News & Views in ...

Interventional Cardiology

News & Views

News

Research Highlights

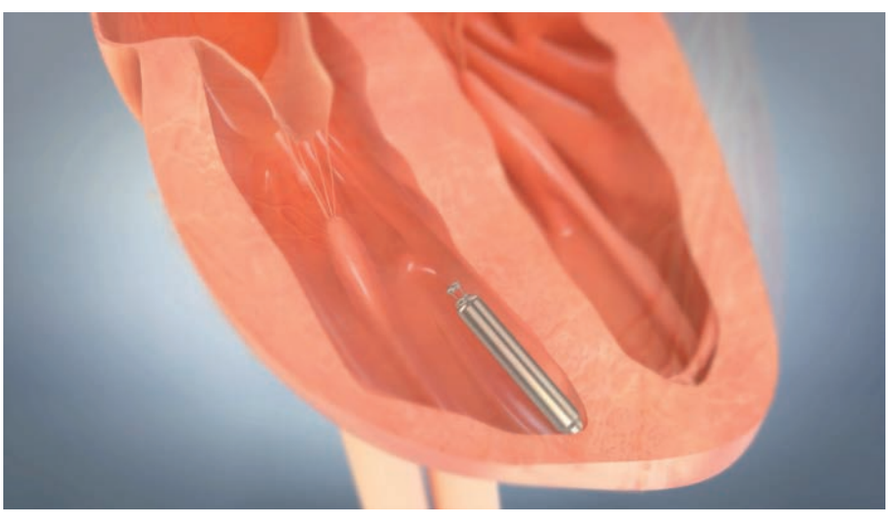
World's first leadless pacemaker receives CE mark approval and is acquired by St Jude Medical

In mid-October 2013, St Jude Medical (MN, USA) announced the acquisition, after a collaborative partnership, of Nanostim, Inc., a private developer of miniaturized leadless pacemakers, one of which, the Nanostim™ leadless pacemaker, recently received CE mark approval.

Leadless pacemakers represent an important advance in pacing technologies, with one of their main advantages being that unlike conventional pacemakers, a lead less pacemaker can be placed directly in to the heart, without the need for a surgical pocket and pacing leads, which have historically been recognized as the most vulnerable component of pacing systems. The Nanostim™ leadless pacemaker (St Jude Medical, MN, USA) has been designed to be implanted via a minimally invasive procedure, via a steerable catheter through the femoral vein, and has recently received CE mark approval, paving the way for its availability in select European markets. The Nanostim leadless pacemaker has also recently received US FDA conditional approval for its Investigational Device Exemption application and pivotal clinical trial protocol, to begin evaluating the Nanostim leadless technology in the USA.

Cardiac pacemakers are primarily used to treat bradycardia and such devices monitor the heart to provide electrical stimulation when the heart beats too slowly for the patient's physiological requirements. It is estimated that four million people worldwide have an implanted pacemaker or other cardiac rhythm management devices and an additional 700,000 patients receive the devices each year.

The Nanostim leadless pacemaker size is 10% of a conventional pacemaker and is comprised of a pulse generator that includes



Nanostim™ leadless pacemaker (St Jude Medical, MN, USA) is designed to be implanted directly into the heart via a minimally invasive procedure.
Reproduced with permission from St Jude Medical Inc.

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Nanostim™ leadless pacemaker (St Jude Medical Inc., MN, USA). Reproduced with permission from St Jude Medical Inc.

a battery and a steroid-eluting electrode that sends pulses to the heart when it recognizes a problem with the heart's rhythm. The small size of the device and lack of a surgical pocket, coupled with the exclusion of a lead, improves patient comfort and can reduce complications, including device pocket-related infection and lead failure. The elimination of the visible lump and scar at a conventional pacemaker's implant site, in addition to the removal of patient activity restrictions that may prevent the dislodgement or damage to a conventional lead, will potentially improve the quality of life for patients.

Johannes Sperzel from the Kerckhoff Klinik (Bad Nauheim, Germany) commented on the technology: "For the past 40 years, the therapeutic promise of leadless pacing has been discussed but, until now, no one has been able to overcome the technical challenges. This revolutionary technology offers my patients a safe, minimally-invasive option for pacemaker delivery that eliminates leads and surgical pockets. This is the future of cardiac pacing."

