CAROTID STENTING: CURRENT STATE, CURRENT QUESTIONS

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Disclosures

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Objectives

- Current indications for CAS.
- Review the high-risk criteria for poor outcomes with CEA.
- Understand the debate for CAS with respect to age, type of protection, etc.

TABLE 2 Multidisciplinary Carotid Stent Guidelines

Indication	Recommendation	Level of Evidence	Guideline (Ref. #)
Symptomatic high surgical risk: Among patients with symptomatic severe stenosis (>70%) in whom the stenosis is difficult to access surgically, medical conditions are present that greatly increase the risk of surgery, or when other specific circumstances exist, such as radiation-induced stenosis or restenosis after CEA, CAS may be considered when performed by an experienced operator	Class IIa	B	American Heart Association and American Stroke Association guideline (26)
It is reasonable to choose CAS over CEA when revascularization is indicated in patients with neck anatomy unfavorable for arterial surgery	Class IIa	B	Multisociety guideline (27)
Symptomatic average surgical risk			
CAS is indicated as an alternative to CEA for symptomatic patients at average or low risk of complications associated with endovascular intervention when the diameter of the lumen of the internal carotid artery is reduced by >70% as documented by noninvasive imaging or >50% as documented by catheter angiography and the anticipated rate of periprocedural stroke or mortality is <6%.	Class I	B	Multisociety guideline (27)
CAS is indicated as an alternative to CEA for symptomatic patients at average or low risk of complications associated with endovascular intervention when the diameter of the lumen of the internal carotid artery is reduced by >70% by noninvasive imaging or >50% by catheter angiography	Class I	B	American Heart Association and American Stroke Association guideline (26)
Asymptomatic high surgical risk patients			
Selection of asymptomatic patients for carotid revascularization should be guided by an assessment of comorbid conditions, life expectancy, and other individual factors and should include a thorough discussion of the risks and benefits of the procedure with an understanding of patient preferences	Class I	C	Multisociety guideline (27)
It is reasonable to choose CAS over CEA when revascularization is indicated in patients with neck anatomy unfavorable for arterial surgery	Class IIa	B	Multisociety guideline (27)
Asymptomatic average surgical risk patients			
Prophylactic CAS might be considered in highly selected patients with asymptomatic carotid stenosis (minimum 60% by angiography, 70% by validated Doppler ultrasound), but its effectiveness compared with medical therapy alone in this situation is not well established	Class IIb	B	Multisociety guideline (27)

Multisociety guideline endorsed by the American College of Cardiology, American Heart Association, American Stroke Association, American Academy Neurology, American Association Neuroscience, American Association of Neurological Surgeons and Nurses, American College Radiology, American Society of Neuroradiology, Society of Cardiovascular Angiography Interventions, Society of Intervention Radiology, Society of Vascular Medicine, Society of Vascular Surgery.

Abbreviations as in Table 1.

Simplified…

	Medicare Guidelines
Symptomatic and High-risk ≥ 70%	CAS reasonable over CEA
Symptomatic and High-risk 50-60%	CEA. CAS only if in a trial
Symptomatic Average to Low Risk	CEA. CAS only if in a trial
Asymptomatic	CEA. CAS only if in a trial

http://www.cms.gov/medicare-coverage-database/details/ncdetails.aspx?NCDId=201&ncdver=9&bc=AAAAgAAAAAAA&.

What are the High-Risk Criteria?

TABLE 1 Features Associated With High Risk of Carotid Endarterectomy

Medical Comorbidity	Anatomic Criteria
Elderly (>75/80 yrs)	Surgically inaccessible lesions
Congestive heart failure (NYHA functional class III/IV)	At or above C2
Unstable angina (CCS III/IV)	Below the clavicle
CAD with ≥2 vessels ≥70% stenosis	Ipsilateral neck irradiation
Recent myocardial infarction (≤30 days)	Spinal immobility of the neck
Planned open heart surgery (≤30 days)	Contralateral carotid artery occlusion
Ejection fraction ≤30%	Laryngeal palsy
Severe pulmonary disease (COPD)	Tracheostoma
Severe renal disease	Previous ipsilateral CEA or neck surgery

Carotid Stenting Questions

Controversies of Carotid Stenting

- SAPPHIRE study (NEJM. 2004;351.) was the first study comparing CEA and CAS in high-risk patients.
- A study with both asymptomatic and symptomatic patients.
- Death and MI were endpoints.

