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Long-Term Prognostic Value of ST-Segment Resolution in Patients Treated With Fibrinolysis or Primary Percutaneous Coronary Intervention

Results From the DANAMI-2 (DANish trial in Acute Myocardial Infarction-2)

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Objectives The purpose of this study was to determine the prognostic value of ST-segment resolution after primary percutaneous coronary intervention (pPCI) versus fibrinolysis.

Background Resolution of the ST-segment has been used as a surrogate end point in trials evaluating reperfusion in acute myocardial infarction; however, its prognostic significance may be limited to patients treated with fibrinolysis.

Methods In the DANAMI-2 (DANish trial in Acute Myocardial Infarction-2) substudy, including 1,421 patients, the ST-segment elevation at baseline, pre-intervention, 90 min, and 4 h was assessed. The ST-segment resolution was grouped as follows: 1) complete ≥70%; 2) partial 30% to <70%; and 3) no resolution <30%. End points were 30-day and long-term mortality and reinfarction.

Results The ST-segment resolution at 90 min was more pronounced after pPCI (median 60% vs. 45%, $p < 0.0001$), and a catch-up phenomenon was observed at 4 h. In the fibrinolysis group, 30-day and long-term mortality rates were significantly higher among patients without ST-segment resolution, whereas reinfarction rates were higher with complete ST-segment resolution. The ST-segment resolution was not associated with the 2 end points in the pPCI group. By multivariate analysis, ST-segment resolution at 4 h was an independent predictor of lower mortality, but higher reinfarction rates among patients receiving fibrinolytic therapy.

Conclusions The ST-segment resolution at 90 min was more complete after pPCI, suggesting better epicardial and microvascular reperfusion, whereas no difference between treatment strategies was seen at 4 h. The ST-segment resolution at 4 h correlated with decreased mortality, but increased reinfarction rates among patients receiving fibrinolytic therapy, whereas no association was seen for patients receiving pPCI. Consequently, 4-h ST-segment resolution remains an important prognosticator after fibrinolysis, but may be overemphasized as a surrogate end point after pPCI.
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Lack of ST-segment resolution despite attainment of TIMI (Thrombolysis In Myocardial Infarction) flow grade 3 in the epicardial coronary artery is associated with an increased mortality risk, and ST-segment resolution is considered a marker for microvascular perfusion (1). Prior studies have shown that TIMI flow grade 3 is obtained in more patients after primary percutaneous coronary intervention (pPCI) than after fibrinolysis (1,2); however, the relationship between the mode of reperfusion and ST-segment resolution is uncertain. Using data from the largest randomized trial comparing pPCI versus fibrinolysis, we hypothesized that early ST-segment resolution is more complete with pPCI, and the prognostic value of ST-segment resolution differs with the mode of revascularization being mechanical or pharmacological.

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Abbreviations and Acronyms

ECG = electrocardiogram
IQR = interquartile range
PCI = percutaneous coronary intervention
pPCI = primary percutaneous coronary intervention
STEMI = ST-segment elevation myocardial infarction
ΣST↑ = sum of ST-segment elevation

Methods

Patient population. The DANAMI-2 (DANish trial in Acute Myocardial Infarction-2) randomly assigned 1,572 patients with ST-segment elevation myocardial infarction (STEMI) to either pPCI or fibrinolysis with front-loaded tissue plasminogen activator (2). The present substudy was conducted in patients with an available randomization 12-lead electrocardiogram (ECG) with complete ST-segment measurements. The DANAMI-2 study complied with the Declaration of Helsinki, and the local Ethics Committee and Danish Data Protection Agency approved data collection.

