My Next Patient Has What Device?
What Do I Do Now?

Richard L. Applegate II MD

I have no relevant disclosures for this talk

SYLLABUS INCLUDES MUCH REFERENCE MATERIAL THAT WILL NOT BE COVERED DURING THE LECTURE
Objectives

As a result of participating in this educational opportunity the learner will be able to:

• Describe differences between and the indications for implantable cardiac devices

• Delineate pre-anesthesia assessment and preparation of patients with a pacemaker, defibrillator or LVAD

• Understand intra-anesthesia management concerns and strategies for patients with a pacemaker, defibrillator or LVAD

• Outline a management plan for post-anesthesia care of patients with a pacemaker, implantable defibrillator or LVAD


You will get these patients for anesthesia

• Wide range of devices are available
  – Many patients have complicated devices
  – Implantation increasingly common as indications widen

• Estimates:
  – ~3 million patients living with cardiac electrical device in North America
  – Widespread: estimated >400,000 pacers & 120,000 ICDs implanted in USA each year

• Older population: get surgical problems & will present for surgery

• New indications mean you will see many more patients with these
Why so many patients?

Dysrhythmia harms

Symptoms go with hemodynamic impact:

- Signs of low cerebral perfusion:
  - Dizziness to syncope (falls may result in other injuries)
  - Confusion
- Signs of low cardiac output
  - Weakness
  - Physiologic response to low output: dyspnea

Some dysrhythmias kill

- About 785,000 USA deaths/year attributable to CV disease
- Sudden cardiac death kills 350,000 to 400,000 in USA annually
- Sudden cardiac death (SCD) about 2/3
  - VF in 80 - 90%
  - Can be preceded by sustained VT
And more of these patients are coming

• Destination LVAD Rx

• Some of these will need surgery...
Safe peri-anesthesia management hinges on answering key questions

*For Patient & Procedure need to know:*

- Why?
  - What?
- How?
  - Where?
  » When?
Key questions about the patient:

• **Why** did the patient need the device?
• **What** is the device (specifications, programming, etc)?
• **How** does the patient function if the device is turned off or non-functional?
• **Where** in the patient’s body is the device implanted?
• **When** was the device last interrogated and when should it be checked / reprogrammed both before & after anesthesia?
Cardiac rhythm devices

Key question about the patient with an implanted cardiac device:

• *Why* did the patient need the device?
Simplified Indications for Pacers

• Sinus node, AV node, conduction system problem that causes symptoms
• Sinus node, AV node, conduction system problem that in presence of some other abnormality puts patient at risk of sudden cardiac death

– Expanded list of indications is in syllabus supplement
Pacing NOT INDICATED FOR

• Asymptomatic bradycardia
• Symptoms that occur when patient is NOT bradycardic
Key question about the patient with an implanted cardiac device

WHAT IS THE DEVICE (SPECIFICATIONS, PROGRAMMING, ETC)?
Pacers described by 5 details


<table>
<thead>
<tr>
<th>Category</th>
<th>Position</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chamber paced</td>
<td>Chamber sensed</td>
<td>Response to sensing</td>
<td>Rate modulation</td>
<td>Multisite pacing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>O = none</td>
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<td></td>
</tr>
<tr>
<td>A = Atrium</td>
<td>A = Atrium</td>
<td>T = Triggered</td>
<td>R = rate</td>
<td>A = atrium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>V = ventricle</td>
<td>V = ventricle</td>
<td>I = inhibited</td>
<td>modulation</td>
<td>V = ventricle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D = dual (A and V)</td>
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<td>D = dual (triggered and inhibited)</td>
<td></td>
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<tr>
<td>Manufacturer designation</td>
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Lead locations

- A: single chamber ventricular pacer, lead in RV
- B: single chamber atrial pacer, lead in RA
- C: dual chamber pacer, leads in RA and RV
- D: dual chamber, biventricular pacer, leads in the RA, RV and coronary sinus
- Any of these leads can be unipolar or bipolar
- Kaszala Mayo Clinic Proc 2008; 83: 1170-1186
## Know the code: examples

<table>
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<th>Code</th>
<th>Interpretation</th>
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<tr>
<td>VOO, VOOO, VOOOO</td>
<td>Asynchronous ventricular pacing; no sensing, rate modulation, or multisite pacing</td>
</tr>
<tr>
<td>VVIRV</td>
<td>Ventricular inhibitory pacing with rate modulation and multisite ventricular pacing</td>
</tr>
<tr>
<td>AAI</td>
<td>Atrial pacing inhibited by atrial activity</td>
</tr>
<tr>
<td>AATOA</td>
<td>Atrial pacing with A output elicited without delay on atrial sensing, without rate modulation but with multisite A pacing (biatrial pacing &amp;/or &gt;1 atrial lead)</td>
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<td>DDD, DDDO, DDDOO</td>
<td>Dual chamber pacing (inhibited by A or V sensing during alert portion of the AV interval, and V pacing triggered after a programmed interval by atrial sensing with no rate modulation or multisite pacing.</td>
</tr>
<tr>
<td>DDDR or DDDR0</td>
<td>Dual chamber, adaptive rate</td>
</tr>
<tr>
<td>DDDOV</td>
<td>Dual chamber without rate modulation but with multisite V pacing</td>
</tr>
<tr>
<td>DDDRD</td>
<td>Dual chamber pacing with rate modulation and multisite A &amp; V pacing</td>
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</table>

So what?

- Code provides detail about how the device works
- This should correspond to the answer to *WHY* the patient needs the device
## Pacemaker choices

*Circulation* 2013; 127: e283-e352

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<th>AV Block</th>
<th>Neurally Mediated Syncope or Carotid Sinus Hypersensitivity</th>
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<td>Single-chamber atrial pacemaker</td>
<td>No suspected abnormality of atrioventricular conduction and not at increased risk for future atrioventricular block Maintenance of atrioventricular synchrony during pacing desired</td>
<td>Not appropriate</td>
<td>Not appropriate</td>
</tr>
<tr>
<td>Single-chamber ventricular pacemaker</td>
<td>Maintenance of atrioventricular synchrony during pacing not necessary Rate response available if desired</td>
<td>Chronic atrial fibrillation or other atrial tachyarrhythmia or maintenance of atrioventricular synchrony during pacing not necessary Rate response available if desired</td>
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## Pacemaker choices

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<td>Dual-chamber pacemaker</td>
<td>Atrioventricular synchrony during pacing desired</td>
<td>Rate response available if desired</td>
<td>Sinus mechanism present</td>
</tr>
<tr>
<td></td>
<td>Suspected abnormality of atrioventricular conduction or increased risk for future atrioventricular block</td>
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<td>Rate response available if desired</td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Atrial pacing desired</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-lead, atrial-sensing ventricular pacemaker</td>
<td>Not appropriate</td>
<td>Desire to limit the number of pacemaker leads</td>
<td>Not appropriate</td>
</tr>
</tbody>
</table>

Circulation 2013; 127: e283-e352
Selection of pacemaker systems for patients with sinus node dysfunction.

Andrew E. Epstein et al.
Circulation.
2013;127:e283-e352
Selection of pacemaker systems for patients with atrioventricular block.

Andrew E. Epstein et al.
Circulation.
2013;127:e283-e352
Key question about the patient with an implanted cardiac device

*WHY DID THE PATIENT NEED RESYNCHRONIZATION DEVICE?*
2012 Indications for CRT Therapy—Algorithm.


Green: Indicated
Yellow: Reasonable
Orange: May be OK
Red: Don’t use

Patient with cardiomyopathy on GDMT for ≥3 mo or on GDMT and ≥40 d after MI, or with implantation of pacing or defibrillation device for special indications

LVEF ≤35%

Evaluate general health status

Comorbidities and/or frailty limit survival with good functional capacity to <1 y

Continue GDMT without implanted device

Evaluate NYHA clinical status

NYHA class I
- LVEF ≤30%
- QRS ≥150 ms
- LBBD pattern
- Ischemic cardiomyopathy
- QRS ≤150 ms
- Non-LBBD pattern

NYHA class II
- LVEF ≤35%
- QRS ≥150 ms
- LBBD pattern
- Sinus rhythm
- LVEF ≤35%
- QRS 120-149 ms
- LBBD pattern
- Sinus rhythm
- LVEF ≤35%
- QRS 150 ms
- Non-LBBD pattern
- Sinus rhythm
- QRS ≤150 ms
- Non-LBBD pattern

NYHA class III & Ambulatory class IV
- LVEF ≤35%
- QRS ≥150 ms
- LBBD pattern
- Sinus rhythm
- LVEF ≤35%
- QRS 120-149 ms
- LBBD pattern
- Sinus rhythm
- LVEF ≤35%
- QRS 150 ms
- Non-LBBD pattern
- Sinus rhythm
- QRS ≤150 ms
- Non-LBBD pattern

Special CRT Indications
- Anticipated to require frequent ventricular pacing (>40%)
- Atrial fibrillation, if ventricular pacing is required and rate control will result in near 100% ventricular pacing with CRT

Colors correspond to the class of recommendations in the ACCF/AHA Table 1.

