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

Dembitzky WP. Semin Carotid Disease 2006; 16:253-255.
Stevenson L.W. (Holt’s Monograph Series, 2006. 1 Chapter 11, p. 181-201)
Fig. 1. Schematic course of Stage C and D heart failure. Sudden death may occur at any point along the course of illness. (1) Initial symptoms of heart failure (HF) develop and HF treatment is initiated. (2) Plateaus of variable length may be reached with initial medical management or after mechanical support or heart transplant. (3) Functional status declines with variable slope, with intermittent exacerbations of HF that respond to rescue efforts. (4) Stage D HF, with refractory symptoms and limited function. (5) End of life.
Ventricular Assist Devices

Flow

Rotor

Outflow Bearing Set

Inflow Bearing Set
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)

Ben Franklin Bridge
# 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>170 (8)</td>
<td></td>
</tr>
<tr>
<td>Age at implant</td>
<td></td>
<td></td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Mean years</td>
<td>61.7</td>
<td>52.7</td>
<td></td>
</tr>
<tr>
<td>Range</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, a David C. Naftel, PhD, a Robert L. Kormos, MD, b Lynne W. Stevenson, MD, e Francis D. Pagani, MD, e Martisa A. Miller, DVM, MPH, e Karen L. Ulisney, MSN, CRNP, f J. Timothy Baldwin, PhD, g and James B. Young, MD h

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 Devices, Advanced Technologies and Surgery Branch, and NHLBI at Duke Clinical Research Institute, Durham, North Carolina; gShands Clinical Center, University of Florida, Gainesville, Florida; and hCleveland Clinic Foundation, Lerner College of Medicine, Cleveland, Ohio

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

The 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
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VADS

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

VADs

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

Patkula V. J. Am. Coll. Cardiol. 2009, 53, 204-271
Examples of Criteria for Implantable LVAD for Lifetime Support

More objective
- Clinical profiles
  - Not crash and burn
  - Not post-surgical
  - Ambulatory for NYT?
- 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

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

*Proposed in JHLT Supplement 2010, 25:45
Slaughter, et al. HMII Investigators

Adapted from Lynne Warner Stevenson
Pacemakers

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

Mond, Pacing and Clinical Electrophysiology 2008; 31(9): 1202-1212.
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
SCD-HeFT

Bardy, et al. NEJM 2006;352:228
ICD

• Inappropriate Shocks
  – Anxiety
  – Depression
  – ED resource utilization

Stevenson, LW, Circ 2006. 114;101-103
The y-axis is confusing, as it is not all mortality. The bottom line is % patients saved by ICD. Might label the axis % patients, then label each line directly, saved by ICD, dead with ICD, dead without ICD.
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

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>LVFS (%)</th>
<th>SIR/AS</th>
<th>QRS (ms)</th>
<th>Endpoints</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONTAM CD**</td>
<td>II, IV</td>
<td>&gt;35%</td>
<td>SR</td>
<td>120</td>
<td>All-cause mortality + HF admission, pH0, EMVT, NYHA, QoL, LVEF, LVFS</td>
<td>CRT-D improved pH0, and EMVT, reduced LVEF, and increased LVFS</td>
</tr>
<tr>
<td>MIRACLE ICD**</td>
<td>II</td>
<td>&gt;35%</td>
<td>SR</td>
<td>130</td>
<td>Vt/Co., pH0, NYHA, Gd, EMVT, IV volumes, LVFS</td>
<td>CRT-D improved NYHA, Vt/Co., IV volumes, and LVFS</td>
</tr>
<tr>
<td>REVERSE**</td>
<td>I, II</td>
<td>&lt;40%</td>
<td>SR</td>
<td>120</td>
<td>(a) Clinical composite endpoint, (b) Vt/Co., (c) HF admission, (d) all-cause mortality</td>
<td>Primary endpoint (a) was NS; CRT-D/CRT-D reduced endpoints (b) and (c) but not (d)</td>
</tr>
<tr>
<td>MAGI CRT**</td>
<td>I, II</td>
<td>&lt;50%</td>
<td>SR</td>
<td>130</td>
<td>(a) HF admission or all-cause mortality, (b) all cause mortality, (c) Vt/Co.</td>
<td>CRT-D reduced endpoints (a) and (c) but not (b)</td>
</tr>
<tr>
<td>RAFT**</td>
<td>III, III</td>
<td>&lt;30%</td>
<td>SIR/AS</td>
<td>130 &gt;200</td>
<td>(a) All-cause mortality or HF admission, (b) all cause mortality, (c) Vt/Co.</td>
<td>CRT-D reduced all endpoints</td>
</tr>
</tbody>
</table>

