APPROCCIO ENDOVASCOLARE TRADIZIONALE (ICD)

Gaetano Senatore

S.C. CARDIOLOGIA
OSPEDALE DI CIRIE' ED OSPEDALE DI IVREA

La storia di BSC (Guidant), pionieri della tecnologia ICD

144 cc/235 g

Sviluppi futuri

1980 **1988** **1997** **1999** **2004**

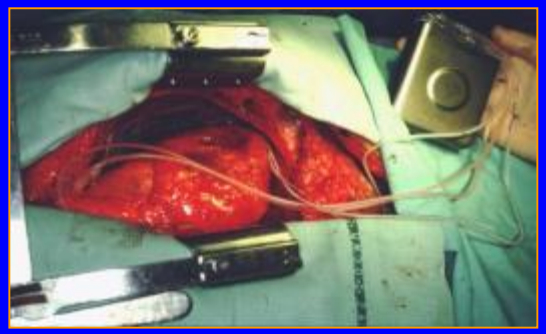
Primo impianto sull'uomo

ENDOTAK - Primo impianto endocardico

Primo ICD a doppia camera

Primo CRT-D d'Europa

Primo dispositivo CRT-D RF



- ICD affermatosi come terapia standard per prevenire SCD
- Cateteri posizionati direttamente nel cuore

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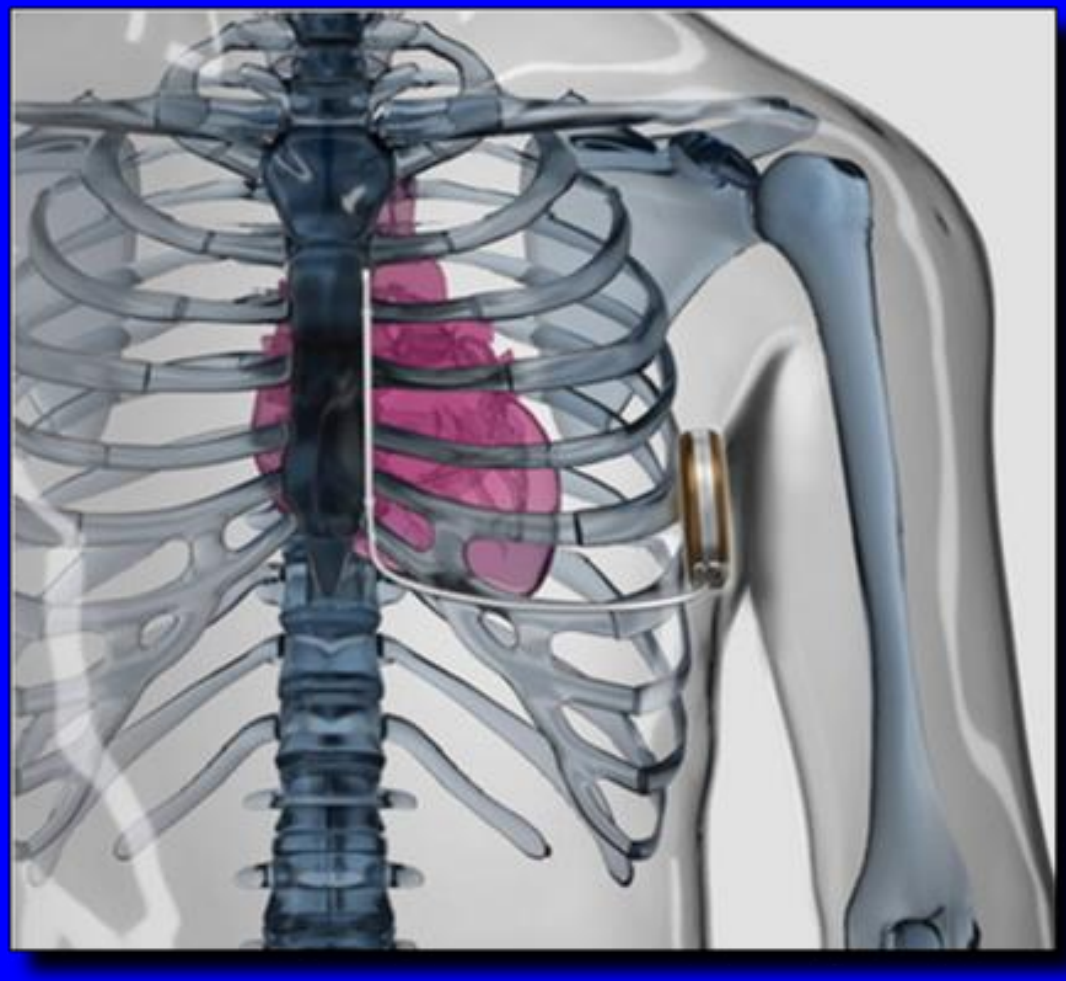
Il Sistema S-ICD
L'approccio sottocutaneo



- **Nessun catetere all'interno del cuore**
  - Sistema venoso preservato
- Impianto semplice chirurgicamente
  - **Puri riferimenti anatomici**
  - **In generale senza bisogno di fluoroscopia**
  - Tempo di impianto prevedibile

Protezione senza toccare il cuore

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Table 3. Comparison of Transvenous ICDs with S-ICDs

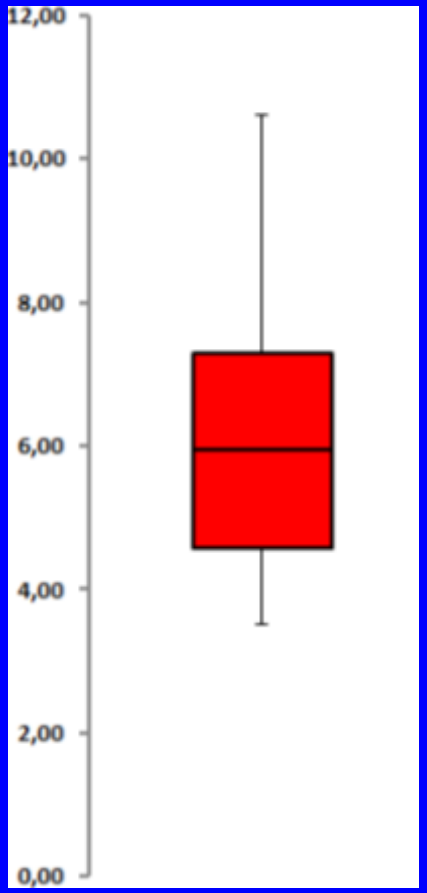
Characteristic	Transvenous ICD	S-ICDs
Location	Subclavicular region	Midaxillary line between the fifth and sixth intercostal spaces
Size of device	Approximately 45 cm^3	59.5 cc (cm^3)
Projected device longevity	Greater than 10 y for single-chamber ICDs	7 y
Risks	Higher risk of infection Higher risk of lead-related complications	Lower risk of infection Lower risk of lead-related complications
Bradycardia pacing	Available	Not available
ATP	Available	Not available
Experience	3 decades	4 y
Need for ECG screening before implantation	No	Yes

ATP indicates antitachycardia pacing; ECG, electrocardiogram; ICDs, implantable cardioverter-defibrillators; and S-ICDs, subcutaneous implantable cardioverter-defibrillators.

