Angioplastia primaria. Tromboaspiración. Del tiempo puerta balón al flujo TIMI III

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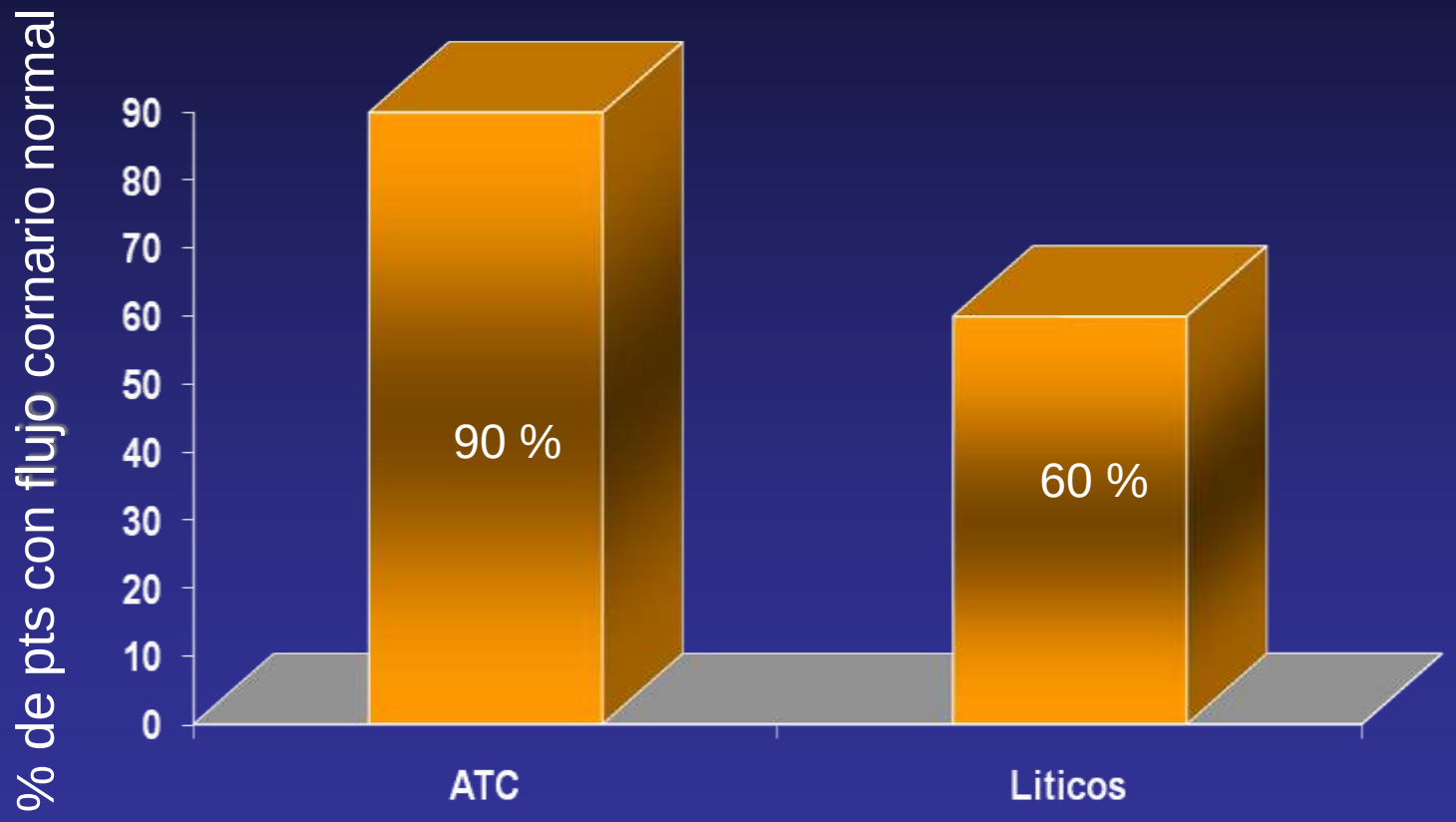
Córdoba, Argentina

