TCT 2010 - Washington

Development, Training and Testing of Carotid Stenting ....

Historical Journey and Philosophical Perspective

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Nothing to disclose in context with this presentation

1974 – Step to Endovascular Therapy

Forssmann 1929

1st catheterization

Moniz 1935

1st angiogram

Seldinger 1954

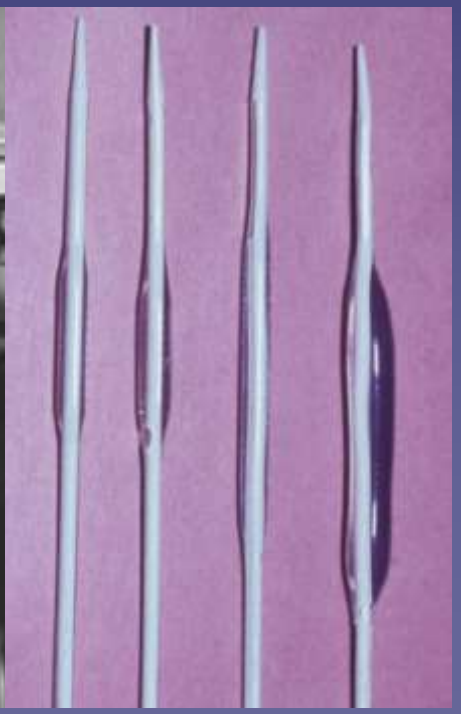
1st percutaneous access

Dotter 1964

1st angioplasty

Grüntzig and Hopf

A German physician and a Swiss engineer develop the first non-compliant balloon catheter



1976 – New Ideas

Selective Angioplasty

Andreas Grützig coronary artery 1977

Felix Mahler renal artery 1978

Klaus Mathias renal graft artery 1979

Why not supra-aortic arteries?

Now every-day practice

1976/77 – Animal Experiments

- artificial carotid stenosis
- balloon dilatation
- blood filtration
- cerebral perfusion

1976/77 – Animal Experiments

- artificial carotid stenosis
- balloon dilatation

... first publication ...

Sonderdruck aus **FORTSCHRITTE DER MEDIZIN** 95. Jg., Nr. 15 vom 21. 4. 1977, S. 1007—1011

Ein neuartiges Katheter-System zur perkutanen transluminalen Angioplastie von Karotisstenosen

Von *K. Mathias*

Aus der Abteilung für Röntgendiagnostik des Zentrums Radiologie (Direktor: Prof. Dr. med. *W. Wenz*) der Universität Freiburg/Br.

... no enthusiastic reaction!

1978 – A Controversy Begins

Don't touch the carotid bifurcation – it is sacred surgical territory!

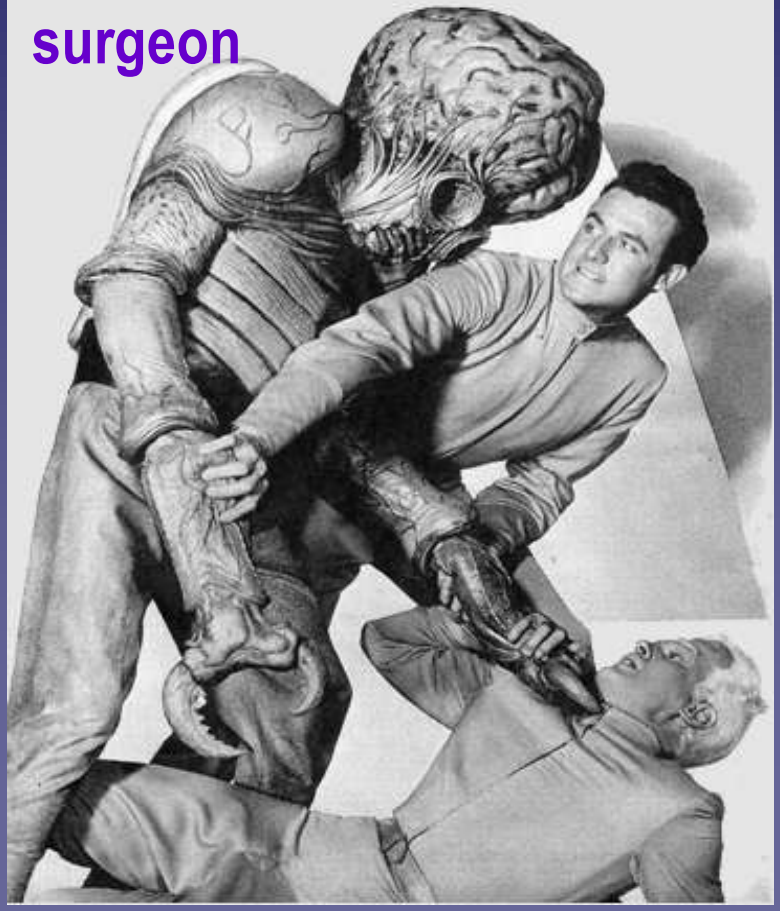
… but vascular surgery had no level 1 evidence at that time.