CRT = cardiac resynchronisation therapy; NYHA = New York Heart Association; LVEF = left ventricular ejection fraction; SR = sine rhythm; AFl = atrial fibrillation; HF = heart failure; pH0 = peak oxygen consumption; EMVT = 6-min walk test; Gd = quality of life; LVEDD = left ventricular end-diastolic diameter; CRT-D = CRT with defibrillator function; Vt/Co. = ventilation/carbon dioxide ratio; LV = left ventricular; LVEF = left ventricular ejection fraction; N.S. = not significant; CRT-P/CRT-P with pacemaker function; LVEF = left ventricular ejection fraction; LV = left ventricular; ** Patients with AFl.

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.
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) n</th>
<th>% of 26</th>
<th>Later (≥1 mo) n</th>
<th>% of 62</th>
<th>Total n</th>
<th>% of 67</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>0%</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>14%</td>
</tr>
<tr>
<td>UCI 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>MOR</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>25</td>
<td>62%</td>
<td>62</td>
<td>100%</td>
<td>07</td>
<td>100%</td>
</tr>
</tbody>
</table>

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

Renal Failure  Unknown  Respiratory failure  Other chronic illness =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

Bramstedt KA, J Heart Lung Transplant. 2001;20:544–0.
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/withholding

• 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, in Bochum, 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 46-year-old depressed patient who committed suicide by disconnecting the driveline of his left ventricular assist device almost 3 years after implantation. We present the mental, psychological, and psychiatric background of this unique case. This report highlights the importance of pre-implant psychological 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.

3 Heart Lung Transplant 2011;29;992-4
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Ethical Analysis of Withdrawal of Pacemaker or Implantable Cardioverter-Defibrillator Support at the End of Life

Mueller, Paul S. MD; Hook, C. Christopher MD; Hayee, David L. MD

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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 if 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.

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
Withdrawning Implantable Defibrillator Shock Therapy in Terminally Ill Patients

William B. Lewis, MD,* Donna L. Luecke, NP,* Nancy J. Johnson, MD,* Michael D. Harrington, MD,*
Ottavio Cecchinetti, MD,* Mark P. Audia, PhD*

*Heart and Vascular Center, MetroHealth Campus, Case Western Reserve University, Cleveland, Ohio; Clinical Ethics Program, MetroHealth Medical Center, Department of Bioethics, Case Western Reserve University, Cleveland, Ohio; Division 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.

METHODS: The charts of ICD patients who had died were reviewed. Two groups emerged: Group 1 (20) included patients whose arrhythmias were turned off through the comprehensive care approach. Group 2 (23) included patients whose clinical course was so rapid that the defibrillator was not turned off. Pacemaker therapy was not withdrawn in either group.

RESULTS: Defibrillator discharges, time to discharge, and time to death were compared. Group 2 patients died more quickly than Group 1. Group 1 received 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.

CONCLUSIONS: 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 Schgal, Rutuke Patel, PA-C, and Ralph J. Verdino, MD

Cardiologists 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 (33%) had been shocked, with a mean of 4.69 shocks. More than 1/2 had executed an AD, but only 1 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, 45% said it would depend, 20% 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 handling of an ICD. When asked who should be responsible for discussing this device for an AD, 31% said electrophysiologists, 48% said general cardiologists, and 18% 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; XXXX)
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
Costs

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!

