Key Findings From the 2007 European Society of Cardiology Congress

Highlights From the 2007 European Society of Cardiology Congress, September 1-5, 2007, Vienna, Austria

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The theme of this year's European Society of Cardiology Congress, held in Vienna, Austria, was heart failure. Many important developments were presented at the meeting. Here we will discuss some of the key findings in percutaneous coronary intervention (PCI), vascular disease in diabetes, heart failure, and angina.

The CARESS in AMI Trial

In the Combined Abciximab Reteplase Stent Study in Acute Myocardial Infarction (CARESS in AMI) trial of ST elevation myocardial infarction (STEMI), patients admitted to centers without PCI facilities received medical management or were transferred to a PCI center.[1] All patients were initially treated with reteplase, heparin, and abciximab. The median time from symptom onset to reteplase administration was 170 minutes.

The primary endpoint of death, reinfarction, or refractory ischemia at 30 days occurred less frequently in the facilitated PCI group than in the medical management group (4.1% vs 11.1%; $P = .001$). This decrease was driven by a reduction in refractory ischemia among patients in the PCI group (0.7% vs 5.0%; $P = .002$) and a trend toward a reduction in reinfarction (0.3% vs 1.7%; $P = .104$). There was no difference in death (3.1% vs 4.4%; $P = .403$) or stroke (1.4% vs 0.7%) between the 2 groups. Any bleeding occurred more frequently in the facilitated PCI group than in the medical management group (12.2% vs 7.4%; $P = .032$). There was no significant difference in major bleeding; it occurred in 3.7% of the facilitated PCI group compared with 2.0% of the medical management group ($P = .208$).

Among STEMI patients admitted to centers without PCI facilities who were initially treated with reteplase, heparin, and abciximab, transfer for PCI was associated with a reduction in the primary endpoint of death, myocardial infarction (MI), or refractory ischemia at 30 days as compared with continued medical management (in which revascularization was performed only for rescue PCI). This study supports the routine transfer of STEMI patients who have been treated with chemical reperfusion therapy to a center with PCI capabilities.

The FINESSE Trial

The goal of the Facilitated Intervention with Enhanced Reperfusion

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Speed to Stop Events (FINESSE) trial was to evaluate use of abciximab with half-dose thrombolytic therapy (reteplase), abciximab alone, and placebo among patients undergoing PCI for STEMI.[2] Patients were 21 years and older and presented within 6 hours of onset of symptoms of prolonged and continuous ischemia (≥ 20 min) that was not relieved with nitroglycerin using specific electrocardiographic criteria. Exclusion criteria included low-risk clinical presentation; PCI administered within 60 minutes before the qualifying electrocardiogram or longer than 4 hours after it; planned use of a direct thrombin inhibitor during PCI; MI precipitated by a condition other than atherosclerotic coronary artery disease; use of a fibrinolytic within 14 days; use of low-molecular-weight heparin within 24 hours; PCI within 7 days; known or suspected bleeding; confirmed, uncontrolled hypertension; other contraindications to fibrinolytic treatment; unfractionated heparin dose greater than 40 U/kg (3000 U maximum); and an activated partial thromboplastin time greater than 70 seconds. The trial was designed so that half of the patients were to be enrolled in non–PCI-capable hospitals, where they would be randomized and receive treatment, and then be transferred urgently to a PCI-capable center.

The primary endpoint was a composite of all-cause mortality or complications of MI by 90 days. Complications of MI were defined as rehospitalization or emergency department visit for congested heart failure, cardiogenic shock, or resuscitated ventricular fibrillation occurring longer than 48 hours after randomization. Secondary endpoints included components of the primary endpoint through 90 days, ST-segment resolution greater than 70% from baseline at 60 to 90 minutes following randomization, thrombolysis in myocardial infarction (TIMI) bleeding through discharge or day 7, and intracranial hemorrhage through discharge or day 7.

Patients with STEMI were randomized in a double-blind, double-dummy manner to abciximab with a half-dose of the thrombolytic reteplase (n = 828), abciximab alone (n = 818), or placebo (n = 806). Patients then underwent PCI. An intravenous infusion of abciximab 0.125 μg/kg/min was administered to all patients in the catheterization laboratory and continued for a 12-hour duration.

