

Controversies in Carotid Bifurcation Disease Management:

Diagnosis, Technique, the Asymptomatic Patient, Physician Training and Reimbursement

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Presenter Disclosure Information

Name: William Gray

Within the past 12 months, the presenter or their spouse/partner have had the financial interest/arrangement or affiliation with the organization listed below.

Company Name:

- CoAptus
- Abbott
- Guidant
- Cordis/J&J
- BSC

Relationship:

Consultant
SAB
Consultant
Consultant
Consultant

Preface

- **Although present in the US for ~10 years, and in multi-center trials for ~6 years, and with device approval for ~1 year, patient access to carotid stenting remains limited**
- **Factors that continue to limit patient access include regulatory and reimbursement issues**
- **To the extent there are controversies in management of these patients, and provide limited or unclear direction, they may contribute to the continued limitation of patient access at the regulatory and reimbursement levels**

Controversies in carotid disease management

- **Diagnosis (imaging)**
- **Technique**
- **The asymptomatic patient**
- **Training**
- **Reimbursement**

Carotid stenter's considerations

- **Access**
 - Arch anatomy
- **Filter placement and retrieval**
 - ICA tortuosity
- **Stent placement and expansion**
 - ICA anatomy and lesion pathology
- **Embolic potential of lesion**
- **Patient factors**
 - Cerebrovascular reserve: may be a measure of embolic tolerance

Ideal imaging

- **Anatomic**
 - **Lesion**
 - severity of stenosis
 - location
 - calcification
 - thrombus
 - ulceration
 - tortuosity
 - **Access pathway qualities**
 - aortic arch anatomy
 - pathology in innominate or common carotid
 - **Collateral circulation integrity**
 - Intra- and extra- pathways
 - **Associated cerebrovascular pathology**
- **Physiologic**
 - **Flow restriction**
 - **Cerebrovascular reserve**
 - **Lesion composition relative to embolic properties**
- **Applicable for post-stent evaluation**



Doppler ultrasound

- **Information provided**
 - **Anatomic**
 - Lesion severity, location, calcification, +/- thrombus or ulceration, +/- tortuosity
 - Some associated cerebrovascular pathologic information
 - Some information on embolic potential
 - Echogenicity has been correlated with emboli, however is highly operator/interpreter dependent
 - **Physiologic**
 - Flow restriction
- **Limitations**
 - No information on cerebrovascular reserve
 - No access information
 - No/minimal collateral information
- **Advantages**
 - Office-based
 - Repeatable after stenting (with modification)

Biasi GM et al. Circulation. 2004 Aug 10;110(6):756-62



Trans-cranial Doppler

- **Information Provided**
 - **Anatomic**
 - Intra-cranial collateral assessment
 - **Physiologic**
 - Potential to assess cerebrovascular reserve and embolic tolerance
 - CO₂ reactivity
- **Limitations**
 - Limited availability and expertise at some centers
 - No lesion/stent anatomic information
- **Advantages**
 - Office-based
 - Best when combined as an adjunct to Doppler ultrasound



Computed tomography angiography

- **Information provided:**
 - **Anatomic**
 - Lesion severity, location, calcification, tortuosity, +/- ulceration, - thrombus
 - **Access anatomy and pathology**
 - **Collateral anatomy**
 - **Cerebral pathology**
- **Limitations**
 - **Generally hospital-based**
 - **Expense**
 - **Contrast and radiation exposure**
 - **No physiologic information**
- **Advantages**
 - **Does not overestimate stenosis**

