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What Are the Hard Data Regarding the Impact of Medical Therapy on Stroke Prevention in Established Severe Carotid Stenosis?

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Disclosure

I have nothing to disclose in regard to this presentation and have no financial interest.

Fresenius Medical Care

Shareholder

W.L. Gore, Inc.

Supervisor “Scaffold Trial”

Honorarium

First Remarks

I will only talk about asymptomatic carotid stenosis.

Invasive trratment (CAS, CEA) of symptomatic carotid stenosis (>60%) is a “must”.

First Remarks

Asymptomatic carotid stenosis

is a clinical definition without regard to the type of plaque, silent infarctions or hemodynamic problems, e.g. isolated MCA.

First Remarks

Medical treatment is necessary in all patients with significant carotid stenosis (>60%).

But is BMT sufficient to prevent strokes in asymptomatic patients?

Stroke Risk

Which role plays the carotid artery?

Carotid artery stenosis	15%
Cardioembolic stroke	30%
Cryptogenic stroke	35%
Cerebral artery disease	20%

F. Palm et al.: Stroke seasonality associations with subtype, etiology and laboratory results in the Ludwigshafen Stroke Study (LuSSt). Eur J Epidemiol. 2013;28:373-81

Some Figures

Asymptomatic carotid artery stenosis is a significant health concern, as out of the 135,701 carotid revascularizations performed in the U.S. in 2005, 122,986 (92%) were for asymptomatic carotid artery stenosis.

McPhee JT, Schanzer A, Messina LM, Eslami MH. Carotid artery stenting has increased rates of postprocedure stroke, death, and resource utilization than does carotid endarterectomy in the United States, 2005. *J Vasc Surg* 2008;48: 1442-50, 1450 e1.

What do the trials tell

Revascularization of asymptomatic carotid stenosis >60%

ACAS 1995

ACST 2004

CREST 2010

Asymptomatic Carotid Stenosis >60%

CEA & CAS Outcomes

	Patients	FU	M&M	M&M/Y
ACAS 1995	1662	2.7	4.0%	1.48%
ACST 2004	3120	3.4	6.4%	1.88%
CREST 2010	1181	2.5	3.6%	1.44%

Choice of Treatment

- local referral patterns
- access to CEA
- access to CAS

Recent trends have raised questions about the applicability of prior randomized trials.

Revascularization & Asympt. ICA Stenosis

Two factors must be considered:

- Mortality is related to heart disease
- Degree of stenosis did not predict benefit of CEA (ACST)

A. Hallday et al.: Asymptomatic Carotid Surgery Trial (ACST) Collaborative Group. Prevention of disabling and fatal strokes by successful carotid endarterectomy in patients without recent neurological symptoms: randomised controlled trial. Lancet 2004;363:1491-1502

Best Medical Treatment

A recent meta-regression analysis of 30 studies with asymptomatic ICA stenosis demonstrated:

Stroke rate before 2000	2.83%
Stroke rate after 2000	1.13%

G. Raman et al.; Management strategies for asymptomatic carotid stenosis: a systematic review and meta-analysis. Ann Intern Med 2013;158:676-85

Best Medical Treatment

The annual stroke rate may be below 1%.

But subgroups with increased risk are not separately considered.

Heart Protection Study Group MRC/BHF Heart Protection Study of cholesterol lowering with simvastin in 20,536 high-risk individuals: a randomised placebo-controlled trial. Lancet 2002;360:7-22

A.L. Abbott et al.: Medical (nonsurgical) intervention alone is now best for prevention of stroke associated with asymptomatic severe carotid stenosis: results of a systematic review and analysis. Stroke 2009;40:e573-83

R.W Yeh et al.: Population trends in the incidence and outcomes of acute myocardial infarction. NEJM 2010;362:2155-65

Best Medical Treatment

short lesion

long lesion

ulcerated lesion

All asymptomatic ICA stenoses - same stroke risk?

