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Randomized Comparison of Distal Protection Versus Conventional Treatment in Primary Percutaneous Coronary Intervention

The Drug Elution and Distal Protection in ST-Elevation Myocardial Infarction (DEDICATION) Trial

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Objectives The purpose of this study was to evaluate the use of distal protection during percutaneous coronary intervention (PCI) for ST-segment elevation myocardial infarction (STEMI) in native coronary vessels.

Background Embolization of material from the infarct-related lesion during PCI may result in impaired myocardial perfusion and worsen the prognosis. Previous attempts to protect the microcirculation during primary PCI have had conflicting results.

Methods We randomly assigned 626 patients with STEMI referred within 12 h to have PCI performed with (n = 312) or without (n = 314) distal protection. The primary end point was complete (≥70%) ST-segment resolution detected by continuous ST-segment monitoring. Blood levels of troponin-T and creatine kinase-MB were monitored before and after the procedure, and echocardiographic determination of the left ventricular wall motion index (WMI) was performed before discharge.

Results Patients were well matched in terms of demographic and angiographic baseline characteristics. There was no significant difference in the occurrence of the primary end point (76% vs. 72%, p = 0.29), no difference in maximum troponin-T (4.8 μg/l and 5.0 μg/l, p = 0.87) or maximum creatine kinase-MB (185 μg/l and 184 μg/l, p = 0.99), and no difference in median WMI (1.70 vs. 1.70, p = 0.35). The rate of major adverse cardiac and cerebral events (MACCE) 1 month after PCI was 5.4% with distal protection and 3.2% with conventional treatment (p = 0.17).

Conclusions The routine use of distal protection by a filterwire system during primary PCI does not seem to improve microvascular perfusion, limit infarct size, or reduce the occurrence of MACCE (Drug Elution and Distal Protection During Percutaneous Coronary Intervention in ST Elevation Myocardial Infarction; NCT00192868).
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Percutaneous coronary intervention (PCI) improves the outcome compared with fibrinolysis treatment in patients with ST-segment elevation myocardial infarction (STEMI) (1–4). However, the prevalence of patients with poor myocardial perfusion and lack of myocardial salvage after primary PCI, factors known to be associated with poor clinical outcomes, is considerable, leaving space for improvements in the acute treatment (5–7).

Previous studies have demonstrated that thrombus material can be retrieved in a considerable number of cases, some of them with favorable clinical outcomes (8–11). However, randomized studies have not demonstrated any beneficial effect using thrombectomy catheters or aspiration of the stagnant blood column proximal to an occluded balloon situated distal to the lesion after stent deployment (12,13). A filterwire system has proven useful to improve

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Abbreviations and Acronyms

ECG = electrocardiogram
MACCE = major adverse cardiac and cerebral events
PCI = percutaneous coronary intervention
STEMI = ST-segment elevation myocardial infarction
TLR = target lesion revascularization
WMI = wall motion index

the clinical outcome in connection with PCI in saphenous vein grafts (14). We performed a trial to evaluate whether the use of a filterwire system could limit the damage of embolized material during PCI in patients with a large STEMI presenting within 12 h of symptom onset. In addition, we examined the impact of using drug-eluting versus bare-metal stents in these patients.

Methods

Study design and patients. The DEDICATION (Drug Elution and Distal Protection in ST-Elevation Myocardial Infarction) trial was a randomized study of distal protection or conventional treatment and implantation of drug-eluting or bare-metal stents during primary PCI conducted at 2 high-volume invasive cardiology centers in Denmark.

Patients with chest pain of >30 min duration presenting within 12 h and a total ST-segment elevation of >4 mm in at least 2 contiguous leads of the electrocardiogram (ECG) were eligible for enrollment provided they were >18 years of age and had a high-grade stenosis or occlusion of a native coronary artery without excessive tortuosity or calcification prohibiting advancement of a filterwire to the distal vascular bed of the vessel. Exclusion criteria were history of a previous myocardial infarction in the target vessel area, culprit lesions in unprotected left main coronary arteries or saphenous vein grafts, gastrointestinal bleeding within 1 month, childbearing potential or pregnancy, known renal failure, life expectancy <1 year, and linguistic problems. The study protocol was approved by the local ethics committees, and all patients gave written informed consent.

