ICDs: Too Many or Not Enough?

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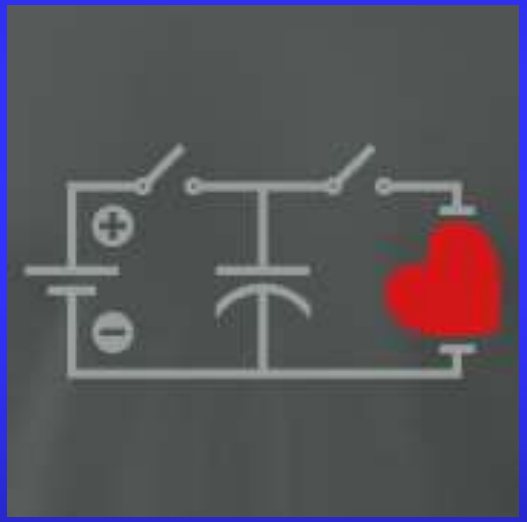
ICDs: Not Enough

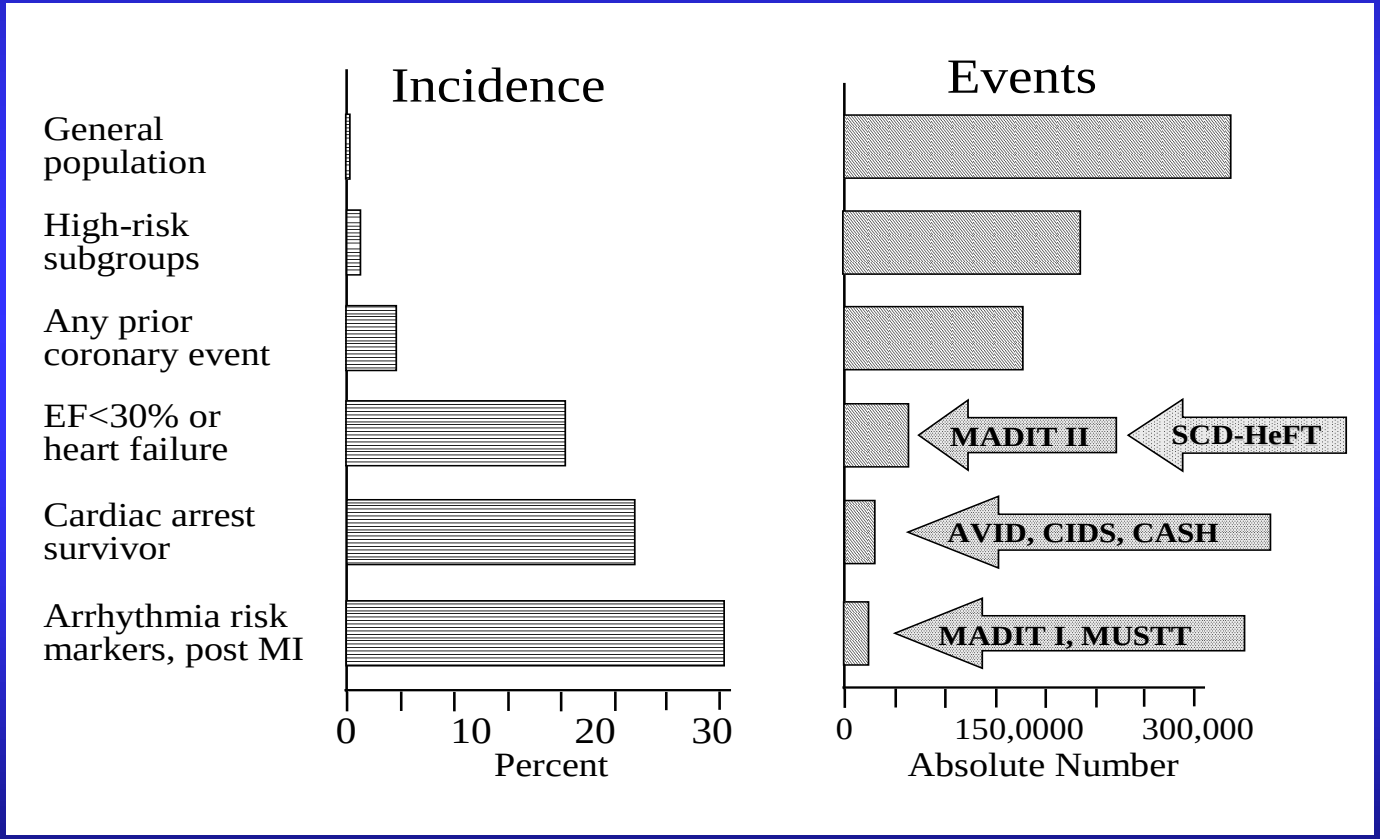
www.teamdefibrillators.com

How many ICDs is the right number??



Epidemiology of VA & SCD

Incidence of Sudden Cardiac Death



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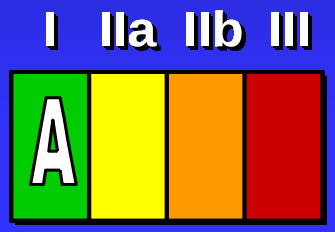
2009 ACC/AHA Heart Failure Guidelines



ICD therapy is recommended for **secondary prevention** of SCD in patients who survived VF or hemodynamically unstable VT, or VT with syncope and who have an LVEF less than or equal to 40%, who are receiving chronic optimal medical therapy, and who have a reasonable expectation of survival with a good functional status for more than 1 year.

Therapies Demonstrated to Reduce Mortality in Patients with Heart Failure and LVD

- ACE inhibitors or ARB
- Beta blockers (evidence based)
- Aldosterone antagonists (mild and moderate-severe HF)
- Hydralazine-isosorbide dinitrate (African Americans)
- ICD
  - LVEF ≤35, Class II or III
- Cardiac resynchronization
  - LVEF ≤35, QRS ≥120 ms, Class III or IV

The CONSENSUS Trial Study Group. *N Engl J Med.* 1987;316:1429-1435.
Packer M et al. *N Engl J Med.* 1996;334:1349-1355.
Pitt B et al. *N Engl J Med.* 1999;341:709-717.
Moss A et al. *N Engl J Med.* 1996;335:1933-1940.
Abraham WT et al. *N Engl J Med.* 2002;346:1845-1853.

