Appropriatness of treatment in Primary PCI: wich drugs and wich devices?

Additional mechanical devices

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Sept 05

Primary PCI: Additional mechanical devices

- Embolic protection devices
- Mechanical circulatory support
- Hyperoxemic reperfusion
- Systemic hypotermia

Background

Why additional devices?

- Primary PCI : epicardial coronary patency > 90%
- Despite it, myocardial reperfusion can be suboptimal in a significant part of cases:
  slow flow, no-reflow

Background

No-Reflow phenomenon

No-reflow may be present,
even with TIMI 3 flow after PPCI,
up to 30% of AMI pts.

No-reflow discrepancy: Angiographic vs real.

Epicardial IRA TIMI 3 flow is necessary but not enough to improve perfusion.

Kloner RA, JACC 2004; 43:284-285

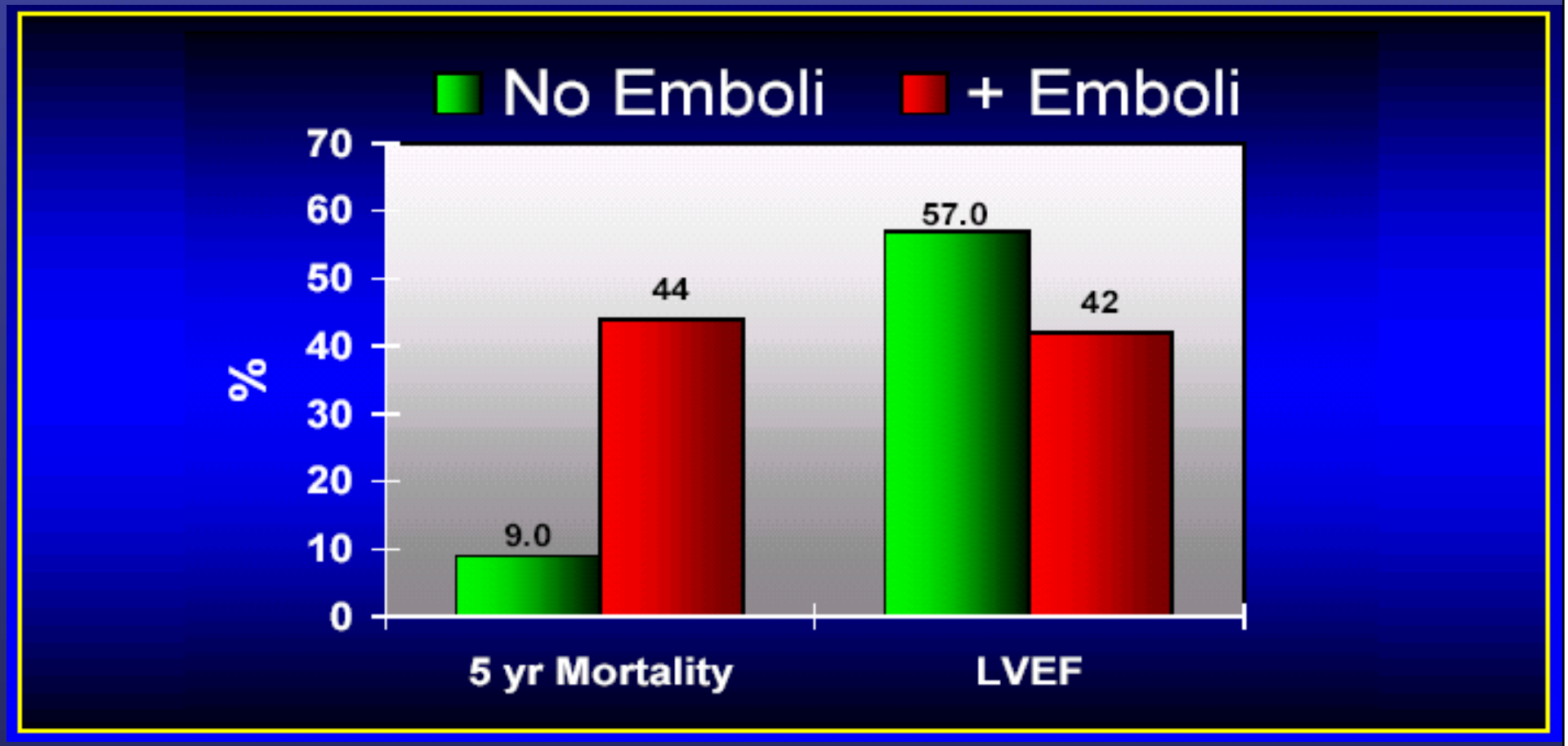
Background

Impaired myocardial perfusion

- Endothelial dysfuntion
- Inflammation
- Myocardial interstizial edema
- Riperfusion injury
- Distal embolization

Background

- Distal embolization may be a major component of impaired myocardial reperfusion: **microvascular obstruction**
- Impaired perfusion correlates with negative clinical outcome



Henriques JP et al. Eur Heart J.2002; 23:1112-7

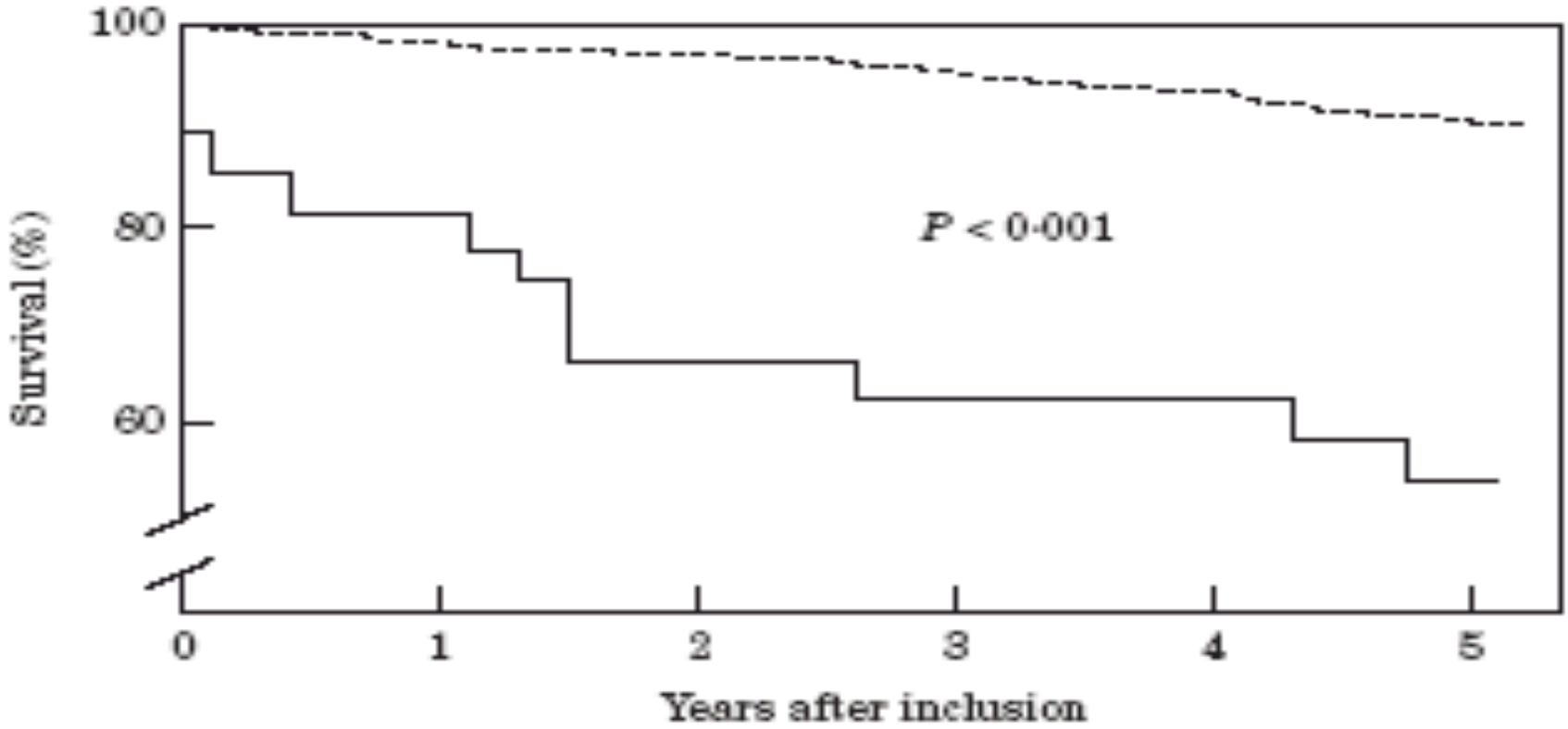


Figure 2 **Long-term survival in patients with (——) or without (– – –) distal embolization ($P<0·001$).**

Henriques JP et al. Eur Heart J.2002; 23:1112-7

Assessment of myocardial reperfusion

- ST resolution
- TIMI flow grade
- corrected TIMI frame count
- Myocardial blush grade

- MRI / nuclear-scan infarct size
- Myocardial contrast-echo

Embolic protection devices

Assessment of Distal embolization

Angiographic	**~**	**15%**
Macroscopic	**~**	**30%**
Microscopic	**up to**	**100%**

Embolic protection devices

14.354 PPCI in Italy, during 2004

2.840 (20%) with thrombus aspiration devices

Società Italiana di Cardiologia Invasiva aprile 2005

Embolic protection devices

Distal

Occlusion + aspiration

- Percusurge Guard-wire

Filter

- Filter-wire, Angioguard

Proximal

- **Thrombectomy**
  - Reolytic: Angiojet
  - Helical cutter: X-Sizer
  - Kerberos: rinspiration
- **Aspiration**
  - Diver CE , Export, Pronto, Rescue, Proxis

