IS SUBCUTANEOUS ICD READY TO REPLACE TRANSVENOUS DEFIBRILLATOR IN SUDDEN CARDIAC DEATH PREVENTION?

Pros

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A.O.R.N. dei Colli Ospedale Monaldi

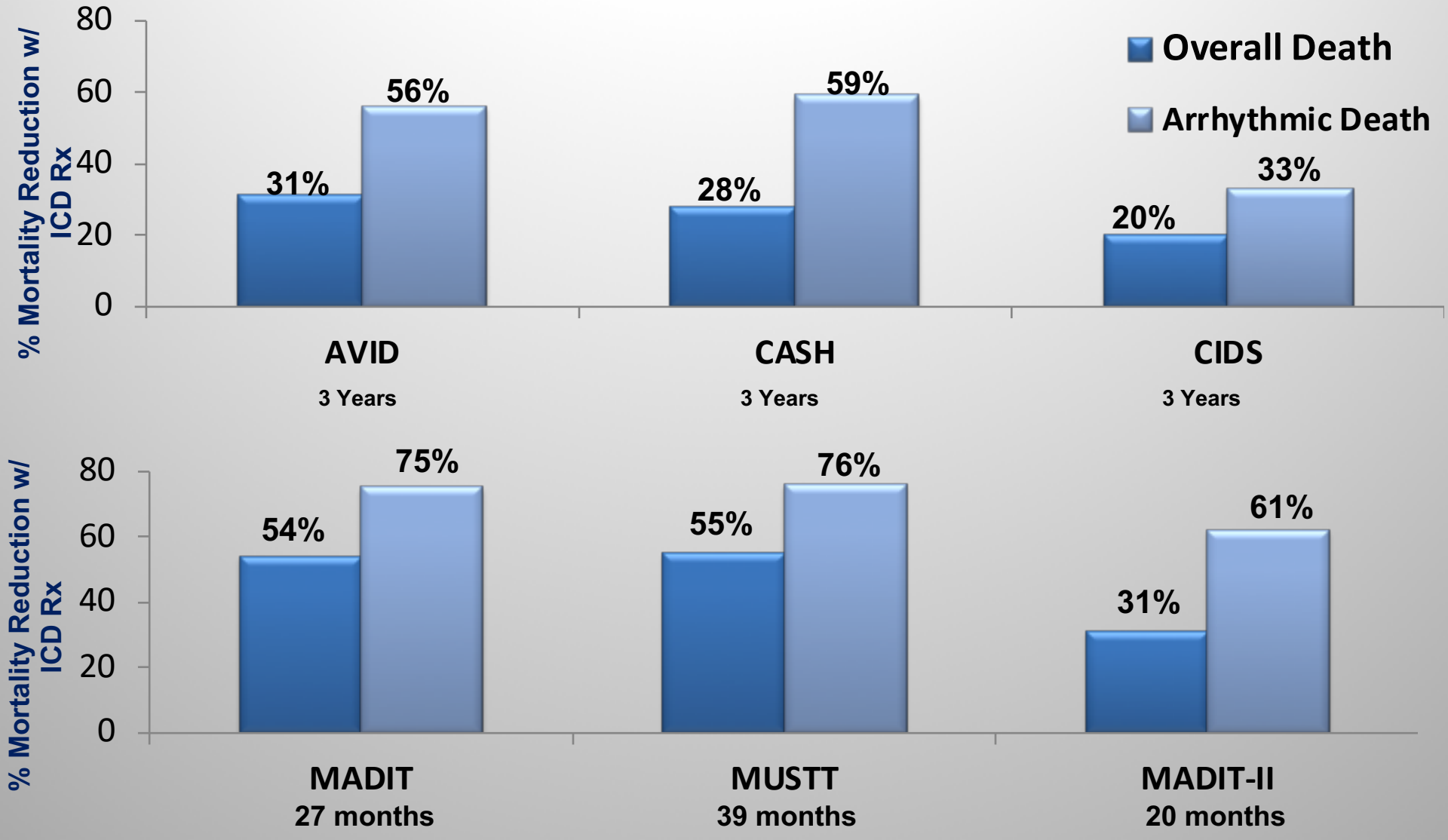
Napoli

DISCLOSURE

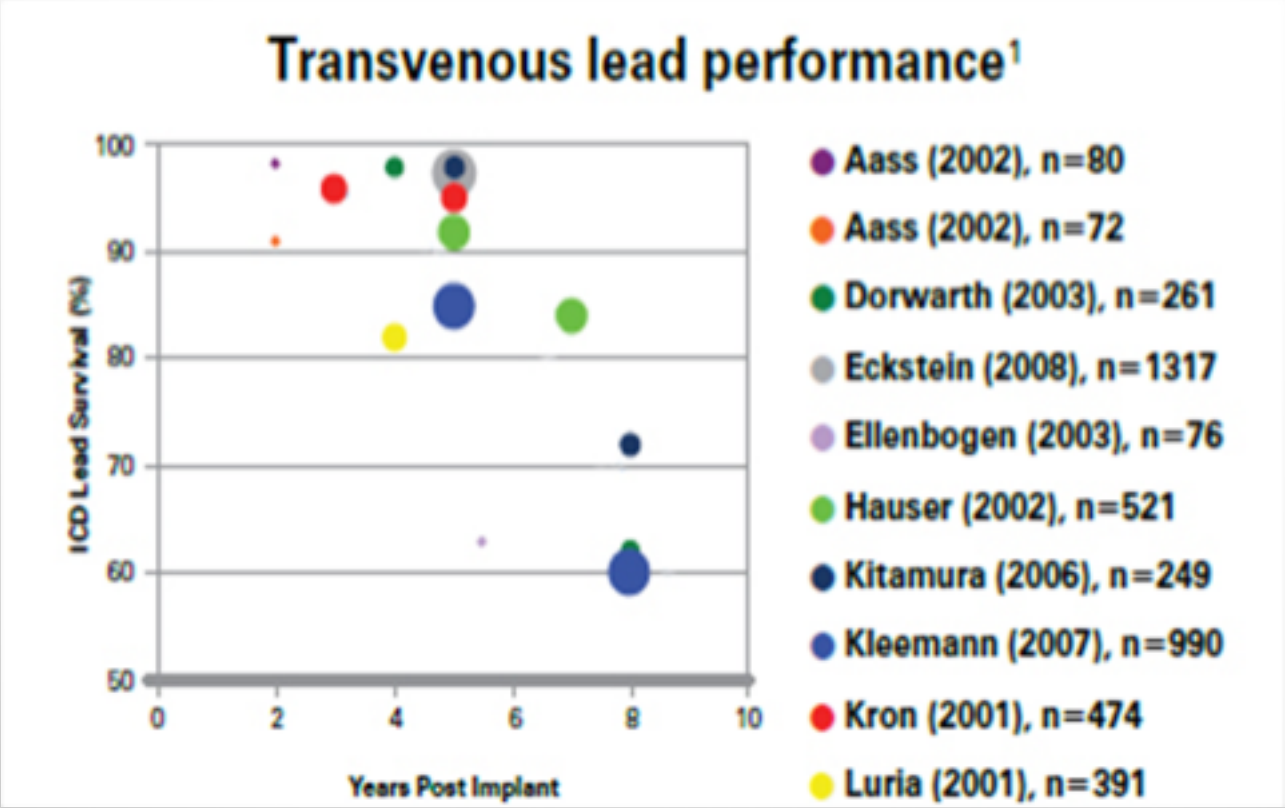
STIMO molto il dott. Mauro Biffi

- **E’ una brava persona**
- **Colto ed Esperto**
- **Onestà intellettuale**

TV-ICD Trials
Prevenzione Primaria e Secondaria



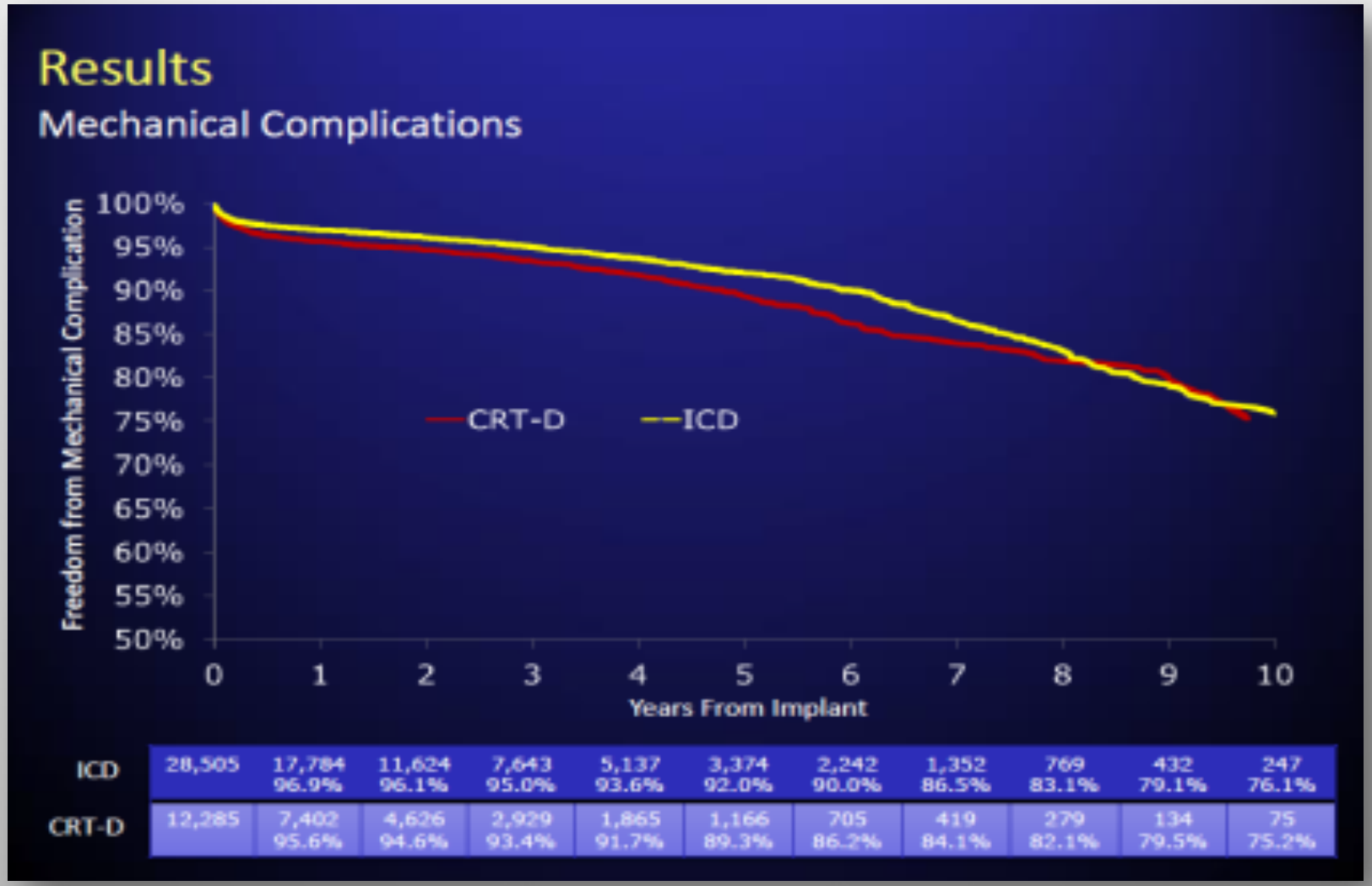
Limiti della tecnologia ICD transvenosa



I sistemi transvenosi sono stati tuttavia associati a complicanze correlate alla difficoltà di mantenere l'integrità dell'elettrocatetere e dell'accesso vascolare a lungo termine.[1]

Kleeman T. Circulation 2007; 115: 2474-80
Borleffs A. Circ Arrhythmia Electrophysiol. 2009; 2: 411-416.

