66th Annual Meeting of the Japanese HRS, Yokohama-Japan, July 24-27 2019

Combined use of S-ICD and PM: feasibility and results

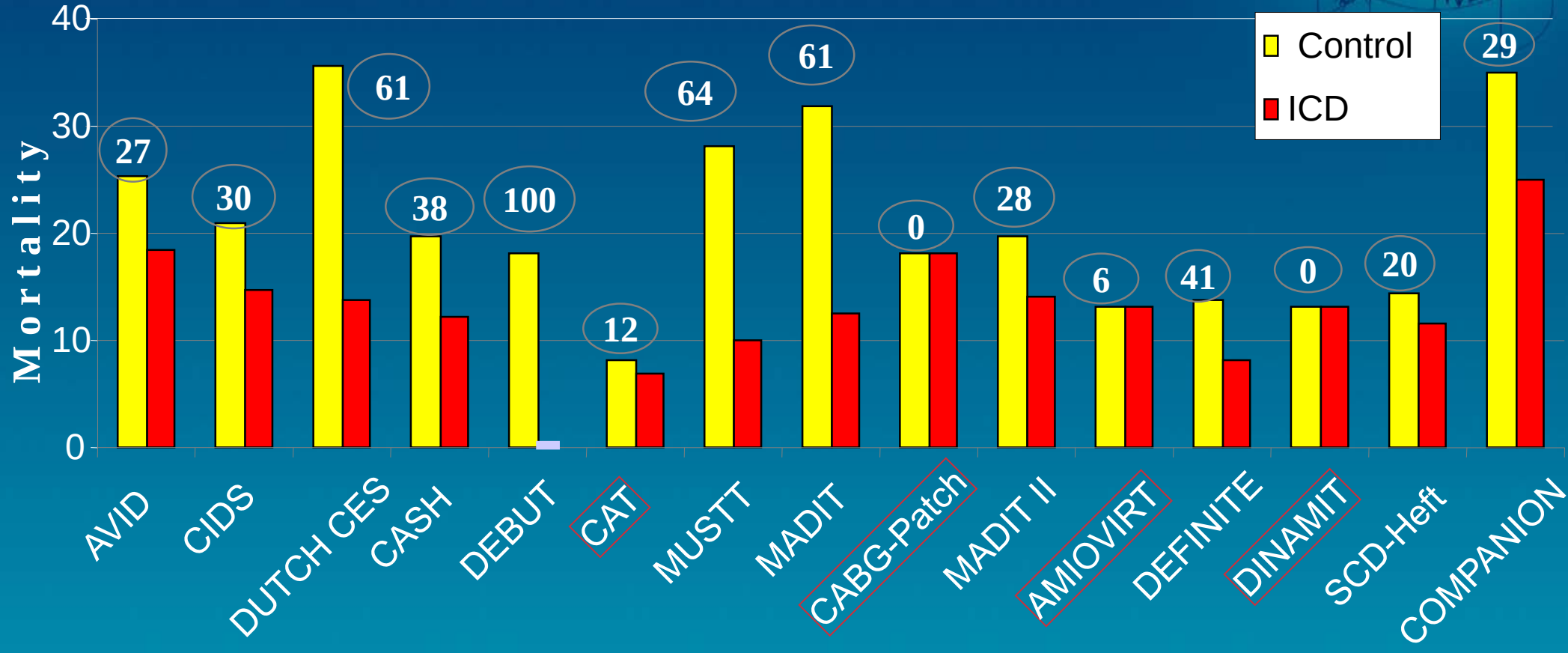
Antonio Raviele, MD, FESC, FEHRA, FHRS

ALFA – Alliance to Fight Atrial fibrillation, Mestre – Venice, Italy

ICD & SCD

- The implantable cardioverter-defibrillator (ICD) has become the standard therapy for patients with aborted SCD and those at high risk of developing potentially letal ventricular tachyarrhythmias

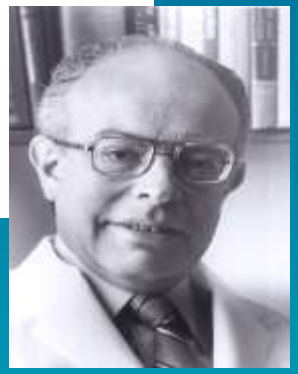
ICD reduces mortality by ~ 40% at 2-year follow-up in randomized controlled trials



Nisam, Breithardt Europace 2006

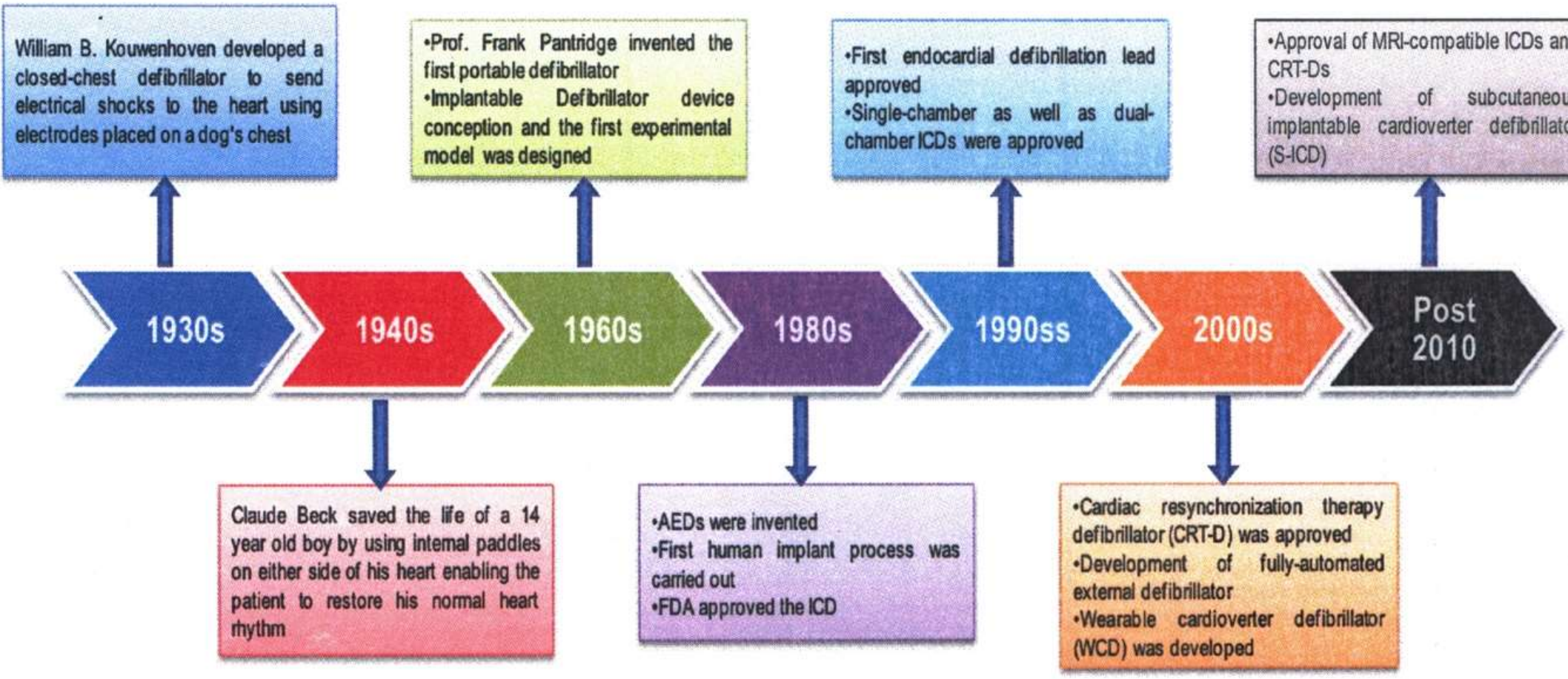
TERMINATION OF MALIGNANT VENTRICULAR ARRHYTHMIAS WITH AN IMPLANTED AUTOMATIC DEFIBRILLATOR IN HUMAN BEINGS

M. Mirowski, M.D., Philip R. Reid, M.D., Morton M. Mower, M.D., Levi Watkins, M.D., Vincent L. Gott, M.D., James F. Schauble, M.D., Alois Langer, Ph.D., M. S. Heilman, M.D., Steve A. Kolenik, M.S., Robert E. Fischell, M.S., and Myron L. Weisfeldt, M.D.

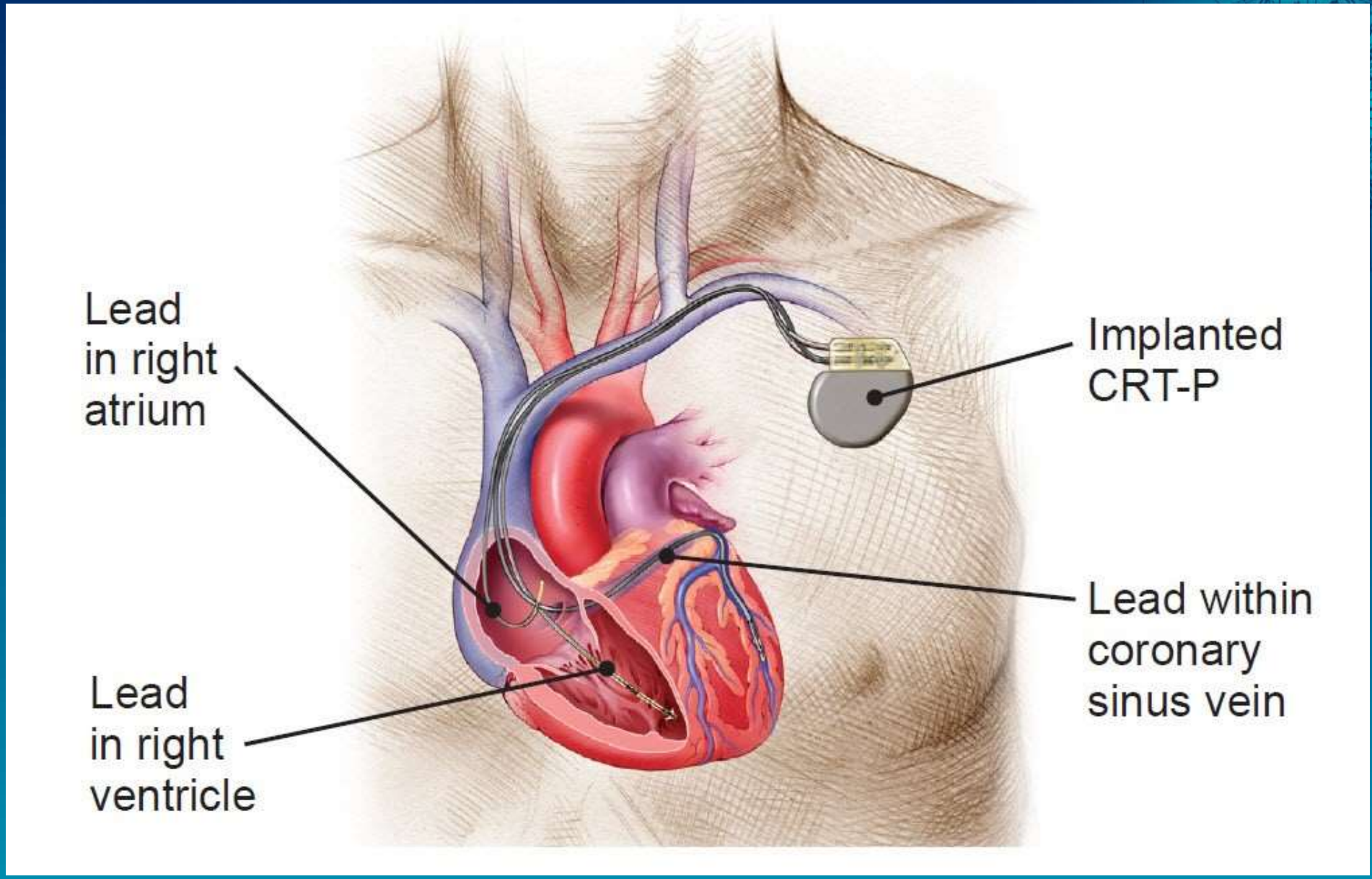


N Engl J Med 1980; 303: 322-4

Evolution of defibrillators



significant advances in ICD technology have been made



Modern transvenous ICDs are miniaturized pectoral devices connected to one or more leads inserted into the venous circulation, and are capable not only of defibrillation but also of pacing and cardiac resynchronization therapy (CRT).

