Effect of thrombus aspiration on infarct size and left ventricular function in high-risk patients with acute myocardial infarction treated by percutaneous coronary intervention. Results of a prospective controlled pilot study

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Background Thrombus aspiration devices have been shown to improve reperfusion criteria and to reduce distal embolization in patients treated by percutaneous coronary interventions (PCI) in the acute phase of ST-elevation myocardial infarction (STEMI). There are, however, little data about their efficacy in the reduction of infarct size.

Methods We sought to assess in a prospective randomized trial the impact of thrombus aspiration on infarct size and severity and on left ventricular function in high-risk patients with a first STEMI. The primary end point was scintigraphic infarct size, and secondary end points were infarct severity and regional and global left ventricular function. Forty-four patients with completely occluded (Thrombolysis in Myocardial Infarction flow 0-1) proximal segments of infarct-related artery were randomly assigned to thrombus aspiration group with the Export catheter (n = 20) (Medtronic, Inc, Minneapolis, MN) or PCI-only group. A rest Tc-99-mibi gated single-photon emission computed tomographic and contrast-enhanced magnetic resonance imaging were performed 6 ± 2 days later.

Results Infarct size was comparable in patients in the thrombus aspiration group and PCI-only group (30.6% ± 15.8% vs 28.5% ± 17.9% of the left ventricle, $P = .7$) as was infarct severity in infarct-related artery territory (55% ± 12% vs 55% ± 14%, $P = .9$). Transmurality score as assessed by magnetic resonance imaging was similar in both groups (2.03 ± 1.05 vs 2.16 ± 1.21, $P = .7$). There was no impact of thrombus aspiration on other secondary end points.

Conclusion In our study, thrombus aspiration with the Export catheter performed as adjunctive therapy in high-risk patients with total occlusion of the proximal part of major coronary arteries does not decrease infarct size or severity and has no effect on left ventricular regional and global function. (Am Heart J 2009;157:583.e1-583.e7.)

Early and successful reopening of the culprit artery by percutaneous coronary intervention (PCI) performed in the acute phase of acute myocardial infarction is the most effective strategy for salvaging myocardial tissue and improving clinical outcome.[1] The restoration of epicardial flow to the ischemic myocardium, however, can induce injury. Studies in animal models of acute myocardial infarction have shown that reperfusion injury accounts for up to 50% of final infarct size.[2] Among several mechanisms proposed to explain this phenomenon, distal embolization of thrombus or atheromatous debris during PCI may play an important role.[3] Recently, several randomized trials have shown that the use of different thrombus-aspiration devices can reduce distal embolization rate and improve indirect parameters of myocardial tissue reperfusion in patients with acute coronary syndromes.[4-13] Nevertheless, there is a paucity of data about the effect of thrombus aspiration on the infarct size which is the best surrogate end point for the assessment of new therapeutic tools in the setting of acute myocardial infarction.[14] In several trials, thrombus aspiration was performed regardless of the presence of visible thrombus on coronary angiography or total coronary occlusion. The presence of these 2 characteristic defines a high-risk group of patients who could obtain in theory a maximal benefit from thrombus

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ClinicalTrials.gov identifier: NCT00456066.
Submitted October 1, 2008; accepted November 26, 2008.
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0002-8703/$ - see front matter
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doi:10.1016/j.ahj.2008.11.017

removal. Therefore, we conducted a randomized trial to evaluate the effect of routine thrombus aspiration by Export catheter (Medtronic, Minneapolis, MN) in a subset of patients with high-risk angiographic characteristics treated by PCI in the acute phase of a first ST-elevation acute myocardial infarction (STEMI).

Material and methods

The study was a prospective, randomized trial in patients with a first STEMI scheduled for emergency PCI during 48 hours from the onset of chest pain. To be eligible for the study, patients needed to fulfill the following criteria: (1) chest pain lasting >30 minutes; (2) sum of ST-segment elevation of at least 2 mm in 2 contiguous leads; (3) total occlusion (Thrombolysis in Myocardial Infarction [TIMI] flow 0-1) of a proximal segment of left anterior descending, left circumflex, or right coronary artery; and (4) success of guidewire to cross the culprit lesion. Exclusion criteria were (1) hemodynamic instability defined as Killip class >II, (2) previous myocardial infarction or (3) by pass surgery, (4) left-bundle brunch block or (5) paced rhythm, and (6) contraindication for single-photon emission computed tomography (SPECT) or magnetic resonance imaging (MRI). Rescue PCI defined as a PCI performed within 12 hours of failed systemic fibrinolysis did not constitute an exclusion criterion. This study was approved by the local ethic committee and informed consent was obtained from all patients.

