Conoscere e Curare il Cuore 2017

VENERDÌ 24 MARZO

QUANDO IL DEFIBRILLATORE SI SCARICA. SIAMO CERTI VADA SEMPRE SOSTITUITO ?

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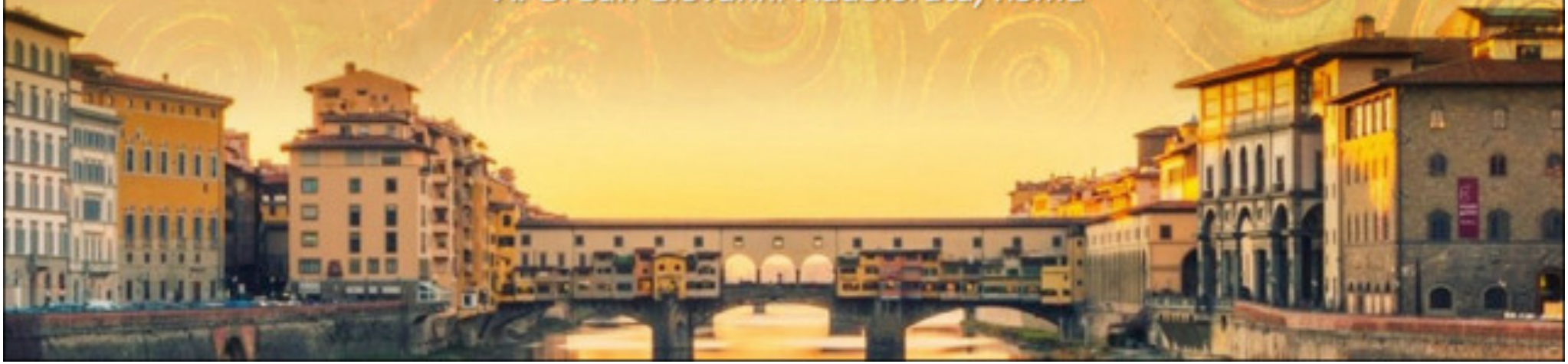
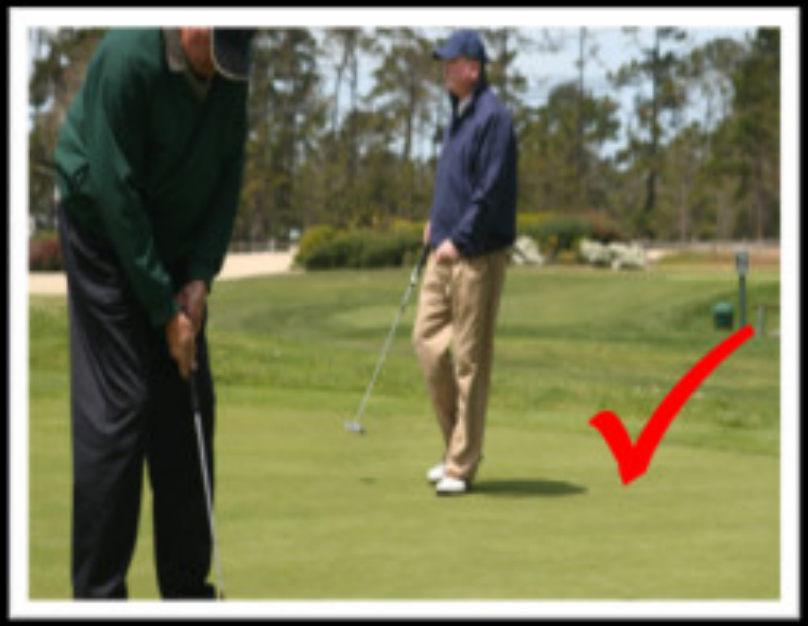
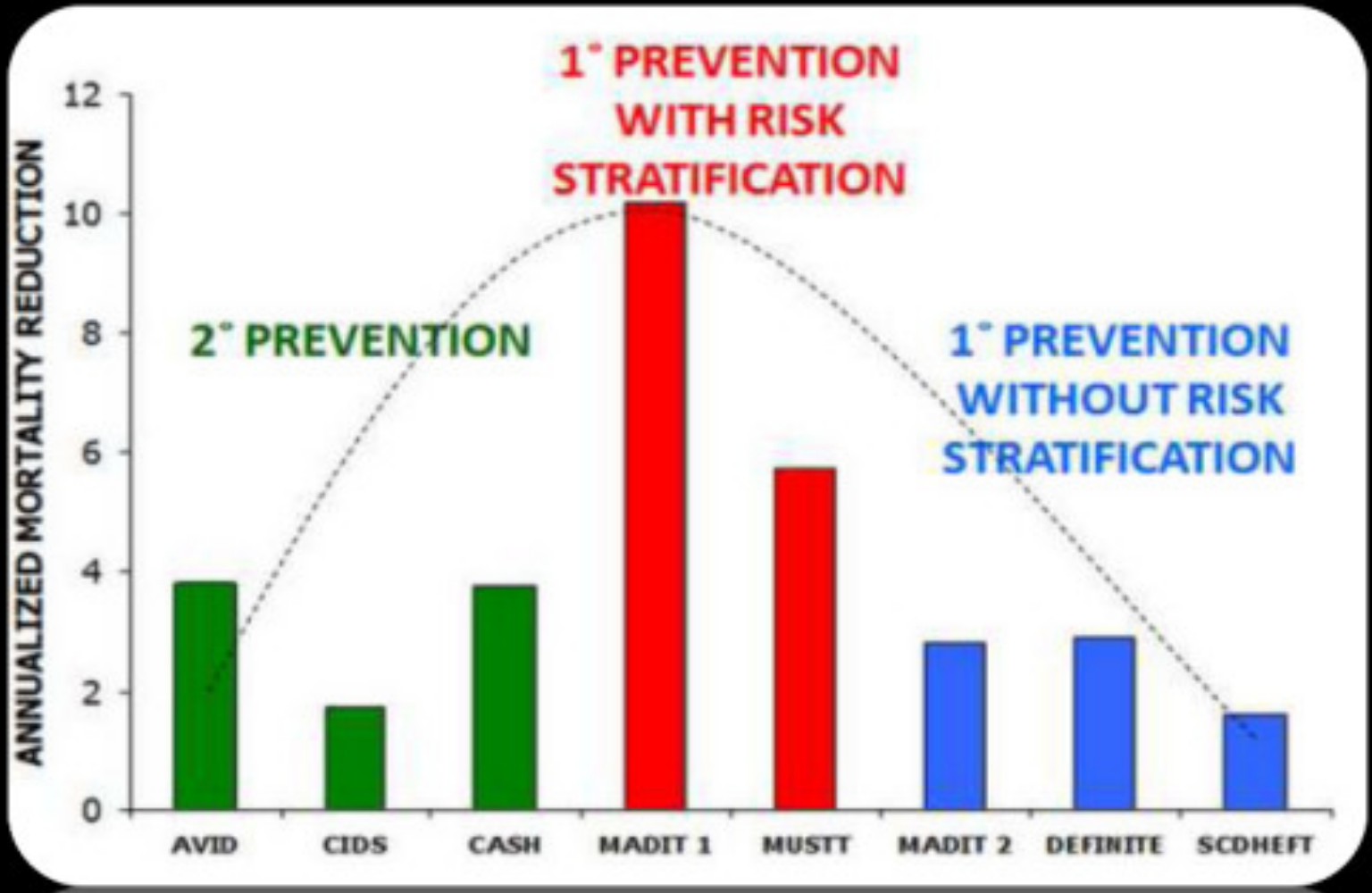




