Tratamiento cirurgico o endovascular de la estenosis carotidea ?

Jiri J. Vitek, MD, Ph.D.

Lenox Hill Heart and Vascular Institute of New York

Do We Need An Alternative To

Carotid Endarterectomy?

Stenosis C2 level **Post. CAS.** **10. months control**

Post CEA restenosis

Wallstent 10x20

CEA 3 times.

Post radiation stenoses.

Post CAS.

M.D. 47M 6/03/05

STENTING v/s CEA

The Undisputed facts

- Less Invasive
- No Gen Anesthesia or sedation
- ALL cases performed using Local Anesth. at femoral access site
- No (ZERO) Cranial Nerve Injuries
- Vascular Hemostasis Devices permit early ambulation

CAROTID STENTING

Ready For Prime Time?

How Do Results of Stenting Compare with Results of CEA?

Why in randomized trials there is a low rate of complications in CEA?

1. "High surgical risk" patients excluded.

2. CEA based on non – invasive studies.

   (US, CTA, MRA)

3. Cranial nerve palsies are not "complications"

   considered "collateral damage"

4. General anesthesia.

   covers procedural events

High Surgical Risks

Group 1 (Anatomic)

- **High Lesions, Low lesions, prior CEA, Contra Occlusion, prior neck radiation, cervical immobility etc**

Group 2 (Co Morbidities)

- **Cardiopulmonary (specific criteria), need for surgery etc. Risk of GA.**

for CAS not high risk

Co-morbidities X Complications

2001-2008 NIS (National Inpatient Sample) hospital discharge data.

	CEA (N – 181.200)	CAS – (12.485)
Co-morbidities		
Acute renal failure	0.4%	2.0%
Chronic renal failure	0.9%	6.0%
Myocardial infarction	0.2%	1.0%
Congestive heart failure	1.6%	11.0%
COPD	2.6%	17.0%
Diabetes	8.4%	26.0%
Hypertension	20.4%	64.0%
Valvular disease	4.6%	5.0%
Hyperlipidemia	16.8%	53.0%
Complications		
Death	0.6%	0.8%
Stroke	1.0%	1.7%

CEA based on non – invasive studies.

June 03 – Oct. 07 1126 patients admitted for revasularization based on non-invasive studies.

All underwent cervico – cerebral angiography.
350 patients (31%) did not fulfill the criteria for revascularization (≥50% stenosis symptomatic; ≥ 75% asymptomatic)

Eligible for revascularization: P – 776

Cranial nerve palsy ??

Minor stroke ? NO

Major stroke ? NO

= Collateral damage

CEA Complications

	NASCET	ECST
	1991	
Death or stroke	5.8% *	7.1%
Cranial nerve palsy	7.6 %	6.4%
Wound complications	8.9 %	3.3%
CVS complications	3.9 %	0.2%
Other	0.3%	
Total complications	**26.2 %**	**19.3%**

*Adjudication at 30 days.

SAPPHIRE – 30 day events in randomized patients

Endpoints	Stent (n=156)	CEA (n=151)	P value
Death	0.6%	2.0%	0.38
Stroke	3.8%	5.3%	0.58
MI	2.6%	7.3%	0.07
Combined	5.8%	12.6%	0.047
Cranial nerve palsy	0%	5.3%	

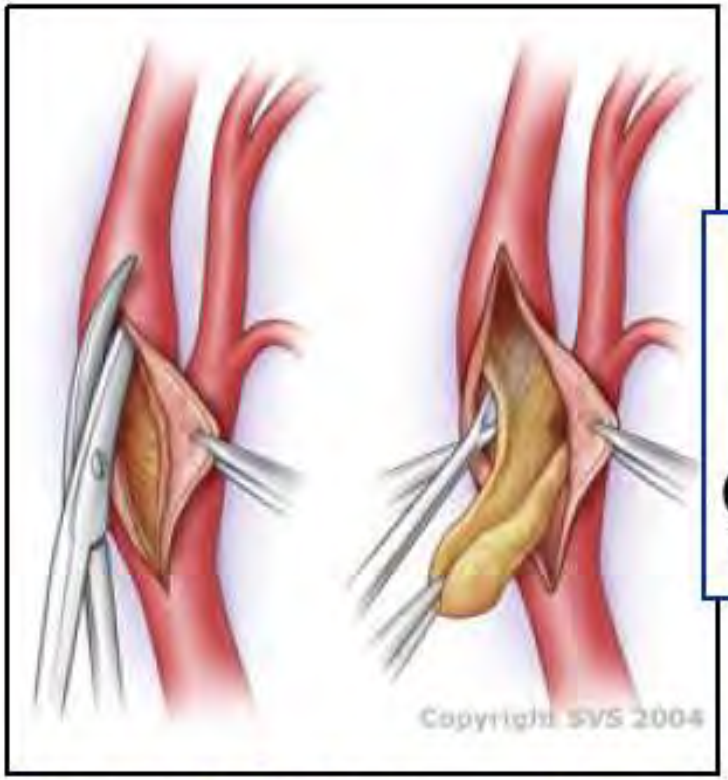
No Observed CAS Related Cranial Nerve Injury in CREST

Patients with study procedure attempted/received	CAS N = 1,131	CEA N = 1,176	p-value
Procedure Related Cranial Nerve Injury	0.0%	**5.3%** (62/1176)	< 0.0001
Unresolved at One Month	0.0%	**3.6%** (42/1176)	< 0.0001
Unresolved at Six Months	0.0%	**2.1%** (25/1176)	< 0.0001

End Points that Matter.

- Neurologists care about Strokes
- Cardiologists care about Myocardial Infarction.
- Patients care about Strokes, MI's and Cranial Nerve Palsy.