At the time of coronary angiography, more patients in the combination facilitated PCI arm (reteplase plus abciximab plus PCI) had an open artery prior to PCI (61%) compared with either the abciximab-facilitated PCI arm (26%; $P < .001$) and the primary PCI alone group (25%; $P < .001$). ST segment resolution of greater than 70% by 60 to 90 minutes was also observed more often in the combination-facilitated PCI arm (44%) compared with both the abciximab-facilitated PCI arm (33%) and the primary PCI alone group (31%).

There was no difference in the primary endpoint of death, cardiogenic shock, heart failure, or resuscitated ventricular fibrillation by 90 days among the 3 groups (9.8% of the combination-facilitated PCI arm, 10.5% of the abciximab-facilitated PCI arm, and 10.7% of the primary PCI alone arm; P = NS). There was also no difference among the groups in the components of the primary endpoint. In the combination-facilitated PCI arm, abciximab-facilitated PCI arm, and primary PCI alone arm, respective rates were: mortality, 5.2%, 5.5%, and 4.5%; heart failure, 1.9%, 2.9%, 2.2%; cardiogenic shock, 5.3%, 4.8%, and 6.8%; and ventricular fibrillation, 0.6%, 0.2%, and 0.4%. TIMI major or minor bleeding through discharge or day 7 was higher in the combination-facilitated PCI arm (14.5%) compared with the abciximab-facilitated PCI arm (10.1%; $P = .008$) and the primary PCI alone group (6.9%; $P < .001$). With door-to-reperfusion time a benchmark for the effectiveness of treating patients with STEMI, the increased ability of a combination of half-dose lytic therapy with abciximab to enhance vessel patency compared with abciximab alone or placebo may lead to its greater utilization, even though there was no significant benefit in the primary endpoints of this study.

The ADVANCE Trial

The goal of the Action in Diabetes and Vascular Disease (ADVANCE) trial was to evaluate blood pressure reduction along with intensive glucose control for the prevention of vascular disease among higher-risk patients with type 2 diabetes.[3] Following a 6-week run-in period of treatment with perindopril and indapamide, patients were randomized to a fixed combination of perindopril and indapamide (n = 5569) or placebo (n = 5571). Blood pressure was an average of 5.6/2.2 mm Hg higher in the placebo group compared with the treatment group ($P < .001$). The final blood pressure in the active treatment group was 134.7/74.8 mm Hg compared with 140.3/77.0 mm Hg in the placebo group.[4]

All-cause mortality was significantly lower in the perindopril/indapamide group (7.3% vs 8.5%; $P = .025$) (Figure 1). The primary endpoint of vascular events was also significantly lower in the perindopril/indapamide group (15.5% vs 16.8%; relative risk reduction, 9%; $P = .041$). This reduction includes a decrease in

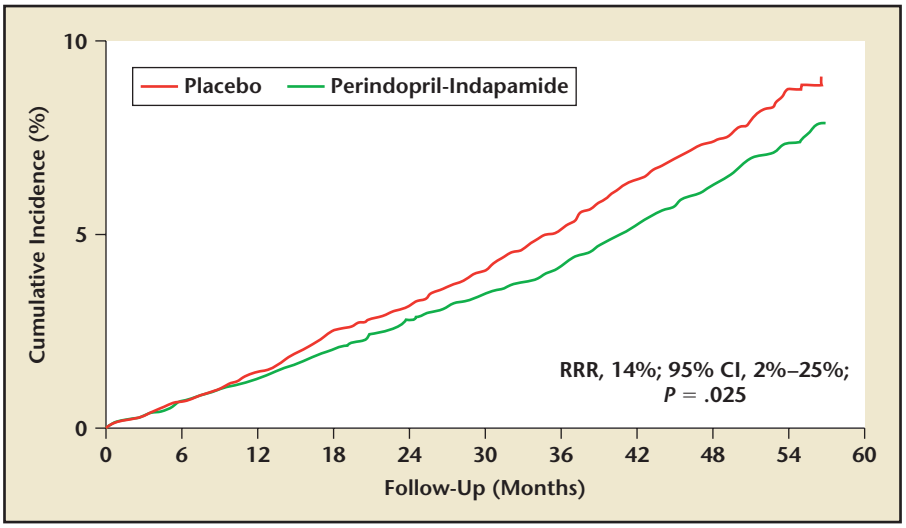


Figure 1. *All-cause mortality in the Action in Diabetes and Vascular Disease (ADVANCE) trial. RRR, relative risk reduction; CI, confidence interval. Reprinted with permission from Patel A et al.*[4]

macrovascular events (8.6% vs 9.3%) and microvascular events (7.9% vs 8.6%) (Figure 2). Coronary heart disease events were reduced by 14% in the perindopril/indapamide group (8.4% vs 9.6%). Renal events were reduced by 21% in the perindopril/indapamide group (22.3% vs 26.9%). The renal event reduction was driven by a decrease in the new-onset microalbumuria.

