



How relevant is the longevity of implanted device from the patient point of view

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Cosa si intende per «longevità»?

letteralmente:
*«durata della vita di un
organismo superiore
alla media»*



parlando di dispositivi
*«durata del tempo di servizio
di un dispositivo superiore alla
media»*

Longevità dei dispositivi impiantabili

Parlando di «longevità» dei dispositivi impiantabili il problema si pone per gli ICD e i CRT-D perché mediamente hanno una vita di servizio molto più breve dei pacemaker ...

Longevità dei dispositivi impiantabili

PAZIENTE

solo i pazienti che sopravvivono più dei loro device necessiteranno di una sostituzione

MEDICO

necessità cliniche e complicanze possono richiedere la sostituzione del device

FATTORI CHE POSSONO INFLUENZARE LA LONGEVITÀ

TIPO DI DISPOSITIVO

i CRT hanno una vita di servizio minore degli ICD e dei pm

PROGRAMMAZIONE

modalità e frequenza di stimolazione, terapie TY, sensori, ...

TECNOLOGIA

in particolare **tipo di batteria** e consumo dei circuiti

Sopravvivenza dei pazienti

Diversi studi dimostrano l'efficacia della terapia con ICD in termini di riduzione della mortalità dei pazienti

The Growing Mismatch Between Patient Longevity and the Service Life of Implantable Cardioverter-Defibrillators

Robert G. Hauser, MD, FACC.

Minneapolis, Minnesota

(J Am Coll Cardiol 2005;45:2022-5)

1280 pz impiantati c/o
Minnesota Heart Institute dal
1987

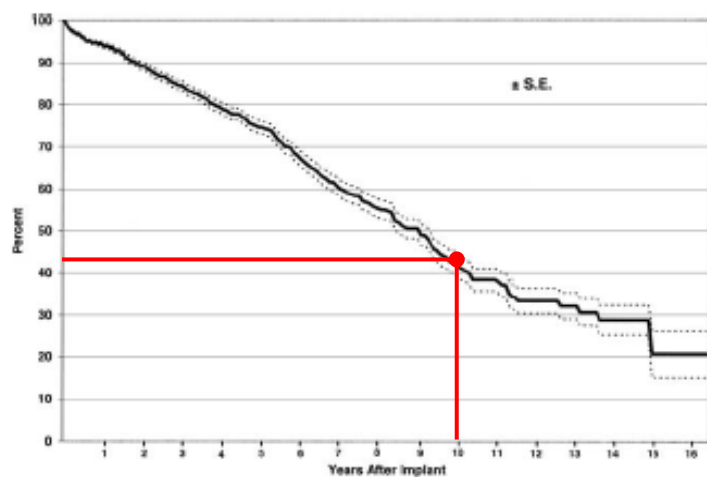


Figure 1. Survival of patients after implantable cardioverter-defibrillator implantation. SE = standard error of the mean.

Inc. (St. Paul, Minnesota) (19%). The average service life of these pulse generators was 4.3 ± 1.5 years (range <1 day to 8.9 years). Only 5% of pulse generators functioned for seven years. After excluding non-battery failures caused by electronic or housing defects, the average service life of 814

The cumulative survival of 1,280 patients who have received ICDs since 1987 at the Minneapolis Heart Institute is shown in [Figure 1](#). The probability of a patient living 4, 5, and 6 years after ICD implantation is $79 \pm 1\%$, $75 \pm 1\%$, and $68 \pm 2\%$. Over 40% of patients were still living at 10 years. The average ejection fraction was $34 \pm 15\%$, and

70% dei pazienti sopravvivono più delle batterie del loro defibrillatore e avranno bisogno di una sostituzione

Sopravvivenza dei pazienti

dallo studio Altitude 185.778 pts

ICD: sopravvivenza del 92% e 68% a 1 e 5 anni

CRT-D: sopravvivenza del 82% e 54% a 1 e 5 anni

(Leslie A, *Circulation* 2012;122:2359-2367)

Influence of Remote Device Follow-Up

The ALTITUDE Survival Study

Leslie A. Saxon, MD; David L. Hayes, MD; F. Roosevelt Gilliam, MD;
Paul A. Heidenreich, MD; John Day, MD; Milan Seth, MS; Timothy E. Meyer, PhD;
Paul W. Jones, MS; John P. Boehmer, MD

Background—Outcome data for patients receiving implantable cardioverter-defibrillator (ICD) and cardiac resynchronization therapy-defibrillator (CRT-D) devices treated outside of clinical trials are lacking. No clinical trial

after ICD shock to be evaluated. One- and 5-year survival rates in 185 778 patients after ICD implantation were 92% and 68% and were 88% and 54% for CRT-D device recipients. In 8228 patients implanted with CRT-only devices, survival was 82% and 48% at 1 and 5 years, respectively. For the 69 556 ICD and CRT-D patients receiving remote follow-up on the network, 1- and 5-year survival rates were higher compared with those in the 116 222 patients who received device follow-up in device clinics only (50% reduction; $P<0.0001$). There were no

92% and 68% and were 88% and 54% for CRT-D device recipients. In 8228 patients implanted with CRT-only devices, survival was 82% and 48% at 1 and 5 years, respectively. For the 69 556 ICD and CRT-D patients receiving remote follow-up on the network, 1- and 5-year survival rates were higher compared with those in the 116 222 patients who received device follow-up in device clinics only (50% reduction; $P<0.0001$). There were no differences between patients followed on or off the remote network for the characteristics of age, gender, implanted device year or type, and economic or educational status. Shock therapy was associated with subsequent mortality risk for both ICD and CRT-D recipients.

Conclusions—Survival after ICD and CRT-D implantation in patients treated in naturalistic practice compares favorably with survival rates observed in clinical trials. Remote follow-up of device data is associated with excellent survival, but arrhythmias that result in device therapy in this population are associated with a higher mortality risk compared with patients who do not require shock therapy. (*Circulation*. 2010;122:2359-2367.)