Stroke. 2011;42:3484-3490;

Controversies of Carotid Stenting

Combined Complications to 360 Days	Randomized Stent (N=167)	Randomized CEA (N=167)	P-value*	Non-Randomized Stent (N=406)
MAE*	12.0% (20)	19.2% (32)	0.10	15.8% (64)
MAE without Non-Neurologic Deaths from 31 days to 360 days[6]	6.0% (10)	12.6% (21)	0.06	10.3% (42)
Death (All Cause)	7.2% (12)	12.6% (21)	0.14	10.1% (41)
Myocardial Infarction (Q or Non-Q)	3.0% (5)	7.2% (12)	0.13	2.7% (11)
Q Wave MI	0.0% (0)	1.2% (2)	0.50	0.5% (2)
Non-Q Wave MI	3.0% (5)	6.0% (10)	0.29	2.2% (9)
Stroke	6.0% (10)	7.2% (12)	0.83	9.1% (37)
Major Ipsilateral Stroke	0.6% (1)	3.0% (5)	0.21	3.2% (13)

http://www.accessdata.fda.gov/cdrh_docs/pdf3/p030047c.pdf

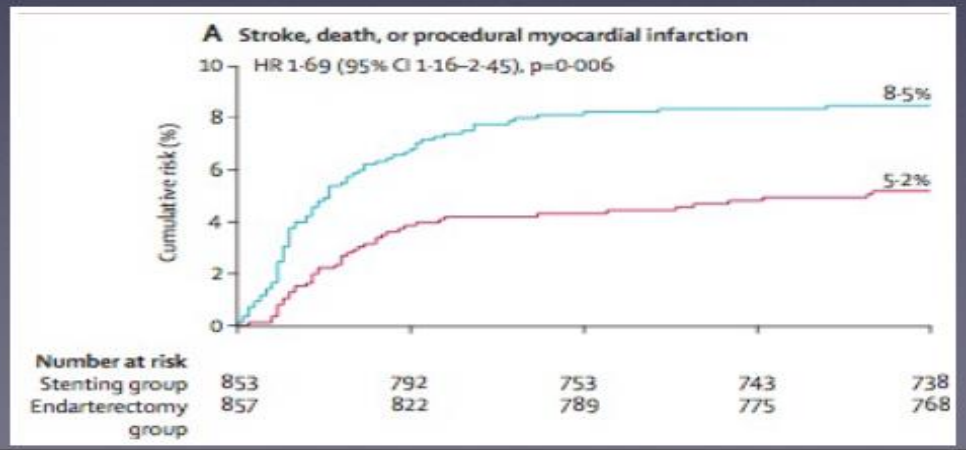
Table 3. Risk of Stroke or Death and Other Treatment-Related Outcomes within 30 Days after Endarterectomy or Stenting.*

Outcome Event	Endarterectomy (N=259)	Stenting (N=261)	Unadjusted Relative Risk (95% CI)	P Value
	no. of patients (%)			
Nonfatal stroke	7 (2.7)†	23 (8.8)‡	3.3 (1.4–7.5)	0.004
Symptoms lasting 7 days or more	6 (2.3)	20 (7.7)		
Nondisabling	6 (2.3)	16 (6.1)		
Disabling§	1 (0.4)	7 (2.7)		
Death	3 (1.2)	2 (0.8)	0.7 (0.1–3.9)	0.68
Fatal stroke	2 (0.8)†	1 (0.4)‡		
Other cause	1 (0.4)¶	1 (0.4)‖		
Any stroke or death	10 (3.9)	25 (9.6)	2.5 (1.2–5.1)	0.01

NEJM. 2006;355;1660-1671.

	Number (%)		Absolute difference*	Odds ratio
	CAS (n=599)	CEA (n=584)	CAS–CEA (90% CI)	CAS/CEA (95% CI)
Primary endpoint	41 (6·84%)	37 (6·34%)	0·51 (-1·89 to 2·91)	1·09 (0·69 to 1·72)

Lancet. 2006;368;1239-1247.



