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MDRD is the eGFR equation most strongly associated with 4-year mortality among patients with diabetes in Colombia

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ABSTRACT

Introduction We compared the association of glomerular filtration rate (GFR) estimated with the Cockcroft-Gault, Modification of Diet in Renal Disease study (MDRD), Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI), or the new CKD-EPI without race (CKD-EPI-NR) equations, with 4-year all-cause mortality in patients with diabetes.

Research design and methods We analyzed a nationwide, centralized database of all adults diagnosed with diabetes assisted by the Colombian Health System between July 1, 2015, and June 30, 2019. Plasma creatinine was used to calculate baseline estimated glomerular filtration rate (eGFR) and classify each patient in a chronic kidney disease (CKD) stage, by each of the four equations. We used multivariate logistic regression to compare the association between CKD stage and mortality, and receiver operating characteristic (ROC) analyses to assess the overall association of eGFR by each equation and mortality.

Results The study included 758,219 patients (58% female, 7.2% black race, mean age 62.3, Glycated hemoglobin A1c [HbA1c] 7.4%). There were 35,296 deaths over the study follow-up. Considering eGFR by each equation as a continuous variable, the odds of death decreased by 1.1%–1.5% for each additional mL/min. Compared with CKD stage 1 of each equation, being placed in CKD stages 3a, 3b, or 4 by MDRD or CKD-EPI-NR was associated with greater odds of death than being categorized in the same stages by CKD-EPI. Among patients of black race, the adjusted OR of mortality for CKD stage 4 relative to stage 1 was 4.63 (95% CI 3.39 to 6.35) for MDRD, 3.66 (2.85 to 4.69) for CKD-EPI-NR, 3.01 (2.38 to 3.81) for CKD-EPI, and 2.82 (2.29 to 3.49) for Cockcroft-Gault. The area under the ROC curve to discriminate by survival status was greatest for MDRD, followed by CKD-EPI-NR, CKD-EPI, and Cockcroft-Gault, in that order ($p<0.001$ for all differences).

Conclusions Compared with other eGFR equations, MDRD showed the strongest association with all-cause mortality in a sample of Latin-American patients with diabetes. This difference was most pronounced among patients of black race.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The association of estimated glomerular filtration rate (eGFR) equations with death and other clinical outcomes in patients with diabetes may differ across populations.

WHAT THIS STUDY ADDS

⇒ In a nationwide study of patients with diabetes in Colombia, Modification of Diet in Renal Disease study (MDRD) showed the strongest association with 4-year mortality, especially among patients of black race.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Regular and universal assessment of eGFR with the MDRD equation may help improve clinical outcomes for patients with diabetes in Latin America.

INTRODUCTION

Diabetes is associated with an increased risk of death,[1] and the coexistence of diabetes and reduced renal glomerular filtration rate further increases such mortality.[2] Also, decreases in estimated glomerular filtration rate (eGFR) over time are associated with higher risk for all-cause mortality independent of initial eGFR and other mortality risk factors at baseline.[3] The association between eGFR loss and mortality is independent of the appearance of the urinary albumin excretion rate, as recently reported in an 8-year community-based study.[4]

Over time, several equations have been developed to estimate glomerular filtration rate (GFR), usually in large studies in which GFR is directly measured by a reference method and regression techniques are employed to predict GFR from plasma biomarkers and demographic factors. Due to its widespread availability and low cost, the most extensively used biomarker is serum creatinine, although adoption of cystatin C is increasing rapidly due to its more accurate performance.[5] Historically, the main focus in the development of these equations has been to minimize the bias of the estimates. Nonetheless, the ability of each eGFR equation

to predict adverse clinical outcomes among patients with diabetes is not necessarily an exact parallel of their GFR-estimating accuracy and may vary substantially across populations. For example, despite better performance in terms of estimating GFR, equations based on both cystatin C and creatinine do not predict mortality as well as equations based on cystatin C alone.[6] Also, the accuracy of each equation is influenced by glomerular function, for example, the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) has improved accuracy over the Modification of Diet in Renal Disease study (MDRD) equation at higher eGFR values and in individuals without diabetes.[7]

