Implantable Devices
...what you need to know

Jean A. Lehman, R.N., RCIS
District Educator
Medtronic
Cardiac Rhythm Management
Indications for Devices

- Pacemakers
- Defibrillators
- Biventricular Devices
Pacemaker Indications

- Sinus node dysfunction
- AV block
- Bifascicular and trifascicular block
- Hypersensitive Carotid Sinus Syndrome (CSS)
- Vasovagal Syncope (VVS)
- AV block associated with myocardial infarction
- Pacing after cardiac transplantation
- Children and adolescents
Causes of SND

- Intrinsic Dysfunction
  - Idiopathic degenerative (most common, may include effects of hypertension)
  - Ischemic chronic CAD (may involve sinus node artery during AMI)
  - Infiltrative disorders (amyloidosis, tumors)
  - Inflammatory/postinflammatory pericarditis
  - MS disorders (Duchenne’s)
  - Collagen-vascular disease
  - Postop Mustard’s procedure, atrial septal defect repair
Causes of SND

- Extrinsic Dysfunction
  - Drug effects
  - Electrolyte disturbances (hyperkalemia)
  - Endocrine conditions (hypothyroidism)
  - MI (IWMI)
  - Neurally mediated bradycardia/hypotension
Drugs Affecting Sinus Node

- Antiarrhythmics drugs
  - Amiodarone, flecainide, propafenone, sotalol, quinidine, disopyramide, procainamide
- Antihypertensives
  - Alpha-methyldopa, reserpine, clonidine
- Beta-adrenergic blocking drugs
  - Propranolol, nadolol, pindolol, acebutolol
- Calcium channel blockers
  - Verapamil and diltiazem more than nifedipine
- Miscellaneous
Causes of AV Block

- Atherosclerotic disease (AMI, old MI)
- Calcific infiltration (valvular)
- Cardiomyopathy
- Collagen-vascular diseases (scleroderma)
- Congenital AV block (transposition)
- Idiopathic fibrosis (Lev’s disease)
- Infiltrative, inflammatory, metabolic and endocrine diseases
Drugs Affecting AV Node

- Beta-adrenergic blockers (AV node conduction slowing)
- Cardiac glycosides (enhances the effect of vagal tone)
- Calcium channel blockers (verapamil and diltiazem) and class IC antiarrhythmics (slow conduction)
# Pacemaker Code

<table>
<thead>
<tr>
<th>I: Chamber Paced</th>
<th>II: Chamber Sensed</th>
<th>III: Response to Sensing</th>
<th>IV: Programmable Functions/Rate Modulation</th>
<th>V: Antitachy Function(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>V: Ventricle</td>
<td>V: Ventricle</td>
<td>T: Triggered</td>
<td>P: Simple programmable</td>
<td>P: Pace</td>
</tr>
<tr>
<td>D: Dual (A+V)</td>
<td>D: Dual (A+V)</td>
<td>D: Dual (T+I)</td>
<td>C: Communicating</td>
<td>D: Dual (P+S)</td>
</tr>
<tr>
<td>O: None</td>
<td>O: None</td>
<td>O: None</td>
<td>R: Rate modulating</td>
<td>O: None</td>
</tr>
<tr>
<td>S: Single (A or V)</td>
<td>S: Single (A or V)</td>
<td>O: None</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Patient Mode Preference

- DDDR 59%
- DDIR 13%
- Any Dual 9%
- No Preference 9%
- VVIR 5%
- DDD 5%

Mode Selection Decision Tree

Symptomatic bradycardia

Are atrial tachyarrhythmias present?

Y

N

Is AV conduction intact?

Y

N

Is SA node function presently adequate?

Y

N

SSS

N

CSS, VVS

AAIR

DDDR

DDD, DDI with RDR

DDIR with SV PVARP

Is AV conduction intact?

Y

N

Are they chronic?

Y

N

VVI

VVIR

Is SA node function presently adequate?

Y

N

N

(SSID)

DDD, VDD DDDR

DDDR
Pacing Mode Clinical Trials

DAVID Trial
JAMA 2002;288:3115-23
RV stimulation may be more deleterious in patients with advanced LV dysfunction (ICD candidates); DDDR-70 was worse than VVI-40; more pacing (60%) was seen in DDDR-70; however, only 30.8% of the patients had a QRS>130ms

MOST Trial
Sweeney M, et al. PACE 2002;25:690
(mode selection trial in sinus-node dysfunction)
Hospitalization was not associated with mode but with prevalence of more than 40% RV pacing

Ventricular pacing, not a lack of AV synchrony, is a more important predictor of LV dysfunction

Danish Pacemaker Study
AAI vs. VVI for SSS
Danish pacemaker study: AAI had slightly better survival and was associated with lower occurrence of CHF (native AV conduction is better)

Pacemaker Selection in the Elderly
VVI vs. DDD for Sinus Node Dysfunction or AV block; no difference in quality of life or outcome (CV or death)
Current Strategies to Manage RV Pacing in Patients with Intact AV Conduction

- AAI(R) pacing
- DDD(R) pacing
  - Static AV interval extensions
  - Automatic AV interval extensions
- DDI(R) pacing
- VVI(R) pacing
- Managed Ventricular Pacing (MVP)
  - “AAI(R)” with “DDD(R)” back-up
MVP (Managed Ventricular Pacing) Mode

What is It?

