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Original Article

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Impact of Applying the CKD-EPI 2021 Formula Compared to CKD-EPI 2009 for the Calculation of Estimated Glomerular Filtration Rate in a Spanish Tertiary Hospital

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ABSTRACT

Background: Throughout the years, the stage of chronic kidney disease (CKD) has been classified according to the Kidney Disease: Improving Global Outcomes (KDIGO) guideline, using equations to calculate the estimated glomerular filtration rate (eGFR). The 2009 CKD-EPI equation is the one currently used, but there is a new version from 2021 that eliminates the race correction factor. In this study, we will compare both equations.

Methods: Sex, age, and serum creatinine data from 64 819 patients were gathered. Glomerular filtration (GF) was estimated using both CKD-EPI equations based on sex and serum creatinine (sCr) value. Concordance was analyzed using the kappa index and Bland–Altman graphical method.

Results: The mean eGFR for males with sCr > 0.90 mg/dL was 58 ± 22 according to the 2009 CKD-EPI and 61 ± 24 according to the 2021 CKD-EPI; for males with sCr ≤0.90 mg/dL, the eGFR was 94 ± 11 according to 2009 CKD-EPI and 98 ± 9 for the 2021 equation. For females with sCr values of >0.70 mg/dL, the mean eGFR was 60 ± 22 for the 2009 CKD-EPI and 64 ± 23 for the 2021 CKD-EPI. For females with sCr ≤0.70 mg/dL, the eGFR was 95 ± 11 for the 2009 CKD-EPI and 99 ± 10 for the 2021 CKD-EPI. The percentages of reclassified patients were 16%, 23%, 17%, and 22% for males with sCr >0.90, sCr ≤0.90, and females with sCr > 0.70 and ≤0.70 mg/dL, respectively.

Conclusion: We found that the 2021 CKD-EPI equation, applied to our population, significantly increases the eGFR values, which causes a meaningful number of people to undergo a reclassification to a less severe of CKD.

Keywords: chronic kidney disease, glomerular filtration estimation, CKD-EPI, serum creatinine.

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INTRODUCTION

Chronic kidney disease (CKD) is currently a significant health issue that requires a proper classification of the patient in different stages that determine the severity and evolution of the medical condition, in order to establish the relevant treatments to avoid a fast evolution of the kidney damage and prevent complications[1] related to a greater risk of suffering from advanced kidney disease, cardiovascular disease, and death.[2]

There are direct methods available that use exogenous markers and radioactive contrast agents, but they are invasive, expensive, and complex, making it impossible to use them on a routine basis.[3]

As a result, serum creatinine concentration has been the main determination used for assessing kidney function and calculating the estimated glomerular filtration rate (eGFR) during the last 85 years. However, it is contingent upon both skeletal muscle mass and kidney function, which is considered a downside.[4]

The determination and use of cystatin C as a marker of alternative glomerular filtration show the advantages of

not being affected by muscle mass and being very sensitive to glomerular filtration changes, but it is not exempt from inconveniences like high intraindividual variability, cost, or worse standardization of measurement methods.[5,6]

Therefore, serum creatinine concentration is the measurement used to calculate eGFR, which is commonly used in clinical practice to assess kidney function.[7] Different equations have been used over the years for the calculation of eGFR, with the Modification of Diet in Renal Disease (MDRD) from 1999 being the most used and recommended until a few years ago.[8]

Currently, both clinical guidelines[7] and the Spanish Society of Laboratory Medicine (SEQC^{ML}) recommend[9] the use of the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) of 2009 to calculate eGFR, which includes the race correction factor in its parameters based upon the assumption that black people present greater muscle mass than non-black people. This correction not only is discussed as a sociological term,[10,11] as it may present social discriminatory connotations, but it also presents doubts from the strictly biological and analytical point of view, since the correction is only applied based on the skin color, but it does not differentiate more populations such as black female and male. In fact, it has been seen in the USA that black females present slight differences in serum creatinine compared to white female.[12]

In 2021, the CKD-EPI published a new equation based on the one from 2009 to calculate eGFR, applying some adjustments in constants and deleting the race correction factor,[13] concluding that this new equation is more accurate and presents a lower prevalence of CKD in non-black people in the USA. It was proposed to be tested in other population groups.

