Cardiac devices in the Golden Years
All that glitters…

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Disclosures

• No related disclosures

• No industry affiliations

• Grant from Greenwall Foundation: Caregiver Stress in Destination Ventricular Assist Devices

• 2 NIH Data Safety Monitoring Boards
Outline

• Device Therapy for Advanced Heart Failure
• Ethical conflicts/considerations
• Complexities of Advance Care Planning in Heart Failure
• “Shiny” Projects
What Broke My Father's Heart

By KATY BUTLER

How putting in a pacemaker wrecked a family's life.
• “The pacemaker bought my parents two years of limbo, two of purgatory and two of hell…”
• “…If we did nothing, his pacemaker would not stop for years. Like the tireless charmed brooms in Disney’s “Fantasia,” it would prompt my father’s heart to beat after he became too demented to speak, sit up or eat.”
Heart Failure

- 23,000,000 worldwide (5.7 million US)
- Incidence: 500-700,000/year in US
- 20% of population will get it
- Including 11% of patients with no CAD
- 5-10% NYHA class IV: 13-40% 2 year survival


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Can vs Do

Heart Failure Devices

Pacemaker, dual-chamber

Implantable Cardioverter Defibrillator (ICD)

Heart
Leads

Dual-chamber pacemaker device

© medmovie.com
Ventricular Assist Devices

- Inflow Bearing Set
- Outflow Bearing Set
- Rotor
- Flow
Ventricular Assist Devices

- **Acute Cardiogenic Shock**
  - Post cardiac surgery
  - Myocarditis
  - Massive MI

- **Chronic Heart failure**
  - Stabilize until transplant

- **Bridges**
  - To Transplant (BTT)
  - To Recovery (BTR)
  - To Decision
  - To the rest of one’s life=Destination Therapy (DT)
## Ventricular Assist Devices

<table>
<thead>
<tr>
<th>Variable</th>
<th>DT patients (N = 385)</th>
<th>All other LVADs (N = 2134)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, No. (%)</td>
<td></td>
<td></td>
<td>0.01</td>
</tr>
<tr>
<td>Male</td>
<td>322 (84)</td>
<td>1,663 (78)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>63 (16)</td>
<td>471 (22)</td>
<td></td>
</tr>
<tr>
<td>Race, No. (%)</td>
<td></td>
<td></td>
<td>0.01</td>
</tr>
<tr>
<td>White</td>
<td>291 (76)</td>
<td>1,452 (68)</td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>69 (18)</td>
<td>506 (24)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>25 (6)</td>
<td>176 (8)</td>
<td></td>
</tr>
<tr>
<td>Age at implant</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mean years</strong></td>
<td>61.7</td>
<td>52.7</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>Range</strong></td>
<td>23–82</td>
<td>19–88</td>
<td></td>
</tr>
</tbody>
</table>

Table 5. Demographics—Adult Primary Implants: INTERMACS, June 2006–June 2010
SPECIAL FEATURE

Third INTERMACS Annual Report: The evolution of destination therapy in the United States

James K. Kirklin, MD, MD, David C. Naftel, PhD, MD, Robert L. Kormos, MD, Lynne W. Stevenson, MD, Francis D. Pagani, MD, Marissa A. Miller, DVM, MPH, Karen L. Ulisney, MSN, CRNP, J. Timothy Baldwin, PhD, and James B. Young, MD

From the aUniversity of Alabama at Birmingham, Birmingham, Alabama; bUniversity of Pittsburgh Medical Center, Presbyterian University Hospital, Pittsburgh, Pennsylvania; cCardiovascular Division, Brigham & Women’s Hospital, Boston, Massachusetts; dUniversity of Michigan, Ann Arbor, Michigan; eNational Heart Lung and Blood Institute (NHLBI), Bethesda, Maryland; fNational Institutes of Health/NHLBI, Division of Cardiovascular Diseases, Advanced Technologies and Surgery Branch, and gNHLBI at Two Rockledge Center, Bethesda, Maryland; and hCleveland Clinic Foundation, Lerner College of Medicine, Cleveland, Ohio

KEY WORDS:
mechanical circulatory support; destination therapy; INTERMACS; LVAD; advanced heart failure

The third annual report of the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) provides documentation of the current landscape of durable mechanical circulatory support in the United States. With nearly 3,000 patients entered into the database, the transition to continuous-flow pump technology is evident and dramatic. This report focuses on the rapidly expanding experience with mechanical circulatory support as destination therapy. The current 1-year survival of 75% with continuous-flow destination therapy provides a benchmark for the evolving application of this therapy. J Heart Lung Transplant 2011;30:115–23
© 2011 International Society for Heart and Lung Transplantation. All rights reserved.
Overall Survival

**Time Period:** June 2006 – September 2010

**Adult Primary Implants, Destination Therapy:** n=385

**Continuous Flow Pump, n=281, deaths=46**

**Pulsatile Flow Pump, n=104, deaths=51**

**By Pump Type**

<table>
<thead>
<tr>
<th>Month</th>
<th>CFP</th>
<th>PFP</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 mo</td>
<td>86%</td>
<td>83%</td>
</tr>
<tr>
<td>6 mo</td>
<td>81%</td>
<td>70%</td>
</tr>
<tr>
<td>12 mo</td>
<td>74%</td>
<td>61%</td>
</tr>
<tr>
<td>24 mo</td>
<td>74%</td>
<td>39%</td>
</tr>
</tbody>
</table>

**Event:** Death (censored at transplant or explant recovery)

**p = .02**

**Months after Device Implant:**
VADS

- Improved organ preservation (perfusion) pre transplant
- Improved survival and QOL

VADs

- Durability?
- Risks
  - GI bleeding (VWF def?)
  - Infections (driveline)
  - Strokes

Figure 1: Post-Transplant Survival of Patients on Intracorporeal VAD Support Compared With UNOS Status 1 Patients Without VAD Support

Examples of Criteria for Implantable LVAD for Lifetime Support

More objective
- Clinical profiles
  - Not crash and burn
  - Not post-surgical
  - Ambulatory for DT?
- Renal function-not on dialysis. eGFR>50*, BUN < 50*
- Hepatic function > 2X normal*
- Lung function-not intubated or on home O2 or steroids
- Infection - Not on systemic antibiotics
- Nutrition- pre-albumin >15*, albumin > 3*
- RV function-not yet defined well
- 2 year prognosis

*Proposed in: JHLT Supplement 2010; 29:4S
Slaughter, et al. HMII Investigators

Crucial But Arguable
- “Frailty”
- Other Co-morbidities
- Psychosocial limitations
- Cognitive limitations
- Social support
- Age?

