

GIORNATE CARDIOLOGICHE TORINESI

LESS IS MORE



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Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark

Table 2 Cumulative incidence of complications at six months^a

	All (n = 5918)	New implant (n = 4355)	Generator replacement (n = 1136)	Upgrade/ lead revision (n = 427)
Any complication	562 (9.5; 8.7–10.2)	432 (9.9; 9.0–10.8)	67 (5.9; 4.5–7.3)	63 (14.8; 11.4–18.1)
Any major complication	329 (5.6; 5.0–6.1)	253 (5.8; 5.1–6.5)	40 (3.5; 2.4–4.6)	36 (8.4; 5.8–11.1)
Any minor complication	250 (4.2; 3.7–4.7)	189 (4.3; 3.7–4.9)	30 (2.6; 1.7–3.6)	31 (7.3; 4.8–9.7)
Major complications				
Lead related re-intervention	143 (2.4; 2.0–2.8)	120 (2.8; 2.3–3.2)	10 (0.9; 0.3–1.4)	13 (3.0; 1.4–4.7)
Infection	49 (0.8; 0.6–1.1)	24 (0.6; 0.3–0.8)	17 (1.5; 0.8–2.2)	8 (1.9; 0.6–3.2)
Local infection	22 (0.4; 0.2–0.5)	10 (0.2; 0.1–0.4)	8 (0.7; 0.2–1.1)	4 (1.0; 0.0–1.9)
Systemic infection/endocarditis	27 (0.5; 0.3–0.6)	14 (0.3; 0.2–0.5)	9 (0.8; 0.3–1.3)	4 (0.9; 0.0–1.9)
Pneumothorax requiring drainage	51 (0.9; 0.6–1.1)	45 (1.0; 0.7–1.3)	0	6 (1.4; 0.3–2.5)
Cardiac perforation	38 (0.6; 0.4–0.8)	35 (0.8; 0.5–1.1)	0	3 (0.7; 0.0–1.5)
No intervention	21 (0.4; 0.2–0.5)	18 (0.4; 0.2–0.6)	0	3 (0.7; 0.0–1.5)
Intervention ^b	17 (0.3; 0.2–0.4)	17 (0.4; 0.2–0.6)	0	0
Pocket revision because of pain	25 (0.4; 0.3–0.6)	10 (0.2; 0.1–0.4)	9 (0.8; 0.3–1.3)	6 (1.4; 0.3–2.5)
Generator-lead interface problem with re-intervention	7 (0.1; 0.0–0.2)	3 (0.1; 0.0–0.1)	4 (0.4; 0.0–0.7)	0
Haematoma requiring re-intervention	10 (0.2; 0.1–0.3)	9 (0.2; 0.1–0.3)	1 (0.1; 0.0–0.3)	0
Other ^c	16 (0.3; 0.1–0.4)	16 (0.4; 0.2–0.5)	0	0
Minor complications				
Haematoma ^d	138 (2.3; 1.9–2.7)	104 (2.4; 1.9–2.8)	20 (1.8; 1.0–2.5)	14 (3.3; 1.6–5.0)
Wound infection treated with antibiotics	69 (1.2; 0.9–1.4)	47 (1.1; 0.8–1.4)	12 (1.0; 0.5–1.7)	10 (2.3; 0.9–3.8)
Pneumothorax conservatively treated	39 (0.7; 0.5–0.9)	32 (0.7; 0.5–1.0)	0	7 (1.6; 0.4–2.8)
Lead dislodgement without re-intervention	10 (0.2; 0.1–0.3)	9 (0.2; 0.1–0.3)	0	1 (0.2; 0.0–0.7)