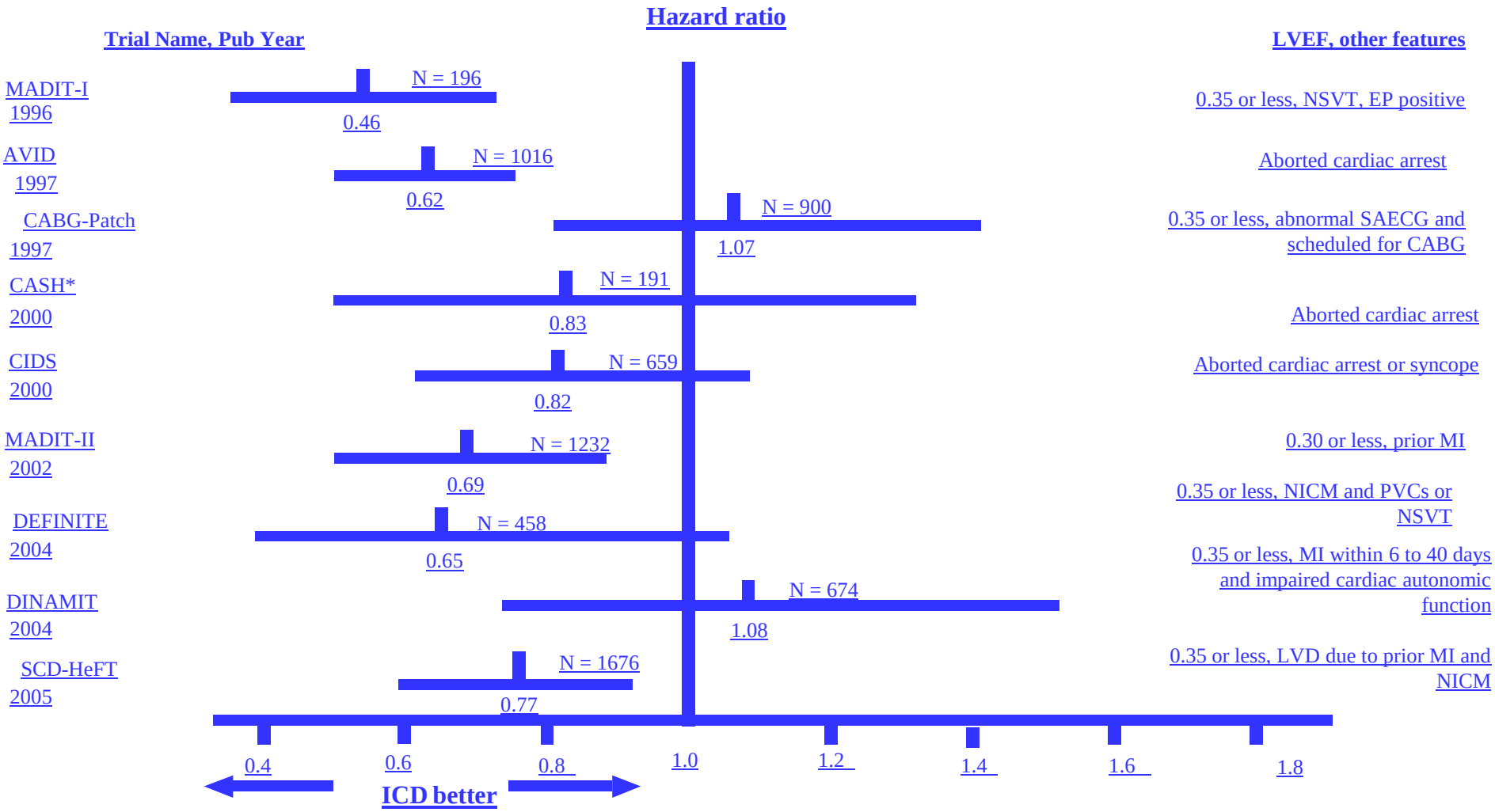
Primary Prevention ICD Use Saves Lives

- In heart failure patients with reduced ejection fraction and post-myocardial left ventricular dysfunction, implantable cardioverter-defibrillator (ICD) therapy reduces mortality by 23% to 36% over a 5 year period.[1]
- National guidelines recommend prophylactic use of ICDs in selected patients.[2,3]

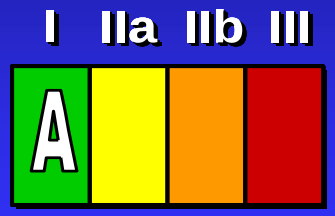
1. Kadish A, Mehra M. Circulation 2005;111:3327-3335
2. Hunt SA, et al. Circulation 2005;112:e154-e235
3. Eptein AE, et al. Circulation 2008;117:e350-e408

Therapies for Ventricular Arrythmias

ICDs: Results from Primary and Secondary Prevention Trials



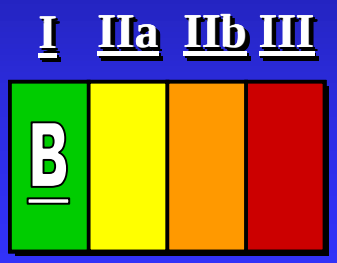
2009 ACC/AHA Heart Failure Guidelines



ICD therapy is recommended for **primary prevention** to reduce total mortality by a reduction in SCD in patients with LV dysfunction due to prior MI who

- are at least 40 days post-MI, have an LVEF less than or equal to 30% to 40%
- are NYHA functional class II or III receiving chronic optimal medical therapy
- who have reasonable expectation of survival with a good functional status for more than 1 year.

2009 ACC/AHA Heart Failure Guidelines



ICD therapy is recommended for **primary prevention** to reduce total mortality by a reduction in SCD in patients with nonischemic heart disease who

- have an LVEF less than or equal to 30% to 35%
- are NYHA functional class II or III
- are receiving chronic optimal medical therapy
- and who have reasonable expectation of survival with a good functional status for more than 1 year.

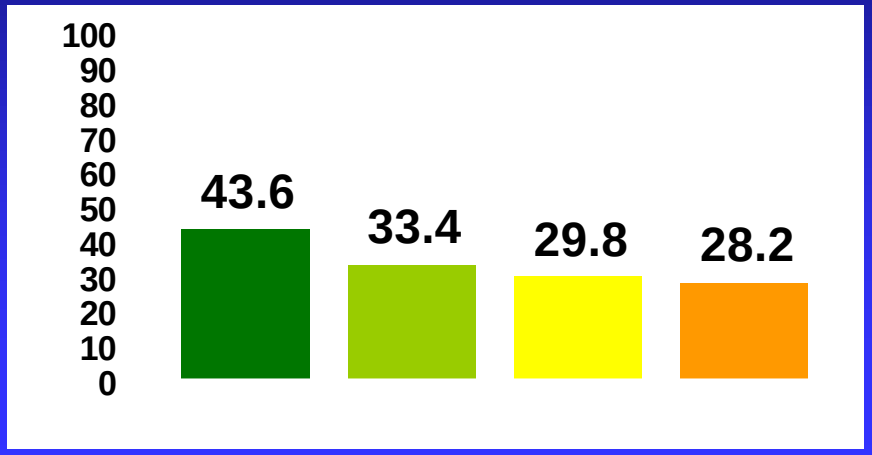
So, do we believe the guidelines?






How good are we at following guidelines?

Race and Gender Disparities in ICD Use at Discharge Among Eligible Patients With HF



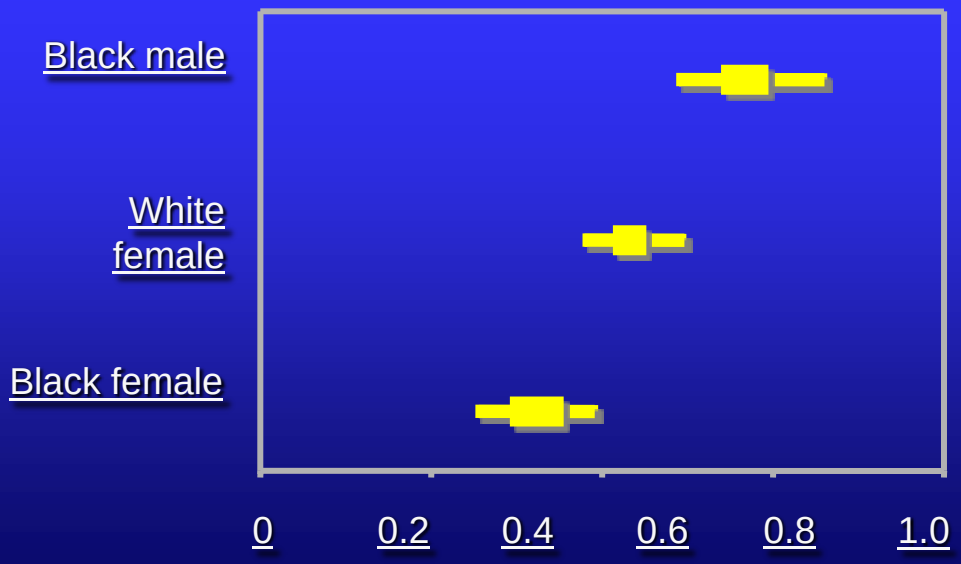


Table 3. Factors Associated With Implantable Cardioverter-Defibrillator Use (or Planned Use) at Discharge Among Eligible Patients With Heart Failure[a]