A very large meta-analysis published a decade ago found that the CKD-EPI equation more accurately categorized the risk for mortality than the MDRD equation across a broad range of populations.[8] However, later studies have found that the performance of eGFR equations on predicting mortality can very much depend on the specific population: A direct comparison of five eGFR equations among patients with diabetes in China found that the 'CKD-EPI Chinese T2DM equation' provided better discrimination in terms of all-cause mortality compared with the standard CKD-EPI equation.[9]

There is very little information on the comparative performance of GFR-estimating equations to identify mortality risk among Latin-American patients with diabetes. For this reason, we undertook a nationwide study of the association between GFR estimated by four different creatinine-based eGFR equations and all-cause mortality among patients diagnosed with diabetes in Colombia.

METHODS

Data sources

For this study, we analyzed data from the Colombian National Registry of Chronic Kidney Disease (NRCKD), a curated, administrative database of all individuals who have been diagnosed with diabetes, hypertension, or chronic kidney disease (CKD) in the Colombian Health System.[10] The NRCKD is administered by the Colombian Fund for High-Cost Diseases ('Fondo Colombiano de Enfermedades de Alto Costo'—in Spanish). This registry was established after a law emitted by the Colombian Ministry of Health in 2008 mandated public and private insurers to report to a centralized database, the NRCKD, a series of pre-established variables in a standardized format, for all eligible patients. Data must be reported by June 30 of each year; hence, each observation period begins on July 1 of the preceding year. Each data point recorded in the database corresponds to the final measurement taken during the observation period for a particular individual. The Colombian Health System has a coverage above 99% of the total population; therefore, the NRCKD has a nationwide scope. The quality and completeness of the data is ensured through a multistep process that includes an initial algorithm designed to identify any errors in the reporting process.[11] Afterwards, a team of experienced professionals conducts a rigorous data monitoring process comparing the reported information with clinical records in a representative sample of cases stratified by hypertension, diabetes, and CKD status. If any inconsistencies are detected, the correct data are retrieved from the clinical records.

Variables

This study uses data from the NRCKD in the period comprised between July 1, 2015, and June 30, 2019. Only adult patients (age >=18 at the start of each observation year) were included. Diagnosis of diabetes or hypertension was analyzed as reported to the NRCKD by the treating physician (Y/N).

Data on date of birth, sex, ethnicity, insurance type, weight, height, and laboratory results were obtained from the NRCKD. Body mass index (BMI) was categorized according to the guidelines established by the WHO.[12] Plasma creatinine values were used to calculate the eGFR using the Cockcroft-Gault,[13] Modification of Diet for Renal Disease (MDRD),[14] Chronic Kidney Disease Epidemiology (CKD-EPI)[15] and the new CKD-EPI without race (CKD-EPI-NR)[16] equations. The NRCKD collects data from multiple hospitals and health centers, but the National Health of Ministry Guidelines for the Management of Chronic Kidney Disease indicates that all commercially available assays in the country should be traceable to the isotope dilution mass spectrometry (IDMS) standard.[17]

From the baseline GFR estimated using the different methods, each patient was classified in a CKD stage according to the Kidney Disease: Improving Global Outcomes (KDIGO) guidelines.[18] Thus, CKD stages were defined as stage 1: eGFR ≥90 mL/min/1.73 m^2; stage 2: eGFR ≥60 and <90 mL/min/1.73 m^2; stage 3a: eGFR ≥45 and <60 mL/min/1.73 m^2; stage 3b: eGFR ≥30 and <45 mL/min/1.73 m^2; stage 4: eGFR ≥15 and <30 mL/min/1.73 m^2; and stage 5: eGFR <15 mL/min/1.73 m^2. Each patient could be classified in different stages by different equations. Insurance type was classified into three categories (third-party payer, state insurance and special/exceptional health insurance -security forces and employees of some public universities-).[19] The NRCKD self-reported race categories 'Raizal', 'Palenquero', and 'Black, Mulatto, Afro-Colombian, or of African descent' were combined into a single category referred to as 'Black', we analyzed race as Black versus all other categories. This was decided because the number of individuals belonging to other race categories, such as indigenous or Roma, accounted for <1% in any given year.[20]

