

The New 2021 CKD-EPI Equation Without Race in a European Cohort of Renal Transplanted Patients

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Background. Whether the new chronic kidney disease-epidemiology (CKD-EPI) equation without the race variable remains accurate enough for glomerular filtration rate (GFR) estimation in non-US kidney transplant recipients (KTRs) is unclear. We sought to compare the predictive performance between this equation and the classical CKD-EPI equation in a French cohort of KTRs. We also evaluated the performance of the European Kidney Function Consortium (EKFC) equation, an estimate that has proved very accurate in nontransplant patients and that does not include race variable. **Methods.** We retrospectively selected 489 KTRs for whom GFR was measured by inulin clearance. Performances of GFR equations were compared according to median bias, imprecision, and accuracy within 30% (P30) and 20% (P20). Differences in P20/P30 were tested using the exact McNemar test. **Results.** Although the 4 equations exhibited a similar level of imprecision, the bias of the new CKD-EPI equation was +5.5 (4.0; 6.6) mL/min/1.73 m², much higher than the bias of the classical CKD-EPI, EKFC, and Modified Diet in Renal Diseases (MDRD) equation (2.4 [1.7;3.5], 2.2 [1.1;3.1], and -0.5 [-1.5; 1.0] mL/min/1.73 m², respectively). The new CKD-EPI equation was significantly less accurate with a P30 of 68.3% as compared with 74.2%, 75.3%, and 77.1% for the classical CKD-EPI, EKFC, and MDRD equation, respectively. The EKFC equation outperformed both versions of the CKD-EPI equation in terms of P20. **Conclusions.** The new CKD-EPI equation is suboptimal for the care and follow-up of European transplanted patients. The EKFC equation shows at least a similar performance to the MDRD and the classical CKD-EPI equation. Further validation of the EKFC equation in KTRs from a diverse ethnic background is needed.

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INTRODUCTION

Since 2012, the chronic kidney disease-epidemiology (CKD-EPI) equation is recommended by the international guidelines to estimate glomerular filtration rate (GFR),¹ even if the Modified Diet in Renal Diseases (MDRD) has been shown

to be slightly better in transplanted patients.^{2–4} However, the race variable in these equations developed in 1999 for the MDRD equation and in 2009 for the CKD-EPI (hereafter the CKD-EPI_{ASR}, ASR for age, sex, and race) has been recently questioned as a source of discrimination in the United States of America (USA).^{5,6} A new equation has thus been proposed in 2021 without the race variable (hereafter the CKD-EPI_{AS}). The new CKD-EPI_{AS} equation does not perform better in Black individuals (with a slight underestimation) and performed slightly worse in non-Black individuals (with a slight overestimation).⁷ The equation has been rapidly endorsed by the National Kidney Foundation and the American Society of Nephrology.⁸ However, the performance of this equation has been poorly tested in both non-US populations and renal transplanted patients.⁹ It has been shown that the performance of all creatinine-based equations is worse in renal transplanted patients than in nontransplanted patients.^{3,10} Moreover, the recent creatinine-based equation European Kidney Function Consortium (EKFC) has been shown to have good performances in healthy and chronic kidney disease populations¹¹ but has not been tested in the specific population of transplanted patients. The goal of the current analysis is to study the performance of these equations (MDRD, CKD-EPI_{ASR}, CKD-EPI_{AS}, and EKFC) in a European cohort of transplanted patients.

MATERIALS AND METHODS

This is an observational, retrospective, monocentric study. Adult kidney transplant recipients with a stable