Adapted from Lynne Warner Stevenson
Pacemakers

- Symptomatic Bradycardia
- US Implants per year – 250,000
- Increased 50% during the 1990s

Implantable Cardioverter Defibrillator (ICD)

• 100,000 ICDs implanted/year in USA

• Aborting sudden cardiac arrest

• Termination of many lethal arrhythmias with antitachycardia pacing (ATP)

• Primary prevention and secondary prevention

--adapted from Ralph Verdino
"Darn, defibrillators."
SCD-HeFT

Bardy, et al. NEJM 2005;352:225
ICD

- Inappropriate Shocks
  - Anxiety
  - Depression
  - ED resource utilization

Hunt, Circulation. 2005; 112(12):e154-235
Stevenson, LW. Circ 2006. 114;101-103
Time Horizon of Lives Saved by ICDs

Adapted from Lynne Warner Stevenson
Patients With ICD for Primary Prevention: “How Many Lives Like Yours Will Be Saved?”

7.2 from SCD-HeFT
None in first year

% of Patients With HF symptoms And LVEF <35

Lives to be saved/ 100 during 5 years

Less than 10 10 25-40 At least 50

Stewart, Stevenson et al, J Cardiac Failure, 2009

Adapted from Lynne Warner Stevenson
If we put an ICD in 100 patients with heart disease like yours, over the next 5 years we would expect:

- 30 patients will die anyway
- 7-8 patients will be saved by the ICD
- 10-20 would have a shock they don’t need
- 5-15 would have other complications
- The rest of patients will not experience their devices at all

Some patients will request to have the device inactivated to allow natural death.

Desai A et al
J Cardiac Failure
2006

Adapted from Lynne Warner Stevenson
Bi V

• Save lives
• Improve symptoms
• EF <35%
• QRS>120ms
• NYHA Class III-IV symptoms

Figure 1. Kaplan–Meier Estimates of the Time to the Primary End Point (Panel A) and the Principal Secondary Outcome (Panel B).

The primary outcome was death from any cause or an unplanned hospitalization for a major cardiovascular event. The principal secondary outcome was death from any cause.
<table>
<thead>
<tr>
<th>Patients</th>
<th>NYHA class</th>
<th>LVEF (%)</th>
<th>SR/AF</th>
<th>QRS (ms)</th>
<th>Endpoints</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONTAK CD&lt;sup&gt;a&lt;/sup&gt;</td>
<td>227</td>
<td>II, IV</td>
<td>≤35%</td>
<td>SR</td>
<td>≥120</td>
<td>All-cause mortality + HF admission, pVO₂, 6MWT, NYHA, QoL, LVEDD, LVEF</td>
</tr>
<tr>
<td>MIRACLE ICD II&lt;sup&gt;a&lt;/sup&gt;</td>
<td>186</td>
<td>II</td>
<td>≤35%</td>
<td>SR</td>
<td>≥130</td>
<td>VE/CO&lt;sub&gt;p&lt;/sub&gt;, pVO₂, NYHA, QoL, 6MWT, LV volumes, LVEF</td>
</tr>
<tr>
<td>REVERSE&lt;sup&gt;a&lt;/sup&gt;</td>
<td>610</td>
<td>I, II</td>
<td>≤40%</td>
<td>SR</td>
<td>≥120</td>
<td>(a) Clinical composite endpoint; (b) LVESVI; (c) HF admission; (d) all-cause mortality</td>
</tr>
<tr>
<td>MADIT CRT&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1820</td>
<td>I, II</td>
<td>≤30%</td>
<td>SR</td>
<td>≥130</td>
<td>(a) HF admission or all-cause mortality; (b) all-cause mortality; (c) LVESV</td>
</tr>
<tr>
<td>RAFT&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1798</td>
<td>II, III</td>
<td>≤30%</td>
<td>SR/AF</td>
<td>≥130, ≥200&lt;sup&gt;*&lt;/sup&gt;</td>
<td>(a) All-cause mortality or HF admission; (b) all-cause mortality; (c) CV mortality; (d) HF admission</td>
</tr>
</tbody>
</table>

CRT = cardiac resynchronisation therapy. NYHA = New York Heart Association. LVEF = left ventricular ejection fraction. SR = sinus rhythm. AF = atrial fibrillation. HF = heart failure. pVO₂ = peak oxygen consumption. 6MWT = 6-min walk test. QoL = quality of life. LVEDD = left ventricular end-diastolic diameter. CRT-D = CRT with defibrillator function. VE/CO<sub>p</sub> = ventilation/carbon dioxide ratio. LV = left ventricular. LVESVI = left ventricular stroke volume index. NS = not significant. CRT-P = CRT with pacemaker function. LVESV = left ventricular end-systolic volume. CV = cardiovascular. * Patients with AF.

Table 3: Inclusion criteria, endpoints, and outcome of randomised clinical trials evaluating CRT in mild and asymptomatic heart failure

Figure 2. CCS and LVESV response rates.

Clinical Composite Score
N = 426

- Improved: 69%
- Unchanged: 15%
- Worsened: 16%

Change in LVESV
N = 286

- ≥15% Reduction: 56%
- Other: 35%
- ≥15% Increase: 9%

Implant complications

• 3.2% (CI, 2.8% to 3.6%)
  – sinus dissection or perforation
  – pericardial effusion or tamponade
  – Pneumothorax
  – hemothorax

“There are no ethical dilemmas; the technology is proved and the patients have short wretched lives.”

Westaby and Poole-Wilson, BMJ. 2007 334(7586): 167–168
Who gets a VAD?

• Transition from “rescue” to “chronic disease management tool”
• How like transplant should it be?
  – Age requirements?
  – Psychosocial Requirements?
  – Ideal candidacy?
  – Palliative VAD?
  – VAD “waiting list”?
Discrimination

- Physiological vs. Numerical Age
- Financial
- Social support
- Mild dementia
- Addictions
End of Life: When the heart is taken out of the equation…

