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Superiority of the Modification of Diet in Renal Disease Equation Over the Cockcroft-Gault Equation in Screening for Impaired Kidney Function in Japanese Americans

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Abstract

The Cockcroft-Gault and the Modification of Diet in Renal Disease (MDRD) Study equations have not been validated in Asian Americans with varying degrees of glucose tolerance. We compared both equations to 24 hour urinary creatinine clearance, the latter as a standard measurement of glomerular filtration rate (GFR), in 398 Japanese Americans (62.1±5.8y, mean±SD) who had normal glucose tolerance (n=138), impaired glucose tolerance (n=136) and diabetes (n=124). Although both the Cockcroft-Gault (r=0.65, P<0.001) and the MDRD (r=0.74, P<0.001) equations correlated well with creatinine clearance, the latter was significantly superior (P=0.013 between r values). ROC curve analysis showed that the area under the curve (AUC) for the MDRD equation was significantly greater than for the Cockcroft-Gault equation (AUC 0.86 vs. 0.80, P=0.015) in classifying subjects as having mildly reduced GFR (<90 ml/min per 1.73 m^2). However, both equations overestimated the number of individuals with decreased GFR. We conclude therefore that while the MDRD equation more accurately identifies Asians who are in the early stages of kidney disease, as for other groups, a correction term appears necessary in order to reduce the number of Asian subjects being falsely diagnosed with CKD.

Keywords

MDRD; Cockcroft-Gault; creatinine clearance; glomerular filtration rate; diabetes

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Introduction

Asians are a fast growing population in the United States representing 12.4 million (4.3% of the U.S. population in 2005) [1]. Despite having a lower average body mass index (BMI) than do Caucasians, they are at increased risk of developing diabetes and have a high prevalence of hypertension, probably because of their greater central adiposity [2-5]. Asians are also at risk for chronic kidney disease (CKD), a significant public health problem that results not only in renal failure but also in increased cardiovascular mortality [6,7].

Most affected subjects with CKD are detected in the early stages of the disease, when renal function is only mildly decreased [6,8]. Since adverse outcomes may be prevented or delayed during these early stages, it is imperative to have a reliable and simple way to screen subjects who are at risk. As a result, the National Kidney Foundation recommends estimation of the glomerular filtration rate (GFR) in all persons at increased risk of developing CKD, such as those with hypertension or diabetes [6].

The most precise method for measuring GFR is inulin clearance, but this is impractical in clinical practice [6]. Thus, the direct estimation of GFR often relies upon a 24-hour urine collection and measurement of serum and urine creatinine to calculate creatinine clearance [9]. However, this method is not useful when rapid therapeutic decisions regarding the use of potentially toxic drugs are required [9] and is too cumbersome for mass screening of at-risk populations. Consequently, several equations have been developed to estimate GFR using a combination of serum creatinine and clinical characteristics such as age, gender and body weight [10]. The Cockcroft-Gault equation, routinely used to estimate GFR in clinical practice, was validated in a sample of only 236 patients, of whom 96% were males and the majority of whom were hospital in-patients [9]. Recently, the Modification of Diet in Renal Disease (MDRD) Study equation was developed and validated in a population consisting of Caucasians and African Americans [10]. However, to make it applicable to different racial/ethnic groups, it was modified by the insertion of a correction factor. Compared to the direct estimation of GFR, the MDRD equation was better than the Cockcroft-Gault equation at predicting GFR in subjects with CKD and renal failure with or without diabetes [10-12]. The National Kidney Foundation recommends a simplified and thus abbreviated form of this equation for estimating GFR [6].

The applicability of these equations in Asians, who generally have a smaller body habitus and consequently, different creatinine metabolism than other ethnic groups is unclear [13-16]. In addition, the utility of the MDRD equation in individuals with normal renal function, diabetic nephropathy or who may vary in glucose tolerance status is still controversial [12,17,18]. Therefore, we compared the estimates derived using the Cockcroft-Gault and the MDRD equations to creatinine clearance measured from a 24-hour urinary collection in a cohort of Japanese Americans who had normal glucose tolerance (NGT), impaired glucose tolerance (IGT) and diabetes mellitus.

