Leadless pacing: current state and future directions

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University Hospital Pisa - Italy
The starting point: conventional PM

- **Technology:**
  - Highly mature and reliable
  - Generator, connectors and leads

- **Procedure:**
  - Surgical pocket
  - Transvenous leads
  - Implant technique
The starting point: device and leads issues

• Device issue:
  • Infection
  • Haematomas
  • Discomfort, cosmetic concerns

• Leads:
  • Infection (endocarditis)
  • Tricuspid regurgitation
  • Dislodgement
  • Mechanical failure
  • Mobility limitations
  • Need for venous access
1970: the first leadless idea
2010’s: the idea becomes reality

WiSE (EBR)  
Nanostim (St Jude Medical)  
Micra (Medtronic)

May 2011  
December 2012  
December 2013
## Totally Leadless PM: a comparison

<table>
<thead>
<tr>
<th>Specification</th>
<th>Nanostim™ leadless cardiac pacemaker</th>
<th>Micra™ transcatheter pacing system</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume (cm³)</td>
<td>1</td>
<td>0.8</td>
</tr>
<tr>
<td>Length (mm)</td>
<td>41.4</td>
<td>25.9</td>
</tr>
<tr>
<td>Weight (g)</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Introducer size (French)</td>
<td>18</td>
<td>23</td>
</tr>
<tr>
<td>Primary fixation mechanism</td>
<td>Screw-in helix</td>
<td>Self-expanding nitinol tines</td>
</tr>
<tr>
<td>Secondary fixation mechanism</td>
<td>Nylon tines</td>
<td></td>
</tr>
<tr>
<td>Pacing mode</td>
<td>VVI/VVIR</td>
<td>VVI/VVIR</td>
</tr>
<tr>
<td>Rate response sensor</td>
<td>Temperature</td>
<td>Accelerometer</td>
</tr>
<tr>
<td>Energy supply Battery</td>
<td>Integrated battery</td>
<td>Integrated battery</td>
</tr>
<tr>
<td>Battery</td>
<td>Lithium carbon-monofluoride</td>
<td>Lithium vanadium oxide/carbon monofluoride</td>
</tr>
<tr>
<td>Battery longevity (years)</td>
<td>9.8 100%/2.5 V/0.4 ms/60 b.p.m.</td>
<td>10 100%/1.5 V/0.24 ms/60 b.p.m.</td>
</tr>
<tr>
<td>Device retrieval option</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Telemetry</td>
<td>Conductive</td>
<td>Radio frequency</td>
</tr>
</tbody>
</table>
Permanent Leadless Cardiac Pacing
Results of the LEADLESS Trial

Vivek Y. Reddy, MD; Reinoud E. Knops, MD; Johannes Sperzel, MD; Marc A. Miller, MD; Jan Petru, MD; Jaroslav Simon, MD; Lucie Sediva, MD; Joris R. de Groot, MD, PhD; Fleur V.Y. Tjong, MD; Peter Jacobson, BS; Alan Ostroff, MS; Srinivas R. Dukkipati, MD; Jacob S. Koruth, MD; Arthur A.M. Wilde, MD, PhD; Josef Kautzner, MD, PhD; Petr Neuzil, MD, PhD
Primary safety results from the LEADLESS Observational Study

Johannes Sperzel\textsuperscript{1*}, Pascal Defaye\textsuperscript{2}, Peter-Paul Delnoy\textsuperscript{3}, Juan Jose Garcia Guerrero\textsuperscript{4}, Reinoud E. Knops\textsuperscript{5}, Claudio Tondo\textsuperscript{6}, Jean-Claude Deharo\textsuperscript{7}, Tom Wong\textsuperscript{8}, and Petr Neuzil\textsuperscript{9}

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Received 12 June 2017; editorial decision 22 November 2017; accepted 29 November 2017
What’s new?