The ALOFT Trial

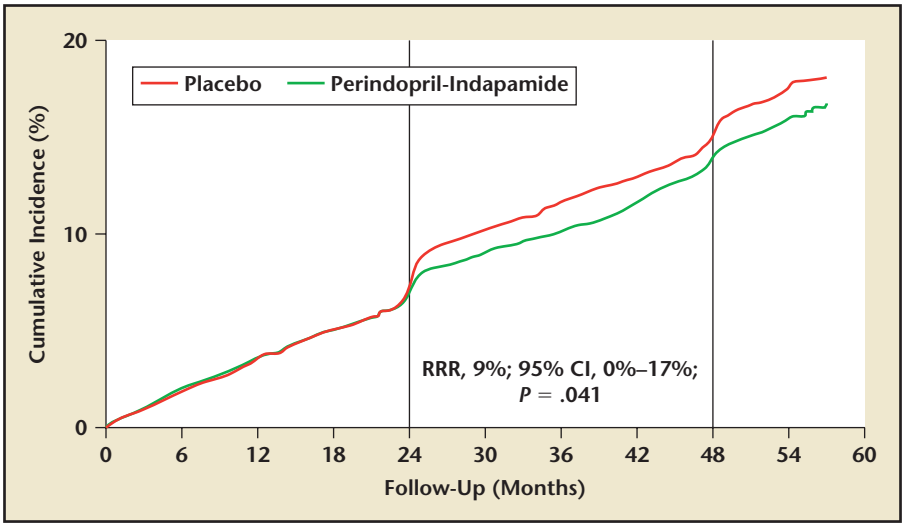
The Aliskiren Observations of Heart Failure Treatment (ALOFT) trial aimed to evaluate the safety and tolerability of the oral renin inhibitor aliskiren as compared with placebo in patients with stable heart failure.[5] Patients had New York Heart Association (NYHA) class II through IV heart failure, current or prior hypertension, and a plasma brain natriuretic peptide level greater than 100 pg/mL. Exclusion criteria were heart failure due to obstructive valve disease; treatment with both an angiotensin-converting enzyme inhibitor and an angiotensin receptor blocker; systolic blood pressure less than 90 mm Hg; serum creatinine greater than 2.0 mg/dL; MI, stroke, transient ischemic attack, or coronary revascularization in the prior 6 months; and cardiac resynchronization therapy. Patients were then followed for 3 months.

Patients were randomized in a double-blind manner to aliskiren (150 mg; n = 156) or placebo (n = 146) for 12 weeks of therapy. In addition, all patients received standard heart failure therapy in addition to the randomized therapy. Biomarker and echocardiographic data were collected at the time of study entry and at 12 weeks.

At study entry, mean left ventricular ejection fraction was 31%, with an average duration of heart failure of 4.1 years in the aliskiren group and 4.9 years in the placebo group. Concomitant heart failure therapy included beta-blockers in 94% of patients, angiotensin-converting enzyme inhibitors in 83%, and angiotensin receptor blockers in 15%. The rate of discontinuation was 9.0% for the study drug group and 7.5% for the placebo group.

There were greater reductions from baseline to 12 weeks in plasma renin activity levels among patients in the aliskiren group as compared with the control group (−5.71 ng/mL/h vs −0.97 ng/mL/h; $P < .001$). A reduction in brain natriuretic peptide was greater in the aliskiren group than the placebo group (−61 pg/mL vs −12.2 pg/mL; $P = .016$). There was no difference in plasma aldosterone (−48.6 pmol/L [aliskiren] vs −30.9 pmol/L [placebo]), but the reduction in urinary aldosterone was greater

Figure 2. *Combined primary outcomes in the Action in Diabetes and Vascular Disease (ADVANCE) trial. RRR, relative risk reduction; CI, confidence interval. Reprinted with permission from Patel A et al.*[4]



with aliskiren (−9.2 mmol/d vs −7.0 mmol/d; $P = .015$).

