

# CAROTID ARTERY STENTING: CMS COVERAGE DECISION

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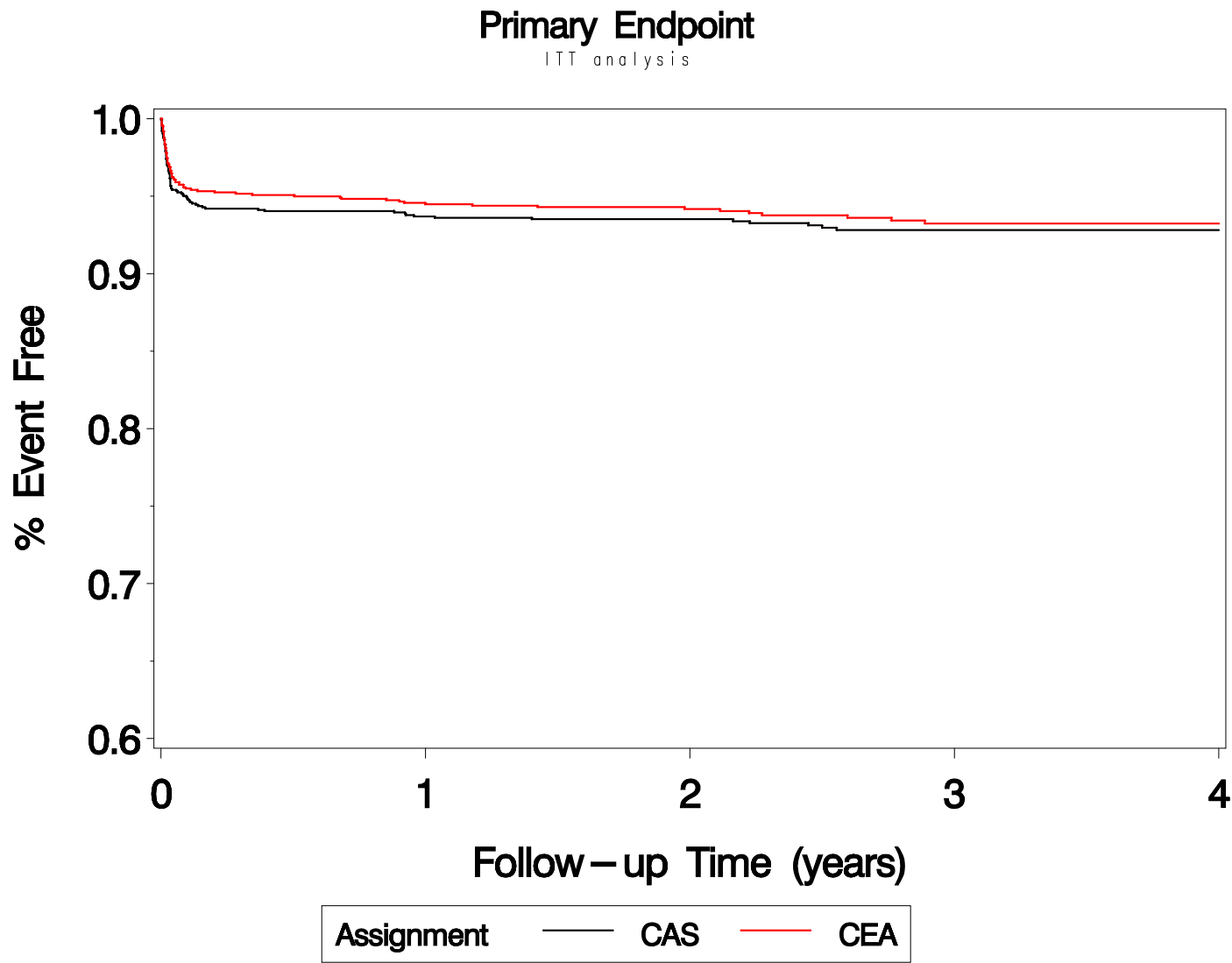
# Disclosures

- Investigator
  - CREST
  - ACT I
  - CHOICE
  - CAPTURE 2
  - EXACT
  - SAPPHIRE WW
  - CANOPY

## Annual Stroke Risk > 30 days (Symptomatic)

	CEA	CAS
NASCET	1.5	
CREST LEAD IN		1.1
EVA-3S	0.7	0.4
SPACE	1.3	1.4
CREST	0.8	0.6

# CREST Event Free Survival, Shows Clinical Durability of CAS and CEA



# Grading Carotid Intrastent Restenosis: A 6 year follow-up study

- 50-69% ISR developed in 73/814 (9%)
- 70-99% ISR developed in 22/814 (2.7%)
  - Reintervention
- 3 stent thromboses (0.4%)

