

Are Protection Devices Really Harmful? Does the Type of Protection Device Matter?

Issam D. Moussa, MD

**Professor of Medicine
Chair, Division of Cardiovascular Diseases
Mayo Clinic
Jacksonville, Florida**

Disclosure Statement of Financial Interest

- I, (Issam Moussa) DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation

Discussion Plan

- **Are protection devices harmful?**
 - How is harm defined?
 - Are protection devices harmful compared to no protection?

- **Does the type of device matter?**

Distal vs. proximal protection

Are Protection Devices Harmful?

How is harm defined after CAS?

- **Micro embolic signals (MES) (TCD)!**
- **New asymptomatic defects on MRI imaging**
- **Neurologic ischemic events**

Are Protection Devices Harmful?

Protection vs. No Protection

- There are no RCTs comparing both techniques
 - Most physicians feel its unethical to do such trials
- Relevant Data is derived from:
 - Indirect comparisons of protected vs. unprotected CAS arms of the RCTs of CAS vs. CEA.
 - Post hoc analysis of protected vs. unprotected cohorts within the CAS arms of the RCTs of CAS vs. CEA.

Comparison of Protected vs. Unprotected CAS Arms of CAS vs.CEA RCTs Symptomatic Patients

	CAVATAS CAS	SPACE CAS	ICSS CAS	EVA3S CAS	CREST (Symp) CAS
PROTECTION	0%	29%	72%	92%	96%
Death	3%	0.67%	2.3%	0.8%	1%
Disabling Stroke	4%	4.01%	1.7%	2.7%	1%
Non Disabling Stroke	4%	3.5%	6%	6.1%	4%
Death or Disabling Stroke	6%	4.67%	4%	3.4%	2%
Death or Any Stroke	10%	7.68%	8.5%	9.6%	6%

The CAVATAS Investigators. Lancet 2001; 357: 1729-37; Mas JL et al. N Engl J Med 2006;355:1660-71; ICSS investigators. Lancet 2010; 375: 985-97; The SPACE Collaborative Group. Lancet. 2006;368:1239-1247.; Silver FL, et al. CREST. Stroke. 2011;

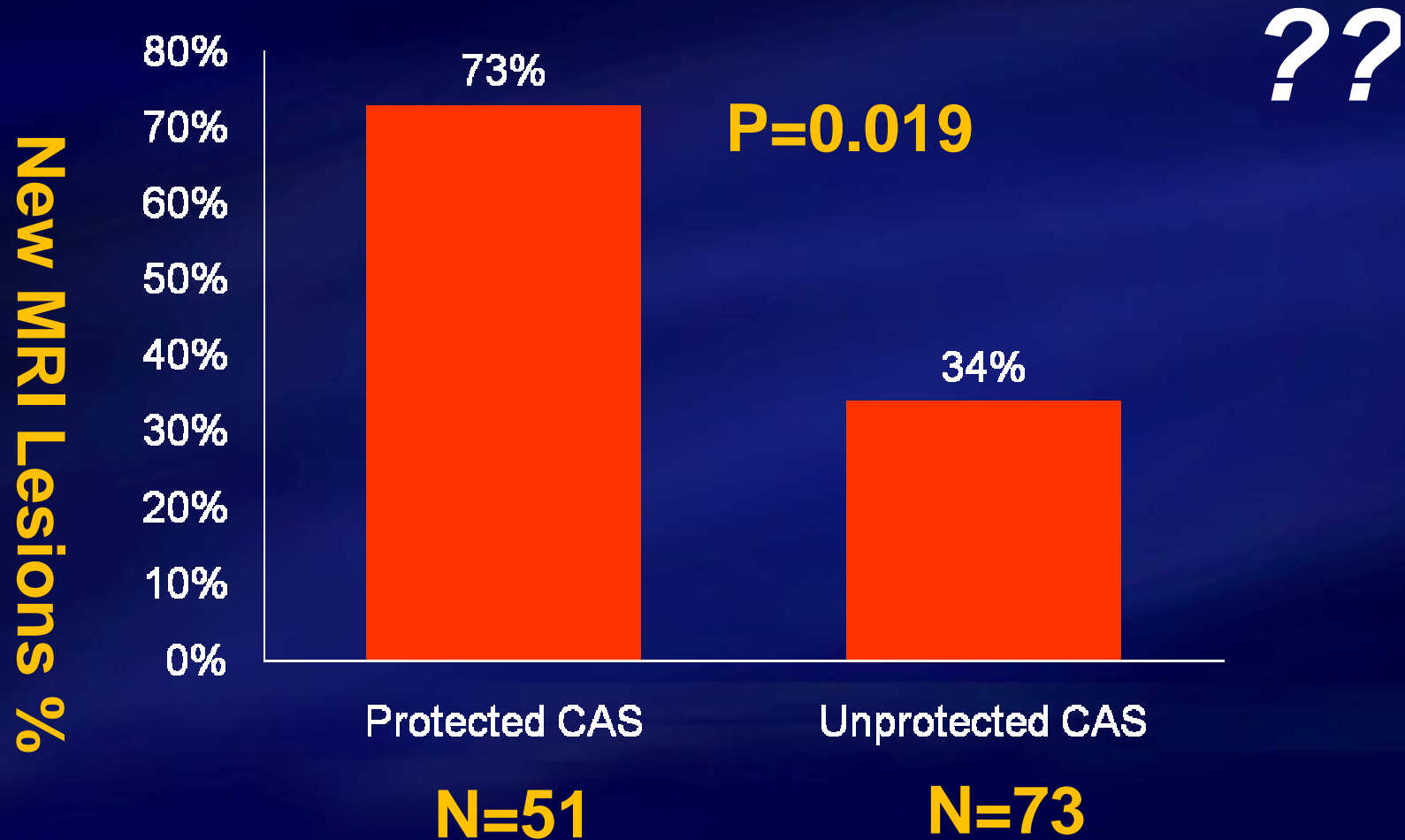
Comparison of protected vs. unprotected cohorts within the CAS arms of the RCTs of CAS vs. CEA.

