

SHOULD CAROTID/STENT  
ANGIOPLASTY BE RE-  
IMBURSED FOR THE  
TREATMENT OF AVERAGE RISK  
SYMPTOMATIC AND  
ASYMPTOMATIC PATIENTS?

# DISCLOSURES

- I am a co-principal investigator for the CREST trial
- I am Professor and Chief, Emeritus, in the Division of Vascular Surgery at UCLA

# ENDOASCULAR SURGERY

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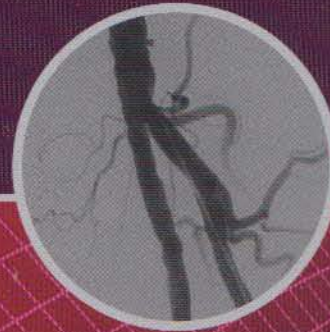
Edited by

WESLEY S. MOORE AND SAMUEL S. AHN



*Moore & Ahn*  
**ENDOVASCULAR  
SURGERY**

FOURTH EDITION



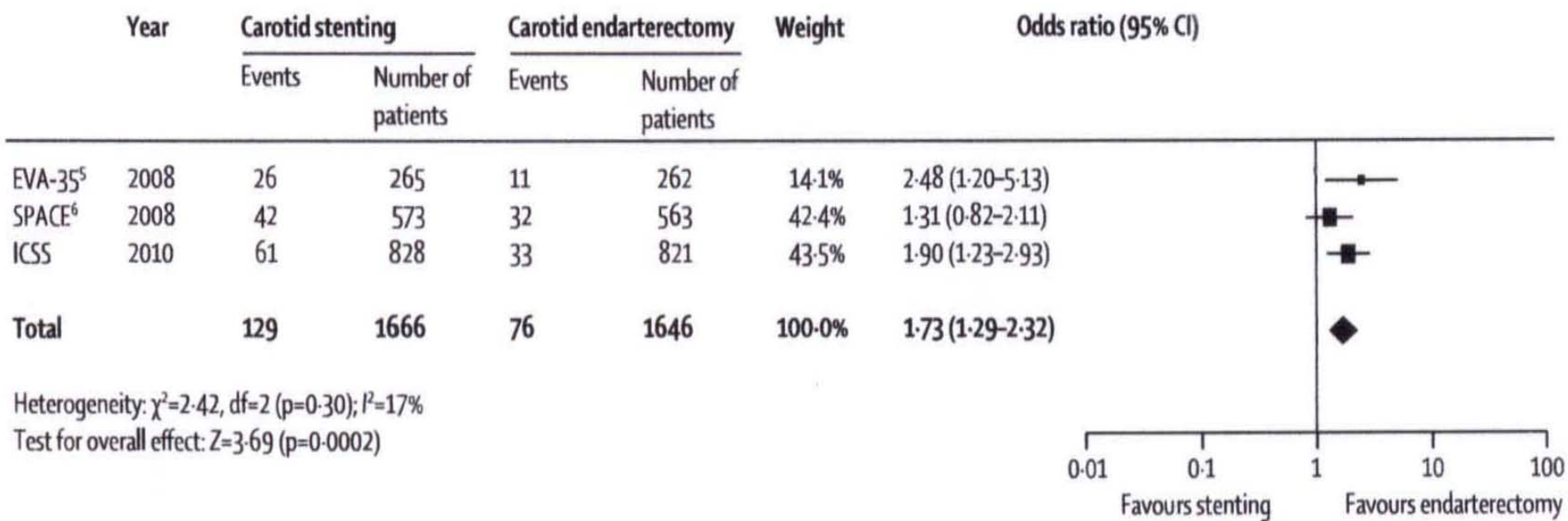
# POSITION

When carotid stent angioplasty(CAS) is as safe and cost effective as carotid endarterectomy(CEA), my vascular surgery colleagues and I will quickly incorporate it into our options for treatment

