2017 MID-ATLANTIC
CONFERENCE

7th ANNUAL CURRENT CONCEPTS IN
VASCULAR THERAPIES
2017

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22 April 2017

SENTARA

65 yr old man with high grade asymptomatic carotid stenosis
THE CASE FOR CAROTID STENTING

Disclosure

Consultant for Silk Road Medical

Medical Management Critical

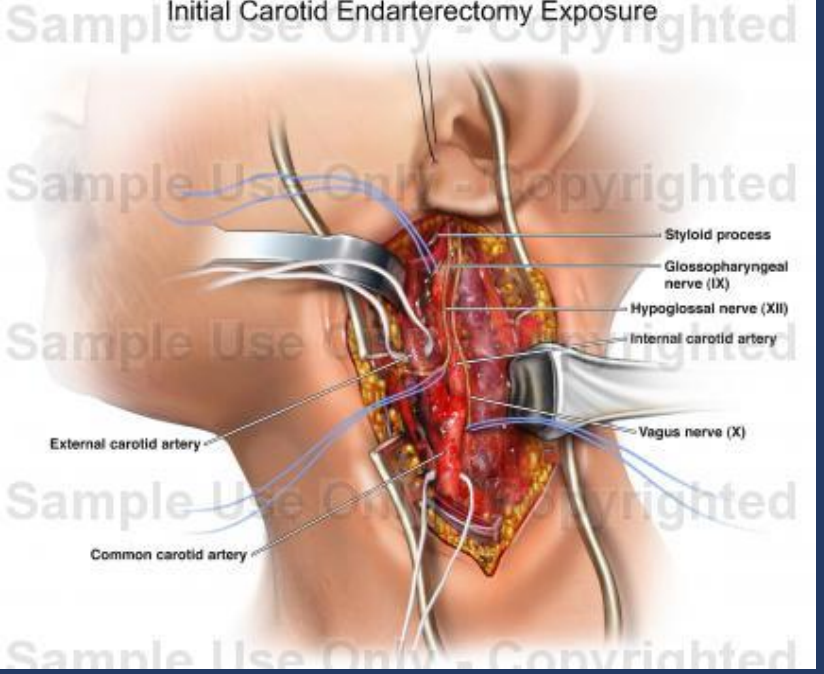
Eat healthy

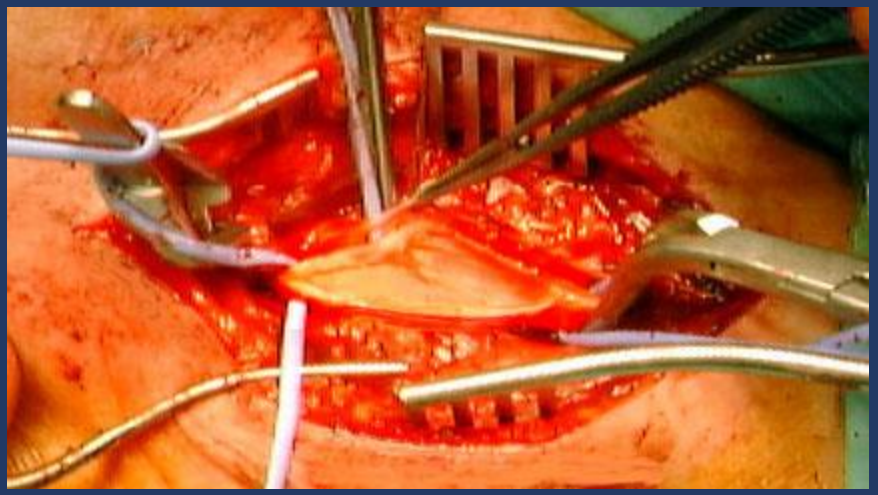
Stop smoking

Anti-platelet
High-dose statin
Anti-hypertensive

exercise

Stress relief





CEA is an excellent operation

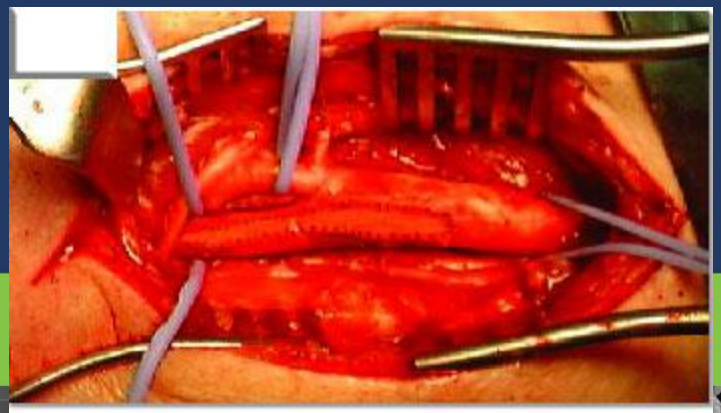
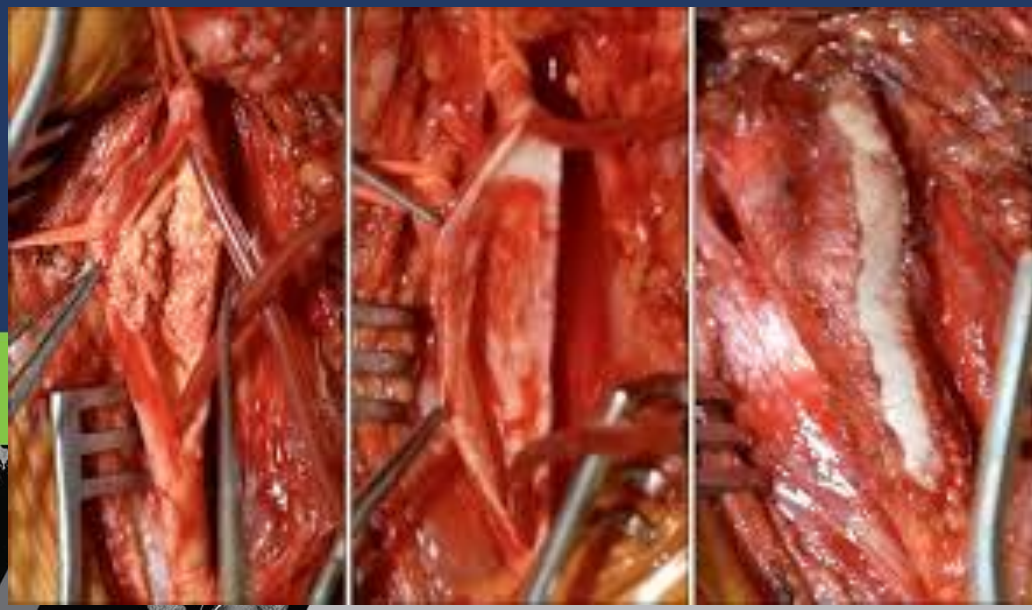
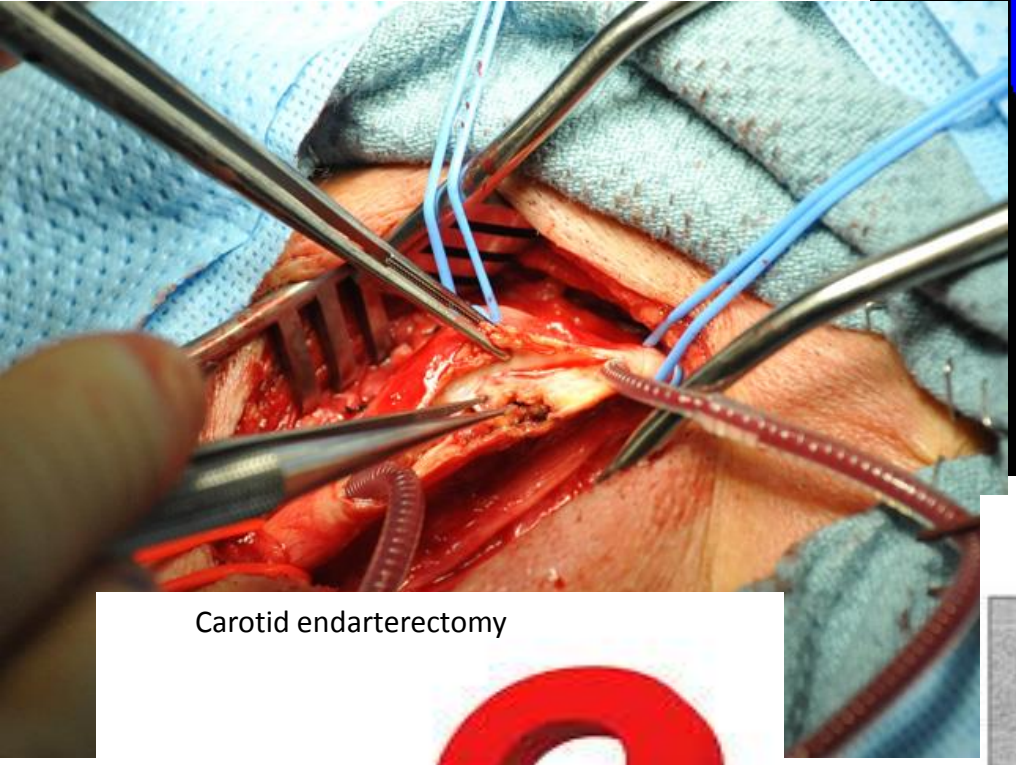


Figure 1: Incision, exposure and completed patch angioplasty of the common and internal carotid artery.





Carotid endarterectomy

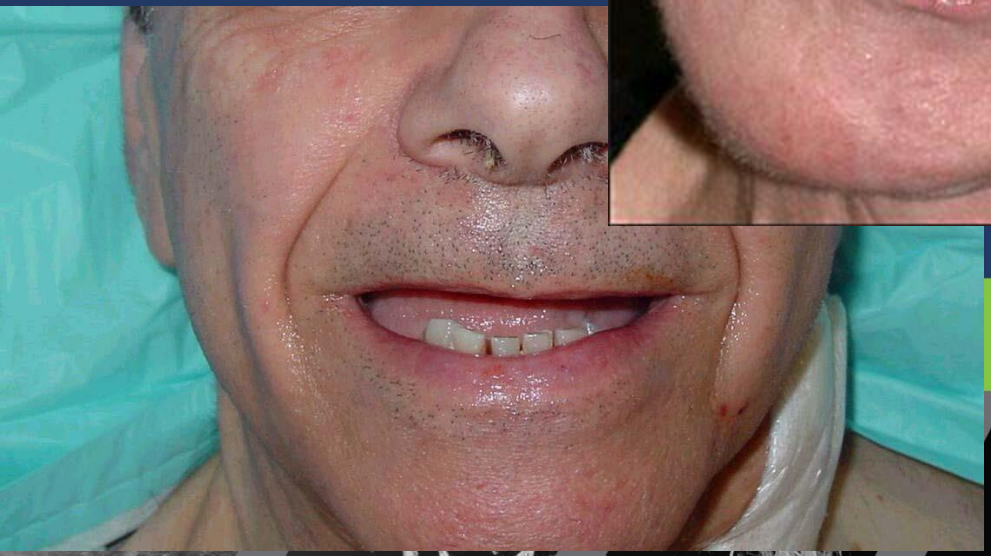
CAROTID ARTERY STENTING

PRE STENT

POST STENT








CEA complications

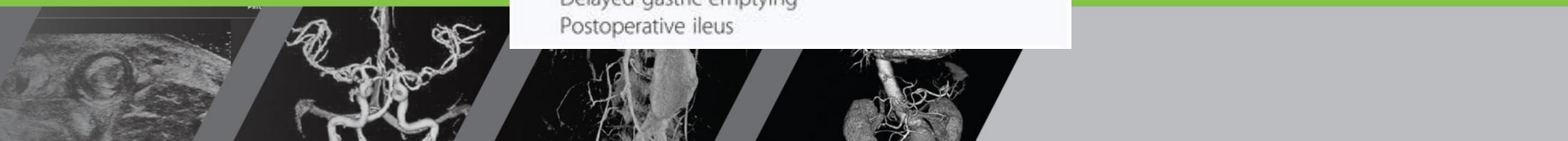
Cerebrovascular
- Stroke (ischemic or embolic)
- Cranial nerve deficits: glossopharyngeal (IX), vagus (X), hypoglossal (XII) predisposing to airway compromise, either by causing airway obstruction or leading to aspiration

