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Thrombus Aspiration During Primary Percutaneous Coronary Intervention Improves Myocardial Reperfusion and Reduces Infarct Size

The EXPIRA (Thrombectomy With Export Catheter in Infarct-Related Artery During Primary Percutaneous Coronary Intervention) Prospective, Randomized Trial

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Objectives The purpose of this study was to evaluate the impact on myocardial perfusion and infarct size as assessed by contrast-enhanced magnetic resonance imaging (CE-MRI) of a manual thrombectomy device, Export Medtronic (EM) (Medtronic Inc., Minneapolis, Minnesota), as adjunctive therapy in primary percutaneous coronary intervention (PPCI) in a subset of patients with anterior ST-segment elevation myocardial infarction (STEMI).

Background PPCI may cause thrombus dislodgment, leading to microvascular damage.

Methods One hundred seventy-five STEMI patients were randomly assigned to standard percutaneous coronary intervention (PCI) (n = 87) or EM-PCI (n = 88). The primary end points were the occurrence of myocardial blush grade ≥2 and the rate of 90-min ST-segment resolution >70%. The CE-MRI substudy was performed in 75 patients with anterior STEMI to assess microvascular obstruction and infarct size.

Results Myocardial blush grade ≥2 and ST-segment resolution occurred more frequently in the EM-PCI group (88% vs. 60%, p = 0.001; and 64% vs. 39%, p = 0.001). In the acute phase, microvascular obstruction extent was significantly lower in the EM-PCI group and at 3 months, infarct size was significantly reduced only in the EM-PCI group. A lower incidence of cardiac death in the EM-PCI group (4.6% vs. 0%, log-rank test p = 0.02) was observed at 9 months.

Conclusions Thrombectomy prevents thrombus embolization and preserves microvascular integrity reducing infarct size, and it therefore represents an useful adjunctive therapy in PPCI. (J Am Coll Cardiol 2009;53:309–15) © 2009 by the American College of Cardiology Foundation

Primary percutaneous coronary intervention (PPCI) is the standard treatment in patients with ST-segment elevation myocardial infarction (STEMI) achieving a Thrombolysis In Myocardial Infarction (TIMI) flow grade 3 in >90% of patients (1). However, despite a "brisk" epicardial coronary flow in the infarct-related artery, microvascular damage frequently limits the efficacy of PPCI. Recent studies suggest that thrombectomy improves myocardial perfusion and reduces left ventricular (LV) remodeling by reducing microvascular damage (2–4). Contrast-enhanced magnetic resonance imaging (CE-MRI) represents the gold-standard technique to identify and quantify microvascular obstruction (MVO) and infarct size (IS) (5,6) and to date, this imaging technique has not been applied to assess the efficacy of thrombectomy. The aim of this trial was to evaluate the impact of a manual intracoronary aspiration thrombectomy device, Export Medtronic (EM) (Medtronic Inc., Minneapolis, Minnesota), as adjunctive therapy for primary percutaneous coronary intervention (EM-PCI) on procedural outcomes, myocardial blush grade (MBG) and 90-min ST-segment resolution (STr) >70%, and on MVO and IS assessed by CE-MRI in patients with anterior STEMI.

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Abbreviations and Acronyms

CE-MRI = contrast-enhanced magnetic resonance imaging

EM-PCI = Export Medtronic-percutaneous coronary intervention

IS = infarct size

LV = left ventricular

MACE = major adverse cardiac events

MBG = myocardial blush grade

MVO = microvascular obstruction

PPCI = primary percutaneous coronary intervention

S-PCI = standard percutaneous coronary intervention

STEMI = ST-segment elevation myocardial infarction

STr = ST-segment resolution

TIMI = Thrombolysis In Myocardial Infarction

Methods

Study population. One hundred seventy-five consecutive patients admitted with STEMI and candidates for PPCI were enrolled. Patients were randomly assigned in a 1:1 manner to EM-PCI or standard percutaneous coronary intervention (S-PCI). In the CE-MRI substudy, a second randomization (1:1) was performed within anterior STEMI patients only (Fig. 1).

