

Accuracy and precision of the CKD-EPI and MDRD predictive equations compared with glomerular filtration rate measured by inulin clearance in a Saudi population

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BACKGROUND: Predictive equations for estimating glomerular filtration rate (GFR) in different clinical conditions should be validated by comparing with the measurement of GFR using inulin clearance, a highly accurate measure of GFR.

OBJECTIVES: Our aim was to validate the Chronic Kidney Disease-Epidemiology Collaboration (CKD-EPI) and Modification of Diet in Renal Disease (MDRD) equations by comparing it to the GFR measured using inulin clearance in chronic kidney disease (CKD) patients.

DESIGN: Cross-sectional study performed in adult Saudi patients with CKD.

SETTING: King Saud University Affiliated Hospital, Riyadh, Saudi Arabia in 2014.

PATIENTS AND METHODS: We compared GFR measured by inulin clearance with the estimated GFR calculated using CKD-EPI and MDRD predictive formulas.

MAIN OUTCOME MEASURE(S): Correlation, bias, precision and accuracy between the estimated GFR and inulin clearance.

RESULTS: Comparisons were made in 31 participants (23 CKD and 8 transplanted), including 19 males (mean age 42.2 [15] years and weight 68.7 [18] kg). GFR using inulin was 51.54 (33.8) mL/min/1.73 m². In comparison to inulin clearance, the GFR by the predictive equations was: CKD-EPI creatinine 52.6 (34.4) mL/min/1.73 m² ($P=.490$), CKD-EPI cystatin C 41.39 (30.30) mL/min/1.73 m² ($P=.002$), CKD creatinine-cystatin C 45.03 (30.9) mL/min/1.73 m² ($P=.004$) and MDRD GFR 48.35 (31.5) mL/min/1.73 m² ($P=.028$) (statistical comparisons vs inulin). Bland-Altman plots demonstrated that GFR estimated by the CKD-EPI creatinine was the most accurate compared with inulin clearance, having a mean difference (estimated bias) and limits of agreement of -1.1 (15.6,-17.7). By comparison the mean differences for predictive equations were: CKD-EPI cystatin C 10.2 (43.7,-23.4), CKD creatinine-cystatin C 6.5 (29.3,-16.3) and MDRD 3.2 (18.3,-11.9). Except for CKD-EPI creatinine, all of the equations underestimated GFR in comparison with inulin clearance.

CONCLUSIONS: When compared with inulin clearance, the CKD-EPI creatinine equation is the most accurate, precise and least biased equation for estimation of GFR in the Saudi population and in all subgroups by age, stage of CKD and transplantation status.

LIMITATIONS: Small sample size and the study did not include patients with comorbid diseases such as diabetes, hepatitis C virus infection, and other co-morbidities as well as old age (>80 years).

Chronic kidney disease (CKD) is a growing major health concern worldwide and is the major cause of end-stage renal disease (ESRD). It carries high risk of cardiovascular events and mortality.^{1,2}

Early detection and intensive care can slow the progression of ESRD. Glomerular filtration rate is a surrogate of kidney function. Measurement of true GFR using inulin clearance or radioisotopes is almost impossible

in either clinical practice or research studies and is expensive, time consuming, and requires hospitalization. Predictive equations provide a rapid and convenient method of assessing GFR.^{3,4} But none are currently ideal and suitable for all ethnic groups, gender, age, and weight variations.

Modification of Diet in Renal Disease (MDRD), cystatin C and creatinine are commonly used predictive equations.⁵ Recently, the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) published an equation for estimation of GFR using age, gender, race and serum creatinine that was found to be more accurate.⁴⁻⁶ CKD is common in Saudi Arabia, with a prevalence rate of 5.7%.⁷ The aim of this study was to validate the CKD-EPI and MDRD equations in diverse clinical subsets by comparison with GFR measured by inulin clearance.

