The 60th International Conference of the Israel Heart Society
22-23 April 2013, ICC International Convention Center, Jerusalem

Real life results of primary PCI in STEMI: Micronet Mesh Covered Stent (Mguard) vs BMS, DES

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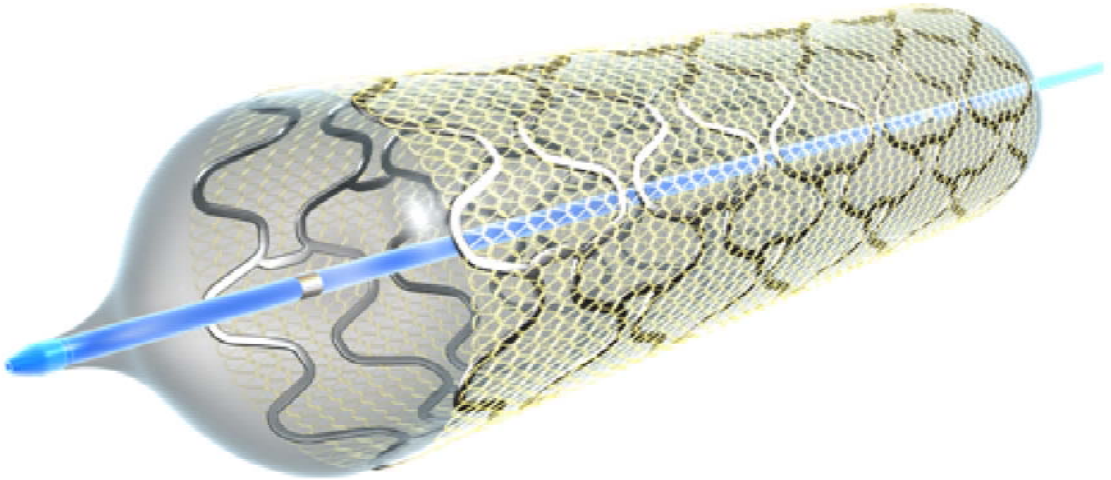
Disclosure of interests

None

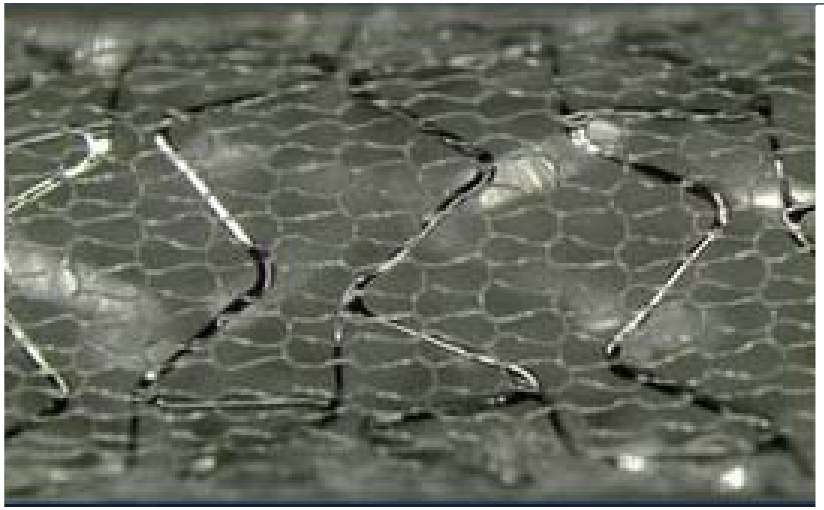


Background

- Suboptimal myocardial reperfusion after PCI in STEMI is common, and results in increased infarct size and mortality

- The MGuard Embolic Protection Stent is a thin-strut metallic stent with micronet covering designed to trap and exclude thrombus and friable atheromatous debris to prevent distal embolization

The Mguard and Mguard Prime Embolic Protection Stent

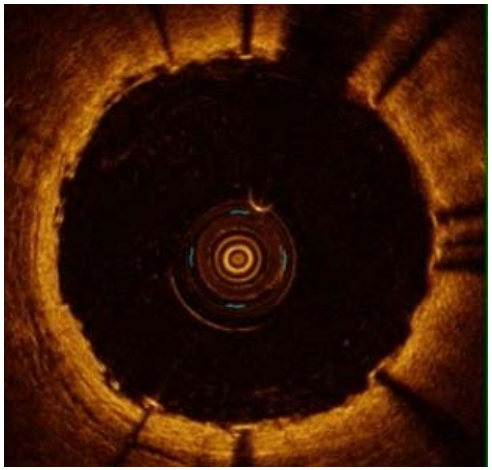


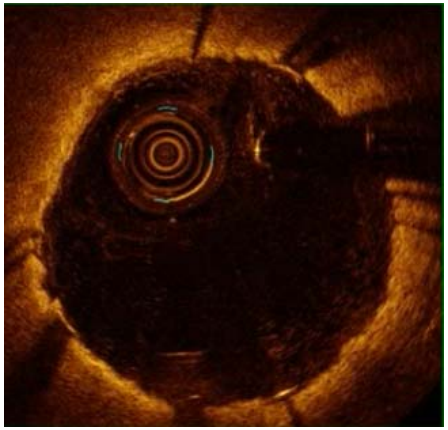
	MGuard	MGuard Prime
Metallic frame	316L stainless steel	L605 cobalt chromium
Strut width	100 microm	80 microm
Crossing profile	1.1-1.3 mm	1.0-1.2 mm
Shaft dimensions	0.65-0.86 mm	0.65-0.86 mm
Mesh sleeve	PET **	PET **
- Fiber width	20 microm	20 microm
- Net aperture size	150-180 microm	150-180 microm

** Polyethyleneterephtalate

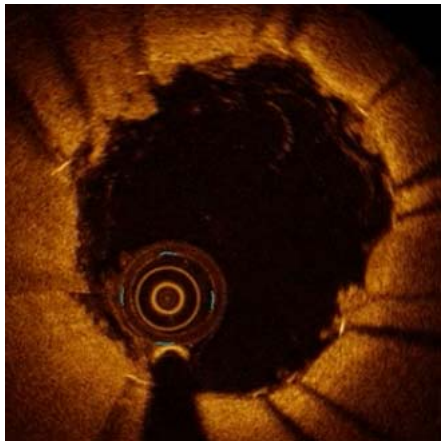
Thrombus entrapment by MGuard stent vs BMS

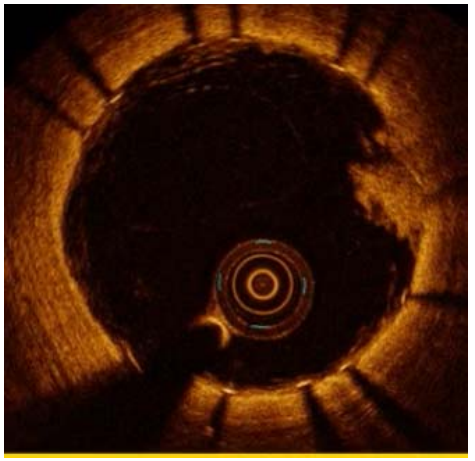
MGuard stent





BMS





EuroPCR 2012: OCT Comparison by Dr. Valdés Chávarri (Spain)

Background - studies

MAGICAL TRIAL

Piscione et al.

IMOS REGISTRY

MASTER TRIAL

…

Objectives

- To capture real world data of usage, efficacy and safety of the MGuard stent in the setting of STEMI
- Clinical follow-up of 2 years
- To compare results of MGuard stent with BMS and DES

Methods

- Single center registry (2010-2011)
- Symptoms consistent with STEMI within 12 hours of symptom onset
- PCI of a single de novo lesion

- Exclusion: patients with > 50% left main stenosis, SVG and cardiogenic shock

Endpoints

- Final TIMI flow grade, MBG
- Follow-up 24 months
- Incidence of stent thrombosis
- MACE = Death, MI, TLR

- Subgroup analysis according to
  - TIMI Thrombus Score
  - Use of aspiration device

Study Population

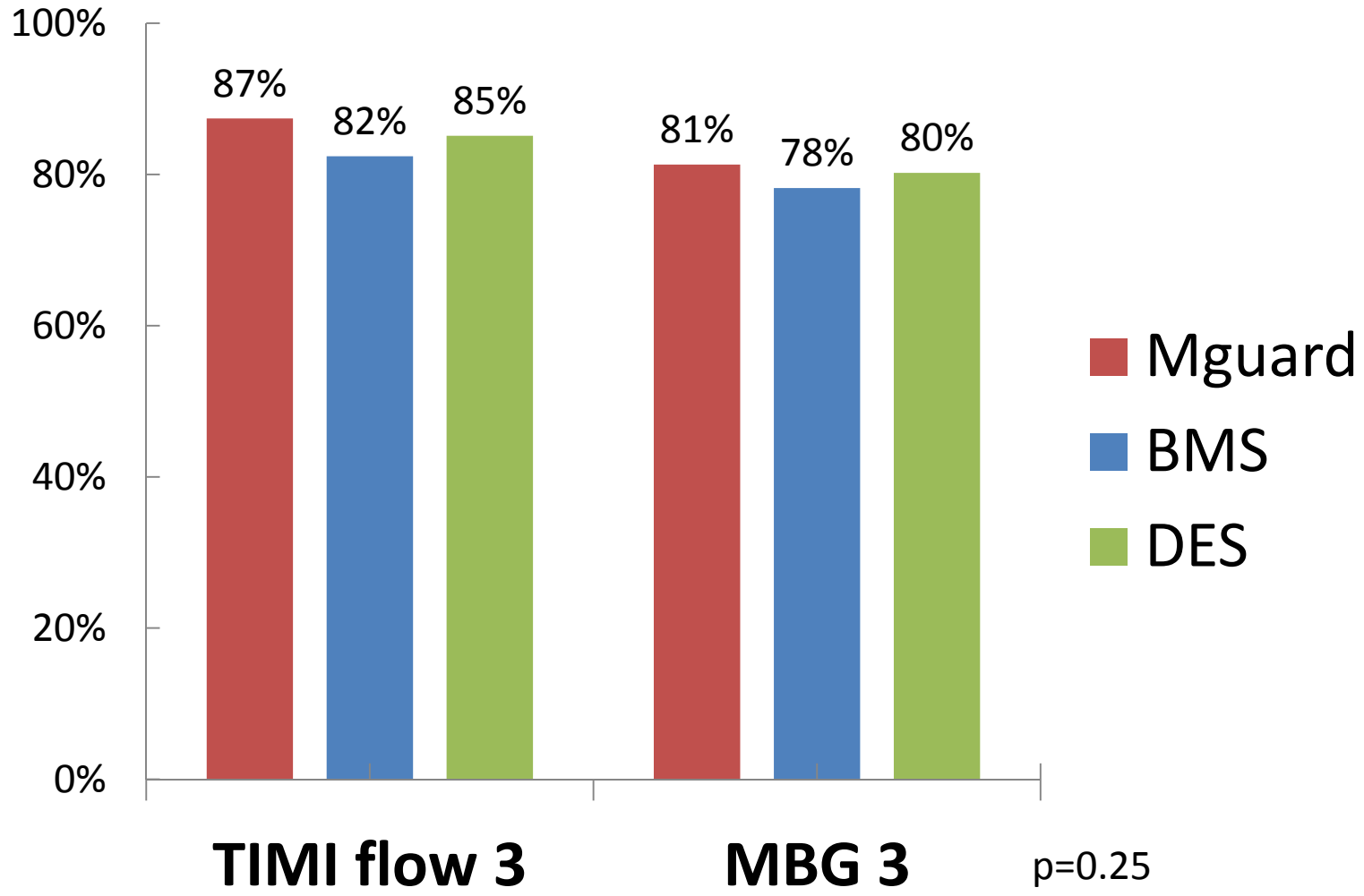
	MGuard (n=79)	BMS (n=143)	DES (n=53)	P value
Age, years old	52.3 ± 6.5	56.1±9.2	60.2±10.2	0.3
Male	78.2%	76.9%	79.2%	NS
Hypertension	35.8%	35.9%	36.3%	0.25
Diabetes Mellitus	15.8%	19.4%	22.4%	0.2
Smoking	66.2%	75.2%	71.1%	0.25
Previous MI	20.1%	17.5%	18.6%	0.5
Symptom onset to first device, min	232±138	207±131	269+/-130	0.4
KK class I	84.9%	87.6%	84.9%	0.9