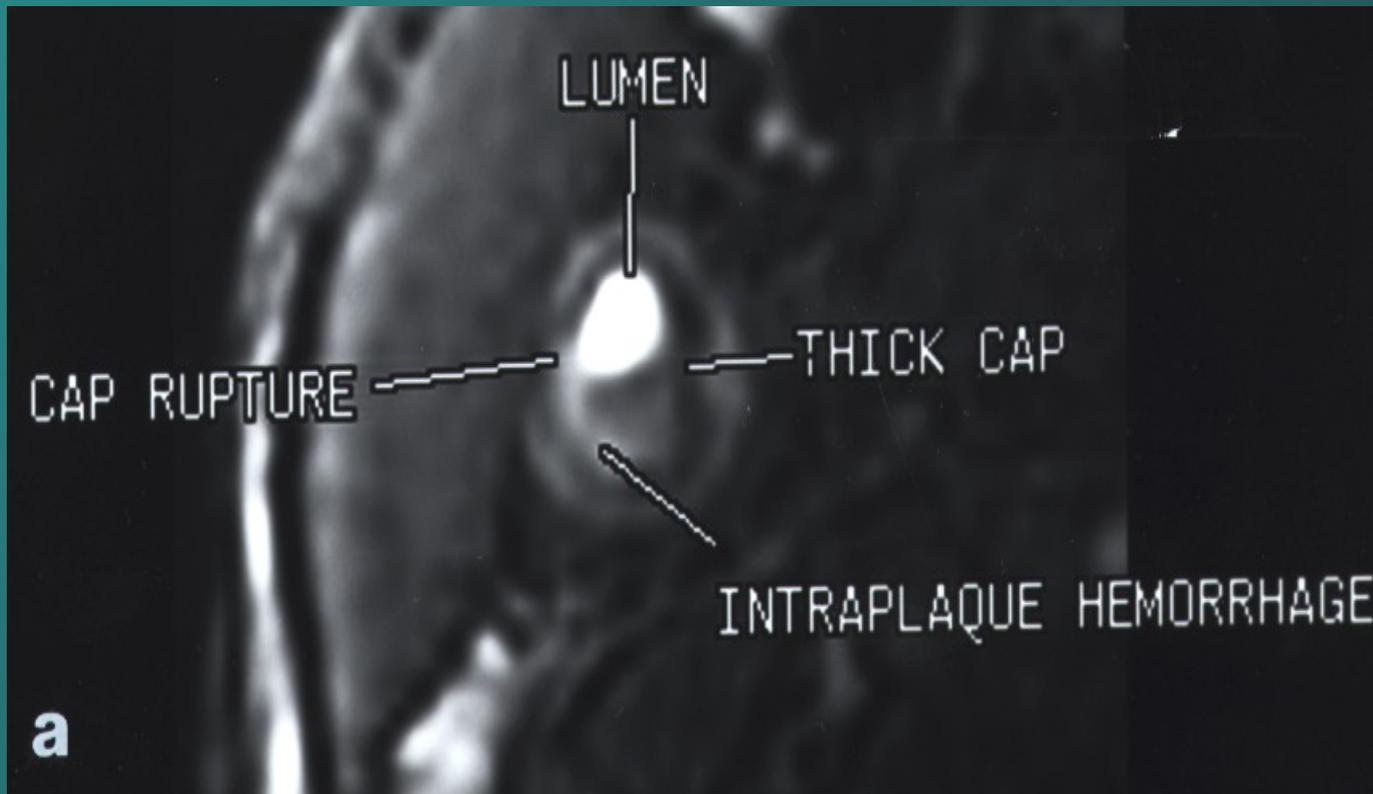


Magnetic resonance angiography

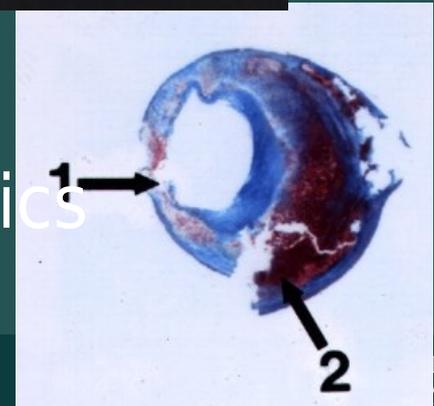
- **Information provided:**
 - **Anatomic**
 - Similar to CTA, but since imaging is based on flow may be limited in low-flow states
 - Close-coil receivers can give information regarding lesion morphology and possibly its embolic potential
- **Limitations**
 - Generally hospital-based
 - Expense
 - Limitations on patients (pacemakers, etc)
 - Imaging sensitive to motion artifact
 - Overestimation of stenosis is occasionally seen
 - No physiologic information
 - Not useful in post-stent evaluation
- **Advantages**
