Is Carotid Stent Design Important ?

" Current Stent Design Is Inadequate & Contributes To Procedure - Related Stroke "

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TCT 2010

Conflicts:

Research / Educational Grants & / or consultancy:

Abbott Vascular

AGA medical

CR Bard

eV3

Le Maitre

Medtronic / Invatec

Pyramed

WL Gore

LIKE YOUR FAMOUS EX-PRESIDENT (ANOTHER BILL) SAID: "I DID NOT HAVE SEXUAL RELATIONS WITH THAT WOMAN"

LET'S EXAMINE THE DEFINITION OF THE WORDS IN THE MOTION

"Procedure-Related Stroke"

Standardized Definitions and Clinical Endpoints in Carotid Artery and Supra-Aortic Trunk Revascularization Trials

Krassen Nedeltchev,[1*] MD, Peter M. Pattynama,[2] MD, Giancarlo Biaminoo,[3] MD, PhD, Nicolas Diehm,[4] MD, Michael R. Jaff,[5] DO, L. Nelson Hopkins,[6] MD, Stephen Ramee,[7] MD, Marc van Sambeek,[8] MD, Aly Talen,[9] RN, Frank Vermassen,[10] MD, PhD, and Alberto Cremonesi,[3] MD

Complications. All major adverse events and vascular complications that occur within 30 days of the procedure are attributed to the procedure.

Catheterization and Cardiovascular Interventions 2010
Published on behalf of SCAI

What is the most relevant population to consider ?

Asymptomatic Patients Pooled Data ACAS & ACST

Absolute Reduction in Risk of Stroke

3 % over 3 years

Need to perform 33 interventions to prevent 1 stroke

No statistical benefit until three years after intervention

NASCET & ECST: Symptomatic Populations

Long-term risk of ipsilateral stroke (includes peri-operative stroke / death)

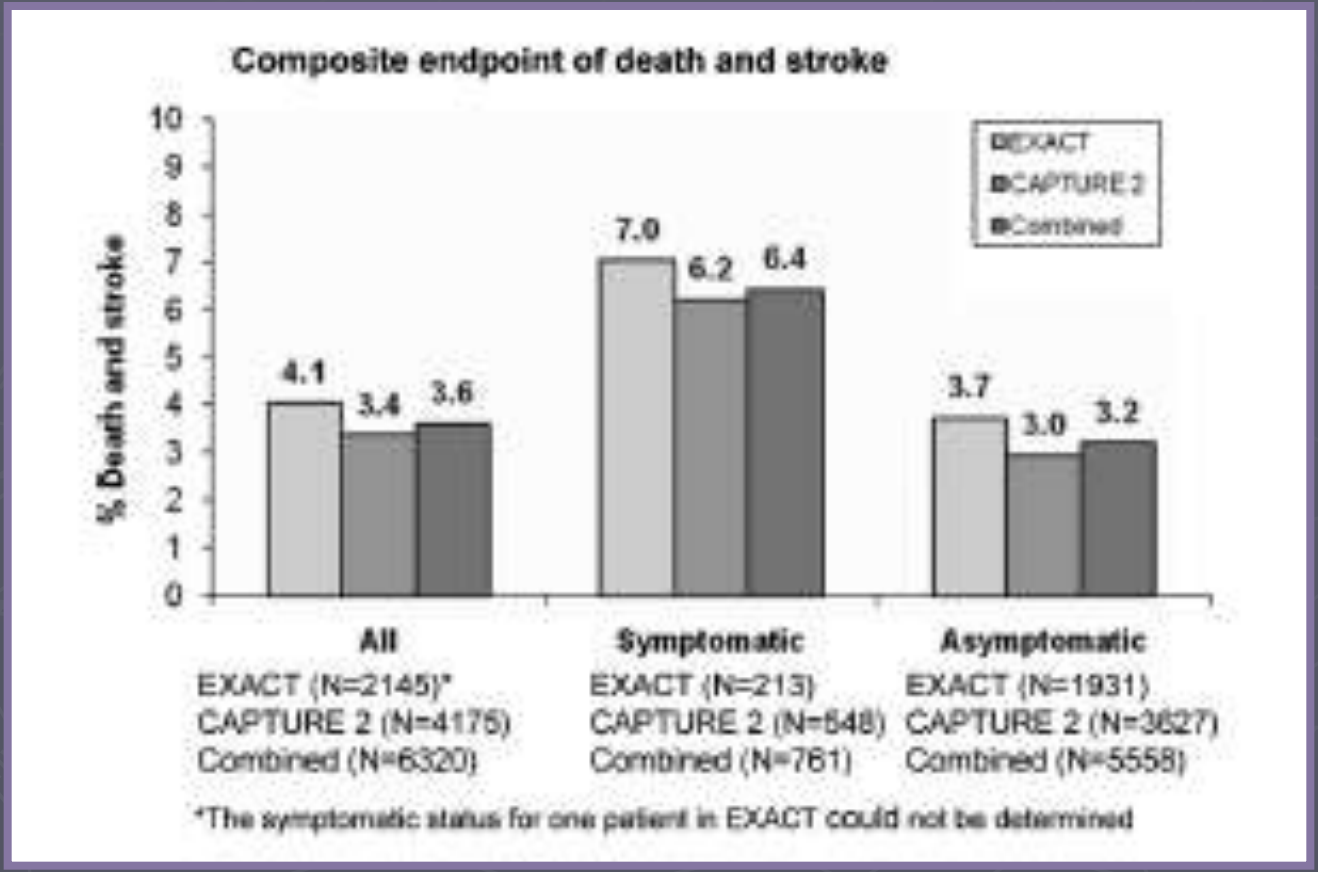
Table 1. Long term risk of ipsilateral stroke *(including peri-operative stroke or death).*

