News & Views in ...

Interventional Cardiology

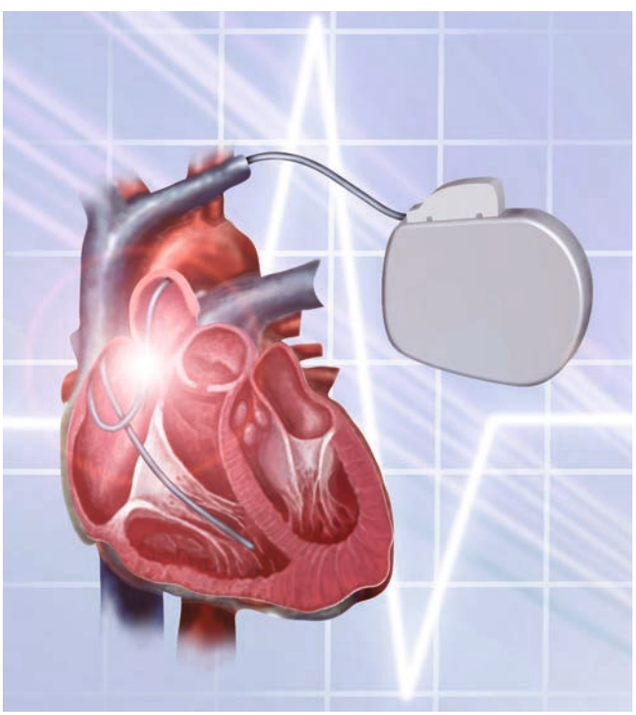
News & Views

Quadra Assura MultiPoint™ cardiac resynchronization therapy defibrillator: the new quadripolar pacing system tailored for success

St Jude Medical, Inc. (MN, USA), the creators of Unify Quadra, the world's first quadipolar pacing system, is now set, once again, to take the interventional cardiology world by storm as it recently received the CE mark for Quadra Assura MultiPoint™ – a next-generation quadripolar device, poised to optimize cardiac resynchronization therapy (CRT).

Congestive heart failure, which is often characterized by asynchronous ventricular beating, is a disease whose burden is felt globally, with an estimated 23 million people currently afflicted. This number showings no signs of declining. CRT can be used in these patients to resynchronize the ventricles to coordinate their contractions. St Jude Medical's first quadripolar pacing system, the Unify Quadra CRT-D, delivered more effective and more efficient CRT therapy by allowing multipacing configurations, giving physicians the flexibility they required to deal with patients who do not respond to traditional CRT. It is easy to see why quadripolar pacing has rapidly a become commonplace in clinics specializing in CRT therapy. Therefore, the approval of St Jude Medical's next-generation quadripolar pacing system may have far reaching clinical implications.

The Quadra Assura CRT-D features MultiPoint™ Pacing (MPP) technology, giving physicians the ability to pace multiple locations on the left side of the heart, facilitating even greater optimization. This new feature has doubled the number of pacing pulses that can be delivered to the left ventricles in each cycle, from the standard single, to two pulses, delivered either simultaneously or sequentially. This new capacity will allow CRT to be tailored for each patient, a critical characteristic for those patients who do not respond to CRT therapy, for example, in those patients with scar tissue on the heart. Indeed, preliminary results have already demonstrated promise. The traditional response to CRT therapy is approximately 70% on average. After just



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3 months of treatment with the Quadra Assura device, the response rose to 89%, an encouraging result that was presented at the Heart Rhythm Society (HRS) Scientific Sessions earlier this year.

Promising results have also been published in over 80 publications, which demonstrate the advantages of the quadripolar technology. There are further investigations are currently underway and hope to demonstrate that MPP causes an enhancement to cardiac function, as well as improvements to the hemodynamics. If the investigations yield positive results, we may see quadripolar technology with MPP become the standard of care in MPP clinics.

Source: St Jude Medical receives CE Mark approval of MultiPoint Pacing CRT-D: http://investors.sjm.com/phoenix.zhtml?c=73836&p=RssLanding&cat=news&id=1832228

New lead extraction devices may improve control in the operating room

Pacemakers and implantable cardioverter defibrillator systems have undoubtedly played a crucial role in the treatment of heart disease. However, occasionally the removal of these devices is required, and this procedure comes hand-in-hand with the potential risk of death or serious complications. Cook Medical (IN, USA), in an attempt to ameliorate these hazards, has recently developed four 'Advanced Platform' lead extraction technologies, which they hope will allow "greater precision, stability and control when removing cardiac leads."

The four devices were recently showcased at the EHRA-Europace 2013 (Athens, Greece), each device boasting several features designed to improve the lead extraction process. The display included Cook Medical's enhanced Evolution® sheath sets, the Evolution RL® and the Evolution Shortie®. These new devices include features such as a rotational sheath and a responsive, contoured handle, which aim to give physicians even more control. The SteadySheath device for tissue stabilization was also exhibited in addition to the One-Tie™ Compression Coil, an accessory designed to bind the lead, cables and coil to Cook's Liberator® Locking Stylet.

