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X-Sizer for Thrombectomy in Acute Myocardial Infarction Improves ST-Segment Resolution

Results of the X-Sizer in AMI for Negligible Embolization and Optimal ST Resolution (X AMINE ST) Trial

Thierry Lefèvre, MD,* Eulegio Garcia, MD,† Bernhard Reimers, MD,‡ Iréne Lang, MD,§ Carlo di Mario, MD,‖ Antonio Colombo, MD,¶ Franz-Joseph Neumann, MD,# Mariano Valdés Chavarri, MD,** Philippe Brunel, MD,†† Eberhart Grube, MD,‡‡ Martin Thomas, MD,§§ Bernard Glatt, MD,‖‖ Joseph Ludwig, MD,¶¶ on behalf of the X AMINE ST Investigators

Massy, Nantes, and Saint-Denis, France; Madrid and Murica, Spain; Mirano and Milano, Italy; Vienna, Austria; Bad Krozingen, Siegburg, and Erlangen, Germany; and London, United Kingdom

OBJECTIVES We sought to compare, in a prospective randomized multicenter study, the effect of adjunctive thrombectomy using X-Sizer (eV3, White Bear Lake, Minnesota) before percutaneous coronary intervention (PCI) versus conventional PCI in patients with acute myocardial infarction (AMI) for <12 h and Thrombolysis In Myocardial Infarction (TIMI) flow grade 0 to 1. The primary end point was the magnitude of ST-segment resolution after PCI.

BACKGROUND Despite a high rate of TIMI flow grade 3 achieved by PCI in patients with AMI, myocardial reperfusion remains relatively low. Distal embolization of thrombotic materials may play a major role in this setting.

METHODS We conducted a prospective, randomized, multicenter study in patients with AMI <12 h and initial TIMI flow grade 0 to 1 who were treated with primary PCI. The magnitude of ST-segment resolution 1 h after PCI was the primary end point.

RESULTS A total of 201 patients were included. Treatment groups were comparable by age (61 ± 13 years), diabetes (22%), previous MI (8%), anterior MI (52%), onset-to-angiogram (258 ± 173 min), and glycoprotein IIb/IIIa inhibitor use (59%). The magnitude of ST-segment resolution was greater in the X-Sizer group compared with the conventional group (7.5 vs. 4.9 mm, respectively; $p = 0.033$) as ST-segment resolution >50% (68% vs. 53%; $p = 0.037$). The occurrence of distal embolization was reduced (2% vs. 10%; $p = 0.033$) and TIMI flow grade 3 was obtained in 96% vs. 89%, respectively ($p = 0.105$). Myocardial blush grade 3 was similar (30% vs. 31%; p = NS). Six-month clinical outcome was comparable (death, 6% vs. 4% and major adverse cardiac and cerebral events, 13% vs. 13%, respectively). By multivariate analysis, independent predictors of ST-segment resolution >50% were: younger age, non-anterior MI, use of the X-Sizer, and a short time interval from symptom onset.

CONCLUSIONS Reducing thrombus burden with X-Sizer before stenting leads to better myocardial reperfusion, as illustrated by a reduced risk of distal embolization and better ST-segment resolution. (J Am Coll Cardiol 2005;46:246–52) © 2005 by the American College of Cardiology Foundation

Percutaneous coronary intervention (PCI) and stenting currently are considered the gold standard treatment (1) in patients with acute myocardial infarction (AMI). This treatment has been shown to increase the rate of acute Thrombolysis In Myocardial Infarction (TIMI) flow grade 3 of the infarct-related artery (IRA) (2,3), which is correlated with better mid- and long-term outcomes. However, TIMI flow grade 3 is only the tip of the iceberg, and a discrepancy between vessel patency and rescue of the jeopardized myocardium after interventional or pharmacologic treatment of AMI has been documented in at least one-third of patients (4–8). This discrepancy between angiographic epicardial flow and myocardial tissue reperfusion is multifactorial (9–13). However, the main issue is probably the occurrence of distal embolization of plaque and thrombus debris, either spontaneously or induced by percutaneous intervention, which may lead to obstruction in distal coronary branches or arterioles, limiting the efficacy and the extent of myocardial tissue reperfusion. In a recent work, Henriques et al. (14) showed that the occurrence of angiographically visible distal embolization during primary PCI was observed in 15% of cases and that it was significantly associated with a high rate of death at five-year follow-up compared with patients who had no distal embolization. New mechanical devices to remove thrombus and to prevent embolization of thrombus and plaque during PCI have become available (15–18), but few randomized studies have been performed in the setting of primary angioplasty (19,20). The present randomized study was designed to evaluate the effects of mechan-

