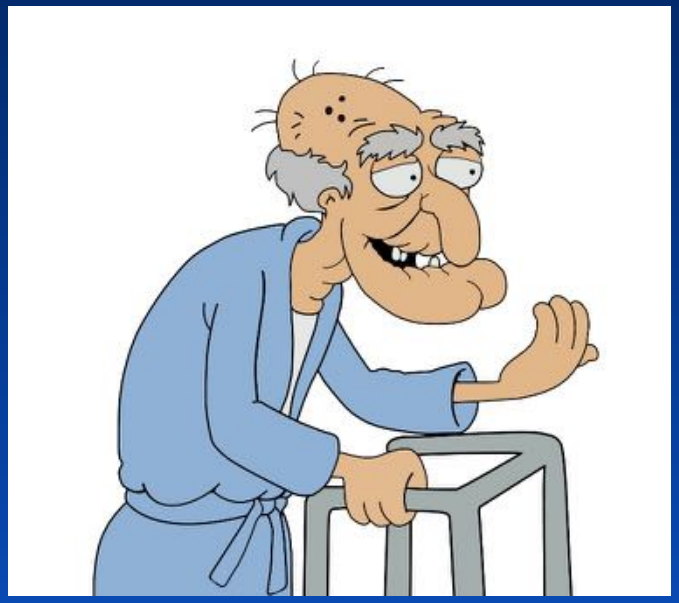


Subcutaneous ICD Therapy: Is there a role in the elderly?

Ronald Berger, MD, PhD

Johns Hopkins University

October 16 - 18
14th EDITION 2015

MY CONFLICTS OF INTEREST ARE:

Consultant: Boston Scientific, Zoll

Royalties: Zoll

Educational Grants: Boston Scientific, Medtronic, St Jude, Biosense Webster

Original Investigation

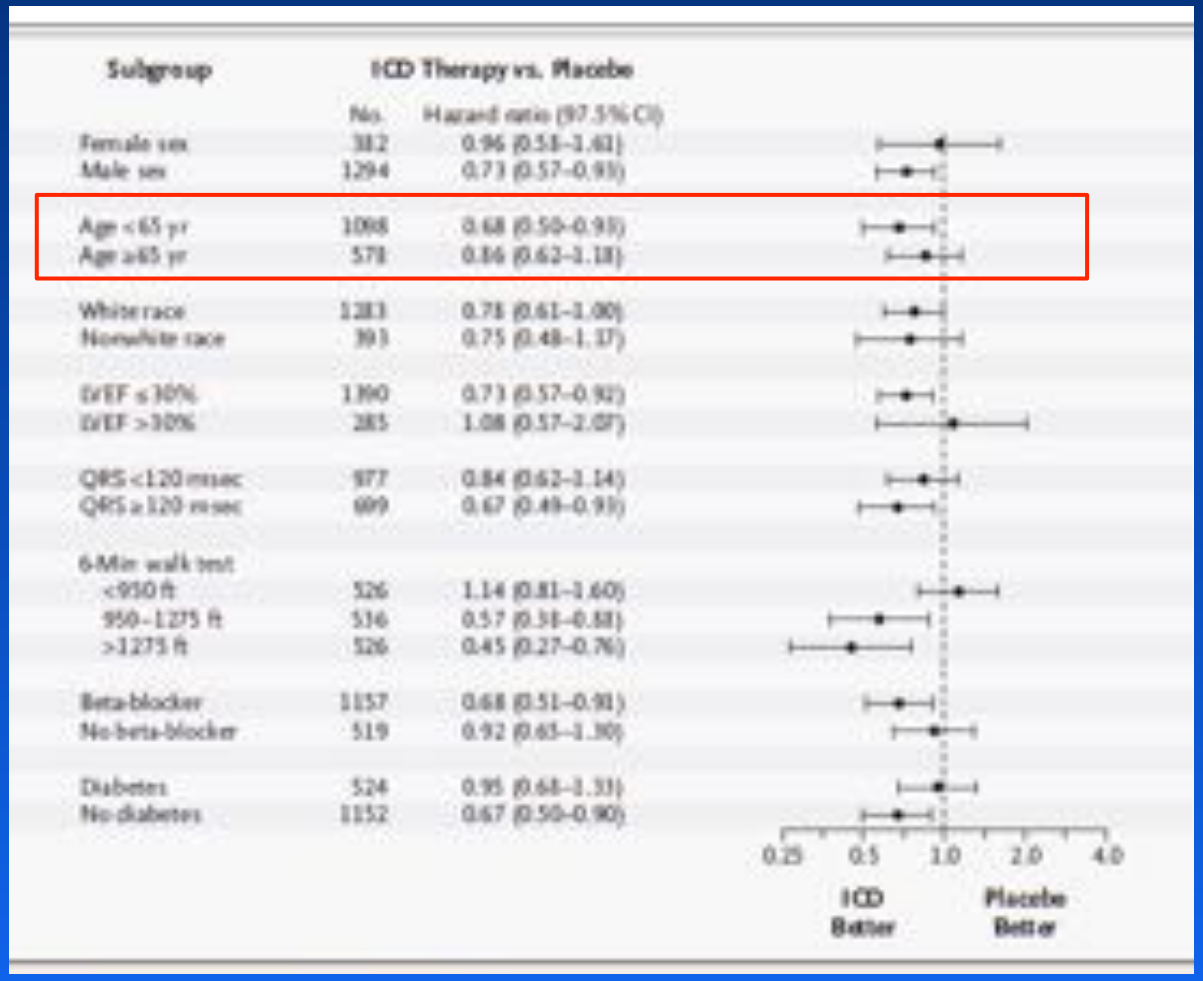
Implantable Cardioverter-Defibrillator Use Among Medicare Patients With Low Ejection Fraction After Acute Myocardial Infarction

Sean D. Pokorney, MD, MBA; Amy L. Miller, MD, PhD; Anita Y. Chen, MS; Laine Thomas, PhD; Gregg C. Fonarow, MD; James A. de Lemos, MD; Sana M. Al-Khatib, MD, MHS; Eric D. Peterson, MD, MPH; Tracy Y. Wang, MD, MHS, MSc

CONCLUSIONS AND RELEVANCE 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.

