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 $HbA_{1c} \leq 7$, 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.

Dr Pathak highlighted that a 1-MET gain in CRF translated into a 12% reduction in AF recurrence risk. In addition, there was a synergistic effect with CRF gain and weight loss.

## Miniature Leadless TPS Shows Favorable Electrical Performance

Written by Maria Vinall

Results of the Micra Transcatheter Pacing Study [Ritter P et al. *Eur Heart J*. 2015], which examined the pacing threshold curve at 3 months following delivery and the projected longevity of a new leadless pacing system delivered using a transcatheter delivery system (TPS), found pacing thresholds were low at the time of implantation and stable at 3 months. Use of a 0.24 vs 0.4 milliseconds pulse width increased the projected battery longevity by 0.83 years noted Clemens Steinwender, MD, Linz University Hospital, Linz, Austria.

The Micra TPS system is a new miniature leadless pacemaker that is interventionally delivered via the femoral vein using a transcatheter delivery system. Because of its small size, the pacing threshold and battery life are of particular interest. Chronaxie is the minimum time (pulse width) required for excitation of a structure (eg, a muscle or nerve) by a voltage of 2 times the rheobase voltage. The rheobase voltage is the threshold at an infinite pulse width. Chronaxie is considered the pulse width that minimizes the use of pacing energy. The Micra TPS device has a nominal pacing pulse width of 0.24 milliseconds, which is close to the chronaxie.

In the Micra Clinical Study, the threshold, impedance, pacing percentage, and heart rate were analyzed in the first 60 patients to reach the 3-month follow-up visit. Pacing threshold measurements were conducted at 0.24, 0.4, and 1.0 milliseconds with a voltage resolution of 0.125 V at implant and 3 months. The Lapicque equation [$V = \text{rheobase} \times (1 + \text{chronaxie} / \text{pulse width})$] was used to determine chronaxie, rheobase, and the strength duration curve given the 2 measurements at 0.24 and 1.0 milliseconds.

Individual patient battery longevity was projected using programmed pacing amplitude, pulse width, impedance, pacing percentage, and heart rate at the 3-month visit assuming a 5-month shelf life prior to implant.

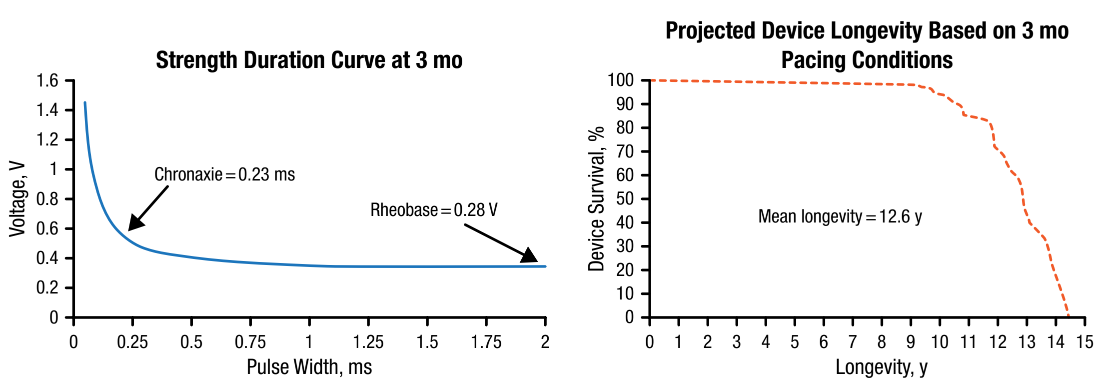
The most common indication for pacing was atrial fibrillation with pauses. At 3 months, the mean impedance was 651 Ω, mean pacing percentage was 49%, mean heart rate was 72 bpm, and 59 of 60 patients were programmed to a pulse width of 0.24 milliseconds. Impedance decreased and R-waves increased over time.

Mean thresholds at implant were 0.57 at 0.24 milliseconds, 0.46 at 0.4 milliseconds, and 0.37 at 1.0 milliseconds. Mean thresholds at 3 months were 0.51 at 0.24 milliseconds, 0.43 at 0.4 milliseconds, and 0.34 at 1.0 milliseconds. There were 4 and 2 patients with thresholds at 0.24 milliseconds > 1.0 V at implant and 3 months, respectively.

The strength duration curve and projected longevity calculated from 55 patients at 3 months are shown in Figure 1. The mean rheobase was 0.28 V and the chronaxie was 0.23 milliseconds. Battery life was projected at greater than 10 years.

The findings of this study were limited by the number of patients and relatively short follow-up. In addition, longevity projections assume that pacing threshold, impedance, pacing rate, and pacing percentage do not change after 3 months. However, the estimated longevity of the device is comparable with current ventricular demand pacemakers. The miniature size of this device does not appear to detract from its electrical performance.

Figure 1. Strength Duration Curve and Projected Device Longevity

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