Benefit for NYHA class I and II patients has only been shown in CRT-D trials, and while patients may not experience immediate symptomatic benefit, late remodeling may be avoided along with long-term HF consequences. There are no trials that support CRT-pacing (without ICD) in NYHA class I and II patients. Thus, it is anticipated these patients would receive CRT-D unless clinical reasons or personal wishes make CRT-pacing more appropriate. In patients who are NYHA class III and ambulatory class IV, CRT-D may be chosen but clinical reasons and personal wishes may make CRT-pacing appropriate to improve symptoms and quality of life when an ICD is not expected to produce meaningful benefit in survival.
## Reminder: NYHA class

<table>
<thead>
<tr>
<th>Functional Capacity</th>
<th>Objective Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I. Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.</td>
<td>A. No objective evidence of cardiovascular disease.</td>
</tr>
<tr>
<td>Class II. Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.</td>
<td>B. Objective evidence of minimal cardiovascular disease.</td>
</tr>
<tr>
<td>Class III. Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitations, dyspnea, or anginal pain.</td>
<td>C. Objective evidence of moderately severe cardiovascular disease.</td>
</tr>
<tr>
<td>Class IV. Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.</td>
<td>D. Objective evidence of severe cardiovascular disease</td>
</tr>
</tbody>
</table>
## Comparison of ACCF/AHA Stages of HF to NYHA Class

<table>
<thead>
<tr>
<th>ACCF/AHA Stages</th>
<th>NYHA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A</strong> At high risk for HF but without structural heart disease or symptoms of HF</td>
<td>None</td>
</tr>
<tr>
<td><strong>B</strong> Structural heart disease but without signs or symptoms of HF</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>No limitation of physical activity. Ordinary physical activity does not cause symptoms of HF.</td>
</tr>
<tr>
<td><strong>C</strong> Structural heart disease with prior or current symptoms of HF</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>No limitation of physical activity. Ordinary physical activity does not cause symptoms of HF.</td>
</tr>
<tr>
<td><strong>II</strong> Slight limitation of physical activity. Comfortable at rest but ordinary physical activity results in symptoms of HF.</td>
<td></td>
</tr>
<tr>
<td><strong>III</strong> Marked limitation of physical activity. Comfortable at rest but less than ordinary activity causes symptoms of HF.</td>
<td></td>
</tr>
<tr>
<td><strong>IV</strong> Refractory HF requiring specialized interventions</td>
<td>IV</td>
</tr>
<tr>
<td></td>
<td>Unable to carry on any physical activity without symptoms of HF or symptoms of HF at rest.</td>
</tr>
</tbody>
</table>
Managing CHF

Prognosis NYHA 3 or 4

- Cumulative survival for patients in the past era and current era - better survival for patients in current era. After an initial higher mortality rate after transplantation, overall one-year survival is comparable to medical therapy for patients in the current era and better than heart failure therapy in the past era. Butler JACC 2004; 43:787-793
HF survival from diagnosis remains poor

Acute decompenated heart failure survival: worse than many cancer types

- Between 1995 and 2004, patients hospitalized with ADHF have become older and increasingly comorbid.
- Significant survival improvement
- Long term prognosis poor: “fewer than 1 in 3 patients hospitalized with ADHF in 2004 survived more than 5 years.”
Lower EF: does worse

- Adjusted for age, sex, history of previously diagnosed atrial fibrillation, diabetes, chronic lung disease, renal failure, and HF, and serum glucose findings during the acute hospitalization.
- EF ≥50% had better survival at 1, 2 and 5 years compared to EF 41-49% and EF <40%.

<table>
<thead>
<tr>
<th></th>
<th>1 yr multivariable adjusted RR</th>
<th>2 yr multivariable adjusted RR</th>
<th>5 yr multivariable adjusted RR</th>
</tr>
</thead>
<tbody>
<tr>
<td>EF ≥50%</td>
<td>1.0</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>EF 41-49%</td>
<td>1.37, 1.65</td>
<td>1.36, 1.55</td>
<td>1.04, 1.10</td>
</tr>
<tr>
<td>EF &lt;40%</td>
<td>1.17, 1.28</td>
<td>1.17, 1.24</td>
<td>1.02, 1.05</td>
</tr>
</tbody>
</table>
Cardiac resynchronization therapy

• Atrial synchronized biventricular pacing
• Why: dyssynchrony worsens CHF
  – Dyssynchrony = differences in the timing of contraction between the different myocardial segments
  – Differs from dyssnergy = differences in systolic function but not timing of contraction
Normal contraction in heart

- Spiral arrangement of fibers
- Optimal AV delay
- Coordinated contraction: relationship of LV myofibrils and electrical activation provides for apex to base “wringing out” of LV during systole, effective ejection of stroke volume into aorta
Dynamic contraction

- Rotational component of contraction visible as LV contracts
Normal ejection

- Depends on coordinated electrical and mechanical function
- Basal RV then RV wall: LV contraction starts before RV is complete, followed by contraction of septum and apex
- Twisting component
But when timing isn’t right

- LV emptying is impeded
- Some segments may contract during mechanical diastole
  - Limits filling: raises LVEDP
  - May be associated with diastolic mitral regurgitation
Dilated cardiomyopathy

- Effects: less efficient emptying related to decreased systolic function and geometric changes in LV
- Mitral valve effects:
  - Shape changes cause MV tethering
  - Loss of mitral annular contraction
  - Decreased LV contraction efficiency and the closing forces

Effect of the diastolic reversal atrioventricular pressure gradient on mitral leaflets in normal subjects and in patients with left ventricular dysfunction and intraventricular and/or atrioventricular (A-V) dyssynchrony. LA, left atrium; LV, left ventricle; LVEDP, left ventricular end-diastolic pressure.

Agricola 2008
Effects of dyssynchrony

• Changes in regional mechanics: stretch, systolic shortening, and mechanical work - impact regional growth
• Total mass increases
• Chamber size increases
• Worsens geometry of LV dysfunction

What’s wrong with RV pacing?

- Induces LV dyssynchrony: drops SV, shifts LV ESPVR to right
- Increases ESV and stress
  - Spragg and Kass: *Pathobiology of Left Ventricular Dyssynchrony and Resynchronization*. Progress in Cardiovascular Diseases, 2006; 49:26-41
Function can deteriorate with pacing

Before pacer apical 4 chamber  
With pacer apical 4 chamber
Function can deteriorate with pacing

Before pacer apical 2 chamber

With pacer apical 2 chamber
Resynchronization

• Leads placed in RA, RV and on LV
  – Epicardial at surgery
  – Via coronary sinus in cardiac cath lab

• Programming allows optimization of AV interval and coordination of ventricular contraction

When effective results in:
• Improved synchronization of LV regions
• Improved pressure generation
• Improved emptying
Benefits of CRT


All-cause mortality

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>CRT-P Events</th>
<th>CRT-P Total</th>
<th>OPT Events</th>
<th>OPT Total</th>
<th>Weight</th>
<th>RR, M–H, random (95% CI)</th>
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<tr>
<td>CARE-HF^36,109–115</td>
<td>38</td>
<td>409</td>
<td>64</td>
<td>404</td>
<td>54.0%</td>
<td>0.59 (0.40 to 0.86)</td>
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<tr>
<td>COMPANION^116–120</td>
<td>53</td>
<td>617</td>
<td>34</td>
<td>308</td>
<td>46.0%</td>
<td>0.78 (0.52 to 1.17)</td>
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<td>Total (95% CI)</td>
<td>1026</td>
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Heterogeneity: $\tau^2=0.00$; $\chi^2=0.99$, df=1 ($p=0.32$); $I^2=0$

Test for overall effect: $z=2.85$ ($p=0.004$)

Heart failure deaths

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Benefits of CRT

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Health Technol Assess. 2014;18:1-560
Benefits of CRT

Worsening Heart Failure

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<tr>
<td>MUSTIC$^{125}$</td>
<td>0</td>
<td>58</td>
<td>1</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>695</td>
<td>100.0%</td>
<td>688</td>
</tr>
</tbody>
</table>

Total events: 204 in CRT-P, 288 in OPT
Heterogeneity: $\tau^2=0.00; \chi^2=1.03, df=2 (p=0.60); I^2=0$
Test for overall effect: $z=5.42 (p<0.00001)$

