Long Term Outcomes of MGuard Stent Deployment in Saphenous Vein Grafts and Native Coronary Arteries: A Single Center Experience

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ABSTRACT: **Background:** The MGuard™ stent (InspireMD, Tel Aviv, Israel) is a bare metal mesh-covered stent, developed to prevent no-reflow phenomenon during percutaneous coronary intervention (PCI) of saphenous vein grafts (SVG) and acute myocardial infarction (MI), both associated with significant atherothrombotic lesions.

Objective: To report on local experience with patients treated with the MGuard stent until follow-up at 1 year.

Methods: We followed 163 consecutive patients who underwent MGuard stent deployment during the period 2009 to 2014 in a large tertiary cardiac center in central Israel.

Results: The MGuard stent was used in 67% of patients who underwent SVG-PCI while 33% were treated for native coronary artery disease, the majority during ST-elevation MI (STEMI). The mean age was 67 years and 83% were males. The clinical presentation was STEMI in 35% and non-STEMI/unstable angina in 58% of patients. Of the total number of patients, 47% had diabetes and 29% had chronic kidney disease. All patients had follow-up at 1 year. Mortality in the native group was 1.9% vs. 10% in the vein graft cohort. ST was 2% in both groups. The major adverse cardiac event (MACE) rates were 11% in the native artery and 29% in the vein graft group, mainly due to respective target lesion revascularization/target vessel revascularization rates of 6% and 7% in the native vessel group and 11% and 15% in the SVG group.

Conclusions: In suitable patients undergoing SVG-PCI or native lesion intervention during acute MI, the MGuard stent is a viable treatment strategy. Its potential merits and limitations warrant further evaluation.

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KEY WORDS: MGuard stent, ST-elevation MI (STEMI), vein grafts, percutaneous coronary intervention (PCI)

Reduced myocardial perfusion is present in most acute myocardial infarction (MI) patients undergoing primary or rescue percutaneous coronary intervention (PCI) [1]. No reflow or slow flow occurs in 3–4% of all PCIs. In the setting of acute MI, occurrence of no reflow is reported in 30% to 40% of interventions when defined by myocardial perfusion techniques such as myocardial contrast echocardiography [2]. The no-reflow phenomenon occurs despite successful treatment of the culprit lesion, as evident by failure of stent thrombosis (ST) segment resolution or poor myocardial blush grade. This is a disabling phenomenon associated with malignant arrhythmias, cardiac failure and increased cardiac mortality [3,4].

No reflow was found highly predictive of post-procedural MI (17.7% vs. 3.5%, $P < 0.001$) in patients without the no-reflow phenomenon, and of death (7.4% vs. 2.0%, $P < 0.001$) [5]. Distal embolization may result in the no-reflow phenomenon in approximately 10–15% of SVG-PCI cases [6]. In such instances, subsequent MI occurs in 31% of patients, with a tenfold increase in in-hospital mortality [7].

The prevention of no reflow is a clinical priority since the treatment options are limited after its occurrence. Pharmacological therapies include intracoronary boluses of adenosine, sodium nitroprusside, glyceryltrinitrate and calcium channel blockers [8]. Alternative mechanical treatments include the use of thrombus aspiration; however, the current recommendations showed limited clinical benefit of routine use, while selected use may improve thrombolysis in myocardial infarction (TIMI) 3 flow or prevent ST [9,10].

Despite the AHA/ESC Guidelines recommendations, data from the CATH-PCI registry reported that the embolic protection device was used in only 21% of SVG-PCI cases [11]. Surprisingly, the embolic protection device was not associated with reduced adverse events after 3 years of follow-up. Moreover, there was an increased adjusted risk of no reflow, dissection and perforation, and periprocedural MI in short-term follow-up. An alternative technology of thrombus entrapment was introduced: the MGuard™ stent (InspireMD, Tel Aviv, Israel) [12]. This bare metal stent is wrapped with an expandable Micronet mesh in order to reduce the risk of plaque rupture and distal embolization in highly thrombotic or friable atherosclerotic lesions. We report our experience with patients treated with the MGuard stent up to 1 year follow-up.

PATIENTS AND METHODS

During the years 2009–2014, 163 consecutive patients underwent MGuard stent deployment. The MGuard stent is a bare metal stent covered with a polyethylene terephthalate mesh. The first generation was made from stainless steel with a strut thickness of 100 µm. The second generation, MGuard Prime, in use at our center since May 2012, was changed to a cobalt chromium alloy with a strut thickness of 80 µm; hence it has a lower crossing profile with no change to the Micronet mesh structure. The fiber thickness of the mesh is 20 µm and the pore size 150 x 180 µm.

