

Interventional Cardiology



NEWS



RESEARCH HIGHLIGHTS



CONFERENCE SCENE



Nearly half of patients do not benefit from their pacemakers

Pacemakers are recommended for patients with an electrocardiogram QRS prolongation over 0.12 s, yet 40% of these patients do not benefit from these devices.

Recent research suggests that three lead cardiac pacemakers, implanted in those with heart failure, fail to help up to 40% of patients. The research was carried out by Ilke Sipahi and James Fang from University Hospitals Case Medical Center (OH, USA) and Case Western Reserve University School of Medicine (OH, USA).

Cardiac resynchronization therapy (CRT) aims to try to correct the impaired synchrony during the contraction of the heart, by pacing both ventricles. This study by Sipahi and Fang, which analyzed almost 6000 patients from a combination of clinical trials, assessed whether the current criteria used in selecting patients for the treatment were appropriate.

Various professional societies support treatment guidelines that advocate the use of these pacemakers in patients with heart failure symptoms. QRS prolongation, observed on the electrocardiogram and caused by the weakened heart muscles, is a hallmark of heart failure. It is recommended that patients with QRS prolongation greater than 0.12 s should receive these devices.

However, the recent meta-analysis by Sipahi and Fang suggests that patients with these devices do not have a reduced

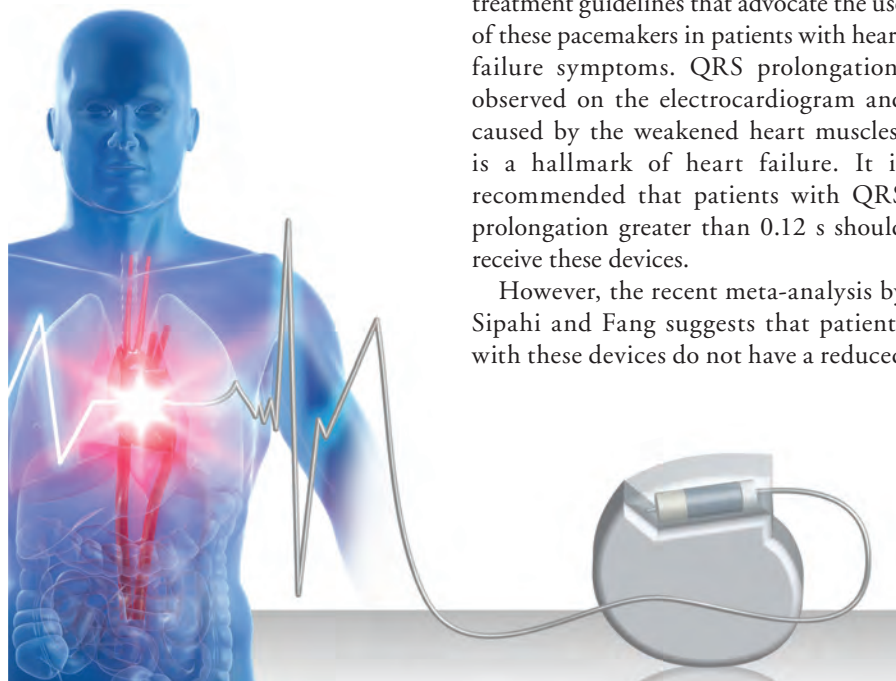
number of hospital admissions, nor do they have a survival benefit, unless they have a QRS prolongation greater than 0.15 s. A total of 40% of patients that received devices had a QRS prolongation of 0.12–0.15 s and did not gain any additional benefits. Sipahi believes that “This study can have profound impact on minimizing unnecessary procedures” and that “revising the criteria for implantation of these devices will help avoid thousands of unnecessary implants and will also lead to cutting down on unwarranted costs.”

On the other hand, the research suggested that patients with a QRS prolongation of greater than 0.15 s were significantly benefited by the devices, living longer, and had less hospitalizations. Fang believes that “Our analysis suggests that this important therapy appears to benefit primarily those patients with the greatest prolongation in the QRS duration,” and that “this study may help to better select patients who are most likely to benefit from this effective but costly procedure.”

Commenting to *Interventional Cardiology* on the implications of this research for the future, Sipahi said “The QRS criterion for CRT implantation is too broad in the treatment guidelines. Our meta-analysis is robust enough to justify a change in the guidelines, given the remarkably concordant findings in all of the clinical trials included.”

Source: University Hospitals press release: www.uhhospitals.org/?tabid=1359&newsid3423=1027

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ULMCA PCI may be a viable option for low-risk patients with normal left ventricular function

Heart bypass surgery is the standard treatment for unprotected left main coronary artery (ULMCA) disease, based on evidence that conveys a survival advantage with this technique. However, in patients with a high risk of adverse surgical outcomes, for example, cerebrovascular disease, severe aortic calcification or limited life expectancy, percutaneous coronary intervention (PCI) may be an option.