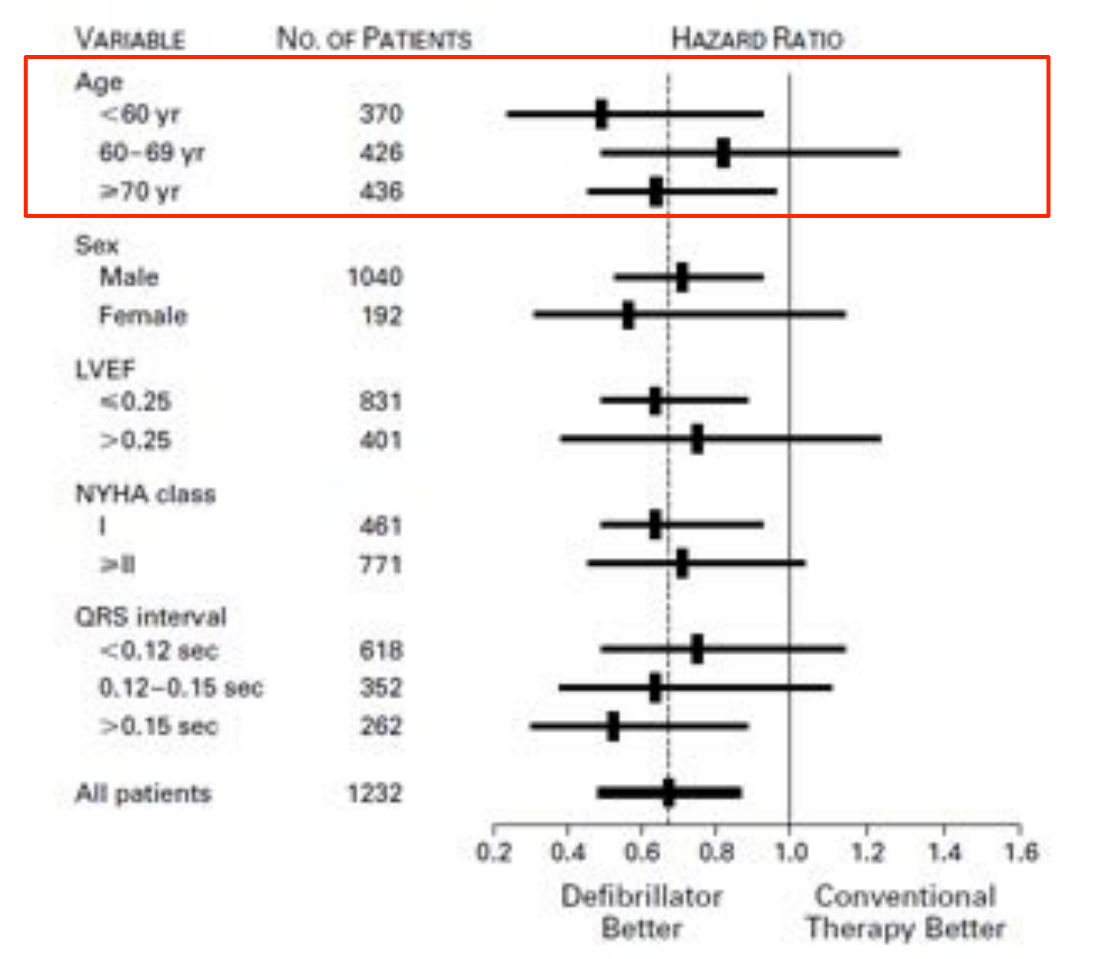
JAMA. 2015; 313:2433-40

SCD-HeFT



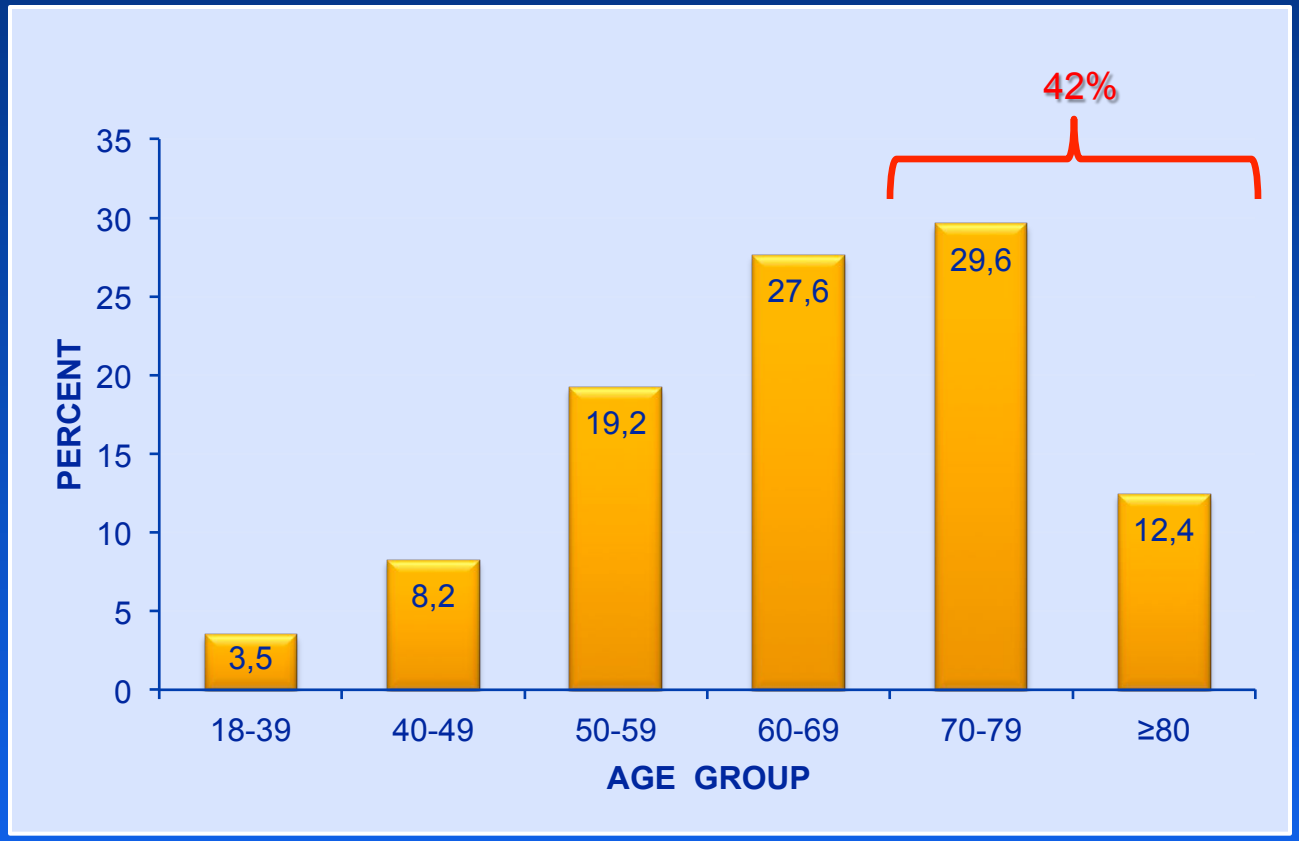
Bardy et al, NEJM 2005; 352:225-37

MADIT-II



Moss et al, NEJM 2002; 346:877-83

NCDR: ICD Implant Age Distribution



Epstein et al, Heart Rhythm 2009; 6:1136-43

S-ICD

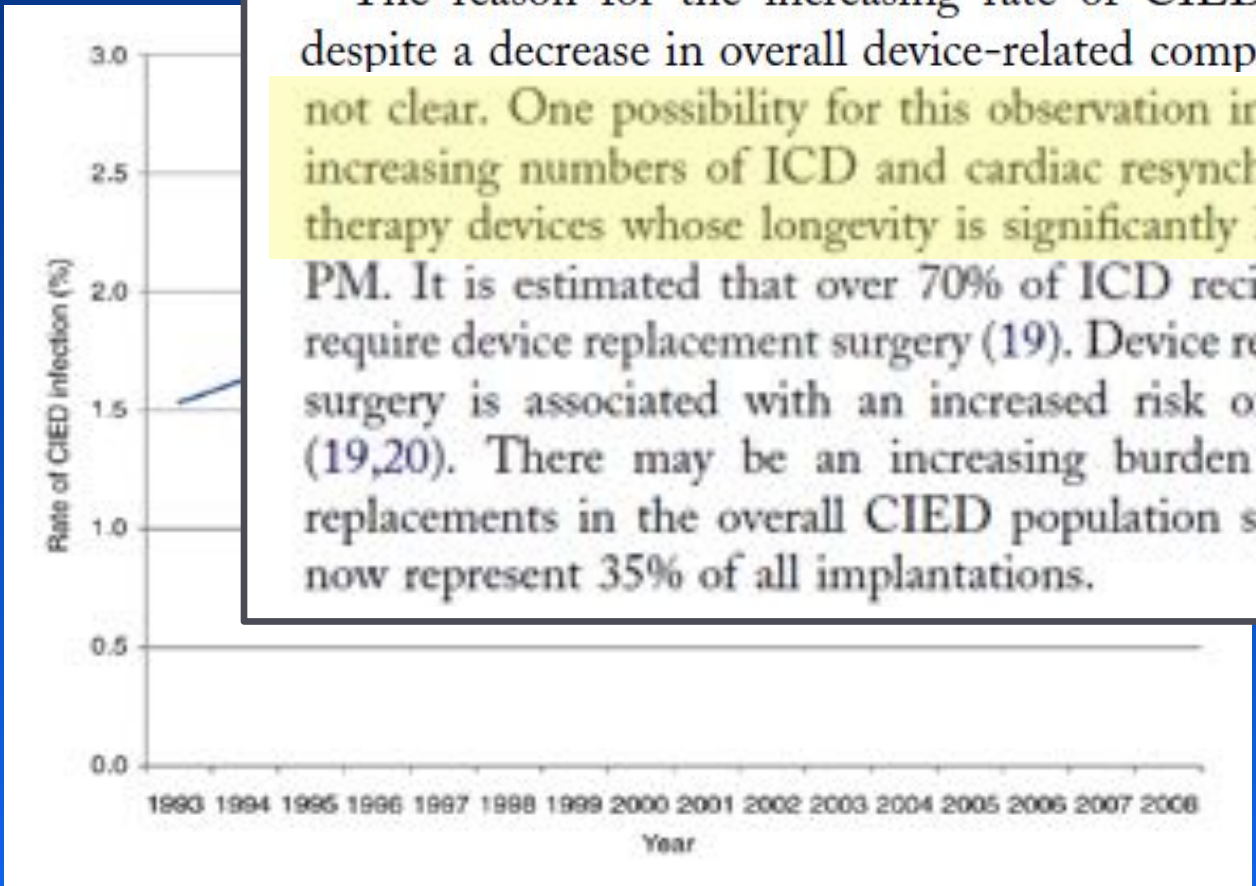
Pros:

- No intravascular/intracardiac leads
- No vascular access or related complications
- No endocarditis
- No downstream need for risky extraction

Cons:

- Multiple incisions
- Need for defib testing
- Greater need for anesthesia at implant
- No brady pacing
- No anti-tachy pacing
- No CRT
- Larger device
- Shorter battery longevity
- Higher cost