Baseline characteristics, procedural details, and quantitative coronary angiographic parameters were collected and available for all patients using a designated Institutional Review Board-approved database. All patients were prescribed lifelong aspirin, and clopidogrel or prasugrel/ticagrelor was prescribed for 12 months. Coronary angiograms were recorded at baseline and after PCI. Using the MDView QA System (Medcon Telemedicine Technology McKesson, Tel Aviv, Israel), experienced cardiologists at the institute's angiographic core laboratory assessed all angiographic images with automated edge detection techniques, independent of clinical outcomes.

A contrast-filled guiding catheter (6 Fr or 7 Fr) was used as the calibration standard. Reference and minimal luminal diameters were determined before and after PCI. Standard morphologic criteria were used to identify lesion location, luminal diameter, stent length and thrombus size.

Based on these measurements, percentage diameter stenosis was determined before and after intervention. TIMI flow grade (0 to 3) was measured before and at completion of the procedure. Immediate and in-hospital events were recorded. Follow-up rates at the 1 year evaluation were available for all patients.

Both hospital and municipal civil registries assessed survival status at follow-up. Repeat revascularization procedures and episodes of acute MI were prospectively recorded in the hospital database.

Records from peripheral hospitals were obtained to confirm outcome diagnoses of patients in the follow-up period. All events were further adjudicated by a research coordinator and reviewed by an experienced cardiologist from our research team. This registry was approved by the ethics committee.

DEFINITION OF ENDPOINTS

The primary endpoints of the study were all-cause mortality, target lesion and vessel revascularization (TLR/TVR) and the occurrence of major adverse cardiac events (MACE) defined as composite death, acute MI, repeat TLR or TVR at 1 year. The secondary endpoint was cardiac mortality. TVR was defined as any revascularization that involved the target vessel. TLR was defined as a successful revascularization procedure (PCI or surgical bypass) due to a stenosis reappearing at the treated site (including 5 mm proximal and distal to the lesion borders).

The diagnosis of reinfarction was based on recurrent chest pain suggestive of acute MI, accompanied by repeated increase in cardiac enzymes up to more than twice the upper limit of normal ≥ 48 hours after PCI and/or new ST elevation or pathologic Q waves. Stent thrombosis was defined according to the Academic Research Consortium definitions as definite in the context of acute coronary syndromes (ACS) and/or reinfarction in the culprit coronary territory with angiographically proven thrombosis (thrombus or occlusion) of the previously implanted stent.

Procedural success was defined as angiographic residual stenosis < 20% by visual estimate or quantitative coronary angiography.

RESULTS

A total of 163 patients underwent MGuard stent deployment. The average age (SD) of the overall group was 67 years (± 12) and 16.5% of patients were female. Basic characteristics and clinical presentation distinguished by SVG and native MI culprit lesions are shown in Table 1.

The demographics confirm a high risk cohort of patients with a prevalence of diabetes, hypertension and dyslipidemia of 47%, 74% and 83%, respectively. Chronic kidney disease was present in 29% of cases. Moderate to severe left ventricular (LV) dysfunction (ejection fraction < 40%) was present in 34% of patients. Two-thirds of the patients had three-vessel coronary artery disease (86%).

Table 1. Patient characteristics and clinical presentation, McGuard 2013–2014

	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%

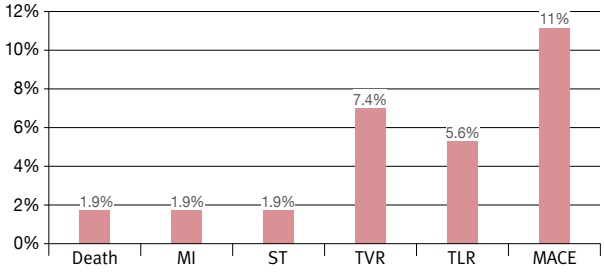
ACS = acute coronary syndromes, CABG = coronary artery bypass graft, LVEF = left ventricular ejection fraction, NIDDM = non-insulin-dependent diabetes mellitus, PCI = percutaneous coronary intervention, STEMI = ST-elevation myocardial infarction