Procedure characteristics

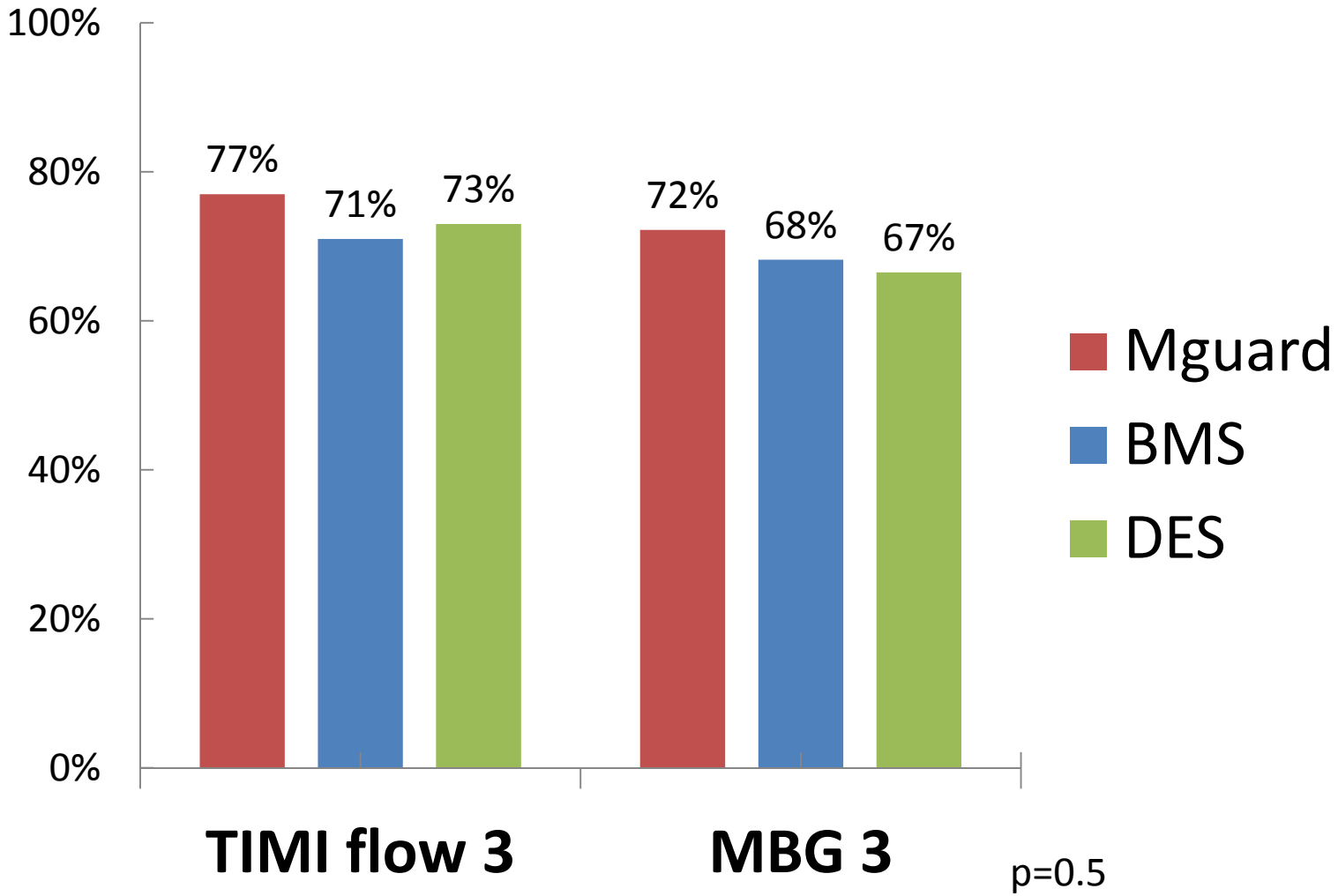
	Mguard (n=79)	BMS (n=143)	DES (n=54)	
Infarct artery lesion location:				
LAD --	31.6%	39.9%	44.4%	0.01
LCX --	24.1%	38.4%	38.9%	0.01
RCA --	44.3%	21.7%	16.7%	0.01
TIMI pre 0	64.4%	50.5%	35.1%	0.006
TIMI thrombus score ≥ 3	85.2%	59.2%	46.5%	0.04
Aspiration	50.0%	58.1%	52.2%	0.4
Balloon pre-dilatation	40.8%	61.8%	73.2%	0.01
Total length stent	20±6.9	19±12.8	32±14.2	0.04
Diameter	3.5	3.5	3.0	0.1

- No other embolic protection device was used
- No differences in use of antiplatelets and anticoagulation protocols