Materials and Methods

Subjects

The study comprised 398-second generation (Nisei) Japanese-American men (n=220) and women (n=178) who participated in the Japanese American Community Diabetes Study, 138 of whom had NGT, 136 IGT, and 124 diabetes. These 398 subjects had complete data available for this analysis and thus represent a subset of the 420 Nisei individuals in the parent study [4]. The study was approved by the University of Washington Human Subjects Review Committee, and all participants provided written informed consent.

Study Procedures and Assays

Standing height (m) and weight (kg) were measured in shoeless subjects wearing light clothing and were used to calculate BMI and body surface area (BSA) [19]. Supine blood pressure was measured three times using a mercury manometer, and the average of the last two measurements was used for analysis. Hypertension was diagnosed if the average systolic blood pressure was ≥140 mmHg, the average diastolic blood pressure was ≥ 90 mmHg, or the participant was taking anti-hypertensive medications.

A standard 75 g oral glucose tolerance test was performed in the morning after a 10-hour overnight fast. Blood samples for measurement of glucose were drawn prior to and 120 minutes after glucose ingestion. A baseline blood sample was also drawn for serum creatinine measurement. Participants were instructed on how to collect a timed 24-hour urinary sample, and were considered as having adhered to the collection procedure if their 24-hour creatinine excretion was 14 to 26 mg/kg for men or 11 to 20 mg/kg for women [20].

Plasma glucose was assayed by an automated glucose oxidase method. Serum and urinary creatinine levels were measured by the automated picric acid method.

Classification of Glucose Tolerance

Using fasting and 2-hour plasma glucose [2-h PG] concentrations, subjects were categorized as having normal glucose tolerance (NGT: fasting plasma glucose [FPG] <7.0 mmol/l and 2-h PG <7.8 mmol/l); impaired glucose tolerance (IGT: FPG <7.0 mmol/l and 2-h PG 7.8-11.0 mmol/l); or diabetes (FPG ≥ 7.0 mmol/l and/or 2-h PG ≥ 11.1 mmol/l). Diabetes was also diagnosed in subjects who reported the use of insulin or oral hypoglycemic medication as prescribed by a physician.

Equations for Estimating Renal Function

The following equations were used to determine creatinine clearance and estimate GFR.

1. Creatinine clearance (ml/min per 1.73 m^2 of BSA):

   Urinary creatinine (mg/dl) × 1440 / serum creatinine (mg/dl) × volume (ml/min) × BSA/1.73 Values of creatinine clearance were adjusted to standard BSA of 1.73 m^2 by multiplying by BSA/1.73 [19]. This adjustment permits a more adequate comparison with the MDRD equation which is already adjusted for BSA [6,9].

2. Cockcroft-Gault (ml/min):

   (140 - age) × weight / 72 × serum creatinine × (0.85 if female)

   The Cockcroft-Gault equation was not adjusted further for BSA in order to prevent double correction as body weight is already accounted for in this equation.

3. Abbreviated MDRD equation (ml/min per 1.73 m^2 of BSA):

   $186 \times (\text{serum creatinine})^{-1.154} \times (\text{age})^{-0.203} \times (0.742 \text{ if female})$

   This equation was not further corrected for BSA as the equation provides a value relative to BSA.

Data Analysis and Statistical Methods

Data are presented as mean ± standard deviation (SD) unless otherwise specified. ANOVA, followed by LSD test, Kruskal-Wallis test or the $\chi 2$ test were used as appropriate. Correlations were performed with the Spearman's rank correlation test. Comparisons between two correlation coefficients from independent samples were tested using a Fisher *z* transformation

[21]. Effect modification was assessed with standard methods involving testing the significance of first-order interaction terms in regression models. Sensitivity and specificity of the MDRD and Cockcroft-Gault equations in correctly classifying CKD stage 2 (GFR <90 ml/min per 1.73 m^2 of BSA) and stage 3 (GFR <60 ml/min per 1.73 m^2 of BSA) were based upon the cut points established by the National Kidney Foundation (1) and were calculated using the Receiver Operating Characteristic (ROC) Curve approach [6,22]. A P<0.05 was considered significant.