- **COMPLICANZE**
- **SHOCK INAPPROPRIATI**

Grande numero di complicanze da molti studi

Complicanze maggiori



Al Khatib (2008) 10,6% - 90 days – 8581 pts > 65yrs*$

Gadler (2014) 8,5% - 1yr - 1298 pts

Prutkin (2014) 7,6% - 6 months – 200909 pts*$

Reynolds (2006) 6,4% - in hospital - 30984 pts$

Kirkfeldt (2013) – 5,7% - 6 months – 4355 pts$

Van Rees (2011) – 5,1% - in hospital – meta analysis$

Kirkfeldt (2011) – 4,4 % - 3 months – 28860 pts$

Peterson (2013) – 3,9% - 90 days - 32034 pts

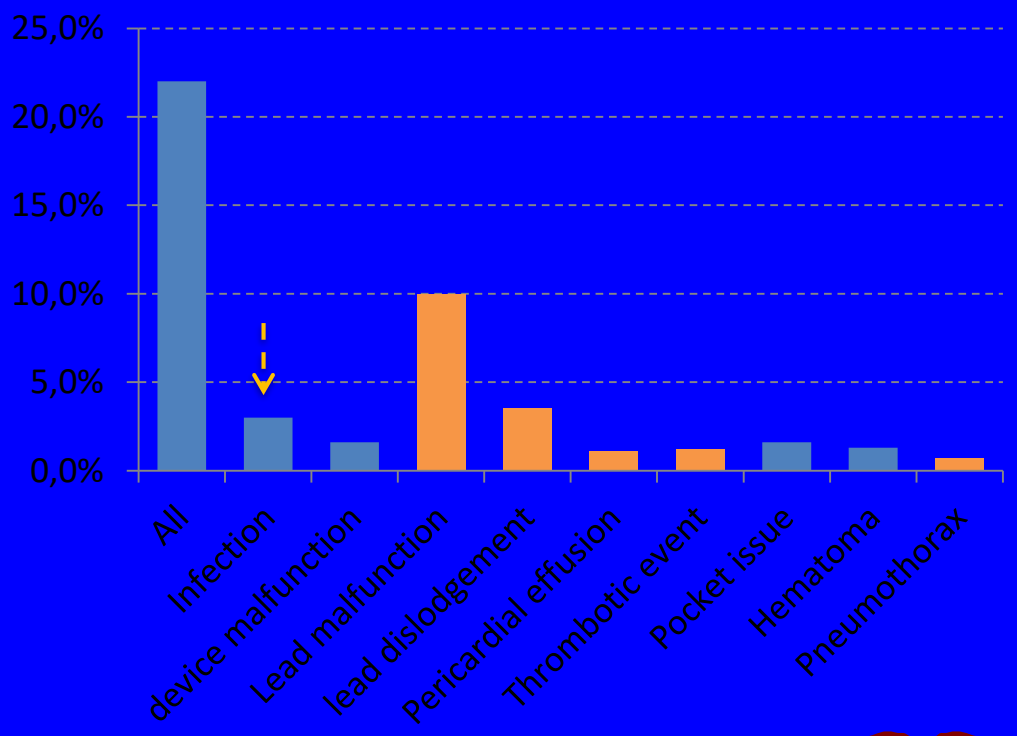
Borleffs (2010) – 3,5% - 38 months - 2415 pts

Reynolds et al. JACC 2006, Prutkin et al. Circulation 2014, Van Rees et al. JACC 2011, Al Khatib et al. Circ Arrhythm Electrophysiol 2008, Borleffs et al. Pacing Clin Electrophysiol 2010, Peterson et al JAMA 2013, Gadler Europace 2014, Kirkfeldt et al Eur Heart J 2013, Kirkfeldt et al Heart Rhythm 2011, 10. Knops R – Pooled analysis CARDIOSTIM 2014

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-analysis of 63 study populations**
- **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**



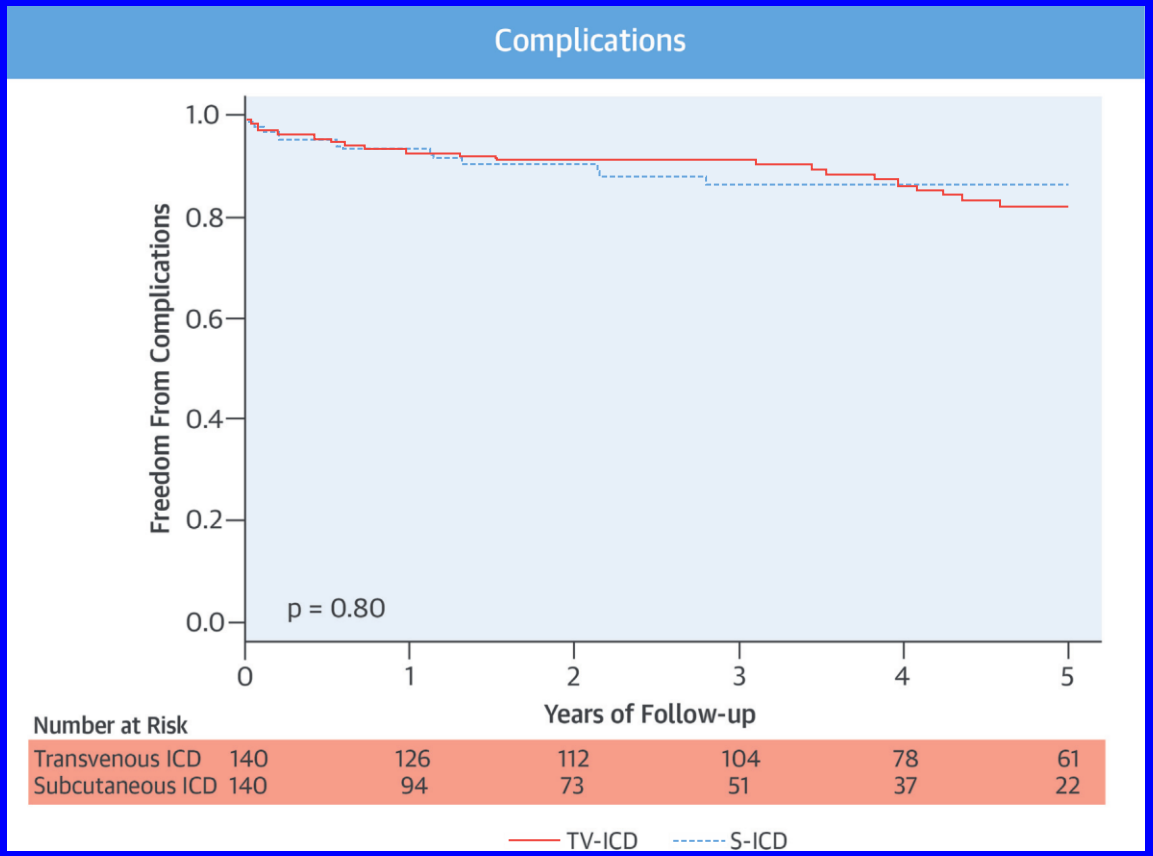
L.R.A. Olde Nordkamp et al. Implantable Cardioverter-Defibrillator Harm in Young Patients with Inherited Arrhythmia Syndromes: A Systematic Review and Meta-Analysis of Inappropriate Shocks and Complications. Heart Rhythm 2015. http://dx.doi.org/10.1016/j.hrthm.2015.09.010

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)	

Long-Term Clinical Outcomes of Subcutaneous Versus Transvenous Implantable Defibrillator Therapy

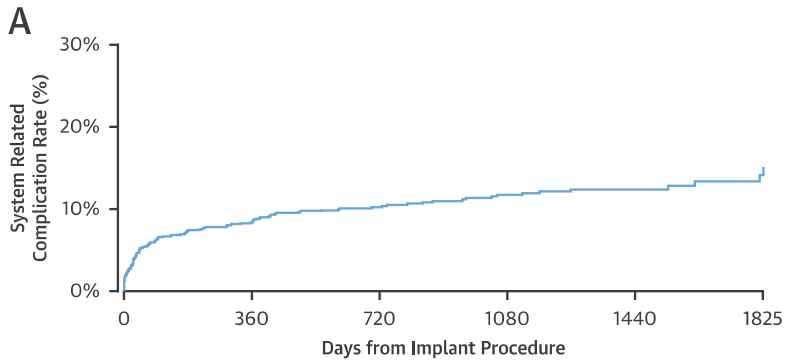
Tom F. Brouwer, MD,[a] Dilek Yilmaz, MD,[b] Robert Lindeboom, PhD,[c] Maurits S. Buiten, MD, PhD,[b] Louise R.A. Olde Nordkamp, MD, PhD,[a] Martin J. Schalij, MD, PhD,[b] Arthur A. Wilde, MD, PhD,[a] Lieselot van Erven, MD, PhD,[b] Reinoud E. Knops, MD[a]

CENTRAL ILLUSTRATION Outcomes Comparison of S-ICD and TV-ICD Therapy: Device-Related Complications

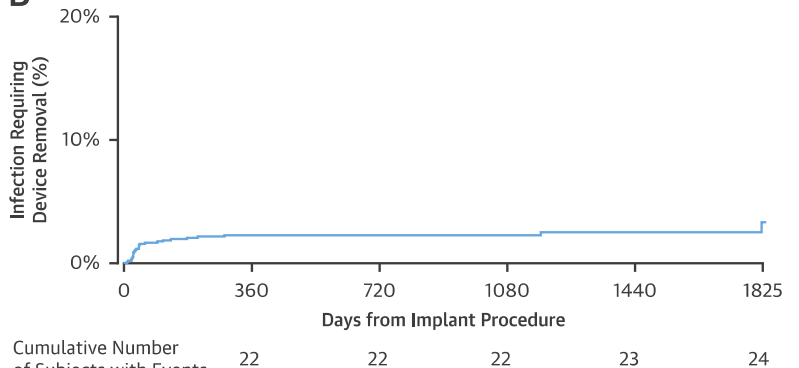


Brouwer, T.F. et al. J Am Coll Cardiol. 2016;68(19):2047–55.

