Université de Montréal

Subcutaneous ICD past, present and future

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INSTITUT DE CARDIOLOGIE DE MONTRÉAL

DISCLOSURES

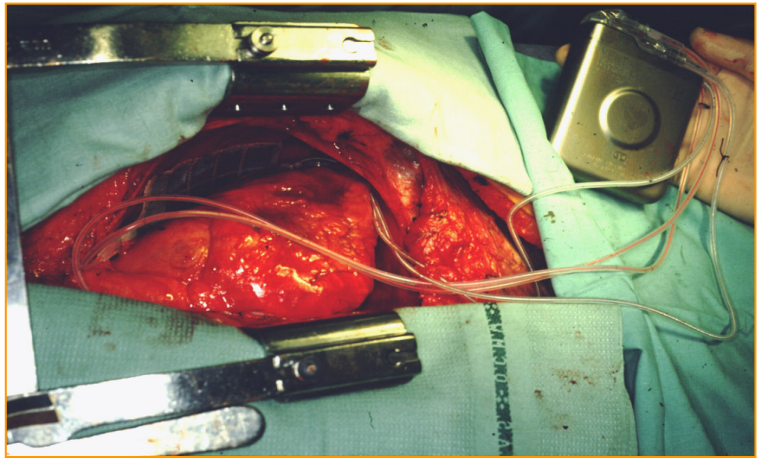
- Grants/Research Support:
  - ✓ Boston Scientific

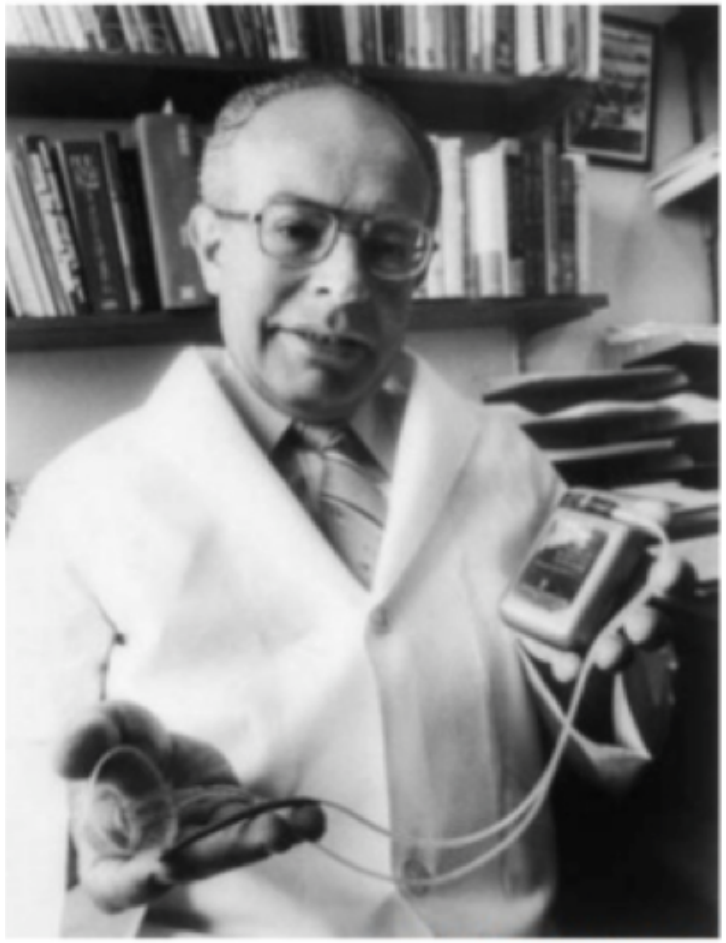
- Speakers Bureau/Honoraria:
  - ✓ Boston Scientific
  - ✓ Medtronic
  - ✓ S^{t} Jude Medical

First ICD, non-endovascular…

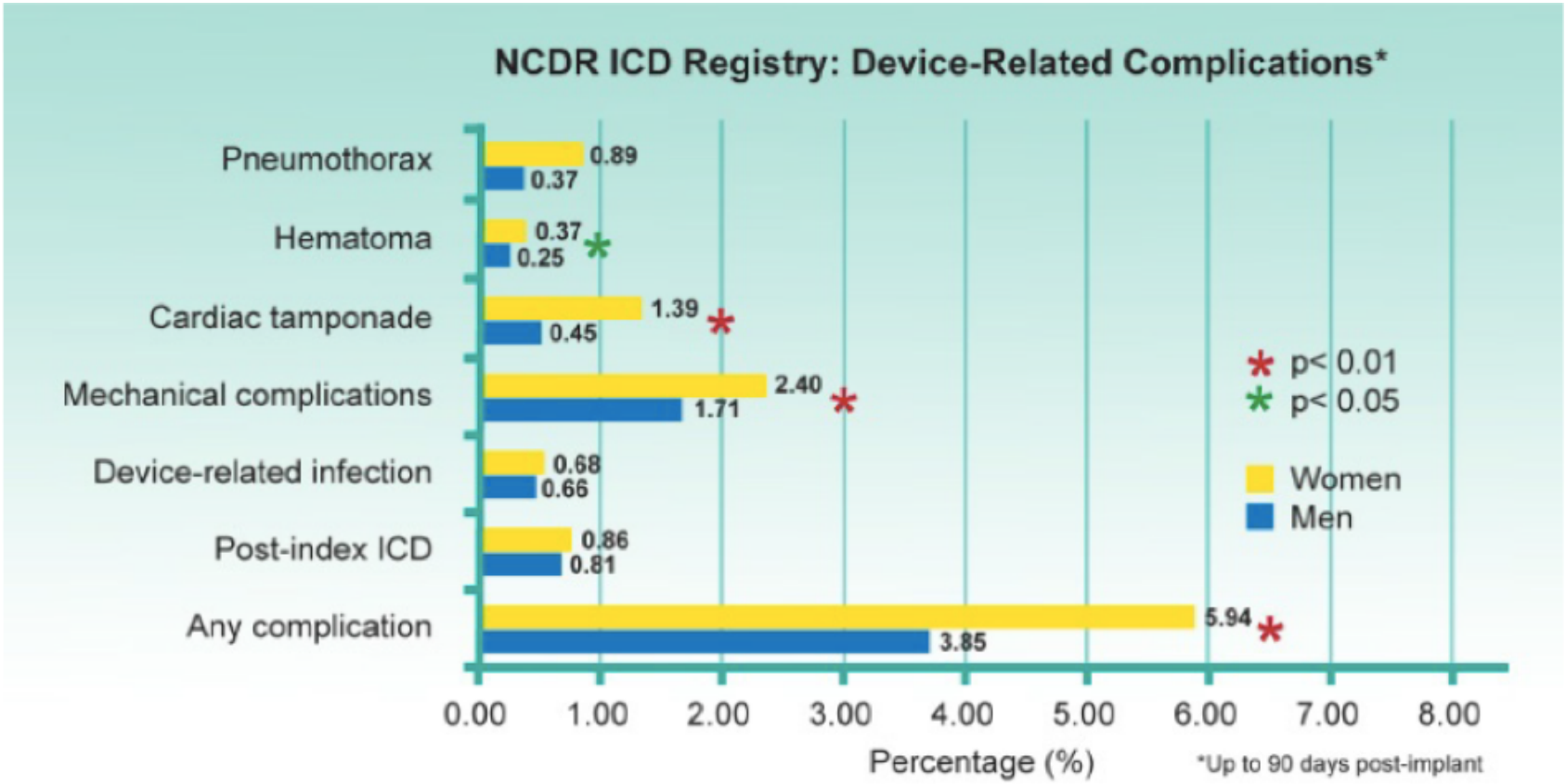
TERMINATION OF MALIGNANT VENTRICULAR ARRHYTHMIAS WITH AN IMPLANTED AUTOMATIC DEFIBRILLATOR IN HUMAN BEINGS

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. August 7, 1980





Acute procedural related complications



2005-2012

Russo et al. Am J of Cardiol 2015

Late complications: Lead Dysfunction

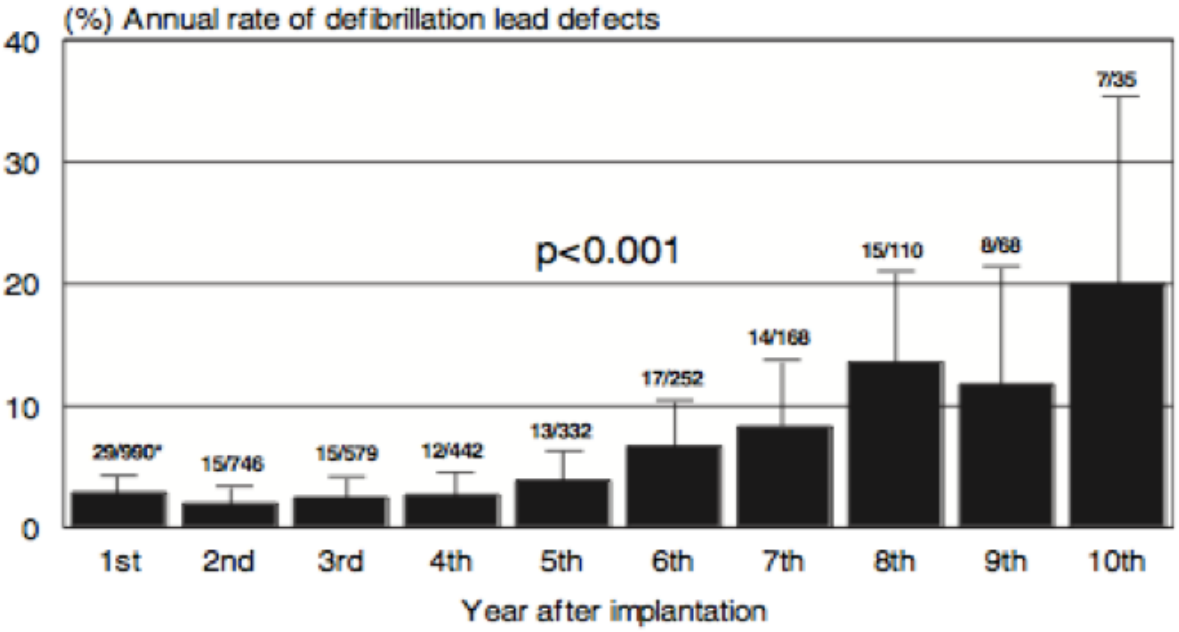
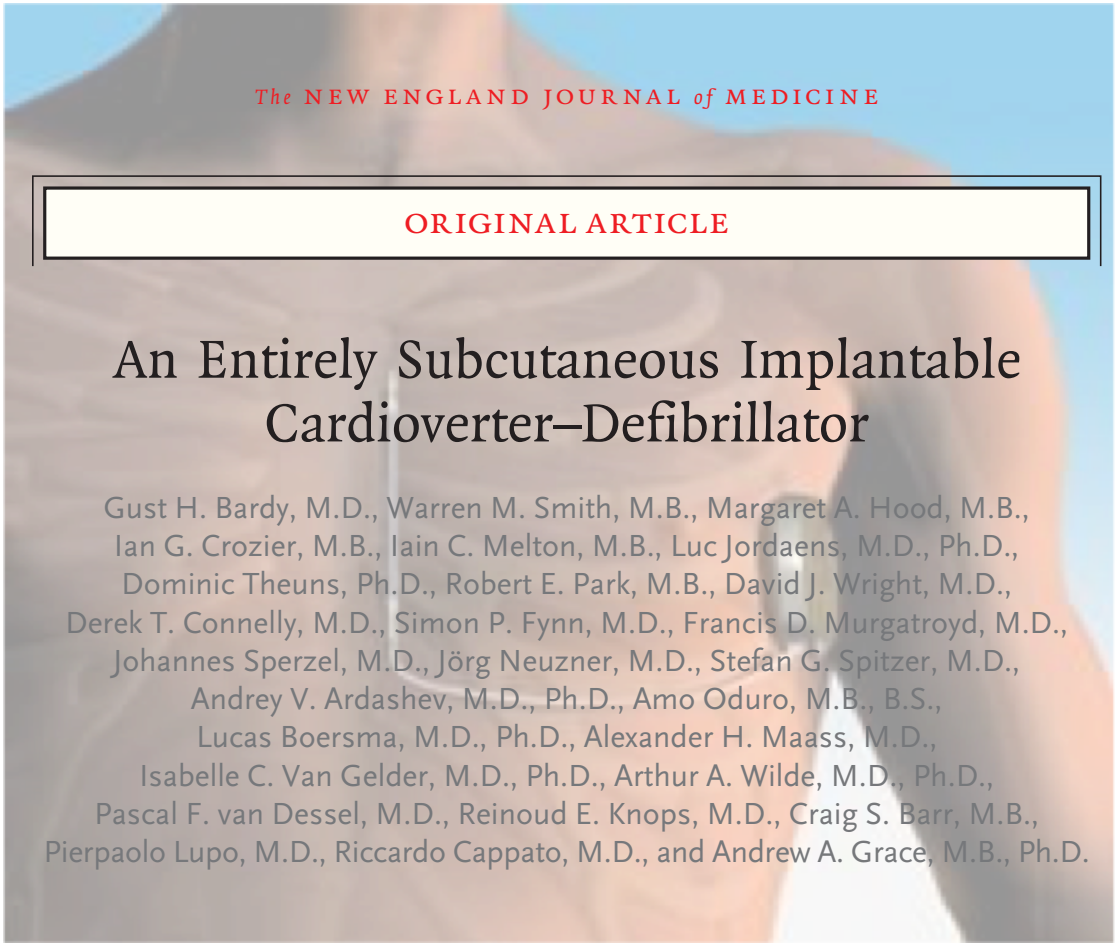


Figure 2. Annual rate of defibrillation lead defects versus time after lead implantation. The annual rate of ICD lead defects increases with time ($P<0.001$, Cochran-Armitage test). *Failures per number at risk.

