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Interventional Cardiology

News & Views

News

PERFECT STENT: the benefits of deploying an endothelial progenitor cell capturing stent with a drug-eluting balloon

An endothelial progenitor cell (EPC)-capturing stent deployed with a drug-eluting balloon may reduce late lumen loss and overall clinical events when compared with patients treated with stents alone, according to the results of the Prospective, Randomized Trial Evaluating a Paclitaxel-Eluting Balloon in Patients Treated with Endothelial Progenitor Cell Capturing Stents for *De Novo* Coronary Artery Disease (PERFECT STENT).

The Genous EPC stent (OrbusNeich, Wanchai, Hong Kong) is a stainless steel stent coated with immobilized murine monoclonal antibodies, which allows the surface of the stent to capture EPCs in the blood, accelerating the rate of endothelialization of the stent strut. Evidence indicates that even though the EPC stent promotes healing faster than that of drug-eluting stents (DES), it has very little effect on the rate of restenosis.

Joachen Wöhrle (University of Ulm, Germany) explained, "Treatment of coronary stenosis with drug-eluting stents reduces the restenosis rate and the need for repeat revascularization, but about one-third of restenoses occur proximal or distal to the stent and there is a continuous risk for late stent thrombosis." This led to the idea that by combining the stent with a paclitaxel-eluting balloon catheter may provide better outcomes than the use of the stent alone.

A total of 120 patients with *de novo* lesions in the coronary artery, no longer than 25 mm and between 2.5 and 4.0 mm in diameter, were randomized between the treatment groups to receive either the Genous stent with a balloon catheter or the EPC stent deployed with the SeQuent paclitaxel-coated balloon (B Braun, Melsungen, Germany).

The average late lumen loss at 6 months was 0.61 mm in the EPC stent-only group and 0.16 mm in the EPC stent/paclitaxel-eluting-balloon group. Wöhrle added, "One-third of restenosis shows up just distal or proximal to the stent and a potential advantage of the drug-eluting balloon over a DES is that the balloon can deliver more of the antirestenosis drug to the areas beyond the ends of the stent, so we compared in-stent, proximal and distal late loss."

In patients who received the EPC stent alone, an average in-stent late lumen loss of 0.88 mm over the course of 6 months was experienced, while those patients who received the combination stent experienced a 0.34 mm late lumen loss, a statistically significant difference favoring the use of the combination ($p < 0.001$).

Proximal late loss was also found to be significant, with a loss of 0.21 mm observed in patients who received the EPC stent alone and a 0.04 mm late loss experienced among patients who received the combination ($p = 0.01$). Distal late loss was 0.09 mm in those receiving the stent and 0.02 mm in those patients who received the combination ($p = 0.20$). Total binary restenosis rate also favored the combination treatment.

Wöhrle said that, "The next step in realizing this concept would be to conduct a trial comparing an everolimus-eluting stent with an EPC stent deployed with a paclitaxel-eluting balloon."

Sources: www.theheart.org/article/1126171.do; www.docguide.com/news/content.nsf/news/852576140048867C852577AB00720350?OpenDocument&c=Interventional%20Cardiology&count=10&id=48DDE4A73E09A969852568880078C249

future medicine part of fsg

Intravascular ultrasound-guided stent implantation and minimal lumen diameter: the results of AVIO

The intravascular ultrasound (IVUS) technique when used to guide the implantation of a drug-eluting stent in complex lesions, resulted in a greater minimal lumen diameter (MLD) than angiography-guided implantation according to the results of AVIO. Clinical results at 30 days and 9 months, however, indicated no significant difference in the combined end point of myocardial infarction, target lesion revascularization, target vessel revascularization and cardiac death.

Lead investigator, Antonio Columbo (Columbus Hospital, Milan, Italy) presented the results at the late breaking trials session at the 2010 Transcatheter Coronary Therapeutics meeting and suggested that "The trial established definite criteria for optimal stent expansion."

In the AVIO study, 142 patients from each arm with complex lesions, such as lesion lengths greater than 28 mm, chronic total occlusions, bifurcation lesions, small vessel lesions or multiple lesions requiring four or more stents, were randomized to receive IVUS-guided or angiography-guided stent implantation.

