Intracardiac Pacemakers

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Pacemakers Indications

Pacemakers treat *slow* heart rates:

- sinus bradycardia
- sick sinus syndrome (bradycardia-tachycardia syndrome)
- atrioventricular heart blocks

Slow heart rates can develop as a result of tissue damage, due to heart disease for example.

Conventional Pacemakers

Conventional pacemakers have two components:

Generator (Battery)

- The generator creates the electrical pulse.
- It is placed in a subcutaneous pocket, typically in the upper chest.

Lead (Electrode)

- A lead or leads deliver the electrical pulse to the heart tissue.
- Leads are usually inserted transvenously into the right atrium and/or right ventricle.
- Leads are tunneled subcutaneously to connect to the generator.

Intracardiac Pacemakers – New Technology

Intracardiac pacemakers are a new technology in which the generator and the electrode are combined into a single device implanted entirely within the heart chamber.

- A subcutaneous pocket for the generator is not used.
- Subcutaneous tunneling for the lead is also not used.

Lack of subcutaneous components eliminates the source of potential complications such as pocket infection, skin erosion and lead fractures.

Intracardiac Devices

Intracardiac pacemakers have the same basic components, but they are miniaturized.

- The generator (battery) and lead (electrode) are combined into one self-contained device.
  - Despite use of the term “leadless”, the pacemaker does have an electrode.
- Though it varies by model, leadless pacemakers are about the length of a quarter.

Insertion Procedure

- The intracardiac pacemaker is delivered by transcatheter approach, typically via puncture of the femoral vein.
- Under fluoroscopy, the pacemaker is advanced into the right atrium, through the tricuspid valve and into the right ventricle.
- The electrode is then secured to the heart tissue.
- The device is tested and programmed.
- The delivery catheter is withdrawn, leaving the pacemaker within the heart chamber.

Device Replacement

As with all pacemakers, the sealed battery within the intracardiac pacemaker device eventually reaches end-of-life.

When this happens, the entire device must be replaced. There are two possible procedures:

- A new device is inserted, while the existing device is removed via a transcatheter approach.
- A new device is inserted, while the existing device is permanently turned off and simply abandoned within the heart chamber.

Device Revision

Although infrequent, it may sometimes happen that the intracardiac pacemaker becomes dislodged within the heart chamber.

- This can lead to loss of electrode contact with the heart tissue and inappropriate or absent pacing.
- Depending on the clinical scenario, the device can be replaced or revised.
- Revision involves snaring the existing device via a transcatheter approach and repositioning it within the heart chamber, performed under fluoroscopy.

Site of Service

It is anticipated that intracardiac pacemakers will be placed in both the inpatient and outpatient sites of service.

- Standard pacemaker procedures are currently performed in both the inpatient and outpatient hospital setting.
- Approximately half of new pacemaker insertion procedures for Medicare patients are performed in the inpatient hospital setting.
- Clinical experience with leadless pacemaker procedures indicates a similar site of service pattern.

Documentation Points

Use of intracardiac pacemakers can be directly identified within the procedure report and from the event log.

- Pocket creation and tunneling are not performed and will not be documented.
- The type of pacemaker will be documented as either “leadless” or “transcatheter”.
  - “Leadless” often appears in the clinical literature, and “transcatheter” refers to the approach.
- Two models are expected to be available in the US in 2016:
  - *Micra*® Transcatheter Pacing System (*Micra TPS*)
  - *Nanostim*® Leadless Pacemaker

Looking Ahead

- At this time, intracardiac pacemakers are available for *single-chamber* pacing, with the device in the right ventricle.
- It is expected that *dual-chamber* pacing will be available in the future, with one device in the right ventricle and a second device in the right atrium.
- Over the next decade or so, there is a potential for leadless pacemakers to become the standard of care.

Data Issues

Having unique ICD-10-PCS codes for insertion of intracardiac pacemakers will enable:

- identification and differentiation of these procedures from conventional pacemaker procedures
- tracking and measurement of utilization over the course of multiple years
- clinically meaningful outcomes analysis based on nationwide data
- development of clinical recommendations supported by data analysis

Clinical Questions?

Micra® is a trademark of Medtronic.
Nanostim® is a trademark of St. Jude Medical.

Caution: Investigational Device. Limited by US law to investigational use.

Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.|
Item approved for U.S. use only.