Randomization and procedures. All patients were pretreated with 3- to 500-mg aspirin, 300- to 600-mg clopidogrel, and 10,000-IU unfractionated heparin as soon as transportation to the catheterization laboratory was arranged. A beta-blocker was administered at the discretion of the transportation team according to blood pressure and heart rate. Provided there was no contraindication, patients were treated with a glycoprotein IIb/IIIa receptor blocker at their arrival in the catheterization laboratory. Coronary angiography was performed and the culprit lesion identified. A guidewire was advanced through the highly stenosed or occluded lesion and dilatation with a small balloon, 1.5 or 2.0 mm in diameter, performed to allow visualization of the peripheral vascular bed. If the operator judged that a filterwire (FilterWire-EZ, Boston Scientific, Santa Clara, California) or a SpiderX protection device (eV3, Minneapolis, Minnesota) could be advanced through the lesion, central telephone randomization was performed by computerized assignment stratified with regard to gender and the presence of diabetes (15). Randomization to distal protection or conventional treatment was followed by randomization to implantation of a drug-eluting or a bare-metal stent in the infarct-related lesion. All stents were implanted under high pressure (>12 atms). Implantation of more than 1 stent of the same type was allowed to cover the entire lesion. Both operator and patient were aware of the assigned treatment. Clopidogrel was prescribed for 1 year and aspirin indefinitely.

Quantitative coronary angiography analysis. Angiographic lesion characteristics were evaluated by independent core laboratory technicians unaware of the treatment sequence using the MEDIS system (16,17). Angiograms were acquired in projections with optimal outlining of the lesions with a minimum of foreshortening and overlap from side branches.

Continuous ECG ST-segment monitoring. Traditional 12-lead ECGs were acquired in the pre-hospital phase, and on arrival at the catheterization laboratory patients had radiolucent carbon fiber electrodes mounted (Ambu Blue Sensor QR electrodes, Ambu A/S, Ballerup, Denmark), enabling ST-segment monitoring during and after PCI as a surrogate for improvement in microvascular perfusion (18). The analog ECG signals were digitized at a sample rate of 500 Hz. The program measures the ST-segment deviation halfway between the J-point and the start of the T-wave in each lead compared with the first acquired 12-lead ECG. A new value is appended to the trend line every 30 s, based on measurements of median beats derived from a newly acquired 10-s epoch of the ECG, and the measured values for all 12 leads are stored every 30 s for 90 min after the PCI.

Standard 12-lead ECGs were analyzed manually. Commercial software (CodeStat Suite, Medtronic Emergency Response Systems, Redmond, Washington) was used for the analysis of continuous ST-segment monitoring data. The maximal cumulated level of ST-segment deviation before primary PCI was estimated by summating the maximal pre-interventional level of ST-segment elevation in each anterior lead (≥0.1 mV ST-segment elevation required in I, aVL, V_4 to V_6, and ≥0.2 mV in V_1 to V_3) and nonanterior lead (≥0.1 mV ST-segment elevation required in II, III, aVF, V_5 to V_6), respectively. In case of posterior wall involvement, numerical ST-segment deviations ≥0.1 mV in V_1 to V_4 contributed to the maximal cumulated ST-segment deviation. Post-interventional ST-segment monitoring data were evaluated to estimate absolute ST-segment elevation 30, 60, and 90 min after insertion of the guidewire, achievement of 70% ST-segment resolution, and time to achievement of 70% and 100% ST-segment resolution.

Cardiac markers and echocardiography. Plasma concentrations of creatine kinase-MB and troponin-T were measured before and at least twice with a 6-h interval after the PCI to include the peak level of both biomarkers during hospitalization. Echocardiography was performed within 2 to 5 days after the PCI procedure and before discharge. Left ventricular systolic function was assessed by 2-dimensional echocardiography using a wall motion index (WMI) score

dividing the left ventricle into 16 segments, attributing a score to each segment, and calculating the average (19). The score reflects dyskinesia (−1), akinesia (0), hypokinesia (1), and normokinesia (2). Wall motion index multiplied by 30 gives an estimate of the left ventricular ejection fraction. Wall motion indexes were graded by an operator who was blinded to the treatment allocation.

Study end points. The primary end point of the study was the rate of patients with ≥70% ST-segment resolution 90 min after PCI. Secondary end points were time to ≥70% ST-segment resolution, maximal level of cardiac biomarkers, echocardiographic WMI at discharge, and the rate of major adverse cardiac and cerebral events (MACCE) occurring within 30 days after treatment: death, nonfatal reinfarction, disabling stroke, and target lesion revascularization (TLR).

