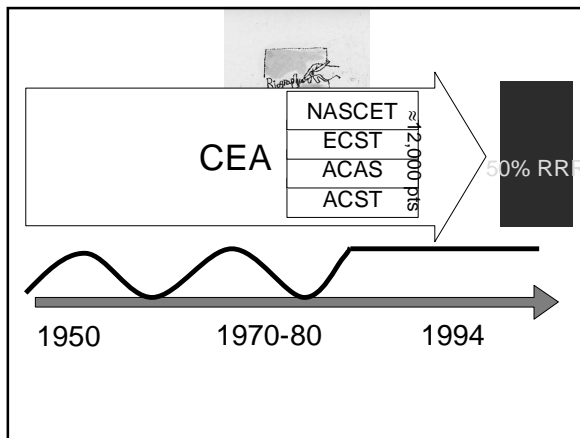


QUESTIONS

- Is carotid artery stenting (CAS) FEASIBLE ?
- Is it SAFE ?
- What are the RESULTS and what are the INDICATIONS ?
- Is carotid endarterectomy (CEA) DEAD?



Is carotid endarterectomy (CEA) DEAD?



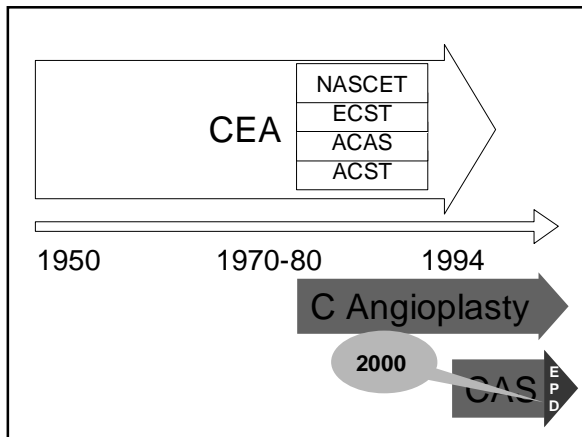
Risk reduction / % stenosis

Pooled Trials	% STENOS	N	ARR @ 5 yrs
NASCET+ECST+VA	50-69% SYMPTO	6092	4.6%
	70-99% SYMPTO		16%
ACAS + ACST	>60% ASYMPTO	4072	5.5%

CEA

Works Well!
Large Amounts of Data!





CAS

IS IT FEASIBLE ?
IS IT SAFE ?