Lancet. 2010;375;985-997

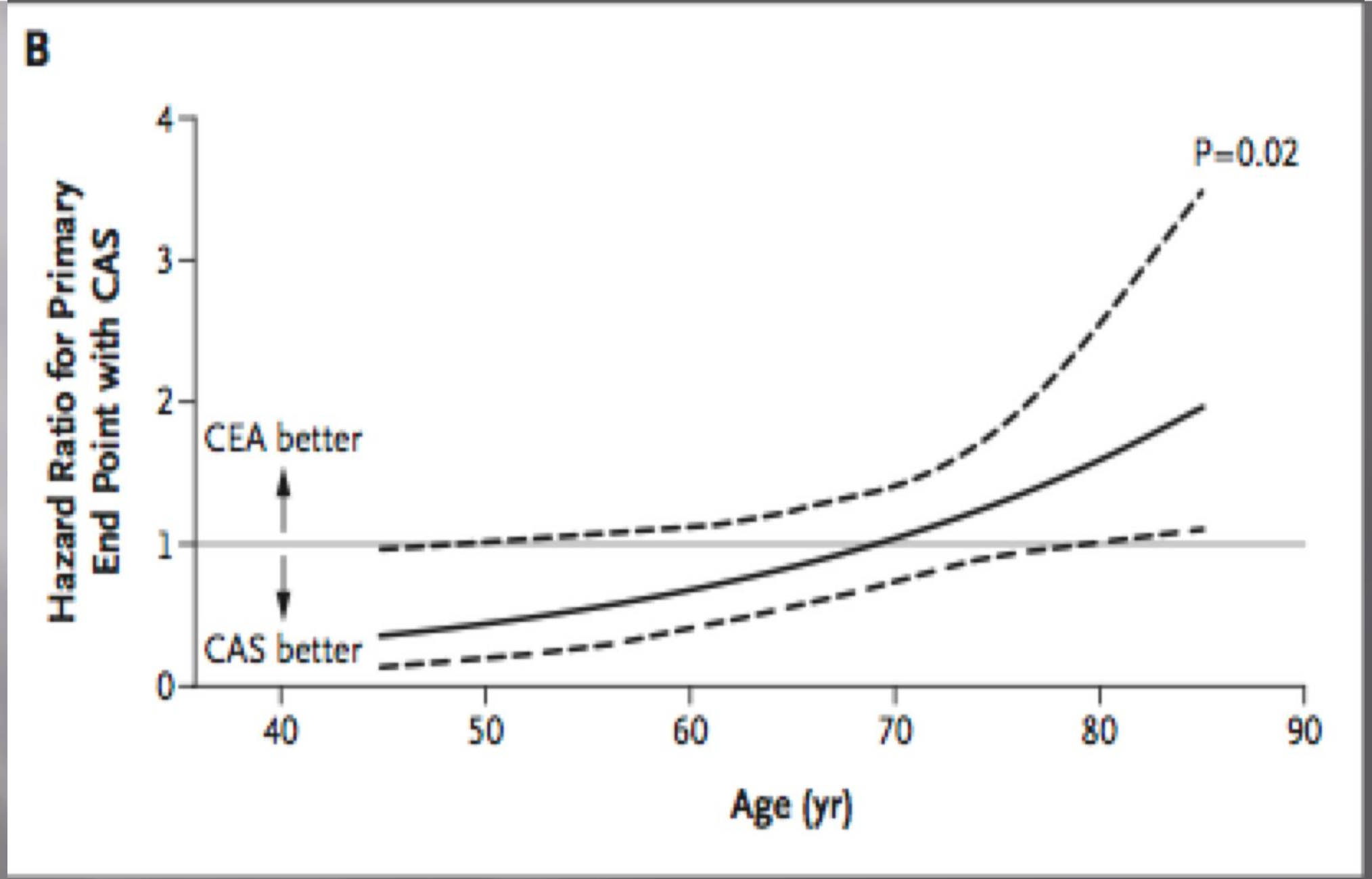
Acceptable rates of complications

	Acceptable rate of stroke
Symptomatic and High-risk ≥ 70%	6%
Symptomatic and High-risk 50-60%	6%
Symptomatic Average to Low Risk	3-5%
Asymptomatic	2-3%

Age with CAS

- Age ≥ 80 was considered a high-risk group in NASCET and SAPPHIRE.
- Elderly were excluded from the lead in phase of CREST due to excessive events, but allowed in the trial if there were no other high risk criteria.

