SVG intervention : Tips & Traps

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SVG PATHOLOGY

SVG's are not like native arteries –

- 300000 CABG's per year.
- Approx. 15% grafts occlude by 1 year
- 40 – 50% grafts occlude by 10 years
- 77% grafts become diseased by 10 years

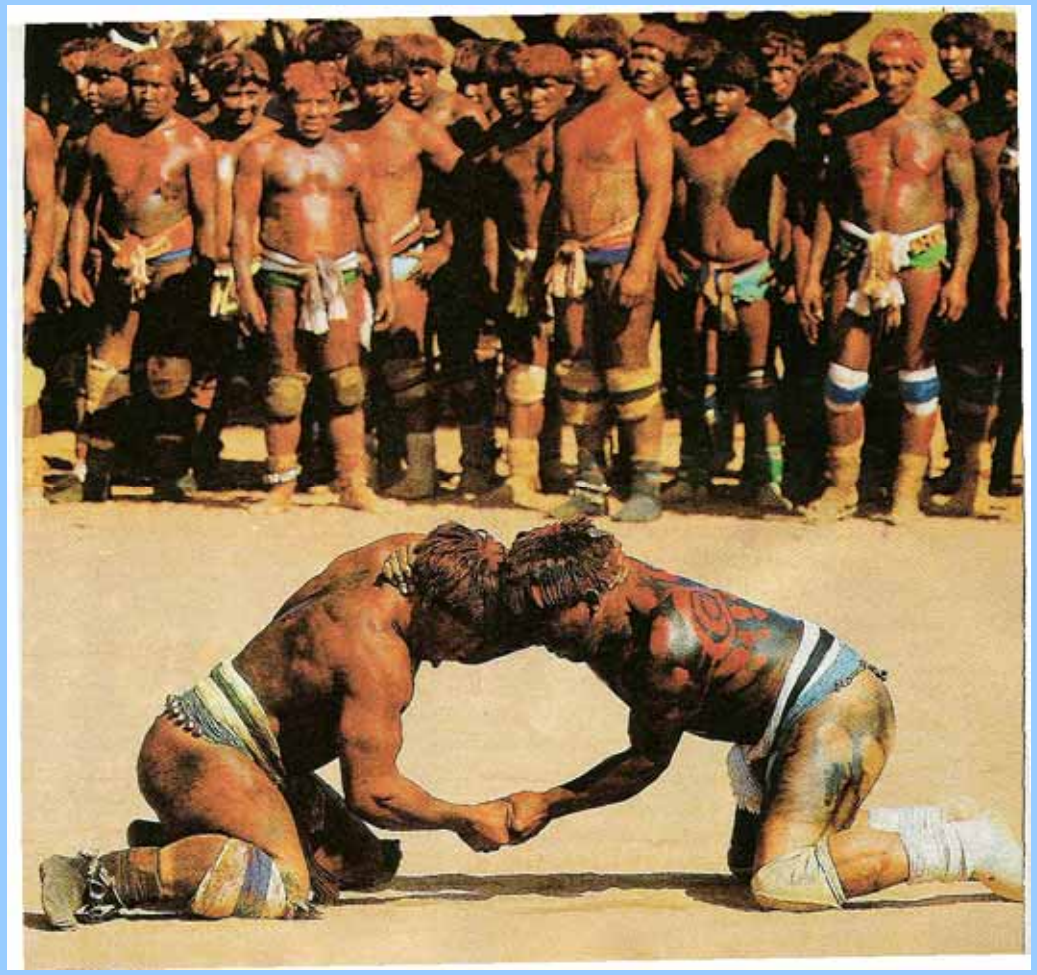
Vein Graft Intervention

- Technically feasible
- Biologically challenging

  Patient population with comorbid conditions, extensive disease, ↓ LV fxn

  Friable atheroma / thrombi → distal embolization

  Restenosis - incidence, location, time course different than native vessels



“***SVG intervention is like wrestling in a mud, to remain clean while fighting is difficult”***

Problem 1: Myonecrosis after SVG PCI

Hong MK et al. Circulation 1999 and JACC 2001

Distal Embolization During SVG Intervention

- Ubiquitous
- Usually results in MI or Death
- Unpredictable

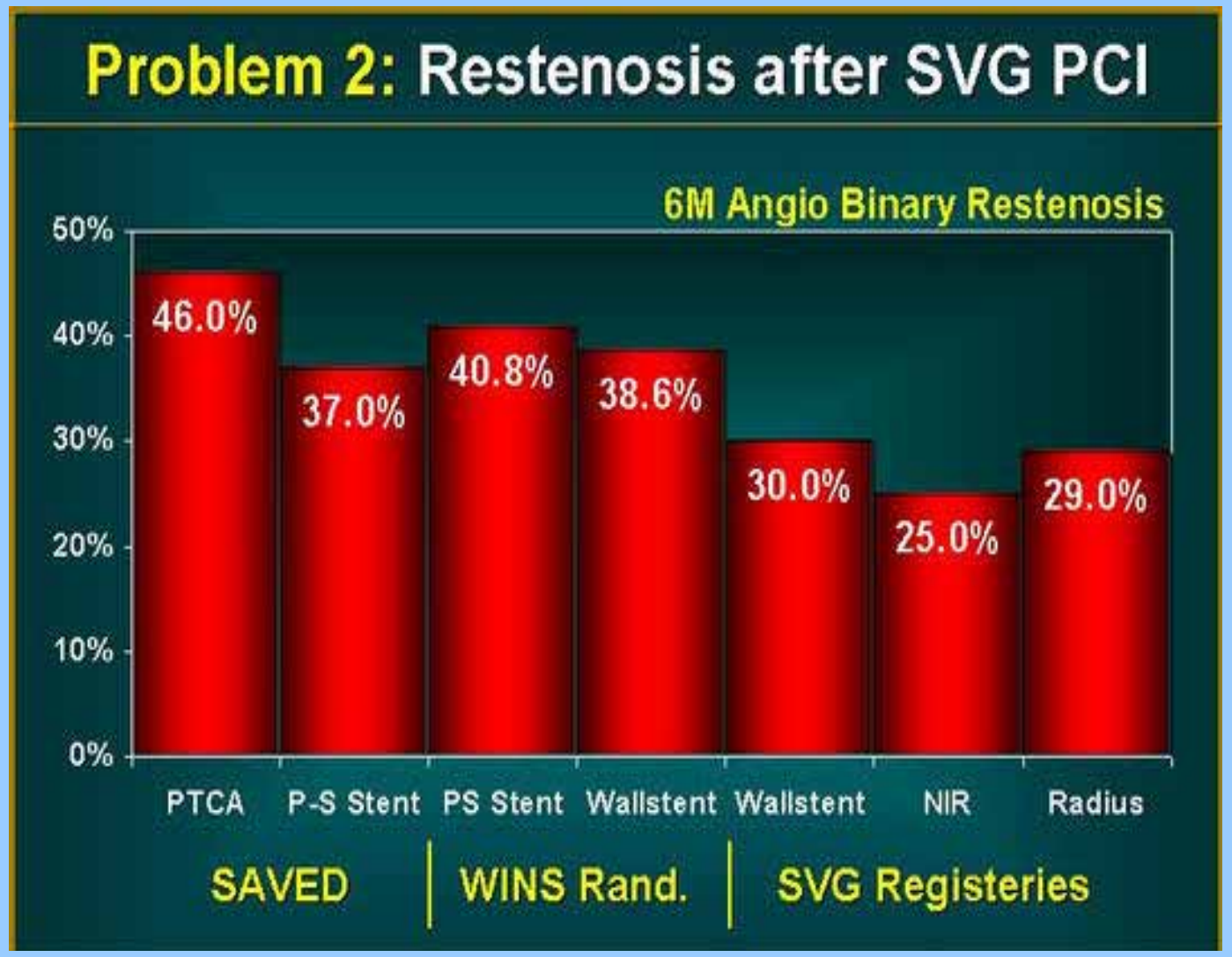
The No-Reflow Problem

- Defn: poor distal flow and ischemia despite widely patent proximal vessel
- Complicates 10–15% of SVG PCI[1]
- 31% acute myocardial infarction rate [2]
- 10-fold in-hospital mortality increases [2]
- Several contributors: Atheroemboli > Mircrovascular spasm > Platelet aggregation[3]

[1] Sdringola, *et al.*, Cathet Cardiovasc Intervent. 2001; 54(3):325-326.
[2] Abbo, *et al.*, American Journal of Cardiology. 1995; 74(12) 15: 778-782
[3] Rezkalla, *et al.*, Circulation. 2002;105:656-662.

Treatment of No Reflow

- Reverse superimposed spasm with IC TNG
- Administer verapamil, diltiazem, nitroprusside or adenosine through the balloon catheter
- Consider IIb/IIIa Inhibitors
- Consider IABP

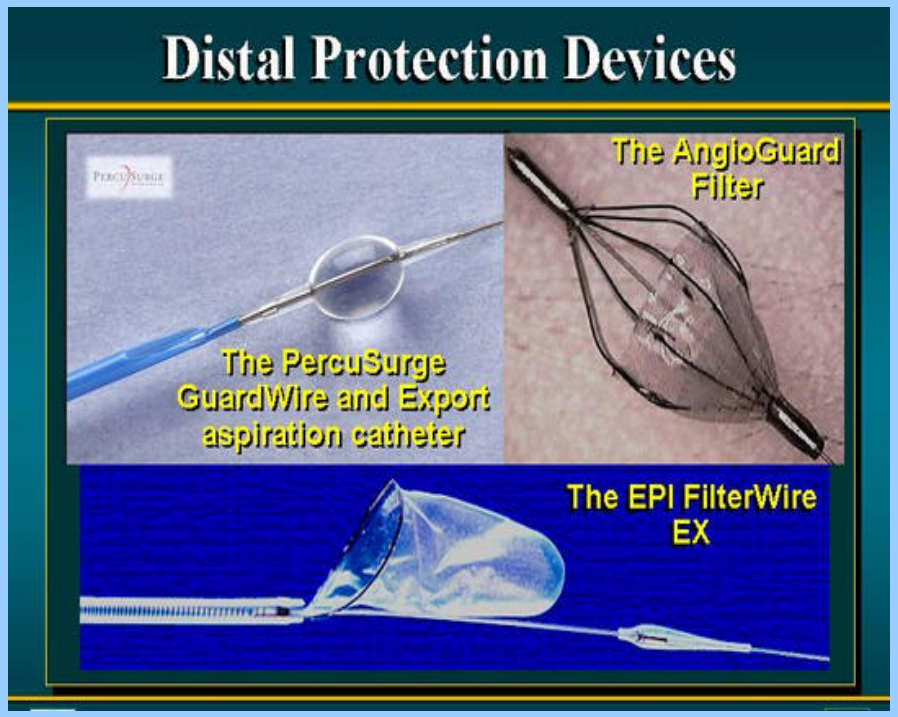

Problem 2: Restenosis after SVG PCI
6M Angio Binary Restenosis
60%
40%
30%
20%
10%
0%
46.0%
37.0%
40.8%
38.6%
30.0%
25.0%
29.0%
PTCA
P-S Stent
PS Stent
Wallstent
Wallstent
NIR
Radius
SAVED
WINS Rand.
SVG Registeries