... needed 13 years

NASCET 1991

ECST 1991

A nightmare from the point of view of a vascular surgeon



Official Warning of the German Society of Vascular Surgery 1978

DEUTSCHE GESELLSCHAFT FÜR CHIRURGIE
SEKTION GEFÄSSCHIRURGIE

Vorsitzender 1977/78
Professor Dr. med. JÖRG F. VOLLMAR

7900 ULM/DONAU 27.6.1978/Lu

Herrn
Prof. Dr. W. Wenz
Direktor der Röntgenabteilung
Chirurgische Universitätsklinik
Hugstetterstr.
7800 Freiburg

Sehr geehrter, lieber Herr Wenz,

anläßlich der Mitgliederversammlung der Sektion Gefäßchirurgie der Deutschen Gesellschaft für Chirurgie ist auf Antrag mehrerer Mitglieder die D e h n u n g s b e h a n d l u n g von Karotisstenosen mittels Gefäßkatheter eingehend diskutiert worden. Es wurde hierbei von allen mit der Karotischirurgie befaßten Mitgliedern die Meinung vertreten, daß dieses Behandlungsverfahren ein nicht vertretbares Risiko des iatrogenen Schlaganfalls durch Mikroembolien einschließt und daher keine Alternative zu einem operativen Vorgehen darstellt. Als derzeitiger Vorsitzender der Sektion bin ich von der Mitgliederversammlung beauftragt worden, Ihnen das Ergebnis dieser Stellungnahme schriftlich mitzuteilen.

Mit freundlichen Grüßen
Ihr

(Prof. Dr. J. Vollmar)

… this procedure includes an unacceptable risk of stroke and is no alternative to vascular surgery.

1979 - First Patient Fibro-muscular Dyplasia

32 yo woman

- severe stenosis of right distal ICA
- bilateral renal artery stenosis

The first patient was referred by the head of cardio-vascular surgery of the Freiburg University Hospital: Prof. Dr. Volker Schlosser

Discussing New Concepts of Angioplasty

PTA Symposium 1980 Nürnberg
Mathias, Dotter Zeitler, Olbert, Grüntzig, Roth

1980 - First Patient with Atherosclerotic Disease

68 yo man

- COPD
- CHD
- myocardial infarction 2x
- minor right mca stroke
- angioplasty with 4 mm balloon catheter shaft 9-F technique: over-the-wire

How to prevent stroke by embolization during balloon angioplasty?

