Why I do not stent symptomatic patients

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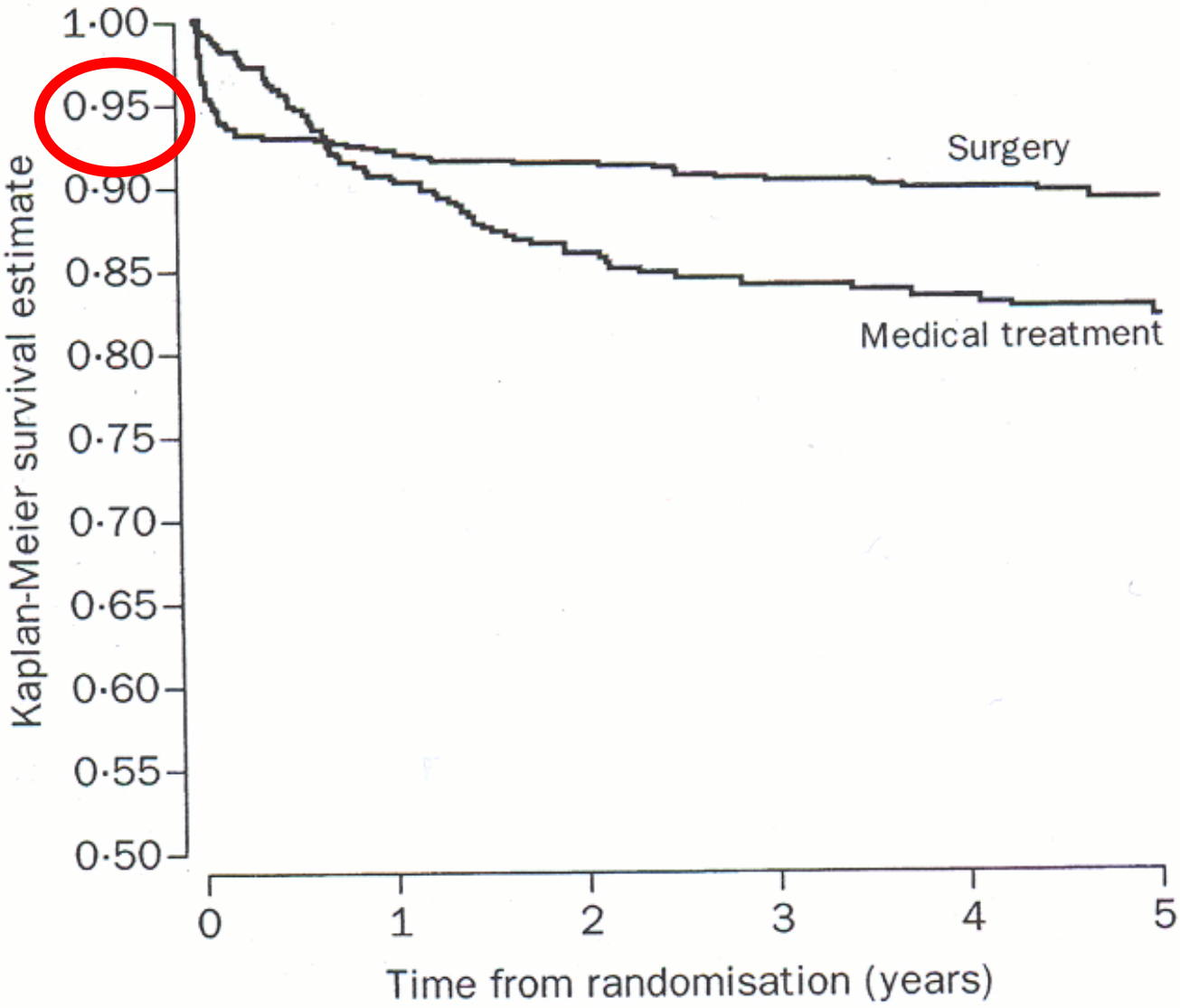


Figure 1: **Effect of carotid endarterectomy on risk of ipsilateral carotid territory major ischaemic stroke and operative major stroke or death in patients with 70–99% carotid stenosis, censoring non-stroke death**

Does CAS match the threshold of less than 5 % of one month death and stroke rate ?