Data analysis

For baseline clinical and demographic characteristics, quantitative variables are presented as means and SDs, whereas categorical variables are presented as absolute and relative frequencies. The primary outcome for all analyses was death from any cause, inferred from the

variable 'date of death' in the NRCKD. This variable was reported by insurers as the date listed on the death certificate if the patient died during the registry cycle or year, or as missing if the patient was still alive. The accuracy of this information was cross-checked against the data warehouse of The Social Protection Integrated Information System (SISPRO) of the Colombian Ministry of Health and Social Protection. If there were any discrepancies, the official national database of death certificates was consulted.

The association between CKD stage as determined by each equation, and death from any cause, was evaluated using multivariable binomial logistic regression models. eGFR was introduced in models either as a continuous predictor in its original units, or as an ordinal variable with indicator variables corresponding to the KDIGO stages. The reference category was always KDIGO stage 1. All models were adjusted for age, type of health insurance, and baseline BMI. We also conducted stratified analyses to explore how CKD stage was related to mortality in subgroups defined by race (black vs all other) for each eGFR equation. All associations are expressed as ORs with 95% CIs. In the last set of analyses, we compared the overall capacity to predict death between eGFR equations using receiver operating characteristic (ROC) analyses, with the eGFR value as continuous classifier and death status as dichotomous outcome. We calculated the area under the curve (AUC) and determined the significance of the differences seen in AUC between each equation and the Cockcroft-Gault equation as reference. As with logistic regressions, we performed ROC analyses stratified by race. All statistical analyses were carried out in Stata V.17 (StataCorp LP). All hypotheses were tested at a two-tailed significance level of 5% (0.05).

Ethical considerations

This study involved only anonymized secondary data sources which did not allow disclosure of any private information that could lead to the identification of individuals. To maintain privacy, a database-specific individual identification system was used to anonymize data. The confidentiality of the information was maintained throughout the data processing (reporting, managing and analysis) to ensure the privacy of the patients. According to Colombian legislation (resolution 8430 of 1993 by the Colombian Ministry of Health), this study classifies as investigation without risk, and no informed consent was necessary. Because the study involved only secondary retrospective analyses of an anonymized database, it did not qualify as human subjects research as was exempted from Internal Review Board (IRB) review.

RESULTS

We studied a total of 758,219 adults with diabetes. Fifty-eight per cent of the participants were female, baseline mean age was 62.3 years (table 1). Close to three-fourths of the study participants had third-party insurance and one-fourth had state insurance. Patients of black race represented 7.2% of the study sample, and about one-third of patients had a BMI in the obesity range. Remarkably, the prevalence of obesity was 7.9 percentage points higher among women than men. The mean glycated hemoglobin A1c (HbA1c) was 7.44% (57 mmol/mol). Participants in CKD stages 1 or 2 added up to 85% of the sample. About a quarter of participants had a urinary albumin excretion rate (UAER) above 30 mg/g of creatinine or 20 mg/L of urine. Additionally, 75.3% of the patients had a prior diagnosis of hypertension.

Distribution of patients in CKD stages by different equations

In general, CKD-EPI tended to classify a larger proportion of patients in more advanced CKD stages (figure 1). This difference was most accentuated for stage 5: CKD-EPI with or without race classified 10 times more individuals in this category compared with MDRD or Cockcroft-Gault. On the other hand, MDRD was the equation that classified the least patients in advanced CKD stages (4 or 5).