Key Words: follow-up studies ■ shock ■ survival

Sopravvivenza dei pazienti

Implantable cardioverter-defibrillator longevity under clinical circumstances: An analysis according to device type, generation, and manufacturer

Joep Thijssen, MD, C. Jan Willem Borleffs, MD, PhD, Johannes B. van Rees, MD, SumChe Man, MD, Mihály K. de Bie, MD, Jeroen Venlet, MS, Enno T. van der Velde, PhD, Lieselot van Erven, MD, PhD, Martin J. Schalij, MD, PhD

From the Department of Cardiology, Leiden University Medical Center, Leiden, The Netherlands.

Heart Rhythm 2012; 9: 513-9

Patients and ICD characteristics

Since 1996, 4673 consecutive ICDs were implanted in 3194 patients [mean age 62 [standard deviation 13] years].

Sopravvivenza a 4 anni:
78%

The majority of patients had a history of heart disease (64%) and a poor left ventricular ejection fraction (mean left ventricular ejection fraction 34% [standard deviation 15%]) (Table 1). During a mean follow-up of 4.1 ± 3.2 years, 708 (22%) patients died and 128 (4%) patients were lost to follow-up.

Of the 4673 implanted devices, 3194 (68%) were initial implantations and 1479 (32%) were replacement ICDs. The types (single-chamber ICD, dual-chamber ICD,

Durata di vita di servizio

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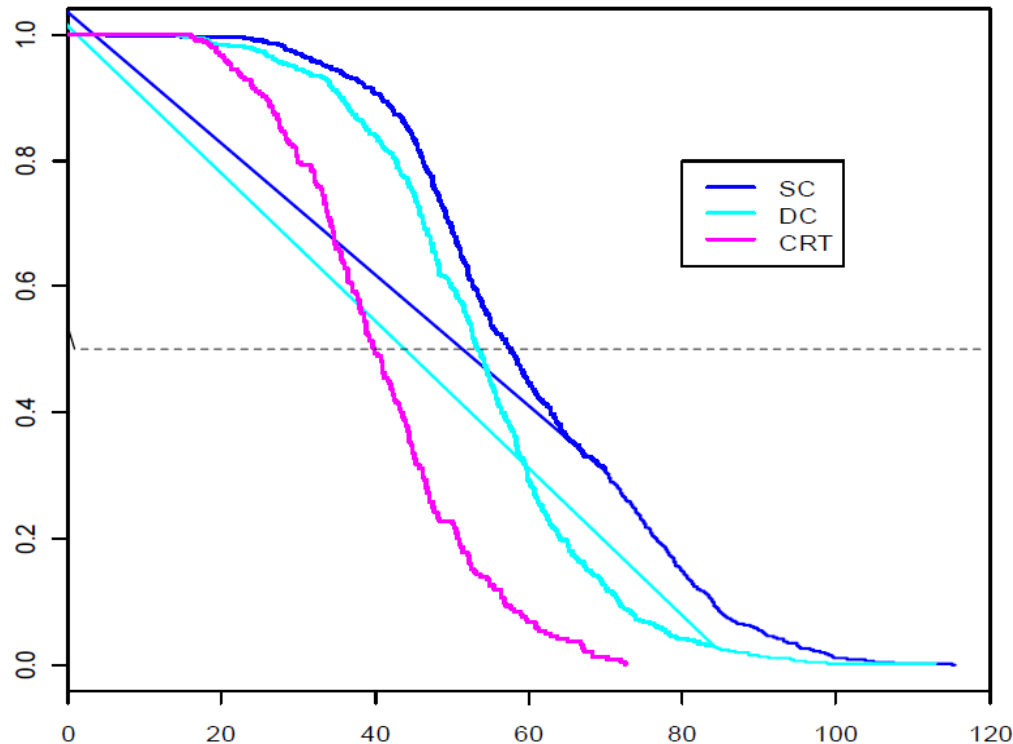
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4673 devices impiantati/sostituiti
dal 1996

Tipo di dispositivo	m	DS
Tutti i dispositivi	5.5	0.1
ICD mono	5.5	0.2
ICD bi	5.8	0.1
ICD CRT	4.7	0.1

Durata degli ICD



Single Chamber:

N = 1057

61 ± 18 months

Dual chamber:

N = 730

55 ± 15 months

CRT:

N = 311

42 ± 13 months

SC vs DC: $p < 0.0001$

SC vs CRT: $p < 0.0001$

DC vs CRT: $p < 0.0001$

SC: 5,0 anni

DC: 4,6 anni

CRT-D: 3,5 anni

**Longevity of ICD Pulse
Generators: 10 year
Multicenter Experience**

Linda Kallinen Retel BS FHRS
Robert G. Hauser MD FHRS
On behalf of the
Multicenter Registry Investigators
USA and Canada

Durata degli ICD

Un'esperienza italiana

Biffi. Europace 2008; 10: 1288-95

Longevity of implantable cardioverter-defibrillators: implications for clinical practice and health care systems

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Table 2 Longevity of 107 implantable cardioverter-defibrillators (ICDs) replaced in the follow-up period

ICD longevity (months)	Single chamber	Double chamber	CRT-D	<i>P</i>
Medtronic	72 (60–85)	84 (50–87)	49 (36–63)	0.150*
Guidant	52 (31–71)	50 (35–58)	45 (43–47)	0.183*
St Jude Medical	55 (40–78)	40 (33–64)	45 (43–46)	0.005*
<i>P</i>	0.028*	0.001*	0.100*	

CRT-D, biventricular ICD.

*Kruskal Wallis.