Registries

• ARCHeR	Abbott	D/S/MI	8.3%
• CREATE	EV 3	MACE	6.3%
• CREATE	(spider)	MACE	5.6%
• MaVeriC	Medtronic	MAE	5.4%
• MOMA	Invatec	MACE	5.7%
• PASCAL	Medtronic	MAE	8%
• PRIAMUS	Invatec	D/S	4.5%
• SECuRITY	Abbott	D/S/MI	7.5%

Capture

US multicenter experience in CAS for high surgical risk patients

	All pts (n=2500)	Asympt. (n=2267)	Sympto. (n=223)
Death, stroke MI	**5,7 %**	**4,9 %**	**14,2 %**
Death	**1,3 %**	**1,3 %**	**4,3 %**
Stroke	**3,5 %**	**3,5 %**	**11,2 %**
MI	**0,7 %**	**0,7 %**	**2,6 %**

WA Gray, J Yadav, LN Hopkins et coll.

CEA / CAS in USA 2003 / 2004

259 080 Carotid Interventions

	Stroke	**Death**
• CAS	2.1%	1,3 %
• CEA	0.88 %	0 .30%

MacPhee JT JVS 2007

P<0.0001

CEA / CAS in USA 2003 / 2004

Symptomatic (8 %)

	Stroke	**Death**
• CAS	4,2 %	7.5 %
• CEA	1,1 %	1 %

P<0.0001

Level 1 evidences

EVA 3 S and Space

Endarterectomy versus Stenting in Patients with Symptomatic Severe Carotid Stenosis

Jean-Louis Mas, M.D., Gilles Chatellier, M.D., Bernard Beyssen, M.D., Alain Branchereau, M.D., Thierry Moulin, M.D., Jean-Pierre Becquemin, M.D., Vincent Larrue, M.D., Michel Lièvre, M.D., Didier Leys, M.D., Ph.D., Jean-François Bonneville, M.D., Jacques Watelet, M.D., Jean-Pierre Pruvo, M.D., Ph.D., Jean-François Albucher, M.D., Alain Viguier, M.D., Philippe Piquet, M.D., Pierre Garnier, M.D., Fausto Viader, M.D., Emmanuel Touzé, M.D., Maurice Giroud, M.D., Hassan Hosseini, M.D., Ph.D., Jean-Christophe Pillet, M.D., Pascal Favrole, M.D., Jean-Philippe Neau, M.D., and Xavier Ducrocq, M.D., for the EVA-3S Investigators*

N Engl J Med 2006;355:1660-71.

Any Stroke or Death at 30-day

CAS	CEA
N = 263	N = 264
25	10
9.6 %	3.9 %

(95 % CI - 0.7 to 7.2)

RR = 2.5

Disabling Stroke or Death at 30-day

CAS	CEA
N = 263	N = 264
9	4
3.4 %	1.5 %

(95 % CI - 0.7 to 7.2)