Symptomatic Patients

	SPACE CAS		ICSS CAS		EVA3S CAS	
	Protected 27%	Unprotected 73%	Protected 72%	Unprotected 28%	Protected 92%	Unprotected 8%
Death or Any Stroke	7%	7%	NA	NA	7.9%	25%

Protected vs. Unprotected CAS (Sub analysis of the ICSS)

Impact on New Brain Defects (DW-MRI)



Predictors of Silent Brain ischemic Lesions after Protected CAS

- Age
- Symptom status
- Stenosis severity
- Contralateral carotid occlusion
- Co morbidities

Discussion Plan

- **Are protection devices harmful?**

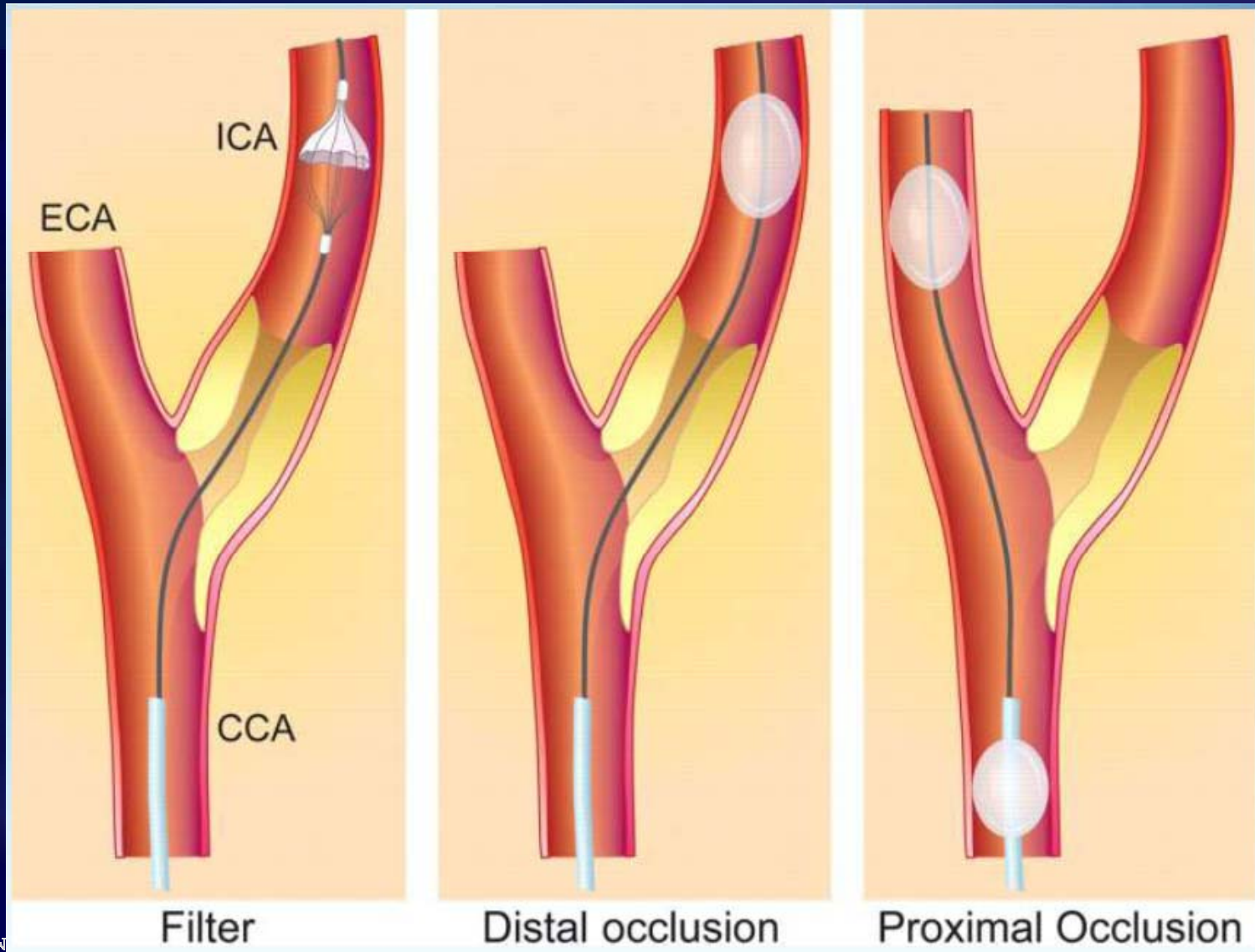
How is harm defined?