Among the echocardiographic parameters, there was no difference in change in the ejection fraction (1.7% in the aliskiren group vs 1.6% in the placebo group; $P = .96$). Patients in the aliskiren group had reductions in the mitral regurgitation to left atrial area (MR/LA) ratio (−4.1 vs +1.3; $P = .0006$) and the EE' ratio (−0.84 vs 0.12; $P = .47$).

Among the safety events, renal dysfunction occurred in 1.9% of the aliskiren group versus 1.4% of the placebo group. Symptomatic hypotension occurred in 3.2% of the aliskiren group versus 1.4% of the placebo group. Hyperkalemia occurred in 6.4% of the aliskiren group versus 4.8% of the placebo group. None of these differences achieved statistical significance.

The PRAGUE-8 Trial

The goal of the PRAGUE-8 trial was to evaluate the impact of a clopidogrel loading dose in patients undergoing elective coronary angiography for stable angina.[6] On the day before undergoing coronary angiography, patients were randomized in an open-label manner to clopidogrel administration more than 6 hours before elective angiography (600 mg; n = 513) or delayed clopidogrel administration in the catheterization laboratory if needed for PCI (600 mg; n = 515). PCI at the time of angiography was performed in only 29% of patients. Only 12% of patients underwent coronary artery bypass grafting, which, in most cases, was performed more than 7 days postangiography. The remaining 59% of patients were managed medically.

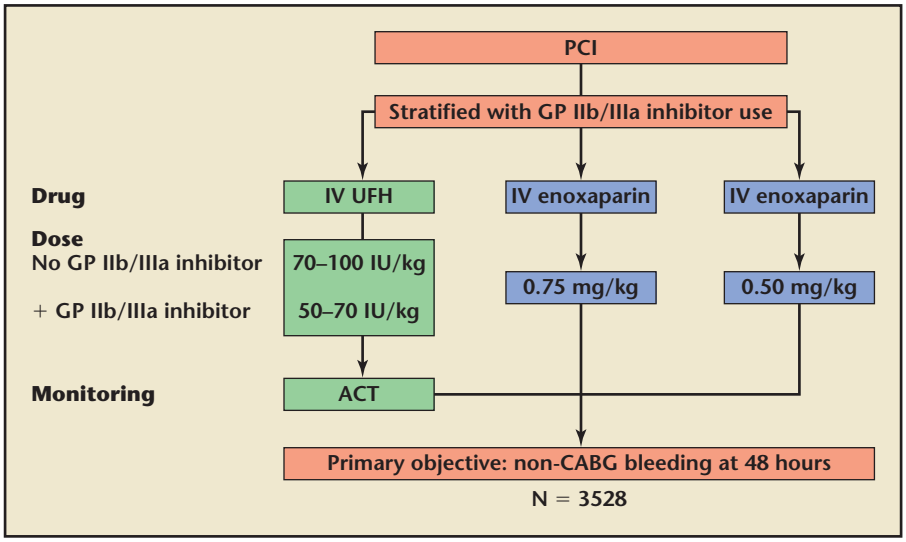
There was no difference in the primary endpoint of death, periprocedural MI, stroke, transient ischemic attack, or reintervention within 7 days between the treatment groups, whether the evaluation included all patients (0.8% in each arm) or only those patients who went on for PCI (2.2% in the selective clopidogrel group vs 1.3% in the early, nonselective clopidogrel group; P = NS). There was also no difference among the treatment groups in the frequency of periprocedural troponin elevation that exceeded 3 times the upper limit of normal. Among all patients, this frequency was 3.0% for the selective clopidogrel group and 2.7% for the early, nonselective clopidogrel group (P = NS). In the PCI cohort, the frequency was 11.1% for the selective clopidogrel group and 8.6% in the early, nonselective clopidogrel group (P = NS). Bleeding events were more frequent in the early, nonselective clopidogrel group than in the selective clopidogrel group overall (3.5% vs 1.2%; $P = .02$) and in the PCI cohort (7.2% vs 0.7%; $P = .006$).

