Heart Failure Device Therapy: ICD and CRT Update 2015

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Disclosure Information

- Medtronic, Boston Scientific, St. Jude Medical,Biotronik:

  Research, DSMB, Consulting, Honoraria

- Fellowship (Institutional) Support

  Medtronic, Boston Scientific

Are We Putting in Too Many ICDs?

Recommendations for ICD Therapy: Primary Prevention

Class I

1) Prior MI
   - LVEF < 35%
   - NYHA II/III
   - ≥ 40 days post MI

   LOE: A

2) Prior MI
   - LVEF < 30%
   - NYHA I
   - ≥ 40 days post MI

   LOE: A

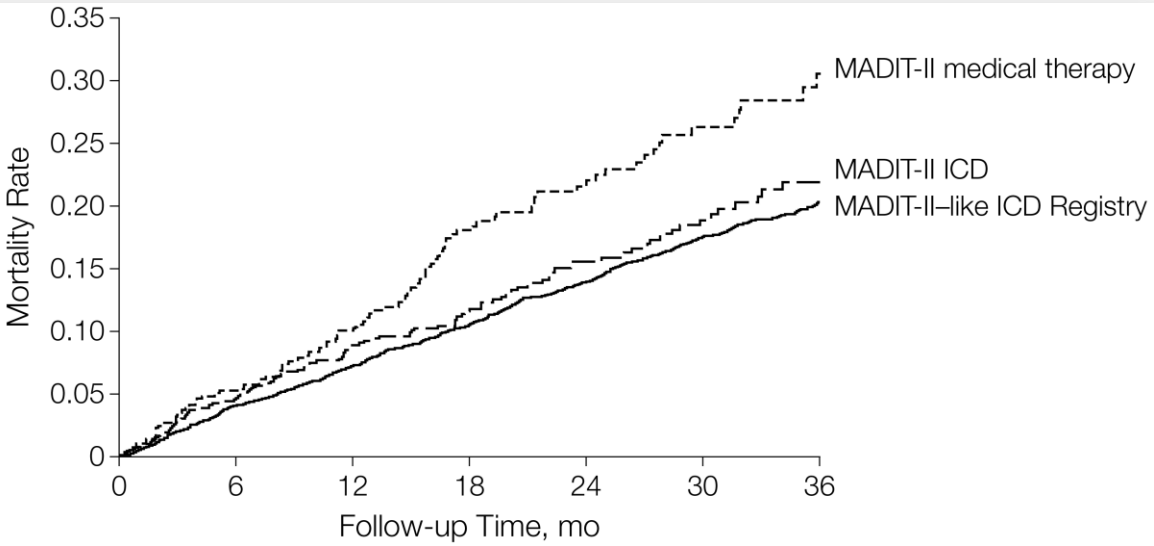
3) Prior MI
   - LVEF < 40%
   - VT-NS
   - VT-S/VF at EPS

   LOE: B

4) NIDCM
   - LVEF ≤ 35%
   - NYHA II/III

   LOE: B

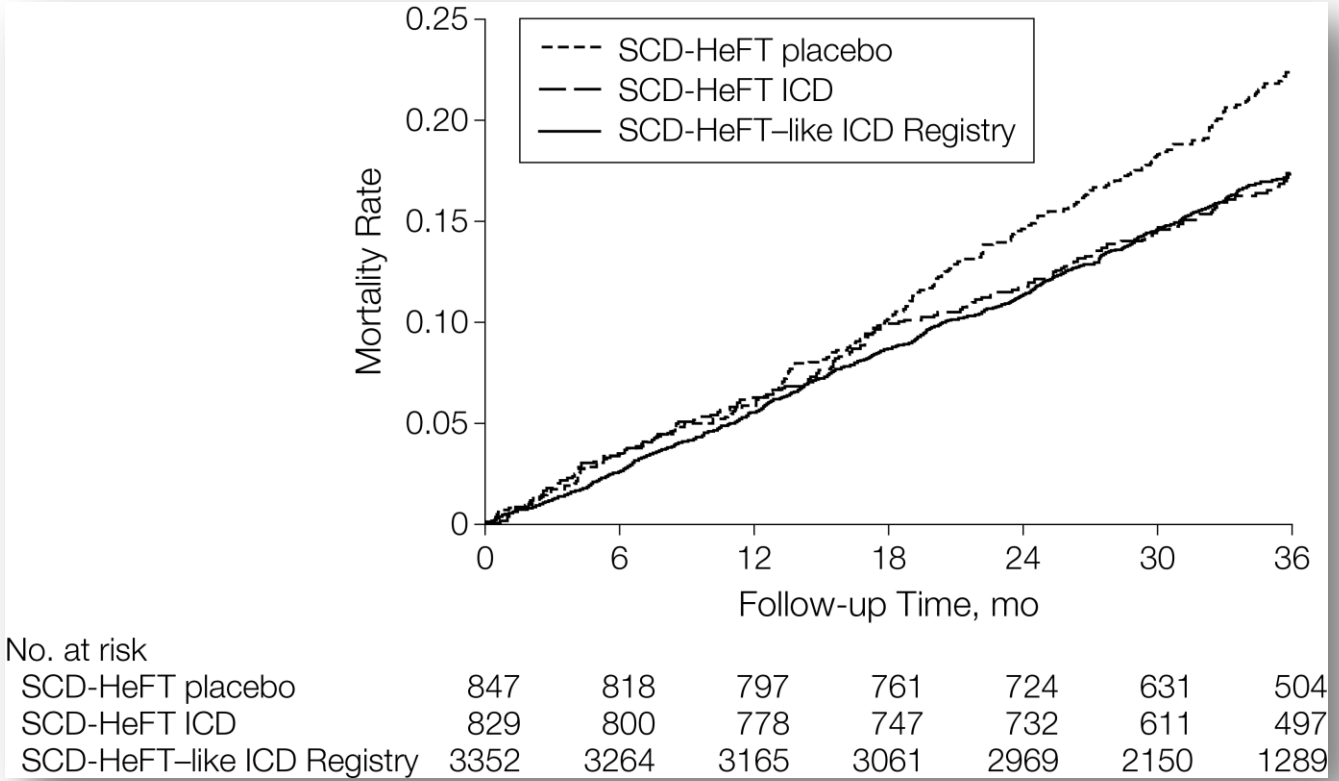
Survival of Patients Receiving a Primary Prevention Implantable Cardioverter-Defibrillator in Clinical Practice vs Clinical Trials



No. at risk

MADIT-II medical therapy	490	425	328	235	169	114	64
MADIT-II ICD	742	639	500	383	267	194	107
MADIT-II–like ICD Registry	2464	2362	2285	2205	2120	1583	997

JAMA. 2013;309(1):55-62. doi:10.1001/jama.2012.157182



No. at risk							
SCD-HeFT placebo	847	818	797	761	724	631	504
SCD-HeFT ICD	829	800	778	747	732	611	497
SCD-HeFT–like ICD Registry	3352	3264	3165	3061	2969	2150	1289

JAMA. 2013;309(1):55-62. doi:10.1001/jama.2012.157182

Association Between Prophylactic Implantable Cardioverter-Defibrillators and Survival in Patients With LVEF Between 30% and 35%

JAMA. 2014;311(21):2209-2215.

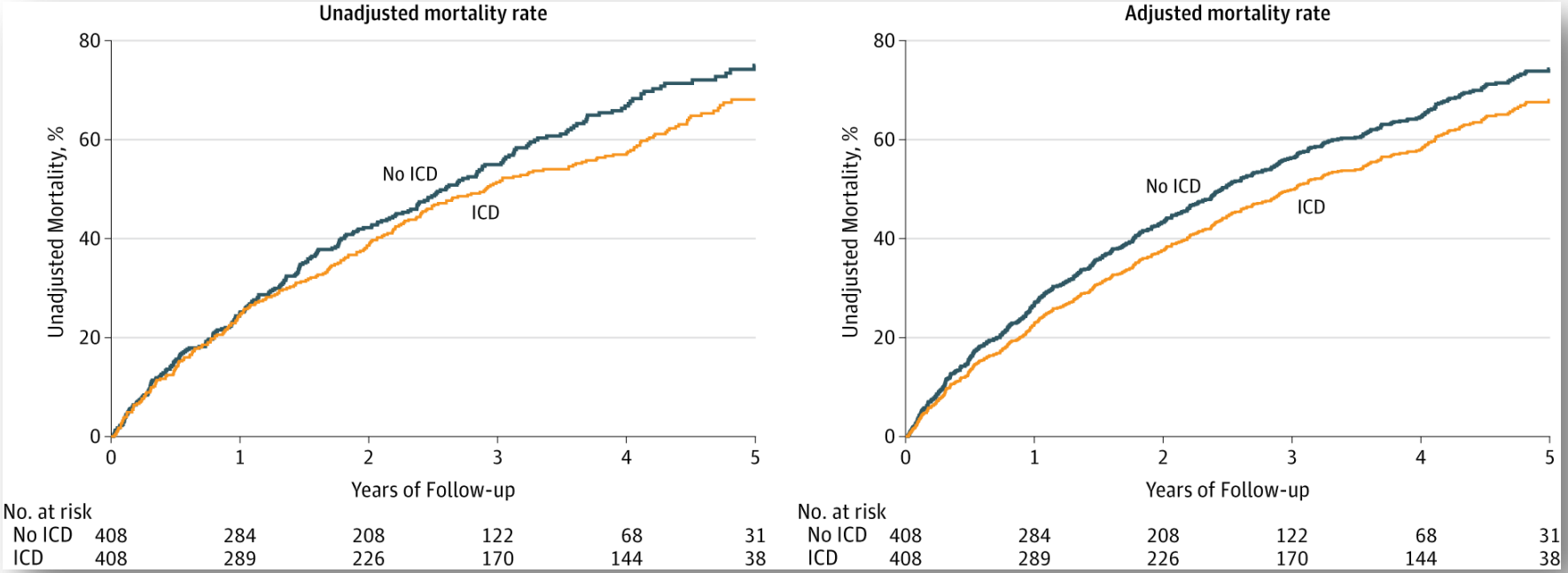


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Table 2. All-Cause Mortality in NCDR ICD Registry and GWTG-HF Database Patients, by LVEF[a]

	LVEF 30%-35%		LVEF <30%	
	ICD (NCDR) (n = 408)	No ICD (GWTG-HF) (n = 408)	ICD (NCDR) (n = 1088)	No ICD (GWTG-HF) (n = 1088)
Follow-up duration among survivors, median (IQR), y	4.4 (2.7 to 4.9)	2.9 (2.1 to 4.4)	4.6 (2.9 to 5.1)	3.1 (2.0 to 4.2)
Total deaths	248	249	634	660
Deaths by 1 y	97	99	234	322
Unadjusted mortality rate at 1 y, % (95% CI)	24.5 (20.5 to 29.0)	24.9 (20.9 to 29.5)	22.0 (19.6 to 24.6)	30.7 (28.0 to 33.6)
Difference between no ICD and ICD in	0.4 (-5.6 to 6.5)		8.7 (4.9 to 12.4)	
Adjusted mortality rate at 1 y, % (95% CI)	22.8 (22.3 to 23.4)	30.0 (29.4 to 30.6)	22.3 (22.0 to 22.6)	29.3 (29.0 to 29.7)
Adjusted mortality rate at 3 y, % (95% CI)	47.1 (46.2 to 47.9)	58.0 (57.1 to 58.8)	46.1 (45.6 to 46.7)	57.0 (56.4 to 57.5)
Adjusted HR (95% CI) for ICD vs no ICD[b]	0.83 (0.69 to 0.99)		0.72 (0.65 to 0.81)	
P value for HR	.04		<.001	
P value for interaction of LVEF group with ICD	.20			

Abbreviations: GWTG-HF, Get With The Guidelines–Heart Failure; HR, hazard ratio; ICD, implantable cardioverter-defibrillator; IQR, interquartile range; LVEF, left ventricular ejection fraction; NCDR, National Cardiovascular Data Registry.

