Measured GFR in Donor Selection, to Do or Not to Do? That is the Question

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Introduction. The accurate assessment of the pre-donation glomerular filtration rate (GFR) is a crucial step in donor selection. We conducted a prospective cross-sectional study to identify the best equation to estimate GFR and the necessity of a radio-nuclear scan in GFR evaluation.

Methods. In this study, 154 potential donors were enrolled, and GFR equations (the MDRD study, the CKD-EPI study, and the full age spectrum [FAS]), and creatinine clearance were compared with measured GFR (mGFR) by the radio-nuclear method.

Results. The study results indicate that Potential donors had an mGFR of 95.56 ± 15.57 mL/min per 1.73 m^2. Though body surface area (BSA) adjusted full age spectrum (FAS) and CKD-EPI equations were most correlated with mGFR, the correlation coefficients were weak (ICC: 0.3 and 0.32, respectively). Misclassification at the cut-off of 80 cc/min/ 1.73 m^2 was about 42% for both equations. Besides, 16.8% of donors with eGFR more than 80 cc/min/ 1.73 m^2 had a difference in split renal function, and 57.1% of participants had a > 2% probability of having an mGFR < 90 mL/min per 1.73 m^2.

Conclusion. If the nuclear scan is easily available, we suggest measuring GFR by ^{99m}Tc -DTPA scan as the preferred method. Otherwise, our data suggest utilizing mGFR in patients with high body mass index, size asymmetry in CT-scan, eGFR less than 90 mL/min per 1.73 m^2 with FAS and/or CKD-EPI equation as these factors deviated the estimated GFR, and also in those with inaccurate creatinine clearance measurements or with posttest probability of having mGFR less than 90 mL/min per 1.73 m^2 more than 2%.

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INTRODUCTION

Annually, about 2100 kidney transplants are performed in Iran, of which nearly 36% are from living kidney donations.[1] The major concern in living kidney donation is posing the donor at the risk of end-stage kidney disease (ESKD). However, the risk is as low as 31 cases per 10,000 donors during 15 years post-donation follow-up, and it depends on multiple factors, such as the age of the donor, male gender, body mass index (BMI), and most importantly baseline GFR.[2,3]

Post nephrectomy GFR of the remained kidney increases and returns to 80% of the baseline pre-donation GFR.[4] Thus, accurate determination of

pre-donation GFR and defining the acceptable threshold for donation is important.

In case of suspected asymmetry, the latest edition of the international guideline development group Kidney Disease Improving Global Outcomes (KDIGO) recommends an initial screening test with estimated creatinine based-GFR ($eGFR_{cr}$) and a confirmatory measured GFR (mGFR), and single kidney GFR evaluation by ^{99m}Tc-DTPA (diethylenetriaminepentaacetic acid).[5]

However, the initial assessment of renal function with $eGFR_{cr}$ and the confirmatory test of measured creatinine clearance are affected by various sources of error, such as non-GFR determinants of creatinine or inappropriate urine collection. In the absence of Inulin excretion test, the most accurate confirmatory method is mGFR by urinary or plasma clearance of iothalamate, urinary or plasma clearance of 51Cr-EDTA (ethylenediaminetetraacetic acid), urinary or plasma clearance of iohexol, and urinary clearance of ^{99m}Tc-DTPA.[6]

Recently, a web-based application has been developed to calculate the posttest probability of mGFR below the threshold based on eGFR. (http://ckdepi.org/equations/donor-candidate-gfr-calculator/).[7] It is recommended that donors with a > 2% posttest probability of having an mGFR < 90 mL/min per 1.73 m^2 undergo a radioisotope scan.[8]

Nevertheless, these radioisotope techniques are not available in many centers. Thus, to introduce the "best locally available" method, we evaluated the potential donors under routine investigation for suitability to identify the best correlated $eGFR_{cr}$ equation with the standard mGFR determined by the urinary clearance of ^{99m}Tc-DTPA in our population and attempted to provide more clear indications for the radio-nuclear scan.

