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Comparison of 24-Hour Urine to Estimated Renal Function using CKD-EPI, MDRD4 and Cockcroft-Gault in Specific Patient Subsets

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Abstract

Background: The purpose of this study was to compare the performance of the Cockcroft-Gault (CG), Modification of Diet in Renal Disease (MDRD-4), and Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equations for estimation of glomerular filtration rate (GFR) using 24-hour urine measurements. Secondary objectives included evaluation of such estimations based on age, body mass index (BMI), and pregnancy.

Methods: This was a retrospective chart review of 195 patients who were ≥ 18 years of age and who had a 24-hour urine sample collected to determine GFR. Subjects were identified based on an ICD-9 search strategy for 24-hour urine sample. Demographic and laboratory data were collected from medical records and used to calculate GFR estimates. CKD-EPI, CG, MDRD-4 and generated estimates of GFR were calculated for each patient included.

Results: Calculated GFR using CG, CKD-EPI, and MDRD-4 resulted in significant underestimation. Reclassification to a higher GFR proved less likely in those who were obese or elderly. As age increased, GFR decreased in both the male and female population for all creatinine based formulas except 24-hour urine collection. CG reported the highest mean average among the creatinine-based equations in all subgroups with a BMI >18.5 while CKD-EPI reported the lowest.

Conclusions: While the equations evaluated did not provide an accurate measure of GFR, these methods are considered the least invasive and most convenient. Based on the results of this study, use of a 24-hour urine collection should be used when accurate estimation of GFR is warranted and measurements of inulin clearance is not feasible.

Keywords: Chronic kidney disease; Epidemiology collaboration (CKD-EPI); Cockcroft-Gault; Modification of Diet in Renal Disease (MDRD); Creatinine Clearance (CrCl); Renal function, Glomerular Filtration Rate (GFR)

Introduction

Assessment of renal function is commonly practiced and utilized on a daily basis in the evaluation of many acute conditions as well as chronic co-morbidities like heart failure, hypertension, and diabetes. Glomerular filtration rate (GFR) is an excellent measure of the filtering capacity of the kidneys. The total GFR can be used as an index of functioning renal mass, since the total kidney GFR is equal to the sum of the filtration rates in each of the functioning nephrons [1]. Inulin clearance is accepted as the gold standard for measuring GFR. However, measurement of GFR by clearance of inulin requires an intravenous infusion followed by timed urine collections over several hours making this method costly and burdensome. In response, several alternative methods for estimating GFR are used clinically. Urinary clearance of 125I-iothalamate and 99mTc-DTPA, exogenous radioactive markers, provide excellent measures of GFR but are not readily available [2]. Plasma clearance of exogenous substances such as iohexol and 51Cr-EDTA are used as well but require estimates of body size that decrease their precision. More recently serum cystatin C has been utilized to estimate GFR but whether it provides sufficient improvement to warrant widespread clinical use is debatable. In clinical practice the most widely used estimates of GFR are based on serum creatinine (SCr) concentration or 24-hour creatinine clearance [3]. Equations that predict GFR and creatinine clearance from SCr are widely used and have been shown to produce more accurate estimates of GFR than SCr alone. The formulas that are most widely used to estimate kidney function in adults are the Cockcroft-Gault (CG) formula [4], Modification of Diet in Renal Disease (MDRD) formula [5,6] and the more recently developed Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula [7]. The current Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines advocate the use of CG and MDRD creatinine-based equations for estimating GFR in adults as opposed to SCr alone. The formula introduced by Cockcroft and Gault in 1976 was derived from 236, relatively young, hospitalized patients at a Veterans Administration facility with mild renal dysfunction. Aside from the limitations due to lack of diversity in the study population, it was validated against measured creatinine clearance (CrCl). Creatinine clearance is an accepted estimate of GFR but is not equal to GFR because creatinine is filtered at the glomerulus and secreted at the proximal tubule. In 1999 Levey et al. proposed the MDRD formula, which included serum urea and albumin as co-variables. Developed in 1,070 predominately middle-aged patients with chronic kidney disease (CKD), the MDRD formula was validated against the renal clearance of 125I-iothalamate in outpatients with moderate to severe renal dysfunction. MDRD is most accurate in predicting GFR in those with mild renal impairment since it was derived from a population with

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suboptimal kidney function; however, the equation is not as precise in estimating GFR in the healthy population with normal renal function, causing it to overestimate CKD prevalence. In 2009, Levey developed a new equation, CKD-EPI, from a large sample of CKD and health subjects. The equation incorporates the same four variables, (SCr, age, gender, and race), that the MDRD-4 equation uses, but applies different coefficients. It was derived and validated among 10 studies that included [8], 254 participants. Additionally, it was externally validated in 16 additional studies consisting of 3,896 participants [8]. Compared to MDRD, CKD-EPI performed just as accurate in subgroups with eGFR <60 ml/min/1.73m2 and substantially more accurate at higher GFR [7]. It also yielded a lower estimated prevalence of CKD thus improving misclassification [9,10].

