News & Views in ...

Interventional Cardiology



News



RESEARCH HIGHLIGHTS





BioSTARTM: a 'shining light' for the treatment of atrial septal defect in children

Atrial septal defect (ASD) is a congenital heart defect where a hole in the wall between the two upper heart chambers is present. Its incidence ranges from a twentieth to a tenth of all congenital heart lesions. Small ASDs may close on their own in early life, but large defects may require surgery to close the opening. If treatment is delayed, the presence of ASD increases the risk of further complications in later life, including atrial fibrillation, heart failure and stroke.

"...common issues associated with permanent implants are avoided with the BioSTAR device."

A novel study by Lee Benson and colleagues from The Hospital for Sick Children, Ontario, Canada have reported that the BioSTARTM biodegradable implant achieved comparable closure rates to the Amplatzer Septal OccluderTM (ASO) in children with small to moderate ASD. This is the first study to compare a bioresorbable device with ASO in children and has found that reduced thrombogenicity, preserved transeptal access and decreased erosion potential, common issues associated with permanent implants are avoided with the BioSTAR device.

A total of 54 children underwent ASD closure with ASO in the study period November 2007 to November 2008. The ASO group median data were: age of 7.4 years, weight of 23.3 kg, defect size of 10 mm and balloon stretch size of 12.7 mm. The BioSTAR implant was used in ten patients with a defect that was deemed as small to moderate by non-invasive studies. In this group, patients'

media data were: age of 11 years, weight of 39.6 kg, defect size of 10 mm, and balloon stretched size of 11.5 mm.

The acute and 6-month follow-up closure rates for the BioSTAR were 90 and 100 versus 100 and 100% closure with ASO implants. No serious complications were reported in either group. However, statistically significant differences in the media procedure time (BioSTAR: 52 min; ASO device: 39.5 min) and fluoroscopy times (BioSTAR: 6.7 min; ASO device: 6.1 min) were observed. Lee Benson commented that, "our study provides evidence that the BioSTAR implant achieves comparable closure rates to the ASO in small to moderate ASD".

It was noted by the study team that decreased long-term thrombogenicity, preserved trans-septal access, decreased inflammatory response, and a reduced potential of arrhythmogenicity and erosion were benefits of using biodegradable implants. In addition, "Minimal foreign material remains after 6 months with the biodegradable implant, reducing the risks associated with devices containing significant amounts of metal," said Lee Benson.

With these benefits, the only drawback seems the longer fluoroscopy and procedure times, however, these "should improve with familiarity with the device and deployment system," concluded Lee Benson.

Sources: Press Release: www.scai.org/Press/ detail.aspx?cid=e885d4c6-4d4f-4fd7-bb54fcb099eccc4f; Morgan G, Lee KJ, Chaturvedi R, Benson L: A biodegradable device (BioSTARTM) for atrial septal defect closure in children. Cathet. Cardiovasc. Interv. 76(2), 241-245 (2010).

NEWS & VIEWS - News



"...the use of DES decreases in-stent restenosis and the frequency of repeat revascularization procedures in patients undergoing PCI..."

Use of drug-eluting stents show improvements in long-term clinical outcome in angioplasty patients

Researchers at the Rabin Medical Center, Israel led by Tamir Bental have determined that the use of drug-eluting stents (DES) improves the long-term clinical outcome for patients undergoing percutaneous coronary intervention (PCI).

Percutaneous coronary intervention is one of the most common and widely used treatments for coronary artery disease. It has been indicated that over 1,313,000 cases of PCI were conducted in the USA in 2006. Results from previously conducted randomized clinical trials have indicated that the use of DES decreases in-stent restenosis and the frequency of repeat revascularization procedures in patients undergoing PCI, but questions regarding the long-term safety and effectiveness of DES in routine clinical practice among large unselected population cohorts still remain.

In this study, researchers examined the benefits and long-term risks of DES by evaluating the established pattern of use of DES and bare-metal stents (BMS) in clinical practice in Israel. Guidelines from the Israel Heart Society and the Ministry of Health require DES to be used in proximal main vessels, diabetic patients and in long lesions to reduce restenosis.

The study population was comprised of all cases of PCI with stent implantation over a 4-year period at two hospitals of the Rabin Medical Center. The cohort of patients was 6583, of which 2633 (40%) patients received a DES whilst 3950 (60%) patients received a BMS. The follow-up time was a minimum of 6 months and a maximum of 5.2 years, with a mean follow-up of 3 years.

Propensity score matching and stratified analysis was used to define the clinical effectiveness and safety profile of DES versus BMS among treated patients, using long-term follow-up mortality and morbidity end points. Propensity score matching was performed using an algorithm to match each DES patient with a BMS patient with the closest propensity score. The propensity matched group consisted of 4398 patients (2199 matched pairs).