MATERIALS AND METHODS

Potential Living Donors

In this observational cross-sectional prospective study, all potential living donors were evaluated at Labffinejad Transplant clinic for suitability and those who consented to participate in the study were enrolled between December 2017 to January 2020. The study was approved by the ethics committee of Shahid Beheshti University of Medical Sciences. (Ethical Code- 890708.9).

Demographic data including age, body weight, height, body mass index (BMI), lean body weight (LBW),[9] and body surface area (BSA)[10] were reported.

GFR Measurement

The potential donors underwent renal dynamic imaging with the injection of ^{99m}Tc-DTPA with radioactive chemical purity of more than 95%. Imaging was performed using SIEMENS (ECAM) single-head gamma camera, with low energy, all-purpose collimation using 128 x 128 matrix, 20% acceptance window, and 140 Kev photopeak. Thirty minutes before the tracer injection, the participants drank 500 to 800 mL (10 mL/kg) of water. A 1-minute image of the syringe before and after injection of ^{99m}Tc-DTPA 1 mL (about 7.5 mCi, 277.5 MBq) was taken at a 30 cm distance from the center of the collimator. With potential donors in the supine position, images were acquired posteriorly at 2 sec/frame for 30 frames and 15 sec/frame for 24 frames. Based on the Gates method, the region of interest (ROI) over each kidney was created manually by a single, expert technician on the frame added after injection by selecting a semilunar-shaped background ROI in the inferior regions of the kidneys.[11] The Gates method for GFR assessment is based on the accumulation of ^{99m}Tc-DTPA within the kidneys during the 2- to 3-minute from the time point of image acquisition and, after background and depth correction, expresses as a percentage of net injected counts. The standardization of GFR_{Gates} (mL/min per 1.73 m^2) according to the standard surface area of 1.73 m^2 was subsequently calculated. Data were reported as mGFR which is normalized for 1.73 m^2 BSA. Split renal function was calculated and considered significant if there was more than a 10% difference between kidneys.[12]

GFR Estimation

Serum creatinine was determined by Jaffe's reaction. Estimated GFR (eGFR) was calculated with the five following equations and adjusted for 1.73 m^2 BSA: Modification of Diet in Renal Disease -4 (MDRD-4), MDRD-6, Cockcroft- Gault (CG), Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI), and full age spectrum ((FAS)).

The 24-hour urine creatinine clearance was calculated, and the accuracy of urine collection was determined by urine creatinine excretion to body

weight (males: 20 to 25 mg/kg/d and females: 15 to 20 mg/kg/d).

The posttest probability of having mGFR < 90 mL/min per 1.73 m^2 was calculated at http://ckdepi.org/equations/donor-candidate-gfr-calculator/.

Statistical Analysis

Agreement of the calculated GFR methods was evaluated by Pearson correlation as well as Kappa statistics, and concordance correlation coefficient (CCC). The diagnostic performance of the selected methods for discrimination of the patients based on a cut-off point of 80 for GFR was also evaluated. Multivariate analyses were performed to overcome potential sources of bias and to conclude a correction formula to be close to the gold standard. Bland-Altman analysis was applied to compare the alternative methods with the gold standard.

RESULTS

In this study, at the end of the evaluation, 154 potential donors were enrolled regardless of donation. Demographic characteristics of the study population are shown in Table 1. The mean age of the donors was 30.16 ± 5.44 years, and 82.6% of the cohort were male. The mean mGFR was 95.56 ± 15.57 mL/min per 1.73 m^2.

The results of GFR estimation with five different equations were reported and adjusted by BSA. mGFR was evaluated in all the study participants as the gold standard. (Table 2).

According to the Pearson Correlation Coefficient, MDRD6 (ICC: 0.23; *P* = .005), MDRD4 (ICC: 0.3; *P* = .0001), FAS (ICC: 0.3; *P* = .0001), and the CKD-EPI equation (ICC: 0.32, *P* = .0001); were mostly correlated with normalized mGFR when adjusted for BSA, although the correlation coefficients were weak.

