Mesh-Covered Embolic Protection Stent Implantation in ST-Segment–Elevation Myocardial Infarction

Final 1-Year Clinical and Angiographic Results From the MGUARD for Acute ST Elevation Reperfusion Trial

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Background—The MGuard, a bare metal stent covered with a polymer mesh, was designed to reduce distal embolization during percutaneous coronary intervention in ST-segment–elevation myocardial infarction. In the MGUARD for Acute ST Elevation Reperfusion trial, the primary end point of complete ST-segment resolution was significantly improved with the MGuard compared with control. We evaluated 1-year clinical and angiographic results.

Methods and Results—Patients with ST-segment–elevation myocardial infarction ≤12 hours undergoing primary percutaneous coronary intervention of a single de novo native lesion were randomized to the MGuard versus any commercially available metallic stent (39.8% drug-eluting). Clinical follow-up was performed through 1 year, and angiography at 13 months was planned in 50 MGuard patients. There was no difference in major adverse cardiac events (1.8% versus 2.3%; *P*=0.75) at 30 days between the groups. Major adverse cardiac events at 1 year were higher with the MGuard, driven by greater ischemia-driven target lesion revascularization (8.6% versus 0.9%; *P*=0.0003). Conversely, mortality tended to be lower with the MGuard at 30 days (0% versus 1.9%; *P*=0.04) and at 1 year (1.0% versus 3.3%; *P*=0.09). Late lumen loss at 13 months in the MGuard was 0.99±0.80 mm, and binary restenosis was 31.6%.

Conclusions—In patients with ST-segment–elevation myocardial infarction undergoing primary percutaneous coronary intervention, a trend toward reduced 1-year mortality was present in patients treated with the MGuard stent. Target lesion revascularization and major adverse cardiac events rates during follow-up were higher in the MGuard group than in the control stent group, and angiographic late loss of the MGuard was consistent with that expected from bare metal stents.

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Key Words: acute myocardial infarction ■ primary angioplasty ■ prognosis ■ stents

Primary percutaneous coronary intervention (PCI), with stent implantation when feasible, is the recommended method of reperfusion in patients with ST-segment–elevation myocardial infarction (STEMI).[1,2] Although stent implantation frequently restores normal epicardial coronary flow in patients with STEMI, myocardial reperfusion is often suboptimal and results in increased infarct size and mortality.[3–5] Numerous strategies have been proposed to improve microvascular perfusion, including pharmacological agents (eg, glycoprotein IIb/IIIa inhibitors, adenosine) and mechanical approaches (eg, thrombus aspiration, distal protection devices).[6–10] Meta-analyses of underpowered randomized trials suggested that manual aspiration thrombectomy might be associated with reduced 30-day mortality, with underlying improvements in epicardial and myocardial perfusion.[11,12] However, in the large-scale, randomized Thrombus Aspiration in ST-Elevation Myocardial Infarction in Scandinavia (TASTE) trial, a survival benefit of routine manual aspiration thrombectomy during primary PCI was not observed.[13]

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WHAT IS KNOWN

- Suboptimal reperfusion in patients with ST-segment–elevation myocardial infarction results in increased infarct size and mortality.
- The MGuard (a bare metal stent covered with a polymer mesh) was designed to reduce distal embolization during primary percutaneous coronary intervention in ST-segment–elevation myocardial infarction.
- In the MGUARD for Acute ST Elevation Reperfusion (MASTER) trail, implantation of the MGuard stent as compared with standard metallic stents (bare metal or drug-eluting) in patients undergoing primary percutaneous coronary intervention for ST-segment–elevation myocardial infarction resulted in improved rates of thrombolysis in myocardial infarction flow and ST-segment resolution, with a trend toward lower 30-day cardiac mortality.

WHAT THE STUDY ADDS

- Implantation of the MGuard stent as compared with standard metallic stents (bare metal or drug-eluting) in patients undergoing primary percutaneous coronary intervention for ST-segment–elevation myocardial infarction resulted in a trend toward lower 1-year mortality.
- The 1-year rates of ischemia-driven target lesion revascularization were higher with the MGuard stent than in the control stent group, with angiographic restenosis rates expected from a bare metal stent.

Distal embolization may occur during stent implantation even after successful thrombus aspiration.[14] Thus, to reduce the risk of distal embolization in thrombus-containing lesions, a mesh-covered stent (MGuard Coronary Stent System, InspireMD Ltd, Tel Aviv, Israel) was developed. The MGuard is a bare metal stent (BMS) covered with an ultrathin, flexible polyethylene terephthalate mesh sleeve.[10,15,16] The mesh is intended to reduce distal embolization by preventing extrusion of atherothrombotic material through the stent struts during its implantation. Feasibility and short-term efficacy of MGuard stent implantation during primary PCI for STEMI was confirmed in early studies.[17,18] Recently, the multicenter, prospective, randomized MGUARD for Acute ST Elevation Reperfusion (MASTER) trial[19] reported that among patients with STEMI, the MGuard resulted in superior rates of epicardial coronary flow and complete ST-segment resolution compared with conventional metallic stents, thus meeting its primary end point. A trend toward lower 30-day cardiac mortality was noted for patients treated with the MGuard stent. However, longer term clinical and angiographic follow-up is needed to characterize late vascular responses to the MGuard stent, especially as the only prior study with late follow-up after MGuard stent implantation was nonrandomized.[20] We herein report the 1-year clinical and 13-month angiographic outcomes from the MASTER study.

