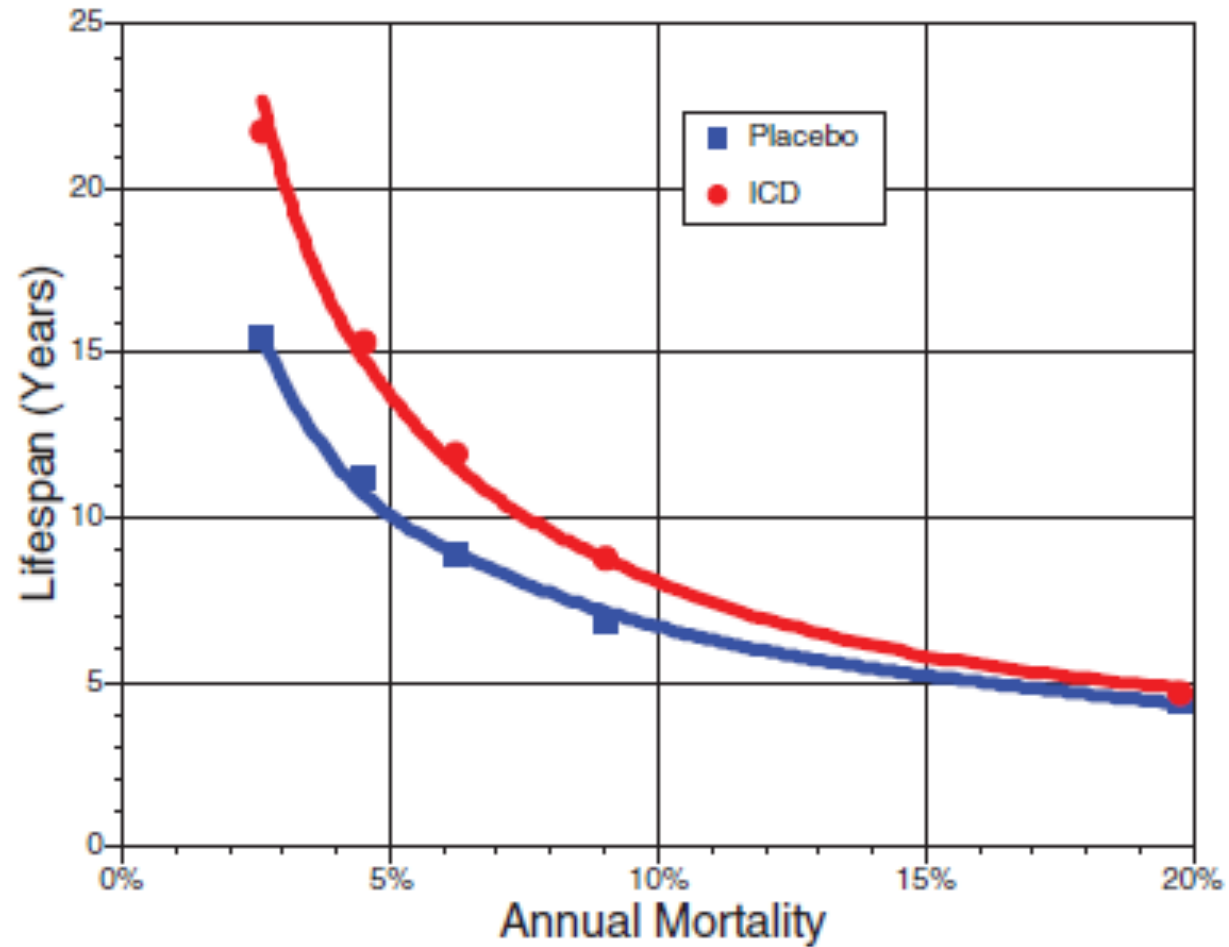


The time is ripe for S-ICD to replace the transvenous ICD ?



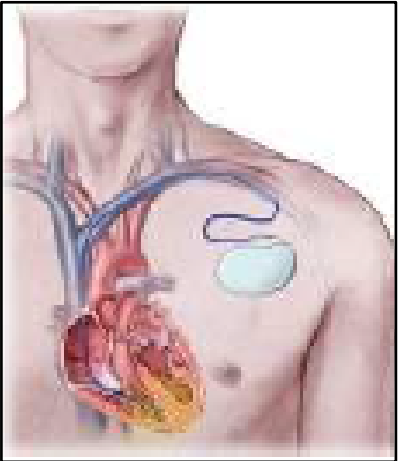
Mauro Biffi
Istituto di Cardiologia
Policlinico S.Orsola-Malpighi
Bologna

Life-expectancy gain by ICD therapy in non-severe (NYHA 4) HF patients



Circulation. 2009;120:835–842.

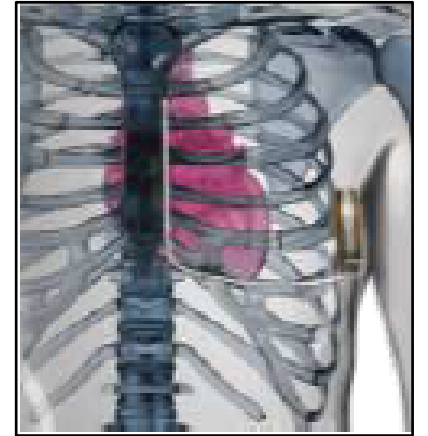
DOES it Matter how you save one life?



כָּל הַמַּצִּיל נֶפֶשׁ אַחַת מִיִּשְׂרָאֵל,
כְּאִילוֹ הִצִּיל עוֹלָם מָלֵא.

Kol hamatzil nefesh achât mi'Yisra'êl,
ke'ilu hitsil olâm malê.

Whoever saves a single life is as if
he had saved an entire universe.



Face to face

Favours S-ICD

- Spares vascular access
- NO intravascular complications
- Endovascular infection unlikely, NO life threatening extraction
- Fewer LEAD complications

Favours TV-ICD

- Smaller device size
- Longer longevity
- Better sensing and noise discrimination
- ATP, brady pacing

What is your preference ?
Raise your hands..

Transvenous SC ICD

Subcutaneous ICD



2015 ESC Guidelines

2017 AHA/ACC Guidelines

Subcutaneous implantable cardioverter defibrillator

Recommendations	Class ^a	Level ^b	Ref. ^c
Subcutaneous defibrillators should be considered as an alternative to transvenous defibrillators in patients with an indication for an ICD when pacing therapy for bradycardia support, cardiac resynchronization or antitachycardia pacing is not needed.	IIa	C	157, 158
The subcutaneous ICD may be considered as a useful alternative to the transvenous ICD system when venous access is difficult, after the removal of a transvenous ICD for infections or in young patients with a long-term need for ICD therapy.	IIb	C	This panel of experts

ICD = implantable cardioverter defibrillator.

^aClass of recommendation.

^bLevel of evidence.

^cReference(s) supporting recommendations.

Recommendations for Subcutaneous Implantable Cardioverter-Defibrillator

References that support the recommendations are summarized in Online Data Supplement 55.

COR	LOE	Recommendations
I	B-NR	1. In patients who meet criteria for an ICD who have inadequate vascular access or are at high risk for infection, and in whom pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated, a subcutaneous implantable cardioverter-defibrillator is recommended (1-5).
IIa	B-NR	2. In patients who meet indication for an ICD, implantation of a subcutaneous implantable cardioverter-defibrillator is reasonable if pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated (1-4).
III: Harm	B-NR	3. In patients with an indication for bradycardia pacing or CRT, or for whom antitachycardia pacing for VT termination is required, a subcutaneous implantable cardioverter-defibrillator should not be implanted (1-4, 6-8).

S-ICD:

- Young
- No need for ATP/pacing
- High infection risk

Individualized approach

- Age
- Infection risk
- Lead issues
- Need for ATP
- Need for pacing
- Etiology
- Indication
- Disease progression
- (Costs)

What does your patient need?

- Treatment of sudden death

Shock BOX

- Treatment of sudden death, + treatment of ventricular tachyarrhythmias, + ?

Shock BOX + ATP +

Is this a case for:
Less is More

Ludwig Mies van der Rohe



Or is it simply
LESS ?



Primary and secondary prevention

Main findings:

- 1) patients treated for secondary prevention experienced appropriate therapy more often;
- 2) the long-term risk for all-cause mortality was comparable for both groups;
- 3) risk for subsequent VA was higher in primary prevention patients than in secondary prevention patients;
- 4) no differences were demonstrated in the incidence of inappropriate shocks.

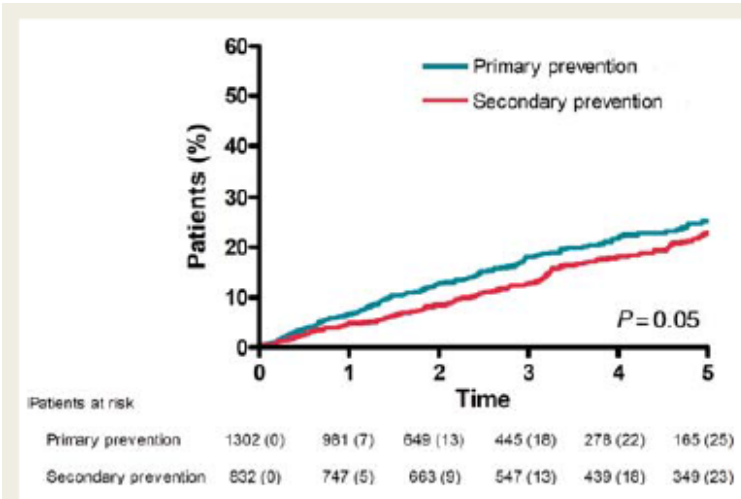


Figure 1 All-cause mortality. Kaplan–Meier curves of all-cause mortality for primary and secondary prevention implantable cardioverter defibrillator recipients. In the parenthesis, next to patients at risk, the yearly incidences (%) per corresponding time point are noted.

Conclusion

During long-term follow-up, compared with secondary prevention ICD patients, primary prevention ICD recipients exhibited a lower risk of VA, which triggered appropriate ICD therapy but demonstrated comparable mortality rates. Both groups showed a similar occurrence of inappropriate shocks.

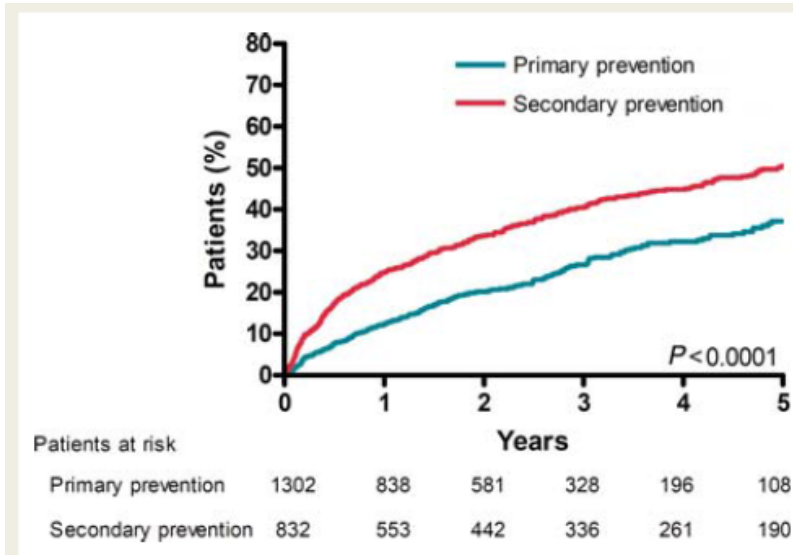


Figure 2 Appropriate therapy. Kaplan–Meier curves of appropriate therapy for primary and secondary prevention implantable cardioverter defibrillator recipients.

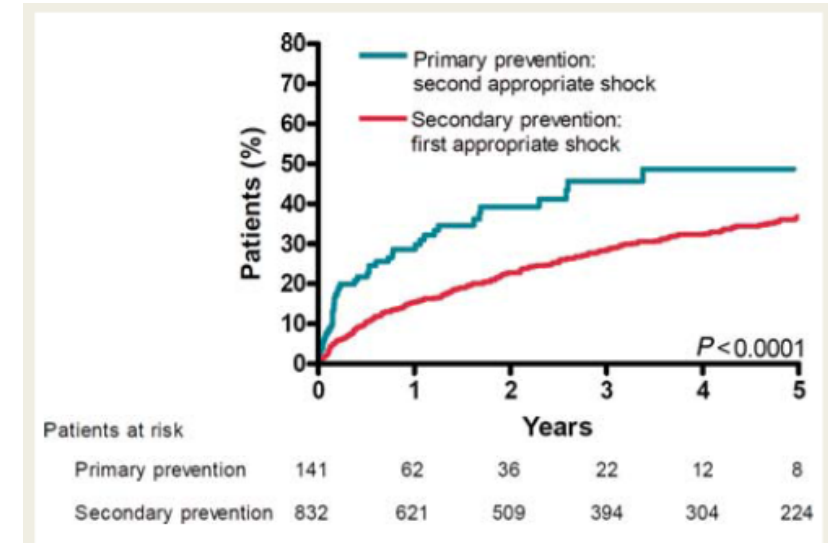
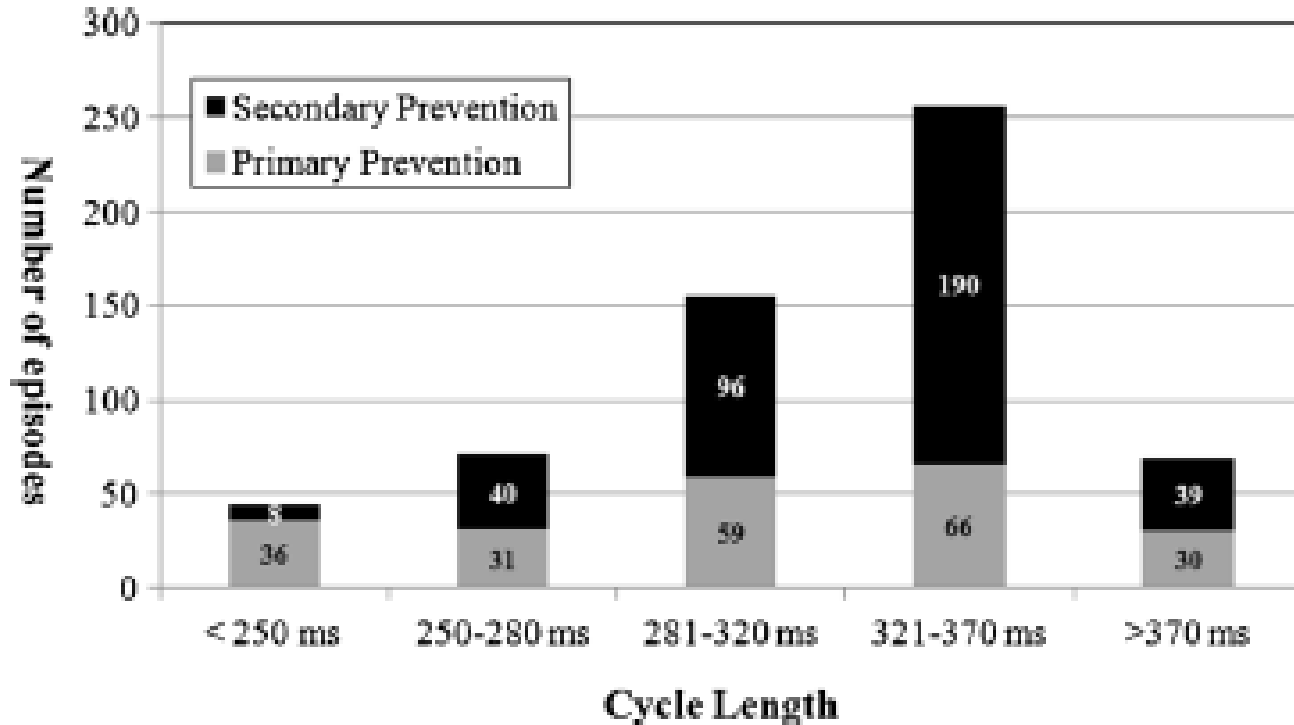


Figure 4 Subsequent risk for appropriate shock. Kaplan–Meier curves of appropriate shock for the second appropriate shock in primary prevention implantable cardioverter defibrillator recipients and the first appropriate shock in secondary prevention implantable cardioverter defibrillator recipients.

Primary and secondary prevention: Arrhythmias cycle length



- Prevalence of VT & VF episodes higher in SP
- SP pts tend to recur with the same arrhythmia
- VTs occurring in SP terminate less frequently with ATP
- SP patients seem to have fewer self-terminating VTs

Arrhythmias:

Ischemic vs Non-ischemic Etiology... it's not enough !!