Results

Subject Characteristics

Table 1 lists the clinical and laboratory characteristics of all subjects as well as by glucose tolerance category. Amongst these individuals, 34.7% had NGT, 34.2% had IGT and 31.2% had diabetes. Subjects with diabetes were more obese and also tended to be of greater body size as determined by BSA. By definition they had a higher fasting glucose level than subjects with NGT and IGT, and as expected 2-hour glucose levels differed among glucose tolerance groups. The prevalence of hypertension increased with deteriorating glucose tolerance and subjects with diabetes had significantly higher systolic blood pressure levels compared with those with NGT and IGT. Diastolic blood pressure was higher in subjects with diabetes compared with those with NGT, but was not different from those with IGT. Serum creatinine, urinary creatinine excretion, creatinine clearance and GFR estimated using the Cockcroft-Gault and the MDRD equations did not differ between glucose tolerance groups (Table 1).

Prediction of GFR in All Subjects

The correlation with creatinine clearance was lower for the Cockcroft-Gault equation than for the MDRD equation (r=0.65, P<0.001 vs. r=0.74, P<0.001), with the difference between these correlation coefficients being significant (P=0.013, Figure 1A). The potential for effect modification by glucose tolerance on the association between creatinine clearance and the Cockcroft-Gault and MDRD equations was tested by insertion of an interaction term (glucose tolerance status * Cockcroft-Gault equation or glucose tolerance status * MDRD equation) in the regression models. There was no significant interaction between glucose tolerance status and the Cockcroft-Gault equation for IGT (β=0.03, P=0.760) or diabetes (β=0.08, P=0.447) and the MDRD equation for IGT (β=0.20, P=0.056) or diabetes (β=0.12, P=0.216).

Diagnostic Accuracy of Cockcroft-Gault and MDRD Equations in All Subjects

Considering creatinine clearance as the standard for estimation of GFR, the diagnostic accuracy of the Cockcroft-Gault and MDRD equations for mildly decreased GFR (GFR <90 ml/min per 1.73 m^2 of BSA) was estimated using ROC curve analysis. The diagnostic accuracy of the Cockcroft-Gault equation was lower than that of the MDRD equation (Fig. 2). This was due to poorer sensitivity (55.4% vs. 84.0%), specificity (29.6% vs. 46.2%) and correct classification (41.0% vs. 62.8%) with the Cockcroft-Gault equation compared to the MDRD equation.

As only four subjects had a creatinine clearance <60 ml/min per 1.73 m^2 of BSA, an assessment of the ability of the Cockcroft-Gault and MDRD equations to predict moderately decreased GFR could not be performed.

Table 2 lists a comparison of the number of subjects determined to have normal, mildly decreased and moderately decreased GFR based on the National Kidney Foundation classification using creatinine clearance and the Cockcroft-Gault and MDRD equations. Two hundred and nineteen subjects had a normal GFR based on the creatinine clearance but this was underestimated by 115 subjects with the MDRD equation and by 171 individuals with the Cockcroft-Gault equation. When considering mildly and moderately decreased GFR, both equations overestimated the number of individuals with these degrees of decreased GFR, with the Cockcroft-Gault equation performing more poorly. Thus, only four subjects had a GFR <60 ml/min per 1.73 m^2 of BSA based on creatinine clearance, yet using the Cockcroft-Gault equation 96 subjects were determined to have this degree of renal dysfunction, while with the MDRD equation 27 individuals were assessed as being this impaired.

Prediction and Diagnostic Accuracy of Cockcroft-Gault and MDRD Equations in Subjects with Differing Glucose Tolerance

The correlations between the Cockcroft-Gault estimate and creatinine clearance (Fig. 1B, C and D) were maintained across all three glucose tolerance groups (NGT: r=0.61, IGT: r=0.68, diabetes: r=0.65, P for all <0.001). Correlations between the MDRD estimate and creatinine clearance (Fig. 1B, C and D) were also maintained across the glucose tolerance groups (NGT: r=0.66, IGT: r=0.72, diabetes: r=0.82, P for all <0.001). The correlation coefficient between creatinine clearance and the MDRD equation was significantly greater than that between creatinine clearance and the Cockcroft-Gault equation for diabetes (P=0.003 between r values), but not for NGT (P=0.463 between r values) or IGT (0.482 between r values).

We also used the ROC curve analysis to calculate the accuracy of the equations for mildly decreased GFR (stage 2) for each one of the glucose tolerance categories. Using this approach, the Cockcroft-Gault and MDRD equations had similar accuracies in the different glucose tolerance categories (Table 3).