Methods

Patients

MASTER was an open-label, prospective, randomized, multicenter trial of the MGuard stent versus any commercially available metallic stent (drug-eluting stent [DES] or BMS) in patients undergoing primary PCI for STEMI.[19,21] In brief, patients with STEMI ≤12 hours in duration intended for primary PCI were eligible for enrollment. The main exclusion criteria were electrocardiographic patterns interfering with assessment of ST-segment resolution (eg, left bundle branch block or paced rhythm); prior PCI within 6 months or coronary artery bypass graft surgery at any time; or bleeding diathesis or indication for long-term oral anticoagulation. Angiographic eligibility required planned PCI of a single de novo lesion ≤33 mm in length with reference vessel diameter ≥3.0 to ≤4.0 mm by visual estimation capable of being covered by a single study stent. Major exclusion criteria were ≥50% left main stenosis; ostial location or involvement of bifurcation with a ≥2.0-mm side branch; and previous stent proximal to or within 10-mm distal to the target lesion. In the case of an occluded infarct vessel, angiographic eligibility was assessed only after restoration of thrombolysis in myocardial infarction (TIMI) flow grade ≥2 by a guidewire, manual aspiration, or balloon predilatation.

Protocol Procedures

The protocol was approved by the ethics committee at each participating center, and informed written consent was obtained from all clinically eligible patients. Before coronary angiography patients received a loading dose of aspirin (300–325 mg chewed or 250–500 mg intravenously) and a loading dose of $P2Y_{12}$ inhibitor (600 mg clopidogrel, 60 mg prasugrel, or 180 mg ticagrelor). Procedural anticoagulation consisted of unfractionated heparin plus intravenous glycoprotein IIb/IIIa inhibition or bivalirudin monotherapy. Emergent coronary angiography was performed using standard technique. If all angiographic eligibility criteria were met, the patient was randomized 1:1 to either the MGuard stent or a control BMS or DES (at operator discretion). Randomization was stratified by infarct-related artery (left anterior descending versus other) and use versus nonuse of thrombus aspiration. All patients were treated with aspirin (75–162 mg/d) indefinitely and a $P2Y_{12}$ inhibitor for 1 year. Clinical follow-up was performed at 30 days (±7 days), 6 months (±15 days), and 1 year (±30 days). To assess late vascular responses, angiographic follow-up at 13 months (after assessment of the 12-month clinical end point) was planned in a subgroup of 50 patients from the MGuard group.

End Points and Definitions

The primary efficacy end point was the rate of complete ST-segment resolution, defined as ≥70% reduction in the summed 12-lead extent of ST-segment elevation from the baseline to the postprocedure ECG.[19,21] Patients were followed up for 1 year for the occurrence of major adverse cardiovascular and cerebral events (the composite of all-cause death, reinfarction, stroke, or ischemia-driven target lesion revascularization [TLR]), major adverse cardiovascular events (MACEs; the composite of cardiac death, reinfarction, or ischemia-driven TLR), stroke, stent thrombosis (Academic Research Consortium definition),[22] and major bleeding (TIMI definition).[23] All end points were adjudicated by an independent clinical events committee blinded to treatment assignment.[19,21] Binary angiographic restenosis was defined as >50% diameter stenosis at the follow-up angiogram and was determined in-stent and in-segment (including the stent and the 5-mm proximal and distal edge margins). Late lumen loss was calculated as the difference between the postprocedure and follow-up angiographic minimal lumen diameter.

Statistical Analysis

Results are presented as numbers of patients (percentages) or mean±SD. Differences in categorical variables were analyzed using the χ^2 test or Fisher exact test, as appropriate. Continuous variables were compared using the Wilcoxon rank-sum test. Cumulative MACE

rates during follow-up were calculated with the Kaplan–Meier method and compared between groups using the log-rank test. Given the modest size of the BMS control arm and the numerous different types of BMS used, a post hoc propensity score–matched analysis was performed to compare the outcomes in the MGuard group with patients treated with non–drug-eluting Express BMS (Boston Scientific, Natick, MA) in the Harmonizing Outcomes With Revascularization and Stents in Acute Myocardial Infarction (HORIZONS-AMI) trial.[24] Missing baseline values for the covariates listed in the Tables in the Data Supplement were imputed using the maximum likelihood method. Matching was performed with up to a 3:1 ratio with a caliper equal to 0.2 of the SD of the logit of the propensity score. The following covariates were used for matching: age, body mass index, male sex, hyperlipidemia, diabetes mellitus, previous angina, previous MI, symptom onset to balloon time, stent length, baseline reference vessel diameter, infarct artery, and baseline TIMI flow. All tests were 2-tailed, and a P value <0.05 was considered statistically significant. All statistical analyses were performed using SAS version 9.2 (SAS Institute Inc, Cary, NC).

