23rd CardioVascular Summit -TCTAP 2018
Seoul, Korea, April 28 - May 1, 2018

EVT Guidelines: What has been changed?
Carotid Artery Stenosis: Optimal Candidate for Revascularization

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Disclosures

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2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS)

ESC European Society of Cardiology

Endorsed by the European Stroke Organization (ESO)

The Task Force for the Diagnosis and Treatment of Peripheral Arterial Diseases of the European Society of Cardiology (ESC) and of the European Society for Vascular Surgery (ESVS)

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A very difficult topic for me!

- I was involved in the development of these guidelines over the last decade
- As you can imagine, with so many others involved, I could not always prevail
- Guidelines are always a compromise
  - Honestly, I prefer to convince rather than to compromise
- Also, I always try **not** to follow the guidelines
  - But instead to **be ahead** of them

What has changed in 2017?

Change in recommendations	
2011	2017
Carotid Artery Disease	
EPDs in carotid stenting	
Asymptomatic 60-99% carotid stenosis	
• Surgery for all	• Surgery for high stroke risk
• Stenting as an alternative	• Stenting in high surgery risk
	• Stenting in average surgical risk

I IIa IIb III

What is new?

2017 New recommendations
Carotid Artery Disease
• Coronary angiography before elective carotid surgery
• Routine prophylactic revascularization of asymptomatic carotid 70-99% stenosis in patients undergoing CABG

I IIa IIb III

New/revised concept

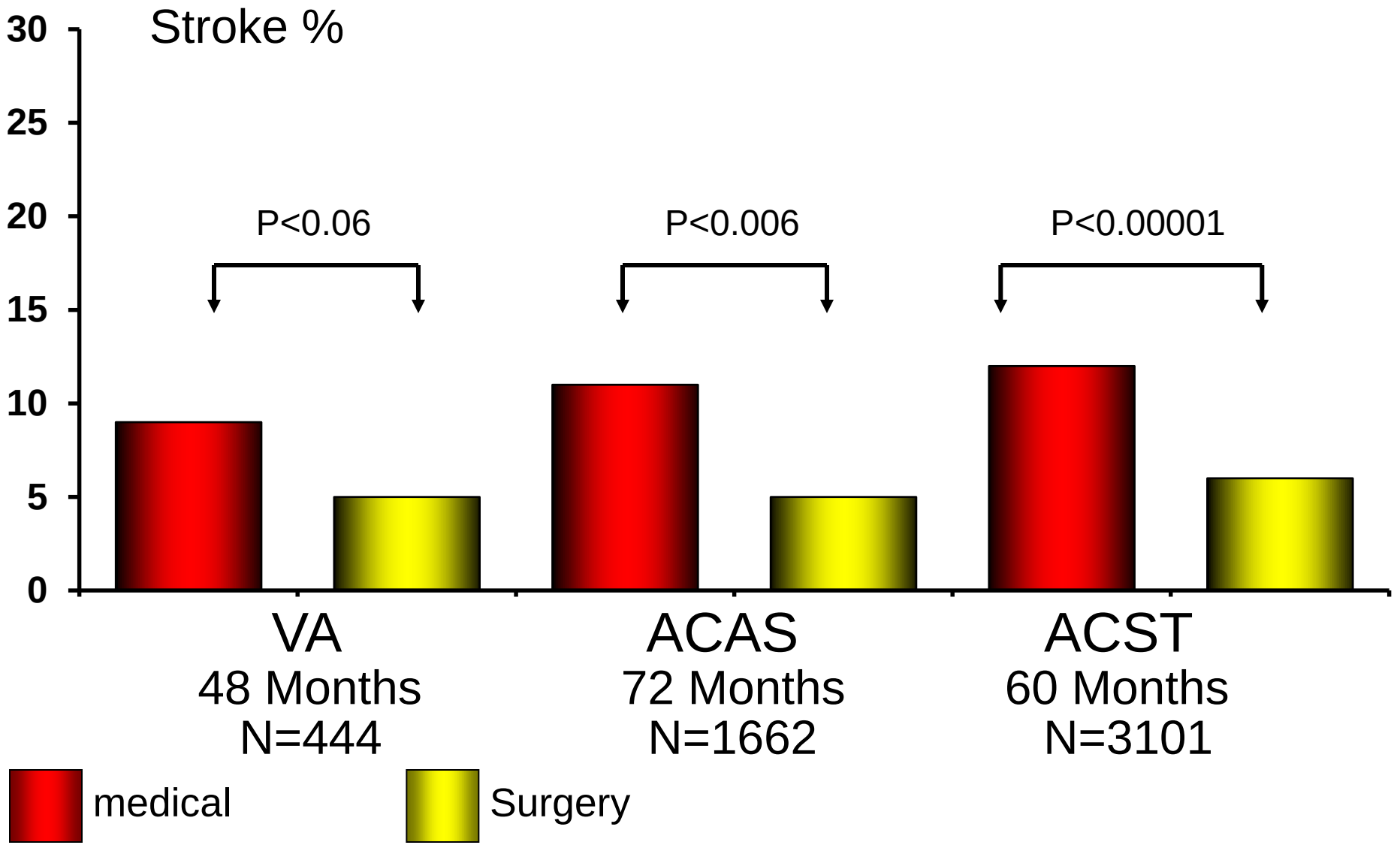
- Risk stratification for asymptomatic carotid disease.

