ORIGINAL ARTICLE

Relative superiority of the revised Lund–Malmö equation over 22 other equations used for glomerular filtration rate estimation in undialyzed patients with end-stage renal disease

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KEY WORDS

end-stage renal disease, glomerular filtration rate, residual renal function, revised Lund–Malmö, undialyzed

ABSTRACT

INTRODUCTION The glomerular filtration rate (GFR) is an important indicator of renal function, and its precise measurement is essential for guiding clinical management. However, studies evaluating the performance of GFR estimation equations in undialyzed patients with end-stage renal disease (ESRD) remain scarce.

OBJECTIVES Our work sought to identify a relatively accurate equation for estimating the residual renal function in undialyzed patients with ESRD.

PATIENTS AND METHODS We used the revised Gates method as the gold standard to measure GFR in 101 undialyzed patients with ESRD. We used a total of 23 equations (CKD-EPI$_{Scr}$, MDRDII, FAS$_{Scr}$, EKFC, revised Lund-Malmö (LMR), Mayo, XiangYa, XiangYa-s, Vilar, Shafi$_{\beta 2M}$, CKD-EPI$_{SCysC}$, FAS$_{SCysC}$, CAPA, Hoek, Yang, CKD-EPI$_{Scr\text{-}SCysC}$, FAS$_{Scr\text{-}SCysC}$, Adachi, Shafi$_{\beta TP}$, Shafi$_{\beta TP\text{-}\beta 2M}$, Wong, CKD-EPI_3M, and CKD-EPI_4M) to estimate the patients' GFR.

RESULTS The GFR measured by the dual plasma sampling method (dGFR) and the revised Gates method (rGFR) showed high agreement. The median dGFR and rGFR were 13.1 ml/min/1.73 m^2 and 10.7 ml/min/1.73 m^2, respectively. In the investigated population, the LMR equation showed a low bias (median, 0.6), high precision (interquartile range [IQR], –3.25 to 1.05), and the highest accuracy (P30, defined as the percentage of eGFR within 30% [70%–130%] of rGFR, 65.3%).

CONCLUSIONS Based on comparison of 23 equations, we recommend using the LMR equation, despite its large deviations, to estimate GFR in undialyzed patients with ESRD.

INTRODUCTION Chronic kidney disease (CKD) has become a worldwide public health problem.[1] Prior studies have demonstrated that CKD prevalence is increasing at an alarming rate.[2,3] The glomerular filtration rate (GFR) is a crucial metric of renal function. Precise GFR measurements are critical for clinical treatment since they are the primary determinants of the need for renal replacement therapy and medication dose. Technetium-99m-diethylene triamine pentaacetic acid (^{99m}Tc-DTPA) renal dynamic imaging has been established to be consistent with inulin clearance and earned wide acceptance as the gold standard in clinical practice. However, this methodology is time-consuming, expensive, and requires continuous injections and repeated blood sampling—all rendering it inconvenient for clinical applications. Therefore, using equations to estimate GFR values has become more common. End-stage renal disease (ESRD) can increase mortality, impose financial burden on the health care, and reduce the quality of life.[4,5] Nevertheless, studies evaluating the performance of estimated GFR (eGFR) equations in undialyzed patients with ESRD remain scarce. Numerous works[6-8] have demonstrated that none of the existing eGFR equations

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WHAT'S NEW?

The glomerular filtration rate (GFR) is an important index of kidney performance, and its precise measurements are indispensable for efficient patient management. There are several methods of GFR estimation. However, studies evaluating the estimated GFR in undialyzed patients with end-stage renal disease (ESRD) remain scarce. Our work sought to characterize a relatively accurate equation for estimating kidney function in undialyzed patients with ESRD. In contrast to prior studies assessing the GFR and using less than 10 equations, we challenged 23 equations with our datasets. Among all the tested equations, the revised Lund–Malmö equation showed a low bias, high precision, and the highest accuracy in estimating the GFR in undialyzed patients with ESRD.

can precisely evaluate the renal function in patients with CKD.

