Embolic Protection is Required for a Small Minority of Vein Graft Interventions!

Jean Fajadet

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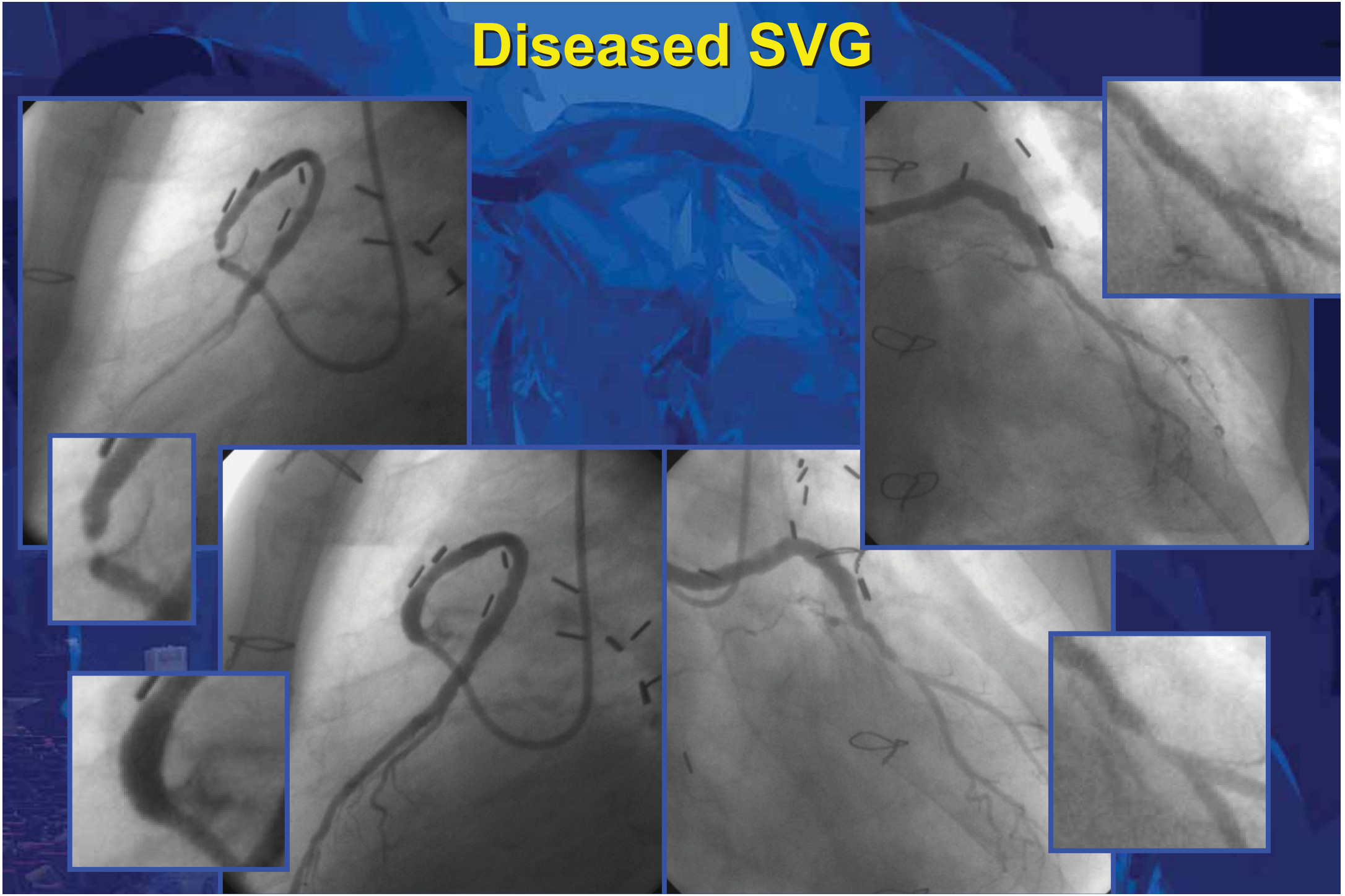
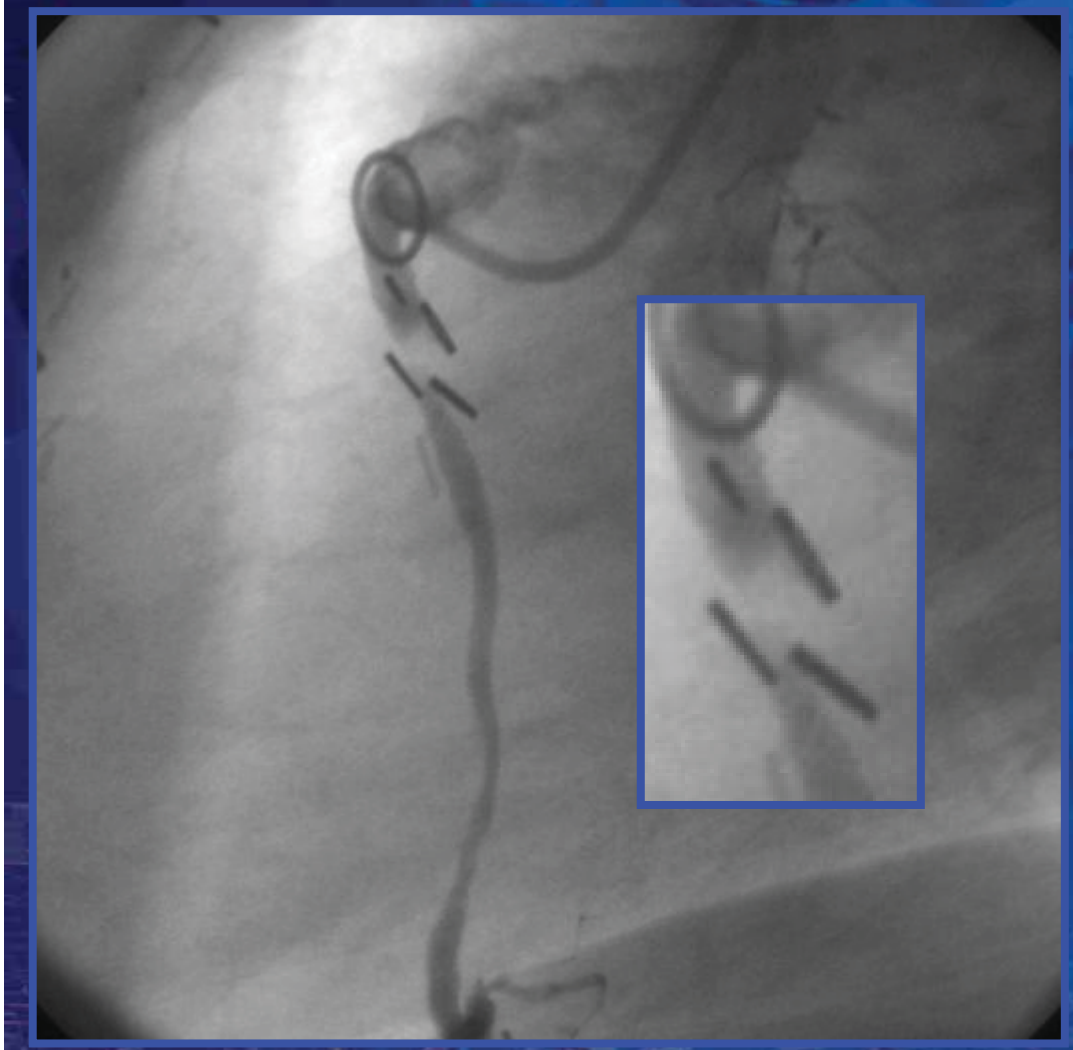
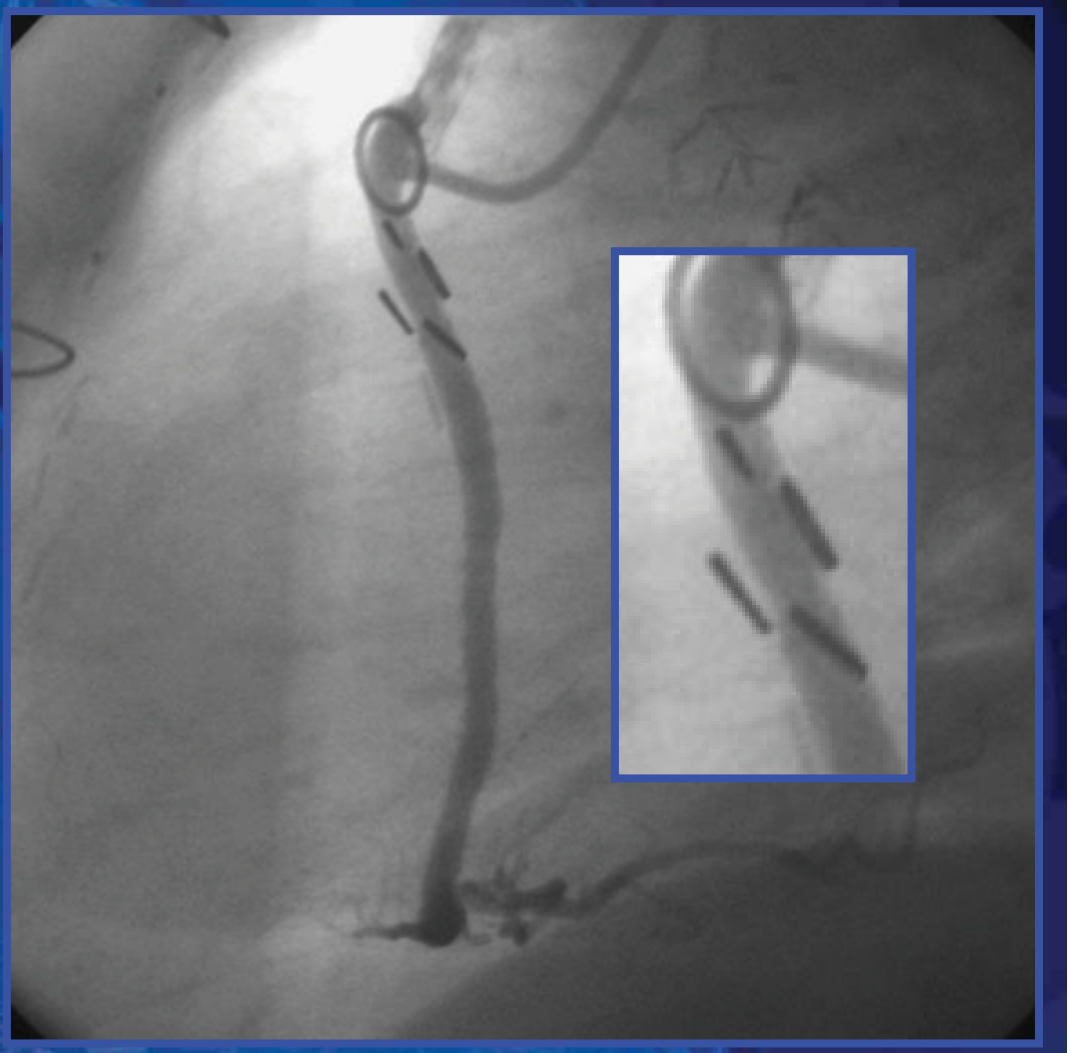
Diseased SVG