Incidenza di complicanze a 6 mesi dopo l'impianto

Maggiore è il numero di elettrocatereteri e maggiori sono le complicanze



Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark

Predittori indipendenti per ogni
complicanza

ICD bicamerale 2.0 (1.4-2.7)
CRTD 2.6 (1.9-3.4)
p<0.001

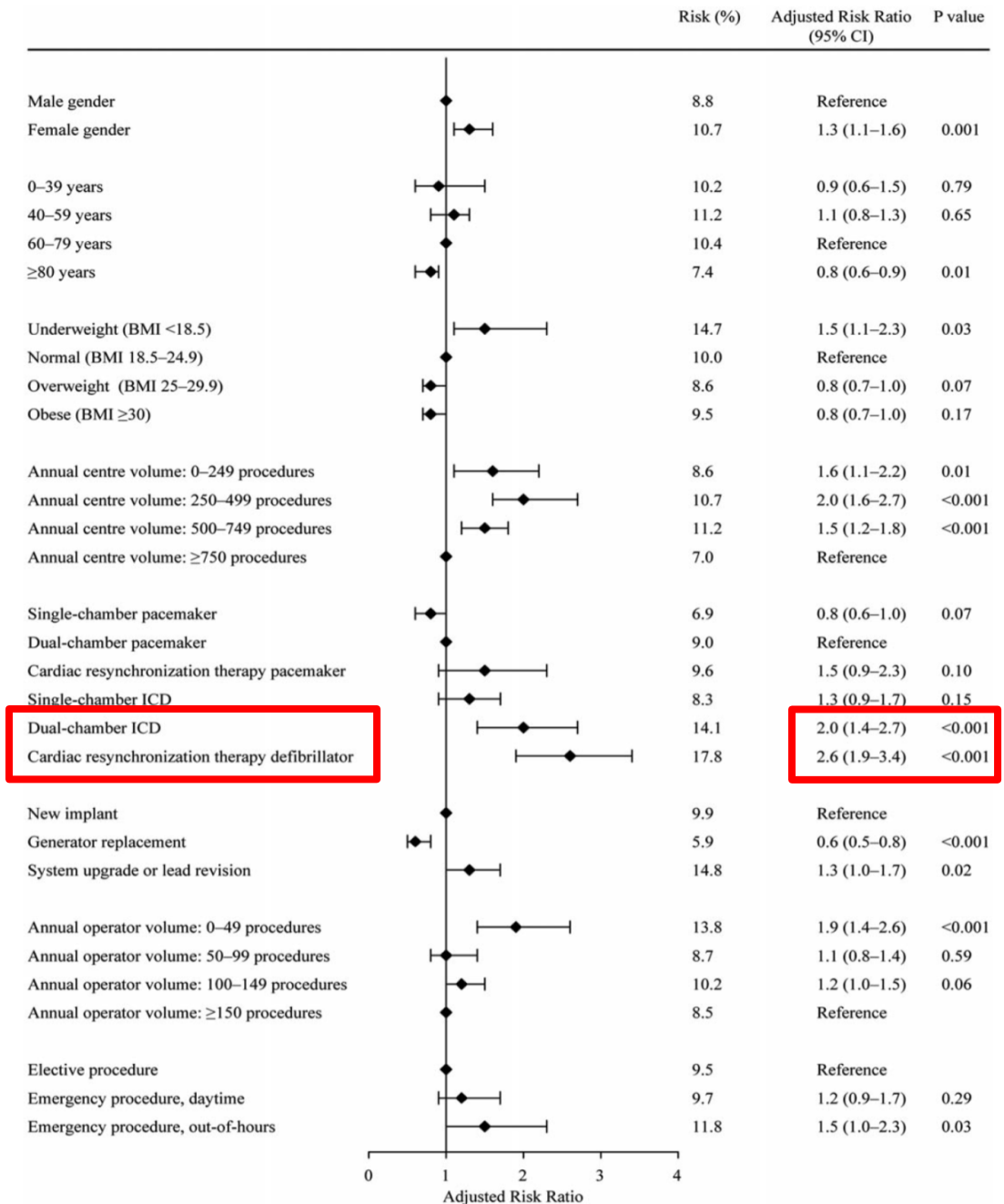


Figure 2 Predictors of any complication.

STATE-OF-THE-ART PAPER

Implantation-Related Complications of Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy Devices

A Systematic Review of Randomized Clinical Trials

1.8% tasso di dislocazioni
negli ICD

5.7% tasso di dislocazioni
nei CRTD

**Aumentare il numero di lead
non è a rischio zero**

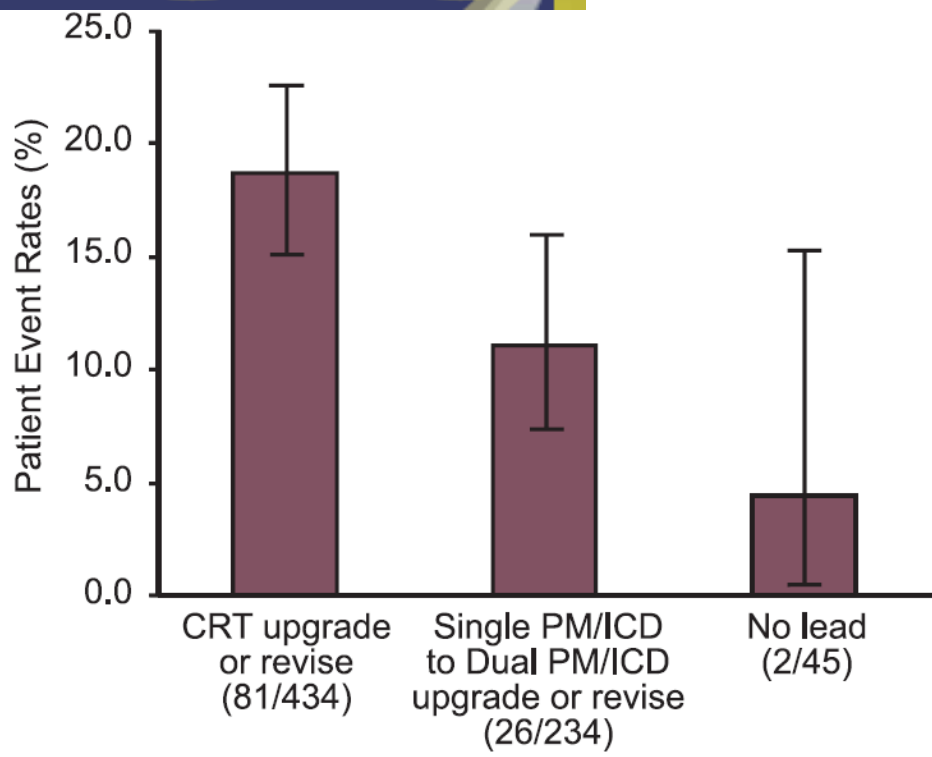
Table 6

Lead Dislodgement During Follow-Up in
Nonthoracotomy Requiring Implanted Devices

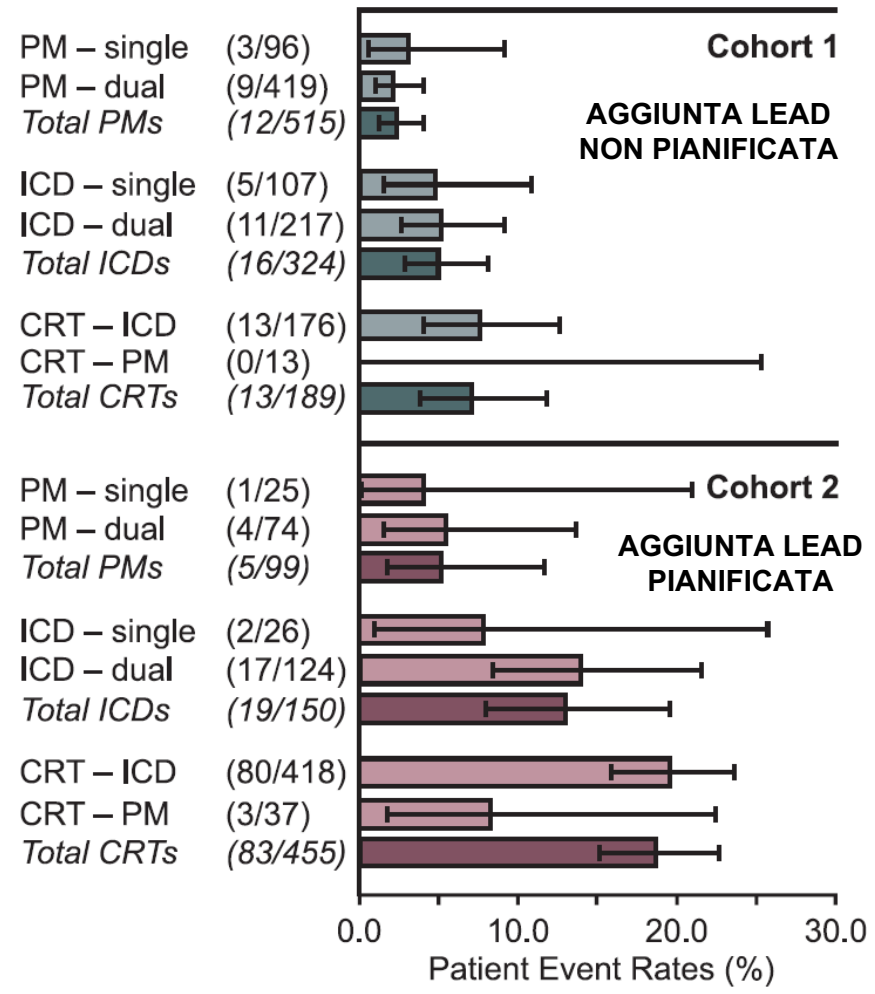
Trial	Year	Successful Implants, n	All Events, n (%)	Duration, months
Nonthoracotomy ICD systems				
AVID*	1997	593	8 (1.5)	27 ± 13
CAT†	2002	50	2 (4.0)	0.5†
DEFINITE*	2004	227	6 (2.6)‡	29 ± 14
Total		870	16 (1.8)	
Nonthoracotomy CRT systems				
MIRACLE*	2002	526	31 (5.9)	6
MIRACLE ICD§	2003	379	11 (2.9)	6
CARE-HF†	2005	390	11 (2.8)	0.5†
RethinQ	2007	172	13 (7.6)¶	6
REVERSE	2008	621	66 (10.6)	12
MADIT-CRT (CRT arm)†	2009	1,007	44 (4.4)#	0.5†
Total		3,095	176 (5.7)	

