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Identify the Accuracy of eGFR Equation for Predicting Glomerular Filtration Rate in Potential Living Kidney Donors.

Tajammul waqar, Sidra German, Sajid Bhatti

Department of Nephrology
SIUT, Karachi, Pakistan.

Abstract:

Objective: To determine the accuracy of estimated glomerular filtration rate (eGFR) equation for predicting GFR in potential kidney donors by taken 24 hours urine creatinine clearance as benchmark.

Methods: This Descriptive Cross-Sectional Study, involving 201 patients, conducted at Sindh Institute of Urology and Transplantation (SIUT) Karachi, Pakistan after approval from institute research board. The duration of the study spanned six months, commencing from June 18, 2020, to December 19, 2020. All patients meeting the predetermined inclusion criteria and visiting SIUT, Karachi, were eligible for inclusion in the study. Informed consent was obtained from each participant after a comprehensive explanation of the study's procedures, associated risks, and potential benefits. The estimated Glomerular Filtration Rate (eGFR) was calculated using the appropriate equation. Participants were instructed to collect their urine over a 24-hour period in a container devoid of any additives or preservatives. The collected urine specimens were subsequently sent to the institutional laboratory for analysis, with GFR determined based on 24-hour urine creatinine clearance to ensure accuracy. All data collected during the study period were meticulously entered into a predefined proforma, which was then electronically stored and utilized for research purposes.

Results: Mean ± SD of age was 33.30±9.12 years. Out of 201 patients, 124 (61.7%) were male while 77 (38.3%) were female. In distribution of accuracy of eGFR by CKD-EPI equation, accuracy of (Cr-Cys) equation was noted as 60 (29.9%), (Cys) as 47 (23.4%) while accuracy of CKD- EPI (PK) equation was documented as 96 (47.8%).

Conclusion: It is to be concluded that accuracy of CKD-EPI is closer to 24 -h urinary creatinine clearance in the calculation of eGFR. However, none of the eGFR formulas can be used in renal transplant donors because of their low accuracy, and 24-h urine creatinine clearance should be used for evaluation of the GFR in this population.

Keywords: Estimated Glomerular Filtration Rate, Kidney Donors, Urine Creatinine, Renal Function, Risk Assessment, End Stage Renal Disease, Chronic Kidney Disease

Corresponding Author:

Tajammul Waqar,
Dept of Nephrology,
SIUT, Karachi. Pakistan
Email: tajammulwaqar@yahoo.com

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Introduction:

Chronic kidney disease (CKD) is a well-known global public health challenge. Since 2005 till 2015, mortality by CKD faced a percentage increase of 31.7 % attributing to 1.1 million deaths worldwide in 2015, hence becoming the 12thmost common cause of death worldwide [1]. The glomerular filtration rate (GFR) is widely accepted as the gold standard indicator to assess kidney function in both states of health and disease. GFR is equal to the sum of the filtration rates in all functioning nephrons. Measurement of GFR can be done by using urinary clearance of exogenous filtration markers like Insulin and Iothalamate, but in routine clinical practice this is burdensome [2]. Thus, GFR estimating equations using endogenous filtration markers like serum creatinine, urea and cystatin C are developed and are recommended in routine clinical practice.

Assessment of estimated GFR (eGFR) for decades has been based on serum creatinine concentration, as it is

