Question 11

Which of the following patients is NOT an appropriate candidate for CAS according to the SAPPHIRE trial?

A. An 82y woman with recent TIA, poorly controlled hypertension and 60% RICA stenosis
B. 72y man with MI 3 weeks ago and an 80% RICA stenosis
C. 60y diabetic man with ischemic CVA 6 weeks ago resulting in residual left upper extremity paresis with 90% LICA stenosis
D. Asymptomatic 85y man with NYHA class III heart failure, severe emphysematous lung disease and bilateral 80% ICA stenoses

XLPAD
Excellence in Peripheral Arterial Disease

Question 11

Which of the following patients is NOT an appropriate candidate for CAS according to the SAPPHIRE trial?

A. An 82y woman with recent TIA, poorly controlled hypertension and 60% RICA stenosis

B. 72y man with MI 3 weeks ago and an 80% RICA stenosis

C. 60y diabetic man with ischemic CVA 6 weeks ago resulting in residual left upper extremity paresis with 90% LICA stenosis

D. Asymptomatic 85y man with NYHA class III heart failure, severe emphysematous lung disease and bilateral 80% ICA stenoses

XLPAD
Excellence in Peripheral Arterial Disease

SAPPHIRE Trial

- Randomized trail of high-risk CEA vs. CAS
- Non-inferiority design, n=334
- Symptomatic≥50% ICA stenosis, asymptomatic ≥80%
- Results:
  - CAS non-inferior to CEA in high-risk patients
  - CAS lower 30d death, MI , stroke by 39%
  - CAS lower target vessel revascularization and shorter hospital stay
  - CAS higher event-free survival (88% vs 79% CEA, p=0.048)

XLPAD
Excellence in Peripheral Arterial Disease

SAPPHIRE Trial High-Risk Features

Clinical

- ≥80y
- CHF NYHA III-IV
- MI <4wk
- LVEF<30%
- Open heart surgery <6wk
- CCS III-IV angina
- Laryngeal nerve palsy

Anatomic

- Lesion above C2
- Lesion below clavicle
- Neck radiation
- Neck dissection
- Prior CEA (restenosis)
- Tandem lesions
- C/L ICA occlusion

XLPAD
Excellence in Peripheral Arterial Disease

SAPPHIRE

723 patients with high risk for CEA

- ≥50% stenosis in symptomatic patients
- ≥80% stenosis in asymptomatic patients
- ≥1 co-morbid condition
- Team of vascular surgeon, neurologist and interventionalist determined if patient was too high risk for randomization; these patients were entered in a registry and not randomized

Treatment Group A
Stenting with protection
(n = 156)

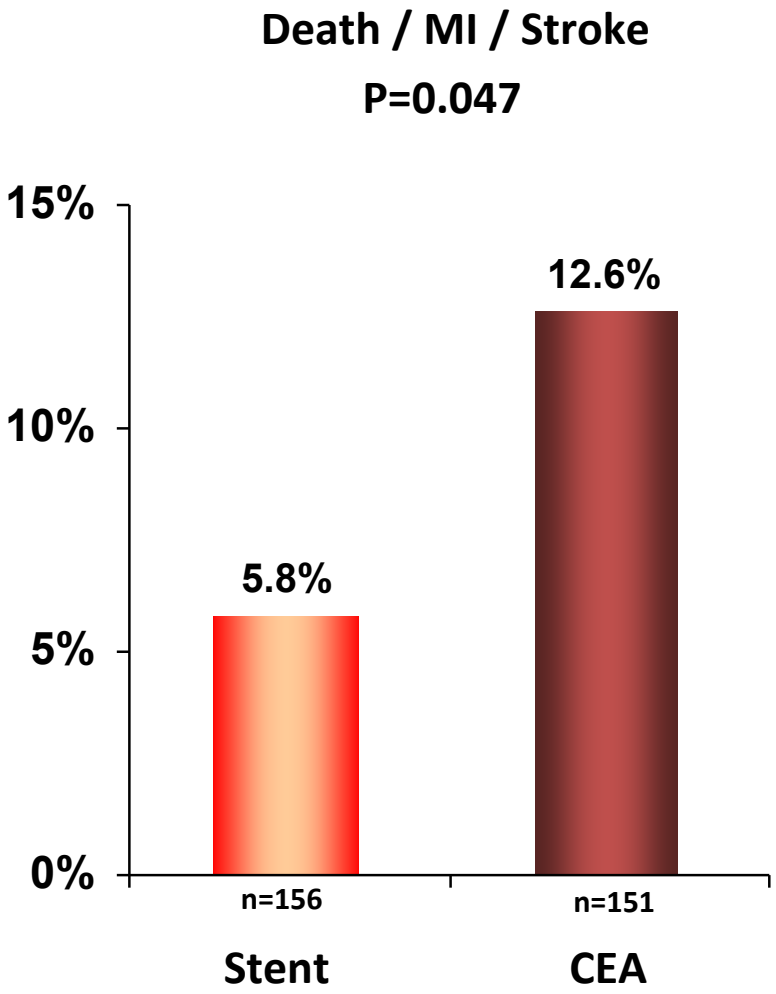
Treatment Group B
Carotid endarterectomy
(n = 151)

Endpoints:

- Primary – 30 day Death, Stroke or MI

XLPAD
Excellence in Peripheral Arterial Disease

SAPPHIRE: Primary Endpoint

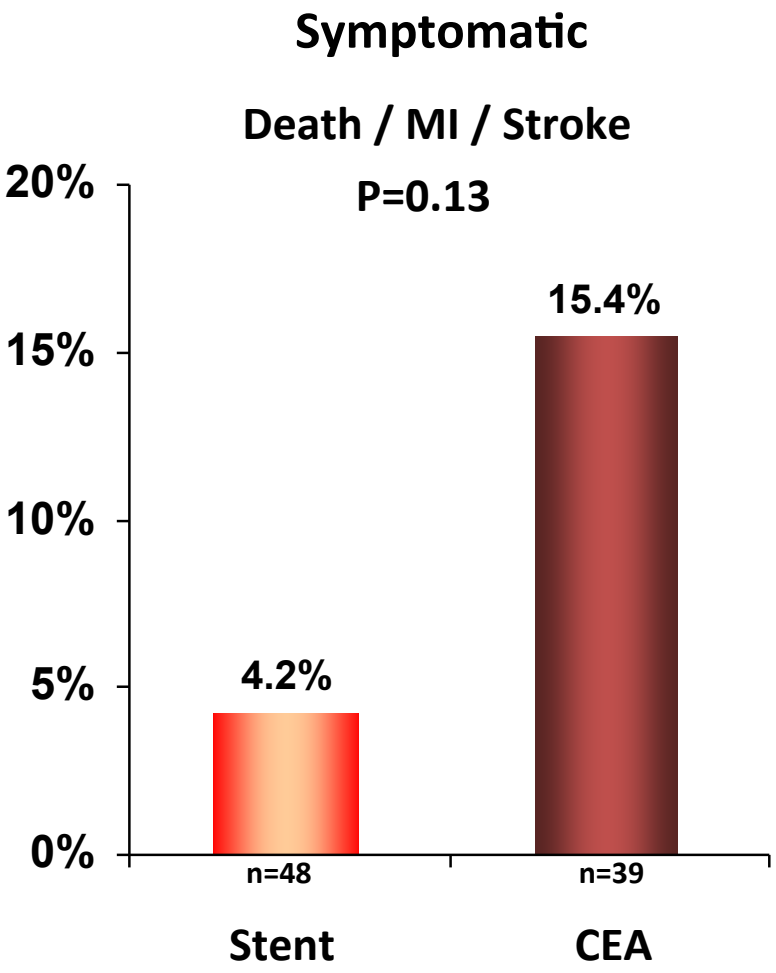


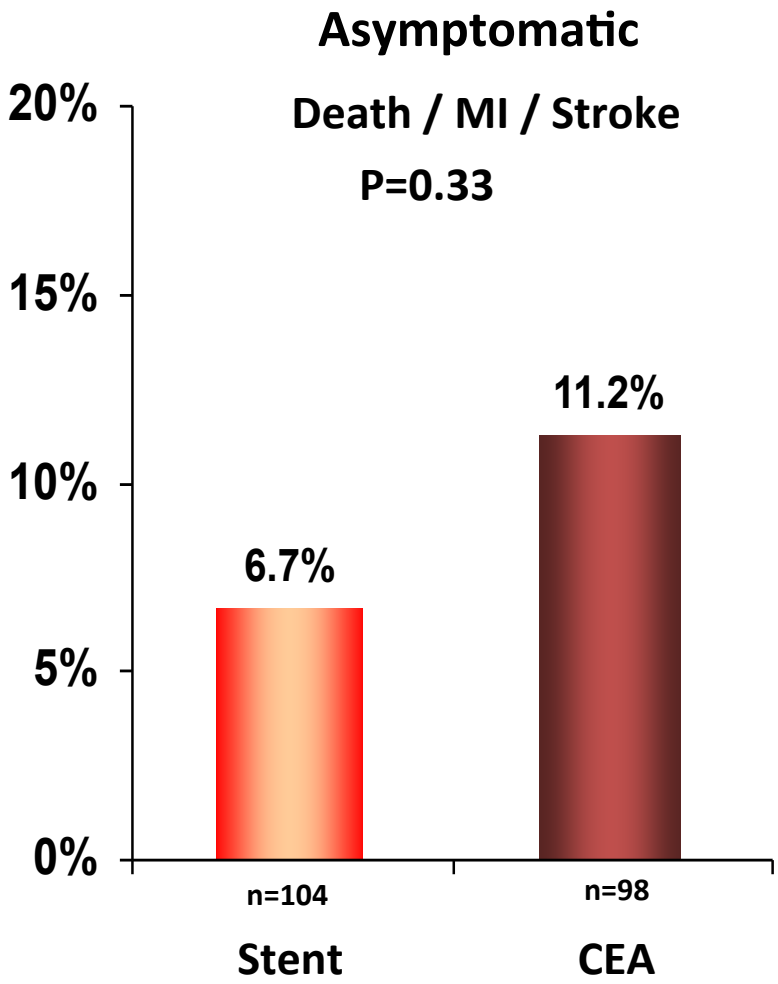
- The trial was discontinued early due to low enrollment

- However, despite the lower than expected enrollment, the rate of the 30 day composite primary endpoint was lower in the stent arm vs the CEA arm

XLPAD
Excellence in Peripheral Arterial Disease

SAPPHIRE: Primary Endpoint by Symptom Status





XLPAD
Excellence in Peripheral Arterial Disease