CGuard™ short-term safety and long-term efficacy from a single-center prospective registry

Gianbattista Parlani, Romano Lydia, Giacomo Isernia, Del Mastro Francesco Pio, **Gioele Simonte**

Vascular & Endovascular Surgery S Maria Misericordia Hospital, Perugia, Italy

Disclosure

Speaker name:

Gioele Simonte

I have the following potential conflicts of interest to report:

- ☒ Consulting for InspireMD
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ☐ I do not have any potential conflict of interest

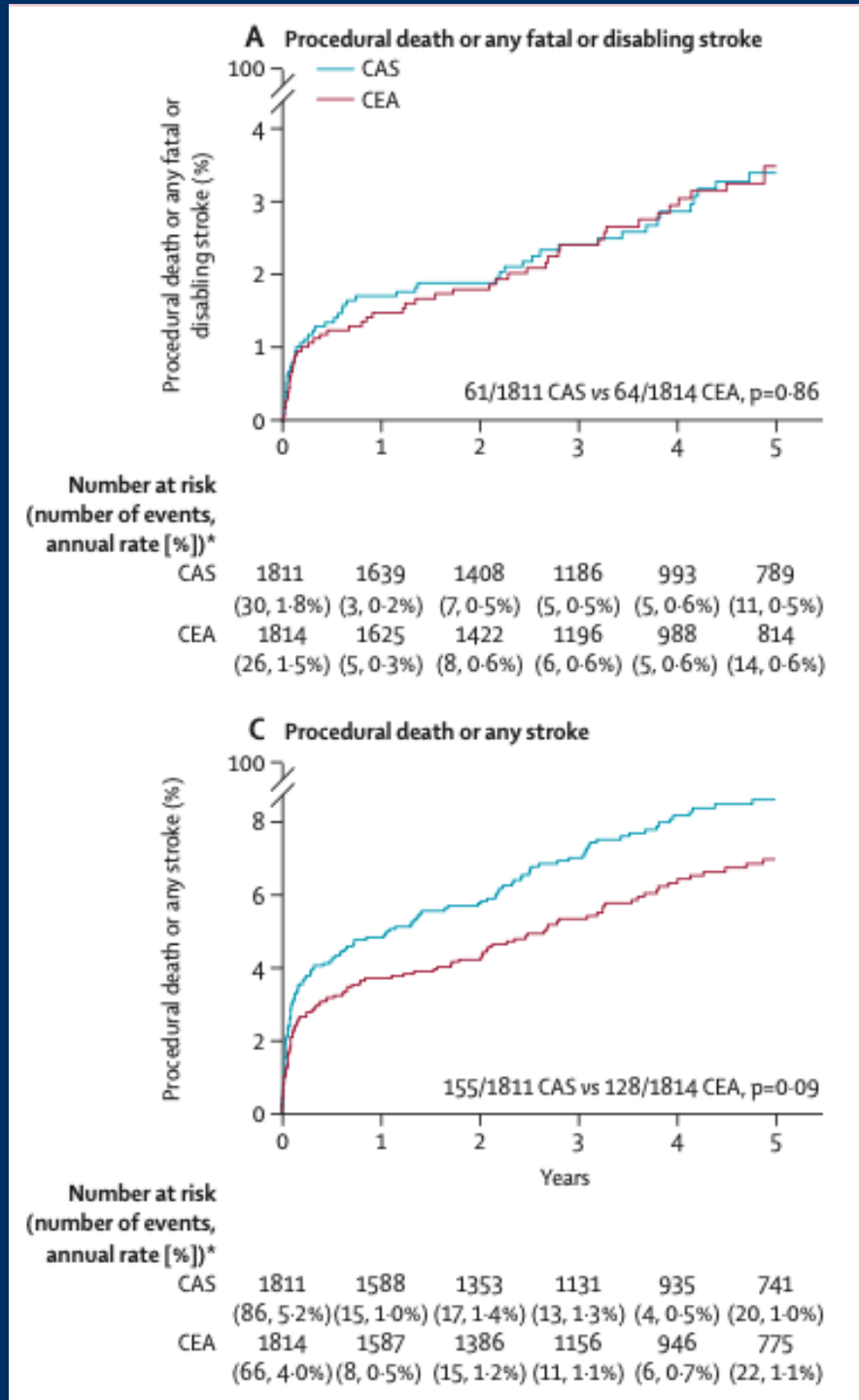
Background

Second asymptomatic carotid surgery trial (ACST-2): a randomised comparison of carotid artery stenting versus carotid endarterectomy

Alison Halliday, Richard Bulbulia*, Leo H Bonati, Johanna Chester, Andrea Cradduck-Bamford, Richard Peto†, Hongchao Pan†, for the ACST-2 Collaborative Group‡*

Lancet 2021; 398: 1065–73

«Serious complications are similarly uncommon after competent CAS and CEA, and the long-term effects of these two carotid artery procedures on fatal or disabling stroke are comparable»



Background

CLINICAL PRACTICE GUIDELINE DOCUMENT

Eur J Vasc Endovasc Surg. 2023 Jan;65(1):7-111.

European Society for Vascular Surgery (ESVS) 2023 Clinical Practice Guidelines on the Management of Atherosclerotic Carotid and Vertebral Artery Disease☆

Ross Naylor [a,*], Barbara Rantner [a], Stefano Ancetti [a], Gert J. de Borst [a], Marco De Carlo [a], Alison Halliday [a], Stavros K. Kakkos [a], Hugh S. Markus [a], Dominick J.H. McCabe [a], Henrik Sillesen [a], Jos C. van den Berg [a], Melina Vega de Ceniga [a], Maarit A. Venermo [a], Frank E.G. Vermassen [a]

ESVS Guidelines Committee [b], George A. Antoniou, Frederico Bastos Goncalves, Martin Bjorck, Nabil Chakfe, Raphael Coscas, Nuno V. Dias, Florian Dick, Robert J. Hinchliffe, Philippe Kolh, Igor B. Koncar, Jes S. Lindholt, Barend M.E. Mees, Timothy A. Resch, Santi Trimarchi, Riikka Tulamo, Christopher P. Twine, Anders Wanhainen

Recommendation 20	Unchanged

For average surgical risk patients with an asymptomatic 60–99% stenosis in the presence of one or more imaging or clinical characteristics that may be associated with an increased risk of late stroke*, carotid stenting may be an alternative to carotid endarterectomy, provided 30 day stroke/death rates are ≤3% and patient life expectancy exceeds five years.

Class	Level	References	ToE
IIb	B	Mannheim *et al.* (2017)[222],	

Recommendation 84	New

For patients undergoing elective carotid artery stenting, dual layer mesh covered stents may be considered.

Class	Level	References	ToE
IIb	C	Imamura *et al.* (2021)[486]	

CGUARD™
Carotid Stent System

Carotid Embolic Prevention System

The CGuard™ Embolic Prevention System (EPS) is designed to prevent peri-procedural and late embolization by trapping potential emboli against the arterial wall while maintaining excellent perfusion to the external carotid artery and branch vessels.