The Stroke Problem

TCD	100%
Centent of filters	
- microscopic particles	60-80%
- visible particles	5-15%
DW-MRI	10-30%
Clinical reactions	3-7%

Two reasons for cerebral protection

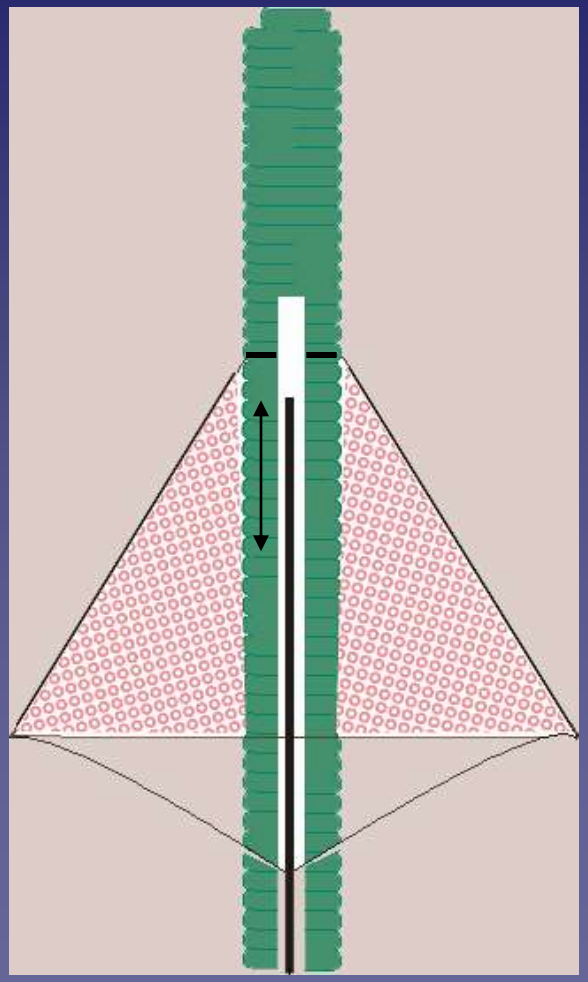
- most strokes are caused by embolism (>95%)
- micro- & macro-embolization occurs during CAS

1981 – Who will produce our filter?

0.035” movable core wire
threads fixed at core and filter
filter fixed at wire
pores of filter membrane 70 µ

filter opened:
- core moved forward
- flow resistance

filter closed:
- core pulled back



1989 - First Patient with Stent

65 yo man

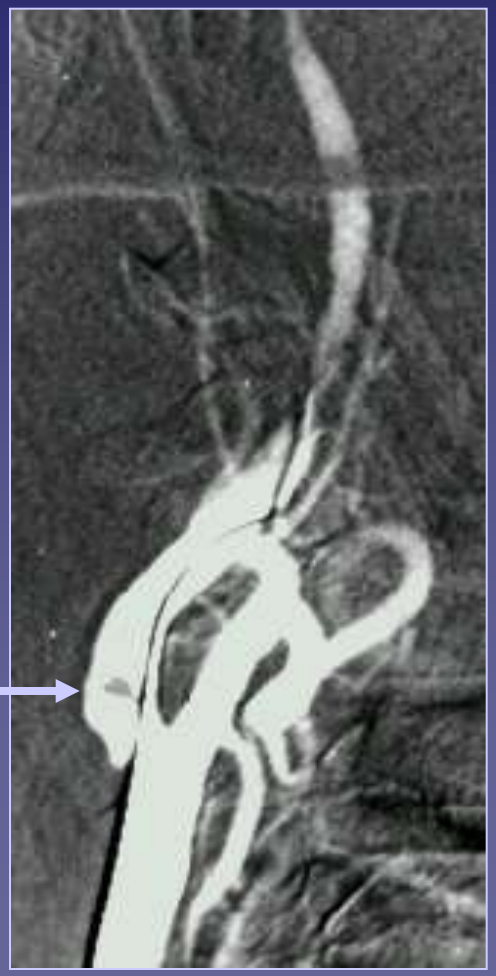
- symptomatic ica stenosis
  > 90%
- balloon dilatation
  over-the-wire technique

1989 - First Patient with Stent

What to do?