Primary endpoint: occurrence of any appropriate ICD therapy

	Ischemic Etiology, n = 53	Nonischemic Etiology, n = 43
LGE positive	51 (95.7)	38 (77.6)
Ischemic pattern	48 (90.5)	1 (2.3)
Nonischemic pattern	3 (5.7)	31 (81.6)
Cx-LGE	21 (39.6)	11 (25.6)
Subtype 1 ^a	16 (34.0)	0 (0.0)
Subtype 2 ^b	0 (0.0)	6 (11.3)
Subtype 3 ^c	0 (0.0)	4 (7.5)
Subtype 4 ^d	5 (9.4)	3 (7.0)

Abbreviations: Cx-LGE, complex late gadolinium enhancement; LGE, late gadolinium enhancement. Data are presented as n (%). ≥1 pattern can coexist in the same patient; patterns are calculated for LGE-positive patients and Cx-LGE for overall patients.

LGE was defined as "complex" (Cx-LGE) in presence of ≥1 of the following:

- ischemic pattern, involving ≥2 different coronary territories (subtype 1);
- epicardial pattern (subtype 2);
- global endocardial pattern (subtype 3);
- presence of ≥2 different patterns (subtype 4).

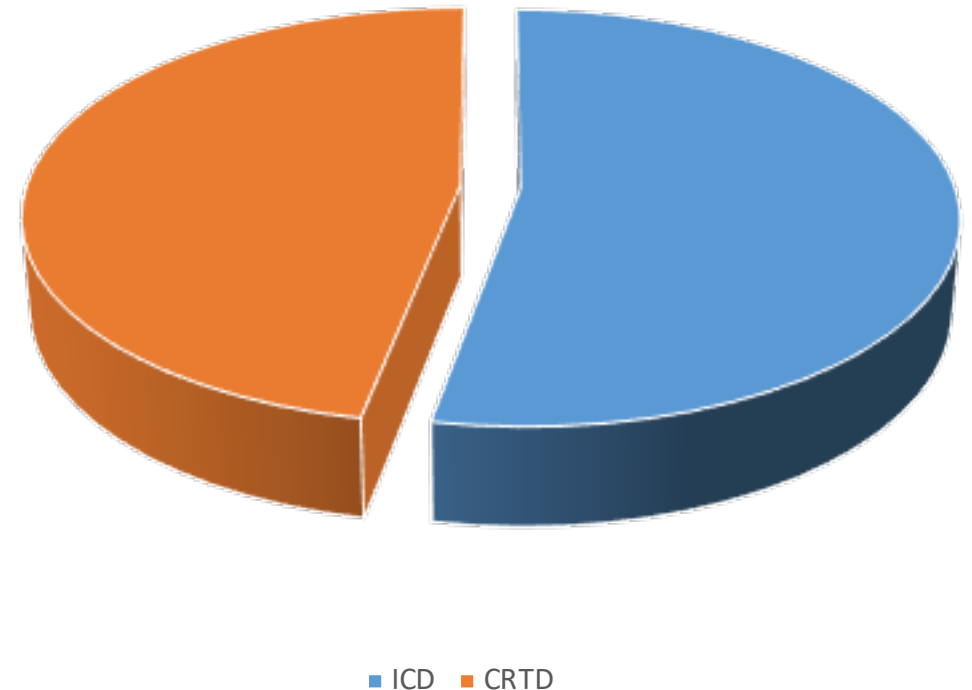
Variables	Sustained VA Requiring ICD Therapy					
	Univariate			Multivariate		
	HR	95% CI	P Value	HR	95% CI	P Value
Sex	1.43	0.59–3.50	0.425	—	—	—
NYHA class III/IV	0.68	0.33–1.39	0.293	—	—	—
Secondary prevention	1.22	0.43–3.49	0.711	—	—	—
AF	0.65	0.16–2.70	0.553	—	—	—
LBBB	0.46	0.22–0.97	0.041	0.68	0.31–1.52	0.348
MR grade 3–4	1.00	0.45–2.23	1.00	—	—	—
LVEF-CMR (10% step)	1.04	0.65–1.67	0.862	—	—	—
LVEDV-CMR (10-mL step)	1.03	0.98–1.08	0.216	—	—	—
RVEF-CMR (10% step)	0.90	0.71–1.13	0.365	—	—	—
RVEDV-CMR (10-mL step)	1.07	1.01–1.14	0.034	1.06	1.00–1.12	0.045
LV aneurysm	1.02	0.46–2.29	0.956	—	—	—
LGE positivity	5.79	0.80–42.14	0.084	—	—	—
Ischemic LGE	1.18	0.58–2.43	0.651	—	—	—
Cx-LGE	3.27	1.59–6.74	0.001	3.22	1.56–6.65	0.002

Abbreviations: AF, atrial fibrillation; CI, confidence interval; CMR, cardiovascular magnetic resonance; Cx-LGE, complex late gadolinium enhancement; HR, hazard ratio; ICD, implantable cardioverter-defibrillator; LBBB, left bundle branch block; LGE, late gadolinium enhancement; LV, left ventricular; LVEDV-CMR, left ventricular end-diastolic volume measured with CMR; LVEF-CMR, left ventricular ejection fraction measured with CMR; MR, mitral regurgitation; NYHA, New York Heart Association; RVEDV-CMR, right ventricular end-diastolic volume measured with CMR; RVEF-CMR, right ventricular ejection fraction measured with CMR; VA, ventricular arrhythmia.

Points of discussion

- Age
- Infection risk
- Lead issues
- Need for ATP
- Need for pacing
- Etiology
- Indications
- Arrhythmic potential
- (Costs)

ICD recipients today



Factors influencing the use of subcutaneous or transvenous ICD: EHRA Survey

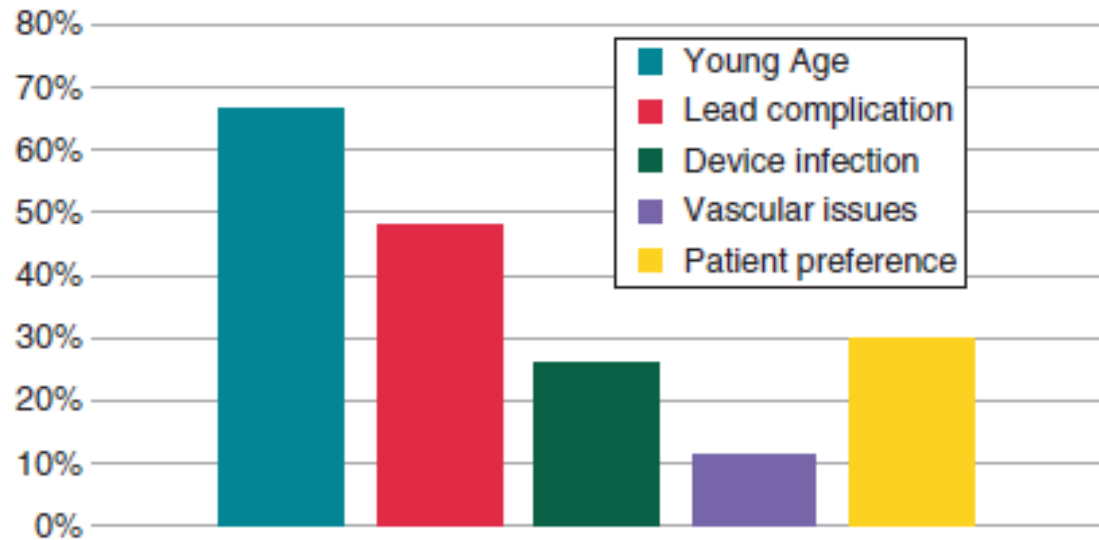


Figure 2 Factors in favour of S-ICD implantation (multiple answers). Each bar represents one possible answer (proportion of responders to each question). S-ICD, subcutaneous implantable cardioverter-defibrillator.

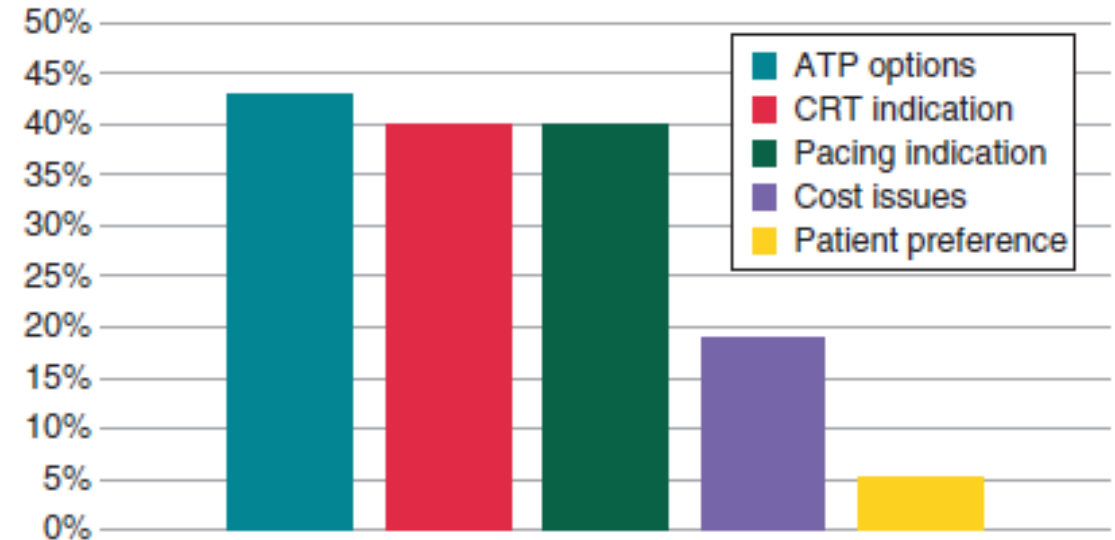


Figure 3 Factors in favour of a transvenous ICD implantation (multiple answers). Each bar represents one possible answer (proportion of responders to each question). ICD, implantable cardioverter-defibrillator.

SICD: why and why not?

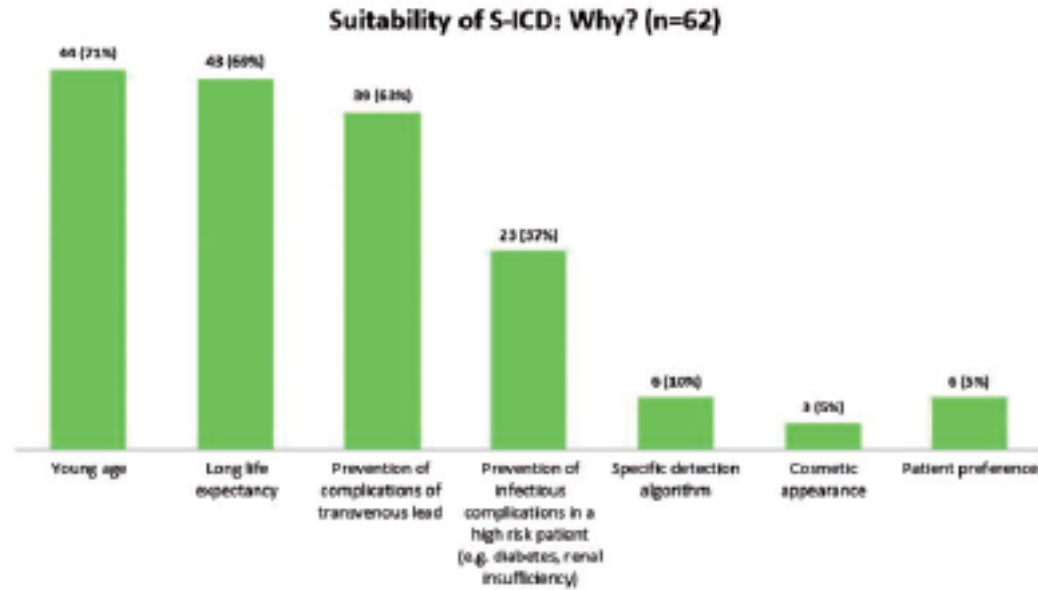


Figure 3 Factors for preferring an S-ICD over a transvenous ICD (n = 62). Multiple factors were reported per patient.

AIAC Survey

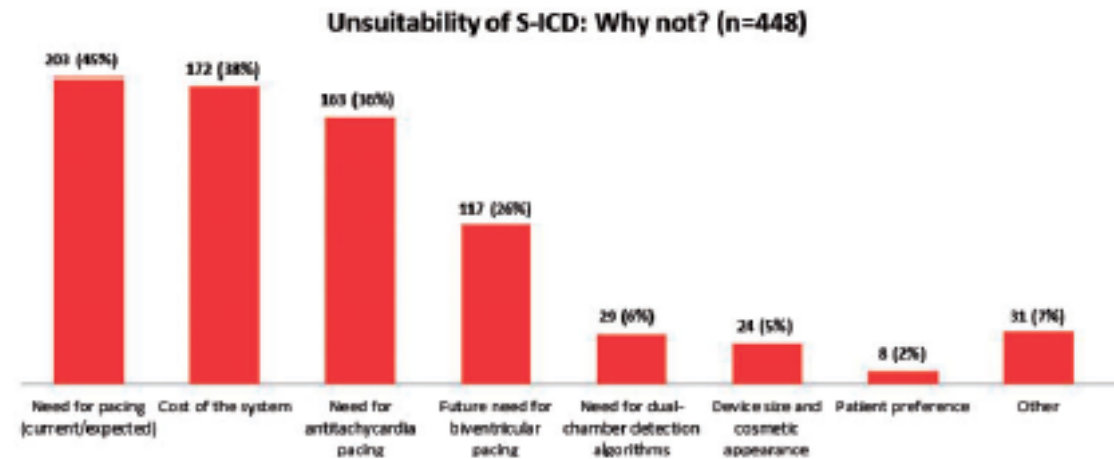
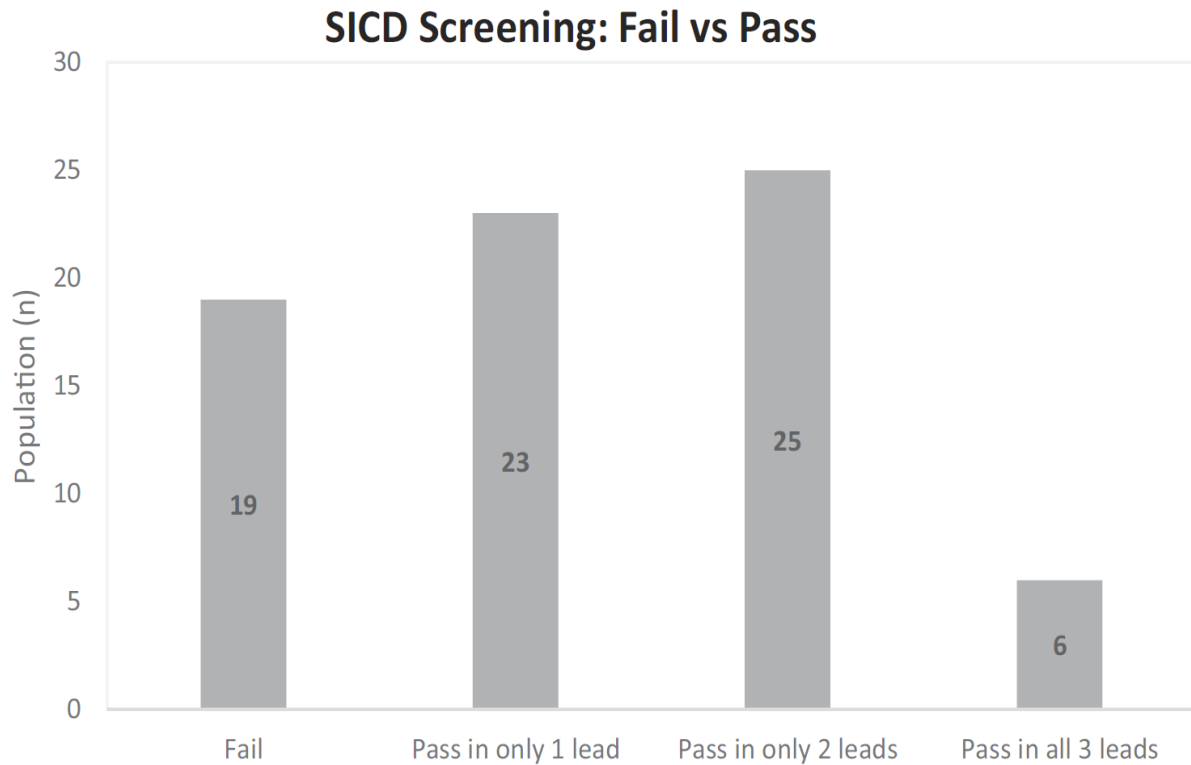
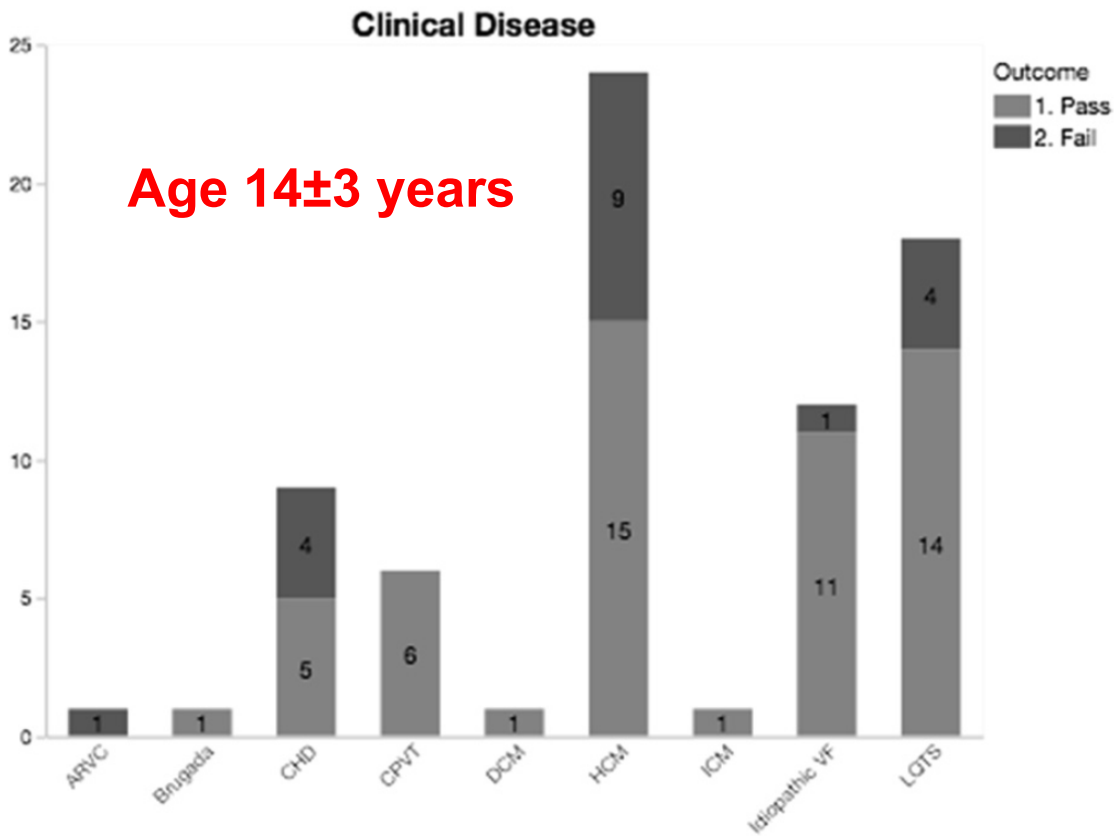


