IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

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Antibody-coated drug-eluting stents for treatment of coronary artery stenosis[1]

Executive Summary

[1] Translation of the executive summary of the final report *Antikörperbeschichtete, medikamentenfreisetzende Stents zur Behandlung von Koronargefäßstenosen* (Version 1.0; Status: 23 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.

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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 F of the full report. No conflicts of interest were detected that could endanger professional independence with regard to the work on the present commission.

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

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

Executive summary

With its letter of 22 October 2013, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess antibody-coated drug-eluting stents for treatment of coronary artery stenosis.

Research question

The aim of the present investigation is

- the benefit assessment of treatment with implantation of an antibody-coated drug-eluting stent (ABC-DES) versus other treatment options

in patients in whom a stent implantation is indicated due to coronary heart disease. The investigation was based on patient-relevant outcomes.

Methods

Randomized controlled trials (RCTs) were included that investigated the implantation of an ABC-DES for treatment of coronary artery stenosis with regard to patient-relevant outcomes.

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 12 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 and preliminary report. In addition, the manufacturer of the only ABC-DES available on the market in Germany (according to the current state of knowledge) was contacted in writing with regard to relevant published or unpublished studies.

The selection of relevant studies from the results of the searches of bibliographic databases and publicly available trial registries, as well as of the screening of documents transferred by the G-BA, was performed by 2 reviewers independently of each other. The selection of relevant studies from the other sources was conducted by 1 reviewer and checked by another.

Data were extracted into standardized tables. To evaluate the certainty of results, the risk of bias at study and outcome level was assessed and in each case rated as low or high. The results of the individual studies were organized by outcomes and described. If the studies were comparable regarding the research question and relevant characteristics, the individual results were pooled quantitatively by means of meta-analyses.

Results

A total of 2 studies (REMEDEE and REMEDEE OCT) were identified as relevant for the research question of the present benefit assessment. Both studies were multi-centre RCTs investigating the use of ABC-DES and DES for treatment of coronary artery stenosis. The studies included 183 and 60 patients, respectively.

Unpublished study protocols and study reports were provided for both studies by the manufacturer of the ABC-DES investigated in the studies; these documents were considered in the assessment.

Both studies showed a low risk of bias at study level.

Data were analysed on the patient-relevant outcomes of all-cause mortality, cardiac mortality, myocardial infarction, acute coronary artery bypass grafting, overall rate of serious adverse events, vascular complications, cerebrovascular events, and bleeding events. However, insufficient data were available for several outcomes.

In both studies a low risk of bias was determined for the reported patient-relevant outcomes of all-cause mortality, cardiac mortality, and myocardial infarction. In addition, in the REMEDEE study, the risk of bias for the outcome of vascular complications was rated as low. A high risk of bias at outcome level was determined for all other patient-relevant outcomes.

No statistical significant differences were shown between the results of the intervention group (ABC-DES) and the control group (DES) for any of the above-mentioned patient-relevant outcomes reported in the studies.

No data for corresponding analyses were available for the patient-relevant outcomes of angina pectoris, hospitalization, health-related quality of life, dependence on outside help or the need for long-term care, as well as physical fitness, coping with daily activities, and capacity to work.

In summary, on the basis of the analyses of the available results for the above-mentioned outcomes, no hint of a benefit or harm of ABC-DES versus DES can be inferred.

Conclusions

In patients in whom a stent implantation is indicated due to coronary heart disease, no hint of a benefit or harm arises for any patient-relevant outcome with regard to treatment with implantation of ABC-DES versus DES. Insufficient data were available for most outcomes. No comparisons with other treatment options were identified.

Keywords: stents, coronary artery disease, myocardial infarction, benefit assessment, systematic review

The full report (German version) is published under

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