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ORIGINAL ARTICLE

Diagnostic accuracy of different methods of early detection of chronic kidney disease

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Abstract
Aim To assess the accuracy of the CG, CG-corrected, MDRD-6, MDRD-4 and CKD-EPI formulae when diagnosing CKD and to compare the results for creatinine clearance.
Subject and methods This cross-sectional study was conducted with hypertensive individuals monitored by the Primary Health Care Service in Brazil (n = 293). Renal function was analyzed based on serum creatinine levels and creatinine clearance (24 h). The GFR was estimated using the CG, CG-corrected, MDRD-6, MDRD-4 and CKD-EPI formulae. The accuracy of the CKD diagnosis was assessed by analyzing sensitivity and specificity with confidence intervals (95%), receiver-operator characteristic (ROC) curve and the area under the curve (AUC) values.
Results The CKD-EPI formula provided the best balance between sensitivity, 76.7 (66.4–85.2), and specificity, 71.9 (65.3–78.0), as well as the highest AUC value (0.808). Concerning the ROC analysis, the curve of the CKD-EPI formula confirmed its greater precision.
Conclusions The results of the present study indicate that the CKD-EPI formula is the best method for estimating the GFR. Thus, it is possible to implement low-cost actions focused on the early detection and prevention of complications of CKD.

Keywords Chronic kidney disease · Disease prevention · Early diagnosis · Kidney function tests

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Introduction

The prevalence of chronic kidney disease (CKD) increases by between 8 and 16% per year (Jha et al. 2013). According to the National Health and Nutrition Examination Survey (NHANES), in the USA, the prevalence of CKD between 2007 and 2012 was approximately 15% of the total population and up to 32% in the elderly population (USRDS 2015). Studies in Australia, Europe and Japan have shown that the prevalence of some degree of CKD ranges between 6 and 16% (Brown et al. 2003). According to Hamer and El Nahas (2006), more than 1 million people die annually around the world because of terminal CKD. According to the Global Burden of Disease Study, CKD was in 18th place on the list of diseases that caused the greatest number of deaths worldwide in 2010. CKD has an annual mortality rate of 16.3 per 100,000 people (Lozano et al. 2013).

In Brazil, 10 million people suffer from some form of kidney abnormality. The fact that the disease is unknown by many of those who have it can aggravate the situation. In addition, 52 million people are at risk of developing the disease as they are elderly, hypertensive or suffer from diabetes

mellitus, all of whom are more prone to kidney problems (Sociedade Brasileira de Nefrologia 2013).

CKD is defined as the progressive and irreversible loss of kidney function. CKD carriers are defined as any individual who, regardless of the cause, exhibits a glomerular filtration rate (GFR) <60 ml/min/1.73 m^2 or a GFR >60 ml/min/1.73 m^2 associated with at least one marker of parenchymal renal damage for at least 3 months (KDIGO 2013).

The GFR is often used to assess kidney function, and it is the measurement that is most easily understood by doctors and patients, as well as being one of the most sensitive and specific markers of alterations in kidney function. GFR is defined as the ability of the kidneys to remove substances from the blood and is expressed as the volume of blood that is completely purified in a unit of time (KDIGO 2013; Levey et al. 1999).

Different methods can be used to diagnose CKD, although there is still no consensus about which is the best method to routinely measure and/or estimate the GFR, which can be a challenge.

In clinical practice, GFR can be determined by measuring and estimating it by formulae, serum creatinine and clearance creatinine values. Several formulae that can calculate the GFR have been previously published in attempts to work around some of the limitations found when determining the GFR using creatinine clearance. Until now, at least 46 different formulae that can estimate the GFR have been published, although the following are the most commonly used: Cockcroft-Gault (CG) (Cockcroft and Gault 1976), Modification of Diet in Renal Disease (MDRD) (Levey et al. 1999) and The Chronic Kidney Disease Epidemiology Collaboration Equation (CKD-EPI) (Levey et al. 2009).