A myocardial infarction was defined as a total creatine kinase elevation ≥2 times the upper normal limit with a concomitant increase in creatine kinase-MB blood concentration in the presence of an acute coronary syndrome. Reinfarction was defined as a myocardial infarction in the target vessel area. Stroke was defined as development of disabling neurologic symptoms and objective findings lasting >24 h. Target lesion revascularization was defined as repeat revascularization (percutaneously of the target lesion or surgical of the vessel containing the target lesion) in the presence of documented ischemia and a significant stenosis/occlusion of the infarct-related lesion.

Statistical analysis. The trial involves a factorial design evaluating the effect of treatment with versus without distal protection and implantation of drug-eluting versus bare-metal stents. With a power of 80% and a 2-sided type 1 error of 5%, we calculated that a total of 450 patients should be included to detect a 12% increase in the primary end point from the anticipated 68% (12) in the conventionally treated group to 80% in the group treated with distal protection. With an expected 25% rate of attrition, 300 patients should be included in each arm evaluating distal protection or not.

All analyses were based on intention-to-treat. Differences in categorical variables including those in subgroups were analyzed by the chi-square test or by the Fisher exact test. Continuous variables were analyzed using the Mann-Whitney *U* test for unpaired samples. The Kaplan-Meier method was used to create survival estimates, and the log-rank test was used to test differences in these estimates. Tests for interaction between the effect of distal protection and stent type were performed using analysis of variance, logistic regression, and multivariable proportional hazard models as appropriate. All p values were 2-sided.

Results

Baseline characteristics and procedural results. From May 2005 to November 2006, we screened patients referred for primary PCI with a STEMI at Rigshospitalet and Skejby Sygehus. Of 1,687 patients 1,061 were excluded: in 68 the screening log was not filled in, the condition of 216 patients did not allow inclusion (clinical or psychological instability or unconsciousness), in 162 patients the total ST-segment elevation was <4 mm in contiguous leads, 141 participated in another study, in 140 patients the operator judged that the distal vessel did not allow advancement of the filterwire, 78 patients had onset of symptoms >12 h before arrival, 72 could not be included due to linguistic problems, 58 had a previous infarction, 43 patients had a severe other cardiac or noncardiac disease, 35 refused to participate, 26 had a culprit lesion in the left main stem or in a saphenous vein graft, 11 patients had an active gastric ulcer or other intestinal bleeding disorder, and 11 patients were admitted for a rescue PCI after fibrinolysis. Thus, 626 patients with STEMI were included in the trial (312 to distal protection and 314 to conventional treatment). Baseline clinical characteristics of the patients were well matched (Table 1), 10% of the patients had diabetes mellitus, and median symptom duration from onset to randomization was approximately 3 h 20 min.

As shown in Table 2, the 2 groups were also well matched with regard to angiographic characteristics. More than one-third of the patients had multivessel disease, and nearly all lesions were highly stenosed or totally occluded.

Of the patients assigned to distal protection, the filterwire was successfully advanced and unfolded distally to the lesion before stent implantation in 254 of 312 patients (81%). The Spider-X system was used in 39 patients. In 58 patients

Table 1 Baseline Clinical Characteristics of the Patients

	Distal Protection (n = 312)	Conventional Treatment (n = 314)	p Value
Age, yrs* (SD)	62 (12.3)	63 (12.1)	0.27
Male gender (%)	232 (74.4)	226 (72.0)	0.53
Diabetes mellitus (%)	28 (9.0)	37 (11.8)	0.30
Hypertension (%)	100 (32.1)	107 (34.1)	0.61
Treatment for hyperlipidemia (%)	58 (18.6)	64 (20.4)	0.35
Current smoker (%)	177 (56.7)	158 (50.3)	0.24
Family history of CAD (%)	114 (36.5)	118 (37.6)	0.80
Previous myocardial infarction (%)	20 (6.4)	20 (6.4)	1.0
Previous PCI/CABG (%)	16 (5.1)	15 (4.8)	0.62
Symptom onset to arrival, min* (range)	200 (26–1,350)	199 (40–996)	0.98
Door to balloon, min* (range)	27 (3–104)	24 (3–92)	0.01
Symptom onset to balloon, min* (range)	233 (59–1,370)	222 (60–1,027)	0.55
Baseline cumulated ST-segment deviation, mV* (range)	1.1 (0.7–2.2)	1.3 (0.8–2.1)	0.13

*Values are medians.