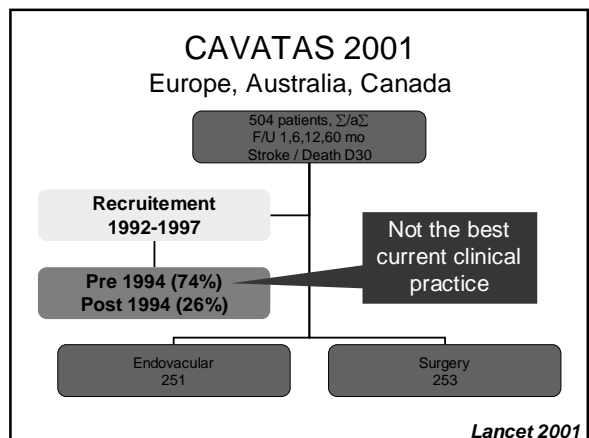
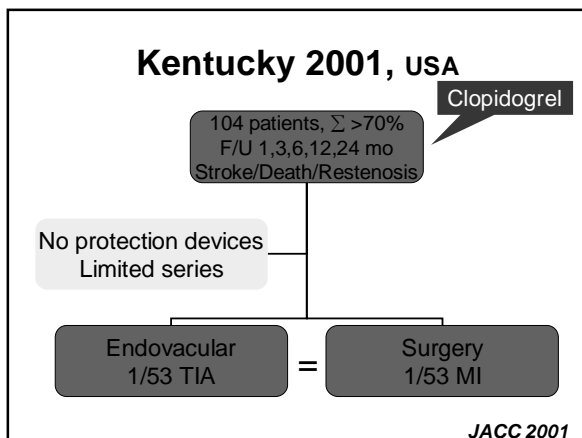
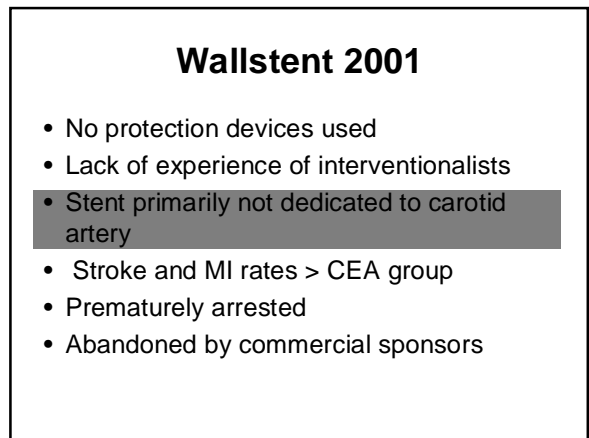
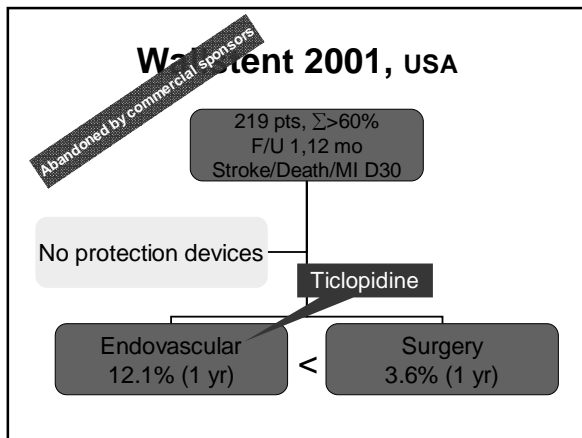
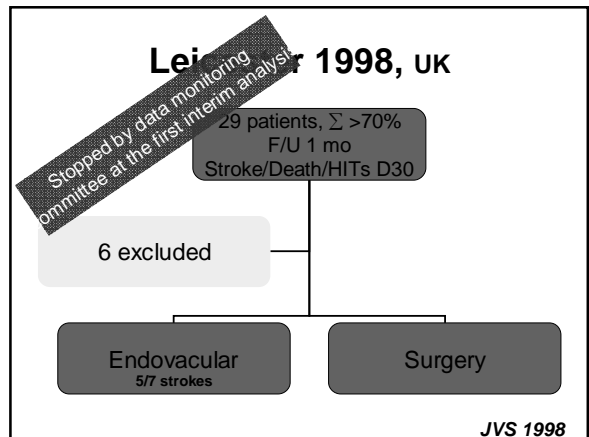
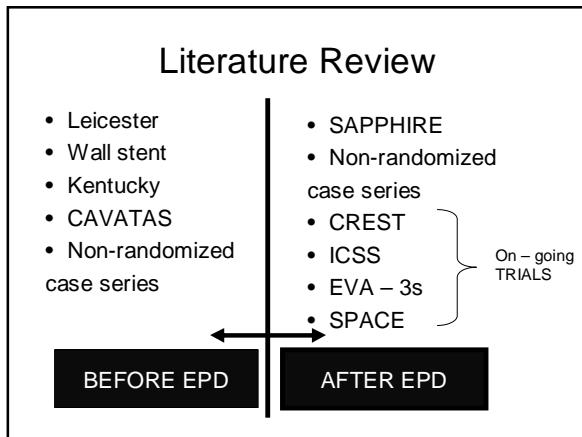


TABLE 1. Carotid Angioplasty and Stent Without Cerebral Protection: Study Characteristics and 30-Day Outcomes

Author	Year	No. of Patients	Male/Female	Mean Age, y	Symp/Asymp	No. of Treated Arteries	Minor Stroke	Major Stroke	Death
AbulRahme ¹	2001	23	11/12	71	18/7	25	1	2	1
Bonaldi ^{2*}	2002	66	41/27	68	60/0	71	3	1	...
Brookes ³	2001	53	NG	66	53/0	53
Cromonesi ⁴	2000	119	93/26	70	28/90	119	3
Cristini ⁵	2002	122	86/46	68	53/79	125	2	1	...
Dargatzis ⁶	2000	133	93/40	71	NG	140	8	1	1
D'Audiffret ⁷	2001	42	NG	68	NG	42	1
Diethrich ⁸	1996	110	79/31	72	31/79	129	10	2	1
Gupta ⁹	2000	100	76/24	76	85/15	100	...	1	...
Hobson ^{10**}	2002	54	28/26	69	19/35	54	1
Jiang ¹¹	2002	67	47/20	67	NG	70	...	1	...
Jordan ¹²	1998	266	184/84	69	72/196	312	20	4	3
Kastrup ¹³	2003	100	75/25	70	63/37	100	2	2	1
Kauf ¹⁴	2000	14	12/2	61	14/0	15	2
Kirsch ¹⁵	2001	53	38/15	71	36/17	57	3	1	...
Lancino ¹⁶	1999	18	12/6	69	9/9	18
Masali ¹⁷	2000	26	18/10	71	18/8	18	...	1	...
Merli ¹⁸	1999	21	13/8	64	12/9	21
Panagoulis ¹⁹	2001	62	NG	67	52/10	69	2	2	1
Pappas ^{20***}	2001	27	NG	NG	25/2	27
Parodi ²¹	2000	21	20/1	70	6/15	21	1
Qureshi ²²	2002	71	43/28	71	27/46	73	...	1	1
Roubin ²³	2001	526	356/172	69	241/287	604	29	6	8
Shaw ²⁴	2000	170	100/70	73	104/66	192	4	1	...
Vizzi ²⁵	1997	22	16/6	68	12/10	19	1	1	...
Wagner ²⁶	1998	53	42/8	NG	14/38	53	1	...	1
Total		2357				2537	94	28	18

