



# ICDs at End-of-Life: Do Term Limits Apply?

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# Campaign Contributors and Lobbyists: (My Disclosures)

- Speaker Honoraria:

- Biosense Webster
- Daiichi Sankyo
- Spectranetics
- Zoll

- Research Involvement:

- Medtronic
- St. Jude Medical



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**DIAPERS & POLITICIANS  
SHOULD BE CHANGED  
OFTEN  
BOTH FOR THE SAME  
REASON**

# Case

## THEN:

79 yo woman undergoes CRT-D implantation in May of 2011 for NICM (LVEF 30%), CHF – NYHA III, and LBBB (150 ms)

## NOW:

84 yo woman with CRT-D at recommended replacement time with normal, chronic lead function.

- LVEF 55-60%
- NYHA II
- No history of appropriate therapies for VT/VF



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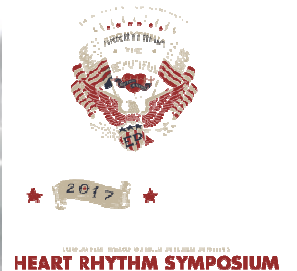


# What now?

What should we do for her?

What options do we have?

Has she benefited from her  
CRT-D?



# The Two Basic ICD Indications

## Secondary Prevention:

- cardiac arrest survivors, patients with sustained VT or VF

## Primary Prevention:

- patients at risk for sudden death, but who have not had a documented arrest or sustained VT/VF
  - Examples: ICM, NICM, HCM, inherited channelopathies, etc.



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# Primary Prevention Trials

Trial (Follow-Up) Year Published	Number of Subjects	Study Group/Entry Criteria	All-Cause Mortality	
			RRR	ARR
MADIT (2-yr analysis) 1996	196	Prior MI, EF $\leq$ 35%, NS VT, inducible VT, failed IV PA	59%	19%
MADIT-II (2-yr analysis) 2002	1232	Prior MI (>1 month), EF $\leq$ 30%	28%	6%
DEFINITE (2.5-yr analysis) 2004	458	Nonischemic CM, history of HF, EF $\leq$ 35%, 10 PVCs/h or NSVT	44%	6%
SCD-HeFT (5-yr analysis) 2005	2521	NYHA functional class II–III CHF, EF $\leq$ 35%	23%	7%

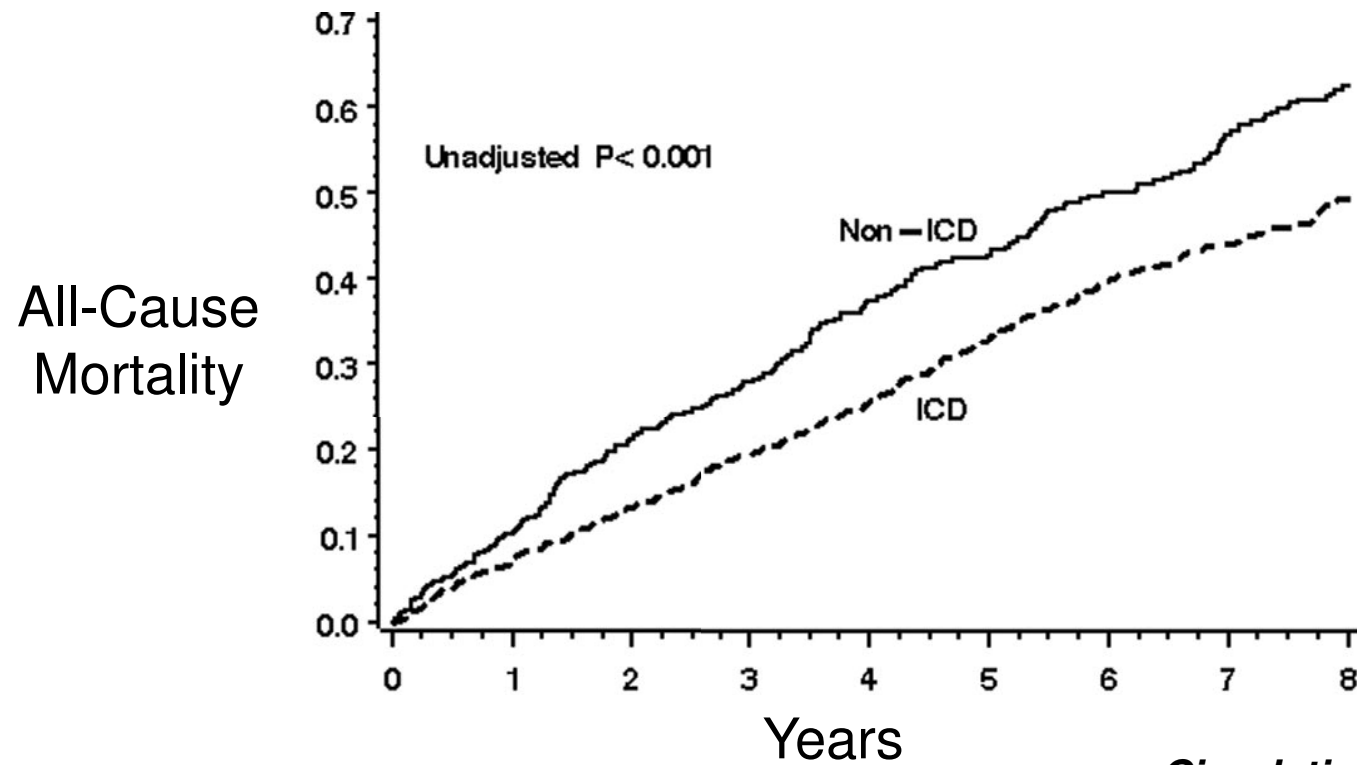


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# MADIT II Eight-Year Follow-Up



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*Circulation* 2010;122:1265-1271





### CLASS III

1. ICD therapy is not indicated for patients who do not have a reasonable expectation of survival with an acceptable functional status for at least 1 year, even if they meet ICD implantation criteria specified in the Class I, IIa, and IIb recommendations above. (*Level of Evidence: C*)

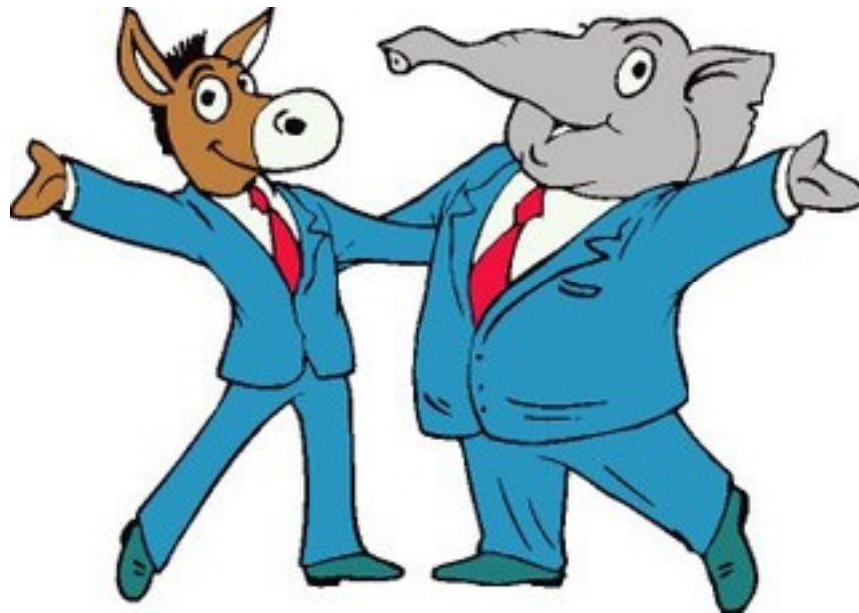


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JACC Vol. 61, No. 3, 2013 January 22, 2013:e6–75