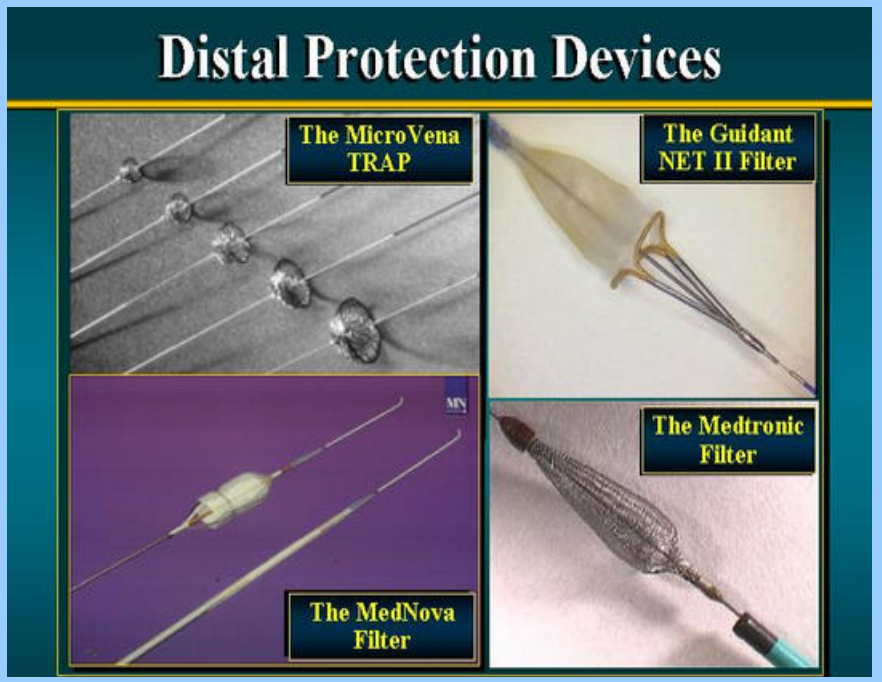
SVG PCI *Possible* Solutions

- To prevent distal embolization and peri-procedural myonecrosis
  - Distal protection systems
  - Thrombectomy devices
  - PTFE and other stent grafts
- To prevent restenosis
  - PTFE and other stent grafts
  - Brachytherapy
  - Drug-eluting stents

Distal Protection Devices

- Balloon occlusion and aspiration systems
  - The Medtronic (PercuSurge) GuardWire
  - The Kensey Nash TriActiv system
  - Proximal occlusion devices
- Catheter-based filters
  - The BSC (EPI) FilterWire
  - The Microvena (eV3) Trap and Spider
  - The Cordis AngioGuard
  - The Mednova CardioShield and NeuroShield
  - The Guidant Acunet and Net II
  - The Medtronic Interceptor


Distal Protection Devices
The PercuSurge GuardWire and Export aspiration catheter
The AngioGuard Filter
The EPI FilterWire EX


Distal Protection Devices
The MicroVena TRAP
The Guidant NET II Filter
The MedNova Filter
The Medtronic Filter

Distal Embolic Protection Devices

Balloon Occlusion Devices:

Advantages

- Easy to use
- Compatible with devices
- Aspirate large and small particles
- Reliably trap debris

Disadvantages

- No antegrade flow
- 5-8% are intolerant
- Balloon-induced injury
- Not as steerable as PTCA wires
- Difficult to image during the procedure

Courtesy of Dr. Max Amor and Dr. Michel Henry

Distal Embolic Protection Devices

Filter Devices:

Advantages

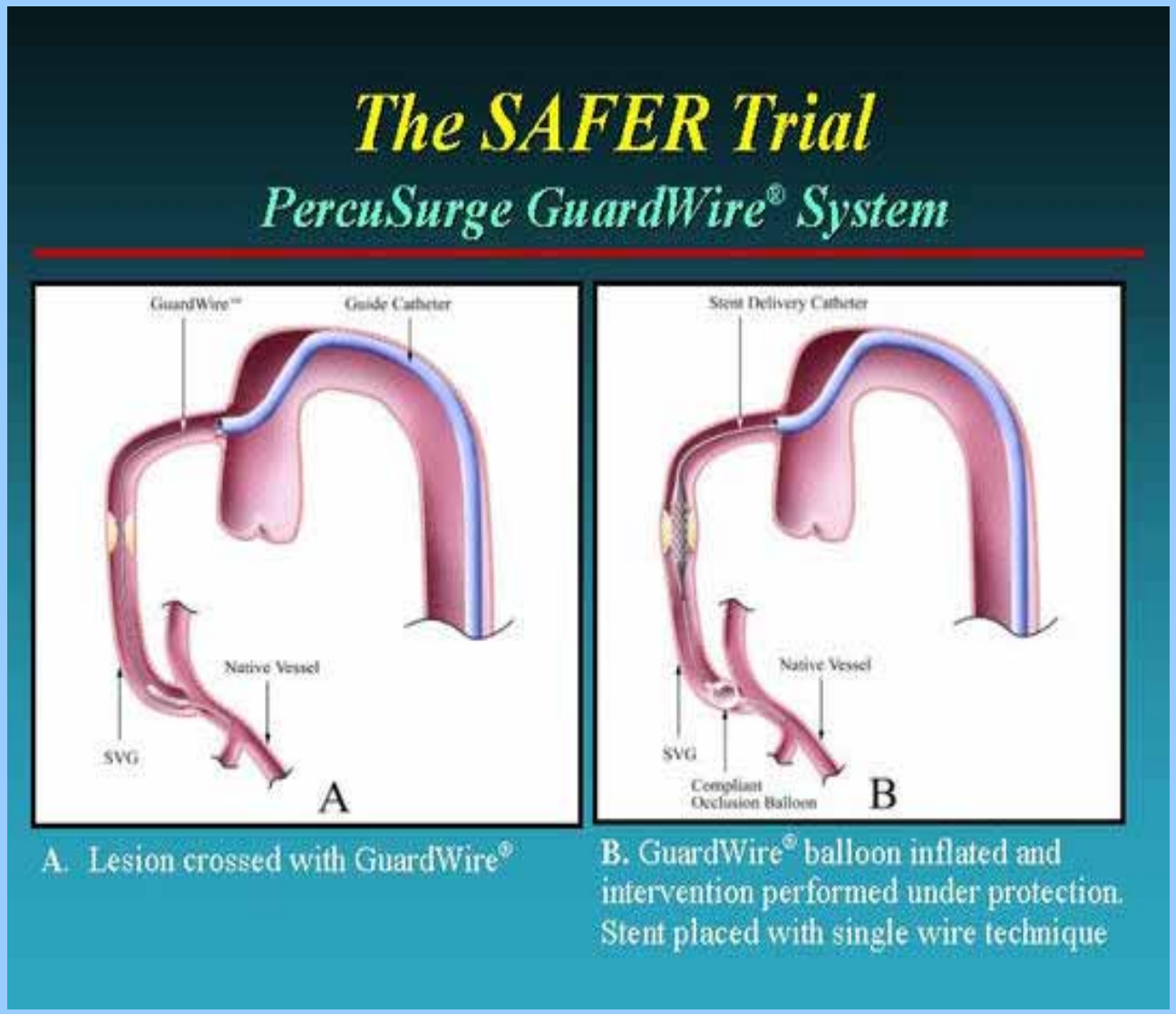
- Preserve antegrade flow
- Contrast imaging is possible throughout the procedure

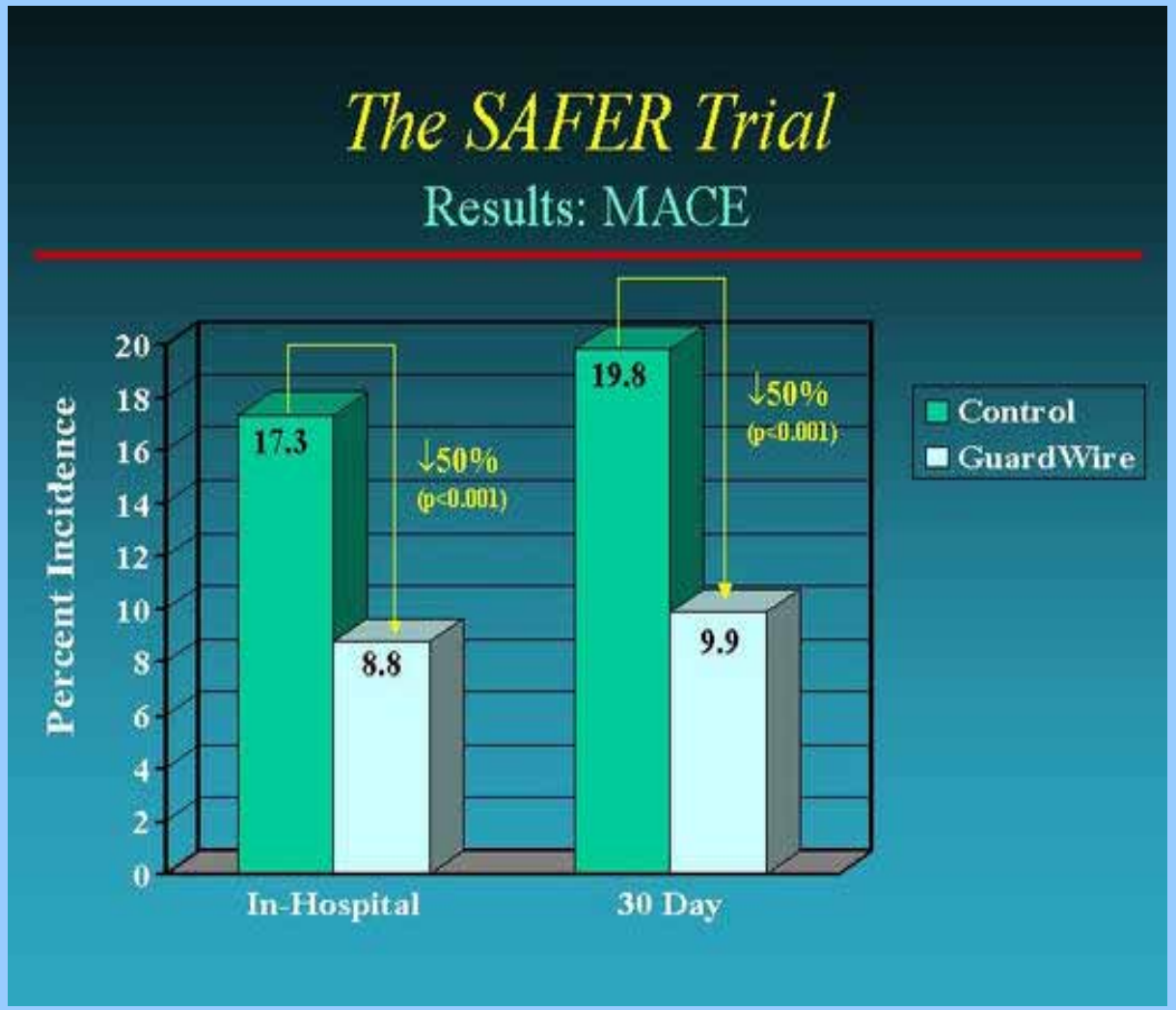
Disadvantages

- May not capture all debris
- Difficult to evaluate retrieval of debris during the procedure
- Filters may clog
- Delivery catheters may cause embolization before filter deployment

