EMOCLINIC SYMPOSIUM
SULLE SPONDE DEL TICINO

NOVARA, 7 e 8 Giugno 2018

"Cardiologia ieri, oggi e domani"

ICD Sottocutaneo: Oggi "Alternativa"… Domani "Scelta Obbligata"?

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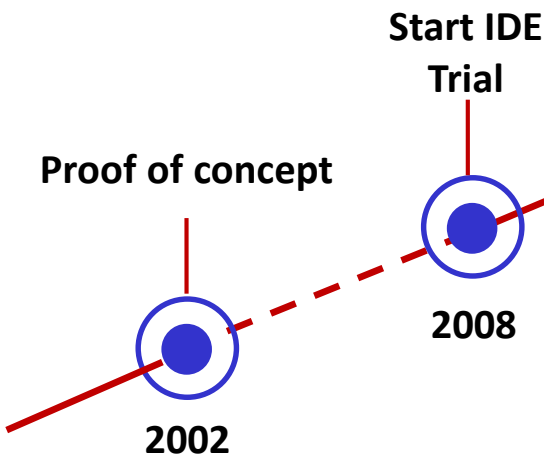
Disclosure Information

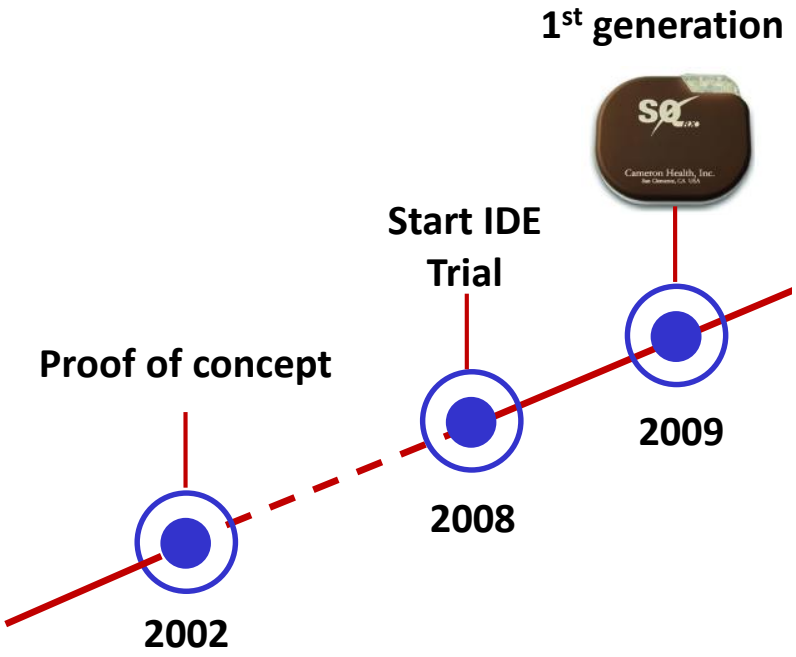
Speaker's honoraria from

- **Boston Scientific**
- **Novartis**

Evolution of S-ICD Therapy



Evolution of S-ICD Therapy



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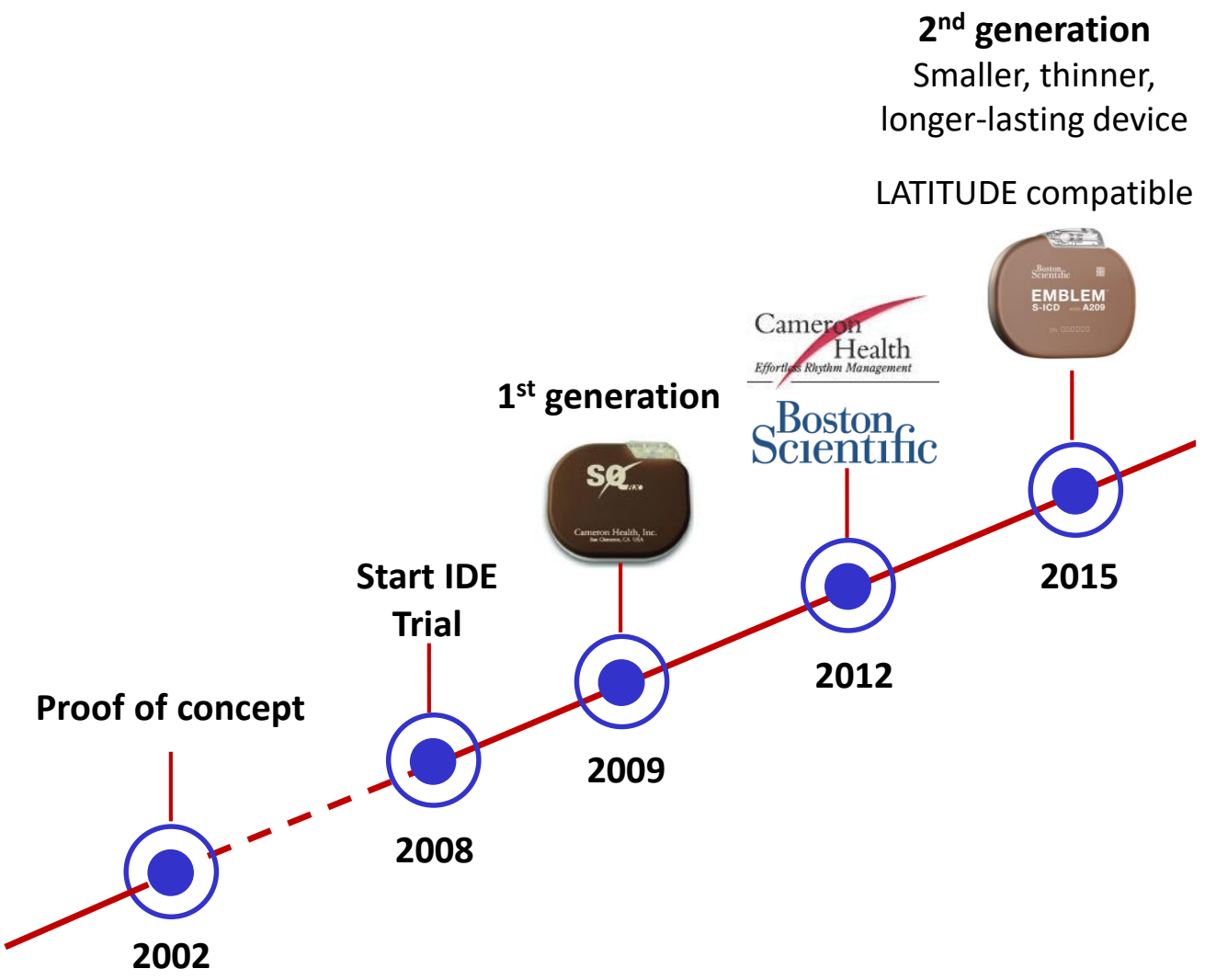

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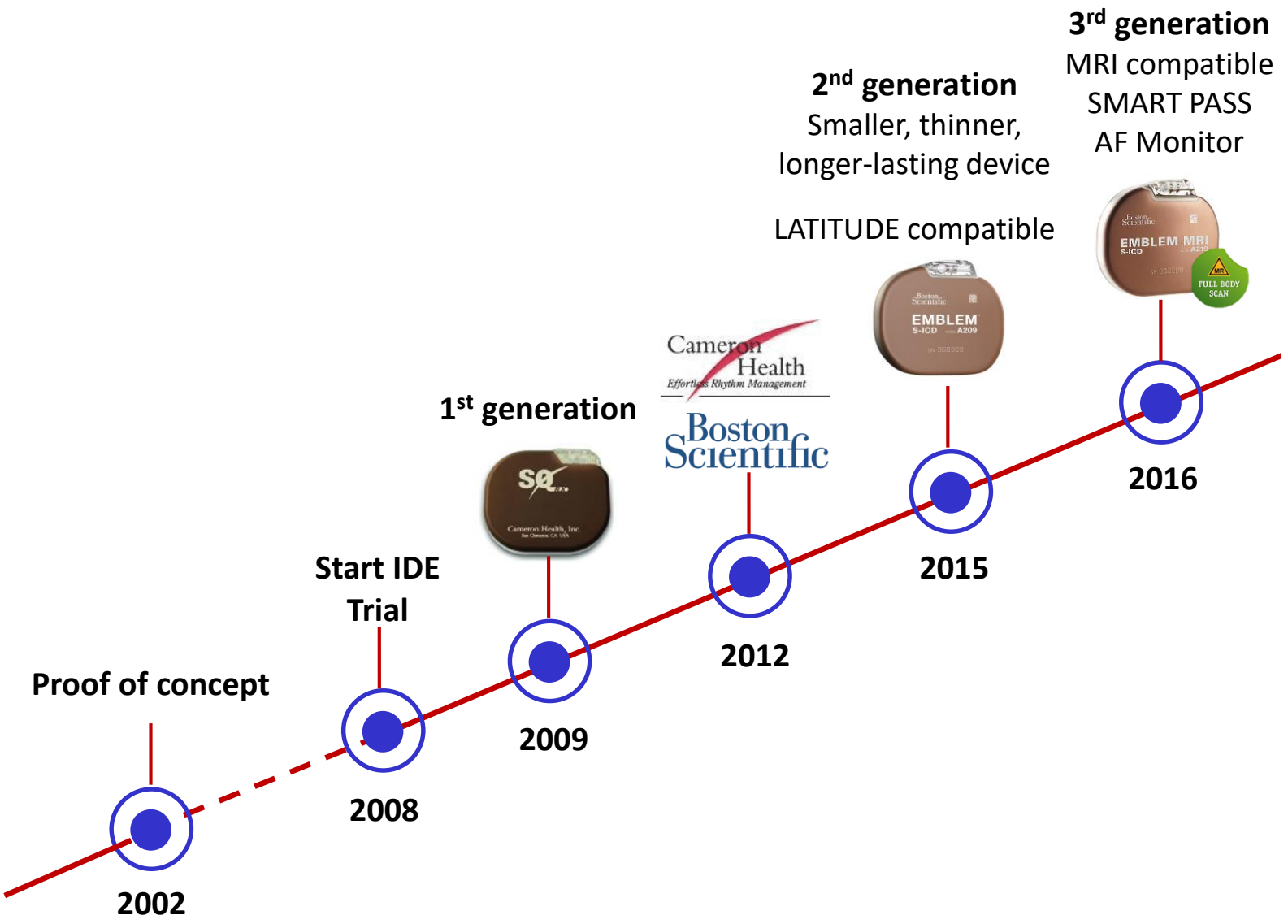