Electrocardiographic data. A standard 12-lead ECG was performed in all patients at randomization (baseline ECG). Additional ECGs were obtained immediately before start of reperfusion treatment, and as timely, as clinically feasible at 90 min and 4 h after initiation of reperfusion treatment. The ECGs were analyzed at a centralized core laboratory blinded to all patient data. The ST-segment deviation was measured manually in the J-point to the nearest 0.5 mm in all leads except aVR. The sum of ST-segment elevation (ΣST↑) in all leads was determined for the individual ECG, and ST-segment resolution was assessed by the reduction in ΣST↑ between the baseline ECG and the following ECG as the percentage of baseline ΣST↑. Patients were divided into 3 groups according to the amount of ST-segment resolution: 1) complete ST-segment resolution (≥70%); 2) partial ST-segment resolution (30% to <70%); and 3) no resolution (<30%) (3).

End points. The end points were 30-day and long-term mortality from any cause or clinical reinfarction (2). Median follow-up was 4.2 years for mortality and 3.0 years for reinfarction. No patients were lost to follow-up.

Statistics. Baseline dichotomous variables were compared using the chi-square test and presented as percentages, and continuous variables were compared using a rank-sum test and presented as median with interquartile range (IQR). The rate of events in the 3 different ST-segment resolution categories at 90 min and 4 h were analyzed using the trend test. Kaplan-Meier curves were compared using log-rank statistics. Univariate analysis was performed for all baseline variables, and significant variables were included in a multivariable backward selection model excluding all variables with a p value >0.05. The Cox proportional hazard model was used to determine predictors of outcome. The ST-resolution was entered into the Cox model as a continuous variable and hazard ratio given per ST-segment resolution increase of 1%. Interactions were assessed by entering the interaction term into the Cox model. A p value (2-sided) ≤0.05 was considered significant. The SAS software, version 8.0 (SAS Institute, Cary, North Carolina) was used.

Results

Demographics for the 1,421 included patients with a baseline ECG are presented in Table 1. The ECGs recorded at pre-intervention, at 90 min, and at 4 h were available for 880, 1,233, and 1,208 patients, respectively.

Table 1 Demography According to Reperfusion Therapy

	Fibrinolysis (n = 711)	pPCI (n = 710)	p Value
Age, yrs	63 (54–73)	63 (54–72)	0.6
Males	524 (75)	517 (73)	0.7
Family history of coronary heart disease	273 (41)	250 (36)	0.1
Hypertension	148 (21)	140 (20)	0.6
Dyslipidemia	44 (6)	43 (6)	0.9
Diabetes mellitus	48 (7)	53 (8)	0.6
Current smoker	410 (59)	415 (59)	0.8
Peripheral arterial disease	30 (4)	30 (4)	1.0
History of stroke	13 (2)	5 (1)	0.06
History of MI	79 (11)	80 (11)	0.9
History of congestive heart failure	37 (5)	22 (3)	0.05
Time from randomization to fibrinolysis injection/first balloon, min	20 (15–30)	69 (52–89)	<0.0001
Systolic blood pressure at randomization, mm Hg	135 (115–150)	137 (120–152)	0.3
Baseline ST-segment elevation, mm	10 (6–14.5)	10 (7–15)	0.3
Infarct location			
Anterior MI	318 (45)	339 (48)	
Inferior/posterior MI	246 (34)	239 (34)	0.5
Other MI location	147 (21)	132 (18)	

Values are median (interquartile range) or n (%). Hypertension, dyslipidemia, and diabetes mellitus were considered present when a patient had been diagnosed before randomization and received treatment (diabetes mellitus: diet, sulfonylurea, or insulin).
MI = myocardial infarction; pPCI = primary percutaneous coronary intervention.

