Tradeoffs of Embolic Protection and Sealing vs Restenosis: Utility of the Micronet MGuard Stent for MI, SVG, Aneurysms, and More

Dariusz Dudek

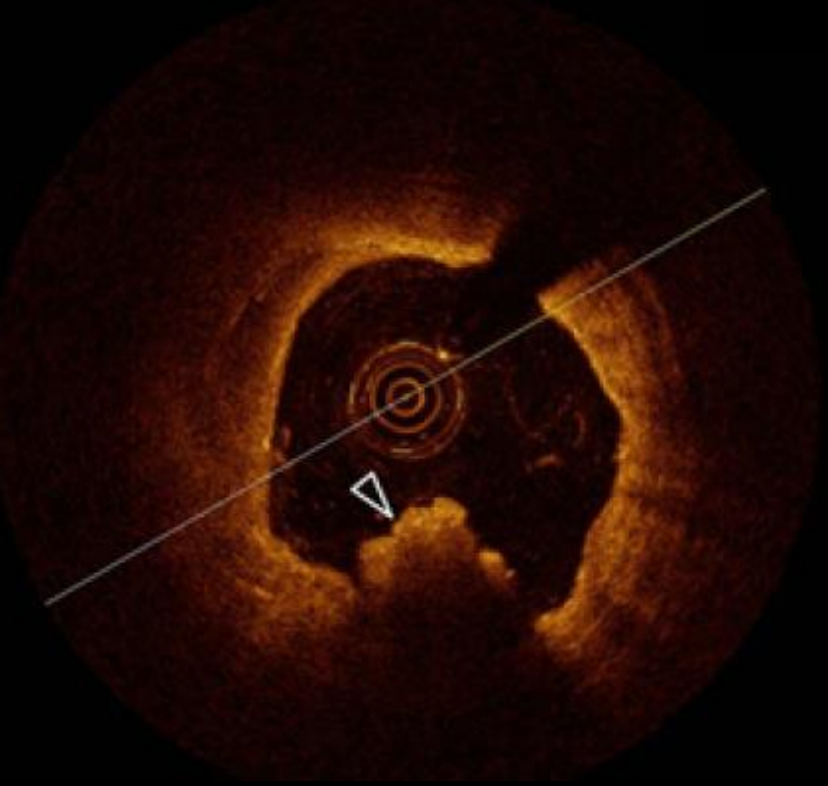
Institute of Cardiology, Krakow, Poland

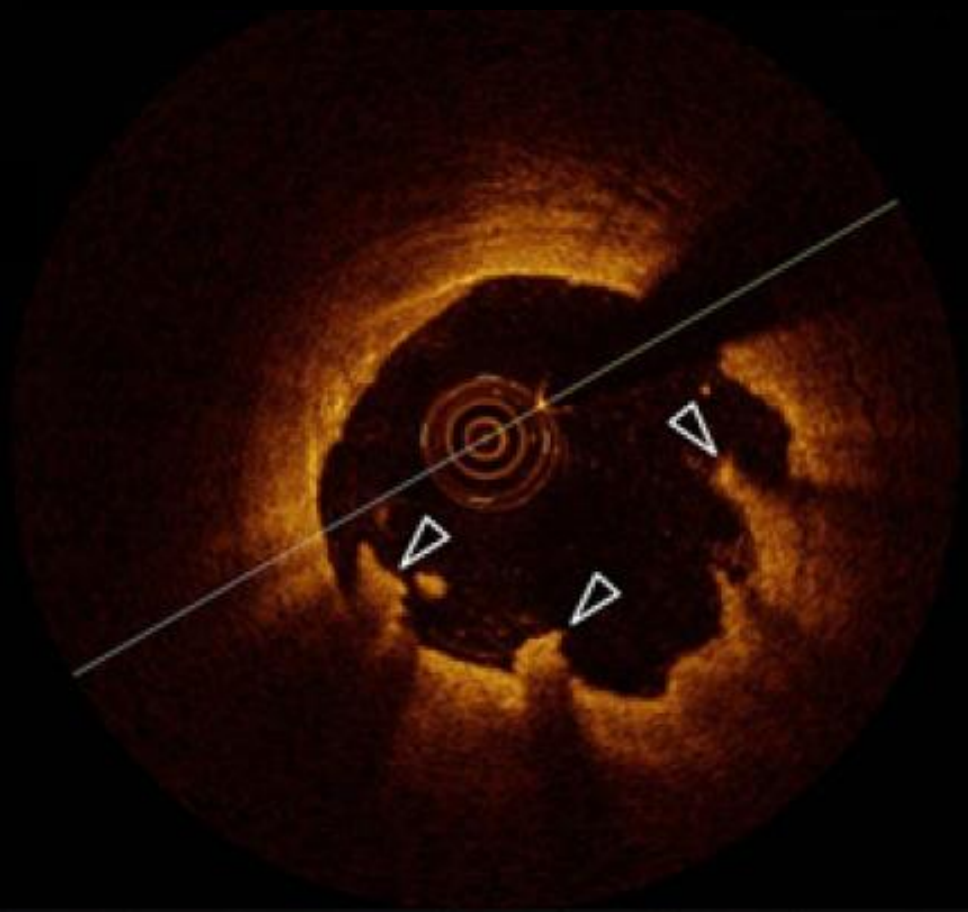
Disclosure Statement of Financial Interest

I, Dariusz Dudek DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

STEMI

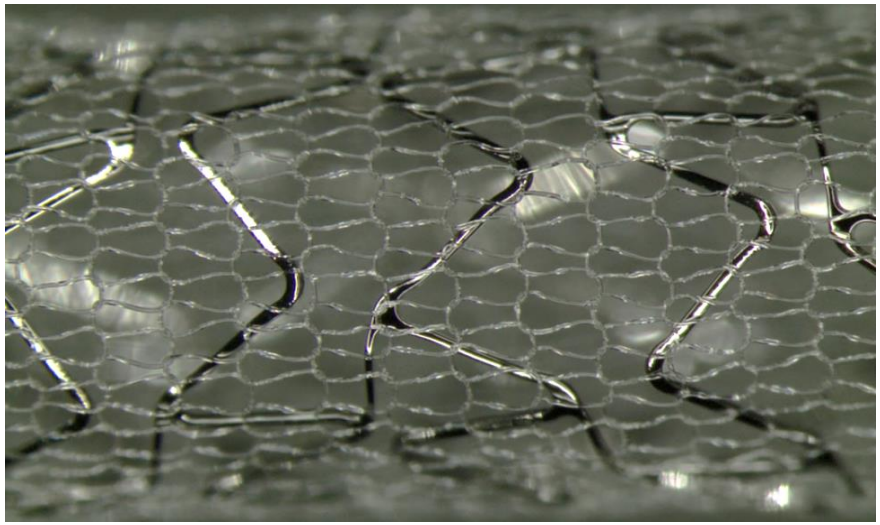
Persistent thrombus protruding into the lumen after aspiration thrombectomy