[Cartoon image of a doctor and patient]
Congressional Budget Office Projections ....
Projected Cost Increases of CVD

Heidenreich, Circulation. 2011;123:933-944
The costs are across the board. Over half of the costs are related to hospitalization and that is key, because the significant benefit and advantage of the institution of evidence-based therapy is a reduction of hospital utilization and I believe all of us are sensitive to the growing burden of providing care, and paying for the same, for the Medicare population.
VADs

$ Implant costs: $122,785 – $264,839

$ 360,407 / 5 years

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

 Prevent (CV) hospitalizations

 Cheaper than Transplant

*Incremental cost-effectiveness ratio over medical therapy

Rogers JG, et al. Circ Heart Fail. 2011
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)
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.

CONCLUSION. We conclude that the efficacy of the ICD is a potential cost-effective strategy for the subset of at-risk cardiac patients who are at increased risk of death but do not have a contraindication to the use of ICDs.
Pie graph of current expenditures for heart failure in the United States \(^{(13)}\) (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.

Stevenson, Am Heart J 161(6) ;2011
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."
Background: As many patients with heart failure develop symptoms limiting daily life, newer therapies may be found to improve functional status without concomitant survival benefit. As some of these therapies may actually increase mortality, it is increasingly relevant to assess patients’ preferences for survival vs improvement in symptoms.

Methods: We enrolled 99 patients with advanced heart failure (ejection fraction 24 6 10, duration 6 6 5 years). Each patient completed time trade-off and standard gamble instruments, Minnesota Living with Heart Failure questionnaires and visual analog scales for dyspnea and overall health. Jugular venous pressure was assessed in all patients and peak oxygen consumption was measured during bicycle exercise in 60 patients.

Results: Strong polarity of preference toward either survival or quality of life was expressed by 60% of patients. There was good correlation between time trade-off and standard gamble utility scores ($r = 0.64$), and between preference and functional class ($r = 0.60$). Higher jugular venous pressure and lower peak oxygen consumption were associated with poorer utility scores ($p < .05$). Higher dyspnea scores and worse Living with Heart Failure scores were also associated with preference to trade time or take risks for better health.

Conclusions: These findings suggest that heart failure patients express meaningful preferences about quality vs length of life. High jugular venous pressure, low peak oxygen consumption and poor Living with Heart Failure scores were related to low utility scores. These cannot be assumed, however, to predict the intensity of individual preference to trade nothing or virtually everything for better health. J Heart Lung Transplant 2001;20:1016–1024.
Patient Preferences After Hospital Discharge

Choices: a Study of Preferences for End-of-life Treatments in Patients With Advanced Heart Failure

Joan Marcus, RN, MS, RNCP; Vivian Roa, MD, PhD; Diego A. Holzgraue, MD, MS; Nitendra Das, MD, PhD; Joan Travers, PhD; Susan Abbey, MD; and Heather J. Ross, MD, MHSc

Background: The purpose of this study is to describe the treatment preferences of patients with heart failure among three distinct treatment options—optimal medical management, oral inotropes or left ventricular device (LVAD) support—to determine if there were differences in preferences between patients with mild heart failure (New York Heart Association [NYHA] Class I) and severe heart failure (NYHA Class IV), and also to determine whether quality of life, perceived severity of symptoms and overall health influenced treatment preferences.

Methods: We enrolled 91 patients who completed the Minnesota Living with Heart Failure Questionnaire (MLHFQ); visual analog scales for depicting their perceived severity of overall health, dyspnea and fatigue; and a treatment trade-off tool.

Results: The most preferred treatment options were oral inotropes, LVAD and standard medical management. There were no differences in treatment preferences between NYHA I and NYHA IV patients. 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.

Conclusion: The results of our study identified two distinct groups of patients: one group preferred treatments that prolonged survival time and another group that favored strategies that improved quality of life but reduced survival time. Treatment preferences were independent of functional or symptom status, suggesting that preferences may be decided early in the course of illness. J Heart Lung Transplant 2008;27:1002-7. Copyright © 2008 by the International Society for Heart and Lung Transplantation.