From the *Institut Cardiovasculaire Paris Sud, Massy, France; †Hospital Gregorio Marañon, Madrid, Spain; ‡Ospedale Civile, Mirano, Italy; §AKH, Vienna, Austria; ‖Ospedale San Raffaele, Milano, Italy; ¶Centro Cuore Columbus, Milano, Italy; #Herzzentrum, Bad Krozingen, Germany; **Hospital Universitario 'Virgen de la Arrixaca', Murcia, Spain; ††Clinique Saint Henri, Nantes, France; ‡‡Heart Center Hospital, Siegburg, Germany; §§King's College Hospital, London, United Kingdom; ‖‖Centre Cardiologique du Nord, Saint-Denis, France; and ¶¶Klinikum der Uni, Erlangen, Germany. This study was supported by eV3.

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Abbreviations and Acronyms

AMI = acute myocardial infarction
CI = confidence interval
cTFC = corrected TIMI frame count
ECG = electrocardiogram/electrocardiographic
GP = glycoprotein
IRA = infarct-related artery
MACCE = major adverse cardiac and cerebral events
OR = odds ratio
PCI = percutaneous coronary intervention
TIMI = Thrombolysis In Myocardial Infarction

ical thrombus removal on myocardial tissue reperfusion in patients undergoing primary PCI. Because the mortality rate after primary PCI has become relatively low, we decided to use ST-segment resolution as a surrogate end point, given that it is one of the most sensitive and reliable markers of myocardial reperfusion (21) and has proved to be highly correlated with long-term outcome (22).

METHODS

Study population. Patients suffering an AMI who were amenable to PCI were included in 14 European centers with previous experience in the use of the X-Sizer device (X-Sizer catheter system; eV3, White Bear Lake, Minnesota). The inclusion criterion was AMI for <12 h (i.e., evidence of ischemic chest pain for >30 min and new ST-segment elevation for ≥2 mm in two or more contiguous electrocardiographic [ECG] leads, de novo lesion, single-vessel treatment in a native vessel ≥2.5 mm in diameter and occluded, thrombus-containing, TIMI flow grade 0 to 1 infarct-related artery). Main exclusion criteria were previous PCI in IRA, rescue PCI, Killip class ≥3, left or right bundle branch block, IRA with excessive proximal tortuosity or severe calcification, left ventricular ejection fraction <30%, contraindication to emergency coronary artery bypass grafting, and current participation in another study protocol.

After providing informed consent, patients fulfilling the inclusion and exclusion criteria were assigned randomly 1:1 to intracoronary thrombectomy, followed by PCI and stenting, or to PCI, excluding anything but balloon angioplasty and stent. Glycoprotein (GP) IIb/IIIa inhibitors were used according to the operator's judgment.

Procedure and device description. Thrombectomy was performed using the X-Sizer catheter system. This device is a two-lumen over-the-wire system (available diameters 1.5 and 2.0 mm) with a helical shape cutter at its distal tip. The cutter rotates at 2,100 rpm driven by a hand-held battery motor unit. One catheter lumen is connected to a 250-ml vacuum bottle, and aspirated debris is collected in an in-line filter. Two or more passages across the lesion from proximal to distal were performed by slowly advancing the activated catheter. Subsequently, additional balloon angioplasty or coronary stenting was performed. Before the intervention, all patients received aspirin. Heparin (70 U/kg) was given to maintain an activated clotting time of >250 s.

Angiographic analysis. The coronary angiograms were analyzed by an independent core laboratory (Dr. Glatt, Corisis, St. Denis, France) that was blinded to other data. In compliance with the protocol, the X-Sizer was systematically filmed with the purpose of measuring its effect on TIMI flow grade and thrombus burden and was, therefore, visible by the operator. Quantitative coronary analysis was performed before and after the procedure using the quantification system CMS-View (version 4.0; MEDIS, Leiden, the Netherlands). Angiographic TIMI flow grade was estimated visually, as previously described (23). The corrected TIMI frame count (cTFC) was measured with a frame counter on a digital film viewer analyzing the number of cine frames required for contrast to first reach a standardized distal coronary landmark (24). Recorded cine film speeds were 12.5, or 25 frames/s. All the results were corrected in 33 frames/s. In the presence of an occluded vessel (visual TIMI flow grade 0 to 1), cTFC was set to a value of 100 (25).

