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Clinical Research

1-Year Survival in a Randomized Trial of Facilitated Reperfusion

Results From the FINESSE (Facilitated Intervention With Enhanced Reperfusion Speed to Stop Events) Trial

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Objectives The aim of this report was to evaluate 12-month outcomes of facilitated percutaneous coronary intervention (PCI) in the FINESSE (Facilitated Intervention with Enhanced Reperfusion Speed to Stop Events) trial.

Background Treatment delays remain common for patients with primary PCI leading to studies evaluating possible benefit of "facilitated" PCI. In the FINESSE trial, no reduction in the 90-day primary ischemic end point and an increase in bleeding were observed with both facilitated approaches, although modest favorable trends were seen for some patient subgroups.

Methods A total of 2,452 patients with ST-segment elevation myocardial infarction (MI) and anticipated 1 to 4 h delay until catheterization were randomized to reduced-dose reteplase + abciximab, abciximab alone, or placebo, followed by expedited primary PCI. Placebo-treated patients received abciximab in the cath lab. One-year mortality was a pre-specified secondary end point.

Results One-year mortalities in the 3 groups noted in the preceding text were 6.3%, 7.4%, and 7.0%, respectively (p = NS), representing 1.1%, 1.9%, and 2.5% increments since the 90-day outcome (p = 0.053 for combination treatment vs. primary PCI). A favorable trend with combination treatment was seen for patients with anterior MI (p = 0.09), but no other specified groups benefited or tended to benefit. Independent baseline correlates of 1-year mortality were systolic blood pressure $<$100 mm Hg, prior MI, age, Killip class $>$1, anterior MI, body mass index $\leq$25 kg/m^2, heart rate $>$100 beats/min, and no statin use.

Conclusions These results suggest that widespread utilization of the facilitated approaches tested cannot be justified, but that high-risk patient groups such as patients with anterior MI may deserve further study. (The FINESSE trial; NCT00046228) (J Am Coll Cardiol Intv 2009;2:909–16) © 2009 by the American College of Cardiology Foundation

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Patient delays during treatment of ST-segment elevation myocardial infarction (STEMI) with primary percutaneous coronary intervention (PCI) remain common (1). The FINESSE (Facilitated Intervention with Enhanced Reperfusion Speed to Stop Events) trial formally evaluated 2 possible "facilitation" strategies, attempting to safely achieve reperfusion before PCI (2). In the aggregate of patients studied, neither half dose reteplase + abciximab (combination facilitated PCI), nor abciximab alone given as soon as possible proved superior to primary PCI with abciximab in the catheterization lab in reducing the primary end point (3). Infarct size as estimated by area under the creatine kinase release curve was, however, reduced by combination therapy (1,625 IU/l /h) compared with both early abciximab (1,782 IU/l/h) and in lab abciximab (1,860 IU/l/h) ($p = 0.01$ and $p < 0.001$, respectively). In addition, modestly favorable trends with combination therapy in the primary clinical end point were seen for patients randomized ≤3 h from symptom onset and for high-risk patients (any of anterior myocardial infarction [MI], Killip class >1, heart rate at presentation >100 beats/min) (3). Conversely, both facilitation approaches increased bleeding (e.g., nonintracranial Thrombolysis In Myocardial Infarction (TIMI) (major or minor bleeding 14.5% vs. 6.9%; $p < 0.001$ combination and primary PCI, respectively) (3).

One-year mortality was a prespecified secondary end point, whose outcome may well be expected to reflect the long-term effects of infarct size modification and bleeding (4–6). The present report summarizes the between-treatment results at 1 year among all randomized patients and various pre-specified subgroups.

Abbreviations and Acronyms

MI = myocardial infarction

PCI = percutaneous coronary intervention

STEMI = ST-segment elevation myocardial infarction

Table 1. Multivariable Logistic Regression Model: Correlation With 1-Year Mortality

Variable	Hazard Ratio	Lower 95% CI	Upper 95% CI	p Value
Randomized treatments				
Combination facilitated PCI vs. primary PCI	0.82	0.56	1.19	0.293
Abciximab facilitated vs. primary PCI	0.99	0.68	1.43	0.952
Baseline variables included in the model				
Age (per yr)	1.08	1.06	1.09	<0.0001
History of prior MI	2.48	1.68	3.65	<0.0001
Systolic BP <100 mm Hg	4.38	2.66	7.21	<0.0001
Killip class >1	2.08	1.45	3.00	<0.0001
Anterior MI	1.81	1.32	2.50	0.0003
BMI ≤25 kg/m^2	1.57	1.14	2.16	0.006
Pulse rate >100 beats/min	1.99	1.21	3.29	0.007
No statin within 7 days before randomization	1.95	1.13	3.35	0.016
Thienopyridine within 7 days before randomization	0.57	0.31	1.04	0.065
Western Europe vs. Eastern Europe	0.69	0.47	1.03	0.068
NA and ROW vs. Eastern Europe	0.55	0.27	1.12	0.100
Diabetes	1.32	0.90	1.93	0.155
Aspirin within 7 days before randomization	1.30	0.90	1.87	0.168
Women	0.84	0.58	1.19	0.325
Hub site	0.87	0.63	1.20	0.387
Prior CHF	1.45	0.57	3.67	0.438
Symptom onset to randomization ≤3 h	0.91	0.66	1.25	0.546
Smoker	0.92	0.66	1.29	0.649
LMWH substudy	0.99	0.67	1.48	0.968

BP = blood pressure; BMI = body mass index; CHF = congestive heart failure; CI = confidence interval; LMWH = low-molecular-weight heparin; MI = myocardial infarction; NA = North America; PCI = percutaneous coronary intervention; ROW = rest of world.