- leave it as it is?
- emergency surgery?

intimal flap



1989 - First Patient with Stent

Options for stent placement

- Palmaz balloon-expandable
- rolling membrane Wallstent

Wallstent developed by a small Swiss company in early eighties

- bought by Schneider
- bought by Pfizer
- bought by Boston Scientific

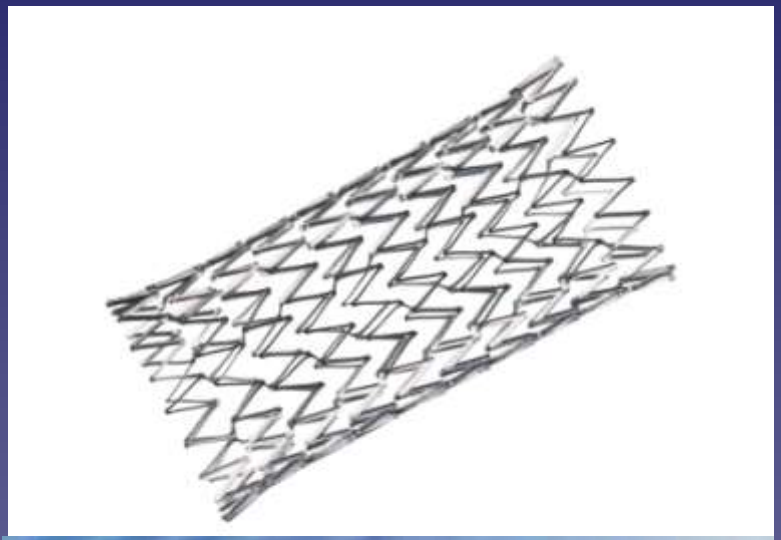
1989 - First Patient with Stent

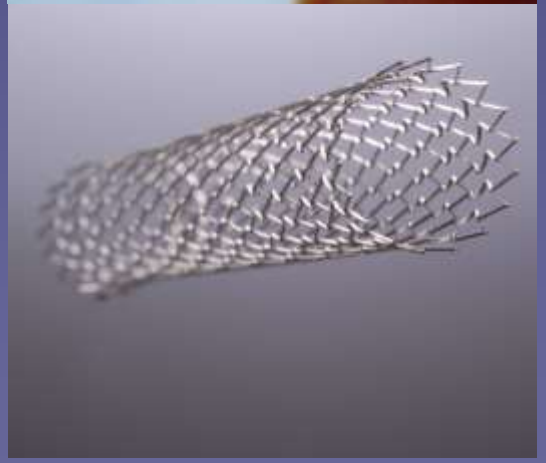
intimal flap attached to vessel wall after placement of a Wallstent across the bifurcation


Fantastic - a stent

Today Routine Stent Placement

self-expandable nitinol stents





Question:
Does stent placement reduce the incidence of procedure-related stroke?

Stroke rate 1979-1989

6.9% (32/467)

?

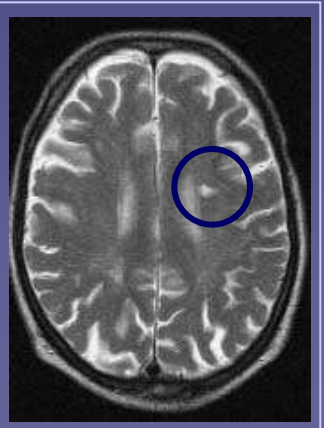
primary stenting: touch the lesion only once

pre-dilatation: less stent shortening

Answer: No!

Stent placement does not influence the embolization rate favorably.

• TCD	100%
• DW-MRI	30%
• transient ischemia	5 - 15%
• permanent deficit	1 - 5%



How to reduce the procedure related stroke rate?

Cerebral Protection

Radiology 1996; 201:627–636

Neuroradiology

Jacques G. Theron, MD • Gilles G. Payelle, MD • Oguzhan Coskun, MD • Hervé F. Huet, MD
Leopoldo Guimaraens, MD

Carotid Artery Stenosis: Treatment with Protected Balloon Angioplasty and Stent Placement[1]

How to Reduce the Procedure Related Stroke Rate?