Transvenous ICD

- Despite the proven efficacy and the continuous technological advances of the transvenous ICD, the implantation of these devices continues to carry a non-negligible risk of acute & long-term complications, which are essentially attributable to endovascular lead(s).

Adverse events following implantable cardioverter defibrillator implantation: a systematic review

Rebecca Persson · Amy Earley · Ann C. Garlitski · Ethan M. Balk · Katrin Uhlig

J Interv Card Electrophysiol 2014; 40: 191-205

Lead-related adverse events during hospitalizations for implantation

2.8% - 3.6%

- Pneumothorax
- Hemotorax
- Pericardial effusion / tamponade
- Lead dislodgement

Lead-related adverse events after hospitalization during 2-70 month fu

< 0.1% - 6.4%

- Central vein thrombosis & Occlusion
- Tricuspid valve insufficiency
- Systemic infections & Endocarditis
- Lead malfunction due to insulation defects or lead fractures
- Consequent inappropriate / Ineffective therapies
- Recall/Withdrawal of the malfunctioning lead from market

Person R et al. J Interv Card Electrophysiol 2014; 40: 191-205

ICD leads

- ICD leads are the most vulnerable component of the ICD systems, especially the RV defibrillation lead. It must remain chemically inert in an hostile biological enviroment, withstand flexible for hundreds of millions of cardiac cycles, and retain electricl integrity during high voltage shocks.

ICD lead failure / Incidence

Table 4 Lead failure rates

Reference	Study design	Lead types	Failure rate	Observation period	Yearly failure rate	Long term failure rates	Accelerating failure rate?
Farwell[124]	Retrospective, single centre	Medtronic fidelis	17/471 (3.5%)	19.8 months	2.12%	Not reported	Yes
Kron[60]	Retrospective analysis of prospective multicentre study	All manufacturers	15/539 (2.8%)	27.0±13.4	1.2%	5% at 5 years	No
Alter[61]	Prospective, single centre	All manufacturers	27/440 (6.1%)	46±37 months	1.6%	Not reported	Not reported
Faulknier[66]	Retrospective, single centre	Medtronic fidelis	38/426 8.92%	2.3 years	3.6%	9% at 3 years	Yes
Hauser[125]	Retrospective, 3 centre	Medtronic fidelis	80/1023 (7.8%)	2.78 y	2.8%	13% at 4 years	Yes
Hauser[125]	Retrospective, single centre	Medtronic quatro	23/1668 (1.4%)	3.18 y	0.43%	1.3% at 4 years	No
Kleemann[63]	Prospective, single centre	All manufacturers	148/990 (15%)	934 days	5.8%	15% at 5 years; 40% at 8 years;	Yes
Eckstein[65]	Retrospective, 3 centre	All manufacturers	38/1317 (2.9%)	6.4 years	0.45%	2.5% at 5 years	No
Luria[30]	Retrospective, single centre	All manufacturers	18/391 (4.6%)	19 months	2.9%	18% failure at 4 years	Yes
Kitamura[126]	Retrospective, single centre	Medtronic models	5/241 (2%)	2.6±2.1 years	Not reported	Not reported	No
Hauser[127]	Retrospective, 3 centre	Transvene 6936/6966	44/521 (8.4%)	4.8±2.1 years	2.2%	16% at 84 months	Yes
Dorwarth[128]	Retrospective, single centre	Transvene 6884, 6966, 6936	31/261 (12%)	4.0±2.6 years	4.75%	38% at 8 years	Yes

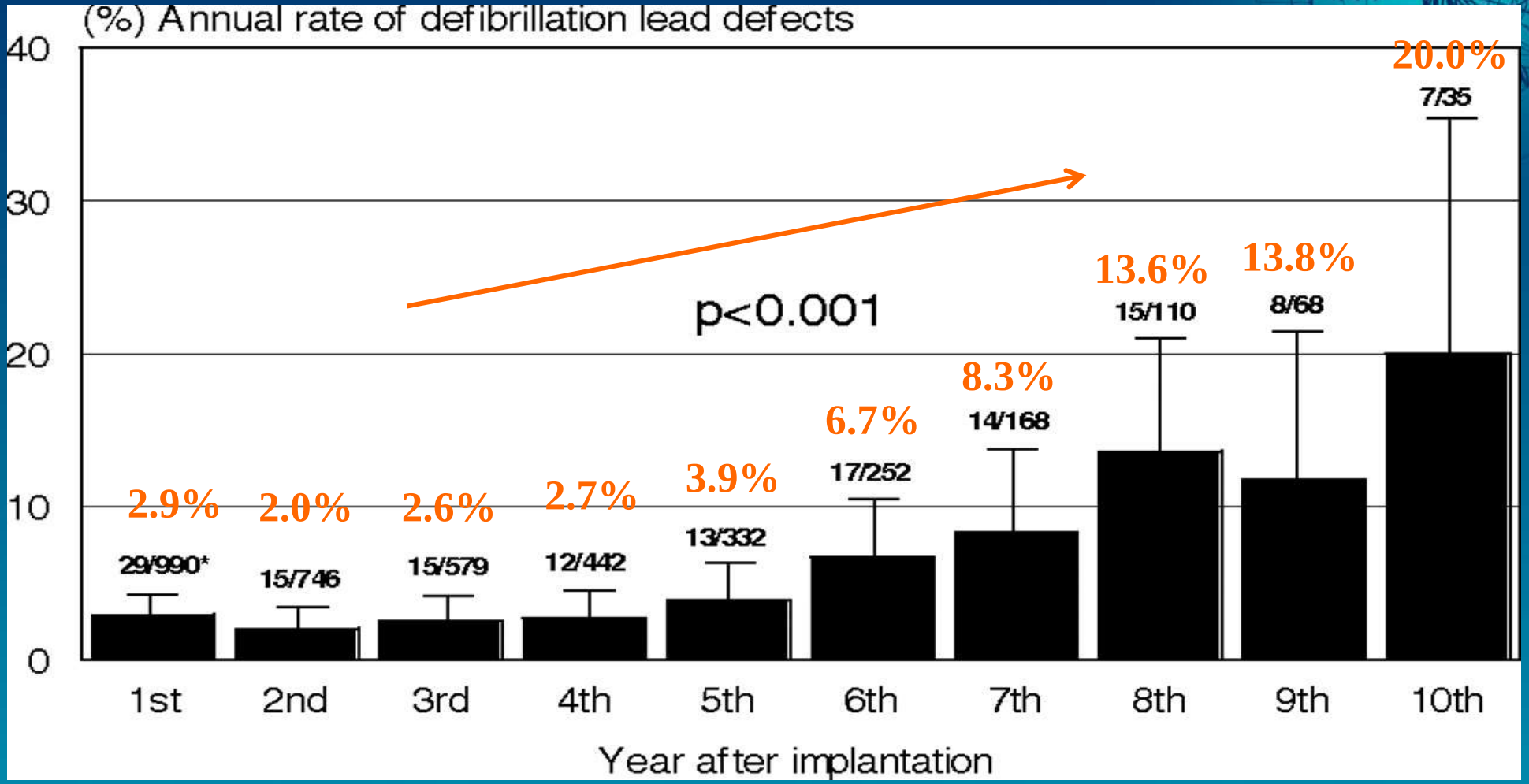
Atwater BD et al. Heart 2012; 98: 764-772

Annual Rate of Transvenous Defibrillation Lead Defects in Implantable Cardioverter-Defibrillators Over a Period of >10 Years

Thomas Kleemann, Torsten Becker, Klaus Doenges, Margit Vater, Jochen Senges, Steffen Schneider, Werner Saggau, Udo Weisse, and Karlheinz Seidl

