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CLINICAL RESEARCH **Interventional Cardiology**

Thrombus Aspiration Before Primary Angioplasty Improves Myocardial Reperfusion in Acute Myocardial Infarction

The DEAR-MI (Dethrombosis to Enhance Acute Reperfusion in Myocardial Infarction) Study

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OBJECTIVES This study sought to test the hypothesis that thrombus removal, with a new manual thrombus-aspirating device, before primary percutaneous coronary intervention (PPCI) may improve myocardial reperfusion compared with standard PPCI in patients with ST-segment elevation acute myocardial infarction (STEMI).

BACKGROUND In STEMI patients, PPCI may cause thrombus dislodgment and impaired microcirculatory reperfusion. Controversial results have been reported with different systems of distal protection or thrombus removal.

METHODS One-hundred forty-eight consecutive STEMI patients, admitted within 12 h of symptom onset and scheduled for PPCI, were randomly assigned to PPCI (group 1) or manual thrombus aspiration before standard PPCI (group 2). Patients with cardiogenic shock, previous infarction, or thrombolytic therapy were excluded. Primary end points were complete (>70%) ST-segment resolution (STR) and myocardial blush grade (MBG) 3.

RESULTS Baseline clinical and angiographic characteristics were similar in the 2 groups. Comparing groups 1 and 2: complete STR 50% versus 68% ($p < 0.05$); MBG-3 44% versus 88% ($p < 0.0001$); coronary Thrombolysis In Myocardial Infarction (TIMI) flow grade 3 78% versus 89% (p = NS); corrected TIMI frame count 21.5 ± 12 versus 17.3 ± 6 ($p < 0.01$); no reflow 15% versus 3% ($p < 0.05$); angiographic embolization 19% versus 5% ($p < 0.05$); direct stenting 24% versus 70% ($p < 0.0001$); and peak creatine kinase-mass band fraction 910 ± 128 μg/l versus 790 ± 132 μg/l ($p < 0001$). In-hospital clinical events were similar in the 2 groups. After adjusting for confounding factors, multivariate analysis showed thrombus aspiration to be an independent predictor of complete STR and MBG-3.

CONCLUSIONS Manual thrombus aspiration before PPCI leads to better myocardial reperfusion and is associated with lower creatine kinase mass band fraction release, lower risk of distal embolization, and no reflow compared with standard PPCI. (Thrombus Aspiration Before Standard Primary Angioplasty Improves Myocardial Reperfusion in Acute Myocardial Infarction; http://clinicaltrials.gov/ct/show/NCT00257153). (J Am Coll Cardiol 2006;48: 1552–9) © 2006 by the American College of Cardiology Foundation

In the last few years, mechanical reperfusion has proven to be a superior treatment strategy compared with systemic thrombolysis in patients with ST-segment elevation acute myocardial infarction (STEMI) (1). In addition, several studies suggest that better short- and long-term results can be obtained with additional stenting and abciximab (2–5), which are part of standard STEMI treatment in most centers. Nevertheless, the presence of a large thrombus load at the lesion site may provide an increased risk of distal embolization of thrombotic or plaque material during balloon inflation or stent deployment (6–12), with possible reduction of distal flow or no reflow and further infarct extension. Angiographic evidence of distal embolization in patients treated with primary angioplasty (PPCI) occurs in about 15% of patients and is associated with more extensive myocardial damage and worse outcome (12).

