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FOLLOW UP OF THE PATIENTS TREATED WITH THE MGUARD STENT SYSTEM IN PERCUTANEOUS CORONARY INTERVENTION (PCI) AT AFIC-NIHD

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Contribution
All the authors contributed significantly to the research that resulted in the submitted manuscript.

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ABSTRACT

Objective: The objective of this study was to conduct a clinical and angiographic follow up of the patients treated with the MGuard Stent used in PCI in the setting of acute coronary syndromes.

Methodology: The study was conducted in AFIC-NIHD Rawalpindi, from April 2010 and October 2010 twenty one patients were treated with a total of 25 MGuard stents. Patients included were those having de novo lesions in saphenous vein grafts or native vessels with angiographic evidence of thrombus and lesion instability with a potential for distal embolization in the setting of acute coronary syndromes.

Results: All patients were male. Mean age was 46.23 years (range 32-70 years). Fourteen patients were admitted with ST elevation MI, 4 with Non-ST elevation MI, and 3 with unstable angina. Two vein grafts were stented while the rest were de novo lesions in native coronary arteries. The mean vessel diameter was 3.0mm (2.5- 3.5). The stent length ranged from 12 to 39 mm. MGuard stent was deployed successfully with no complications of PCI (distal embolization). Secondary endpoints (TIMI– III flow and myocardial blush grade 3) were met in all cases. One patient died within 30 days of PCI. On follow up 9 patients (42%) had critical ISR (2 of these were total occlusions) and all required repeat intervention. Total MACE events were 47% (1 death and 9 TLR).

Conclusion: Angiographic follow up of MGuard stent at 6 month showed significant ISR which needs to be clarified with a larger sample size.

Key Words: MGuard stent, no-reflow, distal protection, PCI.

INTRODUCTION

Distal embolisation is a known peri-procedural complication of PCI, especially in acute coronary syndromes. The embolism leading to no-reflow is closely related to the composition of the ruptured luminal plaque.[1,2] Protection devices reduce distal embolisation, but add complexity and cost to the procedure. The balloon expandable MGuard stent is a unique innovation to counter the phenomenon. 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. Previous study done on Mguard stent have shown it usefulness in preventing no reflow and distal embolization[3].

The purpose of this study was the clinical and angiographic follow up of patients in whom the MGuard Stent had been used for Percutaneous Coronary Intervention (PCI) in the setting of an acute coronary syndrome.

METHODOLOGY

The study was conducted in AFIC-NIHD. Between April 2010 and October 2010 twenty one patients were treated with a total of 25 MGuard stents. Patients included were those having de novo lesions in saphenous vein grafts or native vessels with angiographic evidence of thrombus (as defined in the SYNTAX trial-Spheric, ovoid or irregular intraluminal filling defect or lucency surrounded on three sides by contrast medium seen just distal or within the coronary stenosis in multiple projections or a visible embolization of intraluminal material downstream) and lesion instability (ulceration and dissection) with a potential for distal embolization in the setting of acute coronary syndromes. Patients with stable coronary artery disease were excluded from the study. Use of filter wires or other proximal or distal protection devices was not allowed. All patients received 600 mg loading dose of clopidogrel, and 325 mg of aspirin. Necessary local ethical committee clearance was obtained. All patients received intra-procedural glycoprotein IIb-IIIa inhibitors and heparin to maintain ACT above 250 seconds. Post procedure the patients were prescribed aspirin 300 mg daily and clopidogrel 75 mg daily. Clinical follow up (to document cardiac death, non-fatal MI) was conducted for all patients at 30 days and angiographic follow up of these patients was done at 6 months for documentation of MACE.

Primary end point included the incidence of MACE (composite of cardiac death and non-fatal MI up to 30 days after the procedure and target lesion revascularization at 6 month angiographic follow up). Secondary endpoints included restoration of TIMI grade 3 flows and myocardial blush grade 3 at the end of the procedure.

RESULTS

Baseline characteristics including risk factor profile are provided in table-1. All patients were male. Fourteen patients were admitted with ST elevation MI, 4 with Non-ST elevation MI, and 3 with unstable angina. Two of the patients had previously undergone CABG. Two vein grafts were stented while the rest were de novo lesions in native coronary arteries. The MGuard stent was deployed successfully in call cases and no complications of PCI including distal embolization were noted. Acute gain of vessel lumen was satisfactory (<10% residual stenosis on QCA) in all cases. Secondary endpoints (TIMI – III flow and myocardial blush grade 3) were met in all cases and no distal embolization or no-reflow was seen in any patient. One patient died within 30 days of PCI. This patient had undergone rescue PCI for an eccentric lesion in the left anterior descending artery with one MGuard (15mm ×3.25mm) stent.