NYHA improvement by one or more

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>CRT-P</th>
<th>OPT</th>
<th>RR, M-H, random (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Events</td>
<td>Total</td>
<td>Events</td>
</tr>
<tr>
<td>CARE-HF$^{36,109-115}$</td>
<td>255</td>
<td>409</td>
<td>151</td>
</tr>
<tr>
<td>COMPANION$^{116-120}$</td>
<td>298</td>
<td>489</td>
<td>76</td>
</tr>
<tr>
<td>MIRACLE$^{121-124}$</td>
<td>143</td>
<td>211</td>
<td>74</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>1109</td>
<td>100.0%</td>
<td>799</td>
</tr>
</tbody>
</table>

Total events: 696 in CRT-P, 301 in OPT
Heterogeneity: $\tau^2=0.00; \chi^2=0.70, df=2 (p=0.70); I^2=0$
Test for overall effect: $z=10.05 (p<0.00001)$

Health Technol Assess. 2014;18:1-560
Benefits of CRT

6 minute walk

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>CRT-P Mean</th>
<th>SD</th>
<th>Total</th>
<th>OPT Mean</th>
<th>SD</th>
<th>Total</th>
<th>Weight</th>
<th>IV, random (95% CI)</th>
<th>MD IV, random (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change value</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>COMPANION 119-120</td>
<td>40</td>
<td>96</td>
<td>373</td>
<td>1</td>
<td>93</td>
<td>142</td>
<td>45.6%</td>
<td>39.00 (29.86 to 57.14)</td>
<td>6.20 (2.86 to 9.54)</td>
</tr>
<tr>
<td>MIRACLE 121-124</td>
<td>39</td>
<td>103.9</td>
<td>214</td>
<td>10</td>
<td>69.2</td>
<td>130</td>
<td>44.1%</td>
<td>25.00 (20.24 to 37.66)</td>
<td>7.20 (20.24 to 37.66)</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>597</td>
<td></td>
<td></td>
<td>340</td>
<td></td>
<td></td>
<td>89.7%</td>
<td>54.13 (21.14 to 87.15)</td>
<td>15.42 (21.14 to 87.15)</td>
</tr>
<tr>
<td>Heterogeneity: $I^2 = 0.00$; $Q = 0.57, df = 1 (p = 0.46)$; $p = 0.00$</td>
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<tr>
<td>Test for overall effect: $z = 5.15 (p &lt; 0.00001)$</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>Final value</td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MUSTIC 125</td>
<td>399.2</td>
<td>100.5</td>
<td>45</td>
<td>325.7</td>
<td>134.4</td>
<td>46</td>
<td>10.3%</td>
<td>73.50 (25.60 to 122.00)</td>
<td>38.14 (21.74 to 54.54)</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>633</td>
<td></td>
<td></td>
<td>386</td>
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<td></td>
<td>100.0%</td>
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</tr>
<tr>
<td>Heterogeneity: $I^2 = 58.06$; $Q = 2.93, df = 2 (p = 0.23)$; $p = 22.02$</td>
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<td></td>
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</tr>
<tr>
<td>Test for overall effect: $z = 0.56 (p &gt; 0.00001)$</td>
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</tr>
<tr>
<td>Test for subgroup difference: $I^2 = 2.36, df = 1 (p = 0.12)$; $p = 57.62$</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
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</table>

Quality of life improvement

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>CRT-P Mean</th>
<th>SD</th>
<th>Total</th>
<th>OPT Mean</th>
<th>SD</th>
<th>Total</th>
<th>Weight</th>
<th>IV, random (95% CI)</th>
<th>MD IV, random (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change value</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>COMPANION 116-120</td>
<td>-25</td>
<td>26</td>
<td>460</td>
<td>-12</td>
<td>24</td>
<td>207</td>
<td>33.2%</td>
<td>-13.00 (-16.99 to -9.07)</td>
<td>-13.00 (-16.99 to -9.07)</td>
</tr>
<tr>
<td>MIRACLE 121-124</td>
<td>-18</td>
<td>37</td>
<td>213</td>
<td>-9</td>
<td>24.7</td>
<td>193</td>
<td>18.4%</td>
<td>-9.00 (-15.02 to -2.99)</td>
<td>-9.00 (-15.02 to -2.99)</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>673</td>
<td></td>
<td></td>
<td>400</td>
<td></td>
<td></td>
<td>51.6%</td>
<td>-11.70 (-15.37 to -8.02)</td>
<td>-11.70 (-15.37 to -8.02)</td>
</tr>
<tr>
<td>Heterogeneity: $I^2 = 4.19$; $Q = 1.18, df = 1 (p = 0.28)$; $p = 15.92$</td>
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<td></td>
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</tr>
<tr>
<td>Test for overall effect: $z = 6.24 (p &lt; 0.00001)$</td>
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<td></td>
</tr>
<tr>
<td>Final value</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MUSTIC 125</td>
<td>27.2</td>
<td>23.7</td>
<td>409</td>
<td>35.1</td>
<td>25.6</td>
<td>404</td>
<td>36.9%</td>
<td>-7.50 (-11.29 to -4.51)</td>
<td>-7.50 (-11.29 to -4.51)</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>454</td>
<td></td>
<td></td>
<td>449</td>
<td></td>
<td></td>
<td>48.4%</td>
<td>-9.12 (-13.59 to -4.64)</td>
<td>-9.12 (-13.59 to -4.64)</td>
</tr>
<tr>
<td>Heterogeneity: $I^2 = 2.91$; $Q = 1.32, df = 1 (p = 0.25)$; $p = 24.37$</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Test for overall effect: $z = 3.90 (p &lt; 0.00001)$</td>
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<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Test for subgroup difference: $I^2 = 2.51$; $Q = 4.39, df = 3 (p = 0.22)$; $p = 32.00$</td>
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<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: $z = 6.81 (p &lt; 0.00001)$</td>
<td></td>
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</tr>
</tbody>
</table>

Health Technol Assess. 2014;18:1-560
Function can improve with CRT

Before BiV pacer apical 4 chamber

With BiV pacer apical 4 chamber
Function can improve with CRT

Before BiV pacer apical 2 chamber

With BiV pacer apical 2 chamber
Not all patients have + CRT response

• Zhang et al: Incidence, definition, diagnosis, and management of the cardiac resynchronization therapy nonresponder. Curr Opin Cardiol 2015;30:40-9
• Evaluated studies of CRT impact
• Outcome Measures included NYHA improvement, decrease LVESV, QOL improvements, death / hospitalization
• NON-responders are 15 to 40% of CRT patients
<table>
<thead>
<tr>
<th>No.</th>
<th>References</th>
<th>Patient no.</th>
<th>Inclusion criteria</th>
<th>Parameters of response</th>
<th>Follow-up time</th>
<th>Response (nonresponse)</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Goldstein et al. [12]</td>
<td>1820</td>
<td>EF ≤ 30%, QRS ≥ 130 ms, 55% ischem</td>
<td>≥30% reduction in LVESV</td>
<td>1 year</td>
<td>58% [42%]</td>
</tr>
<tr>
<td>02</td>
<td>Hoogslag et al. [13]</td>
<td>170</td>
<td>EF 27 ± 7%, QRS 154 ± 23 ms, 65% ischem</td>
<td>Improvement by ≥1 NYHA classes; ≥15% reduction in LVESV; ≥15% decrease in NT-proBNP</td>
<td>6 months</td>
<td>66% [34%]</td>
</tr>
<tr>
<td>03</td>
<td>Delnay et al. [14]</td>
<td>199</td>
<td>NYHAA III/IV, EF ≤ 35%, LVEDD ≥ 30 mm/m², QRS &gt; 120 ms, 39% ischem</td>
<td>Improvement by ≥1 NYHA classes or ≥10% increase in EuroQol-Visual Analogue Scale score</td>
<td>6 months</td>
<td>58% [42%]</td>
</tr>
<tr>
<td>04</td>
<td>Khan et al. [15]</td>
<td>220</td>
<td>NYHAA III/IV, EF ≤ 35%, QRS &gt; 120 ms, 56% ischem</td>
<td>≥15% reduction in LVESV; improvement by ≥1 NYHA classes</td>
<td>6 months</td>
<td>70% [30%]</td>
</tr>
<tr>
<td>05</td>
<td>Ritter et al. [16]</td>
<td>238</td>
<td>NYHAA III/IV, EF &lt; 35%, QRS &gt; 150 ms or &gt; 120 ms with mechanical dyssynchrony, 39% ischem</td>
<td>Free from death or hospitalization and improvement by ≥1 NYHA classes or ≥10% decrease in QOL score</td>
<td>1 year</td>
<td>63% [37%]</td>
</tr>
<tr>
<td>06</td>
<td>Gold et al. [17]</td>
<td>426</td>
<td>EF 26 ± 7%, QRS 151 ± 19 ms, 59% ischem</td>
<td>≥15% reduction in LVESV; &gt;10 points decrease in QOL score</td>
<td>6 months</td>
<td>68% [32%]</td>
</tr>
<tr>
<td>07</td>
<td>Khan et al. [18]</td>
<td>131</td>
<td>NYHAA III/IV, EF ≤ 35%, QRS &gt; 120 ms, 57.3% ischem</td>
<td>≥15% reduction in LVESV</td>
<td>6 months</td>
<td>72% [28%]</td>
</tr>
<tr>
<td>08</td>
<td>Leyva et al. [19]</td>
<td>322</td>
<td>EF 24.2 ± 10.2%, QRS 157.4 ± 28.7 ms, 65% ischem</td>
<td>Improvement by ≥1 NYHA classes or ≥25% increase in 6-min hall-walk distance</td>
<td>1 year</td>
<td>78% [22%]</td>
</tr>
<tr>
<td>09</td>
<td>Muto et al. [20]</td>
<td>231</td>
<td>EF &lt; 35%, QRS &gt; 120 ms, NYHAA III/IV, LVEDD ≥ 55 mm, 43% ischem</td>
<td>≥10% reduction in LVESV</td>
<td>6 months</td>
<td>74% [26%]</td>
</tr>
<tr>
<td>10</td>
<td>Boriani et al. [21]</td>
<td>176</td>
<td>NYHAA III/IV, EF ≤ 35%, QRS &gt; 130 ms, LVEDD ≥ 55 mm, 52% ischem</td>
<td>NYHA functional change and ≥5 mm decrease in LVESD or improvement in heart failure composite score or ≥10% decrease in LVESV</td>
<td>6 months</td>
<td>76% [24%]</td>
</tr>
</tbody>
</table>

