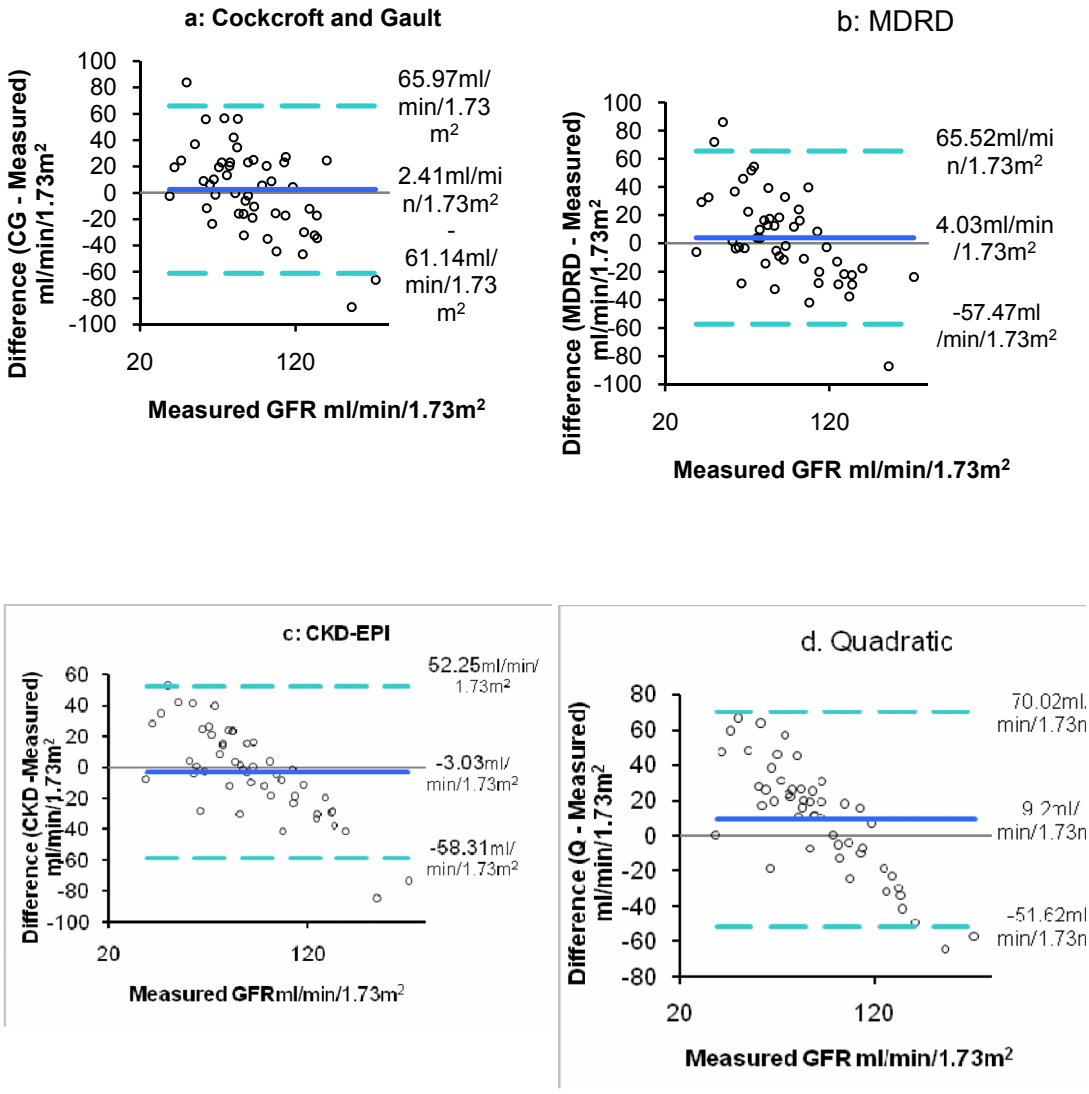


Fig. 2 (a-d). Bland-Altman figures of estimated and measured GFR. Bland-Altman plots– the difference between the estimated and measured renal function– is plotted against the measured GFR; therefore, a positive difference suggests an overestimation by the formula, whereas a negative difference suggests an underestimation. The solid lines represent the mean difference between estimated and measured GFR; the dashed lines represent the lines of agreement, calculated as mean difference plus or minus two times the standard deviation of this difference



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3.3 Utility of the Race/ Ethnic Factor in the Estimating Equations

The factors used for adjusting for African-Americans as recommended in the MDRD and CKD/EPI equations where tested in this study. Table 4 shows significant overestimations of the GFR by MDRD (P=.001) and CKD-EPI equation (P=.05) in both the diabetic and non diabetic group.

Table 4. Effect of the race/ethnic factor on predictive estimation by MDRD and CKD-EPI

	Measured GFR	CG	MDRD(a)	CKD-EPI(a)
Diabetic	91.65±4.16	95.20±3.68	117.78±4.26**	102.63±2.77*
Non diabetic	110.19±5.93	114.47±5.34	133.28±7.23**	118.13±3.88*

*(a) Adjusted for ethnic/ race; *P=.05 when compared with the measured Glomerular Filtration Rate; **P=.001 when compared with the measured Glomerular Filtration Rate*

The mean bias were significantly higher in the two adjusted equations when compared with the Cockcroft and Gault in the two study groups. However, only adjusted MDRD had a significant decrease in accuracy (P=.05) as shown in Table 5.