The inclusion criteria were as follows: first STEMI within 9 h from symptoms onset, infarct-related artery ≥2.5 mm in diameter, thrombus score ≥3, TIMI flow grade ≤1, and age >18 years. Exclusion criteria were a previous PCI on infarct-related artery, previous coronary artery bypass graft, cardiogenic shock, 3-vessel disease, left main disease, severe valvular heart disease, thrombolysis, and a contraindication to glycoprotein IIb/IIIa inhibitors administration.

Study protocol and procedure. All patients were pretreated immediately before the revascularization with aspirin 300 mg, intravenous heparin, abciximab at a standard dose, and clopidogrel 300 mg. Thrombectomy was performed by more than 2 passages across the lesion. Subsequently, patients received aspirin, clopidogrel (12 months), nitrates, beta-blockers, angiotensin-converting enzyme inhibitors, and statins.

The protocol was accepted by the institutional ethical board, and was performed in accordance with the Declaration of Helsinki. All patients provided written informed consent.

Angiographic and electrocardiography analysis. The TIMI flow grade and MBG were estimated visually by 2 experienced observers, as previously described (7,8). Thrombus burden at the lesion site was graded from 0 to 5 according to the thrombus score (9). Interobserver and intraobserver coefficients of variation assessed in 20 randomly selected patients were, respectively, 8% and 5% for MBG and 5% and 3% for TIMI. All patients underwent 12-lead electrocardiography at baseline and 90 min after revascularization. The STr was measured as previously described (10).

CE-MRI acquisition protocol. Cardiac MRI was performed at days 3 to 5 after PPCI and at 3 months using a 1.5-T scanner (Avanto-Siemens, Erlangen, Germany). Left ventricular function was assessed by standard steady-state free precession technique. Consecutive short-axis views were obtained by encompassing the left ventricle from base to apex; vertical and horizontal long-axis views were acquired. Typical image parameters were as follows: TE = 1.6 ms, TR = 3.2 ms, $\alpha = 60^{\circ}$, matrix = 256 × 256, slice thickness 8 mm, gap 2 mm.

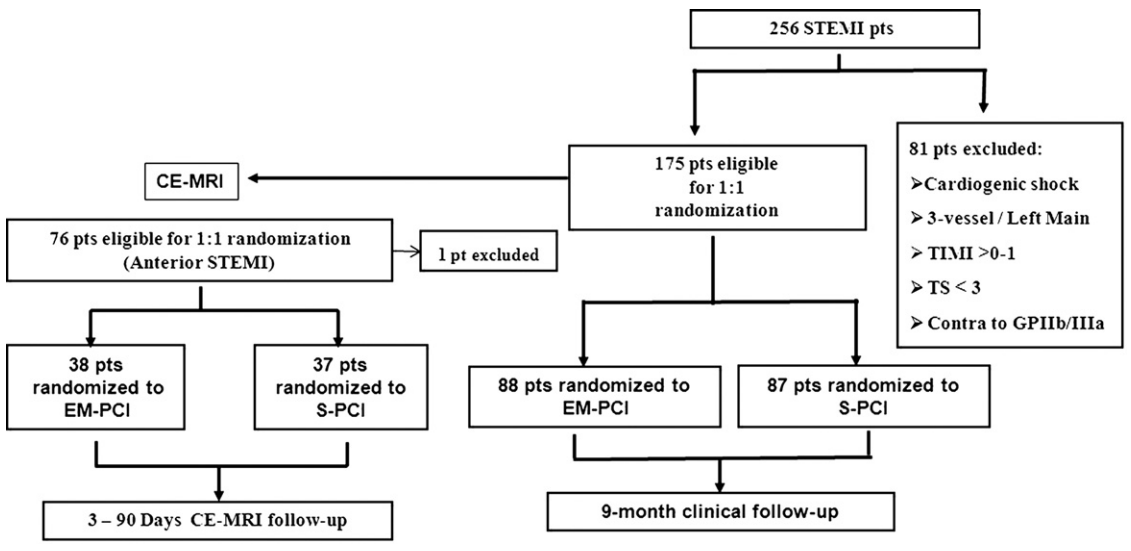

Figure 1 Study Design

CE-MRI = contrast-enhanced magnetic resonance imaging; Contra = contraindication; EM = Export Medtronic; GP = glycoprotein; PCI = percutaneous coronary intervention; pt/pts = patient/patients; S = standard; STEMI = ST-segment elevation myocardial infarction; TIMI = Thrombolysis In Myocardial Infarction; TS = thrombus score.