Imaging

Recommendations	Class	Level
DUS (as first-line), CTA and/or MRA are recommended for evaluating the extent and severity of extracranial carotid stenoses.	I	B
When CAS is being considered, it is recommended that any DUS study be followed either by MRA or CTA to evaluate the aortic arch, as well as the extra- and intracranial circulation.	I	B
When CEA is considered, it is recommended that the DUS stenosis estimation be corroborated either by MRA or CTA (or by a repeat DUS study performed in an expert vascular laboratory).	I	B

Asymptomatic carotid stenoses

After the initial negative randomized trials carotid surgery was finally established in the 1990s by these trials:



These trials comparing CEA with medical therapy are considered to be outdated

I could give another 10 min lecture explaining why I have some doubts

Features associated with increased risk of stroke in patients with asymptomatic carotid stenosis treated medically

Clinical[a]	• Contralateral TIA/stroke[121]
Cerebral imaging	• Ipsilateral silent infarction[122]
Ultrasound imaging	• Stenosis progression (> 20%)[123] • Spontaneous embolization on transcranial Doppler (HITS)[124] • Impaired cerebral vascular reserve[125] • Large plaques[b126] • Echolucent plaques[96] • Increased juxta-luminal black (hypoechogenic) area[127]
MRA	• Intraplaque haemorrhage[128] • Lipid-rich necrotic core

HITS = high intensity transient signal; MRA = magnetic resonance angiography; TIA = transient ischaemic attack.

[a]Age is not a predictor of poorer outcome.

[b]More than 40 mm^2 on digital analysis.

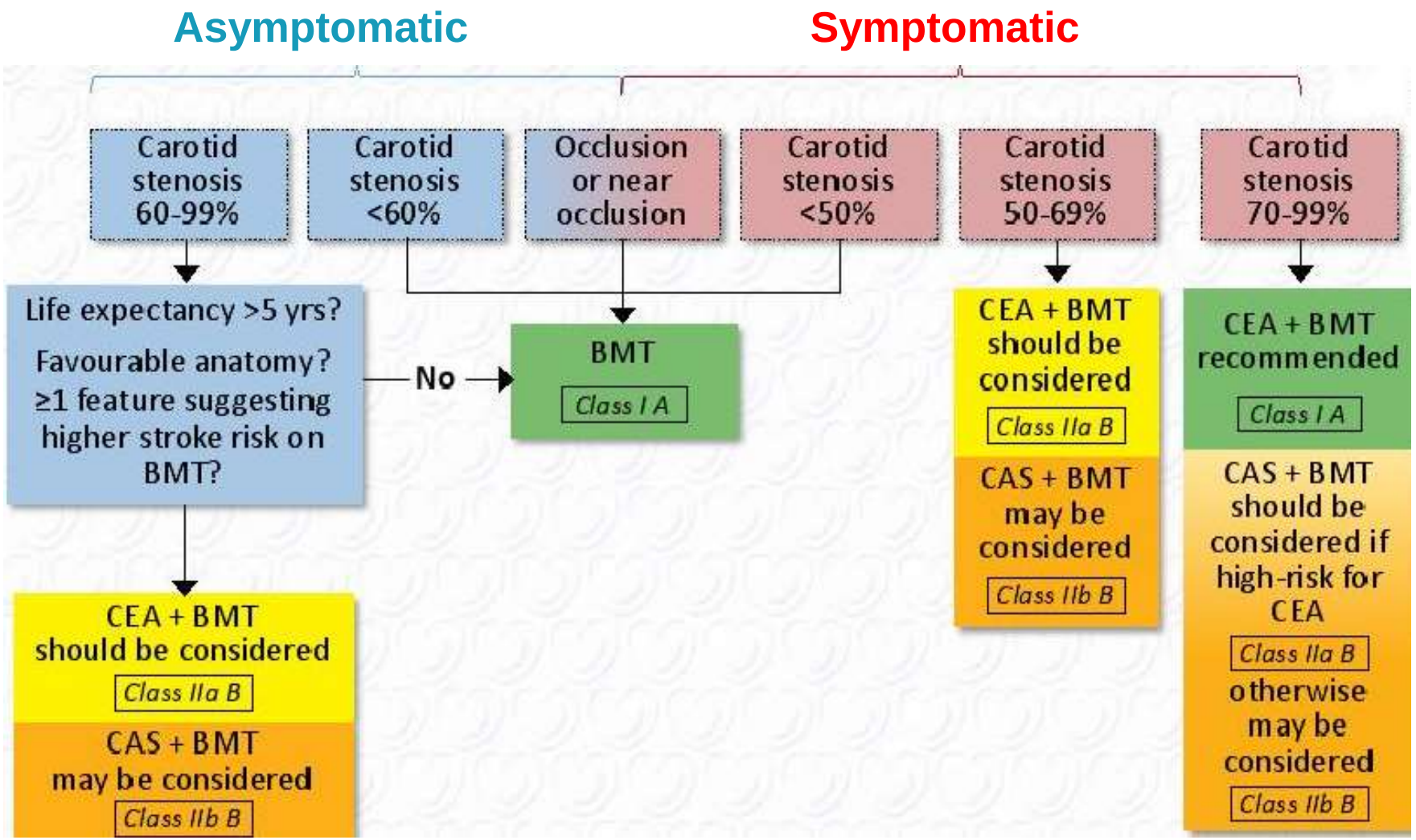
Management of **asymptomatic** carotid stenoses

