TIGULLIO 2024 II Congresso Nazionale di ARITMOLOGIA

16-17 Aprile Sestri Levante (GE)

Presidente del Congresso
Guido Parodi, Lavagna

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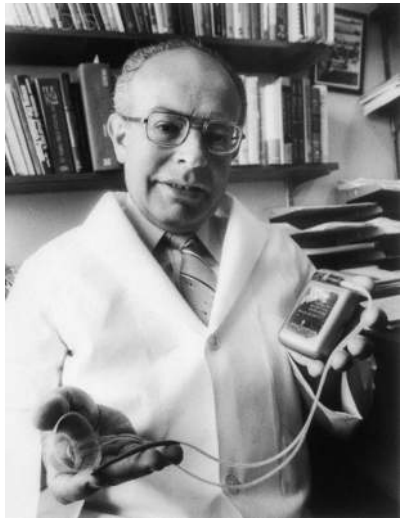
Roberto Maggi, Lavagna

Sede Congressuale
Hotel Vis a Vis ****
Sestri Levante

Defibrillatore sottocutaneo vs transvenoso: letteratura e pratica clinica per orientare la scelta

S. Viani
UO Cardiologia 2 – Aritmologia
AOUP, Pisa

ICD therapy today: multiple choices



Mirowsky M et al.; NEJM, 1980

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., Arno 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.

Bardy GH et al. ; NEJM, 2010

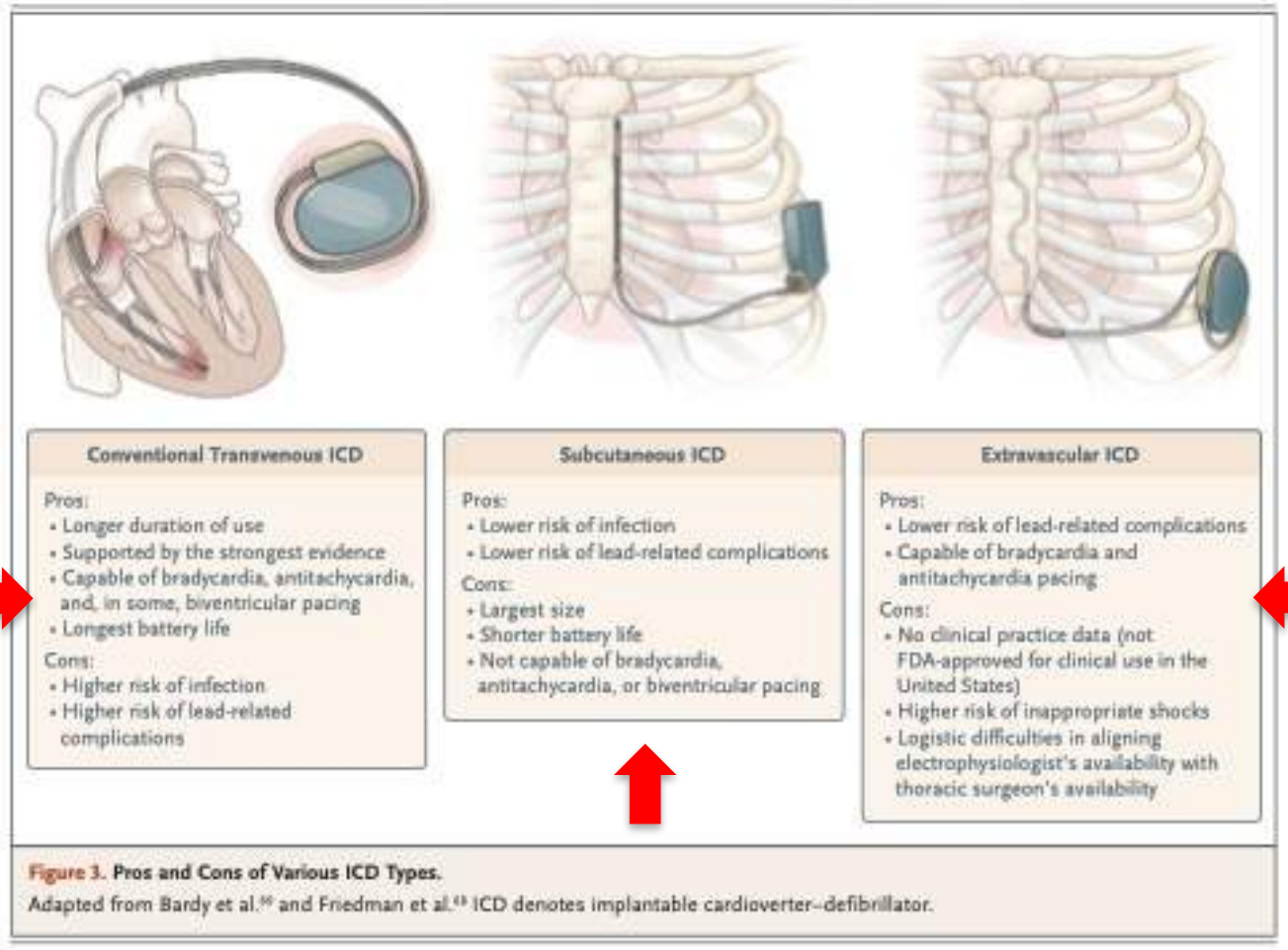


Figure 3. Pros and Cons of Various ICD Types.
Adapted from Bardy et al.[55] and Friedman et al.[53] ICD denotes implantable cardioverter–defibrillator.

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Efficacy and Safety of an Extravascular Implantable Cardioverter–Defibrillator

P. Friedman, F. Murgatroyd, L.V.A. Boersma, J. Manlucu, D. O'Donnell, B.P. Knight, N. Clémenty, C. Leclercq, A. Amin, B.P. Merkely, U.M. Birgersdotter-Green, J.Y.S. Chan, M. Biffi, R.E. Knops, G. Engel, I. Muñoz Carvajal, L.M. Epstein, V. Sagi, J.B. Johansen, M. Sterliński, C. Steinwender, T. Hounshell, R. Abben, A.E. Thompson, C. Wiggenhorn, S. Willey, and I. Crozier, for the Extravascular ICD Pivotal Study Investigators*

Friedman P et al.; NEJM, 2022

Modified from SM Al Kathib; NEJM.org February 1, 2024

Why imagine a *non-vascular* technology for ICD ?

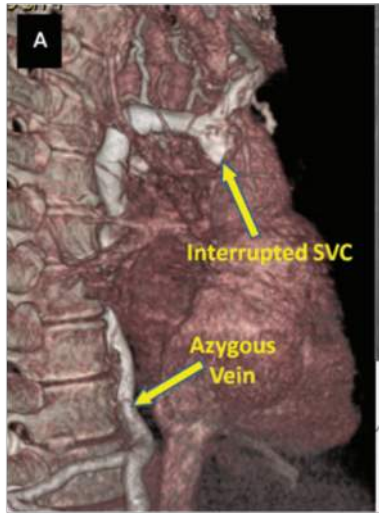
TV-lead is «*the weak link in the chain*»

To overcome inadequate congenital or acquired vascular/ventricular access

Subcutaneous ICD Implantation in the Setting of an Occluded Superior Vena Cava

PETR NEUZIL, M.D. PH.D.,* JAN PETRU, M.D.,* and VIVEK Y. REDDY, M.D.,*,†

*Department of Cardiology, Homnolka Hospital, Prague, Czech Republic; and †Cardiac Arrhythmia Service, Mount Sinai Hospital, New York City, New York, USA



ELSEVIER

Canadian Journal of Cardiology xx (2012) xxx-xxx www.onlinecjc.ca

Case Report

Implantable Cardioverter-Defibrillator Insertion in Congenital Heart Disease Without Transvenous Access to the Heart

Pablo B. Nery, MD,* Martin S. Green, MD,* Paul Khairy, MD, PhD,† Yahya Alhenaidi, MD,* Paul Hendry, MD,‡ and David H. Birnie, MD*

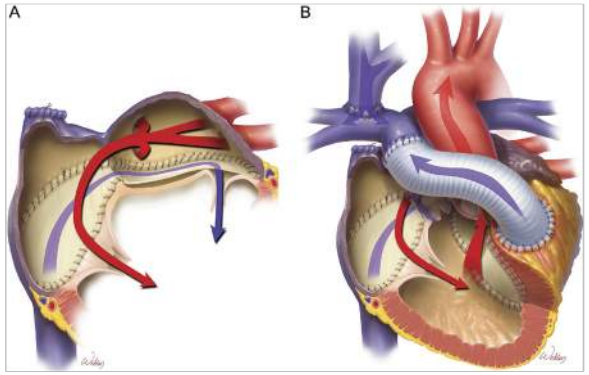
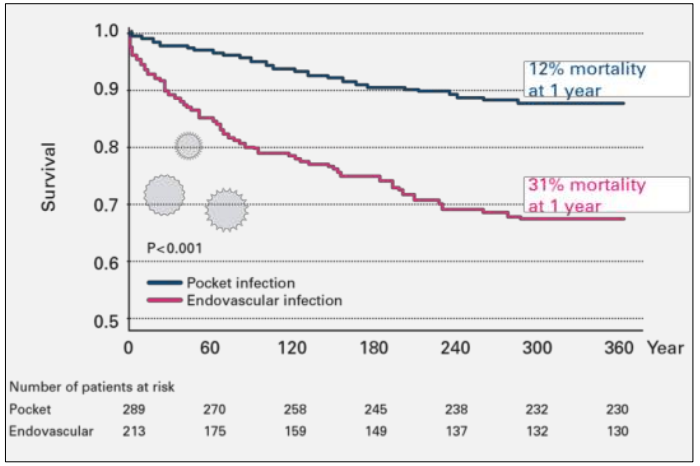


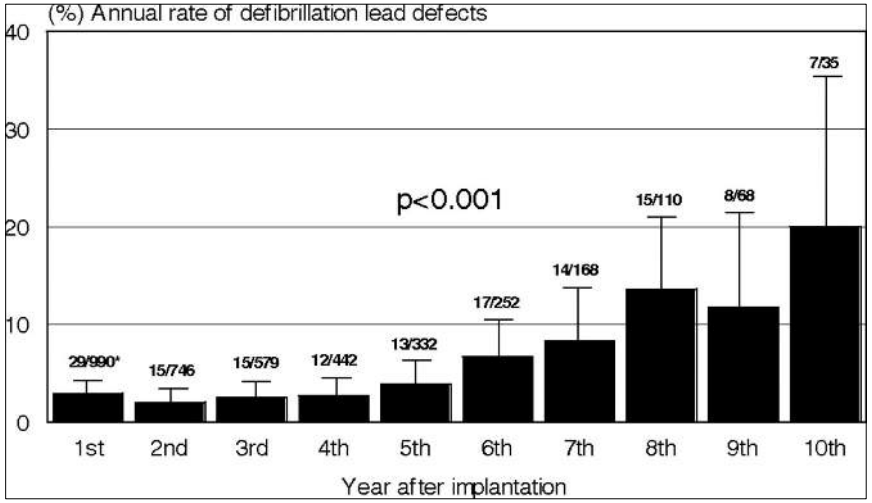
Figure 1. Corrective surgery. (**A**) Hemi-Mustard atrial redirection procedure together with a bidirectional Glenn shunt; (**B**) result after placement of homograft from the outflow tract of the right ventricle to the pulmonic artery. Reproduced from Di Bardino et al.[2] with permission from Cambridge University Press.