This study investigated the performance of 23 GFR-estimating equations, compared eGFR with the measured GFR, and derived a relatively accurate method for estimating residual renal function in undialyzed ESRD patients.

PATIENTS AND METHODS **Study design and participants** This retrospective cohort study investigated 101 undialyzed patients with ESRD, whose GFR was measured by the revised Gates method (rGFR) between January 2013 and December 2021 at the China-Japan Friendship Hospital. Sixteen of these patients also underwent GFR measurement by the dual plasma sampling method (dGFR). The exclusion criteria were: 1) severe heart failure or acute renal failure, 2) pleural abdominal effusion, 3) serious edema or malnutrition, 4) skeletal muscle atrophy, 5) amputation or ketoacidosis, and 6) abnormal thyroid function. The number of included samples varied slightly between equations (Supplementary material, *Table S1*). The study was approved by the ethics committee of our institution (2021-113-K71) and all the procedures were performed in accordance with the Declaration of Helsinki. All participants provided their informed consent.

Data collection and measurements Serum creatinine (Scr) was measured by the enzymatic kinetic assay under fasting conditions before measuring GFR. β-trace protein (βTP) was measured by enzyme-linked immunosorbent assay (ELISA) (Jiangsu Meibiao Biotechnology Co., Ltd, Jiang-Su, China). Other demographic, medical history, and laboratory data were also collected and are presented in TABLE 1.

The GFR of all participants was derived by ^{99m}Tc-DTPA renal dynamic imaging. Before the test, the participants' height and weight were measured, and they were hydrated with 300 to 500 ml of water prior to emptying their bladder. While in a supine position, 185 MBq of ^{99m}Tc-DTPA were administered in a bolus into the antecubital vein, using single-photon emission computed tomography for 60 seconds, counting from the time of syringe loading with the drug. After the image acquisition, the rGFR was calculated by a software (Syngo, Erlangen, Germany). The dGFR was then measured according to the equation

$$GFR = D\frac{\ln\frac{P1}{P2}}{T2 - T1}e^{T1\ln P2 \times T2\ln P1} \times 0.93 \times \frac{1.73}{BSA}$$

where D is the drug injection dose, T1 is the time point of the first blood collection (2 h), P1 is the plasma activity at T1, T2 is the time point of the second blood collection (4 h), and P2 is the plasma activity at T2. The units of measurement were counts per minute per milliliter for D, P1, and P2, and minutes for T1 and T2. The values were expressed per 1.73 m^2 of body surface area according to the Dubois equation

$$BSA = 0.007184 \times \text{body weight (kg)}^{0.425} \times \text{height (cm)}^{0.725}.$$

All eGFR equations[9-26] are shown in Supplementary material, *Table S1*.

Statistical analysis Statistical analysis was performed using SPSS 26.0 (SPSS Inc., Chicago, Illinois, United States) and GraphPad Prism 9.4.0 (GraphPad Software, Inc., San Diego, California, United States). Continuous variables are presented as median (interquartile range [IQR]), and categorical variables are presented as numbers or percentages. The performance of each equation in assessing GFR was decided based on 3 measures, namely bias, precision, and accuracy. The bias was calculated as the median difference (MD) between eGFR and rGFR. Precision was determined as the IQR of difference. Accuracy was defined as the percentage of eGFR within rGFR (70%–130%) (P30). The Bland–Alman analysis was performed and plotted to visually compare measured GFR and eGFR. The smaller the width of 95% limits of agreement (LOA), the greater the consistency, and direct scatter plots were used to further examine the consistency. The difference of bias between 2 equations was compared using the Wilcoxon rank-sum test and multiple comparisons were performed using the Benjamini–Hochberg method. All statistical tests were considered significant at P below 0.05.