It is well documented that CG, MDRD, and CKD-EPI derived GFR estimates deviate from gold standard measures of GFR as well as from one another [2,7]. Since each equation was derived from populations with differing demographics and patient parameters, and considering that different mathematical derivations were utilized in formulating each equation, it is no surprise that the interpretation of these equations remains a topic of great debate.

In this study, the mean and standard deviation of the CG, MDRD-4, CKD-EPI estimates of GFR and 24-hour urine measurements of creatinine clearance were compared to each other. Additionally, the comparable performance of these equations based on age, BMI, and pregnancy was evaluated.

Materials and Methods

Patient selection

This study took place at Hendrick Medical Center a 522-bed community hospital. Records of all hospitalized patients who had a 24-hour creatinine clearance ordered within a 13-month time frame were reviewed retrospectively. Patients receiving dialysis or concurrent medications know to influence GFR (cimetidine, trimethoprim, etc.) were excluded. Patients younger than 18 years old were also excluded. Twenty-four hour creatinine clearance measurements were compared to estimates of GFR utilizing the CKD-EPI, CG, and MDRD-4 equations. Of particular interest was the performance of the above equations in specific patient subgroups. Study population characteristics of interest included age, BMI, and those that were pregnant.

GFR measurements

Renal function was measured directly by 24-hour urine creatinine clearance.

Recognizing that obtaining a 24-hour urine sample is cumbersome for any patient, only samples already collected for inpatients were included. It was determined that inpatient 24-hour urine samples would provide the most accurate and complete data for inclusion into our study. Each 24-hour creatinine clearance measurement was compared to the CKD-EPI, CG and MDRD-4 equations.

Creatinine assay

All creatinine measurements were performed in the Hendrick Medical Center inpatient laboratory. A modified kinetic Jaffé method was used. A five-point calibration was applied in each assay. Per laboratory protocol, two levels of a quality control material with known creatinine concentrations were analyzed to confirm accuracy of the creatinine assay.

Creatinine-Based estimation of GFR

Body weight is a variable used in the CG equation that has a significant influence on estimates of GFR. Therefore, a discussion of the weight utilized for the CG equation is essential Table 1. The methods outlined in Table 1 were utilized to minimize the influence of body weight on the CG formula for obese patients, resulting in a more accurate estimate of true renal function. All MDRD-4 and CKD-EPI GFR estimates were adjusted to mL/min, by multiplying by the subjects' body surface area (BSA), in order to match CG GFR estimate units of mL/min (indicated as MDRD-4 BSA and CKD-EPI BSA GFR respectively) for comparison purposes.

Statistical analysis

A paired t-test was used to compare for statistical significance in continuous variables. Mean ± standard error was reported for continuous variables. Frequency and percentages were used to express categorical data.

Results

Demographics and GFR distribution

The main demographics of the study participants are shown in Table 2. For subsequent analyses, the study population was divided into subgroups according to gender, BMI, age (18 to 64 years and 65 years or older), and measured GFR (≥ 60 and < 60 ml/min).

Gender

Compared with men, women had a lower body weight. The average weight was 94.3 kg (SD 24.1) for men and 87.8 kg (SD 26.34) for women ($p<0.0912$). As would be expected, the average serum creatinine in women (1.31 mg/dL) was significantly less than the male subjects (2.57 mg/dL, $p< 0.0001$). The mean GFR was higher in females than males for all the equations used to calculate GFR. The 24-hour urine collection provided the highest GFR for women at 102.94 mL/min, while MDRD-4 BSA provided the highest GFR for men at 55.09 mL/min. CKD-EPI BSA provided the lowest GFR estimate for both the female and male

