

INITIAL EXPERIENCE WITH THE NOVEL MGuard STENT SYSTEM FOR PERCUTANEOUS CORONARY INTERVENTION AT AFIC - NIHD

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ABSTRACT

Objective: The objective of this study was to assess the efficacy of the MGuard Stent in Percutaneous Coronary Intervention (PCI) in the setting of acute coronary syndromes.

Study Design: Interventional case series

Introduction: Distal embolisation during PCI occurs in acute coronary syndrome from the thrombus occluding the artery. The consequences can vary from a simple sluggish flow to myocardial infarction and death. A number of protection devices reduce distal embolisation, but they add complexity and cost to the procedure. The balloon expandable MGuard stent is a unique innovation to counter the phenomenon. We sought to study its efficacy in the proposed indications.

Patients and methods : The study was conducted in AFIC – NIHD. Between April and July 2010, 18 Patients were included and a total of 21 MGuard stents were deployed. Inclusion criteria included de novo lesions in saphenous vein grafts or native vessels with angiographic evidence of thrombus activity or lesion instability and a potential for distal embolisation in the setting of acute coronary syndromes. Use of filter wires or other proximal or distal protection devices was not allowed in the study. Primary end point included the incidence of MACE (composite of cardiac death, non-fatal MI and need for TLR) up to 30 days after the procedure. Secondary endpoints included restoration of TIMI grade 3 flow and myocardial blush grade 3 at the end of the procedure.

Results: All patients were male. Mean age was 45.61 years (range 32-70 years). All patients were admitted with acute coronary syndromes. Most lesions had complex morphological features and all had some thrombus activity. The MGuard stent was deployed successfully in all cases and without any complications. Secondary endpoints (TIMI – III flow and myocardial blush grade 3) were met in all cases. There was no elevation of cardiac enzymes post procedure in any patient, and there no MACE was reported at 30 days (primary end point).

Conclusions: These preliminary results show that the MGuard stent is a safe option for patients undergoing PCI in the setting of acute coronary syndrome with thrombus burden and saphenous vein graft stenosis.

Keywords: MGuard, no-reflow, distal protection

Initial experience with the novel MGuard stent system containing a protection net in Percutaneous coronary intervention at AFIC – NIHD

Objective

The objective of this study was to assess the efficacy of the MGuard Stent in Percutaneous Coronary Intervention (PCI) in the setting of an acute coronary syndrome.

INTRODUCTION

There are two distinct sources of distal

embolisation during PCI; the thrombus occluding the artery and the luminal plaque. The trigger to the embolisation process is the mechanical trauma induced by the various devices used during PCI. This complication is more common in the setting of PCI for acute coronary syndrome, because of the excess thrombus burden. The distal embolisation leads to the “no-reflow” phenomenon, which is actually the absence of myocardial flow with lack of myocardial blush in spite of restoration of epicardial vessel flow. This translates into an increased in adverse outcomes in terms of myocardial infarction and death.

The purpose of this study was to assess the efficacy of the MGuard Stent in Percutaneous Coronary Intervention (PCI) in the setting of an acute coronary syndrome.

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PATIENTS AND METHODS

The interventional case series was conducted in AFIC - NIHD. Between April and July 2010, 18 consecutive patients were included and a total of 21 MGuard stents were deployed. Inclusion criteria included de novo lesions in saphenous vein grafts or native vessels with angiographic evidence of thrombus activity and lesion instability with a potential for distal embolisation in the setting of acute coronary syndromes. Use of filter wires or other proximal or distal protection devices was not allowed. All patients received 300 mg loading dose of clopidogrel, and 325 mg of aspirin. Primary end point included the incidence of MACE (composite of cardiac death, non-fatal MI and TLR) up to 30 days after the procedure. Secondary endpoints included restoration of TIMI grade 3 flows and myocardial blush grade 3 at the end of the procedure.

RESULTS

All patients were male. Mean age was 45.61 years (range 32-70 years). 12 patients were admitted with ST elevation MI, 3 with Non-ST elevation MI, and 3 with unstable angina. 2 of the patients had previously undergone CABG. 2 vein grafts were stented while the rest were de novo lesions in native coronary arteries. Ejection fraction on echocardiography ranged from 25% to 60% (mean 40.5%). The lesions had complex morphological features 3 lesions were eccentric in morphology, 50% were total occlusions, all had some thrombus activity. The MGuard stent was deployed successfully in all cases and no complications of PCI including distal embolisation were noted. Acute gain of vessel lumen was 100% in all cases. Cardiovascular risk factor profiles of the patients are set out in table-1. Seven of the 18 patients had multiple risk factors (table-2). The distribution of vessels stented is shown in table-3. The vessel diameter ranged from 2.5 to 3.5 mm (mean 3.0 mm). The stent length ranged from 12 to 39 mm. Secondary endpoints (TIMI - III flow and myocardial blush grade 3) were met in all cases. There was no elevation of cardiac enzymes post procedure, and there no MACE was reported at 30 days (primary end point).

DISCUSSION

Distal embolisation is a known peri-procedural complication of PCI. During PCI there are two sources of the distal embolic material; the thrombus occluding the artery and the luminal plaque. The trigger to the embolisation process is the mechanical trauma induced by the various devices used during PCI, such as the PCI wires, balloons, and balloon mounted stents that cross the lesion; the balloon dilatation that fractures the intima and the plaque. Because there is superimposed thrombus on the intimal plaque occluding the vessel during an acute coronary syndrome, the embolic potential is high. Depending upon the thrombus burden embolised the consequences can vary from a simple sluggish flow to myocardial infarction and death. This can lead to what is known as the "no-reflow phenomenon", which is lack of intramyocardial reperfusion after successful epicardial coronary recanalization. In essence this means that although the epicardial coronary artery flow has been restored by stent placement however, there is no "myocardial blush" due to distal embolisation and microvascular occlusion. A number of protection devices have been shown to reduce distal embolisation, but they add complexity and cost to the procedure. The balloon expandable MGuard stent is a unique innovation to counter distal embolization. Its design embodies a stent covered with an ultra thin, micron level, flexible mesh net. Once deployed the stent traps the potentially embolic material between the stent mesh and the arterial wall.