Table 5. Performance of predictive equations when adjusted for race

	Diabetic			Non-diabetic		
	CG	MDRD(a)	CKD-EPI(a)	CG	MDRD(a)	CKD-EPI(a)
Bias	2.41	24.3**	10.26**	4.21	23.02**	7.87
Precision	32.43	34.48	29.02	24.72	27.28	26.08
Accuracy	66	50	62	84.31	62.75*	76.47

*(a) Adjusted for ethnic/ race; *P=.05 when compared with the corresponding Cockroft and Gault; **P=.001 when compared with the corresponding Cockroft and Gault*

4. DISCUSSION

Renal impairment is considered to be a long term complication of diabetes mellitus. The Glomerular filtration Rate is one of the most important physiologic estimates of kidney function and its estimation is central to the National Kidney Foundation classification and staging diagnosis of chronic kidney disease [32]. This had led to increase emphasis on evaluating the performance of equations recommended for estimation of GFR from serum creatinine concentration in adult [33].

This study observed a significant decrease in the measured GFR among the diabetic subjects when compared with the non-diabetic control group. The decrease could be accounted for by the age-related decline in glomerular filtration rate [34] as the control group had a significant lower age range which favours a higher GFR. However, the mean measured GFR (mGFR) of 91.65±4.16ml/min/1.73m^2 among the diabetic group is above the range of 60 to 90ml/min/1.73m^2 classified as early renal impairment by the National Kidney Foundation guideline [33], this finding is in line with a report by Li et al. [35] that most diabetic subjects retain normal renal function. Similarly, such decrease had been reported earlier among Japanese patients with type 2 diabetes mellitus [36].

Among the non diabetics, the MDRD equation had the least bias and the mayo quadratic had the highest precision but the accuracy was significantly lower (P=.05). This lower percentage of bias had earlier been reported among Nigerian with renal disease [25] however, being a positive bias, indicating an overestimation, it is in contrast to the findings of Li et al. [35] who reported an underestimation of GFR by MDRD. CKD significantly underestimated the GFR by up to 7.54ml/min/1.73m^2 (P=.001), when the race factor was considered, it further underestimated it significantly.

The least bias and highest precision was recorded in the Cockcroft and Gault equation among the diabetic group. CKD had the highest accuracy though, not significant (P>0.05) in this group, it however underestimated GFR significantly (P=.05) while the Mayo quadratic significantly overestimated GFR (P=.05).

Performance of the MDRD and CG are close concerted in this study as none of the two is seen to be superior to the other which corroborated the findings of Abefe et al. [25] among healthy and patients with renal disease. CKD-EPI and the Mayo quadratic which are more recent seems not to be useful in the Nigerians studied, a plausible explanation for the performance of CKD-EPI in this study could be due to the fact that the equation was originally designed among patients with established renal insufficiency whose GFR were below 60ml/min/1.73m^2 [23]. The higher precision of the mayo quadratic equation compared to other equations observed in the non diabetic could be probably accounted for by the inclusion of healthy individuals in the cohort sample from which it was designed [22].

Racial adjustments in the MDRD and CKD-EPI were also tested in this study, both the adjusted MDRD (P=.001) and black race CKD-EPI (P=.05) significantly overestimated GFR among the diabetic group while only the adjusted MDRD significantly overestimate GFR (P=.001) and significantly reduced accuracy (P=.05) among the non diabetic group. The unsuitability of the ethnicity factor of 1.212 used to adjust the MDRD equation for Africa-American had earlier been reported among the black South Africans [37]. The views of Goldwasser et al. [38] and Lewis et al. [39] that Africa-Americans have higher renal creatinine excretion per kilogram body weight than whites which may be related to differences in body composition, muscle metabolism or diet thereby having higher serum creatinine levels may not be true among Nigerian blacks just as earlier observed by Van Deventer et al. [37] in the South African blacks. The discrepancy in their study and ours may be attributed to the genetically heterogeneous nature of the Africa-American gene pool which occur as a result of mixing of ethnically diverse African populations (predominantly slaves from West Africa) with each other, as well as with people of mainly European descent [40] as well as environmental influences.

5. CONCLUSION

In conclusion, the results of this study suggested that the renal function of the diabetic subjects is not impaired as evidenced from the glomerular filtration rate. The Cockcroft and Gault equations as well as the MDRD equations which were recommended for use among the diabetic patients by the American Diabetic Association are superior in their predictive ability among Nigerians however, the use of the ethnicity factor is not applicable. This study was limited by the relatively small sample size; it was conducted only at one geographical site which does not adequately represent all population groups in Nigeria. Future studies will be in a larger cohort group and at different geographical locations.

CONSENT

A statement on subjects consent has been presented in the manuscript.

ETHICAL APPROVAL

The study received Institutional Review Board approval (UI/UCH/EC/09/0101) as indicated in the manuscript.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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