Characteristic[b]	Generalized Estimating Equations Model: Odds Ratio (95% Confidence Interval)	Generalized Estimating Equations Model: *P* Value	Hierarchical Model With Site as a Random Effect: Odds Ratio (95% Confidence Interval)	Hierarchical Model With Site as a Random Effect: *P* Value
Age, per 10-y increase	0.83 (0.80-0.86)	<.001	0.81 (0.78-0.84)	<.001
Sex and race				
Women	0.62 (0.56-0.68)	<.001	0.58 (0.52-0.65)	<.001
Black men vs white men	0.73 (0.60-0.88)	.001	0.68 (0.59-0.79)	<.001
Other men vs white men	0.74 (0.63-0.87)	<.001	0.71 (0.59-0.86)	<.001
Black women interaction[b]	1.25 (0.98-1.60)	.08	1.32 (1.07-1.61)	.008
Other women interaction[b]	1.46 (1.14-1.86)	.003	1.55 (1.13-2.12)	.007
Location				
Midwest vs West	1.37 (0.84-2.24)	.21		
Northeast vs West	1.13 (0.65-1.95)	.66		
South vs West	1.70 (1.03-2.80)	.04		
Insurance				
Other vs no insurance	1.92 (1.46-2.53)	<.001	2.07 (1.66-2.58)	<.001
Medicare vs no insurance	2.17 (1.65-2.85)	<.001	2.37 (1.89-2.98)	<.001
Medicaid vs no insurance	1.81 (1.33-2.47)	<.001	1.93 (1.50-2.49)	<.001
Systolic blood pressure, per 10-mm Hg increase	0.89 (0.88-0.91)	<.001	0.89 (0.87-0.90)	<.001
Anemia	0.76 (0.64-0.90)	.03	0.75 (0.65-0.86)	<.001
Atrial fibrillation	1.13 (1.01-1.27)	.03	1.14 (1.03-1.26)	.01
Chronic dialysis	0.67 (0.53-0.85)	.001	0.66 (0.51-0.86)	.002
Diabetes mellitus			0.91 (0.83-0.99)	.03
Hyperlipidemia	1.40 (1.26-1.55)	<.001	1.46 (1.33-1.60)	<.001
Hypertension	0.89 (0.81-0.99)	.03	0.89 (0.81-0.98)	.02
Ischemic heart disease	1.35 (1.19-1.52)	<.001	1.41 (1.28-1.56)	<.001
Smoking	0.72 (0.65-0.80)	<.001	0.69 (0.62-0.76)	<.001

[a] Empty table cells denote nonsignificance.
[b] Listed variables are significant factors in the final model that influenced implantable cardioverter-defibrillator use. Variables in the initial model included age, female sex, race, interaction of race and sex, systolic blood pressure, insurance (Medicare, Medicaid, other, and no insurance), medical history variables including anemia, atrial fibrillation, cerebrovascular accident/transient ischemic attack, depression, diabetes mellitus, dialysis, hypertension, hyperlipidemia, chronic obstructive pulmonary disease, peripheral vascular disease, renal insufficiency, smoker, and geographic region (West, Northeast, Midwest, South).

Hernandez, A. F. et al. JAMA 2007;298:1525-1532.

IMPROVE HF Study Overview

- Largest, most comprehensive registry and quality improvement study for HF patients in the outpatient cardiology practice setting
- Designed to evaluate utilization rates of evidence-based, guideline-recommended HF therapies since release of contemporary guidelines
- Practice based performance improvement intervention being tested to determine if quality of care can be improved.
- 167 US Cardiology Practices, 15,381 patients at baseline and 43,000 total records planned for review

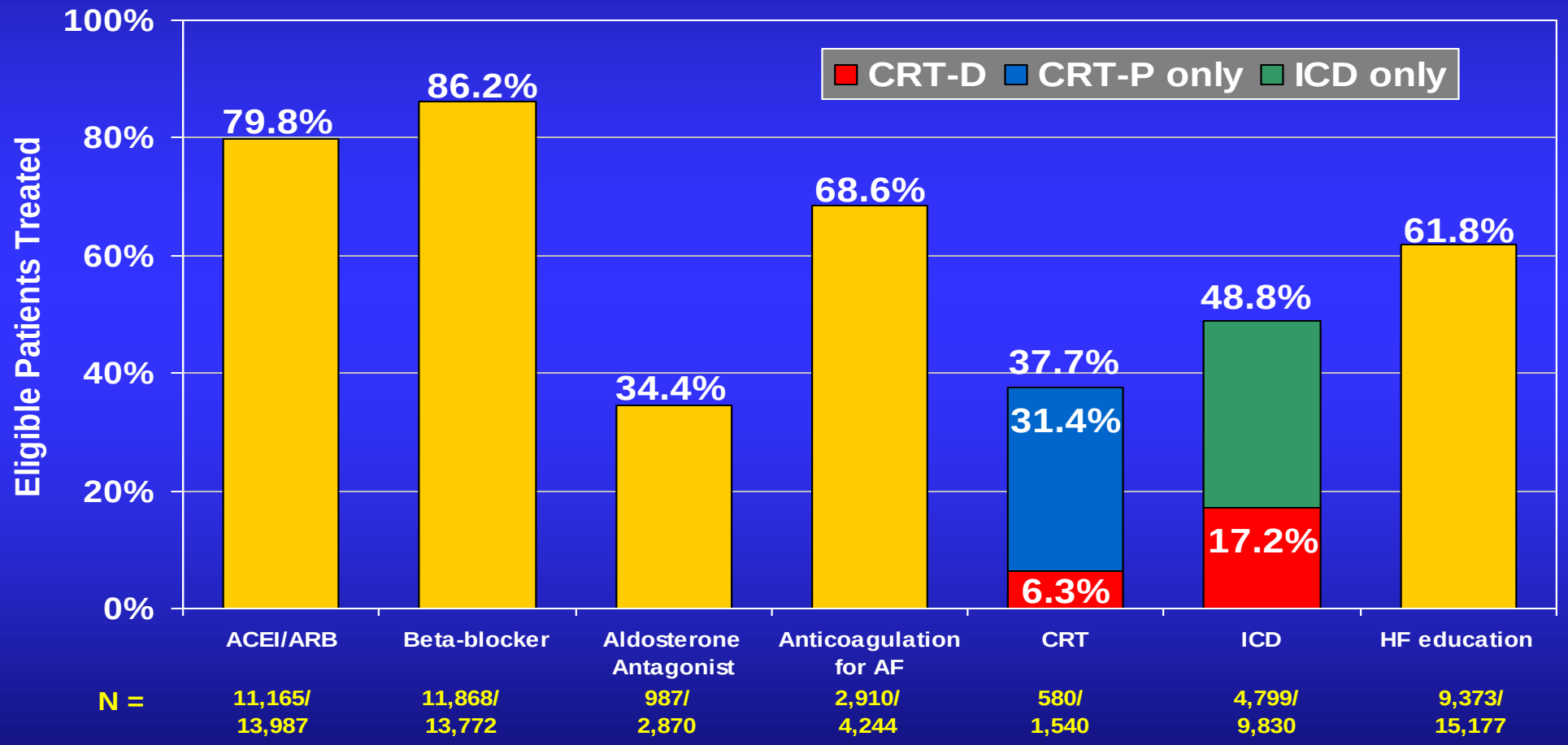
Fonarow GC, et al. Circ Heart Fail. 2008;1:98–106

Methods: Patient Selection, Practice Selection, Data Collection and Management

- Patient Inclusion:
  - Clinical diagnosis of HF or prior MI with at least 2 prior clinic visits within 2 years
  - LVEF ≤ 35% or moderate to severe left ventricular dysfunction
- Patient Exclusion:
  - Cardiac transplantation
  - Estimated survival <1 year from non-cardiovascular condition
- Average of 90 eligible patients per practice randomly selected for each of 3 study cohorts
- Practices: Outpatient cardiology (single specialty or multi-specialty) practices from all regions of the country
- Data quality measures
  - 34 trained, tested chart review specialists
  - Training oversight by study steering committee members
  - Monthly quality reports
  - Automated data field range, format, unit checks
- Chart abstraction quality
  - Interrater reliability averaged 0.82 (kappa statistic)
  - Source documentation audit sample concordance rate range of 92.3% to 96.3%
- Coordinating center: Outcome Sciences, Inc. (Cambridge, MA)
  - Individual practice data not shared with sponsor or steering committee

IMPROVE HF: Baseline quality measures

Conformity with Quality Measures at Baseline



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

Eligibility Criteria for Use of ICDs

Inclusion criteria:

- NYHA class II or class III HF AND quantitative LVEF ≤ 35%

OR

- NYHA class I HF *or* no limitation to physical activity with history of prior MI *or* primary or secondary diagnosis of MI AND quantitative LVEF ≤ 30%

Exclusion criteria:

- Documentation of medical* or patient† reason(s) for not prescribing ICD or CRT-D
- NYHA class missing or outside of eligibility criteria