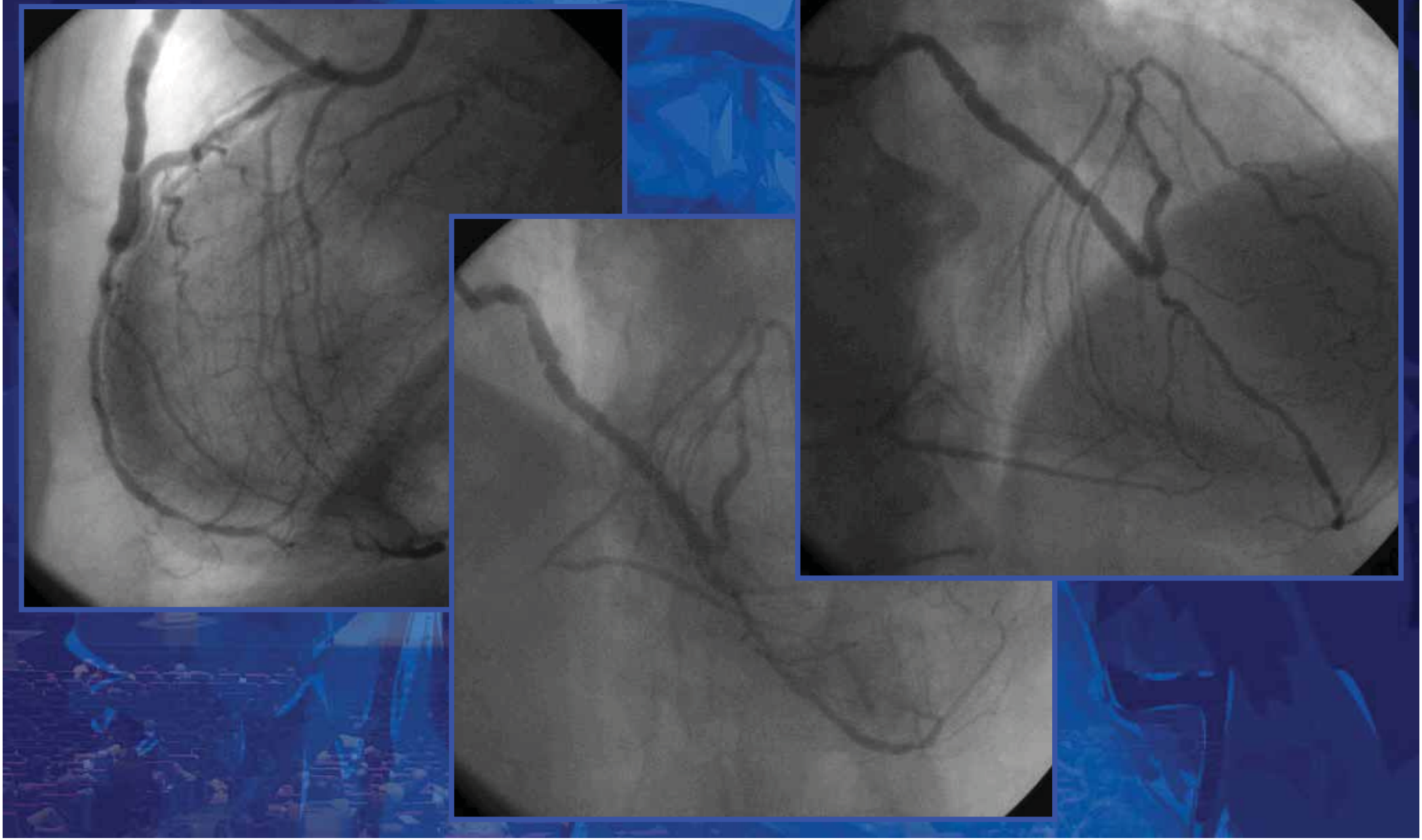


Diseased SVG





Diseased SVG



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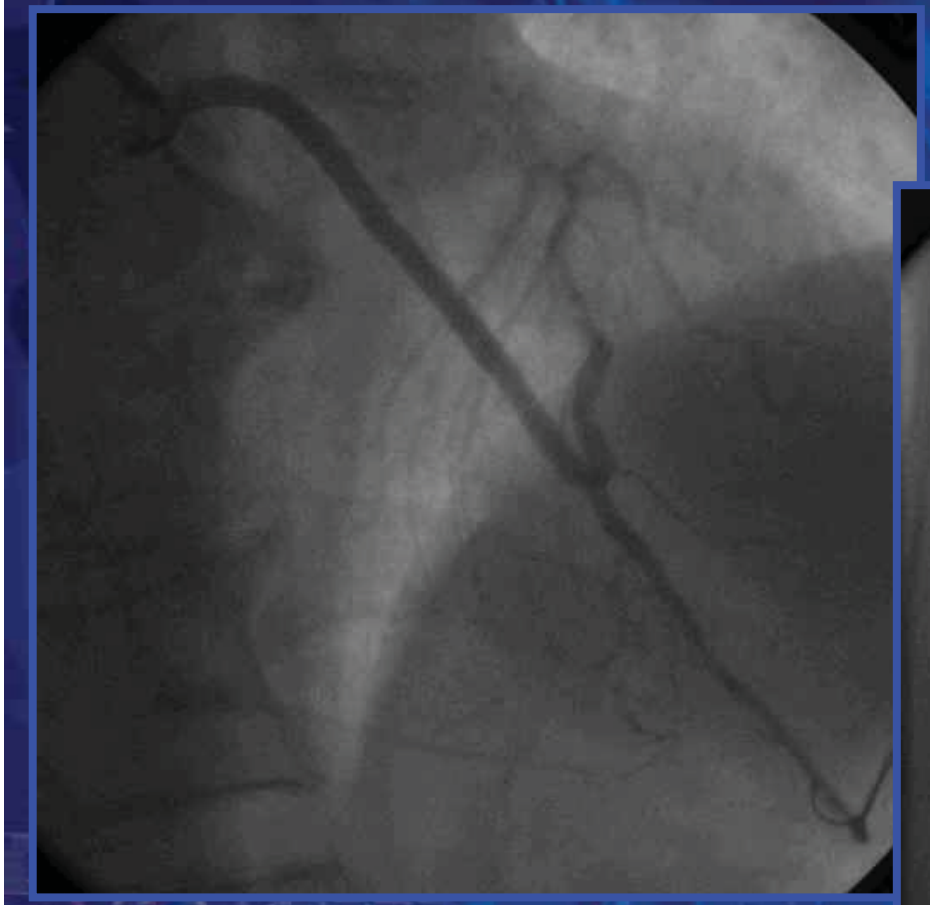
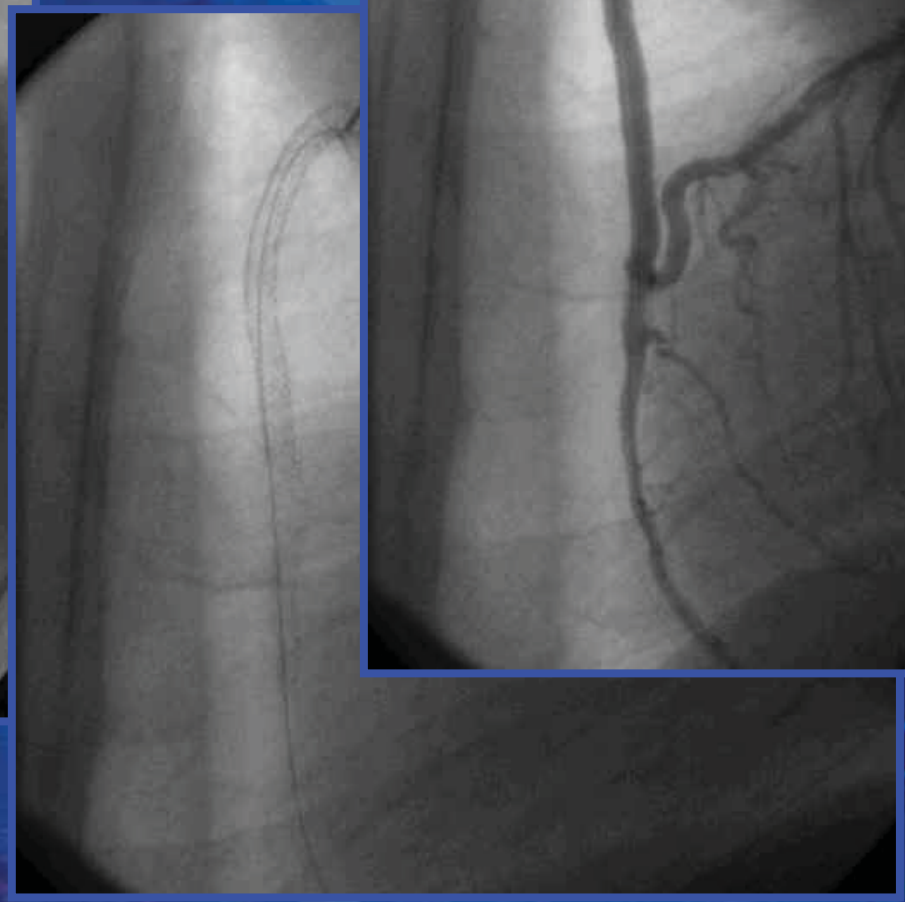
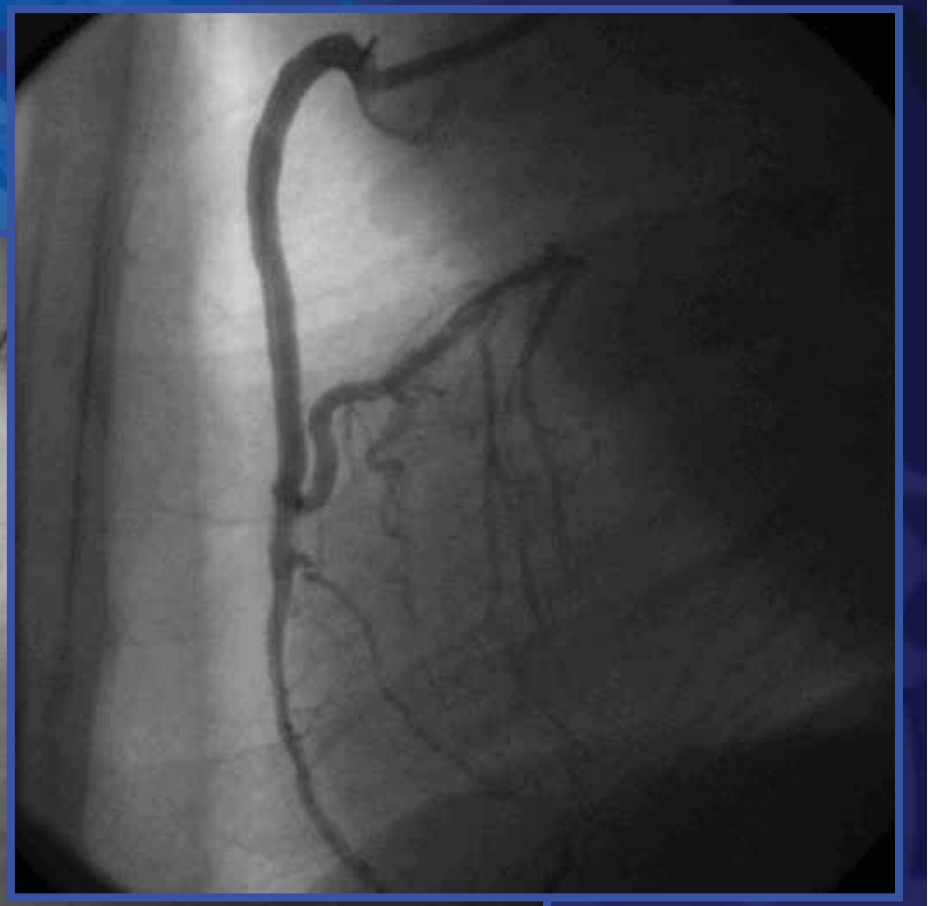


