Heart Failure Device Therapy – ICD and CRT

Systolic Dysfunction, Diastolic Dysfunction

Mitral Regurgitation

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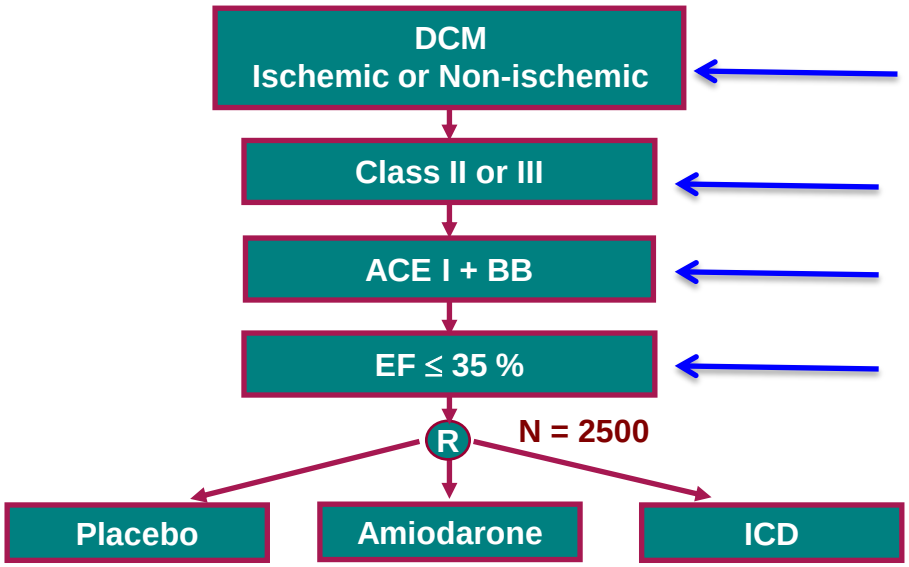
CRT = Cardiac Resynchronization Therapy

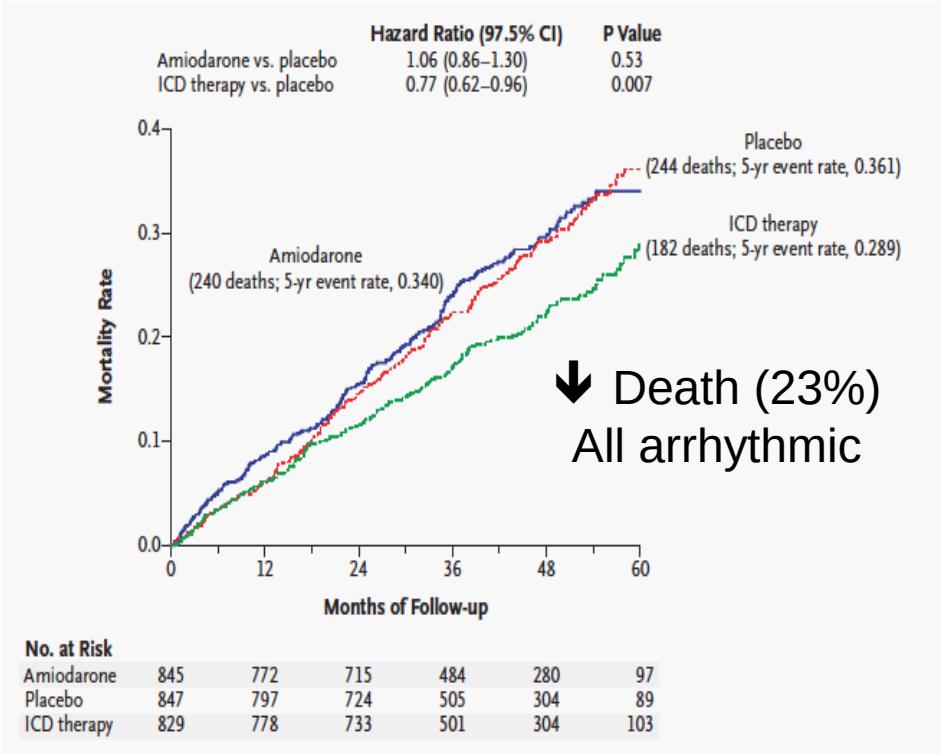
AMERICAN COLLEGE of CARDIOLOGY

Disclosure of Relationships (All Modest)

- *Biotronik: Lecture Honorarium*
- *Boston Scientific: Lecture Honorarium*
- *Medtronic: Lecture Honorarium, Advisory panel*
- *St. Jude Medical: Lecture Honorarium, Advisory Panel*

SCD-HeFT Trial and Impact on Use of ICD in Class II/III Heart Failure





Class

I IIa IIb III

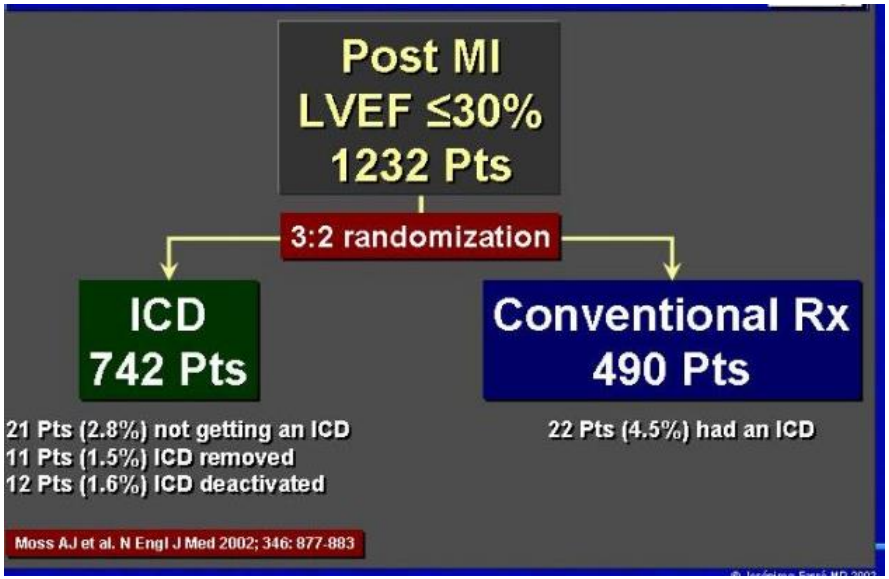
A

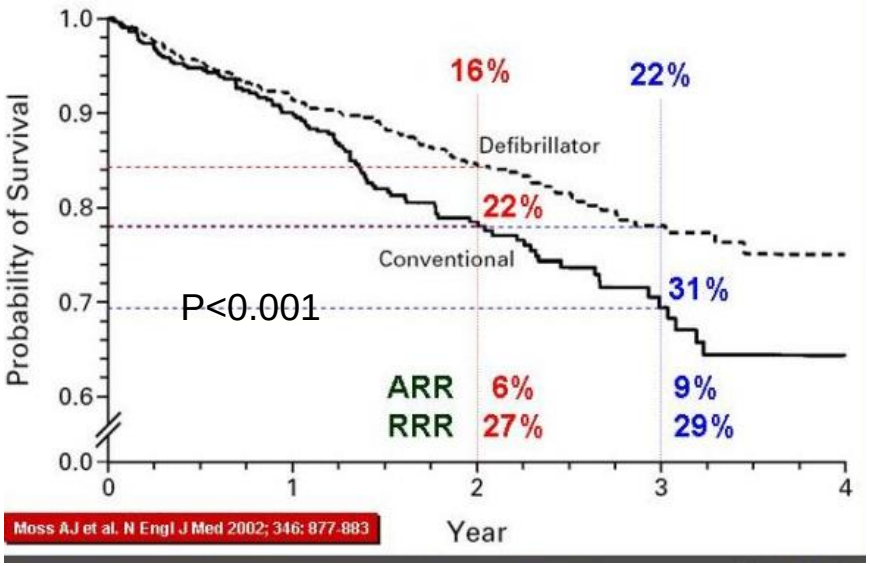
ICD therapy is recommended for primary prevention of SCD in patients with nonischemic or ischemic heart disease (at least 40 days post-MI) with EF ≤ 35%, and NYHA class II or III on GDMT, who have anticipated survival for more than 1 year (Level of Evidence A)