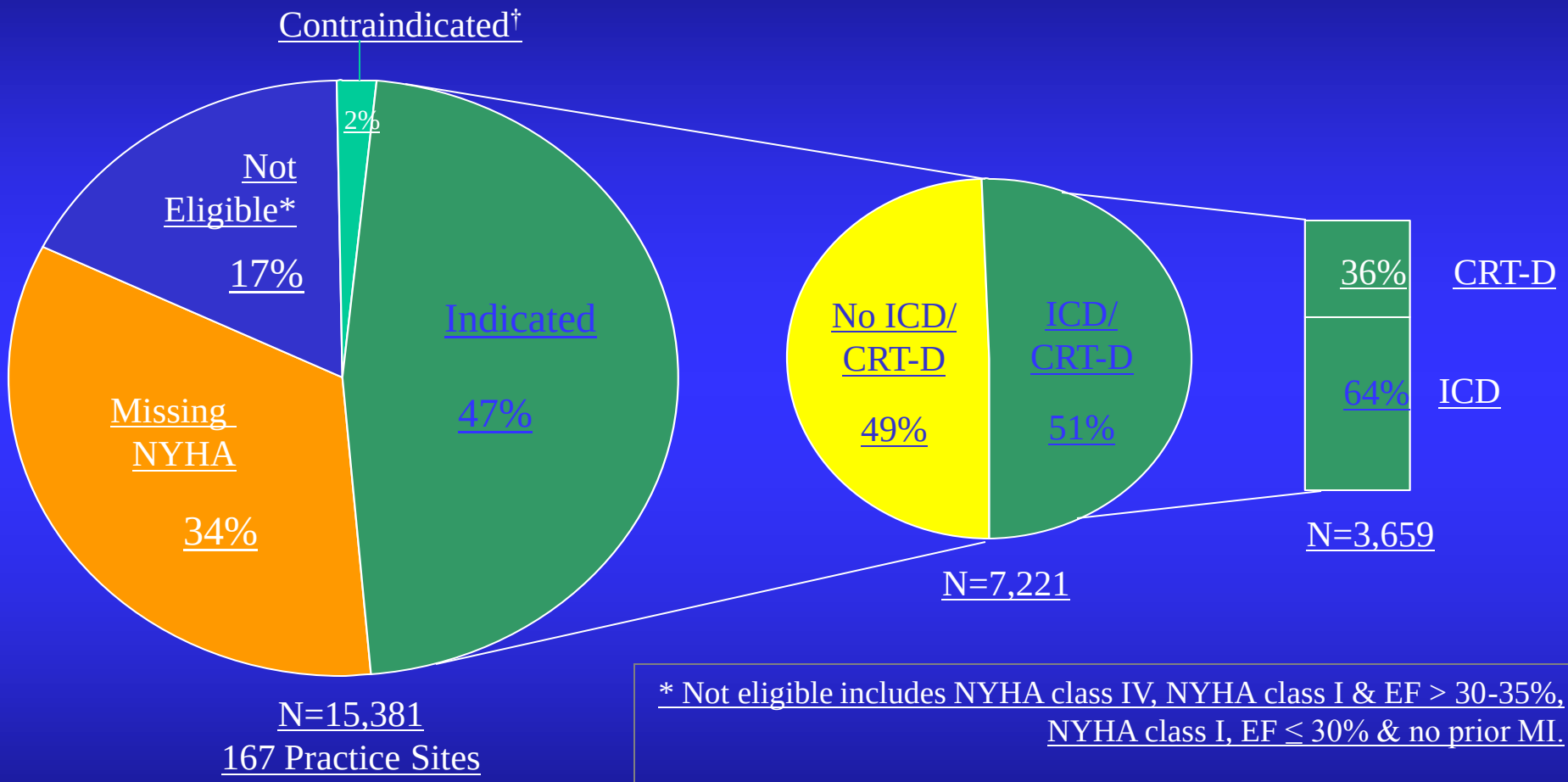
* Including contraindications to standard cardiac pacing OR history of NYHA class IV HF

† including economic, social, religious or other reason noted by patient

Patients with condition(s) which limit one year survival documented or receiving dialysis were excluded from IMPROVE HF

Mehra MR, et al. *Heart Rhythm* 2009;6:1727-1734

Results: 51% of Eligible Patients Received an ICD or CRT-D

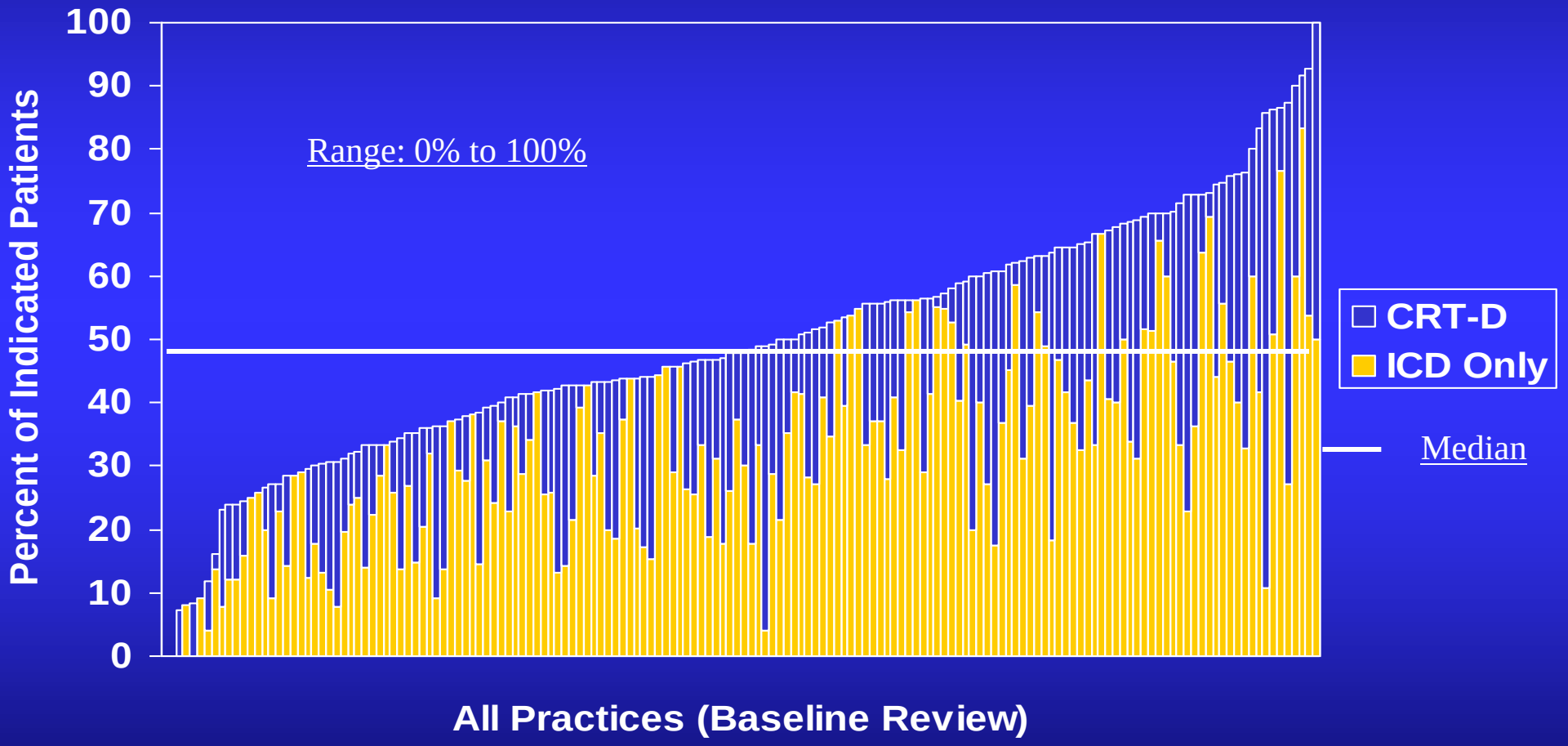


* Not eligible includes NYHA class IV, NYHA class I & EF > 30-35%, NYHA class I, EF ≤ 30% & no prior MI.

† Contraindicated includes documented medical, physician, or patient reasons for lack of implant.