Table 2. Procedural data

	Native arteries	Vein grafts
Lesion location		
RCA	32 (59%)	
LAD	15 (28%)	
LCX-OM	7 (13%)	
VG/LAD/Diagonal		12 (11%)
VG/OM		50 (46%)
VG/RCA		47 (43%)
Degenerated VG		32 (29%)
Lesion type		
Thrombus	46 (85%)	21 (19%)
Ulcerated plaque	14 (26%)	34 (31%)
Pre-dilatation	41 (76%)	55 (51%)
Aspiration catheter	22 (41%)	2 (2%)
Distal protection device	2 (4%)	7 (6%)
Transient no reflow	5 (9%)	9 (8%)
GP IIb/IIIa inhibitors	32 (65%)	16 (15%)
Clopidogrel	47 (87%)	64 (59%)
QCA		
% Stenosis	96 ± 7	88 ± 10
RVD	3.2 ± 0.5	3.5 ± 0.7
MLD	0.1 ± 0.2	0.4 ± 0.3
Lesion length/mm	17 ± 8	15 ± 10
Stent diameter/mm	3.3 ± 0.5	3.5 ± 0.5
Stent length/mm	21 ± 5	18 ± 6
Pre-TIMI 0,1	38 (70%)	8 (7%)
Post-TIMI FLOW III	53 (98%)	108 (99%)

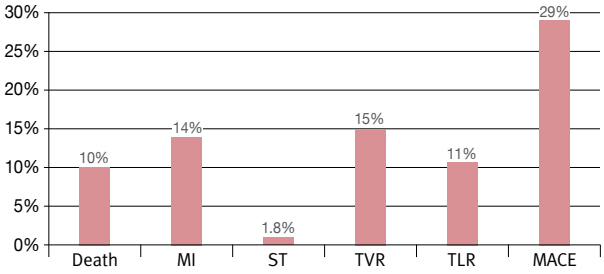
GP = glycoprotein, LAD = left anterior descending artery, LCX = left circumflex artery, OM = obtuse marginal branch, MLD = minimal lumen diameter, RCA = right coronary artery, RVD = reference vessel diameter, QCA = quantitative coronary angiography, TIMI = thrombolysis in myocardial infarction

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

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

The proportion of patients receiving the MGuard stent for SVG and native vessel PCI was 67% and 33%, respectively. The indication for PCI was due to STEMI in 35% of cases, of which 83% were in the native coronary arteries. Non-ST-elevation MI (NSTEMI) accounted for presentation in 58% of patients, the majority in the SVG cohort. One patient had successful MGuard deployment due to vessel perforation.

Catheterization data are shown in Table 2. Within the native vessel cohort the infarcted vessels involved the right coronary artery (RCA) in 59%, the left anterior descending artery (LAD) in 28% and left circumflex artery (LCX) in 13% of patients. SVG-PCI was more common within grafts to the LCX and RCA (46%, 43%). Thrombotic lesions were more frequently in STEMI patients (85%) as compared to SVG-PCI patients (19%). An aspiration catheter and a distal protection device were used in 34% and 5%, respectively, in STEMI patients. As expected, aspiration catheters were more commonly used in STEMI patients (41%) as compared to the SVG group (2%), while distal protection devices were used with a similar frequency in both groups. The mean vein graft age was 14 years. Transient no reflow or slow flow complicated 9% of STEMI-PCI patients as compared to 8% within the SVG group. Most cases resolved with medication, as the final TIMI 3 was observed in 98% of SVG and 99% of native STEMI cases. The average length of the MGuard stent was 21 ± 5 mm and 18 ± 6 mm within the native and SVG groups, respectively. The mean stent diameter within the native and SVG cohorts was 3.3 ± 0.5 mm and 3.5 ± 0.5 mm, respectively. There were two cases of stent delivery failure, one in each group.

None of the patients were lost to follow-up. Within the native vessel PCI group, one patient (1.9%) died as a result of an acute MI secondary to stent thrombosis. TLR and TVR were present in 6% and 7% of patients, respectively [Figure 1]. The mortality rate in the vein graft group was 10%, of which 4% were related to cardiac death. Myocardial infarction (STEMI/NSTEMI) occurred in 14% of cases; seven patients (6%) had TVR-related MI. Definitive ST occurred in two patients (1.8%). The TLR and TVR rates were 11% and 15%, respectively. The overall MACE rate was 29% [Figure 2].

DISCUSSION

We report here one of the largest and longest surveyed single-center cohort using the mesh-covered MGuard stent in native and SVG lesions at high risk for coronary embolization events. Our data confirm that the use of the MGuard stent is a viable treatment option for SVG-PCI and native artery intervention in acute MI.

Previous studies have evaluated the use of the MGuard in patients presenting with STEMI. Dudek et al. [13] studied 60 patients with STEMI < 12 hours after symptom onset. Final TIMI grade 3 flow was observed in 90% of patients, with myocardial blush grade 3 in 73.3% of patients. Complete (> 70%) ST-segment resolution at 60 minutes after PCI was observed in 61.4% of patients. Distal embolization occurred in only 5% of cases. The total major adverse cardiac event rate during the 6 month follow-up was 1.7% [13].