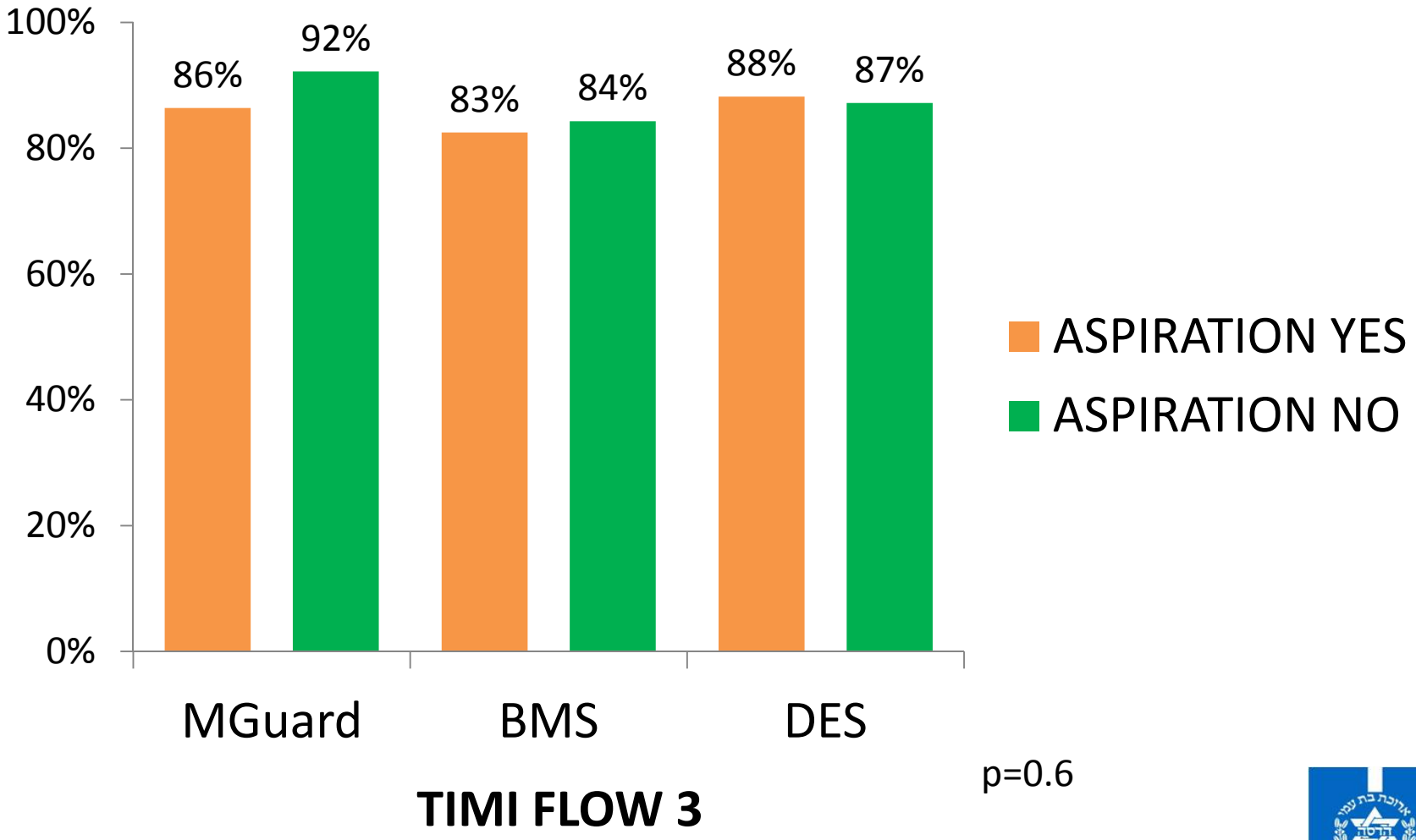
Primary PCI Results



Thrombus Score ≥ 3 and TIMI flow, MBG

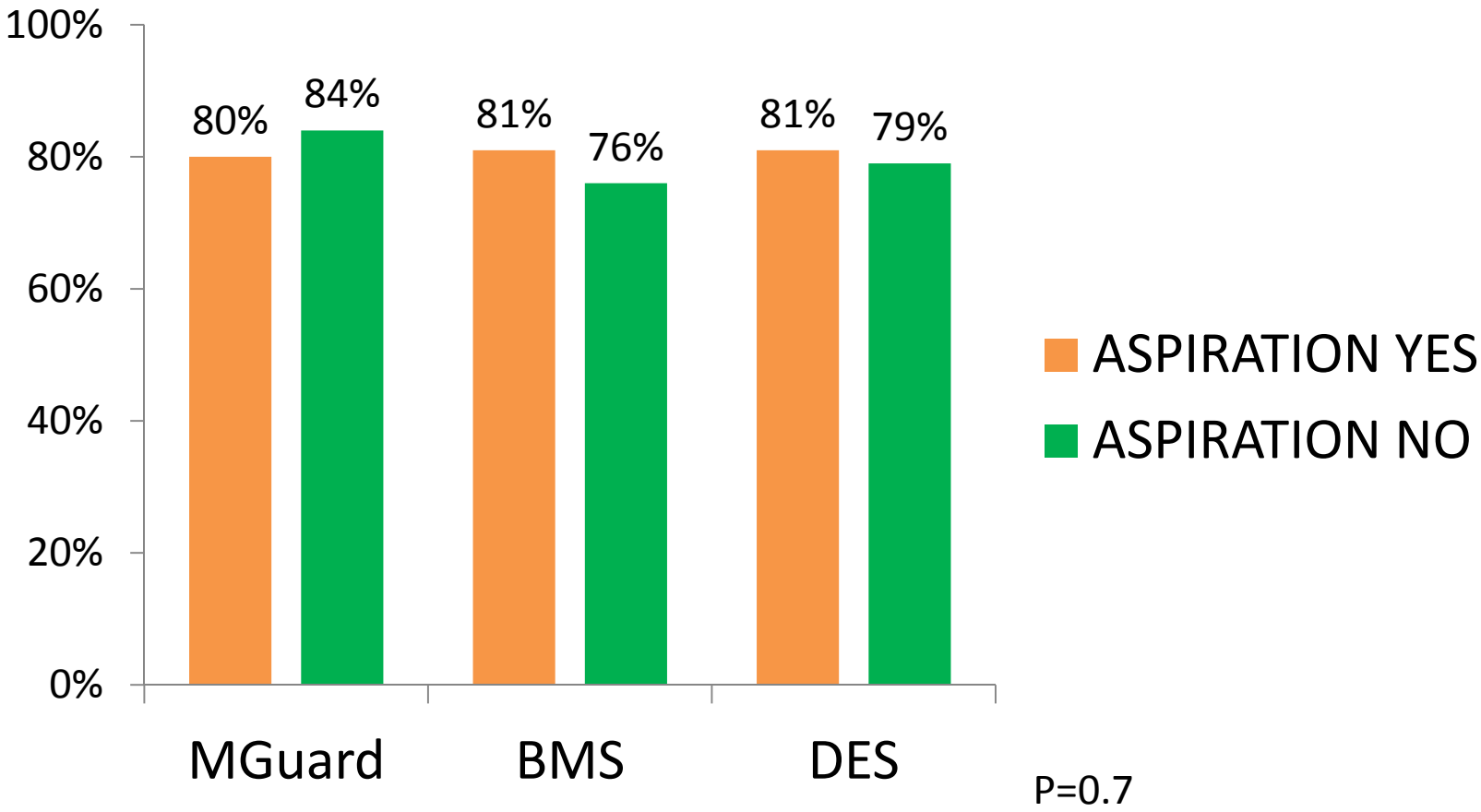


Use of aspiration device and TIMI flow



p=0.6

Use of aspiration device and MBG



MBG 3

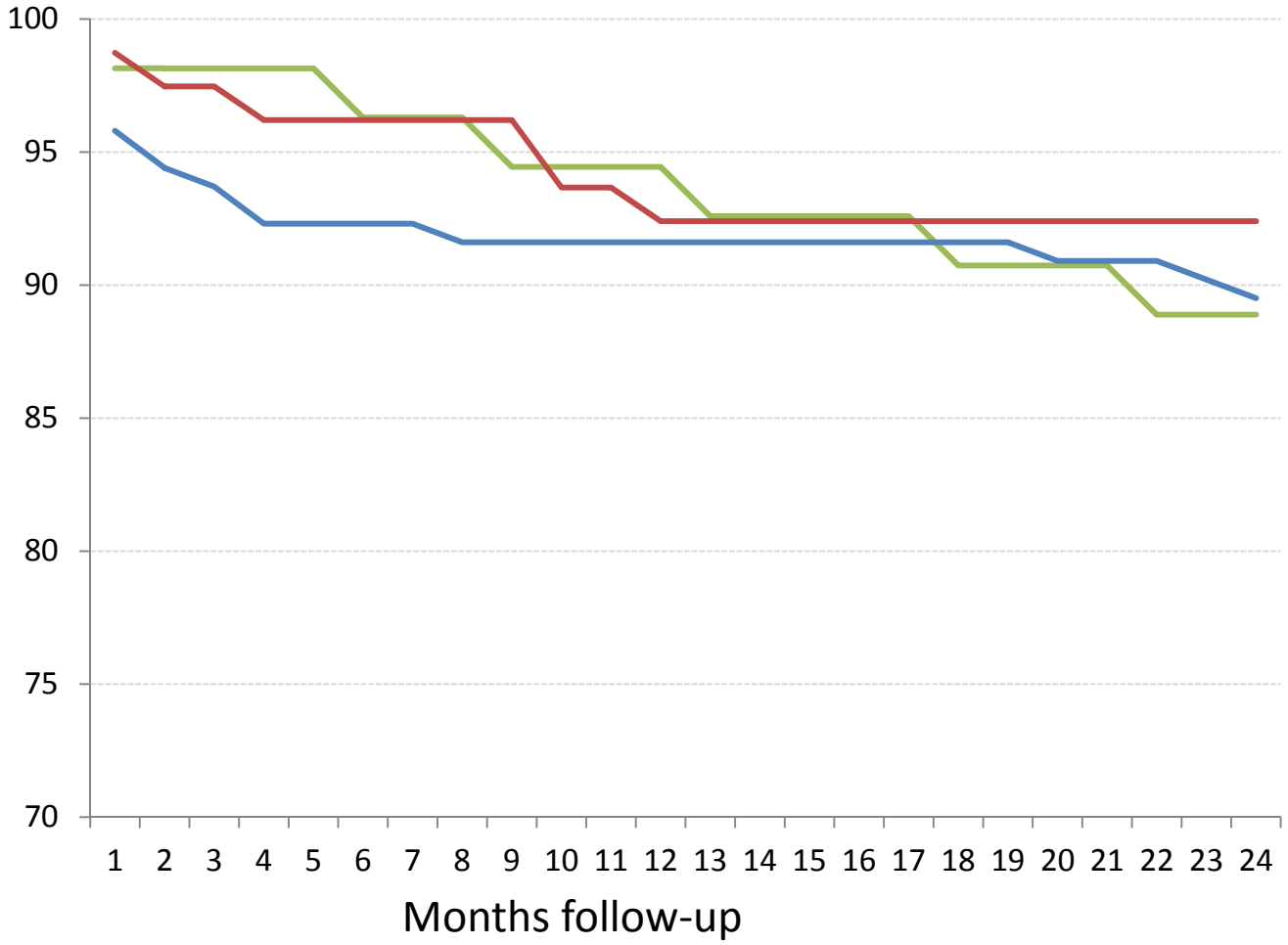
MACE: 2 years follow-up

DES 11.4%

MGuard 7.5%

BMS 10.4%

p=0.1



MACE: Cardiac death, MI, TLR

MACE: 2 years follow-up

	TLR	Death	MI
DES 11.4%	4.5%	9.2%	3.6%
MGuard 7.5%	2.5%	5%	3.5%
BMS 10.4%	5.9%	7%	4.2%

(p=0.6)

STENT THROMBOSIS 2 years

MGuard 2%

BMS 2.8%

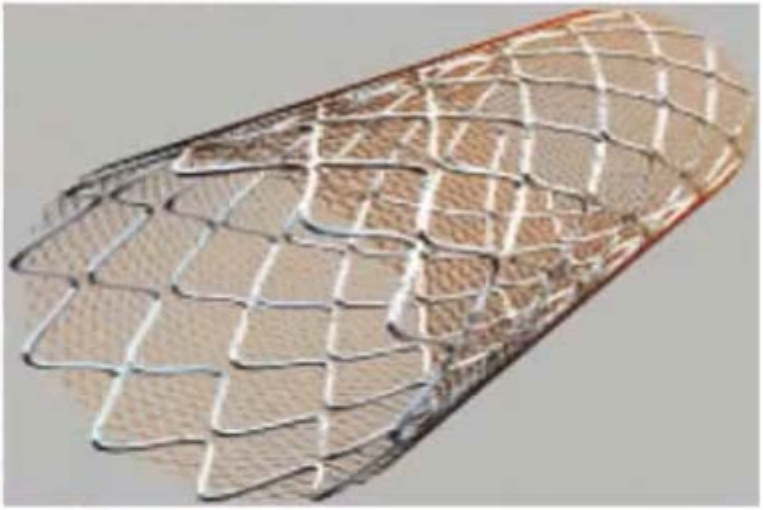
DES 1.8%

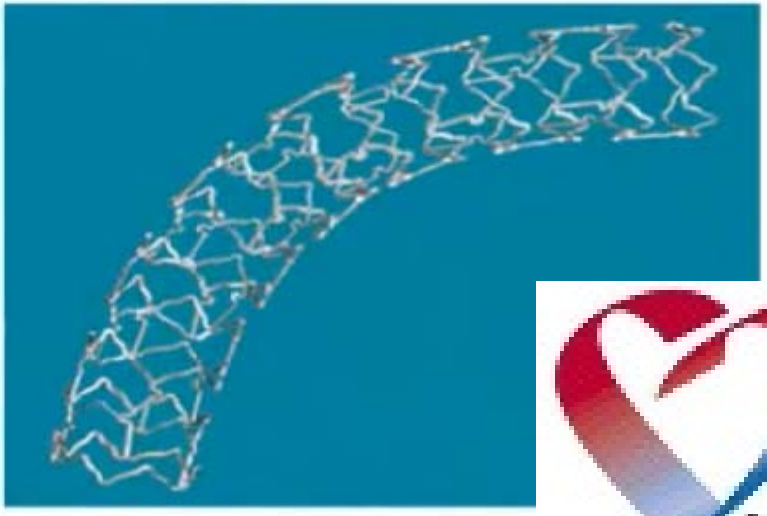
(p=0.8)

Conclusions

- Primary PCI with MGuard stent seems to be highly safe and effective
- Tendency to better angiographic results in lesion with high thrombotic burden
- Use of aspiration device had minimal effect on angioraphic results
- Acceptable TLR, Stent Thrombosis incidence compared to BMS and DES
- Tendency to lower MACE after primary PCI with Mguard stent vs BMS, DES

Just choose the right equipment to go further!!