Optum Database: dati su + 40.000 impianti da assicurazioni USA



ICD	28,505	17,784 96.9%	11,624 96.1%	7,643 95.0%	5,137 93.6%	3,374 92.0%	2,242 90.0%	1,352 86.5%	769 83.1%	432 79.1%	247 76.1%
CRT-D	12,285	7,402 95.6%	4,626 94.6%	2,929 93.4%	1,865 91.7%	1,166 89.3%	705 86.2%	419 84.1%	279 82.1%	134 79.5%	75 75.2%

Il 25% dei pazienti (1 su 4) ha almeno una complicanza in 10 anni

Il panorama dell'estrazione transvenosa degli elettrocateteri in Europa: il Registro ELECTRA EHRA

- ✓ 3500 pazienti in 2 anni in 76 Centri
- ✓ 6433 cateteri estratti di cui 3105 da ICD
- ✓ Infezione 52,7%
- ✓ Malfunzionamento 27,4%
- ✓ Perforazione cardiaca 2,1%

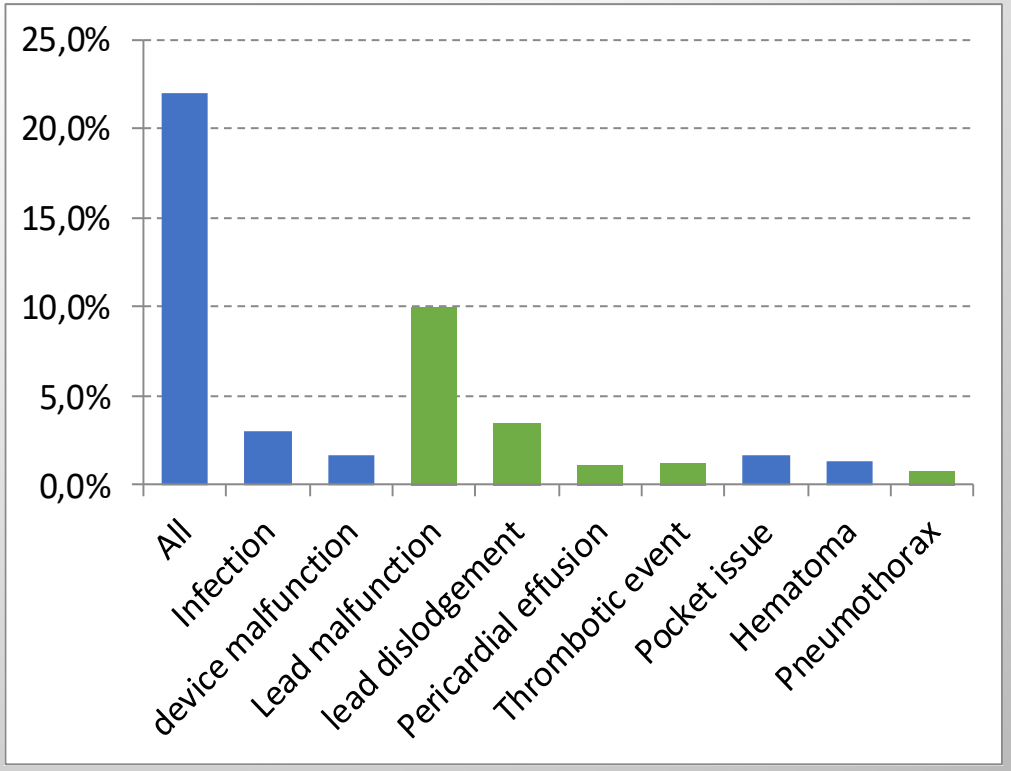
mortalità 6,5% 1 anno post-estrazione

mortalità 15,1% a 1 anno a seguito di infezione sistemica con conseguente estrazione dell'elettrocatetere

Lead Failure Is Most Important Source Of Complications In Young Patients

Up to 70% of all complications in young ICD recipients are lead-related, including both lead malfunction & lead placement issues

- Systematic meta of 63 studies
- N = 4915 ICD recipients with inherited arrhythmia syndromes
  - ARVC: 710
  - BrS: 1037
  - CPVT: 28
  - HCM: 2466
  - LMNA: 162
  - LQT: 462
  - SQT: 51
- Age: 39±15 years
- Follow-up: 53±26 months
- 55% VR-ICD



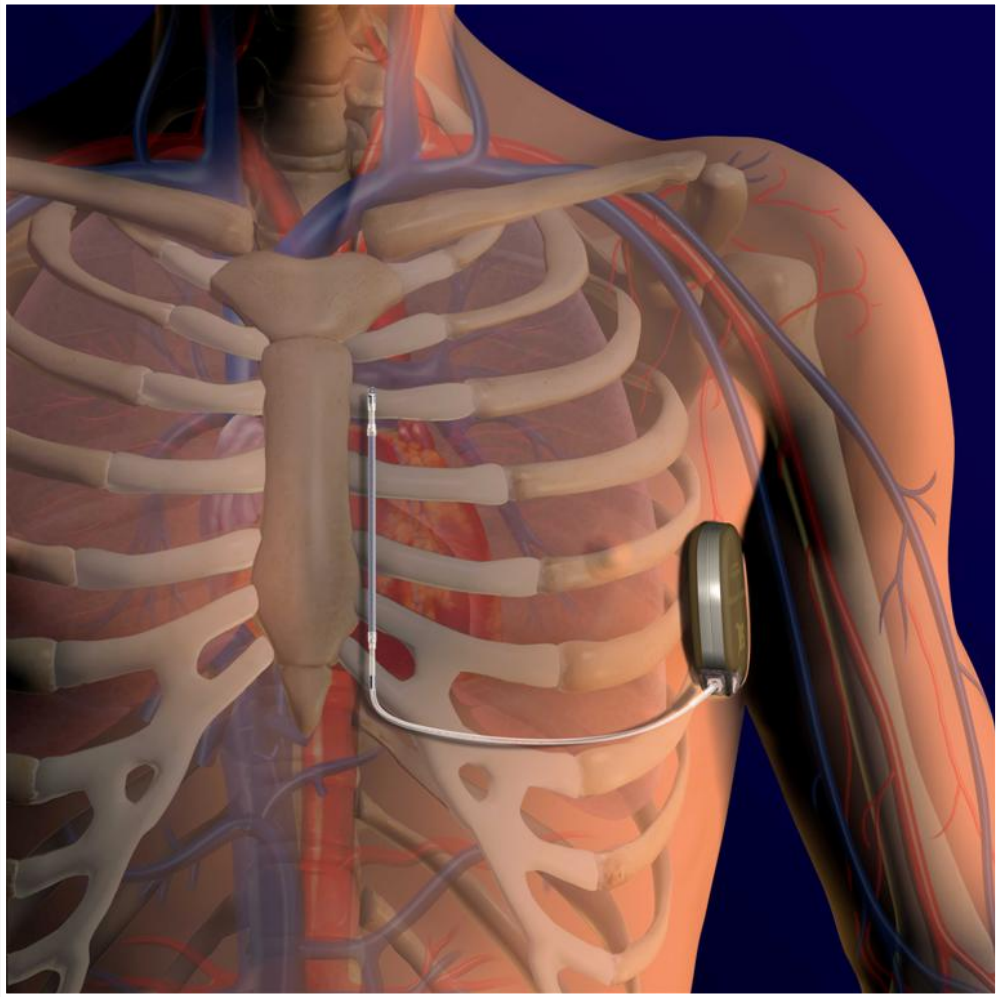
La maggior parte delle complicanze nei PTS ICD giovani sono causate da guasti dell'elettrocatetere (10%) e/o dall'impianto dell'elettrocatetere (6,5%)

L.R.A. Olde Nordkamp LRA. Heart Rhythm 2015

The S-ICD System

Completely Subcutaneous System

- Preserved Venous System
- Safer remotion



- **80 J max output**

  5 shock max for episode

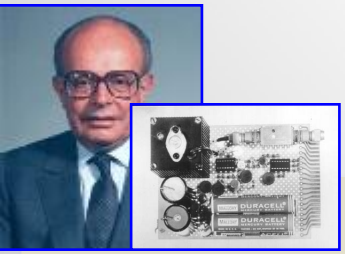
- **Biphasic wave, tilt 50%**
- **Adaptive shock polarity**

  Polarity switch on uneffective shock)

- **Post-shock pacing on demand,**

  max 30s, 50 bpm

S-ICD
Clinical road to the guidelines…



(1966)

Conceptual work

0

(1980)

first human implants

+10

+15

(1985)

first approved ICD

(1993)

first TV-ICD

ACC/AHA Guidelines for ICDs

(2002)

ACC/AHA/ESC Updated Guidelines

(2008)

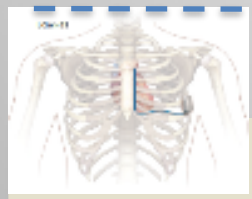
(2015)

…mainstream therapy!

New ESC Guidelines

first ICD guidelines

+36



(2000)

Conceptual work

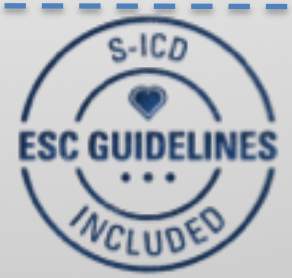
(2008)

first human implants

(2009)

first approved S-ICD

2nd Gen S-ICD



(2015)

AHA/ACC/HRS GUIDELINES

(2017)

Successful journey towards mainstream therapy!

