

Title	Assessment of glomerular filtration rate and serum creatinine levels in the diagnosis of chronic kidney disease in adults
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Reference	ISBNnumber: 978-2-11-128508-8, link to full report: http://www.has-sante.fr/portail/jcms/c_1064297/evaluation-du-debit-de-filtration-glomerulaire-et-du-dosage-de-la-creatinemie-dans-le-diagnostic-de-la-maladie-renal-chronique-chez-ladulte-rapport-d-evaluation .

Aim

- To assess the performance of three equations that estimate glomerular filtration rate (GFR): Cockcroft-Gault (CG), Modification of Diet in Renal Disease (MDRD), Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI). The equation showing the least bias, best precision and best accuracy compared to the GFR measured by exogenous marker will be considered the most useful.
- To assess the analytical performance of methods measuring serum creatinine concentrations, compared with a reference method: isotopic dilution mass spectrometry.

The analysis was not performed in analyser / reagent pairs but by Jaffé or enzymatic assay methods.

Conclusions and results

Estimation of GFR

The results in terms of accuracy, a concept that reflects both bias and precision, support the use of the CKD-EPI equation. Statistically significant results were given by a single study of the general population and for GFR > 60 mL/min/1.73m² where P30 accuracy was 84.7% (83.0 to 86.3) for MDRD and 88% (from 86.9 to 89.7) for CKD-EPI.

The CKD-EPI equation is most accurate compared to the other two equations for screening and monitoring CKD in an adult population. Consequently the CKD-EPI equation should be preferred.

Determination of serum creatinine

The reliability of the enzymatic methods was greater than the Jaffé methods: CV <4% versus CV > 5% for serum creatinine levels less than 80 mmol/L, CV <3.5% versus CV >4.5% for serum creatinine concentration around 150 mmol/L and CV <3% versus CV >4% for serum creatinine concentration around 305 mmol/L.

The analytical performance of the enzymatic methods appeared to be superior compared to the Jaffé methods at low and normal creatinine levels. This superiority decreased as the creatinine concentration increased. The data identified from the literature did not specify the serum creatinine level at which the differences in analytical

performance were narrow enough to permit the use of both methods equally without any clinical impact.

Recommendations

The HAS recommends the use of the CKD-EPI equation for screening and monitoring CKD in an adult population, and the use of an enzymatic assay for determination of serum creatinine concentrations.

Methods

A critical analysis was carried out of data published between 01/2000 and 09/2011 after a search of the Medline, Pascal and Cochrane Library databases. Two studies, four years of national external quality assessments scheme (EQAS) and one year of private EQAS were analysed. The results of this analysis were discussed by a multidisciplinary working group comprising four nephrologists, four medical biologists, two geriatricians, one endocrinologist, one radiologist, one anaesthesiologist, one engineer, one cardiologist and one general practitioner.

The conclusions were reviewed by the National Committee for the Assessment of Medical Devices and Health Technologies, the HAS specialised appraisal committee.

Further research/reviews required

The summaries of product characteristics (SPCs) report adjustment of dosage based on Cockcroft and Gault clearance. It would be helpful if the SPCs were revised to allow dosage adjustment based on GFR estimated with the CKD-EPI equation. The CKD-EPI equation should be used with caution in particular subgroups (see above) in which it has not yet been validated (the other equations have not been validated either). It appears to be important that studies should be carried out in these groups in addition to studies on the ethnic coefficient for French people of African descent. As for determinations of creatinine, it would be appropriate to define a serum creatinine concentration beyond which both serum creatinine methods, the enzymatic and the Jaffé, might equally be used without any clinical impact.

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