The pressing need for cardiac device lead extraction is reflected in the fact that some of the UK's top cardiac centers, including Manchester Heart Centre at the Manchester Royal Infirmary, are already trialing these 'Advanced Platform' lead extraction devices. With the development of devices that permit greater control in the operating room, the safety of lead extraction in the future may be improved, helping to combat the rising rates of infection and lead failure.

Source: Cook Medical introduces new advanced platform technologies for cardiac lead extraction at EHRA-EUROPACE 2013: www.cambridgeresearchcentre.co.uk/news-links-events/breaking-news-archive/breaking-news-cook-medical-june-2013

Double trouble: double bifurcation stents may double the risk of myocardial infarction compared with single stents

A recent meta-analysis carried out by a research team, headed by Marco Zimarino of the Institute of Cardiology and Center of Excellence on Aging (Chieti, Italy), has revealed a greater incidence of myocardial infarction (MI) when double drug-eluting stents (DES) are used to treat bifurcation lesions compared with provisional stenting with DES.

The investigators performed a meta-analysis of 12 major studies, comprising five randomized controlled trials and seven observational studies, which compared single-DES (n = 5093) with double-DES strategies (n = 1868) to treat bifurcation lesions in patients between January 2001 and December 2011.

More than a twofold risk of definite stent thrombosis with double versus single stenting was observed (risk ratio: 2.30; 95% CI: 1.33–4.03). MI risk was also higher after double stenting, whereas mortality and target vessel revascularization demonstrated similar occurrence rates between the two strategies.

However, discussions among the scientific community seeking to explain the association between the higher MI risk and double DES have descended into controversy. Some key opinion leaders argue that stent thrombosis could be the underlying reason for the higher MI risk. If this is indeed true, then researchers are advocating the move toward

more aggressive antiplatelet therapy, perhaps using prasugrel or ticagrelor. However, the 2% stent thrombosis rate observed in this study cannot fully account for the 8% MI rate. On the other hand, some researchers claim that the periprocedural risk may be the main reason for the increased risk of MI. This could be largely due to the much greater technical complexity of double DES, a procedure that demands more manipulations that single stenting.

An important point, which must be stressed, is that regardless of the higher risks, there are some patients for whom double stenting is an unavoidable requirement. The outcome for these patients would be considerably worse if an attempt using a single stent was initially made, only later to then perform a bailout. Therefore, in order to ensure the best outcome for all patients, the decision as to whether to use a single or a double stent is critical.

Source: Zimarino M, Corazzini A, Ricci F et al. *Late thrombosis after double versus single drug-eluting stent in the treatment of coronary bifurcations: a meta-analysis of randomized and observational studies.* JACC Cardiovasc. Interv. *6(7), 687–695 (2013).*

Higher cardiac mortality with drug-eluting versus bare-metal stents in ST-segment elevation myocardial infarction patients

Results from the recent DEDICATION trial, performed by a research team from the University of Copenhagen (Denmark), have demonstrated a higher cardiac mortality after drug-eluting stent (DES) compared with bare-metal stent implantation in patients with ST-segment elevation myocardial infarction (STEMI).

The researchers set out to investigate the long-term effects of DES versus bare-metal stent implantation in patients with STEMI undergoing percutaneous coronary intervention. A total of 626 STEMI patients with a high-grade stenosis/occlusion of a native coronary artery presenting with symptoms <12 h and ST-segment elevation were randomized to various DES (46% sirolimus, 41% paclitaxel and 13% zotarolimus; n = 313) or bare-metal stent (n = 313) treatments. After a 5-year follow-up, clinical end points were taken. The primary endpoint, the rate of major adverse cardiac events (including cardiac death, recurrent MI, and target lesion revascularization), was lower in the DES group, but not significantly. This result was mainly due to the lower need for repeat vascularization, aligning with previous findings. However, cardiac mortality was significantly higher (7.7 vs 3.2%; p = 0.02). Stent thrombosis was also found to be the main cause of late-occurring cardiac deaths, being involved in a total of 78% of cases.

Thus, clinicians may be forced to re-evaluate the use of DES in STEMI patients due to this increased risk. However, further replicative studies are required before any change to the current dogma will arise.

Source: Holmvang L, Kelbæk H, Kaltoft A et al. *Long-term outcome after drug-eluting versus bare-metal stent implantation in patients with ST-segment elevation myocardial infarction: 5 years follow-up from the randomized DEDICATION trial (Drug Elution and Distal Protection in Acute Myocardial Infarction).* J. Am. Coll. Cardiol. Interv. *6, 548–553 (2013).*

– All stories written by Katie Lockwood

About the News and Views

The News and Views highlights some of the most important events and research in the field of interventional cardiology.
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