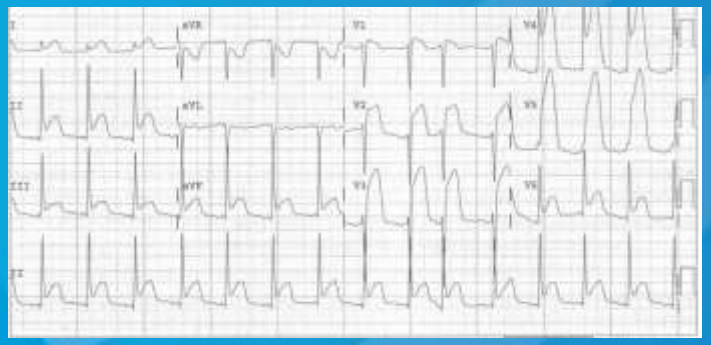
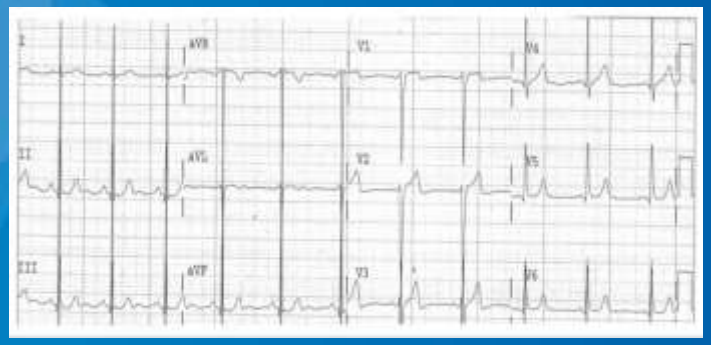
III Curso "José Gabay" para Intervencionistas en Entrenamiento de ProEducar – SOLACI

"Tromboaspiración, protección proximal y distal, stents cubiertos, para optimizar la reperfusión tisular en SCACEST"





Dr. Aníbal Damonte
Departamento de Cardiología Intervencionista
Instituto Cardiovascular de Rosario
Rosario, Argentina

Introducción

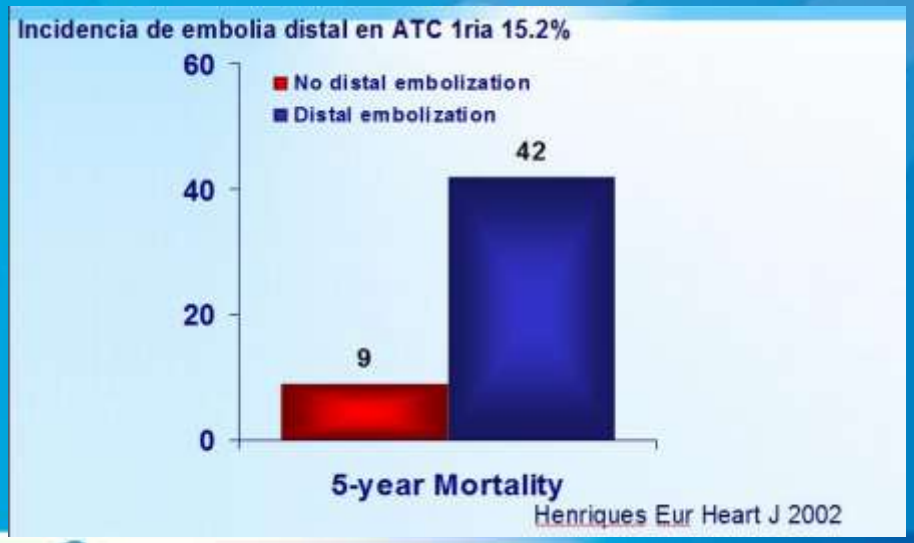
- En pacientes con SCACEST lograr una adecuada reperfusión tisular con ATC primaria o trombolíticos, minimiza el daño miocárdico, preserva la FSVI, y se traduce en una mejor sobrevida y menor incidencia de complicaciones.

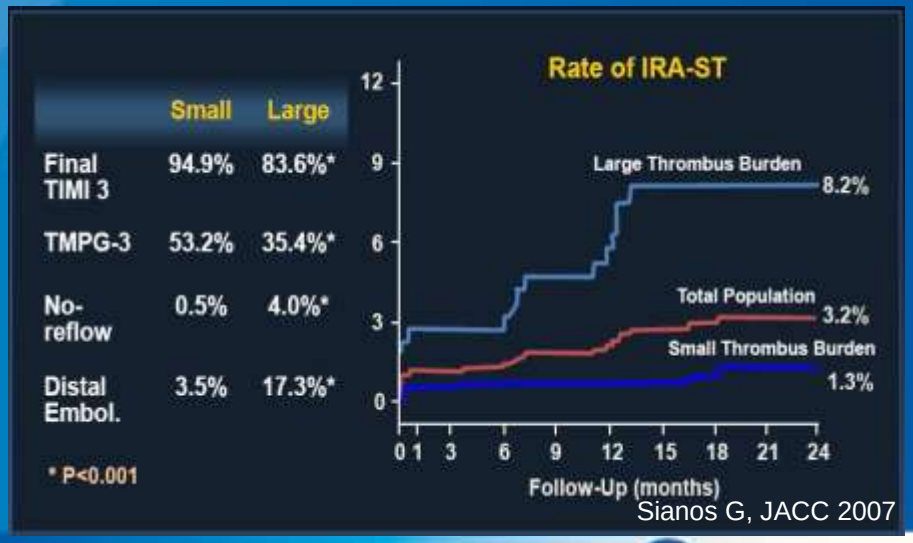
- Sin embargo existe un porcentaje significativo de pacientes (>30%) en los cuales a pesar de una exitosa repermeabilización del vaso epicárdico (flujo TIMI 3), no se alcanza una reperfusión efectiva a nivel tisular, entre otras causas debido a embolia o microembolia distal,mionecrosis con disrupción capilar, injuria de reperfusión, edema tisular, ausencia de salvataje miocárdico.

Introducción

- Prevenir la embolización distal es uno de los principales desafíos durante las interveciones coronarias en SCACEST donde la carga trombótica de la obstrucción representa un gran problema y la embolización distal se asocia a peor pronóstico.

- La macro embolia distal, angiograficamente evidente se ha reportado hasta en 15-17% de pacientes y se manifestó en el seguimiento alejado en un aumento en 5 veces de la mortalidad en comparación con los pacientes sin embolia. El alto contenido trombótico es predictor independiente de MACE y trombosis del stent post ATC 1ria.