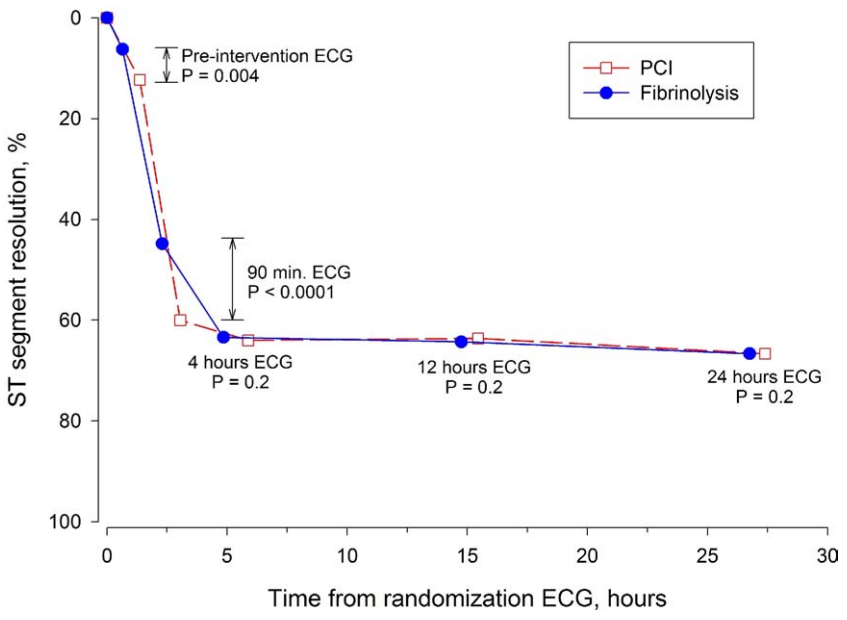

Figure 1 **ST-Segment Resolution**

Resolution of ST-segment elevation according to time after the baseline electrocardiogram (ECG).
The **red line with squares** indicates percutaneous coronary intervention (PCI); the **blue line with circles** indicates fibrinolysis.

ST-segment resolution and treatment groups. Figure 1 demonstrates median percent ST-segment resolution over time in the 2 treatment groups. Before the reperfusion attempt, more ST-segment resolution occurred in patients randomly assigned to pPCI (12%, IQR 0% to 31%, vs. 6%, IQR 0% to 47%; $p = 0.004$). Pronounced normalization of the ST-segment was observed in both groups at 90 min, but significantly more after pPCI (60%, IQR 33% to 82%, vs. 45%, IQR 13% to 71%; $p < 0.0001$). This difference had faded at 4 h (65%, IQR 40% to 80%, vs. 63%, IQR 35% to 85%; $p = 0.2$).

ST-segment resolution and outcome. Patient demographics according to ST-segment resolution at 4 h are listed in Table 2. Patients without ST-segment resolution tended to have the highest mortality rate regardless of treatment strategy; however, this difference only reached statistical significance in the fibrinolysis group (Table 3, Fig. 2). By multivariable analysis, age, diabetes mellitus, congestive heart failure, and ST-segment resolution at 4 h were found to be strong predictors of long-term mortality in all patients (Table 4). A difference in 1% ST-segment resolution increased the mortality risk by 8%. When dividing patients according to treatment group, 4-h ST-segment resolution and time-to-treatment were only independent predictors of mortality in the fibrinolysis group. However, no interaction was found between ST-segment resolution and treatment strategy regarding mortality ($p = 0.4$).

In the fibrinolysis group, reinfarction rates were significantly higher among patients with complete ST-segment resolution, but there was no association between reinfarction and ST-segment resolution for patients receiving pPCI (Table 5). Multivariable analysis of all patients showed that age, diabetes, heart failure, and time to treatment were independent predictors of reinfarction (Table 4). In the fibrinolysis group, the risk of reinfarction increased 1% with each additional 1% of ST-segment resolution, whereas in the pPCI group, ST-segment resolution did not influence reinfarction rate. There was a significant interaction between ST-segment resolution and treatment strategy regarding reinfarction ($p = 0.01$).

Discussion

This study showed that median percent ST-segment resolution at 90 min after reperfusion therapy is more complete with pPCI than with fibrinolysis. However, a catch-up phenomenon occurred at 4 h, resulting in similar levels of ST-segment resolution. Interestingly, ST-segment resolution was only predictive of mortality after fibrinolysis and not after pPCI. Additionally, complete ST-segment resolution was predictive of increased reinfarction among patients receiving fibrinolysis.