widely available and inexpensive. However, its levels are affected by age, sex, muscle mass, diet, race tubular secretion and drug [3]. Cystatin C is an alternative filtration marker for estimating GFR. It is non-glycosylated protein synthesized and secreted by all nuclear cells at constant rate and it is freely filtered by the glomerulus. Cystatin C concentration is influenced mainly by inflammation, obesity, thyroid function, smoking, steroid therapy, HIV and less influenced by age, sex, muscle mass or diet [4,5]. The 2012 Kidney disease Improving Global Outcomes (KDIGO) guidelines recommend use of Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation for the purpose of screening, diagnosis and follow-up of CKD [6]. Recently, CKD-EPI developed eGFR equations based on standardized serum cystatin C (CKD-EPIcys) and standardized serum creatinine plus standardized serum cystatin C (CKD-EPIcr-cys) to minimize ethnic variations due to muscle mass and diet [7]. But to what extent, these equations are accurate in context of Pakistani ethnicity has not been studied separately. A study reported among participants with eGFRCKD- EPI(PK) ≥ 90 mL/min/1.73 m^2, performance of the CKD-EPIPK equation better than the CKD-EPI equation itself (P30, 86.6% [95% CI, 82.5% – 90.6%] vs 77.9% [95% CI, 73.7% – 82.2%], respectively [8]. GFRcr values of 75 mL/min per 1.73 m^2 and eGFRcys values of 80 mL/min per 1.73 m^2, giving post-test probability of eGFR of ≥90 mL/min per 1.73 m^2 of 49% and 54%, respectively [9]. All clearance measurement methods are difficult and time consuming and incur additional cost, and they may be less reliable in routine care than is seen in standardized settings [10]. GFR estimated from serum creatinine (eGFRcr) can be easily calculated, and eGFRcr is commonly used in settings other than donor evaluations to make clinical decisions [11].

In most developed countries, GFR in living kidney donors is usually measured by plasma clearance of exogenous chemicals (lothalamte, loxehol, Inulin) which are excreted by kidneys. However, these chemicals are not available in Pakistan and 24-hour urinary creatinine clearance is still used as the final test for assessment of GFR among kidney donors. Urine collection of 24 hours is cumbersome and predisposed to errors. EGFR equations may be helpful in borderline cases especially the new equation using serum Cystatin C but these eGFR equations are established and well-studied in western population. The accuracy of these newer eGFR equations has not been studied among kidney donors of our population. This study is conducted to measure the accuracy of eGFR equations in living kidney donors of Pakistan. As Pakistani population has different muscle mass and dietary habits so the validity of these eGFR equations is questionable in our population. So, this study will provide the concreate facts and figures regarding accuracy of eGFR equations to represent true GFR in Pakistani population.

Patients and Methods:

This Descriptive Cross-Sectional Study, involving 201 patients, conducted at Sindh Institute of Urology and Transplantation (SIUT) Karachi, Pakistan after approval from institute research board. The duration of the study spanned six months, commencing from June 18, 2020, to December 19, 2020. Patients were selected using Non-Probability, Consecutive Sampling.

Inclusion Criteria:

- Potential kidney donors aged between 18 to 50 years.
- Participants of any gender.
- Body Mass Index (BMI) less than 35 kg/m^2.
- Estimated Glomerular Filtration Rate (eGFR) equal to or greater than 90 mL/min/1.73 m^2.

Exclusion Criteria:

- Individuals with a history of primary renal or systemic diseases known to affect the kidneys.
- History of chronic illnesses such as diabetes mellitus, hypertension, chronic liver, or kidney disease.
- Pregnant women, confirmed through Last Menstrual Period (LMP).
- History of proteinuria, renal stone disease, or any genitourinary malformation or malfunction.
- Those unable to provide accurate timed urine collection.
- Participants who did not consent to be part of the study.

Data Collection Procedure:

Data collection was started after approval of proposal from institute research board (IRB). All participants who fulfilled the inclusion criteria were included in the study. Informed consent was taken after explaining the procedure, risks and benefits of the study. BMI was calculated by taken weight in kilograms by the squared height in meters. Weight in (kg) was measured on a standard weighing scale to the nearest of 0.1 kg. Standing height of the subjects was measured with standard method to the nearest of 0.1 cm at the time of presentation. Estimated GFR was calculated by eGFR equation by researcher himself under the supervision of consultant > 5 years of experience. Every study participant was instructed to collect 24 hours urine in a container (provided by institution) without any additive / preservative. The collected urine was sent to institutional lab and the GFR based on 24 hours urine creatinine clearance to assess efficacy. The collected data was entered into the proforma attached at the end and used electronically for research purpose.

Data Analysis:

Data was entered and analysed on SPSS (Statistical Package for the Social Sciences) version 21.0. Mean and standard deviation were calculated for age, weight, height, BMI, serum creatinine, and 24 hours urinary creatinine clearance. Frequencies and percentages were calculated for gender and accuracy. Stratification was done with regards to age, gender and BMI to see the effect of these on outcome. Chi-square / Fisher's Exact test was applied to see the significant difference in these strata. Considered two-sided $P \leq 0.05$ as significant.