FIGURE 2 Complication Rate



Cumulative Number of Subjects with Events	82	99	108	111	114
N at Risk	878	651	454	267	101
System Related Complication KM Rate	8.4%	10.2%	11.7%	12.4%	14.2%

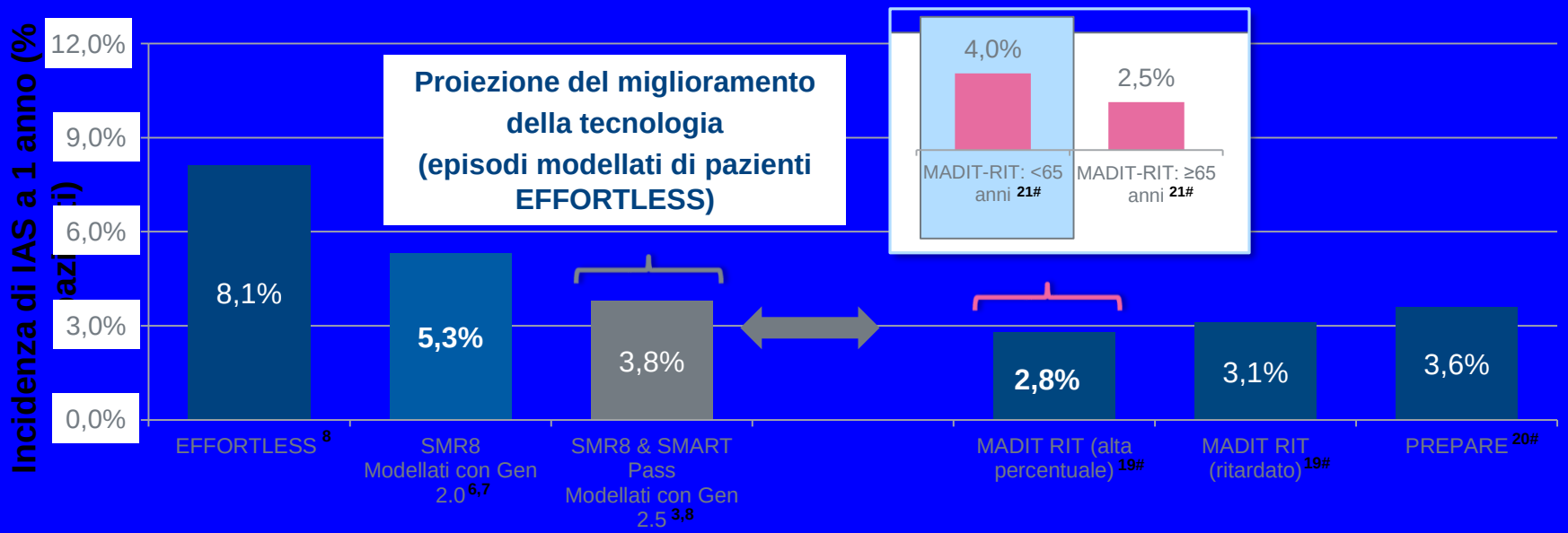


Cumulative Number of Subjects with Events	22	22	22	23	24
N at Risk	921	691	493	295	114
Infection Requiring Device Removal KM Rate	2.3%	2.3%	2.3%	2.5%	3.3%

Implant and Midterm Outcomes of the Subcutaneous Implantable Cardioverter-Defibrillator Registry

The EFFORTLESS Study

SMART Pass riduce gli shock inappropriati



La tecnologia SMART Pass ha ridotto l'oversensing dell'onda T dell'82% rispetto al sistema S-ICD di 1ª generazione e del 71% rispetto al sistema EMBLEM S-ICD (con dati modellati EFFORTLESS)

Implantable Cardioverter Defibrillators in Arrhythmogenic Right Ventricular Dysplasia/Cardiomyopathy

Patient Outcomes, Incidence of Appropriate and Inappropriate Interventions, and Complications

Arend F.L. Schinkel, MD, PhD

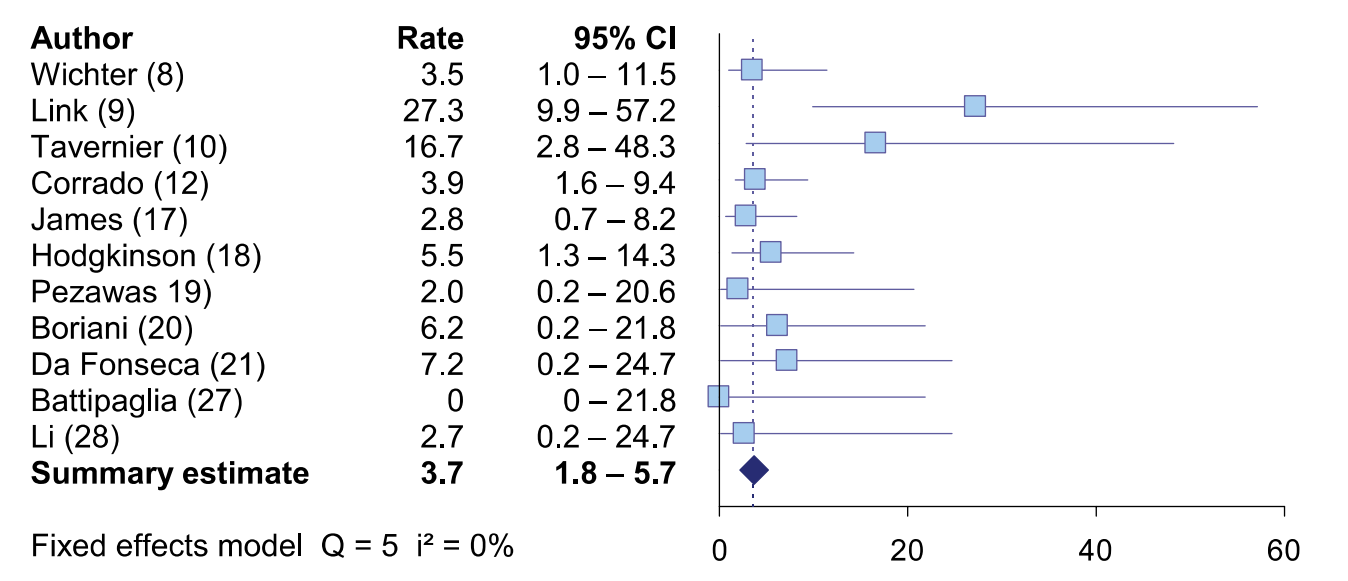


Figure 3. Forest plot of annualized inappropriate implantable cardioverter defibrillators intervention rate (%/y).