# Continuous Dialogue and Education



Prior to Initial Implant



At Each Generator  
Replacement



End of Life Discussions

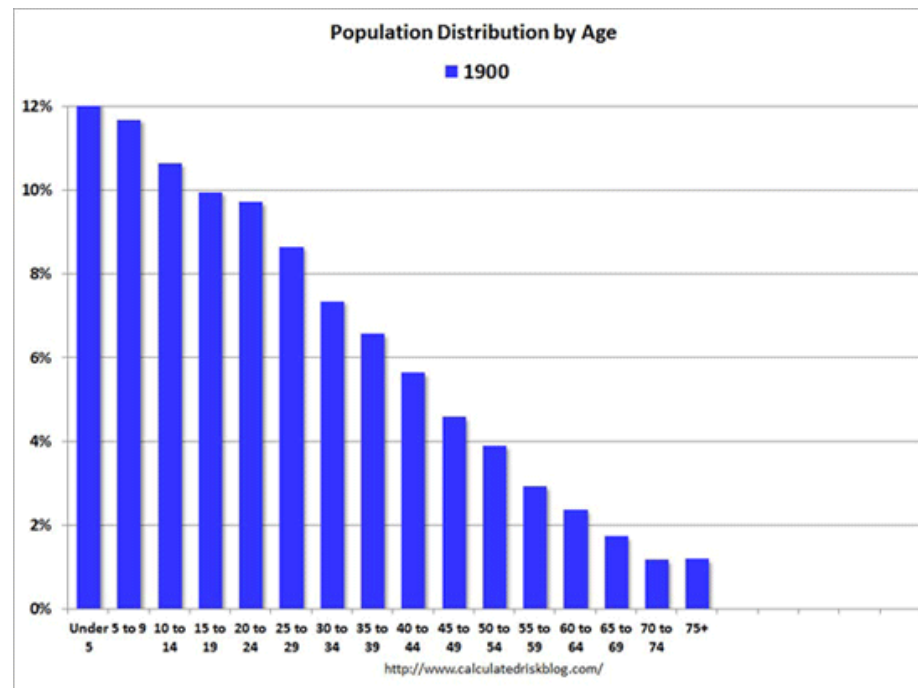


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# US Population Distribution by Age



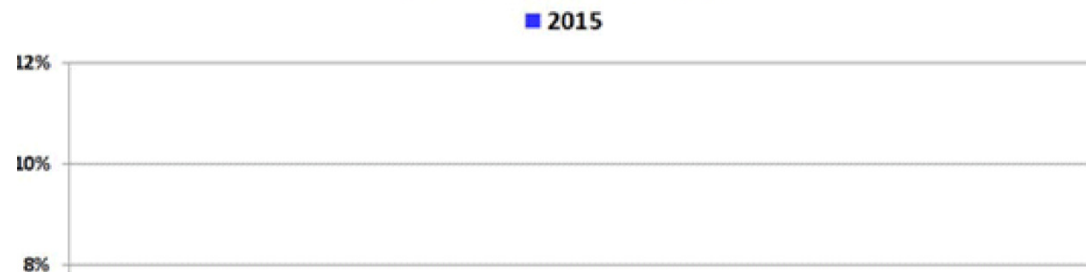
<http://www.calculatedriskblog.com>



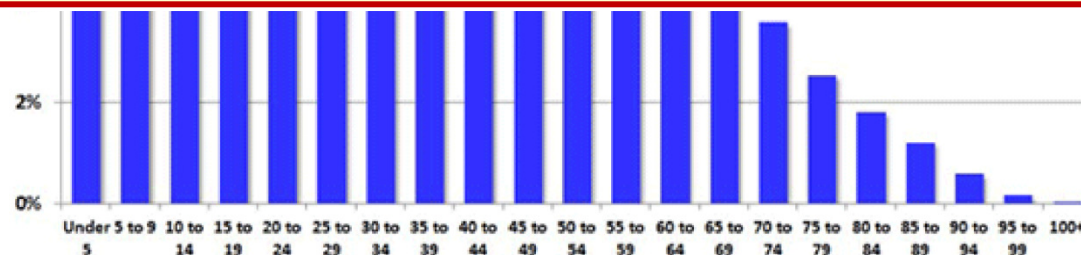
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# US Population Distribution by Age



→ one out of every four 65-yo today will live past age 90,  
 → one out of 10 will live past 95



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<http://www.calculatedriskblog.com>  
[www.socialsecurity.gov/planners/lifeexpectancy.htm](http://www.socialsecurity.gov/planners/lifeexpectancy.htm)



# Comorbidities

- Heart Failure
- Coronary artery disease
- Valvular heart disease
- Diabetes
- Renal dysfunction
- Lung disease
- Cancer
- Cognitive dysfunction
- Depression
- Chronic pain
- Peripheral vascular disease
- Hepatic failure
- Arthritis/orthopedic diseases
- Strokes
- Hypertension
- Psychiatric limitations



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# **2012 ACCF/AHA/HRS Focused Update of the 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities**

A Report of the American College of Cardiology Foundation/  
American Heart Association Task Force on Practice Guidelines

- **Careful selection based upon:**
  - **Estimated life expectancy**
  - **Consideration of comorbidities**
  - **Procedural risk**
  - **Patient preferences**

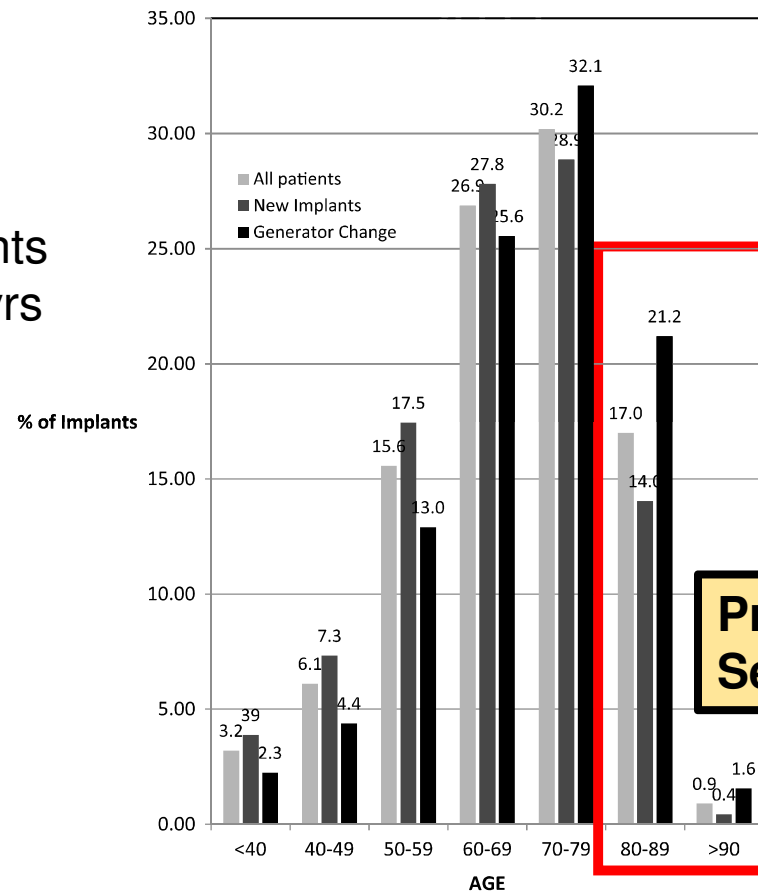


C. Tracy et Al. ACC/AHA/HRS Guidelines, JACC 2012



# The National ICD Registry Report: Years 2010-

N = 263,284 implants  
Age = 67.3 ±13.0 yrs



Over 70 years:

- 47% of all implants

Over 80 yrs:

- Total: 18%

(vs 12.4% in 2009)