Before intervention, patients received unfractionated heparin, acetylsalicylic acid, and a loading dose of 300 mg of clopidogrel. Patients were randomized 1:1 to thrombus aspiration group pretreatment or to PCI-only group. Thrombus aspiration was performed with the Export catheter. It consists of a 6-Fr rapid exchange catheter (1.37 mm internal lumen) and a vacuum syringe connected to its proximal end. The distal tip was advanced on the guidewire up to the thrombus and then vacuum syringe was opened allowing mechanical aspiration of the thrombus from the coronary artery. Administration of glycoprotein (GP) IIb/IIIa receptor antagonists as well as decision of direct stenting or balloon predilatation before stenting was left to the treating physicians' discretion.

Study end points

Primary end point was myocardial infarct size assessed by rest Tc-99m-mibi gated SPECT performed on the sixth day after the PCI procedure. Secondary end points were infarct severity, regional wall motion abnormality (RWMA) score, and regional thickening score in the infarct-related artery territory (all assessed by SPECT), left ventricular volumes, and global ejection fraction, and infarct transmurality score obtained from contrast-enhanced MRI performed within 24 hours from SPECT acquisition.

We also measured angiographic and electrocardiogram (ECG)-derived markers of reperfusion: TIMI flow, distal embolization, myocardial blush grade (MBG), and ST-segment resolution. In addition, troponin T and CK levels were measured before PCI and twice a day during 4 days.

Rest Tc-99m-mibi SPECT acquisition and analysis

A rest Tc-99m-mibi ECG-gated SPECT study was performed 6 ± 2 days after the acute event. Imaging was begun 30 minutes after administration of 14.7 MBq/kg Tc-99m-mibi. Image acquisition was obtained in supine position with a triple-head rotating γ camera (Philips, Eindhoven, Netherlands) equipped with low-energy, high-resolution collimators. A total of 34 projections were acquired over a 180° rotation with an acquisition time of 25 seconds each. At each projection angle, 16 individual ECG-gated frames per R-R interval were acquired. Transverse sections were reconstructed in a 64 × 64-pixel matrix by using a filtered backprojection with a Butterworth filter with an order of 6 and a cut-off frequency of 0.4 cycles per pixel. No attenuation correction was used.

Myocardial perfusion quantitative analysis was performed in 2 ways on the summed sections by commercially available software (Cardiogram, SEGAMI, Columbia, MD).

In the first approach, the activity of each of the 17 sectors was expressed as the mean activity of all pixels belonging to this sector divided by the highest value of pixel activity in the myocardium. Infarct size was defined as a % of LV with pixel activities of <50%. In the second approach, infarct severity was assessed as a mean tracer uptake in the infarct-related artery (IRA) territories. As recommended by the Cardiac Imaging Committee of the Council on Clinical Cardiology of the American Heart Association, the left anterior descending artery territory included sectors 1, 2, 7, 8, 13, 14, and 17; right coronary artery sectors 3, 4, 9, 10, and 15; and left circumflex artery 5, 6, 11, 12, and 16.[15]

Regional wall motion abnormality was assessed using a 5-point scoring system in IRA territories (0—normal wall motion, 1—moderate hypokinesis, 2—severe hypokinesis, 3—akinesis, and 4—dyskinesis). RWMA score was calculated as a sum of scores in sectors belonging to the IRA territories divided by the number of sectors. In a similar way, we assessed regional thickening in the same territories using a 4-point scoring system (0—normal thickening, 1—moderately reduced, 2—severely reduced, and 3—absent).