Discussion

Our results show that the MDRD equation is valid to detect mildly decreased GFR in Japanese Americans with varying degrees of glucose tolerance and is superior to the Cockcroft-Gault equation. The relationship between the MDRD equation calculated GFR and creatinine clearance is significantly better than between the Cockcroft-Gault equation and creatinine clearance. Moreover, by ROC curve analysis, the MDRD equation proved to be more accurate than the Cockcroft-Gault equation in classifying subjects as having mildly decreased GFR (CKD stage 2) with a sensitivity of 84% for the MDRD equation compared with 46.2% for the Cockcroft-Gault equation. This suggests that the former is more appropriate for screening of Japanese Americans at risk for CKD. When considering moderately decreased GFR (CKD stage 3), the number of subjects with this degree of renal impairment was too few to compare the relative accuracies of the two equations. However, it seems that the false positive rate for both equations is quite high. This discrepancy would perhaps unnecessarily increase the number of Japanese-American subjects targeted for further investigation or treated for complications associated with CKD stage 3.

The ability of these equations in predicting GFR was not different in the NGT and IGT groups. However, among those with diabetes who would be considered to be at greatest risk for renal dysfunction, the MDRD equation appeared to be better in predicting those with CKD. This conclusion is based on the finding that the correlation coefficient was significantly greater between the creatinine clearance and the MDRD equation than it was with the Cockcroft-Gault equation. However, we were not able to confirm this with the ROC curve analysis, possibly due to the relatively small number of subjects with diabetes that was analyzed limiting the power to detect a difference. Further, in our cohort of diabetic subjects, the MDRD equation underestimated GFR compared to creatinine clearance, a finding in keeping with those recently reported by Rossing et al [18]

In their study, Rossing et al [18] suggested that there may be significant limitations to the use of the MDRD and the Cockcroft-Gault equations for monitoring kidney function in subjects with diabetic nephropathy. These individuals had microalbuminuria or overt nephropathy and were followed for 5 years. In the microalbuminuric subjects both equations significantly underestimated the GFR as determined using Cr^{51}-EDTA. A similar finding was made in the macroalbuminuric group, although the degree of underestimation was less. Further, in both groups both equations underestimated the rate of decline in GFR. It should be noted that in contrast to their study, in our assessments we did not correct the Cockcroft-Gault equation for BSA as the equation already includes weight and doing this correction would have meant that we would adjust for weight twice. Further, as we did not follow our subjects over time, we have no ability to determine how the equations perform longitudinally in Japanese Americans.

Creatinine clearance can exceed GFR by 10-20% because a fraction of urinary creatinine is derived from tubular secretion. However, we do not believe this to be a serious limitation of our study as tubular secretion of creatinine is mainly an important contributor to urinary creatinine in subjects with GFR below 25 ml/min per 1.73 m^2 of BSA [17,23] and our subjects had normal or mildly decreased renal function. Furthermore, it has been demonstrated that creatinine clearance is adequate for measuring the GFR when compared to inulin clearance in subjects with normal GFR with or without type 1 diabetes [17]. In Japanese subjects, creatinine clearance is an accepted approach for measuring GFR as it has been demonstrated not only to have an excellent correlation with plasma clearance methods like $In\text{-}^{111}$ DTPA but also to be as accurate as gamma camera methods like Tc-99m DTPA scintigraphy in estimating renal function [24]. Finally, our finding of a lower estimate of GFR with the MDRD equation compared to the 24-hour creatinine clearance could be due to the fact that the equation was developed based on measurements in Caucasians and African Americans, and does not take into account disparities in body composition and lean body mass between Asians and these other groups. This difference could be important in changing serum creatinine and consequently could affect the performance of these equations. Consequently, we believe a correction factor for the MDRD equation may be needed in order that it has greater utility as a clinical tool for estimating GFR in Asians. [10,13,14,16,25].

While our analysis was limited to Japanese Americans living in the Seattle area, we believe that our finding of the utility of the MDRD equation to provide information regarding GFR will also be applicable to subjects of Japanese decent living in other parts of the world. We also believe our findings may apply to other populations of Asian decent. These populations, like Japanese Americans [3,5], are at increased risk for the development of hypertension [5], diabetes [26] and renal failure [7].

In summary, we have found that in Japanese Americans, the MDRD equation provides a better estimate of GFR than does the Cockcroft-Gault equation when compared to creatinine clearance. However, our findings also suggest that in order for the MDRD equation to be applicable in clinical practice for screening Japanese Americans and likely other Asian populations who may be at increased risk of CKD, it will need to be modified in order to reduce the number of subjects who would be diagnosed as having a reduced GFR.

