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M-Guard Stent in Stemi Patients with High Thrombus Burden Lesions: A Prospective, Single Arm Study

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ABSTRACT

Introduction: Primary PCI is the preferred modality to restore blood perfusion in STEMI patients, but myocardial reperfusion is sometimes lower than optimal. There is rare evidence suggestive of M-Guard stents; a recent innovation which protects against distal embolization may be beneficial in this circumstance.

Materials and Methods: This was a prospective single arm study. Patients with acute STEMI admitted at the Cardiac Emergency Unit of Imam Reza Hospital from July 2011 to November 2012 who had a large bulk of thrombus in their angiogram, underwent M-Guard stenting and were followed up for six months for chest pain and secondary revascularization.

Results: The 23 patients, aged between 34 and 84; 65.2%, were male and had undergone primary PCI, mechanical thrombus aspiration, and M-Guard stenting. Left Anterior Descending (LAD) (63.9%) and Right Coronary Artery (RCA) (39.1%) were most commonly involved. 78.2%, 13.1%, and 8.9% of patients had primary Thrombolysis in Myocardial Infarction (TIMI) Thrombus grade five, four, and three. Among them, 86.9% achieved TIMI Flow grade three and 13.04% TIMI Flow grade two. The rate of transient "no-reflow" phenomenon was 21%. One patient died after stenting in the setting of cardiogenic shock. There was one case of in-stent restenosis five months after the procedure. Of the other 15 accessible patients, after six months, none experienced a second angioplasty or any ischemic symptoms.

Conclusion: Using M-Guard stents in acute STEMI patients having undergone primary PCI with high thrombus burden is probably associated with lower rates of the "no-reflow" phenomenon and improved vessel reperfusion.

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Introduction

Primary percutaneous coronary intervention (PCI) is the preferred modality to restore blood perfusion in ST-segment Elevation Myocardial Infarction (STEMI) patients (1-3). Various stents and different medications have improved the effect of PCI and developed approximately normal perfusion in the majority of patients (4-6). However, despite the effectiveness of stent implantation during primary PCI for epicardial refl ow, myocardial perfusion is sometimes lower than optimal according to low Myocardial Blush Grade (MBG) and poor resolution of ST-segment elevation in patients undergoing primary PCI. Impaired myocardial reperfusion leads to an increased infracted area size, left sided heart failure, and finally, increased mortality in both short term and long term follow up (7-13).

There are various mechanisms underlying this phenomenon but distal embolization of thrombi and/or fragile atheromatous debri due to PCI, the "no-reflow phenomenon", seems to have the leading role (13-16).

Researchers use different thrombectomy and Protective Emboli Devices (PEDs) and various pharmacological agents to improve post procedural myocardial reperfusion in STEMI patients with conflicting reported results (17-23). M-guard stent is a

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mesh covered stent which prevents plaque fragmentation and distal embolization during stent implantation (24-26). Several trials have shown that among STEMI patients having undergone primary PCI, compared to Bare Metal Stents (BMS), M-guard stents result in higher rates of epicardial perfusion and complete ST resolution (24, 27, 28).

However, there is rare evidence suggestive for M-guard stenting in culprit vessels with a large thrombus bulk with or without primary mechanical aspiration (24). In the present study patients with acute STEMI who had a large bulk of thrombus in their angiogram, underwent M-Guard stenting and acute and long term outcomes were evaluated.

Materials and Methods

Study design: All patients with acute STEMI admitted to the Cardiac Emergency Unit of Imam Reza Hospital, Mashhad, Iran from July 2011 to November 2012 who underwent angiography and had a large thrombus bulk in their angiogram were considered as eligible for further evaluations. This was a prospective, single case group study in which the inclusion criteria was as follows:

1. Acute STEMI (persistent chest pain more than 30 minutes and less than 12 hours and ≥ 2mm ST-segment elevation in V1 –V3 leads or ≥1mm in at least 2 other contiguous electrocardiographic leads).
2. Evidence of a large thrombus bulk on coronary angiogram (TIMI thrombus grade 4-5)
3. No severe tortuosity or heavy calcification in the culprit vessel.
4. Vessel size estimated visually ≥ 3 mm and ≤ 4 mm in diameter.

The study protocol was approved by the Medical Ethics Committee of Mashhad University of Medical Sciences and a written informed consent was obtained from each patient prior to study entrance.

Study device: The M-guard stent is a recent innovation for the prevention of distal embolization of thrombi or plaque debri during stent implantation. It is made of a bared metal stent, covered with a tiny (in micron level) mesh. The bare metal stent is an expandable balloon made of stainless steel, and the mesh is of polyethylene terephthalate microfiber. Stents of three to four mm in diameter and 19 to 39 mm in length were used during this study.

Procedure: Immediately after confirming the diagnosis of Acute STEMI by ECG, the patients were administered 300 mg Aspirin, 600 mg Clopidogrel as well as Beta Blockers, Statins and Nitrates. With a time of Door to Balloon less than 90 minutes, selected patients for primary PCI underwent angiography, and those with a high burden of thrombus (TIMI grade four-five) were selected for primary angioplasty using M-guarded stents. 60 to 90 minutes after the procedure, a control ECG was taken. IIb-IIIa inhibitors (Eptifibatide) were used in only three patients. All patients were prescribed at least five types of medications on their discharge order including: Aspirin, Clopidogrel, Statins, Angiotensin Converting Enzyme (ACE) inhibitors and Beta blockers. All patients were visited monthly by a single cardiologist, and at six months of clinical follow- up, they were contacted by telephone to ask for cardiac symptoms and find out whether they required re-angioplasty on their stent.