Carotid Revascularization Endarterectomy vs Stenting Trial

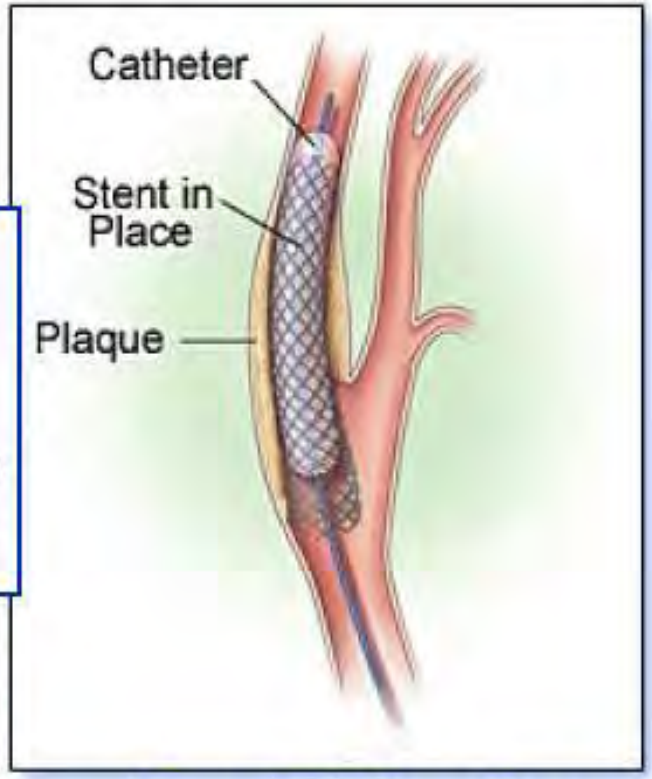


Carotid Endarterectomy

CREST

Carotid Revascularization Endarterectomy vs. Stenting Trial

VS.



Carotid Stenting

Lead – in phase of CREST.

