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Proteome analysis for detection of diabetic nephropathy: Benefit remains unclear

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The German Institute for Quality and Efficiency in Health Care (IQWiG) examined the benefit of a diagnostic-therapeutic strategy using urinary proteome analysis for detection of diabetic nephropathy (DN) versus a conventional diagnostic strategy in patients with diabetes mellitus and arterial hypertension. After publication of the preliminary report in June 2015, interested persons and parties had the opportunity to comment on the preliminary results.

No studies relevant for the research question were identified in the systematic literature search conducted by IQWiG. As no references to relevant studies were submitted in the commenting procedure either, the Institute maintains its conclusion: Due to a lack of studies, the patient-relevant benefit or harm of proteome analysis for detection of DN is equally unclear as the diagnostic or prognostic accuracy of this type of analysis.

Can impending diabetic nephropathy be detected earlier?

DN is a chronic kidney disease caused by chronic hyperglycaemia (high blood sugar levels) in patients with diabetes mellitus and can be negatively influenced by arterial hypertension (high blood pressure). It can lead to permanent failure of the kidneys (end-stage renal disease).

When clear symptoms occur the disease is already far progressed.

Proteome analysis is a new diagnostic method in which the concentration of several biomarkers in the urine is determined by means of mass spectrometry. The values calculated in this analysis are supposed to allow earlier and more precise clinical conclusions on DN than conventional diagnostic methods.

No relevant studies identified

The commission awarded to IQWiG by the Federal Joint Committee (G?BA) specifies two aims: Firstly, the Institute was to assess the patient-relevant benefit or harm of a diagnostic-therapeutic strategy using proteome analysis versus a conventional strategy in patients with diabetes mellitus and arterial hypertension. Secondly, the diagnostic and prognostic accuracy of proteome analysis for the detection of DN was to be assessed.

No completed studies relevant for these assessments were identified by IQWiG's researchers up to publication of the preliminary report in June 2015. The PRIORITY study will run up to the end of 2107. It is yet unclear how informative its results will be for the present research question.

Promising PR messages, but no proof of benefit

No comments with references to further relevant studies were submitted in the public commenting procedure either. This seems astonishing in view of the promising PR messages disseminated in the past months - in part specifically in reference to the current benefit assessment - by a provider of screening tests based on proteome analyses.

This was commented on by Stefan Sauerland, Head of IQWiG's Department of Non-Drug Interventions, as follows: "One cannot just

postulate a `monumental breakthrough`, which proteome analysis is supposed to represent. The benefit for the respective patients has to be proven. As long as the `numerous studies and scientific publications´ proudly referred to do not include a single study proving the benefit of the test for the early detection of diabetic nephropathy, one should not be surprised by a negative conclusion of the assessment."

Thus both the patient-relevant benefit or harm of a diagnostic-prognostic strategy using proteome analysis for detection of DN, as well as the diagnostic and prognostic accuracy of this type of analysis, remain unclear.

More information: www.iqwig.de/download/D13-01_A … ennung-einer-DNP.pdf

Provided by Institute for Quality and Efficiency in Health Care