The median interval between randomization and initiation of reperfusion therapy was 49 min longer with pPCI than with fibrinolysis, inherent to the transportation delay (2). However, time from randomization to artery patency was still similar in the 2 treatment arms because needle to reperfusion time is approximately 45 min with fibrinolysis (4) and momentarily with pPCI. During the time delay, pPCI patients obtained more ST-segment resolution, which

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Table 2 Demographics and Hospital Findings According to Degree of ST-Segment Resolution at 4 Hours

	No Resolution (<30%) (n = 248)	Partial Resolution (30%–70%) (n = 473)	Complete Resolution (>70%) (n = 487)	p Value
Age, yrs	61.5 (53–73)	62.0 (52–71)	63 (55–72)	0.33
Males	199 (80)	359 (76)	328 (67)	0.0003
Family history of coronary heart disease	97 (40)	156 (35)	196 (41)	0.09
Hypertension	50 (20)	90 (19)	107 (22)	0.53
Dyslipidemia	18 (7)	26 (6)	33 (7)	0.60
Diabetes mellitus	27 (11)	35 (7)	25 (5)	0.017
Current smoker	132 (53)	272 (58)	302 (63)	0.05
Peripheral arterial disease	13 (5)	17 (4)	21 (4)	0.58
History of MI	40 (16)	58 (12)	38 (8)	0.0023
History of congestive heart failure	13 (5)	17 (4)	18 (4)	0.51
Time from randomization to fibrinolysis injection/first balloon, min	35 (20–68)	42 (20–71)	41 (20–72)	0.75
Systolic blood pressure at randomization, mm Hg	140 (120–155)	138 (118–153)	135 (116–150)	0.42
Baseline ST-segment elevation, mm	8.0 (5–11)	10.5 (7.5–15)	11.5 (8–16.5)	<0.001
Infarct location				
Anterior MI	127 (51)	248 (53)	192 (39)	<0.0001
Inferior/posterior MI	59 (24)	139 (29)	208 (43)	
Other MI location	62 (25)	86 (18)	87 (18)	
Maximum CK-MB	88 (20–156)	144.5 (77–244)	136 (67–234)	<0.0001
Discharge LVEF	50 (43–60)	50 (40–60)	50 (45–60)	0.01
Cardiogenic shock	16 (6)	23 (5)	17 (4)	0.19
Complete revascularization, TIMI flow grade 3, and stenosis <50%*	43 (53)	134 (59)	126 (54)	0.50
Residual stenosis in IRA, ≥30%*	46 (63)	146 (67)	150 (68)	0.72
No vessel disease*	18 (17)	5 (2)	1 (0)	<0.0001
1-vessel disease	29 (27)	81 (35)	63 (26)	
2-vessel disease	29 (27)	74 (32)	96 (40)	
3-vessel disease	33 (30)	73 (31)	81 (34)	
TIMI flow grade*	3 (3–3)	3 (3–3)	3 (3–3)	0.66

Values are median (interquartile range) or n (%). Hypertension, dyslipidemia, and diabetes mellitus were considered present when a patient had been diagnosed before randomization and received treatment (diabetes mellitus: diet, sulfonylurea, or insulin). *Data available for patients undergoing coronary intervention.

CK-MB = creatine kinase isoenzyme myocardial band; IRA = infarct-related artery; LVEF = left ventricular ejection fraction; TIMI = Thrombolysis In Myocardial Infarction; other abbreviations as in Table 1.

could be explained by either spontaneous regression or likely induced by aspirin and heparin intake at the referral hospital before transfer. On the contrary, patients randomly allocated to fibrinolytic therapy were treated with aspirin and heparin immediately before administration of fibrinolysis. This timing difference could favor the increased ST-segment resolution seen in the pPCI group at 90 min.