Some black-population studies carried out outside the USA did not apply the race correction factor in the CKD-EPI equation and showed better results than when applying it, which is why it could be concluded that this correction would not be applicable outside the USA borders.[14,15]

Other works that compare both CKD-EPI equations have shown slight changes in the calculation of eGFR but they have implied a reclassification to a better stage of CKD,[16] which involves less inadequate care and a reduction of its consequent adverse effects in patients.[17] However, there seems to be some disagreements as to whether to implement or not the 2021 CKD-EPI equation.

While the National Kidney Foundation (NKF) recommends laboratories to implement the new equation in order to eliminate the race correction factor and standardize results,[18] the European Federation on Clinical Chemistry and Laboratory Medicine (EFML), as well as the European Renal Association, recommend not to implement the 2021 equation and maintain the 2009 CKD-EPI one.[19]

In this study, we aim to provide data and results that have come up in our hospital when comparing both CKD-EPI equations (2009 and 2021) in a large cohort of patients from different services of the hospital who were requested determination of serum creatinine, so we could study the differences, if any, in the stage classification of CKD.

MATERIAL AND METHODS

A cross-sectional descriptive observational study was carried out in the area of Laboratory Diagnosis of our hospital. This study was approved by the Ethics Committee of La Ribera University Hospital (June 19, 2023).

The data were gathered from 64 819 patients: 32 489 (50.1%) female and 32 330 (49.9%) male with an average age of 71.9 ± 12.0 years, who have requested a determination of serum creatinine together with the eGFR between October 2021 and March 2022. They were divided by sex and, within this separation, four groups were made: Group A, males with sCr higher than 0.90 mg/dL; group B, males with sCr lower or equal to 0.90 mg/dL; group C, females with sCr higher than 0.70 mg/dL; and group D, females with sCr lower or equal to 0.70 mg/dL. Patients were gathered from different services: primary care (32.1%), urgent care (16.0%), internal medicine (10.4%), nephrology (4.6%), intensive care medicine (3.8%), urology (2.2%), endocrinology (2.0%), traumatology and orthopedic surgery (1.9%), cardiology and cardiac surgery (1.6%), and others (20.8%).

Data were obtained from the laboratory information system (Servolab®).

The determination of creatinine in serum (mg/dL) was done using the Jaffe method (rate-blanked compensated method) in an Atellica Solution autoanalyser (Siemens Healthineers®).

The eGFR obtained was accompanied by a clinical commentary on the stage of CKD following the SEQC^{ML} recommendations.

The eGFR results were obtained using the following equations:

According to the 2009 CKD-EPI (we assume that all of our population is Caucasian and the race correction factor is deleted):

MAIN POINTS

- The equations for calculating eGFR continue to be updated to make them more accurate and closer to the patient's reality.
- The 2021 CKD-EPI equation eliminates the race factor from the 2009 version.
- In a large number of patients, the application of the new equation results in the reclassification of a significant number of patients to less severe stages.
- It is necessary to check if this new classification corresponds to the actual clinical status of the patient.

For female:

$$\text{If } sCr \le 0.70:\ eGFR = 144 \times \left(\frac{sCr}{0.70}\right) - 0.329 \times 0.993^{age}$$

$$\text{If } sCr > 0.70:\ eGFR = 144 \times \left(\frac{sCr}{0.70}\right) - 1.209 \times 0.993^{age}$$

For male:

$$\text{If } sCr \le 0.90:\ eGFR = 141 \times \left(\frac{sCr}{0.90}\right) - 0.411 \times 0.993^{age}$$

$$\text{If } sCr > 0.90:\ eGFR = 141 \times \left(\frac{sCr}{0.90}\right) - 1.209 \times 0.993^{age}$$

Age was expressed in years, sCr in mg/dL, and eGFR in mL/min/1.73 m^2.

According to the 2021 CKD-EPI:

For female:

$$\text{If } sCr \le 0.70:\ eGFR = 142 \times \left(\frac{sCr}{0.70}\right) - 0.241 \times 0.9938^{age}\, x1.012$$

$$\text{If } sCr > 0.70:\ eGFR = 142 \times \left(\frac{sCr}{0.70}\right) - 1.200 \times 0.9938^{age}\, x1.012$$

For male:

$$\text{If } sCr \le 0.90:\ eGFR = 142 \times \left(\frac{sCr}{0.90}\right) - 0.302 \times 0.9938^{age}$$

$$\text{If } sCr > 0.90:\ eGFR = 142 \times \left(\frac{sCr}{0.90}\right) - 1.200 \times 0.9938^{age}$$

Age was expressed in years, sCr in mg/dL, and eGFR in mL/min/1.73 m^2.