Gli ICD riducono la morte improvvisa



Entità del problema

- **Durata media ICD: 5 anni**
- **Sostituzioni: 20-40%** degli ICD impiantati annualmente
- **Assenza** di studi ad hoc: LG della sostituzione = LG impianto
- La **sostituzione** è spesso un **automatismo**

I pz che sostituiscono sono più anziani e con più comorbidità

Table 1 Characteristics of Patients at Initial ICD Implantation and at the Time of ICD Replacement

	Initial Implantation (N = 231)	Generator Replacement (N = 231)	p Value
Age, yrs	65 ± 10 (66)	70 ± 9 (70)	<0.01
White race	184 (80)	—	—
ICM	159 (69)	—	—
NICM	72 (31)	—	—
LVEF, %	23 ± 6 (25)	33 ± 14 (30)	<0.01
CRT-D	86 (37)	—	—
Comorbidities			
Chronic kidney disease (stage III or greater)	51 (22)	68 (29)	<0.01
Hypertension	170 (74)	189 (82)	<0.01
Diabetes	99 (43)	107 (46)	<0.01
Atrial fibrillation	37 (16)	56 (24)	<0.01
History of stroke	33 (14)	37 (16)	0.13
Dialysis dependent	1 (<1)	2 (1)	0.50
Neoplastic disease	6 (3)	33 (14)	<0.01
Cognitive impairment	5 (2)	9 (4)	0.13
Nursing facility resident	1 (<1)	2 (1)	0.50
Medication use			
ACE inhibitor or ARB	198 (86)	194 (84)	0.39
Beta-blocker	177 (77)	200 (87)	<0.01
Antiarrhythmic drug	29 (13)	37 (16)	0.10

Values are mean ± SD (median) or n (%).

ACE = angiotensin-converting enzyme; ARB = angiotensin receptor blocker; CRT-D = cardiac resynchronization therapy with a defibrillator; ICD = implantable cardioverter-defibrillator; ICM = ischemic cardiomyopathy; LVEF = left ventricular ejection fraction; NICM = nonischemic cardiomyopathy.

