

HF and CRT: CRT-P versus CRT-D

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Disclosures

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Speaker's Bureaus/Honoraria:

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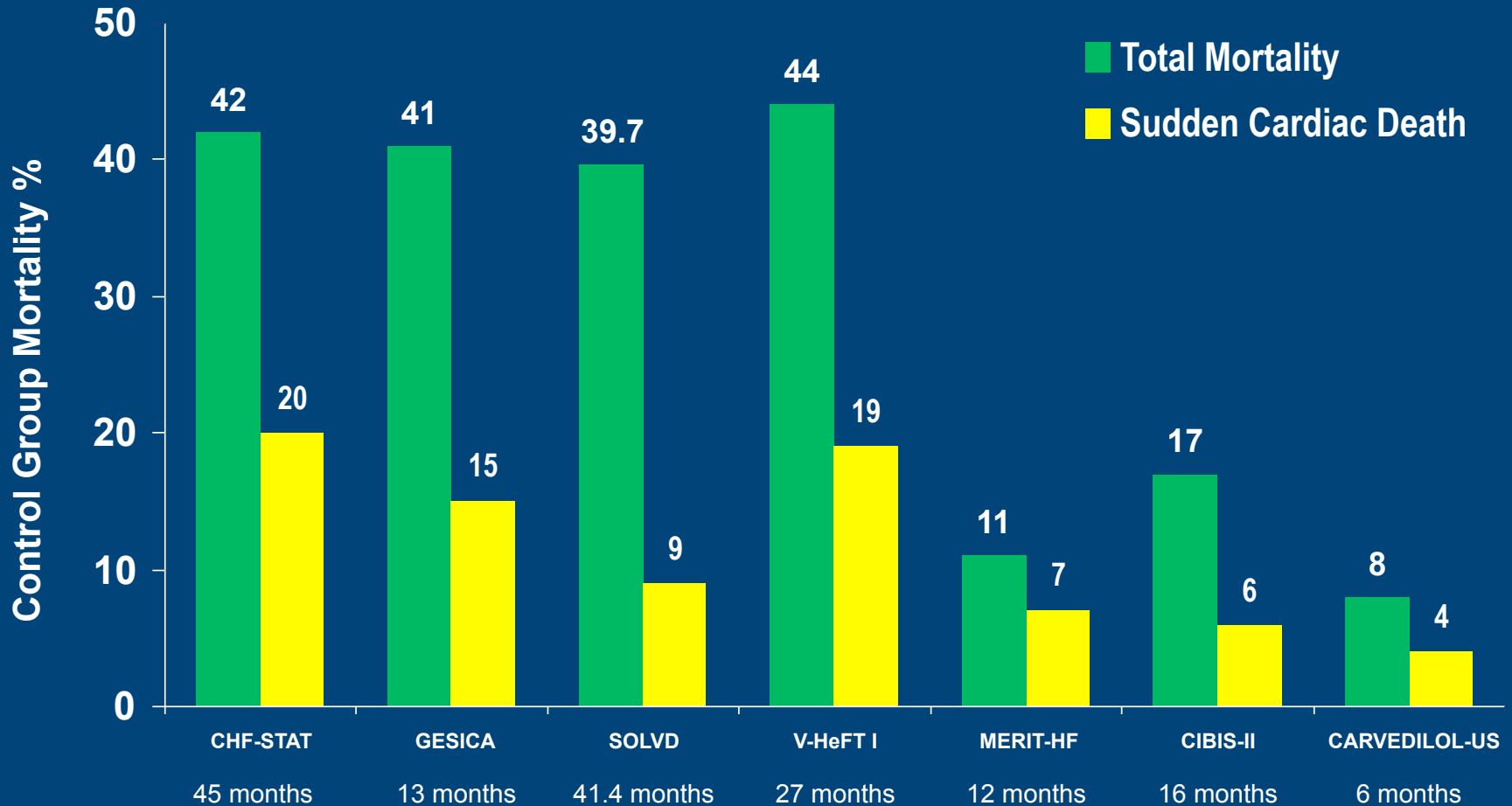
Advisor Relationships:

Boston Scientific, St. Jude Medical

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SCD Risks in HF Patients with LV Dysfunction

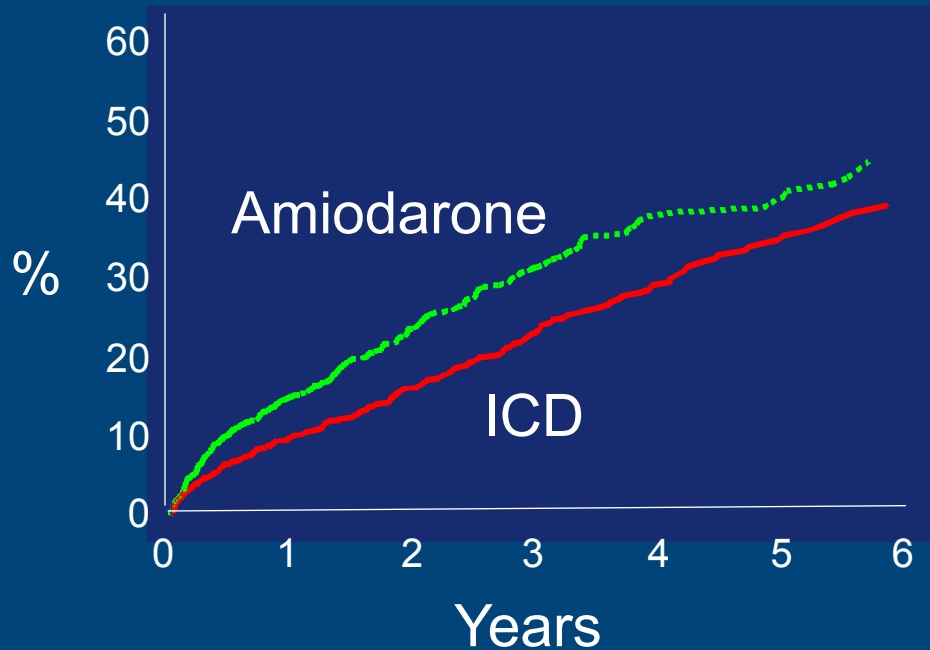


Total Mortality ~15-40%; SCD accounts for ~50% of total mortality.

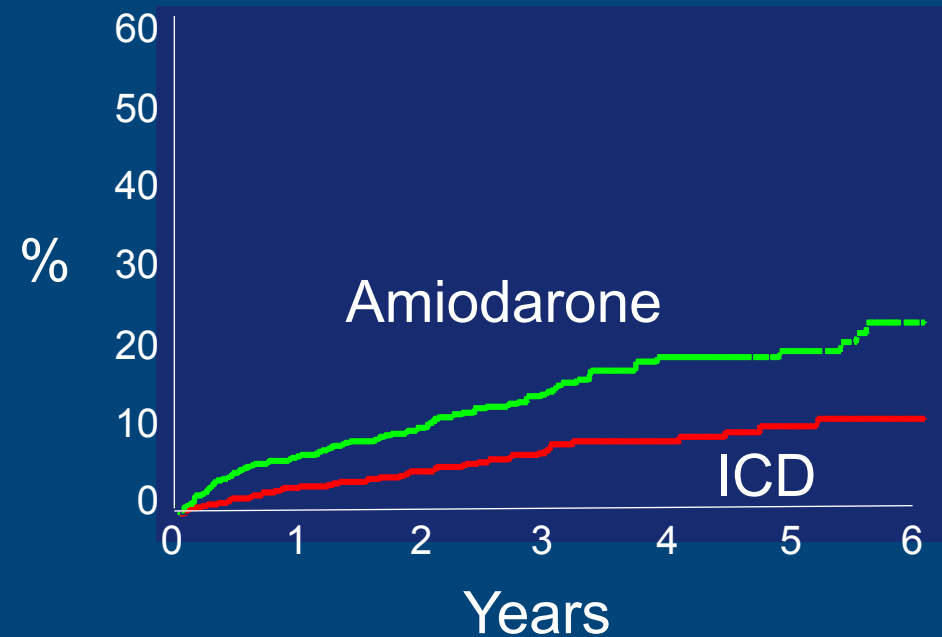
* MADIT II control group total mortality at 24 months 22%.