Our results are supported by an earlier study reporting a significant difference in 2-h ST-segment resolution with pPCI versus fibrinolysis (5). The finding of more patients who were male, and had diabetes, prior myocardial infarction, and anterior myocardial infarction in the group of patients without ST-segment resolution is consistent with earlier findings (3), in which patients without ST-segment resolution tended to have the worst risk profile at baseline. It is noteworthy that these high-risk patients had the least amount of ST-segment elevation at baseline. That may be caused by a difference in etiology, with these patients tending to have general arthrosclerosis with collaterals and a smaller culprit vessel than patients with complete ST-segment resolution, who may have a large epicardial artery with acute occlusion.

Dividing ST-segment resolution into 3 groups is a frequently used method for determining the relationship between treatment and mortality (3,6). Corresponding with our results, van't Hof et al. (6) found that 51% had complete ST-segment resolution 1 h after pPCI; however, we could not show a significant association with mortality. One explanation might be the use of stents in 93% of patients in the present study versus none in the study by van't Hof et al. (6). The placement of stents with high pressure can induce distal embolization, which could influence ST-segment resolution, but not mortality.

Traditionally, ST-segment resolution is determined 90 to 180 min after the start of fibrinolysis (1,7), whereas the optimal timing for determining ST-segment resolution preceding pPCI is uncertain (8) and may be at a much earlier time, given the immediate artery patency with pPCI. That may explain why we, in this study, with the earliest available post-procedure ECG recorded after 90 min, did not detect a relationship between ST-segment resolution and outcome in the pPCI group, while both 90-min and 4-h ECG predicted outcome after fibrinolysis. Consequently, both 90-min and 4-h ECG remain an important predictor in fibrinolysis, whereas early continuous ECG monitoring after pPCI may be necessary to rely on the findings of future trials (8).

Table 3 30-Day and Long-Term Mortality According to Degree of ST-Segment Resolution at 90 Min and 4 Hours After Initiation of Reperfusion Therapy

	No Resolution (<30%)	Partial Resolution (30%–70%)	Complete Resolution (>70%)	p Value
ST-segment resolution, 90 min				
All (n = 1,233)	365 (30%)	461 (37%)	407 (33%)	
pPCI (n = 602)	129 (21%)	233 (39%)	240 (40%)	
Fibrinolysis (n = (631)	236 (37%)	228 (36%)	167 (27%)	
30-day mortality				
pPCI	7 (5%)	15 (6%)	5 (2%)	0.07
Fibrinolysis	22 (9%)	11 (5%)	5 (3%)	0.007
4.2-yr mortality				
pPCI	21 (16%)	40 (17%)	28 (12%)	0.2
Fibrinolysis	49 (21%)	33 (14%)	22 (13%)	0.03
ST-segment resolution, 4 h (%)				
All (n = 1,208)	248 (21%)	473 (39%)	487 (40%)	
pPCI (n = 608)	112 (18%)	246 (41%)	250 (41%)	
Fibrinolysis (n = 600)	126 (22%)	227 (28%)	237 (40%)	
30-day mortality				
pPCI	5 (4%)	14 (6%)	11 (4%)	0.8
Fibrinolysis	14 (10%)	13 (6%)	5 (2%)	0.0007
4.2-yr mortality				
pPCI	22 (20%)	38 (15%)	37 (15%)	0.3
Fibrinolysis	32 (24%)	35 (15%)	25 (11%)	0.0009

Abbreviation as in Table 1.