Recommendations	Class	Level
In **"average surgical risk"** patients with an asymptomatic **60-99%** stenosis, **CEA** should be considered in the presence of clinical and/or more imaging characteristics that may be associated with an increased risk of late ipsilateral stroke, provided documented perioperative stroke/death rates are <3% and the patient's life expectancy is >5 years.	IIa	B
In asymptomatic patients who have been deemed **"high-risk for CEA"** and who have an asymptomatic **60-99%** stenosis in the presence of clinical and/or imaging characteristics that may be associated with an increased risk of late ipsilateral stroke, **CAS** should be considered, provided documented perioperative stroke/death rates are <3% and the patient's life expectancy is >5 years.	IIa	B
In **"average surgical risk"** patients with an asymptomatic **60-99%** stenosis in the presence of clinical and/or imaging characteristics[d] that may be associated with an increased risk of late ipsilateral stroke, **CAS may be an alternative to CEA** provided documented perioperative stroke/death rates are <3% and the patient's life expectancy is >5 years.	IIb	B

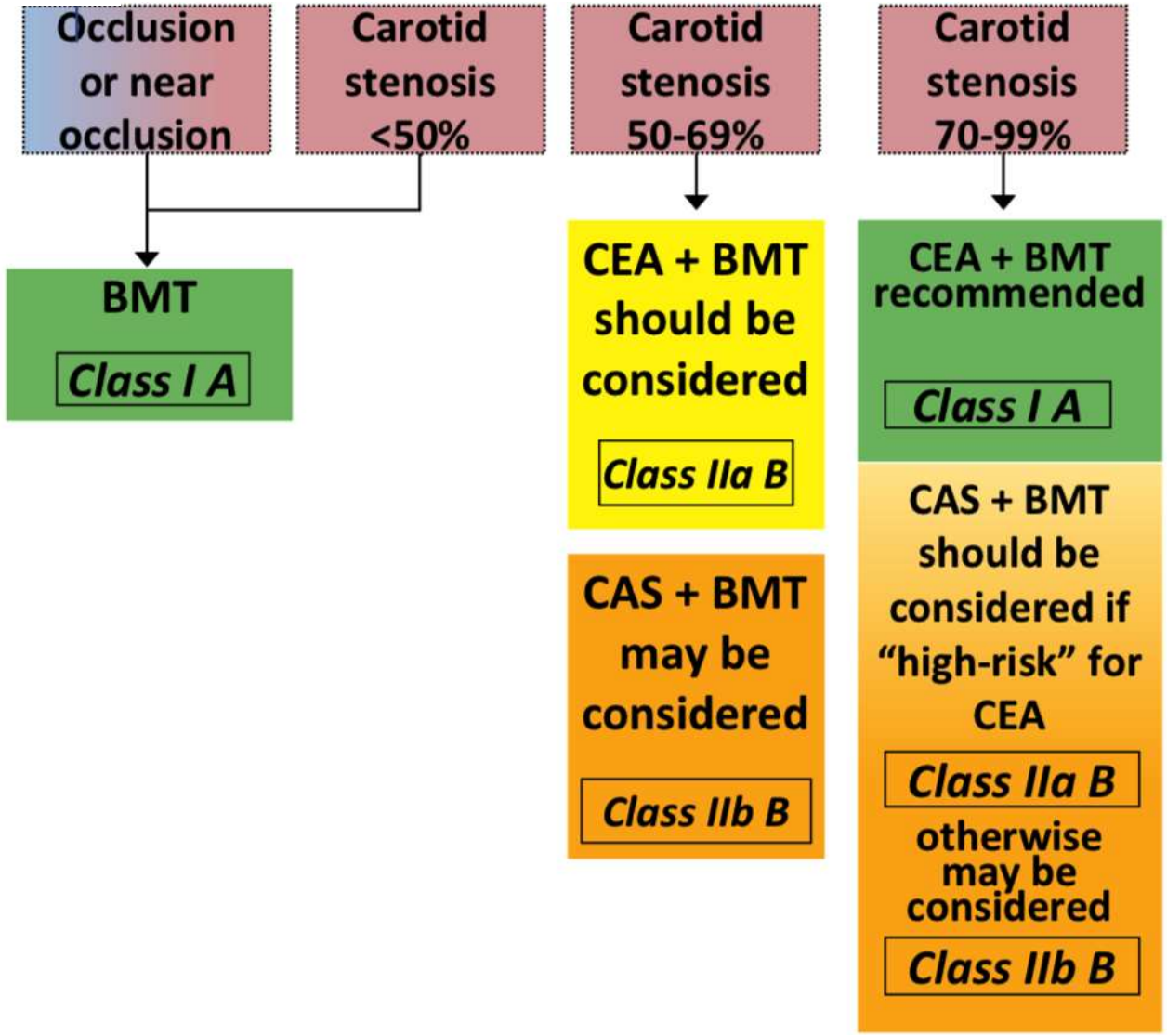
Management of **asymptomatic** carotid stenoses