To avoid morbidity & mortality associated with long-term TV-lead related complications and their treatment



CIED Infections

Tarakj KG et al. Europace 2014



Lead malfunction

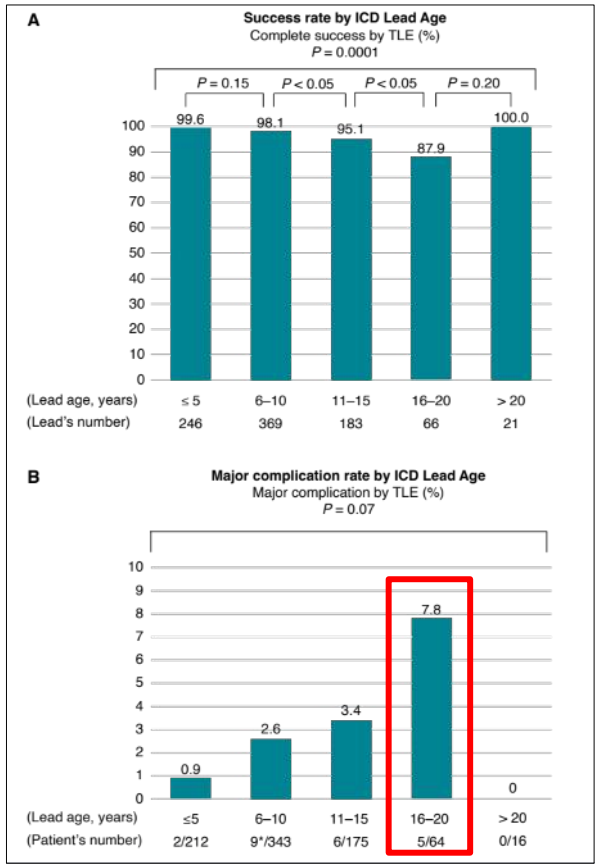
Kleemann T et al. Circulation 2007

TV-ICD lead extraction, even in experienced hands, is not without complications

ESC European Society of Cardiology
Europace (2023) 25, 1–10 https://doi.org/10.1093/europace/euad345
CLINICAL RESEARCH

Extraction outcomes of implantable cardioverter-defibrillator leads vary by manufacturer and model family

Katsuhide Hayashi, Thomas Callahan, John Rickard, Arwa Younis, Bryan Baranowski, David Martin, Shady Nakhla, Chadi Tabaja, and Bruce L. Wilkoff *



- 885 T-ICD leads/810 pts
- Median dw time 8 yrs
- 97.2% TLE success

Table 4 Location of injury in cases requiring emergent surgical or endovascular intervention

	n = 20
Superior vena cava	10 (50)
Right ventricle	3 (15)
Superior vena cava-right atrial junction	2 (10)
Brachiocephalic vein	2 (10)
Left subclavian vein	2 (10)
Superior vena cava-brachiocephalic vein	1 (5)

Categorical data are presented as number (percentage).

30 days all cause mortality 3.5%

- Extraction for infection
- End stage CKD
- Higher NYHA

Hayashi K et al. Europace 2023, 25; 1-10

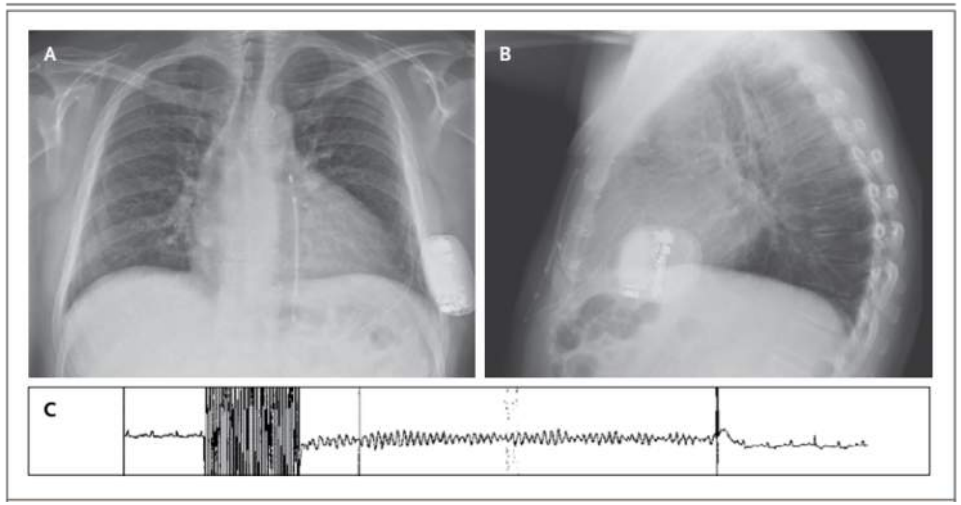
The S-ICD technology

- No lead in the vascular/cardiac system
- Shock only

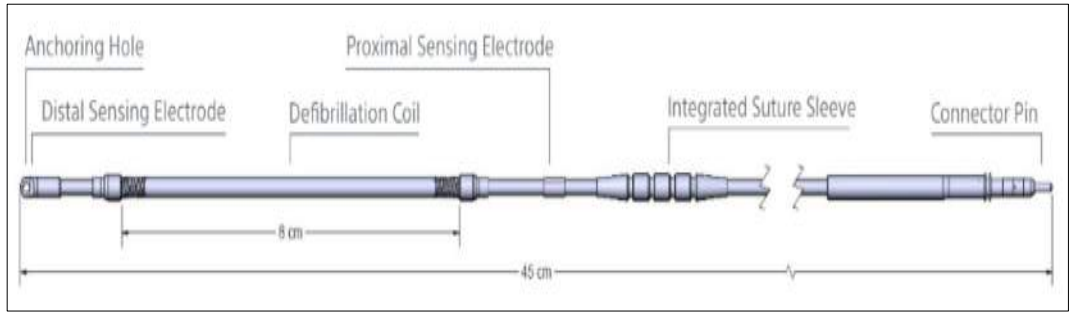
(80 J biphasic, up to 5 shocks/episode)

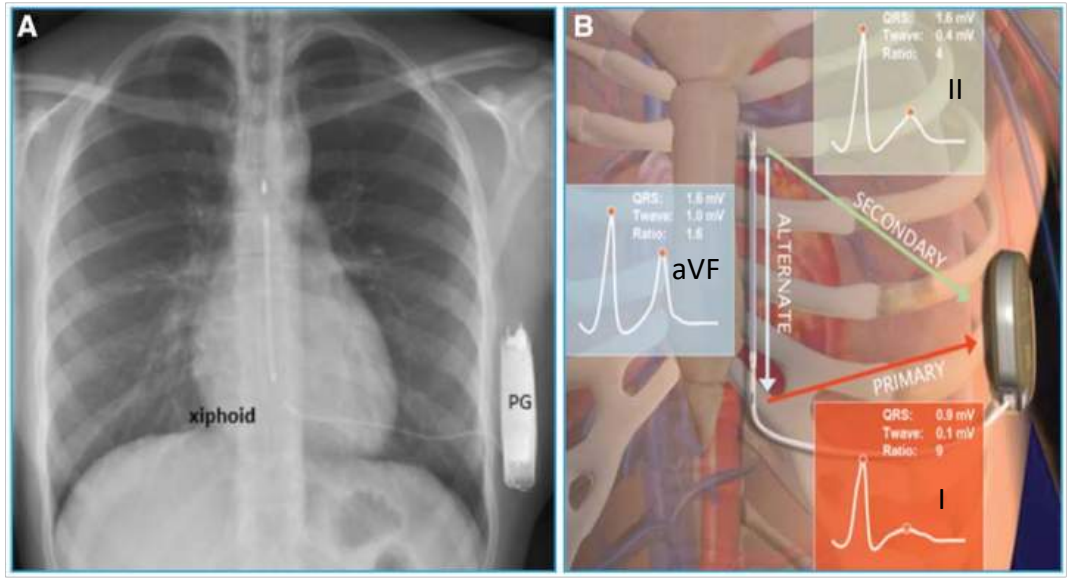
- No pacing /ATP therapy

(Post shock pacing on demand, max 30s, 50 bpm)



Lumen-less lead





3 vettori di rilevamento forniscono diverse prospettive del ritmo cardiaco.
Il sensing in campo lontano consente di acquisire un segnale ad alta risoluzione simile a un ECG di superficie: QRS/T/P ratio

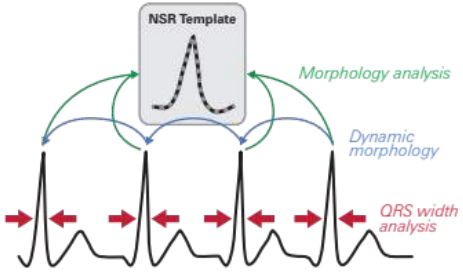
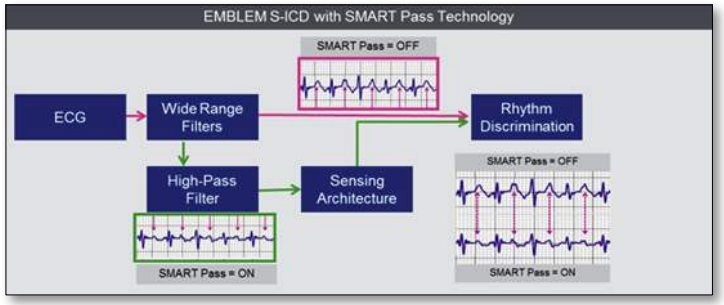
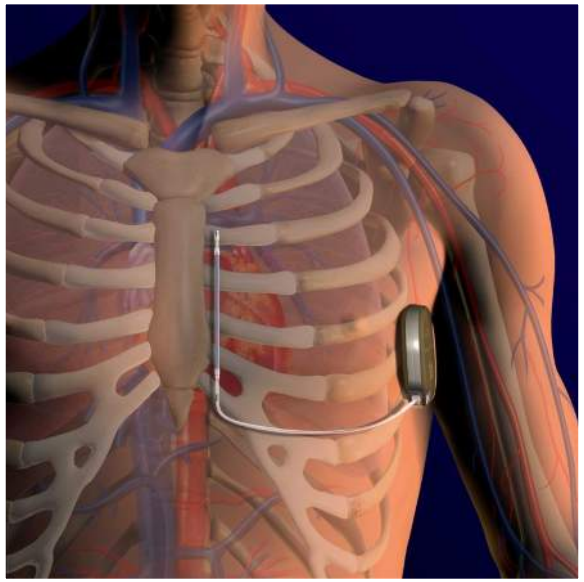


Figure 2. INSIGHT algorithms utilize three analysis methods—morphology, beat-to-beat morphology, and QRS width—to evaluate and identify heart rhythm.