Methods

Patients with ST-segment elevation suggesting acute MI with symptoms <6 h, eligible for either fibrinolytic therapy or primary PCI, and for whom the estimated time to diagnostic catheterization was 1 to 4 h, were eligible for randomization. Patients <60 years of age with isolated inferior wall MI were excluded due to their low risk. Further details of the study design have been previously reported (2). This study was approved by the local institutional review boards, and all patients provided written informed consent.

Patients were randomized in a double-blind double dummy fashion to receive reteplase + abciximab (combination-

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Table 2. Baseline Characteristics and Initial Treatment

	Primary PCI (n = 806)	Abciximab-Facilitated PCI (n = 818)	Reteplase/Abciximab-Facilitated PCI (n = 828)	p Value
Women	207 (25.7)	216 (26.4)	219 (26.4)	0.925
Age (yrs), mean ± SD	62.5 ± 11.4	61.9 ± 11.8	62.6 ± 11.4	
<75	678 (84.1)	695 (85.0)	691 (83.5)	0.702
≥75	128 (15.9)	123 (15.0)	137 (16.5)	
Cigarette smoker				
Past or current	524 (65.0)	549 (67.1)	537 (64.9)	0.561
Current smoker	357 (44.3)	363 (44.4)	347 (41.9)	0.518
Diabetes	133 (16.5)	119 (14.5)	128 (15.5)	0.553
Treated with insulin	29 (3.6)	28 (3.4)	32 (3.9)	0.890
Previous MI	82 (10.2)	80 (9.8)	104 (12.6)	0.146
Previous CHF	13 (1.6)	9 (1.1)	12 (1.4)	0.664
Hypertension	374 (46.4)	405 (49.5)	394 (47.6)	0.448
Hypercholesterolemia	276 (34.2)	249 (30.4)	291 (35.1)	0.510
Treated	131 (16.3)	125 (15.3)	144 (17.4)	
Location of infarction				
Anterior	370 (45.9)	403 (49.3)	400 (48.3)	0.375
Inferior/posterior	358 (44.4)	358 (43.8)	378 (45.7)	
Other	141 (17.5)	117 (14.3)	110 (13.3)	
Not localized	10 (1.2)	4 (0.5)	6 (0.7)	
Killip class				0.376
I	713 (88.5)	714 (87.3)	741 (89.5)	
II	67 (8.3)	81 (9.9)	68 (8.2)	
III	11 (1.4)	6 (0.7)	3 (0.4)	
IV	2 (0.2)	0 (0.0)	3 (0.4)	
Unknown	13 (1.6)	17 (2.1)	13 (1.6)	

Data are reported as n (%) unless otherwise noted.
Abbreviations as in Table 1.

facilitated PCI), abciximab alone (abciximab-facilitated PCI), or placebo as soon as possible, with the latter group receiving abciximab in the cath lab while the other patients received placebo. Dosing regimens and adjunctive antithrombin therapy have been previously described (2).