Du Fatto

Thijssen, Hear

Table 4 Cox proportional hazards regression model

	Univar
	HR
Device type	
Single chamber	Refer
Dual chamber	0.80
CRT-D	2.25
Manufacturer†	
Medtronic	Refer
Boston Scientific/Guidant	1.52
St Jude Medical/Ventritex	1.75
Device generation <2002 vs ≥2002	0.59
Pacing percentage (per 10% increase)	1.16
Pacing output (per V increase)	1.17
Number of shocks	1.00

ICDs at risk						
Single-chamber	730	536	333	86	20	0
Dual-chamber	2090	1353	693	180	4	0
CRT-D	1853	1036	345	17	0	0

	0.52–0.67	<.001*	0.34	0.29–0.40	<.001
	1.14–1.18	<.001*	1.14	1.10–1.17	<.001
	1.09–1.25	<.001*	1.23	1.14–1.32	<.001
	0.98–1.02	.89			

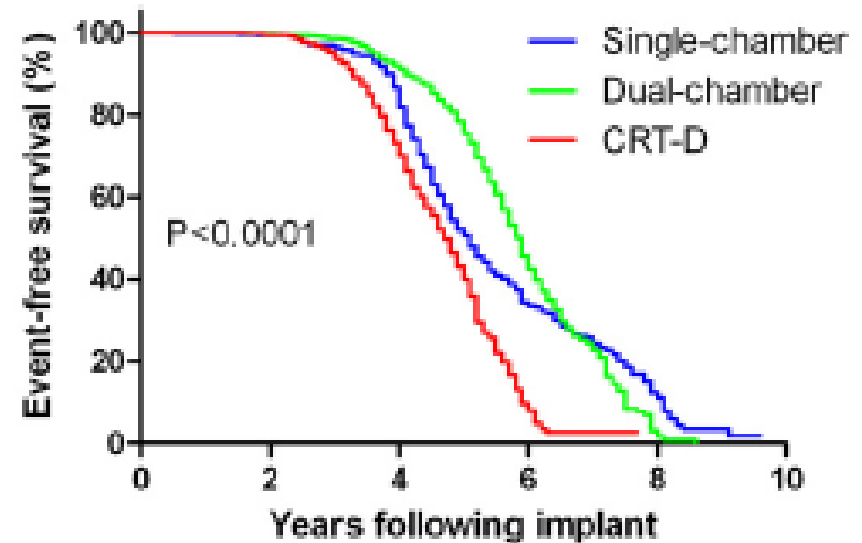


Figure 3 Kaplan–Meier curve for event-free survival of ICDs replaced because of battery depletion in single-chamber (blue line), dual-chamber (green line), and CRT-D (red line) devices.

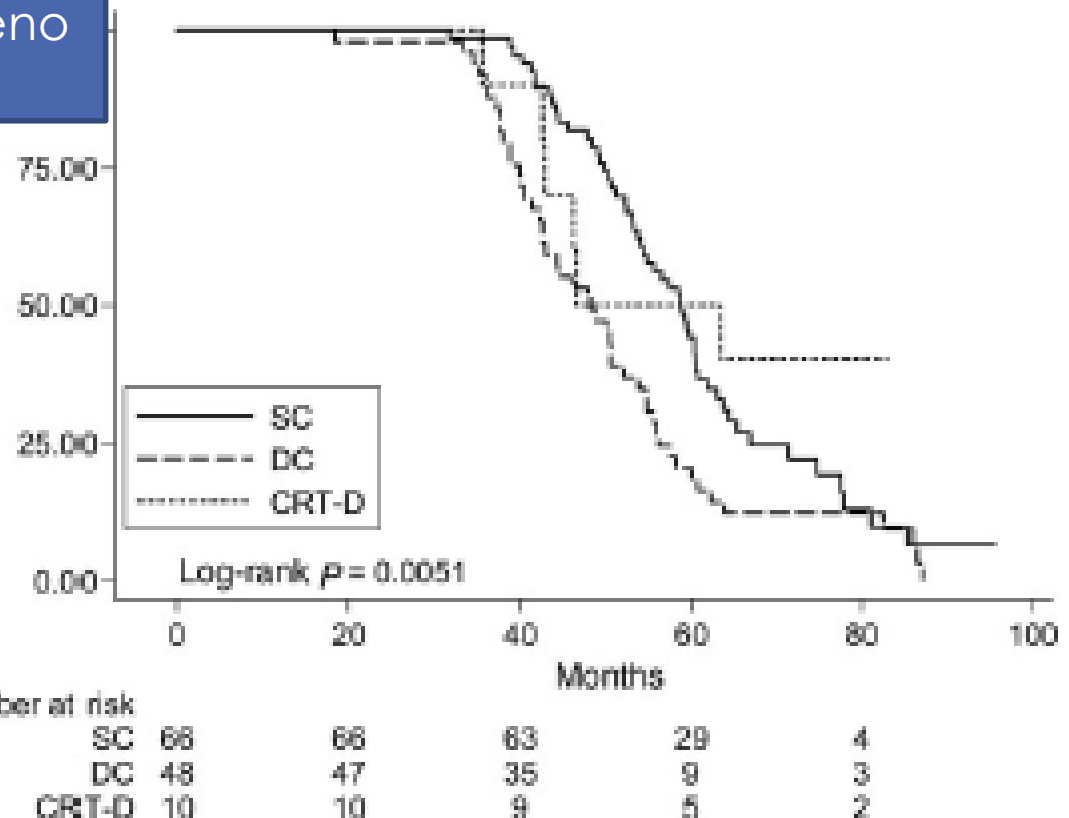
Durata degli ICD

Un'esperienza italiana

Biffi. Europace 2008; 10: 1288-95

Su 107 pz
a 5 anni sono ancora in servizio
circa il 35% dei device SC e meno
del 25% dei DC

SC (n = 66)
DC (n = 48)
CRT-D (n = 10)
SJM (n = 59)
MDT (n = 24)
GDT (n = 41)
Maximum output >31 J (n = 43)
Arrhythmia storm (n = 5)
Paced activity <1% (n = 105)
Paced activity <50% (n = 3)
Paced activity ≥ 50% (n = 16)
Stimulation output ≥ 3 V at 0.4 ms (n = 11)
Delivered shocks = 0 (n = 67)
1-2 shocks/year (n = 26)
3-5 shocks/year (n = 11)
≥ 6 shocks/year (n = 20)
CAD (n = 72)



Ma quanto dura la vita di servizio degli ICD?