Courtesy of Dr. Max Amor and Dr. Michel Henry

Balloon occlusion devices




The SAFER Trial
Results: MACE
Percent Incidence
20
18
16
14
12
10
8
6
4
2
0
17.3
8.8
↓50%
(p<0.001)
19.8
9.9
↓50%
(p<0.001)
In-Hospital
30 Day
Control
GuardWire

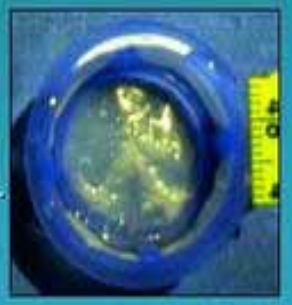
The SAFER Trial
GP IIb/IIIa Use

GP IIb/IIIa inhibitor were used in > 60% in both arms, mostly before intervention

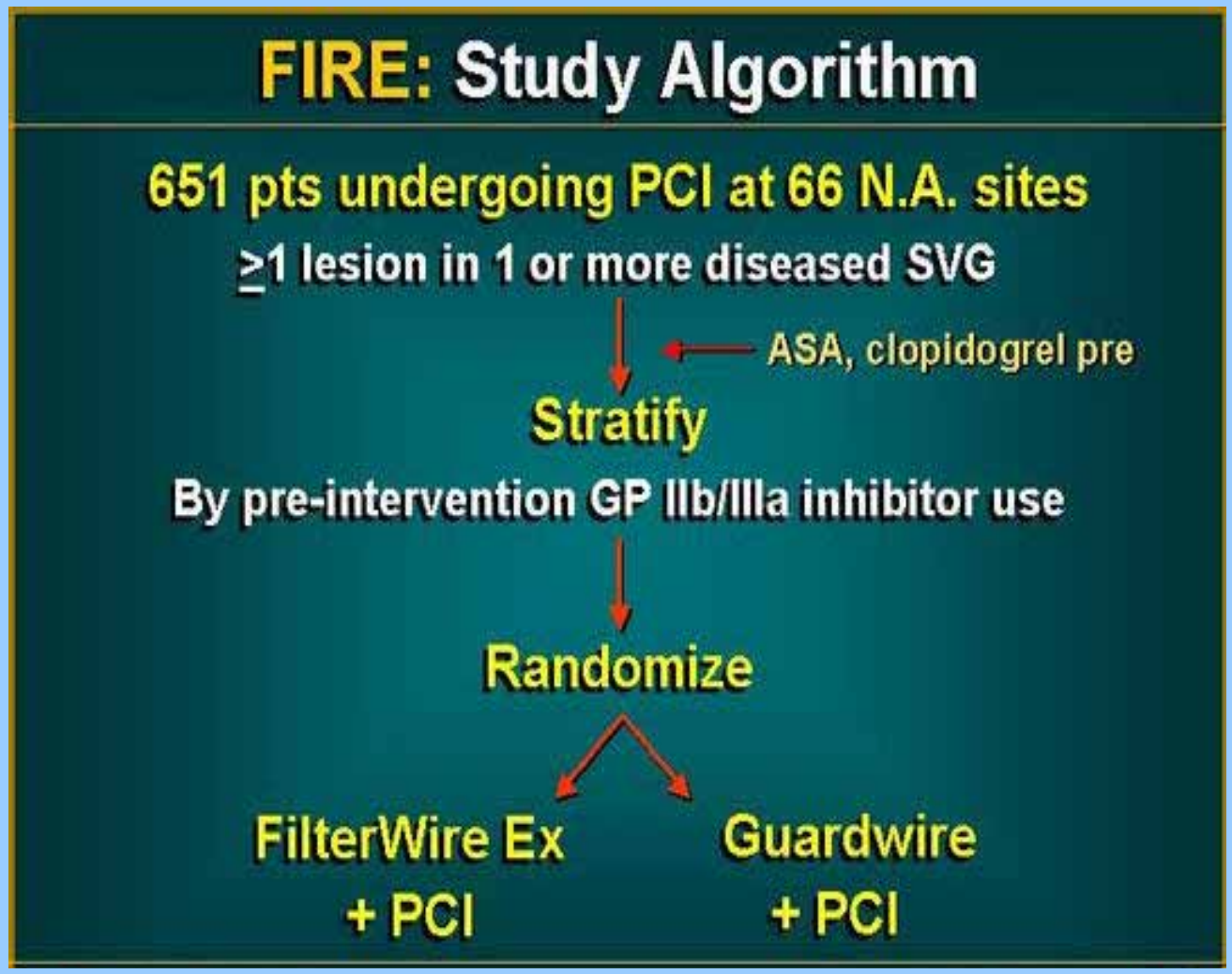
PercuSurge had MACE benefit with or without them

	GuardWire	No GuardWire	p
IIb/IIIa (164 – 182)	11.6%	21.6%	0.007
No IIb/IIIa (109 – 96)	7.3	13.5%	0.17

Why? GP IIb/IIIa's prevent platelet thrombi, but they do *not* dissolve atherosclerotic plaque.

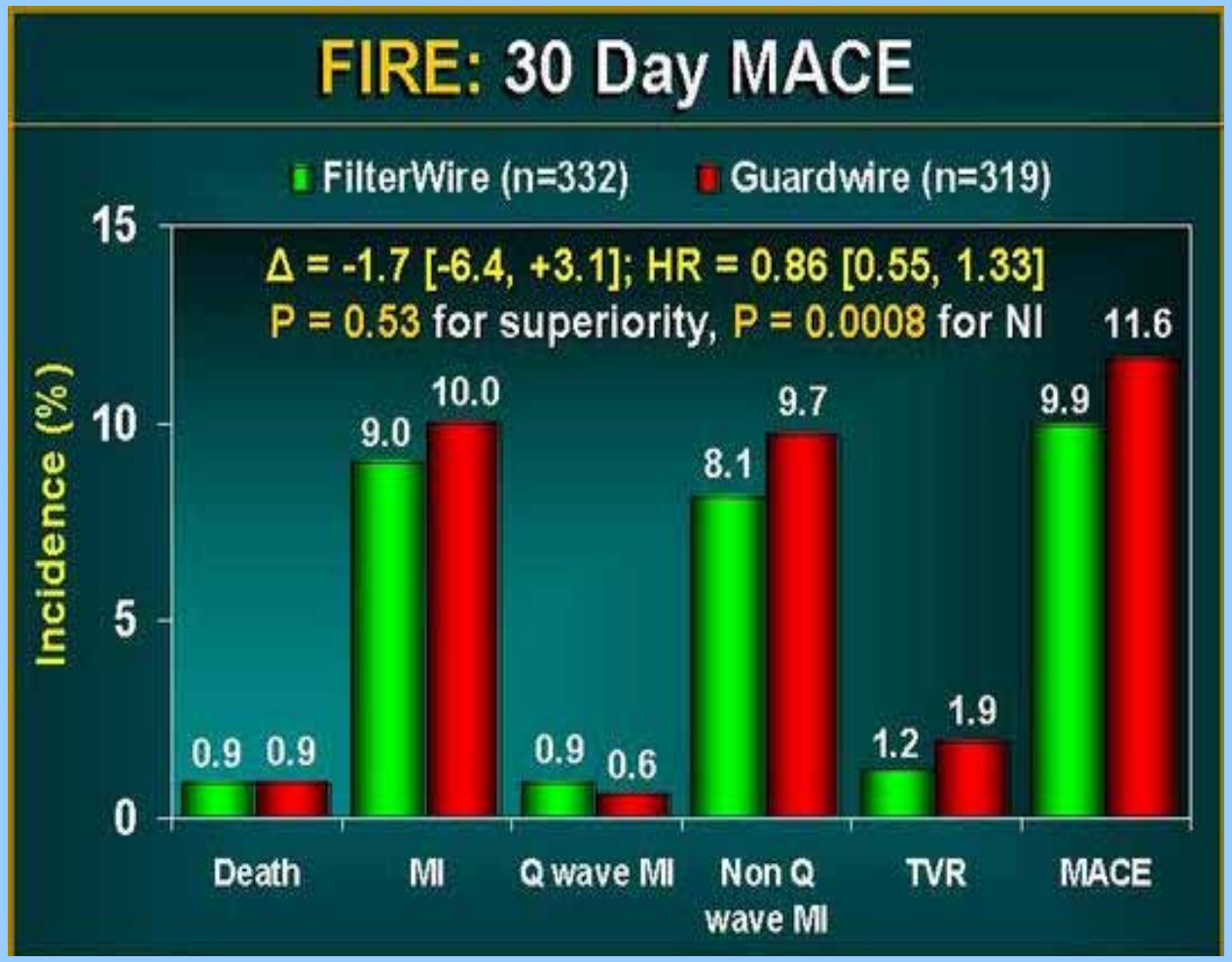


Filter devices

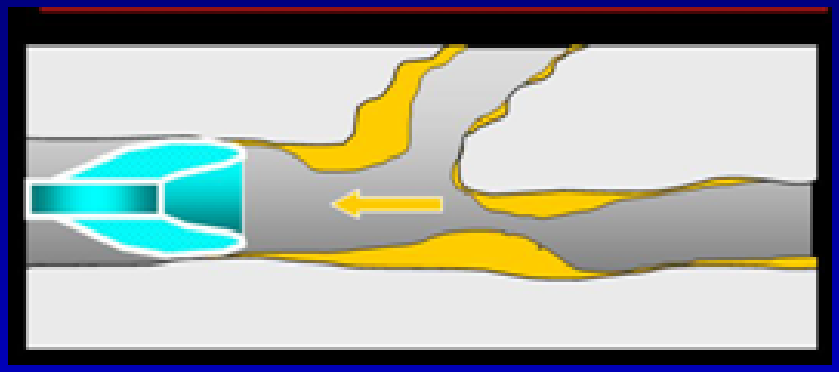


FIRE: Device Failure

	FW	GW	P value
Any failure	4.5%	2.8%	NS
- Failure to deliver	3.9%	0.6%	0.005
- Failure to deploy filter	0.6%	-	-
- Failure to inflate balloon	-	0.9%	-
- Occlusion lost or rupture	-	1.3%	-


FIRE: 30 Day MACE
FilterWire (n=332)
Guardwire (n=319)
Δ = -1.7 [-6.4, +3.1]; HR = 0.86 [0.55, 1.33]
P = 0.53 for superiority, P = 0.0008 for NI
Incidence (%)
15
10
5
0
0.9
0.9
9.0
10.0
0.9
0.6
8.1
9.7
1.2
1.9
9.9
11.6
Death
MI
Q wave MI
Non Q wave MI
TVR
MACE