Circulation 2007; 115: 2474-2480

Annual rate of defibrillation lead defects versus time after lead implantation

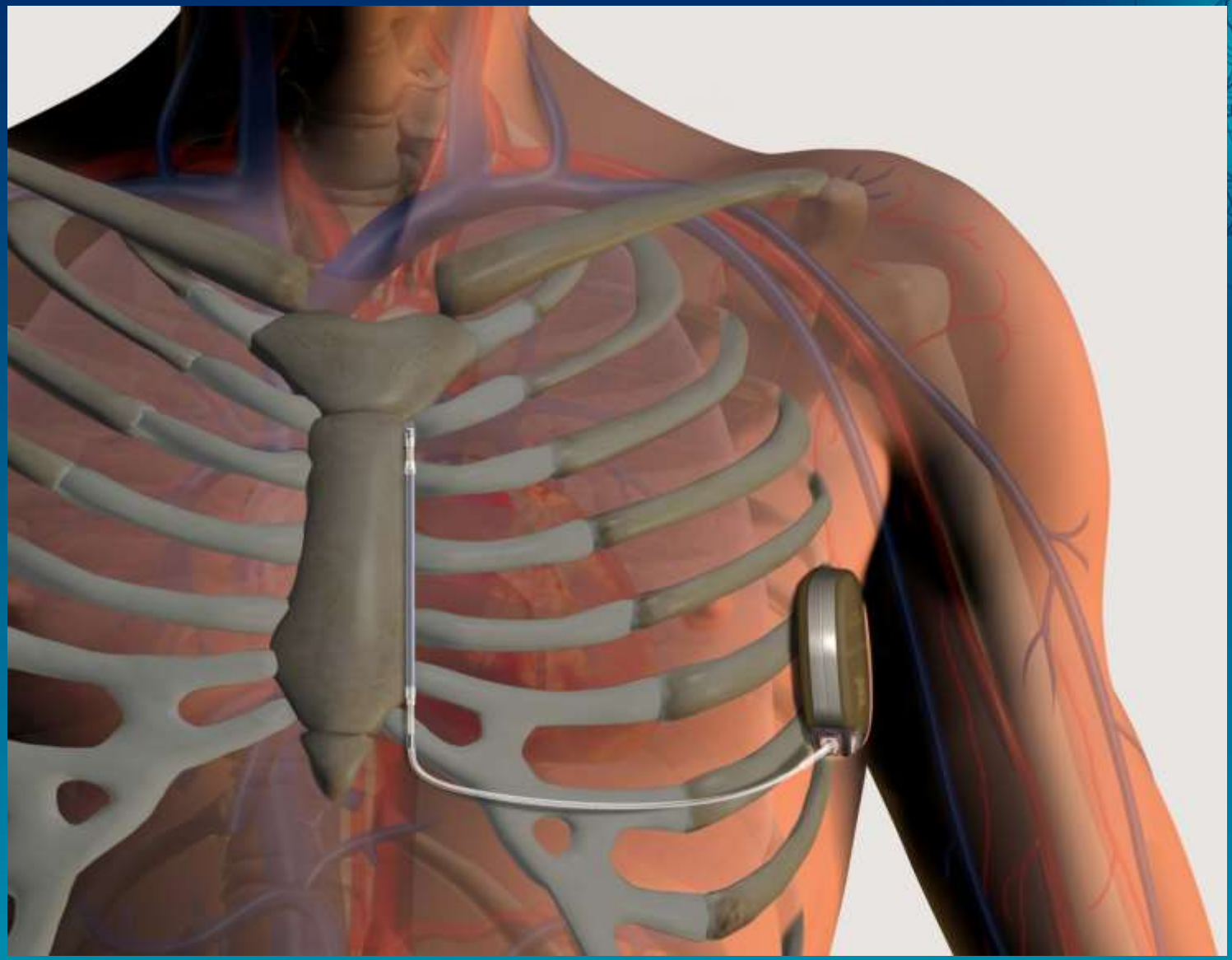


Kleemann T et al. Circulation. 2007;115:2474-2480

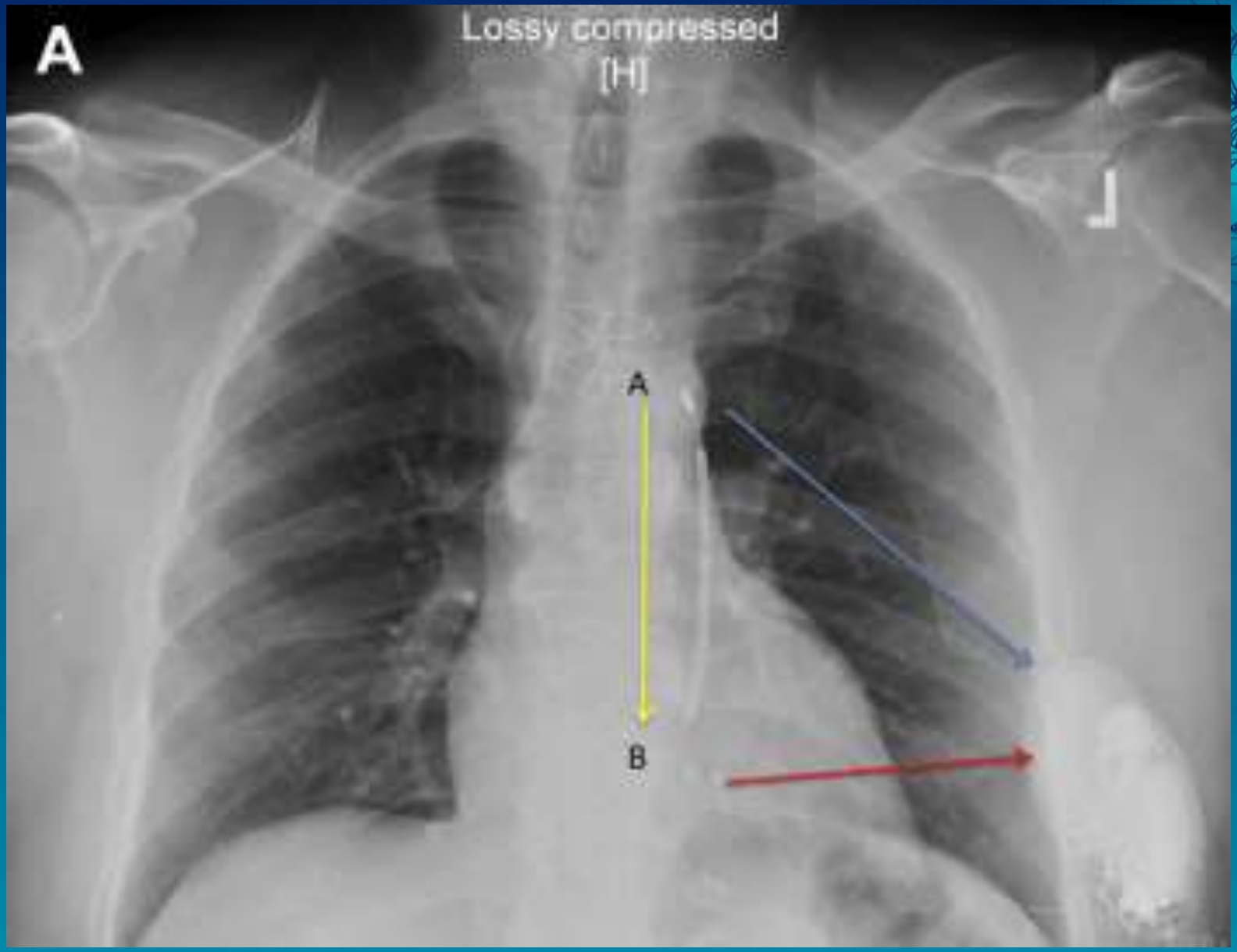
Evolution of Subcutaneous ICD

This high rate of lead-related complications of the transvenous ICD with the consequent need for lead extraction and the potential risks of morbidity and mortality associated to this procedure has led 10 years ago to the development and introduction in clinical practice of the subcutaneous ICD

S-ICD - Subcutaneous Implantable Cardiac Defibrillator

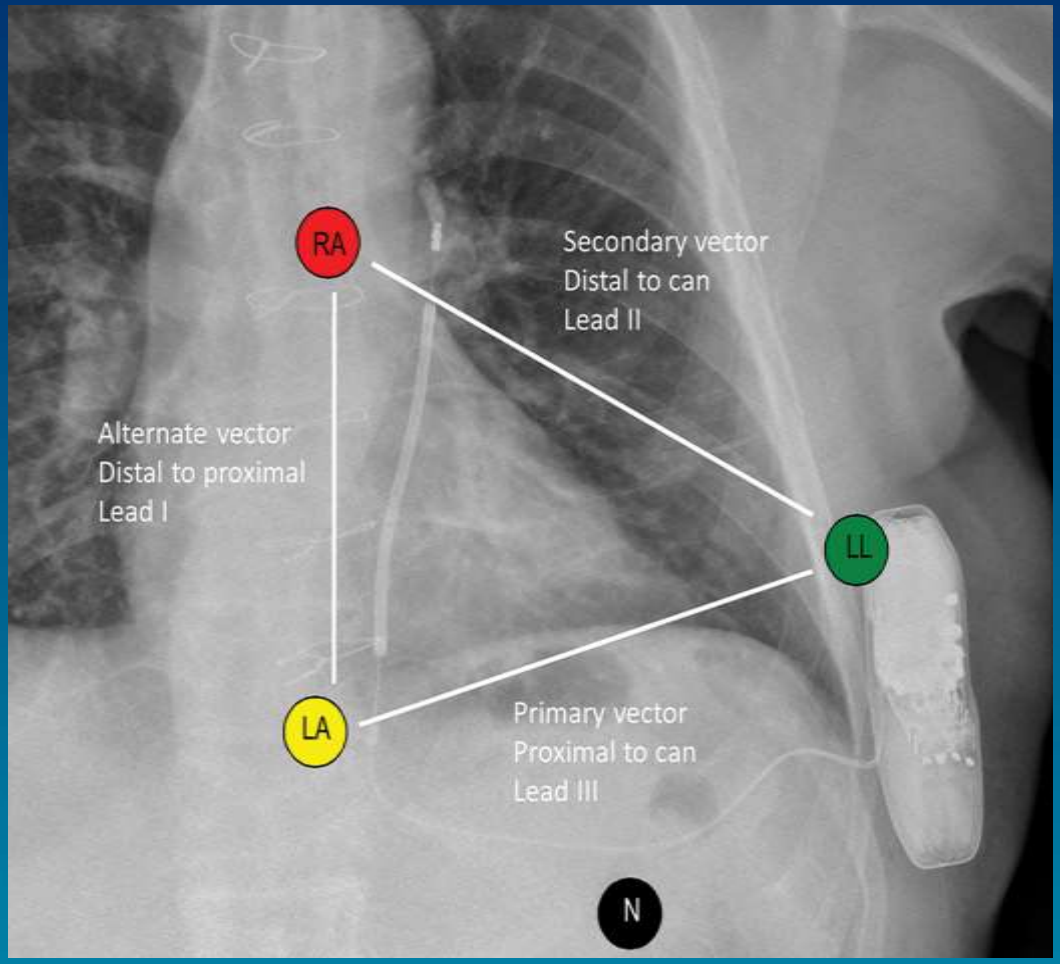


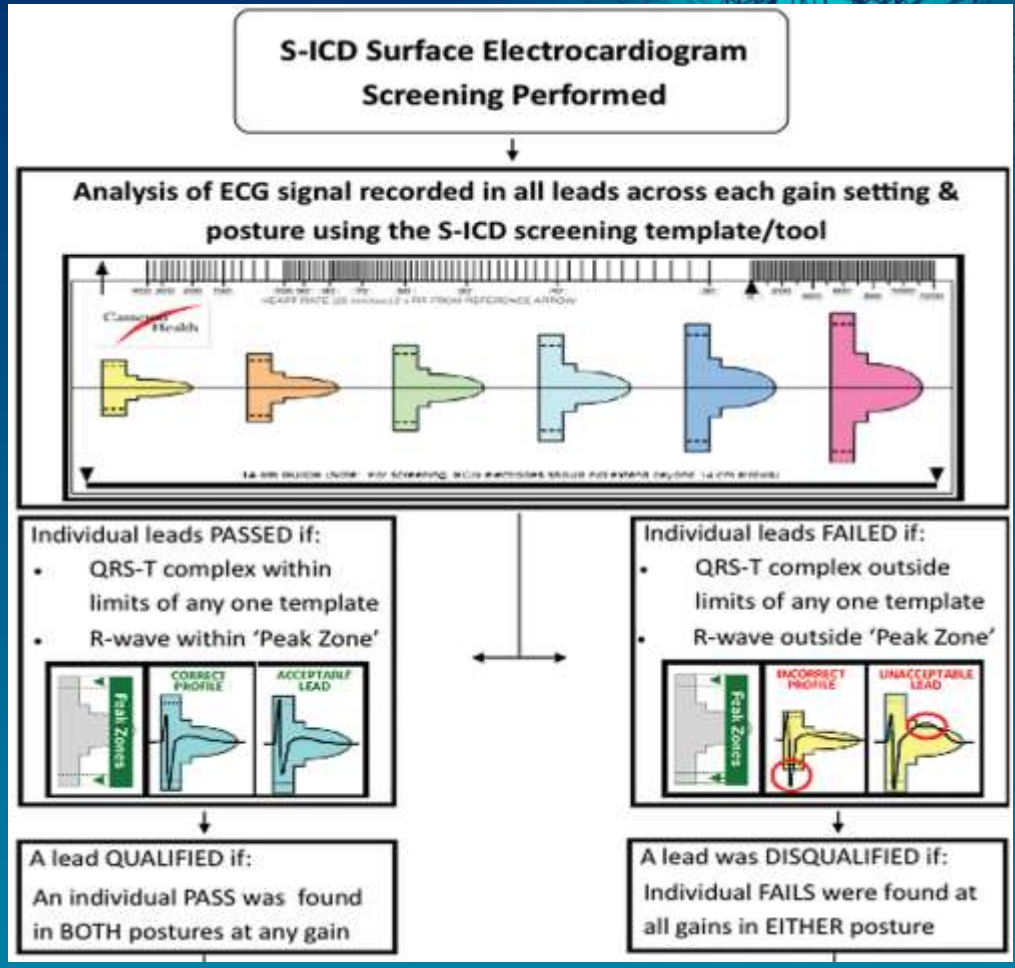
The S-ICD consists of a pulse generator implanted in the left mid-axillary line at the fifth intercostal space and an extravascular lead tunneled in the subcutaneous space from the lateral pocket medially to the xiphoid process and then cephalad to the sternum-manubrium just to the left or right of the parasternal margin. The subcutaneous lead is equipped with two sensing electrodes separated by an 8-cm shock coil, the proximal electrode usually being placed at the xiphoid process and the distal one at the sterno-manubrium level



The device senses subcutaneous signals and detects cardiac rhythm from the two sensing electrodes or from both electrodes and the pulse generator. There are three available sensing vectors (primary: from proximal electrode to pulse generator; secondary: from distal electrode to pulse generator; alternate: from distal to proximal electrode). Arrhythmia detection is performed through the use of one of these three vectors. The system automatically selects the most appropriate vector after implantation, according to the highest R amplitude, the most satisfactory R wave/T wave ratio, and the best noise reduction, to avoid double counting of QRS and T-wave oversensing

S-ICD Preimplantation Electrocardiographic Screening





Not every patient is suitable for a S-ICD implantation. Patients have to pass an electrocardiographic screening test before implantation. The screening test consists of placing three ECG electrodes on the thorax at the sites where the generator and sensing electrodes of the S-ICD are to be implanted, thus simulating the three sensing vectors of the S-ICD. Electrocardiograms from each vector are then recorded at a paper speed of 25 mm/s at gains of 5, 10, and 20 mV for a period of 10 seconds in both supine and upright positions. Using the screening template provided by the manufacturer, the entire QRS and T wave of at least one electrocardiogram must fall within the shaded region of the template, at any gain in both positions, in order to qualify the patient as a candidate for the S-ICD

Preimplantation ECG screening test

7-16%

patients fail the preimplant screening test

and, therefore, do not qualify for the S-ICD

Olde Nordkamp LR et al. J Cardiovascular Electrophysiol 2014; 25: 494-499
Groh CA et al. Heart Rhythm 2014; 11: 1361-1366
Randles DA et al. Europace 2014; 16: 1015-1021

Efficacy and Safety

The subcutaneous implantable cardioverter defibrillator—review of the recent data

Stacy B Westerman[1], Mikhael El-Chami[2]

J Geriatr Cardiol 2018; 15: 222-228

Table 2. Summary of the Major SICD Studies.