Airway obstruction
- Vocal cord paralysis (vagus nerve)
- Airway edema from neck manipulation during surgery
- Postoperative bleeding leading to expanding neck hematoma

Pulmonary (especially after bilateral carotid surgery)
- Abolition of the normocapnic ventilatory response to hypoxia
- Apneic episodes
- Aspiration pneumonitis (slow gastric emptying)

Cardiovascular (especially after bilateral carotid surgery)
- Decreased baroreceptor sensitivity
- Temporary baroreceptor failure
- Increased blood pressure variability
- Orthostatic hypotension
- Hypertension
- Sick sinus syndrome

Gastrointestinal
- Delayed gastric emptying
- Postoperative ileus



CEA Outcomes in High Surgical Risk Patients: Room for Improvement

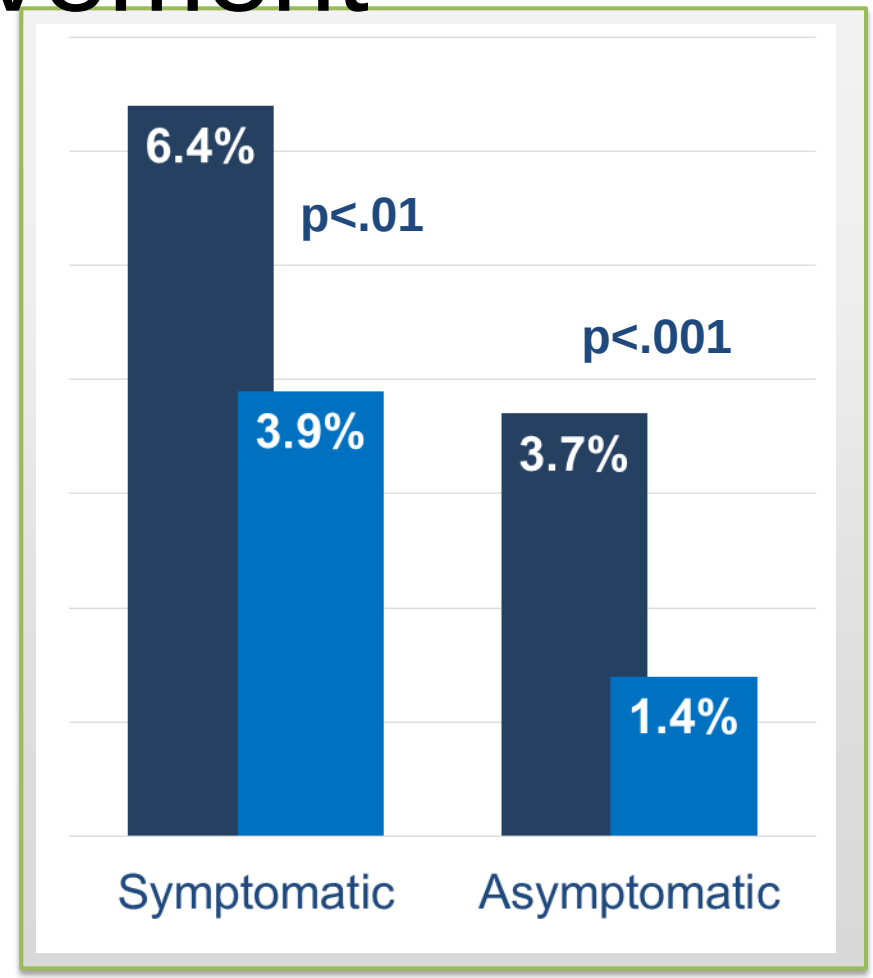
30-Day Stroke/Death

SVS Registry (n=6,370)*

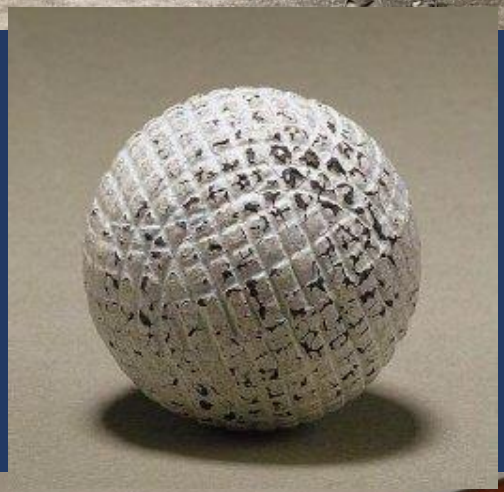
High Surgical Risk CEA

vs

Standard Surgical Risk CEA



Schermerhorn et al. J Vasc Surg. 2013; 57:1318




Titleist
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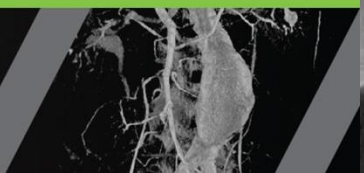
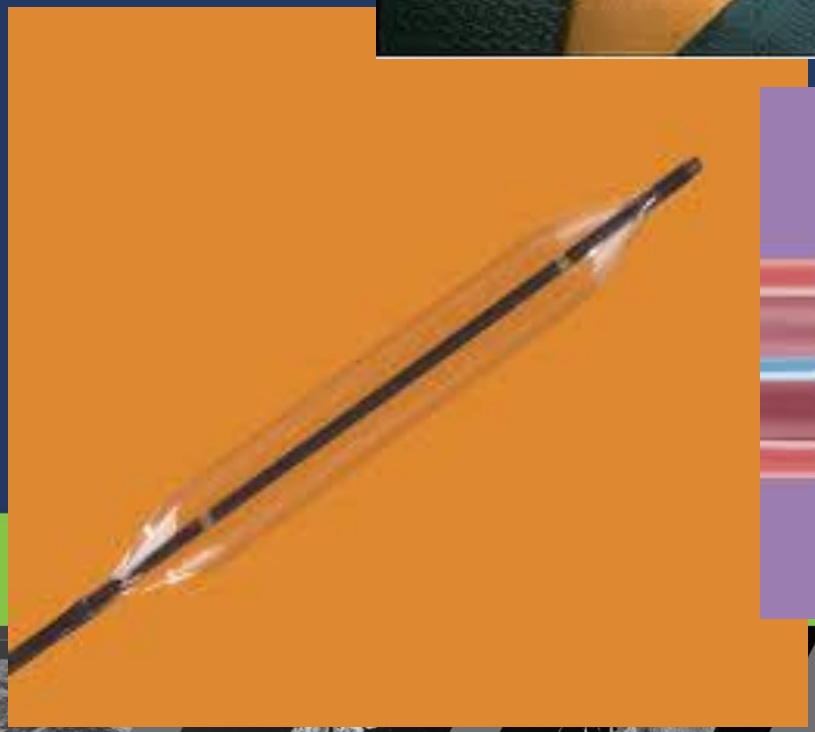
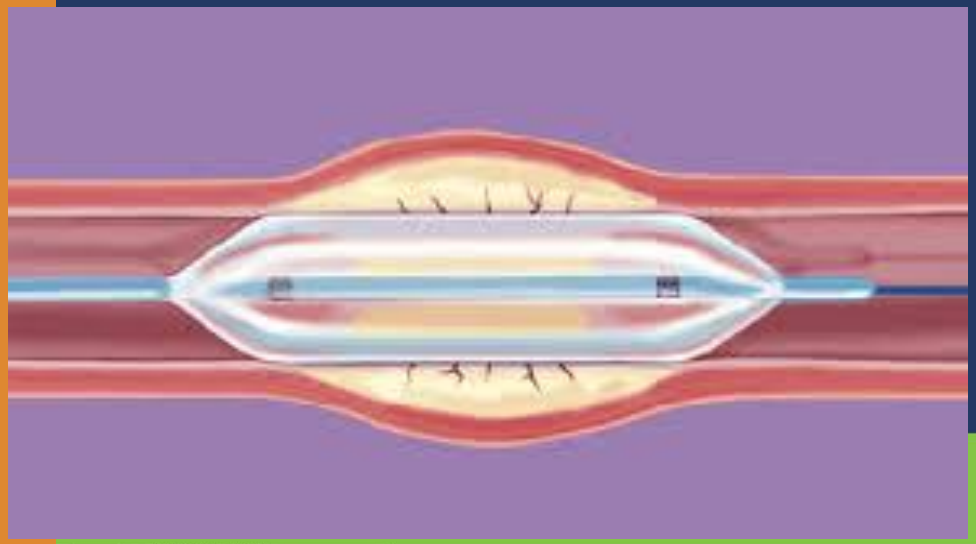
The interventional express

- 1929 Forssmann does first cardiac catheterization does his own cutdown and inserts catheter into antecubital vein, threads it into right atrium.
- 1956 shares Nobel Prize with Cournand and Richards.
- 1958 Sones does first coronary angiogram.
- 1964 Dotter introduces concept of transluminal angioplasty.
- 1974 Gruentzig performs first peripheral balloon angioplasty.



1979, Mathias performs the first carotid PTA





Stenting Arrives

- 2000 Jun;50(2):160-7.
- **Global experience in cervical carotid artery stent placement.**
- Wholey MH[1], Wholey M, Mathias K, Roubin GS, Diethrich EB, Henry M, Bailey S, Bergeron P, Dorros G, Eles G, Gaines P, Gomez CR, Gray B, Guimaraens J, Higashida R, Ho DS, Katzen B, Kambara A, Kumar V, Laborde JC, Leon M, Lim M, Londero H, Mesa J, Musacchio A, Myla S, Ramee S, Rodriquez A, Rosenfield K, Sakai N, Shawl F, Sievert H, Teitelbaum G, Theron JG, Vaclav P, Vozzi C, Yadav JS, Yoshimura SI.