CABG = coronary artery bypass grafting; CAD = coronary artery disease; PCI = percutaneous coronary intervention.

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Table 2 Baseline Angiographic Characteristics of the Patients

	Distal Protection (n = 312)	Conventional Treatment (n = 314)	p Value
Number of diseased vessels (%)			
1-vessel disease	198 (63)	194 (62)	
2-vessel disease	83 (27)	85 (27)	0.86
3-vessel disease	30 (10)	34 (11)	
Infarct-related artery (%)			
RCA	139 (45)	152 (48)	
LAD	138 (44)	119 (38)	0.25
LCX	35 (11)	43 (14)	
Baseline TIMI flow grade (%)			
0 to 1	209 (67)	213 (68)	0.87
2 to 3	103 (33)	101 (32)	
Angiographic lesion characteristics			
Reference vessel diameter, mm* (range)	3.50 (2.20–5.00)	3.50 (2.30–5.00)	0.25
Diameter stenosis, %* (range)	100 (30–100)	100 (50–100)	0.17
Minimal lumen diameter, mm* (range)	0.00 (0.00–3.15)	0.00 (0.00–2.00)	0.20
Visible thrombus (%)	213 (68)	236 (75)	0.14

*Values are medians.
LAD = left anterior descending coronary artery; LCX = left circumflex artery; RCA = right coronary artery; TIMI = Thrombolysis In Myocardial Infarction.

(19%), none of the distal protection systems could be advanced to a sufficient landing zone. Stent lengths and diameters were similar in the 2 groups, and the rate of procedural success was high in both groups (Table 3). Thrombolysis In Myocardial Infarction (TIMI) flow grade 3 was obtained in 95% of patients treated with distal protection compared with 85% who received conventional treatment (p = 0.01).

Table 3 Procedural Results

	Distal Protection (n = 312)	Conventional Treatment (n = 314)	p Value
Use of GP IIb/IIIa inhibitor (%)	301 (97)	302 (96)	0.36
Filterwire attempted (%)	304 (97)	0	—
Filterwire success (%)	254 (81)	0	—
Stent implanted (%)	307 (98)	312 (99)	0.29
Drug-eluting stent (%)	158 (51)	155 (49)	0.81
Stented length, mm* (range)	18 (6–60)	20 (8–107)	0.83
Stent diameter, mm* (range)	3.5 (2.0–5.0)	3.5 (2.0–5.0)	0.20
TIMI flow grade 3 post-procedure (%)	295 (95)	268 (85)	0.01
IABP (%)	4 (1)	6 (2)	0.75
Procedural success (%)	309 (99)	310 (99)	0.69

*Values are medians.
GP = glycoprotein; IABP = intra-aortic balloon pump; TIMI = Thrombolysis In Myocardial Infarction.

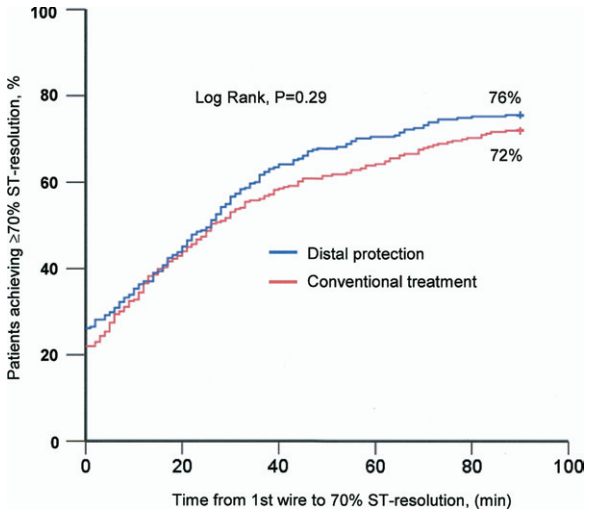

Figure 1 Complete ST-Segment Resolution

Cumulative frequency curves of patients achieving ≥70% resolution of the ST-segment 90 min after primary percutaneous coronary intervention show a small, insignificant difference in the 2 groups receiving distal protection and conventional treatment.