2010

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
Derek T. Connelly, M.D., Simon P. Fynn, M.D., Francis D
Johannes Sperzel, M.D., Jörg Neuzner, M.D., Stefan
Andrey V. Ardashev, M.D., Ph.D., Amo Oduro,
Lucas Boersma, M.D., Ph.D., Alexander H. Ma
Isabelle C. Van Gelder, M.D., Ph.D., Arthur A. Wild
Pascal F. van Dessel, M.D., Reinoud E. Knops, M.D.,
Pierpaolo Lupo, M.D., Riccardo Cappato, M.D., and Andrey

CORRESPONDENCE

An Entirely Subcutaneous Implantable Cardioverter–Defibrillator

implantation may do so in subsequent years.[5] In conclusion, the subcutaneous ICD may have a role in treating patients with good ventricular function and infrequent events but may be an inferior choice, as compared with the conventional or new intravascular devices, for patients with substantial ventricular dysfunction.

Laszlo Buga, M.D.
Ahmed Tageldien, M.D.
John G. Cleland, M.D.

Arrhythmia/Electrophysiology

Safety and Efficacy of a Totally Subcutaneous Implantable-Cardioverter Defibrillator

Raul Weiss, MD; Bradley P. Knight, MD; Michael R. Gold, MD, PhD; Angel R. Leon, MD; John M. Herre, MD; Margaret Hood, MBChB; Mayer Rashtian, MD; Mark Kremers, MD; Ian Crozier, MBChB; Kerry L. Lee, PhD; Warren Smith, MD; Martin C. Burke, DO

2013

Conclusions

The S-ICD System is safe and well tolerated in a broad range of patients requiring ICD therapy. The S-ICD System is effective at detecting and treating both induced and spontaneous VT/VF. Chronic conversion testing results were consistent with acute conversion testing. Significant clinical complications were infrequent. Those that did occur were manageable without invasive intervention in the majority of cases. The S-ICD System represents a viable alternative to conventional ICD therapy in patients at risk of death from VT/VF.

Table 2. Characterization of Patient Groups for S-ICD Implantation

S-ICD is preferred device
No venous access (occluded veins or congenital anomalies)
High risk of complications for transvenous systems have (dialysis, pediatric, and immunocompromised)
Channelopathies (long-QT syndrome, Brugada, hypertrophic cardiomyopathy)
Previous device infections or lead failures
History of endocarditis
S-ICD should be strongly considered
Young patients
Life expectancy >10 y
Primary prevention indicated patients with ischemic/nonischemic heart failure
Prosthetic valves
Women (preferred generator placement lateral wall)
Selected secondary prevention indicated patients (survivors of out-of-hospital VF, no evidence of monomorphic VT
S-ICD should be avoided
Systolic heart failure and LBBB who are indicated for CRT
Symptomatic bradycardia requiring pacemaker
Recurrent sustained monomorphic VT for whom ATP is deemed appropriate

CONTROVERSIES IN ARRHYTHMIA AND ELECTROPHYSIOLOGY

Who Should Receive the Subcutaneous Implanted Defibrillator?

The Subcutaneous Implantable Cardioverter Defibrillator (ICD) Should Be Considered in all ICD Patients Who Do Not Require Pacing

Jeanne E. Poole, MD; Michael R. Gold, MD, PhD

2014

European Heart Journal
doi:10.1093/eurheartj/ehu112

CLINICAL RESEARCH
Arrhythmia/electrophysiology

Worldwide experience with a totally subcutaneous implantable defibrillator: early results from the EFFORTLESS S-ICD Registry

Pier D. Lambiase[1]*, Craig Barr[2], Dominic A
Jens Brock Johansen[6], Margaret Hood[7], Su
Francis Murgatroyd[11], Helen L. Reeve[12], N
on behalf of the EFFORTLESS Investigato

Conclusions

The first large cohort of real-world data from an International patient S-ICD system population demonstrates appropriate system performance with clinical event rates and inappropriate shock rates comparable with those reported for conventional ICDs.

2015

Safety and Efficacy of the Totally Subcutaneous Implantable Defibrillato

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

CONCLUSIONS

The S-ICD showed very high shock efficacy for spontaneous ventricular arrhythmias and a decreasing incidence of inappropriate shocks. The complication-free rate and low mortality rate extended beyond the first year. The rate of inappropriate shocks and the risks of infection and total complications decreased as physicians who performed the procedure gained more experience with the device. These data provided further support for the safety and efficacy of the S-ICD in patients with primary and secondary indications without pacing indications over a 3-year period.

S-ICD guidelines

2014

2015

ESC HCM Guidelines: Class IIb

Recommendations	Class[a]	Level[b]	Ref.[c]
Prior to ICD implantation, patients should be counselled on the risk of inappropriate shocks, implant complications and the social, occupational, and driving implications of the device.	I	C	219,327
ß-Blockers and/or amiodarone are recommended in patients with an ICD, who have symptomatic ventricular arrhythmias or recurrent shocks despite optimal treatment and device re-programming.	I	C	219,403
Electrophysiological study is recommended in patients with ICDs and inappropriate shocks due to regular supraventricular tachycardias, to identify and treat any ablatable arrhythmia substrate.	I	C	403
A subcutaneous ICD lead system (S-ICD™) may be considered in HCM patients who do not have an indication for pacing.	IIb	C	407

ESC SCD Guidelines: Class IIa

Subcutaneous implantable cardioverter defibrillator

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

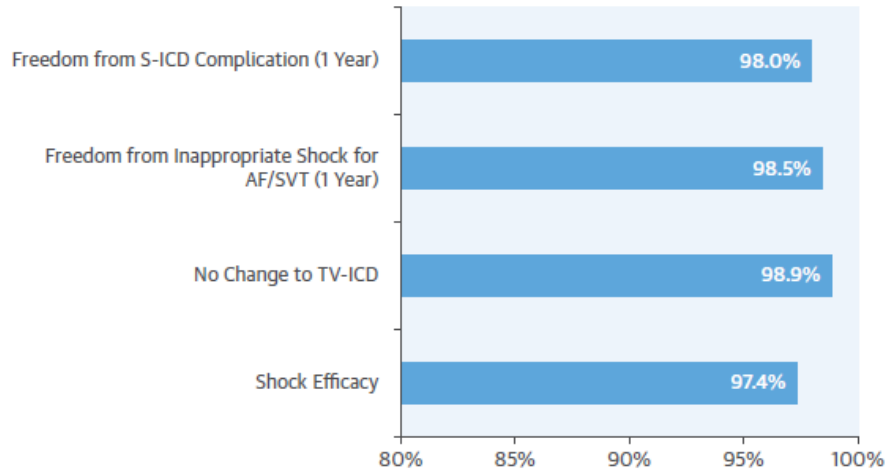
2017

Implant and Midterm Outcomes of the Subcutaneous Impla Cardioverter-Defibrillator R

The EFFORTLESS Study

Lucas Boersma, MD, PhD,[a,b] Craig Barr, MD,[c] Reinoud Knops, MD,[b] I
Petr Neuzil, MD, PhD,[f] Marcoen Scholten, MD, PhD,[g] Margaret Hood
Paul Jones, MS,[k] Elizabeth Duffy, MS,[k] Michael Husby, MS, MPH,[k] K
Pier D. Lambiase, MD, PhD,[l] on behalf of the EFFORTLESS Investiga

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



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

Subcutaneous Implantable Cardioverter-Defibrillator Finding a Place in Sudden Cardiac Death Pre

Emerging or Emerged?*

Jeanne E. Poole, MD, Jordan M. Prutkin, MD, MHS

Based on this and other studies, complication and efficacy rates with the S-ICD support the consideration of this device in any patient who only requires a single-chamber device and does not need bradycardia pacing at the time of implantation, CRT, or ATP. Perhaps **we should no longer consider the S-ICD as a novel or emerging technology, but as a viable alternative for many patients.**

30 Oct 2017

2017 AHA/ACC/HRS GUIDELINES

11.1. Subcutaneous Implantable Cardioverter-Defibrillator

Recommendations for Subcutaneous Implantable Cardioverter-Defibrillator
References that support the recommendations are summarized in Online Data Supplement 55.

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

Recommendation-Specific Supportive Text:

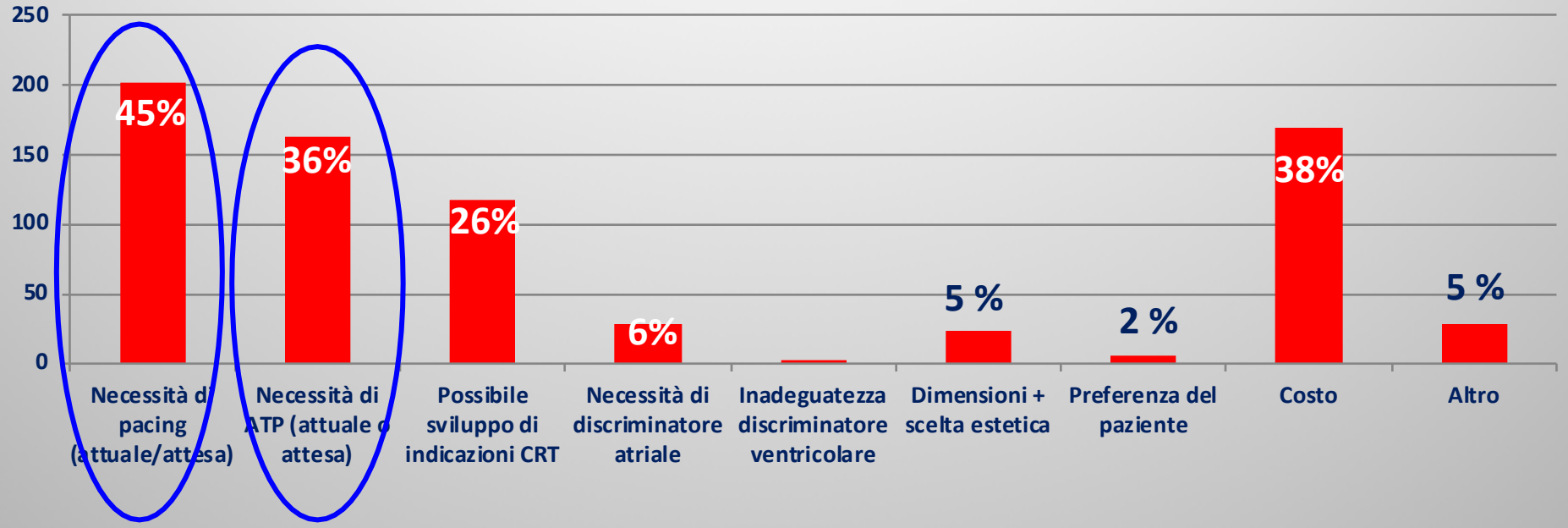
S-ICD preferred in patients at high risk of infection:

