IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

IQWiG Reports – Commission No. D13-01

Urinary proteome analysis for detection of diabetic nephropathy in patients with diabetes mellitus and arterial hypertension[1]

Executive Summary

[1] Translation of the executive summary of the final report *Proteomanalyse im Urin zur Erkennung einer diabetischen Nephropathie bei Patientinnen und Patienten mit Diabetes mellitus und arteriellem Hypertonus* (Version 1.0; Status: 17 September 2015). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

Publishing details

Publisher:

Institute for Quality and Efficiency in Health Care

Topic:

Urinary proteome analysis for detection of diabetic nephropathy in patients with diabetes mellitus and arterial hypertension

Commissioning agency:

Federal Joint Committee

Commission awarded on:

3 January 2013

Internal Commission No.:

D13-01

Address of publisher:

Institute for Quality and Efficiency in Health Care
Im Mediapark 8 (KölnTurm)
50670 Cologne
Germany

Tel.: +49 (0)221 – 35685-0
Fax: +49 (0)221 – 35685-1
E-Mail: berichte@iqwig.de
Internet: www.iqwig.de

This report was prepared in collaboration with an external expert.

The responsibility for the contents of the report lies solely with IQWiG.

According to §139 b (3) No. 2 of Social Code Book (SGB) V, Statutory Health Insurance, external experts who are involved in the Institute's research commissions must disclose "all connections to interest groups and contract organizations, particularly in the pharmaceutical and medical devices industries, including details on the type and amount of any remuneration received". The Institute received the completed *Form for disclosure of potential conflicts of interest* from the external expert. The information provided was reviewed by a Committee of the Institute specifically established to assess conflicts of interests. The information on conflicts of interest provided by the external expert is presented in Appendix C of the full report. No conflicts of interest were detected that could endanger professional independence with regard to the work on the present commission.

External expert:

- Norbert Donner-Banzhoff, Department of General Medicine, Rehabilitative and Preventive Medicine, Philipps University of Marburg, Marburg, Germany

IQWiG thanks the external expert for his collaboration in the project.

IQWiG employees:[2]

- Anne Rummer
- Tracy Slanger
- Ulrich Grouven
- Tatjana Hermanns
- Fülöp Scheibler

[2] Due to legal data protection regulations, employees have the right not to be named.

Executive summary

With its letter of 3 January 2013, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess urinary proteome analysis for detection of diabetic nephropathy (DN) in patients with diabetes mellitus and arterial hypertension.

Research question

The aims of the present investigation are

- the benefit assessment of a diagnostic-therapeutic strategy using proteome analysis versus a diagnostic-therapeutic strategy without using proteome analysis or versus no diagnostic method (= "conventional diagnostic-therapeutic strategy")

in each case in patients with diabetes mellitus and arterial hypertension with regard to patient-relevant outcomes, as well as

- the assessment of the diagnostic and prognostic accuracy of proteome analysis for the detection of DN in this patient group. In this context, the question is to be investigated whether patients developing DN can be identified at an earlier stage with this diagnostic method than with the existing diagnostic standard.

Methods

Comparative randomized and non-randomized intervention studies were included that investigated proteome analysis as part of a diagnostic-therapeutic strategy in respect of

- all-cause mortality
- cardiovascular mortality (coronary, cerebrovascular)
- end-stage renal disease (dialysis or kidney transplantation required)
- morbidity (e.g. coronary, cerebrovascular, peripheral arterial)
- health-related quality of life (including other activities of daily living)
- inpatient treatment of any cause
- all adverse events

In addition, studies on the prognostic accuracy of proteome analysis were included.

For this purpose, a systematic literature search was conducted in the following databases: MEDLINE, EMBASE, and the Cochrane Central Register of Controlled Trials (Clinical Trials). In addition, parallel to the search for relevant primary studies, a search for relevant systematic reviews was conducted in the MEDLINE and EMBASE databases, as well as in the Cochrane Database of Systematic Reviews (Cochrane Reviews), the Database of

Abstracts of Reviews of Effects (Other Reviews), and the Health Technology Assessment Database (Technology Assessments). The last search was conducted on 19 August 2015.

Furthermore, reports from publicly available trial registries were screened, as were documents transferred by the G-BA and publications provided in the hearing procedure for the preliminary report plan.

The selection of relevant studies from the above sources was performed by 2 reviewers independently of each other. As no systematic review relevant for the research question could be identified, these further working steps were dispensed with for systematic reviews.

Results

No study relevant for the research question of the present benefit assessment was identified.

Conclusion

Due to a lack of suitable studies, the patient-relevant benefit or harm of a diagnostic-therapeutic strategy using proteome analysis for detection of DN is unclear.

Diagnostic accuracy could not be assessed, as no reference test is available for the early stage of application of proteome analysis (according to the indication for this test). Due to a lack of suitable studies, the prognostic accuracy of proteome analysis is also unclear.

Keywords: proteomes, diabetic nephropathies, benefit assessment, systematic review

The full report (German version) is published under

https://www.iqwig.de/de/projekte-ergebnisse/projekte/nichtmedikamentoese-verfahren/d13-01-proteomanalyse-im-urin-zur-erkennung-einer-diabetischen-nephropathie-bei-patientinnen-und-patienten-mit-diabetes-mellitus-und-arteriellem-hypertonus.3220.html.