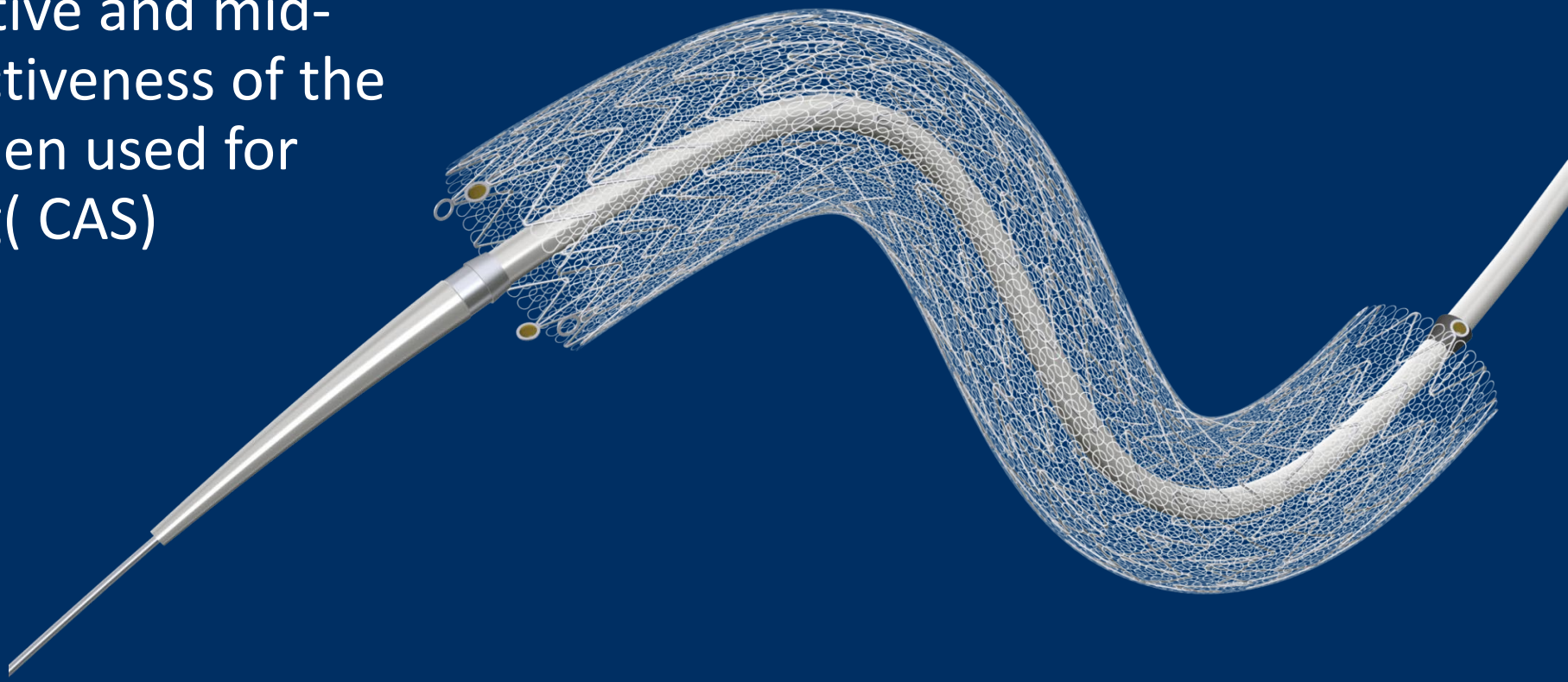
- ✓ **Dual Layer Design**
  Open cell stent platform wrapped in MicroNet mesh
- ✓ **MicroNet™**
  For continuous embolic prevention
- ✓ **SmartFit™ Technology**
  Eliminates need for tapered version

Product Details:

- CGuard material: Nitinol
- MicroNet material: Polyethylene Terephthalate (PET)
- Easy to use RX (Rapid Exchange) delivery system

Aim of the study

To evaluate perioperative and mid-term, safety, and effectiveness of the CGuard EPS device when used for carotid artery stenting(CAS) procedures

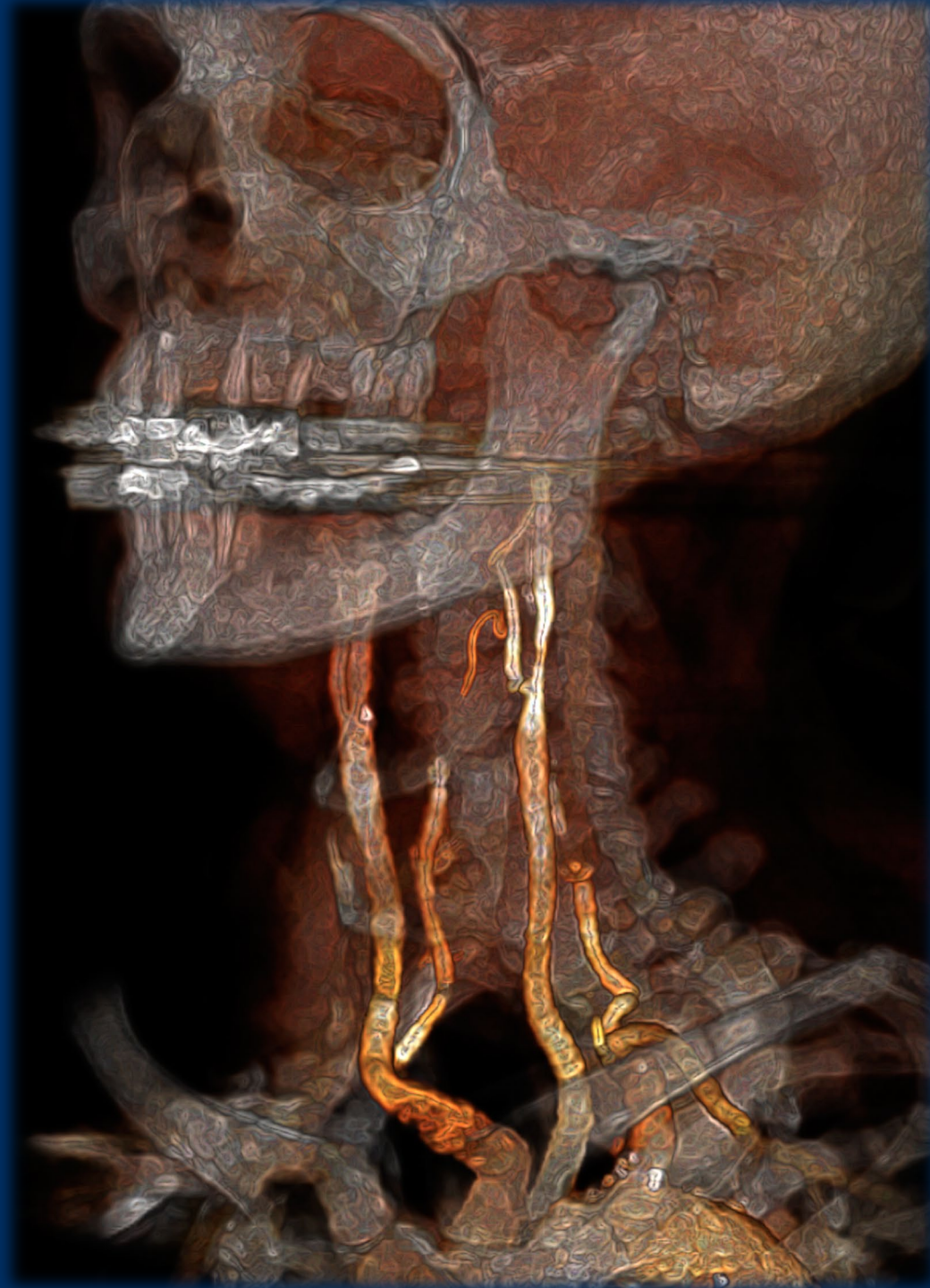


Spontaneous single center registry

Study population

All patients consecutively treated with CGuard for carotid artery stenosis during the period Jan2016-Dec2023 were prospectively enrolled