- New impl.: 14.4%

- Gen. change: 23%

**Primary Prevention: 77%**

**Secondary Prevention: 23%**

Heart Rhythm, Vol 10, No 4, April 2013



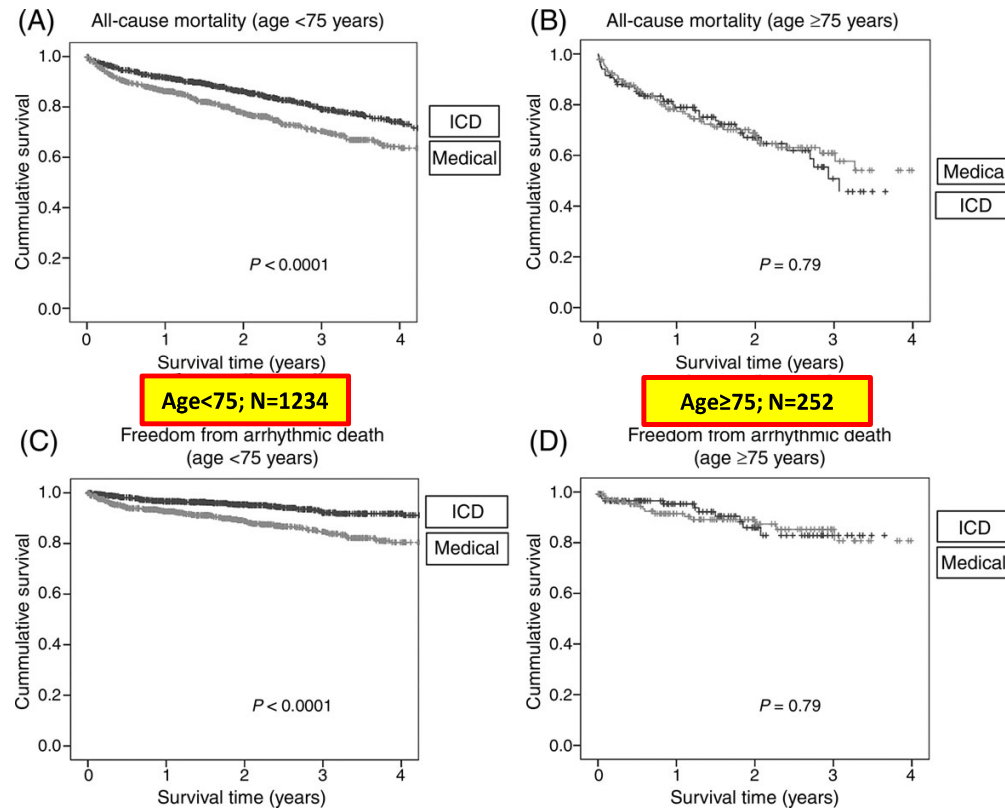
# Initial Implants in the Elderly





# Secondary Prevention in the Elderly: Pooled Data from AVID, CASH, CIDS

**No evidence of  
survival benefit in  
patients over 75**



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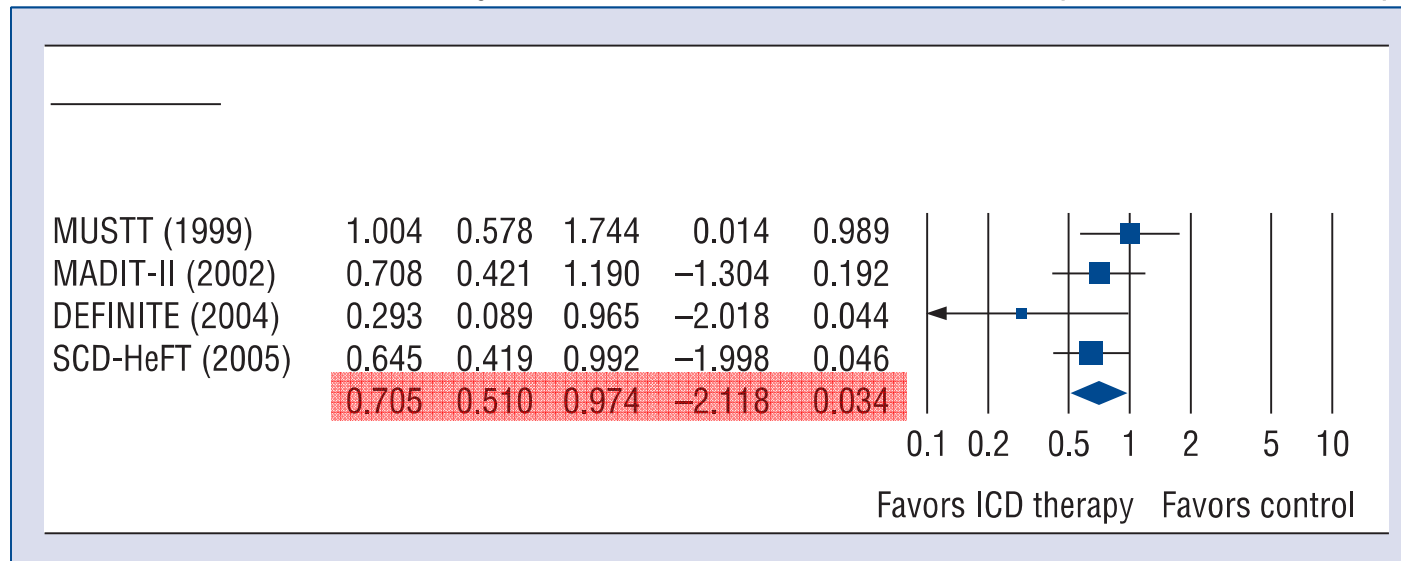
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Healey JS et al. Eur  
Heart J 2007; 28: 1746



## Use of implantable cardioverter-defibrillators for primary prevention in older patients: A systematic literature review and meta-analysis

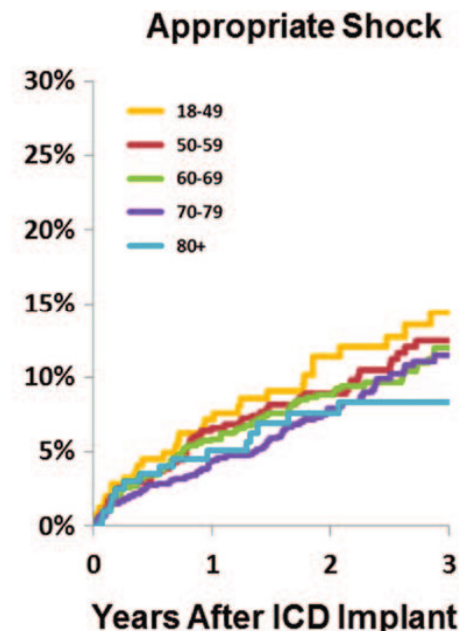
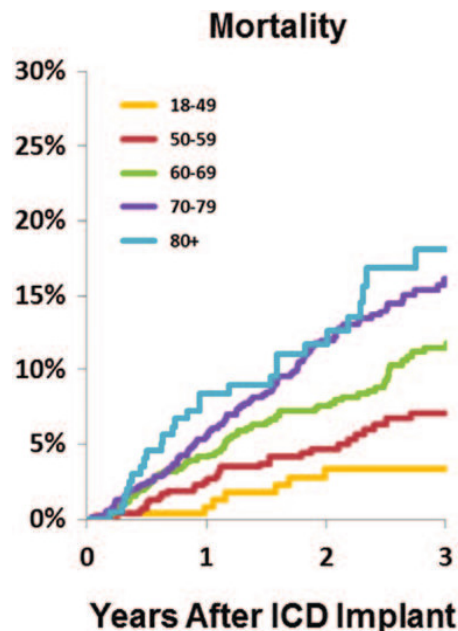
All-Cause Mortality in Patient > 75 Years (11.7% of Pts)



*Primary prevention ICDs may be beneficial in older patients*

Kong M et al. Cardiol J 2011; 18, 5: 503–514

5399 ICD recipients in Ontario, Canada (Feb. 2007 to Sept. 2010)  
 3939 for primary prevention including 275 pts over 80 years (7%)



Elderly patients = increased mortality after ICD implantation, similar appropriate device shocks  
 Decisions regarding ICD candidacy should not be based on age alone consider factors that predispose to mortality

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*Circulation. 2013;127:2383-2392*