Bardy et al NEJM 2005

NYHA ≥ Class 1 - Post MI, EF ≤ 30%

MADIT II





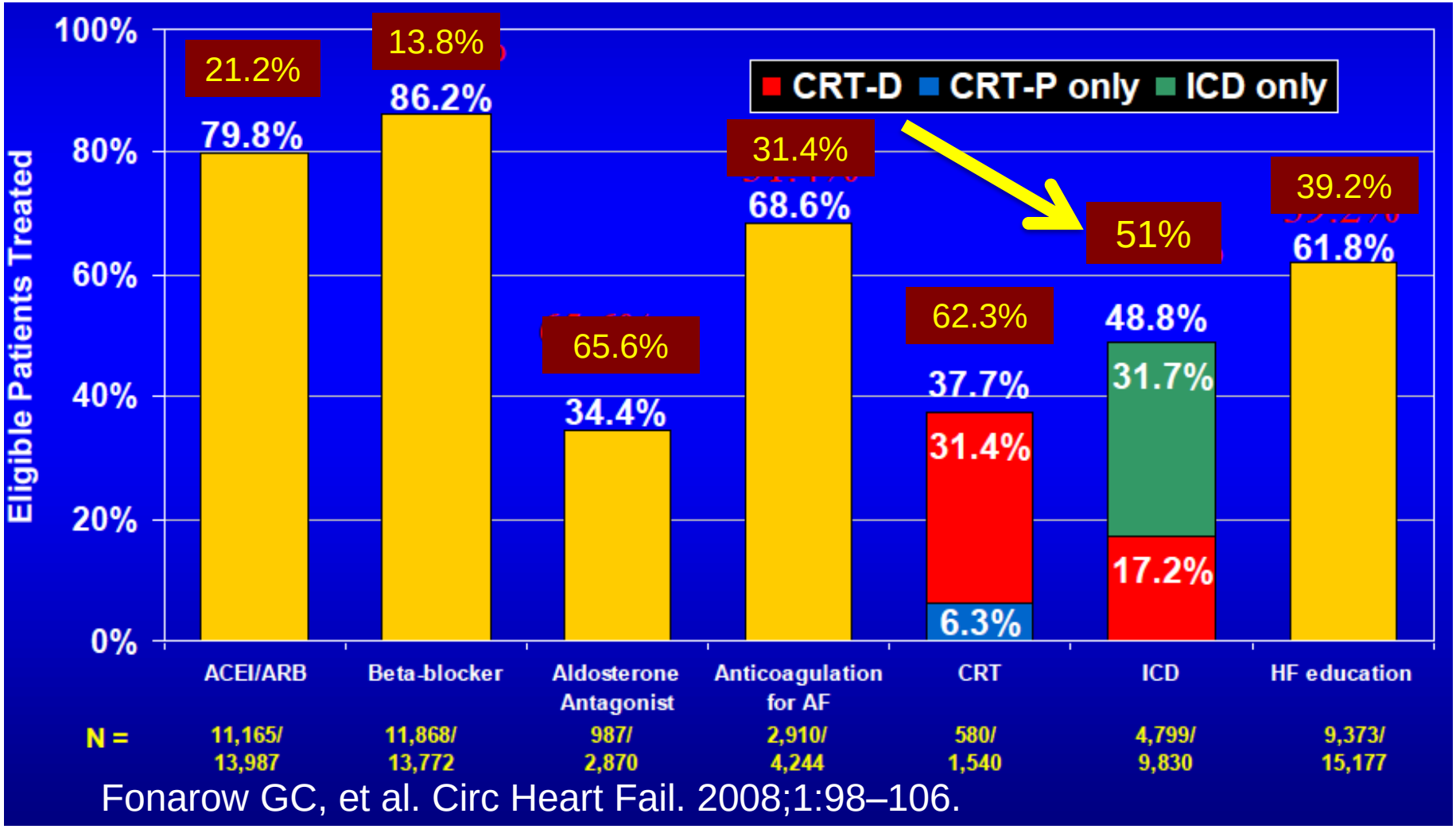
Class

I IIa IIb III

B

ICD therapy is recommended for primary prevention of SCD to reduce total mortality in selected patients at least 40 days post-MI with LVEF ≤ 30%, and NYHA class I symptoms while receiving GDMT..

Failure to conform to baseline quality HF measures



Fonarow GC, et al. Circ Heart Fail. 2008;1:98–106.

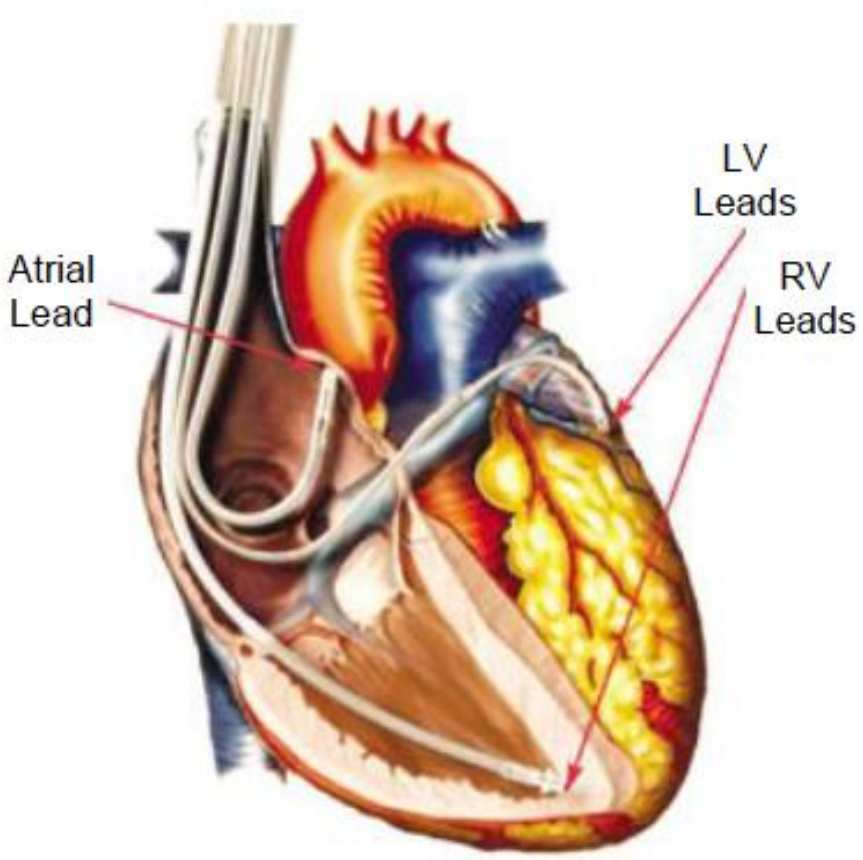
*Underutilization more common in women 79% vs 52% (Hoang et al Heart Rhythm 2014;11:849-55)

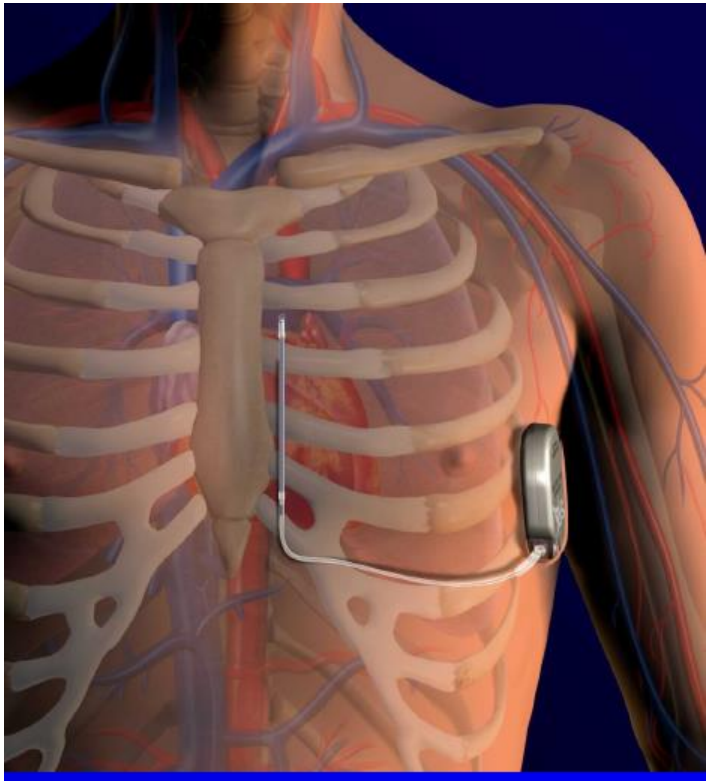
** Underutilization more common in hospitals with underutilization of other guidelines (Shah et al JACC 2009;53:416-22)

Reasons for Not Recommending ICD/CRT

- Questionable?
  - Not aware of the guidelines or data that support it.
  - Patient is too sick when seen in hospital and too well in the office (Class 2 patients with most benefit!!!)
- Legitimate concerns?
  - Don't like implanting ICD in patients who never need it (need better selection criteria)
  - **Too many device related complications!**
    Lead fracture
    Infection
    Inappropriate shocks

Standard (Intravascular Leads) vs SQ ICD





+++ Brady/ Anti Tachy/ Bi V Pacing

\- - - Lead related complications (Failures/Infection/thrombus)

+ + + No intravascular leads

\- - - No Brady/Anti-Tachy/ Bi V Pacing

\- - Longevity/Bigger device

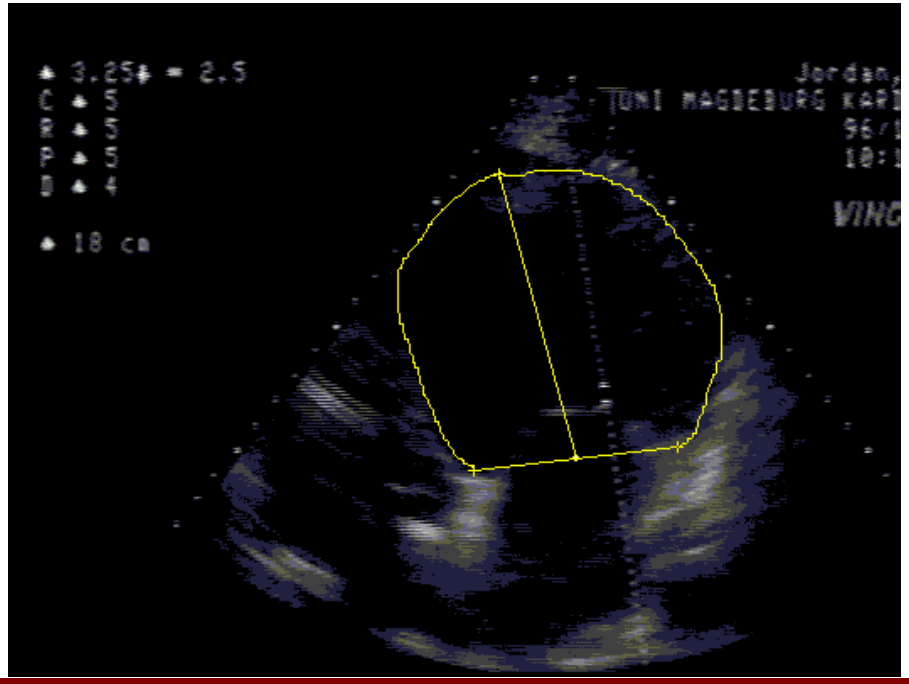
? Role in primary prevention in HF pt

CRT Therapy for Heart Failure – 15 yr Journey

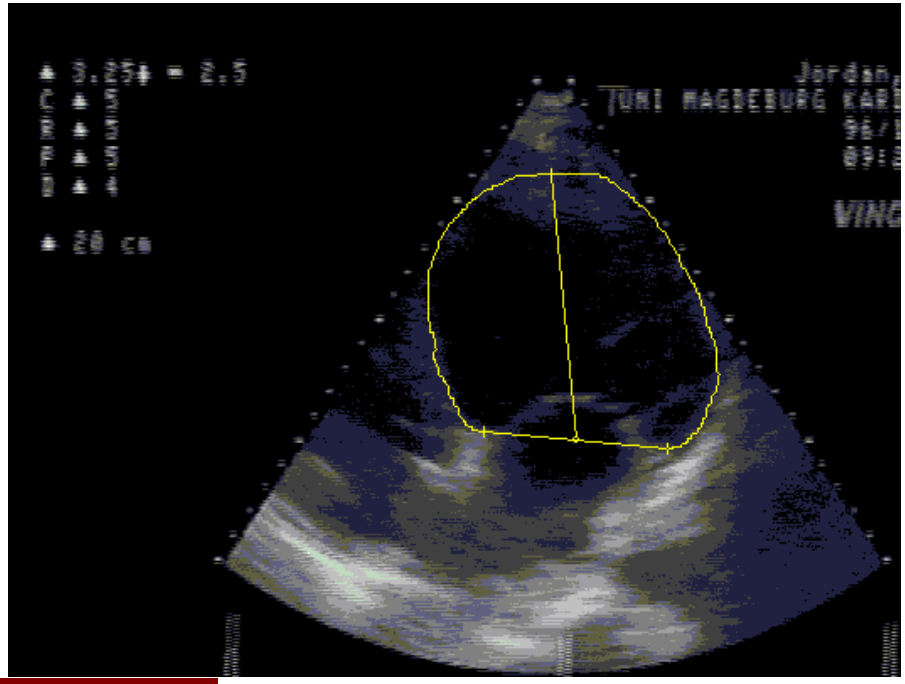
- Initial “feasibility” studies, looking at LV mechanics/mitral regurgitation
- Demonstration of anatomic, CHF hospitalization, and mortality benefit (Guidelines) (COMPANION, CARE-HF, MADIT CRT)
- ***Current studies –*** New Indications (RethinQ, BLOCK HF/Biopace)
- ***Late Outcome studies/Identifying who will respond and how to optimize response***