EF: ejection fraction; LVEDD, left ventricular end-diastolic dimension; LVESV, left ventricular end-systolic volume; NYHA, New York Heart Association; QOL, quality of life.
CRT: anesthesia risks

• CRT improves functional class in symptomatic patients; improves morbidity and mortality related to medical condition
  – BUT 30% - 40% nonresponders
  – Patients don’t necessarily improve to NYHA 1
• What is the impact on perioperative risk?
• Not enough evidence yet
How would you assign ASA PS

- Dilated cardiomyopathy (not ischemic) with a h/o sustained VT; prior NYHA 4
- Now has implanted Bi-V pacing (CRT) with ICD & NYHA 2
- Are they:
  1. ASA 1: Healthy because their disease is treated?
  2. ASA 2: Mild systemic disease because ICD and CRT improve M & M?
  3. ASA 3: Severe systemic disease because the DCM still predicts risks for peri-anesthesia CHF?
  4. ASA 4: Severe systemic disease that is a constant threat to life because turning off ICD/pacing during surgery “unprotects” the patient?
Key questions about the patient with an implanted cardiac device

**WHY DID THE PATIENT NEED DEFIBRILLATION DEVICE?**
Simplified Indications for ICD

- Survivor of dysrhythmic sudden cardiac death
- Structural heart disease that puts the patient at risk for sudden cardiac death
- Inducible rhythm that puts the patient at risk for sudden cardiac death

- Expanded list of indications is in syllabus supplement
ICD is NOT INDICATED for

Patients who:

• Are not likely to survive anyway
• Psychiatric disorder that device implant may worsen
• Incessant VT/VF or VT/VF that is amenable to ablation or other Rx
• VT/VF from reversible causes
• Not candidates for CRT
Presentations leading to ICD

Clinical
• Hemodynamically stable VT: asymptomatic or minimally symptomatic
• Hemodynamically unstable with presyncope/syncope; SCD; sudden cardiac arrest (SCD that is reversed by intervention)

ECG
• Nonsustained VT: spontaneously terminates < 30 seconds
• Sustained VT: lasts > 30 seconds or causes hemodynamic instability
• Bundle branch re-entrant VT
• Torsades de pointes
• Ventricular flutter
• VF
ICD codes

• May be designated using the short form of the NASPE/BPEG defibrillator (NBD) code:
  – ICD-S = ICD with shock capability only
  – ICD-B = ICD with bradycardia pacing as well as shock
  – ICD-T = ICD with tachycardia (and bradycardia) pacing as well as shock

• Alternatively, devices that include defibrillation may be coded using an additional 4 letters:

<table>
<thead>
<tr>
<th>Chamber shocked</th>
<th>Anti-tachycardia pacing chamber</th>
<th>Anti-tachycardia detection</th>
<th>Pacing chamber</th>
</tr>
</thead>
<tbody>
<tr>
<td>O = no action</td>
<td>O = no action</td>
<td>E = ECG</td>
<td>O = no action</td>
</tr>
<tr>
<td>A = atrium</td>
<td>A = atrium</td>
<td>H = hemodynamic</td>
<td>A = atrium</td>
</tr>
<tr>
<td>V = ventricle</td>
<td>V = ventricle</td>
<td></td>
<td>V = ventricle</td>
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<tr>
<td>D = dual</td>
<td>D = dual</td>
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<td>D = dual</td>
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</table>
Evidence supporting ICD – it works

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>ICD</th>
<th>No ICD</th>
<th>Total</th>
<th>Total Weight</th>
<th>RR, M-H, random (95% CI)</th>
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<tbody>
<tr>
<td><strong>Cardiac arrest (secondary prevention)</strong></td>
<td></td>
<td></td>
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<tr>
<td>AVID-71-74</td>
<td>80</td>
<td>507</td>
<td>122</td>
<td>509</td>
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<tr>
<td>CAT-91</td>
<td>39</td>
<td>99</td>
<td>84</td>
<td>189</td>
<td>28.6%</td>
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<tr>
<td>CDYn-88</td>
<td>83</td>
<td>328</td>
<td>98</td>
<td>331</td>
<td>35.5%</td>
</tr>
<tr>
<td>DEBUT pilot82</td>
<td>0</td>
<td>10</td>
<td>3</td>
<td>10</td>
<td>0.6%</td>
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<tr>
<td>DEBUT main83</td>
<td>0</td>
<td>37</td>
<td>4</td>
<td>29</td>
<td>0.5%</td>
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<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td>918</td>
<td>3288</td>
<td>981</td>
<td>3310</td>
<td>100.0%</td>
</tr>
<tr>
<td><strong>Total events</strong></td>
<td>199</td>
<td>311</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Heterogeneity</strong></td>
<td>$I^2 = 0.02; \hat{\tau}^2 = 5.89, df = 4 (p = 0.21); \hat{r}_p = 0.32$</td>
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<tr>
<td></td>
<td>Test for overall effect: $z = 2.59 (p = 0.010)$</td>
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**Recent MI**

<table>
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<tr>
<th>Study or subgroup</th>
<th>ICD</th>
<th>No ICD</th>
<th>Total</th>
<th>Total Weight</th>
<th>RR, M-H, random (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DYNAMIT84</td>
<td>62</td>
<td>332</td>
<td>58</td>
<td>342</td>
<td>31.7%</td>
</tr>
<tr>
<td>IRIS-93:84</td>
<td>116</td>
<td>445</td>
<td>117</td>
<td>453</td>
<td>63.8%</td>
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<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td>777</td>
<td>1975</td>
<td>777</td>
<td>1975</td>
<td>100.0%</td>
</tr>
<tr>
<td><strong>Total events</strong></td>
<td>178</td>
<td>175</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Heterogeneity</strong></td>
<td>$I^2 = 0.00; \hat{r}_p = 0.19, df = 1 (p = 0.66); \hat{r}_p = 0.00$</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test for overall effect: $z = 0.40 (p = 0.69)$</td>
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</table>

**Remote MI**

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>ICD</th>
<th>No ICD</th>
<th>Total</th>
<th>Total Weight</th>
<th>RR, M-H, random (95% CI)</th>
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</thead>
<tbody>
<tr>
<td>MADIT85-91</td>
<td>15</td>
<td>95</td>
<td>39</td>
<td>101</td>
<td>41.1%</td>
</tr>
<tr>
<td>MADIT II86-92</td>
<td>105</td>
<td>742</td>
<td>97</td>
<td>490</td>
<td>98.9%</td>
</tr>
<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td>837</td>
<td>1737</td>
<td>837</td>
<td>1737</td>
<td>100.0%</td>
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<tr>
<td><strong>Total events</strong></td>
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<td>136</td>
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</tr>
<tr>
<td><strong>Heterogeneity</strong></td>
<td>$I^2 = 0.11; \hat{r}_p = 0.34, df = 1 (p = 0.006); \hat{r}_p = 0.72$</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Test for overall effect: $z = 2.06 (p = 0.040)$</td>
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**Cardiomyopathy**

