

# Stenting was noninferior to endarterectomy in patients with severe carotid artery stenosis and coexisting conditions

Yadav JS, Wholey MH, Kuntz RE, et al. **Protected carotid-artery stenting versus endarterectomy in high-risk patients.** *N Engl J Med.* 2004;351:1493-501.

## QUESTION

In patients with severe carotid artery stenosis (CAS) and coexisting conditions, is carotid artery stenting with an emboli-protection device noninferior to carotid endarterectomy?

## METHODS

**Design:** Randomized controlled trial (Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy [SAPPHIRE] trial).

**Allocation:** Concealed.\*

**Blinding:** {Unblinded}†.\*

**Follow-up period:** 1 year.

**Setting:** 29 centers in the United States.

**Patients:** 334 patients ≥ 18 years of age (mean age 73 y, 67% men) with unilateral or bilateral atherosclerotic or restenotic lesions in native carotid arteries who had ≥ 1 coexisting condition that potentially increased the risk posed by carotid endarterectomy (clinically significant cardiac disease, severe pulmonary disease, contralateral carotid occlusion, contralateral laryngeal nerve palsy, previous radical neck surgery or radiation therapy to the neck, recurrent stenosis after endarterectomy, or age > 80 y). Patients with symptomatic CAS were required to have stenosis of ≥ 50% of the luminal diameter

and those with asymptomatic CAS were required to have stenosis of ≥ 80% determined by carotid ultrasonography. Exclusion criteria included ischemic stroke in the previous 48 hours, presence of intraluminal thrombus, total occlusion of target vessel, and intracranial aneurysm > 9 mm in diameter.

**Intervention:** Carotid artery stenting with an emboli-protection device (*n* = 167), or carotid endarterectomy (*n* = 167).

**Outcome:** Cumulative incidence of death, stroke, or myocardial infarction (MI) at 30 days plus death or ipsilateral stroke between 31 days and 1 year.

**Patient follow-up:** 100% (intention-to-treat analysis).

## MAIN RESULTS

Carotid artery stenting with an emboli-protection device was not inferior to carotid endarterectomy in preventing the cumulative incidence of death, stroke, or MI at 30 days plus death or ipsilateral stroke between 31 days and 1 year (Table).

## CONCLUSION

In patients with severe carotid artery stenosis and coexisting conditions, carotid artery stenting with an emboli-protection device was noninferior to carotid endarterectomy.

*Source of funding:* Cordis.

*For correspondence:* Dr. J.S. Yadav, Cleveland Clinic Foundation, Cleveland, OH, USA. E-mail [yadavj@ccf.org](mailto:yadavj@ccf.org).

\*See Glossary.

†Information provided by author.

### Carotid artery stenting vs endarterectomy in patients with severe carotid artery stenosis and coexisting conditions‡

Outcome	Stenting	Endarterectomy	Difference (95% CI)
Cumulative incidence of death, stroke, or myocardial infarction at 30 d plus death or ipsilateral stroke between 31 d and 1 y	12.2%	20.1%	-7.9% (-16.4 to 0.7) <sup>§</sup>

‡CI defined in Glossary.

§Not significant.

## COMMENTARY

Before the SAPPHIRE trial, 4 small randomized trials (1-4) suggested that angioplasty, stenting, or both were associated with a slightly higher procedural risk than endarterectomy and a higher rate of restenosis. However, improvements in cerebral protection devices promised to reduce the procedural risks and prompted evaluation in SAPPHIRE and larger ongoing trials.

The SAPPHIRE trial suggests that stenting with a protection device is an appropriate alternative to endarterectomy in patients at increased risk for perioperative stroke or MI. However, the overall estimates of benefit and risk are imprecise due to the small sample size; further, the long-term effects of stenting beyond 1 year are not known. Moreover, the results of SAPPHIRE are not generalizable to patients at lower risk or to interventionalists who have not achieved comparable results after prospective and independent audit (5).

The use of carotid stenting is likely to increase, but whether it will be confined to cases in which endarterectomy is technically difficult or risky will depend on the overall results of larger trials comparing the short- and long-term benefits and risks of stenting and endarterectomy and the results of prespecified analyses of subgroups (e.g., neurologically symptomatic and asymptomatic stenosis, severity of stenosis, time since symptoms, age, sex, and antiplatelet regimen) (6).

*Graeme Hankey, MBBS, FRCP, FRACP  
Royal Perth Hospital and University of Western Australia  
Perth, Western Australia, Australia*

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