Among patients undergoing elective coronary angiography for stable angina, early, routine use of clopidogrel loading more than 6 hours prior to angiography was not associated with a difference in the frequency of death, MI, stroke, transient ischemic attack, or reintervention within 7 days when compared with selective use of clopidogrel during angiography if PCI was required. Routine clopidogrel loading was associated with a significant increase in bleeding complications.

The RIO-Trial

The ReoPro and Peripheral Arterial Intervention to Improve Clinical Outcome in Patients With Peripheral Arterial Disease Trial (RIO-Trial) evaluated the effect of abciximab administration as compared with placebo in patients undergoing percutaneous interventional recanalization of chronic occlusions in the superficial femoral artery and popliteal artery.[7] The patients were ages 18 to 90 years and had a history of peripheral artery disease (for at least 6 weeks) with superficial femoral or popliteal artery occlusion (> 5 centimeters in length), which mandates percutaneous transluminal angioplasty

Figure 3. *Study design of the Safety and Efficacy of Intravenous Enoxaparin in Elective Percutaneous Coronary Intervention: An International Randomised Evaluation (STEEPLE) trial. PCI, percutaneous coronary intervention; IV, intravenous; GP, glycoprotein; UFH, unfractionated heparin; ACT, activated clotting time; CABG, coronary artery bypass grafting. Reprinted with permission from Montalescot G.*[8]



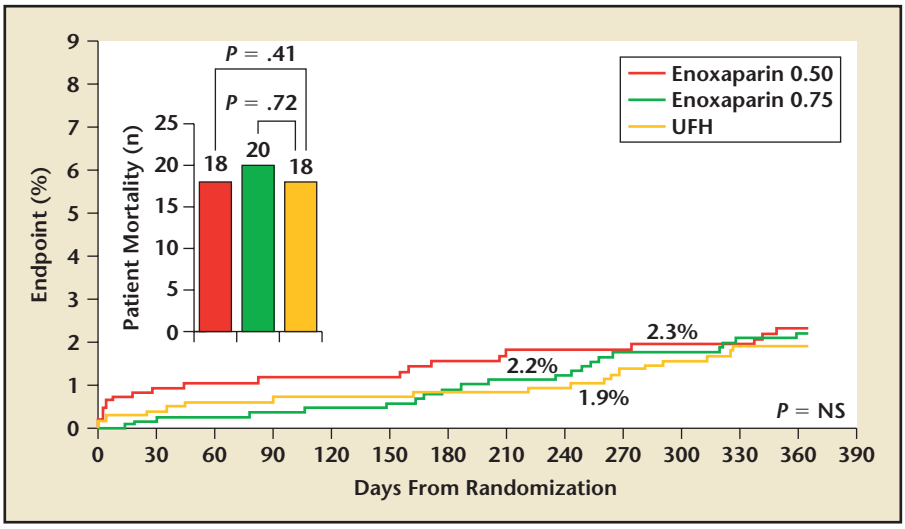


Figure 4. *One-year mortality in the Safety and Efficacy of Intravenous Enoxaparin in Elective Percutaneous Coronary Intervention: An International Randomised Evaluation (STEEPLE) trial. UFH, unfractionated heparin. Reprinted with permission from Montalescot G.*[8]

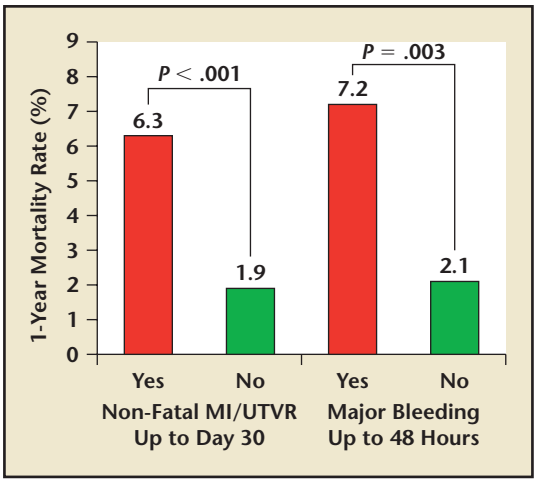
or stent administration as first treatment modality. Exclusion criteria included acute limb ischemia; subacute ischemia that required thrombolysis as first treatment modality; active bleeding or known bleeding diathesis; known severe hepatic or renal disorder; diabetes mellitus treated with metformin; known heparin-induced thrombocytopenia; major surgery or trauma in past 6 weeks; history of stroke within the previous 2 years, any stroke with a residual neurological deficit, or other central nervous system abnormality; gastrointestinal or genitourinary bleeding of clinical significance within the previous 6 weeks; administration of oral anticoagulants within the previous 7 days unless prothrombin time was less than 1.2 seconds; history of bleeding diathesis with platelet count less than 100,000/mm^3; arteriovenous malformations or aneurysms; severe uncontrolled hypertension; hypertensive or diabetic retinopathy; vasculitis; known autoimmune disorders; aspirin intolerance; contraindication or known allergic reactions to abciximab or murine proteins; coexistent condition associated with a limited life expectancy; and previous use of a glycoprotein IIb/IIIa antagonist.