# Outcomes Among Older Patients Receiving Implantable Cardioverter-Defibrillators for Secondary Prevention



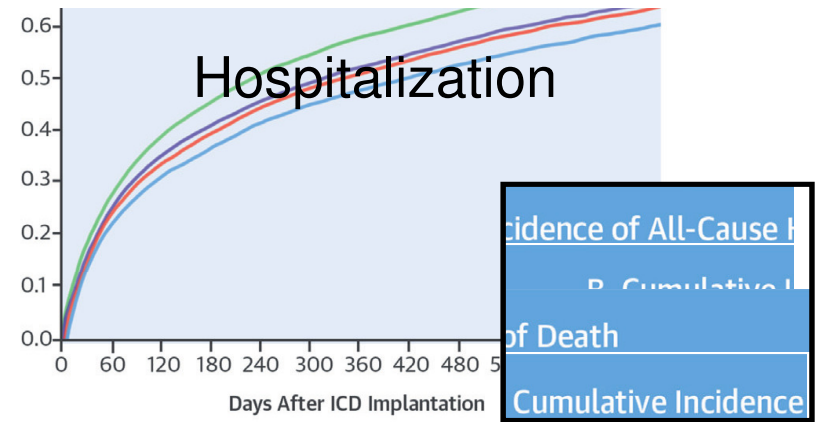
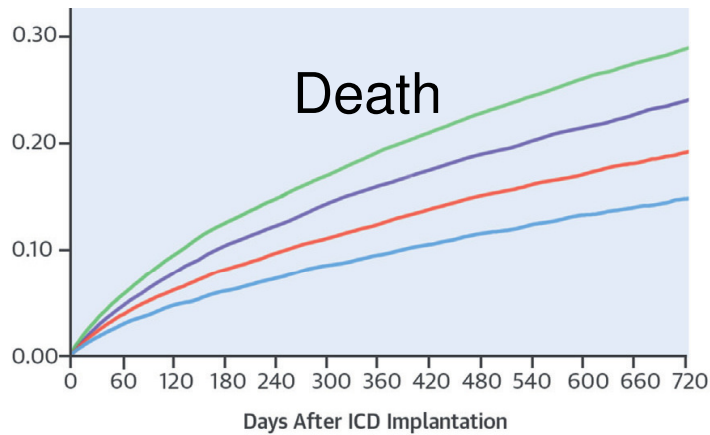
From the NCDR ICD Registry

- 12,420 Medicare beneficiaries undergoing first-time secondary prevention ICD implantation between 2006 and 2009
- mean age 75 years at the time of implantation
  - 25.3% <70 years of age
  - 25.7% were >80 years of age
- Examined 2 year risk of mortality, hospitalization, HF hospitalization, and SNF admission

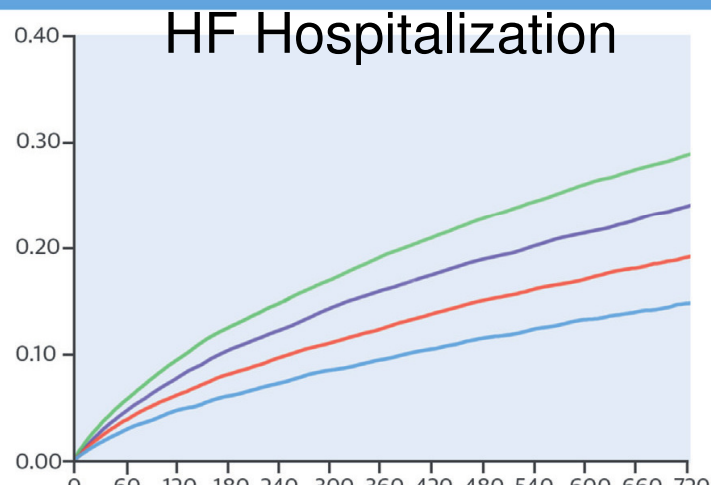


Betz, J.K. et al. J Am Coll Cardiol. 2017;69(3):265–74

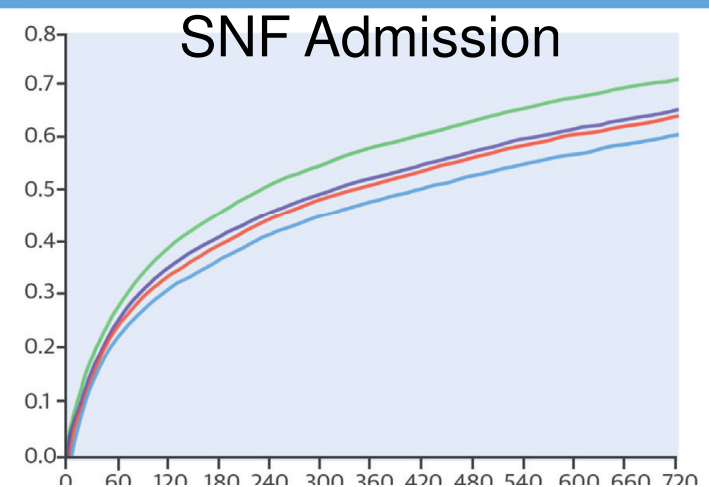




C. Cumulative Incidence of Hospitalization for Heart Failure  
A. Cumulative Incidence of Death



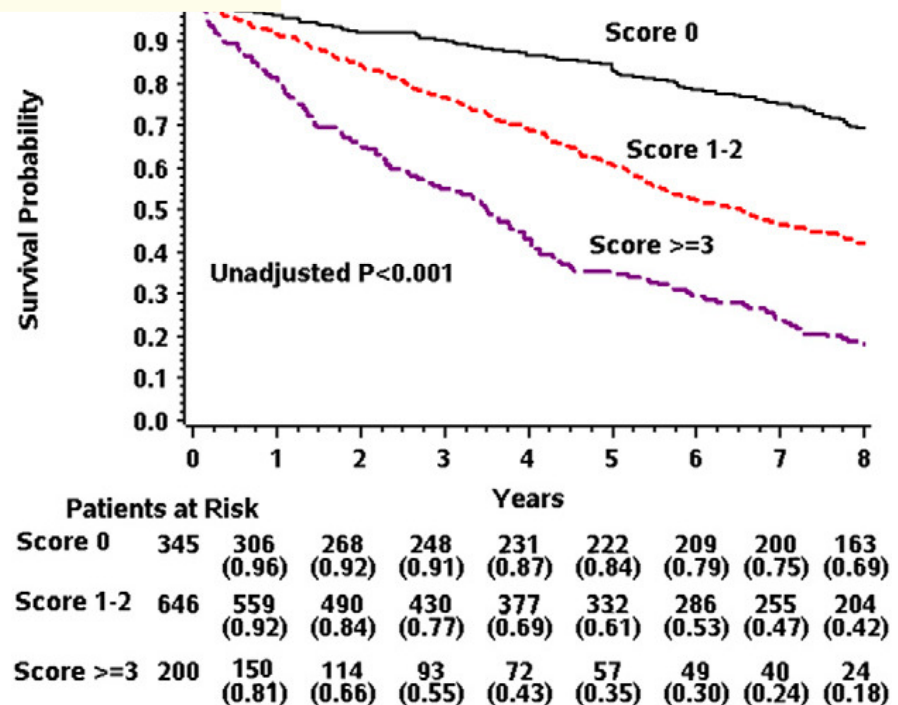
D. Cumulative Incidence of Admission to a SNF  
B. Cumulative Incidence of All-Cause Hospitalization



## Applicability of a Risk Score for Prediction of the Long-Term (8-Year) Benefit of the Implantable Cardioverter-Defibrillator