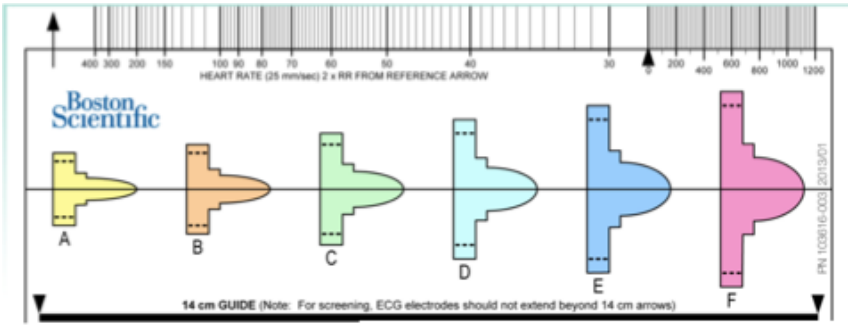
Kleemann T, *Circulation. 2007*

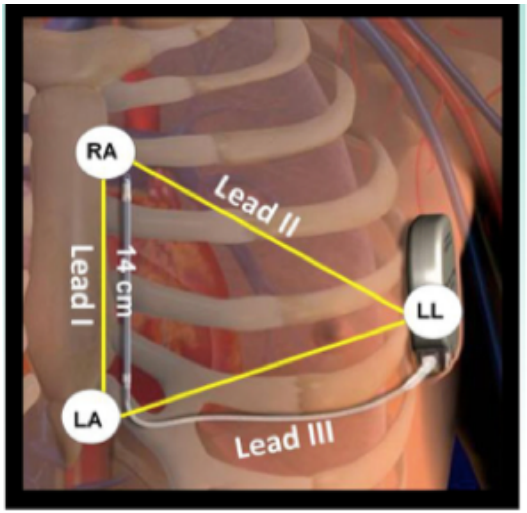
S-ICD

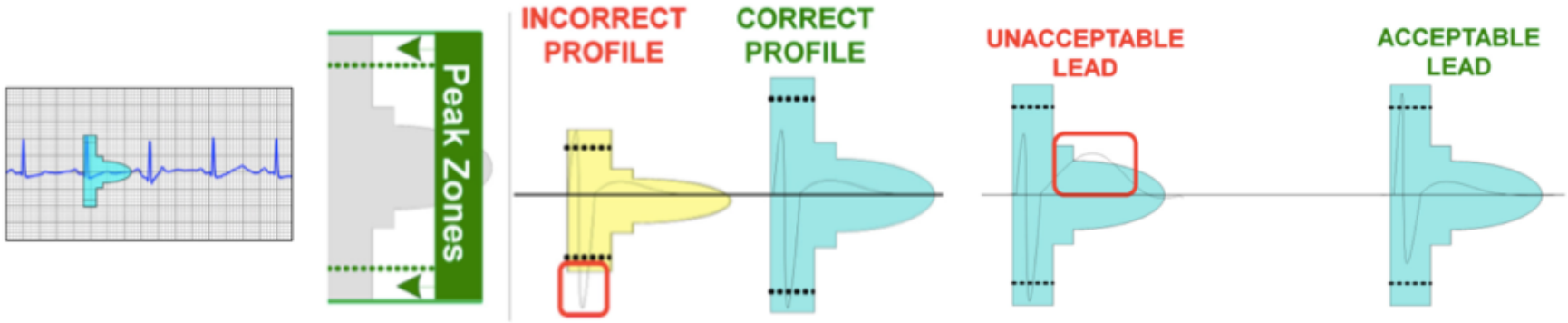

The NEW ENGLAND JOURNAL of MEDICINE
ORIGINAL ARTICLE
An Entirely Subcutaneous Implantable Cardioverter–Defibrillator
Gust H. Bardy, M.D., Warren M. Smith, M.B., Margaret A. Hood, M.B., Ian G. Crozier, M.B., Iain C. Melton, M.B., Luc Jordaens, M.D., Ph.D., Dominic Theuns, Ph.D., Robert E. Park, M.B., David J. Wright, M.D., Derek T. Connelly, M.D., Simon P. Fynn, M.D., Francis D. Murgatroyd, M.D., Johannes Sperzel, M.D., Jörg Neuzner, M.D., Stefan G. Spitzer, M.D., Andrey V. Ardashev, M.D., Ph.D., Amo Oduro, M.B., B.S., Lucas Boersma, M.D., Ph.D., Alexander H. Maass, M.D., Isabelle C. Van Gelder, M.D., Ph.D., Arthur A. Wilde, M.D., Ph.D., Pascal F. van Dessel, M.D., Reinoud E. Knops, M.D., Craig S. Barr, M.B., Pierpaolo Lupo, M.D., Riccardo Cappato, M.D., and Andrew A. Grace, M.B., Ph.D.

Screening

Pre-op screening:
lying down, and seated, 5-10-20 mm/mV
different positions of the device (high, low)
Rest and effort







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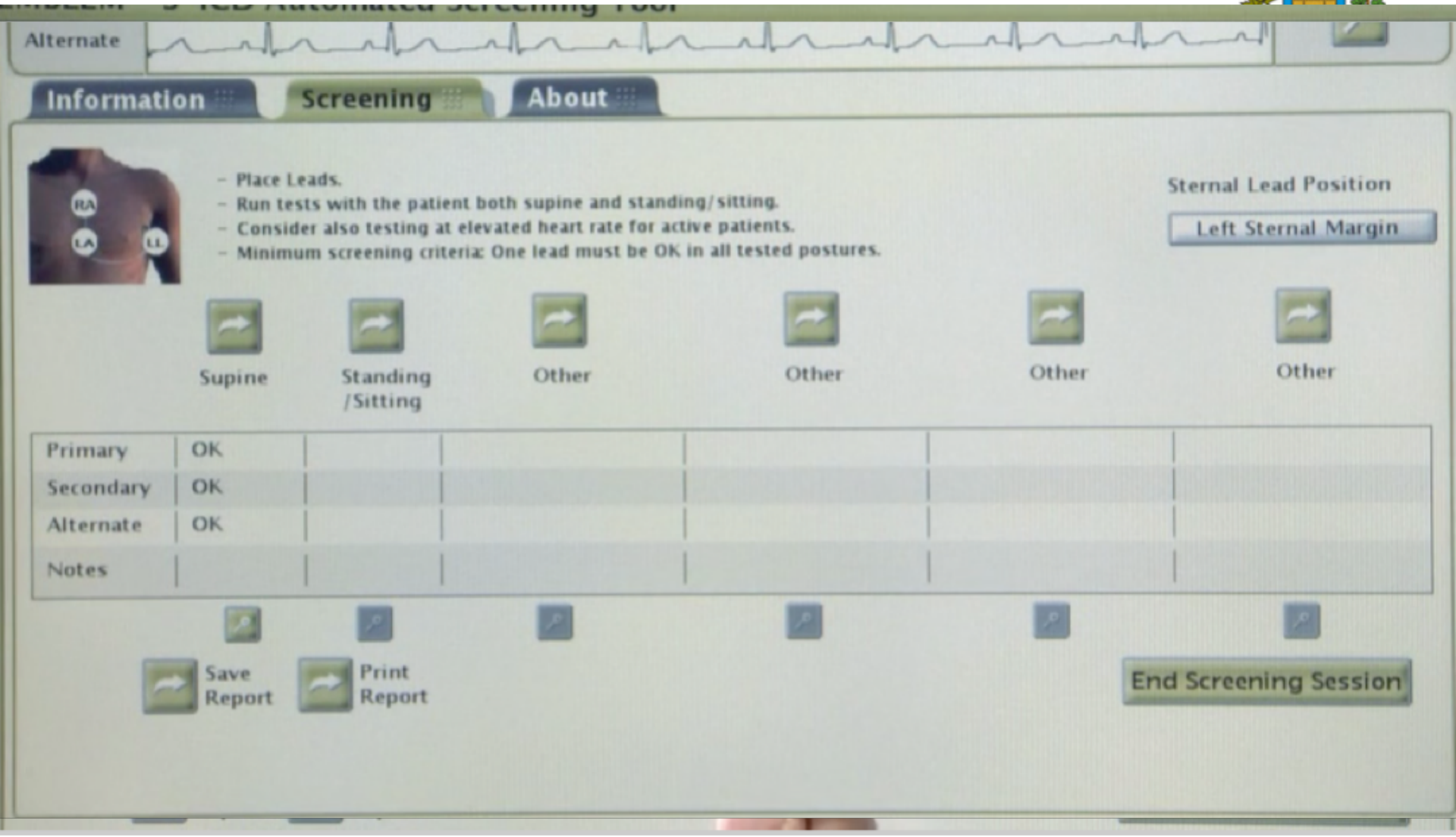

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Safety and Efficacy

	Spontaneous Shock Efficacy	
	First Shock	Final Shock in episode
S-ICD Pooled Data*	90.1%	98.2%
ALTITUDE First Shock Study[1]	90.3%	99.8%
SCD-HeFT[2]	83%	
PainFree Rx II[2]	87%	
MADIT-CRT[3]	89.8%	
LESS Study[4]		97.3%

* Excluded VT/VF Storm events

* Burke MC et al. JACC 2015
1 Cha YM et al. *Heart Rhythm* 2013;10:702–708
2 Swerdlow CD et al. *PACE* 2007; 30:675–700
3 Kutyifa V, et al. *J Cardiovasc Electrophysiol* 2013;24:1246-52
4 Gold MR et al. *Circulation* 2002;105:2043-2048

Safety and Efficacy

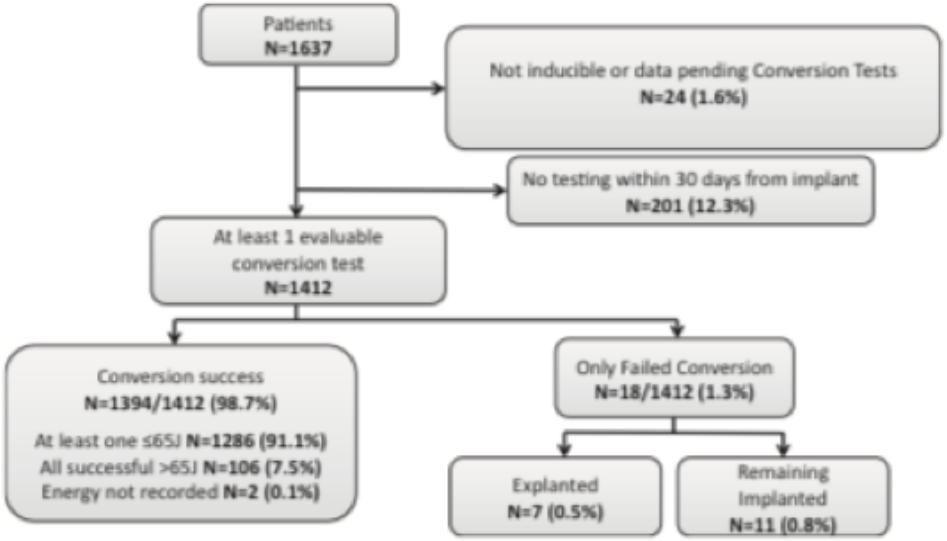


Figure 1 PAS conversion testing. Patient flowchart for the PAS, showing the number of patients who had nonevaluable conversion tests, no testing 30 days from implantation, and at least 1 evaluable conversion test. Of those patients with evaluable conversion tests, all shock success rate and shock failure are shown along with the number of patients explanted and those patients who remained implanted. PAS = Post-Approval Study.

Safety and Efficacy

TABLE 3 Acute Conversion Testing

Final Conversion Result (n = 861)	Without Repositioning	% of Total	With Repositioning	% of Total	Overall	% of Total
Success ≤65 J	777	90.2	12	1.4	789	91.6
Success >65 J	36	4.2	2	0.2	38	4.4
Success at unknown energy	29	3.4	1	0.1	30	3.5
Summary of successful conversion	842	97.8	15	1.7	857	99.5
Failed conversion testing	2	0.2	2	0.2	4	0.5

Boersma L JACC 2017

Complications in studies

Acute Major Complications (% of patients)	S-ICD Pooled Data	TV-ICD NCDR Analysis (Peterson et al, JAMA 2013[1] Meta-analysis (van Rees et. al. JACC 2011)[2]
	2 %	3 - 5 %

(Hematoma, Lead or Device Mal-position or Displacement, Pneumothorax)

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)
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)

Values are n (%).
PG = pulse generator; SVA = supraventricular arrhythmia.