Kini, JACC 2014

La mortalità dopo sostituzione è maggiore che dopo impianto

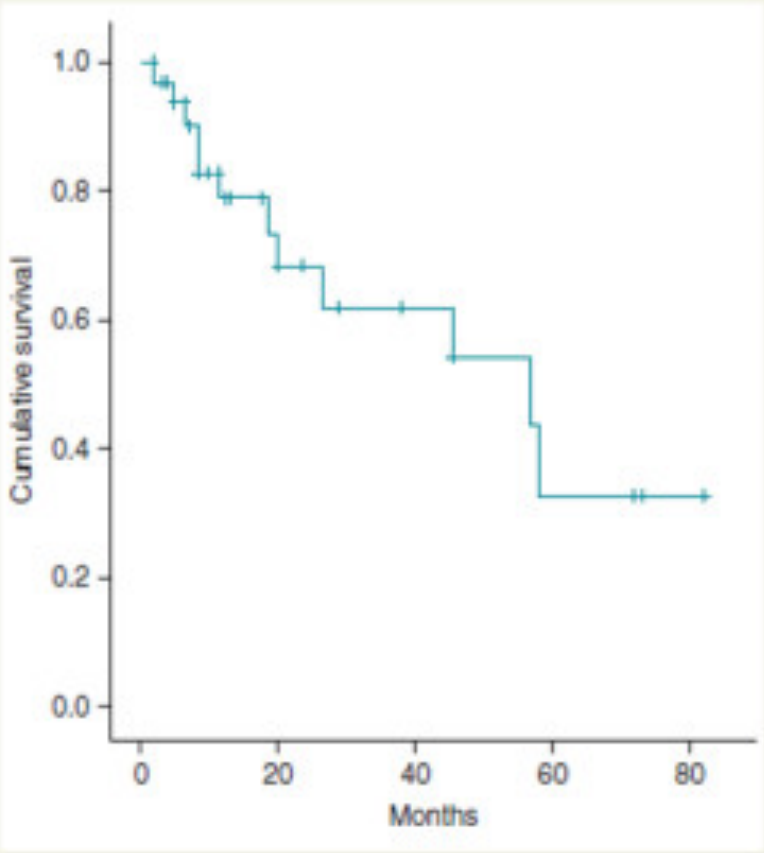


Figure 2 Cumulative survival of octogenarian patients submitted to ICD generator replacement.

Goonewardene Europace 2015

Necessità di rivalutazione:

A. Rischio aritmico
B. Rischio morte totale
C. Rischio della procedura
D. Volontà del paziente

$$\text{Beneficio ICD} = \frac{\text{rischio morte improvvisa}}{\text{rischio di morte totale}}$$

Obiettivi :

Individuare i pz con rischio di **morte aritmica** talmente basso

Individuare i pz con rischio di **morte non aritmica** talmente alto

= nessun beneficio ICD

A) Valutazione rischio aritmico:

Precedenti interventi ICD

ICD entrato in funzione ≠ ICD non entrato in funzione

Valore della FE

- FE rimasta depressa
- FE migliorata ma < 35%
- FE migliorata e > 35% (non più indicazione secondo LG)

Rischio aritmico: scarica/non scarica ICD

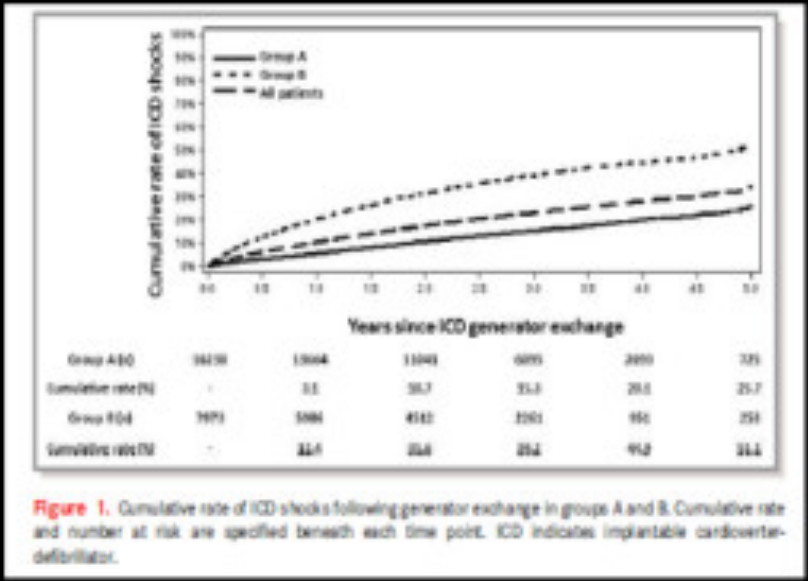


Figure 1. Cumulative rate of ICD shocks following generator exchange in groups A and B. Cumulative rate and number at risk are specified beneath each time point. ICD indicates implantable cardioverter-defibrillator.

Merchant, J Am Heart Assoc 2014

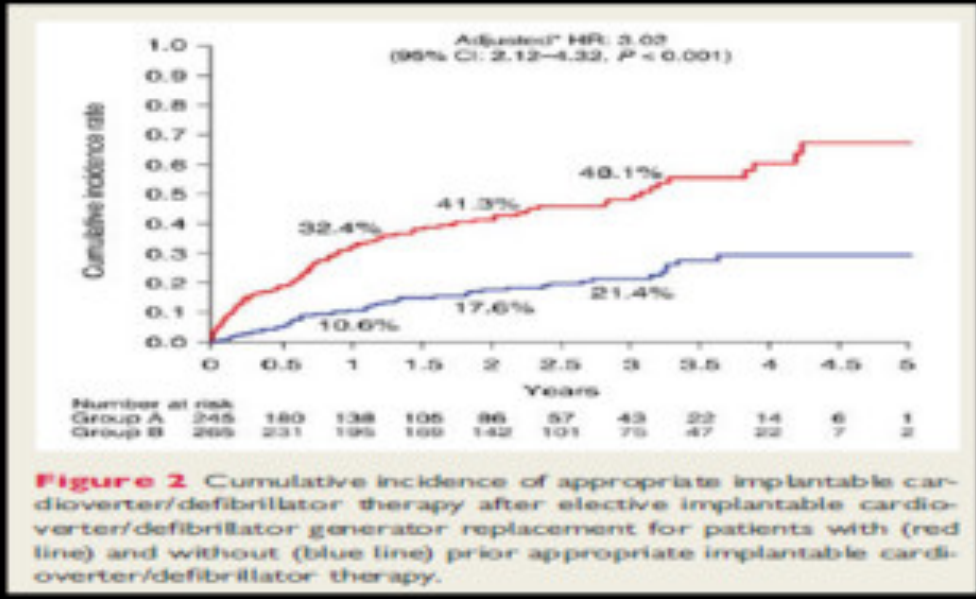


Figure 2 Cumulative incidence of appropriate implantable cardioverter/defibrillator therapy after elective implantable cardioverter/defibrillator generator replacement for patients with (red line) and without (blue line) prior appropriate implantable cardioverter/defibrillator therapy.

