Leadless CRM technology

• Leadless pacemaker: future
• “Leadless” ICD: present
Leadless CRM technology: Physician’s point of view

• To avoid venous system
• To eliminate leads
• To avoid (or cut short) fluoroscopy
Leadless CRM technology: Technology point of view

Different philosophy

- **Leadless PM**: miniaturization, more cosmetic, no surgery

- “**Leadless**” **ICD**: more widespread implantation capability, easy to implant and to extract
Leadless PM: Idea from past – reality in future

- Ultrasound
- Inductive
- Micro-battery
- Biological

First Publication of Concept
J. Electrocardiology, 3 (3-4) 325-331, 1970

Special Article
Totally Self-Contained Intracardiac Pacemaker

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. Since the IC pacemaker eliminates all leads, tension problems associated with the leads such as

1970

Prof. Goran Milasinovic
Ultrasound: LV Endocardial Implant

External Acoustic (US) Power source

Ultrasound Generator and Transmitter

Data Collection Instrumentation

Receiver-electrode Catheter

Lee et al, JACC 2009
Electrical Induction: transmitter + receiver

Figure 1. The figure shows a screw-equipped receiver unit placed on the outer chest wall directly, without external connection.

Figure 3. (A) Receiver unit with an approach, the induced unit without external connection.

(B) Top: Receiver unit is placed on the outer right ventricle. Using this approach.

www.escardio.org/EHRA
Micro-battery

Miniaturized, Leadless VVIR Pacer

- ~20F
- ~24 mm length
- Active fixation
- est 7-10 yr longevity

Steerable Sheath/Catheter

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Smartphone!
Creation of a biological pacemaker by gene- or cell-based approaches

Eduardo Marbán · Hee Cheol Cho

Fig. 1 Suppression of Kir2.1 channels unmask latent pacemaker activity in ventricular cells. a Action potentials evoked by depolarizing external stimuli in control ventricular myocytes. b Spontaneous action potentials in Kir2.1AAA-transduced myocytes with depressed I_{K1.1}. c Baseline electrocardiograms in normal sinus rhythm. d Ventricular rhythms 72 h after gene transfer of Kir2.1AAA. P waves (A and arrow) and wide QRS complexes (V and arrow) march through to their own rhythm.

Prof. Goran Milasinovic
Energy and Longevity

**Energy per Pulse, microJoules**

- Lead: 5.5
- Ultrasound: 7144
- Inductive: 360
- Micro-battery: 4.95

**Longevity, Days**

- Lead: 2746
- Ultrasound: 12
- Inductive: 222
- Micro-battery: 175
“Leadless” ICD
Subcutaneous leads:
Electrical sandwich of the Heart
Guidant-sponsored
Research on Defibrillation Energy Requirements
Using Left Anterior Chest to SQ Shocking Vector

Purpose: to estimate DER in pts using investigational system with external defibrillator and left chest cutaneous (C) electrode to SQ shock vector

LP = left pectoral active can
A = apical patch (cutaneous)

Burke. Heart Rhythm 2005;2:1332-8
Guidant-sponsored Research on Defibrillation Energy Requirements Using Left Anterior Chest to SQ Shocking Vector

- 50-J shock successful in 10/11 (91%) patients.
- 30-J shock successful in 7/9 (78%)
Totally Extravascular System May Offer:

- **Safer** for extraction: resolution of lead or device complications is easier without having hardware in the transvenous space
- Potentially **simpler** implant
- **Shorter** procedure time
- **Easier** and safer for low volume implanters
- **Fluoroless** implant
Potential Patient
Has transvenous Obstruction or Low Arrhythmia Burden

1. In whom transvenous systems are not desirable or possible

2. At lower risk of arrhythmia management: MADIT II, SCD-HeFT, Brugada, HCM, ARVD
Not ideal for patients:

- who could benefit from pacing therapies, e.g., bradycardia pacing
- with high burden of monomorphic, pace-terminable VT
- who are candidates for CRT-D
Do we really need it?

Defibrillator Options

Transvenous

Subcutaneous

www.escardio.org/EHRA
Background

- Non-transvenous implanted defibrillators offer potential advantages over transvenous ICDs

- Without a coil in the heart, more energy is needed to defibrillate
Transvenous ICD defibrillation **Efficacy** is possible with a completely subcutaneous anterior-posterior shock pathway to identify non-transvenous **defibrillation configurations** that provide efficacy comparable to transvenous devices with 70 Joules power.
2 changes throughout the study

1. 2nd Auxiliary anterior coil added
2. Peak voltage increase to 1000 V
3. Lowered capacitance from 275 to 160 \( \mu F \)

Group A
IM; 275\( \mu F \)
N=58

Group D
IM; 160\( \mu F \)
N=14
Medtronic, AHA 2009
Methods

**IM**: Can implanted under pectoral muscle via inframammary incision

**IC**: Can implanted in conventional pocket via infraclavicular incision

**IC-2**: A 15-cm SQ coil connected to the can is added to the IC configuration
Medtronic, AHA 2009

136 pts
VF to Shock time 20 sec.