Proximal Occlusion

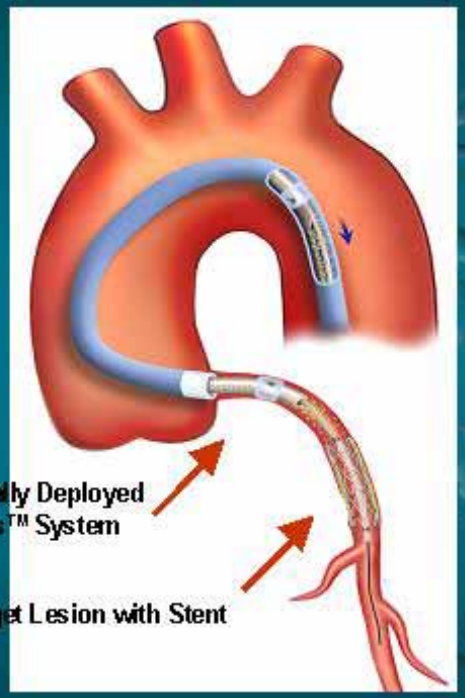


Pluses	Minuses
Possibly reduce complications	Stability of proximal occlusion
-reduce crossing debris	Visualization of target lesion
-potential to pressure-wash	Collateral flow pattern
-more complete debris recovery	Ischemic tolerance
Protect complex anatomy	Only early clinical trial data so far
-bifurcations, branches	

Could be used during placement of distal devices

Pressure-washing could be used with distal devices prior to recovery

Proximal Occlusion Protection Systems



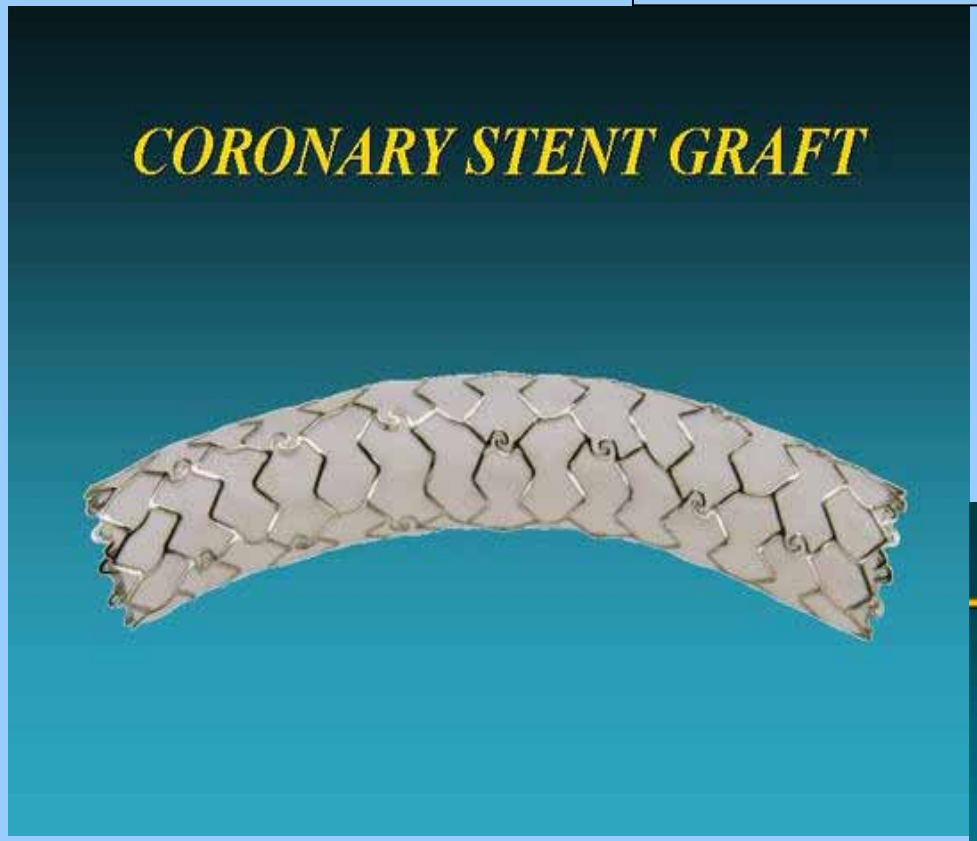
Faster Clinical Trial (Proxis System)

	Study Patients (n=30)	Study + Roll-In Patients (n=35)
30 day MACE	6.6% (2)	5.7% (2)
Death	3.3% (1)	2.9% (1)
MI (3x CK-MB)	3.3% (1)	2.9% (1)
CABG	0	0
TVR - PTCA	0	0

Use EP like you wear your seatbelt…

- Proven Fact: Seatbelts save lives in accidents
- Some people choose not to wear them…
  - *They don't have far to go (most accidents close to home)*
  - *The weather is good (most accidents in good weather)*
  - *They are careful drivers (what about the other guy)*
- The simplest and best approach is to buckle your seatbelt every time you drive
- *And the simplest and best (standard of care) approach to SVG is to use a distal embolic protection device whenever you intervene!*

Covered stents



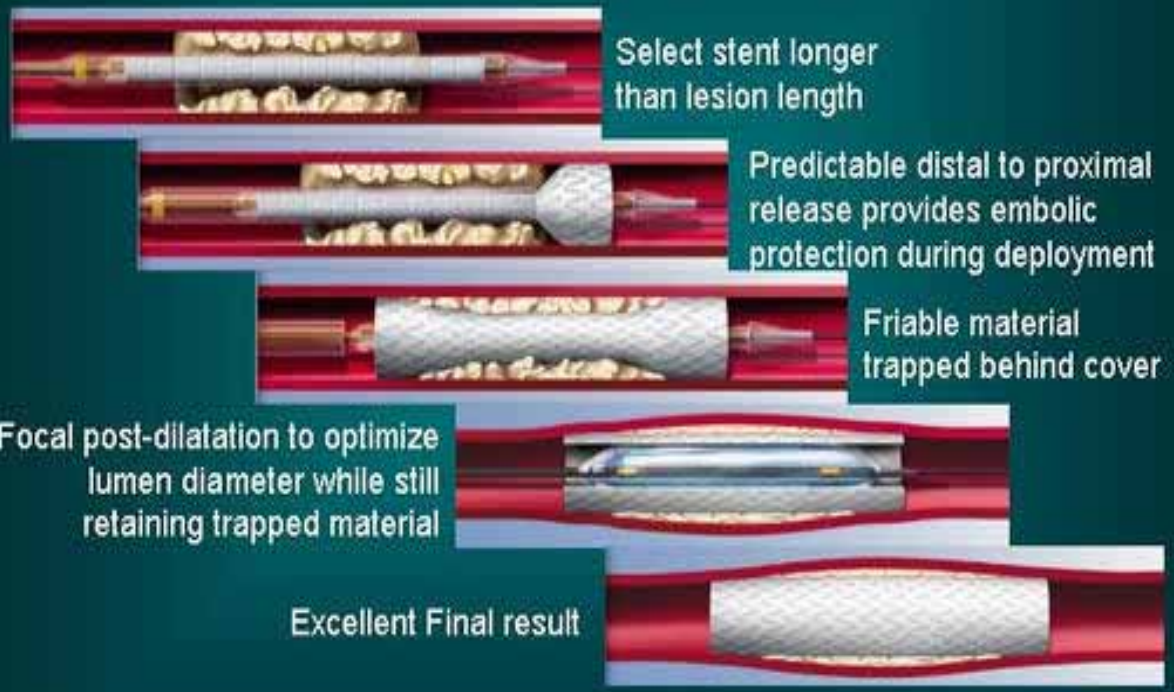
PTFE Coronary Stent Grafts

2 JoStents surrounding 20 um PTFE membrane; stent sandwich; balloon expandable
High pressure required

Self-expanding nitinol stent
2 layers of ultra thin ePTFE (16 um)
Expands distal to proximal

Symbiot™ in SVGs

Deployment Technique



ENTHUSIASM GENERATED BY SYMBIOT II

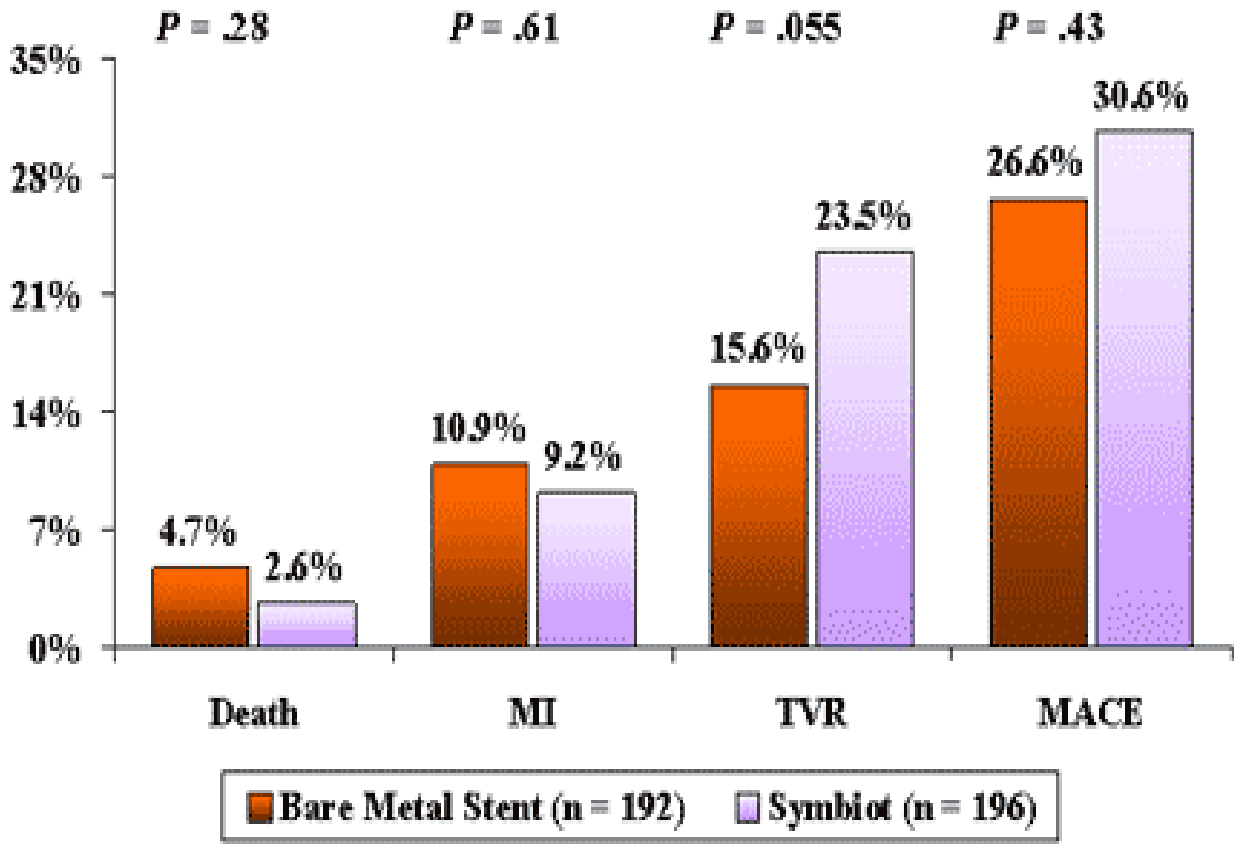
Symbiot II
(Symbiot v/s wallstent)