Kastrup, Stroke 2003

Global Experience in Cervical Carotid Artery Stent Placement

Michael H. Wholey,^{11*} MD, Mark Wholey,² MD, Klaus Mathias,³ MD, Gary S. Roubin,⁴ MD, Edward B. Diethrich,⁵ MD, Michel Henry,⁶ MD, Steven Bailey,⁷ MD, Patricia Bergeron,⁸ MD, Gerry Dorros,⁹ MD, Gustavo Elias,¹⁰ MD, Peter Gaines,¹¹ MD, Camilo R. Gomez,¹² MD, Bill Gray,¹³ MD, Juan Guimaraens,¹⁴ MD, Randal Higashida,¹⁵ MD, David Sai Wah Ho,¹⁶ MD, Barry Katzen,¹⁷ MD, Antonio Kambara,¹⁸ MD, Vijay Kumar,¹⁹ MD, Jean C. Laborde,²⁰ MD, Martin Leon,²¹ MD, Michael Lim,²² MD, Hugo Londero,²³ MD, Juan Mesa,²⁴ MD, Alejandro Musacchio,²⁵ MD, Subbarao Myla,²⁶ MD, Steve Ramee,²⁷ MD, Adolfo Rodriguez,²⁸ MD, Kenneth Rosenfield,²⁹ MD, Nobuyuki Sakai,³⁰ MD, Fayaz Shawl,³¹ MD, Horst Sievert,³² MD, George Teitelbaum,³³ MD, Jacques G. Theron,³⁴ MD, Prochazka Vackay,³⁵ MD, Carlos Vozzi,³⁶ MD, Jay S. Yadav,³⁷ MD, and Shin-ichi Yoshimura,³⁸ MD

Interv Cardiovasc Catheter 2000

STROKE & DEATH

	Number	% based on vessels treated	% based on patients
		5,210	4,757
TIA's	134	2.57%	2.82%
Minor stroke	129	2.48%	2.72%
Major stroke	71	1.36%	1.49%
Neurologic Deaths	41	0.79%	0.86%
Nonneurologic Deaths	58	1.11%	1.22%
Total stroke and procedure-related death rate		4.63%	5.07%
Total stroke and total death rate		5.74%	6.29%

Interv Cardiovasc Catheter 2000



**Embolic Protection Device
EPD**

TABLE 2. Carotid Angioplasty and Stent With Cerebral Protection: Study Characteristics and 30-Day Outcomes

Author	Year	No. of Patients	Male/Female	Mean Age, y	Symp/Asymp	No. of Treated Arteries	Minor Stroke	Major Stroke	Death
Adami ¹	2002	30	22/8	72	15/15	30
Al-Mubarak ²	2002	162	128/34	68	77/85	164	2	...	2
D'Audiffret ³	2001	15	NG	NG	NG	15
Diez ⁴	2001	43	30/13	67	43/0	43	1
Guimaraens ⁵	2002	164	128/36	63	146/18	194	2	...	3
Henry ⁶	1999	167	129/38	70	74/93	184	1
Jiang ⁷	2001	20	12/8	67	13/7	20
Parodi ⁸	2000	25	15/10	69	12/13	25
Reimers ⁹	2001	84	63/21	69	30/54	88	1	...	1
Tubes ¹⁰	2001	54	46/8	69	NG	58	...	1	...
Whitlow ¹¹	2002	75	54/21	67	75/0	75
Total		839				896	5	3	8