Patients implanted with a stent guided by IVUS had a significantly greater postprocedure in-lesion MLD when evaluated by coronary angiography. The study indicated that postprocedure MLD was significantly greater in 75 lesions that had received IVUS-guided treatment, meeting the criteria for optimal stent placement. MLD was not significantly different between the IVUS-guided and angiography-guided treatment arms when operators were unable to optimize the placement of the stent. Columbo explained "When the criteria are met, the final MLD ranges from 2.51 mm (angiography-guided) to 2.86 mm (IVUS-guided), but when the criteria are not met, the MLD is 2.51 mm and 2.6 mm, respectively, which kind of makes sense."

No support for follow-up angiography was available and only 39% of patients underwent quantitative coronary angiography at 9 months. As a result, statements about the benefits of IVUS-guided stent implantation on restenosis rates are unable to be made.

David Kandzari (Piedmont Heart Institute, GA, USA) who uses IVUS in approximately 80% of his cases said that, "Most operators probably do not use the technology as frequently and would be unlikely to meet the quantitative and qualitative criteria set out for determining optimal stent expansion. It raises the question, whether repetitive high-pressure balloon angioplasty might also be effective for obtaining better stent placement."

George Dangas (Mount Sinai Medical Center, NY, USA) added that, "It is necessary to know now whether IVUS-guided stent placement in these complex lesions translates into improved long-term clinical outcomes."

Source: www.theheart.org/article/1128679.do

Evaluating the CoreValve system: US FDA approves trial

The US trial of the CoreValve transcatheter aortic-valve system is ready to begin as the FDA granted Medtronic an investigational device exemption.

Approximately 800 patients with severe aortic stenosis who are at high risk for aortic valve surgery will be randomized in a 1:1 ratio to two treatment cohorts. One cohort will receive a percutaneous implant of CoreValve, while the other cohort will receive surgical valve replacement. In addition, 400 patients who are at extremely high risk for aortic valve surgery ('inoperable' patients) will be randomized in a 2:1 ratio to receive either the CoreValve or medical management only.

Coprimary end points for the inoperable cohort are all-cause death or major stroke at 1 year and a composite of all-cause death, major stroke, days of hospitalization for aortic-valve disease and hospitalizations for aortic-valve disease at 1 year. For the high-risk cohort, the primary end point is all-cause mortality at 1 year. The study, which will be led by David Adams (Mount Sinai Medical Center, NY, USA) and Jerry Popma (Beth Israel Deaconess Medical Center, MA, USA) is due to begin this autumn and will be conducted at 40 clinical sites in the USA.

The CoreValve system received CE mark approval in 2007 and has since been implanted in over 12,000 patients outside the US, with some encouraging results. Clinicians in the USA have long awaited the trial as CoreValve and Medtronic have worked over the last few years to convince the US FDA that the device was safe enough to enter a clincal trial.

"This study represents a significant opportunity to fundamentally change the way we treat Americans with severe aortic stenosis," said Adams. "Cardiologists and cardiac surgeons will collaborate more closely than ever before to carefully select and deliver this innovative therapy."

Source: Medtronic press release: Medtronic Clinical Trial Receives FDA Approval to Evaluate New CoreValve® System for Aortic Valve Implantation: wwwp.medtronic.com/Newsroom/NewsReleaseDetails.do?itemId=1287081500254&lang=en_US; www.theheart.org/article/1137437.do

When is carotid artery stenting an acceptable alternative to surgery in stroke prevention?

New stroke prevention guidelines addressing the recently published body of clinical trials comparing carotid artery stenting (CAS) and carotid endarterectomy (CEA) have been released by the American Heart Association/American Stroke Association, outlining when CAS is an acceptable alternative to surgery. In addition, the same guidelines address the treatment of metabolic syndrome and percutaneous closure of patent foramen ovale (PFO).

"...CAS is indicated as an alternative to CEA for symptomatic patients who are at average or low risk of complications associated with endovascular interventions..."

Researchers led by Karen Furie (Massachusetts General Hospital Stroke Service, MA, USA), performed a comprehensive review of the literature in order to provide evidence-based recommendations for the prevention of ischemic stroke in survivors of stroke or transient ischemic attack (TIA). Since the last guidelines were issued in 2006, CAS has continued to evolve and has emerged as a therapeutic alternative to CEA for the treatment of extracranial carotid artery occlusive disease. The proposed advantages of the procedure are clear: less invasiveness, decreased patient discomfort and a shorter recovery period. The authors however indicate that, "its durability remains unproven."

From the available evidence, Furie and colleagues made a Class I recommendation (Level of Evidence B) that CAS is indicated as an alternative to CEA for symptomatic patients who are at average or low risk of complications associated with endovascular interventions when the lumen diameter of the carotid artery is reduced by more than 70% on noninvasive imaging or 50% on catheter angiography.