Figure 2 Factors for preferring a transvenous ICD over an S-ICD (n = 448). Multiple factors were reported per patient.

Predictors of electrocardiographic screening failure for the subcutaneous implantable cardioverter-defibrillator in children: A prospective multicenter study

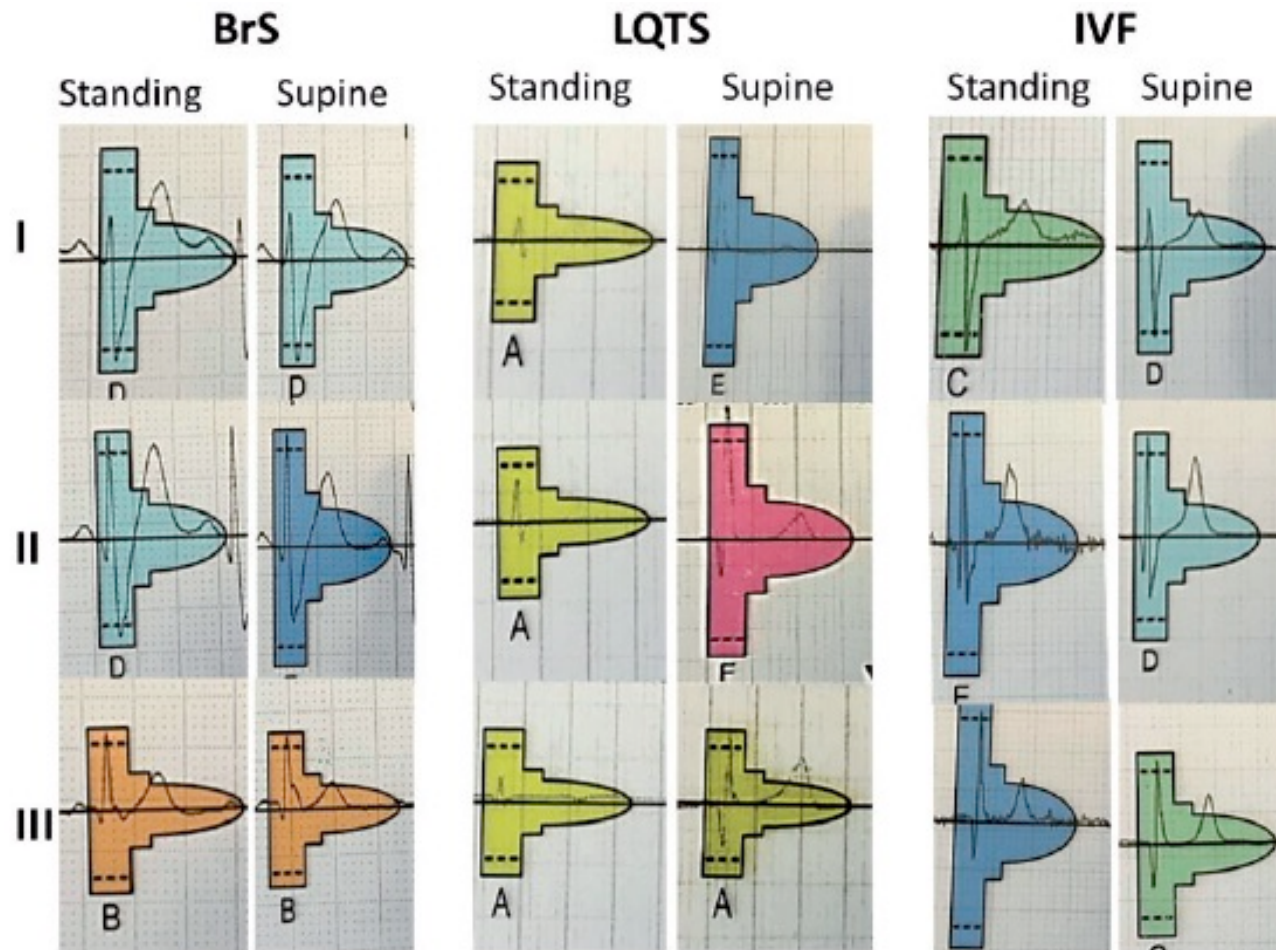
Matthew Campbell, MD,^{*} Jeremy P. Moore, MD, MS,[†] Narayanswami Sreeram, MD, PhD,[‡] Johannes C. von Alvensleben, MD,[§] Anjan Shah, MD,^{||} Anjan Batra, MD,[¶] Ian Law, MD,[#] Shubhayan Sanatani, MD, FRCPC, FHRS,^{**} Vincent Thomas, MD,^{††} Farnoosh Nik-Ahd, BS, BA,[†] Stephen Williams, MD,^{||} Nina Nosavan, MD,[¶] Jennifer Maldonado, BS,[#] Amelia Hart, RCT,^{**} Thuan Nguyen, MD, MS, PhD,^{*} Seshadri Balaji, MBBS, FRCP, PhD^{*}

Heart Rhythm 2018, In Press



Variable	Exp β	Odds ratio	Pr>ChiSq
QTc interval (>440 ms)	1.60	5.0	.016
QRS duration (>120 ms)	2.20	8.6	.016
R:T ratio in lead aVF (<6.5)	2.42	11.3	.017

High rate of subcutaneous implantable cardioverter-defibrillator sensing screening failure in patients with Brugada syndrome: a comparison with other inherited primary arrhythmia syndromes



S-ICD screening failure occurs in up to 13% of patients with inherited primary arrhythmia syndromes.

Patients with BrS present the highest rate of screening failure as compared with other cardiac channelopathies.

18% Screening Failure in Brugada patients amongst other primary arrhythmia syndromes

Table 1 Clinical, ECG, and S-ICD screening characteristics of patients with BrS and patients with other inherited primary arrhythmias syndromes

	BrS (<i>n</i> = 61)	LQTS/IVF/ERS (<i>n</i> = 39)	<i>P</i> value
Age (years)	42.5 ± 15.3	44.0 ± 18.2	0.46
Male gender, <i>n</i> (%)	50 (82%)	22 (56%)	0.007
BMI (kg/m ²)	23.8	22.7	0.84
Aborted SD, <i>n</i> (%)	9 (14.7%)	24 (61.5%)	<0.001
Syncope, <i>n</i> (%)	13 (21.3%)	8 (20.5%)	1.0
Family history of SD, <i>n</i> (%)	20 (32%)	7 (17%)	0.11
Inducible at EPS, <i>n</i> (%)	7 (11.4%)	—	—
Spontaneous type 1 ECG, <i>n</i> (%)	34 (55.7%)	—	—
AV conduction disturbances, <i>n</i> (%)	22 (36.0)	14 (35.8%)	1.00
S-ICD screening failure rate (%)	11 (18%)	2 (5%)	0.07
Absolute number of appropriate vectors, <i>n</i> (%)	786 (49.6%)	595 (84.7%)	<0.001
Mean number of appropriate vectors per patient, <i>n</i>	1.5 ± 0.9	2.0 ± 0.9	0.72

Patients want an infection-free life & longer lasting devices

73% of patients are concerned about battery life and device longevity¹

Perspectives from patients

“I want it to last as long as possible, worry-free”² —Gary, Congestive Heart Failure



“There is no minor surgery...anytime you get cut open you are opening yourself up to getting an infection”² — Tom, ICD Patient

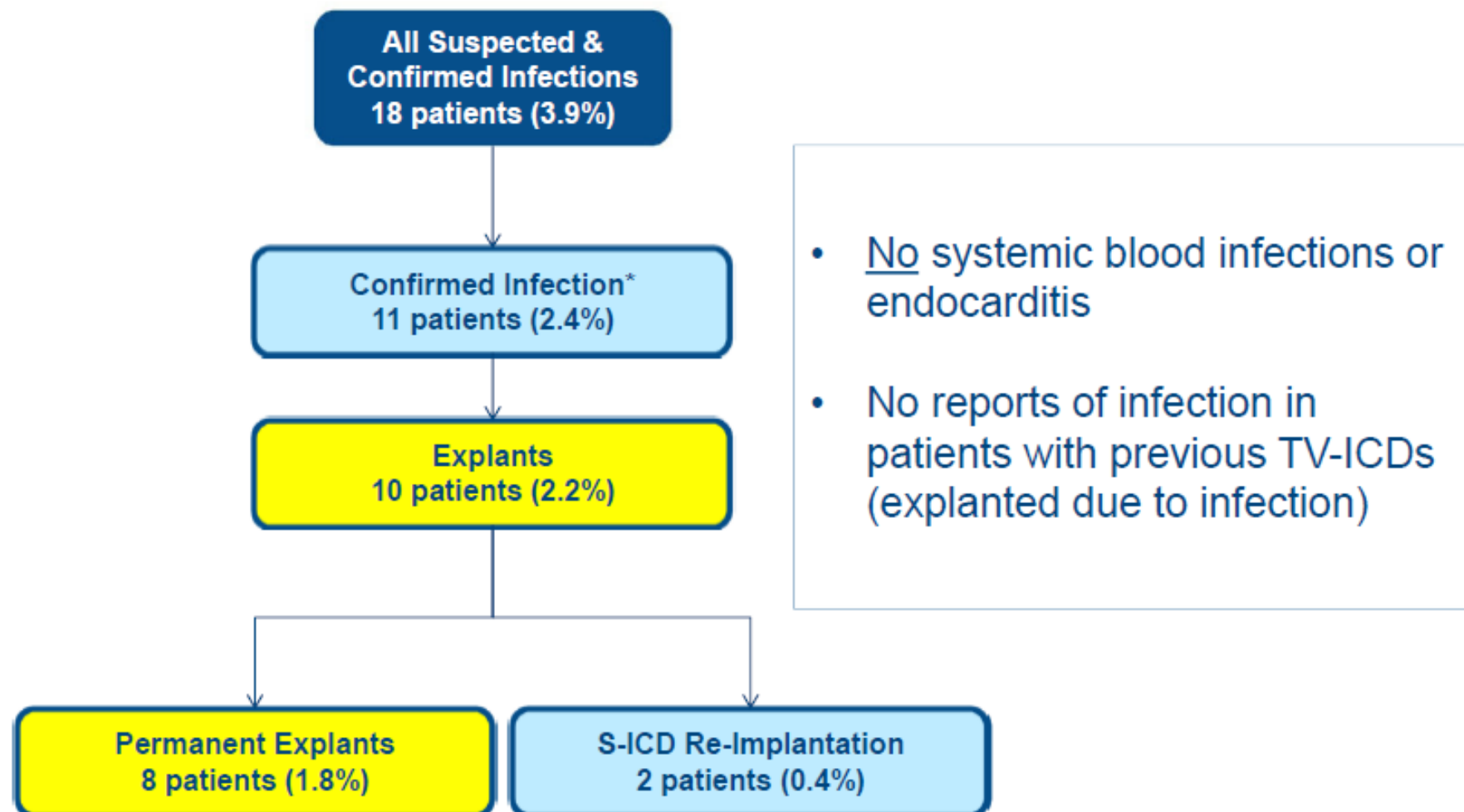
¹High Voltage Patient Survey, January 2011. Double-blind online survey administered by 3rd party vendor; conducted among 189 high voltage device patients.

²Verbatims from double-blinded focus groups of congestive heart failure patients, led by independent moderators in Minneapolis, Philadelphia, and San Francisco.

EFFORTLESS S-ICD™ System Registry

Infections

Boston
Scientific



DEtect long-term **CO**mplications after ic**D** **rE**placement: a multicenter Italian registry

Registro **DECODE**

**983 patients, ICD and CRTD Replacement or upgrade
Minumum 12 months FU**

Infection rate 1.2%



Clinical-decode@isis.it

DECODE Registry Group

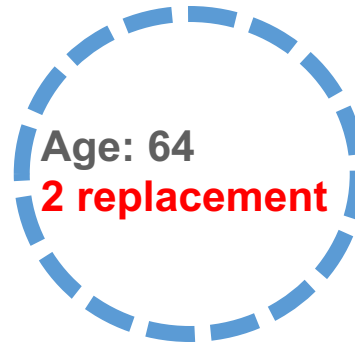
Pag. 1/1



Longevity: SICD vs TVICD

Which device in a 28 yrs old pt?