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,1 George J. Annas, JD, MPH,1 Margaret A. Farley, PhD,9 Nathan E. Goldstein, MD,1 Robert M. Hamilton, MD,** G. Neal Kay, MD, FHRS,† Daniel B. Kramer, MD,† Paul S. Mueller, MD, MPH,1 Lucio Padeletti, MD,†† Leo Pozuelo, MD,†† Mark H. Schoenfeld, MD, FHRS,* Panos E. Vardas, MD, PhD,*** Debra L. Wiegand, PhD, RN,††† Richard Zelinger, JD, MA†††

*Yale University, School of Medicine, New Haven, CT. †Mayo Clinic, Rochester, MN. ‡Boston University, School of Public Health, Boston, MA. §Yale University Divinity School, New Haven, CT. ¶Mount Sinai School of Medicine, New York, NY. and the James J. Peters VA Medical Center, Bronx, NY. **The Hospital for Sick Children, Toronto, Canada. ***The University of Alabama at Birmingham, Birmingham, AL. ‡‡Beth Israel Deaconess Medical Center, Boston, MA. ‡‡‡University of Florence, Institute of Cardiology, Florence, Italy. ‡‡‡Cleveland Clinic, Cleveland, OH. ***Harokiti University Hospital, Crete, Greece. ‡‡‡‡University of Maryland, School of Nursing, Baltimore, MD. ‡‡‡‡Patient representative. Adjunct lecturer at Case Western Reserve University, Bioethics Department, Cleveland, OH.
**HRS Expert Consensus Statement on Management of CIEDs in patients nearing end of life or requesting withdrawal of therapy. Heart Rhythm. 2010; 7(7):1008-26.**

<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>
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. McGillivray, MD, PhD, FRCP(C) (Chair),b Gordon W. More, MD, FRCP(C) (Co-Chair),b Anson Cheung, MD, FRCP(C), Jeannine Costigan, RN, MScN, APN,a Anique Ducharme, MD, FRCP(C), Estrella Estrella Hollier, RN, BN, MScA, CCN(C),1 Justin A. Azadovzina, MB, BCH, MSc, FRCP(C),2 John Floras, MD, DPhil, FRCP(C), FACC, FESC, FRCPC, Nadia Giammarini, MD, FRCP(C), Arlyn Grozda, MD, CT(TP, RCIP),4 Kate Harkness, RN, BScN, CCNS, PhD,a George A. Heckman, MD, MSc, FRCP(C),ab Jonathan G. Howell, MD, FRCP(C), Simon Kozl, MD, FACC, Kori Leblanc, BScPharm, ACPR, PharmD,a Elizabeth Mann, MD, FRCP(C), Eileen O’Meara, MD, FRCP(C), Miroslav Rajda, MD, FRCP(C), Vivek Rao, MD, FRCP(C), Jessica Simon, MB, ChB, MRCP(UK), FRCP(C), Elizabeth Swiggum, MD, FRPC(C), and Shelley Zionoth, MD, FRCP(C), Secondary Panel Authors: J. Malcolm O. Arnold, MD, FRCP(C), Tom Ashon, MD, FRCP(C), Michel D’Asous, MD, FRCP(C), Paul Dorian, MD, FRCP(C), Haisam Haddad, MD, FRCP(C), Debra L. Isaac, MD, FRCP(C), Marie-Hélène Leblanc, MD, FRCP(C), Peter Liu, MD, FRCP(C), Bruce Sussex, MD, FRCP(C), and Heather J. Ross, MD, FRCP(C)
<table>
<thead>
<tr>
<th>Introducing the notion that heart failure is potentially fatal</th>
<th>“...Heart failure is a very serious disease, from which many patients ultimately die. Thankfully we have some extremely good treatments...”</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>“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.”</td>
</tr>
<tr>
<td>Assessing readiness</td>
<td>“…is there anyone you trust to make medical decisions for you, and have you talked with this person about what is important to you?...”</td>
</tr>
</tbody>
</table>

Complicated Issues

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

- Dialogue

- Joint Consensus Statements/Guidelines
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

Mond, Pacing and Clinical Electrophysiology 2005;31:1202-12
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. 2006; 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

National Funeral Directors Association. 2010 Selected Funeral Service Information and Statistics.
## Infection