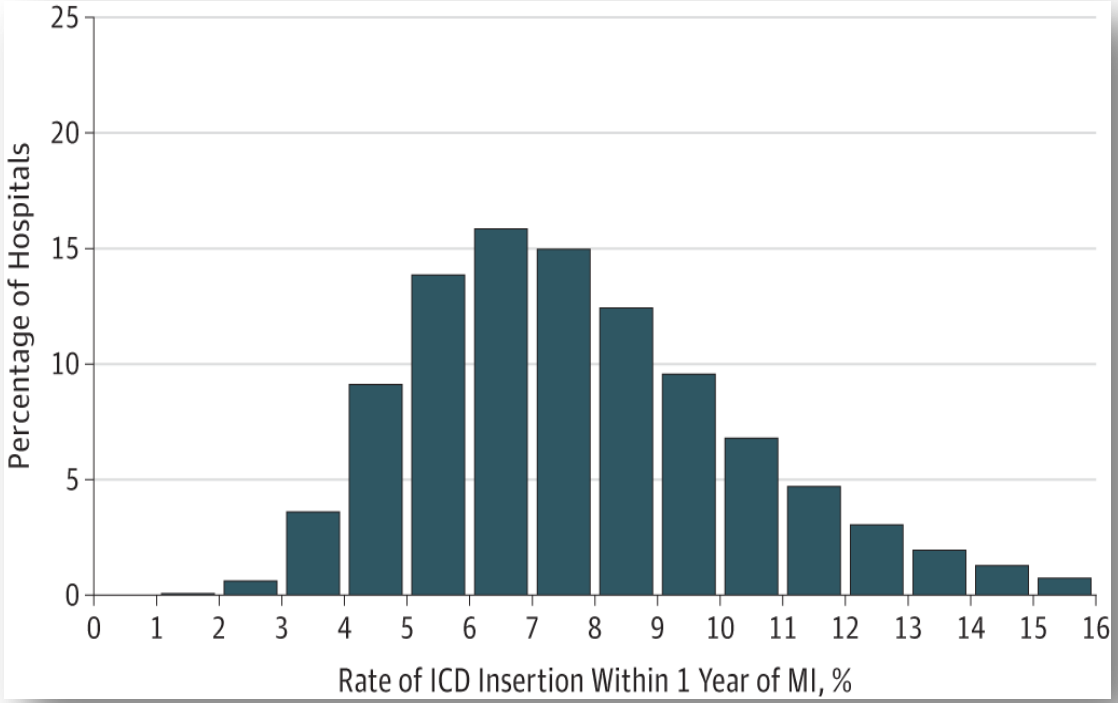
[a] Adjusted rates, hazard ratios, and *P* values are from Cox models that include age, sex, race, LVEF, ischemic heart disease, prior atrial arrhythmia, systolic blood pressure, diabetes, hypertension, and baseline use of angiotensin-converting enzyme inhibitor, angiotensin receptor blocker, calcium channel blocker, digoxin, diuretic, or statin.

[b] C-index for the model = 0.78.

JAMA. 2014;311(21):2209-2215.

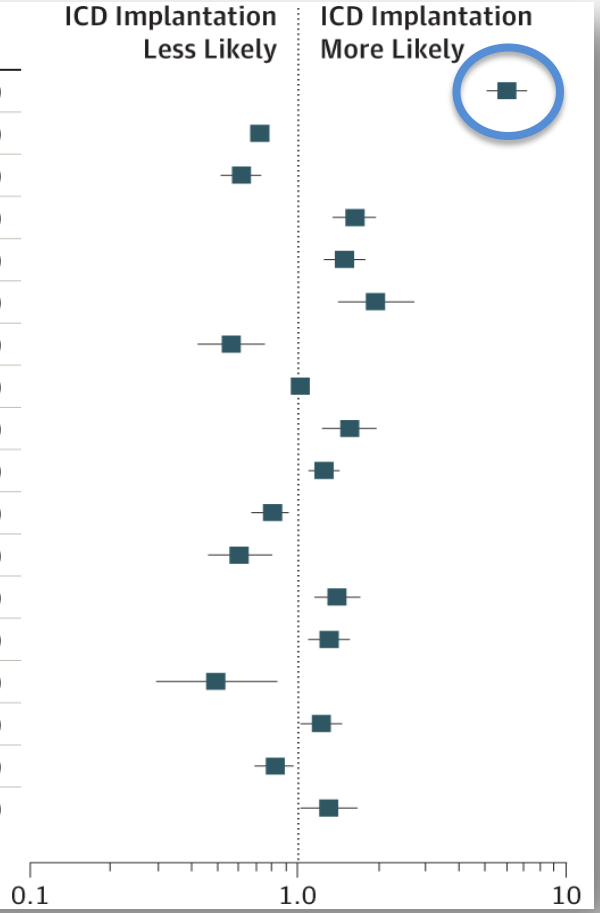
ICD Use Among Medicare Patients With Low Ejection Fraction After Acute Myocardial Infarction

JAMA. 2015;313(24):2433-2440. doi:10.1001/jama.2015.6409



In this large registry study of older patients who experienced MI from 2007-2010, **fewer than 1 in 10 eligible patients with low EF received an ICD within 1 year after MI**, although ICD implantation was associated with lower risk-adjusted mortality at 2 years. **Additional research is needed to determine evidence-based approaches to increase ICD implantation among eligible patients.**

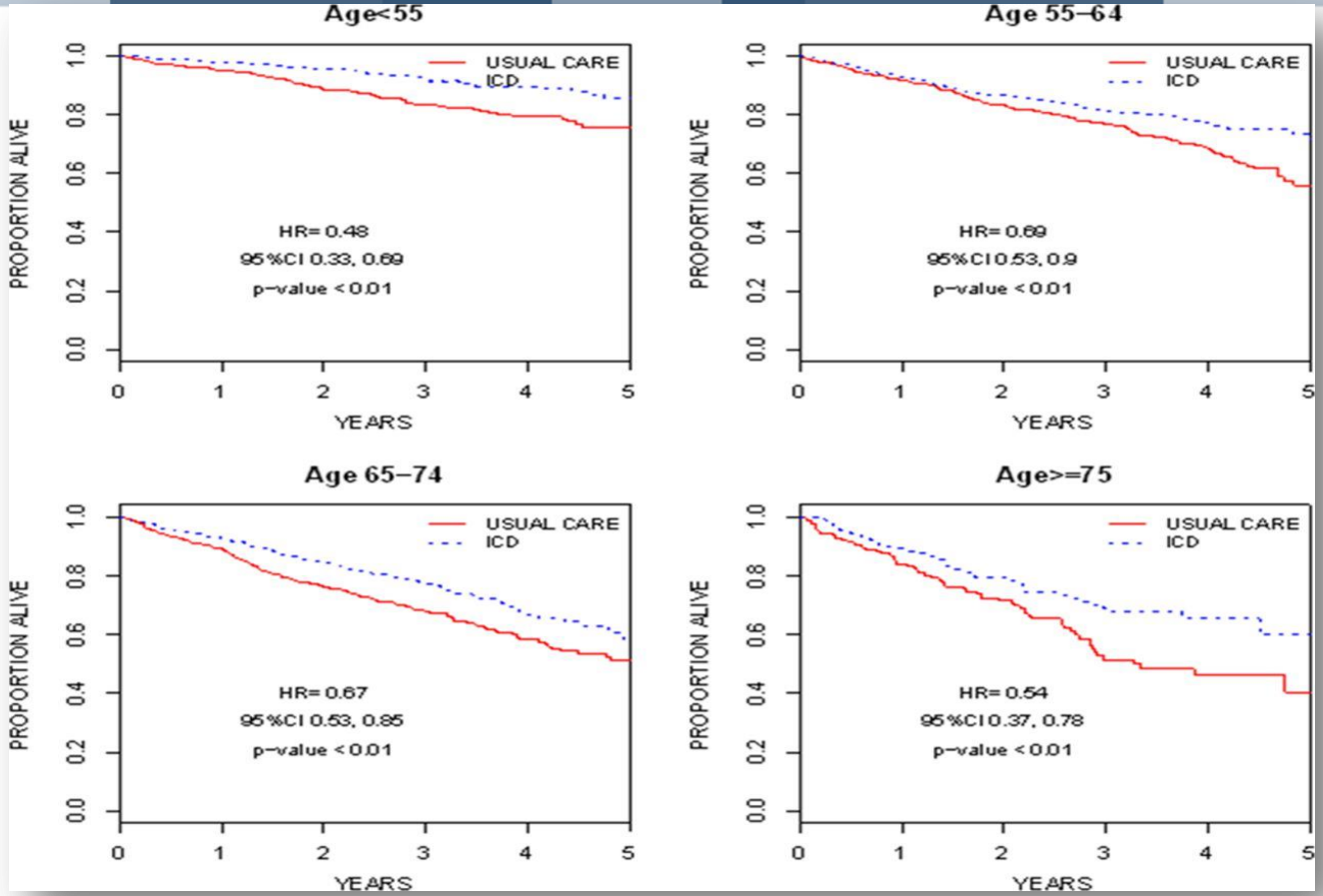
Variable	HR (95% CI)
Heart failure readmission	6.06 (5.11-7.19)
Age (per 5-year increase)	0.73 (0.69-0.78)
Female sex (vs male sex)	0.62 (0.52-0.73)
Early cardiology follow-up	1.64 (1.37-1.95)
Prior CABG	1.49 (1.26-1.78)
Readmission for MI	1.97 (1.43-2.71)
End-stage renal disease	0.57 (0.43-0.75)
Peak troponin (per 10× ULN increase)	1.02 (1.01-1.03)
In-hospital cardiogenic shock	1.57 (1.25-1.97)
BMI <30, per 5-unit increase	1.25 (1.10-1.43)
BMI ≥30, per 5-unit increase	0.80 (0.68-0.93)
Prior stroke	0.61 (0.47-0.80)
Prior heart failure	1.41 (1.17-1.70)
Prior MI	1.31 (1.11-1.55)
Prior cancer	0.50 (0.30-0.84)
Prior atrial fibrillation or atrial flutter	1.22 (1.03-1.45)
Diabetes	0.83 (0.70-0.97)
Aldosterone antagonist use at discharge	1.31 (1.03-1.66)



"Even though the use of ICDs for primary prevention may not seem to make as much sense for an 80-year-old patient as it does for a patient in his or her 50s or 60s, an older patient at risk for sudden cardiac death should have the same opportunity to choose potentially life-saving therapy."