An atrial-based dual chamber pacing mode that provides functional AAI/R pacing with ventricular monitoring and back-up DDD/R pacing, only as needed during episodes of AV block.

- Beat-to-beat AV conduction checks;
  Unacceptable AV ratio (AV block)

- AAI/R

- Conduction restored?

- DDD/R

MVP Basic Operation

**AAI(R) Mode**
Atrial based pacing allowing intrinsic AV conduction

PR Intervals are only restricted by the underlying atrial rate or sensor rate; VS events simply need to occur prior to the next AS or AP.
MVP Basic Operation

**Ventricular Backup**
Ventricular pacing only as needed in the presence of transient loss of conduction
MVP Basic Operation

**DDD(R) Switch**
Ventricular support if loss of A-V conduction is persistent
A significant portion of SND and AVB patients have or will develop atrial fibrillation. How do you appropriately manage their atrial arrhythmias?

- Reduce patient symptoms with quick and precise mode switching
- Assess arrhythmia progression with diagnostics
Disease Prevalence and Progression

AFib
2.3 million

SND
435k

AVB
469k

135k

47k

SND with AFib
Yr 1  Yr 10
31%  57%

AVB with AFib
Yr 1  Yr 10
10%  26%

US Prevalence. Medtronic Internal Data
Pacing for the Prevention of Atrial Fibrillation

- Overdrive pacing
  - Prevents pauses in rhythm
  - Suppresses atrial premature
  - Can be used to pre-excite areas of atrial conduction delay, increasing their refractory period and preventing microreentry
  - Dual site pacing to achieve atrial resynchronization
AT Termination Therapies

- Anti-tachycardia pacing: Ramp or Burst+
  - Burst+: an adaptive burst with 2 premature stimuli at the end of the burst
- Manual 50 Hz High Frequency Burst (AF)
- Optional VVI Backup during the therapy
Indications for Device Therapy

• Evidence and/or general agreement that device therapy is:
  - Beneficial
  - Useful
  - Effective
Indications for Device Therapy

Class II

- Conflicting evidence and/or divergence of opinion as to the necessity of device therapy

- Class IIa
  - Evidence is weighed in favor of device therapy

- Class IIb
  - Evidence is well established
Indications for Device Therapy

• Agreement that device therapy is unnecessary
Indications for ICD

**Class I**

1. **Cardiac Arrest**
   - Due to VT or VF
   - Not due to transient or reversible cause

2. **Spontaneous sustained VT**
   - Structural heart disease must be present

3. **Syncope of undetermined origin with:**
   - Sustained VT that has clinical relevance and/or hemodynamic significance
   - VF induced during EP study when drug therapy to sustained VT is not preferred
Indications for ICD

Class I

4. Nonsustained VT with:
   - Coronary disease
   - Prior MI
   - LV Dysfunction
   - Inducible VF or sustained VT (Non-suppressible by antiarrhythmic drugs)

5. Spontaneous sustained VT
   - Not amenable to other treatments
Indications for ICD

Class IIA

1. LVEF <30% at:
   - 1 month post MI
   - 3 months post coronary revascularization
Indications for ICD

1. Cardiac Arrest
   - Assumed due to VF
   - EP test precluded by other medical conditions
2. Symptomatic sustained VT while awaiting cardiac transplant
3. Conditions with life-threatening risk
   - Long QT Syndrome
   - Hypertrophic cardiomyopathy
6. RBBB and ST Segment Elevation with:
   - Syncope of unexplained origin, or
   - Family history of SCD

7. Syncope and:
   - Structural heart disease
   - Extensive testing failed to identify cause
Indications for ICD

Class IIb

4. Nonsustained VT with:
   - Coronary disease
   - Prior MI
   - LV Dysfunction
   - Inducible VF or sustained VT

5. Syncope of undetermined origin with:
   - Ventricular dysfunction
   - Inducible ventricular arrhythmias
   - All other causes of syncope excluded
Indications for ICD

1. Syncope of undetermined origin
   - Without structural heart disease
   - No inducible VT or VF
2. Incessant VT or VF
3. VT or VF with an ablatable or surgically treatable cause
   - WPW, LVOT VT, ILVT, Fascicular VT
4. Transient or reversible VT
   - Due to AMI, electrolyte imbalance, drugs or trauma
Why Implant Rate Is Rising