### 5 Risk factors:

1. NYHA > II
2. Age >70 years
3. BUN >26 mg/dl
4. QRS duration >0.12 s
5. Atrial fibrillation



# Generator Replacement



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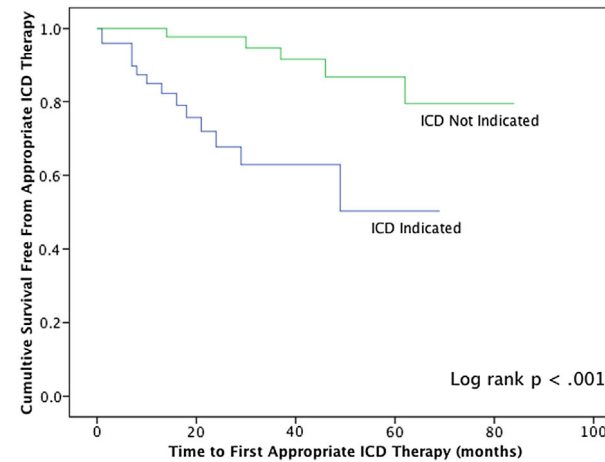
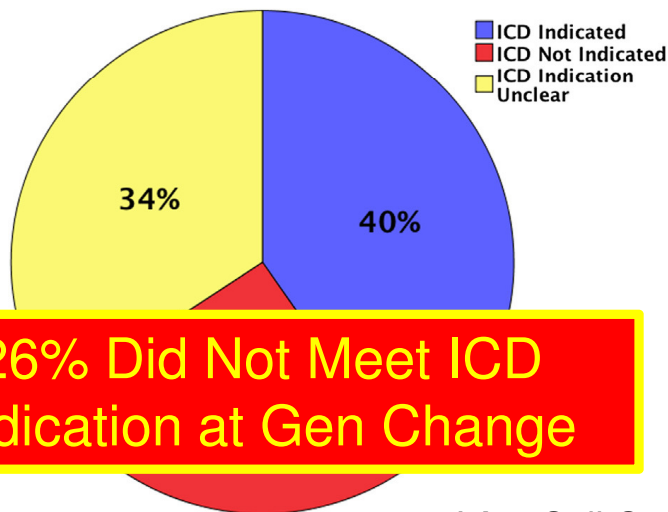


# Appropriateness of Primary Prevention Implantable Cardioverter-Defibrillators at the Time of Generator Replacement

Are Indications Still Met?



Retrospective chart review of 231 VA patients undergoing replacement of primary prevention ICD



J Am Coll Cardiol 2014;63:2388–94





**Left Ventricular Function Does Not Predict the Risk of  
Death and Ventricular Tachyarrhythmias in Patients  
following Elective Implantable Cardioverter Defibrillator  
Generator Replacement**

Single Center Retrospective Review of 175 Patients

	<b>LVEF &lt; 35 n=117</b>	<b>LVEF &gt; 35 n=57</b>	<b>P value</b>
<b>Death</b>	35 (30%)	14 (25%)	0.461
<b>VTA</b>	15 (13%)	5 (8%)	0.411

Median follow-up of  $2.19 \pm 2.23$  years

Mohan, R. et al. Heart Rhythm Society Scientific Session 2015

# **Left Ventricular Function Does Not Predict the Risk of Death and Ventricular Tachyarrhythmias in Patients following Elective Implantable Cardioverter Defibrillator Generator Replacement**

Single Center Retrospective Review of 175 Patients

## **Predictors of All-Cause Mortality:**

	<b>HR</b>	<b>95% CI</b>	<b>P</b>
<b>Time dependent VTA post generator replacement<sup>1</sup></b>	<b>2.25</b>	<b>1.06-4.62</b>	<b>0.032</b>
<b>Age at GR <sup>2</sup></b>	<b>1.06</b>	<b>1.02-1.09</b>	<b>0.002</b>

Mohan, R. et al. Heart Rhythm Society Scientific Session 2015

# **Left Ventricular Function Does Not Predict the Risk of Death and Ventricular Tachyarrhythmias in Patients following Elective Implantable Cardioverter Defibrillator Generator Replacement**

Single Center Retrospective Review of 175 Patients

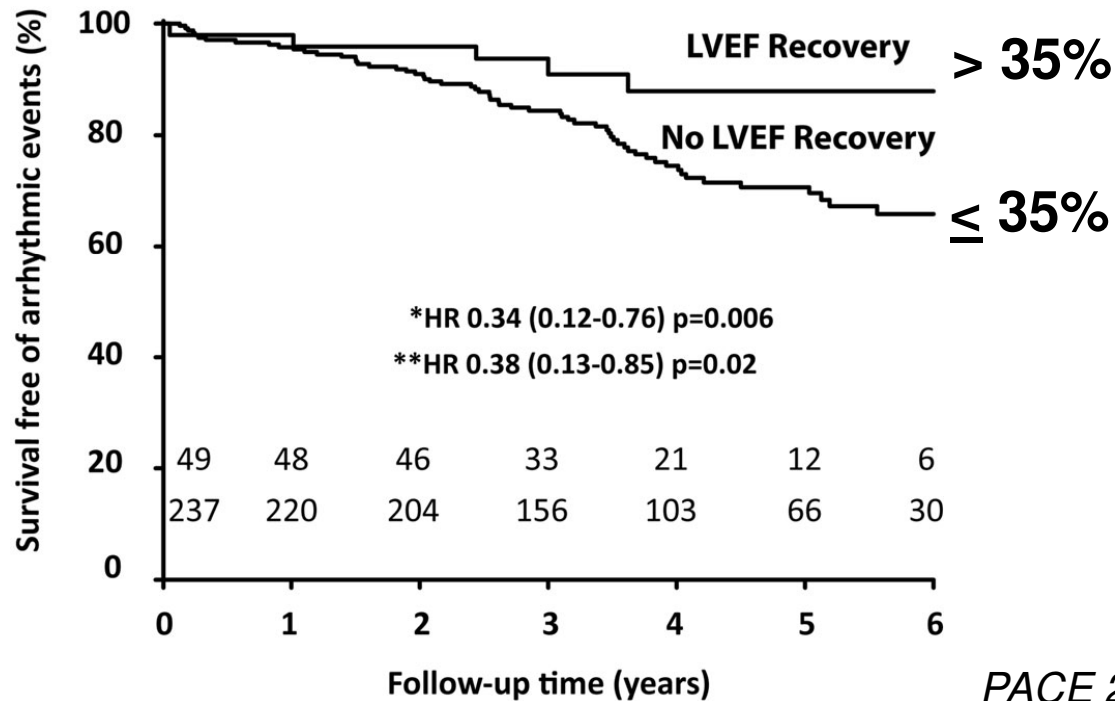
**Predictors of VTA after generator replacement:**

	<b>HR</b>	<b>95% CI</b>	<b>p</b>
<b>NYHA class III-IV</b>	<b>4.11</b>	<b>1.49-11.42</b>	<b>0.006</b>
<b>VTA prior to GR</b>	<b>2.57</b>	<b>0.99-6.62</b>	<b>0.051</b>

Mohan, R. et al. Heart Rhythm Society Scientific Session 2015

# Arrhythmic Risk Following Recovery of Left Ventricular Ejection Fraction in Patients with Primary Prevention ICD

## Single Center Retrospective Analysis of 286 Patients



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*PACE* 2016; 39:680–689



# Arrhythmic Risk Following Recovery of Left Ventricular Ejection Fraction in Patients with Primary Prevention ICD

## Single Center Retrospective Analysis of 286 Patients

A ISCHEMIC CARDIOMYOPATHY  
SUBGROUP

B NON-ISCHEMIC CARDIOMYOPATHY  
SUBGROUP

LVEF Recovery

*“In conclusion, patients with nonischemic cardiomyopathy who improved their LVEF to >35% after primary prevention ICD implantation were at very low absolute arrhythmic risk. Our study raises the possibility that the LVEF cutoff to safely withhold ICD replacement might be higher in patients with ischemic compared to nonischemic cardiomyopathy.”*

Follow-up time (years)

Follow-up time (years)

PACE 2016; 39:680–689



“It’s JUST a gen change, right?”