- Life prolongation
- Relief of symptoms
  - There may be more time to consider goals of care
  - There may be more time for patients and surrogates to change their minds about goals of care
<table>
<thead>
<tr>
<th>Primary cause of death</th>
<th>Early (&lt;1 mo)</th>
<th></th>
<th>Later (≥1 mo)</th>
<th></th>
<th>Total</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer</td>
<td>0</td>
<td>0%</td>
<td>1</td>
<td>2%</td>
<td>1</td>
<td>1%</td>
</tr>
<tr>
<td>Cardiac Failure</td>
<td>2</td>
<td>5%</td>
<td>7</td>
<td>11%</td>
<td>9</td>
<td>9%</td>
</tr>
<tr>
<td>Cardiovascular: Other</td>
<td>4</td>
<td>11%</td>
<td>4</td>
<td>6%</td>
<td>8</td>
<td>8%</td>
</tr>
<tr>
<td>Device Malfunction</td>
<td>0</td>
<td>0%</td>
<td>3</td>
<td>5%</td>
<td>3</td>
<td>3%</td>
</tr>
<tr>
<td>Hematologic Other</td>
<td>0</td>
<td>0%</td>
<td>1</td>
<td>2%</td>
<td>1</td>
<td>1%</td>
</tr>
<tr>
<td>Hemorrhage: Disseminated Intravas Coagulation</td>
<td>2</td>
<td>5%</td>
<td>0</td>
<td>0%</td>
<td>2</td>
<td>2%</td>
</tr>
<tr>
<td>Hemorrhage: Post-Operative surgery related</td>
<td>4</td>
<td>11%</td>
<td>0</td>
<td>0%</td>
<td>4</td>
<td>4%</td>
</tr>
<tr>
<td>Hemorrhage: Pulmonary</td>
<td>2</td>
<td>5%</td>
<td>0</td>
<td>0%</td>
<td>2</td>
<td>2%</td>
</tr>
<tr>
<td>Hemorrhage: Other</td>
<td>0</td>
<td>0%</td>
<td>3</td>
<td>5%</td>
<td>3</td>
<td>3%</td>
</tr>
<tr>
<td>Infection</td>
<td>1</td>
<td>2%</td>
<td>5</td>
<td>8%</td>
<td>6</td>
<td>6%</td>
</tr>
<tr>
<td>Other chronic illness</td>
<td>1</td>
<td>2%</td>
<td>0</td>
<td>0%</td>
<td>1</td>
<td>1%</td>
</tr>
<tr>
<td>Pulmonary: Respiratory Failure</td>
<td>2</td>
<td>5%</td>
<td>2</td>
<td>3%</td>
<td>4</td>
<td>4%</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>1</td>
<td>3%</td>
<td>2</td>
<td>3%</td>
<td>3</td>
<td>3%</td>
</tr>
<tr>
<td>Other</td>
<td>4</td>
<td>11%</td>
<td>10</td>
<td>16%</td>
<td>14</td>
<td>14%</td>
</tr>
<tr>
<td>Unknown</td>
<td>3</td>
<td>11%</td>
<td>11</td>
<td>21%</td>
<td>14</td>
<td>18%</td>
</tr>
<tr>
<td>CNS cause of death</td>
<td>4</td>
<td>11%</td>
<td>5</td>
<td>8%</td>
<td>9</td>
<td>9%</td>
</tr>
<tr>
<td>MOF</td>
<td>5</td>
<td>14%</td>
<td>8</td>
<td>13%</td>
<td>13</td>
<td>13%</td>
</tr>
<tr>
<td>Total</td>
<td>35</td>
<td></td>
<td>62</td>
<td></td>
<td>97</td>
<td>100%</td>
</tr>
</tbody>
</table>

CNS, central nervous system; LVAD, left ventricular assist device.
Cardiac Failure includes RV Failure and VT/VF.

Renal Failure: 14%
Cancer: 1%
Other chronic illness: 13%
Respiratory failure: 21%
Other: 5%
Unknown: 21%

= 38%
Palliative and End of Life VAD care

- Surgical removal incompatible with palliative care?
- “Letting nature take its course”?
- Deactivation as a terminal (planned) event
- Physician Assisted Suicide? (constitutive or replacement therapy)
VAD discontinuation

• Back pressure on failing heart
• Disruption of apical contractility
• Thrombus formation
  → Hastens death
  → Leaving endotrachal tube in after extubation

VAD discontinuation

- Physician Assisted Suicide/Euthanasia
  - Constitutive therapy—integrated part of the body
  - Replacement therapy
  - Surrounding responsibility
  - OK if Non-cardiac cause of death

Asscher J. Bioethics. 2008;22(5):278-85
Rizzieri, A.G., Philosophy, Ethics, and Humanities in Medicine, 2008; 3, 20-35.
VAD withdrawal/witholding

• Planned withdrawal
  – Anxiolytics
  – Analgesics
  – Palliative sedation

• Withholding device changeout

VADs in Hospice

• How should they be managed?
• When and how should devices be deactivated?
• Can hospice meet the growing need?
• What to do if there is no hospice?
Suicide after ventricular assist device implantation

Katharina Tigges-Limmer, PhD, Michael Schönbrodt, MD, Daniela Roefe, RN, Latif Arusoglu, MD, Michel Morshuis, MD, and Jan F. Gummert, MD

From the Clinic for Thoracic and Cardiovascular Surgery, Heart Center North Rhine-Westphalia, Ruhr-University of Bochum, Bad Oeynhausen, Germany.

KEYWORDS:
LVAD; destination therapy; heart failure; suicide; depression; quality of life

Depression and anxiety are well documented in patients with end-stage heart failure and correlate with a higher risk of suicide. We report a 69-year-old depressed patient who committed suicide by disconnecting the driveline of his left ventricular assist device almost 3 years after implantation. We provide the medical, psychologic, and psychiatric background of this unique case. This report highlights the importance of pre-implant psychologic screening, the need for regular and long-term psychologic support for this vulnerable patient population, and the need for more qualitative research on patients' views on living with a left ventricular assist device, together with research exploring risk profiles for depression and suicide.

J Heart Lung Transplant 2010;29:692-4
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Ethical Analysis of Withdrawal of Pacemaker or Implantable Cardioverter-Defibrillator Support at the End of Life
[Original Article]
Mueller, Paul S. MD; Hook, C. Christopher MD; Hayes, David L. MD
From the Division of General Internal Medicine (P.S.M.), Division of Hematology and Internal Medicine (C.C.H.), and Division of Cardiovascular Diseases and Internal Medicine (D.L.H.), Mayo Clinic, Rochester, Minn.
Address reprint requests and correspondence to Paul S. Mueller, MD, Division of General Internal Medicine, Mayo Clinic, 200 First St SW, Rochester, MN 55905.
Management of Implantable Cardioverter Defibrillators in End-of-Life Care

Nathan E. Goldstein, MD; Rachel Lampert, MD; Elizabeth Bradley, PhD; Joanne Lynn, MD, MA, MS; and Harlan M. Krumholz, MD

Background: Implantable cardioverter defibrillators (ICDs) can prevent premature death from an arrhythmia but may also prolong the dying process and make it more distressing.

Objective: To describe the frequency, timing, and correlates of discussions about deactivating ICDs.

Design: Retrospective cohort study.

Setting: Telephone survey.