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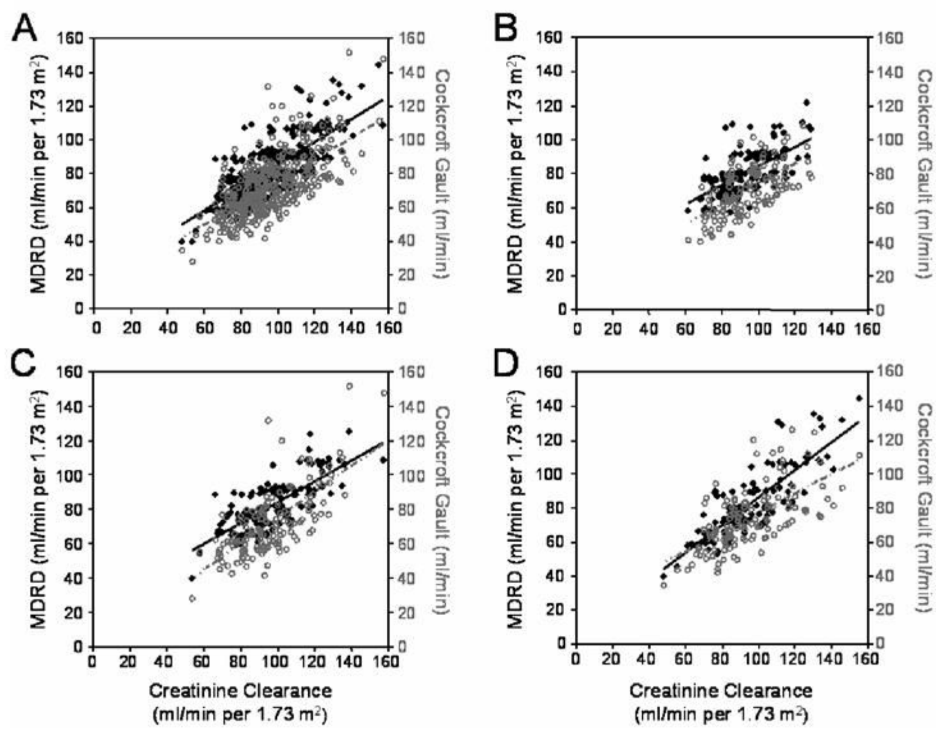

Figure 1.

Correlations between 24-hour urinary creatinine clearance with GFR estimated using the MDRD (♦; solid line) and Cockcroft-Gault (o; broken line) equations in all 398 subjects (A), and in 138 subjects with NGT (B), 136 subjects with IGT (C) and 124 subjects with diabetes (D).

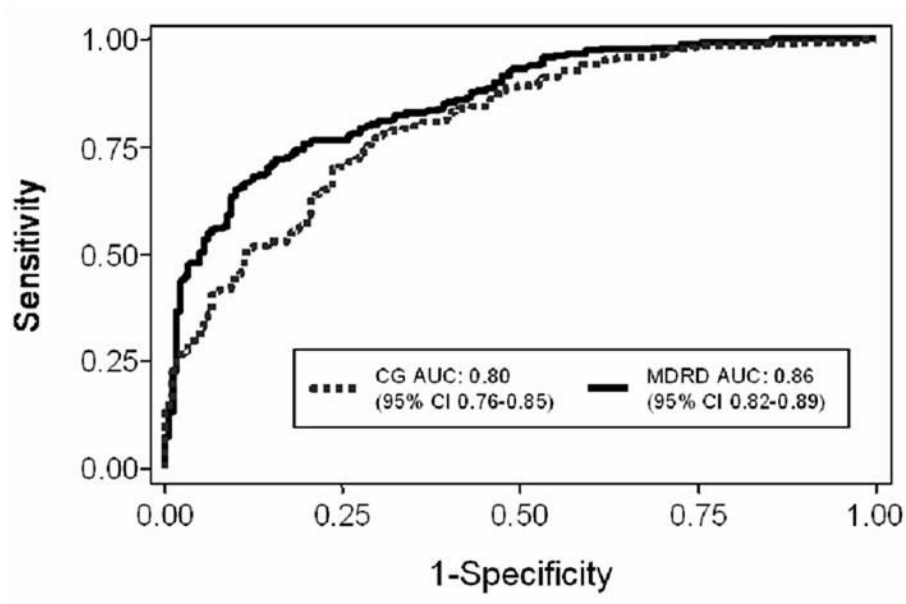

Figure 2.