Robert Hauser JAMA 2015; 313: 2429-30

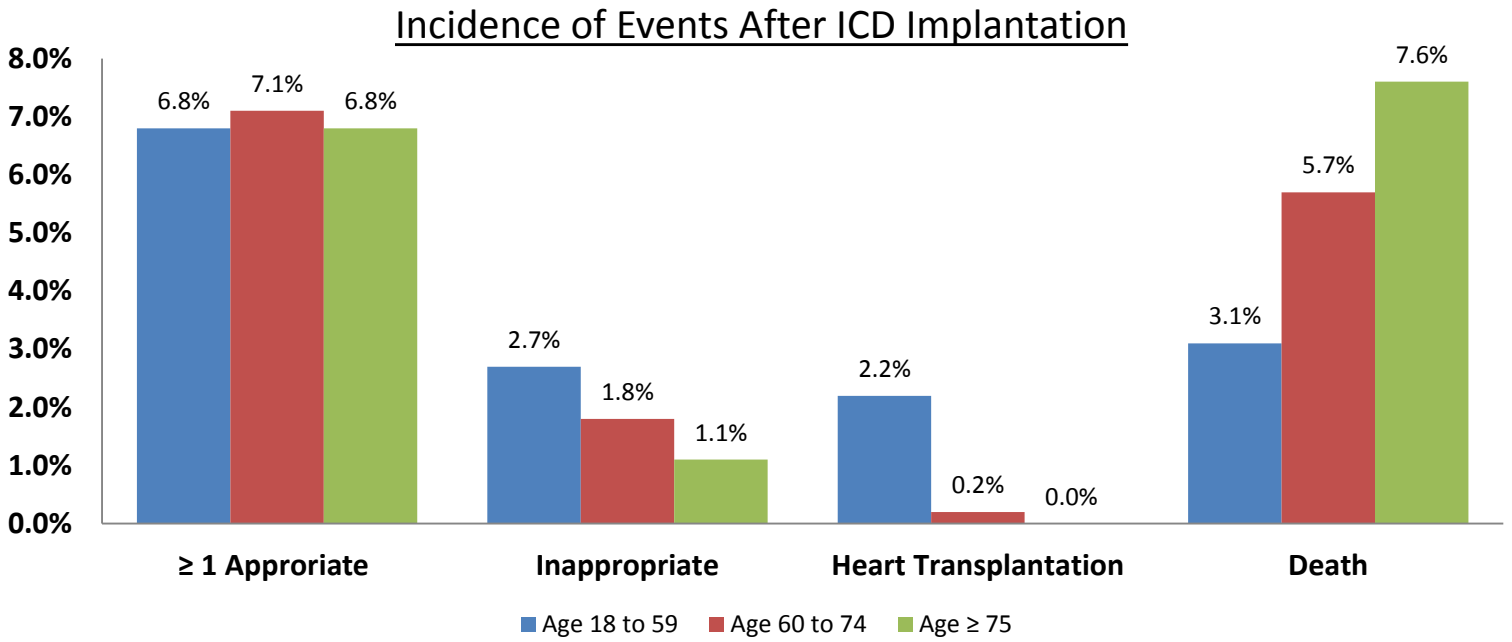
Unadjusted Kaplan–Meier survival curves by age



Paul L. Hess et al. Circ Cardiovasc Qual Outcomes. 2015;8:179-186

Fauchier L, et al on behalf of the DAI-PP Investigators

Effect of Age on Survival and Causes of Death After Primary Prevention ICD Implantation



Fauchier L, Marijon E, Defay P et al. Effect of Age on Survival and Causes of Death After Primary Prevention Implantable Cardioverter-Defibrillator Implantation. *Am J Cardiol.* 2015;115:1415-1422.

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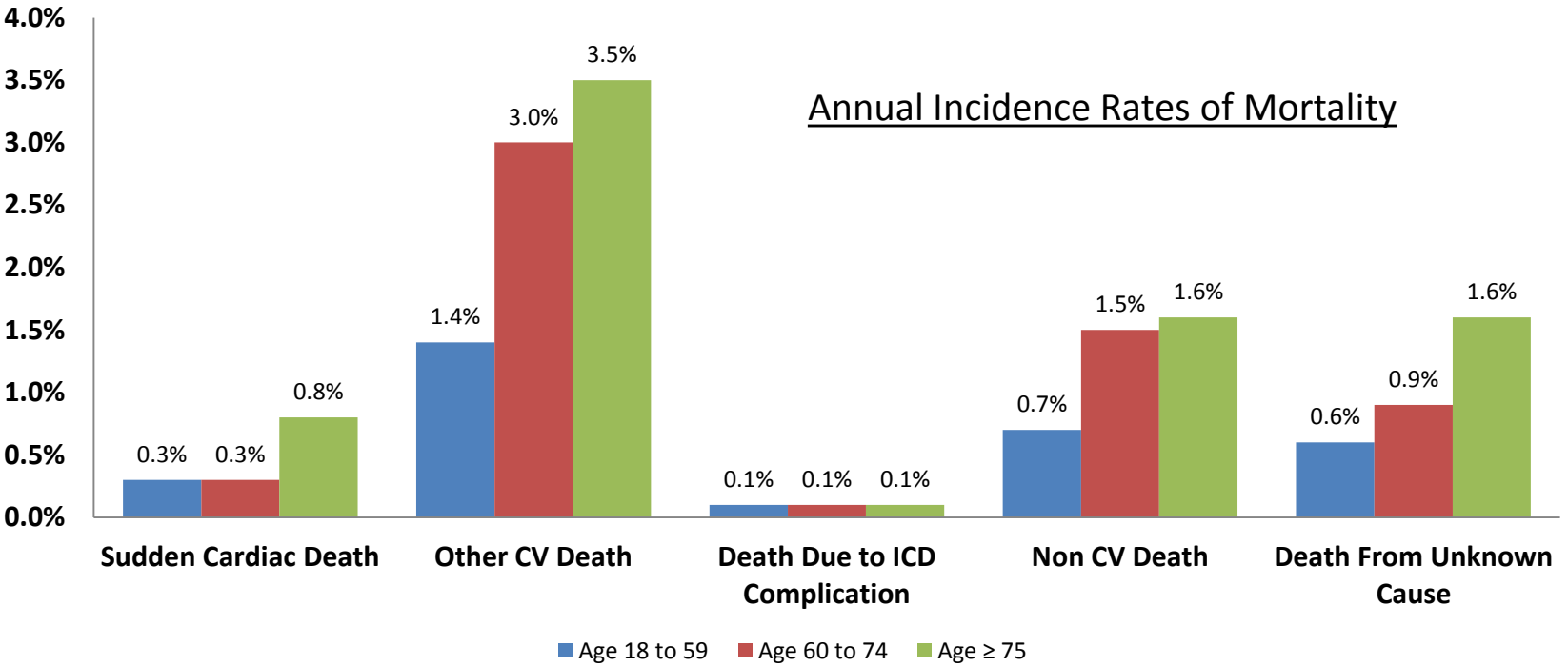
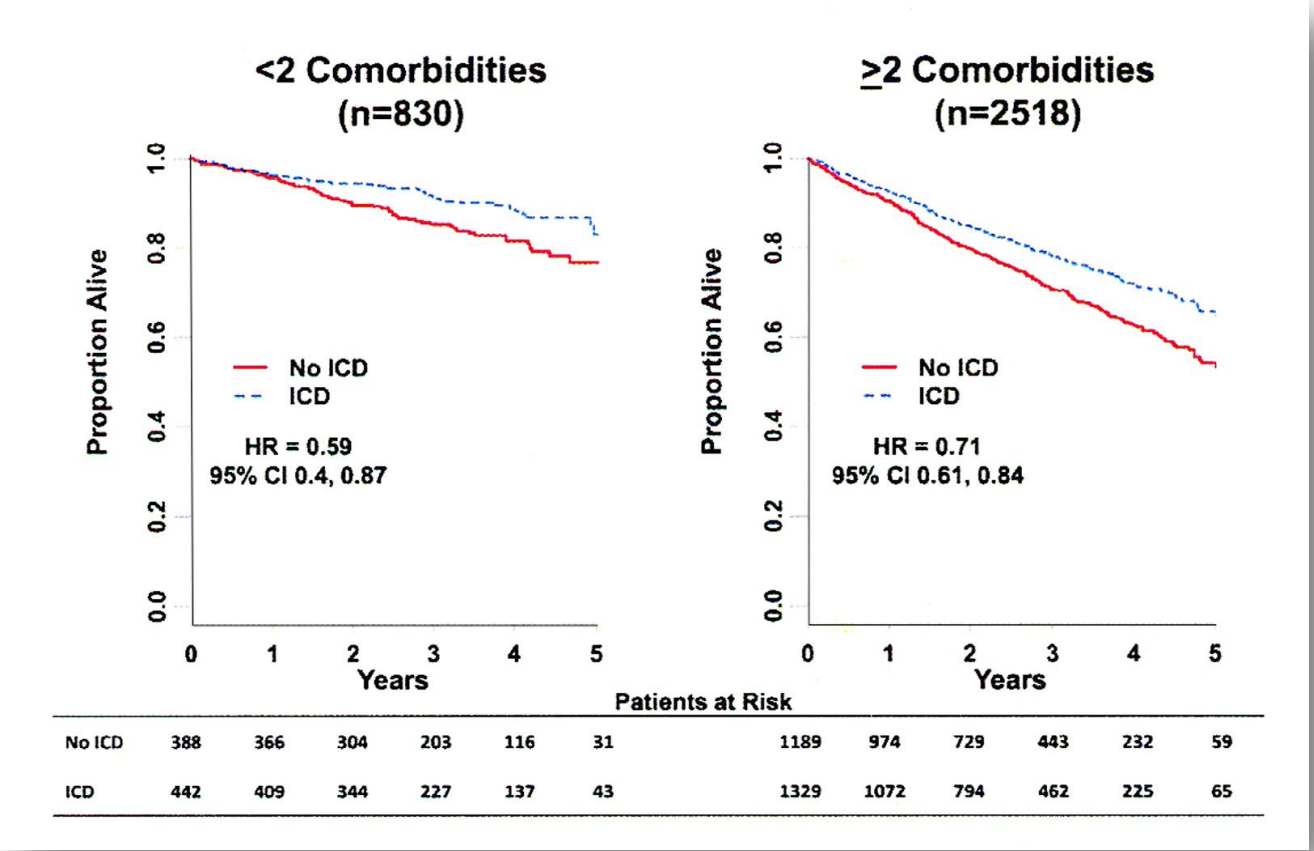
Effect of Age on Survival and Causes of Death After Primary Prevention ICD Implantation