RR = 2.2

Stroke or Death
6 months

CAS	CEA
N = 263	N = 264
9	4
11,7 %	6 %

P = 0.024

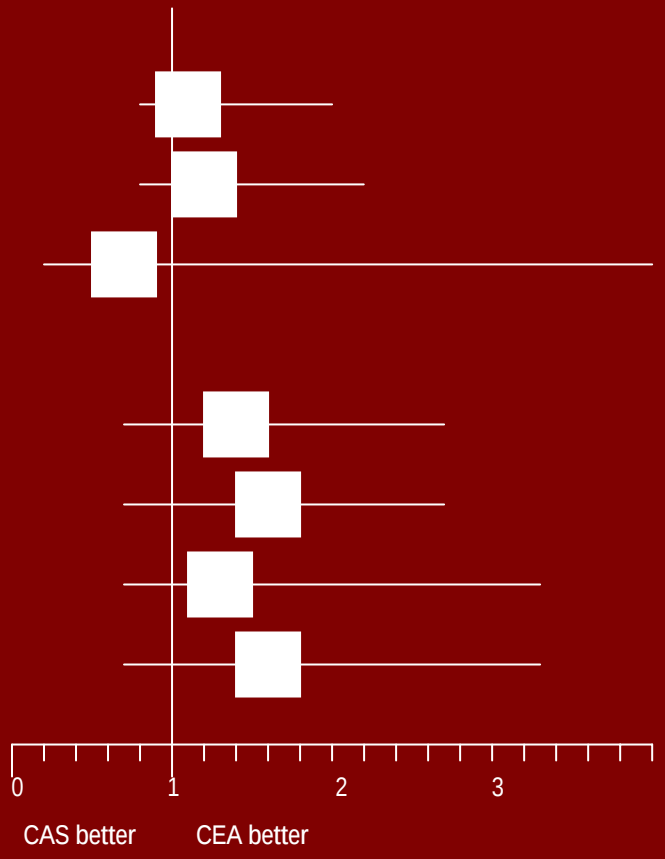
SPACE trial

1183 patients

The Lancet. 2006;368 (9543):1239-1247

Space Trial : 1183 patients

	Event rate (%)		Odds ratio (95 % CI)
	CAS	CEA	
Primary endpoint	6.84	6.34	1.09 (0.69 – 1.72)
Ipsilateral Stroke	6.68	5.99	1.12 (0.70 – 1.79)
Death	0.67	0.86	0.78 (0.15 – 3.64)
Secondary endpoint			
Disabling[1] ipsilat. stroke or death	4.67	3.77	1.25 (0.71 – 2.22)
Disabling[1] ipsilateral. stroke	4.01	2.91	1.39 (0.74 – 2.62)
Any stroke	7.51	6.16	1.24 (0.79 – 1.95)
Procedural failure[2]	3.17	2.05	1.56 (0.71 – 3.56)



1: defined as a value of at least 3 on the modified Rankin scale

2: inclueds inability of treatment with the allocated technique, remaining stenosis of ≥50%NASCET, or vessel occlusion up to 30 days after procedure

Ipsilateral stroke and death between randomization and day 30

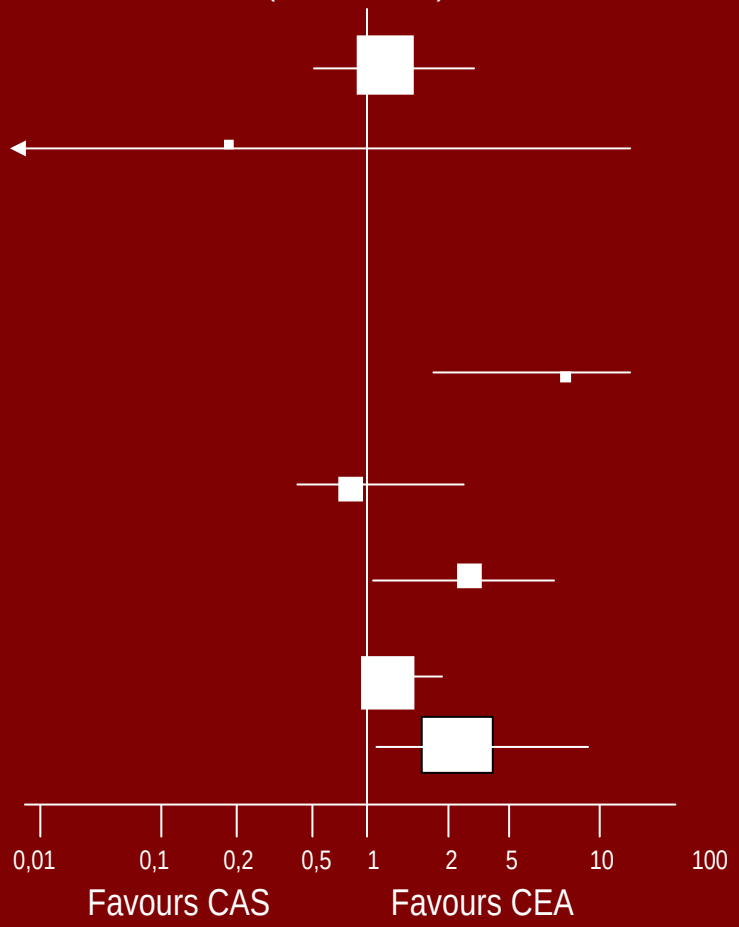
	CAS (n=607)	**CEA (n=589)**	**Absolute Difference (95% CI)**
Intent-to-treat-analysis	**42 (6.92%)**	**38 (6.45%)**	**4 0.47% (-2,41-3.35%)**
Per-protocol-analysis	**39 (6.81%)**	**31 (5.51%)**	**8 1.3% (-1.53% - 4.17%)**