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>ICD</th>
<th>No ICD</th>
<th>Total</th>
<th>Total Weight</th>
<th>RR, M-H, random (95% CI)</th>
</tr>
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<tbody>
<tr>
<td>AMIDOS93,84</td>
<td>6</td>
<td>51</td>
<td>7</td>
<td>52</td>
<td>15.2%</td>
</tr>
<tr>
<td>CAT82-83</td>
<td>4</td>
<td>50</td>
<td>2</td>
<td>54</td>
<td>5.8%</td>
</tr>
<tr>
<td>DEFINITE94</td>
<td>28</td>
<td>229</td>
<td>40</td>
<td>229</td>
<td>79.0%</td>
</tr>
<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td>338</td>
<td>634</td>
<td>338</td>
<td>634</td>
<td>100.0%</td>
</tr>
<tr>
<td><strong>Total events</strong></td>
<td>38</td>
<td>49</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Heterogeneity</strong></td>
<td>$I^2 = 0.00; \hat{r}_p = 1.73, df = 2 (p = 0.42); \hat{r}_p = 0.00$</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Test for overall effect: $z = 1.27 (p = 0.20)$</td>
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</table>

**CABG surgery**

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>ICD</th>
<th>No ICD</th>
<th>Total</th>
<th>Total Weight</th>
<th>RR, M-H, random (95% CI)</th>
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<tbody>
<tr>
<td>CABG Patch85-86</td>
<td>102</td>
<td>446</td>
<td>96</td>
<td>454</td>
<td>100.0%</td>
</tr>
<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td>446</td>
<td>1392</td>
<td>446</td>
<td>1392</td>
<td>100.0%</td>
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<tr>
<td><strong>Total events</strong></td>
<td>102</td>
<td>96</td>
<td></td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Heterogeneity</strong></td>
<td>Not applicable</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Test for overall effect: $z = 0.62 (p = 0.53)$</td>
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**Mild to moderate HF**

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>ICD</th>
<th>No ICD</th>
<th>Total</th>
<th>Total Weight</th>
<th>RR, M-H, random (95% CI)</th>
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<tr>
<td>SCD HeFT87-89</td>
<td>182</td>
<td>829</td>
<td>484</td>
<td>1602</td>
<td>100.0%</td>
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<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td>829</td>
<td>3622</td>
<td>829</td>
<td>3622</td>
<td>100.0%</td>
</tr>
<tr>
<td><strong>Total events</strong></td>
<td>182</td>
<td>484</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Heterogeneity</strong></td>
<td>Not applicable</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Test for overall effect: $z = 3.49 (p = 0.0005)$</td>
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### Evidence supporting ICD

#### Arrhythmia / SCD death

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>ICD</th>
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<th>RR, M-H, random (95% CI)</th>
<th>RR, M-H, random (95% CI)</th>
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<tr>
<td><strong>ICD</strong></td>
<td><strong>Events</strong></td>
<td><strong>Total</strong></td>
<td><strong>Total Weight</strong></td>
<td><strong>Events</strong></td>
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<tr>
<td><strong>Cardiac arrest (secondary prevention)</strong></td>
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<tr>
<td>AVDI</td>
<td>29</td>
<td>507</td>
<td>59</td>
<td>0.44 (0.20 to 0.79)</td>
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<tr>
<td>CASH</td>
<td>13</td>
<td>99</td>
<td>62</td>
<td>189</td>
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<tr>
<td>CCMPI</td>
<td>30</td>
<td>328</td>
<td>43</td>
<td>331</td>
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<tr>
<td>DEBUT pilot</td>
<td>0</td>
<td>8</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>DEBUT main</td>
<td>8</td>
<td>0</td>
<td>37</td>
<td>4</td>
</tr>
<tr>
<td><strong>Total events</strong></td>
<td>67</td>
<td>167</td>
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<td><strong>Heterogeneity</strong></td>
<td>(\phi = 0.64)</td>
<td>(\chi^2 = 5.47, \text{df} = 26)</td>
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<td>(\phi = 0.27)</td>
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<td><strong>Test for overall effect</strong></td>
<td>(p = 0.001)</td>
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<tr>
<td><strong>Recent MI</strong></td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>DINA5T</td>
<td>12</td>
<td>332</td>
<td>29</td>
<td>342</td>
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<td>IRB5T4</td>
<td>27</td>
<td>445</td>
<td>60</td>
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<td>Subtotal (95% CI)</td>
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<td>777</td>
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<td>(\chi^2 = 0.03, \text{df} = 1)</td>
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<td>(\phi = 0.00)</td>
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<td>(p = 0.001)</td>
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<tr>
<td><strong>Remote MI</strong></td>
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<tr>
<td>MADIT II</td>
<td>8</td>
<td>95</td>
<td>13</td>
<td>101</td>
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<td>MADIT II 01-14</td>
<td>28</td>
<td>742</td>
<td>49</td>
<td>490</td>
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<td>Subtotal (95% CI)</td>
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<td>1113</td>
<td>79%</td>
<td>100%</td>
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<tr>
<td><strong>Total events</strong></td>
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<td>62</td>
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<td>(\chi^2 = 0.42, \text{df} = 1)</td>
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<td>(\phi = 0.00)</td>
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<td><strong>Test for overall effect</strong></td>
<td>(p = 0.000001)</td>
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<td><strong>Cardiomyopathy</strong></td>
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<tr>
<td>AMIOPRTT</td>
<td>1</td>
<td>5</td>
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<td>52</td>
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<tr>
<td>CATH5</td>
<td>0</td>
<td>50</td>
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<td>54</td>
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<td>DEFINITE</td>
<td>3</td>
<td>229</td>
<td>14</td>
<td>229</td>
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<tr>
<td>Subtotal (95% CI)</td>
<td>330</td>
<td>335</td>
<td>100%</td>
<td>0.20 (0.09 to 0.77)</td>
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<tr>
<td><strong>Total events</strong></td>
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<td>16</td>
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<td><strong>Heterogeneity</strong></td>
<td>(\phi = 0.00)</td>
<td>(\chi^2 = 0.81, \text{df} = 1)</td>
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<td><strong>Test for overall effect</strong></td>
<td>(p = 0.0002)</td>
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<td><strong>CABG surgery</strong></td>
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<td>CABG Patch</td>
<td>8</td>
<td>166</td>
<td>128</td>
<td>454</td>
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<tr>
<td>CABG Patch 01-14</td>
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<td>166</td>
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<td>454</td>
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<tr>
<td><strong>Total events</strong></td>
<td>16</td>
<td>256</td>
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<td><strong>Heterogeneity</strong></td>
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<td><strong>Test for overall effect</strong></td>
<td>(p = 0.05)</td>
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<td><strong>Mild to moderate HF</strong></td>
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<tr>
<td>SCD HeFT</td>
<td>8</td>
<td>329</td>
<td>178</td>
<td>1692</td>
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<td>Subtotal (95% CI)</td>
<td>829</td>
<td>1692</td>
<td>100%</td>
<td>0.44 (0.31 to 0.61)</td>
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<tr>
<td><strong>Total events</strong></td>
<td>38</td>
<td>178</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Heterogeneity</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Test for overall effect</strong></td>
<td>(p = 0.00001)</td>
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</tbody>
</table>

**Test for subgroup difference**: \(\chi^2 = 2.59, \text{df} = 5, p = 0.06\); \(\phi = 0.00\)

Assessment

• Pacemakers, ICD implants and CRT are associated with improved survival in symptomatic patients
• Benefits may extend to patients with limited symptoms
• CRT may lead to an improvement in functional status that is accompanied by improvement in echocardiographic and other markers of CHF
Implications of indications

• Many patients will be referred for evaluation and eventually placement of pacemaker, ICD or CRT devices
• Some of these will end up requiring surgery
• This is a group of potentially very sick patients
• As always, best care requires careful management of the various aspects of the patient’s condition and treatment
  – Need to know what indication was reason for placing device
  – Need to understand what device is/does
Destination LVAD

• Not all who meet criteria can get heart transplant
• Some are “bridged” until transplant
• Increasing number are given LVAD implant as “destination” for their remaining lives
Does destination LVAD work?

Estep et al: Risk Assessment and Comparative Effectiveness of Left Ventricular Assist Device and Medical Management in Ambulatory Heart Failure Patients. Results From the ROADMAP Study. JACC 2015; 66:1747–61

• Note: Actuarial survival for all patients with continuous-flow LVADs at 1 and 2 years has reached 80% and 70%, respectively, with 1-year survival of 75% for DT.

