

Title Endovascular thrombectomy of intracranial arteries

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Reference ISBN number: 978-2-11-151446-1, link to full report in French: http://www.has-

sante.fr/portail/jcms/c 2624413/fr/evaluation-de-thrombectomie-des-arteres-intracraniennes-par-voie-

endovasculaire-rapport-d-evaluation-technologique

Aim

Assessment of the efficacy and safety of mechanical thrombectomy (MT) for the treatment of Acute Ischaemic Stroke (AIS)

Conclusions and results

Data from the literature analysed suggest that mechanical thrombectomy in combination with intravenous thrombolysis (IVT), , when used jointly with non-invasive arterial imaging, in some patients with acute ischaemic stroke occurring in the anterior circulation, when using second-generation devices (stent retriever), has a beneficial effect on morbidity and functional impact (autonomy and independence) and quality of life at 90 days, but no effect on all-cause mortality at 90 days.

The results of nine randomized controlled trials (RCT) and of six supplemental studies did not reveal any negative signals on the safety of mechanical thrombectomy with respect to all-cause mortality at 90 days, symptoms of intracerebral haemorrhage and recurrence of ischaemic strokes compared to standard treatment, in selected patients.

The guidelines analysed are based mainly on the RCT analysed in this report, and are consistent to recommend the introduction of mechanical thrombectomy in the management of AIS. Moreover, they recommend the use of the devices studied in the five most recent trials, primarily stent retrievers, for clinical practice.

Overall, the stakeholders indicate that mechanical thrombectomy has its place in the strategy for management of AIS within the first 6 hours, following an occlusion of the ICA of the proximal MCA in the acute phase. Cerebral and vascular imaging is a prerequisite for making the indication for MT. The decision to perform MT must be made jointly by a vascular neurologist working in a Stroke and an experienced Unit interventional neuroradiologist. Neurologists emphasise the inaccuracy of complications reported, especially for ruptures. Anaesthetists specify that the technique requires a full neuroradiology emergency infrastructure with an available anaesthetist and a nurse anaesthetist. The choice of anaesthetic method depends on the clinical condition of the patient. Stakeholders identify areas that remain to be documented for clinical research, in particular AIS outside of the time window, the benefit of MT in patients with a

low NIHSS score, general anaesthesia compared to local anaesthesia.

Recommendations

Considering all of the data available and especially the benefit on morbidity, functional impact (autonomy and dependence) and quality of life at 90 days, HAS indicates that mechanical thrombectomy is of interest in the management of patients with AIS, in relation to an occlusion of a large calibre intracranial artery of the anterior circulation, visible in imaging within a period of 6 hours after the onset of symptoms, either initially in combination with intravenous thrombolysis (IVT), or as recourse technique: after failure of treatment with IVT, or alone in case of contraindication to IVT. It also recommends the establishment of a comprehensive register of patients treated with this technique, to monitor the spread of the technique and to have usage data in everyday practice.

Methods

The assessment method is based on:

- the Health Technology Assessment report on MT prepared in 2015 as part of the EUnetHTA (European Network for Health Technology Assessment) project. This report, for which HAS was a reviewer, presents a comprehensive analysis of the data in the literature;
- supplemental bibliographic research to identify publications published since the completion of the EUnetHTA report;
- consultation with organisations of the healthcare professionals concerned, in their capacity as stakeholders, particularly on the conditions for performing the technique and criteria for patient eligibility for the technique;

The whole report has been reviewed by the National Commission for the Assessment of Medical Devices and Health Technologies and then validated by the HAS Board.

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