Researchers led by Lee *et al.* from the University of California, Los Angeles Medical Center (CA, USA) investigated the safety and efficacy of ULMCA PCI with drug-eluting stents (DES) in patients with normal left ventricular function. A multicenter international registry of data was analyzed, and identified a total of 221 patients who had undergone elective PCI for ULMCA disease between 2002 and 2009. The patients had a mean age of 68 years, 75% were male, 39% had had previous heart attacks, 25% had diabetes and 40% had a prior PCI.

“Our analysis confirms that elective PCI with DES in patients with normal left ventricular function is a safe and effective treatment for ULMCA disease,”

said Lee. During the first 30 days postangioplasty, no cardiac death, target lesion revascularization, stent thrombosis, or stroke occurred. However, while no cases of Q-wave myocardial infarction were reported, seven patients suffered periprocedural myocardial infarction. Lee *et al.* determined that event-free survival estimates at 5 years were 96% for cardiac death and 89% for target lesion revascularization. Researchers also found that patients 75 years of age or older, with a history of myocardial infarction, were independent predictors of cardiac death. Lee commented that “Research comparing the safety and efficacy of ULMCA PCI with DES versus coronary artery bypass grafting are needed and results from a large multicenter trial are forthcoming” and concluded that “ULMCA PCI may be a viable option for low-risk patients with normal left ventricular function.”

Source: Lee MS, Yang T, Biondi-Zoccai G *et al.* Long-term outcomes of elective drug-eluting stenting of the unprotected left main coronary artery in patients with normal left ventricular function. *Catheter Cardiovasc. Interv.* 77(7), 945–951 (2011).

Lower risk of myocardial infarction reported in carotid artery stenting compared with carotid endarterectomy

Recent research by Joseph Blackshear (FL, USA) and colleagues, which analyzed the recent Carotid Revascularization Endarterectomy Versus Stenting Trial (CREST), has suggested that there may be an increased risk of myocardial infarction (MI) after carotid endarterectomy compared with carotid artery stenting. Protocol-defined MI and biomarker positivity were both associated with increased long-term mortality, which

suggests that patients with an increased risk of death can be identified by the occurrences of periprocedural MI and so-called ‘enzymatic leaks’ on follow-up.

A total of 2502 patients were included in the study. A statistically significant difference was observed in MI occurrence between the two groups: 14 MIs occurred in the carotid-stenting group, compared with 28 MIs in the carotid endarterectomy group. A further 12 patients treated with

carotid endarterectomy and eight patients treated with stenting were found to have elevated cardiac biomarkers, including troponin, yet the difference between the two groups was not found to be statistically different. Both MI and biomarker positivity, which was approximately 14-times the upper limit of normal, were associated with a more than threefold greater risk of mortality 4 years post-treatment.



The authors commented that “Although the degree of biomarker increase was relatively small compared with spontaneous MI events, the presence of either MI or biomarker (positivity) only was associated with significantly higher risk for subsequent mortality, even after adjustment for baseline risk factors.”

Joseph Broderick from the University of Cincinnati (OH, USA) commented that “although stenting places less stress on the heart and that an increased risk of MI is associated with surgery, there may be a degree of bias in the analysis”. For example, patients being treated with endarterectomy tend to be in hospital for longer periods of time than stenting patients, meaning that more MIs may be detected in this group.

Blackshear and colleagues reported that patients with biomarker positivity and MI were generally older and had a greater frequency of cardiovascular disease and

lower creatinine clearance in comparison to patients with no biomarker positivity or MI.

The authors believe that it is currently too early to speculate whether this data should be used to guide clinical practice. However, they suggested that to reduce the risk of MI in these high-risk patients, they could be treated with high-dose statins or more intensive antiplatelet therapy. They concluded that “Certainly, for asymptomatic patients identified to be at higher risk for MI or stroke after carotid endarterectomy or carotid artery stenting, optimal medical therapy may actually be the preferred option and should be evaluated in a prospective controlled trial.”

Source: Blackshear JL, Cutlip DE, Roubin GS et al. Myocardial infarction after carotid stenting and endarterectomy: results from the Carotid Revascularization Endarterectomy Versus Stenting trial. *Circulation* 123(22), 2571–2578 (2011).

Correct assessment of transcatheter aortic-valve implantation by echocardiogram depends on sample location

Researchers at Columbia University (NY, USA) have suggested that among patients with aortic stenosis who undergo transcatheter aortic-valve implantation (TAVI), in-stent flow acceleration influences echo-Doppler measurements used to assess the valve’s function. The research was presented at the American Society of Echocardiography (ASE) 2011 Scientific Sessions.

Postoperative data from 40 patients, with a mean age of 85.4 years who underwent TAVI and received a Sapien™ valve (Edward Lifesciences) was analyzed by Shames and colleagues. The Sapien valve consists of bovine cusps mounted inside a cylindrical stent. Of the 40 participants, 20 patients (four men) received the 23 mm Sapien valve and 20 patients (16 women) received the 26 mm Sapien valve.