The serum creatinine level is a good indicator when diagnosing CKD. However, there are conditions in which the GFR is reduced but the serum creatinine level remains normal, according to the limits considered normal by laboratories (Kirsztajn et al. 2011). Isolated creatinine exhibits an inverse relationship with the GFR, and creatinine values only begin to alter when the GFR decreases by 50 to 60% (Shemesh et al. 1985).

In practice, creatinine clearance through the kidney has been the most commonly used method when seeking to obtain GFR data, based on urine collections for 24 h. However, the main problem with creatinine clearance is the need to collect urine for 24 h, which is inconvenient for the patients, often leading to imprecise data (Bastos and Kirsztajn 2011). Nevertheless, creatinine clearance is still one of the most commonly used indicators in the assessment of renal function (Sodré et al. 2007).

To work around some of the limitations found in the determination of the GFR through isolated serum creatinine levels or creatinine clearance, several formulae have been created to estimate the GFR. Estimating the GFR using equations based on endogenous filtration markers is simpler, cheaper and easy to apply in practice but suffers from limited accuracy and reproducibility (Lamb and Stevens 2014). New studies should be conducted, since several earlier studies have reported a satisfactory correlation, while others have shown only moderate correlations between the GFR estimated by the formulae and the GFR measured directly using different laboratory methods (Silva et al. 2010).

The aim of the present study was to determine the sensitivity, specificity and accuracy of the CG, CG-corrected, MDRD-6, MDRD-4 and CKD-EPI formulae, as well as to compare them with creatinine clearance, when diagnosing CKD.

Methods

This cross-sectional study was conducted between June and August 2012 using hypertensive patients from the Primary Health Care Service in the urban zone of the municipality of Porto Firme, Minas Gerais, Brazil.

In this municipality, 697 hypertensive patients are registered in the Basic Healthcare Data System (SisHiperDia 2012). Of this total, 300 individuals participate in monthly educational group programs provided by the Primary Health Care Service. All of the hypertensive individuals in these groups were invited to participate in the present study.

The following inclusion criteria were applied: individuals aged 18 years or more, who suffer from hypertension, participate in the monthly education groups carried out in the municipality and agreed to participate in the research after it was explained to them. The following exclusion criteria were applied: individuals who exhibited severe clinical conditions that required specialized care, pregnant women and individuals with a history of drug and/or alcohol abuse. After applying these criteria, 293 individuals were accepted for participation in the present study, which corresponds to 42% of all hypertensive patients registered in the municipality.

Data were collected through individual interviews as well as biochemical and anthropometric assessments. A semi-structured interview script was used, addressing sociodemographic variables and lifestyle habits. Alcohol consumption was evaluated in the last 12 months, according to the report of each study participant. To assess physical activity, the short version of the International Questionnaire for Physical Activity was applied. This questionnaire was previously validated for use in Brazil (Matsudo et al. 2001). Participants were classified as physically active when they complied with the recommendations of: (1) vigorous activity: ≥3 days/week and ≥20 min per session and/or (2) moderate and/or walk activity: ≥5 days/week and ≥30 min per session and/or (3) any activity added: ≥5 days/week and ≥150 min/week (moderate + vigorous + walk).

Participants were classified as not physically active when they did not comply with the recommendations regarding the frequency or duration of physical activity. To accomplish this classification, the frequency and duration of the different types of activities (moderate + vigorous + walk) were added (Matsudo et al. 2001).

Weight, height and waist circumference (WC) were assessed for the anthropometric data. Weight was measured using an electronic scale with a maximum capacity of 150 kg and 50-g divisions. Height was measured using a portable anthropometer with a metallic platform (for the positioning of the individuals) and a removable wooden column containing a millimeter measuring tape and a cursor (for reading), as previously described by Jelliffe (1968). The body mass index (BMI) was calculated based on the ratio between weight and height and classified according to the World Health Organization criteria (World Health Organization 2000) for adults and according to Lipschitz (1994) for elderly individuals. The WC was measured in centimeters using a non-elastic tape from the mid-point between the iliac crest to the external face of the last rib. The values were classified based on the risk of cardiovascular diseases and metabolic complications using the cutoff points proposed by the World Health Organization (2000).