Are protection devices harmful compared to no protection?

- **Does the type of device matter?**

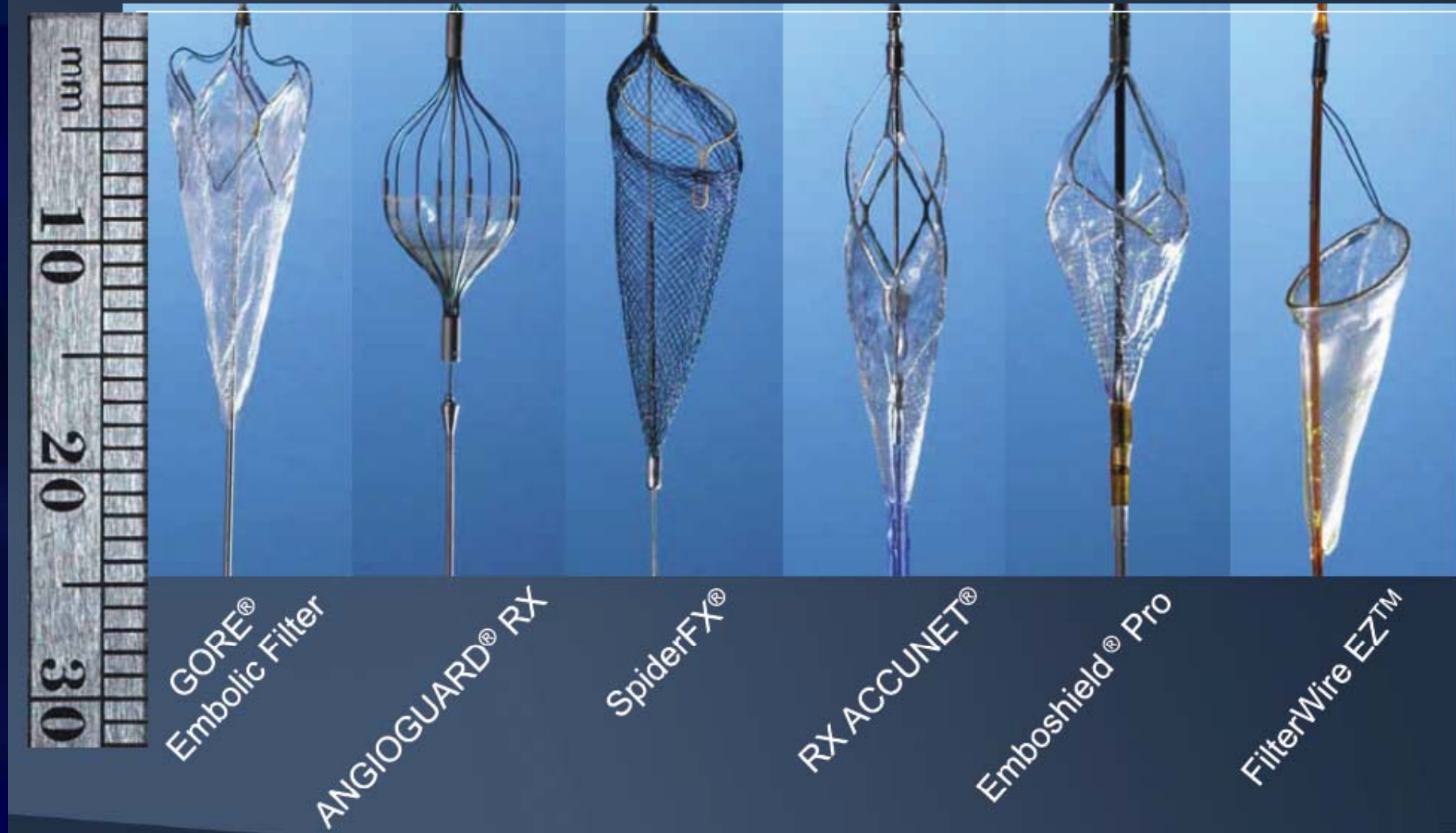
Distal vs. proximal protection

Embololic Protection Devices



Distal Filters

Landing Zone



Distal Filters

Tip Transition



GORE®
Embolic Filter

ANGIOGUARD® RX

SpiderFX®

RX ACCUNET®