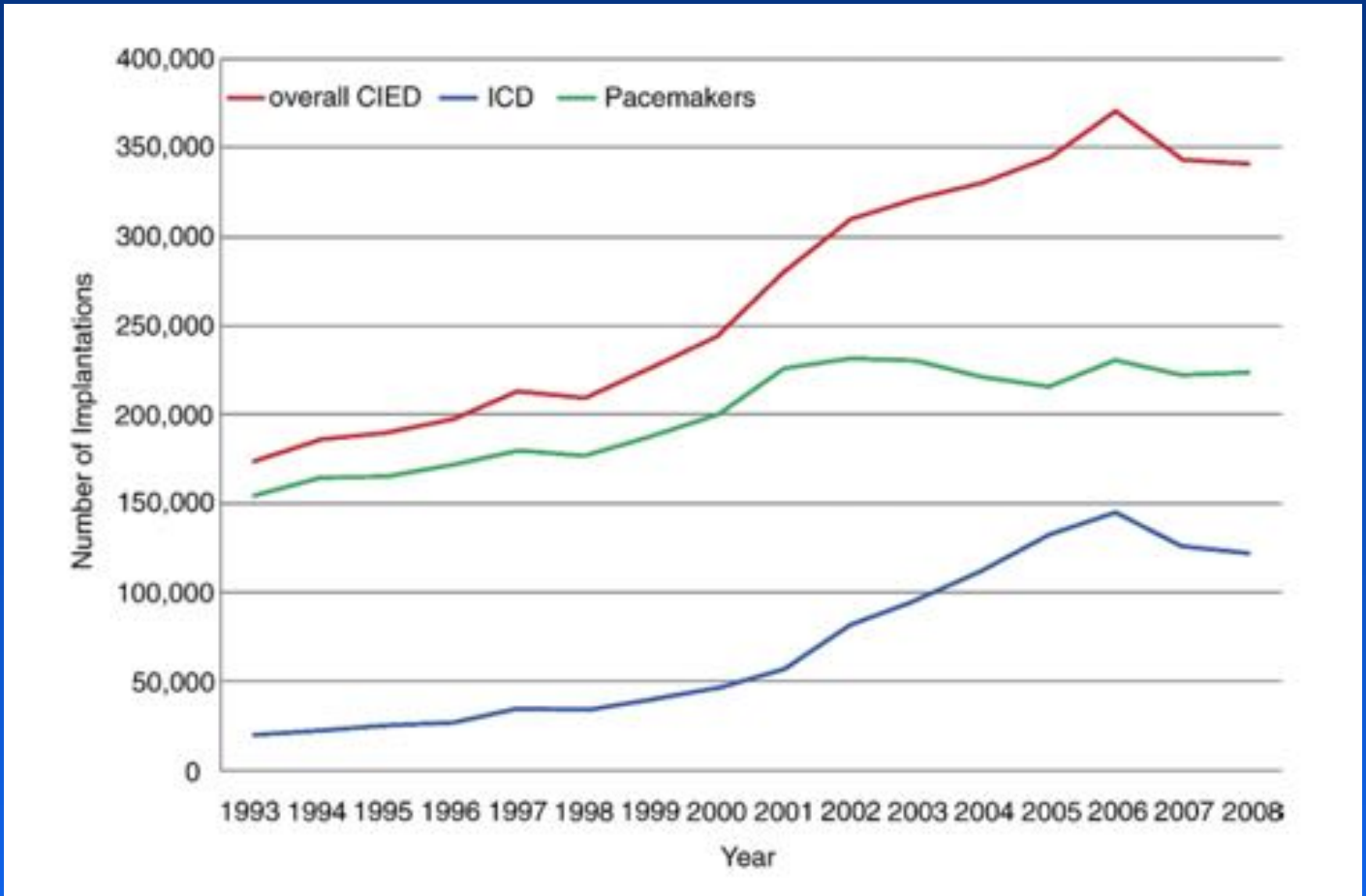
Rate of Infection in ICDs and Pacers



The reason for the increasing rate of CIED infection despite a decrease in overall device-related complications is not clear. One possibility for this observation includes the increasing numbers of ICD and cardiac resynchronization therapy devices whose longevity is significantly lower than PM. It is estimated that over 70% of ICD recipients will require device replacement surgery (19). Device replacement surgery is associated with an increased risk of infection (19,20). There may be an increasing burden of device replacements in the overall CIED population since ICDs now represent 35% of all implantations.

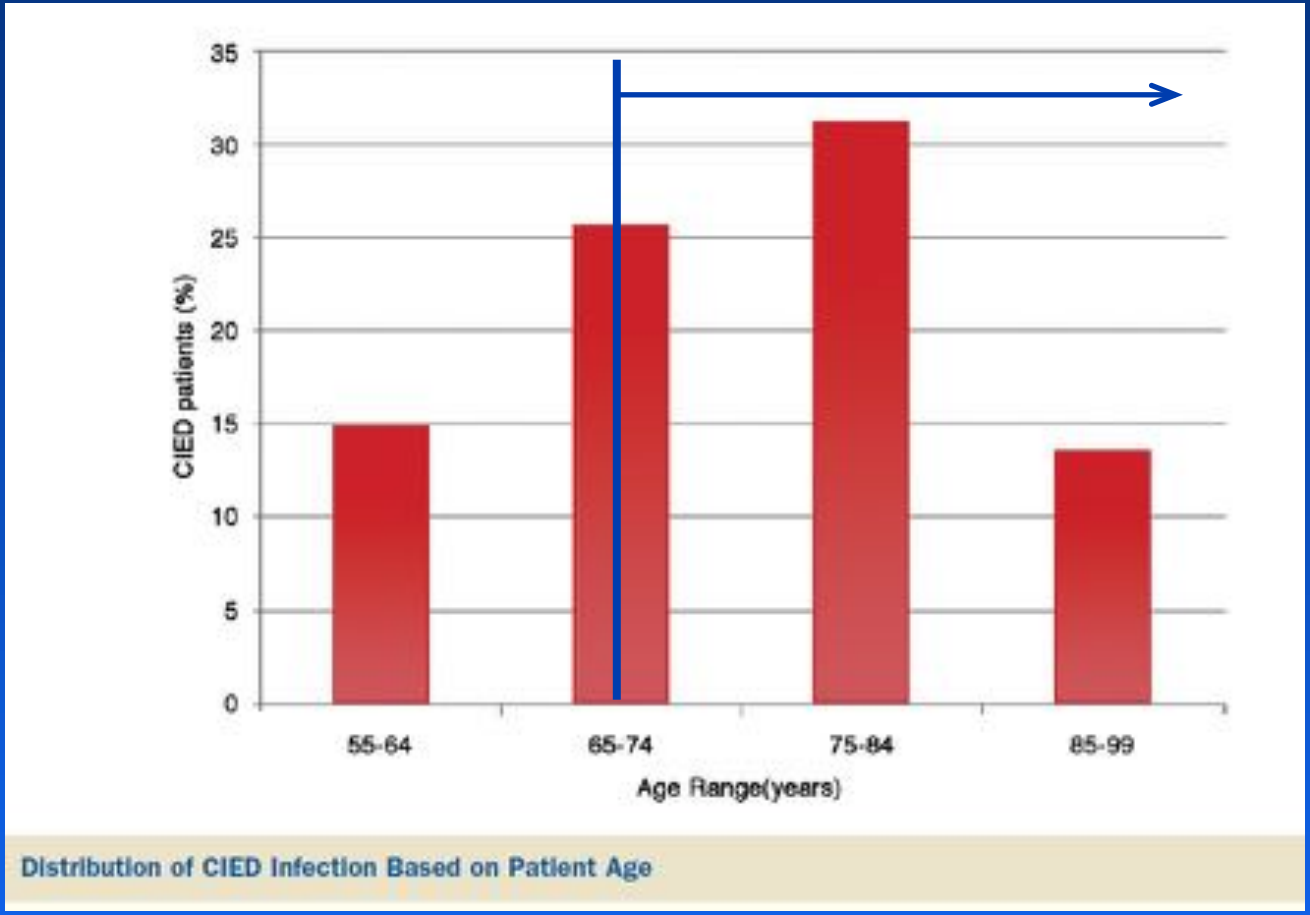
Greenspon et al, JACC 2011; 58:1001-6

Rising Rates of ICD Implants



Greenspon et al, JACC 2011; 58:1001-6

High rate of CIED infections in elderly



Distribution of CIED Infection Based on Patient Age

Greenspon et al, JACC 2011; 58:1001-6

Mortality with CIED Infection

197 patients with infected CIED followed ≥1 yr (median 25 months)

Table 4 Univariate and multivariate predictors of long-term mortality in patients with cardiac implantable electronic device infection