CGuard was used for the preferred stent used during the whole period



Endpoints - methods

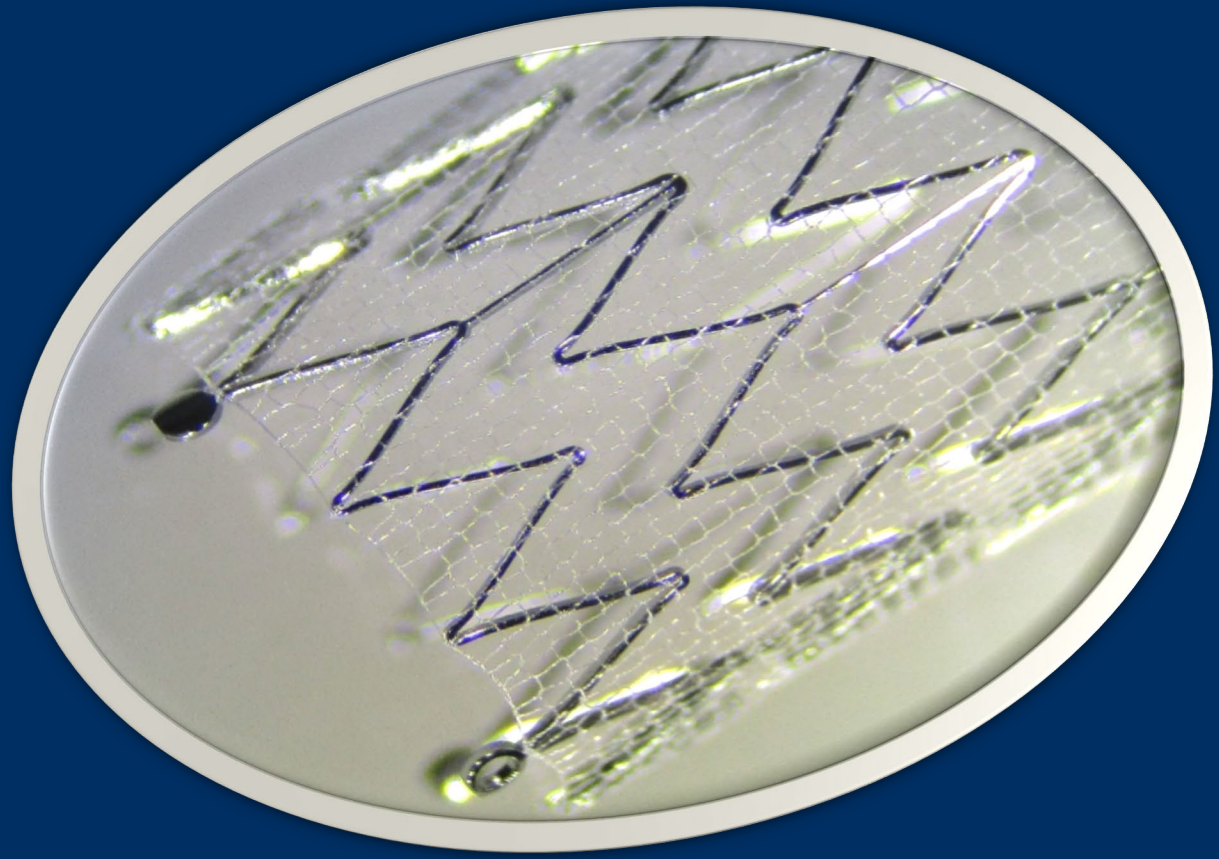
Primary endpoints

- technical success
- perioperative neurological events .

Secondary endpoint

- rate of neurologic, cardiac events, and death (major adverse event or MAE) at 30 days.

Patency of CGuard, were evaluated at 30 days, 6 months, 12 months and yearly thereafter. with duplex ultrasound.



CGUARD™ Carotid Stent System

Study population

183 total patients included in the study cohort

Risk factors	n (%)
Mean age	72,6 ± 8.1
Male	118 (64.5)
Hypertension	167 (91.2)
Diabetes	59 (32.2)
Hyperlipemia	113 (61.7)
COPD	54 (29.5)
CAD	61 (33.3)
Anticoagulant	16 (8.7)

Study population

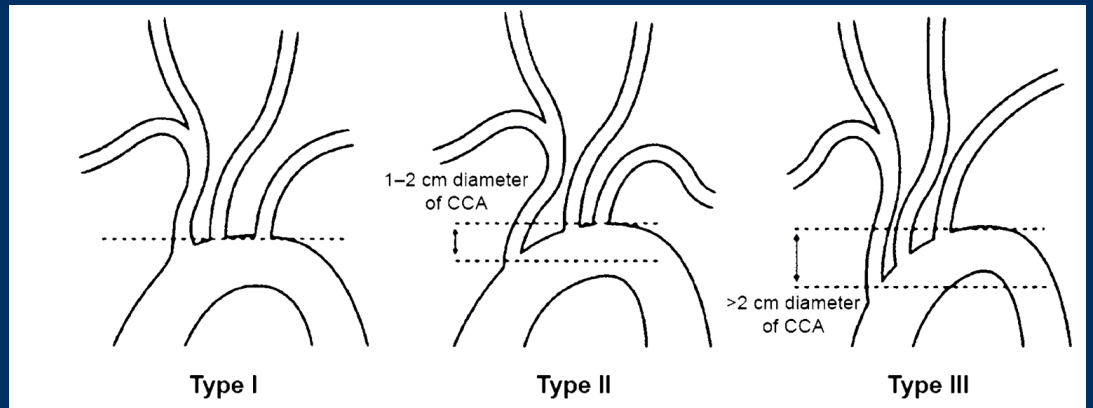
49 (26.8%) patients had a symptomatic carotid stenosis

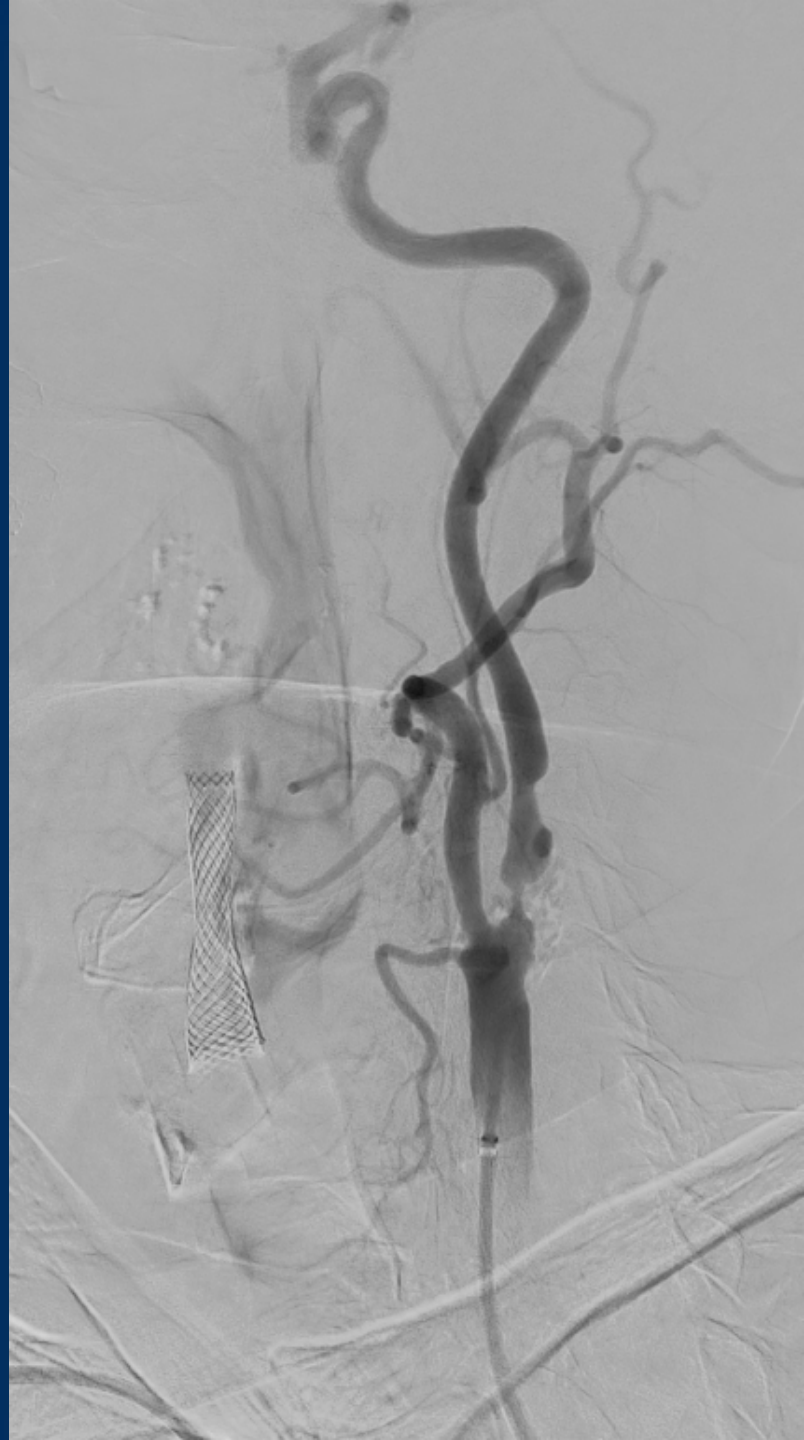
- 11 TIA
- 7 retinal stroke/amaurosis
- 31 stroke