Medtronic

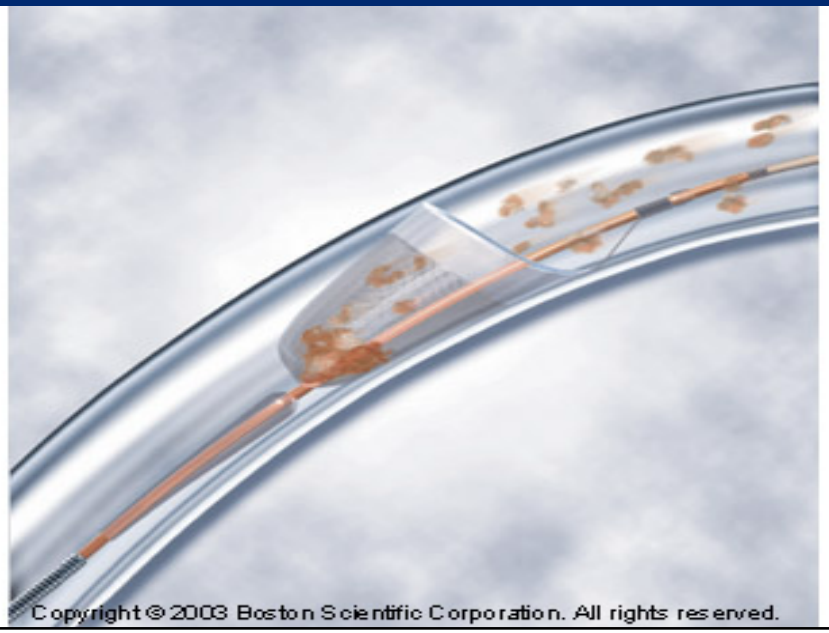
Distal ballon occlusion + post PCI debries aspiration

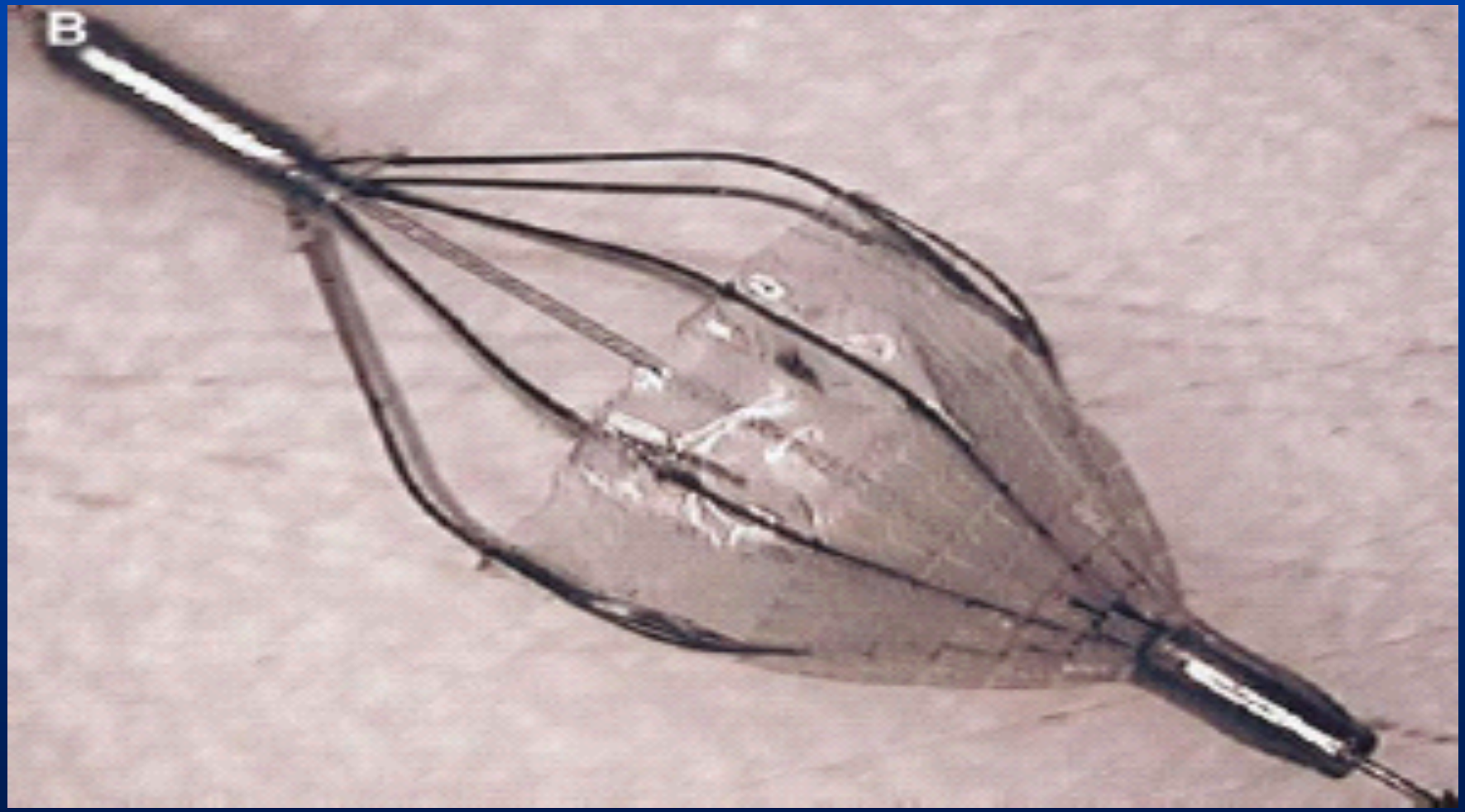
EX

Boston Scientific Corp.

EZ

Filter Wire EZ ™

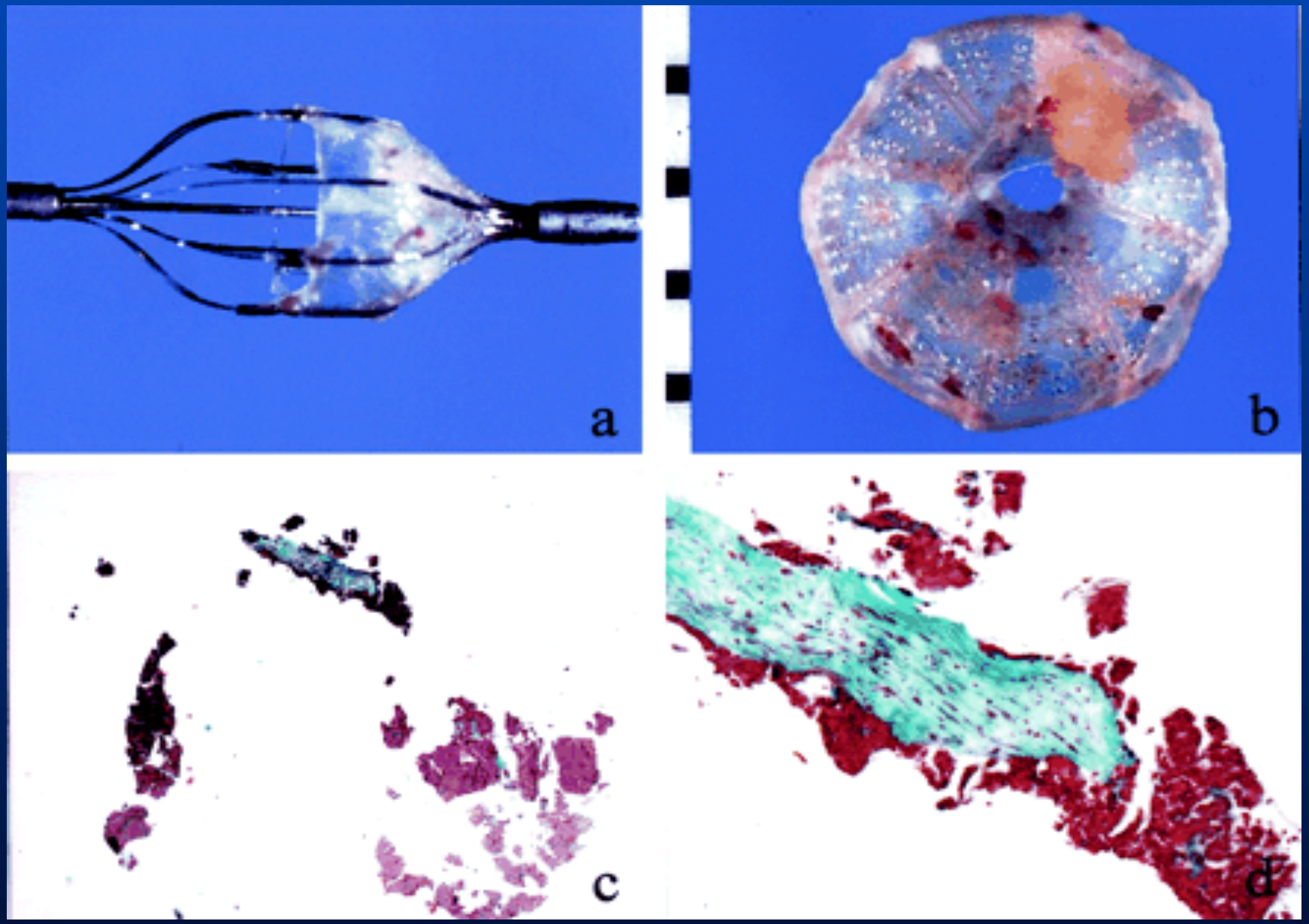




Cordis Corp.