- prior device infection
- ESRD
- diabetes mellitus
- chronically immunosuppressed

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

2016

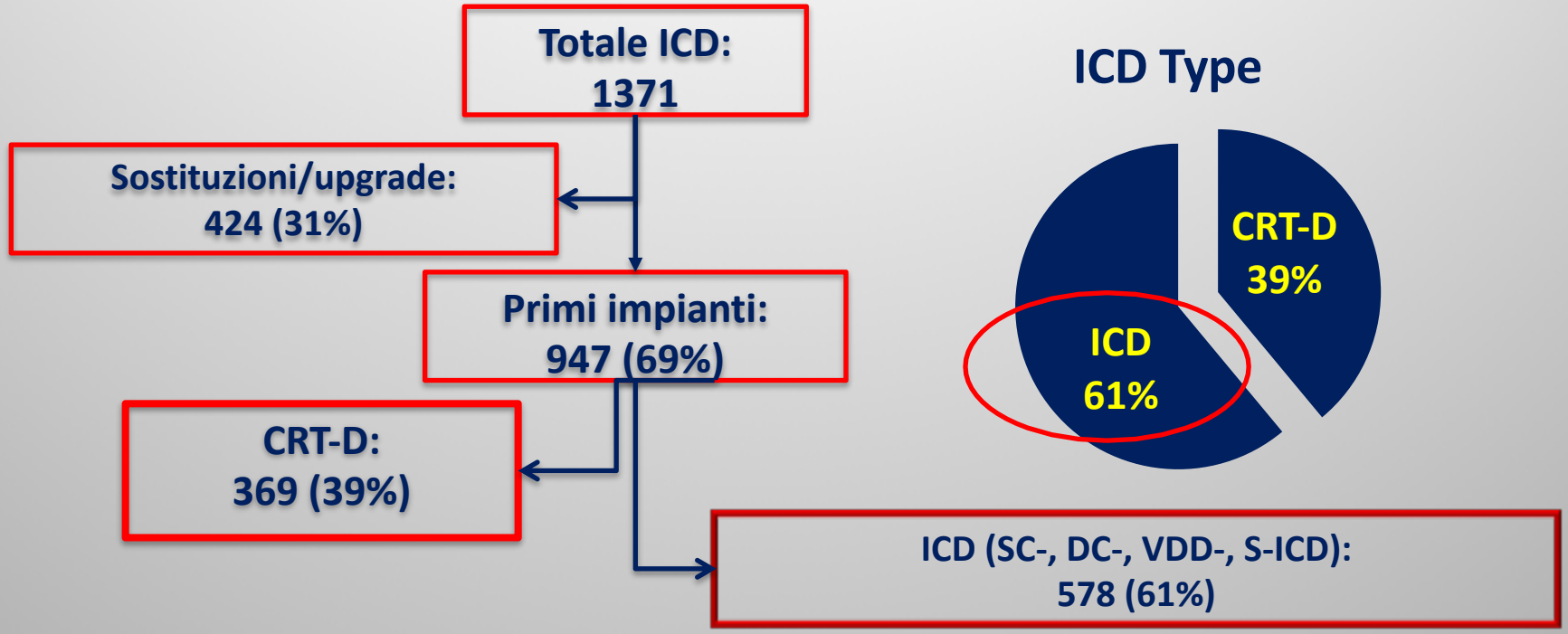
Giovanni Luca Botto[1*], Giovanni B. Forleo[2], Alessandro Capucci[3], Francesco Solimene[4], Antonello Vado[5], Giovanni Bertero[6], Pietro Palmisano[7], Ennio Pisanò[8], Antonio Rapacciuolo[9], Tommaso Infusino[10], Alessandro Vicentini[11], Miguel Viscusi[12], Paola Ferrari[13], Antonello Talarico[14], Giovanni Russo[1], Giuseppe Boriani[15], Luigi Padeletti[16], Mariolina Lovecchio[17], Sergio Valsecchi[17], Antonio D'Onofrio[18], on behalf of 'AIAC S-ICD Why Not' Survey Investigators



Europace Advance Access published December 23, 2016

Result From AIAC Survey

Survey in sintesi	
CENTRI partecipanti	33
>50 primi impianti/anno	24 (73%)
Durata media dell'osservazione	4 mesi
Totale procedure ICD nel periodo di osservazione	1371



Botto GL et al : Europace Advance Access published December 23, 2016

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

Giovanni Luca Botto[1]*, Giovanni B. Forleo[2], Alessandro Capucci[3], Francesco Solimene[4], Antonello Vado[5], Giovanni Bertero[6], Pietro Palmisano[7], Ennio Pisanò[8], Antonio Rapacciuolo[9], Tommaso Infusino[10], Alessandro Vicentini[11], Miguel Viscusi[12], Paola Ferrari[13], Antonello Talarico[14], Giovanni Russo[1], Giuseppe Boriani[15], Luigi Padeletti[16], Mariolina Lovecchio[17], Sergio Valsecchi[17], Antonio D'Onofrio[18]; on behalf of 'AIAC S-ICD Why Not' Survey Investigators

2016

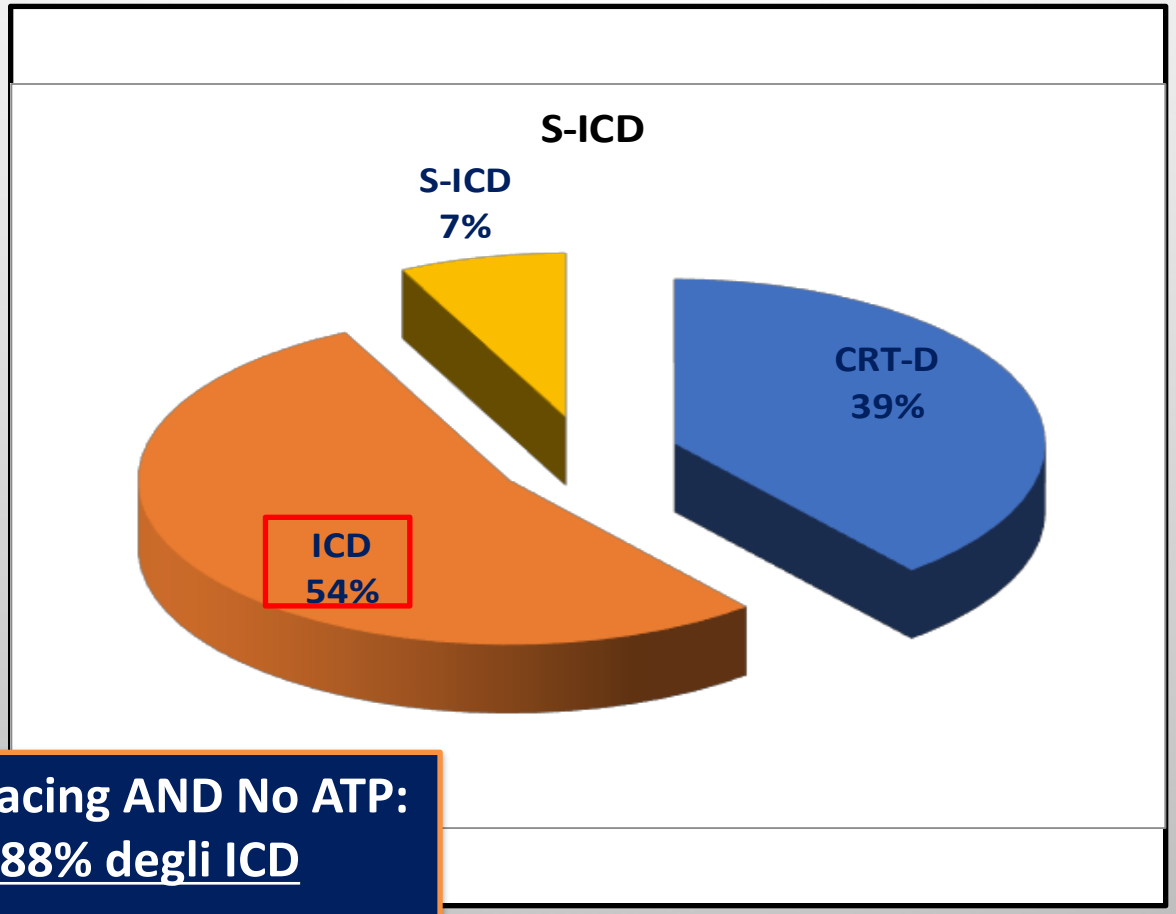
with channelopathies. Moreover, although the most common reasons for preferring a T-ICD over an S-ICD were the need for permanent pacing or ATP therapy, at the time of ICD implantation, only 7% of patients fulfilled conditions for Class I recommendation for permanent pacing. An additional 4% of patients presented with a history of unstable MVT that might have been treatable with ATP. The vast majority of patients needing therapy for SCD prevention might therefore be suitable candidates for S-ICD implantation.

Europace Advance Access published December 23, 2016

S-ICD : Why Not ?