Rest myocardial perfusion was evaluated with a first-pass technique using a T1-weighted multishot gradient echo echoplanar inversion-recovery sequence (TR = 6.6 ms, TE = 1.3 ms, TI = 240 ms, 25° flip angle, slice thickness 10 mm). Three short-axis slices (basal, mid-cavity, and apical levels) were obtained injecting 0.1 mmol/kg gadolinium-BOPTA (Multihance, Bracco, Milan, Italy) at 2 ml/s followed by 20 ml saline flush in the right anterocubital vein. The CE-MRI images were acquired in long- and short-axis views with a segmented inversion-recovery fast gradient echo sequence 15 min after contrast injection. Sequence parameters were as follows: TR = 600 ms, TE = 3.8 ms, α = 25°, slice thickness 8 mm, gap 2 mm. The inversion time was progressively optimized to null normal myocardium.

CE-MRI analysis. All measurements were performed by 2 fully blinded operators using an off-line dedicated workstation (Siemens-Argus, Siemens AG, Erlangen, Germany). Left ventricular ejection fraction, end-diastolic and -systolic volumes, and LV mass were calculated from the short-axis views.

The MVO and IS were quantified by manually drawing the regions of hypointensity on the first-pass perfusion images and the regions of hyperintensity on the CE-MRI short-axis slices, respectively. The MVO was included in the infarcted area. The MVO and IS are expressed in grams (assuming 1.05 g/ml as the specific gravity of the myocardium) and as a percentage of the LV mass.

Interobserver and intraobserver coefficients of variation, assessed in 20 randomly selected patients, were 3% and 1% for MVO and 3% and 2% for IS, respectively.

Clinical follow-up. Clinical follow-up was performed at 9 months in all patients to assess the occurrence of the following major adverse cardiac events (MACE): cardiac death, nonfatal reinfarction, and target vessel revascularization. The incidence of stent thrombosis was also evaluated.

End points. Primary study end points were the occurrence of final MBG ≥2 and the rate of STr. End points of the CE-MRI substudy were the presence and extent of MVO in the acute phase and IS extent at 3 months.

Statistical analysis. We estimated that 45 patients would be required in each study group to have a power of 80% to detect an absolute difference in the occurrence of MBG ≥2 of 30% with a 2-sided alpha value of 0.05. Categorical variables were analyzed by the chi-square or Fisher exact test, as appropriate. All continuous variables were expressed as mean ± SD and analyzed by the Student *t* test. Event-free survival curve for MACE was constructed using the Kaplan-Meier method, and statistical differences between curves were assessed by the log-rank test. Statistical analysis was performed with StatView (version 5.0, SAS Institute, Cary, North Carolina).

Results

Baseline characteristics. Two hundred fixty-six consecutive STEMI patients were recruited, and 81 patients were excluded (Fig. 1). Clinical and angiographic characteristics of EM-PCI and S-PCI are shown in Tables 1 and 2.

Angiographic and periprocedural findings. The EM-PCI showed a significant reduction of the thrombus burden (TS0-1: EM-PCI 63% vs. S-PCI 42%, p = 0.006). The rate of post-thrombectomy TIMI flow grade ≥2 was higher in EM-PCI (92% vs.77%, p = 0.006), with a similar final rate (EM-PCI 100% vs. S-PCI 98%, p = 0.9) (Table 3). Primary end points occurred more frequently in EM-PCI (MBG ≥2: 88% vs. 59%, p < 0.0001; STr: 63% vs. 39%, p = 0.001) (Table 3, Fig. 2).