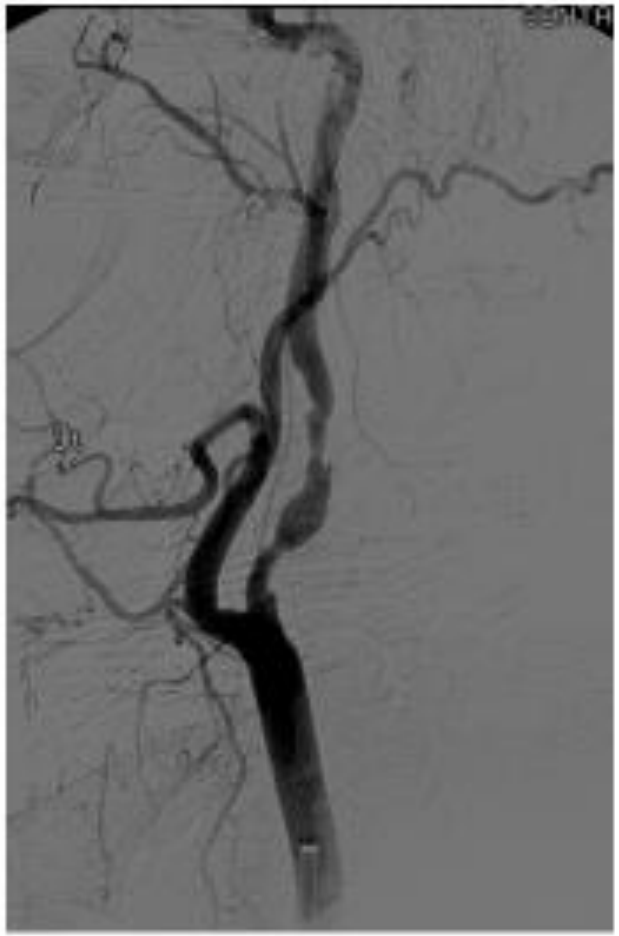
- The total number of endovascular carotid stent procedures that have been performed worldwide to date included 5,210 procedures involving 4,757 patients. There was a technical success of 98.4% with 5,129 carotid arteries treated. Complications that occurred during the carotid stent placement or within a 30-day period following placement were recorded. Overall, there were 134 transient ischemic attacks (TIAs) for a rate of 2.82%. Based on the total patient population, there were 129 minor strokes with a rate of occurrence of 2.72%. The total number of major strokes was 71 for a rate of 1.49%. There were 41 deaths within a 30-day postprocedure period resulting in a mortality rate of 0.86%. The combined minor and major strokes and procedure-related death rate was 5.07%.

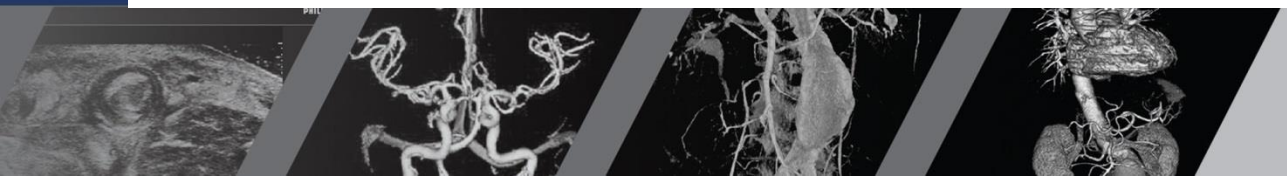
- August 31, 2004
  - FDA approves the first carotid stent system: Guidant corporation platform composed of the Acculink Carotid Stent and the Accunet Embolic Protection Device.

CAS

Selective Lt Carotid Angio

Long Lt ICA ulcerated lesion
(>80% stenosis)





CAS

Completion Angiogram

Free flow into the ICA

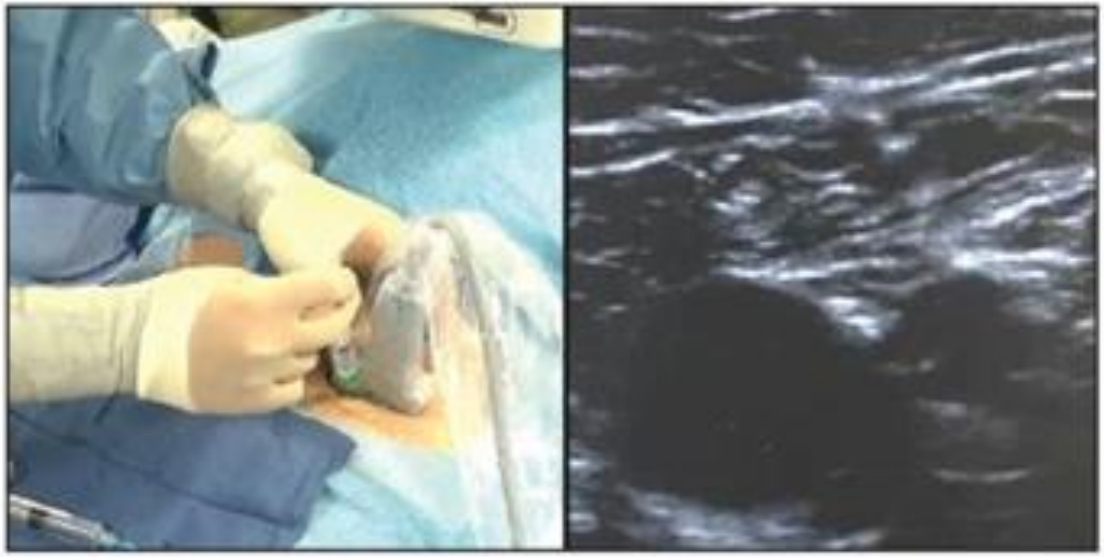
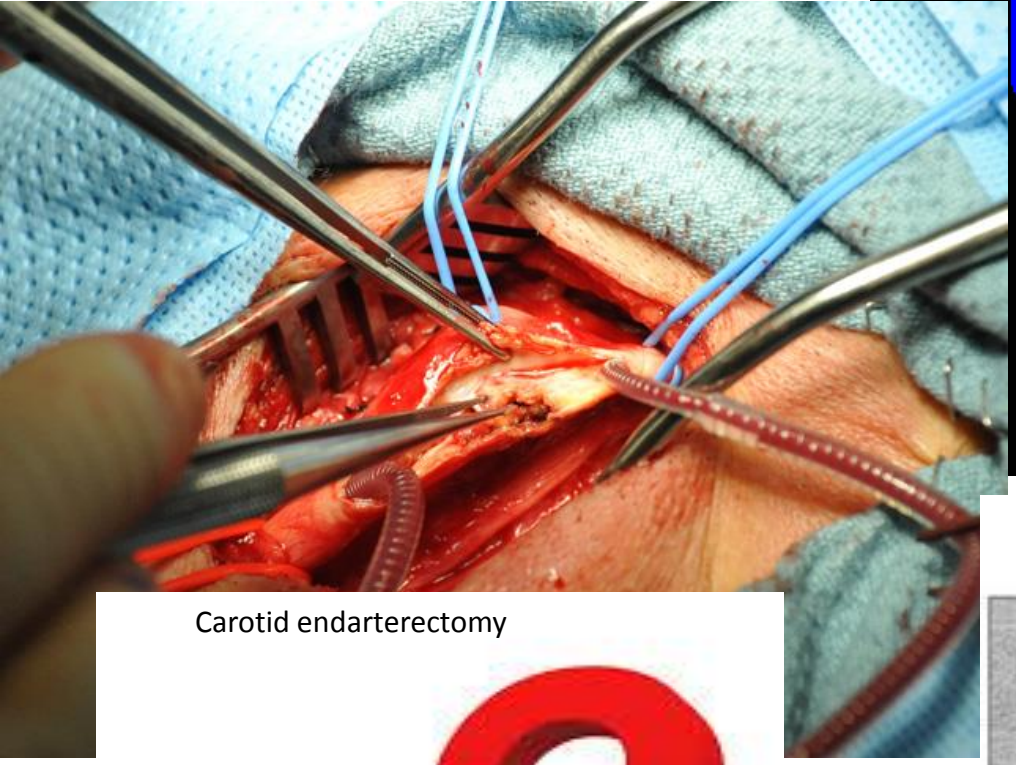


Figure 2. Ultrasound guidance of the micropuncture needle into the anterior surface of the common femoral artery.



Carotid endarterectomy

CAROTID ARTERY STENTING

PRE STENT

POST STENT

Why embolic protection?

Embolic Stroke

- Catheterization
- Crossing the Lesion
- Angioplasty – pre or post
- Placement of Stent
- Retrieval of EPD

Embolic Stroke

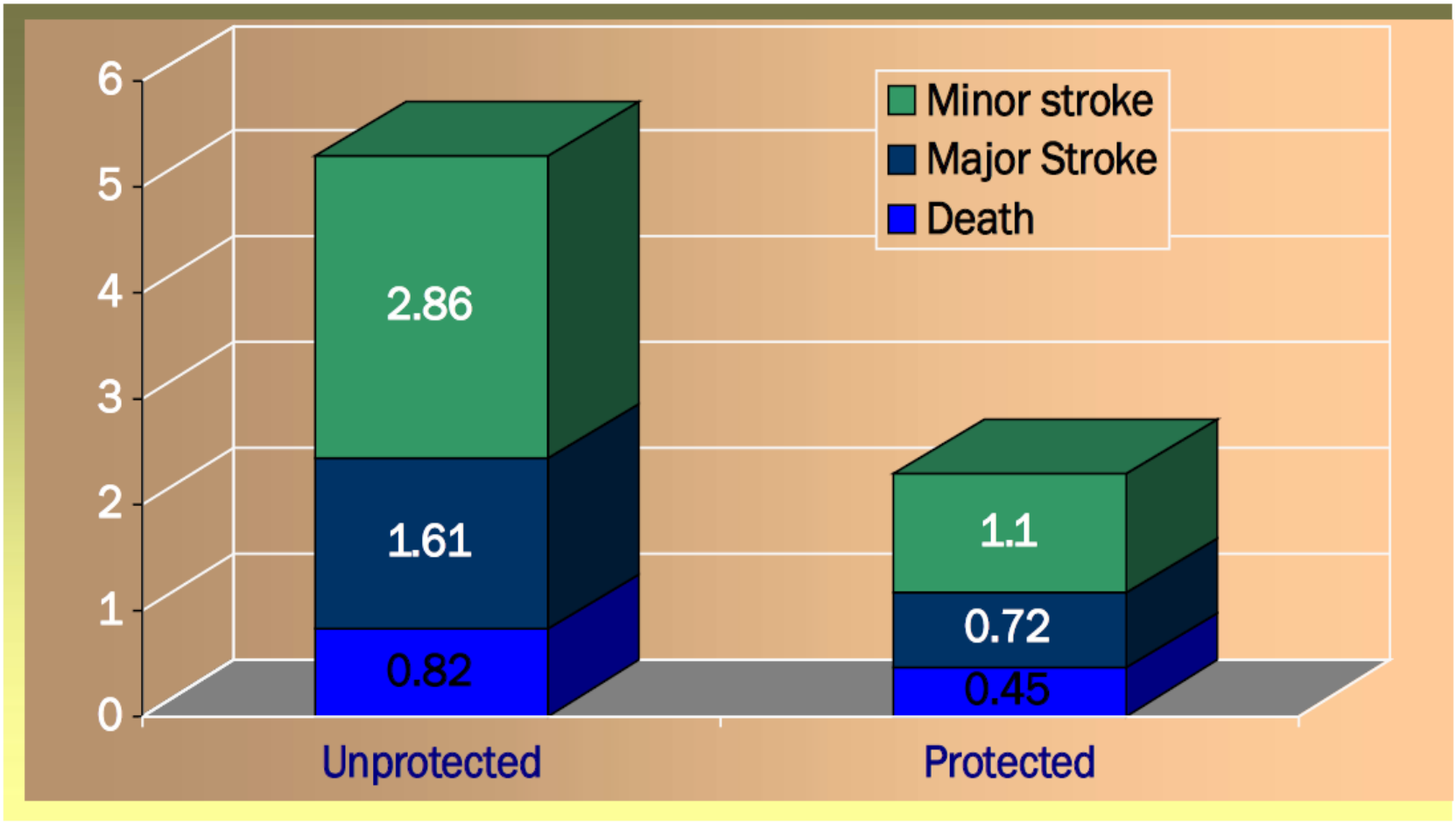
Quantification of emboli
Transcranial Doppler