S-ICD technology evolution



1ª Generazione

2ª Generazione
Dispositivo
più piccolo,
più sottile,
più duraturo[5*]

Compatibilità
LATITUDE™[5]

3ª Generazione
SMART Pass[5]
Compatibilità RM[1**]
AF Monitor™ [5]

Futuro

2017-2022

Verifica
concettuale

Inizio
trial clinico IDE

2002

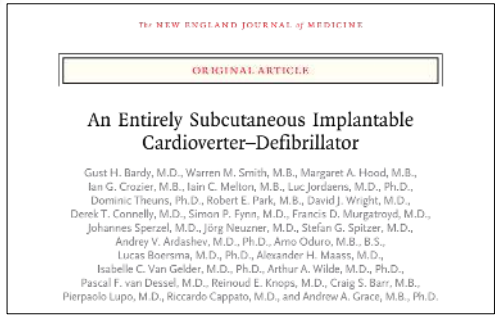
2008

2009

2012

2015

2016


The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

An Entirely Subcutaneous Implantable Cardioverter–Defibrillator

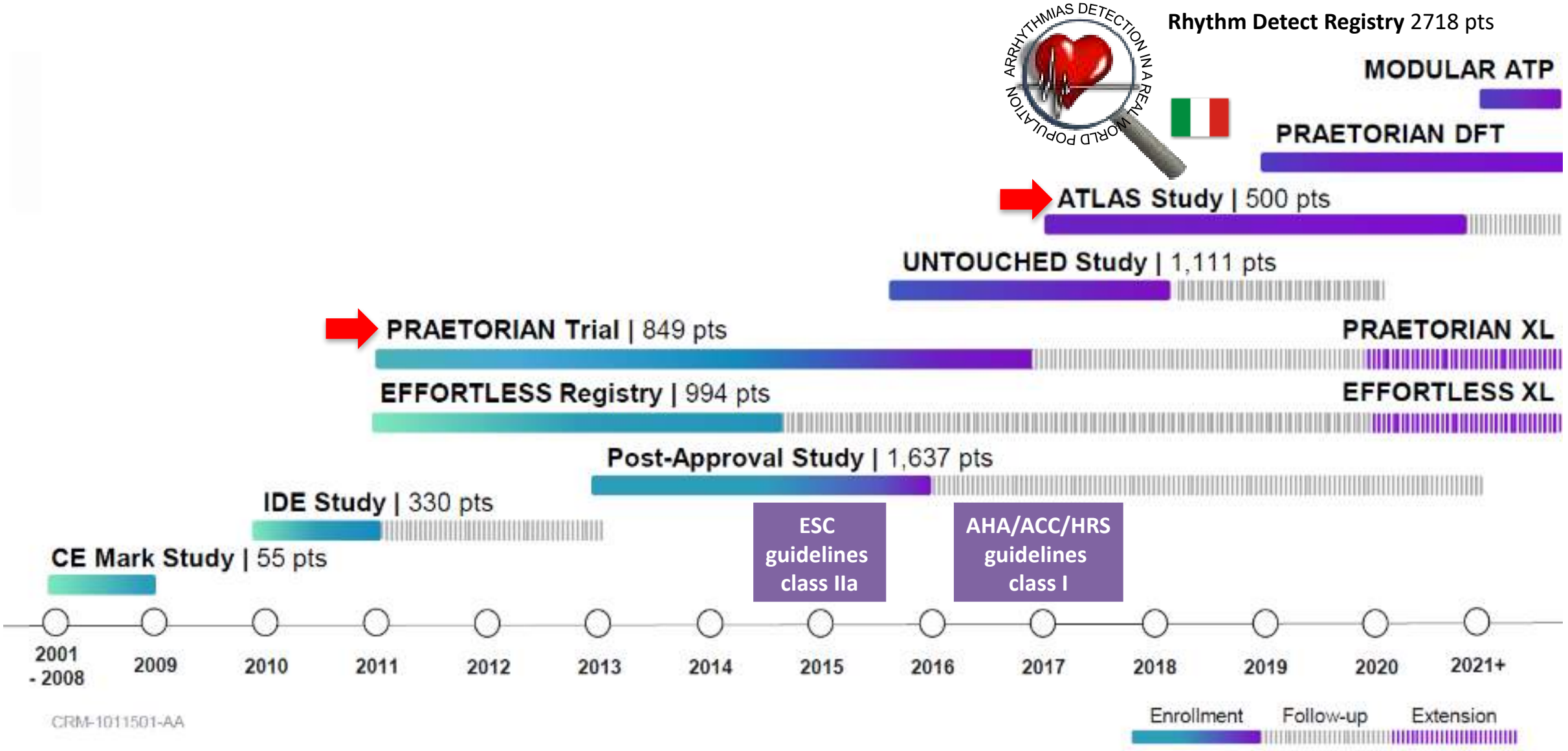
Gust H. Bardy, M.D., Warren M. Smith, M.B., Margaret A. Hood, M.B., Ian G. Crozier, M.B., Iain C. Melton, M.B., Luc Jordaens, M.D., Ph.D., Dominic Theuns, Ph.D., Robert E. Park, M.B., David J. Wright, M.D., Derek T. Connelly, M.D., Simon P. Fynn, M.D., Francis D. Murgatroyd, M.D., Johannes Sperzel, M.D., Jörg Neuzner, M.D., Stefan G. Spitzer, M.D., Andrey V. Ardashev, M.D., Ph.D., Arno 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.

Ottimizzazione dell'impianto S-ICD:

- ☑ Automated Screening Tool
- ☑ Elettrocatetere 3501
- ☑ Labeling tecnica a 2 incisioni
- ☑ Labeling intermuscolare
- ☑ Nuovo elettrocatetere 3501
- ☑ Blocco ecoguidato del serrato

The S-ICD journey in literature

> 5000 patients enrolled in registries/clinical trials



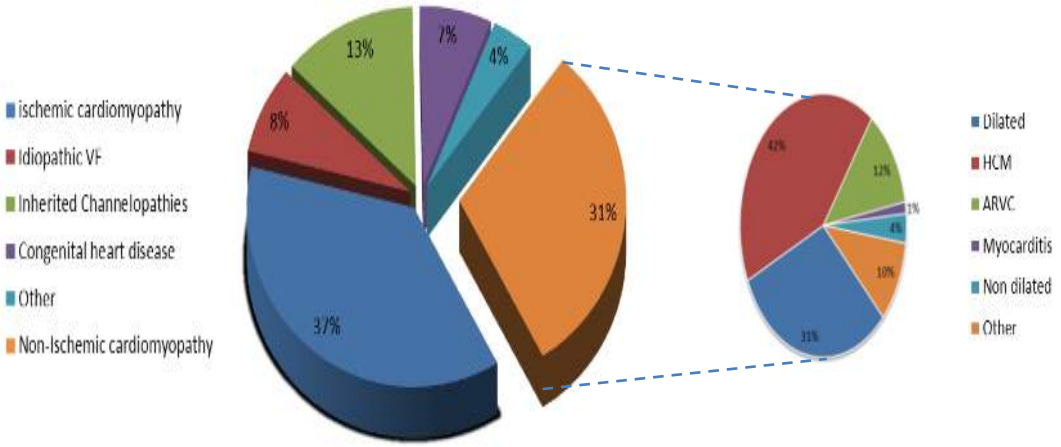
S-ICD: Effectiveness over time in clinical trials

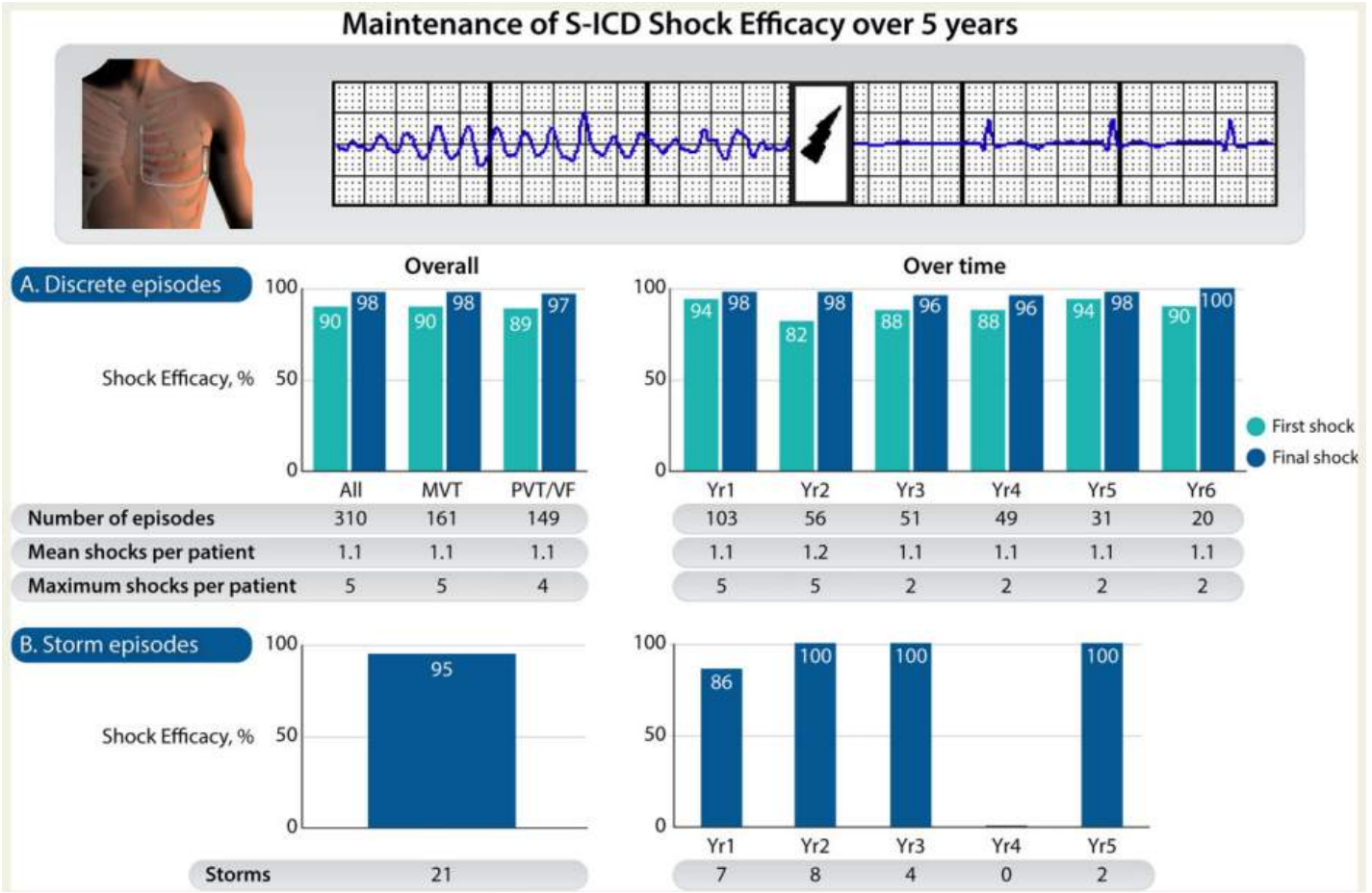
ESC European Society of Cardiology
European Heart Journal (2022) 43, 2037–2050
https://doi.org/10.1093/eurheartj/ehab921
CLINICAL RESEARCH
Clinical trials

Subcutaneous implantable cardioverter-defibrillators: long-term results of the EFFORTLESS study

Pier D. Lambiase[1]*, Dominic A. Theuns[2], Francis Murgatroyd[3], Craig Barr[4], Lars Eckardt[5], Petr Neuzil[6], Marcoen Scholten[7], Margaret Hood[8], Jürgen Kuschyk[9], Amy J. Brisben[10], Nathan Carter[10], Timothy M. Stivland[10], Reinoud Knops[11], Lucas V.A. Boersma[11,12], and on behalf of the EFFORTLESS Investigators

984 pts





Lambiase PD et al. European Heart Journal (2022) 43, 2037–2050

S-ICD: Safety in Clinical trials

Journal of the American Heart Association

SYSTEMATIC REVIEW AND META-ANALYSIS

Subcutaneous Versus Transvenous Implantable Defibrillator Therapy: A Systematic Review and Meta-Analysis of Randomized Trials and Propensity Score–Matched Studies

VS

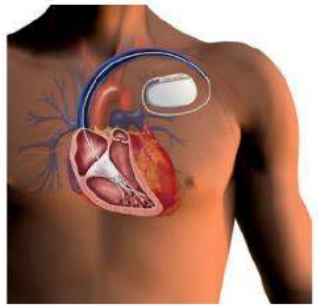
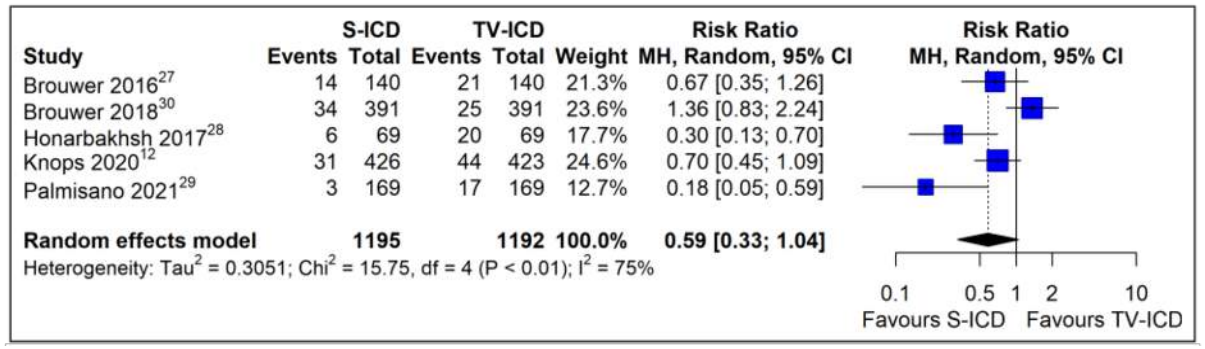