Clinical outcomes. At 9 months, no differences were observed in terms of cumulative MACE (log-rank p =

Table 1 Baseline Clinical and Demographic Characteristics of the Study Patients

	Total (n = 175)	S-PCI (n = 87)	EM-PCI (n = 88)	p Value
Age, yrs	65.3 ± 11.2	64.6 ± 12.5	66.7 ± 14.1	0.298
Males (%)	105 (60.0)	48 (55.1)	57 (64.7)	0.218
Risk factors				
Hypertension (%)	102 (58.3)	43 (49.4)	59 (67.0)	0.021
Diabetes (%)	37 (21.1)	16 (18.4)	21 (23.8)	0.459
Smoking (%)	66 (37.7)	23 (26.4)	43 (48.8)	0.003
Obesity (%)	7 (4.0)	2 (2.3)	5 (5.7)	0.443
Family history of CAD (%)	58 (33.1)	32 (36.8)	26 (29.5)	0.338
Cholesterol, mg/dl ± SD	163 ± 27	167 ± 15	161 ± 11	0.002
Triglycerides, mg/dl ± SD	122 ± 37	125 ± 26	124 ± 31	0.817
Renal failure (%)	14 (8.0)	7 (8.0)	7 (7.9)	1.00
Killip class III (%)	42 (24.0)	25 (28.7)	17 (19.3)	0.160
Symptoms to balloon, h ± SD	6.1 ± 1.3	6.1 ± 1.8	6.2 ± 0.9	0.642
LVEF, % ± SD	41 ± 13	40.7 ± 9.3	42 ± 10.5	0.192
ST-segment elevation, mV	22.9 ± 13.5	22.3 ± 9.3	23.6 ± 10.5	0.384

CAD = coronary artery disease; EM-PCI = Export Medtronic percutaneous coronary intervention; LVEF = left ventricular ejection fraction; S-PCI = standard percutaneous coronary intervention.

Table 2 Baseline Procedural Characteristics of the Study Population

	Total (n = 175)	S-PCI (n = 87)	EM-PCI (n = 88)	p Value
Location of infarct-related artery (%)				
LAD	76 (43.4)	38 (43.7)	38 (43.2)	1.00
LCX	42 (24.0)	20 (23.0)	22 (25.0)	0.859
RCA	57 (32.6)	29 (33.3)	28 (31.8)	0.872
BARI score, %	28.9 ± 10.3	28.1 ± 9.2	29.7 ± 6.1	0.17
Multivessel disease (%)	37 (26.8)	16 (18.4)	21 (23.8)	0.459
Bifurcation (%)	23 (13.1)	11 (12.7)	12 (13.6)	1.00
Lesion length, mm ± SD	14.5 ± 5.3	14.4 ± 6.6	14.7 ± 3.9	0.714
Vessel reference diameter, mm ± SD	2.9 ± 0.6	2.9 ± 0.5	2.9 ± 0.6	1.00
MLD before thrombectomy, mm ± SD	0.85 ± 0.4	0.86 ± 0.2	0.83 ± 0.3	0.438
Pre-thrombectomy thrombus score (%)				
3	18 (10.3)	9 (10.3)	9 (10.6)	1.00
4	62 (35.4)	32 (36.8)	30 (34.1)	0.753
5	95 (54.3)	47 (54.0)	48 (54.5)	1.00

BARI = Bypass Angioplasty Revascularization Investigation; LAD = left anterior descending artery; LCX = left circumflex artery; MLD = minimal lumen diameter; RCA = right coronary artery; other abbreviations as in Table 1.

0.14) (Fig. 2). However, S-PCI had a higher incidence of cardiac death (log-rank p = 0.02) than did EM-PCI (Fig. 3). No stent thrombosis occurred in either group.

CE-MRI evaluation. Seventy-five patients underwent cardiac MRI (Fig. 4). One patient was excluded from the analysis owing to incomplete image acquisition (because of claustrophobia), and 2 patients declined the follow-up scan at 3 months.

No differences in the baseline ejection fraction, volumes, and IS were observed between the 2 groups. Post-procedural rate of MBG ≥2 and STr >70% was higher in the EM-PCI group (89% vs. 59% and 84% vs. 40%, respectively; p = 0.0001). In the acute phase, greater incidence and extent of MVO was observed in the S-PCI group versus the EM-PCI group (72.9% vs. 31.5%, p = 0.0005; and 3.7 ± 2.6 g vs. 1.7 ± 1.9 g, p = 0.0003, respectively); no differences were observed in IS (Table 4).

At 3 months, a reduction in final IS was detected in the EM-PCI group (IS mass from 17 ± 15 g to 11 ± 8.7 g, p = 0.004; IS% from 14 ± 12% to 9 ± 4.5%, p = 0.001), whereas no changes were observed in the S-PCI group (Table 4). MVO was not observed in either group at follow-up.

