the choice of revascularization approach and whether it is needed at all for this group of patients.

The consensus from the studies that he reviewed indicates that interventional revascularization is gaining parity with surgery for those diabetic patients who fall into a high-risk group, but for stable patients without high-risk CAD and ischemia, revascularization can be deferred. Intensive medical interventions, as described in consensus guidelines [Smith SC Jr. *Circulation* 2006], are recommended for all diabetic patients with CAD.

The Emory Angioplasty versus Surgery Trial (EAST), which compared coronary angioplasty (percutaneous transluminal coronary angioplasty; PTCA) with coronary bypass surgery (coronary artery bypass graft; CABG) for patients with multivessel CAD, was the first study to suggest slightly (but not significantly) better survival outcomes for diabetic patients who received CABG compared with those who received angioplasty [King SB III et al. *J Am Coll Cardiol* 2000]. This trend was confirmed in the Bypass Angioplasty Revascularization Investigation (BARI I) trial, in which the survival rate for diabetic patients who received CABG was significantly (p=0.001) improved when compared with those who received PTCA [King SB III et al. *N Engl J Med* 1994]. This difference was not apparent when comparing similar procedures in nondiabetic patients.

The SYNTAX (Synergy between PCI with TAXUS and Cardiac Surgery) trial, which assessed the optimal revascularization strategy for patients with previously untreated three-vessel or left main CAD, reported no difference between the treatment approaches in medically treated diabetic patients with regard to all-cause death/cerebrovascular events/myocardial infarction (MI) at 12 months. However, a follow-up subgroup analysis suggested that at 1 year, the MACE and cerebrovascular event rates were higher in the angioplasty group, driven by an increase in repeat revascularization and MACE in patients with high SYNTAX scores [Banning AP et al. *J AM Coll Cardiol* 2010].

One year results from the Coronary Artery Revascularization in Diabetes (CARDIA) trial showed no apparent difference between CABG and PCI in terms of the composite endpoints of death, nonfatal MI, and non-fatal stroke; however, repeat revascularization was higher in the PCI group, which was expected [Kapur A. ESC 2008].

The question of which treatment approach is best, remains unanswered. The Future REvascularization Evaluation in patients with Diabetes mellitus: Optimal management of Multivessel disease (FREEDOM; NCT00086450) Trial is an ongoing study that is designed to provide the definitive answer to which treatment approach is best. This trial enrolled 1901 patients with diabetes and multivessel CAD who were eligible for PCI or CABG. Results are anticipated in 2012.

But is revascularization needed in all diabetic patients with CAD? The BARDI 2D trial compared prompt revascularization with delayed or no revascularization for patients with type 2 diabetes, CAD, and ischemia and no prior CABG or PCI within the past 12 months. The choice of PCI or CABG was selected, based on clinical or angiographic factors. Among high-risk patients (based on angiographic severity) who were selected for CABG, prompt revascularization reduced major cardiovascular (CV) events compared with delayed or no revascularization (p=0.01). Among lower-risk patients who were selected for PCI, the rates of major CV events were similar for the three options.

CV morbidity is a major burden in patients with type 2 diabetes. A target-driven, long-term, intensified intervention that is aimed at multiple risk factors in patients with type 2 diabetes and microalbuminuria reduces the risk of CV and microvascular events by about 50% [Gaede P et al. *New Engl J Med* 2003].

Strategies for Thrombus Management In STEMI Interventions

Written by Phil Vinall

"The major procedural difference between elective primary percutaneous coronary intervention (PCI) and an ST-segment elevation myocardial infarction (STEMI) intervention is thrombus, and you will encounter thrombus," warned Sameer Mehta, MD, University of Miami, Miami, Florida, USA. "The major component of intervention for STEMI is understanding thrombus and how to manage it effectively."

In a retrospective study that investigated the impact of thrombus burden on clinical outcomes in 812 consecutive patients who were treated with drug-eluting stents (DES), large thrombus burden (defined as thrombus burden ≥2 vessel diameters) was an independent predictor of mortality (HR, 1.76; p=0.023) and major adverse cardiac events (MACE; HR, 1.88; p=0.001) [Sianos G et al. *J Am Coll Cardiol* 2007]. Small thrombus burden was associated with less distal emboli and incidence of no reflow, greater final TIMI 3 flow, and higher rates of myocardial blush grade 3. The initial amount of thrombus impacted both acute and long-term outcomes.