That time has not yet arrived

# LEVEL 1 EVIDENCE

- EVA 3-S TRIAL-FRANCE
- SPACE-GERMAN SPEAKING COUNTRIES
- ICSS-INTERNATIONAL TRIAL
- CREST-NORTH AMERICA



# INTERNATIONAL CAROTID STENTING STUDY(ICSS) DESIGN

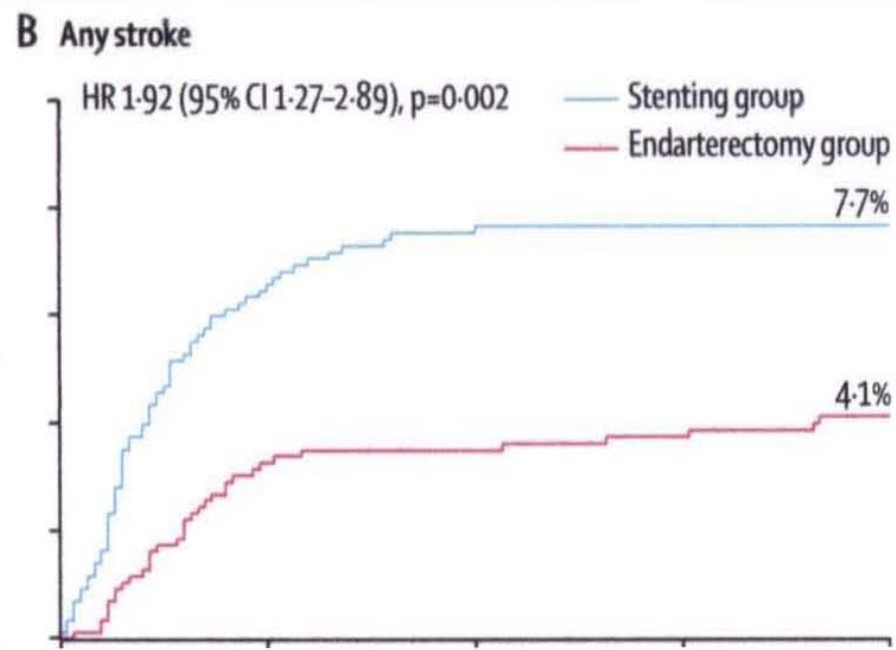
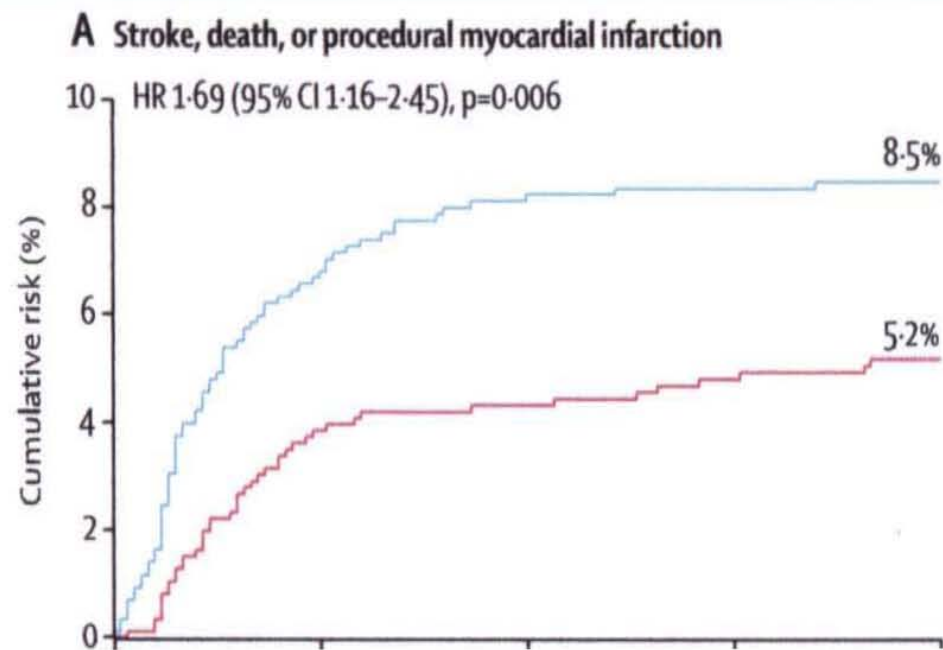
- Prospective Randomized Trial Comparing CEA with CAS in Symptomatic Patients
- 50 Academic Centers in Europe, Australia, New Zealand, and Canada
- Primary Outcome in 120day Interim Analysis included Death, Stroke, or Procedural Myocardial Infarction