Results TIMI flow Subgroups like in MASTER

Age
65 more
less
Time to
220 less
more
Infarct vessel
LAD
RCA
LCX
ASPIRATION
YES
NO
INITIAL TIMI FLOW 0-1
FLOW 2-3
Stent DIAMETER
More than 3.5
Less than 3.5
Stent length
Less than 12
More than 12

ischemia-driven TLR in STEMI is modest (34) and must be weighed against the potential utility of the MGuard stent in reducing infarct size, heart failure events, and mortality. Both BMS and DES are currently used in a substantial proportion of patients undergoing primary PCI in STEMI, with DES use reserved at most centers for lesions at high risk of restenosis. However, these longer and more complex lesions may possess greater potential for embolization and thus theoretically may benefit most by use of the MGuard stent. Moreover, stent thrombosis is common in STEMI with both BMS and DES (35,36), and although no significant differences in the rates of thrombotic events between the MGuard and conventional stents at 30 days were observed, the present study was underpowered in this regard. These considerations reinforce the need for a larger randomized trial comparing the MGuard stent with both BMS and DES across the range of lesions encountered among patients with STEMI, with long-term follow-up to fully characterize the competing risks and benefits of these devices.

Study limitations. The MASTER trial was underpowered to draw definitive conclusions regarding infarct size and clinical events, and all subgroup analyses should be considered hypothesis-generating. Longer-term clinical and angiographic follow-up is ongoing to characterize the late vascular responses of the MGuard stent. More experience with the MGuard Prime device in STEMI is required. The

2. Nabel EG, Braun myocardial infarctio
3. Claeys MJ, Bosman Determinants and elevation after prim importance of micr Circulation 1999;9
4. Kondo M, Nakano vascular no-reflow gated albumin scint tion. J Am Coll Ca
5. Maes A, Van de W mans L. Impaired thrombolysis. Impa late follow-up. Circ
6. Erbel R, Heusch coronary syndromes
7. Schwartz RS, Burk obstruction in acute relation to epicard 2009;54:2167–73.
8. Henriques JP, Zijls significance of dista myocardial infarctio
9. Svilaas T, Vlaar P during primary per 2008;358:557–67.
10. Inaba Y, Chen JA multicentre study d of adjunctive devic myocardial infarctio
11. Thiele H, Wöhrle J intravenous bolus a coronary interventio intravenously Drug tion (AIDA STEM

was used in 39.9% of males and 39.3% of females. Both genders derived a significant long-term clinical benefit from DESs compared to BMSs; advantages were observed for mortality (men: HR=0.78, 95% CI: 0.64 - 0.96, p=0.016; women: HR=0.62, 95% CI: 0.45 - 0.85, p=0.003) and major adverse cardiac events (men: HR=0.73, 95% CI: 0.63-0.84, p<0.001; women: HR=0.76, 95% CI: 0.52-0.84, p=0.001). Among BMS-treated patients, women had worse cumulative clinical outcomes than men. DESs eliminated the gender differences in cardiac prognosis.

Conclusion: Our analysis indicated a profound prognostic advantage for DESs versus BMSs among both genders, though female patients appeared to derive the greatest benefit.

TCT-205

The Nine-Month Outcomes of a Polymer-Free Drug-Eluting Stent (YUKON) Compared with Different Polymer Based Drug-Eluting Stents in Real-World Coronary Artery Lesions

Ted Spase Trajceski, Lulzim Brovina, Zivko Petrovski, Blerim Zuna, Borce Petrovski
Spitali Zemres, Prishtina, Albania

Background: We compared the safety and efficacy of different permanent polymer based drug-eluting stents (PBS) with a polymer-free drug-eluting stent (PFS-Yukon). In unselected real-world patients with coronary lesions of various complexities, we retrospectively compared both stent designs.

Methods: A total of 617 lesions in patients with symptomatic CAD were treated with PBS (n = 383) or with PFS (n = 234). The PBS group consisted of 44(12%) Cypher, 101(26%) Xience, 107(28%) Endeavor, 55(14%) Infinium and 75(20%) Coroflex Please stents, assigned to patients and lesions by shelf disposal and target vessel dimensions. The primary clinical endpoint of this study was a composite of cardiac death, myocardial infarction and clinical-indicated target vessel revascularisation (MACE).

Results: Follow-up was obtained in 98,2% of patients. All patients were treated with clopidrogrel and aspirin during follow up. Polymer free stents were non-inferior to polymer- stents for the primary endpoint at 9 months (13 [5.6%] vs 21 [5.5%], HR: 0.98 [95% CI 0.48-2.01], p for superiority=0.96). Frequency of cardiac death (5 [2.1%] vs 6 [1.6%], p for superiority=0.41), myocardial infarction (4 [1.7%] vs 16 [4.2%], p=0.07), and clinically-indicated target vessel revascularisation (8 [3.4%] vs 18 [4.7%], p=0.29) were similar for both stent types. Analysis of MACE after 9 months resulted in 4 (1.7%) definitive stent thrombosis causing MI in PFS vs. 18(4.7%) in PBS treated lesions, with borderline significant difference (log rank, p=0.052). In the cox proportional regression analysis of MACE, none of the stents showed different survival according to stratification by presence of Diabetes, ST-elevationMI, multivessel disease, Left anterior, long or small vessel lesions, (p=0.93; p=0.97; p=0.99; p=0.95;

TCT-207

Interim Analysis of the IMG

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[1]Hadassah University Medica of Cardiology, Sao Paulo, Br Balatonfüred, Hungary; [4]Ger [5]Ospedale Maggiore Policlin

Background: Despite the s deployment in opening up phenomenon of distal emboli myocardial recovery and ren MGUARD™ stent (InspireM around a balloon-expandable and fragile plaque against the thereby preventing distal Observational Study) Regi MGUARD™ stent with the o

Methods: The IMOS regi multinational, observational exclusion criteria include heav endpoint is MACE at 6 mont

Results: A total of 382 patient enrolled to date, and were sc number and type of stent depl in the registry), who present implanted, were analyzed and hyperlipidemia, 59.4% from PCI and 9.9% had previous M and in the LAD in 36.2%. A aspiration was used. Procedur in 93.5% of patients. At 30 d and 6.0% respectively.

Conclusion: PCI with MGU treating STEMI patients, wit angiographic success.

TCT-208

J Interv Cardiol. 2013 Feb;26(1):1-7. doi: 10.1111/j.1540-8183.2013.12011.x.

MGuard mesh-covered stent for treatment of ST-segment elevation myocardial infarction with high thrombus burden despite manual aspiration.

Romaguera R, Gómez-Hospital JA, Sánchez-Elvira G, Gómez-Lara J, Ferreiro JL, Roura G, Gracida M, Homs S, Teruel L, Cequier A.

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Abstract

OBJECTIVES: To assess the usefulness of the MGuard stent in patients with ST-segment elevation myocardial infarction (STEMI) in whom a high thrombus burden persists after manual aspiration.

BACKGROUND: In some patients with STEMI, a high thrombus burden may persist after manual aspiration. These patients may be at high risk of distal embolization and therefore impaired myocardial reperfusion. The MGuard is a novel mesh-covered stent designed to minimize thrombus embolization.

METHODS: Single-arm, prospective registry of patients with STEMI and high thrombus burden after aggressive thrombus aspiration treated with the MGuard stent. High thrombus burden was defined as thrombus burden grade 4 or 5 according to the TIMI score. Lesions with a side branch ≥2 mm and patients with cardiogenic shock were not included. The study end-points were proportion of final TIMI 3 flow, normal myocardial blush, and complete ST-segment resolution.

RESULTS: Fifty-six patients were included. After MGuard stent implantation >85% of cases had thrombus score = 0. Final TIMI 3 flow was achieved in 82% of cases, normal myocardial blush in 55%, and complete ST-segment resolution in 59%. Occlusion of a side branch (<2 mm) occurred in 2 cases (3.5%), embolization to a distal branch in 5 cases (8.9%), and transient no-reflow in 4 cases (7.1%). Major adverse cardiac events rate at 9 months was 3.6%, including 1 definite acute stent thrombosis and 1 target-vessel revascularization.

CONCLUSIONS: The MGuard stent may be useful to prevent distal embolization in patients with STEMI and high thrombus burden despite mechanical aspiration.

PMID: 23419104 [PubMed - in process]

Catheter Cardiovasc Interv. 2011 Dec 1;78(7):1095-100. doi: 10.1002/ccd.22980. Epub 2011 Jul 22.

One-year results of the INSPIRE trial with the novel MGuard stent: serial analysis with QCA and IVUS.

Costa JR Jr, Abizaid A, Feres F, Costa R, Staico R, Siqueira D, Centemero M, Tanajura LF, Sousa A, Sousa JE.

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Abstract

BACKGROUND: The newly developed balloon-expandable Mguard stent system, a combination of an ultra-thin polymer mesh sleeve attached to the external surface of a BMS, was conceived to provide embolic protection during PCI of SVG and thrombus-containing lesions. Although the acute results (<30 days) have pointed to the efficacy of this novel device, few is known about its long-term performance.

METHODS: The present article address the 1-year clinical results of a cohort of 30 patients enrolled in the INSPIRE trial. Inclusion critiria was de novo lesions in SVG or native vessels with angiographic evidence of instability with potential to provoke flow disturbances and/or distal embolization. The primary endpoint (incidence of MACE-composite of cardiac death, nonfatal MI, and TLR) up to 30 days of the procedure has already been published. Secondary endpoints here presented included in-stent late lumen loss (QCA), % of stent obstruction (IVUS) at 6 months and combined MACE at 1 year. QCA and IVUS were performed by independent corelabs.