- Treatment only if
  - degree of stenosis is **60**-99%
  - If there are additional stroke risk factors (clinical, imaging)
  - If risk of treatment in your center is <3%
  - If life expectancy is > 5 yrs
- CAS in hight surgical risk patients
- Surgery in "average surgical risk" patients
  - but surgery may be considered

Management depends upon degree of stenosis
Slightly different thresholds for symptomatic stenoses



Management of symptomatic stenoses



Management of symptomatic stenoses

Recommendations	Class	Level
CEA is recommended in symptomatic patients with **70-99%** carotid stenoses, provided the documented procedural death/stroke rate is <6%.	I	A
CEA should be considered in symptomatic patients with **50-69%** carotid stenoses, provided the documented procedural death/stroke rate is <6%.	IIa	A
In recently symptomatic patients with a **50–99%** stenosis who present with adverse anatomical features or medical comorbidities that are considered to make them "high-risk for CEA", **CAS** should be considered, provided the documented procedural death/stroke rate is <6%.	IIa	B

Management of symptomatic stenoses

Recommendations	Class	Level
When revascularization is indicated in “average surgical risk” patients with symptomatic carotid disease, CAS may be considered as an alternative to surgery, provided the documented procedural death/ stroke rate is <6%.	IIb	B
When decided, it is recommended to perform revascularization of symptomatic 50–99% carotid stenoses as soon as possible, preferably within 14 days of symptom onset.	I	A
Revascularization is not recommended in patients with a <50% carotid stenosis.	III	A

Embolic protection devices

Recommendations	Class	Level
The use of embolic protection devices should be considered in patients undergoing carotid artery stenting.	IIa	C

Carotid stenoses in patients undergoing CABG

Recommendations	Class	Level
In patients undergoing CABG, DUS is recommended in patients with a recent (<6 months) history of TIA/stroke.	I	B
In patients with no recent (< 6 months) history of TIA/stroke, DUS may be considered in t years, multivessel coronary LEAD, or carotid bruit.		
Screening for carotid stenos requiring urgent CABG with		

Recommendations	Class	Level
It is recommended that the indication (and if so the method and timing) for carotid revascularization be individualized after discussion within a multidisciplinary team, including a neurologist.	I	C
In patients scheduled for CABG, **with recent (<6 months) history of TIA/stroke**:		
• Carotid revascularization should be considered in patients with 50–99% carotid stenosis,	..	
• Carotid revascularization with CEA should be considere choice in patients with 50–99% carotid stenosis,		
• Carotid revascularization is not recommended in patier carotid stenosis <50%.		

Recommendations	Class	Level
In neurologically **asymptomatic** patients scheduled for CABG:		
• Routine prophylactic carotid revascularization in patients with a 70-99% carotid stenosis is not recommended.	III	B
• Carotid revascularization may be considered in patients with bilateral 70-99% carotid stenoses or 70-99% carotid stenosis + contralateral occlusion.	IIb	B
• Carotid revascularization may be considered in patients with a 70–99% carotid stenosis, in the presence of one or more characteristics that may be associated with an increased risk of ipsilateral stroke, in order to reduce stroke risk beyond the perioperative period.	IIb	C

Carotid stenoses in patients undergoing CABG

- Perform CEA or CAS if indicated anyway
- There is only one special indication:
  - CEA or CAS may be considered in asymptomatic bilateral high grade stenosis 70-99% or unilateral + contralateral occlusion (IIB, level B)
- Routine CEA or CAS should not be performed