Discussion

In accordance with previous data (2–4), manual thrombectomy improves MBG and increases STr in selected STEMI patients with angiographically visible thrombus. The present study showed a lower incidence and extent of MVO after recanalization and a reduced IS at 3 months for

Table 3 Post-Procedural Angiographic Characteristics of the Study Population

	Total (n = 175)	S-PCI (n = 87)	EM-PCI (n = 88)	p Value
Procedure (%)				
"Direct" stenting	69 (39.4)	2 (2.3)	67 (76.2)	0.0001
Stent type (%)				
Bare-metal stent	73 (41.7)	34 (39.1)	39 (44.3)	0.540
Drug-eluting stent	102 (58.3)	53 (60.9)	49 (55.7)	0.540
Post-stenting MLD, mm ± SD	2.9 ± 0.8	2.9 ± 0.7	2.9 ± 0.1	1.00
CK-MB peak, ng/ml	105 ± 125	108 ± 111	109 ± 119	0.605
90-min ST-segment resolution (%)	90 (51.4)	34 (39.1)	56 (63.6)	0.001
ST-segment elevation, mV	10.2 ± 15.3	12.8 ± 12.3	7.6 ± 9.7	0.002
Post-stenting TIMI flow grade (%)				
≥2	174 (99.4)	86 (98.9)	88 (100)	0.975
0 to 1	1 (0.6)	1 (1.1)	0 (0.0)	0.997
Post-stenting MBG (%)				
≥2	130 (74.3)	52 (59.8)	78 (88.6)	<0.0001
0–1	45 (25.7)	35 (40.2)	10 (11.4)	<0.0001

CK-MB = creatine kinase-myocardial band; MBG = myocardial blush grade; TIMI = Thrombolysis In Myocardial Infarction; other abbreviations as in Tables 1 and 2.

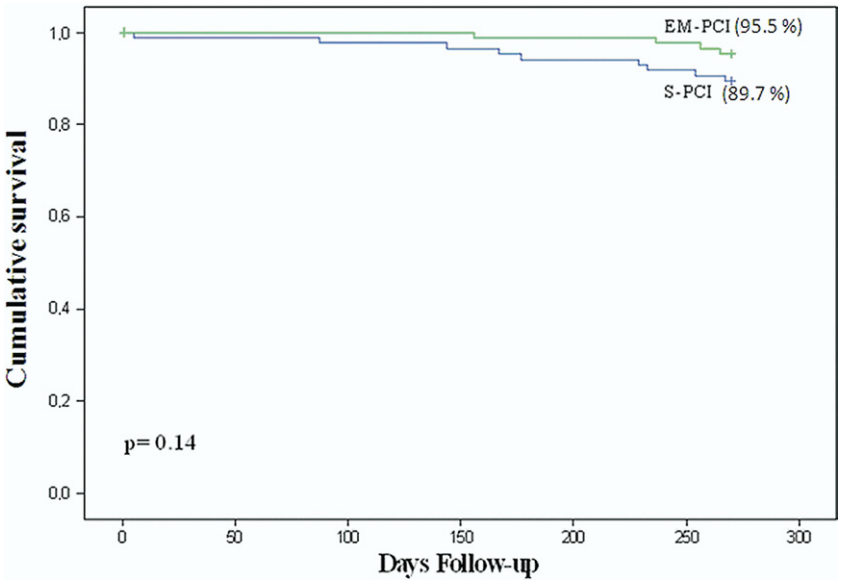

Figure 2 **Kaplan-Meier 9-Month Cumulative Event-Free Survival**

Kaplan-Meier analysis shows 9-month cumulative event-free survival of the standard percutaneous coronary intervention (S-PCI) treatment group as compared with the Export Medtronic percutaneous coronary intervention (EM-PCI) treatment group.

EM-PCI as compared with S-PCI. To our knowledge, this is the first study evaluating the effects of thrombectomy on MVO and IS using CE-MRI.

CE-MRI is a noninvasive, high-resolution imaging modality that identifies myocytes necrosis (IS) and microvascular damage (MVO), providing in vivo tissue characterization in patients with myocardial infarction (5,6,11). Poor contrast penetration due to microvascular damage reflects the complex pathophysiological mechanisms of no-reflow, from endothelial cell swelling and contracture to microvascular plugging and microemboli of atherosclerotic debris.