Our finding of complete ST-segment resolution being associated with an increased rate of reinfarction in patients treated with fibrinolysis is new. An explanation may be that patients with complete ST-segment resolution are experiencing a large acute occlusion. When the occlusion is removed by fibrinolysis, it leaves a vulnerable plaque prone

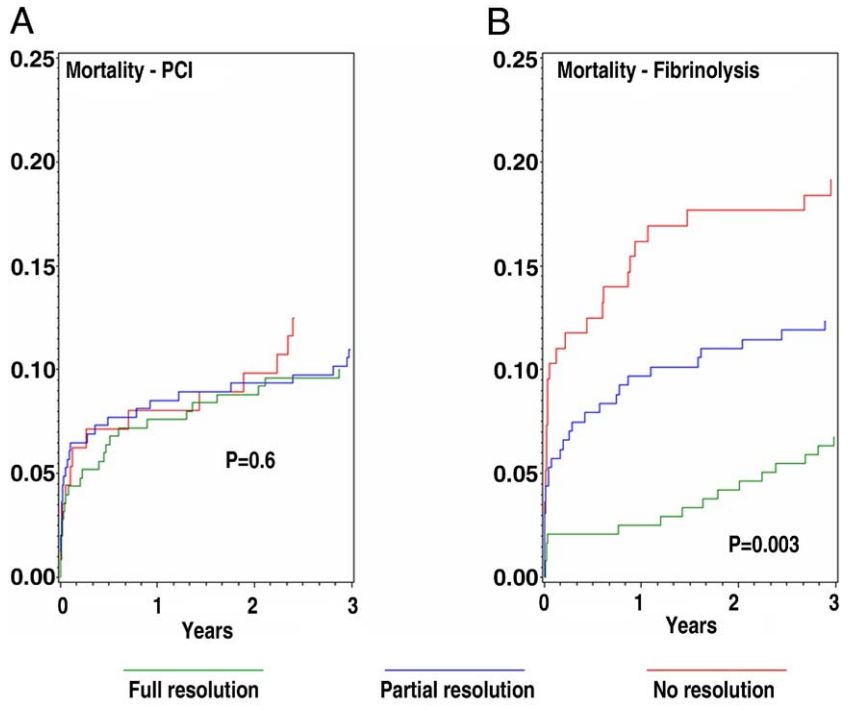

Figure 2 Mortality Rates

Kaplan-Meier curves illustrating mortality rates in the 2 treatment groups. The **green line** indicates full resolution, the **blue line** indicates partial resolution, and the **red line** indicates no resolution. PCI = percutaneous coronary intervention.

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Table 4 Predictors of Long-Term Outcome in Relation to ST-Segment Resolution 4 Hours After Start of Reperfusion Therapy

	Mortality	Reinfarction
All patients		
Age	1.08 (1.07–1.10)*	1.03 (1.01–1.04)*
Diabetes mellitus	2.21 (1.48–3.32)*	3.22 (2.00–5.21)*
Heart failure	2.15 (1.59–2.92)*	1.58 (1.07–2.32)†
4-h ST-segment resolution	0.994 (0.990–0.999)*	1.01 (1.00–1.01)
Time to treat	1.16 (0.89–1.50)	0.68 (0.48–0.97)†
pPCI-treated patients		
Age	1.08 (1.05–1.10)*	1.02 (0.99–1.05)
Diabetes mellitus	2.40 (1.42–4.04)*	5.37 (2.86–10.08)*
Heart failure	2.63 (1.71–4.04)*	2.16 (1.21–3.86)*
4-h ST-segment resolution	0.997 (0.990–1.004)	0.999 (0.990–1.008)
Time to treat	0.96 (0.61–1.50)	0.69 (0.37–1.29)
Fibrinolysis-treated patients		
Age	1.09 (1.07–1.11)*	1.03 (1.01–1.05)*
Diabetes mellitus	1.95 (1.00–3.80)†	1.41 (0.56–3.52)
Heart failure	1.62 (1.04–2.52)†	1.19 (0.70–2.01)
4-h ST-segment resolution	0.992 (0.986–0.998)*	1.011 (1.002–1.020)†
Time to treat	2.25 (1.07–4.73)†	0.45 (0.15–1.39)