	SICD-IDE Study	Effortless Registry	SICD-PAS Study
Number of Patients	330	472	1637
Average Age, yrs	51.9 ± 15.5	49 ± 18	53.2 ± 15
Mean EF, %	36.1 ± 15.9	42 ± 19	32 ± 14.6
Complications, %	7.9% (180-day complication rate)	3% and 6% (30-day and 1 year complication rate respectively)	3.8% (30-day complication rate)
Acute Conversion Success of Induced VF	100%	99.7%	98.7%
Spontaneous VT/VF Total Shock Efficacy	97.1%	100%	N/A*

*The SICD-PAS was an acute complication study. Long-term Follow-up not published at this time. EF: ejection fraction; IDE: Investigational Device Exemption; PAS: post approval registry; SICD: subcutaneous implantable cardioverter defibrillator; VT/VF: ventricular tachycardia/ventricular fibrillation. This table is modified from Gold MR.[24]

The acute success rate in converting induced VF at implant is 98.7%-100% and the shock efficacy rate in converting spontaneous VT/VF during the follow-up is 97.1%-100%. These conversion rates are similar to those of contemporary studies on transvenous ICD systems.

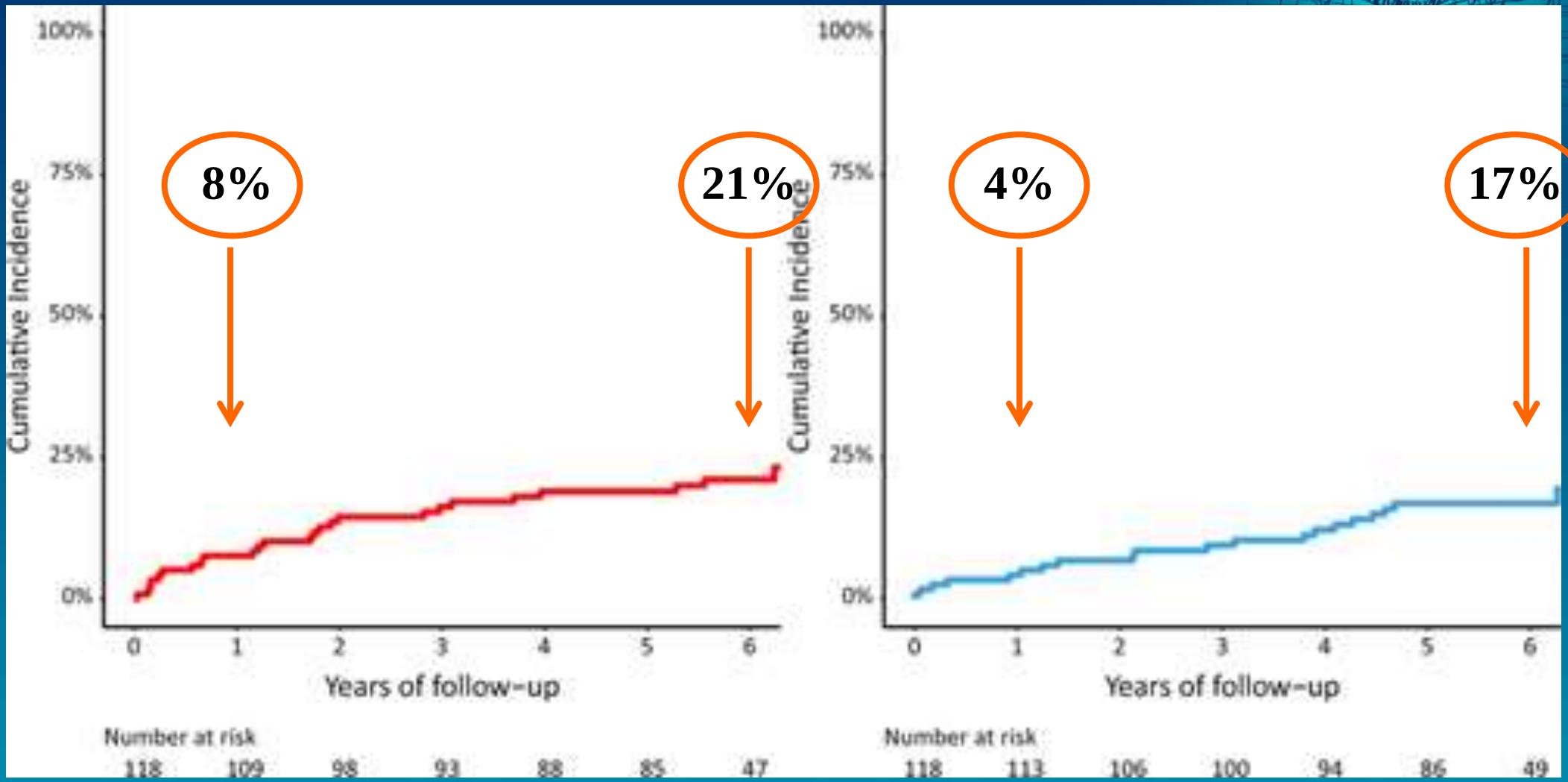
Westerman SB et al. J Geriatr Cardiol 2018; 215: 222-228

Six-year follow-up of the initial Dutch subcutaneous implantable cardioverter-defibrillator cohort: Long-term complications, replacements, and battery longevity

Anne-Floor B. E. Quast MD[1] | Vincent F. van Dijk MD[2] | Sing-Chien Yap MD, PhD[3]
Alexander H. Maass MD, PhD[4] | Lucas V. A. Boersma MD, PhD[2] |
Dominic A. Theuns PhD[3] | Reinoud E. Knops MD, PhD[1]

J Cardiovasc Electrophysiol 2018; 29: 1010-1016

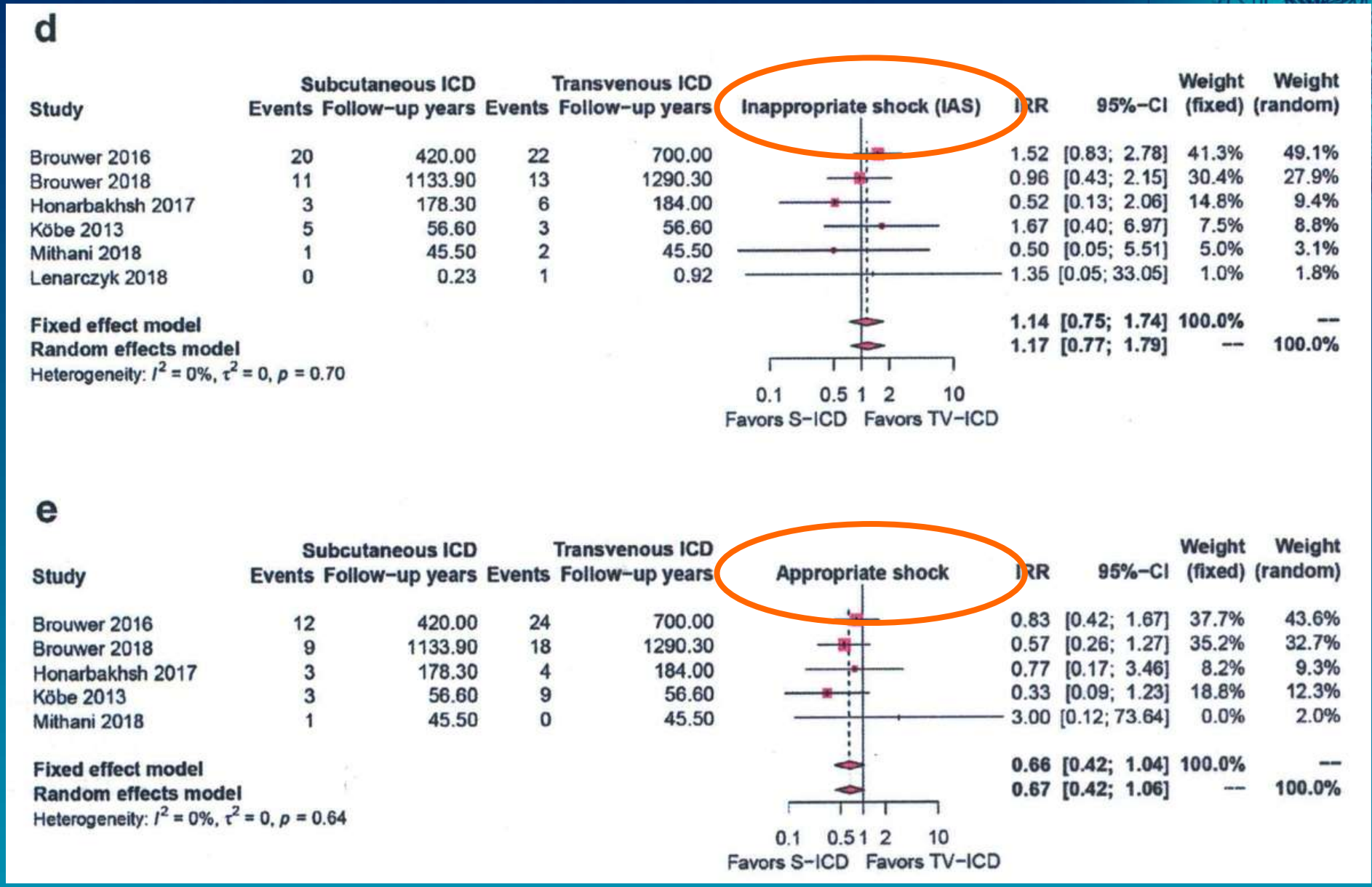
S-ICD therapy. Kaplan-Meier plot of the inappropriate shock rate (red) and appropriate shock rate (blue) during 6-year follow-up



the incidence of appropriate shocks is 4% at 1 year and 17% at 6 years and the incidence of inappropriate shocks is 8% at 1 year and 21% at 6 years