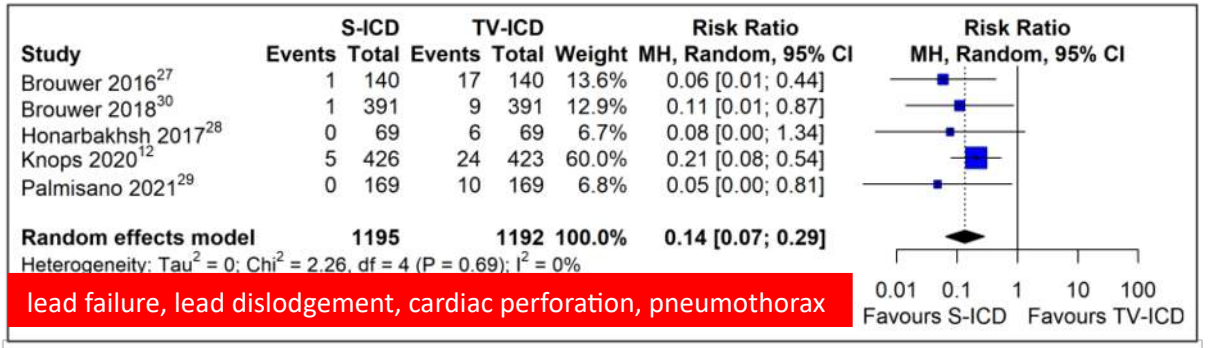
Table. Characteristics of Included Studies

Study	Participating countries	Study type	Arm	Number of patients (women)	Age, y*	Primary prevention, n (%)	Ischemic cardiomyopathy, n (%)	LVEF, %*	Diabetes, n (%)	Hypertension, n (%)	CABG, n (%)	AF, n (%)	Follow-up duration, mo*
Brouwer et al, 2016[27]	Netherlands	PSM	S-ICD	140 (56)	41 (26–52)	93 (66)	26 (19)	50	8 (5.7)	30 (21)	3 (0.21)	13 (9.3)	60
			TV-ICD	140 (53)	42 (32–50)	86 (61)	41 (29)	49	5 (3.6)	34 (24)	3 (0.21)	21 (15)	
Honarbakhsh et al, 2017[28]	United Kingdom	PSM	S-ICD	69 (17)	35±13	56 (81)	6 (9)	57±15	0	6 (8.7)	NR	NR	32±21
			TV-ICD	69 (17)	40±10	56 (81)	5 (7)	58±13	0	4 (5.8)	NR	NR	31±19
POINTED (Palmisano et al, 2021)[29]	Italy	PSM	S-ICD	169 (31)	55.6±13.0	142 (84)	71 (42)	37.9±14.7	31 (18)	89 (53)	18 (11)	39 (23)	30.3 (16.1–46.0)
			TV-ICD	169 (42)	57.4±15.5	130 (77)	60 (36)	37.9±14.4	34 (20)	95 (56)	15 (8.9)	50 (30)	31.3 (19.1–53.4)
PRAETORIAN (Knops et al, 2020)[12]	United States, Europe	RCT	S-ICD	426 (89)	63 (54–69)	346 (81)	289 (68)	30 (25–35)	112 (26)	227 (53)	86 (20)	115 (27)	48
			TV-ICD	423 (78)	64 (56–70)	339 (80)	298 (70)	30 (25–35)	126 (30)	240 (57)	85 (20)	93 (22)	51
SIMPLE-EFFORTLESS (Brouwer et al, 2018)[30]	Multiple countries worldwide	PSM	S-ICD	391 (92)	54±16	272 (70)	187 (48)	39.4±17.3	66 (17)	168 (43)	51 (13)	80 (20)	35±17
			TV-ICD	391 (72)	55±13	279 (71)	194 (50)	39.8±16.9	64 (16)	169 (43)	42 (11)	77 (20)	40±10

Device-related complications



Lead-related complications



lead failure, lead dislodgement, cardiac perforation, pneumothorax

Inappropriate shocks

Figure S5. Forest plot of inappropriate shocks.

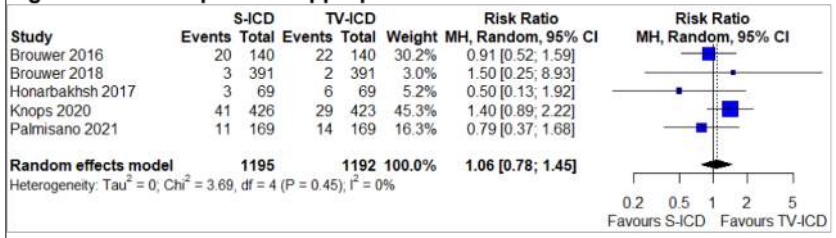


Figure S6. Forest plot of cardiac oversensing as a cause of inappropriate shocks.

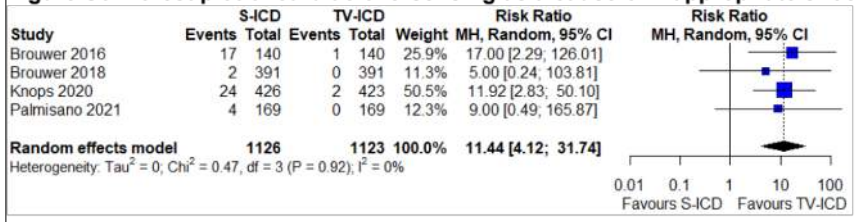
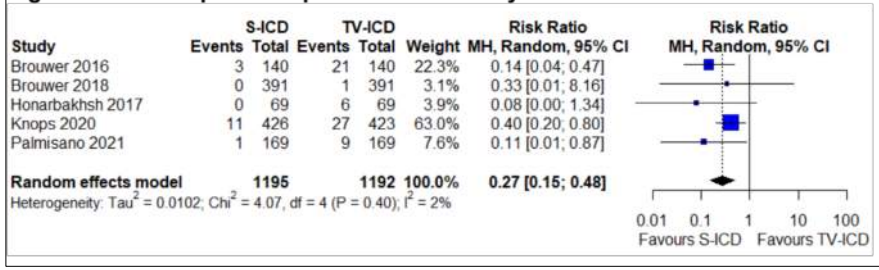
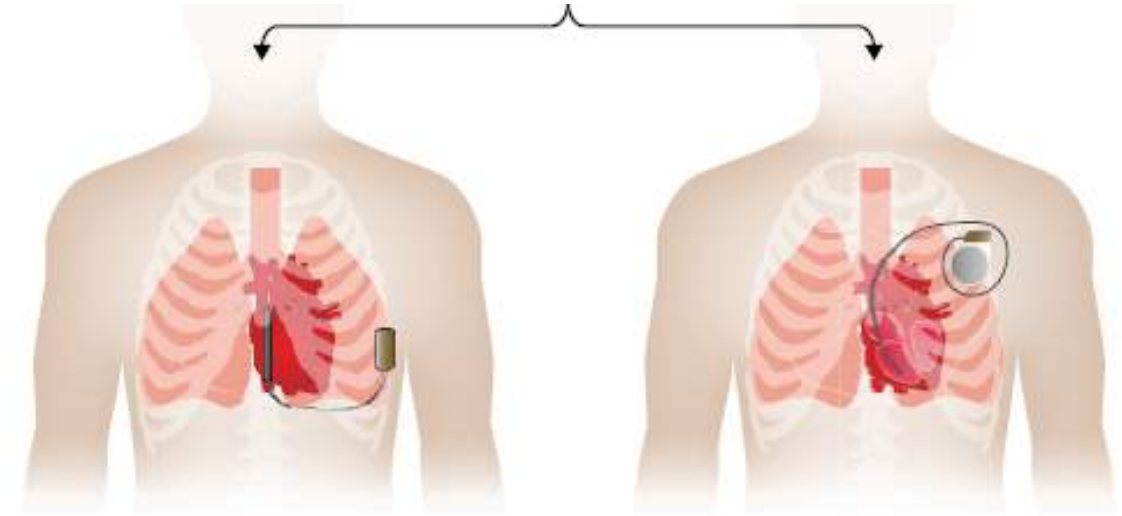


Figure S7. Forest plot of supraventricular tachycardia or atrial fibrillation as a cause of inappropriate shocks.