Table 1. Baseline Characteristics of the Study Participants and Estimated Glomerular Filtration Rate

Variable	Value
Age, y (mean ± SD)	30.1 ± 5.4
Male Gender, %	82.6
Body weight, kg (mean ± SD)	73.3 ± 14.3
BMI, kg/m^2 (mean ± SD)	24.8 ± 4.2
LBW, kg (mean ± SD)	59.1 ± 9.5
Height, cm (mean ± SD)	172.1 ± 8.9
BSA, m^2 (mean ± SD)	1.86 ± 0.19
Serum Creatinine, mg/dL (mean ± SD)	1.06 ± .16
Urine Creatinine Excretion, mg/kg/d (mean ± SD)	20.48 ± 6.85
Creatinine Clearance, cc/min/ 1.73 m^2 (mean ± SD)	77.95 ± 29.13
eGFR by CG, cc/min/ 1.73 m^2 (mean ± SD)	84.96 ± 19.79
eGFR by MDRD-4, cc/min/ 1.73 m^2 (mean ± SD)	85.43 ± 17.17
eGFR by MDRD-6, cc/min/ 1.73 m^2 (mean ± SD)	81.87 ± 12.94
eGFR by CKD-EPI, cc/min/1.73 m^2 (mean ± SD)	90.64 ± 15.94
eGFR by FAS, cc/min/ 1.73 m^2 (mean ± SD)	83.90 ± 17.97
mGFR, cc/min/1.73 m^2 (mean ± SD)	95.56 ± 15.57

Abbreviations: BMI, body mass index; BSA, body surface area; LBW, lean body weight; CG, Cockcroft- Glaut; CKD-EPI, chronic kidney disease epidemiology collaboration; eGFR, estimated GFR; FAS, full age spectrum; MDRD-4, modification of diet in renal disease -4; MDRD-6, modification of diet in renal disease -6; mGFR, measured GFR

The lack of correlation between mGFR by creatinine clearance and ^{99m}Tc-DTPA scan could be attributed to the fact that 45.1% of donors did not collect their 24 hours urine precisely, as evidenced by low urine creatinine excretion to body weight (less than 20 mg/kg/d and 15mg/kg/d among male and female donors, respectively).

The strongest correlations were found between the CKP-EPI and FAS equations, respectively, and mGFR (Figure 1). With respect to Concordance Correlation Coefficient (CCC), the most correlated

Table 2. Pearson Correlation and Mean Difference and Agreement of Various Methods/BSA with Normalized GFR

Statistical Methods	CG	CrCl	MDRD4	MDRD6	CKD-Epi	FAS
Pearson Correlation Coefficient (ICC)	0.12	0.06	0.30	0.23	0.32	0.30
P	.14	.48	.0001	.005	.0001	.0001
Concordance Correlation Coefficient (CCC)	0.10	0.02	0.26	0.10	0.31	0.29
95% CI	-0.03 to 0.24	-0.04 to 0.09	0.13 to 0.39	0.03 to 0.17	0.16 to 0.44	0.14 to 0.42
Bias Correction Factor	0.85	0.42	0.88	0.44	0.97	0.95
Mean Difference (SE)	9.4 (1.8)	34.3 (3.3)	8.2 (1.7)	31.4 (3.0)	3.4 (1.6)	4.8 (1.6)
P	.0001	.0001	.0001	.0001	.04	.003

Abbreviations: CrCl, creatinine clearance; CG, Cockcroft- Glaut; CKD-EPI, chronic kidney disease epidemiology collaboration; FAS, full age spectrum; MDRD-4, modification of diet in renal disease -4; MDRD-6, modification of diet in renal disease -6