Setacci et al. STROKE 2008; 39: 1189-1196

# CEA

- Stroke/death
- MI
- Cranial nerve injury
- Wound hematoma
- Wound infection

# CAS

- Stroke/death
- MI
- Access hematoma
- Access infection
- GI bleeding

# Ipsilateral Stroke CEA (Symptomatic)

	STENOSIS	MEDICAL	CEA
NASCET (2 yrs)	70-99%	26%	9%
NASCET II (5 yrs)	50-69%	22%	16%

N Engl J Med 1991;325:445-53

N Engl J Med 1998;339:1415-25

# ACAS and ACST – CEA for Asymptomatic Stenosis

5 Years	Medical ACAS	CEA ACAS	Medical ACST	CEA ACST
Any Ipsilateral Stroke	11%	5.1% p=0.004	11.8%	6.4% P<0.001
Major/Fatal Ipsilateral Stroke	6.1%	3.4% p=0.12	6.1%	3.5% P=0.004

JAMA 1995; 273:1421-1428  
Lancet 2004; 363:1491-1508



# CEA Versus CAS in High Risk Patients (SAPPHIRE)

- 334 Patients, Symptomatic (>50%) and Asymptomatic (>80%)
- “High Risk” for CEA
- Endpoints
  - 30d death, stroke, MI
  - 31-365d death, stroke

# CEA Versus CAS in High Risk Patients (SAPPHIRE)

	CAS	CEA
30d Stroke, Death, MI	4.4% (7) p=0.06	9.9% (15)
+ One year Stroke, Death	12.0% (19) p=0.05	20.1% (30)
30d MI	1.9% (3) p=0.04	6.6% (10)

NEJM 2004;351:1493-501

# CMS APPROVAL 2005

- Symptomatic > 70% stenosis AND “high risk” for CEA
- Symptomatic > 50%, Asymptomatic > 80% AND “high risk” for CEA AND enrolled in an FDA-approved clinical trial
- Randomized trials for normal risk patients
  - CREST, ACT I

# Randomized Trials Comparing CAS and CEA

- EVA-3S - France
- SPACE - Europe
- ICSS - UK
- CREST – North America
  - Symptomatic and asymptomatic patients

# Problem: Required Training of Carotid Stenting Physicians

- EVA-3S
  - Zero Carotid Stents, zero cerebral Angiograms
- SPACE
  - 25 carotid or vertebral stents
- ICSS
  - Zero Carotid Stents, zero cerebral angiograms

# CREST

- Credentialing of CAS operators
  - 5-20 Lead-in cases based on prior experience with CAS procedures
- Required EPD

*J Stroke Cerebrovasc Dis.* 2010 March ; 19(2): 153–162.

# 30 Day S/D Symptomatic

	CEA (%)	CAS (%)
NASCET ( '91)	5.8	
NASCET II ( '98)	6.7	
SPACE ( '06)	6.3	6.8
EVA-3S ( '06)	3.9	9.6
ICSS ( '09)	3.4	7
ARCHeR		11.0
CAPTURE		10.6
BEACH		7.4
CREST LI		5.8 (4.5<75 yo)
CREST ( '10)	3.2	6.0

# 30 Day S/D Asymptomatic

	CEA (%)	CAS (%)
ACAS	2.3*	
ACST	3.1	
ARCHeR		5.4
CAPTURE		4.9
BEACH		3.4
CREST RI		3.7
CREST	1.4	2.5
ACT I	??	??



# CREST

	CEA	CAS
S/D/MI + Stroke x 4 years	6.8%	7.2% (p=0.51)
S/D/MI 30 days	4.5%	5.2% (p=0.38)
Major Stroke 30 days	0.7%	0.9% (p=0.51)
Any Stroke 30 days	2.3%	4.1% (p=0.01)
MI 30 days	2.3%	1.1% (p=0.03)
Cranial nerve palsy	4.8%	0.3% (p=0.0001)
Stroke after 30 days	2.4%	2.0% (p=0.85)

# Average Risk Symptomatic Patients

## PRO

- Both CEA and CAS have a wide margin of benefit over the natural history (>70% stenosis)
- Composite endpoint of S/D/MI in CREST is equivalent
- Equivalent major strokes
- Meets AHA recommendations (6%)

## CON

- Other RCTs have shown superiority of CEA
- Minor stroke higher in CAS
- MI is not as important as minor stroke?
- More emboli with CAS?

