

**Treatment of Carotid Stenosis in Asymptomatic
Non-Octogenarian, Standard Risk Patients with
Stenting Versus Endarterectomy:
A Pooled Analysis of the CREST and ACT 1
Trials**

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American Stroke Association

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Disclosures

- **JM: Research grant support: Abbott, Cook, Medtronic, Endologix, Gore.**
- The Xact carotid stent is off-label or investigational for standard risk patients.
- CREST was sponsored by NINDS and Abbott Vascular
- ACT I was sponsored by Abbott Vascular

Background

Asymptomatic severe carotid stenosis is the most common indication for carotid intervention in the United States.

Only two of the five recent, large randomized trials have compared carotid stenting (CAS) and carotid endarterectomy (CEA) in asymptomatic patients.

Pooled analysis may better inform decision making about these procedures.

CREST & ACT 1

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Stenting versus Endarterectomy for Treatment of Carotid-Artery Stenosis

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Randomized Trial of Stent versus Surgery for Asymptomatic Carotid Stenosis

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CREST & ACT 1

Carefully selected surgeons and interventionalists
with lead-in phases

Single stent and routine distal embolic protection

Acculink/Accunet for CREST & Xact/Emboshield for ACT 1

Independent neurologic assessment

Routine cardiac enzyme screening

Central clinical event adjudication committees

DSMB oversight

Methods

Trial leadership met and agreed to patient level, pre-specified, pooled analysis:

Primary endpoint composite of death, stroke, or myocardial infarction in the periprocedural period, or any ipsilateral stroke within 4 years after randomization

All randomized, non-octogenarian, asymptomatic subjects

Analysis by university biostatisticians who replicated prior trial findings with databases in house

Methods

2544 (1637 CAS, 907 CEA) asymptomatic patients less than 80 years old (upper age eligibility of ACT 1) were analyzed:

CREST 1091 (548 CAS, 543 CEA)

ACT 1 1453 (1089 CAS, 364 CEA), 3:1 weighted randomization

Demographics

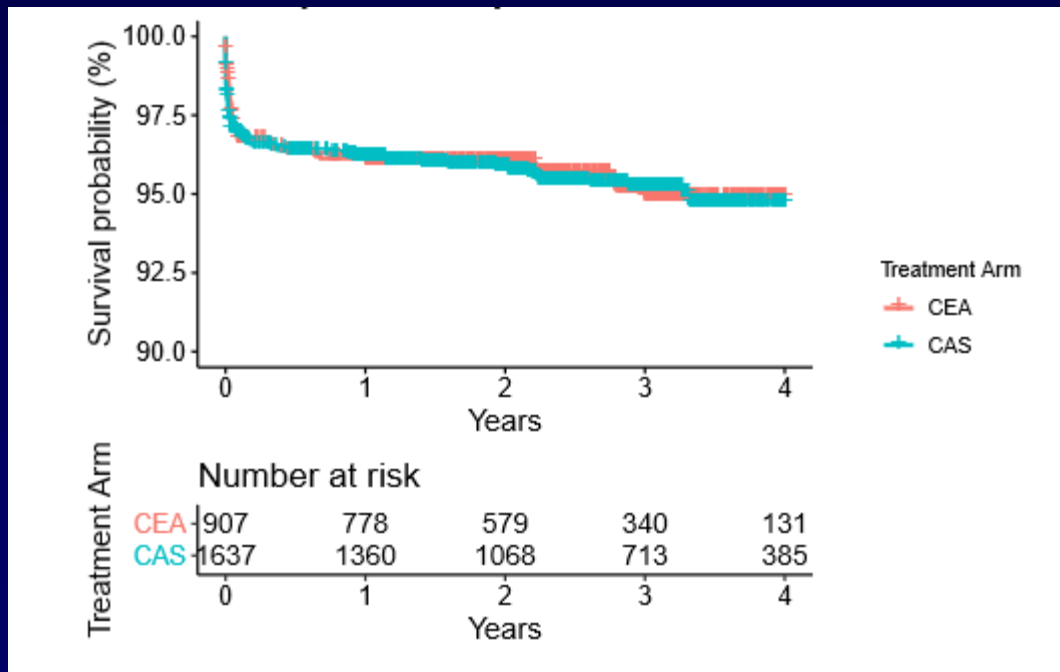
	CAS (N=1637)	CEA (N=907)	p-value
Age (years) [Mean +/- SD]	67.7 +/- 7.07	68.25 +/- 7.15	0.062
Age >= 65 [N (%)]	1135 (69.3)	643 (70.9)	0.417
Sex: Male [N (%)]	1021 (62.4)	574 (63.3)	0.669
Race: White [N (%)]	1501 (91.8)	845 (93.2)	0.244
Hypertension [N (%)]	1470 (89.8)	801 (88.5)	0.315
Hyperlipidemia [N (%)]	1477 (90.3)	813 (89.9)	0.781
Current Cigarette Smoking [N (%)]	418 (25.6)	196 (21.8)	0.033
Diabetes Mellitus [N (%)]	573 (35)	305 (33.7)	0.542

Results: Primary Endpoint

Composite of periprocedural death, stroke, myocardial infarction or 4 year ipsilateral stroke is similar:

CAS 5.3% vs CEA 5.1%

Hazard ratio 1.02, 95% CI, 0.7 to 1.5, P=0.91



Results: Component Endpoints Periprocedural

Periprocedural component rates:

	CAS vs CEA	
Stroke:	2.7% vs 1.5%	P=0.07
Myocardial infarction:	0.6% vs 1.7%	P=0.01
Death:	0.1% vs 0.2%	P=0.62
Stroke or death:	2.7% vs 1.6%	P=0.07