Inappropriate Implantable Cardioverter-Defibrillator Shocks in MADIT II

Frequency, Mechanisms, Predictors, and Survival Impact

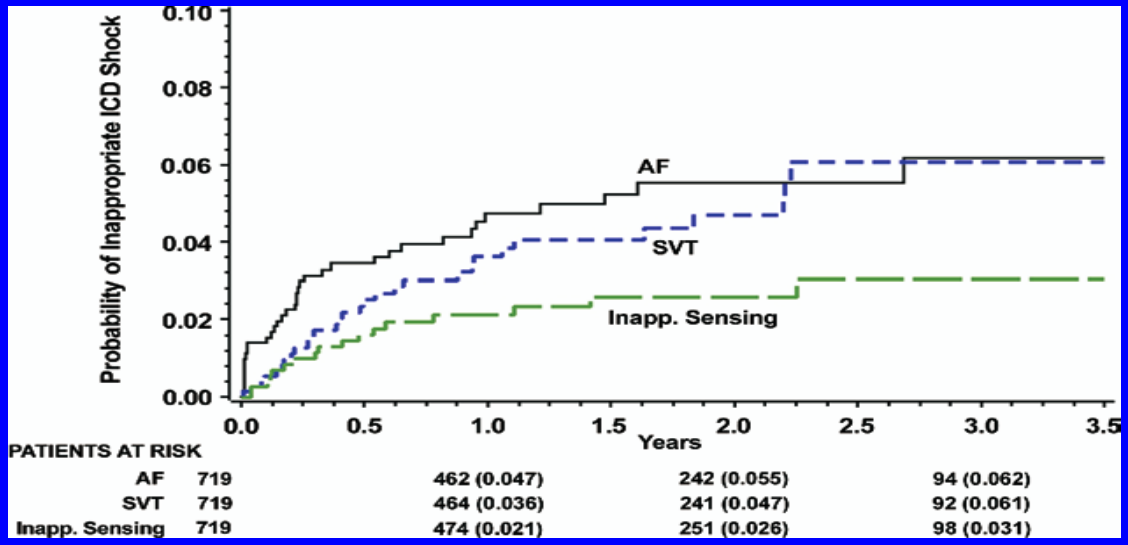


Figure 2 Time-Dependent Occurrence of Inappropriate Shock by Type

Inappropriate Implantable Cardioverter-Defibrillator Shocks in MADIT II

Frequency, Mechanisms, Predictors, and Survival Impact

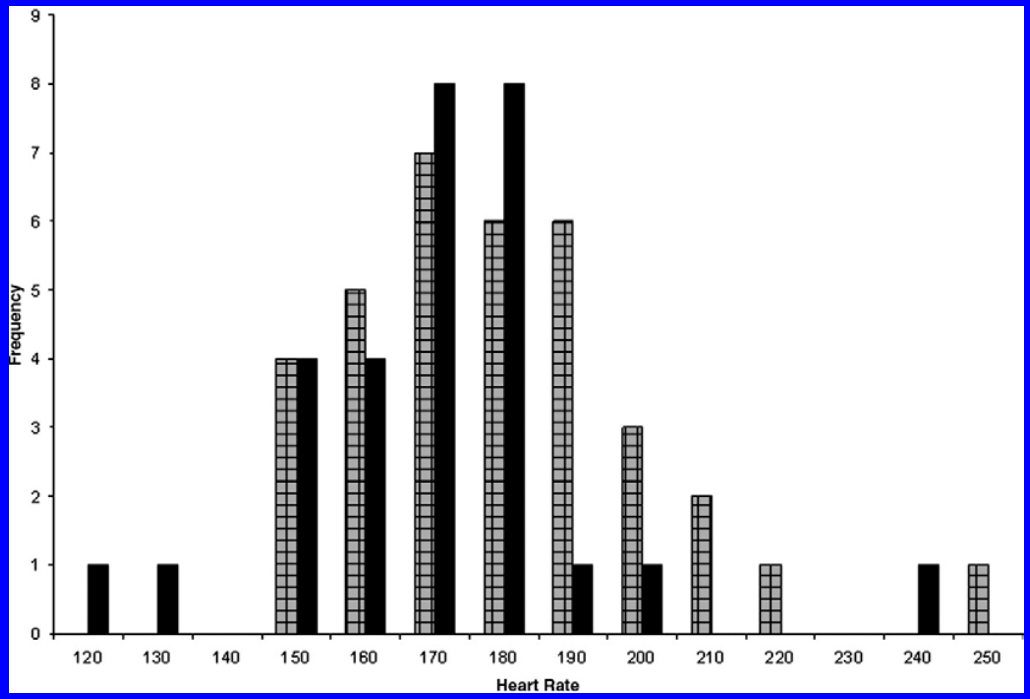


Figure 3 Ventricular Rate Precipitating Inappropriate Shock

Inappropriate Implantable Cardioverter-Defibrillator Shocks in MADIT II

Frequency, Mechanisms, Predictors, and Survival Impact

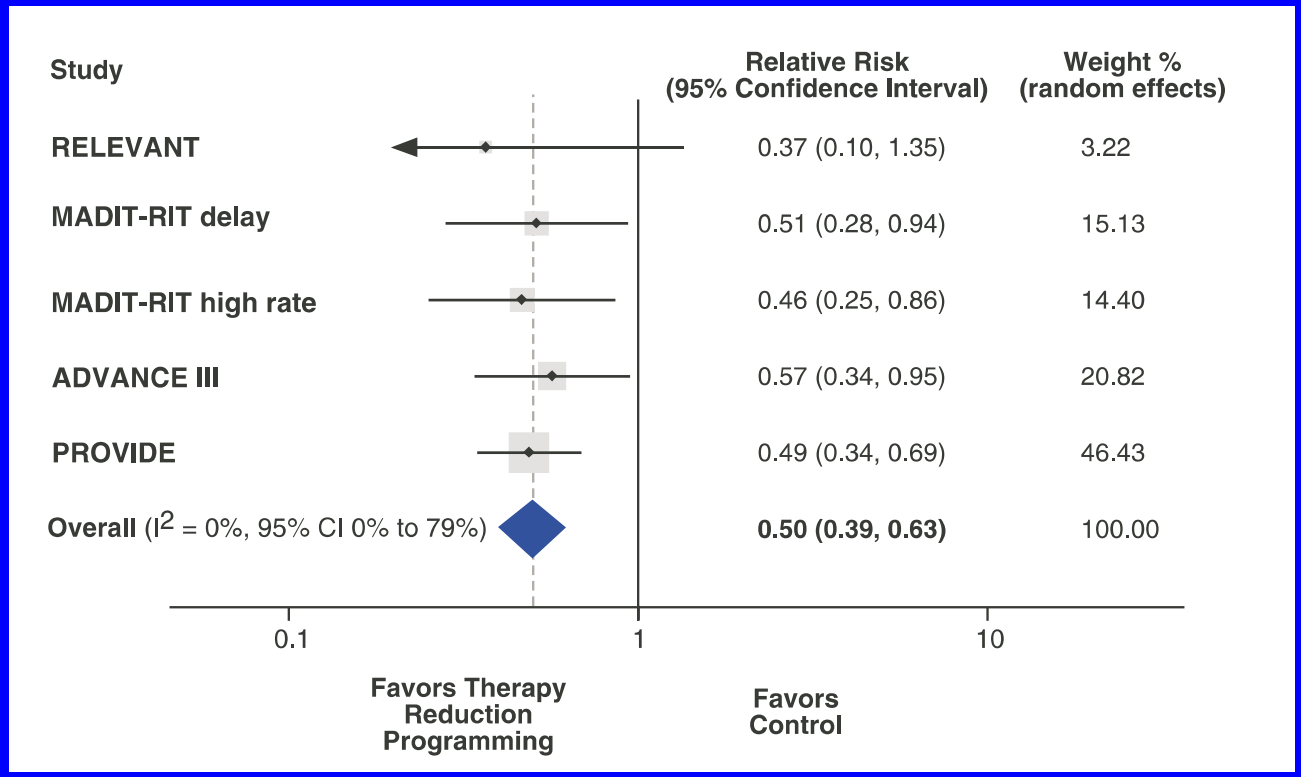
Table 5 ICD Programming in Patients With and Without Inappropriate ICD Shocks

Programming	Inappropriate Shock	No Inappropriate Shock	p Value*
Single-chamber and dual-chamber devices			
Number of patients	83	83†	
Lowest VT zone (beats/min)	169.3 ± 19.9	171.9 ± 14.5	0.540
Lowest VT zone detection time (s)	2.45 ± 1.99	2.42 ± 2.07	0.830
Stability on, % (n)	17 (14)	36 (30)	0.030
Sudden onset on, % (n)	16 (13)	23 (19)	0.160
Dual-chamber devices only			
Number of patients	32	36	
V>A on, % (n)	31 (10)	50 (18)	0.054
Atrial fibrillation discriminator on, % (n)	34 (11)	44 (16)	0.210

Impact of Programming Strategies Aimed at Reducing Nonessential Implantable Cardioverter Defibrillator Therapies on Mortality

A Systematic Review and Meta-Analysis

Vern Hsen Tan, MBBS, MRCP; Stephen B. Wilton, MD, MSc; Vikas Kuriachan, MD, FHRS; Glen L. Sumner, MD; Derek V. Exner, MD, MPH, FHRS



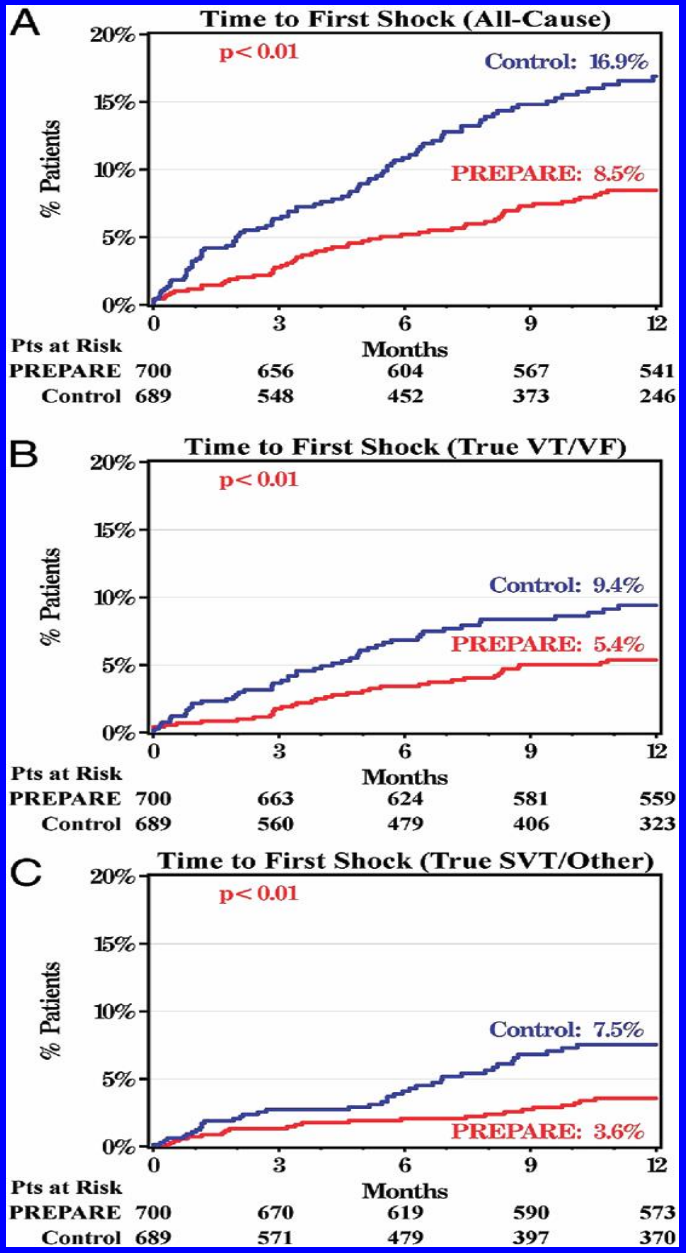


Figure 3 Time to First Shock by Study Cohort

Strategic Programming of Detection and Therapy Parameters in Implantable Cardioverter-Defibrillators Reduces Shocks in Primary Prevention Patients

