Εμφύτευση βηματοδοτών χωρίς καλώδια.
Εντός και εκτός ενδείξεων

Εμμ. Μ. Κανουπάκης MD PhD FESC
Διευθυντής ΕΣΥ
Πανεπιστημιακό Νοσοκομείο Ηρακλείου
Hyman’s “artificial pacemaker” in 1930’s...never found a manufacturer

“a machine...that interferes with the will of God”
After World War II...
Στη δεκαετία του 1950
To 1958!
Η εξέλιξη...

- Battery longevity
- Algorithms
- EC recordings
- Monitoring
- Remote f-up
- MRI compatible
...lead and pocket problems
1-Month Complication Rate

- Lead Related: 2.5%
- Thoracic Trauma: 4.8%
- Perforation: 0.3%
- Infection: 1.2%
- Pocket Complications: 0.3%

Acute Complications - 7.7%
Long-Term (1-36 months) Complications - 6.4%

RWD from 72,701 TVP implantations

Cantillon DJ et al. JACC Clin Electrophysiol. 2017;3:1296-1305
Ψάχνοντας κάτι διαφορετικό...
1970: μια αρχική ιδέα...

J. ELECTROCARDIOLOGY, 3 (3-4) 325-334, 1976

**Special Article**

**Totally Self-Contained Intracardiac Pacemaker**

J. WILLIAM SPICKLER, PH.D., NED S. RASOR, PH.D., PAUL KEZDI, M.D.
S. N. MISRA, M.D., K. E. RÖBENS, P.E., AND CHARLES LÉBOEUF, P.E.

**SUMMARY**

Recent developments in miniature long-life power sources and electronics, such as nuclear batteries and integrated circuits, make feasible a new generation of pacemakers, the intracardiac pacemaker (IC), i.e., a completely self-contained pacemaker implanted inside the right ventricle by transvenous insertion.

Circuits have been improved substantially. In addition, the development of the endocardial catheter electrode has broadened the choice of operative procedures to include a larger portion of the patient population. Two major problems that still exist with conventional pacemakers are perforation or dislocation of the transvenous electrode and the short life of the batteries that are presently used. In addition...
A Miniature Pacemaker Introduced Intravenously and Implanted Endocardially. Preliminary Findings from an Experimental Study

P.E. VARDAS, C. POLITOPOULOS, E. MANIOS, F. PARTHENAKIS, and C. TSAGARAKIS

Cardiology Dent., University of Crete Medical School, Greece
2012: η βιομηχανία παρουσιάζει...
The Problem with Leads and Pockets

Path for pathogens - sepsis → Pneumothorax

Fibrosis/extraction risk

Repetitive motion: lead fracture

Tricuspid Regurgitation

Pocket Infection Erosion Hematoma

Lead thrombus + PFO: stroke risk
Micra TPS (Medtronic)
1st Human Implantation: December 2013
EU Market Release: April 2015
FDA approved
Implantations in Europe: ≈2,500

Nanostim LCP (Abbott)
1st Human Implantation: December 2012
EU Limited Market Release
Awaiting FDA approval
Implantations in Europe: ≈500
## Μικρές διαφοροποιήσεις...

<table>
<thead>
<tr>
<th>Nanostim LCP</th>
<th>Micra TPS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dimensions (mm)</strong></td>
<td>42.0 x 5.99</td>
</tr>
<tr>
<td><strong>Volume (cc), weight (g)</strong></td>
<td>1, 2</td>
</tr>
<tr>
<td><strong>Sheath size (French)</strong></td>
<td>18 (id)/ 21 (od)</td>
</tr>
<tr>
<td><strong>Fixation mechanism</strong></td>
<td>Screw-in helix</td>
</tr>
<tr>
<td><strong>Pacing mode</strong></td>
<td>VVI(R)</td>
</tr>
<tr>
<td><strong>Rate Response Sensor</strong></td>
<td>Temperature</td>
</tr>
<tr>
<td><strong>Communication</strong></td>
<td>Conductive (250kHz)</td>
</tr>
<tr>
<td><strong>Battery longevity (yrs)</strong></td>
<td>8.5-9.8</td>
</tr>
<tr>
<td><strong>Nitinol tines fixated in tissue</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Dimensions (mm)</strong></td>
<td>25.9 x 6.7</td>
</tr>
<tr>
<td><strong>Volume (cc), weight (g)</strong></td>
<td>0.8, 2</td>
</tr>
<tr>
<td><strong>Sheath size (French)</strong></td>
<td>23 (id) / 27 (od)</td>
</tr>
<tr>
<td><strong>Fixation mechanism</strong></td>
<td>Nitinol tines</td>
</tr>
<tr>
<td><strong>Pacing mode</strong></td>
<td>VVI(R)</td>
</tr>
<tr>
<td><strong>Rate Response Sensor</strong></td>
<td>3-axis accelerometer</td>
</tr>
<tr>
<td><strong>Communication</strong></td>
<td>Radio-frequency</td>
</tr>
<tr>
<td><strong>Battery longevity (yrs)</strong></td>
<td>4.7-9.6</td>
</tr>
</tbody>
</table>

**Nanostim LCP** - LCP advanced in RV covered by protective sleeve

**Micra TPS** - Delivery catheter and TPS advanced into RV, TPS released in RV, Tines remain retracted in delivery cup, Tines engaged in myocardial tissue.
**Percutaneous Implantation of an Entirely Intracardiac Leadless Pacemaker**