Results

Patients and Procedures

Between July 22, 2011, and May 29, 2012, 433 patients with STEMI were randomly assigned to the MGuard (n=217) or a control stent (n=216). The baseline clinical and angiographic characteristics were well balanced between the groups.[19] The median age was 59 years, and 24% of patients were women. In 51.3% of patients the infarct-related artery was the right coronary. Baseline TIMI grade 2 or 3 flow was present in 29.8% of patients. Predilatation before stent implantation was performed in ≈50% of patients and thrombus aspiration was done in approximately two thirds of patients in each group. In the MGuard group, 96.3% of patients received the intended stent. In the control group, 86 patients (39.8%) were treated with DES, and the remainder with only BMS.

As previously reported,[19] the primary end point of post-procedure complete ST-segment resolution was significantly improved in patients randomized to the MGuard stent compared with control patients (57.8% versus 44.7%; P=0.008). The MGuard stent compared with control stents also resulted in superior rates of TIMI grade 3 flow (91.7% versus 82.9%; P=0.006) and comparable rates of myocardial blush grade 2 or 3 (83.9% versus 84.7%; P=0.81).

Clinical Outcomes

One-year follow-up was completed in 204 patients (94.9%) in the MGuard group and in 206 patients in the control group (98.6%). During follow-up there was no difference between the groups in the frequency of aspirin use (30 days: 99.5% versus 99.1%, P=0.62; 6 months: 98.1% versus 98.6%, P=0.99; and 1 year: 99.5% versus 98.6%, P=0.62) or $P2Y_{12}$ inhibitor use (30 days: 99.1% versus 98.6%, P=0.68; 6 months: 97.2% versus 99.0%, P=0.28; and 1 year: 93.6% versus 95.7%, P=0.36).

As shown in Table 1, lower 30-day all-cause and cardiac mortality was observed in the MGuard group as compared with that in the control stent group (both 0.0% versus 1.9%; P=0.04). A similar trend was noted at 1-year follow-up (all-cause mortality: 1.0% versus 3.3%; hazard ratio, 0.28; 95% confidence interval, 0.06–1.36; P=0.09 and cardiac mortality, 0.5% versus 2.3%; hazard ratio, 0.20; 95% confidence interval, 0.02–1.69; P=0.10). The 1-year rates of major adverse cardiovascular and cerebral event and MACE were higher in the MGuard group, driven by more frequent ischemia-driven TLR (8.6% versus 0.9%; hazard ratio, 9.24; 95% confidence interval, 2.14–39.8; P=0.0003). A trend toward greater definite stent thrombosis at 1 year was present with the MGuard stent compared with control (2.3% versus 0.5%; P=0.10), with no significant differences in definite/probable stent thrombosis or reinfarction between the 2 groups. Time-to-event curves for all-cause mortality, MACE, ischemia-driven TLR, and stent thrombosis (definite or probable) are shown in the Figure (A–D).

When the MGuard results were compared with DES or BMS considered separately in a post hoc, nonrandomized analysis, 1-year all-cause mortality was lower with the MGuard than with DES (1.0% versus 4.7%; P=0.04), but nonsignificantly different for patients treated with MGuard and BMS (1.0% versus 2.4%; P=0.29). The rates of ischemia-driven TLR were higher for MGuard as compared with either DES (8.6% versus

Table 1. Event Rates at 30 Days, From 30 Days to 1 Year, and at 1 Year According to Stent Randomization

