# Proximal Embolic Protection With Aspiration in Percutaneous Coronary Intervention of Acute Myocardial Infarction Using the Proxis™ Device

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*Distal embolization during primary percutaneous coronary intervention (PCI) occurs in at least 15% of patients and is a strong predictor of more extensive myocardial damage and a poor prognosis. Several devices are designed to evacuate the intracoronary thrombus or to prevent distal embolization. The Proxis device is a proximal embolic protection system that completely blocks antegrade flow during PCI. It may prevent distal embolization during recanalization of thrombotic coronary occlusion and thus improve outcome. We created a registry of 172 patients with ST-segment elevation myocardial infarction who underwent primary PCI with proximal embolic protection and aspiration. The mean ST-segment elevation resolution (STR) at 1 hour was 77.7% ± 15.2; STR was greater than 50% in 94% and greater than 70% in 72% of patients. The 1-year cumulative major adverse cardiac and cerebrovascular events rate was 10.5%. The overall mortality at 1 year was 2.3%.*
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**Key words:** Primary percutaneous coronary intervention • ST-elevation myocardial infarction • Embolic protection

Primary percutaneous coronary intervention (PCI) has been shown to be superior to thrombolytic therapy in the treatment of ST-segment elevation myocardial infarction (STEMI) in patients admitted to high-volume angioplasty centers. Primary PCI reduces major adverse cardiac events, including death and nonfatal myocardial reinfarction, as compared with thrombolytic

therapy, irrespective of the type of thrombolytic regimen used.[1-4] Primary PCI aims at early and sustained restoration of flow in the infarct-related coronary artery in order to reperfuse the myocardium at the tissue level.[5] However, distal embolization may occur during recanalization of the thrombotic coronary occlusion, leading to less optimal angiographic results during PCI. Angiographic evidence of distal embolization, either before or after primary PCI, is associated with reduced epicardial and myocardial perfusion. Distal embolization during primary PCI occurs in at least 15% of patients and is a strong predictor of more extensive myocardial damage and a poor prognosis.[6-8]

Several devices are designed to evacuate the intracoronary thrombus or to prevent distal embolization. Thus far, randomized evaluation of a variety of these devices has not demonstrated beneficial effects compared with the standard primary PCI technique. There have been no improvements in surrogate endpoints, such as ST-segment-elevation resolution (STR), myocardial blush grade (MBG), thrombolysis in myocardial infarction (TIMI)-graded coronary flow, and scintigraphic infarct-size, or in clinical endpoints, such as mortality or major adverse cardiac events.[9-12] The Proxis™ Embolic Protection System (St. Jude Medical, St. Paul, MN) provides embolic protection before the thrombotic coronary occlusion is crossed by the proximal balloon-occlusion, thus blocking flow in the infarct-related artery during manipulation of the thrombotic occlusive lesion with guide wires, balloons, and stents. In addition, it enables aspiration of embolic material prior to restoration of coronary flow.

A single-center registry was initiated after the Proxis device became available for use in clinical practice in the European Union. The study focused on feasibility and safety of the device in the setting of acute myocardial infarction (MI).

## Methods

*Patient Population*

Primary PCI with proximal embolic protection with aspiration using the Proxis device was routinely performed in 172 patients with STEMI who were admitted to the Academic Medical Center, University of Amsterdam, between February 2004 and October 2005. Inclusion criteria comprised clinical presentation of STEMI within 6 hours after onset of complaints, ST-segment elevation of at least 1 or 2 mm in leads—preferentially, TIMI 0 to 1 flow at first angiogram—and a coronary anatomy suitable for the Proxis system.

Anatomic exclusion criteria were a proximal location of the lesion that led to an insufficient "landing zone" for the Proxis device (generally $< 10$ to 12 mm), a small infarct-related artery ($< 2.5$ mm in diameter), heavy proximal calcifications, a left main stenosis of more than 30%, and a left main occlusion. Patients in cardiogenic shock or under assisted respiration were not included.