Fong KY et al. J Am Heart Assoc. 2022;11:e024756. DOI: 10.1161

PRAETORIAN: Complications a secondary analysis

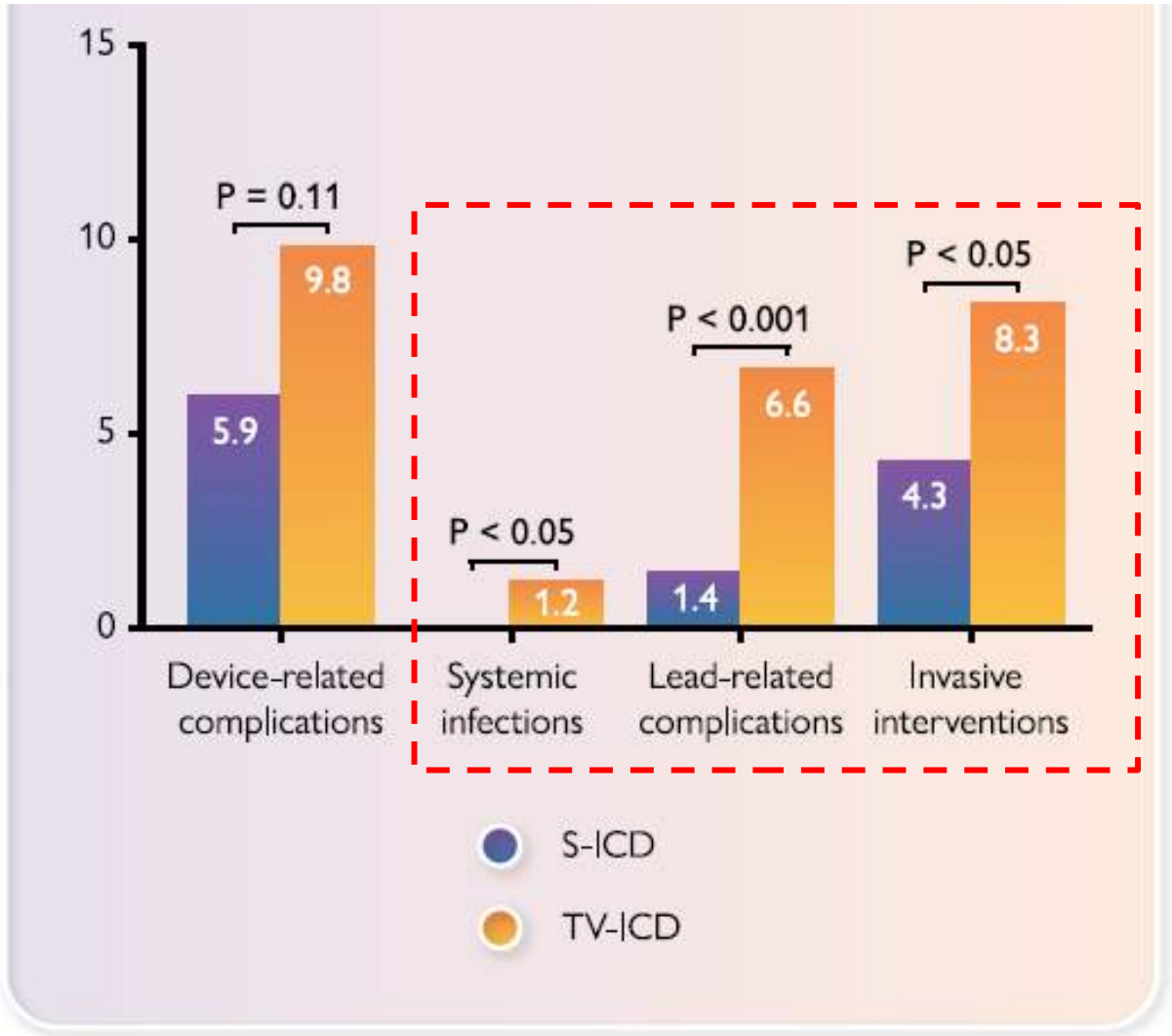


S-ICD
N = 426

TV-ICD
N = 423

39 EU & US Centers

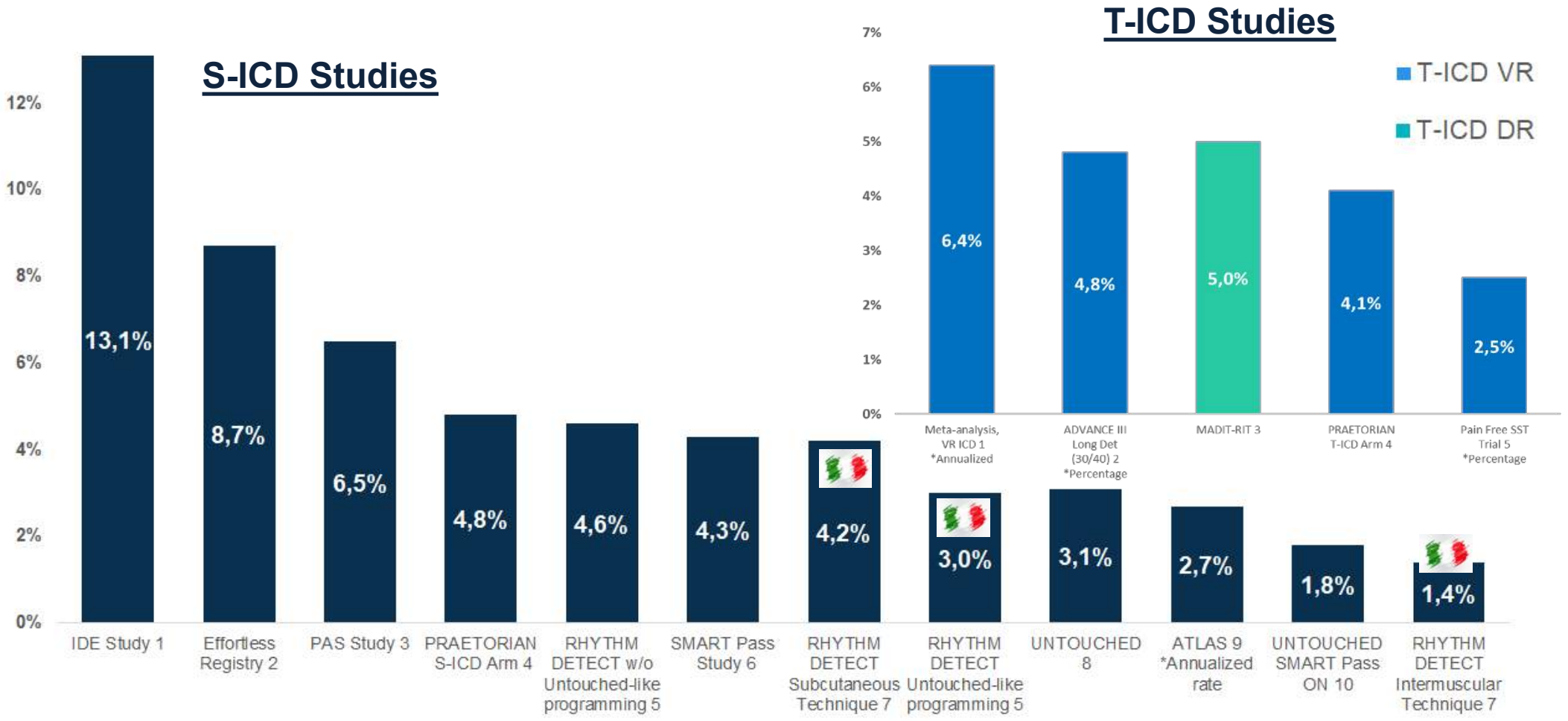
Median follow-up: 49.1 months



Knops RE, et al. European Heart Journal,2022, 43; Volume 43, Issue 47, 14 December 2022, Pages 4872–4883

Inappropriate Shock Rates

One Year, Kaplan-Meier Rates except where indicated



# Patients	314	984	1637	422	1042	1984	290	426	1111	251	1111	290

1. Weiss R., et al., *Circulation* 2013;128:944–953.
2. Lambiase P.L. et al., *European Heart Journal* 2022; 00,1-14.
3. Burke M.C. et al., *JACC Clin Electrophysiol* 2020; 6(12):1537-1550.
4. Knops R.E. et al., *N Engl J Med* 2020; 383(6): 526-536.
5. Rordorf R., et al., *Europace* 2022;00:1-9.
6. Theuns D., et al., *Heart Rhythm*. 2018;15:1515-1522.
7. Botto GL., et al., *Europace* 2023;00:1-9.
8. Gold M.R. et al., *Circulation* 2021; 143(1): 7-17
9. Healey JS., et al., *Ann Int Med* 2022; 175(12): 1658-1665.
10. Boersma EHRA Congress 2022, Abstract #41073.

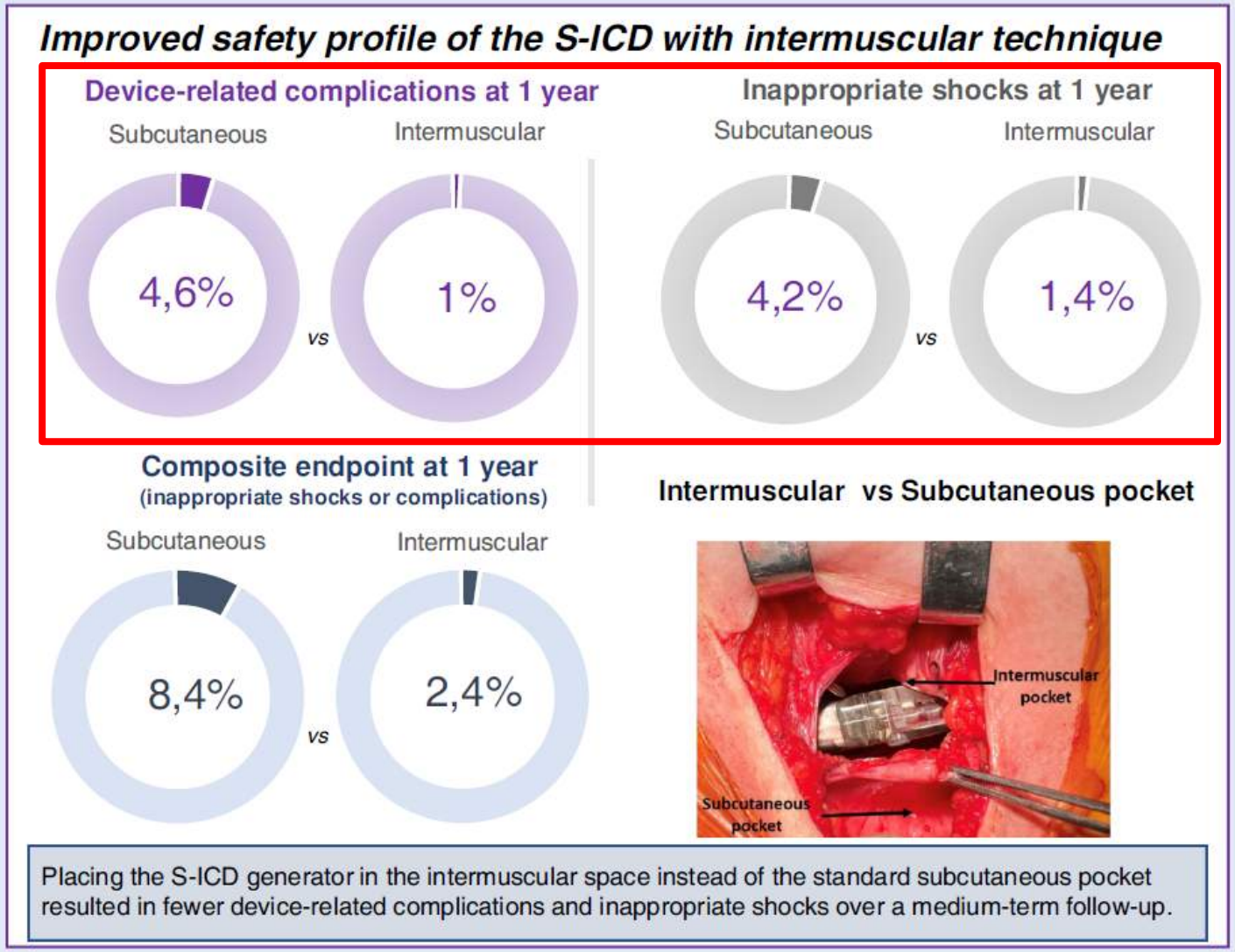
ESC European Society of Cardiology
Europace (2023) 00, 1–9
https://doi.org/10.1093/europace/euad028
CLINICAL RESEARCH

Intermuscular technique for implantation of the subcutaneous implantable defibrillator: a propensity-matched case–control study

Giovanni Luca Botto [1]*, Matteo Ziacchi [2], Gerardo Nigro [3], Antonio D'Onofrio [4], Antonio Dello Russo [5], Pietro Francia [6], Stefano Viani [7], Ennio Pisanò [8], Giovanni Bisignani[9], Fabrizio Caravati [10], Federico Migliore [11], Paolo De Filippo[12], Luca Ottaviano [13], Roberto Rordorf [14], Michele Manzo [15], Fabio Lorenzo Canevese [1], Mariolina Lovecchio[16], Sergio Valsecchi [16], and Luca Checchi [17]on behalf of 'S-ICD Rhythm Detect' Investigators

RHYTHM DETECT[1]	
Overall	1577 patients 66 centers
Patients in analysis	290 SC vs 290 IM (propensity matched)
Devices in analysis	Emblem
Outcomes	• Device-related complications • Inappropriate shocks • Composite of complications and IAS
Duration	Median 28 months