Results

This study investigated 23 patients with acute STEMI admitted to the Cardiac Emergency Unit of Imam Reza Hospital, Mashhad from July 2011 to November 2012 who underwent Percutaneous Coronary Intervention (PCI) with Mesh Guard stent.

Demographic data of the patients is shown in Table1.

Table 1: Demographic data of the studied patients

Age	63.48 ±14.8
Sex (male %)	15 (65.2%)
Diabetes mellitus (%)	5 (21.73)
Hypertension (%)	10 (43.47)
Smoking (%)	10 (43.47)
Hypercholesterolemia (%)	7 (30.43%)
Mean door to balloon time (minute)	59
Mean stent inflation pressure (atm.)	17

63.9% of the patients had lesions in their LAD artery, and in 39.1%, the RCA was involved. In every patient, only one lesion was treated. After angiography and primary thrombus aspiration (in 20 patients), 87% of patients still had no flow in their culprit vessel (TIMI thrombus grade five and TIMI flow grade zero-one).

Stent implantation was done successfully in all patients, and there was no dislodgement or peripheral stent embolization during stenting. Stents with a length of 19 to 39 mm (mean: 28.78 mm) and a diameter of three to four mm (mean: 3.22 mm) were deployed.

High-pressure stent inflation (at least 14 atm) was performed in every patient (Table-1). In three patients, post dilatation with noncompliant balloon was done due to obvious non-expanded stents. TIMI flow grade three was attained in 87% of patients after stenting. Among the 78.28% of patients with primary TIMI thrombus grade 5, 65. 22% achieved TIMI flow grade three, and 13.04% reached TIMI flow grade two after M-guard stent deployment. All patients with a smaller thrombus bulk experienced complete reperfusion after stent implantation. The rate of transient "no-reflow" phenomenon was 21.7%. One patient died after successful stenting due to cardiogenic shock at the time of admission. There was one case of diffuse in-stent restenosis five months after primary PCI in ostioproximal LAD in a 49-year-old diabetic male.

After six months, only 15 out of 22 patients were accessible by telephone. They all mentioned monthly visits by a non-faculty cardiologist. None of them experienced secondary angioplasty during the six months of follow-up.

Discussion

To date, different studies have supported the PCI strategy in acute STEMI patients as a therapeutic option (1-5) and reported significant results in restoring blood flow in involved vessels (4-6). However, this epicardial blood flow is not always associated with effective flow in myocardial microcirculation level as reflected in low rates of MBG (Myocardial Blush Grade) and poor ST resolution (7-11,29,30). Moreover, large thrombus bulk in acute STEMI patients undergoing primary PCI results in an increased risk of distal embolization and causes poor myocardial perfusion (13,16). A prospective, randomized, multicenter study on Polyethylene Terephthalate Micronet Mesh-Covered stents in STEMI patients (The MASTER Trial) showed that using M-guard stents results in lower rates of distal embolization and in addition to effective epicardial blood flow, improves myocardial perfusion (27) besides decreasing the rate of mortality and adverse cardiac events (26). Different studies with controversial results have been performed focusing on other protection devices for distal embolization; they include Proximal and Distal Protection Devices and Thrombectomy Catheters (31-33). Distal Balloons create high MBG and TIMI Flow grade while Distal Filters do not. No significant effect on ST-resolution, prevention of no-reflow phenomenon or decreasing the risk of distal embolization has been reported for either of them (33). Also, two Meta analyses on the mechanical protection devices have shown that despite the improved myocardial perfusion and decreased distal embolization, the survival rate demonstrates no significant change (31, 32). Numerous studies have suggested that mechanical aspiration along with PCI reduces mortality (17, 34, 35); yet aspiration has the risk of distal embolization (36).

In the current study patients with a large thrombus bulk in spite of primary thrombosuction, which reflected their high risk for distal embolization, were treated by Mguard stents. Our endpoint measures included TIMI Flow grade as a marker of epicardial blood flow, the rate of no-reflow phenomenon, six months clinical follow up of chest pain, the need for revascularization therapy, and mortality. Achieving a high rate of TIMI flow grade three (87%), low rates of no-reflow phenomenon (21%), and no mortality in six month follow-up are all in favor of the hypothesis that deploying M-Guard stents results in restoring effective blood flow in culprit vessels, reduces the risk of distal embolization, and creates near optimal myocardial perfusion which are reflected in the lower rates of target lesion revascularization and mortality, thus resulting in a higher survival rate. Although a secondary angiography is required to comment on restenosis formation more precisely, our clinical outcomes did not suggest it. The small number of cases, missing out on some patients during follow-up, and being a single arm study with no control group were the main limitations of our study.

Conclusion

This prospective single arm study suggests that using Mesh guard stents in acute ST-segment Elevation Myocardial Infarction (STEMI) patients who undergo primary percutaneous intervention (P-PCI) and despite thrombus aspiration still have a high burden of thrombus, may probably be associated with lower rates of the no-reflow phenomenon and improved flow of the culprit vessel. Extended controlled trials will be a matter of benefit.

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