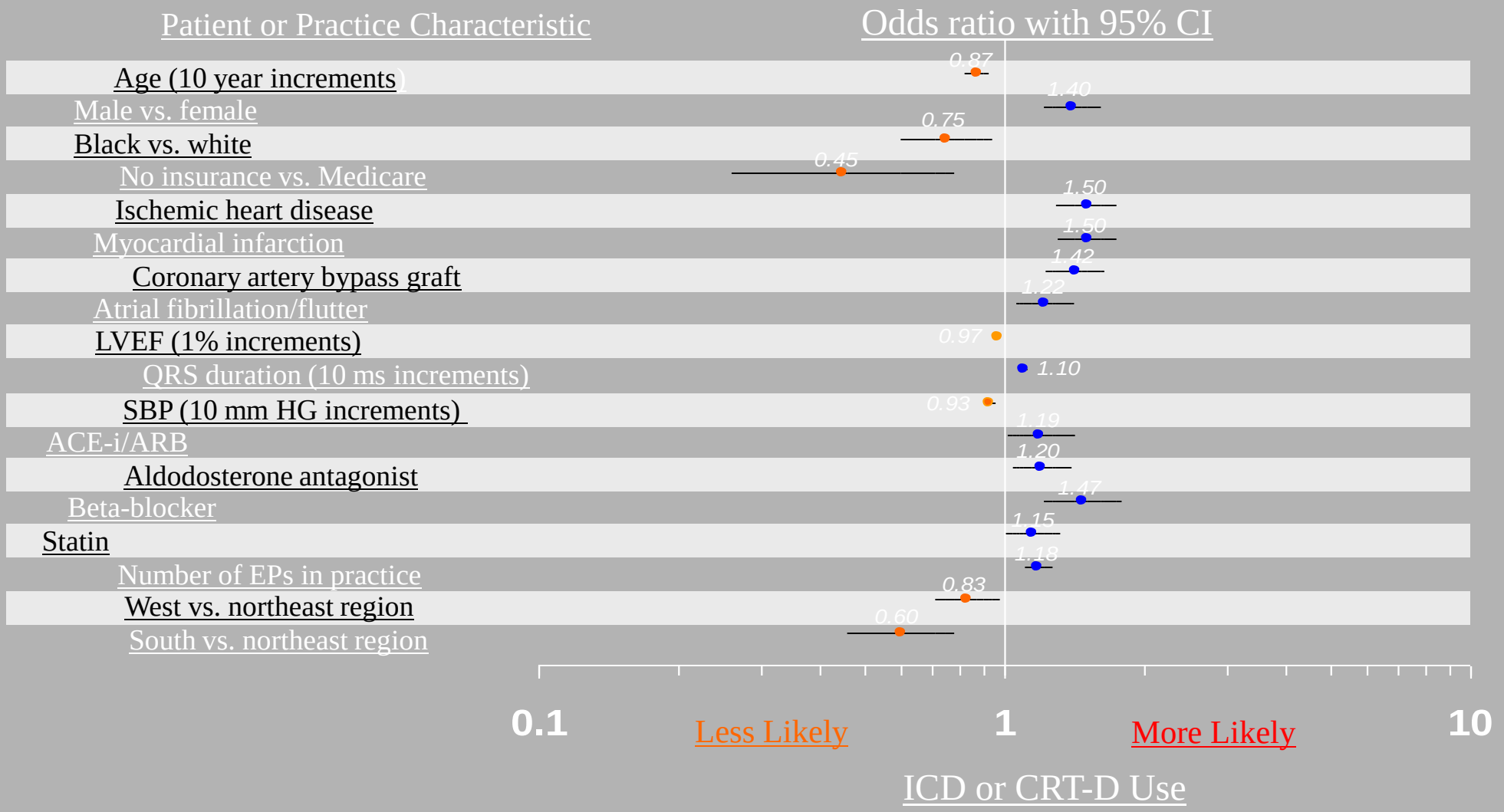
Mehra MR, et al. *Heart Rhythm* 2009;6:1727-1734

Results: Wide Practice Variation in Guideline Recommended ICD Use (sites with ≥ 5 eligible patients)



Mehra MR, et al. *Heart Rhythm* 2009;6:1727-1734

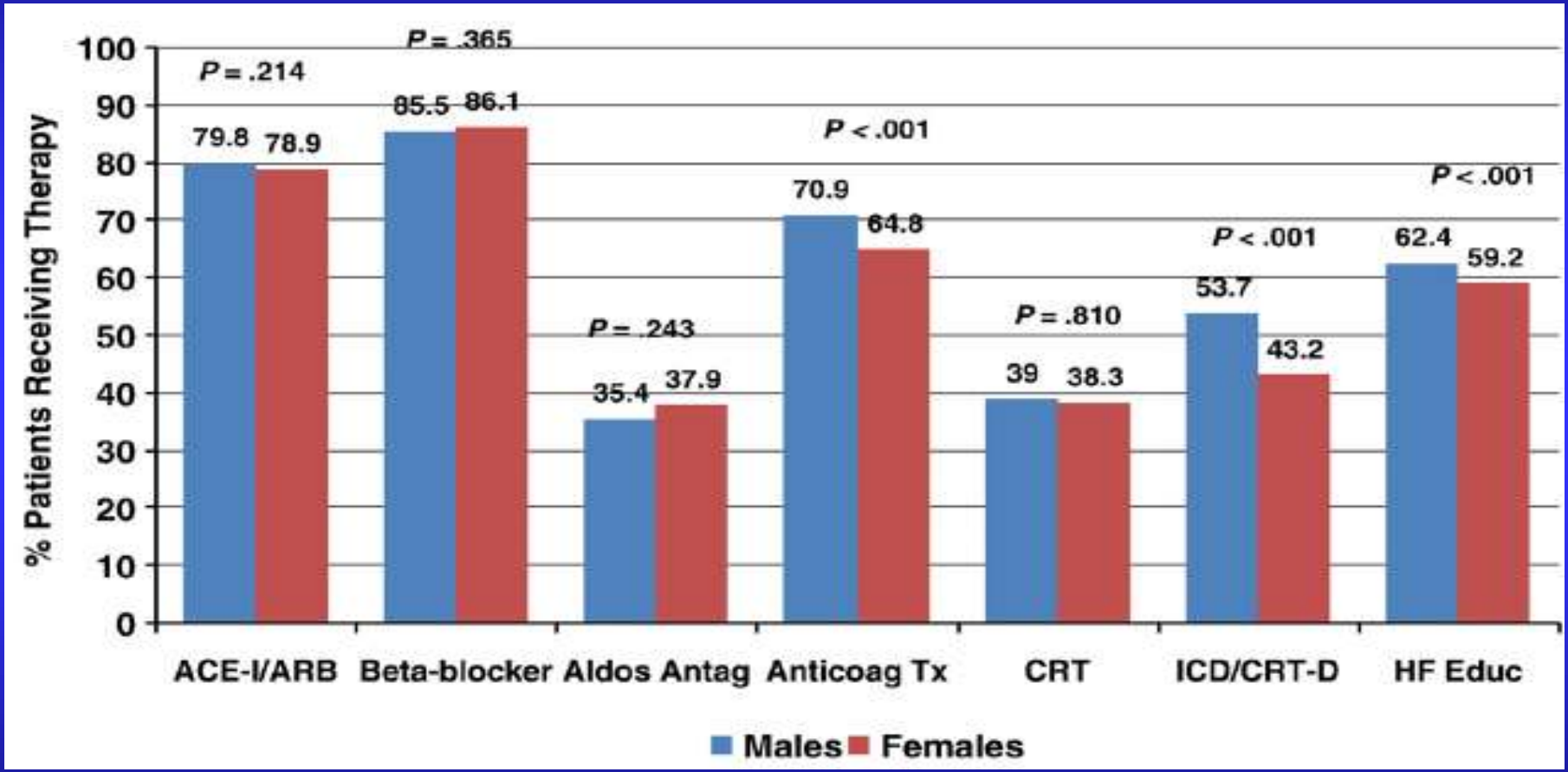
Results: Significant Predictors of ICD/CRT-D Use from Multivariate Analysis



Mehra MR, et al. *Heart Rhythm* 2009;6:1727-1734

IMPROVE HF

Patients Receiving Recommended HF Therapies – by Sex



Conclusions: Significant differences by sex were observed for anticoagulant therapy, ICD/CRT-D therapy, and HF education, with higher rates evident for men.

Yancy CW et al. Am Heart J. 2009 Apr;157(4):754-762.e2.