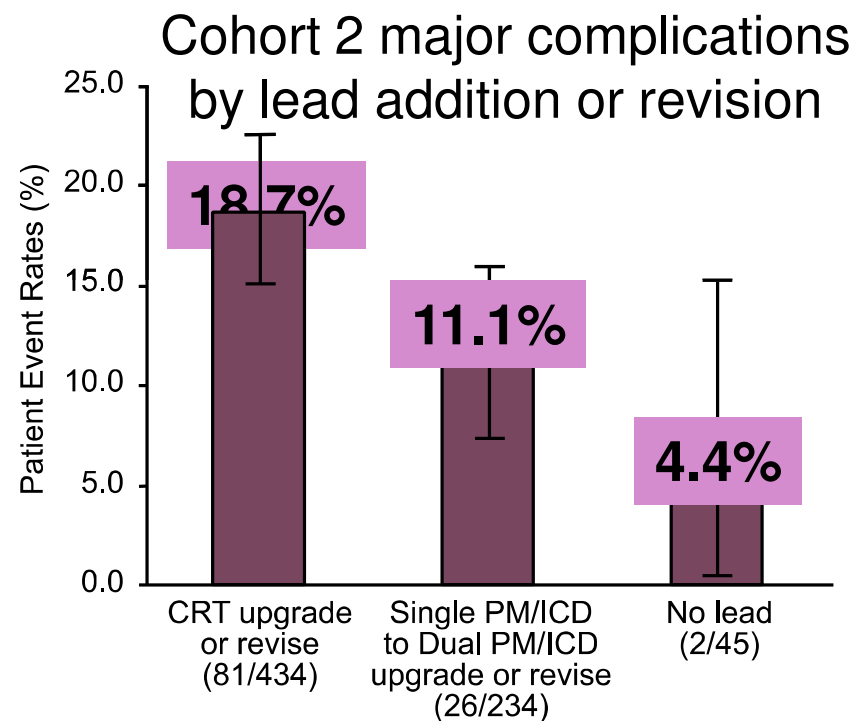
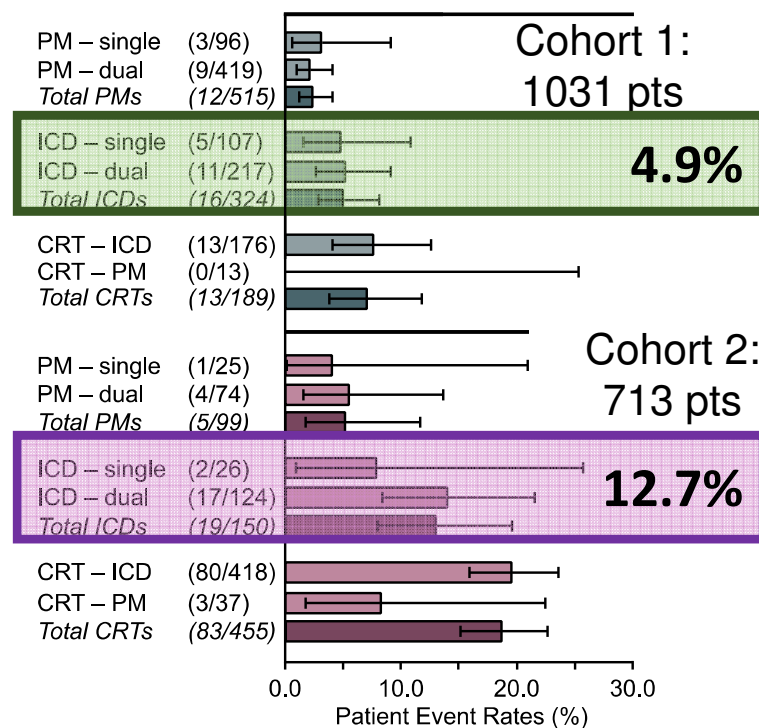
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# Complication Rates Associated With Pacemaker or Implantable Cardioverter-Defibrillator Generator Replacements and Upgrade Procedures

Results From the REPLACE Registry



*Circulation.* 2010;122:1553–1561

### Characteristics of Patients at Initial ICD Implantation and at the Time of ICD Replacement

Many comorbidities appear after ICD implantation.



94



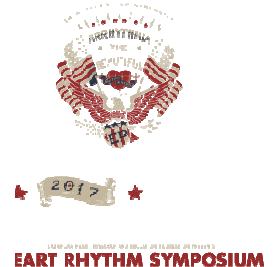
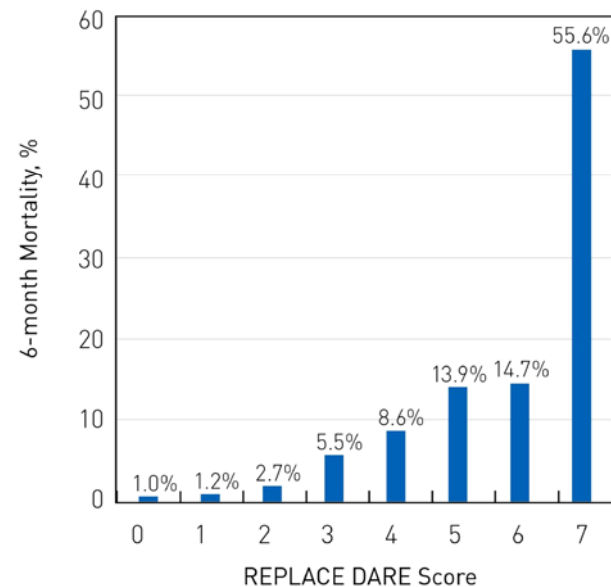
## REPLACE DARE (Death After Replacement Evaluation) Score

### Determinants of All-Cause Mortality After Implantable Device Replacement or Upgrade From the REPLACE Registry

#### 6 Variables predictive of survival:

- HF admission within 12 months [0=No; 1=Yes]
- NYHA Class [0=0, I, II; 1=III, IV]
- CKD stage [1–5]
- Class I or III antiarrhythmic drug use [0=No; 1=Yes]
- History of cerebrovascular disease [0=No; 1=Yes]
- Age quartiles [1=<63; 2=63–72; 3=73–79; 4=80+]

**B** Distribution of Mortality Across Risk Scores



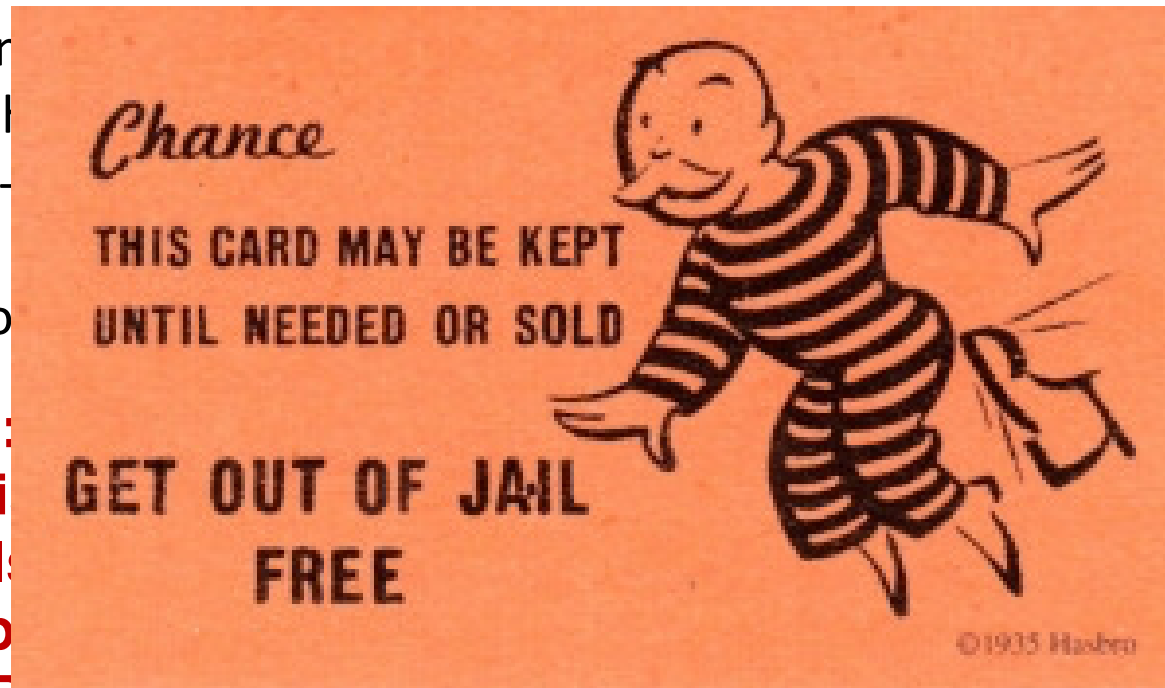
*Circ Arrhythm Electrophysiol.* 2014;7:1048-1056