Vivek Y. Reddy, M.D., Derek V. Exner, M.D., M.P.H., Daniel J. Cantillon, M.D., Rahul Doshi, M.D., T. Jared Bunch, M.D., Gery F. Tomassoni, M.D., Paul A. Friedman, M.D., N.A. Mark Estes, III, M.D., John Ip, M.D., Imran Niazi, M.D., Kenneth Plunkitt, M.D., Rajesh Banker, M.D., James Porterfield, M.D., James E. Ip, M.D., and Srinivas R. Dukkipati, M.D., for the LEADLESS II Study Investigators*

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**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*

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*N Engl J Med 2015;373:1125-35*  
*N Engl J Med 2016;374:533-41*
**PACEMAKER CLINICAL STUDY SAFETY AND PERFORMANCE DATA**

<table>
<thead>
<tr>
<th></th>
<th>LEADLESS II&lt;sup&gt;1&lt;/sup&gt; (N = 526)</th>
<th>Medtronic™ Micra™ TPS&lt;sup&gt;2&lt;/sup&gt; (N = 725)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Implant success</strong></td>
<td>95.8%</td>
<td>99.2%</td>
</tr>
<tr>
<td><strong>Major complications</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(†Using Micra TPS study definition)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perforation or effusion</td>
<td>4.5%</td>
<td>4.0%</td>
</tr>
<tr>
<td>Device dislodgement (with percutaneous retrieval)</td>
<td>1.1%</td>
<td>1.6%</td>
</tr>
<tr>
<td>AV fistula/psuedoaneurysm (access site complications)</td>
<td>0.6%</td>
<td>0.6%</td>
</tr>
<tr>
<td>Infection (implant site infection)</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

*low complication rate*
pacing thresholds remained low and stable
Στον "πραγματικό κόσμο" ακόμα καλύτερα...

![Bar chart showing comparison between Pre-Market and Post-Market events.]

<table>
<thead>
<tr>
<th>Event</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>18</td>
</tr>
<tr>
<td>Deep Vein Thrombosis</td>
<td>1</td>
</tr>
<tr>
<td>Groin Issue</td>
<td>6</td>
</tr>
<tr>
<td>Severe Cardiac Injury*</td>
<td>4  (0.8%)</td>
</tr>
<tr>
<td>Pacing Issue</td>
<td>3</td>
</tr>
<tr>
<td>Other</td>
<td>4</td>
</tr>
<tr>
<td>Embolization</td>
<td>0</td>
</tr>
<tr>
<td>Device Infection</td>
<td>0</td>
</tr>
</tbody>
</table>

**Consequences**

- **Death**: 3
- **Hospitalization**: 7
- **Prolonged Hospitaliz.**: 9
- **System Revision**: 2

*Roberts et al, Heart Rhythm 2017; 14:1375-1379*
96 % freedom from major complications through 12 mo postimplant

Dury et al, Heart Rhythm 2017;14:702-709
ΠΟΙΟΙ ΕΙΝΑΙ ΥΠΟΨΗΦΙΟΙ ΓΙΑ ΒΗΜΑΤΟΔΟΤΗ ΧΩΡΙΣ ΚΑΛΩΔΙΑ;
Ειδικές περιπτώσεις...

no venous access

high risk for infection
• 99 patients
• 99% implant success
• Mean duration between prior CIED explant and Micra implant was \(6.4 \pm 7.0\) days
  – Micra implanted on same day as CIED explant in 36.4%
• Mean follow-up duration was 5.5 \(\pm\) 5.9 months
• No recurrent infections requiring Micra removal
26-30% risk of PM syndrome in sinus rhythm
Σε ποιους απευθύνονται;

- AVB Only: 40%
- SND Only: 30%
- SND + AVB: 10%
- AVB + AF: 16%
- Other: 4%
Το στοίχημα:

η επέκταση των ενδείξεων

- AVB + AF: 16%
- SND Only: 30%
- SND + AVB: 10%
- AVB Only: 40%
- Other: 4%
Είναι εφικτή η VDD βηματοδότηση;
Accelerometer sensing of cardiac activity

- **A1** -> MV/TV closure
- **A2** -> AoV/PV closure
- **A3** -> passive ventricular filling
- **A4** -> atrial contraction

*Chinitz et al., Heart Rhythm 2018;15:1363–1371*
Accelerometer based AV synchrony
AV synchrony obtainable more than 80% of the time

Chinitz et al., Heart Rhythm 2018;15:1363–1371
Είναι εφικτή η ΑΑΙ βηματοδότηση;
...the mode of fixation in a thin-walled atria
Είναι εφικτή η DDD βηματοδότηση;
...safe device-to-device communication and energy consumption
Ovine pre-clinical implant
Είναι εφικτή η επίκοινωνία;

Combined ATP-enabled LP and S-ICD
1. Leadless PM designed to sense and treat bradycardia independently from the S-ICD
2. ATP schemes built into the leadless PM, activated only by the S-ICD or the programmer
3. S-ICD will sense tachycardia, followed by command for ATP to leadless PM prior to shock
S-ICD discriminates high-rate LP pacing

ATP delivered by the LP

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Battery advisory...

October 2016: worldwide alert of battery malfunction

≈2% Lithium-CFx cell dryness (28/1,423 implants)

>> abrupt loss of pacing and communication

Revision in pacer-dependant patients recommended
Retrievability is possible...

Retrieval of LCP

- Single-loop retrieval snare
- Capture of LCP
- Protective sleeve advanced over LCP

Retrieval of TPS

- 6Fr sheath within 8.5Fr sheath advanced through introducer
- TPS captured by snare
- TPS removed by pulling device back into introducer

...acutely and midterm
Retrieval or abandon?
Transthoracic recharging...
Είναι νωρίς ακόμα;
The big obstacle...

COSTS
The miniaturization era
Ευχαριστώ...