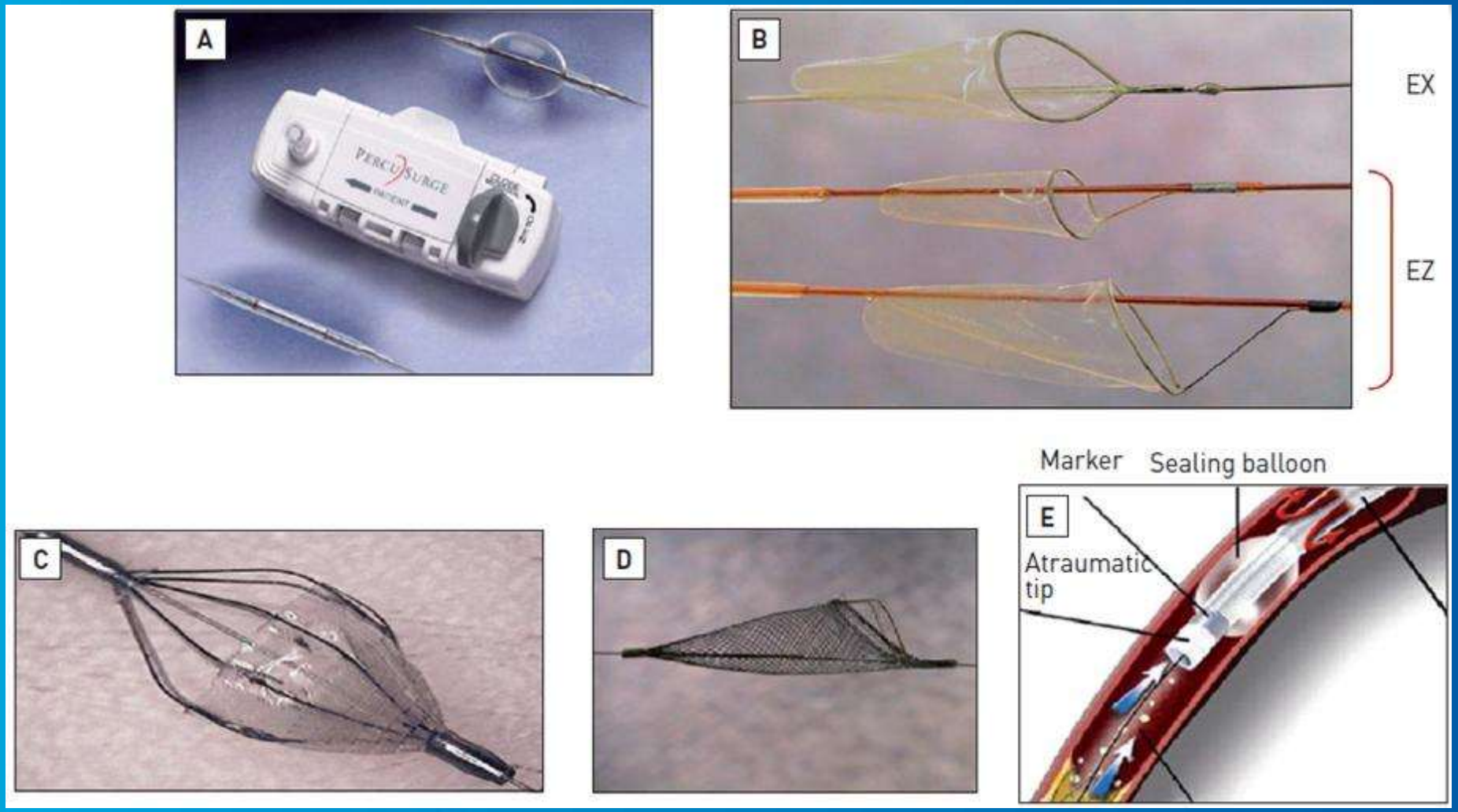




THROMBECTOMY DEVICES	
MANUAL ASPIRATION CATHETERS	
CATHETER	**COMPANY**
Eliminate™ Aspiration Catheter	Terumo Medical Corporation, Somerset, NJ, USA
DiverCE™	Invatec S.p.a., Roncadelle (BS), Italy
Export® XT - Export® AP Aspiration Catheter	Medtronic, Minneapolis, MN, USA
Pronto V3	Vascular Solutions, Inc., Minneapolis, MN, USA
QuickCat™ Extraction Catheter	Spectranetics, Inc., Colorado Springs, CO, USA
Fetch®2 Aspiration Catheter	Possis Medical, Inc./MEDRAD, Inc., Minneapolis, MN, USA
Xtract™ Aspiration Catheter	Volcano Corporation, San Diego, CA, USA
MECHANICAL THROMBECTOMY (ACTIVE THROMBUS DEFRAGMENTATION)	
AngioJet Rheolytic Thrombectomy System	Possis Medical, Inc./MEDRAD, Inc., Minneapolis, MN, USA
Excimer laser coronary atherectomy	Spectranetics Corporation, Colorado Springs, CO, USA
Thromcat	Spectranetics Corporation, Colorado Springs, CO, USA
DISTAL PROTECTION DEVICES	
FILTER-BASED SYSTEMS	
FilterWire EZ™	EPI, Boston Scientific, Natick, MA, USA
SpiderFX	eV3 Inc., Plymouth, MN, USA
CardioShield®	Abbott Laboratories, Abbott Park, IL, USA
TRAP	Microvena, White Bear Lake, MN, USA
Interceptor® PLUS	Medtronic Vascular, Santa Rosa, CA, USA
OCCLUSION-BASED SYSTEMS	
PercuSurge GuardWire	Medtronic Vascular, Santa Rosa, CA, USA
TriActiv FX Embolic Protection System	Kensey Nash Corporation, Exton, PA, USA
PROXIMAL OCCLUSION DEVICES	
Kerberos Embolic Protection Technology: "Rinspirator System".	Kerberos Proximal Solutions, Inc., Sunnyvale, CA, USA
Proxis	St. Jude Medical, St. Paul, MN, USA

• Múltiples dispositivos han sido desarrollados para minimizar el riesgo de embolización de lesiones trombóticas incluyendo sistemas de tromboaspiración, y sistemas de protección distal o proximal.

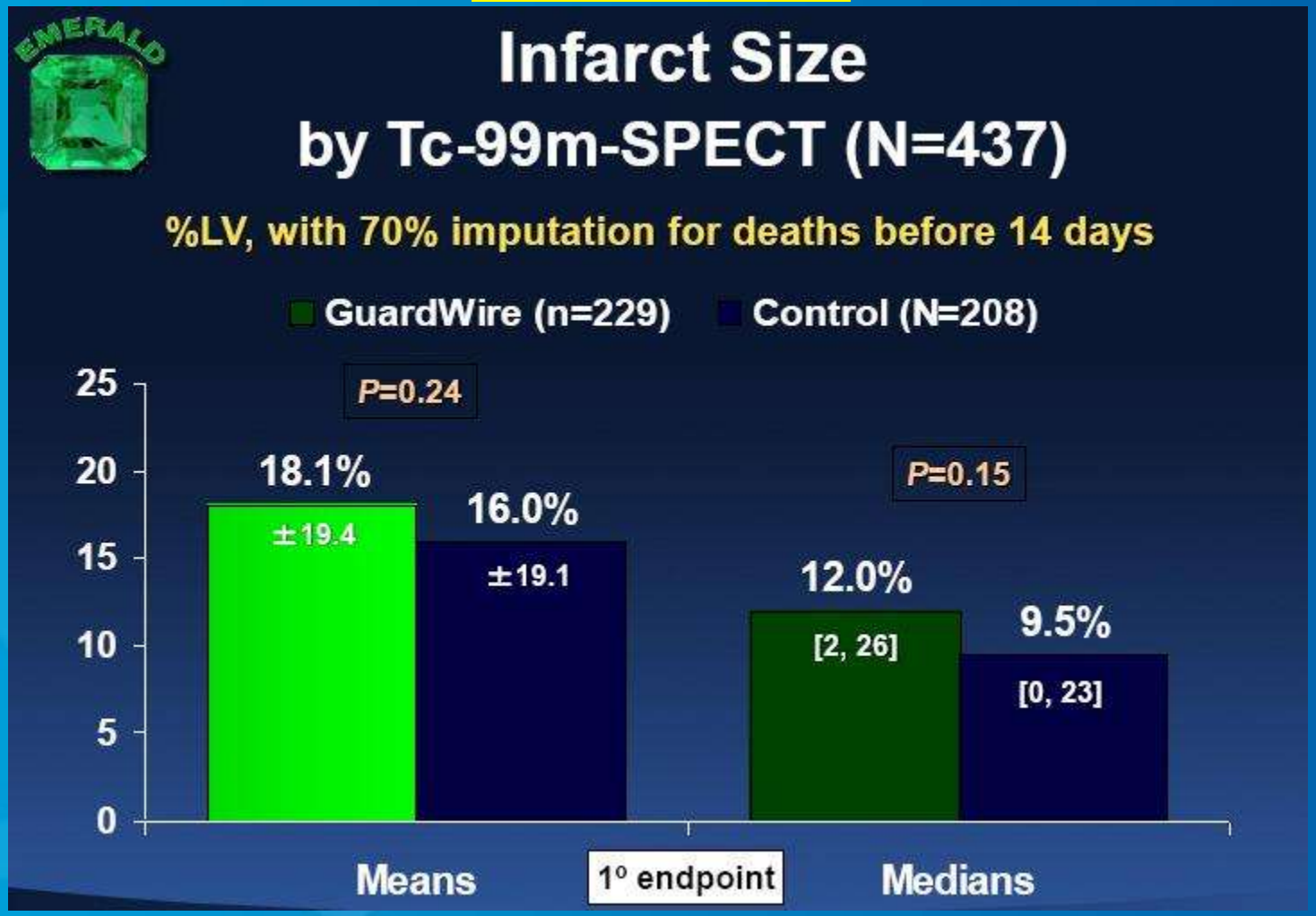
Sistemas de Protección



Sistemas de Protección

DISPOSITIVO	VENTAJAS	DESVENTAJAS
Oclusión distal	• < Perfil de cruce. • Protección completa.	• Interrupción de fllujo. • No control angiográfico. • Múltiples pasos. • No protege ramas.
Filtros	• Preservación del flujo. • Permite control angio durante PCI.	• No filtra mediadores humorales ni micropartic. • Potencial oclusión.
Oclusión proximal	• Protección completa. • Protección de ramas. • Cuerda de elección.	• Interrupción de flujo. • No control angiográfico. • Catéter guía > diámetro.

Protección Distal con oclusor: Estudio EMERALD



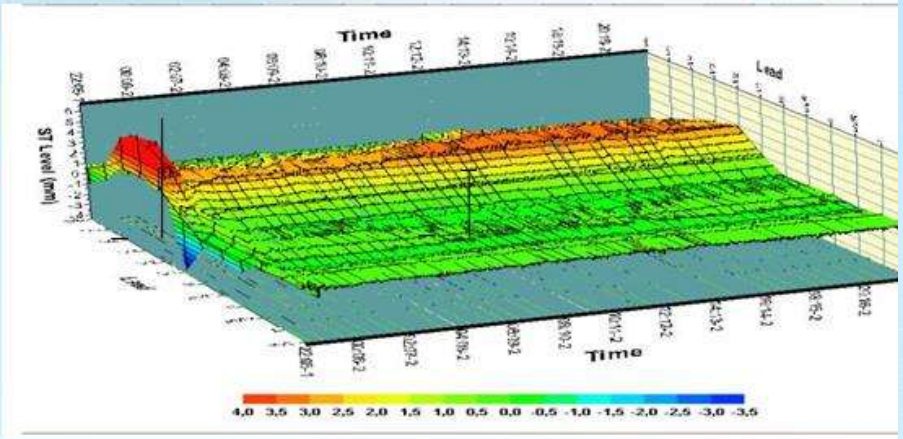
Stone G, JAMA 2005

Protección Distal con Filtro: Estudio PREMIAR

PREMIAR

Primary Endpoint
Continuous ST-segment monitoring

Corelab: Duke Un
Mitch Krucoff



PREMIAR

Complete STR (≥70%) after PCI

Cura F, Am J Cardiol 2007

SOCIME

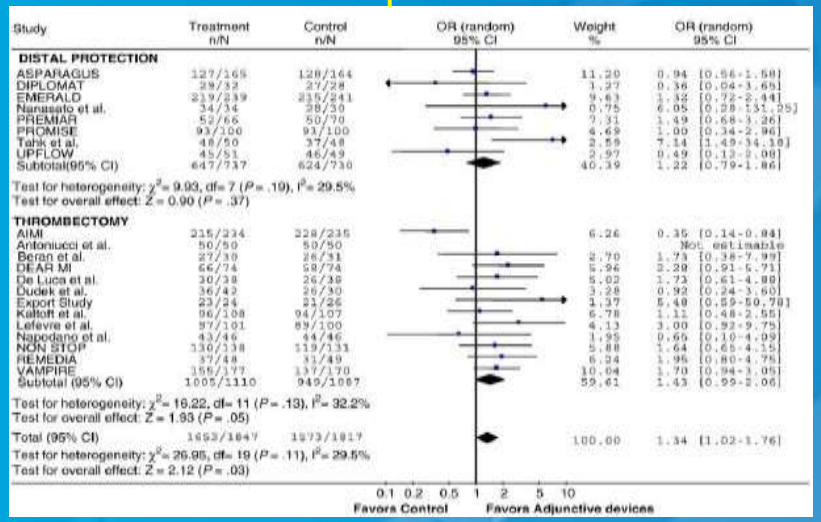
SOLACI '12 MEXICO DF
In partnership with

Adjunctive mechanical devices to prevent distal embolization in patients undergoing mechanical revascularization for acute myocardial infarction: A meta-analysis of randomized trials