The incidence of distal embolization during the procedure also was assessed as previously described by Henriques et al. (14), as well as the occurrence of slow flow (TIMI flow grade decreasing from 3 to 2 during the procedure) or no reflow (TIMI flow grade decreasing from 2 or 3 to 0 or 1 during the procedure). The composite angiographic end point of slow-flow, no reflow, or distal embolization also was assessed. Thrombus burden at the lesion site was graded from 0 to 5 using the TIMI thrombus score (26). Partial thrombus removal after X-Sizer was defined by a reduction by at least one grade but remaining thrombus and complete removal by a reduction of more than one grade with no residual thrombus. All data were determined at baseline, after guidewire positioning, after thrombectomy, and at the end of the procedure. Myocardial blush grade was assessed before and after the procedure by a different independent core laboratory, which originally described the technique (Dr. Suryapranata, Zwolle, the Netherlands) (8).

ECG analysis. In each patient, a 12-lead ECG was recorded at admission, 60 min after the procedure, and at discharge. Electrocardiograms were analyzed by Corisis using the MPTronic ECG analyzer (MPTronic, Paris, France). The algebraic sum of ST-segment elevation and depression 20 ms from the J-point was assessed as previously described by Claeys et al. (22). Scanned images from original recording ECG were used. The image obtained was scaled on the squaring according to the speed and the amplitude of recording. For each lead, the baseline was automatically determined by the software (determination multipoints Iso segment between ST-T and P). For one QRS complex analyzed, the software determines automatically, after manual marking the end of the QRS complex, the time selected for the measurement of ST-segment elevation. The software identified for each derivation the point of intersection corresponding ST-segment and mea-

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sures the height of ST-segment elevation or depression expressed in mV.

Study end points. The primary end point was the magnitude of resolution of the sum of ST-segment before and 1 h after the procedure. Secondary end points were: ST-segment resolution >50%; the occurrence of distal embolization; the composite angiographic end point of slow flow, no reflow, and/or distal embolization; cTFC; myocardial blush score; and the major adverse cardiac and cerebral events (MACCE) at one and six months. Safety end points were defined as the incidence of procedural and six months X-Sizer–related severe adverse events.

Device performance. To assess the performance of the device, the following definitions were used: acute X-Sizer success was defined as successful delivery of the X-Sizer catheter system to the IRA, achieving a TIMI flow grade improvement greater than one grade. Acute procedure success was defined as the achievement of a final diameter stenosis <30% by quantitative coronary analysis with a final TIMI flow grade 3 and no occurrence of slow-flow, no-reflow phenomenon, or distal embolization.

Statistical analysis. The number of patients included in the study was based on the estimation of the sample size needed to identify a significant difference for the primary end point (i.e., the magnitude of ST-segment resolution) and main secondary end point (i.e., the percentage of patients with ST-segment resolution >50%). Under the assumption that the secondary end point is the ratio of complete ST-segment resolution and that a ratio of 65% would be improved by the X-Sizer catheter to 90%, the necessary sample size (based on a two-tailed Fisher exact test, calculated with SAS, version 8.2; SAS Institute, Cary, North Carolina) was calculated to 65 patients in each arm (alpha = 0.05, power = 90%). Considering potential dropouts of patients during the study, the sample size in each arm was increased to 100 patients. All analyses were performed according to the intention-to-treat principle. Categorical variables are presented as frequency values and were compared by using the Fisher exact test. Continuous variables are expressed as mean ± SD and were compared by using the Wilcoxon rank sum test. For the primary end point, the Student *t* test and analysis of variance also were performed. Repeated measures of continuous variables were analyzed by non-parametric repeated measures analysis of variance without correction for multiple comparisons because of their exploratory nature. Multivariate linear regression analysis was performed to identify independent predictors of ST-segment resolution. This model included age, infarct location, diabetes, Killip class, ischemic time, previous myocardial infarction, multivessel disease, use of GP IIb/IIIa inhibitors, direct stenting, and thrombectomy using X-Sizer. A $p \leq 0.05$ was interpreted as statistically significant. Statistical analysis was performed using SAS software.

