

UNIVERSITA' DI PADOVA DIPARTIMENTO DI SCIENZE CARDIOLOGICHE, TORACICHE, VASCOLARI E SANITA' PUBBLICA



Cardiopatia Aritmogena: una malattia evolutiva S-ICD in quali pazienti ? Pacing quando e in quali siti ?

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Transvenous-ICD therapy provides the most effective life-saving protection for patients with ARVC

Mean follow-up: 39 \$ 27 months (3.3 years)

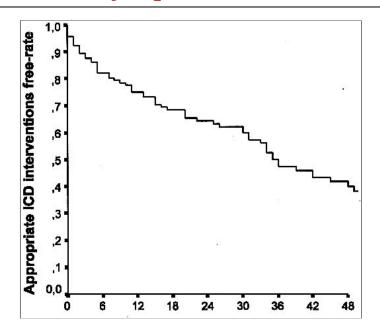
Appropriate ICD interventions: 64/132 patients (48%)

*Shocks (31)

*ATP (13)

*both (20)

(a total of 1271disharges)



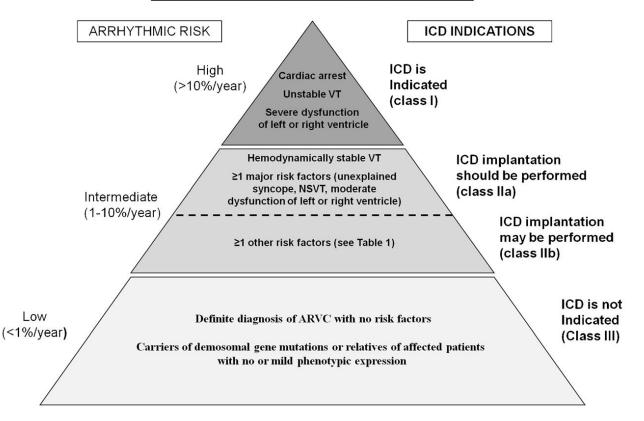
ICD interventions in high-risk patients occurred despite concomitant AADs, a finding supporting the concept that AAD therapy may not confer adequate protection against SCD

TV-ICD Appropriate therapies in ARVC patients

First Author	Year	Patients (n)	Study design	Men (%)	Follow- up (months)	Primary prevention (%)	Mortality overall (%)	Appropriate interventions (%)	Life-saving interventions (%)	Inappropriate Interventions (%)	Complications (%)
Breithardt ⁴⁹	1994	18	SC	72	17±11	0	0	50	N/A	N/A	N/A
Link ⁵⁰	1997	12	SC	58	22±13	0	8	67	50	33	33
Tavernier ⁵¹	2001	9	SC	89	32±24	0	0	78	44	44	N/A
Corrado ⁵²	2003	132	MC	70	39±25	22	3	48	24	16	14
Wichter ⁵³	2004	60	SC	82	80±43	7	13	68	40	23	45
Rougin ⁵⁴	2004	42	MC	52	42±26	40	2	78	N/A	24	14
Hodgkinson ⁵⁵	2005	48	MC	63	31	73	0	70ª	30a	10	6
Piccini ⁵⁶	2005	67	SC	35	53±11	42	9	66	21	24	21
Boriani ⁵⁷	2007	15	SC	12	65±42	40	0	33	40	7	47
Corrado ⁵⁸	2010	106	MC	58	58±35	100	0	24	16	19	17
Bhonsale ⁵⁹	2011	84	SC	46	57±41	100	2.4	48	19	24	24
Schuler ⁶⁰	2012	26	SC	81	128	4	8	46	N/A	N/A	8

☐ ICD Appropriate therapies: 9.5%/yr

Risk stratification and indications to ICD implantation according to 2015 International Task Force consensus on ARVC treatment

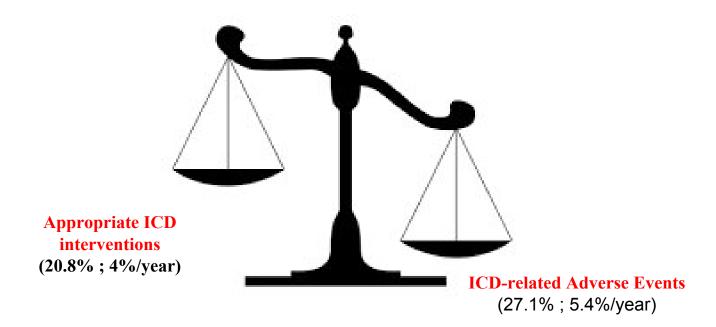


TV-ICD complications AND inappropriate therapies in ARVC patients

First Author	Year	Patients (n)	Study design	Men (%)	Follow- up (months)	Primary prevention (%)	Mortality overall (%)	Appropriate interventions (%)	Life-saving interventions (%)	Inappropriate Interventions (%)	Complications (%)
Breithardt ⁴⁹	1994	18	SC	72	17±11	0	0	50	N/A	N/A	N/A
Link ⁵⁰	1997	12	SC	58	22±13	0	8	67	50	33	33
Tavernier ⁵¹	2001	9	SC	89	32±24	0	0	78	44	44	N/A
Corrado ⁵²	2003	132	MC	70	39±25	22	3	48	24	16	14
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- ☐ Lead/device related complications: 3.7%/yr
- ☐ Inappropriate ICD therapies: 4.4%/yr