PATIENTS AND METHODS

The present study was a cross-sectional study conducted in 31 Saudi adults with chronic kidney disease following the Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines for qualification of CKD with renal transplant.⁸ The study is a re-analysis of our previous study conducted in 2009.⁹ It was performed from January 2014 to June 2014 in affiliation with King Saud University in Riyadh, Saudi Arabia by reevaluating the data using the old CKD and MDRD formula compared with the new CKD-EPI formula.^{3,5,8}

- MDRD equation:

$$\text{GFR} = 1.86 \times (\text{SCr})^{-1.154} \times \text{Age}^{-0.203} \times 0.742 \text{ [If female]}$$

- CKD-EPI creatinine equation:

$$\text{GFR} = 141 \times \min(\text{SCr}/\kappa, 1)^\alpha \times \max(\text{SCr}/\kappa, 1)^{-1.209} \times 0.993^{\text{Age}} \times 1.018 \text{ [If female]}$$

- CKD-EPI cystatin C equation:

$$\text{GFR} = 133 \times \min(\text{Scys}/0.8, 1)^{-0.499} \times \max(\text{Scys}/0.8, 1)^{-1.328} \times 0.996^{\text{Age}} \times 0.932 \text{ [If female]}$$

- CKD-EPI creatinine-cystatin C equation:

$$135 \min(\text{SCr}/\kappa, 1)^\alpha \max(\text{SCr}/\kappa, 1)^{-0.601} \times \min(\text{Scys}/0.8, 1)^{-0.375} \times \max(\text{Scys}/0.8, 1)^{-0.711} \times 0.995^{\text{Age}} \times 0.969 \text{ [If female]}$$

The National Kidney Foundation (NKF) considers a normal GFR value to be 90-120 mL/min/1.73 m². An eGFR below 60 mL/min/1.73 m² suggests kidney damage.^{1,3,8}

Inclusion criteria were that subjects be Saudi adults of either gender and older than 18 years of age. Exclusion criteria were acute renal failure, heart failure, pregnancy, malignancy, or infection. Thirty-one patients gave consent to participate in data collection. The eight patients were recently transplanted (6 months to 9 months), medically stable for more than

6 months, had stable renal function for 3 months and were using transplant medications (predisone, azothioprine or mycophenolate mofetil and cyclosporine or tacrolimus).

In all subjects, blood samples were drawn for estimation of serum creatinine, fasting blood sugar, and other biochemistry tests for auto-analysis in the clinical laboratory of King Khalid University Hospital, Riyadh, which is accredited by the College of American Pathology and Clinical Laboratory Improvement Amendments (CLIA). Serum creatinine was analyzed using Jaffe's method which was standardized to isotope dilution mass spectrometry. Serum cystatin C was measured by nephroimmunoassay, which is described in our previous article,⁹ using the third generation automated Dimension RxL Integrated Chemistry analyzer (Dade Behring) and commercially available assay kits. An inulin clearance test was also performed as reported previously.⁹ Patients gave informed consent to participate and were not exposed to any risks or hazards. All procedures were in accordance with the ethical standards and approved by the Institutional Review Board, Deanship of Scientific Research of King Saud University.

SPSS version 17 was used for statistical analysis (SPSS Illinois Chicago USA, <https://goo.gl/G0S4LT>). Quantitative variables are expressed as mean and standard deviation. Pearson correlation and paired t test samples were used to compare the predictive equations with inulin, and the Wilcoxon signed-rank test was used to measure small samples. The Bland-Altman plot and regression analysis were used to evaluate the accuracy and bias of paired sample tests. The mean difference in the Bland-Altman plot is the estimated bias, and the standard deviation of the differences measures the random fluctuations around this mean. Statistical significance was a *P* value <.05.

Table 1. The clinical characteristics of study participants.

Variable	Mean (SD)	Range
Age	42.26 (15.45)	19-74
Male	19	
Height (cm)	160.58 (10.6)	134-178
Weight (kg)	68.76 (18)	42.6-131.7
BSA (m ²)	1.73 (0.23)	1.35-2.5
Serum creatinine (ml/min/1.73 m ²)	199.8 (164.15)	51-815

BSA=body surface area.

