Niraj Varma, MD, PhD, Cleveland Clinic, Cleveland, Ohio, USA, presented data from a retrospective study of sex-specific survival after a CIED implant. The purpose of the study was to use "big data" to characterize CIED utilization and postimplant mortality in women compared with men.

In this observational study, data from a cohort of 269 471 patients who received a CIED between 2008 and 2011 were evaluated for the primary outcome of all-cause mortality. CIEDs included pacemakers, ICDs, CRT pacemakers (CRT-P), and CRT defibrillators (CRT-D) from a single manufacturer. All devices were enabled with wireless remote monitoring, and all patients were followed for a minimum of 90 days. Patient demographics were accessed through the St Jude Medical device tracking database, and descriptive statistics were linked by patient ZIP code from the 2012 American Community Survey, which is administered by the US Census Bureau. Date of death was determined by the US Social Security Death Index Master File. The primary end point of all-cause survival was determined for each device type using unadjusted mortality incidence rates and adjusted Cox proportional hazards modeling stratified by age.

The mean age of the cohort was older than 70 years and two-thirds were men. Patients who received ICD implants were on average younger than patients implanted with other CIED devices. Across all device types, follow-up duration and remote monitoring utilization were comparable between sexes. The analysis revealed that a greater proportion of men received CIED implants across all device types. In particular, ICDs and CRT-Ds were implanted significantly less in women than in men. Survival was similar among men and women implanted with a pacemaker or ICD. Importantly, women who received CRT (CRT-D or CRT-P) experienced dramatically improved survival over men in the first 4 to 5 years post-CIED implant.

Dr Varma acknowledged that the limitations of this study included the limited clinical data available for a retrospective, observational analysis and the lack of a nondevice comparison group. However, he also noted that the strengths of the analysis were that it assessed a "real world" cohort of more than 200 000 patients and that it adds a large-scale evaluation of pacemaker and CRT-P patients.

Dr Varma concluded that this analysis suggests that women who receive a CRT-P or CRT-D have enhanced survival rates compared with men. In addition, women implanted with ICDs experienced similar survival rates as men. Therefore, strategies should be developed that ensure appropriate and full utilization of these devices in eligible women.

Micra Transcatheter Pacing System Safe, Effective

Written by Emma Hitt Nichols, PhD

The Micra Transcatheter Pacing System (TPS)—which is about 10-fold smaller than the conventional pacemaker and is implanted from the femoral vein and fixed in the right ventricle—was safe and effective in a range of patients who required ventricular pacing. Philippe Ritter, MD, Hospital Haut-Lévèque, Pessac, France, presented data from the Micra Transcatheter Pacing Study [Ritter P et al. *Eur Heart J*. 2015].

Currently, the only treatment for symptomatic bradycardia is permanent cardiac pacing. However, transvenous pacing systems may result in serious adverse events (AEs) in up to 12.4% of patients [Udo EO et al. *Heart Rhythm*. 2012]. The purpose of this study was to determine if the Micra TPS was effective and resulted in fewer serious AEs.

In this international phase 3 trial, patients with a class I or II indication for ventricular pacing [Epstein AE et al. *Heart Rhythm*. 2008] received the Micra TPS system. The Micra TPS system is about 10 times smaller than the conventional pacemaker and consists of an intracardiac accelerometer with flexible tines. At baseline, the median age was 78 years; 61% were men; and the median body mass index was 26 kg/m^2. In addition, 65% were diagnosed with bradycardia with permanent or persistent atrial tachyarrhythmia or atrial fibrillation; 16% had sinus node dysfunction; 14% had atrioventricular block; and 6% had another indication.

The primary safety end point was freedom from major Micra TPS–associated complications or procedures in the 6 months following implantation. The primary efficacy end point was a low and stable pacemaker threshold at 6 months. This analysis of 6-month outcomes included data from 140 patients, and analyses using longer term outcomes are planned.

The mean implantation time was 37 minutes, and the success rate was 100%. The Micra TPS implant was placed within the apex in 77% of patients, in the septum in 16%, in the midseptum in 6%, and in the right ventricular outflow tract in 1%. The median deployment per patient was 1, with successful first deployment in 59%, success achieved within 2 deployments in 81%, and success achieved within 4 deployments in 96%.

The serious AE rate was 5.7%, and 1.4% of patients required prolonged hospitalization; however, there were no device telemetry issues, dislodgements, infections, reoperations, or device-related deaths. Serious AEs included transient atrioventricular block, right bundle branch block, ventricular tachycardia, and ventricular fibrillation (Table 1).