Restoration of normal flow in the epicardial infarct-related artery (IRA) is not always indicative of myocardial salvage (13,14). Even in the presence of normal epicardial flow, impaired myocardial perfusion assessed with contrast echocardiography (15,16) or angiographic myocardial blush grade (MBG) (14,17) after PPCI is associated with poor recovery of ventricular function and is an independent predictor of long-term mortality. On the other hand, although the resolution of ST-segment elevation (STR) correlates with IRA patency (18), its absence does not

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Abbreviations and Acronyms

CI = confidence interval
CK-MB = creatine kinase mass band fraction
ECG = electrocardiogram
IRA = infarct-related artery
MBG = myocardial blush grade
PPCI = primary percutaneous coronary intervention
STmax = maximal ST-segment elevation
STEMI = ST-segment elevation acute myocardial infarction
STR = ST-segment resolution
TIMI = Thrombolysis In Myocardial Infarction

predict an occluded artery (19). However, several studies suggest that STR failure indicates inadequate myocardial reperfusion and is associated with poor recovery of left ventricular function and increased mortality, even in the presence of patent IRA (18,20–24). In recent years, controversial results on myocardial reperfusion have been reported with different strategies of mechanical distal protection or thrombus removal (25–30). This study was designed to test the hypothesis that thrombus aspiration before standard PPCI may improve myocardial reperfusion as compared with the standard procedure.

METHODS

Patient population. Between March 2004 and June 2005, 160 consecutive STEMI patients undergoing primary angioplasty within 12 h of symptom onset were randomized to standard PPCI, including stenting and abciximab, or thrombus aspiration before standard PPCI. Inclusion criteria were continuous chest pain ≥30 min, ST-segment elevation >0.1 mV (0.2 mV in case of anterior leads) in ≥3 contiguous leads on a 12-lead electrocardiogram (ECG), and technical feasibility for primary angioplasty independently of initial Thrombolysis In Myocardial Infarction (TIMI) flow or angiographic evidence of intraluminal thrombus in the culprit artery. Exclusion criteria were cardiogenic shock, previous myocardial infarction or coronary bypass surgery, bundle branch block or pacemaker-induced rhythm on admission ECG, and contraindication to glycoprotein IIb/IIIa inhibitors.

The study protocol was approved by the local ethics committee, and informed consent was obtained from all patients.

Procedure and device description. After enrollment, patients were 1:1 randomly assigned to standard angioplasty with stenting and abciximab (group 1) or thrombus aspiration plus standard angioplasty (group 2).

Thrombus aspiration was performed using the Pronto extraction catheter (Vasc.solutions, Minneapolis, Minnesota). The device (Fig. 1) is a simple, dual-lumen, monorail design, 6-F compatible catheter. The smaller lumen is to accommodate a standard 0.014-inch guidewire. The larger extraction lumen allows the removal of thrombus, which is aspirated with a 30-ml locking vacuum syringe. The catheter has a rounded distal tip designed to maximize thrombus aspiration and to protect the vessel wall while advancing and during aspiration.

After crossing the culprit lesion with a standard guidewire, several passages across the lesion were performed by slowly advancing the catheter. Predilatation was performed with a 2-mm balloon catheter only when the initial attempt failed to cross the lesion. Subsequently, direct stenting was recommended to all patients. Before intervention, all patients received aspirin and heparin (60 U/kg). Glycoprotein IIb/IIIa inhibitors were used in all patients before the procedure.

Angiographic analysis. Coronary angiograms were performed using a digital technique (Integris 3000, Philips Medical Systems, Best, the Netherlands). At least 2 orthogonal projections of the coronary segment scheduled for coronary intervention were filmed before and after the

