Cardiac Devices—Past, Present, and Future

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11 September 2016

Outline

• Introduction
• Native conduction system
• Indications for PPMs
• Indications for ICDs
• Typical troubleshooting
• What’s on the horizon?
• Left atrial appendage closure
Permanent Pacemakers

- Treat slow heart rhythms
- If the heart is in its own rhythm, the pacemaker only observes
- If the heart slows down, the pacemaker jumps in and keeps the heart rate from dropping
- Pacemakers do not prevent atrial fibrillation
- They do not treat fast heart rhythms
  - But most do have a tachycardia log, and will keep track of fast atrial and ventricular rates

Implantable Cardioverter-Defibrillator (ICD)

- Treat a fast heart rhythm
  - Ventricular tachycardia/ventricular fibrillation
- All modern ICDs are also pacemakers
- Treat arrhythmias with two strategies
  - Antitachycardia pacing
  - High energy shocks
Native conduction

Sinoatrial (SA) Node
- Prevent impulse generation in the SA node
- Inhibit impulse conduction

Atrioventricular (AV) Node

Diseased Heart Tissue May:

- Prevent impulse generation in the SA node
- Inhibit impulse conduction
Pacemaker Components Combine with Body Tissue to Form a Complete Circuit

- Pulse generator: power source or battery
- Leads or wires
- Cathode (negative electrode)
- Anode (positive electrode)
- Body tissue

Pacemakers

- Treat slow heart rhythms
  - Disorders of impulse formation
  - Disorders of impulse propagation
- Implanted in the infraclavicular region with 1-3 leads placed in the heart
- Very reliable
- Normal follow-up involves interrogation of device every 6 months
- "battery" lasts 8-10 years
A Brief History of Pacemakers

Pacemaker--CXR
Pacemakers

• Generally, pacemakers will observe the native heart rhythm, and only pace if native activity is not sensed
• This allows for maximal native conduction, which is preferred over pacing
• Patients with pacemakers have minimal restrictions
  – No arc welding
  – No large engine mechanical work
  – No using a chainsaw
  – Generally can not undergo MRI scanning, but we can do MRIs on pts with PPMs at OHSU

Pacemaker indications

• Symptomatic bradycardia
  – Very broadly defined
  – Includes
    • Heart block
    • Sick sinus syndrome
    • Chronotropic incompetence
    • Syncope (sometimes)
### Pacemaker Code

<table>
<thead>
<tr>
<th>I Chamber Paced</th>
<th>II Chamber Sensed</th>
<th>III Response to Sensing</th>
</tr>
</thead>
<tbody>
<tr>
<td>V: Ventricle</td>
<td>V: Ventricle</td>
<td>T: Triggered</td>
</tr>
<tr>
<td>A: Atrium</td>
<td>A: Atrium</td>
<td>I: Inhibited</td>
</tr>
<tr>
<td>D: Dual (A+V)</td>
<td>D: Dual (A+V)</td>
<td>D: Dual (T+I)</td>
</tr>
<tr>
<td>O: None</td>
<td>O: None</td>
<td>O: None</td>
</tr>
<tr>
<td>S: Single (A or V)</td>
<td>S: Single (A or V)</td>
<td></td>
</tr>
</tbody>
</table>

### Pacemaker interrogation

- **Programmer**
- **Wand**
Pacemaker follow up

- Interrogation every 6 months
- Battery lasts 8-10 years
- Outpatient procedure to change generator (battery)
- Every patient should have an ID card in their wallet
  - And know the brand of their device
    - Biotronik
    - Boston Scientific/Guidant
    - Medtronic
    - St. Jude Medical

Implantable cardioverter-defibrillators (ICDs)

- Treat fast ventricular heart rhythms
  - Ventricular tachycardia
  - Ventricular fibrillation
- Every ICD has a pacemaker function
  - Except for the S-ICD
- Implanted in the infraclavicular region with 1-3 leads placed in the heart
- Very reliable
- Normal follow-up involves interrogation of device every 3 months
- “battery” lasts 3-5 years
Implantable Cardioverter-Defibrillators