Complication Rates Associated With Pacemaker or Implantable Cardioverter-Defibrillator Generator Replacements and Upgrade Procedures

Results From the REPLACE Registry



Aggiungere un catetere in un secondo momento, gestire dispositivi o elettrodi con avvisi di richiamo e programmare upgrade a sistemi più complessi porta a tassi di complicanze ancora maggiori



SVANTAGGI DEL CATETERE ATRIALE:

DISLOCAZIONI



Arrhythmia/Electrophysiology

The 1+1 Trial

A Prospective Trial of a Dual- Versus a Single-Chamber Implantable Defibrillator in Patients With Slow Ventricular Tachycardias

Dietmar Bänsch, MD; Frank Steffgen; Gerian Grönefeld, MD; Christian Wolpert, MD; Dirk Böcker, MD; Ralph-Uwe Mletzko, MD; Wolfgang Schöls, MD; Karlheinz Seidl, MD; Michael Piel; Feifan Ouyang, MD; Stefan H. Hohnloser, MD; Karl-Heinz Kuck, MD

50 ICD DR: 5
sposizionamenti atriali,
e 1 undersensing
atriale, event rate 12%.

Il rischio di reintervento per problemi sul catetere atriale è 1.3% (ICD/CRT-D), e il rischio per il catetere sinistro è 1.8% (CRT-D).



European Heart Journal (2014) 35, 1186–1194
doi:10.1093/eurheartj/eh511

CLINICAL RESEARCH
Arrhythmia/electrophysiology

Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark

Rikke Esberg Kirkfeldt^{1,2*}, Jens Brock Johansen^{2,3}, Ellen Aagaard Nohr⁴, Ole Dan Jørgensen^{2,5}, and Jens Cosedis Nielsen¹

SVANTAGGI DEL CATETERE ATRIALE: IL RISCHIO INFETTIVO CRESCE CON IL N° DEGLI ELETTRODI



PATIENT PROCEDURES	ODDS RATIO FOR DEVELOPING A CIED INFECTION
Early Reintervention*	15.04
CRT-D vs ICD/PM	7.57
>2 Leads in Place	5.41
Device Replacement/Revision**	3.67
Temporary Pacing Wire	2.46

PATIENT MEDICATIONS	ODDS RATIO FOR DEVELOPING A CIED INFECTION
Corticosteroid Use****	13.90
Oral Anticoagulant	2.82

PATIENT CHARACTERISTICS	ODDS RATIO FOR DEVELOPING A CIED INFECTION
Renal Failure	11.97
Fever <24 hr Prior to Implantation	5.83
Renal Insufficiency	5.46
Congestive Heart Failure	2.57
Male Gender	2.23

Klug D et al. Circulation 2007;116(12):1349-1355. - Lekkerkerker JC et al. Heart 2009;95(9):715-720.
Margey R et al. Europace 2010;12(1):64-70. - Sohail MR et al. Clin Infect Dis. 2007;45(2):166-173.
Bloom H et al. Pacing Clinical Electrophysiology 2006;29(2):142-145.

SVANTAGGI DEL CATETERE ATRIALE: RISCHIO DI OSTRUZIONE VENOSA



Il rischio di ostruzione severa o occlusione è **8** volte più alto in presenza di 3 elettrocateri

Table 3 Logistic analysis with severe obstruction/occlusion as dependent variable, adjusted for age >65 years, and the presence of dilated cardiomyopathy (either ischaemic or non-ischaemic)

Predictor factor	OR	95% CI	P
Secondary prevention of SCD as indication	7.1	1.43–35.29	0.017
ICD	3.68	1.08–12.5	0.037
CRT+CRT-D	8.49	1.74–41.35	0.008

Abbreviations as in Table 1.

Santini M et al, Prevalence and predictor factors of severe venous obstruction after cardiovascular electronic device implantation, *Europace* (2016) 18 (8): 1220-1226.

SVANTAGGI DEL CATETERE ATRIALE: ESTRAZIONI

Fattori predittivi associati alle complicanze da estrazione

2017 HRS Expert Consensus
Statement on Cardiovascular
Implantable Electronic Device
Lead Management and
Extraction. Kusumoto et al.
Heart Rhythm 2017. DOI:
10.1016/j.hrthm.2017.09.001

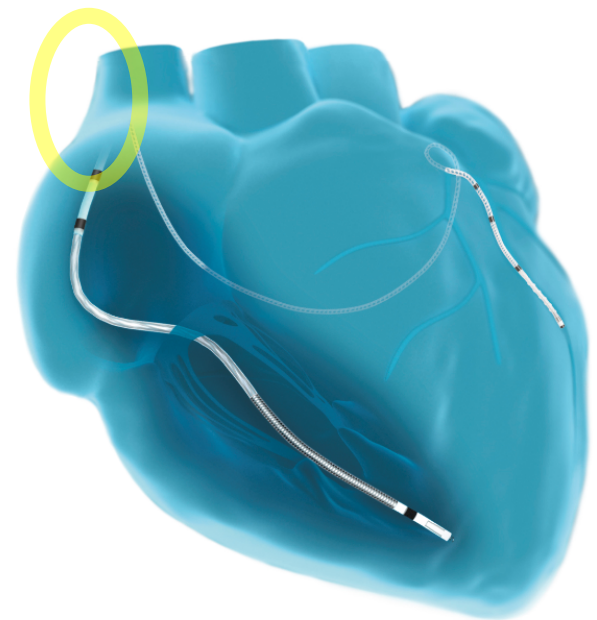
Low body mass index (<25 kg/m ²)	1.8-fold ↑ risk of 30-day mortality ⁶⁴ ↑ no. of procedure-related complications ²¹⁹
History of cerebrovascular accident	2-fold ↑ risk of major complications ⁶⁴
Severe LV dysfunction	2-fold ↑ risk of major complications ⁶⁴
Advanced HF	1.3- to 8.5-fold ↑ risk of 30-day mortality ⁶⁴ 3-fold ↑ 1-year mortality ²⁵⁷
Renal dysfunction	ESRD: 4.8-fold ↑ risk of 30-day mortality ⁶⁴ Cr ≥2.0: ↑ in-hospital mortality ²¹⁶ and 2-fold ↑ risk of 1-year mortality ²⁵⁷
Diabetes mellitus	↑ in-hospital mortality ²¹⁹ 1.71-fold ↑ mortality ²⁸⁵
Platelet	Low platelet count: 1.7-fold ↑ risk of major complications ⁶⁴
Coagulopathy	Elevated INR: 2.7-fold ↑ risk of major complications and 1.3-fold ↑ risk of 30-day mortality ⁶⁴ Anticoagulant use: 1.8-fold ↑ 1-year mortality ²⁵⁷
Anemia	3.3-fold ↑ risk of 30-day mortality ⁶⁴
Number of leads extracted	3.5-fold ↑ risk of any complication ²⁴⁹ 1.6-fold ↑ long-term mortality ²⁵⁰
Presence of dual-coil ICD	2.7-fold ↑ risk of 30-day mortality ⁶⁴
Extraction for infection	2.7- to 30-fold ↑ risk of 30-day mortality ^{64,249} 5- to 9.7-fold ↑ 1-year mortality ^{64,250} CRP >72 mg/L associated with ↑ 30-day mortality ²⁵² 3.52-fold ↑ mortality ²⁸⁵
Operator experience	2.6-fold ↑ no. of procedure-related complications ²⁹⁰
Prior open heart surgery	↓ risk of major complications ²⁴⁹