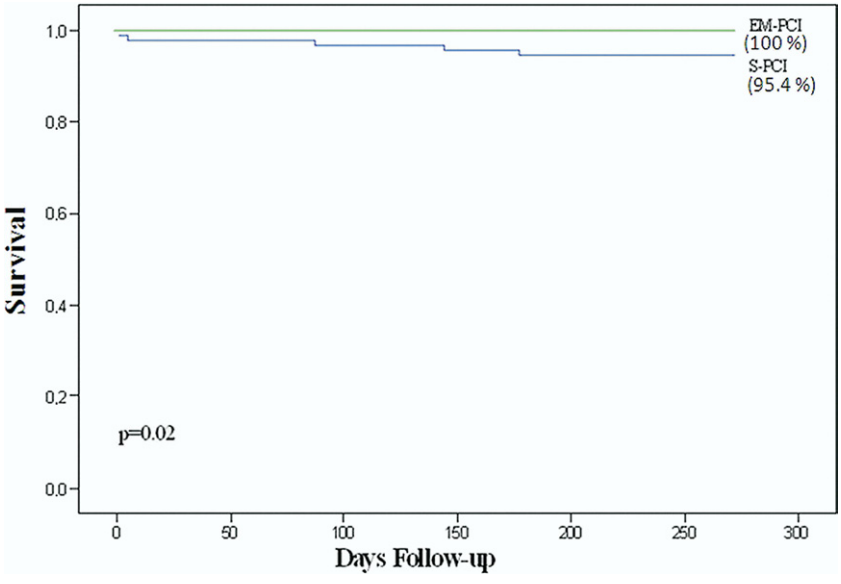

Figure 3 **Kaplan-Meier 9-Month Event-Free Survival for End Point of Death**

Kaplan-Meier analysis shows 9-month event-free survival for the end point of death in the standard percutaneous coronary intervention (S-PCI) treatment group as compared with the Export Medtronic percutaneous coronary intervention (EM-PCI) treatment group.

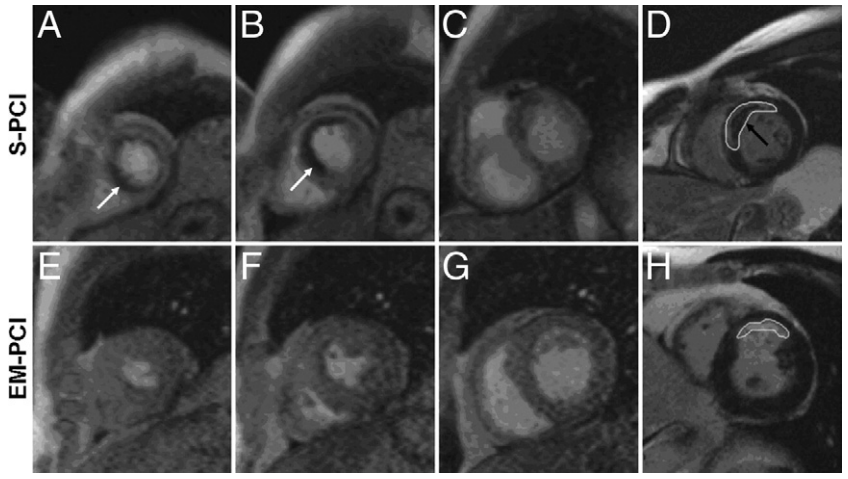

Figure 4 Cardiovascular MRI

(A to C, E to G) Short-axis rest perfusion images acquired at the apical, mid-cavity, and basal level. **(D, H)** Short-axis contrast-enhanced magnetic resonance imaging (CE-MRI) scans with infarct planimetry. The patient in the standard percutaneous coronary intervention (S-PCI) group shows microvascular obstruction (MVO) in the apical and mid-cavity slices **(A and B, white arrows)** that persists in the CE-MRI images **(D, black arrow)** within the septal and anterior infarction (planimetered area). The patient in the Export Medtronic percutaneous coronary intervention (EM-PCI) group has no MVO in the rest perfusion images **(E to G)**. The CE-MRI image **(H)** shows an anterior infarction (planimetered area).