Secondary Prevention Trials: AVID/CASH/CIDS Meta-analysis

Death

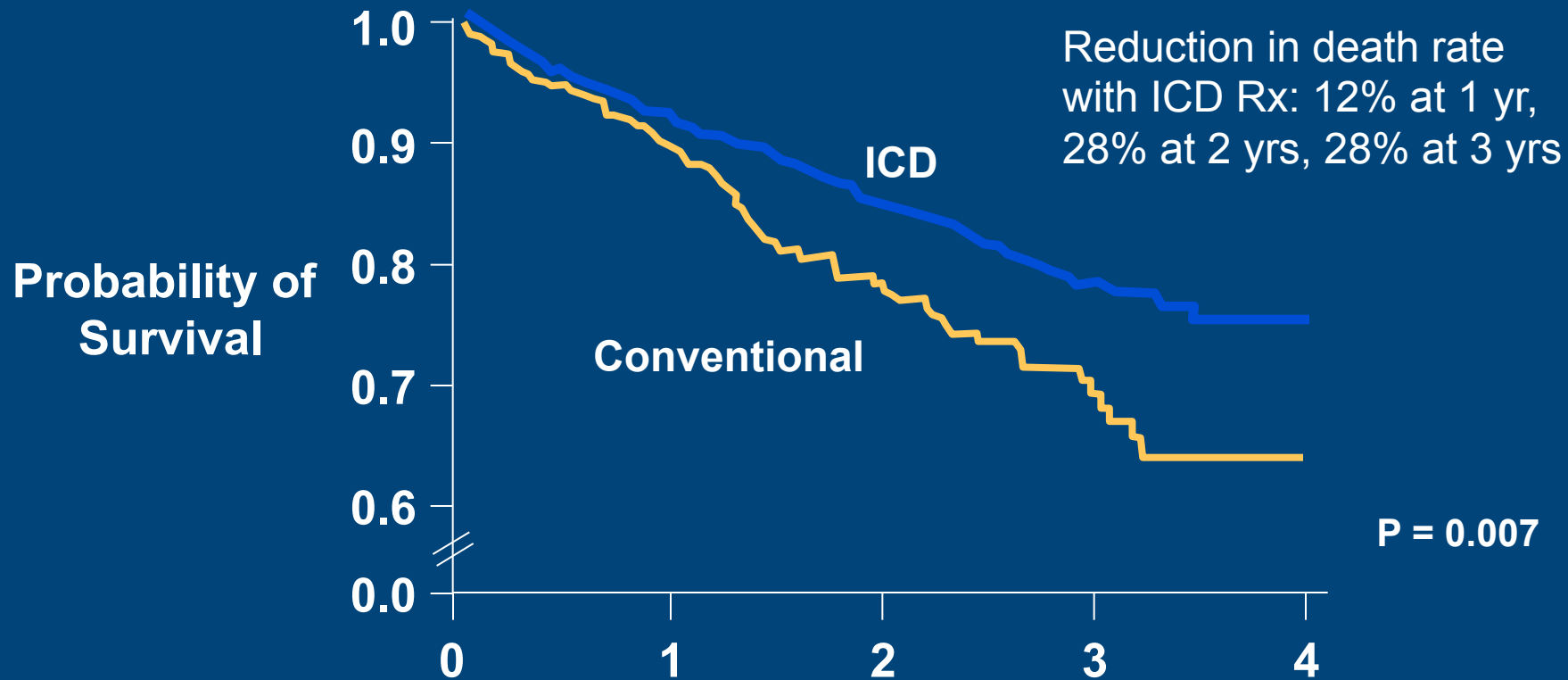


Arrhythmic death



MADIT II

Conventional versus ICD Therapy

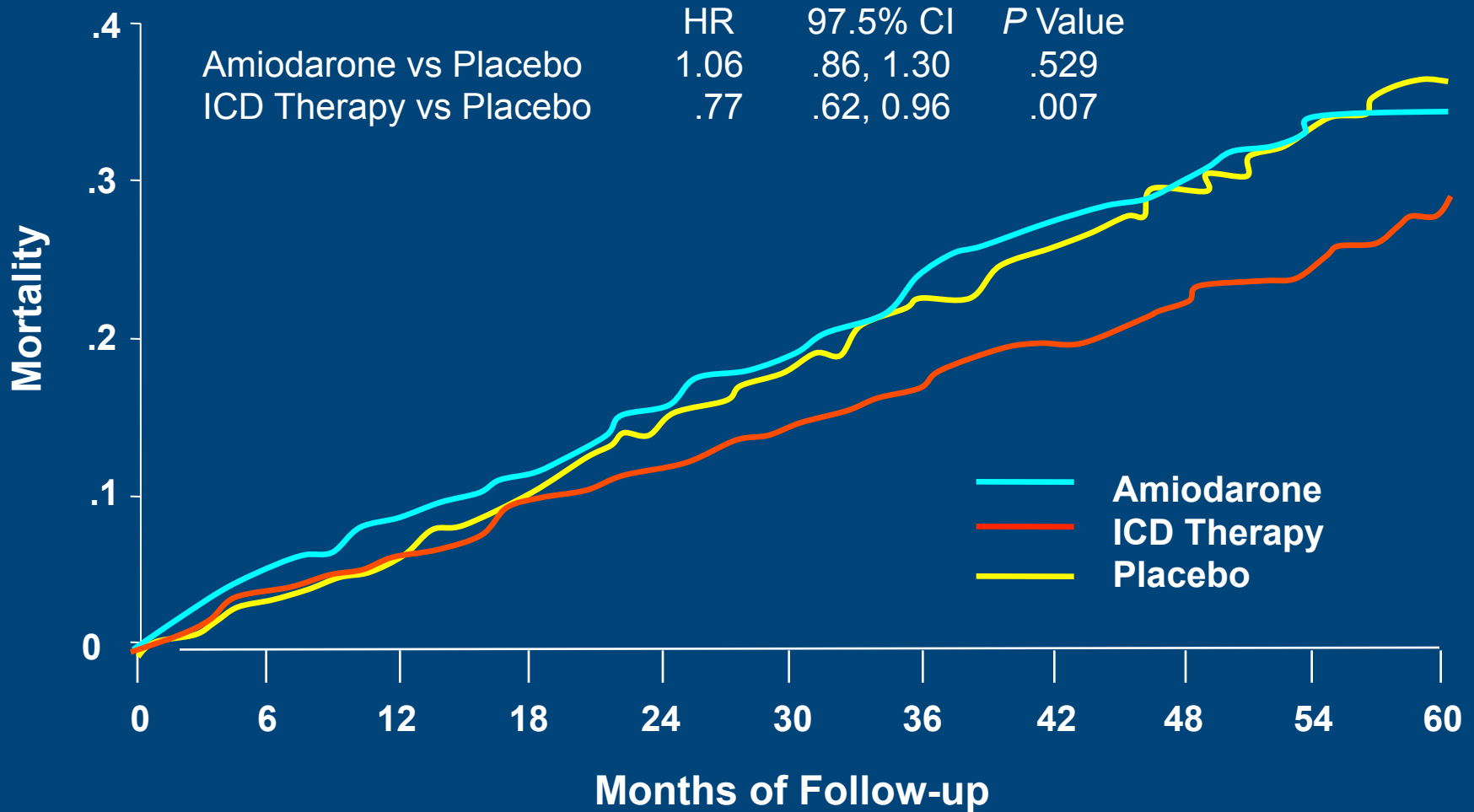


No. At Risk

| | 0 | 1 | 2 | 3 | 4 |
|---------------|-----|------------|------------|------------|---|
| Defibrillator | 742 | 502 (0.91) | 274 (0.84) | 110 (0.78) | 9 |
| Conventional | 490 | 329 (0.90) | 170 (0.78) | 65 (0.69) | 3 |

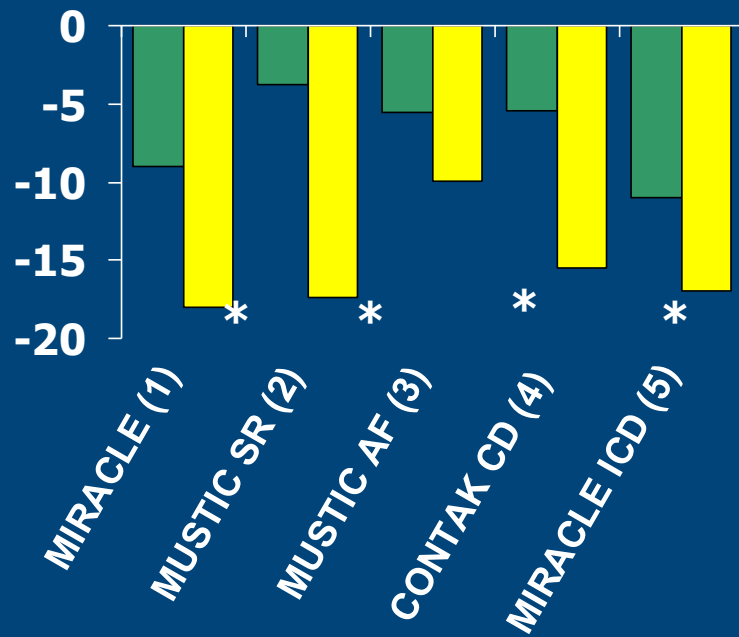
SCD-HEFT

Mortality by Intention-to-treat

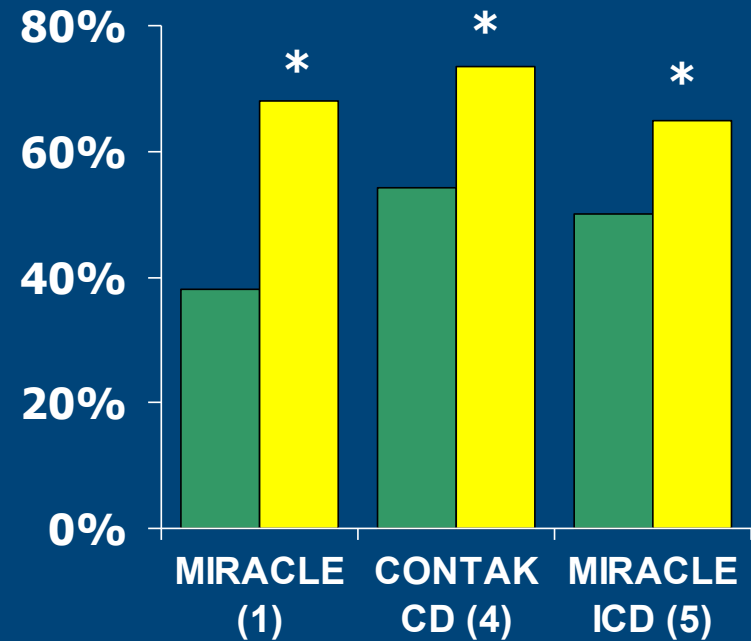


CRT Improves Quality of Life and NYHA Functional Class

Average Change in QoL Score (MLWHF)