Stenosis (%)	Surgical risk (%)	Medical risk (%)	ARR (%)	RRR (%)	NNT	Strokes prevented per 1000 CEAs
ECST						
< 30	9.8 at 5 years	3.9 at 5 years	−5.9	n/a	n/a	n/a
30–49	10.2 at 5 years	8.2 at 5 years	−2.0	n/a	n/a	n/a
50–69	15.0 at 5 years	12.1 at 5 years	−2.9	n/a	n/a	n/a
70–99	10.5 at 5 years	19.0 at 5 years	8.5	45	12	83 at 5 years
NASCET						
30–49	14.9 at 5 years	18.7 at 5 years	3.8	20	26	38 at 5 years
50–69	15.7 at 3 years	22.2 at 3 years	6.5	29	15	67 at 3 years
70–99	8.9 at 3 years	28.3 at 3 years	19.4	69	5	200 at 3 years

ARR = absolute risk reduction, RRR = relative risk reduction, NNT = number of CEAs to prevent one ipsilateral stroke, n/a = not applicable.

30-day Outcomes for CAS in 6320 Patients From 2 Prospective, Multicenter, High Surgical Risk Registries

(EXACT & CAPTURE2)



Gray WA, Circ Cardiovasc Intervent 2009;2:159-166

Symptomatic patients have more to gain from carotid intervention & suffer higher procedural hazard.

What Does The Timing Of Stroke Following CAS Tell Us About The Mechanisms of Stroke ?

SPACE Trial;

Timing Of Adverse Events

Time Point	Navigation	Periinterventional	Postinterventional	HPS
Total stent group (39/563 pat)	4/39	19/39	11/39	4/39
	10%	49%	31%	10%
Stents without protection (27/419 pat)	4/27	12/27	6/27	4/27
	15%	44%	26%	15%
Stents with protection (12/145 pat)	. . .	7/12	5/12	. . .
		58%	42%	

HPS indicates hyperperfusion syndrome.

Jansen O et al. Protection or Nonprotection in Carotid Stent Angioplasty: The Influence of Interventional Techniques on Outcome Data from the SPACE Trial Stroke 2009;40:841-846

SPACE:

Table 1. Interventional Devices (stents; protection devices) Approved for Use Within the SPACE Trial if the Interventionalist Was Certified for the Specific Device

Stent		Protection Device
Closed cell stent	Wallstent (Boston Scientific)	GuardWire (PercuSurge)
Open cell stent	Precise (Cordis)	Epifilter (Boston Scientific)
	Acculink (Guidant)	AngioGuard (Cordis)
		NeuroShield (MedNova)
		Trap NFS (Microvena)

Olav J et al. Protection or Nonprotection in Carotid Stent Angioplasty: The Influence of Interventional Techniques on Outcome Data from the SPACE Trial. Stroke 2009;40:841-846

SPACE:

Table 4. Influence of Different Stent Types on OE Rate

Stent	Wallstent	Acculink	Precise
No. of patients	436	92	35
Pat. with OE	24	9	5
OE rate (95% CI)	5.5% (3.6–8.1%)	9.8% (4.6–17.8%)	14.3% (4.8–30.3%)
			Combined OE rate: 11.0% (6.2–17.8%)

European Registry Data:

" Free Cell Area " & Outcome N =3179

Stent name	Precise
X-act	Protégé
Nexstent	Acculink
Wallstent	Exponent

Table 5. *P*-values for the test that event rates differ between stents

Population	Outcome	*p*-value
Total	All events	0.018
	Post-procedural events	0.002
Symptomatic	All events	0.006
	Post-procedural events	<0.0001
Asymptomatic	All events	0.248
	Post-procedural events	0.790

" Post - procedural ": between removal of all endovascular devices & 30 days

Bosiers M e al. Does Free Cell Area Influence the Outcome in Carotid Artery Stenting ? EJVES 2007;33:135 - 141

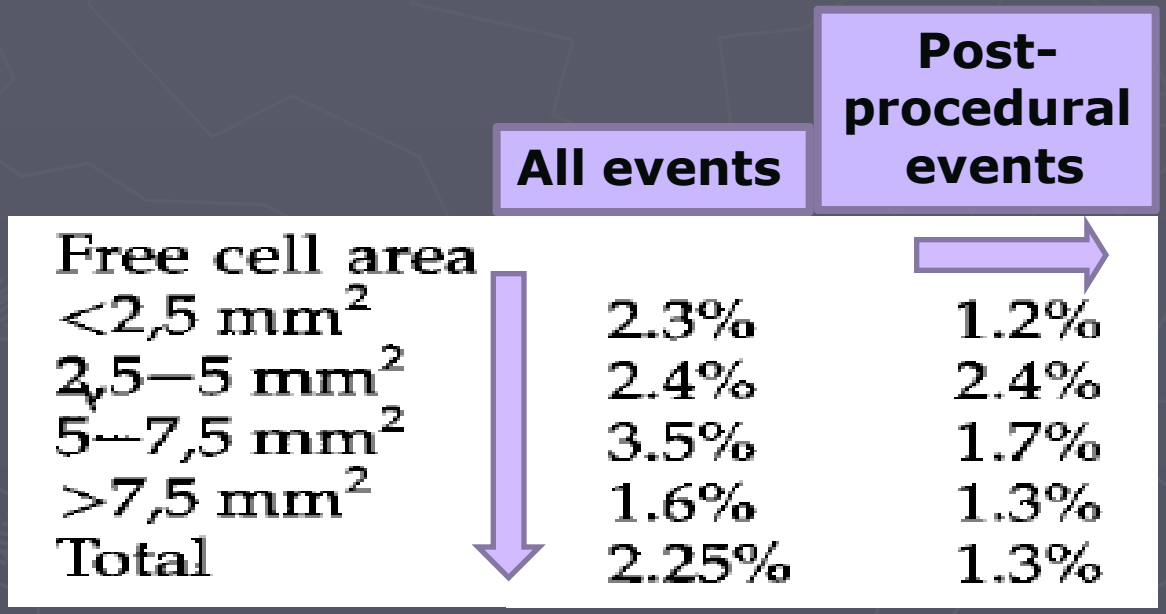
" Free Cell Area " & Outcome

Symptomatics: N = 1317

Free cell area		All events	Post-procedural events
$<2{,}5\ mm^2$		2.3%	1.2%
$2{,}5–5\ mm^2$		1.9%	1.9%
$5–7{,}5\ mm^2$		6.5%	5.2%
$>7{,}5\ mm^2$		7.5%	7.0%
Total	1317	3.6%	2.73%