Risk—benefit ratio of ICD therapy in young patients with cardiomyopathies and channelopathies should be carrefully assesed



Including Inappropriate ICD interventions (9.4%)
Device-related complications requiring surgical revision 20.8%)

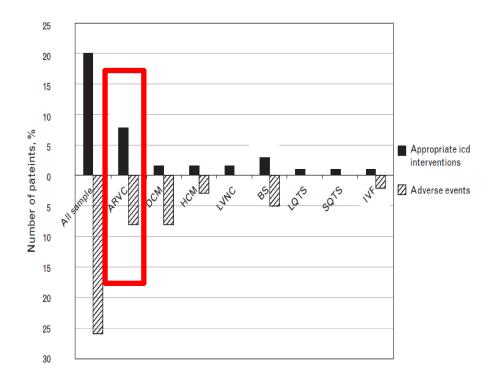
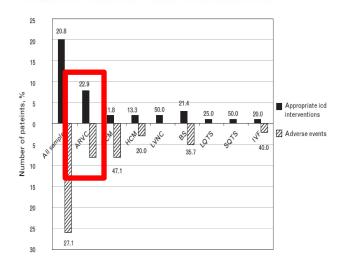


Table 5 Predictors of device-related complications during follow-up

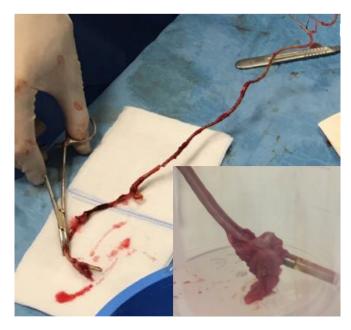
	Ur	nivariate anal	ysis	Multivariate analysis			
	HR	Cl	Р	HR	Cl	Р	
Age (years)	1.07	1.0-1.2	0.051	1.08	0.91-1.16	0.32	
Sex (male)	0.66	0.3 - 1.7	0.374				
Primary prevention	1.99	0.7 - 6.0	0.219				
Structural cardiomyopathy	1.35	0.5 - 3.8	0.560				
Previous cardiac arrest	1.24	0.4 - 3.7	0.697				
Underweight	3.86	1.1-13.4	0.034	5.43	1.5-19.4	0.01	
Single-lead ICD	1.83	0.4-7.9	0.417				
Right ventricular apical position	1.02	0.1-7.9	0.983				
Double coil	1.14	0.3-4.3	0.843				
Active fixation lead	2.63	0.9 - 7.6	0.072				
Antiarrhythmic drug therapy	0.87	0.3-2.3	0.770				

Implantable cardioverter defibrillator therapy in young patients with cardiomyopathies and channelopathies: a single Italian centre experience

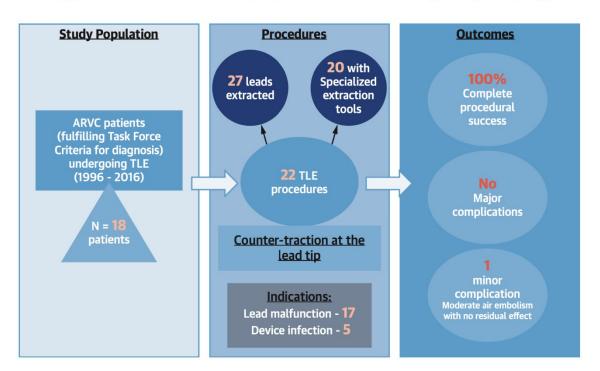
Federico Migliore, Maria Silvano, Alessandro Zorzi, Emanuele Bertaglia, Mariachiara Siciliano, Loira Leoni, Pietro De Franceschi, Sabino Iliceto and Domenico Corrado



Lead failure/fracture requiring lead extraction was the most common complication (9.4%)

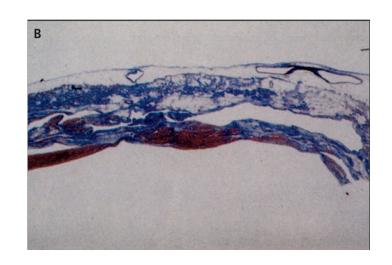


Transvenous Lead Extraction in Patients With Arrhythmogenic Right Ventricular Cardiomyopathy

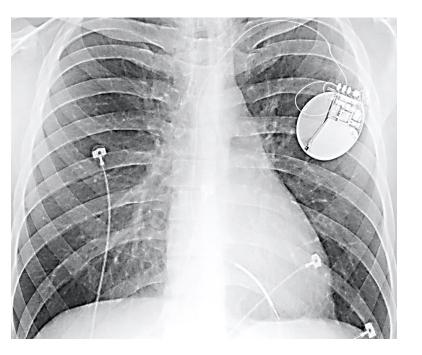


High rate of lead-related adverse events in in ARVC Patients

Complication	Number (n=98)
Lead-related complications (2-68)	
Lead fracture	19 (19)
Decreased sensing on the RV	6 (6)
Lead dislodgment	8 (8)
Led recall	12 (12)
Subclavian/IJ vein thrombosis	2 (2)
Lead malfunction*	19 (19)
Tamponade	2 (2)