- **Advanced Technology**
  - Transthoracic ——> Transvenous
  - Size Reduction - 4 fold
  - Increased Longevity - 2yr ——> 7yr

- **Superior Therapy**
  - MADIT I & II Studies
  - AVID Study
  - Cardiac Resynchronization Therapy Trials
  - SCDHeFT

- Physician Awareness
<table>
<thead>
<tr>
<th>MADIT(^1)</th>
<th>MUSTT(^2)</th>
<th>MADIT-II(^3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MI, EF ≤ 35%, NSVT, inducible VT at EPS, nonsuppressible with AA drug</td>
<td>CAD, EF ≤ 40%, NSVT, inducible VT at EPS (95% MI Hx)</td>
<td>MI, EF ≤ 30%</td>
</tr>
</tbody>
</table>
| 196 pts:  
  101 Conv. Rx  
  95 ICD Rx | 704 randomized pts:  
  353 no EP guided  
  352 EP guided:  
  190 AA drugs  
  161 ICDs | 1232 pts:  
  742 ICD Rx  
  490 Conv. Rx |
| **54% reduction in mortality with ICD Rx**  
 (27 months mean follow-up) | **55-60% reduction in mortality with ICD Rx**  
 (39 months mean follow-up) | **31% reduction in mortality with ICD Rx**  
 (20 months mean follow-up) |

<table>
<thead>
<tr>
<th></th>
<th>I: Shock Chamber</th>
<th>II: Antitachy Pacing Chamber</th>
<th>III: Tachycardia Detection Source</th>
<th>IV: Antibradycardia Pacing Chamber</th>
</tr>
</thead>
<tbody>
<tr>
<td>V</td>
<td>V: Ventricle</td>
<td>V: Ventricle</td>
<td><strong>E-electrogram</strong></td>
<td>V: Ventricle</td>
</tr>
<tr>
<td>A</td>
<td>A: Atrium</td>
<td>A: Atrium</td>
<td>H-hemodynamics</td>
<td>A: Atrium</td>
</tr>
<tr>
<td>D</td>
<td>D: Dual (A+V)</td>
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</table>
Device Complications

- **Acute**
  - Pneumothorax
  - Lead Dislodgment
  - Pocket Hemorrhage
  - Subclavian / Cephalic Vein Thrombosis
  - Infection

- **Assessment**
  - Chest Xray
  - Lead Analysis
    - Change in Threshold
    - Change in Amplitude
    - Change in Impedance
  - Inspect Incision & Arm
  - Antibiotics for Cellulitis
Device Complications

• Chronic
  • Lead Fracture
  • Device Migration
  • Infection

• Assessment and Treatment
  • Chest Xray or Fluoroscopy
  • Lead Analysis
    • Change in Threshold
    • Change in Amplitude
    • Change in Impedance
    • Replace Lead
  • Inspect Incision and Pocket
  • Revision of System
  • Removal of System and Antibiotics if Infection
Evaluation - Therapies

Tachycardia Events

Retrieve

Appropriate
- No Changes
- Optimize

Inappropriate
- Trouble Shoot
  - SVT
  - VT
  - EMI
ICD Shock Perception Problem

Perception:
The only therapy that ICDs can deliver is a shock

Universally Believed:
- Family practice/GPs
- Cardiologists
- Caregivers/family members
- Patients
ICD Shock Perception Problem

Truth:
1) Currently, most ICD therapies are shocks
   - Early defibrillators only shocked
   - Current ICD programming still results in many shocks

2) Most of the shocks could be painless ATP
Truth About Arrhythmias
From the PainFREE™ Rx Clinical Study

True VF accounted for only 3% of all ventricular arrhythmias$^1$

PainFREE Rx Implications

ICD patients can be spared the majority of painful shocks if ATP is programmed as the first therapy for FVT. This could potentially result in:

- Improved patient Quality of Life
- Reduction in potential hospitalizations associated with shocks
- Improved ICD longevity

Studies evaluating the efficacy of ATP therapy in non-CAD patient populations could expand the application of the therapy.