Erkapic Eur H J 2013

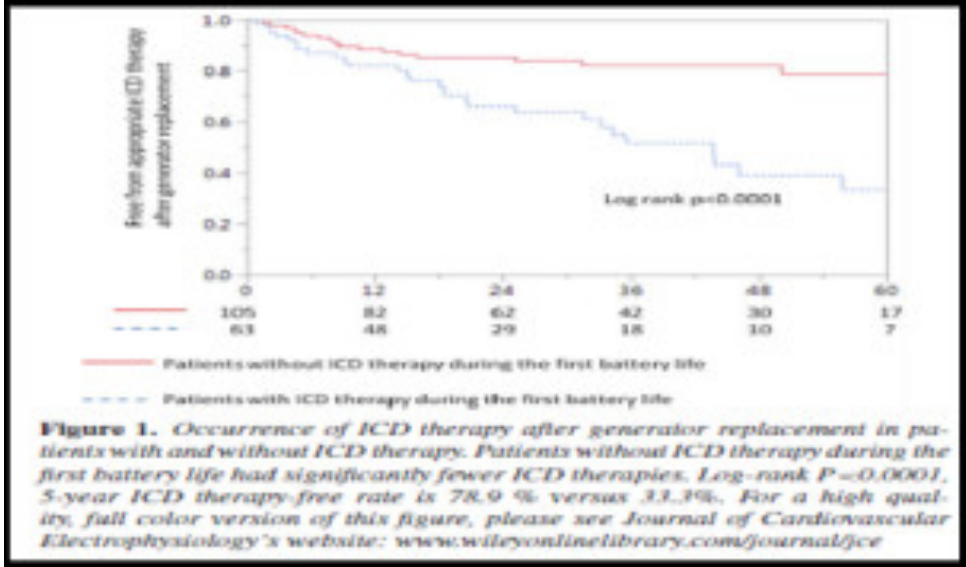


Figure 1. *Occurrence of ICD therapy after generator replacement in patients with and without ICD therapy. Patients without ICD therapy during the first battery life had significantly fewer ICD therapies. Log-rank P=0.0001. 5-year ICD therapy-free rate is 78.9 % versus 33.3%. For a high quality, full color version of this figure, please see Journal of Cardiovascular Electrophysiology's website: www.wileyonlinelibrary.com/journal/jce*

Kawata, J Cardiovasc Electrophysiol 2016

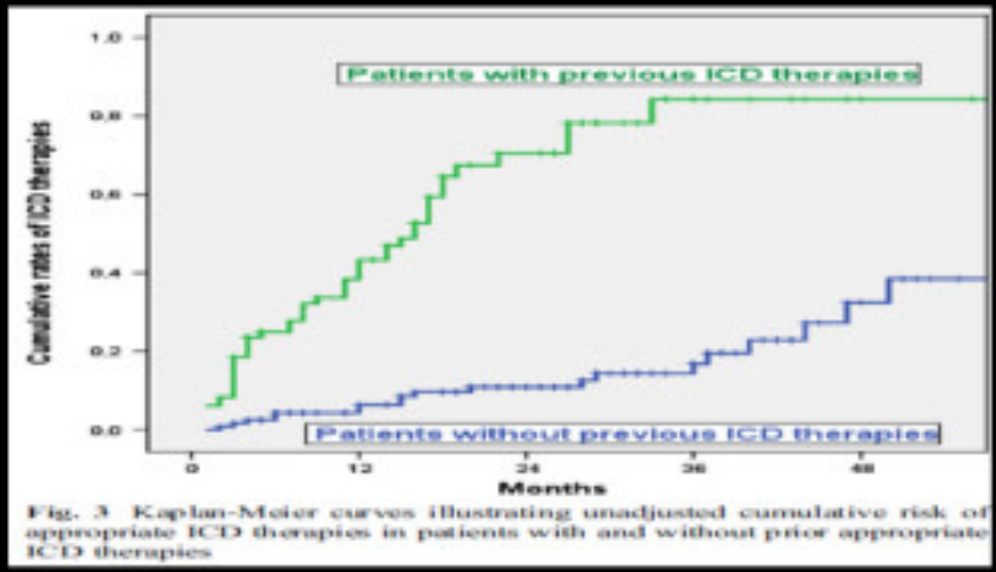


Fig. 3 Kaplan-Meier curves illustrating unadjusted cumulative risk of appropriate ICD therapies in patients with and without prior appropriate ICD therapies