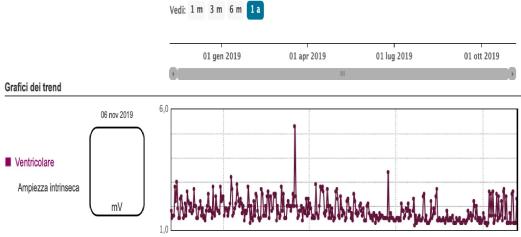
High rate of lead-related adverse events may be explained by the peculiar ARVC/D pathobiology which leads to progressive loss of myocardium with fibrofatty replacement, also affecting the site of RV lead implantation



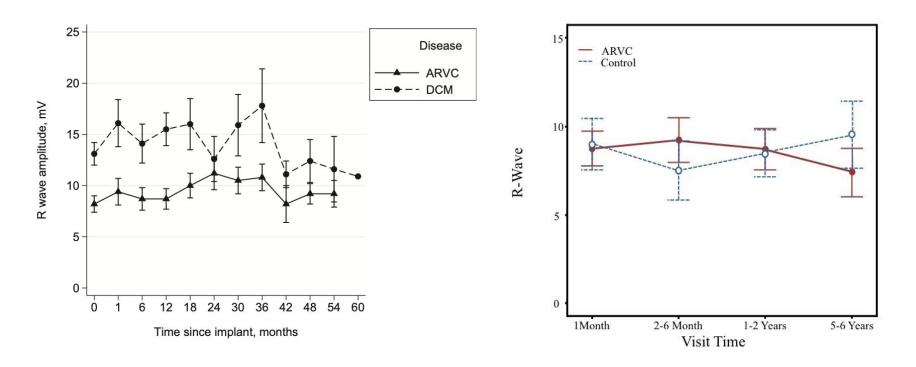
At the implant: sensing 4.2 mV

Elettrocateteri (Visualizza dettaglio)

Ampiezza intrinseca ventricolare destra o monocamerale fuori intervallo. Misurazione **Misurazione** ambulatoriale giornaliera più più recente recente (22 lug 2019) (06 nov 2019) **Ventricolare** 1,2 mV Ampiezza intrinseca 2,3 mV (05 nov 2019) Impedenza di pacing 9**0**0 Ω 934 12 (05 nov 2019) Soglia di pacing 1,0 V @ 0,4 ms N/R



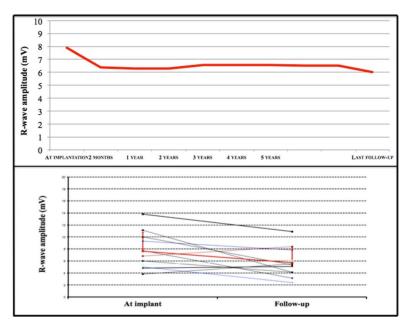
R-wave amplitudes in ARVC patients vs control

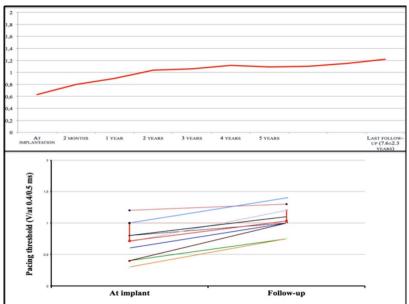


Jem D. Lane et al. Indian Pacing and Electrophysiology Journal 2019;49e54

Herman et al. Heart Rhythm 2016;13:1964-70

R-wave amplitudes AND pacing thresholds during follow- up in ARVC patients

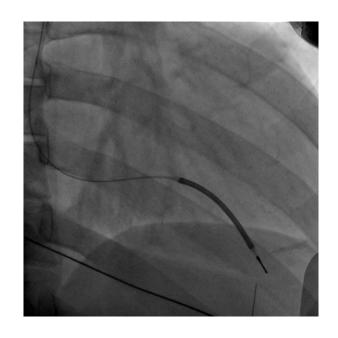




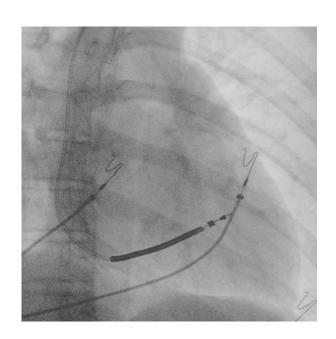
A low R-wave may result in:

- ✓ Undersensing of ventricular tachyarrhythmias
- ✓ **Inappropriate ICD therapy** due to T-wave oversensing because of the automatic algorithm of ICD for sensing

Where we have to implant the ICD lead in ARVC patients?



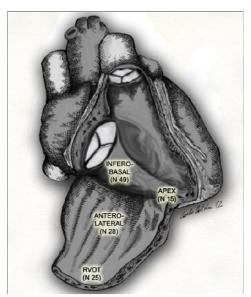
OR

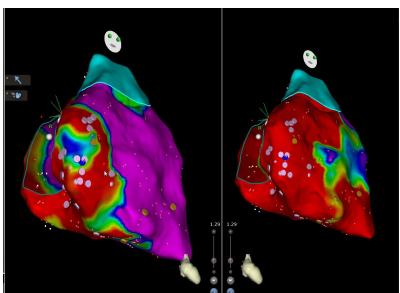


In the RV Apex?

In the septum?