Association between eGFR by different equations and mortality

During the four observational years of the study, 35,296 participants died (cumulative total mortality 4.66%). For all equations, each additional mL/min of eGFR was associated with significantly lower odds of death (1.1%–1.5% lower). Nonetheless, the extent of the increase in mortality as CKD stage progressed was different among equations. Being placed in CKD stages 3a, 3b, or 4 by MDRD or CKD-EPI-NR was associated with greater odds of death than being categorized in the same stages by CKD-EPI (figure 2).

Association between eGFR and mortality, by race

As seen in figure 3, classification in more advanced CKD stages by MDRD showed a clearly stronger association with death among patients of black race. The difference was specially marked for stage 4, but was also evident for stages 3a and 3b. Relative to patients in CKD stage 1, the OR of mortality for those in stage 4 was 4.63 (95% CI 3.39 to 6.35) for MDRD, 3.66 (2.85 to 4.69) for CKD-EPI-NR, 3.01 (2.38 to 3.81) for CKD-EPI, and 2.82 (2.29 to 3.49) for Cockcroft-Gault. For patients of all other races, MDRD and CKD-EPI-NR had a very similar performance, while CKD-EPI exhibited a weaker association with mortality.

Comparison of the equations' ability to predict death using ROC analysis

For the complete study sample, the area under the ROC curve to discriminate by survival status was greatest for MDRD, followed by CKD-EPI-NR, CKD-EPI, and Cockcroft-Gault, in that order ($p<0.001$ for all differences, table 2). Among patients of black race only, ROC analyses also indicated superiority of MDRD, followed by CKD-EPI, CKD-EPI-NR, and again in the last place Cockcroft-Gault (absolute AUC difference vs MDRD 1.6% to 6.4%, $p<0.001$ for all pairwise differences). For

Table 1 Baseline characteristics of study participants

	Men (n=312,647)	Women (n=445,572)	Total (n=758,219)
Age (years)	61.5 (12.6)	62.9 (12.5)	62.3 (12.6)
Age group (%)			
<40	4.8	3.8	4.2
40–49	11.7	9.6	10.4
50–59	25.6	23.4	25.5
60–69	30.8	30.4	30.6
70–79	20.0	21.6	21.0
>=80	7.1	9.3	8.4
Health insurance (%)			
Third party	78.8	68.6	72.8
State	20.4	30.8	26.5
Special/exceptional	0.9	0.6	0.7
Race (%)			
Black	7.0	7.3	7.2
Other	93.0	92.7	92.9
n for body mass index	312 621	445 514	758 135
BMI (kg/m^2)	27.7 (4.6)	28.6 (5.6)	28.2 (5.2)
BMI category (%)			
Normal weight	27.3	26.5	26.8
Overweight	44.8	37.7	40.6
Obesity	27.9	35.8	32.6
n for blood pressure	312 066	445 043	757 109
SBP (mm Hg)	124.0 (13.7)	124.3 (13.9)	124.2 (13.8)
DBP (mm Hg)	76.6 (8.6)	76.5 (8.5)	76.6 (8.5)
n for HbA1c	284 260	394 391	678 651
HbA1c (%)	7.46 (2.0)	7.42 (2.0)	7.44 (2.0)
HbA1c (mmol/mol)	58	57	57
n for blood lipids	293 103	419 567	712 670
Non-HDLc (mg/dL)	137.1 (45.1)	144.8 (46.3)	141.6 (46.0)
LDLc (mg/dL)	103.3 (37.7)	110.9 (39.6)	107.8 (39.0)
CKD stage (%)*			
1	47.3	41.7	44.0
2	39.6	42.0	41.0
3a	8.0	11.2	9.9
3b	2.9	3.5	3.2
4	0.9	0.9	0.9
5	1.3	0.7	1.3
Urinary albumin excretion (%)			
<30 mg/g or <20 mg/L	71.1	78.7	75.5
30–299 mg/g or 20–199 mg/L	23.4	17.8	20.2
>=300 mg/g or >=200 mg/L	5.5	3.6	3.4
Hypertension (%)	71.3	78.1	75.3

Data are means (SD) unless indicated otherwise.
*As reported by the treating physician to the NRCKD.
CKD, stages were defined according to the KDIGO classification; DBP, diastolic blood pressure; KDIGO, Kidney Disease: Improving Global Outcomes; LDLc, low-density lipoproteins cholesterol; non-HDLc, non-high density lipoproteins cholesterol; NRCKD, Colombian National Registry of Chronic Kidney Disease; SBP, systolic blood pressure.