Study population

Anatomical Features

Characteristics	n (%)
Stenosis rate	81.7 ± 7.5
Significant calcification >50%	41 (22.4)
Hypoecoic plaque	39 (21.3)
Left side	91 (49.7)
Bovine arch	24 (13.1)
Type lll arch	79 (43.2)
Contralateral ICA occlusion	12 (6.6)



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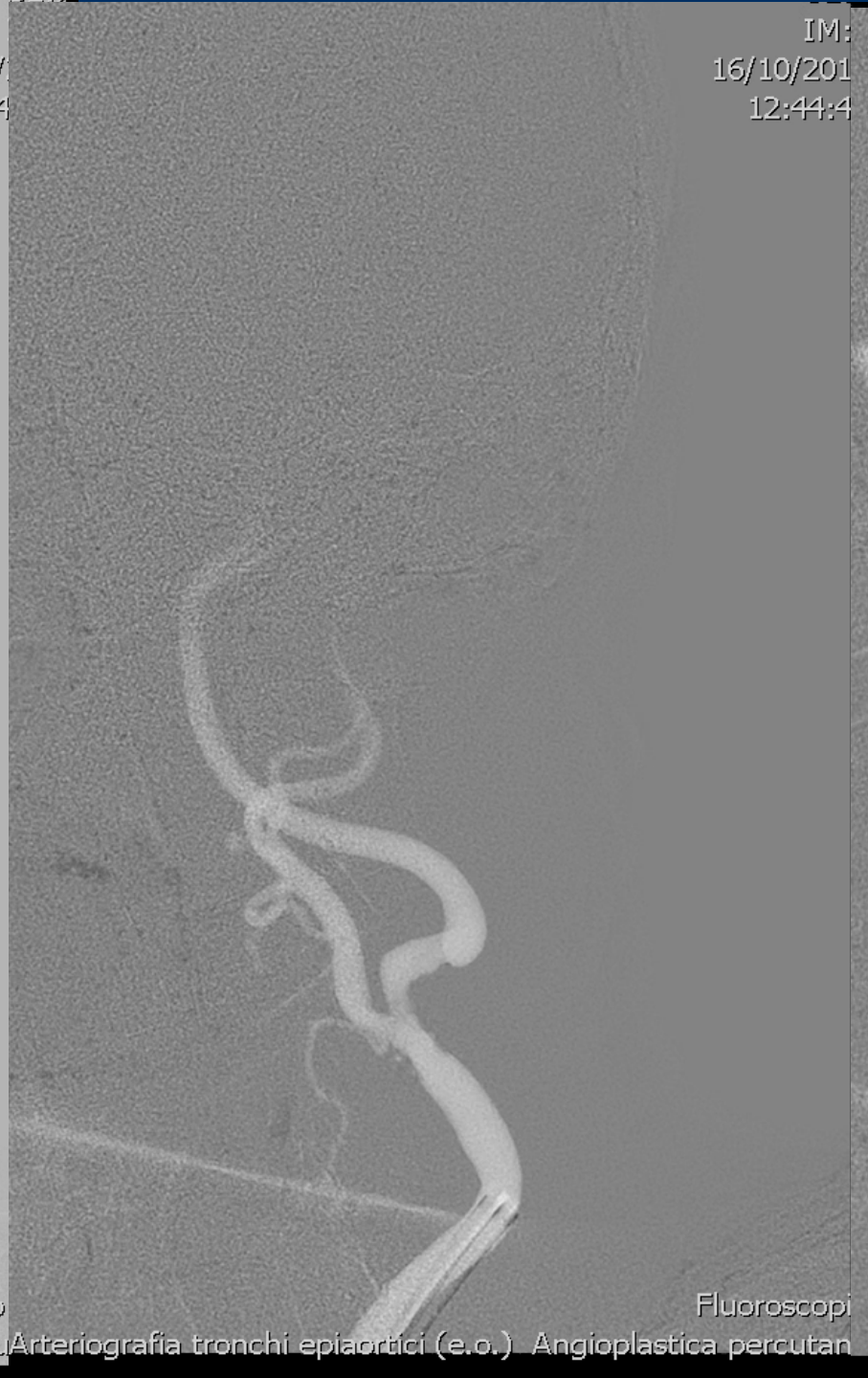
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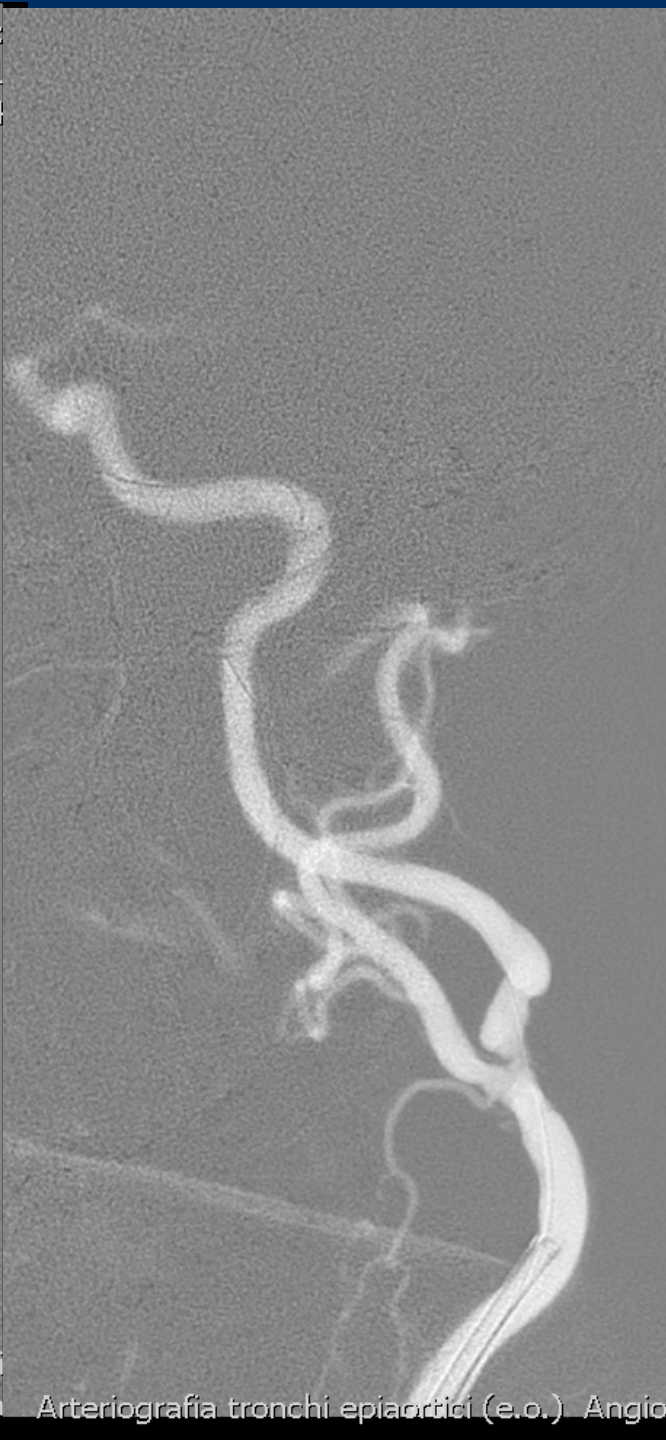