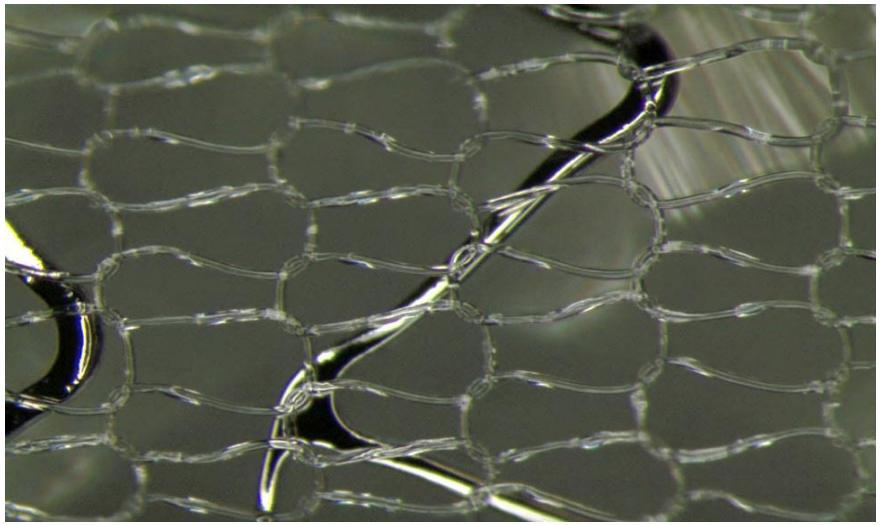




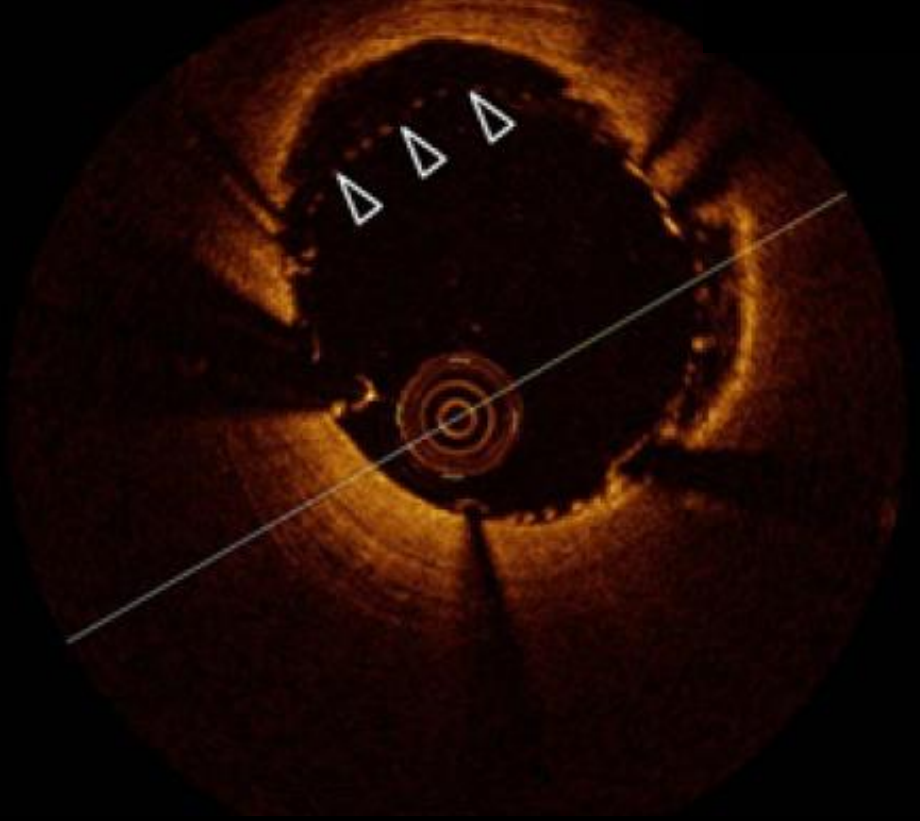
J Am Coll Cardiol 2011 58: e39.

The MGuard and MGuard Prime Embolic Protection Stent (EPS)

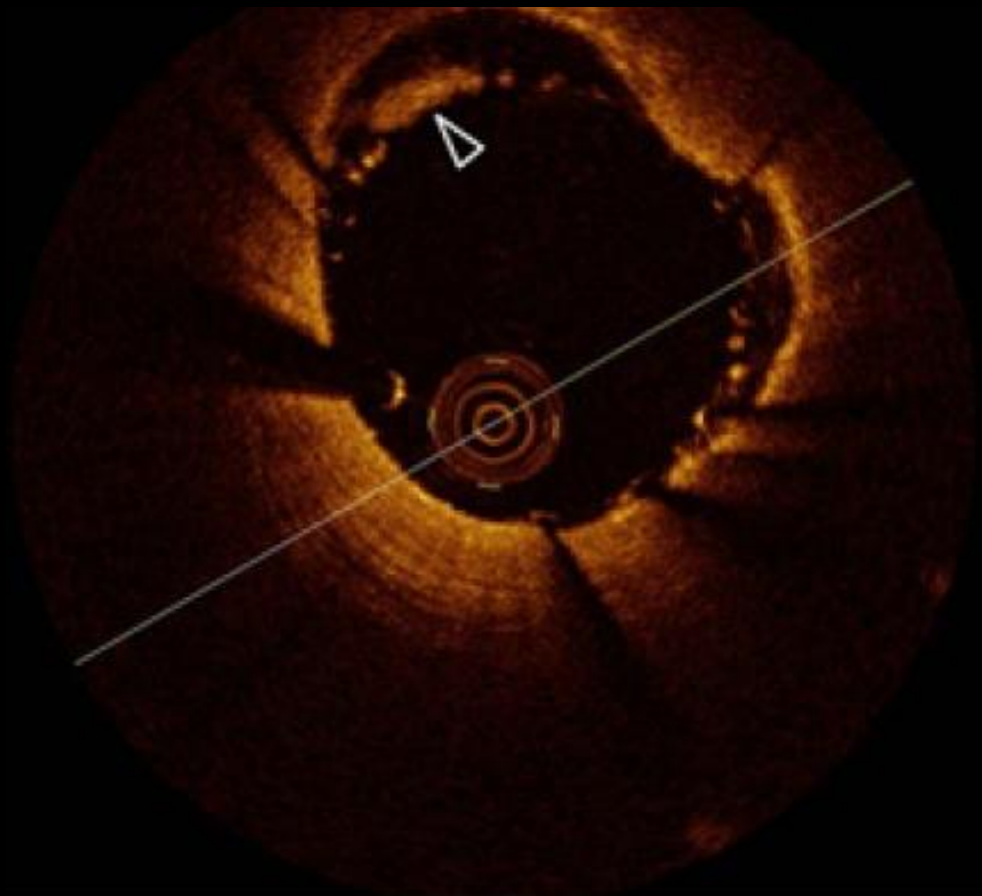




	MGuard	MGuard Prime
Metallic frame	316L stainless steel	L605 cobalt chromium
Strut width	100 µm	80 µm
Crossing profile	1.1 – 1.3 mm	1.0 – 1.2 mm
Shaft dimensions	0.65 – 0.86 mm	0.65 – 0.86 mm
Mesh sleeve	PET	PET
- Fiber width	20 µm	20 µm
- Net aperture size	150 - 180 µm	150 - 180 µm



The mesh covering of the stent and the presence of thrombus “trapped” behind the mesh



J Am Coll Cardiol 2011 58: e39.

EuroIntervention

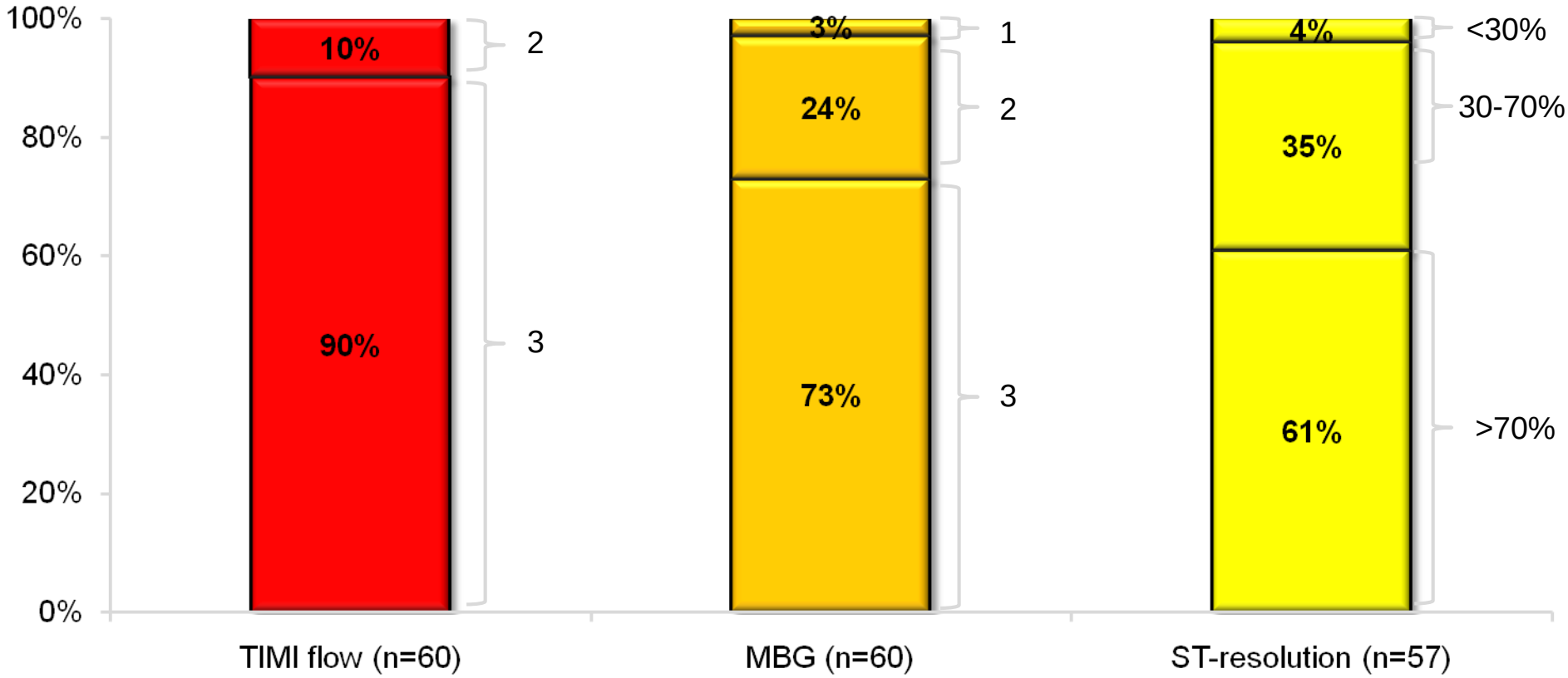
Mesh covered stent in ST-segment elevation myocardial infarction

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

1. Department of Interventional Cardiology, Jagiellonian University Medical College, Krakow, Poland; 2. 2nd Department of Cardiology, Jagiellonian University Medical College, Krakow, Poland; 3. Department of Interventional Cardiology, Nowy Sacz, Poland; 4. Department of Interventional Cardiology, Nowy Targ, Poland; 5. Columbia University Medical Center, Cardiovascular Research Foundation, New York, NY, USA