RESULTS

There were 31 participants, (23 CKD and 8 transplant patients, with 19 males) with a mean age of 42.26 (15.21) years and mean weight of 68.76 (18) kg (**Table 1**). GFR inulin was 51.54 (33.8) mL/min/1.73m², GFR MDRD was 48.35 (31.5) mL/min/1.73m², GFR CKD-EPI creatinine was 52.61 (34.39) mL/min/1.73m², GFR cystatin C was 41.39 (30.02) mL/min/1.73 m², and GFR CKD cystatin C and creatinine was 45.0 (30.9) mL/min/1.73 m² (**Table 2**). Comparison of estimated GFR by the predictive equations with GFR measured by inulin clearance (a highly accurate measure of GFR), under the subsets of age, gender, BMI, CKD and kidney transplant are shown in **Table 2**. In contrast to other predictive equations, eGFR CKD-EPI creatinine was closer to the inulin clearance and the difference between GFR inulin and eGFR CKD-EPI creatinine was statistically insignificant in all CKD patients, and in

transplant patients, as well as by gender, age, and BMI. The MDRD equation appeared to underestimate GFR. **Table 3** shows the correlation of GFR measured by inulin clearance with predictive equations. MDRD and CKD-EPI creatinine were less advantageous compared with CKD-EPI cystatin C and CKD-EPI cystatin-creatinine. **Figure 1** shows the linear relationship between inulin clearance and CKD-EPI creatinine ($y=0.9537x + 1.367$, $r^2=0.9391$). **Figure 2** shows the linear relationship between the MDRD formula and inulin clearance ($y=1.0464x + 0.9481$, $r^2=0.95$). The Bland-Altman plot and regression analysis was performed to compare the relative performance of all the predictive equations by comparing with GFR measured by inulin clearance. When the difference in GFR values by the inulin clearance versus each of the four methods was compared with the null hypothesis of no difference (zero), the difference between GFR by inulin clearance versus three

Table 2. Table 2. Mean and standard deviation for GFR by inulin clearance compared with estimated GFR by predictive equations in different subsets.

	Mean (SD) Inulin Clearance	CKD-EPI creatinine		MDRD		CKD-EPI cystatin C		CKD-EPI cystatin C and creatinine	
		Mean (SD)	P value	Mean (SD)	P value	Mean (SD)	P value	Mean (SD)	P value
Total patients	51.54 (33.8)	52.61 (34.39)	.490	48.35 (31.5)	.028	41.39 (30.02)	.002	45.03 (30.9)	.004
CKD patients (23)	46.3 (35.6)	47.6 (35.9)	.499	44.2 (33.4)	.22	41.43 (33.9)	.220	43.3 (34.6)	.094
Transplant patients (8)	66.6 (23.7)	67 (26.5)	.874	60.25 (23.2)	.025	41.25 (15.4)	.013	50 (17.5)	.014
Male patients (n=19)	58.5 (32.8)	58.3 (34.8)	.9	53.5 (31)	.008	42.21 (26.11)	.001	47.7 (28.4)	.001
Female patients (n=12)	40.6 (34)	43.6 (33)	.213	40.2 (31.6)	.88	40 (36)	.823	40.75 (35.5)	.937
<40 years (n=12)	60.5 (35)	64.8 (36)	.202	58.5 (33)	.459	50.58 (28.2)	.122	55.08 (29.9)	.195
40–60 years (n=14)	48 (35.6)	47.6 (35.7)	.736	44 (33)	.032	37.6 (34)	.042	41 (39.3)	.041
>60 years (n=5)	39.6 (25)	37.2 (18)	.538	36.0 (16.3)	.427	29.8 (17.9)	.003	32.2 (18.4)	.007
BMI <30 kg/m ² (n=23)	52.6 (35)	53.8 (36)	.423	49.7 (34)	.03	39.87 (29.06)	.003	44.7 (31.8)	.007
BMI ≥30kg/m ² (n=8)	48.5 (31.8)	49 (28.06)	.907	44.38 (24.4)	.363	45.75 (34.3)	.482	45.8 (30.5)	.375