Burke et al. JACC 2015

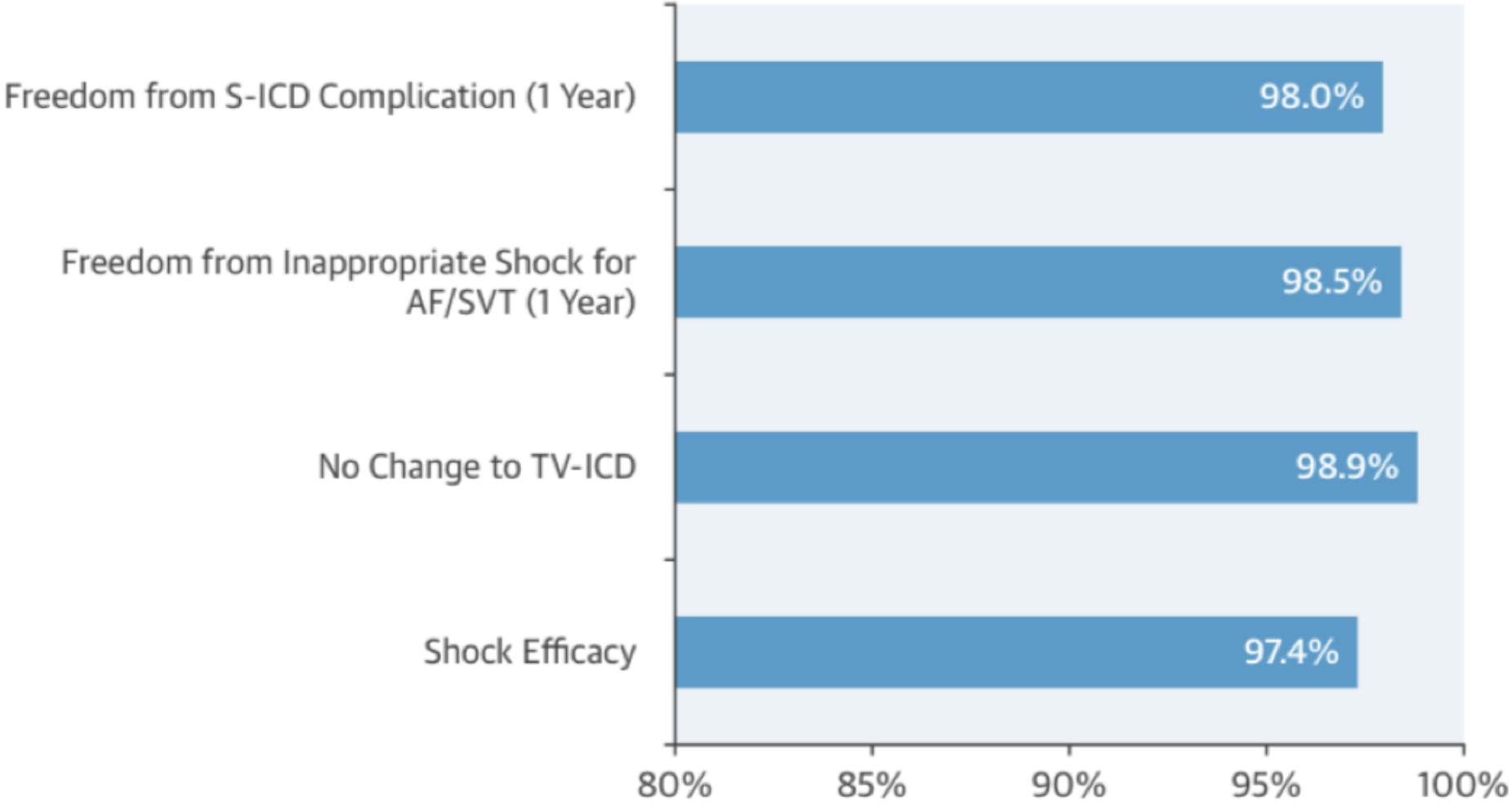
Complications

Table 2 Device- and procedure-related complications within 30 d of implantation

Description	All patients		Female patients		Male patients	
	No. of events	n (%)	No. of events	n (%)	No. of events	n (%)
Device-related complications						
Unable to convert during the procedure	7	7 (0.4)	1	1 (0.2)	6	6 (0.5)
Inappropriate shock: oversensing	3	3 (0.2)	2	2 (0.4)	1	1 (0.1)
PG movement/revision	2	2 (0.1)	2	2 (0.4)	–	–
PG-related discomfort	2	2 (0.1)	2	2 (0.4)	–	–
Pulseless electrical activity	1	1 (0.1)	1	1 (0.2)	–	
Suspected device malfunction	1	1 (0.1)	–	–	1	1 (0.1)
Total	16	16 (1.0)	8	8 (1.6)	8	8 (0.7)
Procedure-related complications						
S-ICD system infection	19	19 (1.2)	9	9 (1.8)	10	10 (0.9)
Hematoma	7	7 (0.4)	4	4 (0.8)	3	3 (0.3)
Suboptimal electrode position	7	7 (0.4)	4	4 (0.8)	3	3 (0.3)
Inadequate healing of the incision site	2	2 (0.1)	2	2 (0.4)	–	–
Incisional/superficial infection	2	2 (0.1)	2	2 (0.4)	–	–
Adverse reaction—hypotension	1	1 (0.1)	1	1 (0.2)	–	–
Adverse reaction—respiratory	1	1 (0.1)	–	–	1	1 (0.1)
Adverse reaction to medications	1	1 (0.1)	–	–	1	1 (0.1)
Cardiac arrest	1	1 (0.1)	–	–	1	1 (0.1)
Heart failure/worsening of heart failure	1	1 (0.1)	–	–	1	1 (0.1)
Pleural effusion	1	1 (0.1)	–	–	1	1 (0.1)
Pneumothorax	1	1 (0.1)	1	1 (0.2)	–	–
Respiratory failure	1	1 (0.1)	–	–	1	1 (0.1)
Trauma—procedure related	1	1 (0.1)	–	–	1	1 (0.1)
Total	46	45 (2.7)	23	22 (4.6)	23	23 (2.2)
Grand total	62	61 (3.7)	31	30 (5.8)	31	31 (2.8)

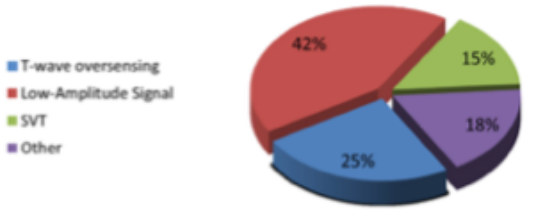
PG = pulse generator; S-ICD = subcutaneous implantable-cardioverter.

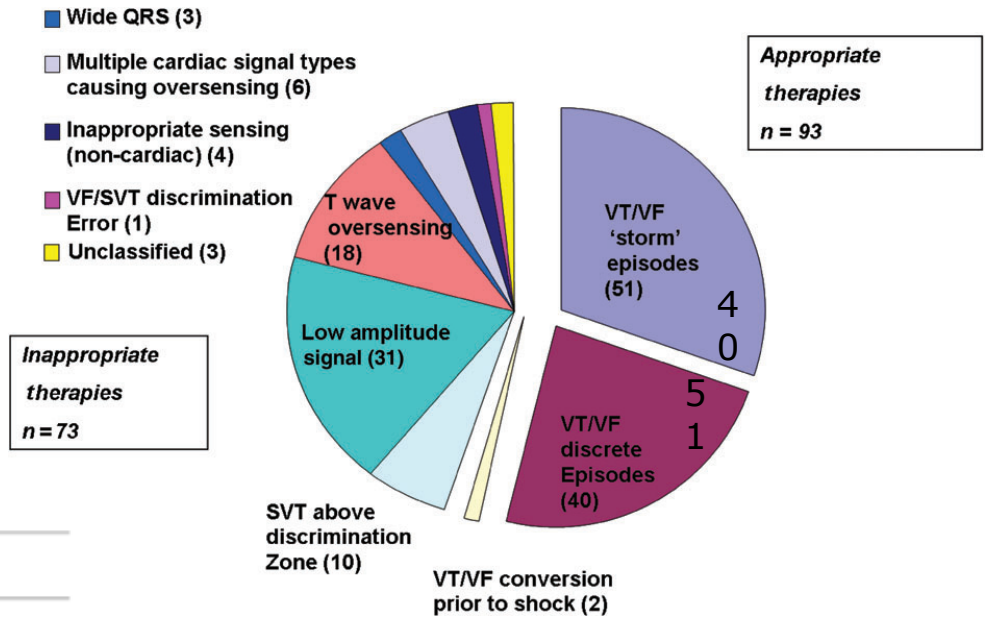
CENTRAL ILLUSTRATION **Outcomes After S-ICD Implantation: 1-Year EFFORTLESS Registry**

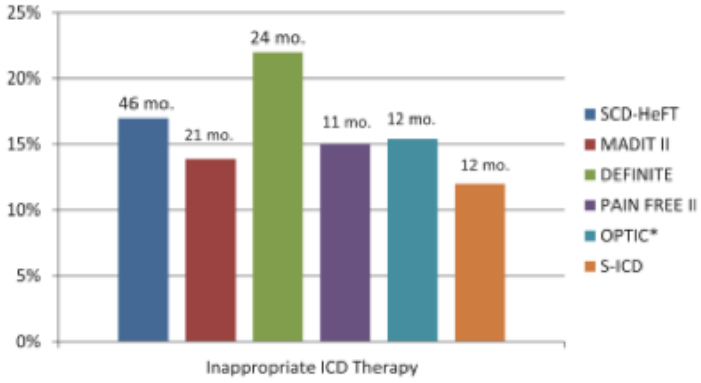


Boersma, L. et al. J Am Coll Cardiol. 2017;70(7):830-41.

Appropriate and inappropriate therapies



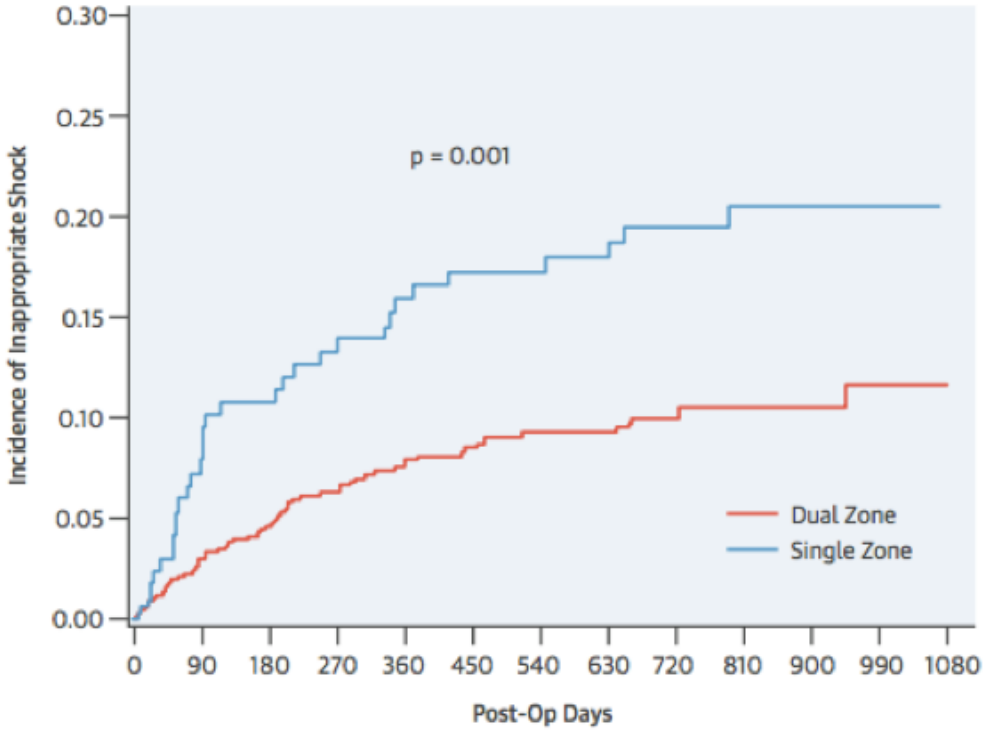




Lambiase EHJ 2014

Poole JE, Circ EP 2013

Complications: Inappropriate Therapies



Dual Zone	No. at Risk	688	634	576	546	494	441	378	279	180	120	89	66	56
	K-M Estimate (%)	0.0	3.0	4.6	6.2	7.7	8.5	9.3	9.3	10.0	10.5	10.5	11.7	11.7
Single Zone	No. at Risk	170	153	141	134	126	122	117	108	96	75	53	43	36
	K-M Estimate (%)	0.0	7.8	10.8	13.3	15.9	17.3	17.3	18.0	19.5	20.5	20.5	20.5	20.5

Burke et al. JACC 2015

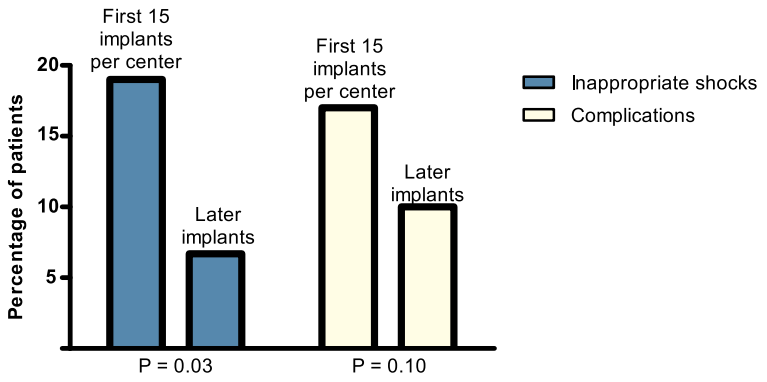


Figure 1 **Comparison of Inappropriate Shock and Complication Rate Between First and Later S-ICD Implants**

Inappropriate shocks and complications occurred more frequently in the first 15 patients per center who were implanted with the subcutaneous implantable cardioverter-defibrillator (S-ICD) than in subsequent patients (inappropriate shocks 19% vs. 6.7%; complications 17% vs. 10%).

