Facilitated PCI Fails in Multicenter FINESSE Trial

**V**IENNA — The once-promising concept of pharmacologically facilitated percutaneous coronary intervention for patients with ST-elevation MI now appears relegated to the scrap heap on the basis of the negative results of the large definitive randomized trial, FINESSE, he noted, didn’t require enoxaparin or up-front clopidogrel because the trial was designed prior to publication of persuasive evidence of the importance of these therapies in STEMI patients.

He added that FINESSE may also have been doomed because it studied the wrong population, since it enrolled patients presenting up to 6 hours after symptom onset. “It’s clear that in patients presenting after 3-4 hours there’s little to gain by a slightly higher patency rate achieved by giving pharmacological therapy,” asserted Dr. Van der Werf, professor and chairman of the department of cardiology at University Hospital Gathushberg, Leuven, Belgium.

While he concurred with Dr. Ellis that facilitated PCI using the strategy tested in FINESSE can’t be recommended, Dr. Van der Werf also announced that a variant approach will be put to the test in a large randomized trial called to begin early next year. (See sidebar below.) FINESSE was funded by Centocor and Eli Lilly.

**Pharmacoinvasive’ Strategy in STEMI**

A reinvigorated role for thrombolytic therapy in STEMI was when a delay of an hour or more was anticipated, improved clinical outcomes could be achieved by opening the infarct-related artery early with a thrombolytic agent and/or glycoprotein IIb/IIIa inhibitor while waiting for PCI. FINESSE, the largest-ever facilitated PCI trial, showed that’s not the case, said Dr. Ellis of the Cleveland Clinic Foundation.

FINESSE involved 2,453 patients in 20 countries who presented with STEMI within 6 hours of chest pain onset and had an anticipated 1- to 4-hour delay to cardiac catheterization for primary PCI. They were randomized to one of two facilitat-
ed PCI strategies or to primary PCI with abciximab administered in the cath lab. The facilitated PCI approaches studied were half-dose reteplase plus abciximab, or abciximab alone. Average door-to-balloon time was 2.2 hours.

The primary end point was a 90-day composite of all-cause mortality, rehospitalization or treatment of heart failure in the emergency department, cardiogenic shock, or revascularization treatment of choice for rescue PCI only in the immediate transfer group. Major bleeding occurred in 4.8% of patients with combined faciliation, 4.1% with abciximab facilitation, and 2.6% with primary PCI. The combined rate of TIMI major or minor bleeding was 14.5% with dual reteplase/abciximab facilitated PCI, 10.1% with abciximab-facilitated PCI, and 6.9% with primary PCI. There was also a strong albeit nonsignificant trend for more intracranial hemorrhages in the combined facilitation group.

Discussant Dr. Hans Van der Werf said one explanation for the negative results was the use of suboptimal antithrombotic cotherapy. FINESSE, he noted, didn’t re-

**CARESS: Immediate Transfer for PCI Best After Successful Lysis**

**V**IENNA — Immediate transfer for percutaneous coronary intervention after successful thrombolytic therapy in patients with ST-elevation MI provides markedly better outcomes than does a more conventional strategy of continued medical treatment in the non-PCI hospital, with transfer for rescue PCI only in the event of continued ST elevation at 90 minutes, Dr. Carlo Di Mario reported at the annual congress of the European Society of Cardiology.

This was the key finding of the Combined Abciximab Reteplase Stent Study in Acute Myocardial Infarction (CARESS in AMI). The three-country European trial compared two strategies for managing ST-segment elevation myocardial infarction (STEMI) patients for whom the preferred treatment—primary PCI—is anticipated to be unavailable due to long minutes of their presentation at a non-PCI hospital.

CARESS involved 600 such pa-

tients who received half-dose reteplase, abciximab, aspirin, and unfractionated heparin. They were then randomized to imme-
diate transfer for PCI or to trans-
fer for rescue PCI only in the event of continued ST elevation at 90 minutes, which occurred in 36% of patients assigned to that study arm, explained Dr. Di Mario of Royal Brompton Hospital, London.

The primary study end point was a compo-
site of death, repeat MI, or refractory ur-
cemia at 30 days. The rate was 4.1% in the im-
mediate transfer/PCI-
for-all group, compared with 11.1% in the rescue PCI group. A thrombin-activated partial thromboplastin (TAT) was also performed in favor of the immediate transfer strategy, noted Dr. Di Mario, a CARESS coprincipal investigator.

Patients averaged 170 minutes from onset of chest pain to reteplase. The median time from reteplase to PCI was 116 minutes in the immediate transfer group and 212 minutes in the rescue PCI patients.

Although the rate of any bleed-
ing was significantly increased in the immediate transfer/PCI-for-
all group—12.2% compared with 7.4%—severe bleeding and intracranial hemorrhages were rare and not significantly different between the two study arms.

“I believe this was due to the exclusion of patients at high risk of bleeding,” he commented.

Indeed, the mean age of study participants was just 60 years.

Discussant Dr. Freek W.A. Verheugt noted that CARESS is the fourth study to show that STEMI patients should routine-
ly undergo early PCI following successful lytic therapy. All four trials were small to moderate in size.

Where do things stand with respect to STEMI management in 2007? FUTURE PCI can be performed by experienced operators within 90 minutes of patient presentation, the treat-
ment of choice is clearly prima-
ry PCI. If primary PCI within 90 minutes isn’t available, a lytic should be given. If it doesn’t ac-
complish reperfusion, urgent transfer for rescue PCI is war-
ranted, said Dr. Verheugt, pro-
fessor and chairman of the de-
partment of cardiology at VU University Hospital, Amsterdam, the Netherlands.

Even if there is reperfusion, however, PCI is still nec-
essary as shown in CARESS and three other trials. The key ques-
tion is, when should it be done? That’s unresolved.

CARESS showed excellent outcomes with an average interval between lym-
ic therapy and PCI of about 2/5 hours. That brief interval could be tough to duplicate in clinical practice, especially for patients who present to hospitals in remote areas. At the other ex-
treme, the Spanish GRACIA 1 trial showed similar benefits with a 17-hour interval, which is a lot more convenient for pa-
ients, transport crews, and cath lab personnel than a rushed dead-of-night transfer, he continued.

“We need a randomized trial of early versus late transport for auxiliary PCI in patients who are reperfused and stable after lytic therapy,” Dr. Verheugt con-
cluded.

CARESS was sponsored by the Italian Society of Interventional Cardiology, with grants from Eli Lilly & Co. and Biotronik AG.