

Summary of
Thrombectomy for Stroke at 6 to 16 Hours with Selection by Perfusion Imaging
NEJM med 378;8. February 22, 2018, Albers GW.

BACKGROUND

- Thrombectomy is currently recommended for eligible patients with stroke who are treated within 6 hours after the onset of symptoms.

METHODS

- Multicenter (38 centers), randomized, open-label trial, with blinded outcome assessment, of thrombectomy in patients 6 to 16 hours after they were last known to be well and who had remaining ischemic brain tissue that was not yet infarcted.
- Patients with proximal middle-cerebral-artery or internal-carotid-artery occlusion, an initial infarct size of less than 70 ml, and a ratio of the volume of ischemic tissue on perfusion imaging to infarct volume of 1.8 or more were randomly assigned to endovascular therapy (thrombectomy) plus standard medical therapy (endovascular-therapy group) or standard medical therapy alone (medical-therapy group).
- The primary outcome was the ordinal score on the modified Rankin scale (range, 0 to 6, with higher scores indicating greater disability) at day 90.

INCLUSION

- 18-90yo
- NIHSS \geq 6
- Pts were enrolled if they met clinical and imaging eligibility requirements and could undergo initiation of endovascular therapy between 6 and 16 hrs after the time that they had last been known to be well.
- Must have initial infarct volume (ischemic core) <70 ml, a ratio of volume of ischemic tissue to initial infarct volume of 1.8 or more, and an absolute volume of potentially reversible ischemia (penumbra) of 15 ml or more.
- Estimates of the volume of the ischemic core and penumbral regions from CT perfusion or MRI diffusion and per-fusion scans
- Pts were required to have an occlusion of the cervical or intracranial internal carotid artery or the proximal middle cerebral artery on CT angiography (CTA) or magnetic resonance angiography (MRA).

EXCLUSION

- Pregnancy
- Pre-existing or terminal illness
- tPA given >4.5 hrs after onset
- Seizure preventing NIHSS determination
- Glucose <50 or >400
- Platelets <50 k or INR >3
- Sustained HTN SBP >185 or Diastolic >110 not treatable with meds

RESULTS

- The trial was conducted at 38 U.S. centers and terminated early for efficacy after 182 patients had undergone randomization (92 to the endovascular-therapy group and 90 to the medical-therapy group).

- Endovascular therapy plus medical therapy, as compared with medical therapy alone, was associated with a favorable shift in the distribution of functional outcomes on the modified Rankin scale at 90 days (odds ratio, 2.77; $P < 0.001$) and a higher percentage of patients who were functionally independent, defined as a score on the modified Rankin scale of 0 to 2 (45% vs. 17%, $P < 0.001$).
- The 90-day mortality rate was 14% in the endovascular-therapy group and 26% in the medical-therapy group ($P = 0.05$), and there was no significant between-group difference in the frequency of symptomatic intracranial hemorrhage (7% and 4%, respectively; $P = 0.75$) or of serious adverse events (43% and 53%, respectively; $P = 0.18$).

SAFETY OUTCOMES

- Mortality at 90 days was 14% in the endovascular-therapy group and 26% in the medical-therapy group ($P = 0.05$). The rate of symptomatic intra-cranial hemorrhage did not differ significantly between the two groups (7% and 4%, respectively; $P = 0.75$).
- Five patients with symptomatic intracranial hemorrhages in the endovascular-therapy group died, as compared with two with symptomatic intracranial hemorrhages in the medical-therapy group.
- Parenchymal hematoma type 2 (dense blood clot exceeding 30% of the infarct volume with substantial space-occupying effect) occurred in 9% of the patients in the endovascular-therapy group and 3% of those in the medical-therapy group ($P = 0.21$).
- Thrombectomy-related complications occurred in two patients: a vessel perforation resulting in subarachnoid hemorrhage that was associated with a 3-point increase in the NIHSS score (90-day score on the modified Rankin scale, 5), and device-related vasospasm that did not lead to neurologic worsening.
- Serious adverse effects were reported in 43% of the patients in the endo-vascular-therapy group and 53% of those in the medical-therapy group ($P = 0.18$).

CONCLUSIONS

- Endovascular thrombectomy for ischemic stroke 6 to 16 hours after a patient was last known to be well plus standard medical therapy resulted in better functional outcomes than standard medical therapy alone **among patients with proximal middle-cerebral-artery or internal-carotid-artery occlusion** and a region of tissue that was ischemic but not yet infarcted. (Funded by the National Institute of Neurological Disorders and Stroke;