The objective of the Fractional Flow Reserve Versus Angiography for Multivessel Evaluation [FAME] study was to compare revascularization using angiography plus FFR with angiography only in patients with MVD. The primary endpoint was mortality, MI, or repeat revascularization at 1 year [Tonino PA et al. *N Engl J Med* 2009]. In the FFR-guided group, PCI was performed in patients with FFR ≤0.80. PCI was performed on indicated lesions in the angiography-guided group.

At 1 year, the primary endpoint occurred in 13.2% of the FFR group versus 18.3% of the angiography group (p=0.02). The number of drug-eluting stents (DES) per patient was 1.9±1.3 in the FFR group versus 2.7±1.2 in the angiography group (p<0.001). Less contrast agent was used in the FFR group (272±133 mL) versus the angiography group (302±127 mL; p<0.001). The rate of MACE was lower in the FFR versus angiography group by 2.9% at 30 days, 3.8% at 90 days, 4.9% at 180 days, and 5.3% at 360 days.

At 2 years, among 509 FFR-guided patients with 513 deferred lesions, there were 31 MIs, of which 22 were periprocedural; 9 were late MIs, 8 due to a new lesion or stent-related, and 1 (0.2%) due to an originally deferred lesion [Pijls NHJ et al. *J Am Coll Cardiol* 2010]. In this group, there also were 53 repeat revascularizations (37 in a new lesion and/or a restenotic lesion); 16 of these were in originally deferred lesions (6 without FFR or despite FFR >0.80), 10 of which showed clear progression.

This study showed that, in patients with MVD, revascularization based on angiography plus FFR compared with angiography alone reduces MACE and death/MI rate by about 30%, despite using fewer stents and less contrast medium. FAME challenges the definition of MVD and the concept of completeness of revascularization.

The FAME 2 study evaluated FFR-guided PCI plus OMT versus OMT alone in patients with stable CAD in randomized and registry cohorts [De Bruyne B et al. *N Engl J Med* 2012]. Stable patients scheduled for 1, 2, or 3 vessel DES stenting had FFR in all target lesions. In the randomized cohort, patients with at least 1 stenosis with FFR ≤0.80 were randomized to PCI plus OMT or OMT. In the registry cohort, patients with all FFR >0.80 were treated with OMT. The independent data and safety monitoring board recommended halting patient recruitment due to a significantly increased risk of MACE among patients randomized to OMT alone compared with patients randomized to OMT plus FFR-guided PCI.

The primary endpoint, a composite of death, MI, or urgent revascularization, occurred in 4.3% in the PCI plus OMT group and 12.7% in the OMT group (HR with PCI, 0.32; 95% CI, 0.19 to 0.53; p<0.001). This difference was driven by a reduction in revascularization (1.7% vs 12.1%; HR, 7.63; 95% CI, 3.24 to 18.0; p<0.0001). The harder endpoints of death or MI were not reduced with PCI plus OMT (3.4% vs 3.9%; HR, 0.61; 95% CI, 0.28 to 1.35; p=0.22). There was no significant difference in revascularization rates between the randomized PCI plus OMT group and the registry OMT group (p=0.54).

Based on the DEFER and FAME studies, the European Society of Cardiology/European Association for Cardio-Thoracic Surgery Guidelines on myocardial revascularization [Wijns W et al. *Eur Heart J* 2010] recommend FFR-guided PCI for detection of ischemia-related lesions when objective evidence of vessel-related ischemia is not available. According to the 2011 American College of Cardiology Foundation/American Heart Association/ Society for Cardiovascular Angiography and Interventions Guideline for percutaneous coronary intervention [Levine GN et al. *Circulation* 2011], FFR is reasonable to assess angiographic intermediate coronary lesions (50% to 70% diameter stenosis) and can be useful in guiding revascularization decisions in patients with stable ischemic heart disease.

Stent for Life: Egypt

Written by Toni Rizzo

Almost 2 years ago, Egypt was chosen to be 1 of 10 countries to participate in the international Stent for Life (SFL) Initiative. The mission of the SFL Initiative in Egypt, presented by Mohamed Sobhy, MD, Alexandria University, Alexandria, Egypt, is to improve delivery and patient access to the life-saving indications of percutaneous coronary intervention (PCI), thereby reducing the mortality and morbidity of patients suffering from acute coronary syndromes.