The CKD stage classification has been carried out according to the 2021 KDIGO.

As for the statistical analysis, the mean and standard deviation of age, sCr, and eGFR values, according to the 2009 and 2021 CKD-EPI, for each studied group and for the total of patients were calculated. The qualitative variable (requesting medical service) was expressed in frequency and percentage. The median and standard deviation, trend, and range of sCr were calculated.

In order to study the reclassification, a table that shows the number of reclassified patients that have undergone stage changes after applying the 2021 CKD-EPI equation compared to that of 2009 for the calculation of eGFR was created. The number of reclassified patients for each group was calculated, obtaining the percentage of patients that were reclassified to other stages of CKD when using the 2021 CKD-EPI equation and the percentage of patients that maintained the same stage with both equations.

The prevalence of patients in each CKD stage was calculated under both equations. The correlation coefficient between both equations was obtained for the total cases, per sex, and sCr and it was observed if there were significant differences ($P < .001$).

To identify concordances between both equations, Bland–Altman analysis was carried out for the differences and means of the eGFR obtained by both of them, taking the 2009 CKD-EPI as a reference. We also evaluated the concordance by sex and sCr subgroups according to the stage, between the two eGFR methods using Cohen's kappa coefficient and the respective 95% CI. The deviation around the mean reflected the dispersion and precision of the eGFR obtained. The analysis for the four studied groups was carried out.

All data were processed with the programs Microsoft Office Excel 2013 and SPSS 20.0 (IBM SPSS Corp.; Armonk, NY, USA).

Ethics Approval

This study was approved by the Ethics Committee of La Ribera University Hospital (June 19, 2023).

RESULTS

Table 1 shows the number of patients classified in each service with their age (mean and standard deviation), which is comprised between 65.9 ± 16.6 years in primary care patients and 78.0 ± 9.4 years in traumatology and orthopedic surgery patients, together with the median and trend of sCr as centralization values and frequency, along with the maximum and minimum levels of sCr.

Table 2 shows the eGFR values (mean and standard deviation) from the total of patients and each group for both equations compared with the CKD stage. Neither group B nor group D have patients classified in stages G3a, G3b, G4, and G5.

The services that had the most petitions were primary care (32.1%) and urgent care (16.0%).

When applying the 2009 CKD-EPI equation, we found that the highest percentages of patients from all services were in stages

Table 1. Classification of the Number of Patients by Service, Age, and sCr Values

	n	Age	Median sCr	Trend sCr	Maximum sCr	Minimum sCr
Primary care	20 849	65.9 (14.6)	0.85	0.73	10.37	0.19
Urgent care	10 384	77.3 (9.3)	1.00	0.93	14.62	0.15
Internal medicine	6721	77.8 (9.2)	1.01	0.87	9.92	0.17
Nephrology	2986	74.7 (7.9)	3.72	2.60	16.03	0.32
Oncology	2963	72.0 (7.5)	0.86	0.83	13.77	0.30
Intensive care medicine	2483	70.3 (6.1)	0.79	0.57	13.14	0.15
Urology	1449	74.4 (8.0)	1.03	0.93	11.17	0.29
Endocrinology	1278	69.9 (8.0)	0.91	0.72	9.80	0.37
Traumatology and orthopedic surgery	1211	78.0 (9.4)	0.85	0.73	6.08	0.32
Cardiology and cardiac surgery	1012	72.7 (9.6)	0.99	0.87	8.31	0.47
Others	13 483	73.0 (9.5)	0.89	0.80	16.84	0.17

"n" the number of patients, sCr serum creatinine in mg/dL, and age in years.

G1 and G2 (the percentage of patients of both stages fluctuating between 52.7% from internal medicine and 83.9% from primary care). Within the nephrology service, 0.7% of patients were classified in stage G1, 4.3% of them were classified in stage G2, 7.6% were classified in stage G3a, 20.3% were classified in stage G3b, 26.7% were classified in stage G4, and 40.4% were classified in stage G5.

After applying the 2021 CKD-EPI equation, the results showed an increase in the number of patients included in stages G1 and G2 (which fluctuate between 57.1% from internal medicine and 87.7% from primary care medicine). The nephrology service experienced a decrease of 3.3% and 1.4% of patients in stages G4 and G5, respectively, compared to the 2009 equation. The rest of the stages showed an increase of 0.5% for stage G1, 0.6% for stage G2, 2.1% for stage G3a, and 1.5% for stage G3b.