Procedure	CEA	CAS
Number of hits	52±64	202±119

Crawley F, Clifton A, Buckenham T, et al.. Stroke 1997

Protection Device

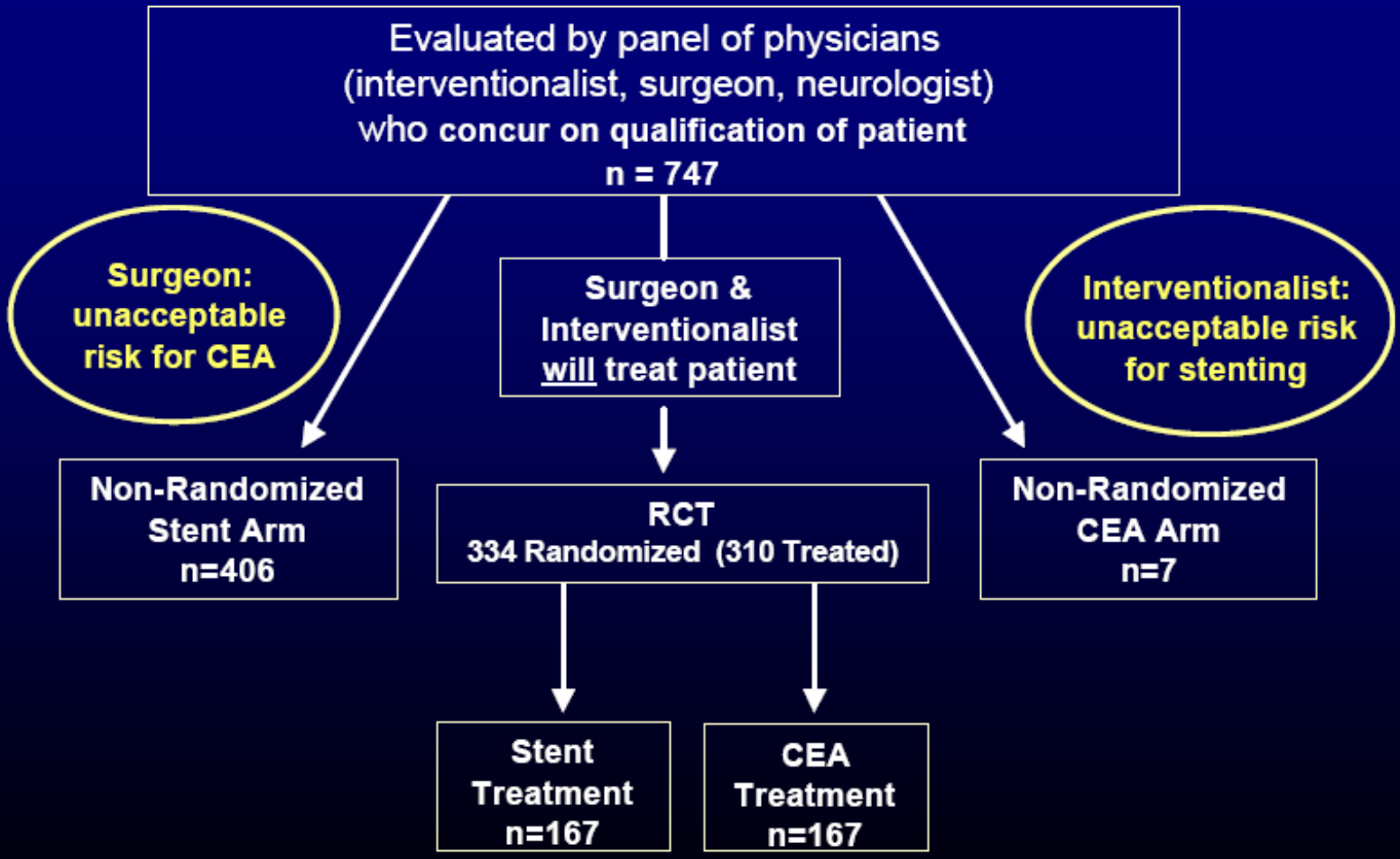
Carotid Artery Stenting
Impact of NeuroProtection – Global Registry



N = 6,688 cases

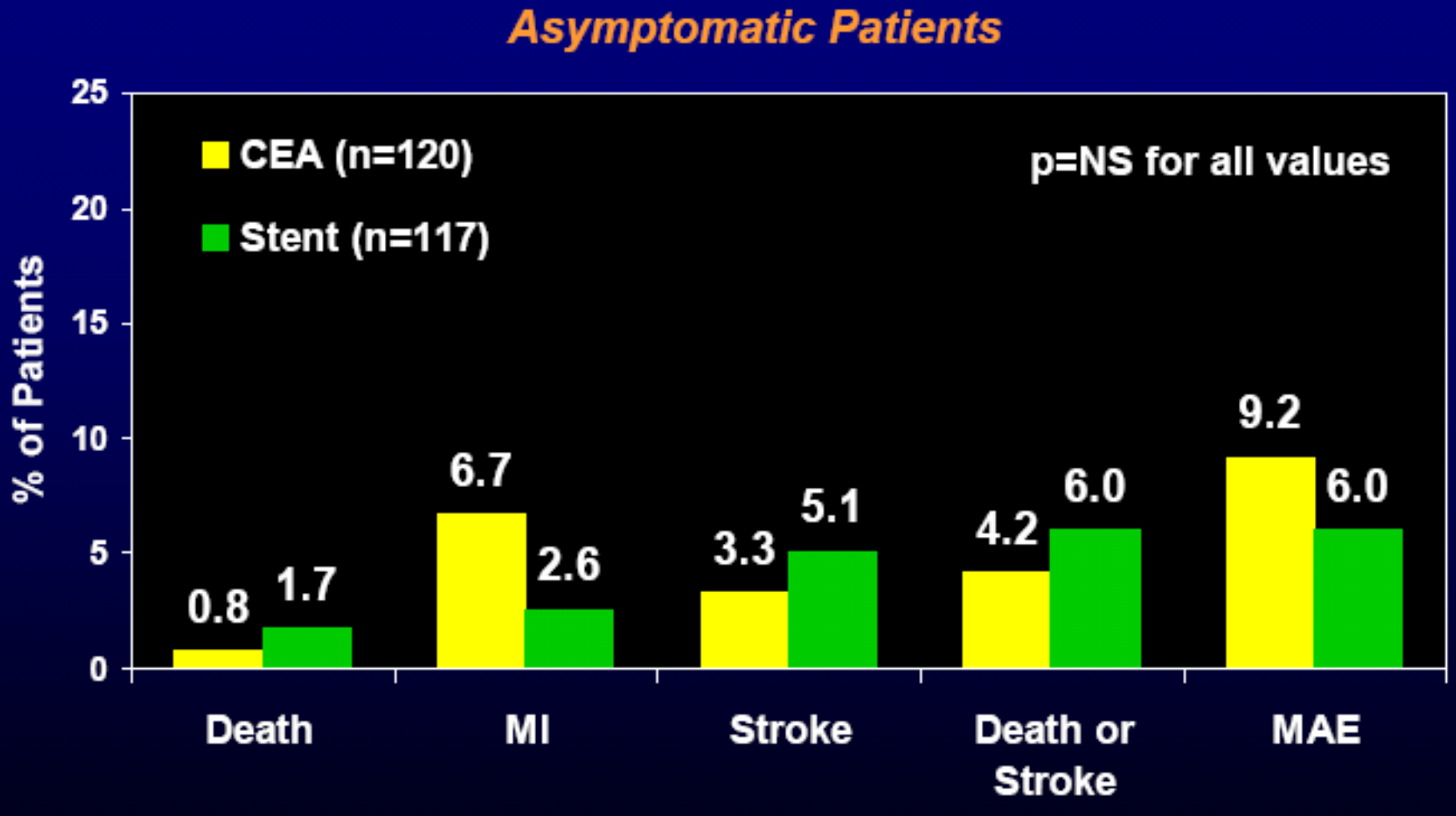
4,005 cases

SAPPHIRE: Design and Patient Flow



Yadav J.S., et. al., *N Engl J Med* 2004;351:1493-501.

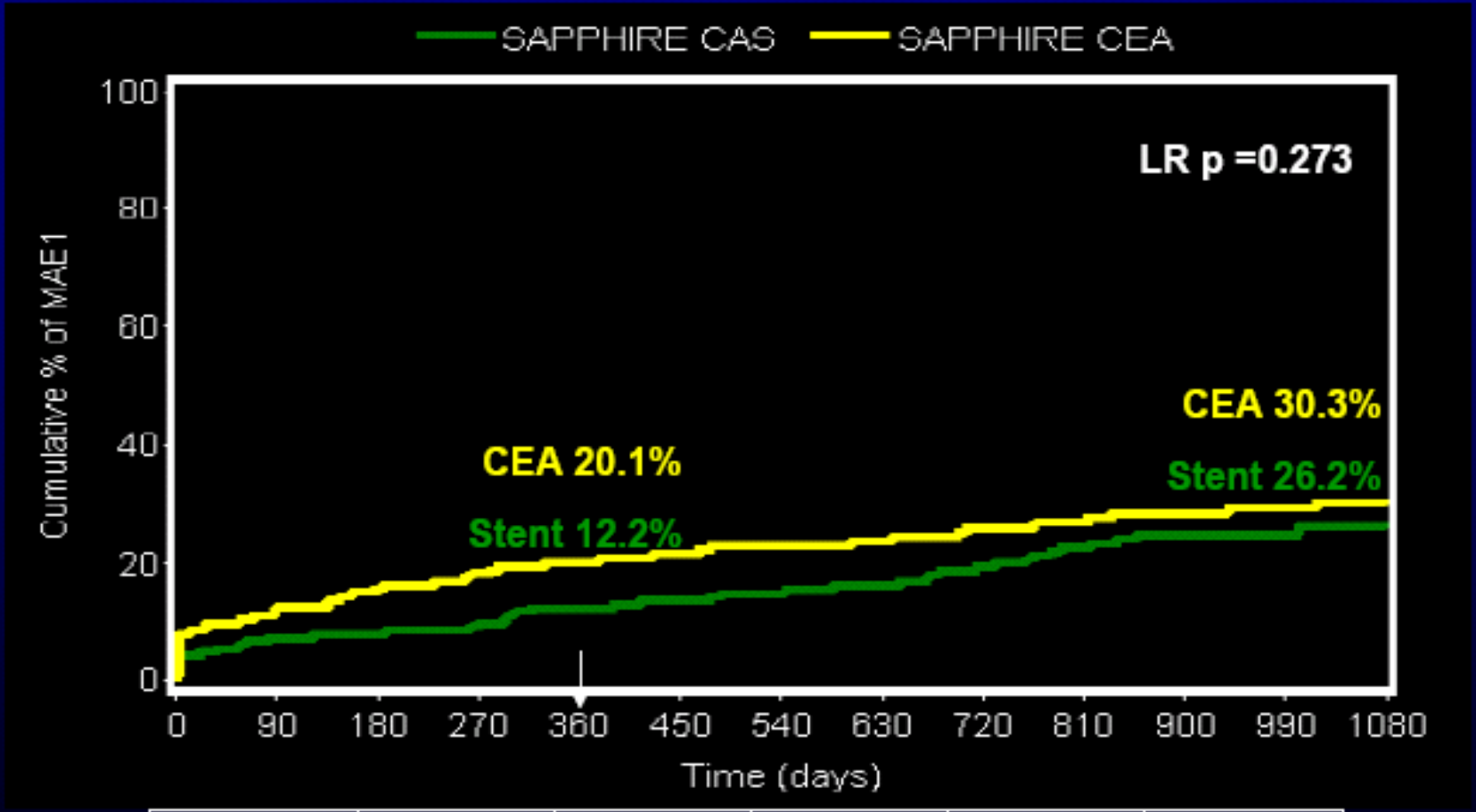
30-Day MAE



H. S. Gurm et al., *N Engl J Med* 2008; 358:1572-79.

Cumulative Percentage of MAE at 1080 days

All Randomized Patients



Days:	0	90	360	720	1080
Stent:	167	164	146	129	106
CEA:	167	163	124	100	79

MAE defined as death, MI, and/or stroke to 30 days, plus death and/or ipsilateral stroke from 31-360 days