Painfree Programming

Episode duration = 5.3 s

Treatment Approach for Chronic CHF

Adapted from Hunt SA et al. ACC/AHA Guidelines for the Evaluation and Management of Chronic Heart Failure in the Adult, 2001

Stage A
At high risk, no structural disease

Therapy
- Treat Hypertension
- Treat lipids
- Regular exercise
- Discourage alcohol
- ACE inhibition

Stage B
Structural heart disease, asymptomatic

Therapy
- All measures under stage A
- ACE inhibitors
- Beta-blockers

Stage C
Structural heart disease with prior/current symptoms of HF

Therapy
- All measures under stage A

Drugs:
- ACE inhibitors
- Beta-blockers
- Aldosterone blockers
- Digitalis
- Diuretics as needed

CRT

Stage D
Refractory HF requiring specialized interventions

Therapy
- All measures under stage C
- Mechanical assist devices
- Transplantation
- Continuous (not intermittent) IV inotropic infusions for palliation
- Hospice care

Therapy
- Treat Hypertension
- Treat lipids
- Regular exercise
- Discourage alcohol
- ACE inhibition
Severity of Heart Failure
Modes of Death

Achieving Cardiac Resynchronization

Goal: Atrial synchronous biventricular pacing
Transvenous approach for left ventricular lead via coronary sinus
Back-up epicardial approach
Cumulative Enrollment in Cardiac Resynchronization Randomized Trials

Results Presented

- Actual
- Projected
SCD-HeFT

**Sudden Cardiac Death in Heart Failure Trial**

**Study design**

- Prospective, randomized trial with three arms looking at all cause mortality in ICD versus medical therapy.

SCD-HeFT

_Sudden Cardiac Death in Heart Failure Trial_

**CAD**
Dilated cardiomyopathy (DCM)
Heart failure (NYHA II and III)
LVEF < 35%

**I**
Conventional Rx + Placebo

**II**
Conventional Rx + Amiodarone

**III**
Conventional Rx + ICD

Double blind

Single lead, pectoral implant

Follow-up 2.5 years
SCD-HeFT

Results

- In NYHA Class II or III patients with EF ≤ 35% on optimal medical therapy showed a **23% reduction** in mortality in the ICD arm.
- Amiodarone does not improve survival when used as in primary prevention.
CRT + SCD-HEFT
Indications

**CRT Criteria**
- Class III/IV Heart Failure
- Stable HF Meds
- QRS $\geq$ 130 ms
- LVEF $\leq$ 35%

**SCD-HEFT Criteria**
- CAD
- LVEF $\leq$ 35%
- Class II/III
Impedance reduction preceded patients symptoms and HF admission in every case

An automatic detection algorithm was developed with 76% sensitivity with low false detects

Using intrathoracic impedance from an implantable device

- Fluid status of heart failure patients can be tracked
- Is a surrogate measure of fluid status
Insync Sentry

- OptiVol™ Fluid Status Monitoring
- 35 J output
- 6.0 Year Longevity
- 7.1-9.0 sec charge time
As fluid accumulates in lung, intrathoracic impedance decreases.
As pulmonary congestion clears, intrathoracic impedance will increase.
Insight into Patient Status

Heart Failure Management Report


OptiVol Fluid index = an accumulation of the difference between the daily and previous day's volumes.

Patient Activity

Resting Night HR

HR Variability

% Pacing

V rate during AF

Data from Medtronic, Inc. 2004
Clinical Concerns/Questions

**OptiVol™ Fluid Index**
- Has the OptiVol Threshold been crossed/when?
- Does the crossing of the OptiVol Threshold agree with patient symptoms?
- Is medical intervention required?

**Thoracic Impedance Trend**
- Is the reference impedance consistent with the daily impedance measurements?
Patient Education and Safety

Patient Identification Card

- Medtronic USA, Inc.
  Implanted Device Identification
  I HAVE AN ACTIVITYTRAX PACEMAKER IMPLANTED

  In case of a medical question or emergency, please contact my doctor(s):

  JOHN SMITH, MD
  (612) 555-1212

  My name:
  JOHN DOE
  123 MAIN ST
  MINNEAPOLIS, MN 55434-2823

  My pacing system model, serial numbers, and implant dates:
  8400    I1234567H 8/28/93
  400458  PS1234567V 8/28/93
Device Magnet Use

Identify device with patient’s ID Card.

- Medtronic  800.723.4636
- Guidant   800.227.3422
- St. Jude (Ventricular)  800.733.3455
Device Magnet Use

What is the procedure?

- Location of procedure?
- Cautery usage?
- Grounding pad placement?
Patient Safety
Device Magnet Use

Ease of Magnet use: NO
phone calls
waiting
risk
Device Magnet Use

Demonstrate Tones

To demonstrate tone:
1. Position programming head.
2. Select tone.

- High-Urgency Condition Met
- Low-Urgency Condition Met
- No Conditions Met

Close
Health Information
Conditions and diseases and how Medtronic products and therapies can help.

Information for Patients
Information for patients (and their families) being treated with Medtronic products and therapies.

Information for Physicians
Information on Medtronic products and therapies for physicians, nurses and other healthcare professionals.

About Medtronic
Information about Medtronic, Inc., including our mission and technology, Investor Relations, Corporate Governance, Newsroom, Career Opportunities and Medtronic in the Community.

Current Medtronic Stock Information: MDT 50.27 ▼ -0.92 (Aug 27, 2004 10:38 AM ET)

Recognize those with spasticity...
Questions?