The MAGICAL Trial

Detailed final angiographic perfusion and ST-segment resolution data*



* ST resolution obtained from 57 patients due to technical issues

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

Evidence for mesh-covered stent implantation in STEMI

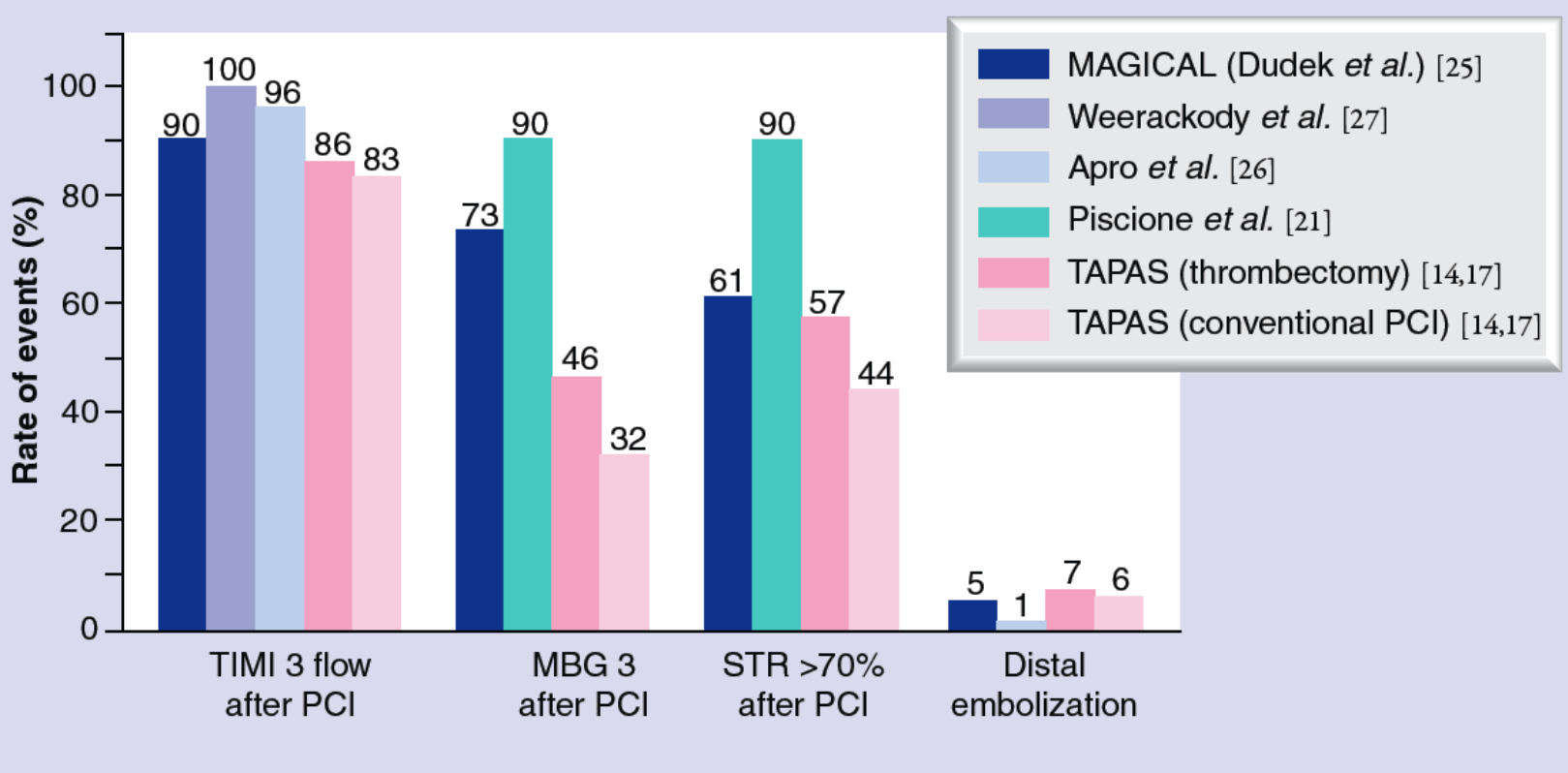


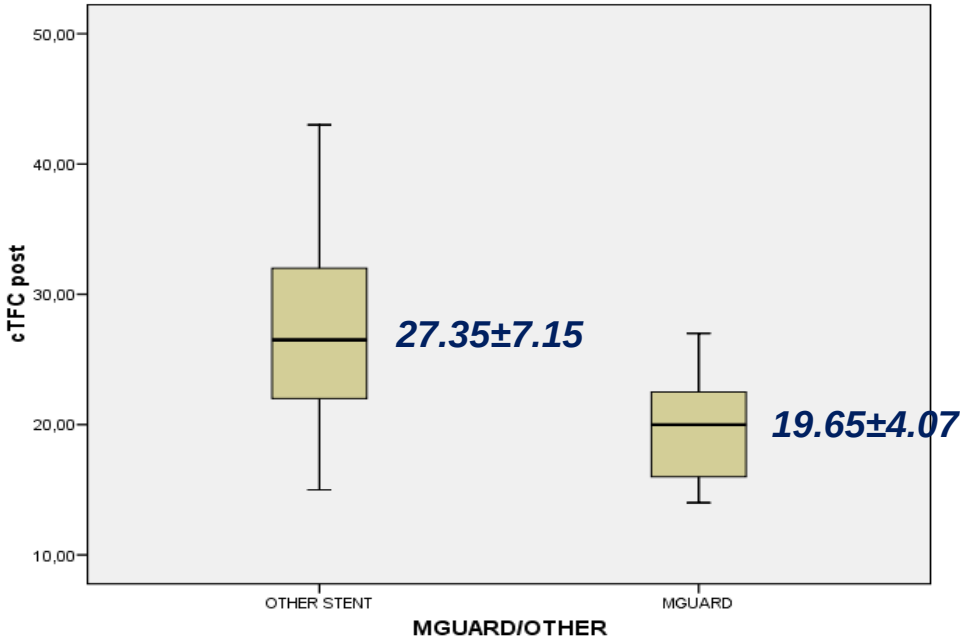
Figure 2. Angiographic and electrocardiographic results of studies assessing the impact of MGuard stent implantation during primary angioplasty for ST-segment elevation myocardial infarction. Data from the MAGICAL study represent independent core laboratory assessment. Results of TAPAS given as comparison.

Dziewierz A, Dudek D. Interventional Cardiology. 2011; 3: 291-7

MICAMI: MGuard Randomized Trial

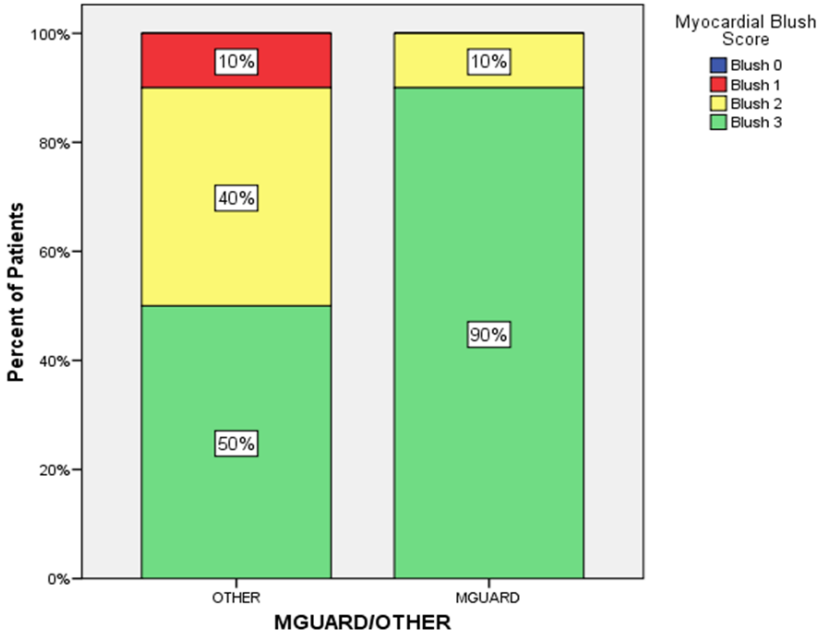
Superior corrected TIMI frame count in MGuard group compared to BMS group

p=0.001*



Superior myocardial blush grade in MGuard group compared to BMS group

p=0.006*



Cardiovasc Revasc Med. 2013;14(1):4–8.

MASTER study

MGuard vs conventional stent (BMS, DES) in STEMI

Journal of the American College of Cardiology
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Published by Elsevier Inc.

Vol. xx, No. x, 2012
ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2012.09.004