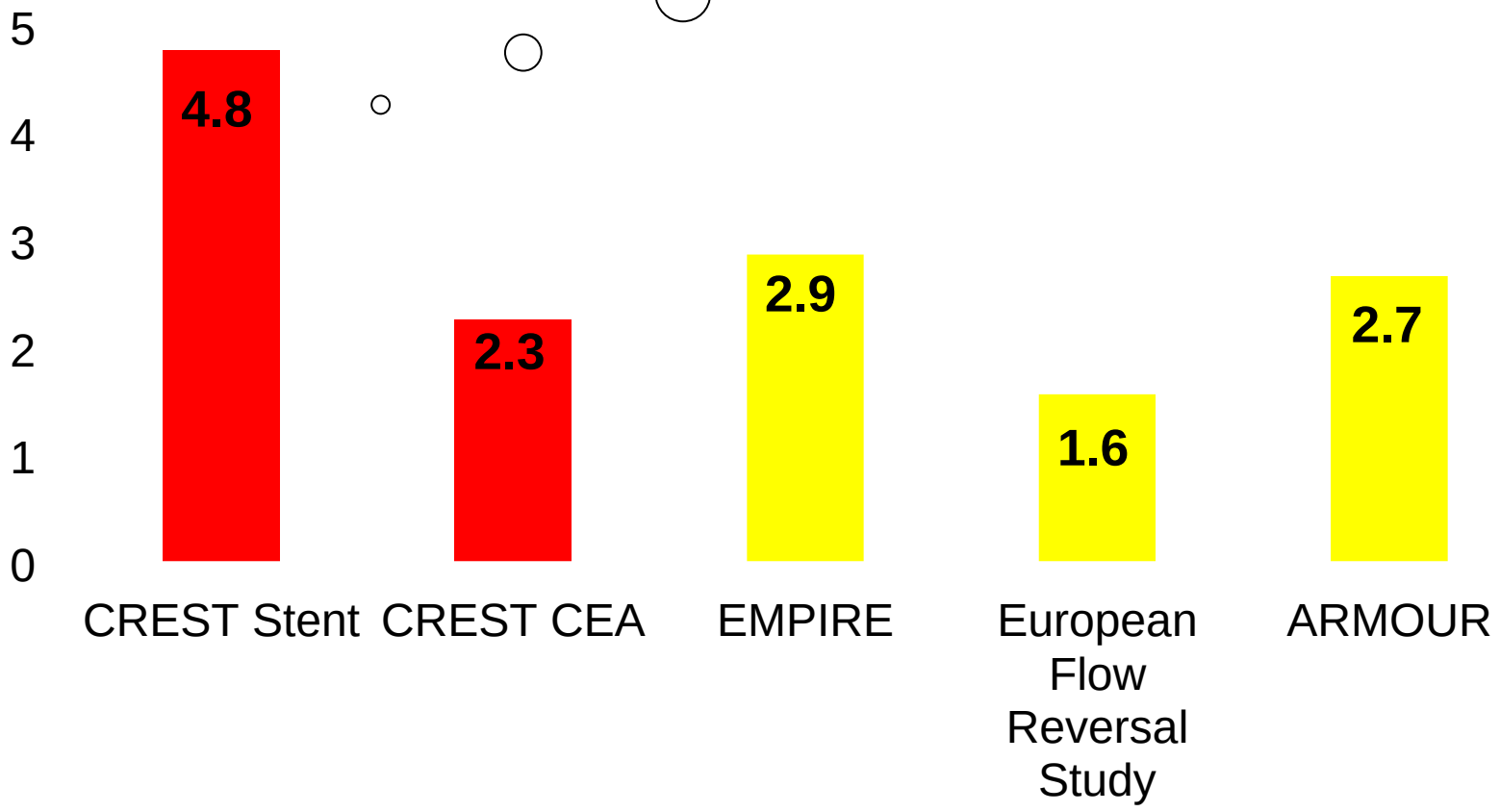
As always ….

… guidelines are outdated
at the time when they are
published

We now have several prospective controlled clinical trials with proximal protection and a 30 day stroke rate < 3%

CREST vs newer tri
30 day

Imagine CREST with proximal protection!



