# Miniaturized Leadless Pacing System Is a Promising Solution to Permanent Pacing

Written by Wayne Kuznar

A self-contained, miniaturized, leadless transcatheter pacing system demonstrated excellent electrical performance and a rate of serious adverse events (AEs) in line with traditional transvenous pacing systems. Data from the Micra Transcatheter Pacing study [NCT02004873]—a first-in-human safety and efficacy study—were reported by Philippe Ritter, MD, Hôpital Haut-Lévêque, Pessac, France.

At 0.8 cc, the Micra pacing system is <10% the size and mass of conventional transvenous pacing systems. The device is fixated directly in the right ventricle via the femoral vein through 4 protractible nitinol tines, and it delivers electrical impulses through an electrode.

Dr Ritter described the experience from the first 140 patients (mean age, 78 years) to undergo implantation during a single-arm 23-center global trial. All patients had class I or II indications for ventricular inhibited pacing, with the primary indication being bradycardia with permanent or persistent atrial tachyarrhythmia (65%). They were followed for an average of 1.9 months, with early performance analysis conducted in the first 60 patients who were followed to 3 months. Ninety-seven percent of patients had ≥1 comorbidity.

Outcomes of interest were serious AEs related to the device (as adjudicated by an independent clinical events committee) and the electrical parameters and function of the device.

Implant success was 100%. Mean implant time was 37 minutes, and the median number of deployments per procedure was 1. Site implant was the apex in 77%, septum in 16%, midseptum in 6%, and right ventricular outflow tract in 1%. At baseline, 44% of patients were on anticoagulation, and 29% were on antiplatelet agents. During the procedure, 40% of patients received a heparin intravenous bolus. One patient died from a noncardiovascular-related cause 139 days after implant. There were no procedure-related deaths.

The rate of serious AEs was 5.7%, a rate comparable to the 7.3% rate observed in a Medtronic reference data set, said Dr Ritter. There were no unforeseen events, device telemetry issues, dislodgements, infections, reoperations, or related deaths. Eight patients had a total of 9 serious AEs related to the device or procedure, resulting in 2 prolonged hospitalizations (>48 hours; Table 1). One patient had a pericardial effusion without tamponade after persistent device repositioning, which was resolved with drainage. Another patient was hospitalized after an arterial pseudoaneurysm.

Table 1. Serious Adverse Events With Micra Miniaturized Leadless Pacing System

| Adverse Events | Death/Reoperation/Hospitalization? | n | Patients, n (%) |
|---|---|---|---|
| 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 prolonged >48 h for both events in same patient[a] | 1 | 1 (0.7) |
| Acute MI | | 1 | 1 (0.7) |
| Pericarditis | No | 1 | 1 (0.7) |
| Other: arterial pseudoaneurysm | 1 hospitalization prolonged >48 h[b] | 1 | 1 (0.7) |
| Total | 3 (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 patient with 18 deployments who had 3-vessel disease.

[b]Resolved after thrombin injection.

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Electrical measurements, including R-wave sensing amplitude and pacing, were as expected. Specifically, the median pacing percentage was 49%; the median pacing capture threshold at 0.24 milliseconds was 0.38 V; and the median pacing impedance was 640 Ω. Based on the mean pacing percentage, the projected battery longevity is estimated at an average of 12.6 years.

A miniaturized leadless pacing system is a promising solution to permanent cardiac pacing that may reduce the risks associated with traditional technology and improve patient satisfaction, said Dr Ritter. Long-term safety and benefit are being evaluated in an ongoing clinical trial.

## CREDO: Electrical and Structural Failure Rates of Endocardial Leads

Written by Alla Zarifyan

Ratika Parkash, MD, Queen Elizabeth II Health Sciences Centre, Halifax, Nova Scotia, Canada, presented results of the Canadian Registry of Cardiac Implantable Electronic Device Outcomes (CREDO) study, demonstrating that over a mean follow-up of 7.5 years, the rate of electrical failure was similar for 7 French (Fr) and 8 Fr Riata leads, with an average failure rate of 5.9%.