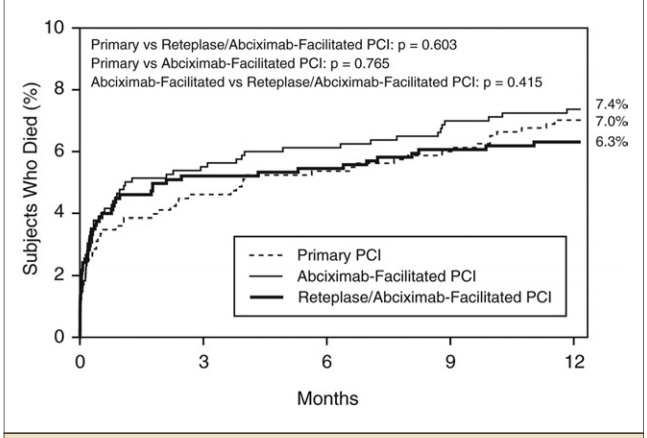


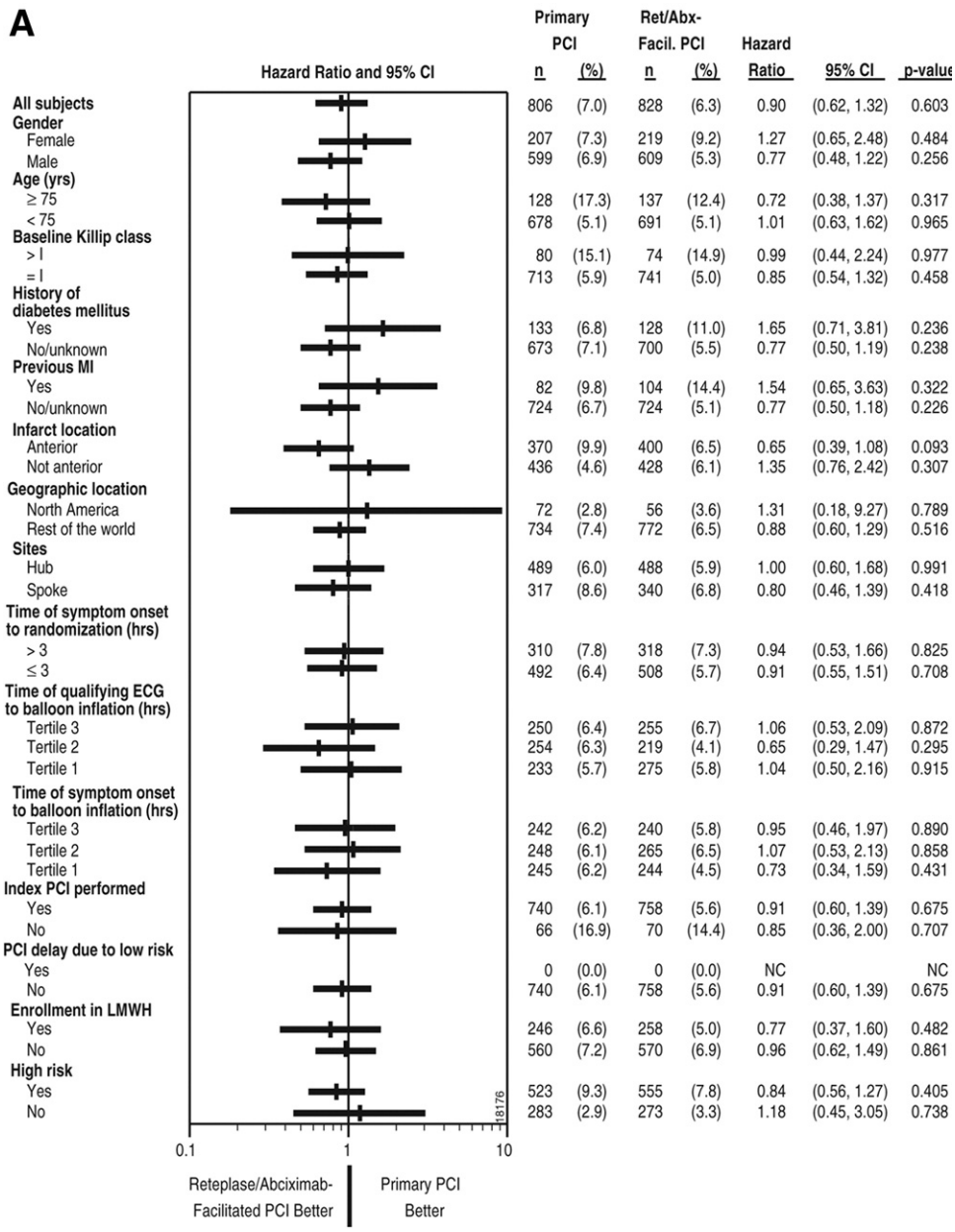
Figure 1. All-Cause Mortality Through 1 Year for Each of the 3 Treatment Groups (Intention to Treat)

PCI = percutaneous coronary intervention.

Table 3. Independent Correlates of 1-Year Mortality: Landmark Analysis From Day 7

Variable	Hazard Ratio	Lower 95% CI	Upper 95% CI	p Value
Randomized treatments				
Combination facilitated PCI vs. primary PCI	0.55	0.33	0.93	0.026
Abciximab facilitated vs. primary PCI	0.89	0.56	1.43	0.633
Post-randomization variables				
TIMI major or minor bleed through day 7	3.18	1.99	5.08	<0.0001
Baseline variables				
Age (per yr)	1.08	1.05	1.10	<0.0001
History of prior MI	3.35	2.06	5.46	<0.0001
Anterior MI	2.04	1.34	3.12	<0.0001
Killip class >1	2.17	1.33	3.53	0.002
Western Europe vs. Eastern Europe	0.48	0.28	0.82	0.007
Thienopyridine within 7 days before randomization	0.36	0.14	0.91	0.031
Systolic BP <100 mm Hg	2.54	1.07	5.99	0.034

MI = myocardial infarction; PCI = percutaneous coronary intervention; TIMI = Thrombolysis In Myocardial Infarction; other abbreviations as in Table 1.