ROC curve comparing area under the curve (AUC) of the Cockcroft-Gault (CG) and MDRD equations for the diagnosis of mildly decreased GFR (<90 ml/min per 1.73 m^2 of BSA). The MDRD equation was more accurate than the Cockcroft-Gault equation in determining the presence of mildly decreased GFR (P=0.015).

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Table 1

Clinical and laboratory characteristics according to glucose tolerance status

		Glucose Tolerance Status			
	All Subjects (n=398)	**NGT (n=138)**	**IGT (n=136)**	**DM (n=124)**	**P**
Female sex - n (%)	178 (44.7)	65 (47.1)	64 (47.1)	49 (39.5)	0.372
Age (years)	62.1 ± 5.8	61.9 ± 5.6	62.0 ± 6.0	62.3 ± 5.9	0.822
Body mass index (kg/m^2)	24.7 ± 3.2	24.0 ± 2.9	24.6 ± 3.4	25.4 ± 3.1	0.001
Body surface area (m^2)	1.66 ± 0.19	1.64 ± 0.17	1.64 ± 0.19	1.69 ± 0.19	0.052
Arterial hypertension – n (%)	220 (53.3)	58 (42.0)	75 (55.1)	87 (70.2)	<0.001
Systolic blood pressure (mmHg)	137.9 ± 19.2	133.6 ± 19.2	137.1 ± 18.7	143.5 ± 18.4	<0.001
Diastolic blood pressure (mmHg)	79.0 ± 9.4	77.6 ± 10.2	79.0 ± 9.2	80.7 ± 8.3	0.028
Fasting plasma glucose (mmol/l)	6.5 ± 2.5	5.3 ± 0.5	5.5 ± 0.6	8.9 ± 3.2	<0.001
2-hour plasma glucose (mmol/l)	10.9 ± 5.7	6.4 ± 1.0	9.0 ± 0.9	17.8 ± 5.4	<0.001
24-hour urinary creatinine excretion (mg/kg)	18.6 ± 3.0	18.6 ± 3.1	18.7 ± 2.9	18.4 ± 3.1	0.817
Serum creatinine (mg/dl)	0.9 [0.3]	0.9 [0.2]	0.9 [0.3]	1.0 [0.3]	0.262
Creatinine clearance (ml/min per 1.73 m^2 of BSA)	92.1 [23.0]	91.5 [21.0]	93.5 [24.0]	90.8 [26.0]	0.573
Cockcroft-Gault equation (ml/min)	69.7 [20.2]	69.6 [20.6]	67.7 [19.9]	72.1 [20.7]	0.217
MDRD equation (ml/min per 1.73 m^2 of BSA)	78.9 [18.6]	78.8 [18.0]	78.7 [19.1]	79.3 [19.8]	0.731

Data expressed as mean ± SD, or median and [IQR].

Table 2

Number of subjects classified according to National Kidney Foundation criteria for GFR based on 24 urinary creatinine clearance, MDRD and Cockcroft-Gault equations

National Kidney Foundation Classification	Creatinine clearance (n)	Cockcroft-Gault equation (n)	MDRD equation (n)
Normal GFR (≥90 ml/min per 1.73 m^2 of BSA)	219	48*	104*
Mildly decreased GFR (≥60 and <90 ml/min per 1.73 m^2 of BSA)	175	254*	267*
Moderately decreased GFR (<60 ml/min per 1.73 m^2 of BSA)	4	96*	27*

* $P \leq 0.001$ vs. creatinine clearance

Table 3

ROC curve analysis: performance of the Cockcroft-Gault and MDRD equations in detecting stage 2 chronic kidney disease in different glucose tolerance categories

	Cockcroft-Gault equation (AUC)	**MDRD equation (AUC)**	**P**
NGT	0.81 (0.74-0.89)	0.86 (0.79-0.93)	0.210
IGT	0.82 (0.74-0.90)	0.86 (0.79-0.92)	0.437
Diabetes	0.81 (0.74-0.89)	0.88 (0.82-0.94)	0.088