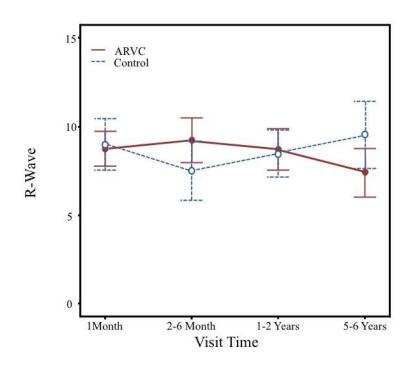
"Triangle" of dysplasia

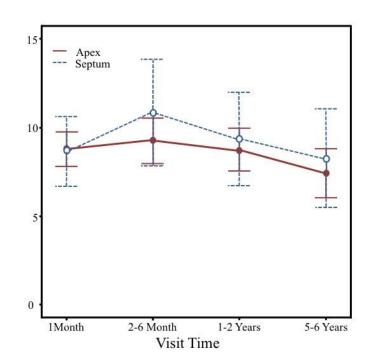


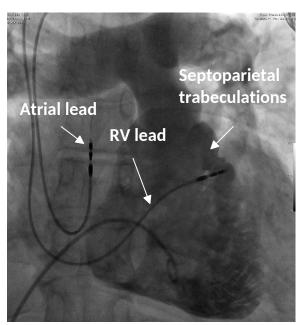


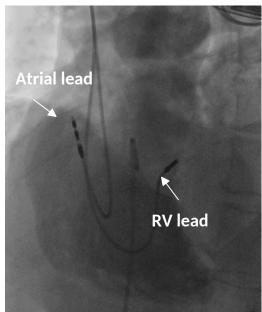


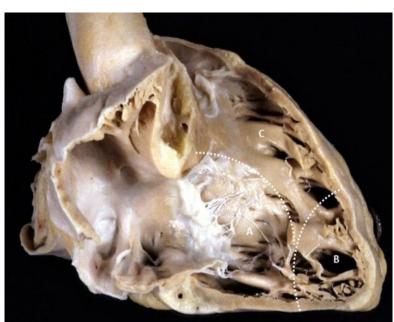
Where we have to implant the ICD lead in ARVC patients?











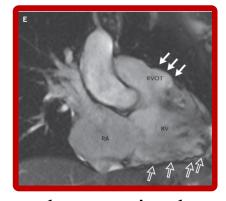
RAO LAO

Boukens, Basso, Migliore, Rizzo, Thiene Cardiac Mapping, Fifth Edition 2019

ARVC phenotypes

RV phenotype: either isolated or associated with some LV involvement





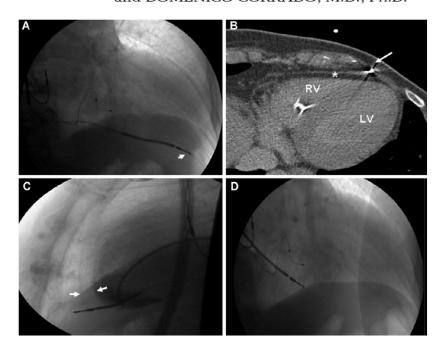
Biventricular phenotype: characterized by equal involvement of both ventricles

Left dominant phenotype: with early and prominent LV manifestations.



Incidence, Management, and Prevention of Right Ventricular Perforation by Pacemaker and Implantable Cardioverter Defibrillator Leads

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EMANUELE BERTAGLIA, M.D.,* LOIRA LEONI, M.D., Ph.D.,*
MARIACHIARA SICILIANO, M.D.,* MANUEL DE LAZZARI, M.D.,*
BARBARA IGNATIUK, M.D.,+ MARTA VERONESE, M.D.,‡ ROBERTO VERLATO, M.D.,\$
GIUSEPPE TARANTINI, M.D., Ph.D.,* SABINO ILICETO, M.D.,*
and DOMENICO CORRADO, M.D., Ph.D.,*



- ✓ *RV perforation is rare* complication regardless of the lead fixation mechanism
- ✓ Avoid the true apex

A single or dual-chamber ICD in ARVC patients?

Treatment of arrhythmogenic right ventricular cardiomyopathy/dysplasia: an international task force consensus statement

Domenico Corrado^{1*}, Thomas Wichter², Mark S. Link³, Richard Hauer⁴, Frank Marchlinski⁵, Aris Anastasakis⁶, Barbara Bauce¹, Cristina Basso¹, Corinna Brunckhorst⁷, Adalena Tsatsopoulou⁸, Harikrishna Tandri⁹, Matthias Paul¹⁰, Christian Schmied⁷, Antonio Pelliccia¹¹, Firat Duru⁷, Nikos Protonotarios⁸, NA Mark Estes III³, William J. McKenna¹², Gaetano Thiene¹, Frank I. Marcus¹³, and Hugh Calkins⁹

Device selection

A single-chamber ICD system is recommended in order to minimize the incidence of long-term lead-related complications, mostly in young patients.

Association of Single- vs Dual-Chamber ICDs With Mortality, Readmissions, and Complications Among Patients Receiving an ICD for Primary Prevention