The Nanostim leadless pacemaker has been designed to be fully retrievable, which means that it can easily be repositioned during the implant procedure and later retrieved if necessary, such as at the time of normal battery replacement. Initial results from the LEADLESS study, a prospective, single-arm, multicenter study evaluating patients with the Nanostim leadless pacemaker, were presented earlier this year and demonstrated overall device performance to be comparable to conventional pacemakers. Total implant procedure times averaged 28 min. Even with miniaturization, the device battery is expected to have an average lifespan of more than 9 years at 100% pacing, or more than 13 years at 50% pacing.

– Written by Michael Dowdall

Source: St Jude Medical announces acquisition and CE mark approval of world's first leadless pacemaker: http://investors.sjm.com/phoenix.zhtml?c=73836&p=irol-newsArticle&ID=1863989

Favorable Re-ROUTE trial data for the OffRoad™ Re-Entry Catheter System

Data from the Re-ROUTE clinical trial were recently presented by Koen Keirse, Regional Hospital Heilig Hart Tienen (Tienen, Belgium) in a late-breaking clinical trial session at the Vascular Interventional Advances Conference in Las Vegas (NV, USA) held on 8–11 October 2013.

"*The OffRoad™ Re-Entry Catheter System (Boston Scientific, MA, USA) demonstrated excellent performance in facilitating the treatment of chronic total occlusions...*"

The OffRoad™ Re-Entry Catheter System (Boston Scientific, MA, USA) demonstrated excellent performance in facilitating the treatment of chronic total occlusions (CTOs), often associated with peripheral artery disease. In the Re-ROUTE trial, investigators were successful in navigating around challenging CTOs in the enrolled trial patients 84.8% of the time using the OffRoad device, exceeding the prespecified trial goals.

Principal Investigator for the Re-ROUTE trial, Andrej Schmidt, Parkhospital Leipzig, Center for Vascular Medicine (Leipzig, Germany) commented: "CTOs in the legs can lead to pain due to lack of blood flow. They also are an indicator of increased risk for major cardiovascular events and can lead to limb amputation and an overall diminished quality of life. In my experience, I found the OffRoad System to be a very effective tool for navigating around these challenging blockages, enabling me to treat more patients with peripheral artery disease."

The Re-ROUTE trial is a prospective, single-arm, nonrandomized, multicenter (Europe and Canada), postmarket study. Highlights of the results presented include that investigators achieved an 84.8% (78/92) technical success rate using the OffRoad System to cross CTOs in the femoropopliteal arteries; and at 30 days post procedure, 75% of patients experienced an improvement of at least one category in the Rutherford classification, a six-stage scale commonly used to assess the severity of symptoms associated with peripheral artery disease, and a 3.3% device-related major adverse event rate was seen at 30 days, which is below the prespecified trial goals.

"*The OffRoad Re-Entry Catheter System has received CE mark approval and is pending FDA clearance.*"

The OffRoad Re-Entry Catheter System itself includes a balloon catheter with a microcatheter lancet and is intended to help physicians navigate around complete

arterial occlusions that may otherwise prevent minimally invasive treatment. The system is designed to pass around the occlusion by traveling within the subintimal space. Once the catheter has passed the occlusion, it re-enters the vessel lumen. A unique conical-shaped positioning balloon is used to expand the subintimal space and direct the microcatheter lancet to re-enter the lumen. This allows the physician to position a guidewire across the occlusion and treat the blockage using traditional endovascular techniques, such as angioplasty and stenting.

The OffRoad Re-Entry Catheter System has received CE mark approval and is pending FDA clearance.

– Written by Michael Dowdall

Source: Boston Scientific reports favorable clinical trial results assessing the OffRoad™ Re-Entry Catheter System: www.tctmd.com/show.aspx?id=120203

Research suggests that delay in treating heart attack patients can postpone return to work

Research presented at the Acute Cardiac Care Congress 2013 indicates that working-age ST-elevation myocardial infarction (STEMI) patients are likely return to work later or retire earlier if their initial treatment is delayed. This finding suggests not only an undesirable impact on the individual patient, but also highlights that an economic burden is placed on society if patients cannot return to work following a heart attack.