Carotid Revascularization Endarterectomy vs Stenting Trial

427 interventionalists applied

73 (17%) exempt lead – in phase

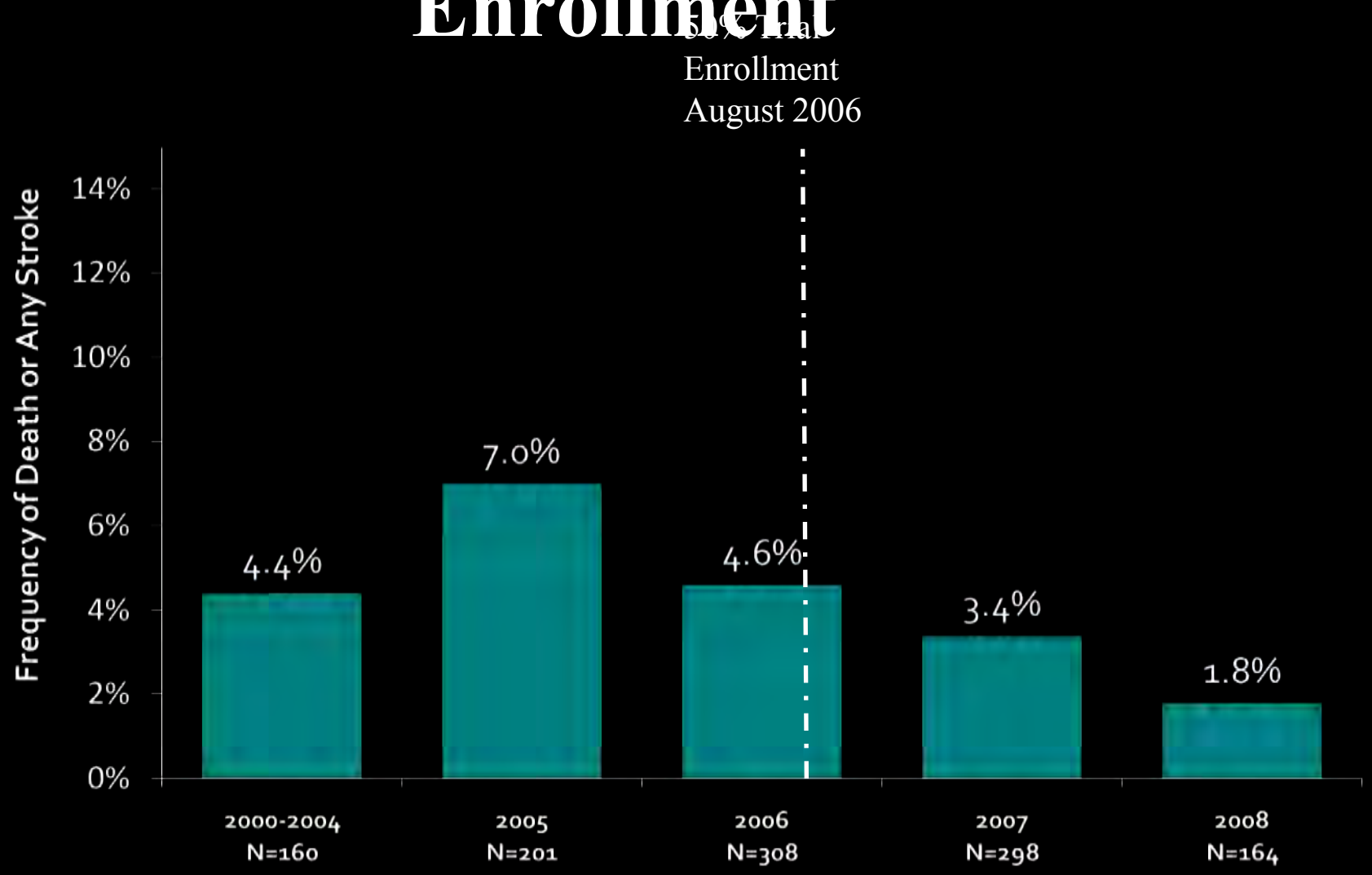
116 (27%) rejected

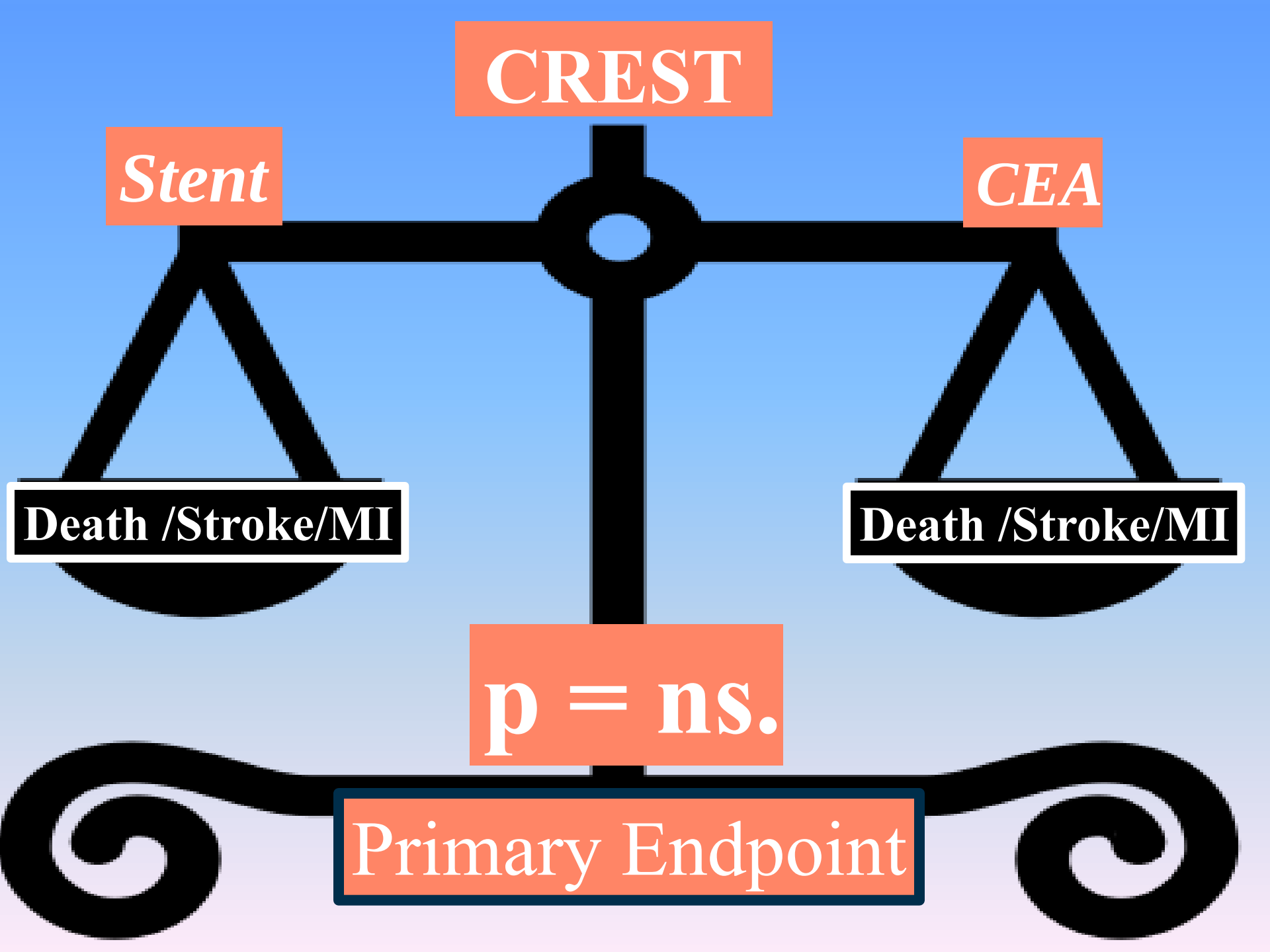
238 (56%) selected to participate in lead – phase

14 (6%) rejected

224 (52%) selected to participate in CREST

Death or Any Stroke Rates Decrease for CAS over the Period of CREST Enrollment




CREST
Stent
CEA
Death /Stroke/MI
Death /Stroke/MI
p = ns.
Primary Endpoint

Peri-procedural Stroke and MI

	CAS vs. CEA	Hazard Ratio 95% CI	P-Value
Stroke	4.1 vs. 2.3%	HR = 1.79; 95% CI: 1.14-2.82	0.01*
MI	1.1 vs. 2.3%	HR = 0.50; 95% CI: 0.26-0.94	0.03

* Driven by Minor Stroke

CREST

Peri-procedural.