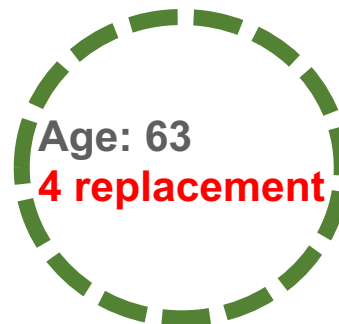
Age : 28
TVICD implant
Longevity Device



Infection risk

3-4%

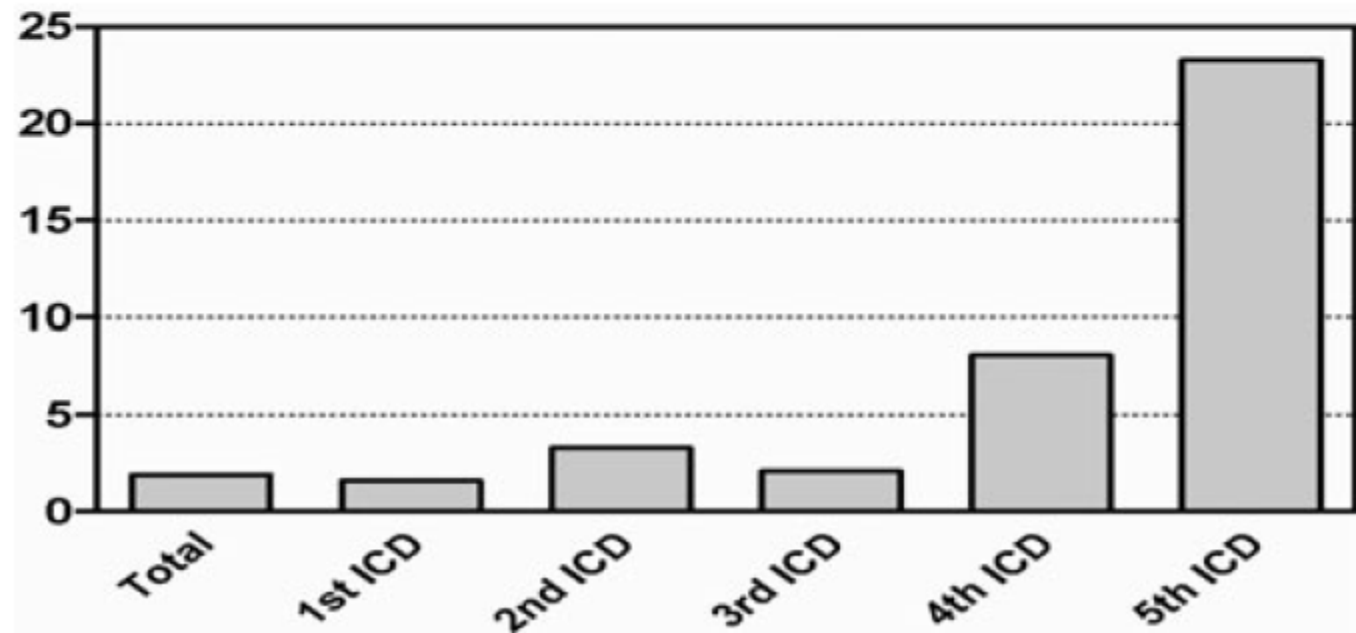
Age: 28
SICD implant
Longevity Device



13-15%

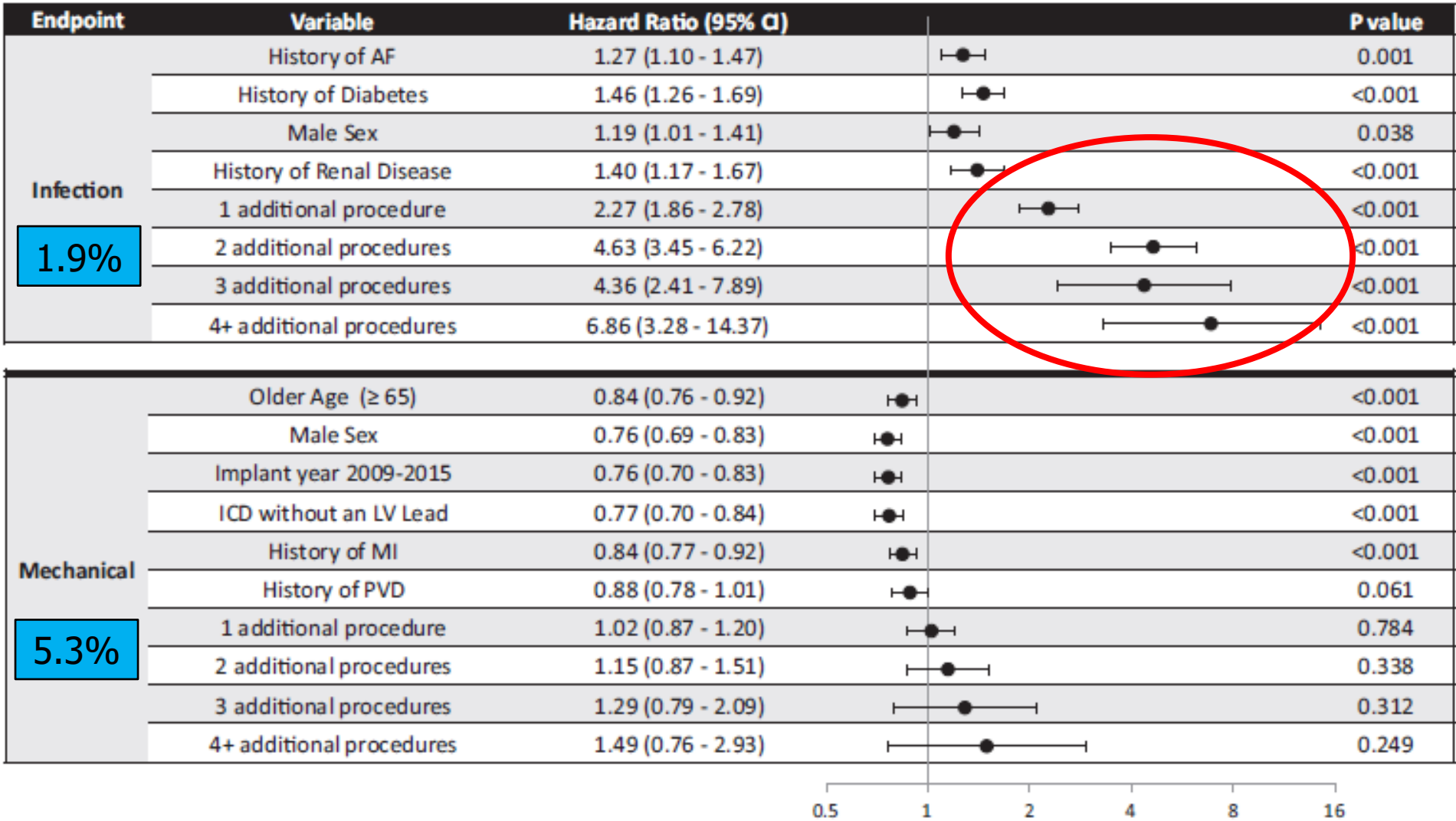
Requirement for Re-intervention per Consecutive Implanted ICD

	Total	1st ICD	2nd ICD	3rd ICD	4th ICD	5th ICD
Number of ICDs	3,161	2,415	609	107	24	6
Events	145	90	46	5	3	1
Total years implanted	7,632.3	5,949	1,406	236	37	4.3
Events per 100 ICD-years (95% CI)	1.9 (1.6–2.2)	1.5 (1.2–1.9)	3.3 (2.4–4.4)	2.1 (0.7–4.9)	8.1 (1.7–18.3)	23.3 (0.6–129.6)



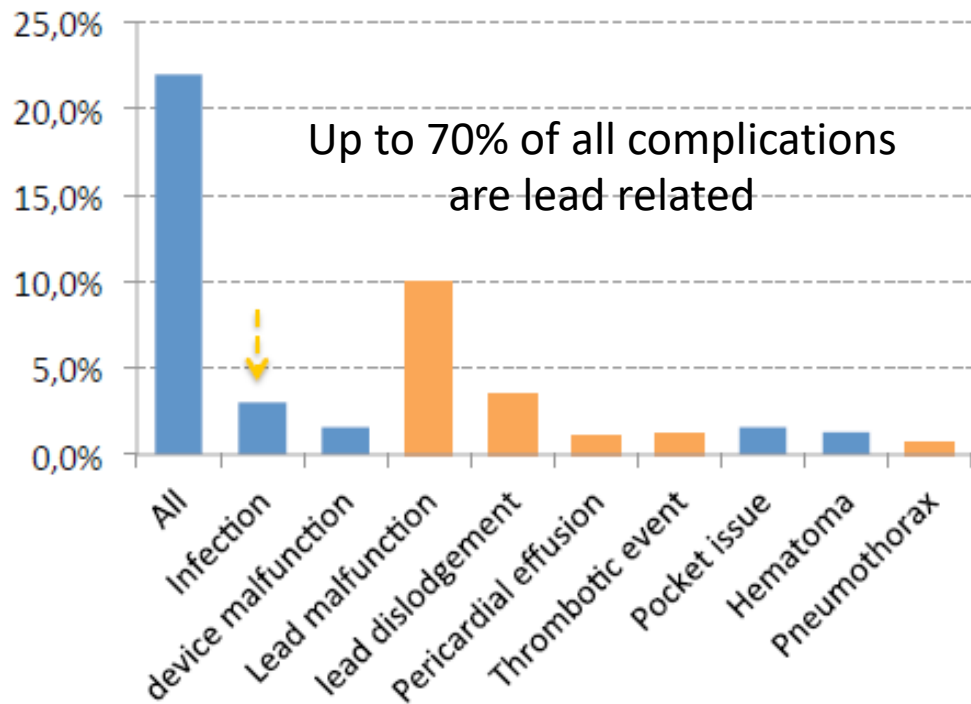
Complications : Risk factors

The study involves a retrospective analysis of claims data from the OptumLabs™ Data Warehouse (OLDW), which includes de-identified claims data for privately insured and Medicare Advantage enrollees in a large, private, U.S. health plan

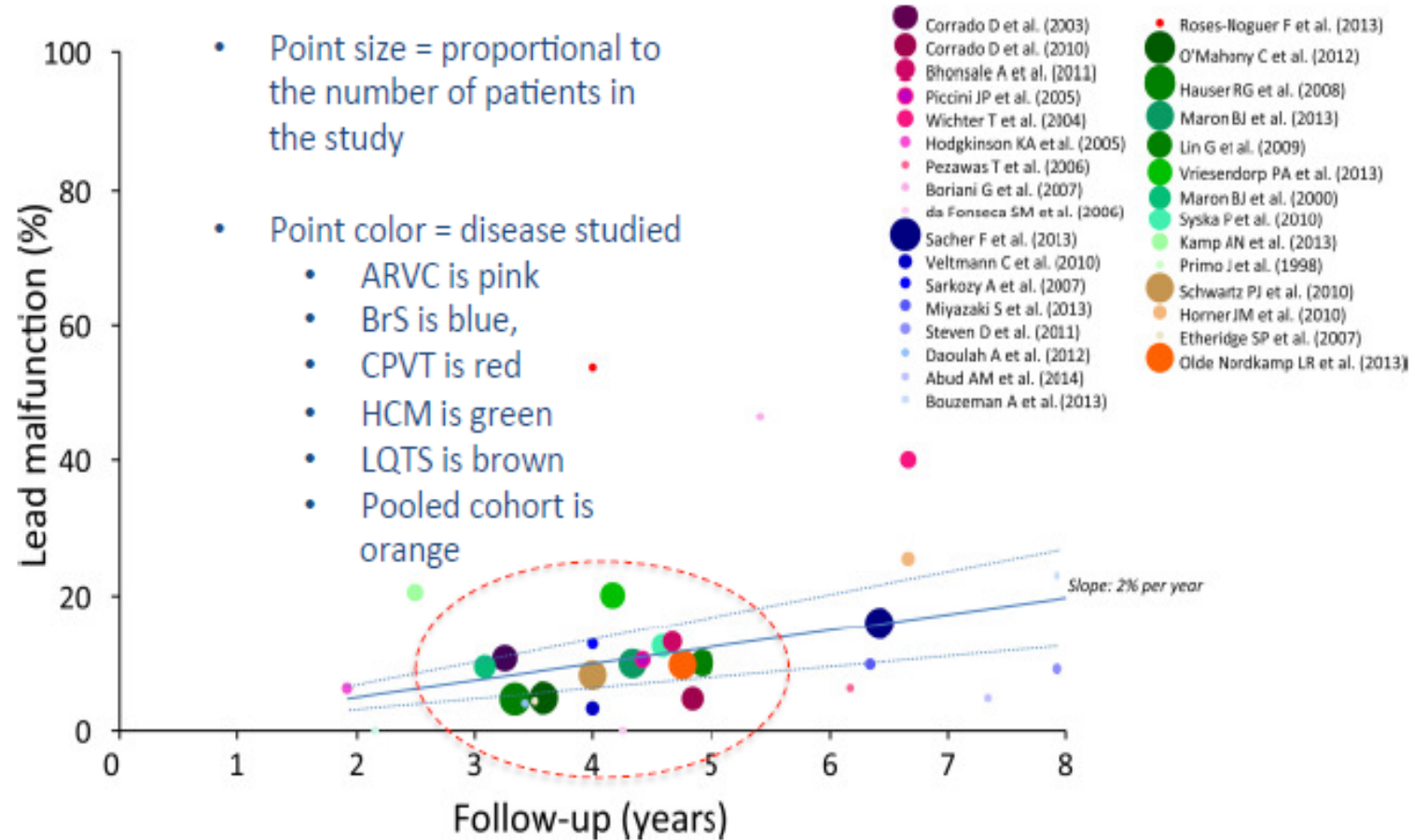


40837 CIED
(28537 SC/DC
ICD)

Lead Failure is most important source of complications in “young” pts



- Metanalysis of 63 study populations
- N=4195 ICD
- Mean Age: 39±15
- FUP: 53±26 months



High crude annual slope rate of 2% per year (20% at 10 yrs), but long term FU studies beyond 5 yrs after implant are scarce

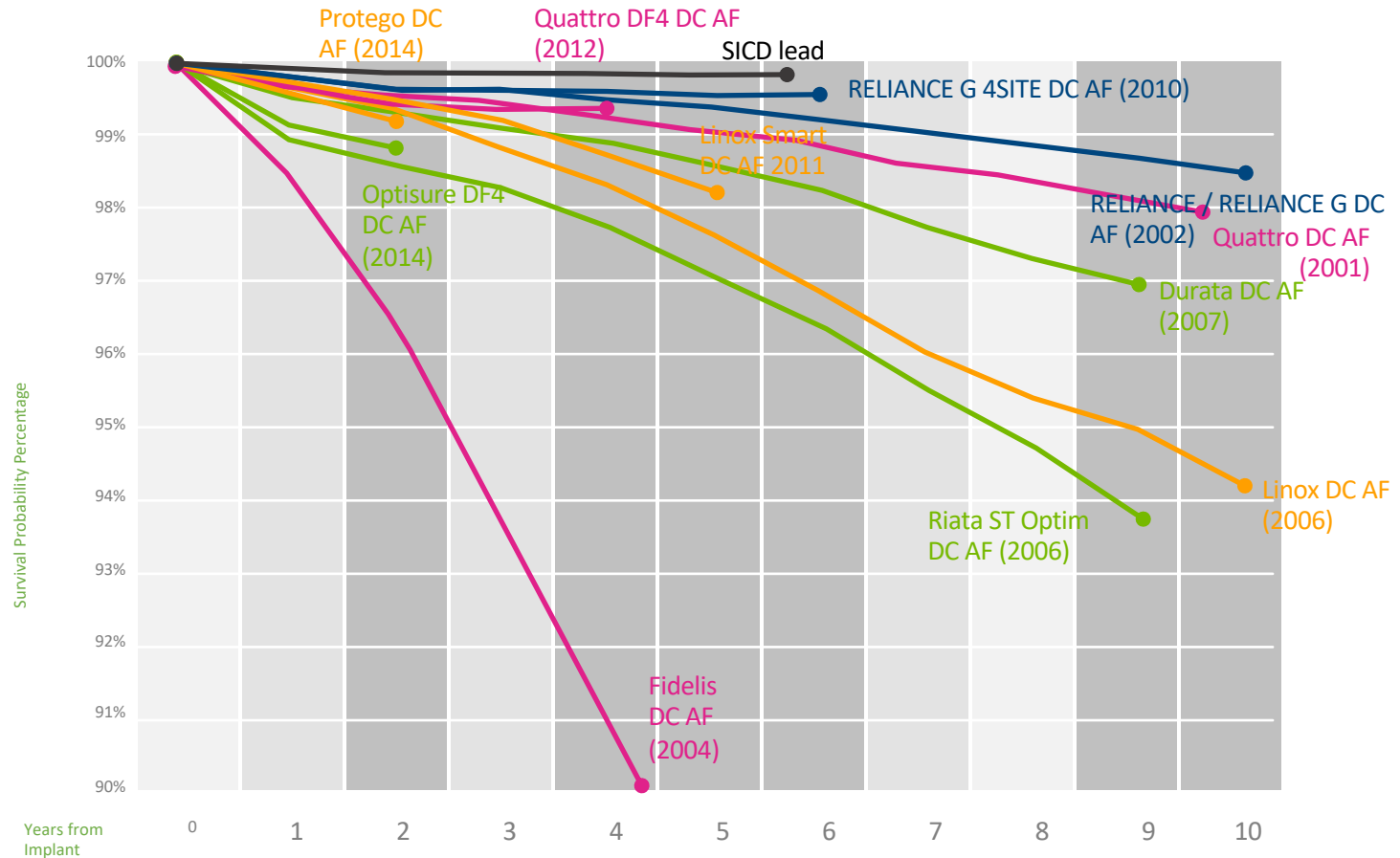
Proven Lead Reliability

Mismatch between PPR and real world: what's the problem?