Conclusion From AIAC Survey

- ✓ **39% CRT-D**
- ✓ **7% S-ICD** (12% dei pazienti senza indicazioni di CRT)
- ✓ **54% ICD** (VR/DR)



No pacing AND No ATP:
88% degli ICD

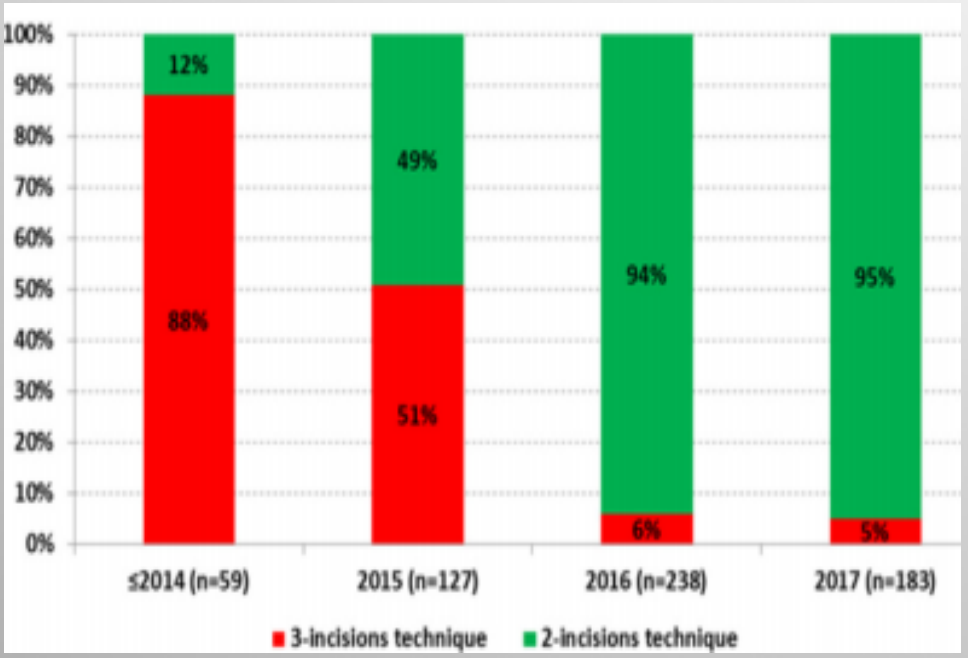
Contents lists available at ScienceDirect

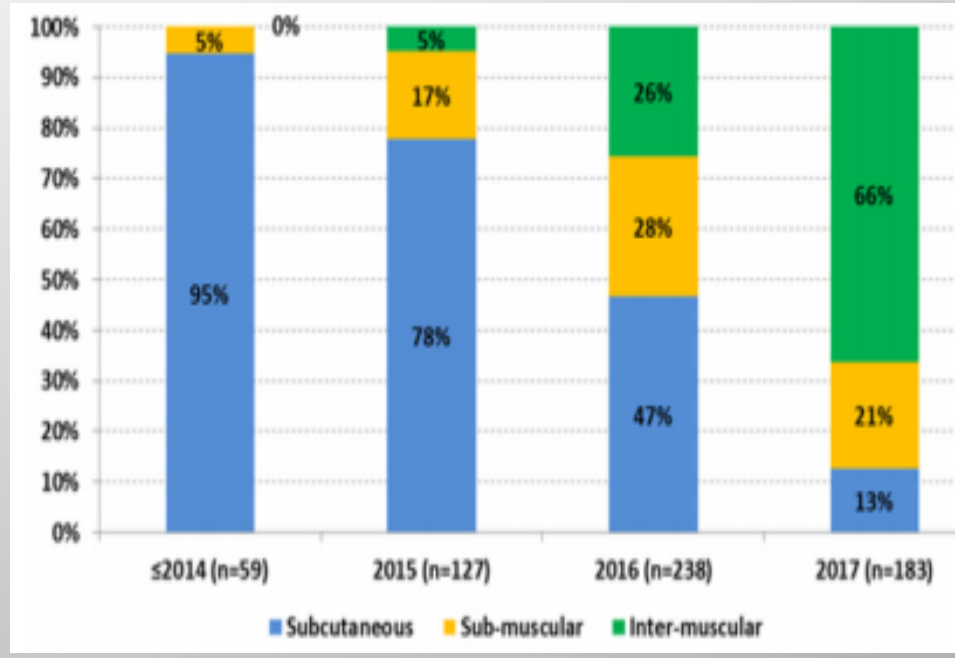
International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Subcutaneous implantable cardioverter defibrillator implantation: An analysis of Italian clinical practice and its evolution☆

Antonio D'Onofrio [a,*,1], Paolo Pieragnoli [b], Mauro Biffi [c], Gerardo Nigro [d], Federico Migliore [e], Pietro Francia [f], Paolo De Filippo [g], Alessandro Capucci [h], Giovanni Luca Botto [i], Massimo Giammaria [j], Pietro Palmisano [k], Ennio Pisanò [l], Giovanni Bisignani [m], Carmelo La Greca [n], Berardo Sarubbi [o], Simone Sala [p], Miguel Viscusi [q], Maurizio Landolina [r], Mariolina Lovecchio [s], Sergio Valsecchi [s], Maria Grazia Bongiorni [t], on behalf of "S-ICD Rhythm Detect" Investigators





Int J Cardiol (2018), https://doi.org/10.1016/j.ijcard.2018.07.139

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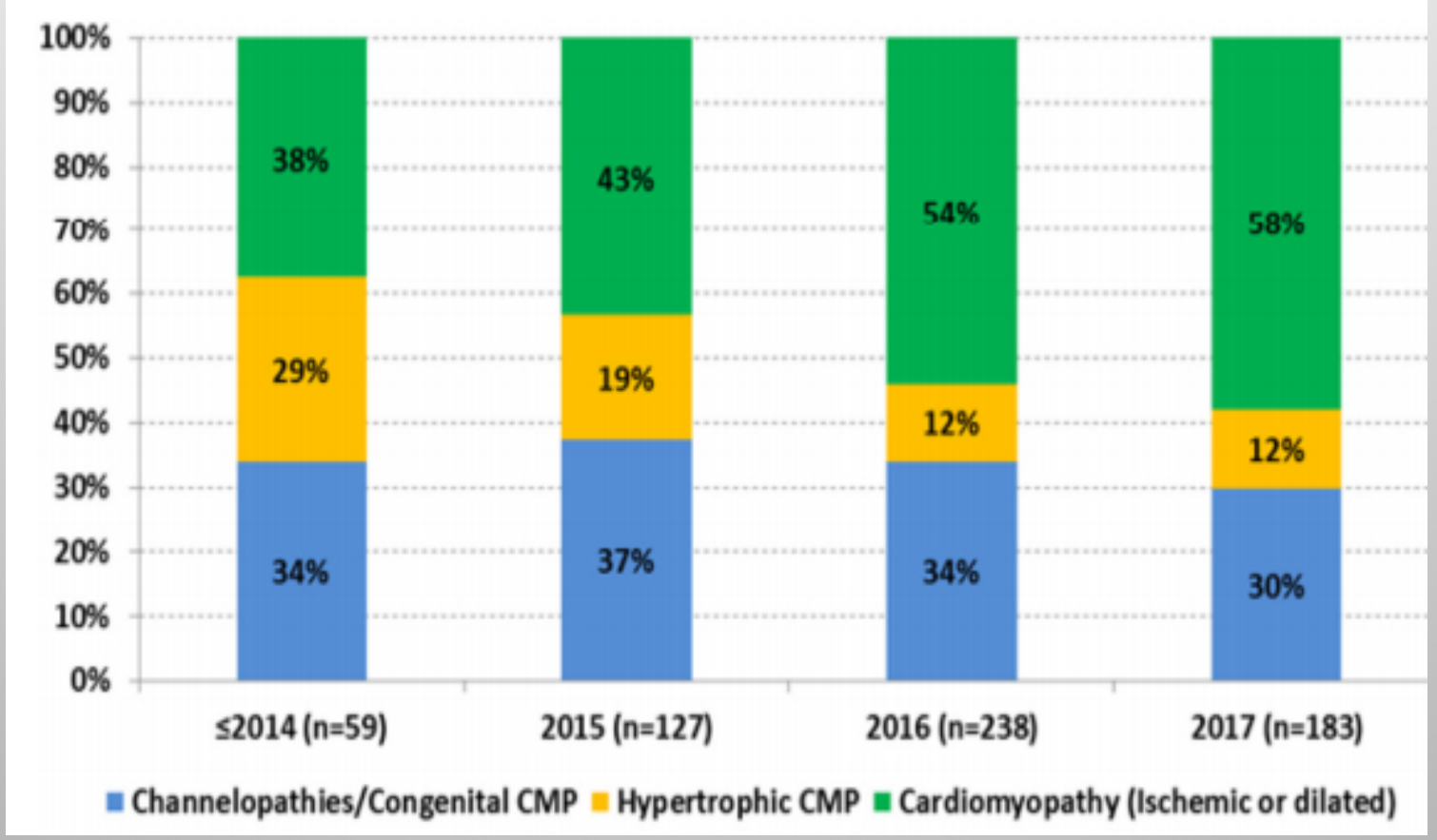

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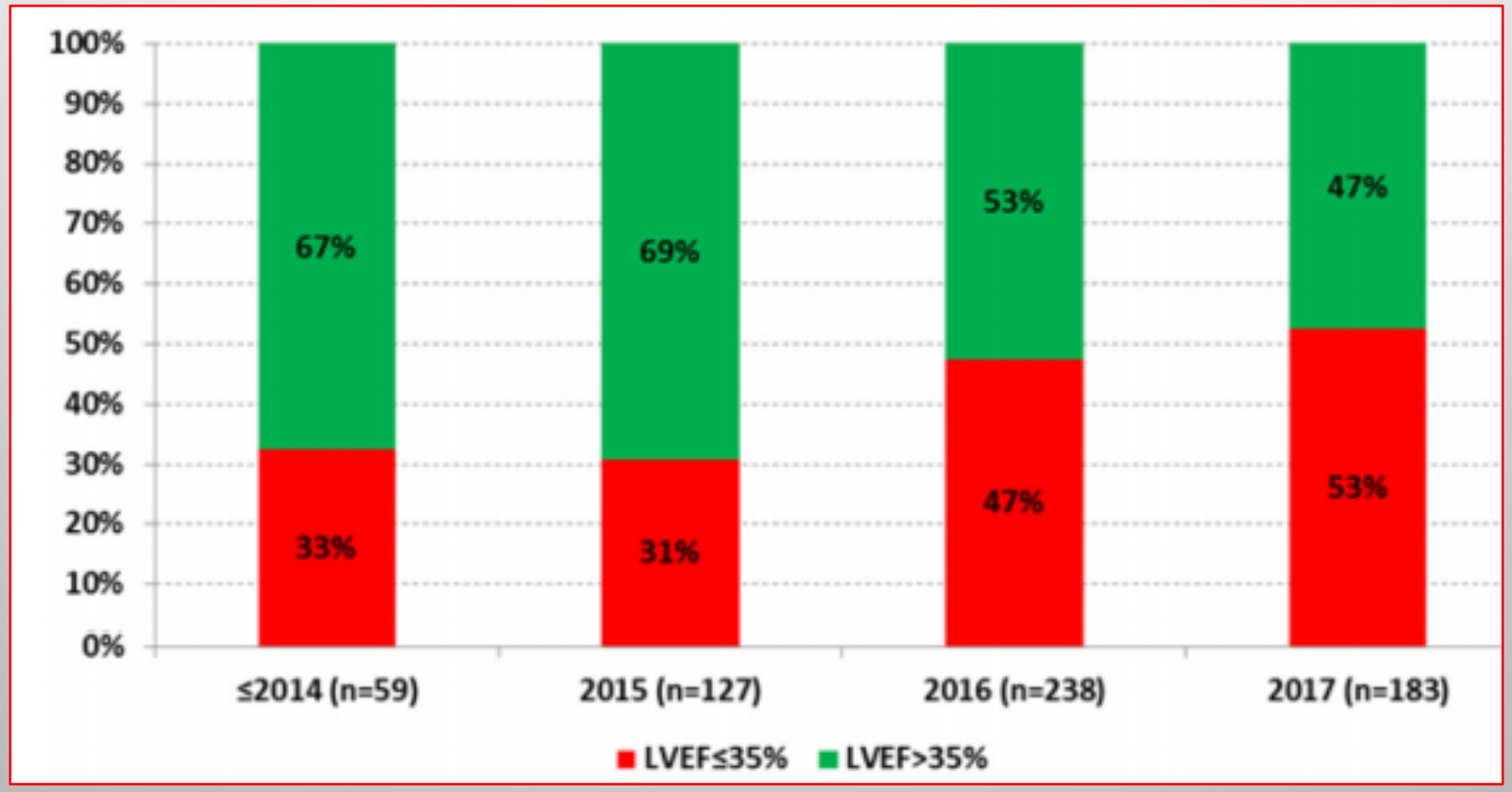


A D'Onofrio et al : Int J Cardiol (2018), https://doi.org/10.1016/j.ijcard.2018.07.139

IS SUBCUTANEOUS ICD READY TO REPLACE TRANSVENOUS DEFIBRILLATOR IN SUDDEN CARDIAC DEATH PREVENTION?