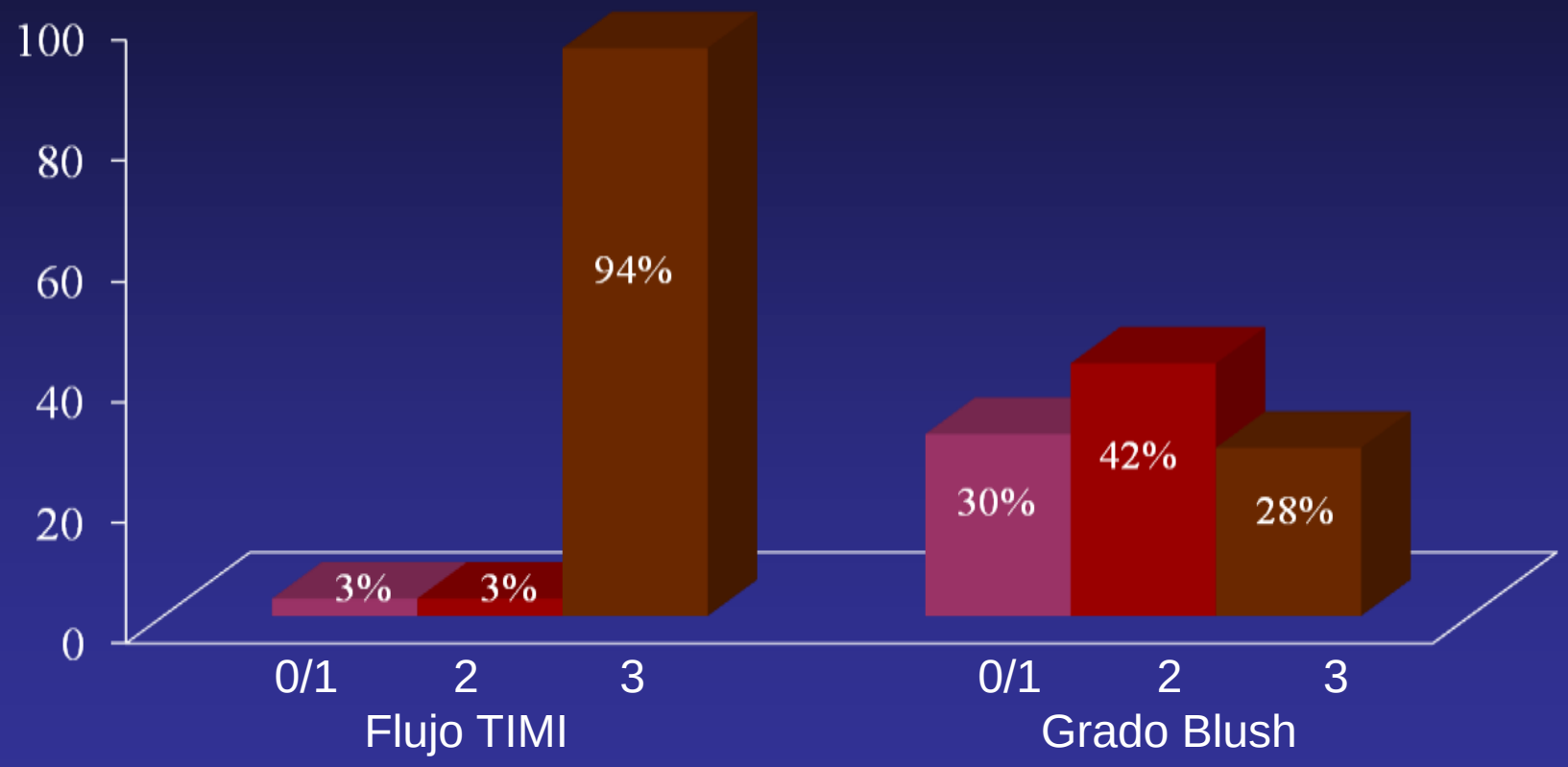
Sin conflictos de Interés

Pacientes con flujo TIMI 3 tratados con Trombolíticos vs. ATC primaria



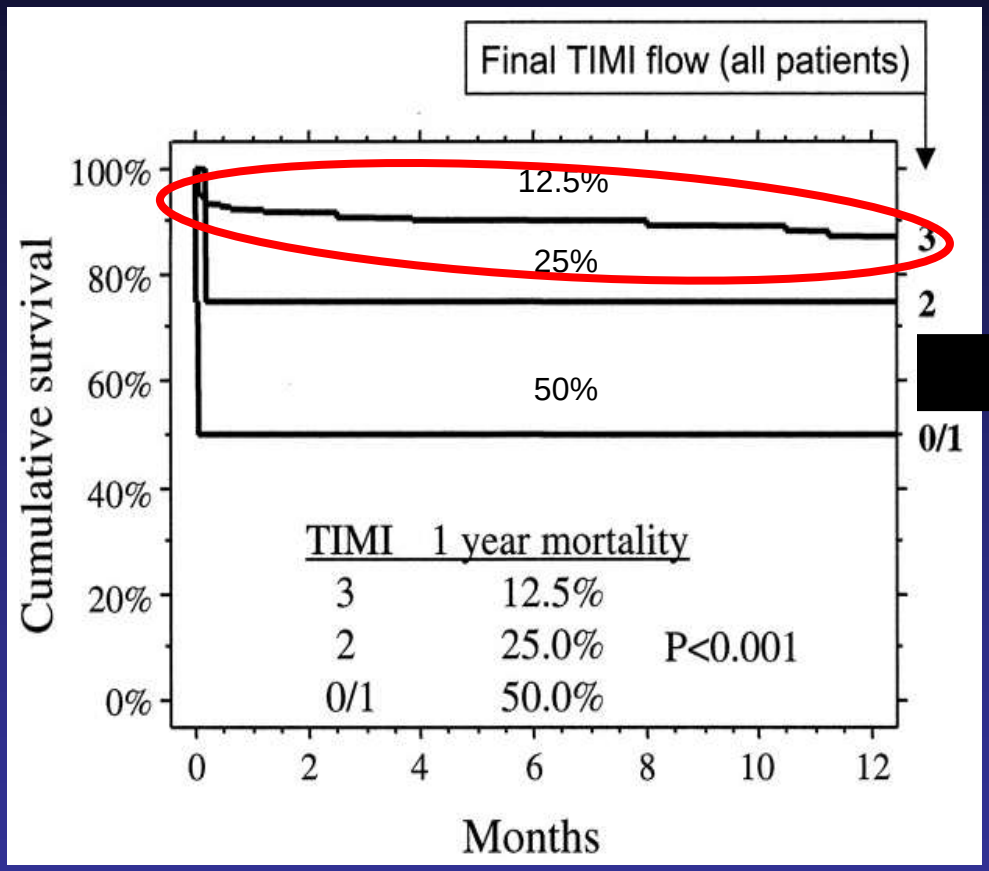
JACC 1998;32:1312-1319

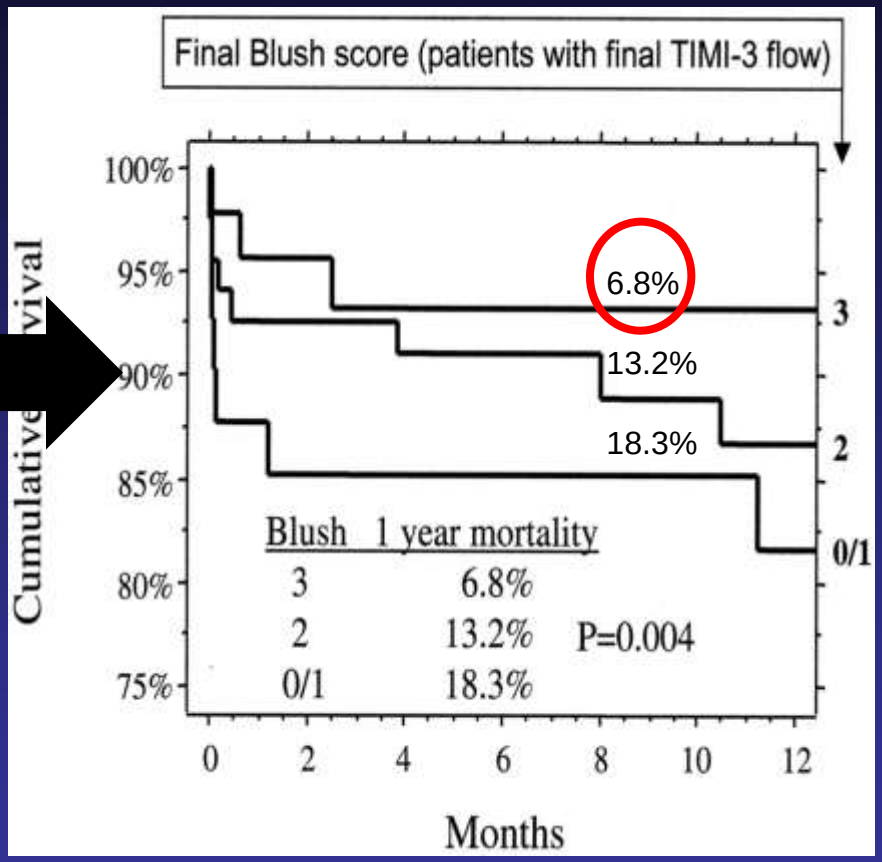
Grados de Flujo TIMI y Blush Miocárdico Post ATC Primaria



JACC 2002;39:591-597

Mortalidad en base al Flujo TIMI 3 y al grado de Blush Miocárdico

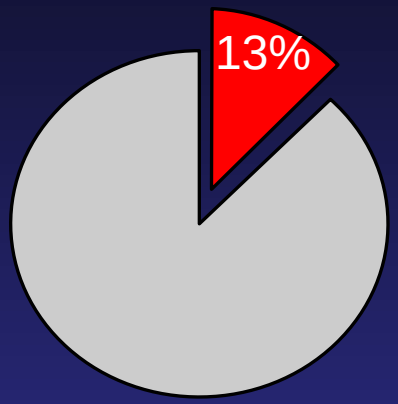




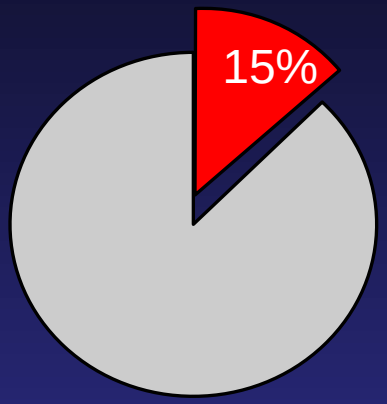
JACC 2002;39:591-597

Resultados luego de ATC primaria

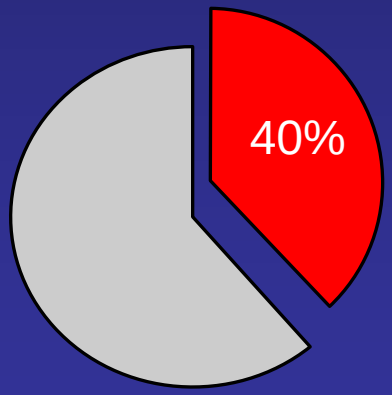
Final TIMI 0-2



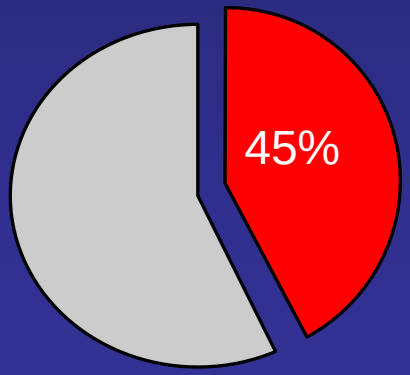
Angiographic distal embolization



TIMI Blush score 0-1

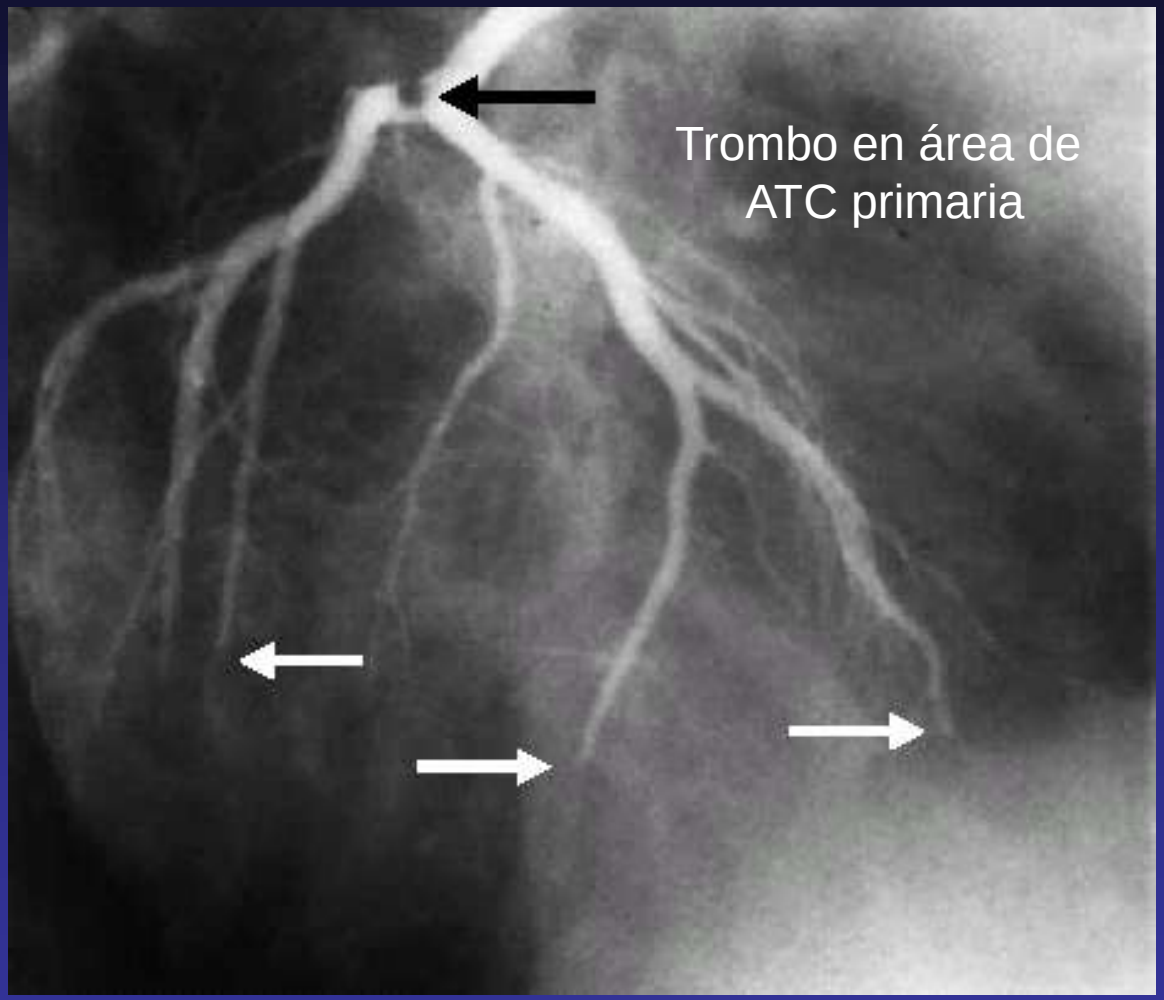


Non complete STR



Cura F, Am J Cardiol 99, 2007

Evidencia de embolización distal Macroscópica



Embolos macrocópicos distales

Impacto de la embolización macroscópica post ATC primaria

Evento	Emb (+)	Emb (-)	P
Flujo TIMI 3	70 %	90 %	0.01
LDH	1612	847	0.05
FE	42 %	51 %	0.01
Mortalidad	44 %	9 %	0.01

EHJ 2002;23:1112-7

Razones para el uso de la trombectomía

- La apertura de la arteria no asegura perfusión miocardica:

  Compromiso microvascular (no reflow, Blush 0,1, no resolucion del ST)