	No	o. (%) of Patier	nts	ρ,	
	I	Chaml	oer ICD	l 5:"	
	Overall (n = 23 238)	Single (n = 11 619)	Dual (n = 11 619)	Difference (single-dual), % (95% CI)	P Value
30-Day results Pneumothroax requiring chest tube	122 (0.53)	51 (0.44)	71 (0.61) -	-0.17 (-0.36 to 0.01)	.07
Hematoma requiring blood transfusion or evacuation	52 (0.22)	24 (0.21)	28 (0.24) -	-0.03 (-0.16 to 0.09)	.58
Cardiac tamponade	158 (0.68)	51 (0.44)	107 (0.92) -	-0.48 (-0.69 to -0.27)	<.001
90-Day results Mechanical complications requiring system revision	396 (1.70)	166 (1.43)	230 (1.98) -	-0.55 (-0.88 to -0.22)	.001
Device-related infection	151 (0.65)	68 (0.59)	83 (0.71) -	-0.13 (-0.34 to 0.08)	.22
ICD replacement	175 (0.75)	85 (0.73)	90 (0.77) -	-0.04 (-0.27 to 0.18)	.70
Any complication	956 (4.11)	408 (3.51)	548 (4.72) -	-1.20 (-1.72 to -0.69)	<.001
Outcomes at 1 y after implant All-cause mortality	2280 (9.81)	1145 (9.85)	1135 (9.77)	0.09 (-0.68 to 0.85)	.83
All-cause hospitalization	10189 (43.85)	5096 (43.86)	5093 (44.83)	0.03 (-1.25 to 1.30)	.97
Heart failure hospitalization	3498 (15.05)	1711 (14.73)	1787 (15.38)	-0.65 (-1.57 to 0.27)	.16

Conclusions and Relevance

Dual-chamber device:

- ✓ Higher risk of device-related complications
- ✓ Similar 1-year mortality

The decision to implant a dual-chamber ICD for primary prevention should be considered carefully

Reduction in Inappropriate Therapy and Mortality through ICD Programming

Arthur J. Moss, M.D., Claudio Schuger, M.D., Christopher A. Beck, Ph.D., Mary W. Brown, M.S., David S. Cannom, M.D., James P. Daubert, M.D., N.A. Mark Estes III, M.D., Henry Greenberg, M.D., W. Jackson Hall, Ph.D.,* David T. Huang, M.D., Josef Kautzner, M.D., Ph.D., Helmut Klein, M.D., Scott McNitt, M.S., Brian Olshansky, M.D., Morio Shoda, M.D., David Wilber, M.D., and Wojciech Zareba, M.D., Ph.D., for the MADIT-RIT Trial Investigators;

Conventiona	programming	g (≥170 bpm))
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High-rate programming (≥200 bpm)

Delayed programming (60-second delay, ≥170 bpm)

✓ "aggressive" ICD programming may overestimate the real incidence of appropriate therapies

✓ "unnecessary therapies" VT/VF episodes self-terminated

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

[✓] reduction in inappropriate therapy

Tip and tricks for TV-ICD implantation in ARVC patients

- ✓ Avoid subclavian vein puncture and prefer axillary vein
- ✓ At lead implantation, multiple endocardial sites should be tested if sensing or pacing values are not optimal
- ✓ It may be preferable to avoid implanting ICD leads at the true apex AND free wall
- ✓ Avoid dual-coil
- ✓ Longer term follow-up
- ✓ A single-chamber ICD system is recommended in order to minimize the incidence of long-term lead-related complications, mostly in young patients
- Optimal ICD programming: High-rate programming (≥200 bpm); Delayed programming (60-second delay, ≥170 bpm); favoring more ATP



S-ICD in young with Cardiomyopathies/Channelopathies

- ✓ The lack of transvenous and intracardiac components
- ✓ No pacing indication
- ✓ SCD is precipitated by polymorphic VT/VF

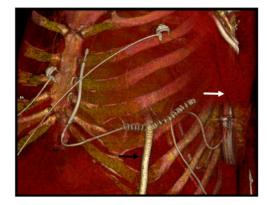
....make it an attractive choice for these patients!

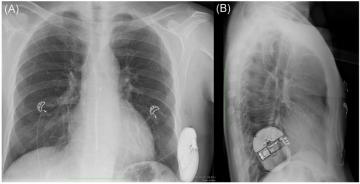
Multicentre experience with the second-generation subcutaneous implantable cardioverter defibrillator and the intermuscular two-incision implantation technique

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Federico Migliore MD, PhD¹ | Giulia Mattesi MD¹ | Pietro De Franceschi MD¹ |
Giuseppe Allocca MD² | Martino Crosato MD³ | Vittorio Calzolari MD³ |
Mauro Fantinel MD⁴ | Benedetta Ortis MD⁵ | Domenico Facchin MD⁶ |
Elisabetta Daleffe MD⁶ | Tommaso Fabris MD¹ | Elena Marras MDⁿ |
Manuel De Lazzari MD¹ | Francesco Zanon MD®  | Lina Marcantoni MD® |
Mariachiara Siciliano MD⁰ | Domenico Corrado MD, PhD¹ | Sabino Iliceto MD¹ |
Emanuele Bertaglia MD, PhD¹ | Massimo Zecchin MD⁵
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- ✓ Appropriate shocks: 9.9%
- ✓ Inappropriate shocks: 2.9%





Il defibrillatore sottocutaneo nella pratica clinica

Federico Migliore^{1*}, Giulia Mattesi^{1*}, Alessandro Zorzi¹, Stefano Viani², Maria Grazia Bongiorni², Pietro Francia³, Antonio Curcio⁴, Igor Diemberger⁵, Emanuele Bertaglia¹

¹Dipartimento Cardio-Toraco-Vascolare, Università degli Studi, Padova ²U.O. Malattie Cardiovascolari 2, Azienda Ospedaliero-Universitaria Pisana, Pisa ³U.O.C. Cardiologia, Sapienza Università di Roma, A.O. Sant'Andrea, Roma

⁴U.O. Cardiologia, Dipartimento di Scienze Mediche e Chirurgiche, Università degli Studi Magna Graecia, Campus di Germaneto, Catanzaro ⁵Istituto di Cardiologia, Dipartimento di Medicina Specialistica Diagnostica e Sperimentale, Università degli Studi, Bologna

Terza generazione S-ICD EMBLEM (Boston Scientific)



Spessore 12.7 mm
Volume 595 cc
Peso 130 g
Longevità 7.3 anni
Monitoraggio remoto LATITUDE
Risonanza compatibile Sì
SMART Pass Sì

QUALI SONO I POSSIBILI VANTAGGI DI S-ICD?