Participants: Next of kin of patients with ICDs who died of any cause. Of 136 next of kin contacted, 100 (74%) participated.

Measurements: Incidence of discussions about deactivating ICDs and timing of last shock from ICD.

Results: Next of kin reported that clinicians discussed deactivating the ICD in only 27 of the 100 cases. Most discussions occurred in the last few days of life. Family members reported that 8 patients received a shock from their ICD in the minutes before death.

Limitations: This retrospective survey relied on the reports of next of kin.

Conclusions: Next of kin reported that clinicians discussed deactivating ICDs with few patients. Individuals who choose to receive this device should have the opportunity to choose to discontinue it as death approaches.

For author affiliations, see end of text.

In this survey of the next of kin of 100 patients who died with ICDs in place, only 27 reported that physicians discussed deactivation of the ICD and often did so only in the last few days of life.
“Every 20 minutes, he would [get a shock and get] jolted awake. Meanwhile he was on morphine. . . . I saw this pattern . . . he was waking up from like a really bad dream type of thing . . . and he would say a word or something, and after 20 seconds he would be unconscious again.”
Should implantable cardioverter-defibrillators and permanent pacemakers in patients with terminal illness be deactivated?

Deactivating Implantable Cardioverter-Defibrillators and Permanent Pacemakers in Patients With Terminal Illness

An Ethical Distinction

G. Neal Kay, MD; Gregory T. Bittner, JD
CLINICAL RESEARCH STUDY

Withdrawing Implantable Defibrillator Shock Therapy in Terminally Ill Patients

William R. Lewis, MD,a Donna L. Luebke, NP,a Nancy J. Johnson, MD,a Michael D. Harrington, MD,a Ottorino Costantini, MD,a Mark P. Aulisio, PhDb

aHeart and Vascular Center, MetroHealth Campus, Case Western Reserve University, Cleveland, Ohio; bClinical Ethics Program, MetroHealth Medical Center, Department of Bioethics, Case Western Reserve University, Cleveland, Ohio; cDivision of Geriatrics and Palliative Care, MetroHealth Medical Center, Cleveland, Ohio.

ABSTRACT

When compared to Group 2, Comparing pacemaker dependent and non-dependent patients, there was no difference in the time between therapy discontinuation and death. Receiving devices. Once protected from an arrhythmic death, these patients may develop other terminal diseases such as cancer or congestive heart failure. It is appropriate to withdraw defibrillator shock therapy when such patients desire only comfort care.

METHODS: The charts of ICD patients who had died were reviewed. Two groups emerged: Group 1 (20) included patients whose defibrillator was turned off through the comprehensive comfort care approach. Group 2 (43) included patients whose clinical course was so rapid that the defibrillator was not turned off. Pacing therapy was not withdrawn in either group.

RESULTS: Defibrillator discharges, cause of death, and time from ICD discharge to death were compared. Group 2 patients died more acutely than Group 1. Group 1 experienced fewer shocks prior to death when compared to Group 2. Comparing pacemaker dependent and non-dependent patients, there was no difference in the time between therapy discontinuation and death.

CONCLUSION: This is the largest study to date to review the characteristics of patients with ICDs and terminal illness. Only one-third of terminally ill patients with ICDs were able to have shock therapy withdrawn as part of a comfort care strategy. These patients experienced fewer shocks in the final days of their illness. © 2006 Elsevier Inc. All rights reserved.

KEYWORDS: Implantable defibrillator; Palliative care; Do not resuscitate
Deactivation: ICD vs. PPM

- ICD
  - Shocking function + ATP?
  - Backup pacing?
  - Predictability of lethal arrhythmia?
  - DNR=deactivation?

- PPM
  - Symptom relief vs. life prolongation
    - Indication?
    - Underlying rhythm?

- CRT
  - d/c defibrillation only?

→ EP consult
What do patients think about ICDs?

• Would you want your device turned off if you had
  – Cancer: 30%
  – Certain death within 1 month: 40%
  – Daily shocks: 50%
  – I would never want the device turned off: 10-40%

Deactivation of Implantable Cardioverter Defibrillators in Terminal Illness and End of Life Care

James N. Kirkpatrick, MD*, Maia Gottlieb, Priya Sehgal, Rutuke Patel, PA-C, and Ralph J. Verdino, MD

Cardiology professional societies have recommended that patients with cardiovascular implantable electronic devices complete advance directives (ADs). However, physicians rarely discuss end of life handling of implantable cardioverter defibrillators (ICDs), and standard AD forms do not address the presence of ICDs. We conducted a telephone survey of 278 patients with an ICD from a large, academic hospital. The average period since implantation was 5.15 years. More than 1/3 (38%) had been shocked, with a mean of 4.69 shocks. More than 1/2 had executed an AD, but only 3 had included a plan for their ICD. Most subjects (86%) had never considered what to do with their ICD if they had a serious illness and were unlikely to survive. When asked about ICD deactivation in an end of life situation, 42% said it would depend, 28% favored deactivation, and 11% would not deactivate. One quarter (26%) thought ICD deactivation was a form of assisted suicide, 22% thought a do not resuscitate order did not mean that the ICD should be deactivated, and 46% responded that the ICD should not be automatically deactivated in hospice. The answers did not correlate with any demographic factors. Almost all (95%) agreed that patients should have the opportunity to execute an AD that directs handing of an ICD. When asked who should be responsible for discussing this device for an AD, 31% said electrophysiologists, 45% said general cardiologists, and 14% said primary care physicians. In conclusion, the results of the present study highlight the lack of consensus among patients with an ICD on the issue of deactivation at the end of a patient’s life. These findings suggest cardiologists should discuss end of life care and device deactivation with their patients with an ICD. © 2011 Elsevier Inc. All rights reserved. (Am J Cardiol 2011; xx:xxx)
278 ICD patients

- 5.15 years since implant
- 1/3 received shocks (avg. 4.7 shocks)
- 50% had advance directives
  - Only 3 had included plan for ICD
What should be done with your ICD?
What should be done with ICDs?
ICD

Quality of Death

“...we rescue people from a relatively sudden death from myocardial infarction only to inflict on them a more prolonged death from progressive heart failure.”

Taking away your chance to die quickly and painlessly.