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Heart Rhythm Disorders: Viewpoint

The Growing Mismatch Between Patient Longevity and the Service Life of Implantable Cardioverter-Defibrillators

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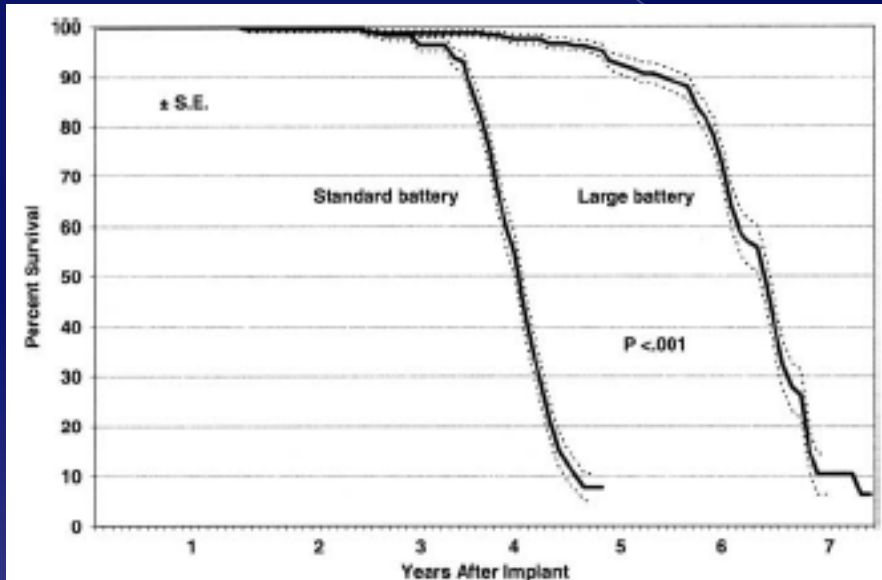


Figure 2. Longevity of standard and large-battery-capacity implantable cardioverter-defibrillator pulse generators. Non-battery failures were censored. SE = standard error of the mean.

JACC 2005; 45: 2022-5.

The Multicenter Registry has gathered ICD pulse generator failure data since 1999. To date, of 1,107 ICD pulse generator failures, 90% were caused by normal battery depletion and 10% were caused by electronic or housing defects. The majority of pulse generators were manufactured by Guidant Inc. (St. Paul, Minnesota) (49%), Medtronic Inc. (Minneapolis, Minnesota) (31%), and St. Jude Medical Inc. (St. Paul, Minnesota) (19%). The average service life of these pulse generators was 4.3 ± 1.5 years (range <1 day to 8.9 years). Only 5% of pulse generators functioned for seven years. After excluding non-battery failures caused by electronic or housing defects, the average service life of 814 single-chamber pulse generators was 4.7 ± 1 year compared with 4.0 ± 1 year for 293 dual-chamber pulse generators

ampere-level current. One manufacturer (Guidant Inc.) has offered four ICD models with a choice of battery capacities, i.e., a standard battery (0.92 to 1.06 AmpHr) or a large battery (1.44 to 1.75 AmpHr). This allowed a multicenter comparison of the effect of different battery capacities on pulse generator service life (13). The results are shown in Figure 2. Large-capacity batteries increased average service life by 2.3 years. The number of therapeutic shocks did not seem to affect battery longevity in either group. Large-

Perché vengono sostituiti i device?

Longevity of ICD Pulse Generators: 10 year Multicenter Experience

Linda Kallinen Retel BS FHRS
Robert G. Hauser MD FHRS
On behalf of the
Multicenter Registry Investigators
USA and Canada

- 8 centri attivi in U.S. e Canada
- Report di malfunzionamenti e sostituzioni raccolti dall'anno 1998
- Dichiarazione di esaurimento della batteria evidenziata dal raggiungimento dell'ERI

	All PGs N=2,508 (100%)	Boston Scientific N=1095 (44%)	Medtronic N=1101 (44%)	St. Jude Medical N=312 (12%)
Battery Depletion	2345 (93%)	1045 (95%)	1008 (92%)	291 (93%)
Electronic, Housing & Other	93 (4%)	34 (3%)	43 (4%)	16 (5%)
Advisory	71 (3%)	16 (2%)	50 (4%)	5 (2%)

Perché vengono sostituiti i device?

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From the Department of Cardiology, Leiden University Medical Center, Leiden, The Netherlands.

Thijssen, Heart Rhythm 2012; 9: 513-9

516

Heart Rhythm, Vol 9, No 4, April 2012

Table 3 Indication for replacement

Indication	Total (n = 1479)	Single-chamber ICD (n = 379)	Dual-chamber ICD (n = 645)	CRT-D (n = 455)
End of service, n (%)	1072 (72)	279 (74)	420 (65)	373 (82)
Device upgrade, n (%)	145 (10)	49 (13)	96 (15)	0 (0)
Device infection, n (%)	118 (8)	20 (5)	53 (8)	45 (10)
Device advisory or recall, n (%)	49 (3)	8 (2)	34 (5)	7 (2)
System malfunction, n (%)	83 (6)	23 (6)	38 (6)	22 (5)
Heart transplantation, n (%)	12 (1)	0 (0)	4 (1)	8 (2)

CRT-D = cardiac resynchronization therapy-defibrillator; ICD = implantable cardioverter-defibrillator.

La prima causa di sostituzione dei device è l'End of Service della batteria ma la percentuale di sostituzioni legate ad altre cause è comunque non trascurabile

**Quali sono le implicazioni
per i pazienti legate alla
longevità degli ICD?**

COMPLICANZE MAGGIORI ASSOCIATE ALLA SOSTITUZIONE O REINTERVENTI

Complication Risk with Pulse Generator Change: Implications When Reacting to a Device Advisory or Recall

SURAJ KAPA, M.D., LINDA HYBERGER, M.A., ROBERT F. REA, M.D., and DAVID L. HAYES, M.D.

From the *Division of Cardiology, Mayo Clinic, Rochester, Minnesota

Tasso di complicanze:

5,8 %

of cases from 17 ICD implanting centers in Canada suggested that ICD generator replacements in patients with advisory devices were associated with a high complication rate, with major complications requiring reoperation in 5.8% of patients.¹ This ex-

EDITORIAL COMMENTARY

The “natural” history of implantable defibrillators under advisory

Mark H. Schoenfeld, MD, FHRS, FACC, FAHA

From Yale University School of Medicine, Cardiac Electrophysiology and Pacemaker Laboratory, Hospital of Saint Raphael, New Haven, Connecticut.