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kidney function at the University Hospital of Saint-Etienne for whom GFR was measured by inulin after the first 3 mo posttransplant were included. Only patients with measured GFR (mGFR) below 15 mL/min/1.73 m² were excluded ($n = 4$). Only 1 (the first) GFR result was considered per patient. The protocol for inulin clearances was used, as previously described.¹² Briefly, after a loading dose of 0.03 g/kg, inulin (Inutest, Fresenius Kabi, Austria) was administered by continuous infusion. After an initial equilibration period of 45 min, 3 clearance periods of 30 min were analyzed. Urinary samples were collected by spontaneous voiding. GFR was measured as the mean of each clearance period. All results were then corrected for the body surface area. Serum creatinine was collected at the same day of the clearance procedure. Blood samples were stored at -80°C until the enrollment of all patients. Measurements of serum creatinine were performed with the same isotope dilution mass spectrometry traceable assay. All patients included were non-Black subjects. Sex- and age-specific median creatinine values (Q-values) in healthy subjects from different populations were established in independent cohorts to be used in the EKFC equation. For White Europeans, Q-values were 0.70 mg/dL for females and 0.90 mg/dL for males.¹¹ The equations are summarized in Table S1 (SDC, <http://links.lww.com/TP/C472>). The study protocol was approved by the Saint-Etienne Institutional Review Board, which waived the need for written informed consent.

Statistical Analyses

All analyses and calculations were performed using SAS 9.4 (SAS Institute Inc, Cary, NC).

Lin's concordance correlation coefficient (CCC), with 95% confidence interval (CI), evaluated the degree to which pairs of observations fell on the 45° line through the origin. It is a measure of both correlation and agreement¹³ and is only suited in the wide range of GFR-values (whole population). Performance of GFR equations was then compared with usual metrics: median bias (ie, estimated GFR [eGFR]—mGFR) with 95% CI, imprecision (interquartile range, and P30 and P20 accuracy (percentage of eGFR-values within $\pm 30\%$ or 20% of mGFR) with 95% CI. Biases were compared and evaluated step by step. First, we considered equations as unbiased when the bias was not different from zero (when 95% CI includes zero). Second, among biased equations, we compared the absolute bias by the paired t test. Third, to use a clinically relevant threshold, we considered an absolute bias of ≥ 5 mL/min/1.73 m² as relevant.

Regarding the accuracy, the difference in P20/P30 in the overall group between eGFRs was tested using the exact McNemar test. From a clinical perspective, the goal for P30 was 100%, yet P30 $>75\%$ has been considered as "sufficient for good clinical decision making" by Kidney Disease Outcomes Quality Initiative. Significance is considered at the 5% significance level.

Graphically, median bias and P30 against age and mGFR were presented using median quantile regression with fourth degree polynomials.

Stratified analysis in different GFR-subgroups was performed according to mGFR ranges ([15–30], [30–45], [45–60], and ≥ 60 mL/min/1.73 m²).¹ We also performed analyses stratified by age ([18–40], [40–65], and ≥ 65 y) and sex.

RESULTS

Of the 489 patients included, 32.5% were females. Median (percentile 25; percentile 75) age, serum creatinine, measured GFR (mGFR), and body mass index were 57.0 (47.0; 66.0) y, 1.44 (1.15; 1.77) mg/dL, 47.7 (35.3; 62.2) mL/min/1.73 m², and 24.2 (22.0; 27.1) kg/m², respectively. Lin's CCCs were 0.7445 (0.7023; 0.7815), 0.7470 (0.7061; 0.7830), 0.7161 (0.6730; 0.7544), and 0.7545 (0.7141; 0.7899) for the MDRD, CKD-EPI_{ASR}, CKD-EPI_{AS}, and EKFC, respectively. The CKD-EPI_{AS} presented the lowest CCC, even if differences were not statistically significant. Bias, precision, and P30 of the MDRD, CKD-EPI_{ASR}, CKD-EPI_{AS}, and EKFC are shown in Table 1. In the whole population, all equations had a significant bias, except the MDRD equation (bias of -0.4 [-1.5 ; 1.0] mL/min/1.73 m²). All biases are significantly different from each other ($P < 0.0001$). Only the bias of the CKD-EPI_{AS} equation was higher than 5 mL/min/1.73 m² (5.5 [4.0; 6.6] mL/min/1.73 m²), whereas the bias of the CKD-EPI_{ASR} and EKFC equations was 2.4 (1.7; 3.5) and 2.2 (1.1; 3.1) mL/min/1.73 m², respectively. All 4 equations had the same level of imprecision. P30 of the CKD-EPI_{AS} equation (68.3%) was significantly lower than the 3 other equations ($P < 0.0001$). P30 of the CKD-EPI_{ASR} equation (74.2%) was not different from EKFC equation (75.3%) but worse than the MDRD equation (77.1%, $P = 0.0133$). P30 of EKFC and MDRD equations were not different. Only the MDRD and EKFC equations had P30 results over 75%. P20 results showed better results for the EKFC equation (60.3%) than the CKD-EPI_{AS} (55.2%, $P = 0.0019$) and CKD-EPI_{ASR} (56.6%, $P = 0.0020$) equations. P20 of the MDRD equation (58.5%) was not different from other equations.