- A mayor carga trombótica mayor probabilidad de embolia distal macroscópica

- Resultados a largo plazo todavía desfavorables

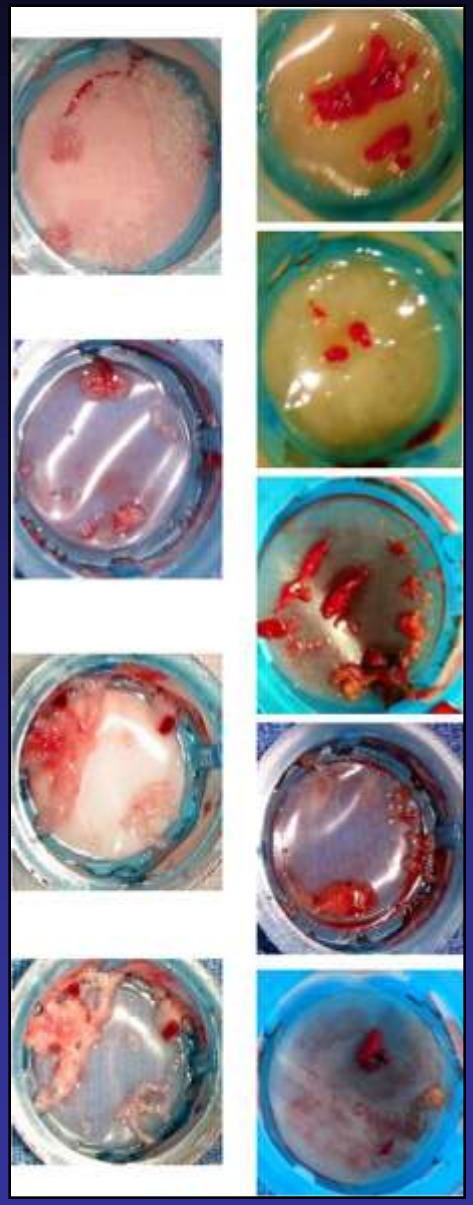
Estrategias para reducir la carga trombótica

Farmacológica

- Gp IIb/ IIIa

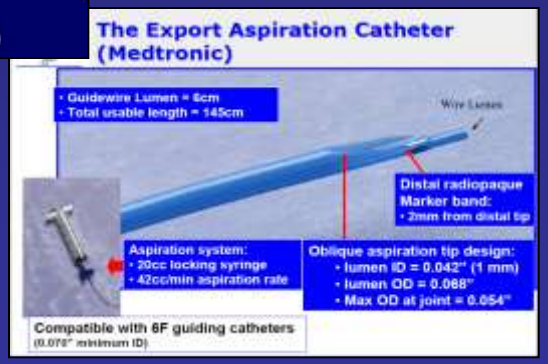
Mecánica

- Dispositivos de protección
- Trombectomía mecánica
- Trombectomía manual

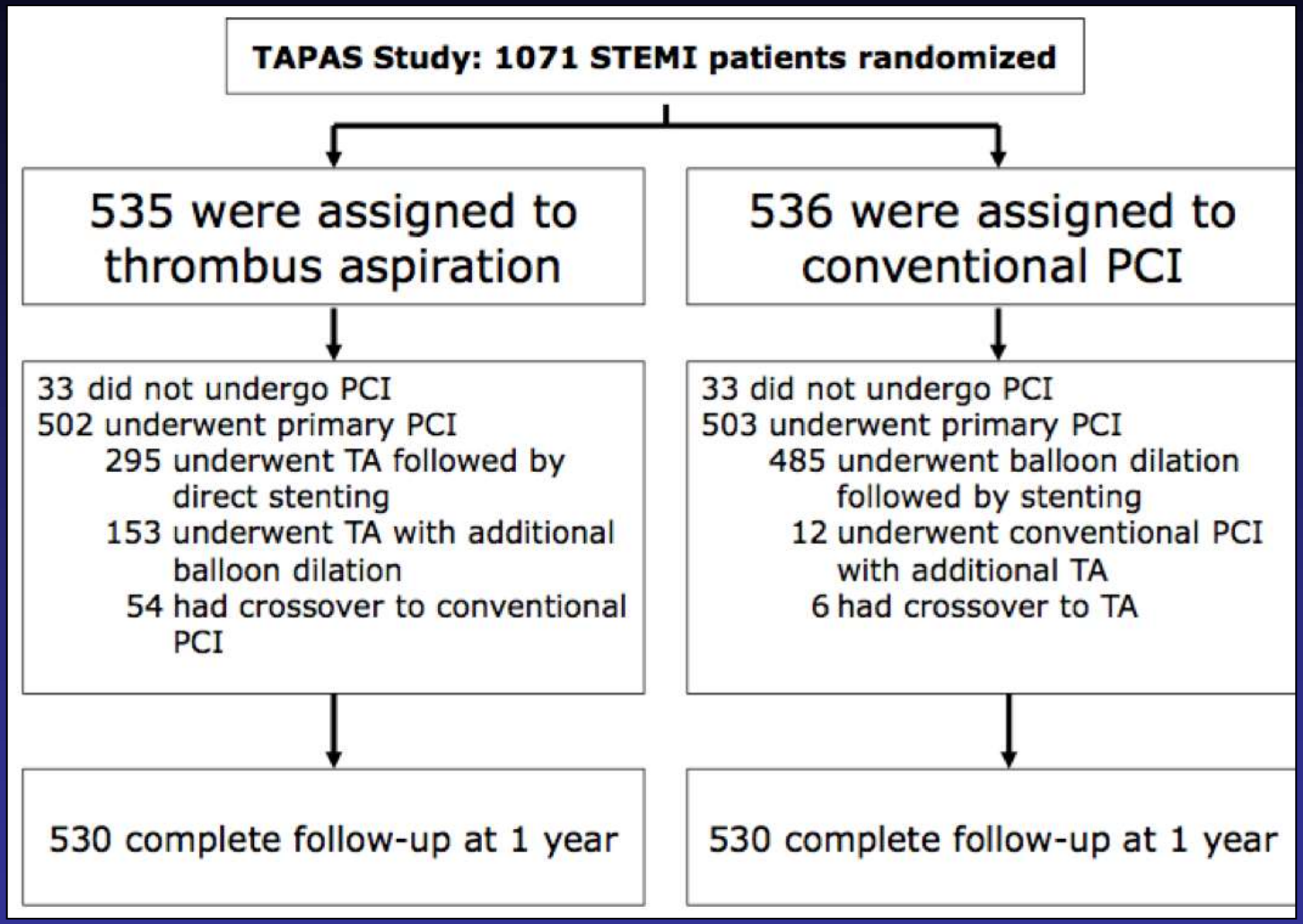


Trombectomía manual

- Simple de usar
- No tiene curva de aprendizaje
- Es 6F compatible
- No incrementa en forma significativa el tiempo para lograr reperfusión
- Permite la administración de droga distalmente



Estudio TAPAS

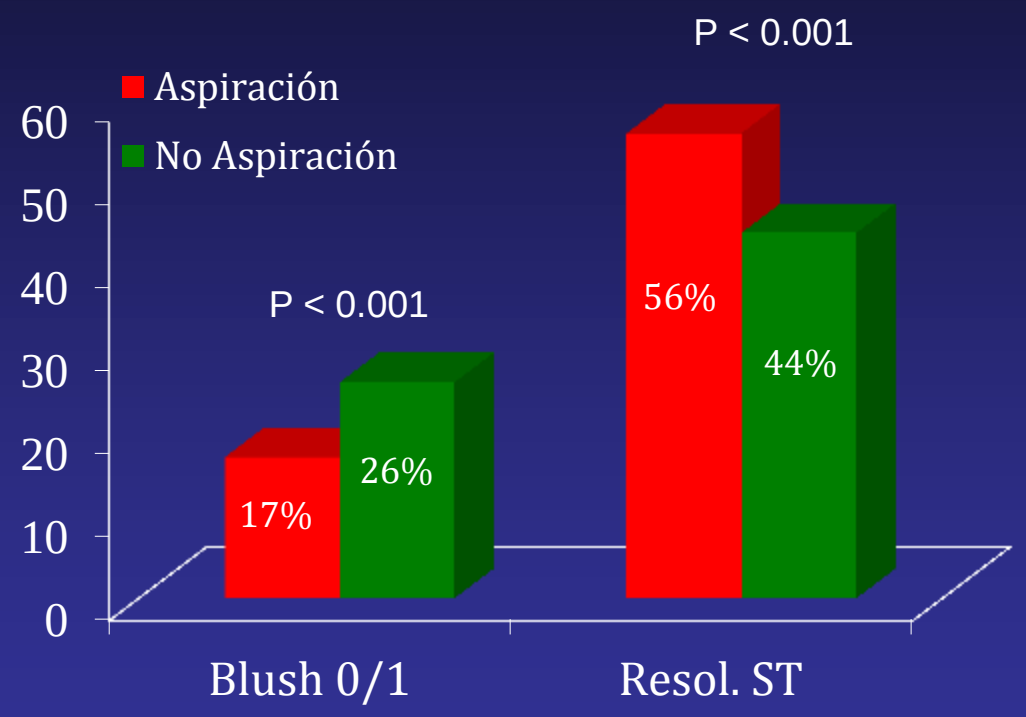


Svilaas et al, NEJM 2008;358:557-67
Lancet 2008;371:1915-1920

Estudio TAPAS

- Se randomizaron 1.071 pts con IAM a ATC primaria con o ATC sin aspiración Manual
- Se utilizaron Stents en 90% e Inh Gp IIbIIIa en 90% de los pacientes
- Se obtuvo material con la aspiración en 72% de los casos
- El punto final primario fue la incidencia de Blush 0/1 y la Resolución del ST
- Se evaluó mortalidad al año de seguimiento

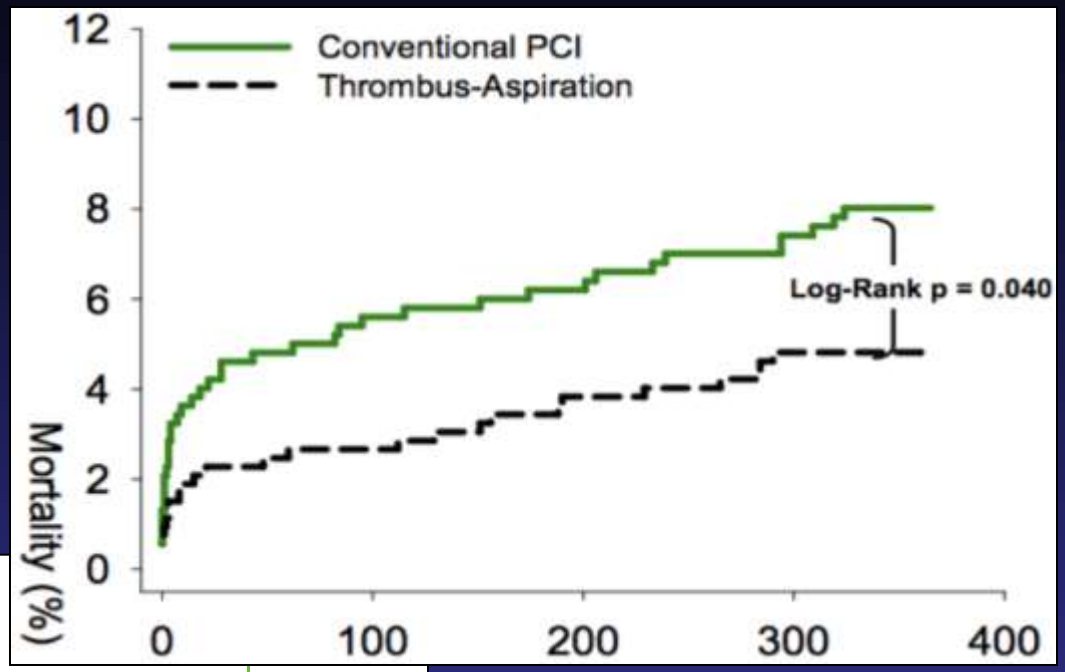
Punto final primario:
Blush 0/1 - Resolución del ST