Results From the PREPARE (Primary Prevention Parameters Evaluation) Study

Factors influencing the use of subcutaneous or transvenous implantable cardioverter-defibrillators: results of the European Heart Rhythm Association prospective survey

Serge Boveda[1]*, Radoslaw Lenarczyk[2], Stefano Fumagalli[3], Roland Tilz[4], Kinga Gościńska-Bis[5], Maciej Kempa[6], Pascal Defaye[7], Christelle Marquié[8], Alessandro Capucci[9], Laura Ueberham[10], and Nikolaos Dagres[10]

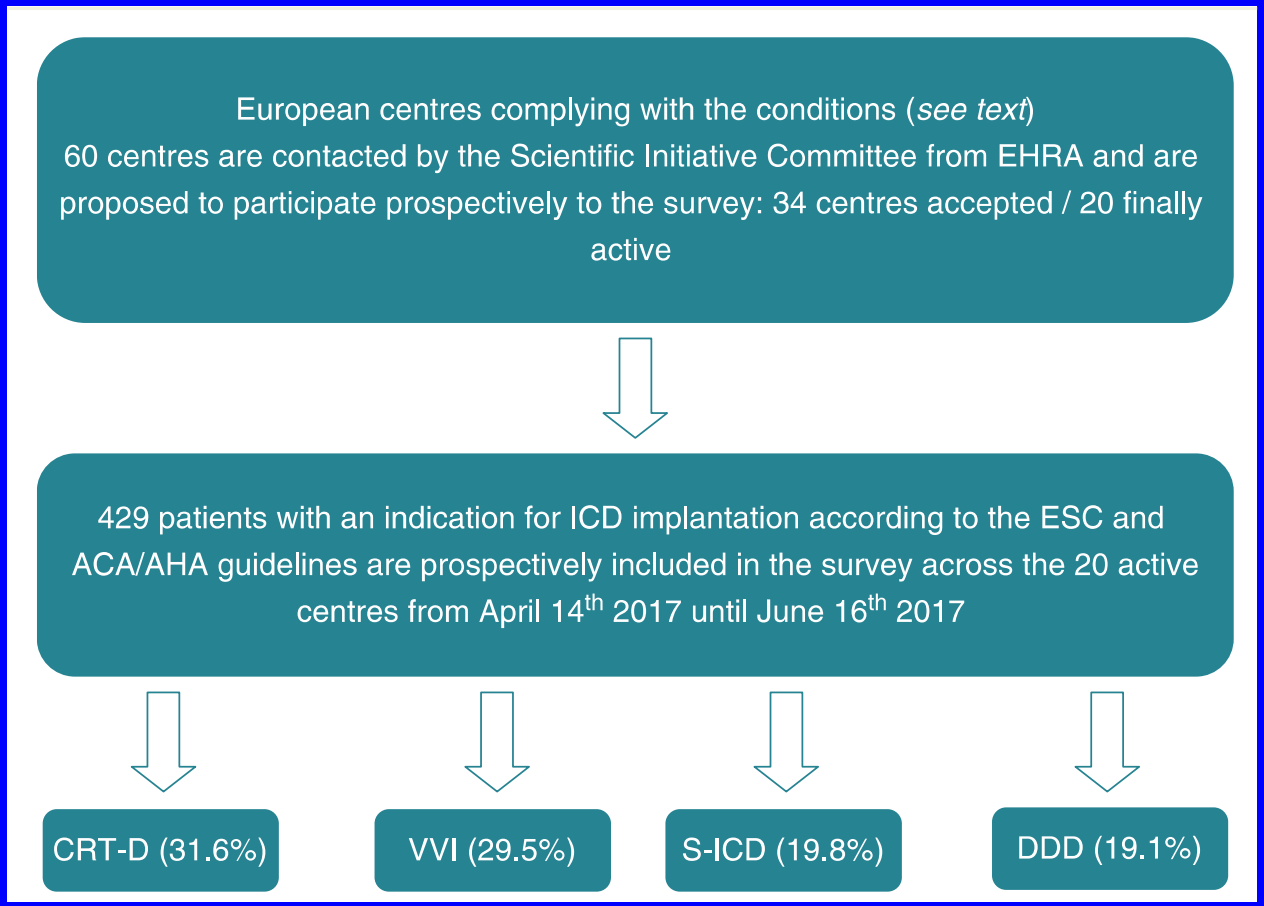


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Table I Baseline characteristics of patients

	Total	S-ICD patients ($n = 76$)	TV-ICD patients ($n = 307$)	*P*-value[a]
Age[b]				
<18	4 (1.0)	2 (2.6)	2 (0.6)	0.13
18–30	15 (3.9)	10 (13.2)	5 (1.6)	<0.01
31–45	38 (9.8)	18 (23.7)	20 (6.5)	<0.01
46–55	52 (13.4)	18 (23.7)	33 (10.7)	<0.01
56–65	111 (28.5)	19 (25.0)	90 (29.3)	0.46
66–75	100 (25.7)	7 (9.2)	90 (29.3)	<0.01
76–85	67 (17.2)	2 (2.6)	65 (21.2)	<0.01
86 and over	2 (0.5)	0	2 (0.6)	0.48
LVEF	33.8 ± 14	43.8 ± 17	31.3 ± 12	<0.01
Structural heart disease	342 (89.3)	55 (72.4)	287 (93.5)	<0.01
Idiopathic VF	18 (4.7)	9 (11.8)	9 (2.9)	<0.01
Brugada syndrome	9 (2.3)	8 (10.5)	1 (0.3)	<0.01
Conduction disturbances at implant				
LBBB	64 (17.2)	3 (4.0)[c]	61 (20.4)[d]	<0.01
RBBB	19 (5.1)	3 (4.0)[c]	16 (5.4)[d]	0.63
QRS duration				
<120 ms	200 (53.6)	60 (80.0)[c]	140 (46.9)[d]	<0.01
>120 ms and <150 ms	63 (16.9)	14 (18.7)[c]	49 (16.4)[d]	0.65
>150 ms	110 (29.5)	1 (1.3)[c]	109 (36.6)[d]	<0.01
Arrhythmia leading to ICD implantation				
Primary prevention: no documented VT nor syncope	232 (62.2)	42 (56.0)[c]	190 (63.7)[d]	0.21
Primary prevention: non-sustained VT or/and syncope	40 (10.7)	7 (9.3)[c]	33 (11.1)[d]	0.66
Secondary prevention: sustained monomorphic VT	42 (11.3)	3 (4.0)[c]	39 (13.1)[d]	0.03
Secondary prevention: sustained polymorphic VT	8 (2.1)	2 (2.7)[c]	6 (2.0)[d]	0.72
Secondary prevention: VF/cardiac arrest survivor	43 (11.5)	19 (25.3)[c]	24 (8.0)[d]	<0.01
Induced VT/VF during EP study	8 (2.1)	2 (2.7)[c]	6 (2.0)[d]	0.73

Factors influencing the use of subcutaneous or transvenous implantable cardioverter-defibrillators: results of the European Heart Rhythm Association prospective survey

Serge Boveda[1]*, Radoslaw Lenarczyk[2], Stefano Fumagalli[3], Roland Tilz[4], Kinga Gościńska-Bis[5], Maciej Kempa[6], Pascal Defaye[7], Christelle Marquié[8], Alessandro Capucci[9], Laura Ueberham[10], and Nikolaos Dagres[10]

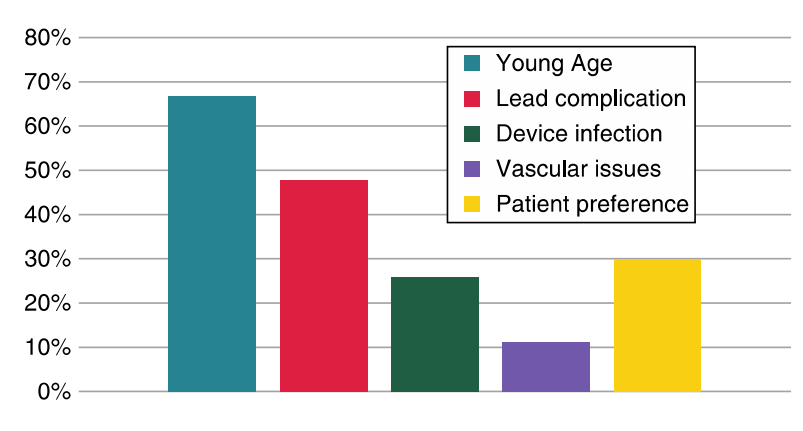


Figure 2 Factors in favour of S-ICD implantation (multiple answers). Each bar represents one possible answer (proportion of responders to each question). S-ICD, subcutaneous implantable cardioverter-defibrillator.