Magnetic resonance image acquisition and analysis

Magnetic resonance imaging was performed with a 1.5-T system (Sonata, Siemens Medical System, Germany) by using a phased-array chest coil and ECG triggering. To define the position and long axis of the left ventricle, 3 short survey scans were performed. Then the patients were injected with 0.2 mmol/kg body weight of gadopentate dimeglunine (gadodiamide, Omniscan; Amersham Biosciences, Pantin, France) and a period of 10 minutes was allowed to elapse before infarct imaging. Contrast-enhanced magnetic resonance images demonstrating viable and nonviable myocardium were acquired from base to apex in the short-axis orientation using a segmented inversion-recovery turbo fast low-angle shot sequences. Imaging parameters were as follows: field of view 340 × 340 mm, matrix size 192 × 192 pixels, slice thickness 7 mm with 3.5-mm gap. Inversion time set to null normal myocardium was between 250 and 320 milliseconds.

For the analysis of images, the same 17-sector model was applied. Left ventricular volumes and global ejection fraction were calculated from manually drafted endocardial borders in end systole and end diastole. The transmural extent of necrosis was calculated from contrast enhanced images in the IRA territories using a 5-point scoring system (0—% of the wall thickness, 1—1% to 25%, 2—26% to 50%, 3—51% to 75%, and 4—76% to 100%). Transmurality score was calculated as a sum of

Table I. Baseline clinical and angiographic characteristics

Characteristic	Overall	Thrombus aspiration group (n = 20)	PCI-only group (n = 20)	*P* value
Age, y, mean ± SD	59 ± 13	59 ± 13	59 ± 13	.9
Male sex, n (%)	30 (68)	12 (60)	18 (75)	.3
Clinical characteristics, n (%)				
Diabetes mellitus	3 (7)	1 (5)	2 (8)	.9
Current smoker	16 (36)	7 (35)	9 (38)	.9
Hypertension	13 (30)	5 (25)	8 (33)	.5
Hypercholesterolemia	11 (25)	6 (30)	5 (21)	.5
Ischemic time, hours ± SD	7.2 ± 5.9	7.1 ± 4.9	7.4 ± 6.8	.9
Prehospital fibrinolysis, n (%)	5 (11)	3 (15)	2 (8)	.6
Angiographic characteristics				.5
No. of diseased vessels				
1	19 (43)	9 (45)	10 (42)	
2	18 (41)	8 (40)	10 (42)	
3	7 (16)	3 (15)	4 (16)	
Infarct-related artery				.7
Left anterior descending	18 (41)	7 (35)	11 (46)	
Left circumflex	3 (7)	2 (10)	1 (4)	
Right coronary artery	23 (52)	11 (55)	12 (50)	
Baseline TIMI flow				1
0	40 (91)	19 (95)	21 (88)	
1	3 (7)	1 (5)	2 (8)	
2	1 (2)	0 (0)	1 (4)	
*Collateral circulation				.5
0	19 (43)	10 (50)	9 (38)	
1	23 (52)	10 (50)	13 (54)	
2	2 (5)	0 (0)	2 (8)	

* Collateral circulation was assessed using the Rentrop classification.[16]

scores in sectors belonging to the IRA territories divided by the number of sectors. RWMA score was calculated in the same way as for SPECT data.

Angiographic analysis

Coronary angiograms were obtained with a digital equipment (Integris 3000, Philips Medical System, Best, Netherlands). Semiquantitative analysis of coronary flow was performed off-line by 2 experienced interventional cardiologists (JL and ND). Anterograde flow in the IRA, presence of significant stenosis in other coronary arteries, and collateral circulation were analyzed on initial sequences before PCI procedure. Final TIMI flow, MBG, and presence of distal embolization were assessed at the end of the procedure. Attention was paid to avoid superimposition of territories other than that of IRA in the assessment of MBG, and filming was prolonged until some venous filling was seen to evaluate the washout phase of contrast dye.[17]

Electrocardiogram assessment

A 12-lead ECG was recorded before PCI procedure, immediately after the PCI, at 90 minutes, and 24 hours after PCI. ST-Elevation was calculated 20 milliseconds after point J. The number of leads with ST-elevation and their sum were calculated for each time-point record. ST-Segment resolution was assessed on the 90-minute ECG using Schröder classification (>70%—complete resolution, 30% to 70%—incomplete, and <30%—absent).[18]