>97%

Survival after 10 years of follow-up
Reliability of most recent active fixation model families.

- Boston Scientific
- Medtronic
- St. Jude / Abbott
- Biotronik



*Mandatory:
more attention to the implant technique !*

Liu J et al. Am J Cardiol 2014; 113: 103-106

Van Malderen S CH et al. Heart rhythm 2016; 13: 2299-2305



Pathways for **training** and accreditation for transvenous **lead extraction**

europace.oxfordjournals.org/lookup/.../eur338? - Traduci questa pagina

di JC Deharo - 2012 - Citato da 11 - Articoli correlati

A full appreciation of the pathophysiology of CIED implantation is critical to understanding of the risks and the **training** required for successful **lead extraction**.

Pathways for **training** and accreditation for transvenous **lead ...**

europace.oxfordjournals.org/content/.../124.extract - Traduci questa pagina

di JC Deharo - 2012 - Citato da 11 - Articoli correlati

Pathways for **training** and accreditation for transvenous **lead extraction**: a European Heart Rhythm Association position paper. Authors (EHRA Task Force ...

Pacemaker and Defibrillator **Lead Extraction** - Circulation

circ.ahajournals.org/content/123/11/e378.full - Traduci questa pagina

di E Buch - 2011 - Citato da 6 - Articoli correlati

These guidelines outline the indications for **lead extraction**, and the tools and techniques for **lead extraction**, and the tools and techniques for **lead extraction**.

Lead extraction

my.clevelandclinic.org/.../LeadExtraction.aspx - Traduci questa pagina

The Cleveland Clinic Heart & Vascular Institute is a leader in heart care and is the only heart hospital in the United States.

Transvenous **Lead Extraction**: Heart Rhythm Society Expert ...

https://www.hrsonline.org/content/.../2009-HRS_LeadExtraction.pdf

di LM Epstein - Articoli correlati

Transvenous **Lead Extraction**: Heart Rhythm Society. Expert Consensus on Facilities, **Training**, Indications, and. Patient Management. This document was ...

HRS & AHA Guidelines | Spectranetics

www.spectranetics.com/.../Lead_Extraction/guidelines - Traduci questa pagina

NO Training course on Lead Implantation !!

SICD : learning curve

Table 2 Complications in the first 6 months

Description	Number of events
System infection	16
Electrode movement	7
Suboptimal electrode position	7
Erosion	5
Discomfort	4
Haematoma	4
Suboptimal pulse generator and electrode position	4
Adverse reaction to medication	3
Inadequate/prolonged healing of incision site	3
Incision/superficial infection	3
Pulse generator movement/revision	3
Suboptimal pulse generator position	2
Failed defibrillation threshold test	2
Acute hypoxic respiratory failure	1
Incomplete electrode connection to the device	1
Near syncope/dizziness/shortness of breath/confusion	1
Pleural effusion	1
Pneumothorax	1
Seroma	1
Suspected worsening of ischaemia	1
Suture discomfort	1
Undersensing	1
Grand total	72

Significative but very similar

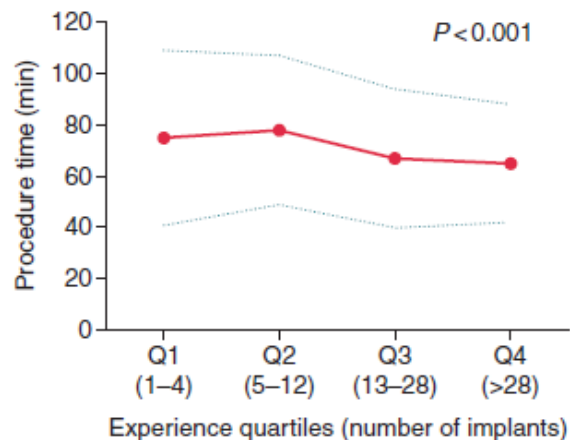


Table 3 Multivariable Cox proportional hazard model for complications

Characteristic	Hazard ratio (95% CI)	P value
Physician experience (per quartile)	0.78 (0.61, 0.99)	0.045
BMI (per 5 units)	1.15 (0.98, 1.34)	0.090
Age (per 5 years)	0.89 (0.82, 0.96)	0.005
Atrial fibrillation (yes vs. no)	1.91 (1.00, 3.67)	0.051

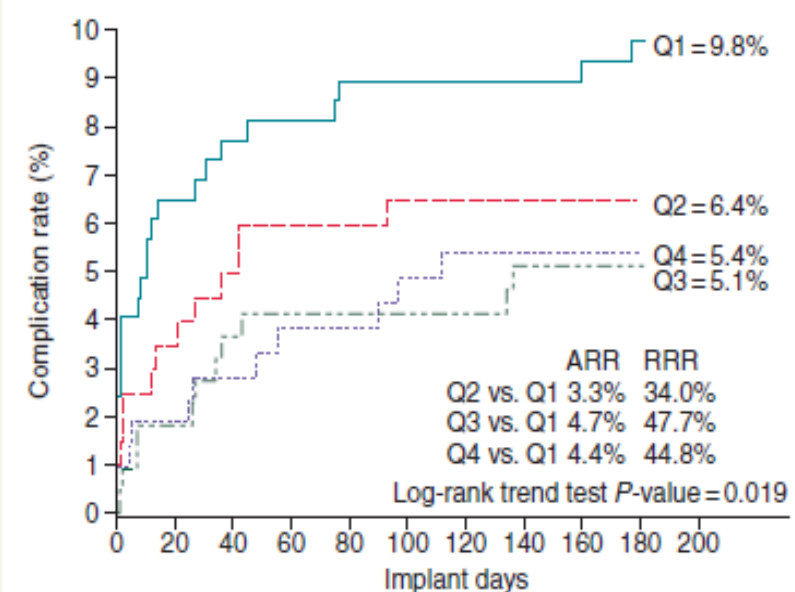


Figure 1 Kaplan–Meier analysis of experience quartiles and complications at 180 days. Q1: Experience Quartile 1 (implants 1–4); Q2: Experience Quartile 2 (implants 5–12); Q3: Experience Quartile 3 (implants 13–28); Q4: Experience Quartile 4 (implants >28); ARR, absolute risk reduction; RRR, relative risk reduction. P value is Kaplan–Meier trend test.

The complication rate of 9.8% decreased with increasing experience of individual implanters and stabilized after 13 implants per implanter at 5.4%

Non-lead complications

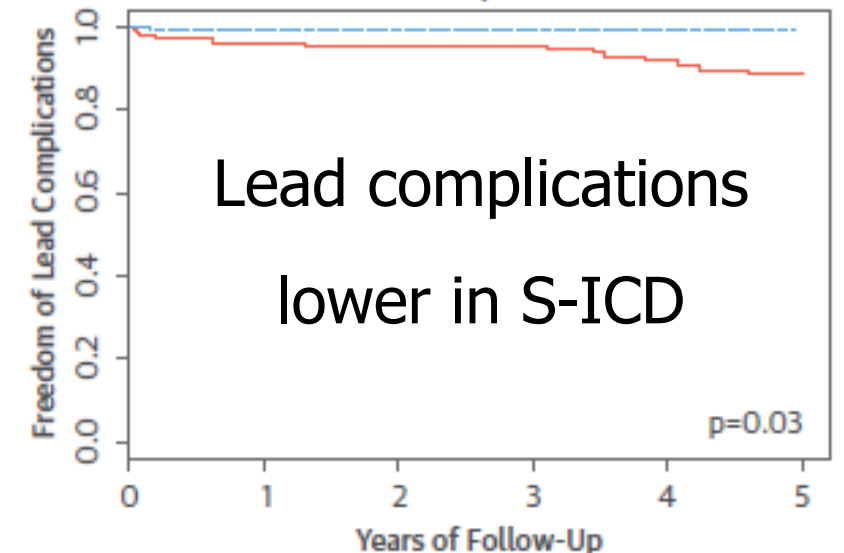
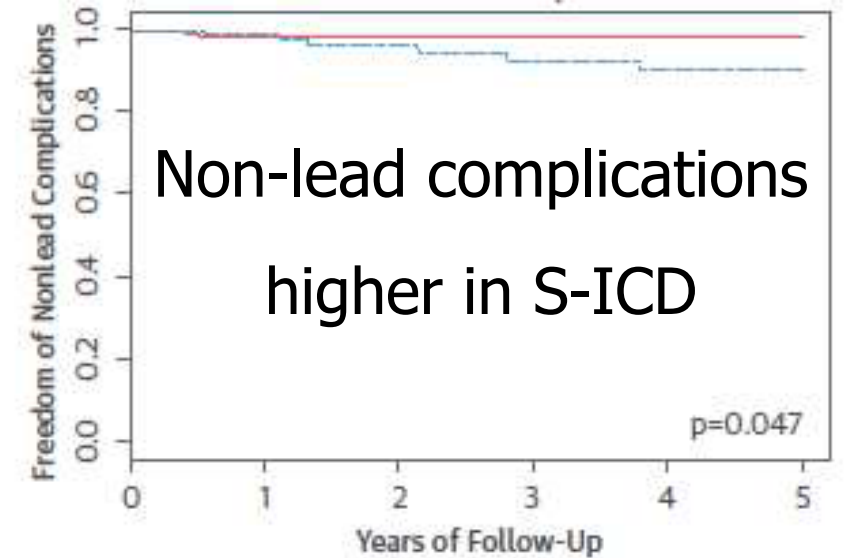
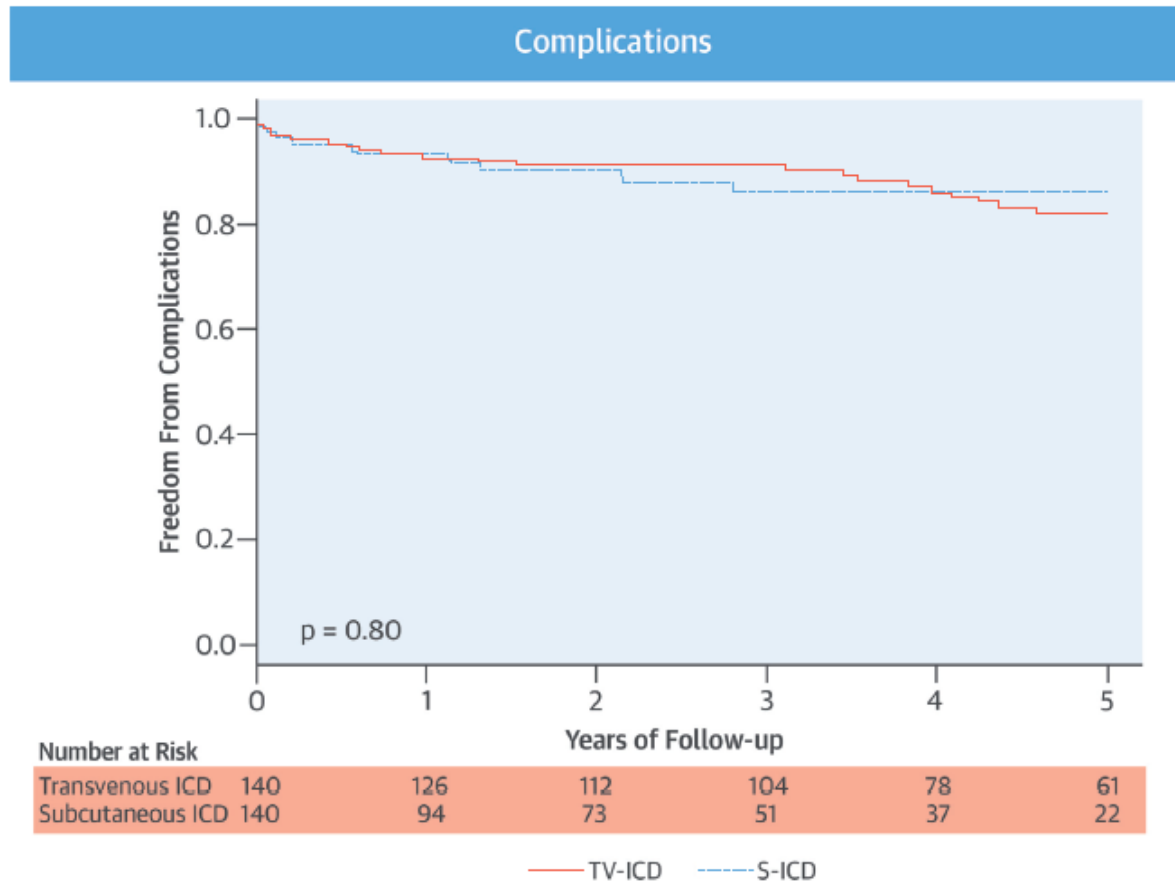
Complication	S-ICD		TV-ICD	
	N	KM rate, %	N	KM Rate, %
Total	14	13.7	21	18.0
Lead	1		17	
Infection	5	4.1	4	3.6
Erosion	3	3.0	2	1.5
DFT failure	1	0.7	0	0
Inappropriate sensing	2	3.2	0	0
Device failure	1	1.1	1	0.8
Appropriate therapy	12	17.0	39	31.1
Inappropriate shocks	20		22	
SMART PASS reduces IS due to TWO				
SVT	3	4.2	21	17.6
Cardiac death	1	2.0	2	1.7