RESULTS **Characteristics of the participants** A total of 101 patients were included. Their main clinical characteristics are shown in TABLE 1. Their age was 26 to 83 years, with a median (IQR) of 59 (48.5–69) years, 68 (67.3%) were men and 33 (32.7%) were women. Primary diseases included chronic glomerulonephritis in 45 cases (44.5%), diabetic nephropathy in 18 cases (17.8%), immunoglobulin A nephropathy in 11 cases (10.8%), hypertensive kidney damage in 11 cases (10.8%), focal segmental glomerulosclerosis in 4 cases (3.9%), polycystic kidney disease in 3 cases (2.9%), lupus nephritis in 3 cases (2.9%), and other diseases in 6 cases (5.5%). The median dGFR and rGFR were 13.1 (IQR, 11.4–14.3) ml/min/1.73 m^2 and 10.7 (IQR, 7.7–13.2) ml/min/1.73 m^2, respectively. As compared with rGFR, the eGFR values calculated by FAS_{Scr}, XiangYa, XiangYa-s, $CKD\text{-}EPI_{SCysC}$, FAS_{SCysC}, $FAS_{Scr\text{-}SCysC}$, Adachi, and CKD-EPI_3M

TABLE 1 Demographic and clinical characteristics of the study population (n = 101)

Variable	Value
Age, y	59 (48.5–69)
Male sex, n (%)	68 (67.3)
Height, m	1.7 (1.6–1.7)
Body weight, kg	67.5 (60.3–78)
Body mass index, kg/m^2	24.1 (21.8–27.1)
Body surface area, m^2	1.77 (1.7–1.9)
Serum creatinine, µmol/l	574.2 (461.8–820.1)
Uric acid, µmol/l	470 (387.5–547.5)
Potassium, mmol/l	4.6 (4.2–5.1)
Sodium, mmol/l	140 (137–141)
Calcium, mmol/l	2.1 (1.9–2.2)
Phosphorus, mmol/l	1.6 (1.4–1.8)
β-2-microglobulin, mg/l	14.7 (10.8–18.4)
Serum cystatin, mg/l	4.4 (3.8–5)
Urinary cystatin, mg/l	3.6 (1.5–6.1)
Urinary creatinine, µmol/l	4788.5 (3674–6351)
β-trace protein, mg/l	5.6 (2.1–10.8)

Data are presented as median (interquartile range) unless indicated otherwise.

TABLE 2 Measured and estimated glomerular filtration rate

Formula	Value
dGFR, ml/min/1.73 m^2	13.1 (11.4–14.3)
rGFR, ml/min/1.73 m^2	10.7 (7.7–13.2)
eGFR, ml/min/1.73 m^2	
CKD-EPI$_{Scr}$	8.2 (5.5–10)
MDRDII	8.3 (5.6–10.4)
FAS$_{Scr}$	10.9 (8.3–13)
EKFC	8.7 (6.2–10.7)
LMR	9.6 (7.3–11.3)
Mayo	9.2 (7.6–10.4)
XiangYa	25.7 (21.5–27.9)
XiangYa-s	25.8 (23–27.2)
Vilar	6.7 (4.6–10.7)
Shafi$_{β2M}$	5.8 (3.4–13.1)
CKD-EPI$_{SCysC}$	10.8 (9.3–13.2)
FAS$_{SCysC}$	16.3 (14.3–19.9)
CAPA	9.8 (7.8–12.7)
Hoek	4.4 (3.8–5.2)
Yang	4.1 (3.4–4.8)
CKD-EPI$_{Scr-SCysC}$	8.5 (7.0–10.8)
FAS$_{Scr-SCysC}$	12.9 (10.8–16.1)
Adachi	12.0 (10.2–14.3)
Shafi$_{βTP}$	3.9 (0.7–19.2)
Shafi$_{βTP-β2M}$	5.6 (2.2–15)
Wong	5.5 (2.6–8)
CKD-EPI_3M	12.3 (9.6–15.1)
CKD-EPI_4M	9.5 (7.3–11.4)

Data are presented as median (interquartile range).