Decreased Restenosis rate 36% v/s 7%
Decreased Mace rate 13.5% v/s 5.2%

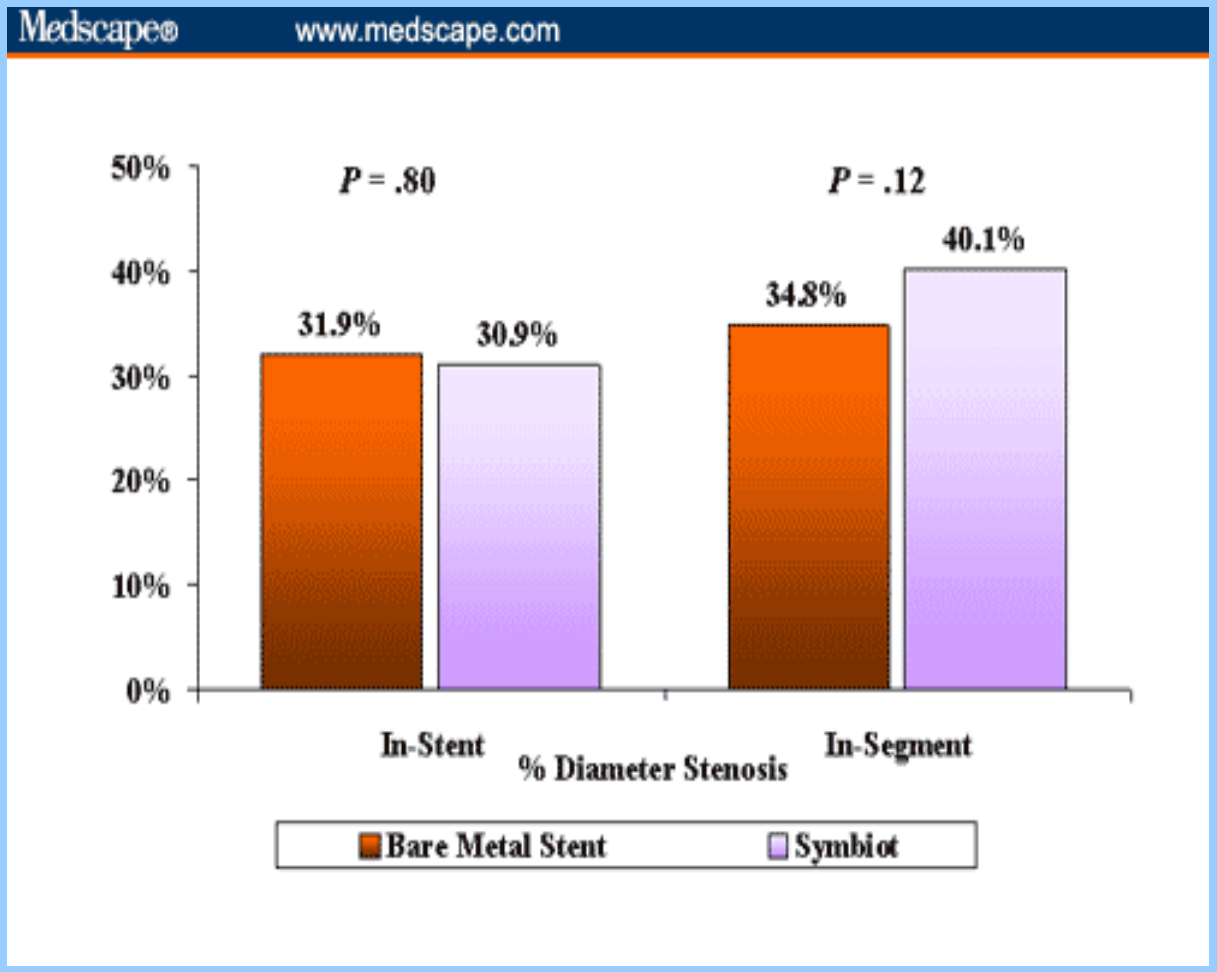
SYMBIOT III RESULTS

Medscape® www.medscape.com

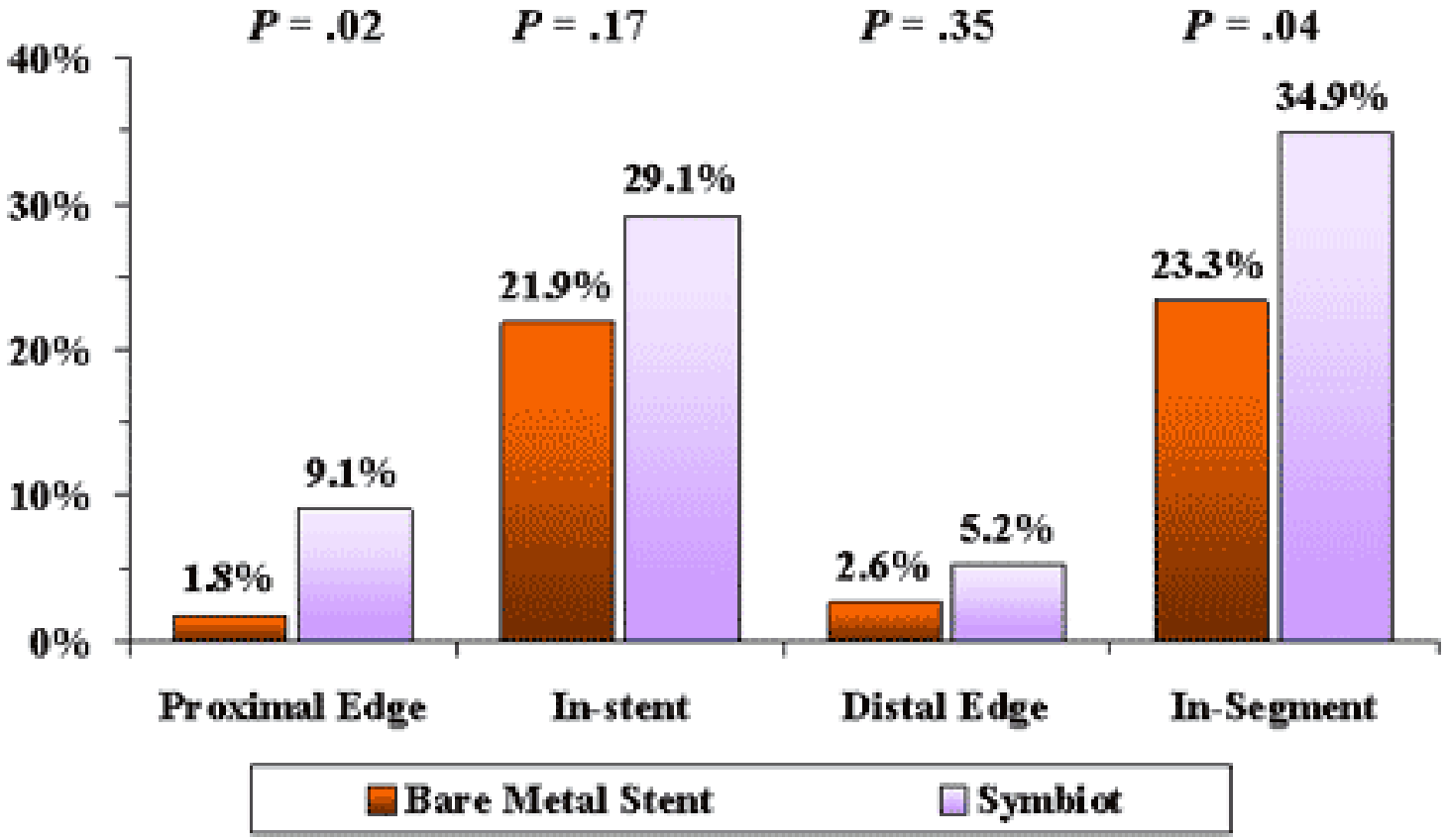
Clinical outcomes at 8-month follow-up.



Percent diameter stenosis at 8-month angiographic follow-up (primary endpoint).



Binary Restenosis Rates

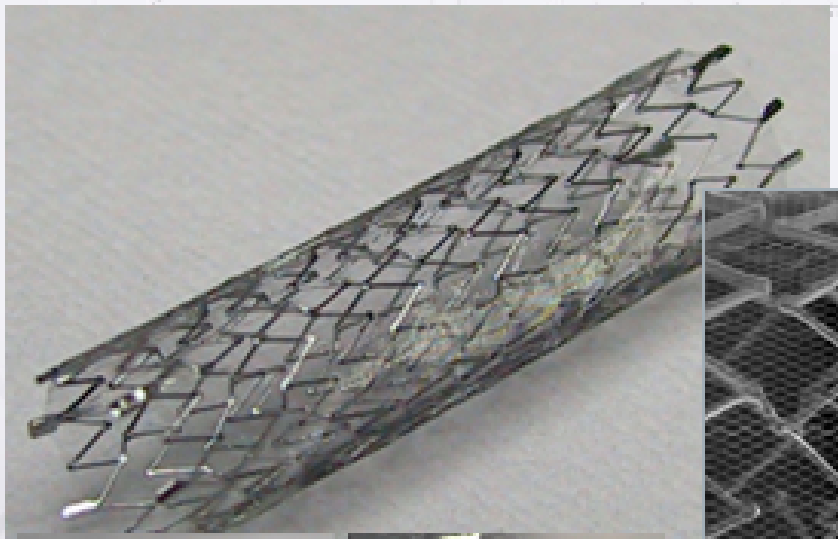


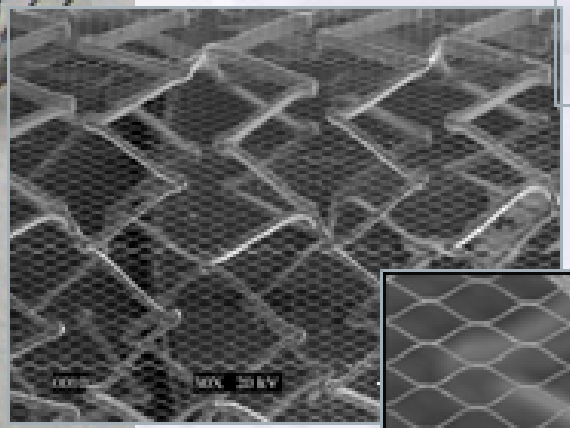
INITIAL ENTHUSIASM DAMPENED BY SYMBIOT III

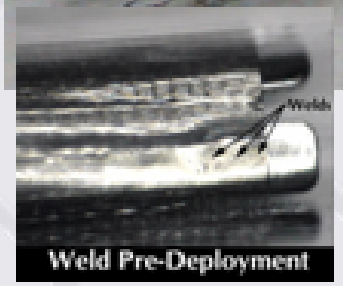
- The *Symbiot* stent did not provide any advantage over bare metal stents regarding restenosis rates.
- The addition of a PTFE barrier did not appear to reduce intimal hyperplasia.
- The higher rate of TVR in *Symbiot* patients may have been attributable to the use of longer stents in this arm of the study.