Biventricular pacing – Cardiac Resynchronization (CRT)

Severe LV dysfunction with LBBB



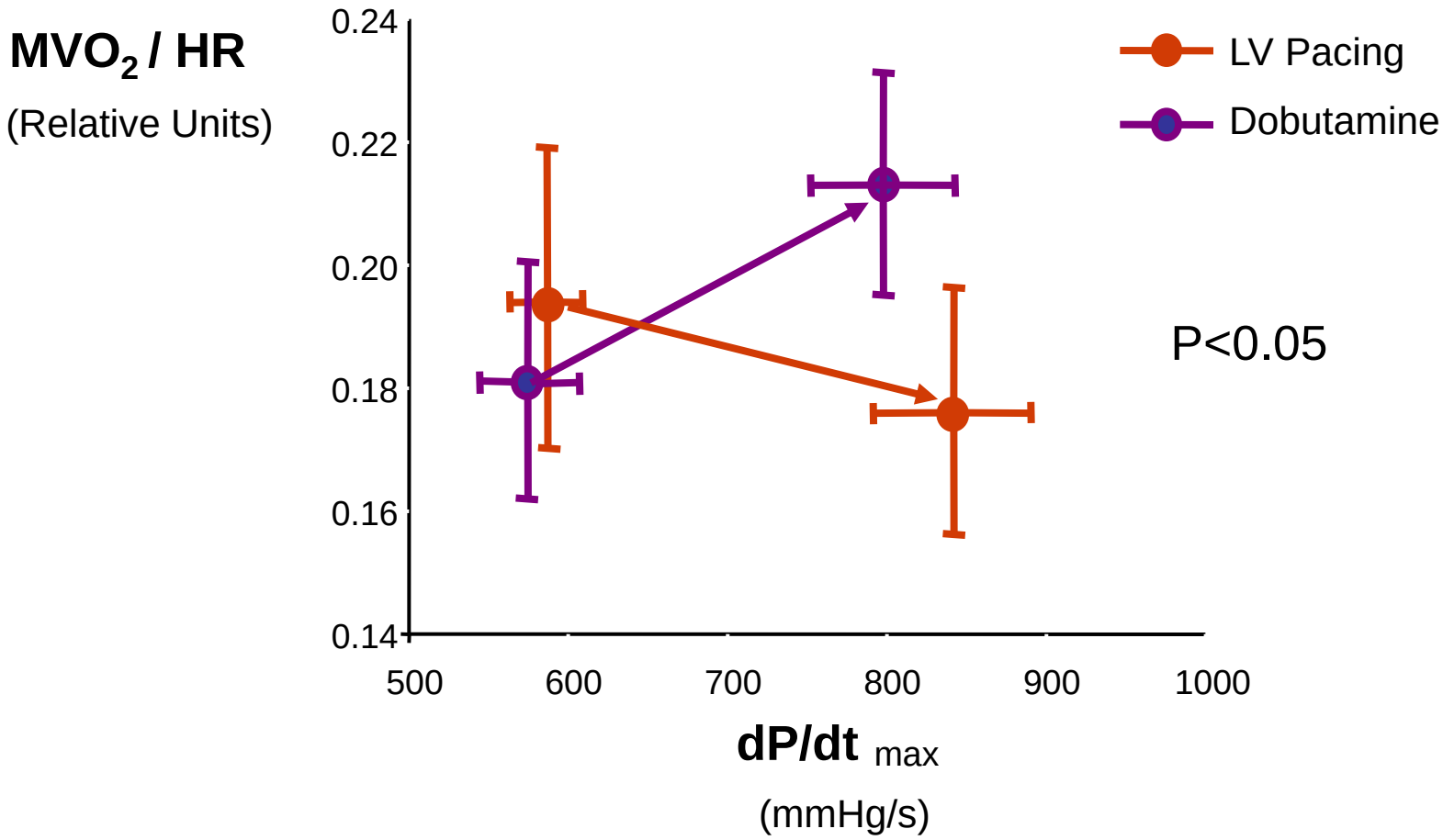
DCM - CRT



- Increases diastolic filling time
- Improves LV dP/dt

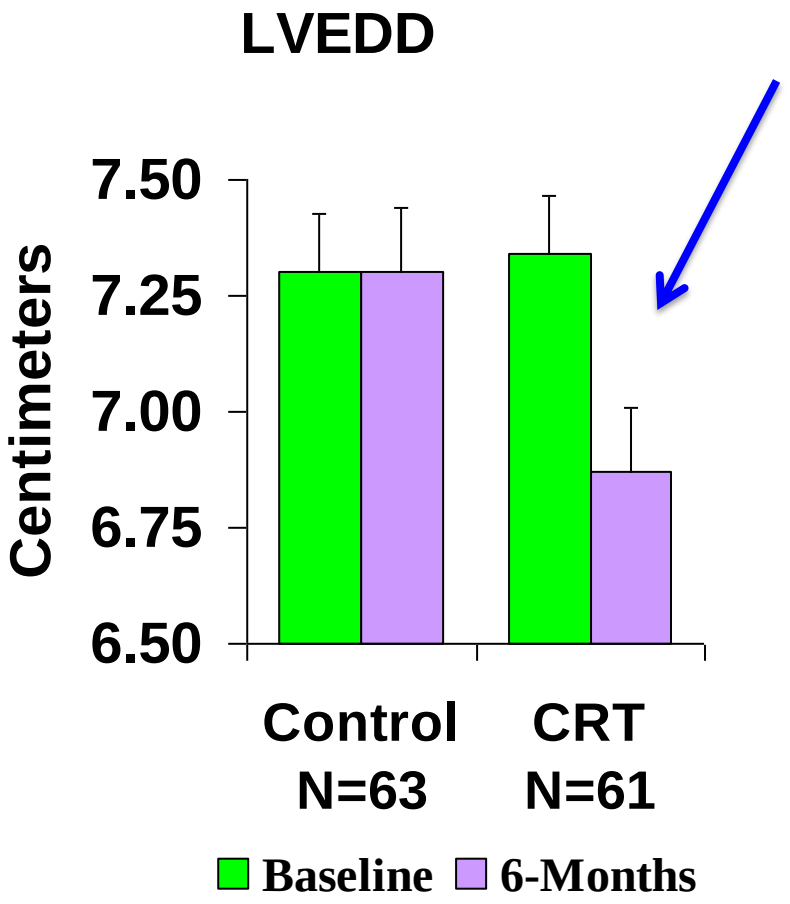
Courtesy of C. Stellbrink, MD.

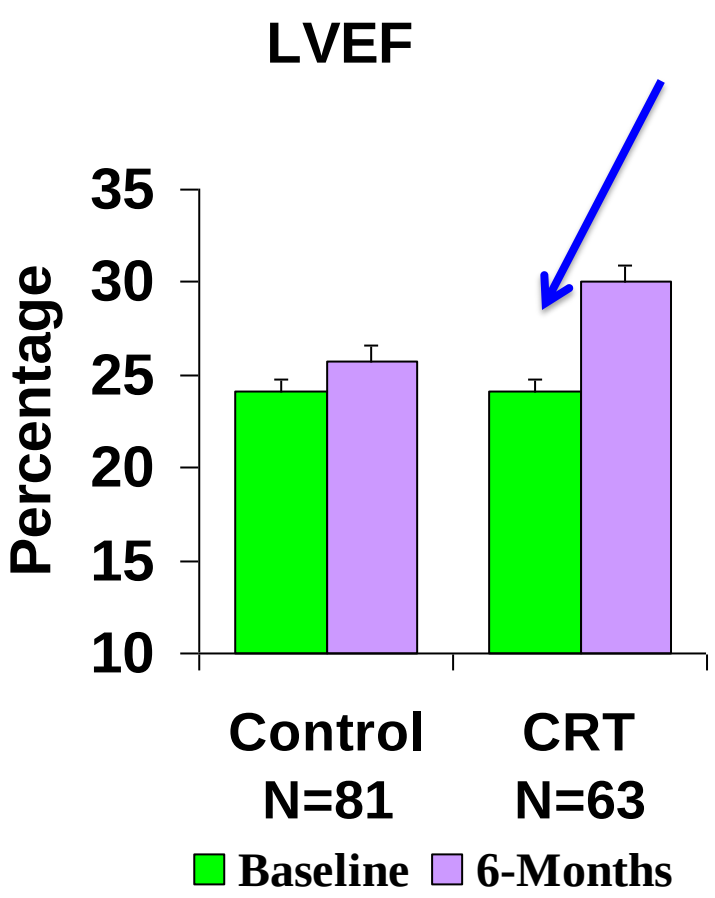
Metabolic “cost” of biventricular pacing



Nelson GS,: *Circulation*. 2000;102:3057.