# Back to Our Case...

84 yo woman  
normal, clinical  
• LVEF 55-60%  
• NYHA II  
• No history of

**My Plan:**  
**Office visit to review**  
**her goals and**  
**decide between**  
**likely CRT-P vs. CRT-D gen**  
**change.**



with

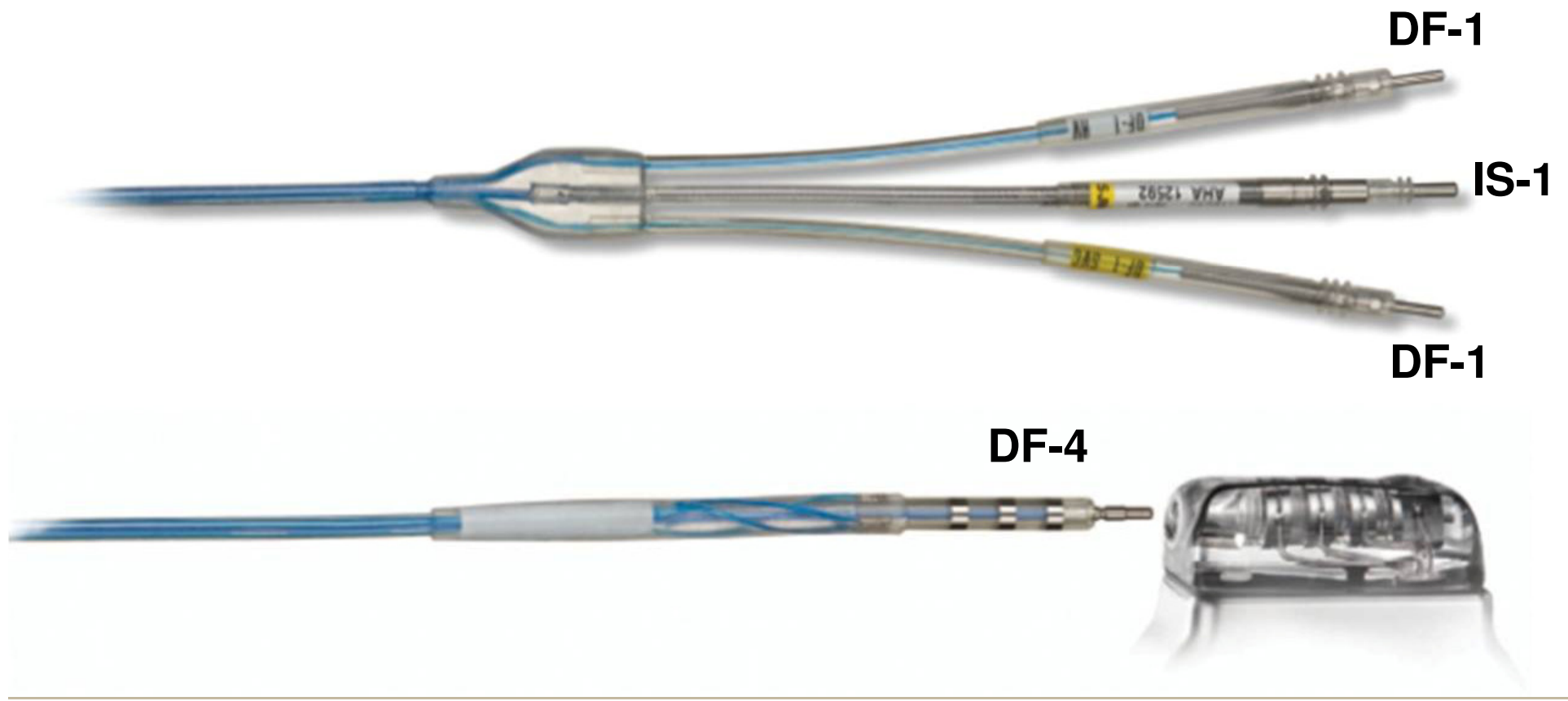


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# Upcoming Political Scandal: The DF-4 Dilemma



# End-of-Life Discussions



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“When I die, I want to die like  
my grandfather who died  
peacefully in his sleep. Not  
screaming like all the  
passengers in his car.”  
- Will Rogers



## Case #2 (From March, 2016)

73 yo man with CAD – s/p inferior MI, ICM, CHF, VT – s/p RFA, h/o AF, upgraded from dual chamber ICD to CRT-d 4/14 for complete AV block

- Stable NYHA III CHF sx.
- No ICD shocks since prio to VT ablation
- Last ATP for slow VT 12/15 (single episode)
- Progressive Alzheimer's dementia, impacting QOL to the point that patient no longer wishes to receive ATP or ICD shock



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# When should we de-activate a patient's ICD?



**The short answer to the question:  
Whenever the patient or his/her  
surrogate ask us to.**



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# Our Ethical & Legal Responsibilities

Fundamental underlying principle of both Ethical and Legal aspects of ICD deactivation is the same.

- “Centered upon patient autonomy and authority over their own medical treatment”
- “Respect for autonomy and individual personhood supports a patient’s right to dictate decisions about one’s own treatment”



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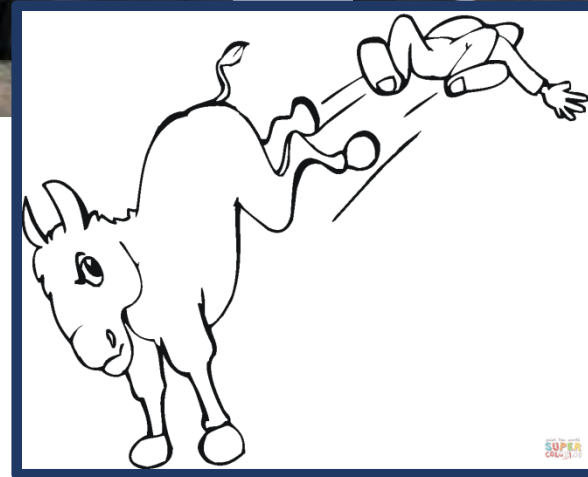
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Kramer DB, et al: Prog Cardiovasc Dis 2012; 55: 290-299





# What Does an ICD Shock Feel Like?



Ahmad et al. PACE 2000



# ICD Benefits Beyond Shocks to Prevent Sudden Death

- Source of comfort and reassurance for some patients
- Pacing – painless and rarely an issue in end-of-life discussions
- Arrhythmia monitoring/management
  - e.g., monitoring AF to guide anticoagulation and other treatment options
- Painless termination of arrhythmias: anti-tachycardia pacing
  - May be palliative in preventing symptomatic VT or slow VT that causes worsening of heart failure



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## Brief Communication: Management of Implantable Cardioverter-Defibrillators in Hospice: A Nationwide Survey

Nathan Goldstein, MD; Melissa Carlson, MBA, PhD; Elayne Livote, MPH, MS, MA; and Jean S. Kutner, MD, MSPH

- 414 hospice surveys returned (900 requests)
- 97% admit patients with ICDs
- 58% had patient with shock in last year
- 10% had policy re: deactivation
- 42% had ICDs deactivated