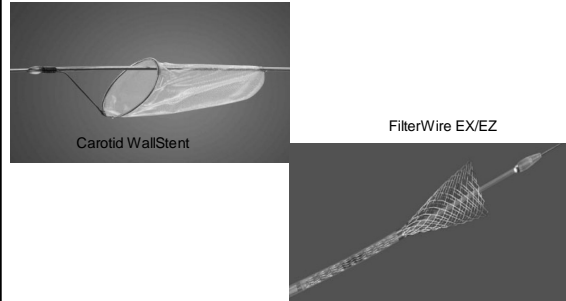
Kastrup, Stroke 2003

TABLE 4. Comparison of Overall Minor, Major Stroke or Death Within 30 days of Carotid Angioplasty and Stenting With and Without Cerebral Protection

	Events per Procedure	
	Without Cerebral Protection	With Cerebral Protection
Minor stroke	94/2537 = 3.7%	5/896 = 0.5%
Major stroke	28/2537 = 1.1%	3/896 = 0.3%
Death	18/2537 = 0.8%	8/896 = 0.8%
Any stroke or death	140/2537 = 5.5%	16/896 = 1.1%

Kastrup, Stroke 2003

Embolic protection methods



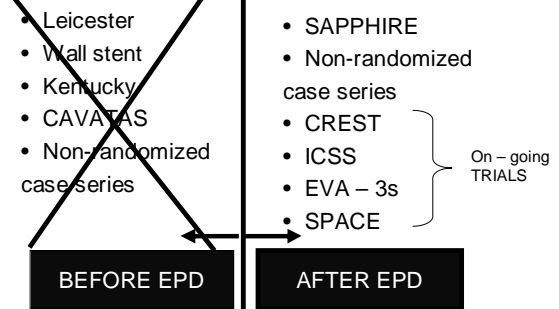
Interv Cardiovasc Catheter 2006

Table 1 Features of different protection devices

Device	Pore size (µm)	Crossing profile (inches)	Capture sheath profile (inches)	Diameters available (mm)
Angioguard XP	100	0.042-52	0.066	4-8
Medtronic II	120	0.058-68	0.096	4-6
Medtronic III	140	0.046-51	0.084	4-6
BSC FilterWire EZ	80	0.039	0.039	3.5-5.5
Medtronic AVE	100	0.039	0.039	3.5-5.5
Gardiner Angiomed	120	NA	NA	4-8
MicroGuard Dop	200	0.037	0.066-78	2.5-7
FilterSurge	No pores	0.028-36	0.042-70	3-6

Heart 2003

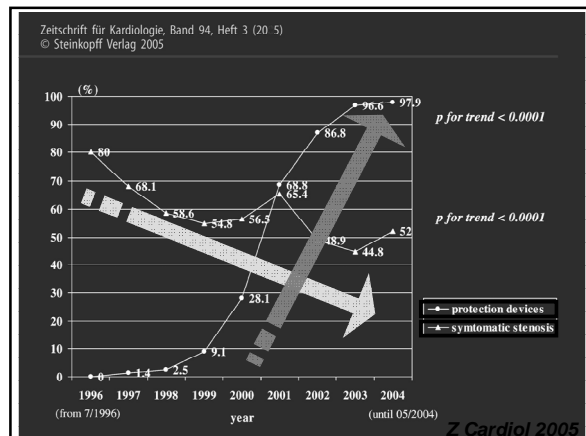
Literature Review

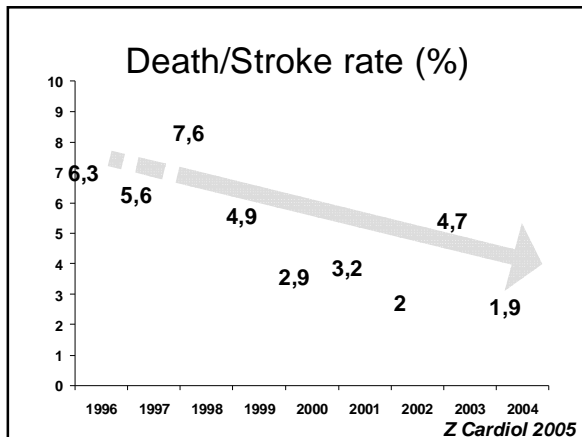


ALKK CAS registry hospitals

- 28 centres
- 7/1996-5/2004
- 1888 pts

Z Cardiol 2005

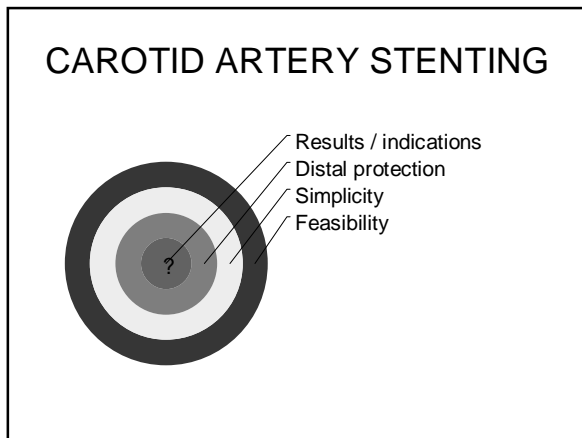




Short-Term Impact of EPDs

« Embolic protection should be considered the standard of care in carotid stenting. When use of an EPD is precluded by anatomic factors, alternative treatment strategies (CEA or medical therapy) must be strongly considered »