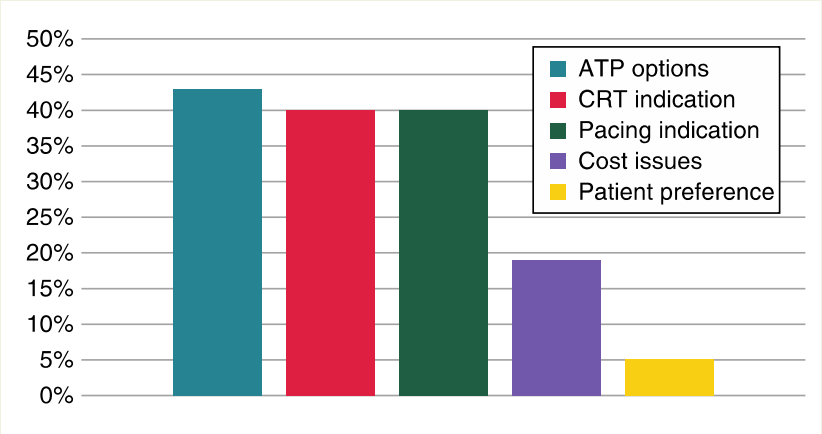


Figure 3 Factors in favour of a transvenous ICD implantation (multiple answers). Each bar represents one possible answer (proportion of responders to each question). ICD, implantable cardioverter-defibrillator.

Factors influencing the use of subcutaneous or transvenous implantable cardioverter-defibrillators: results of the European Heart Rhythm Association prospective survey

Serge Boveda[1]*, Radoslaw Lenarczyk[2], Stefano Fumagalli[3], Roland Tilz[4], Kinga Gościńska-Bis[5], Maciej Kempa[6], Pascal Defaye[7], Christelle Marquié[8], Alessandro Capucci[9], Laura Ueberham[10], and Nikolaos Dagres[10]

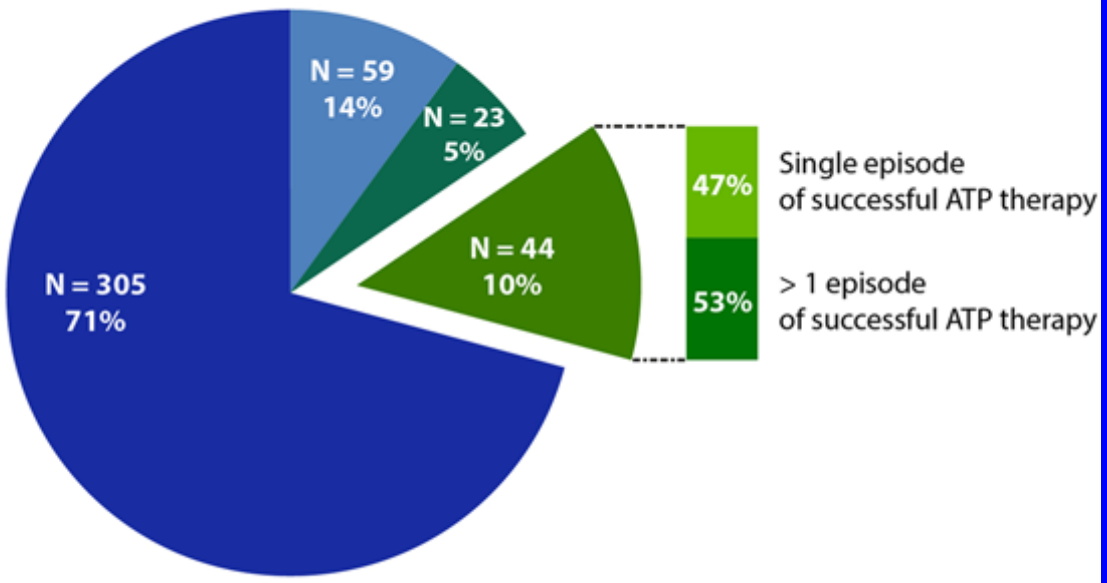
Patients were in atrial fibrillation in 14.2% of cases. Pacing dependency was found in less than 5% of the patients: 2.9% for sick sinus syndrome and 1.9% for high degree atrioventricular block. In addition, left bundle branch block was reported in 17.2% and right bundle branch block in 5.1% of the patients.

Selecting the right defibrillator in the younger patient: Transvenous, epicardial or subcutaneous?

Nikolay Bogush [b], Raul E. Espinosa [a], Bryan C. Cannon [c], Philip L. Wackel [a], Hideo Okamura [d], Paul A. Friedman [a], Christopher J. McLeod [a,*]

mortality [4]. Pediatric patients account for approximately 1.1% of patients who undergo implantable cardioverter-defibrillators (ICD) placement in the United States, with the majority of these being implanted for primary prevention (61.9%) [5].

Distribution of successful ICD therapy modalities in patients during follow-up.



Received: 17 October 2017 | Revised: 12 April 2018 | Accepted: 7 May 2018
DOI: 10.1111/pace.13411

DEVICES

WILEY PACE

Clinical parameters to optimize patient selection for subcutaneous and transvenous implantable defibrillator therapy

Anne-Floor B.E. Quast MD | Tom F. Brouwer MD | Fleur V.Y. Tjong MD | Arthur A.M. Wilde MD, PhD | Reinoud E. Knops MD, PhD

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LABORATORIO di ELETTROFISIOLOGIA

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Subcutaneous Versus Transvenous Implantable Defibrillator Therapy

A Meta-Analysis of Case-Control Studies

Indranill Basu-Ray, MD,[a] Jing Liu, MD,[b] Xiaoming Jia, MD,[b] Michael Gold, MD,[c] Kenneth Ellenbogen, MD,[d] James DiNicolantonio, PharmD,[e] András Komócsi, MD,[f] András Vorobcsuk, MD,[g] Jitae Kim, BS,[h] Hamid Afshar, MD,[i] Wilson Lam, MD,[i] Nilesh Mathuria, MD,[a] Mehdi Razavi, MD,[a] Abdi Rasekh, MD,[a] Mohammad Saeed, MD[a]

TABLE 3 Clinical Outcomes Between S-ICD and TV-ICD Groups

	S-ICD	TV-ICD	OR (95% CI)
Lead complications	0.14	1.02	0.13 (0.05–0.38)
System failure	0.32	0.24	1.13 (0.43–3.02)
Infection	0.34	0.31	0.75 (0.30–1.89)
Total inappropriate therapy	8.30	9.46	0.87 (0.51–1.49)
T-wave oversensing, episode oversensing	8.99	0.72	9.81 (2.60–37.05)
SVT	1.08	10.43	0.12 (0.0–0.35)

Values are % unless otherwise indicated.

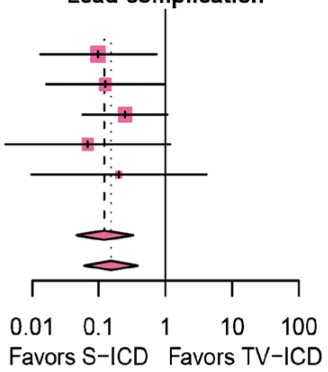
CI = confidence interval; OR = odds ratio; SVT = supraventricular tachycardia; other abbreviations as in Table 2.