Mechanical thrombus removal followed by direct stenting may explain the better results obtained in EM-PCI. Conversely, mechanical damage occurring during pre-dilation may explain the higher incidence and extent of MVO and IS detected in S-PCI.

Infarct shrinkage at 5 months was reported by Ingkanisorn et al. (12) and Baks et al. (5) (34% and 31% decrease in IS, respectively). In our study, IS decreased at 3 months, by 35% in the EM-PCI group and by 7% in the S-PCI group. In this latter group, impaired restoration of normal blood flow may have led to inadequate scar healing. The smaller definitive IS may explain the lower incidence of MACE and the higher survival observed in the EM-PCI group. Recently, the TAPAS (Thrombus Aspiration During Percutaneous Coronary Intervention in Acute Myocardial Infarction Study) trial showed a surprisingly low rate of death in the thrombus aspiration group at 30 days and at 1-year follow-up (13). Improved myocardial reperfusion and higher infarct shrinkage achieved by EM-PCI is likely related to a protective effect of thrombus aspiration on microvascular flow and might explain the significantly lower incidence of cardiac death in the EM-PCI group. These findings are valuable in spite of the fact that the study was not powered to assess MACE.

In our cohort of patients, we did not observe significant LV remodeling at 3 months. In agreement with Galiuto et al. (14), there was a trend toward higher increase in end-diastolic volumes with S-PCI. However, in our study population, IS was relatively small; prompt revascularization and use of state-of-the-art pharmacological therapy could partially account for this.

Study limitations. This study represents a single-center experience with a limited number of patients. Assessing MVO only on the 3 short-axis rest perfusion slices (basal, mid, and apical) is likely to underestimate the size of MVO.

Table 4 Cardiac Magnetic Resonance Imaging Results

	Acute Phase			3-Month Follow-Up		
	S-PCI (n = 37)	EM-PCI (n = 38)	p Value	S-PCI (n = 36)	EM-PCI (n = 36)	p Value
EDV, ml	137.5 ± 18.6	131.5 ± 14.4	0.1	144.5 ± 20.3	136.2 ± 19.9	0.08
ESV, ml	77.4 ± 15.4	71.3 ± 17.3	0.1	76.1 ± 16.5	69.3 ± 17.7	0.09
EF, %	44.3 ± 9.5	46.3 ± 8.6*	0.3	46.7 ± 10.6	49.0 ± 9.3*	0.3
IS, %	13 ± 6.7	14 ± 12†	0.6	11 ± 8.7	9 ± 4.5†	0.2
IS, g	14 ± 7.5	17 ± 15‡	0.2	13 ± 12	11 ± 8.7‡	0.4
MVO, n	27 (72.9%)	9 (31.5%)	0.0005	—	—	—
MVO, g	3.7 ± 2.6	1.7 ± 1.9	0.0003	—	—	—

*p = 0.08. †p = 0.001. ‡p = 0.004.
EDV = end-diastolic volume; EF = ejection fraction; ESV = end-systolic volume; IS = infarction size; MVO = microvascular obstruction; other abbreviations as in Table 1.

Some authors have recently observed the presence of MVO in the delayed enhancement images (15). However, the classical definition of MVO by cardiac MRI is made on the basis of the images acquired early after contrast injection, either first-pass imaging, as used in our study, or images acquired 1 to 3 min after contrast injection (6). The MVO represents areas of poor contrast penetration, but these areas usually fill in over time. Therefore, assessing MVO in the late images could also potentially underestimate the areas of MVO. In fact, in the time frame of 15 min (as opposed to 1 to 3 min), these areas of poor contrast penetration could fill in with contrast. Both methods of first-pass perfusion with 3 representative short-axis slices or complete short-axis stack acquired at 15 min after contrast injection present some advantages and limitations.

Conclusions

Manual aspiration thrombectomy preserves microvascular integrity and reduces final IS after STEMI; thus, it may represent a useful adjunct to pharmacotherapy. Based on our findings, CE-MRI could provide a very useful tool for large clinical trials.

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Key Words: myocardial infarction ■ magnetic resonance imaging ■ microcirculation ■ infarct size.