Absolute Improvement in Quality Measures for Only Patients With Baseline and 24-Month Data by Patient Sex

Quality Measure (expressed in %)	Men (N=5,422)			Women (N=2,181)			P Value		
	Base-line	24 mo	Δ	Base-line	24 mo	Δ	Base-line*	24 mo*	Δ†
ACEI/ARB	83.2	86.1	+2.9	82.3	87.4	+5.1	.384	.201	.125
ß-blocker	88.3	93.6	+5.3	88.8	93.5	+4.7	.616	.866	.594
Aldosterone Antagonist	32.7	59.8	+27.1	40.8	66.3	+25.5	.005	.029	.700
Anticoagulation for AF	73.1	70.7	-2.4	69.2	64.4	-4.8	.094	.004	.465
CRT-P/CRT-D	40.5	65.8	+25.3	42.5	75.2	+32.7	.618	.003	.142
ICD/CRT-D	57.4	80.4	**+23.0**	47.1	75.6	**+28.5**	<.001	<.001	**.006**
HF education	60.3	71.6	+11.3	58.1	69.1	+11.0	.083	.034	.864
Composite	71.2	80.5	+9.3	68.8	79.1	+10.3	<.001	.013	.123
All-or-none	27.0	43.8	+16.9	25.0	44.1	+19.1	.079	.838	.033

* Comparison of % of men vs. women receiving quality measure † Difference in absolute change percentage between sexes

Walsh MN, et al. J Cardiac Fail. 2010;122:.

Circulation
Heart Failure
JOURNAL OF THE AMERICAN HEART ASSOCIATION

American Heart Association
Learn and Live

Quality of Care and Outcomes in Women Hospitalized for Heart Failure

Liviu Klein, Maria V. Grau-Sepulveda, Robert O. Bonow, Adrian F. Hernandez, Mark V. Williams, Deepak L. Bhatt and Gregg C. Fonarow

Circ Heart Fail 2011;4;589-598; originally published online August 23, 2011;
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 Print ISSN: 1941-3289. Online ISSN: 1941-3297

Table 3. Performance Measures and Other Quality Metrics, Stratified by Sex

Characteristic	Women (n=49 225)	Men (n=50 616)	P*
Complete set of written instructions at time of discharge (n=72 659)	85	87	<0.001
Documentation of evaluation of LV function (n=88 483)	95	96	<0.001
ACEI/ARB prescription for LVSD (n=34 087)	89	89	0.43
Adult smoking cessation counseling (n=15 291)	94	94	0.42
b-blocker prescription for LVSD (n=37 910)	92	93	<0.001
Defect-free measure (100% compliance with all 5 primary measures) (n=89 282)	80	79	<0.001
Composite measure (n=48 430)	91	92	<0.001
Warfarin at discharge for patients with atrial fibrillation (n=27 365)	59	64	<0.001
Evidence based β-blockers prescription for LVSD (n=37 539)	72	74	<0.001
Aldosterone antagonists prescription for LVSD (n=39 660)	25	26	<0.001
Black patients with LVSD prescribed hydralazine/isosorbide dinitrate (n=11 332)	24	28	<0.001
ICD in patients with LVEF ≤35% (before admission or placed during admission) (n=31 783)	32	45	<0.001

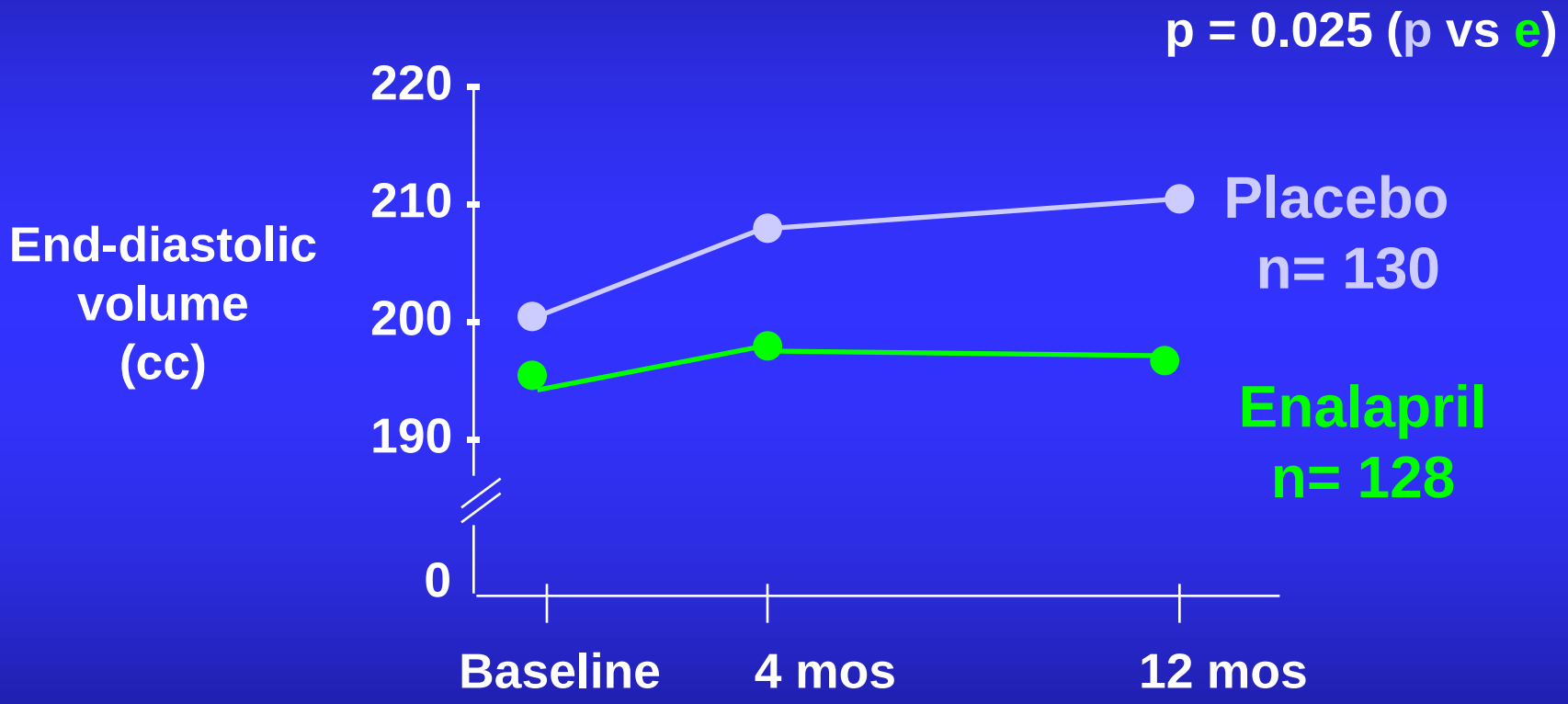
So, How Do We Decide Which of OUR Patients Will Benefit From an ICD?

1) Make sure they're maximally treated

Therapies That Reverse Remodeling and Improve Ejection Fraction

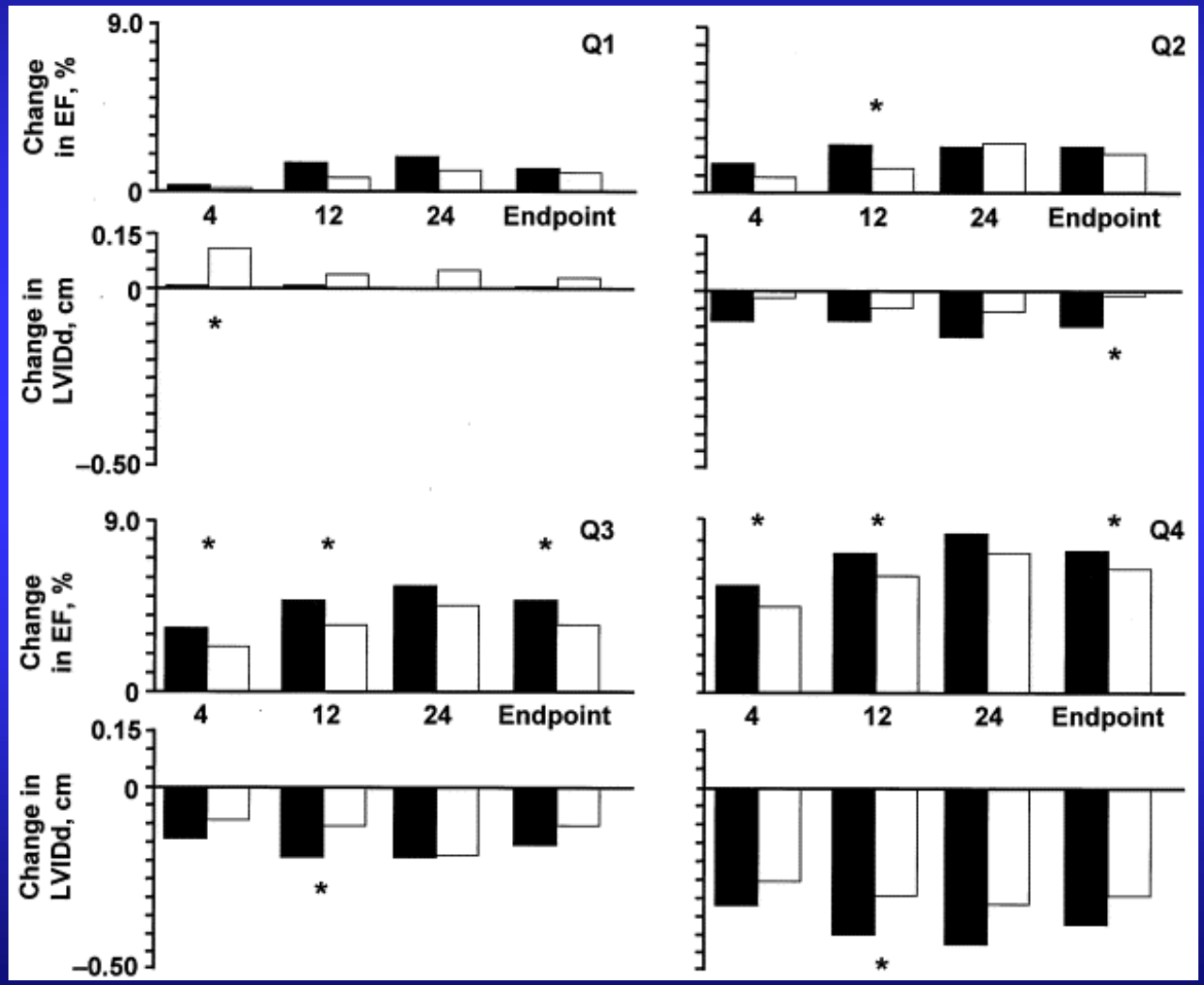
- ACE inhibitors
- ARBs
- Beta blockers
- Aldosterone inhibitors
- Revascularization (CABG, PTCA)
- CRT
- Treatment of tachyarrhythmias