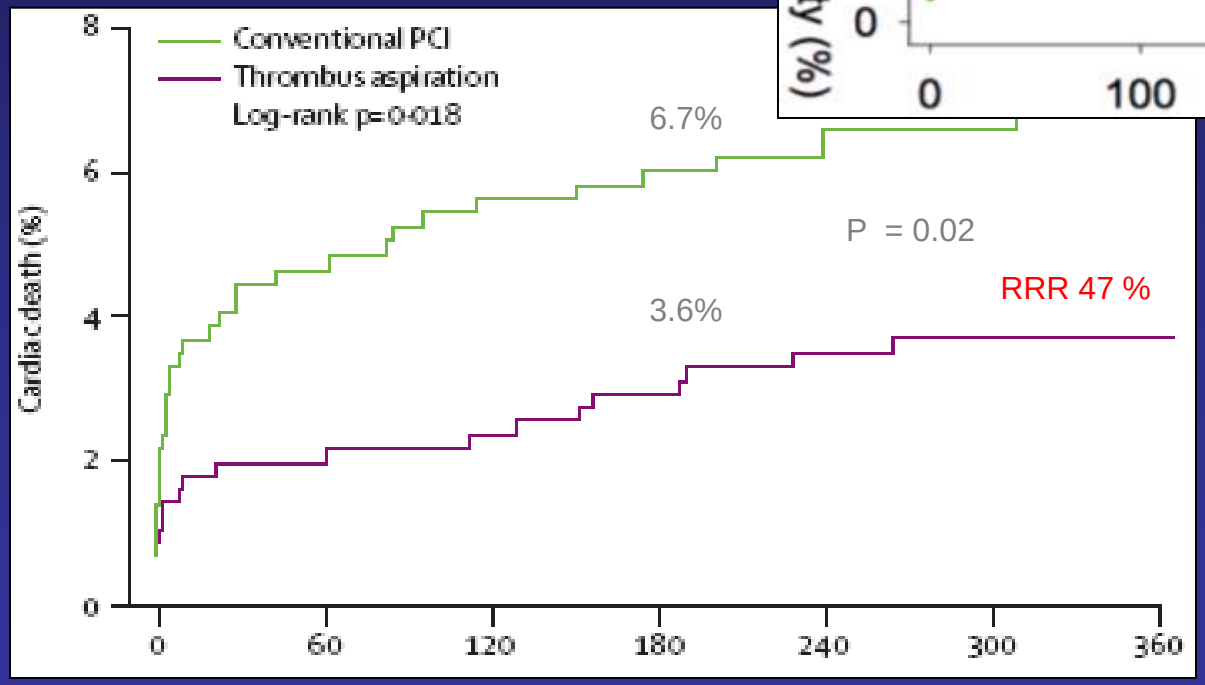


Svilaas et al, NEJM 2008;358:557-67
Lancet 2008;371:1915-1920

Estudio TAPAS

Mortalidad total y cardíaca al año





Svilaas et al, NEJM 2008;358:557-67
Lancet 2008;371:1915-1920

Estudio EXPIRA

(G.Sardella et al presented at TCT 2007)

Design

- Prospective, randomized, double-arm, mono-centric study.
- *Primary end-point :*
  - *Final MBG ≥ 2 ;*
  - *90′ ST resolution*

  (> 70% decrease of ST segment after PCI)

Secondary end-point :

- ***MACE at 9 month clinical f-u***
- *Principal investigator*

  G.Sardella MD

256 pts.
(STEMI, at 6.8 ± 2.3 h from symptoms onset)

175 pts. eligible for 1:1 randomization
(Heparin 7.500 U/I, GPIIb/IIIa, Aspirin, Clopidogrel 300 mg)

81 pts.excluded:
- Cardiogenic shock
- 3-vessel / Left Main
- TIMI >0-1
- TS < 3
- Contra to GPIIb/IIIa

87 pts randomized to Standard PCI

88 pts randomized to Thrombectomy + PCI

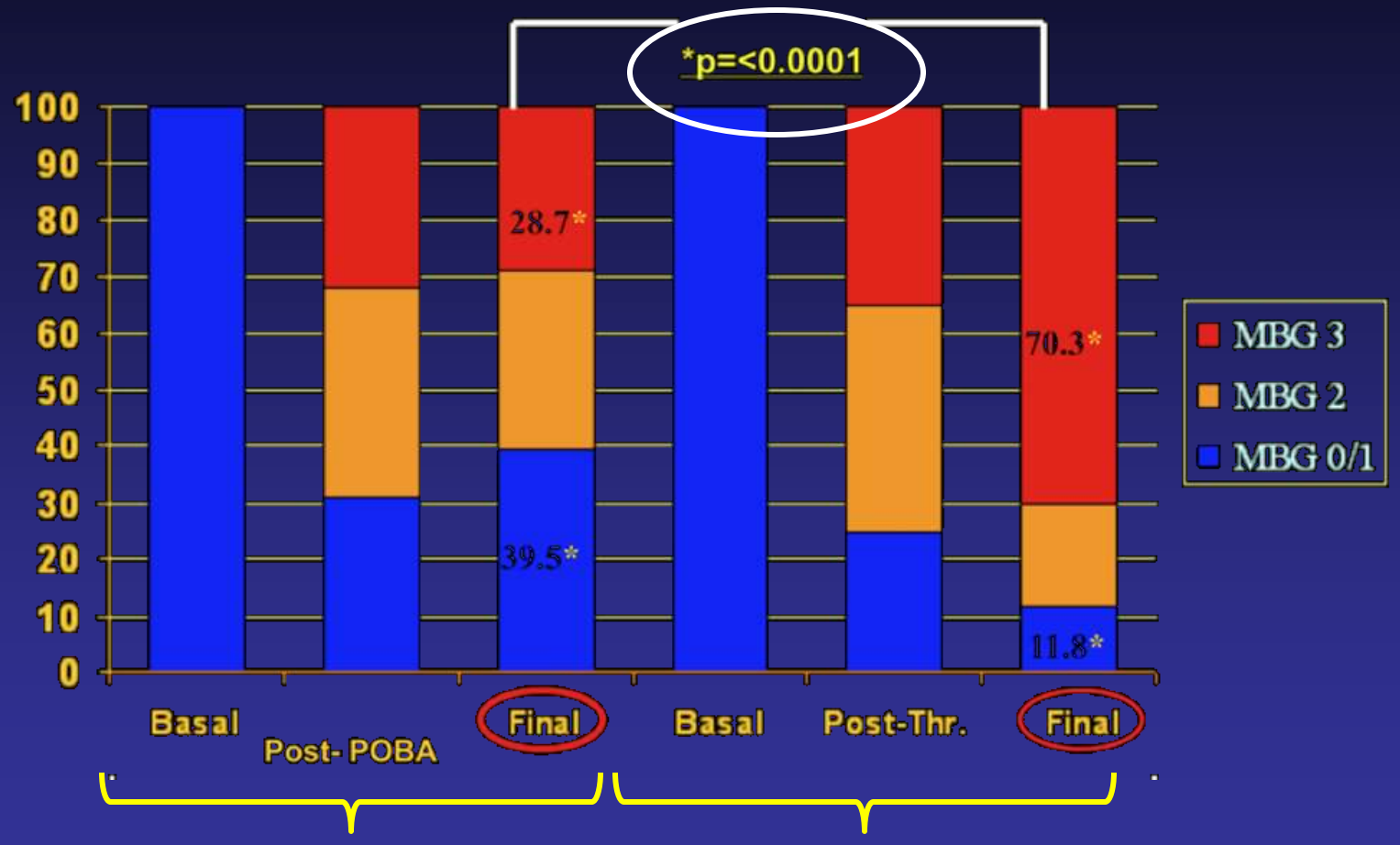
9 months clinical f-u

Dip.di SCIENZE CARDIOVASCOLARI
POLICLINICO UMBERTO I

G.Sardella et al J. Am. Coll. Cardiol 2009;53;309-315

Estudio EXPIRA.