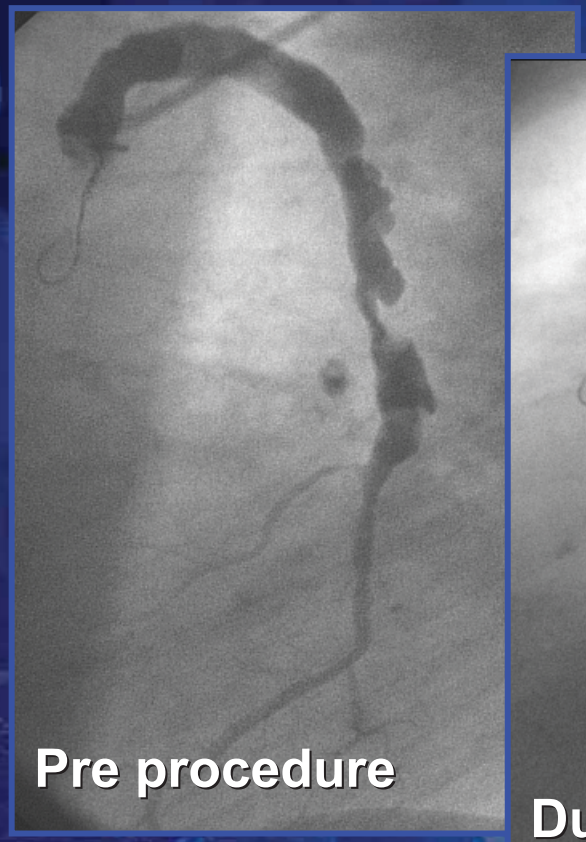




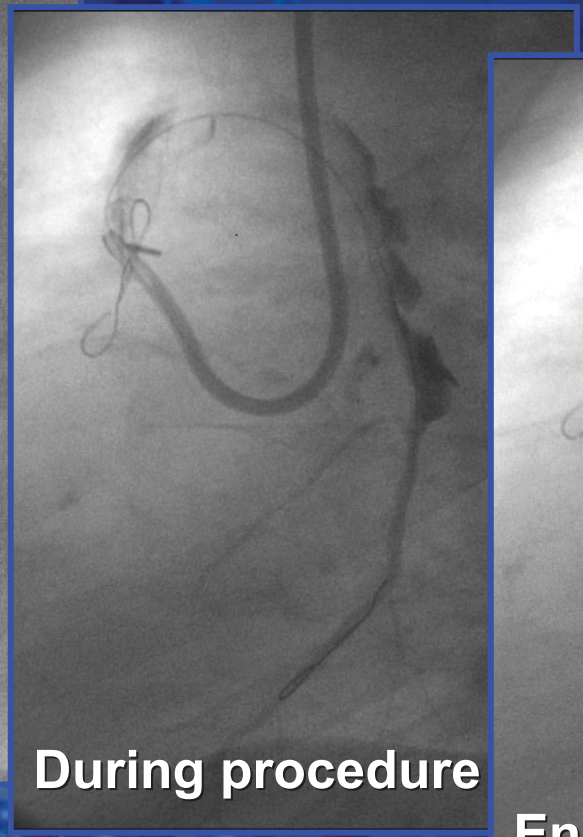

1/ What is exactly the
procedural risk?