Meta analysis

- Cochran Review 2007
- Luebke et al EJVS 2007
- Brahmanandam S J Vasc Surg 2007
- Van de Waard Am J Surg 2008

Meta-analysis
Endpoint: death or any stroke within 30 days

Study	CAS n / N	CEA n / N	Weight %	Peto odds ratio (95 % CI fixed)
CAVATAS 2001	25 / 251	25 / 253	28.0	1.01 (0.56, 1.81)
Kentucky 2001	0 / 53	1 / 51	0.6	0.13 (0.00, 6.56)
Kentucky 2004	0 / 43	0 / 42	0.0	* (excluded)
Leicester 1998	5 / 11	0 / 12	2.5	12.88 (1.85, 89.61)
SAPPHIRE 2005	8 / 167	9 / 167	10.0	0.88 (0.33, 2.34)
Wallstent 2001	13 / 107	5 / 112	10.3	2.76 (1.05, 7.22)
SPACE 2006	46 / 599	38 / 584	48.5	1.19 (0.77, 186)
EVA3S	25 / 263	10 / 264	29	2.5 (1.2, 45.1)
Combined	117/ 1492	88 / 1480	100.0	1.8 (0.93, 1.72)



Test for heterogeneity chi²=10.46, df=5; p=0.063
Test for overall effect z=1.48; p=0.14

Meta-analysis

Death or any stroke within 30 days

CAS = 7.8%

CEA = 5.9%

Why is CEA > CAS

Are they factors which may have biaised the results ?

Potential Factors

- Devices
- Cerebal protection devices
- Experience with CAS /CEA
- Disease

Potential Factors

- Devices
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YOGA :The Indian Way

Asanas with Props

The ancient yogis used logs of wood, stones, and ropes to help them practice asanas effectively. Extending this principle, Yogacharya Iyengar invented props which allow asanas to be held easily and for a longer duration, without strain.

YOGACHARYA IYENGAR IN SETUBANDHA SARVANGASANA

This version of the posture requires considerable strength in the neck, shoulders, and back, requiring years of practice to achieve. It should not be attempted without supervision

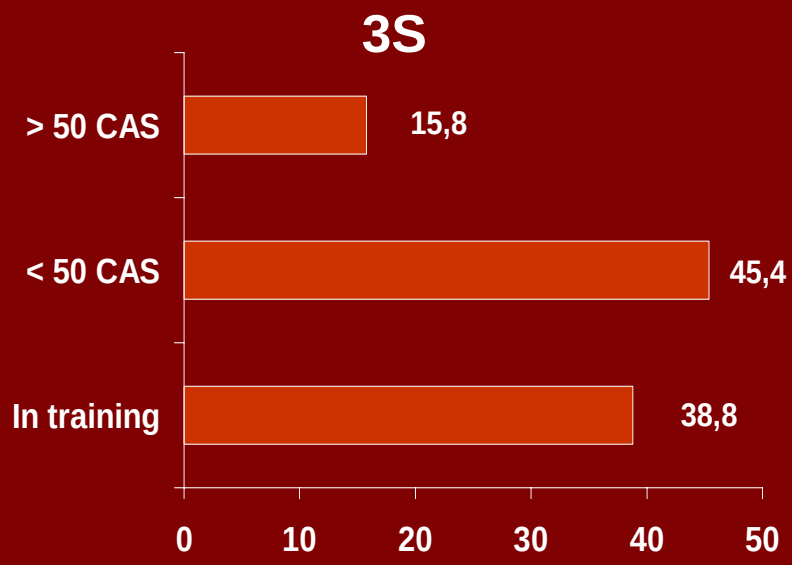
!

