Abstract

Importance and current status of standardization of creatinine test for the management of kidney disease

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The kidneys are essential organs for maintaining homeostasis in the body. Decreases in renal function increase the risk of morbidity and mortality and often result in high medical expenses. Since most kidney diseases are often asymptomatic during clinical progress, tests that can evaluate the presence and extent of renal function abnormalities should be appropriately used. The best single indicator used for overall renal function evaluation is glomerular filtration rate (GFR), which cannot be measured directly, so it must be measured indirectly using exogenous substances or estimated using endogenous substances. Currently, creatinine is the most widely used substance for calculating the estimated glomerular filtration rate (eGFR).

According to the Kidney Disease: Improving Global Outcomes (KDIGO) 2012 Clinical Practice Guideline, it is recommended that eGFR be reported using the 2009 CKD-EPI creatinine equation in addition to the serum creatinine concentration in adults. The currently used creatinine test methods include those based on the traditional Jaffe reaction and the enzymatic method that measures creatinine using several enzymatic reactions. Since the diversity of creatinine measurement methods can affect the eGFR, quality control of the creatinine test and standardization between the test methods plays an important role in the accurate prediction of renal function.

International creatinine standardization programs have been established and operated in cooperation with various international organizations to reduce differences among clinical laboratories reporting creatinine and to more accurately estimate GFR. The creatinine standardization recommendations recommend that clinical laboratories should use creatinine methods that has calibration traceable to IDMS and validated IDMS-traceable equations.

The Korea Disease Control and Prevention Agency (KDCA) established the National Medical Reference Laboratory to improve the standardization of tests. To standardize creatinine tests, accuracy-based proficiency test and in-vitro diagnostic product quality assurance are implemented to evaluate the status of creatinine standardization and encourage each entity participating in the test to make efforts for standardization. In order to improve the standardization of creatinine tests in the Republic of Korea in the future, active cooperation from related professional academic organizations and support and efforts at the national level will be continuously needed.

Keywords: Creatinine, Estimated glomerular filtration rate, Standardization

Table 1. GFR categories in CKD [3]

GFR category	GFR (mL/min/1.73m^2)	Terms
G1	≥90	Normal or High
G2	60–89	Mildly decreased[a]
G3a	45–59	Mildly to moderately decreased
G3b	30–44	Moderately to severely decreased
G4	15–29	Severely decreased
G5	〈15	Kidney failure

Abbreviations: CKD, chronic kidney disease; GFR, glomerular filtration rate

[a] Relative to young adult level

In the absence of evidence of kidney damage, neither GFR category G1 nor G2 fulfill the criteria for CKD.

Table 2. Analytical performance goals for creatinine measurement recommended by NKDEP [7]

	Total error[a] (%)	Accuracy (% bias)	Analytical imprecision (%CV)
Minimum	≤11.4%	≤5.1%	≤3.2%
Desirable	≤7.6%	≤3.4%	≤2.2%
Optimum	≤3.8%	≤1.7%	≤1.1%

Abbreviations: NKDEP, National Kidney Disease Education Program

[a] % total error = % bias + 1.96 (%CV)