CEA

Death /Major/Minor Stroke

Stent

Delta = 1.8%

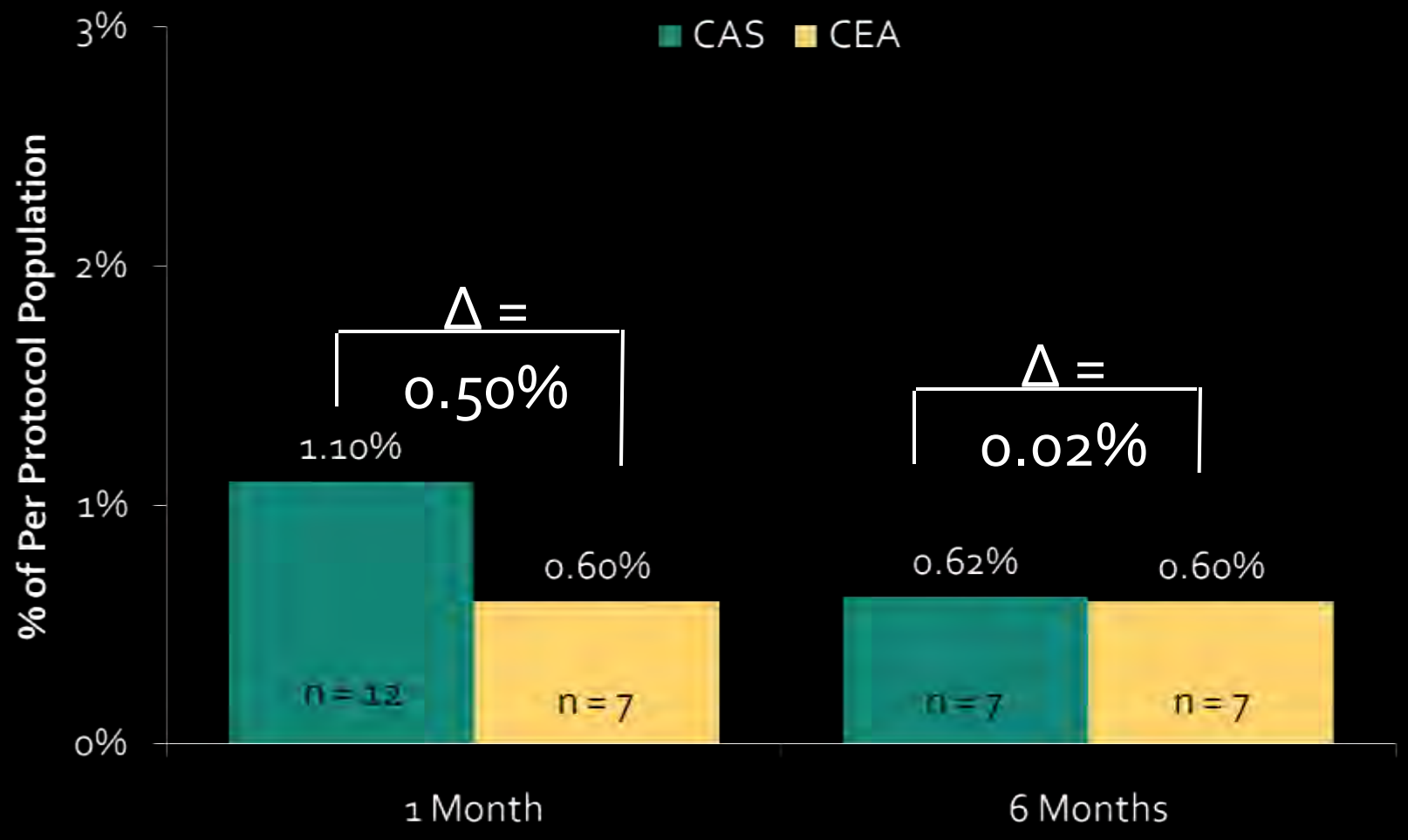
Predominantly Minor Strokes = 1.5%

Death /Major /Minor Stroke

Ignoring MI's and cranial nerve palsies.

Residual neurological findings (based on NIHHS scale) in minor strokes.

At 6 months - no difference.



Cranial Nerve Palsies

Peri-procedural

CAS vs. CEA	Hazard Ratio, 95% CI	P-Value
0.3 vs. 4.7%	HR = 0.07; 95% CI: 0.02-0.18	<0.0001

CREST

Stent

Death /Major /Minor Stroke
Cranial N. Palsy/ MI

CEA

Delta = 3.6%

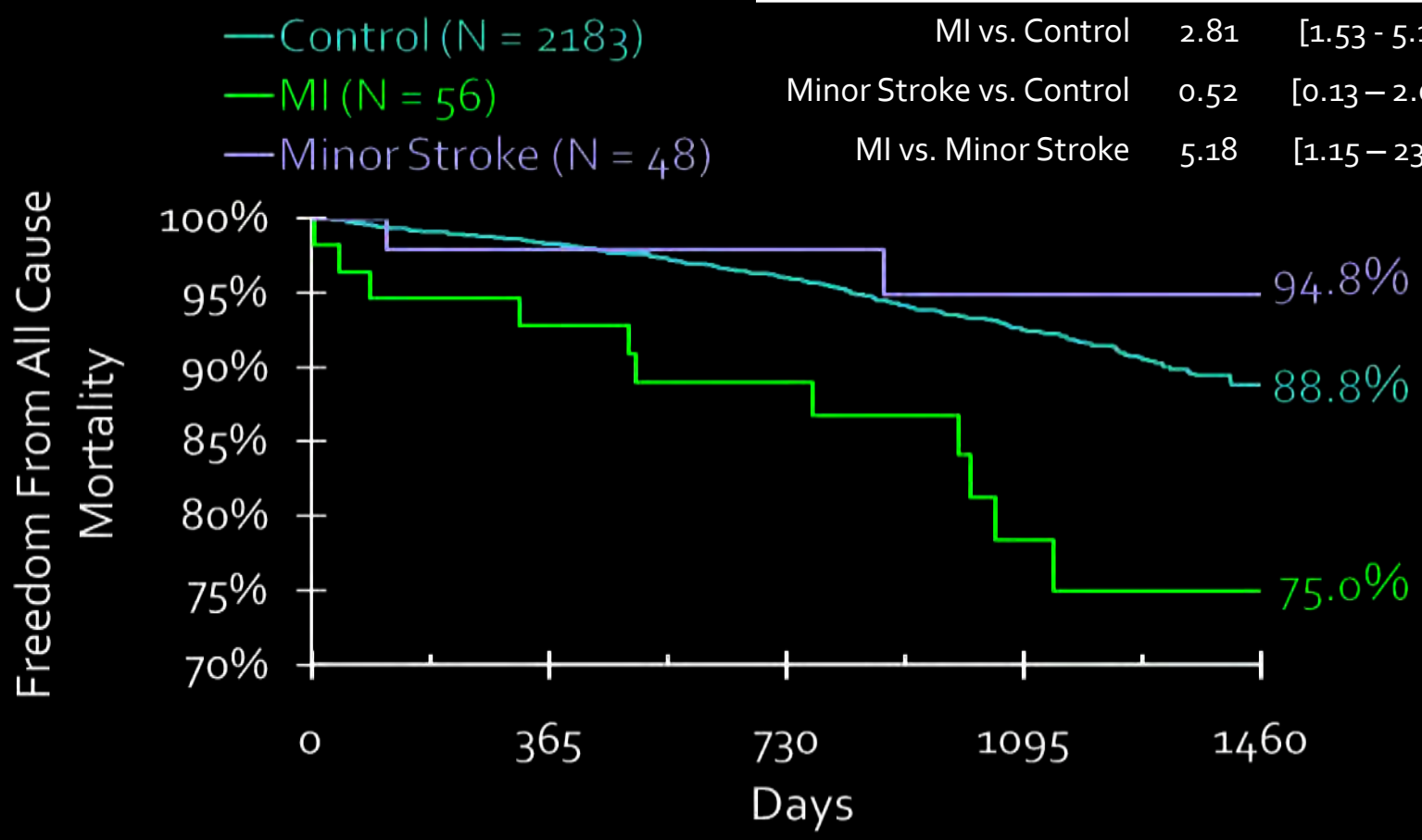
(4.5 % minus 2.1% plus 1.1% MI.)

Death /Major /Minor Stroke
Cranial N. Palsy/ MI

Stenting is looking like a less morbid revascularization alternative to CEA

Importance of minor strokes and MI on long term mortality.

Comparison	HR	HR Confidence Interval	Log Rank P-value
MI vs. Control	2.81	[1.53 - 5.17]	0.0005
Minor Stroke vs. Control	0.52	[0.13 – 2.09]	0.34
MI vs. Minor Stroke	5.18	[1.15 – 23.4]	0.02



1. Los pacientes con infarto de miocardio (IM) o solo elevacion de los biomarcadores tuvieron una probabilidad 3 o 4 veces mayor de fallecer durante el periodo de seguimiento que los pacientes sin signos de IM.