Results:

In this study, we examined 201 potential kidney donors to evaluate the accuracy of estimated glomerular filtration rate (eGFR) equations in predicting GFR, using 24-hour urine creatinine clearance as the benchmark. The mean age of the participants was 33.30 years with a standard deviation of 9.12. The mean weight was 64.36 kg (SD 12.56), while the mean height was 159.75 cm (SD 13.94). The average body mass index (BMI) was 25.36 kg/m2 (SD 4.54). Serum creatinine levels averaged at 0.775 mg/dl (SD 0.163), and 24-hour urinary creatinine clearance was 107.72 ml/min (SD 19.36). Additionally, the mean eGFR values by CKD-EPI equations were 113.15 ml/min (CR-CYS), 110.3 ml/min (CYS), and 103.13 ml/min (PK). (Table # 1)

Table 1: Baseline characteristics of 201 potential living related donors.

Variable	Mean	Std. Deviation	Min	Max
Age (Years)	33.30	9.12	19	56
Weight (kg)	64.36	12.56	39.00	102.00
Height (cm)	159.75	13.94	138.0	265.00
BMI (kg/m²)	25.36	4.54	16.20	36.10
Serum Creatinine (mg/dl)	0.77	0.16	0.35	1.19
24-hour Urinary Creatinine Clearance (ml/min)	107.72	19.36	67	183
Serum Cystatin C (mg/dl)	0.79	0.12	0.53	1.09
eGFR by CKD-EPI (CR-CYS) Equation (ml/min)	113.15	14.20	78.80	145.40
eGFR by CKD-EPI (CYS) Equation (ml/min)	110.33	15.30	75.50	139.40
eGFR by CKD-EPI (PK) Equation (ml/min)	103.13	12.86	61.97	133.70

Regarding gender distribution, 124 participants (61.7%) were male, while 77 (38.3%) were female.

The accuracy of eGFR varied among different equations, with 60 participants (29.9%) accurately predicted by the CKD-EPI (CR-CYS) equation, 47 (23.4%) by the CKD-EPI (CYS) equation, and 96 (47.8%) by the CKD-EPI (PK) equation. (Table # 2)

Furthermore, we stratified the participants based on age group, BMI, and gender to assess the significance of these factors in predicting eGFR accuracy using CKD-EPI equations (CR-CYS, CYS, PK). The results of these stratifications are detailed in Tables # 3-5, highlighting any significant differences observed across the subgroups.

Table 2: FREQUENCY FOR ACCURACY OF eGFR BY CKD-EPIEQUATION (n=201)

ACCURACY		FREQUENCY	PERCENTAGE
CKD-EPI (Cr-Cys)	Yes	60	29.9%
	No	141	70.1%
CKD-EPI (Cys)	Yes	47	23.4%
	No	154	76.6%
CKD-EPI (Pk)	Yes	96	47.8%
	No	105	52.2%

Overall, our findings provide valuable insights into the accuracy of eGFR equations and the influence of demographic factors on their predictive capabilities in potential kidney donors.

TABLE 3: STRATIFICATION FOR AGE GROUP WITH ACCURACY OF EGFR BY CKD-EPI EQUATION (n=201)

ACCURACY		AGE GROUP [In years]		P-VALUE
		18 - 30	>30	
CR-CYS	Yes	17 (8.5%)	43 (21.4%)	0.007
	No	69 (34.3%)	72 (35.8%)	
CYS	Yes	21 (10.4%)	26 (12.9%)	0.764
	No	65 (32.3%)	89 (44.3%)	
PK	Yes	49 (24.4%)	47 (23.4%)	0.024
	No	37 (18.4%)	68 (33.8%)	

Discussion:

Living donor kidney transplantation provides the best outcomes for patients with ESRD [12,13]. Traditionally, kidney donation was considered safe with a relatively low early surgical risk (0.03% mortality and less than 1% risk of major morbidity) [14] and without increased long-term risks compared to the general population [15-17]. However, recent studies incorporating comparisons to healthy non donors' outcomes suggest low, but increased, risks of ESRD and other medical conditions in donors over intermediate-term follow-up [18,19]. These data have led to a need for reconsideration of how donor candidates are evaluated and selected for donation [20]. In August 2017, Kidney Disease: Improving Global Outcomes (KDIGO) published a comprehensive clinical practice guideline for evaluation of living kidney donor candidates [21,22]. Glomerular filtration rate (GFR), defined as the volume of fluid filtered by the kidney glomeruli into the Bowman's spaces per unit time, is the best assessment of overall kidney

function. Assessment of GFR is a critical component of the donor candidate evaluation and is used to detect the presence of kidney disease and aid the prediction of long-term kidney failure risk.

TABLE 4: Stratification for body mass index with accuracy of egfr by ckd-epi equatioN (n=201)

ACCURACY		BMI [In kg/m^2]		P-VALUE
		16 – 24	>24	
CR-CYS	Yes	15 (7.5%)	45 (22.4%)	0.003
	No	67 (33.3%)	74 (36.8%)	
CYS	Yes	18 (9.0%)	29 (14.4%)	0.691
	No	64 (31.8%)	90 (44.8%)	
PK	Yes	49 (24.64%)	47 (23.4%)	0.005
	No	33 (16.4%)	72 (35.8%)	

TABLE 5: Stratification for gender with accuracy of eGFR by CKD-EPI equation (n=201)

ACCURACY		GENDER		P-VALUE
		Male	Female	
CR-CYS	Yes	33 (16.4%)	27 (13.4%)	0.203
	No	91 (45.3%)	50 (24.9%)	
CYS	Yes	28 (13.9%)	19 (9.5%)	0.733
	No	96 (47.8%)	58 (28.9%)	
PK	Yes	64 (31.8%)	32 (15.9%)	0.165
	No	60 (29.9%)	45 (22.4%)	

GFR is considered as the best overall measure of kidney function because the degree of GFR reduction is closely correlated with alterations in kidney structure and with complications related to CKD. In the general population as well as in patients with CKD, decreased GFR is associated with a higher risk of kidney failure, cardiovascular disease, and death [23,24]. In adults younger than age 40 years, the normal range of GFR in men is 100-130 mL/min per 1.73 m2 and slightly lower in women (90 mL/min per1.73 m2 to 120 mL/min per1.73 m2) [25]. After age 40 years, there is a progressive decline in GFR of approximately 6-8 mL/min per 1.73 m2 with each decade of aging [26]. AGFR of 90 mL/min per 1.73 m2 or greater is considered "normal," while a GFR,60 mL/min per 1.73 m2 is considered low in adults of any age. Controversy exists in differentiating disease from normal variation when GFR is in the 60 to 89 mL/min/1.73 m2 range, especially in persons over the age of 40 years and without significant proteinuria [25,27].

GFR can be estimated from serum levels of endogenous filtration markers (substances originating or synthesized within the human body and freely filtered at the glomerulus). This process is easier and less expensive compared to measurement of GFR. However, the serum levels of endogenous filtration markers are determined not only by the level of GFR, but also by non-GFR determinants (generation, kidney tubular secretion and re-absorption, and extra renal elimination). These physiological processes are generally not measured, so estimating equations use easily measured clinical variables as surrogates for these non-GFR determinants. The equations provide more accurate estimates of GFR than serum levels alone, but estimated GFR (eGFR) captures only the average relationship of the surrogates to the unmeasured physiological processes of the population used in the development of the equation, a potential source of error when the equations are applied outside the development population [28].
The most commonly used endogenous filtration marker for GFR estimation is serum creatinine. Creatinine based GFR estimating equations include age, sex, and race or weight as surrogates for creatinine generation from muscle mass or diet [29]. People with extremes of muscle mass and dietary meat intake, who are malnourished or have a reduction in muscle mass from illness or amputation, are likely to have large differences between measured and estimated GFRcr. Cystatin C is an alternative endogenous filtration marker that is less influenced by muscle and diet than creatinine, although other factors (e.g., diabetes and inflammation) impact its levels [30,31]. eGFR based on cystatin C (eGFRcys) is not more accurate than eGFRcr, but eGFR based on both markers (eGFRcr-cys) is more precise than either alone [32,33]. The findings of our study are comparable with multiple studies conducted worldwide. The mean age in our study was 33.30±9.12 years. Tent H, et al found a mean age of 49.5±10.5 years [34]. Another study noted age as 44.1 years [35]. Ehrich J, et al noted as 32 ±23 years [36]. Kakuta Y, et al reported mean age as 57.6±10.6 years [37]. Gaillard F, et al reported as 50.6±11.8 years [38]. Tsai SF, et al found age as 46.3±12.5 years [39].

