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Comparison of CKD-EPI, C-G and MDRD equations for estimating glomerular filtration rate in chronic kidney disease population in South-Western Nigeria.

***Braimoh, R.W.[1], Ediale, T.I.[2], Mabayoje, M.O.[1], Ale, O.K.[1], Bello, B.T.[1], Amira, C.O.[1]**

Abstract

Background: Ethnic variabilities make reliability of formula equations for assessing glomerular filtration rate (GFR) doubtful in many populations. We compared Cockroft-Gault (CG), modification of diet in renal disease (MDRD), and chronic kidney diseases epidemiology collaboration (CKD-EPI) equations in adult Nigerian CKD subjects.

Methodology: We measured 24-hour-urinary creatinine clearance of 311 adult CKD patients and compared with the three estimated equations. Bland-Altman plots were used to assess agreement between estimated equations and measured creatinine clearance (mGFR). Receiver-operating curve (ROC) analysis was used to assess the diagnostic power of the equations. Equation with accuracy within 30% of mGFR of ≥90% was considered acceptable for use.

Results: Mean age was 41.9±12.7 years with 182(58.5%) females. The mean GFR using CKD-EPI, MDRD and CG equations were 69.5±33.9, 65.9±33.0 and 66.2±30.9 mls/min/1.73m^2 respectively (mGFR 68.3±31.1mls/min/1.73m^2). The 3 equations showed positive correlation to mGFR (r=0.95) but CKD-EPI had the least bias.

Conclusion: All three equations can be used but CKD-EPI equation is preferable in Nigerian CKD patients, especially with GFR> 60mls/min.

Keywords: CKD, MDRD, CKD-EPI and CG equations, black population.

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Comparaison des équations CEMRC, CG et MRAMR pour estimer le taux de filtration glomérulaire dans la population d'insuffisance rénale chronique dans le sud-ouest du Nigéria

***Braimoh, R.W.[1], Ediale, T.I.[2], Mabayoje, M.O.[1], Ale, O.K.[1], Bello, B.T.[1], Amira, C.O.[1]**

Résumé

Contexte général de l'étude : Les variabilités ethniques rendent douteuse la fiabilité des équations des formules d'évaluation du débit de filtration glomérulaire (DFG) dans de nombreuses populations. Nous avons comparé les équations de Cockroft-Gault (CG), de la modification du régime alimentaire dans les maladies rénales (MRAMR) et de la collaboration sur l'épidémiologie des maladies rénales chroniques (CEMRC) chez des sujets adultes nigérians atteints de CEMRC

Méthode de l'étude: Nous avons mesuré la clairance de la créatinine urinaire sur 24 heures de 311 patients adultes atteints d'IRC et comparé avec les trois équations estimées. Des tracés de Bland-Altman ont été utilisés pour évaluer la concordance entre les équations estimées et la clairance de la créatinine mesurée (DFGm). L'analyse de la courbe de fonctionnement du récepteur (ROC) a été utilisée pour évaluer la puissance diagnostique des équations. Une équation avec une précision dans les 30 % du DFGm $\geq$90 % a été considérée comme acceptable pour l'utilisation.

Résultat de l'étude : L'âge moyen était de 41,9 ± 12,7 ans avec 182 (58,5 %) femmes. Le DFG moyen en utilisant les équations CEMRC, MRAMR et CG était respectivement de 69,5 ± 33,9, 65,9 ± 33,0 et 66,2 ± 30,9 ml/min/1,73 m^2 (mGFR 68,3 ± 31,1 ml/min/1,73 m^2) . Les 3 équations ont montré une corrélation positive avec le DFGm (r = 0,95) mais CEMRC avait le moins de biais.

Conclusion : Les trois équations peuvent être utilisées, mais l'équation CEMRC est préférable chez les patients nigérians atteints d'IRC, en particulier avec un DFG> 60 ml/min.

Mots-clés : EMC, MRAMR, CEMRC et équations CG, population noire.

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INTRODUCTION

Chronic kidney disease (CKD) is a leading cause of mortality worldwide and is associated with reduced quality of life and high cost of treatment[1]. It's of major public health concern with prevalence tending towards epidemic proportions[2,3]. The mortality of end-stage renal disease (ESRD) is high in many African countries[4,5]. Therefore, early treatment is of utmost importance, especially in resource-constrained countries[6]. The preferred index of kidney function is glomerular filtration rate (GFR) which is best measured by inulin clearance[7]. However, this is not clinically useful because of its cumbersome method. This led to the development of alternative methods[8,9] which, unfortunately also have many drawbacks[10-13].