Shames and colleagues then carried out echo-Doppler studies at discharge, 30 days, 3 months, 6 months, 1 year and

then yearly. Pulsed Doppler was recorded using the apical 5- or 3-chamber views, with sample volumes directly proximal to the stent, within the stent but proximal to the cusps and distal to the cusps. They determined that when subvalvular flow was measured within the stent, as opposed to before the stent, the aortic-valve area (mean effective orifice area) was overestimated: $2.54 \pm 0.46 \text{ cm}^2$ compared to $1.79 \pm 0.34 \text{ cm}^2$. They also found that false measurement variability could occur due to inconsistent sampling locations, which Shames explained means that “We have to make sure that we sample before the stent, because the stent itself contributes to acceleration, which affects the assessment of valve performance”.

“Percutaneous aortic valves have emerged as a potential alternative to medical management or surgery in high-risk patients with critical aortic

stenosis, although their long-term performance is still not known. Accurate echocardiographic assessment will be essential in the longitudinal follow-up of these valves, mandating an understanding of their flow characteristics, particularly features that differ from those of conventional surgical valves. The findings of our study draw attention to one such feature, flow acceleration with the valve stent and its potential for influencing the accuracy and reproducibility of echocardiographic assessment of valve function. Recognition of this phenomenon is essential in echocardiographic follow-up of balloon-expandable transcatheter valves,” explained Shames.

Source: ASE 2011 Presentation Abstract: www.abstractsonline.com/Plan/ViewAbstract.aspx?sKey=13de0705-894d-4d15-83f4-52dcde4b52b&cKey=70067903-f0e3-4ad6-9771-9b66f2a20efb&mKey=%7bAE58A7EE-7140-41D6-9C7E-D375E33DDABD%7d



Incomplete revascularization may be as effective as complete revascularization for some patients

Recent research suggests that 5-year mortality rates are not statistically different in patients undergoing incomplete revascularization and complete revascularization for the treatment of multivessel coronary disease.

Researchers at the Asan Medical Center (Seoul, South Korea), led by Young-Hak Kim, studied 1400 patients undergoing drug-eluting stent implantation and 514 patients undergoing treatment with bypass surgery for multivessel coronary disease.

Angiographic complete revascularization was performed in 917 patients (573 percutaneous coronary intervention [PCI] and 344 coronary artery bypass graft [CABG] patients). Angiographic complete revascularization was defined according to the synergy between PCI with taxus and cardiac surgery (SYNTAX) classification, as revascularization in all diseased segments. The decision to carry out complete or incomplete revascularization was made by the surgeon, based on comorbidities, objective ischemia evidenced by stress test, jeopardized myocardium of diseased segment, presence of viable myocardium, left ventricular ejection fraction and anatomical complexity. Generally younger patients with more extensive coronary disease were selected for complete revascularization than those for incomplete revascularization. The researchers determined that mortality was the same in both the completely revascularized and incompletely revascularized groups during a 5-year follow up.

However, Kim *et al.* commented that they “Observed a borderline significant association between multivessel incomplete revascularization and clinical prognosis,” implying that there are limits to what incomplete revascularization can achieve. A total of 368 patients were left with two or more vessels incompletely revascularized, these patients had a small increase in risk of death, MI, stroke or repeat revascularization compared with the other patients in the study, but this

difference was not statistically significant. However, there was a significantly greater chance of adverse events in patients where multiple vessels were not revascularized.

The researchers stated that “Despite the poor association between complete revascularization and patient prognosis, a large degree of myocardial ischemia had to be revascularized with either PCI or CABG.” Similarly it was also shown that patients measured with ischemia reduction after treatment, with pre- and post-treatment thallium scans, had a decreased risk of MI and death in the Outcomes Utilizing Revascularization and Aggressive Drug Evaluation (COURAGE) trial. “Thus, the association between complete revascularization and clinical outcomes in previous studies may be indirectly related to the extensive reduction of ischemia and not directly related to anatomic revascularization.”

The study’s senior author Seung-Jung Park, also from the Asan Medical Center, commented that “Although the mechanism is not clear, the lack of association between complete revascularization and clinical prognosis may be closely related to the limitation of angiography to determine objective ischemia, therefore, the strategy of angiographic complete revascularization might induce unnecessary procedures and subsequently fail to improve clinical outcome. Further studies comparing ischemia-guided complete revascularization and incomplete revascularization need to be performed based on the functional evaluations.”

Source: Kim YH, Park DW, Lee JY et al. Impact of angiographic complete revascularization after drug-eluting stent implantation or coronary artery bypass graft surgery for multivessel coronary artery disease. *Circulation* 123(21), 2373–2381 (2011).