Angioguard guard-wire: distal filter

Angioguard guard-wire



x6

x 31

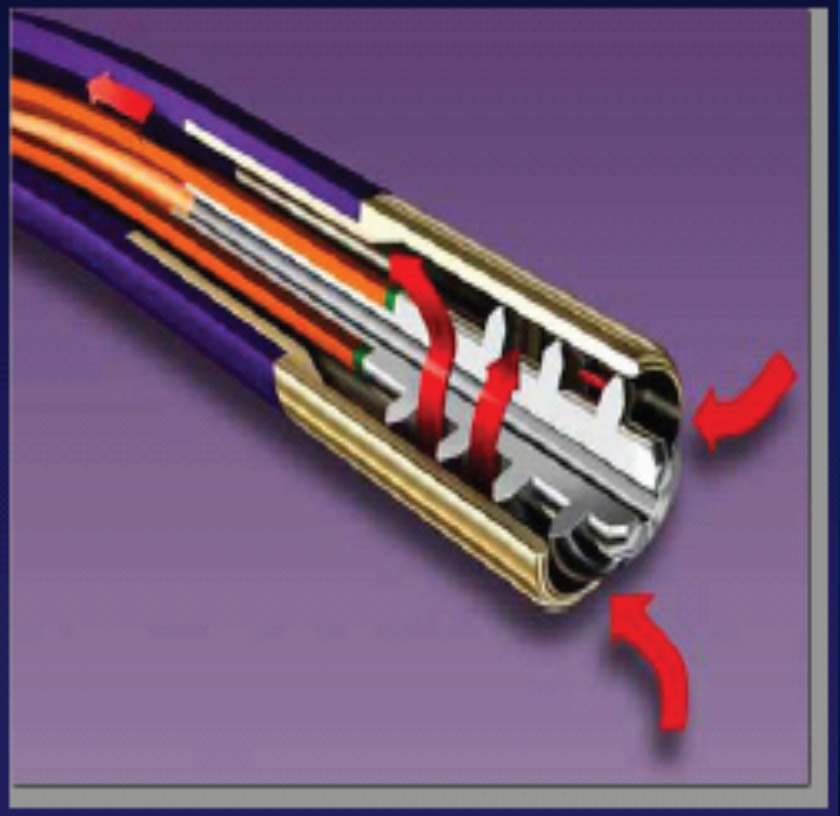
Angelini A et al. Circulation. 2004 Aug 3;110(5):515-21.