CRT Effect on Echo - LV size and EF





Sutton M: Circulation 2002

Effect of CRT(biventricular pacing) on MR

LA-LV resynchronization

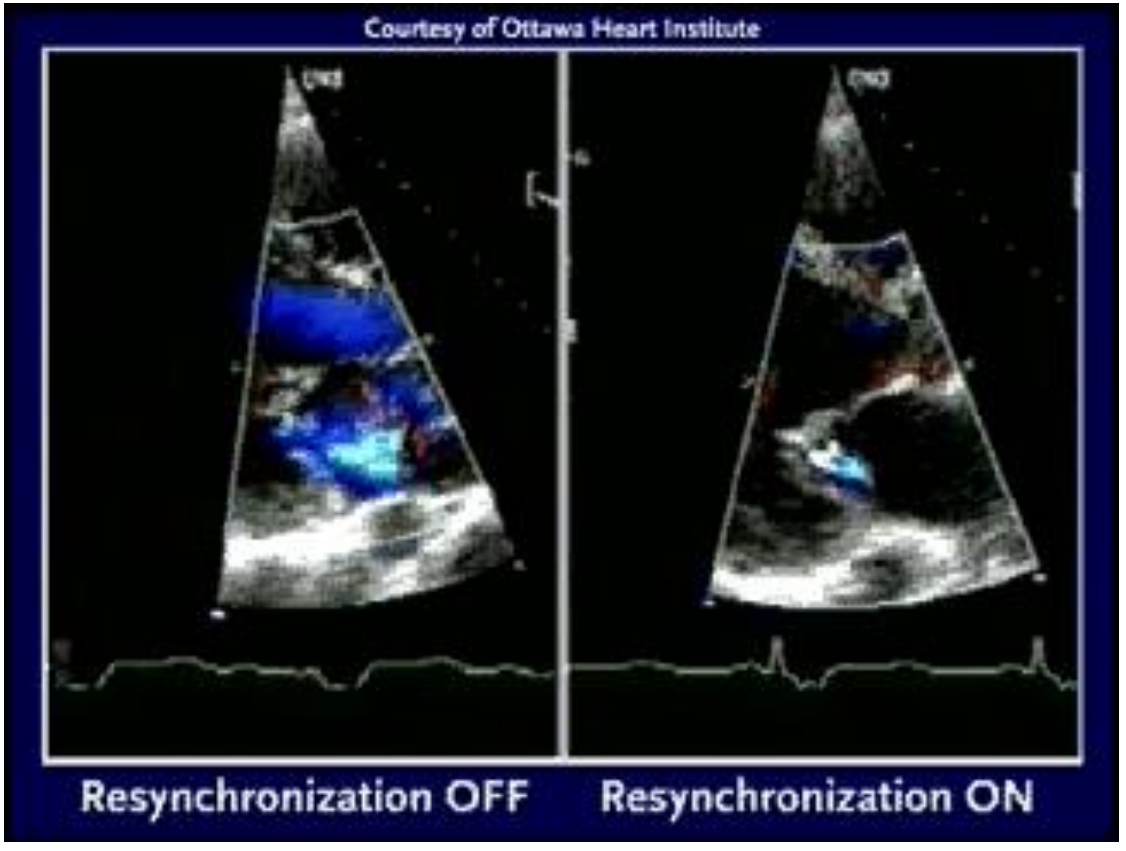
- Reduces mitral regurgitation[1,2,3]

-Restores synchronous activation of pap muscles

-Decrease in LV size

•MR - common in CRT HF patient (35% with grade 3-4 MR)
• Reduction of MR was observed in 46% of subjects (> 1 grade)
• Improvement in MR was associated with better CRT functional response

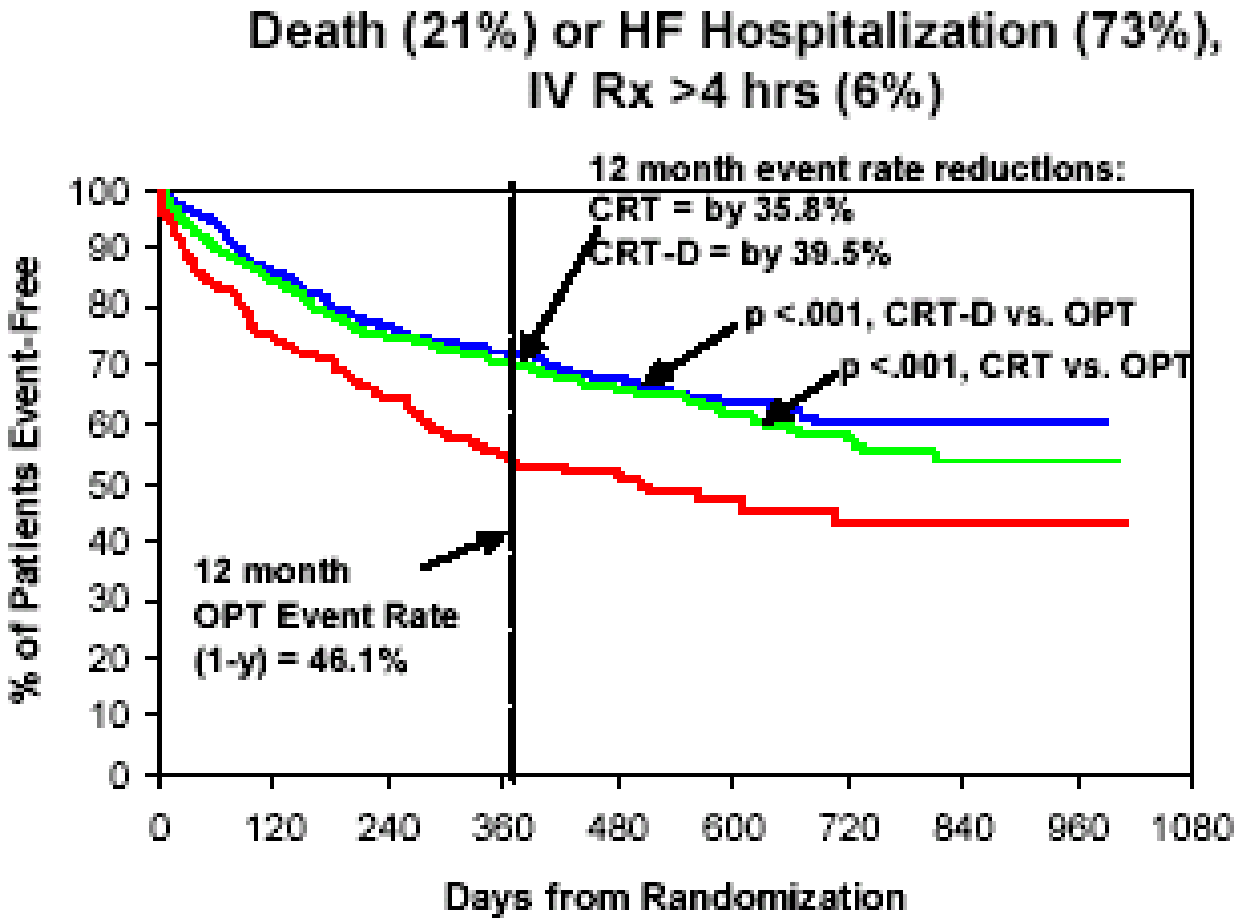
Di Biase et al Europace 2011; 13:829-838



[1] Nishimura et al. J Am Coll Cardiol. 1995; 25:281.
[3] Brecker et al. Lancet. 1992;340:1308.