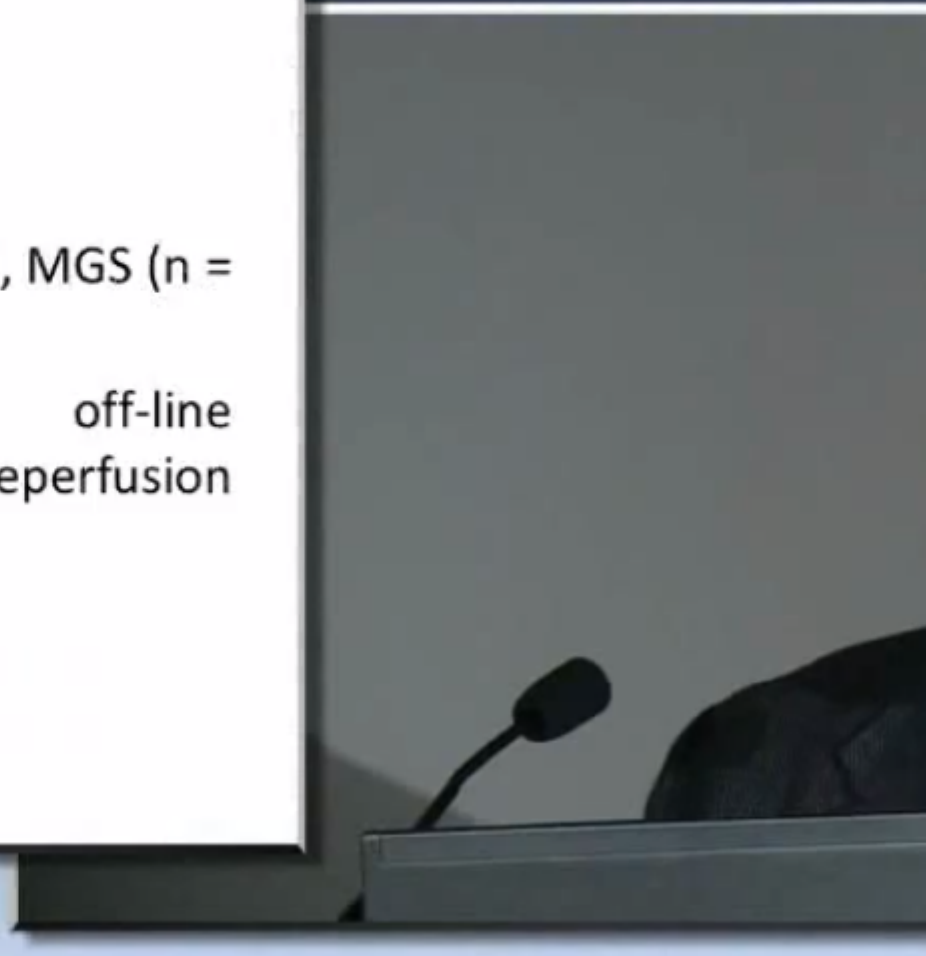
RESULTS: Mean population age was 63 years with 38% of diabetics. Overall, 55% presented with ACS and 57% of lesions were located in SVG. Most lesions had complex morphology including the presence of thrombus (26%) and ulceration (20%). Distal/proximal protection devices were not used. Preprocedural QCA data showed lesion length and reference vessel diameter of 12.0 ± 4.5 mm and 3.0 ± 0.5 mm. The MGuard stent was successfully delivered in all cases and final TIMI-3 was achieved in 100% with no MACE up to 30 days. At 6 months, in-stent late loss and % of stent obstruction were 1.0 ± 0.4 mm and 28.5 ± 15.6%. Up to 1 year there was no case of cardiac death, two MI (one Q-wave and one non-Q-wave) and six cases of ischemia-driven TLR. Of note, there was no case of definite/probable stent thorombosis.

CONCLUSIONS: In this series of patients treated with MGuard stent, the novel device showed no midterm efficacy and safety concerns.

PMID: 21786400 [PubMed - indexed for MEDLINE]

Methods:

- 3 Chilean Hospitals.
- Patients with STEMI randomized 1:1, MGS (n = 20) or a BMS (n = 20).
- Blinded experts performed off-line measurements of angiographic reperfusion criteria:
  - TIMI flow grade,
  - myocardial blush,
  - corrected TIMI frame count (cTFC).



Results:

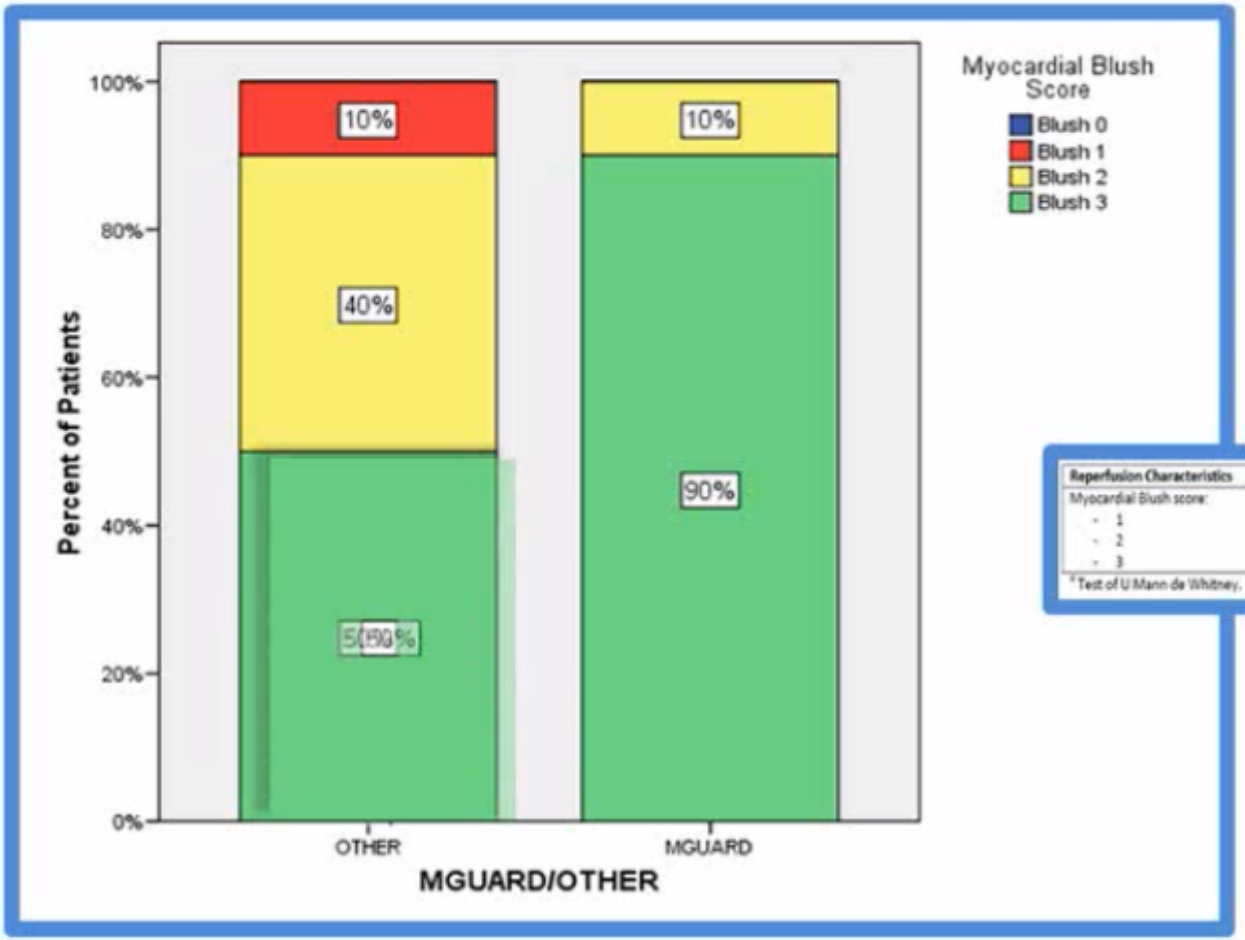
- Procedural variables were not different between groups.

Angiographic Characteristics	# Mguard Stent (%)	# Other Stent (%)	Significance
Initial TIMI flow grade:			NS
- 0	14 (70%)	13 (65%)	
- 1	2 (10%)	4 (20%)	
- 2	2 (10%)	3 (15%)	
- 3	2 (10%)	0	
TIMI Thrombus score:			NS[4]
- 1	1 (5%)	0	
- 2	0	0	
- 3	1 (5%)	2 (10%)	
- 4	4 (20%)	6 (30%)	
- 5	14 (70%)	12 (60%)	
PCI to other vessel (same procedure)	2 (10%)	0	NS[1]
Complementary PCI aid:			
- Thrombus aspiration	5 (25%)	8 (40%)	NS[3]
- IIb/IIIa inhibitors	1 (5%)	0	NS[1]
# stent			NS[4]
- 1	18 (90%)	18 (90%)	
- 2	2 (10%)	2 (10%)	
Stent			
- Diameter (mm)	3.48 ± 0.41	3.39 ± 0.37	NS[4]
- Length (mm)	20.65 ± 4.09	17.10 ± 2.63	2p = 0.001[4*]
Balloon predilatation	17 (85%)	12 (60%)	NS[3]
Balloon postdilatation	0	2 (10%)	NS[1]

[1] Fisher´s exact test. [2] Student t test. [3] χ^2 test. [4] Test of U Mann de Whitney. * 2p asimptotic. * Welch correction.

Results:

- ***Better myocardial Blush grade in MG group compared to BMS***



Reperfusion Characteristics	#
Myocardial Blush score:	
- 1	0
- 2	2
- 3	18

[1] Test of U Mann de Whitney. [2] p as

MAGICAL Trial Results

Clinical research

EuroIntervention

Mesh covered stent in ST-segment elevation myocardial infarction

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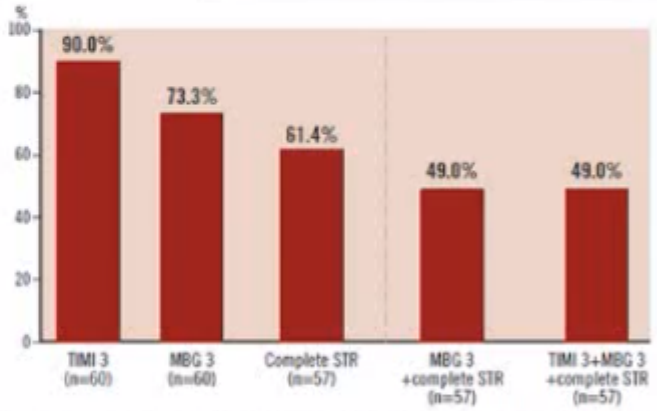