Evolution of S-ICD Therapy

Proof of concept
2002

Start IDE Trial
2008

1st generation


2009

Cameron Health
Effortless Rhythm Management
Boston Scientific
2012

2015

2nd generation
Smaller, thinner,
longer-lasting device

LATITUDE compatible

3rd generation
MRI compatible
SMART PASS
AF Monitor

2016

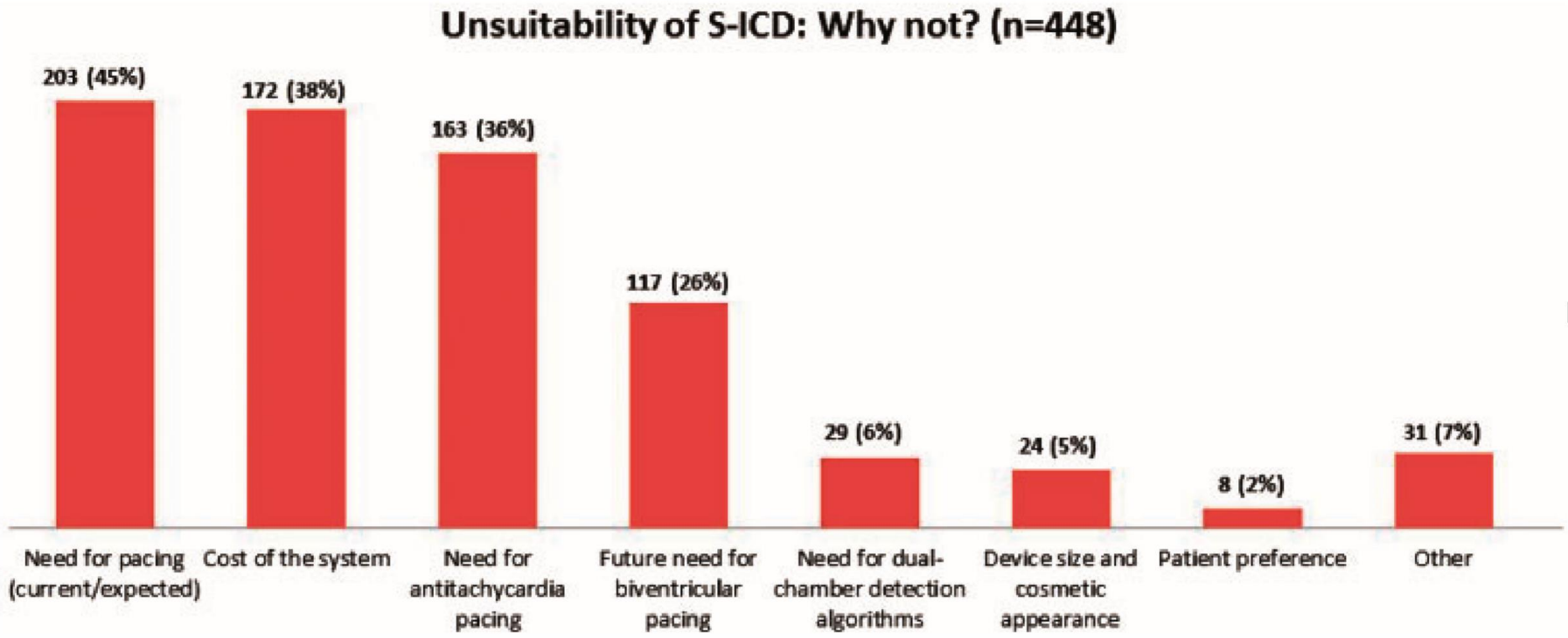
2017
2018

S-ICD IMPLANT OPTIMIZATION

- Automated screening tool
- Electrode #3501
- 2 incisions labelling
- Intermuscular labelling
- Electrode delivery system

ESC European Society of Cardiology
Europace (2017) **19**, 1826–1832
doi:10.1093/europace/euw337

The Italian subcutaneous implantable cardioverter-defibrillator survey: S-ICD, why not?



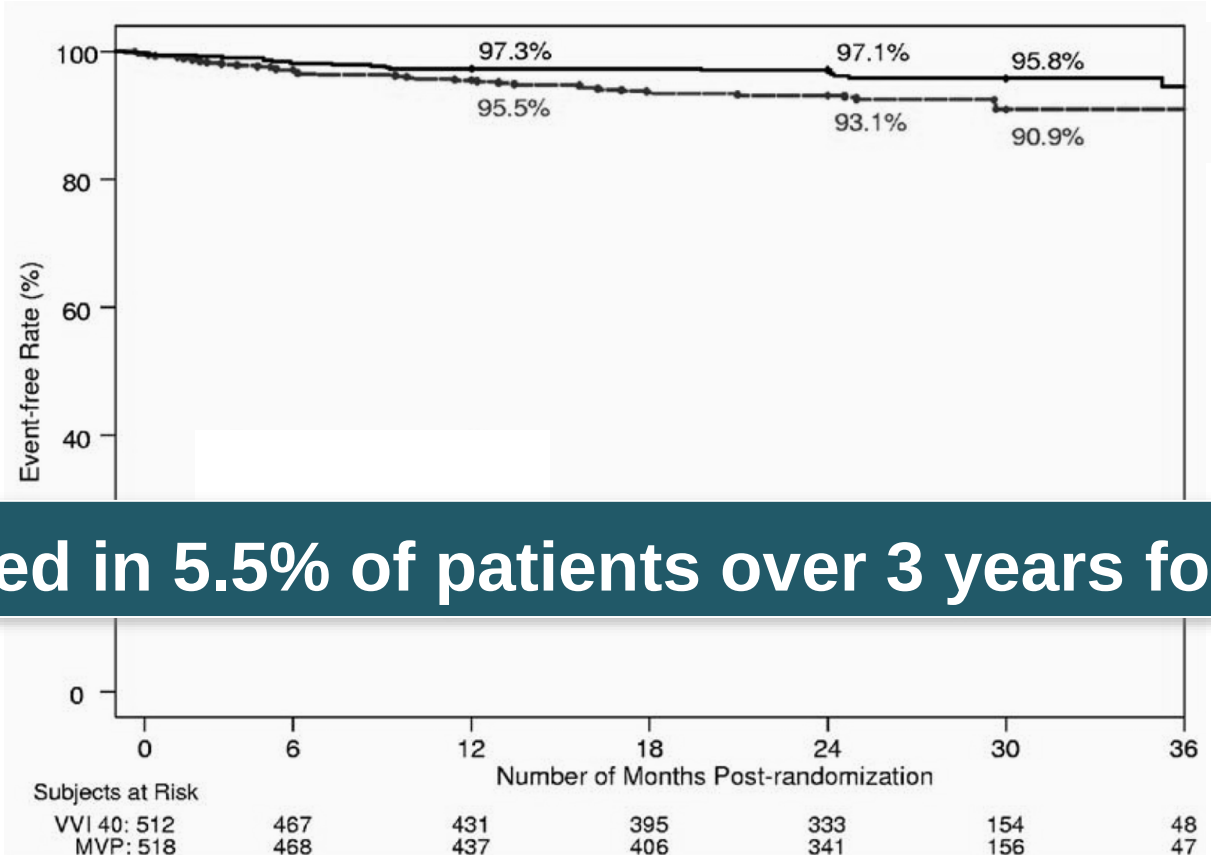
Botto G, Europace 2017; 19(11):1826-1832

Reasons Not To Implant a S-ICD

Development of Pacing Need in ICD Patients

MVP Trial - 1030 ICD Candidates Without Pacing Indication

MVP 60 bpm vs. VVI 40 bpm



PM Need in 5.5% of patients over 3 years follow-up

Sweeney M et al, Heart Rhythm 2010; 7:1552-1560

Anti-Brady Pacing Need in ICD patients

Study	Percentage
MVP Trial	5.5%
SCD-HeFT Trial	3.0%

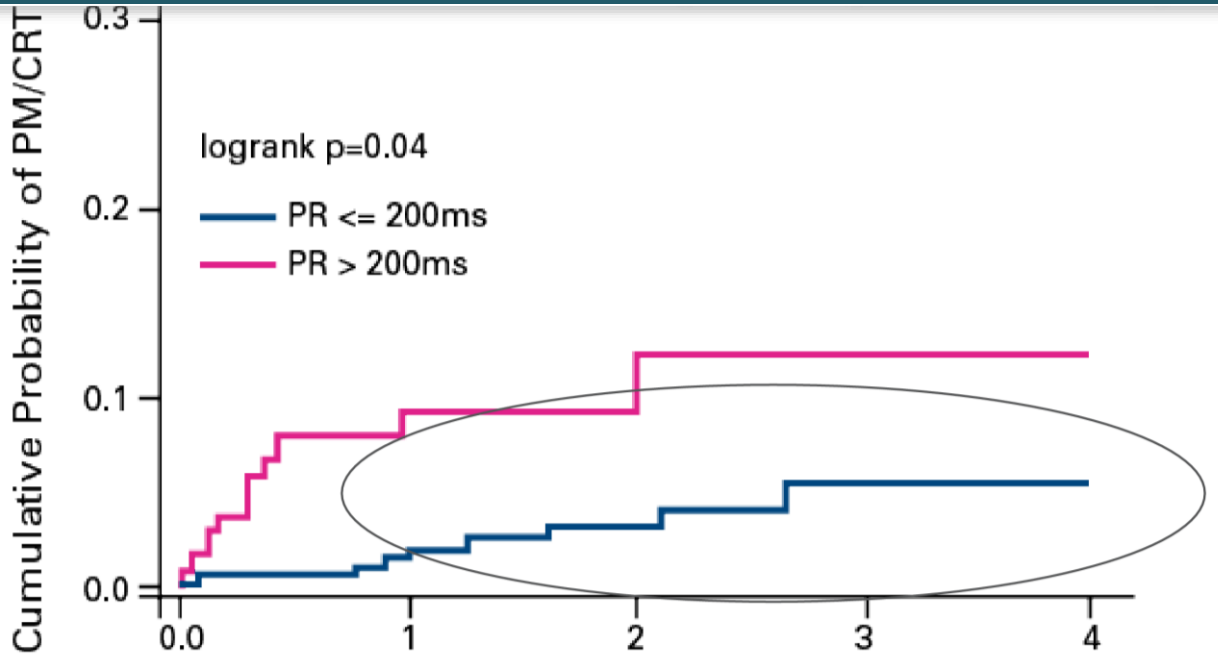
Does PM need in ≈ 6%
justify transvenous lead in 100%?

MADIT II	4.1%

Prediction of Anti-Brady Pacing Need

MADIT II Trial – Conventional Arm (458 pts, 20 months FU)

5.2% implanted with PM (4.1%) or CRT (1.1%)



Number of patients at risk

300	209 (.02)	111 (.03)	44 (.06)	1 (.06)
109	65 (.09)	30 (.12)	12 (.12)	1 (.12)

Kutyifa V et al, Eur Heart J 2014; 35(Suppl. 1):513–850

Prediction of Anti-Brady Pacing Need

Implantable Loop Recorder (ILR) Registry
521 Patients - 3.5 years Follow-up

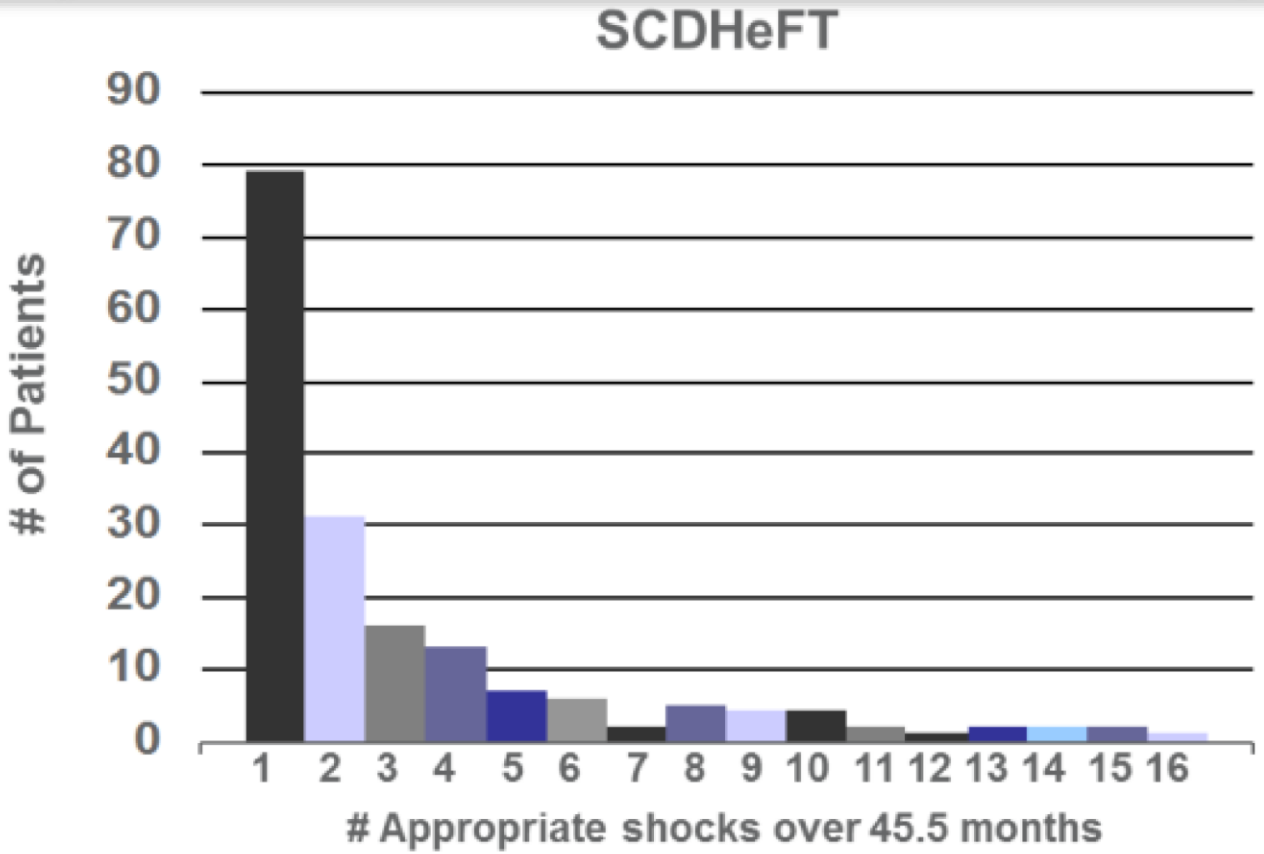
Variable	OR (95% CI)
Age (10 years)	1.04 (0.75 – 1.35)
Gender	0.55 (0.12 – 1.09)
Valvular heart disease	3.12 (0.61 – 15.86)
PR/PQ Interval (10 ms)	1.09 (0.97 – 1.21)
QRS Interval (10 ms)	1.34 (1.11 – 1.58)
Q waves	2.58 (0.45 – 14.80)