The primary study endpoint was death, amputation, repeat target vessel intervention, or target vessel reocclusion within 30 days. The secondary endpoints included restenosis at 6 months, target lesion revascularization, change in the clinical status, change of ankle-brachial index, and days spent in the hospital.

Patients undergoing interventional recanalization of chronic occlusions in the superficial femoral artery or popliteal artery were randomized in a double-blind manner after wire passage to abciximab (n = 212) or placebo (n = 211). Doppler ultrasound was performed at 30 days, 6 months, and 12 months. Median duration of symptoms at entry was 12 months. The average lesion length was 17 cm, and 14% of patients had recurrent lesions. Stents were used in 43% of patients.

There was no significant difference in the primary endpoint of death, amputation, repeat target vessel intervention, or target vessel reocclusion within 30 days for the abciximab group (5.1%) versus the placebo group (5.6%). Distal embolization was lower in the abciximab group (6.1% vs 12.3%; P = .02). Severe bleeding occurred more frequently in the abciximab arm (5.1% vs 1.0%; P = .02). At 6-month follow-up, target vessel reocclusion was lower in the abciximab group as compared with the placebo arm (22% vs 39%; P < .001), as was binary restenosis (56% vs 68%; P = .026). No significant differences were observed in the need for amputation (4.7% vs 2.1%) or reintervention (18% vs 23%).

Figure 5. *Effects of initial ischemic events and major bleeding on 1-year mortality in the Safety and Efficacy of Intravenous Enoxaparin in Elective Percutaneous Coronary Intervention: An International Randomised Evaluation (STEEPLE) trial. MI, myocardial infarction; UTVR, urgent target vessel revascularization. Reprinted with permission from Montalescot G.*[8]



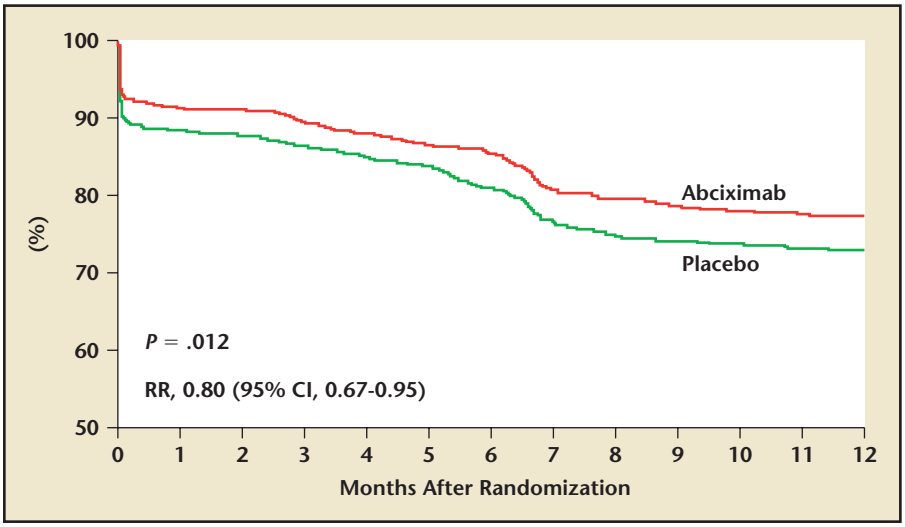


Figure 6. *Primary endpoint after 12 months in Intracoronary Stenting and Antithrombotic Regimen: Rapid Early Action for Coronary Treatment 2 (ISAR-REACT 2). RR, relative risk; CI, confidence interval. Reprinted with permission from Seyfarth M.*[9]

The RIO-Trial showed that in patients undergoing percutaneous recanalization of chronic occlusions in the superficial femoral and popliteal artery, treatment with abciximab as compared with placebo was not associated with a difference in the frequency of the composite of death, amputation, repeat target vessel intervention, or target vessel reocclusion within 30 days. Abciximab treatment was associated with a reduction in restenosis and an increase in bleeding complications.