A number of treatments for no-reflow have been investigated. Pharmacological treatments that have been investigated include intra coronary nitroprusside¹, adenosine², verapamil³, isosorbide dinitrate⁴ and carvedilol⁵. However, to date no consensus has been developed about which drug fares better than the others.

Distal protection to prevent the distal embolisation of any material downstream using different devices has also been investigated in this regard. These devices fall into different

categories; distal protection devices, proximal protection devices, thrombectomy devices.

The MGuard stent is a unique innovation in the line of protection devices in that it traps the thrombotic material at its source, i.e, at the vessel wall. The MGuard stent design embodies a balloon expandable stent covered with an ultra thin micron level non-crease meshwork⁶. (see figs 1,2) This mesh stretches over the stent it expands and forms a sleeve outside the stent that is apposed to the vessel wall. Once deployed the MGuard stent traps embolic material between the mesh and the vessel wall.

Initial studies have been performed with the MGuard stent. The First (FIM) in Man study has shown promising results⁷ when the MGuard stent system was used in twenty-nine patients with de novo coronary artery lesions and saphenous vein graft lesions with adverse characteristics. There were no MACE at 6 months of follow up. In another FIM twin centre trial⁸ 41 patients were implanted with at least one MGuard stent. 23 patients (56%) were treated for SVG lesions and the rest for native coronary lesions. Embolic protection devices were not used during any SVG procedure. No cardiac death occurred during the 6 months follow-up. Upon further follow up and consented release of medical information between 6 and 12 months no MACE were reported. Similarly, in another study of saphenous vein graft lesions⁹ stented with MGuard the periprocedural success rate was 100% without any no-reflow and no MACE were reported at 30 days. A case report has shown optical coherence tomographic evidence of complete plaque sealing of a large thrombus containing coronary lesion.¹⁰

In the Inspire¹¹ trial 30 patients with de novo coronary artery and vein graft lesions with features of instability and embolic potential were included. Satisfactory angiographic results without any distal embolisation or no-reflow were reported in all the patients without any MACE at 30 days. Another multicentre study¹² of 100 consecutive patients with ST elevation MI undergoing PCI with the MGuard stent concluded that the

MGuard stent might represent a safe and feasible option for PCI in STEMI patients, providing high perfusional and ECG improvement. The authors recognized the need for further randomized trials comparing this strategy with the conventional ones to assess the impact on clinical practice of this strategy. The MGuard stent was put to a novel use in treating a large dissection of the right coronary artery in a patient with ST elevation MI on whom a primary PCI was being performed¹³.

In our study of the MGuard stent we found results consistent with the available evidence so far. The acute luminal gain was 100% without any evidence of distal embolisation. Secondary end points were achieved in all patients. No peri or post-procedural MI was documented in any of the patients. In three patients MGuard was actually used as a bail-out stent. One of these patients actually had acute stent thrombosis 36 hours after deployment of another drug eluting stent for a critical lesion in the left anterior descending artery. While the other two patients developed thrombus activity during a routine PCI for unstable angina. Our experience in the use of this stent in the vein graft patients was also uneventful. No MACE were reported at 30 days.

The authors recognize that as with the other trials or studies of this stent the sample size was small. And they also understand the need for long term studies with large sample size focusing upon long term issues such as target lesion revascularization, in-stent restenosis and long term MACE need to be conducted. So far the preliminary data for the efficacy of the novel MGuard stent system seem to be convincing for its indicated use.

CONCLUSIONS

These preliminary results show that the MGuard stent is a safe option for patients undergoing PCI in de novo coronary artery lesions in the setting of acute coronary syndrome with thrombus burden and saphenous vein graft stenosis.

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Table-1 Distribution of cardiovascular risk factors in the population studied

Risk factor	No of patients
Hypertension	3(16.7%)
Diabetes	3(16.7%)
Family History	4(22.2%)
Smoking	6(33.3%)
Dyslipidimia	4(22.2%)

Table - 2: Distribution of vessels stented

Vessel	Number
LAD	11 (61.1%)
LCx	3 (16.7%)
RCA	2 (11.1%)
VG to RCA	1 (5.6%)
VG to OM	1 (5.6%)

Figure - 1: The balloon mounted MGuard stent covered with a sleeve mesh is seen.

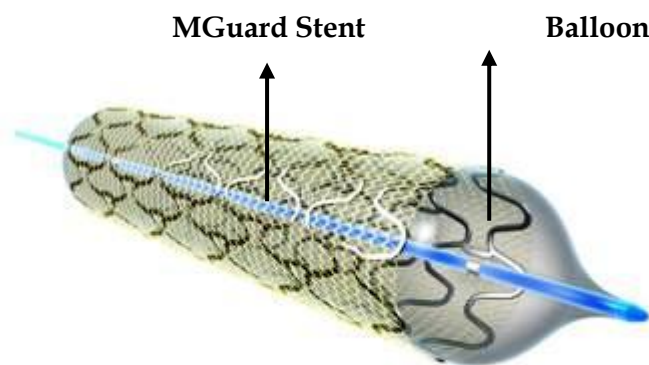


Figure - 2 The stent struts and covering sleeve is shown clearly.