*The Device*

The Proxis device consists of a short, flexible catheter (ID 0.058″) attached to a hypertube catheter shaft, with a short circumferential balloon at the distal tip and a small balloon placed proximally on the catheter to seal the lumen of the guiding catheter. The device can be introduced through a 7-French guiding catheter and advanced into the proximal part of the occluded artery. The balloon at the tip of the device is inflated at two thirds atmosphere, thus blocking coronary flow. The sealing balloon on the proximal end allows direct luminal contact between the guiding catheter and the tip of the device, thus enabling coronary aspiration. The components of this system have been described previously.[13]

*Interventional Procedure*

The Proxis device was used in a standard manner, and the operator in charge was proficient with the device. The device was advanced just proximal to the occlusion, and the balloon at the tip was inflated. Crossing of the coronary occlusion with the guidewire, balloon dilatation, and stent placement were performed through the device and carried out under total proximal blockade of the vessel. The adequacy of the impairment of coronary flow was confirmed by a gentle injection of contrast dye. After withdrawal of the dilatation or stent balloons, aspiration of the stagnant column was performed and continued after coronary flow was restored by deflation of the device balloon. Embolic protection by temporary proximal vessel occlusion and aspiration was repeated during each step of the PCI procedure. Noninfarct-related coronary lesions were not treated during the same procedure.

*Angiographic Measurements*

Procedural success and angiographic recovery parameters, such as TIMI-graded coronary flow, MBG (0 to 1 or 2 to 3), and angiographic signs of distal embolization, were assessed after PCI. Two experienced observers performed all angiographic measurements. Flow was visually estimated and graded according to the TIMI score.[14]

*ECG Assessment*

To evaluate STR, clinicians compared a 12-lead electrocardiogram (ECG) taken immediately before the first contrast injection with ECGs taken

immediately after the last contrast injection and after 60 minutes. ST-segment elevation was calculated 20 ms after the J-point. The sum of the ST-segment elevation was calculated in leads I, aVL, and $V_1$ through $V_6$ for anterior MIs and leads II, III, aVF, $V_5$, and $V_6$ for nonanterior MIs.[15] The STR calculations were given as the magnitude of the resolution (percentage) and categorized as greater than 70% resolution or greater than 50% resolution.[16,17] STR was not evaluated in patients without ST-segment elevation at baseline (< 0.2 mV in anterior leads and < 0.15 mV in inferior leads), or in patients with bundle branch block, lasting accelerated idioventricular rhythm, paced rhythm, atrioventricular block, or early recurrent second stage MI. The ECG assessment was performed by an experienced independent observer (GS) blinded to the angiographic result of the PCI.

*Laboratory Tests*

Creatine kinase–myocardial bound levels were measured before the procedure and after it at 5, 7, 10, 12, 18, and 24 hours.

*Pathology*

Aspirated material was assessed by inspection and histopathologic analysis of the filter content. A pathologist (AW), blinded to the angiographic findings and the result of PCI, performed the histopathologic analyses.

*Follow-Up*

Clinical follow-up was collected at 30 days, 6 months, and 12 months after PCI to assess major adverse cardiac and cerebrovascular events (MACCE), which included death, coronary artery bypass grafting, repeat PCI of the infarct-related artery, recurrent MI, and stroke. In the event of a repeat PCI of the infarct-related artery, the angiograms were reviewed for evidence of (re)stenosis at the site where the Proxis device had been inflated. All non–infarct-related artery interventions were documented as well. The information was gathered from the patients' clinical records, either at our hospital or at the referring hospital. (This information is routinely collected in all patients who undergo PCI in our institution, with the exception of patients who have made their objections known.)

## Results

*Patient Characteristics*

Patient characteristics are summarized in Table 1. Baseline demographic and angiographic features did not substantially differ from most primary PCI populations. There was a slight preponderance of MIs related to the right coronary artery as compared with the left anterior descending coronary artery (LAD), which was mainly due to the

**Table 1**
**Characteristics of Patients With Acute Myocardial Infarction Treated With Primary PCI Using a Proxis Device**

| **Patients** | **N = 172** |
|---|---|
| Age (y) | 60.7 ± 12.7 |
| Male sex | 132 (77%) |
| Previous MI | 18 (11%) |
| Previous CABG | 3 (2%) |
| Multivessel disease | 73 (42%) |
| Risk factors | |
| Hypercholesterolemia | 41 (24%) |
| Current smoking | 86 (50%) |
| Previous smoking | 22 (13%) |
| Diabetes | 28 (16%) |
| Hypertension | 60 (35%) |
| Family history of CAD | 70 (41%) |
| Infarction-related artery | |
| LAD | 70 (41%) |
| RCA | 90 (52%) |
| LCx | 12 (7%) |
| Lesion location | |
| Proximal | 60 (35%) |
| Mid | 88 (51%) |
| Distal | 24 (14%) |
| Pre-procedural TIMI flow | |
| 0 | 155 (90%) |
| 1 | 8 (5%) |
| 2 | 8 (5%) |
| 3 | 1 (1%) |