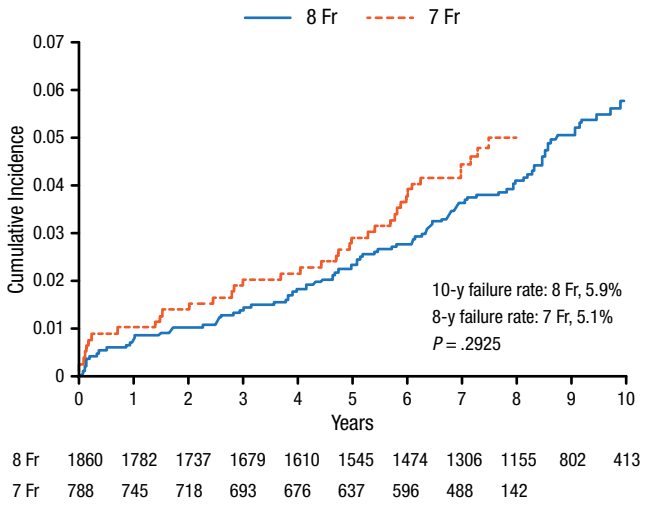
Cable externalization and insulation abrasion are known to occur with Riata silicone endocardial defibrillation leads. The electrical and structural failure rates have been described, but the current rates are not known. Also, the relationship of cable externalization to electrical failure is not well described.

CREDO was a prospective, observational cohort study that involved 15 Canadian centers. The overall objective was to perform an observational study of Riata leads under advisory in Canada. The specific objectives were to determine the electrical and structural failure rates of the leads over time and to determine the predictors of such failure.

The patient population included patients with a St Jude Medical Riata model implanted under advisory in Canada. Patients were followed as per Canadian guidelines for device follow-up. Radiographic screening was not mandated and was left up to the discretion of each center. The end points were death attributable to lead malfunction, incidence of cable externalization, and incidence of electric lead failure.

A total of 2707 patients were observed (mean age 63.2 years; 19.3% women) with a mean follow-up time of 7.47 years. Across all centers, 8 Fr leads were used in 70.2% of cases and 7 Fr leads were used in 29.8% of cases.

Figure 1. Cumulative Incidence of Electrical Failure




Fr, French.

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On average, 8 Fr leads had a longer follow-up and the 10-year failure rate of 8 Fr leads was 5.9%, while an 8-year failure rate of 7 Fr leads was 5.1% (Figure 1). The difference was not statistically significant, and the average failure rate was 5.9% over a mean follow-up of 7.5 years.

Cable externalization occurred at a rate of 7.4% in 8 Fr leads vs 4.9% in 7 Fr leads, mainly occurring after 4 years of follow-up. Among patients who underwent radiographic screening (n = 1187), cable externalization occurred in 6.7% of all patients. A total of 10.1% of patients experienced cable externalization with electrical failure (9.4% with 8 Fr leads vs 13.3% with 7 Fr leads).

Multivariate predictors of lead failure were younger age (HR, 0.84; 95% CI, 0.75 to 0.95; $P < .01$; per 10 years) and higher left ventricular ejection fraction grouped into 10% deciles (HR, 1.26; 95% CI, 1.10 to 1.45; $P < .01$).

The risk of major complications in lead revisions was 6.32%. Complications included infection, pneumothorax, death, lead dislodgement, reoperation, and hematoma.

Dr Parkash concluded that over a mean follow-up of 7.5 years, the rate of electrical failure was similar for 7 Fr and 8 Fr Riata leads. There was a trend toward a higher failure rate with cable externalization with 8 Fr leads. The risk of major complications in lead revisions at 6.3% was similar to the rate of electrical failure (5.9%). Finally, Dr Parkash stressed that isolated lead revision or extraction due to advisory is not warranted.