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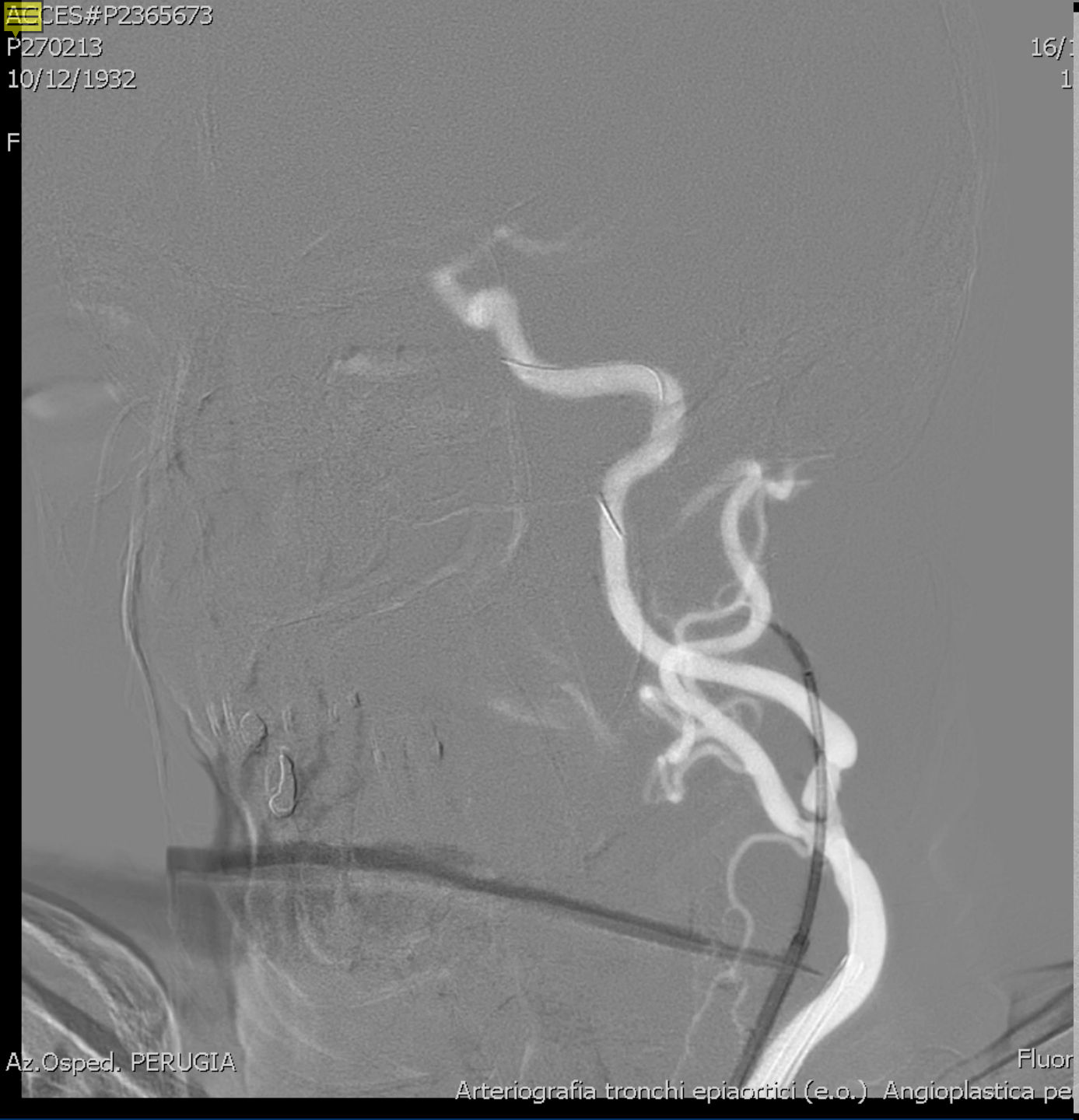
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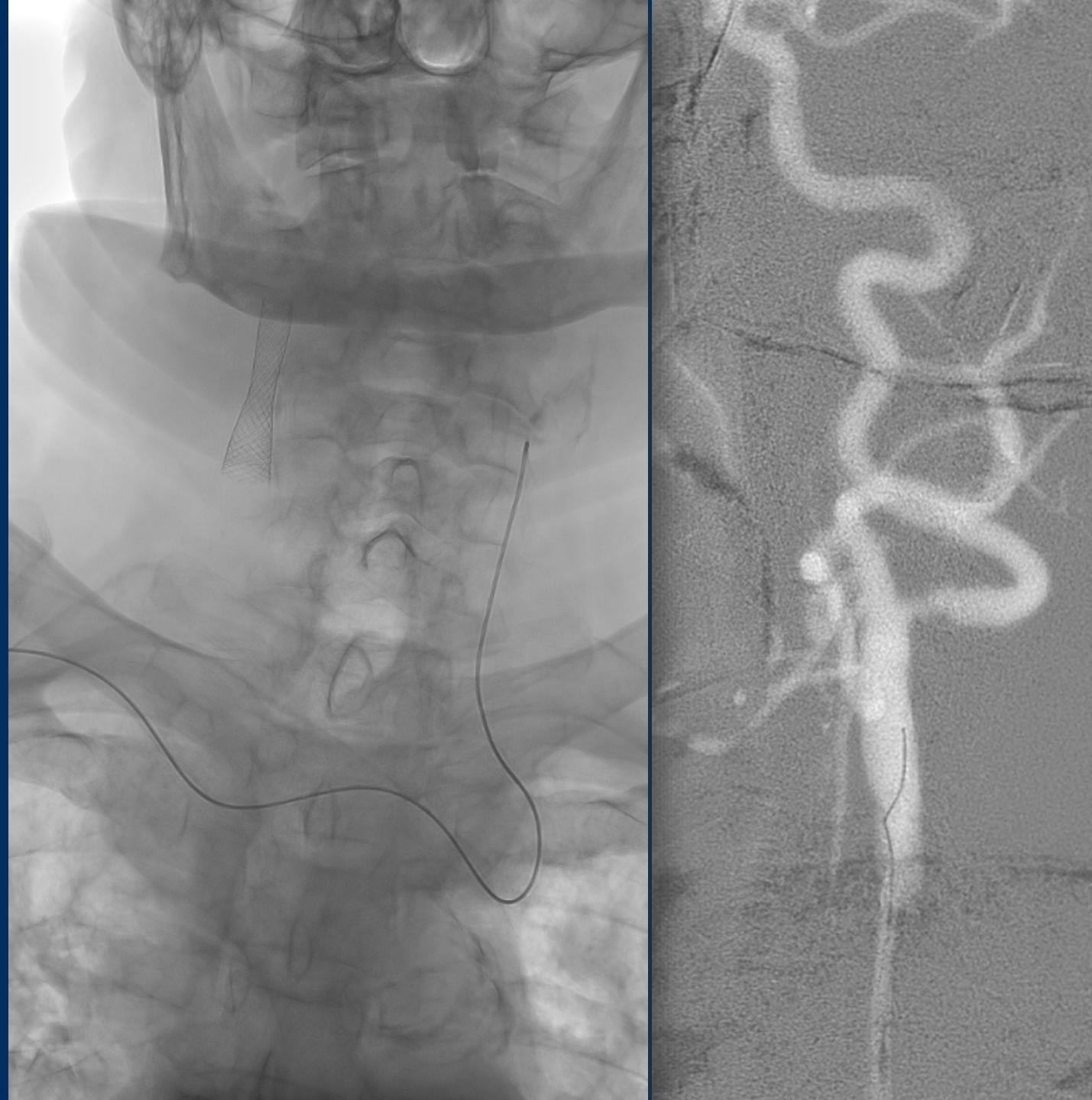
Results

intraoperative

- 3 (1.6%) Brachial access
- 180 (98.3%) Femoral access
- 19 (10.4%) Need for ECA cannulation
- 183 (100%) Distal protection filter
- 4 (2.1%) Predilatation

