NOVEL DEVICE TECHNOLOGIES

Leadless Pacemakers and Subcutaneous ICDs

Do the Benefits Outweigh MRI Incompatibility?

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Disclosures

- None
Background

- PPMs and ICDs are very effective therapy for treating brady-arrhythmias and VT/VF.
- Short- and long-term complications are mostly related to intravascular leads.
- These complications can be as high as 20% especially in a patient receiving the device at a young age.
Complications:
- Perforation
- Dislodgement
- Pneumothorax
- Cardiac tamponade
- Lead failure
- Inappropriate therapy
- Infection
- Vascular complications
- Extraction
New Solutions

- Leadless devices
- Subcutaneous systems
Micra™ Transcatheter Pacing System

- 25.9 mm, < 1cc miniaturized VVIR pacemaker
- 10 year longevity
- Percutaneous access to RV apex via femoral vein
- Active fixation via 4 self-expanding “tines”
Patient selection

Poor venous access
H/o or high risk for infection
Hemodialysis
High risk for complications
Multiple lead fractures
Severe comorbidities
Pulmonary disease (pneumothorax)
Difficult anatomy
Congenital heart disease
Micra

23 F

Micra delivery system

Introducer and dilator

Guide wire

Needle

http://www.cardiostim.com/?IdNode=958&Zoom=0b3432ba3d00a5e85ce68df41f643ccf&Lang=GB

• Prospective, multicenter, historical comparison study
• Successfully implanted in 719/715 (99.2%) pts
• **Primary safety endpoint**: Freedom of system- or procedure related major complications: 96% (CI 93.9-97.3, \( p<0.001 \)).
• **Primary efficacy endpoint**: Low stable pacing thresholds at 6 months: 98% (CI 96.1-99.5, \( p<0.001 \)).
• 28 major complications; no dislodgements (HR 0.49; CI 0.33-0.75; \( p=0.001 \)).

**Absence of major complications**
Differences

- **Nanostim (St Jude Medical)**
  - 18 Fr Introducer
  - Protective cover
  - Volume 1.0 cc (l=42mm)
  - Conducted communication
  - Active fixation screw
  - Extraction catheter developed and used
  - MRI compatible as of 3/2016!
  - FDA pending

- **Micra (Medtronic)**
  - 23 Fr Introducer
  - Long introducer
  - Volume 0.8 cc (l=26mm)
  - RF communication
  - Passive fixation tines (nitinol)
  - Extraction with conventional material (no human data)
  - Not MRI compatible
Subcutaneous ICD
SICD
SICD

- Completely subcutaneous ICD system.
- It delivers 80-J transthoracic shocks via a subcutaneous pulse generator implanted in the left lateral chest.
- and a subcutaneous left parasternal lead-electrode.
- Approval in U.S. by FDA in 2012 on the basis of pilot studies and the European (EFFORTLESS) S-ICD Registry (~890 patients).
EFFORTLESS Trial: HRS 2016

- 985 patients (mean age 48 years; 28% women) implanted with Emblem S-ICD
- 8/2009 – 12/2014, 42 sites, 50% retrospective and 50% prospective
- **Primary endpoints:** 30- and 360-day complication rates and inappropriate shocks
- Average follow-up was 3.1 years, with 8% of patients completing 5 years of follow-up.

**Complications:**
- Infection prompted device extraction: 24 (2.4%).
- Failed conversion at implant: 4 (0.4%).
- Brady pacing needed: 1 (0.1%).
- Only 11 patients needed a change of device.
- No lead fractures.
- Freedom from complications 99.7% at 30 days, 98% at 360 days.

**Inappropriate shock** rate: 8.1% at 1 year, 11.7% at 3 years (before new algorithms that can reduce to 3.8%)

97.4% conversion rate, with a 100% clinical efficacy, 99.5% successful testing at implant had acute conversion testing.
SICD

- Connector Pin (Compatible with Cameron Health S-ICD only)
- Proximal Sensing Electrode
- Defibrillation Coil
- Distal Sensing Electrode
- Anchoring Hole

- Max Diameter 4.0 mm
- Diameter 3.0 mm
- 8 cm
- 45 cm

- Cameron Health, Inc.
  - MODEL 1010
  - SN 1010-X123456
  - San Clemente, CA USA
2008: 1st generation

- 15.7 mm
- 69.6 cc
- 145 gram

→

2015: 2nd generation

- 12.7 mm
- 59.5 cc
- 130 gram
Xyphoid (lower margin of the heart)

Mid-axillary line
(posterior margin of the heart)
Ideal Patients

• Teenagers/young adults

• Channelopathies without need for routine pacing (usually young patients)

• Congenital or structural cardiac abnormalities or with limited or difficult vascular access

• Awaiting cardiac transplantation

• H/o or high risk for infection (hemodialysis, chemotherapy, indwelling catheters)
The PRAETORIAN Trial  
(investigator initiated)

- S-ICD versus transvenous ICD
- Randomized, multicenter (EU+US; 35 sites)
- Inclusion: class I or IIA indication for ICD
- Exclusion: Indication for pacing (brady, CRT or ATP)
- 2x425 patients (FU > 4.5 yrs)
- Primary endpoint: Composite of inappropriate shocks + complications

- Study design published AHJ May 2012
- Status: enrolling: n= ~710 (goal 850)
Future wishlist?

- Size reduction
- MRI compatibility
- Event monitoring
- Improve Inappropriate Shock Management
- ATP and Bradypacing
Animal Studies: S-ICD and Leadless ATP pacemaker

Full animal dataset (n=16):

HRS 2016 San Francisco
Future generation S-ICD

Combined with a Leadless Pacemaker for:

- Sensing confirmation
- ATP
- Bradypacing
CONCLUSION

- Leadless devices have fewer long-term complications
- Durable performance
- Do not fulfill all pacing requirements at this point
- For now: Niche but may become standard of care some day....