Nordkamp, JACC 2012

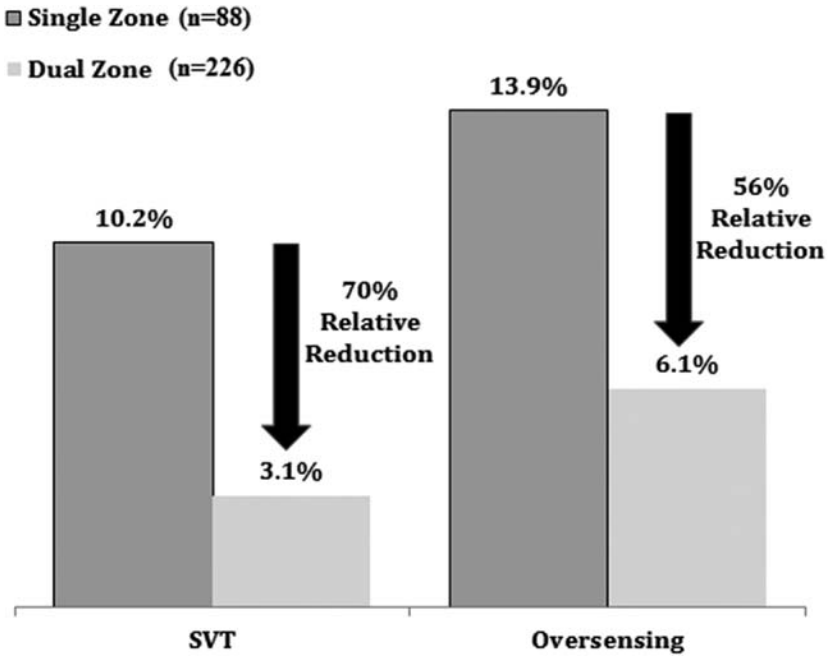


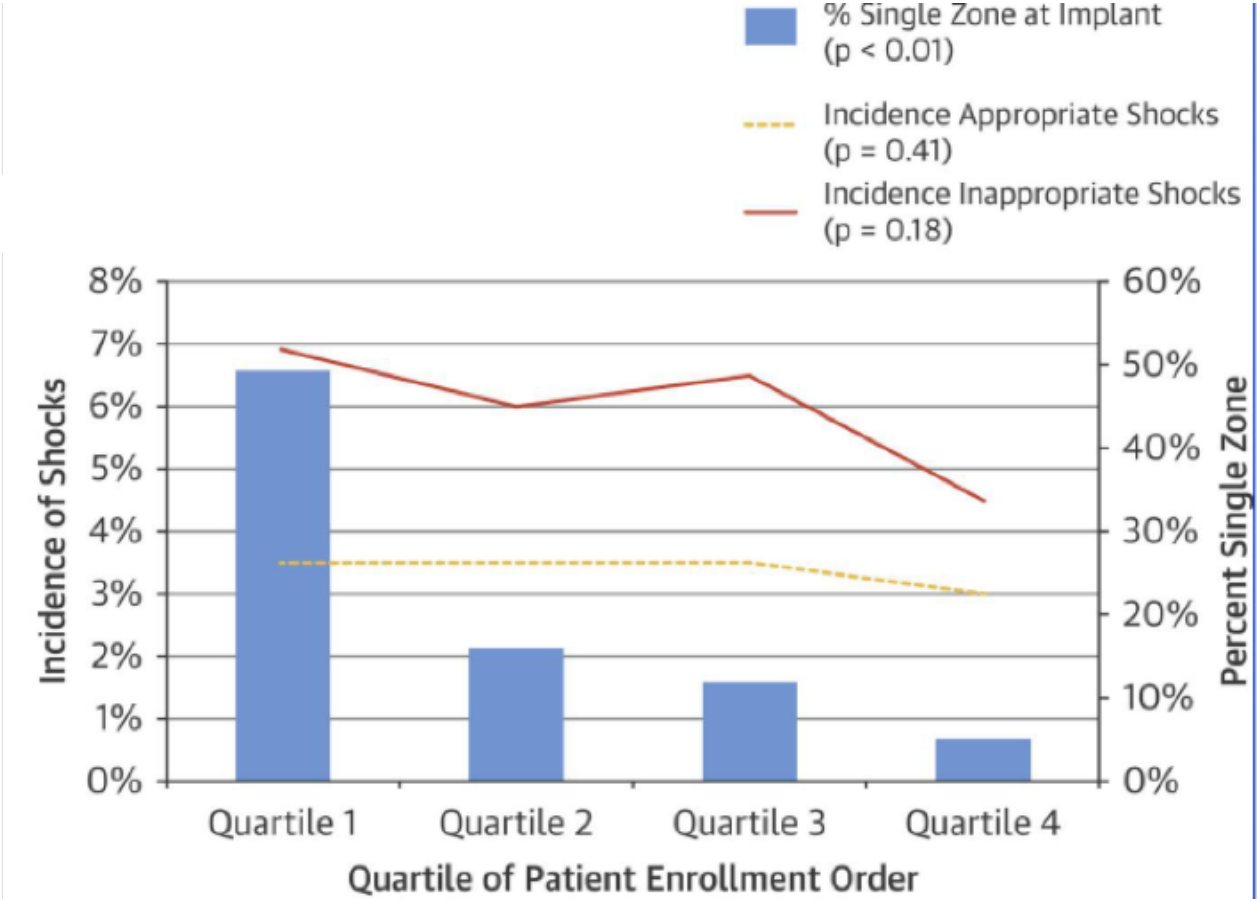
Figure 3. Relative reduction of inappropriate shocks (for supraventricular tachyarrhythmias [SVT] or oversensing) associated with programming an arrhythmia discrimination zone at discharge.

Weiss, Circulation 2013

Programmation

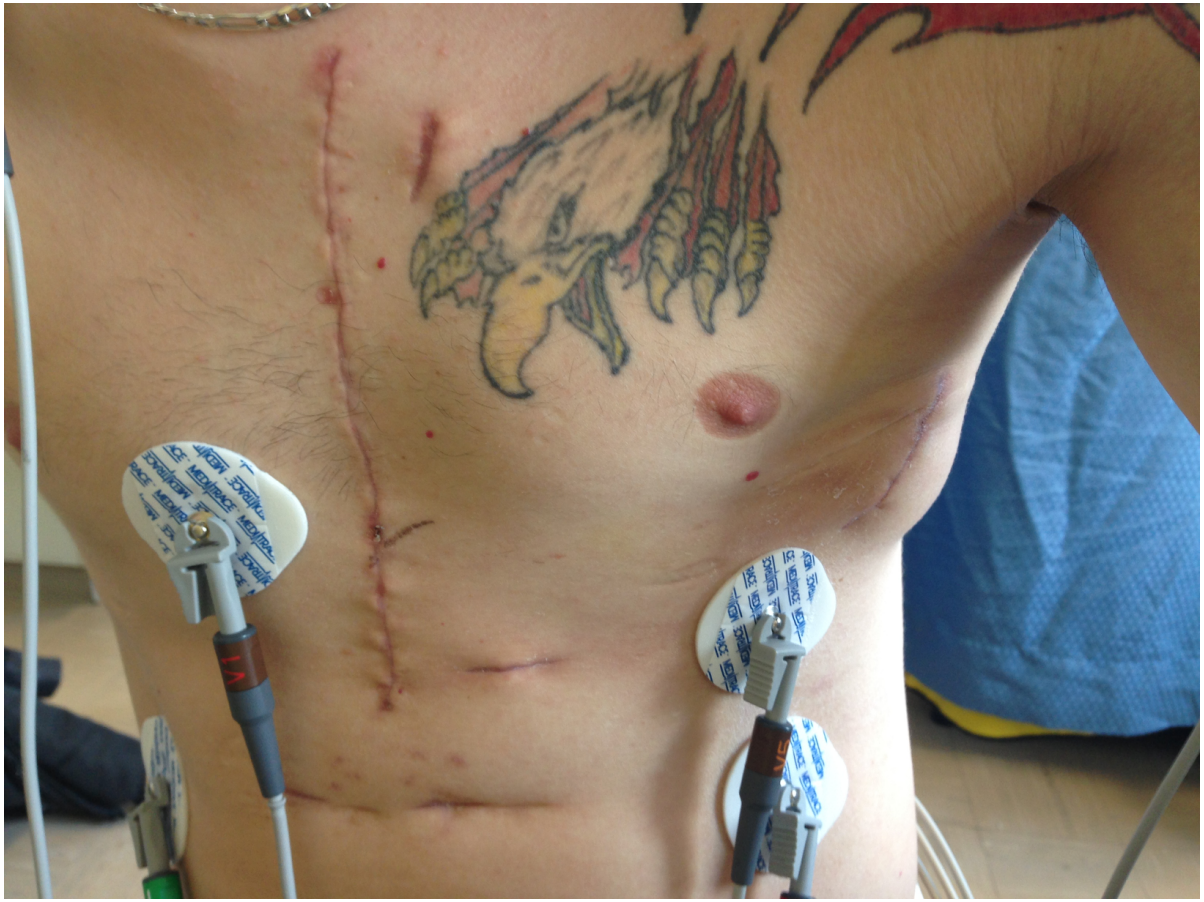
Statistic / Category	Pooled IDE and EFFORTLESS Patients
Lowest Rate Zone	Mean ± SD: 197.5 ± 19.2 bpm Median: 200.0 bpm
Zones (n, %)	
Dual Zone	689 (80%)
Single Zone	170 (20%)
Vector (n, %)	
Primary	452 (53%)
Secondary	313 (37%)
Alternate	94 (11%)

Inappropriate Therapies

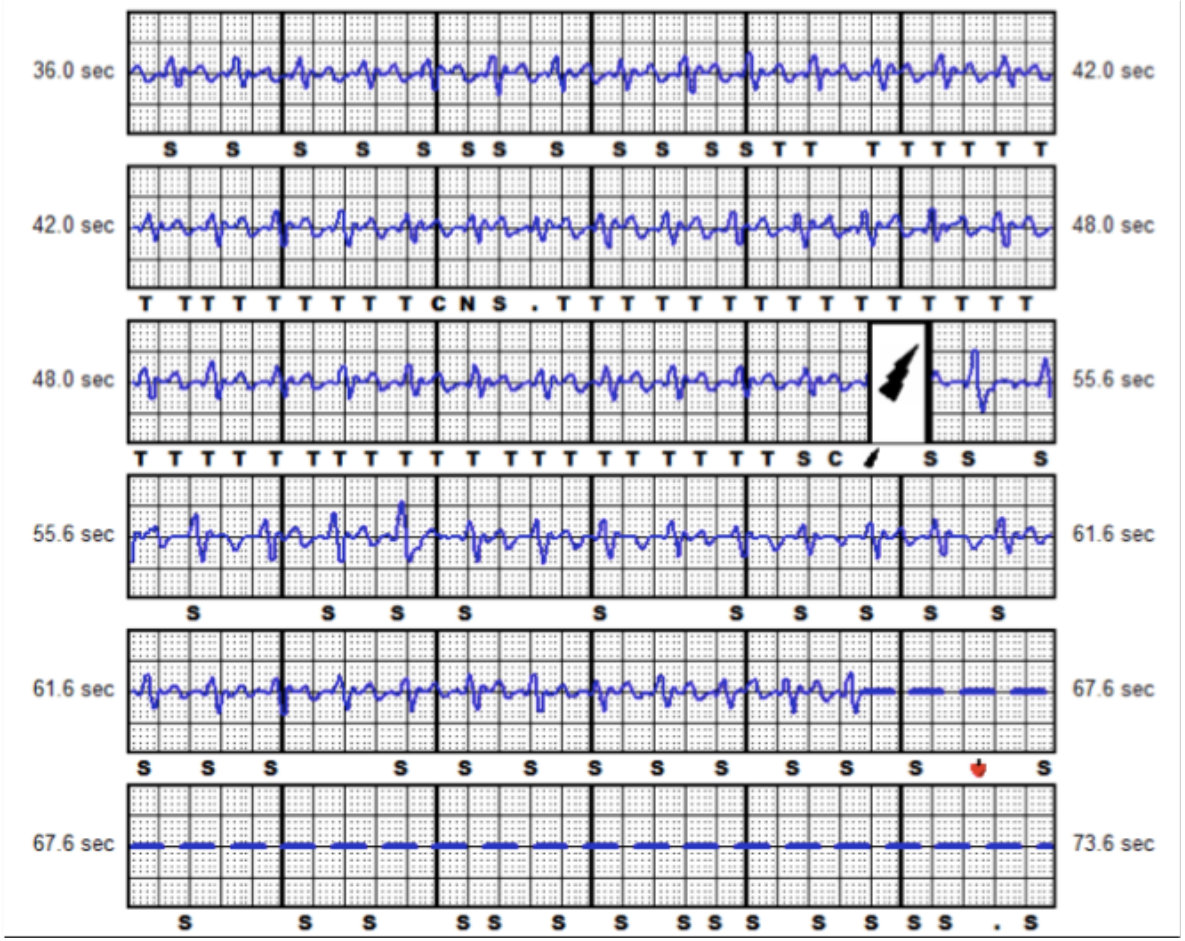


Burke et al. JACC 2015

Inappropriate Therapies



April 2015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42.0 sec
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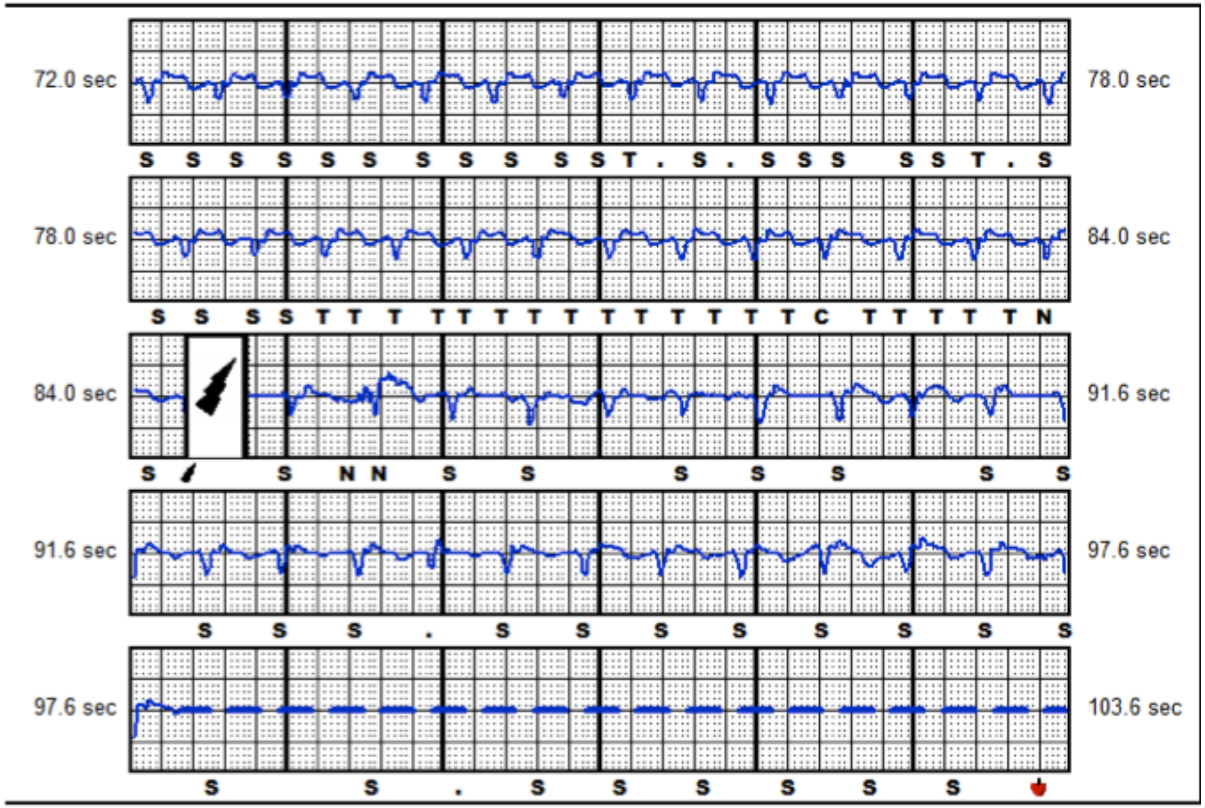
48.0 sec
55.6 sec
55.6 sec
61.6 sec
61.6 sec
67.6 sec
67.6 sec
73.6 sec