Castagno D et al, In preparation

Reasons Not To Implant a S-ICD

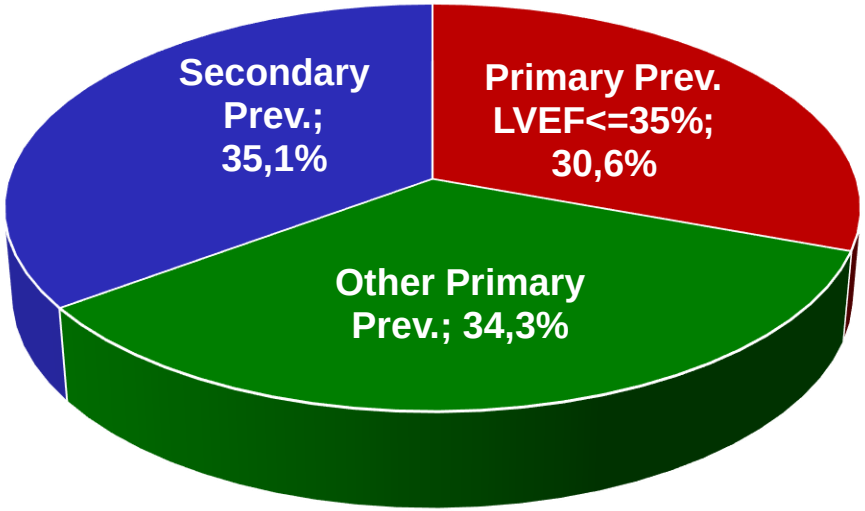
Monomorphic VT in ICD Recipients

15% of pts had monomorphic VT (mVT) but only 1.8%/year risk of more than one mVT episode



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

EFFORTLESS Registry – 985 Patients



Variable	Mean / Percent
Average Age	48 ± 17
Male	72%
LVEF	43% ± 18%
QRS width, msec	106 ± 25
BMI	27 ± 6

Primary Cardiac Disease	Percentage
Non-Ischaemic	38.5%
ARVC	3.5%
Congenital	2.1%
Dilated	9.3%
HCM	11.7%
Ischaemic	31.1%
Inherited	18.6%
Idiopatic VF	6.0%
Valvular Disease	2.3%
Other	2.2%
CHF	1.2%

Boersma L et al, J Am Coll Cardiol 2017; 70:830-841

EFFORTLESS – Appropriate Therapy VT/VF

Rhythm	Patient	Episode	1st Shock Conversion	≥1 Shock Conversion
MVT	55	95	90.5% (86/95)	98.9% (94/95)
PVT/VF	55	97	86.6% (84/97)	95.9% (93/97)
Total	99	192	88.5% (170/192)	97.4% (187/192)

Some conversions outside/new frame, clinical conversion success 100%, all pts survived

Reliable VT/VF therapy by S-ICD shock

Regardless of aetiology, indication, LVEF

Boersma L et al, J Am Coll Cardiol 2017; 70:830-841

EFFORTLESS – Appropriate Therapy VT/VF

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Some conversions outside/new frame, clinical conversion success 100%, all pts survived

50% of all episodes were sustained MVT

2.2% of patients had >1 treated MVT episode

Boersma L et al, J Am Coll Cardiol 2017; 70:830-841

EFFORTLESS – Indications to Device Change

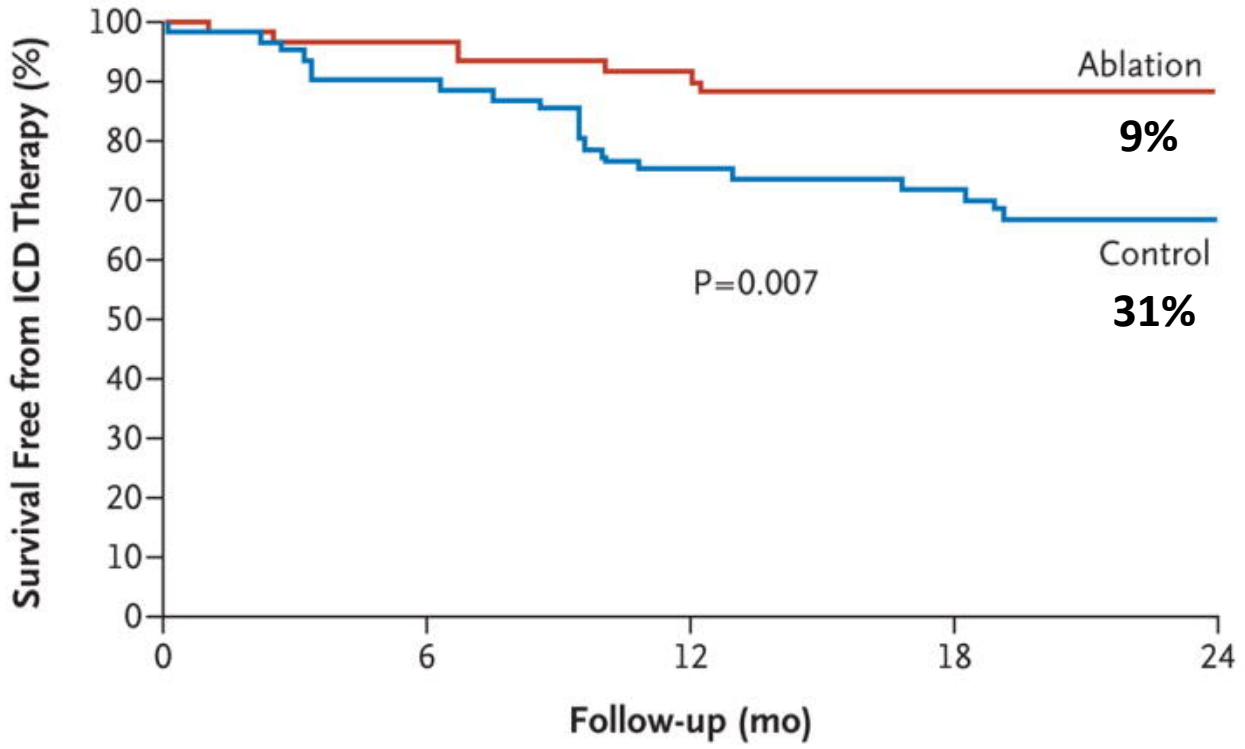
Reason		Patients N = 985
Pacing	ATP	5 (0.5%)
	Biv Pacing	4 (0.4%)
	Bradycardia	1 (0.1%)
Improved LV Function	No longer ICD indication	2 (0.2%)
Programmability for VT< 170 bpm		1 (0.1%)

Through average follow-up of 3.1 years only 1% of patients changed to transvenous ICD for pacing

Boersma L et al, J Am Coll Cardiol 2017; 70:830-841

VT Ablation in Secondary Prevention

- **SMASH VT Trial randomized 128 ICD pts with spontaneous or inducible VT/VF to catheter ablation vs. conventional therapy**
- **During follow-up ICD therapy (ATP or shock) for VT/VF was needed in only 15% of ablation pts compared to 33% of control pts**



Reddy VY. et al, NEJM 2007; 357:2657-65

Catheter Ablation for Sustained MVT

Catheter ablation for the treatment of sustained monomorphic ventricular tachycardia

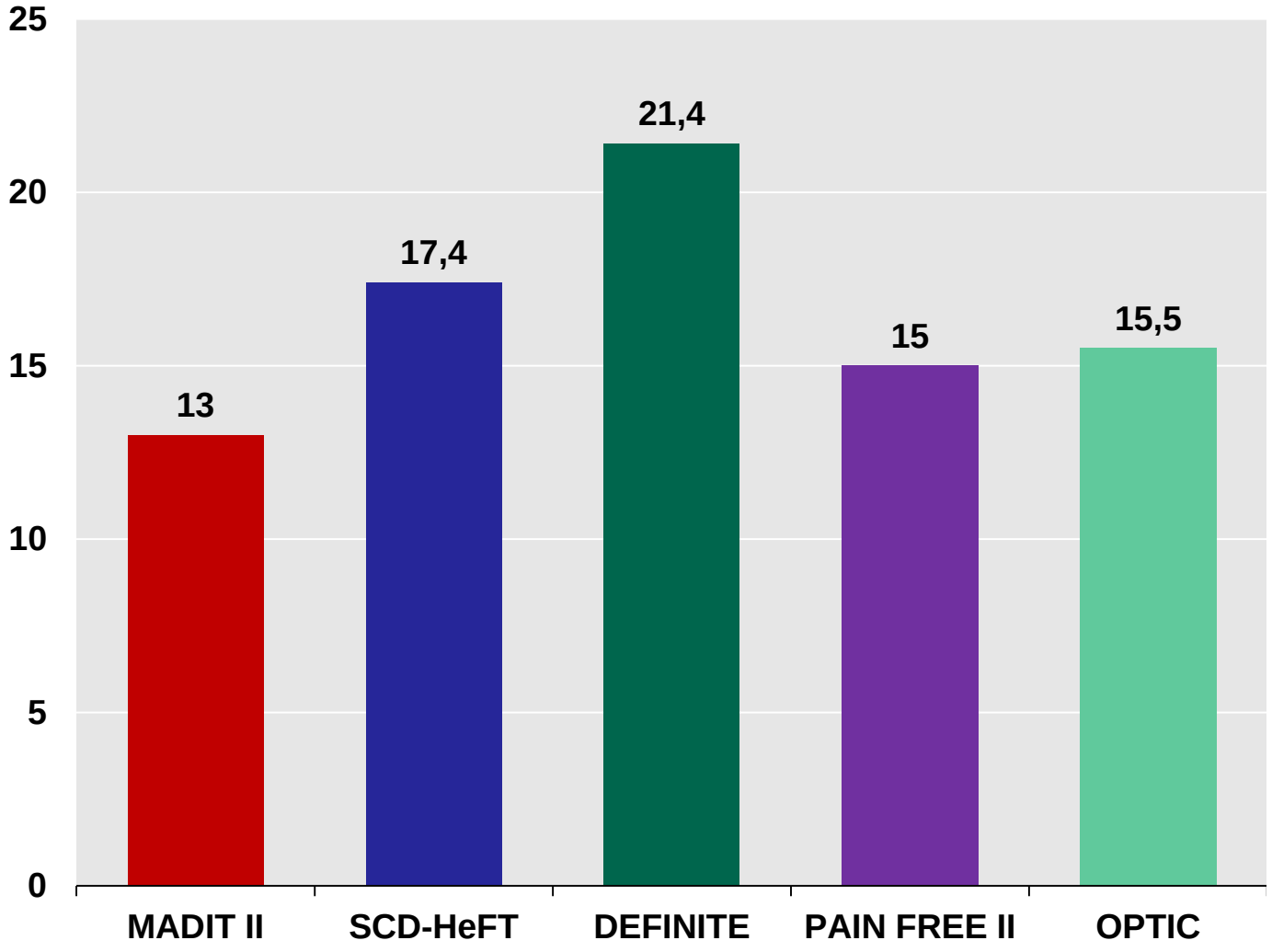
Recommendations	Class[a]	Level[b]
Urgent catheter ablation is recommended in patients with scar-related heart disease presenting with incessant VT or electrical storm.	I	B
Catheter ablation is recommended in patients with ischaemic heart disease and recurrent ICD shocks due to sustained VT.	I	B
Catheter ablation should be considered after a first episode of sustained VT in patients with ischaemic heart disease and an ICD.	IIa	B