Emboshield® Pro

FilterWire EZ™

Distal Filters

Pore Size / Pattern

100um

100um

50-300um

120um

140um

110um



GORE®
Embolic Filter

ANGIOGUARD® RX

SpiderFX®

RX ACCUNET®

Emboshield® Pro

FilterWire EZ™

Proximal Protection Devices

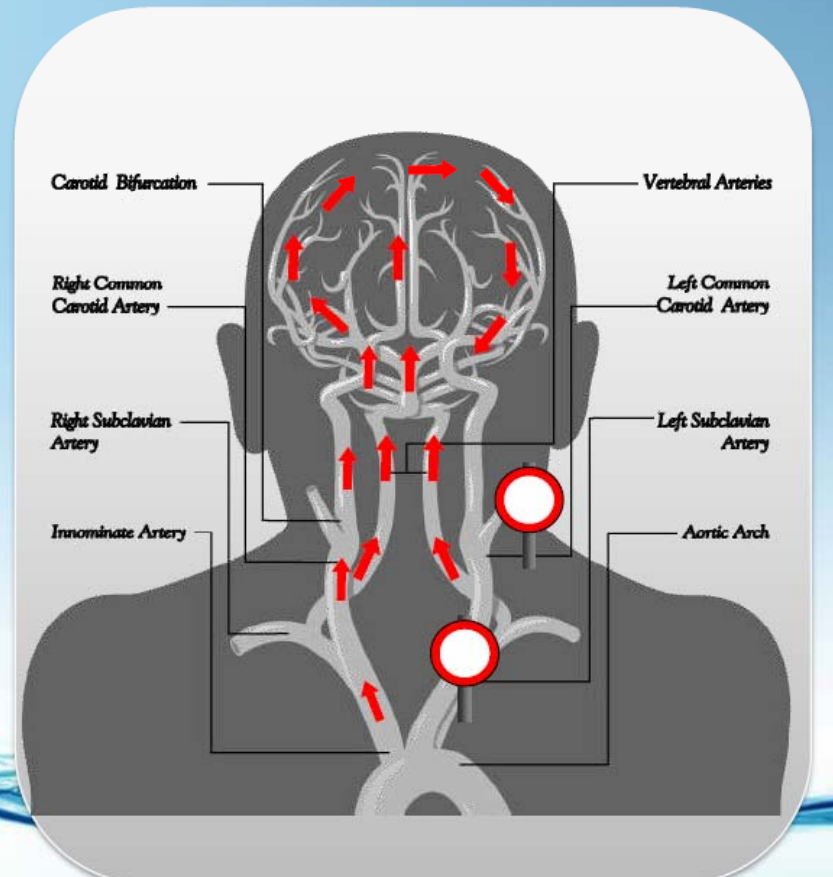
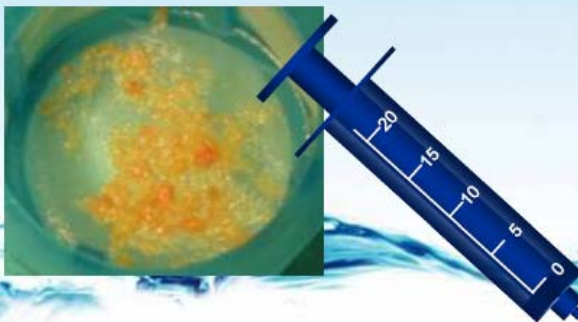
MO.MA