March 2016


72.0 sec
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S S S S S S S S S S S T . S . S S S S S T . S
78.0 sec
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S S S S T T T T T T T T T T T T T C T T T T T N
84.0 sec
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S S S N N S S S S S S S S
91.6 sec
97.6 sec
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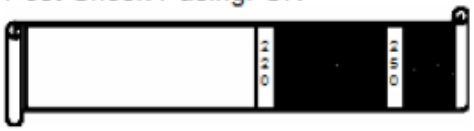
97.6 sec
103.6 sec
S S . S S S S S S

Device Settings

WARNING Therapy: OFF

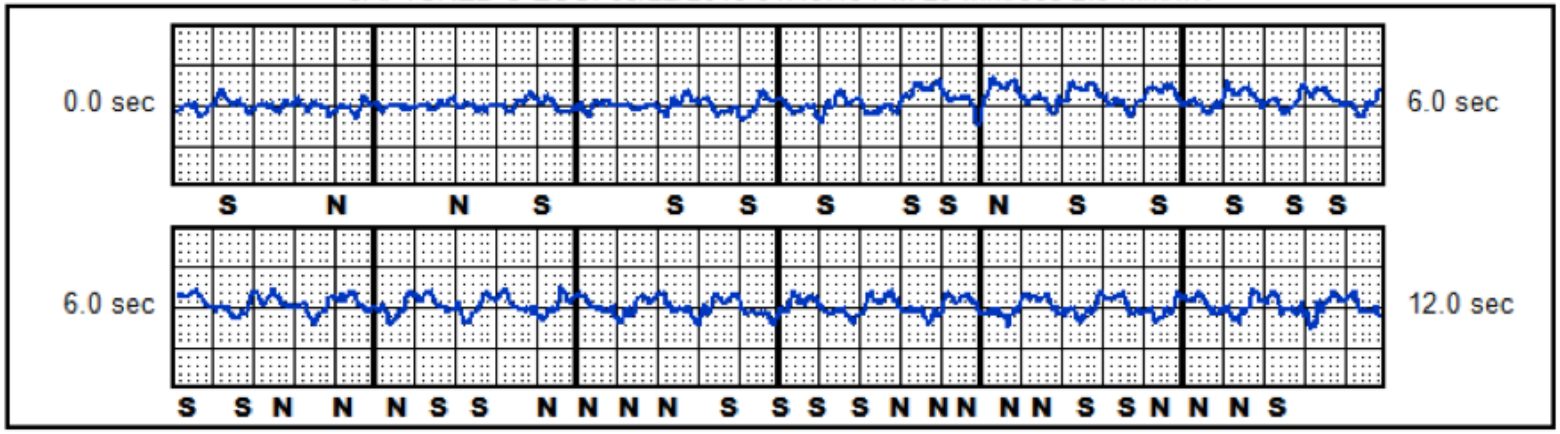
Shock Zone: 250 bpm
Conditional Shock Zone: 220 bpm
Post Shock Pacing: ON



Gain Setting: 1X
Sensing Configuration: Alternate

S = Sense
P = Pace
N = Noise
T = Tachy Detection
C = Charge Start
. = Discard
= Shock
= Episode End

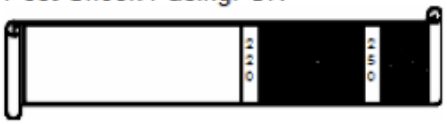
CAPTURED S-ECG: 03/22/2016 04:13:48 PM 25 mm/sec 2.5 mm/mV



Device Settings

WARNING Therapy: OFF

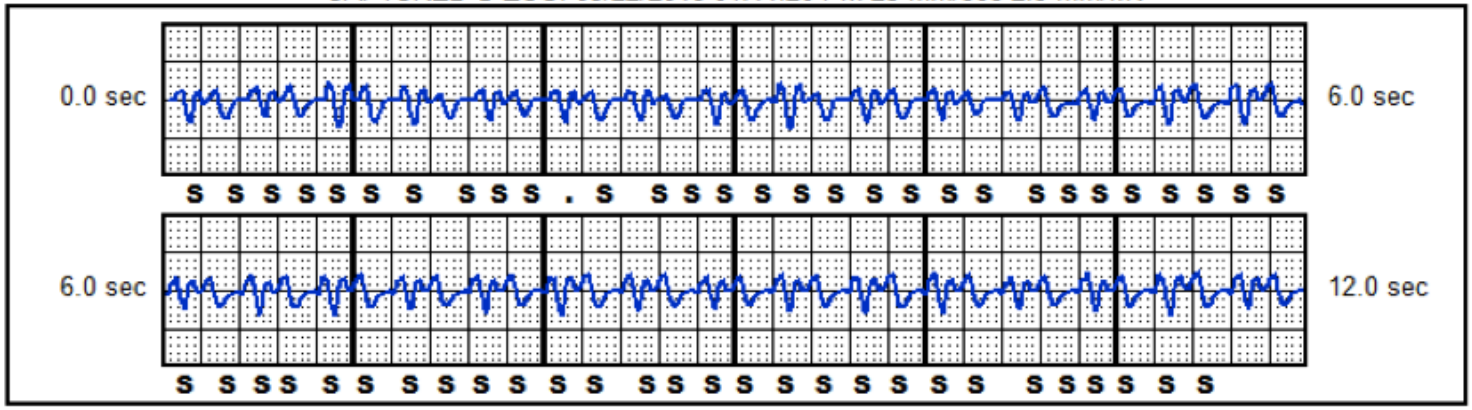
Shock Zone: 250 bpm
Conditional Shock Zone: 220 bpm
Post Shock Pacing: ON



Gain Setting: 1X
Sensing Configuration: Primary

S = Sense
P = Pace
N = Noise
T = Tachy Detection
C = Charge Start
. = Discard
= Shock
= Episode End

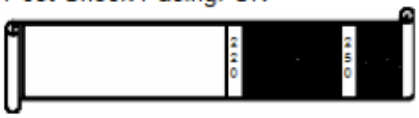
CAPTURED S-ECG: 03/22/2016 04:14:20 PM 25 mm/sec 2.5 mm/mV



Device Settings

WARNING Therapy: OFF

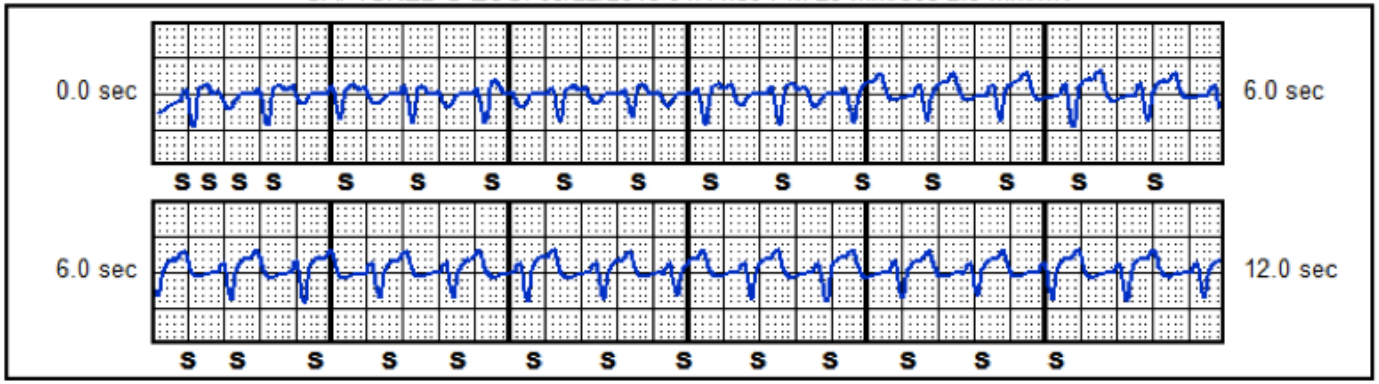
Shock Zone: 250 bpm
Conditional Shock Zone: 220 bpm
Post Shock Pacing: ON



Gain Setting: 1X
Sensing Configuration: Secondary

S = Sense
P = Pace
N = Noise
T = Tachy Detection
C = Charge Start
. = Discard
= Shock
= Episode End

CAPTURED S-ECG: 03/22/2016 04:14:39 PM 25 mm/sec 2.5 mm/mV

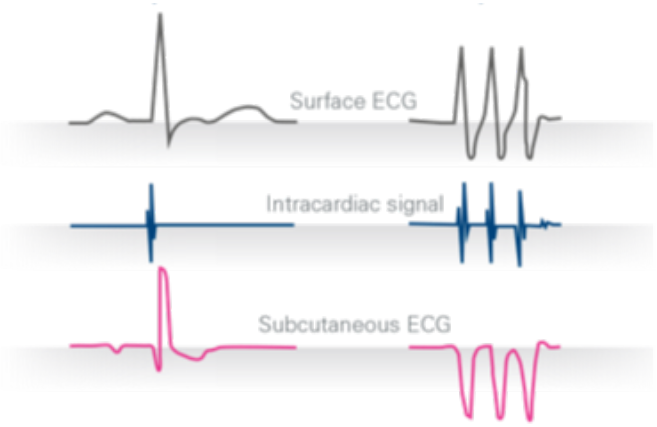


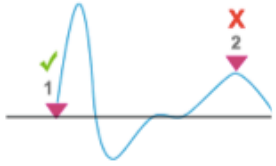
INSIGHT™ Algorithm: Architecture

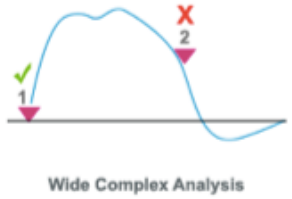
PHASE I: Detection → Subcutaneous signal detection

PHASE II: Certification → Heart rate determined

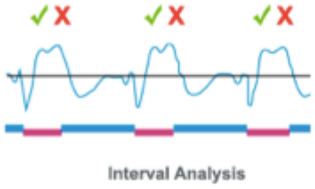
PHASE III: Therapy Decision → HR assessed, therapy confirmed

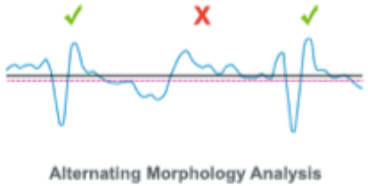


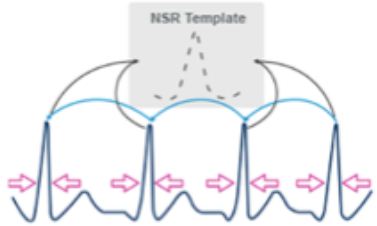




- **Static Morphology Analysis**
  Identifies non shockable rhythms, utilizing the Normal Sinus Rhythm (NSR) template
- **Dynamic Morphology Analysis**
  Identifies shockable polymorphic rhythms by comparing each complex to the previous ones
- **QRS Width Analysis**
  Compares the QRS width to the NSR QRS width







S-ECG signal similar to a surface ECG

4 double-detection algorithms designed to reduce over-sensing

3 rhythm discriminators to confirm therapy

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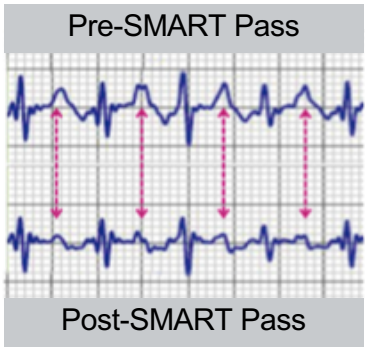
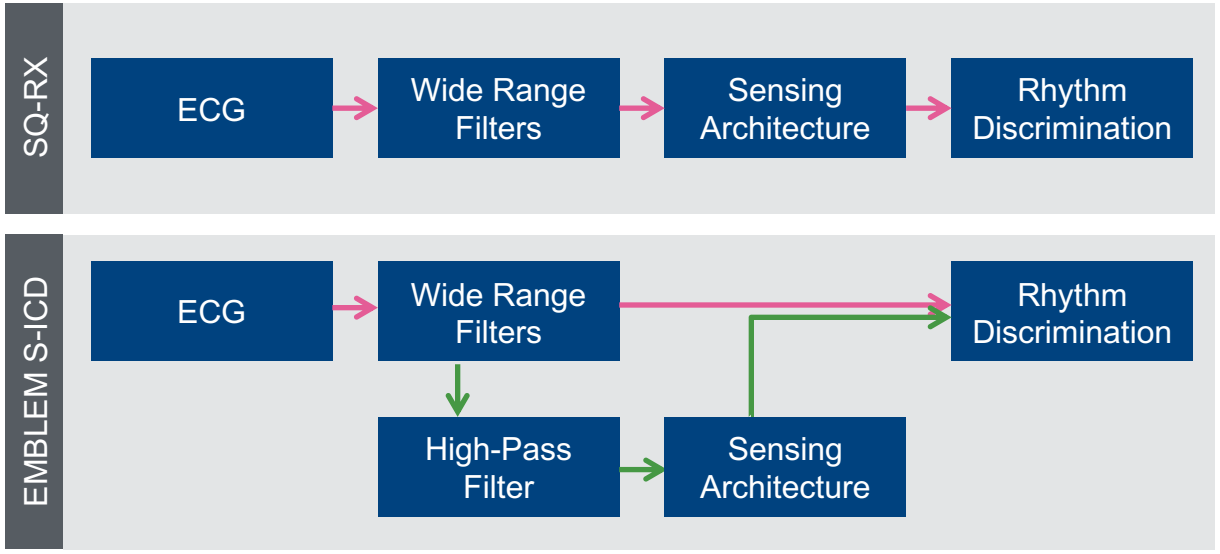
INSIGHT™ with SMART Pass Technology