	30-d Event Rates			30-d to 1-y Event Rates			1-y Event Rates		
	MGuard Stent (n=217)	Control Stent (n=216)	P Value	MGuard Stent (n=217)	Control Stent (n=216)	P Value	MGuard Stent (n=217)	Control Stent (n=216)	P Value
MACCE	5 (2.3)	5 (2.3)	0.98	16 (7.8)	5 (2.4)	0.01	21 (10.0)	10 (4.7)	0.04
MACE	4 (1.8)	5 (2.3)	0.72	15 (7.3)	2 (0.9)	0.001	19 (9.1)	7 (3.3)	0.02
All-cause mortality	0 (0.0)	4 (1.9)	0.04	2 (1.0)	3 (1.4)	0.65	2 (1.0)	7 (3.3)	0.09
Cardiac mortality	0 (0.0)	4 (1.9)	0.04	1 (0.5)	1 (0.5)	0.99	1 (0.5)	5 (2.3)	0.10
Reinfarction	3 (1.4)	2 (0.9)	0.66	0 (0.0)	0 (0.0)	N/A	3 (1.4)	2 (0.9)	0.66
TLR, ischemia driven	4 (1.8)	1 (0.5)	0.18	14 (6.8)	1 (0.5)	0.0006	18 (8.6)	2 (0.9)	0.0003
TVR, ischemia driven	5 (2.3)	1 (0.5)	0.10	18 (8.7)	1 (0.5)	<0.0001	23 (11.0)	2 (0.9)	<0.0001
Stent thrombosis, definite/probable	3 (1.4)	2 (0.9)	0.67	2 (1.0)	0 (0.0)	0.16	5 (2.3)	2 (0.9)	0.26
Stent thrombosis, definite	3 (1.4)	1 (0.5)	0.32	2 (1.0)	0 (0.0)	0.16	5 (2.3)	1 (0.5)	0.10
Stroke	1 (0.5)	0 (0.0)	0.32	0 (0.0)	2 (1.0)	0.16	1 (0.5)	2 (1.0)	0.56
TIMI bleeding, major or minor	5 (2.3)	4 (1.9)	0.75	4 (1.9)	3 (1.6)	0.70	8 (3.8)	7 (3.4)	0.80

Values are n (%) with the percentages representing Kaplan–Meier estimates. MACCE indicates major adverse cardiovascular or cerebral events; MACE, major adverse cardiac events; TIMI, thrombolysis in myocardial infarction; TLR, target lesion revascularization; and TVR, target vessel revascularization.