• ROADMAP Evaluated status in 97 LVAD compared to 103 optimal medical management patients at 12 months

• “Survival with improved functional status was better with HMII LVAD compared with OMM.

• Despite experiencing more frequent adverse events, LVAD patients improved more in HRQoL and depression.

• The results support HMII use in functionally limited, noninotrope-dependent HF patients with poor HRQoL.”
ROADMAP Results

Event free survival as treated  
Change in NYHA class

Event Free Survival (%)

Time Post-Enrollment (Months)

LVAD: 97
OMM: 103

Remaining at risk:
LVAD: 97
OMM: 103

80 ± 4%
63 ± 5%

HR = 1.71 [1.07 - 2.73] P = 0.024

OMM (n=52)

Enrollment: 22%
Month 12: 11%
Class II = 29%
Class III = 29%

LVAD (n=71)

Enrollment: 54%
Month 12: 6%
P<0.001 LVAD vs OMM

Patient Distribution by NYHA Class:
- Class I: 77%
- Class II: 31%
- Class IIIA: 29%
- Class IIIB: 29%
- Class IV: 25%

[Graphs showing event-free survival and NYHA class changes]
ROADMAP Results

Change in 6 minute walk distance

Change in QOL

[Bar charts showing changes in 6 minute walk distance and QOL over time with comparison between OMM and LVAD groups.]
ROADMAP Results: Risk Benefit Analysis

Primary End Point
- Alive at 12 mo with
  - Δ6MWD ≥ 75m

Survival
- As treated on original therapy
- Intent-to-treat

NYHA Class, HRQoL, and Depression
- Alive at 12 mo with
  - ΔNYHA improvement ≥ 1 class
  - ΔEQ-5D VAS improvement > 20 points
  - ΔPHQ-9 improvement ≥ 5 points

Adverse Events
- Composite

Ratio [LCL, UCL] p-value
Q.R
2.4 [1.2, 4.8] p=0.012

H.R
1.71 [1.07, 2.73] p=0.024
1.02 [0.59, 1.77] p=0.931

Q.R
8.9 [4.5-17.8] p<0.001
4.1 [1.9-8.9] p<0.001
4.2 [1.7-10.2] p<0.001

R.R
0.44 [0.35-0.56] p<0.001
Key questions about the patient with an implanted cardiac device

**HOW** DOES THE PATIENT FUNCTION IF THE DEVICE IS TURNED OFF OR NON-FUNCTIONAL?
How is the patient doing (functional status)?

• Pacing dependent?
  – History
  – Symptomatic bradycardia
  – AV ablation
  – No spontaneous ventricular activity

• Defibrillations?

• Pacemaker syndrome?
Key questions about the patient with an implanted cardiac device

**WHERE** IN THE PATIENT’S BODY IS THE DEVICE IMPLANTED?
Preoperative evaluation

- Is a CRMD present?
  - Focused history
    - Cardiologist note / summary helpful
  - Physical exam: scar? Device in pocket in “usual” places?
- What kind of CRMD?
  - ID card valuable: device info, contact info for rep if no local resource available to interrogate / reprogram device
  - CXR may help

Rozner Curr Opin Anaesthesiol 2007; 20:261–268
Key questions about the patient with an implanted cardiac device

**WHEN** WAS THE DEVICE LAST INTERROGATED AND WHEN SHOULD IT BE CHECKED / REPROGRAMMED BOTH BEFORE & AFTER ANESTHESIA?
Guidelines


• “...because of the complexity of modern devices and the variety of indications for which they are implanted, the perioperative management of patients with CIEDs must be individualized, and a single recommendation for all patients with CIEDs is not appropriate”


“To perform a preoperative evaluation:
• Establish whether a patient has a CIED
• Define the type of device
• Determine whether a patient is CIED-dependent for pacemaking function
• Determine CIED function
To manage CIED patients postoperatively:
• Interrogate and restore CIED function in the PACU or ICU
Anesthesiology run pacer service


• Trained anesthesiologists to manage devices
  – EPCS managed 254 CIEDs, ADS managed 548, 227 by neither
  – ADS increased management over time
  – Only two CIEDs managed by the ADS required immediate assistance from the EPCS.
  – Patients who were unstable postoperatively were referred to the EPCS
Anesthesiology Pacer Service: Rooke et al 2015

Caseload over time

- EPCS
- ADS
- No Active Management

Distibution: after hours cases

- EPCS
- ADS
- No Active Management

Time Period

Oct09-June10  July10-Mar11  Apr11-Dec11  Jan12-Sep12  Oct12-Jun13

Number of Devices Managed During Regular Hours

Oct09-June10  July10-Mar11  Apr11-Dec11  Jan12-Sep12  Oct12-Jun13

Number of Devices Managed After Hours
# Issues recorded

<table>
<thead>
<tr>
<th>Issues</th>
<th>Comments</th>
<th>EPCS</th>
<th>ADS First 274</th>
<th>ADS Second 274</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to inactivate tachyarrhythmia sensing</td>
<td>Error recognized after the device-delivered therapy during an episode of ventricular tachycardia during reoperation for bleeding after cardiac surgery</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Tachyarrhythmia sensing disabled in patients with no use of monopolar cautery</td>
<td>Patient now dependent on external defibrillation</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Failure to restore original device settings</td>
<td>See below for details*</td>
<td>15</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Missing note in the medical record</td>
<td>Poor record keeping</td>
<td>4</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Unintentional entering of values for atrial tachycardia therapy</td>
<td>This error did not activate those therapies so no potential adverse consequence to patient</td>
<td>2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Asynchronous pacing when not pacing dependent†</td>
<td>Could create a tachycardia due to competing rhythms or pose a risk of R-on-T and ventricular fibrillation</td>
<td>13</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Minute ventilation sensor turned “off”‡</td>
<td>Using “off” instead of “passive” mandated a 4-min baseline ventilation acquisition</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Could not figure out how to program asynchronous pacing§</td>
<td>If pacing dependent, patient would be vulnerable to low heart rates with inhibition of demand pacing</td>
<td>3</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Failure to turn off rate–response feature</td>
<td>Potential for undesired pacemaker-induced tachycardia</td>
<td>18</td>
<td>5</td>
<td>2</td>
</tr>
</tbody>
</table>

Total: 50 16 6

Entries were left blank if it was not possible to determine occurrence. For the ADS, the incidence of each event is divided between that service’s first and second half of their 548 cases. For the ADS, the difference in the rate of management issues between the first 274 and the second 274 cases was significant (P < 0.05).

* Failure to reinitiate autothreshold testing (twice), failure to recognize that dynamic atrioventricular delay had turned on with restoration of demand pacing and failure to turn on the Monitor zone when restoring tachyarrhythmia detections. † As determined by baseline programming of ventricular demand pacing at a base rate of 40 per minute (virtually always indicates that the patient is not pacing dependent) and/or comments in the record that clearly identify the patient as having an adequate underlying rhythm before surgery. Three additional cases were likely not pacing dependent. ‡ Applied only to Boston Scientific pacemakers. § In devices that could be converted to asynchronous pacing.

ADS = Anesthesiology Device Service; EPCS = Electrophysiology/Cardiology Service.
Summary: Key questions about the patient with CIED

- **Why** did the patient need the device?
- **What** is the device (specifications, programming, etc)?
- **How** does the patient function if the device is turned off or non-functional?
- **Where** in the patient’s body is the device implanted?
- **When** was the device last interrogated and when should it be checked / reprogrammed both before & after anesthesia?
Key questions about the planned procedure

- **Why** does the patient need the procedure? (Indication for the procedure but also is this an emergency or would it be safe to wait some days for further evaluation and preparation?)
- **What** is the planned procedure? (Open or endoscopic? Superficial or open cavity? Major blood loss or fluid shifts anticipated)?
- **How** is the patient doing (functional status; comorbid conditions) at the time of presentation for anesthesia?
- **Where** is the proposed procedure going to be performed? (Inpatient admission at tertiary care center? Free standing surgery center? Office? Imaging lab?)
- **When** is the procedure going to be performed? (Weekday, weekend, night – are consultants going to be available if you need help?) And **When** must the procedure be performed?
Pre-anesthesia evaluation and preparation

• Answer the important questions about the patient and procedure
• Get consultative input *IF:*
  – Answers do NOT fit the expectation
  – Function of patient / device is NOT what is expected
  – New findings / symptoms are discovered
Peri-anesthesia management of patients with cardiac rhythm devices
Basic Goals

• Patient safety is paramount
• Problems that can develop with CRMD during anesthesia and surgery:
  – Damage to the device
  – Device failure
  – Device malfunction: inappropriate deactivation by electrocautery, inappropriate delivery of shocks, or inappropriate reprogramming of the device
Interference with function