Priori S. et al, Eur Heart J 2015; 36:2793-2867

Reasons Not To Implant a S-ICD

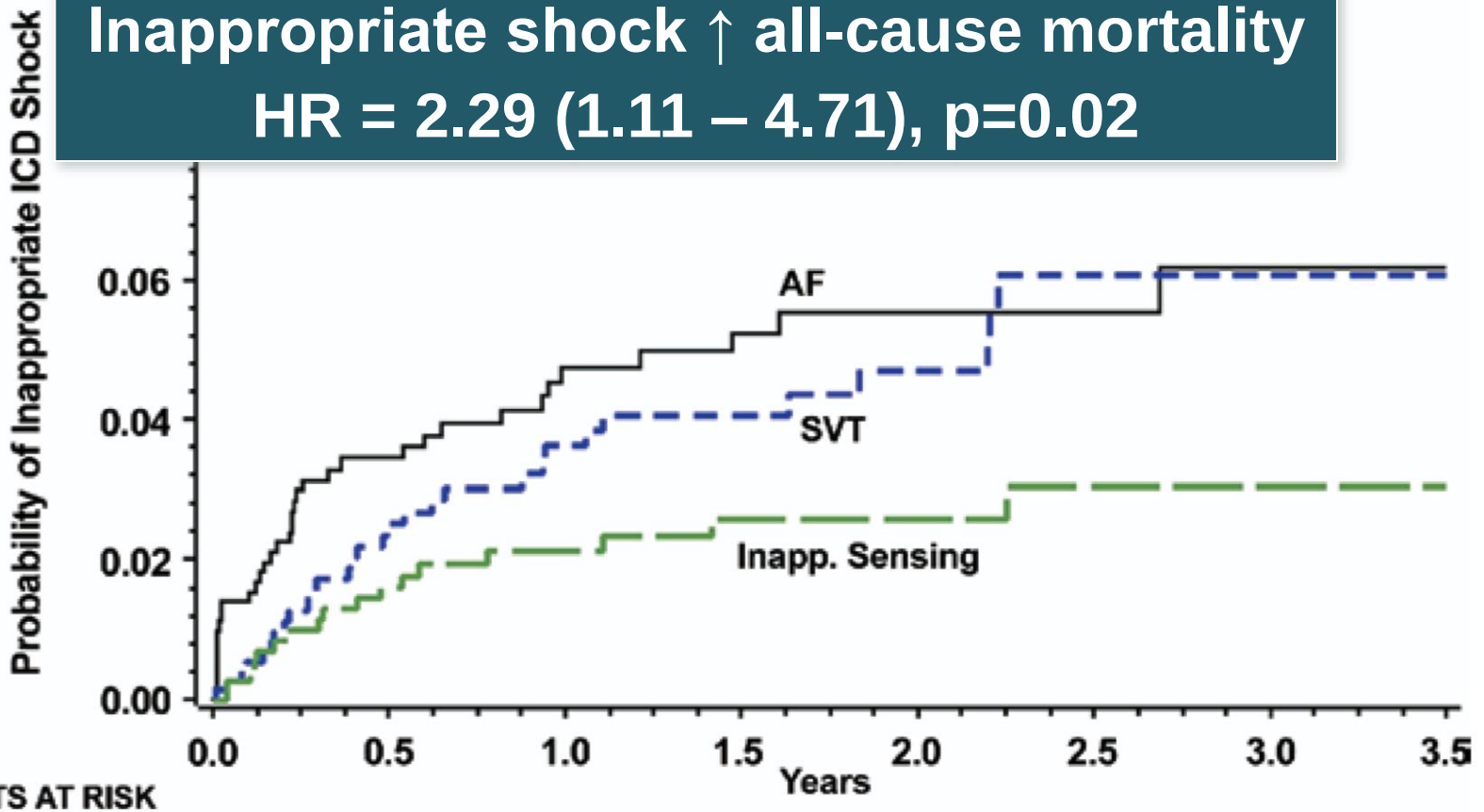
Poor event discrimination

Inappropriate Shocks in TV- ICD



Effects of TV-ICD Inappropriate Shocks

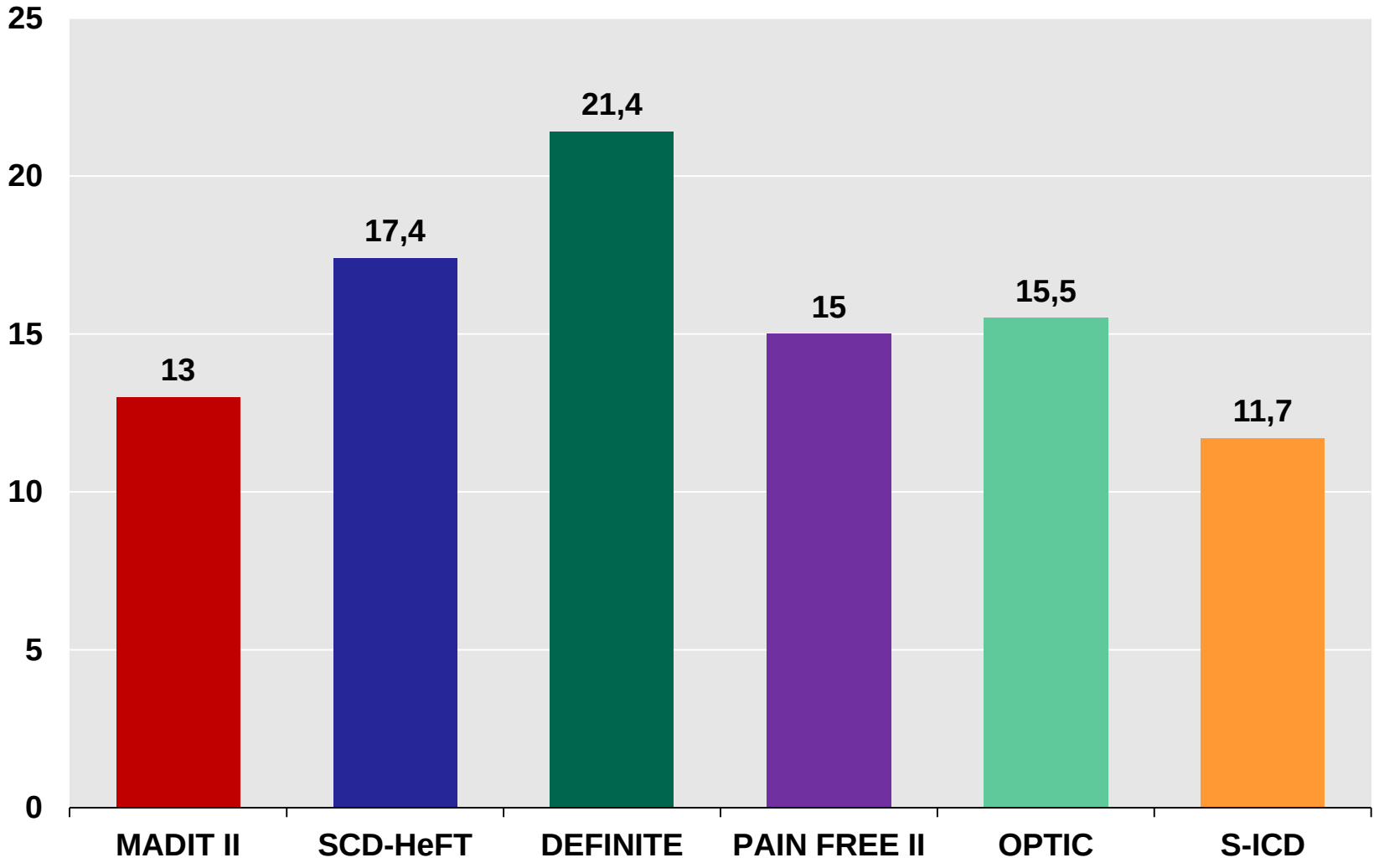
Inappropriate shock ↑ all-cause mortality
HR = 2.29 (1.11 – 4.71), p=0.02



PATIENTS AT RISK				
AF	719	462 (0.047)	242 (0.055)	94 (0.062)
SVT	719	464 (0.036)	241 (0.047)	92 (0.061)
Inapp. Sensing	719	474 (0.021)	251 (0.026)	98 (0.031)

Daubert J et al, J Am Coll Cardiol 2008; 51:1357-1365

Inappropriate Shocks in TV- ICD and S-ICD



EFFORTLESS - Inappropriate Therapy

	First Year		Total FU (avg 3.1 yrs)	
Type	Patients (%)	Episode	Patients (%)	Episode
Oversensing, Cardiac	52 (5.3%)	109	76 (7.7%)	173
Oversensing, Non-cardiac	15 (1.5%)	19	22 (2.2%)	31

Inappropriate shock for:
- Oversensing = 9.9%
- AF/SVT = 2.3%

→ **Reduced by high rate programming**

Boersma L et al, J Am Coll Cardiol 2017; 70:830-841

Subcutaneous Versus Transvenous Implantable Defibrillator Therapy

A Meta-Analysis of Case-Control Studies

Author	Study Design	# of Patients	Patient Population	Study Duration
			Single tertiary center, St	21±10 (S-ICD)
et al.	matched case-control study	140 TV-ICD	Medical Center, Netherlands	5 years
	Retrospective, case-control,			
et al.	matched to dialysis status, gender, and age	91 TV-ICD	University Hospital, Camden, NJ	180 days
Köbe, et al.	Sex- and age-matched case-control prospective study	69 S-ICD, 69 TV-ICD	University Hospitals of Düsseldorf, Munich, and Münster	217 ± 130 days

Over 6,400 patients were included in analysis, comparing lead and non-lead complications, infections, and inappropriate shocks

No significant difference in Inappropriate Shock Rates

S-ICD (8.3%) vs. TV-ICD (9.5%), p = 0.60

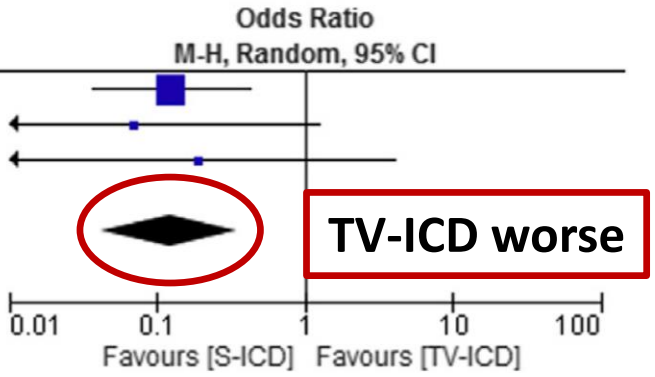
Basu-Ray I et al. JACC EP 2017; 3:1475-1483

Inappropriate Shocks – S-ICD vs. TV-ICD

Inappropriate Shocks due to SVT

Study or Subgroup	SICD Events	SICD Total	Transvenous ICD Events	Transvenous ICD Total	Weight	Odds Ratio M-H, Random, 95% CI
Brouwer 2016	3	140	21	140	74.4%	0.12 [0.04, 0.43]
Honarbakhsh 2016	0	69	6	69	13.5%	0.07 [0.00, 1.27]
Köbe 2013	0	69	2	69	12.1%	0.19 [0.01, 4.12]
Total (95% CI)		**278**		**278**	**100.0%**	**0.12 [0.04, 0.35]**
Total events	3		29			

