INNOVATIONS IN DEVICE THERAPY:
Subcutaneous ICDs, Leadless Pacemakers,
CRT Indications

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Disclosures: ACC Foundation: Consultant; Biosense / Webster: Consultant, Investigator; Medtronic: Consultant, Investigator
TRANSVENOUS ICD LEAD ISSUES

- TV ICD lead failure estimated at 0.68%-3.75% annually
  - Lead survival at 2 years: 91-99%
  - Lead survival at 5 years: 81-98%
  - Lead survival at 8 years: 60-95%

- Up to 1/10 PM implants associated with adverse events
  - Lead related (dislodgement, fracture, insulation failure, infection, cardiac perforation, venous occlusion, tricuspid regurgitation)
  - Surgical pocket or generator related (skin erosion, hematoma, infection)
SUBCUTANEOUS ICD

• Indications
  – Current indication for ICD implantation
  – Not suited for pts who need
    • Pacing for bradycardia
    • Pacing for VT
    • CRT

• Initial target populations
  – Unfavorable anatomy, venous occlusion
  – Prior transvenous device infection or high risk for infection
  – Younger patients with need for lifelong therapy
DEVICE / IMPLANT CONSIDERATIONS

- Surface ECG screening
- Sensing vectors
- Minimal programming
  - Unconditional zone
  - Conditional zone – morphology algorithms to discriminate SVT, cardiac signal oversensing
- DFT testing at 65 J
  - Device delivers 80J
- Large PG size (60-70 cc)
- Can provide 30 s post shock demand pacing
- Episode EGM storage (not remote monitoring)
EFFORTLESS REGISTRY: REAL WORLD EXPERIENCE

- 472 pts, mean 18 mo f/u
- Age 49±18 yr
- LVEF 42±19%
- 63% primary prevention
- Heart disease:
  - Ischemic (37%)
  - Channelopathy/IVF (21%)
  - HCM (8%)
  - Other nonischemic CM (23%)
- Device infection 4%, 2.2% required explant
- One arrhythmic death

Lambiase et al, EHJ 2014; 35:1657-1665
S – ICD FUNCTION

- 882 pts followed for mean of 651 days
- A total of 111 VT/VF episodes treated in 59 patients.
- Single shock successful in terminating VF in 90.1% of episodes, and 98.2% of VT/VF episodes after 5 shocks

- Pocket hematomas 0.4% of pts
- Superficial infection treated conservatively in 0.3% of pts
- Infection requiring device removal or revision occurred in 1.7% of pts

Burke et al, J Am Coll Cardiol 2015. 60:1605-1650
Subcutaneous Versus Transvenous Implantable Defibrillator Therapy
A Meta-Analysis of Case-Control Studies

Indranill Basu-Ray, MD, a Jing Liu, MD, b Xiaoming Jia, MD, b Michael Gold, MD, c Kenneth Ellenbogen, MD, d James DiNicolantonio, PharmD, a András Komócsi, MD, e András Vorobcsuk, MD, g Jitae Kim, BS, h Hamid Afshar, MD, i Wilson Lam, MD, i Niles Mathuria, MD, a Mehdi Razavi, MD, a Abdi Rasekh, MD, a Mohammad Saeed, MD a

A

B

C

D

E

F

JACCEP 2017: online before print
PRAETORIAN TRIAL

- Noninferiority randomized comparison of single chamber TV-ICD vs S-ICD
- Primary endpoint: composite of device-related complications and inappropriate shocks
- Secondary endpoints:
  - Device related complications
  - Inappropriate shocks
  - Appropriate shocks
  - QOL, MACE, death, syncope
- Target enrollment 700 pts
- First enrollment 2/2011
- Estimated completion 2018

Olde Nordkamp et al Am Heart J, 2012; 163:753-760
LEADLESS TRANSVENOUS PACING

• Up to 1/10 PM implants associated with adverse events
  – Lead related (dislodgement, fracture, insulation failure, infection, cardiac perforation, venous occlusion, tricuspid regurgitation)
  – Surgical pocket or generator related (skin erosion, hematoma, infection)

• Small (1cc) self contained devices with encapsulated battery, electronics, and electrodes have been developed

• Implantation via a transfemoral venous delivery-retrieval device with fixation in the RV

• Current devices for single chamber pacing indication only
LTP: SJM NANOStim

- Dimension 4.2 X 0.6 cm
- Active fixation, rate adaptive
- Successful implant 504/526 pts (96%)
  - Implant time 47±25 min
- 6 mo adverse event rate 6.7%
  - 1.6% perforation
  - 1.1% dislodgement
  - 0.8% new device for elevated pacing threshold

LTP: MEDTRONIC MICRA

- Dimension 2.6 X 0.7 cm
- Rate adaptive, APC
- Passive fixation
- Successful implant 719/725 pts (99%)
- 6 mo adverse event rate 4%
- Perforation or effusion 1.6%, elevated threshold
- requiring revision 0.2%
- no dislodgements

FUTURE PERSPECTIVES

• Unresolved issues:
  – Battery longevity
  – Long-term stability of pacing parameters
  – Long-term ease of removal

• Potential integration into more complex devices

JACC 2015; 65:2207
CURRENT CRT INDICATIONS

Patient with cardiomyopathy on GDMT for ≥3 mo or on GDMT and ≥40 d after MI, or with implantation of pacing or defibrillation device for special indications