Study organization. The Data and Safety Monitoring Board and the Clinical Events Committee were separate designated groups of qualified individuals not involved in the study that monitored safety and adjudicated clinical end points, respectively. The angiographic committee was in charge of resolving disagreements between the angiographic core laboratory and the study investigators.

Table 1. Baseline Clinical Characteristics

	No Thrombectomy	Thrombectomy	p Value
Patients, n	101	100	
Age, yrs	62 ± 11	61 ± 13	NS
Female gender, %	27	24	NS
Risk factors, %			
Diabetes	18	25	NS
Hypertension	50	54	NS
Dyslipidemia	61	58	NS
Current smoking	51	52	NS
Previous MI, %	6	10	NS
BMI, kg/m^2	27 ± 4	27 ± 5	NS
Anterior MI, %	50	54	NS
Killip class >I, %	19	18	NS
Onset-to-angiogram, min	264 ± 194	251 ± 151	NS
1-vessel disease, %	58	61	NS
2-vessel disease, %	24	26	NS
3-vessel disease, %	18	13	NS

Continuous data presented as mean ± SD and are compared using the Wilcoxon rank sum test; categorical data are presented as frequency values and are compared using the Fisher exact test.

BMI = body mass index; MI = myocardial infarction; NS = not significant.

RESULTS

Of the 201 patients included in the study, 101 patients were assigned randomly to the control group and 100 patients to the X-Sizer group. There were no significant differences in baseline clinical characteristics between the two groups (Table 1).

Procedural data and angiographic analysis. Procedural data are reported in Table 2. The only differences between both groups was the procedure duration, which was longer in the X-Sizer group compared with the control group (54 ± 28 min vs. 45 ± 25 min, respectively; p = 0.003) and the rate of stenting without balloon predilation, which was higher in the X-Sizer group (60% vs. 34%, respectively; p < 0.001). Angiographic results were fully available in 97 patients in the X-Sizer group and 100 in the control group (Table 3). There was a trend for a better TIMI flow grade at the end of the procedure in the X-Sizer group (2.96 ± 0.20 vs. 2.89 ± 0.31; p = 0.070) with a higher rate of TIMI flow grade 3 (95.9% vs. 89.0%; p = 0.105) and a better cTFC (22.6 ± 8.2 frames/s vs. 25.1 ± 15.0 frames/s; p = 0.898). Distal embolization was observed less frequently in the X-Sizer group (2.1% vs. 10%; p = 0.033), as was the composite angiographic end point of slow flow, no reflow, or distal embolization (6.0% vs. 19.8%; p = 0.006).

Thrombectomy results and device safety. The 1.5-mm X-Sizer device was used in 81.2% of cases and the 2-mm device in the remaining cases. Acute X-Sizer success was obtained in 87% of cases. Thrombus removal was complete in 38.8% of cases and partial in 58.0%. A TIMI flow grade

Table 2. Baseline Angiographic Data and Procedural Data

	No Thrombectomy	Thrombectomy	p Value
Patients, n	101	100	
Target vessel, %			
LAD	48	55	
LCX	5	7	NS
RCA	43	37	
Lesion length, mm	13.7 ± 5.0	12.7 ± 5.0	NS
Reference diameter pre-PCI, mm	3.10 ± 0.60	3.13 ± 0.62	NS
TIMI flow grade pre-PCI, %	0.18 ± 0.52	0.15 ± 0.46	NS
MLD pre-PCI, mm	0.10 ± 0.26	0.08 ± 0.27	NS
Stenosis pre-PCI, %	96.3 ± 10.1	97.2 ± 9.0	NS
cTFC pre-PCI, 25 frames/s	97.3 ± 11.9	98.2 ± 9.5	NS
Procedural details			
Glycoprotein IIb/IIIa inhibitors, %	65	55	NS
Coronary stenting, %	99	100	NS
Stenting without predilation, %	34	60	<0.001
Procedural time, min	45 ± 25	54 ± 28	0.009
Number of stents, mean	1.37 ± 0.65	1.32 ± 0.61	NS
Stent length, mm	22.7 ± 9.9	22.2 ± 12.0	NS
Maximum pressure, atm	13.9 ± 2.6	13.7 ± 2.7	NS
Stent/vessel ratio	1.14 ± 0.45	1.07 ± 0.27	NS

Continuous data presented as mean ± SD and are compared using the Wilcoxon rank sum test; categorical data are presented as frequency values and are compared using the Fisher exact test.

cTFC = corrected TIMI frame count; LAD = left anterior descending coronary artery; LCX = left circumflex coronary artery; MLD = mean luminal diameter; NS = not significant; PCI = percutaneous coronary intervention; RCA = right coronary artery; TIMI = Thrombolysis In Myocardial Infarction.