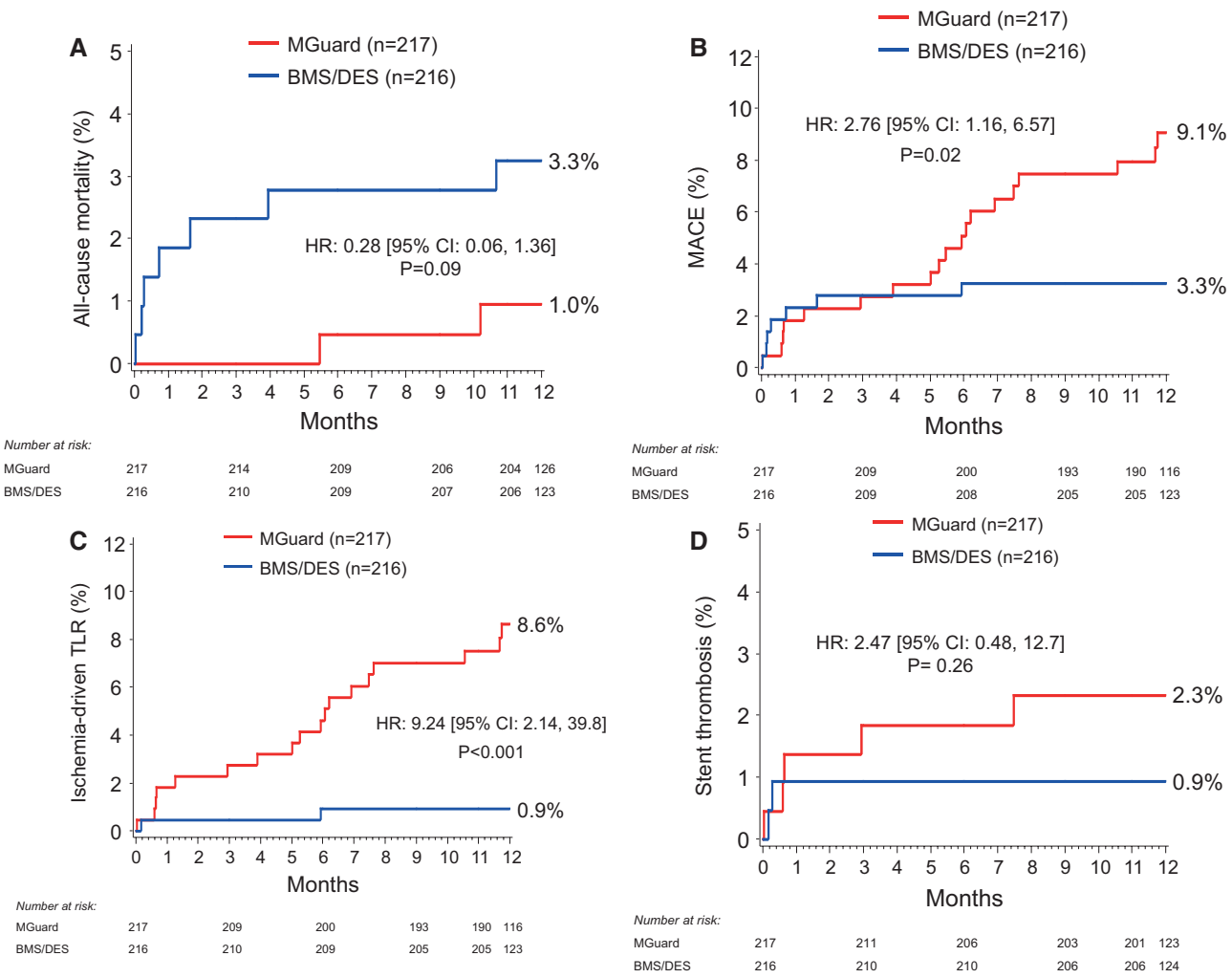

Figure. Time-to-event curves for (**A**) all-cause mortality, (**B**) major adverse cardiac events (MACE), (**C**) ischemia-driven target lesion revascularization (TLR), and (**D**) definite or probable stent thrombosis. BMS indicates bare metal stent; CI, confidence interval; DES, drug-eluting stent; and HR, hazard ratio.

0.0%; *P*=0.002) or BMS (8.6% versus 1.6%; *P*=0.002). These differences resulted in higher rates of MACE with the MGuard when compared with DES (9.1% versus 3.5%; *P*=0.11) and BMS (9.1% versus 3.1%; *P*=0.04). No differences in the rates of stent thrombosis (definite or probable) were observed between the groups.

Propensity Score Analysis

Using the propensity score method, 191 patients from the MGuard group were matched according to baseline characteristics with 443 BMS-treated patients from the HORIZONS-AMI trial. After matching, the groups were similar in terms of baseline characteristics, except for slight differences in the rates of prior angina, preprocedure TIMI flow, and stent length (see Tables in the Data Supplement). No differences in the 30-day or 1-year rates of MACE or ischemia-driven TLR and TVR were present between the groups (Table 2).

Angiographic Substudy

A total of 48 consecutively enrolled patients randomized to the MGuard stent were consented to return at 13 months for follow-up angiography. One patient died before the end of follow-up. Four patients refused control coronary angiography, 2 patients exited the study before the end of follow-up, and 3 patients were not available during the visit window. Finally, follow-up coronary angiography was conducted in 38 patients (79.2%), 31 of whom received a single MGuard stent. Results of the 13-month angiographic substudy are shown in Table 3.

Discussion

The MGuard stent was designed to decrease distal embolization during primary PCI for STEMI. As we reported previously, implantation of the MGuard stent compared with standard metallic stents (BMS or DES) in patients undergoing primary PCI for STEMI resulted in higher rates of TIMI grade 3 flow and complete ST-segment resolution after the procedure, achieving its primary end point. Importantly, all-cause and cardiac mortality at 30 days were greater in patients without complete ST-segment resolution after primary PCI, resulting in fewer deaths in patients in whom the MGuard stent was implanted compared with a control stent.[19] Between 30 days and 1 year, the survival curves stayed roughly parallel, with 2

Table 3. Results of 13-Month Angiographic Follow-Up in the MGuard Stent Group

	All Substudy Patients (n=38)	Single MGuard Stent (n=31)	Two MGuard Stents (n=7)
Reference vessel diameter, mm	3.02±0.37	3.04±0.34	2.92±0.50
Minimal luminal diameter (in-stent), mm	1.84±0.85	1.95±0.76	1.34±1.10
Minimal luminal diameter (in-segment), mm	1.68±0.76	1.77±0.68	1.29±1.03
Late lumen loss (in-stent), mm	0.99±0.80	0.88±0.70	1.48±1.09
Late lumen loss (in-segment), mm	0.82±0.75	0.72±0.65	1.26±1.01
Diameter stenosis (in-stent), %	40.1±26.3	36.3±23.0	56.82±34.8
Diameter stenosis (in-segment), %	45.2±23.4	42.1±20.5	58.56±31.9
Binary restenosis (in-stent)	9 (23.7%)	6 (19.4%)	3 (42.9%)
Binary restenosis (in-segment)	12 (31.6%)	9 (29.0%)	3 (42.9%)

Data are expressed as mean±SD or n (%).