Table 1. Serious Adverse Events in Patients With the Micra Transcatheter Pacing System

	Adverse Events		
	Resulting in Death, Reoperation, or Hospitalization	No.	Patients, No. (%)
Dysrhythmias			
Transient AV block	No	2	2 (1.4)
RBBB	No	1	1 (0.7)
VT	No	1	1 (0.7)
VF	No	1	1 (0.7)
Cardiac			
Pericardial effusion, no tamponade	1 hospitalization > 48 h[a]	1	1 (0.7)
Acute MI	1 hospitalization > 48 h[a]	1	1 (0.7)
Pericarditis	No	1	1 (0.7)
Groin			
Arterial pseudoaneurysm	1 hospitalization > 48 h[b]	1	1 (0.7)
Total	3 events (2 patients, 1.4%)	9	8 (5.7)

AV, atrioventricular; MI, myocardial infarction; RBBB, right bundle branch block; VF, ventricular fibrillation; VT, ventricular tachycardia.

[a]Occurred in same patient with 18 deployments who had 3-vessel disease.

[b]Resolved after thrombin injection.

Source: Ritter P et al. *Eur Heart J*. 2015.

The R-wave sensing amplitude was a mean of 11 mV at time of implant and 16 mV at 3 months. The pacing capture threshold remained steady—0.64 V at the time of implant and 0.51 V at 3 months. Pacing impedance was 731 Ω at the time of implant and 651 Ω at 3 months.

In conclusion, Prof Ritter stated that according to the early performance measurements, the Micra TPS system was safe and effective in a large range of patients. However, long-term safety and efficacy will be studied in an ongoing trial.

CARDIO-FIT: Cardiorespiratory Fitness Reduces AF Burden in Patients With Obesity

Written by Emma Hitt Nichols, PhD

Improvement in cardiorespiratory fitness (CRF) or weight loss or both resulted in a decrease in atrial fibrillation (AF) burden in obese patients with AF. Rajeev Kumar Pathak, MBBS, Royal Adelaide Hospital, Adelaide, Australia, presented data from the CARDIO-FIT study [Pathak RK et al. *J Am Coll Cardiol*. 2015].

Weight gain is associated with an increased risk of the development and progression of AF, whereas weight reduction reduces the risk [Pathak RK et al. *J Am Coll Cardiol*. 2015; Tedrow UB et al. *J Am Coll Cardiol*. 2010]. In addition, CRF decreases the risk of cardiac death, regardless of a change in body mass index (BMI) [Lee DC et al. *Circulation*. 2011]. The purpose of the CARDIO-FIT trial was to determine if preserved CRF improved outcomes in obese patients with AF.

In the trial, 308 patients with BMI ≥27 kg/m^2 and AF were enrolled in a structured exercise program and stratified by CRF: low (<85% predicted), adequate (86% to 100% predicted), and high (>100% predicted). The exercise program was age and ability matched by metabolic equivalent (MET) and included 3 to 5 days of low- to moderate-intensity aerobic and strength training. Patients exercised for a total of 60 to 200 minutes each week. At baseline, the mean age was 61 years; about half were men; 46% had nonparoxysmal AF; and the mean BMI was 33.2 kg/m^2.

The primary end points were AF symptom burden as measured by the Atrial Fibrillation Severity Scale questionnaire and freedom from AF as measured by 7-day Holter monitoring. The secondary end points included left atrioventricular and left ventricle thickness, as well as metabolic and inflammatory markers.

CRF was associated with freedom from AF without the use of medication or ablation in a dose-response fashion. When stratified by CRF gain, freedom from AF was achieved in 61% of patients who gained ≥2 METs, compared with 18% of patients who gained <2 METs (P<.001). In addition, arrhythmia-free survival was achieved in 84% of patients with high CRF, compared with 76% and 17% of patients with adequate and low CRF, respectively (P<.001). When stratified by CRF gain, arrhythmia-free survival was achieved in 85% of patients who gained ≥2 METs, compared with 44% of patients who gained <2 METs (P<.001). Weight loss also improved freedom from AF and arrhythmia-free survival regardless of the number of METs gained; however, patients who gained ≥2 METs and lost ≥10% of their body weight experienced the greatest benefit.

In addition, compared with baseline stress testing, patients who gained CRF demonstrated substantial weight loss, lower systolic blood pressure, reduced use of antihypertensive medications, better diabetes mellitus control with a HbA_{1c} ≤7, lower fasting insulin, lower low-density lipoprotein and triglyceride levels, reduced use of lipid-lowering therapy, and lower mean high-sensitivity C-reactive protein. Furthermore, patients who gained ≥2 METs experienced a significant improvement in left atrial volume (P<.001) and left ventricular diastolic function (P<.001) when compared with baseline.