	Stenting group (n=853)	Endarterectomy group (n=857)	Hazard ratio (95% CI)	Risk difference, % (95% CI)	p value*
Stroke, death or procedural myocardial infarction	72 (8.5%)	44 (5.2%)	1.69 (1.16 to 2.45)	3.3% (0.9 to 5.7)	0.006
Any stroke	65 (7.7%)	35 (4.1%)	1.92 (1.27 to 2.89)	3.5% (1.3 to 5.8)	0.002
Any stroke or death	72 (8.5%)	40 (4.7%)	1.86 (1.26 to 2.74)	3.8% (1.4 to 6.1)	0.001
Any stroke or procedural death	68 (8.0%)	36 (4.2%)	1.95 (1.30 to 2.92)	3.8% (1.5 to 6.0)	0.001
Disabling stroke or death	34 (4.0%)	27 (3.2%)	1.28 (0.77 to 2.11)	0.8% (-0.9 to 2.6)	0.34
All-cause death	19 (2.3%)	7 (0.8%)	2.76 (1.16 to 6.56)	1.4% (0.3 to 2.6)	0.017

Data are number of first events (Kaplan-Meier estimate at 120 days). Risk differences are calculated from Kaplan-Meier estimates at 120 days. \*Log-rank test.

**Table 3: Outcome measures within 120 days of randomisation (intention-to-treat population)**



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# New ischaemic brain lesions on MRI after stenting or endarterectomy for symptomatic carotid stenosis: a substudy of the International Carotid Stenting Study (ICSS)



*Leo H Bonati, Lisa M Jongen, Sven Haller, H Zwenneke Flach, Joanna Dobson, Paul J Nederkoorn, Sumaira Macdonald, Peter A Gaines, Annet Waajier, Peter Stierli, H Rolf Jäger, Philippe A Lyrer, L Jaap Kappelle, Stephan G Wetzel, Aad van der Lugt, Willem P Mali, Martin M Brown, H Bart van der Worp, Stefan T Engelter, for the ICSS-MRI study group\**