	Primary PCI n	(%)	Ret/Abx-Facil. PCI n	(%)	Hazard Ratio	95% CI	p-value
All subjects	806	(7.0)	828	(6.3)	0.90	(0.62, 1.32)	0.603
Gender							
Female	207	(7.3)	219	(9.2)	1.27	(0.65, 2.48)	0.484
Male	599	(6.9)	609	(5.3)	0.77	(0.48, 1.22)	0.256
Age (yrs)							
≥ 75	128	(17.3)	137	(12.4)	0.72	(0.38, 1.37)	0.317
< 75	678	(5.1)	691	(5.1)	1.01	(0.63, 1.62)	0.965
Baseline Killip class							
> I	80	(15.1)	74	(14.9)	0.99	(0.44, 2.24)	0.977
= I	713	(5.9)	741	(5.0)	0.85	(0.54, 1.32)	0.458
History of diabetes mellitus							
Yes	133	(6.8)	128	(11.0)	1.65	(0.71, 3.81)	0.236
No/unknown	673	(7.1)	700	(5.5)	0.77	(0.50, 1.19)	0.238
Previous MI							
Yes	82	(9.8)	104	(14.4)	1.54	(0.65, 3.63)	0.322
No/unknown	724	(6.7)	724	(5.1)	0.77	(0.50, 1.18)	0.226
Infarct location							
Anterior	370	(9.9)	400	(6.5)	0.65	(0.39, 1.08)	0.093
Not anterior	436	(4.6)	428	(6.1)	1.35	(0.76, 2.42)	0.307
Geographic location							
North America	72	(2.8)	56	(3.6)	1.31	(0.18, 9.27)	0.789
Rest of the world	734	(7.4)	772	(6.5)	0.88	(0.60, 1.29)	0.516
Sites							
Hub	489	(6.0)	488	(5.9)	1.00	(0.60, 1.68)	0.991
Spoke	317	(8.6)	340	(6.8)	0.80	(0.46, 1.39)	0.418
Time of symptom onset to randomization (hrs)							
> 3	310	(7.8)	318	(7.3)	0.94	(0.53, 1.66)	0.825
≤ 3	492	(6.4)	508	(5.7)	0.91	(0.55, 1.51)	0.708
Time of qualifying ECG to balloon inflation (hrs)							
Tertile 3	250	(6.4)	255	(6.7)	1.06	(0.53, 2.09)	0.872
Tertile 2	254	(6.3)	219	(4.1)	0.65	(0.29, 1.47)	0.295
Tertile 1	233	(5.7)	275	(5.8)	1.04	(0.50, 2.16)	0.915
Time of symptom onset to balloon inflation (hrs)							
Tertile 3	242	(6.2)	240	(5.8)	0.95	(0.46, 1.97)	0.890
Tertile 2	248	(6.1)	265	(6.5)	1.07	(0.53, 2.13)	0.858
Tertile 1	245	(6.2)	244	(4.5)	0.73	(0.34, 1.59)	0.431
Index PCI performed							
Yes	740	(6.1)	758	(5.6)	0.91	(0.60, 1.39)	0.675
No	66	(16.9)	70	(14.4)	0.85	(0.36, 2.00)	0.707
PCI delay due to low risk							
Yes	0	(0.0)	0	(0.0)	NC		NC
No	740	(6.1)	758	(5.6)	0.91	(0.60, 1.39)	0.675
Enrollment in LMWH							
Yes	246	(6.6)	258	(5.0)	0.77	(0.37, 1.60)	0.482
No	560	(7.2)	570	(6.9)	0.96	(0.62, 1.49)	0.861
High risk							
Yes	523	(9.3)	555	(7.8)	0.84	(0.56, 1.27)	0.405
No	283	(2.9)	273	(3.3)	1.18	(0.45, 3.05)	0.738