- First report of the primary results on the 300-subject cohort used to meet the condition of Nanostim™ leadless pacemaker (LP) approval requirements in Europe, as well as additional results on the total cohort enrolled as of March 2017 in the prospective, single-arm, multi-centre, post-market study.
- First report on the study pause of April 2014 due to two separate events of cardiac perforation, presenting stratifying implant data results between pre- and post-pause, which were statistically significant.
- We report on the successful implantation of the Nanostim LP in 96.6% of subjects with stable device measurements at 6 months, similar to those observed in traditional pacemakers.
- Our report of safety data in the primary cohort confirms short-term safety of the LP, with a serious adverse device effect-free rate at 6 months of 94.6%, thus meeting the primary endpoint of the study.

<table>
<thead>
<tr>
<th>Visit type</th>
<th>Pacing threshold (V) at 0.4 ms pw, mean ± SD</th>
<th>R-wave amplitude (mV), mean ± SD (n)</th>
<th>Impedance (Ω), mean ± SD (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implantation</td>
<td>0.80 ± 0.59 (446)</td>
<td>7.2 ± 2.8 (400)</td>
<td>737.9 ± 303.2 (450)</td>
</tr>
<tr>
<td>Pre-discharge</td>
<td>0.56 ± 0.50 (441)</td>
<td>8.8 ± 2.9 (433)</td>
<td>664.8 ± 218.6 (446)</td>
</tr>
<tr>
<td>90 days</td>
<td>0.56 ± 0.42 (418)</td>
<td>9.5 ± 2.8 (407)</td>
<td>532.9 ± 158.7 (427)</td>
</tr>
<tr>
<td>6 months</td>
<td>0.54 ± 0.47 (390)</td>
<td>9.6 ± 2.8 (375)</td>
<td>516.5 ± 148.2 (395)</td>
</tr>
</tbody>
</table>
A Leadless Intracardiac Transcatheter Pacing System

Dwight Reynolds, M.D., Gabor Z. Duray, M.D., Ph.D., Razali Omar, M.D.,
Kyoko Soejima, M.D., Petr Neuzil, M.D., Shu Zhang, M.D.,
Calambur Narasimhan, M.D., Clemens Steinwender, M.D.,
Josep Brugada, M.D., Ph.D., Michael Lloyd, M.D., Paul R. Roberts, M.D.,
Venkata Sagi, M.D., John Hummel, M.D., Maria Grazia Bongiorni, M.D.,
Reinoud E. Knops, M.D., Christopher R. Ellis, M.D., Charles C. Gornick, M.D.,
Matthew A. Bernabei, M.D., Verla Laager, M.A., Kurt Stromberg, M.S.,
Eric R. Williams, B.S., J. Harrison Hudnall, B.S., and Philippe Ritter, M.D.,
for the Micra Transcatheter Pacing Study Group

November 2015
A Leadless Intracardiac Transcatheter Pacing System

Long-term performance of a transcatheter pacing system: 12-Month results from the Micra Transcatheter Pacing Study

Gabor Z. Duray, MD, PhD,* Philippe Ritter, MD,† Mikhael El-Chami, MD, FHRSM,‡ Calambur Narasimhan, MD § Razali Omar, MD, FHRSM,‖ Jose M. Tolosana, MD, PhD ¶

A leadless transcatheter pacemaker in the real-world setting: A comparison to the investigational study and a transvenous historical control

Paul R. Roberts, MD∗ Jose Luis Martinez-Sande, MD,‡ Nicolas Clementy, MD,‡ Christophe Garweg, MD,§ Jose Luis Martinez-Sande, MD,‖ Jonathan P. Piccini, MD, MHS, FHRSM,¶ Saverio Iacopino, MD,¶ Michael Lloyd, MD, FHRSM∗ Xavier Viñolas Prat, MD,‡‡ Michael Dilou Jacobsen, MD,‡‡ Philippe Ritter, MD,‡‡ Jens Brock Johansen, MD, PhD,§§ Claudio Tondo, MD, PhD,¶¶ Fang Liu, MD, MS,¶¶ Dedra H. Fagan, PhD,¶¶ Alyssa K. Eakley, MS,¶¶ Paul R. Roberts, MD##
GLOBALLY DIVERSE PATIENT POPULATION
TWO CLINICAL STUDIES SPANNING THE GLOBE