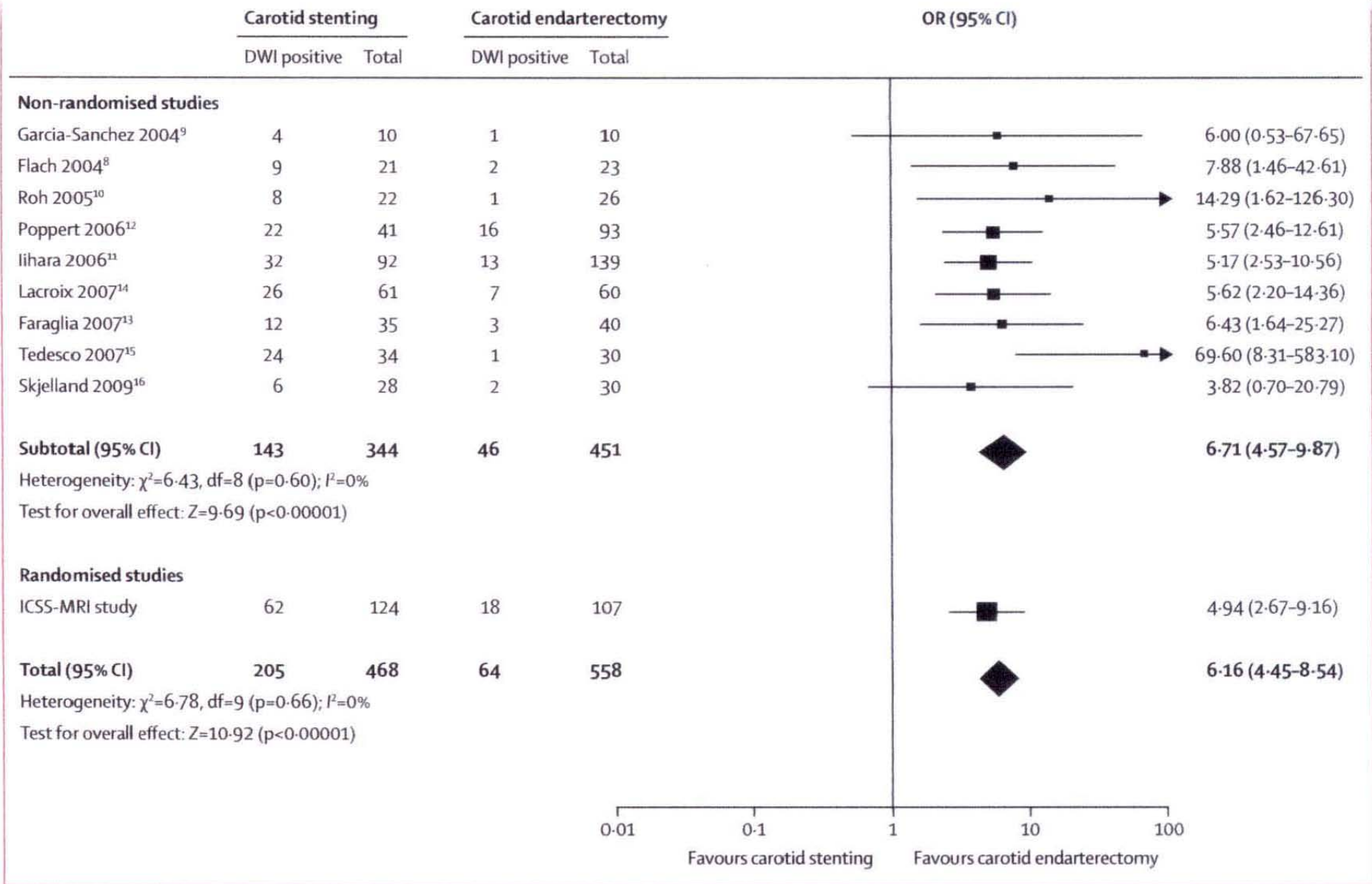
	Carotid stenting (n=124)	Carotid endarterectomy (n=107)	OR (95% CI)	p*
At least one new lesion	62 (50%)	18 (17%)	4.94 (2.67–9.16)† 5.21 (2.78–9.79)‡	<0.0001 <0.0001
Single lesion	18 (15%)	9 (8%)	..	..
Multiple lesions	44 (35%)	9 (8%)	..	..
Location of lesions				
Ipsilateral carotid circulation only	34 (27%)	14 (13%)	..	..
Ipsilateral carotid and non-ipsilateral (contralateral carotid or vertebrobasilar) circulations	22 (18%)	3 (3%)	..	..
Non-ipsilateral (contralateral carotid or vertebrobasilar) circulations only	6 (5%)	1 (1%)	..	..
Ischaemic events in patients with new DWI lesions§	9 (7%)	3 (3%)	..	..
Hemispheric stroke	8 (6%)	3 (3%)	..	..
Retinal infarct	1 (1%)	0	..	..
TIA	0	0	..	..
None	53 (43%)	15 (14%)	..	..

Data are number (%). DWI=diffusion-weighted imaging. TIA=transient ischaemic attack. \*Logistic regression.

†Unadjusted. ‡Adjusted for interval between treatment and post-treatment scan. §Events occurring between start of treatment and post-treatment scans only. No ischaemic event occurred between the start of treatment and the post-treatment scan in patients without new DWI lesions.

**Table 4: New DWI lesions on post-treatment scans**





**Figure 4: Meta-analysis of studies comparing ischaemic lesions on DWI after carotid stenting versus carotid endarterectomy**

Mantel-Haenszel fixed effect model comparing the proportions of patients with hyperintense DWI lesions after stenting versus endarterectomy in nine non-randomised studies, and in the ICSS-MRI study. Data are numbers of patients with new DWI lesions on post-treatment scans (DWI positive) and total numbers of patients in studies. Squares and horizontal lines are odds ratios (OR) and 95% CIs, with size of squares representing study weight. Diamonds represent aggregate OR and 95% CI. DWI=diffusion-weighted imaging.