 - No ionizing radiation or iodinated contrast exposure



Imaging improvements: High-resolution MRI



May allow greater insight into lesion characteristics



Ideal imaging: 2005

- **Anatomic**
 - **Lesion**
 - severity of stenosis
 - location
 - calcification
 - thrombus
 - ulceration
 - tortuosity
 - **Access pathway qualities**
 - aortic arch anatomy
 - pathology in innominate or common carotid
 - **Collateral circulation integrity**
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- **Physiologic**
 - **Flow restriction**
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 - **Lesion composition relative to embolic properties**
- **Applicable for post-stent evaluation**

Doppler ultrasound
with TCD



Ideal imaging: future

Will add to the “mechanical” fund of knowledge necessary to perform the procedure by **stratifying patients according to both their embolic potential (lesion specific) as well as ability to tolerate emboli (cerebrovascular reserve)**

Will almost certainly be multi-modal

Technique

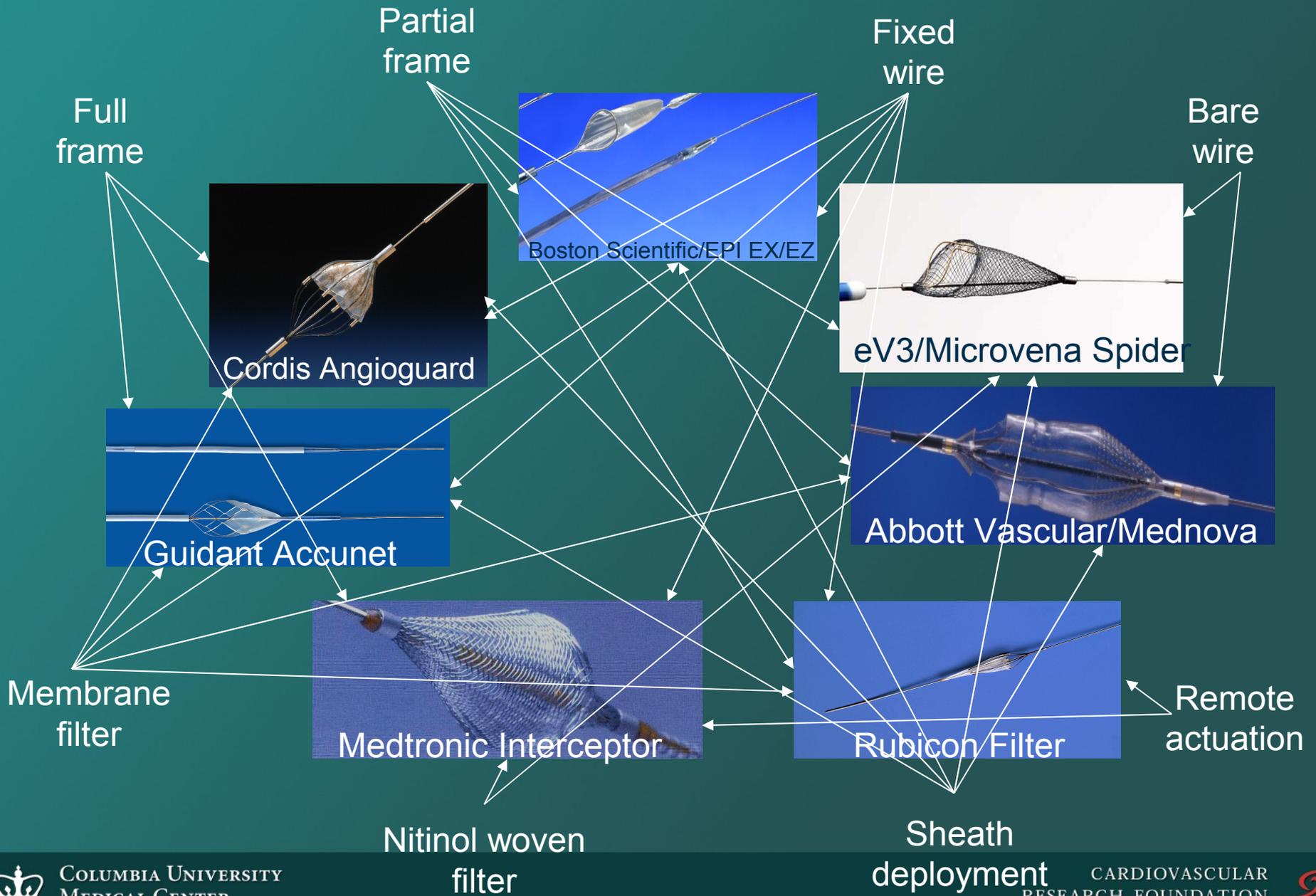
- The carotid stenting technique has been significantly “homogenized” as a result of:
 - Multi-center trials, especially CREST
 - Training targeted at specialties with different skill sets
- No significant controversies to report in the technique of carotid stenting