Degenerated SVG

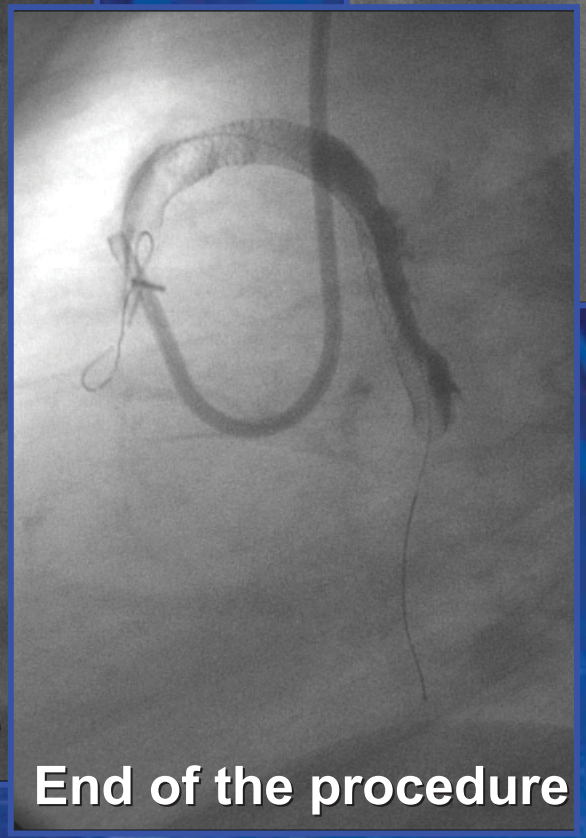
Distal Embolization : 1 - 17%



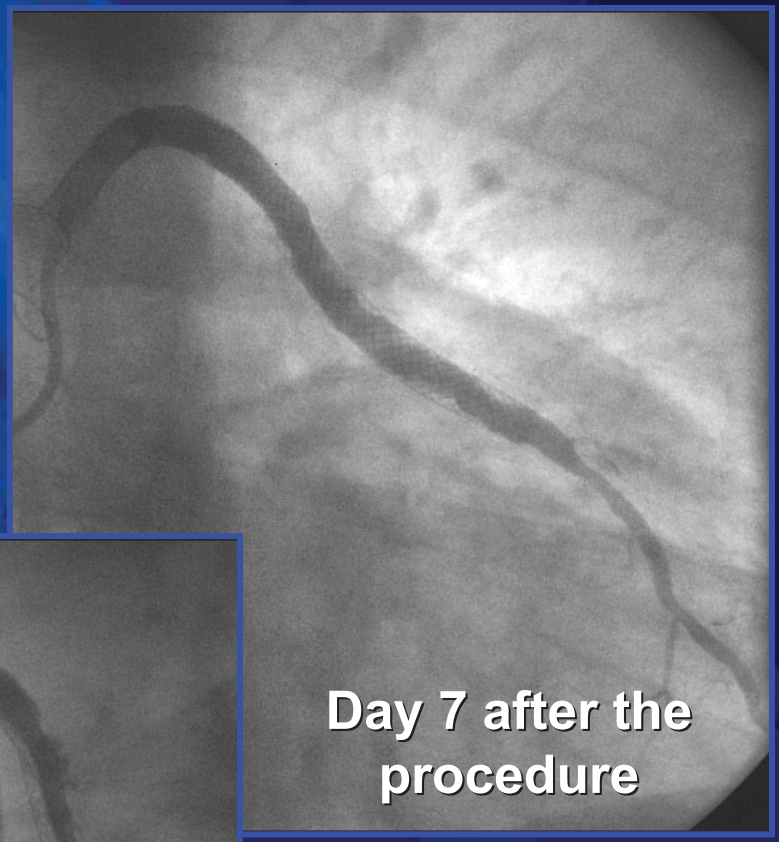
Pre procedure



During procedure



End of the procedure

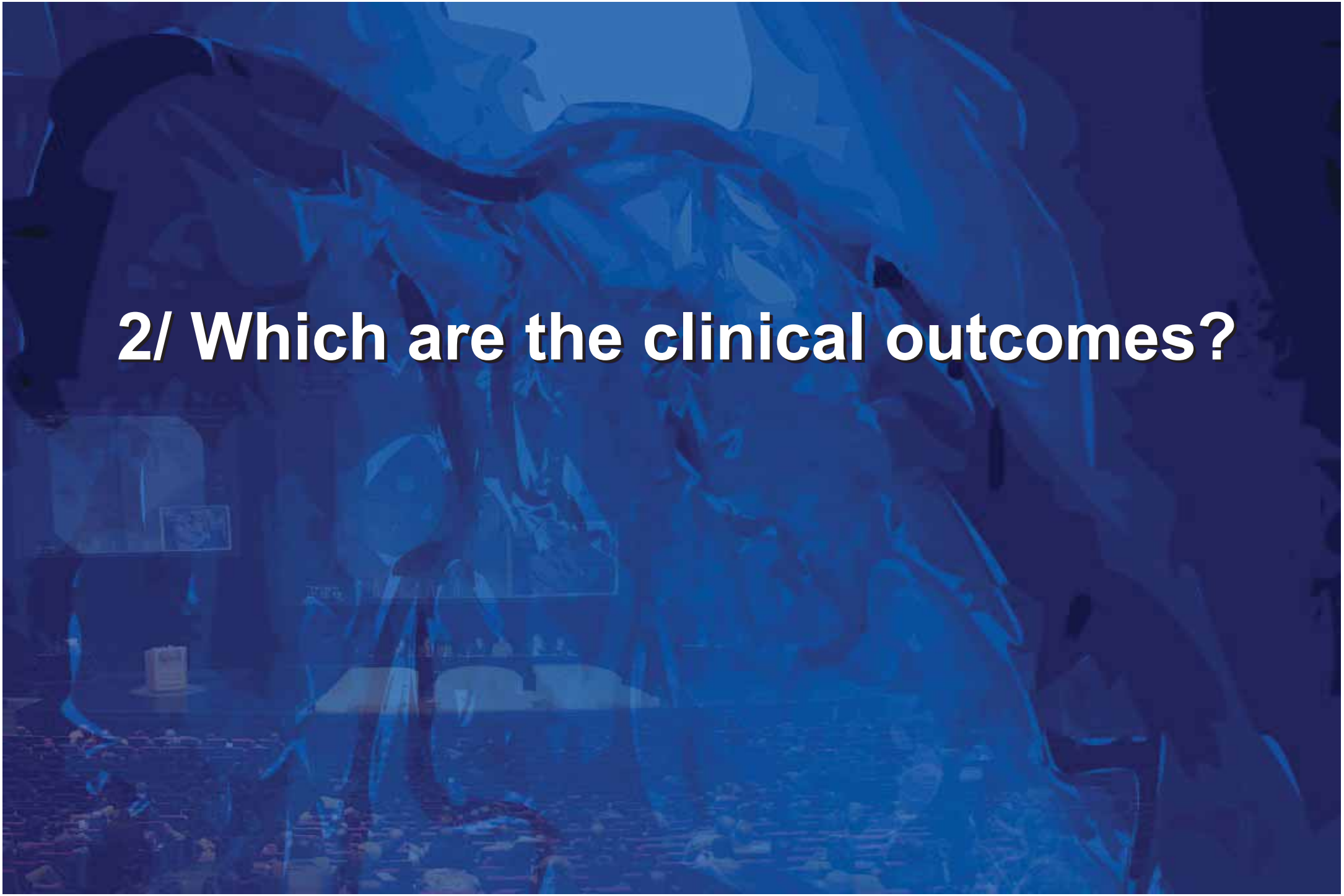


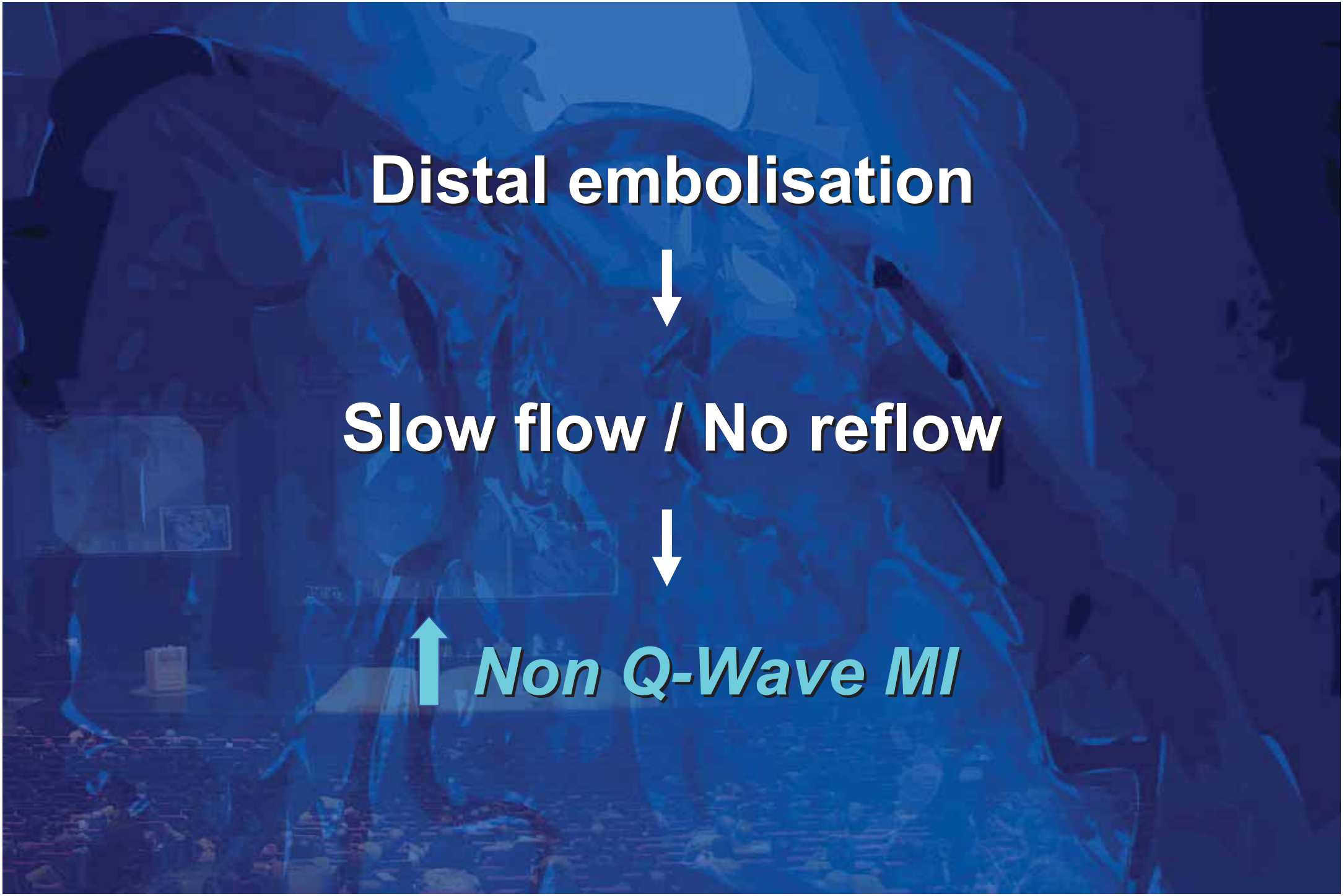
Day 7 after the procedure

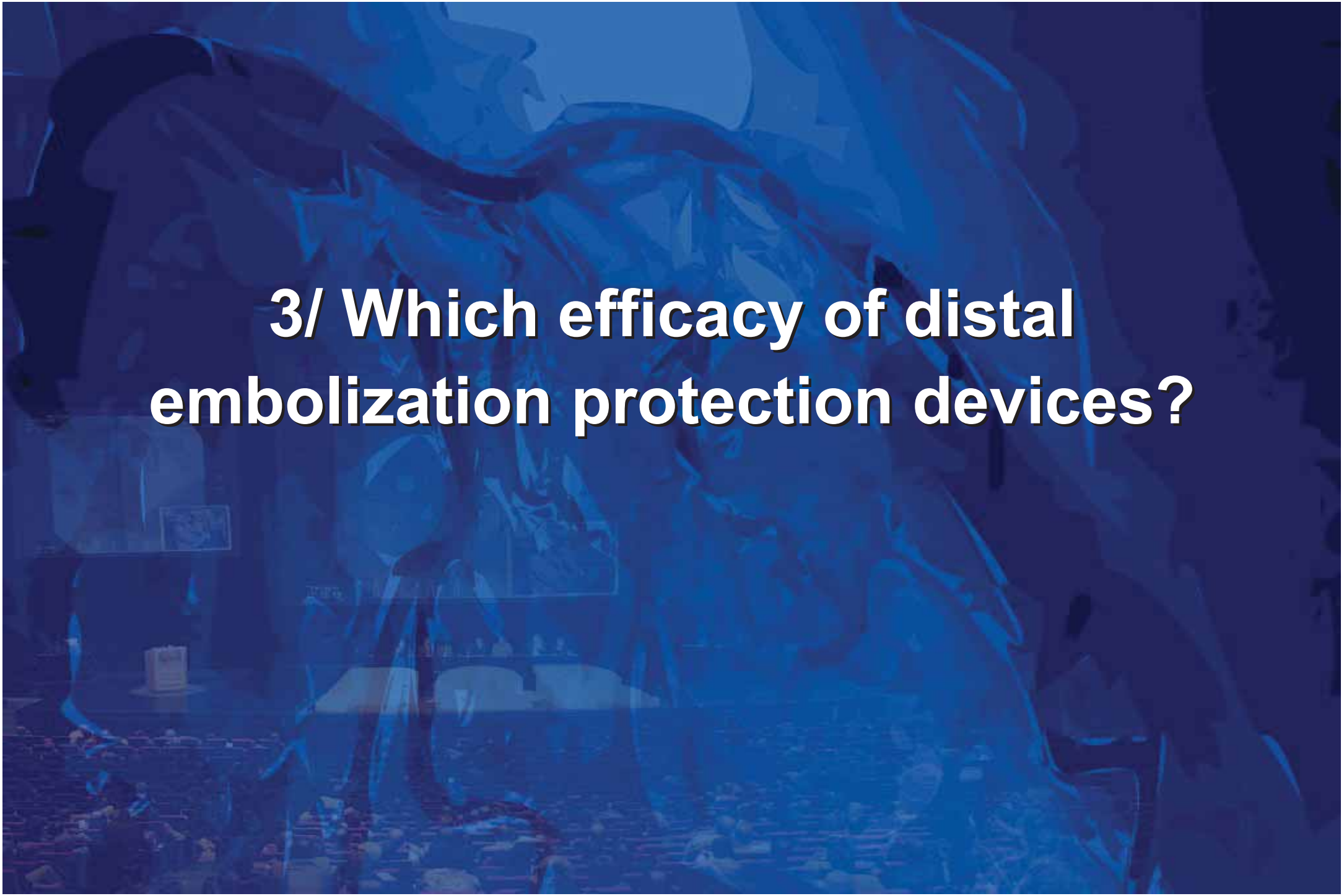
Palmaz-Schatz Stent Placed 3 days Antemortem in a SVG