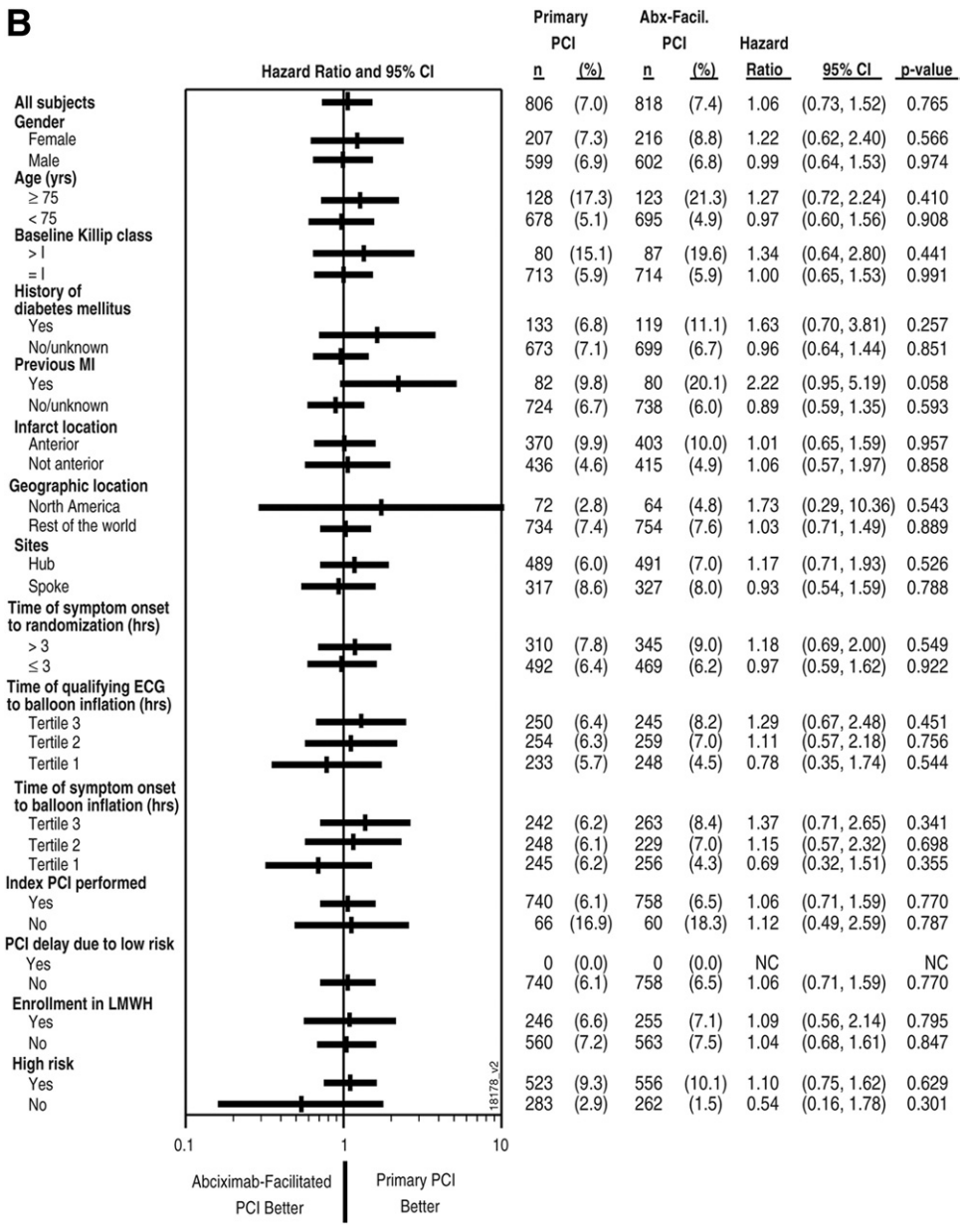
Figure 2. Comparison of 1-Year All-Cause Mortality in Subgroups

Comparison of 1-year all-cause mortality in subgroups. **(A)** Combination treatment versus primary percutaneous coronary intervention (PCI) (with in lab abciximab). *Continued on next page*

The primary end point was a composite of death from all causes, ventricular fibrillation occurring >48 h after randomization, cardiogenic shock or congestive heart failure at 90 days and has been previously reported (3).

Follow-up through 1 year was obtained in 98.6%, 98.3%, and 97.6% of the combination-facilitated, abciximab-facilitated, and primary PCI groups (p = NS).

Survival analysis was performed using Cox proportional hazards models to evaluate independent baseline risk factors. Comparisons of area under creatine kinase curve to estimate infarct size and subgroup analyses were performed as previously described (3). To assess the association between baseline variables and also outcomes through day 7 post-randomization and 1-year mortality,



	Primary PCI n	Primary PCI (%)	Abx-Facil. PCI n	Abx-Facil. PCI (%)	Hazard Ratio	95% CI	p-value
All subjects	806	(7.0)	818	(7.4)	1.06	(0.73, 1.52)	0.765
Gender							
Female	207	(7.3)	216	(8.8)	1.22	(0.62, 2.40)	0.566
Male	599	(6.9)	602	(6.8)	0.99	(0.64, 1.53)	0.974
Age (yrs)							
≥ 75	128	(17.3)	123	(21.3)	1.27	(0.72, 2.24)	0.410
< 75	678	(5.1)	695	(4.9)	0.97	(0.60, 1.56)	0.908
Baseline Killip class							
> I	80	(15.1)	87	(19.6)	1.34	(0.64, 2.80)	0.441
= I	713	(5.9)	714	(5.9)	1.00	(0.65, 1.53)	0.991
History of diabetes mellitus							
Yes	133	(6.8)	119	(11.1)	1.63	(0.70, 3.81)	0.257
No/unknown	673	(7.1)	699	(6.7)	0.96	(0.64, 1.44)	0.851
Previous MI							
Yes	82	(9.8)	80	(20.1)	2.22	(0.95, 5.19)	0.058
No/unknown	724	(6.7)	738	(6.0)	0.89	(0.59, 1.35)	0.593
Infarct location							
Anterior	370	(9.9)	403	(10.0)	1.01	(0.65, 1.59)	0.957
Not anterior	436	(4.6)	415	(4.9)	1.06	(0.57, 1.97)	0.858
Geographic location							
North America	72	(2.8)	64	(4.8)	1.73	(0.29, 10.36)	0.543
Rest of the world	734	(7.4)	754	(7.6)	1.03	(0.71, 1.49)	0.889
Sites							
Hub	489	(6.0)	491	(7.0)	1.17	(0.71, 1.93)	0.526
Spoke	317	(8.6)	327	(8.0)	0.93	(0.54, 1.59)	0.788
Time of symptom onset to randomization (hrs)							
> 3	310	(7.8)	345	(9.0)	1.18	(0.69, 2.00)	0.549
≤ 3	492	(6.4)	469	(6.2)	0.97	(0.59, 1.62)	0.922
Time of qualifying ECG to balloon inflation (hrs)							
Tertile 3	250	(6.4)	245	(8.2)	1.29	(0.67, 2.48)	0.451
Tertile 2	254	(6.3)	259	(7.0)	1.11	(0.57, 2.18)	0.756
Tertile 1	233	(5.7)	248	(4.5)	0.78	(0.35, 1.74)	0.544
Time of symptom onset to balloon inflation (hrs)							
Tertile 3	242	(6.2)	263	(8.4)	1.37	(0.71, 2.65)	0.341
Tertile 2	248	(6.1)	229	(7.0)	1.15	(0.57, 2.32)	0.698
Tertile 1	245	(6.2)	256	(4.3)	0.69	(0.32, 1.51)	0.355
Index PCI performed							
Yes	740	(6.1)	758	(6.5)	1.06	(0.71, 1.59)	0.770
No	66	(16.9)	60	(18.3)	1.12	(0.49, 2.59)	0.787
PCI delay due to low risk							
Yes	0	(0.0)	0	(0.0)	NC		NC
No	740	(6.1)	758	(6.5)	1.06	(0.71, 1.59)	0.770
Enrollment in LMWH							
Yes	246	(6.6)	255	(7.1)	1.09	(0.56, 2.14)	0.795
No	560	(7.2)	563	(7.5)	1.04	(0.68, 1.61)	0.847
High risk							
Yes	523	(9.3)	556	(10.1)	1.10	(0.75, 1.62)	0.629
No	283	(2.9)	262	(1.5)	0.54	(0.16, 1.78)	0.301