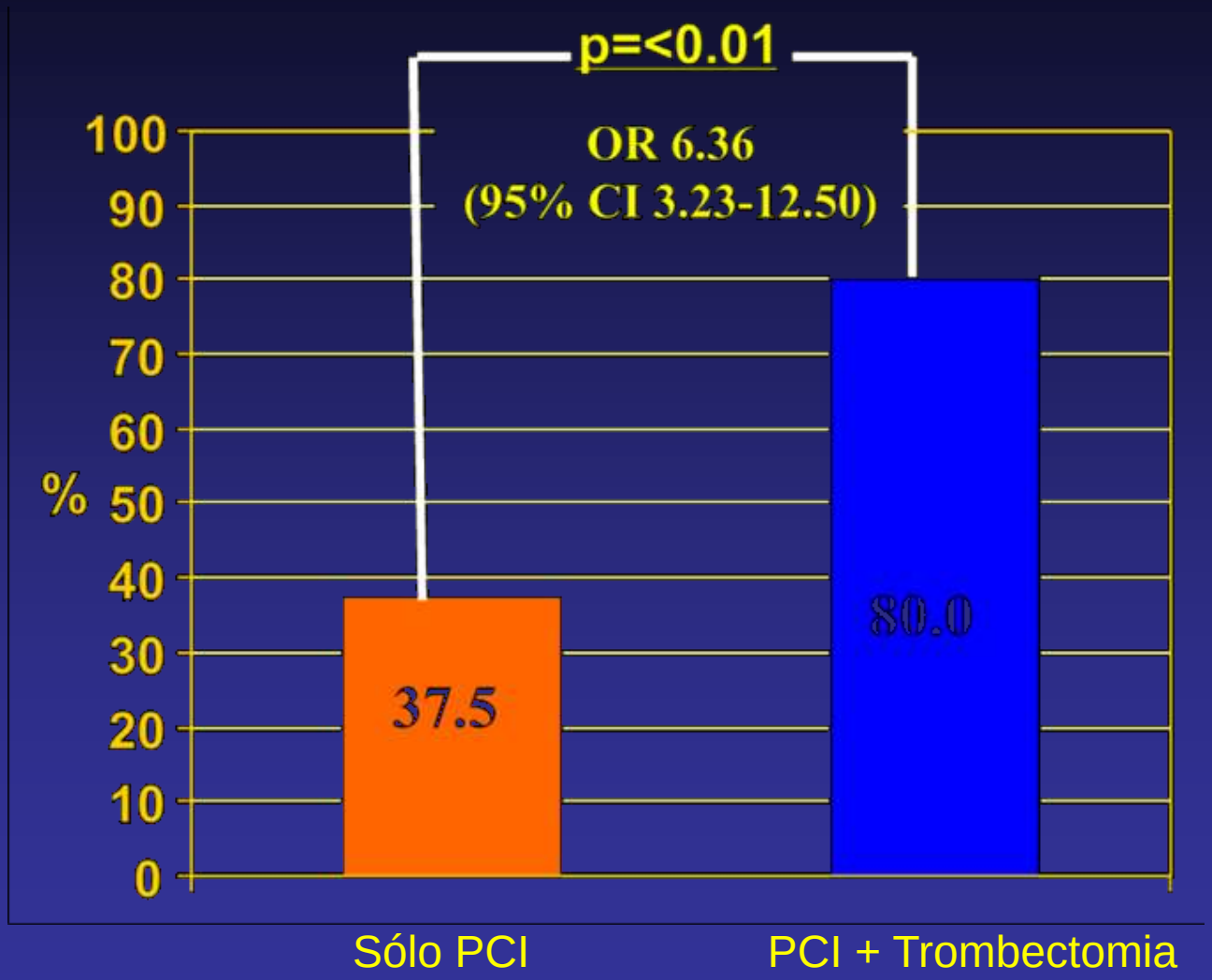
Resultados del Blush miocardico



G.Sardella et al J. Am. Coll. Cardiol 2009;53;309-315

Estudio EXPIRA.

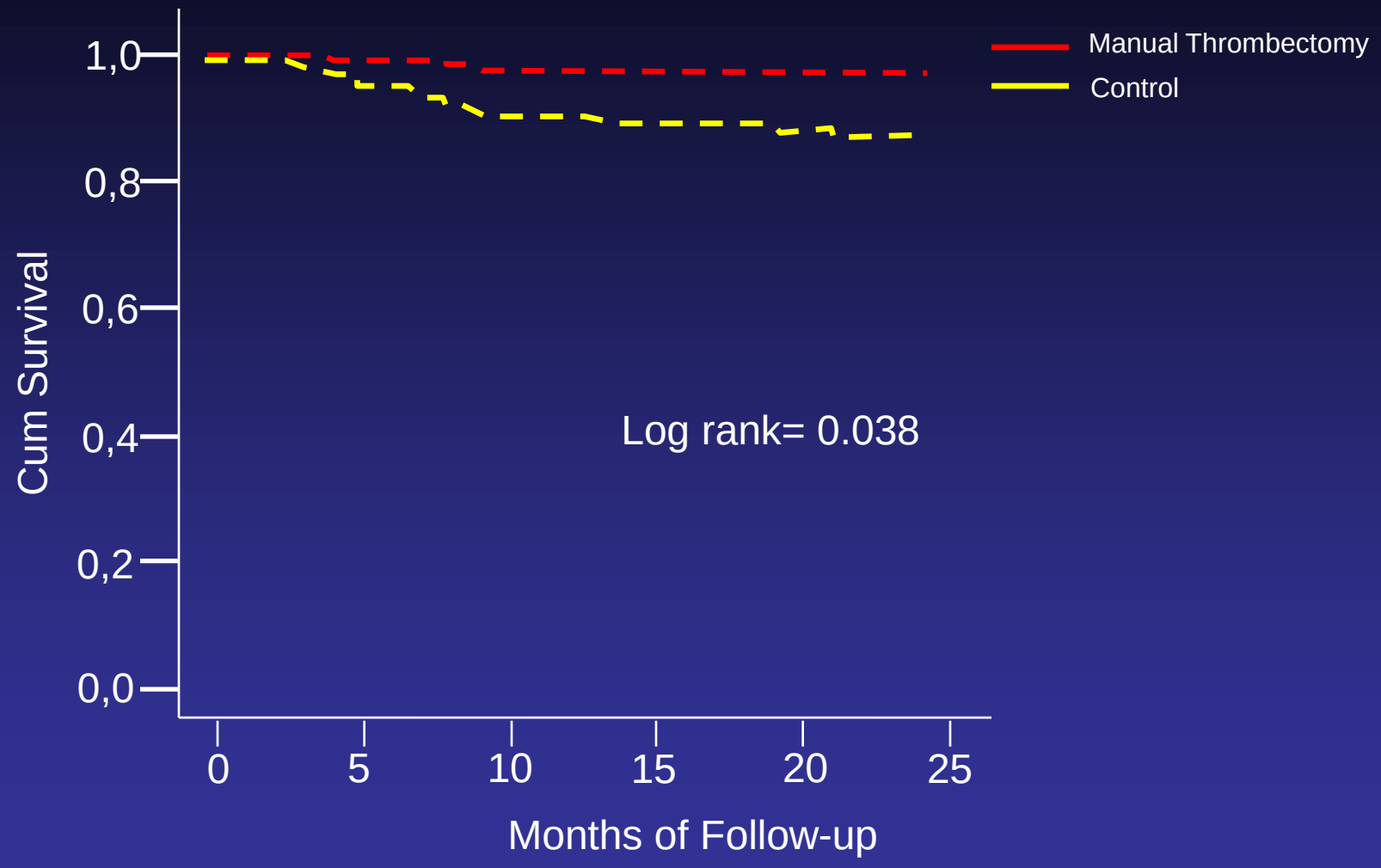
Resultados de la disminución del ST a los 90´



G.Sardella et al J. Am. Coll. Cardiol 2009;53;309-315

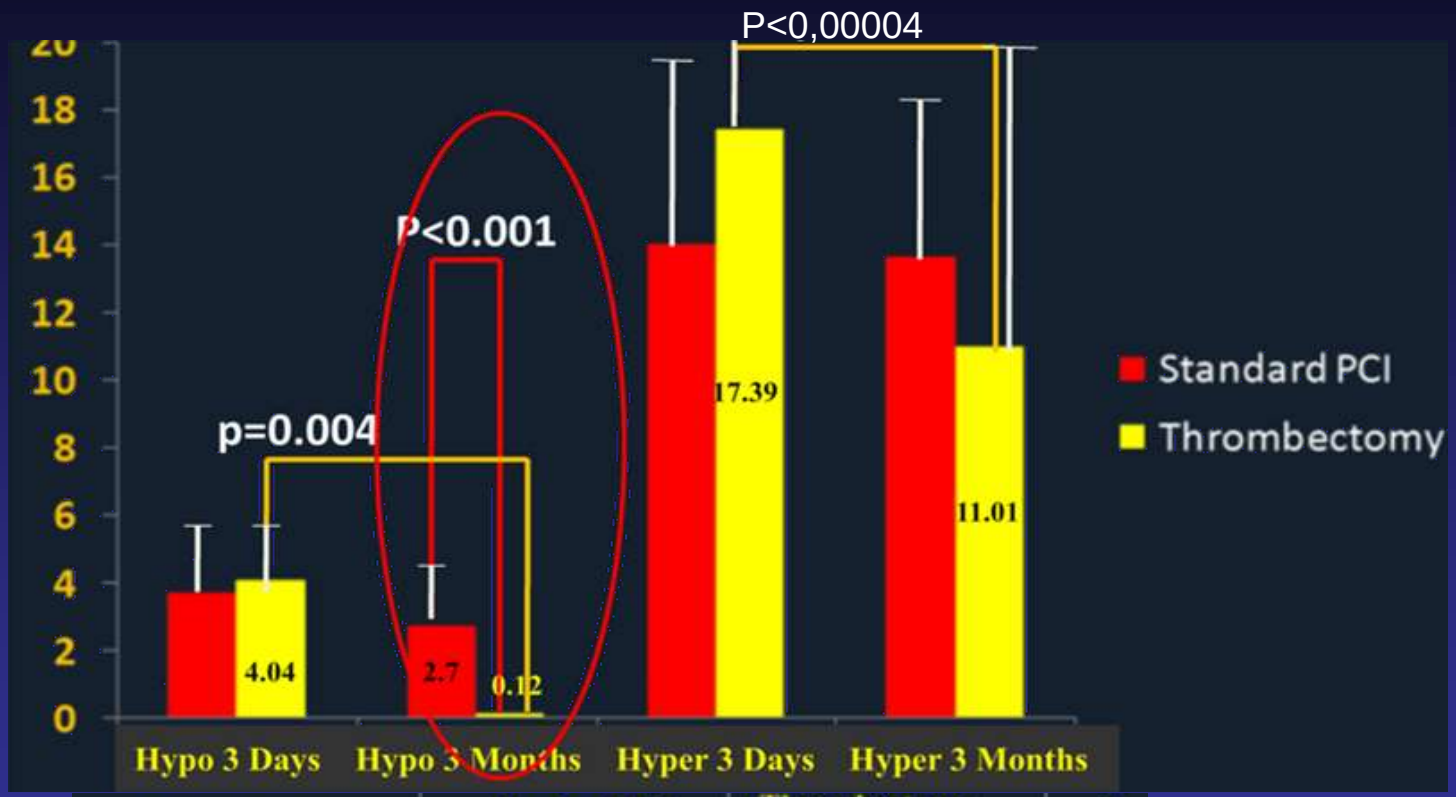
Estudio EXPIRA.

Sobrevida libre de eventos a 2 años



Estudio EXPIRA.