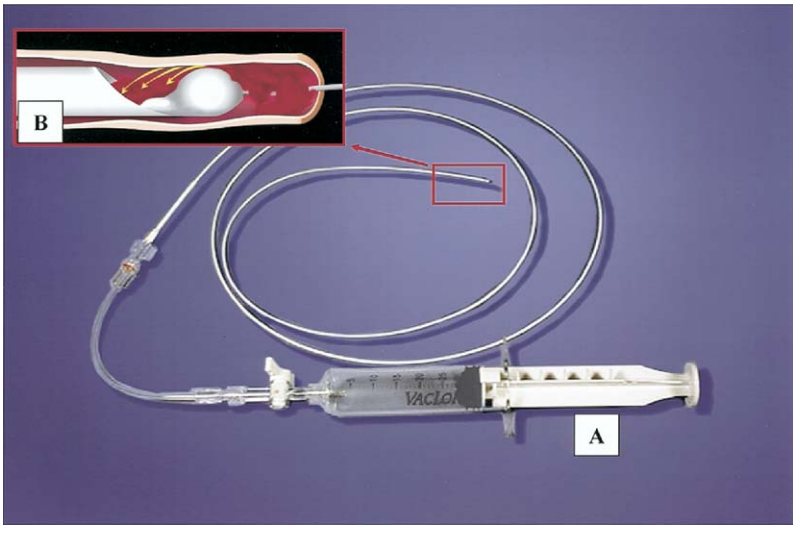

Figure 1. The dual-lumen extraction catheter (Pronto) with the proximal locking vacuum syringe **(A)** and the tip of the device **(B)**; see text for explanations.

JACC Vol. 48, No. 8, 2006
October 17, 2006:1552–9

intervention. Each angiogram was preceded by intracoronary injection of nitrates (Nitroglycerin 100 to 200 μg). Quantitative coronary analysis was performed using the Coronary Quantification Package (Philips Medical Systems, Eindhoven, the Netherlands). At least 1 film after complete treatment included the myocardial territory of contrast distribution to allow estimation of TIMI flow (23-inch field) and MBG (23-inch field). Views were chosen to minimize superimposition of noninfarcted territories in the assessment of the MBG: laterolateral view for the left anterior descending coronary, right anterior oblique 45° view for the right coronary artery, and laterolateral or right anterior oblique 45° (in the presence of big marginal branch) views for the circumflex artery were used in most cases. The duration of cine filming was long enough to see some filling of the venous system to evaluate the washout phase of contrast dye. To facilitate the subjective grading of MBG, angiograms were digitized and a logarithmic nonmagnified mask-mode background substraction was applied to the image subset to eliminate noncontrast medium densities. Final analysis of TIMI flow grade, corrected TIMI frame count, and MBG was carried out by 2 experienced cardiologists (P.C. and P.S.) who were blinded to the study database, according to standard methods (14,31,32).

Coronary TIMI flow and MBG of 50 qualifying angiograms were analyzed, and both observers categorized the TIMI flow grade into TIMI 3, 2, and 0/1 and the MBG into 3, 2, and 0/1. The interobserver agreement was calculated with weighted k statistics, which resulted in a k value of 0.91 (95% confidence interval [CI] 0.78 to 1.03) for TIMI flow and 0.85 (95% CI 0.70 to 0.99) for MBG. Disagreement was resolved by consensus.

Electrocardiographic analysis. A 12-lead ECG was recorded at admission, at the end of the procedure, and at 90 min and 24 h after the procedure. Two observers blinded to randomization and angiographic results analyzed ECG recordings. The ST score, defined as the sum of ST-segment elevation measured at 20 ms from the J-point in the leads V_1 to V_6, I, and aVL for anterior and D_2, D_3, aVF, and V_5 to V_6 for nonanterior infarctions, as well as maximal ST-segment (STmax) elevation in the worst single lead were calculated in all patients. Reciprocal changes of ST-segment depression were not considered. Percent ST score and STmax resolution was calculated from admission and post-PPCI ECG and categorized as complete (>70%), partial (30% to 70%) and no reperfusion (<30%), as previously suggested (18). Interobserver agreement in ECG reading was evaluated by k statistics in 50 admission and post-PPCI ECGs: k value was 0.90 (95% CI 0.77 to 1.03). Disagreement was resolved by consensus.

Enzymatic infarct size. Infarct size was estimated by measurement of enzyme activity by using creatine kinase mass band fraction (CK-MB) as a reference. The enzymatic activity was reported as μg/l, and was assessed every 6 h in the first 48 h after admission. Peak release value from 8 serial measurements up to 48 h after admission is reported.