Barra, J Interv Card Electrophysiol 2016

Rischio aritmico: non scarica ICD / FE

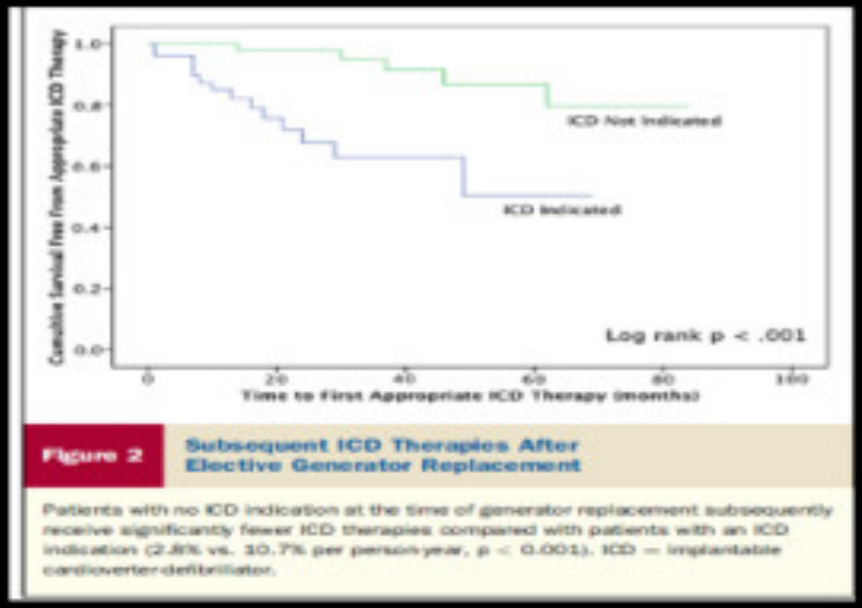


Figure 2 **Subsequent ICD Therapies After Elective Generator Replacement**

Patients with no ICD indication at the time of generator replacement subsequently receive significantly fewer ICD therapies compared with patients with an ICD indication (2.8% vs. 10.7% per person-year, $p < 0.001$). ICD = implantable cardioverter-defibrillator.

Kini, JACC 2014

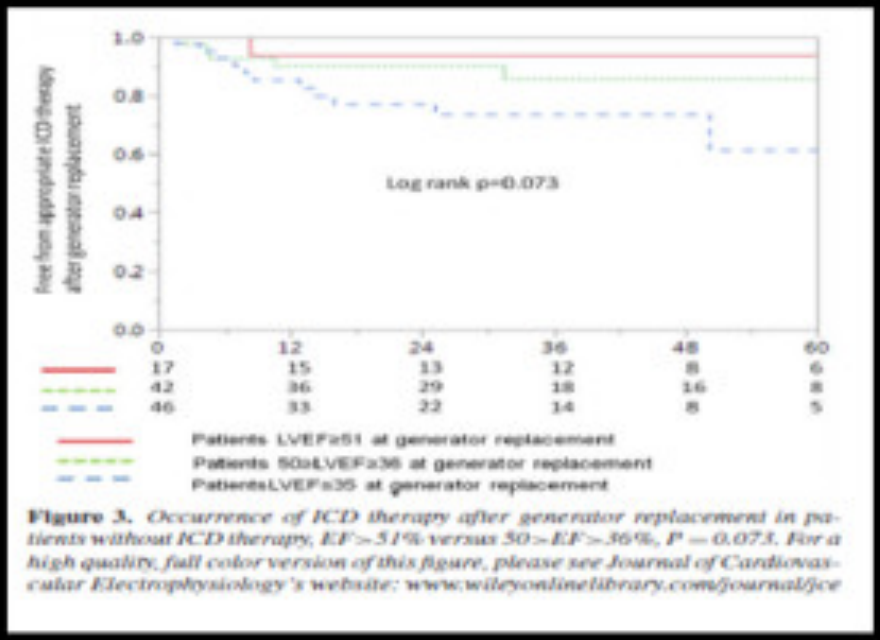
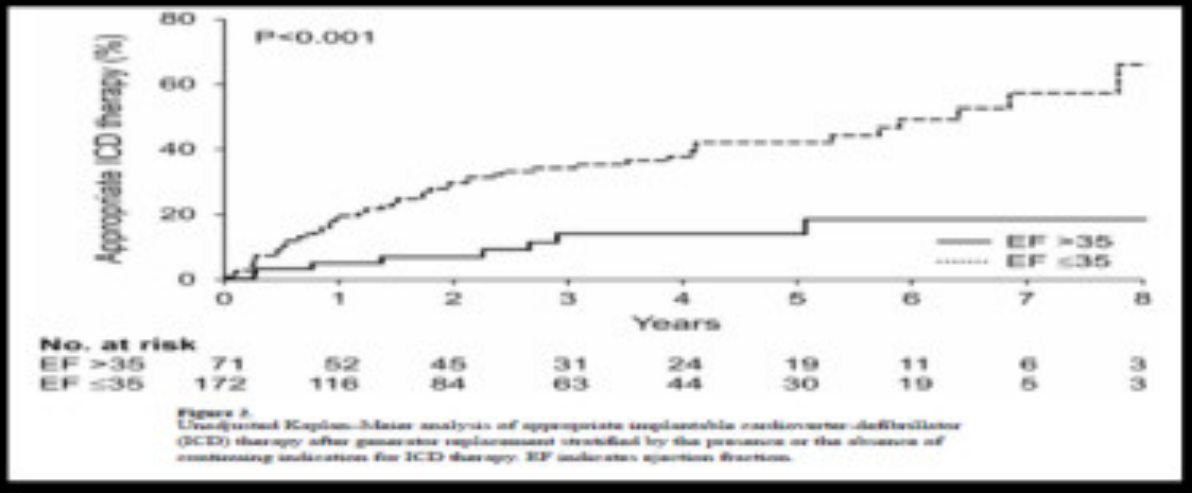


Figure 3. *Occurrence of ICD therapy after generator replacement in patients without ICD therapy, EF>51% versus 50>EF>36%, P = 0.073. For a high quality, full color version of this figure, please see Journal of Cardiovascular Electrophysiology's website: www.wileyonlinelibrary.com/journal/jce*

Kawata, J Cardiovasc Electrophysiol 2016



Madhavan Circ Arrhythm Electrophysiol 2016

B)Valutazione rischio di morte totale:

Risk score clinici

MADIT 2 SHOCKED REPLACE DARE

Risk score clinici: MADIT 2

Table 2 Multivariate Analysis: Risk of Long-Term (8-Year) Mortality in the MADIT-II Population by the Type and Number of Risk Factors

	Hazard Ratio	95% CI	p Value
Risk factor			
BUN >26 mg/dl	1.90	1.59–2.27	<0.001
NYHA >II	1.79	1.50–2.13	<0.001
AFIB	1.45	1.12–1.86	0.004
Age >70 yrs	1.38	1.16–1.65	<0.001
QRS >120 ms	1.33	1.12–1.58	0.001
Risk score*			
Low risk (risk score 0)		Reference	
Intermediate risk (scores 1–2)	2.44	1.92–3.10	<0.001
1	2.10	1.61–2.74	<0.001
2	2.86	2.21–3.72	<0.001
High risk (risk score ≥3)	4.97	3.80–6.51	<0.001

Adjusted also for ICD versus non-ICD treatment (HR: 0.68, 95% CI: 0.57 to 0.81, p<0.001); 41 patients were excluded due to missing data. *Analysis was carried out in a separate model adjusting for ICD treatment and risk score groups.

AFIB = atrial fibrillation; CI = confidence interval; HR = hazard ratio; MADIT-II = Multicenter Automatic Defibrillator Implantation Trial II; other abbreviations as in Table 1.