Rebuttal Pros

Antonio D'Onofrio MD, FAIAC, FANMCO, FESC

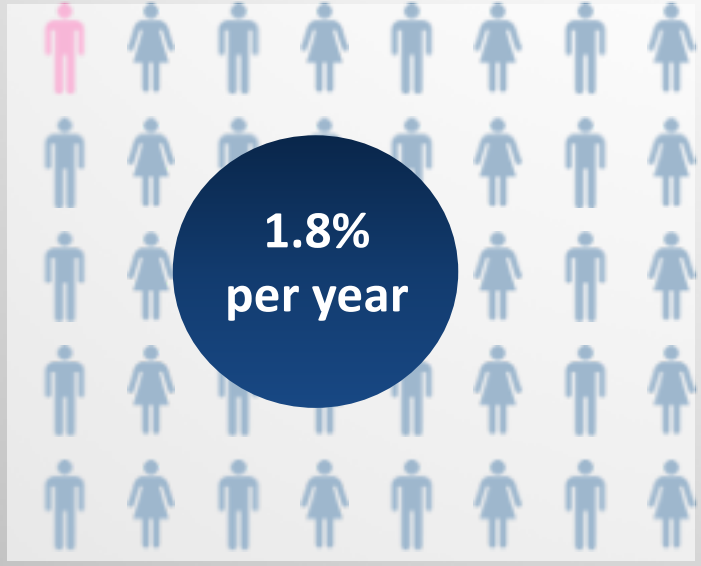
UOSD di Elettrofisiologia Studio e Terapia delle Aritmie

A.O.R.N. dei Colli Ospedale Monaldi

Napoli

ATP and ICD

What is the percentage of patients that **are at risk for recurrent monomorphic VT?**



On a yearly basis, **1.8% incidence** of Recurrent Monomorphic Ventricular Tachycardia, **for which ATP might be beneficial**[1]

However, at 4-year follow-up:

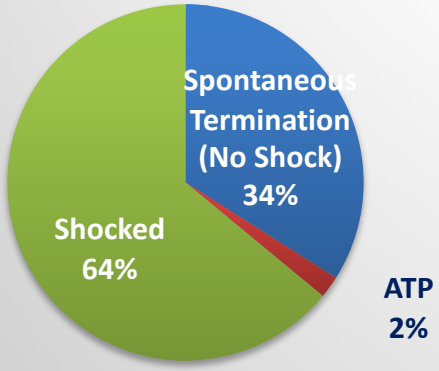
Risk of recurrent MVT[1]	**1.8% per year**
Risk of Transvenous Lead Failure Rate[2-4]	**3.0% per year**

While 100% of patients will benefit from freedom of transvenous lead failure thanks to the S-ICD System[5]

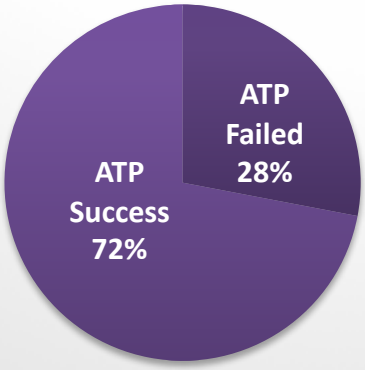
1. Poole, et al. Who Should Receive the Subcutaneous Implanted Defibrillator? The Subcutaneous Implantable Cardioverter Defibrillator (ICD) Should Be Considered in all ICD Patients Who Do Not Require Pacing. Circulation: Arrhythmia and Electrophysciology 2013; 6: 1236-1245.
2. Kleemann et al. Ciculation 2007. 3. Atallah et al. Circulation 2013. 4. Borleffs et al. Circ Arrhythmia Electrophysiol. 2009
5. Leon, A, et al. Outcomes in Patients Receiving a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD): IDE Results at 22 Months. Abstract, HRS 2014.

ATP and ICD

Shock ARM
(N=147 Episodes)



ATP ARM
(N=284 Episodes)



In the PAINFREE RX II trial[1], ATP was successful in 72% of the time for fast VT > 188bpm, but:

About 50% of episodes counted as 'ATP success' may have had terminated spontaneously (34% spontaneous conversions in shock arm)

46% of ATP success conversions were attributed to only 2 patients

Table 2. First Occurrence, Any Occurrence, and Total Occurrences of Appropriate and Inappropriate Device Therapy According to Treatment Group.*

Variable	Conventional Therapy (N=514)	High-Rate Therapy (N=500)	Delayed Therapy (N=486)	P Value for High-Rate Therapy vs. Conventional Therapy	P Value for Delayed Therapy vs. Conventional Therapy
First occurrence of therapy — no. of patients (%)					
Appropriate therapy	114 (22)	45 (9)	27 (6)	<0.001	<0.001
Shock	20 (4)	22 (4)	17 (3)	0.68	0.74
Antitachycardia pacing	94 (18)	23 (5)	10 (2)	<0.001	<0.001
Inappropriate therapy	105 (20)	21 (4)	26 (5)	<0.001	<0.001
Shock	20 (4)	11 (2)	13 (3)	0.12	0.28
Antitachycardia pacing	85 (17)	10 (2)	13 (3)	<0.001	<0.001
Any occurrence of therapy — no. of patients (%)					
Appropriate therapy					
Shock	28 (5)	26 (5)	19 (4)	0.86	0.25
Antitachycardia pacing	111 (22)	38 (8)	20 (4)	<0.001	<0.001
Inappropriate therapy					
Shock	31 (6)	14 (3)	15 (3)	0.01	0.03
Antitachycardia pacing	104 (20)	20 (4)	25 (5)	<0.001	<0.001
Total occurrences of therapy — no. of occurrences					
Appropriate therapy	517	185	196	<0.001	<0.001
Shock	71	72	53	0.35	0.15
Antitachycardia pacing	446	113	143	<0.001	<0.001
Inappropriate therapy	998	75	264	<0.001	<0.001
Shock	105	25	49	0.001	0.16
Antitachycardia pacing	893	50	215	<0.001	<0.001

* Crude rates of the first occurrence of therapy and any occurrence of therapy were compared with the use of chi-square tests, and mean counts of total occurrences of therapy were compared with the use of negative binomial regression models.

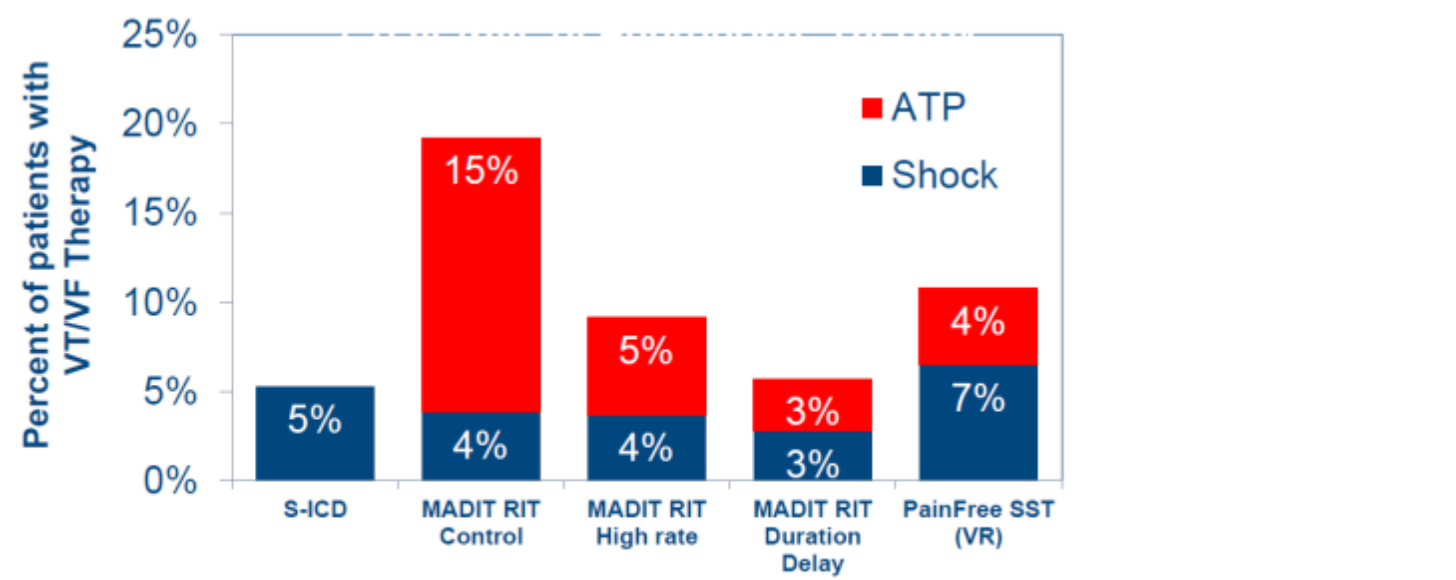
In MADIT-RIT[2]:

- **In the delayed therapy arm, ATP has shown an incidence of 4%**
- **80% reduction in the need for ATP with delayed therapy**
- **No appropriate shock reductions with lower ATP rates**

1. Wathen, MS et al (2004) Prospective Randomized Multicenter Trial of Empirical Antitachycardia Pacing versus Shocks for Spontaneous Rapid Ventricular Tachycardia in Patients with Implantable Cardioverter Defibrillators. Pacing Fast VT Reduces Shock Therapies (PainFREE Rx II) Trial Results. *Circulation.* 2004; 110: 2591-2596.
2. Moss, et al. Reduction in Inappropriate Therapy and Mortality through ICD programming. *NEJM* 376:24 2275-2283.