Equations for Body Weight:
IBW(male) = 50 + (2.3 X (ht - 60))
IBW(female) = 45.5 + (2.3 X (ht - 60))
Adjusted body weight = IBW + 0.4(ABW - IBW)
**ht: height in inches*
**ABW = actual body weight*
Cockcroft-Gault:
CG(male) = ((140 - age) X wt) / (72 X SCr)
CG(female) = 0.85 X CG(male)
***If ABW > IBW then wt = IBW*
***If ABW < IBW then wt = ABW*
***If ABW/IBW >= 1.2 then wt = adjusted body weight*
Modification of Diet in Renal Disease:
$MDRD^4 = (186 X (SCr)^{-1.154} X (age)^{-0.203} X (0.742 \text{ if female}) X (1.212 \text{ if African American}))$
$MDRD^6 = (170 X (SCr)^{-0.999} X (age)^{-0.176} X (0.762 \text{ if female}) X (1.180 \text{ if African American}) X (BUN)^{-0.170} X (albumin)^{0.318}$
Chronic Kidney Disease Epidemiology Collaboration:
CKD-EPI= 141 X min(SCr/κ,1)α X max(SCr/κ,1)-1.209 X 0.993Age X 1.018 [if female] X 1.159 [if African-American]
***α = -0.329 if female*
***α = -0.411 if male*
***κ= 0.7 if female*
***κ= 0.9 if male*
***min= the minimum of SCr/K or 1*
***max= the maximum of SCr/K or 11*
0.993^{Age} X 1.018 [if female] X 1.159 [if African-American]

Table 1: Equations used for study comparison

	Overall (N = 195)	Female (n=125)		Male (n=70)	
		Age<65 y (n=93)	Age ≥65 y (n=32)	Age <65 y (n= 32)	Age ≥65 y (n= 38)
Serum creatinine (mg/dL)	1.8 (1.5)	1.1 (1.0)	1.9 (1.1)	3.0 (2.4)	2.3 (1.4)
24-hour urine CrCl (mL/min)	85.2 (67.3)	124.9 (73.3)	42.4 (24.2)	52 (34.8)	55.2 (36.5)
Age (y)	52.0 (20.7)	35.2 (14.3)	76.2 (6.9)	54.1 (9.5)	75.2 (6.6)
Weight (kg)	90.1 (25.7)	91.7 (27.8)	79.3 (18.6)	96.4 (25.9)	95 (23)
Height (in)	65.3 (4.2)	63.6 (3.0)	65.6 (4.4)	69.2 (3.2)	70.4 (3.8)
BSA (m^2)	2.1 (1.9)	2.0 (0.3)	1.9 (0.3)	2.9 (4.6)	2.1 (0.3)
BMI (kg/m^2)	32.6 (8.5)	34.6 (9.4)	31.4 (6.9)	31.4 (8.6)	31.4 (36.5)

*Data listed as mean (SD)
BSA = body surface area; BMI = body mass index; CrCl = creatinine clearance; y = years

Table 2: Demographic and clinical characteristics of study population*

subgroup at 81.82 and 43.11 mL/min. Subgroup analyses of non-pregnant and pregnant subjects yielded a mean serum creatinine of 1.78 mg/dL and 0.68 mg/dL, respectively. Non-pregnant women's serum creatinine was still less than the male subjects (p=0.003). Performance of equations based on gender is shown in Table 3.

Age

The subjects in this study were divided by gender and age into 6 groups: IF (Age<39, n=65); IIF (Age 40-59, n=20); IIIF (Age>60, n=41); IM (age<39, n=2); IIM (age 40-59, n=17); IIIM (age>60, n=50). The mean of the MDRD-4 BSA, CG, CKD-EPI BSA, and 24h urine collection are shown in Table 4. On average, the CG equation yielded higher values and CKD-EPI BSA yielded lower values. As age increased, GFR decreased in both the males and female population for all creatinine based formulas except 24-hour urine collection.

Body mass index

The subjects in the study were divided into 4 groups based on BMI. Ranges were: <18.5, 18.5 to 25, 25 to 30, and >30. CG reported the highest mean average among the creatinine based equations in all subgroups >18.5 while CKD-EPI BSA reported the lowest mean average as shown in Table 4.

Reclassification

Comparing MDRD-4 BSA to CKD-EPI BSA, we found that 16 subjects could be reclassified from a GFR >60 mL/min to CKD stage 3, while 2 subjects could be reclassified from CKD stage 3 to GFR >60 mL/min.

Comparing CG to CKD-EPI BSA, we found that 10 subjects could be reclassified from a GFR >60 mL/min to CKD stage 3, while 5 subjects could be reclassified from CKD stage 3 to GFR >60 mL/min.