Goodman NW. BMJ. 314(7092):1484, 1997
The good news is that we managed to save your life! The bad news is that you are going to spend it paying for the good news!
Congressional Budget Office Projections ....
Projected Cost Increases of CVD

Heidenreich, *Circulation.* 2011;123:933-944
Estimated Direct and Indirect Costs of HF in US

- Hospitalization: $20.9 billion (53%)
- Nursing Home: $4.7 billion (14%)
- Lost Productivity/Mortality*: $4.1 billion (8%)
- Home Healthcare: $3.8 billion (8%)
- Physicians/Other Professionals: $2.5 billion (10%)
- Drugs/Other Medical Durables: $3.2 billion (7%)

Total Cost: $39.2 billion

--Lynne Warner Stevenson

VADs

$ Implant costs: $122,785 – $264,839

$ 360,407 / 5 years

$ ICER* = $198,184
(CE benchmark: $50,000-100,000)

*incremental cost-effectiveness ratio over medical therapy

Rogers JG, et al. Circ Heart Fail. 2011

😊 Prevent (CV) hospitalizations

😊 Cheaper than Transplant
PPM and ICD

- Basic pulse generators
  - $2,200-5,100
- Basic leads
  - $400 to $1,000
- ICD generator
  - $20,000 to $40,000
- ICD leads
  - $10,000

Personal communication, device purchasing agents for the Hospital of the University of Pennsylvania, 2009 and Syracuse VA, 2011
Costs

- CRT-D (additional $4,000 to $16,000 above ICD)
Cost-Effectiveness of Implantable Cardioverter–Defibrillators

Gillian D. Sanders, Ph.D., Mark A. Hlatky, M.D., and Douglas K. Owens, M.D.

ABSTRACT

BACKGROUND

Eight randomized trials have evaluated whether the prophylactic use of an implantable cardioverter–defibrillator (ICD) improves survival among patients who are at risk for sudden death due to left ventricular systolic dysfunction but who have not had a life-threatening arrhythmia. From Duke Clinical Research Institute, Duke University, Durham, N.C. (G.D.S.); the Department of Health Research and Evidence Synthesis, Duke Clinical Research Institute, Duke University, Durham, N.C. (M.A.H.); and the Department of Medicine, Duke University Medical Center, Durham, N.C. (D.K.O.). These six populations ranged from $34,000 to $70,200 per QALY gained. Sensitivity analyses showed that this cost-effectiveness ratio would remain below $100,000 per QALY as long as the ICD reduced mortality for seven or more years.

RESULTS

Use of the ICD increased lifetime costs in every trial. Two trials — the Coronary Artery Bypass Graft (CABG) Patch Trial and the Defibrillator in Acute Myocardial Infarction Trial (DINAMIT) — found that the prophylactic implantation of an ICD did not reduce the risk of death and thus was both more expensive and less effective than control therapy. For the other six trials — the Multicenter Automatic Defibrillator Implantation Trial (MADIT) I, MADIT II, the Multicenter Unsustained Tachycardia Trial (MUSTT), the Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation (DEFINITE) trial, the Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) trial, and the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) — the use of an ICD was projected to add between 1.01 and 2.99 quality-adjusted life-years (QALY) and between $608,000 and $101,000 in cost. Using base-case assumptions, we found that the cost-effectiveness of the ICD as compared with control therapy in these six populations ranged from $34,000 to $70,200 per QALY gained. Sensitivity analyses showed that this cost-effectiveness ratio would remain below $100,000 per QALY as long as the ICD reduced mortality for seven or more years.

Copyright © 2005 Massachusetts Medical Society.
Pie graph of current expenditures for heart failure in the United States\textsuperscript{10} (excluding estimates for lost productivity) with superimposed cost of additional implantable devices as proposed in the theoretical target projection, if divided over 2 years. MD = physician staff.
Costs

- How do we fairly (justly) allocate resources?
- What is “cost effective” and how is it determined?
- Should we ration devices?
  - Who Rations?
  - Inclusion vs. exclusion
    - How do we identify a high enough risk group?

Implant Restrictions

• Medicare funding restrictions—what does this mean for cardiac devices?
• Discrimination
  – Elderly vs. young—physiological age
  – Mild dementia—Am. With Disabilities Act
  – Severe Depression—“
→ Waiting list?
→ ”Device committee”?
Complexities in Advance Care Planning

It's complicated.
Complexities

- Changing preferences
- Timing of AD discussions
- Who is responsible for the discussions?
- What should be discussed?
- How do you bring up the topic?
“My advance directive was for you not to show up.”
Patient Preferences After Hospital Discharge

Patient preferences correlated poorly with MLHFQ, symptom and overall health scores. Although not statistically significant, there was a trend toward patients with worse quality of life and symptom scores preferring more aggressive treatment.
When should AD for ICD be discussed?
Who should discuss AD for ICD?
HRS Expert Consensus Statement on the Management of Cardiovascular Implantable Electronic Devices (CIEDs) in patients nearing end of life or requesting withdrawal of therapy

This document was developed in collaboration and endorsed by the American College of Cardiology (ACC), the American Geriatrics Society (AGS), the American Academy of Hospice and Palliative Medicine (AAHPM); the American Heart Association (AHA), the European Heart Rhythm Association (EHRA), and the Hospice and Palliative Nurses Association (HPNA).

Rachel Lampert, MD, FHRs, David L. Hayes, MD, FHRs, George J. Annas, JD, MPH, Margaret A. Farley, PhD, Nathan E. Goldstein, MD, Robert M. Hamilton, MD, G. Neal Kay, MD, FHRs, Daniel B. Kramer, MD, Paul S. Mueller, MD, MPH, Luigi Padeletti, MD, Leo Pozuelo, MD, Mark H. Schoenfeld, MD, FHRs, Panos E. Vardas, MD, PhD, Debra L. Wiegand, PhD, RN, Richard Zellner, JD, MA

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<table>
<thead>
<tr>
<th>Timing of Conversation</th>
<th>Points to be Covered</th>
<th>Helpful Phrases to Consider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients at End of Life</td>
<td>Re-evaluation of benefits and burdens of device</td>
<td>“I think at this point we need to re-evaluate what your [device] is doing for you. Given how advanced your disease is we need to discuss whether it makes sense to keep it active. I know this may be upsetting to talk about, but can you tell me your thoughts at this point?”</td>
</tr>
<tr>
<td></td>
<td>Discussion of option of deactivation / disabling device addressed with all patients, though not required</td>
<td></td>
</tr>
</tbody>
</table>

Helpful Phrases to Consider:

- “I think at this point we need to re-evaluate what your [device] is doing for you. Given how advanced your disease is we need to discuss whether it makes sense to keep it active. I know this may be upsetting to talk about, but can you tell me your thoughts at this point?”
Society Guidelines

The 2011 Canadian Cardiovascular Society Heart Failure Management Guidelines Update: Focus on Sleep Apnea, Renal Dysfunction, Mechanical Circulatory Support, and Palliative Care