If ATP prevents unnecessary shocks, why are appropriate shock rates the same?

- Appropriate shock rates similar with or without ATP
- MADIT-RIT found no difference in rate of appropriate shocks despite large differences in ATP delivery
- Similar rate of VT/VF shocks in S-ICD, MADIT RIT*, PainFREE SST*



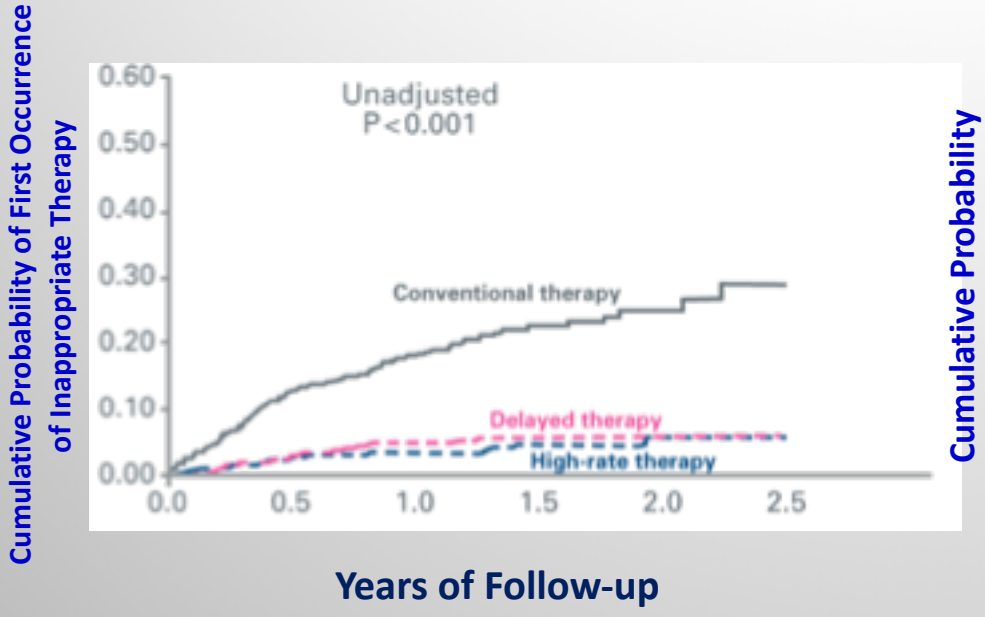
1 year Kaplan Meier incidence shown for S-ICD and PainFREE SST. 1 year rate for MADIT-RIT annualized at an average follow-up of 1.4 years. *MADIT-RIT and PainFREE SST did not include S-ICD devices

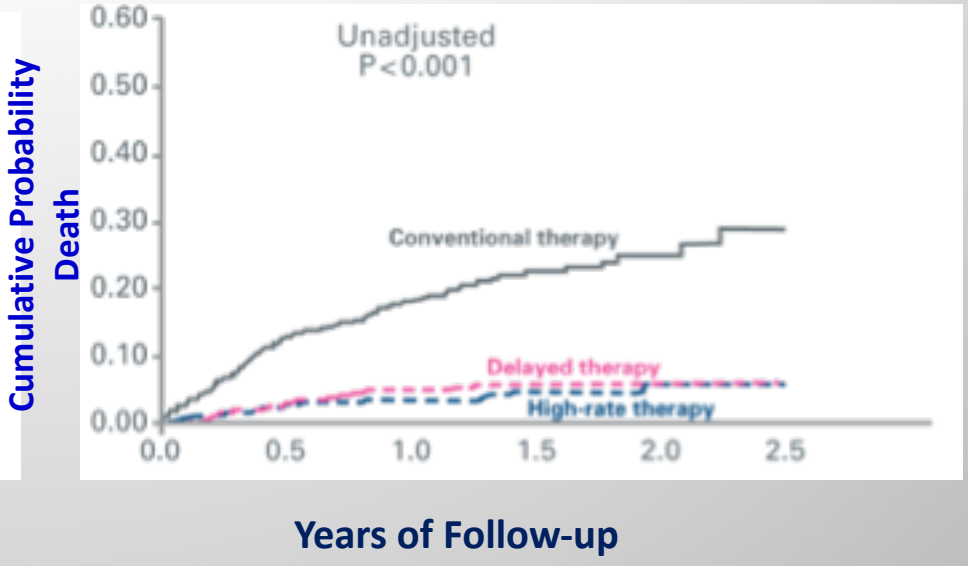
Moss A .et al. NEJM 2012; 367:2275-2283.

Auricchio A, et al. Heart Rhythm, online before print http://dx.doi.org/10.1016/j.hrthm.2015.01.017

MADIT RIT trial: ATP

Indiscriminate device programing is associated with higher IAT rates (75%) and increased mortality (50%)[1]





~75% reduction in 1st inappropriate therapy

~50% reduction in all-cause mortality due to DELAYED therapy

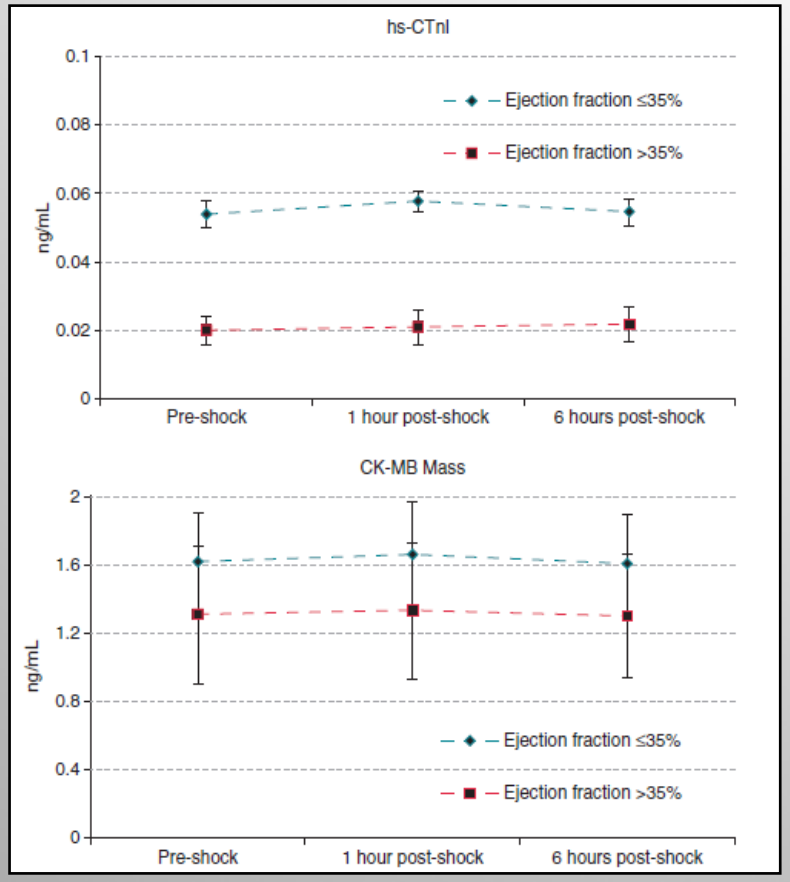
1. Moss, et al. Reduction in Inappropriate Therapy and Mortality through ICD programming. NEJM 376:24 2275-2283.

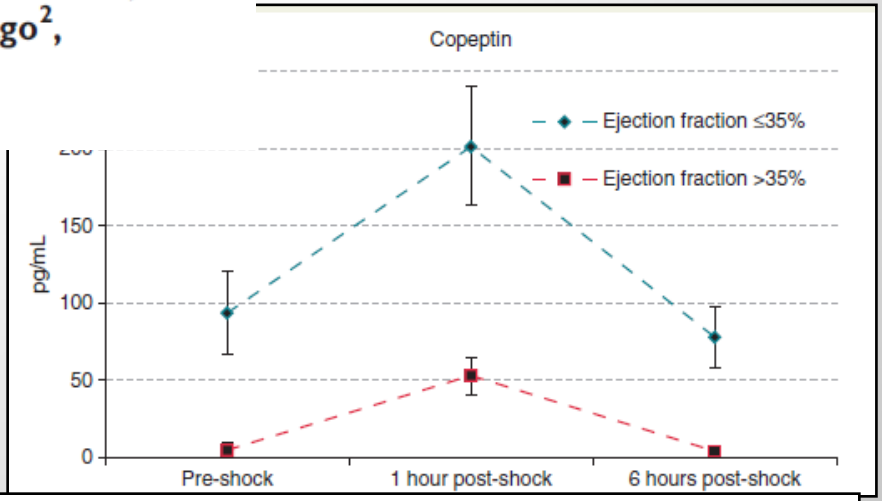
Effects of defibrillation shock in patients implanted with a subcutaneous defibrillator: a biomarker study

2017

Europace. 2017 Oct 31.

Antonio D'Onofrio[1]*, Vincenzo Russo[2], Valter Bianchi[1], Ciro Cavallaro[1], Silvia Leonardi[3], Stefano De Vivo[1], Filippo Vecchione[1], Anna Rago[2], Ernesto Ammendola[2], Vincenzo Tavoletta[1], Luigi Atripaldi[3], Paola Elvira Mocavero[4], and Gerardo Nigro[2]





Conclusions

Serum levels of biomarkers of myocardial damage were not found to be elevated after high-energy DFT in patients who had undergone S-ICD device implantation, regardless of their ejection fraction value. We did not find a stable increase in haemodynamic stress biomarkers after high-energy DFT. Our prospective observational study is the first to suggest that S-ICD DFT does not cause acute myocardial injuries in humans. Further studies are necessary to confirm our results and to directly compare S-ICD with transvenous ICD in terms of the damage caused by DFT.

Brady Pacing

What is the percentage of patients with brady pacing need at implant?

What is the percentage of patients develop brady pacing need after implant?

Brady Pacing need at implant is low[2]

Brady Pacing developed after implant is very low[1], especially in patients with normal PR interval (≤ 200ms) [MADIT II, SCD-HeFT[1]]

In the POOLED Data Analysis, only 1 patient (0.1%) out of 889 developed a Brady pacing need that led to S-ICD explant[3].