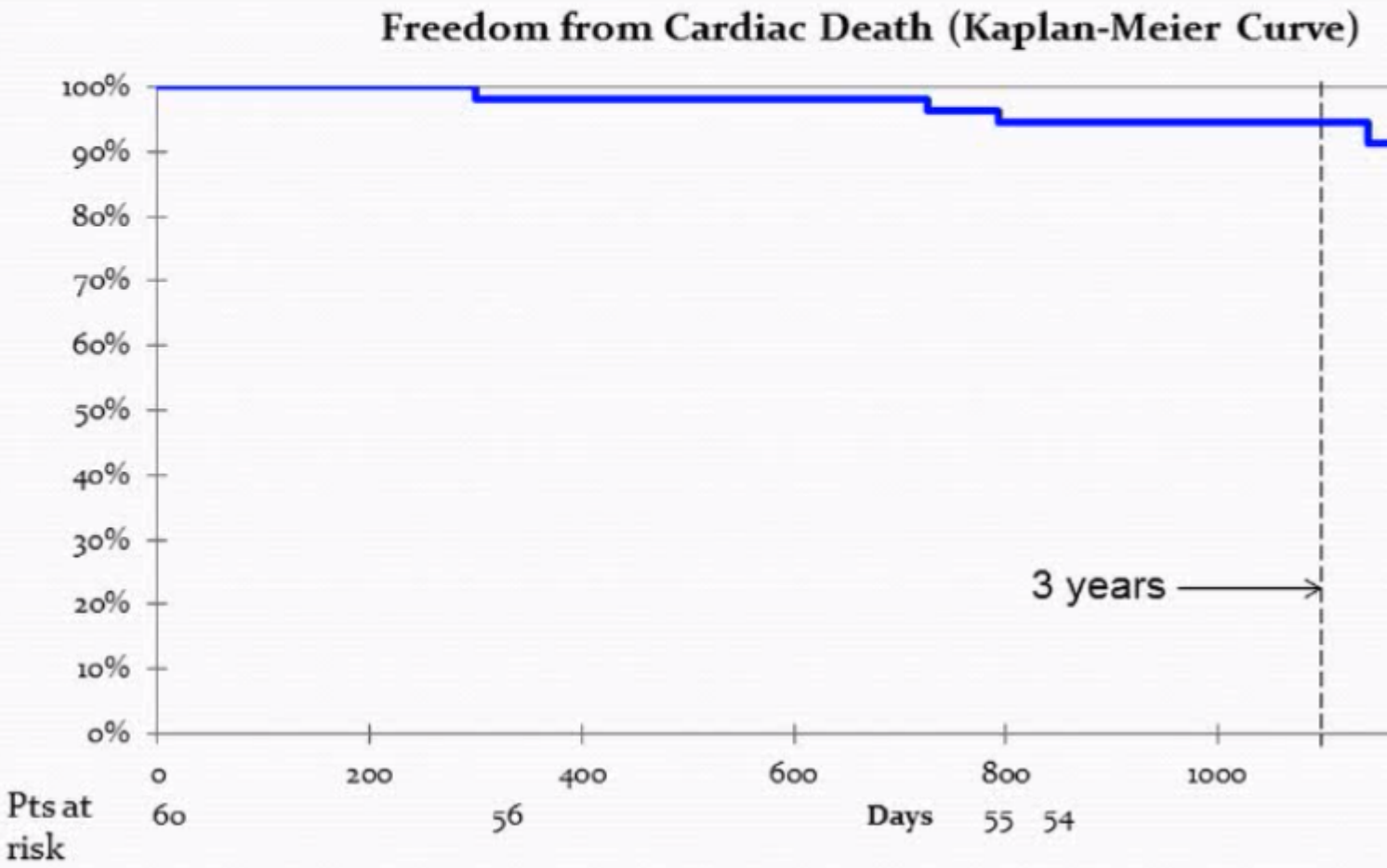
Figure 1. Primary and combined endpoints of the MAGICAL study. Frequency of final Thrombolysis In Myocardial Infarction (TIMI) grade 3 and Myocardial Blush Grade (MBG) 3, and complete ST-segment resolution (STR) >70% 60 to 90 minutes after procedure.

MACCE at 6 months was 1.7% due to one patient suffering from hemorrhagic stroke

3 Year Results

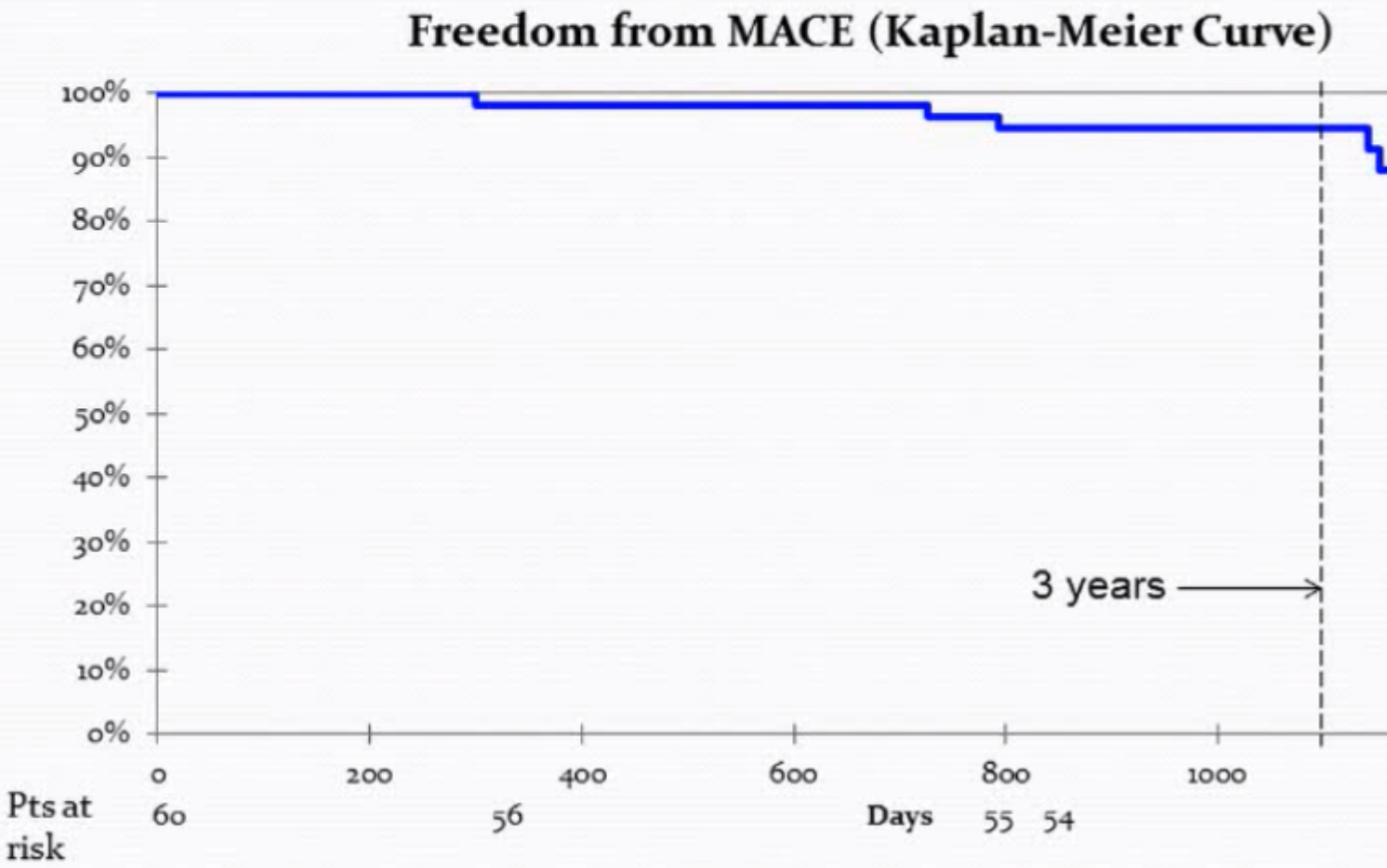
Number of patients available for follow-up	57/60 (95%)
Average Follow-up (Average, SD, min, max)	3.2y±0.3y ; (2.9-3.7)
Patients on ASA	83%
Patients on Clopidogrel	8%
Cardiac death	7.0% (4)
Non-cardiac death	1.8% (1)
TLR	1.8% (1)
TVR	3.5% (2)
Ischemic Stroke	1.8% (1)
Re-MI	0% (0)
definite/probable ST	0% (0)
MACE	8.8% (5)
MACCE	10.5% (6)

Cardiac Death



MACE

cardiac death, MI, TLR



Conclusions

- Long term data at 3 years of MGuard in STE population shows:
  - 7.0% Cardiac death
  - 10.5% MACCE
  - Preserved LVEF and LVEDD values over the
- The early safety and efficacy of MGuard is m in the long term

InspireMD at TCT 2011: Dr. Federico Piscione

Published/unpublis
analysis of MGuard
patients: reperfusi

	N	TIMI 3
Piscione	100	N/A
Weerackody	51	100%
Dudek	60	90%
Apro	100	96%
Average	**311**	**95%** (n=211)

Apro D. 2010, Transcatheter and Therapeutics Congress, San
Weerackody R. 2010, European Percutaneous Revascularizati

TABLE II. Angiographic Characteristics of the Study Group

Multivessel disease	41 (%)
Location of lesion	
LAD	30 (%)
RCA	54 (%)
RVD	3.23 ± 0.4 (mm)
MLD	0.18 ± 0.53 (mm)
Lesion length	16.98 ± 7.42 (mm)
Preprocedural stenosis	96.40 ± 8.28 (%)
Lesion classification ACC/AHA	
Type B2	32 (%)
Type C	68 (%)
Predilation	42 (%)
Calcification: moderate to heavy	10 (%)
Thrombus present	100 (%)
Concentric lesion	48 (%)
Bifurcation or side branch lesion	8 (%)
Angulated lesion >45°	31 (%)
Preprocedural cTFC (*n*)	65.78 ± 34.40
Pre-PCI TIMI flow grade (mean)	0.80 ± 1.19

Data are shown as percentages (%) or mean ± 1 standard deviation. LAD, left anterior descending; RCA, right coronary artery; RVD, reference vessel diameter; MLD, minimum lumen diameter; cTFC, corrected TIMI frame count.

TABLE III. Procedural Findings a the Study Group

Post-PCI residual stenosis	
Post-PCI cTFC (*n*)	
ΔcTFC (*n*)	
Post-PCI TIMI flow grade (mean)	
Post-PCI MB	
Grade 3	
Grade 2	
Grade 0-1	
Thrombus aspiration device	
Direct stenting	
Stent/lesion (n)	
Post dilation	
Post-PCI Troponin I (ng/mL)	
Post-PCI CK-MB (ng/mL)	
Post-PCI Max ST-segment elevation	
ST-resolution 60 min post-PCI	
≥70%	
>30 to <70%	

Data are shown as percentages (%) or
cTFC, corrected TIMI frame count; M

InspireMD at TCT 2011: Dr. Federico Piscione

Long-term results a

TCT2010

MACE§
All death *Cardiac death*
Target Vessel Revascularization
Myocardial Infarction
Stent thrombosis (ARC)** *Definite* Acute Subacute Late