Values are hazard ratio (95% confidence interval). Hazard ratio for age is given per 10 years, for ST-segment resolution per absolute change in 1%. Other variables excluded from the model because of insignificant predictive values were clinical variables as listed in Table 1. *$p \leq 0.01$; †$0.01 < p \leq 0.05$.

pPCI = primary percutaneous coronary intervention.

to reinfarction later. Conversely, in patients without ST-segment resolution, the microcirculation is disrupted, leaving no or only minor viable myocardium exposed for later reinfarction. The consequence of reinfarction after the index infarct is a higher mortality rate (9), making any method that can identify patients at increased risk of reinfarction important. Our results suggest that all patients receiving fibrinolysis may benefit from catheterization. Accordingly, rescue PCI in patients with failed fibrinolysis has been shown not only to reduce reinfarction rates but also to lower heart failure and mortality (10). Thus, it is tempting to speculate whether fibrinolysis followed by PCI could be an alternative to pPCI in areas where pPCI is not ready available. However, caution should be taken regarding both timing and which fibrinolytic regime to use, as facilitated PCI has been shown to increase stroke rate, ischemic cardiac complications, heart failure, shock, and mortality rates (11). On the contrary, the CARESS (Combined Abciximab REteplase Stent Study) trial (12) found improved outcome for STEMI patients immediately transferred for PCI after half-dose reteplase plus abciximab, compared to management at the local hospital.

Study limitations. ST-segment resolution was measured at different time points after the presumed time of an open artery in the 2 treatments groups. This difference could have biased the findings in favor of pPCI. An ECG immediately after PCI may have been preferable and more comparable to a 90-min ECG in patients receiving fibrinolytic agents. Additionally, continuous ST-segment monitoring would have been preferable as opposed to the static standard 12-lead ECG because within-patient variability may confound the present observations.

Conclusions

Our results indicate that ST-segment resolution in the conventional 90-min and 4-h ECG remains an important prognostic factor after fibrinolysis, and confirm the clinical

Table 5 30-Day and Long-Term Reinfarction According to Degree of ST-Segment Resolution at 90 Min and 4 Hours After Initiation of Reperfusion Therapy

	No Resolution (<30%)	Partial Resolution (30%–70%)	Complete Resolution (>70%)	p Value
ST-segment resolution, 90 min				
All (n = 1,233)	365 (30%)	461 (37%)	407 (33%)	
pPCI (n = 602)	129 (21%)	233 (39%)	240 (40%)	
Fibrinolysis (n = 631)	236 (37%)	228 (36%)	167 (27%)	
30-day reinfarction				
pPCI	3 (2%)	3 (1%)	3 (1%)	0.5
Fibrinolysis	9 (4%)	13 (6%)	18 (11%)	0.006
3-yr reinfarction				
pPCI	14 (11%)	17 (7%)	17 (7%)	0.2
Fibrinolysis	21 (9%)	24 (11%)	27 (16%)	0.03
ST-segment resolution, 4 h (%)				
All (n = 1,208)	248 (21%)	473 (39%)	487 (40%)	
pPCI (n = 608)	112 (18%)	246 (41%)	250 (41%)	
Fibrinolysis (n = 600)	126 (22%)	227 (28%)	237 (40%)	
30-day reinfarction				
pPCI	3 (3%)	4 (2%)	3 (1%)	0.3
Fibrinolysis	6 (4%)	7 (3%)	23 (10%)	0.01
3-yr reinfarction				
pPCI	15 (14%)	14 (6%)	26 (10%)	0.8
Fibrinolysis	11 (8%)	17 (7%)	40 (17%)	0.003

pPCI = primary percutaneous coronary intervention.

utility of these ECGs in selecting patients for rescue PCI. The provocative finding of limited prognostic value of ST-segment resolution in a population of STEMI patients treated with pPCI deserves further investigation, especially because it is already widespread as a surrogate end point in trials.

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Key Words: primary percutaneous coronary intervention ■ fibrinolysis ■ ST-segment elevation myocardial infarction ■ ST-segment resolution ■ outcome.