Proximal Flow Blockage Cerebral Protection Device

MO.MA

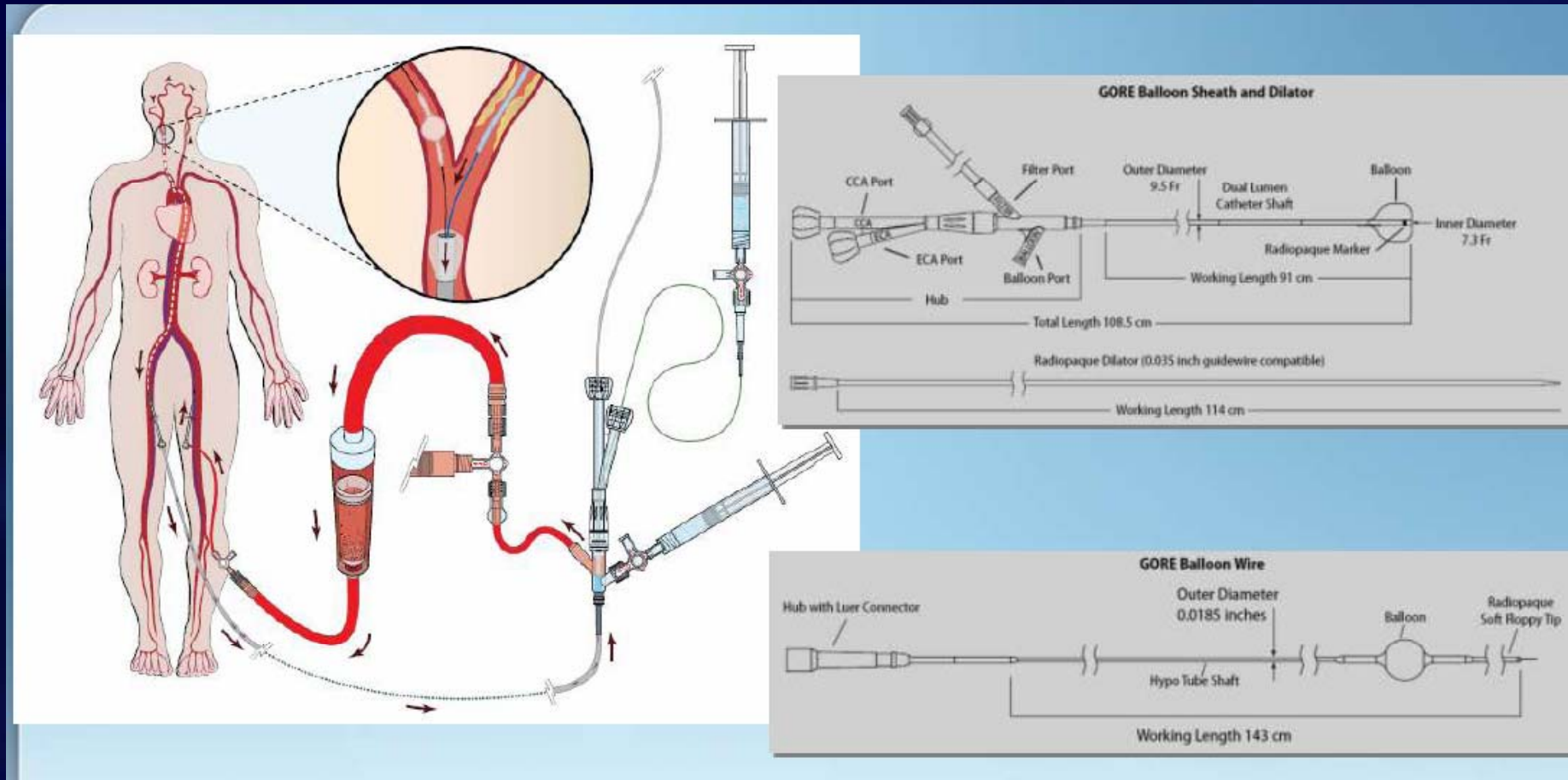
- CCA clamping: blockage of antegrade blood flow
- ECA clamping: blockage of retrograde blood flow