Graphical Abstract



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

S-ICD Limitations: perception vs reality

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

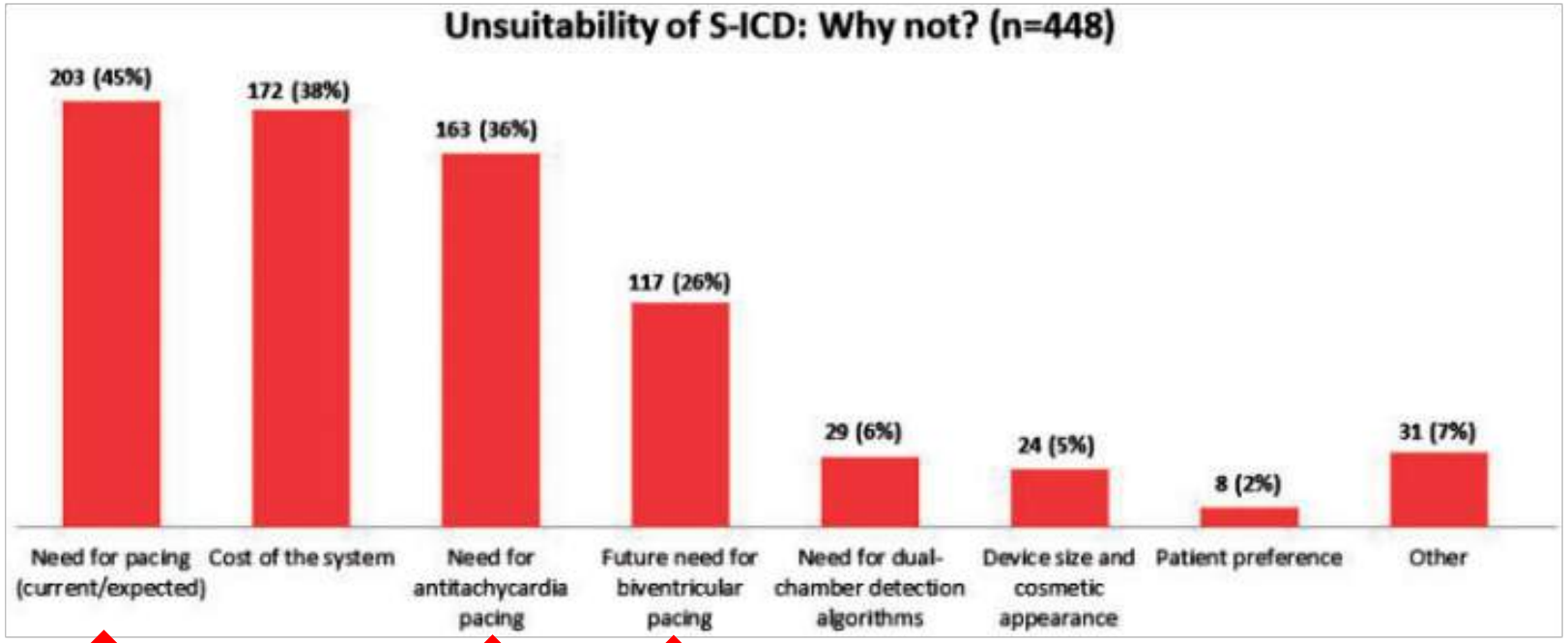


Figure 2 Factors for preferring a transvenous ICD over an S-ICD ($n = 448$). Multiple factors were reported per patient.

Botto GL et al. Europace (2017) 19, 1826–1832

ORIGINAL ARTICLE

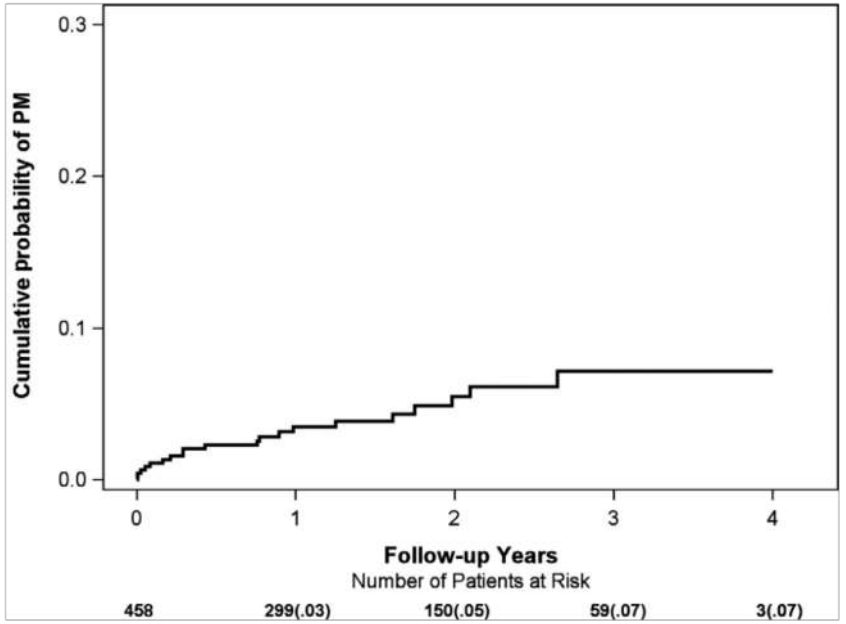
WILEY

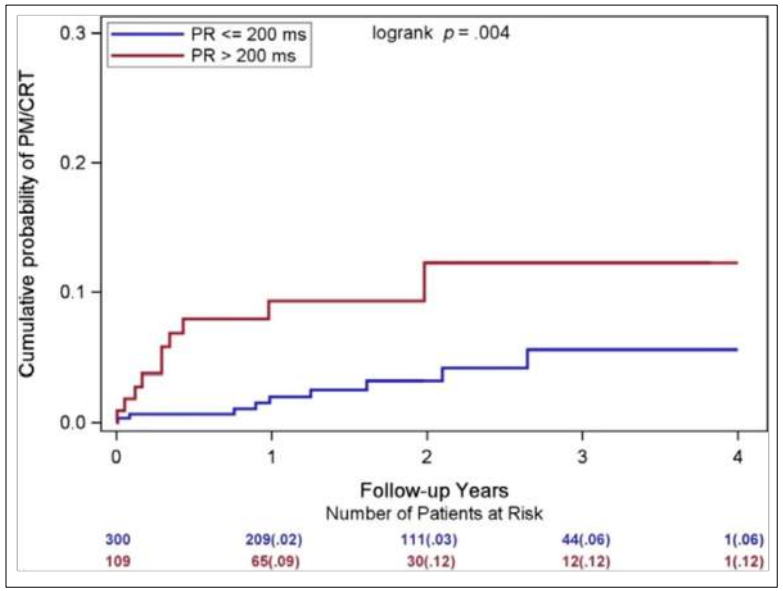
Need for pacing in patients who qualify for an implantable cardioverter-defibrillator: Clinical implications for the subcutaneous ICD

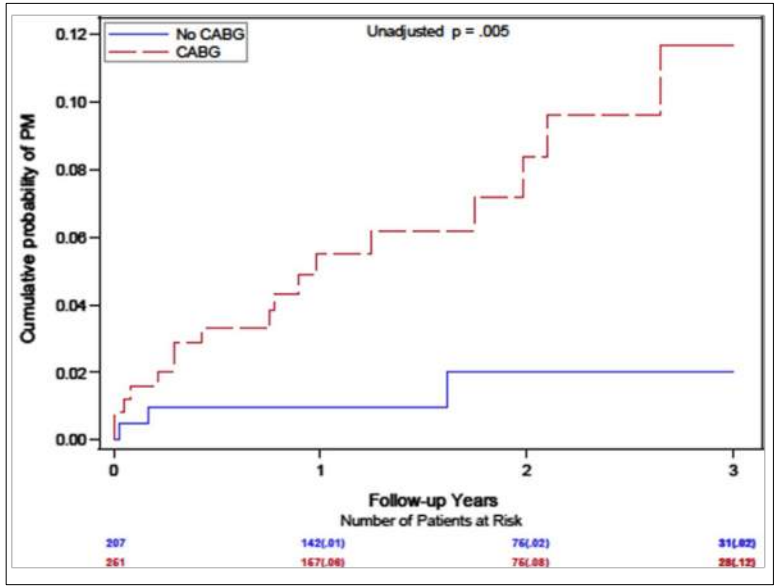
458 MADIT II (control group) pts
Median FU 20 months

PM/CRT: 5.2%

- PM SSS: 3%
- PM AVB: 1.1%
- CRT: 1.1%







Kutyifa V et al. Ann Noninvasive Electrocardiol. 2020;25:e12744

Incidence of recurrent MVT in typical ICD pts: SCD-HeFT

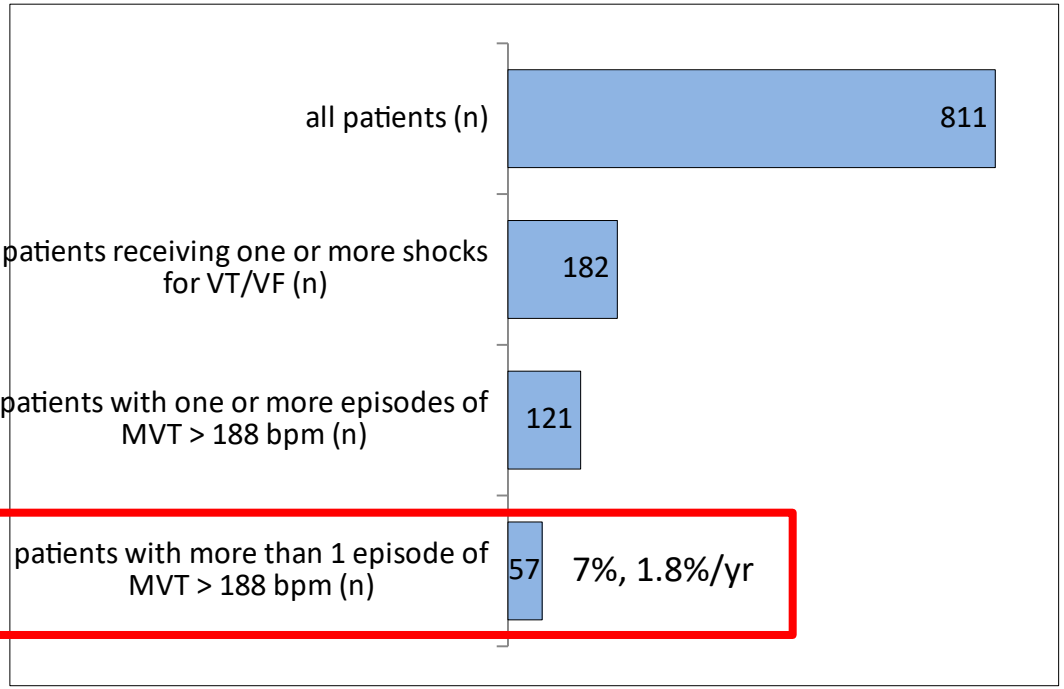
FU 45.5 months **7%** had > than a single episode of **fast MVT** > 188 bpm.

This corresponds to a **1.8% incidence per year**,

it is unknown how many are self-terminable events,

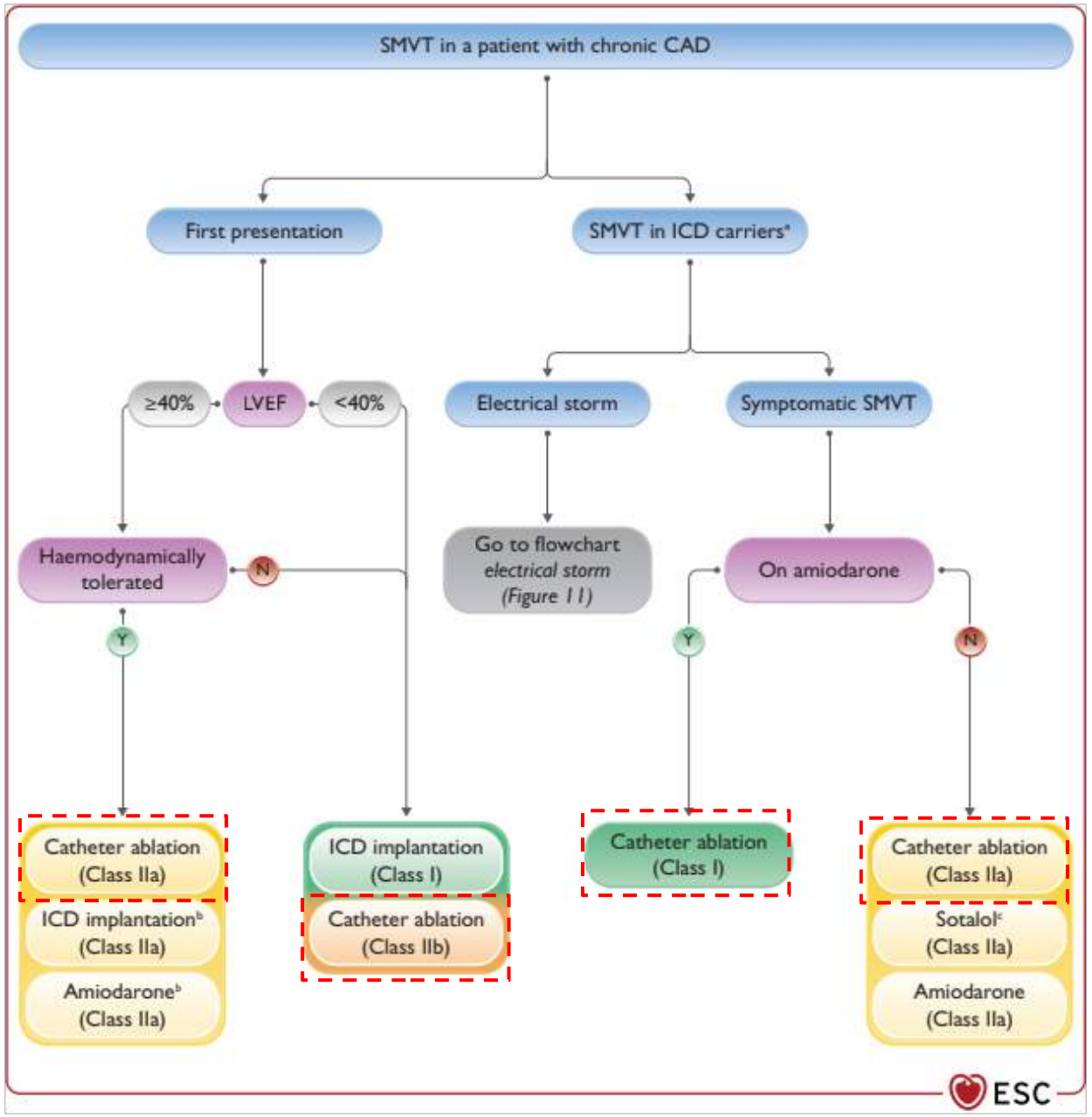
or would have been treated successfully by ATP