Table II. Procedural data and angiographic results

	Thrombus aspiration group	PCI-only group	*P* value
GP IIb/IIIa inhibitors n (%)			
Prehospital	1 (5)	3 (12)	.6
Per procedure	5 (25)	15 (62)	.01
Stenting, n (%)	19 (95)	22 (92)	1.0
Direct stenting, n (%)	10 (55)	6 (33)	.04
Final TIMI flow, n (%)			.08
3	11 (55)	20 (83)	
2	7 (35)	4 (17)	
1	2 (10)	0 (0)	
0	0 (0)	0 (0)	
MBG, n (%)			.8
0	8 (57)	11 (61)	
2	6 (43)	7 (39)	
Distal embolization, n (%)	2 (10)	3 (13)	1.0
Peak CK release (UI/L)	2312 ± 1912	2375 ± 1820	.9
Peak Tn-T release (μg/L)	5.72 ± 4.18	8.14 ± 8.10	.2

Power calculation and statistical analysis

The target sample size was calculated on assumption of a 40% reduction in infarct size in the thrombus aspiration group and considering a mean infarct size of 20% in the control group. With a 40% reduction in infarct size from 20% to 12%, we estimated that 22 patients would be required in each group to have a power of 95% to detect the difference with a 2-sided α value of .05.

Table III. Scintigraphic data

	Thrombus aspiration group	PCI-only group	*P* value
Infarct size (% ± SD)	30.6 ± 15.8	28.5 ± 17.9	.7
Infarct severity (% ± SD)	55 ± 12	55 ± 14	.9
RWMA score	1.06 ± 0.78	1.50 ± 0.92	.09
Regional thickening score	1.20 ± 0.76	1.38 ± 0.79	.45

Infarct size is presented as % of left ventricle with tracer uptake <50% of maximal count. Infarct severity is measured as a mean tracer uptake (in %) in the infarct-related artery territory.

Continuous variables are expressed as mean values ± SD and compared with Student *t* test or analysis of variance as appropriate. Categorical variables are expressed as frequency values and were compared by χ^2 test.

A *P* value < .05 was considered as statistically significant. Statistical analysis was performed using the SAS statistical package (SAS Institute, Cary, NC).

Our study was in major part supported by a Regional Project of Clinical Research grant from Auvergne Region, France. Medtronic Company (Minneapolis, MN) funded part of the study providing us without charge with the Export catheter.

Results

Fifty patients were prospectively included in this study. Among them 6 were subsequently excluded for various reasons (consent withdrawal in 3 cases, claustrophobia during MRI in one, cerebral hemorrhage occurred at the beginning of the procedure in one, and cardiogenic shock developed during the PCI procedure in one). The final population consisted of 44 patients; 20 in thrombus aspiration group and 24 in PCI-only group. There were no significant differences in clinical and basal angiographic characteristics between the 2 groups (Table I).

Percutaneous coronary intervention data and angiographic results

Thrombectomy was successfully performed in all patients allocated to this treatment. Thrombus aspiration performed before PCI resulted in direct stenting more frequently than in the PCI-only group (Table II). In contrast, GP IIb/IIIa receptor antagonists were more frequently used in the latter group. There was no difference in final TIMI flow, MBG, or distal embolization rate between the 2 groups. Additional PCI procedure on another IRA artery was performed during hospital stay in 32% of patients (25% in the thrombus aspiration group and 37% in the PCI-only group, *P* = .4).

Tc-99m-mibi SPECT and MRI evaluation

The primary end point of the present study, scintigraphic infarct size, was not different between the 2 groups (30.6% ± 15.8% vs 28.5% ± 17.9% of the left ventricle, in the thrombus aspiration group and PCI-only group, *P* = .7). There was neither statistical difference in infarct severity, RWMA, or regional thickening scores (Table III). Similarly, transmurality score on contrast-enhanced MRI was comparable between the 2 groups as well as RWMA score. There was no difference in left ventricular volumes or global left ventricular ejection fraction between both groups 1 week after the PCI procedure (Table IV).