Study end points. The primary end point of this study was the achievement of myocardial reperfusion, defined by postprocedural complete (>70%) ST-segment resolution and post-PPCI MBG-3. Prespecified secondary end points were the comparison between the incidence of angiographic distal embolization and no reflow, peak of CK-MB release, and direct stenting in the 2 groups. Information on the in-hospital and 30-day occurrence of adverse events including death, nonfatal reinfarction, new hospitalization for heart failure, target vessel revascularization, stroke, and major bleedings was also collected.

Definitions. Cardiogenic shock was defined as hypotension with systolic blood pressure <90 mm Hg and tachycardia >100 beats/min, not caused by hypovolemia and requiring inotropic support or balloon counterpulsation.

Technical success of thrombectomy (device success) was defined as the ability of the device to cross the target lesion and to increase TIMI flow by >1.

Procedural success of the intervention was defined by the achievement of a final TIMI flow grade ≥2 and a residual stenosis <20%.

The diagnosis of reinfarction was supported by either ECG changes (new onset, significant Q waves in at least 2 ECG leads, recurrent or increased ST-segment elevation in the previous infarct leads, or new-onset ST-segment elevation in different ECG leads) accompanied by ≥30 min chest pain or cardiac enzyme release (CK-MB >50% above the prior level) occurring >24 h after coronary revascularization.

Distal embolization was defined as the migration of a filling defect or the distal occlusion of the target vessel or one of its branches at the end of or during the procedure.

No reflow was defined as a TIMI flow grade <2 not attributable to dissection, occlusive thrombosis, or epicardial spasm.

Statistical analysis. The target sample size was calculated on an assumption of a 30% improvement in the ST reduction in the study arm considering a 50% complete ST-segment resolution in the control arm (13,24,33). We estimated that 75 patients would be required in each group to have a power of 90% to detect an absolute difference in the occurrence of complete ST-segment resolution with a 2-sided alpha value of 0.05. Considering a 10% drop-out or lose to lecture, we planned to enroll a total of 160 patients. All analyses were performed according to the intention-to-treat principle. Categorical variables are presented as frequency values and were compared by chi-square test. Continuous variables are expressed as mean values ± SD, and were compared with Student *t* test or analysis of variance as appropriate. Stepwise logistic regression analysis was performed to identify the independent predictors of MBG-3 and complete ST-segment resolution after the procedure. The following variables were entered into model: age >65 years, hypertension, diabetes, infarct location, Killip class >2, ischemic time (from symptom onset to wire crossing), procedure duration (from arrival to the angiographic room to last

Table 1. Baseline Clinical and Angiographic Characteristics

	Thrombus Removal	No Thrombus Removal	p Value
Patients, n	74	74	
Age (yrs)	57.3 ± 13	58.9 ± 14	0.472
Male gender	62 (84%)	56 (76%)	0.314
Diabetes	16 (21%)	11 (15%)	0.465
Hypertension	28 (37%)	32 (46%)	0.349
Dyslipidemia	26 (34%)	18 (25%)	0.309
Smoking habit	38 (54%)	43 (60%)	0.571
Killip class >1	8 (11%)	4 (5%)	0.297
Anterior infarction	32 (42%)	38 (51%)	0.355
Ejection fraction	53 ± 7%	51 ± 9%	0.133
Ischemic time (min)	206 ± 115	199 ± 124	0.722
Target vessel			
LAD	32 (43%)	38 (51%)	0.420
LCX	7 (10%)	10 (14%)	0.623
RCA	35 (47%)	26 (35%)	0.191
CAD extension			
1 vessel	36 (49%)	36 (49%)	0.876
2 vessels	23 (31%)	24 (32%)	0.965
3 vessels	15 (20%)	14 (19%)	0.958
TIMI flow grade			
0/1	60 (81%)	54 (73%)	0.657
2	12 (16%)	16 (22%)	0.646
3	2 (3%)	4 (5%)	0.822

CAD = coronary artery disease; LAD = left anterior descending coronary artery; LCX = left circumflex coronary artery; RCA = right coronary artery; TIMI = Thrombolysis In Myocardial Infarction.

angiogram), heart rate at admission, multivessel disease, occluded IRA at baseline (TIMI 0/1), angiographic evidence of thrombus, presence of collaterals, direct stenting, and use of aspiration catheter.