Accunet Filter Gore Flow Reversal MOMA

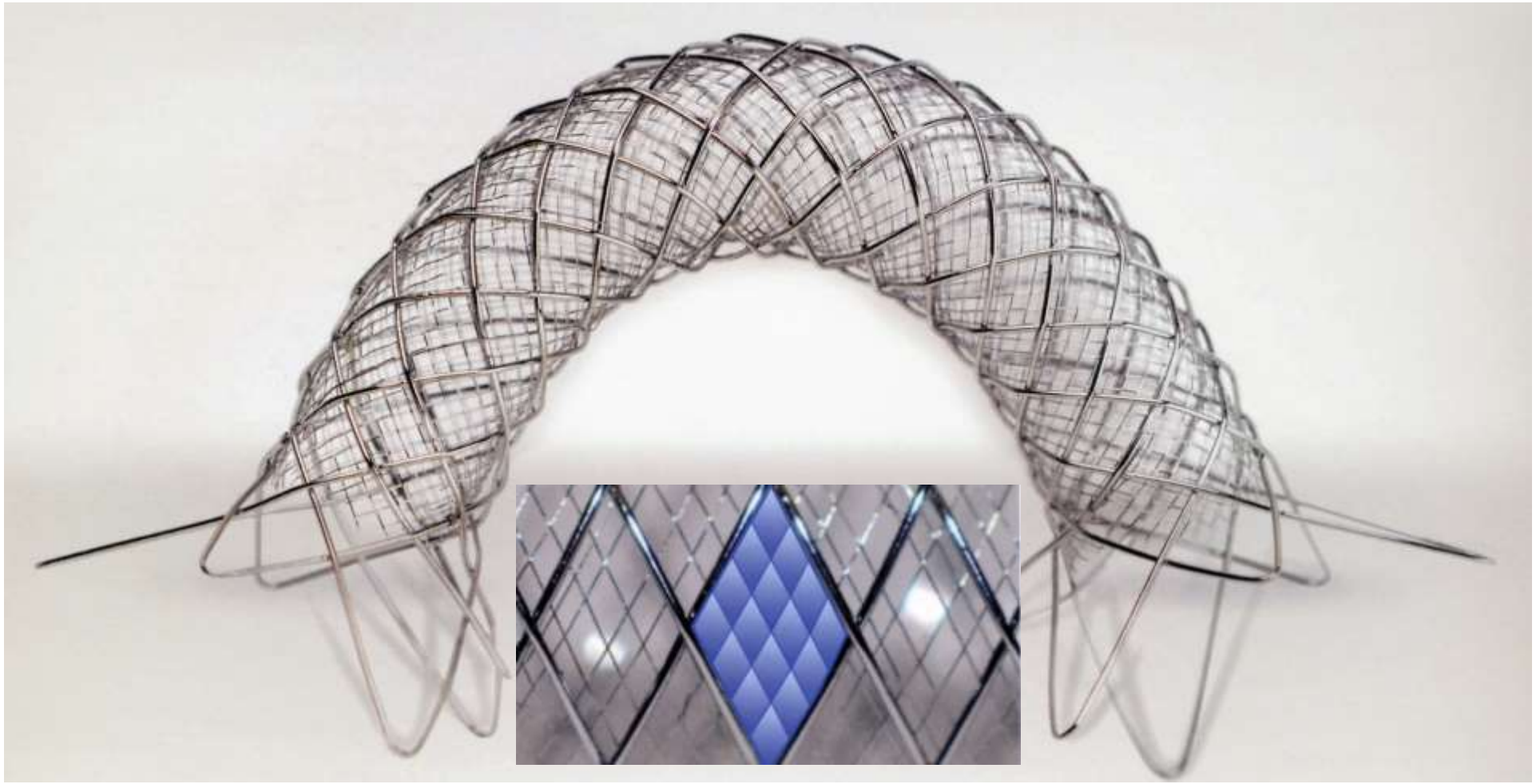
CVC Frankfurt:
Stroke rate is even lower if you use proximal protection in **all** patients and not only in "high risk"

	@ **discharge**	@ **30 day FU**
Death	0	0
Stroke	0	1 (0.8%)
TIA	0	0
Myocardial infarction	0	0