Debris removal: syringe blood aspiration



Proximal Protection Devices

Gore Flow Reversal



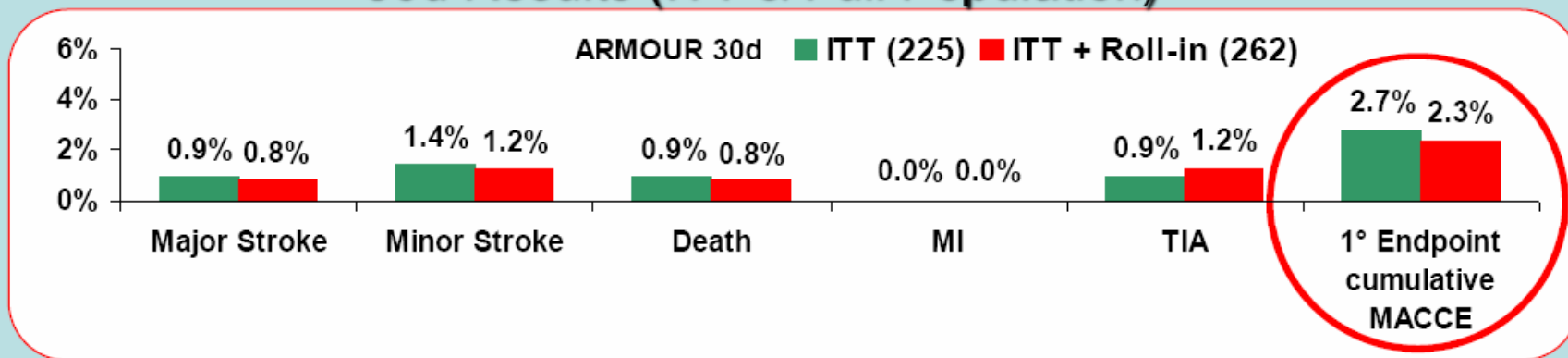
CAS with Proximal Protection (MO.MA)

The ARMOUR Registry

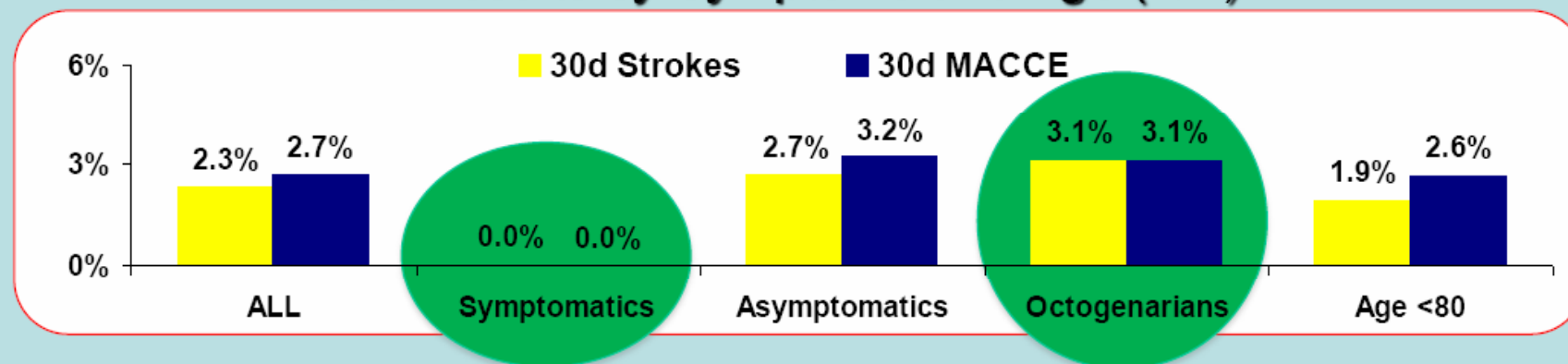
1° Endpoint...High Risk Pts

ARMOUR

30d Results (ITT & Full Population)