2 or 3 was present before wiring the lesion in 4.1% of cases, after wiring the lesion in 20.6%, and after thrombectomy in 88.0%. No case of acute coronary perforation or other serious device-related adverse event was observed. However, in one patient with anterior AMI, in which a 1.5-mm X-Sizer device failed to cross the lesion, a coronary arteriovenous fistula was observed at follow-up, which was treated medically.

Assessment of myocardial reperfusion. Blush data were fully available in 92 patients in the X-Sizer group and in 91 in the control group (Table 3). No difference was found between either of the groups (Table 3). However, by using the predefined ECG criteria, a significant difference was observed (Table 4): postprocedural ST-segment elevation regressed >50% in a significantly higher percentage of patients treated with thrombectomy (67.8% vs. 52.6%; p = 0.037), and the median magnitude of ST-segment resolution at 1 h after PCI was increased with thrombectomy when compared with the control group (7.50 vs. 4.90 mm; p = 0.033). By using multiple logistic regression analysis, we discovered that the independent predictors of ST-segment resolution >50% were: younger age (with an odds ratio [OR] of 0.73 per 10 years and a 95% confidence interval [CI] of 0.56 to 0.95; p = 0.021), anterior AMI (OR 2.23, 95% CI 1.17 to 4.24; p = 0.015), use of X-Sizer (OR 0.49, 95% CI 0.26 to 0.94; p = 0.031), and shorter time

Table 3. Postprocedural Angiographic Data

	No Thrombectomy	Thrombectomy	p Value
Patients, n	101	100	
Reference diameter post-PCI, mm	3.27 ± 0.48	3.30 ± 0.51	NS
MLD post-PCI (mm)	2.72 ± 0.53	2.76 ± 0.52	NS
Stenosis final, %	17.2 ± 9.7	16.9 ± 9.5	NS
TIMI flow grade	2.89 ± 0.31	2.96 ± 0.20	0.070
TIMI flow, % grade 3	89.0	95.9	0.105
cTFC, final	25.1 ± 15.0	22.6 ± 8.2	0.898
Myocardial blush grade (0–3)	2.05 ± 0.75	2.03 ± 0.81	0.898
0–1	25.0	24.7	
2	44.6	44.1	NS
3	30.4	31.2	
Distal embolization, %	10.0	2.1	0.033
Slow flow, %	5.9	1.0	0.119
No flow, %	9.9	3.0	0.082
Composite angiographic end point, %	19.8	6.0	0.006
Angiographic success, %	79.0	86.6	0.189
Procedural success, %	75.0	84.5	0.112

Abbreviations as in Table 2.

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Table 4. Electrocardiographic Analysis

	No Thrombectomy	n	Thrombectomy	n	p Value
ST-segment elevation pre (mm) (min/max)	14.14 (0.80/55.30)	98	14.35 (0.00/46.30)	96	
SD	9.25		8.72		
Median	11.70		12.70		0.6036*
ST-segment elevation 1 h post (mm) (min/max)	7.15 (0.00/32.90)	96	6.33 (0.00/48.50)	94	
SD	6.62		7.68		
Median	5.10		4.20		0.1397*
ST-segment resolution pre–post (mm) (min/max)	6.80 (−13.20/48.10)	95	8.53 (−27.90/42.37)	90	
SD	9.28		10.08		0.0331*
Median	4.90		7.50		(0.031)†
ST-segment resolution >50%, %	52.60	95	67.8	90	0.0373
ST-segment resolution pre–end/ pre (min/max)	0.41 (−2.00/1.00)	95	0.52 (−1.35/1.00)	90	
SD	0.49		0.50		
Median	0.56		0.66		0.0296*

*Wilcoxon rank sum test; †nonparametric repeated-measures analysis of variance (pre–post comparison).

interval from symptom onset to PCI (OR, 0.88 per h, 95% CI 0.79 to 0.99; p = 0.028). The use of GP IIb/IIIa inhibitors was not associated with better ST-segment resolution.