Table 2. Clinical Outcomes After Propensity Score Matching of Patients Treated With the MGuard Stent in the MASTER Study and Patients Treated With a Bare Metal Stent in the HORIZONS-AMI Study

	HORIZONS-AMI BMS (n=443)	MASTER MGuard (n=191)	*P* Value
30 d			
MACE	13 (2.9)	4 (2.1)	0.48
All-cause mortality	5 (1.1)	0 (0.0)	0.99
Reinfarction	8 (1.8)	3 (1.6)	0.95
TLR, ischemia driven	10 (2.3)	4 (2.1)	0.84
TVR, ischemia driven	10 (2.3)	4 (2.1)	0.84
Stent thrombosis, definite	10 (2.3)	3 (1.6)	0.61
Stent thrombosis, definite or probable	11 (2.5)	3 (1.6)	0.52
1-y			
MACE	33 (7.5)	17 (9.2)	0.77
All-cause mortality	9 (2.0)	1 (0.5)	0.13
Reinfarction	18 (4.1)	3 (1.6)	0.13
TLR, ischemia driven	26 (6.0)	16 (8.7)	0.35
TVR, ischemia driven	30 (6.9)	19 (10.3)	0.24
Stent thrombosis, definite	14 (3.2)	5 (2.6)	0.67
Stent thrombosis, definite or probable	15 (3.4)	5 (2.6)	0.59

Values are n (%). Event rates were compared using a proportional hazards model stratified by matched pair. BMS indicates bare metal stent; HORIZONS-AMI, Harmonizing Outcomes With Revascularization and Stents in Acute Myocardial Infarction; MACE, major adverse cardiac events; MASTER, MGUARD for Acute ST Elevation Reperfusion; TLR, target lesion revascularization; and TVR, target vessel revascularization.

additional deaths in the MGuard group and 3 additional deaths in the control group, and thus a trend for survival was also present at 1 year. However, as the study was not powered for mortality, these findings should be interpreted with caution. Moreover, 1-year mortality was low in both groups, below that reported in most previous randomized studies[24,25] and registries[26,27] of DES and BMS in patients undergoing primary PCI for STEMI. Nonetheless, effective epicardial and microcirculatory reperfusion, which was more frequently observed in patients treated with the MGuard than with a standard metallic stent, may improve long-term survival.[3,4,14] These observations require confirmation in larger randomized trials.

Before this study, data on the long-term performance (≥1 year) of the MGuard stent were limited. In a group of 41 patients treated with the MGuard stent during PCI of aged degenerated saphenous vein grafts and native coronary artery lesions in patients with acute coronary syndromes, the MACE rate at mean follow-up of 20 months was 24.4%, with all-cause mortality of 2.4%.[28] Similarly, among 57 patients treated with the MGuard stent during primary PCI for STEMI, cardiac mortality at mean follow-up of 38.7±3.1 months was 7.0%, with a major adverse cardiovascular and cerebral event rate of 8.8%.[20]

As expected, the 12-month rates of ischemic TLR and TVR in the MGuard group were higher than in the control stent group, as the control group consisted of patients treated with DES as well as with BMS. The 8.6% and 11.0% 1-year TLR and TVR rates with the MGuard in the present study are similar to those observed with this device in the first-in-human study (11.1% TVR),[15] but higher than reported previously for the MGuard in STEMI (1.7% 3-year TLR rate in the MGuard Coronary Stent System in ST-Elevation Myocardial Infarction–A European Post-Market Clinical Study [MAGICAL] study),[20] likely because of inclusion of longer and more complex lesions in the present trial. The 1-year TLR rates of the BMS-treated patients in the present trial were also surprisingly low, perhaps because of chance.[24] Propensity score–matched analysis of patients treated with the MGuard stent from the MASTER trial and the Express BMS from the HORIZONS-AMI trial demonstrated similar rates of ischemic TLR, TVR, and MACE between the groups, suggesting similar performance to other BMS. The 0.99-mm in-stent late loss with the MGuard in the present study supports this contention. However, few MGuard patients underwent angiographic follow-up in the present protocol, and greater experience with the MGuard is required to examine low-frequency safety events, such as stent thrombosis. Compared with the first-generation stainless steel MGuard stent (which was used in most patients in this trial), the MGuard Prime stent with thinner cobalt chromium struts (80 μm as compared with 100 μm for the MGuard) may improve not only device deliverability and acute performance but might also reduce the rate of restenosis. The MGuard Prime was available and used in only 26 patients enrolled in the MASTER study.[19]

Two large, multicenter randomized trials assessing the MGuard during primary PCI for STEMI are ongoing. In the MGuard Prime Stent System Clinical Trial in Patients With

Acute ST Elevation Myocardial Infarction (MASTER-II; NCT01869738), 1114 patients undergoing primary PCI are being randomized to MGuard Prime stent implantation versus Food and Drug Administration–approved BMS/DES. The primary efficacy end point of the study is complete ST-segment resolution within 60 to 90 minutes after primary PCI, powered for superiority. The primary safety end point is a composite of all-cause death or recurrent target-vessel MI at 1 year, powered for noninferiority. Cardiac MRI at 3 to 7 days will be performed in patients with anterior MI, powered to demonstrate reduced infarct size in MGuard Prime–treated patients, and follow-up angiography and intravascular ultrasound are planned among the strata of patients randomized to MGuard Prime versus BMS. In the MGuard Stent in ST-elevation Myocardial Infarction (GUARDIAN; NCT01124942) trial, patients are being randomized to the MGuard stent alone versus thrombus aspiration with BMS implantation. Enrolment of 350 patients is planned with complete ST-segment resolution and flow within the infarct-related artery after primary PCI as primary end points.[29] Results of these studies should afford a balanced assessment of the competing benefits (potentially improved myocardial reperfusion, reduced infarct size, and greater survival) and risks (potentially greater restenosis) of the MGuard in comparison with conventional metallic stents.