Cr = creatinine; CRP = C-reactive protein; ESRD = end-stage renal disease; HF = heart failure; ICD = implantable cardioverter defibrillator; INR = international normalized ratio; LV = left ventricular.

Elettrocatereteri non necessari non sono a rischio zero per il paziente

- Incremento del rischio di infezione
- Incremento della difficoltà di estrazione
- Incremento del rischio di ostruzione venosa
- Possibile rischio di interazione tra elettrodi presenti/abbandonati
- Possibile divieto di effettuare scansioni MRI

- Il CRT DX è il defibrillatore tricamerale con due elettrocatereteri
- Il dipolo flottante garantisce segnali atriali affidabili che regolano la sincronia atrio-ventricolare
- Il segnale atriale è amplificato dalla tecnologia DX di un fattore X4 rispetto alla PSA
- Il sensing atriale è accurato e stabile nel tempo^{1,2,3,4}



1 Sticherling et al. Circ Arrhythm Electrophysiol. 2011;4:56-63
2 BIOTRONIK Master Studies and Home Monitoring Data; data on file
3 Stazi et al. PACE 2012; 00:1-7
4 Iori et al. PACE 2014;37(10):1265-73

Comparison of a Novel, Single-Lead Atrial Sensing System With a Dual-Chamber Implantable Cardioverter- Defibrillator System in Patients Without Antibradycardia Pacing Indications

Results of a Randomized Study

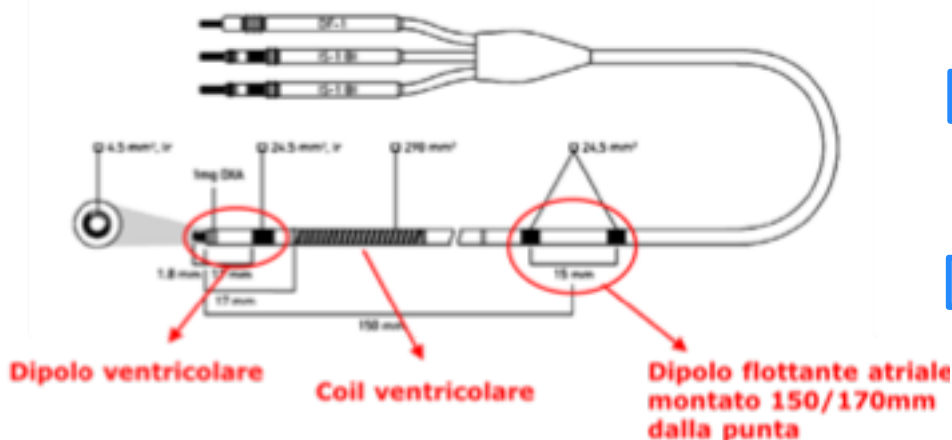


Table 5. Discrimination Algorithm Results and GEE-Corrected Specificity

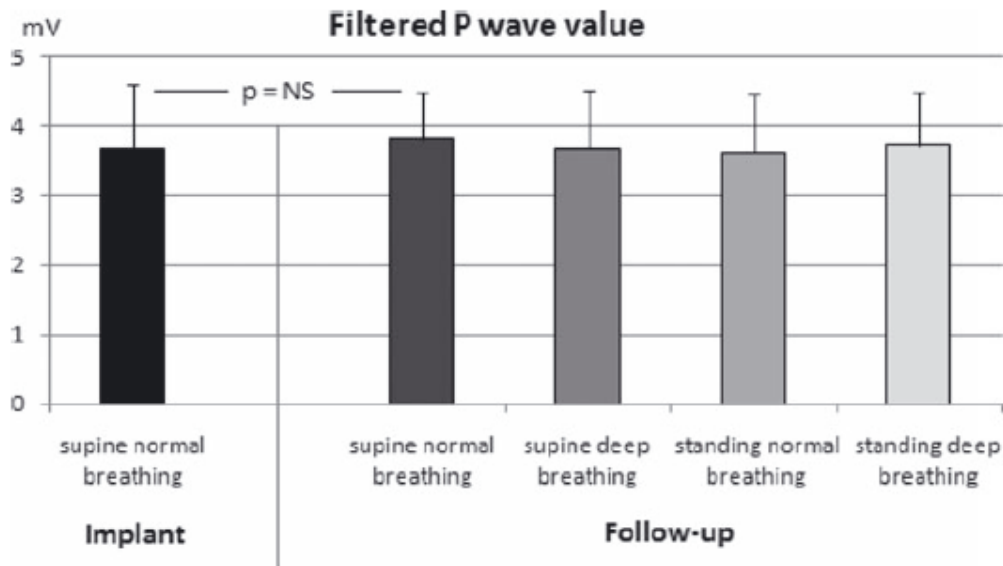
	A+-ICD	DR-ICD	P	All Patients
VF or VT, n	328	265	NS	593
True-positive	328	265	...	593
False-negative	0	0	...	0
Sensitivity, %	100	100	NS	100
SVT, n	1521	1043	NS	2564
True-negative	830	663	...	1493
False-positive	691	380	...	1071
Specificity, %	61.8	66.2	NS	64.4
Lower 95% CI bound, %	55.7	59.4	...	60.0
Upper 95% CI bound, %	67.9	72.9	...	69.1