Primary Panel Authors: Robert S. McKelvie, MD, PhD, FRCPC (Chair),
Gordon W. Moe, MD, FRCPC (Co-Chair),
Anson Cheung, MD, FRCSC,
Jeannine Costigan, RN, MScN, APN,
Anique Ducharme, MD, FRCPC,
Estrellita Estrella-Holder, RN, BN, MScA, CCN(C),
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John Floras, MD, DPhil, FRCPC, FACC, FESC,
Nadia Giannetti, MD, FRCPC,
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George A. Heckman, MD, MSc, FRCPC,
Jonathan G. Howlett, MD, FRCPC,
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Miroslav Rajda, MD, FRCPC,
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Debra L. Isaac, MD, FRCPC,
Marie-Hélène Leblanc, MD, FRCPC,
Peter Liu, MD, FRCPC,
Bruce Sussex, MD, FRCPC,
Heather J. Ross, MD, FRCPC.
| Introducing the notion that heart failure is potentially fatal | “…Heart failure is a very serious disease, from which many patients ultimately die. Thankfully we have some extremely good treatments…” |
| Assessing readiness | “People may die from heart failure, but it is not like cancer in that it is very hard to predict how long people with heart failure will live.” |
| | “…is there anyone you trust to make medical decisions for you, and have you talked with this person about what is important to you?…” |

Complicated Issues

- Multidisciplinary approach
  - Geriatrics
  - Cardiology
  - Primary care
  - Palliative care
  - Subspecialty cardiology
  - Nursing
  - Social work
  - Ethics

- Dialogue

- Joint Consensus Statements/Guidelines
Pacemaker/ICD Reuse
VAD Advance Directive
Pacemaker Implant Disparities

• Western world implants/million population
  – >450 for each western country
  – USA: 752

• Lower/Middle Income Countries (LMIC)
  – Peru: 14
  – Bangladesh: 4
  – Thailand: 22
  – South Africa: 54
Overseas Need

- Cardiovascular disease burden in LMIC
  - Increased 137% 1990 to 2020
  - 14 million cardiovascular deaths
  - Younger age
    - Loss of economic productivity

Joshi, J Am Coll Cardiol. 2008; 52:1817-25
WHO. Cardiovascular Disease. Factsheet
Cost

• “The average wage in Bolivia is between $50 and $100 a month…”

• LMIC Healthcare budgets focus on prevention
Device Donations

• New, expired Devices

• Used Devices
  – Upgrades
  – Post mortem
Post Mortem

• Pacemaker deaths
  – 20% within 33 months
  – 40% within 4 years
• Patients > 80 y/o
  – 32% of pacemaker implants
• Pacemaker longevity: 10 years

Post Mortem Removal

- Pacemakers and ICDs explode and damage the crematorium chamber.

- Cremation projected to reach 59% of all deaths in the United States by 2025.
Infection

<table>
<thead>
<tr>
<th>Study</th>
<th>Reuse TotalEvents</th>
<th>New TotalEvents</th>
<th>OR</th>
<th>95%-CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rosengarten⁸</td>
<td>18</td>
<td>52</td>
<td>3.00</td>
<td>[0.18; 50.61]</td>
</tr>
<tr>
<td>Pescariu⁷</td>
<td>365</td>
<td>358</td>
<td>1.18</td>
<td>[0.36; 3.90]</td>
</tr>
<tr>
<td>Linde⁶</td>
<td>100</td>
<td>100</td>
<td>0.27</td>
<td>[0.05; 1.34]</td>
</tr>
<tr>
<td>Panja²⁷</td>
<td>120</td>
<td>4479</td>
<td>0.94</td>
<td>[0.41; 2.16]</td>
</tr>
<tr>
<td>Grendahl⁵</td>
<td>310</td>
<td>1690</td>
<td>3.95</td>
<td>[1.97; 7.91]</td>
</tr>
<tr>
<td>Meta-analysis</td>
<td>913</td>
<td>6679</td>
<td>1.31</td>
<td>[0.50; 3.40]</td>
</tr>
</tbody>
</table>

Baman, *Circ Arrhythm Electrophysiol*. April, 2011
Device Malfunction

- Low rate:
  - 0.68% (0.27 to 1.28)
- Increased compared with new
  - OR 5.80 [1.93 to 17.47], p = 0.002
  - Set screws
  - "technical errors"

Baman, *Circ Arrhythm Electrophysiol*. April, 2011
Precedent for Reuse

- 1991: 14% of primary implants were reused device
- 1996: 5% (incorporation in European Common Market)
<table>
<thead>
<tr>
<th>Method of Disposition</th>
<th>Respondents Who Reported Using the Method (N=71)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Put in medical waste</td>
<td>31 (44)</td>
</tr>
<tr>
<td>Donate for human use in medically underserved nations</td>
<td>13 (18)</td>
</tr>
<tr>
<td>Give to family</td>
<td>7 (10)</td>
</tr>
<tr>
<td>Keep on site</td>
<td>6 (8)</td>
</tr>
<tr>
<td>Return to manufacturer</td>
<td>3 (4)</td>
</tr>
<tr>
<td>Send to hospital where patient died</td>
<td>3 (4)</td>
</tr>
<tr>
<td>Donate for animal use</td>
<td>2 (3)</td>
</tr>
<tr>
<td>Unknown or no answer</td>
<td>17 (24)</td>
</tr>
</tbody>
</table>

*Some respondents reported more than one method.*
“Living Wills for Pacemakers”

→ Device specific advance directive
  – Options for post-mortem handling of device
  – Information
    • Donation
    • Return to manufacturers
  – Appointment of surrogate
  – (Deactivation at end of life)
Living Will for Patients with Pacemakers and Defibrillators

A will is a document that indicates what a person wants done with his or her resources after death. A living will is a document in which patients indicate what they want done (or not done) regarding their health care if they lose the ability to make medical decisions. A living will for patients with pacemakers and defibrillators not only indicates what they would want done or not done with regard to these devices during the course of treatment, but also what they want done with these health care devices after death.

When patients with pacemakers or defibrillators die, the device is often buried with them or discarded before it can be checked with a computer by companies that make or distribute the devices. Sometimes information on these devices also doesn’t get back to the company when pacemakers and defibrillators are removed as part of regular clinical care, such as the battery wearing out, devices getting infected or devices malfunctioning. This prevents the companies from examining the pacemakers and defibrillators to obtain data that may be useful in developing better devices. If the device is returned to the company and the checking is done, the devices can, in most cases, be returned to the patient, or the family, if the patient has died. Although pacemakers and defibrillators are not supposed to be reused nor resold in this country, some devices can be donated, enabling charities to clean (sterilize) them, check them for trouble and battery life, and send them overseas to be used in people who otherwise can’t afford them. The devices may also be donated to animal hospitals for placement into pets or racehorses.