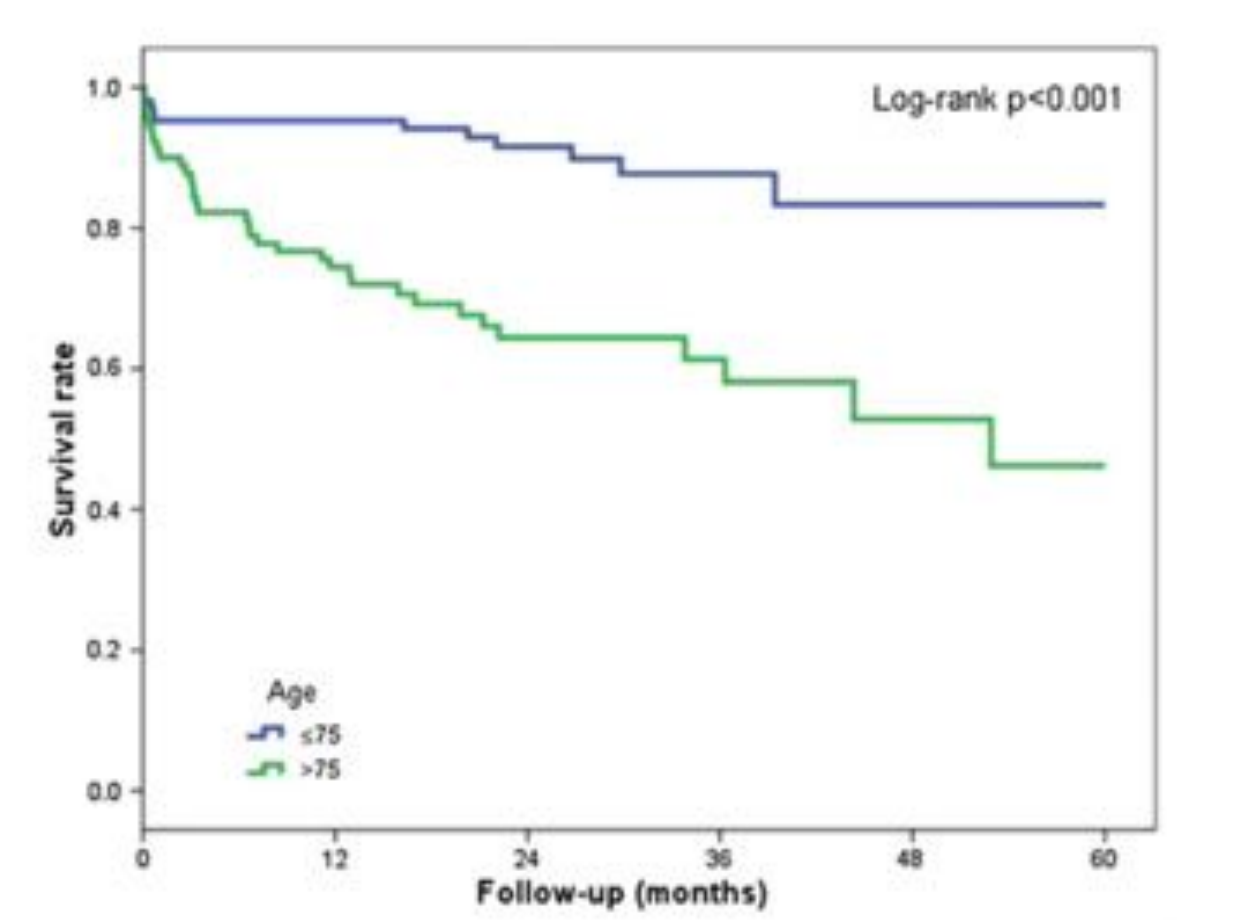
	Univariate analysis		Multivariate	
	HR (95% CI)	p Value	HR (95% CI)	p Value
Age, per 1 year increase	1.07 (1.03 to 1.10)	<0.001	1.10 (1.06 to 1.14)	<0.001
Male gender	0.78 (0.41 to 1.47)	0.439		
Lead vegetation	0.76 (0.41 to 1.39)	0.369		
Infectious endocarditis	0.75 (0.37 to 1.51)	0.414		
ICD infection	0.85 (0.47 to 1.53)	0.577		
CRT device infection	1.96 (0.97 to 3.96)	0.061	3.34 (1.50 to 7.44)	0.003
Pacemaker dependency	1.06 (0.56 to 2.03)	0.849		
Thrombocytopenia at admission	3.01 (1.07 to 8.44)	0.036	4.63 (1.56 to 13.74)	0.006
Creatinine >150 µmol/l	3.31 (1.73 to 3.36)	<0.001	2.66 (1.32 to 5.36)	0.006
Diabetes	0.98 (0.47 to 2.04)	0.965		
Use of oral anticoagulants	1.78 (0.99 to 3.19)	0.054		
Left ventricular ejection fraction <35%	1.80 (0.97 to 3.32)	0.060		
Pulmonary embolism	1.45 (0.66 to 3.17)	0.352		
Right ventricular dysfunction	3.49 (1.36 to 8.92)	0.009		
Severe tricuspid regurgitation, n (%)	0.86 (0.31 to 2.40)	0.772		
Negative blood cultures	0.79 (0.44 to 1.44)	0.446		
Negative cultures for tissue and explanted material	1.62 (0.90 to 2.93)	0.110		
Negative cultures for blood, tissue and explanted material	1.05 (0.54 to 2.03)	0.889		
Staphylococcus aureus	1.93 (1.04 to 3.59)	0.038		
Coagulase negative *Staphylococcus*	0.32 (0.14 to 0.72)	0.006	0.23 (0.09 to 0.56)	0.001
Non-staphylococcus microorganism	1.14 (0.57 to 2.25)	0.713		

ICD, implantable cardioverter defibrillator; CRT, cardiac resynchronisation therapy.

Deharo et al, Heart 2012; 98:724-31

Mortality with CIED Infection

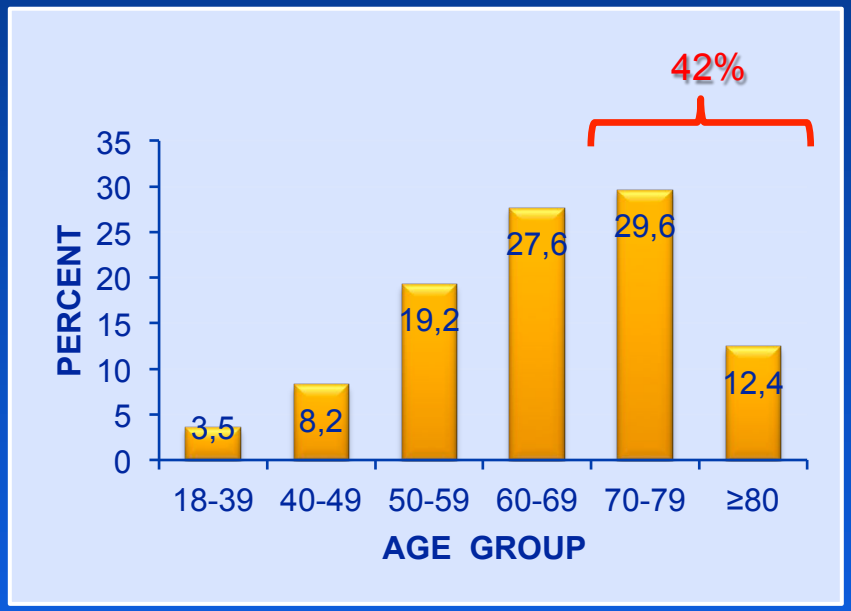
197 patients with infected CIED followed ≥1 yr (median 25 months)



Deharo et al, Heart 2012; 98:724-31

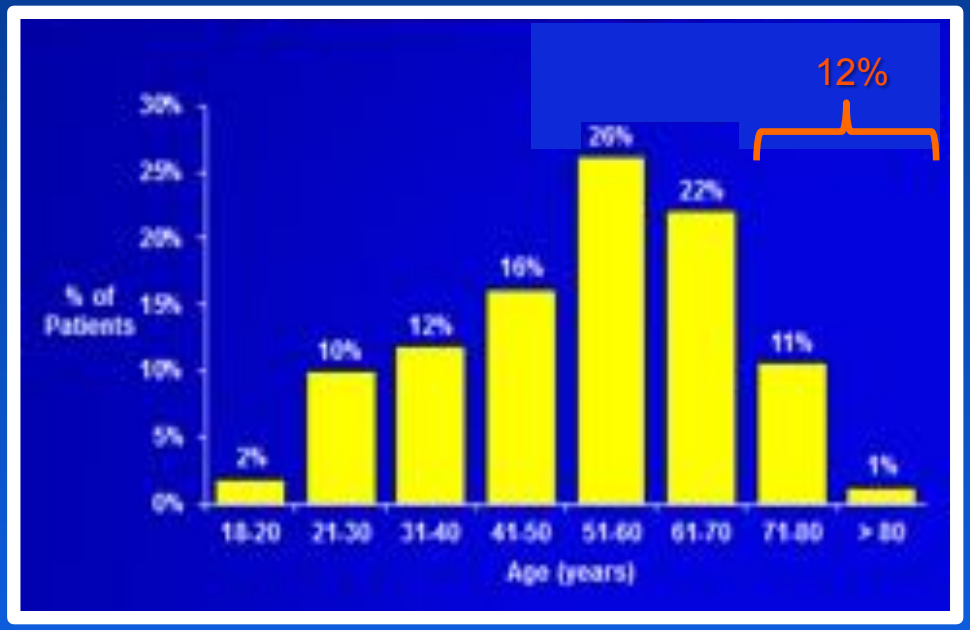
Comparison of Age Distributions at Implant

NCDR



Epstein et al, Heart Rhythm 2009

S-ICD IDE Trial



Courtesy: Boston Scientific Corp.

S-ICD Implant

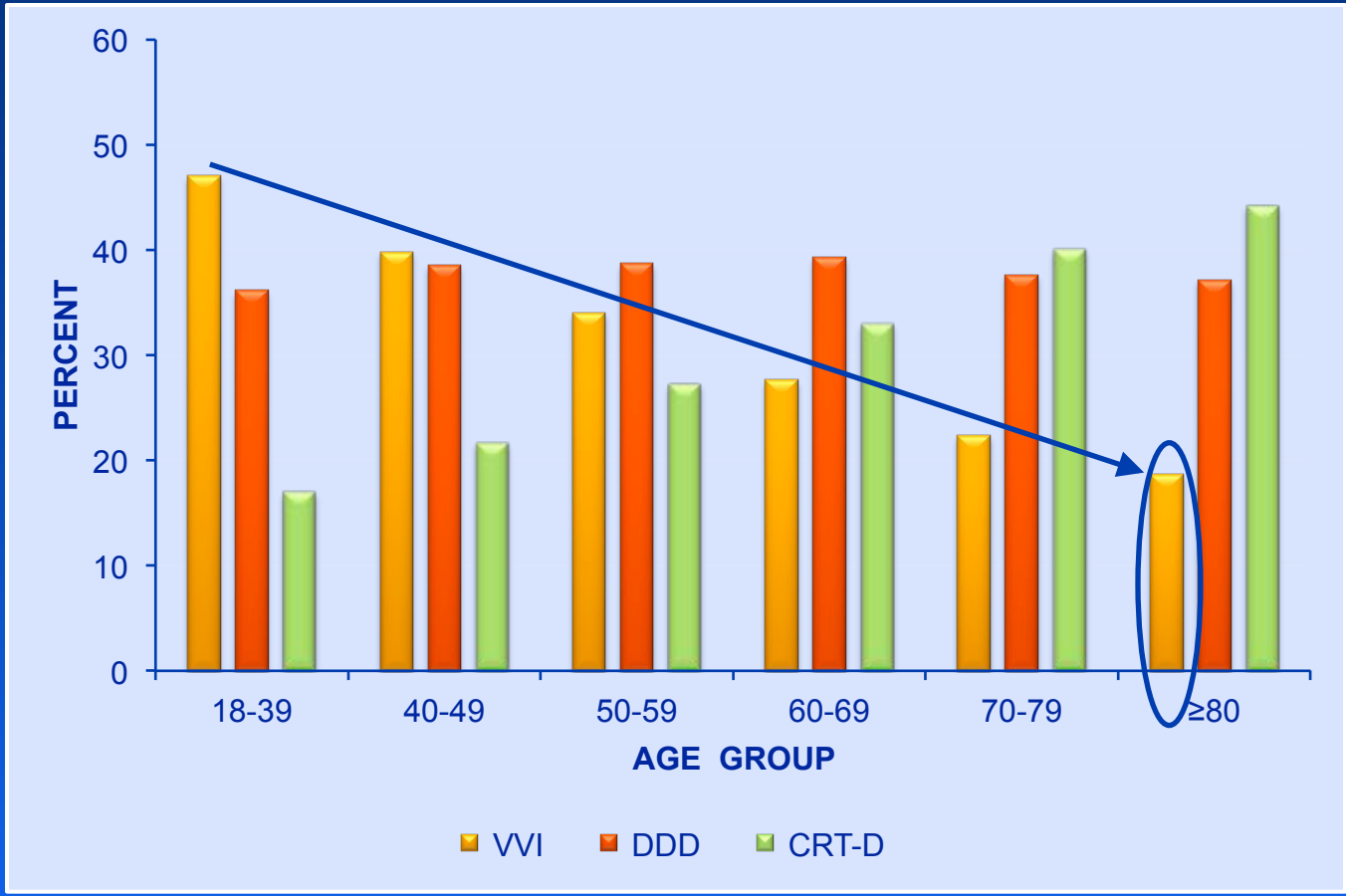
- Requires large incision/pocket + 1 or 2 more incisions
- Requires subcutaneous lead tunneling
- Requires defibrillation testing (unlike TV-ICD)
- Usually requires general anesthesia