The following factors were assessed to analyze renal function: serum creatinine levels; 24-h creatinine clearance; serum albumin and urea values. Each participant received personal instructions for the 24-h urine collections. They also received written instructions and the urine receptacles for the sample collection. On the scheduled day, the participants came to the accredited laboratory to deliver the receptacles and to provide blood samples. They were instructed to maintain their normal eating habits during the day and fast for 12 h prior to the collection. Urine samples of less than 500 ml for the 24-h period were not included in the analysis. The collection and analysis of the biological material were conducted in a single accredited laboratory in the municipality of Porto Firme using commercial kits.

The GFR was estimated using the CG, CG-corrected, MDRD-6, MDRD-4 and CKD-EPI formulae. The CG formula is the oldest and most widespread strategy for estimating GFR. In addition, it has broad clinical applicability, considering age, sex, weight and serum creatinine. The corrected CG aims at correcting flaws and inaccuracies in the previous formula, adding the body surface area to its calculation. MDRD-6 differs from MDRD-4 because it considers six parameters: age, sex, ethnicity, serum creatinine, urea and albumin values, while the latter does not evaluate urea and albumin values. In addition, CKD-EPI is the most recent and recommended formula for calculating the GFR and seems to be associated with higher diagnostic accuracy; the variables analyzed by this method are: age, sex, ethnicity and serum creatinine level.

The formulae can be seen below:

CG: $[(140 - \text{age}) \times \text{weight}]/(72 \times \text{Scr}) \times 0.85$ [if female]

CG-corrected: $[(140 - \text{age}) \times \text{weight}] / (72 \times \text{Scr}) \times 0.85$ [if female] × (1.73/BSA), where BSA is body surface area, which was calculated as follows: $0.007184 \times \text{weight}^{0.425} \times \text{height}^{0.725}$

MDRD-6: $170 \times [\text{Scr}]^{-0.999} \times [\text{age}]^{-0.176} \times [0.762$ if female] × [1.18 if black] × $[\text{blood urea nitrogen}]^{-0.17} \times [\text{albumin}]^{0.318}$

MDRD-4: $186 \times (\text{Scr})^{-1.154} \times (\text{age})^{-0.203} \times 0.742$ [if female] × 1.212 [if black]

CKD-EPI: $141 \times \min(\text{Scr}/\kappa, 1)^{\alpha} \times \max(\text{Scr}/\kappa, 1)^{-1.209} \times 0.993^{\text{age}} \times 1.018$ [if female] × 1.159 [if black], where κ 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/κ or 1; max indicates the maximum of Scr/ κ or 17

*Scr is serum creatinine

To classify CKD, the following stages were used: (1) GFR ≥90 ml/min/1.73 m^2; (2) GFR between 60 and 89 ml/min/1.73 m^2; (3A) GFR between 45 and 59 ml/min/1.73 m^2; (3B) GFR between 30 and 44 ml/min/1.73 m^2; (4) GFR between 15 and 29 ml/min/1.73 m^2; (5) GFR <15 ml/min/1.73 m^2 (KDIGO 2013).

The data were displayed based on frequency tables, measurements of central tendency and variability. The Kolmogorov-Smirnov test was used to assess the normality of the distribution of the continuous variables.

To assess the accuracy of the CKD diagnosis based on estimations of the GFR using the formulae and creatinine clearance, we analyzed the sensitivity (true positive rate) and specificity (true negative rate) together with their respective confidence intervals (95%), receiver operator characteristic (ROC) curves and the area under the curve (AUC) values.

The AUC values were classified as: excellent (0.90–1.00), good (0.80–0.90), regular (0.70–0.80); poor (0.60–0.70), bad (0.50–0.60) and insufficient as a diagnostic test (<0.50) (Motta and Oliveira Filho 2009). Version 20.0 of SPSS for Windows was used in the data analysis (Version 20.0; SPSS Inc., Chicago, IL) with the level of significance set at $p < 0.05$.

The present study was approved by the Human Research Ethics Committee of the *Universidade Federal de Viçosa* (UFV) under protocol number 044/2012. As per Resolution 466/2012 of the National Health Council, which regulates research involving human subjects, the participants signed a free and informed statement of consent, which ensured the confidentiality of the data and the anonymity of the participants.