Figure 2. Continued

(B) Abciximab-facilitation versus primary PCI (with in lab abciximab). CI = confidence interval; ECG = electrocardiogram; LMWH = low molecular weight heparin; MI = myocardial infarction.

landmark analyses (7,8), which included patients alive through day 7, were carried out using Cox models with time varying hazards. To investigate which baseline characteristics were associated with 1-year mortality in the study population, a multivariate Cox model was used including pre-selected covariates (Table 1). No model selection procedure was undertaken to control the bias that may be introduced by model uncertainty. Statistical significance was determined at the 2-sided value of $p < 0.05$. Analyses were performed with SAS software, version 8.02 (SAS Institute Inc., Cary, North Carolina).

Results

Summary baseline demographics and medical history for the patients in the 3 treatment groups are provided in Table 2. Median interval from symptom onset to qualifying electrocardiogram was 2.1 (1.2 to 3.3 interquartile) h. Door-to-

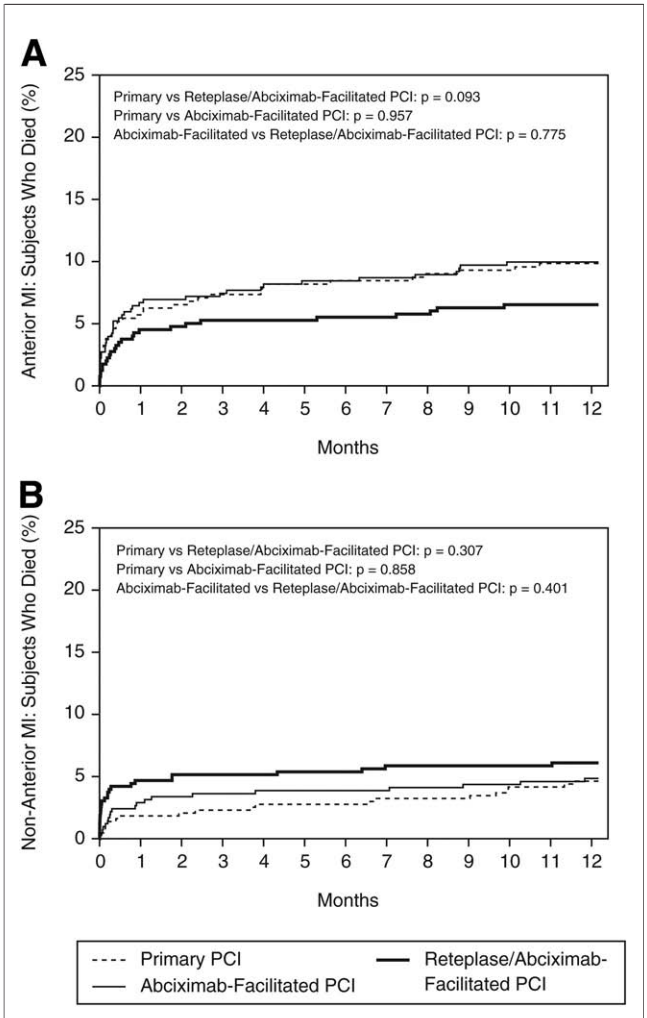


Figure 3. All-Cause Mortality Through 1 Year for Each of the 3 Treatment Groups

All-cause mortality through 1 year for each of the 3 treatment groups for **(A)** anterior MI subgroup and **(B)** nonanterior MI subgroup. Abbreviations as in Figure 2.