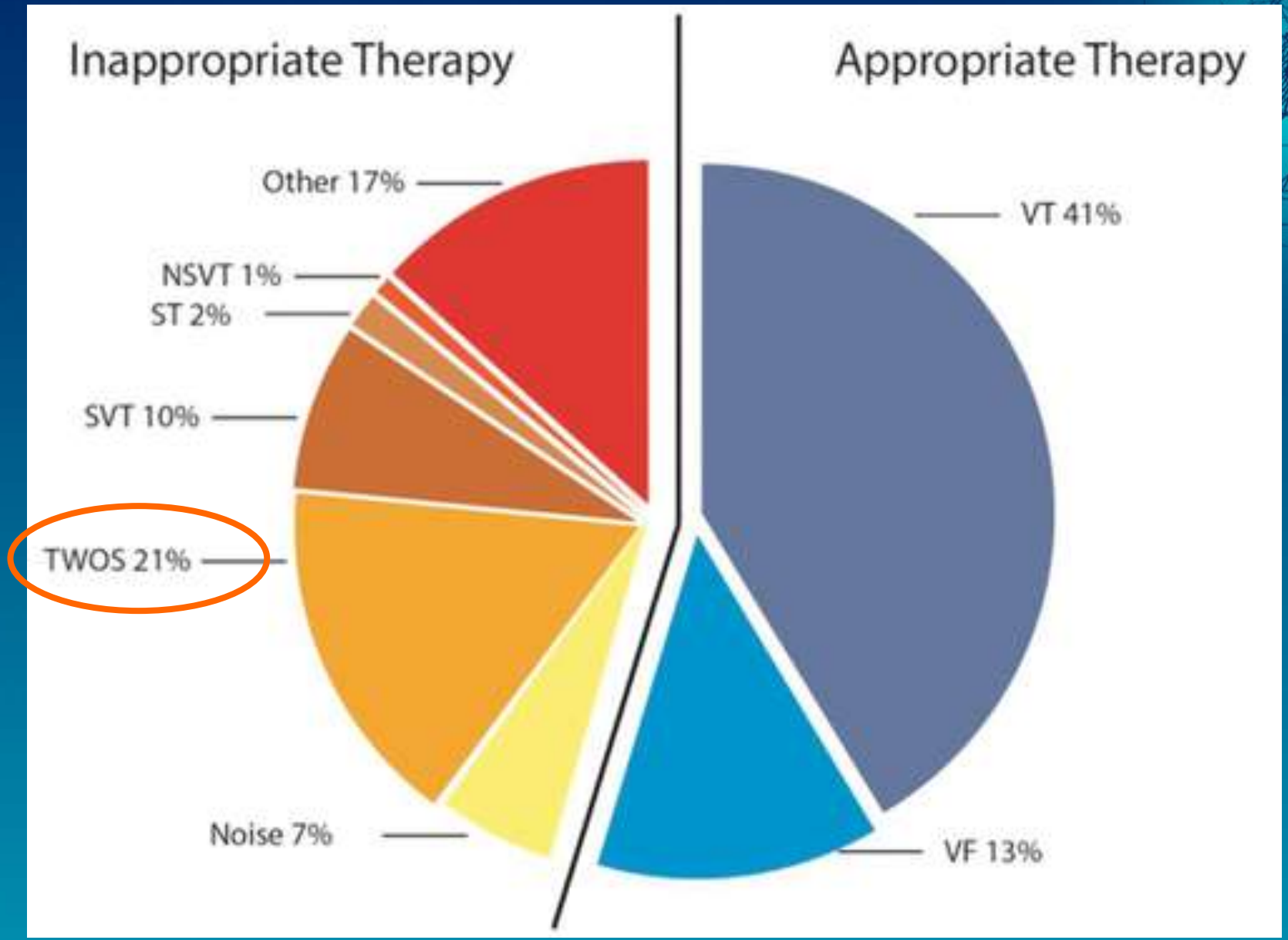
Quast AFBE et al. J Cardiovasc Electrophysiol 2018; 29: 1010-1016

An overview of clinical outcomes in transvenous and subcutaneous ICD pts



These rates are not significantly different from those reported for transvenous ICD

Baalman SWE et al. Curr Cardiol Rep 2018; 20:72



The main cause of inappropriate shocks is T-wave oversensing in case of S-ICD, whereas it is supraventricular tachyarrhythmias in case of transvenous ICD

Quast AFBE et al. J Cardiovasc Electrophysiol 2018; 29: 1010-1016

a

Study	Subcutaneous ICD Events	Subcutaneous ICD Follow-up years	Transvenous ICD Events	Transvenous ICD Follow-up years	IRR	95%-CI	Weight (fixed)	Weight (random)
Brouwer 2016	14	420.00	21	700.00	1.11	[0.57; 2.18]	16.9%	19.4%
Brouwer 2018	34	1133.90	25	1290.30	1.55	[0.92; 2.59]	25.1%	23.8%
Friedman 2016	12	5.30	39	10.50	0.61	[0.32; 1.16]	28.1%	20.1%
Honarbakhsh 2017	3	178.30	14	184.00	0.22	[0.06; 0.77]	14.8%	9.4%
Köbe 2013	3	56.60	3	56.60	1.00	[0.20; 4.95]	3.2%	6.4%
Mithani 2018	7	45.50	7	45.50	1.00	[0.35; 2.85]	7.5%	12.0%
Lenarczyk 2018	3	0.23	10	0.92	1.21	[0.33; 4.40]	4.3%	8.9%
Fixed effect model					**0.94**	**[0.70; 1.26]**	**100.0%**	--
Random effects model					**0.90**	**[0.58; 1.42]**	--	**100.0%**

Heterogeneity: $I^2 = 45\%$, $\tau^2 = 0.1502$, $p = 0.09$

All-cause complication

0.1 0.5 1 2 10

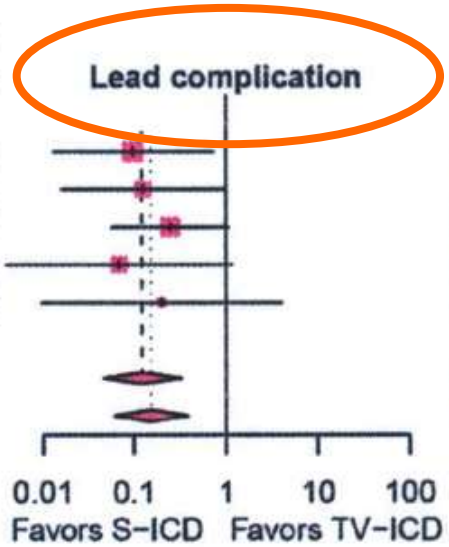
Favors S-ICD Favors TV-ICD

Baalman SWE et al. Curr Cardiol Rep 2018; 20:72

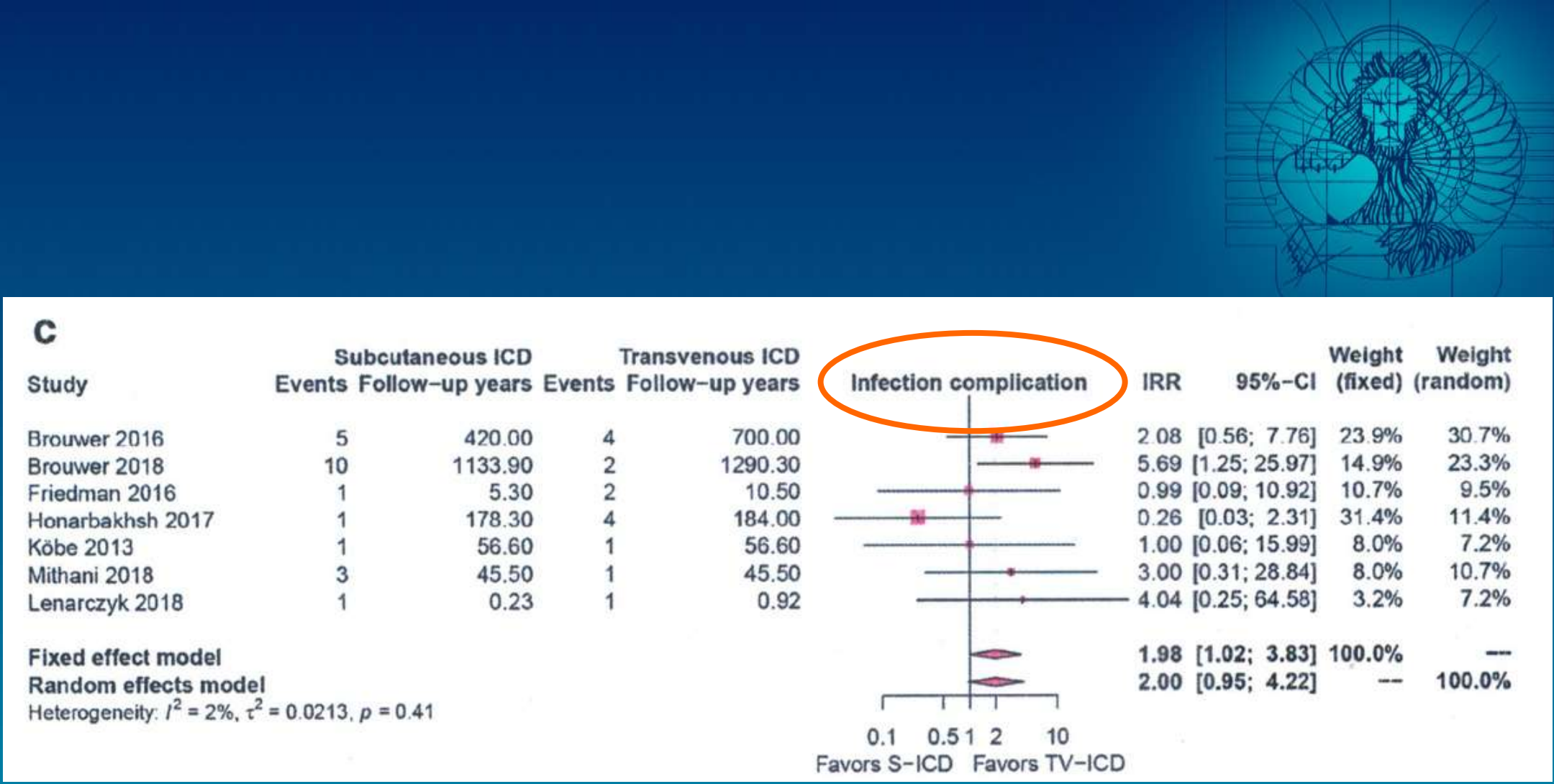
b

Study	Subcutaneous ICD Events	Subcutaneous ICD Follow-up years	Transvenous ICD Events	Transvenous ICD Follow-up years	IRR	95%-CI	Weight (fixed)	Weight (random)
Brouwer 2016	1	420.00	17	700.00	0.10	[0.01; 0.74]	31.3%	21.0%
Brouwer 2018	1	1133.90	9	1290.30	0.13	[0.02; 1.00]	20.6%	20.0%
Friedman 2016	2	5.30	16	10.50	0.25	[0.06; 1.08]	26.3%	39.4%
Honarbakhsh 2017	0	178.30	7	184.00	0.07	[0.00; 1.20]	16.9%	10.4%
Köbe 2013	0	56.60	2	56.60	0.20	[0.01; 4.17]	4.9%	9.2%
Fixed effect model					**0.12**	**[0.05; 0.33]**	**100.0%**	---
Random effects model					**0.15**	**[0.06; 0.39]**	---	**100.0%**

Heterogeneity: $I^2 = 0\%$, $\tau^2 = 0$, $p = 0.88$



Baalman SWE et al. Curr Cardiol Rep 2018; 20:72



Baalman SWE et al. Curr Cardiol Rep 2018; 20:72

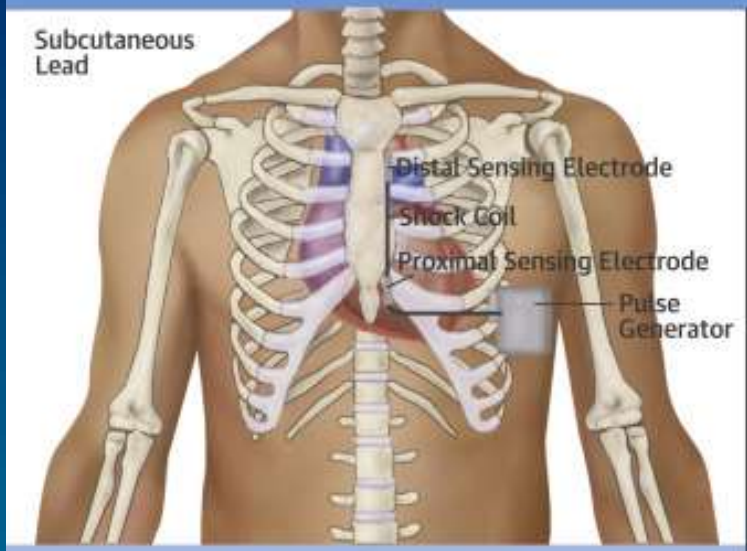
S-ICD / Complications

No electrode failures during the follow-up

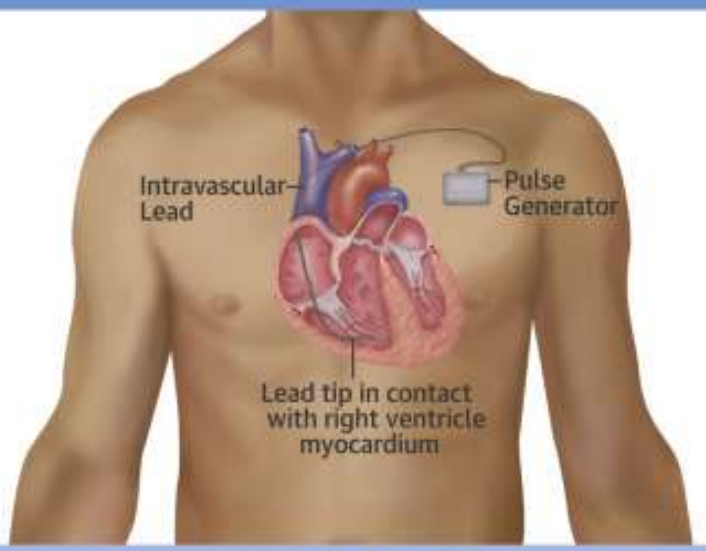
nor any cases of S-ICD related bacteremia or endocarditis

have been reported for the S-ICD

S-ICD



Transvenous ICD



S-ICD Advantages

- Eliminate need for vascular access
- Possible to implant without fluoroscopy
- Reduced mid-term risk of lead malfunction
- Eliminate certain procedural risks (e.g. pneumothorax, tamponade)
- Improved arrhythmia discrimination
- Relative ease of extraction
- Hardware infections not associated with endocarditis