A value of $p < 0.05$ was interpreted as statistically significant. Statistical analysis was performed using SPSS 11.0 (SPSS Inc., Chicago, Illinois) and S-plus (release 2000) statistical package (Insightful Corporation, Seattle, Washington) and the Harrell's Design and Hmisc libraries were used for analysis.

The authors had full access to the data and take responsibility for its integrity. All authors have read and agree to the manuscript as written.

RESULTS

Twelve (12.5%) of the 160 patients who were initially enrolled were dropped out because of protocol reasons unknown at the moment of randomization (need for coronary surgery in 6, previous infarction in 2, previous angioplasty with stenting in 1, distal embolization on the basal angiogram in 1, no significant ST-segment deviation in 1, and cardiogenic shock in 1). Thus, the final population consisted of 148 patients who were allocated to the 2 treatment groups. In 7 of the 74 patients assigned to group 2, aspiration was not performed because of technical reasons, whereas 3 of the 74 patients assigned to standard PCI underwent aspiration to remove residual thrombus after stenting. There were no significant differences in baseline clinical and angiographic characteristics between the 2 groups (Table 1).

Procedural data and angiographic analysis. Procedural data are reported in Table 2. All patients received glycoprotein IIb/IIIa inhibitors, and a stent was positioned in all but 3 patients (2 in the control and 1 in the aspirated group). In case of multivessel coronary artery disease, only the culprit vessel was treated during the initial PPCI. Stent length, number of stents per patient, and stent/vessel ratio

Table 2. Procedural Data and Angiographic Results

	Thrombus Removal	No Thrombus Removal	p Value
Patients, n	74	74	
Glycoprotein IIb/IIIa inhibitors	100	100	—
Stenting	73 (99%)	72 (97%)	—
Direct stenting	52 (70%)	18 (24%)	<0.0001
Stent length (mm)	21.1 ± 8.7	20.9 ± 9.5	0.841
Reference diameter post-PPCI (mm)	3.3 ± 0.46	3.2 ± 0.43	0.174
Minimal lumen diameter post-PPCI (mm)	3.3 ± 0.41	3.1 ± 0.61	0.020
% vessel stenosis post-PPCI	0.27 ± 1.64	1.3 ± 8.49	0.307
TIMI flow grade pre-PPCI	0.52 ± 0.86	0.71 ± 0.99	0.214
TIMI flow grade post-PPCI	2.87 ± 0.36	2.68 ± 0.5	0.008
TIMI flow grade 3 post-PPCI	66 (89%)	58 (78%)	0.119
Corrected TIMI frame count post-PPCI	17.3 ± 6	21.5 ± 12	0.007
Procedural time (min)	57 ± 19	54 ± 21	0.363
Procedural success	74 (100%)	73 (99%)	0.767
Device success	66 (89%)	—	—
Myocardial blush grade post-PPCI			
0/1	0 (0%)	5 (6%)	0.098
2	9 (12%)	37 (50%)	<0.0001
3	65 (88%)	32 (44%)	<0.0001
Distal embolization	4 (5%)	14 (19%)	0.019
No reflow	2 (3%)	11 (15%)	0.024
Peak CK-MB	790 ± 132	910 ± 128	<0.0001

CK-MB = creatinine kinase-mass band fraction; PPCI = primary percutaneous coronary intervention; TIMI = Thrombolysis In Myocardial Infarction.