Thrombectomy devices

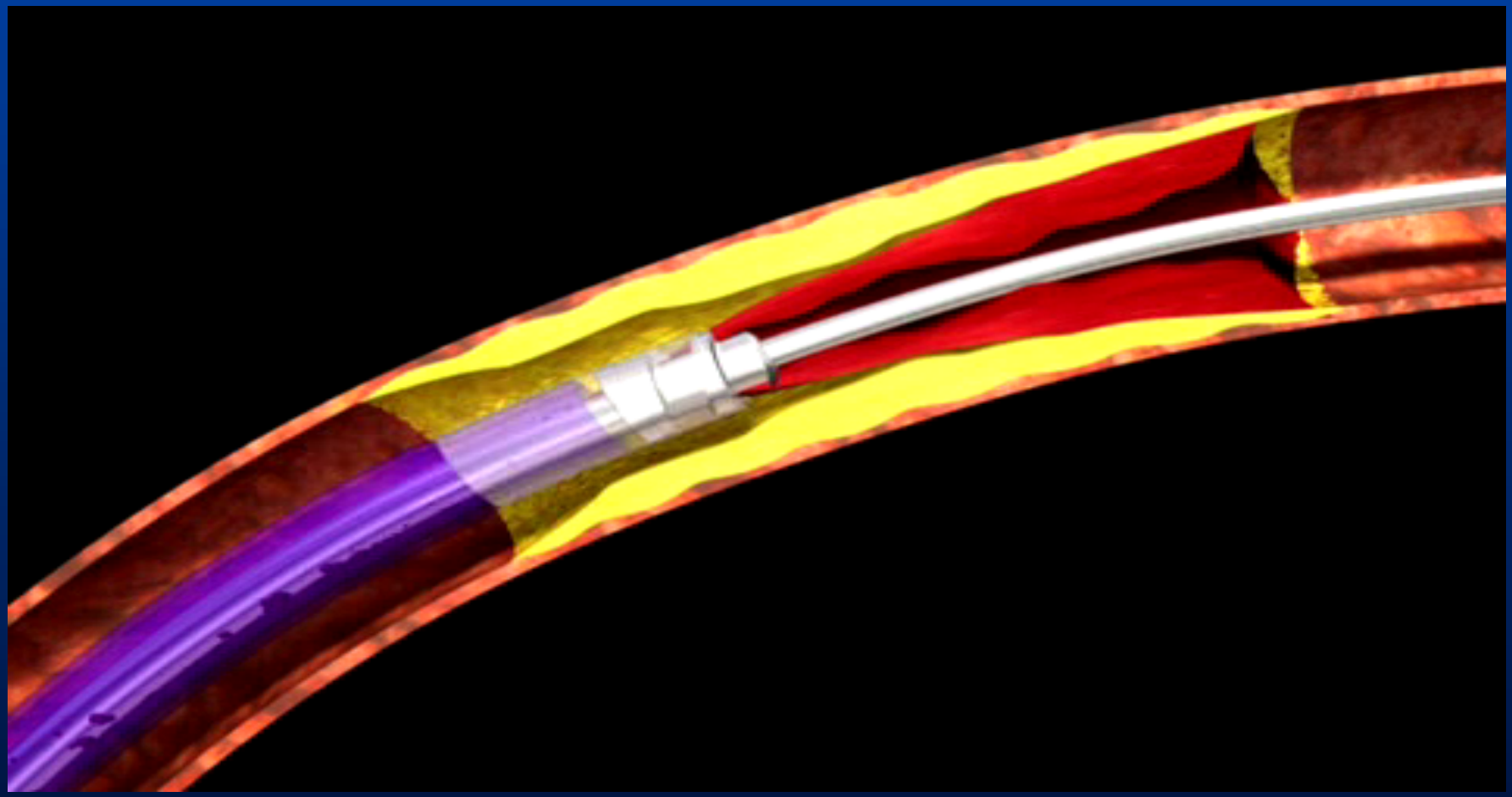
AngioJet®XMI™

Possis

Ev3 (EndiCOR) X-Sizer



Thrombectomy + aspiration

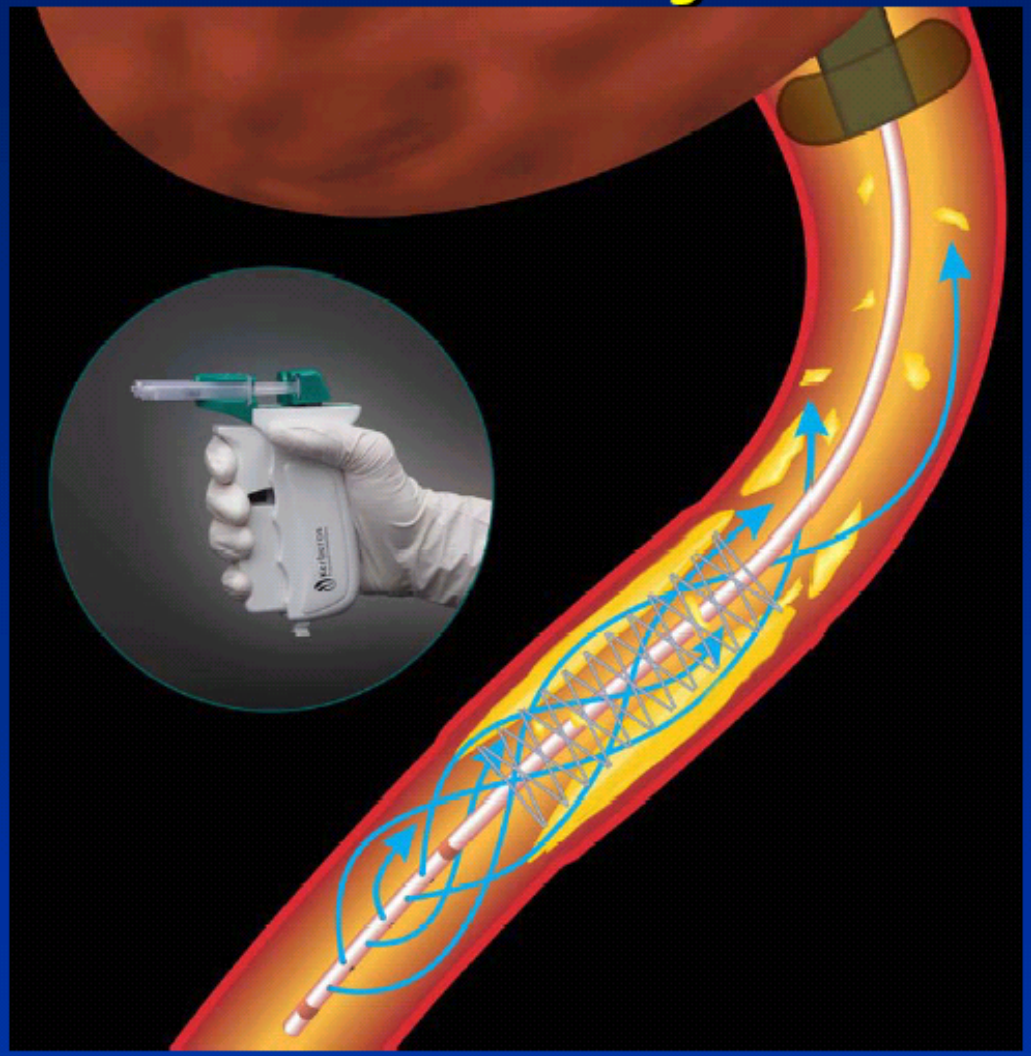


X-Sizer

Rinspiration with Proximal Occlusion

Proximal Protection = Embolic Protection

The KEPT System

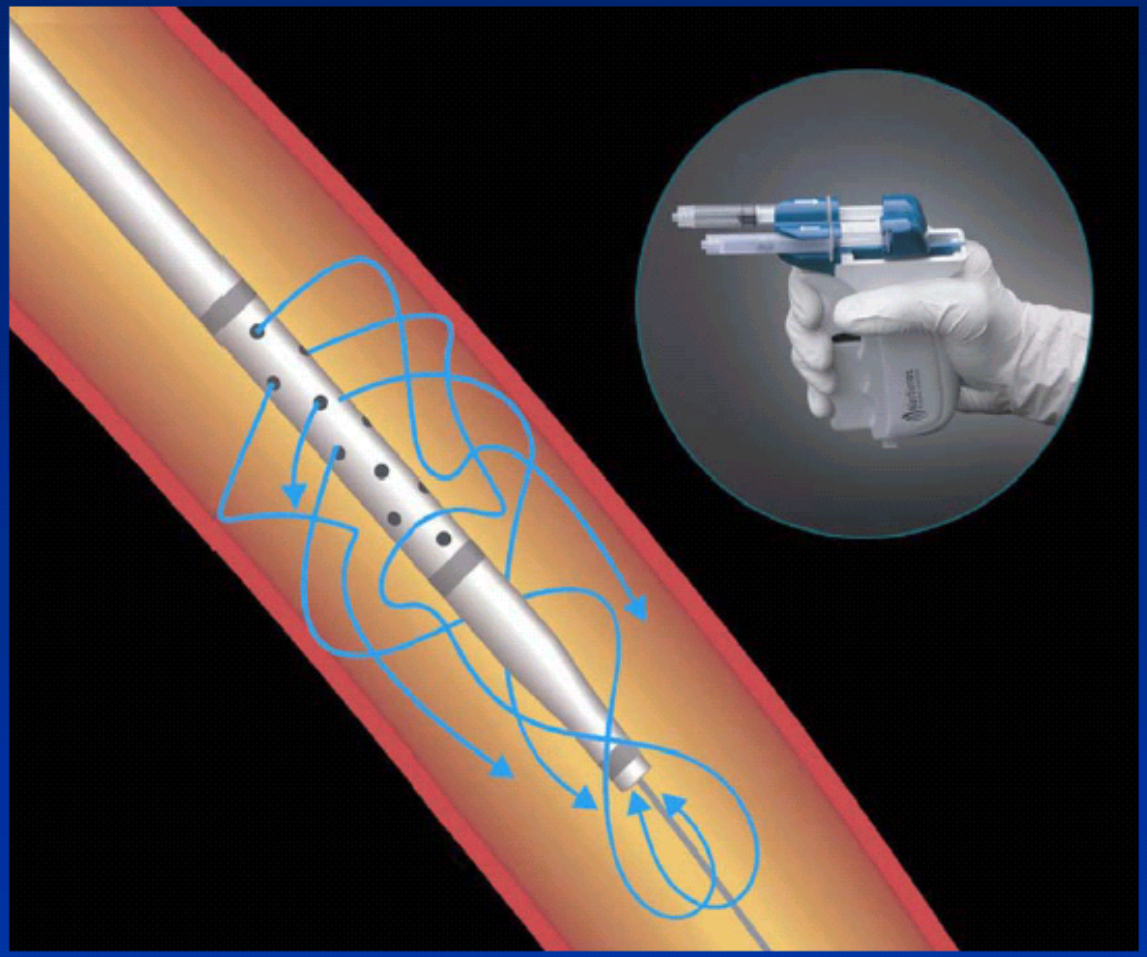


Kerberos

Rinspiration without Occlusion

The Rinspiration System

Indicated for Coronary & Peripheral Use
Simultaneous rinsing and aspiration



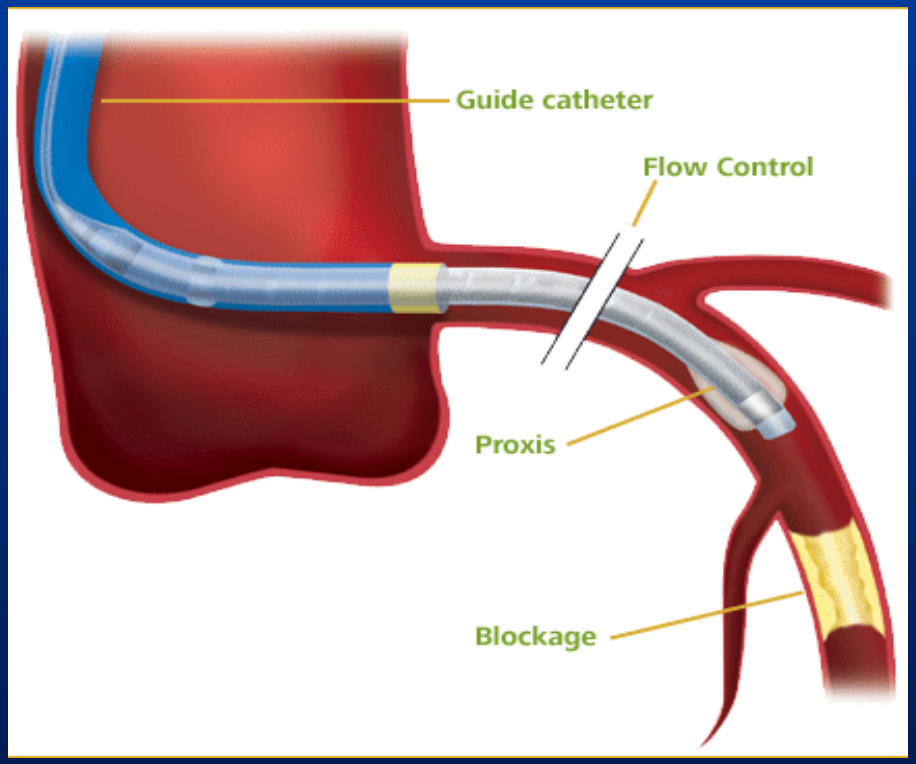
- CRAFT

- German Rinspiration in AMI

Kerberos

Proxis ™

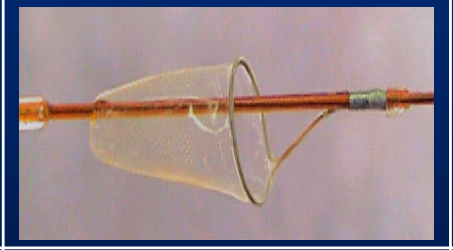
Embolic Protection System



St. Jude Medical

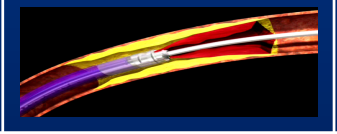
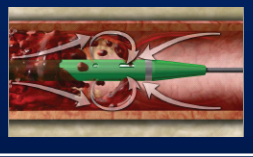
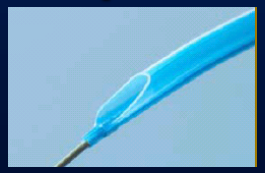
Distal protection in AMI

Occlusion / filter Trials

Trial	Devices	sites	pts	results	publication
●Emerald	Percusurge	38	501	-	JAMA Mar 05
●Asparagus		22	329	-	no: TCT 04
●Promise	Filter wire	1	200	-	Circ Sept 05
●Limbruno		1	53	+	Circ Jul 03
● Diplomat	Angioguard	5	60	+	no : TCT 04
					

Proximal protection in AMI

Thrombectomy-aspiration Trials

Trial	Device	sites	pts	results	publication
●Remedia	Diver CE	1	100	+	JACC Jul 05
●APSAC		8	120	+	no: ANMCO 05
●X-Amine	X-Sizer	13	201	+	JACC Jul 05
●Napodano		1	92	+	JACC Oct 03
●AiMI	AngioJet	31	480	-	no : TCT 04
●Antoniucci		1	100	+	Am J Card Apr 04
●Export	Export	1	50	+	no : PCR 05
					

Embolic protection devices

Distal protection

conclusions

Despite efficacy (70 to 100%) in prevention of distal embolization

distal protection fails to improve reperfusion after

PPCI in AMI. (EMERALD, PROMISE)

"Too little, too late" to achieve meaningful myocardial salvage? (Gregg Stone)

Embolic protection devices

Proximal protection

conclusions

Better results in some trials, but

- Many single centre study
- Small number of patients
- Surrogate endpoints
- Controversial results

More data are needed, based on large trials with clinical endpoints, to get appropriate level of evidence.

Embolic protection devices

ESC guidelines for PCI:

At present, no definite recommendations can be given regarding the use of embolic protection devices in the setting of STEMI.

Eur. Heart J. 2005 Apr;26(8):804-47

Percutaneous Mechanical Circulatory Support

IABP Intra-Aortic ballon counterpulsation

LVADs Left Ventricular Assist devices

IABP

More than 160.000 IABPs /year worldwide

Reduce ventricular afterload

Increase cardiac output

Increase coronary perfusion

Indications:

Cardiogenic shock (class I ACC/AHA 2004 guidelines)

Prophylattic in high risk:

- EF < 30%,
- lesion location (left main, only rem. Vessel)