Tasso di complicanze:

9,1 %

Gould et al reported 41 (9.1%) complications in 451 advisory devices replaced, with 27 (5.9%) requiring reoperation, including two deaths. This complication outcome is

Recurrent Implantable Cardioverter-Defibrillator Replacement Is Associated with an Increasing Risk of Pocket-Related Complications

C. JAN WILLEM BORLEFFS, M.D.,*,‡ JOEP THIJSSEN, M.D.,*,‡ MIHÁLY K. DE BIE, M.D.,*
JOHANNES B. VAN REES, M.D.,* GUIDO H. VAN WELSENES, M.S.,*
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(*PACE* 2010; 33:1013–1019)

2415 Pz con ICD, anni 1992 – 2008

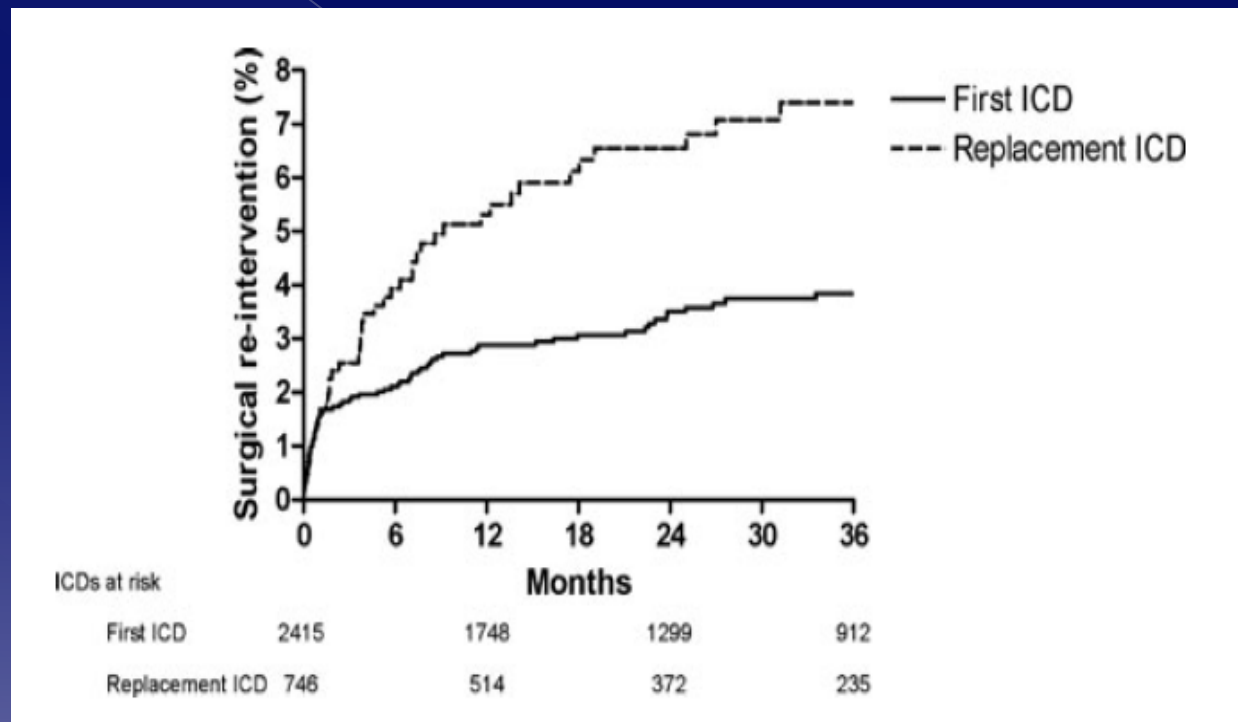
Complicanze dopo
sostituzione ICD:

7,5 %

vs

Complicanze dopo
primo impianto ICD:

3,9 %



COMPLICANZE MAGGIORI ASSOCIATE ALLA SOSTITUZIONE O REINTERVENTI

Recurrent Implantable Cardioverter-Defibrillator Replacement Is Associated with an Increasing Risk of Pocket-Related Complications

C. JAN WILLEM BORLEFFS, M.D.,*,‡ JOEP THIJSSEN, M.D.,*,‡ MIHÁLY K. DE BIE, M.D.,* JOHANNES B. VAN REES, M.D.,* GUIDO H. VAN WELSENES, M.S.,* LIESELOT VAN ERVEN, M.D., Ph.D.,* JEROEN J. BAX, M.D., Ph.D.,* SUZANNE C. CANNEGIETER, M.D., Ph.D.,‡ and MARTIN J. SCHALIJ, M.D., Ph.D.*

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(*PACE 2010; 33:1013–1019*)

Conclusions

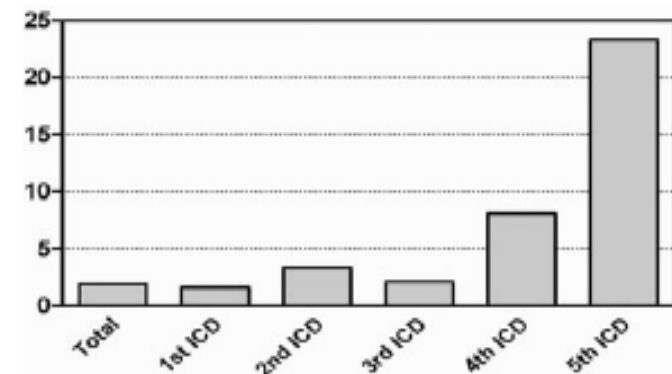
Replacement ICDs demonstrated a doubled occurrence of pocket-related surgical re-interventions when compared to first implanted ICDs. Furthermore, both the requirements for surgical re-intervention due to infectious and noninfectious causes seemed to be increased in replacement ICDs and the requirement for re-intervention increased with every consecutive replacement. Therefore, every effort should be addressed to improve ICD longevity, hence decreasing the need for device replacement.

SURGICAL RE-INTERVENTION IN ICD PATIENTS

Table III.