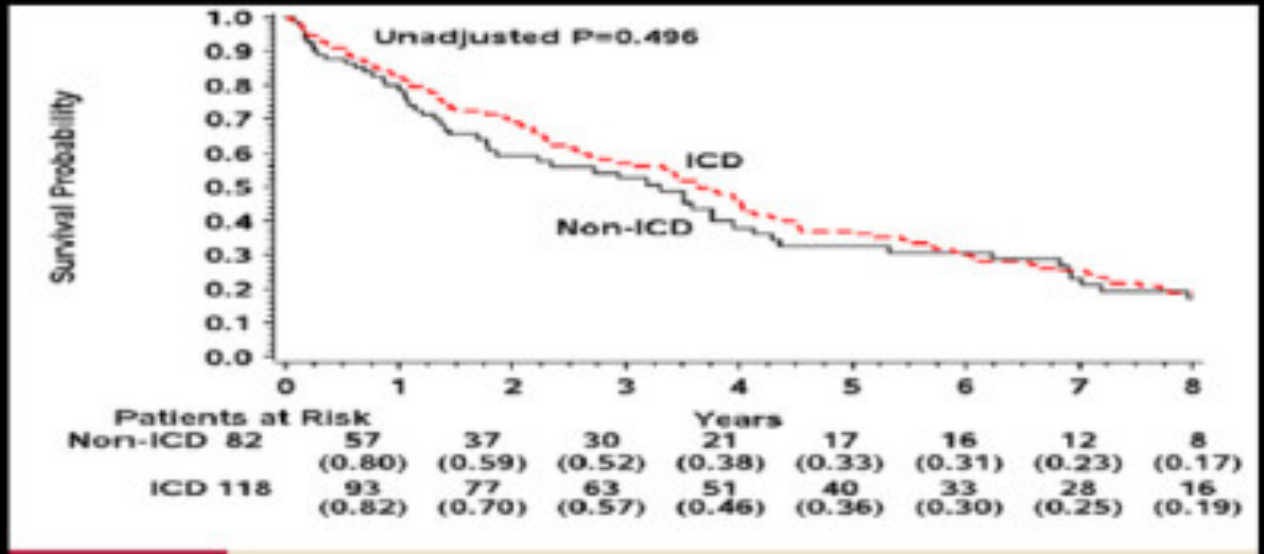


Figure 4 Probability of Survival Among High-Risk Patients

Risk score clinici: SHOCKED

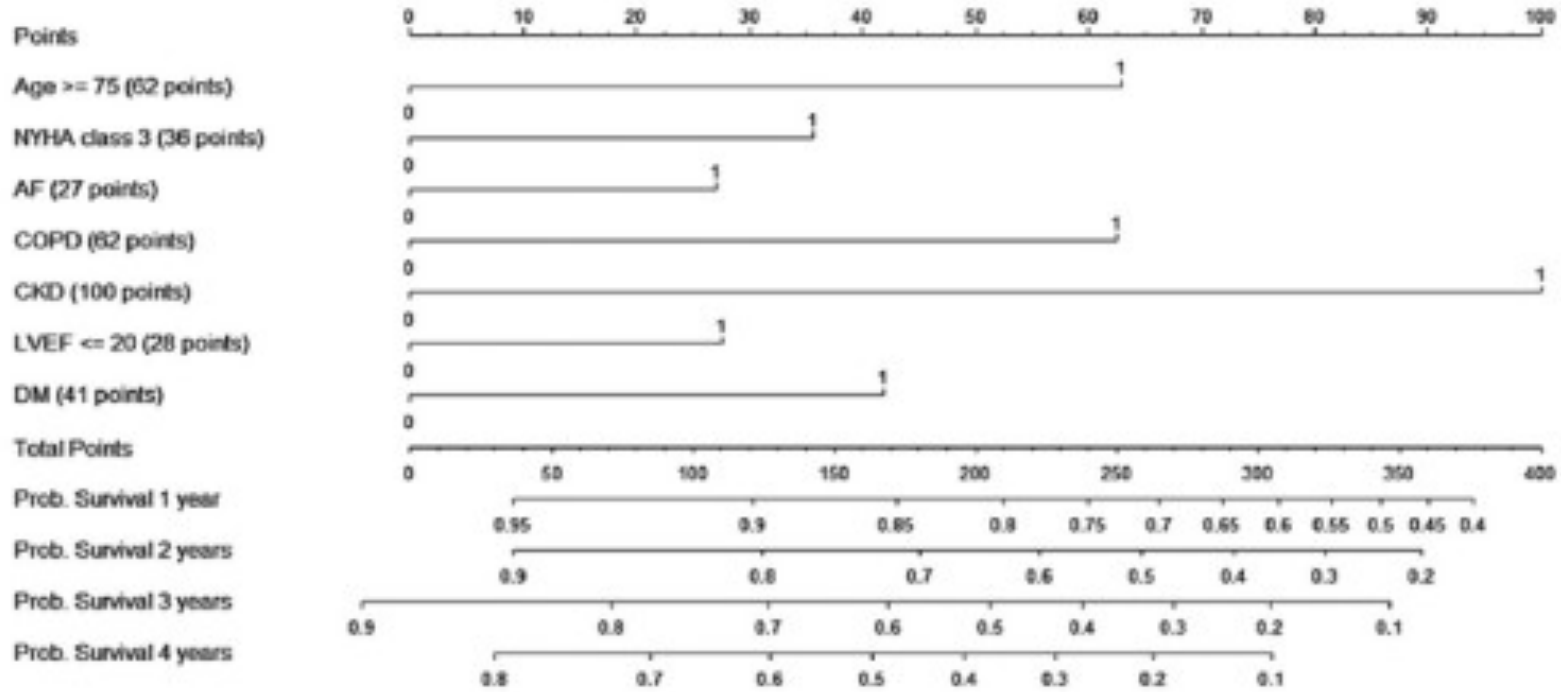


Figure 2 **Nomogram for Determination of Survival Probabilities After ICD Implantation**

A nomogram is presented for the estimation of survival 1 to 4 years after implantable cardioverter-defibrillator (ICD) implantation on the basis of the 7 "SHOCKED" risk factors from the abbreviated model. To calculate patient survival probabilities, obtain points for each covariate value by dropping a vertical line from the points axis to the value of each covariate, calculate the total points obtained from all 7 covariate values, and then drop a vertical line from the total points axis to locate the associated probability of survival for the patient at the time point of interest after the procedure. AF = atrial fibrillation; CKD = chronic kidney disease; COPD = chronic obstructive pulmonary disease; DM = diabetes mellitus; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association.

Risk score clinici: REPLACE DARE

REPLACE DARE Mortality Risk Score

CALCULATOR | OVERVIEW

The REPLACE DARE (Death After Replacement Evaluation) mortality risk score *is a tool designed to further assist physicians in predicting expected 6-month all-cause mortality rates for patients prior to replacing an existing cardiac implantable electrical device (CIED). Its validity in patients undergoing the initial implant of a CIED has not been established.*

REPLACE DARE Mortality Risk Score Calculator

Admitted for Heart Failure in Previous 12 Months

Yes | ✔ NO

NYHA Classification

Class I | Class II | Class III | Class IV

✔ None *(for subjects without a diagnosis for Heart Failure)*

Chronic Kidney Disease Stage

1 (Normal, or minimal disease with normal GFR of ≥ 90)

Class I or Class III Anti-arrhythmic Drug Use

Yes | ✔ NO

History of Cerebrovascular Disease

Yes | ✔ NO

Age

✔ < 63 | 63 - 72 | 73 - 79 | > 80

SCORE: 0.0

Reset

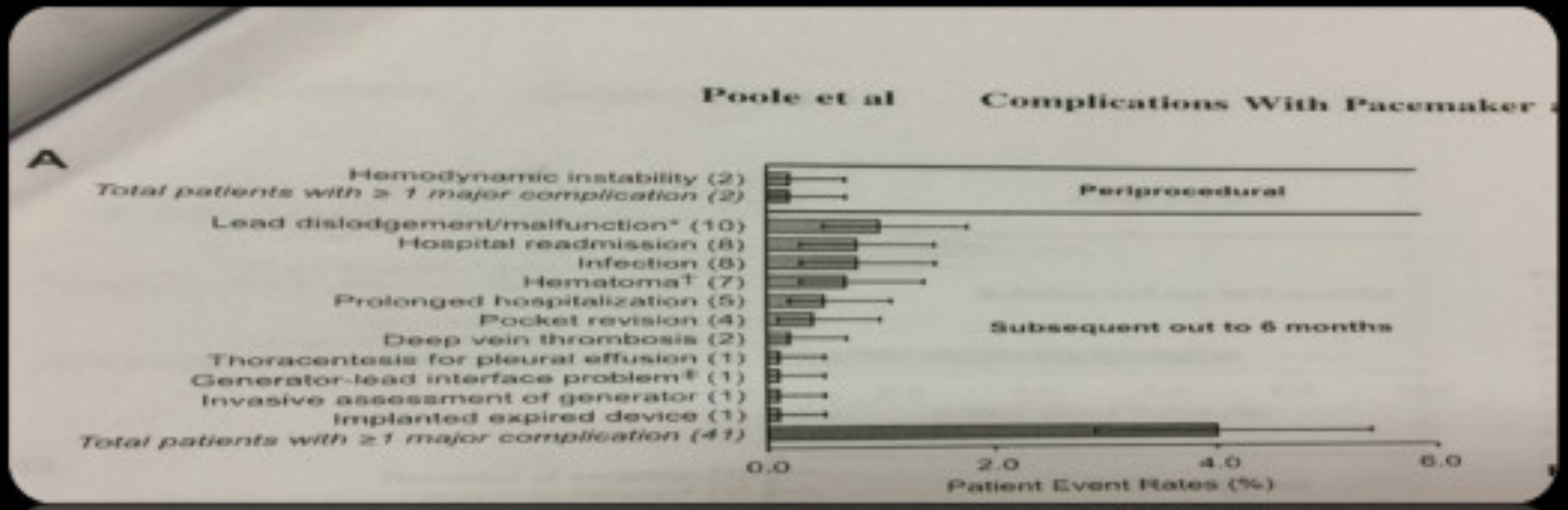
Mortality Risk Score	Observed Mortality in REPLACE (%)
0	2/198 (1.0)
1	6/484 (1.2)
2	12/446 (2.7)
3	16/291 (5.5)
4	11/128 (8.6)
5	10/72 (13.9)
6	5/34 (14.7)
7	5/9 (55.6)