Angiographic follow up details of the patients are provided in the table – 2. Nine patients had TLR (with PCI) due to critical Instent restenosis (ISR). A total of 10 MACE events occurred

Table 1: Baseline Characteristics

Variables	%,n
Mean age (years)	46.23 (range 32-70 years)
Mean stent Length (mm)	25 range(12-39)
Mean stent diameter	3.0 (Range 2.5-3.5)
Mean Ejection fraction (%)	40 (range 25-60)
Smoking(% of total patients)	58
Hypertension (% of total patients)	8
Diabetes mellitus	17
Dyslipidemia	17

Table 2: Follow up Details of the Patients Treated with the MGuard Stent

TOTAL	21
Angiography	12
CT angio	3
Death within 30 days	1
Loss to follow up	3
Un willing	2

(47%). Five patients had minor ISR not requiring any further intervention. Others were continued on optimised medical therapy.

DISCUSSION

Distal embolization leading to "no-reflow" is more of a risk in the setting of acute coronary syndromes. This translates into increased adverse outcomes in terms of myocardial infarction and death.[4-6] A number of pharmacological treatments for no-reflow has been proposed. Pharmacological treatments that have been investigated include intra coronary nitroprusside 7, adenosine[8], verapamil[9], isosorbidedinitrate 10 and carvediolol 11. Prevention of distal embolisation using different devices has also been investigated in this regard. These devices can be distal protection devices[2,12] or thrombus aspiration devices.[7]

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 meshwork.[13] 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 in Man study has shown promising results with no MACE at 6 months of follow up in a total study population of 29 patients.[14] In another twin centre trial 41 patients were implanted with at least one MGuard stent. Fifty six percent were treated for SVG lesions and the rest for native coronary lesions. 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, only 1 new event (TLR).[15] Similarly, in another study of saphenous vein graft lesions stented with MGuard the periprocedural success rate was 100% without any no-reflow and no MACE were reported at 30 days.[16] A case report has shown optical coherence tomographic evidence of complete plaque sealing of a large thrombus containing coronary lesion.[17] In the INSPIRE18 trial which included 30 patients similar lesions subsets no MACE were reported at 30 days.

ISR leading to target lesion revascularization with the Mguard stent have been cited at 19.5% at 6 months.[19] These ISR rates are similar to the current ISR rates in bare metal stents (BMS) of about 20-40% in different studies.[20] ISR can present with stable angina or in a more sinister situation as an acute coronary syndrome.[21]

The MGuard stent is essentially a BMS which has an extra sleeve around it. The increase in area of thrombogenic surface of the stent could be the cause of the high ISR rates. The evidence for this comes from reduction in stent strut size actually reduces the rates of ISR requiring repeat revascularization.[22,23]

In our study a total of 10 MACE events (1 Death, and 9 TLR) occurred with a MACE rate of 47%. This does not compare well with the literature review quoted above. However, a closer look at the above mentioned studies will reveal that the primary end points in all these studies were different from ours and were driven by immediate periprocedural results and death in 30 days. In contrast the TLR was actually a secondary endpoint in most of these studies. The high MACE rate in our study was primarily TLR driven, and not death due to any cause. In our study the ISR rate was quite high. The ISR rates towards the higher end could be because of the small sample size. Secondary endpoints (TIMI – III flow and myocardial blush grade 3) were met in all cases and no distal embolization and no-reflow was seen in any patient. In present study the gender bias was recognized in this small sample size.

We recognise the need for long term studies with a large sample size focusing upon long term issues such as target lesion revascularization, in-stent restenosis and long term MACE. So far the preliminary data for the efficacy of the novel MGuard stent system seems to be convincing for its indicated use.

CONCLUSIONS

These preliminary results show that the MGuard stent is a safe option for preventing distal embolization and no-reflow in patients undergoing PCI in acute coronary syndrome with thrombus burden and saphenous vein graft stenosis. However the 6 month angiographic follow up of these patients shows significant ISR which needs to be clarified with a larger sample size.

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