• Electrical interference:
  – Reported causes: electrocautery, muscle activity/shivering, ESWL, ECT, radiofrequency ablation, and nerve stimulation (evoked potential, etc)
  – Degree of electrical interference varies with the type of stimulus
  – Interference varies with the type of lead used, with bipolar leads less susceptible to electrical interference than unipolar leads

• Magnetic / MRI
Impact of interference

• Physiologic problems:
  – Hypotension
  – Dysrhythmias
  – Myocardial damage/ischemia
  – Ischemia of other organs

• Other impact:
  – Delay or cancellation of procedure
  – Increased hospital LOS because of problem or as readmission to address device malfunction
  – Increased resource use: increased medical costs
During anesthesia:

• Is electromagnetic interference (EMI) unlikely?
  – No special precautions needed
  – Many imaging studies, some surgical procedures

• EMI likely?
  – Pacer: reprogram to asynchronous (VOO, DOO)
  – ICD: suspend antitachyarrhythmia functions
  – Combined device, pacer dependent pt: set pacing to asynchronous, suspend rate responsiveness, suspend antitachyarrhythmia functions

• Distance from cautery to device matters

• 497 consecutive surgical procedures analyzed retrospectively

• PACED-OP protocol – associated with a significant reduction in the odds of device reprogramming (adjusted odds ratio [aOR] 0.19, P < 0.001)

• Postoperative complications that could be indirectly or possibly linked with electrocautery-mediated CRMD damage did not differ
A Perioperative Management Algorithm for Cardiac Rhythm Management Devices: The PACED-OP Protocol

Pacing and Clinical Electrophysiology
Volume 36, Issue 2, pages 238-248, 18 DEC 2012 DOI: 10.1111/pace.12049

Revised 5/27/09 by UTMCK Departments of Cardiology and Anesthesiology
A Perioperative Management Algorithm for Cardiac Rhythm Management Devices: The PACED-OP Protocol

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* USG, Bipolar, and Harmonic Scalpel do not constitute EMI. For ESWL, consider deactivation of rate response.
** Critical zone define as area between mandible and zygophoid.
*** “Hit List” items are Boston Scientific/Guidant modes H170, H173, H175, H179, H177, H230, H235 & H239. If Hit List item, must re-program shock “OFF” prior to surgery and reprogram shock “ON” post surgery. If unknown Boston Scientific/Guidant model or unknown ICD manufacturer, call 1-800-227-3422 to obtain model number.

Routine cardiology F/U is typically twice yearly in office evaluation.

Pacer and ICD Algorithms that minimize the re-programming may reduce the risk of inappropriate...

Revised 5/27/09 by UTMCK Departments of Cardiology and Anesthesiology
Intraop management

• Usual monitoring, be aware of discordant findings between ECG and pulse oximeter

• Electrocautery:
  – Minimize current across leads
  – Short bursts of cautery if possible
  – Consider bipolar cautery or ultrasonic scalpel
Problems with EMI/Pacer interaction:

• Asynchronous pacing may not be benign: can lower CO / BP
• VOO pacing can cause dysrhythmias
• EMI can reprogram the device
• EMI can trigger defibrillation delivery
Other interference sources

- Radiofrequency catheters: minimize current across leads; avoid direct contact with leads
- Lithotripsy: focus beam away from device; if R wave triggered, disable atrial pacing
- XRT: limit radiation exposure to device and leads
- ECT:
  - Unclear impact on ICD function
  - Case reports of inappropriate discharge
  - Consider disabling or reprogramming
  - Some advocate for NOT disabling to protect from dysrhythmia during ECT
  - May need to reprogram immediately after ECT while still monitoring ECG and Pulse
- MRI: Older may be OK with some precautions; newer devices might be OK following manufacturer instructions
  - Gimbel JR: Magnetic resonance imaging of implantable cardiac rhythm devices at 3.0 Tesla. PACE 2008; 31:795–801
  - Verma et al: Canadian Heart Rhythm Society and Canadian Association of Radiologists consensus statement on magnetic resonance imaging with cardiac implantable electronic devices. Can J Cardiol. 2014;30:1131-41
Defibrillation

• Schoenfeld, M. H. Circulation 2007;115:638-653
• V Tach with atrial rate about half ventricular
• Device senses, delivers 29.9 J shock
• SR and 1:1 conduction restored
Emergency management

• Need to cardiovert / defibrillate
  – ICD disabled by magnet: remove magnet
  – ICD program disabled: reprogram
  – May need ACLS, external pacing (ant - post pads)
Can’t I just slap a magnet on?

- Pacer: magnet switches to asynchronous mode at manufacturer specified rate
  - DDD may go to VOO or DOO
  - Remains in this mode while magnet on
- ICD or combined Pacer/ICD:
  - Magnet should disable antitachyarrhythmia functions (shocks)
  - Usually does not disable pacing functions
  - Newer revert to usual programming BUT older models may or may not revert to usual programming after removal of magnet
  - If you anticipate EMI problems: get a specialist to reprogram device
- Be aware of risks
Systematic protocol simplifies perioperative ICD management during electrocautery procedures more than 6 inches from the ICD
Gifford 2014: magnet OK?

<table>
<thead>
<tr>
<th></th>
<th>Reprogrammed N = 26</th>
<th>MAGNET N = 33</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure time (minutes)</td>
<td>110.53</td>
<td>87.91</td>
<td>0.45</td>
</tr>
<tr>
<td>Cautery time (minutes)</td>
<td>80.08</td>
<td>63.94</td>
<td>0.58</td>
</tr>
<tr>
<td>ICD off time (minutes)</td>
<td>195.54</td>
<td>91.45</td>
<td>0.002</td>
</tr>
<tr>
<td>Excess ICD “off” time (minutes)</td>
<td>115.46</td>
<td>27.51</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

“An important finding of this study is the longer ICD off time and excess ICD off time in patients whose ICDs are reprogrammed, which has important clinical implications.”

“For pacemaker-dependent ICD patients, providers must understand that magnet application to an ICD does not change pacing to asynchronous mode as in pacemakers.”
CIED periop management summary

• Ideally preop evaluation by trained specialist to verify function, settings; allows correction of problems before anesthesia
  – ACC/AHA recommends within 6 months
  – OR is not a good place to discover a problem with CIED

• Emergency: have a magnet, but sometimes best to NOT disable device
  – May be better to limit or manage risks of EMI

• Postop: interrogation, reprogramming if needed
LVAD patients

- Patient functional status **NOW** should dictate management (not at time of implant)
  - 6 minute walk distance: improving?
  - Any hospitalizations?
  - Anticoagulation status?
  - Status of comorbid conditions?

- Procedure specific factors
  - Where on body?
  - How invasive?
  - Blood loss likely?

- Monitoring:
  - MAC: usual but BP / perfusion by talking with patient?
  - GA: continuous NIBP (finger?) vs art cath – how invasive, bloody, etc
• 99 LVAD patients; 34 needed Gen Surg consults; 27 needed surgery

<table>
<thead>
<tr>
<th>Procedure</th>
<th>#</th>
<th>%</th>
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<tbody>
<tr>
<td>Tracheostomy</td>
<td>16</td>
<td>57</td>
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<tr>
<td>Abdomen</td>
<td>5</td>
<td>18</td>
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<tr>
<td>Colectomy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small bowel resection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Splenectomy</td>
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<td></td>
</tr>
<tr>
<td>Sleeve gastrectomy</td>
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</tr>
<tr>
<td>Abdominal exploration</td>
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<td>11</td>
</tr>
<tr>
<td>Hernia</td>
<td>3</td>
<td>11</td>
</tr>
<tr>
<td>Biliary tree</td>
<td>3</td>
<td>11</td>
</tr>
<tr>
<td>Hemorrhoidectomy</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>

• “Patients with LVADs frequently require consultation from noncardiac surgeons

• ...within the scope of general surgeons and often require operation.

• Patients with second-generation LVADs are more likely to become outpatients and develop more elective surgical problems.

• Noncardiac surgeons will be increasingly involved in caring for patients with LVADs and should anticipate the problems unique to this patient population.”
**LVAD patients, noncardiac surgery**

- 86 HM2 patients, 13 major, 12 minor operations
- Art cath used in 18 of 25 procedures

- “No peri-operative deaths, strokes, device thromboses, or device malfunctions.
- The incidence of bleeding requiring transfusion of PRBC was 36.0%, occurring in 9 procedures.
- Bleeding occurred in 3 of 12 patients (25%) undergoing minor surgeries and in 6 of 13 (46.2%) patients undergoing major surgeries (p < 0.004)”
Management after anesthesia:

• Continue monitoring ECG/pulse (*remember that LVAD patient may NOT have pulsatile flow*)
• External pacing/defibrillation available
• Specialist to intervene with device settings if needed
Conclusions

• Aging population, expanding indications: we will see more and more patients presenting for anesthesia with pacers, ICD and LVAD in place

• Careful management includes appropriate preoperative evaluation and preparation, monitoring appropriate to the patient & coordination of postoperative care
Questions?