CONCLUSIONS S-ICD reduced lead-related complications but was similar to TV-ICD with regard to non-lead-related complications, including inappropriate therapy. These results support the concept that S-ICD is a safe and effective alternative to TV-ICD in appropriate patients. (J Am Coll Cardiol EP 2017;3:1475–83)

b

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

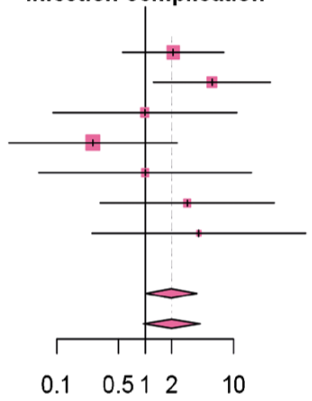
Heterogeneity: $I^2 = 0\%$, $\tau^2 = 0$, $p = 0.88$



c

Study	Subcutaneous ICD Events	Subcutaneous ICD Follow-up years	Transvenous ICD Events	Transvenous ICD Follow-up years	IRR	95%-CI	Weight (fixed)	Weight (random)
Brouwer 2016	5	420.00	4	700.00	2.08	[0.56; 7.76]	23.9%	30.7%
Brouwer 2018	10	1133.90	2	1290.30	5.69	[1.25; 25.97]	14.9%	23.3%
Friedman 2016	1	5.30	2	10.50	0.99	[0.09; 10.92]	10.7%	9.5%
Honarbakhsh 2017	1	178.30	4	184.00	0.26	[0.03; 2.31]	31.4%	11.4%
Köbe 2013	1	56.60	1	56.60	1.00	[0.06; 15.99]	8.0%	7.2%
Mithani 2018	3	45.50	1	45.50	3.00	[0.31; 28.84]	8.0%	10.7%
Lenarczyk 2018	1	0.23	1	0.92	4.04	[0.25; 64.58]	3.2%	7.2%
Fixed effect model					**1.98**	**[1.02; 3.83]**	**100.0%**	--
Random effects model					**2.00**	**[0.95; 4.22]**	--	**100.0%**

Heterogeneity: $I^2 = 2\%$, $\tau^2 = 0.0213$, $p = 0.41$



Current Cardiology Reports (2018) 20: 72
https://doi.org/10.1007/s11886-018-1021-8

INVASIVE ELECTROPHYSIOLOGY AND PACING (EK HEIST, SECTION EDITOR)

CrossMark

An Overview of Clinical Outcomes in Transvenous and Subcutaneous ICD Patients

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Published online: 10 July 2018

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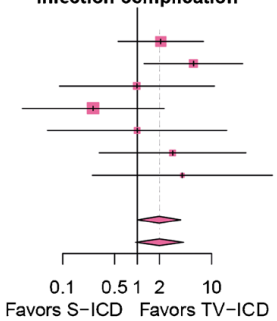
Study	Subcutaneous ICD Events	Subcutaneous ICD Follow-up years	Transvenous ICD Events	Transvenous ICD Follow-up years	IRR	95%-CI	Weight (fixed)	Weight (random)
Brouwer 2016	5	420.00	4	700.00	2.08	[0.56; 7.76]	23.9%	30.7%
Brouwer 2018	10	1133.90	2	1290.30	5.69	[1.25; 25.97]	14.9%	23.3%
Friedman 2016	1	5.30	2	10.50	0.99	[0.09; 10.92]	10.7%	9.5%
Honarbakhsh 2017	1	178.30	4	184.00	0.26	[0.03; 2.31]	31.4%	11.4%
Köbe 2013	1	56.60	1	56.60	1.00	[0.06; 15.99]	8.0%	7.2%
Mithani 2018	3	45.50	1	45.50	3.00	[0.31; 28.84]	8.0%	10.7%
Lenarczyk 2018	1	0.23	1	0.92	4.04	[0.25; 64.58]	3.2%	7.2%
Fixed effect model					**1.98**	**[1.02; 3.83]**	**100.0%**	--
Random effects model					**2.00**	**[0.95; 4.22]**	--	**100.0%**

Heterogeneity: $I^2 = 2\%$, $\tau^2 = 0.0213$, $p = 0.41$



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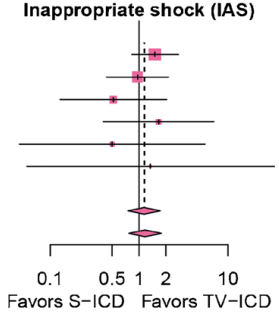
Study	Subcutaneous ICD Events	Subcutaneous ICD Follow-up years	Transvenous ICD Events	Transvenous ICD Follow-up years	IRR	95%-CI	Weight (fixed)	Weight (random)
Brouwer 2016	20	420.00	22	700.00	1.52	[0.83; 2.78]	41.3%	49.1%
Brouwer 2018	11	1133.90	13	1290.30	0.96	[0.43; 2.15]	30.4%	27.9%
Honarbakhsh 2017	3	178.30	6	184.00	0.52	[0.13; 2.06]	14.8%	9.4%
Köbe 2013	5	56.60	3	56.60	1.67	[0.40; 6.97]	7.5%	8.8%
Mithani 2018	1	45.50	2	45.50	0.50	[0.05; 5.51]	5.0%	3.1%
Lenarczyk 2018	0	0.23	1	0.92	1.35	[0.05; 33.05]	1.0%	1.8%
Fixed effect model					**1.14**	**[0.75; 1.74]**	**100.0%**	--
Random effects model					**1.17**	**[0.77; 1.79]**	--	**100.0%**

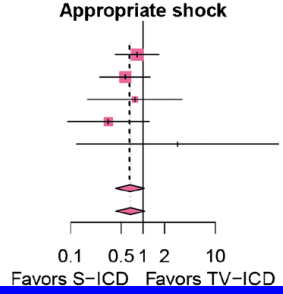
Heterogeneity: $I^2 = 0\%$, $\tau^2 = 0$, $p = 0.70$



e

Study	Subcutaneous ICD Events	Subcutaneous ICD Follow-up years	Transvenous ICD Events	Transvenous ICD Follow-up years	IRR	95%-CI	Weight (fixed)	Weight (random)
Brouwer 2016	12	420.00	24	700.00	0.83	[0.42; 1.67]	37.7%	43.6%
Brouwer 2018	9	1133.90	18	1290.30	0.57	[0.26; 1.27]	35.2%	32.7%
Honarbakhsh 2017	3	178.30	4	184.00	0.77	[0.17; 3.46]	8.2%	9.3%
Köbe 2013	3	56.60	9	56.60	0.33	[0.09; 1.23]	18.8%	12.3%
Mithani 2018	1	45.50	0	45.50	3.00	[0.12; 73.64]	0.0%	2.0%
Fixed effect model					**0.66**	**[0.42; 1.04]**	**100.0%**	--
Random effects model					**0.67**	**[0.42; 1.06]**	--	**100.0%**

Heterogeneity: $I^2 = 0\%$, $\tau^2 = 0$, $p = 0.64$



Current Cardiology Reports (2018) 20: 72
https://doi.org/10.1007/s11886-018-1021-8

INVASIVE ELECTROPHYSIOLOGY AND PACING (EK HEIST, SECTION EDITOR)

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LABORATORIO di ELETTROFISIOLOGIA

CARDIOLOGIA CIRIE' & IVREA

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Associazione Italiana Aritmologia e Cardiostimolazione

MODELLO INFORMATIVO

Informazioni riguardanti l'intervento di

IMPIANTO DI DEFIBRILLATORE TRANSVENOSO/SOTTOCUTANEO

I CD transvenosi (I CD, CRT-D):

1) shock elettrico ad alta energia, utilizzato generalmente per interrompere aritmie più rapide e/o irregolari (p. es in caso di arresto cardiaco da fibrillazione ventricolare), percepito come una scossa elettrica interna;

2) breve stimolazione cardiaca, in grado di interrompere, in maniera del tutto asintomatica, tachicardie meno rapide e regolari.

In caso di rallentamento della frequenza cardiaca l'ICD transvenoso è inoltre in grado di stimolare il cuore in modo analogo a un normale pacemaker.

I CD sottocutaneo (S-I CD):

1) possibile soltanto lo shock elettrico ad alta energia, con breve stimolazione di back-up post shock. Lo S_ICD non presenta cateteri tradizionali, quindi è in grado di erogare la sola terapia di defibrillazione. Non può stimolare il cuore per interrompere tachicardie meno veloci e regolari, e non può stimolare continuativamente il cuore come un pacemaker.

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Di seguito sono riportate le percentuali di complicanze per gli ICD/ICD-CRT secondo i dati della letteratura medica.