Table 3 shows the total number of patients that have undergone modifications and have been reclassified to a better stage of CKD after applying the 2021 CKD-EPI equation instead of the 2009 version.

Figure 1 shows a comparison of the total number of patients framed in each one of the stages according to both equations. We can observe a decrease in the number of patients in all stages when calculating the eGFR with the 2021 CKD-EPI equation instead of calculating it with the 2009 version, except for stage 1, which presents an increase in patients.

Table 2. eGFR Values According to Stages of Chronic Kidney Disease (CKD)

			CKD stage					
		Total	G1	G2	G3a	G3b	G4	G5
eGFR (2009 CKD-EPI)		70 (26)	100 (10)	77 (9)	53 (4)	38 (4)	23 (4)	9 (3)
eGFR (2021 CKD-EPI)		74 (26)	100 (9)	77 (9)	53 (4)	38 (4)	23 (4)	9 (3)
Group A	eGFR (2009 CKD-EPI)	58 (22)	97 (7)	74 (8)	53 (4)	38 (4)	23 (4)	9 (3)
	eGFR (2021 CKD-EPI)	62 (24)	96 (6)	75 (8)	53 (2)	38 (4)	23 (4)	9 (3)
Group B	eGFR (2009 CKD-EPI)	94 (11)	100 (10)	85 (4)	_	_	_	_
	eGFR (2021 CKD-EPI)	98 (9)	100 (8)	87 (3)	_	_	_	_
Group C	eGFR (2009 CKD-EPI)	60 (22)	99 (8)	74 (8)	53 (4)	38 (4)	24 (4)	9 (3)
	eGFR (2021 CKD-EPI)	64 (23)	97 (8)	75 (8)	53 (4)	38 (4)	24 (4)	9 (3)
Group D	eGFR (2009 CKD-EPI)	95 (11)	100 (10)	85 (4)	_	_	_	_
	eGFR (2021 CKD-EPI)	99 (10)	101 (9)	87 (2)	_	_	_	_

Being eGFR estimated glomerular filtration rate, using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation in mL/min/1.73 m^2, and sCr serum creatinine in mg/dL. Group A, males with sCr higher than 0.90 mg/dL; group B, males with sCr lower or equal to 0.90 mg/dL; group C, females with sCr higher than 0.70 mg/dL; and group D, females with sCr lower or equal to 0.70 mg/dL.

Table 3. Number of Patients that have Undergone a Stage Reclassification when Applying the 2021 CKD-EPI Equation compared to the 2009 CKD-EPI One

	Total of Patients	Group A	Group B	Group C	Group D
From stage G5 to stage G4	177	95	0	82	0
From stage G4 to stage G3b	700	331	0	369	0
From stage G3b to stage G3a	1527	770	0	757	0
From stage G3a to stage G2	2904	1409	0	1495	0
From stage G2 to stage G1	6553	949	2343	1165	2096

Creatinine values appear in mg/dL. Population values are expressed in number of patients. Group A, males with sCr higher than 0.90 mg/dL; group B, males with sCr lower or equal to 0.90 mg/dL; group C, females with sCr higher than 0.70 mg/dL; and group D, females with sCr lower or equal to 0.70 mg/dL.

The prevalence of stages varied from the 2009 CKD-EPI equation to the 2021 version, from 21.8% to 31.9% in stage G1, from 46.2% to 40.6% in stage G2, from 13.9% to 11.8% in stage G3a, from 9.3% to 8.0% in stage G3b, from 5.4% to 4.6% in stage G4, and from 3.4% to 3.1% in stage G5.

In relation to age, the largest number of patients (56%) are over 76 years old, 42% are between 36 and 70 years old, and only 2% are 35 years old or younger. The percentage of change to a less severe stage is 21%, 15%, and 1%, respectively. This 1% improvement in the younger age group is mainly due to the fact that most of them do not usually present kidney pathology at this age.

The correlation coefficient between both equations was 0.9969, being 0.9993 in group A; 0.9865 in group B; 0.9991 in group C; and 0.9898 in group D. The eGFR values were significantly different ($P < .001$) for the equations, both for the considered group and the total of patients. When stratified by sex and sCr, the highest concordance between CKD stages was observed in group A, with a kappa index of 0.918, and the lowest in subgroup B, which had a kappa index of 0.886.