balloon time was 2.2 (1.8 to 2.8 interquartile) h. There were no significant differences in any of the baseline parameters measured. Infarct size estimated by CK curve analyses for anterior MIs, stratified by treatment group, reteplase + abciximab, abciximab, primary PCI were 1,684 (p = 0.015 vs. primary PCI), 1,792 (p = 0.247 vs. primary PCI) and 1,966 (median value [IU/l/h]). For nonanterior MIs, the values were 1,147 (p = 0.015 vs. primary PCI), 1,288 (p = 0.857 vs. primary PCI), and 1,322 IU/l/h, respectively. TIMI major and minor bleeding was seen in 17.3%, 10.4%, and 7.0% of patients in the anterior MI subgroup and 12.2%, 9.6%, and 7.6% in the nonanterior MI subgroups, respectively, for the 3 treatment groups noted in the preceding text. At hospital discharge or Day 7 (whichever was earlier), 75.0%, 75.9%, 74.2%, and 83.5%, 85.5%, and 84.1% in the combination-facilitated, abciximab-facilitated, and primary PCI groups received angiotensin-converting enzyme inhibitors (or angiotensin II receptor blockers) and beta-blockers, respectively (all p = NS).

All-cause mortality at 1 year was, 6.3%, 7.4%, and 7.0% in the combination- facilitated PCI, abciximab-facilitated PCI, and primary PCI with in-lab abciximab groups, respectively (p = NS) (Fig. 1), which represented a 1.1%, 1.9%, and 2.5% increment from the initial 90-day end point (p = 0.053 for combination vs. primary PCI). The mortality difference between combination-facilitated PCI and primary PCI after correction for confounders in multivariate landmark analysis for survivors at day 7 was significant at p = 0.026 (Table 3).

One-year mortalities in pre-specified subgroups, referenced against the primary PCI control, are shown in Figures 2A and 2B. Although these results must be interpreted with caution, patients with anterior MI (35% relative reduction in mortality [subset p = 0.093, interaction p = 0.065]) appeared possibly to benefit with combination-facilitated PCI (Fig. 3).

Independent correlates of 1-year mortality in the entire study cohort are presented in Tables 1 and 3. Table 1 shows the impact of variables available before randomization, notably hypotension, prior MI, age, Killip class, and infarct location. The treatment to which the patient was randomly allocated (reteplase + abciximab combination, abciximab alone, or placebo with later in-lab abciximab) was not correlated with outcome after consideration of other variables. In Table 3 landmark analysis from day 7 shows correlates of mortality from that point onward, the risk associated with TIMI major or minor bleeding and covariates from the baseline analysis, as well as the benefit of combination reteplase and abciximab on mortality from that time forward. Figure 4 shows the impact on 1-year mortality of TIMI major or minor bleeding in the landmark analysis from day 7 for all treatment groups and by each treatment group separately.

Discussion

The competing treatment outcomes of infarct size reduction and major bleeding have been shown to strongly influence long-term survival in patients treated with STEMI (4–6). In the 2,452 patient FINESSE trial, combination facilitation therapy with half-dose reteplase + abciximab was shown to significantly reduce infarct size but also increase major bleeding compared with primary PCI and in-lab abciximab at 7 days, but to have no overall clinical benefit at the time of the primary study end point at 90 days (3). The principal findings of this 12-month outcome analysis are: of pre-specified secondary end points: 1) there was no difference among the 3 treatment groups in overall mortality; 2) the anterior MI subgroup exhibited a strong trend toward improved survival with combination facilitated PCI compared with primary PCI with abciximab in the lab (p = 0.093); and in post hoc analyses; 3) advanced age, prior MI,