S-ICD vs TV-ICD Comparison

ATP	no	yes
Brady pacing	no	yes
Volume	59.5 cc	~30 cc
Longevity	7 yrs	10-12 yrs

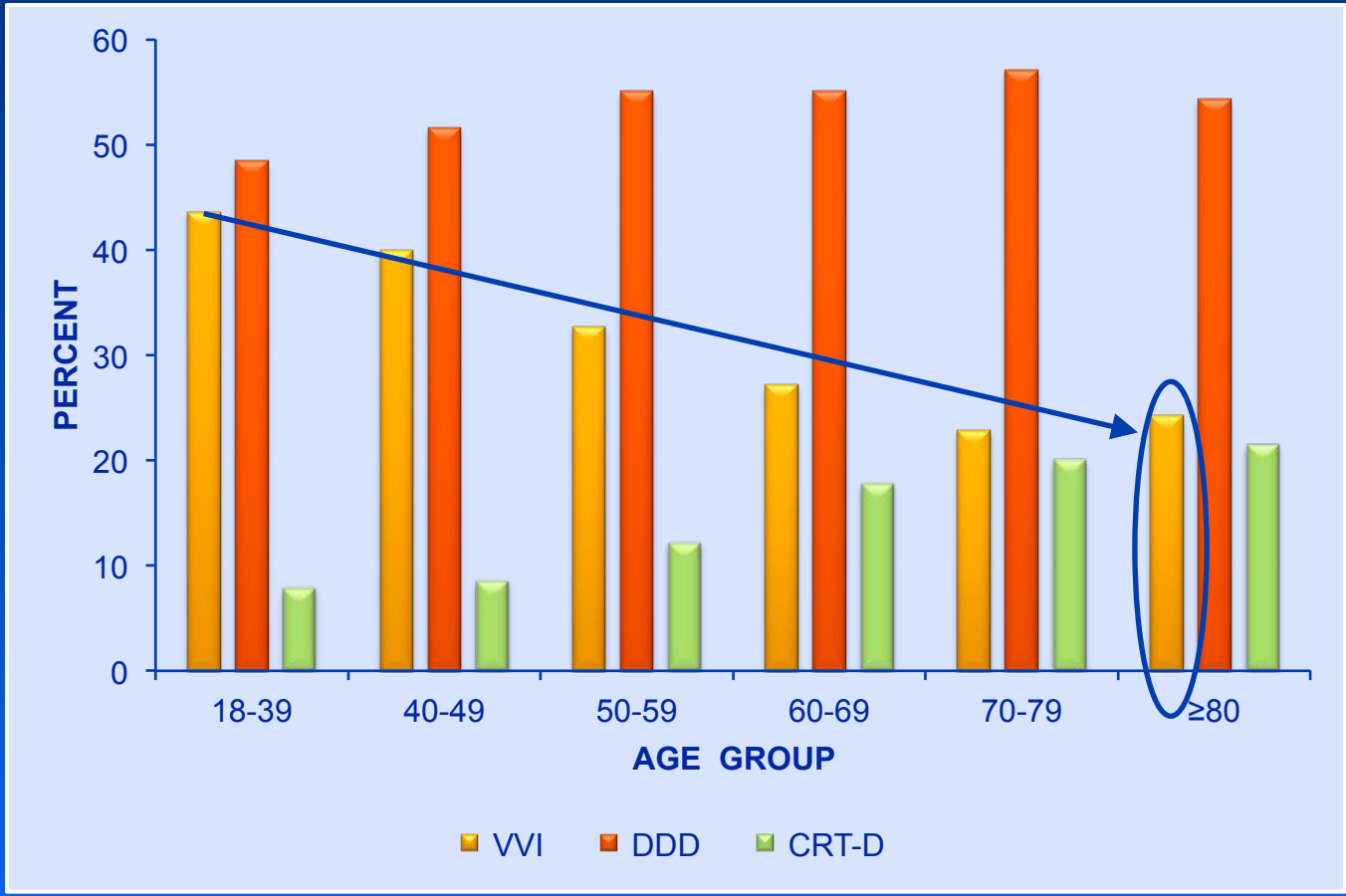
How big is the need for pacing in this population?

NCDR Distribution of Devices – 1° Prevention (81%)



Epstein et al, Heart Rhythm 2009; 6:1136-43

NCDR Distribution of Devices – 2° Prevention (19%)

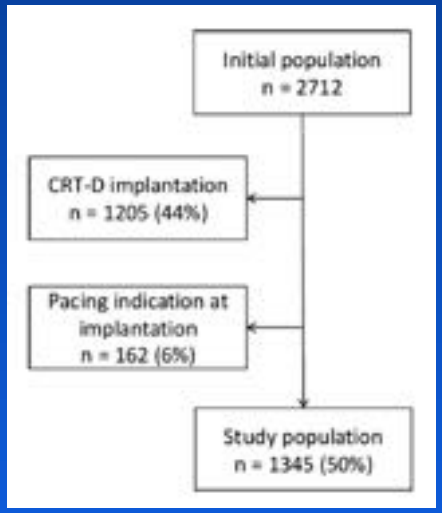


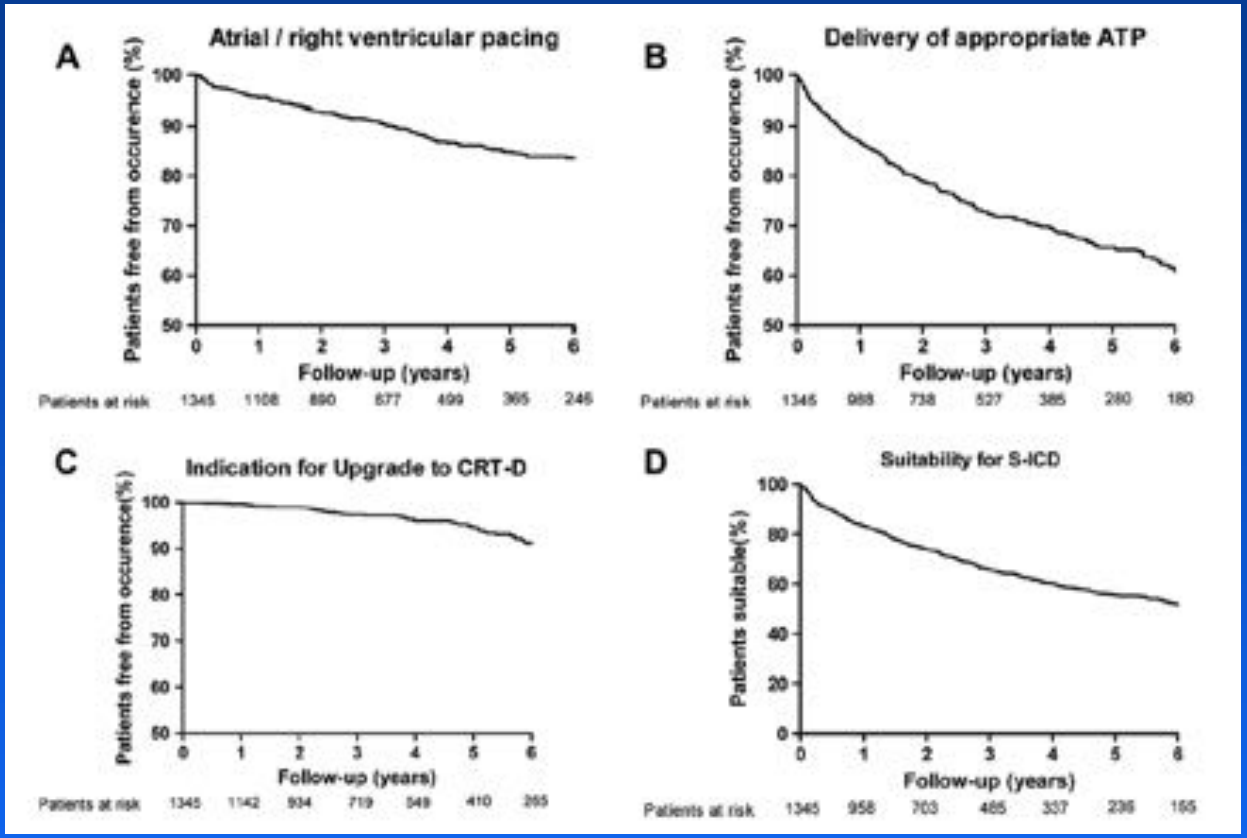
Epstein et al, Heart Rhythm 2009; 6:1136-43

How many ICD pts are S-ICD suitable?