In addition, changes to the recommendations were made in relation to CEA. Patients with recent TIA or ischemic stroke and ipsilateral moderate (50–60%) carotid stenosis, CEA was proposed dependent on patient specific factors as a Class I recommendation (Level of Evidence A). In the new statement, CEA is preferred in these patients dependent on the same factors if the perioperative morbidity and mortality risk is estimated at less than 6%. This remains a Class I recommendation, but with a Level of Evidence B. All other recommendations regarding CAS and CEA remain the same.

The guidelines do not recommend the screening of patients for metabolic syndrome after stroke. However, patients who become diagnosed can be managed with diet alterations, exercise and weight loss to reduce vascular risk. Preventative care is recommended for individual components known to be stroke risk factors.

Insufficient data are available to determine whether anticoagulation is equivalent or superior to aspirin for secondary stroke prevention in patients with PFO (Class IIb, Level of Evidence B), and state that no recommendation can be made regarding PFO closure in patients with PFO and stroke (Class IIb, Level of Evidence C). The randomized CLOSURE I trial to be presented at the AHA Scientific Sessions in November 2010 has evaluated the safety and efficacy of the StarFlex septal closure system (NMT Medical, Boston, MA, USA) versus medical therapy in patients with PFO and stroke or TIA due to embolism and may add more information on their treatment.

Sources: Furie KL, Kasner SE, Adams RJ et al.*: Guidelines for the prevention of stroke in patients with stroke or transient ischemic attack: a guideline for healthcare professionals from the American Heart Association/American Stroke Association.* Stroke *DOI: 10.1161/STR.0b013e3181f7d043 (2010) (Epub ahead of print); www.tctmd.com/show.aspx?id=103452*

New guidance on the use of arterial closure devices from the American Heart Association

The American Heart Association has issued a scientific statement, which provides guidance on the use of arterial closure devices after cardiac catheterization in a forthcoming issue of *Circulation*.

Closure devices were first introduced in 1995 and have been developed as an alternative to manual compression. These devices have now undergone several generations of design and current models use a variety of mechanisms.

"The potential benefits of closure devices are: improved patient comfort and satisfaction, faster homeostasis, shorter time to ambulation and shorter hospitalization periods."

Manesh Patel (Duke Medical University Center, NC, USA) explained that, "The potential benefits of closure devices are: improved patient comfort and satisfaction, faster homeostasis, shorter time to ambulation and shorter hospitalization periods. However, they also introduce the possibility of unique vascular complications requiring specialized care".

Patel and colleagues propose stratifying patients by their projected rate of vascular complications with closure devices, which range from low risk (<1%) for diagnostic angiographic procedures to moderate risk (1–3%) for routine percutaneous coronary intervention and high risk for certain subgroups, such as older subgroups (>3%).

In light of the available evidence, the authors offer the following recommendations:

- Patients deemed suitable candidates for closure devices during femoral access, should undergo a femoral angiogram to identify the sheath insertion site. Atherosclerosis and calcification should also be identified to ensure anatomic suitability (Class I; Level of Evidence C);
- Centers using standard manual compression should aim to achieve vascular complication rates of less than 1% in patients undergoing 5 Fr diagnostic angiography (Class I; Level of Evidence C);
- The use of closure devices is reasonable after PCI is performed via the femoral artery, but the risk–benefit equation should take into account such factors as age, gender, sheath size and presence of systemic disease (Class IIa; Level of Evidence B);
- Closure devices "should not be used routinely for the specific purpose of reducing vascular complications" in patients undergoing PCI via the femoral artery (Class III; Level of Evidence B);
- Data on periprocedural and postprocedural complications should be collected either locally or nationally, and reported to the US Food and Drug Administration (Class I; Level of Evidence C).

When designing future trials it will be important to have consistent criteria for the assessment of arterial closure devices. Patel said, "What we realized in the literature was that many different patient populations were being studied and different outcomes were evaluated. It becomes difficult to recognize if there are any incremental steps forward."

Robert Applegate (Wake Forest University Baptist Medical Center, NC, USA) commented that, "The most valuable response to these recommendations would be for the National Institute of Health to sponsor an adequately powered randomized clinical trial to really answer the safety issue in comparable patients".

Sources: Patel MR, Jneid H, Derdeyn CP et al.*: Arteriotomy closure devices for cardiovascular procedures: a scientific statement from the American Heart Association.* Circulation *122(18), 1882–1893 (2010); www.tctmd.com/show.aspx?id=103164*