Svilaas and colleagues randomly assigned 1071 patients to receive manual thrombus aspiration or conventional

PCI before undergoing coronary angiography and found that even minimal aspiration resulted in better reperfusion and clinical outcomes than conventional PCI, irrespective of clinical and angiographic characteristics at baseline [Svilaas T et al. *N Eng J Med* 2008]. Patients who were pretreated with a manual thrombectomy device before PCI had better epicardial and myocardial perfusion, less distal embolization, and significant reduction in 30-day mortality (p=0.003). Thus, if not contraindicated, adjunctive manual thrombectomy devices should be routinely used in STEMI patients who are undergoing primary angioplasty [De Luca G et al. *Eur Heart J* 2008]. Both the United States and European guidelines support the use of aspiration thrombectomy for patients who are undergoing PCI for STEMI

The Mehta Classification [Mehta S et al. *Cath Lab Digest* 2011] provides a selective strategy for thrombus management, based upon the thrombus grade. The first step is to identify the grade of thrombus using a scale, where Grade 0 represents no thrombus and Grade 5 represents complete occlusion of the vessel. For Grades 0 and 1, direct stenting is possible. For Grades 2 and 3, aspiration thrombectomy is recommended, followed by PCI. Passes with the aspiration catheters should be made throughout the entire length of the thrombus until there is no angiographic evidence remaining; often, just 2 passes is sufficient. For Grades 4 and 5, the use of a mechanical approach (eg, the AngioJet® or Clearway™) is recommended. The rheolytic thrombectomy device is effective for debulking voluminous thrombi. If AngioJet devices are not available, a default catheter, such as an aspiration catheter, may be used for high-grade thrombus. Early upstream antiplatelet pharmacology must be incorporated as well.

In summary, said Dr. Mehta, "to eliminate the thrombus, you must first identify the grade of thrombus. The thrombus-graded approach to using these devices, as in the SINCERE (Single Individual Community Experience Registry for Primary PCI) database, produces excellent clinical results."

Catheter Mitral Valve Repair

Written by Maria Vinall

Mitral regurgitation (MR), the most common type of heart valve insufficiency, affects more than 4 million people in the United States [Nkomo VT et al. *Lancet* 2006]. The volume overload that is associated with MR and heart failure (HF) contributes to ventricular remodeling and, over time, may lead to irregular heartbeat, HF, stroke, heart attack, or death. Dilated cardiomyopathy is characterized by significant enlargement of cardiac chambers, which can lead to functional mitral regurgitation (FMR), which increases the risk of morbidity and mortality even further. Horst Sievert, MD, CardioVascular Center Frankfurt, Frankfurt, Germany, reviewed two new techniques that are under development for percutaneous repair of the mitral valve.

The CARILLON Mitral Contour System™ is a nonsurgical, minimally invasive device that is designed to repair the mitral valve and reduce FMR. It combines a proprietary implantable device and a percutaneous delivery system. The procedure starts with a venogram to characterize anatomy, then placement of a distal anchor near the anterior commissure; tension is applied to plicate the tissue to reduce MR. If a good position and reduction in MR are confirmed, the device is released. The efficacy and safety of the CARILLON system in FMR were evaluated in the Phase I TITAN trial of 53 patients with dilated ischemic or nonischemic cardiomyopathy (LVEDd >55 mm). Implantation was successful in 68% (36/53) of patients. Treatment with the system was associated with an average 40% reduction in echocardiography core lab-derived quantitative measures of FMR over a period of 12 months. Six-minute walk distance and NYHA Class also improved (Table 1). There were no device-related major adverse events (AEs) at 12 months. Mortality in the implanted and nonimplanted groups was similar at 1 year [Siminiak T et al. ESC 2010].

Table 1. Functional Changes.

	6MWD (m)			
	Baseline	**6 months**	**12 months**	**p value**
Implanted (n=36)	302±74	436±208	427±193	p=0.0036
Nonimplanted (n=17)	338±83	322±105	330±139	p=0.915
	NYHA Class			
	Baseline	**6 months**	**12 months**	**p value**
Implanted (n=36)	3.1±0.2	2.1±0.7	2.1±0.8	p<0.0001
Nonimplanted (n=17)	2.9±0.2	2.7±0.7	2.4±0.5	p=0.135

Mean±SD; p-value by ANOVA; 6MWD=6-minute walking distance.

The MitraClip® System is a catheter-based therapy that is adapted from the open surgical double-orifice technique. The system is intended to be an additional option for patients who are suitable for a percutaneous approach. It consists of three major subsystems: a steerable guide catheter, a clip delivery system, and the MitraClip device (implant). The EVEREST II (Endovascular Valve Edge-to-Edge Repair Study) trial compared percutaneous mitral valve repair using the MitraClip system with surgical