2,543 patients, >300 implanters, 208 centers, 31 countries
As of April 2018 data freeze

Nesse H. Micra Clinical Evidence from IDE Trial and Post-Approval Registry. May 2018. Medtronic Data on File
Key Clinical Overview

Met all efficacy and safety objectives from the IDE study (N=726 pts)

• 99.2% implant success rate\(^1\)
• 98.3% of patients with low, stable pacing capture thresholds at 6 months\(^1\)
• 96% freedom from device / procedure-related major complications at 12 months\(^2\)
• 48% fewer major complications than traditional pacemakers\(^2\)

• Registry reinforces safety and long-term performance*:
  • N=1817 with 465 patients with at least 12 months follow-up\(^3\)
  • 99.1% implant success rate\(^3\)
  • Low 2.7% (CI: 2.0% - 3.6%) rate of major complications through 12 months\(^3\)
  • Very low rate of dislodgement (1, 0.06%) and procedure-related infection (3, 0.17%)\(^3**\)

*As of April 2018 data freeze
**None device-related

\(^3\)El-Chami, MF, et al. Leadless Pacemaker Implant in Patients with Pre-Existing Infections: Results from the Micra Post-Approval Registry. Presented at: HRS 2018; May 10, 2018; Boston, MA.
Major Complications through 12 months$^{1,2}$

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2. El-Chami, MF, et al. Leadless Pacemaker Implant in Patients with Pre-Existing Infections: Results from the Micra Post-Approval Registry. Presented at: HRS 2018; May 10, 2018; Boston, MA.
MAJOR COMPLICATIONS: PERFORATION/EFFUSION RATES TRENDING LOWER\textsuperscript{1,2}

*For the IDE study, there were 13 total perforations/effusions (1.8%), 11 met the major complication criteria. For the Registry, there were 14 total perforations/effusions (0.77%), 8 met the major complication criteria.


\textsuperscript{2}El-Chami, MF, et al. Leadless Pacemaker Implant in Patients with Pre-Existing Infections: Results from the Micra Post-Approval Registry. Presented at: HRS 2018; May 10, 2018; Boston, MA.
Implant site placement

IDE Site Placement \((N=720)\)\(^1\)  

- RVOT: 1%
- Other: <1%
- Septum: 33%
- Apex: 66%

Post Approval Site Placement \((N=1801)\)\(^1\)

- RVOT: 1%
- Other: 1%
- Septum: 64%
- Apex: 32%
- NR: 1%

\(^1\)Nesse, H. Micra Clinical Evidence from IDE Trial and Post-Approval Registry. May 2018. Medtronic Data on File.
63% Fewer major complications than transvenous pacemakers VVI

Reference Dataset = Historical control of 2667 patients with traditional pacemakers

1El-Chami, MF, et al. Leadless Pacemaker Implant in Patients with Pre-Existing Infections: Results from the Micra Post-Approval Registry. Presented at: HRS 2018; May 10, 2018; Boston, MA.
Fewer major complications with Micra versus transvenous VVI (30 days)

3 Cantillon DJ, Exner DV, Badie N, et al. Complications and Health Care Costs Associated with Transvenous Cardiac Pacemaker in a Nationwide Assessment, JACC: Clinical Electrophysiology (2017), DOI: 10.1016/j.jacep.2017.05.007
Micra implant in patients with prior CIED infection (#99) from Post Approval Registry

- Implantation of Micra is safe and feasible in patients with a CIED infection
  - high 99% implant success rate
  - no recurrent infections requiring Micra removal
- Leadless pacemakers appear to be a safe pacing alternative for patients with CIED infection