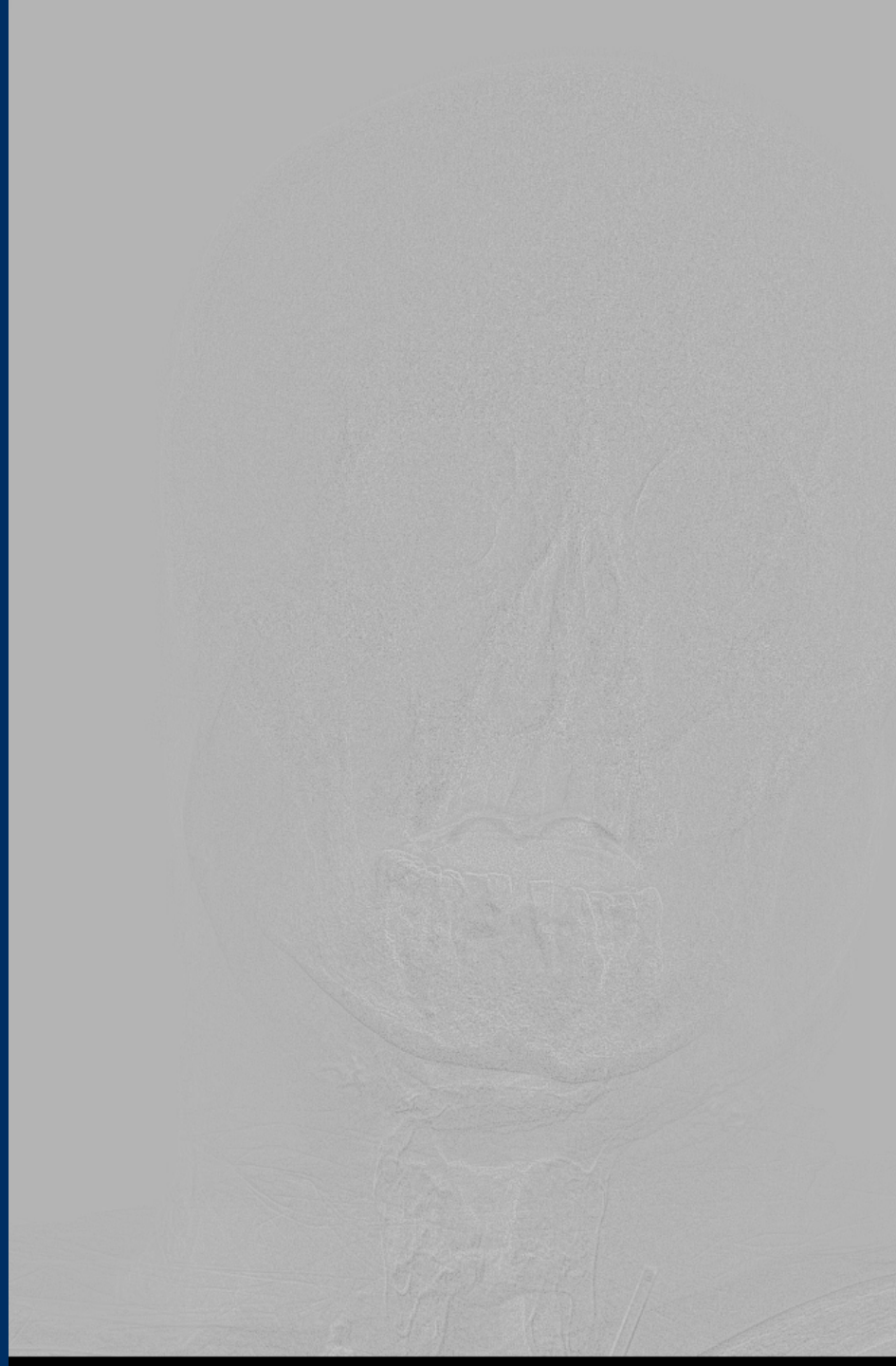
Failure to advance introducer sheath into CCA occurred in 2 patients during the whole study period -> excluded from study cohort



Results

procedures

Characteristics	Mean ± st.dev
Procedure time	33.6 ± 13.0
Fluoro time	11.2 ± 9.5
Contrast media	43.3 ± 16.2

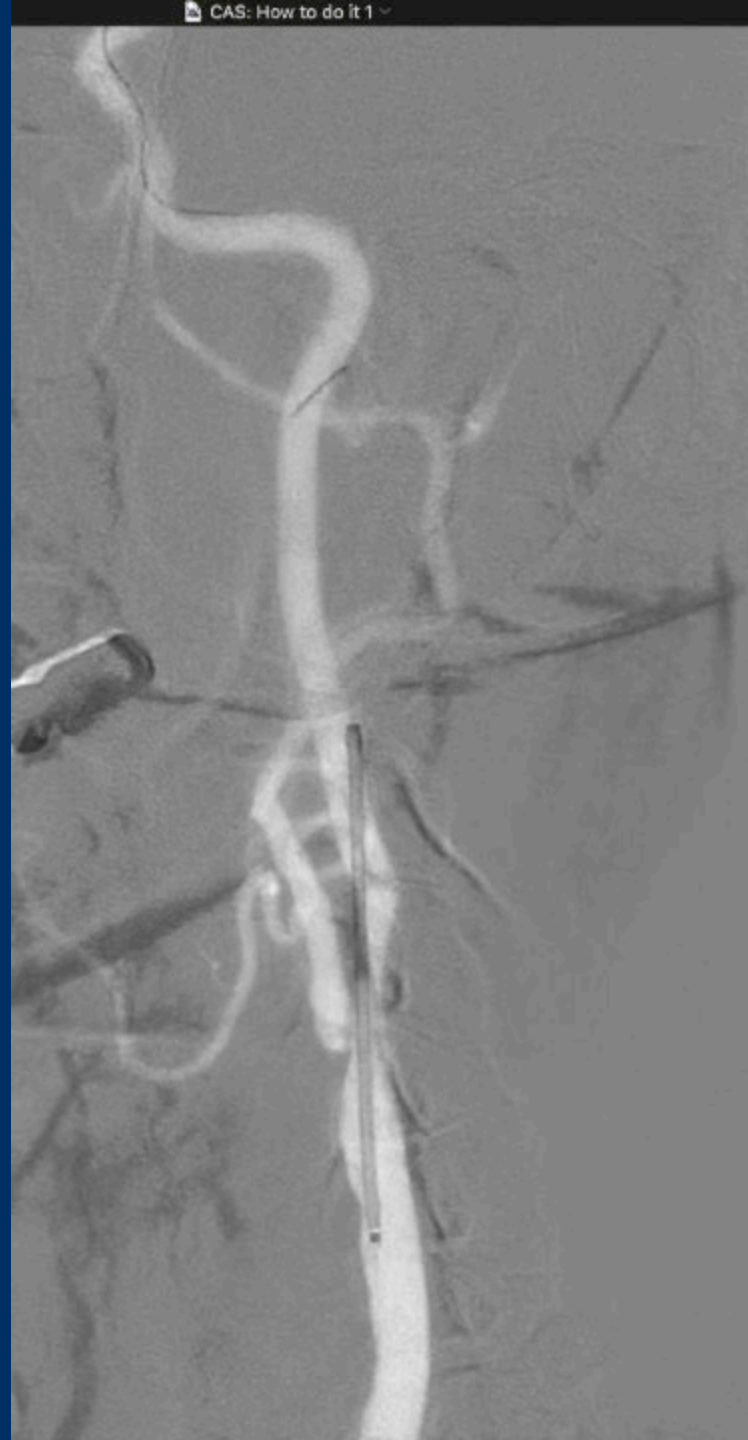


Results
procedures

Characteristics	n (%)
Technical success	182 (99.5)*
Residual stenosis >30%	0
Neurological complications**	1 (0.5) minor stroke 1 (0.5) TIA
Access complications	2 (1) surgical conversion