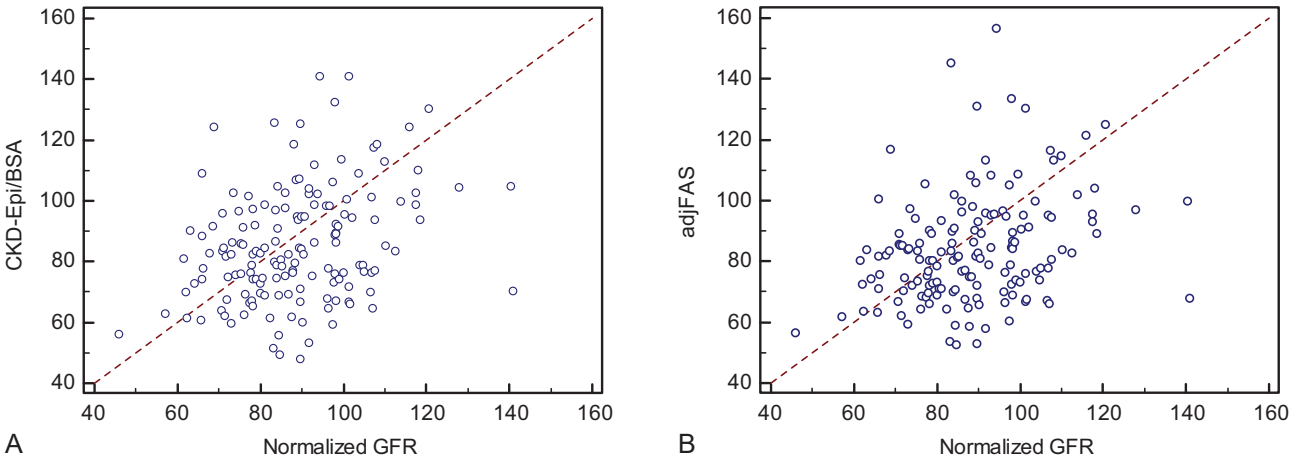

Figure 1. (A) Pearson Correlation Coefficient between CKD-EPI (BSA- adjusted) and mGFR, (B) Pearson Correlation Coefficient between FAS (BSA- adjusted) and mGFR

equation was CKD-EPI with a CCC of 0.31 (95% CI: 0.16 to 0.44), with the FAS equation being the second most correlated equation (CCC: 0.29, 95% CI: 0.14 to 0.42). Additionally, these two equations had the higher bias correction factor and smallest mean difference with the mGFR. A summary is illustrated in Table 3. However, comparing pairs, FAS and CKD-EPI techniques overestimated and MDRD formulas underestimated GFR compared to normalized mGFR and the correlations were weak.

The most correlated methods, CKD-EPI and FAS equations, were further evaluated for agreement with the gold standard method. When analyzed with the Bland-Altman plot, both CKD-EPI and FAS equations had acceptable agreement with mGFR, as shown in Figure 2. The visual distribution of data in different techniques (mGFR, CKD-EPI, and FAS equation), were similar (Supplementary file-S1).

Table 3. Diagnostic Performance of BSA-adjusted FAS and BSA-adjusted CKD-EPI to Classify Donors at GFR of 80 cc/min/1.73 m^2 Compared to Normalized GFR as the Gold-standard

Method	Index	Value	95% CI
CKD-EPI GFR	Sensitivity	72.2%	62.8 to 80.4
	Specificity	23.4%	12.3 to 38.0
	Positive LR	0.94	0.77 to 1.15
	Negative LR	1.19	0.65 to 2.16
	Accuracy	57.4%	49.2 to 65.3
FAS GFR	Sensitivity	58.8%	49.9 to 69.2
	Specificity	51.1%	36.1 to 65.9
	Positive LR	1.22	0.88 to 1.70
	Negative LR	0.79	0.55 to 1.13
	Accuracy	57.1%	48.9 to 65.1

Abbreviations: BSA, body surface area; CI, confidence interval; CKD-EPI, chronic kidney disease epidemiology collaboration; FAS, full age spectrum; GFR, glomerular filtration rate; LR, likelihood ratio

As the policy of our center is to preclude donors with mGFR less than 80 mL/min per 1.73 m^2