Focal extrusion of necrotic core contents into the lumen secondary to penetration of stent struts into the lipid core.

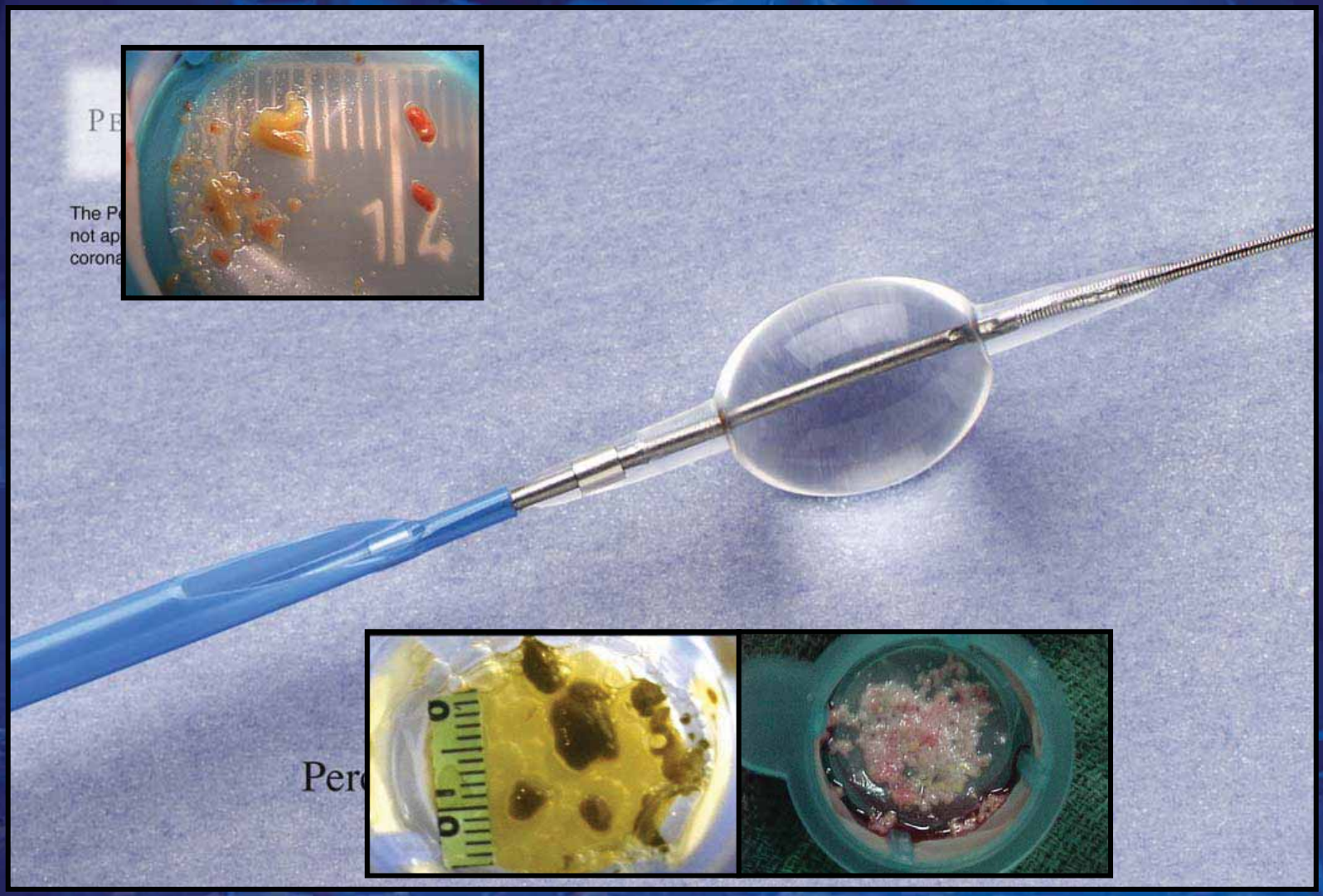
Farb A et al. Circulation 1999; 99: 44-52


2/ Which are the clinical outcomes?


Distal embolisation
Slow flow / No reflow
Non Q-Wave MI


3/ Which efficacy of distal
embolization protection devices?

The GuardWire® Protection System (PercuSurge)



SAFER Study (N=801 patients, 875 lesions)

Postprocedure angiographic characteristics	GuardWire N=406 (442)	Control N=395 (433)	p value
No reflow (%)	3	9	0.001
Distal cut-off (%)	2.2	3.2	0.40
No reflow or distal cut-off (%)	4.8	9.7	0.02
TIMI flow			
0,1	1.5	0.7	0.51
2	0.7	4.2	0.001
3	98	95	0.04

Baim et al. Circulation. 2002; 105: 1285-1290

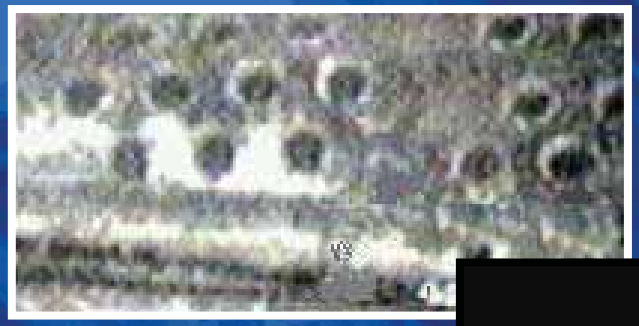
SAFER Study (N=801 patients, 875 lesions)

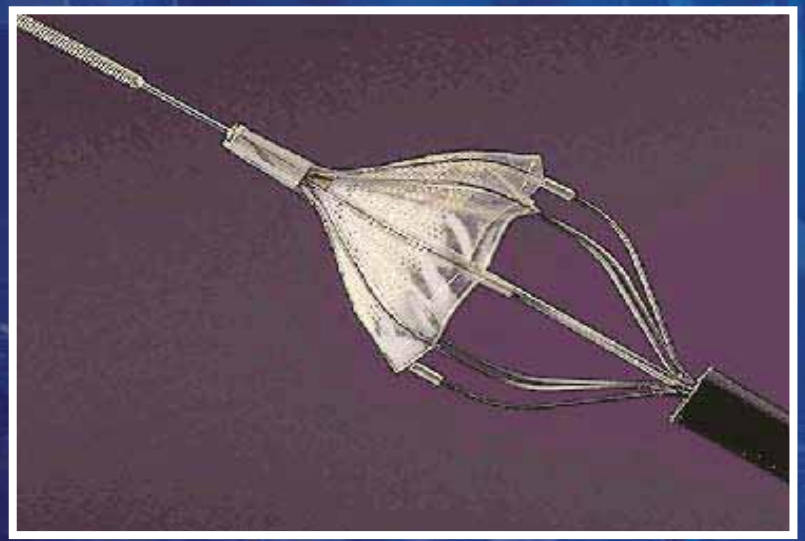
Clinical outcome @ 30 days	GuardWire N=406 (442)	Control N=395 (433)	p value
Myocardial infarction (%)	8.6	14.7	0.008
Q-wave MI (%)	1.2	1.3	NS
Non Q-wave (%)	7.4	13.7	<0.05
Death (%)	1.0	2.3	NS
Em. CABG (%)	0	0.5	NS

Baim s. et al. Circulation 2002; 105: 1285-1290


4/ Are all devices equal?