Units are mL/min/1.73 m²

methods (MDRD formula, CKD-EPI cystatin and CKD cystatin-creatinine) were statistically significant. With the CKD-EPI creatinine method, the difference was not statistically significant compared with the values by the inulin clearance method. This indicates significant agreement between inulin clearance and the CKD-EPI creatinine methods. The Bland-Altman plot also showed a bias of 1.07 with 95% confidence interval (-2.05, 4.19) which indicates good agreement between inulin clearance and the CKD-EPI creatinine methods when compared the bias of other methods as shown in **Table 4**. The standard deviation of the precision was 8.50 and the limits of agreement of these two methods are -15.60, 17.74. From the Bland-Altman plot, the equal distribution of values around the mean indicates that the two tests produce similar results (the average difference is close to zero). To assess proportional bias, the regression between the difference of GFR between these two methods (CDK-EPI creatinine and MDRD) and the mean GFR of these two methods showed a non-significant proportional bias ($b=-0.16$, $t=-0.35$, $P=.730$). **Table 4, Figure 3 and 4.**

DISCUSSION

GFR estimation is mandatory for evaluation of renal function in transplanted kidney patients and in staging of CKD. Since GFR predictive equations⁴⁻⁶ are not perfect and their performance is affected by age, gender, ethnicity, BMI and clinical category of the patient,⁵ it is

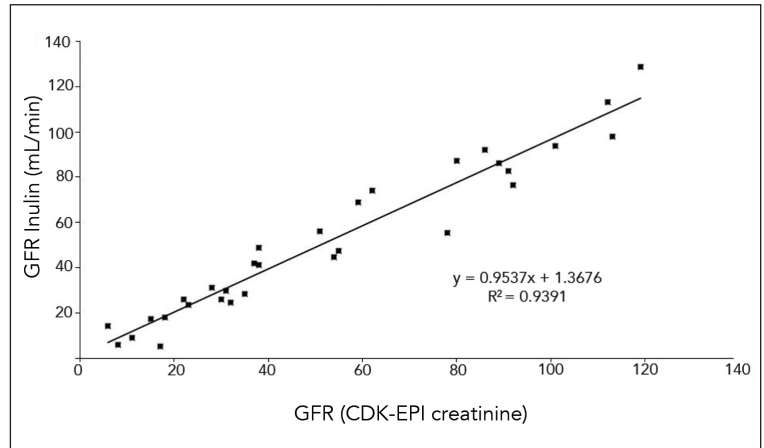


Figure 1. Correlation of eGFR determined by CKD EPI creatinine and GFR measured by inulin clearance.

Table 3. Correlation between glomerular filtration rate equations and inulin clearance test in various clinical subgroups.

Patient's category	GFR CKD-EPI-creatinine vs. GFR Inulin	GFR MDRD vs. GFR Inulin	GFR cystatin vs. GFR Inulin	GFR CKD cystatin creatinine vs. GFR Inulin
Kidney transplant	0.963 .001	0.964 .001	0.442 .132	0.793 .009
CKD patients	0.968 .001	0.975 .001	0.946 .001	0.973 .001
Male	0.968 .001	0.976 .001	0.822 .001	0.928 .001
Females	0.972 .001	0.974 .001	0.978 .001	0.984 .001
Age <40 years	0.952 .001	0.966 .001	0.811 .001	0.924 .001
Age >60 years	0.979 .001	0.985 .001	0.993 .001	0.989 .001
BMI <30 (kg/m ²)	0.980 .001	0.986 .001	0.853 .001	0.934 .001
BMI >30 (kg/m ²)	0.932 .001	0.942 .001	0.953 .001	0.969 .001
Overall	0.969 .001	0.975 .001	0.863 .001	0.939 .001
Age 40-60 years	0.990 .001	0.986 .001	0.877 .001	0.944 .001

Values are ml/min/1.73 m².