Although this sub-analysis of the REPLACE registry was retrospective, the REPLACE data, including mortality, were collected prospectively. Data collection, though extensive, may have missed some confounding factors. The REPLACE DARE score was constructed using hazard ratios reflecting relative risk contributions of each variable which were combined into an additive mortality risk score equation. Internal validation was performed.

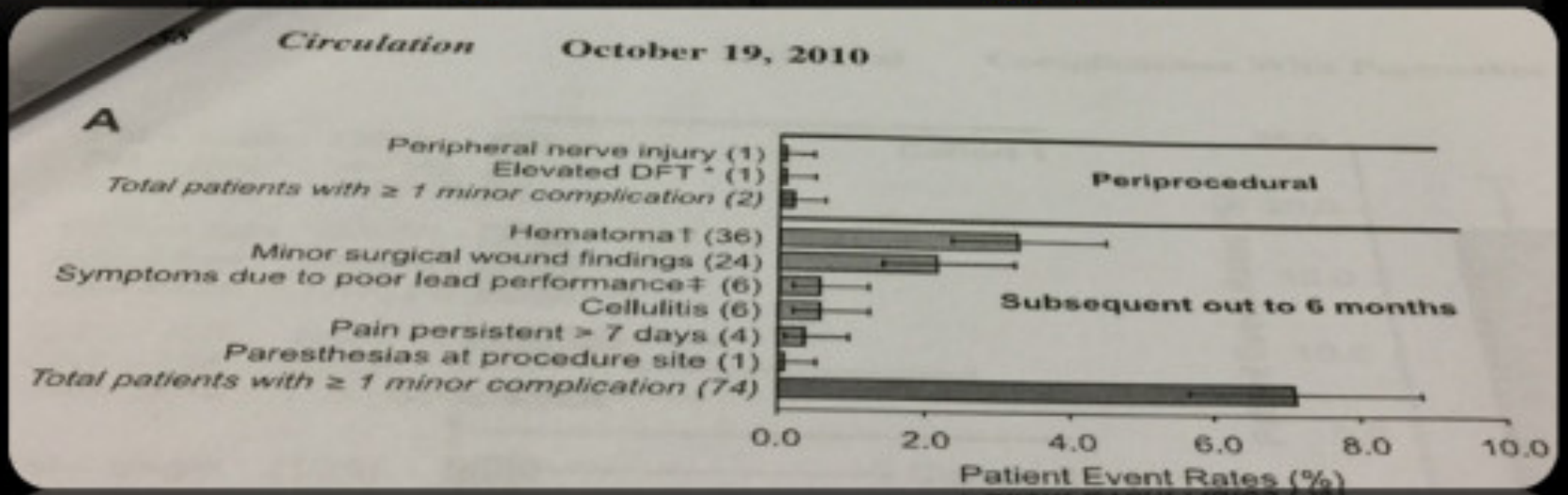
C) Rischio connesso alla procedura

REPLACE: Complicanze maggiori (4%)

Poole, Circulation 2010



REPLACE: Complicanze minori (7,4%)



C) Rischio connesso alla procedura

Ulteriori complicanze:

- Danni degli elettrocateteri a comparsa tardiva: 1,2%

- Shock inappropriati. 4,7% a 26 mesi, 8,3% a 30 mesi

D) Volontà del paziente

Considerazioni differenti dal primo impianto:

- Al pz ormai è nota la vita con l'ICD
- Le sue riflessioni sul tipo di morte e sul rapporto qualità/quantità di vita possono essere variate
- Il paziente ha il diritto di rifiutare o chiedere il ritiro di qualsiasi trattamento
- Il paziente ha diritto di rifiutare un trattamento cui aveva prima acconsentito qualora tale trattamento non si concili più con i suoi obiettivi

D) Volontà del paziente

LA NON SOSTITUZIONE DI UN GENERATORE

LA NON SOSTITUZIONE DI UN GENERATORE

NON è EUTANASIA

NON è SUICIDIO ASSISTITO

Take home message (1)

- Le attuali conoscenze non consentono di stabilire chi si può giovare o meno della sostituzione dell'ICD (pochi dati, assenza di studi di confronto ad hoc)
- Considerando il solo rischio aritmico, non si potrebbe negare a nessuno la sostituzione dell'ICD
- Considerando le coomorbidità e le complicanze procedurali il reale beneficio potrebbe essere inferiore a quello atteso

Take home message (2)

La sostituzione «automatica» del dispositivo non è prassi corretta

L'esaurimento della batteria del dispositivo deve imporre una rivalutazione delle condizioni del paziente e del suo rischio di morte sia aritmica che globale

La decisione va individualizzata con coinvolgimento informato del paziente e/o familiari: possibilità di non sostituzione

GRAZIE PER L'ATTENZIONE