Results

As can be seen in Table 1, 74.1% of the participants in the present study were female. The mean age was 65.79 ± 11.8 years, with the youngest participant aged 25

Table 1 Characteristics of the participants in the present study (Porto Firme, Brazil, 2012–2013)

Variables		n	%
Gender	Female	217	74.1
	Male	76	25.9
Age (years)	25–50	26	8.9
	51–60	65	22.2
	61–70	89	30.4
	≥71	113	38.6
Marital status	Partner	181	61.8
	No partner	112	38.2
Education	High school or more	23	7.8
	Up to the 8th grade	24	8.2
	Up to the 4th grade	171	58.4
	Illiterate	75	25.6
Family income (minimum salaries)	>3	30	10.3
	1 to 3	245	83.6
	<1	18	6.1
Tobacco	Never smoked	189	64.5
	Ex-smoker	81	27.6
	Smoker	23	7.8
Alcohol consumption	No	257	87.7
	Yes	36	12.3
Physical activity	Active	192	65.5
	Not active	101	34.5
Time with hypertension	<10 years	174	59.4
	>10 years	119	40.6
Cardiovascular risk	No	41	14.0
	Yes	252	86.0
Excess weight	No	97	33.1
	Yes	196	66.9

and the oldest participant aged 89. Concerning the sociodemographic characteristics of these individuals, 61.8% had a partner, 58.4% had completed primary education, and 83.6% received an income ranging between one and three minimum salaries. Concerning their lifestyle, most of the participants stated that they had never smoked, had not consumed alcohol in the last 12 months and were physically active. In the anthropometric assessment, 86% of these participants assessed exhibited a cardiovascular risk and 66.9% were overweight. The mean weight of the participants was 70.9 ± 15.6 kg while the mean BMI value was 29.6 ± 5.8 kg/m^2.

In the biochemical assessment, the following mean values were recorded: creatinine 1.03 ± 0.22 mg/dl (0.66–2.91 mg/dl); urea 38.05 ± 8.13 mg/dl (23–73 mg/dl); albumin 3.98 ± 0.19 (3.11–4.40 mg/dl).

Table 2 displays the number of individuals classified in each stage of CKD, according to the recommendations of Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease (KDIGO) (2013), as well as the total number of CKD patients diagnosed using the different diagnostic methods analyzed. The number of individuals diagnosed with CKD ranged from 86 to 135, depending on the diagnostic method used. The greatest prevalence of CKD was found with the CG formula (46.1%), for which a greater number of individuals were classified in stage 3B when compared to the other methods assessed.

Table 3 displays the sensitivity, specificity and AUC of each of the formulae assessed. Note that the CG formula exhibited the greatest sensitivity (88.37) and the lowest specificity (53.62). The MDRD-4 formula exhibited a high rate of specificity (85.02), although its sensitivity rate was low (61.63). The CKD-EPI formula provided the best balance between sensitivity and specificity. The CKD-EPI formula provided the highest AUC value (0.808) and was classified as an adequate diagnostic test with the best accuracy. The other formulae were classified as regular, with the CG providing the lowest AUC value (0.775).

Figure 1 displays the greater accuracy of the CKD-EPI formula, given that the curve for this formula was closer to the upper left corner of the graph, which confirmed the greater precision of the test in terms of the detection of CKD.

Table 2 Number of individuals classified in each stage of CKD according to the recommendations of KDIGO and the total number of CKD patients diagnosed using the different methods assessed (Porto Firme, Brazil, 2012–2013)

	Creatinine clearance	CG	CG-corrected	MDRD-6	MDRD-4	CKD-EPI
Stage 1	62	40	32	9	10	12
Stage 2	145	118	145	182	179	168
Stage 3A	54	84	81	90	90	97
Stage 3B	24	42	30	10	12	12
Stage 4	8	9	5	2	2	4
Total CKD (%)	86 (29.4%)	135 (46.1%)	115 (39.2%)	102 (34.8%)	104 (35.5%)	113 (38.6%)