YOGA : The French Way

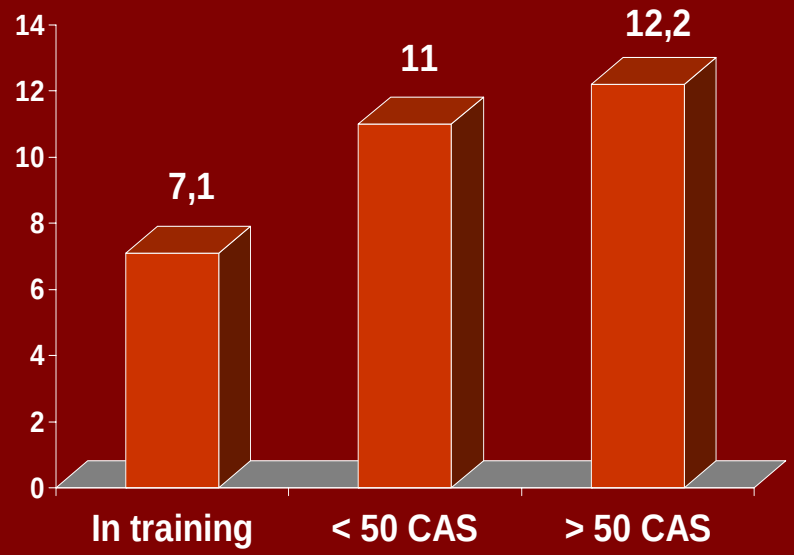
EVA 3S interventionnalist Operator's experience

Prior experience with CAS

% patients treated in EVA



30-day risk of stroke and death (%)



