Therapeutics

Adding neurovascular thrombectomy to IV t-PA reduced disability in acute ischemic stroke

Clinical impact ratings: (EM) ★★★★★★☆ (N) ★★★★★★★

Question

In patients with acute ischemic stroke and occlusion of an intracranial vessel, does adding rapid neurovascular thrombectomy to IV tissue plasminogen activator (t-PA) reduce disability?

Methods

Design: Randomized controlled trial (RCT) using a minimization algorithm (Solitaire with the Intention for Thrombectomy as Primary Endovascular Treatment [SWIFT PRIME] trial). ClinicalTrials.gov NCT01657461.

Allocation: {Concealed}*.†

Blinding: Blinded† {data collectors, outcome assessors, and safety committee}*.

Follow-up period: 90 days.

Setting: 39 clinical centers in the USA and Europe.

Patients: 196 adults 18 to 80 years of age (mean age 66 y, 51% men) with clinical signs of acute ischemic stroke; prestroke modified Rankin score (mRs) ≤ 1; National Institutes of Health Stroke Scale (NIHSS) score 8 to 29; initiation of IV t-PA within 4.5 hours of symptom onset; and thrombotic occlusion in the intracranial internal carotid, M1 segment of the middle cerebral artery, or carotid terminus confirmed by computed tomography angiography (CTA) or magnetic resonance angiography (MRA). Exclusion criteria included inability to treat within 6 hours of symptom onset and within 1.5 h of CTA or MRA to groin puncture, rapid neurologic improvement, other contraindications to IV t-PA or stent retrieval, or comorbid conditions that could compromise evaluations or survival.

Intervention: Neurovascular thrombectomy with the Solitaire Flow Restoration or Solitaire 2 device plus IV t-PA (n = 98) or IV t-PA alone (n = 98).

Outcomes: Shift in distribution of disability (mRs scores) at 90 days. Secondary outcomes included functional independence (mRs score 0 to 2) and death at 90 days, and change in neurologic deficit (NIHSS score) at 27 hours. Safety outcomes included serious adverse events at 90 days.

Patient follow-up: 95% {intention-to-treat analysis}*.

Main results

The study was stopped early when prespecified stopping criteria for efficacy were met. Thrombectomy had greater reductions in disability (shift in mRs scores at 90 d, $P < 0.001$) and neurologic deficit at 27 hours (reduction in NIHSS scores −8.5 vs −3.9, $P < 0.001$) than t-PA alone. Thrombectomy increased likelihood of functional independence compared with t-PA only, but groups did not differ for death or serious adverse events (Table).

Conclusion

In patients with acute ischemic stroke and occlusion of an intracranial vessel, adding rapid neurovascular thrombectomy with the Solitaire device to IV tissue plasminogen activator reduced disability.

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*Information provided by author.

†See Glossary.

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Commentary

The SWIFT PRIME trial confirms the results of 4 other RCTs of patients with acute ischemic stroke due to occlusion of the intracranial proximal anterior circulation (1-4). The 5 studies, with a total of 1288 patients, found that adding intraarterial thrombectomy to standard care, including IV t-PA, resulted in a 1.7- to 2.6-fold increased likelihood of improving by ≥ 1 point on the mRs.

In SWIFT PRIME, the first 71 patients required evidence of a small core of infarction and a large ischemic penumbra on CT or MR perfusion imaging, similar to EXTEND IA (2). However, the next 125 patients required only an Alberta Stroke Program Early CT Score > 6 on plain CT or MR diffusion-weighted imaging, as an approximation for a small-to-moderate core infarction, as in ESCAPE (3) and REVASCAT (4). It is uncertain which imaging and threshold measures of volume of core infarction and penumbral mismatch may optimize patient selection and possibly extend the time window for effective endovascular therapy beyond 6 hours.

Implementation of endovascular therapy in clinical practice will require local algorithms to enable emergency medical services to rapidly and accurately identify, triage, and transport the 10% of stroke patients suitable for endovascular therapy directly to comprehensive stroke centers where appropriately resourced, immediately accessible, and specialized stroke teams with neuroimaging and interventional expertise can restore reperfusion within 90 minutes of arrival.

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References

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2. **Campbell BC, Mitchell PJ, Kleinig TJ, et al; EXTEND-IA Investigators.** Endovascular therapy for ischemic stroke with perfusion-imaging selection. N Engl J Med. 2015;372:1009-18.

3. **Goyal M, Demchuk AM, Menon BK, et al; ESCAPE Trial Investigators.** Randomized assessment of rapid endovascular treatment of ischemic stroke. N Engl J Med. 2015;372:1019-30.

4. **Jovin TG, Chamorro A, Cobo E, et al; REVASCAT Trial Investigators.** Thrombectomy within 8 hours after symptom onset in ischemic stroke. N Engl J Med. 2015;372:2296-306.

Neurovascular thrombectomy plus t-PA vs t-PA alone in acute ischemic stroke‡

Outcomes	Event rates		At 90 d	
	Thrombectomy + t-PA	t-PA alone	RBI (95% CI)	NNT (CI)
Functional independence§	60%	35%	70% (23 to 133)	5 (3 to 13)
			RRR (CI)	
Death	9%	12%	26% (−68 to 67)	Not significant
			RRI (CI)	**NNH**
Serious adverse event	36%	31%	15% (−22 to 72)	Not significant

‡t-PA = tissue plasminogen activator; other abbreviations defined in Glossary. RBI, RRR, RRI, NNT, and CI calculated from control event rates and risk ratios in article.

§Modified Rankin score 0 to 2; range 0 (no symptoms) to 6 (death).