Implant and Long-Term Evaluation of Atrial Signal Amplification in a Single-Lead ICD

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M. TERESA LAUDADIO, Ph.D.,‡ ALESSIO GARGARO, Ph.D.,§
and GIOVANNI BATTISTA DEL GIUDICE, M.D.*

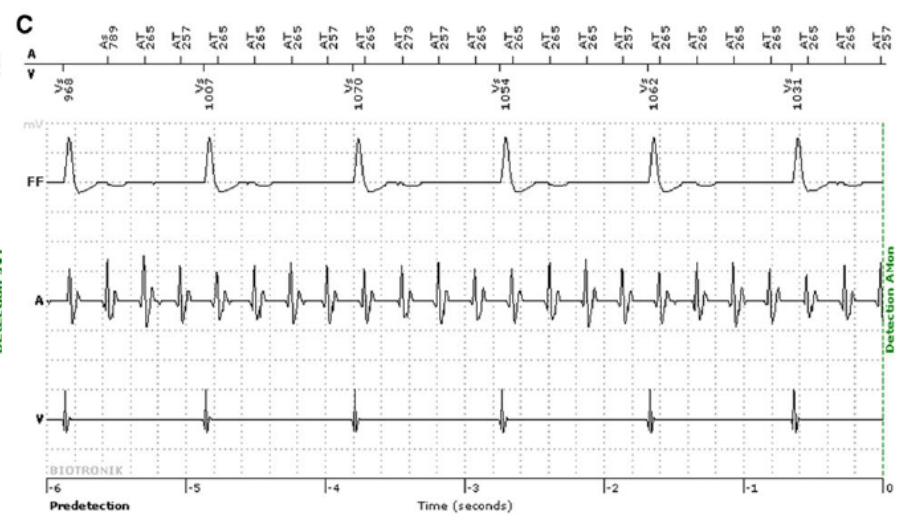
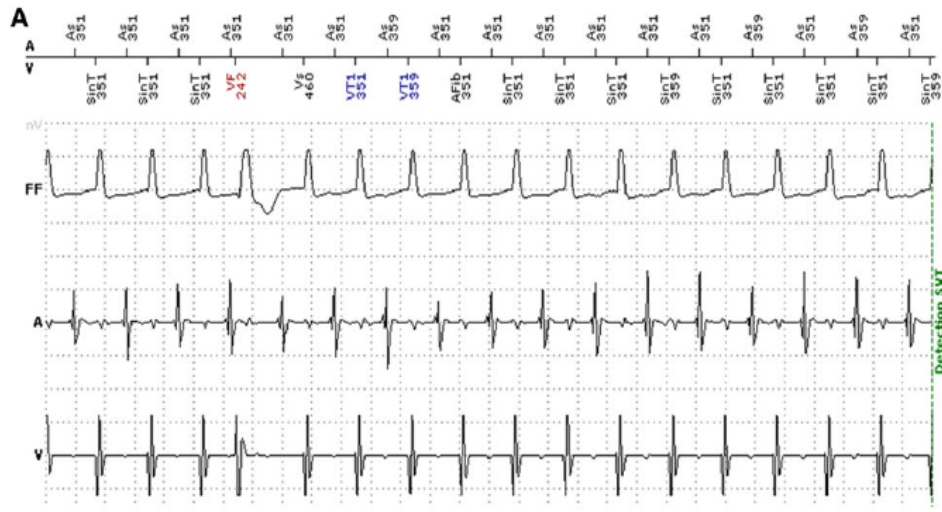
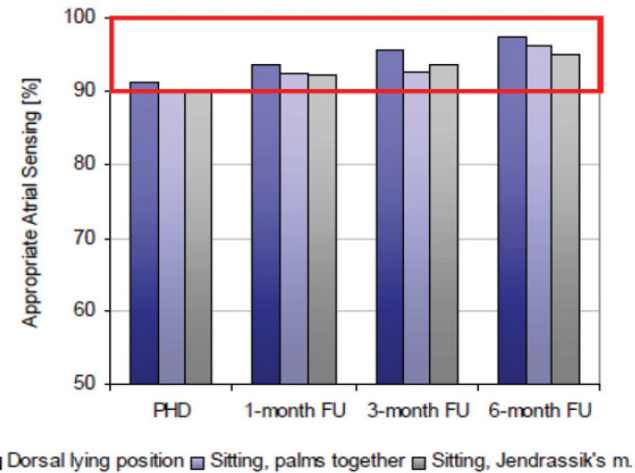
From the *Department of Cardiology, San Giovanni Addolorata Hospital, Rome, Italy; †Centro per la Lotta contro l'Infarto (CLI) Foundation, Rome, Italy; ‡Gelmec s.r.l., Rome, Italy; and §Biotronik Italia, Rome, Italy

- 43 pts arruolati
- F-UP medio di 384 ± 244 giorni. Test di sensing atriale eseguiti in posizioni diverse (supina o in piedi e respirando normalmente o profondamente)
- **Valori stabili nelle diverse posizioni**



SENSING ATRIALE: AFFIDABILITA' IN RS E ARITMIA

Sensing atriale affidabile sia durante ritmo sinusale che durante aritmia atriale, con appropriatezza di detection atriale del 93.8%



Safak et al. PACE 2013; Worden et al. PACE 2016

**Atrial Support Pacing in Heart Failure: Results from the
Multicenter PEGASUS CRT Trial**

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and MICHAEL R. GOLD, M.D., Ph.D., F.H.R.S.α