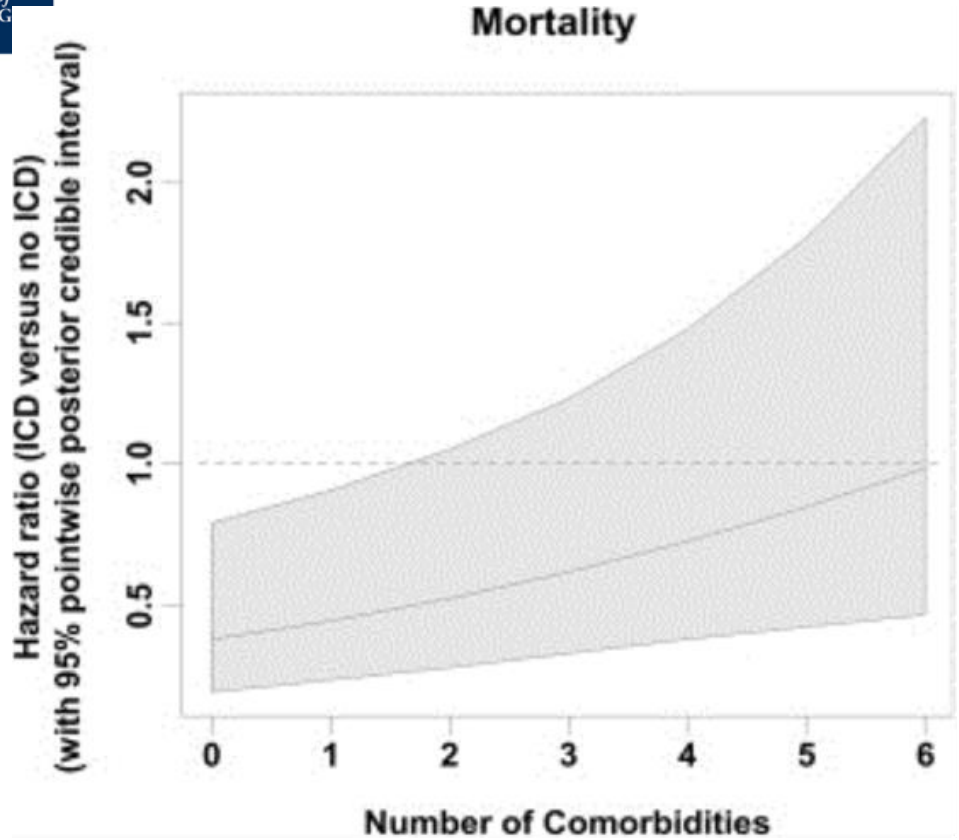
Fauchier L, Marijon E, Defay P et al. Effect of Age on Survival and Causes of Death After Primary Prevention Implantable Cardioverter-Defibrillator Implantation. *Am J Cardiol.* 2015;115:1415-1422.

All-Cause Mortality by Treatment Group



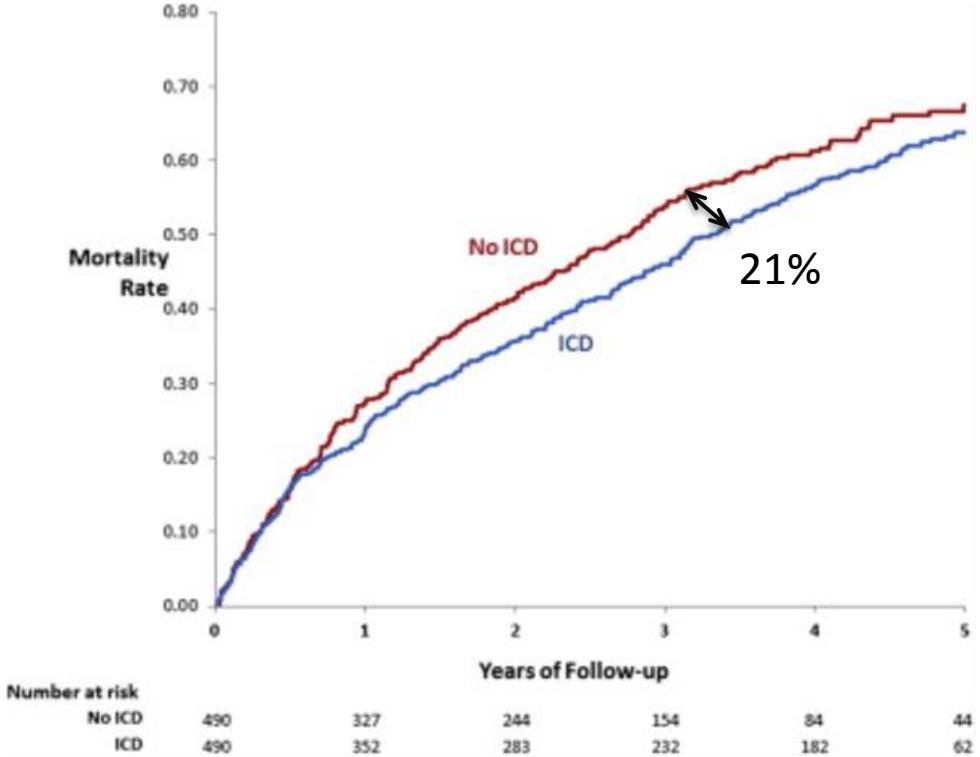
From: Steinberg BA et al., J Am Coll Cardiol HF 2014; 2: 623-629

Outcomes of ICD Use in Pts with Co-Morbidities



Extensive comorbid conditions may result in increased incidence of competing risk due to non sudden death. Incremental benefit of ICD may be reduced in this population.

Primary prevention ICD and Survival in Women



JCHF. 2015;3(2):159-167. doi:10.1016/j.jchf.2014.09.006

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HRS/ACC/AHA Expert Consensus Statement on the Use of Implantable Cardioverter-Defibrillator Therapy in Patients Who Are Not Included or Not Well Represented in Clinical Trials

Fred M. Kusumoto, MD, FHRS (Chair),[1] Hugh Calkins, MD, FHRS (Chair),[2] John Boehmer, MD,[3§] Alfred E. Buxton, MD,[4*] Mina K. Chung, MD, FHRS,[5] Michael R. Gold, MD, PhD, FHRS,[6] Stefan H. Hohnloser, MD, FHRS,[7] Julia Indik, MD, PhD, FHRS,[8] Richard Lee, MD, MBA,[9‡] Mandeep R. Mehra, MD,[10*] Venu Menon, MD,[11†] Richard L. Page, MD, FHRS,[12†] Win-Kuang Shen, MD,[13*] David J. Slotwiner, MD,[14] Lynne Warner Stevenson, MD,[15†] Paul D. Varosy, MD, FHRS,[16] Lisa Welikovitch, MD[17]

Heart Rhythm 2014;11:1270-1303.

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ACCF/HRS/AHA/ASE/HFSA/SCAI/SCCT/SCMR 2013 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy

A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, Heart Rhythm Society, American Heart Association, American Society of Echocardiography, Heart Failure Society of America, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance

Endorsed by the American Geriatrics Society

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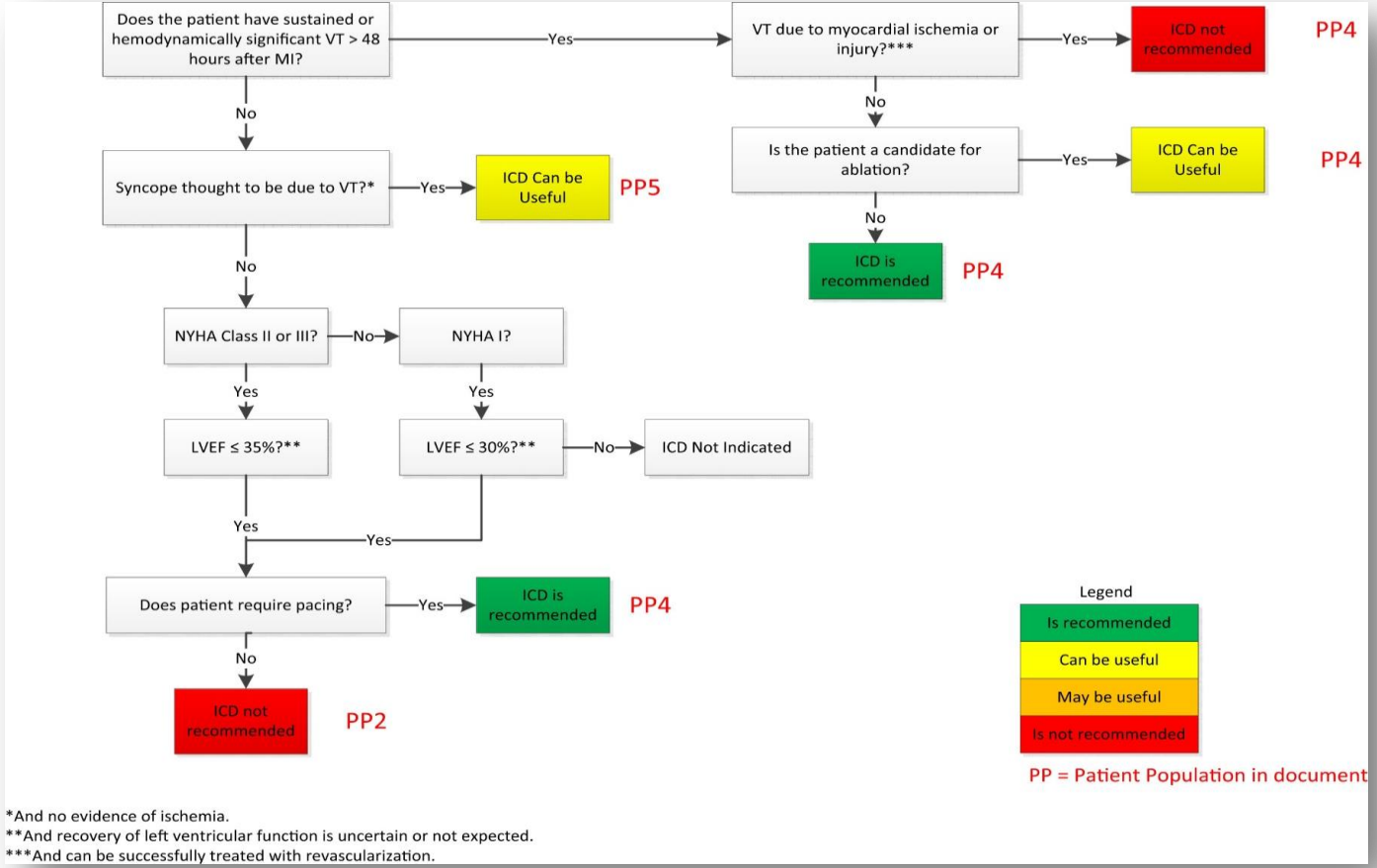
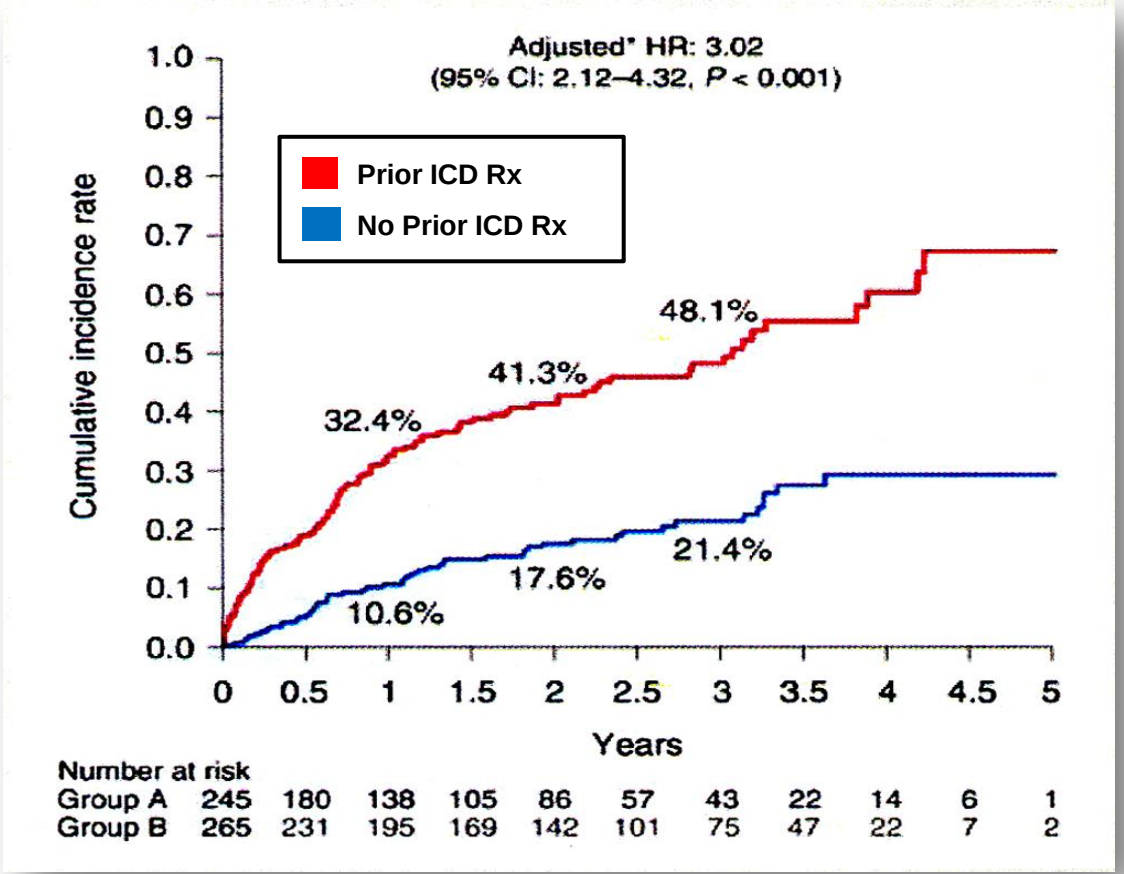
*Heart Rhythm Society Representative; †Served on Writing Group starting December 2011; ‡Served on Writing Group through December 2011