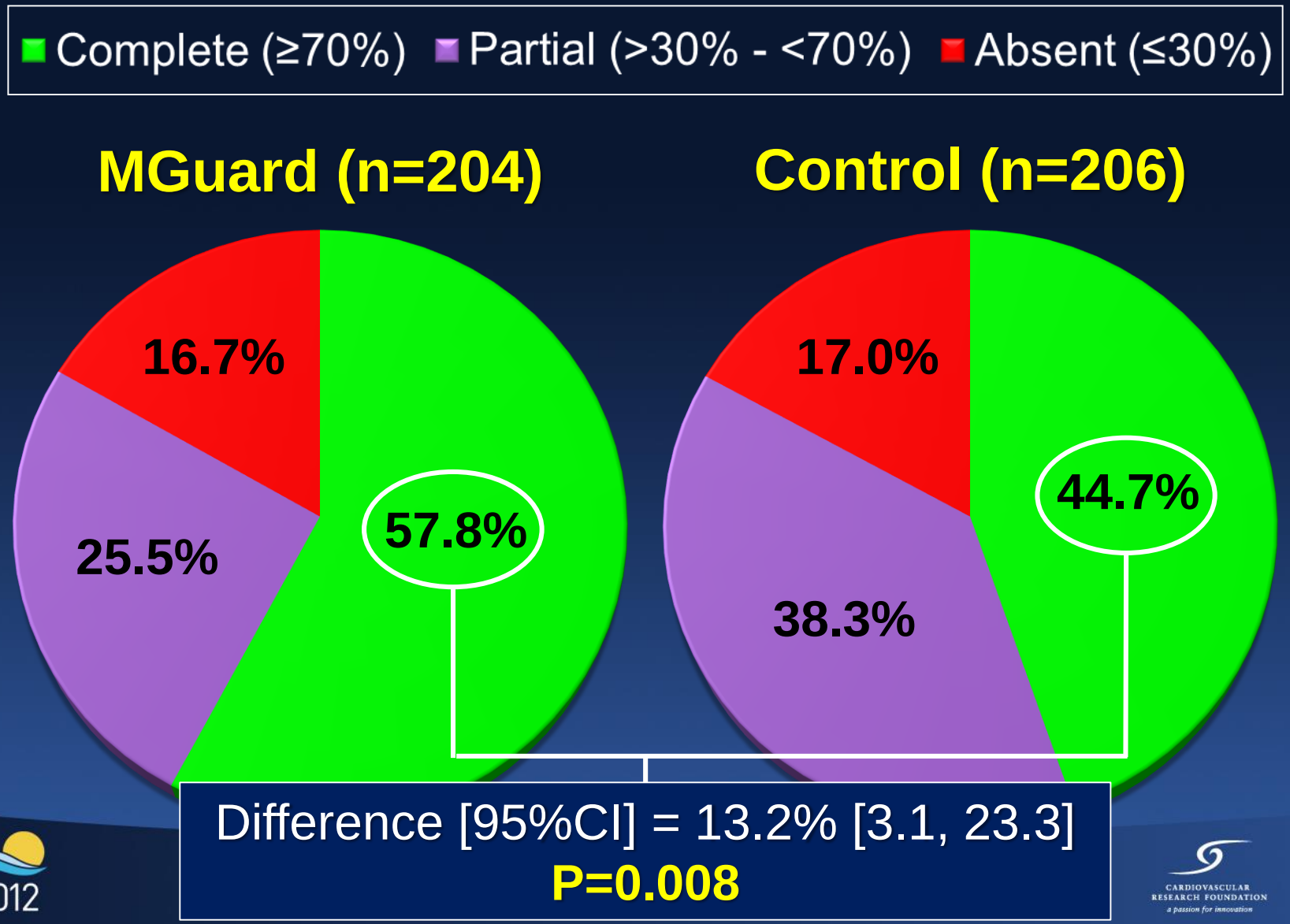
Prospective, Randomized, Multicenter Evaluation of a Polyethylene Terephthalate Micronet Mesh–Covered Stent (MGuard) in ST-Segment Elevation Myocardial Infarction

The MASTER Trial

Gregg W. Stone, MD,*† Alexandre Abizaid, MD, PHD,‡ Sigmund Silber, MD, PHD,§ Jose M. Dizon, MD,*† Béla Merkely, MD,‖ Ricardo A. Costa, MD,‡ Ran Kornowski, MD,¶ Andrea Abizaid, MD, PHD,‡ Roman Wojdyła, MD,# Akiko Maehara, MD,*† Ovidiu Dressler, MD,† Sorin J. Brener, MD,†** Eli Bar, BSC,†† Dariusz Dudek, MD, PHD‡‡

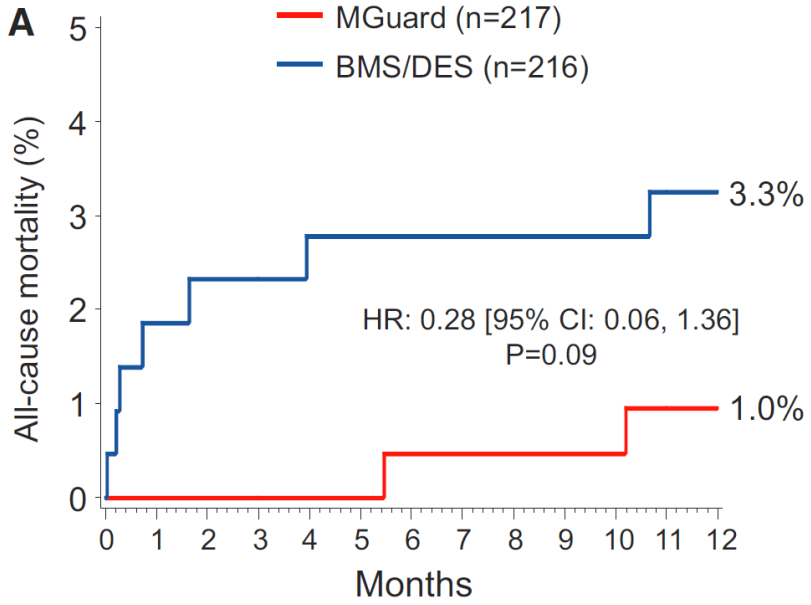
New York and Brooklyn, New York; Sao Paulo, Brazil; Munich, Germany; Budapest, Hungary; Petach Tiqva and Tel Aviv, Israel; and Krakow, Poland

Primary Endpoint:
Complete ST-segment resolution



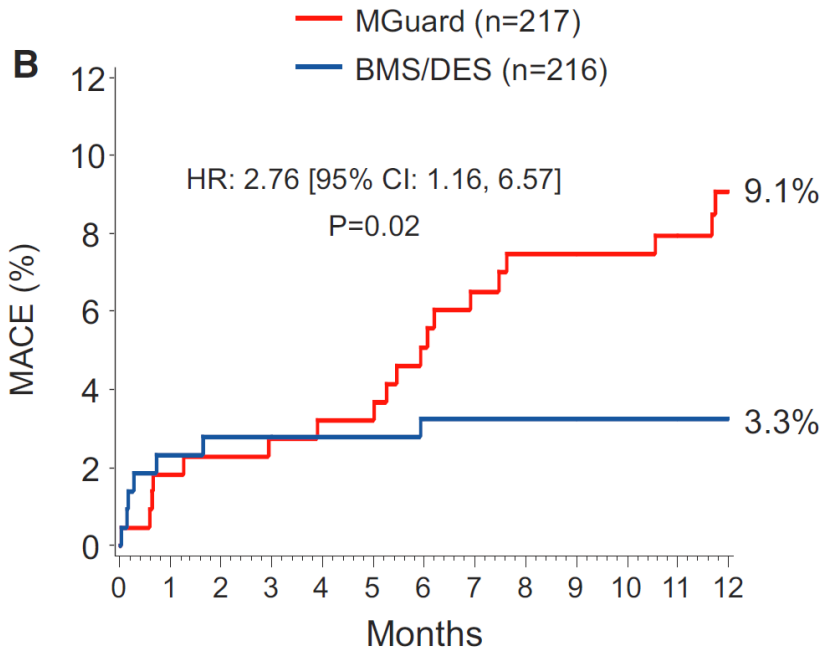
Difference [95%CI] = 13.2% [3.1, 23.3]
P=0.008

MASTER study: 12 months



Number at risk:

MGuard	217	214	209	206	204	126
BMS/DES	216	210	209	207	206	123



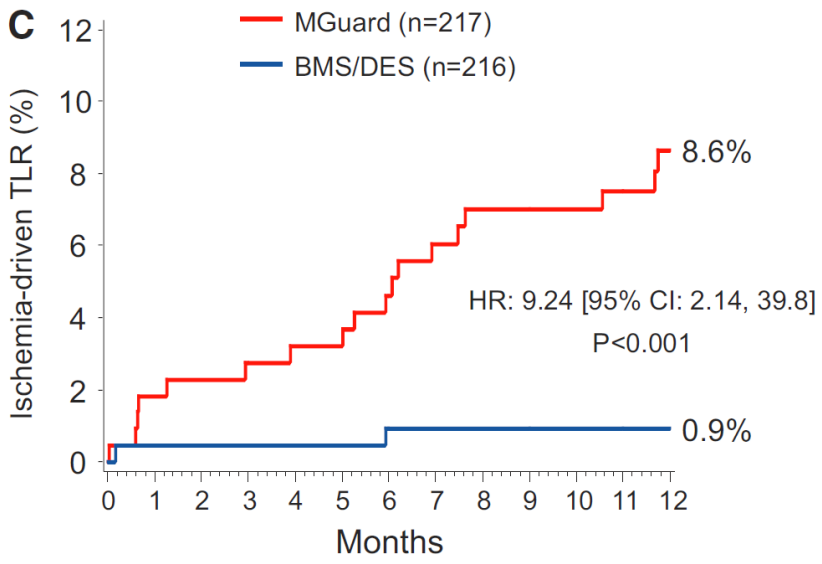
Number at risk:

MGuard	217	209	200	193	190	116
BMS/DES	216	209	208	205	205	123

- **In the MASTER trial of patients with STEMI undergoing primary PCI, patients treated with the MGuard stent had a trend toward reduced cardiac and all-cause mortality at 1 year.**
- **The 1-year rates of MACE in the MGuard group were higher than in the control stent group, driven by increased rate of ischemia- driven TLR, consistent with that expected from BMS.**

Dudek D. et al. Circ Cardiovasc Interv. 2015;8:e001484

MASTER study: 12 months



Number at risk:

MGuard	217	209	200	193	190	116
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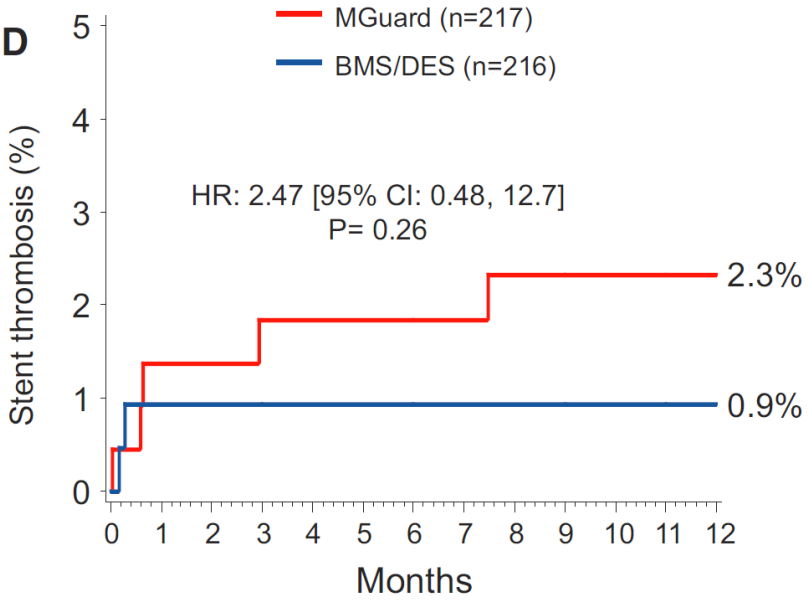


Number at risk:

MGuard	217	211	206	203	201	123
BMS/DES	216	210	210	206	206	124

- **Data from ongoing randomized clinical trials powered for clinical end points are needed to weigh the competing risks and benefits of the MGuard as an alternative to conventional metallic stents in patients with STEMI.**

Dudek D. et al. Circ Cardiovasc Interv. 2015;8:e001484

The MGuard coronary stent: safety, efficacy, and clinical utility

Table 1 Summary of studies with the MGuard stent in patients with STEMI

	n	Comparative treatment	Follow-up	ST-segment resolution	TIMI flow 3 achieved	Blush grade 3	Mortality 30 days/1 year	TLR 30 days/1 year	Stent thrombosis 30 days/1 year
Randomized trials									
MASTER I[12]	433	BMS/DES	1 year	57.8 vs 44.7 *P* (0.008)	91.7 vs 82.9 *P* (0.006)	74.2 vs 72.1 *P* (NS)	0 vs 1.9 *P* (NS)/ 1 vs 3.3 *P* (NS)	1.8 vs 0.5 *P* (NS)/8.6 vs 0.9 *P* (0.0003)	1.4 vs 0.9 *P* (NS)/2.3 vs 0.9 *P* (NS)
MICAMI-MGUARD[33]	40	BMS	6 months	–	90 vs 80 *P* (NS)	90 vs 50 *P* (0.006)	0 vs 0/NA	0 vs 0/NA	0 vs 0
MASTER II[14]	310	BMS/DES	30 days	56.9 vs 59.3 *P* (NS)	91.4 vs 89 *P* (NS)	–	0.6 vs 1.9 *P* (NS)/NA	2.6 vs 2.6 *P* (NS)/NA	2.6 vs 3.2 *P* (NS)/NA
MASTER I + II[14] (pooled analysis)	743	BMS/DES	30 days	57.5 vs 50.7 *P* (NS)	91.6 vs 85.4 *P* (0.008)	–	0.3 vs 1.9 *P* (0.04)/NA	2.2 vs 1.3 *P* (NS)/NA	1.9 vs 1.9 *P* (NS)/NA
Nonrandomized									
[a]Piscione et al[15]	100	–	24 months	90	2.85 (mean)	90	2.3/2.2[b]	–/3.4[b]	2.3/1.1[b]
MAGICAL[16]	60	–	36 months	61.4	90	73	0/7[c]	0/1.8[c]	0/0[c]
Romaguera et al[13]	56	–	9 months	58.7	82.3	55.4	0[d]	1.8[d]	1.8[d]
REWARD-MI[18]	158[e]	BMS	10 months	–	97.5 vs 94.9 *P* (NS)	–	NA/6.3 vs 6.3 *P* (NS)	NA/11.4 vs 1.3 *P* (0.009)	NA/2.4 vs 1.3 *P* (NS)
iMOS registry[19] (STEMI only)	268	–	12 months	86	94	74	–	–	–

Notes: Values expressed as %. [a]Excluding 16 cardiogenic shock patients, in whom five events of in-hospital deaths occurred; [b]at 24 months; [c]at 36 months; [d]at 9 months; [e]matched group.

Abbreviations: BMS, bare metal stent; DES, drug-eluting stent; NA, not available; NS, not significant; STEMI, ST-segment elevation myocardial infarction; TLR, target lesión revascularization; TIMI, thrombolysis in myocardial infarction.

The online version of this article is located at http://www.minervamedica.it
Minerva Cardioangiologica 2016 June;64(3):265-83

REVIEW

CONTEMPORARY ISSUES RELATED TO STEMI MANAGEMENT

Choosing the right stent for patients with ST-segment elevation myocardial infarction: the evidence-based approach

Artur DZIEWIERZ [1]*, Dariusz DUDEK [2]

Additional randomized clinical trials powered for clinical endpoints are needed to weigh the competing benefits *(potentially improved myocardial reperfusion, reduced infarct size and greater survival)* and risks *(potentially greater restenosis)* of the MGuard as an alternative to metallic stents in patients with STEMI.

SVG

Non-randomized

Coronary Stenting with MGuard: First-In-Man Trial

§Edo Kaluski, MD, ‡Karl Eugen Hauptmann, MD, *Ralf Müller, MD, §Steve Tsai, MD, §Marc Klapholz MD, *Eberhard Grube, MD

Characteristic	
Age (*years, mean ± SD*)	68.1 ± 11.0
Female gender, *n, (%)*	5 (17.2%)
Previous myocardial infarction, *n, (%)*	12(41.4%)
Congestive heart failure, *n, (%)*	4 (13.8%)
Left ventricular ejection fraction (*mean ± SD*)	56.9 ± 13.5%
Diabetes mellitus, *n, (%)*	10 (34.5%)
Hypertension, *n, (%)*	23 (79.3%)
Hyperlipidemia, *n, (%))*	23 (79.3%)
Former or current smokers, *n, (%)*	13 (44.8%)
Acute coronary syndromes, *n, (%)*	21 (72.4%)
Degenerated vein grafts, *n, (%)*	17 (58.6%)
Native coronaries (*7* RCAs, *3* LADs, *2* LCXs), *n, (%)*	12 (41.4%)
Percent stenosis (*% mean ± SD*)	89 ± 9.7%
Mean reference diameter (*mm, mean ± SD*)	3.64 ± 0.63
Stents deployed (*mean ± SD*)	1.46 ± 0.63
Predilatation with undersized balloon (*2–2.5 mm*)	23 (78.3%)
Postdilatation, *n, (%)*	8 (27.6%)
Aspirin clopidogrel and UFH use, *n, (%)*	29 (100%)
Glycoprotein IIb/IIIa inhibitors use, *n, (%)*	0 (0%)
Embolic protection device use, *n, (%)*	0 (0%)
Preprocedural TIMI flow (*mean ± SD*)	2.4 ± 0.63

LAD = left anterior descending artery; LCX = left circumflex artery; SD = standard deviation; TIMI = thrombolysis in myocardial infarction; UFH = unfractionated heparin

n=29 pts

Device and procedural success were 100% and 96.5%, respectively. One patient experienced a procedure-related CPK rise. No MACE were reported at 1 month.

J Invasive Cardiol 2008;20:511–515

Final Results of the INSPIRE Trial

TABLE IV. Intravascular Ultrasound Main Findings at Postprocedure and 6-Month Follow-up

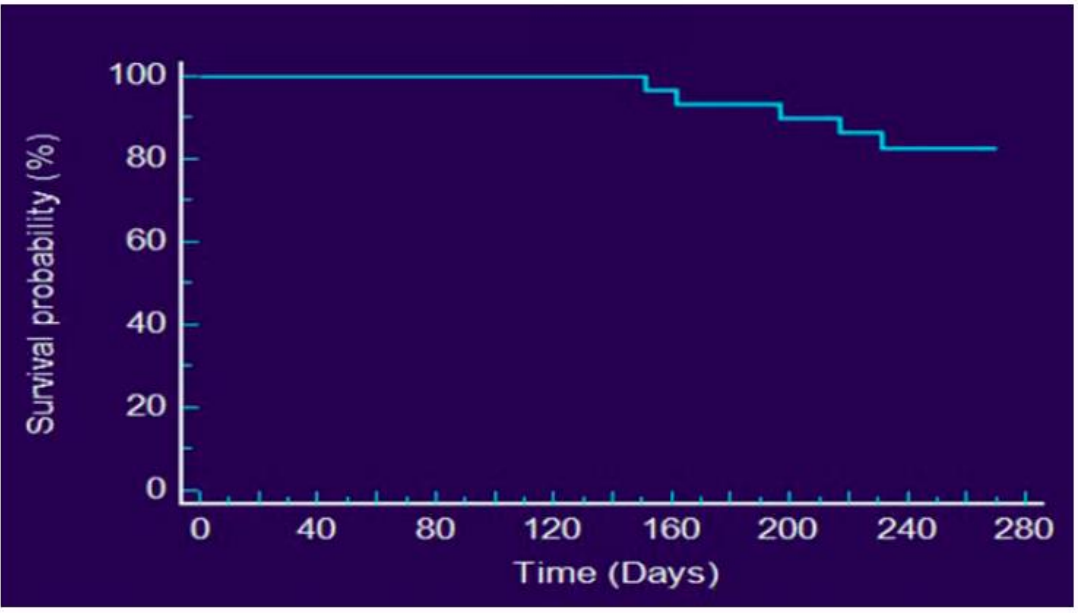
	Postprocedure	
	SVG ($n = 10$)	Native coronary ($n = 10$)
Mean reference CSA (mm^2)	8.7 ± 3.7	10.2 ± 3.5
In-stent minimum CSA (mm^2)	7.1 ± 2.8	7.8 ± 2.0
Stent expansion (%)	83.0 ±13	77.9 ± 8.1
Plaque prolapsed (%)	0	0
Acute incomplete stent apposition (%)	0	0
Six-month follow-up		
	SVG ($n = 10$)	Native coronary ($n = 10$)
% of stent obstruction	28.8 ± 13.5	33.6 ± 13.5
Late acquired incomplete stent apposition (%)	0	10% (1)