The SMART Pass feature activates an additional high-pass filter designed to reduce cardiac over-sensing while still maintaining an appropriate sensing margin
SMART Pass is only applied in the sensing path, while the morphology is unchanged



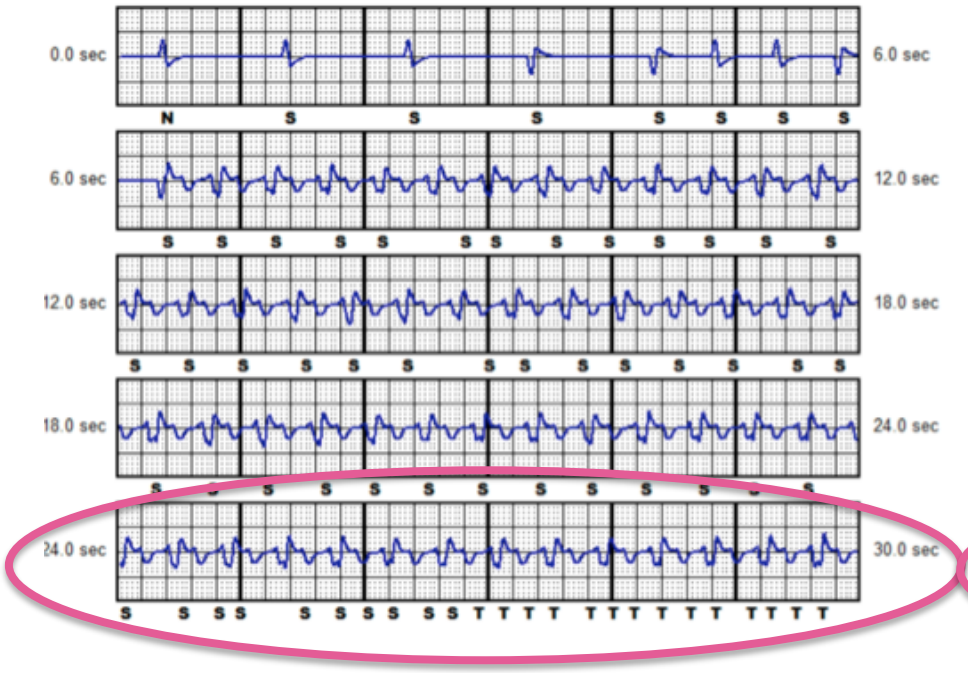


The SMART Pass filtering reduces the amplitude of lower frequency (slower moving) signals such as T-waves, by applying an additional High Pass filter (lets higher frequencies "pass" through).

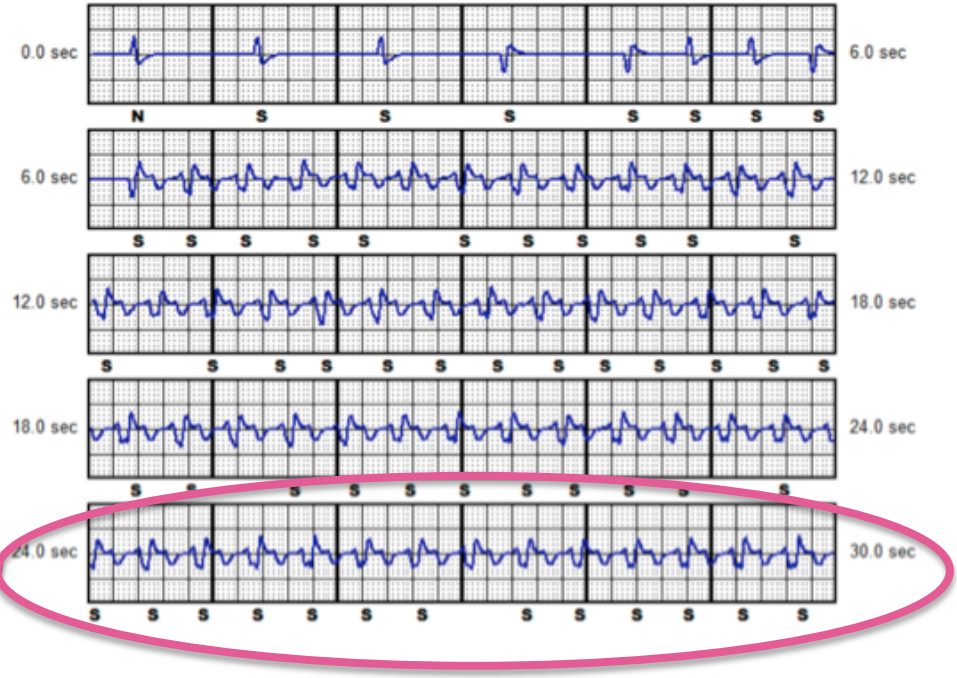
Higher Frequency (faster moving) signals such as R-waves, VT and VF amplitudes remain largely unchanged.

SMART Pass example

SMART Pass OFF



SMART Pass ON



Difference in sensing when comparing SMART Pass OFF versus ON*

*Bench test Data

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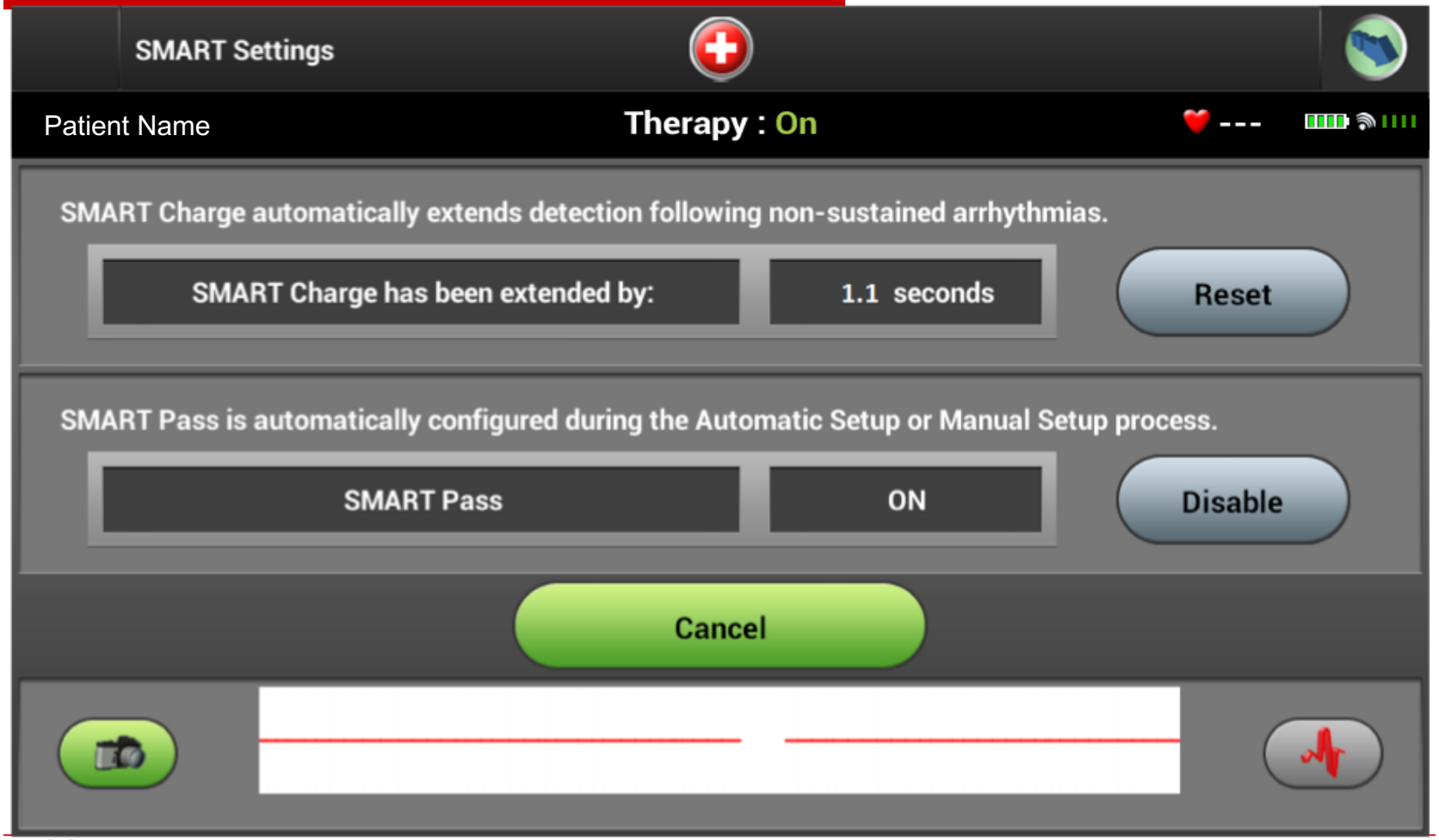
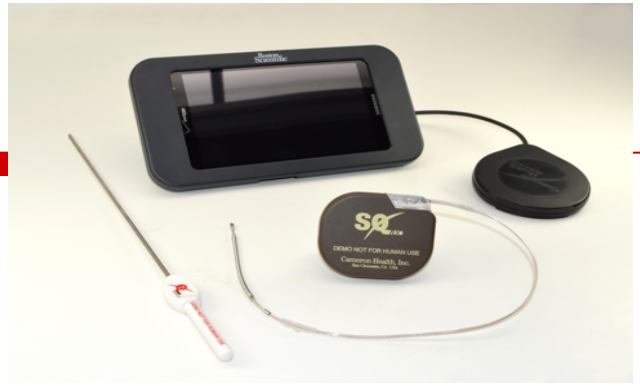
SMART Settings Screen



S-ICD




DEMO NOT FOR HUMAN USE
Cameron Health, Inc.
San Clemente, CA USA
Boston Scientific
EMBLEM
S-ICD MODEL A209
Not for human use
RV
DF4-LLHH
Tiny Can,
Huge Breakthrough

EMBLEM™ S-ICD System

The EMBLEM™ S-ICD System:
20% thinner with a 40% increase in projected longevity

Improves the implant experience and patient comfort

20% reduction in device profile, resulting in a device thinner than the MDT Evera™ XT ICD[1]

Decreases the need for change-out procedures

2 year improvement in projected longevity with Boston Scientific battery technology[2]

Designed to provide remote patient management

Remote Patient Management Enabled[3]

1. Medtronic Evera XT manual. www.medtronic.com/manuals
2. EMBLEM S-ICD Labeling.
3. Latitude NXT 4.0 is an investigational device and restricted under U.S. Federal law to investigational use only. Not available for sale in the U.S.

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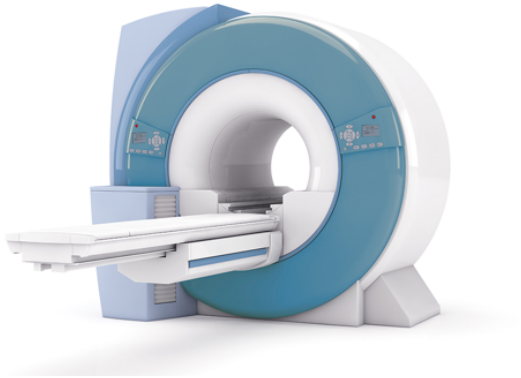
EMBLEM MRI S-ICD System: 3rd Generation Technology



ImageReady™ technology

Full Body, 1.5T
MR-conditional System*[21,22]

Backwards Compatible with EMBLEM S-ICD System

* When conditions of use are met

Advanced INSIGHT™ with SMART Pass technology

Effective AF/SVT discrimination[23] and further **reduction in Inappropriate Shocks** due to cardiac over-sensing[21]

Backwards Compatible with EMBLEM S-ICD System

AF Monitor™

Designed to assist in the **detection of** silent, new onset or the progression of **AF**[21]

2-incision technique

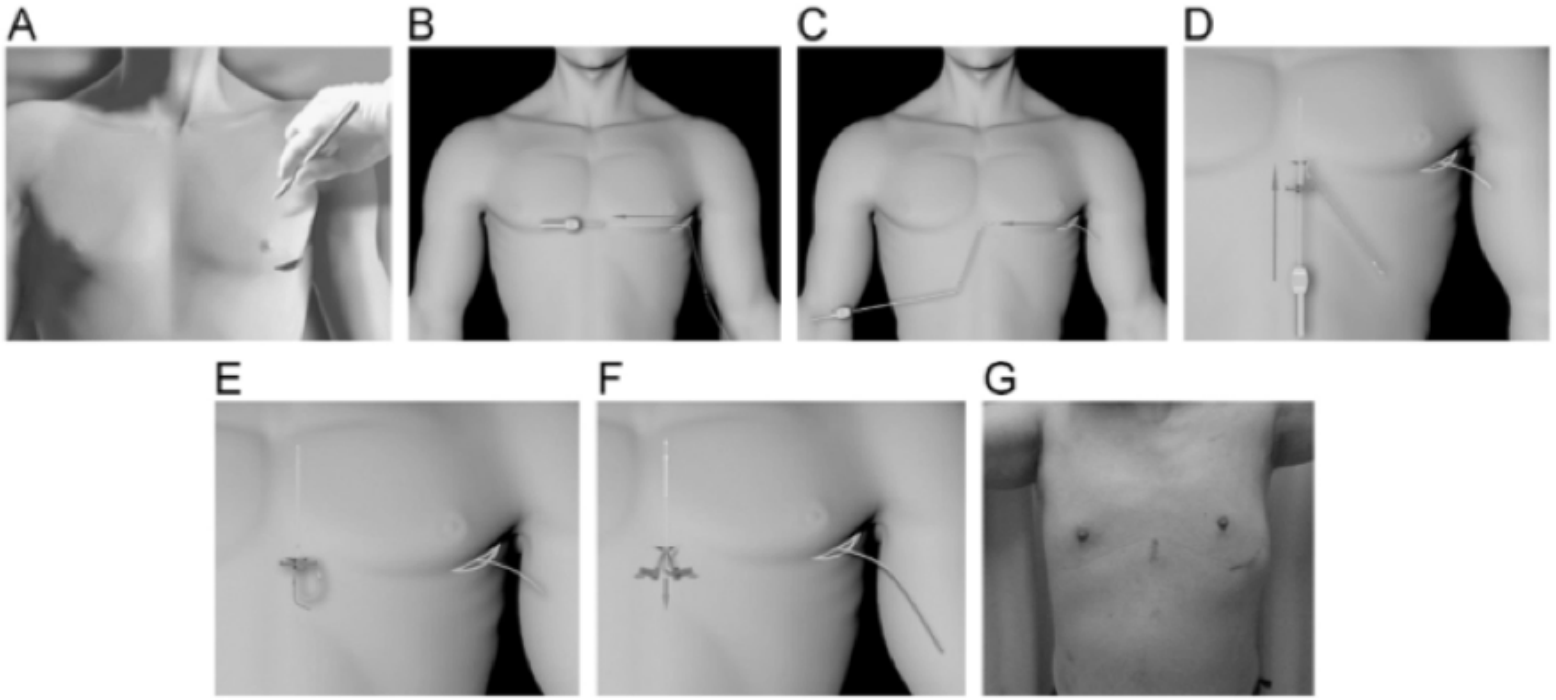


Figure 1 **A:** Creating the device pocket. **B:** Connecting distal end of electrode to the electrode insertion tool (EIT). **C:** Pulling the lead to the inferior parasternal incision. **D:** Tunneling the EIT and peel-away sheath to the superior parasternal position without making a parasternal incision. **E:** After the EIT is removed, the electrode is inserted in the sheath. **F:** Peeling away the sheath, leaving the electrode in the desired subcutaneous position. **G:** Final result after 2 weeks of follow-up.