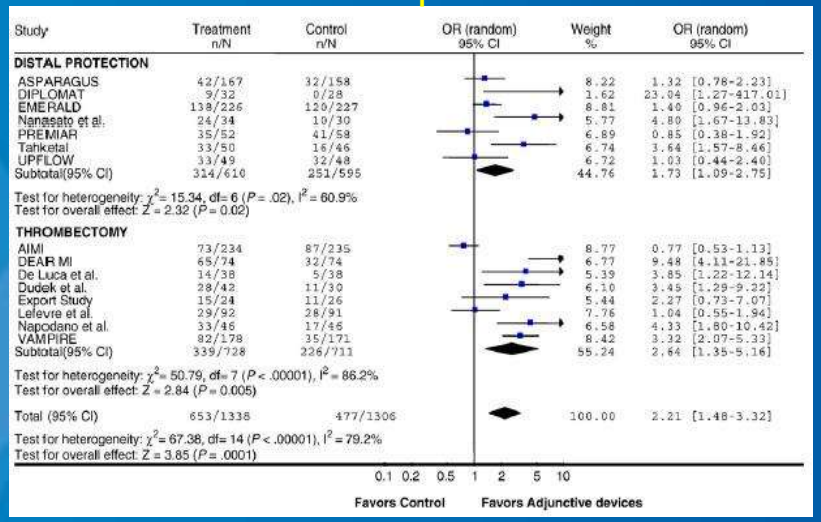
Giuseppe De Luca, MD,[a,J] Harry Suryapranata, MD,[b] Gregg W. Stone, MD,[c] David Antoniucci, MD,[d] Franz-Joseph Neumann, MD,[e] and Massimo Chiariello, MD[a] *Novara, Naples, and Florence, Italy; Zwolle, The Netherlands; New York, NY; and Bad Krozingen, Germany*

American Heart Journal
March 2007

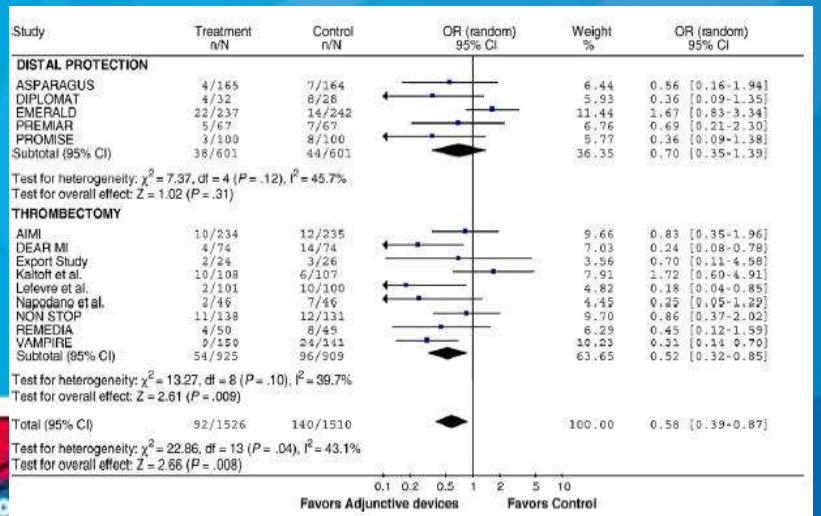
TIMI 3 post PCI



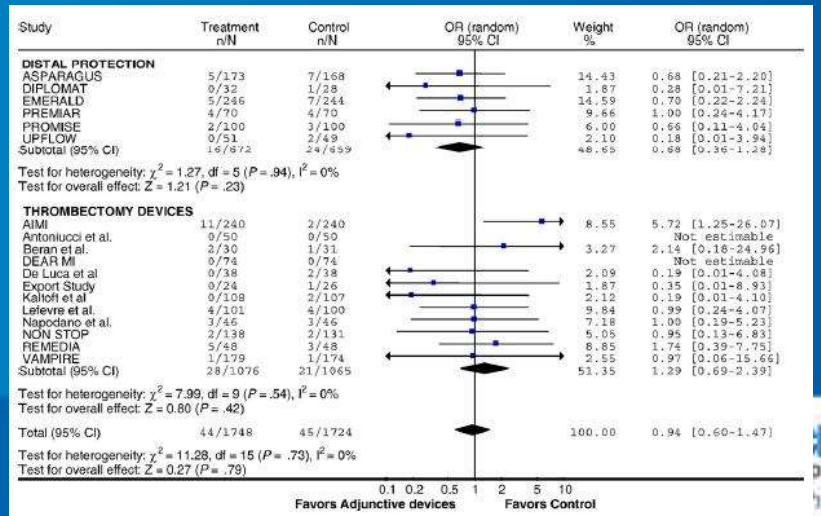
MBG 3 post PCI



Embolización Distal



Mortalidad a 30 días



Protección Proximal: Estudio PREPARE

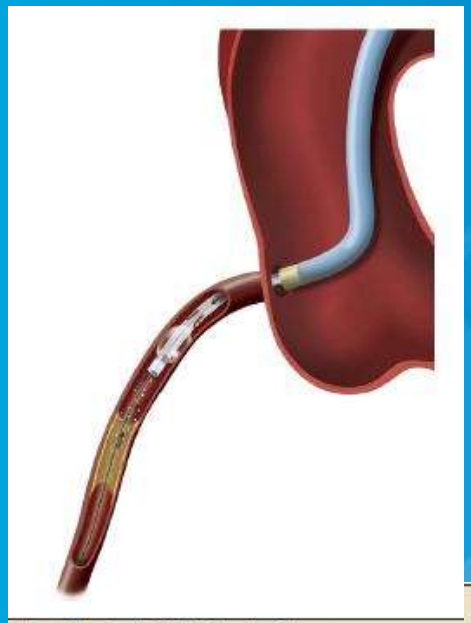


Figure 1. The Proxis Embolic Protection System

Randomized Comparison of Primary Percutaneous Coronary Intervention With Combined Proximal Embolic Protection and Thrombus Aspiration Versus Primary Percutaneous Coronary Intervention Alone in ST-Segment Elevation Myocardial Infarction

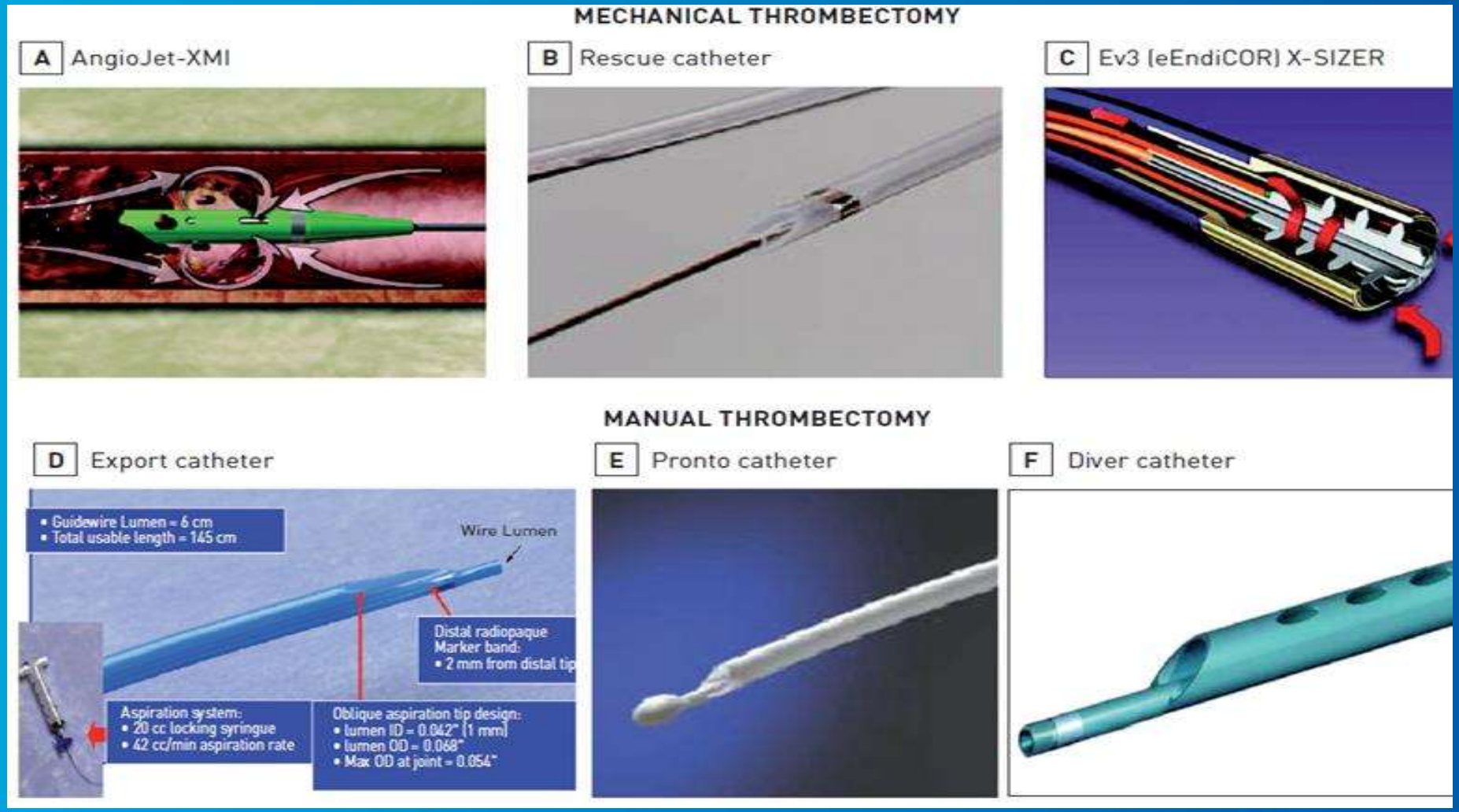
The PREPARE (PRoximal Embolic Protection in Acute myocardial infarction and Resolution of ST-Elevation) Study

Continuous ST-Segment Recovery Parameters

	PCI With Proxis (n = 141)	Primary PCI Alone (n = 143)	p Value
ST-segment resolution, %			
Immediate	79 (63–98)	69 (43–92)	0.015
At 30 min	83 (70–97)	78 (63–93)	0.13
At 60 min	88 (72–100)	84 (67–97)	0.15
At 90 min	87 (75–99)	85 (67–98)	0.45
At 120 min	86 (72–99)	87 (73–97)	0.74
ST-segment curve area,* μV/min	5,192 (3,793–7,626)	6,250 (4,221–9,186)	0.037

Haeck J, JACC Card Interventions 2009

Sistemas de Tromboaspiración



“Angioplastía Primaria”

Cómo podemos optimizar la perfusión tisular?