1345 TV-ICD pts without pacing indication at implant

Age 60 ± 14





de Bie et al, Heart 2013; 99:1018-1023

How common are complications in S-ICD recipients?

Combined S-ICD IDE + EFFORTLESS Trials

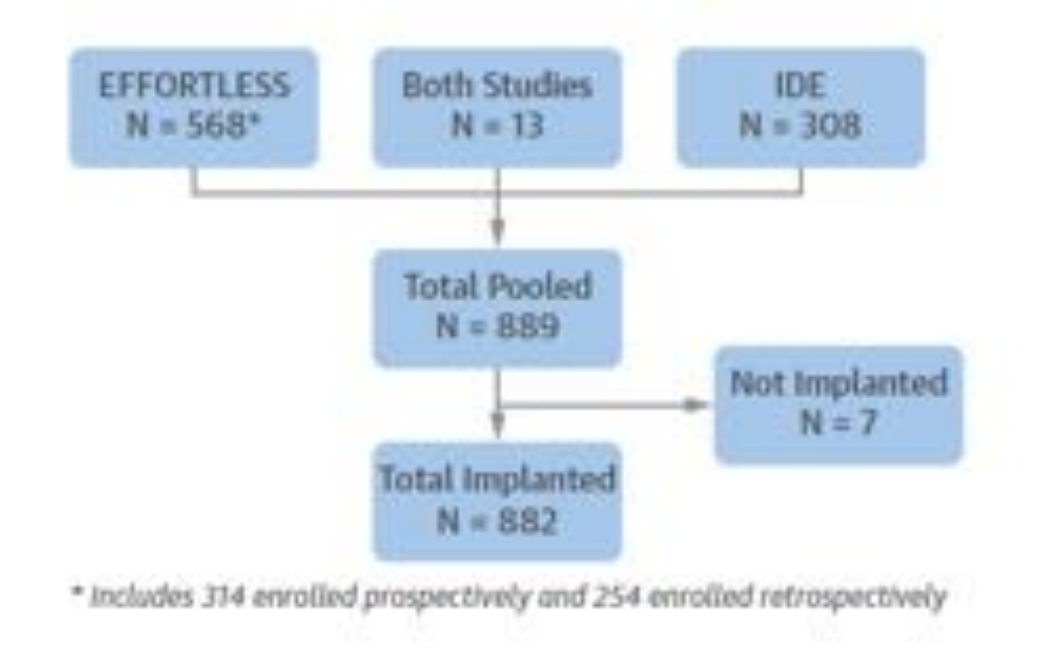


TABLE 1 Baseline Demographic and Medical History

	Pooled IDE and EFFORTLESS Patients
Age, yrs	50.3 ± 16.9 (52.6) 7.0-88.0

Burke et al, JACC 2015; 65:1605-15

Combined S-ICD IDE + EFFORTLESS Trials

TABLE 3 All Type I to III Complications

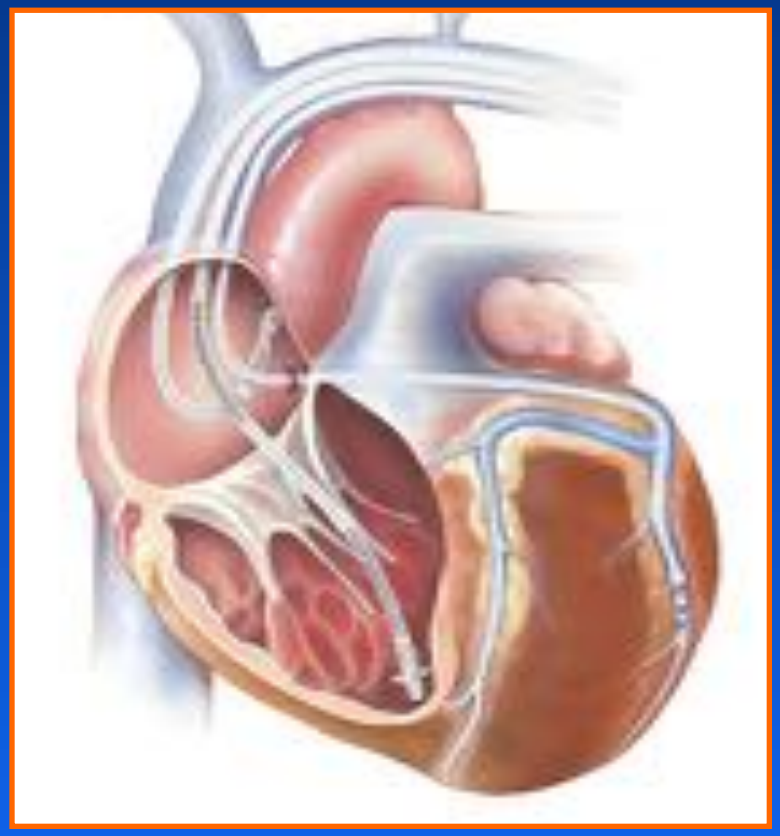
Description	Complications	
	Events	Patients
Infection requiring device removal/revision	17	14 (1.7)
Erosion	12	11 (1.2)
Discomfort	8	8 (0.9)
Inappropriate shock: oversensing	8	8 (0.9)
Suboptimal electrode position	7	7 (0.8)
Electrode movement	7	5 (0.6)
Inappropriate shock: SVA above discrimination zone (normal device function)	6	6 (0.7)
Premature battery depletion	5	5 (0.6)
Hematoma	4	4 (0.4)
Suboptimal PG and electrode position	4	4 (0.4)
Adverse reaction to medication	3	3 (0.3)
Inability to communicate with the device	3	3 (0.3)
Inadequate/prolonged healing of incision site	3	3 (0.3)
Incision/superficial infection	3	3 (0.3)
Suboptimal PG position	2	2 (0.2)
Other procedural complications	11	8 (0.9)
Other technical complications	5	5 (0.6)
Total	108	85 (9.6)