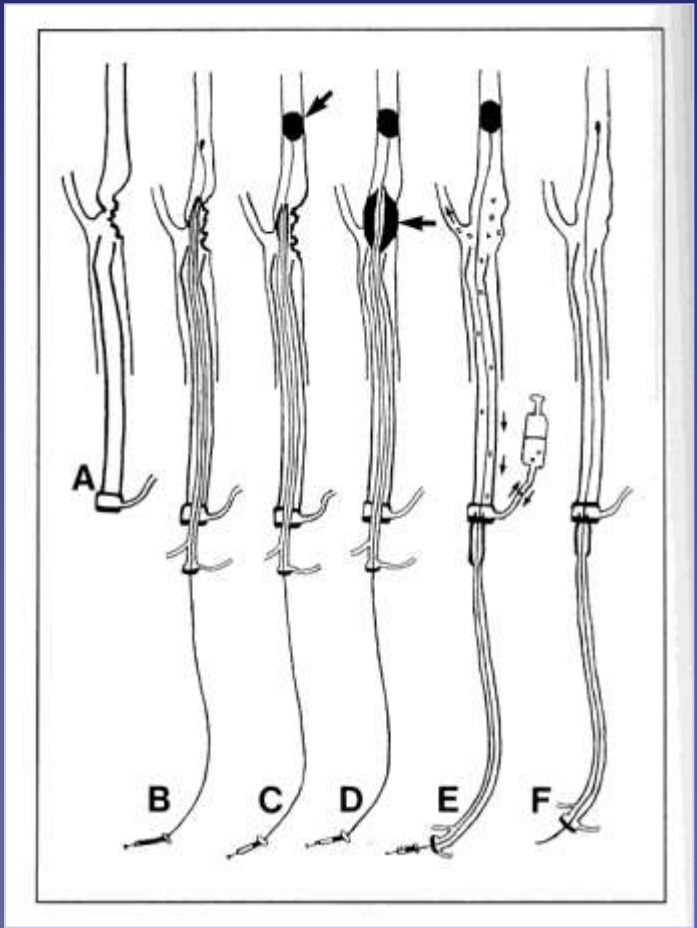


Figure 2. Lateral radiograph shows the triple coaxial catheter system in place (Fig 1d). The inflated occlusive balloon (small solid arrow), the inflated angioplasty balloon (large solid arrow), and the guiding catheter (open arrow) are seen.

Own hand made balloon protection device 1996

How to reduce the procedure related stroke rate?

When we block the blood flow in the common and external carotid artery we will get reversed flow in the internal carotid artery and will prevent embolization.

Rainer Kachel / Erfurt

1996

How to reduce the procedure related stroke rate?

Juan Parodi
Buenos Aires

We have developed a device with one balloon on a catheter and one on a wire blocking the CCA and ECA: Flow reversal