2. Por otro lado CREST no demostro asociacion alguna entre la presencia de pequena isquemia cerebral y la mortalidad a largo plazo. Comparado con la isquemia cerebral pequena, el IM se asocio a una mortalidad 5.2 veces mayor a largo plazo.

3. En los pacientes que sufrieron un IM peri-procedimiento o inmediatamente despues de este, la superviviencia a los 4 anos del mismo fue del 75% frente al 94% de los que padecieron una isquemia cerebral menor.

CREST conclusions

1. La revascularizacion Carotidea es segura y efectiva en la prevencion de la ischemia cerebral.

2. Segun los resultatos del End point promarios ambas technicas son eqivalentes en cuatnto a la aparicion de eventos mayores cardion – vasculater.

3. El peso de la evidencia demuestra que el CAS es un preccedimiento con una menor morbilidad.

4. Los resultados de CAS continua mejorardo debido a la creciente experiencia y a un mejor conocimiento de los factores de riesgo.

Avoiding complications is vital….

Key to avoiding Complications

=

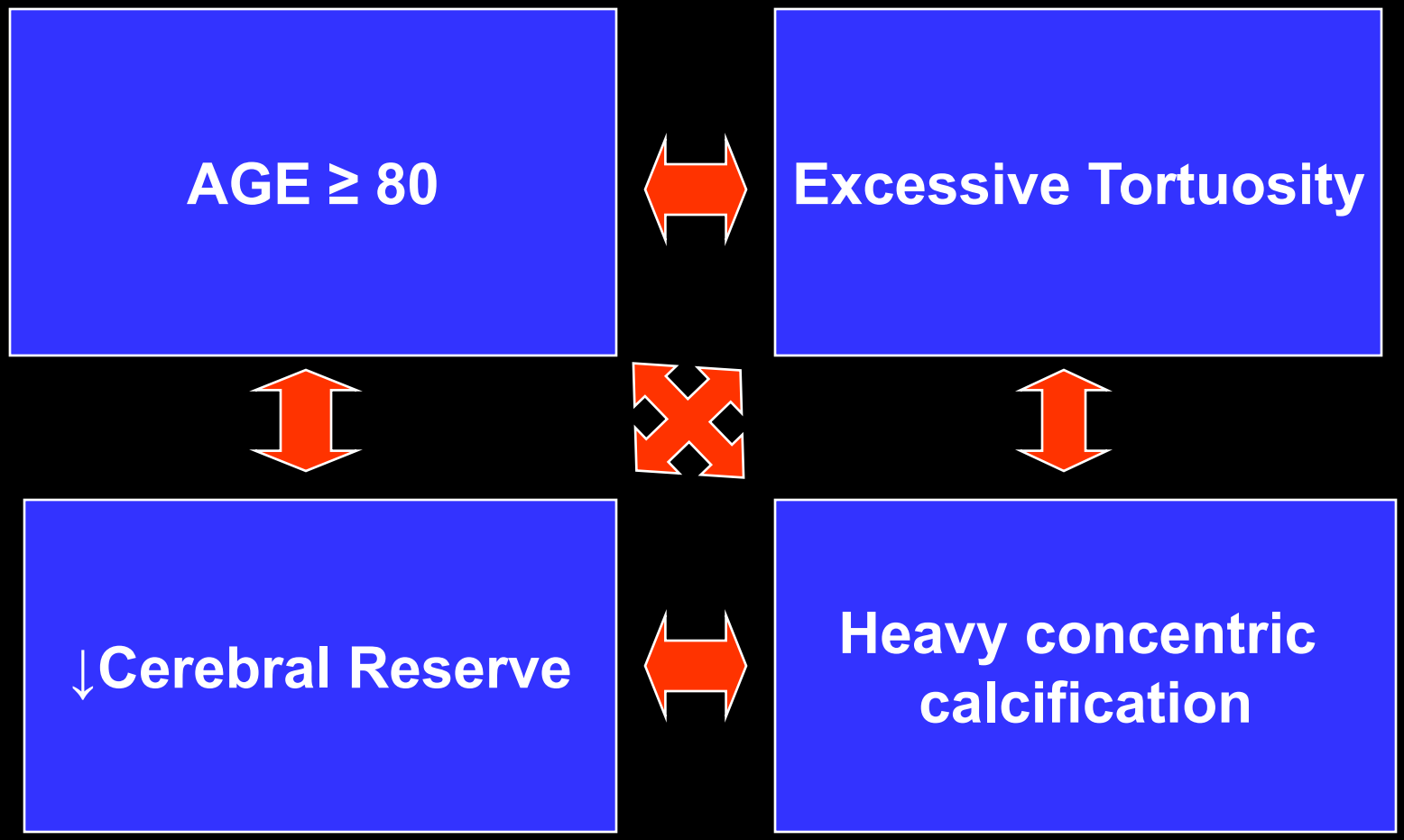
Recognizing Situations where complications can be expected