ST-segment resolution and myocardial infarct size. Technical difficulties prohibited recording of the ST-segments in 23 patients. As delineated in Figure 1 and Table 4, the primary end point of ≥70% ST-segment resolution 90 min after PCI occurred in 230 of 302 patients (76%) allocated to distal protection and in 218 of 301 patients (72%) receiving conventional treatment (p = 0.29).

Creatine kinase-MB mass and troponin-T concentrations were measured in all but 7 patients, and echocardiograms allowed determination of the WMI in 477 (76%) patients. There was no difference in the rise in cardiac biomarkers 6 to 18 h after PCI, and echocardiography performed before discharge did not show any difference in WMI (Fig. 2).

There were no significant interactions between distal protection and stent type and the primary, secondary, or explanatory variables, respectively. All p values for interaction were >0.10.

MACCE. Death and stroke occurred with similar frequency 30 days after primary PCI in the groups treated with or without distal protection as seen in Figure 3. A tendency toward a higher rate of reinfarction and TLR was observed in the group treated with distal protection. No significant difference was observed in MACCE between the 2 groups.

Subgroup analysis. Figure 4 shows that no differences could be detected in any subgroup with regard to the primary end point. All p values for interaction were >0.10.

Table 4 ST-Segment Monitoring Data

	Distal Protection (n = 302)	Conventional Treatment (n = 301)	p Value
≥70% ST-segment resolution within 90 min of first wire	230 (76%)	218 (72%)	0.29
Time from first wire to ≥70% ST-segment resolution (min)	26 (0–80)	26 (4–90)	0.28
100% ST-segment resolution within 90 min of first wire	211 (70%)	198 (66%)	0.23
Time from first wire to 100% ST-segment resolution (min)	26 (0–90)	30 (4–90)	0.21
Single-lead ST-segment elevation 30 min after first wire (mV)	0.12 (0.04–0.26)	0.13 (0.05–0.26)	0.44
Single-lead ST-segment elevation 60 min after first wire (mV)	0.09 (0.04–0.20)	0.11 (0.04–0.21)	0.24
Single-lead ST-segment elevation 90 min after first wire (mV)	0.08 (0.03–0.17)	0.09 (0.03–0.19)	0.43

Continuous variables are presented by their medians (interquartile range).

Discussion

The present study evaluated the ECG, cardiac biomarker, echocardiographic, and clinical outcomes of routine use of a distal filterwire protection device in patients with a large STEMI. Distal protection was successfully performed in more than 80% of the patients assigned to this treatment. However, there appeared to be no significant differences in any of these parameters between the 2 groups, indicating that distal protection has no short-term benefit on myocardial function. In the PROMISE (Protection Devices in PCI Treatment of Myocardial Infarction for Salvage of Endangered Myocardium) study, the filterwire was also used to protect the distal coronary vasculatory bed in patients with myocardial infarction referred within 48 h of symptom onset (20). In that study, approximately two-thirds of the patients had STEMI, but coronary perfusion measured by a Doppler flow wire did not show any difference whether PCI was performed under distal protection or not. Infarct size determined by magnetic resonance as the volume of the left ventricle with delayed enhancement was similar in the 2 groups.

The prognostic utility of ECG ST-segment resolution after primary PCI has been described previously (21,22), and the value of continuous ST-segment monitoring after the procedure was stressed in a recent study, which also demonstrated the heterogeneous ST-segment changes in patients with STEMI (18). None of these sensitive prognostic markers was affected by the use of a filterwire during primary PCI in the present study.

Distal protection by inflation of a balloon and concomitant aspiration of blood and debris released from the stented lesion was performed in the EMERALD (Enhanced Myocardial Efficacy and Removal by Aspiration of Liberated Debris) randomized trial, including both patients with STEMI and patients referred for rescue angioplasty (12). Despite a relatively high success rate with regard to protection during stent deployment and extraction of visible debris in more than 70% of the cases, no improvement could be detected in the primary end point, complete ST-segment resolution during ECG monitoring after PCI. In addition, infarct size determined by ^{99m}Tc-sestamibi single-photon emission computerized tomography, the coprimary end point of the study, tended to be larger in the patient group assigned to distal protection. Embolization of thrombus material during manipulation of the device in the infarct-related area is an inherent risk of the mechanical interventions that has to be taken into account when the lack of efficacy of both the EMERALD and the present studies are interpreted (23). In addition, the Boston Scientific filterwire requires a landing zone of the device at least 30 mm distal to the segment that is going to be stented.