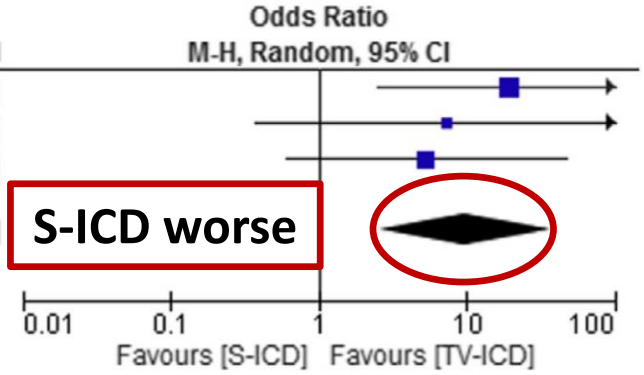
Heterogeneity: Tau² = 0.00; Chi² = 0.23, df = 2 (P = 0.89); I² = 0%
Test for overall effect: Z = 3.88 (P = 0.0001)



Inappropriate Shocks due to oversensing

Study or Subgroup	SICD Events	SICD Total	Transvenous ICD Events	Transvenous ICD Total	Weight	Odds Ratio M-H, Random, 95% CI
Brouwer 2016	17	140	1	140	42.8%	19.21 [2.52, 146.47]
Honarbakhsh 2016	3	69	0	69	19.9%	7.32 [0.37, 144.35]
Köbe 2013	5	69	1	69	37.4%	5.31 [0.60, 46.71]
Total (95% CI)		**278**		**278**	**100.0%**	**9.81 [2.60, 37.05]**
Total events	25		2			

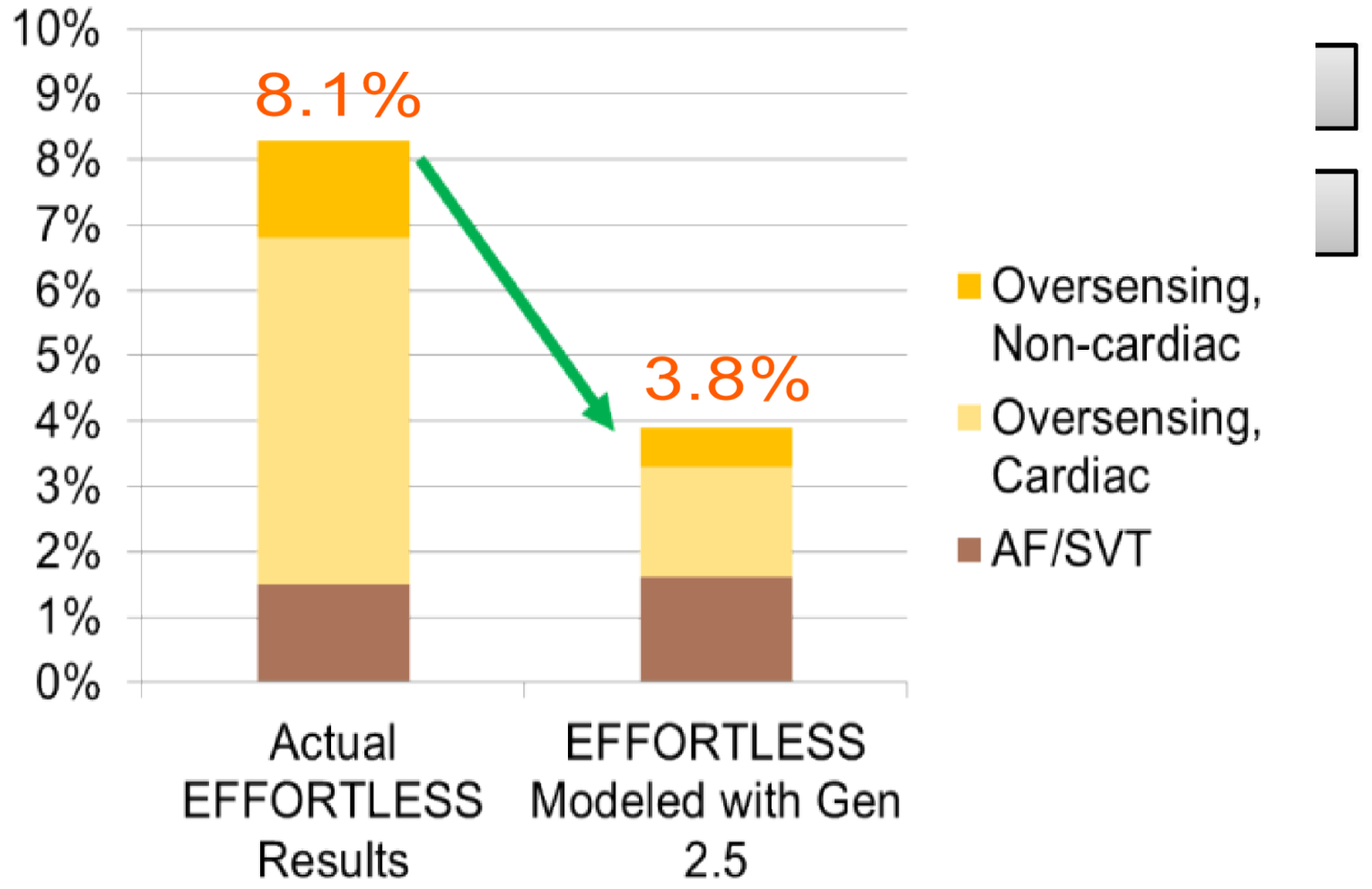
Heterogeneity: Tau² = 0.00; Chi² = 0.80, df = 2 (P = 0.67); I² = 0%
Test for overall effect: Z = 3.37 (P = 0.0008)