# Average Risk Asymptomatic Patients

## PRO

- Both CEA and CAS have a margin of benefit over the natural history as defined by ACAS and ACST
- Composite endpoint of S/D/MI in CREST is equivalent
- Equivalent major strokes
- CAS meets AHA (3%)

## CON

- Minor stroke higher in CAS
- MI is not as important as minor stroke?
- More emboli with CAS?
- Medical therapy has improved—maybe no revascularization needed

# Anatomic High Risk

- Radiation
- Ipsilateral CEA
- High lesion
- Contralateral laryngeal nerve palsy
- Neck immobility
- Contralateral occlusion?

# Anatomic High Risk

- 5% risk of cranial nerve injury in patients *without* these risk factors
- May favor CAS over CEA in this group for symptomatic and asymptomatic patients

# Cardiovascular High Risk

- CHF Class III/IV
- LVEF < 30%
- Recent MI (6 weeks)
- Unstable angina
- Severe emphysema

# Cardiovascular High Risk

- Symptomatic patients
  - The lower risk of MI may favor CAS over CEA in these patients
- Asymptomatic patients
  - Reasonable to question the advisability of any revascularization procedure
  - The lower risk of MI may favor CAS over CEA if the recommendation is to revascularize

# What About Average Risk Patients?

- How important is minor stroke?
- Is MI important?
- Are there more “silent” emboli with CAS?
- Should asymptomatic patients be treated at all? (Why approve CAS when maybe nothing should be done?)



# How Important Are Minor Strokes?

- Very important in CREST
  - Was not associated with increased mortality
  - NIHSS was equal to control at 6 months
  - *IS* associated with decreased HRQOL at 1 year
- The risk decreased in the second half of CREST
- *May* decrease further with technology improvements

# Impact of Minor Stroke on HRQOL in CREST

- SF-36, 2502 CREST patients 2 weeks, 1 month, 1 year
- HRQOL better with CAS than CEA at 1 month
- No difference overall at 1 year
- Minor stroke associated with decreased HRQOL at 1 year, MI and CN palsy were not

# Importance of MI in CREST

- 14 in CAS vs 28 in CEA group (by protocol)
  - HR 0.5 (0.26-0.94,  $p=0.3$ )
- 8 in CAS vs 12 in CEA biomarker only (NS)
- Mortality higher at 4 years in patients with MI by protocol or biomarker only
  - HR 3.4 (1.67-6.92) by protocol
  - HR 3.57 (1.46-8.68) biomarker only

# Are There More Emboli With CAS?

- 7 of 50 ICSS centers had MRI pre/post
- 231 patients (124 CAS, 107 CEA)
- New DWI lesions in 50% CAS, 17% CEA
  - OR 5.21, CI 2.78-9.79,  $p < 0.0001$
- Statistically more likely to have DWI in patients *treated with EPD*

Lancet Neurology 2010; 9:353-362

# Is Cognition Impaired After CAS?

- 2 Centers in ICSS had neuropsychological examination before and 6 months after CAS/CEA
- 120 patients (140 total, 20 did not have both exams)
  - Planned enrollment was 200
- Non-significant trend of decreased cognitive sum score (-0.17, CI -0.38-0.03)
- “Any difference is small”

Neurology 2011; 77: 1084-1090

# Should Asymptomatic Patients be Revascularized?

- Two randomized trials supporting revascularization over medical treatment (ACAS and ACST, identical results, a decade apart)
- The 30 day event rate in SAMMPRIS in the medical arm was ½ of the anticipated rate based on historical data (WASID)
  - 5.8% vs 12.2%
  - Indicates the improvement in medical therapy
  - These were recently ***symptomatic*** patients
- The hypothesis that medical treatment for asymptomatic carotid stenosis has improved is...a *hypothesis* worth *testing*

# SNIS Considerations for CAS

- CAS has met a much higher bar than most medical procedures
  - Room for improvement with CAS
- Neuroscience-based specialists see a high proportion of symptomatic patients
- CAS occasionally performed in conjunction with acute stroke intervention
  - Often without EPD

# SNIS Position

- Coverage Extension
  - Extend coverage for all *symptomatic* patients
  - Extend coverage for “Anatomic High Risk” *asymptomatic* patients and “Cardiovascular High Risk” patients when revascularization is deemed appropriate
  - Continue coverage for enrollment in clinical trials
    - to improve technique/devices to lower periprocedural stroke and periprocedural emboli
    - Potentially to re-evaluate medical treatment verses revascularization
  - Extend coverage for CAS during an acute stroke intervention, with or without EPD