In 1973, Cockcroft and Gault developed an equation for creatinine clearance (CrCl) estimation as a point-of-care measurement of kidney function[14]. Other equations were also developed, all with limitations[15-16]. This prompted the CKD-EPI study group to develop an equation from a wide and varied population, including African-Americans, diabetics, and kidney transplant recipients[17]. However, a major setback to this equation is the limited number of racial and ethnic minorities included in the original study[17]. The fact that this equation was developed based on the body surface area of a predominantly Caucasian population limits its accuracy in many other racial and ethnic populations as body compositions differ among ethnic groups even within nations; causing varying performance in different cohorts[18-19]. This prompted us to compare the performance of the CKD-EPI, CG, and MDRD equations in a cohort of CKD subjects in Nigeria, a country with the largest black African population in the world.

MATERIALS AND METHODS

This was a cross-sectional study of CKD patients attending the renal clinics of the Lagos University Teaching Hospital and healthy controls recruited from the community. The sample size was determined by Fisher's formula for descriptive studies[20] (with additional 10% attrition rate), to make a total of 311 each for CKD patients and control subjects.

Inclusion and exclusion criteria: CKD patients were selected by choosing every third CKD patient that met the inclusion criteria which are: a diagnosis of CKD (defined as GFR of $\leq$ 60mls/min/1.73m^2 for at least 3 months) in stable condition, aged 18 years and above, who gave their consent. Excluded were CKD patients who require in-hospital treatment for acute conditions like sepsis, hypertensive or diabetic emergencies, acute stroke, and those who did not consent. The control subjects were consenting healthy adults, aged 18 years and above, from the community who had no history of kidney disease, acute conditions such as febrile illness, hypertensive or diabetic emergencies, or acute stroke. Urine dipstick test was performed using Accutest® uriscreen strips (Jant Pharma USA) to rule out kidney damage in them; and individuals with proteinuria of $\geq$ +1 were excluded from the control group.

Ethical approval was obtained from health research ethics committee of Lagos University Teaching Hospital (ADM/DCST/HREC/APP/1731) and written informed consent was obtained from all study participants.

Relevant clinical data were obtained with questionnaire. Weight (in kilograms, to the nearest 0.1kg.) was measured using a weighing scale (Secca 770 Floor Digital Scale, Hamburg Germany) with each subject in light clothing and barefooted. Height (in meters to the nearest 0.01metre) was measured using a stadiometer (Secca 240 wall mounted, Hamburg Germany) with the patient barefooted. Body mass index (BMI) was determined by dividing the weight (in kilograms) by the square of the height (in meters). Body surface area (BSA) was calculated using the Mosteller formula[21]. Office blood pressure was measured (with subject sitting in a relaxed position) with mercury sphygmomanometer (Accoson, England) using appropriate cuff size. Twenty-four-hour urine samples were obtained in 5-litre containers after participants had been taught how to correctly obtain urine samples. Ten milliliters (mls) of venous blood were collected via venipuncture between 7:00am and 8.00am in the morning of completion of 24-hour urine collection for serum creatinine, fasting glucose and serum albumin analysis. Serum and urinary creatinine levels were analyzed by Jaffe-kinetic method using Randox kit (Randox Lab. USA) calibrated with an isotope dilution mass spectrometry traceable calibrator. Fasting blood glucose analysis was done using Roche Hitachi 902 auto-analyzer (Roche Basel, Switzerland). Serum albumin was analyzed with a spectrophotometer using 2, 4-dinitrophenyl hydrazine reaction. The 24-hour urinary protein estimation was performed with Robert Riele 4040 photometer (Robert Riele GmbH & Co. Berlin, Germany) using sulphosalicylic acid method.

Calculations: Cockcroft-Gault(1973): GFR=[(140-age) (years) x weight (kg) / (72 x serum creatinine) x 0.85 (if female) (umol/L). MDRD equation(1999): GFR=175 x (serum Cr in umol/L)$^{-1.154}$ x age$^{-0.203}$ x 1.212 if black x 0.742 if female. CKD-EPI equation(2009): GFR=141 x min(Scr/k, 1)$^{\alpha}$ x max(Scr/k, 1) $^{-1.209}$ x 0.993^{age} x 1.018 if female -1.159 if black; where k= 0.7 for females, 0.9 for males; α= -0.329 for females, -0.411 for males.