Kutyifa. et al. The Need for Pacing in patients who qualify for and ICD: Clinical Implications. ESC abstract 2014

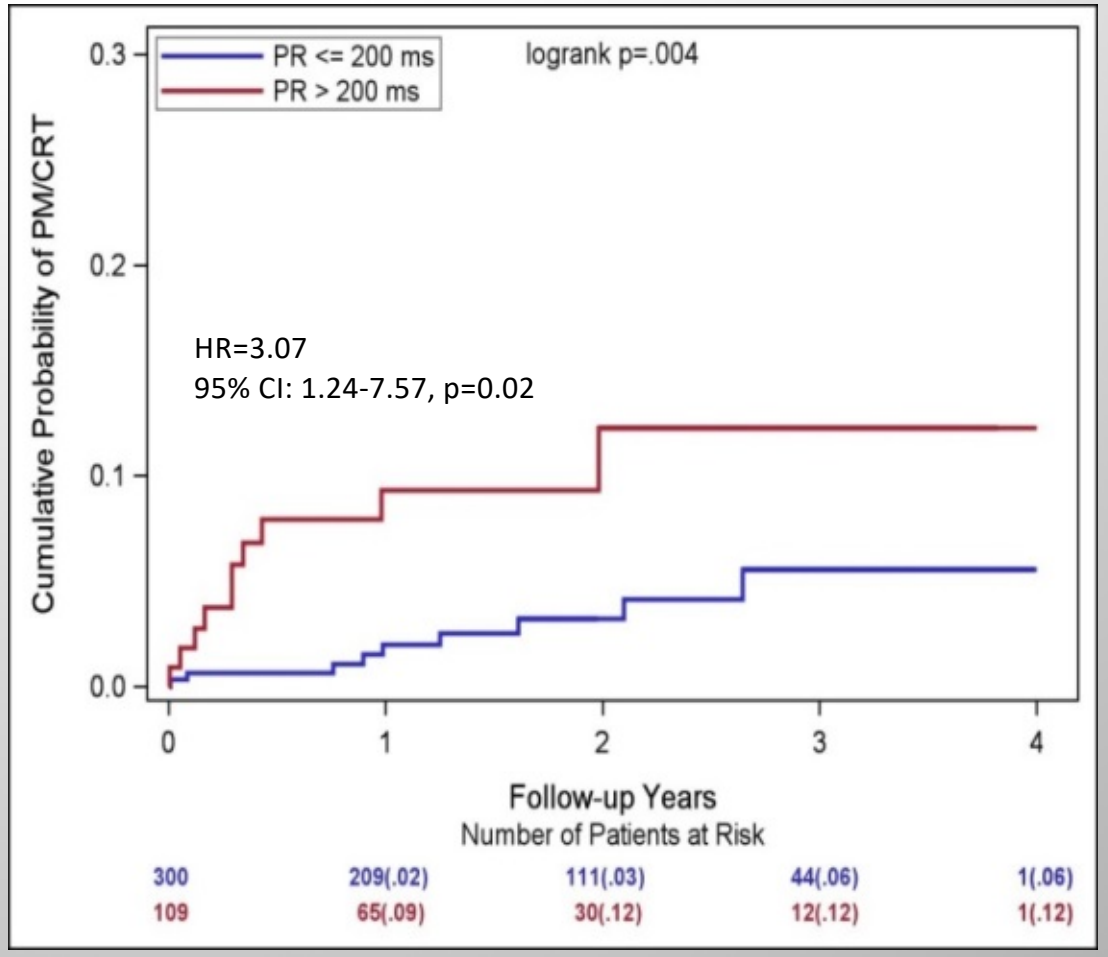
2. de Bie MK, et al. Heart 2013;99:1018–1023. doi:10.1136/heartjnl-2012-303349
3. MC Burke, MR Gold, et al. JACC 2015;65:1605-15 *(POOLED Data Analysis)*

Predictors of Bradycardia Pacing Need Development?

- 458 pts from MADIT II control arm
- 20 month median follow-up

Baseline PR interval >200 ms significant predictor of subsequent PM/CRT implantation

- Total PM rate is ~2% per year
- Need for PM in MADIT-II pts is low, especially in those with normal PR interval (≤ 200ms)



Kutyifa V. Presented at ESC 2014; Abstract P434

Has DR ICD a better AF/SVT discrimination?

Answer: No, there is no proof that DR ICDs have better discrimination.

Moreover, from the START study:

START study: A Head-To-Head Comparison on Bench testing

- Simultaneous recordings of surface and intra-cardiac signals of induced atrial (n=50) and ventricular (n=46) arrhythmias
- Direct comparison of arrhythmia classification by the S-ICD system and 3 TV-ICD systems

	Single Chamber	Dual Chamber	S-ICD System
Appropriate Shock for VF/VT	**99.3%**	**100%**	**100%**
Appropriately withheld for AF/SVT	**76.7%**	**68%**	**98%**

- Pooled results from 3 manufacturers with devices programmed in single chamber or dual chamber mode. Devices: BSC Teligen DR, MDT Secura VR and Virtuoso DR, and SJM Atlas II+HF.
- Matched dual zone configurations (VT≥170 bpm; VF≥240 bpm)

Gold, M. et al J Cardiovasc Electrophysiol . 2012

S-ICD - Price

2016

A propensity matched case–control study comparing efficacy, safety and costs of the subcutaneous vs. transvenous implantable cardioverter defibrillator

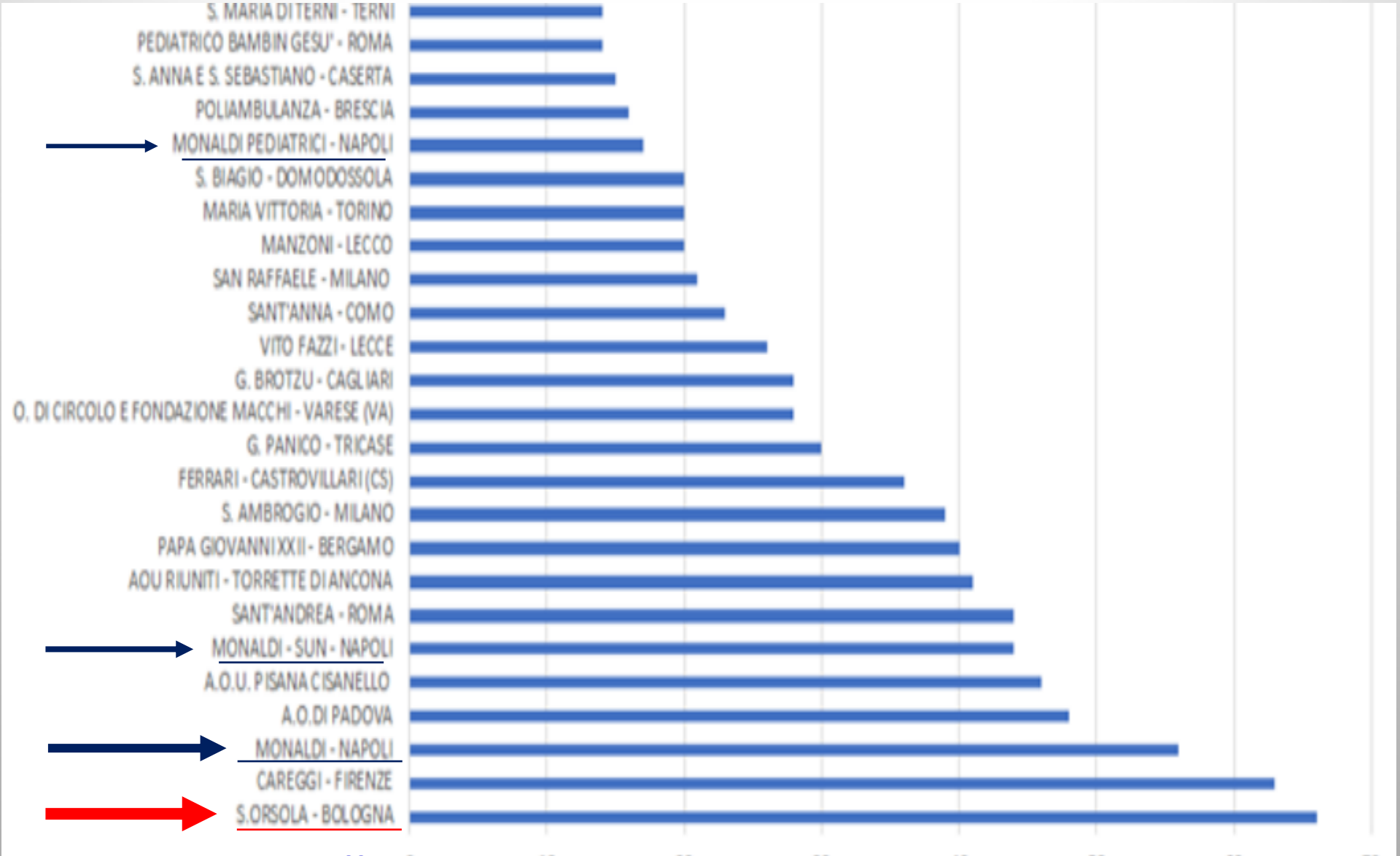
S. Honarbakhsh, R. Providencia, N. Srinivasan, S. Ahsan, M. Lowe, E. Rowland, RJ Hunter, M. Finlay, O. Segal, MJ Earley, A. Chow, RJ Schilling, PD Lambiase *

5. Conclusion

Device-related complication rates associated with TV-ICDs are higher than that of S-ICDs. There is no significant difference in inappropriate shock rates between these two groups. Despite there being a significant difference in unit cost of the S-ICD, overall S-ICD costs may be mitigated versus TV-ICD over a longer period of follow-up. This will need to be further evaluated in a randomized controlled study.

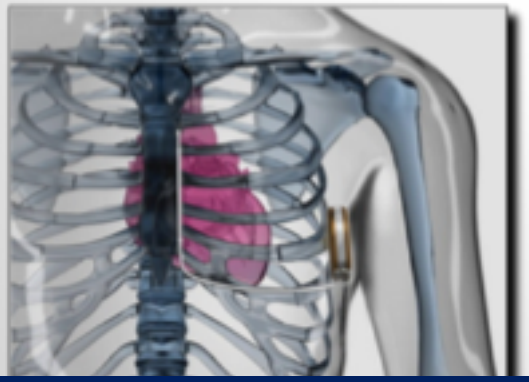
Int. J Cardiology 2017, Feb. 1; 228:280-285

ARRHYTHMIAS DETECTION IN A REAL WORLD POPULATION: THE RHYTHM DETECT REGISTRY



Mauro Biffi

Take away messages



Sistema Venoso preservato: No complicanze

Terapia efficace ed affidabile validata da numerosi studi clinici

Indicato per tutti i pazienti che necessitano di un ICD ma che non richiedono pacing o ATP

Sistema alternativo agli ICD convenzionali che non preclude la terapia transvenosa se necessaria

Nessuna limitazione funzionale per i pazienti: migliore qualità di vita

Terapia consolidata e non inferiore all'ICD convenzionale

PROTEZIONE SENZA TOCCARE IL CUORE