NYHA: Proportion Improving 1 or More Class



■ Control ■ CRT

■ Control ■ CRT

1. *NEJM* 2002;346:1845-53

2. *NEJM* 2001;344:873-80

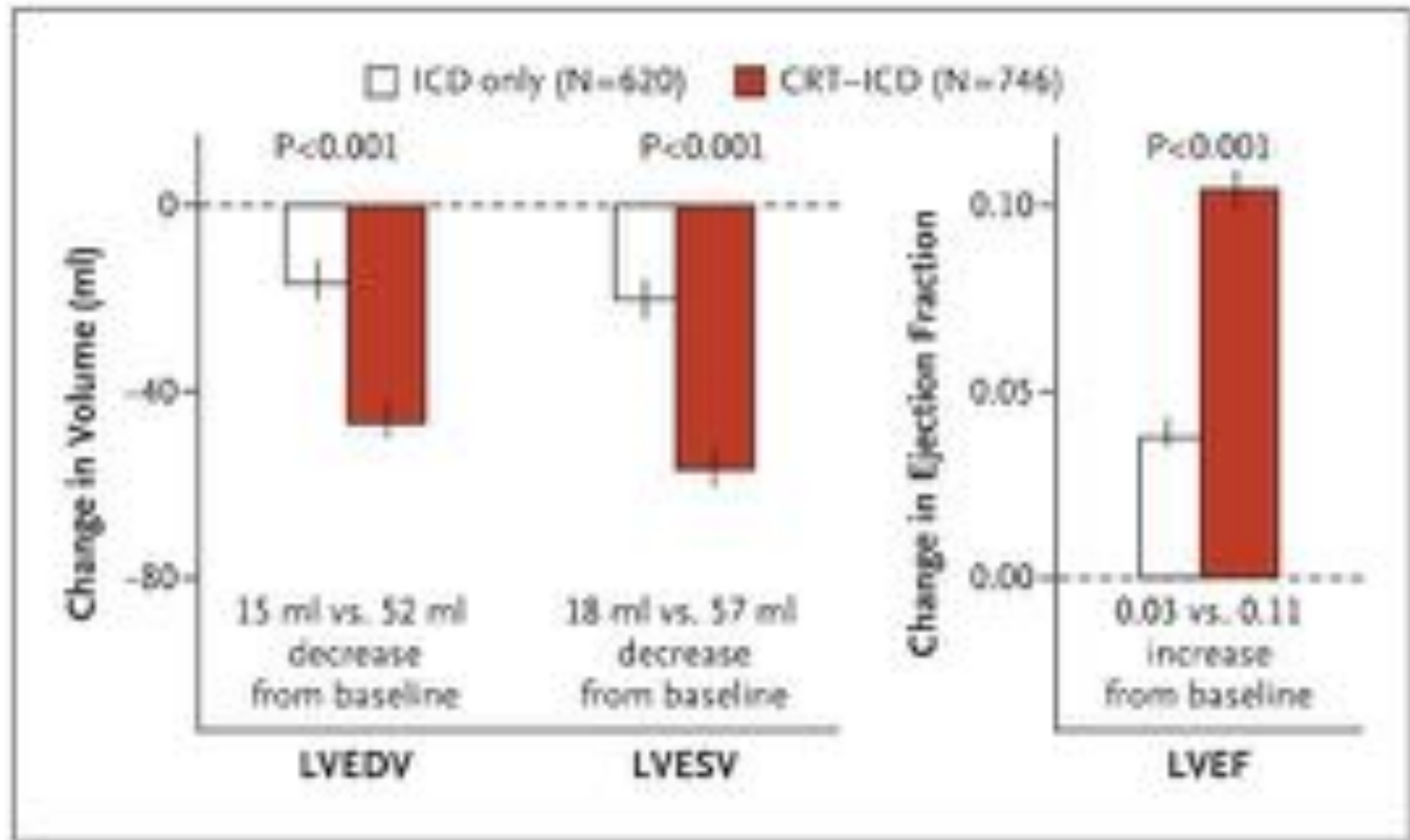
3. *Eur Heart J* 2002;23:1780-1787

4. <http://www.fda.gov/cdrh/pdf/P010012b.pdf>. Accessed August 2, 2002

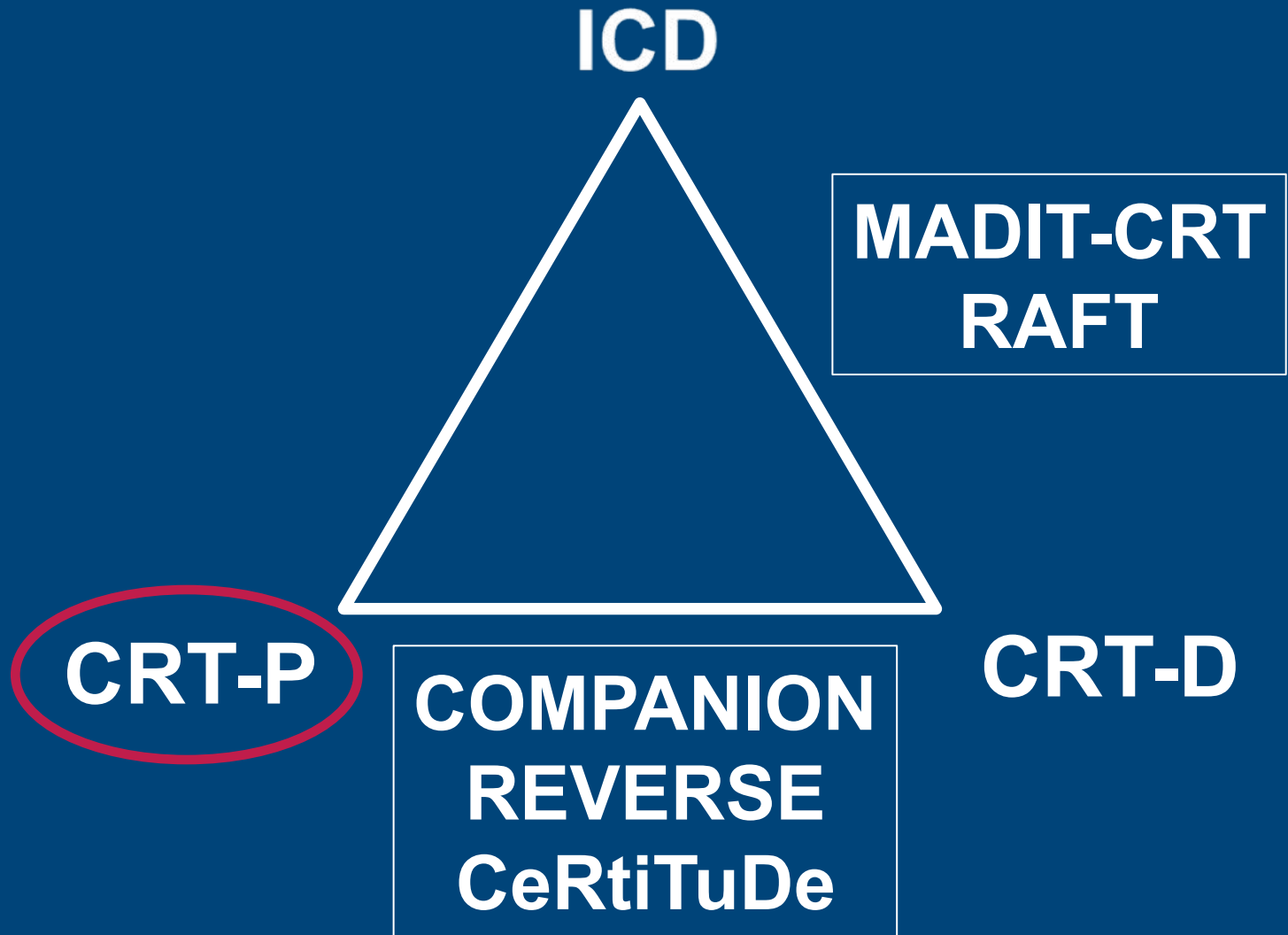
5. *JAMA* 2003; 289:2685-94

* P < 0.05

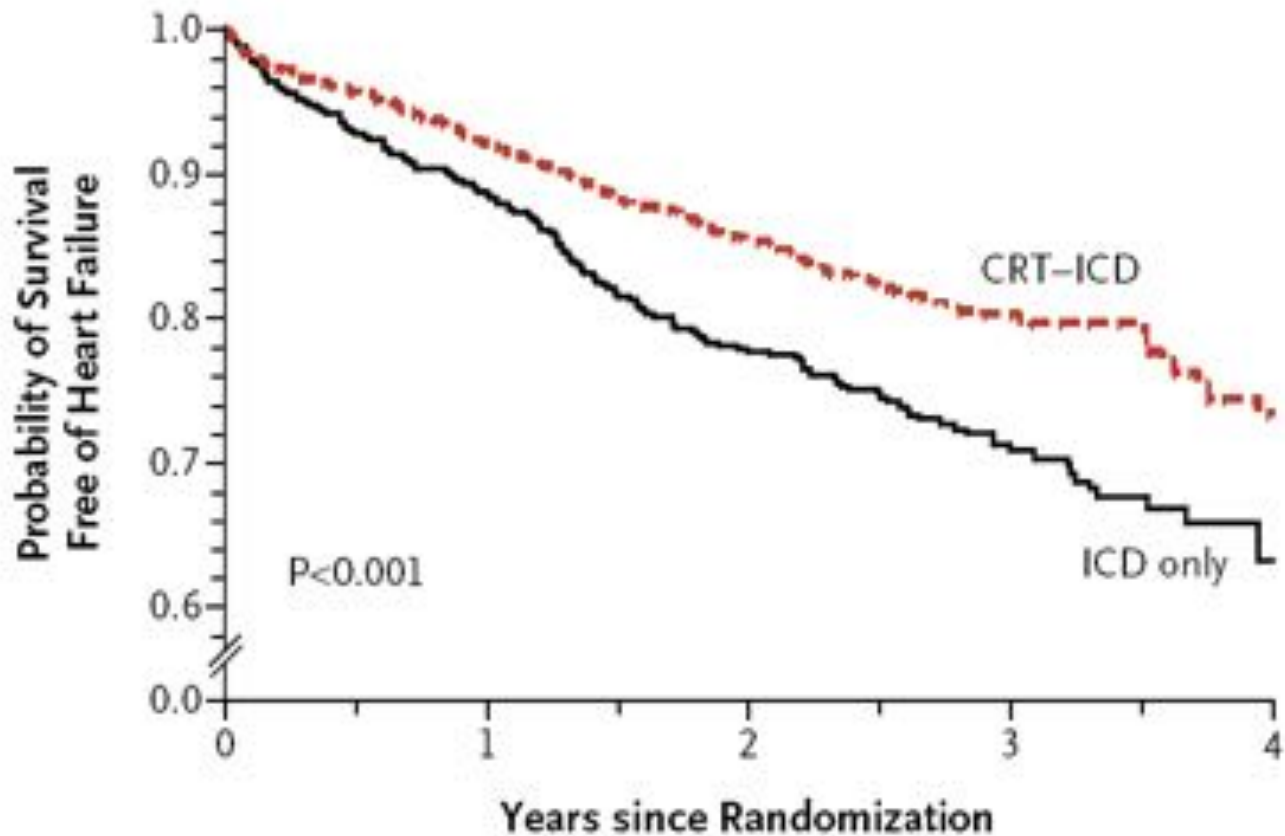
MADIT CRT: Changes in Mean LV Volumes and EF at 1 Year