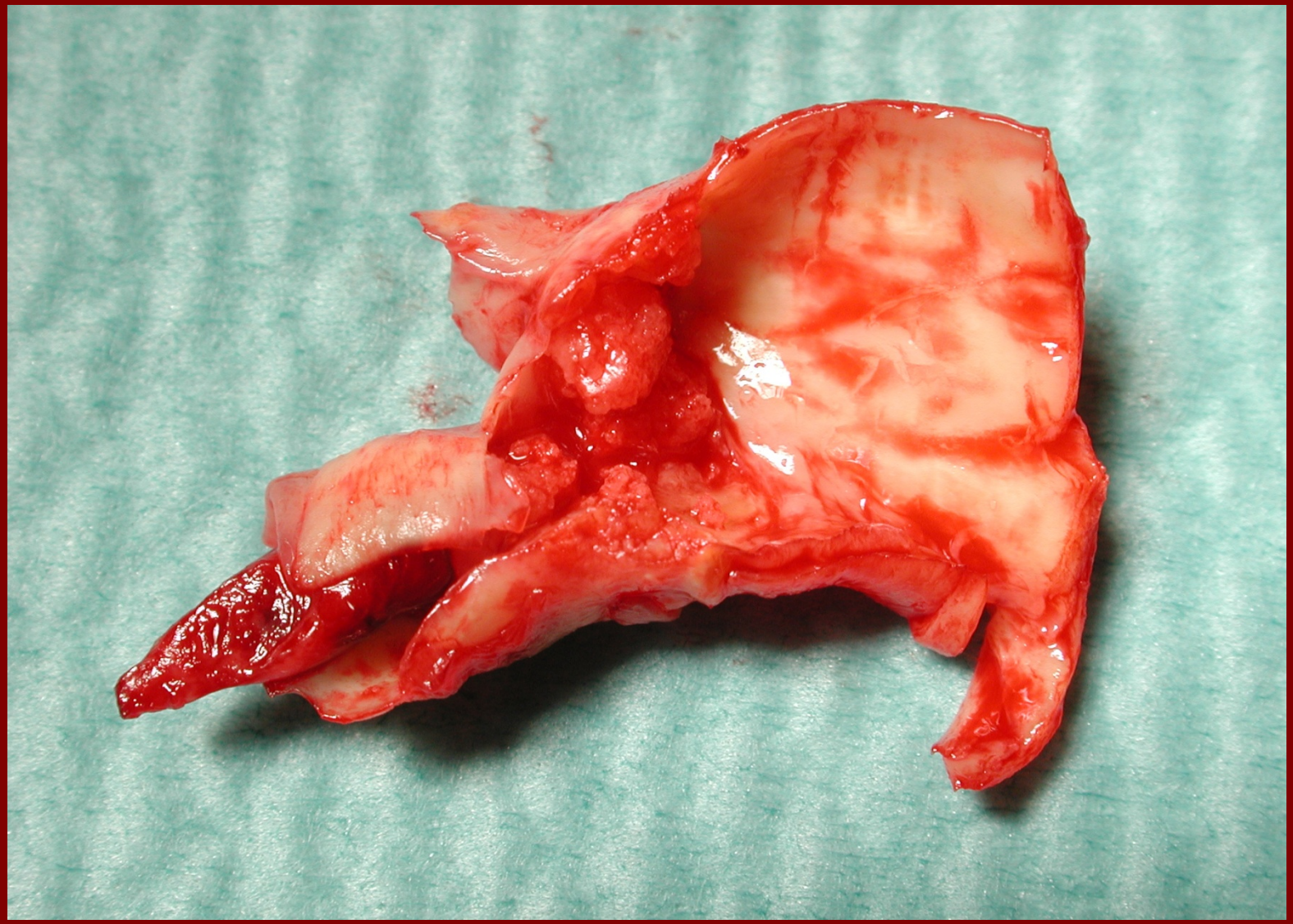
Capture
Physician experience level

CAPTURE (N=1603) [a] Non-hierarchical [b] Hierarchical	High N=166	Medium N=1177	Low N=260
Death[a]	0.0%	1.6%	2.3%
Stroke[a]	5.4%	3.7%	4.6%
Major	1.2%	1.7%	2.7%
Minor	4.2%	2.0%	1.9%
MI[a]	0.6%	0.8%	1.2%
S/D/MI[b]	6.0%	4.8%	5.8%
S/D[b]	5.4%	4.3%	5.0%