Before the initiative, there was no consistent pathway for a patient experiencing an acute myocardial infarction (AMI) to access medical care. The patient might call a cardiologist, private hospital, private insurance physician, or emergency medical system (EMS). Only ambulances from specialized cardiac hospitals had a physician on board, and most of them were not properly trained. Electrocardiograms were only available in new ambulances. With no clear unified protocol, patients were taken to the nearest hospital. Additionally, cardiac catheterization labs were not prepared to treat AMI patients and not all were open 24/7. Before the initiative, only 8% of AMI patients in Egypt were treated with primary PCI (p-PCI) and more than 60% did not receive any reperfusion therapy. With the SFL initiative, Egypt aims to increase p-PCI to about 22%.

Implementation of the SFL Initiative began with work on physician education, patient education, EMS staff and problems, creation of an Egyptian Registry, and pilot PCI center detection. The first phase of the Egyptian SFL registry took place from May 2011 to January 2012. During this phase, a total of 1324 patients with ST-segment elevation MI (STEMI) were hospitalized. At the time there were 35 PCI hospitals, 20 of which had 24/7 primary PCI service. The mean time from symptom onset to first medical contact for all STEMI patients was 600 minutes. The mean time from first medical contact to the PCI center was 120 minutes; first medical contact to thrombolysis treatment was 420 minutes; PCI center arrival to p-PCI was 70 minutes.

PCI procedures were performed in 820 of the 1324 STEMI patients, with 688 (52%) p-PCI procedures (Table 1). A total of 21 (1.6%) patients received coronary artery bypass grafts; 18 (1.4%) received coronary angiography and medical treatment; 93 (7.0%) received medical treatment with no reperfusion. A total of 504 patients were treated with thrombolysis, with 147 (11.1%) undergoing rescue procedures, while 21 (1.6%) were treated with thrombolysis as part of a pharmaco-invasive approach. Of the 688 primary PCI procedures, GPIIb IIIa inhibitor was used in 424 patients (61.7%); thrombus aspiration was performed in 294 patients (42.7%); 545 patients (79.2%) received a bare metal stent.

Table 1. Distribution of the Studied Cases According to Reperfusion.

Variables	Total Number of Patients (n=1324)	
	Number	Percent
No Thrombolytic		
Primary PCI	688	52.0%
Sent to CABG	21	1.6%
Coronary angio and MT	18	1.4%
MT without angio	93	7.0%
Thrombolytic		
Rescue	147	11.1%
Facilitated	21	1.6%
Sent to CABG	9	0.7%
Coronary angio and MT	15	1.1%
MT without angio	312	23.5%

CABG=coronary artery bypass graft; MT=medical treatment; PCI=percutaneous coronary intervention.

The SFL-Egypt Action Plan for 2012 is shown in Table 2. The SFL public campaign will call on all members of the public to "look after the hearts of those that are close to them" to raise awareness among family, friends, colleagues, and social and business groups. Individuals and groups will be educated on the signs of a heart attack, the importance of acting quickly and calling an ambulance, and the benefits of p-PCI. Partners in the first phase of the public awareness campaign include medical, government, and industry organizations.

Table 2. 2012 Action Plan.

Year Quarter	Duties
One	• Launch of Egyptian registry • SFL session in Cardio Egypt 2012 • SFL session in Magdi Yaacoub Foundation conference • Pilot center Application-Committee • Start of public awareness campaign (Alexandria and Cairo regions)
Two	• SFL Session in CardioAlex 2012 • Education program (guidelines, physical education, satellites) • Start of public awareness campaign (Alexandria and Cairo regions) • Satellite meetings plan (Delta and Upper Egypt) • EMS education program (Alexandria and Cairo regions) • Vodafone application in ambulances • Industry partners meeting (June 2011)
Three	• Education program (guidelines, physical education, satellites) • Start of public awareness campaign (Delta and Upper Egypt) • Satellite meetings plan (Alexandria and Cairo regions) • Preparation EMS education plan
Four	• SFL Scientific Day in Egypt Intervention 2012 • EMS education program (Alexandria and Cairo regions) • Satellite meetings plan (Alexandria and Cairo regions)

EMS=emergency medical system; SFL=Stent for Life.

The SFL-Egypt mission for 2012 includes guidelines implementation and physician education, registry and questionnaire/database collection, pilot centers detection, media campaign; public/patient awareness campaign, and preparation of an Egyptian SFL map.

TAVI with Balloon and Self-expandable Devices: Results from the Milan Registry

Written by Toni Rizzo

Transcatheter aortic valve implantation (TAVI) is a viable treatment option for high-risk surgical patients with severe symptomatic aortic stenosis (AS). The SAPIEN XT™ (SXT) and CoreValve® with AccuTrak™ delivery system (MCVAT) are new generation devices currently available in Europe for transfemoral TAVI. To date, no prospective comparisons between these 2 devices have