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1 El-Chami, MF, et al. Leadless Pacemaker Implant in Patients with Pre-Existing Infections: Results from the Micra Post-Approval Registry. Presented at: HRS 2018; May 10, 2018; Boston, MA.
Pisa Experience
LCP Pisa Experience

90 patients received Micra TPS implant in our Institution between May 2014 and January 2019.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years, mean ± SD)</td>
<td>77.3 ± 9</td>
</tr>
<tr>
<td>Male gender, n (%)</td>
<td>68 (76%)</td>
</tr>
<tr>
<td>Ejection Fraction (%, mean ± SD)</td>
<td>56.5 ± 7.5</td>
</tr>
<tr>
<td>Implant success rate, n (%)</td>
<td>90 (100%)</td>
</tr>
</tbody>
</table>

Unpublished data
All patient fulfilled standard criteria for pacemaker implantation with specific indication to receive \textbf{VVI} pacing

<table>
<thead>
<tr>
<th>Condition</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bradycardia associated with persistent or permanent atrial tachyarrhythmia</td>
<td>42 (46.7%)</td>
</tr>
<tr>
<td>Parox sinus node dysfunction</td>
<td>23 (25.6%)</td>
</tr>
<tr>
<td>Parox atrio ventricular block</td>
<td>20 (22.2%)</td>
</tr>
<tr>
<td>Other reason</td>
<td>5 (5.5%)</td>
</tr>
</tbody>
</table>

In our experience, almost a half of the patients presented one or more clinical conditions that discouraged the use of a traditional pacing device, and the majority of them had undergone previous trans-venous lead extraction.
Implantation

When M-TPS was implanted in a non-apical position, a significant lower rate of single device delivery was observed.

Targeting a non-apical position when feasible

<table>
<thead>
<tr>
<th>Site of implantation, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apical position</td>
</tr>
<tr>
<td>23 (25.5)</td>
</tr>
<tr>
<td>Non apical position</td>
</tr>
<tr>
<td>67 (74.5)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deployments, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
</tr>
<tr>
<td>58 (64.5)</td>
</tr>
<tr>
<td>&gt;1</td>
</tr>
<tr>
<td>32 (35.5)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Procedure duration, mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>29.5 ± 15.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fluoroscopy time, mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.3 ± 6.9</td>
</tr>
</tbody>
</table>

Unpublished data
Patients were followed up for an average of 16±9 months.

No device-related events were registered during follow-up, with 3 non-cardiac deaths, and 2 admissions for cardiac causes (1 acute coronary syndrome, and 1 acute heart failure).

In particular, no device infection and/or malfunction were reported.

Unpublished data
On implantation: the average **pacing threshold** was $0.38 \pm 0.25 \text{ V @ } 0.24 \text{ ms}$, the average **impedance** was $707 \pm 149 \text{ Ohm}$, the average **sensing** was $9.2 \text{ mV}$

The major electrical variables stabilized during follow-up, with only 3 patients (4%) showing an elevated pacing threshold ($1.92 \pm 0.92 \text{ V @ } 0.24 \text{ ms}$) at the last available follow-up.

Unpublished data
Feasibility and long-term effectiveness of a non-apical Micra pacemaker implantation in a referral centre for lead extraction

Maria Grazia Bongiorni, Veronica Della Tommasina, Valentina Barletta, Andrea Di Cori, Sara Rogani, Stefano Viani, Luca Segreti, Luca Paperini, Ezio Soldati, Raffaele De Lucia, and Giulio Zucchelli*

Cardiac Thoracic and Vascular Department, University Hospital of Pisa, Via Paradisa 2, 56100 Pisa, Italy

Received 25 November 2017; editorial decision 16 April 2018; accepted 20 April 2018
The major finding of our study is that the long-term electrical parameters of M-TPS seem not to be influenced by the site of implantation.