The MASTER I trial [14] was the first large randomized controlled trial to evaluate whether a mesh-covered stent could improve myocardial reperfusion in 433 STEMI patients undergoing primary PCI. The MGuard stent, as compared to a conventional stent, resulted in superior rates of complete ST-segment resolution (≥ 70%) at 60–90 minutes post-procedure (57.8% vs. 44.7%, $P = 0.008$), thus meeting its primary endpoint. The MGuard stent also resulted in superior rates of TIMI-3 flow (91.7% vs. 82.9%, $P = 0.006$). Mortality rates at 30 days (0% vs. 1.9%, $P = 0.06$) and MACE (1.8% vs. 2.3%, $P = 0.75$) were not significantly different between patients randomized to the MGuard versus control stent, respectively [14]. Long-term follow-up at 1 year was published by Dudek and colleagues [15] regarding 204 patients who received the MGuard stent and 206 controls. Cardiac mortality, MI, or ischemia-driven target lesion revascularization was significantly higher in the MGuard group (9.1% vs. 3.3%, $P = 0.02$) due to an increased rate of ischemia-driven target lesion revascularization (8.6% vs. 0.9%, $P = 0.0003$). There was a numerical trend toward increased definitive stent thrombosis at 1 year (2.3 vs. 0.5, $P = 0.1$). Interestingly, of the 38 patients in the MGuard group who had angiographic follow-up, the binary restenosis was 31.6% at 13 months [15]. The REWARD MI trial published by Fernández-Cisnal and co-authors [16] was a retrospective study including 79 STEMI patients treated with the MGuard stent and propensity-match analysis for patients treated with bare metal stents. There was no significant difference in mortality or fatal MI, although increased repeat revascularizations were seen in the MGuard group (11.3% vs. 1.3%, $P = 0.01$). In our study, the TLR and TVR rates after 1 year were somewhat lower (5.6% and 7.4%).

There is a paucity of long-term data on the use of the MGuard stent in SVG. A recognized consequence of SVG intervention is distal embolization of atheroembolic debris with decreased epicardial and microvascular perfusion [17]. Three prospective randomized trials failed to demonstrate benefit with a fully covered stent using PTFE (polytetrafluorethylene) membrane: The SYMBIOT III [18], RECOVERS [19] and BARRICADE [20] trials all showed a higher incidence rate of adverse ischemic and thrombotic events compared with conventional stents. Long-term data comparing the MGuard device to bare metal stents in SVG lesions are lacking. In 2008 our center published data showing a significant benefit in the treatment of SVG stenosis using drug-eluting stents compared to bare metal stents, with MACE rates of 11.8% vs. 30.2% ($P = 0.02$), respectively after 1 year. The TLR/TVR rate was significantly lower with the drug-eluting stents (7.4%/10.3% vs. 21%/23%, $P = 0.04$) [21].

Our data are comparable with the bare metal stent group in the above-mentioned trials as well as with similar groups of patients in the ISAR-CABG trial [22]. This was a prospective trial of 610 patients randomized to treatment with medicated versus bare stents for the reduction of restenosis in bypass grafts. At 1 year the MACE rates were 15.4% with drug-eluting stents vs. 22% with bare metal stents ($P = 0.03$). This was mainly due to a near 50% reduction in the risk of repeat revascularizations (7.2% vs. 22%, $P = 0.02$) but with no difference in mortality. In our study, patients treated with the mesh-covered stent had a MACE rate of 29% mainly caused by repeat revascularizations with SVGs (~15%) at 1 year.

Based on these integrated results and in the context of our clinical experience, we believe that in STEMI or SVG interventions the MGuard stent is a viable interventional technique used to achieve optimal short-term PCI with reasonable follow-up data among patients at high risk for distal coronary embolization. The long-term results are somewhat compromised by restenosis and need for repeat revascularization. Thus, the potential merits and limitations of this type of stent warrant further evaluation. The main limitation of our study is its retrospective design with no head-to-head comparison groups. Thus, without a control group it is difficult to view our results in the proper comparative perspective.

CONCLUSIONS

Our study assessed the long-term follow-up among patients undergoing catheter-based SVG interventions using the MGuard stent. For STEMI patients our results are comparable to previous findings. The use of the Mguard stent is a viable strategy in the management of thrombotic lesions. Long-term comparison of the MGuard stent with other approved stents in the treatment of SVG stenosis is required.

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