Pregnancy

We compared creatinine clearance by 24-hour urine collection, the CG formula, MDRD-4 formula, and CKD-EPI formula. Table 4 presents the mean (SD) of GFR measurements for the pregnant and non-pregnant subpopulations. GFR obtained by the different equations were statistically different (p<.0001). The mean value of the creatinine-based formulas had a maximum difference of over 32 mL/min ranging from 123.44 mL/min with CKD-EPI BSA to 155.44 mL/min with CG. The average age of a pregnant group (25.7 years) was lower than the average age of the non-pregnant group (60 years, p<0.0001).

Discussion

Analyzing a study population that consisted of a representative sample of patients within our institution was a priority of the study and why so few exclusion criteria were used. A unique aspect of our study population is that it included subjects with measured GFR ranging from 4 to 406 mL/min. Therefore, the performance of the CG and MDRD-4 formulas were assessed over a wide range of kidney function.

Recent reports emphasize the importance of careful calibration of serum creatinine measurements to estimate GFR reliably in patients with normal or near-normal renal function, when using creatinine-based equations [3,10]. Differences among clinical laboratories in calibration of serum creatinine assays can account for errors in GFR estimates as high as 20% [11,12]. Variation is proportionately greater at low serum creatinine values than at higher values, making the impact of this variability especially influential in individuals with near-normal serum creatinine concentration. Development of an international calibration standard in the future will improve laboratory differences in measurement of serum creatinine. For this study, a five-point calibration was applied in each assay in the absence of a calibration standard. Per laboratory protocol, at least once each day, two levels of a quality control were analyzed to confirm accuracy of the creatinine assay.

Differences in equations were more significant in women than in men. This could be explained by the statistically significant difference in serum creatinine between male and female as they differed by 1.26 mg/dL. However, upon removing the pregnant subgroup from the female population the difference between non-pregnant females compared to males was 0.79 mg/dL. CrCl can therefore be skewed in the younger population and gender analysis if pregnancy is not taken into consideration.

Patients who had higher body weight had higher GFR and higher BMI on average. Nothing of significance can be assumed for those with a BMI <18.5 considering an insignificant sample size. However, as BMI increased, there is a noticeable trend in CrCl throughout all the creatinine-based formulas. MDRD-4 BSA and CG showed an increase in CrCl of approximately 19 mL/min while CKD-EPI BSA showed an increase of about 16 mL/min. This indicated that BMI is an independent determinant of CrCl, however, the mechanism of how increased body weight affects renal function is still not well understood [13]. We would expect GFR to decrease over time because the number of nephrons in the human body doesn't increase with body weight, resulting in hyperfiltration and increased glomerular intracapillary

	Female (n=125)	Male (n=70)	p-value
Age (y)	45.3 (21.3)	64.3 (12.4)	< 0.0001
Weight (kg)	87.8 (26.4)	94.3 (24.1)	0.0912
Serum creatinine (mg/dL)	1.3 (1.0)	2.6 (1.9)	< 0.0001
24-hour urine CrCl (mL/min)	102.9 (73.9)	52.9 (35.2)	< 0.0001
CG (mL/min)	98.4 (71.3)	49.1 (32.4)	< 0.0001
MDRD-4 BSA (mL/min)	89.1 (53.2)	55.1 (36.5)	< 0.0001
CKD-EPI BSA (mL/min)	81.8 (48.2)	43.1 (27.7)	< 0.0001
*Data listed as mean (SD) CrCl = creatinine clearance			