Companion trial: Mortality/HF Hospitalization

1520 pts randomized 1:2:2 to optimal CHF therapy: OPT + biV PM: OPT + biV ICD

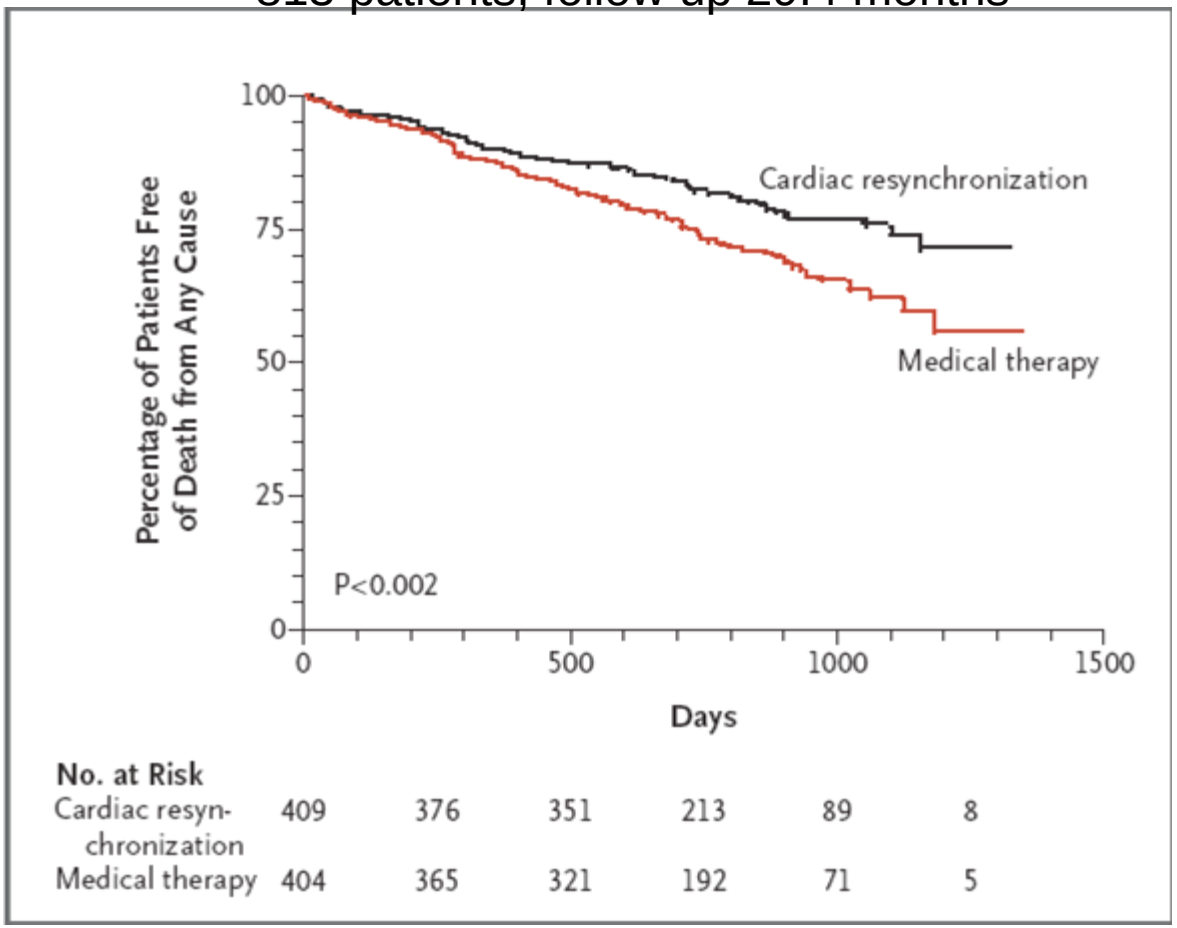


Inclusion:
NYHA class III or IV
LVEF ≤ 35%
QRS ≥120
LVEDD ≥ 60 mm

Bristow M: N Engl J Med ;350:2140-50.2004

CARE-HF: All cause mortality

813 patients, follow up 29.4 months



Inclusion:
NYHA class III or IV
LVEF ≤ 35%
QRS ≥120

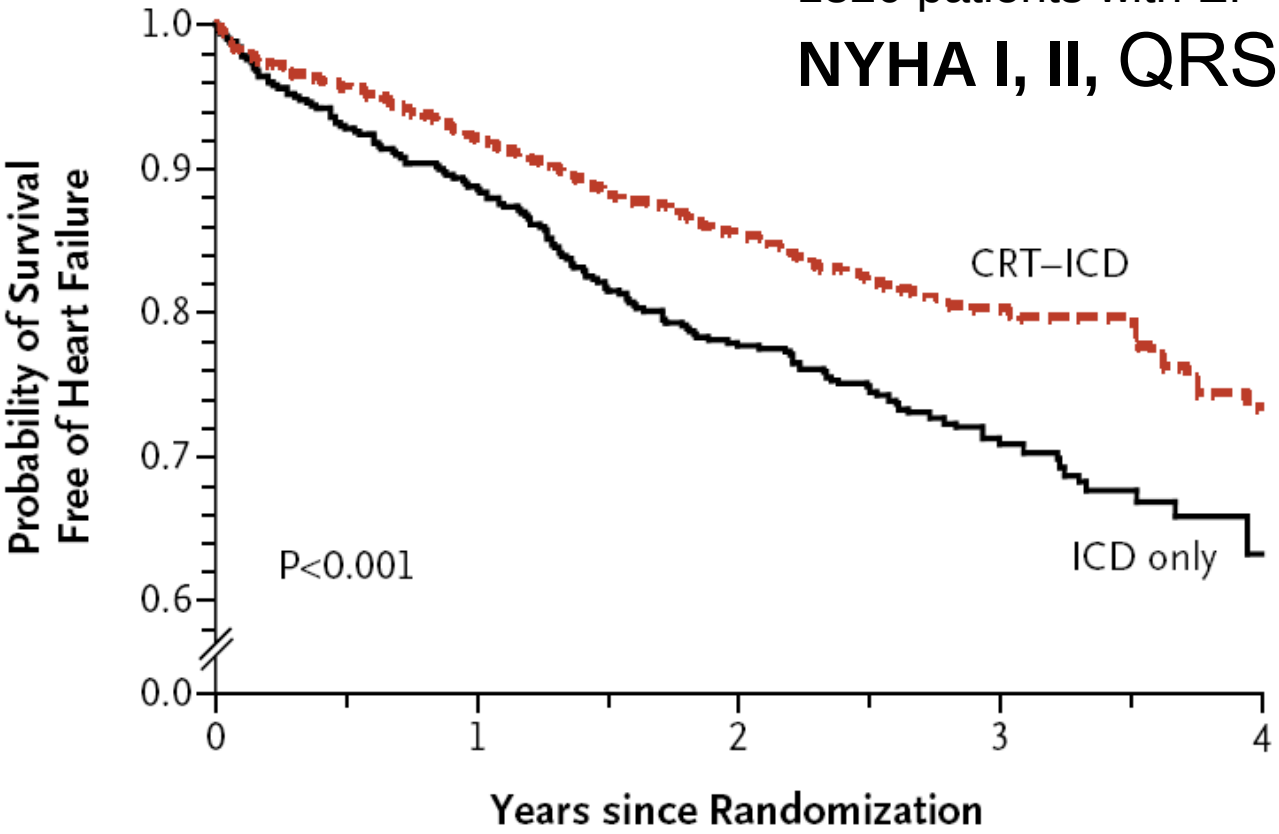
CRT therapy resulted in 36% reduction in total mortality (80 vs.120)

Cleland JGF: N Engl J Med 2005;352:1539-49

MADIT – CRT (HF Events-ICD vs CRT ICD)

1820 patients with EF ≤ 30,

NYHA I, II, QRS ≥ 130



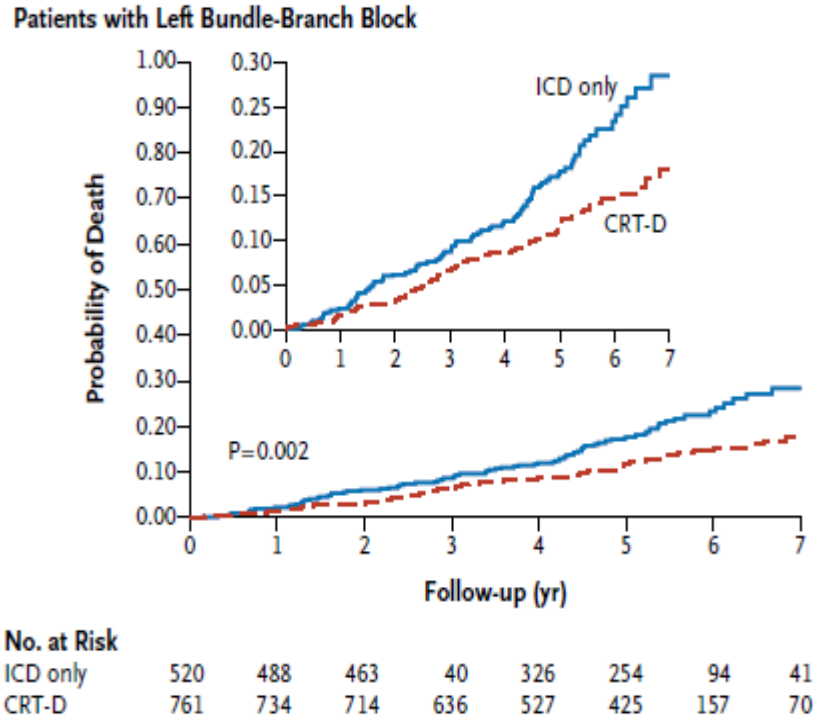
41% reduction of heart failure events

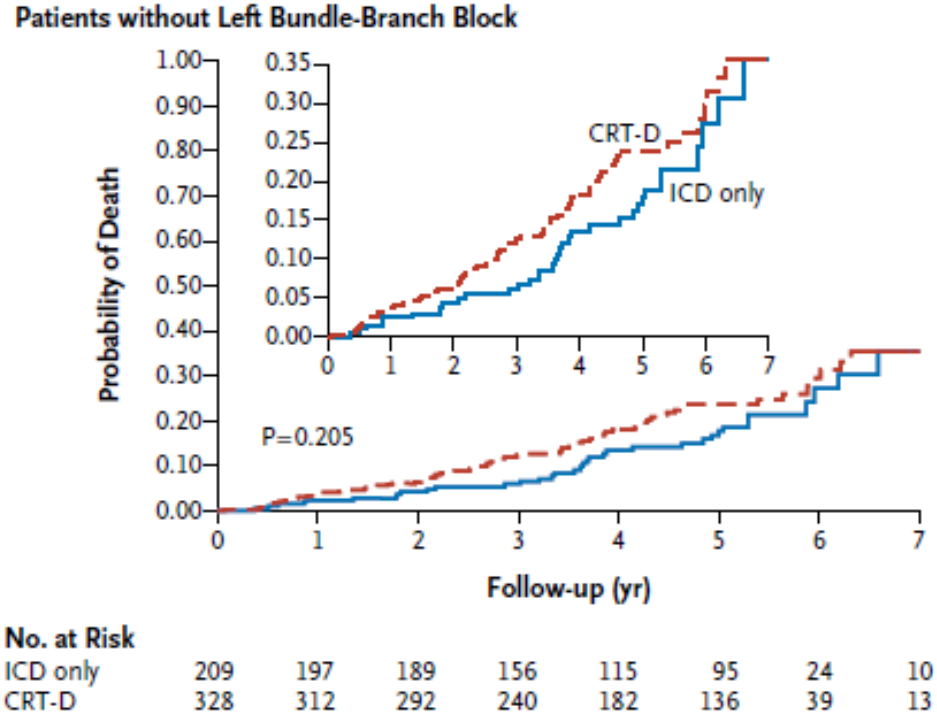
No. at Risk (Probability of Survival)

ICD only	731	621 (0.89)	379 (0.78)	173 (0.71)	43 (0.63)
CRT–ICD	1089	985 (0.92)	651 (0.86)	279 (0.80)	58 (0.73)

Moss et al. *N Engl J Med* 2009:361:1329-1338.