Table IV. Data obtained from contrast-enhanced MRI study

	Thrombus aspiration group	PCI-only group	*P* value
Infarct transmurality score	2.03 ± 1.05	2.16 ± 1.21	.7
RWMA score	1.07 ± 0.57	1.14 ± 0.77	.8
End diastolic volume (mL ± SD)	118 ± 33	114 ± 32	.6
End systolic volume (mL ± SD	64 ± 24	63 ± 24	.9
Left ventricular EF (% ± SD)	48 ± 12	45 ± 11	.4

Table V. Electrocardiogram analysis

	Thrombus aspiration group	PCI group	*P* value
No. of leads with ST-segment elevation			
Baseline	3.25 ± 0.85	3.61 ± 1.61	.4
Postprocedure	1.89 ± 1.41	3.30 ± 1.84	.01
At 90 min	1.95 ± 1.31	2.82 ± 2.08	.12
Σ ST-elevation			
Baseline	8.28 ± 6.24	13.09 ± 9.72	.06
Postprocedure	2.53 ± 2.71	8.5 ± 8.8	.009
At 90 min	2.18 ± 2.11	5.84 ± 6.46	.02
90-min ST-segment resolution			.7
Complete	11 (58)	11 (52)	
Incomplete	5 (26)	4 (19)	
Absent	3 (16)	6 (29)	
24-h ST-segment resolution			.2
Complete	15 (79)	12 (55)	
Incomplete	2 (11)	7 (32)	
Absent	2 (11)	3 (14)	

Electrocardiographic analysis

The ECG results are presented in Table V. The sum of the ST-elevation tended to be more important in the PCI-only group before the procedure; this difference became statistically significant immediately after the PCI and remained, although in a lesser manner, 90 minutes later. ST-Segment resolution, however, did not differ between both groups either at 90 minutes or at 24 hours after PCI.

Discussion

Effect of thrombus aspiration on infarct size

Infarct size measurement can be used as a surrogate end point in measurement of efficacy of different

reperfusion therapies for STEMI, being much more feasible than the assessment of their effect on cardiac mortality. The quantification of infarct size can be done using several methods; those used most often in clinical practice are serum markers and SPECT imaging. Infarct size as assessed by Tc-99m-mibi SPECT correlates closely with actual fibrosis in human hearts and with subsequent patient mortality.[14] A measurement of myocardial salvage and infarct size by this technique has been used as an end point in several trials measuring the efficacy of different pharmacologic therapies in acute myocardial infarction. There are, however, a few data about the effect of thrombus aspiration devices on infarct size. In a recent prospective trial, Kaltoft et al[8] assessed the efficacy of thrombus aspiration with the Rescue catheter (Boston Scientific [Natick, MA]/Scimed [Maple Grove, MN]) in the setting of patients with STEMI reperfused within 12 hours from the onset of chest pain. They failed to show any benefit in terms of myocardial salvage index or final infarct size after thrombus aspiration. In contrast, theirs results suggested a possible deleterious effect of this technique, resulting in increased final infarct size. In that study, patients were randomized to thrombus aspiration pretreatment regardless of visible thrombus. Our study extends the results obtained by Kaltoft et al[8] for a subset of patients with total occlusion of proximal segment of infarct-related artery, that is, in patients who could, in theory, obtain a maximal benefit from thrombus aspiration in infarct size reduction related to thrombus dislodgment. The high-risk profile of patients included in our study is confirmed by a much more important final infarct size than that in patients in Kaltoft's study.

We have also assessed by 2 independent methods infarct severity which is an important predictive factor of left ventricular remodeling.[19] This is, to the best of our knowledge, the first study that measured the effect of thrombus aspiration on this parameter. Similarly to the infarct size, we did not find any reduction in infarct severity as assessed by Tc-99m-mibi SPECT or in infarct transmurality as assessed by contrast-enhanced MRI. No benefit in reduction of scintigraphic infarct size was observed in the AIMI study either, which included 480 patients with STEMI to rheolytic thrombectomy or PCI-only strategy.[9] In contrast, a reduction in infarct size as assessed by Tc-99m-mibi rest SPECT performed at 1 month from the acute event was observed by Antoniucci et al[5] in a study using also rheolytic thrombectomy device, but the analysis of results is somewhat difficult because of the imbalance between groups.