SOLVD Echocardiographic Substudy
Effects of enalaril on remodeling



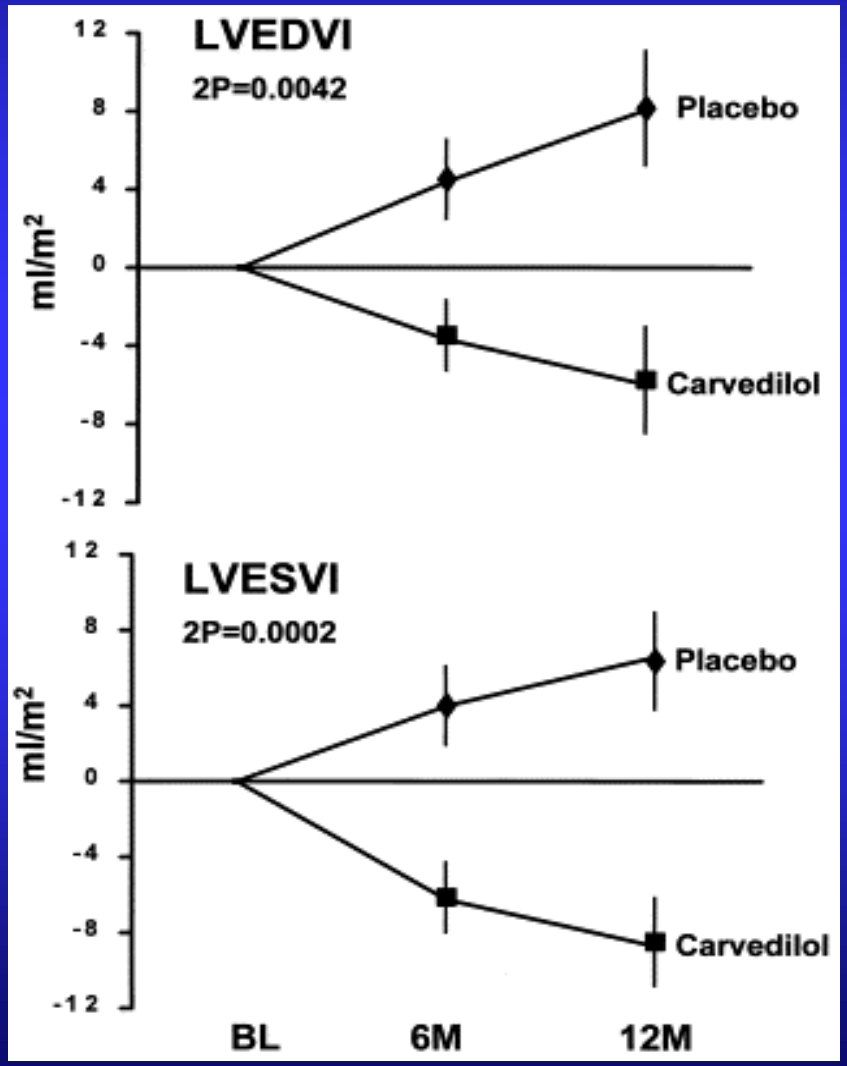
Greenberg B., et al. Effects of long-term enalapril therapy on cardiac structure and function in patients with left ventricular dysfunction. Results of the SOLVD echocardiography substudy. Circulation 1995;91:2573-2581.