H. S. Gurm et al., *N Engl J Med* 2008; 358:1572-79.

Conclusions

- Carotid artery stenting with embolic protection achieved primary endpoint of non-inferiority to CEA for MAE at 1-year
- CAS demonstrated a significant decrease in cranial nerve injury as compared with CEA
- CAS is a durable procedure out to 3 years with similar long-term risk of stroke* as CEA (8.0% vs. 6.7%, LR p=0.799) and a lower number of repeat procedures (3.0% vs. 7.1%, LR p=0.084), respectively

* All stroke to 30 days and Ipsilateral stroke between 30 days and 3 years

H. S. Gurm et al., *N Engl J Med* 2008; 358:1572-79.

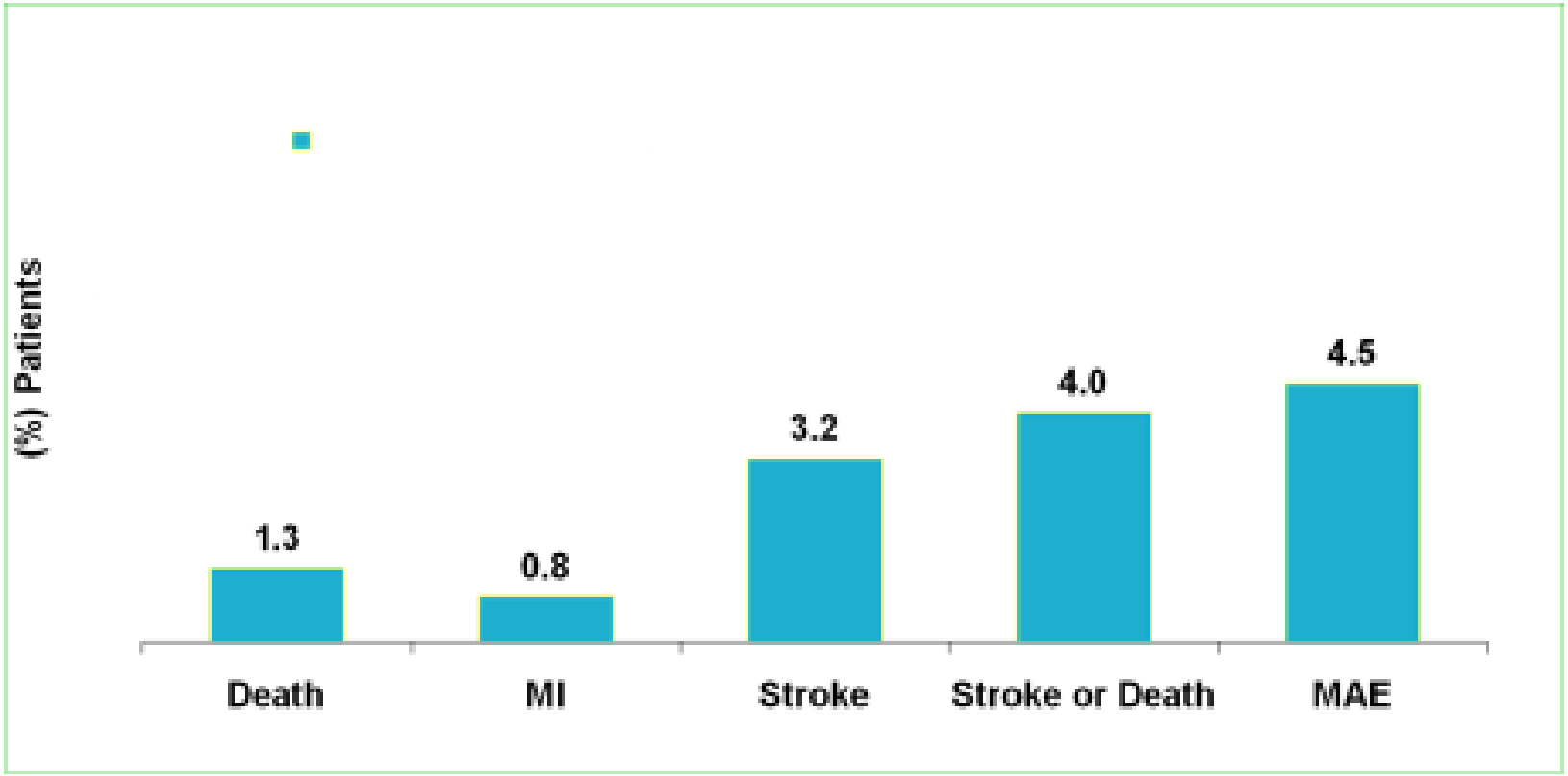
SAPPHIRE WW: Study Design

- Design: Multicenter, prospective, post-approval registry to evaluate CAS using the Cordis PRECISE® Nitinol Stent and ANGIOGUARD® XP/RX Emboli Capture Guidewire System

- Inclusion Criteria: Patients were included if considered high-risk for adverse events from carotid endarterectomy and met the following criteria:
  - Symptomatic with ≥50% stenosis by ultrasound or angiogram
  - Asymptomatic with ≥80% stenosis by ultrasound or angiogram

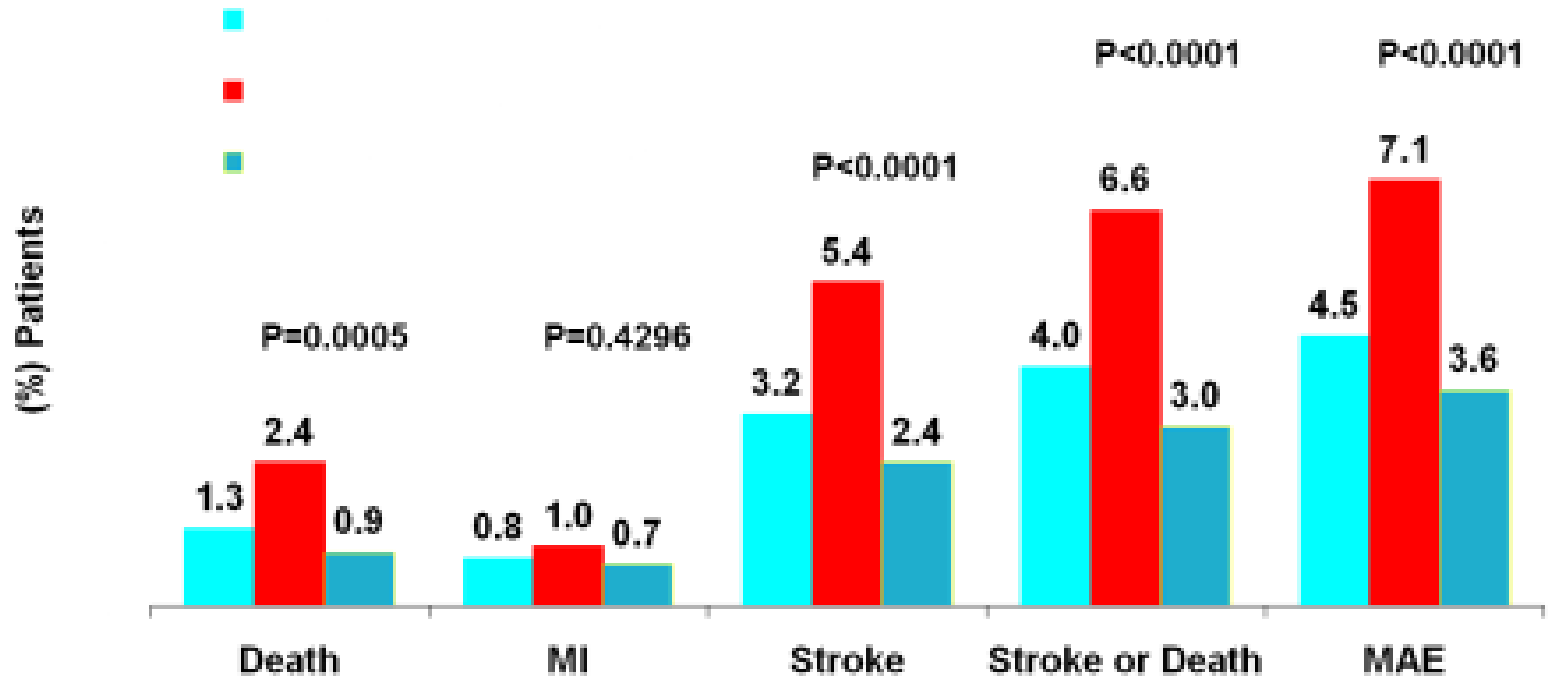
- Primary Endpoint: Major adverse events (MAE) including any death, myocardial infarction or stroke to 30 days after the procedure (CPKs, NIHSS)

Major Adverse Events at 30 Days:
All Patients



MAE defined as any death, MI or stroke

Major Adverse Events at 30 Days:
Symptomatic vs. Asymptomatic



MAE defined as any death, MI or stroke
p-values are based on comparison of symptomatic vs. asymptomatic patients

Sapphire WW conclusions

- MAE at 30 days are significantly lower in asymptomatic (3.6%) vs. symptomatic patients (7.1%), $p<0.0001$
- Outcomes from SAPPHIRE WW along with other contemporary CAS registries will continue to provide evidence in support of optimal patient selection in performing CAS in patients at high risk for surgery

Randomized Trials: CAS vs CEA

N Engl J Med. 2010 July 1; 363(1): 11–23. doi:10.1056/NEJMoa0912321.

Stenting versus Endarterectomy for Treatment of Carotid-Artery Stenosis

- Composite endpoint (4yr):
  - CAS 7.2%
  - CEA 6.8% (ns)

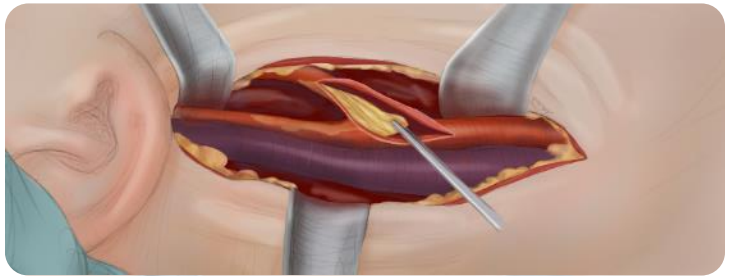
- *CAS clearly established as safe / effective*
- *Debate shifting away from CAS vs CEA*
- *Focus now on optimizing CAS outcomes*

ACT-I

Current Treatments for Carotid Disease

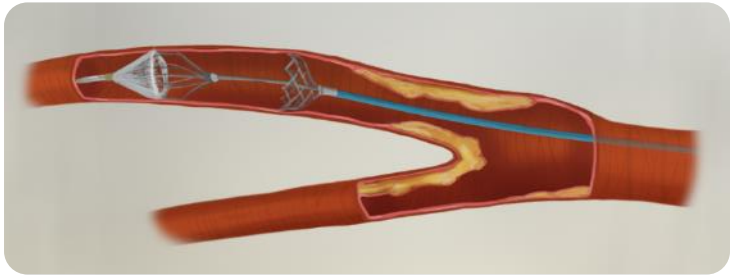
Gold Standard: **Carotid Endarterectomy**

- Low stroke risk[1], but…
- Invasive; risk of surgical complications
- Certain patients at higher surgical risk