Transvenous ICD Advantages

- Pacemaker and ATP functionality
- Smaller pulse generator
- Better battery longevity
- Shorter charge time-faster shock delivery
- Able to deliver CRT
- No pre-implant ECG screening required
- Long-term follow-up data available

Lewis, G.F. et al. J Am Coll Cardiol. 2016; 67(4):445-54.

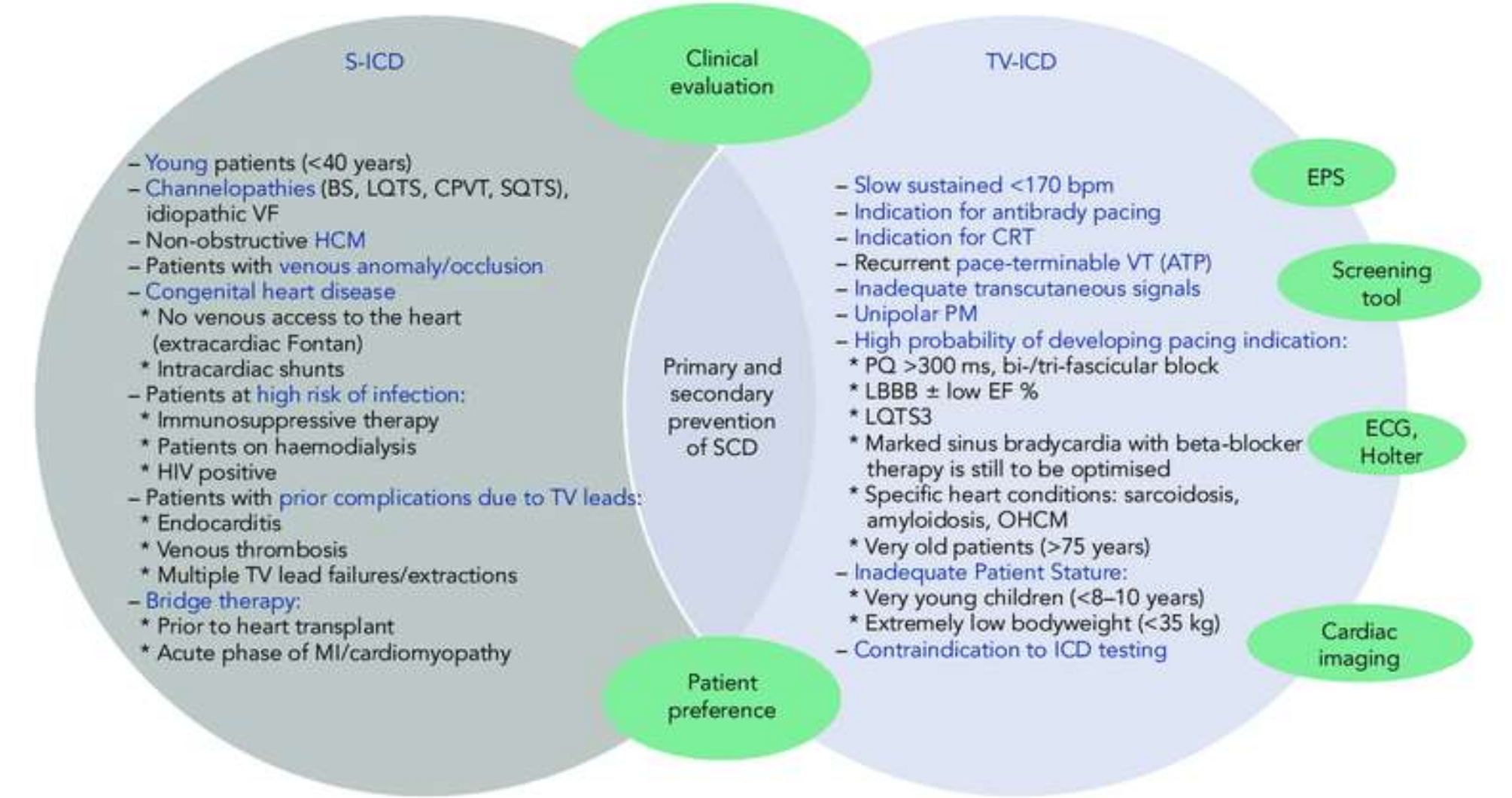
Advantges and disadvanteges of S-ICD

Advantages	Comments	Disadvantages	Comments
No vascular access required	• *Specific potential procedural complications omitted (eg cardiac tamponade, pneumothorax, vascular lesions)* • *Suitable for patients with complex anatomy (eg congenital heart diseases) or no venous access*	**Pacing for bradycardia, ATP and CRT functions not available**	
No fluoroscopy required		**Pulse generator larger/heavier, compared to conventional ICD**	*New generation devices are significantly smaller/lighter*
No risk of bacterial endocarditis		**Longevity shorter (~5 years) compared to conventional ICD**	*Longevity of new generation devices >7 years*
Better discrimination of supraventricular arrhythmias		**Longer charge time & time-to-therapy**	*Prolongation of detection-to-shock time may reduce inappropriate shocks*
Simpler extraction procedure		**Simpler diagnostic and therapeutic algorithms**	
		Remote monitoring not available	*Available in new generation models*
		Limited clinical experience	*Up-to-date evidence suggests efficacy and safety*
		Significant incidence of inappropriate shocks (mostly due to oversensing)	*Equivalent to conventional ICD*
		Significant incidence of pocket infection	*Equivalent to conventional ICD*
		Defibrillation test mandatory	
		Pre-implantation ECG screening required	
		Higher cost compared to conventional ICD	

Table 3. Advantages and disadvantages of S-ICDs.

Sideris S et al. Hellenic J Cardiol 2017; 58: 4-16

Suitable candidates for S-ICD and TV-ICD



Ali H et al. Arrhythm Electrophysiol Rev 2015; 4: 116-121

S-ICD / Contraindication

The need for antibradycardia pacing, ATP, or CRT

at the time of ICD implantation is usually considered a

contraindication for S-ICD.

S-ICD / Need for cardiac pacing

However, some patients with S-ICD may subsequently develop indication for cardiac pacing during follow-up.

It is also possible that patients with traditional pacemakers or CRT devices may subsequently require, for different reasons, implantation of an S-ICD or conversion from a transvenous ICD to an S-ICD.

S-ICD / Need for cardiac pacing

How many are these patients

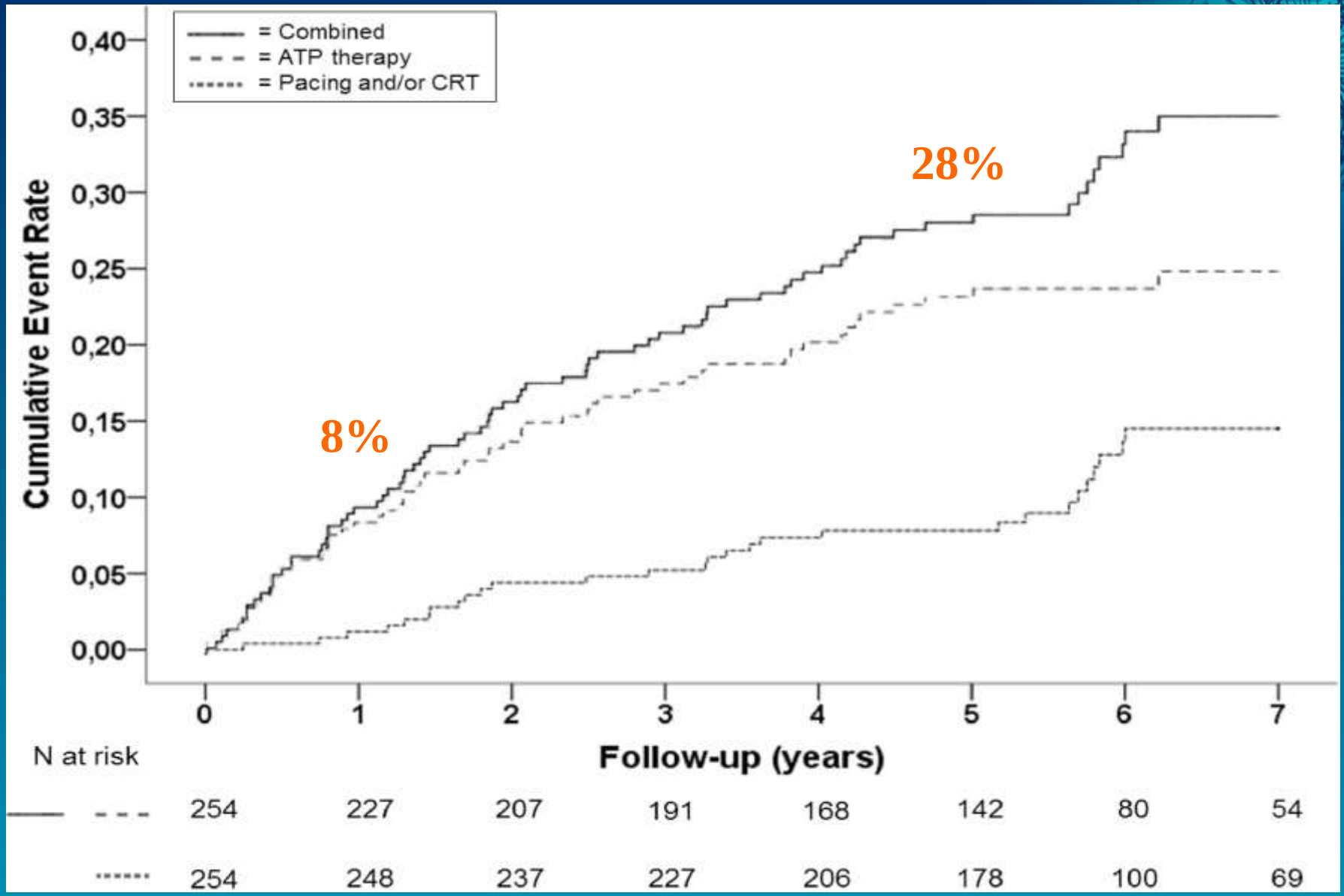
?