Timing

Correct IABP Timing

A = One complete cardiac cycle

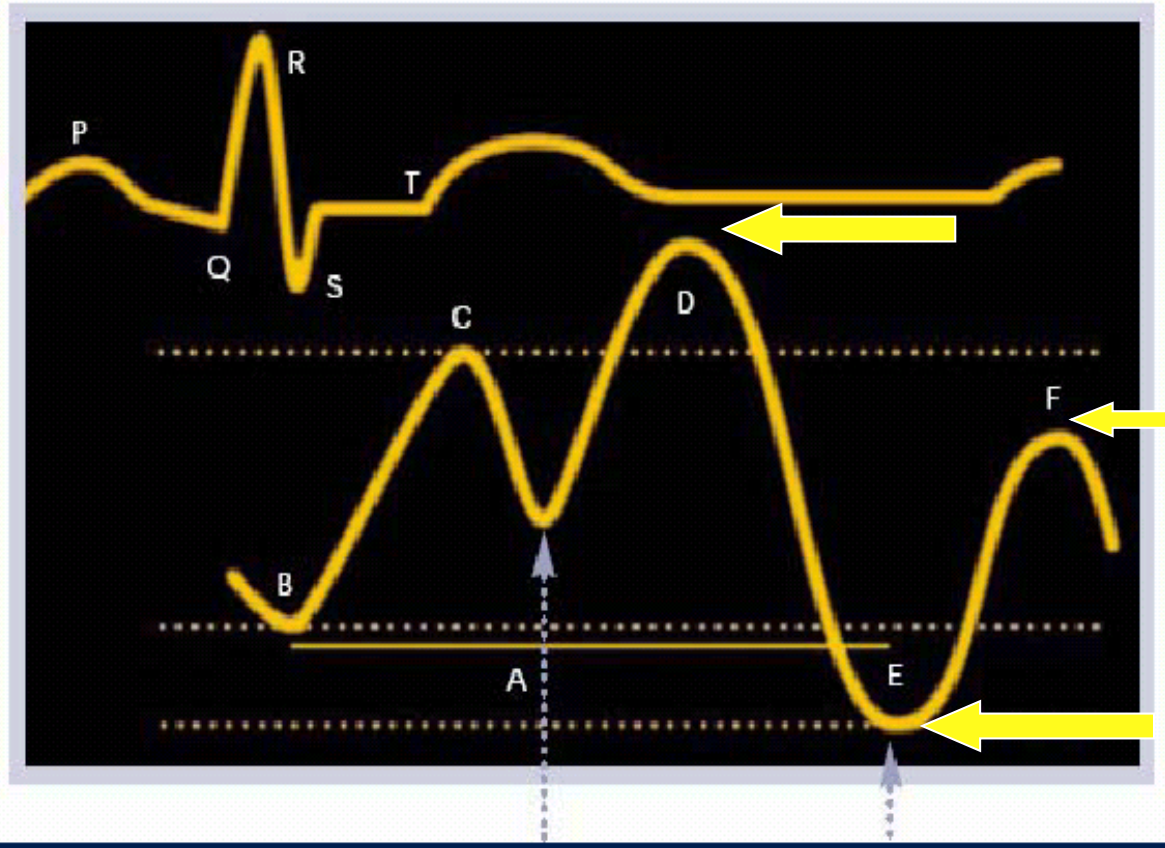
B = Unassisted aortic end diastolic pressure

C = Unassisted systolic pressure

D = Diastolic augmentation

E = Reduced aortic end diastolic pressure

F = Reduced systolic pressure



IABP

IABP cannot provide adeguate circulatory support in up to 30% of cardiogenic shock

In these cases, more sophisticated devices, as LVAD , can be usefull as bridge to recovery or to transplantation

LVAD

Tandem Heart ™

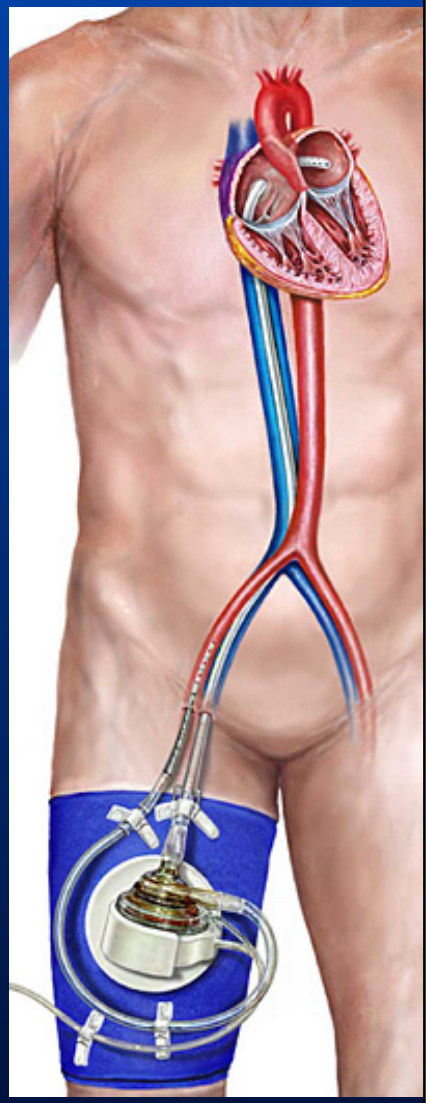
continuous-flow centrifugal pump

Left atrial, 21 F transseptal cannula

to femoral artery, 9-17 F

Up to 4 l / m’

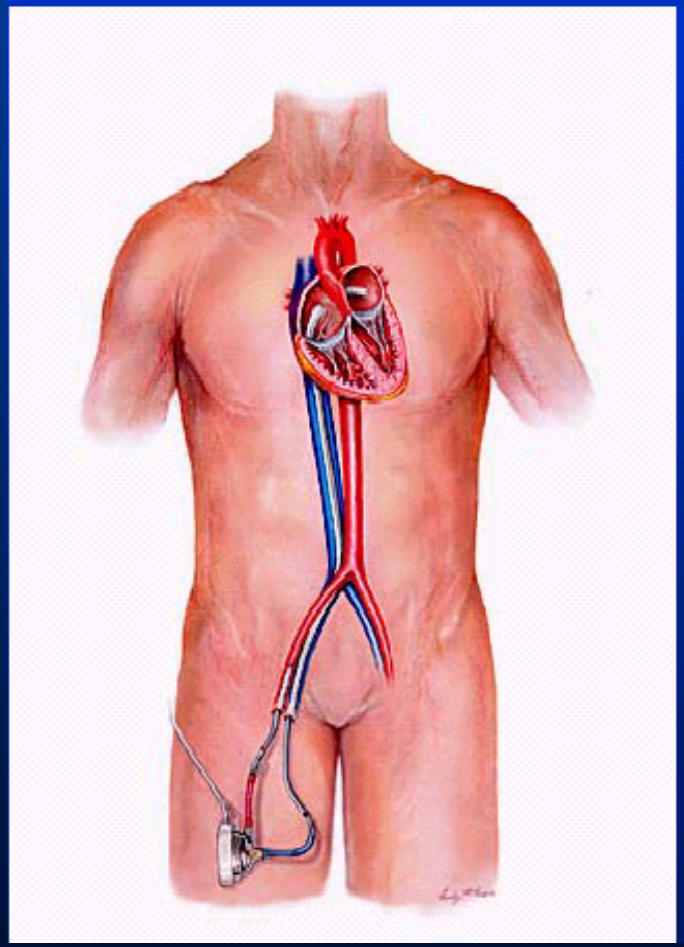
Up to 18 days

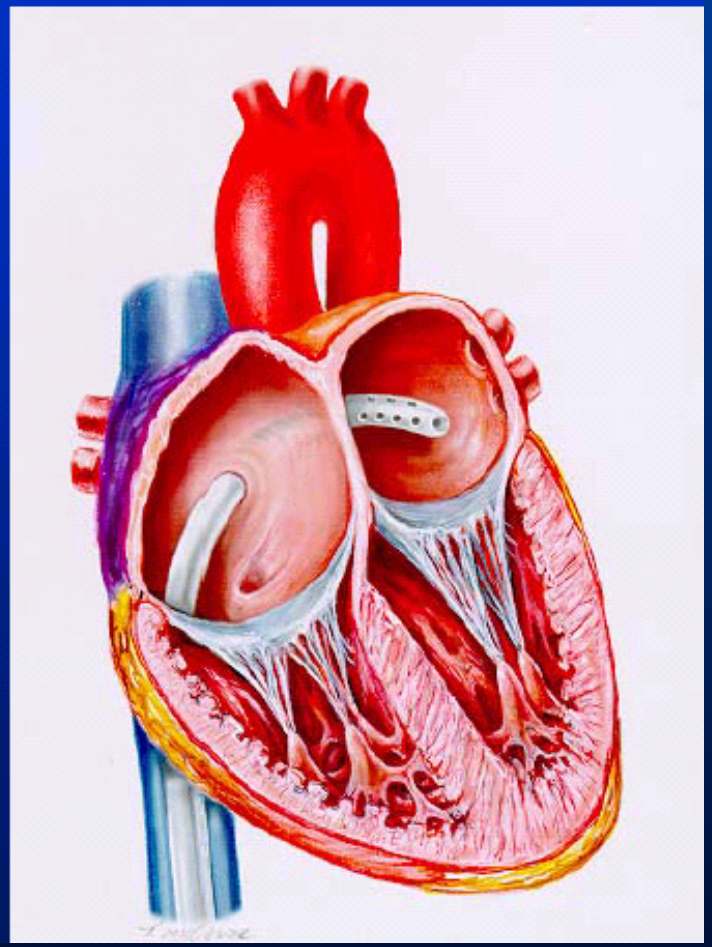


Cardiac Assist Technologies Inc.

Left Ventricular Assist Device

Tandem Heart™





LVAD

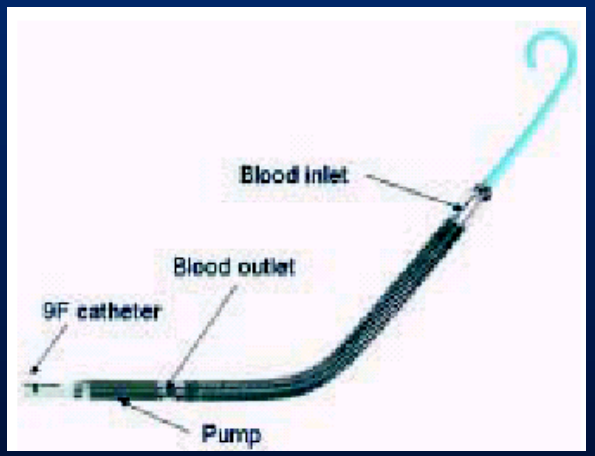
Impella ™

Intracardiac micro-assial flow pump, 12 F

It pumps from LV, into ascending Ao

Up to 2.5 l /m’