Roubin, Circulation 2006



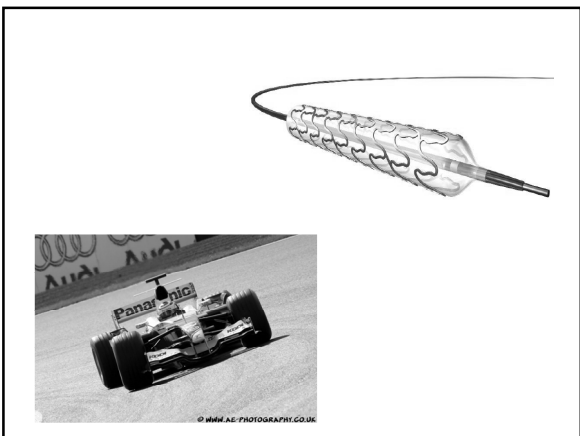
CAS vs CEA

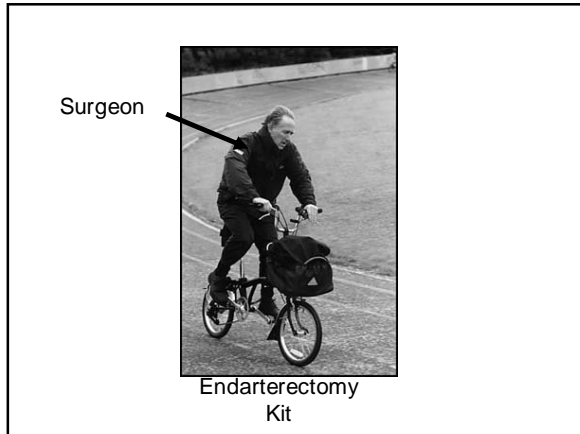
WHAT ARE THE RESULTS ?

Larry King Live

CAS VS CEA

WHAT ARE THE RESULTS ?





GUIDELINES for CEA

INDICATION LEVEL	SYMPTOMATIC	ASYMPTOMATIC
PROVEN	70 -99 % RISK < 6 %	> 60 % RISK < 3 % Life expectancy > 5 y
ACCEPTABLE	50 -69 % RISK < 3 %	> 60 % RISK < 3 % Planned CABG
UNACCEPTABLE	< 29 % OR RISK > 6 %	< 60 % OR RISK > 5 % No CABG

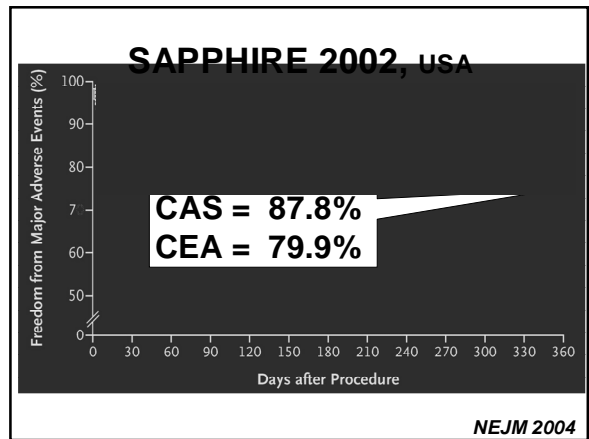
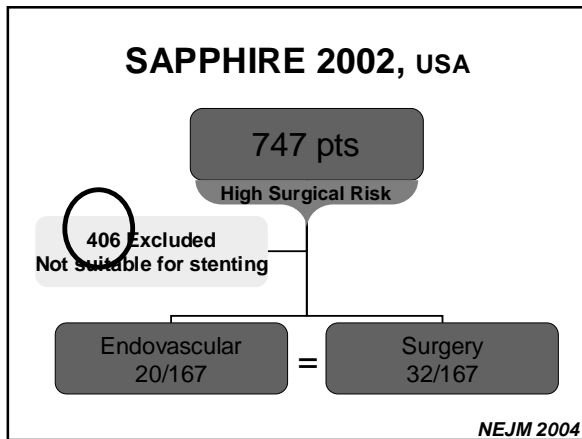
Stroke Council, AHA, Stroke 1998