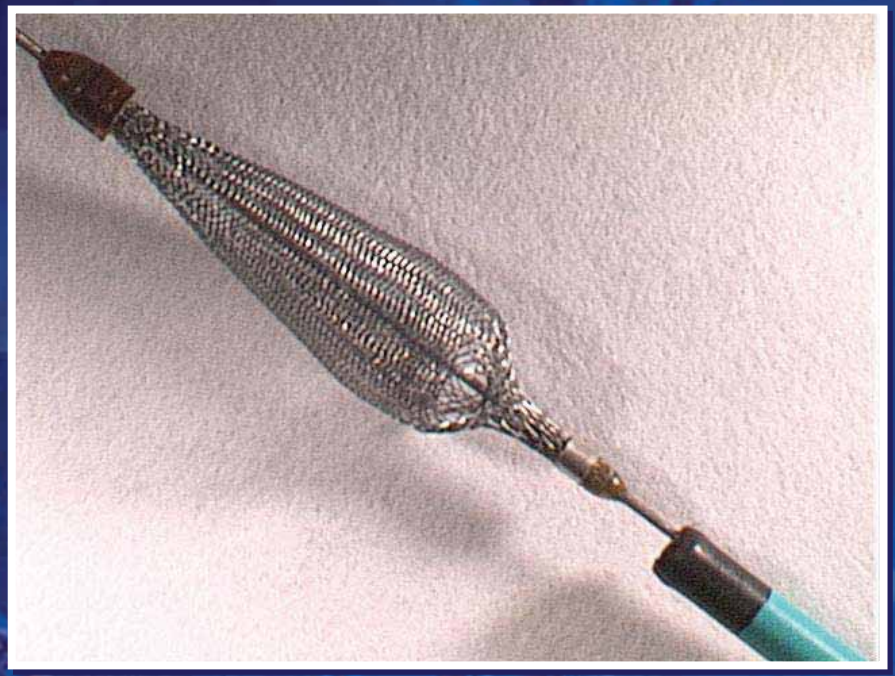
Angioguard (Cordis)

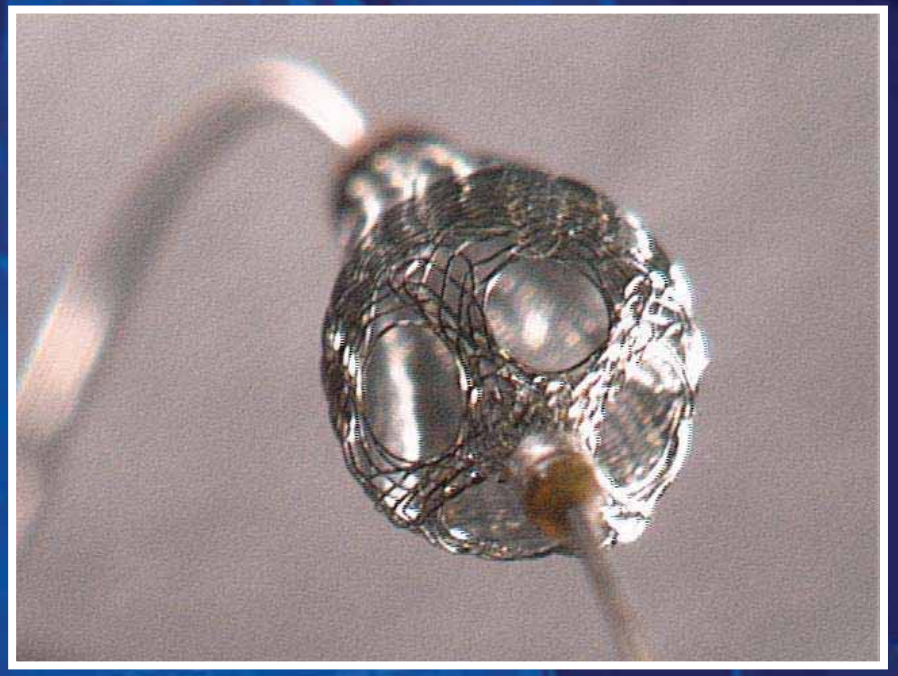




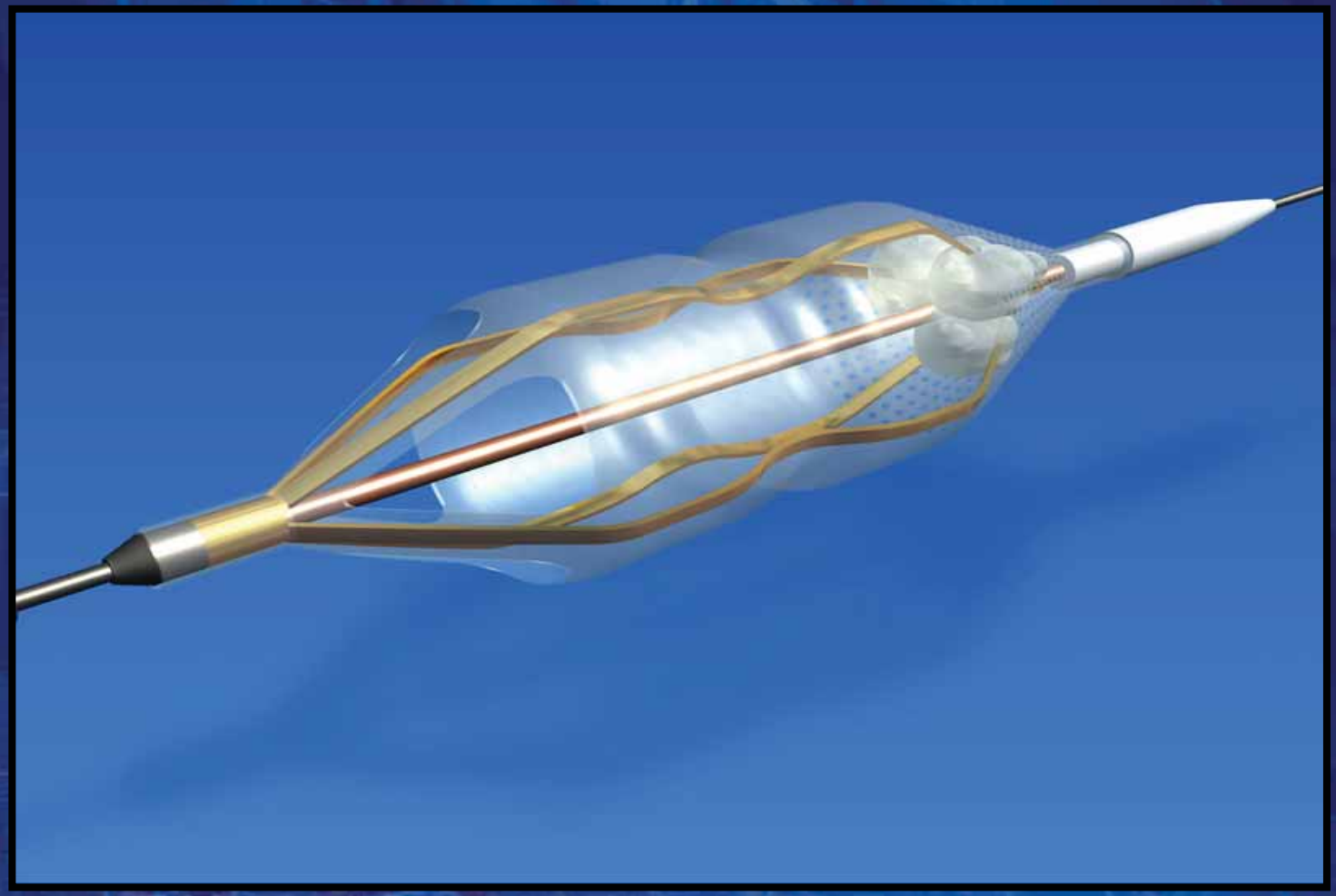
Medtronic

Distal Protection Device

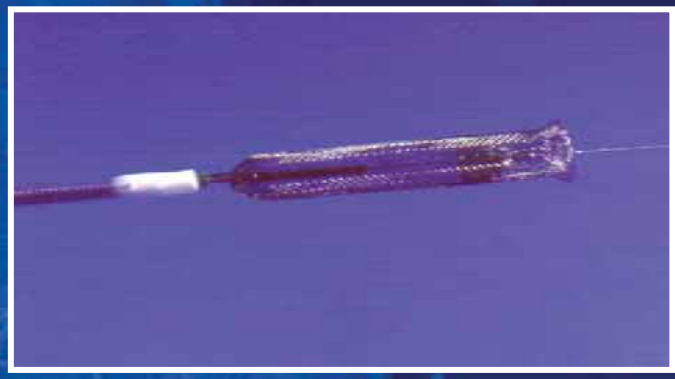




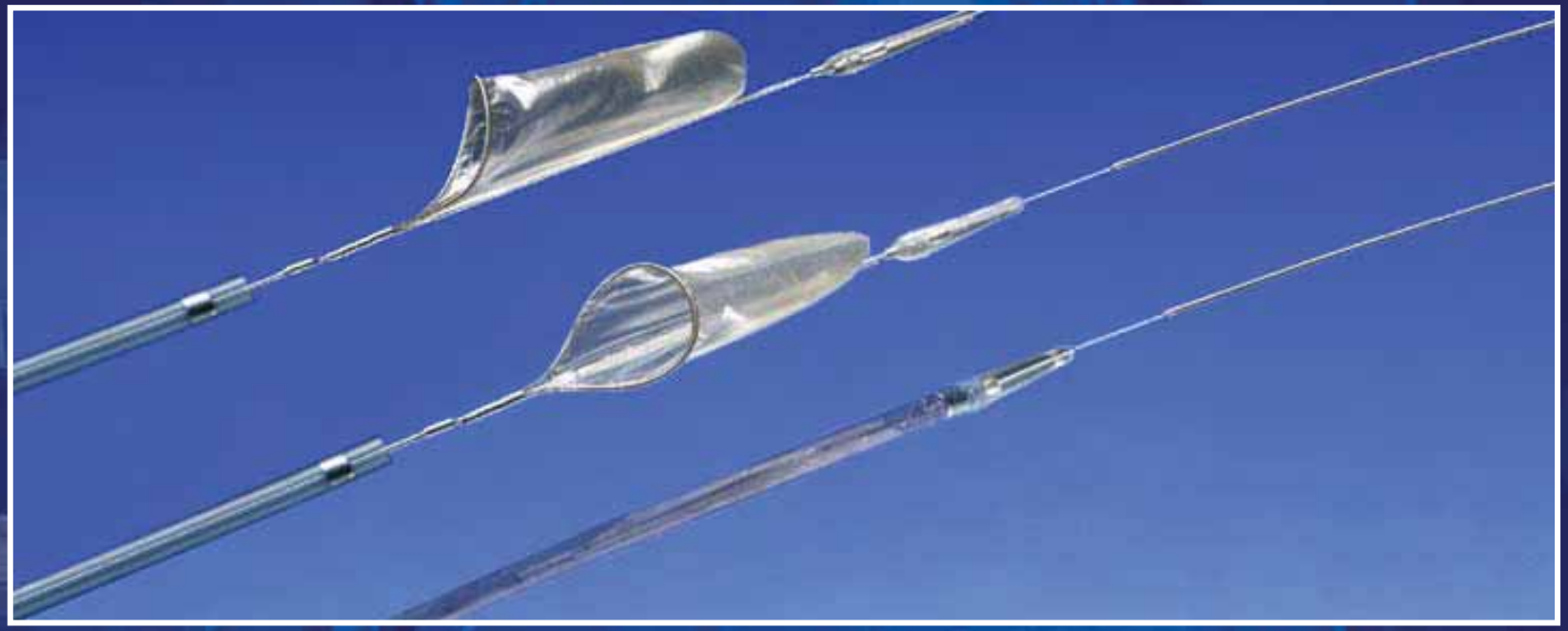
CardioShield MedNova



Trap Microvena



Filter Wire (Boston)