N = 124

Hornung M et al, EuroIntervention 2014

Micro-mesh Stents

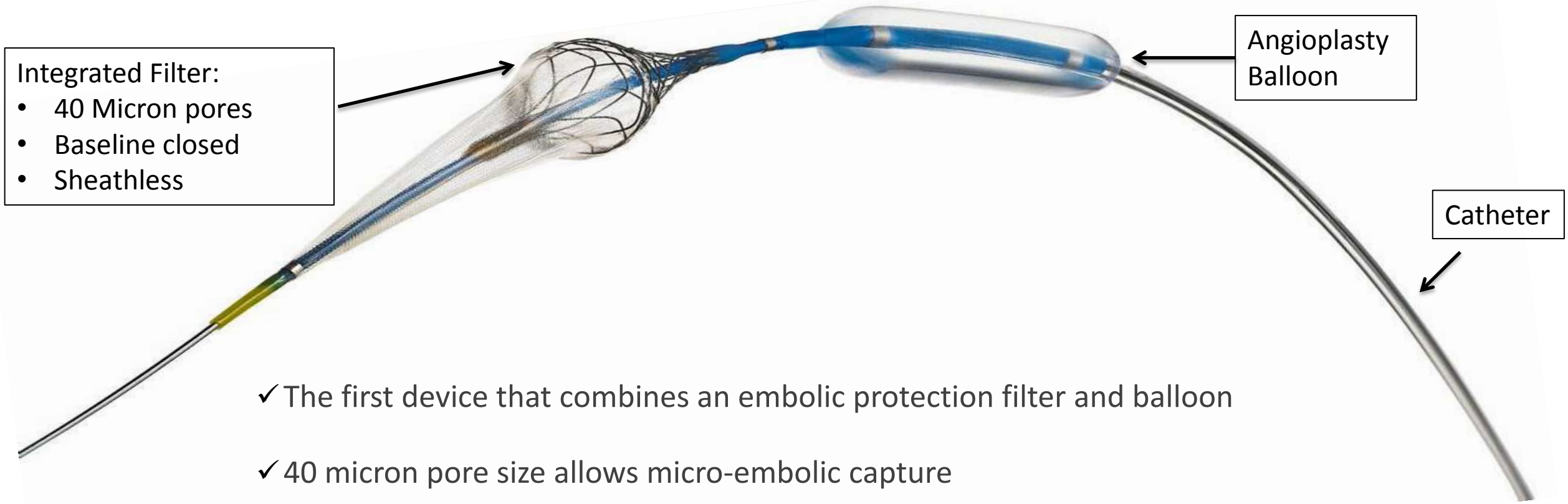


CARENET trial (CGuardTM)

	Post Procedure	Discharge	30 days
Device success	100%	NA	NA
MACE	0%	0%	0%
Death	0%	0%	0%
MI	0%	0%	0%
Stroke	0%	0%	0%

SCHOFER J, MUSIALEK P, KOLVENBACH R, SIEVERT H: TCT 2014

Integrated Embolic Protection (IEP)™ for post-dilatation



✓The first device that combines an embolic protection filter and balloon

✓40 micron pore size allows micro-embolic capture

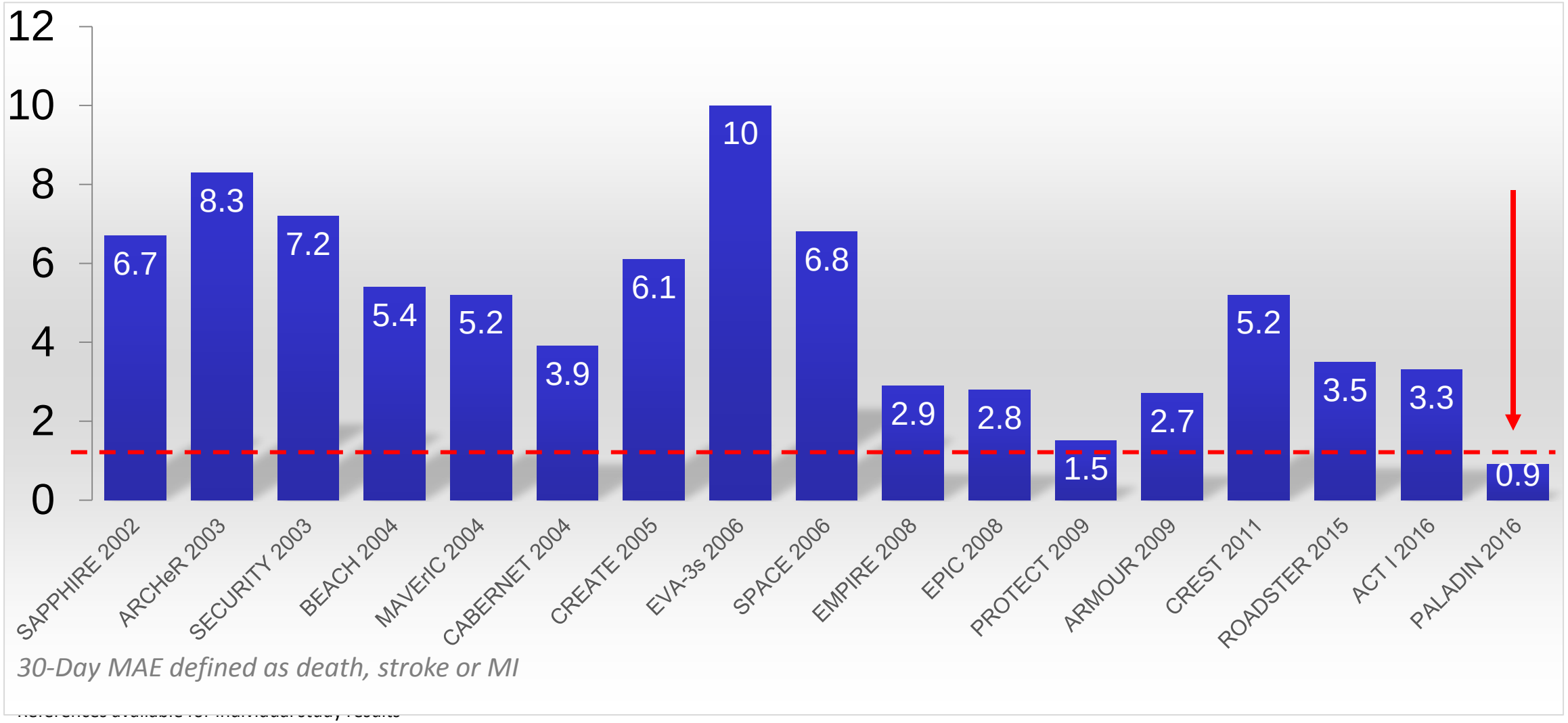
✓Filter size can be adjusted to suit each patient's unique anatomy