Long term outcomes: S-ICD vs TV-ICD

Brouwer TF et al. JACC 2016; 68(19):2047-55

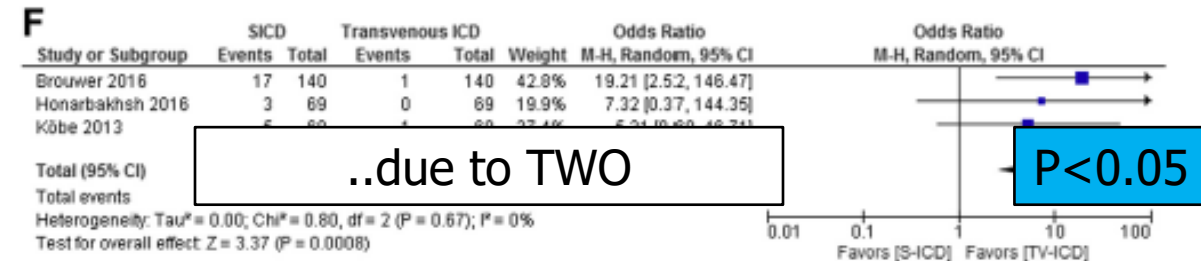
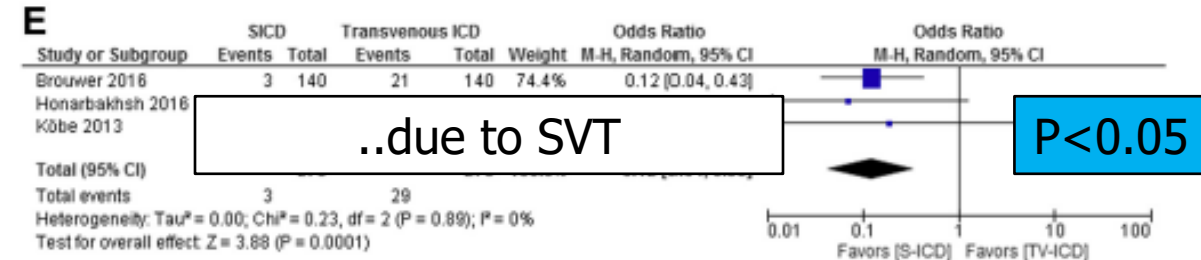
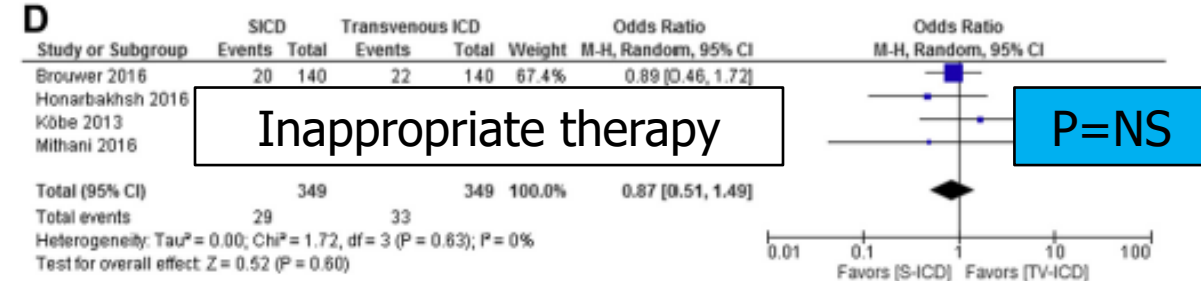
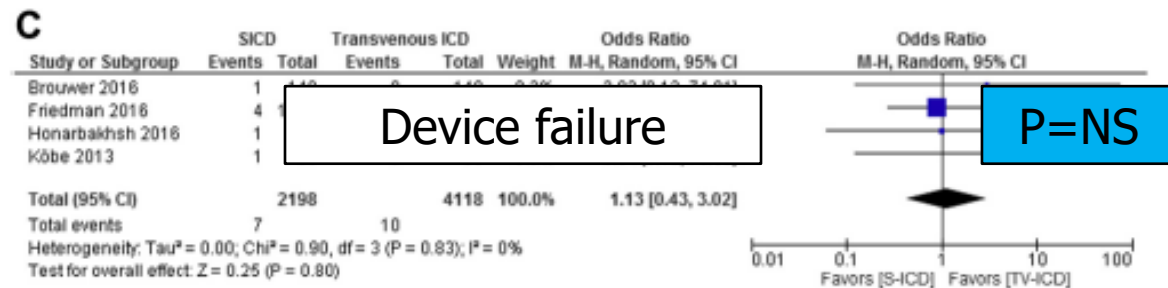
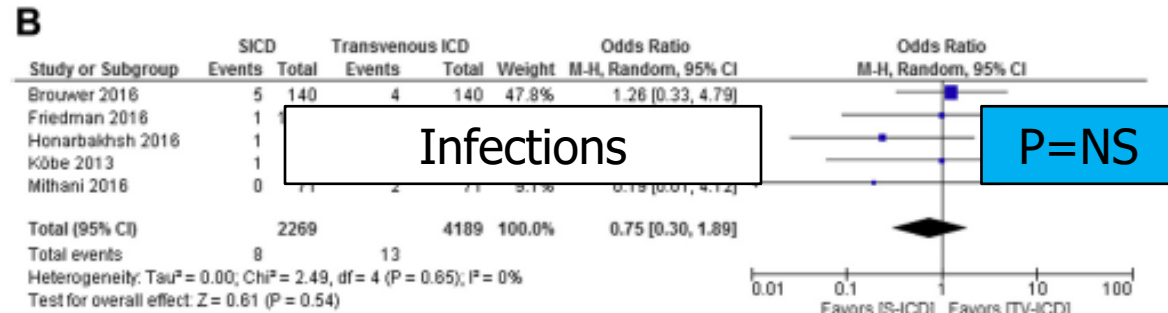
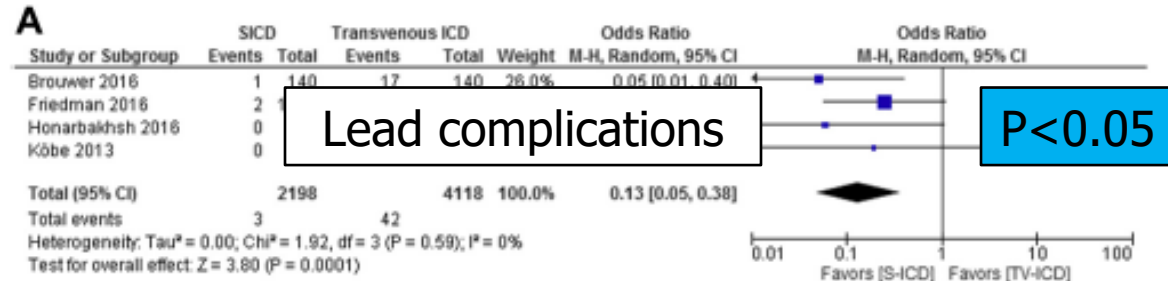
140 S-ICD vs 140 TV-ICD after propensity match

NO differences in overall complication



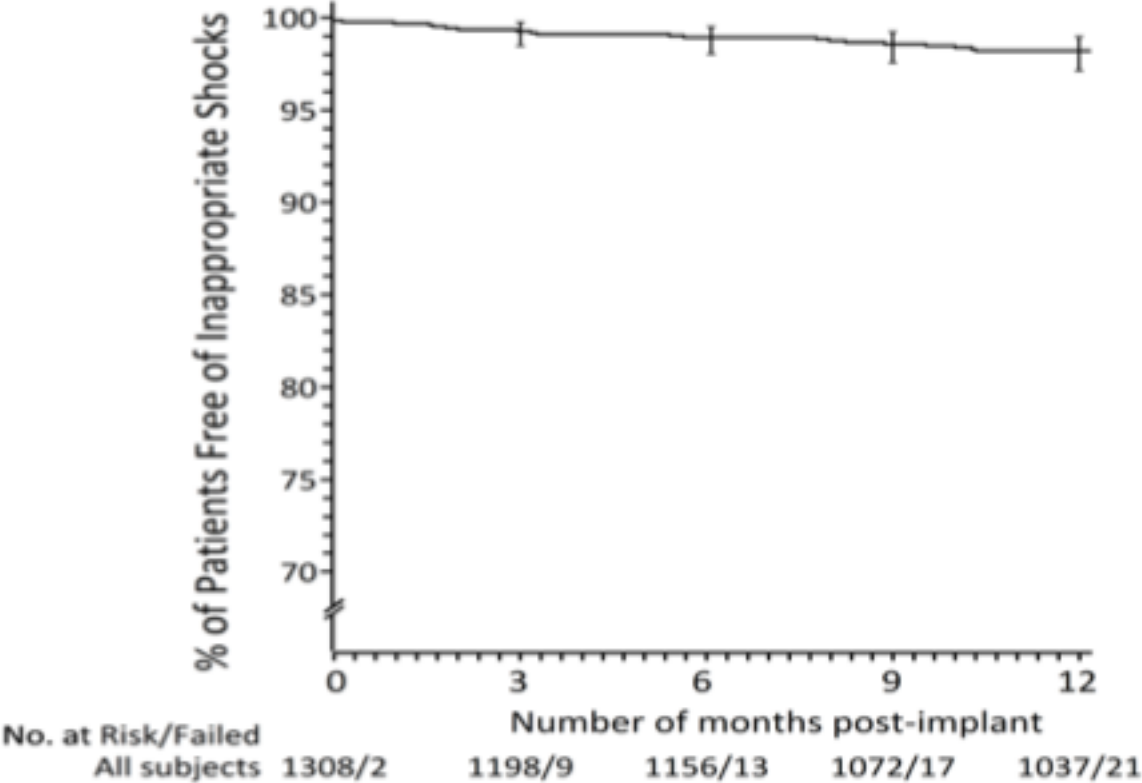
Subcutaneous Versus Transvenous Implantable Defibrillator Therapy

A Meta-Analysis of Case-Control Studies



Inappropriate Shock Free Rate: PAINFREE SST-2

98.2% inappropriate shock free rate at 1 year



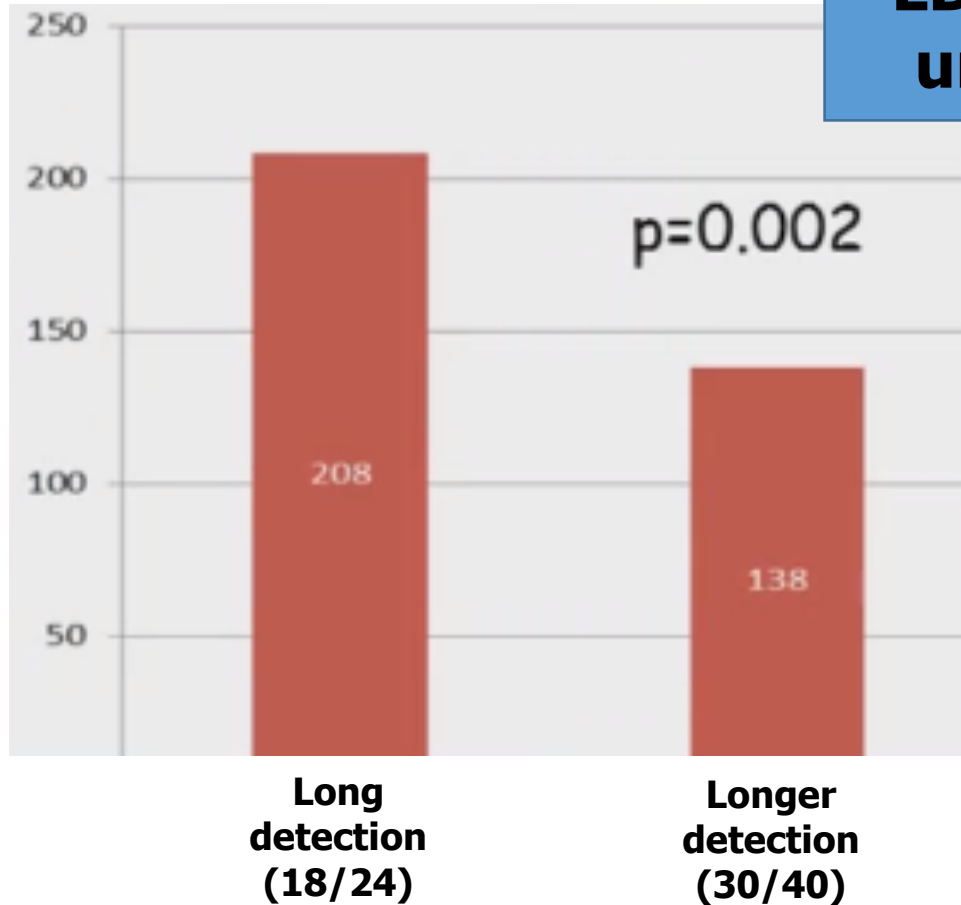
NO More ES !!



Inappropriate Shock Free Rate at 1 year	95% C.I. Lower Bound	95% C.I. Upper Bound	N. pts with inappropriate shock
0.982	0.974	0.990	21

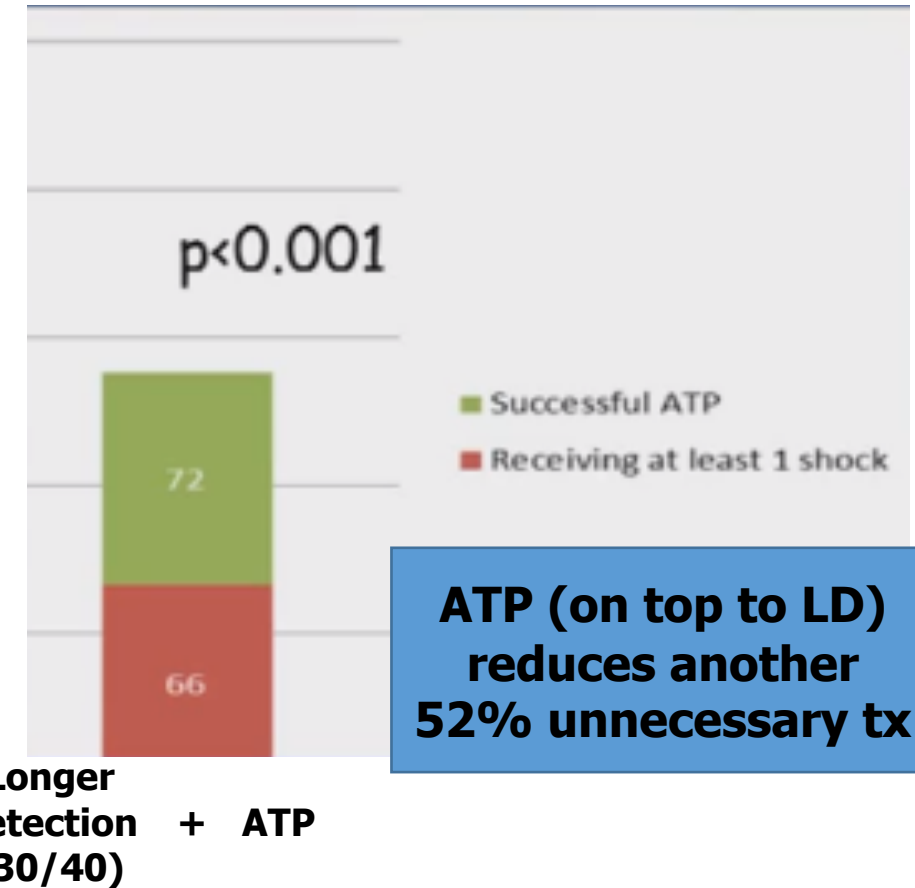
Different impact of long-detection interval and anti-tachycardia pacing in reducing unnecessary shocks: data from the ADVANCE III trial

Considering Shock only....



LD reduces 37% unnecessary tx

But



ATP (on top to LD) reduces another 52% unnecessary tx

Why anti-tachycardia pacing?