Abbreviations: β2M, β-2-microglobulin; βTP, β-trace protein; CAPA, Caucasian and Asian Pediatric and Adult; CKD-EPI, Chronic Kidney Disease Epidemiology Collaboration; dGFR, glomerular filtration rate measured by the dual plasma sampling method; eGFR, estimated glomerular filtration rate; EKFC, European Kidney Function Consortium; FAS, Full Age Spectrum; LMR, revised Lund–Malmö; MDRD, Modification of Diet in Renal Disease; rGFR, glomerular filtration rate measured by the revised Gates method; Scr, serum creatinine; SCysC, serum cystatin C

equations were overestimated to a different degree, and those calculated by the remaining 15 equations were underestimated (TABLE 2).

Agreement between measured and estimated glomerular filtration rate In general, the Bland–Alman plots showed that the median rGFR was slightly lower than dGFR. The Mayo equation displayed the highest concordance with rGFR (width of 95% LOA, 11.7 ml/min/1.73 m^2; mean difference, –1.08 ml/min/1.73 m^2), followed by the CKD-EPI$_{Scr-SCysC}$ (11.8 ml/min/1.73 m^2; –1.13 ml/min/1.73 m^2), Hoek (12.1 ml/min/1.73 m^2; –5.73 ml/min/1.73 m^2), Yang (12.1 ml/min/1.73 m^2; –6.14 ml/min/1.73 m^2), and LMR (12.5 ml/min/1.73 m^2; –0.87 ml/min/1.73 m^2) equations (FIGURE 1, Supplementary material, *Figure S1*). The results on consistency presented on direct scatter plots are shown in Supplementary material, *Figure S2*.

Bias, precision, and accuracy of the estimated glomerular filtration rate equations The MD of CKD-EPI_4M (–0.25, P <0.001) yielded the lowest bias among all equations as compared with CKD-EPI$_{Scr}$. FAS$_{Scr}$, CAPA, and LMR followed (0.50, 0.50, and –0.60, respectively, all P <0.001). Moreover, the XiangYa-s equation showed the smallest IQR (13.30–16.90) among all 23 equations, followed by the MDRDII (–4.20 to –0.15), CKD-EPI$_{Scr}$ (–4.50 to –0.35), and LMR (–3.25 to –1.05). As for accuracy, the LMR equation had the highest P30 in assessing eGFR (P30, 65.3%), followed by the Mayo (P30, 64.3%) and the CKD-EPI$_{Scr-SCysC}$ (P30, 64.2%) equations (Supplementary material, *Table S2*).

DISCUSSION

In contrast with previous studies that assessed eGFR using less than 10 equations, this study evaluated the performance of 23 equations in establishing the bias, agreement, precision, and accuracy in calculating eGFR. It demonstrated that the LMR methodology has low bias, high precision, and the highest accuracy among the 23 tested equations. Therefore, we recommend using the LMR equation to estimate GFR in undialyzed patients with ESRD.

A GFR-estimating equation operates best in the populations for which it was designed.[27] As in earlier studies, at the measured GFR below 30 ml/min/1.73 m^2, the LMR equation was the only one in this group with a P30 accuracy close to 75%.[28] Similar findings were observed in 2 earlier regional Swedish investigations[29,30] and in a national Swedish Renal Registry analysis of over 2000 patients with measured