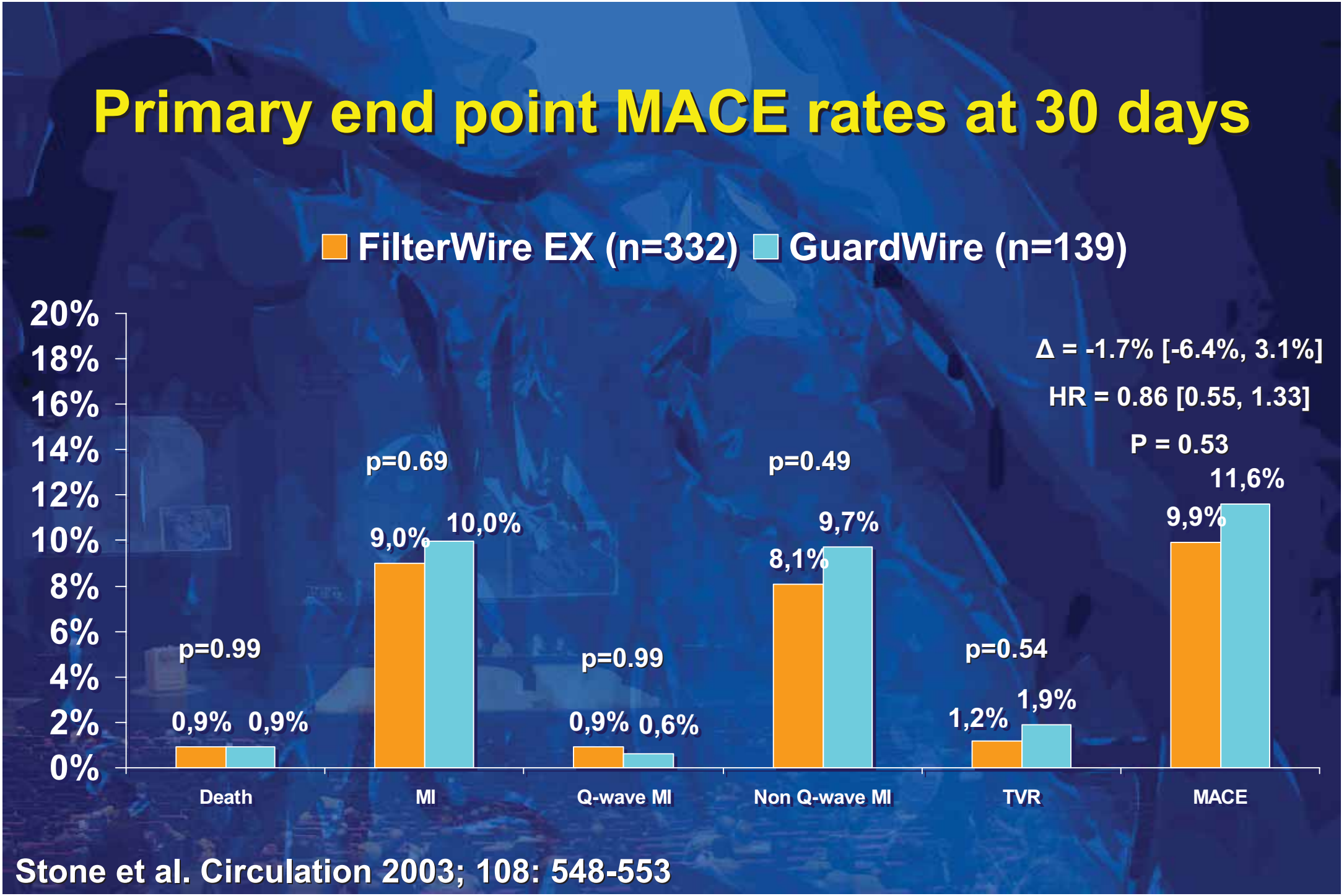
FIRE study (N=651 patients, 682 lesions)

Randomized Comparison of Distal Protection With a Filter-Based Catheter and a Balloon Occlusion and Aspiration System During Percutaneous Intervention of Diseased Saphenous Vein Aorto-Coronary Bypass Grafts

Clinical outcome	GuardWire N=319 (334)	FilterWire N=332 (348)	pvalue
Device Success (%)	97.2	95.5	NS
Clinical Success (%)	86.2	85.8	NS
Distal Embolisation (%)	2.0	2.5	NS
30-day MACE (%)	10.7	9.6	NS
Non Q-wave MI (%)	9.7	8.1	NS

Stone et al. Circulation. 2003; 108: 548-553

Primary end point MACE rates at 30 days



Stone et al. Circulation 2003; 108: 548-553

5/ Critical analysis of SAFER trial

Major Exclusion Criteria in SAFER trial

Ostial graft lesions

Proximal graft lesions

Distal graft lesions

Distal anastomosis lesions

Recent MI

LVEF<25%

Creatinine >2.5mg/dL

Atherectomy device

Baim s. et al. Circulation 2002; 105: 1285-1290

SAFER Study (N=801 patients, 875 lesions)

Procedural characteristics	GuardWire N=406 (442)	Control N=395 (433)
Device failure (%)	9.9	---

Baim s. et al. Circulation 2002; 105: 1285-1290

SAFER Study (N=801 patients, 875 lesions)

Procedural characteristics	GuardWire N=406 (442)	Control N=395 (433)	p value
Direct stenting (%)	79.4	67.7	<0.001
Post stent dilatation (%)	27.3	40	<0.001
Mean balloon size for post dilatation (mm)	4.2 ±0.7		
Ref. Vessel D. (mm)	3.44 ± 0.69	3.42 ± 0.66	NS

Baim s. et al. Circulation 2002; 105: 1285-1290


6/ Can we achieve similar results
without distal protection?

Stent Placement Compared with Balloon Angioplasty for Obstructed Coronary Bypass Grafts

Savage et al. N. Engl. J. Med. 1997; 337: 740

Stent group n=108

Angiographic success: 97%

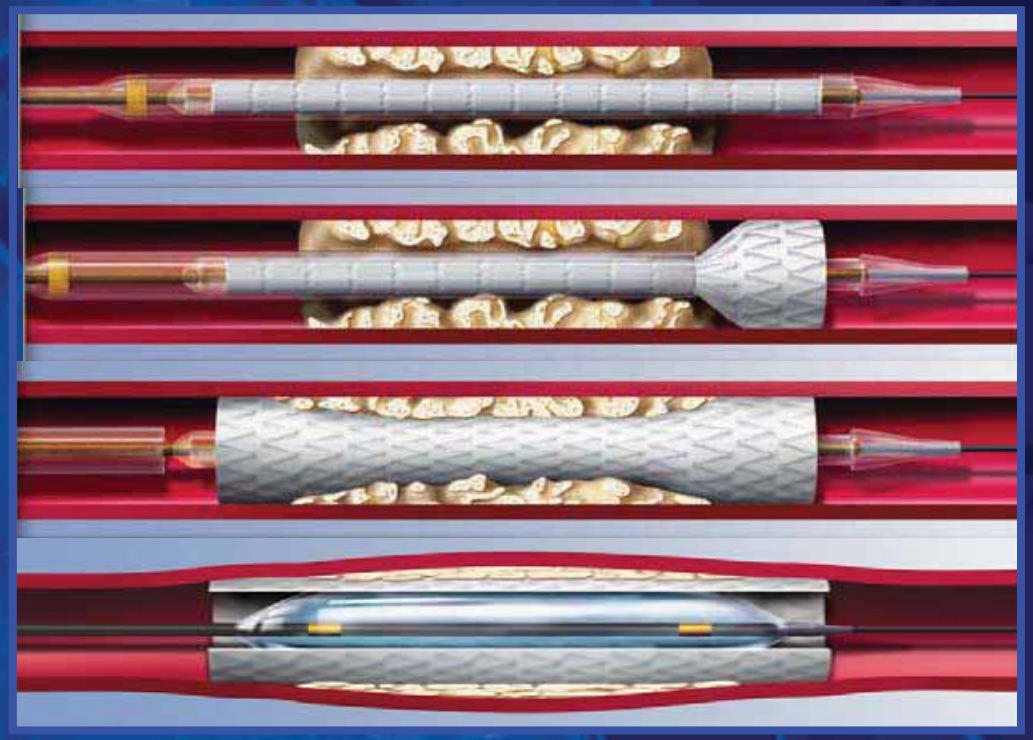
In-hospital events

- Death: 2%
- Q-wave MI: 2%
- Non Q-wave MI: 2%
- CABG: 2%
- Repeat PCI: 1%
- Abrupt vessel closure: 1%

Any event: 6%

7/ Are there other ways to reduce distal embolisation?

Symbiot™ -
An another SVG Solution ?



