New study again shows: More strokes with intracranial stents

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The risk of experiencing another stroke is higher if patients, after dilation of their blood vessels in the brain, receive not only clot-inhibiting drugs, but also have stents inserted. The recently published results of the VISSIT study confirm this conclusion of a rapid report by the German Institute for Quality and Efficiency in Health Care (IQWiG) of October 2014. Thus, the available studies still provide no evidence of a benefit of treatment with intracranial stents (also called "percutaneous transluminal angioplasty and stenting", PTAS). This is the conclusion of a working paper by IQWiG published on 18 June 2015.

Stents also problematic in acute treatment

The working paper also provides answers to further questions on the healthcare situation in Germany. According to this, there is no reason why the results of the randomized controlled trials (RCTs) already assessed, which investigated patients who received intracranial stents in non-acute situations, should not be applied to acute treatment. However, in Germany, if stents are implanted into cerebral vessels, this is mostly done in non-acute situations.

VISSIT also discontinued due to security concerns

Of the total of 4 RCTs that IQWiG analysed for the rapid report in October 2014, the SAMMPRIS study was decisive for the assessment.

The recently published VISSIT study compared the use of stents plus medical therapy versus medical therapy alone in patients with symptomatic intracranial stenosis. In contrast to the SAMMPRIS study, in which so-called wingspan stents (self-expandable stent system, SES) were inserted, the study participants in the VISSIT study received Pharos Vitesse stents (balloon-expandable stent system, BES). After publication of the SAMMPRIS results an unplanned data analysis was conducted in the VISSIT study, which was subsequently discontinued.

VISSIT results confirm SAMMPRIS results

The publication of the VISSIT results was the reason for IQWiG to examine in a working paper whether these results would challenge the conclusion of last year's rapid report. The comparison of VISSIT and SAMMPRIS clearly demonstrates: the study results agree in all important points and in both studies harm is shown through the increased risk of stroke.

This also confirms IQWiG's benefit assessment from 2014 - independent of the type of stent used. Worse results for stent therapy were shown in both studies, especially for periprocedural strokes (all strokes within 30 days after the intervention). None of the studies showed an advantage of treatment with intracranial stents.

Only few case series on acute treatment

As the SAMMPRIS study excluded patients with acute neurological symptoms (acute treatment), it was often challenged whether the results were at all applicable to the healthcare situation in Germany. This is because in this country intracranial stents are primarily used in acute situations. IQWiG also investigated this question in its working paper.

Only 6 small retrospective case series provide information on the outcomes of mortality (overall mortality) and strokes (cerebrovascular morbidity) in acute treatment (? 48 hours after a stroke) with a stent in patients with intracranial stenosis in Germany. Of the total of 31 patients in the case series, most of them with a rather poor prognosis, 13 (42%) died and 11 (35%) experienced impairment of a medium to severe degree. A favourable result was shown in 7 patients (23%).

These data are difficult to interpret due to a lack of informative comparisons. However, they provide no evidence that (intracranial) stenting in acute treatment is to be evaluated completely differently from stenting in non-acute Treatment.

RCT results applicable to acute treatment

Stefan Sauerland, Head of the Non-Drug Interventions Department at IQWiG, notes: "There is no reason why the results of the RCTs already assessed, which investigated patients in non-acute situations, should not be applied to acute treatment in Germany. Whether intracranial stents produce more benefit than harm in acute treatment can only be investigated in comparative, preferably randomized studies. Current results on the use of mechanical thrombectomy procedures in acute stroke show that such studies are possible."

Intracranial stents rarely used in acute treatment

Ten case series in Germany investigated patients with intracranial stenosis in whom stent therapy was indicated. In this context, the proportion of patients treated acutely, that is patients with a stroke within the past 48 hours, was investigated. In 40 of the overall 299 patients (about 13%, i.e. only a small proportion of patients) a stent was inserted in the context of acute treatment.

The Institute Director Jürgen Windeler summarizes: "According to these data the large majority of intracranial stents is not inserted after 1 to 2 days, but several days or weeks after a stroke." The results of the SAMMPRIS and VISSIT study are therefore of great importance for stent therapy, also in Germany.

Legislator increases requirements for medical devices

High-risk medical devices are repeatedly used in Germany, even before the benefit and harm of the intervention have been sufficiently examined. To date, information on their risks is usually obtained only belatedly due to the occurrence of specific detrimental events in patients after treatment, and unfortunately often outside the supervision of a trial.

To avoid similar problems in future as those experienced with intracranial stents, on 11 June 2015 the German Parliament decided on a change in the law: new invasive treatment procedures based on a medical device will as a rule undergo an early benefit assessment. Jürgen Windeler welcomes this change: "If this new law had already existed during the introduction of intracranial stents, the dissemination of harmful treatments could have been avoided. And thanks to high-quality studies we would know more about stents in acute treatment."

More information: www.iqwig.de/download/GA15-02_ … r-Akutbehandlung.pdf

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