Limitations

The MASTER trial was powered for ST-segment resolution, and not for clinical events. Thus, end points other than ST-segment resolution should be considered exploratory and hypothesis generating. As the study was open-label, some degree of bias cannot be excluded. In addition, the control arm in the MASTER trial consisted of a mixture of patients treated with a commercially available DES and BMS, and randomization was not stratified by stent type. The results of the post hoc propensity-adjusted analysis should be considered hypothesis generating only. Angiographic follow-up was conducted in a small subgroup (38 patients) and was limited to patients from the MGuard stent group; thus, comparison of angiographic outcomes between study groups was not possible. Despite these limitations, this is the largest cohort of patients with STEMI treated with the MGuard stent during primary PCI with long-term clinical outcome data available.

Conclusions

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. 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.

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Disclosures

Drs Dudek, Merkely, Kornowski, and Silber have received research grants from and are consultants to InspireMD. E. Bar is a full-time employee of InspireMD and owns options. Dr Stone is a past consultant to Boston Scientific, InspireMD, Eli Lilly, and Daiichi Sankyo. The other authors report no conflicts.

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Mesh-Covered Embolic Protection Stent Implantation in ST-Segment–Elevation Myocardial Infarction: Final 1-Year Clinical and Angiographic Results From the MGUARD for Acute ST Elevation Reperfusion Trial

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Supplemental Material

Supplementary Table 1. Baseline characteristics and procedural details after propensity score matching of patients treated with the MGuard stent in the MASTER trial and patients treated with a bare metal stent in the HORIZONS-AMI trial.

	HORIZONS-AMI BMS (n=443)	MASTER MGuard (n=191)	*P* Value
Age (years)	59.0 [52.1, 68.8]	59.0 [52.0, 66.0]	0.32
Male	75.8	73.8	0.59
Body mass index (kg/m^2)	26.8 [24.6, 30.4]	26.6 [24.6, 29.9]	0.93
Arterial hypertension	47.4	44.2	0.46
Hyperlipidemia	35.7	28.9	0.10
Diabetes mellitus	12.9	12.0	0.77
Current cigarette smoking	51.9	56.6	0.28
Congestive heart failure	0.7	0.5	1.00
Family history of coronary artery disease	31.4	32.4	0.80
Previous angina	17.4	9.9	0.02
Previous myocardial infarction	6.5	4.2	0.25
Previous percutaneous coronary intervention	5.9	4.2	0.39
Prior coronary artery bypass grafting	0.5	0.0	1.00
Lesion location			
LAD	43.2	39.8	0.41
RCA	45.4	50.8	0.20
LCX	11.4	9.4	0.46
Number of lesions treated (n)	1.0 [1.0, 1.0]	1.0 [1.0, 1.0]	1.00
Maximum device size (n)	3.5 [3.0, 3.5]	3.5 [3.0, 3.5]	0.17
Baseline reference vessel diameter (mm)	3.0 [2.6, 3.3]	3.1 [2.8, 3.4]	0.0001
Pre-procedure TIMI grade 0 to 2 flow	76.4	83.6	0.04
Post-procedure TIMI grade 3 flow	90.1	91.1	0.69
>1 stent	16.2	13.1	0.31
Total stent length (mm)	20.0 [16.0, 28.0]	19.0 [15.0, 24.0]	0.03

Symptom onset to balloon time (minutes)	199.8 [153.0, 304.0]	211.5 [158.0, 309.0]	0.44

Values are % or median [Q1, Q3]. LAD = left anterior descending artery; LCX = left circumflex artery; RCA = right coronary artery; TIMI = Thrombolysis In Myocardial Infarction.