Trials of CRT and ICDs



MADIT-CRT

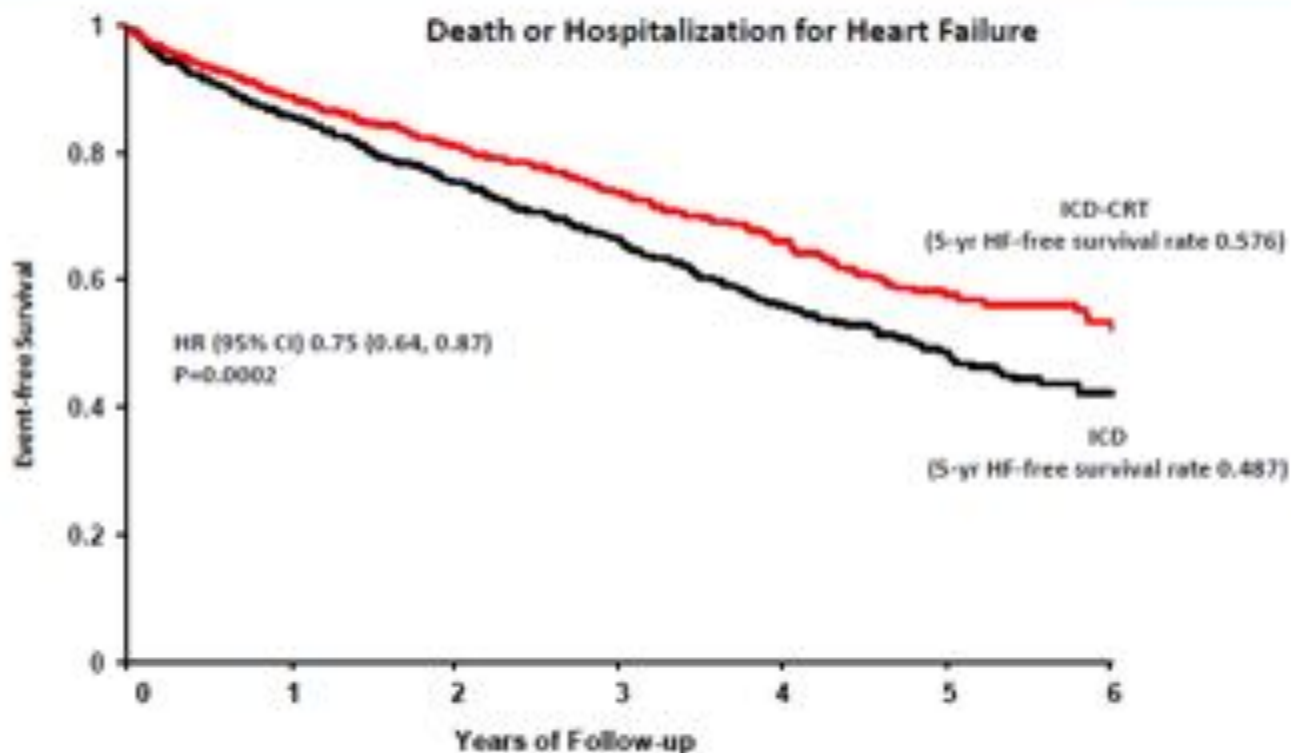


No. at Risk (Probability of Survival)

| | | | | | |
|----------|------|------------|------------|------------|-----------|
| 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) |



Kaplan-Meier Estimates of the Primary Outcome

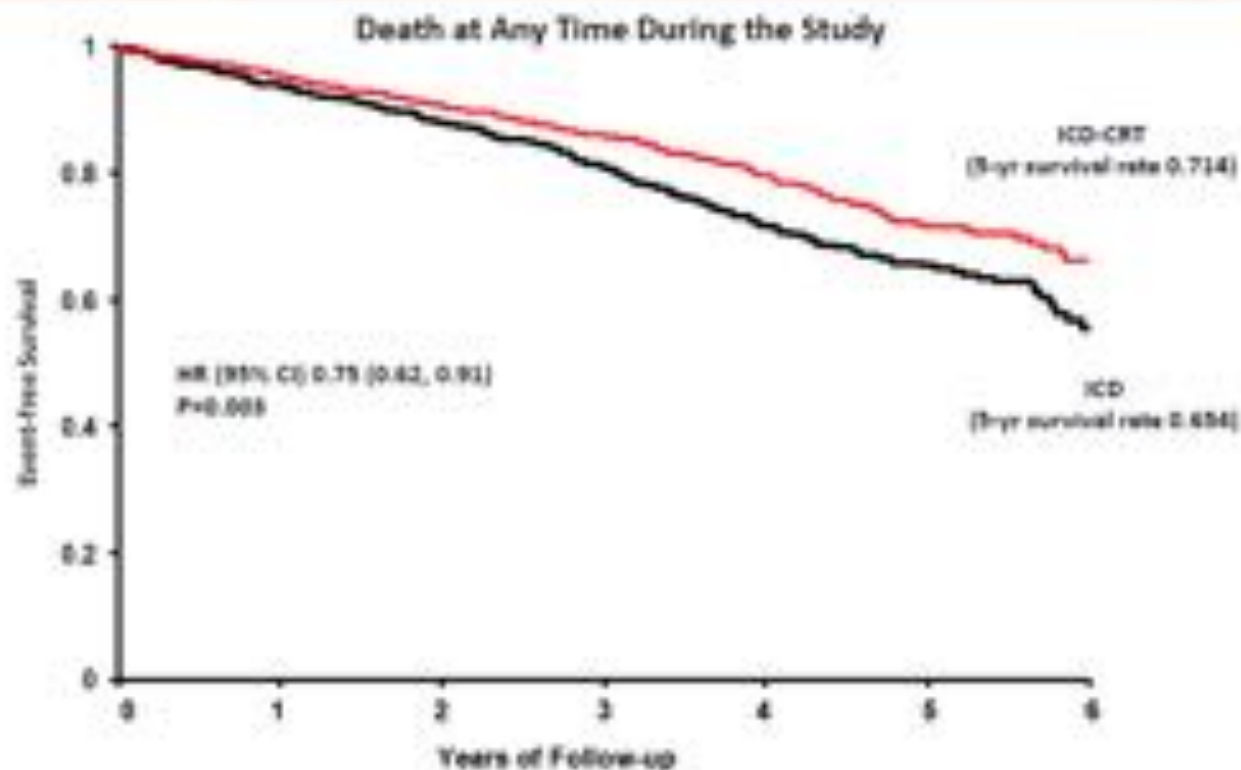


No. at Risk

| | | | | | | | |
|---------|-----|-----|-----|-----|-----|-----|----|
| ICD/CRT | 894 | 790 | 615 | 429 | 278 | 130 | 41 |
| ICD | 904 | 770 | 572 | 384 | 214 | 101 | 19 |



Kaplan-Meier Estimates of All cause Mortality

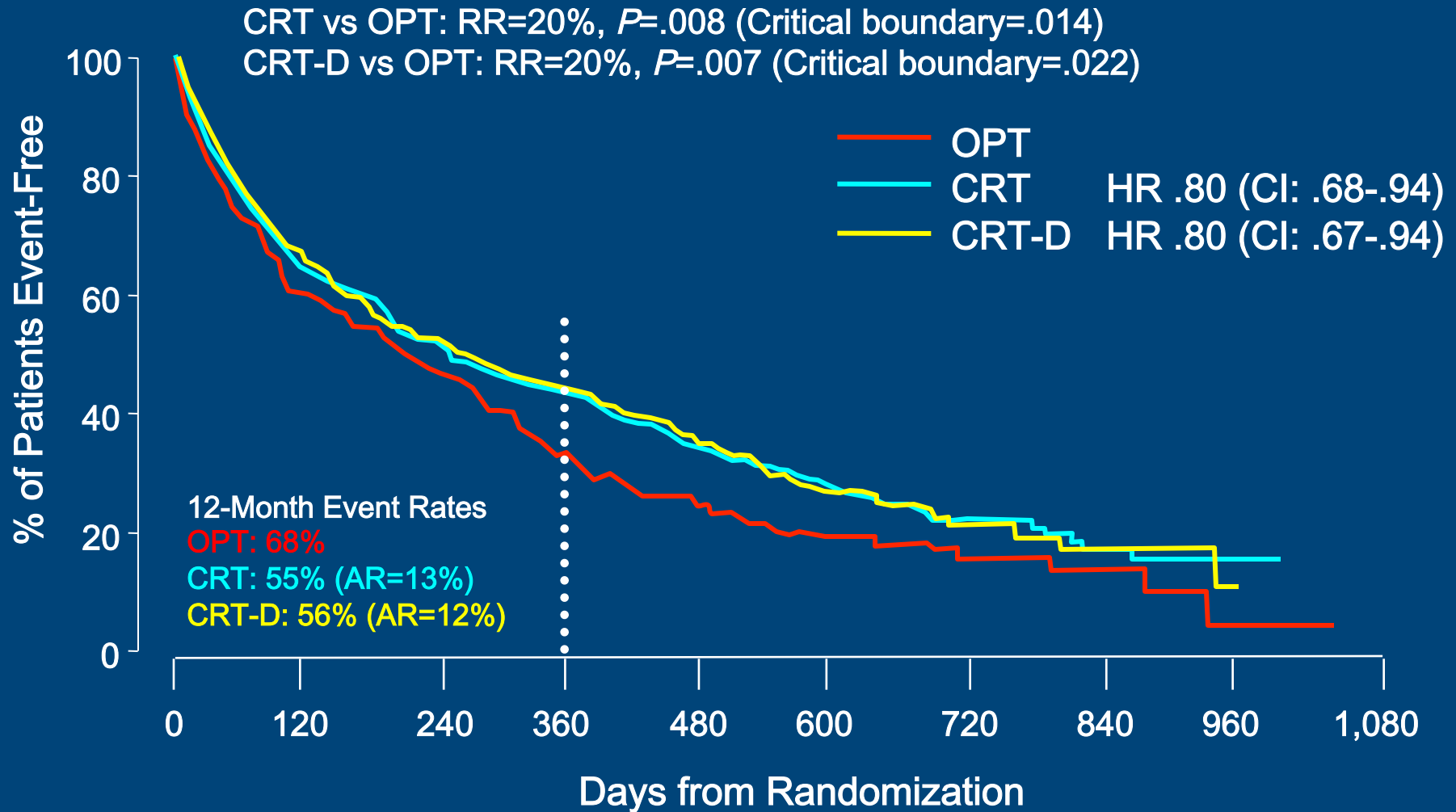


No. at Risk

| | | | | | | | |
|---------|-----|-----|-----|-----|-----|-----|----|
| ICD/CRT | 894 | 849 | 685 | 502 | 333 | 167 | 53 |
| ICD | 904 | 841 | 670 | 482 | 299 | 149 | 35 |