Tromboaspiración Manual: Estudio TAPAS

TAPAS Study Setup

Single-center, Prospective, Randomized, Open Trial

All consecutive patients with
a possible ST-elevated Acute Myocardial
Infarction within
12 hours after onset of symptoms

Conventional PCI
n = 536

1:1 pre-angiography randomization
N = 1'071 patients
University Medical Center Groningen,
the Netherlands

Thrombus Aspiration with
Export®
n = 535

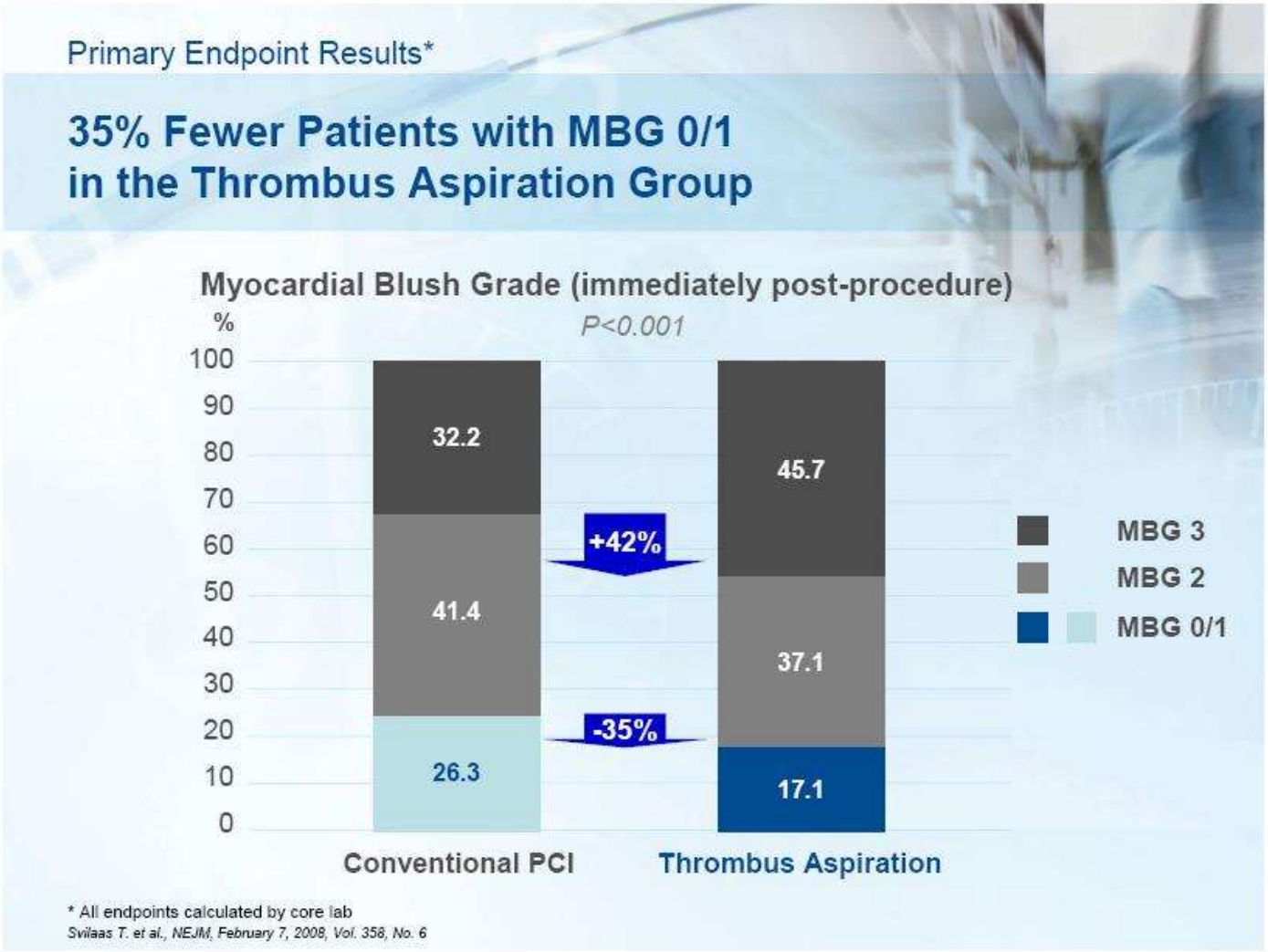
Clinical
Proc — 30d — 1yr

Primary Endpoint: MBG 0 or 1 as assessed by core lab

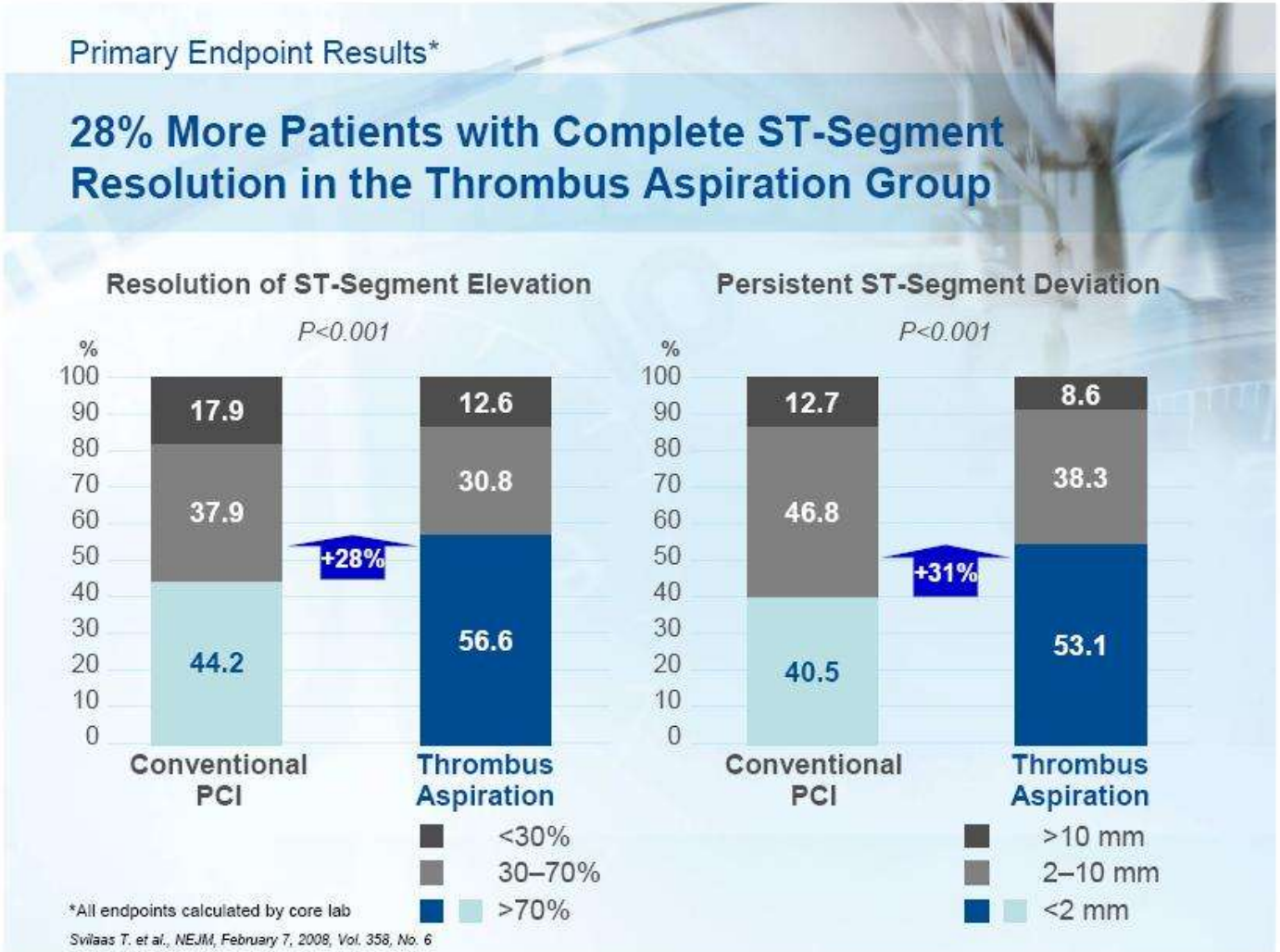
Secondary Endpoints: TIMI 3 flow, complete resolution of ST-segment elevation, absence of persistent ST-segment deviation, TVR, reinfarction, death, and MACE by 30 days

Svilaas T. et al., NEJM, February 7, 2008, Vol. 358, No. 6

Tromboaspiración Manual: Estudio TAPAS

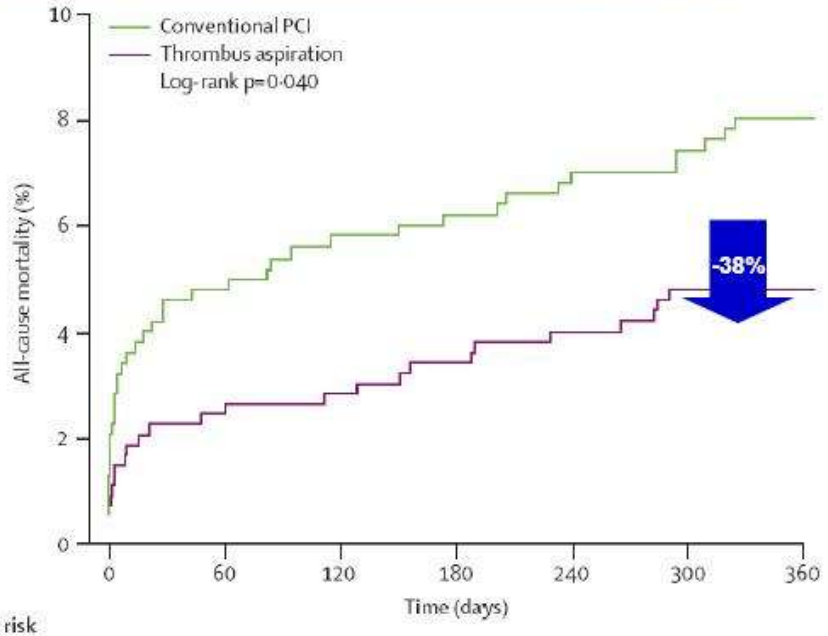


Tromboaspiración Manual: Estudio TAPAS



Tromboaspiración Manual: Estudio TAPAS

Statistically Significant Reduction of all-cause mortality in Favor of thrombus aspiration Group at 1 year (-38%)