AUC publications reflect an effort by the ACCF to critically and systematically create, review, and categorize clinical situations that may or may not be addressed in guidelines, and provide management guidance.



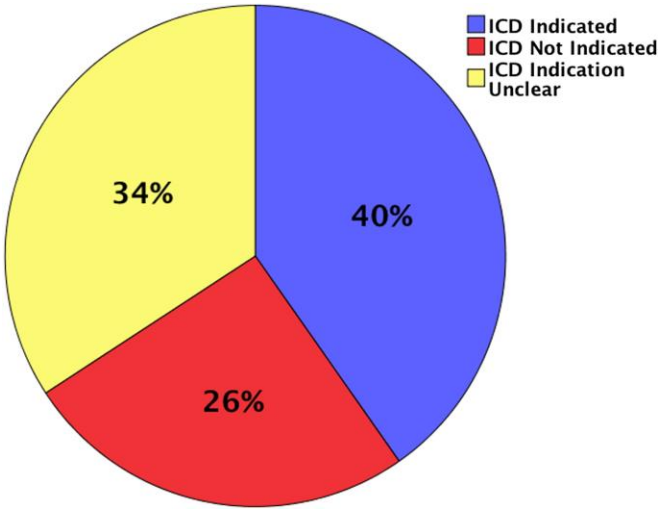
Heart Rhythm 2014 11, 1270-1303DOI: (10.1016/j.hrthm.2014.03.041)

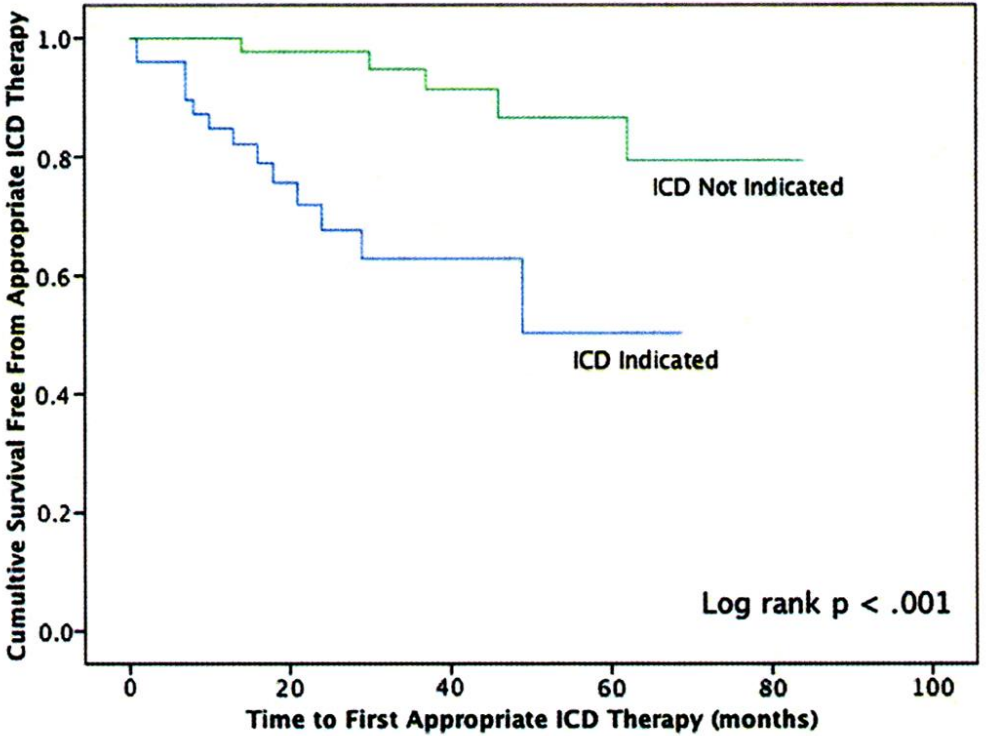
Cumulative Incidence of Appropriate ICD Therapy After Elective ICD Generator Replacement; INSURE Study



From: Erkapic D European Heart Journal 2013; 34: 130-137

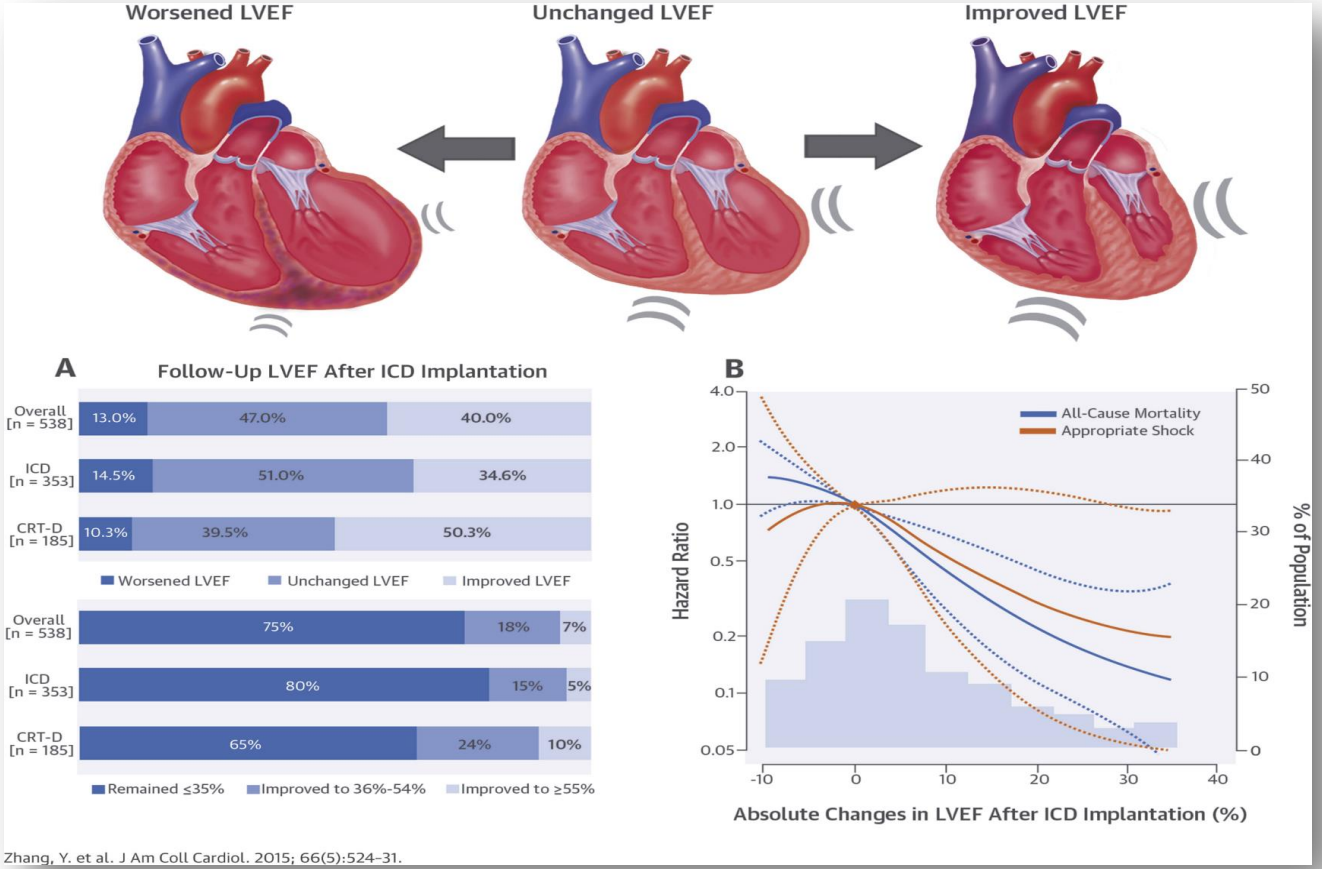
Subsequent ICD Therapies After Elective Generator Replacement when ICD No Longer Indicated





From: Kini V J Am Coll Cardiol 2014; 63: 2388-94

Changes in Follow-Up LV EF Associated With Outcomes in Primary Prevention ICD and CRT Recipients



Zhang, Y. et al. J Am Coll Cardiol. 2015; 66(5):524–31.