Clinical outcome. The one-month occurrence of re-infarction, re-intervention, stroke, emergency coronary artery bypass grafting, or death was similar in both groups (Table 5). In the thrombectomy group, four patients died, all during the in-hospital phase: one with refractory cardiogenic shock, one secondary to electromechanical dissociation, one because of intestinal ischemia, and one because of free wall rupture. In the control group, four patients died, one because of refractory cardiogenic shock, two secondary to free wall cardiac rupture, and one secondary to electromechanical dissociation. Re-infarction occurred in one patient assigned to thrombectomy and in three patients assigned to conventional strategy. At six months' follow-up, there were two additional deaths in the thrombectomy group, one secondary to stroke at day 35 and one during angiographic follow-up at five months that was complicated by pulmonary edema and shock. The six-month MACCE rate was similar (13%) in both groups.

Table 5. Clinical Outcome at One- and Six-Month Follow-Up (MACCE Are Given in Hierarchical Order per Patient)

	No Thrombectomy	Thrombectomy	p Value
Patients, n	101	100	
One month			
MACCE	7	9	NS
Death	4	4	NS
Stroke	0	2	NS
Emergency CABG	0	0	NS
MI	3	1	NS
TVR	0	2	NS
Six months			
MACCE	13	13	NS
Death	4	6	NS
Stroke	0	2	NS
Emergency CABG	0	0	NS
MI	4	2	NS
TVR	5	3	NS

CABG = coronary artery bypass grafting; MACCE = major adverse cardiac and cerebrovascular events; MI = myocardial infarction; NS = not significant; TVR = target vessel revascularization.

DISCUSSION

Thrombus removal, epicardial flow, and myocardial reperfusion. The goal of PCI for the treatment of AMI is not only the restoration of normal epicardial flow, which has been shown to improve outcome (27), but also the achievement of optimal myocardial tissue reperfusion (4), which is a more reliable predictor of long-term outcomes (8,21–30). Thrombus and plaque embolization is one of the mechanisms affecting myocardial reperfusion by inducing mechanical capillary obstruction, endothelial dysfunction, and inflammation (29,30) and has been shown to be associated with a poor long-term outcome (14).

In the present randomized study, patients undergoing thrombectomy before coronary stenting had a lower risk of distal embolization (2.1% vs. 10%; p = 0.033) and had a reduced angiographic composite end point of slow flow, no reflow, or distal embolization (6.0% vs. 19.8%; p = 0.006). These traits were associated with a non-significant trend toward improved epicardial reperfusion, as assessed by final TIMI flow grade and cTFC. The absolute ST-segment resolution after the procedure was significantly greater in the thrombectomy group (8.5 ± 10.1 mm vs. 6.8 ± 9.3 mm; p = 0.003). This primary end point was chosen because it is an easy to measure and is a reliable marker of myocardial reperfusion and clinical outcome (21,22,28). The simpler ST-segment resolution >50% criterion (4,5,19–22,28,31) also was improved in the thrombectomy group (67.8% vs. 52.6%; p = 0.037). Hence, it appears that effective removal of thrombotic or soft plaque material by X-Sizer at the lesion site improves myocardial reperfusion by reducing distal embolization during mechanical reperfusion. Further evidence of effective thrombus removal is given by the significant angiographic reduction in thrombus burden after thrombectomy.

Myocardial blush. In previous studies, myocardial blush has been related to infarct size, left ventricular function (31),

and long-term mortality after AMI (8,25). In our study, the core laboratory evaluation did not show a significantly better myocardial blush in patients treated with thrombectomy. The main explanation for this is probably that in a multicenter and relatively small study myocardial blush is not as powerful as ST-segment resolution as a surrogate marker. Furthermore, acquisition quality and length is crucial and visual assessment of myocardial blush remains subjective.

Clinical outcome. A similar rate of MACCE at the six-month follow-up (13%) was found in both groups. Death rate was relatively high compared with previous studies (6% in the thrombectomy group vs. 4% in the conventional group; $p = 0.537$), reflecting the fact that only patients with TIMI flow grade 0 or 1 were included. It is important to note that the study was not powered to demonstrate benefits in clinical outcome.