Bias according to age and mGFR is illustrated in Figure 1. P30 according to age and mGFR is illustrated in Figure 2. Figures and results according to subgroups showed that both the CKD-EPI_{AS} had systematically the worst bias (except in patients with mGFR >60 mL/min/1.73 m², where the MDRD equation had the worst bias) and the worst P30. Bias and P30 of the EKFC equation were better in young patients than those of the 2 CKD-EPI equations and slightly worse than those of the MDRD equation. In patients older than 65 y, the EKFC equation showed the best bias and P30. A subanalysis according to the timing of GFR measurement (before or after 1 y of transplantation) leads to similar results and conclusions (poorer performance of the CKD-EPI_{AS}, data not shown).

DISCUSSION

In a cohort of European transplanted patients, we showed that the performance of the new CKD-EPI_{AS} is lower than the previous MDRD and CKD-EPI_{ASR} equations but also lower than the new EKFC equation. The EKFC equation was also better than the CKD-EPI_{ASR} regarding the P20 result. A point already underlined by other authors is the particularly large bias of both CKD-EPI equations in young populations.^{11,14} Performance of the MDRD study equation might be considered as good in transplanted patients, which has been illustrated by others in the literature.²⁻⁴ This is not unexpected, as this equation has been developed from chronic kidney disease patients. Also not unexpected for the same reason is the large bias of the MDRD equation in patients with higher GFR levels.¹⁵

TABLE 1.**Performance of the creatinine-based equation in the whole population and in subgroups according to age, mGFR, and sex**