Bongiorni et al. Europace 2018
Feasibility and long-term effectiveness of a non-apical Micra pacemaker implantation in a referral centre for lead extraction

Maria Grazia Bongiorni, Veronica Della Tommasina, Valentina Barletta, Andrea Di Cori, Sara Rogani, Stefano Viani, Luca Segreti, Luca Paperini, Ezio Soldati, Raffaele De Lucia, and Giulio Zucchelli

What’s new?

- A non-apical site of implantation is achievable even in clinically challenging patients with no significant differences in the electrical performances compared with apical implant at long-term follow-up.
- A non-apical site of implantation is associated with a higher number of device re-deployments compared with apical delivery, with no impact on device safety profile and electrical parameters.
- Micra leadless pacemaker implant is a safe and effective procedure even in a real-life population at high risk of complications, as patients who previously underwent transvenous lead extractions.
Leadless pacing: current state and future directions

LCP Retrievability
Given the early in-human experience with leadless pacemakers, safety and effectiveness of chronic retrieval of such devices is still under question.
Retrievability: when to think about?

- **INFECTION**: there is probably a lower overall risk of infection, but infections can occur.

- **DISLODGEMENT**: rates of dislodgement of leadless devices over time are unknown and are of potential concern.

- **BATTERY DEPLETION**: abandonment?
Micra device has been successfully retrieved after 28 months in chronic animal models using a custom sheath combined with market-released tools.
NANOSTIM

Reddy HR 2017
NANOSTIM retrieval

• Early animal experience using the retrieval system has been positive: retrieval was attempted in sheeps and was successful in 18/18 cases, with no complications.

• In LEADLESS II registry 15 patients underwent an attempted retrieval: 14/15 devices were successfully retrieved (91%) with no complications.

• The primary reasons for retrieval were worsening heart failure and elevated thresholds.
Micra Retrieval

- Currently available delivery systems allow for the device to be positioned multiple times during the initial implant procedure. However, once the device has been fully delivered, device recapture is much more challenging.

- The Micra device has been designed with a proximal retrieval feature to aid in recapture
After 1 year
Male, 82 years old
To retrieve, or not to retrieve: System revisions with the Micra transcatheter pacemaker

Eric Grubman, MD, FHRS, Philippe Ritter, MD, Christopher R. Ellis, MD, FHRS, Michael Giocondo, MD, Ralph Augustini, MD, FHRS, Petr Neuzil, MD, Bipin Ravindran, MD, Anshul M. Patel, MD, FHRS, Pamela Omdahl, MBA, Karen Pieper, BS, Kurt Stromberg, MS, J. Harrison Hudnall, BS, Dwight Reynolds, MD, FHRS, for the Micra Transcatheter Pacing Study

METHODS Patients with implants from the Pre-market Micra Transcatheter Pacing Study and the Micra Transcatheter Pacing System Continued Access Study (N = 989) were analyzed and compared with 2667 patients with transvenous pacemakers (TVPs). Revisions included TPS retrieval/explant, repositioning, replacement, or electrical deactivation (with or without prior attempt at retrieval, generally followed by TVP implant) for any reason. Kaplan-Meier revision rates were calculated to account for varying follow-up duration and were compared using a Fine-Gray competing risk model.

CONCLUSION The overall system revision rate for patients with TPS at 24 months was 1.4%, 75% lower than that for patients with TVPs. TPS was disabled and left in situ in 64% of revisions, and percutaneous retrieval was successful as late as 14 months postimplant.
Techniques for successful early retrieval of the Micra transcatheter pacing system: A worldwide experience

Muhammad R. Afzal MD *, Emile G. Daoud MD, FHRS *, Ryan Cunnane MD †, Shiva K. Mulpuru MD ‡, Alan Koay MD §, Azlan Hussain MD §, Razali Omar MD, FHRS §, Koh Kok Wei MD §, Anish Amin MD ‡, Gregory Kidwell MD †, Nirav Patel MS †, Charles Love MD, FHRS **, Michael Lloyd MD, FHRS ††, Maciej Sterbiński MD ‡‡, Seth Goldbarg MD, FHRS ‡‡‡, Miguel A. Leal MD, FHRS ‡‡‡, James Gabriels MD ‡‡, Apoor Patel MD ‡‡ … Ralph S. Augustini MD, FHRS * ‡, ☕️