Knops RE, HR 2013

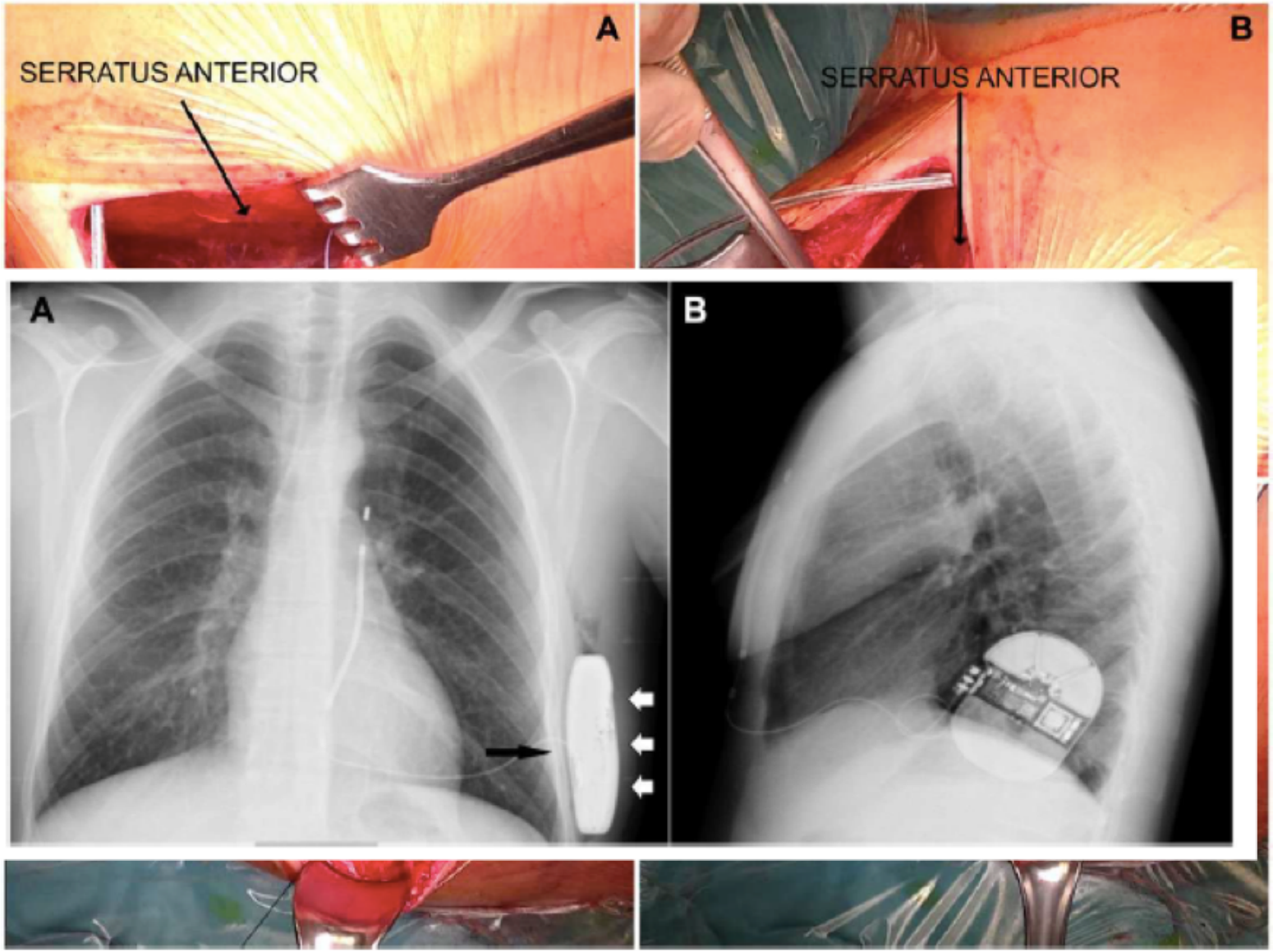


Figure 2. *Intermuscular pocket is created by blunt dissection between anterior surface of the serratus anterior muscle and the posterior surface of the latissimus dorsi muscle, over the left sixth rib between the midline and anterior axillary line (A and B). The pulse generator is placed into the virtual anatomical space between the two muscles and anchored to the fascia to prevent possible migration. Subsequently, the two muscles are sutured using conventional absorbable suture (C and D). [Color figure can be viewed at wileyonlinelibrary.com]*

Local anesthsia

- Not anymore on general anesthesia
- Conscious sedation
- Local anesthesia and intercostal block

- PAS: 64.1% GA, 35.8% conscious sedation, 0.2% local anesthesia

MR Gold HR 2017

- Monitored anesthesia care

Essandoh MK, J Cardiotho Vasc Anesth 2016

- Serratus plane block

Ueshima H, J Clin Anesth 2016

- Midazolam and nabulphine

Peyrol M, JICE 2017

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Canadian Guidelines

17. We recommend a subcutaneous ICD be considered in patients with limited vascular access or pocket sites in whom an ICD is recommended **(Strong recommendation; Low quality evidence)**

Practical tip. The implantation of an S-ICD might be considered in patients in whom an ICD is recommended who have 1 of the following conditions: (1) congenital heart disease with no access to the ventricles; (2) congenital heart disease with right to left shunt resulting in increased risk of thromboembolic complications with transvenous ICD system; and (3) absence of a pocket site due to either previous device-related infection and/or chronic indwelling catheters.

CCS/CHRS 2016 Implantable Cardioverter-Defibrillator (ICD) Guidelines
on line on CJC since October 6Th

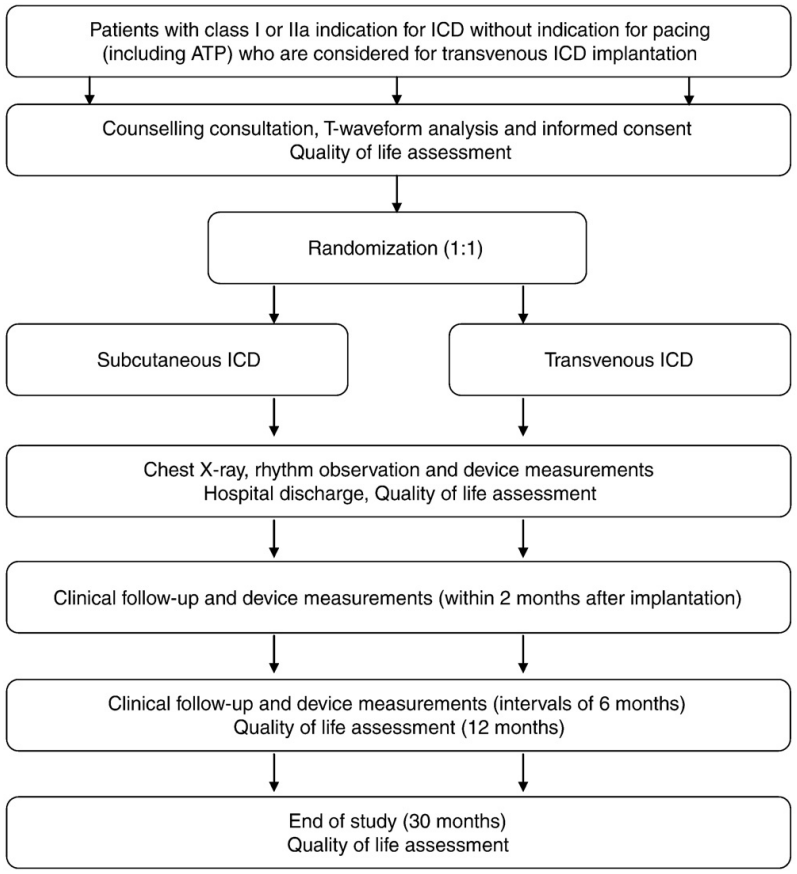
The PRAETORIAN trial

Rationale and design of the PRAETORIAN trial: A Prospective, RAndomizEd comparison of subcuTaneOus and tRansvenous ImplANtable cardioverter-defibrillator therapy

- Patients with documented therapy refractory monomorphic VT*
- Patients with VT <170 beats/min
- Patients having an indication for pacing therapy, according to the ACC/AHA/HRS 2008 guidelines for device-based therapy for cardiac rhythm abnormalities[17]
- Patients failing appropriate QRS/T-wave sensing with the S-ICD ECG patient screening tool provided by Cameron Health
- Patients with incessant VT
- Patients with a serious known concomitant disease with a life expectancy of <1 y
- Patients with circumstances that prevent follow-up (eg, no permanent home or address)
- Patients who are unable to give informed consent

700 patients
7 centers in Netherlands

	TV-ICD			S-ICD	
	Monitor zone	Fast VT zone	VF zone	Conditional zone	Unconditional zone
Arrhythmia detection zones (beats/min)	>167	>182	>250	>180	>250
Time to initiate therapy (charge for shock or ATP)	11 s	10 s	7.2 s	Fixed (18/24: 6 s)	Fixed (18/24: 4.3 s)
Charge time ICD (expected)		7-8 s		10-12 s	
Time to shock therapy (expected)		14-18 s		14-18 s	
Therapy	No therapy	(1) 1 burst of ATP* (2) Shocks at maximum output	Shocks at maximum output	Shocks at maximum output	Shocks at maximum output
Pacing programming		VVI 40 beats/min		Postshock pacing: "On"	



PRAETORIAN trial: Flow chart.

NordKamp AHJ 2012

ATLAS trial

Avoid Transvenous Leads in Appropriate Subjects

- Hypothesis:

Compared to standard, single-chamber transvenous implantable cardioverter defibrillators (TV-ICDs), the use of a sub-cutaneous ICD (S-ICD) will result in fewer perioperative and long-term device-related complications, and will have a similar rate of failed appropriate clinical shocks and arrhythmic death

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Futur

- PRAETORIAN
  - ✓ Netherlands
  - ✓ 700 patients
  - ✓ VVI TV-ICD vs S-ICD (1:1)
  - ✓ Combined endpoint (inappropriate shocks chocs and ICD complications (non-inferiotity)
  - ✓ Efficacy
  - ✓ Mortality

- ATLAS:
  - ✓ Canadian
  - ✓ 500 patients
  - ✓ VVI TV-ICD vs S-ICD (1:1)
  - ✓ Peri-op and long-term complications (superiority)
  - ✓ Failure of appropriate therapy and rhythmic death (non-inferiority)
  - ✓ Specific group in population

NordKamp O, Am Heart J 2012;163:753-760.e2

Futur

Multicenter Automatic Defibrillator Implantation Trial–Subcutaneous Implantable Cardioverter Defibrillator (MADIT S-ICD): Design and clinical protocol

Valentina Kutyifa, MD, PhD,[a] Christopher Beck, PhD,[b] Mary W. Brown, MS,[a] David Cannom, MD,[c] James Daubert, MD,[d] Mark Estes, MD,[e] Henry Greenberg, MD,[f] Ilan Goldenberg, MD,[g] Stephen Hammes, MD, PhD,[h] David Huang, MD,[i] Helmut Klein, MD,[a] Reinoud Knops, MD, PhD,[j] Mikhail Kosiborod, MD, PhD,[k] Jeanne Poole, MD,[l] Claudio Schuger, MD,[m] Jagmeet P. Singh, MD, PhD,[n] Scott Solomon, MD,[o] David Wilber, MD,[p] Wojciech Zareba, MD, PhD,[a] and Arthur J. Moss, MD[a], On behalf of the MADIT S-ICD Executive Committee *Rochester, NY; Los Angeles, CA; Durham, NC; Boston, MA; New York, NY; Tel Hashomer, Israel; Amsterdam, the Netherlands; Kansas City, MO; Seattle, WA; Detroit, MI; and Maywood, IL*

Patients with diabetes mellitus, prior myocardial infarction, older age, and a relatively preserved left ventricular ejection fraction remain at risk for sudden cardiac death that is potentially amenable by the subcutaneous implantable cardioverter defibrillator with a good risk-benefit profile. The launched MADIT S-ICD study is designed to test the hypothesis that post–myocardial infarction diabetes patients with relatively preserved ejection fraction of 36%-50% will have a survival benefit from a subcutaneous implantable cardioverter defibrillator. (Am Heart J 2017;189:158-66.)

Futur: No more testing?