Long Term Mortality in MADIT-CRT (5year) – Influence of LBBB





LBBB

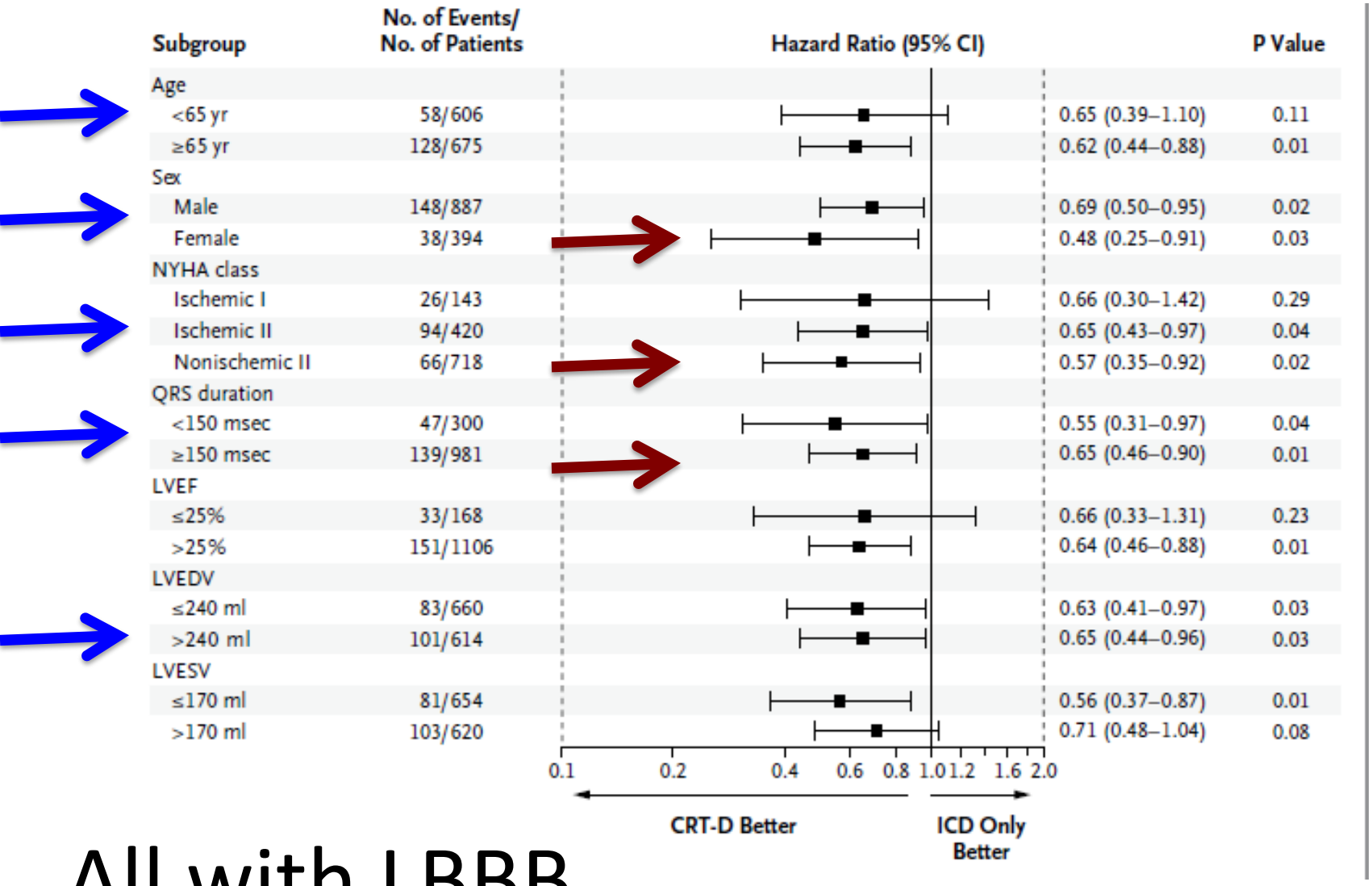
1 V1 V6

Loss of septal Q

No LBBB (IVCD, RBBB)

Goldenberg et al.NEJM 2014;370:1694-1701

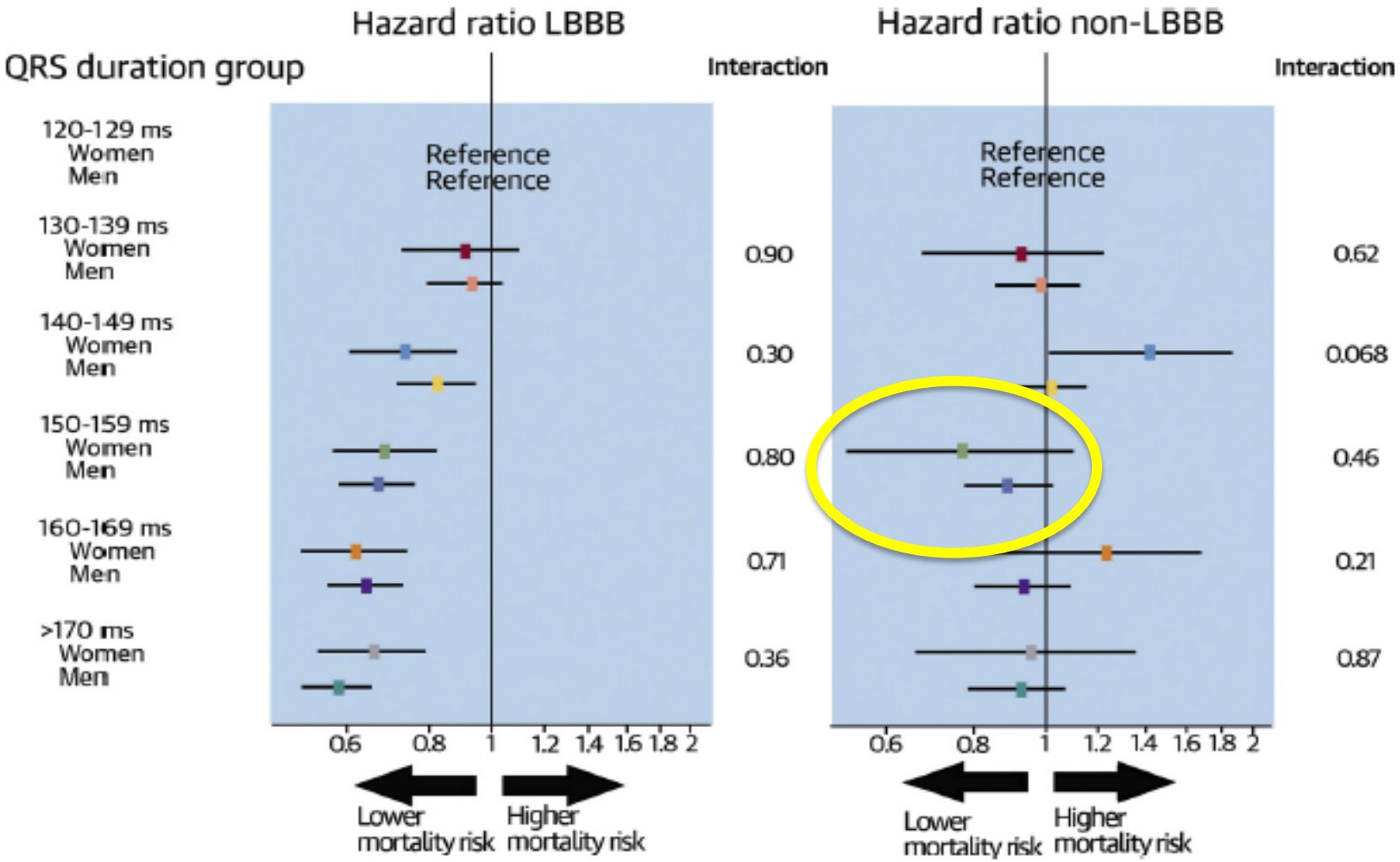
Long Term (5yr) Outcome (Survival) in MADIT-CRT – All patient groups benefit



All with LBBB

Goldenberg et al.NEJM 2014;370:1694-1701

Mortality after CRT-D implantation by sex, QRS morphology, and duration. NCDR ICD Registry 31892 patients (median 2.9 yrs fu)



If LBBB, women had 21% lower mortality risk than men
(HR: 0.79; 95% CI: 0.74 to 0.84; p < 0.001

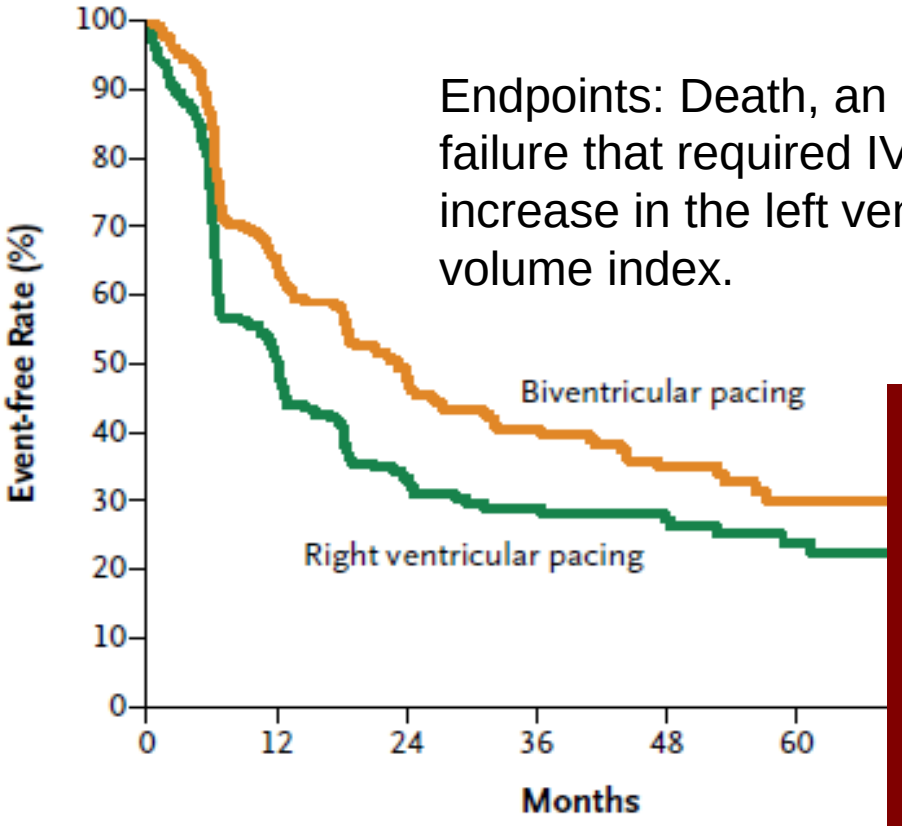
Zusterzeel R et al J Am Coll Cardiol 2014;64:887–94)

If LBBB is Bad – How about if we need to RV pace- CRT? In less sick patients?

BLOCK HF trial (691 patients with AV block)

AV block / EF 50% or less (average 40%)

Endpoints: Death, an urgent care visit for heart failure that required IV therapy, or a 15% or more increase in the left ventricular end-systolic volume index.