**To Reduce Pain and
Anxiety
and Increase
Device Acceptance**



**To Reduce
Healthcare Burden
and Improve
Patient Quality of
Life**

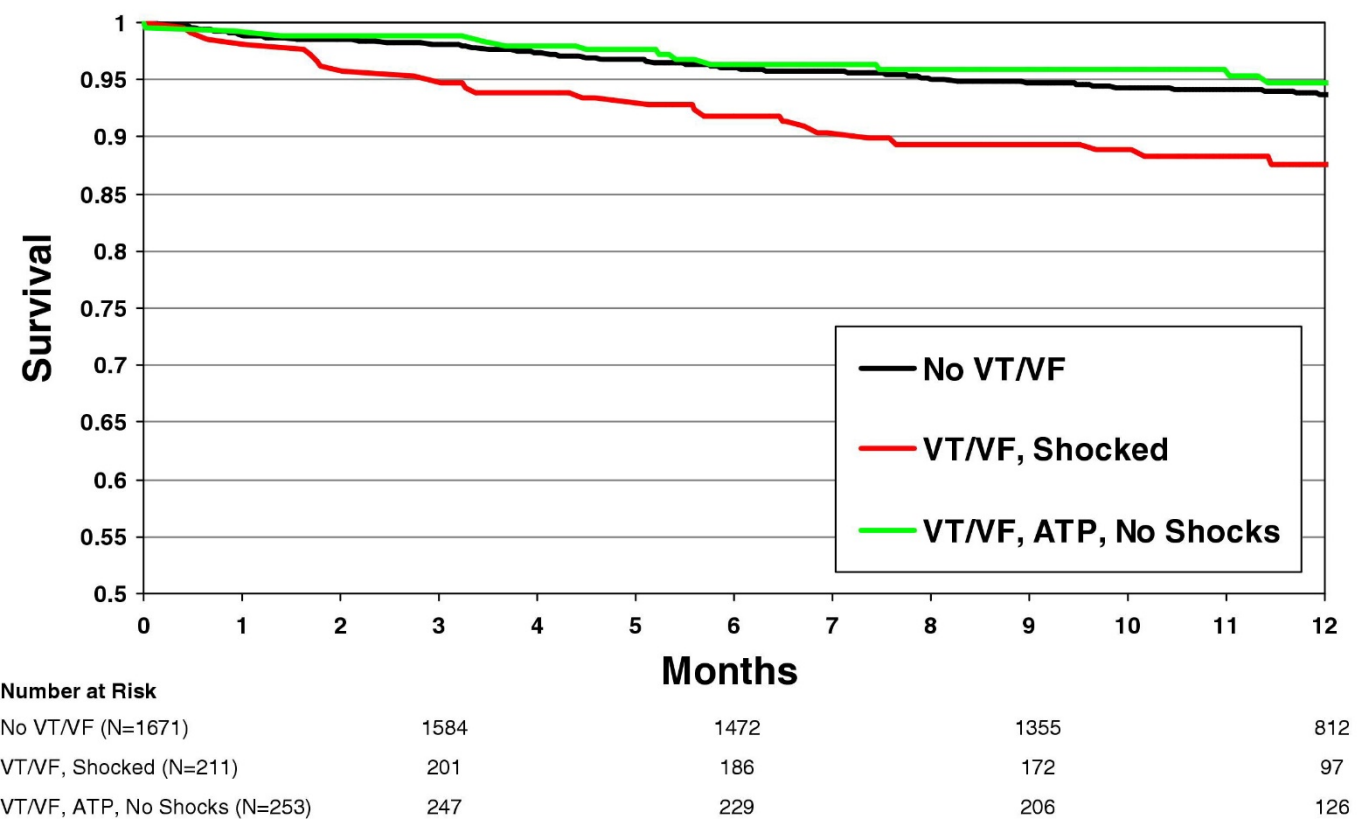


**Avoiding Shocks
May Improve
Survival/Heart
Failure**

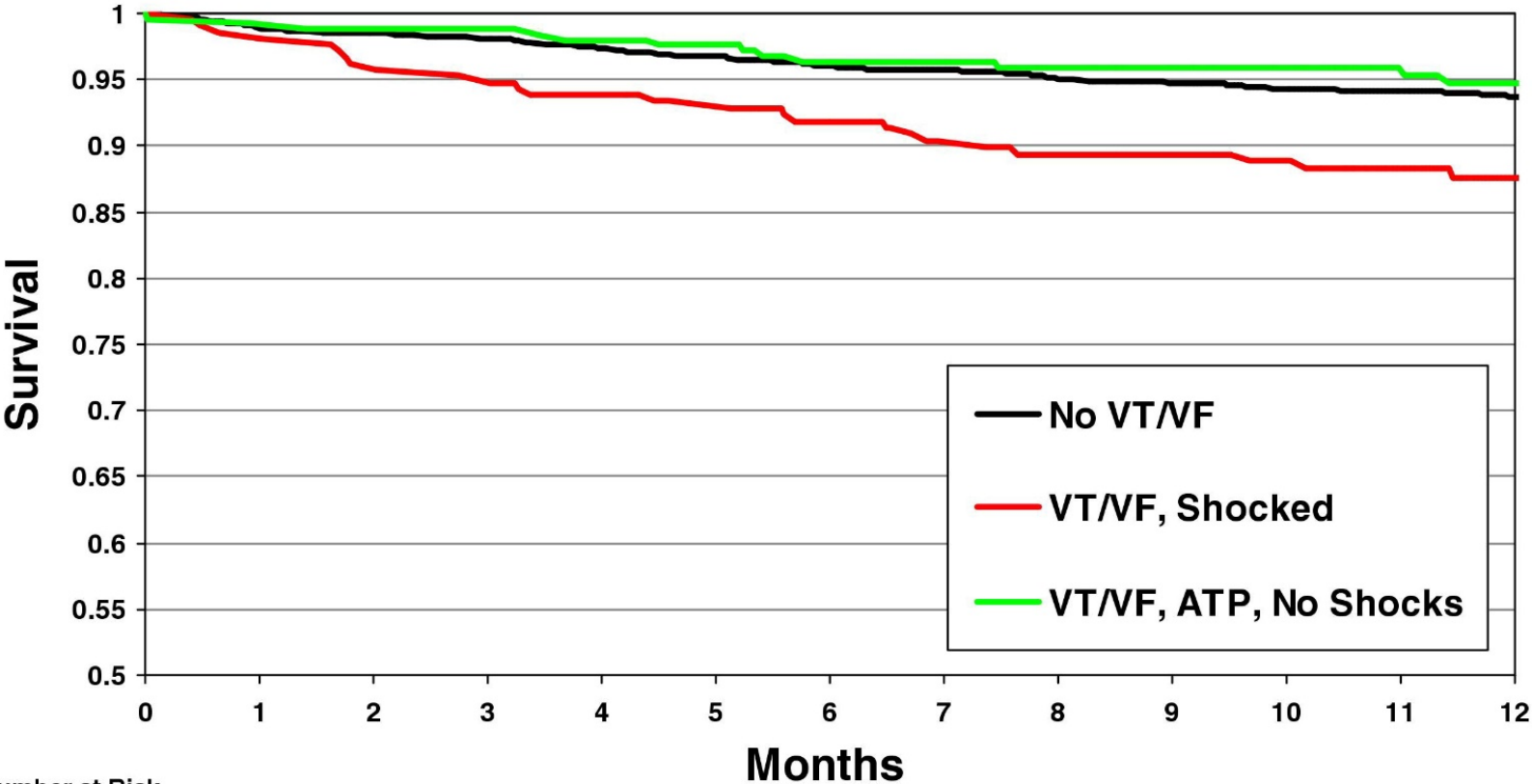
Differences in effects of electrical therapy type for ventricular arrhythmias on mortality in implantable cardioverter-defibrillator patients

For FVT (32% shocked, 68% ATP), episode and therapy effects could be uncoupled.

ATP-terminated FVT did not increase episode mortality risk, whereas shocked FVT increased risk by 32%.



ATP vs Shock



Number at Risk

No VT/VF (N=1671)	1584	1472	1355	812
VT/VF, Shocked (N=211)	201	186	172	97
VT/VF, ATP, No Shocks (N=253)	247	229	206	126

ATP recommendations

Recommendations for all pts with SHD and ATP-capable ICDs, to reduce total shocks, except when ATP is documented to be ineffective or proarrhythmic:	Class of Recommendation and level of evidence
ATP therapy to be active for all ventricular tachyarrhythmia detection zones to include arrhythmias up to 230 bpm	I A
ATP therapy to be programmed to deliver at least 1 ATP attempt with a minimum of 8 stimuli and a CL of 84-88% of the tachycardia CL for ventricular tachyarrhythmias	I A

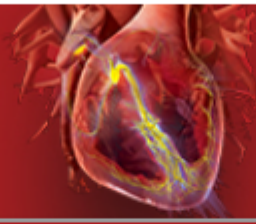
Wilkoff B et al. Heart Rhythm 2015

Sweeney MO et al. Heart Rhythm 2010;7:353–360.



VT-1 313 VT-1 310 VT-1 313 VT-1 315 VT-1 308 VT-1 315 VT-1 313 VT-1 313 VT-1 315 VT-1 313 VP 275 VP 275 VP 275 VP 275 VP 275 VP 275 VP 275 VP 275 - VS 655 VS 448 VS 510 VS 490 VS 498 VS 493 VS 493 VS 495 VS 495

U0% U0% U0% U0% U0% U0% U0% U0% U0% RID-
V-Detect1



Implantable cardioverter-defibrillator programming and electrical storm: Results of the OBSERVational registry On long-term outcome of ICD patients (OBSERVO-ICD)



ES: 4.7% at 3 years

ES predicts CHF-related deaths and Overall Mortality

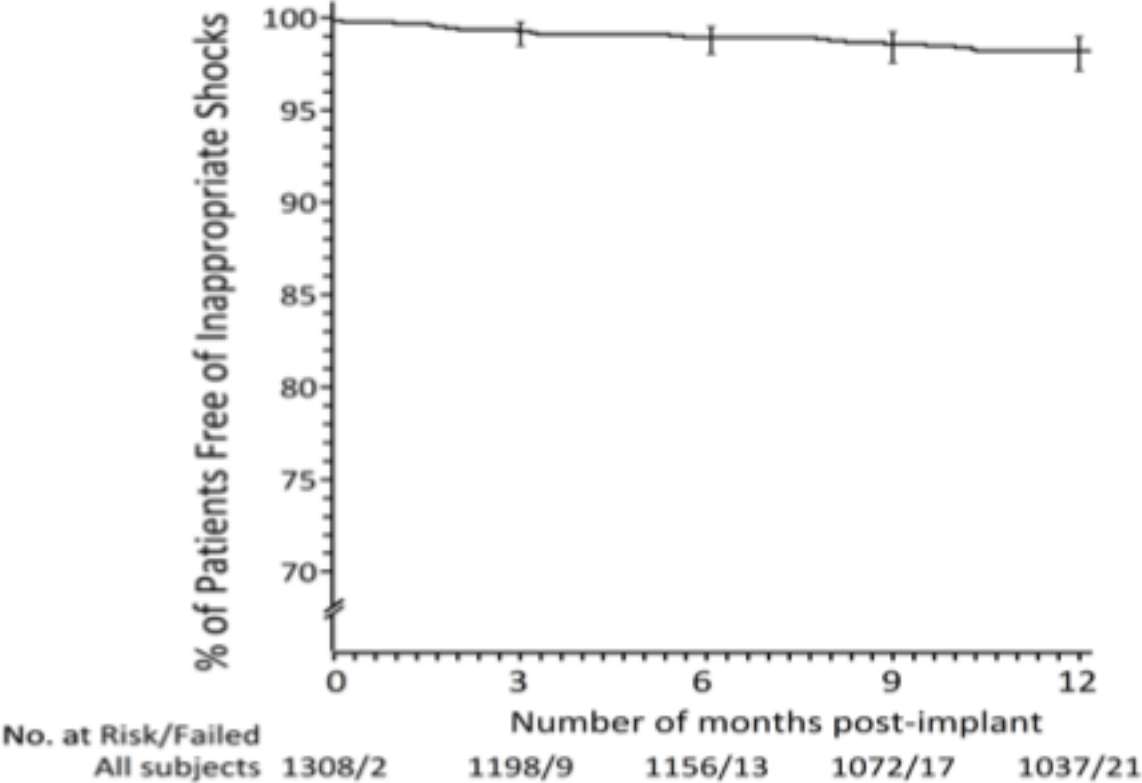
Slow VF detection zone
NO ATP Before or During Charging
SHORT detection Time of VT or VF



**ALL predict
Electrical
storms**

Inappropriate Shock Free Rate: PAINFREE SST-2

98.2% inappropriate shock free rate at 1 year



NO More ES !!



Inappropriate Shock Free Rate at 1 year	95% C.I. Lower Bound	95% C.I. Upper Bound	N. pts with inappropriate shock
0.982	0.974	0.990	21

ATP is effective

But

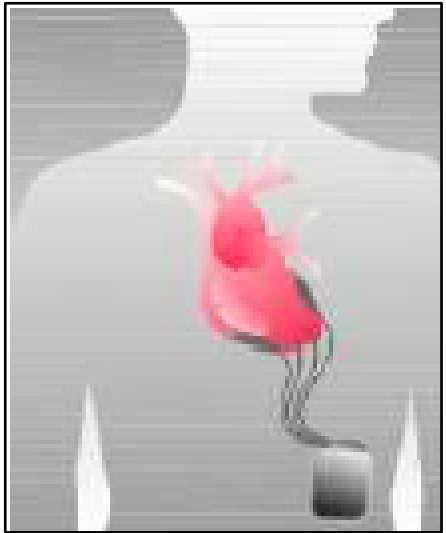
We don't have strong predictors of effectiveness

How much are we willing to pay?

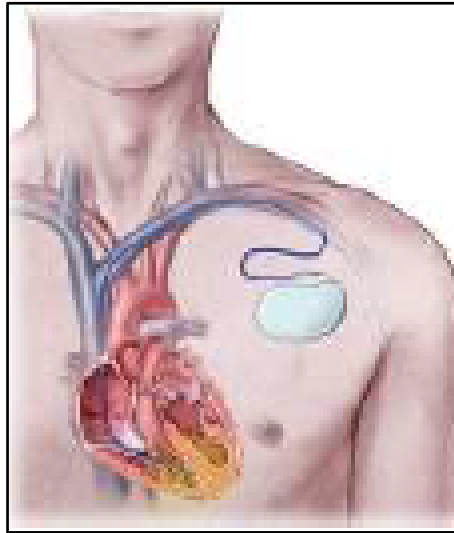
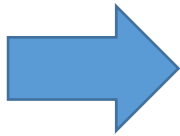
Cost



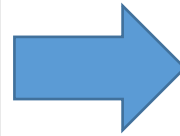
ICD History



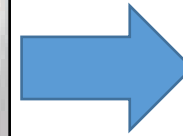
Abdominal ICD
with epicardial lead
and patch



Subcutaneous ICD
with transvenous
lead



Intermuscular ICD
with subcutaneous
lead



String defibrillator

PAST

PRESENT

FUTURE



**THE TIME IS NOT
RIPE. BUT WE DO
NOT RULE OUT THE
POSSIBILITY IN THE
FUTURE.**

S-ICD Weakness



The more you need it



The more you miss it

S-ICD screening failure

In 13% of patients with inherited primary arrhythmia syndromes.

In 18% with BrS

In 6% HOCM patients

In 25% of pediatric patients

Endurance is an Issue

Age : 28
TVICD implant
Longevity Device

I

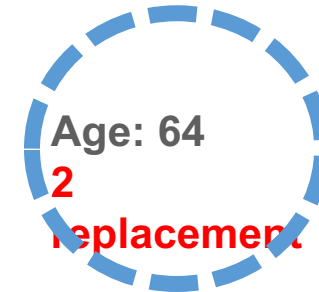
12 years

R

12 years

R

12 years



Infection risk

3-4%

I

7 years

R

7 years

R

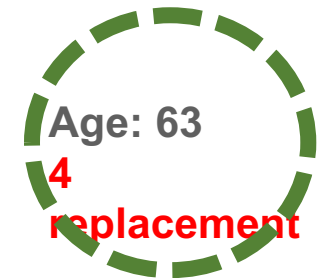
7 years

R

7 years

R

7 years



Age: 28
SICD implant
Longevity Device

13%

That drives cost along

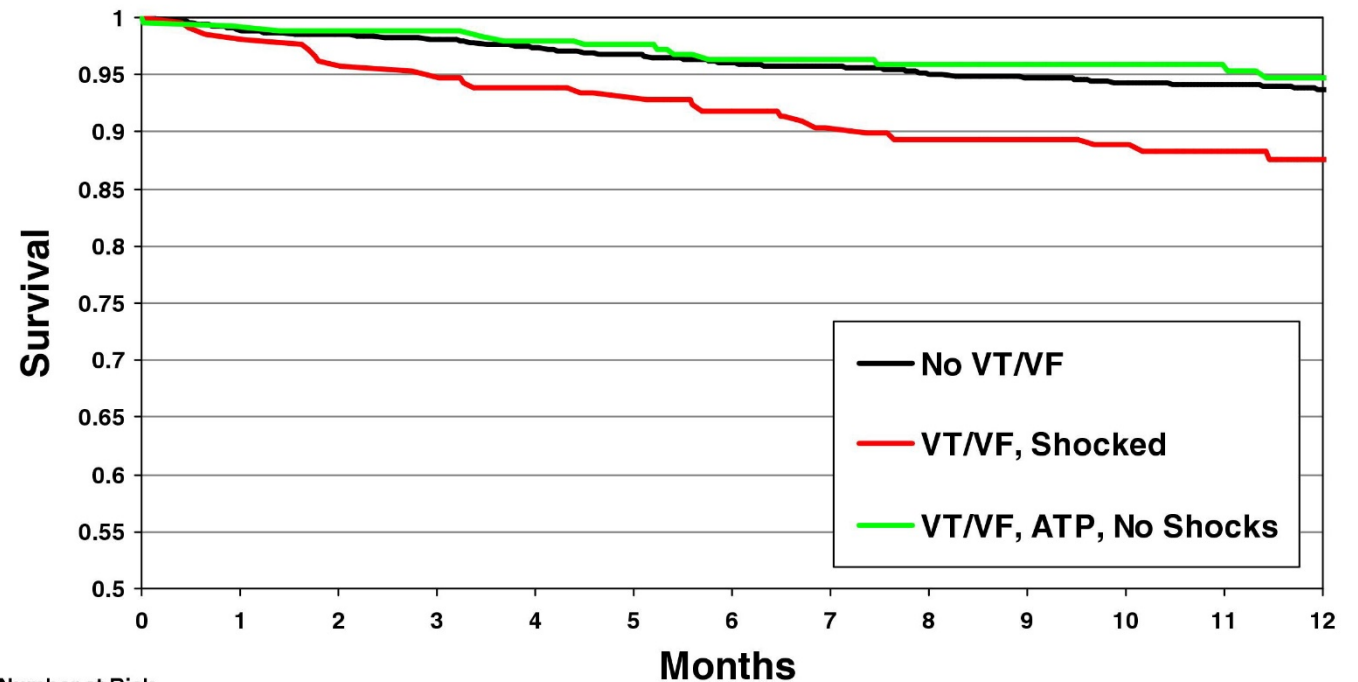


If you don't miss it,

ATP-terminated FVT did not increase
episode mortality risk,

whereas

shocked FVT increased risk by 32%.