Stent characteristics as a function of design

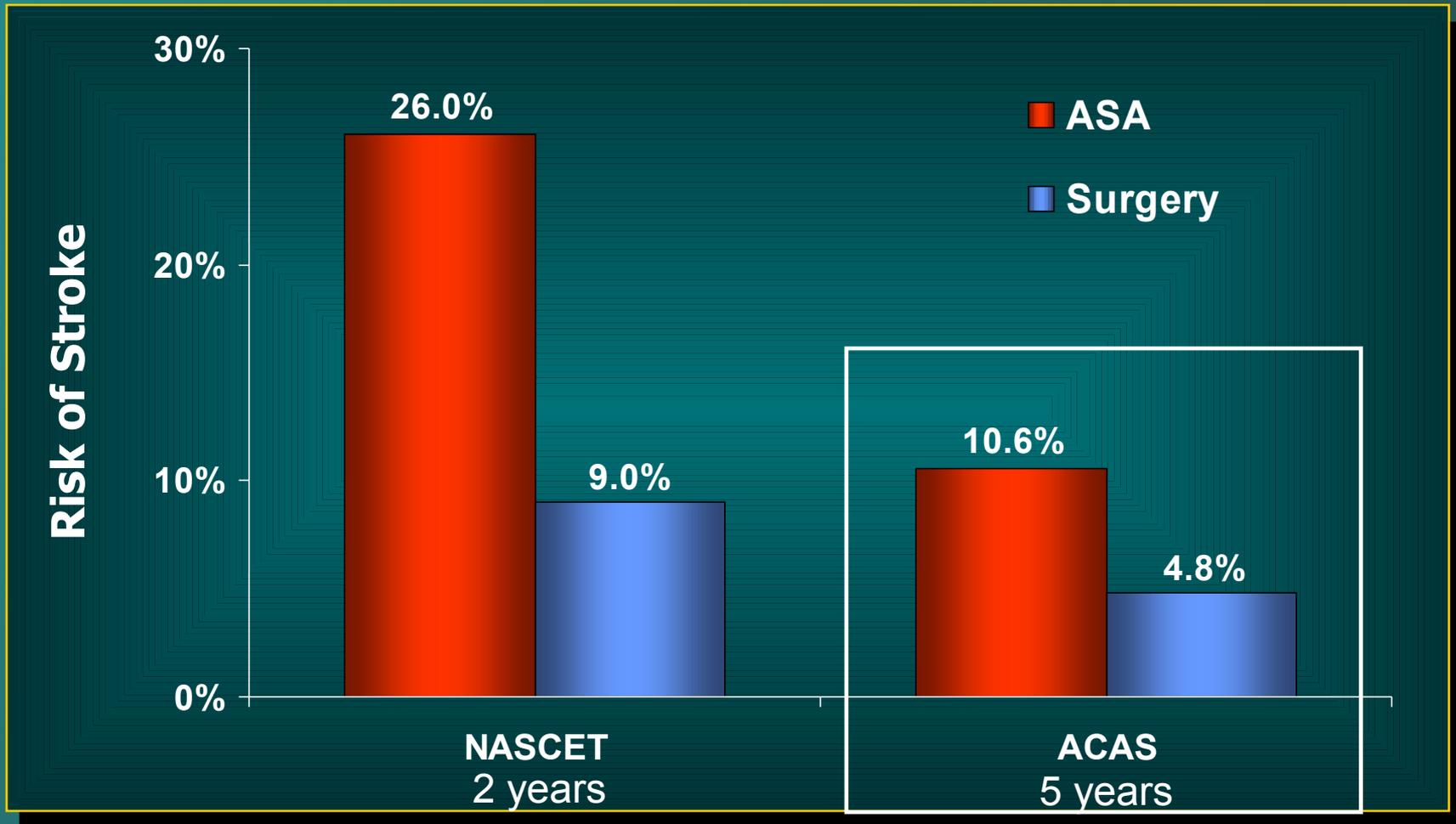
	Woven Stainless Steel: closed cell	Nitinol tube: Closed cell	Nitinol tube: Open cell	Nitinol sheet: Closed cell
Flexibility	-	-	++	+
Conformability	-	-	++	0
Radial/outward force	0	++	++	+
Vessel coverage	++	++	0	++
Foreshortening	++	0	+	0
Prototypical lesion	Straight, with soft plaque (prolapse prevention)	Straight, short calcified lesion	Tortuous anatomy, irregular vessel	Soft plaque (prolapse prevention)