Table 3 Sensitivity, specificity and AUC of the different methods used to detect CKD (Porto Firme, Brazil, 2012–2013)

Formulae	Sensitivity (CI 95%)	Specificity (CI 95%)	AUC (CI 95%)
CG	88.3 (79.7–94.3)	53.6 (46.6–60.6)	0.775 (0.723–0.822)
CG-corrected	75.5 (65.1–84.2)	71.5 (64.8–77.5)	0.800 (0.749–0.844)
MDRD-6	63.9 (52.9–74.0)	84.0 (78.3–88.8)	0.791 (0.740–0.836)
MDRD-4	61.6 (50.5–71.9)	85.0 (79.4–89.6)	0.789 (0.738–0.834)
CKD-EPI	76.7 (66.4–85.2)	71.9 (65.3–78.0)	0.808 (0.758–0.851)

Discussion

The present study assessed the accuracy of several diagnostic methods for CKD. The CKD-EPI formula provided the greatest accuracy when estimating the GFR. The standard used as a comparison reference was creatinine clearance with 24-h urine collection.

In clinical practice, creatinine clearance through the kidneys has often been used to collect GFR data. Urine is collected for 24 h, and the excretion of urinary creatinine is divided by the concentration of serum creatinine (Bastos and Kirsztajn 2011).

The use of creatinine clearance as a clinical method for assessing GFR was based on the following observations: creatinine clearance exhibits an adequate correlation with the determination of GFR using inulin, which is one of the gold standards in the diagnosis of CKD; the excretion of creatinine is relatively constant during the day; the determination of creatinine serum or plasma is relatively straightforward, easily reproducible and performed in the vast majority of laboratories that use clinical analysis (Bastos et al. 2007).

In the present study, when creatinine clearance was compared with the different GFR estimation formulae (Table 2), it exhibited a lower prevalence of CKD (29.4%). Studies have shown that creatinine clearance may overestimate the true GFR (Ma et al. 2006), thereby decreasing the number of individuals diagnosed with the disease.

However, the main problem with creatinine clearance is the need to collect urine samples for 24 h, which is inconvenient for the patients. Consequently, the collections are often imprecise, especially when the participants are very old or suffer from cognitive problems or urinary incontinence (Bastos and Kirsztajn 2011).

The formulae developed by CG (Cockcroft and Gault 1976), the MDRD (Levey et al. 1999) and, more recently, CKD-EPI (Levey et al. 2009) are the most widely used.

The CG formula estimates creatinine clearance and was the first of these equations to gain acceptance. It systematically overestimates the GFR to values >60 ml/min/1.73 m^2, given that the secretion of tubular creatinine and the increase in weight caused by obesity or fluid overload are not taken into consideration (Bastos and Kirsztajn 2011), unlike in the present study. In Table 2, note the greater number of individuals in stages 3A, 3B and 4 (GFR <60 ml/min/1.73 m^2) according to the CG formula. When compared with the other formulae, the CG method overestimated the quantity of CKD patients (46.1%). This finding corroborates the results of Rossing et al. (2006), who stated that the CG underestimated the GFR.

The original version of the MDRD equation required determinations of serum albumin and urea nitrogen (MDRD-6). More recently, an abbreviated version of the MDRD, with four variables (MDRD-4), has been recommended as it