Reanimation scene, *Young Frankenstein*, 1974
EXPANDED LIST OF INDICATIONS
Symptomatic:

- SND with brady/sinus pauses; chronotropic incompetence; Sinus brady as a result of required drug Rx
- 3° or advanced 2° AV block with brady or ventricular escape; including if from required drug Rx or after MI
- 2° AV block with bradycardia
- Recurrent syncope caused by spontaneously occurring carotid sinus stimulation and carotid sinus pressure that induces ventricular asystole of more than 3 seconds
Class I Indications for pacemakers
Circulation 2013; 127: e283-e352

Asymptomatic:

• 3° or advanced 2° AV block with ≥3 sec pause or ventricular escape <40 per min or AF with ≥5 sec pause
• 3° or advanced 2° AV block following AV nodal ablation; or postoperative that is not expected to resolve
• Persistent 3° AV block with ventricular rate <40 or faster if cardiomegaly / LV dysfunction / block below AV node
Class I Indications for pacemakers

Circulation 2013; 127: e283-e352

With or without symptoms:

- 3° or advanced 2° AV block with some NM diseases; exercise induced without ischemia;
- Bifascicular block with intermittent 3° or advanced 2° AV block, Type II 2° block or alternating bundle branch block
- Acute STEMI with persistent 2° AV block with alternating bundle or 3° AV block below His-Purkinje system; transient 2° or 3° AV infranodal block
- After heart transplant for persistent inappropriate or symptomatic bradycardia not expected to resolve
- Sustained pause-dependent VT, with or without QT prolongation
Class II Indications for pacemakers

Symptomatic:

- SND <40 bpm but clear association bradycardia not documented; syncope of unexplained origin with SND
- 1° or 2° AV block with pacer syndrome or hemodynamic compromise
- Bifascicular block with syncope NOT due to AV block AND other causes excluded
- Syncope with hypersensitive cardioinhibitory response ≥3 sec without clear provocative events OR neurocardiogenic syncope associated with bradycardia documented spontaneously or at the time of tilt-table testing
- After heart transplant if relative bradycardia impedes function / discharge OR with syncope even if bradycardia not documented
- Drug-refractory, recurrent AF in patients with coexisting SND
- Recurrent SVT that is reproducibly terminated by pacing when catheter ablation and/or drugs fail to control the arrhythmia or produce intolerable side effects
Class II Indications for pacemakers

Asymptomatic:

- SND dysfunction found at EPS; chronic heart rate <40 while awake
- Persistent 3° AV block with escape <40 without cardiomegaly; 2° or 3° AV block intra- or below His at EPS;
- Bifascicular block with prolonged HV interval OR non-physiological incidental pacing-induced infra-His block at EPS

With or without symptoms:

- Type II 2° AV block with narrow QRS; AV block from drug Rx / toxicity if expected to persist/recur
- Some NM diseases
- Persistent 2° or 3° AV block at AV node level
- High-risk patients with congenital long-QT syndrome
Class III Don’t Use Pacemaker for Circulation 2013; 127: e283-e352

- SND: ASYMPOTOMATIC; clearly documented symptoms WITHOUT BRADYCARDIA; resulting from nonessential drug Rx
- AV block: ASYMPOTOMATIC 1° block OR 2° type I OR fascicular block WITHOUT AV block; expected to resolve / not recur after drug reaction etc
- Acute MI: transient AV block in the absence of intraventricular conduction defects; transient AV block in the presence of isolated left anterior fascicular block; new bundle-branch block or fascicular block in the absence of AV block; persistent ASYMPOTOMATIC first-degree AV block in the presence of bundle-branch or fascicular block
- Carotid hypersensitivity / neurocardiogenic: hypersensitive cardioinhibitory response to carotid sinus stimulation without symptoms or with vague symptoms; situational vasovagal syncope in which avoidance behavior is effective and preferred
- SVT: presence of an accessory pathway that has the capacity for rapid anterograde conduction;
- Frequent or complex ventricular ectopic activity without sustained VT in the absence of the long-QT syndrome
- Torsade de pointes VT due to reversible causes
- Prevention of AF in patients WITHOUT other indication for pacemaker
Indications for Resynchronization
Circulation 2013; 127: e283-e352

Class I: Indicated
- LVEF ≤35%, SR with LBBB & QRS ≥150 msec, NYHA II, III or ambulatory IV on GDMT

Class IIA: Reasonable
- LVEF ≤35%, sinus rhythm, LBBB with a QRS duration 120 to 149 ms, and NYHA class II, III, or ambulatory IV symptoms on GDMT.
- LVEF≤35%, sinus rhythm, a non-LBBB pattern with a QRS duration greater than or equal to 150 ms, and NYHA class III/ambulatory class IV symptoms on GDMT.
- AF & LVEF ≤35% IF needs V pacing or meets other CRT criteria & AV nodal ablation or pharmacologic rate control will allow near 100% ventricular pacing with CRT.
- LVEF ≤35% on GDMT & undergoing new or replacement device placement with anticipated requirement for significant (>40%) ventricular pacing.

Class IIB: May be OK
- LVEF ≤30% & ischemic heart failure, SR, LBBB with a QRS duration ≥150 ms, and NYHA class I symptoms on GDMT.
- LVEF ≤35%, sinus rhythm, a non-LBBB pattern with QRS duration 120 to 149 ms, and NYHA class III/ambulatory class IV on GDMT.
- LVEF ≤35%, sinus rhythm, a non-LBBB pattern with a QRS ≥150 ms, and NYHA class II symptoms on GDMT.

Class III: No Benefit
- NYHA class I or II symptoms and non-LBBB pattern with QRS ≤150 msec.
- Patients whose comorbidities and/or frailty limit survival with good functional capacity to less than 1 year.
Class I Indications for ICD
Circulation 2013; 127: e283-e352

• Survivor of cardiac arrest from VF or unstable VT after other causes / reversible factors excluded
• Structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable
• Syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT or VF induced at EPS
• LVEF ≤35% due to prior MI & ≥40 days post-MI & NYHA II or III
• Nonischemic DCM with LVEF ≤35% & NYHA II or III
• LV dysfunction due to prior MI & ≥40 days post-MI, with LVEF ≤30%, & NYHA I
• Nonsustained VT due to prior MI, LVEF ≤40%, and inducible VF or sustained VT at EPS
Class II indications for ICD

Class IIa

- Unexplained syncope, significant LV dysfunction, and nonischemic DCM with sustained VT and normal or near-normal ventricular function
- HCM who have 1 or more major risk factors for SCD
- Prevention of SCD in patients with ARVD/C who have 1 or more risk factors for SCD
- Long-QT syndrome who are experiencing syncope and/or VT while receiving beta blockers
- Nonhospitalized patients awaiting transplantation with Brugada syndrome who have had syncope
- Catecholaminergic polymorphic VT who have syncope and/or documented sustained VT while receiving beta blockers
- Cardiac sarcoidosis, giant cell myocarditis, or Chagas disease

Class IIb

- Nonischemic heart disease with ≤35% & NYHA I
- Long-QT syndrome & risk factors for SCD
- Syncope & advanced structural heart disease in whom thorough invasive and noninvasive investigations have failed to define a cause
- Familial cardiomyopathy associated with sudden death
- LV noncompaction
ICD: Class III – Don’t Use Here

• Patients who **do not have a reasonable expectation of survival** with an acceptable functional status for at least 1 year, even if they meet ICD implantation criteria specified

• Patients with **incessant VT or VF**

• Patients with significant **psychiatric** illnesses that may be **aggravated** by device **implantation** or that may preclude systematic follow-up

• NYHA **Class IV** patients with drug-refractory congestive heart failure who are **not candidates for cardiac transplantation or CRT-D**

• **Syncope** of undetermined cause in a patient **without inducible VT** and without structural heart disease

• VF or VT **amenable** to surgical or catheter **ablation** (eg, atrial arrhythmias associated with the Wolff-Parkinson-White syndrome, RV or LV outflow tract VT, idiopathic VT, or fascicular VT in the absence of structural heart disease)

• Ventricular tachyarrhythmias due to a **completely reversible disorder** in the absence of structural heart disease (eg, electrolyte imbalance, drugs, or trauma)