IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

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Stents for the treatment of intracranial arterial stenosis: VISSIT study and acute treatment in Germany[1]

Executive Summary

[1] Translation of the executive summary of the working paper *Stents zur Behandlung intrakranieller arterieller Stenosen: VISSIT-Studie und Akutbehandlung in Deutschland* (Version 1.0; Status: 21 May 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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Executive summary

The present working paper was prepared within the context of the general commission.[3]

Research question

The aim of this working paper is to determine

- whether the results of the VISSIT study challenge the conclusion of rapid report N14-01 (question 1: VISSIT study)
- whether justified doubts exist that the benefit assessment on the basis of the currently available results from randomized controlled trials (RCTs) can be applied to acute treatment, particularly of symptomatic patients (question 2a: results of acute treatment in Germany)
- how large the proportion is in Germany of patients in whom a stent is implanted due to symptomatic intracranial arterial stenosis in the context of acute treatment (question 2b: proportion of acute treatment in Germany).

The assessment of questions 1 and 2a was conducted on the basis of patient-relevant outcomes.

Methods

For question 1, the data of the VISSIT study were extracted and analysed analogous to the methods used in rapid report N14-01. No update search was conducted.

For question 2a, studies were included that, with regard to all-cause mortality and cerebrovascular morbidity, investigated acute treatment (neurological event within the last 48 hours) with a stent for intracranial arterial stenosis. Further patient-relevant outcomes investigated in rapid report N14-01 (e.g. health-related quality of life) were not analysed for this question in the present working paper.

For question 2b, studies were included that investigated patients with intracranial arterial stenosis in whom stent insertion was indicated and that reported the proportion of patients who had undergone acute treatment (neurological event within the last 48 hours).

For questions 2 a and 2b, a systematic literature search was conducted in the MEDLINE and Embase databases. The last search was conducted on 31 March 2015. In addition, a search for relevant systematic reviews was conducted in MEDLINE and Embase, parallel to the search for relevant primary studies. Two reviewers independently of one another selected the

[3] The Federal Joint Committee (G-BA) awarded a general commission to IQWiG in December 2004, which was extended in March 2008. This allows IQWiG to select topics for scientific evaluation independently. The topics do not have to be approved by the G-BA or the Federal Ministry of Health (BMG).

relevant studies from the results of the bibliographic literature search and from the pool of potentially relevant studies identified in systematic reviews. The data were extracted into standardized tables.

Results

Question 1

As in the SAMMPRIS study, the VISSIT study also showed a statistically significant difference in periprocedural strokes (within 30 days) to the disadvantage of the stenting group (i.e. the "percutaneous transluminal angioplasty and stenting" [PTAS] group). As in the SAMMPRIS study, this difference was noticeable both for haemorrhagic and ischaemic strokes.

No statistically significant differences were determined for the patient-relevant outcomes of all-cause mortality, cerebrovascular mortality, severe strokes, and adverse events. In the VISSIT study, only events occurring in the brain territory treated were available for the outcome of stroke. Here too, a difference was shown to the disadvantage of stenting.

Question 2a

Six retrospective case series (evidence level IV) with a total of 31 patients were included. Treatment with stents was primarily performed in the arteria basilaris and arteria vertebralis; this was largely necessary because of a thrombotic occlusion due to high-grade symptomatic stenosis (> 75%). Thirteen of the 31 patients died; 7 showed a favourable result (no or only minor cerebrovascular morbidity).

Question 2 b

Ten case series with a total of 299 patients were included. In 40 cases (13%) a stent was inserted within the context of acute treatment.

Conclusion

The results of the VISSIT study confirm those of the SAMMPRIS study and thus support the assessment presented in rapid report N14-01.

There are currently no indications that the results underlying the rapid report cannot be applied to the acute treatment of symptomatic patients.

The case series of stent implantations in Germany show that only a small proportion of patients were treated because of an acute situation (neurological event within the last 48 hours).

Keywords: stents, intracranial arteriosclerosis, benefit assessment

The full report (German version) is published under

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