JACC Vol. 48, No. 8, 2006
October 17, 2006:1552–9

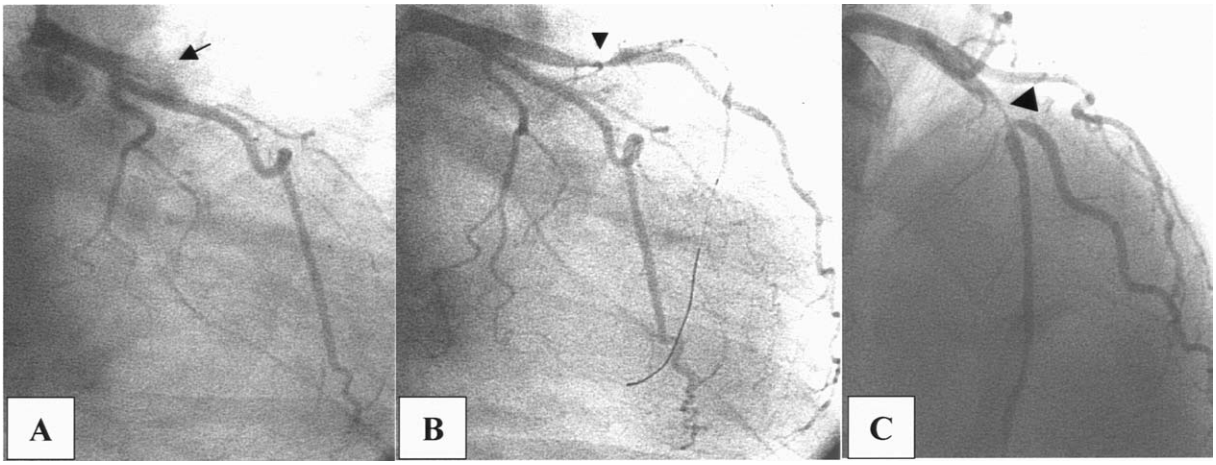

Figure 2. Coronary angiogram in acute anterior myocardial infarction. The basal angiogram **(A)** shows total occlusion of the left anterior descending artery (LAD) with thrombus image bulging into the left main artery **(arrow)**. After thrombus removal **(B and C)**, the culprit lesion **(arrowheads)** is observed in the mid-LAD more than 20 mm distal to the original occlusion site.

were similar between both groups. Procedural success was obtained in all patients with thrombus aspiration and in 73 (99%) of the 74 patients treated with standard PPCI. Postprocedural percent stenosis, minimal luminal diameter, and reference vessel diameter were similar in the 2 groups. Stent implantation without predilation was possible in 70% of patients with thrombus aspiration and in 24% of those with standard PCI ($p < 0.0001$).

Thrombus aspiration. Technical success of thrombectomy was observed in 89% of patients assigned to thrombus aspiration (Table 2). Failure was caused by the impossibility of crossing the target lesion because of iliac or coronary tortuosity, tight lesion, or both in 7 and no change in TIMI flow after aspiration in 1 patient.

After aspiration, TIMI flow grade increased from 0.5 ± 0.86 to 2.87 ± 0.36 ($p < 0.01$). Final TIMI flow and corrected TIMI frame count significantly improved in patients with thrombus removal in comparison with standard PCI: 2.87 ± 0.36 frames versus 2.68 ± 0.5 frames ($p < 0.01$); and 17.3 ± 6 frames versus 21.5 ± 12 frames ($p < 0.01$), respectively. In particular, TIMI flow increased by 1 grade in 17.6% versus 20.2% (p = NS), by 2 grades in 21.6% versus 28.4% (p = NS), and by 3 grades in 58.1% versus 39.2% ($p < 0.05$) of patients. One patient from each treatment group showed persistent TIMI flow grade 1 after the procedure, whereas no patient showed persistent TIMI flow grade 0. In 20% of patients, after thrombus removal, the culprit lesion was located distal to the initial occlusion site, in some cases more than 20 mm, changing the technical approach to the procedure (Fig. 2). Macroscopic aspirated material was observed in 70 of 74 (95%) patients. Angiographic transient no reflow and distal embolization were significantly less frequent in group 2 than in group 1: 3% versus 15% ($p < 0.05$) and 5% versus 19% ($p < 0.05$), respectively. Coronary perforation or intimal dissection were not observed.