" Free Cell Area " & Outcome

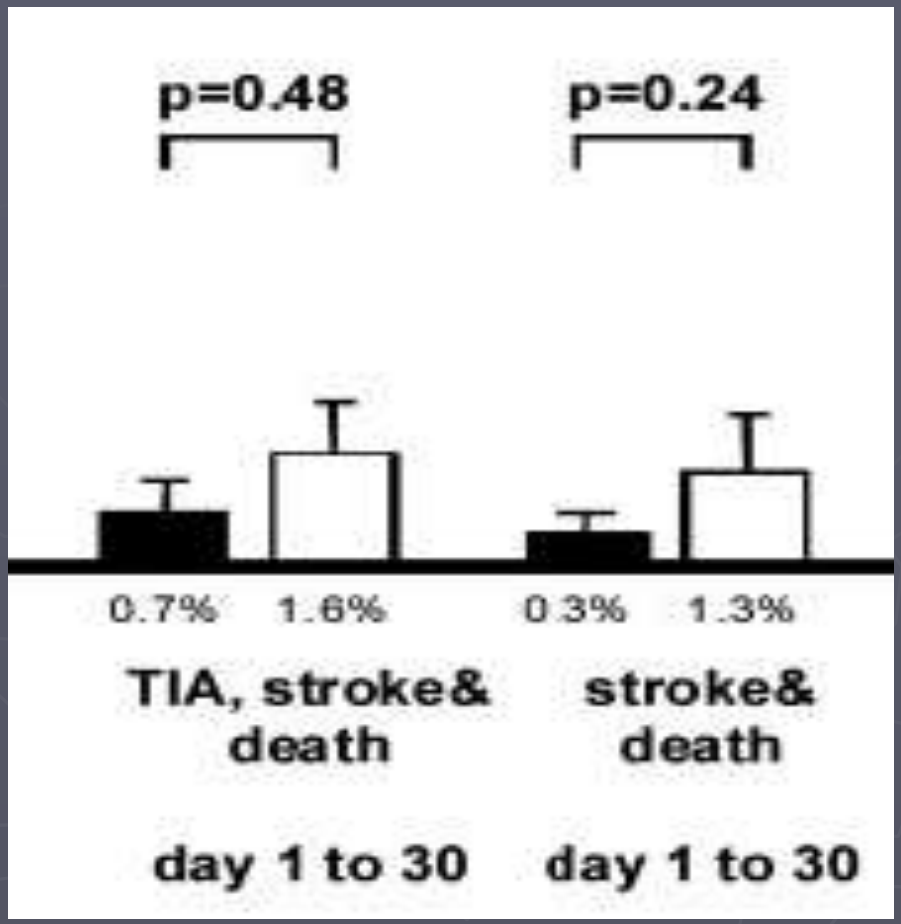
Asymptomatics: N = 1862



Free cell area	All events	Post-procedural events
$<2{,}5\ mm^2$	2.3%	1.2%
$2{,}5–5\ mm^2$	2.4%	2.4%
$5–7{,}5\ mm^2$	3.5%	1.7%
$>7{,}5\ mm^2$	1.6%	1.3%
Total	2.25%	1.3%

Does Carotid Stent Cell Design Matter ?

Symptomatics N= 674



Schillinger M et al. Stroke. 2008 Mar;39(3):905-9. Epub 2008 Jan 31.

" Operator expertise,
lesion demands, chicken and egg "...

US Registry Data:

30-day Outcomes for CAS in 6320 Patients From 2 Prospective, Multicenter, High Surgical Risk Registries

(EXACT & CAPTURE2)

Second, the results seem to be independent of devices used and are likely to be generic to the procedure, because the EX and C2 studies used different CAS systems (bare wire filter/closed cell stent and fixed wired filter/open cell stent, respectively).