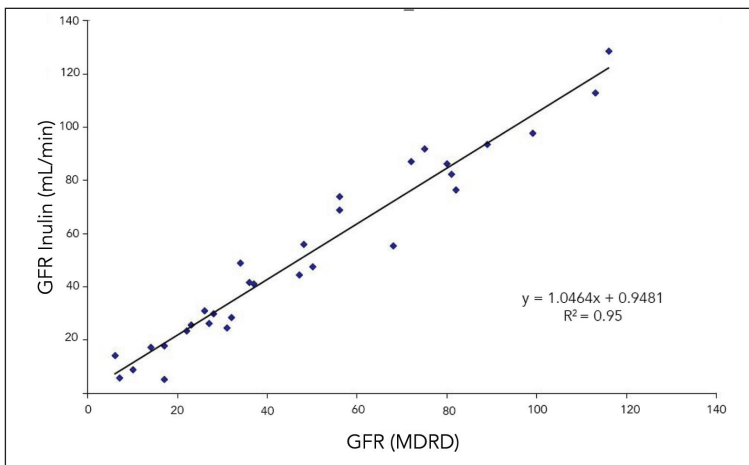


Figure 2. eGFR determined by MDRD and GFR measured by inulin clearance.

Table 4. Performance of predictive equations for estimation of GFR in relation to GFR measured by inulin.

Category	Mean GFR (SD)	Mean difference	95% CI for bias	SD of bias precision	Limits of agreement
GFR inulin	51.54 (33.8)				
MDRD	48.35 (33.7)	-3.2	-6.02 to 0.32	7.71	-18.3, 11.92
CKD-EPI-creatinine	52.6 (34.4)	-1.1	-2.05 to 4.19	8.5	-15.6, 17.76
Cystatin C	41.4 (30)	-10.2	-16.4 to 3.89	17.1	-43.66, 23.35
CKD cystatin creatinine	45.03 (30.9)	-6.5	-10.78 to 2.24	11.6	-29.33, 16.3

Values are ml/min/1.73 m².

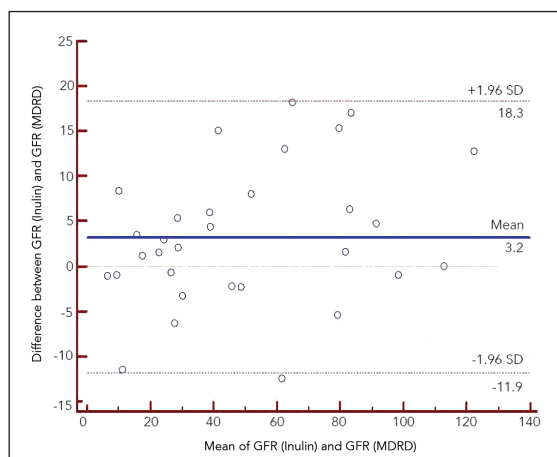


Figure 3. Bland-Altman plots comparing the GFR calculated by MDRD with the GFR measured by the inulin clearance.

therefore necessary to evaluate the performance of estimated GFR predictive equations in order to determine the selection of a most appropriate simple and most applicable equation for GFR estimation in a Saudi population. In our previous study that compared the MDRD and Cockcroft-Gault serum and reciprocal serum cystatin C equations to inulin clearance, we found that MDRD had a strong correlation with inulin clearance.⁹

A recent study found that in a Saudi population, CKD-EPI creatinine was most appropriate, most accurate, and had less bias in estimating GFR as compared to conventional GFR estimating equations (MDRD, CKD-EPI cystatin C, and CKD-EPI cystatin C-creatinine). Other studies have also reported that the CKD-EPI creatinine equation has better performance in other ethnic populations with different clinical presentations. Levey et al showed that CKD-EPI creatinine is more accurate, precise and had less bias compared with urinary clearance by iothalamate.⁵

Wienek et al compared GFR measurement using 125I-iothalamate to determine the performance of CKD-EPI, MDRD and Cockcroft-Gault. It appeared that absolute bias for all the predictive equations was influenced by both gender and age. They also reported that CKD-EPI creatinine gave the best estimation of GFR although its accuracy was close to that of the MDRD.⁴ Kilbride et al measured GFR in an elderly European population using iohexol clearance and compared it to predictive equations. They concluded that the CKD-EPI creatinine equation appeared to be have less bias and was more accurate than the MDRD equation. They also reported that the CKD-EPI creatinine equation is suitable in older people as in younger people of European ancestry.¹⁰