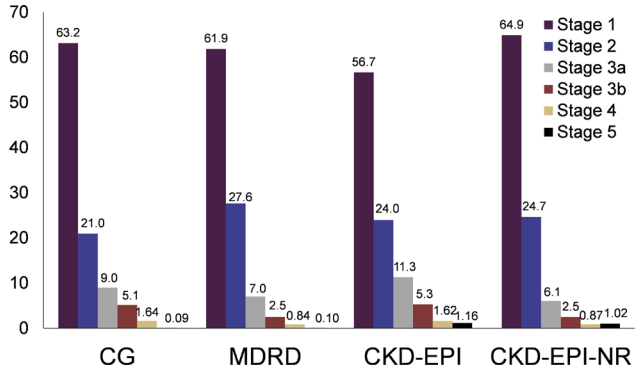

Figure 1 Distribution of study participants in chronic kidney disease (CKD) stages, according to each estimated glomerular filtration rate equation. CKD-EPI, Chronic Kidney Disease Epidemiology Collaboration; CKD-EPI-NR, Chronic Kidney Disease Epidemiology Collaboration without race; MDRD, Modification of Diet in Renal Disease study.

patients of other races, MDRD also performed significantly better than any of the other equations by a smaller, yet significant margin (AUC 1.0% to 3.2% higher for MDRD, p<0.001 for all differences).

Sensitivity analyses

In order to confirm that our results would not be modified by other confounding variables, we performed sensitivity analyses in which all logistic models were additionally adjusted by baseline HbA1c, non-high-density lipoproteins cholesterol, urinary albumin excretion rate and systolic blood pressure. The results continued to show that being placed in CKD stages 3a, 3b, or 4 by MDRD or CKD-EPI-NR was associated with greater odds of death than being categorized in the same stages by CKD-EPI. Among patients of black race, classification in more advanced CKD stages by MDRD continued to show a stronger association with death, with a more marked difference for stage 4 (OR vs stage 1 for MDRD: 4.27 (2.75 to 6.62), for Cockcroft-Gault: 2.67 (1.98 to 3.59), for CKD-EPI: 3.13 (2.31 to 4.24), for CKD-EPI-NR: 3.40 (2.42 to 4.78)).

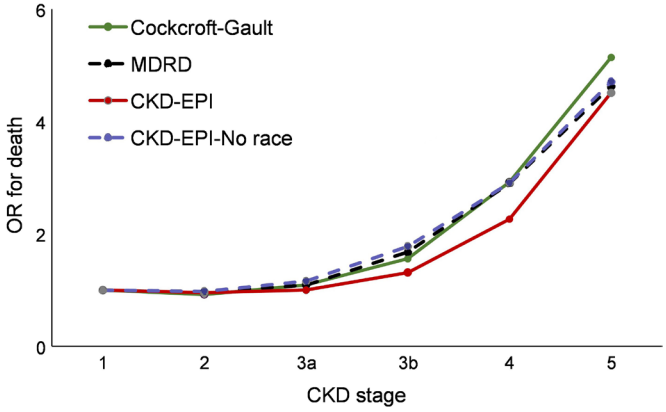

Figure 2 Association between chronic kidney disease (CKD) stage, according to each estimated glomerular filtration rate equation, and all-cause mortality. Data are ORs compared with participants classified in CKD stage 1 by each equation, adjusted for age, insurance type and baseline body mass index. CKD-EPI, Chronic Kidney Disease Epidemiology Collaboration; MDRD, Modification of Diet in Renal Disease study.