§ Cardiac Death, Myoca

** Definite/Probal

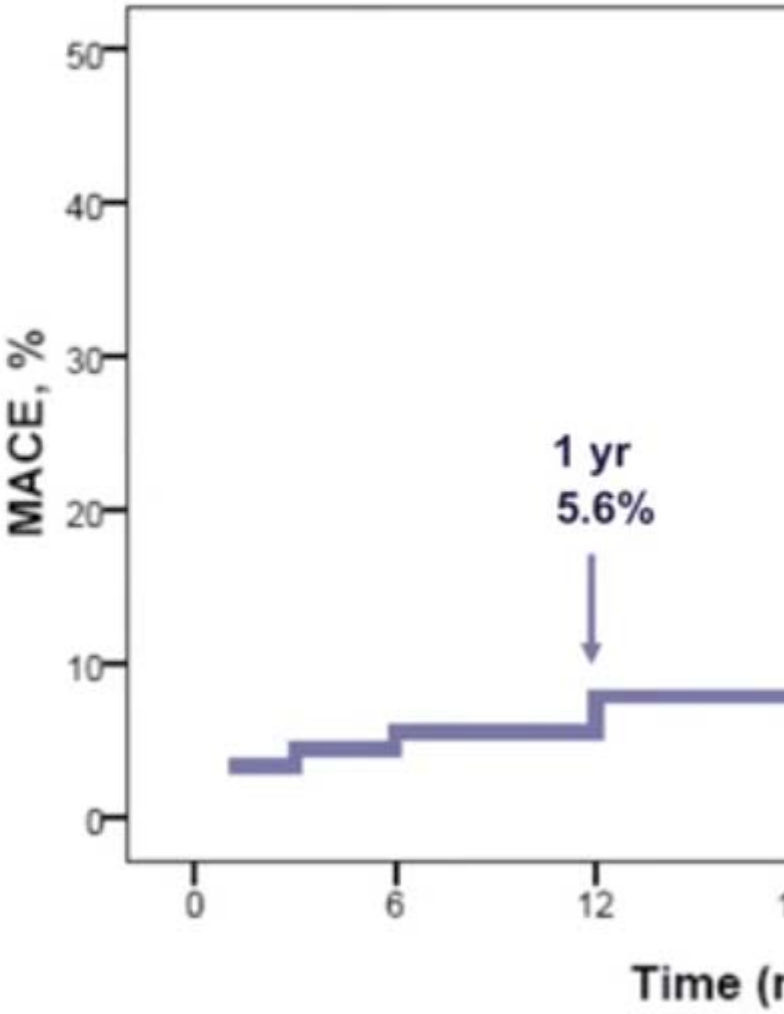
Long-term results a

	p
MACE§	
All death *Cardiac death*	
Target Vessel Revascularization	
Myocardial Infarction	
Stent thrombosis (ARC)* *Definite* Acute Subacute Late Very Late	

§ Cardiac Death, Myoca

* Definite/Probab

MACE at 3-yea



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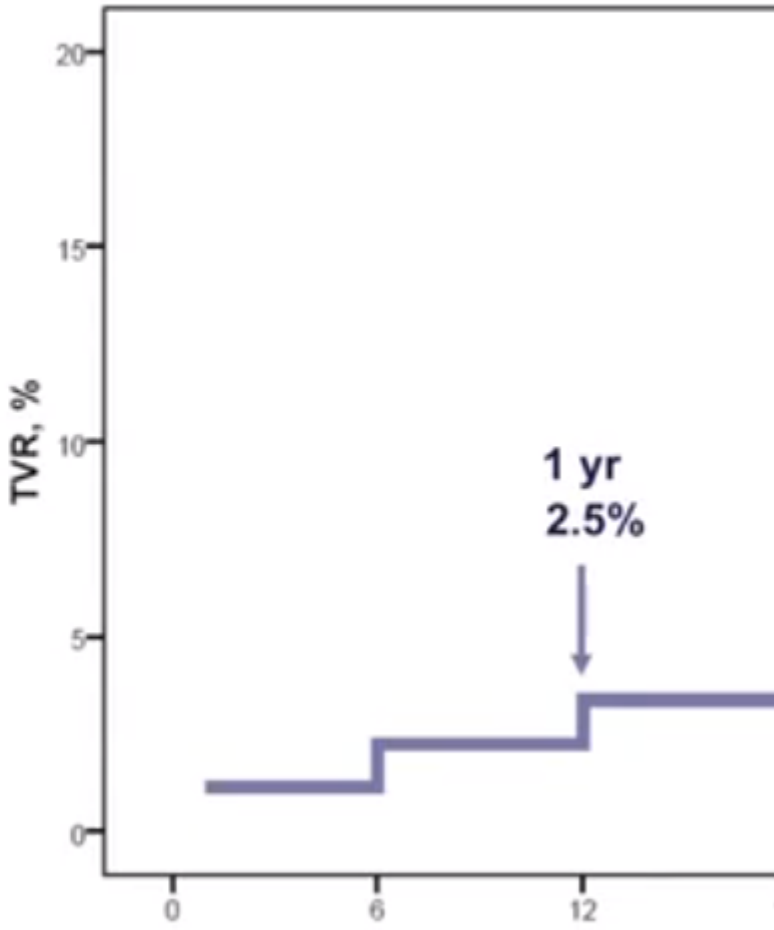
TVR at 3-yea



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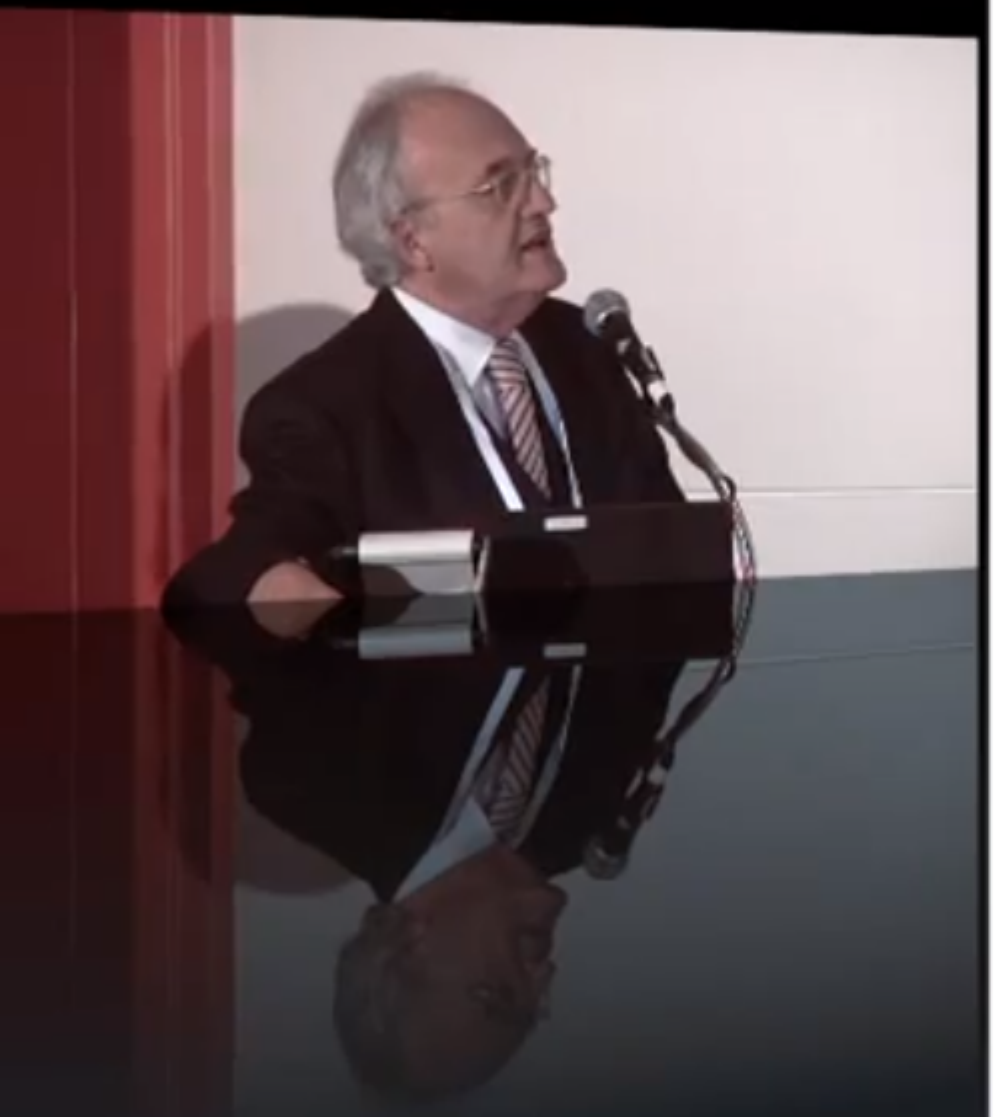


Conclu

According to the reported
MGuard™ net protective ste
and feasible option, both at
up, for STEMI patients un
thrombus burden evidence at c

Adjunctive Devices for PCI:

Manual catheter thrombus aspiration should be considered during PCI of the culprit lesion in STEMI.
For PCI of unstable lesions, i.v. abciximab should be considered for pharmacological treatment of no-reflow.
Drug-eluting balloons[d] should be considered for the treatment of in-stent restenosis after prior BMS.
Proximal embolic protection may be considered for preparation before PCI of SVG disease.
For PCI of unstable lesions, intracoronary or i.v. adenosine may be considered for pharmacological treatment of no-reflow.
Tornus catheter may be used for preparation of heavily calcified or severely fibrotic lesions that cannot be crossed balloon or adequately dilated before planned stenting.
Cutting or scoring balloons may be considered for dilatation of in-stent restenosis, to avoid slipping-induced vessel of adjacent segments.
IVUS-guided stent implantation may be considered for unprotected left main PCI.
Mesh-based protection may be considered for PCI of highly thrombotic or SVG lesions.