The SYMBIOT II Registry

77 patients

Mean graft age: 12 years

Mean lesion length: 13.9 mm, Ref. Vessel diam. : 3.5mm

MACE@ 30 day: 5.2% (4/77)

Q-wave : 0

Non-Q-Wave : 3.8%

TVR: 2.6%

(1 pt had>1 event)


8/ Is distal embolisation really the main problem?

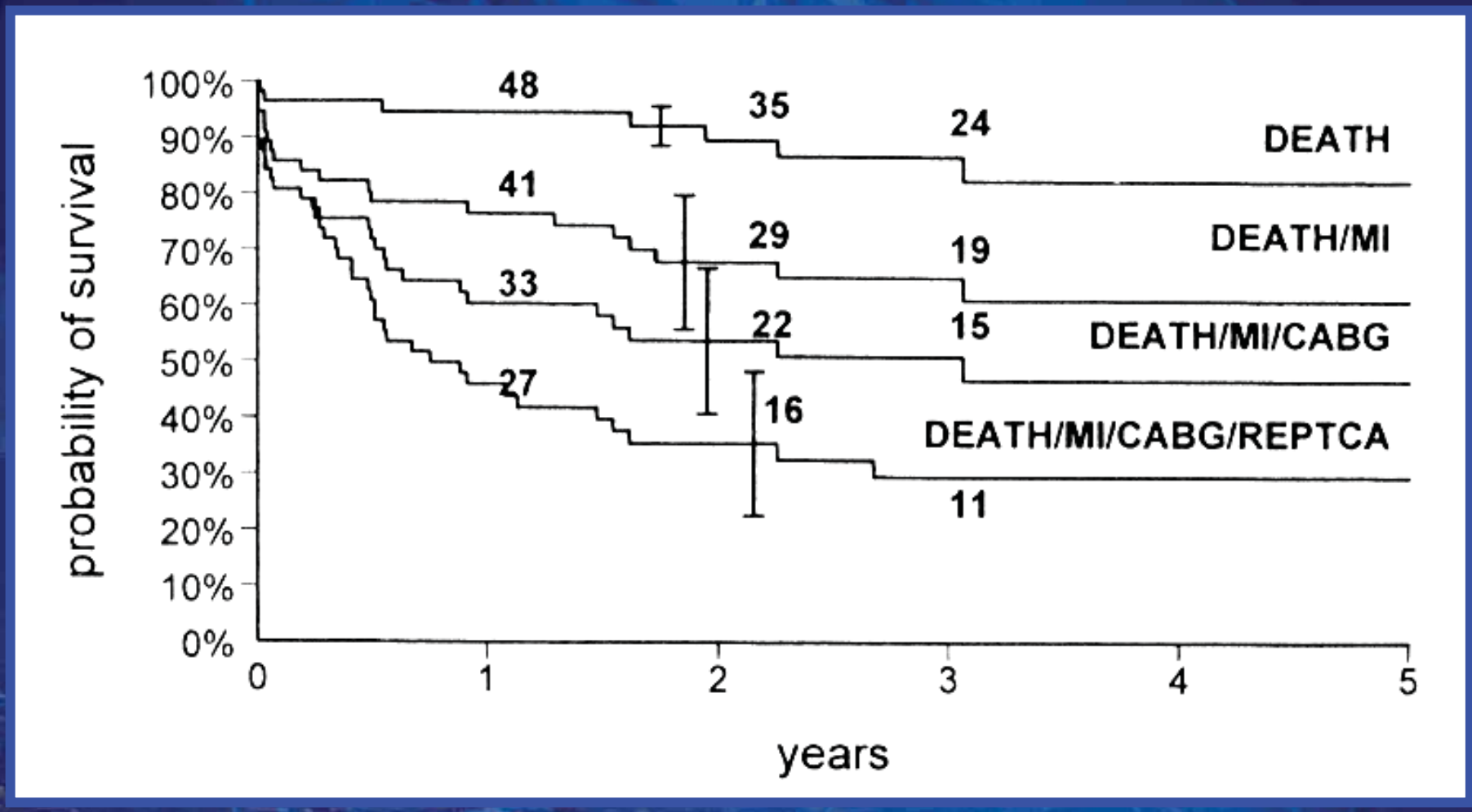
Long Term Outcome of SVG Stenting in High Risk Patients

186 pts (224 lesions) underwent SVG stenting with Palmaz-Schatz stent
(mean graft age 9.4 years)

Procedural success	97.3%
Major acute complications	
Death, Q-wave MI, CABG	*2.7%*
Survival at 4 years	79.0%
Event free survival 4 years	29.0%

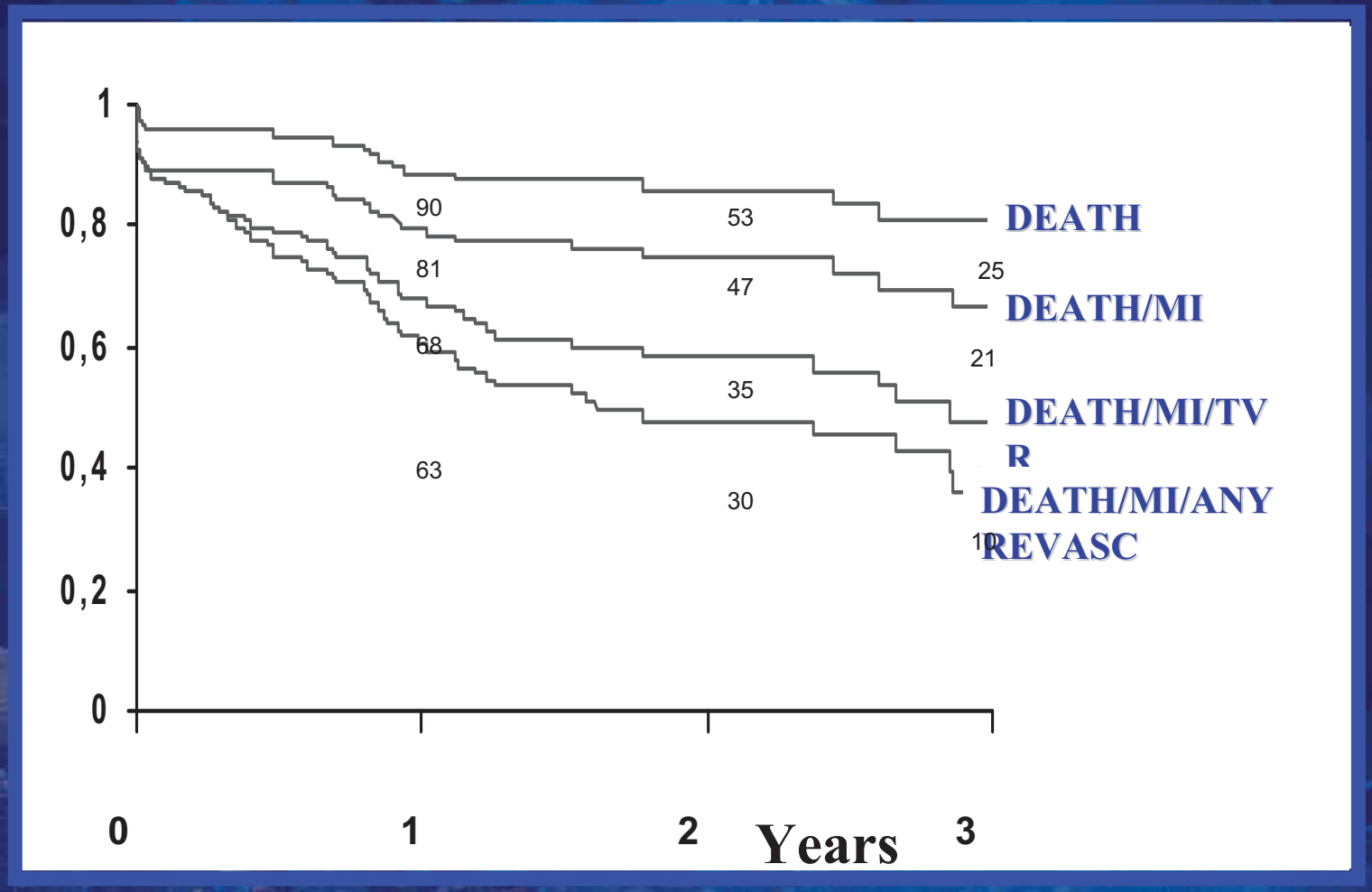
Frimerman et al. J Am Coll Cardiol 1997; 31: 252-258

Long-term outcome after stenting of vein grafts



De Jaegere et al. J Am Coll Cardiol 1996; 28-1: 89-96

Survival and Event-Free Survival Curves of Pts who underwent Wallstent Implantation in a Vein Graft



R. Choussat et al. J Am Coll Cardiol 2000; 36: 387- 394


9/ Can we use these devices in selected patients?

Variables correlating with MACE within 30 days

. Lesion length
. Diameter stenosis
. Presence of thrombus
. SVG degeneration score
. Number of stents
. Total stent length

Stone et al. J Am Coll Cardiol 2002; 40: 1882-8

Stone et al. Circulation. 2003; 108: 548-553

In-Stent Restenosis in Degenerated SVG

Ashby et al. J Am Coll Cardiol 2003; 41: 749-52

N=54 patients

. Without distal embolic protection

. Procedural success: 98%

. No reflow / slow flow: 0

. <u>In-hospital events:</u>

Death:	2%
Cardiac death:	0
Q-wave MI:	0
Non Q-wave MI:	0
Repeat PCI:	0

1/ Lesions of proximal anastomosis: NO

2/ Lesions of distal anastomosis: NO

3/ Lesions of distal native vessel beyond distal anastomosis: NO

4/ In-stent restenosis: NO

4/ Lesions of the body of the graft:

Young graft	NO	Old graft	YES
Low degeneration score		Degenerated	
Short lesion		Long lesion	
Single stent		2 or more stents	
No visible thrombus		Thrombus	
Moderate diameter stenosis		High grade lesion	

10/ Conclusion

These devices are effective to prevent distal embolisation

A selective use based on a careful patient selection, could be considered as an alternative to systematic embolic protection.