The mean weight was 64.36±12.56 kg. Kakuta Y, et al reported weight as 57.9±10.7 kg [37]. Gaillard F, et al noted weight as 71.0±14.1 kg [38]. The mean height was 159.75±13.94 cm. Kakuta Y, et al stated height as 159.5±9.1 cm [37]. The study of Gaillard F, et al also noted height as 167.4±9.0 cm [38]. The mean body mass index was 25.36±4.54 kg/m2. Tent H, et al further noted body mass index as 26±4 kg/m2 [34]. Bhuvanakrishna T, et al noted BMI as 25.8 kg/m2 [35]. The study of Kakuta Y, et al
found body mass index as 22.7±3.0 kg/m2 [37]. Gaillard F, et al also noted BMI as 25.3±4.1 kg/m2 [38]. In this study mean serum creatinine was 0.775±0.163 mg/dl. The mean 24 hours urinary creatinine clearance was 107.72±19.36 ml/min. The mean serum creatinine was 0.795±0.123 mg/dl. The mean eGFR by CKD-EPI(CR-CYS) equation was 113.15±14.20 ml/min. The mean eGFR by CKD-EPI(CYS) equation was 110.3±15.30 ml/min. The mean eGFR by CKD-EPI(PK) equation was 103.13±12.86 ml/min. Out of 201 patients, 124 (61.7%) were male while 77 (38.3%) were female. Jessani S, et al noted to have 50% male patients [38]. Gaillard F, et al reported to have 38% men and 62% women [38]. Tsai SF, et al also reported to have 45 (42.85%) males and 60 (57.15%) females [39]. Ehrich J, et al further noted to have 53% males and 47% females [40].
In distribution of accuracy of eGFR by CKD-EPI equation, accuracy of (Cr-Cys) equation was found in 60 (29.9%) patients, (Cys) in 47 (23.4%) while accuracy of (PK) equation was noted in 96 (47.8%) patients. While one study has found that accuracy of (Cr-Cys) equation is 11.3% [41], another study found the accuracy of (Cr-Cys) equation as 9.8% and accuracy of (Cys) as 11.7% [42]. In recent study, stratification of confounders / effect modifiers with respect to accuracy of eGFR by CKD-EPI equation, insignificant difference was noted in age group [CR-CYS] as P=0.007 and age group [CYS] as P=0.764 whereas significant difference as documented in age group [PK] as P=0.024.

In this study, stratification of confounders / effect modifiers with respect to accuracy of eGFR by CKD-EPI equation, significant difference was noted in BMI group [CR-CYS] as P=0.003 and age group [PK] as P=0.005 whereas insignificant difference as documented in age group [CYS] as P=0.691.

In our study, stratification of confounders / effect modifiers with respect to accuracy of eGFR by CKD-EPI equation, insignificant difference was noted in gender group [CR-CYS] as P=0.203, gender group [CYS] as P=0.733 ad gender group [PK] as P=0.165.

Conclusion:

It is to be concluded that accuracy of CKD-EPI is closer to 24 -h urinary creatinine clearance in the calculation of eGFR. However, none of the eGFR formulas can be used in renal transplant donors because of their low accuracy, and 24-h urine creatinine clearance should be used for evaluation of the GFR in this population. As the study was applied only on small sample of single hospital, so results may not reflect the scenario countrywide, and needs to be evaluated further in a larger group of patients at different hospital of the country to generalize the findings of our study.

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