Table 3: Performance of equations based on gender*

	n (%)	CKD-EPI BSA, mL/min	MDRD-4 BSA, mL/min	CG, mL/min	24-hour urine CrCl, mL/min
Total (N=195)	n/a	68.3 (46.0)	77.2 (50.7)	81.3 (64.8)	85.4 (67.4)
BMI: 18.5	2 (1)	80.5 (57.7)	66.5 (40.3)	65.0 (46.7)	39.5 (10.6)
BMI: 18.5-25	32 (16)	50.0 (47.7)	50.9 (39.5)	55.8 (75.9)	57.8 (72.5)
BMI: 25-30	55 (28)	66.6 (46.2)	70.3 (47.1)	73.6 (58.1)	79.1 (59.5)
BMI: >30	104 (53)	83.0 (47.2)	89.7 (52.2)	93.7 (62.5)	98.5 (67.4)
Non-Pregnant	72 (37)	50.6 (37.6)	57.3 (43.7)	55.6 (47.7)	58.3 (47.1)
Pregnant	54 (28)	123.4 (22.2)	131.6 (30.1)	155.4 (56.0)	162.5 (59.8)
Female <39 y	65 (33)	121.1 (22.8)	130.2 (31.3)	152.1 (54.4)	93.8 (70.7)
Female 40-59 y	20 (10)	47.0 (36.5)	53.7 (42.5)	53.8 (44.2)	85.6 (63.4)
Female >60 y	41 (21)	36.5 (23.8)	41.3 (26.5)	35.0 (20.5)	125.9 (79.6)
Male <39 y	2 (1)	91.1 (12.4)	111.5 (31.8)	121.5 (33.2)	30.5 (17.7)
Male 40-59 y	17 (8.7)	46.7 (33.0)	57.1 (40.5)	55.1 (35.9)	50.8 (44.7)
Male >60 y	50 (26)	40.0 (24.5)	52.2 (34.0)	44.2 (27.6)	54.5 (32.1)
*Data listed as mean (SD) CrCl = creatinine clearance; y= years					

Table 4: Performance of equations based on patient subsets*

pressure [14].

Overall, when comparing CKD-EPI BSA to MDRD-4 BSA, we found that approximately 7.2% of the subjects were reclassified to having a GFR lower than 60 mL/min. When CKD-EPI BSA was compared to CG, we found that 2.56% of the subjects were reclassified to having a GFR lower than 60 mL/min. Individuals who were reclassified to having a GFR less than 60 mL/min from general population had higher risk as the average age was about 63 years old, and the average BMI of 38.6 kg/m2. Those who were reclassified to a higher GFR were younger on average, 40 years old, and had a BMI of 23 kg/m^2. Although previous studies have shown CKD-EPI may be better at lessening the chances of misclassification compared to MDRD in the general population, our study showed that reclassification to a higher GFR is less likely in those who were obese or elderly [7,10].

Forty seven percent of the female study population was pregnant. This large group of pregnant females, who were mostly young and healthy, impacted demographic data including age, weight and BMI as well as GFR values. All pregnant subjects had above normal measured GFR with a high of 406 mL/min. This significantly increased GFR falsely elevated mean measured GFR in females < 65 years old.

The mean serum creatinine of our pregnant population was 0.68 mg/dL, which falls within the expected normal pregnancy range of 0.4 to 0.8mg/dL indicating no renal impairment [15]. In this study, the mean GFR of our pregnant patient is well over 60 mL/min. MDRD-4 BSA underestimated GFR by 31 mL/min which confirms the general consensus from previous studies that MDRD is inaccurate and underestimates GFR over 60 mL/min/1.73 m2; therefore, it is not reliable in predicting the GFR of our pregnant populations. Cockcroft-Gault surprisingly did not overestimate GFR, but underestimated by approximately 7 mL/min. We had expected the increase in body weight and decrease in serum creatinine to result in a higher GFR than 24-hour urine collection. CKD-EPI BSA had the most significantly underestimated GFR by 39 mL/min. Given that these formulas are creatinine-based, 24-hour urine collection for creatinine clearance should remain the standard for GFR estimation in pregnancy [16].

There were several limitations to this study. First, the study was retrospective and with a small sample size. In order to extrapolate our results more data must be collected to ensure adequate sample size for the subgroups analyzed such as BMI. The second limitation is that we did not have a direct measurement of GFR; therefore it is difficult to draw conclusions about the relationship between the equations. Compared to the renal clearance of 125I-iothalamate, 24-hour urine creatinine clearance is certainly not as accurate, but in this setting was the only means of direct GFR measurement readily available for comparison. There were two reasons we did not use 24-hour urine collection as our

standard. The first reason is that there were non-systematic errors that can interfere with the result which includes collecting excess urine by going over the 24-hour period, losing or forgetting to collect some of the urine, or not eliminating some of the foods like soft drinks, coffee, tea, and citrus fruits that can affect the results. Secondly, 24-hour urine collection is known to overestimate CrCl in subjects who have renal impairment [17,18].

Conclusion

In a study population of 195 hospitalized patients, the CG formula provided less biased estimations of kidney function than other renal function estimation equations. However, all formulas largely lacked precision in all patient subsets. In the pregnant population, 24-hour urine collection should remain the standard to estimate GFR as all creatinine-based formulas significantly underestimate GFR.

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