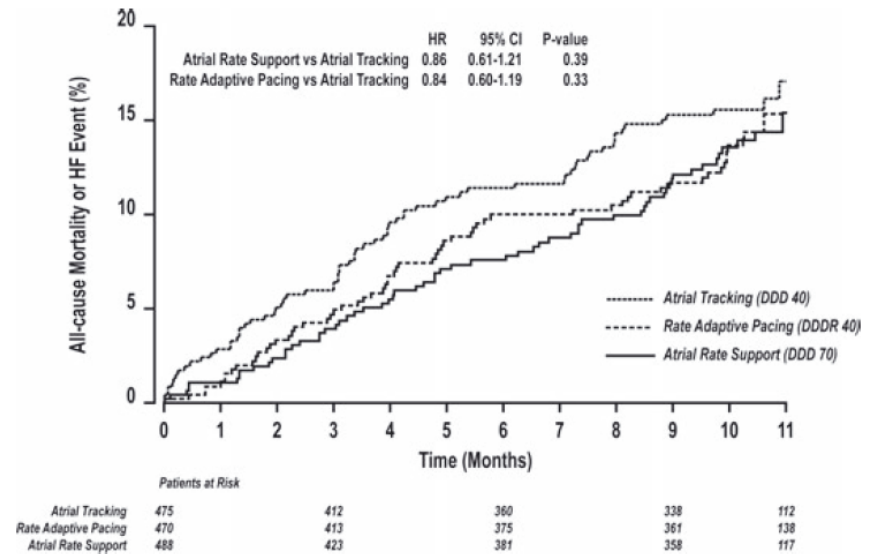
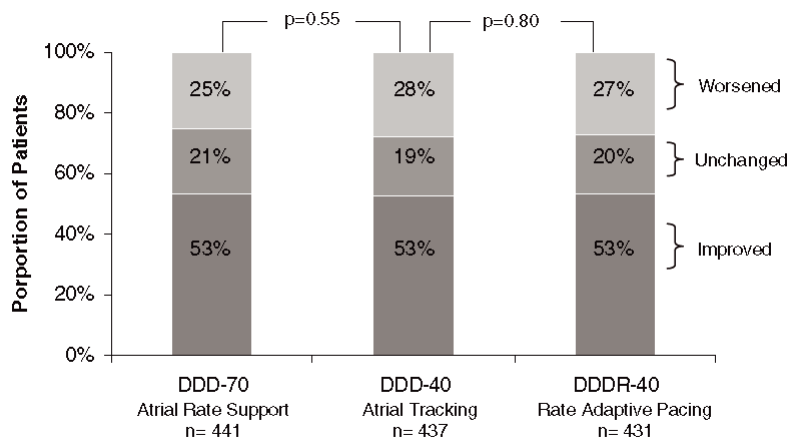
From the *Department of Cardiovascular Medicine, Cleveland Clinic Foundation, Cleveland, Ohio, USA; †Department of Cardiology, Intermountain Medical Center, Salt Lake City, Utah, USA; ‡Department of Cardiology, Memorial Medical Center/Gould Medical Group, Modesto, California, USA; ¶Department of Medicine, Riverside Regional Medical Center, Newport News, Virginia, USA; §Department of Medicine, University of Chicago Medical Center, Chicago, Illinois, USA; ψDepartment of Cardiology, Self Regional Healthcare, Greenwood, South Carolina, USA; βDepartment of Cardiology, Tyler Cardiovascular Consultants, Tyler, Texas, USA; κDepartment of Biostatistics, The Integra Group, Brooklyn Park, Minnesota, USA; ϕClinical Affairs, Boston Scientific, St. Paul, Minnesota, USA; and αDepartment of Medicine, Medical University of South Carolina, Charleston, South Carolina, USA

J Cardiovasc Electrophysiol 2012; 23(12): 1317-1325.

Studio randomizzato a 3 bracci su 1,400 pazienti con indicazione a CRT-D, non selezionati:

- DDD @ 70 bpm
- DDD @ 40 bpm
- DDDR @ 40 bpm

Nessuna differenza negli endpoint, incluse mortalità e ospedalizzazioni



Composite score endpoint*

*all-cause mortality, HF events, NYHA functional class, and the patient portion of the global assessment tool

Effetti trascurabili del pacing atriale sul profilo di frequenza

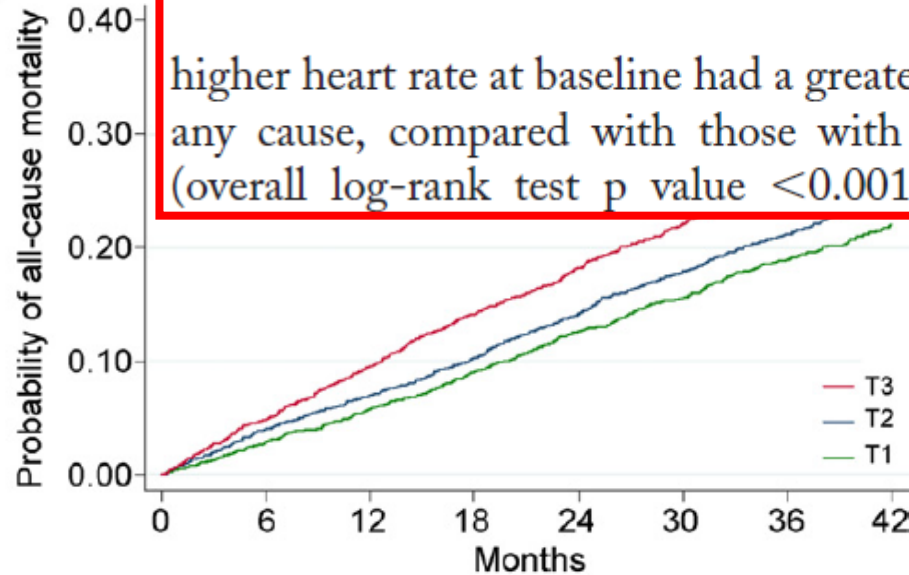
TABLE 3
Last Reported Device Measurements and Reported Heart Rate

Device Measurements		DDD-70 n = 442	DDD-40 n = 422	DDDR-40 n = 418
Percent atrial pacing	Mean \pm SD	43.3 \pm 29.8	3.0 \pm 12.2	3.7 \pm 13.7
	(95% CI)	(40.5, 46.0)	(1.80, 4.2)	(2.3, 5.0)
	Median (IQR)	35 (16, 61)	0 (0, 0)	0 (0, 0)
Percent left ventricular pacing	Mean \pm SD	96.5 \pm 7.4	96.1 \pm 8.1	96.0 \pm 6.9
	(95% CI)	(95.8, 97.2)	(95.3, 96.8)	(95.3, 96.6)
	Median (IQR)	98 (96, 99)	98 (95, 99)	98 (95, 99)
Percent of day active	Mean \pm SD	8.0 \pm 4.7	7.7 \pm 4.1	8.4 \pm 4.4
	(95% CI)	(7.6, 8.4)	(7.3, 8.0)	(8.0, 8.9)
	Median (IQR)	7.2 (4.8, 10.3)	7.1 (4.7, 10.0)	7.8 (5.1, 10.7)
Heart Rate (mean \pm SD)		DDD-70 n = 372	DDD-40 n = 349	DDDR-40 n = 355
Implant		72.3 \pm 12.5	71.6 \pm 12.6	72.6 \pm 12.6
6 weeks		72.1 \pm 11.7	72.0 \pm 12.1	73.7 \pm 13.1
12 months		74.00 \pm 8.8	70.3 \pm 11.9	71.9 \pm 11.7
Within group change (12 month–6 week)		1.9 \pm 11.6 P = 0.002	-1.7 \pm 12.7 P = 0.012	-1.8 \pm 12.5 P = 0.008

Association of Heart Rate and Outcomes in a Broad Spectrum of Patients With Chronic Heart Failure

Results From the CHARM (Candesartan in Heart Failure: Assessment of Reduction in Mortality and morbidity) Program