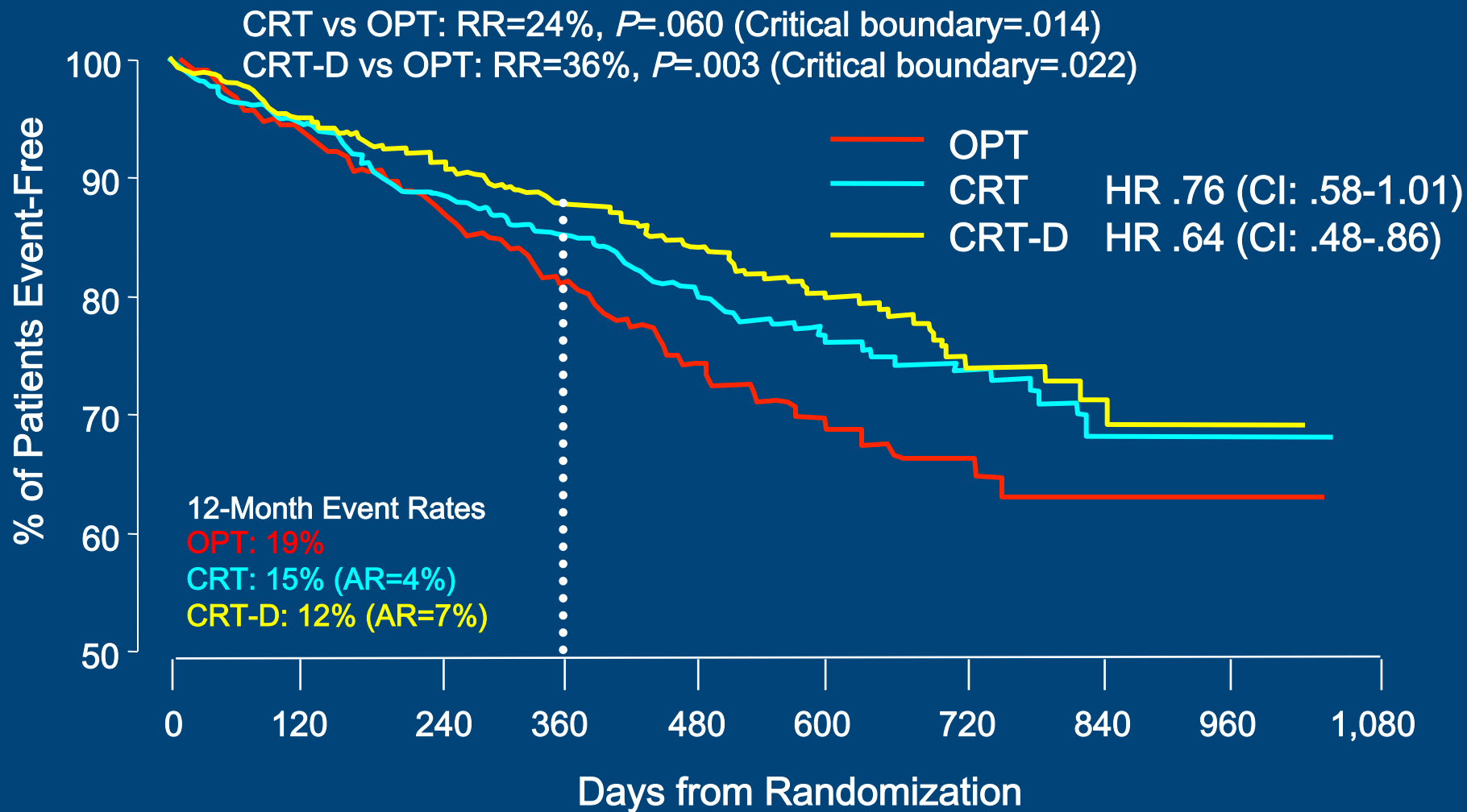
COMPANION:

Primary Endpoint: Mortality+Hospitalization

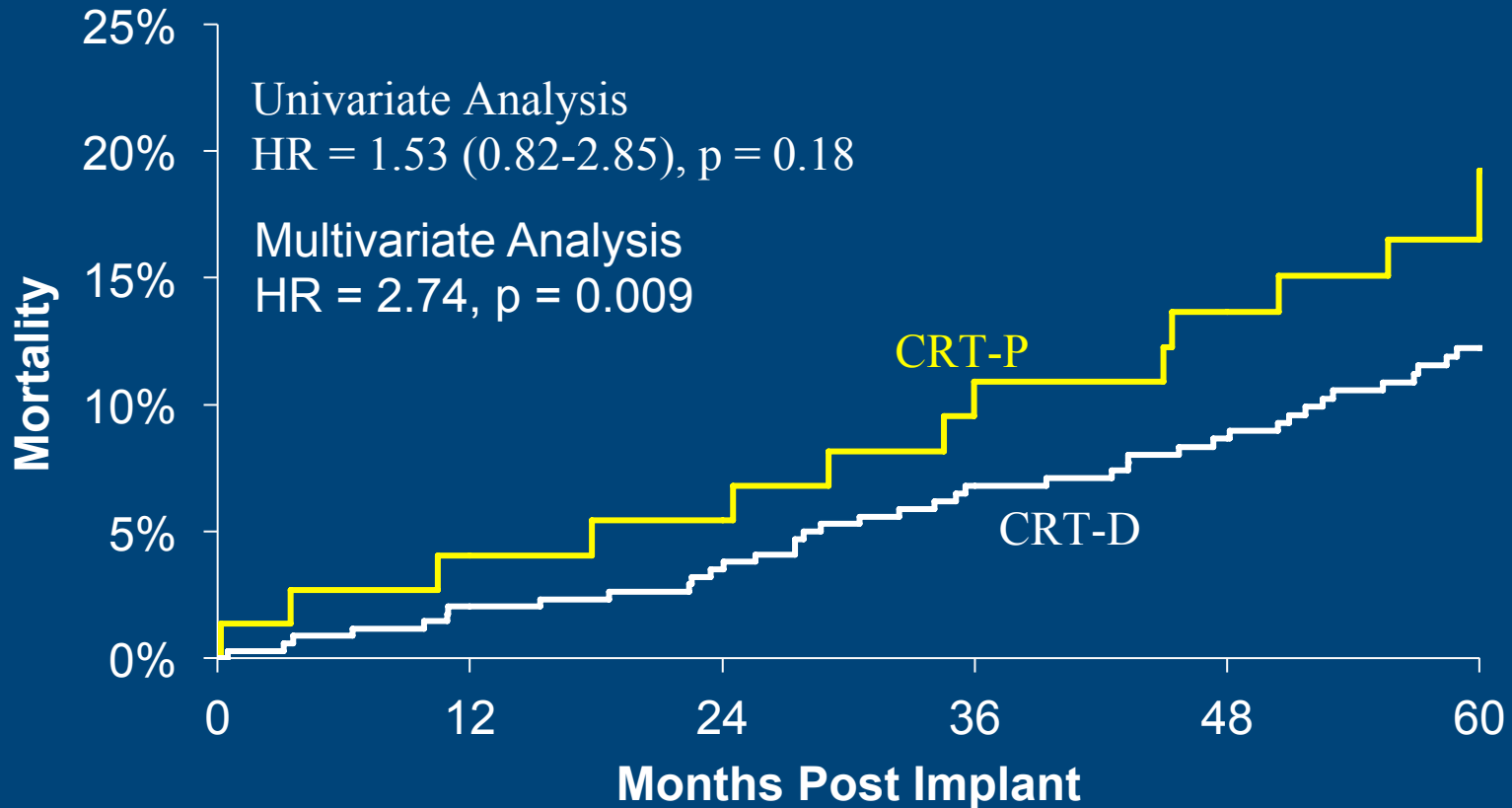


COMPANION:

Secondary Endpoint: All-Cause Mortality



REVERSE CRT "ON": Mortality CRT-P vs. CRT-D



Number at Risk

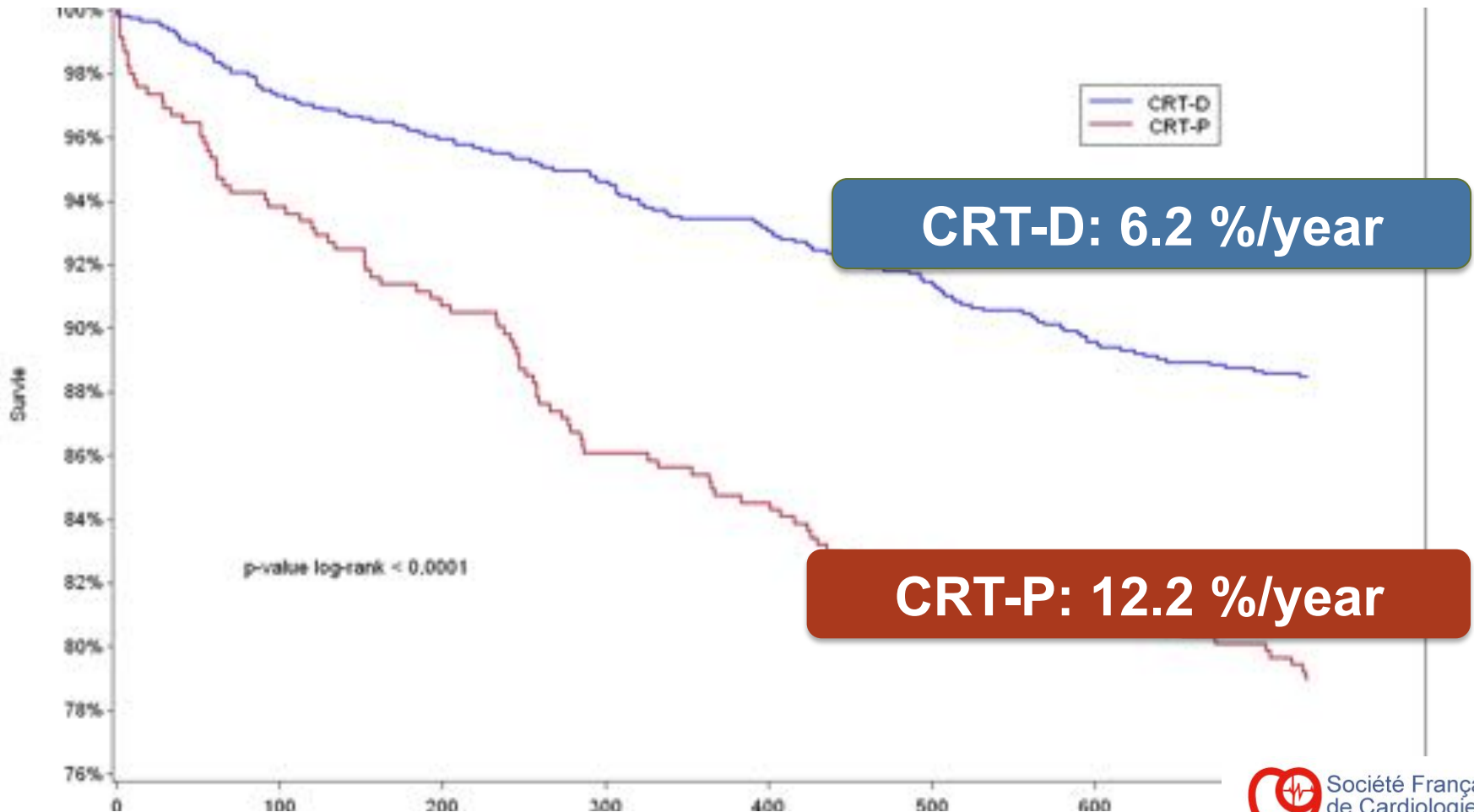
| | | | | | | |
|-------|-----|-----|-----|-----|-----|-----|
| CRT-P | 74 | 71 | 69 | 65 | 62 | 29 |
| CRT-D | 345 | 337 | 326 | 308 | 292 | 129 |

CeRtiTuDe

- Prospective Multicenter Cohort Study
 - Funded and Coordinated by the French Society of Cardiology
- To evaluate the extent to which:
 - CRT-P patients differ from CRT-D patients in real life settings
 - CRT-P patients could have additionally benefited from a back-up defibrillator
- Enrollment from Jan. 2008 to Dec. 2010
- 1,705 patients: 535 CRT-P and 1170 CRT-D
- Follow-up at 6, 12, 18, and 24 months
 - Clinical / Echo / Rhythm
 - Completed in 1,611 (94.5%)

CeRtiTuDe - Overall Mortality

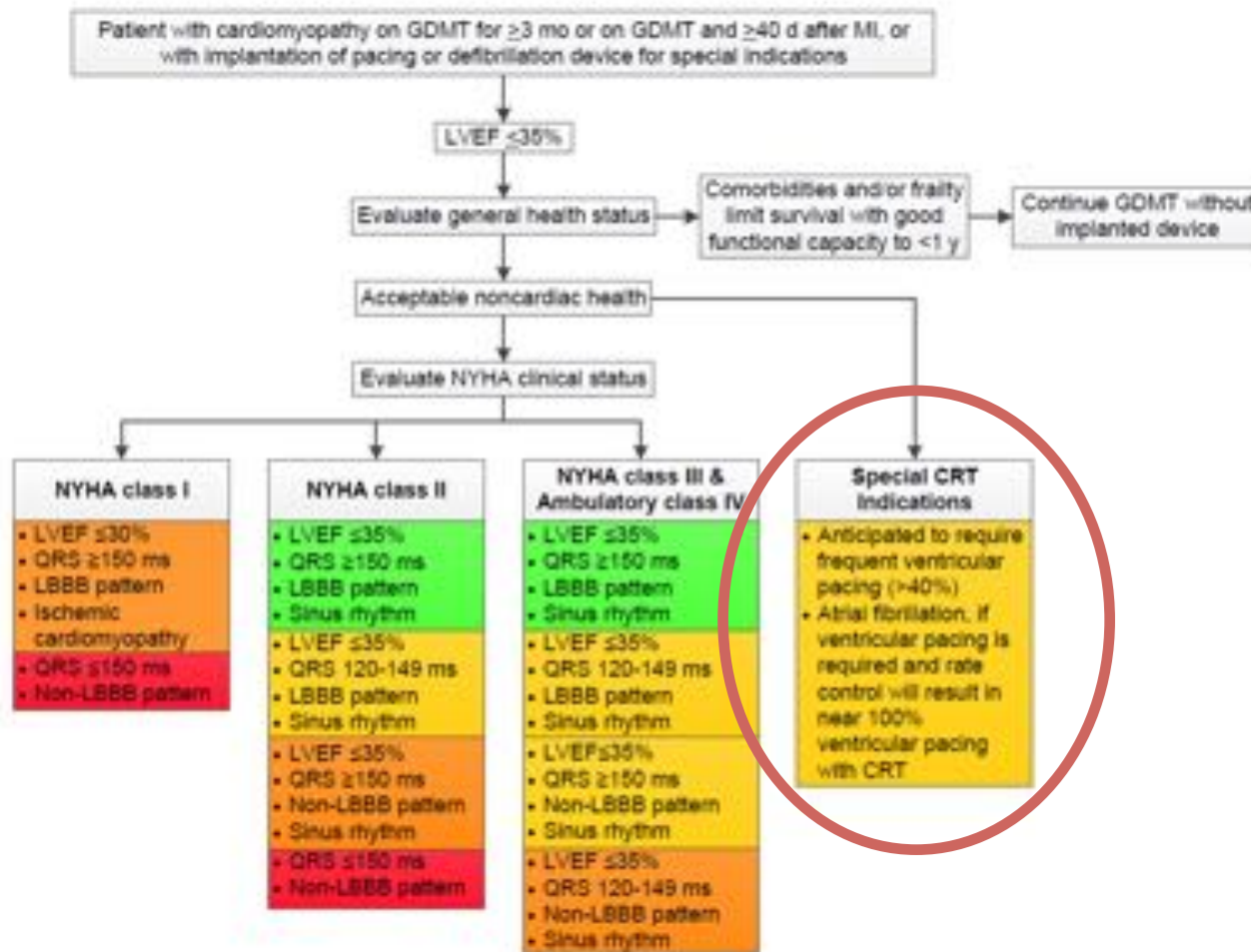
Among the 1,611 patients with complete follow-up, 286 deaths



Why Consider CRT-P without “D”?

1. Both appropriate and inappropriate shocks are avoided.
2. Some patients may not want “D”.
3. Some CRT-P indications are independent of ICD indications.
4. If LVEF is anticipated to improve, the benefit of “D” may be minimized.
5. CRT-P saves lives (COMPANION and CARE-HF)
6. Decreased cost.