Basu-Ray I et al. JACC EP 2017; 3:1475-1483

SmartPass Algorithm to Avoid T Wave Oversensing

Hi



Boersma L , Europace Congress 2018

Reasons Not To Implant a S-ICD

Bulky Subcutaneous ICD

Jarman JW, Eur Heart J 2012; 33:1351-1359

Reasons Not To Implant a S-ICD

S-ICD™ System

Mass = 145 g
Volume = 69.9 cm^3

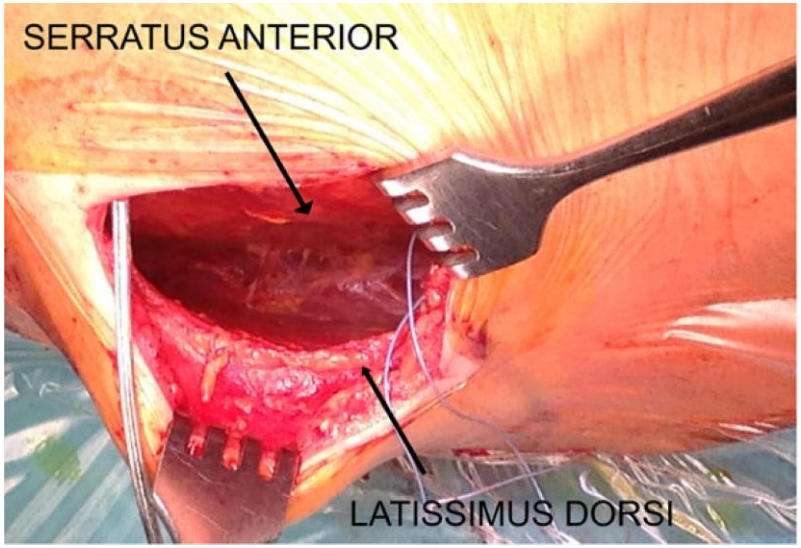
EMBLEM™ S-ICD System

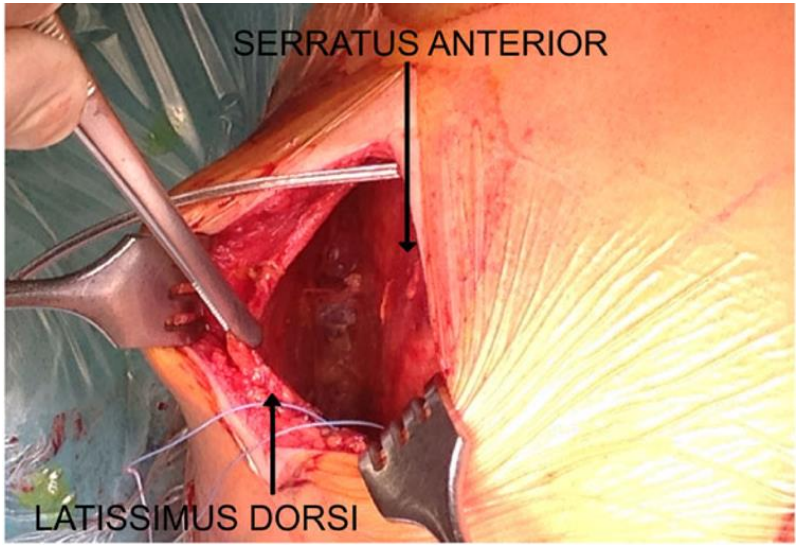
Mass = 130 g
Volume = 59.5 cm^3

Single Chamber ICD

Mass = 72 g
Volume = 30.5 cm^3

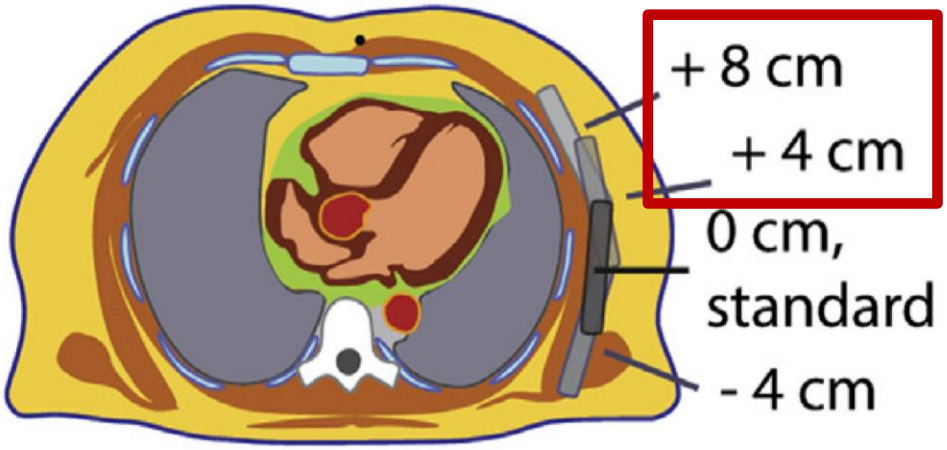
Intermuscular S-ICD Implantation

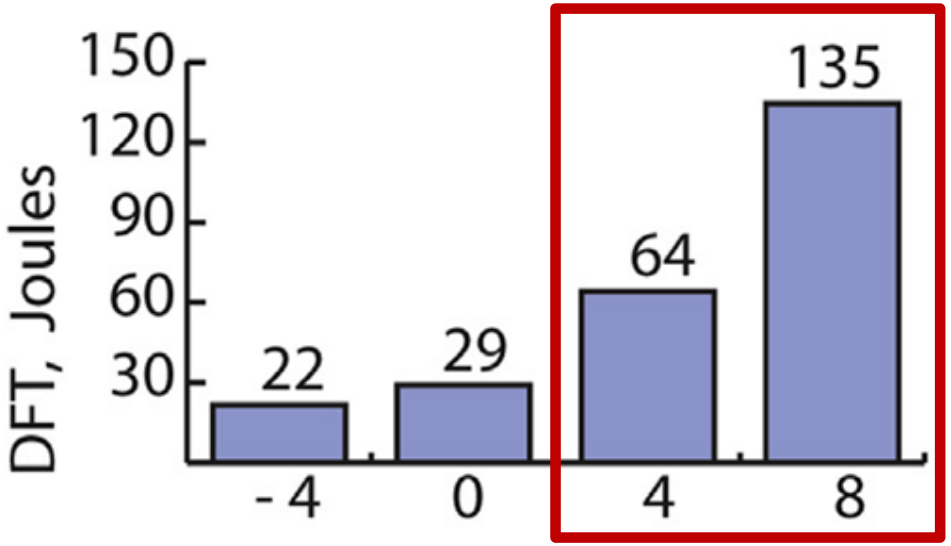




Migliore F, PACE 2017; 40:278-285

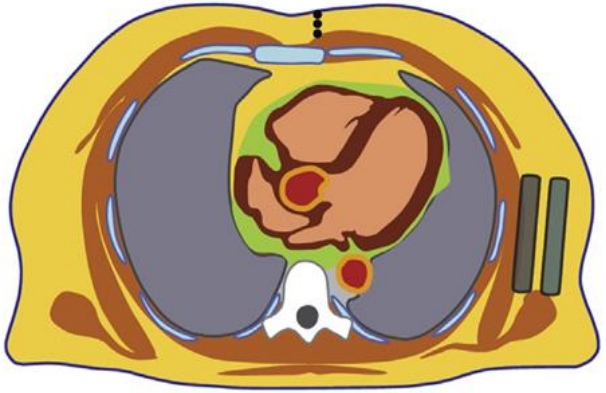
Determinants of S-ICD Shock Efficacy

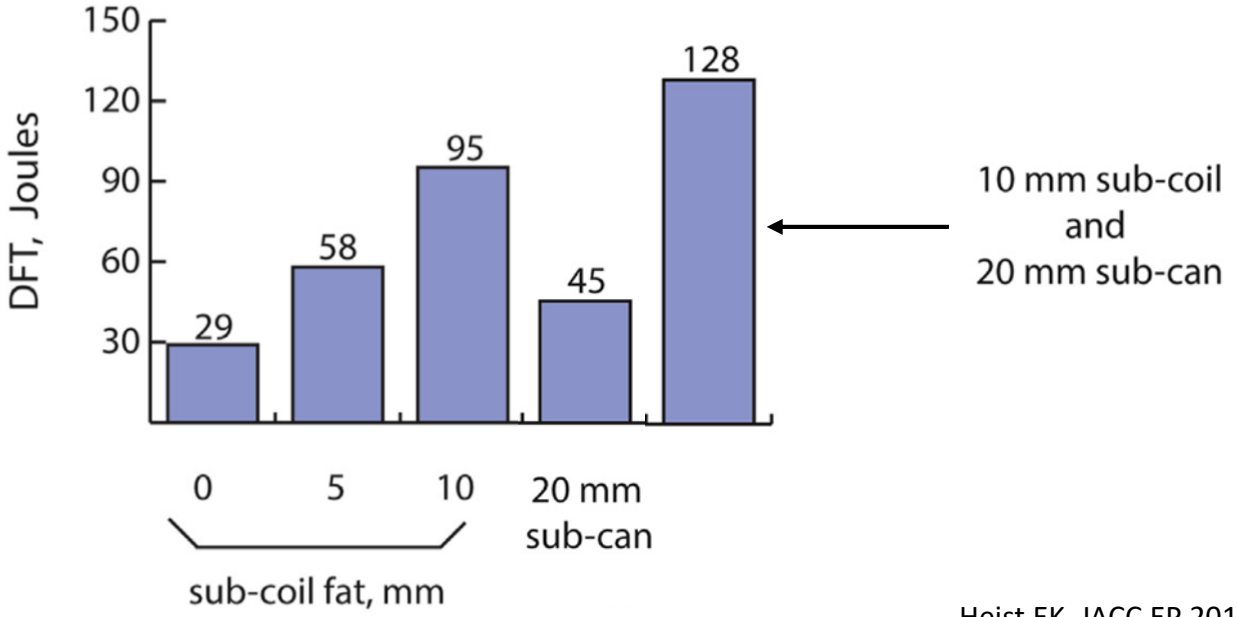




Heist EK, JACC EP 2017; 405-414

Determinants of S-ICD Shock Efficacy





Heist EK, JACC EP 2017; 405-414

Infections Leading to S-ICD Explant

Study	EFFORTLESS[1]	IDE[2]	US Post-approval[3]
Explants/pts	24/998	4/304	8/1643
	2.4%	1.3%	0.5%
Re-implants	12/998		
	1.2%		

No mortality nor serious adverse events during explantation of the S-ICD system

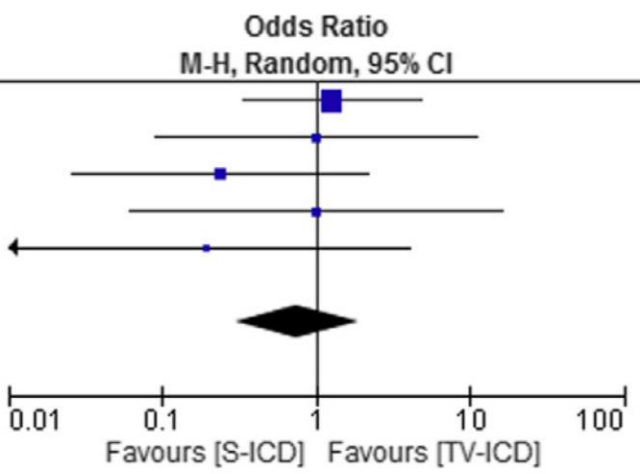
Boersma L et al. Heart Rhythm 2017. Weiss R et al. Circulation 2013. Gold M et al. Heart Rhythm 2017.

S-ICD vs. TV-ICD Infection Rates

Study or Subgroup	SICD Events	SICD Total	Transvenous ICD Events	Transvenous ICD Total	Weight	Odds Ratio M-H, Random, 95% CI
Brouwer 2016	5	140	4	140	47.8%	1.26 [0.33, 4.79]
Friedman 2016	1	1920	2	3840	14.8%	1.00 [0.09, 11.04]
Honarbakhsh 2016	1	69	4	69	17.3%	0.24 [0.03, 2.19]
Köbe 2013	1	69	1	69	10.9%	1.00 [0.06, 16.32]
Mithani 2016	0	71	2	71	9.1%	0.19 [0.01, 4.12]
Total (95% CI)		**2269**		**4189**	**100.0%**	**0.75 [0.30, 1.89]**
Total events	8		13			

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 2.49$, $df = 4$ ($P = 0.65$); $I^2 = 0\%$

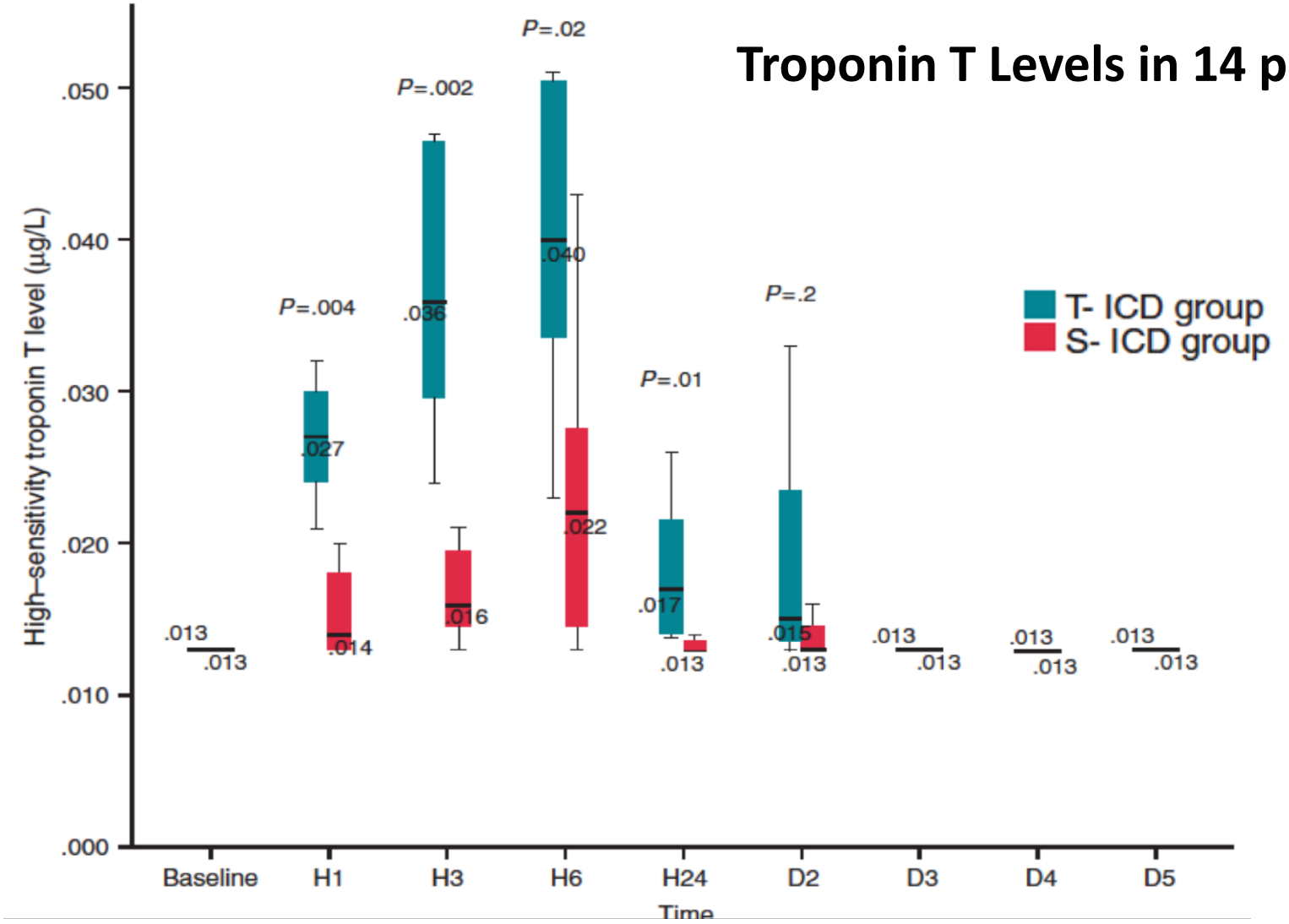
Test for overall effect: $Z = 0.61$ ($P = 0.54$)



Infection rate with S-ICD was low at 0.35% and similar to TV-ICD with 2 out of 5 studies favoring S-ICD

Basu-Ray I et al. JACC EP 2017; 3:1475-1483

Are High Energy Shocks (80 J) Dangerous?



