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Background

- Tandem occlusion refers to stroke due to middle cerebral artery (MCA) or distal internal carotid artery (ICA) AND ipsilateral cervical ICA occlusion or near-occlusion¹
- It is found in 12-30% of patients undergoing endovascular thrombectomy (EVT)¹
- Optimal acute management of the cervical ICA lesion is uncertain and may include no definitive revascularization versus acute stenting²
- Practice varies widely across centres and interventionalists and no RCT data or clear guidelines exist to guide decision-making
- An RCT is the best way forward to determine whether the ICA should be routinely stented during cases of stroke with tandem occlusion undergoing EVT³

Factors influencing decision-making

- Use of IV thrombolysis
- Prior use of antiplatelet agents
- Degree of collaterals
- Degree of final intracranial recanalization
- Degree and morphology of residual ICA stenosis
- Etiology of stenosis (atherosclerosis versus dissection)
- Pre-EVT infarct volume/ASPECTS

Technical issues

- ICA lesion stented prior (“anterograde”) to or after (“retrograde”) intracranial thrombectomy
- Type of ICA stent
- Use of distal embolic protection
- Use of balloon angioplasty
- Use of thrombo-aspiration in the ICA

Benefits and risks of acute stenting

Benefits:

- Treats the causative embolic lesion
- Improves cerebral perfusion
- May contribute to spontaneous clot lysis

Risks:

- Iatrogenic dissection or perforation
- Artery-to-artery embolization
- ICH risk (hyperperfusion, antiplatelet agents)

Methods

- We propose a pragmatic, multicentre PROBE RCT of adult acute stroke patients undergoing EVT which will compare acute stenting for high-grade cervical ICA stenosis/occlusion versus deferred ICA intervention (if indicated).
- For pragmatic reasons, consent and treatment allocation will occur after confirmation of a tandem occlusion on initial non-invasive vascular imaging (CTA or MRA) but prior to EVT
- A standard antiplatelet regimen of ASA and Clopidogrel will be strongly recommended but final decisions will be made by the treating team
- Anterograde ICA stenting will be encouraged
- Cases of ICA “pseudo-occlusions” identified on CTA or MRA but not confirmed on angiography will be considered screen failures
- A pilot phase of 100 patients will be completed with anticipated initial participation of sites in Montréal, Québec City, Ottawa and Calgary and eventual expansion to other sites
- Our primary hypothesis assumes a greater proportion of patients with 90-day mRS 0-2 in the stenting group versus the no stenting group (50% versus 40%). In order to detect this 10% difference in the primary outcome with power of 0.8, 408 patients per group will be required
- Assuming a loss to follow-up of 12 patients per group, this would require a total sample size of 420 patients per group (n=840)

Inclusion criteria:

Patients aged ≥ 18 years

Acute ischemic anterior circulation stroke eligible for EVT according to local guidelines (with or without prior intravenous thrombolysis)

Ipsilateral high-grade (>70%) cervical ICA stenosis or occlusion

Informed consent according to local ethics policies

Exclusion criteria:

Pre-existing neurological impairment (modified Rankin score ≥3)

Any underlying disease or condition making protocol adherence and/or 3-month follow-up unlikely

Any known contra-indication to EVT, angioplasty/stenting, or antiplatelet therapy

Symptomatic ICA stenosis or occlusion attributable to confirmed arterial dissection

Conclusions

A randomized clinical trial is justified and feasible given the persistent clinical equipoise in cases of tandem occlusion

The EASI-TOC study plans to begin recruitment by the Fall of 2018 and should provide data regarding the use of routine ICA stenting in acute stroke patients with tandem occlusions

Results

- **Primary hypothesis:** Acute ICA stenting is superior to deferred intervention, with a proportion of favorable modified Rankin Scale score (0-2) at 90 days of 50% vs 40%
- **Primary outcome:** Proportion of patients with a favorable mRS (0-2) at 90 days
- **Secondary outcomes:** NIHSS at 24 hours and 90 days; TICl 2b-3; ICA revascularization, Procedural complications; Early symptomatic ICH; Stroke recurrence at 90 days

1. Sivan-Hoffmann, R., et al. (2017). "Stent-Retriever Thrombectomy for Acute Anterior Ischemic Stroke with Tandem Occlusion: A Systematic Review and Meta-Analysis." *Eur Radiol* 27(1): 247-254.

2. Steglich-Arnholm, H., et al. (2015). "Thrombectomy assisted by carotid stenting in acute ischemic stroke management: benefits and harms." *J Neuro* 262(12): 2668-2675.

3. Behme, D., et al. (2017). "Emergent Carotid Stenting After Thrombectomy in Patients With Tandem Lesions." *Stroke*.