Thrombectomy performed with an aspiration catheter in patients with STEMI did not have any beneficial impact on myocardial salvage determined by ^{99m}Tc-sestamibi single-photon emission computerized tomography in the RESCUE (Routine Thrombectomy in Percutaneous Coronary Intervention for Acute ST-Segment Elevation Myocardial Infarction) study (13). There was no difference between ST-segment resolution in the 2 groups in that study, whereas the release of cardiac biomarkers was higher in the thrombectomy group. In addition, scintigraphic evaluation showed a significantly smaller final infarct size in the control group. The bulky profile of the Rescue catheter (Boston Scientific/Scimed, Inc., Maple Grove, Minnesota) may at least theoretically be detrimental to the vessel wall during aspiration, especially in angulated areas of the infarct-related artery, besides the potential risk to embolize thrombus material with this device as well.

Previous studies reported improvement in coronary blood flow and ST-segment resolution and a reduction in development of large myocardial infarctions by aid of thrombectomy using a combined helical cutter and vacuum extraction system or manual thrombus aspiration in patients with acute myocardial infarction (24–26). In addition, distal embolization was observed more frequently in the control patients, a finding that was confirmed by a meta-analysis of the use of thrombectomy devices in patients with acute myocardial infarctions (7). However, no beneficial effect was observed in 30-day mortality in any of these studies, and in a recent large randomized study rheolytic thrombectomy resulted in a significant increase in the scintigraphic infarct size compared with the control treatment (27).

As opposed to the results of the PROMISE and EMERALD trials, we found a 10% increase in the fraction of patients who obtained TIMI flow grade 3 after PCI

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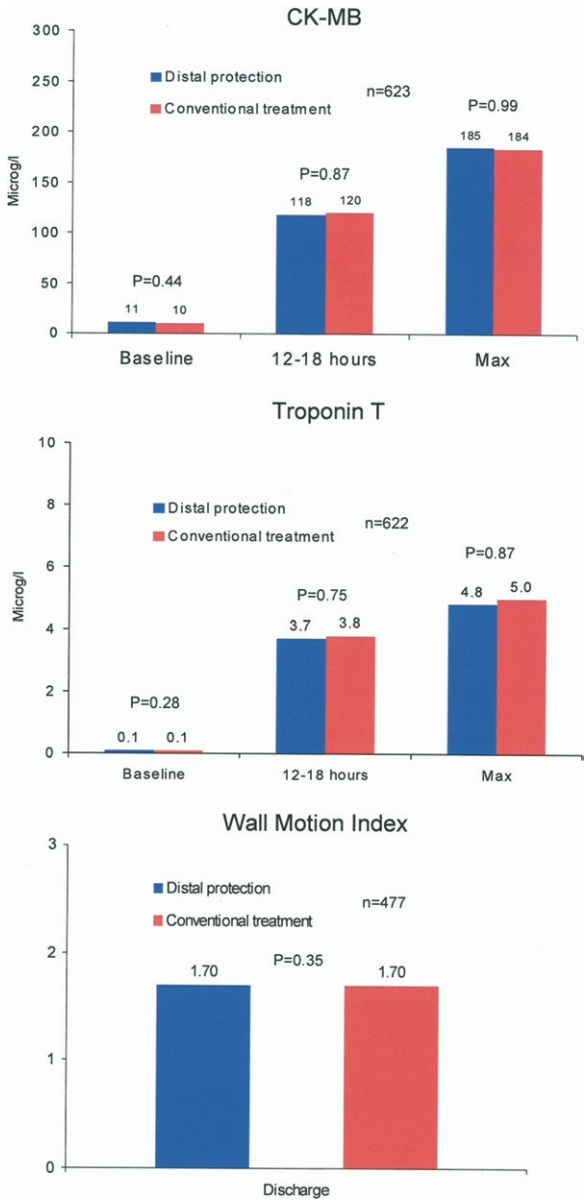

Figure 2 **Cardiac Biomarkers and WMI**

Maximal levels of cardiac biomarkers and echocardiographic determination of left ventricular wall motion index (WMI) after primary percutaneous coronary intervention in the 2 groups receiving distal protection and conventional treatment. CK-MB = creatine kinase-MB.