Data are presented as percentage (n) or mean ± standard deviation, unless otherwise specified. CABG, coronary artery bypass graft; CAD, coronary artery disease; LAD, left anterior descending artery; LCx, left circumflex coronary artery; MI, myocardial infarction; PCI, percutaneous coronary intervention; RCA, right coronary artery; TIMI, thrombolysis in myocardial infarction.

**Table 2**
**Procedural Characteristics of Patients With Acute Myocardial Infarction Treated With Primary PCI Using a Proxis Device**

| Patients | N = 172 |
|---|---|
| Stenting with predilation | 152 (88%) |
| Direct stenting | 10 (6%) |
| Balloon angioplasty | 8 (5%) |
| Thrombosuction only/Proxis only | 2 (1%) |
| Guiding size | |
| 7-French | 160 (93%) |
| 8-French | 12 (7%) |
| Intra-aortic balloon pump | 12 (7%) |
| Treated with glycoprotein IIb/IIIa receptor antagonist | 78 (45%) |
| Time intervals (minutes) | |
| Symptoms to balloon | 189 (135,294) |
| Cathlab call to arterial puncture | 51 ± 22 |
| Arterial puncture to balloon | 17 ± 8 |

Data are presented as percentage (n) or mean ± standard deviation or median and interquartile range.
PCI, percutaneous coronary intervention.

exclusion of patients with an ostial LAD occlusion. The majority of patients had a complete occlusion of the infarct-related artery; at the first angiogram, there was a TIMI 0 to 1 flow in 95% of patients. MI was associated with late stent thrombosis in 4 patients at 7, 13, 16, and 22 months after drug-eluting stent implantation for PCI that was not related to MI.

*Procedural Results and Angiographic Outcome*

The procedural results are summarized in Tables 2 and 3. Except during the early phase of the study, the Proxis device was used in the majority of patients. Adequate positioning of the device was obtained in all but 1 patient, in whom an 8F device did not pass the proximal section of a calcified LAD. There were no device-related complications. Procedural success and procedural characteristics were in line with most reports on primary angioplasty. Direct stenting was performed in a minority of patients because of the high number of patients with TIMI 0 flow. The operators chose to visualize the actual vessel anatomy after balloon predilation, especially because the protocol preferred wire crossing under proximal occlusion. Stand-alone protection and aspiration were performed in a 31-year-old man with a thrombus in the mid segment of the LAD, which was aspirated successfully. In this patient, no visible angiographic lesions were demonstrated after thrombus removal, which was confirmed by control angiography at 5 days.

*ST-Segment Resolution*

STR was evaluable in 132 out of 174 patients (Table 4). Immediately after PCI, the mean STR was 62.9%. STR greater than 70% occurred in 45% of

**Table 3**
**Angiographic and Enzymatic Outcomes**

| Patients | N = 172 |
|---|---|
| TIMI flow after PCI | |
| 0-1 | 4 (2%) |
| 2 | 25 (15%) |
| 3 | 143 (83%) |
| Myocardial blush grade after PCI | |
| 0-1 | 27 (16%) |
| 2-3 | 145 (84%) |
| Angiographic signs of distal embolization | 14 (8%) |
| Infarct size by peak CK-MB (μg/L)* | n = 171 |
| 0-25 | 6 (4%) |
| 26-100 | 33 (19%) |
| 101-200 | 38 (22%) |
| 201-400 | 55 (32%) |
| 401-1000 | 35 (20%) |
| > 1000 | 4 (2%) |
| Pathology-confirmed material aspirated | 132 (77%) |

Data are presented as percentage (n) or mean ± standard deviation, unless otherwise specified.
*The CK-MB upper limit of normal is 7. Peak CK-MB was not available for 3 patients.
CK-MB, creatine kinase–myocardial band; PCI, percutaneous coronary intervention; TIMI, thrombolysis in myocardial infarction.