5558 ASYMPTOMATIC

Gray WA, Circ Cardiovasc Intervent 2009;2:159-166

EPIC: Patients at High-Risk for CEA

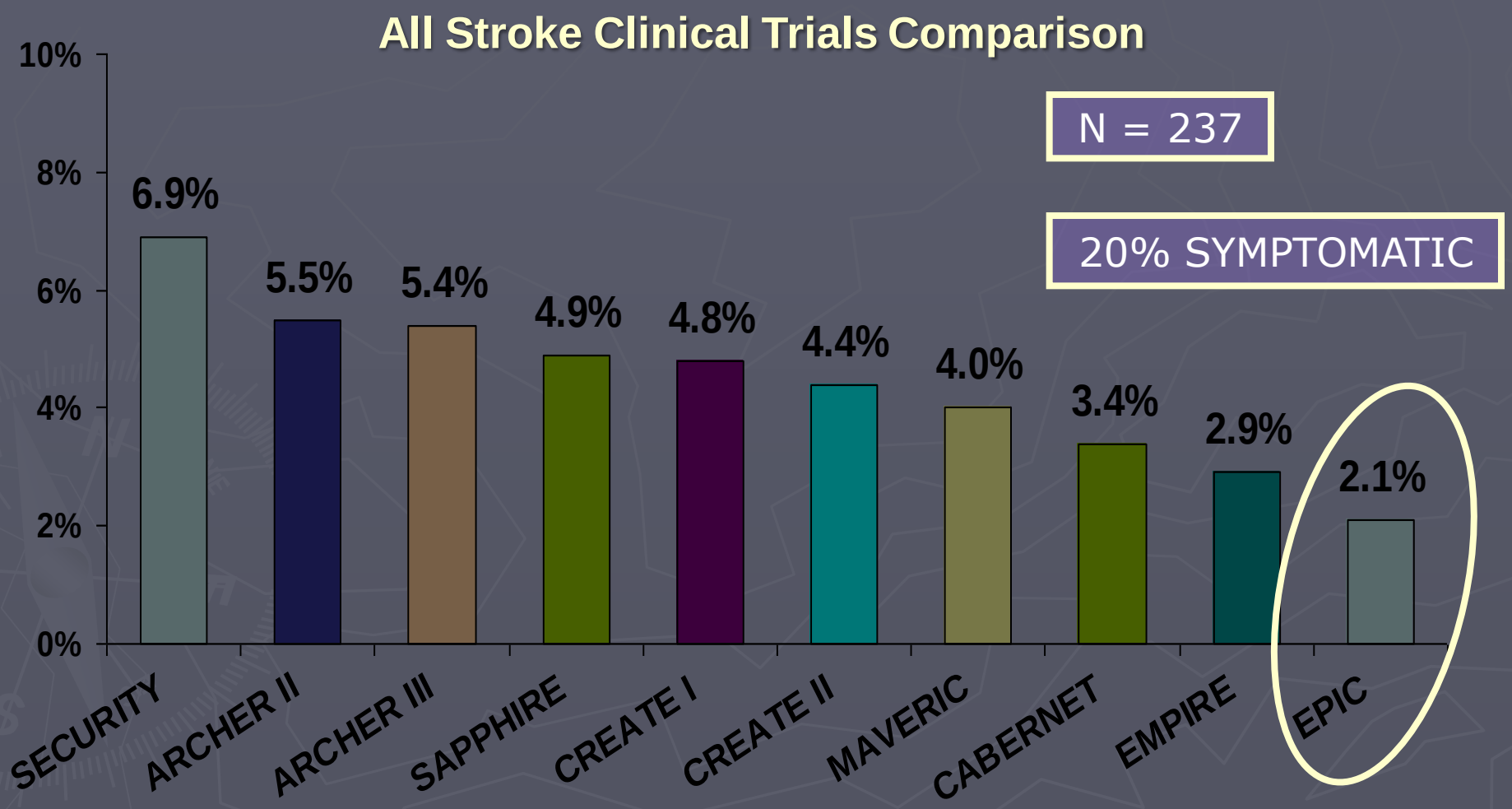
Prospective, Multi-center, Non Randomized Trial Evaluating the FiberNet® Embolic Protection System for Use During Carotid Artery Stenting Procedures (26 Sites)

ANY CAROTID STENT

" There are no differences between open cell or closed cell stent design using FiberNet in the EPIC clinical Trial ".

Catheterization and Cardiovascular Interventions 75:817–822 (2010)

30 Day Event Rates



ARMOUR

Safety and Effectiveness of the INVATEC MO.MA® Proximal Cerebral Protection Device During Carotid Artery Stenting: Results From the ARMOUR Pivotal Trial

ANY CAROTID STENT

Ansel GM et al.
Catheterization & Cardiovascular Interventions 2010;76:1-8

ARMOUR

Group	30 Day stroke rate
All subjects (N = 225)	2.3% (5/220)
Symptomatic (N = 34)	0.0% (0/32)
Asymptomatic (N = 191)	2.7% (5/188)
Age ≥80 octogenarians (N = 65)	3.1% (2/65)
Age <80 (N = 155)	1.9% (3/155)

Strokes:

Acculink
Precise
Protégé
XAct
One pre stent deployment

EMPiRE:

" Results Of Gore EMPiRE Clinical Study – Study Reports Low Major Adverse Event Rates Using The GORE Flow Reversal System "