Catheter Cardiovasc Interv. 2011 Dec 1;78(7):1095-100

Final Results of the INSPIRE Trial

TABLE V. One-Year MACE Rate and Stent Thrombosis

	Total ($n = 30$)	SVG ($n = 16$)	Native coronary ($n = 14$)
Cardiac death	0	0	0
Myocardial infarction (%)	6.7% (2)	0	6.7% (2)
Q-wave MI	3.35% (1)	0	3.35% (1)
Non-Q-wave MI	3.35% (1)	0	3.35% (1)
TLR	20% (6)	18.8% (3)	21.2% (3)
Total MACE	23.3% (7)	18.8% (3)	35.7% (3)
Stent thrombosis[a]	0	0	0



Case Report

Case series

Preliminary Experiences Using the MGuard Stent Platform in Saphenous Vein Graft Lesions

Seven patients
Eight SVGs (mean age 15 y) treated with 12 MGuard Stents

Clinical presentation of ACS: 6 pts; 86%
Diabetes melitus: 5 pts; 71%

Embolic protection device: 1 pt

No graft related embolization
Procedurel success: 100%
NO MACE during 30-day follow up

Catheterization and Cardiovascular Interventions 2009;74:1055–1057

MGuard Stent in SVGs and Native Coronary Arteries

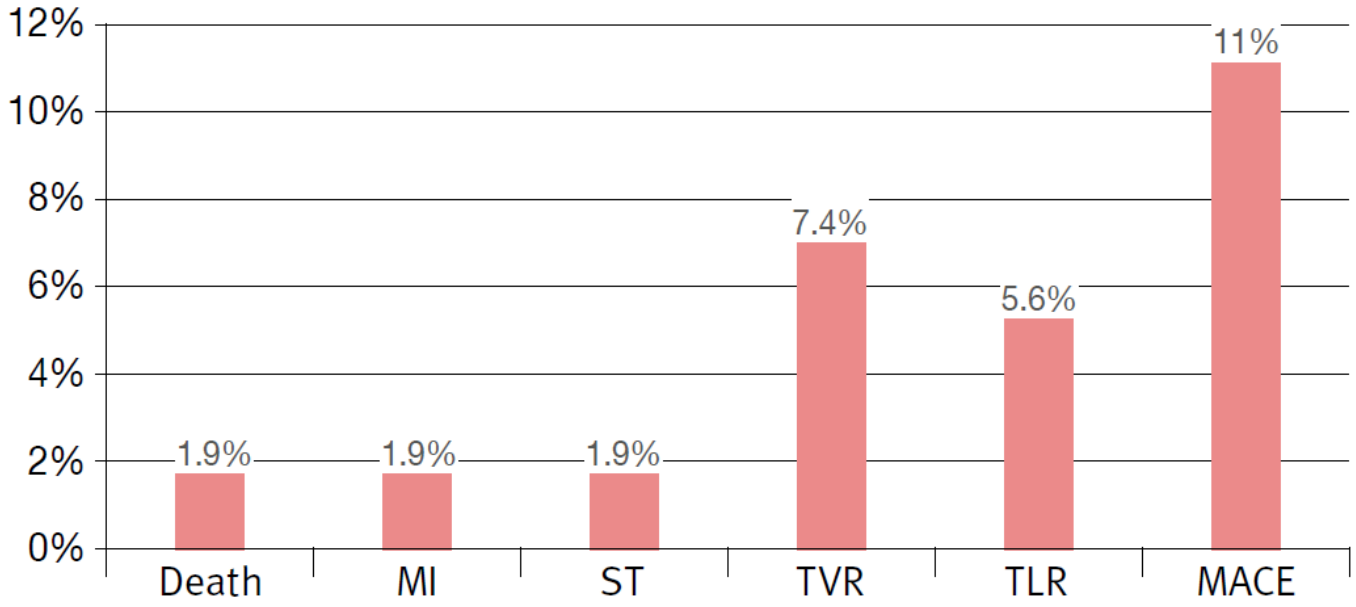
	Native artery (n=54)	Vein grafts (n=109)
Patient characteristics		
Age (yrs)	61 ± 12	74 ± 10
Male	44 (82%)	92 (84%)
NIDDM	14 (26%)	62 (57%)
Hypertension	30 (57%)	91 (84%)
Dyslipidemia	39 (72%)	96 (88%)
Current smoker	30 (57%)	9 (8%)
Previous PCI	13 (24%)	50 (46%)
Previous CABG	2 (4%)	100%
Renal failure	5 (9%)	41 (38%)
Clinical presentation		
STEMI	45 (83%)	12 (11%)
ACS	9 (17%)	86 (79%)
Stable angina	0	11 (10%)
Silent ischemia	0	4 (4%)
LVEF ‹ 40%	18 (33%)	37 (34%)
Double- and triple-vessel disease	32 (59%)	100%

- **163 consecutive patients who underwent MGuard stent deployment during the period 2009 to 2014 in a large tertiary cardiac center in central Israel.**

IMAJ 2017; 19: 172–176

MGuard Stent in SVGs and Native Coronary Arteries

Figure 1. Patient outcomes at 1 year for native arteries

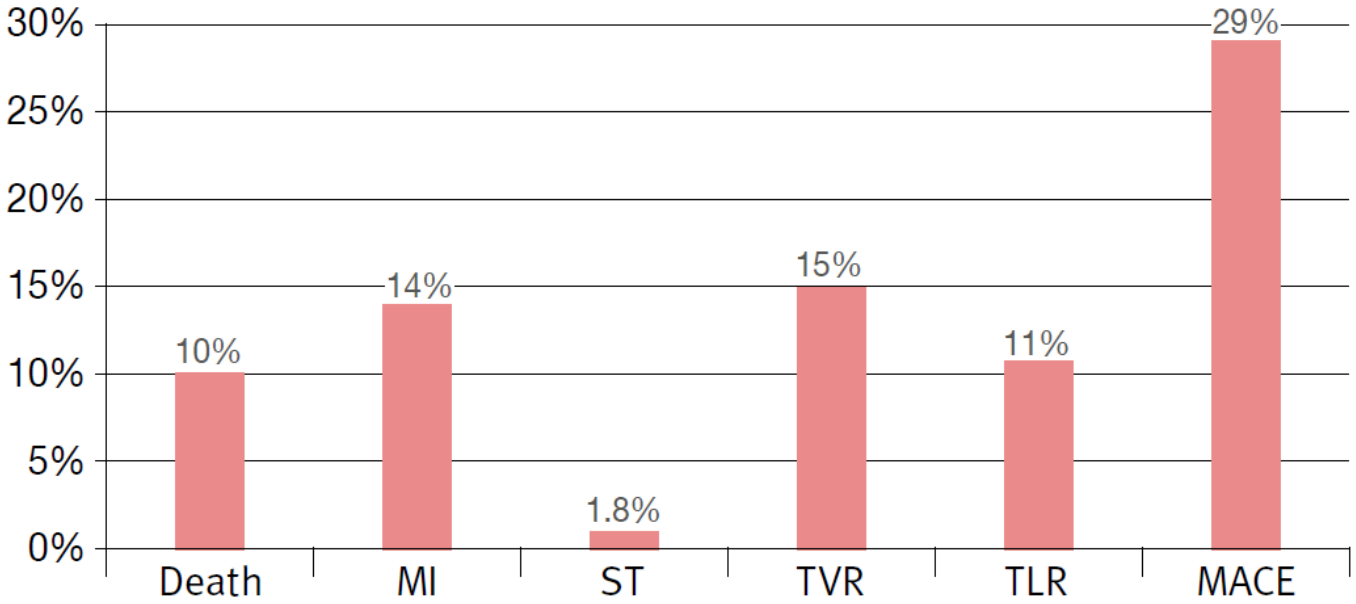


MI = myocardial infarction, ST = stent thrombosis, TVR = target vessel revascularization, TLR = target lesion revascularization, MACE = major adverse cardiac events

IMAJ 2017; 19: 172–176

MGuard Stent in SVGs and Native Coronary Arteries

Figure 2. One year outcomes of saphenous vein grafts–percutaneous coronary interventions



MI = myocardial infarction, ST = stent thrombosis, TVR = target vessel revascularization, TLR = target lesion revascularization, MACE = major adverse cardiac events