**Table 4**
**Electrocardiographic Outcomes**

| | |
|---|---|
| **Immediate ST Measurements** | |
| *All patients* | N = 132 |
| % Immediate ST resolution | 62.9 ± 23.2 |
| Immediate ST resolution > 50% (%) | 101 (77%) |
| Immediate ST resolution > 70% (%) | 60 (45%) |
| *Patients with anterior infarction* | n = 53 |
| % Immediate ST resolution | 55.0 ± 23.3 |
| *Patients with non-anterior infarction* | n = 79 |
| % Immediate ST resolution | 68.2 ± 21.6 |
| **One-hour ST Measurements** | |
| *All patients* | N = 119 |
| % 1-hour ST resolution | 77.7 ± 15.2 |
| 1-hour ST resolution > 50% (%) | 112 (94%) |
| 1-hour ST resolution > 70% (%) | 86 (72%) |
| *Patients with anterior infarction* | n = 47 |
| % 1-hour ST resolution | 67.4 ± 15.4 |
| *Patients with non-anterior infarction* | n = 72 |
| % 1-hour ST resolution | 84.4 ± 10.7 |

Data are presented as percentage (n) or mean ± standard deviation, unless otherwise specified.

patients. At 1 hour after PCI, the mean STR was 77.7%, and STR greater than 70% occurred in 72% of patients.

*Pathology*

Debris was confirmed on pathology in 77% of patients. It contained fresh thrombus in all specimens, plaque material in 30%, foam cells in 17%, calcifications in 13%, lytic cellular changes in 7%, and cellular ingrowth of fibroblasts in 6%.

*One-Year Clinical Follow-Up*

Clinical follow-up until 1 year was completed in all patients (Table 5). One-year mortality was low (2.3%). The overall MACCE rate was mainly driven by target vessel revascularization (accounting for 13 out of 18 MACCE events). None of the repeat angiograms showed evidence of a (re)stenotic lesion at the site where the Proxis device had been inflated.

## Discussion

This registry demonstrated the safety and feasibility of proximal embolic protection with thrombus aspiration using the Proxis device in PCI for acute MI. Angiography showed adequate impairment of coronary runoff during inflation of the device. TIMI 3 coronary flow and MBG 2 to 3 were obtained in a substantial number of patients, and early STR could be demonstrated. Debris confirmed by pathology was aspirated in more than 75% of patients. Angiographic distal embolization occurred in 8% of patients. Therefore, we conclude that proximal embolic protection does not completely prevent distal embolization. One-year follow-up showed a low mortality (2%). There were no device-related complications during the initial procedure or during follow-up.

It has been recently demonstrated that the effectivity of this proximal embolic protection system is equivalent to that provided by distal protection in PCI of saphenous vein grafts.[18] To our knowledge, this report is the first on the use of a proximal embolic protection device in the setting of primary PCI in a large number of patients. Recent trials on

**Table 5**
**Clinical Outcomes**

| | 30 Days (n = 172) | 6 Months (n = 172) | 12 Months (n = 172) |
|---|---|---|---|
| Death | 3 (1.7%) | 4 (2.3%) | 4 (2.3%) |
| MI | 3 | 7 | 7 |
| Percutaneous TVR | 3 | 9 | 13 |
| Surgical TVR | 0 | 0 | 0 |
| Acute stent closure | 2 | 6 | 6 |
| Stroke | 1 | 2 | 2 |
| Overall MACCE | 7 (4.1%) | 14 (8.1%) | 18 (10.5%) |
| Percutaneous NTVR | 7 | 10 | 10 |
| Surgical NTVR | 0 | 2 | 2 |

Data are presented as n (percentage %).
MACCE, major adverse cardiac or cerebral event; MI, myocardial infarction; NTVR, nontarget vessel revascularization; TVR, target vessel revascularization.

the use of embolic protection and thrombectomy devices during primary PCI have demonstrated mostly neutral or even negative effects on myocardial reperfusion, infarct size, and clinical outcome. These trials evaluated various devices with different structures and operational mechanisms.