Results: Component Endpoint Non-Procedural Ipsilateral Stroke

After periprocedural period, rate of ipsilateral stroke is similar:

CAS 2.3%

CEA 2.2%

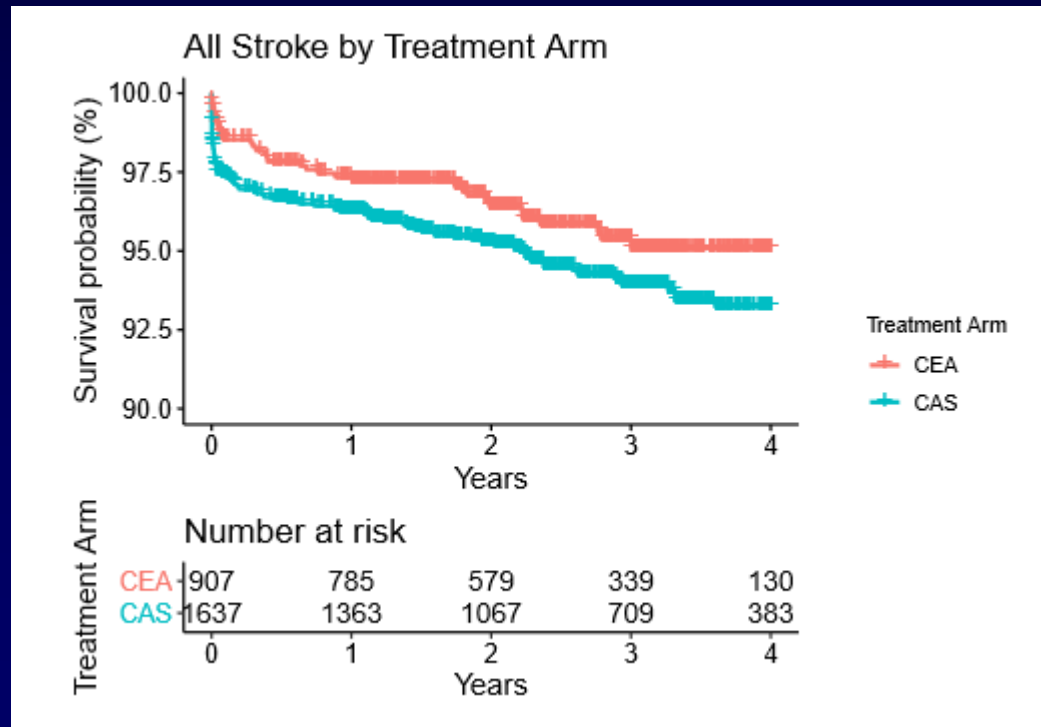
P=0.97

Secondary Results: Survival from Any Stroke

Cumulative 4 year rate of stroke-free survival (Ipsilateral and non-ipsilateral):

CAS 93.2% vs CEA 95.1%

P=0.10

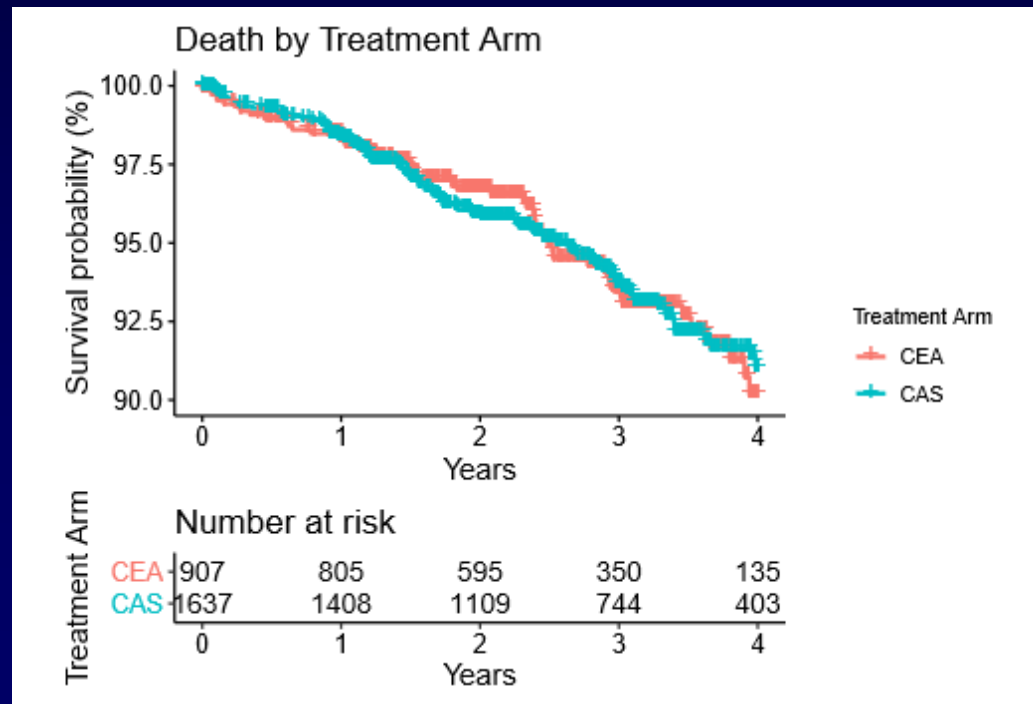


Secondary Results: Survival

Cumulative 4 year survival:

CAS 91% vs CEA 90.2%

P=0.923



Summary

This pooled analysis is the largest of randomized standard risk asymptomatic patients.

Carotid stenting and carotid endarterectomy have similar rates of composite of procedural complications and four year ipsilateral stroke.

Thank you

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