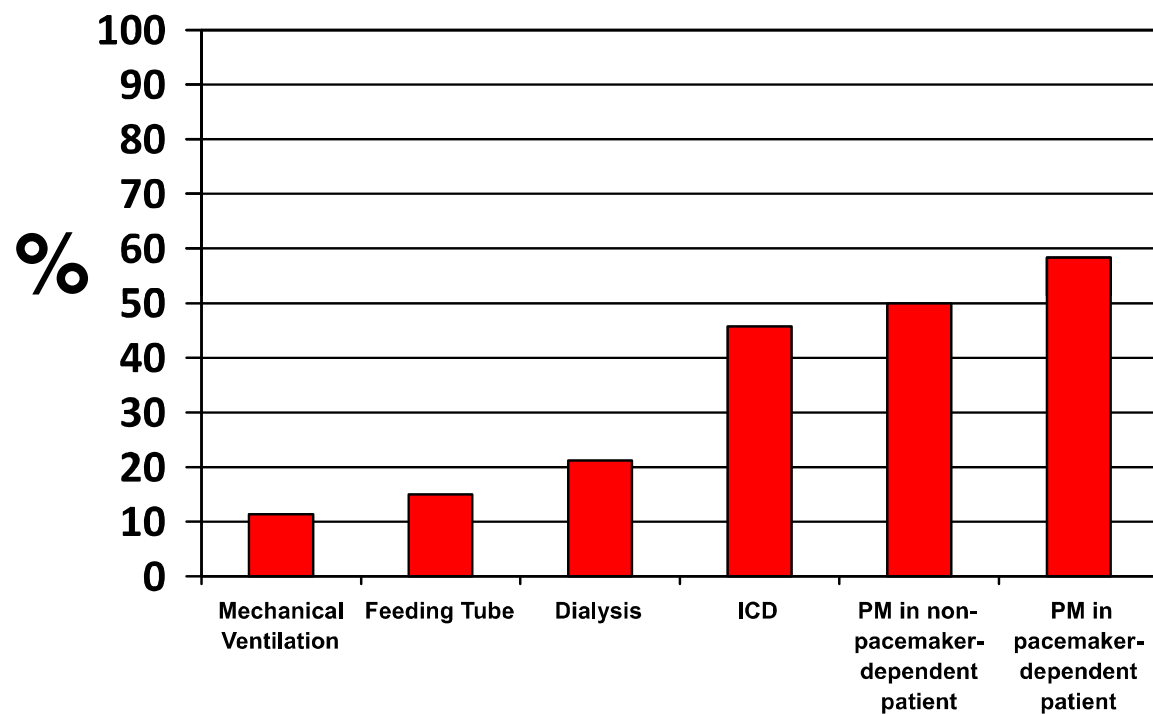


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Ann Intern Med. 2010 March 2; 152(5): 296–299



# Physicians' Lack of Comfort Discussing Withdrawal of Specific Life-Sustaining Therapies



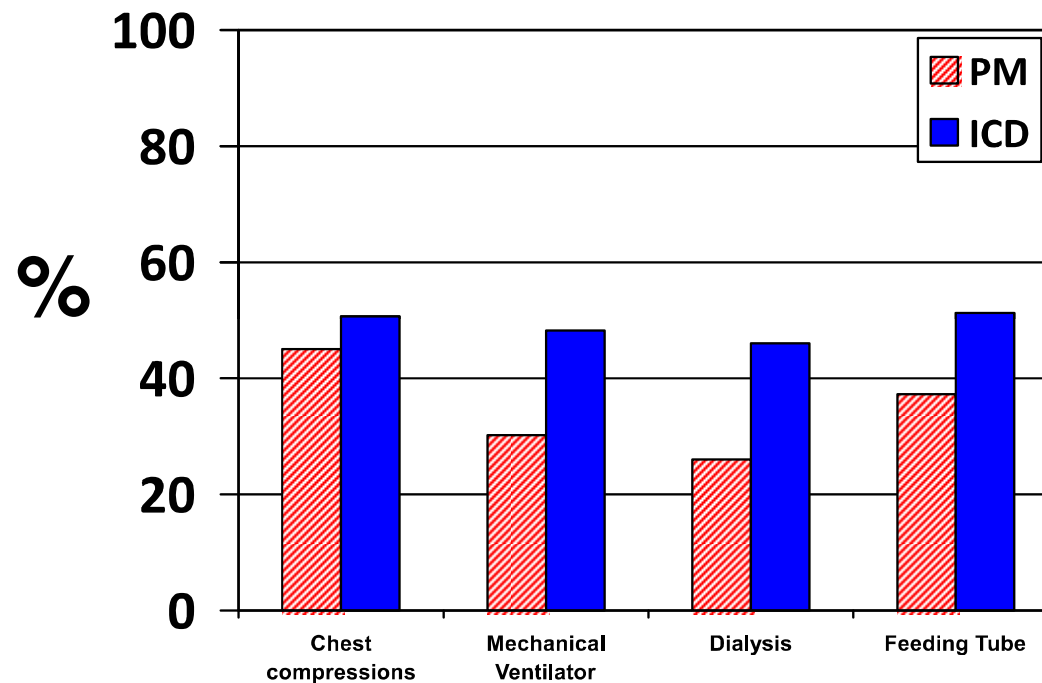
Heart Rhythm 2010;7:1537–1542



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# Physicians Viewing PM or ICD Withdrawal as Different from Specific Therapy



Heart Rhythm 2010;7:1537-1542



# 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).*

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[www.hrsonline.org](http://www.hrsonline.org)



## Case #2 (March 2016) - Outcome

73 yo man with CRT-D, slow VT → ATP, but no recent shocks

- All tachycardia therapies were disabled.
- CRT pacing left on without any changes
- Referred for hospice
- 2/1/17 – Patient's wife called in for med refill. He is bedbound and still on hospice.



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# Conclusions

- ICDs prevent sudden cardiac death and improve survival.
- US population aging.
- Patient age and comorbidities impact survival benefit of ICD.
- Detailed discussion regarding benefit and risk for ICD implantation or generator replacement are required, especially as the patient ages and develops other comorbidities.
- Ultimately, the patient has a right to consent or refuse care regarding ICD implantation, replacement, or de-activation.

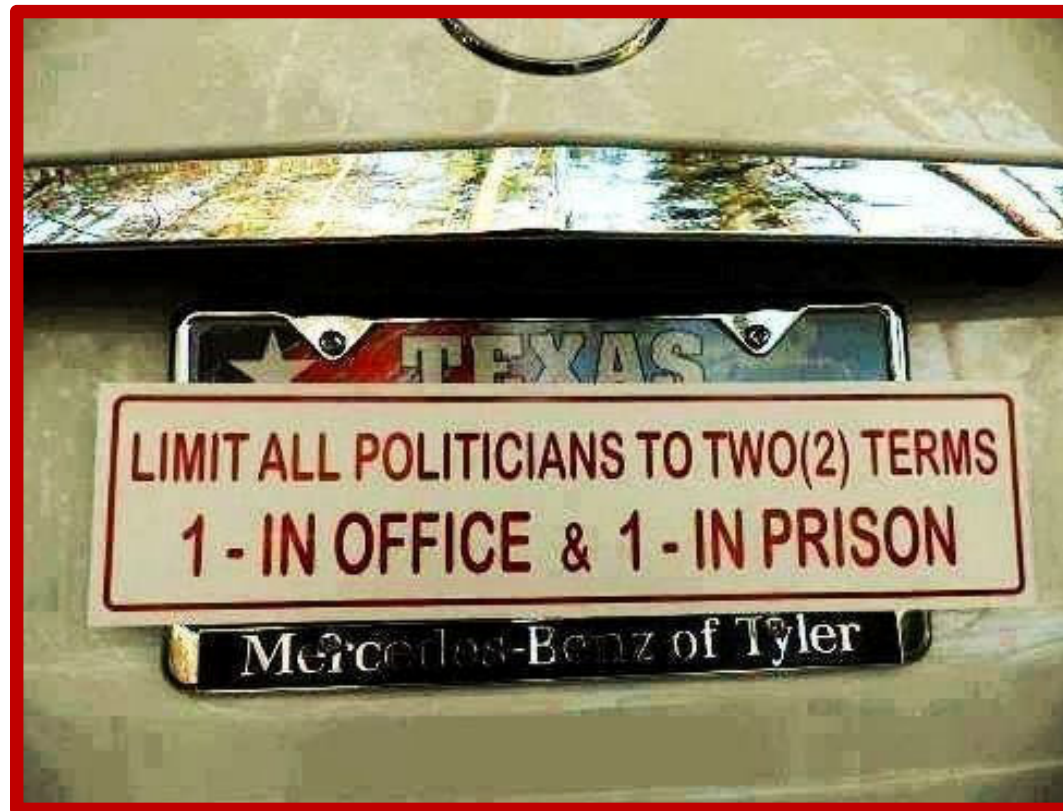


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Thank You and God Bless Arrhythmia...



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