The effects of distal protection (FilterWire EZ™ Embolic Protection System, Boston Scientific, Natick, MA) were studied in the Protection Devices in PCI Treatment of Myocardial Infarction for Salvage of Endangered Myocardium (PROMISE) trial, with neutral results.[19] Thrombus aspiration combined with distal occlusion (GuardWire® Temporary Occlusion and Aspiration System, Medtronic, Minneapolis, MN) was examined in the Enhanced Myocardial Efficacy and Recovery by Aspiration of Liberalized Debris (EMERALD) trial, again with neutral results.[10] Thrombectomy (X-SIZER®, ev3, Plymouth, MN) in the X-sizer in Acute MI Negligible Embolization and optimal ST resolution (X-AMINE ST) trial showed a slight improvement in STR without an effect on TIMI flow, MBG, or clinical outcome. Thrombus suction (AngioJet®, Possis, Minneapolis, MN) in the Angiojet in Acute Myocardial Infarction (AIMI) trial was adverse.[9,20]

Several explanations have been proposed for these outcomes. Visible debris was obtained in 73% of aspirated patients in EMERALD and in 77% of our patients, which suggests that distal embolization occurs during primary PCI. However, embolization may induce only limited additional damage, which is small against the background of necrosis due to ischemia and reperfusion, including mediators of inflammation, endothelial dysfunction, capillary leakage, and interstitial edema. Still, it is conceivable that the negative outcomes of these studies are device-related. The use of Proxis did not delay angioplasty, as occurred with the device used in the EMERALD trial (mean, 21 minutes). Initial lesion crossing with the distal embolic protection devices used in EMERALD and PROMISE may lead to embolization before any actual protection is provided. This finding may be of particular importance in regard to totally occlusive lesions (TIMI 0 to 1 flow), which were found in the majority of the patients in our study. Furthermore, side branches may remain unprotected with a device that provides distal protection. Proximal protection may overcome some of the limitations of the distal embolic protection devices, and aspiration of debris may be performed additionally during each step of the procedure.

Complete STR (> 70%) at 60 minutes could be demonstrated in 72% of the patients in our study. In the EMERALD study, complete STR was demonstrated in 68% of the treatment arm and 65% of the control arm, which suggests that the device at least did no harm. In contrast, in the AIMI trial, after 90 minutes STR was 60% in the treatment group and 68% in the control group. More than 90% of our patients had complete obstruction of the infarct-related artery, which had a proximal or mid-vessel location in the majority of patients, providing a large myocardial area. Despite this factor, 1-year mortality was low (2.3%). Target vessel revascularization was the main driver of MACCE at 1 year (8%), as can be expected in patients treated with bare-metal stents. Of note,

## Main Points

- Angiographic evidence of distal embolization, either before or after primary percutaneous coronary intervention (PCI), is associated with reduced epicardial and myocardial perfusion.
- The Proxis embolic protection device provides embolic protection before the thrombotic coronary occlusion is crossed by the proximal balloon-occlusion, thus blocking flow in the infarct-related artery during manipulation of the thrombotic occlusive lesion with guide wires, balloons, and stents.
- A single-center registry of 172 patients with ST-segment elevation myocardial infarction demonstrated the safety and feasibility of proximal embolic protection with thrombus aspiration using the Proxis device in PCI for acute myocardial infarction.
- Thrombolysis in myocardial infarction 3 coronary flow and myocardial blush grade 2 to 3 were obtained in a substantial number of patients.
- ST-segment elevation resolution (STR) was evaluable in 132 out of 174 patients. Immediately after PCI, the mean STR was 62.9%. STR greater than 70% occurred in 45% of patients. At 1 hour after PCI, the mean STR was 77.7%, and STR greater than 70% occurred in 72% of patients.

there was no indication that the low pressure inflation of the compliant Proxis balloon caused early or late coronary damage.

*Study Limitations*

This report did not generate comparative data. It showed only safety and feasibility of an attractive concept that must be studied in a randomized manner.

## Conclusion

Proximal embolic protection with aspiration using the Proxis device is feasible and safe in the setting of primary PCI. The results suggest that this device is highly effective for aspiration of embolic material during primary PCI. Moreover, this registry shows good angiographic and myocardial recovery and low 1-year mortality. Randomized trials are needed to prove whether these preliminary observations translate into substantial patient benefit. ■

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