- ### CAS vs CEA RESULTS IN SUBGROUPS
- SYMPTOMATIC PATIENTS
 - ASYMPTOMATIC PATIENTS
 - MODERATE CAROTID STENOSIS
 - SEVERE CAROTID STENOSIS
 - HIGH SURGICAL RISK

- ### SAPPHIRE 2002, USA
- 747 pts
 - $\Sigma > 50\%$ stenosis,
 - $a\Sigma > 80\%$ stenosis
 - F/U 1,12 mo
 - Stroke/Death/MI D30
 - HIGH SURGICAL RISK
- NEJM 2004

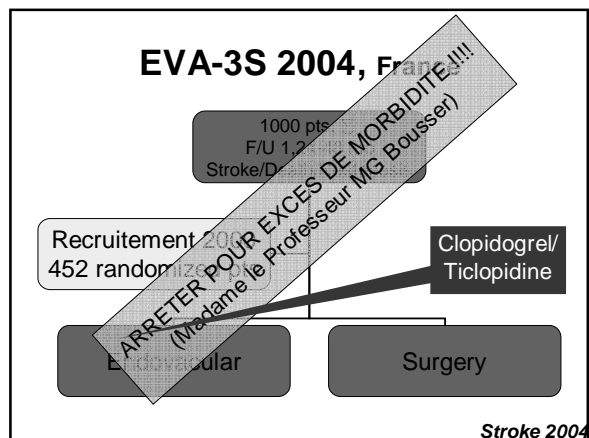
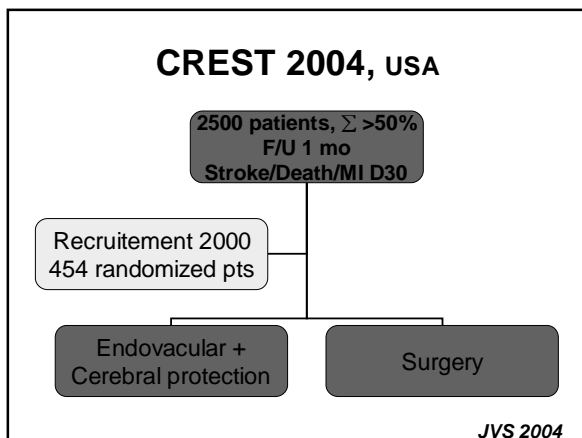
- ### Criteria for high risk
- Age >80 yr
 - Clinically significant cardiac disease
 - (CHF, abnormal stress test, or need for CABG)
 - Severe COPD
- NEJM 2004

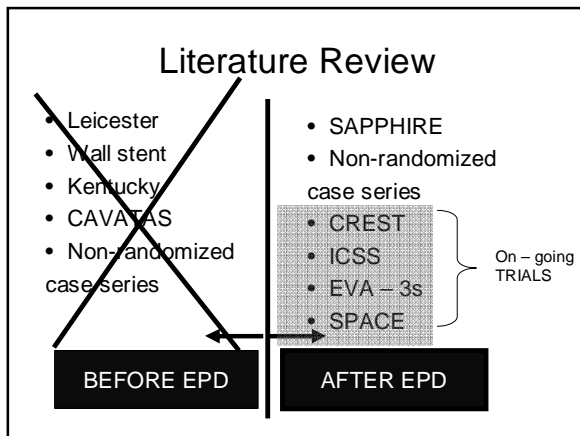
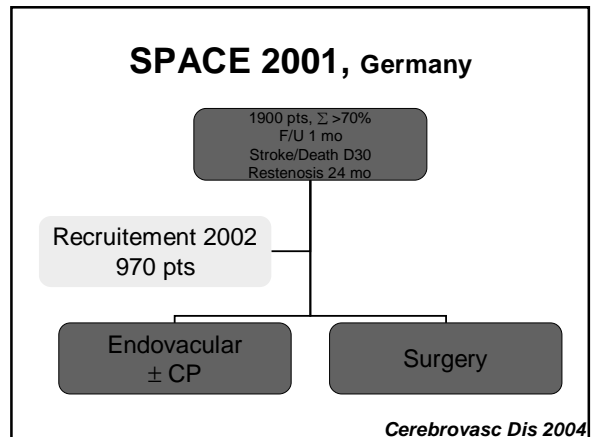
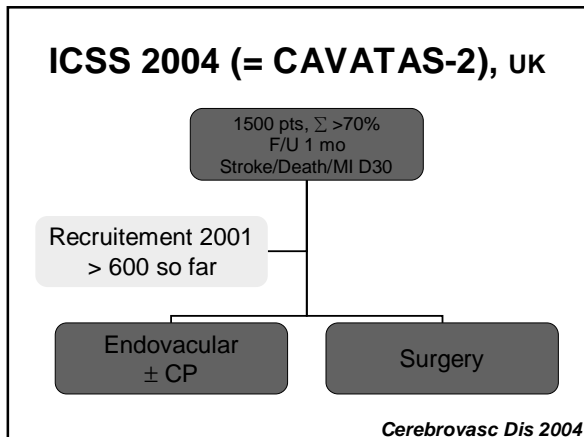
- ### Criteria for high risk
- Contralateral carotid occlusion
 - Previous radical neck surgery or radiation therapy to the neck
 - Recurrent stenosis after endarterectomy
 - High lesions behind the mandible
 - Low lesions requiring thoracic exposure
- NEJM 2004