Frequency of Need for Antitachycardia or Antibradycardia Pacing or Cardiac Resynchronization Therapy in Patients With a Single-Chamber Implantable Cardioverter-Defibrillator

Mireille C. Melles, MSc, Sing-Chien Yap, MD, PhD, Rohit E. Bhagwandien, MD, Rafi Sakhi, MD, Tamas Szili-Torok, MD, PhD, and Dominic A.M.J. Theuns, PhD*

Am J Cardiol 2018; 122: 2068-2074

Cumulative event rates for the individual end points and combined end point. Solid line—combined end point; long dashed line—ATP therapy; squared dotted line—bradycardia pacing and CRT indication.



ATP = antitachycardia pacing; CRT = cardiac resynchronization therapy.

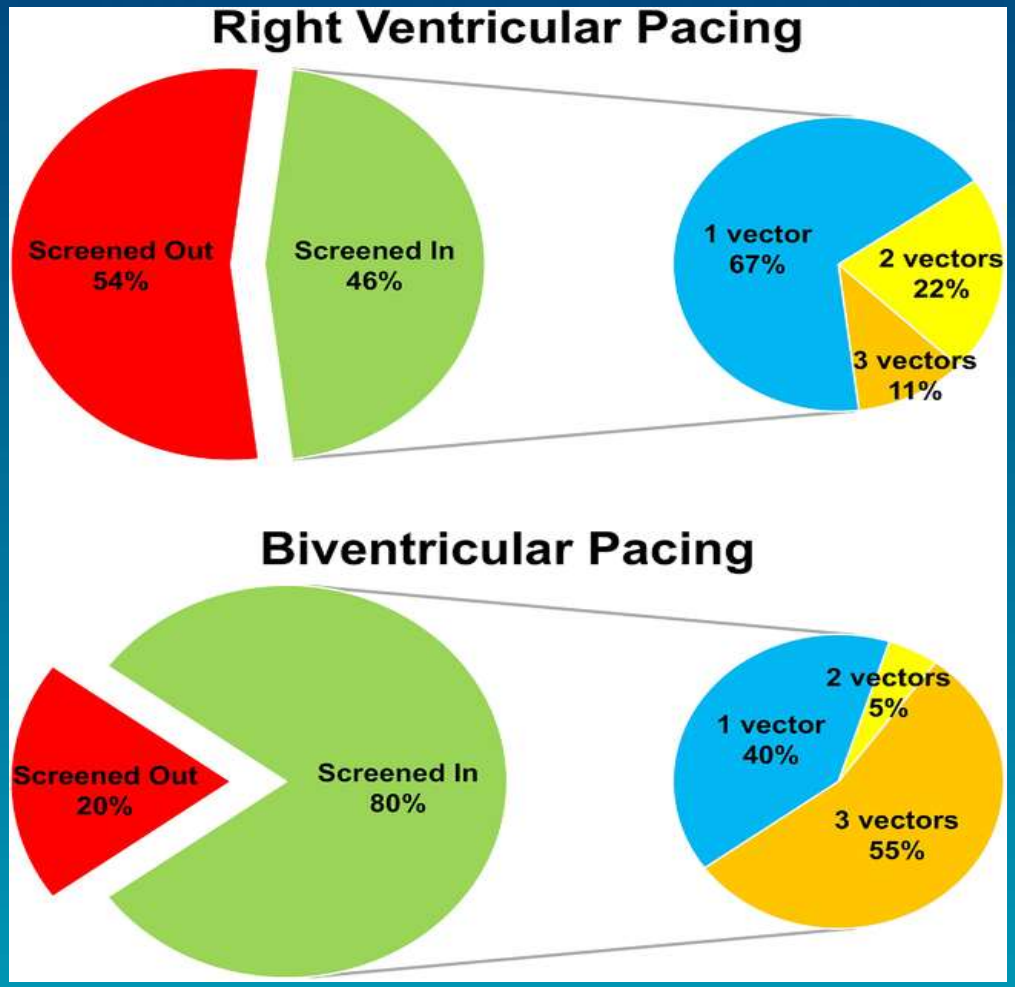
Melles MC et al. Am J Cardiol 2018 122, 2068-2074

Eligibility of Pacemaker Patients for Subcutaneous Implantable Cardioverter Defibrillators

JAMES E. IP, M.D., MICHAEL S. WU, M.D., PETER J. KENNEL, M.D., GEORGE THOMAS, M.D., CHRISTOPHER F. LIU, M.D., JIM W. CHEUNG, M.D., STEVEN M. MARKOWITZ, M.D., and BRUCE B. LERMAN, M.D.

J Cardiovasc Electrophysiol 2017; 28: 544-548

Methods and Results: We evaluated 100 patients with transvenous pacemakers/ICDs, including 25 biventricular devices to determine S-ICD candidacy during right ventricular (RV) pacing and biventricular pacing based on the recommended QRS:T-wave ratio screening template. Fifty-eight percent of patients qualified for an S-ICD based on their QRS morphology during ventricular pacing. More patients during biventricular pacing met criteria compared to during RV pacing alone (80% vs. 46%, P <0.01). Patients that were paced from the RV septum were more likely to qualify compared to those paced from the RV apex (67% vs. 37%, respectively, P <0.01).



Ip JE et al. J Cardiovasc Electrophysiol 2017; 28: 544-548

PM/CRT devices + S-ICD

These interesting results provide valuable insight

into the possibility of using a transvenous PM/CRT device

together with an S-ICD in the same patient.

PM+S-ICD / Possibilities of cross-talk

- First, the pacemaker stimulus may be detected by the S-ICD system, which may result in double counting togheter with the QRS complex or even triple counting in case of sequentially atrio-ventricular pacing.
- Second, in case of low amplitude VT/VF, detection of stimulation spikes may decrease the S-ICD sensitivity, which may lead to undersensing.

PM+S-ICD / Steps recommended (1)

- During implantation, S-ICD screening of native and paced ECG morphologies should be performed. The sensing vector that is least likely to have pacemaker artifacts should be used.
- A bipolar stimulation configuration should be selected, since the stimulation spike amplitude is lower than in unipolar configuration.

PM+S-ICD / Steps recommended (2)

- Pacemakers that can automatically switch from a bipolar into a unipolar pacemaker should not be combined with S-ICD systems.
- A dual detection zone is recommended, as the conditional shock zone contains longer blanking periods than the non-conditional shock zone, which reduces the risk for oversensing of stimulation spikes.

PM+S-ICD / Steps recommended (3)

- Whenever compatible with the patient's need, the upper tracking limit of the pacemeker should not exceed 100 bpm, and the conditional shock zone should start at 210-220 bpm to avoid inappropriate shocks in case of double counting.
- Dual-chamber PM algorithms that reduce ventricular pacing may also reduce the risk of innapropriate shocks.

PM+S-ICD / Steps recommended (4)

- Sensitivity of pacemaker systems should be kept high for a proper sensing of ventricular tachyarrhythmia and withholding of pacing in VT due to undersensing.
- Septal pacing may be more suitable due to a narrower QRS complex.
- Post-shock pacing of S-ICD should be deactivated.

PM+S-ICD / Steps recommended (5)

- At implantation, defibrillation threshold testing should be performed to confirm appropriate VF sensing by the pacemaker and the S-ICD.
- Since PM patients are prone to rate-dependent BBB, an exercice test or high-rate atrial pacing is advised as an additional optional that may reduce the risk of inappropriate shocks.

PM/CRT devices + S-ICD

Due to the risk of cross-talk, clinical experience regarding

the concurrent use of pacemaker and S-ICD

has been quite limited so far

Safety and Efficacy of the Totally Subcutaneous Implantable Defibrillator

2-Year Results From a Pooled Analysis of the IDE Study and EFFORTLESS Registry

Martin C. Burke, DO,* Michael R. Gold, MD, PhD,† Bradley P. Knight, MD,‡ Craig S. Barr, MD,§ Dominic A.M.J. Theuns, PhD,|| Lucas V.A. Boersma, MD, PhD,¶ Reinoud E. Knops, MD,# Raul Weiss, MD,** Angel R. Leon, MD,†† John M. Herre, MD,‡‡ Michael Husby, MS, MPH,§§ Kenneth M. Stein, MD,§§ Pier D. Lambiase, PhD||||

J Am Coll Cardiol 2015; 65: 1605-1615

A pooled analysis of the IDE study and EFFORTLESS registry reported no adverse events during 2-year follow-up in 19 patients who had a preexisting pacemaker and subsequently underwent S-ICD implantation.

Subcutaneous implantable cardioverter-defibrillator: First single-center experience with other cardiac implantable electronic devices

Jürgen Kuschyk, MD,*† Ksenija Stach, MD,*† Erol Tülümen, MD,*† Boris Rudic, MD,*† Volker Liebe, MD,*† Rainer Schimpf, MD, PhD,*† Martin Borggrefe, MD, PhD,*† Susanne Röger, MD*†

Heart Rhythm 2015; 12: 2230-2238

In 3 patients with combined transvenous pacemaker and S-ICD, Kuschyk et al. reported excellent functioning of both devices during follow-up, without inappropriate shocks.

Concomitant Use of the Subcutaneous Implantable Cardioverter Defibrillator and a Permanent Pacemaker

JASON HUANG, M.D., KRISTEN K. PATTON, M.D., and JORDAN M. PRUTKIN, M.D.M.H.S.
From the Division of Cardiology, Department of Medicine, University of Washington, Seattle, Washington

Pacing Clin Electrophysiol 2016; 39: 1240-1245

Huang et al. identified 4 S-ICD patients with a coexisting transvenous pacemaker who did not experience any trouble during 1-year follow-up.

PM/CRT devices + S-ICD

Other sporadic problem-free cases

of combined use of transvenous PM and S-ICD

have been reported in the literature

Porterfield C et al. Am J Cardiol 2015; 115:276-278
Steinberg C et al. Heart Rhythm Case Reports 2015; 1: 419-423
Gemein C et al. Europace 2016; 18: 1279

PM/CRT devices + S-ICD

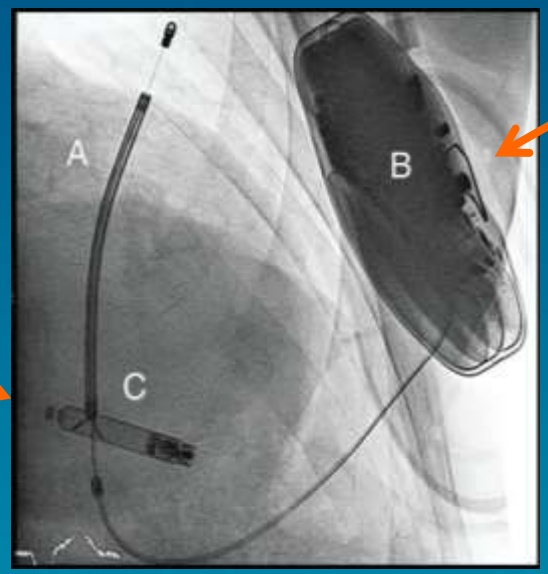
This initial experience provides some evidence that a transvenous pacemaker/CRT device can be used safely with an S-ICD.

Leadless PM + S-ICD

- An intriguing possibility is the concurrent implantation of a leadless pacemaker and an S-ICD, which could allow the use of any intravascular lead to be avoided in pts requiring both cardiac pacing and defibrillation.
- This may particularly benefit pts without venous access or with recurrent lead and pocket complications, such as pocket infection, endocarditis or lead failure.

Leadless PM + S-ICD

In the literature, there are as yet only seven reports of a patient with both an LP and an S-ICD.



Mondesert B et al. Heart Rhythm Case reports 2015; 1: 469-471 Tjong FVY et al. Europace 2016; 18: 1740-1747
Ahmed FZ et al. Can J Cardiol 2017; 33: 1066.e%-1066.e7 Ito R et al. J Arrhythm 2019; 35: 311-313
Ng JB et al. J Arrhythm 2019; 35: 136-138 Baroni M et al. J Electrocardiol 2019; 54: 43-46
Ljungstrom E et al. J Electrocardiol 2019; 56: 1-3

Leadless PM + S-ICD

- At implantation, no interference between LP and S-ICD was observed in any patient during normal rhythm, LP pacing or defibrillation threshold testing via the S-ICD.
- During the follow-up, effective defibrillation was reported in all 3 pts who had spontaneous VT/VF

LPs / Possibility of ATP

While LPs do not have the ability to defibrillate,

they could perform ATP if appropriately programmed

and triggered by the S-ICD.