Stroke. 2011;42:3484-3490;



10.1056/NEJMoa0912321

Age Conundrum

- Age by itself may not be a high risk criteria, but may be associuated with other high risk factors which would favor CAS over CEA. We advocate for screening all patients and stratifying them to the appropriate treatment based on their risk profile.
- The trials do not reconcile with each other. Age $\geq$ 80 is still considered a high-risk criterion based on re-imbursement.
- We advocate that complication rates of CEA or CAS operators should remain low to justify equipoise in a particular institution.

Is there an advantage to the type of stent or protection device?

- No evidence that closed cell stents offer more protection from stroke than an open design.

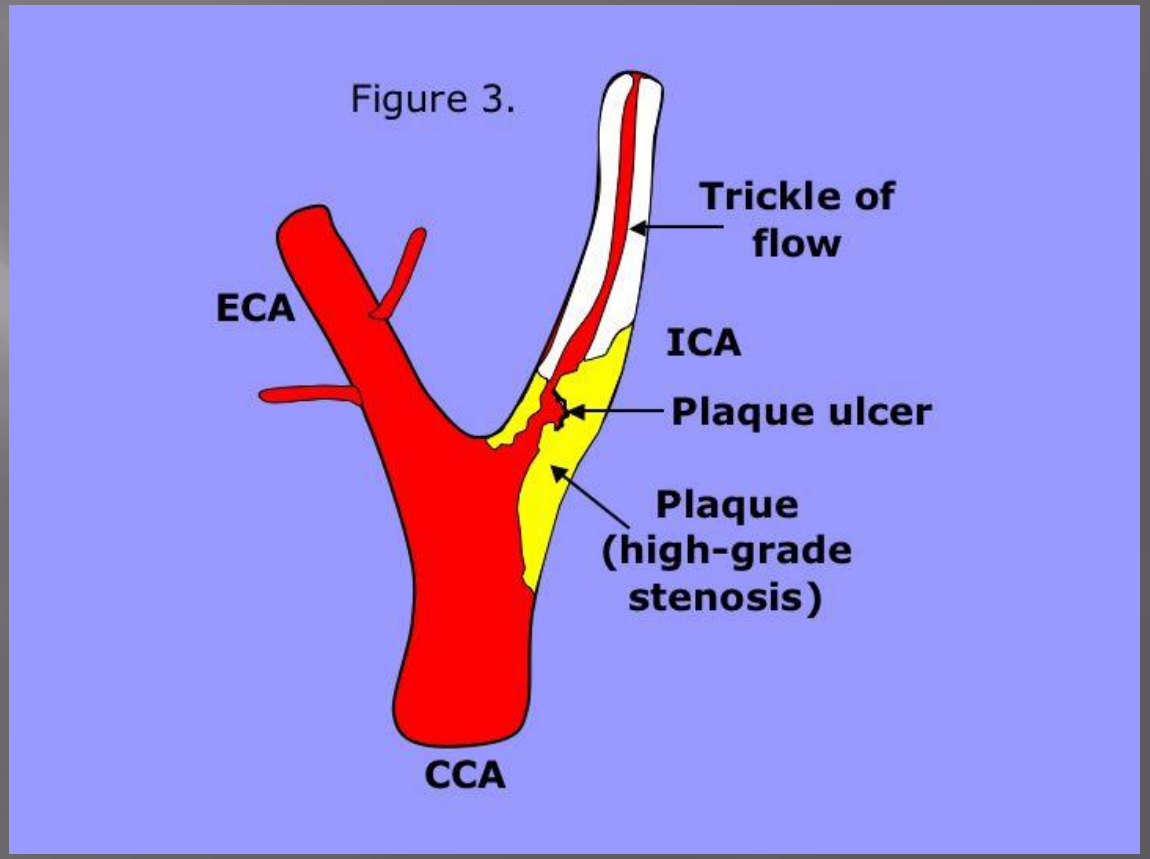
- The same can be said regarding the type of protection device. Data is conflicting in the amount of cerebral emboli is seen between the two techniques, but there is no difference in outcomes.

JACC VOL. 64, NO. 7, 2014

(J Am Coll Cardiol 2012;59:1383-9)

String Sign

- Excluded from NASCET and CAS trials.
- Exhibit a high risk of stroke.
- Feasible to treat with stenting.
- Advocate searching for other high- surgical risk criteria for stenting.



JACC: CARDIOVASCULAR INTERVENTIONS, VOL. 3, NO. 3, 2010
MARCH 2010:298–304

When to do the Surgery?