DISCUSSION

In this nationwide study of patients diagnosed with diabetes, we compared the magnitude of the association of eGFR estimated with four different equations (Cockcroft-Gault, MDRD, CKD-EPI or CKD-EPI-NR) with 4-year all-cause mortality. We found that overall, MDRD had the strongest association with death, either when patients were classified in KDIGO stages based on MDRD eGFR, or when the overall discriminative capacity of the four equations was compared using ROC analysis.

These are clinically relevant results because they may influence the decision about which equation to use when caring for Latin-American patients with diabetes. In addition to the use of different biomarkers or their combinations for the estimation of GFR, the mathematical expression employed may have a relevant influence on the performance of eGFR to predict not just advanced CKD, but also death and other serious adverse clinical outcomes in patients with diabetes. For example, an analysis of data from the US National Health and Nutrition Survey (NHANES) found the CKD-EPI-based calculation of eGFR to better predict the risk of death, as compared with the MDRD-based calculation, or to serum creatinine concentrations.[21] Similarly, a study in Italy found the CKD-EPI eGFR to better stratify patients with diabetes according to their total and cardiovascular mortality risk.[22] The contrast between these results and ours highlights the different performance of eGFR equations when applied to different populations.

The finding that in our sample more advanced CKD stages according to CKD-EPI showed a relatively weaker association with death may be related to the fact that this equation classified a much larger proportion of patients as having advanced CKD. Hence, many lower risk subjects could have been classified in these stages, which resulted in a lower OR. Other studies have found large discrepancies in the proportion of individuals being classified as having advanced CKD depending on the eGFR equation employed.[23]

The difference between MDRD and the other equations in terms of association with death was much larger among patients of black race, providing support for the use of this equation in black Latin-American patients. Unexpectedly, even in black patients, the CKD-EPI equation that does not include race had a stronger association with mortality than the original version with race. One prior study in Brazil had found the use of CKD-EPI equations without race/ethnicity adjustment to be more appropriate for the Brazilian population.[24] This finding may have major implications, as patients of African descent tend to have a lower overall prevalence of CKD,[25] but a higher incidence of end-stage renal disease[26]

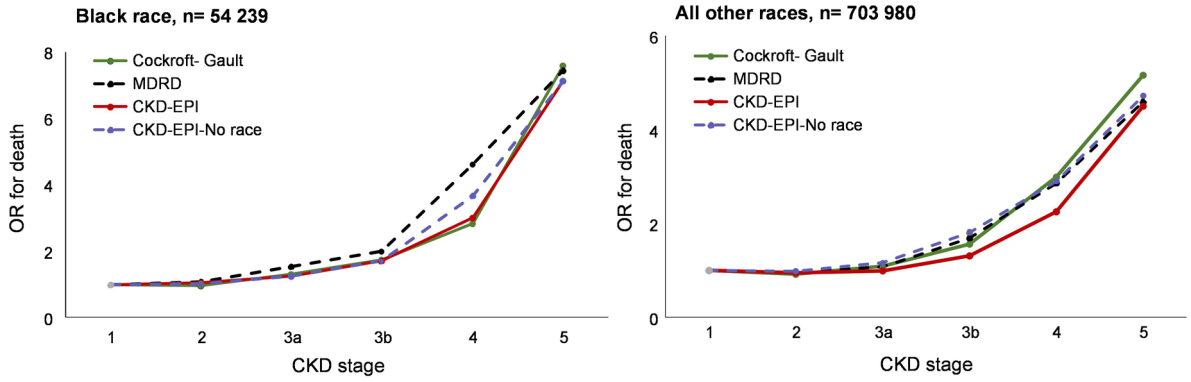

Figure 3 Association between chronic kidney disease (CKD) stage, according to each estimated glomerular filtration rate equation, and all-cause mortality, by race. Data are ORs compared with participants classified in CKD stage 1 by each equation, adjusted for age, insurance type and baseline body-mass index. CKD-EPI, Chronic Kidney Disease Epidemiology Collaboration; MDRD, Modification of Diet in Renal Disease study.