CRT Indications Algorithm



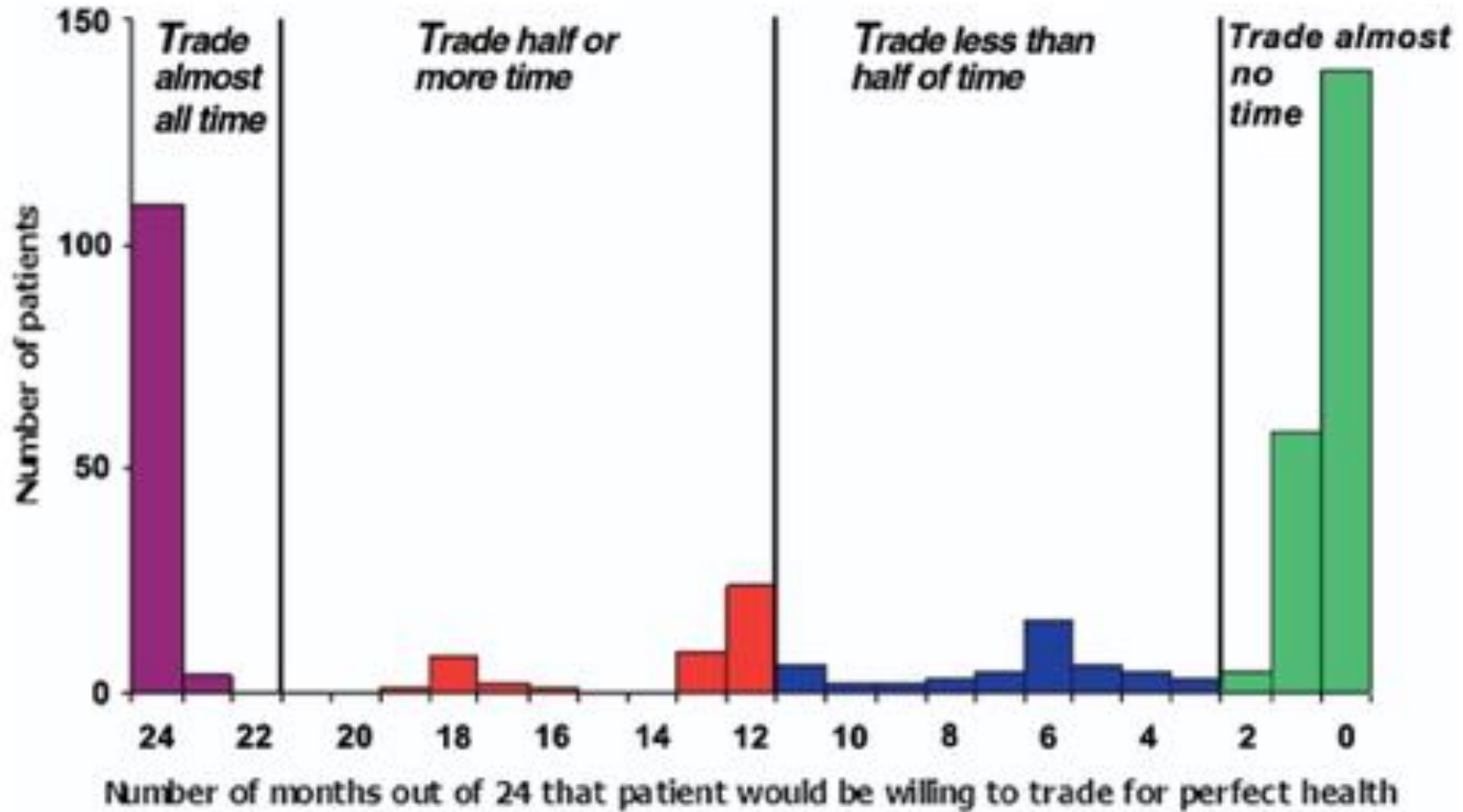
Colors correspond to the class of recommendations in the ACCF/AHA Table 1.

Benefit for NYHA class I and II patients has been shown in CRT-D trials, and while patients may not experience immediate symptomatic benefit, late remodeling may be avoided along with long-term HF consequences. There are no trials that support CRT-pacing (without ICD) in NYHA class I and II patients. Thus, it is anticipated these patients would receive CRT-D unless clinical reasons or personal wishes make CRT-pacing more appropriate. In patients who are NYHA class III and ambulatory class IV, CRT-D may be chosen but clinical reasons and personal wishes may make CRT-pacing appropriate to improve symptoms and quality of life when an ICD is not expected to produce meaningful benefit in survival.

DBT Considerations Regarding Longevity and Comorbidities: What are the Patient's Goals/Focus on the Elderly

- “Physicians, patients, and their families increasingly will be faced with decisions about device-based therapies (ICD and CRT) in elderly patients who meet conventional criteria for implantation. These decisions require ... estimates of life expectancy, consideration of comorbidities and procedural risk, and patient preferences. Although these factors are important when device implantation is considered in any age group, they assume greater weight in clinical decision-making among the elderly.”

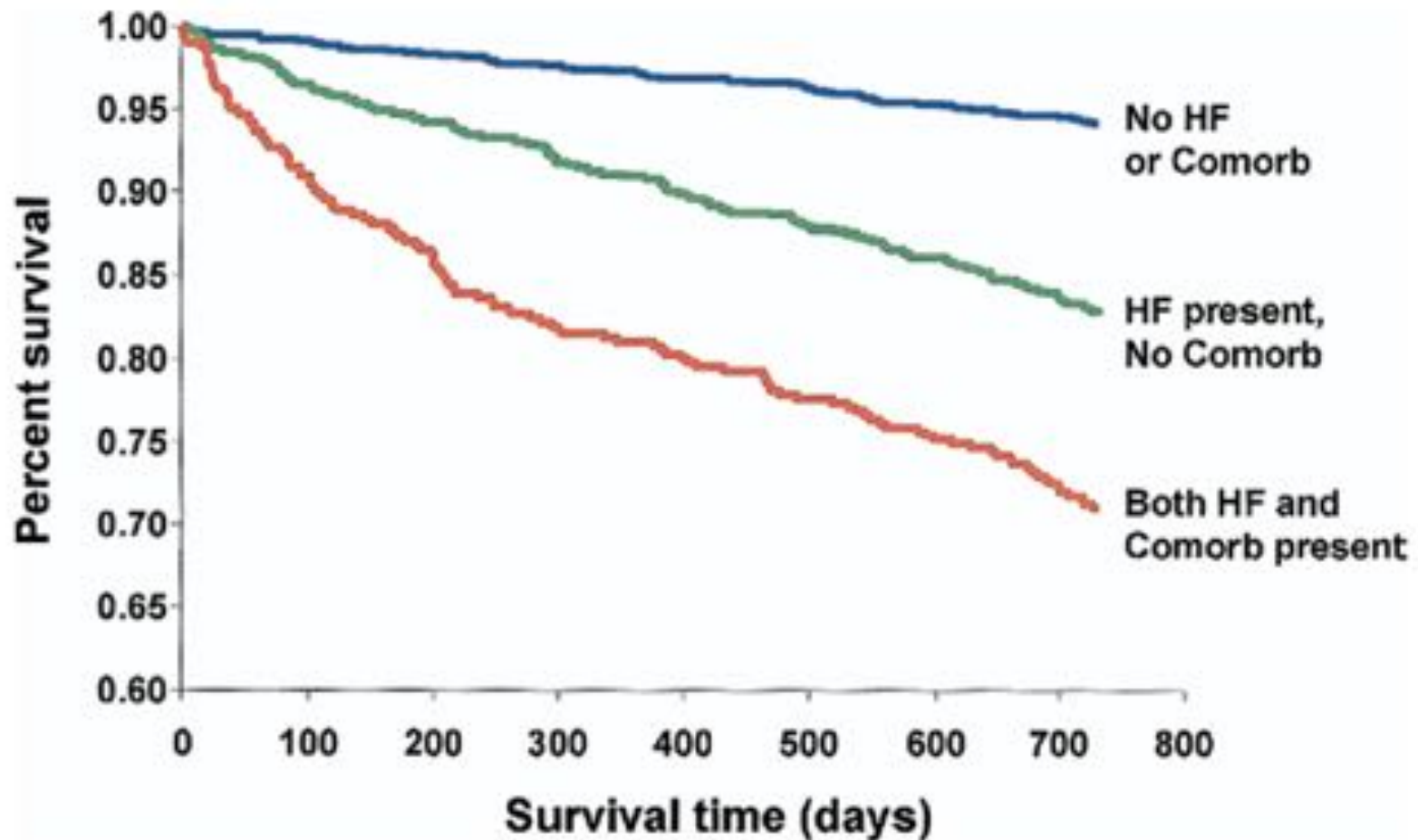
Survival vs QOL



Comorbidities and Survival

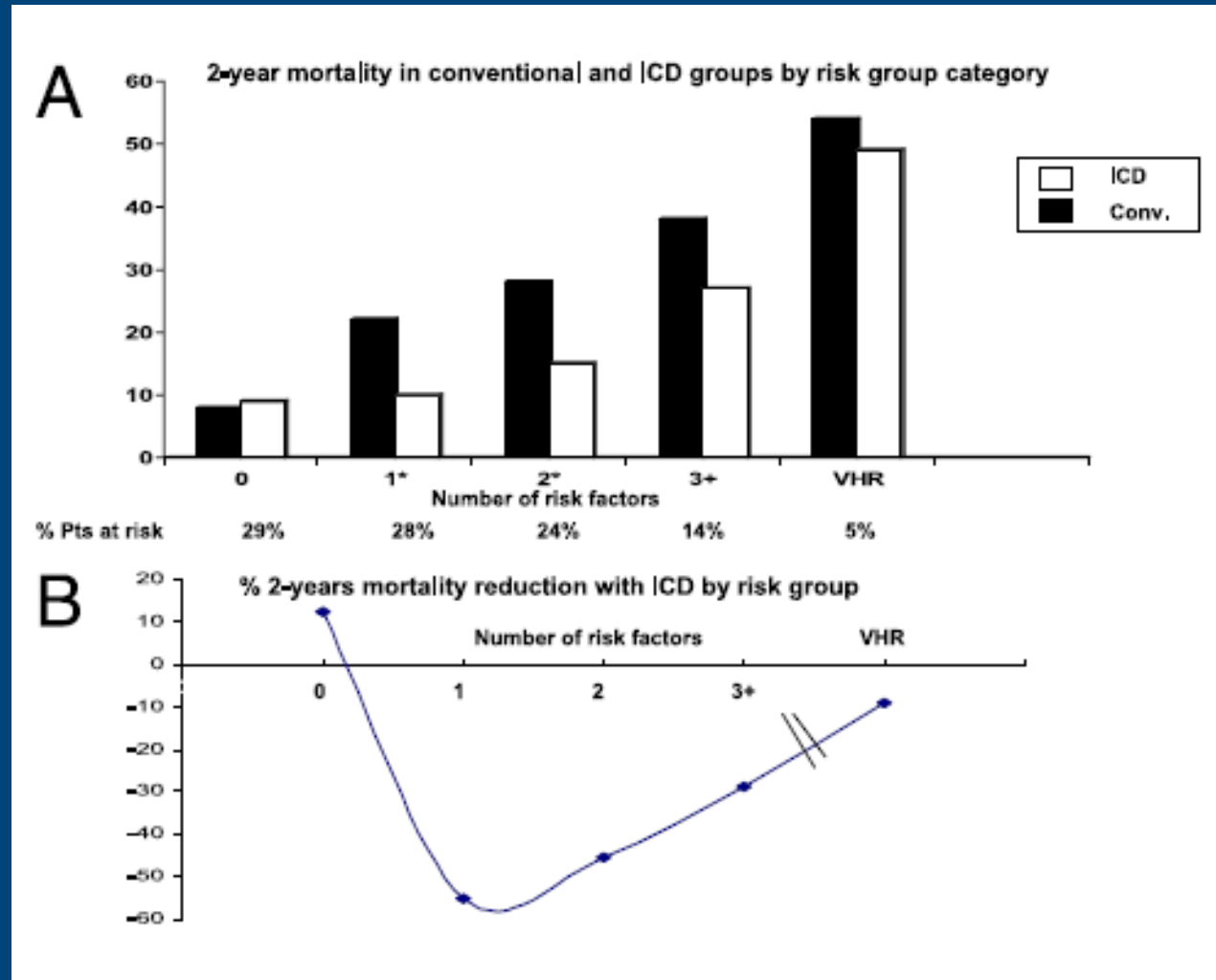
- Observational study of ICD outcomes in Canada
- 2,467 patients age ≥ 18 and ≤ 105 years
- Comorbidities associated with death
 - PVD
 - Pulmonary disease
 - CKD
 - HF
- HRs adjusted for age, gender, and HF
 - 1 noncardiac comorbidity: 1.72
 - 2 noncardiac comorbidities: 2.79
 - 3 noncardiac comorbidities: 2.98