*The only technical failure was due to impossibile lesion crossing in a post-attinic stenosis.
Solved with repeated pre-dilatation and different stent usage (Wallstent)

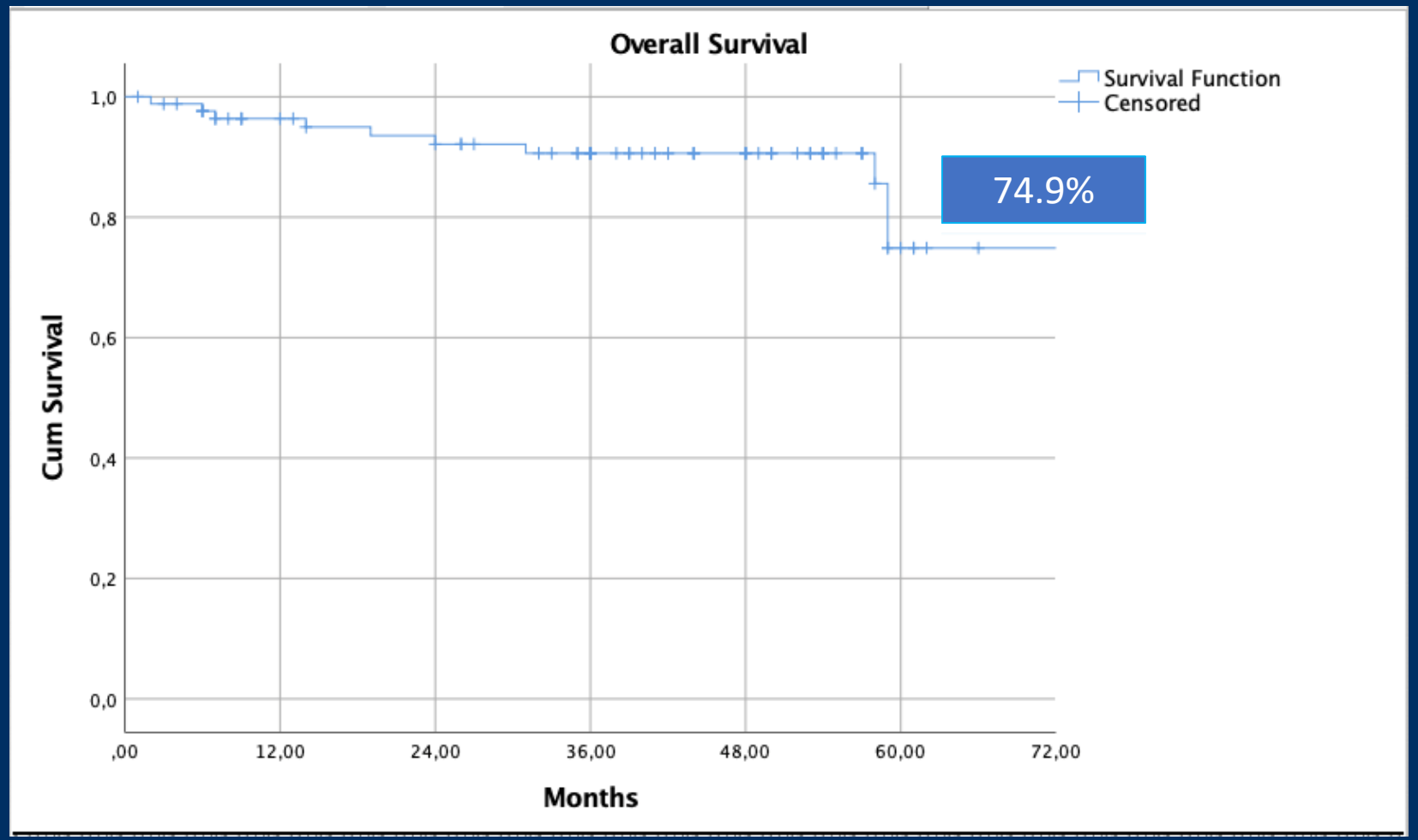
**0 complications in asymptomatic patients