Whole population, n = 489	MDRD	CKD-EPI _{ASR}	CKD-EPI _{AS}	EKFC
Median bias	-0.4 (-1.5 to 1.0)	2.4 (1.7-3.5)	<i>5.5 (4.0-6.6)</i>	2.2 (1.1-3.1)
IQR (Pct25; Pct75)	14.5 (-7.0 to 7.4)	16.2 (-5.0 to 11.1)	16.6 (-2.2 to 14.4)	15.3 (-5.4 to 9.9)
P20	58.5 (54.1-62.9)	56.6 (52.2-61.1)	55.2 (50.8-59.6)	60.3 (56.0-64.7)
P30	77.1 (73.4-80.8)	74.2 (70.3-78.1)	68.3 (64.2-72.4)	75.3 (71.4-79.1)
According to age (years)				
(<40 [n = 72])				
Median bias	-1.7 (-4.7 to 3.5)	<i>6.5 (3.1-9.2)</i>	<i>9.6 (5.5-12.2)</i>	4.4 (1.1-9.9)
IQR (Pct25; Pct75)	15.1 (-8.0 to 7.1)	17.7 (-2.6 to 15.1)	19.6 (-1.1 to 18.5)	17.5 (-2.5 to 15.0)
P30	83.3 (74.5-92.2)	76.4 (66.3-86.4)	<i>66.7 (55.5-77.8)</i>	77.8 (67.9-87.6)
(40–65 [n = 279])				
Median bias	-0.5 (-1.9 to 0.9)	2.1 (1.5-3.7)	<i>5.0 (3.5-6.7)</i>	2.6 (1.5-3.7)
IQR (Pct25; Pct75)	15.9 (-8.9 to 7.1)	16.9 (-6.2 to 10.7)	17.4 (-3.4 to 14.0)	16.6 (-5.9 to 10.7)
P30	78.1 (73.3-83.0)	75.3 (70.2-80.4)	<i>69.2 (63.7-74.6)</i>	75.3 (70.2-80.4)
(≥65 [n=138])				
Bias	1.5 (-1.1 to 3.7)	1.7 (-0.3 to 3.3)	4.5 (2.9-6.4)	-0.4 (-1.8 to 1.8)
IQR (Pct25; Pct75)	13.3 (-4.3 to 8.9)	13.2 (-3.9 to 9.3)	13.7 (-0.7 to 12.9)	13.9 (-6.3 to 7.6)
P30	<i>71.7 (64.1-79.3)</i>	<i>71.0 (63.3-78.7)</i>	<i>67.4 (59.5-75.3)</i>	<i>73.9 (66.5-81.3)</i>
According to sex				
Female, n=159				
Median bias	-1.2 (-3.6 to 0.9)	1.6 (0.4-3.2)	3.8 (2.6-5.5)	1.1 (-1.0 to 2.7)
IQR (Pct25; Pct75)	13.5 (-8.0 to 5.4)	13.2 (-5.0 to 8.1)	14.2 (-3.2 to 11.0)	13.7 (-6.4 to 7.3)
P30	79.2 (72.9-85.6)	77.4 (70.8-83.9)	<i>74.2 (67.3-81.1)</i>	79.2 (72.9-85.6)
Male, n=330				
Median bias	0.1 (-1.1 to 2.0)	3.0 (2.0-4.6)	<i>6.2 (4.8-7.6)</i>	2.9 (1.6-3.8)
IQR (Pct25; Pct75)	15.5 (-6.8 to 8.7)	17.6 (-5.0 to 12.6)	18.3 (-2.1 to 16.2)	16.7 (-5.0 to 11.7)
P30	76.1 (71.4-80.7)	<i>72.7 (67.9-77.6)</i>	<i>65.5 (60.3-70.6)</i>	<i>73.3 (68.5-78.1)</i>
According to mGFR (mL/min/1.73 m ²)				
GFR (15–30 [n=82])				
Median Bias	<i>6.6 (4.3-8.9)</i>	<i>7.5 (5.6-8.7)</i>	<i>9.2 (7.1-11.2)</i>	<i>7.6 (5.7-9.3)</i>
IQR (Pct25; Pct75)	10.9 (1.8-12.7)	11.4 (2.2-13.6)	12.2 (3.9-16.2)	11.2 (2.6-13.8)
P30	<i>50.0 (38.9-61.1)</i>	<i>47.6 (36.5-58.6)</i>	<i>39.0 (28.2-49.8)</i>	<i>46.3 (35.3-57.4)</i>
GFR (30–45 [n=133])				
Median bias	0.8 (-0.7 to 3.2)	2.2 (0.7-4.0)	4.9 (2.9-7.0)	2.2 (0.4-4.6)
IQR (Pct25; Pct75)	11.6 (-4.4 to 7.2)	12.3 (-3.2 to 9.1)	13.4 (-1.0 to 12.4)	12.4 (-2.7 to 9.7)
P30	80.5 (73.6-87.3)	76.7 (69.4-84.0)	<i>69.9 (62.0-77.8)</i>	76.7 (69.4-84.0)
GFR (45–60 [n=136])				
Median bias	-1.2 (-2.8 to 0.9)	2.1 (0.4-3.9)	<i>5.5 (3.2-7.0)</i>	1.6 (-1.2 to 4.2)
IQR (Pct25; Pct75)	14.4 (-6.8 to 7.6)	18.6 (-5.0 to 13.6)	18.8 (-2.3 to 16.5)	18.5 (-6.4 to 12.1)
P30	83.8 (77.6-90.1)	79.4 (72.5-86.3)	<i>70.6 (62.8-78.3)</i>	80.9 (74.2-87.6)
GFR (≥60 [n=138])				
Median bias	<i>-6.9 (-10.3 to -4.7)</i>	-2.3 (-5.8 to 2.0)	2.0 (-2.1 to 6.0)	-4.3 (-7.0 to -0.5)
IQR (Pct25; Pct75)	18.3 (-15.7 to 2.5)	19.5 (-11.5 to 8.0)	20.4 (-8.1 to 12.3)	17.1 (-11.9 to 5.1)
P30	83.3 (77.0-89.6)	82.6 (76.2-89.0)	81.9 (75.4-88.4)	85.5 (79.6-91.5)