J Am Coll Cardiol. 2015;66(5):524-531. doi:10.1016/j.jacc.2015.05.057

Guidelines - 2012

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

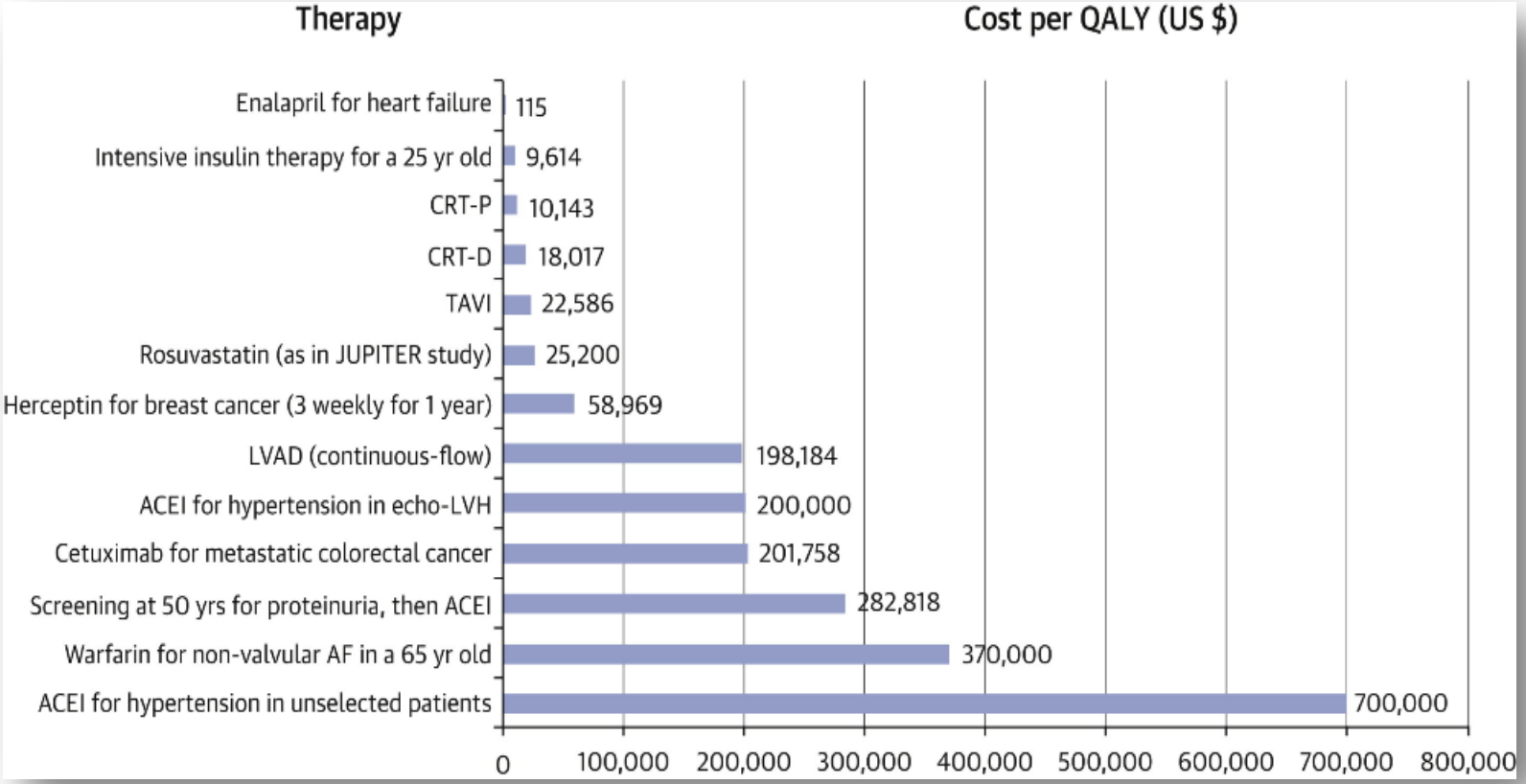
Developed in Collaboration With the American Association for Thoracic Surgery, Heart Failure Society of America, and Society of Thoracic Surgeons

Endorsed by the American Association for Thoracic Surgery, Heart Failure Society of America, and Society of Thoracic Surgeons

J Am Coll Cardiol 2012;60:1297–1313.

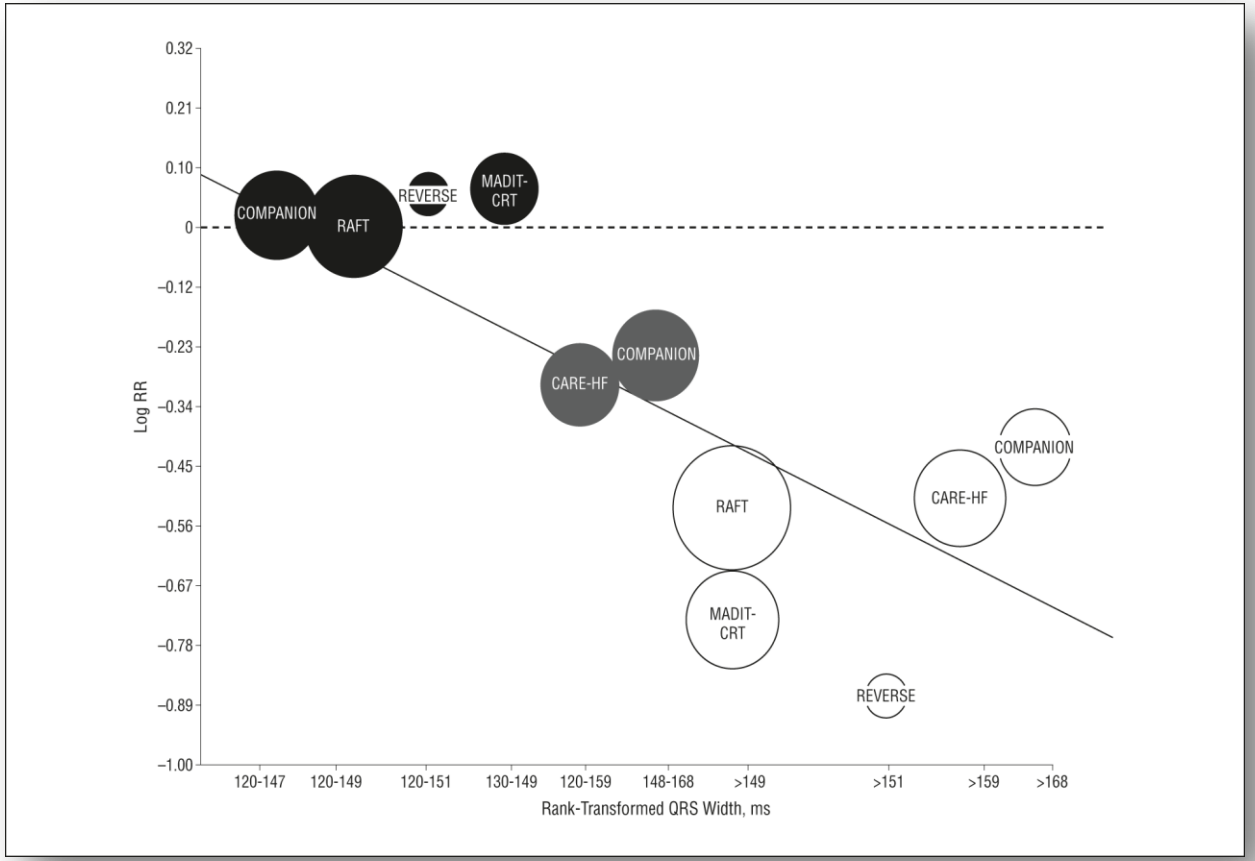
Major Changes in 2012 Update

1. Limitation of Class I indication to patients with QRS_d ≥150 ms.
2. Limitation of Class I indication to patients with LBBB.
3. Expansion of the Class I indication to NYHA class II (and with LBBB with QRS_d ≥150 ms).
4. Addition of a Class IIb recommendation for patients with LVEF ≤30%, ischemic etiology of HF, SR, LBBB with QRS_d ≥150 ms, and NYHA class I symptoms.



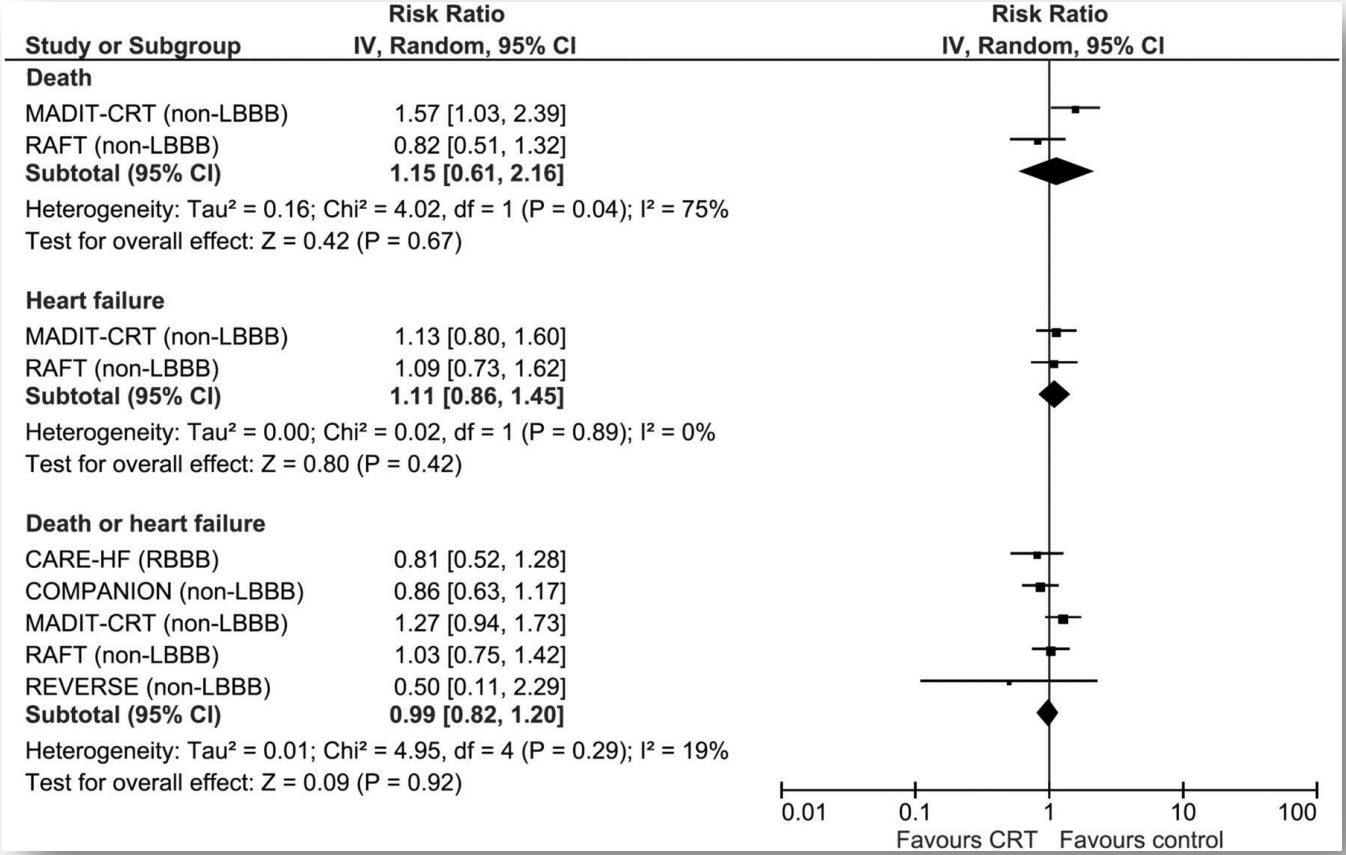
J Am Coll Cardiol. 2014;64(10):1047-1058. doi:10.1016/j.jacc.2014.06.1178

Impact of QRS Duration on Clinical Event Reduction With Cardiac Resynchronization Therapy: Meta-analysis of Randomized Controlled Trials



Arch Intern Med. 2011;171(16):1454-1462.