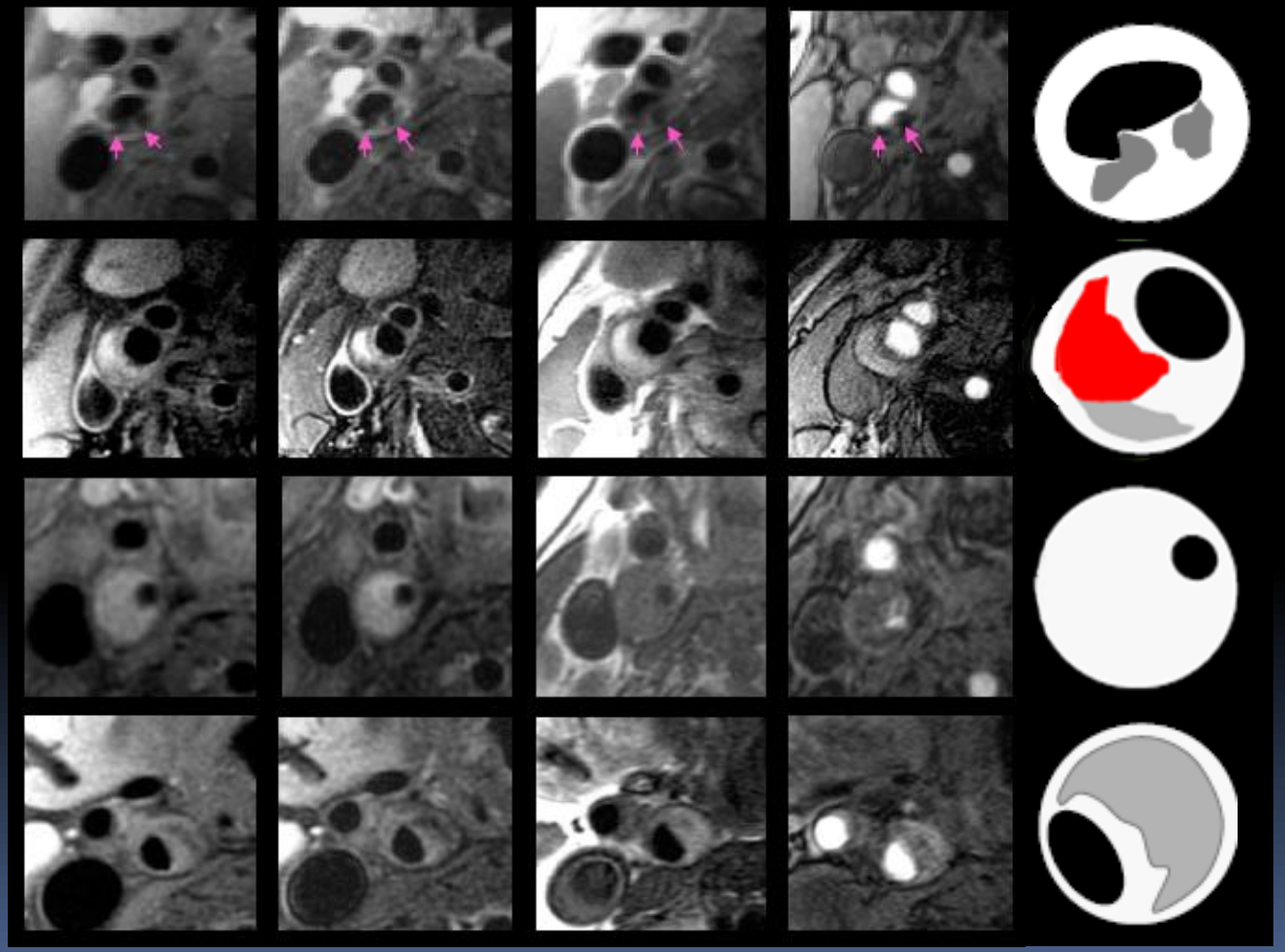
Best Medical Treatment

calcification

hemorrhage

thick fibrous cap

liquid core



Oppenheim et al. Radiographics 2009

CAS and Asymptomatic ICA Stenosis

Carotid revascularization represents a controversial area in the management of asymptomatic ICA stenosis

SPACE 2

CREST 2

PR CAS Trials are needed

Why SPACE 2 failed

- Psychological barrier for the patient
- Insufficient enrolment rate

and ...

... CEA and CAS of asymptomatic carotid stenosis are paid in Germany. When you have a large number of patients you may loose money by randomization.

PR CAS Trials are needed

CREST 2

- Similar protocol as SPACE 2, but CAS in asymptomatic patients is generally not reimbursed in the US.
- Results will be available in the *far* future.

What shall we do today?

My Personal Proceeding

- high degree stenosis (>80%)
- irregular plaque surface
- no severe co-morbidity
- life expectancy > 5 years
- no increased anatomical risk

In these cases I will perform CAS!

Many patients report improved memory and vividness during FU visits! Placebo effect? Improved brain perfusion?

Achilles Heel

Carotid revascularization has to prove again its superiority to BMT alone.

Trials should include plaque analysis, cerebral reserve capacity and cognitive tests to define a subgroup of patients with an increased stroke risk.