Filters by type

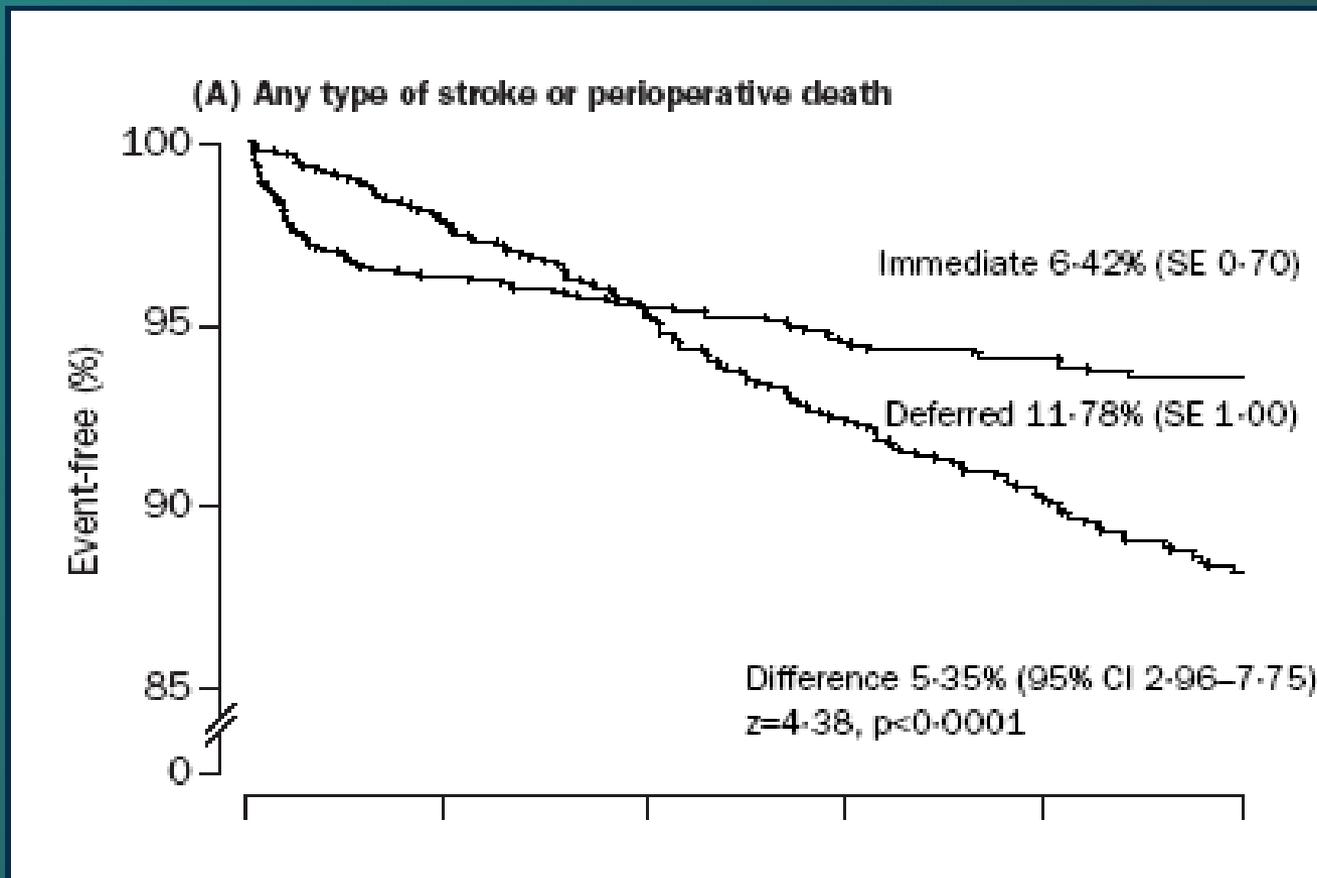


The asymptomatic patient



ACST

Any Stroke or Perioperative Death



ACST Investigators. *Lancet* 2004;363:1491-1502



The asymptomatic patient

- In neurology circles some controversy about the beneficial effects in this cohort still exists
- The *de facto* practice of CEA in the US, however, includes about 70% asymptomatic patients
- Regarding carotid stenting the following apply:
 - The FDA has approved for symptomatic and asymptomatic patients at high risk for surgery
 - CMS has approved coverage for only symptomatic high risk patients
 - Ongoing trials (ACT I and CREST) are randomizing the normal surgical risk patients



Training summary

- **With the entry of Abbott, BSC, Cordis, etc into the marketplace, along with Society-sponsored courses, there will be no shortage of training opportunities available**
- **Limitations to training will center around access to patients secondary to restrictive regulatory or reimbursement policy**
- **Although late to the game, vascular surgery will likely assume a greater, although not dominant, role in carotid stenting, likely at the expense of IR**
- **Availability of fellowship trained operators will not likely have an influence on the practice of carotid stenting for at least 5 years and then will parallel the coronary experience (paucity, saturation, paucity) over the next 15-20 years**



Coverage and reimbursement

- **CMS is appears to be undertaking a broad effort of establishing a “pay-for-performance” algorithm**
 - **Carotid stenting is the poster child**
- **Recent conversations regarding expanding coverage indications to asymptomatic high risk patients will be at a minimum predicated on PMS results which demonstrate:**
 - **The successful transference of the trial results into “real world” settings at all levels of experience**
 - **No device related issues**
- **Independent/unbiased data collection (such as the ACC-NCDR effort), with transparency, is a paramount condition of any expansion of reimbursement**