performed with distal protection. It is possible that disturbances in the blood flow pattern may not only be caused by embolization of thrombotic plaque material per se, but may also be a sign of reperfusion damage or indicate a condition of irreversibly impaired microvascular circulation. Blush grade was not determined, and it is possible that ST-segment resolution and circulating biomarkers are not adequately sensitive to detect small improvements in the microcirculation. In addition, it cannot be excluded that the devices used in this or other trials were inadequate to

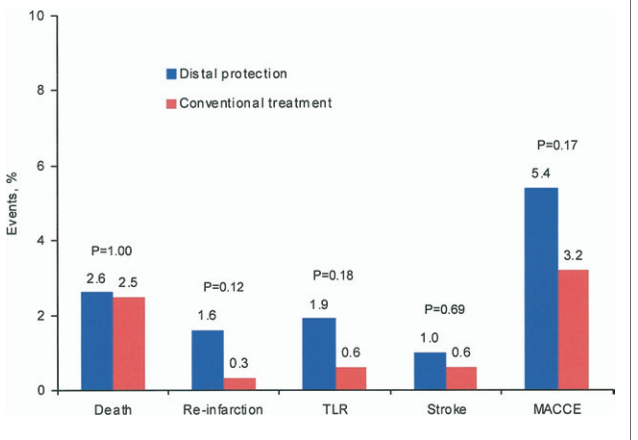

Figure 3 **MACCE After 30 Days**

Major adverse cardiac and cerebral events (MACCE) 30 days after primary percutaneous coronary intervention. TLR = target lesion revascularization.

prevent distal embolization, and that distal protection is indicated in the proportion of STEMI patients in whom a protection device can be successfully advanced and unfolded distally to a well-defined thrombus without embolization of thrombus material by the device itself, with subsequent balloon dilatation and deployment of stents.

Recent research did not indicate any safety problems using drug-eluting stents during primary PCI (28,29).

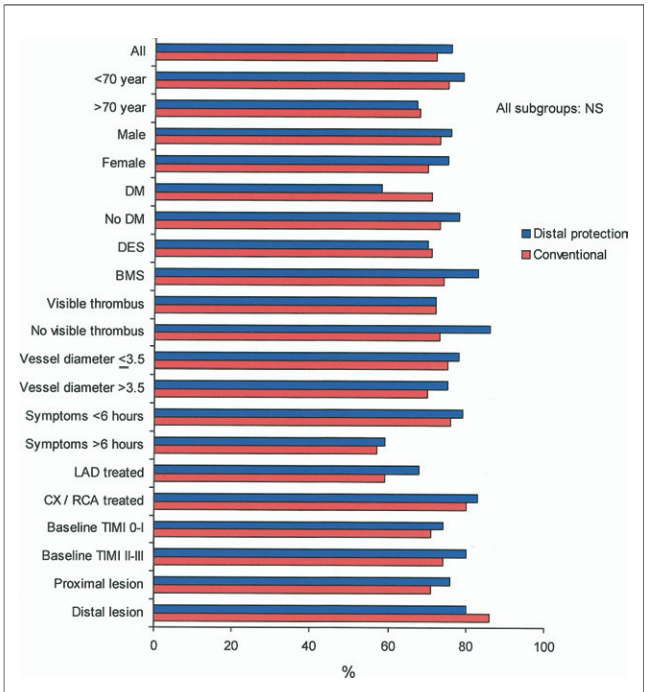

Figure 4 **Subgroup Analyses for the Primary End Point**

Subgroup analyses with regard to complete ST-segment resolution. BMS = bare-metal stent; CX = circumflex coronary artery; DES = drug-eluting stent; DM = diabetes mellitus; LAD = left anterior descending coronary artery; RCA = right coronary artery; TIMI = Thrombolysis In Myocardial Infarction.

However, in light of the slightly increased risk of late stent thrombosis occurring after implantation of drug-eluting stents (30–32), a risk that may potentially be considerably elevated in patients with a current burden of thrombus in the lesion to be stented, long-term observation of these studies is needed to make firm statements of stent choice in patients with STEMI.

Together with the results of other trials evaluating the effect of distal protection and thrombectomy, the results of the present study demonstrate that routine use of adjunctive mechanical devices cannot be advocated during PCI treatment of patients with STEMI.

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