Resultados de la evaluación mediante MRI



MRI evaluation	Standard PCI (n=37)		Thrombectomy (n=38)		*p*
	3 d	3 m	3 d	3 m	
Hypoenhancement (gr)	3.7±5.04	2.7±2.3 ✝	4.04±5.87 *	0.12±0.4 * ✝	<.001
Hyperenhancement (gr)	14.02±7.5	13.6+ 12,7	17.39±15.6 §	11.01±8.07 §	

G.Sardella et al J. Am. Coll. Cardiol 2009;53;309-315

Meta-analisis evaluando trombectomía manual en ATC primaria

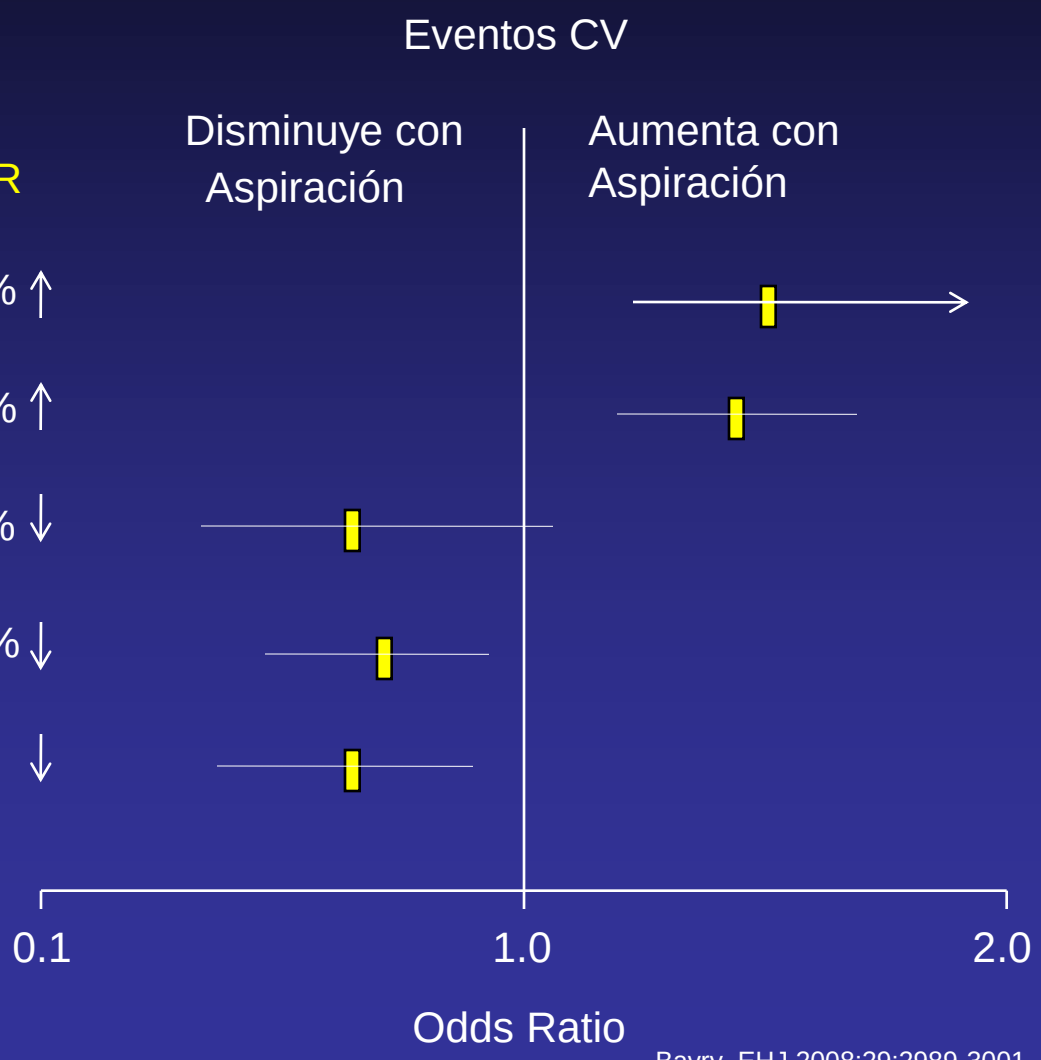
Meta-analysis	Number of Trials	Number of Patients	TIMI 3 Flow	MBG	STR	No Re-flow	Distal Emboli	Mortality
Bavry et al[5]	13	3,026		positive	positive	positive		
De Luca et al[7]	9	2,417	positive	positive			positive	positive
Burgotta et al[8]	11	2,686						
Mongeon et al[16]	16	3,365	positive	positive	positive		positive	positive

TIMI-3 Flow = TIMI 3 Flow post-PCI; MBG = myocardial blush grade post-PCI; STR = ST-segment resolution post-PCI
Positive indicates significant benefit with aspiration thrombectomy compared with control.
Neutral indicates no significant difference between aspiration thrombectomy and control.

Meta-análisis de Estudios Randomizados que incluyeron trombectomia manual

Incluyó a 13 estudios y a 3026 pacientes

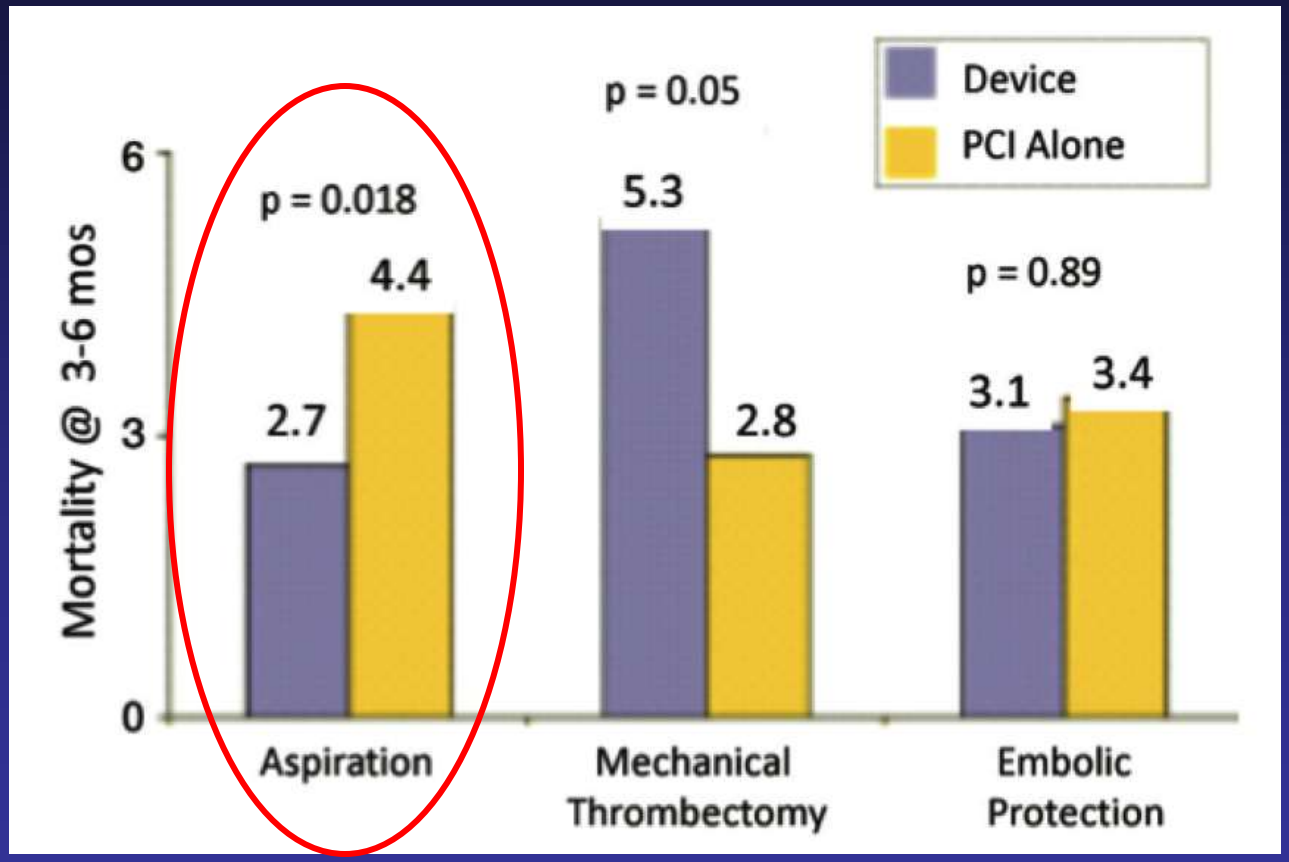
Evento	RR (95% CI)	RRR
TIMI Blush 3	1.69 (1.26-2.28)	69% ↑
Resolución ST	1.41 (1.21-1.64)	41% ↑
Re IAM	0.65 (0.37-1.12)	35% ↓
MACE	0.76 (0.62-0.95)	24% ↓
Mortalidad	0.63 (0.43-0.93)	8% ↓



Bavry, EHJ 2008;29:2989-3001

Meta-análisis de Estudios Randomizados Utilizando Catéteres de Aspiración

Incluyó a 13 estudios y a 3026 pacientes



Bavry, EHJ 2008;29:2989-3001

ATTEMPT study: Pooled-Analysis of Trials on ThrombEctomy in acute Myocardial infarction based on individual PatienT data.

A comprehensive *meta-analysis 11* Randomized Clinical Trial N= 2686 pts

STUDY DESIGN*

MEDLINE search → 12 trials → **17 trials** ← 5 trials ← EuroPCR and TCT web-site search

Principal investigators (PIs) have been contacted to provide data regarding the patients included in their study

PIs of 11 trials agreed to participate the ATTEMPT DATABASE
(patients pre-PCI characterictics and longest available clinical FU)

* Published as full paper (De Vita et al, Vasc Health and Risk Management 2009)
* Registered in clinicaltrials.org website NCT00766740

(Burzotta F. et al EHJ Sept.2 , 2009)