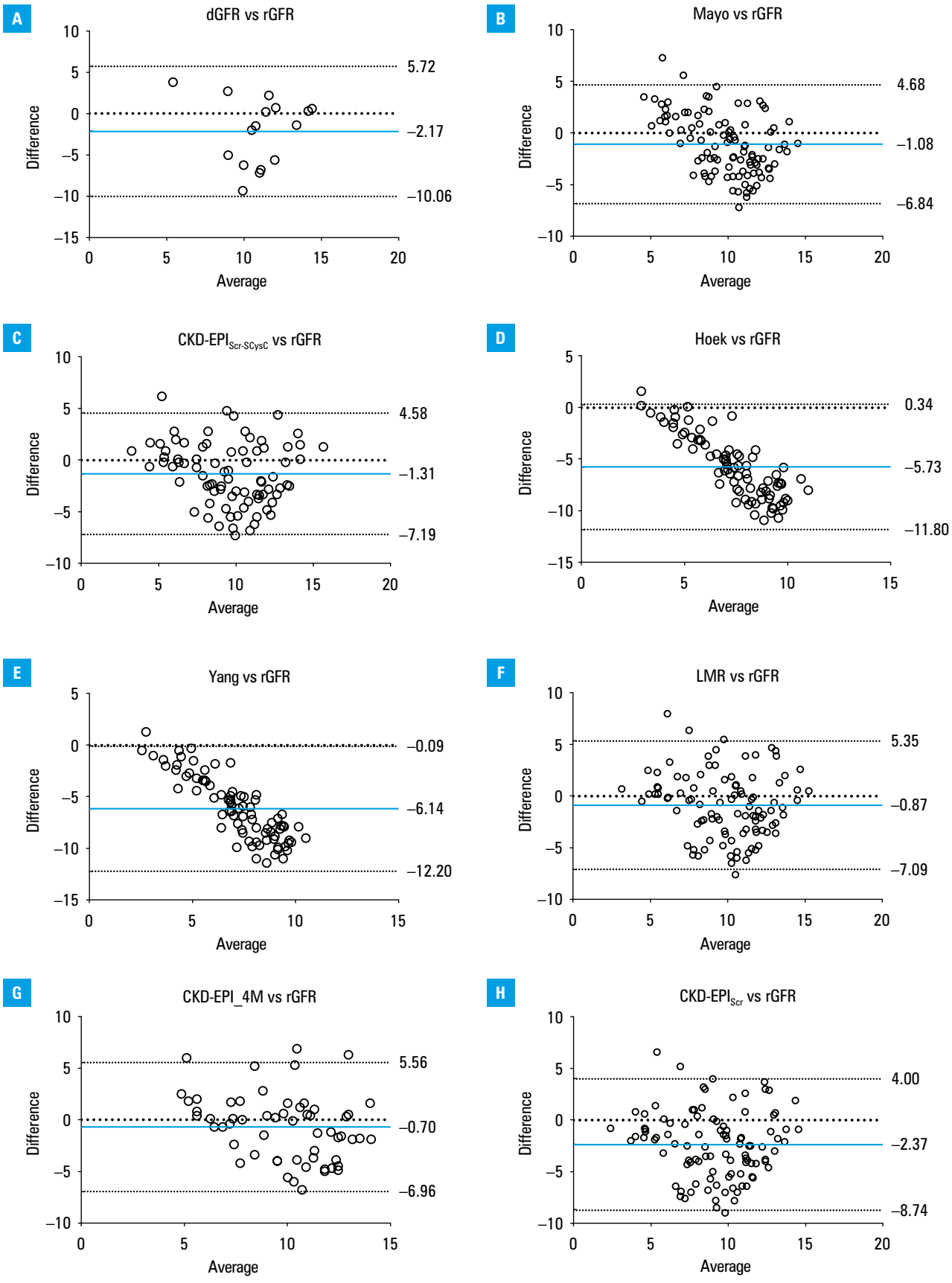

FIGURE 1 Bland–Altman plots of glomerular filtration rate (ml/min/1.73 m^2) measured according to the dual plasma method and 11 equations: rGFR (A); Mayo (B); CKD-EPI$_{Scr-SCysC}$ (C); Hoek (D); Yang (E); revised Lund–Malmö (F); CKD-EPI_4M (G); CKD-EPI$_{Scr}$ (H); solid lines represent the mean difference between 2 methods, and dotted lines denote the 95% limits of agreement.
Abbreviations: see TABLE 2