Data collected were analyzed using a statistical package for social sciences version 22 software (IBM SPSS Inc. USA). Data on age, weight, height, BMI, SBP, DBP and biochemical parameters were expressed as means and standard deviations (SD). Paired sample T-test was used to compare eGFR formulae and measured GFR (mGFR). Correlation between mGFR and the 3 equations (CG, MDRD and CKD-EPI) was assessed using Pearson's correlation coefficient. Agreement between mGFR and the 3 equations was analyzed using Bland-Altman plots. Receiver-operating curve (ROC) analysis was used to assess the diagnostic power of the equations. P-value < 0.05 was considered statistically significant at 95% confidence interval.

RESULTS

The mean age of the CKD population was 41.9 ±12.7 years with 182(58.5%) females. CKD subjects had mean BMI of 25.1±4.42kg/m^2 and mean weight of 69.7±13.0kg. Using the serum creatinine concentrations to calculate the eGFRs, the mean ± SD eGFRs did not differ significantly. The CKD-EPI equation consistently overestimated GFR in this cohort by 2.2 ml/min/1.73m^2. Table 1 shows the clinical and laboratory parameters of the study population while the comparative diagnostic performance of the estimating equations in CKD patients is shown in table 2. CKD-EPI was more sensitive and had better positive predictive value than MDRD in GFR above 90ml/min/1.73m^2; more precise than CG and had its most bias in stage 1 and least bias in stage 3. Within 15% of mGFR, there was significant difference between CKD-EPI and CG in stage 4 and 5 with CG being more accurate (p=0.003). MDRD equation had similar accuracy with CKD-EPI equation at this level. Within 30% of mGFR, CKD-EPI and CG differed significantly in stage 5; with CG being more accurate (p=0.02). Within 50% of mGFR, there was similar accuracy among the 3 equations across stage 1 to 5.

Hypertension was the commonest cause of CKD (figure1). All 3 equations showed a strong correlation to mGFR (r=0.96 p<0.001) (figure 2) and had narrow limits of agreement (Figure 3). Overall, all three equations had good accuracy and minimal bias although CKD-EPI had the least bias. Figure 4 shows the receiver operating curves (ROC) of the three equations in detecting those above or below 60 ml/min/1.73m^2.

The CKD-EPI equation correctly classified 82% of the study population when compared with mGFR to the various CKD staging. Of the remaining 18%, 8.0 % was under-estimated and 10.0 % were over-estimated (Cohen's k=0.77) but using MDRD and CG equations, 81% of CKD patients were classified correctly while 15.5% of the rest was under-estimated GFR and 3.5% over-estimated (Cohen's k=0.76).

DISCUSSION

The three equations performed well against mGFR. They had minimal bias and good accuracy. The CKD-EPI was more sensitive in detecting patients with stage 1 and 2 CKD than those with stage 3 to 5 CKD, more specific in detecting stage 3 to 5 in the CKD population. The original CKD-EPI study showed that the CKD-EPI equation has less bias than the MDRD equation, similar to our finding. Unlike CG and MDRD equations, the CKD-EPI equation had similar bias and precision in levels above and below 60ml/min/1.73m^2 but was more accurate in GFR levels above 60 ml/min/1.73^2. This suggests that the CKD-EPI equation is acceptable for use to detect early stages of CKD among Nigerians. This is similar to the findings of Steven *et al*[22] as well as Eastwood and colleagues [23].

From this study, CKD-EPI equation over-estimated GFR in CKD subjects by 2.2 ml/min/11.73m^2 but the Ghanaian study which used a similar reference standard showed a more pronounced over-estimation (19ml/min/1.73m^2).[23] The reason for this is not clear but could be due to the lower BMI and weight of the Ghanaian study population. Within 15% of mGFR, CKD-EPI equation was more accurate in stages 3-5 of CKD than MDRD, similar to finding by Michels *et al*[24] and Murata *et al*[25] but contrasted the findings of the original CKD-EPI validation study[17], in which the CKD-EPI showed better accuracy than MDRD mainly in GFR > 60ml/min/1.73m^2. This disparity could be due to the larger population of the original CKD-EPI study which increased its statistical power. In addition, the CKD-EPI's African-

American population may not fully represent the ethnic black African population.