The Israel Ministry of Health directives were followed, with 40% of the procedures including a DES. Patients who received DES were slightly younger and more likely to be diabetic but their index intervention was less likely to be emergent. The DES group displayed certain features, which included the use of longer or more stents per lesion, treatment of more territories, more sites per territory and of more proximal main vessels. Of the patients with DES, 66% had a DES only, whereas 34% had a combination of a DES and a BMS.

The study results demonstrate that the use of DES compared with BMS reduced the occurrence of myocardial infarction (5.17 vs 5.83%) and the need for target lesion vascularization (9.76 vs 12.28%). Mortality was also significantly lower in the DES group, indicating a persistent benefit of DES over time (23.38 for DES vs 26.07% in BMS).

Bental explained that, "The main effect of DES is reduced restenosis, which is evident in the analysis. This outcome was sustained over time and could certainly be a major factor contributing to the survival benefit of DES. We suggest that a possible additional factor contributing to our results could be the pattern of use of the DES in our practice-treatment of more territories and more sites per territory, probably leading to a more complete revascularization. Another salient feature was the preferential treatment of more proximal main vessel. Therefore, treatment of proximal lesions could contribute to a better outcome."

Source: The Society for Cardiovascular Angiography and Interventions Press Release: www.scai.org/Press/detail.aspx?cid=d2265cd9–33e5–41c2-a7d9–7227a981979d

News - News & Views

AXXESSTM biolimus A9[®]-eluting coronary bifurcation stent receives CE mark

bifurcations.

stent architecture and believe that it offers significant advantages over other devices."

The Devax AXXESS system technology is a proprietary self-expanding nitinol stent, which is designed for treating coronary and vascular bifurcation lesions. The conical shape of the stent is designed to conform to the bifurcation anatomy and provide full access to both branches for additional interventional procedures. Devax has licensed the drug Biolimus A9 and bioabsorbable coating from Biosensors International Group.

Source: Press Release: www.businesswire. com/news/home/20100729005556/en/Devax-Receives-CE-Mark-AXXESS%E2%84%A2-Drug-Eluting

Intra-aortic balloon pump not associated with improved

Divaka Perera and colleagues at Kings College London, UK, have reported that high-risk patients undergoing a coronary procedure such as placement of a stent who electively received an intra-aortic balloon pump prior to the procedure did not experience a significantly lower overall rate of events such as myocardial infarction (MI), revascularization or death.

Bifurcation lesions occur in approximately

20% of patients treated for ischemic heart

disease with coronary angioplasty and stent-

ing. Large-scale clinical studies, such as

SYNTAX and LEADERS, have indicated

that lesions located at vessel bifurcations

increase the frequency of major adverse

cardiac events by as much as 40% compared

Devax, Inc. (Irvine, CA, USA) announced

on 29 July 2010, that they had received the

CE mark for its AXXESSTM Biolimus

A9[®]-eluting coronary bifurcation stent

system (AXXESS system), allowing the

company to initiate sales in the European

Union and other countries that recognize

the CE mark.

with lesions in straight vessel segments.

The authors wrote that, "In these circumstances, vital hemodynamic support can be provided by an intra-aortic balloon pump (IABP), which simultaneously augments coronary blood flow and decreases myocardial oxygen demand." They continued that, "Observational studies have previously reported that elective IABP insertion may improve outcomes following high-risk percutaneous coronary intervention (PCI)". However, this has not been tested in a randomized trial.

The Balloon Pump-Assisted Coronary Intervention Study (BCIS)-1 aimed to assess the efficacy and safety of elective IABP use in patients undergoing highrisk PCI. The randomized controlled trial was conducted in 17 tertiary referral cardiac centres in the UK between December 2005 and January 2009.

The patients included in the study (n = 301) had severe left ventricular dysfunction and extensive coronary disease. The primary outcome measure included major adverse cardiac and cardiovascular events (MACCE; defined as death, MI, cerebrovascular event or further revascularization at hospital discharge, up to 28 days).

Perera and colleagues found that the primary end point of MACCE at hospital discharge occurred in 15.2% of the elective IABP group and 16.0% of the no-planned IABP group. All-cause mortality at 6 months was 4.6 and 7.4%, respectively.

Procedural complications, which had been predefined, occurred more often in the no-planned IABP group (16 patients [10.7%]) than in the group undergoing elective IABP insertion (two patients [1.3%]). Prolonged procedural hypotension, was the most common component of these complications, which occurred in 13 patients in

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the group with no planned IABP insertion and two patients in the group with elective IABP insertion. Major or minor bleeding occurred in 19.2% of the elective IABP group and 11.3% of the no-planned IABP group. There was no difference between the groups in the incidence of major bleeding, but minor bleeding occurred more in the elective IABP group (15.9%) compared with the no-planned IABP group (7.3%).