ATTEMPT study: Trials incluidos

EUROPEAN SOCIETY OF CARDIOLOGY®

MANUAL ASPIRATION

DIVER CE

REMEDIA | De Luca | PIHRATE

PRONTO

DEAR-MI

EXPORT

EXPORT | EXPIRA | TAPAS

NON-MANUAL THROMBECTOMY

ANGIOJET

Antoniucci

X-SIZER

X-AMINE ST

RESCUE

Kaltoft

TVAC

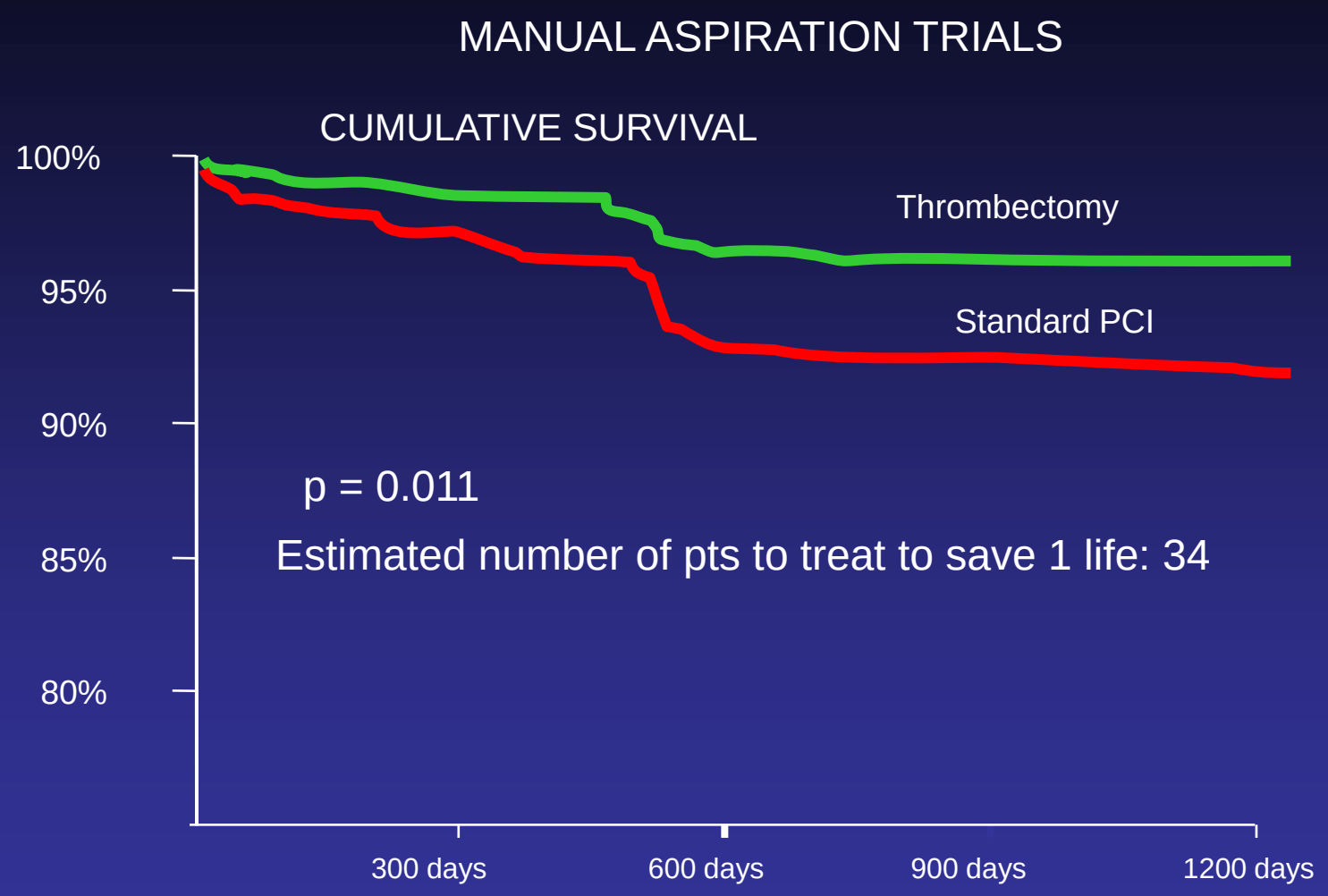
VAMPIRE

2686 pts

Median FU available for ATTEMPT study: 365 days
(significantly extended compared to published median FU of included trials: 135 days)

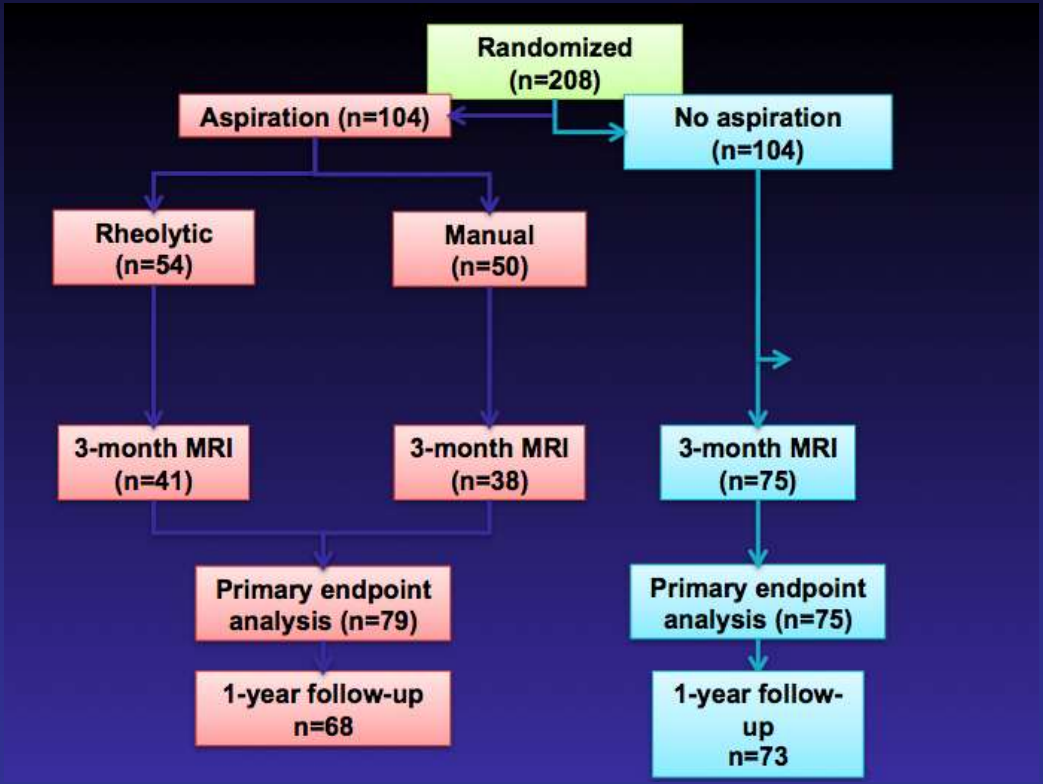
ATTEMPT study

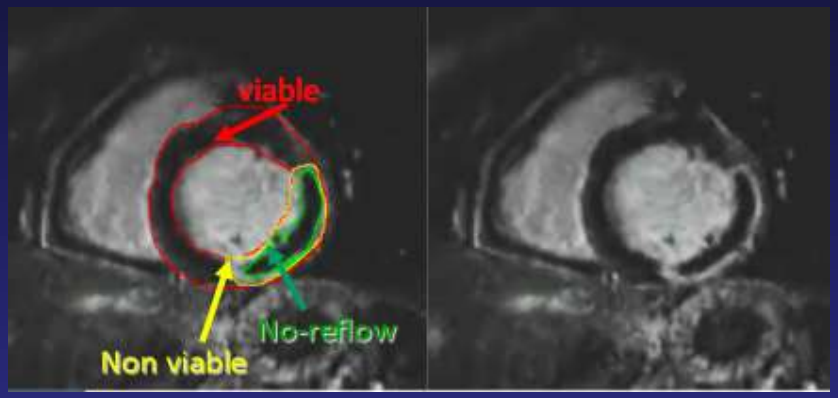
Sobrevida en el grupo de trials de trombectomia manual.



Burzotta F. et al EHJ Sept.2 , 2009

Mustela Trial: A Prospective, Randomized Trial of Thrombectomy vs. no Thrombectomy in Patients with STEMI and Thrombus-Rich Lesions





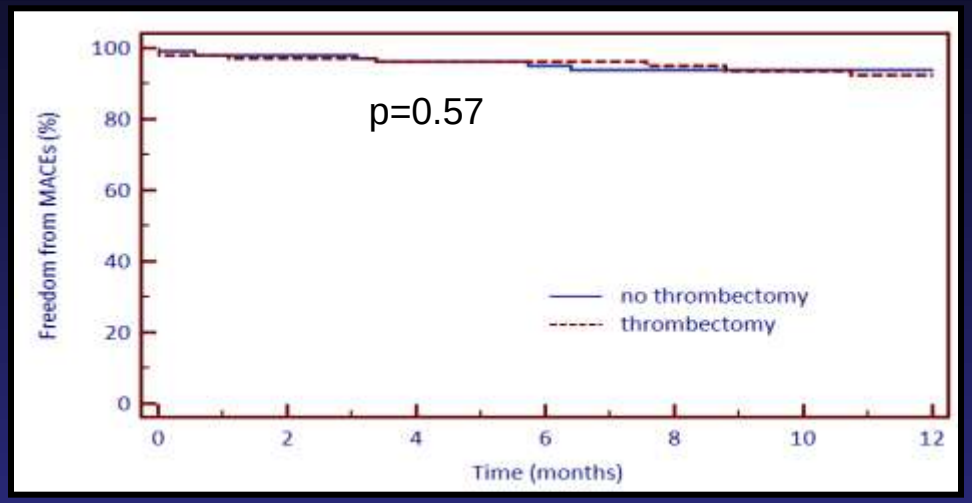
End point primarios

- Tamaño de infarto a tres meses (evaluado con retraso en el realce con MRI)
- ST-segment elevation resolution >70% at 60 minutes after primary PCI

De Carlo M et al.J Am Coll Cardiol Intv. 2012;5:1223-1230

Mustela Trial

Resolución del ST, TIMI y Blush. Evolución libre de MACEs



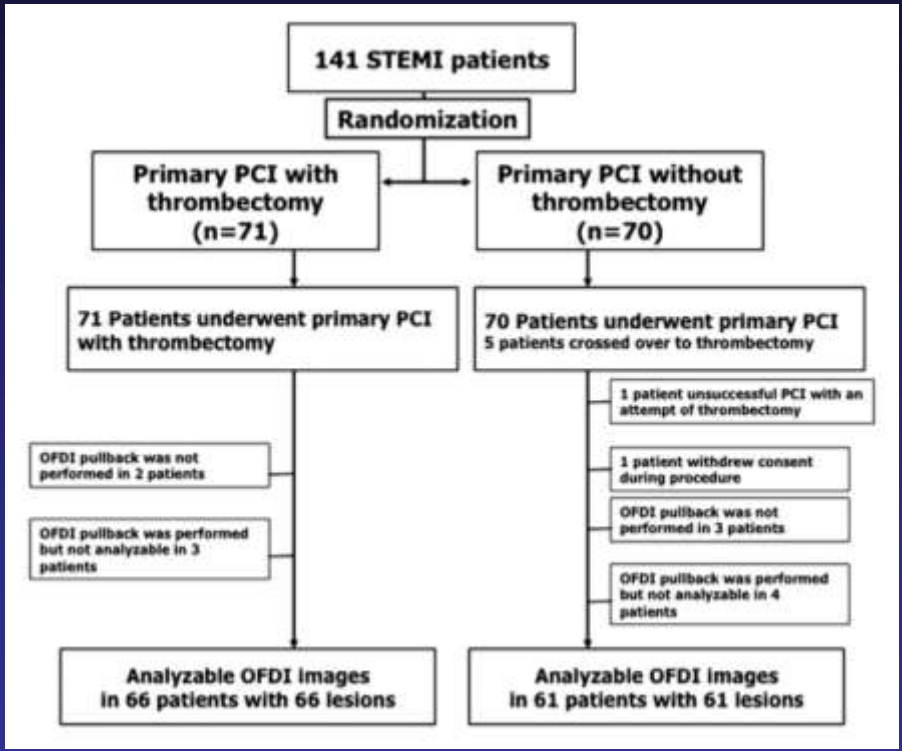
	Trombectomía (n = 104)	Sin Trombectomía (n = 104)	Valor *P*
Resolución TS > 70%	57.4%	37.3%	0.004
Grado Final de Blush Miocárdico= 3	68.3%	52.9%	0.03
Flujo Final TIMI = 3	90.4%	81.7%	0.07