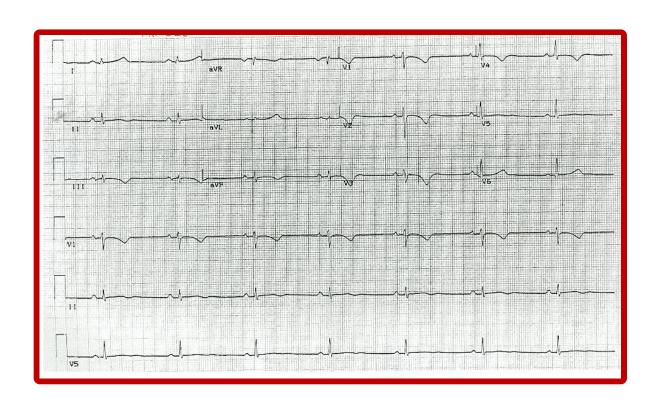
- · Riduce e potenzialmente annulla il rischio di infezioni sistemiche
- Assenza di danni vascolari
- · Preserva gli accessi vascolari
- · Riduce l'esposizione radiologica per il paziente e per il medico
- Riduce il rischio di danni del catetere dovuto a stress biomeccanico
- Potenziale minore interferenza con la risonanza magnetica cardiaca per l'assenza dell'elettrocatetere in sede intravascolare

QUALI SONO I POTENZIALI LIMITI DI S-ICD?

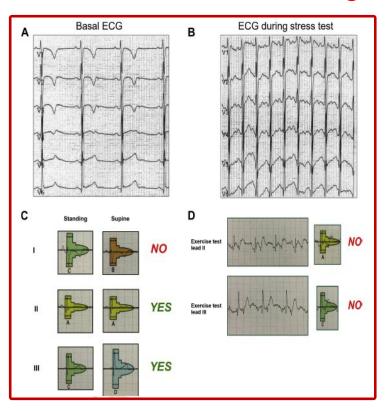
- Necessità di eseguire uno screening pre-impianto
- Incapacità di erogare pacing per il trattamento di bradicardi clinicamente rilevanti o per la terapia di resincronizzazione cardiaca
- Incapacità di erogare ATP per la potenziale interruzione (pain-free) di tachicardie ventricolari monomorfe sostenute
- Durata della batteria (nei nuovi dispositivi ~7 anni)
- Popolazione pediatrica (dimensioni del dispositivo)

G Ital Cardiol 2019;20(11):641-650

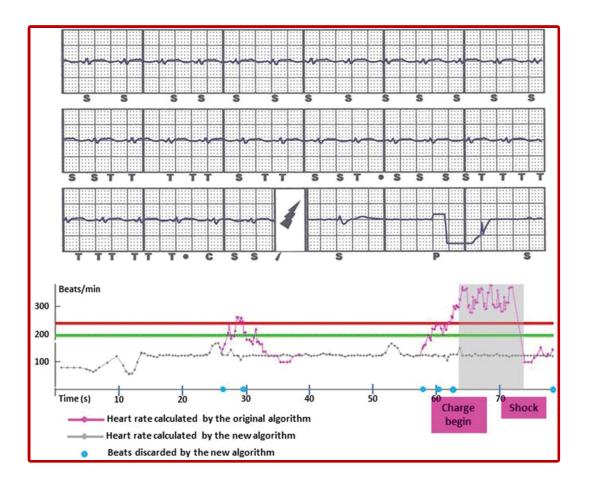
ECG features in ARVC

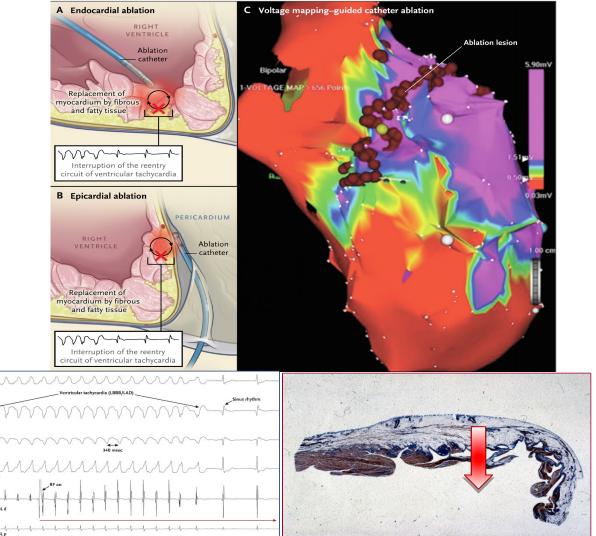


Pseudonormalization of negative T –waves during effort: Limititation of S-ICD screening eligibility