Requirement for Re-intervention per Consecutive Implanted ICD

	Total	1st ICD	2nd ICD	3rd ICD	4th ICD	5th ICD
Number of ICDs	3,161	2,415	609	107	24	6
Events	145	90	46	5	3	1
Total years implanted	7,632.3	5,949	1,406	236	37	4.3
Events per 100 ICD-years (95% CI)	1.9 (1.6–2.2)	1.5 (1.2–1.9)	3.3 (2.4–4.4)	2.1 (0.7–4.9)	8.1 (1.7–18.3)	23.3 (0.6–129.6)



Recurrent Implantable Cardioverter-Defibrillator Replacement Is Associated with an Increasing Risk of Pocket-Related Complications

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- Rischio di reintervento per infezione, sostituzione vs primo impianto: OR 2,5; 95% CI 1,6 – 3,7

Fattori di rischio di infezione

- ✱ presenza di ematoma postoperatorio ($P=0.03$)
- ✱ durata della procedura ($P=0.009$)
- ✱ reintervento/sostituzione ($P=0.02$)
- ✱ non-uso della profilassi antibiotica ($P=0.016$)

Infection after pacemaker implantation: infection rates and risk factors associated with infection in a population-based cohort study of 46299 consecutive patients

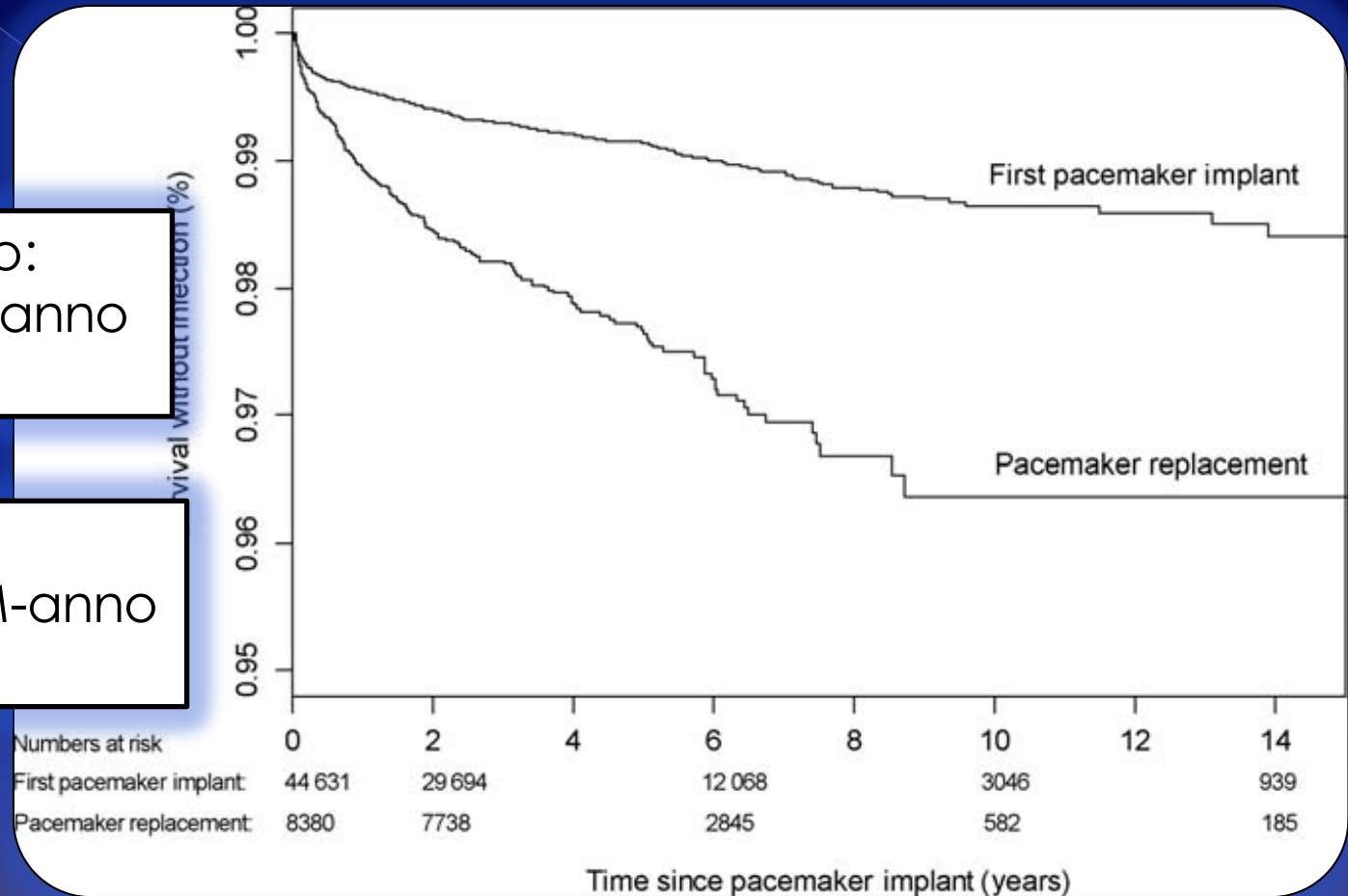
Jens Brock Johansen^{1,2*}, Ole Dan Jørgensen^{1,3}, Mogens Møller^{1,4}, Per Arnsbo^{1,4}, Peter Thomas Mortensen², and Jens Cosedis Nielsen²

- Fattori di rischio indipendenti:
 - › Impianto nei primi anni dello studio
 - › Numero di interventi
 - › Non uso della profilassi antibiotica

Fattori di rischio di infezione: sostituzione

Primo impianto:
4,82/1000 PM-anno

Sostituzioni:
12,12/1000 PM-anno



RISCHIO DI INFEZIONE: sostituzione

Infection after pacemaker implantation: infection rates and risk factors associated with infection in a population-based cohort study of 46299 consecutive patients