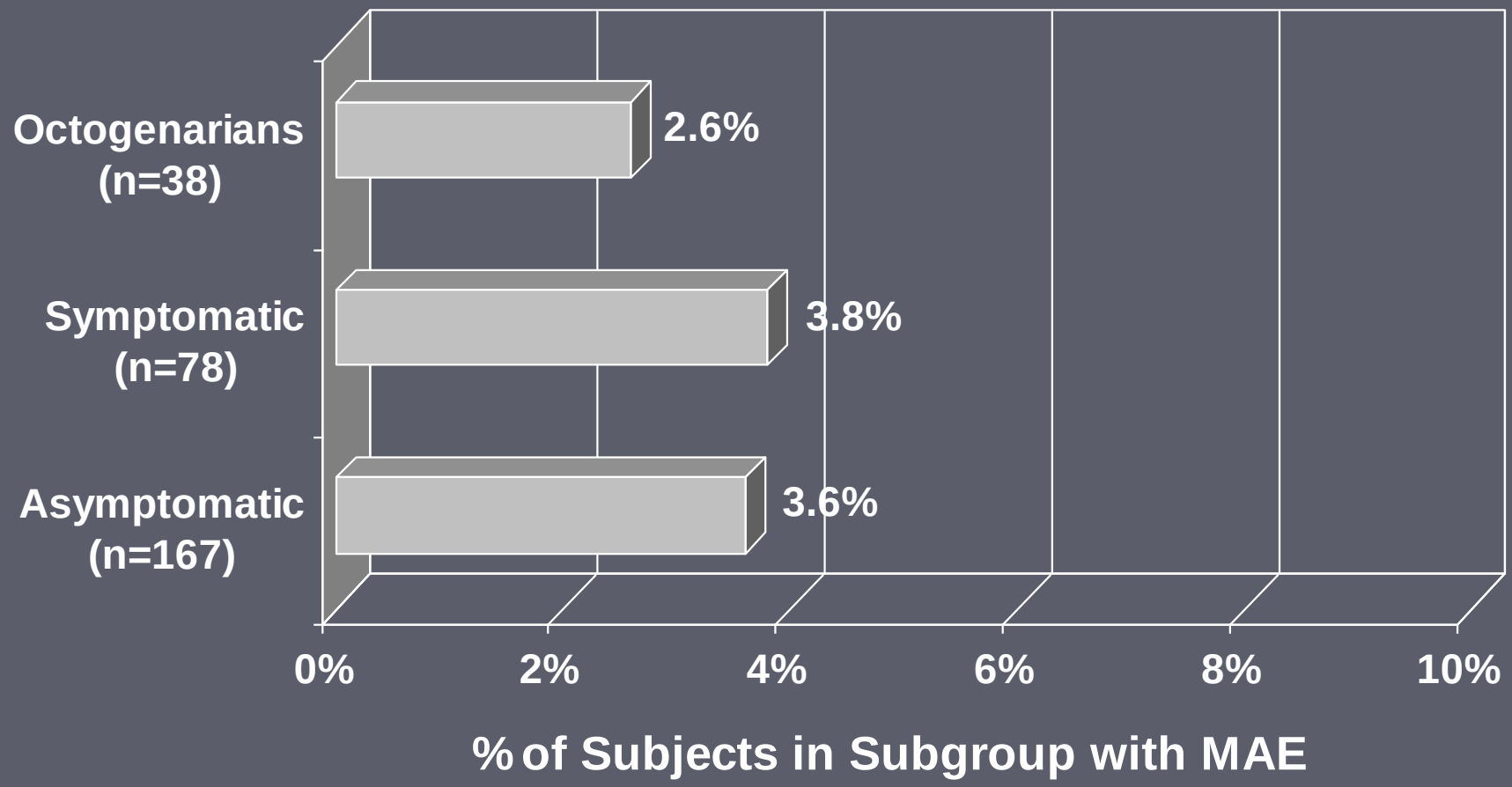
ANY CAROTID STENT

N = 245

32% SYMPTOMATIC

Hopkins LN Clair D; EMPiRE Investigators.
Transcatheter Cardiovascular Therapeutics
20th Annual Scientific Symposium; October 12 -17, 2008;
Washington, DC.

EMPiRE:


Octogenarians (n=38)
2.6%
Symptomatic (n=78)
3.8%
Asymptomatic (n=167)
3.6%
0%
2%
4%
6%
8%
10%
% of Subjects in Subgroup with MAE


Brilliant but tempermental
Can do amazing work, but the slightest thing can set him off. Difficult to keep happy. Pain in the ass, but worth it... until someone else comes along who can do what he does without all the "issues".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