Less Invasive Alternative: **Carotid Artery Stenting**

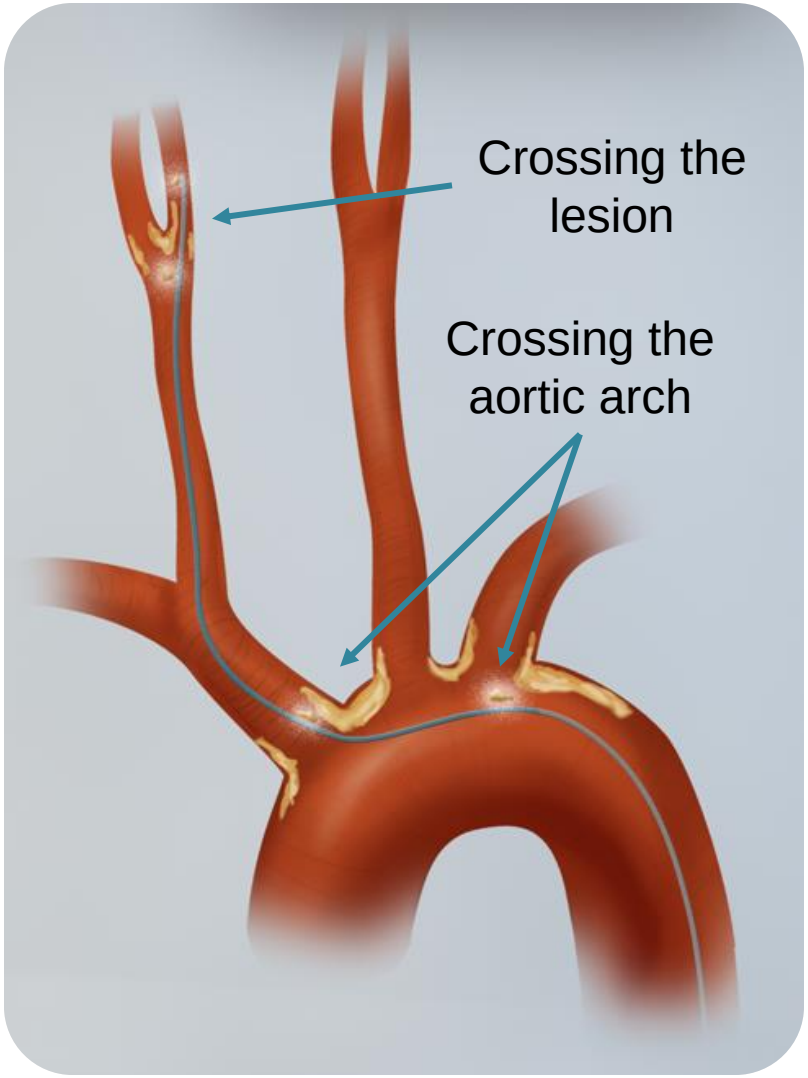
- Patient friendly, durable[1], but…
- Excess procedural stroke risk[1]
- Procedure itself can create thrombo-embolism



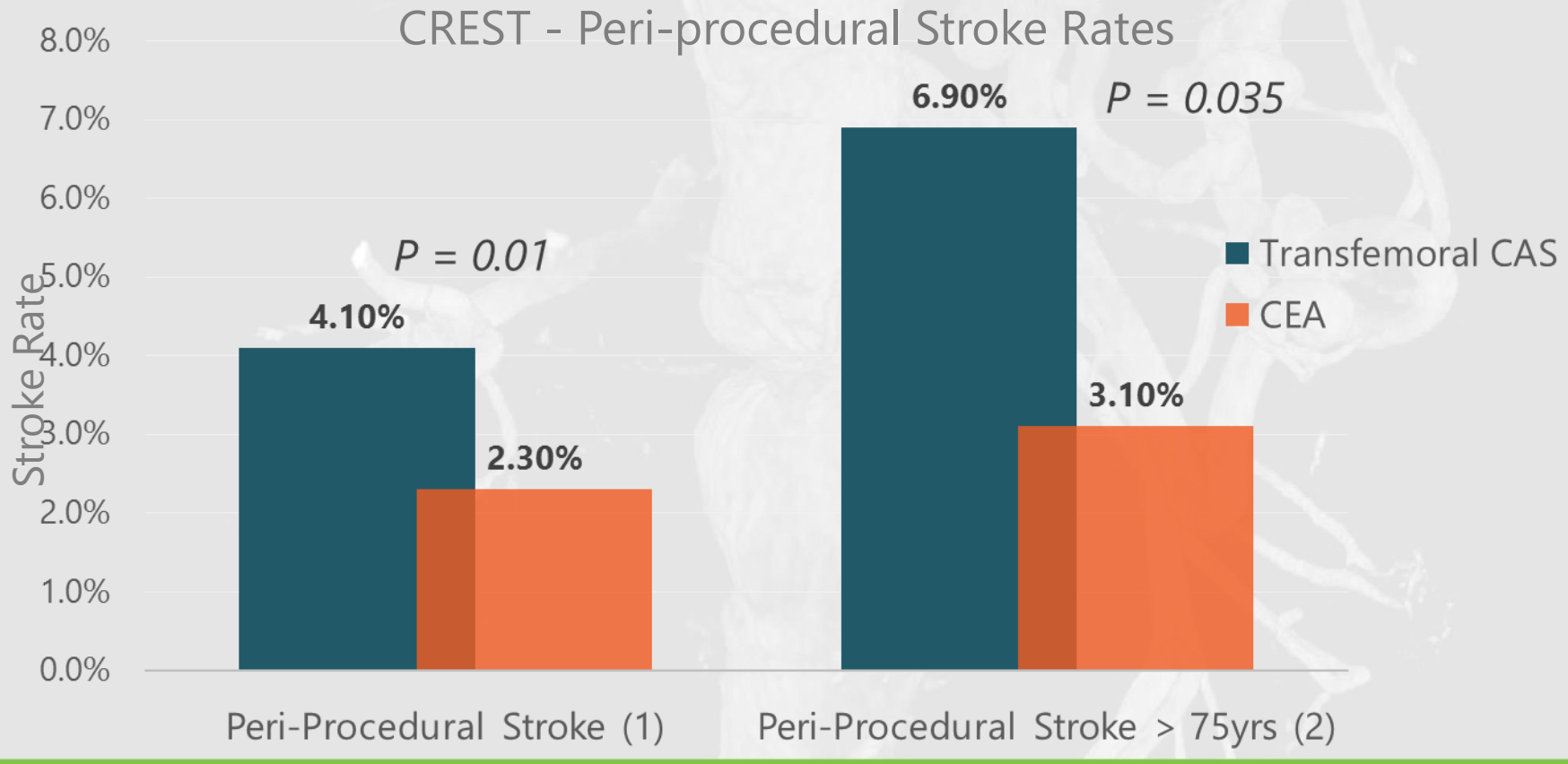
Why embolic protection?

Causes of Peri-procedural Stroke

- Traditional CAS requires several steps that create embolic risk
  - Advancing a catheter from the femoral artery
  - Navigating the lesion before a protection device is in place

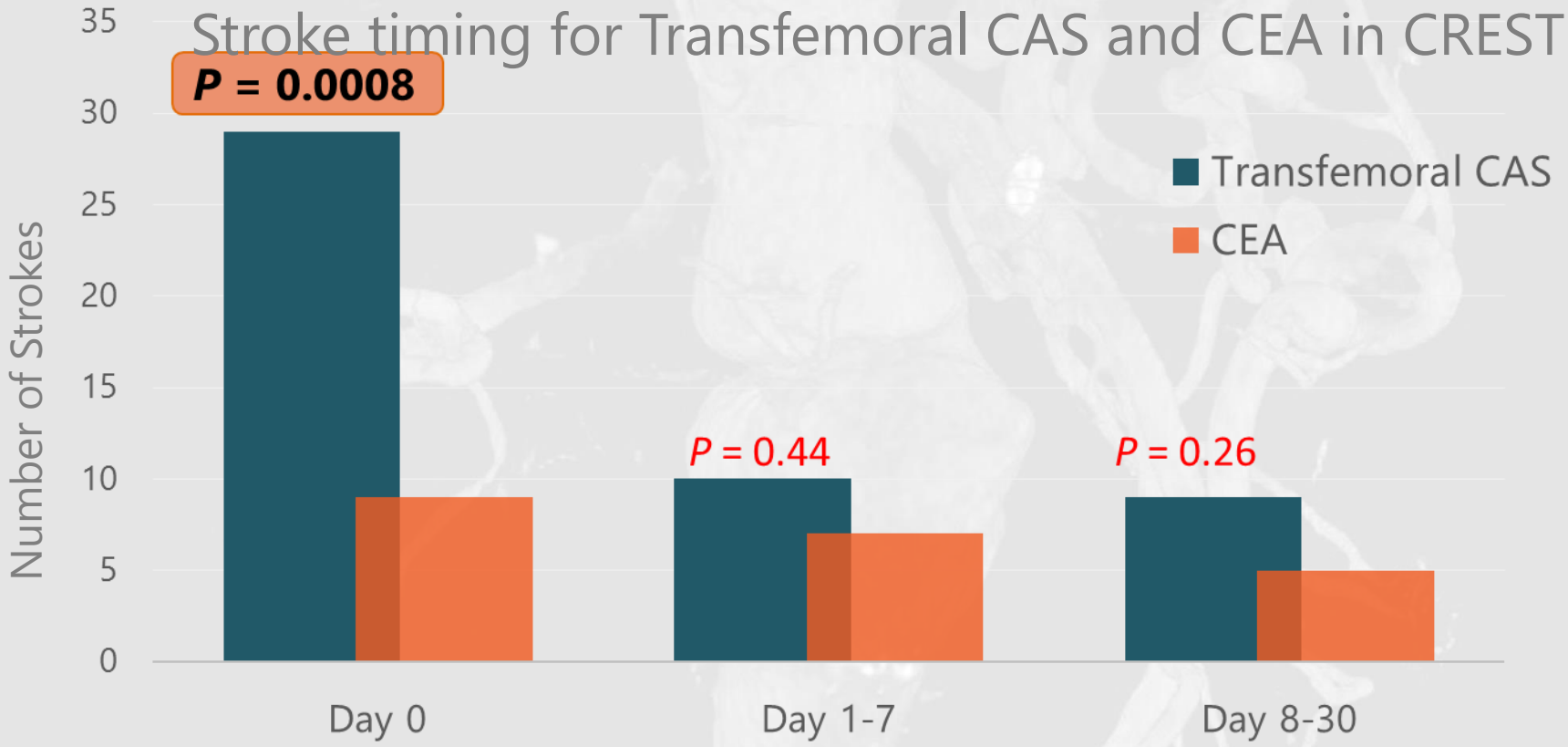


2x Peri-Procedural Stroke rate for Transfemoral CAS



1. N Engl J Med 2010;363:11-23
2. Stroke. 2011;42:00-00

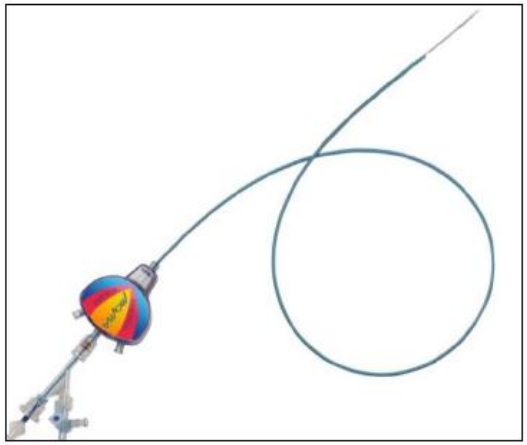
Day 0 Stroke is the Culprit



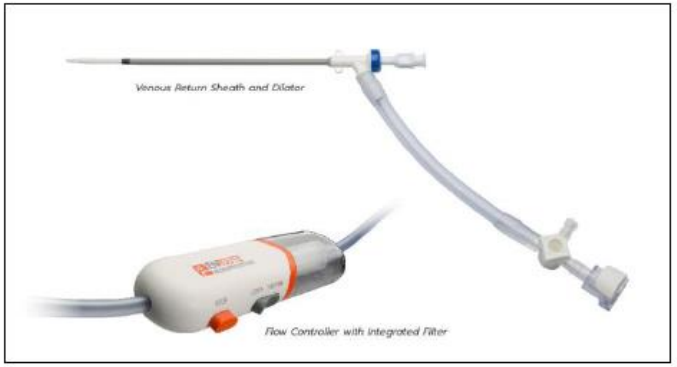
[1]Circulation. Nov. 29, 2012. P-value calculated post hoc by independent statistician.