Table 2 Infection of pacemaker systems and its associated risk factors

Variable	Devices	Device-years	Events	Univariate	Multivariate ^a		
Rischio di infezione, sostituzione vs 1° impianto: RR 2.79, CI 2.38 – 3.28, p<0.001							
Replacement	12 027	47 201	251	2.79(2.38–3.28)			
Sex							
Male	30 294	121 238	384	1	<0.001	1	<0.001
Female	26 363	115 650	212	0.60(0.51–0.71)		0.67(0.57–0.80)	
Age							
0–19	571	2499	22	1.63(0.96–2.78)		1.41(0.83–2.38)	
20–49	2551	14 352	69	1	<0.001	1	<0.001
50–59	3938	21 045	9	0.75(0.55–1.03)		0.79(0.58–1.08)	
60–69	9527	46 552	150	0.62(0.47–0.83)		0.68(0.51–0.90)	
70–79	19 186	86 155	181	0.39(0.29–0.51)		0.44(0.34–0.59)	
80–89	17 812	59 396	89	0.24(0.17–0.32)		0.29(0.21–0.39)	
90–	3072	6888	6	0.11(0.05–0.25)		0.31(0.06–0.30)	

Fattori di rischio di infezione

PEOPLE Study

	Percent of Overall Population	Variable*		Analysis					
				Single Variable			Multiple Variable†		
		Present	Absent	OR	95% CI	P	aOR	95% CI	P
Age, mean, y	76	...	...	...	...	0.14	...	...	0.79
Female sex	40.3	0.57	0.77	0.74	0.39–1.40	0.35	...	...	...
Diabetes mellitus	10.1	0.81	0.67	1.21	0.48–3.06	0.61	...	...	...
Immunosuppression	3.4	2.2	0.65	3.07	0.36–2.62	0.02	...	...	0.02
Variabile		Frequenza del fattore di rischio (%)		aOR		IC 95%		P	
Febbre 24h prima dell'impianto		1.6		5.89		2.00 - 16.98		<10 ⁻²	
PM temporaneo		8.8		2.46		1.09 - 5.13		<10 ⁻⁷	
Primo impianto		70.3		0.46		0.24 - 0.87		0.02	
Reintervento precoce		1.7		15.04		6.70 - 33.73		<10 ⁻⁴	
Profilassi antibiotica		88.3		0.40		0.18 - 0.86		0.02	
Postprocedural fever	2.4	2.01	0.66	3.05	0.95–9.75	0.08	...	...	0.67
Early reintervention	1.7	8.91	0.55	16.29	8.01–33.15	<10 ⁻⁷	15.04	6.70–33.73	<10 ⁻⁴

PM indicates pacemaker; ICD, implantable cardioverter-defibrillator; ipsilateral intravenous infusion, intravenous infusion on the same body side as the device implantation site; and vein puncture, percutaneous subclavian venous catheterization.

*Rates of infection when variable was present vs absent.

†Final model included fever 24 hours before implantation, cutaneous lesions, temporary pacing wire operating room, antibiotic prophylaxis, and early reintervention. Hosmer-Lemshow test, $P=0.28$.

Klug et al. Circulation
2007;116;1349-1355

Quali soluzioni per ridurre il problema?

Impact of ICD Battery Longevity on Need for Device Replacements—Insights from a Veterans Affairs Database

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Background: *The number of implantable cardioverter defibrillator (ICD) replacements is increasing, which adds to patient risk and costs.*

Objectives: *To understand the impact of increasing ICD longevity on need for replacements, costs, and some of the risks.*

Methods: *Using the Veterans Affairs records, veterans with ICD implants between June 1992 and April 2007 and dead as of April 2009 were identified. Data were obtained by retrospective records review. The longevity of each ICD was the duration from implant to explant. For each ICD, the longevity needed to avoid one replacement was defined as longevity of that ICD plus the longevity of the subsequent ICD.*

Results: *The study cohort had 164 patients with 301 ICD implants. Ninety-two patients had at least one ICD replacement. Two patients were excluded for missing data. Twenty-seven patients had an ICD explanted for reasons other than battery depletion. Sixty-three patients received 83 ICDs for battery depletion alone. Among 27 patients who had ICD replacements for other reasons, four patients may have avoided a device infection related to ICD replacement if the initial ICD had lasted 7 years. If all ICDs had lasted 5, 7, or 9 years, then 26%, 58%, and 84% of patients, respectively, would not have needed an ICD replacement. Also 17, 37, and 53 ICD replacements, respectively, would have been avoided, saving US\$314,500–US\$980,500 over 15 years at 2005 Medicare re-imbursement rates.*

Conclusions: *Prolongation of battery life to 7 or 9 years is important to reduce patient risks and decrease costs. (PACE 2010; 33:314–319)*

ICDs, replacements, longevity

Impact of ICD Battery Longevity on Need for Device Replacements—Insights from a Veterans Affairs Database

PACE 2010;33:314

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Con durate di 5, 7 e 9 anni il 26, 58 e 84% di pazienti avrebbe evitato una sostituzione

Infezioni dopo sostituzione: 1/5 (20%) e 4/5 (80%) evitate se la durata dell'ICD fosse stata di 7 e 9 anni rispettivamente

The consequences of ICD device replacement can be grouped in terms of impact on clinical, economic and patient outcomes

CLINICAL	ECONOMIC	PATIENT
▪ Death ▪ Stroke ▪ Cardiac arrest ▪ Respiratory arrest or failure ▪ Acute coronary syndrome ▪ Cardiac perforation ▪ Pneumothorax, Haemothorax; Haemodynamic instability; Haematoma; Primary embolus; Peripheral arterial embolus; DVT; Cardiac valve injury	▪ Monetary costs of treating complications ▪ Opportunity costs of having to remove a device and replace a new one ▪ The capacity / productivity of the hospital	▪ Quality of life (QoL) and the fear of the patient ▪ Anxiety surrounding operation and infection risk ▪ Psychological counselling of patient prior to surgery via cardiac nurse ▪ Insurance issues for the patient ▪ Limitations and restrictions on the activities of daily life

Complications from device replacement result in high costs and have a significant impact on patients' lives

Impatto economico della longevità dei device

Impact of ICD Battery Longevity on Need for Device Replacements—Insights from a Veterans Affairs Database

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Effect on Costs

The direct costs of ICD replacement are estimated to be around US\$18,500 in 2005 Medicare dollars. For the patients in both groups, if all ICDs were to last 5, 7, or 9 years then US\$444,000, US\$1,110,000, and US\$1,609,500 in replacements costs, respectively, would have been avoided for this healthcare system over a period of 15 years.