Number at Risk				
No VT/VF (N=1671)	1584	1472	1355	812
VT/VF, Shocked (N=211)	201	186	172	97
VT/VF, ATP, No Shocks (N=253)	247	229	206	126

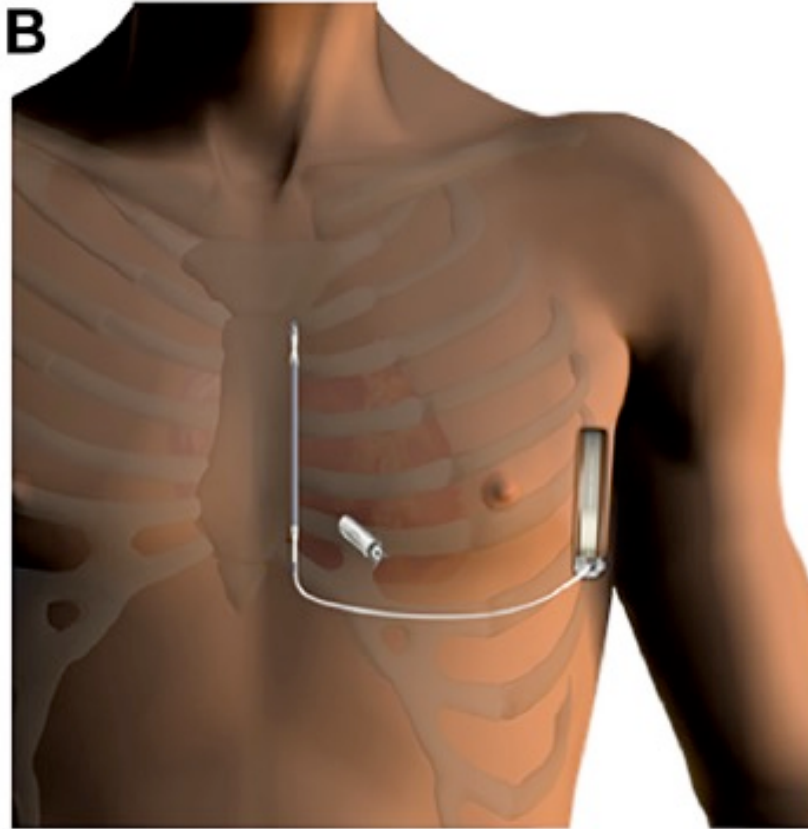
Why striving after all of this ?

A



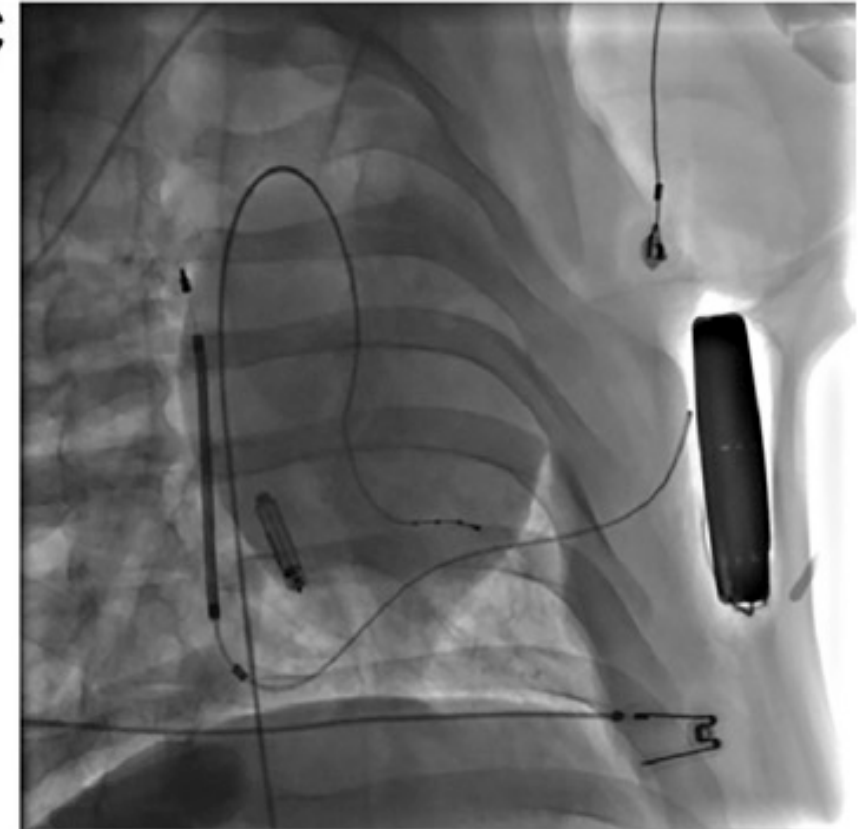
S-ICD, Leadless unit

B



**NEED for ATP / VVIR
pacing**

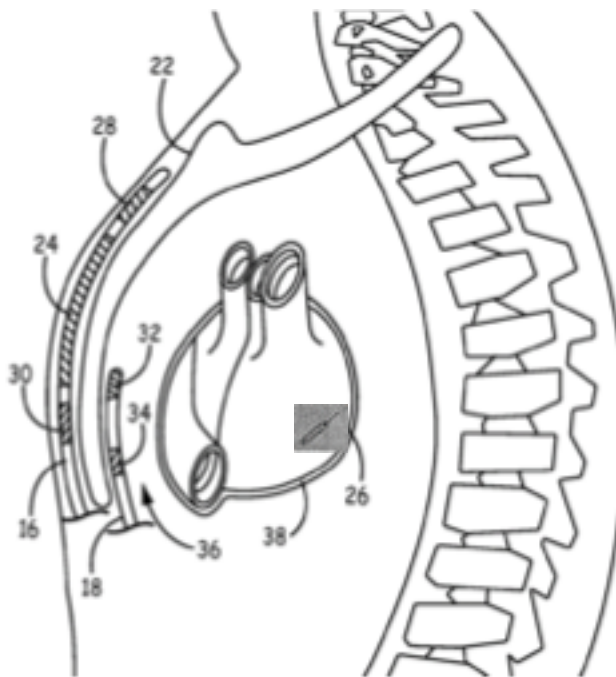
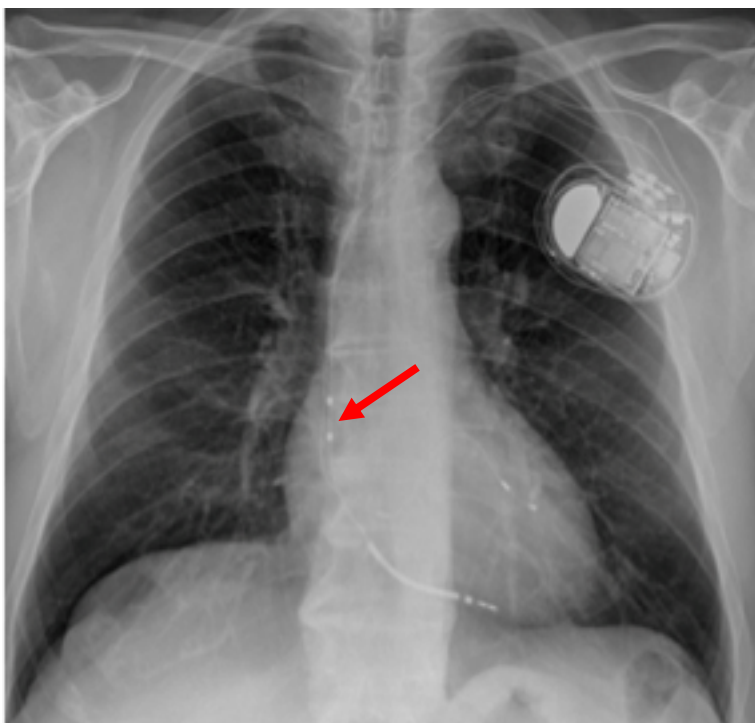
C



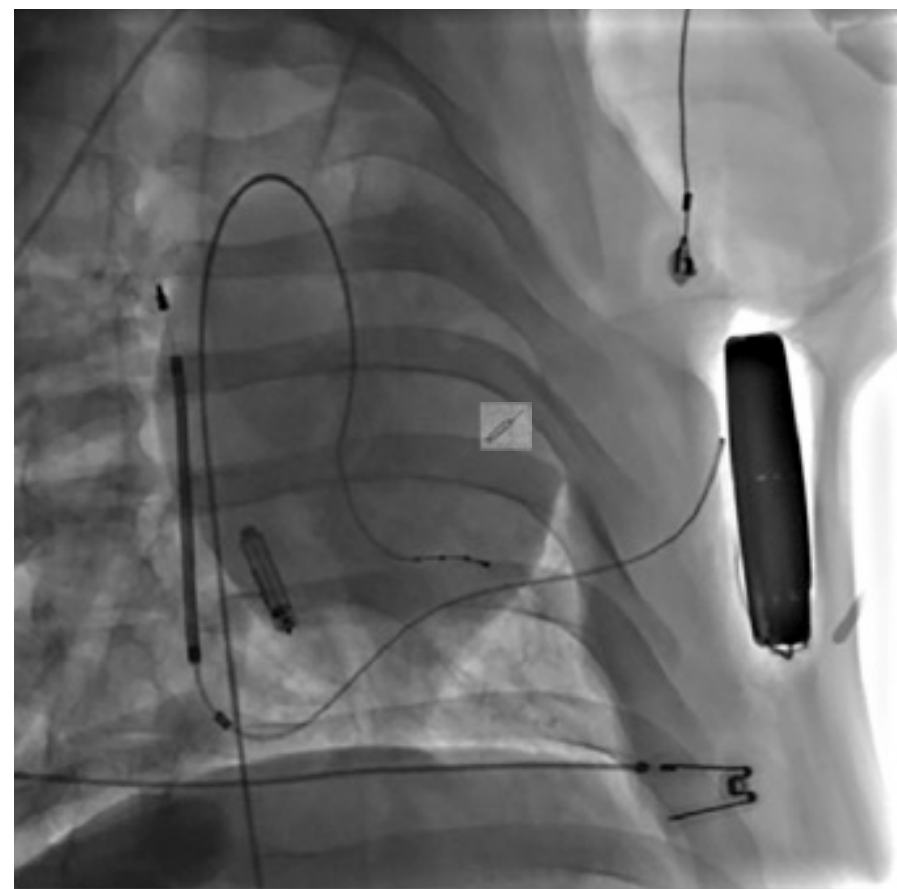
**P detection, quad LV
lead**

Key ISSUE of modular systems in SR Patients

P wave detection !



Substernal ICD



The Future of implantable devices ?



Minimization



Leadless



Multitasking



Low consumption





Low energy communication



Rechargeable battery



Energy Harvesting



LIEBHERR

D'ANAFRIA



ISSUES with leadless devices : diagnostic data



Remote patient management



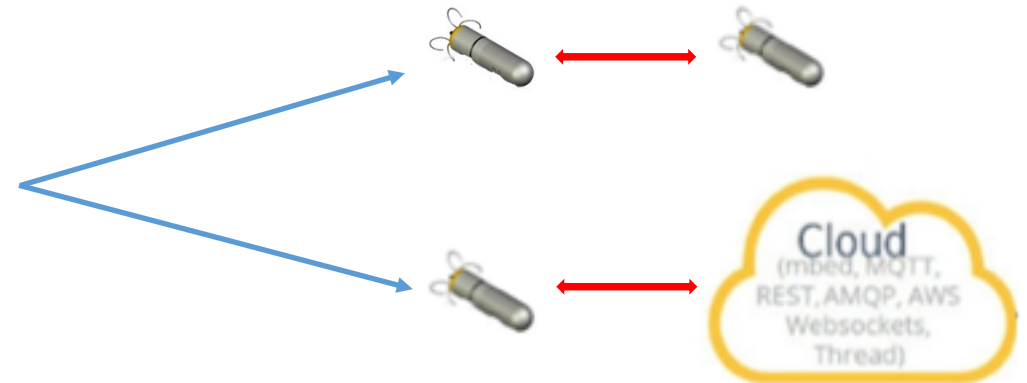
Multiparameter patient assessment



Energy supply



SMALL DEVICES



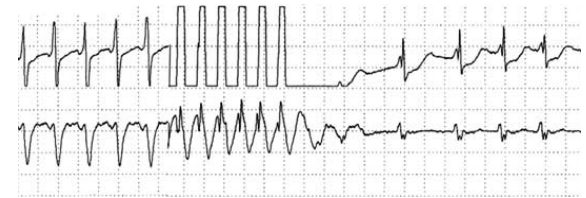
DOES it Matter how you save one life?



כָּל הַמַּצִּיל נֶפֶשׁ אַחַת מִיִּשְׂרָאֵל,
כְּאִילוֹ הִצִּיל עוֹלָם כָּלֵא.

Kol hamatzil nefesh achât mi'Yisra'êl,
ke'ilu hitsil olâm malê.

Whoever saves a single life is as if
he had saved an entire universe.



EFFORTLESS S-ICD™ System Registry

Implant Procedure and Follow-up

Boston
Scientific

Attribute	Statistic/Category	N	%
Implant Procedure	Patients implanted	456	95
	General anesthesia		63
	Medical imaging		13
	Skin-to-skin time, min*	69 ± 27	

+ 1 hour for patient setup

+ 30 minutes for patient weaning to cardiology ward

Conclusions

What do you prefer today?

TV-ICD



S-ICD



... in a long-term perspective ?

SICD : learning curve

Table 2 Complications in the first 6 months

Description	Number of events
System infection	16
Electrode movement	7
Suboptimal electrode position	7
Erosion	5
Discomfort	4
Haematoma	4
Suboptimal pulse generator and electrode position	4
Adverse reaction to medication	3
Inadequate/prolonged healing of incision site	3
Incision/superficial infection	3
Pulse generator movement/revision	3
Suboptimal pulse generator position	2
Failed defibrillation threshold test	2
Acute hypoxic respiratory failure	1
Incomplete electrode connection to the device	1
Near syncope/dizziness/shortness of breath/confusion	1
Pleural effusion	1
Pneumothorax	1
Seroma	1
Suspected worsening of ischaemia	1
Suture discomfort	1
Undersensing	1
Grand total	72

Significative but very similar

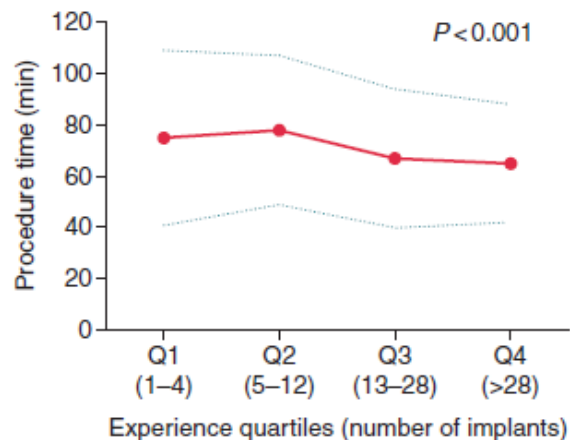


Table 3 Multivariable Cox proportional hazard model for complications

Characteristic	Hazard ratio (95% CI)	P value
Physician experience (per quartile)	0.78 (0.61, 0.99)	0.045
BMI (per 5 units)	1.15 (0.98, 1.34)	0.090
Age (per 5 years)	0.89 (0.82, 0.96)	0.005
Atrial fibrillation (yes vs. no)	1.91 (1.00, 3.67)	0.051

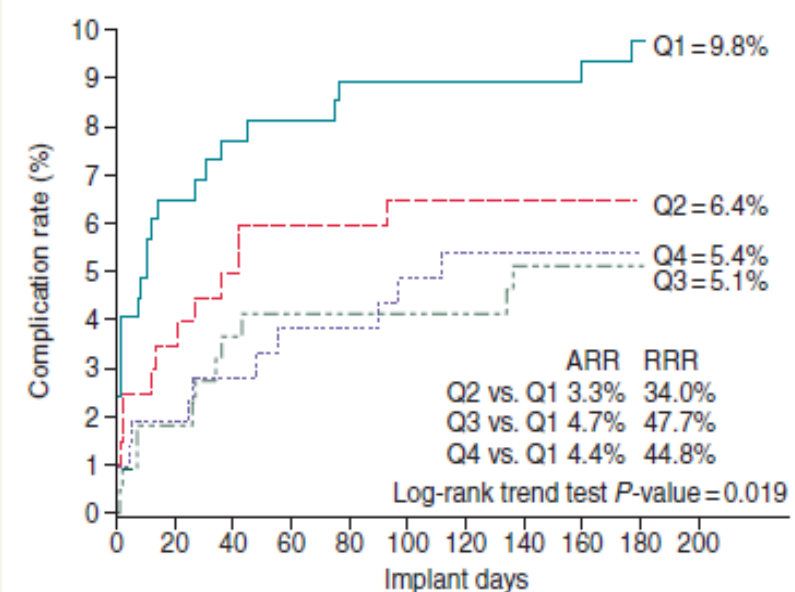


Figure 1 Kaplan–Meier analysis of experience quartiles and complications at 180 days. Q1: Experience Quartile 1 (implants 1–4); Q2: Experience Quartile 2 (implants 5–12); Q3: Experience Quartile 3 (implants 13–28); Q4: Experience Quartile 4 (implants >28); ARR, absolute risk reduction; RRR, relative risk reduction. P value is Kaplan–Meier trend test.

The complication rate of 9.8% decreased with increasing experience of individual implanters and stabilized after 13 implants per implanter at 5.4%