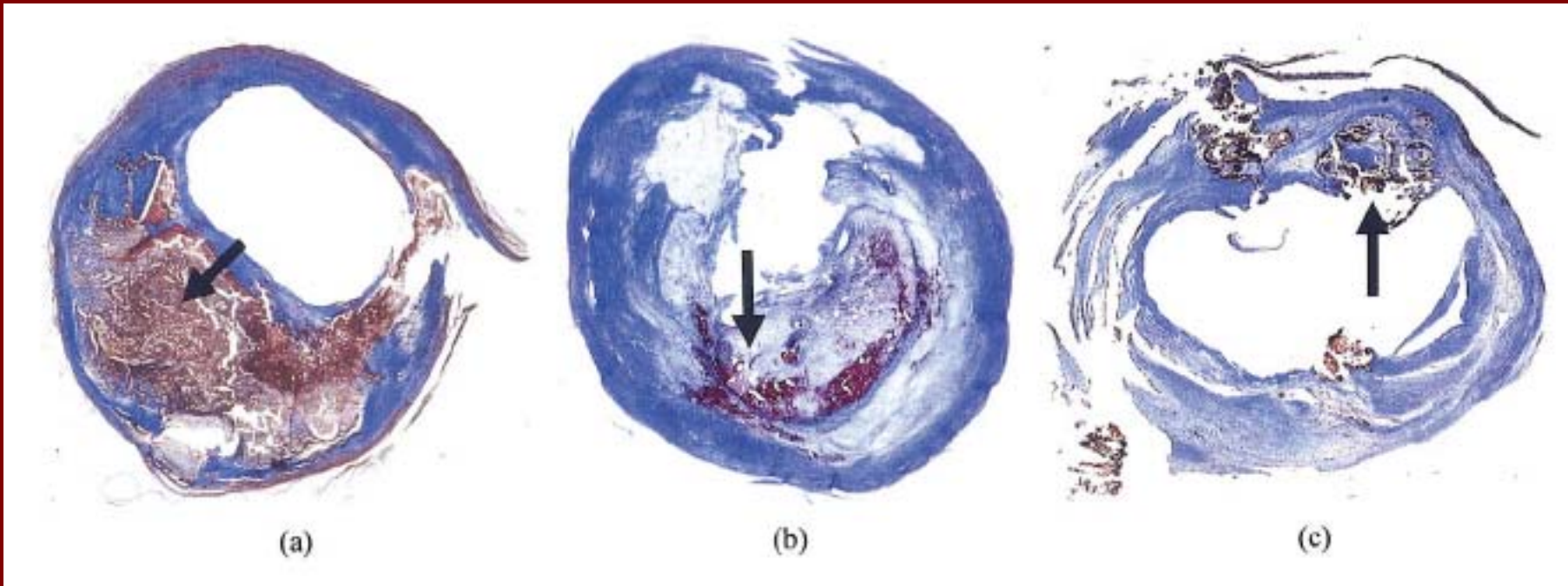
Potential Factors

- Devices
- Cerebal protection devices
- Experience with CAS
- Disease

Symptoms = Vulnerable Plaque



Vulnerable plaque



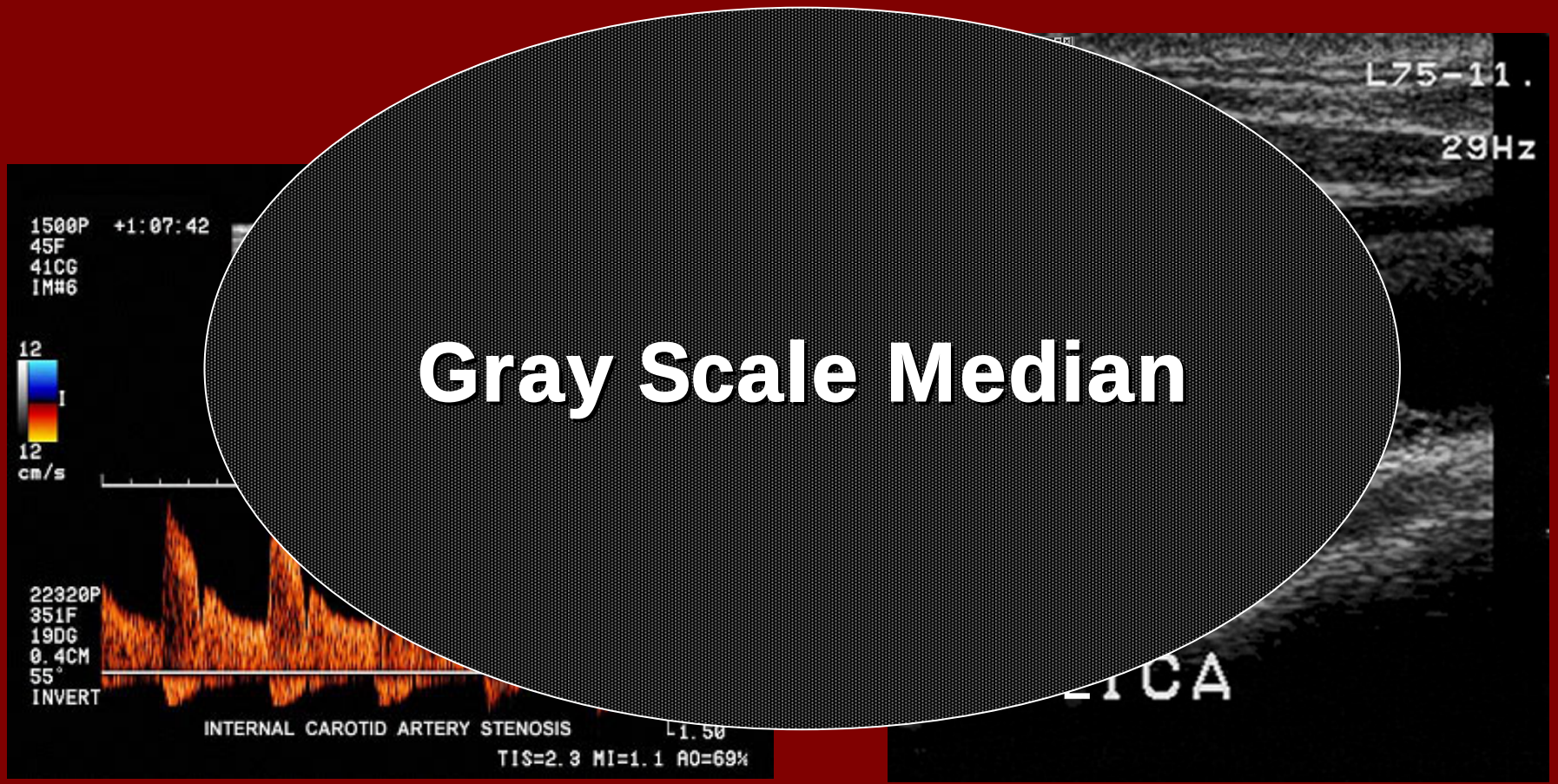
(a) Rich lipid Core divided from the lumen by a thin fibrous cap