Show more

https://doi.org/10.1016/j.hrthm.2018.02.008

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Leadless pacing: current state and future directions

Physiological Pacing
AV Synchronous Pacing With a Ventricular Leadless Pacemaker:
Primary Results from the MARVEL Study

Larry A. Chinitz, MD, FHRs; Philippe Ritter, MD; Surinder Kaur Khelae, MBBS, FHRs;
Saverio Iacopino, MD; Christophe Garweg, MD; Maria Grazia Bongiorni, MD; Petr
Neuzil, MD, PhD; Jens Brock Johansen, MD; Lluis Mont, MD, PhD; Efrain H. Gonzalez,
MD; Venkata S. Sagi, MD, FHRs; Gabor Z. Duray, MD, PhD; Nicolas Clementy, MD;
Todd J. Sheldon, MS; Vincent Splett, MS; Kurt Stromberg, MS; Nicole Wood, BS;
Clemens Steinwender, MD
P wave Marvel Algorythm

- A1 – Isovolumic contraction and mitral/tricuspid valve closings
- A2 – Aortic/pulmonic valve closing
- A3 – Early passive ventricular filling
- A4 – Atrial contraction generating active filling
Key Results Marvel Summary

• AV synchrony during a period of rest in 64 patients was 87%

• Sinus arrhythmia, low A4 amplitude, and PVCs contributed to lack of AV synchrony
  • no association between time of implant and AV synchrony
  • no pauses, no instances of PM-mediated tachycardia
  • no adverse event related to the device or algorithm were reported
Key Results Marvel Summary

- Accelerometer based atrial sensing is both feasible and significantly improves AV synchrony in patients with AV block and a single-chamber leadless pacemaker implanted in the RV
  - improvements in AV synchrony led to improvements in stroke volume in AV block patients
  - AV synchrony was similar during postural maneuvers
- AV synchrony was not compromised in patients with intrinsic AV conduction
- Future clinical studies and circuitry enhancements are planned to further assess this novel technology for providing AV synchrony in a leadless pacemaker (MARVEL II)
Leadless pacing: current state and future directions

Leadless Pacing in HF patients
WiSE-CRT

CO-IMPLANT DEVICE
Co-implanted pacemaker, ICD or CRT paces the right ventricle.

RECEIVER ELECTRODE
Implanted onto the endocardium, the receiver electrode converts ultrasound energy into electrical energy to pace the left ventricle.

BATTERY
Implanted subcutaneously on the left mid axillary line, powers the transmitter.

TRANSMITTER
Phased array ultrasound transmitter is implanted sub-muscular over a cardiac echo window. Synchronizes with an RV pacing pulse to transmit ultrasound energy to the receiver electrode to provide Bi-V endocardial pacing.
Feasibility, safety, and short-term outcome of leadless ultrasound-based endocardial left ventricular resynchronization in heart failure patients: results of the Wireless Stimulation Endocardially for CRT (WISE-CRT) study

Angelo Auricchio¹, Peter-Paul Delnoy², Christian Butter³, Johannes Brachmann⁴, Lieselot Van Erven⁴, Stefan Spitzer⁴, Tiziano Moccetti¹, Martin Seifert³, Thanasie Markou², Karolyi Laszo⁴, and François Regoli⁴, for the Collaborative Study Group

**Aims**

Left ventricular (LV) endocardial pacing may address the limitations in the selection of an LV pacing site and provide improvements in cardiac resynchronization therapy (CRT) effectiveness. We report on the feasibility, the safety, and the short-term outcome of a leadless ultrasound-based technology for LV endocardial resynchronization in heart failure (HF) patients enroled into the Wireless Stimulation Endocardially for CRT (WISE-CRT) study.