Comorbidities and Survival



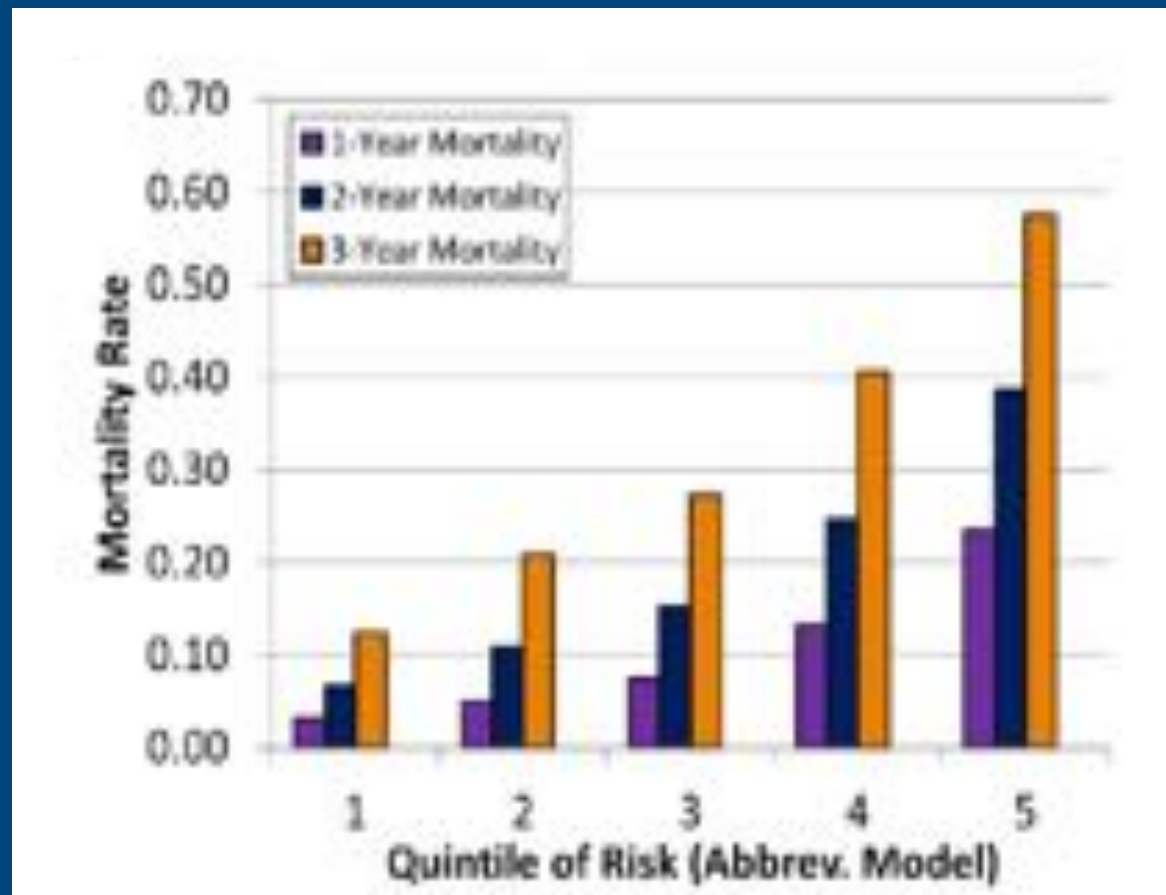
Risk and Mortality in MADIT II: U-shaped Curve of ICD Efficacy

- 5 risk factor model
 - Age
 - NYHA class
 - BUN
 - Atrial fibrillation
 - QRS duration
- Excluded VHR patients (BUN ≥ 50 and/or Cr ≥ 2.5 mg/dl [MADIT II exclusion BUN ≥ 70 and/or Cr ≥ 3.0 mg/dl]). N = 60



Mortality by Risk Score Quintile in Patients with ICDs

Age \geq 75 (62 points)
NYHA class 3 (36 points)
AF (27 points)
CCPD (52 points)
CKD (100 points)
LVEF \leq 20 (28 points)
DM (41 points)
Total Points
Prob. Survival 1 year
Prob. Survival 2 years
Prob. Survival 3 years
Prob. Survival 4 years

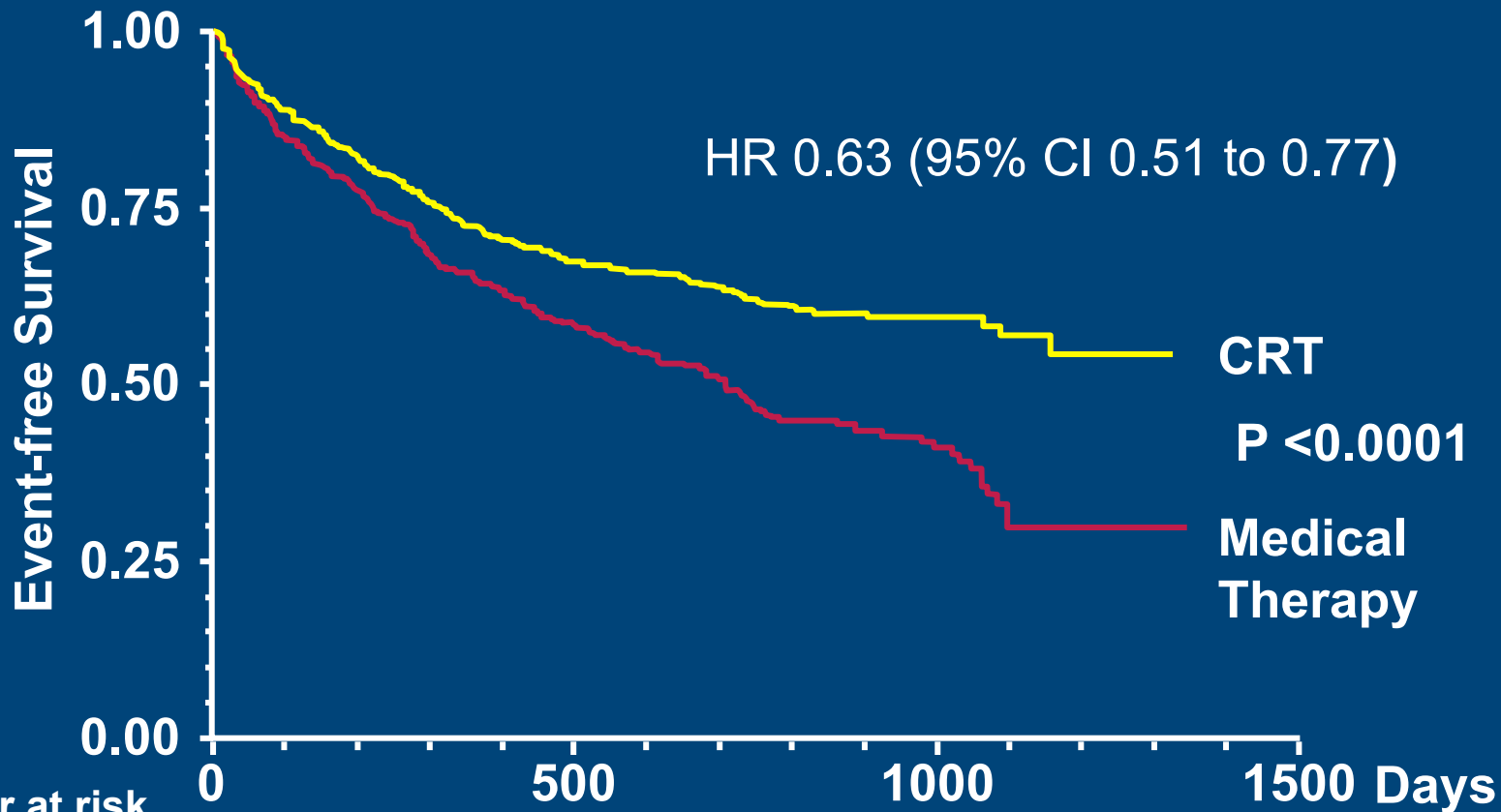


CARE-HF

Care - HF

Primary Endpoint

(All-cause Mortality or Unplanned Hospitalization for Major CV Event)



Number at risk

| | | | | | | |
|-----------------|-----|-----|-----|-----|----|---|
| CRT | 409 | 323 | 273 | 166 | 68 | 7 |
| Medical Therapy | 404 | 292 | 232 | 118 | 48 | 3 |

Summary

- CRT alone (CRT-P) or with an ICD (CRT-D) is highly effective therapy to decrease morbidity and mortality.
- Almost all patients with a CRT-P indication have an indication for and ICD at the time of implantation, and CRT-D is reasonable.
- The decision to implant a CRT-P or CRT-D requires discussion with the patient and their telling you what are their goals.
- CRT-P is appropriate when LVEF is relatively well-preserved and pacing is needed (CHB, AF/slow VR), but CRT-D is appropriate in borderline circumstances to avoid second operation/pocket opening.