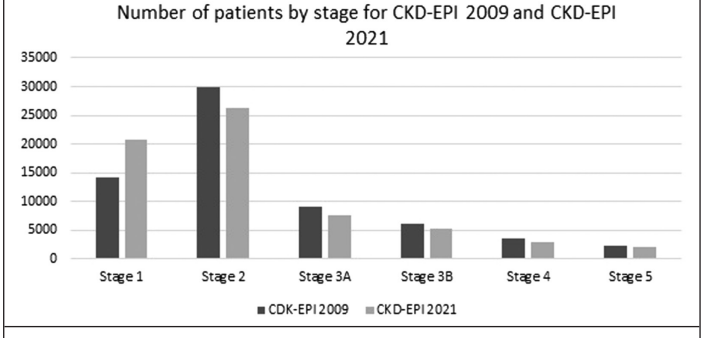

Figure 1. Comparison in total number of patients in each stage according to the 2009 and 2021 CKD-EPI equations.

The Bland–Altman analysis results, which represent the differences between the eGFR of both equations compared to its average for each group, were −3.94 (−6.48 to −0.24) for group A, −3.94 (−6.64 to 23.11) for group B, −4.13 (−6.39 to −2.19) for group C, and −4.45 (−6.52 to 11.30) for group D.

The negative value states an underestimation of the eGFR values obtained from the 2009 CKD-EPI equation compared to the 2021 one.

DISCUSSION

The current clinical guidelines[20] include a value of eGFR of <30 mL/min/1.73m^2 as a criterion to refer to the nephrology service. When the eGFR value stands between 30 and 60 mL/min/1.73 m^2, it is advisable to assess other factors like albuminuria or other alarm signs[21] in order to decide if it can be referred to the nephrology service. Therefore, an increase in eGFR values would reduce the number of patients that attend the nephrology service.

We have obtained an overall eGFR value (mL/min/1.73 m^2) for both sexes of 70 (26) for the 2009 CKD-EPI and 74 (26) for the 2021 CKD-EPI. The eGFR values obtained in the different stages of CKD with the 2021 equation have been higher than the ones obtained with the 2009 version (Table 2), which has meant a change of CKD category of 18.3% from the total of patients divided into 16% in group A, 23% in group B, 17% in group C, and 22% in group D.

These results are significantly higher than the ones obtained by Meeusen,[16] which showed slight variation when applying the 2021 CKD-EPI equation, but also meant reclassifications to a less severe CKD stage in about −5.1% of non-black patients and 6.4% of black patients; the results obtained by Fu[22] also meant a reclassification to a better stage of CKD in 9.9% of the patients in his study.

According to our study, prevalence in the different CKD stages when comparing both CKD-EPI equations showed a decrease of the percentage of patients assigned to each stage, except for stage G1, where it went from having 21.8% of patients classified to having 31.9%. In this sense, the study carried out by Betzler[17] in 2022 found a prevalence of CKD of 8.6% with the 2009 CKD-EPI version and 6.4% with the 2021 equation. Moreover, none of the patients were reclassified to a more severe CKD stage, and between 1.7% and 4.2% of patients were reclassified to a less severe stage.

This study has limitations. First, the glomerular filtration rate measured by direct methods is not considered for comparison with eGFR because of its complexity and the large number of patients in the sample. Secondly, the CKD-EPI equations use

the creatinine value to calculate eGFR, which is influenced by factors such as body mass, weight, diet, etc. In addition, we did not use enzymatic creatinine because it is not currently widely implemented in Spain due to its high cost. The urine albumin value has not been taken into account to classify patients into the different stages of CKD. Finally, another limitation of the study is the assumption that the entire population is of Caucasian origin, as this is the majority percentage in our population.

According to our study, the value of eGFR would increase with the 2021 CKD-EPI equation, and the prevalence of CKD would be reduced for our population, although, there are still few studies that compare both equations to be able to choose to change to the new version of CKD-EPI or not. Even scientific societies show disparity in applying the new equation, such as the one commented on between the NKF and the European EFML. Our results show a significant variation to a better stage of CKD, but its clinical impact must be studied to determine if this change is in line with the reality of the pathology or not.

Data Availibility Statement: The data that support the findings of this study are available on request from the corresponding author.

Ethics Committee Approval: This study was approved by the Ethics Committee of La Ribera University Hospital (June 19, 2023).

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