Supplementary Table 2. Baseline Characteristics, Variable Balance Checks

Variable	Variable Description	Pre Match Case Mean	Pre Match Control Mean	Pre Match Diff	Pre Match Stand Diff (%)	Post Match Case Mean	Post Match Control Mean	Post Match Diff	Post Match Stand Diff (%)
age	Age	59.2488	60.1453	-0.8964	-8.21	58.9948	60.1820	-1.1872	-11.01
bmi	BMI	27.4504	27.6553	-0.2049	-4.56	27.4587	27.5532	-0.0945	-2.12
male	Male	0.7512	0.7511	0.0000	0.01	0.7382	0.7585	-0.0202	-4.66
htn	History of Hypertension	0.4194	0.5170	-0.0977	-19.64	0.4398	0.4740	-0.0343	-6.87
hpl	History of Hyperlipidemia	0.2811	0.4059	-0.1248	-26.48	0.2984	0.3567	-0.0582	-12.41
dm	History of diabetes mellitus	0.1198	0.1526	-0.0328	-9.55	0.1204	0.1287	-0.0082	-2.49
dmonins	Insulin	0.0138	0.0444	-0.0306	-18.26	0.0157	0.0271	-0.0114	-7.86
pre_smk	Smoker - Former	0.1198	0.1585	-0.0387	-11.18	0.1152	0.1445	-0.0293	-8.71
curr_smk	Smoker - Current	0.5530	0.5126	0.0404	8.09	0.5602	0.5192	0.0410	8.22
chf	History of CHF	0.00461	0.0281	-0.0235	-18.61	0.00524	0.00677	-0.0015	-1.99
cad	History of family premature CAD	0.3272	0.3126	0.0146	3.12	0.3351	0.3138	0.0213	4.54
ang	History of prior Angina	0.0876	0.2267	-0.1391	-38.90	0.0995	0.1738	-0.0743	-21.73
mi	History of prior MI	0.0369	0.1037	-0.0668	-26.34	0.0419	0.0655	-0.0236	-10.46
pci_	History of prior PCI	0.0369	0.0741	-0.0372	-16.29	0.0419	0.0587	-0.0168	-7.68
cabg	History of prior CABG	0	0.0193	-0.0193	-19.80	0	0.00451	-0.0045	-9.51

Supplementary Table 3. Lesion Characteristics, Variable Balance Checks

Variable	Variable Description	Pre Match Case Mean	Pre Match Control Mean	Pre Match Diff	Pre Match Stand Diff (%)	Post Match Case Mean	Post Match Control Mean	Post Match Diff	Post Match Stand Diff (%)
lad	LAD	0.4009	0.4206	-0.0196	-3.99	0.3979	0.4325	-0.0346	-7.01
rca	RCA	0.5069	0.4246	0.0823	16.54	0.5079	0.4536	0.0543	10.86
cfx	CFX	0.0922	0.1495	-0.0574	-17.65	0.0942	0.1139	-0.0197	-6.44
brvd	Baseline Reference Diameter (mm)	3.1466	2.8992	0.2474	55.01	3.1268	2.9735	0.1533	34.38
maxdevsize	Maximum Device Size	3.4482	3.4587	-0.0105	-0.71	3.4280	3.4517	-0.0237	-1.99
timi2	TIMI2 Pre-procedure	0.1814	0.1562	0.0252	6.72	0.1852	0.1730	0.0122	3.17
timi3	TIMI3 Pre-procedure	0.1535	0.2777	-0.1242	-30.52	0.1640	0.2363	-0.0723	-18.10
timi01	TIMI0 or 1 Pre-procedure	0.6651	0.5661	0.0990	20.43	0.6508	0.5907	0.0601	12.38
ftimi2	TIMI2 Final	0.0645	0.0975	-0.0329	-12.08	0.0681	0.0949	-0.0269	-9.82
ftimi3	TIMI3 Final	0.9171	0.8932	0.0239	8.14	0.9110	0.9008	0.0102	3.47
ftimi01	TIMI0 or 1 Final	0.0184	0.00935	0.0091	7.76	0.0209	0.00422	0.0167	15.01

Supplementary Table 4. Procedural Data, Variable Balance Checks

Variable	Variable Description	Pre Match Case Mean	Pre Match Control Mean	Pre Match Diff	Pre Match Stand Diff (%)	Post Match Case Mean	Post Match Control Mean	Post Match Diff	Post Match Stand Diff (%)
lestrt	Number of lesions treated	1.0000	1.0000	0.0000		1.0000	1.0000	0.0000	
stnum1	1 Stent Implanted	0.8664	0.7511	0.1152	29.58	0.8639	0.8375	0.0264	7.40
stnum2	>1 Stent Implanted	0.1290	0.2474	-0.1183	-30.58	0.1309	0.1625	-0.0316	-8.92
stnuma	Any Stent Implanted	0.9954	1.0000	-0.0046	-9.60	0.9948	1.0000	-0.0052	-10.23
ballfst_onset_mn	Symptom Onset to Balloon Time (min)	248.5	278.3	-29.7868	-18.49	250.7	248.8	1.8730	1.33
dtb_mn	Door to Balloon Time (min)	64.3041	114.3	-50.0029	-75.59	68.5969	91.2967	-22.6998	-37.47
onset_er_mn	Symptom Onset to Hospital Arrival Time (min)	184.2	183.7	0.5594	0.38	182.1	167.6	14.5457	11.05
total_length	Total stents length implanted	20.5899	25.4034	-4.8136	-48.81	20.8848	22.4864	-1.6016	-21.07