Leadless Devices: Who Should Receive One?

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Background
Risks Associated with Traditional Pacemakers

• 350,000 pacemakers annually in the U.S. and nearly 1 million worldwide

• Acute traumatic complication (pneumothorax, tamponade) in 2.8% of implants

• 11% lead complication rate at 5 years

• 8% pocket complication rate at 5 years

• Complication requiring reoperation in 8% of implants

Leadless Pacemakers

- Single-chamber, programmable VVIR device
- Capsule contains battery and electronics
- Inserted into right ventricle via femoral vein catheter

Leadless Pacemakers - Advantages

• Simplified implant procedure
• Smaller electrode tip allows shorter impulse duration (pulse width) and prolongs battery life
• MRI conditional
• No reported infections
Leadless II study

- Implant successful in 289/300 patients (96%)
- Device met pre-specified efficacy and safety endpoints:
  - 90% of patients had adequate capture threshold and sensing in ITT analysis
  - 7% major adverse event at 6 months

Micra Transcatheter Pacing Study

**Primary efficacy outcome met:**
Stable pacing capture threshold at follow-up

**Primary safety outcome met:**
Freedom from major complication 96% at 6 months
Complication Rates: Micra versus Historic Controls

51% reduction in major complications

2012 ACCF/AHA/HRS Focused Update for Device-Based Therapy of Cardiac Rhythm Abnormalities

Major Class I Indications

• Sinus node dysfunction
• Chronotropic incompetence
• High-degree AV block
  ➢ Symptoms
  ➢ Pause > 3 seconds
  ➢ Rate < 40
  ➢ Infra-Hisian escape rhythm

Trial implant indication:

Micra
- AV block: 15%
- Sinus node dysfunction: 17%
- Chronic AF with bradycardia: 64%
- Other: 4%

Leadless II
- AV block: 9%
- Sinus node dysfunction: 35%
- Chronic AF with AV block: 56%
Single versus Dual-chamber Device

- Permanent AF with pacing indication
- Intermittent pacing need
  - Sinus node dysfunction
  - Post-conversion pauses
- Complete heart block?
Pacemaker selection in CHB

Death from All Causes

Cumulative Risk of Death

- Single-chamber pacing
- Dual-chamber pacing

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<th>Single-chamber pacing</th>
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Heart Failure

Proportion with Event

- Single-chamber pacing
- Dual-chamber pacing

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Pacemaker selection in CHB

- No difference in incidence of atrial fibrillation or stroke
Meta-analysis: Dual-chamber pacing may reduce incidence of AF and stroke

Circulation. 2006;114:11-17.
When to consider Leadless Pacemaker Implantation

• Standard VVI pacemaker indication:
  ➢ Permanent AF with pacing indication
  ➢ Sinus node dysfunction (intermittent pacing indication)
  ➢ Complete heart block (>70 years old, limited function)

• Unique indication:
  ➢ Prior device infection
  ➢ Vascular access issue (dialysis, Porta-cath)
Limitations to Leadless Pacemakers

• Single-chamber devices (< 10% of implants)
• Development of pacemaker syndrome
• Large peripheral access catheter
• Lack of compatibility for upgrade to ICD or CRT
• Unclear management at battery End-of-Life
Management of Leadless Devices at End of Battery Life

Conclusion

• Leadless pacemakers represent new leap forward in technology
• May address the “Achilles’ heel” of traditional pacemaker device
• Appropriate patients include those currently indication for single-chamber device
• May see “creep” in single chamber implants for other indications until technology catches up