**Methods and results**

Seventeen HF patients were enroled and categorized as: (i) patients in whom attempted coronary sinus lead implantation for CRT had failed (n = 7); (ii) patients with a previously implanted CRT device, not responding to CRT (n = 2); and (iii) patients with previously implanted pacemakers or implantable cardioverter-defibrillator and meeting the standard indications for CRT (n = 8). System implantation was achieved in 13 patients (76.5%); mean R-wave amplitude was 5.6 ± 3.2 mV and the mean pacing threshold was 1.6 ± 1.0 V, respectively. In one patient, no sufficient pacing thresholds were found; in three patients pericardial effusion occurred. Biventricular pacing was recorded in 83% and 92% of the patients at 1 month and 6 months, respectively. QRS duration was shorter during biventricular pacing compared with right ventricular pacing at 1 month (−41 ms; P = 0.0002) and 6 months (−42 ms; P = 0.0011), respectively. At the 6-month follow-up, two-thirds of the patients had at least one functional class change. Left ventricular ejection fraction significantly increased (P < 0.01) by 6 points at the 6-month follow-up.

**Conclusion**

The feasibility of providing an endocardial stimulation for CRT with a leadless technology was successfully demonstrated. Despite the promising results for a novel technology, further study is required to definitively conclude the safety and the performance of the system.

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*March 2012 study stopped*

- redesign catheter
- more echo guided implant

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Cardiac Resynchronization Therapy With Wireless Left Ventricular Endocardial Pacing
The SELECT-LV Study

Cardiac Resynchronization Therapy With Wireless Left Ventricular Endocardial Pacing

The SELECT-LV Study

**TABLE 3** Device- or Procedure-Related Adverse Events (n = 35)

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Events</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;24 h</td>
<td>3 (8.6%)</td>
<td></td>
</tr>
<tr>
<td>VF during catheter contact with LV endocardium</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Electrode embolization to lower extremity</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Femoral artery fistula (required surgical repair)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>24 h to 1 month</td>
<td>8 (22.3%)</td>
<td></td>
</tr>
<tr>
<td>Acute CVA (AF noncompliant with anticoagulation)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Femoral pseudaneurysm</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Pocket hematoma (generator)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Suspected infection (generator site)</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Death (following VF during initial implant procedure)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>1 to 6 months</td>
<td>3 (8.6%)</td>
<td></td>
</tr>
<tr>
<td>Defective transmitter circuitry</td>
<td>3</td>
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</tr>
</tbody>
</table>

**FIGURE 4** Clinical Composite Score in SELECT-LV Compared With Historical Control Subjects

Leadless pacing: current state and future directions

Leadless Pacing in S-ICD patients
S-ICD and LCP

......... they work together
Case 1. B. G. 65 y male: High infective risk.

Case 2. D. G. 74 y male: SVC syndrome

Case 3. G. M. 71 y male: High infective risk & chronic vein obstruction

Case 4. A. S. 58 y male: Transvenous & epicardial leads infection
Where are we moving to?
In the next future S-ICD and leadless (A/RV/LV) PM would probably work together for the best care of our patients.
The Future: Modular CRM System (mCRM™)*
EMBLEM™ S-ICD Family | EMPOWER™ Modular Pacing System*

- Options:
  - **A**: Leadless Pacemaker Implanted First
    - S-ICD Implanted Later
  - **B**: Leadless Pacemaker and S-ICD Implanted Together
  - **C**: S-ICD Implanted First
    - Leadless Pacemaker Implanted Later
Operation of the Modular CRM System

1. Leadless pacemaker designed to sense and treat bradycardia independently from the S-ICD
2. ATP schemes will be built into the leadless pacemaker, but can be activated only by the S-ICD or the programmer
3. S-ICD will continue to sense tachycardia, following which it is designed to command ATP in the leadless pacemaker prior to a shock
4. *LPM tachy sensing integrated?*
FUTURE CLINICAL OUTLOOK

Modified from Tjong, Reddy, Jacc 2017