originally ArteriA 11-Fr

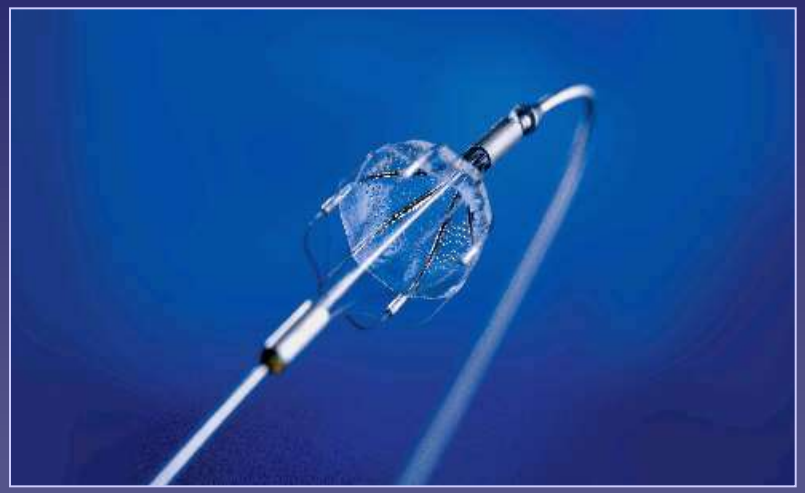
now Gore NAV 9-Fr

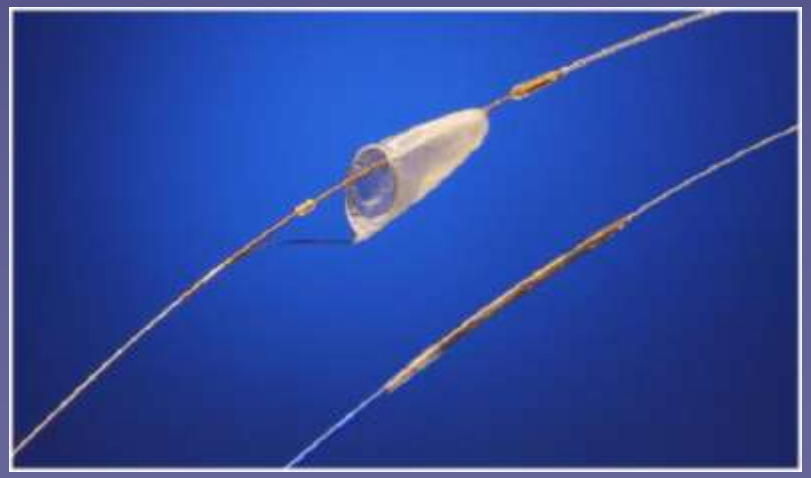
Parodi JC; La Mura R; Ferreira LM; Mendez MV; Cersosimo H; Schonholz C; Garelli G Initial evaluation of carotid angioplasty and stenting with three different cerebral protection devices. **J Vasc Surg 2000;32:1127-36**

Endeavors for Cerebral Protection

1981	**K. Mathias** **Concept of an umbrella-like filter** no product
1996	**G. Bockenheimer** **J. Theron** **Distal balloon protection** prototypes – no commercially available products
1997	**Percusurge**
1999	**Filters** (numerous US interventionalists)
1999	**R. Kachel**
2000	**J. Parodi (ArteriA)**
2002	**G. Biamino (Mo.Ma)** **Proximal balloon protection**

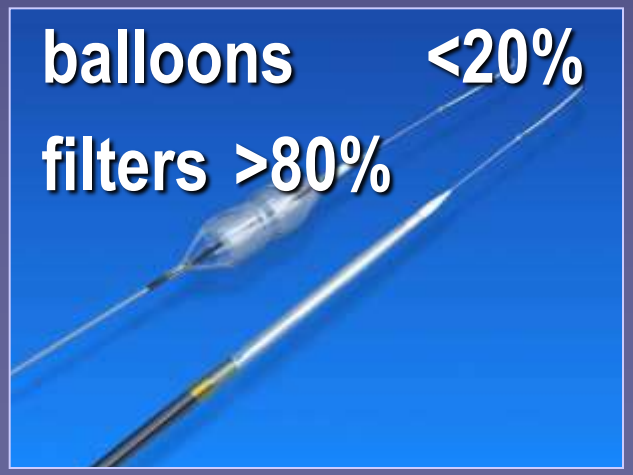
1999 – Routine Use of Cerebral Protection





balloons <20%

filters >80%



What else happened over the years?