Comparison with other studies. The X-sizer was recently evaluated by Stone et al. (18) in a randomized study involving 797 patients with lesions at high risk for distal embolization (bypass grafts or native thrombotic coronary arteries) and, therefore, associated with a high risk of Q-wave or non–Q-wave MI. This study showed a significant reduction in the risk of extended MI (5.5 vs. 9.6; $p = 0.002$) but did not demonstrate any clinical benefit at one year.

In the present study, the rate of ST-segment resolution >50% at 1 h after the procedure after adjunct thrombectomy was relatively high (67.8%) compared with results of conventional balloon angioplasty initially reported by Claeys et al. (22), who showed a ST-segment resolution >50% in 64% of cases but in a selected group of patients with better initial TIMI flow grade who had successful PCI (32). In a single center randomized trial that included 49 patients with ST-segment elevation AMI, Beran et al. (19) reported a significantly improved ST-segment resolution but no difference in myocardial blush and coronary flow reserve after adjunctive intracoronary thrombectomy with the X-Sizer catheter compared with conventional PCI. More recently, in a larger single-center randomized trial that included 92 patients, Napodano et al. (20) reported a better ST-segment resolution and myocardial blush with the X-Sizer catheter. Clinical follow-up was limited to one month in both studies.

Other mechanical approaches to reducing embolization of thrombus during direct PCI have been used successfully. They include rheolytic thrombectomy (15), thrombus aspiration devices (33), and distal protection devices (34). Data from randomized studies on the effects of these devices on myocardial reperfusion during direct percutaneous transluminal coronary angioplasty have not been reported so far. Several pharmacologic approaches to improving myocardial reperfusion during direct angioplasty have been used. Intracoronary adenosine and verapamil (35,36) are administered to reduce reperfusion injury but do not affect intracoronary thrombus burden. The use of GP IIb/IIIa inhibitors in patients undergoing direct PCI has been shown to improve microvascular function by limiting the effects of embolized thrombus and platelets and by reducing the inflammatory response of the coronary microvasculature, as assessed by coronary flow velocity (37). The combination of GP IIb/IIIa inhibitors and thrombolytic therapy showed a 59% rate of complete ST-segment resolution (38). In the present study, mechanical thrombectomy showed results that were at least equivalent to those achieved with aggressive pharmacologic treatment for the reduction of distal embolization (35,36). It is unlikely that the results were affected by the use of GP IIb/IIIa inhibitors, which were administered at similar rate in both groups. Furthermore, multivariate analysis did not identify any beneficial effect of this drug on ST-segment resolution. Similar results were found in a large randomized trial (39) showing that the use of GP IIb/IIIa inhibitors as an adjunct to direct PCI did not enhance ST-segment resolution or improve myocardial recovery at seven months. These data underline the importance of mechanical adjuncts for improving the outcome of direct PCI.

Study limitations. The study reflects a multicenter experience in a limited number of patients and represents a mechanical attempt at optimizing myocardial reperfusion in patients undergoing direct PCI. Apart from considerations as to the safety of the X-Sizer thrombectomy device and its effect on myocardial reperfusion as assessed by ST-segment resolution, no conclusions about long-term myocardial function and its relationship to long-term clinical follow-up can be drawn. The study was limited to patients with high-risk thrombus-containing lesions with TIMI flow grade 0 or 1 and did not include the entire AMI population, particularly those undergoing rescue PCI after failed thrombolysis. Another limitation of the study is that the possible treatment benefit of adjunct pharmacologic therapy was not evaluated. Myocardial reperfusion represents such a wide and complex scenario that synergistic mechanical and pharmacologic strategies may be required to preserve microvascular integrity.

Conclusions. Intracoronary thrombectomy with the X-Sizer catheter during catheter-based treatment of AMI improved myocardial reperfusion in patients presenting with TIMI flow grade 0 to 1, as assessed by a lower rate of distal embolization and a higher rate of ST-segment resolution. Further clinical trials involving larger numbers of patients are warranted to assess the impact of thrombectomy on infarct size as well as on clinical outcome.

Reprint requests and correspondence: Dr. Thierry Lefèvre, Institut Hospitalier Jacques Cartier, 6 avenue du Noyer Lambert, 91300 Massy, France. E-mail: t.lefevre@icps.com.fr.

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