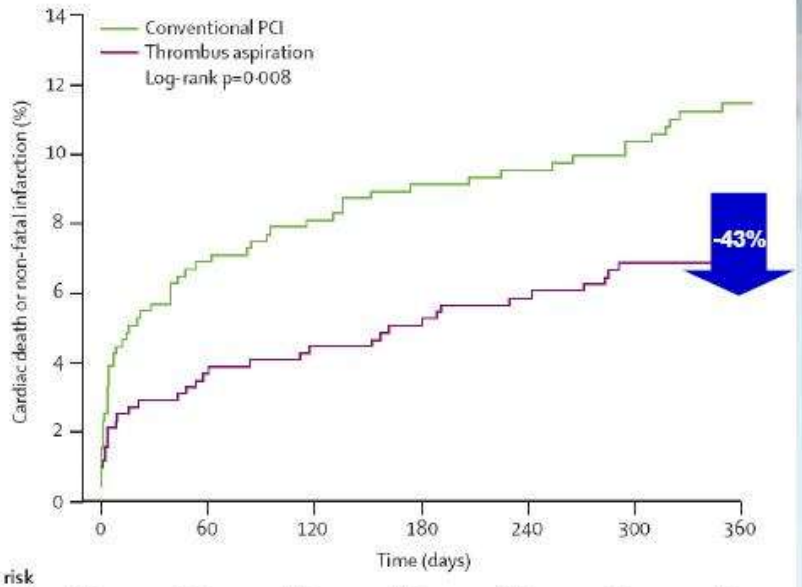
Number at risk							
Conventional PCI	536	506	501	499	495	494	489
Thrombus aspiration	535	519	517	514	510	506	505
Total	1071	1025	1018	1013	1005	1000	994

Ref. Vlaar et al, Cardiac death and reinfarction after 1 year in the Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study (TAPAS): a 1-year follow-up study, Lancet 2008; Vol 371: June 2008; 1915-1920

Svilaas T. et al., NEJM, February 7, 2008; Vol. 358, No. 6

Tromboaspiración Manual: Estudio TAPAS

Statistically Significant Reduction of Cardiac death or non-fatal reinfarction in Favor of thrombus aspiration Group at 1 year (-43%)

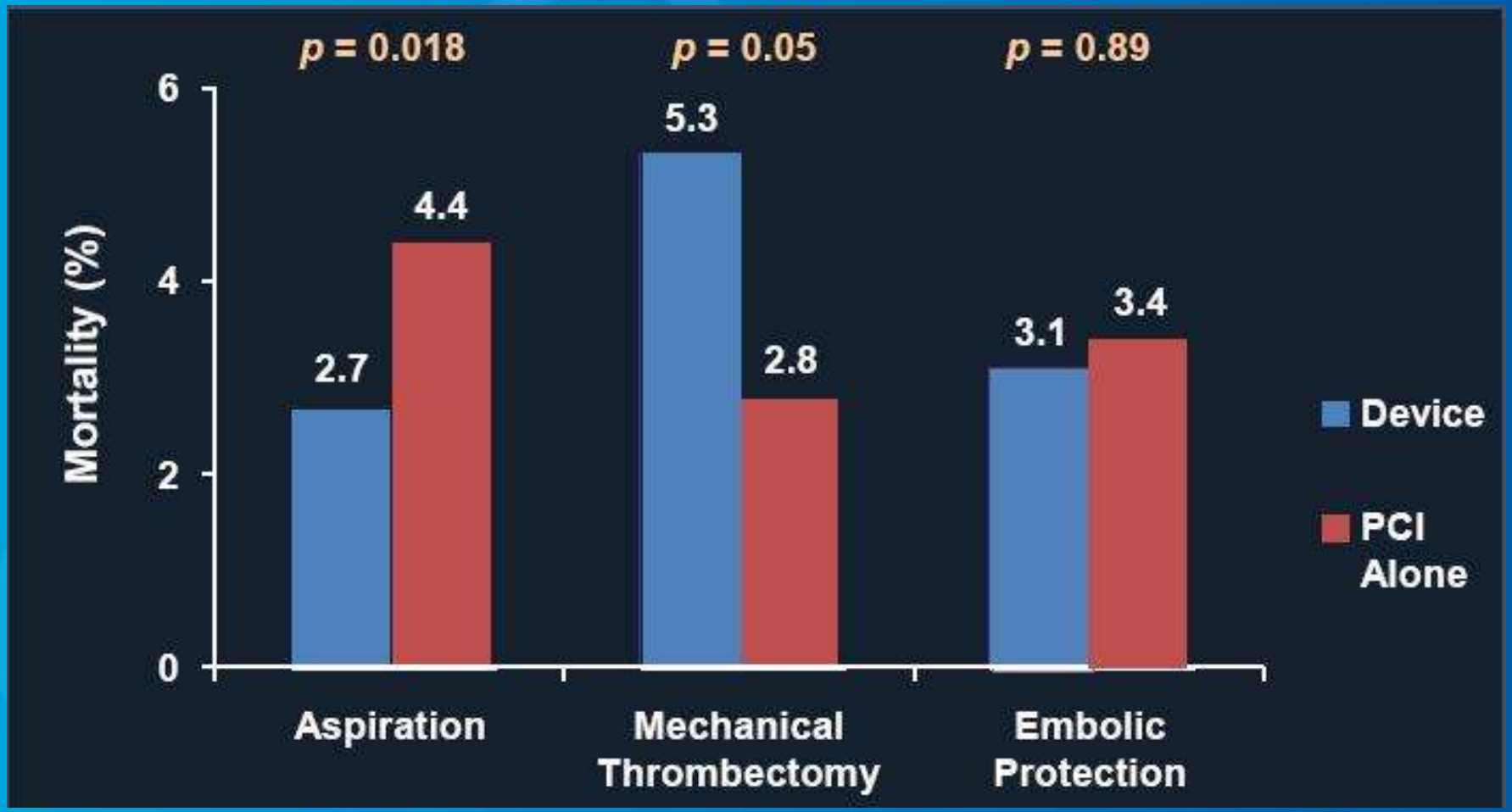


Number at risk							
Conventional PCI	536	495	489	484	482	479	472
Thrombus aspiration	535	512	508	504	500	495	494
Total	1071	1007	997	988	982	974	966

Ref. Vlaar et al, Cardiac death and reinfarction after 1 year in the Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study (TAPAS): a 1-year follow-up study, Lancet 2008; Vol 371: June 2008; 1915-1920

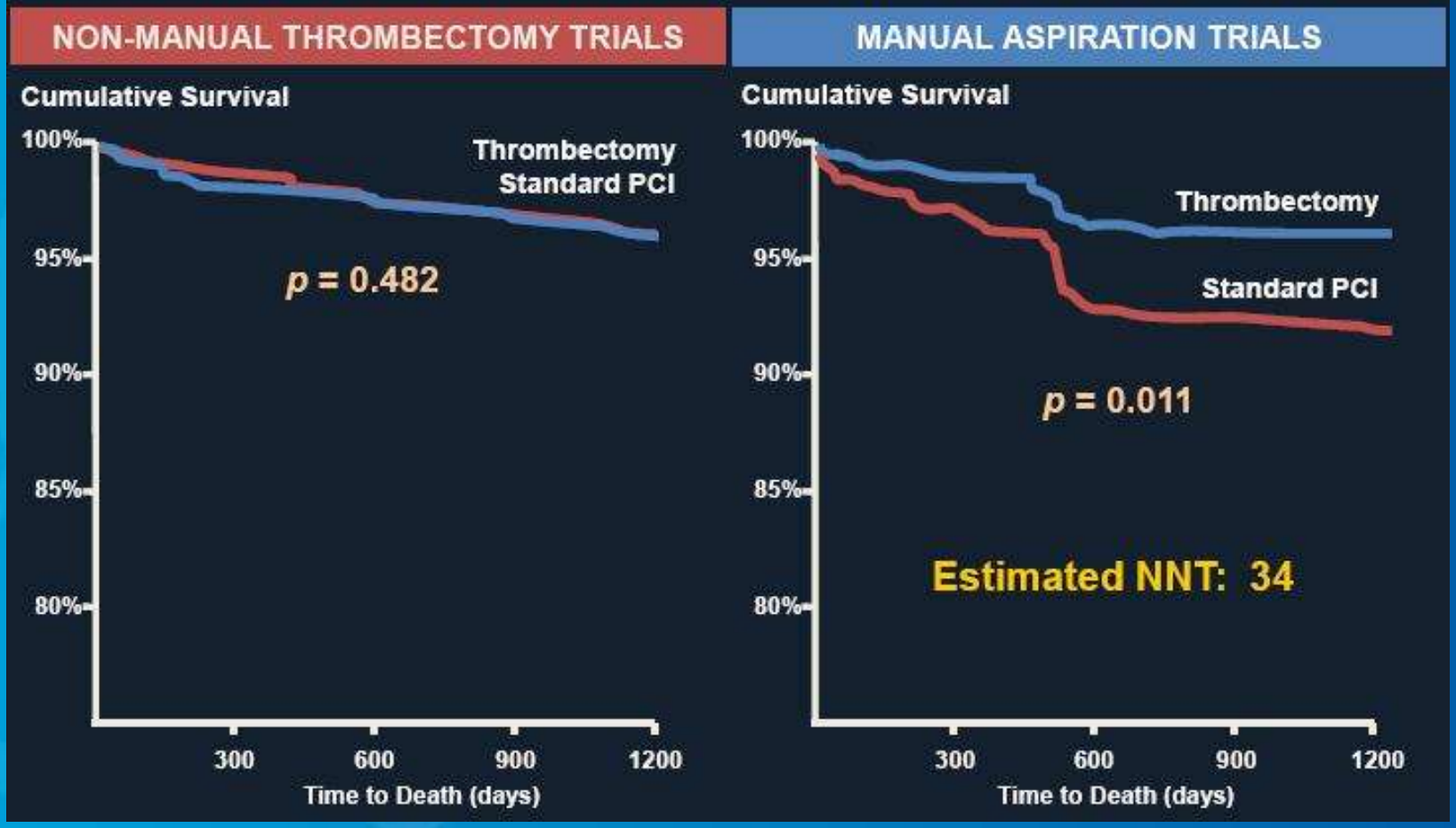
Meta Análisis: Impacto de Trombectomía y Protección distal en Mortalidad