High Risk Patients
High Risk Lesions
for
CAROTID STENTING

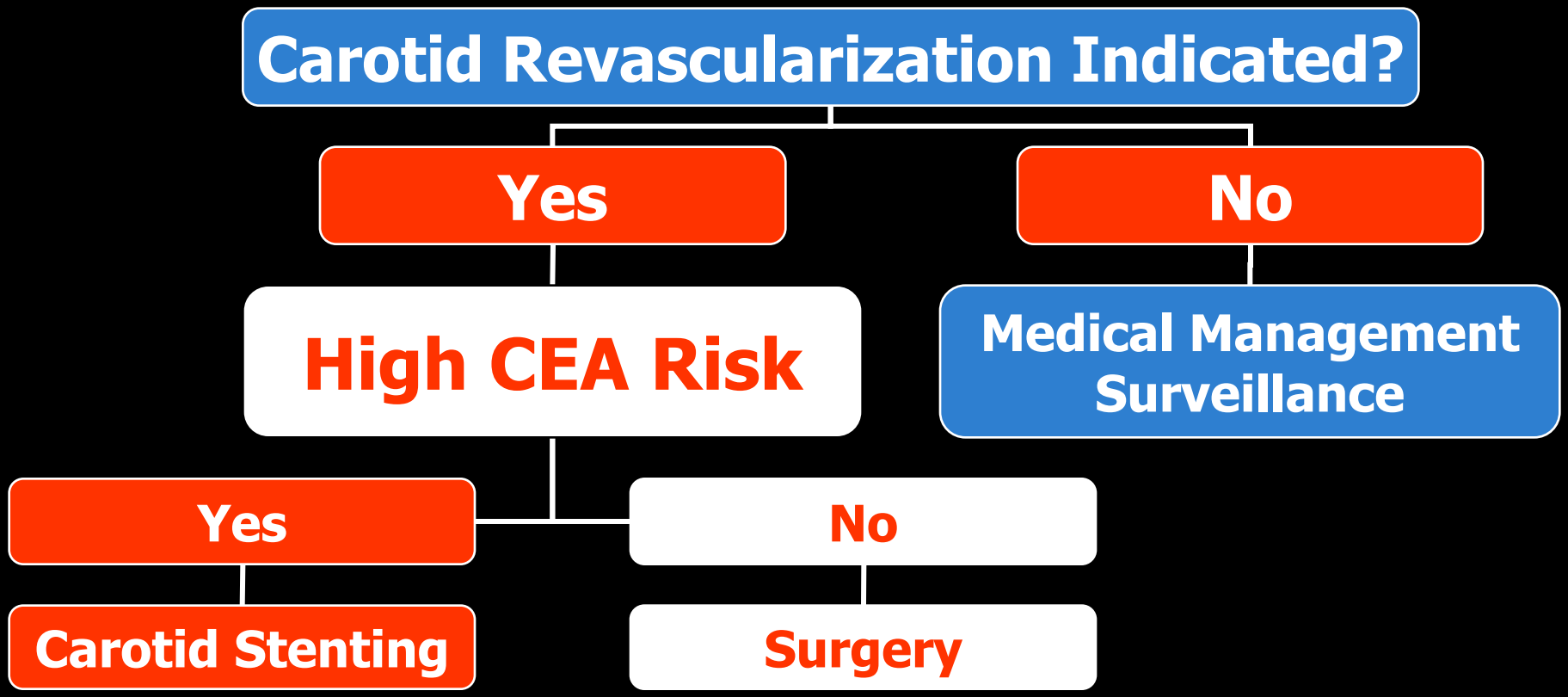
Criteria of High Risk Carotid Stenting

- **Clinical**
  - **Age >80y.**
  - **Cerebral Reserve**
    - **Dementia**
    - **Prior CVA**
    - **Microangiopathy**
    - **Multiple lacunar infarcts**
- **Anatomic**
  - **Excessive Tortuosity**
    - **≥ 2 90 bend points, including take off from CCA→ICA, within 5cm of each other AFTER sheath placement**
  - **Heavy concentric calcification**
    - **≥ 3mm and deemed by at least 2 orthogonal views to be circumferentially situated around lesion**

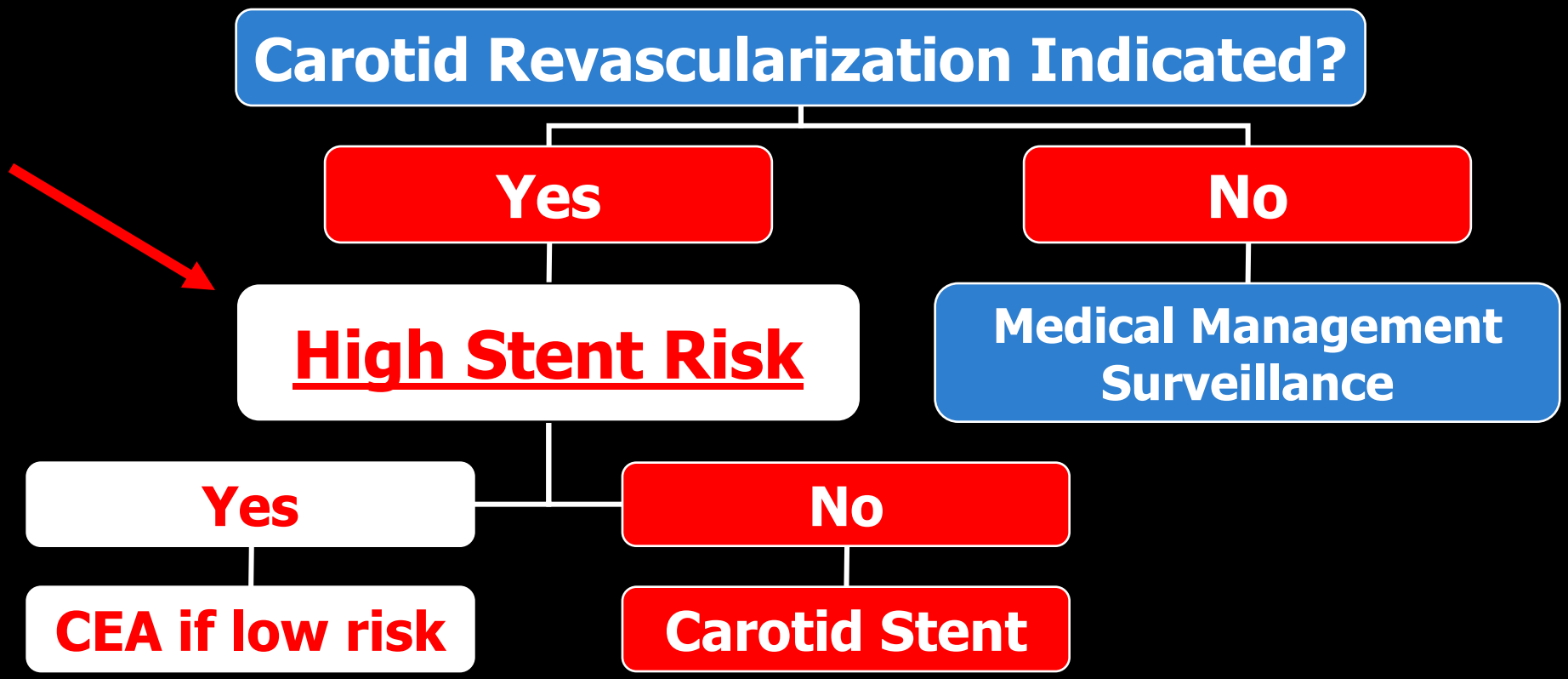
Any 2 of the following = High Risk



Traditional Paradigm



Proposed New Paradigm



If high risk for both – MEDICAL THERAPY

Patient Selection
Lesion Selection
is
Critical for CAS

C A V E A T

BE SELECTIVE !