<table>
<thead>
<tr>
<th>Study</th>
<th>Reuse Total Events</th>
<th>Reuse Total Events</th>
<th>New Total Events</th>
<th>OR</th>
<th>95%-CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rosengarten⁶</td>
<td>18</td>
<td>1</td>
<td>52</td>
<td>1</td>
<td>3.00 [0.18; 50.61]</td>
</tr>
<tr>
<td>Pescariu⁷</td>
<td>365</td>
<td>6</td>
<td>358</td>
<td>5</td>
<td>1.18 [0.36; 3.90]</td>
</tr>
<tr>
<td>Linde⁵</td>
<td>100</td>
<td>2</td>
<td>100</td>
<td>7</td>
<td>0.27 [0.06; 1.34]</td>
</tr>
<tr>
<td>Panja²⁷</td>
<td>120</td>
<td>6</td>
<td>4479</td>
<td>237</td>
<td>0.94 [0.41; 2.16]</td>
</tr>
<tr>
<td>Grendahl³</td>
<td>310</td>
<td>14</td>
<td>1690</td>
<td>20</td>
<td>3.95 [1.97; 7.91]</td>
</tr>
<tr>
<td><strong>Meta-analysis</strong></td>
<td><strong>913</strong></td>
<td><strong>29</strong></td>
<td><strong>6679</strong></td>
<td><strong>270</strong></td>
<td><strong>1.31 [0.50; 3.40]</strong></td>
</tr>
</tbody>
</table>

Favors Reuse: < 1  
Favors New: > 1

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 research.

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. Sweit, MD; MONICA R. FREEMAN, MSW; OMER F. ABD ELAZZIZ, MD, CM; KARI A. CARTER, RN, TNP; DARRYL DOHLEN, MD; MBBC, ABDIJE L. OTTENBERG, MA; SOON J. PAK, 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 charts of patients who received DT between January 15, 2009, and January 1, 2016.

RESULTS: of 18 patients identified, 12 (66%) 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 (72%) 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 advance care work was handled more effectively. Currently, palliative medicine involvement in patients receiving DT is viewed as routine by cardiologist 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 the benefit of palliative care planning, thorough exploration of goals of care, and expert symptom management and end-of-life care when appropriate.

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.”

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,* LYNN E. BASSIL,† BARBARA L. CARROLL,† LISA PRADO,§ SHELLY R. HANKS,† HOWARD J. EISEN,† AND JOHN W. ENTHIEL§

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 leading 375 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 consultation of advance directives specific to BTT/DT, competency determination, and identification of 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 10-phase 10-point model addresses the ethical and psychosocial issues that should be discussed with patients undergoing VAD support. ASAIO Journal 2011; 57:266–273.

considered in patients who were too old for transplantation. Despite approval for this indication in the United States and Europe,2 utilization rates were low, primarily because survival beyond 2 years was poor. Currently, miniaturized pumps that provide continuous flow have demonstrated significant improvements in durability and long-term patient outcomes and, thus, are being implanted in larger numbers for both the BTT and DT indications.4,5

Patients on a VAD face issues related to their unique medical characteristics, the length of time they may be supported on the device, and the increased potential for unexpected outcomes with this technology. These issues are creating challenges related to patient selection for device implantation, management of device-related complications, and withdrawal of care.6–8 As VAD centers accumulate more patients on long-term support,9 the potential increases for ethical and psychosocial issues to arise. Although predicting all the potential areas of conflicts may be overwhelming, proper patient preparation may minimize many of these issues before they arise. Although many ethical standards have been developed for use of other life-supporting technologies and treatment of serious medical conditions such as stroke and cancer, these standards are not necessarily applicable to VAD patients. Improvements in this

105
Ethics and Cardiology

Cardiologists Come Under the Glare of a Senate Inquiry

Researchers are paying increasing attention to financial conflicts of interest among faculty members. Last week, Columbia University came under scrutiny for financial dealings involving a group of cardiologists who had received millions of dollars in research grants. The university is being investigated for alleged financial improprieties.

Columbia's actions raise concerns about the influence of industry on academic research. The institution's financial dealings have led to questions about the integrity of academic research and the potential for conflicts of interest.

Although the university has not commented on specific financial dealings, the Senate inquiry highlights the need for greater transparency in academic research funding.
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.

AJC, 2001
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
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
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

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

---

Return all devices to manufacturers!
Competing Interests

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