- ### CAS vs CEA RESULTS IN SUBGROUPS
- SYMPTOMATIC PATIENTS
 - ASYMPTOMATIC PATIENTS
 - **HIGH SURGICAL RISK**
 - MODERATE CAROTID STENOSIS
 - SEVERE CAROTID STENOSIS

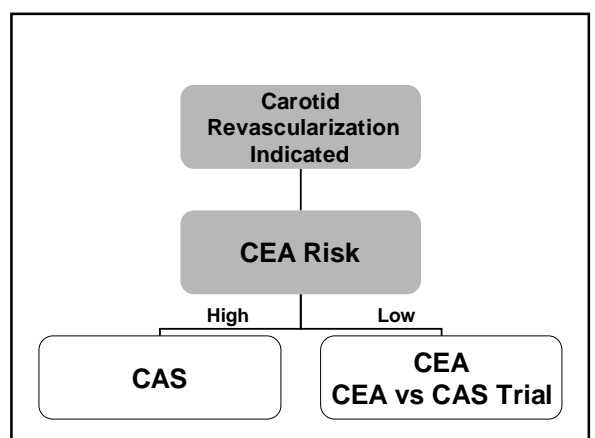
- ### CAS vs CEA RESULTS IN SUBGROUPS
- SYMPTOMATIC PATIENTS
 - ASYMPTOMATIC PATIENTS
 - **?**
 - MODERATE CAROTID STENOSIS
 - SEVERE CAROTID STENOSIS

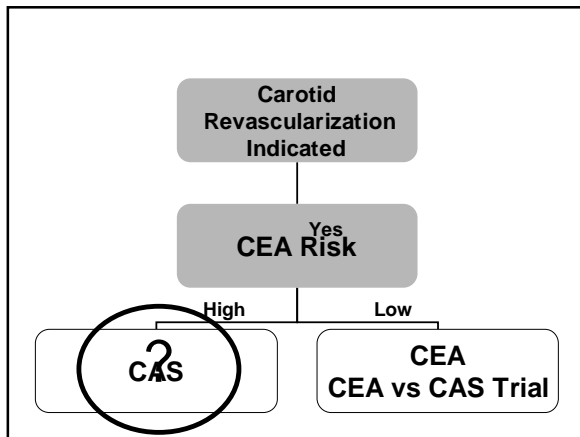




CAS or CEA

1. Available data (one trial) show that CAS is superior to CEA in selected high risk patients.
2. In all other patient groups no data is currently available to answer this question





CAS: Contradictions

- Intolerance to antiplatelet agents.
- Major surgery within 3 to 4 weeks that will require cessation of antiplatelet therapy

- Contrast nephropathy (< 75 mL of contrast)
- Intracranial arterial stenoses
- arteriovenous malformations
- Stable aneurysms

Relative

Roubin, Circulation 2006

CAS: Contradictions

- Specific angiographic findings
 - excessive tortuosity
 - massive calcifications circumferential
 - Thrombus burden

Roubin, Circulation 2006

Increased Procedural Risks After CAS

	Risk Factor	Features
Clinical	Advanced age	Age > 80 y
	Decreased Cerebral reserve	Dementia Prior (remote) stroke Multiple lacunar infarcts Intracranial microangiopathy
Angiographic	Excessive tortuosity	2 90° bends within 5 cm of the lesion
	Heavy calcification	Concentric, circumferential, Width 3 mm