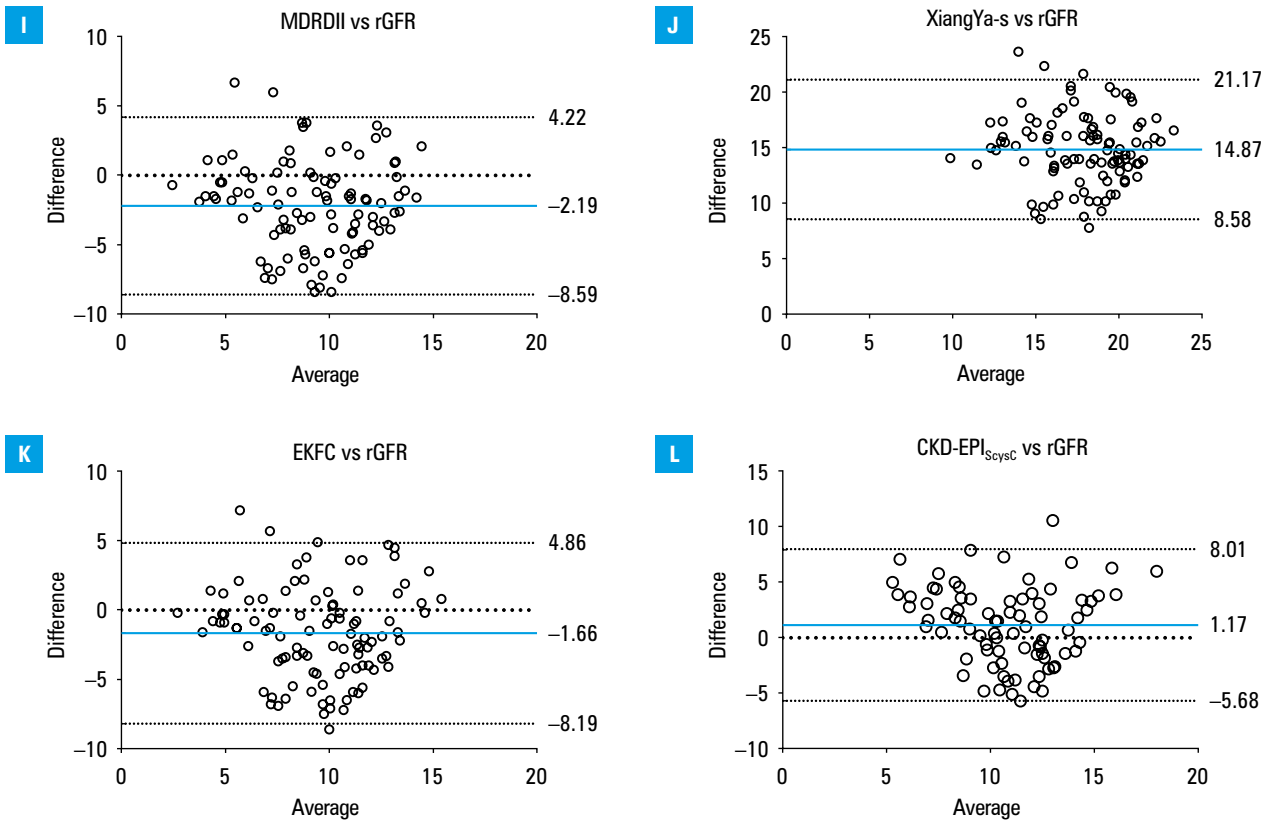

FIGURE 1 Bland–Altman plots of glomerular filtration rate (ml/min/1.73 m^2) measured according to the dual plasma method and 11 equations: MDRDII (I); XiangYa-s (J); EKFC (K); CKD-EPI$_{SCysC}$ (L); solid lines represent the mean difference between 2 methods, and dotted lines denote the 95% limits of agreement.
Abbreviations: see TABLE 2