Myocardial reperfusion. The ECG results are reported in Table 3. Complete ST-segment resolution (>70%) was significantly more frequent in group 2 than in group 1 evaluated as score (68% vs. 50%, $p < 0.05$) or STmax (68% vs. 50%, $p < 0.05$). By multivariate analysis, thrombus removal was independently associated with

Table 3. Electrocardiographic Analysis

	Thrombus Removal	No Thrombus Removal	p Value
Patients, n	74	74	
ST-segment score pre-PPCI (mm)	13.75 ± 10.37	12.60 ± 8.9	0.470
ST-segment score post-PPCI (mm)	3.98 ± 5.17	4.88 ± 5.3	0.297
ST-segment resolution score			
Complete (>70%)	50 (68%)	37 (50%)	0.043
Partial (30–70%)	21 (28%)	26 (35%)	0.639
None (<30%)	3 (4%)	11 (15%)	0.046
Maximum ST-segment elevation pre-PPCI (mm)	4.6 ± 2.71	4.52 ± 2.52	0.852
Maximum ST-segment elevation post-PPCI (mm)	1.45 ± 1.69	1.68 ± 1.72	0.413
Maximum ST-segment resolution			
Complete (>70%)	50 (68%)	37 (50%)	0.041
Partial (30–70%)	21 (28%)	27 (36%)	0.388
None (<30%)	3 (4%)	10 (13%)	0.096

PPCI = primary percutaneous coronary intervention.

ST-segment resolution considered as score (odds ratio 1.77, 95% CI 0.89 to 3.52) or STmax (odds ratio 2.11, 95% CI 1.03 to 4.3).

The MBG was significantly higher among patients treated with thrombus aspiration compared with conventional PCI: 2.84 ± 0.32 versus 2.38 ± 0.59 ($p < 0.001$). In particular, final MBG-3 was observed in 88% versus 44% ($p < 0.0001$), respectively, in the 2 groups.

After adjusting for potentially confounding covariates, multivariate analysis showed thrombus aspiration (odds ratio 15.37, 95% CI 5.49 to 43) and the duration of the procedure (odds ratio 0.31, 95% CI 0.16 to 0.60) to be the only independent predictors of MBG-3.

The peak CK-MB release was significantly lower in patients with thrombus removal compared with the control group: 790 ± 132 μg/l vs. 910 ± 128 μg/l ($p < 0.0001$).

Clinical outcomes. In-hospital occurrence of death, reinfarction, left ventricular failure, and new revascularization were similar in the 2 groups. No death or reinfarction was observed during the hospital stay. In the thrombus aspiration group, 1 patient needed a new PCI of the target vessel. In the control group, 1 patient had left ventricular failure.

DISCUSSION

Thrombus removal, epicardial flow, and myocardial reperfusion. Currently, PPCI with stent and abciximab is considered the treatment of choice in patients with acute myocardial infarction (1–3). However, myocardial reperfusion assessed with angiographic (14) and electrocardiographic (34) parameters is not always achieved. Thrombus and plaque embolization is one of the mechanisms affecting myocardial reperfusion by inducing capillary obstruction, endothelial dysfunction, and inflammation (35,36) and is associated with a poor long-term outcome (12).

The present randomized study included all consecutive patients with STEMI presenting within 12 h from symptom onset independently of the angiographic evidence of thrombus, assuming that thrombus is always present in a recent myocardial infarction. Cardiogenic shock, previous infarction, and bypass surgery were regarded as exclusion criteria to minimize the risk of misinterpretation in the assessment of angiographic reperfusion. The main finding was that thrombus aspiration was associated with a better epicardial flow, significant improvement of myocardial reperfusion, and reduction of peak CK-MB release. In addition, it conveyed a significantly lower risk of distal embolization and no reflow. Thus, it seems that effective thrombus removal by manual aspiration at the lesion site improves myocardial reperfusion by reducing distal embolization occurring during mechanical revascularization. We previously found (37) severe and diffuse coronary flow impairment after stenting in patients treated with PPCI despite the use of distal protection with a filter. This may suggest a role of humoral mediators released from the thrombus during stenting.