A



Individuals with a higher heart rate at baseline had a greater risk of death from any cause, compared with those with a lower heart rate (overall log-rank test p value <0.001) (Fig. 1A). Beta-

Heart Rate Group at Baseline (beats/min)

T1	T2	T3
n = 2,553 (33.6%)	n = 2,689 (35.4%)	n = 2,355 (31.0%)
60 (57-64)*	72 (70-75)*	85 (80-91)*

T1,2,3: terzili della frequenza cardiaca all'ECG basale

Number at risk

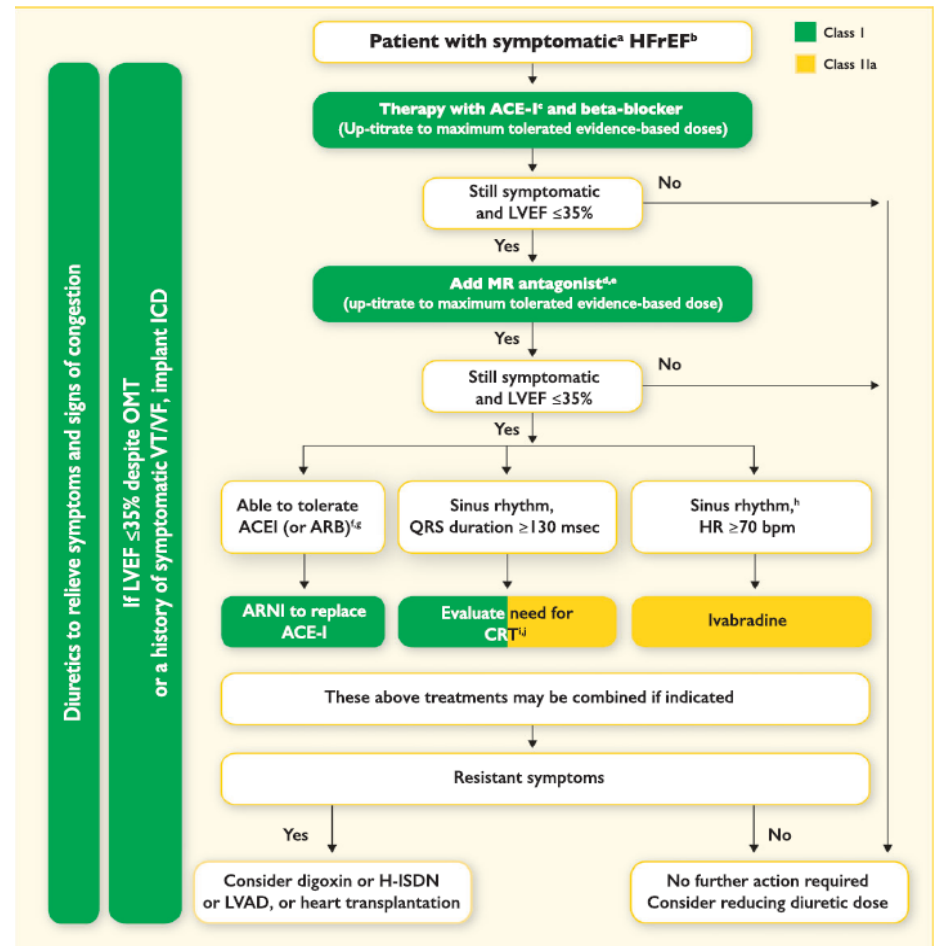
T1	2553	2478	2405	2323	2230	2073	1565	663
T2	2689	2582	2501	2412	2306	2109	1634	686
T3	2355	2239	2127	2019	1922	1755	1338	585

J Am Coll Cardiol 2012;59:1785-95



2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC)





European Heart Journal (2016) 37, 2129–2200
doi:10.1093/eurheartj/ehw128

ESC GUIDELINES



2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC)

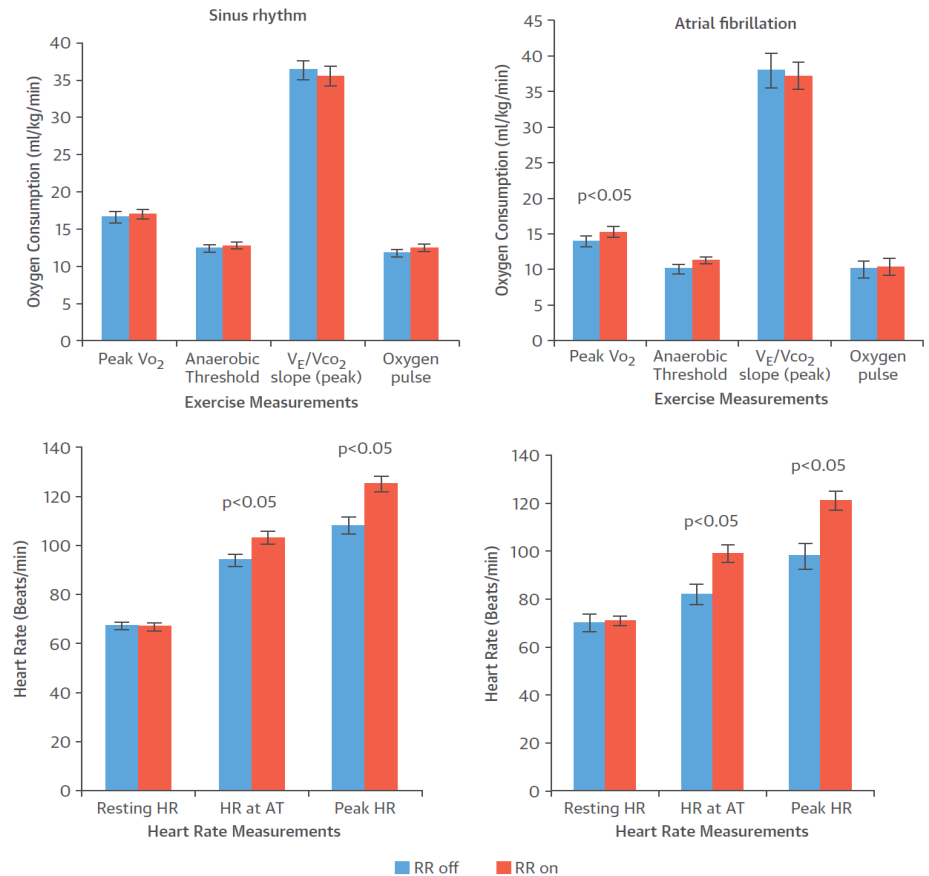


Recommendations for the management of bradyarrhythmias in heart failure

Recommendations	Class ^a	Level ^b	Ref ^c
When pauses >3 seconds are identified on the ECG, or if the bradycardia is symptomatic and the resting ventricular rate is <50 bpm in sinus rhythm or <60 bpm in AF, it should be considered whether there is need for any rate limiting medications prescribed; for patients in sinus rhythm beta-blockers should be reduced in dose or withdrawn only as a last resort.	IIa	C	
For patients with symptomatic, prolonged or frequent pauses despite adjustment of rate limiting medication, either beta-blocker withdrawal or pacing may be considered as the next step.	IIb	C	
Pacing solely to permit initiation or titration of beta-blocker therapy in the absence of a conventional pacing indication is not recommended.	III	C	
In patients with HFrEF who require pacing and who have high degree AV block, CRT rather than RV pacing is recommended.	I	A	274, 275, 290
In patients with HFrEF who require pacing who do not have high degree AV block, pacing modes that avoid inducing or exacerbating ventricular dyssynchrony should be considered.	IIa	C	