Mortalità ospedaliera e a 30 giorni	0.2-0.7%
Dislocazione elettrodi atriali/ventricolari	0,6-1%
Dislocazione elettrodo dal seno coronarico (CRT-D)	6,8%
Pneumotorace	0.9%
Ematoma della tasca	2,2-2,4%
Infezione/decubito	0,5-2,3%
Versamento pericardico	0,1-0,8%
Trombosi della vena succlavia	0,4-0,7%
Lesione transitoria delle vene del seno coronarico (CRT-D)	2,5-6%

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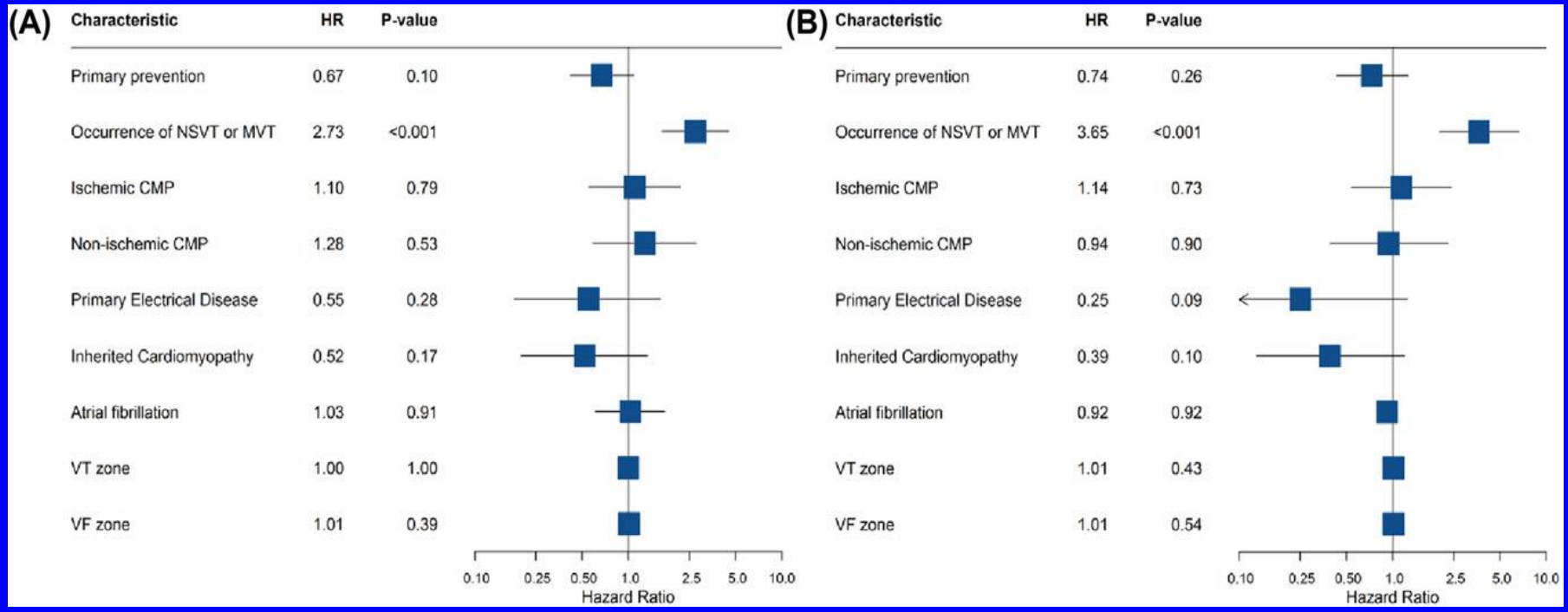
Nel caso dell'S-ICD, i potenziali effetti indesiderati possono verificarsi a carico del paziente e del sistema di defibrillazione.

A carico del paziente possiamo avere reazione allergica, ematoma, emorragia, formazione di cheloidi o cisti, infezione, necrosi tissutale, erosione/estrusione, rari casi di danni nervosi, emotorace e pneumotorace.

A carico del sistema di defibrillazione, si potrebbero avere problematiche riguardanti l'elettrodo (spostamento, deformazione o rottura, connessione inadeguata) anche se al momento attuale tali problematiche sono trascurabili; e, come si è verificato per i dispositivi convenzionali, potrebbero aversi problematiche riguardanti la batteria (ad esempio, esaurimento precoce, malfunzionamento).

Dai dati della letteratura l'incidenza d'interventi non appropriati va dal 7 al 13% e la necessità di reintervento intorno al 4%.

Il successo nell'interruzione dell'aritmia è intorno al 99%. L'incidenza di infezione è del 5-6%, ma questa può essere trattata conservativamente con terapia antibiotica nei 4/5 dei casi.



Received: 17 October 2017 | Revised: 12 April 2018 | Accepted: 7 May 2018
DOI: 10.1111/pace.13411
DEVICES
WILEY PACE

Clinical parameters to optimize patient selection for subcutaneous and transvenous implantable defibrillator therapy

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Limiti

TV-ICD

- Rischio di infezione e endocarditi
- Necessita di un accesso venoso
- Complicanze intraoperatorie legate all'approccio transvenoso (tamponamento, pnx)
- Rischi legati alla procedura di estrazione

S-ICD

- Necessita di uno screening pre-impianto
- Non disponibile stimolazione antibradicardica
- Non disponibile l'ATP

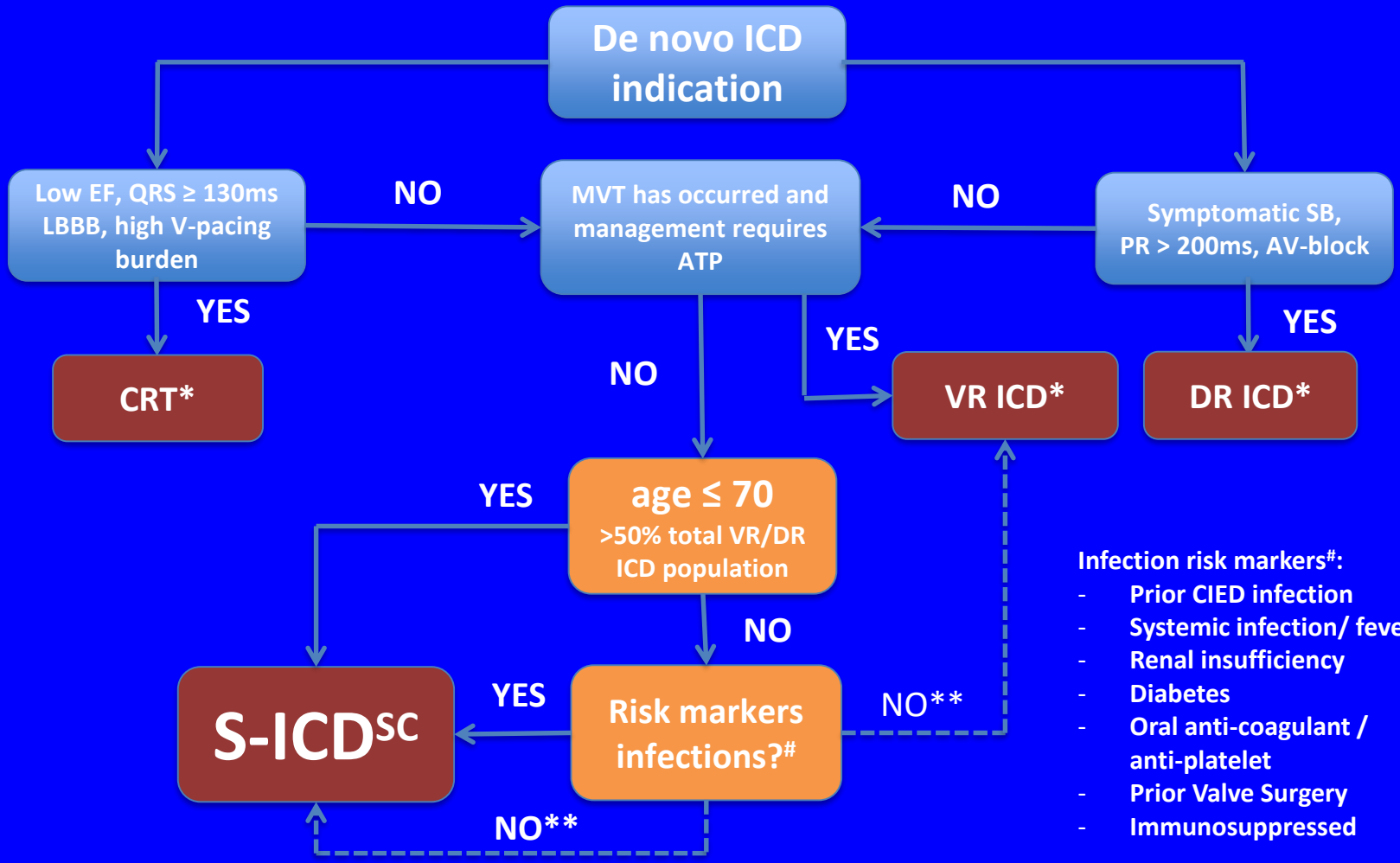
Vantaggi

TV-ICD

- Erogazione differenti terapie : shock, ATP, pacing
- Numerosi dati clinici e trials randomizzati

S-ICD

- Elimina i rischi legati alla presenza di elettrocatetere transvenoso
- Impianto semplice senza uso di fluoroscopia
- Non richiede particolari limitazioni funzionali del paziente



Device choice should be based on shared-decision making between HCP and patient
SC ECG screening is mandatory to evaluate suitability of sensing vectors for the S-ICD
* Extended Life (EL) TV-ICD models should be prioritized to minimize risk of clinical complications related to device replacement
** VR-ICD option can be considered if the patient is NOT expected to survive his device