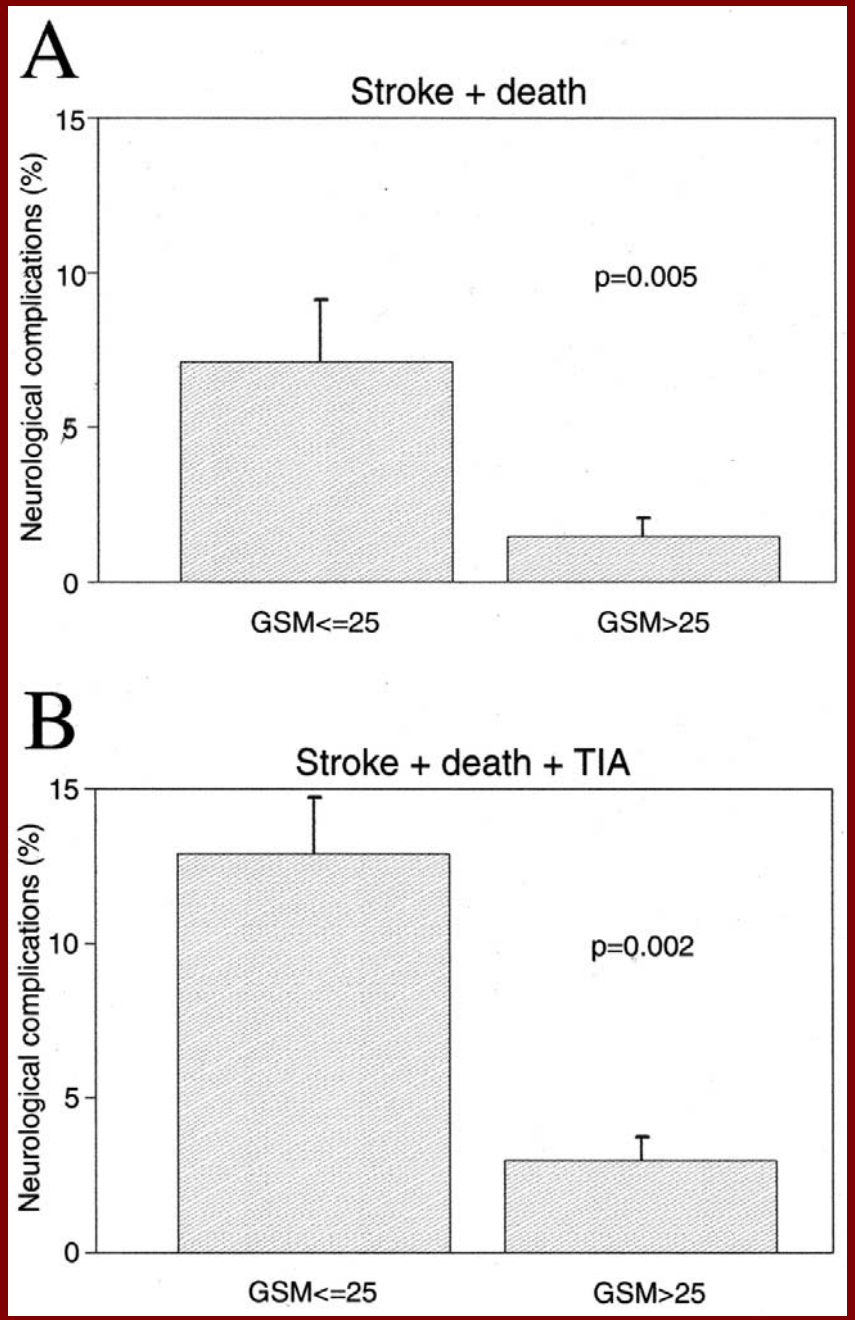
(b) Neoangiogenessis

(c) Calcified nodes entering the lumen

Yuan et al. J. Magn. Reson. Imaging 2004;19:710–719.

How to recognize vulnerable plaque ?





ICAROS STUDY

GSM and CAS

Biasi, G. M. et al. Circulation 2004

CONCLUSIONS

Facts show that in symptomatic patients CAS do not beat surgery

Misunderstandings of the current available data can lead to catastrophe

Technical expertise alone can not replace the wisdom in selecting patients who can benefit most from CAS