Burke et al, JACC 2015; 65:1605-15

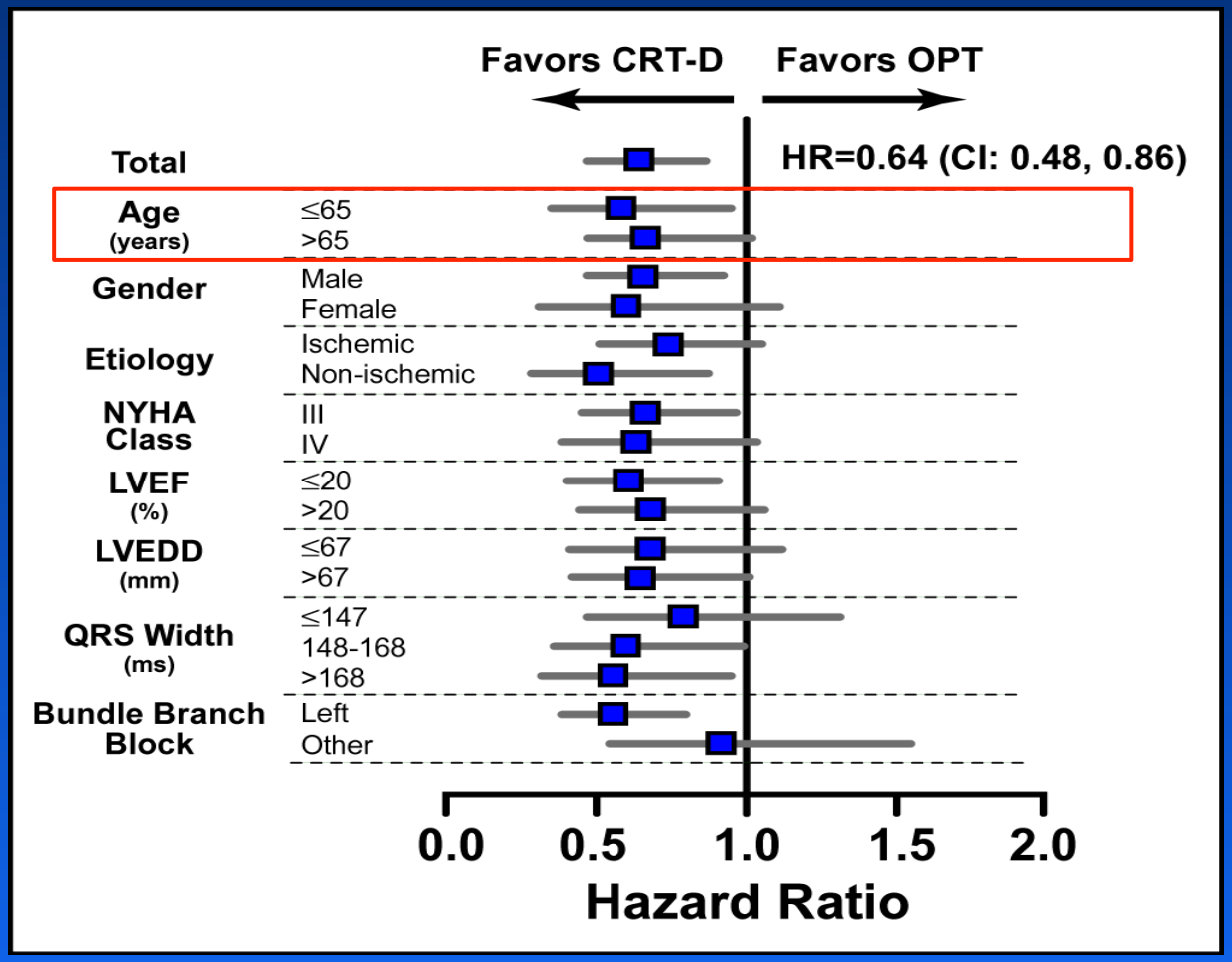
Conclusions

- Elderly patients (≥ 70 yrs) comprise 42% of ICD recipients, but only 12% of S-ICD recipients.
- Roughly 20% of elderly transvenous ICD recipients get a single-chamber system implanted.
- True need for brady pacing or ATP in this population is uncertain.
- Over half of CEID infections occur in elderly patients, and associated mortality risk increases with age.
- S-ICD implants are not immune to infection, but treatment is simpler than for transvenous system.
- Relationship of S-ICD complications to age has not been studied.
- Choice of S-ICD in elderly should weigh advantage of non-transvenous access against need for brady pacing/ATP, larger device, and need for defib testing and anesthesia at implant.

What about CRT in the elderly?

