Diabetic nephropathy: Study results on proteomic analysis do not show benefit

July 6 2020

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One of the consequences of diabetes mellitus, particularly if accompanied by high blood pressure (hypertension), can be a chronic kidney disease (diabetic nephropathy), which can lead to permanent

failure of the kidneys (end-stage renal disease). The German Institute for Quality and Efficiency in Health Care (IQWiG) now produced a rapid report to investigate the advantages or disadvantages of a diagnostic-therapeutic strategy using a proteomic analysis of the urine in comparison with a conventional diagnostic-therapeutic strategy to prevent renal disorders by early diagnosis and therapy.

This investigation was prompted by the results of the first randomized trial on an early therapy of patients who, according to the proteomic analysis, had a high risk of a kidney disease. These patients received either treatment with spironolactone or placebo. However, the study results did not suggest any advantages or disadvantages of an early proteomic analysis in combination with the administration of spironolactone for any of the patient-relevant outcomes.

This conclusion is the update of an earlier benefit assessment of proteomic analysis conducted by IQWiG in 2015 (D13-01).

Proteomic analysis aims to detect impending diabetic nephropathy earlier

When clear symptoms occur, diabetic nephropathy (DN) is already far progressed. Proteomic analysis determines the concentration of several biomarkers in the urine by means of mass spectrometry. The values calculated in this analysis are supposed to allow earlier and more precise clinical conclusions on the development of DN than conventional diagnostic methods.

However, the PRIORITY study provided no hint of a benefit or harm of spironolactone administration based on a proteomic analysis regarding the following patient-relevant outcomes: all-cause mortality, chronic kidney disease, cardiovascular morbidity (ischaemic heart disease,

stroke, cardiac failure, etc.), damage to the retina of the eyes in need of treatment (retinopathy), and serious adverse events. There were no data on health-related quality of life.

With the results of the PRIORITY study, it is therefore still unknown which therapeutic consequence from the test result of the proteomic analysis could offer a benefit for patients. Further ongoing or planned studies on proteomic analysis in people with diabetes and hypertension were not identified.

Process of report production

IQWiG had sent the first benefit assessment on proteomic analysis as final report D13-01 in September 2015 to the commissioning agency, the Federal Joint Committee (G-BA). The G-BA then suspended its decision on proteomic analysis in patients with diabetes mellitus and arterial hypertension with the provision that the hitherto unanswered questions had to be answered on the basis of informative scientific documents.

The G-BA resumed the assessment procedure in 2019, and commissioned IQWiG in December 2019 with the assessment of the benefit of proteomic analysis in patients with diabetes mellitus and arterial hypertension, particularly under consideration of the results of the PRIORITY study, which had been completed in the meantime. IQWiG was to prepare the report in an accelerated process, known as a "rapid report". Interim products were therefore not published and were not the subject of a hearing.

More information: www.iqwig.de/en/projects-resul … pertension.3220.html

Provided by Institute for Quality and Efficiency in Health Care