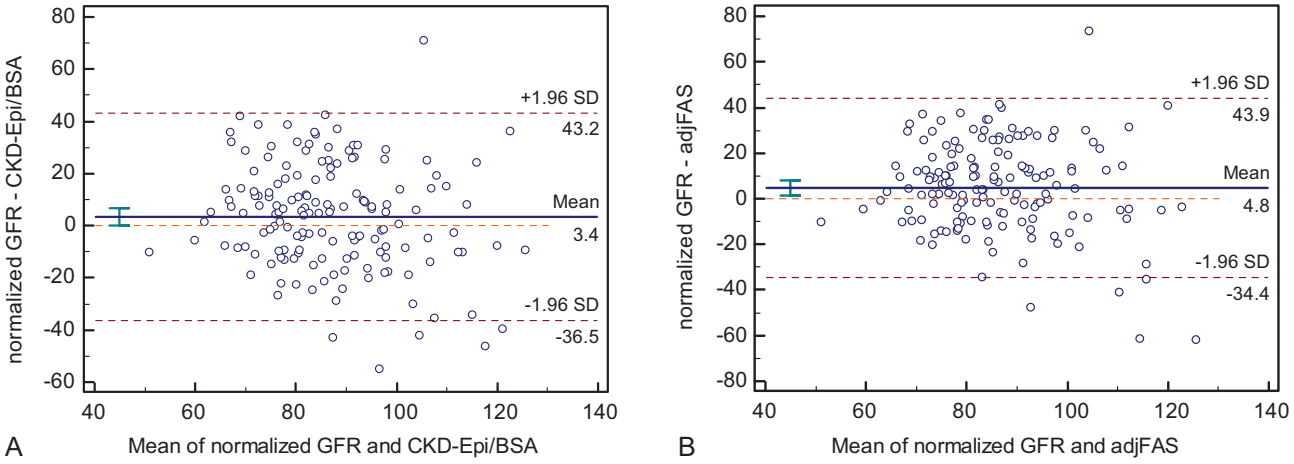

Figure 2. Bland-Altman plot, both CKD-EPI (A) and FAS (B)

from donation, the diagnostic performance of two equations to classify donors with a mGFR of 80 mL/min per 1.73 m^2 was assessed and illustrated in Table 3. Both tests had a similar accuracy of about 57%. Nonetheless, the FAS equation had a higher positive likelihood ratio (PLR) than CKD-EPI, 1.22 vs. 0.94, respectively, which means better predictivity of FAS in the diagnosis of mGFR of 80 mL/min per 1.73 m^2. The percentage of misclassification of GFR at 80 mL/min per 1.73 m^2 was depicted in Figure 3. Both equations showed about 42% misclassification. Among donors with mGFR less than 80 cc/min/ 1.73 m^2, eGFR was overestimated in 14.9% and 23.2% with FAS and CKD-EPI equations, respectively.

Multivariable analyses demonstrated that a prediction model could be achieved by a correction formula, both for CKD-EPI and FAS methods. For the CKD-EPI equation, a model which contains BMI, gender, and GFR can predict mGFR with more accuracy. Based on data in the corrected formula which includes FAS- eGFR, BMI, and gender has better predictivity of mGFR; however, R^2 of the prediction was not strong enough.

Besides the fact that formula based GFR calculation might not be as accurate as mGFR by radioisotope scan, in about 15% of donors difference in split renal function (SRF) was detected between the kidneys. Interestingly, significant SRF was found in 16.8% of donors with eGFR > 80 mL/min per 1.73 m^2 based on the two most accurate formulas (CKD-EPI and FAS).

With respect of the posttest probability of having mGFR < 90 mL/min per 1.73 m^2 using the web-based calculator (http://ckdepi.org/equations/donor-candidate-gfr-calculator/), 57.1% of participants had a > 2% probability of having an mGFR < 90 mL/min per 1.73 m^2.