NOT ALL LESIONS ARE AMENABLE TO CAS especially when using protection devices.

It is proper to recommend surgery rather then to risk complication.

Is Carotid Stenting *Better* Than CEA?

CONCLUSIONS

CEA

Complementary Methods for stroke prevention

CAS

Selection of the method depends on:

Condition of the patient + age
Anatomy of the lesion
Patient preference
Experience of the operator

Patient Preference

Although all of us love our surgeons,

NOBODY loves surgery!

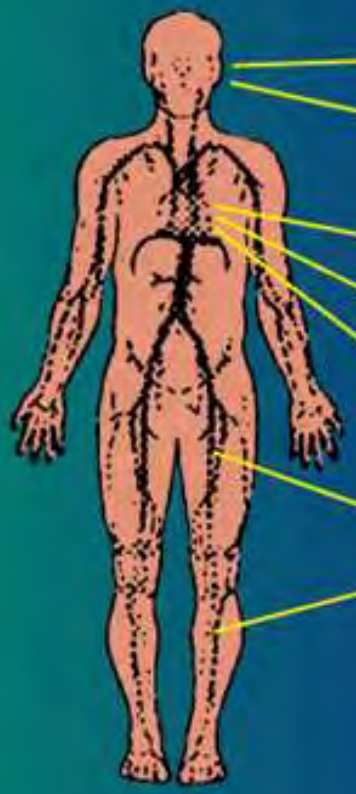
Estenosis Carotidea y enfermedad Coronaria

J. Vítek MD,PhD S. Iyer MD, FACC

Lenox Hill Heart and Vascular Institute of New York

Peripheral Arterial Disease

Manifestations of Atherosclerosis



- Transient ischemic attack
- Ischemic stroke
- Unstable angina pectoris
- Non-Q-wave myocardial infarction
- Q-wave myocardial infarction
- Claudication
- Critical limb ischemia, rest pain, gangrene, amputation

Ischemic sudden death

Combined Carotid and Coronary Artery Disease

Background

- **Actualmente no existe consenso sobre cual es la mejor estrategia para el tratamiento combinado de la enfermed arteriel coronaria y carotidea.**

- **Debido a la ausencia de estudios randimisados.**
  - El riesgo actual de ictus con tratamiento medico optimo no es conocido.
  - La mejor estrategia de revascularizacion: CEA vs. CAS is not known

- **La practica habitual sobre la populacion con enfermedad carotidea y coronaria se basa en la extrapolacion de los resultados de los estudios randomizados sobre los pacientes con enfermedada carotidea aislada. .**

Combined Carotid and Coronary Artery Disease

Background

- **Despite these limitations carotid revascularization in this setting is common**

- **Vast majority of procedures (96%) are performed for asymptomatic carotid artery disease**

- **Controversy arises because:**
  - Recent advances in medical treatment (DAPT and

Cardiac mortality in patients undergoing carotid endarterectomy (1990)

(Survival table)

	Coronary disease	No coronary disease + risks (tabakism, diabetes, cholesterol)	No coronary disease
30 days	98.5%	100%	100%
5 years	68.6%	86.4%	90.5%
10 years	44.9%	72.3%	87.9%
15 years	36.4%	54.3%	87.9%

Late mortality in patients with carotid disease post CEA is not stroke related, but related to coronary disease.

Mackey WC, O'Donnel Jr. TF, Callow AD: Cardiac risk in patients undergoing CEA. Impact on perioperative and long-term mortality. J Vasc Surg 11:226-34, 1990

SAPPHIRE Study

Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy

Randomized, multi-center trial comparing stenting with protection to endarterectomy in high surgical risk patients