Garcia R, Europace 2018; 5: 873-879

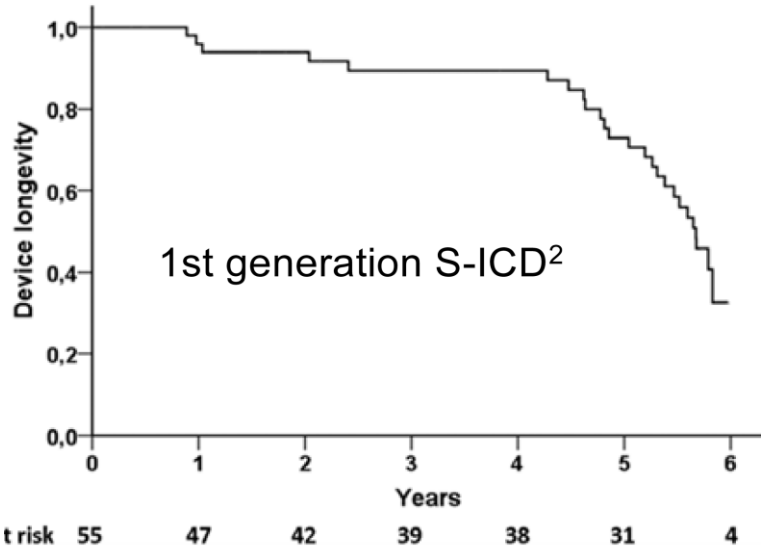
Reasons Not To Implant a S-ICD

Common cardiologist reaction to cost issues

Improving S-ICD Longevity

1st Generation S-ICD

A. 55 pts CE mark cohort, FU 5.8 yrs
   Median time to ERI = 5.0 yrs
B. 118 pts Dutch cohort, FU 6 yrs
   Median time to ERI = 5.7 yrs

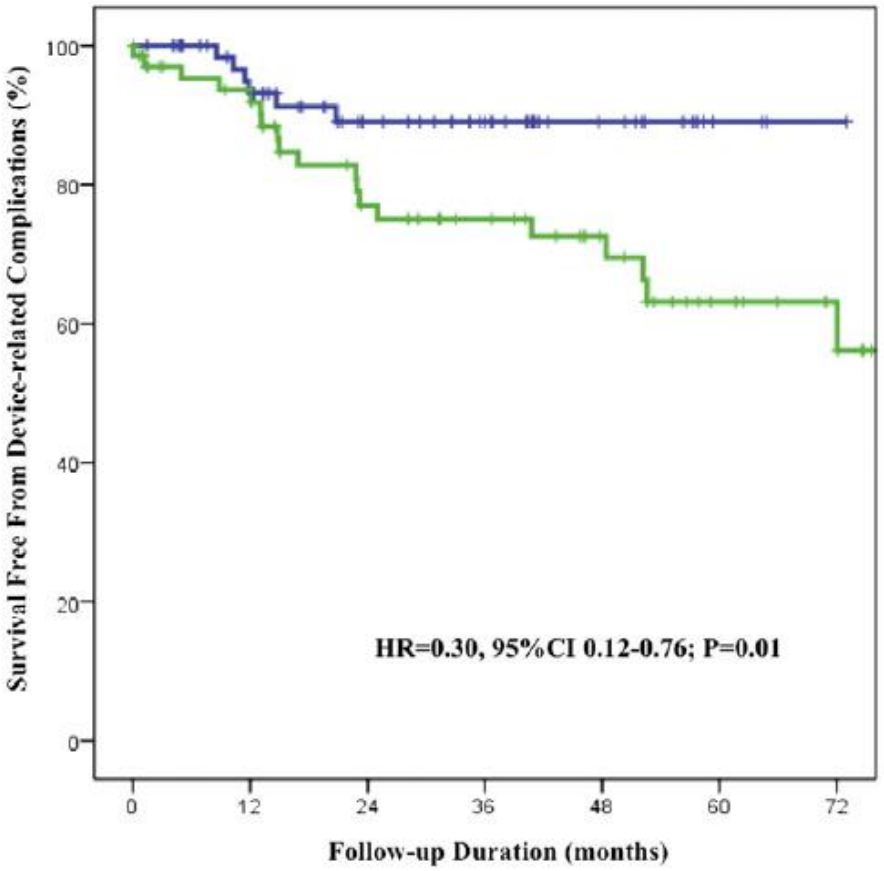


2nd Generation EMBLEM S-ICD

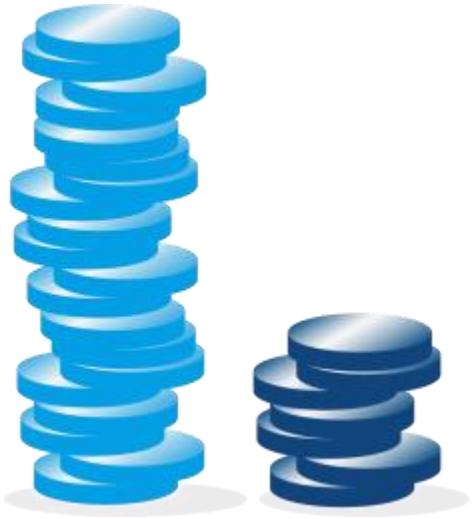
- Longevity by labelling = 7.3 yrs
- Projection by Latitude = 8.7 yrs

Bardy M et. al. NEJM 2010
Theuns et al. Circ Arrhythm Electrophysiol 2015
Quast et al. HRS 2017

S-ICD May Reduce Costs of Complications



N at Risk	0	12	24	36	48	60	72
S-ICD	69	54	36	28	15	3	1
TV-ICD	69	55	39	33	24	14	9



The cost to treat device-related complications was

2.5x HIGHER[1]

with a **TV-ICD** than with an **S-ICD**.

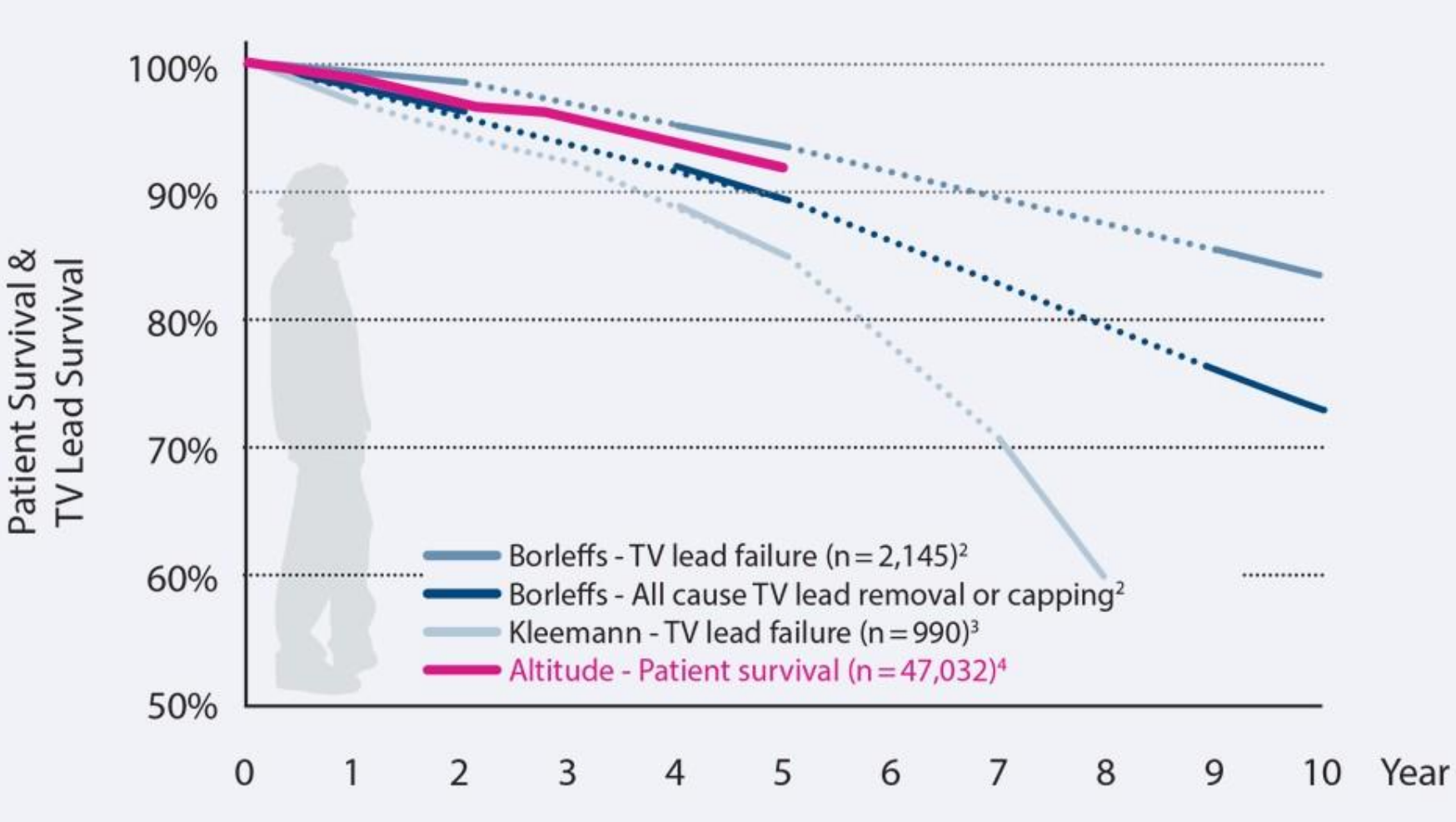
Honarbakhsh S., et al. Int J Cardiol 2017; 228:280-5.

Take Home Messages

- **S-ICD is a safe and effective defibrillating device with rates of inappropriate therapies comparable to conventional TV-ICD**
- **Anti-bradycardia and anti-tachycardia pacing are probably less needed than commonly perceived but they still prevent S-ICD spread**
- **Selection of appropriate candidates, adequate screening and optimized programming remain crucial to increase S-ICD technology yield**

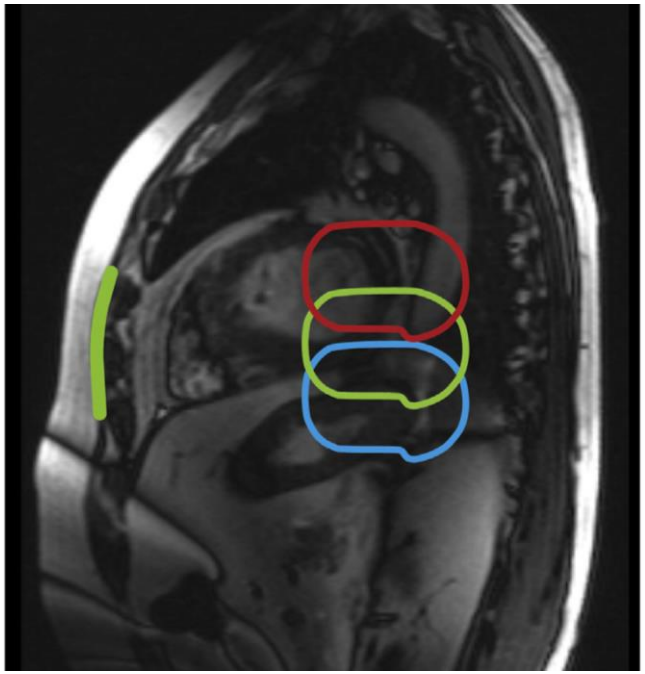

Thank you for your attention!