LVEF ≤35%

Evaluate general health status

Comorbidities and/or frailty limit survival with good functional capacity to <1 y

Continue GDMT without implanted device

Acceptable noncardiac health

Evaluate NYHA clinical status

NYHA class I
- LVEF ≤30%
- QRS ≥150 ms
- LBBB pattern
- Ischemic cardiomyopathy
- QRS ≤150 ms
- Non-LBBB pattern

NYHA class II
- LVEF ≤35%
- QRS ≥150 ms
- LBBB pattern
- Sinus rhythm
- LVEF ≤35%
- QRS 120-149 ms
- LBBB pattern
- Sinus rhythm
- LVEF ≤35%
- QRS ≤150 ms
- Non-LBBB pattern
- Sinus rhythm
- QRS ≤150 ms
- Non-LBBB pattern

NYHA class III & Ambulatory class IV
- LVEF ≤35%
- QRS ≥150 ms
- LBBB pattern
- Sinus rhythm
- LVEF ≤35%
- QRS 120-149 ms
- LBBB pattern
- Sinus rhythm
- LVEF ≤35%
- QRS 120-149 ms
- Non-LBBB pattern
- Sinus rhythm
- LVEF ≤35%
- QRS 120-149 ms
- Non-LBBB pattern
- Sinus rhythm

Special CRT Indications
- Anticipated to require frequent ventricular pacing (>40%)
- Atrial fibrillation, if ventricular pacing is required and rate control will result in near 100% ventricular pacing with CRT

J Am Coll Cardiol 2012. 60:1297-313
### CRT Benefit in Non-LBBB

#### Study or Subgroup

<table>
<thead>
<tr>
<th></th>
<th>Risk Ratio IV, Random, 95% CI</th>
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<tbody>
<tr>
<td><strong>Death</strong></td>
<td></td>
<td></td>
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<tr>
<td>MADIT-CRT (non-LBBB)</td>
<td>1.57 [1.03, 2.39]</td>
<td></td>
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<tr>
<td>RAFT (non-LBBB)</td>
<td>0.82 [0.51, 1.32]</td>
<td></td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>1.15 [0.61, 2.16]</td>
<td></td>
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</tbody>
</table>
| Heterogeneity:  
  \( \tau^2 = 0.16 \);  
  \( \chi^2 = 4.02, \text{df} = 1 (P = 0.04) \);  
  \( I^2 = 75\% \) |
| Test for overall effect:  
  \( Z = 0.42 (P = 0.67) \) |
| **Heart failure** |                                |                                |
| MADIT-CRT (non-LBBB) | 1.13 [0.80, 1.60]              |                                |
| RAFT (non-LBBB)  | 1.09 [0.73, 1.62]               |                                |
| Subtotal (95% CI)| 1.11 [0.86, 1.45]               |                                |
| Heterogeneity:  
  \( \tau^2 = 0.00 \);  
  \( \chi^2 = 0.02, \text{df} = 1 (P = 0.89) \);  
  \( I^2 = 0\% \) |
| Test for overall effect:  
  \( Z = 0.80 (P = 0.42) \) |
| **Death or heart failure** |                            |                                |
| CARE-HF (RBBB)  | 0.81 [0.52, 1.28]               |                                |
| COMPANION (non-LBBB) | 0.86 [0.63, 1.17]              |                                |
| MADIT-CRT (non-LBBB) | 1.27 [0.94, 1.73]              |                                |
| RAFT (non-LBBB)  | 1.03 [0.75, 1.42]               |                                |
| REVERSE (non-LBBB) | 0.50 [0.11, 2.29]               |                                |
| Subtotal (95% CI)| 0.99 [0.82, 1.20]               |                                |
| Heterogeneity:  
  \( \tau^2 = 0.01 \);  
  \( \chi^2 = 4.95, \text{df} = 4 (P = 0.29) \);  
  \( I^2 = 19\% \) |
| Test for overall effect:  
  \( Z = 0.09 (P = 0.92) \) |

*Cunnington et al, Heart 2015; 101: 1456-1462*
WOMEN AND CRT

CRT FOR NON-LBBB AND LONG PR INTERVALS

MADIT CRT SUBSTUDY

Kutyifa et al, Circulation A&E 2014; 7:645-651
NEW DIRECTIONS IN CRT

• Clinical response rate ~ 70%, objective indices (LVEF improvement, reduced ventricular volumes) in ~ 50%

• Practical considerations
  – % biventricular pacing as close to 100% as possible
  – Major issues are ventricular ectopy and AF
  – Assure LV contribution to pacing on surface ECG

• Quadripolar leads improve transvenous lead placement success, may be associated with reduced mortality

• Targeted placement at site of latest LV activation (electrogram timing) or contraction (LV strain imaging)

• Endocardial lead placement appears to produce better hemodynamic response, and allows tailoring to individual abnormal contraction patterns (AL-SYNC, WISE-CRT)
SUMMARY

• Use of Subcutaneous ICD expanding rapidly
  – High effectiveness for sensing and terminating ventricular arrhythmias has been maintained
  – Adverse events declining with experience
• Initial experience with leadless pacemakers promising, longer follow-up needed, size of target population unclear
• CRT: new twists
  – Gender interaction with QRS duration and efficacy
  – Possible benefit in non-LBBB with long PR intervals