What’s new for SVG intervention

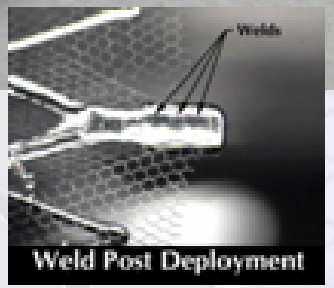
SESAME eNitinol™ Covered Stent for SVG Therapy







Weld Pre-Deployment



Weld Post Deployment

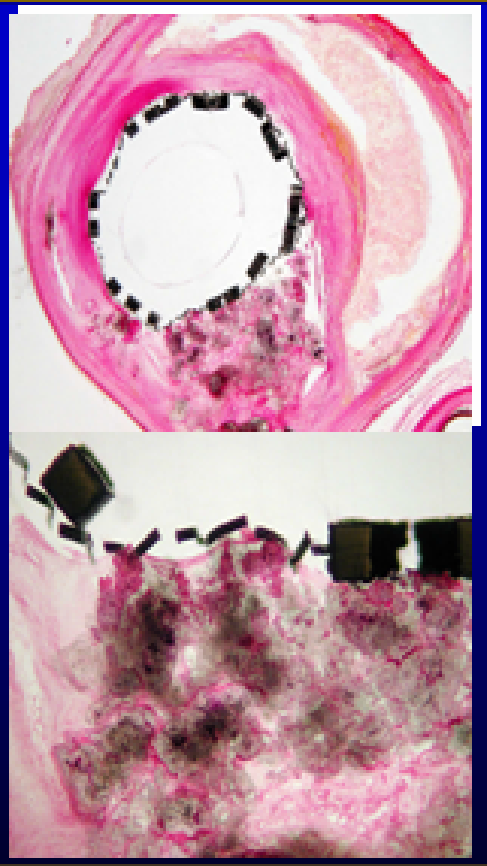
Sizes

Diameter: 4.1 mm
4.8 mm
5.8 mm

eNitinol Cover Thickness 5 micron

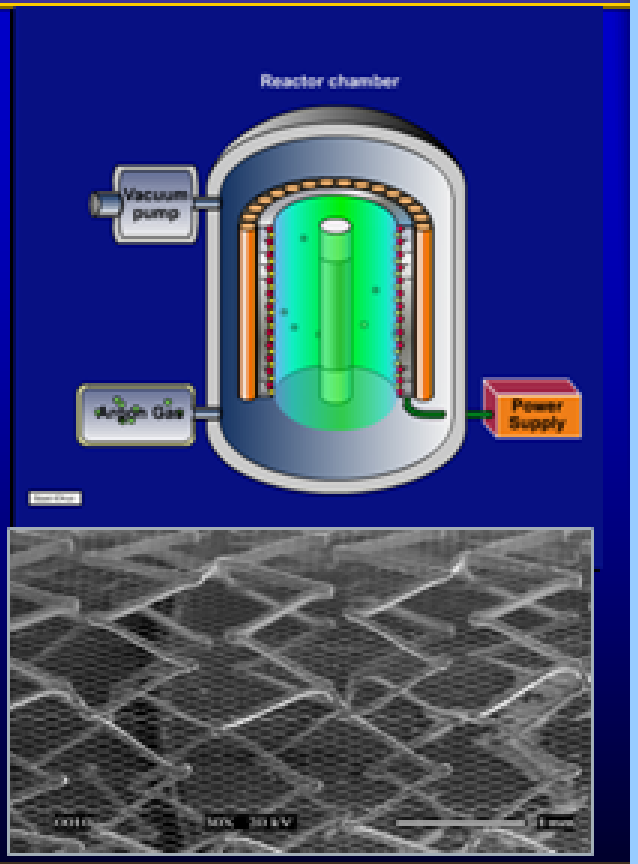
eNitinol Membrane Covered Stent for SVG Disease

- Improve Acute Procedural Outcomes
  - **Exclude friable material**
  - **Avoid deep penetration of plaque**
- Promote Long Term Healing
  - **Improved endothelial cell migration**



SESAME^{tm} eNitinol Membrane Covered Stent

- Self Expanding Stent Platform
- 5 Micron Nanosynthesized Microporous Membrane
- Vessel Range: 3.0-5.0 mm
- Stent Length: 20 mm
- Shortening < 5 %



Comments:
SESAME™ First In Man Registry

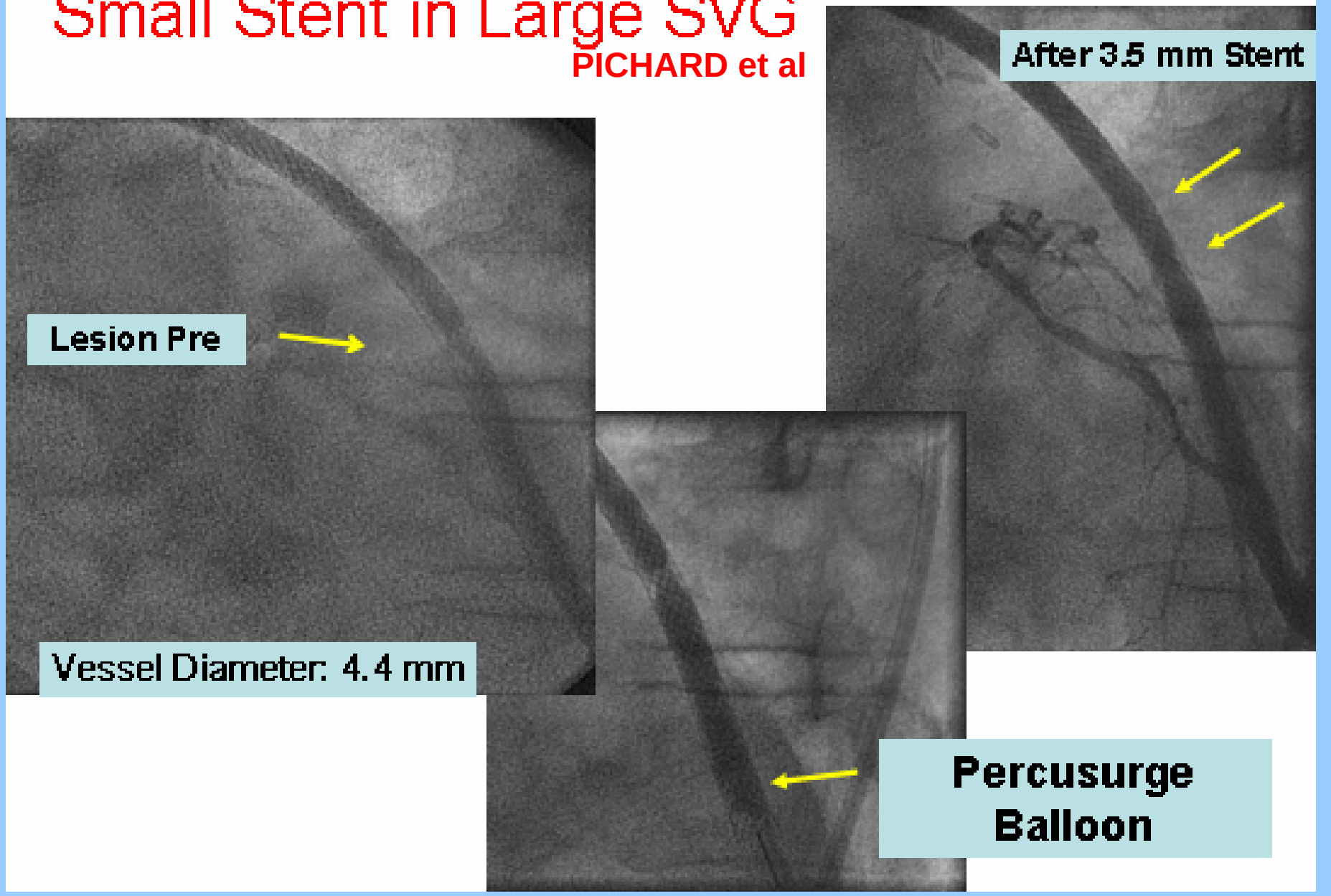
- Early studies of SVG covered stents have been optimistic compared to larger randomized trial results.
- PTFE covered stents have demonstrated increased edge restenosis and thrombotic complications.
- The ABPS Thin Film eNitinol™ Covered Stents unique design and accelerated healing properties, may improve clinical outcomes in complex bulky lesions, such as SVG and Carotid Arteries.