Overall, we found CG equation to be more accurate in established CKD patients than MDRD at lower GFRs (GFR below 60 ml/min/1.73m^2) which is contrary to some studies when the two equations were compared against the gold standard[26-28]. However, most African studies are limited by sample size and non-availability of gold standard reference materials for appropriate evaluation of these equations. Till date, van Deventer's[29] study is the only African study that used the gold standard marker to validate the performance of MDRD and CKD-EPI in a predominantly black population. In his study, CG had an accuracy (within 30% of ^{51}Cr-EDTA) of 58% compared to MDRD (52%). Jafar *et al*[30] also documented superior accurate performance of CG to MDRD equation (65% versus 50%, respectively). However, Michel's finding in a similar study comparing the 3 equations against the gold standard found that CKD-EPI was significantly more accurate than CG[24] and more sensitive than the MDRD in CKD stages 1 and 2, which suggest that the CKD-EPI can be used to detect early stages of CKD better than the MDRD equation. This is similar to the finding of Stevens *et al*.[26]

Overall, CKD-EPI may rightly classify patients better than the MDRD equation. This is contrary to the findings of Steven *et al* [26]. This difference may be attributed to the relatively smaller sample size of our study compared to theirs.

The strength of this study includes a 100% black African population and therefore little doubt about the racial factor. Also, the method of serum creatinine assay was rate-blanked compensated Jaffe method traceable to isotope dilution mass spectrophotometry, thus improving on variability error between laboratory methods. Also, urban population was used where age is more accurately recorded. Validation of CKD-EPI has shown it is better than the MDRD in classifying higher stages of CKD patients. The limitations include the use of creatinine clearance as a standard to estimate GFR with formula equations; a relatively small sample size relative to that used in the MDRD and CKD-EPI formulae and validation are major limitations. Also, there was verification bias as the CKD population was selected from patients' records. Finally, since GFR was measured only once, some individuals thought to be stable CKD may have been misclassified. However, our objective was not the prevalence of CKD but a comparison of eGFR equations.

CONCLUSION

The 3 estimating equations performed well against mGFR in our ethnic black population but CKD-EPI was the least biased, most precise, and more accurate in staging CKD in GFR levels >60 ml/min/1.73m^2 in CKD patients and so is recommended for use in our CKD patients, especially in early stages.

Conflict of interest: The authors declare no conflict of interest.

Acknowledgement: Nil

Authors' contribution: Braimoh RW carried out the protocol design, literature search, data collection and analysis, and manuscript writing. Ediale TI was involved in protocol design, literature review, data collection and analysis. Mabayoje MO did the protocol design, literature search, data analysis and manuscript review. Ale OK, Bello BT and Amira CO was involved in data analysis. Ale OK did the manuscript writing while Bello BT and Amira CO did the manuscript review.

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Table 1: Clinical and laboratory characteristics of the study population

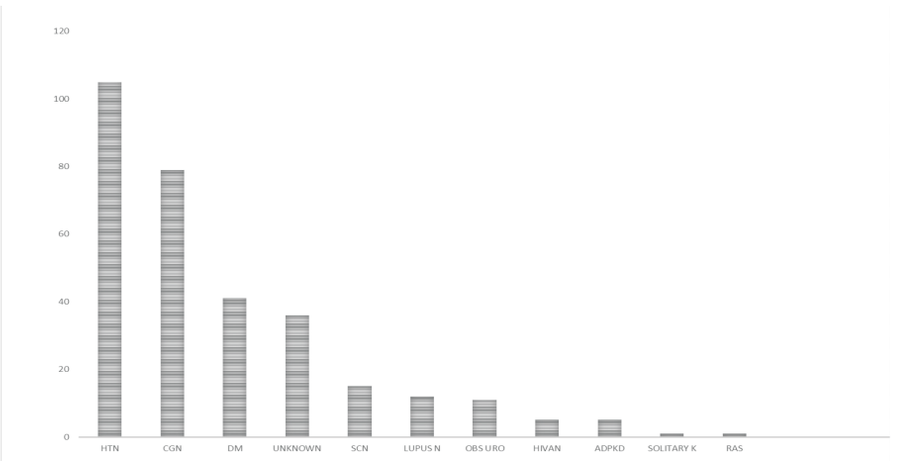
Variables	All (n=622)	CKD(n=311)	Control(n=311)	p-value (CKD vs control)
Mean age(yrs)	41.9±12.7	42.0 ±12.7	41.8 ± 12.7	0.85
Female n(%)	364(58.5)	182(58.5)	182(58.5)	0.94
Male n(%)	258 (41.5)	129(41.5)	129(41.5)	0.94
Mean weight (kg)	70.9 ± 12.9	69.7±13.0	72±12.7	0.03*
Mean height (m^2)	1.67±0.09	1.67±0.09	1.68±0.08	0.14
Mean BMI (kg/m^2)	25.4±4.47	25.1±4.42	25.6±4.55	0.14
Mean BSA(m^2)	1.79±0.17	1.77±0.18	1.81±0.17	<0.001*
Mean SBP(mmHg)	122±22.0	129.9±25.5	114.2±14.5	<0.001*
Mean DBP(mmHg)	77.5±14.4	82.0±17.3	72.9±8.7	<0.001*
Mean plasma glucose(mg/dl)	83.8±24.9	87.8±30.7	79.9±16.6	<0.001*
Mean urine protein(mg/dl)	238.7±190.5	281±213	198±156	<0.001*
Mean serum creatinine(mg/dl)	1.4±1.7	1.98±2.2	0.83±0.14	<0.001*
Mean urine creatinine(mg/dl)	82.4±28.9	80.8±26.2	83.9±31.3	0.18
Mean measured GFR(ml/min/1.73m^2	89.3±33.0	68.3±31.1	110.2±18.3	0.001*
Mean estimated GFR(ml/min/1.73m^2)				
Cockcroft-Gault	85.3±32.6	66.2±30.9	104.3±20.9	0.001*
MDRD	87.4±35.7	65.9±33.0	108.7±23.5	0.001*
CKD-EPI	91.5±35.5	69.5±33.9	113.5±20.1	0.001*