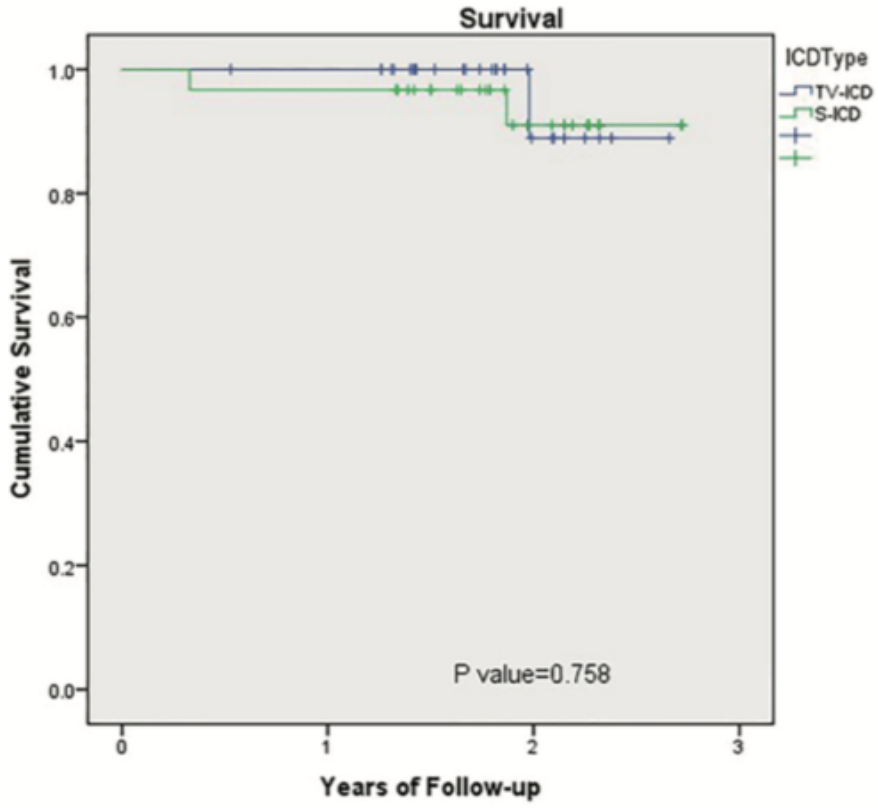
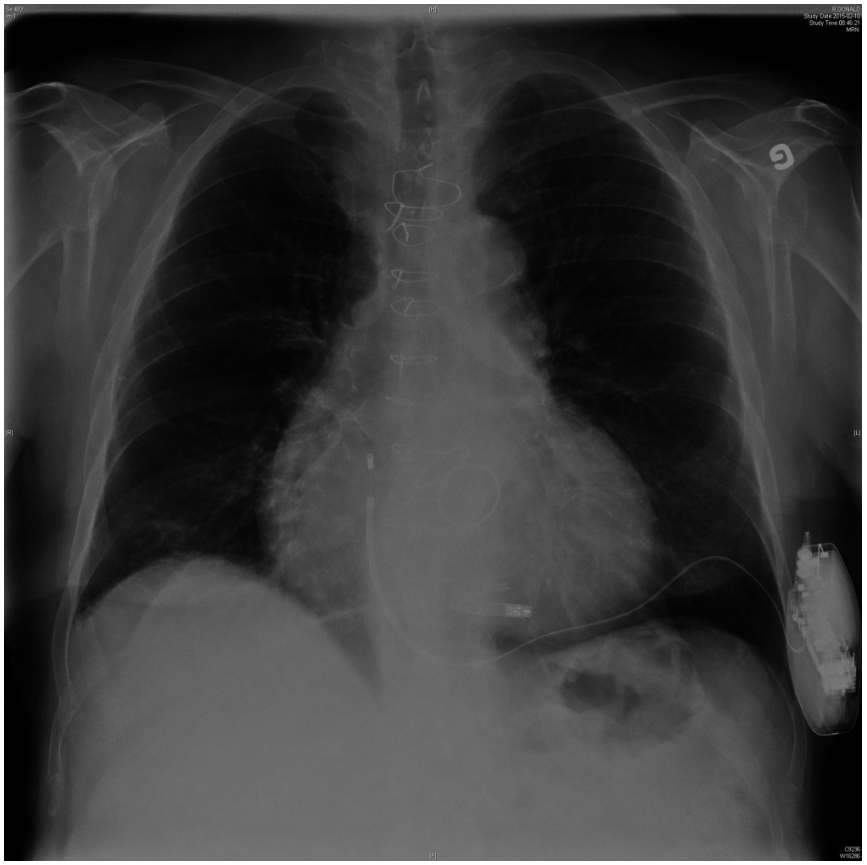
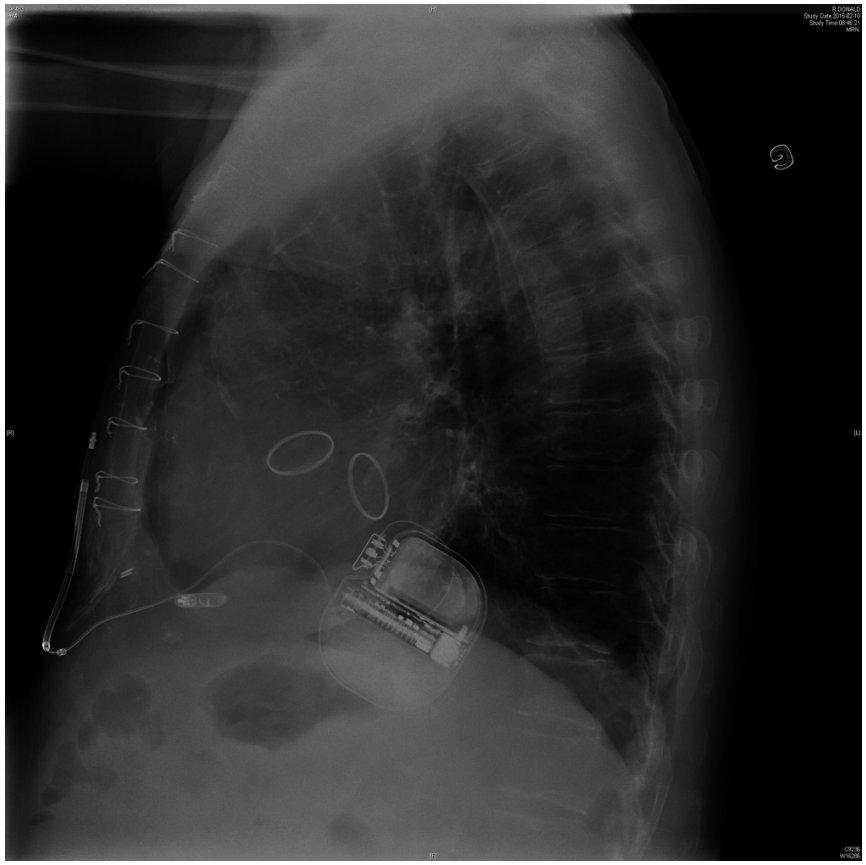


Figure 1. Outcomes comparison of S-ICD and TV-ICD: survival. Kaplan-Meier plot of survival in the S-ICD and TV-ICD patients. S-ICD: subcutaneous implantable cardioverter defibrillators; TV-ICD: transvenous implantable cardioverter defibrillators.





Mondésert et al. Heart Rhythm case report 2015

Futur

- Leadless + S-ICD with communication

Futur

Europace. 2016 Nov;18(11):1740-1747. Epub 2016 Mar 3.

Combined leadless pacemaker and subcutaneous implantable defibrillator therapy: feasibility, safety, and performance.

Tjong FV[1], Brouwer TF[2], Smeding L[2], Kooiman KM[2], de Groot JR[2], Ligon D[3], Sanghera R[4], Schalij MJ[5], Wilde AA[2], Knops RE[2].

Author information

Abstract

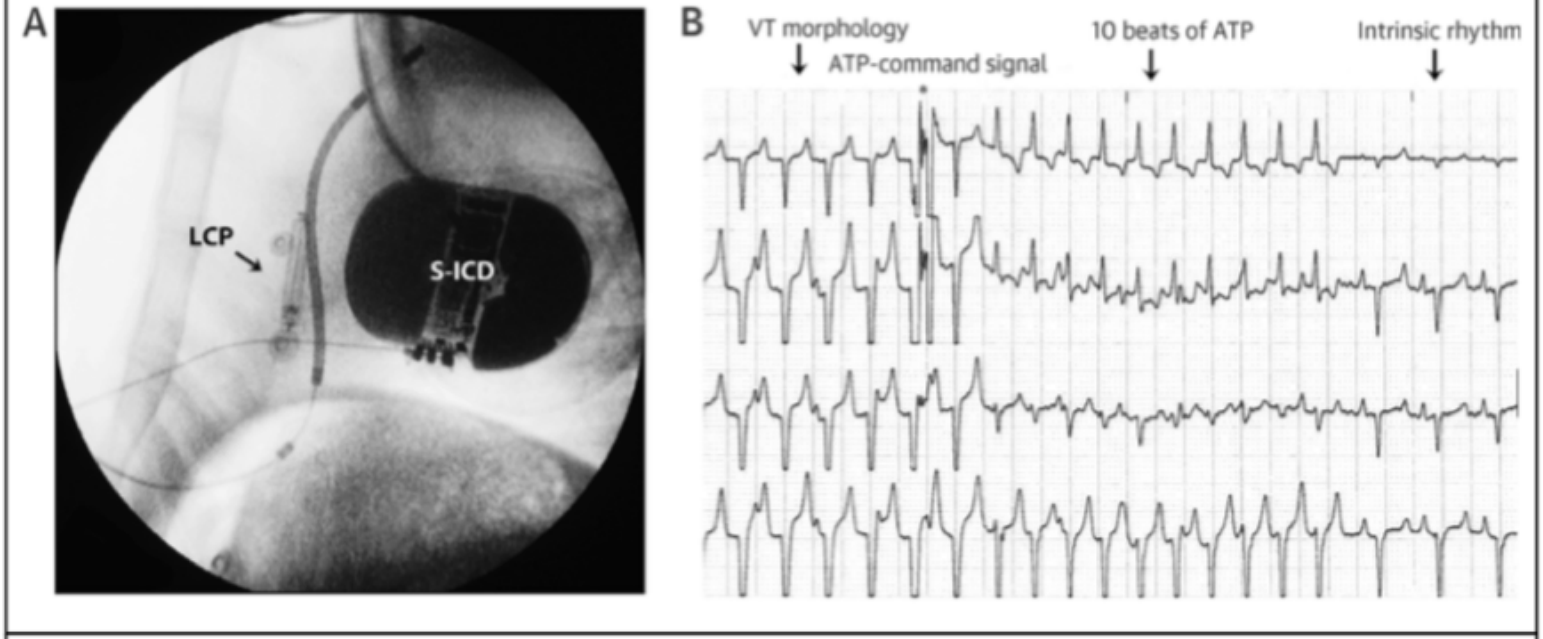
AIMS: The subcutaneous implantable cardioverter-defibrillator (S-ICD) and leadless pacemaker (LP) are evolving technologies that do not require intracardiac leads. However, interactions between these two devices are unexplored. We investigated the feasibility, safety, and performance of combined LP and S-ICD therapy, considering (i) simultaneous device-programmer communication, (ii) S-ICD rhythm discrimination during LP communication and pacing, and (iii) post-shock LP performance.

METHODS AND RESULTS: The study consists of two parts. Animal experiments: Two sheep were implanted with both an S-ICD and LP (Nanostim, SJM), and the objectives above were tested. Human experience: Follow-up of one S-ICD patient with bilateral subclavian occlusion who received an LP and two LP (all Nanostim, SJM) patients (without S-ICD) who received electrical cardioversion (ECV) are presented. Animal experiments : Simultaneous device-programmer communication was successful, but LP-programmer communication telemetry was temporarily lost (2 ± 2 s) during ventricular fibrillation (VF) induction and 4/54 shocks. Leadless pacemaker communication and pacing did not interfere with S-ICD rhythm discrimination. Additionally, all VF episodes (n = 12/12), including during simultaneous LP pacing, were detected and treated by the S-ICD. Post-shock LP performance was unaltered, and no post-shock device resets or dislodgements were observed (24 S-ICD and 30 external shocks). Human experience : The S-ICD/LP patient showed adequate S-ICD sensing during intrinsic rhythm, nominal, and high-output LP pacing. Two LP patients (without S-ICD) received ECV during follow-up. No impact on performance or LP dislodgements were observed.

CONCLUSION: Combined LP and S-ICD therapy appears feasible in all animal experiments (n = 2) and in one human subject. No interference in sensing and pacing during intrinsic and paced rhythm was noted in both animal and human subjects. However, induced arrhythmia testing was not performed in the patient. Defibrillation therapy did not seem to affect LP function. More data on safety and performance are needed.

Futur

FIGURE 1 Combined Implant of ATP-Enabled Leadless Cardiac Pacemaker and S-ICD



(A) Combined implantation of the leadless cardiac pacemaker (LCP) prototype in right ventricular apex and subcutaneous implantable cardioverter-defibrillator (S-ICD) in sheep. **(B)** Episode of simulated ventricular tachycardia (VT) (left ventricular pacing) followed by manually triggered S-ICD anti-tachycardia pacing (ATP)-command resulting in successful ATP-delivery by the LCP (10 beats, at 81% of coupling interval).

Merci!

Table 3 Comparison of major cohorts with S-ICD

Variable	PAS	EFFORTLESS[7]	IDE study[5]	Dutch cohort[8]
Year published	2017	2014	2013	2012
Region	United States	Primarily European Union	Primarily United States	The Netherlands
No. of patients	1637	450	330	118
Age (y)	53.2 ± 15.0	49 ± 18	51.9 ± 15.5	50 ± 14
Sex: male	68.6	72	74.1	75
EF (%)	32.0 ± 14.6	42 ± 19	36.1 ± 15.9	41 ± 15
Primary prevention	76.7	63	79.4	38 ± 12
Heart failure	74.0	29	61.4	–
Hypertension	61.6	24	58.3	–
Diabetes	33.6	12	28.0	–
Kidney disease	25.6	9	–	–
Previous ICD	12.9	15	13.4	11

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