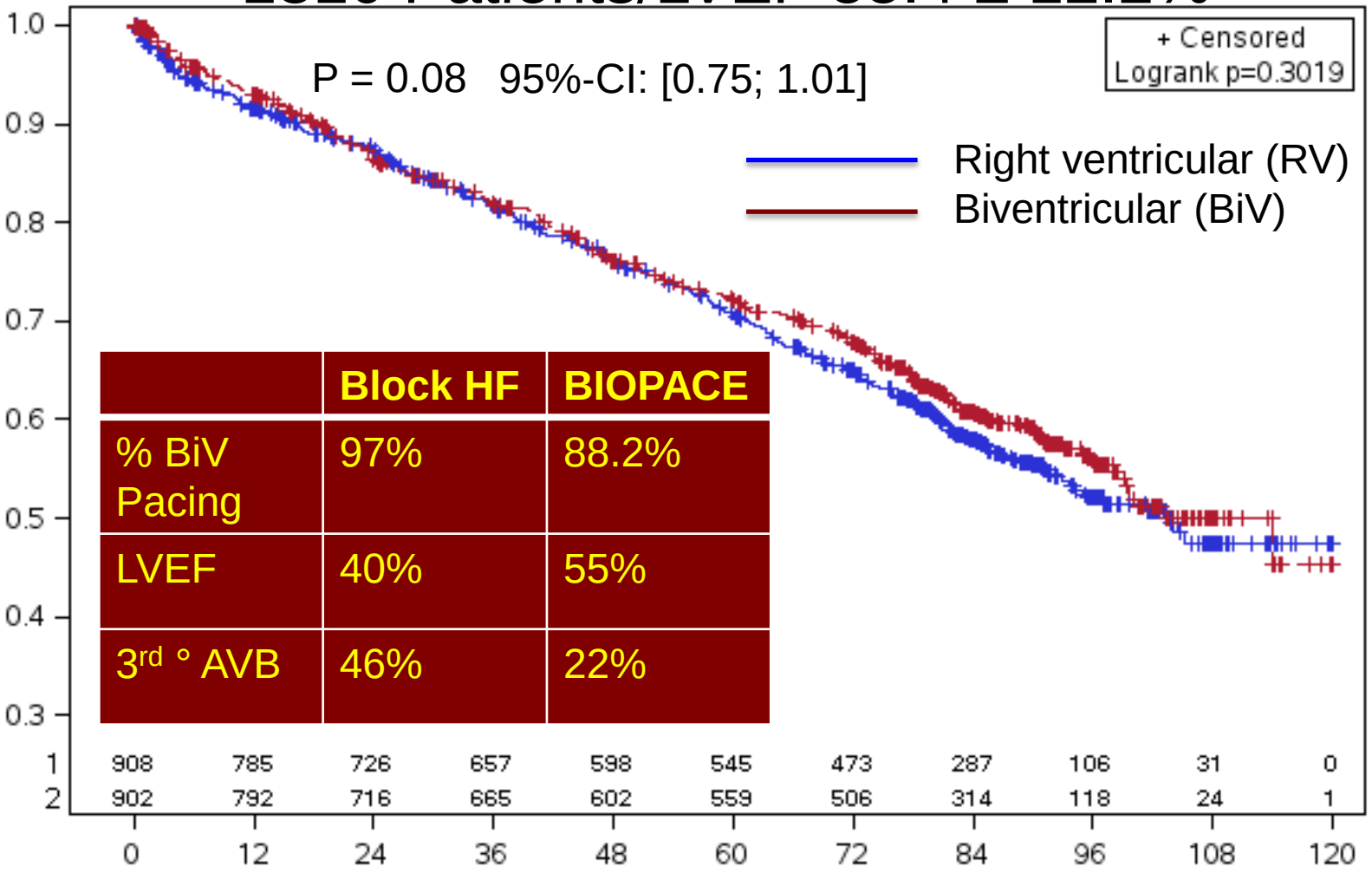
No. at Risk							
Biventricular pacing	349	161	87	62	38	17	3
Right ventricular pacing	342	126	59	39	28	18	10

Primary outcome occurred in 64.3 (RV pacing) and 55.3% (BiV pacing) pts; hazard ratio for BiV 0.74; 0.60 to 0.90.

Curtis A: N Engl J Med 2013;368:1585-93

Freedom from Mortality /CHF Hospitalization

1810 Patients/LVEF 55.4 ± 12.2%



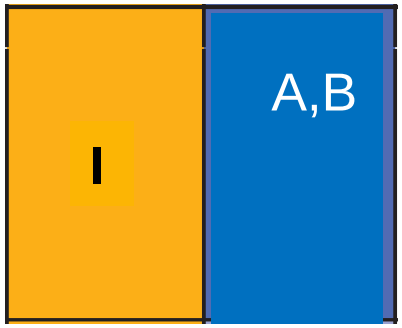
	Block HF	BIOPACE
% BiV Pacing	97%	88.2%
LVEF	40%	55%
3rd ° AVB	46%	22%

BIOPACE TRIAL PRELIMINARY RESULTS – ESC Presentation 2014

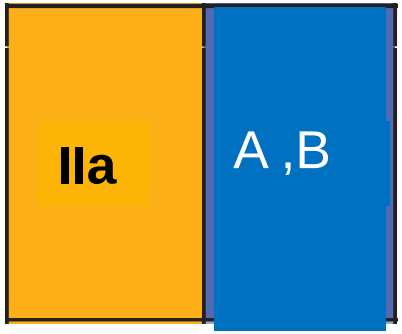
CRT: Guidelines

ACCF/AHA/HRS
Focused Update of 2008 DBT Guidelines
Tracy C et al JACC 2012;60:1297-1313

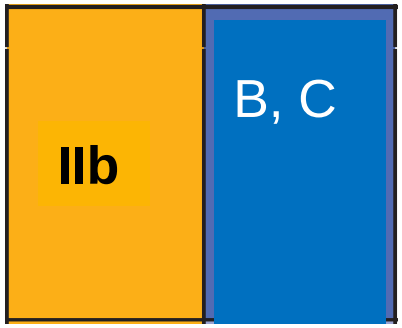
EF ≤ 35, NSR, LBBB,
QRS ≥ 150, class II, III, ambulatory IV HF on GDMT



EF ≤ 35, class II, III, IV HF
and one of the following:
1)LBBB and QRS 120-149;
2)AF or Heart Block with RV pacing > 40%;
3)non LBBB QRS ≥ 150, class III,IV



EF≤ 30, class I; LBBB>150 (MADIT CRT);
EF ≤ 35, non LBBB (QRS 120- 150, Class III/IV; and EF ≤ 35, non LBBB QRS ≥ 150, class II HF



CRT: Guidelines

ACCF/AHA/HRS
Focused Update of 2008 DBT Guidelines
Tracy C et al JACC 2012;60:1297-1313

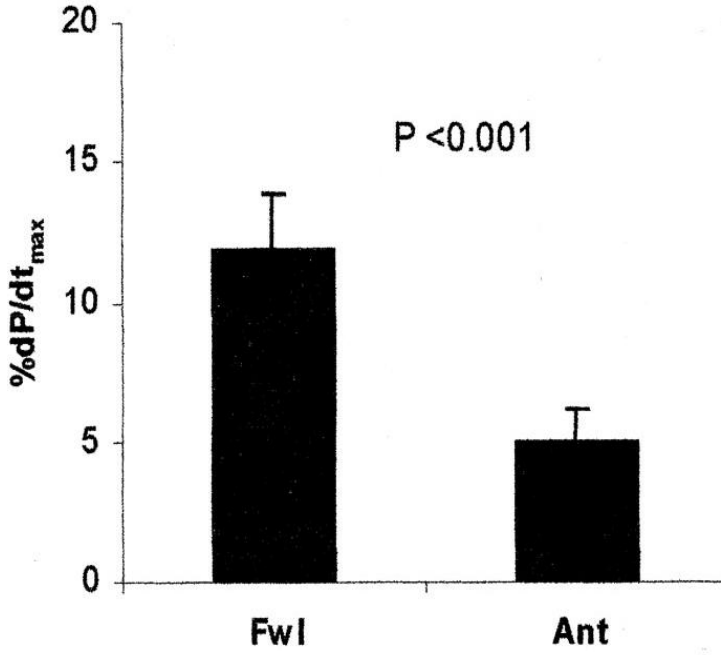
CRT is not recommended for patients with NYHA class I or II symptoms and non-LBBB pattern with QRS duration less than 150 ms.

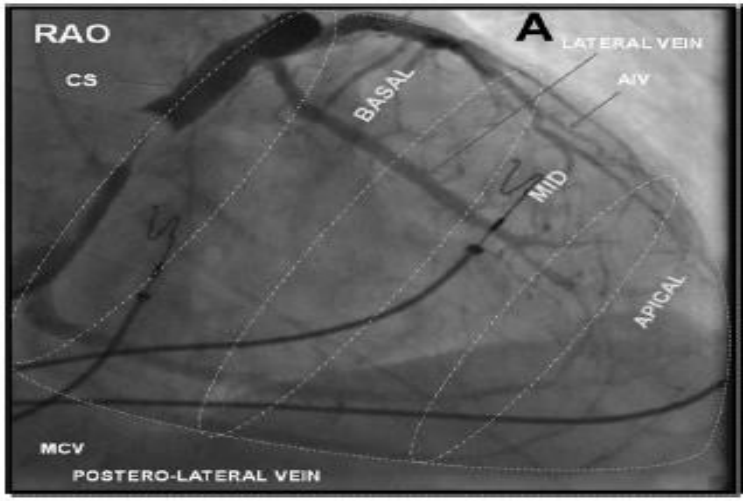
CRT is not indicated for patients whose comorbidities and/or frailty limit survival with good functional capacity to less than 1 year.

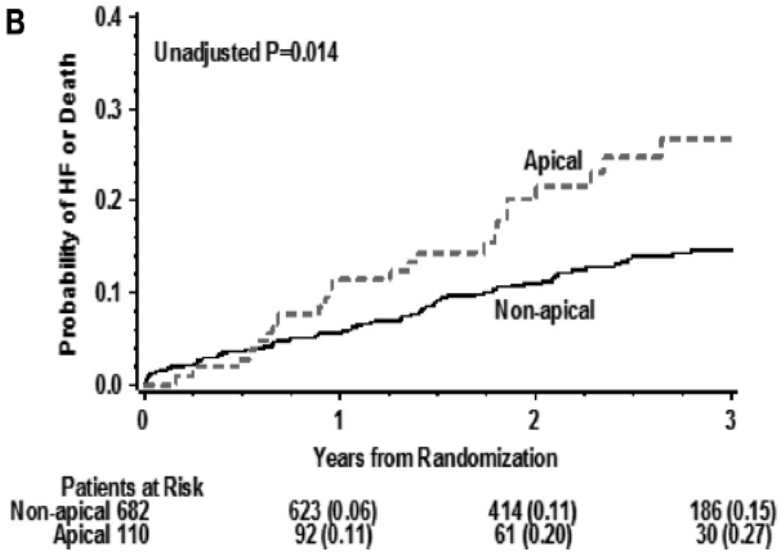
Important Questions?