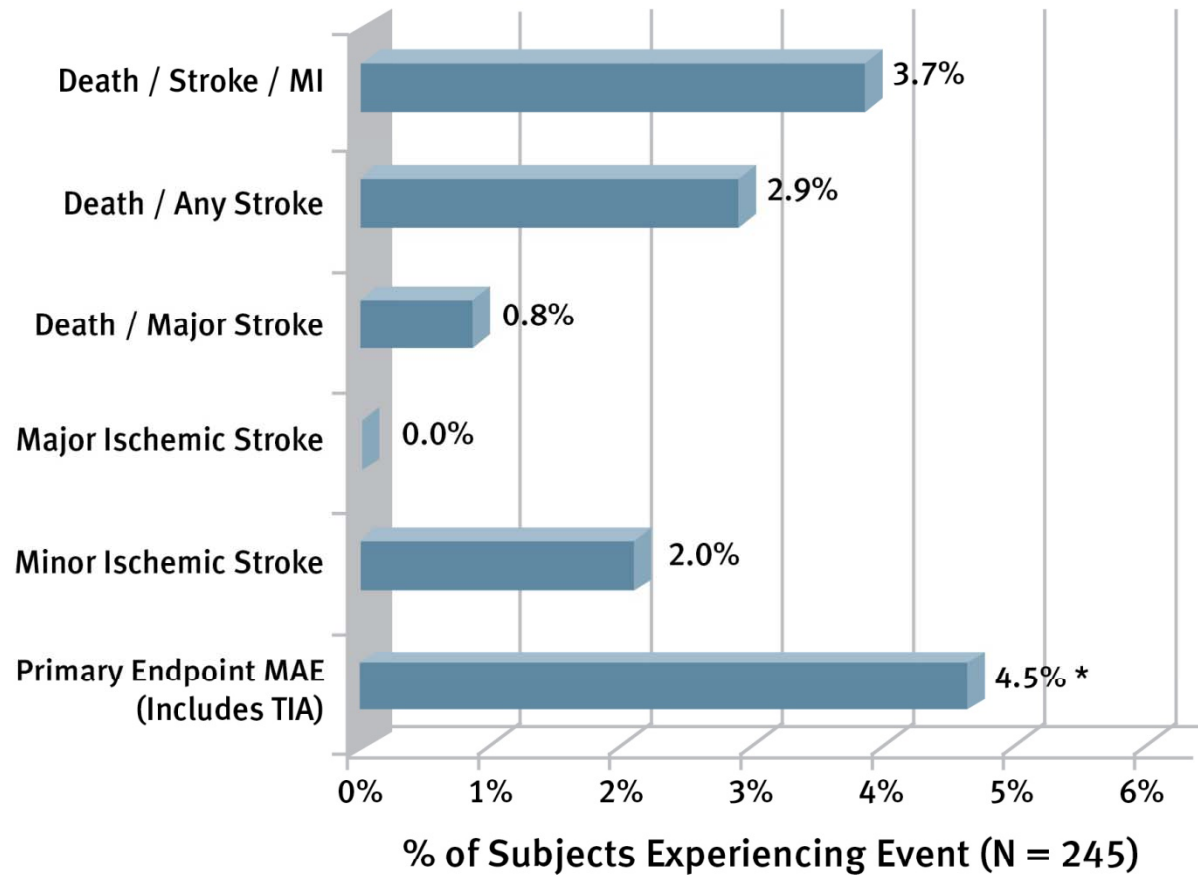
30d Results by Symptoms and Age (ITT)



CAS with Proximal Protection (Gore Flow Reversal)

The EMPiRE Registry

MAJOR ADVERSE EVENTS



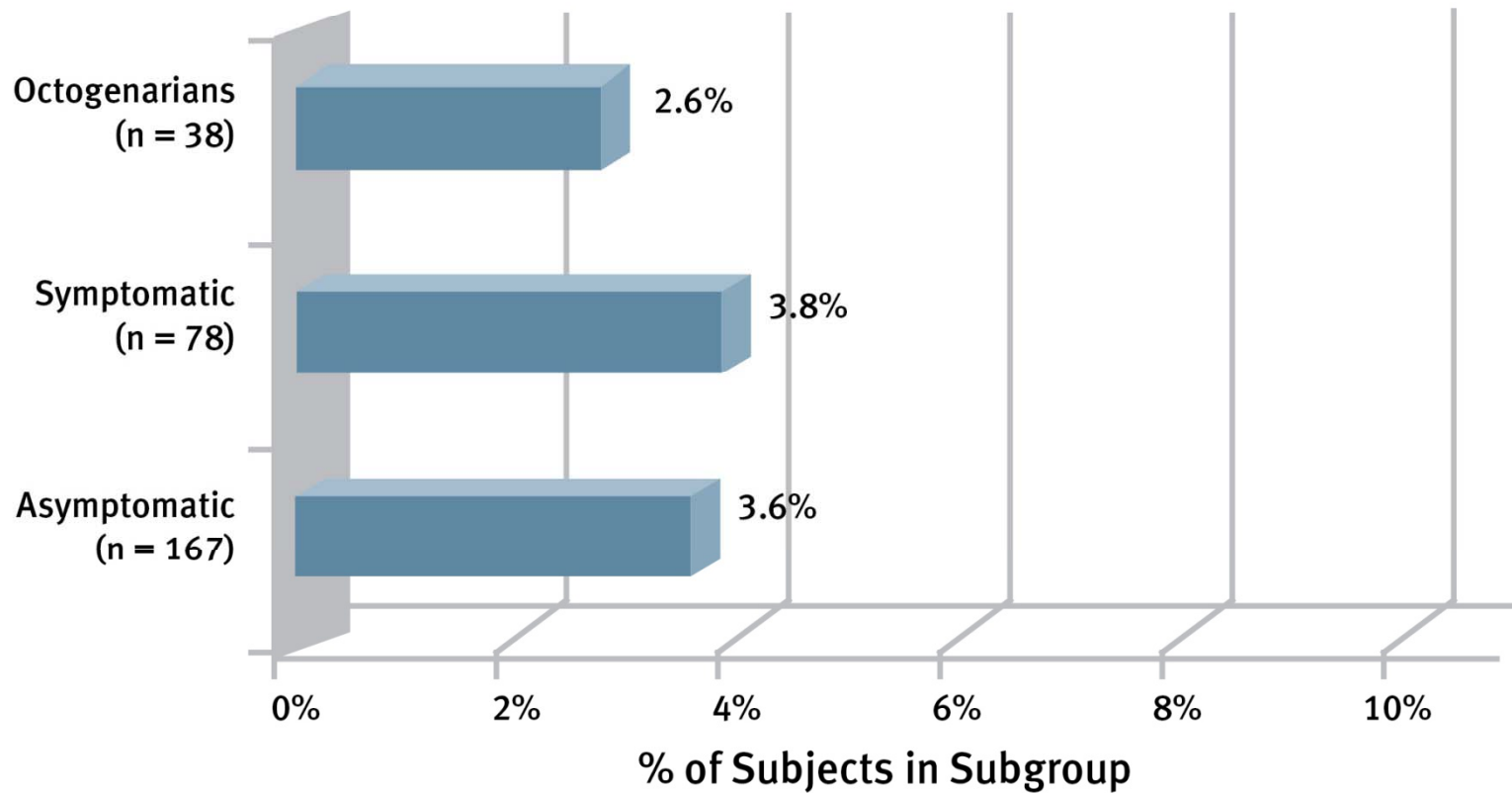
* < OPC of 11.83% (p = 0.002)