Results in italic are those with P30 <75% or (absolute) bias ≥5 mL/min/1.73 m².CKD-EPI_{AS}, chronic kidney disease epidemiology with variables age and sex; CKD-EPI_{ASR}, chronic kidney disease epidemiology with variables age, sex and race; EKFC, European Kidney Function Consortium; GFR, glomerular filtration rate; IQR, interquartile range; MDRD, Modified Diet in Renal Diseases; mGFR, measured glomerular filtration rate; P20, accuracy within 20%; P30, accuracy within 30%; Pct, percentile.

Moreover, the MDRD equation also used a race coefficient for Black subjects, which is not acceptable in the USA. The EKFC equations have the most constant bias in the whole age range and also in transplanted patients. The worst performance of the CKD-EPI_{AS} is not totally unexpected. Indeed, in the seminal publication, a large bias was also observed in the White American population with this new equation compared with the CKD-EPI_{ASR} equation. This

larger bias was considered as a “price to pay” to use an equation without the questionable race variable.⁷ Having said that, the performance of creatinine-based equations in the transplanted population is even lower than in non-transplanted populations.^{2,3,10,12} Therefore, the “already lower” performance of the CKD-EPI_{AS} leads to a really poor global performance: a bias over 5 mL/min/1.73 m² and a P30 far lower the 75%, suggested by the Kidney

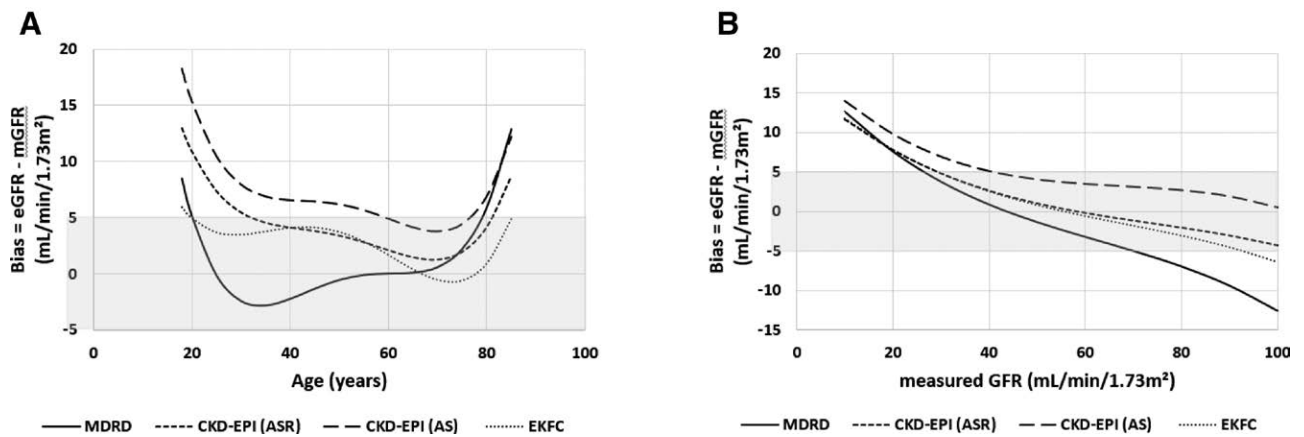


FIGURE 1. Bias against age (A) and mGFR (B). The gray area indicates the region where the absolute bias <5 mL/min/1.73 m². CKD-EPI_{AS}, chronic kidney disease epidemiology with variables age and sex; CKD-EPI_{ASR}, chronic kidney disease epidemiology with variables age, sex and race; EKFC, European Kidney Function Consortium; eGFR, estimated glomerular filtration rate; MDRD, Modified Diet in Renal Diseases; mGFR, measured glomerular filtration rate.