Perera and colleagues concluded that, "The study did not demonstrate a difference in MACCE at hospital discharge and therefore does not support routine elective IABP insertion before high-risk PCI. However, 12% of patients who underwent PCI without elective IABP insertion required rescue IABP support, which highlights the importance of adopting a standby IABP strategy when undertaking high-risk PCI."

Source: Perera D, Stables R, Thomas M et al.: Elective intra-aortic balloon counterpulsation during high-risk percutaneous coronary intervention: a randomized controlled trial. JAMA 304(8), 867-874 (2010).

outcomes prior to percutaneous coronary intervention

Two clinical studies conducted out-

side the USA have allowed Devax to

implant over 430 AXXESS stents. The

DIVERGE study enrolled 302 patients at

16 clinical centers in Europe, Australia,

and New Zealand and showed high

rates of clinical success and low rates of

restenosis compared with other studies of

Devax, said, "The treatment of coronary

bifurcations represents a large market and

is one of the most challenging procedures

for interventional cardiologists. Our clini-

cal data has shown the long-term bene-

fits of the AXXESS stent and so we are

pleased to be able to provide this unique

Jeff Thiel, President and CEO of



NEWS & VIEWS - News



Molecular imaging to identify high-risk patients best suited for implantable cardioverter defibrillator therapy

A Japanese study has found that molecular imaging can help identify high-risk patients with potentially life-threatening cardiovascular conditions and aid physicians in determining which are best suited for implantable cardioverter defibrillator (ICD) therapy.

Kimio Nishisato from Muroram City General Hospital, Japan, said that, "If the molecular imaging techniques are used for appropriate selection of ICD candidates, not only overuse but also underuse of ICD could be avoided and the assessment may be shown to be more cost effective."

The study indicates that molecular imaging can play an important role in diagnosing and guiding the treatment strategy for arrhythmia, coronary artery disease, and heart failure, whilst reducing unnecessary medical costs by better targeting treatment for each individual patient.

Tomoaki Nakata, Sapporo Medical University School of Medicine, Sapporo, Japan explained that, "This research holds significant potential for the detection, diagnosis and treatment of many common cardiovascular conditions and with molecular imaging, physicians can improve patient care by pinpointing the precise location of the disease in order to eliminate the need for invasive medical devices and unnecessary surgical techniques."

The team of researchers hypothesized that both the impairment of myocardial perfusion and/or cell viability and cardiac sympathetic innervations are responsible for heart arrhythmias and sudden cardiac death. No established reliable method of imaging was available.

The prognostic implications of cardiac presynaptic sympathetic function was investigated and quantified by cardiac MIBG activity and myocyte damage or viability quantified by cardiac tetrofosmin activity in patients treated with prophylactic use of ICD, by correlating with lethal arrhythmic events that would have been documented during a prospective follow-up. This study is the first to show the efficacies of the method for more accurate identification of patients at greater risk of lethal arrhythmias and sudden cardiac death (SCD).

Ichiro Matsunari from the Medical and Pharmacological Research Center Foundation (Hakui, Japan) said that, "Sudden cardiac death due to lethal arrhythmia represents an important health care problem in many developed countries, and while implantable cardioverter defibrillator therapy is an effective option over antiarrhythmic medications to prevent SCD, the balance of clinical benefits, efficacy and risks is still a matter of discussion."

Better, more precise strategies such as the molecular imaging technique used in this study are needed to identify highrisk patients for SCD, and who are more likely to benefit from ICD therapy. SCD is often the first manifestation of an underlying disease that current treatments cannot always detect. Molecular imaging will help to guide diagnosis and treatment as well as avoid unnecessary ICD treatment.

"...molecular imaging can play an important role in diagnosing and guiding the treatment strategy ... whilst reducing unnecessary medical costs by better targeting treatment for each individual patient..."

"SCD is often the first manifestation of an underlying disease that current treatments cannot always detect."

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Sources: www.docguide.com/news/content.nsf/ news/852576140048867C8525777B0071CE23 ?OpenDocument&c=Interventional%20Cardio logy&count=10&id=48DDE4A73E09A96985 2568880078C249; Nishisato K, Hashimoto A, Nakata T et al.: Impaired cardiac sympathetic innervation and myocardial perfusion are related to lethal arrhythmia: quantification of cardiac tracers in patients with ICDs. J. Nucl. Med. 51(8), 1241–1249 (2010).