Late Eighties: CAS goes from Europe to the USA

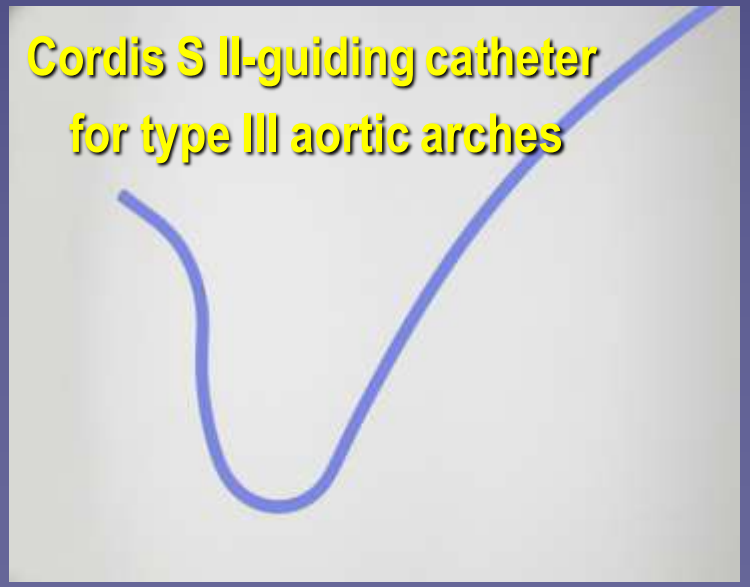
Technical Development

Change of technique

Over-the wire approach replaced by long sheath and guiding catheters

Change of technique

Anchor technique replaced by telescoping technique



Technical Development

Balloon catheters:

9F

seventies & first half of eighties

7F

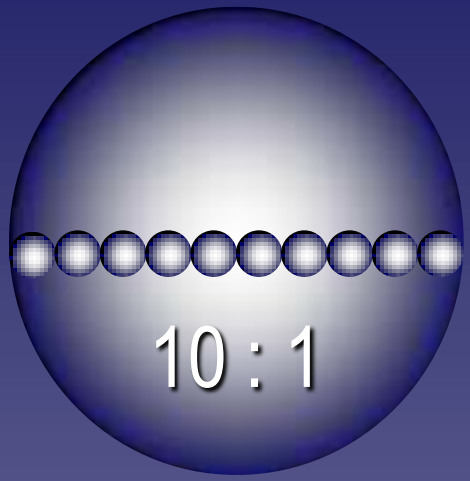
second half of eighties

5F

first half of nineties

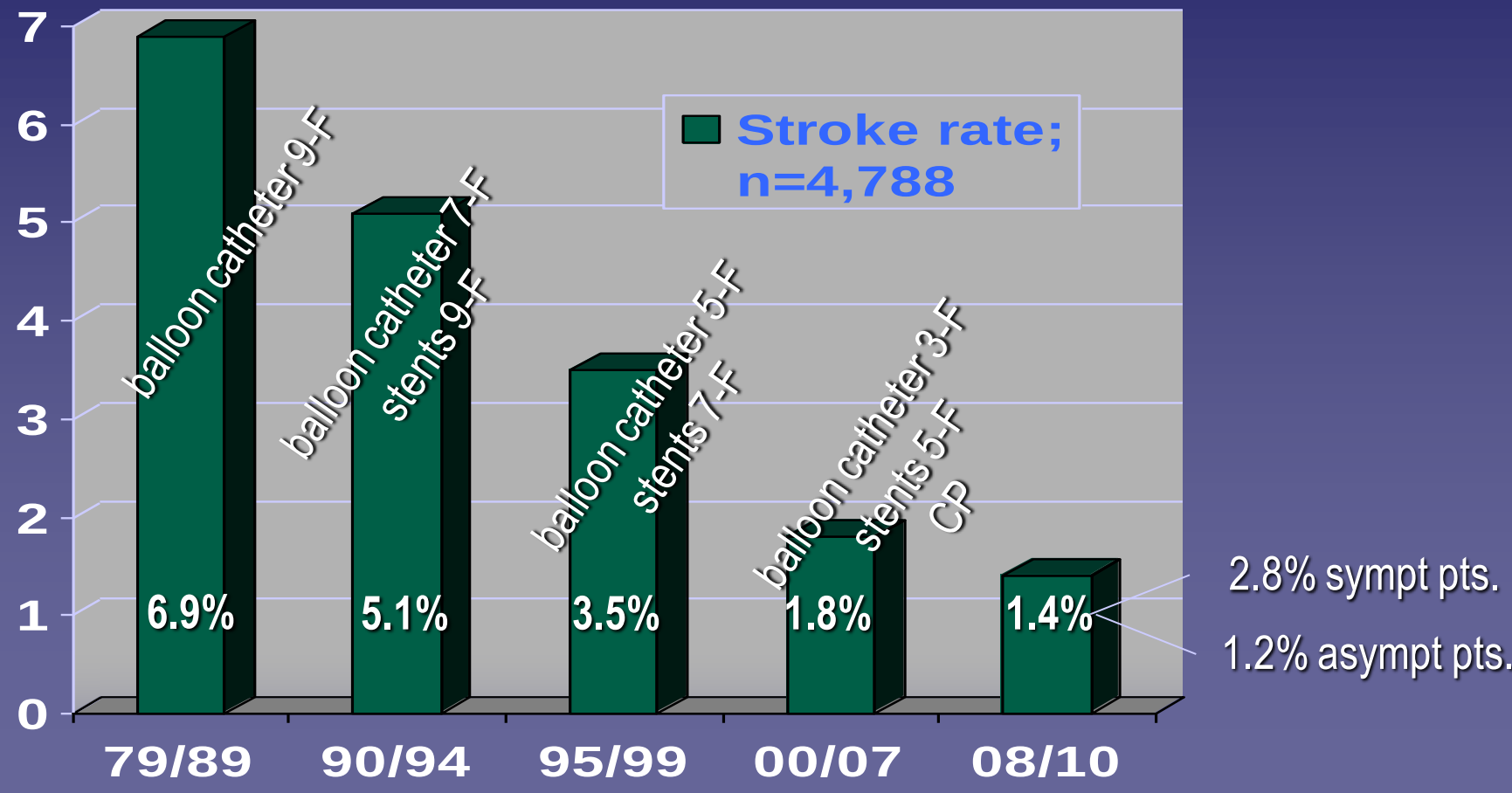
3F

presently used



relationship of
cross sectional areas
10 : 6 : 3 : 1

How does refinement of devices and growing experience influence the outcome of CAS?



Durability of Results

K.L.H. (m)	13.02.24
treated	04.02.90
controlled	09.08.01

- CAS of right ICA 11 years ago
- left ICA occluded

Wallstent

From controversy to evidence based medicine

From first reports to evidence based medicine

- Case reports
- Single center retrospective reports
- Single center prospective reports
- Registries
- Single center prospective studies with independent neurological control
- Multi-center prospective trials
- Multi-center prospective randomized trials

For many years surgeons claimed:

We reject prospective trials, because CEA is well established, its efficacy is evidence based, and CAS is too dangerous for our patients.

After CAVATAS (1992-1996):

These are poor results. How can vascular surgeons have such a high complication rate of 10%?

After SAPPHIRE:

What a bad trial!

How can you treat asymptomatic high risk patients?

What has myocardial infarction to do with carotid artery disease?

Is non-Q-wave MI a disease?

…

ProCAS

German Quality Assurance Program

- founded 1999
- intention to treat
- more than 12,000 patients registered

Clearly shown - experience matters

- stroke rate 1.2% to 14.8%

Experience counts!

EVA-3S, SPACE, ICSS

European trials have shown:
Experienced vascular surgeons have better results than unexperienced interventionalists !!!

None of the trials fulfill the criteria of *Good Medical Practice !!!*

When is CAS clearly better than CEA?

- patients < 65 yrs
- increased medical risk
- hostile neck
- contra-lateral carotid occlusion

<u>CEA preferred</u>

- patients > 80 yrs
- difficult anatomy


A fascinating journey is going on
Thank you for your interest