DISCUSSION

The precise evaluation of donors' kidney function is the first crucial step in donor selection to minimize the risk of ESKD in the future. The latest version of the KDIGO guideline recommends a two-step evaluation of kidney function in donation candidates. It also recommends expressing GFR in ml/min per 1.73 m^2. Accordingly, in this study 154 donation candidates with creatinine-based eGFR equations were evaluated as an initial test, followed by mGFR by the means of creatinine clearance and ^{99m}Tc-DTPA scan. With the respect to the time of urine collection for creatinine clearance calculation, about 45% of samples were collected inaccurately, which is one of the main drawbacks of this technique. Thus, we evaluated the performance of five different eGFR equations in comparison with the ^{99m}Tc-DTPA scan as a gold standard. Our data indicated that BSA-adjusted FAS and CKD-EPI were the most correlated equations with mGFR, although the correlation was weak. This finding was in line with the results of Gaillard *et al.*, who found a better diagnostic performance of these two equations.[13] However, this weak correlation made us evaluate the performance of the equations in identifying donors with mGFR less than 80 cc/min/ 1.73 m^2, which is the threshold of exclusion from donation

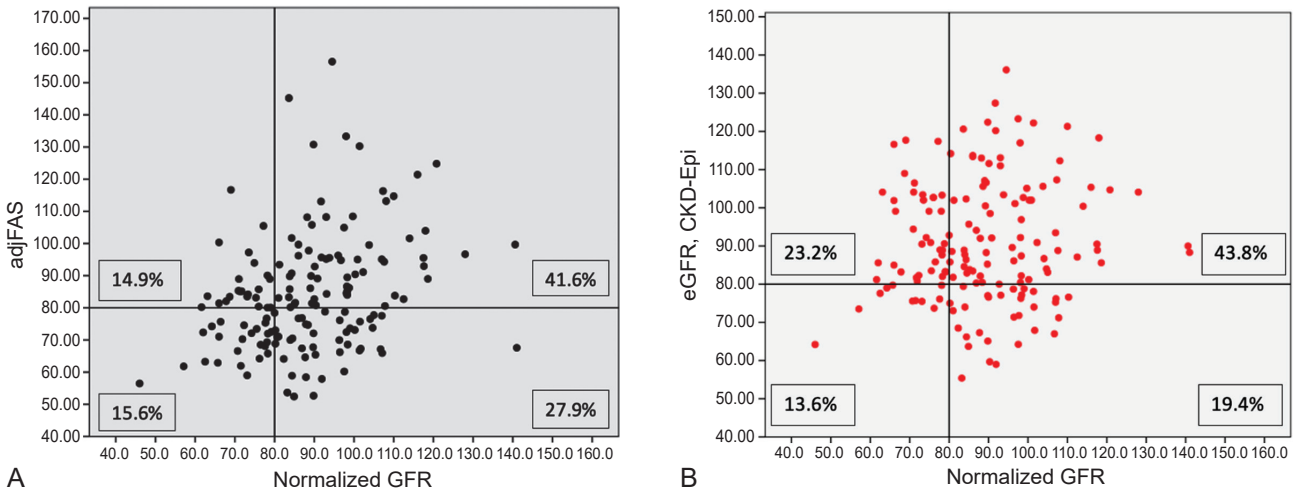

Figure 3. The percentage of misclassification of GFR at 80 mL/min per 1.73 m^2, both CKD-EPI (A) and FAS (B)

in our center. Both equations overestimated eGFR, leading to the misclassification of potential donors with mGFR less than 80 mL/min per 1.73 m^2 to higher GFR category in 14.9% and 23.2% of cases with the means of FAS and CKD-EPI equations, respectively. Thus, using these equations as the only mean of evaluating a potential donor may lead to inappropriate donor selection. Gaillard *et al.* suggested using age adapted threshold to reduce misclassification in situations where mGFR is not available; however, this did not apply to our cohort, as our candidates were younger, mostly between 20 to 40 years and only 3.2% of them were older than 40 years compared to 80.5% in the mentioned study.[13] In a meta-analysis of 12 studies, Pottel *et al.*, also demonstrated that mGFR in adults between 20 to 40 years of age is closest to the FAS equation in healthy donation candidates.[14]

We evaluated the effects of demographic characteristics on eGFR, both BMI and gender influence the relationship between eGFR and mGFR. Thus, eGFR should be interpreted with caution in obese and male candidates, yet this might need confirmation in future studies.