As you can see, there are several options about what to do with your pacemaker or defibrillator after your death or if it is removed before death. The statement that follows provides you with an opportunity to indicate your wishes. The first part of the document applies only to patients with pacemakers and defibrillators; the second applies mostly to people with defibrillators (see note at bottom of page). If you change your mind about what you write, the document can be changed at any time. You should keep a copy in your records and a copy should be given to your doctor(s) and your next of kin.
<table>
<thead>
<tr>
<th>Disposition</th>
<th>Number (% of Patients Choosing Option*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donation for human use in medically underserved nations</td>
<td>93 (91%)</td>
</tr>
<tr>
<td>Return to manufacturer</td>
<td>92 (90%)</td>
</tr>
<tr>
<td>Donation for animal use</td>
<td>81 (79%)</td>
</tr>
<tr>
<td>Did not care what happened to device</td>
<td>46 (45%)</td>
</tr>
<tr>
<td>Refused interrogation and removal</td>
<td>3 (3%)</td>
</tr>
<tr>
<td>Return to family</td>
<td>2 (2%)</td>
</tr>
</tbody>
</table>

*Patients could express more than one preference.*
Reuse of Pacemakers

• Survey patients in hospice re: willingness to donate their devices
• Pilot test “pacemaker living will” in hospice patients
• Establish Penn as a collection and distribution center for cardiac devices overseas
Cardiac Device
Advance Directives

• Specific/individualized decisions re: devices
  – ICDs (discontinuation at DNR, hospice, ATP)
  – Pacemakers and QOL vs. life prolongation (pacemaker dependent)
  – CRT (QOL)
  – VAD withdrawal
Palliative Medicine Consultation for Preparedness Planning in Patients Receiving Left Ventricular Assist Devices as Destination Therapy

KEITH M. SWETZ, MD; MONICA R. FREEMAN, MSW; OMAR F. ABOUEZZEDDINE, MD, CM; KARI A. CARTER, RN, FNP; BARRY A. BOILSON, MD, MBBCH; ABIGALE L. OTTENBERG, MA; SOON J. PARK, MD; AND PAUL S. MUeller, MD

OBJECTIVE: To assess the benefit of proactive palliative medicine consultation for delineation of goals of care and quality-of-life preferences before implantation of left ventricular assist devices as destination therapy (DT).

PATIENTS AND METHODS: We retrospectively reviewed the cases of patients who received DT between January 15, 2009, and January 1, 2010.

RESULTS: Of 19 patients identified, 13 (68%) received proactive palliative medicine consultation. Median time of palliative medicine consultation was 1 day before DT implantation (range, 5 days before to 16 days after). Thirteen patients (68%) completed advance directives. The DT implantation team and families reported that pre-implantation discussions and goals of care planning made postoperative care more clear and that adverse events were handled more effectively. Currently, palliative medicine involvement in patients receiving DT is viewed as routine by cardiac care specialists.

CONCLUSION: Proactive palliative medicine consultation for patients being considered for or being treated with DT improves advance care planning and thus contributes to better overall care of these patients. Our experience highlights focused advance care planning, thorough exploration of goals of care, and expert symptom management and end-of-life care when appropriate.


whelmed with financial and psychosocial issues related to DT and are at risk of burnout and isolation because of outpatient needs and limited community support.

Several analyses have concluded that goals of care of patients receiving DT are often undefined. Many patients either have inadequate advance directives that do not address potential problems (such as worsening comorbid conditions, complications, and worsening QOL) or simply lack advance care documents. Without clearly defined goals and/or explicit advance directives, DT may merely maintain circulation in a moribund patient, a situation referred to as “destination nowhere.” Also, protocols and processes regarding LVAD management and comfort at the end of life are often lacking; hence, ethical quandaries (eg, withdrawal of device support) may arise.

To avoid situations in which advance care wishes are unclear or unknown, palliative medicine (PM) consultation has been suggested to address end-of-life preferences, facilitate advance care planning, manage symptoms, and address psychosocial issues.
VAD Advance Directives

• Supplement to 5 wishes
• Offer pre-implant
• Re-address at 3 months post implant
• VAD specific issues
Recap

• Cardiac devices definitely glitter, but there ARE ethical dilemmas, especially in the golden years

• Cardiac advance directives “are golden” but complicated and require multidisciplinary input

• Reused pacemakers are worth their weight in gold for poor patients in developing world countries
Thanks for your attention
HF Scores and Palliative Care

“Although these scores may be useful for defining a population for a clinical trial…their applicability in facilitating the decision between aggressive care and palliative care remains somewhat limited by the inability to precisely determine prognosis for the individual patient within the framework of rapidly changing parameters.”

Lewis, Current Treatment Options in Cardiovascular Medicine (2011) 13:7
Definitions of Death

- Irreversible cessation of cardiopulmonary function
- Irreversible cessation of (whole or brainstem) neurological function

Futile Therapy

• What is “futility?”
  – Physiological futility
    • Won’t work (defibrillation in PEA arrest)
  – Quantitative futility
    • Very little chance of working (LVAD in myocardial depression from bacterial sepsis)
  – Qualitative futility
    • Won’t produce adequate QOL (DT LVAD in end stage Alzheimer)

Adult Circulatory Support

Ethical Considerations for Ventricular Assist Device Support: A 10-Point Model

Ralph J. Petrucci, Lynne A. Benish, Barbara L. Carrow, Lisa Prato, Shelley R. Hanks, Howard J. Eisen, and John W. Entwistle

The potential for long-term support on a ventricular assist device (VAD) in the bridge-to-transplant (BTT) and destination therapy (DT) settings has created unprecedented ethical challenges for patients and caregivers. Concerns include the patient's adaptation to life on a device and the ethical, clinical, and practical issues associated with living on mechanical support. On the basis of our experience treating 175 consecutive VAD patients, we have developed a model to address the ethical and psychosocial needs of patients undergoing VAD implantation. Patient preparation for VAD implantation encompasses three phases: 1) initial information regarding the physical events involved in implantation, risks and benefits of current device technology, and the use of VAD as a rescue device; 2) preimplant preparation including completion of advance directives specific to BTT/DT, competency determination, and identifying a patient spokesperson, multidisciplinary consultants, and cultural preferences regarding device withdrawal; and 3) VAD-specific end-of-life issues including plans for device replacement and palliative care with hospice or device withdrawal. This three-phase 10-point model addresses the ethical and psychosocial issues that should be discussed with patients undergoing VAD support. ASAIO Journal 2011; 57:268–273.
Ethics and Cardiology

CONFLICTS OF INTEREST

Cardiologists Come Under the Glare of a Senate Inquiry

Research universities are nervously viewing an expanding Senate inquiry into alleged financial conflicts of interest among faculty members. Last week, Columbia University came under the spotlight. Senator Chuck Grassley (R-IA) publicly challenged the university to explain the industry ties of a group of Columbia cardiologists who work with a nonprofit that receives funding from medical device makers. This money may be biasing some faculty members' views on stem and other heart devices, Grassley suggests.