Technical changes during angioplasty. In keeping with previous reports (25–27), the present study shows that thrombus removal allows direct stenting in a significantly higher proportion of patients. The higher rate of direct stenting could have played a role in the reperfusion benefit observed in the aspirated group. However, the multivariate analysis showed thrombus aspiration, but not direct stenting, to be independently associated with reperfusion. Direct stenting avoids unnecessary manipulation of the lesion and diminishes the use of balloons. In addition, the culprit lesion was located distally to the initial occlusion site in 20% of patients treated with thrombus removal. When the initial occlusion is at an important bifurcation site (Fig. 2), thrombus removal may avoid acute complications and improve the long-term result.

Although the aspirated thrombus was very proximal to the lesion and direct stenting should result in shorter stent coverage in many cases, we did not observe a significant difference in stent length between the 2 groups. This likely could be explained by the common approach to the procedure, which included a full coverage of the lesion starting from the occlusion site.

Differently from other studies with distal protection using the GuardWire (Medtronic Corp., Santa Rosa, California) (28) or thrombus removal with X-Sizer (ev-3, White Bear Lake, Minnesota) (26), which included an additional procedural time of 10 to 20 minutes, the duration of the procedure was similar in the 2 groups of our study.

Comparison with other studies. In the present study, the rate of MBG-3 (88%) and complete ST-segment resolution (68%) after thrombus removal was higher compared with previous reports on conventional angioplasty (14,24). A large multicenter randomized trial with a distal balloon occlusion and aspiration system (28) showed that distal protection and retrieval of embolic debris did not result in improvement of myocardial reperfusion or infarct size. Other recent randomized trials comparing thrombectomy with the X-Sizer device and conventional angioplasty have shown a higher rate of MBG-3 and >50% ST-segment resolution in patients treated with thrombus removal (25,26). Two randomized studies using AngioJet (POSSIS Medical Inc., Minneapolis, Minnesota) have shown controversial results in myocardial reperfusion and infarct size reduction (29,30). Differences in patient selection (inclusion of patients with previous infarction, bypass surgery, or treatment with fibrinolytic agents), procedural duration, and type of device could explain in part these discrepancies. More recently, Burzotta et al. (27) reported the results of a randomized trial on thrombus removal versus conventional angioplasty with a different manual aspiration system in patients with STEMI. They found a significant improvement in complete (>70%) ST-segment resolution (58% vs. 36%) and MBG >2 (68% vs. 45%). The

evidence of better reperfusion observed in the present study could be explained, at least in part, by differences in patient selection. In fact, although the angiographic evidence of thrombus was not an inclusion/exclusion criteria in both studies, patients with previous infarction, cardiogenic shock, and previous thrombolysis were not included in our study, although they account for >30% of patients in the REMEDIA (Randomized Evaluation of the Effect of Mechanical Reduction of Distal Embolization by Thrombus Aspiration in Primary and Rescue Angioplasty) trial (27).

Study limitations. The study reflects a single-center experience and was not designed to test differences in clinical outcome. In fact, it dealt with a low-risk population with a short follow-up period and no in-hospital mortality. Another limitation is that the study did not include the entire STEMI population, particularly patients with shock, previous infarction, bypass surgery, or previous treatment with fibrinolytic agents.

Conclusions. In selected patients, thrombus aspiration with the Pronto catheter in the setting of primary angioplasty is a simple and safe procedure. It improves myocardial reperfusion as assessed by myocardial blush and ST-segment resolution. It is associated with a lower CK-MB release and a lower rate of distal embolization and no reflow. Larger randomized trials are warranted to address the impact of thrombus removal on clinical outcome.

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