INTRACRANIAL ARTERY STENOSIS: MEDICAL VS. ENDOVASCULAR (STENT) TREATMENT - ENDOVASCULAR

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One score and 4 years after the first PTA for treatment of intracranial atherostenosis I did the first in man WINGSPAN-procedure for intracranial atherosclerotic disease (ICAD). This was the beginning of an encouraging trial known as WINGSPAN trial (HDE-Trial). Target patients had symptomatic ICAD and had failed antithrombotic therapy. Technical success rate was 100% and the 30-day composite ipsilateral stroke/death rate was 4.5% (1). On the other hand the SAMMPRIS trial the first randomized trial comparing endovascular therapy (EVT) with optimized medical therapy for symptomatic IACD was stopped, because the rate of periprocedural stroke in the EVT group was higher than expected and the rate of stroke in the medical-management group was lower than estimated (2). What are the implications and possible criticisms of these contradictionary findings?

In the SAMMPRIS trial patients with recent transient ischemic attack or stroke related to 70–99% stenosis of a major intracranial artery were randomly assigned to EVT. So inclusion criterion was well beyond the level required so far in clinical practice before intracranial stent angioplasty is performed. Usually intracranial stenosis is only be treated if the patient despite medical therapy is symptomatic or there is a hemodynamic compromise by one high-grade intracranial stenosis.

SAMMPRIS did not follow the current HDE indication for use of the Wingspan Stent system; it focused on studying the treatment of severe ICAD early in the treatment lifecycle and with an aggressive drug treatment regimen. The Wingspan Stent System is for patients who are refractory to medical therapy. In the SAMMPRIS trial, it was not required for patients to be refractory to medical therapy. Regardless these criteria the SAMMPRIS study attempted a significant extension of the indication to establish stent angioplasty as a first-line therapy.

The sample size calculations and expected values for the SAMMPRIS trial based primarily on data from the HDE study a technical safety and feasibility study with predominantly simple lesions. To compare both studies in terms of periprocedural complications is problematic. Results from multicenter registries (3, 4) reflect more the real world scenario and showed higher technical and procedural complication rates. On the other hand, if one compares the morbidity and mortality rate of 10.7% in the historical control data of the WASID study, the MM-rate in the endovascular arm of SAMMPRIS with 14.7% is only moderately increased.

The majority of these strokes in SAMMPRIS occurred within one day after the procedure and therefore might correctly be considered as direct procedural complications. The high rate of these complications in part reflects the fact that intracranial stenting is still an uncommon procedure. Another potential source for vascular injury and subsequent complications is the cumbersome carrier system and the use of a 300 cm exchange wire to introduce the Wingspan stent after balloon angioplasty. This drawbacks can be overcome with other stent devices and direct microcather delivered selfexpanding neurostents wich may reduce the procedural risk. Maybe closed cell neurostents and primary stenting with subsequent PTA as in stent protected carotid artery revascularization may further reduce the acute M&M rate.

Furthermore, the higher complication rate in SAMMPRIS compared to other studies and also to the HDE study is seen in the inclusion criteria. In SAMMPRIS, patients with a stenosis of 70 - 99% were enrolled with a stroke within the last 30 days. However, the HDE study and mainly the register studies included patients with a stenosis of > 50%, vessel 2.5 to 4.5 mm in diameter, and a qualifying event beyond 30 days. If there is an unstable or ruptured plaque EVT carries a considerable risk when performed early after the qualifying event.

In the SAMMPRIS trial the proportion of patients who had a stenosis of the middle cerebal artery (ACM) (41 %) was very high in both treatment arms. The ACM has a very small vessel diameter and is distally located. Also with optimized stent systems, it is often difficult, sometimes impossible to access these lesions. The fact that of the 244 patients of the endovascular therapy arm 15 (6.7%) did not receive a stent, suggesting that it is often complex stenoses and / or a difficult vascular anatomy. A drawback of all published interventional trials dealing with ICAS is the lack of information about lesion type e.g. length and degree of stenosis, contour, angulations, calcifications as well as information about the tortuosity of the proximal segment and the accessibility of the lesion. These factors have significant impact oft the technical and procedural success of ICAS (6, 7). Looking to the literature and our daily practice we have to notice a change toward a more aggressive approach with EVT to more complex lesions. Early experiences with the improved stent designs and low rate of angiographic and clinical complications, the indication for IACS expanded from simple target lesions to more complex lesions in the posterior and the anterior circulation (7).

Yet few, if any, studies published give informations about risk of stroke due to plaque morphology and plaque localization. Plaque imaging with high resolution MRI could prove useful to establish the particular stroke mechanism associated with ICAS and provide detailed information about

atherosclerotic plaque formation e. g. plaque morphology and extension over small penetrating artery ostia. Patients without branch atheromatous disease may be at lower procedural risk when treated with stent angioplasty.
Additionally, high grade stenosis with the presence of hemodynamic compromise and poor collateral flow increases the risk of recurrent stroke among drug therapy to more than four times. For these patients EVT continue to take a real, usually the only alternative.
Although SAMMPRIS is the largest available prospective series of intracranial EVT to date, the overall number of events is still relatively small. Stent assisted angioplasty was, by defined indication never intended for use in any but failed medical outcomes. The available data support modification but not discontinuation of EVT for intracranial stenosis. There are potential patients in whom EVT might be the best approach, and a new trial with appropriate modifications in patient selection with lesion-based risk models may be warranted.

Literature

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