ORIGINAL ARTICLE

# Stenting versus Endarterectomy for Treatment of Carotid-Artery Stenosis

Thomas G. Brott, M.D., Robert W. Hobson, II, M.D.,\* George Howard, Dr.P.H., Gary S. Roubin, M.D., Ph.D., Wayne M. Clark, M.D., William Brooks, M.D., Ariane Mackey, M.D., Michael D. Hill, M.D., Pierre P. Leimgruber, M.D., Alice J. Sheffet, Ph.D., Virginia J. Howard, Ph.D., Wesley S. Moore, M.D., Jenifer H. Voeks, Ph.D., L. Nelson Hopkins, M.D., Donald E. Cutlip, M.D., David J. Cohen, M.D., Jeffrey J. Popma, M.D., Robert D. Ferguson, M.D., Stanley N. Cohen, M.D., Joseph L. Blackshear, M.D., Frank L. Silver, M.D., J.P. Mohr, M.D., Brajesh K. Lal, M.D., and James F. Meschia, M.D.,  
for the CREST Investigators†

# CREST TRIAL UNIQUE FEATURES

- Both average risk symptomatic and asymptomatic patients
- Careful, two stage screening of participating interventionist
- Specific training with the Acunet and Aculink systems
- Required up to 20 lead-in cases with good results before approval to enter randomized trial

# FINAL RANDOMIZATION

- CEA            1240 PATIENTS
  - CAS            1262 PATIENTS
  - TOTAL        2502 PATIENTS
- 
- MEDIAN FOLLOWUP 2.5 YEARS



# OVERALL RESULTS

PRIMARY ENDPOINT	CEA	CAS	P VALUE
DEATH,ST, MI	61(4.9%)	75(5.9%)	0.38
DEATH	4(0.3%)	9(0.7%)	0.18
STROKE	29(2.3%)	52(4.1%)	0.01
DEATH+ST	33(2.6%)	61(4.8%)	0.005

# CREST ANALYSIS ERROR

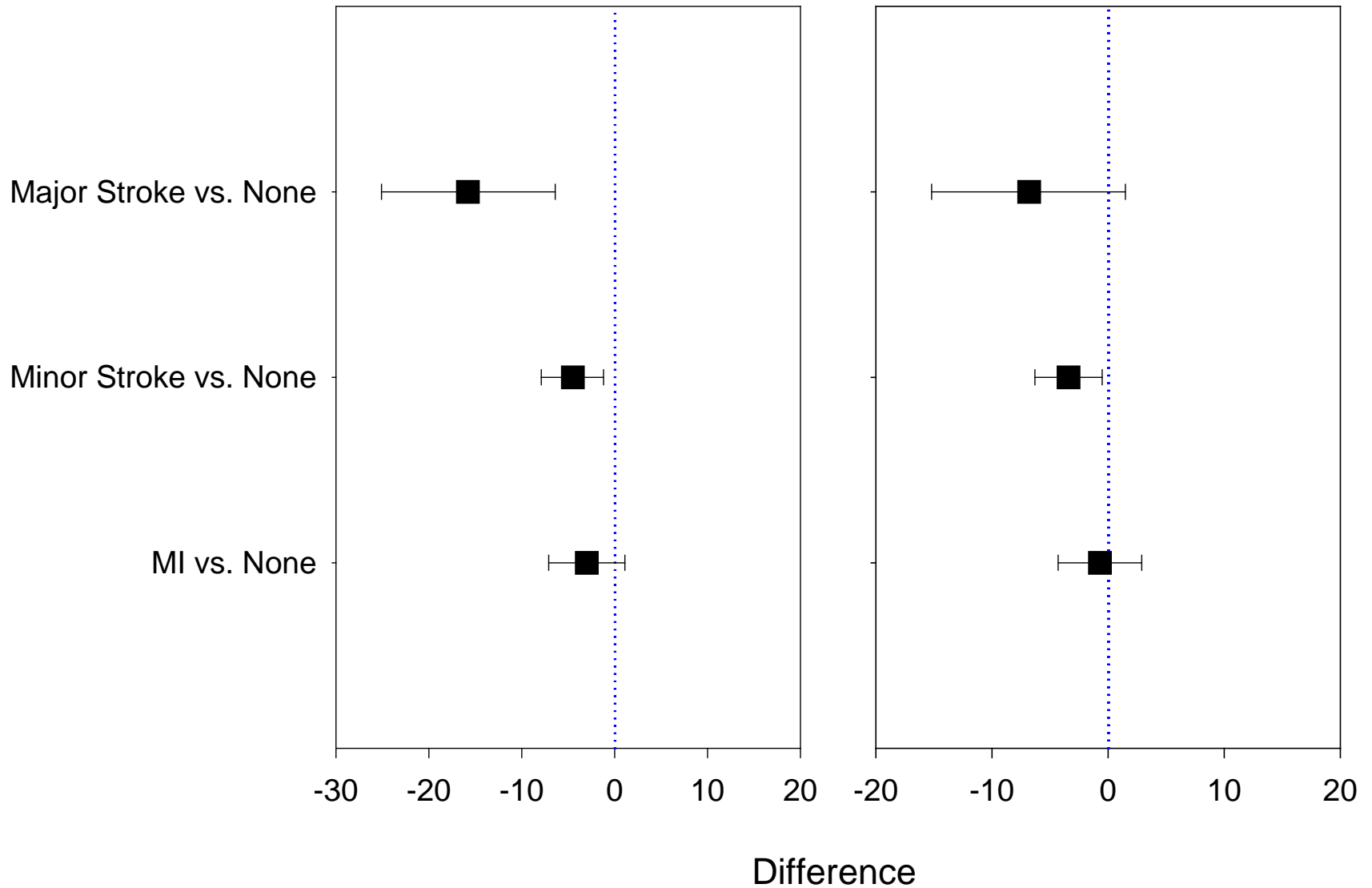
- Simple addition of primary endpoints says that,
- Death=stroke=MI
- All primary endpoints are important, but should be weighed according to severity