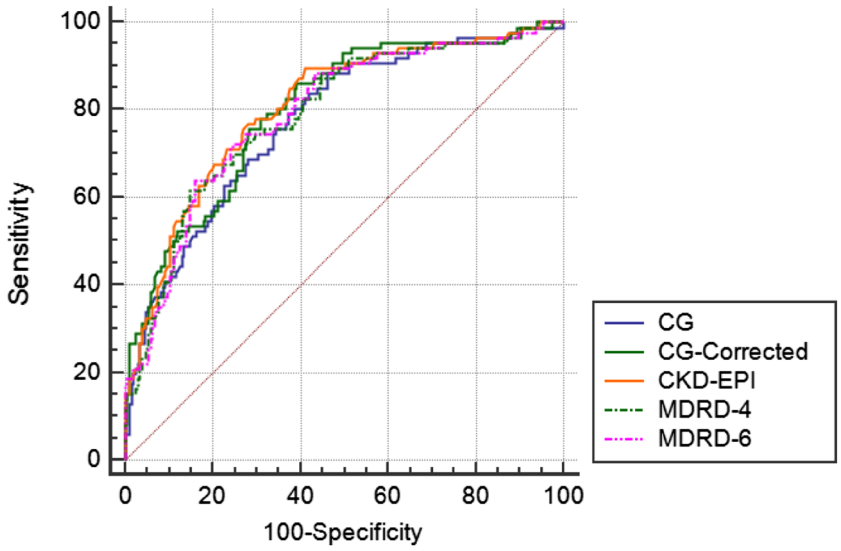

Fig. 1 Receiver-operating characteristic curves of the different methods used to detect CKD (Porto Firme, Brazil, 2012–2013)

performed as well as the initial equation in tests (Levey et al. 2000). This can be seen in Table 2, which contains very similar values in all stages of CKD when comparing the MDRD-6 and MDRD-4.

The GFR that is calculated using the MDRD equation and the real GFR are similar in the results for <60 ml/min/1.73 m^2, whereas the real GFR exceeded the rate estimated when the GFR was >60 ml/min/1.73 m^2 (Levey et al. 2006; Rule et al. 2004). As can be seen in Table 2, when comparing the different methods, the prevalence value for CKD that was closest to the value found by creatinine clearance was calculated using the MDRD-6 formula. In addition, a greater number of individuals were classified in stages 1 and 2 (GFR >60 ml/min/1.73m^2) when using creatinine clearance than when using the MDRD formulae.

Considering that these two equations were obtained from CKD patients, additional studies were carried out to estimate the GFR among people with normal or slightly impaired kidneys (Coresh et al. 2007). The Chronic Kidney Disease Epidemiology Collaboration used a cohort study that included individuals with and without CKD to develop a new equation and a variation of the MDRD (Levey et al. 2009). The equation, which is known as the CKD-EPI, uses the same four variables as the MDRD-4, although comparative studies have shown that it performs better and predicts risk more accurately than the MDRD-4. The lower bias and greater accuracy of the CKD-EPI equation, particularly in the GFR >60 ml/min/1.73 m^2 range, tend to correct the flaws of the MDRD (Levey et al. 1999). This was corroborated in the present study based on the sensitivity and specificity values of the different formulae used to detect CKD.

As can be seen in Table 3, the CG formula exhibited the highest sensitivity (88.37) and the lowest specificity (53.62). The MDRD-4 formula exhibited high specificity (85.02) and low sensitivity (61.63). However, for CKD screening, a balance between sensitivity and specificity is needed to decrease the number of false positives and negatives. Thus, the CKD-EPI formula exhibited the greatest balance between the sensitivity (76.74) and specificity (71.98) values. This was confirmed by the analysis of the AUC values. The CKD-EPI formula exhibited the highest AUC value (0.808). Knowledge of the AUC values enables researchers to quantify the accuracy of a diagnostic test and to compare diagnostic tests. Figure 1 shows that the curve for the CKD-EPI formula is closer to the upper left corner of the diagram, which confirms a higher AUC value and thus greater accuracy in terms of a diagnosis of CKD.

The results of the present study suggest that the CKD-EPI formula is the most accurate method of estimating the GFR. The selection of a diagnostic method requires scientific considerations as well as considerations on the context of its use, the level of complexity and the costs involved. The CKD-EPI is inexpensive and easy to use, which favors its use in Primary Health Care Services as a method of detecting CKD at an early stage, thereby preventing the disease or the worsening of health conditions.

Compliance with ethical standards

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Disclosure of potential conflicts of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

The present study was approved by the Human Research Ethics Committee of the *Universidade Federal de Viçosa* (UFV) under protocol no. 044/2012.

Informed consent Informed consent was obtained from all individual participants included in the study. As per Resolution 466/2012 of the National Health Council, which regulates research involving human subjects, the participants signed a free and informed statement of consent, which ensured the confidentiality of the data and the anonymity of the participants.

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