- Terminate fast ventricular rhythms in two ways
  - Anti-tachycardia pacing for VT
    - Pace slightly faster than VT
    - Can “break” reentrant circuit
    - Generally felt as light palpitations by the patient
  - High energy shock
    - Depolarizes all heart cells
    - Terminates all electrical activity
    - Normal rhythm then starts
    - Feels like getting kicked in the chest by a horse
      - But this is a life-saving event!
      - Often, patients will lose consciousness before shock is delivered

Implantable Defibrillators (1989-2001)

- 209 cc
- 113 cc
- 80 cc
- 80 cc
- 72 cc
- 54 cc
- 62 cc
- 49 cc
- 39.5 cc
- 39 cc
- 39.5 cc
- 39 cc
- 39.5 cc
- 36 cc
ICD Evolution

High Voltage Leads

SVC Coil (Superior Vena Cava)

RV Coil (Right Ventricle)
ICD Evolution

Evolution of ICD Therapy and Adoption: 1980 to Present

AHA/ACC guidelines for placement of an ICD:

• Secondary prevention: History of VT/VF/SCD
  – Includes inducible VT/VF in the EP lab
• Primary prevention:
  – Ischemic and nonischemic cardiomyopathy with
    • Left ventricular ejection fraction less than 35%
  – High risk inherited cardiomyopathies
    • Long QT syndrome and other channelopathies
    • Hypertrophic cardiomyopathy
MADIT-II
Multicenter Automatic Defibrillator Implantation Trial II

• 1232 patients with prior MI and EF<=30%
  – At least 30 days following last MI
  – At least 3 months since last revascularization
  – No history of VT/VF
• Randomized:
  – conventional Rx
  – ICD
• Trial stopped early


SCD-HeFT
Sudden Cardiac Death in Heart Failure Trial

• 2521 patients with EF<=35%, Class II or III CHF
  – 52% ischemic, 48% non-ischemic
• Randomization to:
  – Conventional Rx
  – Amiodarone
  – ICD

SCD-HeFT

Ischemic

Non-ischemic

Biventricular Pacemakers
Cardiac Resynchronization

- For patients with profound heart failure and LBBB, a special pacemaker can be placed
- This is usually combined with an ICD
- A “Bi-V” has pacing leads placed
  - To right atium (normal location)
  - To right ventricle (normal location)
  - To coronary sinus (lateral left ventricle)
  * Allows for resynchronization of ventricular contraction
Cardiac Resynchronization Therapy--CXR

CARE-HF Results

<table>
<thead>
<tr>
<th>No. at Risk</th>
<th>Cardiac resynchronization</th>
<th>Medical therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>409</td>
<td>376</td>
<td>331</td>
</tr>
<tr>
<td>213</td>
<td>391</td>
<td>192</td>
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<tr>
<td>89</td>
<td>86</td>
<td>71</td>
</tr>
<tr>
<td>8</td>
<td>6</td>
<td>5</td>
</tr>
</tbody>
</table>

P<0.002
Indications for cardiac resynchronization therapy

- Class III heart failure symptoms
  - On optimal medical therapy
- Left ventricular ejection fraction less than 35%
- Left bundle branch block on ECG
- Generally combined with an ICD
  - Although BiV pacers are available

Micra leadless pacemaker

First leadless pacer available in US

- Single chamber ventricular pacing only
- Delivered from groin with a 27Fr (!) sheath
- Secured via flexible tines
- Battery 6-8 years
Totally subcutaneous ICD
S-ICD

- FDA Approved
- No pacing
  - Brady
  - ATP
- Doesn’t have any hardware in the vaculature

Cameron Health
Device management major concerns

- Device erosion/pain at pocket
- Infection
- Lead failure
- Device recalls
- Extracardiac stimulation (BiVs)

Anticoagulation management at time of PPM/ICD procedure

- Traditionally, coumadin held and heparin/enoxaparin “transition” used
  - This leads to a high incidence of pocket hematomas
- Performing device procedures on therapeutic warfarin is safe and leads to lower risks of hematoma

Cheng... Henrikson, HR 2011; 8:536-40
Birnie, NEJM 2013; 368:2084
MRIs on patients with PPMs and ICDs

- Traditionally, patients with PPMs and ICDs have been excluded from MRI scans
  - Concerns over damage to device by the magnet
- These concerns are largely absent in current generation devices
- At OHSU, we can do any clinically indicated MRI on most patients with PPMs and ICDs under a current research protocol
  - We have completed over 150 scans without any significant complications
  - For more information, please email me (henrikso@ohsu.edu) or call Karen at 503 494 1459

Why close the left atrial appendage?