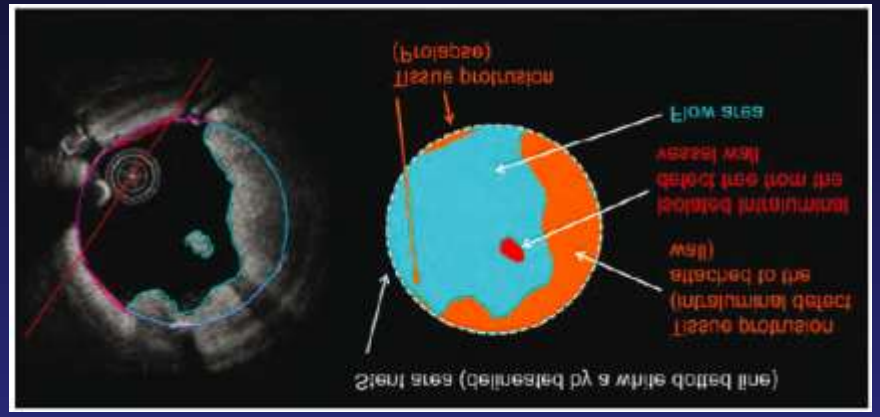
Conclusion: La trombectomía no fue asociada con reducción significativa del tamaño del infarto a 3 meses con MRI, *aunque si a mejoría en el flujo TIMI, Blush y resolución del ST.*

No hubo diferencias en MACEs al año

De Carlo M et al.J Am Coll Cardiol Intv. 2012;5:1223-1230

TROFI study: Randomized study to assess the effect of thrombus aspiration on flow area in patients with STEMI: An optical frequency domain imaging study.





	Thrombectomy (n = 71)	No Thrombectomy (n = 70)	*P* Value
Minimal Lumen Diameter, mm	2.69 ± 0.47	2.49 ± 0.46	0.01
Reference Vessel Diameter, mm	3.01 ± 0.48	2.79 ± 0.48	0.007
Minimum Flow Area, mm^2	7.08 ± 2.14	6.51 ± 1.99	0.12
Minimum Stent Area, mm^2	7.62 ± 2.26	7.07 ± 2.09	0.16

Conclusión: El estudio randomizado y controlado utilizando OFDI no mostró diferencias significativas en el area de flujo entre PCI con y sin trombectomia.

Onuma Y et al Eur Heart J 2013; 34: 1050-1060

Estudios en proceso: TOTAL Trial

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Brief Title ICMJE	A **Trial** of Routine Aspiration Thrombectomy With Percutaneous Coronary Intervention (PCI) Versus PCI Alone in Patients With ST-Segment Elevation Myocardial Infarction (STEMI) Undergoing Primary PCI
Official Title ICMJE	**TOTAL Trial**: A Randomized **Trial** of Routine Aspiration ThrOmbecTomy With PCI Versus PCI ALone in Patients With STEMI Undergoing Primary PCI
Brief Summary	This is an international, randomized, controlled, parallel group **study** in which patients with ST-Segment Elevation Myocardial Infarction (STEMI) will be allocated to one of the following: Manual aspiration thrombectomy with Percutaneous Coronary Intervention (PCI) or PCI alone.
Detailed Description	The hypothesis for TOTAL is that the routine use of manual aspiration thrombectomy with an aspiration catheter (Export®) with PCI compared to PCI alone will reduce the incidence of cardiovascular death, recurrent myocardial infarction, cardiogenic shock, or new or worsening NYHA Class IV heart failure (HF) at 180 days in patients with STEMI undergoing primary PCI.
Recruitment Status ICMJE	Recruiting
Estimated Enrollment ICMJE	6000
Completion Date	*Not Provided*
Estimated Primary Completion Date	June 2014 (final data collection date for primary outcome measure)

Estudios en proceso: DISSOLUTION Trial

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Brief Title ICMJE	Local Thrombolytics Before Thrombectomy in STEMI
Official Title ICMJE	Local Delivery of thrombolytIcs Before Thrombectomy in patientS With ST-elevatiOn myocardiaL Infarction Undergoing Primary percuTaneous Coronary interventION - The **DISSOLUTION** Randomized Trial
Brief Summary	Background Prompt reperfusion with percutaneous coronary intervention (PCI) in the setting of ST-elevation myocardial infarction (STEMI) improves clinical outcomes through salvage of myocardial tissue. Although the use of thrombus aspiration with PCI can result in improved rates of normal epicardial flow and myocardial perfusion, several unmet needs remain. Purpose The purpose of this trial will be to evaluate the hypothesis that local delivery of thrombolytics vs. saline infusion prior to thrombus aspiration and PCI is safe and effective in patients with STEMI.
Detailed Description	The study will select patients with ST-elevation myocardial infarction (STEMI) with angiographic evidence of massive thrombosis in the culprit artery undergoing manual thrombectomy followed by primary percutaneous coronary intervention (PCI). Patients will be randomized to receive local bolus of 200,000 units urokinase or saline solution
Current Primary Outcome Measures ICMJE (submitted: March 30, 2012)	MACE at 30 days [Time Frame: Up to 30 days] [Designated as safety issue: No] 30-day Major adverse cardiac events (MACE), defined as the occurrence of death, new Q-wave myocardial infarction, coronary artery bypass grafting, target lesion revascularization, stroke, or stent thrombosis
Original Primary Outcome Measures ICMJE	*Same as current*
Change History	Complete list of historical versions of study NCT01568931 on ClinicalTrials.gov Archive Site
Current Secondary Outcome Measures ICMJE (submitted: March 30, 2012)	Myocardial reperfusion after Primary CI [Time Frame: Up to 90 minutes after Primary PCI] [Designated as safety issue: No] ST-segment resolution (STR)>70% as assessed 90 minutes after Primary PCI

Conclusiones

- Aunque se logra Flujo TIMI 3 en > 90% de pts con IAM tratados con ATC primaria, un porcentaje significativo (50% a 70%) evidencia perfusión miocárdica subóptima (Blush miocárdico disminuído o incompleta resolución del ST)
- La trombectomia manual es un procedimiento simple, sin curva de aprendizaje, no incrementa el tiempo para lograr reperfusión y le da al operador un importante feedback al ver el trombo removido.
- La trombectomia ha demostrado mejoría en el flujo TIMI, Blush y resolucion del ST
- Existe discusión sobre la mejoría en la mortalidad y tamaño del infarto medido por MRI
- El nicho actual de la trombectomia manual aspirativa se localiza en pacientes con poco tiempo de isquemia y gran carga trombótica

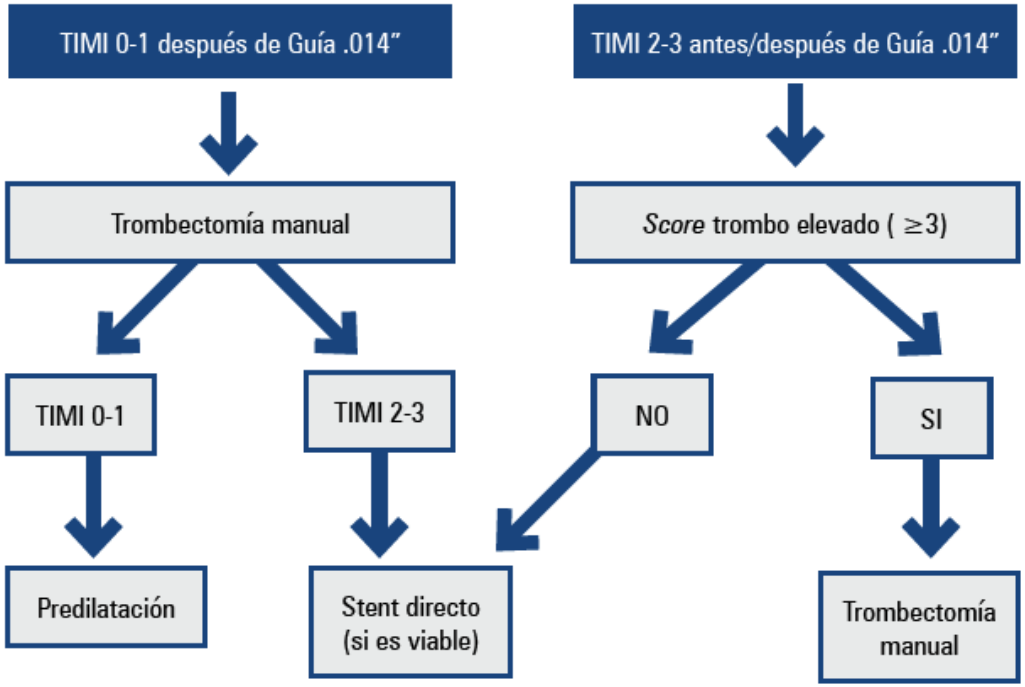
Algoritmo para su utilización:

"Take home message"

Dr. Jamil Abdalla Saad
Coordinador de los servicios de hemodinamia de los hospitales Felicio Rocho y SOCOR- Belo Horizonte-MG-Brasil

Dr. José Carlos Faria Garcia
Miembro del servicio de hemodinamia del Hospital UFECENTER- Belo Horizonte-MG-Brasil

IAMST – VASO CULPABLE O DE CALIBRE ADECUADO Y SIN TORTUOSIDAD ACENTUADA (Preferentemente si Δ t <6 hs)



GRACIAS