Grassley zeros in on the Cardiovascular Research Foundation (CRF), which conducts clinical trials on devices and drugs, according to its Web site. It also holds an annual educational conference. Three Columbia cardiologists sit on CRF’s board; others are listed as ‘leadership’ or ‘affiliated’ physicians. In a 16 October letter to Columbia president Lee Bollinger, Grassley and Senator Herb Kohl (D-WI) request details on outside income for about 20 of these faculty members. In a similar letter to CRF they write: “We are . . . concerned that funding from the medical device industry may influence the practices of non-profit organizations that purport to be independent in their viewpoints and actions.”

Columbia and CRF say they will respond to the questions. Although none of the Columbia faculty members appears to have grants from the U.S. National Institutes of Health, and therefore may not come under NIH’s rules, the university has its own conflict-of-interest policies and “expect[s] that they are followed by all . . . faculty,” Columbia says.

Although it may not be unusual for industry-funded charities to have ties to academic medical centers, some observers see a potential problem. “I suspect that individuals set up [charities] up to bypass university oversight procedures,” suggests health policy expert Eric Campbell of Harvard Medical School in Boston.

But Susan Ehrenreich of the Association of American Medical Colleges in Washington, D.C., cautions against generalizing. The important first step, she says, is that industry funds be fully disclosed. CRF’s Web site states that it has corporate funding, and two of its Columbia directors acknowledged in an article in The Lancet last year that the foundation has ties to four companies. The Columbia inquiry came as a related probe of financial conflicts among NIH-funded researchers was heating up. Last week, news emerged that NIH recently responded to concerns about an Emory University psychiatrist by taking a rare step: It suspended a grant to the university after Grassley alleged that the principal investigator, Charles Nemeroff, had failed to report at least $1.2 million in outside consulting income (ScienceNOW, 14 October: http://scienconow.sciencemag.org/cgi/content/full/2008/1014/1). The $9.3 million, 5-year study comparing depression treatments was transferred to another faculty member in July, but NIH halted funding in mid-August, Emory says. The frozen grant has put univeristies in high alert to get their conflict-of-interest policies in order, says one biomedical research lobbyist.

—JOCELYN KAISER
End-of-Life Care-Related Publications in Cardiology Journals

Nirav J. Mehta, MD, Ijaz A. Khan, MD, Rajal N. Mehta, MD, Furqan Tejani, MD, Balendu C. Vasavada, MD, and Terrence J. Sacchi, MD

FIGURE 1. Percentage of publications on end-of-life care-related issues in specialty journals.
Pilot Data: LVAD DT caregivers

- 10 caregivers
- 90% female, mean age 59 years
- 60% reported feeling emotionally and physically overwhelmed
- 70% reported feeling uninformed or ill prepared
- 60% reported feeling have no choice in accepting caregiver role
- 90% had not considered plans for deactivating LVAD
- Employed caregivers: 100% reported adverse impact on work

Sarah Hull, MD, MBE
Events Prompting Decision to Withdraw MCS

- Declining functional ability
- Worsening/new comorbidities
- Limited family interaction due to declining neuro-cognition

End of Life Decision-making Process

- Discussed a priori among patient and caregiver
- Requested ongoing multidisciplinary team involvement
- Relieved to understand the process of pump deactivation

Feedback on Level of Assistance at End of Life

- Relieved at comprehensive plan for supportive care at end of life
- Appreciated palliative care for symptom relief at withdrawal
- Desired that hospice providers be more educated about LVAD

Brush, et al, J Heart and Lung Transpl 29(12), 2010
Is ongoing mechanical support futile to meet these goals?
Chaga’s Disease

- *Trypanosoma cruzi*
- Reduviid “kissing” bugs
- Heart block
- Heart failure/aneurysms
- Ventricular arrhythmias
SUDS

- Sudden Unexplained Death Syndrome
  - the leading cause of death in young, healthy Southeast Asian males
  - Ventricular fibrillation
  - High risk of recurrence
  - ICD superiority over Beta blockers

Nademane K, Circulation. 2003;107:2221-6
Used Devices

• Upgrades
  – RV pacing
  – ICD
  – CRT

• Infections
  – 0.13% to 12.6%
  – Mean time 52 days (quartile 1 to 3, 24 to 162 days)

Wilkhoff, JAMA. 2002; 288:3115-3123
Preliminary Experience Regarding Re-Use of Explanted, Resterilized Defibrillators

- 31 patients Mean age 52±15 (range 16 – 77)
- Follow up: 795±579 (range 13 – 2237) days
- No infectious complications
- LV lead dislodgement in 1 pt.
- 42% pts experienced appropriate shocks
- 5 pts received a second explanted ICD after 1057±807, range 362 – 2162 days

Pavri, Circulation. 2010; 122:A18350
Feasibility of Device Acquisition with Adequate Battery Life for Potential Reuse in Underserved Nations

Timir S. Baman, Lindsey Gakenheimer, Nathan E Sovitch, Patricia Sovitch, Joshua Romero, James N. Kirkpatrick, Brad Wasserman, George Samson, Howard Jones, Thomas Crawford, Hakan Oral, Kim A Eagle

- 2172 devices donated
- 10% with ≥75% battery life or 4 years
- Average time since implantation was 2.1±1.0 years
Caregivers

• Majority of VAD patients traditionally men, but with smaller devices entering the market more women expected to benefit from this technology
• Traumatic spinal cord injury patients’ relationships do not fare as well when patient is woman and caregiver is man
• Will this translate to VAD patients as well?
Bridge vs. Destination Caregivers

- The few small studies that do exist suggest that partners/caregivers of VAD patients experience significant psychological distress.

- This is often counterbalanced by feelings of pride and hope in caregivers of bridge patients (has not yet been studied specifically in Destination Therapy).
Competing Interests

- Post-market surveillance
- “Bench” analysis of generators
- Post-mortem≠ changeouts

Return all devices to manufacturers!

Ellenbogen KA, et al. JACC 2003;41:73-80
Competing Interests

• All devices with inadequate battery life sent to manufacturers
• Increased return from donations → increase rate of return to manufacturers