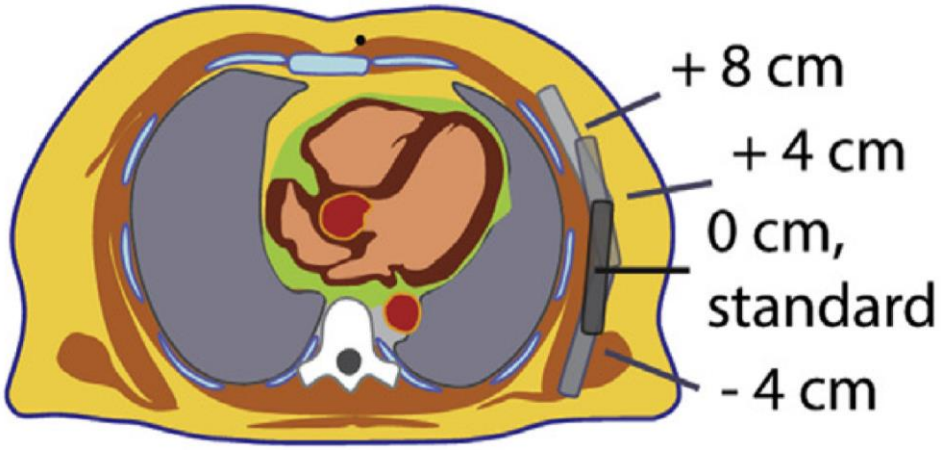
Transvenous Lead Survival

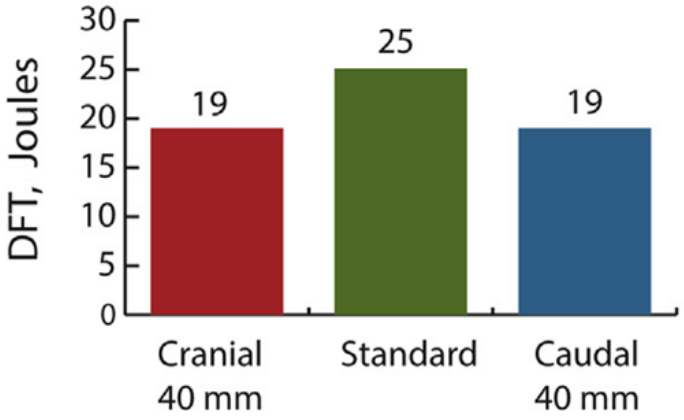


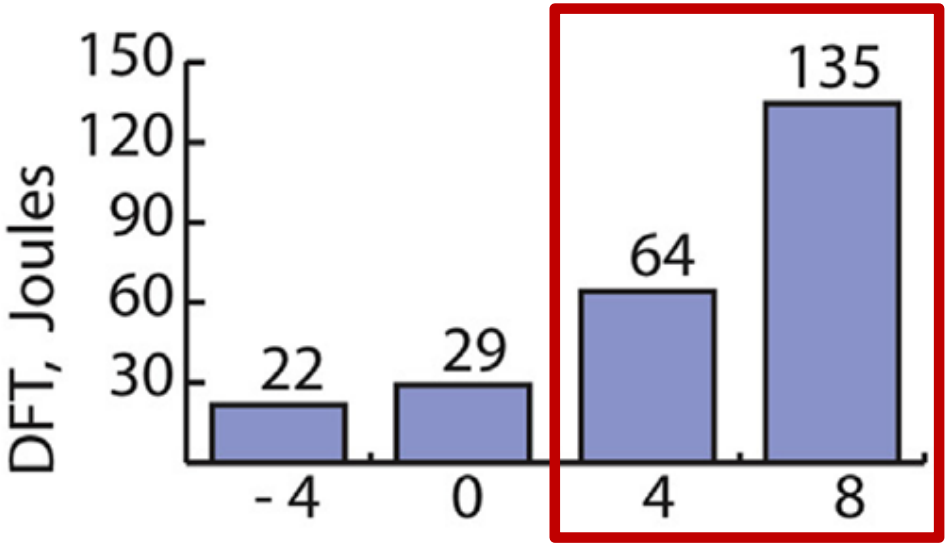
Patients live longer than their transvenous system

Determinants of S-ICD Shock Efficacy





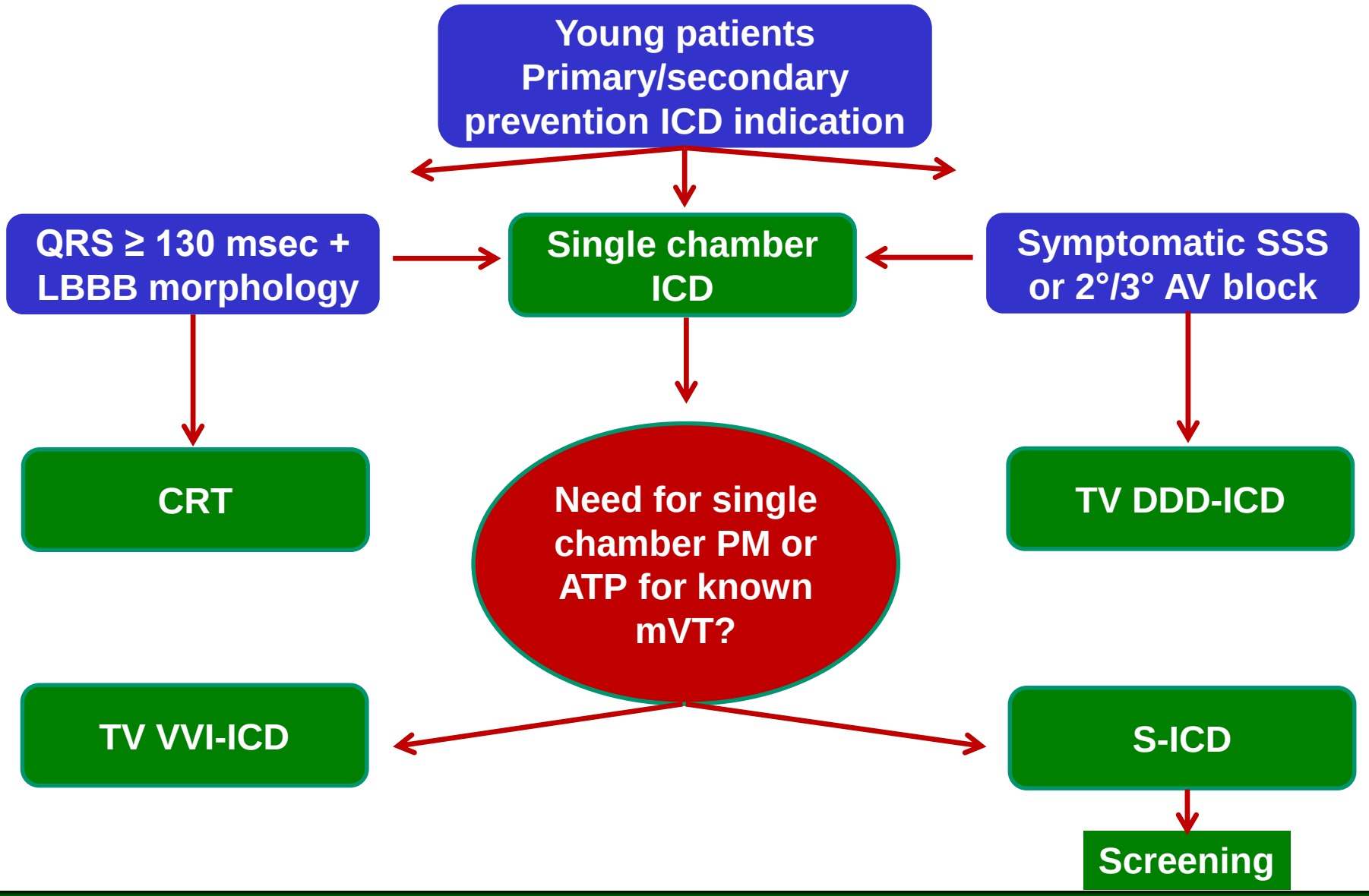




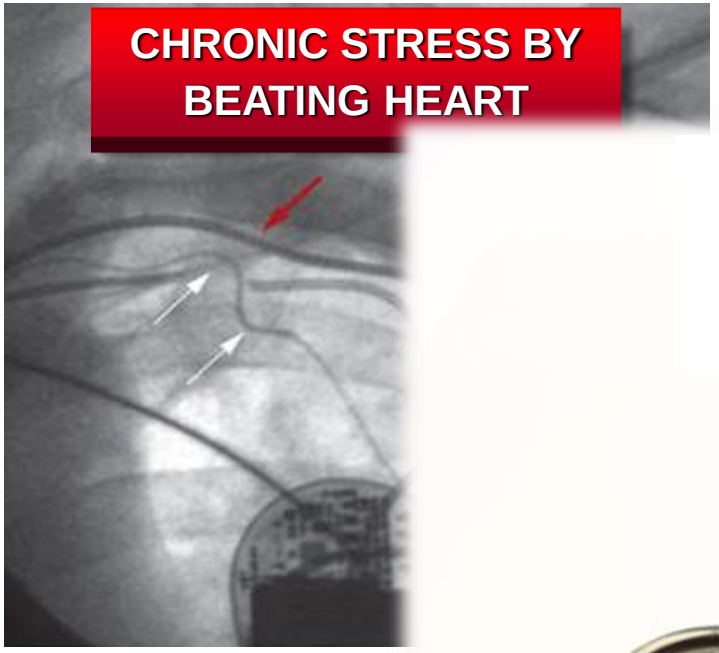
Heist EK, JACC EP 2017; 405-414

Find the Outlier

Selection of S-ICD Candidates



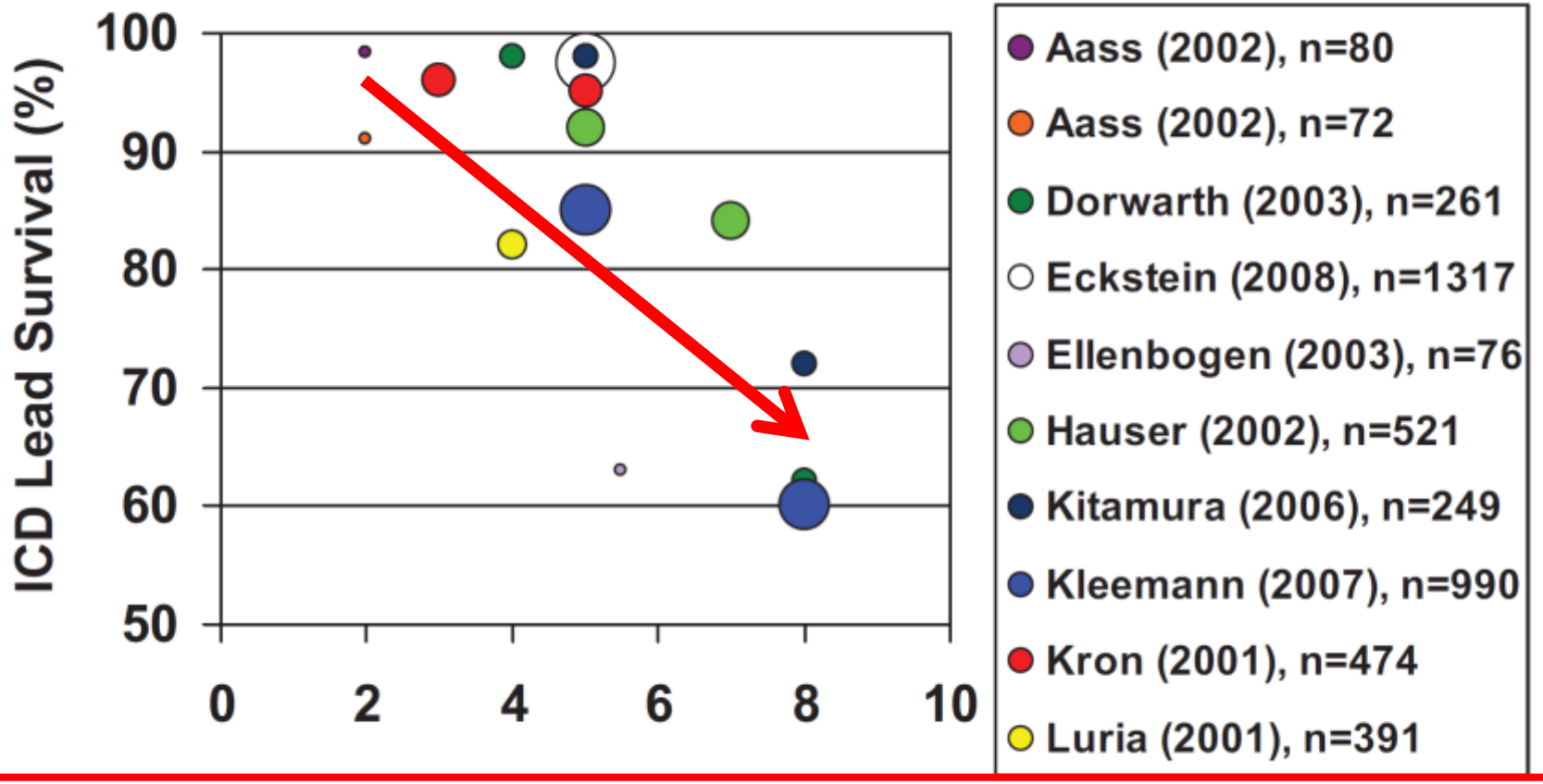
Lead as The Weakest Link of an ICD



Wazni O et al. Nat Rev Cardiol 2010; 7: 376-383

Hauser RG New Engl J Med 2012; 366:10

ICD Lead Performance



≈ 20-30% ICD transvenous lead fail by 10 yrs

Circulation 2007; 115: 2474-2480

Circulation 2008; 117: 2721-2723