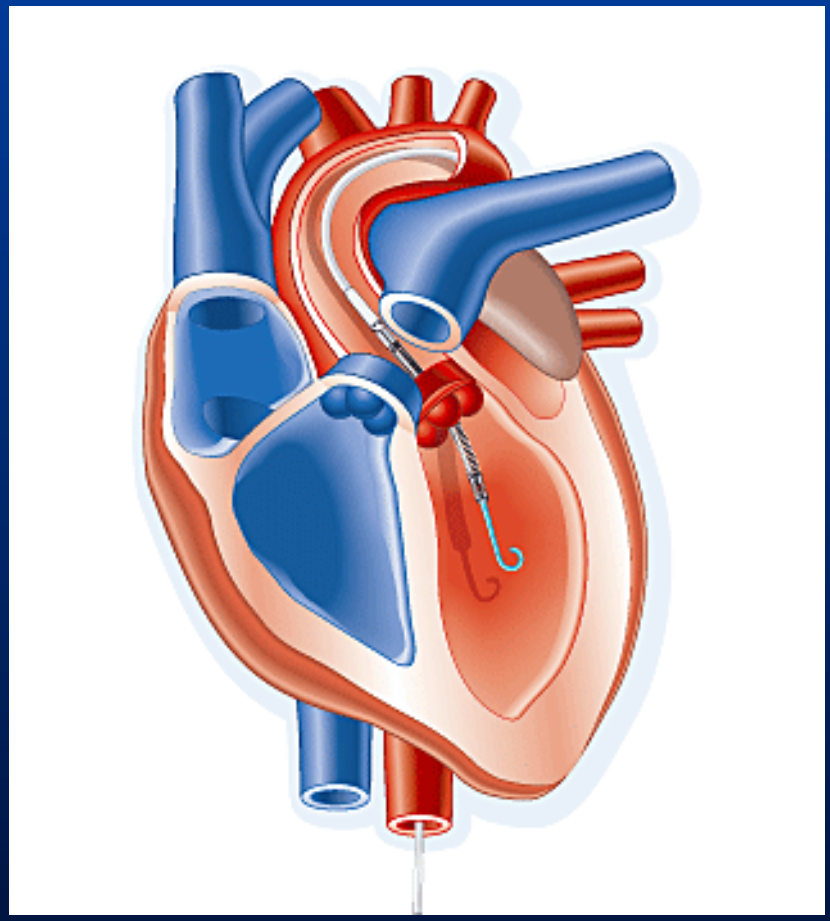
Up to 5 days



Aachen, Germany

Left Ventricular Assist Device

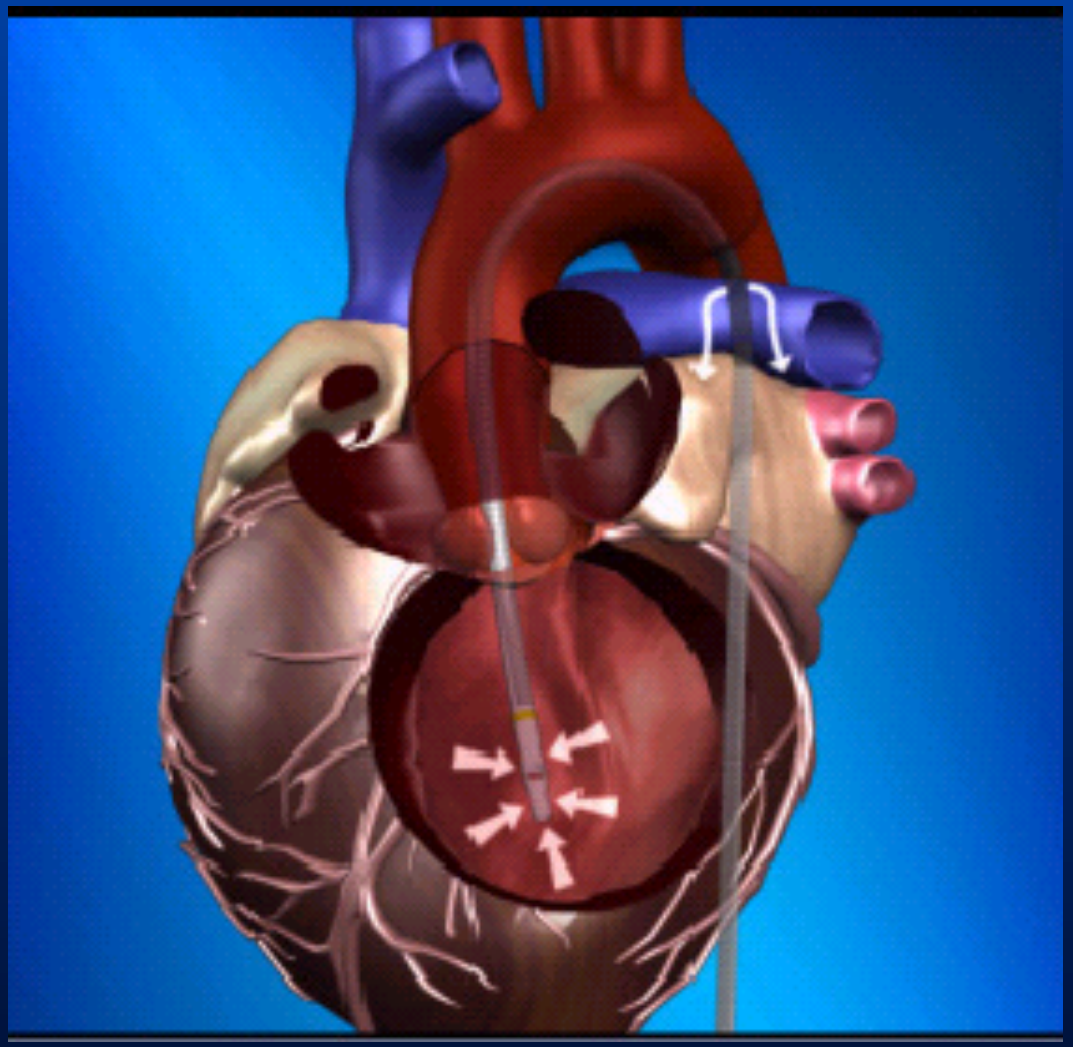
Impella Recover ™ LP 2.5



Aachen, Germany

Left Ventricular Assist Device

A-MED™



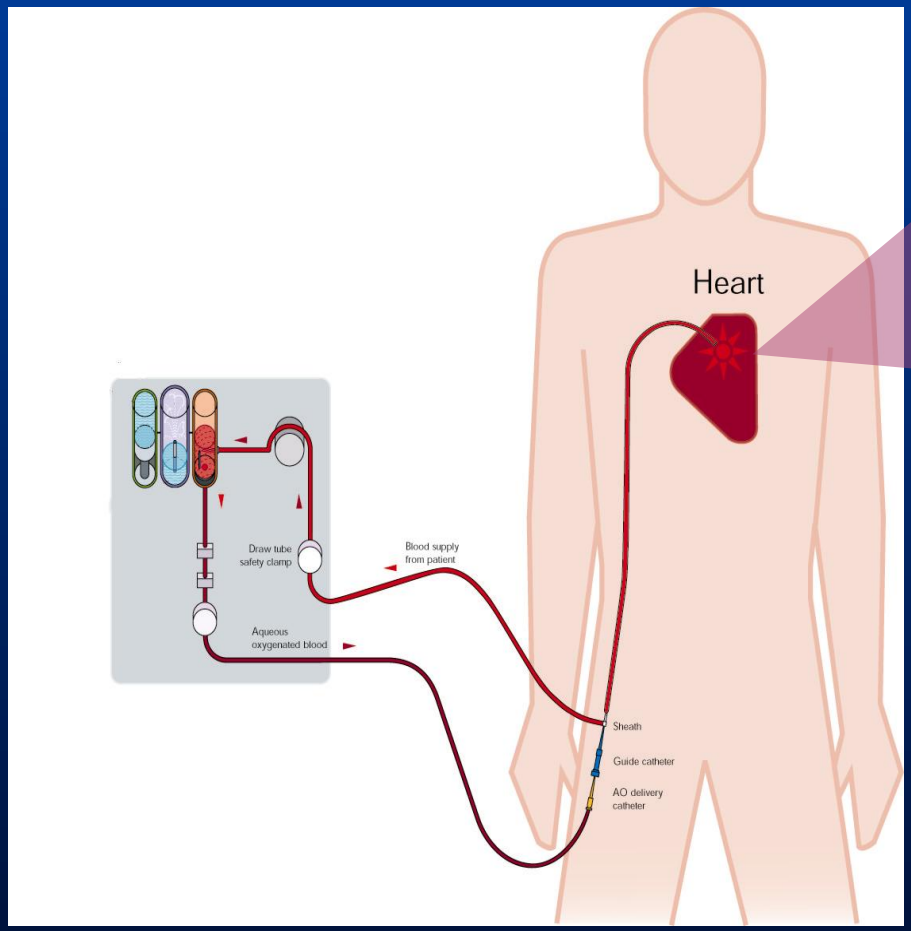
Hyperoxemic reperfusion

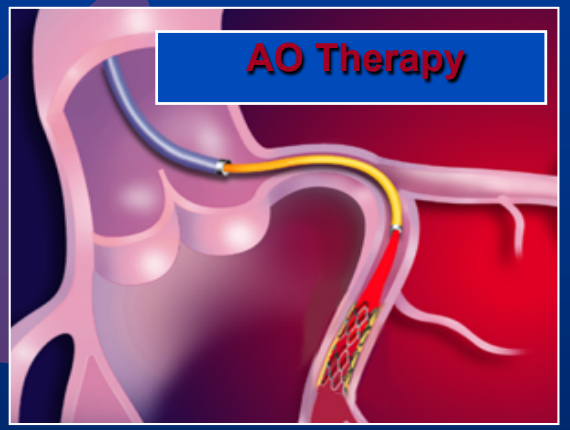
Hyperbaric oxygen in solution ("*Aqueous Oxygen*" or "*AO*")