GFR below 30 ml/min/1.73 m^2.[31] One explanation was that the LMR equation was designed to improve estimations at low measured GFR levels[13] and employed the more current and standard approach to detecting creatinine to decrease a measurement error. Another reason could be comparability of GFR measurement methodologies. GFR was assessed in both the LMR development study and our study using exogenous markers, namely iohexol and ^{99m}Tc-DTPA, respectively. However, a previous study by Xie et al[32] showed that the LMR equation is not the best, possibly because their cohort was different than ours. The patients included in the aforementioned study had a measured GFR of 50.30 (SD, 31.43) ml/min/1.73 m^2, whereas our cohort comprised undialyzed patients with ESRD who had a measured GFR of 10.7 (IQR, 7.7–13.2) ml/min/1.73 m^2.

eGFR equations established for dialyzed patients (eg, Vilar, Shafi$_{\beta 2M}$, Hoek, Yang, Shafi$_{\beta TP}$, Shafi$_{\beta TP\text{-}\beta 2M}$, Wong) do not perform well in patients with ESRD who are not dialyzed. First, non-GFR determinants of endogenous filtration indicators for dialyzed patients are expected to differ from undialyzed patients due to the chronic disease and dietary changes, increased extrarenal clearance, higher proportion of tubular secretion, and dialysis-induced marker removal. Second, as most GFR-estimating equations are based on linear regression, the range and mean GFR observed in the source population is predicted to influence the estimates. Dialyzed patients have lower GFR values than the majority of CKD patients, hence the equations created for those populations underestimate GFR.[17,18,22,23,25]

Except for the Yang, XiangYa, XiangYa-s, and Adachi equations, the remaining equations were established in the American and European populations, with a majority of Caucasian patients. The eGFR demonstrated that the non-white populations bore larger error margins than the white populations. However, using ethnicity-specific corrective factors or population-specific equations had no effect on the accuracy or precision of eGFR values. In Chinese and Japanese patients, customized equations or population-specific formulas did not increase the accuracy of eGFR.[33-41]

Cystatin C (CysC) appears to be less affected by non-GFR variables than creatinine. Indirect evidence implies that CysC is affected by factors other than GFR, such as inflammation, smoking, thyroid disease, and fat mass. Regardless of whether CysC or creatinine / CysC equation is used, research has demonstrated that eGFRcys is no more accurate than eGFRcr.[19]

βTP and β-2-microglobulin (β2M) appear to be potential endogenous GFR indicators. βTP assays are exclusively available in research laboratories as nephelometric, immunodiffusion, ELISA, and immunofluorescence assays.[42] There are no defined methodologies for either βTP or β2M

assays, and too many problems associated with their performance, glomerular filtration, tubular secretion, and extrarenal elimination have prohibited their widespread adoption. Finally, earlier formulas have not been outperformed by the equations based on βTP or β2M.[43]

This study also has some limitations. First, the reference standard used has been the revised Gates method and not ^{99m}Tc-DTPA dual plasma sampling or inulin clearance method. Additionally, due to the retrospective and observational nature of this investigation, despite numerous variables having been included in our analyses, data on some hidden or unknown factors such as medication and participants' blood pressure were missing. Finally, because clinical indicators such as βTP and urinary CysC are not routinely tested in actual clinical practice, the number of patients that can be included is limited, resulting in different numbers of cases included in the 23 formulas.

In conclusion, of the currently published GFR-estimating equations, the LMR formula yielded the most consistent estimation of rGFR in undialyzed patients with ESRD, albeit with large deviations. Currently, no GFR-estimating equation is recommended by the authorities in China, which may be related to different gold standards and small sample sizes adopted by different research institutions. The need to establish a GFR-estimating equation that is accurate, standardized, and easy to replicate for all patients in the Chinese population is urgent.

SUPPLEMENTARY MATERIAL

Supplementary material is available at www.mp.pl/paim.

ARTICLE INFORMATION

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CONFLICT OF INTEREST None declared.

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