compared with other races. Many biological and social factors have been postulated to explain this apparent paradox, but imprecision in GFR estimation with race adaptation could be one contributor. Recent evidence suggests that the use of cystatin C for eGFR estimation in black patients may provide an even better prediction of the end-stage renal failure and mortality risk associated with low eGFR.[27]

Implications

Our results have clinical implications for professionals treating patients with diabetes in Colombia and other countries of similar demographics, especially countries with a sizeable population of African origin. First, they highlight the importance of always performing a thorough evaluation of renal function since diabetes diagnosis, including but not restricted to eGFR. Second, they suggest that in such context the estimation of GFR with MDRD may provide a more accurate estimation of mortality risk, so that even if less patients are classified in more advanced CKD stages, the limited resources available in our countries will be better focalized to those patients who really are at increased risk.

It is also important to highlight that eGFR is only one of a portfolio of CKD risk assessment tools that frequently must include other markers such as urinary albumin/creatinine ratio, cystatin C, 24-hour urinary albumin excretion and others. Thus, it is not possible to expect a single marker to perform well in all patients.

In terms of directions for future research, our results can be expanded and complemented by longer follow-up of the Colombian population, by the replication of our analyses in other Latin-American countries and/or by the incorporation of new and emerging CKD markers. Nonetheless, they do encourage the routine assessment of renal function and inform the choice of the tool to do so.

Strengths and limitations

Our study involved a nationwide sample, and laboratory and demographic variables were obtained from a centralized, curated database of all patients diagnosed with diabetes in Colombia. The primary endpoint of all-cause death is unequivocal, and the survival status of each participant was ascertained against official sources. Despite the potential limitations of self-reported race, previous studies have demonstrated a consistent association between

Table 2 ROC analyses, comparison versus Cockcroft-Gault equation, by race

	Race					
	Black		Other		All participants	
eGFR equation	AUC	P value vs Cockcroft-Gault	AUC	P value vs Cockcroft-Gault	AUC	P value vs Cockcroft-Gault
Cockcroft-Gault	0.327	–	0.395	–	0.392	–
MDRD	0.391	<0.001	0.427	<0.001	0.423	<0.001
CKD-EPI	0.375	<0.001	0.417	<0.001	0.414	<0.001
CKD-EPI-NR	0.371	<0.001	0.420	<0.001	0.418	<0.001

AUC, area under the ROC curve; CKD-EPI, Chronic Kidney Disease Epidemiology Collaboration; CKD-EPI-NR, Chronic Kidney Disease Epidemiology Collaboration without race; eGFR, estimated glomerular filtration rate ; MDRD, Modification of Diet in Renal Disease study; ROC, receiver operating characteristic.

self-reported race and health outcomes in Colombia.[28] Even though a 4-year follow-up might be insufficient to evaluate association between exposures like eGFR and mortality, the sample size was large enough to allow us to reveal existing differences in the association of the different eGFR equations with mortality. One relevant limitation is the absence of cystatin C measurements to perform a comparison of the equations using this newer biomarker. However, the penetration of this test in the Colombian system is still very low and did not permit us to undertake such analyses. Finally, our study is subject to the limitations of all routinely collected data studies, in which the data were not initially collected to answer the specific research question.

In summary, our results suggest that GFR estimated with the MDRD equation may have a stronger association with all-cause mortality in Latin-American patients with diabetes, especially if they are of black race.

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Contributors COM acts as guarantor of the article's content, conceived the study, performed data analyses, supervised project activities and participated in the writing and critical assessment of the manuscript. SG-G performed data analyses and participated in the writing and critical assessment of the manuscript. LJH-P performed data analyses and participated in the writing and critical assessment of the manuscript. JAHV performed data analyses and participated in the writing and critical assessment of the manuscript. NR-G performed data analyses and participated in the writing and critical assessment of the manuscript. LA-M performed data analyses and participated in the writing and critical assessment of the manuscript.

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