Pacemakers, ICD’s, and New Devices

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Financial Disclosures

No financial disclosures.
Overview

- Pacing- brief history
  - Leadless “capsule” pacing
  - His bundle pacing
- MRI conditional devices
- ICD
  - Subcutaneous ICD, reduction of shocks
- Future directions
Historical Perspective
History of Pacing

- Pacemaker unit 1957
Evolution of Pacemakers
Transvenous Leads

Active Fixation

- The helix extends into the endocardial tissue
- Allows for lead positioning anywhere in the heart's chamber
Lead Extraction

• Lead removal may be required
  – Infection
  – Malfunction
  – Obstruction of vein
• Due to dwell time, fibrosis and calcification can make removal difficult
Lead Extraction

• Manual extraction

• Mechanical/ Laser Lead Extraction
Lead Extraction
Leadless Pacing
Ventricular pacing only !!
- AF patients
- Rare backup pacing
His Bundle Pacing
Pacemaker leads come into heart through the subclavian vein

Approaching the His bundle

Named for discoverer Wilhelm His Jr. (1863-1934), the His bundle is a collection of highly conductive muscle cells that transmit electric impulses to make the heart’s lower ventricles beat. The His bundle can be stimulated directly, recreating a natural heart rhythm instead of the “elongated” heartbeat that causes problem in some patients over time.
His Bundle Pacing

• Benefits of reducing abnormal ventricular activation are to lessen:
  – Heart failure
  – Atrial fibrillation
  – Decline in ejection fraction

• Cons:
  – May have worsen battery life
  – Long term data lacking
MRI and Cardiac Devices

- MRI’s have long been an issue due to concerns for
  - Lead heating resulting in myocardial injury
  - Device injury leading to pacing malfunction
When Someone Forgets MRI Has a Magnet...
MRI Conditional Devices

• For 5 years, pacemaker and ICD systems labelled “MRI-conditional” by FDA
  – Generator and leads

• Beware…
  – MRI Tesla and protocol vary
Non-MRI Conditional Device?

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Assessing the Risks Associated with MRI in Patients with a Pacemaker or Defibrillator

CONCLUSIONS

In this study, device or lead failure did not occur in any patient with a non-MRI-conditional pacemaker or ICD who underwent clinically indicated nonthoracic MRI at 1.5 tesla, was appropriately screened, and had the device reprogrammed in accordance with the prespecified protocol. (Funded by St. Jude Medical and others; MagnaSafe ClinicalTrials.gov number, NCT00907361.)

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Urinary Stream Wars

THE AUTHORS REPLY: The theoretical concerns of Delfino et al. are not supported by the clinical results...Although not every potential...combination was tested, no serious adverse events were observed...The results show...access should not be denied to these patients owing to an overestimation of the risk...

To the Editor: “Inadequate screening...nonadherence to labeling...carry a serious risk of adverse advents, including death...Physicians should include the very real risk of serious adverse events in risk-benefit decisions with regard to performing MRI scans on an off-label basis.

Jana G. Delfino, Ph D.
Ingmar Viohl, Ph. D.
Terry O. Woods, Ph. D.
Food and Drug Administration, Silver Spring, MD
Subcutaneous ICD’s (S-ICD)

- Completely subcutaneous
  - Larger output (80 J) requires larger device
  - Battery life is less
  - More sedation required
  - No pacing component to device
Subcutaneous ICD’s (S-ICD)
Subcutaneous ICD’s (S-ICD) Why?
Subcutaneous ICD’s (S-ICD)

• Considered less invasive option
  • No transvenous lead requirement
  • Leads *should* last longer

• Most useful in patients:
  • Infection is an overwhelming concern
  • Transvenous access problematic (ie dialysis)
  • ? Younger patient (because the transvenous lead will fail)
• A 24 yo Brugada patient with aborted sudden cardiac death who is on long-term dialysis, has had recurrent bacteremia, and is concerned about risk of lead malfunction presents for defibrillator implant.

• You recommend:
Subcutaneous ICD’s (S-ICD)

• Caveats:
  • *Does not provide bradycardia pacing support*
  • Does not provide antitachycardiac pacing
  • Device larger (slightly)
  • Battery life reduced
  • Long-term data missing
ICD Shock Reduction
ICD’s Reduce Mortality
ICD Shock

• Shocks typically occur due to
  – Appropriate (VT/VF)
  – Inappropriate (Atrial Fibrillation/ Flutter)

• Devices now increasingly reduce shock rate by affecting both of these
  – “Pace terminate” VT
  – New algorithms to not inappropriately shock
Ways to Reduce Shocks

- Anti-tachycardia pace termination

Low inappropriate shock rates in patients with single- and dual/triple-chamber implantable cardioverter-defibrillators using a novel suite of detection algorithms: PainFree SST trial primary results

Angelo Auricchlo, MD, PhD, Edward J. Schloss, MD, FHRs, Takashi Kurita, MD, Albert Meijer, MD, Bart Gerritse, PhD, Steven Zweibel, MD, FHRs, Faisal M. AlSmaili, MD, FHRs, Charles T. Leng, MD, Laurence D. Sterns, MD on behalf of the PainFree SST Investigators
The Future

• Bluetooth technology
  – Remote monitoring, patient data?
  – Security concerns

• Biologic pacemakers

• Novel charging technology
Biologic pacemakers, novel charging
Thank you!

- Please call if I can be of assistance!

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