- The data from surgical literature suggests the worse outcomes occurred in those receiving an operation within 2 weeks. Maybe due to hyperperfusion or "stroke in evolution."
- Meta-analyses of clinical trials suggest that the risk of recurrent stroke is greatest in the first 2 weeks while the risk of surgical complications are low.
- Risk of complications are lower for CAS in < 4 weeks compared to > 4 weeks.

JAMA. 1969; 209:1889-1895.
Lancet. 2004;363;915-924.
JNIS. 2010;2:55-58.

Acute Stroke

Emergent Stenting of Extracranial Internal Carotid Artery Occlusion in Acute Stroke Has a High Revascularization Rate

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Background and Purpose—Acute ischemic stroke attributable to extracranial internal carotid artery (ICA) occlusion is frequently associated with severe disability or death. In selected cases, revascularization with carotid artery stenting has been reported, but the safety, recanalization rate, and clinical outcomes in consecutive case series are not known.

Methods—We retrospectively reviewed all of the cases of ICA occlusions that underwent cerebral angiography with the intent to revascularize over a 38-month period. Two groups were identified: (1) patients who presented with an acute clinical presentation within 6 hours of symptom onset (n=15); and (2) patients who presented subacutely with neurologic fluctuations because of the ICA occlusion (n=10).

Results—Twenty-five patients with a mean age of 62±11 years and median National Institutes of Health Stroke Scale (NIHSS) of 14 were identified. Twenty-three of the 25 patients (92%) were successfully revascularized with carotid artery stenting. Patients in group 1 were younger and more likely to have a tandem occlusion and higher baseline NIHSS when compared with group 2. Patients in group 2 were more likely to show early clinical improvement defined as a reduction of their NIHSS by ≥4 points and a modified Rankin Score of ≤2 at 30-day follow-up. Two clinically insignificant adverse events were noted: 1 asymptomatic hemorrhage and 1 nonflow-limiting dissection.

Conclusions—Endovascular treatment of acute ICA occlusion appears to have a high-recanalization rate and be relatively safe in our cohort of patients with acute ICA occlusion. Future prospective studies are necessary to determine which patients are most likely to benefit from this form of therapy. (***Stroke*. 2005;36:2426-2430.**)

Acute Stroke

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Endovascular Treatment of Tandem Extracranial/ Intracranial Anterior Circulation Occlusions

Preliminary Single-Center Experience

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Background and Purpose—Acute ischemic stroke due to tandem occlusions of the extracranial internal carotid artery and intracranial arteries has a poor natural history. We aimed to evaluate our single-center experience with endovascular treatment of this unique stroke population.

Methods—Consecutive patients with tandem occlusions of the internal carotid artery origin and an intracranial artery (ie, internal carotid artery terminus, M1 middle cerebral artery, or M2 middle cerebral artery) were studied retrospectively. Treatment consisted of proximal revascularization with angioplasty and stenting followed by intracranial intervention. Endpoints were recanalization of both extracranial and intracranial vessels (Thrombolysis In Myocardial Ischemia ≥2), parenchymal hematoma, and good clinical outcome (modified Rankin Scale ≤2) at 3 months.

Results—We identified 77 patients with tandem occlusions. Recanalization occurred in 58 cases (75.3%) and parenchymal hematoma occurred in 8 cases (10.4%). Distal embolization occurred in 3 cases (3.9%). In 18 of 77 patients (23.4%), distal (ie, intracranial) recanalization was observed after proximal recanalization, obviating the need for distal intervention. Good clinical outcomes were achieved in 32 patients (41.6%). In multivariate analysis, Thrombolysis In Myocardial Ischemia ≥2 recanalization, baseline National Institutes of Health Stroke Scale score, baseline Alberta Stroke Programme Early CT score, and age were significantly associated with good outcome.

Conclusions—Endovascular therapy of tandem occlusions using extracranial internal carotid artery revascularization as the first step is technically feasible, has a high recanalization rate, and results in an acceptable rate of good clinical outcome. Future randomized, prospective studies should clarify the role of this approach. **(*Stroke*. 2011;42:1653-1657.)**

Summary

- The decision for carotid stenting is based more on the symptomatic status and surgical risk of the patient.
- An active neuro-interventional presence can guide general neurologists in the decision tree process.
- Vigilance for outcomes, particularly in the elderly, will support the practice.