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.

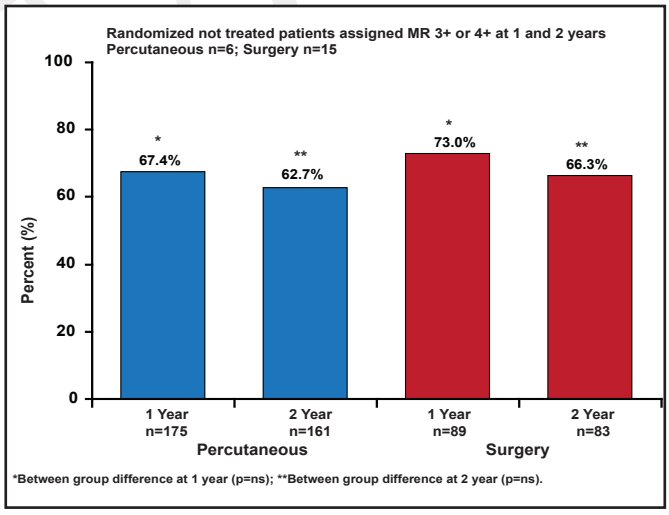
	6MWD (m)			
	Baseline	**6 months**	**12 months**	**p value**
Implanted (n=36)	302±74	436±208	427±193	p=0.0036
Nonimplanted (n=17)	338±83	322±105	330±139	p=0.915
	NYHA Class			
	Baseline	**6 months**	**12 months**	**p value**
Implanted (n=36)	3.1±0.2	2.1±0.7	2.1±0.8	p<0.0001
Nonimplanted (n=17)	2.9±0.2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

repair or replacement in 279 patients with moderate/severe (3+) or severe (4+) MR who were candidates for mitral valve (MV) surgery. The primary efficacy endpoint was freedom from death, MV surgery/reoperation, or grade 3+ or 4+ MR at 12 months. The primary safety endpoint was a composite of major AEs within 30 days. Through 2 years, there has been no device embolization, fracture, erosion, or migration [Feldman T et al. *N Engl J Med* 2011]. No additional occurrence of single leaflet device attachment occurred between 1 and 2 years (the 1-year rate was 6.3%). At Year 2, in an intent-to-treat analysis, significantly more patients in the surgical group met the primary efficacy endpoint (66.3% vs 51.7%; p=0.04). However, the difference was not significant when using a comparison of treatment strategy analysis (62.7% and 66.3%, percutaneous and surgery, respectively; p=NS; Figure 1). Patients who underwent percutaneous MV repair had significant improvements in left ventricular (LV) end systolic/diastolic volume and NYHA functional classification compared with patients who had surgery (p<0.005 in all comparisons).

Figure 1. Primary Effectiveness Analyses at 1 and 2 Years.



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Although surgery provided more complete MR reduction, percutaneous repair was associated with increased safety, improved LV dimensions, and clinical improvements in NYHA class and quality of life. The system's positive risk-benefit profile supports its use as a treatment for patients who are not good candidates for surgery and have few other options, including elderly or frail patients and those who are at high risk for surgery.

Further reading: Feldman T et al. *N Engl J Med* 2011;364:1395-1406.