Migliore F et al. JACC Clinical Elecrophysiology 2016

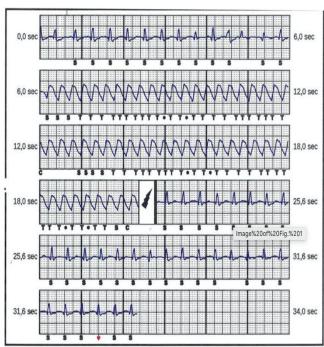




Subcutaneous implantable cardioverter defibrillator in patients with arrhythmogenic right ventricular cardiomyopathy: Results from an Italian multicenter registry*

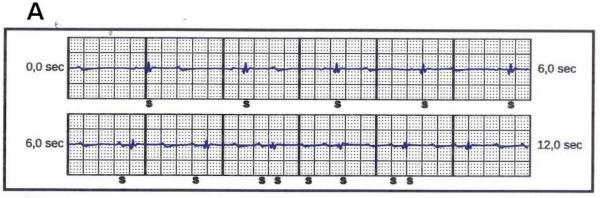
Federico Migliore ^a, Stefano Viani ^b, Maria Grazia Bongiorni ^b, Alessandro Zorzi ^a, Massimo Stefano Silvetti ^c, Pietro Francia ^d, Antonio D'Onofrio ^e, Pietro De Franceschi ^a, Simone Sala ^f, Stefano Donzelli ^g, Giuseppe Ricciardi ^h, Endry Menardi ⁱ, Massimo Giammaria ^j, Carmelo La Greca ^k, Barbara Bauce ^a, Ilaria Rigato ^a, Sabino Iliceto ^a, Emanuele Bertaglia ^a, Igor Diemberger ^{1,1}, Domenico Corrado ^{a,*,1}

	n = 44
Male gender	25 (57)
Age, years	37 ± 17
Height, cm	174 ± 10
Weight, kg	73 ± 14
BMI	24 ± 4
LV ejection fraction	53 ± 11
LV ejection fraction ≤50%	13 (30)
New York Heart Association	
Class I	39 (89)
Class II	5 (11)
Previous transvenous ICD	7 (16)
Primary prevention	26 (59)
History of sustained VT	17 (39)
History of SCD	1 (2)
NSVT	14 (32)
Syncope	10 (23)
Inducibility at EPS	3/13 (23)
ECG characteristics	
Sinus rhythm	44 (100)
QRS duration, ms	94 ± 16
PQ interval	175 ± 4
QTc interval	429 ± 9
Negative T-wave in V1-V3 leads	26 (59)
Negative T-wave in lateral/inferior leads	14(32)
Epsilon wave	4 (9)
Medications at implant	
Beta-blockers	26 (59)
Amiodarone	2 (4)
Sotalol	11 (25)

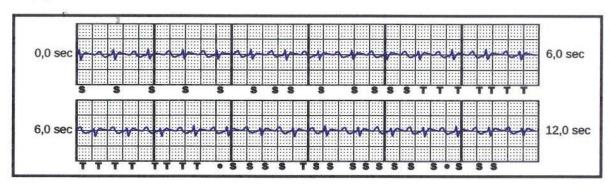


- ✓ Appropriate and successful shocks on VA: 14%
- ✓ Inappropriate shocks :14%
- ✓ No patients had the device explanted due to the need for ATP

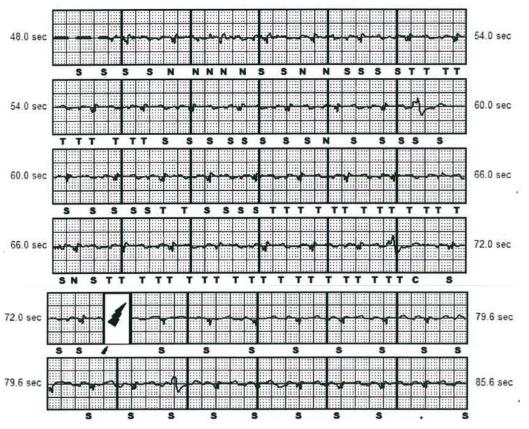
Oversensing due to P/T-wave oversensing during rest

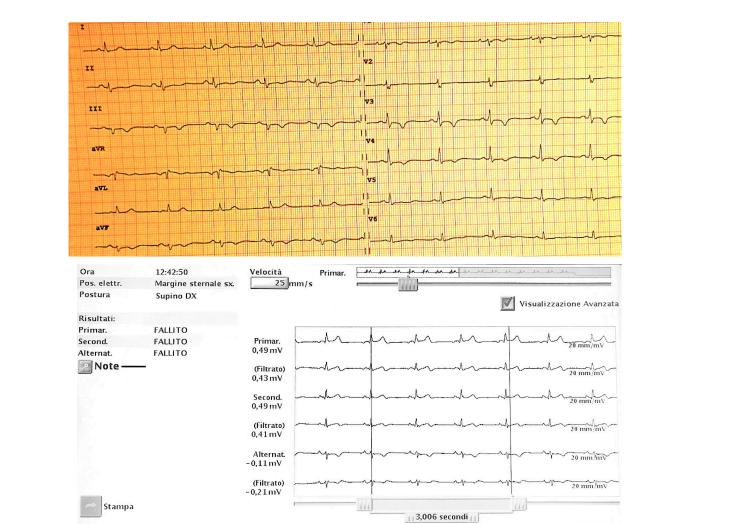




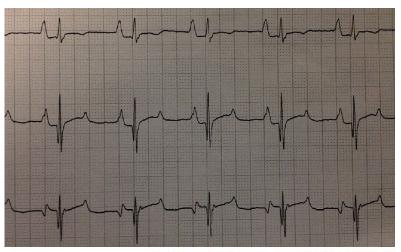


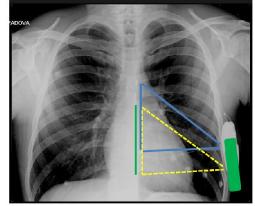
Inappropriate Shock due to P/T-wave oversensing during effort