Progression of EPD Technology in CAS

Distal Protection



Proximal Protection



Transcervical Access with Flow Reversal

A New Endovascular Alternative

with Surgically-Inspired Neuroprotection

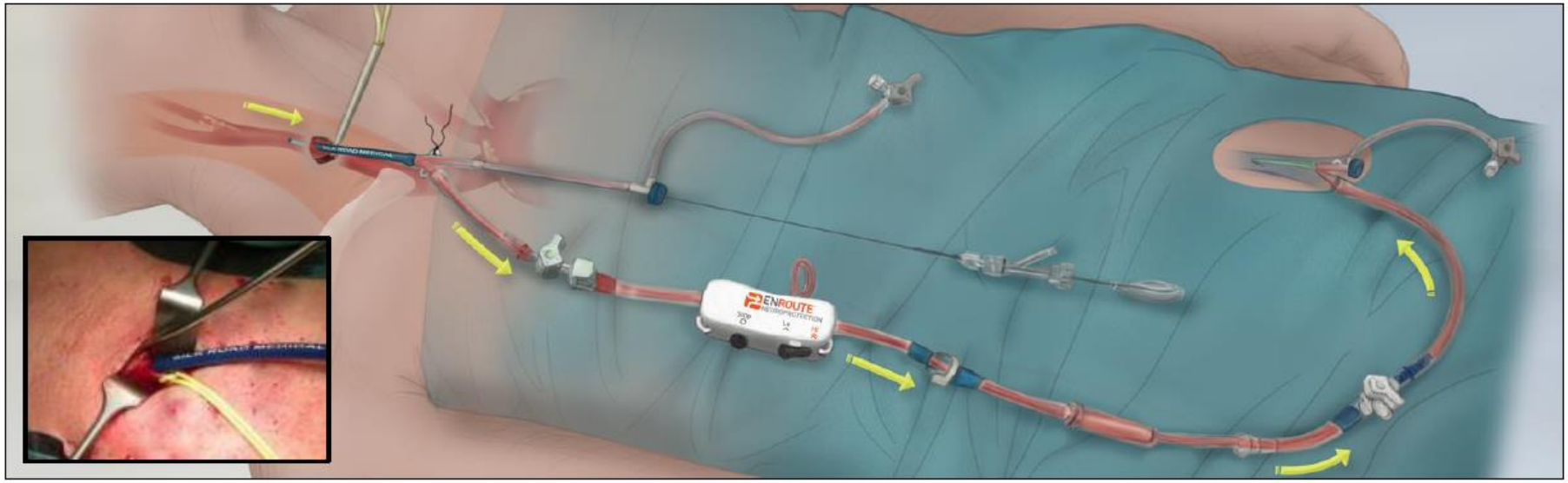
TCAR

Transcarotid Stenting with Dynamic Reverse Flow

Transcervical Carotid Artery Revascularization

TCAR

- 1-2cm Incision
- Local anesthesia
- Flow reversal circuit: carotid artery to femoral vein



Proof of Concept

TransCarotid Revascularization With Flow Reversal - Literature

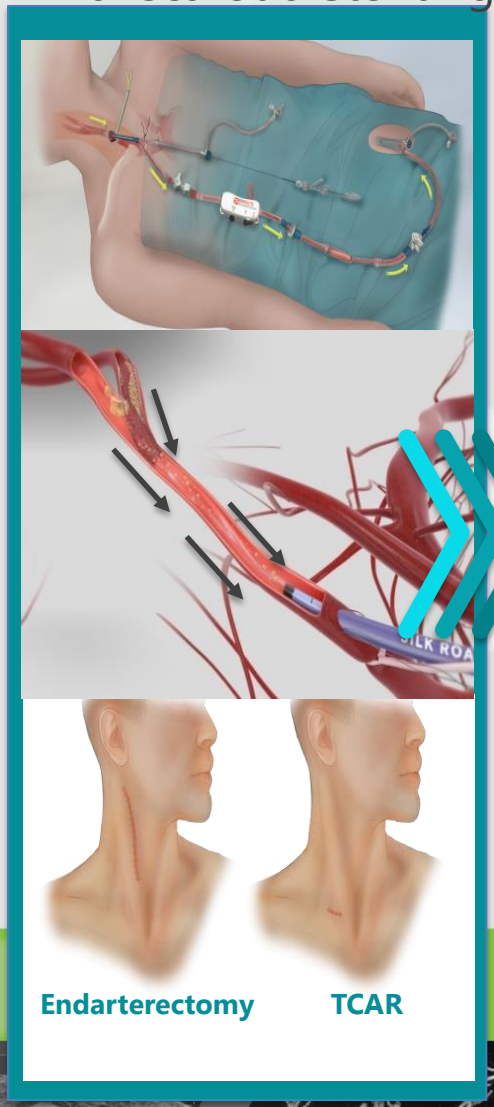
Study	# Stents	Death (30 days)	Major Stroke (30 days)	Minor Stroke (30 days)	Patency
Chang 2004	21	0	0	0	100% at 6M
Lin 2005	31	0	0	2	100% at 6M
Pippinos 2005	17	0	0	0	100% at 12M
Matas 2007	62	0	2	0	98% at 6M
Criado 2007	104	0	0	2	97% at 40M
Faraglia 2008	48	0	0	1	100% at 6M
Leal 2010	35	0	0	0	100% at 3M
TOTAL	**318**	**0**	**0.6%**	**1.6%**	

Silk Road Clinical Program

	PROOF	LOTUS	TESLA	ROADSTER
Study type	First In Man	Single Center Registry	Multicenter EU Post-Market Registry	US Pivotal IDE
Number of Patients	75	30	56	140
Profile	All-comers	Symptomatic, Elderly	All-comers	High Surgical Risk
Status	Complete	Complete	Complete	Complete

ROADSTER STUDY

Pivotal results of a prospective, single-arm, multi-center trial of Transcarotid Stenting with Dynamic Flow Reversal in high surgical risk patients



Demographics and Technical Results	
High Surgical Risk Pivotal ITT	ROADSTER (n=141)
Age	72.9
Age ≥75	47%
Age ≥80	28%
Female	35%
Symptomatic	26%
Local Anesthesia	53%
Reverse Flow Time	10 minutes
Acute Device Success	99%
Technical Success	99%
Procedural Success	96%

Clinical Results		
S/D/MI*	5	3.5%
Major stroke	0	0%
Minor stroke	2	1.4%
Death	2	1.4%
MI	1	0.7%
Stroke & Death	4	2.8%
Cranial Nerve Injury	1	0.7%
CNI at 6 months	0	0.0%

*Hierarchical

SILKROAD MEDICAL

AP056.A

ROADSTER 1 IDE Outcomes Compare Favorably

TCAR 30-Day Outcomes on Par with CEA

	ROADSTER 1* High Surgical Risk			CREST** Standard Surgical Risk
	Pivotal (n=141)	**Con't Access (n=78)**	**All (n=219)**	**CEA Arm (n=1251)**
S/D/MI	3.5%	3.8%	3.7%	4.5%
Stroke	1.4%	1.3%	1.4%	2.3%
Death	1.4%	0.0%	0.9%	0.3%
MI	0.7%	2.6%	1.4%	2.3%
Stroke & Death	2.8%	1.3%	2.3%	2.6%
Cranial Nerve Injury (CNI)	0.7%	1.3%	0.9%	4.8%
Unresolved at 6 Mos	0.0%	0.0%	0.0%	2.0%

*Kwolek, LaMuraglia, Cambria. SVS Vascular Annual Meeting 2016

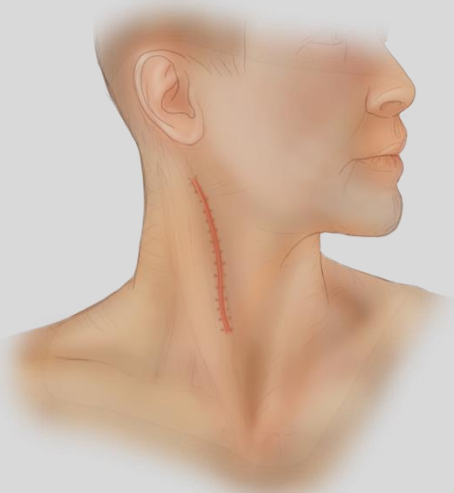
**Brott, et al. N Engl J Med 2010;363:11

ROADSTER 1 Study Outcomes

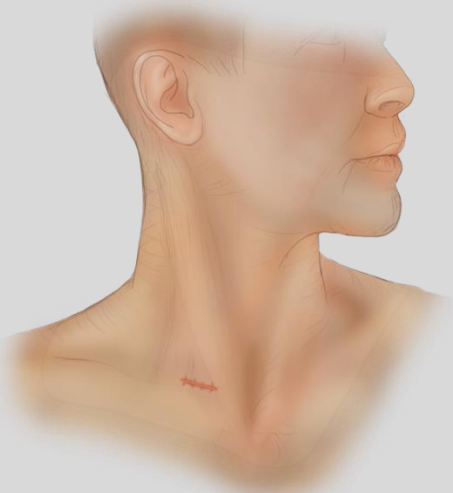
TCAR ***not*** contraindicated in "at risk" sub-groups

High Surgical Risk	Age ≥ 75 (n=91)	Symptomatic (n=43)	Female (n=83)
S/D/MI	6.6%	2.3%	2.4%
Major Stroke	0.0%	0.0%	0.0%
Minor Stroke	1.1%	0.0%	0.0%
Death	2.2%	2.3%	1.2%
MI	3.3%	0.0%	1.2%
Stroke & All Death	3.3%	2.3%	1.2%
Stroke & Cardiovascular or Neurological Death	1.1%	0.0%	0.0%

Patient-Friendly, Less Invasive Procedure

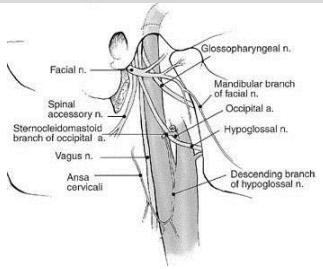


Endarterectomy



TCAR

- Reduced rate and severity of cranial nerve injury
- Local anesthesia can improve recovery time
- Cosmetic result of a less invasive procedure
  - Smaller scar in a less obvious location than with surgery



CNI was 5% in CREST, with 2% unresolved at 6 months

Transcervical Carotid Artery Revascularization

TCAR

Advantages of TCAR Procedure:

- Establish embolic protection before lesion crossing (proximal protection)
- Flow reversal ("surgical" back-bleeding)
- Avoiding the aortic arch