The STEEPLE Trial

Results from the Safety and Efficacy of Intravenous Enoxaparin in Elective Percutaneous Coronary Intervention: An International Randomised Evaluation (STEEPLE) trial were presented.[8] The primary objective of this study was to compare the safety profile of intravenous enoxaparin (at doses of 0.50 mg/kg and 0.75 mg/kg) with that of unfractionated heparin administered up to 48 hours after an elective PCI (Figure 3).

Treatment with reduced-dose enoxaparin was associated with lower rates of major or minor bleeding by 48 hours after PCI, as compared with unfractionated heparin administration driven by activated clotting time. There were no mortality differences among the 3 arms at 1 year (approximately 2% in each group; P = NS) (Figures 4 and 5).

The ISAR-REACT 2 Trial

The Intracoronary Stenting and Antithrombotic Regimen: Rapid Early Action for Coronary Treatment 2 (ISAR-REACT 2) trial is a randomized comparison of abciximab versus placebo in patients with non-ST segment elevation acute coronary syndromes who underwent PCI after pretreatment with clopidogrel. The 1-year results demonstrate a sustained benefit of abciximab therapy, based on a 20% risk reduction in the primary endpoint of death, MI, or urgent target vessel revascularization (23.3% vs 28.0%; P = .012) (Figure 6).[9]

Abciximab led to a decrease in the primary endpoint in patients with elevated troponin (28.6% vs 33.3%; relative risk, 0.82) and in those without elevated troponin (17.8% vs 22.0%; relative risk, 0.79). No difference in death or MI was seen for troponin-negative patients, but a significant benefit was seen in reduction of target vessel revascularization in these patients.

The ACUITY Trial

In the Acute Catheterization and Urgent Intervention Triage strategy (ACUITY) trial, bivalirudin plus provisional glycoprotein IIb/IIIa inhibitor therapy was compared with heparin (unfractionated heparin or enoxaparin) plus glycoprotein IIb/IIIa in patients with acute coronary syndrome.[10] Both groups had similar 30-day composite ischemic event rates, but the bivalirudin group had less bleeding and superior net clinical outcomes. The ACUITY PCI subgroup consisted of 2528 patients in the PCI cohort who were already receiving heparin or

Table 1
The ACUITY Trial: Ischemic Events and Major Bleeding

Endpoint	Hazard Ratio (95% CI)*
Composite ischemic endpoint	1.10 (0.85-1.42)
Major bleeding	0.52 (0.36-0.74)

*Hazard ratio (bivalirudin vs heparin/enoxaparin plus a glycoprotein IIb/IIIa inhibitor) of ischemic events and major bleeding in percutaneous coronary intervention patients who received heparin/enoxaparin before randomization.
ACUITY, Acute Catheterization and Urgent Intervention Triage strategY; CI, confidence interval. Data from White H.[10]

Table 2
The ACUITY Trial: The Effect of Clopidogrel Pretreatment on 1-Year Mortality

Group	Hazard Ratio (95% CI)*
Clopidogrel pretreatment (n = 3429)	1.02 (0.69-1.50)
Clopidogrel after end of angiography to 30 minutes after PCI (n = 1044)	1.14 (0.89-2.03)
Clopidogrel after 30 minutes post-PCI (n = 519)	0.43 (0.17-1.11)
No clopidogrel (n = 88)	3.20 (0.34-31.1)

*Effect of clopidogrel pretreatment on the hazard ratio for 1-year mortality (bivalirudin vs heparin/enoxaparin plus a glycoprotein IIb/IIIa inhibitor).
ACUITY, Acute Catheterization and Urgent Intervention Triage strategY; CI, confidence interval; PCI, percutaneous coronary intervention. Data from White H.[10]