70 Joules, 20 J. Safety Margin

93% Efficacy

86% Efficacy

ASSURE trial: 94% Efficacy

2nd Coil
Results: % Meeting Implant Testing

- **Group A**: IM; 275µF, N=58
- **Group B**: IC; 275µF, N=15
- **Group C**: IC-2; 275µF, N=25
- **Group D**: IM; 160µF, N=14
- **Group E**: IC-2; 160µF, N=24

95% CI
Results: Defibrillation Efficacy Curves

Predicted Average 1st Shock Success Rate

- **Group A**
  - IM; 275µF
  - N=58

- **Group B**
  - IC; 275µF
  - N=15

- **Group C**
  - IC-2; 275µF
  - N=25

- **Group D**
  - IM; 160µF
  - N=14

- **Group E**
  - IC-2; 160µF
  - N=24

Energy (Joules)
Discussion

• Efficacy is highly dependent on can position
  – A conventional can position has poor efficacy
  – A sternally placed coil tied to the can improves efficacy

• Higher voltage, lowered capacitance improves efficacy
Conclusion

• Defibrillation efficacy comparable to a transvenous ICD was obtained with an anterior-posterior shock vector using a 160-μF capacitance and 70-J maximum output.
1st Clinical Evaluation of the Subcutaneous Implantable Defibrillator (S-ICD®) System

55 pts
Primary Objective: VF Detection + 65 J
No Fluoroscopy, 80 J power device

Results:
55/55 Detection, 53/55 (98%) VF Conversion
Mean time to therapy: 14±2.5 sec.
Implant time: 74±38 min.

Ian G. Crozier, MD, Iain C. Melton, Robert E. Park, Warren M. Smith, Margaret A. Hood, Luc Jordaens, Dominic Theuns, Lucas Boersma, Alexander H. Maass, Isabelle C. van Gelder, Arthur A. Wilde, Pascal van Dessel, Reinoud Knops, Gust H. Bardy, Riccardo Cappato, Pierpaolo Lupo, Craig Barr and Andrew A. Grace, HRS 2009, Boston, Late Breaking Trials
An Entirely Subcutaneous Implantable Cardioverter–Defibrillator

Gust H. Bardy, M.D., Warren M. Smith, M.B., Margaret A. Hood, M.B., Ian G. Crozier, M.B., Iain C. Melton, M.B., Luc Jordaens, M.D., Ph.D., Dominic Theuns, Ph.D., Robert E. Park, M.B., David J. Wright, M.D., Derek T. Connelly, M.D., Simon P. Fynn, M.D., Francis D. Murgatroyd, M.D., Johannes Sperzel, M.D., Jörg Neuzner, M.D., Stefan G. Spitzer, M.D., Andrey V. Ardashev, M.D., Ph.D., Amo Oduro, M.B., B.S., Lucas Boersma, M.D., Ph.D., Alexander H. Maass, M.D., Isabelle C. Van Gelder, M.D., Ph.D., Arthur A. Wilde, M.D., Ph.D., Pascal F. van Dessel, M.D., Reinoud E. Knops, M.D., Craig S. Barr, M.B., Pierpaolo Lupo, M.D., Riccardo Cappato, M.D., and Andrew A. Grace, M.B., Ph.D.
Tripolar parasternal lead (polycarbonate-urethane 55D, 3 mm diameter) + Active can PG

Implantation
Energy Delivered

Energy Delivered

Detection

1. Signals - free of noise and double detection
2. Feature analysis: rate detection
3. Rhythm type - need for therapy
4. Arrhythmia reconfirmation to avoid shocking non-sustained ventricular arrhythmias
5. Capacitor charging
6. All shocks - 80J, reverse polarity possible
7. 50 bpm demand (>3 sec. pause) post-shock pacing (30 sec.) available: 200 mA biphasic transthoracic pulse - can to coil
S-ICD: Group questions
Patient Acceptance?

- 80 J output
- Potential erosion/migration issues (tunneling along rib margin and parasternally)
- No painless therapies (ATP)
- No bradycardia support
- No heart failure monitors
- No remote patient follow up
General anesthesia to deliver subcutaneous lead?

• Do you typically implant devices under general anesthesia?
• What kind of anesthesia do you use to place subcutaneous leads?
• Would this affect your interest in this technology if general anesthesia was required?
Will longer time to therapy impact acceptance?

• Currently devices that deliver 36J can deliver therapy in <10 seconds
• These devices deliver nearly twice the energy and will take longer to charge, maybe 20 seconds
• At what time does syncope become a concern?
Conclusions:

• Development of an effective “leadless” (or totally extravascular) ICD system is a challenge, but not an insurmountable one
Conclusions:

- There may be potential advantages, including the ease of implantation, reduction in total therapy cost, and more widespread implantation capability due to the simplicity of the surgical approach.
Conclusions:

- Further investigation is warranted to allow more widespread use of ICDs in patients who have indications for primary prevention devices.