PALADIN Registry	
Post-Procedural and 30-Day Outcomes	% (N/105[1])
Stroke, Death and MI	**0.95 % (1)**
Death	0
Stroke	0.95 % (1)
Myocardial Infarction	0
Stroke and Death	0.95 % (1)

- 106 patients
- Technical success 99%
- No Deaths, strokes, MI or other Major Adverse Events (MAE) through discharge
- **1 stroke at day 12 due to stent thrombosis of a mesh-covered stent**

[1] Of the 106 subjects enrolled, one (1) subject withdrew consent following discharge, and 105 were eligible for follow up at 30 days.
This patient had no neurological events

Using PALADIN, clinical outcome was superior compared to almost all other carotid stenting studies

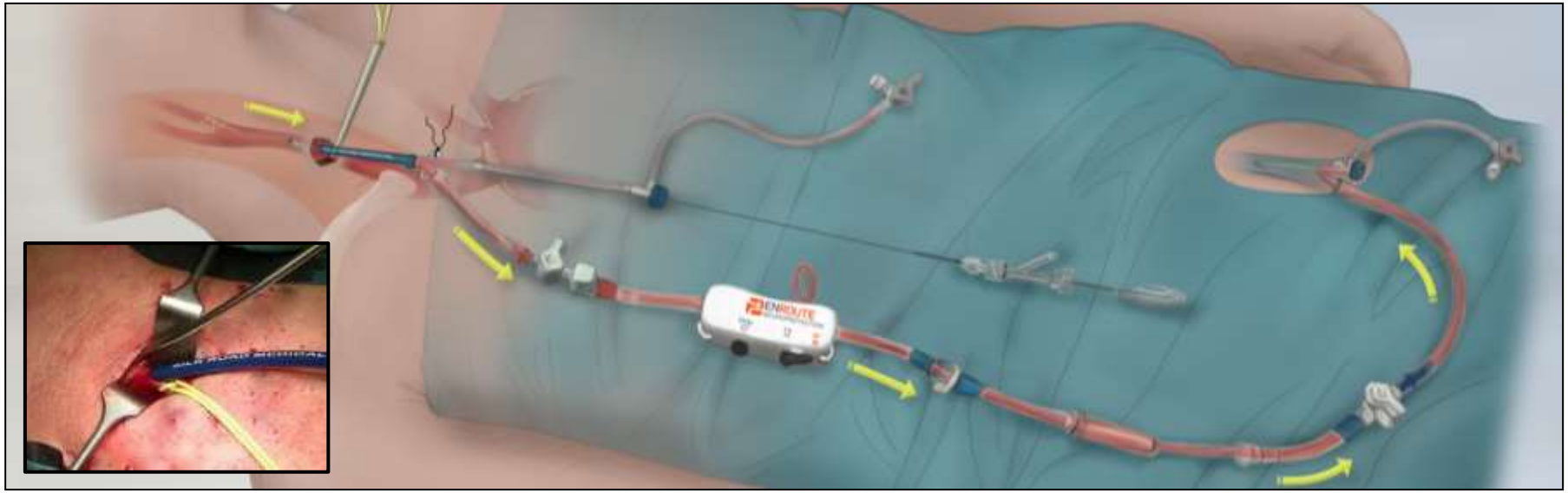


Prospective multi-center studies with >100 patients

Transcervical Carotid Artery Revascularization

TCAR

- 1-2cm Incision
- Local anesthesia
- Flow reversal circuit: carotid artery to femoral vein



Transcervical Carotid Artery Revascularization

TCAR

ROADSTER Trial 12-month Outcomes

High Surgical Risk	Pivotal Group, ITT (n=141)		Pivotal Group, PP (n=136)	
S/D/MI*	5	3.5%	4	2.9%
Major Stroke	0	0%	0	0%
Minor Stroke	2	1.4%	1	0.7%
Death	2	1.4%	2	1.5%
MI	1	0.7%	1	0.7%
Stroke & Death	4	2.8%	3	2.2%
Cranial Nerve Injury (CNI)	1	0.7%	1	0.7%
CNI Unresolved at 6 Mos	0	0%	0	0%

Summary

- According to the recent ESC guidelines, asymptomatic carotid stenoses should be treated by CEA or CAS only if there are defined additional clinical or morphologic risk factors for stroke
- Symptomatic stenoses > 50% should be treated as early as possible
  - CAS should be considered in high surgical risk patients
  - CEA should be considered in patients without high surgical risk but CAS can be considered
- More recent CAS technologies like **proximal occlusion**, **flow reversal**, **double filtration** and **mesh-stents** with stroke rates < 1% are used now as a routine in many centers
  - But these have not been included in the 2017 guidelines
- The debate goes on

They have no idea …

… what we are talking about

Thank you!

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