Conclusions: SESAME First in Man Trial

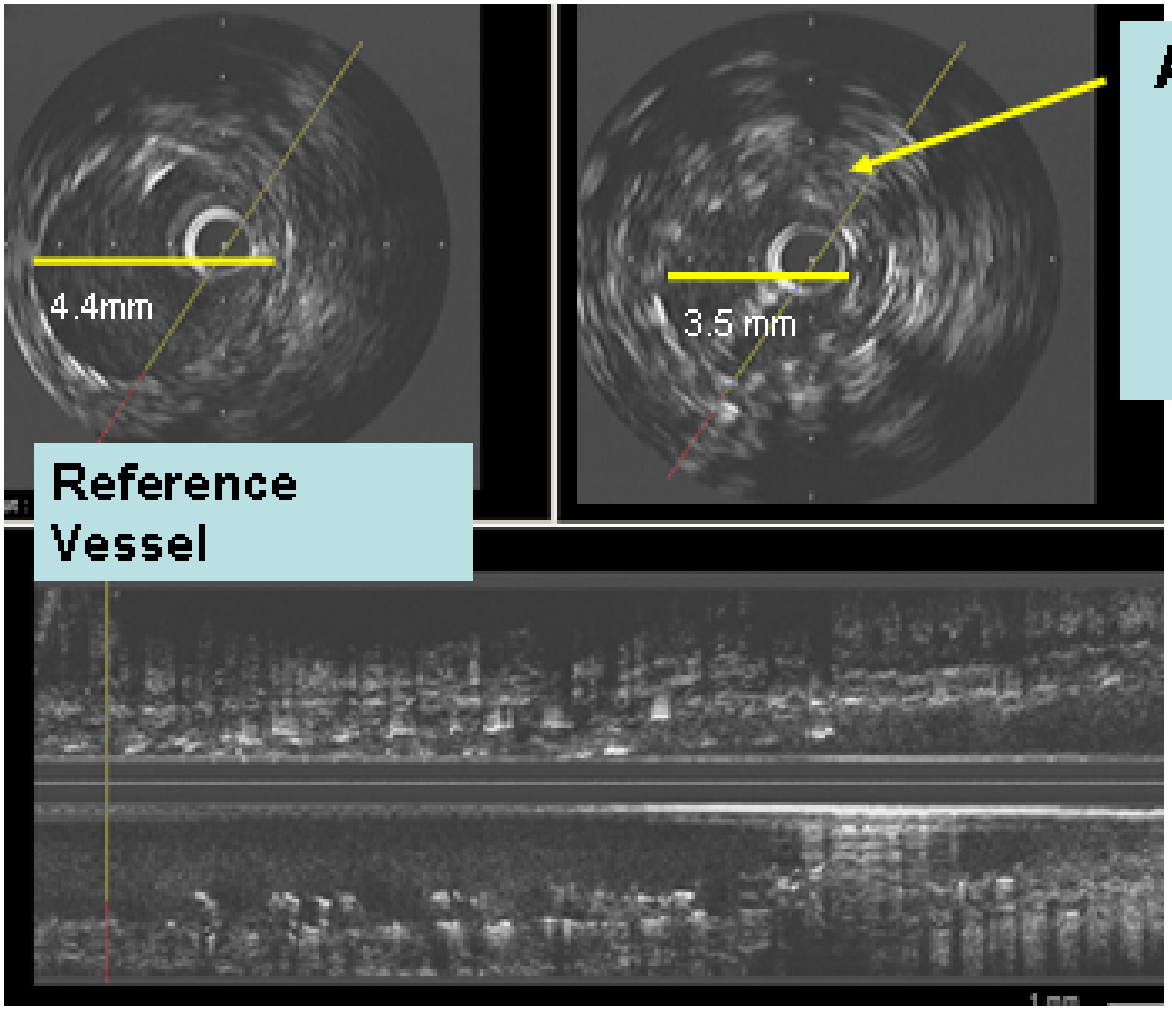
- ABPS Thin Film eNitinol™ Covered Stent can be safely used to treat SVG lesions
- To date, a low 30 day MACE rate is present in patients enrolled in the Multicenter SESAME FIM trial
- Nine month clinical and angiographic outcome data are currently pending
- Safety data supports a larger randomized trial to evaluate efficacy of this new stent design in SVG

Small Stent in Large SVG

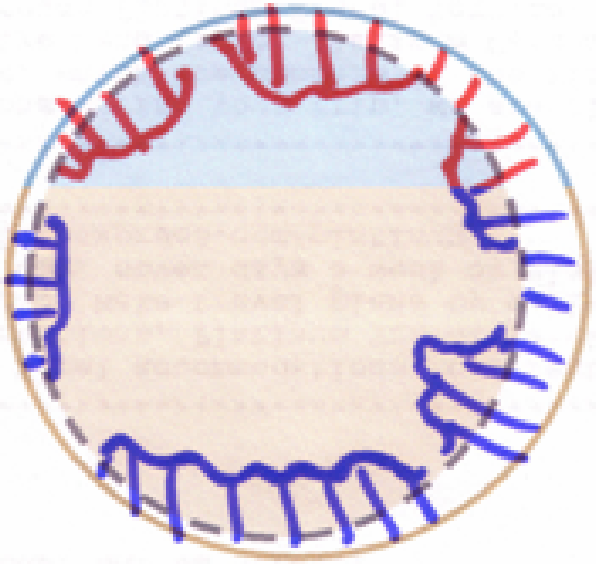
PICHARD et al



Small Stent in Large SVG

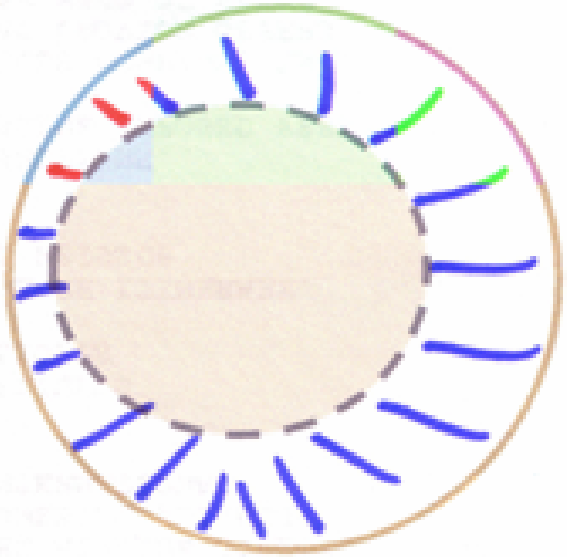


Large Stent
in Large Vein



Plaque extrudes
through the stent
into the lumen

Small Stent
in Large Vein

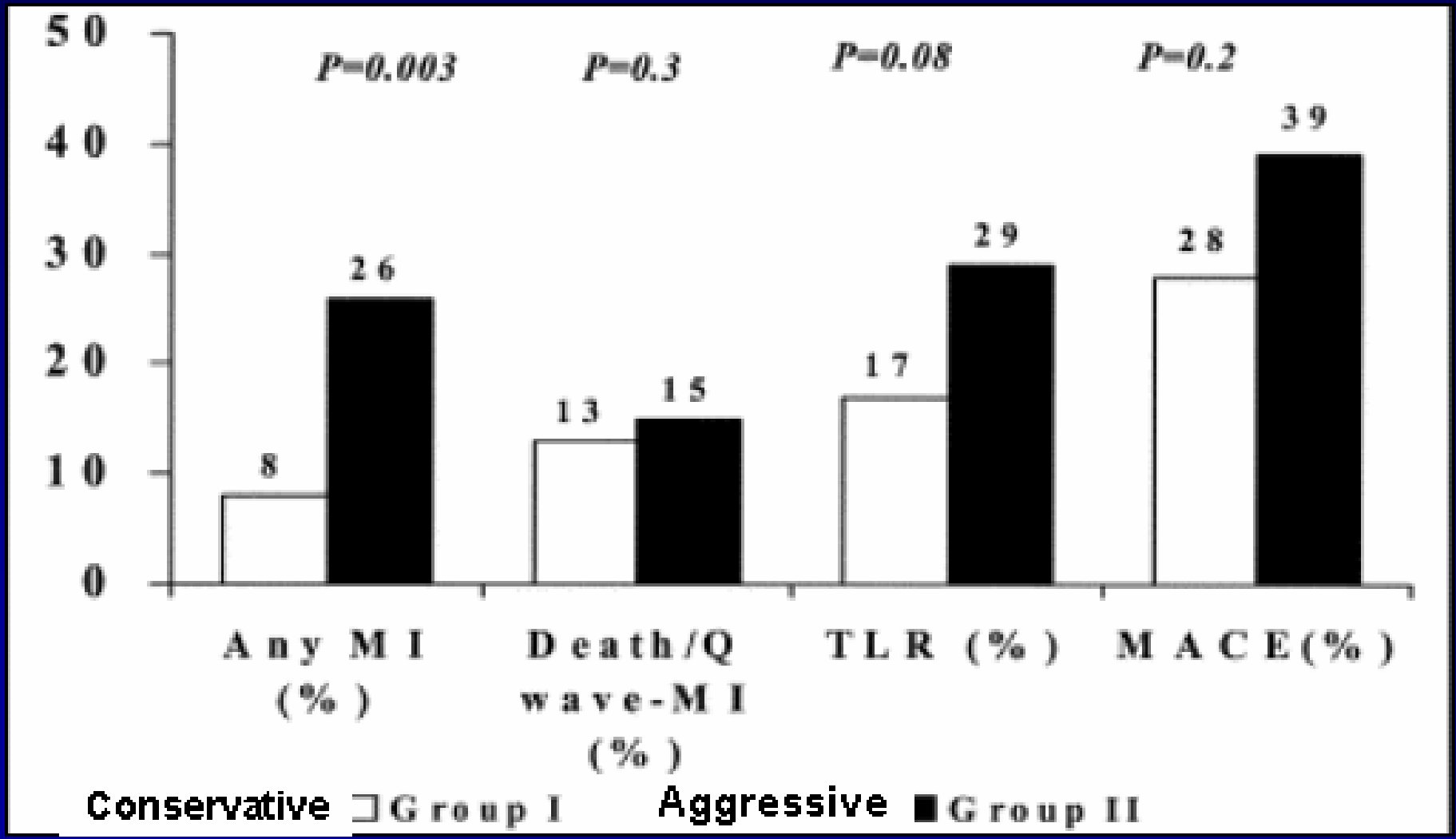


Plaque stays
behind the
stent struts

Aggressive Treatment of SVG

Am J of Cardiol 2004;93:963-968

226 patients with IVUS guided PCI of SVG
176 pts. stent area < than Reference Vessel Diameter and 50 pts. stent > than RVD.



The “**SMALL STENT IN LARGE SVG**”

strategy is an attractive new option for treatment of degenerated vein grafts.

DES in SVG’s

Large RCT's comparing DES v/s BMS in SVG's still lacking.

Various registry data:

Chu & coworkers – 56 pts with 70 SVG lesions (SES) v/s 721 SVG lesions (BMS)

- SES group – lower in hospital CK-MB elevations
- Lower non Q MI's at 30 days.

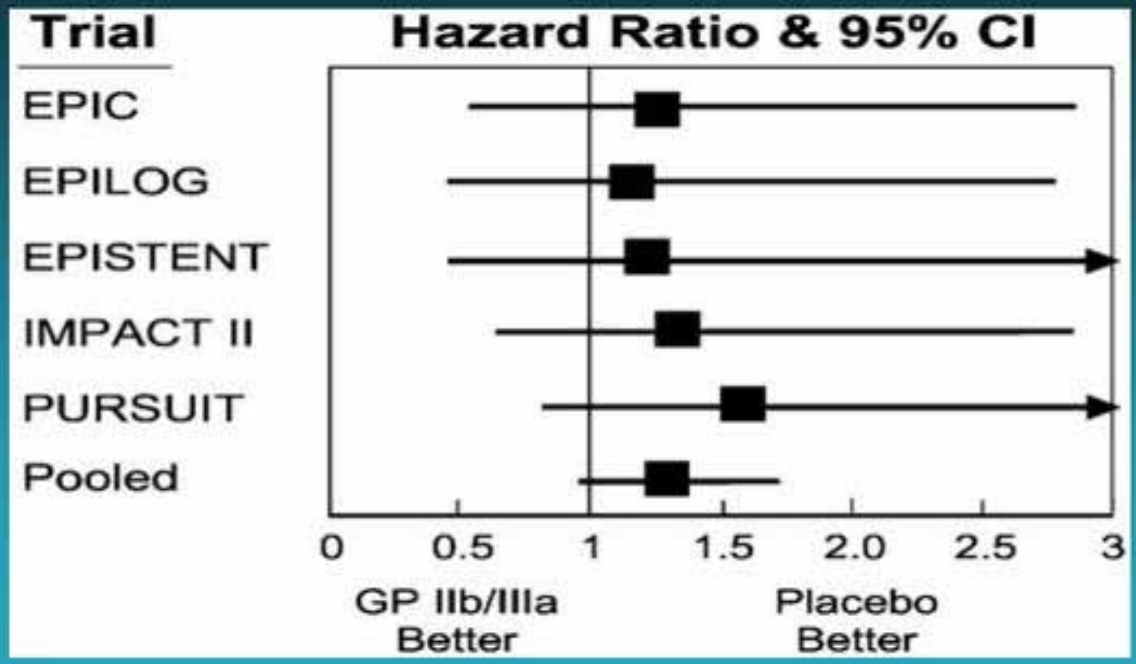
E – Cypher registry data compared outcomes of SES in native coronary lesions v/s SVG lesions (14068 pts. v/s 248 pts.)