Several trials assessing thrombus aspiration devices measured infarct size using biochemical markers (peak of serum CK or its MB fraction or troponine release) with variable results. In the largest study published to date, using the Export catheter system, the TAPAS trial,[11,12] there was no difference in peak CK and CK-MB levels between groups with and without thrombus aspiration. Similar results were obtained by Napodano et al[4] with the X-sizer catheter, and Burzotta et al[6] and De Luca et al[12] with the Diver catheter (Invatec, Brescia, Italy). An increase in infarct size as assessed by peak of CK-MB level was also observed after thrombus aspiration in the study of Javaid et al[13] with the Export catheter. The only study showing a reduction in enzymatic infarct size after thrombus aspiration is that of Silva-Orrego et al[7] using the Pronto catheter. In that study, however, a surprisingly very high myocardial blush grade 3 rate of 88% was observed in the thrombus aspiration group. In our study, no differences were observed in peak CK or troponin levels although the latter tended to be reduced in the thrombus aspiration group.

Effect of thrombus aspiration on left ventricular function

Only a few studies have analyzed the impact of thrombus aspiration on left ventricular function. In a retrospective study comparing conventional angioplasty with thrombectomy with the Thrombuster device (Kaneka Medix, Osaka, Japan), a reduction in the incidence of the left ventricular remodeling was observed if the infarct-related artery was the proximal left anterior descending or right coronary artery.[20] Similarly, a higher rate of left ventricular remodeling was observed by Kondo et al[21] in another retrospective study using the Rescue catheter. Of interest, in both studies, the global ejection fraction and left ventricular volumes at 6 months were comparable between groups with and without thrombus aspiration. In contrast, no difference in left ventricular volumes or global ejection fraction as assessed by gated Tc-99m-mibi SPECT 14 to 28 days after an acute event was observed by Ali et al.[9] A similar rate of left ventricular remodeling was also observed in a study by Galiuto et al,[22] despite a significant reduction in myocardial obstruction as assessed by contrast echocardiography. Results of our study are in keeping with these 2 previous trials showing no benefit in terms of global or regional left ventricular function after thrombus aspiration.

Effect of thrombus aspiration on reperfusion criteria

Recently, 3 meta-analyses were published concerning trials assessing thrombus aspiration devices.[23-25] All concluded in an improvement in myocardial reperfusion criteria as assessed by angiography with TIMI flow, MBG analysis, and distal embolization or ST-elevation resolution on ECG. However, a significant heterogeneity between studies was observed in the first 2 analyses. In the most recent meta-analysis published so far,[25] the reduction in distal embolization rate, observed with thrombus aspiration devices, is

driven by 2 studies, with surprisingly high prevalence of this complication in the PCI-only groups. In addition, the impact of direct stenting on improving reperfusion has not been analyzed. In almost all trials evaluating the efficacy of thrombus aspiration devices, the rate of direct stenting is much higher in patients with this pretreatment than in those with PCI only, even in subgroups with nonocclusive thrombus. It has been suggested that direct stenting without predilatation may decrease embolization and the incidence of the no-reflow phenomenon.[26,27] What the respective role of direct stenting and thrombus aspiration is in the improvement of myocardial reperfusion needs further investigations.

Limitations of the study

Our results need validation by a larger multicenter randomized trial. The small sample of our study does not allow the analysis of thrombus aspiration on functional outcome. The objective of 40% reduction in infarct size can appear somewhat ambitious, but this degree of reduction has been recently obtained by a postconditioning technique by Staat et al.[28] The use of GP IIb/IIIA antagonists was less frequent in the thrombus aspiration group in our study, which could influence the final infarct size. However, in the study of Korn et al,[29] no influence of this comedication on reperfusion criteria was observed in patients treated by the Export catheter.

Conclusions

In summary, our pilot study does not support the hypothesis that thrombus aspiration with the Export catheter performed as an adjunctive therapy in high-risk patients with total occlusion of the proximal part of major coronary arteries decreases infarct size or severity or has a positive effect on left ventricular regional and global function.

Disclosures

The sponsors did not interfere with study design, conduction of the trial or analyses of the results, or drafting of the manuscript. None of the authors received individual funding from Medtronic.

The authors are solely responsible for the design and conduct of this study, all study analyses, and the drafting and editing of the paper and its final content. The authors had full access to the data, had read, and agreed to the manuscript as written.

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