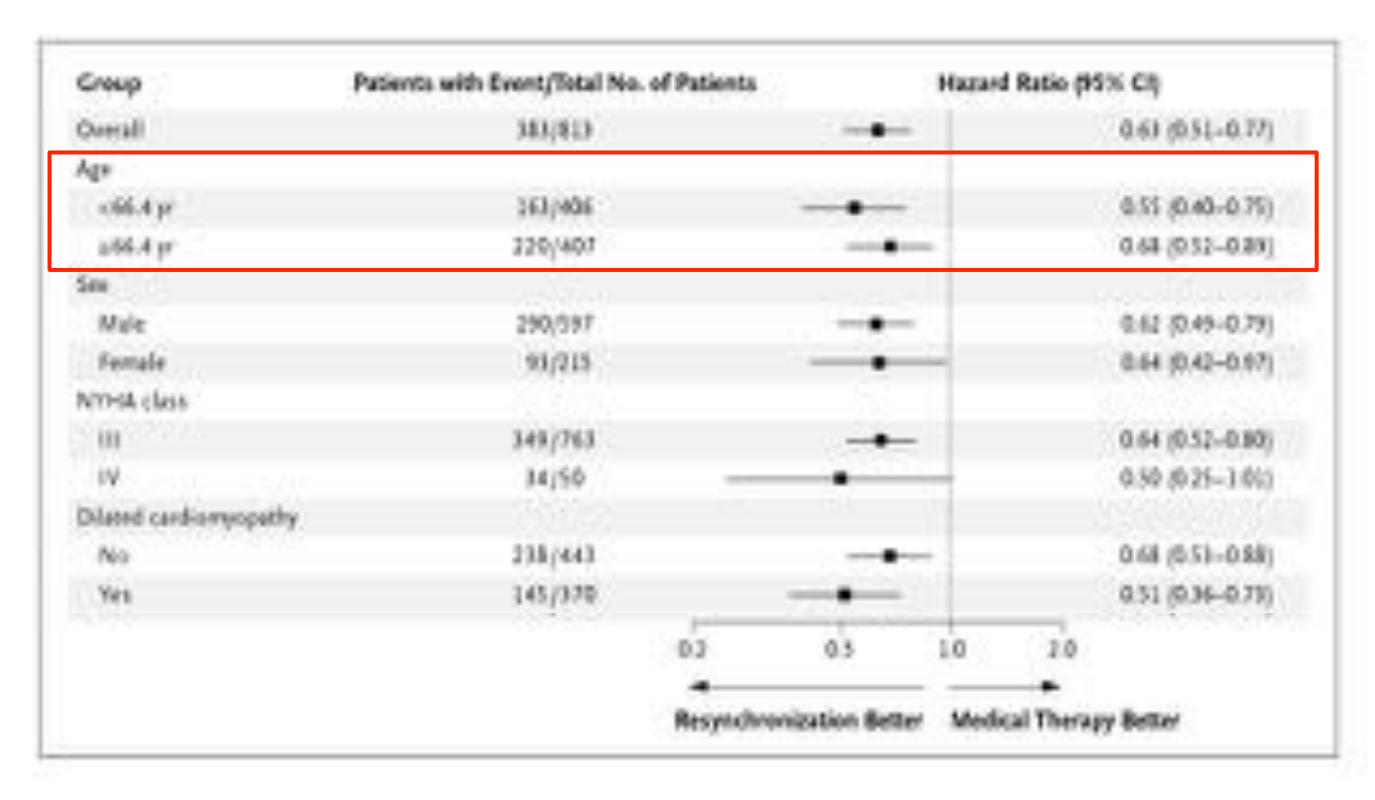


COMPANION – All Cause Mortality



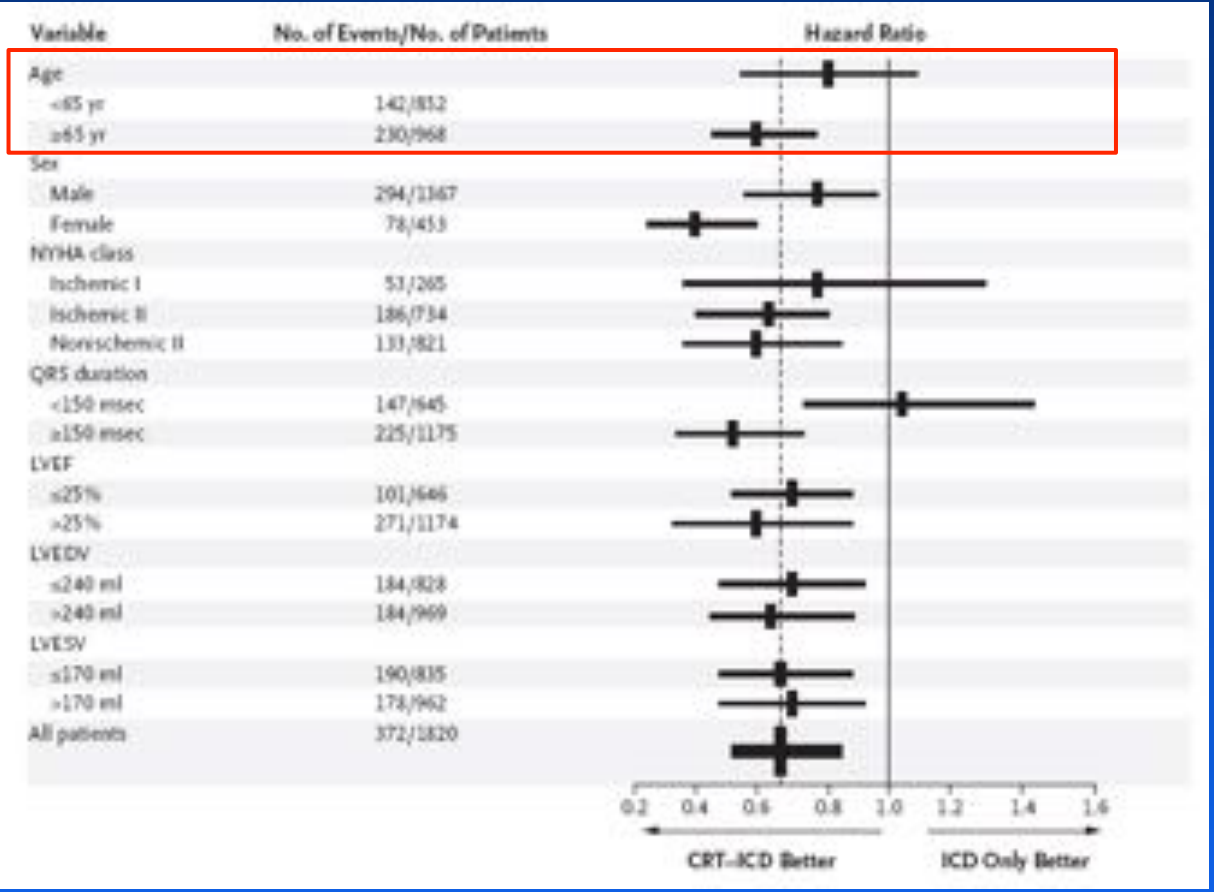
Bristow et al, NEJM 2004; 350:2140-2150

CARE-HF – All Cause Mortality or CV Hospitalization



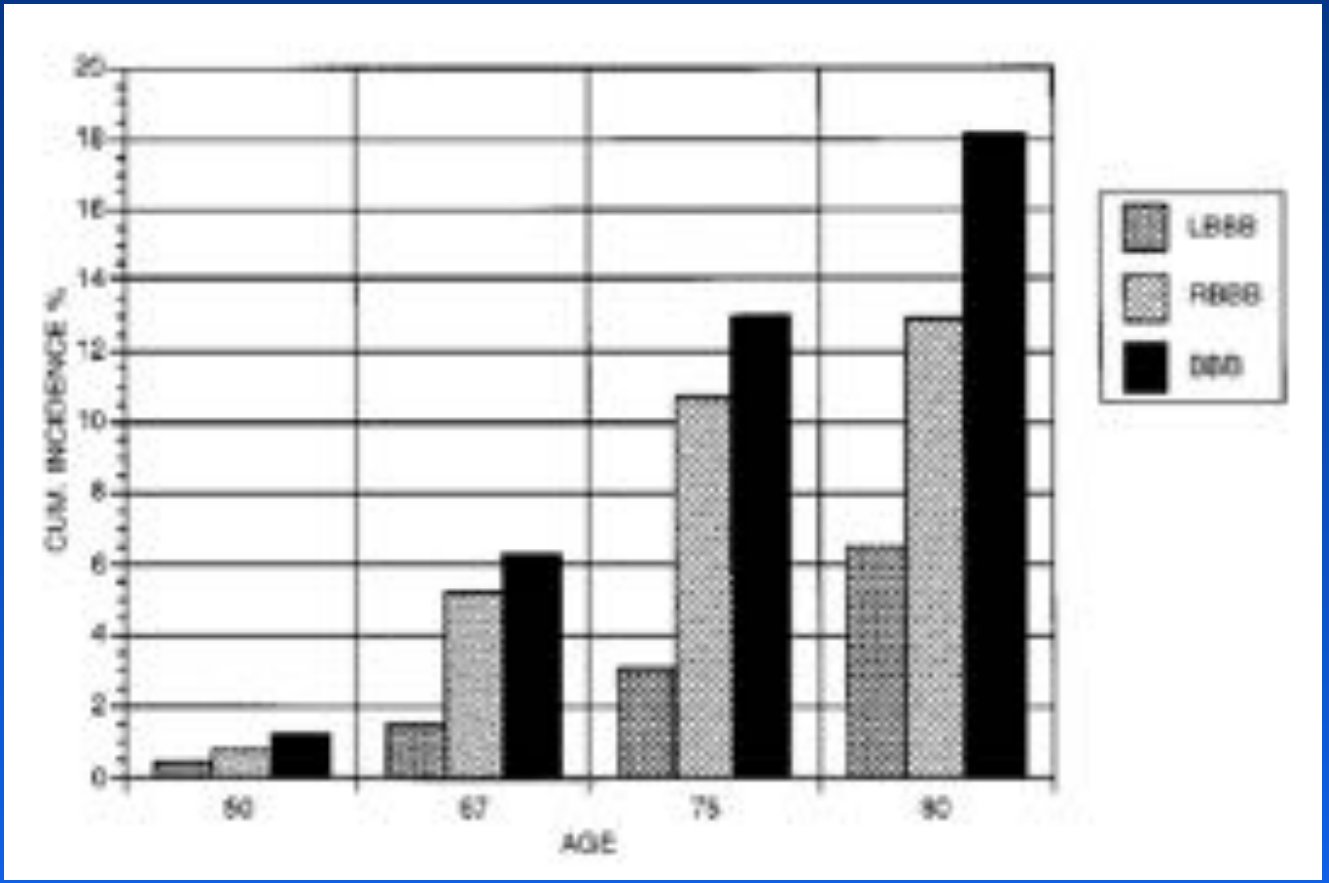
Cleland et al, NEJM 2004; 352:1539-1549

MADIT - CRT



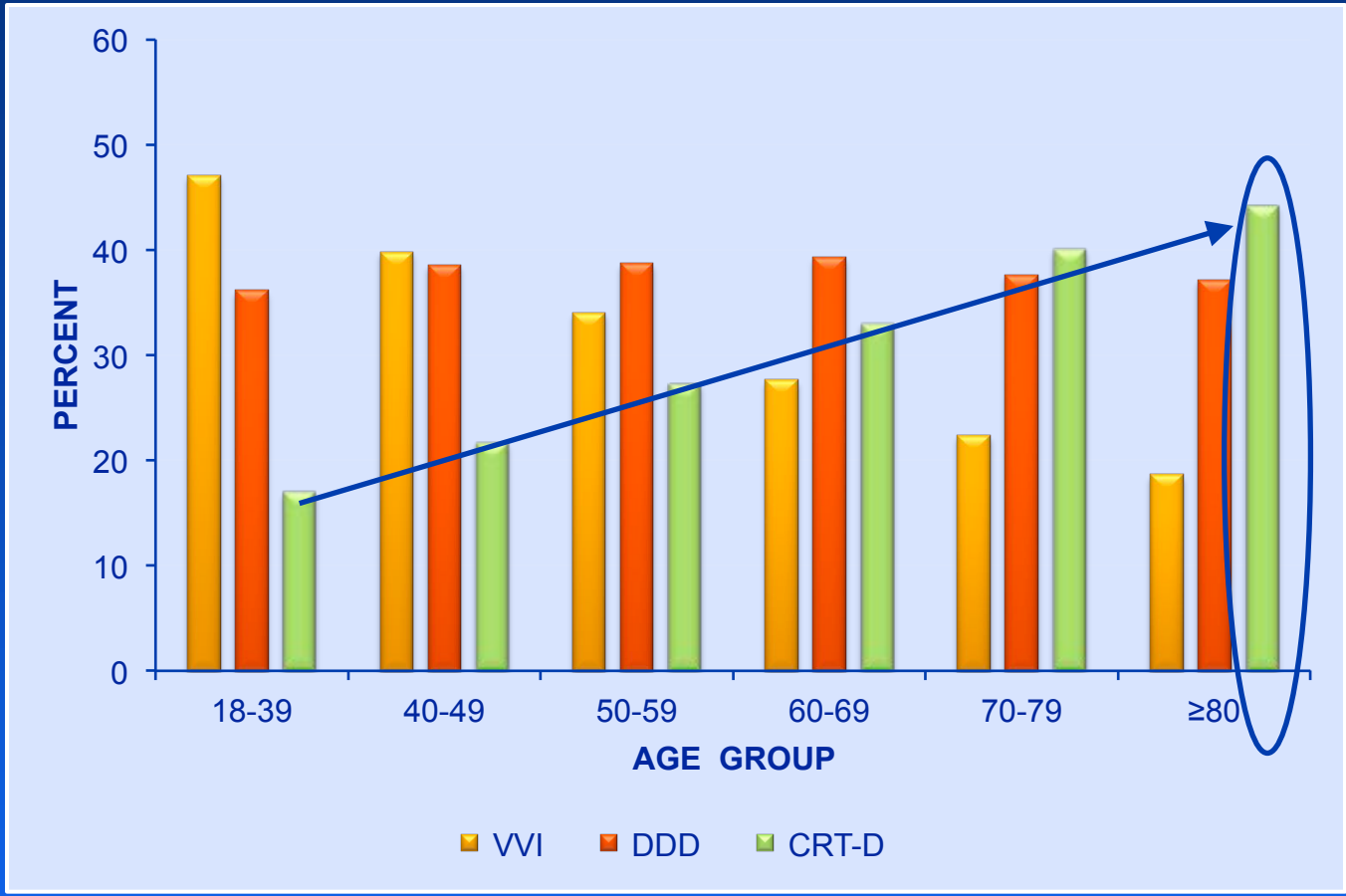
Moss et al, NEJM 2009; 361:1329-1338

Bundle Branch Block – Incidence with Age



Eriksson et al, Circ 1998; 98:2494-2500

NCDR Distribution of Devices – 1° Prevention (81%)



Epstein et al, Heart Rhythm 2009; 6:1136-43

CRT Utilization – Swedish Heart Failure Registry

Patient category	Age ≤65 years	Age 66–80 years	Age >80 years	P*
(A) CRT indication based on ESC 2013 guidelines, class I-A to IIb-B: EF ≤35%, QRS ≥120 ms and NYHA class II–IV (III–IV if atrial fibrillation)				
CRT yes#	283 (6%)	524 (8%)	124 (4%)	<0.001
Of these, concurrent ICD	197 (70%)	244 (47%)	23 (19%)	
CRT no but indication‡ yes	1034 (23%)	2167 (32%)	1279 (37%)	
CRT no and indication‡ no	3199 (71%)	4090 (60%)	2013 (59%)	
Total	4516	6781	3416	

Lund et al, Eur J of Heart Fail. 2014; 16:1073-81

European CRT Survey

2438 patients, 141 centers, 13 countries

	CRT-D	CRT-P	P-value
Age (years, median)	68 (61–74)	75 (68–80)	<0.0001
Age ≥75	396 (23)	337 (52)	0.0001
Women	363 (21)	194 (30)	<0.0001
RBBB[a]	120 (7)	34 (5)	0.10
QRS duration[b]			
<130 ms	269 (18)	75 (8)	0.37
130 to <160 ms	450 (30)	137 (30)	0.82
160–180 ms	493 (33)	155 (33)	0.86
>180 ms	277 (19)	95 (21)	0.35
Previous VF/sustained VT	295 (20)	15 (2)	< 0.0001

Bogale et al, Eur J Heart Fail 2012; 14:61-73

Conclusions

- CRT outcomes are similar in elderly and younger patients.
- LBBB prevalence increases with age, so CRT indications increase with age.
- But CRT utilization decreases with age.
- CRT-P (rather than CRT-D) is utilized more often in elderly than in younger patients, likely due to comorbidities and reluctance for ICD among the elderly.