30 estudios clínicos, 6415 pacientes, seguimiento promedio 5 meses



Bavry A, Eur Heart J 2008

ATTEMPT: Impact of Type of Thrombectomy Device on Mortality

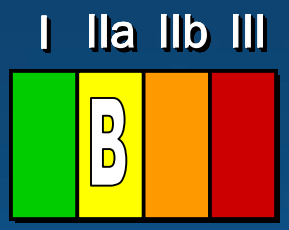


Burzotta, Eur Heart J 2009

Recommendations for Thrombus Aspiration during PCI for STEMI

Thrombus Aspiration During PCI for STEMI

NEW Recommendation



Aspiration thrombectomy is reasonable for patients undergoing primary PCI

ONLINE FIRST

Intracoronary Abciximab and Aspiration Thrombectomy in Patients With Large Anterior Myocardial Infarction
The INFUSE-AMI Randomized Trial

JAMA®
The Journal of the American Medical Association

INFUSE-AMI: Background

- Myocardial recovery after primary PCI is often suboptimal despite restoration of TIMI 3 flow, in part due to thrombus embolization which results in impaired microvascular perfusion and increased infarct size
- Two strategies proposed to reduce embolization after primary PCI are bolus IC abciximab and manual thrombus aspiration
- However, prior studies have reported conflicting results as to whether IC abciximab or manual aspiration reduce infarct size or improve clinical outcomes, in part due to enrollment of a high proportion of small infarcts (e.g. non-anterior and/or with TIMI 3 flow), and/or pts presenting late (>4-6 hrs)
- Single center thrombectomy trials have mostly been positive, whereas multicenter trials have mostly been negative

INFUSE-AMI Trial

452 pts with anterior STEMI

Anticipated S x to PCI <5 hrs, TIMI 0-2 flow in prox or mid LAD

Primary PCI with bivalirudin anticoagulation

Pre-loaded with aspirin and clopidogrel 600 mg or prasugrel 60 mg

Stratified by symptoms to angio <3 vs ≥3 hrs, and prox vs mid LAD occlusion

R 1:1

Manual aspiration

No aspiration

R 1:1

R 1:1

IC Abcx

No Abcx

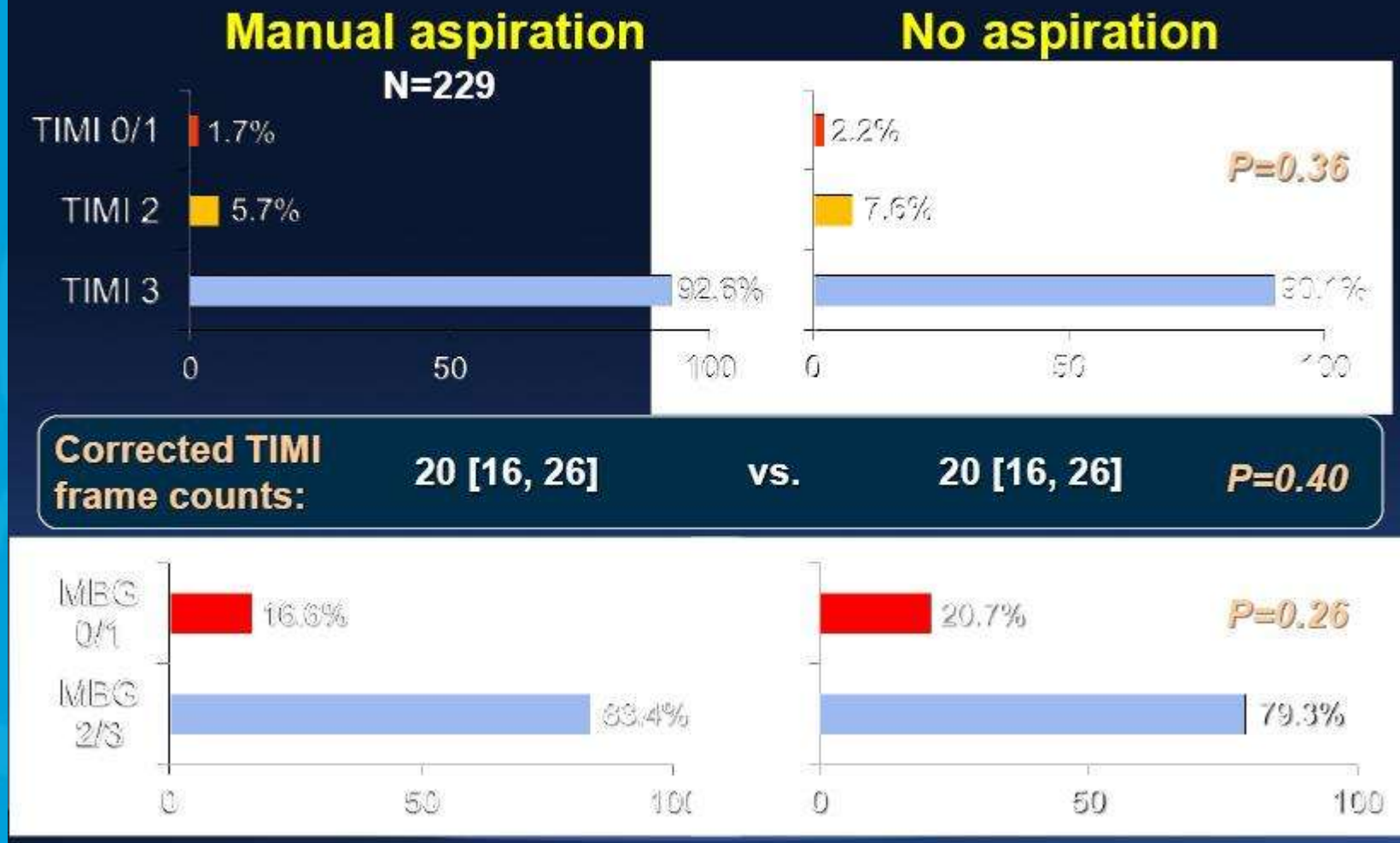
IC Abcx

No Abcx

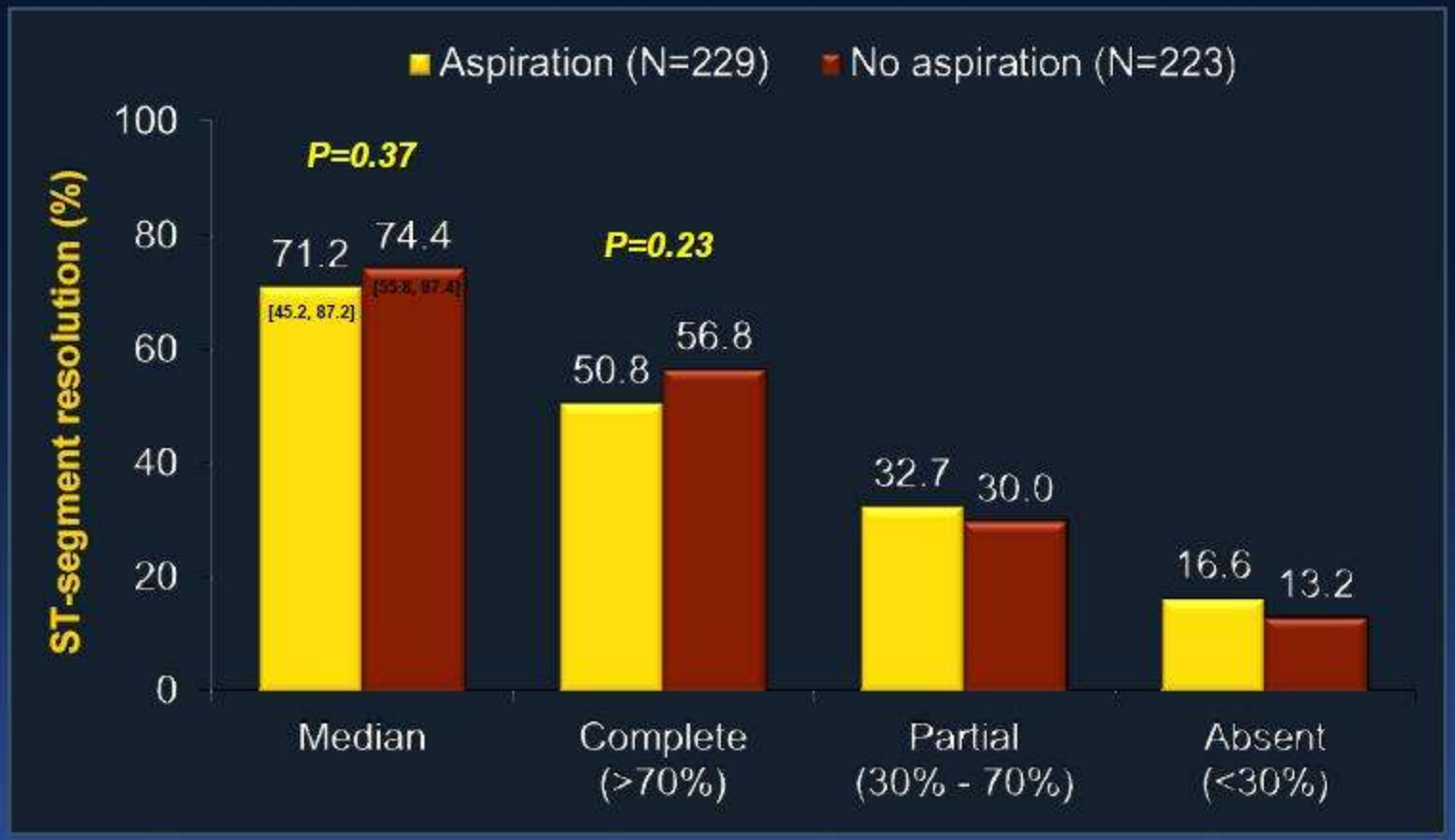
Primary endpoint: Infarct size at 30 days (cMRI)

2º endpoints: TIMI flow, blush, ST-resolution, MACE (30d, 1 yr)