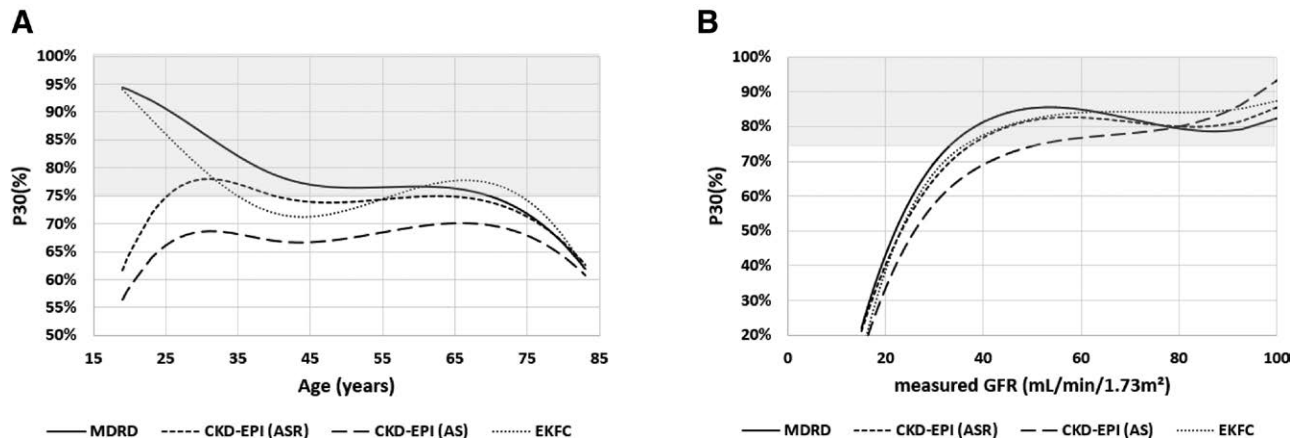


FIGURE 2. P30 (%) accuracy against age (A) and mGFR (B). The gray area indicates the region where P30 $>75\%$. CKD-EPI_{AS}, chronic kidney disease epidemiology with variables age and sex; CKD-EPI_{ASR}, chronic kidney disease epidemiology with variables age, sex and race; EKFC, European Kidney Function Consortium; MDRD, Modified Diet in Renal Diseases; mGFR, measured glomerular filtration rate; P30(%), accuracy within 30%.

Disease Outcomes Quality Initiative to be “acceptable performance”.

Several authors have shown that the race correction used in Black Americans was useless (and a source of larger bias) in Black Africans and Black Europeans, leading to the frequent recommendation in Europe and Africa not to use the race correction in the CKD-EPI_{ASR} equation.^{9,16-20} Using an equation (CKD-EPI_{AS}) for a problem (race correction) specific to the USA (but not relevant in Europe) with poorer performances is thus difficult to accept outside the USA.⁹ The EKFC equation is independent on race. Because serum creatinine can, however, be different in some populations,^{17,21} dedicated, specific (not a correction of White European results) Q-values can be obtained from these populations.¹⁶

Our work must be analyzed with these limitations. This is a monocentric and retrospective analysis in a moderately sized, limited sample of White Europeans. The percentage of transplanted recipients with a kidney from living donor is too low ($<10\%$) to make a dedicated analysis. The results should be confirmed in Black European transplanted patients. Moreover, we did not consider cystatin C

in this publication because the EKFC equation based on cystatin C is still under development.¹²

The new CKD-EPI_{AS} equation seems to have poorer performance in our cohort, suggesting that it is not adapted for the care and follow-up of European transplanted patients. The EKFC equation shows similar (and, in some instances, superior) performance than the classical CKD-EPI equation. Further validation of this equation in populations from diverse ethnic backgrounds and especially in Black Americans is urgently needed. In all cases (and especially in patients with very low GFR), equations remain estimations,^{22,23} and mGFR may be required in specific populations.

Pierre Delanaye, Hans Pottel, and Christophe Mariat are members of the European Kidney Function Consortium.

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