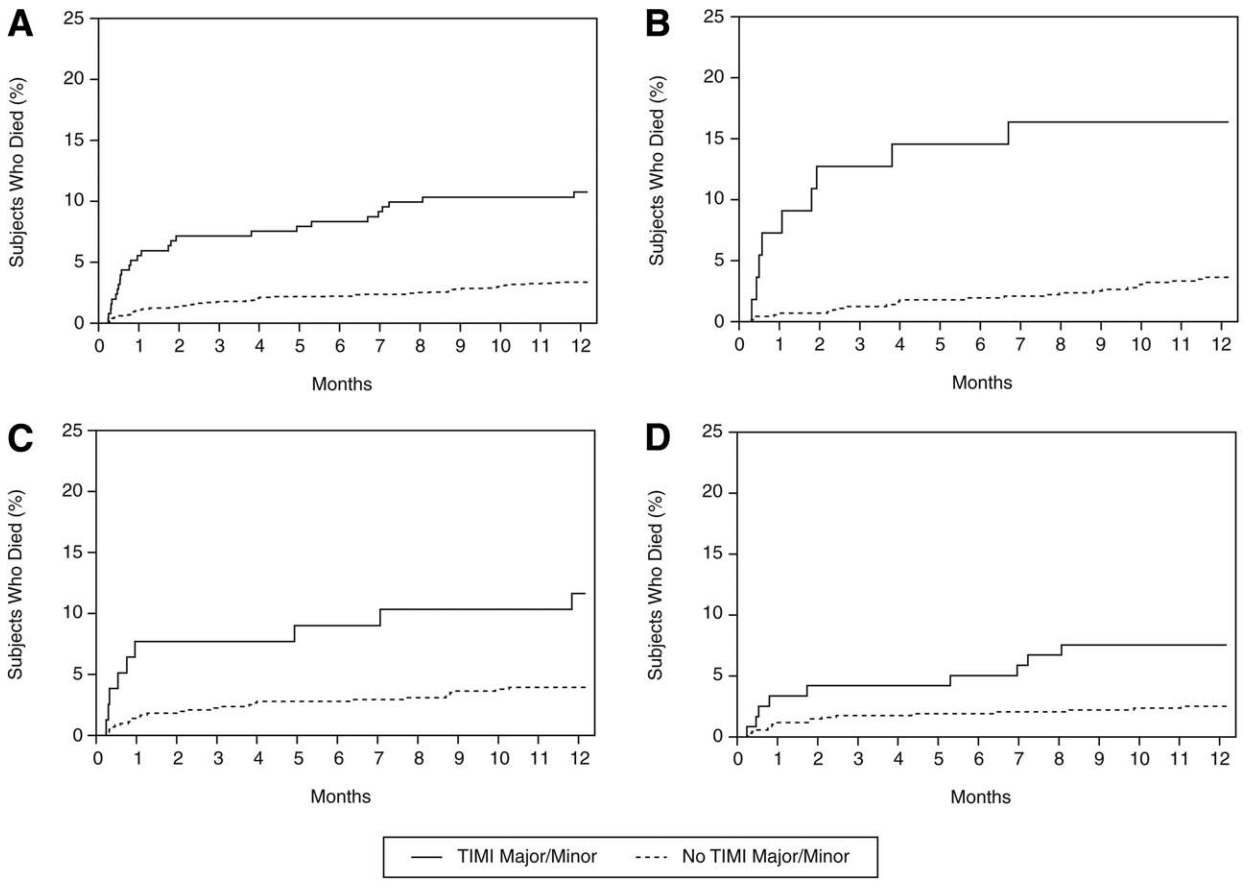


Figure 4. Landmark Analysis From Day 7 Through 1 Year

Landmark analysis from day 7 through 1 year showing impact of Thrombolysis In Myocardial Infarction (TIMI) major or minor bleeding on subsequent mortality overall and in each of the 3 treatment groups: **(A)** all treatment groups; **(B)** primary percutaneous coronary intervention; **(C)** abciximab-facilitated percutaneous coronary intervention; and **(D)** combination facilitated percutaneous coronary intervention.

TIMI major or minor bleeding through day 7, anterior MI, Killip class >1 at presentation, body mass index ≤25 kg/m^2, heart rate >100 beats/min, and Eastern (vs. Western) European origin were the strongest correlates of 12-month mortality; and 4) combination facilitated PCI significantly reduced 12-month mortality compared with primary PCI in a landmark analysis from day 7 ($p = 0.026$).

The majority of independent correlates of 1-year mortality (systolic blood pressure, prior MI, age, MI location, and Killip class) have been previously described (9,10). In the baseline model, after adjusting for these factors, neither facilitated treatment was associated with a survival benefit at 1 year. Importantly, TIMI bleeding was a strong independent correlate of risk (hazard ratio: 3.18, $p < 0.0001$). Nevertheless, even with that considered in the model, treatment with half-dose reteplase + abciximab was correlated with improved survival (hazard ratio: 0.55, $p = 0.026$), suggesting that if there was no excess bleeding with combination therapy it would have improved 1-year survival. Clearly, bleeding cannot be eliminated, but these and the landmark findings suggest a clear early hazard, late benefit, and influence with reteplase + abciximab.

Although subgroup analysis must be performed with considerable caution in a study whose overall treatment benefit was not statistically different compared with the control group and in which multiple subgroups of patients were pre-specified for subsequent examination, the trend toward a reduction in 1-year mortality in the anterior MI group treated with combination therapy is intriguing. These patients had larger infarcts but no excess in bleeding risk compared with patients with other types of infarcts, and hence potentially the most to gain from early reperfusion therapy. These data complement the previously reported trends toward benefit in the primary composite end point at 90 days in early treated and high-risk individuals (3), and hence suggest the patient substrate most requiring further study of similar early reperfusion strategies to be utilized in conjunction with primary PCI.

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In considering these results, several limitations should be kept in mind. Principally, these include the fact that multiple post hoc secondary analyses are considered without Bonferroni or other adjustment (both 12-month mortality and the anterior MI subgroup analyses were pre-specified, however) and that the study was not powered for such comparisons (even the primary end point was somewhat underpowered due to early termination of the study). Hence, findings are intended to be hypothesis-generating. Finally, the project had follow-up scheduled only through 12 months. Conclusions regarding outcomes of high-risk or other subgroups (e.g., anterior MI) might change with longer time of follow-up.

Conclusions

In summary, 1-year follow-up survival data in the FINESSE trial confirms the overall lack of significant clinical benefit with either of the treatment regimens tested, although at the same time suggesting further study may be needed in certain high-risk groups and the need to find therapies that improve reperfusion without greatly increasing bleeding risk.

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