IMAJ 2017; 19: 172–176

Anurysms

MGuard to Treat Coronary Aneurysms

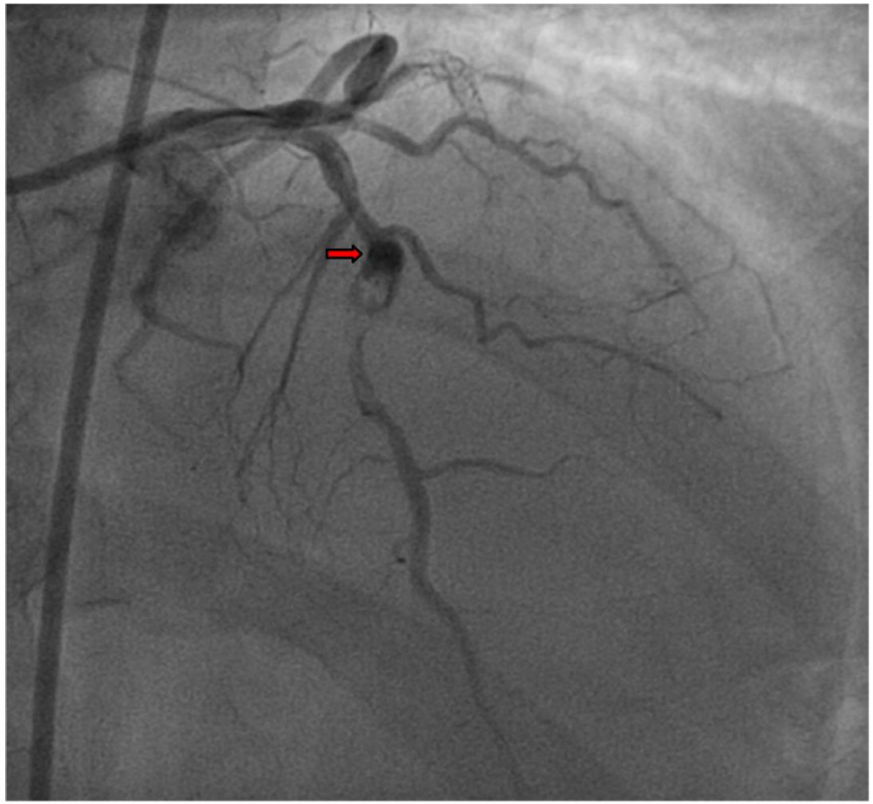


Fig. 1 – Aneurysm at the proximal end of the stent and angiographically. Visible thrombus.

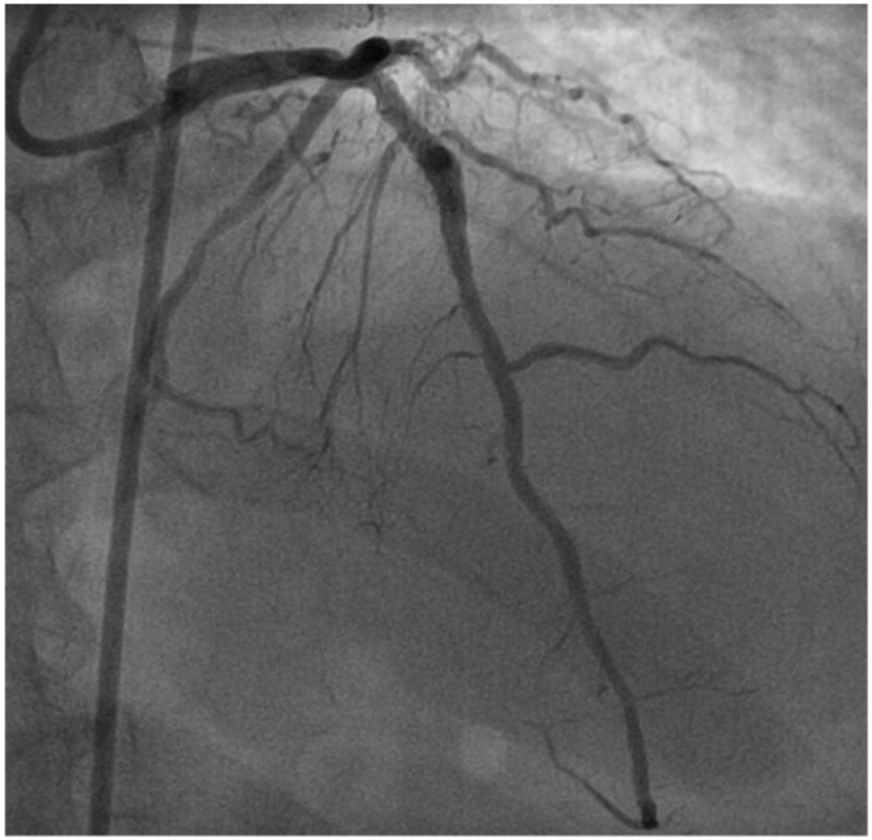
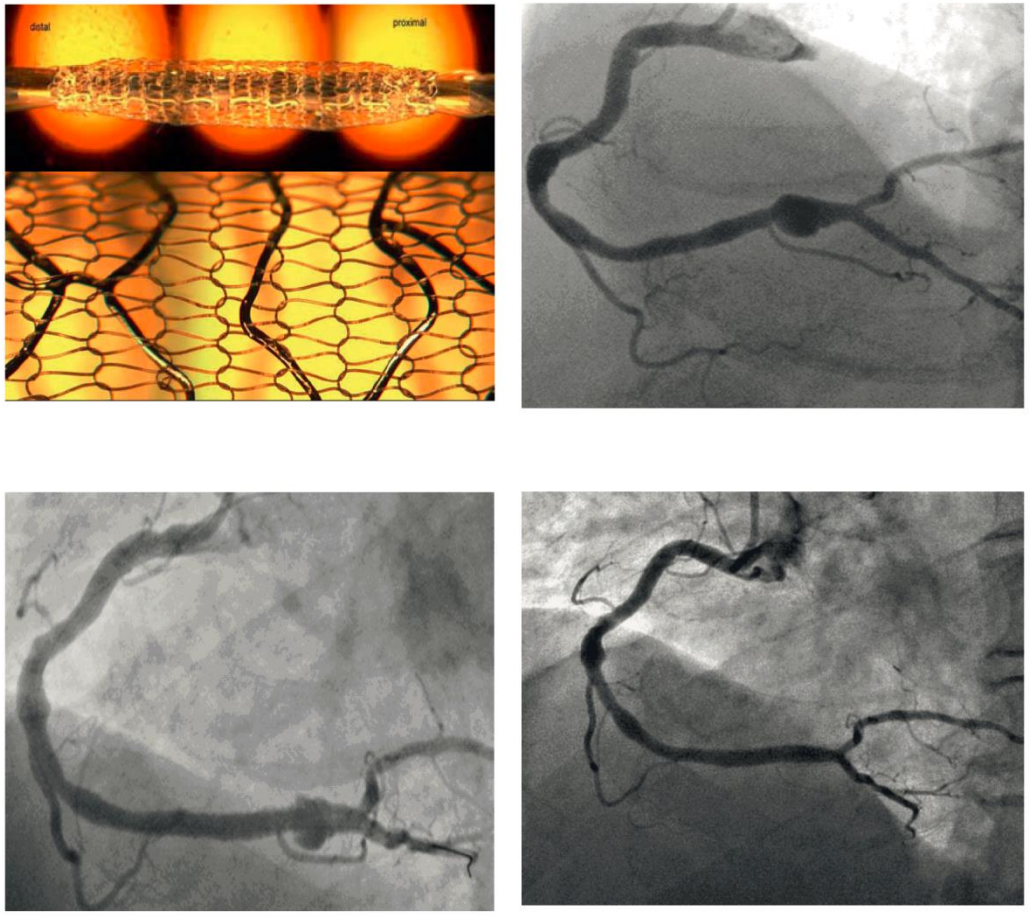


Fig. 5 – Final picture after deploying MGuard stent with TIMI 3 flow.

MGuard to Treat Coronary Aneurysms



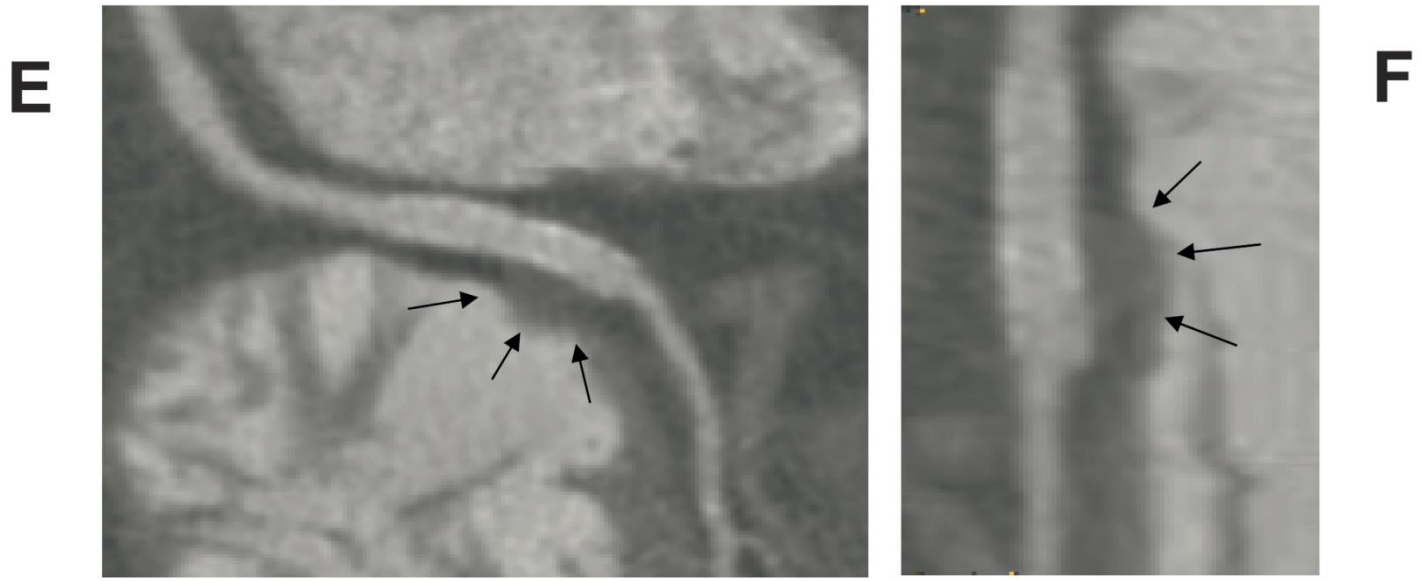
B. Angiography of RCA with the presence of a large saccular aneurysm involving the distal part of the artery to the crux cordis.