Long-term (3-5 year) FU after DES vs. BMS in AMI

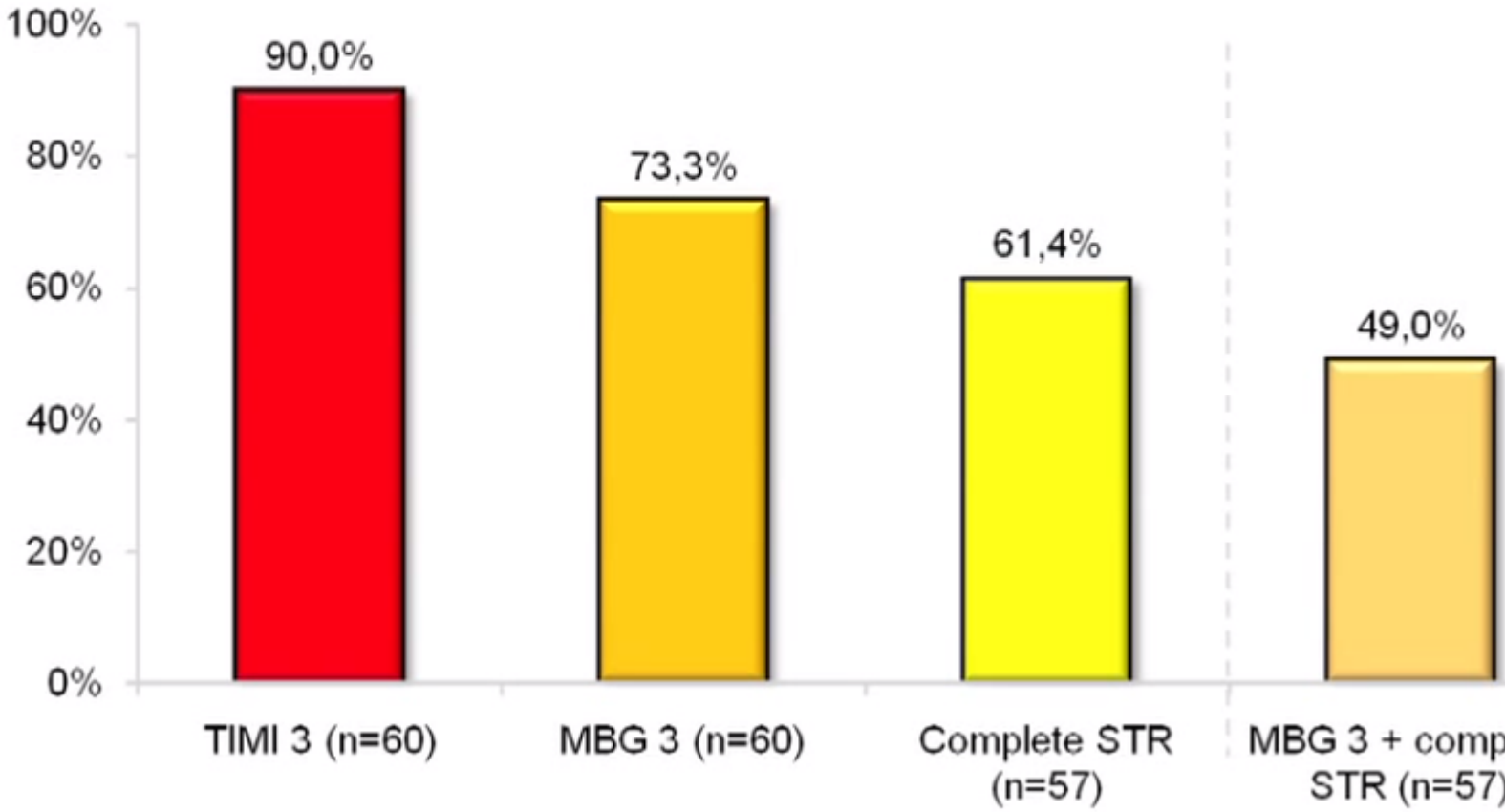
Stent thrombosis (N=6,026 pts)

Stent thrombosis	DES	BMS	OR [95%CI]	P
DEDICATION	2.9%	3.2%	0.90 [0.36, 2.24]	0.82
PASEO	1.1%	2.2%	0.49 [0.07, 3.57]	0.48
STRATEGY	6.9%	7.9%	0.86 [0.28, 2.66]	0.79
SESAMI	5.1%	5.1%	1.00 [0.37, 2.73]	1.00
MISSION	3.1%	2.0%	1.69 [0.40, 7.20]	0.48
TYPHOON	5.3%	5.5%	0.90 [0.42, 2.00]	0.83
PASSION	4.2%	3.4%	1.19 [0.52, 2.69]	0.68
HORIZONS-AMI	5.1%	4.4%	1.15 [0.77-1.72]	0.50
META-ANALYSIS			**1.06 [0.81-1.39]**	**0.67**

Adapted from Ziada KM et al. JACC CI Int 2011;4:39-41

The MAGICAL Trial

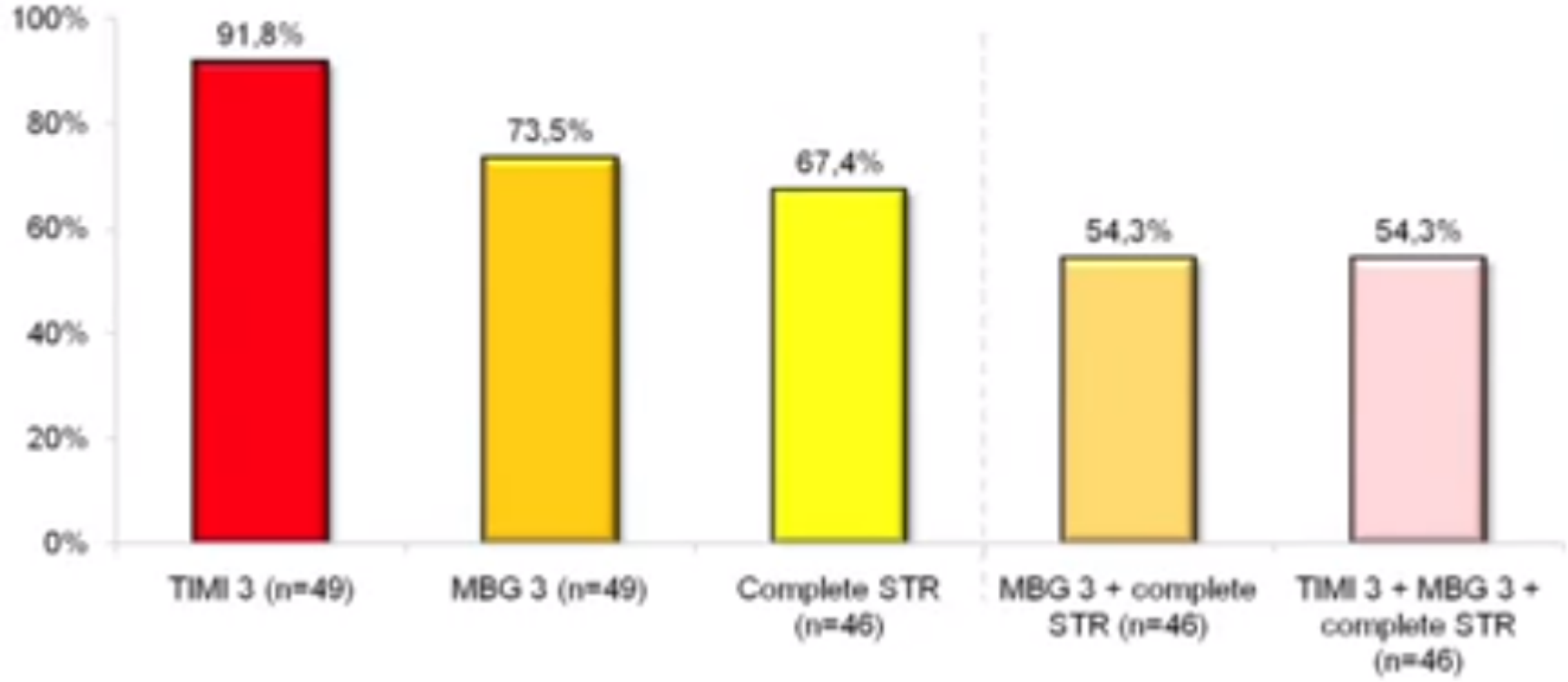
Primary and major secondary endpoints of MAGICA



* ST resolution obtained from 57 patients due to technical issues

No prior aspiration subgroup (n=49)

Primary and major secondary endpoints of MAGICAL Study*



* ST resolution obtained from 46 patients due to technical issues

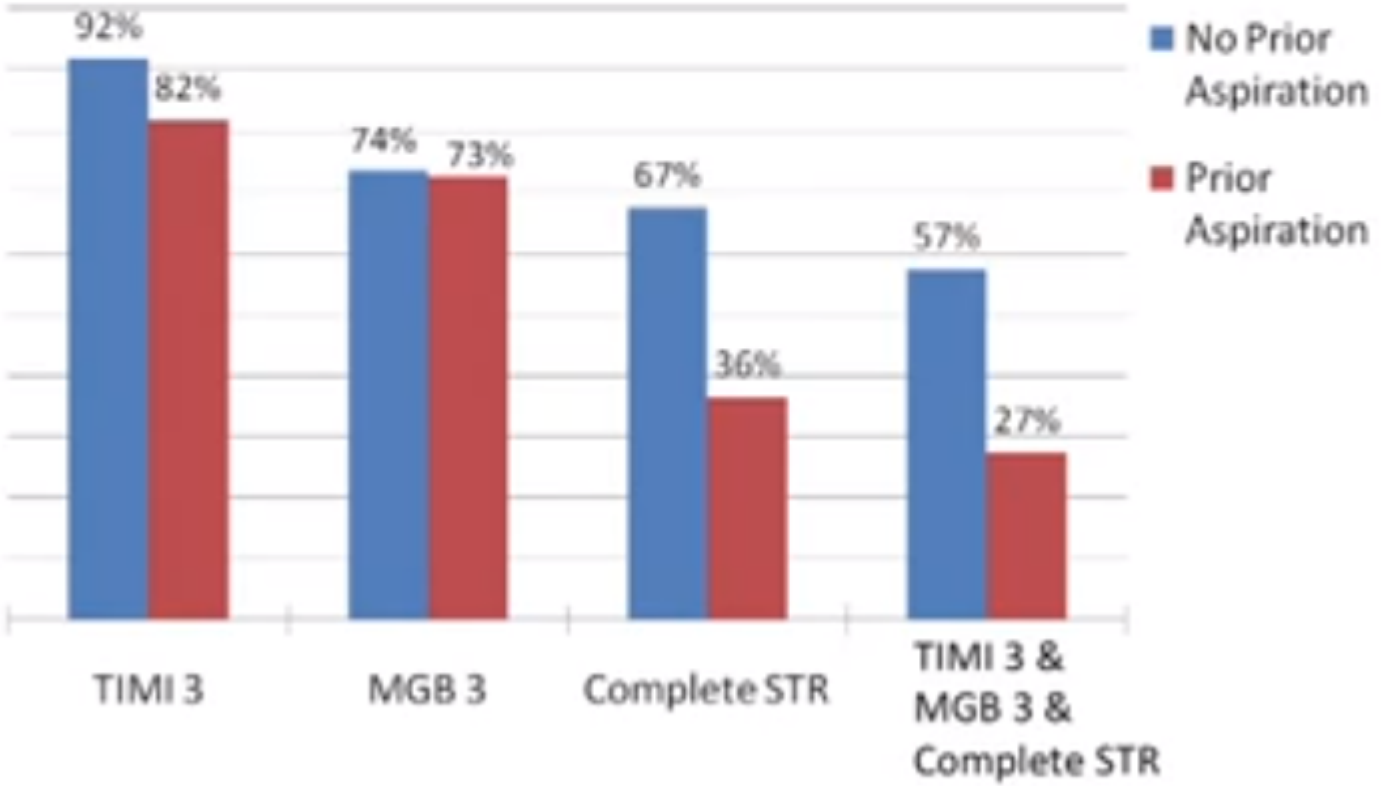
EuroIntervention. 2010 Nov;6(5):582-9.

The MAGICAL Trial

No prior aspiration subgroup* (n=49)

Prior aspiration subgroup (n=11)

Primary and major secondary endpoints of MAGICAL Study*



* ST resolution obtained from 46 patients due to technical issues