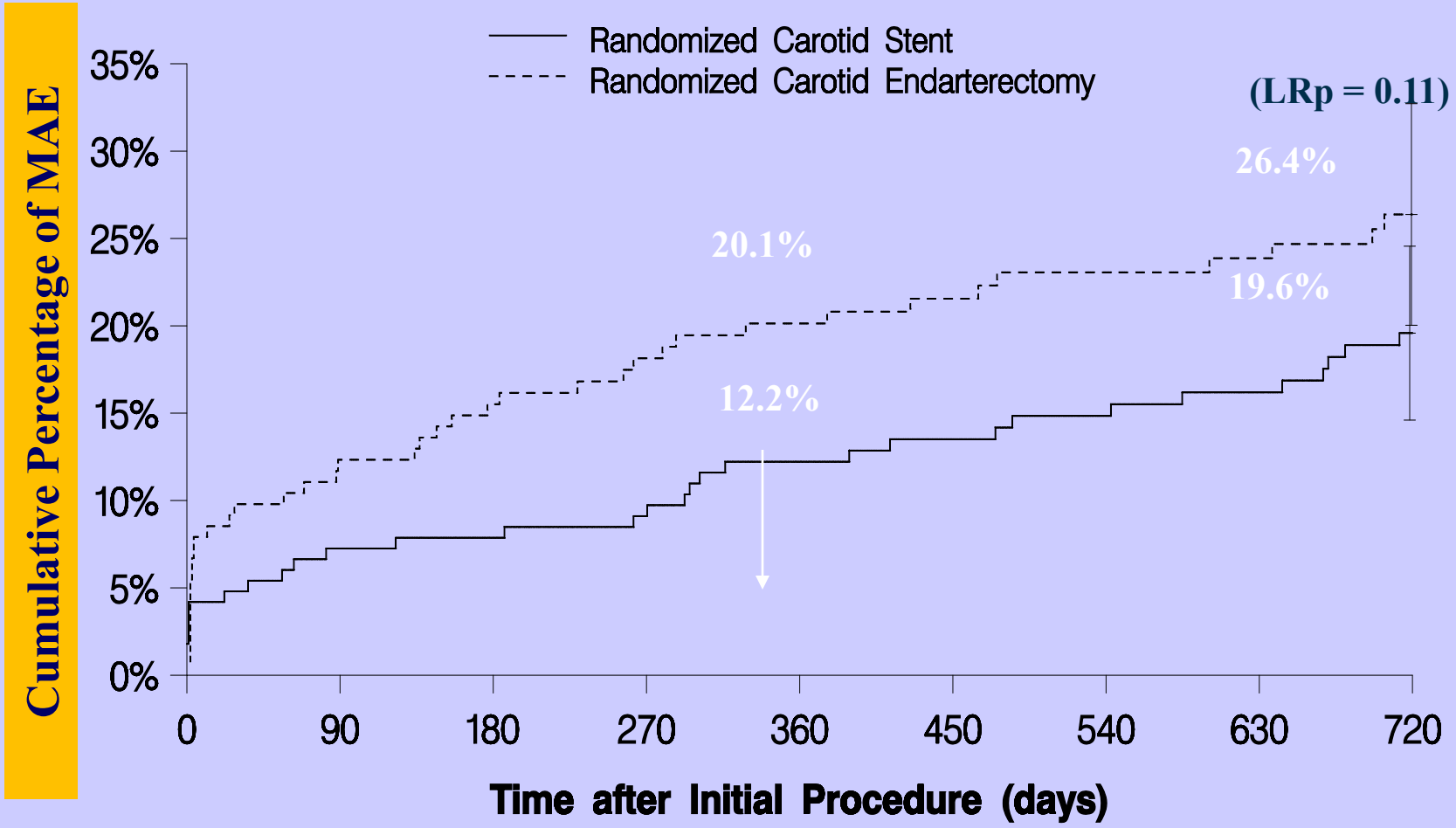
Key Inclusion Criteria

- **Symptomatic ≥ 50% stenosis by US or angiogram**
- **Asymptomatic ≥80% stenosis by US or angiogram**
- **Patients must have one or more of the following conditions that place them at increased surgical risk:**
  - **congestive heart failure (class III/IV) and/or known severe left ventricular dysfunction LVEF <30%**
  - **open heart surgery needed within six weeks**
  - **recent MI (>24 hrs. and <4 weeks)**
  - **unstable angina (CCS class III/IV)**
  - **contralateral carotid occlusion**
  - **contralateral laryngeal nerve palsy**
  - **radiation therapy to neck**
  - **previous CEA with recurrent stenosis**
  - **high cervical ICA lesions or CCA lesions below the clavicle**
  - **severe tandem lesions**
  - **age greater than 80 years**

SAPPHIRE – 30 day events in randomized patients

Endpoints	Stent (n=156)	CEA (n=151)	P value
Death	0.6%	2.0%	0.38
Stroke	3.8%	5.3%	0.58
MI	2.6%	7.3%	0.07
Combined	5.8%	12.6%	0.047
Cranial nerve palsy	0%	5.3%	

Sapphire Study – 2 Year Data
Cumulative % of MAE to 720 Days
Randomized Patients – Kaplan Meier Analysis



Asymptomatic Carotid Disease in Patients undergoing CABG

Prevalence

- **>80% Carotid Stenosis in the CABG population: 8-12%**

(Salasidis GC, J Vasc Surg 1995)

- **>70% Carotid Stenosis + 3V CAD or Left Main: 7-11%**

(Steinvil A J AM Coll Cardiol 2011)

Unilateral carotid occlusions in 1-1.5% of CABG patients

- **Bilateral Carotid Disease in CABG population (3%):**

Bilateral 50-99% stenosis (2.2%)

Unilateral 50-99% Stenosis + contra lateral occlusion

Bilateral Carotid occlusions

Carotid revascularization and surgery

Screening

Rational: To prevent stroke in presence of carotid stenosis by BP drop.

Symptomatic patient : ≥ 50% **revascularization**
Asymptomatic patient: ≥ 80%
Asymptomatic (contralat. occl.) : ≥ 70% (?)

1. **US / Doppler** SV ≥ 230 (less important)
   DV ≥ 120
   in uncertainty

2. **MRA** (over estimates by 15%)

   if contraindicated

3. **CTA** (calcifications)

4. **Revascularization** **CEA**
   CAS

Asymptomatic Carotid Disease in Patients undergoing CABG

Do we need to screen all patients?

Selective screening strategy recommended for the asymptomatic patient

(AHA/ACC 2004 Guidelines; Class I Ia Level C)

- **Left Main disease**
- **> 65 years (? 70 years)**
- **Smoking**
- **PAD**

Asymptomatic Carotid Disease in Patients undergoing CABG

Risk of Stroke

Stroke is a well known complication od CABG

- 2008 Medicare Data: 1.3% incidence of peri-operative stroke
- Patients Specific Variables: Older age, Female gender
  Aortic calcifications
  CHF
  Priori h/o Stroke
  Atrial fibrilation
  Atheroma aortic arch

(25% strokes from cross clamping

Carotid Revascularization and CABG

CEA	combined	CEA than CABG
	staged	CABG than CEA
		CEA than CABG
CAS	staged	CAS than CABG
		dual anti platelet therapy
		CABG in one month

1. Confusing observational data – difficult to recommend one approach over another
2. Combined generally acknowledged higher complications
3. Advantage of CAS – less invasive usually before surgery.

Carotid Disease in Patients and CABG

Revascularization

- **With symptomatic stenosis: Treat**

- **With unilateral asymptomatic 80 – 99% may benefit.**
- **With bilateral asymptomatic 80 - 99% may benefit**
  - **Treat one side**: The side with more severe stenosis or the dominant hemisphere

- **Contralateral occlusion**
  - Opposite side symptomatic stenosis with >50%: **Treat**
  - Opposite side asymptomatic stenosis: **Treat if lesion is > 70%**

Summary

- **Con el envejecimiento de la populacoin sometida a CABG la presencia de enfermedad carotidea presenta un problema importante.**

- **Symptomatic stenosis should be treated**

- **Absence of randomized trials – unanswered questions for Asymptomatic stenosis**
  - Should asymptomatic carotid artery disease be treated? If so, which ones?
  - What kind of treatment: CEA or CAS?
  - If CEA: what should be the sequence or should it be

Summary

CAS si es antomicamente y technicamente posible puede ser considerado como el procidimento de eleccion en los pacientes asimptomaticos con enfermedad coronari severa antes de sicugia dado el riesgo de infarcto de miocardia con la ECA – segun CREST.