CAS with Proximal Protection (Gore Flow Reversal)

The EMPiRE Registry

STROKE, DEATH, MI RATES BY SUBGROUP



A RCT of Proximal vs. Distal Protection on Microembolization During CAS in Patients with High Risk Lipid Plaques

Patients with $\geq 75\%$ (Asx) or $\geq 50\%$ (Sx in the previous 6 months) carotid stenosis by Doppler US

Lipid plaque composition by CT-angiography (Hounsfield unit < 50 , average of 3 measurements) and TCD suitability

DW-MRI sub study:
pre, post, 30 days

Randomization

CAS with FilterWire EZ
N=27

CAS with MO.MA System
N=26

Primary End Point
Number of MES during CAS

Proximal vs. Distal Protection Devices During CAS

Patients with MES

	FilterWire EZ N=27	MO.MA N=26	P value
Lesion Wiring	96%	73%	ns
Pre-dilation	86%	40%	ns
Stent crossing of the lesion	100%	27%	0.000
Stent deployment	100%	27%	0.000
Stent post-dilation	96%	27%	0.000
Device retrieval	81%	96%	ns

Proximal vs. Distal Protection Devices During CAS

Frequency of MES

	FilterWire EZ N=27	MO.MA N=26	P value
Lesion Wiring	18 [11-30]	2 [0-4]	<.0001
Pre-dilation	7 [6-12]	0 [0-1]	ns
Stent crossing of the lesion	23 [11-34]	0 [0-1]	<.0001
Stent deployment	30 [9-35]	0 [0-1]	<.0001
Stent post-dilation	16 [8-30]	0 [0-1]	<.0001
Device retrieval	2 [1-6]	8.5 [3-17]	<.0001
Mean MES / Patient	18 [10-27]	3 [1-7]	<.0001
Total MES	93 [59-136]	16 [7-36]	<.0001

Proximal vs. Distal Protection Devices During CAS In Hospital and 30-Day Complications

	FilterWire EZ N=27	MO.MA N=26	P value
Procedural Success %	100	100	ns
Clinical Success %	96.3	96.1	ns
Death %	0	3.8*	ns
Major Stroke %	0	0	ns
Minor Stroke / Retinal Embolism %	3.7	0	ns
TIA %	3.7	0	ns
Myocardial Infarction %	0	0	ns

Proximal vs. Distal Protection Devices During CAS

Impact on Frequency of Brain Lesions by DW-MRI

	FilterWire EZ N=21	MO.MA N=14	P value
MRI lesions	9 (42.8%)	2 (14.2%)	0.14

MRI lesions were silent in all but one case (in the FilterWire group)

Summary

- **The concept that embolic protection devices during CAS can be harmful is flawed and is based on misinterpretation of the data**
- **In experienced hands, embolic protection devices are likely to reduce major strokes**
- **The available evidence indicate that proximal protection devices are more protective than distal filters, particularly in symptomatic patients**



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