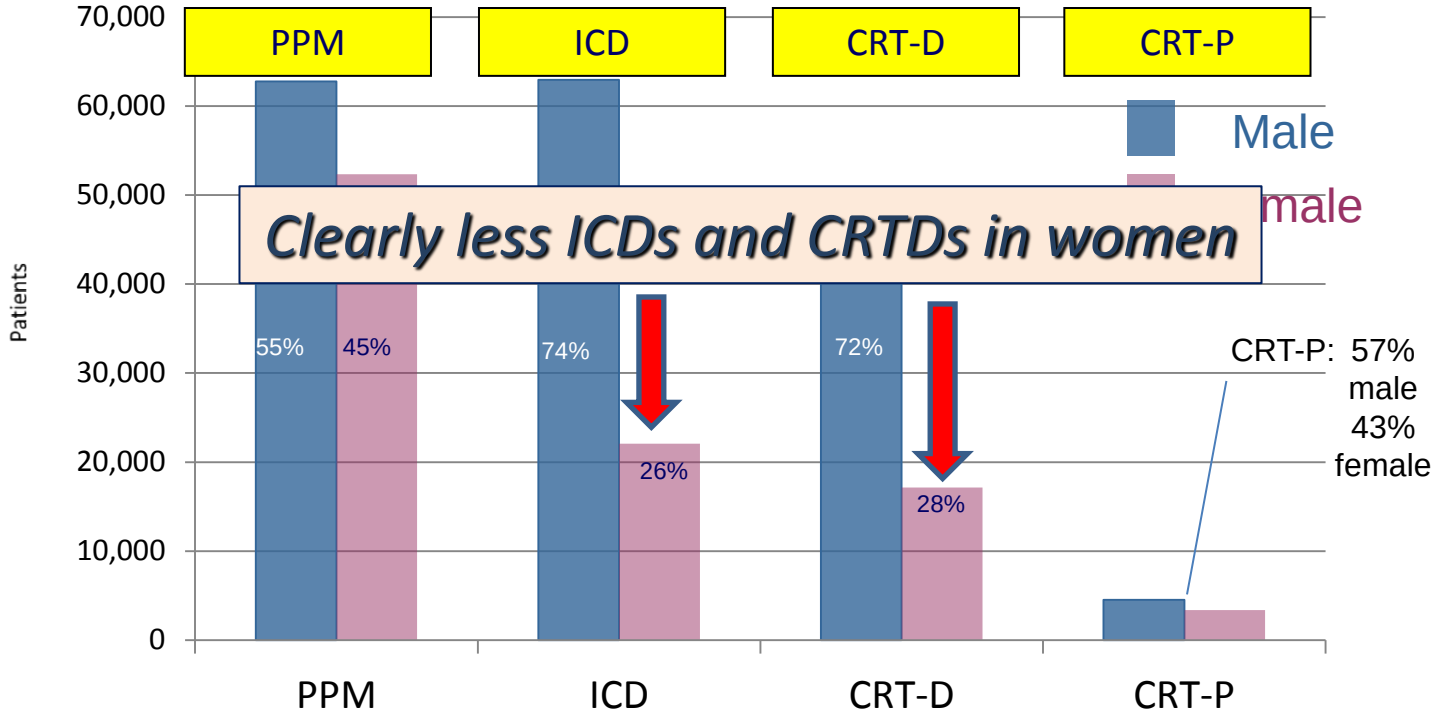
Risk of adverse outcomes among patients with non-LBBB QRS morphology who did/ did not receive CRT



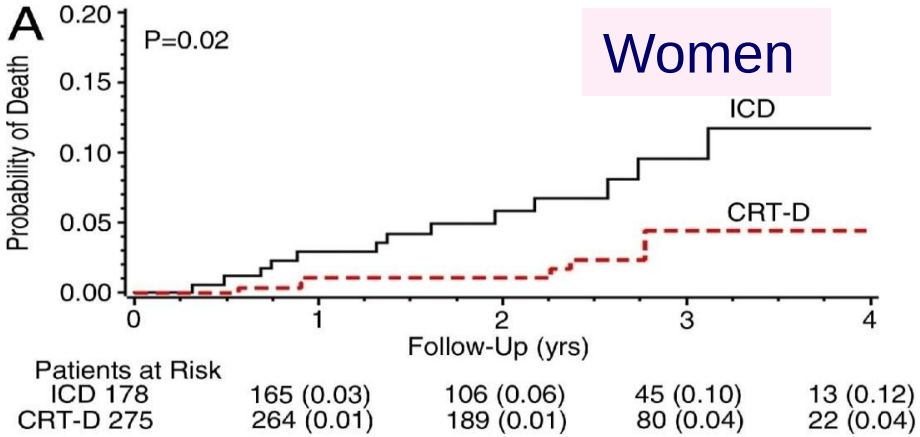
Heart

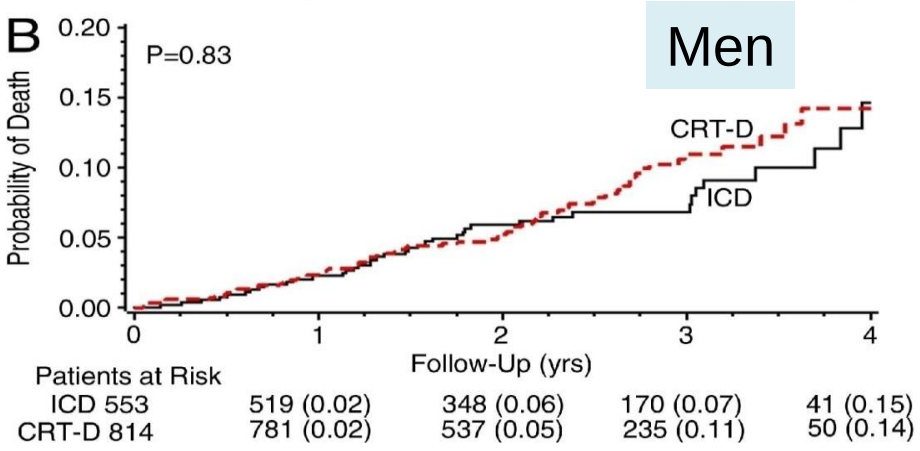
Colin Cunnington et al. Heart 2015;101:1456-1462