Values are in mean± standard deviation. MDRD modification of diet in renal disease. CKD-EPI chronic kidney disease epidemiological study group. *p<0.05.

Table 2. The comparative diagnostic performance of the estimated equations in CKD cohort

GFR	CKD-EPI n	MDRD	CG	P-value CKD-EPI vs MDRD	P- value CKD-EPI vs CG	ml/min/1.73m^2
Bias						
=90	69	3.2	-1.3	-3.8	<0.001*	<0.001*
60-89	136	2.4	-2.7	-2.3	<0.001*	<0.001*
30-59	60	-0.7	-2.4	-1.2	0.32	0.39
15-29	23	-3.1	-3.4	-4.8	0.79	0.13
<15	23	-3.1	-2.8	-3.6	0.34	0.13
Overall	-	1.2	-2.4	-2.1	<0.001*	<001*
Sensitivity (%)						
=90	69	85.5	66.7	75.4	0.02*	0.2
60-90	136	81.6	87.5	83.1	0.24	0.87
30-59	60	73.0	81.7	88.3	0.36	0.06
15-29	23	82.6	78.3	95.7	0.99	0.34
<15	23	100	100	100	-	-
Specificity (%)						
=90	69	93.8	99.2	97.9	0.21	0.44
60-89	136	87.4	83.4	86.9	0.45	0.95
30-59	60	96.0	94.0	92.4	0.93	0.65
15-29	23	93.6	98.3	99.7	0.95	0.74
<15	23	98.6	98.3	100	0.27	0.23
Positive predictive value (%)						
=90	69	79.7	95.8	91.2	0.01*	0.09
60-89	136	83.5	80.4	83.1	0.61	0.94
30-59	60	81.5	76.6	73.6	0.66	0.41
15-29	23	82.6	78.3	95.7	0.99	0.34
<15	23	85.3	82.0	100	0.92	0.18
Negative predictive value (%)						
=90	69	95.8	91.3	93.3	0.47	0.79
60-89	136	85.9	89.6	86.9	0.46	0.95
30-59	60	93.8	95.6	86.9	0.97	0.33
15-29	23	98.6	98.3	99.7	0.27	0.23
<15	23	100	100	100	-	-
Precision						
=90	69	1.6	1.5	1.5	1.00	0.6
60-89	136	8.1	7.1	7.4	0.13	0.30
30-59	60	9.9	8.7	7.9	0.32	0.09
15-29	23	4.0	3.7	3.4	0.7	0.45
<15	23	1.1	1.0	1.1	0.66	1.00
Overall	-	10.4	9.7	9.2	0.22	0.03*
Accuracy						
15%						
=90	69	72.5	73.9	79.7	0.99	0.43
60-89	136	83.1	83.8	83.1	0.99	0.87
30-59	60	58.3	51.7	65.0	0.59	0.57
15-29	23	34.8	26.1	82.6	0.75	0.003*
<15	23	8.7	13.0	82.6	0.99	0.001*
Overall	-	66.9	65.9	78.8	0.86	0.001*
30%						
=90	69	97.1	97.1	97.1	0.61	0.61
60-89	136	99.3	99.3	99.3	0.47	0.47
30-59	60	90.0	91.7	91.7	0.99	0.99
15-29	23	87.0	87.0	95.7	0.66	0.59
<15	23	52.2	78.3	100.0	0.12	<0.001*
Overall	-	92.6	94.9	97.1	0.3	0.02*
50%						
=90	69	100.0	98.6	100.0	0.97	-
60-89	136	100.0	100.0	100.0	-	-
30-59	60	96.7	100.0	100.0	0.78	0.78
15-29	23	100.0	100.0	100.0	-	-
<15	23	100.0	100.0	100.0	-	-
Overall	-	99.4	99.7	100.0	0.97	0.53