AO mixing with the patient's blood in a cartridge

Intracoronary catheter delivery

Hyperoxemic reperfusion

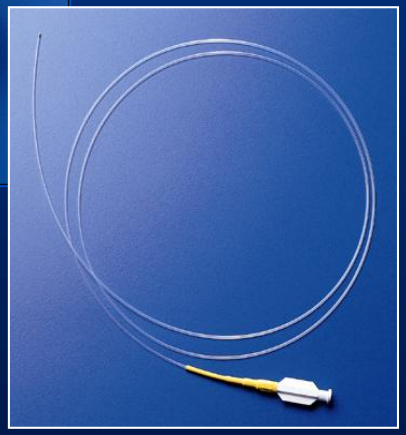


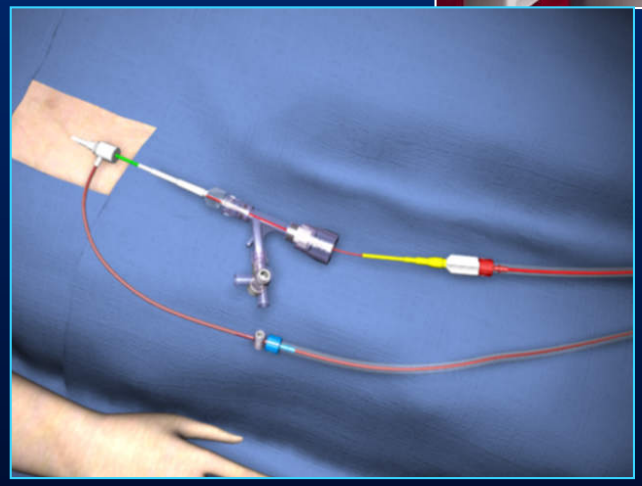


Hyperoxemic reperfusion

AO System Disposables

AO System Hardware





TherOx

AMIHOT Trial Algorithm

Major exclusion:
- Cardiogenic shock
- Need for IABP
- Systemic pO_2 <80mmHg

AMI ≤ 24-hrs
(Primary or Rescue) n=269

Anterior MI or Inferior MI with anterior ST↓

Successful PCI

Initial TIMI flow ≤ 2

Normoxemic Reperfusion (Standard Therapy)