(ATP was not available)

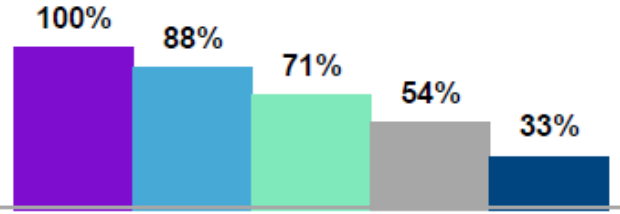
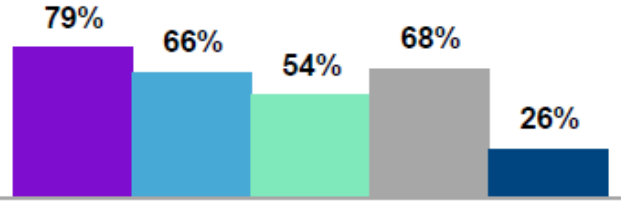
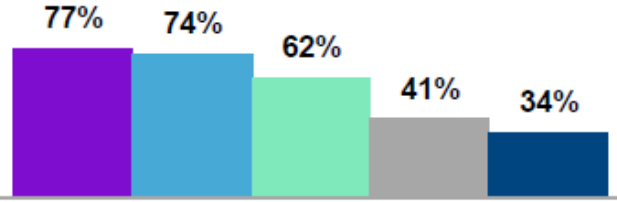
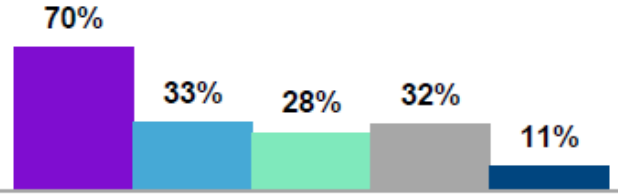


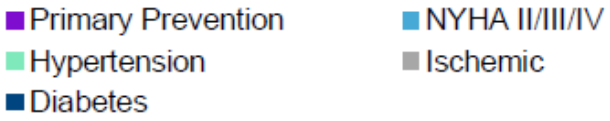
Poole J. NEJM 2008; 359: 1009–1017

How often ATP is really needed ?: MADIT-RIT



ATP/Pacing Indications at FU in S-ICD implanted patients in clinical trials

	Patient Demographics[1-4]	ATP	Pacing
UNTOUCHED | 1,111 pts Enrolled 2015 – 2018 | **18 Month Follow-up** Mean Age: 56 ± 12 | LVEF %: 26 ± 6		**2** (0.2%)	**0** (0.0%)
PRAETORIAN | 426 pts Enrolled 2011 – 2017 | **4 Year Follow-up** Median Age: 63 | LVEF %: 30 ± 5		**1** (0.2%)	**4** (0.9%)
PAS | 1,637 pts Enrolled 2013 – 2015 | **1 Year Follow-up** Mean Age: 53 ± 15 | LVEF %: 32 ± 15		**0** (0.0%)	**2** (0.1%)
EFFORTLESS | 984 pts Enrolled 2011 – 2014 | **5 Year Follow-up** Mean Age: 48 ± 18 | LVEF %: 43 ± 18		**7** (0.7%)	**4** (0.4%)



CRM-1011501-AA

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Save this study

Effectiveness of the EMPOWER™ Modular Pacing System and EMBLEM™ Subcutaneous ICD to Communicate Antitachycardia Pacing (MODULAR ATP)

⚠ The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT04798768

Recruitment Status : Active, not recruiting
First Posted : March 15, 2021
Last Update Posted : June 3, 2022

Sponsor:
Boston Scientific Corporation

Information provided by (Responsible Party):
Boston Scientific Corporation

Study Details | Tabular View | No Results Posted | Disclaimer | How to

MODULAR ATP Clinical Study

Effectiveness of the EMPOWER™ Modular Pacing System and EMBLEM™ Subcutaneous ICD to Communicate Antitachycardia Pacing

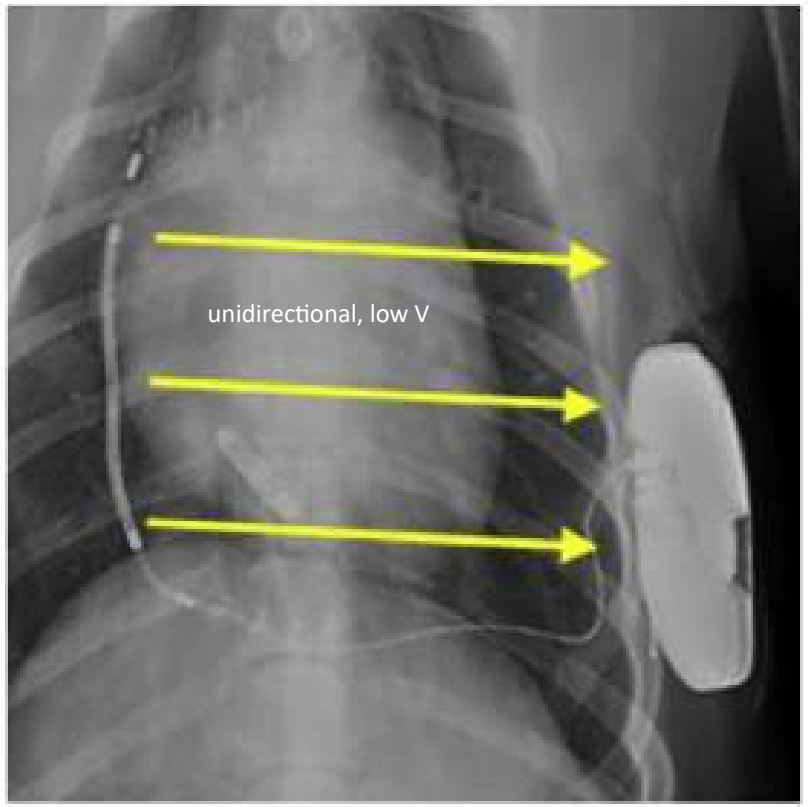
C1907

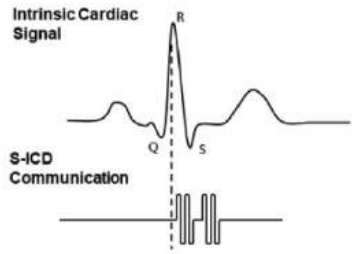
CLINICAL INVESTIGATION PLAN

2 Protocol Synopsis

MODULAR ATP Clinical Study Effectiveness of the EMPOWER™ Modular Pacing System and EMBLEM™ Subcutaneous ICD to Communicate Antitachycardia Pacing	
Study Objectives	To demonstrate the safety, performance and effectiveness of the EMPOWER™ Modular Pacing System (MPS), as well as the EMPOWER and EMBLEM™ Subcutaneous ICD Coordinated System. Additionally, data from this study may be used to support pre-market and post-market approval requirements for the EMPOWER MPS.
Planned Indication(s) for Use	The mCRM Modular Therapy System is intended to provide: • Defibrillation (tachyarrhythmia) therapy from the S-ICD, which is used to treat rhythms associated with sudden cardiac death (SCD), such as VT and VF • Anti-tachycardia pacing (ATP) therapy, commanded from the S-ICD and provided from the EMPOWER System for the treatment of MVT • Anti-bradycardia pacing from the EMPOWER System to detect and treat bradyarrhythmias and to provide pacing support after defibrillation therapy

Operation of the Modular CRM System



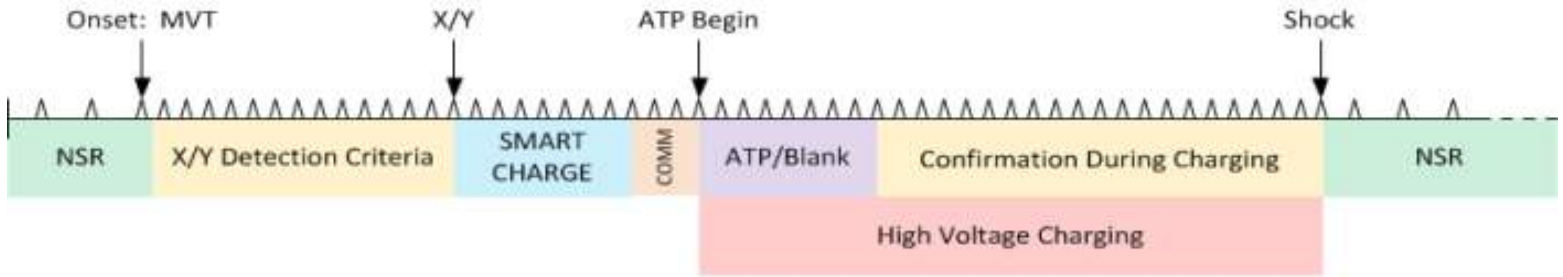


- Communication coupled to sensed R-wave
- Emitted signals are approximately 0.5-4V amplitude and 25kHz frequency
- Built-in redundancy of 2 messages sent

Modularity:
S-ICD first, LPM later
LPM first, S-ICD later
SICD & LPM together

1. **LPM** designed to sense and treat **bradycardia** independently from the S-ICD
2. **ATP** schemes are built into the leadless pacemaker, but can be activated only by the S-ICD or the programmer
3. **S-ICD** will continue to sense tachycardia, following which it is designed to command ATP in the leadless pacemaker prior to a shock

Example of ATP during charge in the Shock Zone



ESC European Society of Cardiology
Europace (2023) 25, 1–6
https://doi.org/10.1093/europace/euad347
CLINICAL RESEARCH