Table 3
Primary Arrhythmia Endpoints in MERLIN-TIMI 36

Arrhythmic Endpoint	Ranolazine (%)	Placebo (%)	*P*
Ventricular tachycardia ≥ 3 beats	52.0	60.6	< .001
Ventricular tachycardia ≥ 8 beats	5.3	8.3	< .001
Supraventricular tachycardia ≥ 4 beats	44.7	55.0	< .001
New-onset atrial fibrillation	1.7	2.4	.08
Bradycardia < 45 beats per min, complete heart block, or pause ≥ 2.5 sec	39.8	46.6	< .001
Pause ≥ 3 sec	3.1	4.3	.01

MERLIN-TIMI 36, Metabolic Efficiency With Ranolazine for Less Ischemia in Non–ST-Elevation Acute Coronary Syndromes-Thrombolysis in Myocardial Infarction 36. Adapted with permission from Scirica BM et al. Effect of ranolazine, an antianginal agent with novel electrophysiological properties, on the incidence of arrhythmias in patients with non ST-segment elevation acute coronary syndrome: results from the Metabolic Efficiency With Ranolazine For Less Ischemia In Non ST-Elevation Acute Coronary Syndrome Thrombolysis in Myocardial Infarction 36 (MERLIN-TIMI 36) Randomized Controlled Trial. *Circulation*. 2007;116:1647-1652.[11]

enoxaparin at the time of randomization and were then randomized to continue on that treatment or to switch to bivalirudin. These patients experienced similar outcomes to the main results of the trial, showing a similar rate of ischemic events. The bivalirudin group, however, had a 48% reduction in bleeding (Table 1).

In addition, new data were presented that addressed the issue of a clopidogrel interaction and the effect on event rates in patients treated with bivalirudin. There was no difference in 1-year mortality between the 3429 bivalirudin patients who had been pretreated with clopidogrel and the 1044 who had not been pretreated (Table 2).

MERLIN-TIMI 36

Ranolazine was approved in 2006 for use in treating chronic angina, but because the drug is associated with modest increases in the QT interval, there have been concerns that it might have proarrhythmic effects. The Metabolic Efficiency With Ranolazine for Less Ischemia in Non–ST-Elevation Acute Coronary Syndromes–Thrombolysis in Myocardial Infarction 36 (MERLIN-TIMI 36) trial examined the safety of ranolazine.[11]

The investigators originally enrolled 6560 non–ST-elevation acute coronary syndrome patients within 48 hours of ischemic symptoms who were then treated with ranolazine or placebo and followed up for a median of 348 days. Ranolazine was administered as a 200-mg intravenous infusion given over 1 hour, followed by an 80 mg/h infusion for up to 96 hours. Oral treatment (1000 mg twice daily) was then given for approximately 1 year. As previously reported, there was no significant difference in the primary efficacy endpoint composite of cardiovascular death, MI, or recurrent ischemia through the end of the study. There was, however, a significant reduction in recurrent ischemia in the ranolazine group.

Because of concerns about the prolongation of the QT interval with ranolazine and potential proarrhythmic potential, this large safety assessment included continuous 7-day Holter monitoring to gauge the risk of clinically significant arrhythmia. Investigators observed a significant reduction in arrhythmic events with ranolazine (Table 3). The results of MERLIN should allay concern that the modest QT prolongation associated with the use of ranolazine has proarrhythmic effects. Ranolazine may actually provide an antiarrhythmic effect. ■

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Main Points

- Among ST elevation myocardial infarction (MI) patients admitted to centers without percutaneous coronary intervention (PCI) facilities who were initially treated with reteplase, heparin, and abciximab, transfer for PCI was associated with a reduction in the primary endpoint of death, MI, or refractory ischemia at 30 days as compared with continued medical management.
- In a study that evaluated blood pressure reduction along with intensive glucose control for the prevention of vascular disease among higher-risk patients with type 2 diabetes, treatment with perindopril and indapamide significantly reduced rates of all-cause mortality and vascular events as compared with placebo.
- Among patients undergoing elective coronary angiography for stable angina, early, routine use of clopidogrel loading more than 6 hours prior to angiography was not associated with a difference in the frequency of death, MI, stroke, transient ischemic attack, or reintervention within 7 days when compared with selective use of clopidogrel during angiography if PCI was required.
- In patients with non-ST segment elevation acute coronary syndromes who underwent PCI after pretreatment with clopidogrel, abciximab therapy was associated with a sustained benefit.
- New data should allay concern that the modest QT prolongation associated with the use of ranolazine has proarrhythmic effects.