- Atrial fibrillation is a strong risk factor for stroke
- Presumably, this relates to thrombus in the heart
  - Chiefly in the left atrial appendage
- Thus, closing the left atrial appendage should reduce the risk of stroke
Percutaneous closure

- Stand alone open closure is not done
- Several potential percutaneous devices being developed/tested
- Major systems are Lariat, Watchman, and Amplatzer cardiac plug (ACP)
- Watchman was in development for 10 years
  - Involves placement of a covered cage in the appendage
Watchman data

• Endovascular “cage” placed in LA via transseptal puncture
• Occludes the left atrium and stimulates endothelialization
• Protect AF study
  – 707 patients with afib and CHADS2>=1 randomized 2:1 to Watchman v. continued warfarin
  – Warfarin continued for 45 days in watchman arm, then clopidogrel for 4.5 months, then lifelong ASA
• Now FDA approved!
  – Watchman will be available at OHSU starting next month

Watchman indications

- Increased risk of stroke or systemic embolism based on CHADSVASC score
- Deemed suitable for warfarin
- Have an appropriate rationale to seek a non-pharmacologic alternative to warfarin

Lariat
left atrial appendage closure

Bartus 2013, JACC 62:108
Figure 4   TEE Guidance for the Closure of the LAA

Transesophageal echocardiography (TEE) imaging of the LA and LAA at baseline (A) and during the placement of the balloon at the orifice of the LAA (B). The balloon is used to define the orifice of the LAA.

Bartus 2013, JACC 62:108
Criteria for Lariat

- atrial fibrillation
- a CHADS2 score of 2 or higher
- contraindication to warfarin.
- **No prior chest surgery**
- not being offered to patients who just want to get off warfarin (or the equivalent)

Thanks!

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Implantable Pacemaker Systems Contain the Following Components:

- Implantable pulse generator (IPG)
- Lead wire(s)
Leadless pacemaker

- Several companies have devices in development
- Single chamber pacing only
- Investigational only

Lariat consortium complications

Major Bleeding Events During Hospitalization in the Study Population (n = 154)*

<table>
<thead>
<tr>
<th>Event</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major bleed</td>
<td>14 (9.1)</td>
</tr>
<tr>
<td>Any transfusion with overt bleeding</td>
<td>7 (4.5)</td>
</tr>
<tr>
<td>Overt bleed, hemoglobin drop &lt;5 g/dl</td>
<td>5 (3.2)</td>
</tr>
<tr>
<td>Overt bleed, hemoglobin drop ≥5 g/dl</td>
<td>3 (1.9)</td>
</tr>
<tr>
<td>Cardiac tamponade</td>
<td>7 (4.5)</td>
</tr>
<tr>
<td>Bleeding requiring surgical control</td>
<td>2 (1.3)</td>
</tr>
<tr>
<td>Bleeding requiring vasoactive agents</td>
<td>4 (2.6)</td>
</tr>
<tr>
<td>Fatal bleeding</td>
<td>0</td>
</tr>
</tbody>
</table>

Price, JACC 2014; epub prior to print
Lariat consortium

- Retrospective report of Lariat experience at 8 centers in the US
- Total of 154 patients
- Failures & Complications
  - 60% on oral anticoagulation pre!
  - 25% on oral anticoagulation post!
  - 20% residual leak rate at follow up

Price, JACC 2014; epub prior to print

Lariat consortium failures

Reasons for Procedural Failure of Left Atrial Appendage Ligation With the Lariat Device (N = 22)

- Lariat unable to be deployed: 9
  - Pericardial adhesions: 5
  - LAA anatomy: 2
  - Aborted procedure after RV perforation: 2

Price, JACC 2014; epub prior to print