ValHeFT:Changes in LVEF and LV volume with Valsartan



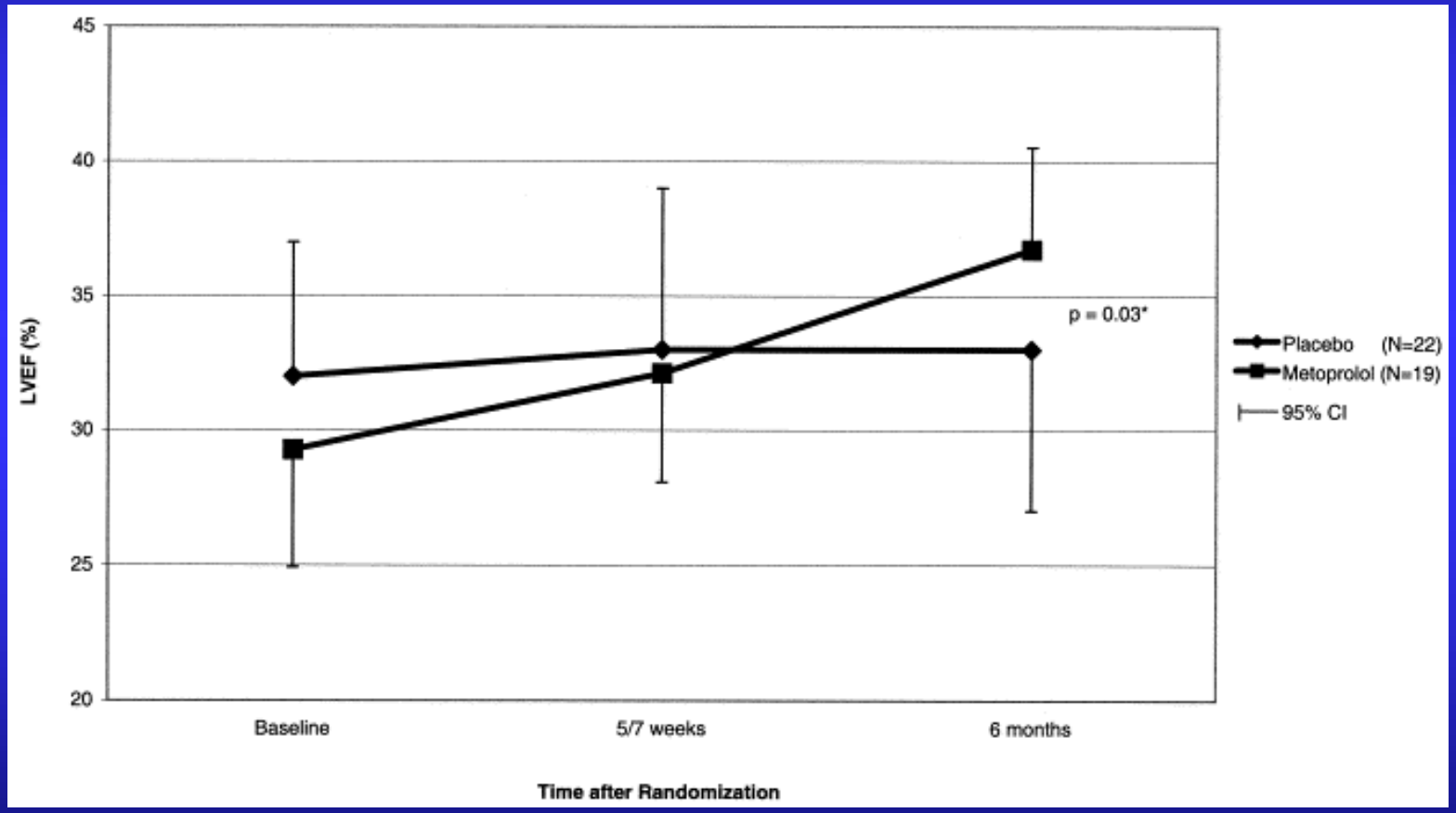
J Am Coll Cardiol 2004;43:2022

Australia-New Zealand Trial: Carvedilol



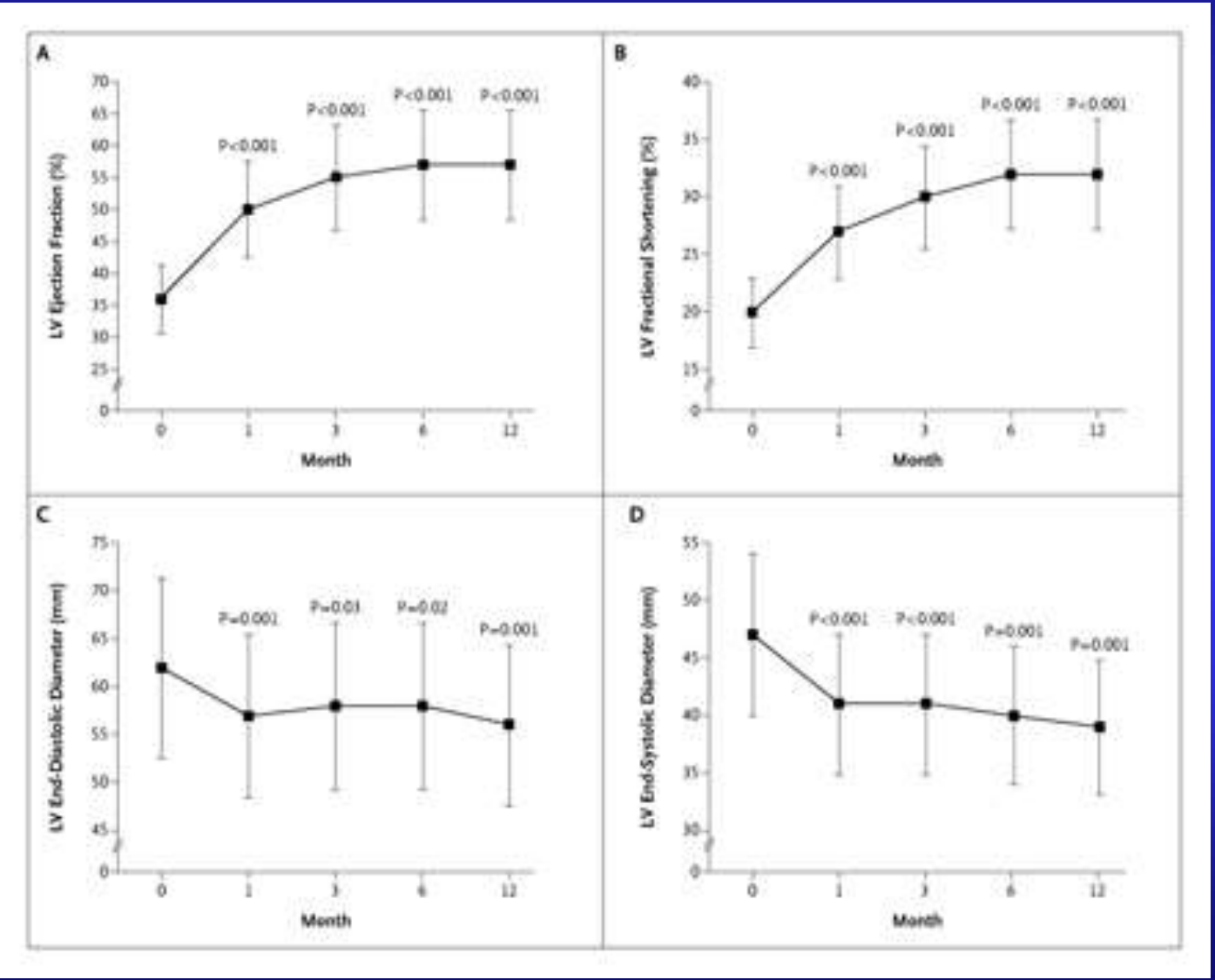
J Am Coll Cardiol 1997;29:1060

MERIT-HF: Changes in LVEF with Metoprolol (MRI)



J Am Coll Cardiol 2000;36:2072

Affect of Afib Ablation on LVEF in Patients with CHF



N Engl J Med 2004;351:2373

So, How Do We Decide Which of OUR Patients Will Benefit From an ICD?

1) Make sure they're maximally treated
2) Reassess the ejection fraction

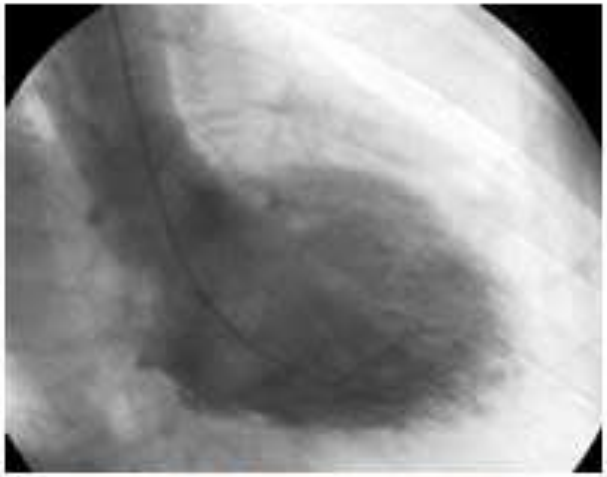
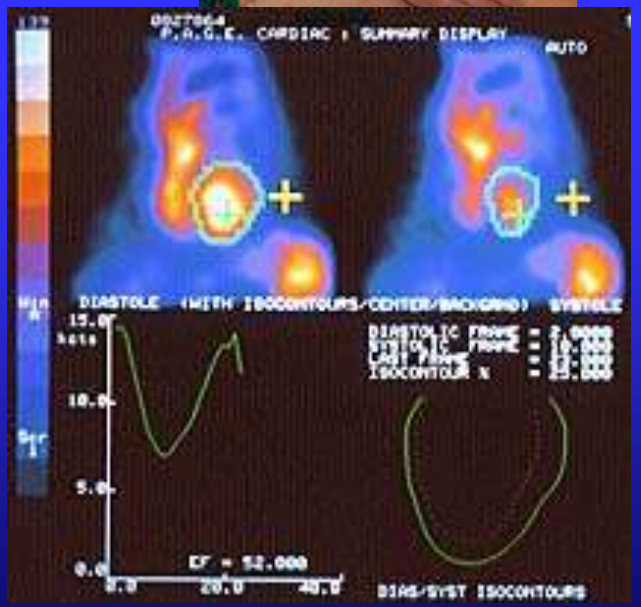


Figure 3: Left Ventriculogram
(heart filled in diastole)



So, How Do We Decide Which of OUR Patients Will Benefit From an ICD?

1) Make sure they're maximally treated
2) Reassess the ejection fraction
3) Know your patient; assess comorbidities

Should THESE Patients with a Low EF have an ICD?

How About These Patients?

What role does the patient play?

Shared Decision Making

- “the process of interacting with patients who wish to be involved in arriving at an informed, values-based choice among two or more medically reasonable alternatives”

Shared Decision Making involves:

- estimating patients' outcomes as a function of their individual risks
- defining these outcomes as a function of alternative treatments
- sharing this information with patients in a manner that they can understand

Many Patients with a Low Ejection Fraction Will Benefit From a Defibrillator

After:

- **aggressive medical management**
- **accurate reassessment of LV function**
- **A critical eye toward issues of longevity/other disease**
- **TEAMWORK between EP and CHF docs**
- **Shared decision making**


I
My
Electrophysiologist