Long-term performance of single-connector (DF4) implantable defibrillator leads

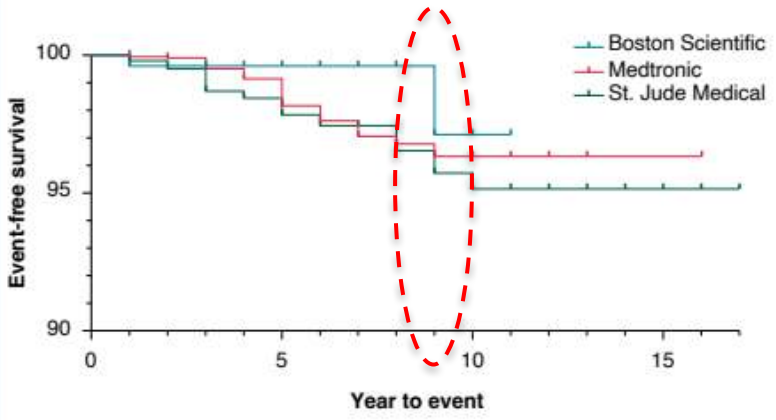
Rand Ibrahim, Mounir Al-Gibbawi, Wissam Mekary, Neal Kumar Bhatia, Soroosh Kiani, Stacy B. Westerman, Anand D. Shah, Michael S. Lloyd, Miguel Leal, David B. De Lurgio, Anshul M. Patel, Christine Tompkins, Angel R. Leon, Faisal M. Merchant, and Mikhael F. El-Chami *

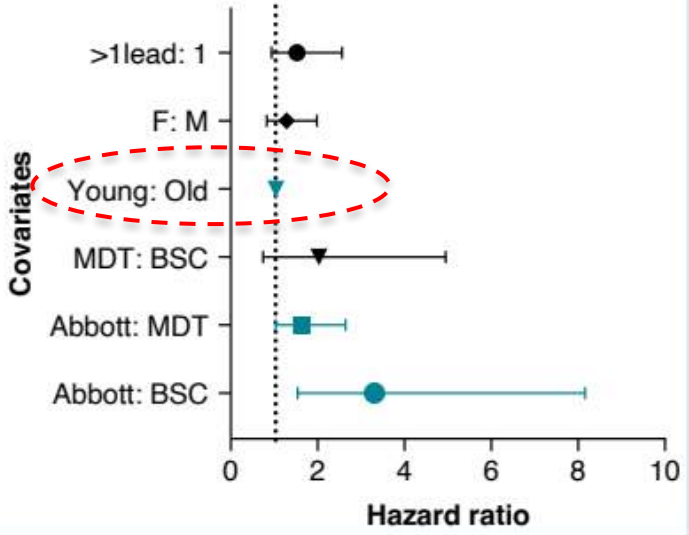
Improved performance of contemporary TV lead *(but still time-dependent)*

Lead malfunction was defined as any *electrical abnormality requiring lead revision*

Graphical Abstract

5,289 DF4 ICD leads followed at our institution. Mean FU after implant: 4.15±3.6 years (median=3.63)
Failure rate during follow-up 1.5% Median time to failure 3.5 yrs
Different survival rates among manufacturers noted





Ibrahim R et al; Europace (2023) 25, 1–6

ESC European Society of Cardiology
Europace (2023) 25, 1–11 https://doi.org/10.1093/europace/euad239
CLINICAL RESEARCH

Modern subcutaneous implantable defibrillator therapy in patients with cardiomyopathies and channelopathies: data from a large multicentre registry

Federico Migliore [1]*, Mauro Biffi [2], Stefano Viani [3], Raimondo Pittorru [1], Pietro Francia [4], Paolo Pieragnoli [5], Paolo De Filippo [6], Giovanni Bisignani[7], Gerardo Nigro [8], Antonio Dello Russo [9], Ennio Pisanò [10], Pietro Palmisano [11], Antonio Rapacciuolo [12], Massimo Stefano Silvetti [13], Carlo Lavalle [14], Antonio Curcio [15], Roberto Rordorf [16], Mariolina Lovecchio[17], Sergio Valsecchi [17], Antonio D'Onofrio [18†], and Giovanni Luca Botto [19†], on behalf of 'S-ICD Rhythm Detect' Investigators

Retrospective analysis of 628 CM/Channel. pts (Rhythm Detect Italian Registry) implanted with a *«modern» S-ICD model* (equipped with SMART-Pass filter) from Jan 2016 to Dec 2020, with at least 2 yrs FU (median FU 43 months).

Table 1 Baseline clinical characteristics and implantation variables of the overall study population and of patients stratified according to the type of underling cardiomyopathy and channelopathy

	Overall (*n* = 628)	Dilated Cardiomyopathy (*n* = 192)	HCM (*n* = 183)	ACM (*n* = 64)	BrS (*n* = 100)	LQTS (*n* = 16)	Idiopathic VF (*n* = 73)
Age, years	46 ± 15	52 ± 12	44 ± 15	38 ± 16	44 ± 12	36 ± 16	45 ± 15
Male gender, *n* (%)	480 (76)	157 (82)	143 (78)	42 (66)	80 (80)	8 (50)	50 (68)
Body mass index, kg/m^2	26 ± 4	27 ± 5	26 ± 4	24 ± 3	25 ± 4	24 ± 4	25 ± 3
Ejection fraction, %	49 ± 16	30 ± 8	60 ± 10	53 ± 10	62 ± 5	61 ± 5	56 ± 9
Primary prevention, %	506 (81)	181 (94)	173 (94)	54 (84)	88 (88)	10 (62)	0 (0)
S-ICD in intermuscular pocket, *n* (%)	484 (77)	153 (80)	140 (77)	53 (83)	77 (77)	12 (75)	49 (67)
Two-incision technique, *n* (%)	581 (93)	182 (94)	167 (91)	61 (95)	91 (91)	14 (88)	66 (90)
Emblem generator, model A219	503 (80)	155 (81)	142 (78)	58 (91)	82 (82)	14 (87)	52 (71)
Dual-zone programming, *n* (%)	622 (99)	188 (98)	181 (99)	64 (100)	100 (100)	16 (100)	73 (100)
Conditional zone, b.p.m.	210 (200–220)	200 (200–210)	210 (200–220)	210 (200–220)	210 (200–220)	210 (200–220)	210 (200–220)
Shock zone, b.p.m.	230 (210–250)	220 (210–250)	230 (230–250)	230 (220–250)	230 (220–240)	235 (225–240)	230 (210–250)
Sensing vector:							
• Primary, *n* (%)	367 (58)	121 (63)	113 (62)	39 (61)	44 (44)	12 (75)	38 (52)
• Secondary, *n* (%)	217 (35)	58 (30)	52 (28)	22 (34)	52 (52)	3 (19)	30 (41)
• Alternate, *n* (%)	44 (7)	13 (7)	18 (10)	3 (5)	4 (4)	1 (6)	5 (7)

HCM, hypertrophic cardiomyopathy; ACM, arrhythmogenic cardiomyopathy; BrS, Brugada syndrome; LQTS, long-QT syndrome; VF, ventricular fibrillation.

I EP IAS/AS

- Total IAS: 10%; 11% CM, 8% Chann. **83% managed by reprogramming/medical TX**
- Total AS: 6%
  Final conversion rate 97%

II EP Device Related Complications

- Pocket infection/erosion: 1%
- Lead-related: 1.1%
- **Battery depletion: 8%**
- Need for pacing: 0.8%
- No replacement for ATP

Table 2 Rate of endpoints at 12 months: inappropriate shocks, appropriate shocks, and device-related complications

Twelve-month rate (95% CI)	Inappropriate shocks	Appropriate shocks	Device-related complications
Overall (*n* = 628)	3.5% (95% CI: 2.2–5.3)	2.2% (95% CI: 1.2–3.7)	1.8% (95% CI: 0.9–3.1)
Cardiomyopathies (*n* = 439)	4.6% (95% CI: 2.8– 6.9)	2.3% (95% CI: 1.1– 4.1)	0.9% (95% CI: 0.3– 2.3)
• Dilated cardiomyopathy (*n* = 192)	3.1% (95% CI: 1.2–6.7)	1.6% (95% CI: 0.3–4.5)	1.0% (95% CI: 0.1–3.7)
• HCM (*n* = 183)	3.8% (95% CI: 1.6–7.7)	1.6% (95% CI: 0.3–4.7)	0.5% (95% CI: 0.1–3.9)
• ACM (*n* = 64)	10.9% (95% CI: 4.5–21.2)	6.3% (95% CI: 1.7–15.2)	1.6% (95% CI: 0.0–8.4)
Channelopathies (*n* = 189)	1.1% (95% CI: 0.1– 3.8)*	2.1% (95% CI: 0.6– 5.3)#	3.2% (95% CI: 1.2– 6.8)$
• Brugada syndrome (*n* = 100)	0.0% (95% CI: 0.0–3.6)	0.0% (95% CI: 0.0–3.6)	3.0% (95% CI: 0.6–8.5)
• Long-QT syndrome (*n* = 16)	6.3% (95% CI: 0.2–30.2)	0.0% (95% CI: 0.0–20.6)	6.3% (95% CI: 0.2–30.2)
• Idiopathic VF (*n* = 73)	1.4% (95% CI: 0.0–7.4)	5.5% (95% CI: 1.5–13.4)	2.7% (95% CI: 0.3–9.5)

HCM, hypertrophic cardiomyopathy; ACM, arrhythmogenic cardiomyopathy; VF, ventricular fibrillation.
*$P = 0.032$, #$P = 1.000$, and $P = 0.074$ vs. cardiomyopathies.

Migliore F et al., Europace 2023; 25, 1-11

TV-ICD vs S-ICD: come personalizzare la terapia nella pratica clinica ?

Circulation

PERSPECTIVE

Precision Medicine Versus Evidence-Based Medicine

Individual Treatment Effect Versus Average Treatment Effect

LIMITATIONS OF RANDOMIZED TRIALS FOR INDIVIDUAL PATIENT TREATMENT DECISIONS

Randomized trials focusing on average treatment effect hide heterogeneity in individual patient response.

Blackstone EH, Circulation. 2019;140:1236–1238

- the right treatment
- to the right patient
- at the right time

FDA definition

A proposed contemporary flow-chart

Class I or II indication for ICD

NO — *Current* need for: — YES

I step

Atrial pacing (3% of typical ICD population) → ICDDR

CRT (30% of HF patients with ICD indication) → CRTD

S-ICD or ICDVR

← *first choice* if age < 70 yrs or High Infection Risk

← *first choice* if age ≥ 70 yrs or unsuitable S-ICD screening

NO — Clinical history of SMVT — YES

II step

S-ICD or ICDVR

← *first choice* if age < 70 yrs or High Infection Risk

← *first choice* if age ≥ 70 yrs or unsuitable S-ICD screening

ICDVR or S-ICD →

first choice especially if: MVT ≤ 170 (+ ablation ?) or unsuitable S-ICD screening

should be considered if FVT and young age or HIR (consider ablation)

Conclusioni

Dopo quasi 15 aa di pratica clinica, ricerca scientifica ed evoluzione tecnologica S-ICD ha dimostrato un'efficacia paragonabile a quella di TV-ICD nel trattamento della morte improvvisa tachi-aritmica.

Le complicanze «lead-related», in particolare quelle a lungo termine (malfunzionamento/infezioni), sono significativamente inferiori nei pazienti impiantati con S-ICD e significativamente più sicuro è il loro trattamento e migliore l'outcome ad esso correlato.

Nei pazienti che, al momento dell'impianto, hanno una più lunga aspettativa di vita (e quindi una più alta probabilità di avere complicanze lead-related a lungo termine), S-ICD dovrebbe essere considerato *la prima scelta* quando non via sia indicazione al pacing di resincronizzazione, anti-bradicardico o anti-tachicardico.

TV-ICD resta una valida opzione in tutti gli altri casi, anche in relazione al miglioramento della performance degli elettrocateteri transvenosi di generazione più recente. Studi sono in corso sulla possibilità di associare un sistema S-ICD a un LPM che sia in grado di erogare pacing (VVIR) e ATP.

Oggi la tecnologia garantisce la possibilità di effettuare una «medicina di precisione» individuando la terapia ottimale per il singolo paziente al momento opportuno della sua storia clinica.

…In ricordo del Dr. Ezio Soldati…

Un saluto e un grazie, Ezio..!