# OVERALL RESULTS

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Physical Component Scale

Mental Component Scale



Impact of periprocedural events (stroke/MI) on SF-36 at 1 year adjusting age, sex, symptomatic cerebrovascular disease and baseline SF-36 measures – Growth Curve Modeling.



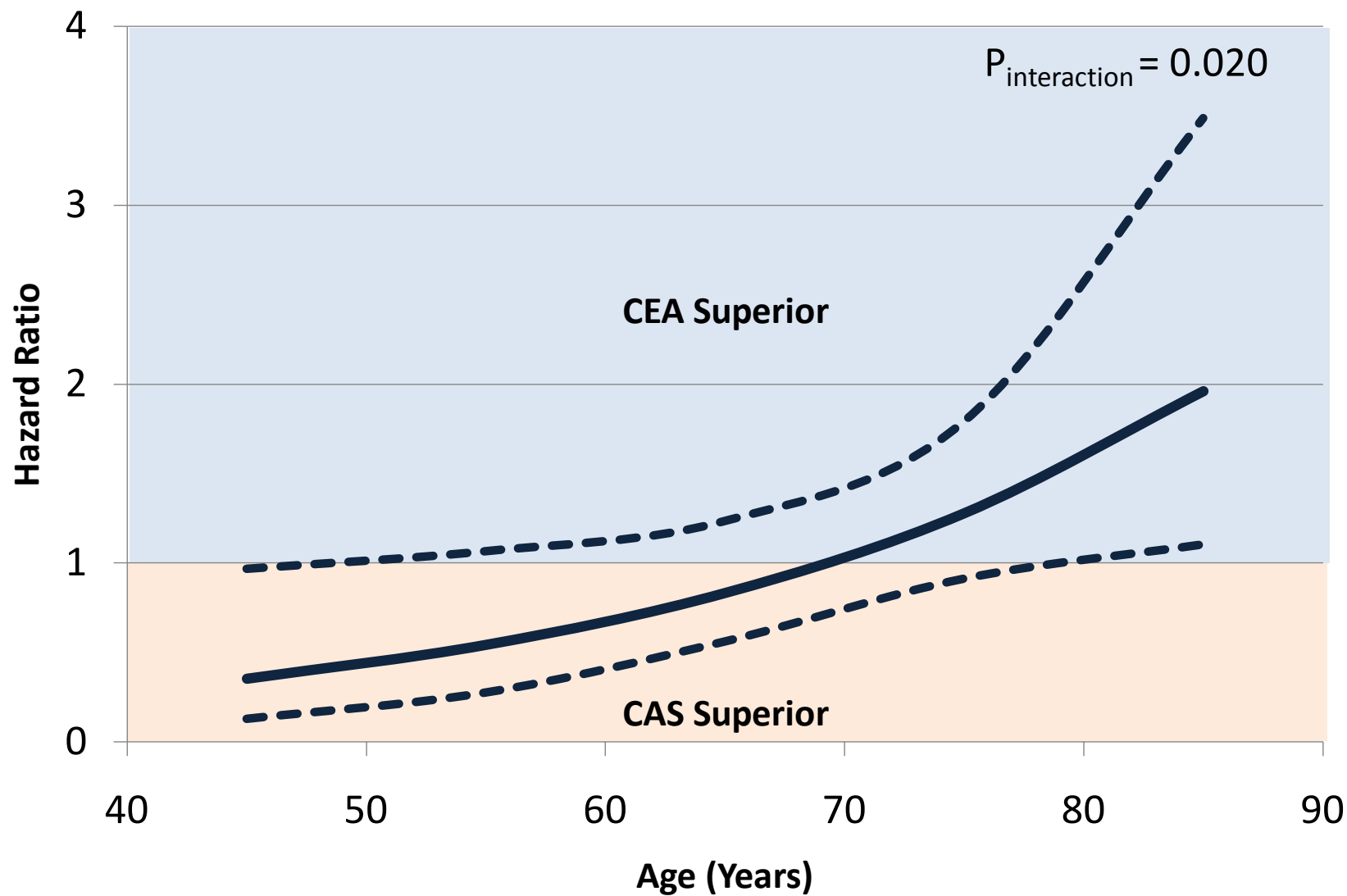
# FOUR YEAR MORTALITY

- WITH MYOCARDIAL INFARCTION  
19.1%
- WITHOUT M.I.  
6.7%

# FOUR YEAR MORTALITY

- WITH ANY STROKE
- 20%
- WITHOUT STROKE
- 11.6%

# Primary outcome – 4 year



# CREST INTERVENTIONIST APPROVAL PROCESS

- 427 Interventionists applied for approval.
- 227 Interventionists(52%) were approved.
- This highly selected group may not be representative of the community.
- The CREST results, in the short term, may not be re-producible community-wide.

# COMMUNITY EXPERIENCE COMPARISON

- CMS MANDATED REGISTRY
- NATIONAL HOSPITAL DISCHARGE  
DATA BASE

# SVS PRACTICE REGISTRY

CMS has mandated all hospitals who wish to perform carotid stenting to submit their data to a registry. SVS has established an approved