> *"Approximately 45% of patients admitted with ST-elevation myocardial infarction are of working age, but until now it was not known whether system delay impacts on timing of return to work and retirement."*

Kristina Laut, a PhD student from Aarhus, Denmark, explains why her work was important, "Approximately 45% of patients admitted with STEMI are of working age, but until now it was not known whether system delay impacts on timing of return to work and retirement. We decided to investigate this association because of the heavy burden to society with loss of production."

The study looked at 4061 patients of working age who were admitted to hospital with STEMI, between the years 1999 and 2011, and treated with primary percutaneous coronary intervention. Only patients who were under the age of 67 years and were either full- or part-time employed 3 weeks before hospital admission owing to STEMI were included.

Overall, 91% of the study population had returned to work at the 4-year follow-up point. At the 8-year follow-up point, 29% of the patient population had retired. After adjusting for confounding factors, it was found that a system delay of more than 120 min (between first contact with medical professionals and primary percutaneous coronary intervention) was associated with postponed return to work and earlier retirement from work.

"We found that a large proportion of STEMI patients did return to the labor market within 4 years but 14% came back to work later because of a prolonged system delay. We also discovered that after 8 years, people with a long system delay had a 21% increase in retirement rate," Laut said.

> *"...system delay is an important performance measure in treating patients with ST-elevation myocardial infarction."*

Speaking of what we can learn from the study, Laut says, "Our results show that system delay is an important performance measure in treating patients with STEMI. A lot can be done within healthcare systems to make sure STEMI patients get quick access to primary percutaneous coronary intervention, such as optimizing prehospital diagnosis. Patients also need to react quickly to their symptoms and call an ambulance."

– Written by Laura McGuinness

Source: European Society of Cardiology press release: www.escardio.org/about/press/press-releases/pr-13/Pages/heart-attack-patients-return-work-later-retire-earlier-treatment-delayed.aspx?hit=dontmiss

Risk associated with noncardiac surgery in patients with coronary stents

Noncardiac surgery in the years immediately following stent placement could be related to an increased risk of major adverse cardiac events. A recent study analyzing the risk factors for this patient group recommends that guidelines detailing risk associated with stent type and length of time since stent placement should be re-evaluated.

According to the study published in *JAMA*, current guidelines recommend delaying noncardiac surgery for 1 year after drug-eluting stent placement and

for 6 weeks after bare-metal stents are inserted. However, after analyzing information from 41,989 operations carried out on patients, between 2000 and 2010, who had undergone cardiac stent procedures in the previous 2 years, the authors of the study concluded that the guidelines could be improved.

In the study cohort analyzed, the authors found that major adverse cardiac events were indeed associated with emergency surgery and advanced cardiac disease, but were only associated with stent type and timing of surgery for the first 6 months after stent implantation.

The study, carried out by Mary Hawn and colleagues from the University of Alabama (AL, USA) was recently presented at the American College of Surgeons 2013 Annual Clinical Congress. The study cohort was one in which 22.5% of patients underwent noncardiac operations within the 2 years following a coronary stent procedure. In total, 4.7% of patients experience major adverse cardiac events.

"*The three factors most strongly associated with major adverse cardiac events were nonelective surgical admission, myocardial infarction in the 6 months prior to surgery and a revised cardiac risk index score greater than 2.*"

All-cause mortality, myocardial infarction and cardiac revascularization, within 30 days after the operation, were all classified as major adverse cardiac events. The three factors most strongly associated with major adverse cardiac events were nonelective surgical admission, myocardial infarction in the 6 months prior to surgery and a revised cardiac risk index score greater than 2.

It should be noted that since the study sample was comprised of primarily older male patients these results may not be applicable to women or younger men. Also some patients had received more than one coronary intervention in the study period, so this could have introduced confusion in the dates between the original cardiac procedure and the noncardiac operation.

– Written by Laura McGuinness

Source: Hawn MT. Risk of major adverse cardiac events following noncardiac surgery in patients with coronary stents. JAMA *310(14), 1462–1472 (2013).*

About the News and Views

The News and Views highlights some of the most important events and research in the field of interventional cardiology.
If you have newsworthy information, please contact: Michael Dowdall, Managing Commissioning Editor, *Interventional Cardiology*, Future Medicine Ltd, Unitec House, London, N3 1QB, UK;
m.dowdall@futuremedicine.com