Bias is defined as mean difference between eGFR and mGFR in mls/min/1.73m2. Precision is the standard deviation (SD) of bias. Accuracy is the percentage of eGFR that falls within 30% of mGFR. * Means p <0.05 for correlation between mGFR and eGFR.



HTN hypertension, CGN chronic glomerulonephritis, DM diabetes mellitus, SCN sickle cell nephropathy, OBS URO obstructive uropathy, HIVAN hiv associated nephropathy, ADPKD autosomal dominant polycystic kidney disease, RAS renal artery stenosis, LUPUS N lupus nephritis, SOLITARY K solitary kidney.

Figure 1: Etiology of CKD in the study population

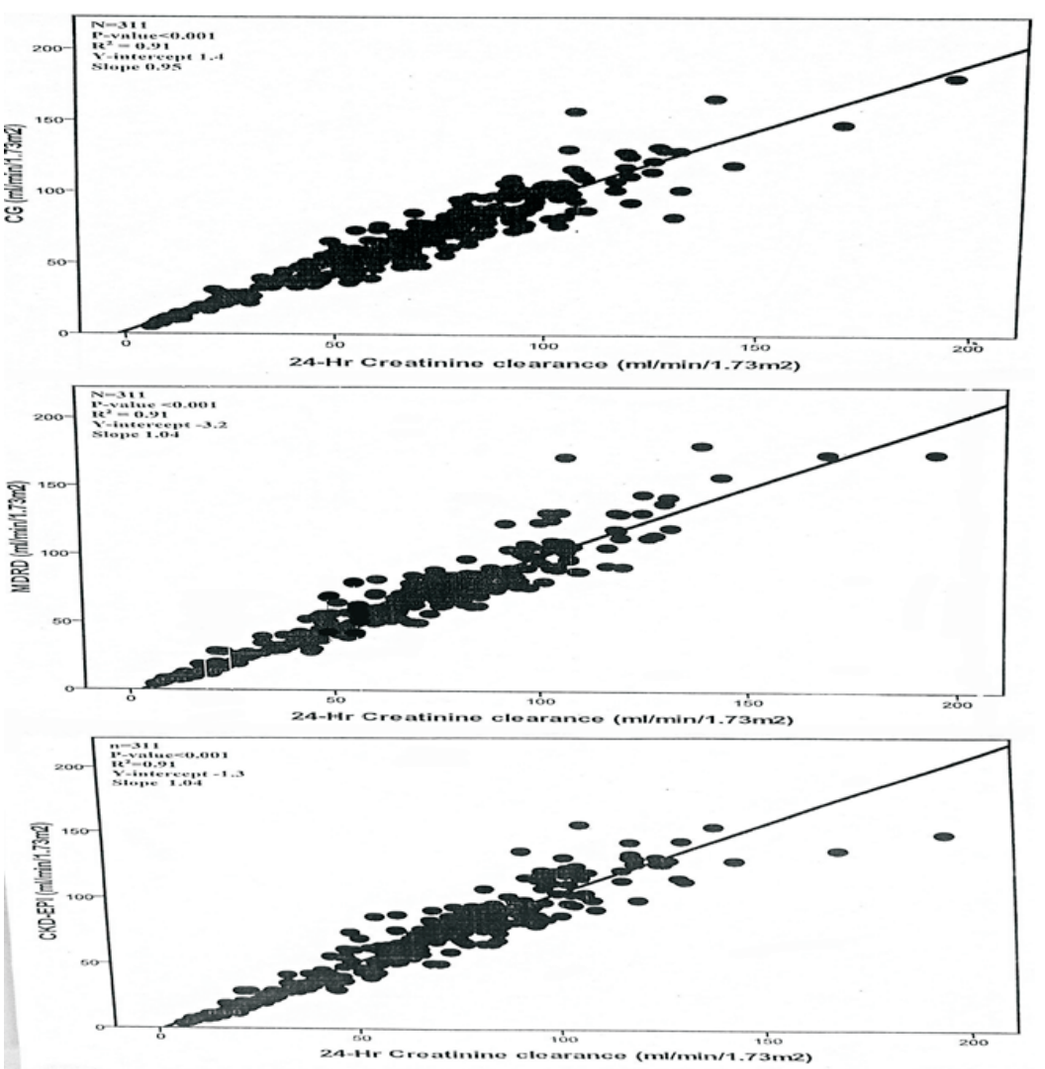
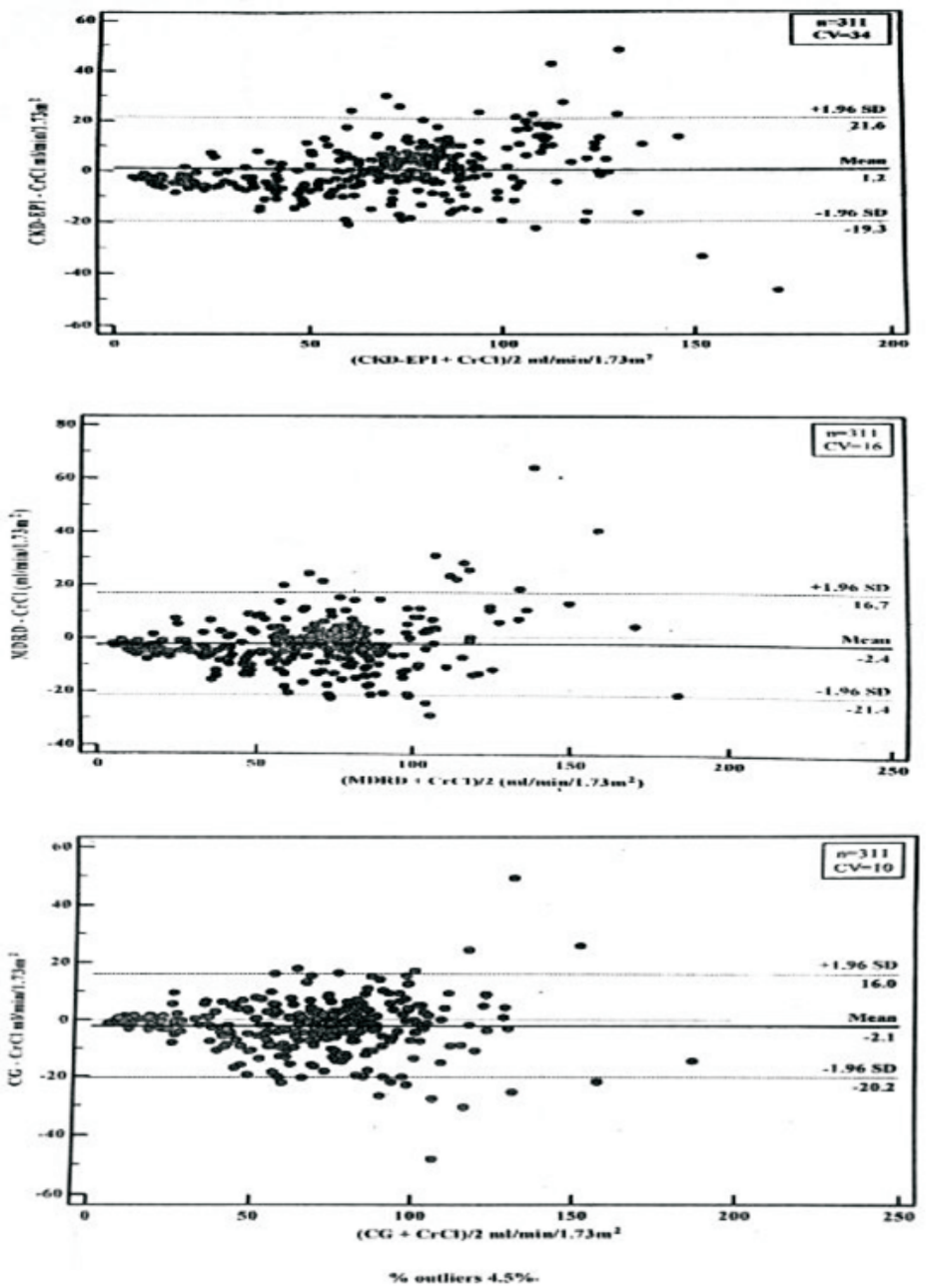
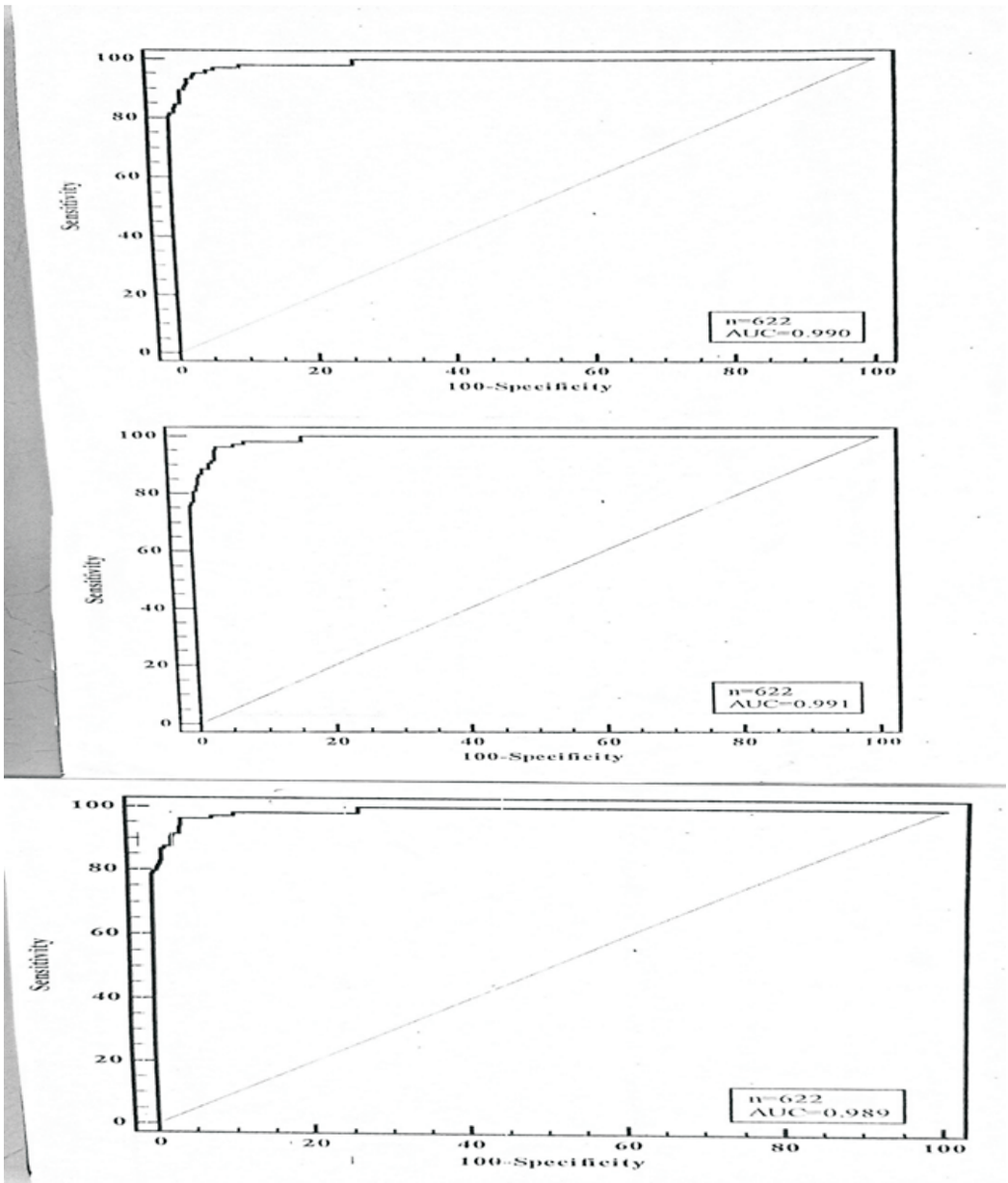


Figure 2: Correlations of the eGFR equations with creatinine clearance (mGFR) in the CKD population



Cr Cl=creatinine clearance, CG=Cockroft-Gault, CKD-EPI=chronic kidney disease epidemiology, MDRD=modification of diet in renal disease, SD= standard deviation CV, coefficient of variation, n, number of CKD patients

Figure 3: Bland-Altman plots between creatinine clearance (mGFR) and the 3 equations (mls/min/1.73m²) plus observed mean difference and 95% limits of agreement in CKD subjects.



(A) MDRD (B) CG (C) CKD-EPI

Figure 4: Receiver operating curve for the 3 equations in the CKD population