Regulatory perspectives

- With the approval of carotid stent systems from multiple manufacturers, but for only limited indications, there will be many devices chasing only a small subset of CEA (<10,000 of 200,000), certainly not the original billion dollar market projection
- Further expansion in the mainstream is predicated on the **successful** completion of ACT I and CREST
- The earliest anticipated approval for normal risk is 2010*
- However IDE sites (via post-market surveillance studies, industry and site-sponsored IDE's) will be operating with significant freedom. Depending on enrollment criteria, particularly for PMS registries, a more significant impact in patient access/market penetration/research is likely

*based on current enrollment rates in ACT I and CREST with optimal rates anticipated of ~30-50/month, 1 year follow-up to primary endpoint, and 1 year regulatory process (6 month to data lock/submission, 6 month FDA)

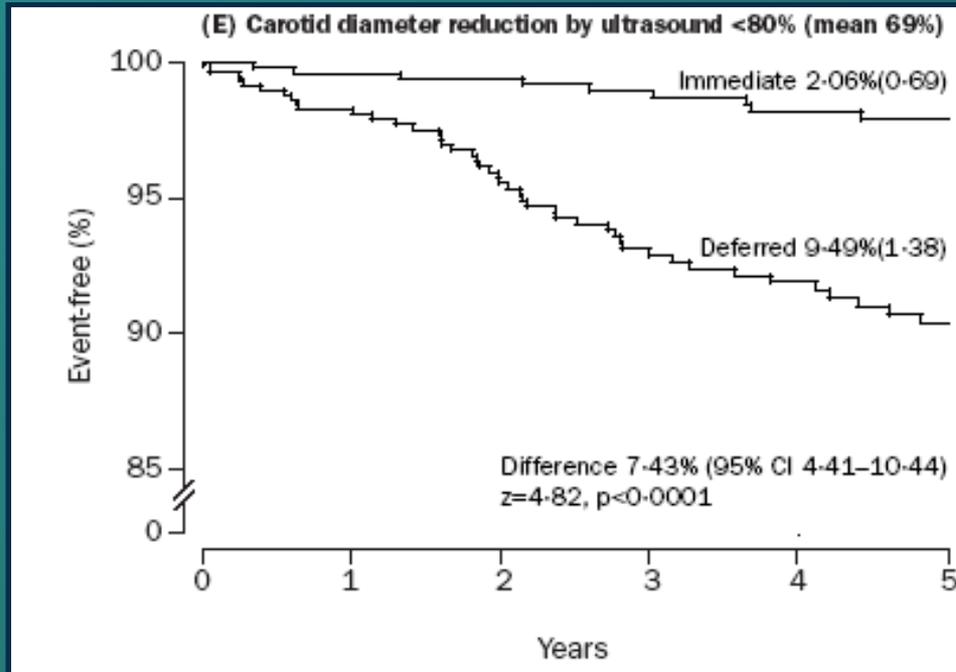


Conclusions

- The emergence of an option for carotid stenting for patient with bifurcation disease has expanded a once solitary surgical domain into other specialties
- There will not be a shortfall of trained/trainable MDs that would limit therapy
- Much of the current clinical decision-making is based on coverage and reimbursement decisions by CMS. No new data is anticipated for 4-5 years that would expand FDA-approved indications
- As carotid stenting becomes more proven in broader patient subsets, as selection for therapy improves based on individual patient characteristics, and as more physicians from all specialties become trained, the majority of carotid therapy will shift to CAS
- The clinical paradigm (able, available, and affable) will dominate once the therapy is fully diffused, and carotid stenting operators become “commoditized” by the referring community
- This will take years...

Early vs. Deferred Carotid Endarterectomy in Asymptomatic Patients with >70% ICA Stenosis

<80% ICA Stenosis



80-99% ICA Stenosis