- Why doesn’t a patient respond to CRT therapy?
- What can you do about it?

Lead placement: part of failure to respond – anatomy and operator dependent



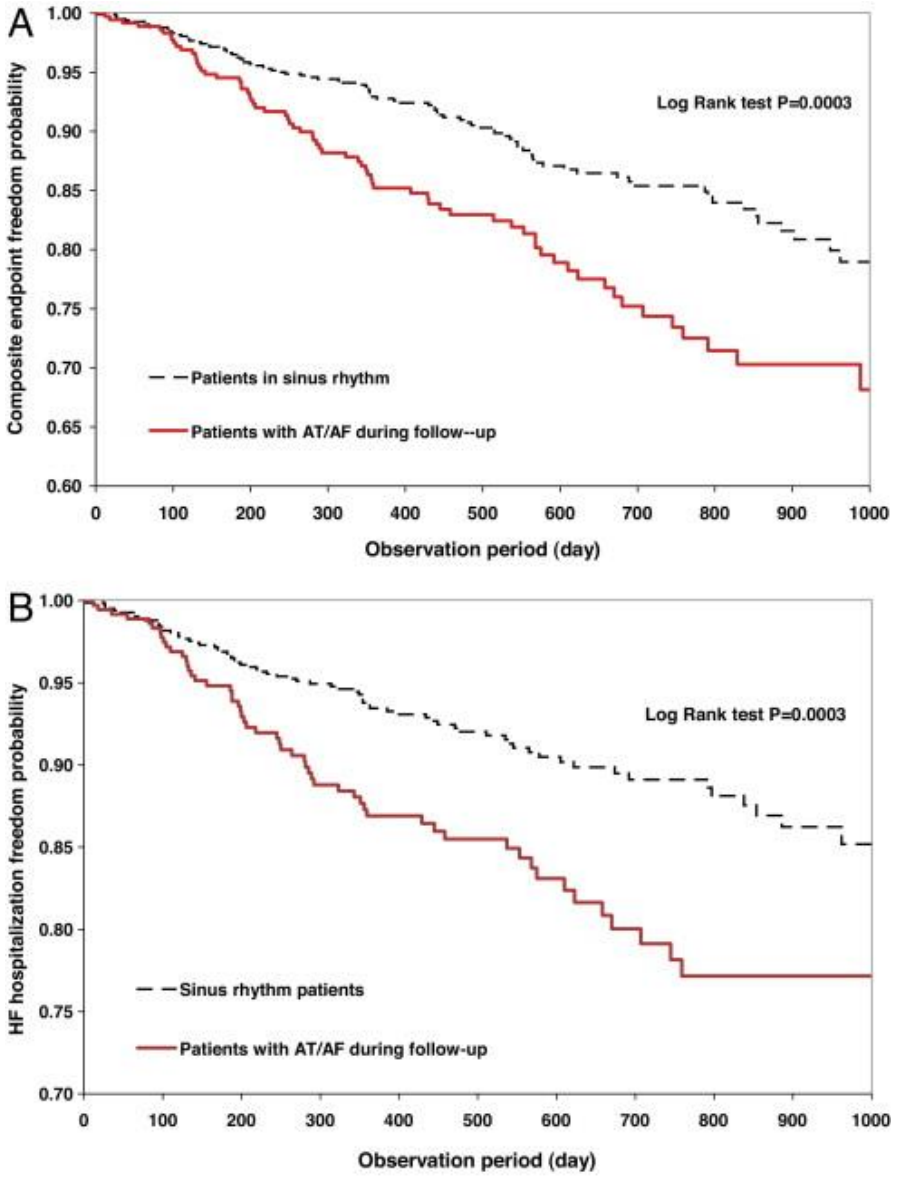




Butter C et al Circulation 2001;104:3026-29

Singh J et al Circulation. 2011;123:1159-1166.

Atrial Fibrillation and CRT



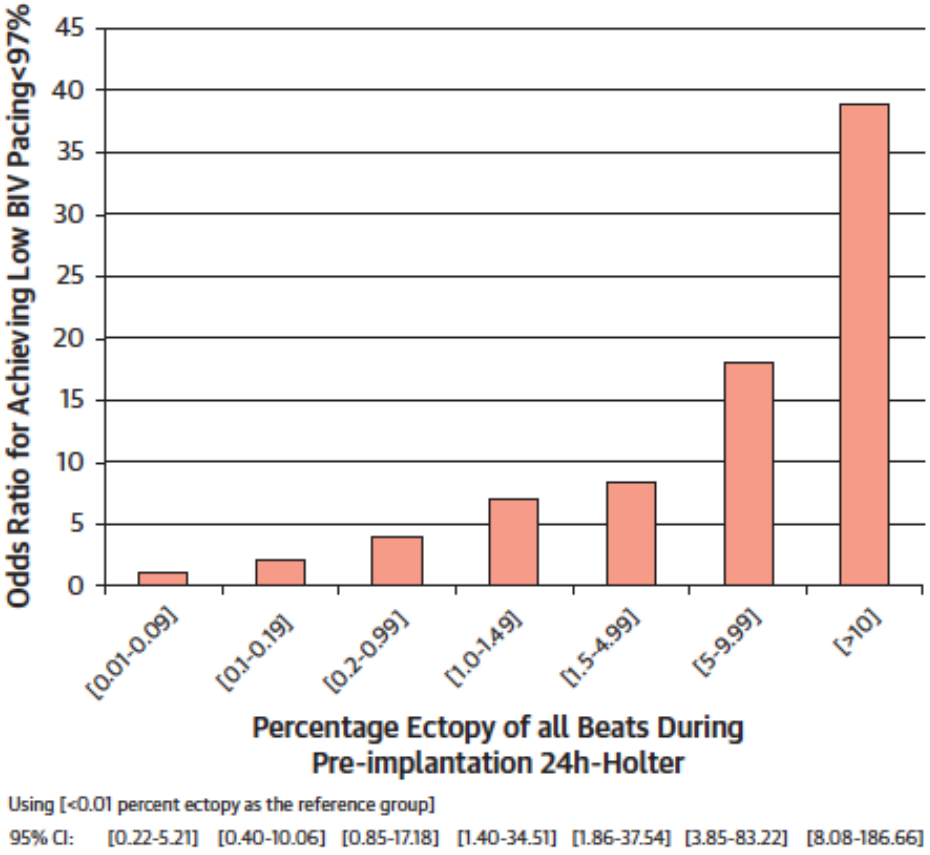
- **Pts with AT/AF had worse outcomes**
- 1193 pts with CRT-D in SR at implant followed mean 13 months
- BiV pace% 98% during SR and 71% during AT/AF

- **BiV pace% of >95% associated with better outcome**

Santini et al JACC 2011;57:167

Effect of Ectopy on BiV Pacing/Efficacy (Goal >97% pacing)

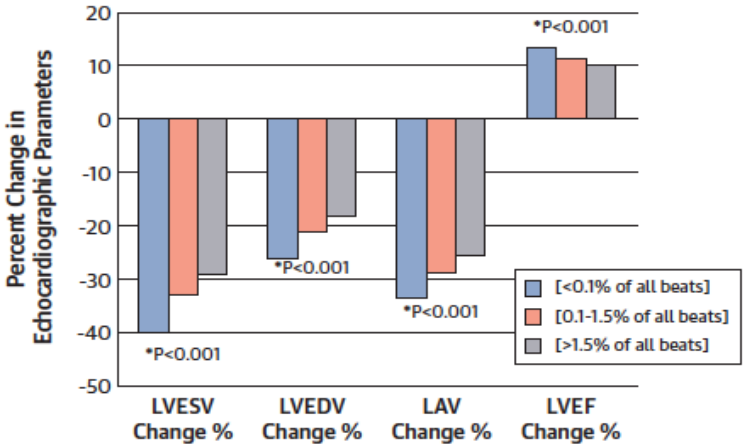
MADIT- CRT with Holter (801 patients)



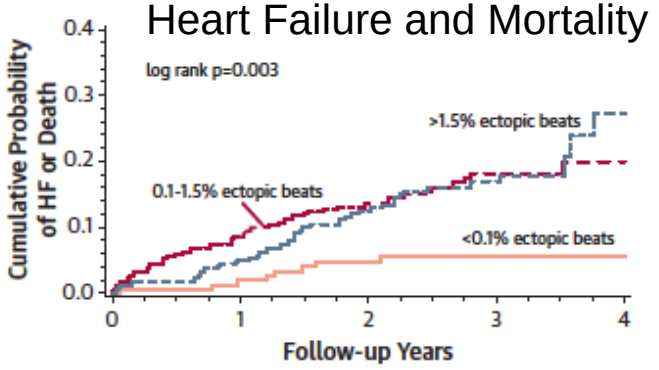
Using [<0.01 percent ectopy as the reference group]

95% CI: [0.22-5.21] [0.40-10.06] [0.85-17.18] [1.40-34.51] [1.86-37.54] [3.85-83.22] [8.08-186.66]

Echo Parameters after 1 year



Heart Failure and Mortality



Patients at Risk

160	156 (0.02)	106 (0.05)	41 (0.05)	12 (0.05)
321	291 (0.08)	202 (0.14)	93 (0.18)	24 (0.20)
320	302 (0.05)	192 (0.12)	93 (0.17)	16 (0.27)

Ruwald M et al JACC 2014:64:971-981

Heart Failure Device Therapy – ICD and CRT

- ICD if EF < 35% and class II/III HF on GDMT; Class I HF and EF<30%, prior MI
- CRT
  - In appropriate patients, CRT improves objective variables (LV size/function, reduces HF admissions and mortality)
  - Most marked EF + mortality benefit in patients with wide LBBB and EF ≤ 35% regardless of gender (F> M), chamber size, age, both ICM and NICM,
  - Critical to get LV lead in the right position and make sure pacing at least 95 -97% of the time with AF and eliminate frequent VPDs