- Higher MACE rate in SVG gp. V/S native gp. (6.5% v/s 3.2%)
- Low rate of 6 mth TLR 2.5%
- Higher MACE because of higher TVR (non TLR) rates.
- No difference in subacute or late stent thrombosis

DOES GpIIb/IIIa INHIBITORS HAVE ANY ROLE IN SVG INTERVENTION ?

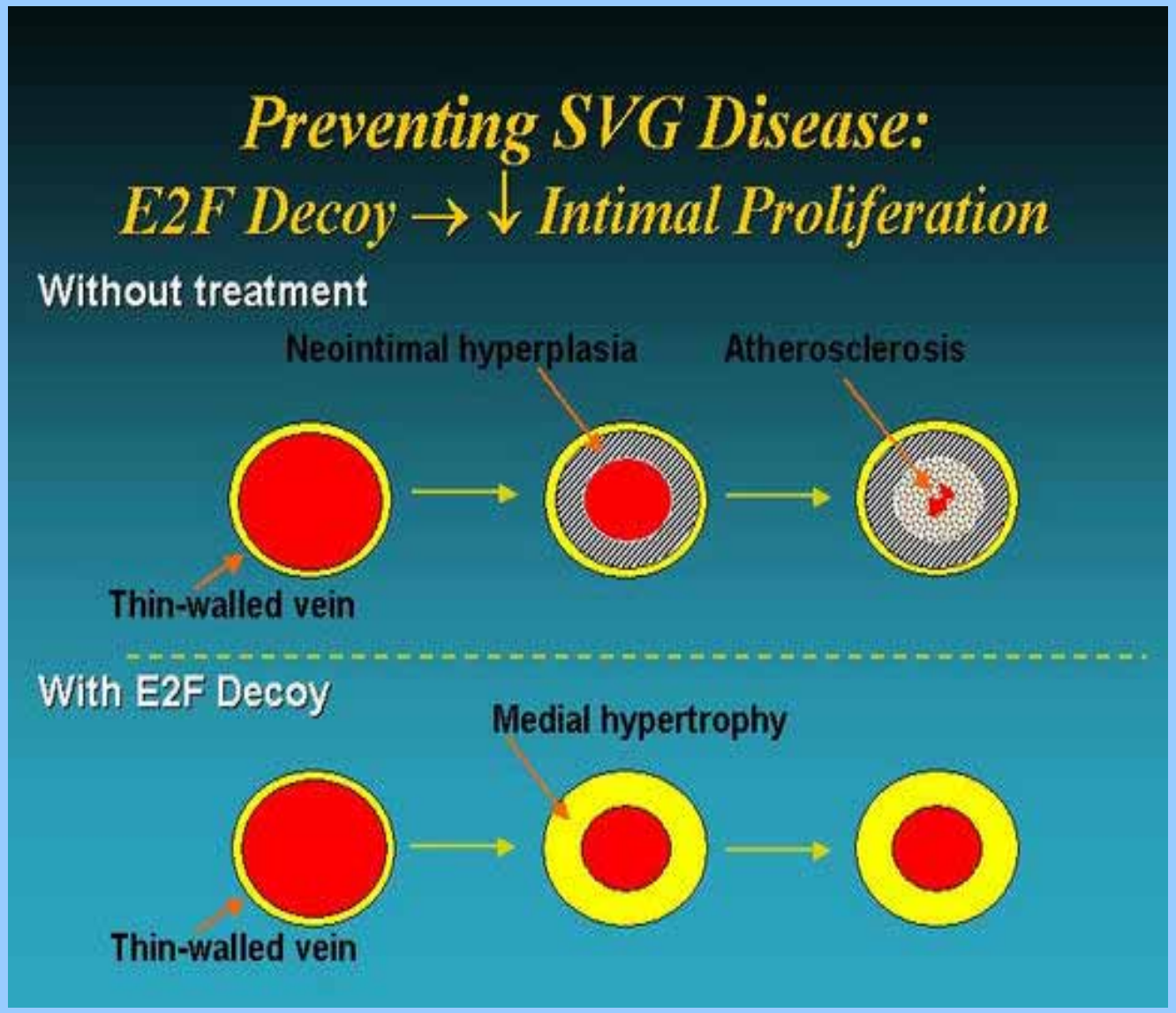
GP IIb/IIIa Inhibitors and Graft PCI (n=627):

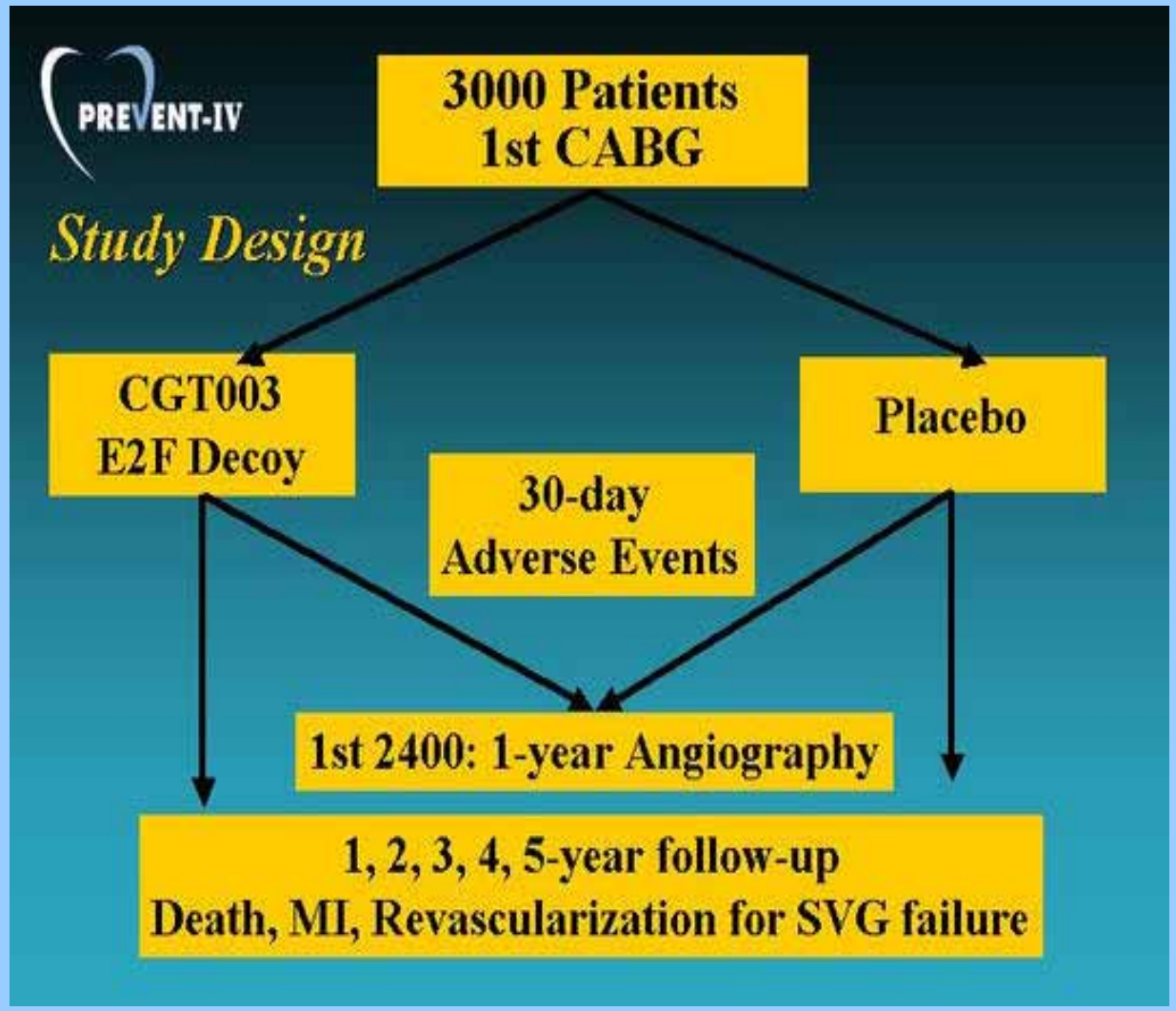
Pooled Analysis of 5 RCTS (6-month death/MI/revasc)



Roffi M, et al. Circulation 2002;106:3063

IS PREVENTION OF SVG Ds. FEASIBLE ?


Preventing SVG Disease:
E2F Decoy → ↓ Intimal Proliferation
Without treatment
Neointimal hyperplasia
Atherosclerosis
Thin-walled vein
With E2F Decoy
Medial hypertrophy
Thin-walled vein


PREVENT-IV
3000 Patients
1st CABG
Study Design
CGT003
E2F Decoy
Placebo
30-day
Adverse Events
1st 2400: 1-year Angiography
1, 2, 3, 4, 5-year follow-up
Death, MI, Revascularization for SVG failure

- **IF CHOICE OF FIXING NATIVE A./SVBG – FIX NATIVE A**

TIPS

- Risk stratify a pt. according to LV function & myocadium supplied by culprit graft.
- Assess condition of a graft as a whole (diffuse ds. or not).
- Choose a proper guiding catheter with a good support (Multipurpose or amplatz)
- Infuse NTG/Diltiazem liberally into the graft.
- Use smaller balloon diameter for predilatation.
- Choose stent length so as to adequately cover the lesion.

- Individualize DPD use – consider landing zone, size of conduit, consequences of prolonged occlusion.
- Covered stents should also be considered.
- Individualize use of GpIIB/IIIA inhibitors.
- Keep IABP ready.
- Keep praying to god.

TRAPS

- SVG intervention – itself is a trap.
- Avoid touching a diffusely diseased graft.
- Think thrice before intervening to vein graft to non infarcted LAD.
- Consider prior IABP for intervention to a graft supplying substantial myocardium.
- Never feel overconfident.

BEST WAY TO KEEP SAPHENOUS V. PATENT IS TO LEAVE IT IN LEG.

Factors Influencing Revascularization Decisions in Post-Bypass Patients

Often leads to PTCA

- Patent arterial grafts (esp. LAD)
- ≥ 2 patent grafts
- 1-3 culprit lesions
- Inadequate conduits

Often leads to CABG

- Diseased SVG to LAD
- Bulky SVG atheroma
- > 3 culprit lesions
- EF 25 - 35%