C. Partial opacification of the aneurysmal sac through the holes of the mesh just after stent implantation.

D. Coronary angiography at one month follow-up showing the exclusion of the aneurysm.

Gian et al. Journal of Medical Case Reports 2010, 4:238

MGuard to Treat Coronary Aneurysms



E. Coronary CT scan at one month: multiplanar reformation of RCA near the crux cordis; on the right ventricle side of the distal part of the stent, is clearly demonstrated the water density remnant of the treated aneurysm (arrows): low density fat is surrounding the proximal stent.

F. Coronary CT scan at one month: The magnified view of the stent allows for a better identification of the treated aneurysm (arrows).

Gian et al. Journal of Medical Case Reports 2010, 4:238

Perforations

MGuard to Treat Coronary Arterial Perforations

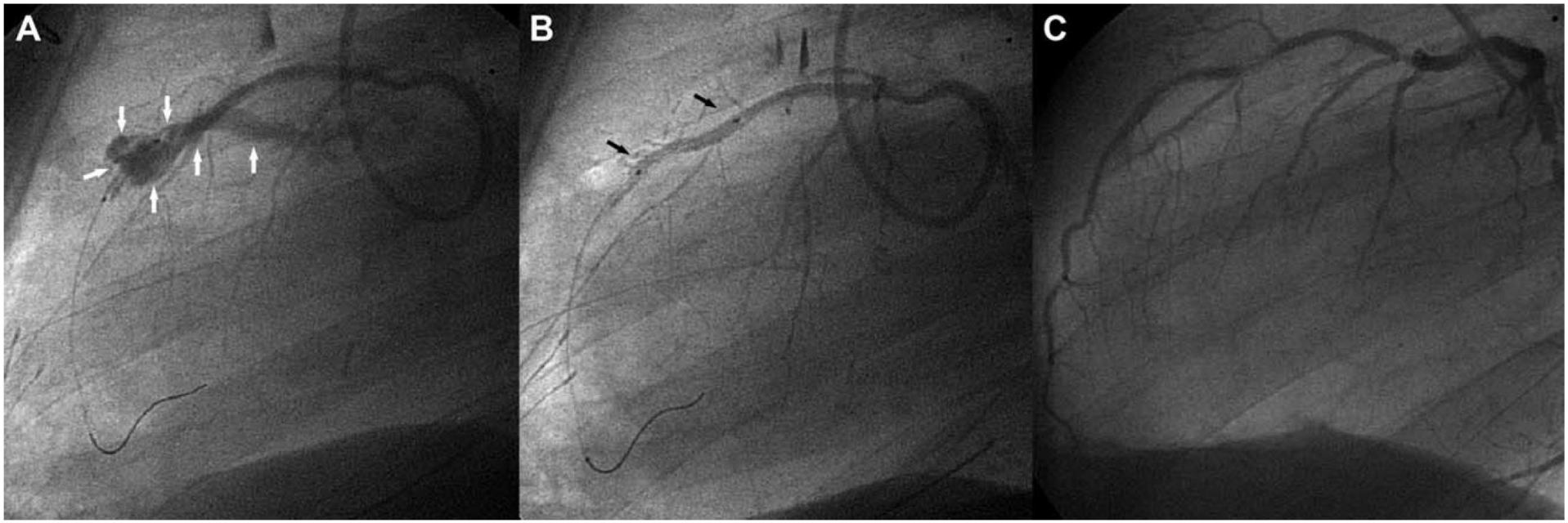


Fig. 2. Case 1: Coronary angiogram (90° lateral projection) showing (A) vessel rupture with free contrast extravasation (white arrows) and (B) successful sealing of the perforation with no further contrast extravasation after implantation of the second mesh-covered stent (black arrows). The 12-months follow-up angiogram (C) demonstrated TIMI 3 flow, although significant in-stent restenosis was noted.

Catheterization and Cardiovascular Interventions 2012; 80:75–78.

MGuard to Treat Coronary Arterial Perforations

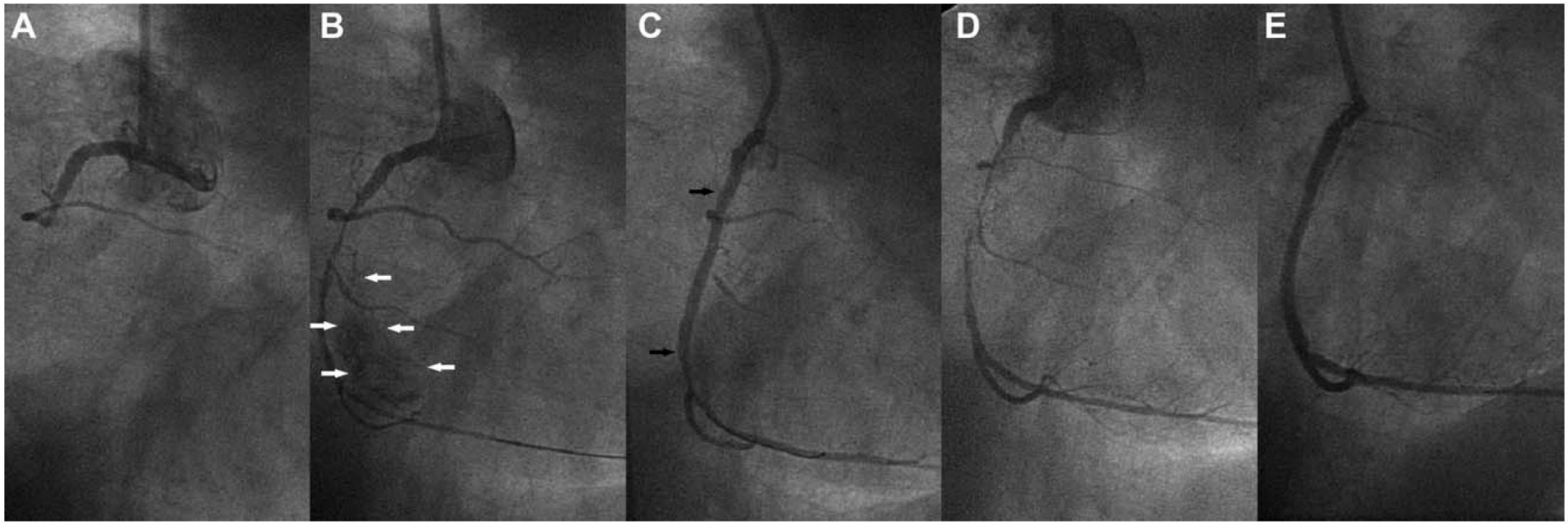


Fig. 3. Case 2: Coronary angiogram (30° right oblique projection) showing (A) preintervention total occlusion of the RCA; (B) free contrast extravasation (white arrows) after guidewire repositioning; (C) successful sealing of the perforation with no further contrast extravasation after implantation of the mesh-covered stent (black arrows); (D) 12-months follow-up angiogram with diffuse in-stent restenosis; (E) final result after everolimus-eluting stents implantation.

Catheterization and Cardiovascular Interventions 2012; 80:75–78.

MGuard to Treat Coronary Arterial Perforations

- **In conclusion, the MGuard mesh-covered stent can be successfully used to seal CPs. However, when they are used in this bailout situation, *higher rates of restenosis may be expected*.**

Catheterization and Cardiovascular Interventions 2012; 80:75–78.

European Heart Journal
doi:10.1093/eurheartj/ehq277

ESC/EACTS GUIDELINES

Guidelines on myocardial revascularization

The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

„The use of mesh-based protection may be considered for PCI of highly thrombotic or coronary vein grafts lesions (IIb C)"

Eur Heart J. 2010 Oct;31(20):2501-55.

The use of MGuard stent is NOT recommended in:

- vessel with extreme tortuosity
- heavy calcifications
- lesions located distally to previously implanted coronary stents
- coronary bifurcation lesions with large side branch (branches can potentially be compromised by the presence of polymer mesh)

The online version of this article is located at http://www.minervamedica.it
Minerva Cardioangiologica 2016 June;64(3):265-83

REVIEW

CONTEMPORARY ISSUES RELATED TO STEMI MANAGEMENT

Choosing the right stent for patients with ST-segment elevation myocardial infarction: the evidence-based approach

Artur DZIEWIERZ [1]*, Dariusz DUDEK [2]

The greater restenosis of the MGuard may be limited with the introduction of sirolimus-eluting version of the stent, which is hopefully under development.