INFUSE-AMI: Reperfusion post-PCI*

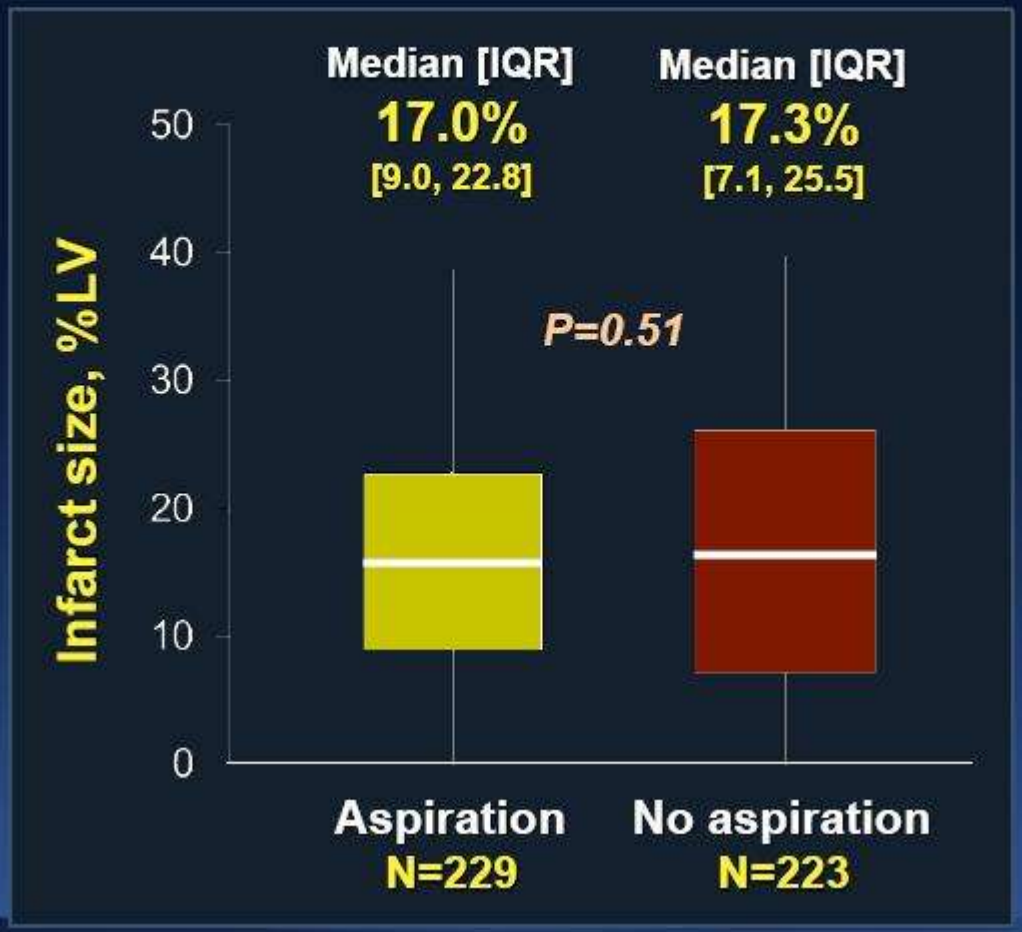


INFUSE-AMI: STR 60 minutes post-PCI*

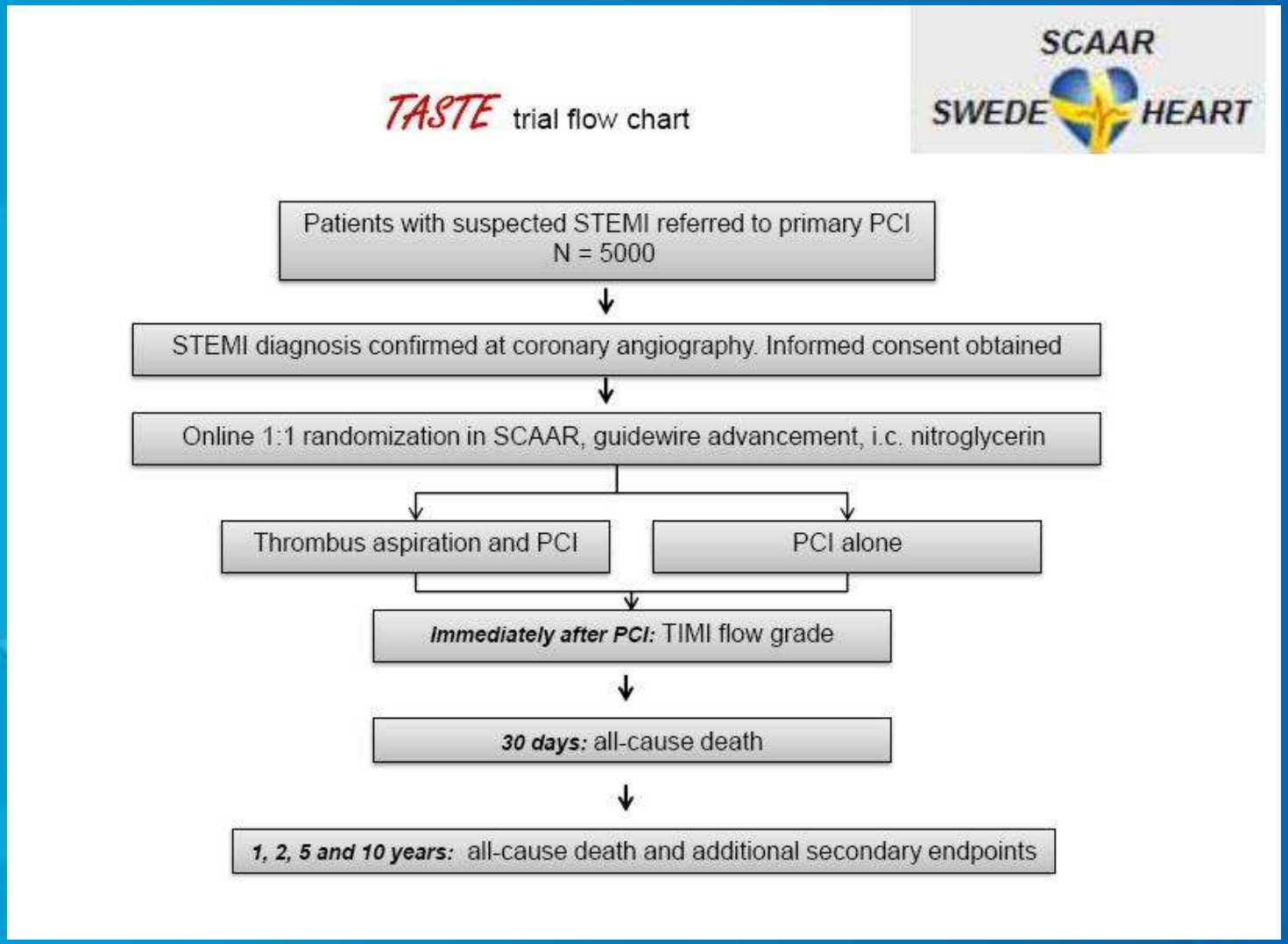


INFUSE-AMI: Infarct size at 30 days*

- Major secondary endpoint -



Tromboaspiración Manual: Estudios en curso



Tromboaspiración Manual: Estudios en curso

TOTAL

TOTAL trial Study Design

PHRI

4000 STEMI* patients referred for Primary PCI and randomized within 12 hours of symptom onset

↓

1:1 Randomization
(prior to diagnostic angiography)

↓

Manual Aspiration Thrombectomy followed by PCI

PCI Alone
(with bailout thrombectomy possible)

↓

Follow-Up Visits (in clinic or by telephone) at 30 days, 180 days and 1 year

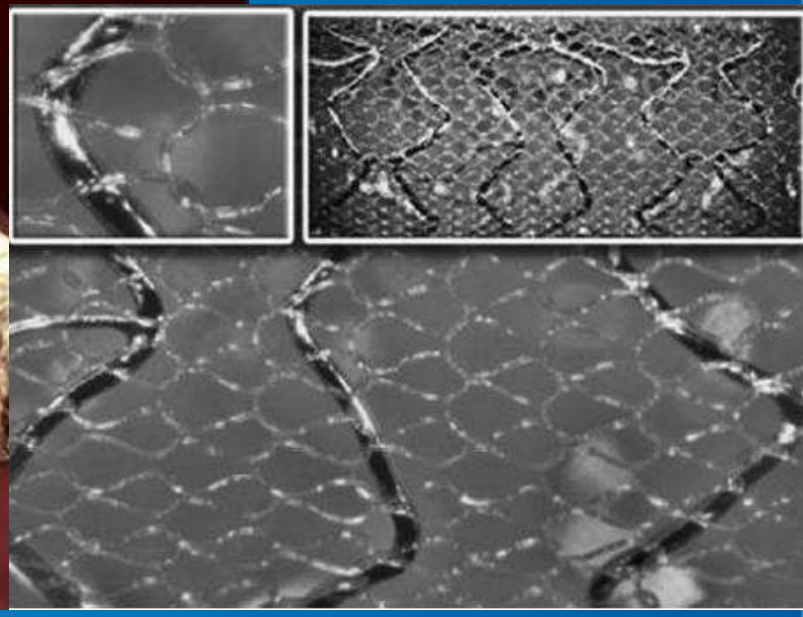
** Symptoms of myocardial ischemia lasting for ≥ 30 min, and*

Definite ECG changes indicating STEMI (ST elevation of >0.1 mV in two contiguous limb leads or >0.2 mV in two contiguous precordial leads, or presumed new left bundle branch block)

Contact email: total @phri.ca

Primary outcome: CV death, recurrent MI, cardiogenic shock and new or worsening NYHA Class IV HF at 180 days