In the present study, the other predictive equations underestimated GFR in all patients and in clinical subsets of CKD, transplant, GFR categories, different ages, and BMI groups. This finding has an important implication in that predictive equations other than CKD-EPI might be misinterpreted and increase the risk of a false positive distribution of CKD among the Saudi population. The accuracy of CKD-EPI has an important implication for public health and clinical practice and can even replace other predictive equations for estimation of GFR in Saudi adults. Another study have also reported an underestimation of GFR by MDRD equation.¹¹

Cater et al estimated GFR in an adult UK population and found a higher eGFR by CKD-EPI, particularly among patients 18-59 years old as compared to the MDRD equation.¹² Lujan et al reported that the GFR MDRD equation predicted a lower GFR than CKD-EPI creatinine in a comparison of 85 living kidney do-

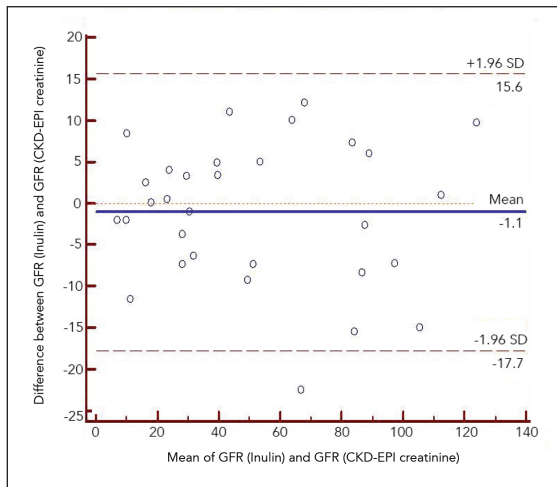


Figure 4. Bland and Altman plot comparing the GFR calculated by the CKD-EPI creatinine formula with the GFR measured by inulin clearance.

nors using non-radiolabeled iothalamate clearance.¹³ In contrast to our result, the study by Veronese et al of South Brazilian patients showed that CKD-EPI GFR underestimated GFR for GFR >60 and had low accuracy. Their explanation was that the population was of mixed ethnicity with a predominance of Germans, Italians, Portuguese, Spanish, along with native Indians and African blacks.¹⁴ Mixed ethnicity may have uniquely affected creatinine production and the performance of estimated GFR formulas.

In the present study, the CKD-EPI cystatin C and creatinine equation had maximum bias compared with the CKD-EPI and MDRD. This is in agreement with Liu et al who reported that the bias of the CKD-EPI creatinine-cystatin C equation was greater than with other equations.¹⁵ However, they suggested that the CKD-EPI creatinine-cystatin C equation is suitable for an elderly Chinese population.

The present study has shown that the value of GFR in renal transplant patients using the CKD-EPI creati-

nine equation was more accurate and closer to measured GFR by inulin clearance and had less bias than the other equations. In contrast to our findings, the study of Masson et al¹⁶ and Uwe et al,¹⁷ found that the CKD-EPI creatinine equation did not provide a better GFR prediction in renal transplant patients compared with the MDRD study equation even in the earlier CKD stages in Caucasian patients. However, our findings are consistent with the findings of White et al¹⁸ who studied 207 stable kidney transplanted patients using the plasma clearance of (99m)Tc-diethylenetriamine penta-acetic acid and compared to the GFR equation. They showed that CKD-EPI creatinine improved the GFR in renal transplant and that CKD-EPI can replace MDRD.

The present study is the first comprehensive study from the region using inulin clearance to compare with GFR estimated by predictive equations. Furthermore, we have evaluated the performance of different predictive equations in several subsets of clinical conditions like renal transplant, chronic kidney disease, BMI, age, and gender, which were lacking in previous studies from the region. However, the present study had a small sample size and we did not include comorbid diseases like diabetes, HCV, and other co-morbidities as well as old age >80 years.

In conclusion, we conclude that the CKD-EPI creatinine equation is more accurate, precise and less biased in the estimation of GFR in a Saudi population and in all subgroups such as age, stages of CKD and transplanted patients. GFR predicted by MDRD was second after CKD-EPI creatinine while other predictive equations such as CKD-EPI cystatin C, and CKD-EPI creatinine-cystatin were inferior to CKD-EPI creatinine and MDRD formula in accuracy and precision.

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