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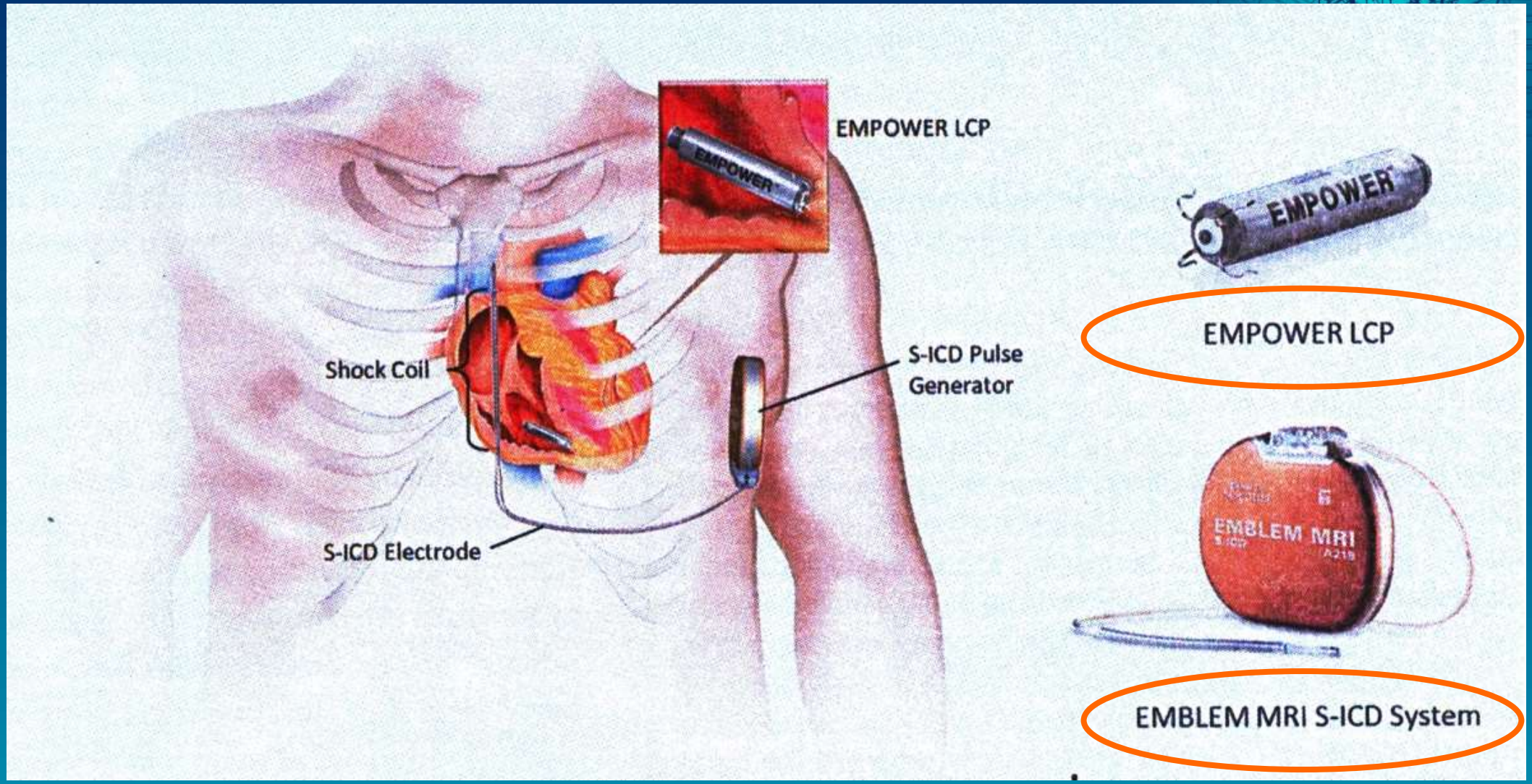
The modular cardiac rhythm management system: the EMPOWER leadless pacemaker and the EMBLEM subcutaneous ICD

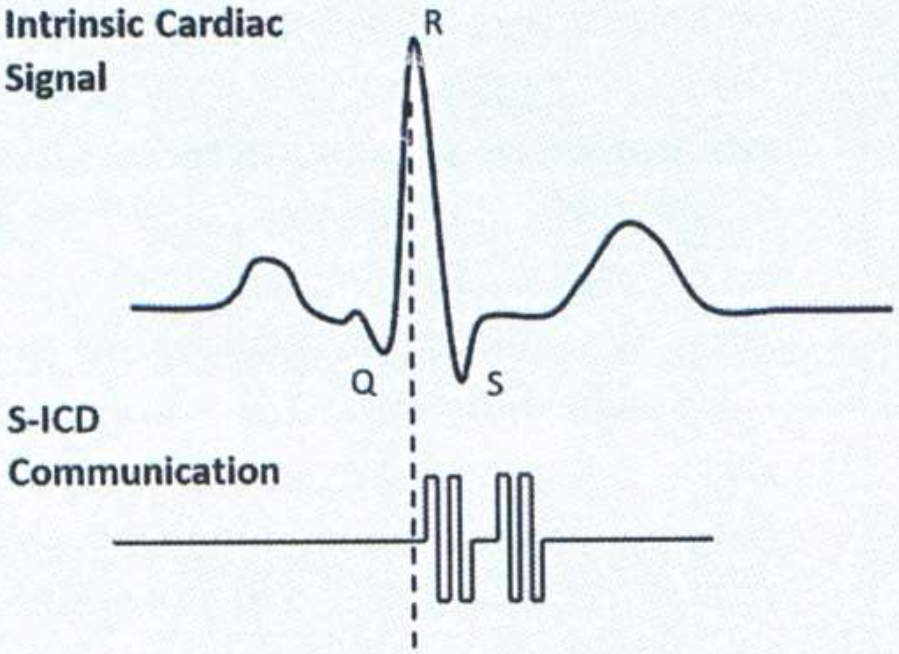
The modular cardiac rhythm management (mCRM) system



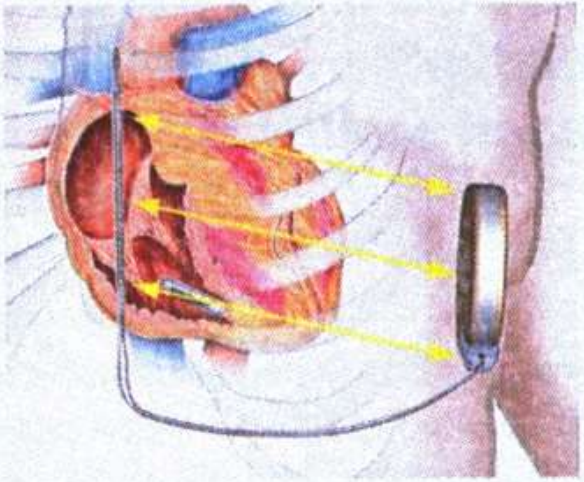
a communicating antitachycardia pacing-enabled EMPOWER™ LCP and EMBLEM™ S-ICD system, that allows synchronized pacing, in particular leadless ATP, and defibrillator therapy.

Tjong FVY, Koop BE Herzschr Elektrophys 2018; 29: 355-361

Device–device communication of the mCRM system

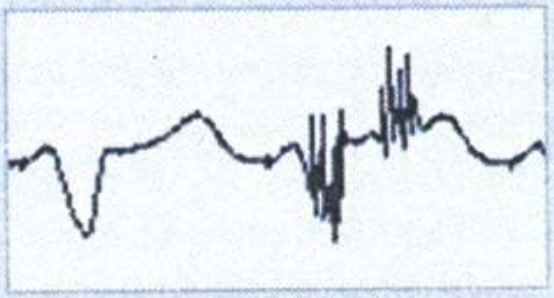


- Communication coupled to sensed R-wave
- Emitted signals are approximately 0.5-4 V amplitude and 25 kHz frequency
- Built-in redundancy of two messages sent



S-ICD Communication Vector
Shock coil to pulse generator can

Example canine body surface recording of intrinsic cardiac signal during ventricular tachycardia with ATP request sent from S-ICD to LCP



The S-ICD pulse generator, when recognizes a tachyarrhythmia episode using its usual detection criteria, sends bursts pulses of 0.5-4 volts amplitude and 25 kiloherz frequency from the shock coil to the generator can in coincidence with the R-wave. The LCP senses these conducted signals via its cathode and anode and performs ATP therapy according to programmed parameters.

Tjong FVY, Koop BE Herzschr Elektrophys 2018; 29: 355-361

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Acute and 3-Month Performance of a Communicating Leadless Antitachycardia Pacemaker and Subcutaneous Implantable Defibrillator

of the Modular CRM system

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OBJECTIVES The primary objective was to assess the acute and 3-month performance of the modular antitachycardia pacing (ATP)-enabled leadless pacemaker (LP) and subcutaneous implantable cardioverter-defibrillator (S-ICD) system, particularly device-device communication and ATP delivery.

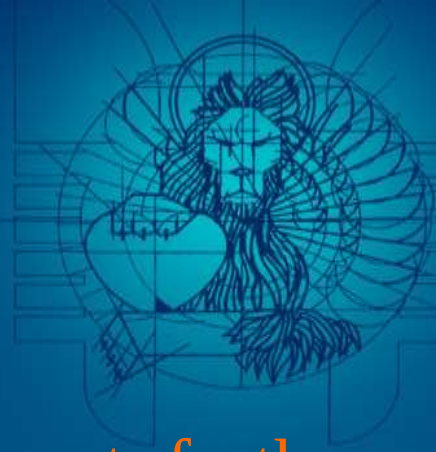
BACKGROUND Transvenous pacemakers and implantable cardioverter-defibrillators (ICDs) have considerable rates of lead complications. We examined the next step in multicomponent leadless cardiac rhythm management: feasibility of pacing (including ATP) by a LP, commanded by an implanted S-ICD through wireless, intrabody, device-device communication.

METHODS The combined modular cardiac rhythm management therapy system of the LP and S-ICD prototypes was evaluated in 3 animal models (ovine, porcine, and canine) both in acute and chronic (90 days) experiments. LP performance, S-ICD to LP communication, S-ICD and LP rhythm discrimination, and ATP delivery triggered by the S-ICD were tested.

RESULTS The LP and S-ICD were successfully implanted in 98% of the animals (39 of 40). Of the 39 animals, 23 were followed up for 90 days post-implant. LP performance was adequate and exhibited appropriate VVI behavior during the 90 days of follow-up in all tested animals. Unidirectional communication between the S-ICD and LP was successful in 99% (398 of 401) of attempts, resulting in 100% ATP delivery by the LP (10 beats at 81% of the coupling interval). Adequate S-ICD sensing was observed during normal sinus rhythm, LP pacing, and ventricular tachycardia/ventricular fibrillation.

CONCLUSIONS This study presents the preclinical acute and chronic performance of the combined function of an ATP-enabled LP and S-ICD. Appropriate VVI functionality, successful wireless device-device communication, and ATP delivery were demonstrated by the LP. Clinical studies on safety and performance are needed. (J Am Coll Cardiol EP 2017;3:1487-98)

Modular CRM system



- These data are encouraging and will prompt further research into the safety and efficacy of this novel approach, especially in human beings.
- Clinical studies of the modular Cardiac Rhythm Management sistem in patients are expected to commence this year

Conclusions (1)

- According to the the literature data currently available, the combined use of transvenous PM/CRT with S-ICDs seems to be feasible and safe.
- This will likely lead to a further expansion of current indications for S-ICD.

Conclusions (2)

- Moreover, some recent reports also pave the way for the concurrent implantation of LPs and S-ICDs.
- Although still in an early experimental stage, this therapeutic option has the potential to provide full bradycardia and tachycardia therapy without permanent transvenous leads, ushering in a new era in device-based cardiac rhythm management.