Hyperoxemic Reperfusion with AO for 90-minutes

Enrollment in 20 US and European sites Jan 2002 – Dec 2003

ST-Monitor 24-hours

SPECT Scan 14-days

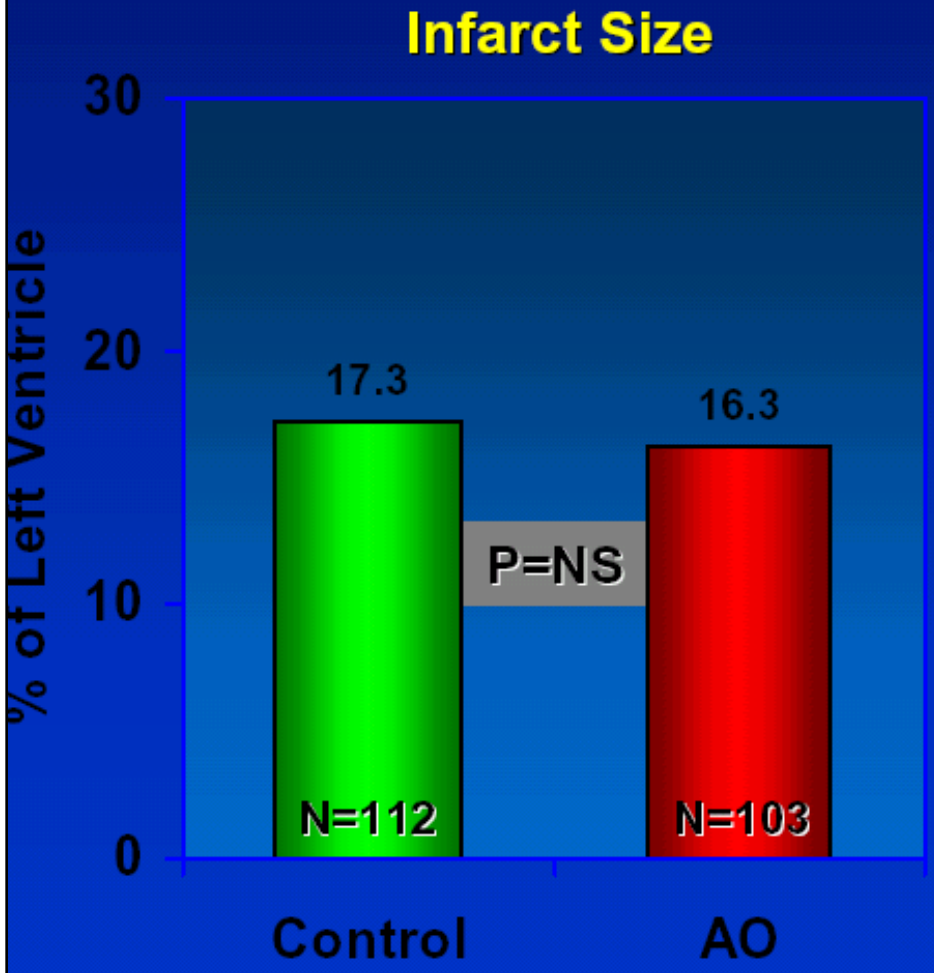
Contrast Echo 1 month

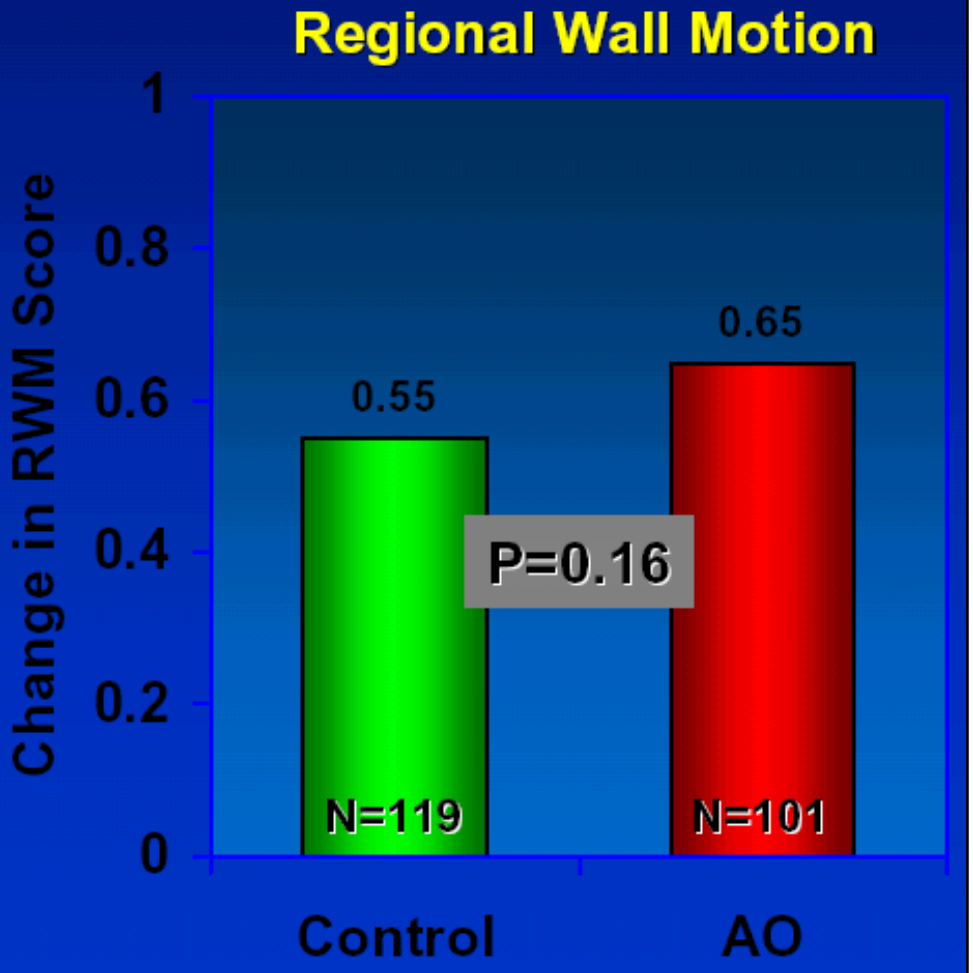
Contrast Echo 3 months

AMIHOT

Regional Wall Motion & Infarct Size

Primary Endpoints



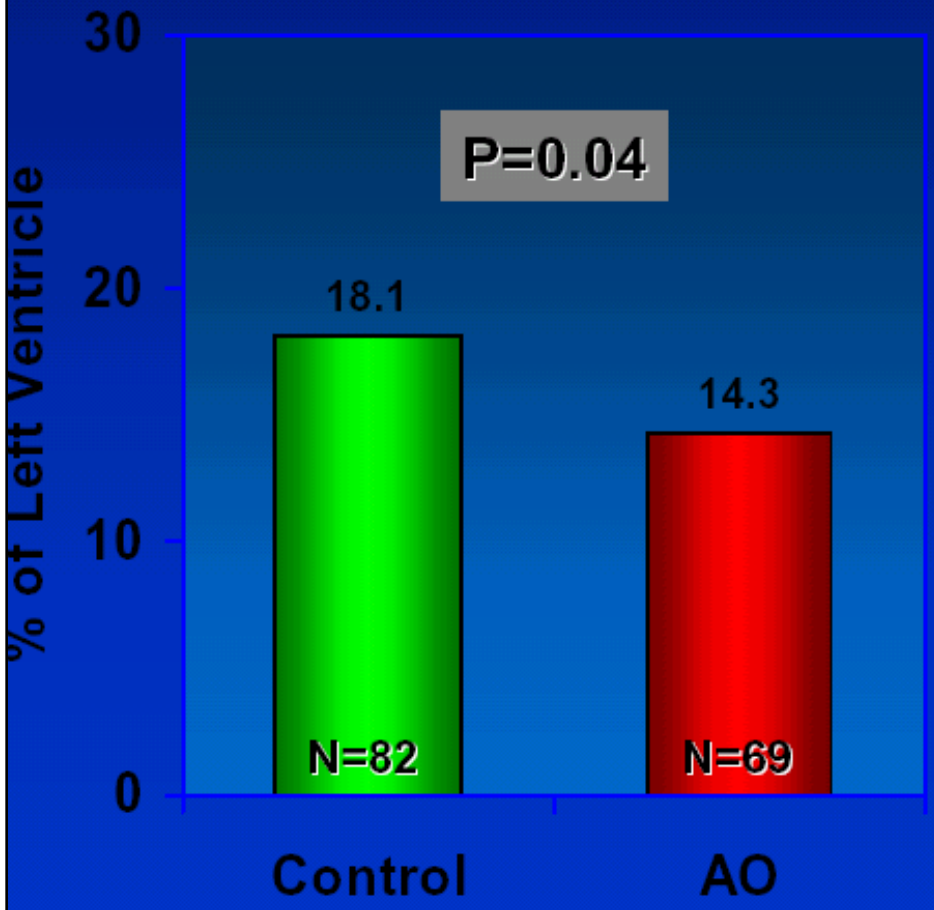


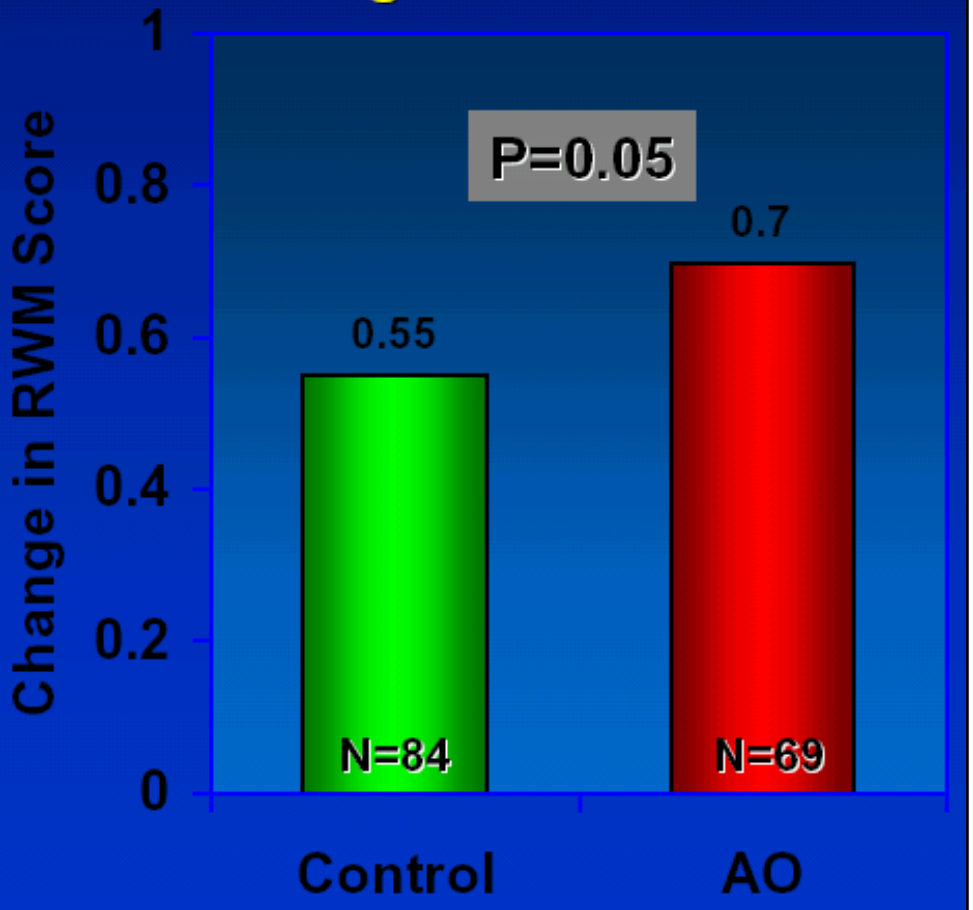
Dixon SR, TCT 2004

Time to Reperfusion <6 hrs

AMIHOT

All Patients

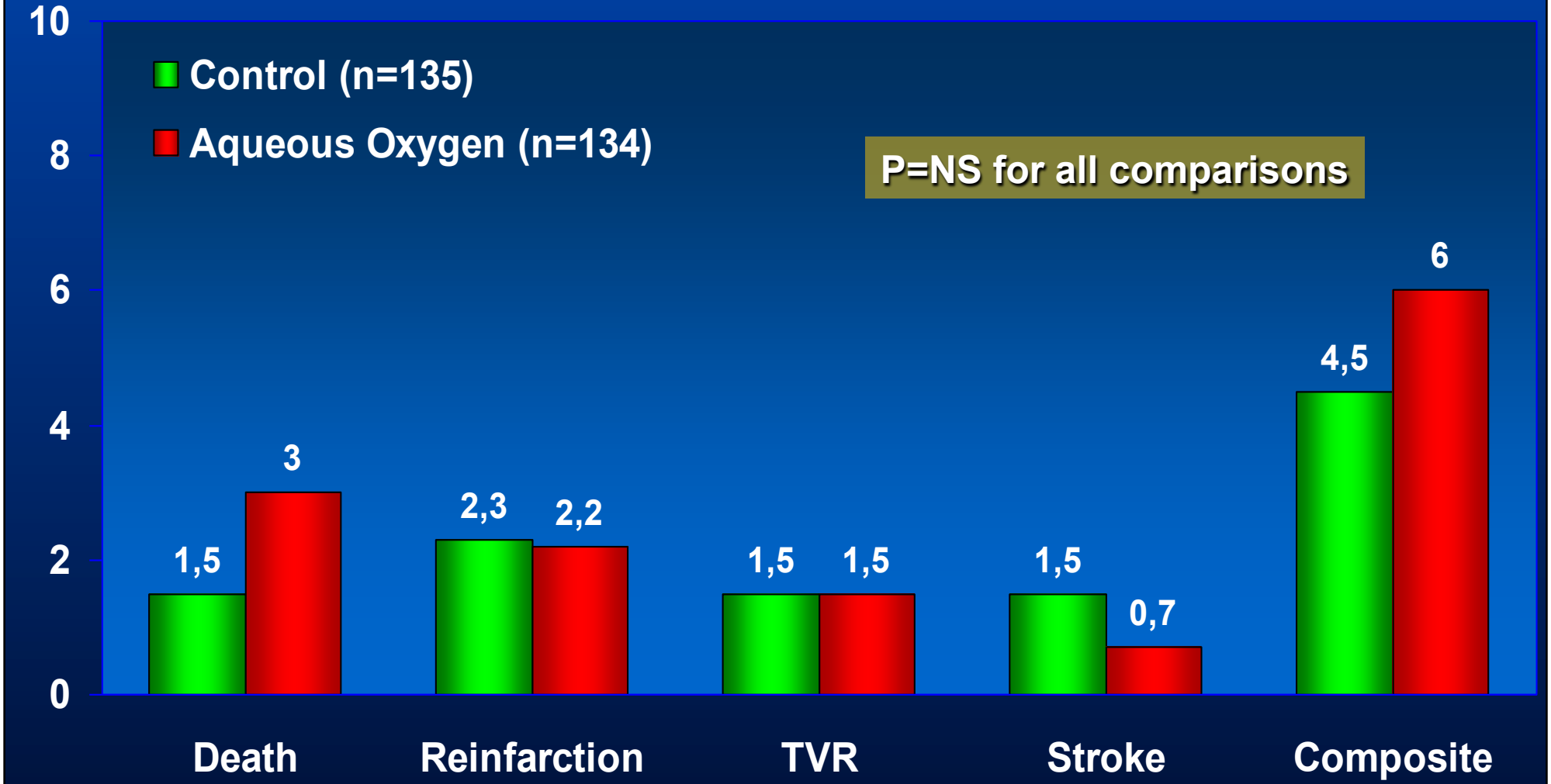




Dixon SR, TCT 2004

AMIHOT: 30-Day MACE

Primary Safety Endpoint



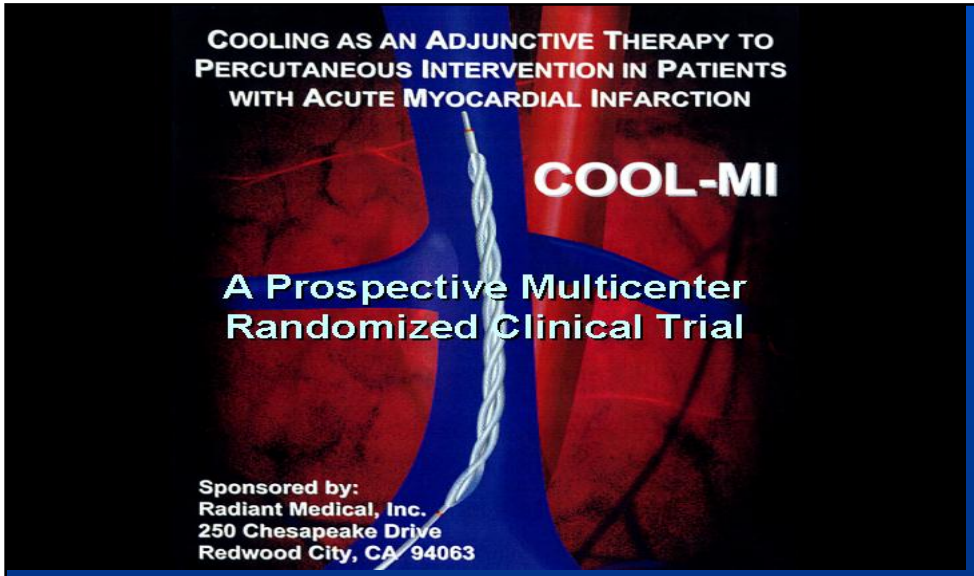
Dixon SR, TCT 2004

Systemic hypothermia

Trials

- Cool-MI
- ICE-it
- Low Temp

Radiant Medical



Endovascular Cooling during PPCI in AMI

COOL-MI

- 357 AMI pts
- No reduction in infarct size : 14.1 vs 13.8
- Better results in anterior MI: 9.3 vs 18.2
- No difference in 30 days MACE

…next: COOL-MI 2

O'Neill W. at TCT 2003

References