registry that tracks results on not only CAS but also CEA. This registry provides a unique opportunity to compare, side by side, the results of both techniques.



# 30 DAY OUTCOME IN SYMPTOMATIC PATIENTS

	CAS N=645	CEA N=506	P value
Death	2.17%	0.79%	0.091
Stroke	5.27%	2.37%	0.015
MI	0.93%	0.59%	0.739
Death/ Stroke	7.44%	3.16%	0.014

# 30 DAY OUTCOME IN ASYMPTOMATIC PATIENTS

	CAS N=805	CEA N=606	P value
Death	1.99%	0.7%	0.03
Stroke	2.11%	1.28%	0.252
MI	1.37%	0.58%	0.135
Death/Stroke	4.1%	1.98%	0.003

# summary

- CAS carries twice the stroke morbidity/mortality compared to CEA
- CAS is more expensive than CEA
- Older patients do better with CEA
- Community studies show that CREST results for CAS have not been replicated, but have been replicated with CEA

# RECOMMENDATIONS FOR CMS

- 1.Continue policy of limiting CAS reimbursement to symptomatic, high risk patients.
- 2.Do NOT extend CAS reimbursement to symptomatic and asymptomatic patients at average risk for CEA
- 3.Continue to support clinical trials designed to evaluate new technology for making CAS safer