The importance of the functional difference between kidneys, as an index to decide which kidney should be donated, is a matter of debate. Nearly, 17% of our cohort with eGFR greater than 80 mL/min per 1.73 m^2 had a difference in SRF. Follow-up evaluation of donor and recipient renal function was out of the scope of our study; however, Seo *et al.*, reported no difference in graft function in recipients along with lower GFR post-donation among donors donating kidneys with high SRF.[15] Furthermore, Harper *et al.*, assessed SRF based on computed tomography (CT) and nuclear renography, and could not introduce CT scan as an alternative to nuclear renography, and recommended to use renography in all cases to choose kidneys with lower function for donation.[12] KDIGO clinical guideline for living donors suggested measuring GFR in situations where precise GFR values are needed and split renal function assessment in those with asymmetry in kidney size.[5] Keeping in mind the young age of our cohort and the long life ahead of them, we recommended calculating SRF among all potential donors to avoid nephrectomy of the kidney with higher GFR.

As the complexity, cost, and unavailability of ^{99m}Tc-DTPA scan might be troublesome in some transplant centers, a web-based application has been developed to calculate the posttest probability of mGFR less than 90 mL/min per 1.73 m^2. Accordingly, potential donors with more than 2% posttest probability of having mGFR less than 90 mL/min per 1.73 m^2 should be evaluated with a nuclear renal scan.[7,8] We calculated the posttest probability of candidates with creatinine-based formula as the cystatin-c test was not available. In 57% of our cohort population, the posttest probability was more than 2%, which made them suitable for GFR measurement. Interestingly, the web-based application uses the CKD-EPI equation to calculate eGFR, and how this could affect the applicability of the application, needs further evaluation.

CONCLUSION

Overall, based on our findings, we suggest evaluation of renal function in donors according to the availability of a nuclear scan and considering the donors' characteristics. In centers where a nuclear scan is easily available, we suggest measuring GFR by ^{99m}Tc -DTPA scan as the preferred method. Otherwise, our data suggest utilizing mGFR in patients with high body mass index, size asymmetry in CT-scan or eGFR less than 90 ml/min per 1.73m^2 with FAS and/or CKD-EPI equation as these factors deviated the estimated GFR, and also in those with inaccurate creatinine clearance measurements or with posttest probability of having mGFR less than 90 ml/min per 1.73m^2 more than 2%.

LIMITATIONS

Limitations of our study include a small sample size, single-center design, and a lack of post-donation GFR follow-up of donors. The strength of our study is the evaluation of various eGFR equations in the Iranian population of healthy young potential donors. In conclusion, mGFR with ^{99m}Tc -DTPA scan might be the preferred assay in living donors and is suggested to be used as the main tool in the evaluation of candidates. A larger prospective study with long post-donation kidney function monitoring is required.

AUTHOR CONTRIBUTIONS

S. S. supervised the findings of this work and took the lead in writing the manuscript. H. M.

and S.H. carried out the project and wrote the manuscript. A. A. conceived the original idea. M.N. supervised the project. A.F. and N.D. contributed to write the final version of the manuscript. F. P. and F.S. contributed to sample preparation. A. K. contributed to the interpretation of the results and provided critical feedback and support the research design, analysis, and manuscript drafts.

STATEMENTS AND DECLARATIONS

The authors declared no competing interests.

ABBREVIATIONS

^{99m}Tc-DTPA: Diethylenetriaminepentaacetic Acid
BMI: Body Mass Index
BSA: Body Surface Area
CG: Cockcroft- Glaut
CKD-EPI: Chronic Kidney Disease Epidemiology Collaboration
eGFR: Estimated GFR
ESKD: End Stage Kidney Disease
FAS: full Age Spectrum
GFR: Glomerular Filtration Rate
LBW: Lean Body Weight
mGFR: Measured GFR
MDRD-4: Modification of Diet in Renal Disease -4
MDRD-6: Modification of Diet in Renal Disease -6
ROI: Region of Interest
SRF: Split Renal Function

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