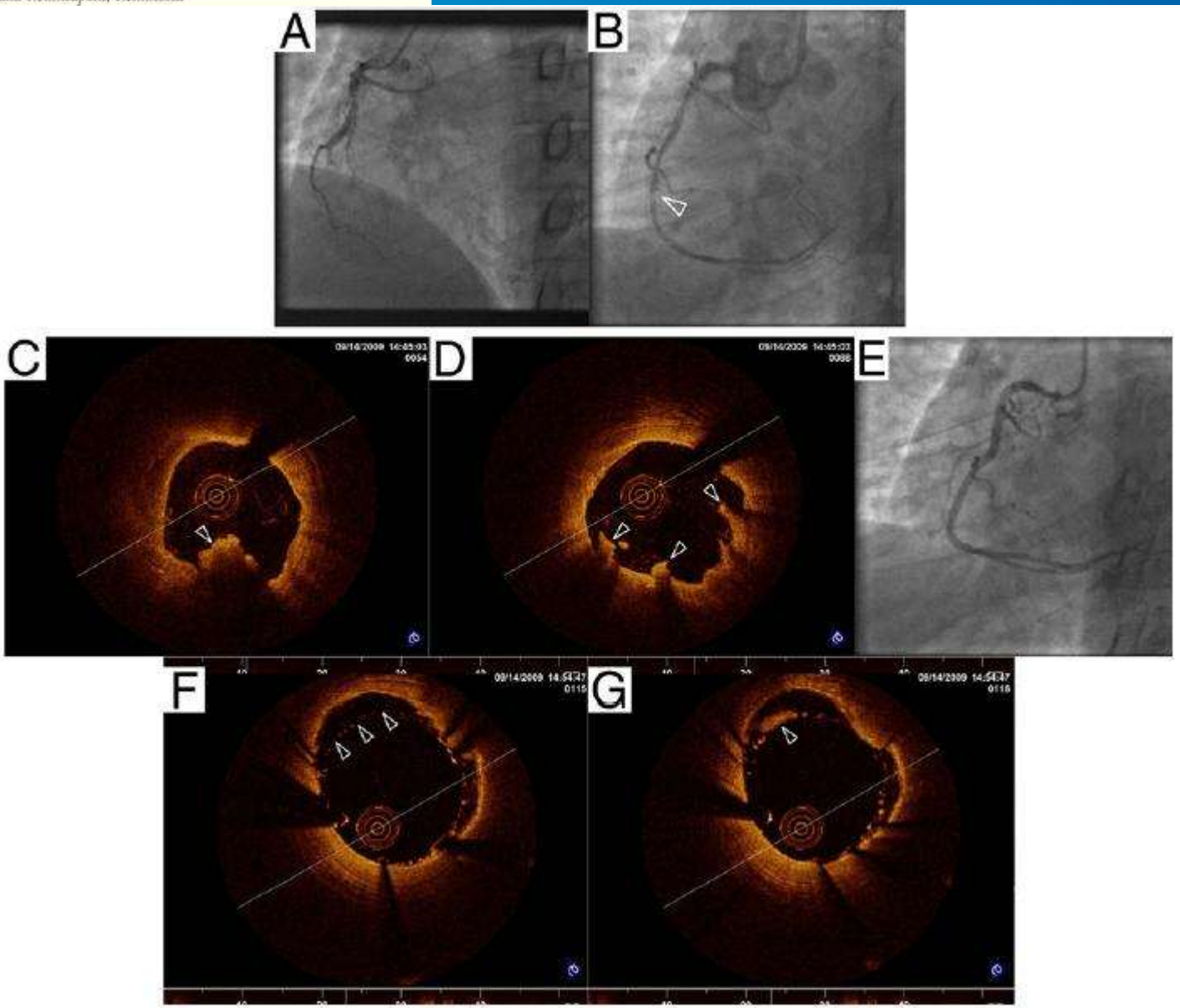
Stents cubiertos: MGuard



IMAGES IN CARDIOLOGY

Thrombus Entrapment by a Novel Mesh-Covered Stent in ST-Segment Elevation Myocardial Infarction

Ajay K. Jain, MD,* Martin T. Rothman, MD*†
London, United Kingdom; and Minneapolis, Minnesota



Stents cubiertos: MGuard

Catheterization and Cardiovascular Interventions 75:715–721 (2010)

Multicentre Experience With MGuard™ Net Protective Stent in ST-Elevation Myocardial Infarction: Safety, Feasibility, and Impact on Myocardial Reperfusion

Federico Piscione,[1*] MD, Gian Battista Danzi,[2] MD, Salvatore Cassese,[1] MD, Giovanni Esposito,[1] MD, Plinio Cirillo,[1] MD, Gennaro Galasso,[1] MD, Antonio Rapacciuolo,[1] MD, Dario Leosco,[1] MD, Carlo Briguori,[3] MD, Ferdinando Varbella,[4] MD, Bernardino Tuccillo,[5] MD, and Massimo Chiariello,[1] MD

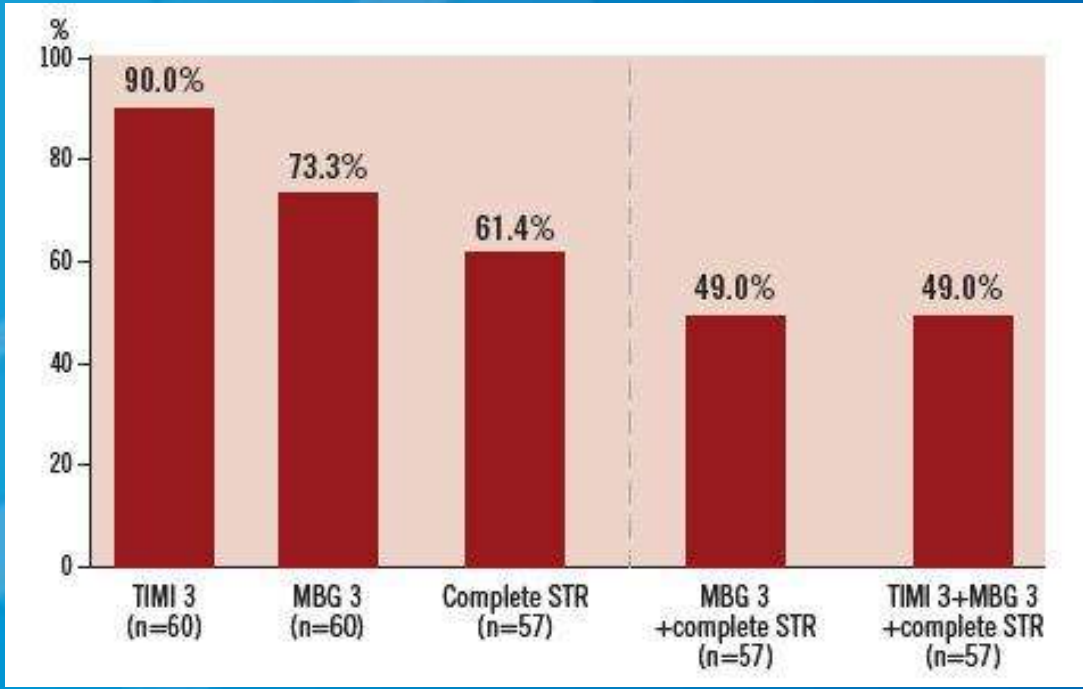
TABLE III. Procedural Findings and ST Segment Resolution of the Study Group

Post-PCI residual stenosis	3.10 ± 9.80 (%)
Post-PCI cTFC (*n*)	17.20 ± 10.51
ΔcTFC (*n*)	48.16 ± 32.13
Post-PCI TIMI flow grade (mean)	2.85 ± 0.40
Post-PCI MB	
Grade 3	90 (%)
Grade 2	10 (%)
Grade 0-1	0 (%)
Thrombus aspiration device	10 (%)
Direct stenting	58 (%)
Stent/lesion (n)	1.28 ± 0.57
Post dilation	22 (%)
Post-PCI Troponin I (ng/mL)	18.53 ± 21.44
Post-PCI CK-MB (ng/mL)	144.17 ± 320.96
Post-PCI Max ST-segment elevation (mm)	1.77 ± 3.34
ST-resolution 60 min post-PCI	
≥70%	90 (%)
>30 to <70%	10 (%)

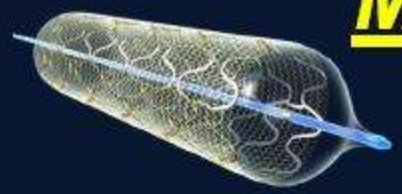
Stents cubiertos: MGuard

Mesh covered stent in ST-segment elevation myocardial infarction

Dariusz Dudek[1]*, MD, PhD; Artur Dziewierz[2], MD, PhD; Łukasz Rzeszutko[1], MD, PhD; Jacek Legutko[1], MD, PhD; Wojciech Dobrowolski[3], MD; Tomasz Rakowski[2], MD, PhD; Stanisław Bartus[1], MD, PhD; Jacek Dragan[3], MD; Artur Klecha[4], MD, PhD; Alexandra-J Lansky[5], MD, FACC; Zbigniew Siudak[2], MD, PhD; Krzysztof Zmudka[1], MD, PhD



EuroIntervention 2010;6:582-589



MGUARD for Acute ST Elevation Reperfusion
The MASTER Trial

STEMI with symptom onset within 12 hours at 432 pts at 50 sites in EU, Israel, Mexico and SA

R

PCI with BMS or DES

PCI with MGuard

Follow-up: 30 days, 6 months, 1 year

Primary endpoint: ST resolution at 60-90 minutes

Substudies:

MRI: 60 pts (30 in each arm) at 3-5 days

Angio FU: 60 pts in MGuard arm at 13 months

Principal investigators: Alex Abizaid, Dariusz Dudek, Sigmund Silber

Study Chairman: Gregg W. Stone

TCT 2011

CARDIOVASCULAR RESEARCH FOUNDATION

SOCIME

SOLACI '12 MEXICO DF

In partnership with TCT

Dispositivos para mejorar la reperfusión tisular
Conclusiones

- Los resultados beneficiosos mostrados por los sistemas de oclusión distal y filtros en las intervenciones en puentes venosos no se confirmaron en los estudios que evaluaron su performance en las intervenciones en SCACEST. Sin embargo pueden ser de utilidad en situaciones especiales de alto contenido trombótico.
- Existe escasa experiencia aún con los sistemas de protección proximal, requiriendose de ensayos clínicos con > número de pacientes para evaluar sus beneficios en términos de perfusión y eventos clínicos.
- Los resultados contradictorios respecto al rol de la tromboaspiración manual requieren esperar los resultados de los grandes estudios clínicos actualmente en curso para definir la recomendación de su utilización sistemática en ATC primaria (Clase IIa a Clase I)
- El concepto del stent cubierto como dispositivo de protección embólica es atractivo, y sus resultados iniciales demuestran la factibilidad de su utilización.
- A pesar de las drogas y dispositivos disponibles en la actualidad, existe un significativo porcentaje de pacientes que no alcanzan una reperfusión miocárdica completa, lo cuál se asocia con una peor evolución, y refuerza la necesidad de persistir en la búsqueda de estrategias para optimizar la reperfusión miocárdica tisular.

“MUCHAS GRACIAS”