Impact of age on risk of stroke and death D30

CREST lead-in phase

Age & risk of Stroke / Death

Age strata	N	Events (%)	OR (95% CI)
<60	120	2 (1.7%)	1.0
60-69	229	3 (1.3%)	0.78 (0.13-4.75)
70-79	301	16 (5.3%)	3.31 (0.75-14.63)
80+	99	12 (12.1%)	8.14 (1.78-37.30)

CREST lead-in phase, JVS 2004

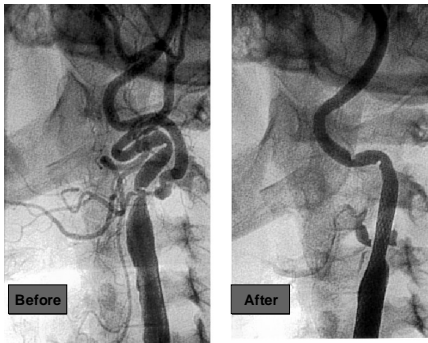
Increased Procedural Risks After CAS

	Risk Factor	Features
Clinical	Advanced age	Age > 80 y
	Decreased Cerebral reserve	Dementia Prior (remote) stroke Multiple lacunar infarcts Intracranial microangiopathy
Angiographic	Excessive tortuosity	2 90° bends within 5 cm of the lesion
	Heavy calcification	Concentric, circumferential, Width 3 mm

Excessive tortuosity



- Difficulty of access
- Failure of device delivery
- Prevent EPD positioning
- Unsufficient "landing zone"
- Atheroembolism
- Air embolism
- Excessive contrast
- Bifurcation plaque disruption
- ICA dissection



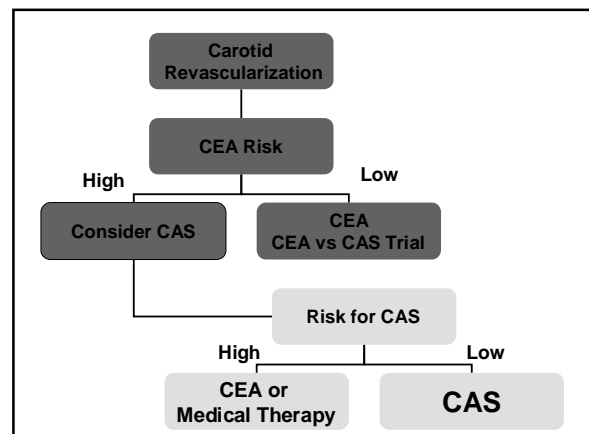
Increased Procedural Risks After CAS

	Risk Factor	Features
Clinical	Advanced age	Age > 80 y
	Decreased Cerebral reserve	Dementia Prior (remote) stroke Multiple lacunar infarcts Intracranial microangiopathy
Angiographic	Excessive tortuosity	2 90° bends within 5 cm of the lesion
	Heavy calcification	Concentric, circumferential, Width 3 mm

Plaque Calcifications



- Difficulty in
- Tracking devices
 - Lesion dilation
 - Stent positioning
 - Achieving adequate expansion





Angiographic Restenosis

	Interval Since Procedure			
	30 d	6 mo	12 mo	24 mo
No. of treated arteries reaching interval	136	136	121	78
Clinical				
No. of treated arteries with clinical follow-up	136 (100%)	136 (100%)	119 (98%)	77 (99%)
Death* (non-neurologic)	2 (1.6%)	6 (4.9%)	10 (9.3%)	9 (13.2%)
Ipsilateral stroke (new since previous interval)	1 (0.7%)	0 (0%)	1 (0.8%)	0 (0%)
Doppler				
No. of treated arteries with Doppler follow-up (% of eligible)		127 (98%)	102 (92%)	61 (88%)
Normal (systolic velocity ≤ 1.0 m/s)		71 (56%)	59 (58%)	37 (61%)
Mild neointimal hyperplasia (systolic velocity $>1.0 \leq 1.75$ m/s)		35 (28%)	27 (26%)	19 (31%)
Moderate neointimal hyperplasia (systolic velocity $>1.75 \leq 2.5$ m/s)		13 (10%)	10 (10%)	5 (8%)
Severe neointimal hyperplasia (systolic velocity ≥ 2.5 m/s)		8 (6%)	5 (5%)	1 (2%)
Angiographic				
Restenosis $\geq 50\%$ diameter stenosis (new since previous interval)		4 (3.1%)	2 (2.0%)	0 (0%)

Gray, STROKE 2002

- ### RESTENOSIS
- 2167 pts CAS (stenting rate 95%)
 - 5-year follow-up
 - 85% of pts alive & free from ipsilateral stroke
 - Restenosis rate 4%.
- Bosier, J Cardiovasc Surg (Torino) 2005*