**Incrementare la
frequenza di
stimolazione per
correggere l'IC
non migliora la
capacità
funzionale**

FIGURE 3 Interventional Study 1 Exercise Testing (Sinus Rhythm and Atrial Fibrillation)

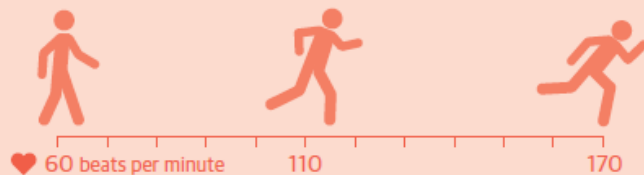


HR and CPX variables with rate-adaptive pacing (RR on) and fixed rate pacing (RR off). Values are mean \pm SE. CPX = cardiopulmonary exercise test; VCO_2 = carbon dioxide output; V_E = ventilation; other abbreviations as in Figures 1 and 2.

CENTRAL ILLUSTRATION The Relationship Between Heart Rate Rise and Exercise Capacity

Healthy Patients

Response to exercise



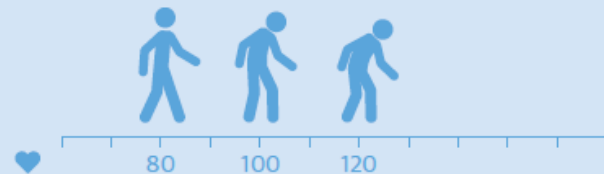
Observational study
Correlation between
heart rate rise (HRR)
and exercise capacity?



Strong correlation

Patients With Left Ventricular Systolic Dysfunction (LVSD)

Response to exercise



Observational study
Correlation between
HRR and exercise capacity?



Both reduced, but weaker
correlation; HRR reduced
relative to severity of LVSD

Interventional study 1
Does *increasing* HRR
increase exercise capacity?

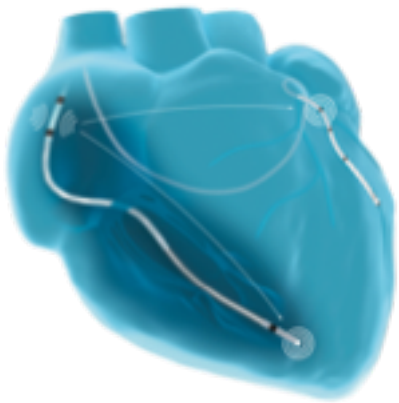


Interventional study 2
Does *reducing* HRR
reduce exercise capacity?



Jamil, H.A. et al. J Am Coll Cardiol. 2016;67(16):1885-96.

Heart rate rise and exercise capacity are related in health but not in heart failure, where increases and decreases in heart rate rise (correcting or exacerbating chronotropic incompetence) have no effect on exercise capacity. HRR = heart rate rise; LVSD = left ventricular systolic dysfunction.



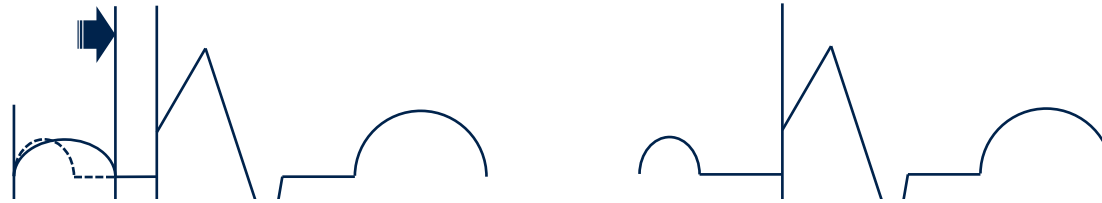
- La riduzione della frequenza cardiaca **riduce la mortalità** nei pazienti con SC e CMD¹
- Ad ogni riduzione di 5 bpm nella frequenza cardiaca **si riduce il rischio di morte del 18%²** (CI 95%: 6-29%) nei paz con scompenso cardiaco
- È la frequenza cardiaca che incide sulla sopravvivenza, non la dose di Beta-Bloccante³⁻⁴

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Right Atrial Pacing Impairs Cardiac Function During Resynchronization Therapy

Acute Effects of DDD Pacing Compared to VDD Pacing

Alain Bernheim, MD, Peter Ammann, MD, Christian Sticherling, MD, Peter Burger, MD, Beat Schaer, MD, Hans Peter Brunner-La Rocca, MD, Jens Eckstein, MD, Stephanie Kiencke, MD, Christoph Kaiser, MD, Andre Linka, MD, Peter Buser, MD, Matthias Pfisterer, MD, Stefan Osswald, MD



Conclusioni:

evitare il pacing atriale favorisce

- un più alto grado di resincronizzazione cardiaca
- un sostanziale prolungamento del periodo di riempimento LV
- una migliorata prestazione del miocardio.

Pertanto, la modalità VDD sembra essere superiore alla modalità DDD nei pazienti CRT.



LESS IS MORE

il CRT-DX nei pazienti in ritmo sinusale

I dispositivi CRT-DX BIOTRONIK sono gli unici ICD biventricolari che consentono l'erogazione della terapia di resincronizzazione con due elettrocatteteri, senza i rischi associati all'impianto di un elettrocattetero atriale, nella maggior parte dei pazienti candidati a CRTD, escluse le indicazioni alla stimolazione atriale



Less is more: Can we achieve cardiac resynchronization with 2 leads only?☆

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“While atrial sensing is of key importance for CRT delivery, atrial stimulation has a marginal role”

L'assenza dell'elettrodo atriale:

Riduzione dei tempi d'impianto, grazie all'esclusione dell'impianto di un elettrocatetere

Un numero minore di elettrodi riduce il rischio di infezioni, di dislocazioni, di occlusioni venose.

Riduce il rischio di complicanze in caso di estrazione

Riduce il rischio di complicanze tecniche secondarie alla presenza di più elettrodi

Limita il rischio di oversensing ventricolare e di riduzione della CRT grazie al sensing BIOTRONIK DX