Results

Follow up

Mean follow up 35.4 ± 24.2



Results

Follow up

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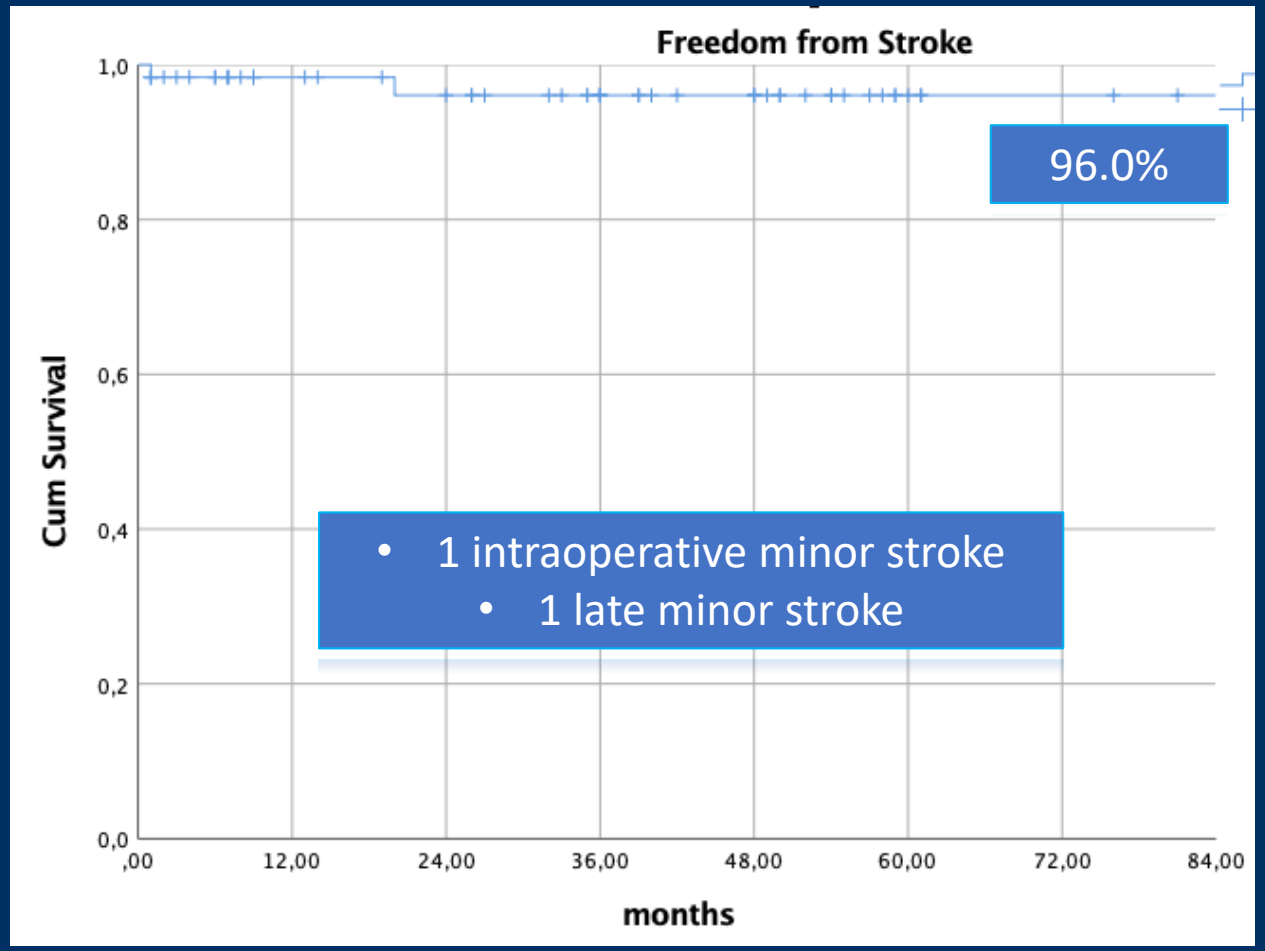
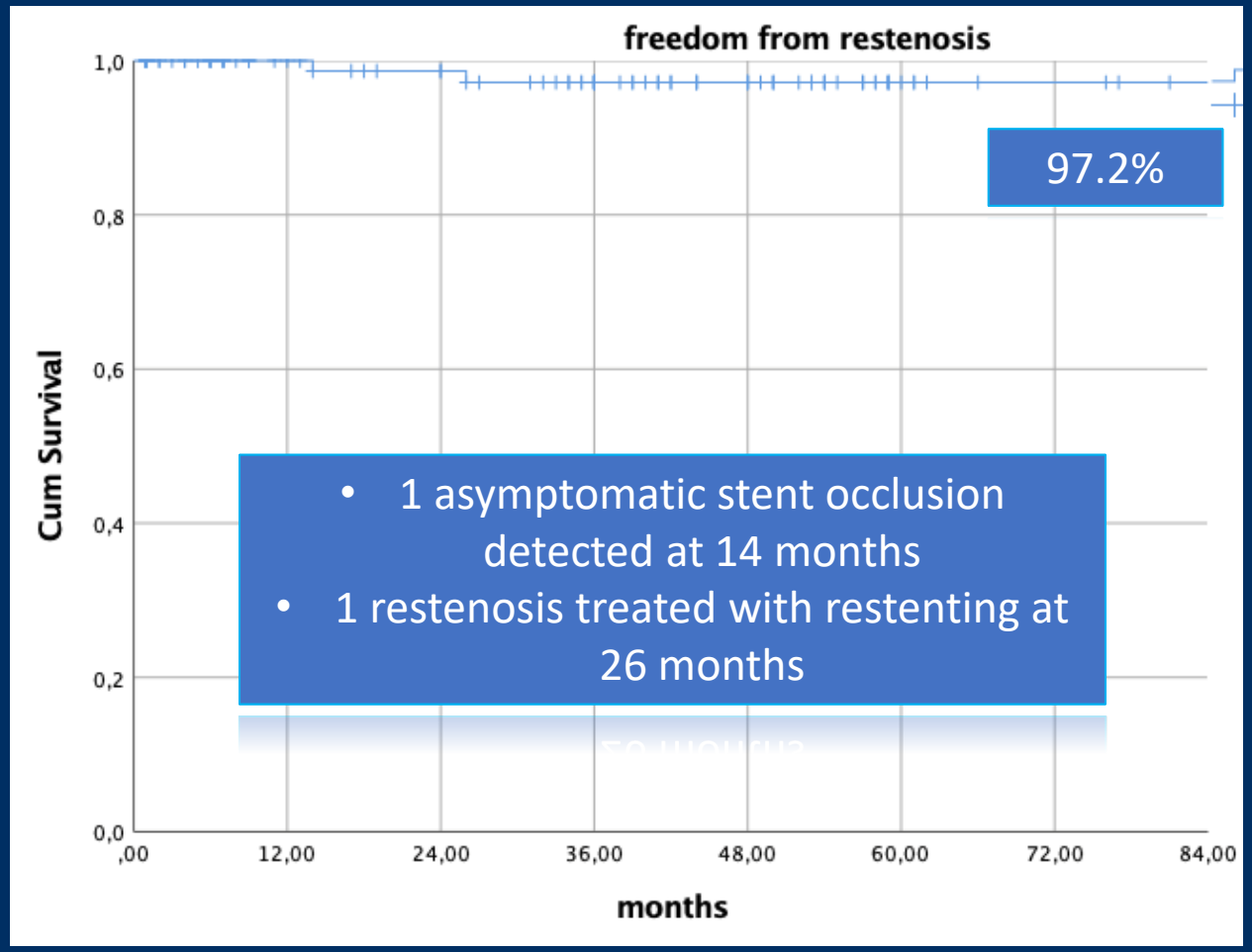


96.0%

- 1 intraoperative minor stroke
- 1 late minor stroke

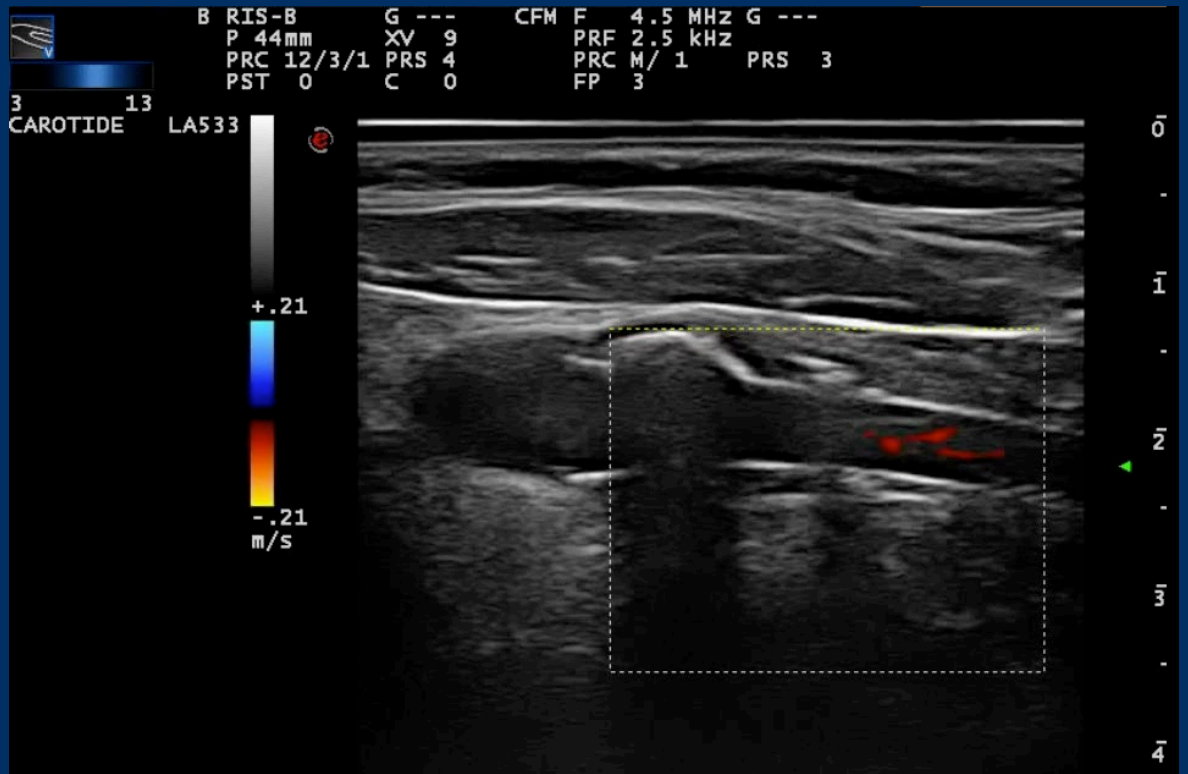


97.2%

- 1 asymptomatic stent occlusion detected at 14 months
- 1 restenosis treated with restenting at 26 months

Conclusions

CGuard stent with EPS appears as an effective and safe device for the treatment of carotid artery stenosis with acceptable low perioperative neurologic events and durable patency rate. Larger multicenter and randomized studies are necessary to confirm its long-term efficacy.




Thanks for your attention