Distribution of Device Type



Time to death in women and men in the RCT
MADIT CRT in HF pts in NYHA I-II





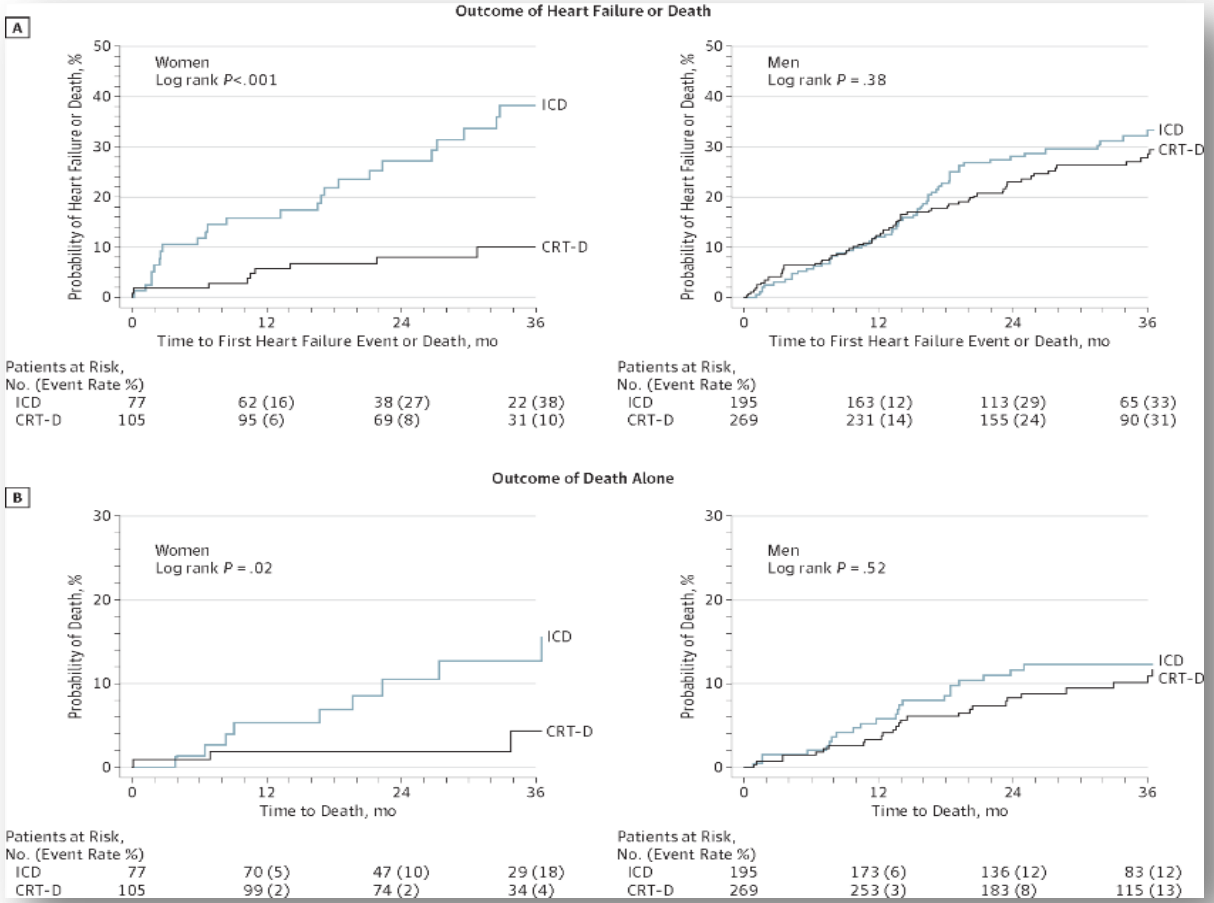
72% relative risk reduction

In men no survival benefit

Arshad A et al , JACC 2011;57:813

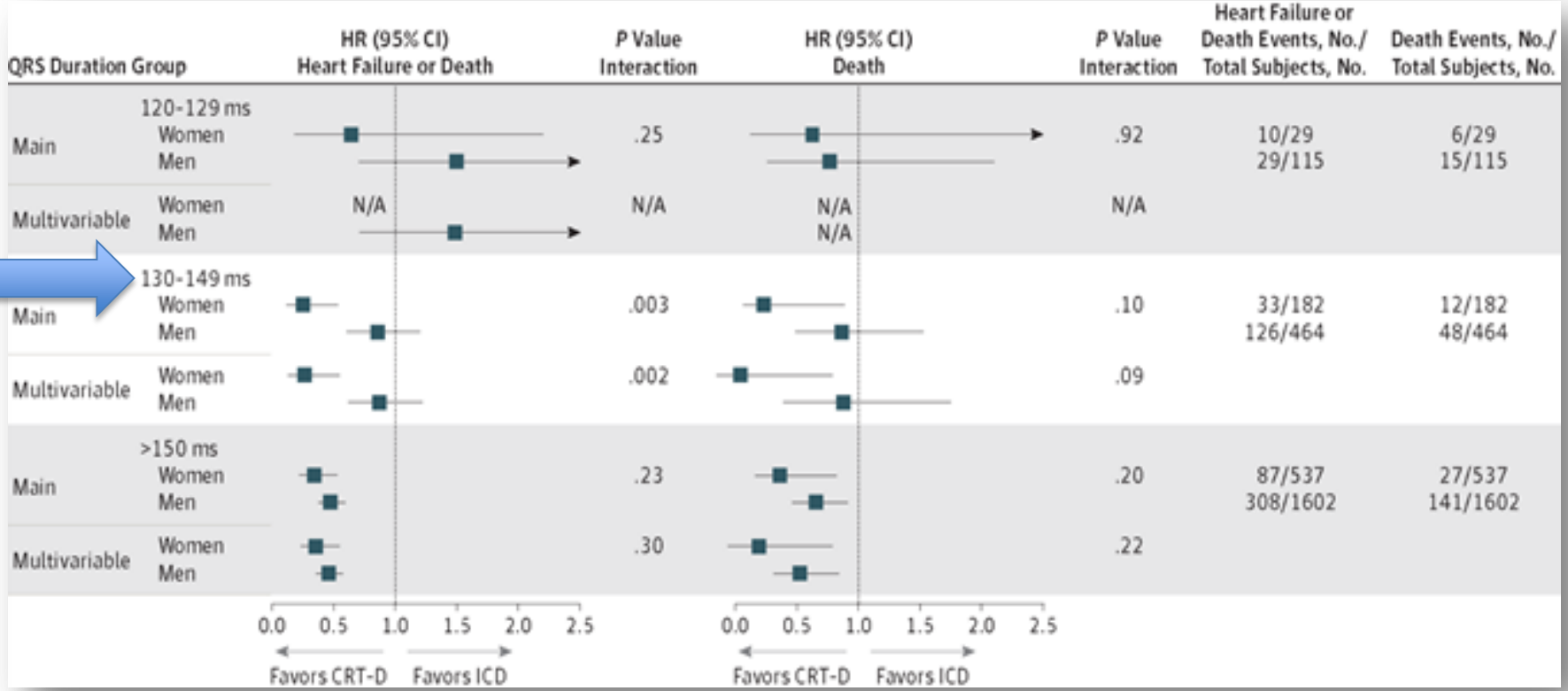
Cardiac Resynchronization Therapy in Women:

US Food and Drug Administration Meta-analysis of Patient-Level Data

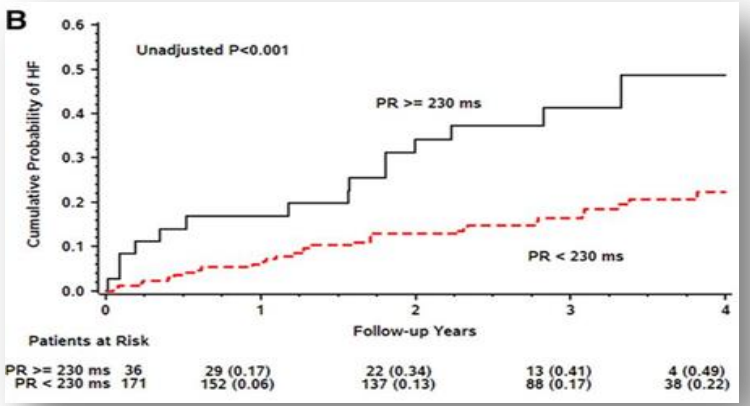


JAMA Intern Med. 2014;174(8):1340-1348

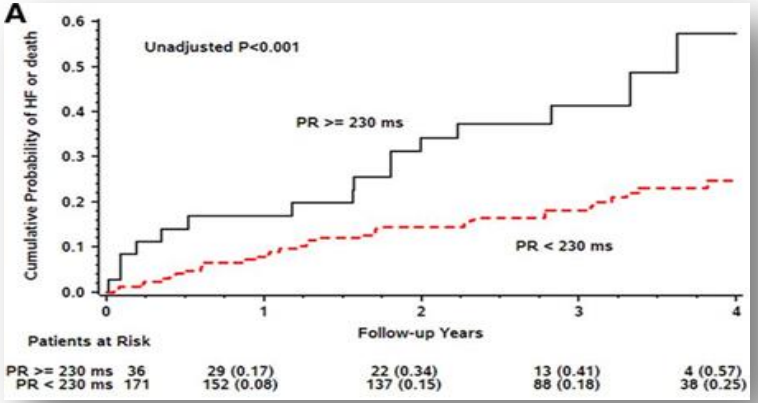
Cardiac Resynchronization Therapy in Women

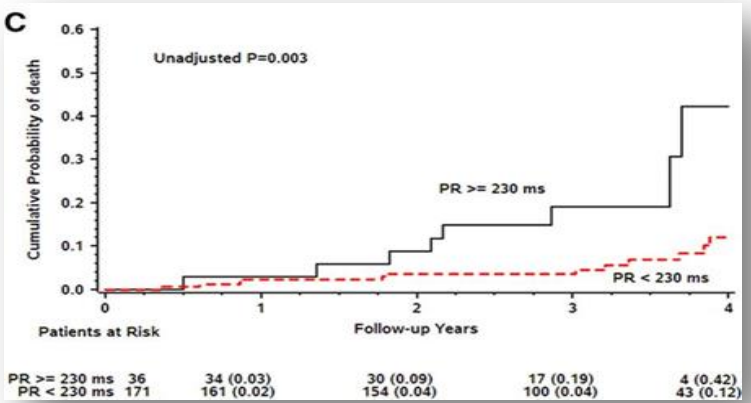


Kaplan–Meier cumulative probability of (A) **heart failure (HF)/death,** (B) **HF only, and** (C) **all-cause mortality in implantable cardioverter defibrillator patients with non–left bundle branch block by baseline PR interval**



Valentina Kutyifa et al. Circ Arrhythm Electrophysiol. 2014;7:645-651





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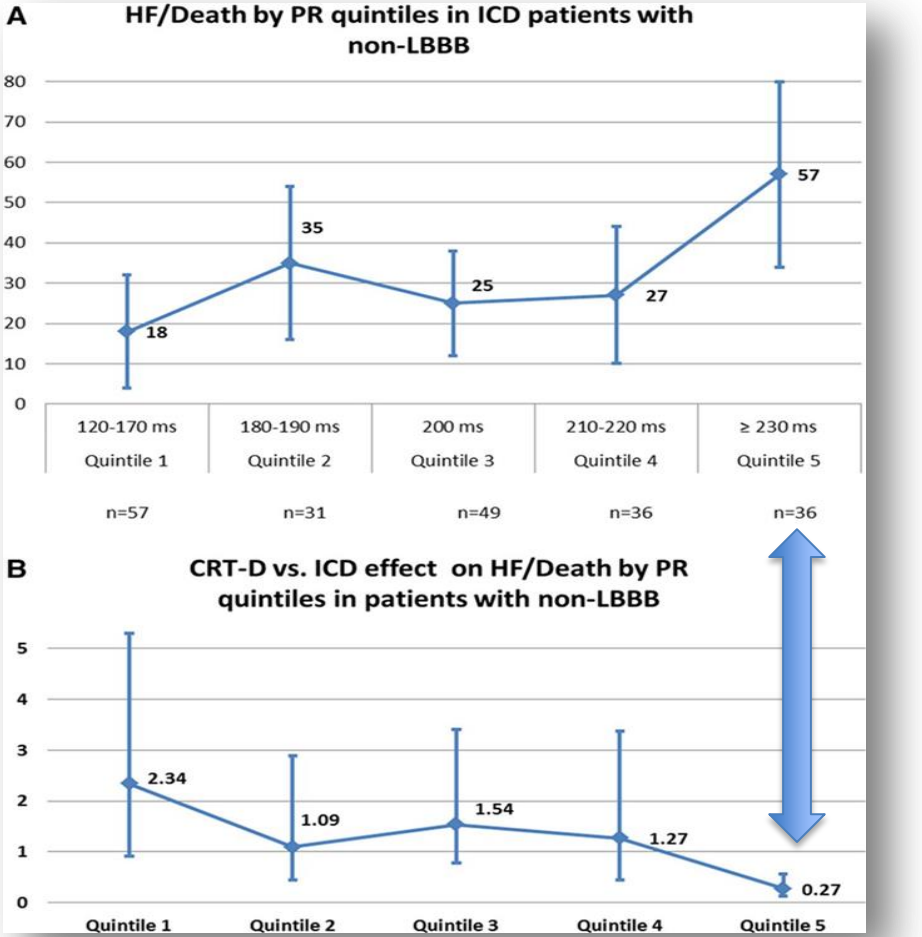
The risk of (A) HF or death in ICD patients and (B) CRT-D vs ICD effect on the risk of HF/death in patients with non–LBBB by PR quintiles



Take Home Messages

- ICDs are underimplanted in the elderly & women
- ICDs should be replaced at time of PG generator change in the majority of patients with persistent SHD/low EF/ICD Rx
- CRT in all patients with LBBB
- CRT in non-LBBB patients with PR prolongation ≥ 230 ms and more data showing benefit in pts with mild HF
- Risk stratification/co-morbidities have not been prospectively tested, but useful for talking to patients