The P-wave in ARVC



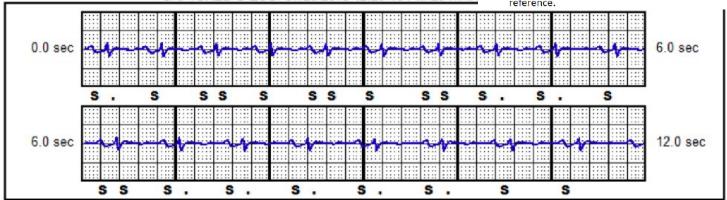


IA PABSWA

Blue lines represent current vectors

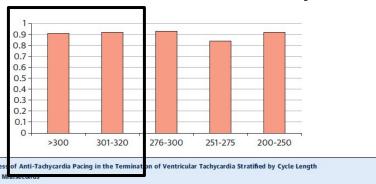
CAPTURED S-ECG: 07/20/2015 12:20:46 PM 25 mm/s

Yellow lines represent potential vectors if system is repositioned to match green reference.



Need for ATP?

- ☐ A potential limitation of the S-ICD is the inability to deliver ATP which may be an effective "pain-free" therapy in ARVC patients
- ☐ However, to judge whether this should be regarded as an absolute contraindication to S-ICD in ARVC, other factors should be taken into account
- ☐ First of all, it has to be noted that $\approx 2/3$ of VTs that were interrupted by ATP in the North American study (3) were slower than 200 beats per minute, i.e. probably non-life-threatening and potentially self-limited, considering that the majority of ARVC patients have a normal or near-normal LV ejection fraction



Even rapid ventricular tachycardias had a high likelihood of termination with anti-tachycardia pacing.

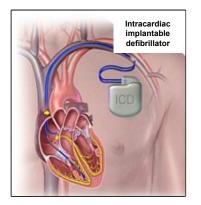
Link et al. J Am Coll Cardiol 2014

Tip and tricks for S-ICD implantation in ARVC patients

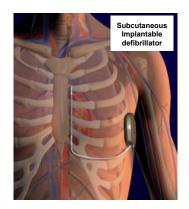
Need for effective strategies to prevent inappropriate shocks

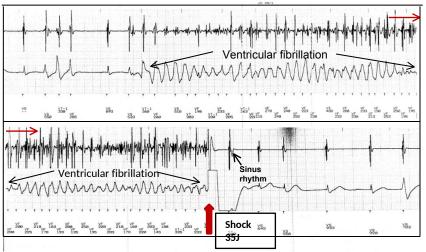
- ✓ Appropriate pre-implantation ECG screening
 - Rest/stress
 - at least 2 or 3 leads suitable in the S-ICD screening template
 - left/right parasternal screening
 - <u>ECG R-wave amplitude > 1 mV at implant</u>
- ✓ Accurate implantation technique
- ✓ Better device programming (Conditional zone, shock zone)
- ✓ Software upgrade (SMART Pass)
- ✓ Post-operative follow-up
- ✓ Drug therapy and catheter ablation of VT in ARVC should be considered a potentially effective strategy for eliminating frequent both fast or slow VT

TV-ICD vs S-ICD in ARVC Patients











Treatment of arrhythmogenic right ventricular cardiomyopathy/dysplasia: an international task force consensus statement

Domenico Corrado^{1*}, Thomas Wichter², Mark S. Link³, Richard Hauer⁴, Frank Marchlinski⁵, Aris Anastasakis⁶, Barbara Bauce¹, Cristina Basso¹, Corinna Brunckhorst⁷, Adalena Tsatsopoulou⁸, Harikrishna Tandri⁹, Matthias Paul¹⁰, Christian Schmied⁷, Antonio Pelliccia¹¹, Firat Duru⁷, Nikos Protonotarios⁸, NA Mark Estes III³, William J. McKenna¹², Gaetano Thiene¹, Frank I. Marcus¹³, and Hugh Calkins⁹

Device selection



A decision whether to implant an S-ICD device needs to be patient specific, balancing the likelihood of recurrent and life-threatening VT with the prevalence of serious lead-related complications.

PRO e CONTRO di S-ICD nei pazienti con ARVC

Candidato ottinale all' S. ICD

FORTE INDICAZIONE

Non storia di TV sostenute

"hot phases"

Paziente giovane con lunga aspettativa di vita

Prevenzione primaria

Difficoltà nell'accesso venoso

Precedente infezione

Presenza di fattori di rischio per infezione

CONTROINDICAZIONE RELATIVA

Necessità di ATP (difficile da definire clinicamente; considerare terapia farmacologica e ablativa)

Bradicardia

CONTROINDICATO

Chiara indicazione al *pacing* (bradicardia o CRT)

Screening non idoneo (potenziale alto rischio di *shock* inappropriate)

Implantable defibrillators in primary prevention of genetic arrhythmias. A shocking choice?

Domenico Corrado (1) 1, Mark S. Link (1) 2, and Peter J. Schwartz (1) 3*