Transcervical Carotid Artery Revascularization

TCAR

Advantages of TCAR Procedure:

- Flow reversal ("surgical" back-bleeding)

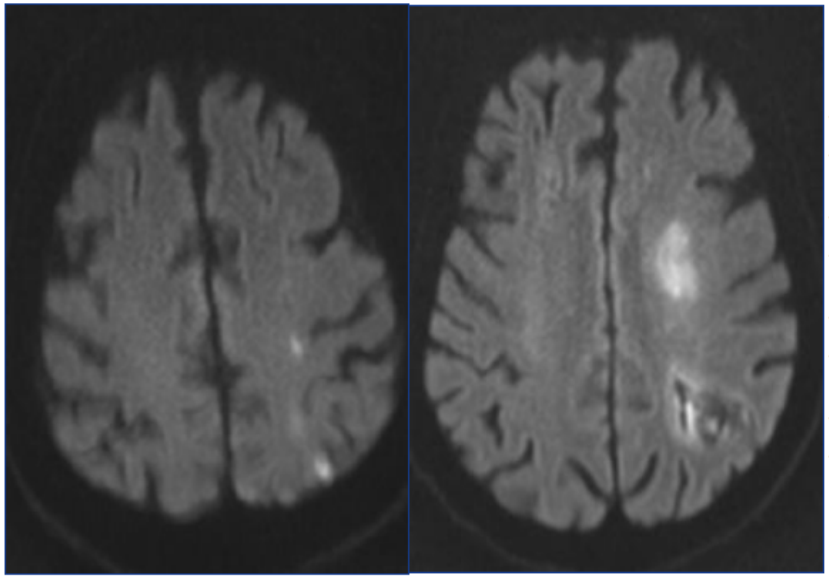
- *Plaque components range from calcium to soft thrombotic core*
- *Filter porosity is is variable*
- *Vasospasm at filter site*
- *Thrombus above filter*

Transcervical Carotid Artery Revascularization

TCAR

Advantages of TCAR Procedure:

- Avoiding the aortic arch



DW-MRI Lesions with CAS/CEA

- Common after carotid intervention
- Incidence / location varies approach
- Bilateral w/ transfemoral CAS
- Evidence of correlation to neurocognitive decline [1]

[1] Akkaya E, et al. Int J Cardiol. 2014;176(2):478-83.

Transcervical Carotid Artery Revascularization

TCAR

Advantages of TCAR Procedure:

- Avoiding the aortic arch

Study	Access	EPD	Embolic Protection	Patients	% w/ New DWI Lesions
ICSS[2]	CEA	Clamp, backbleed	Clamp, backbleed	107	17%
ICSS[2]	Femoral	Distal	Distal filter (various)	51	73%
PROFI[1]	Femoral	Distal	Distal filter (Emboshield)	31	87%
PROFI[1]	Femoral	Transfemoral CAS	Proximal occlusion (MoMA)	31	45%
PROOF[3]	Transcervical	Flow Reversal	Transcarotid Access, w/ Flow Reversal	56	19%

Should All Patients Be Treated with TCAR?

- *Transfemoral CAS / Arch Manipulation*

- *Stroke (?)*
- *Neurocognitive Decline*

Transcervical Carotid Artery Revascularization

Outcomes of Contemporary CAS & CEA Trials

TCAR

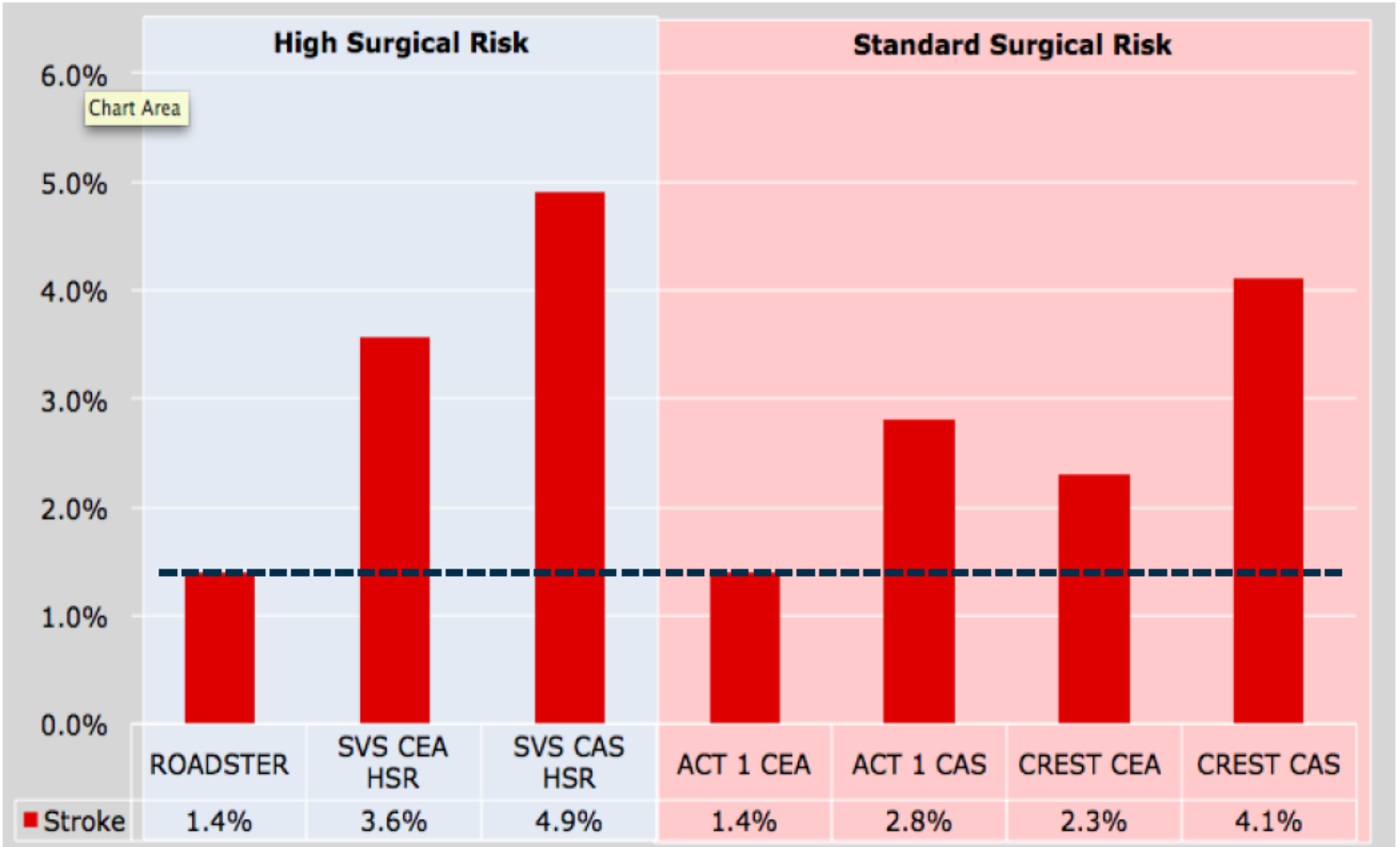


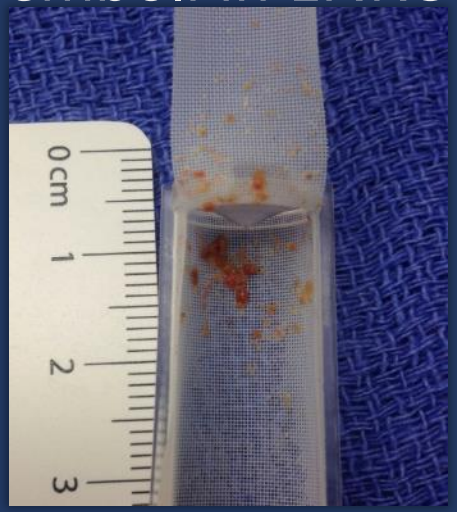
Table 2: Periprocedural Stroke Rates in Contemporaneous Publications of TCAR, CEA and Transfemoral CAS

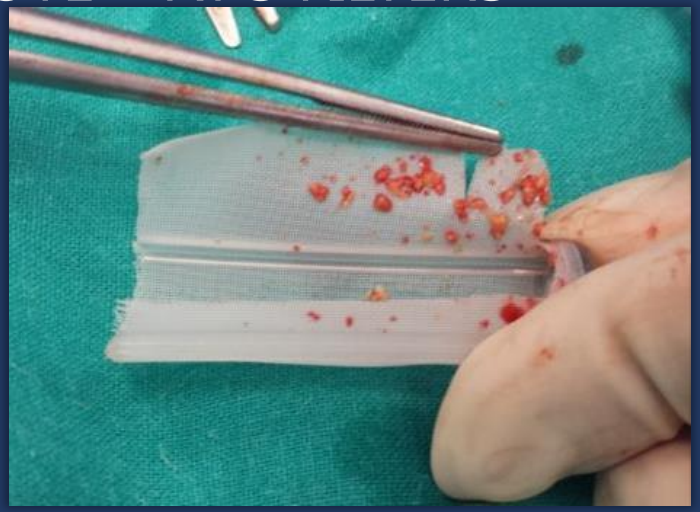
The New Bar?

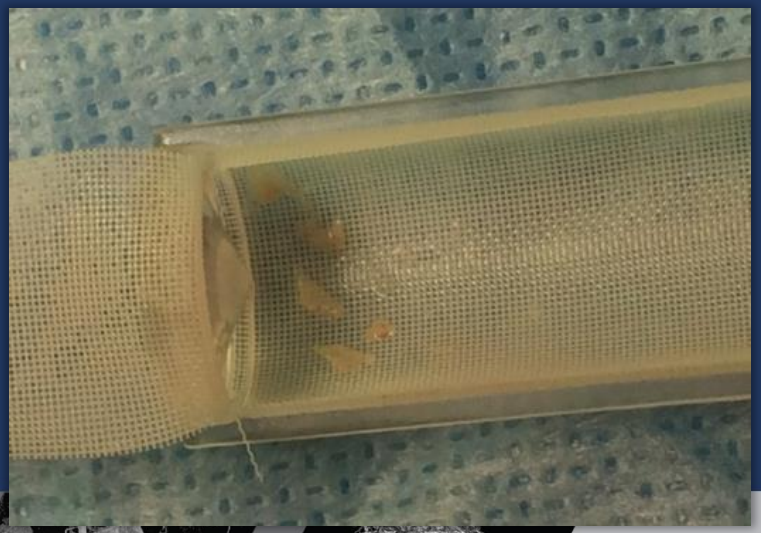
Stuff Gets By…

THE PROOF IS IN THE FILTER

Macro & Micro emboli in ENROUTE™ NPS FILTERS







TCAR

- Minimally invasive
- Avoids the arch
- Ultimate neuroprotection, minimal emboli
- Durable
- The new gold standard for Carotid Artery Stenting ???

TCAR

The new gold standard for carotid revascularization ???

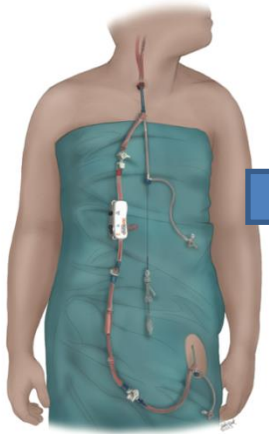
Medical Management Critical

Eat healthy

Stop smoking

Anti-platelet
High-dose statin
Anti-hypertensive

exercise



Stress relief!!!!


THANK YOU

- Click to edit Master text styles
  - Second level
    - Third level
      - Fourth level
        - » Fifth level