Attuali tecnologie per le batterie degli ICD

- Li/SVO: Litio - OSSIDO DI VANADIO & ARGENTO (primo impianto ICD nel 1987)
Elevata densità di energia, alta capacità
Incremento del tempo di carica a metà vita
- Li/CFx-SVO: Litio – Policarb. monofluoride - OSSIDO DI VANADIO & ARGENTO
Alta capacità, celle più piccole (elevata densità energetica), stabilità del tempo di carica
- Li/MnO₂ : Litio – Diossido di Manganese
Alta capacità, alta densità di energia, curva di scarica altamente predittiva, stabilità tempo di carica

Perchè l'anodo di Litio?

- Litio consente alta capacità
- Litio è l'elemento metallico più leggero tra tutti gli elementi metallici
- Litio consente di raggiungere alti voltaggi

Longevità e capacità della batteria

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Heart Rhythm Disorders: Viewpoint

The Growing Mismatch Between Patient Longevity and the Service Life of Implantable Cardioverter-Defibrillators

Robert G. Hauser, MD, FACC.
Minneapolis, Minnesota

La capacità della batteria di un defibrillatore di erogare corrente è un elemento fondamentale per definirne la longevità

I pazienti preferiscono un dispositivo di dimensioni maggiori ma più longevo per ridurre il numero delle sostituzioni

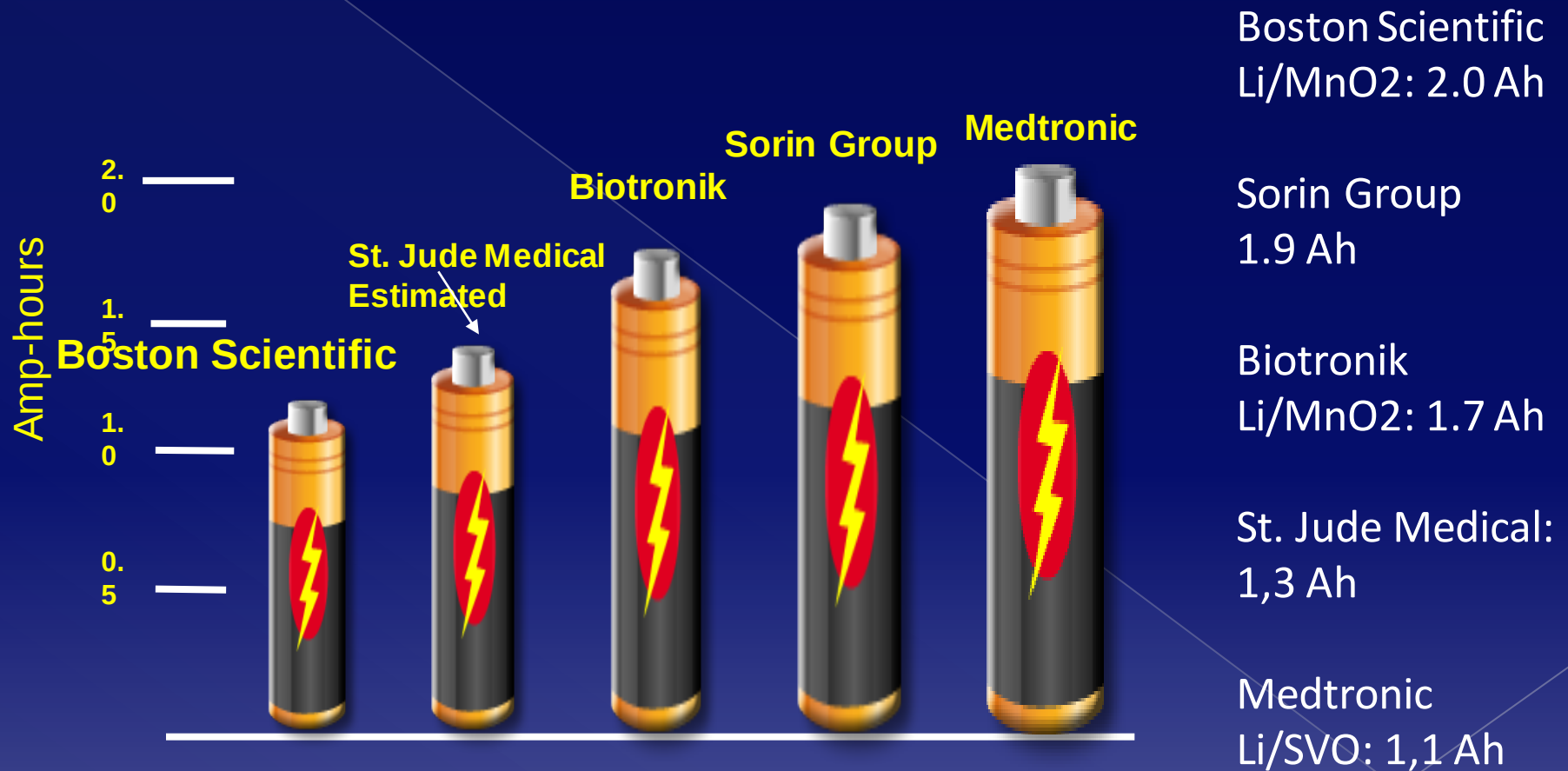
EFFECT OF BATTERY CAPACITY ON SERVICE LIFE

The ICD pulse generators use proprietary lithium silver vanadium oxide batteries that are capable of delivering ampere-level current. One manufacturer (Guidant Inc.) has offered four ICD models with a choice of battery capacities, i.e., a standard battery (0.92 to 1.06 AmpHr) or a large battery (1.44 to 1.75 AmpHr). This allowed a multicenter comparison of the effect of different battery capacities on pulse generator service life (13). The results are shown in Figure 2. Large-capacity batteries increased average service life by 2.3 years. The number of therapeutic shocks did not seem to affect battery longevity in either group. Large-capacity batteries increased pulse generator size and weight by 5 cc and 11 g. The added battery longevity reduced annual pulse generator costs by \$1,000 to \$1,600 per patient. These data suggest that larger batteries can reduce costs by significantly prolonging the service life of ICDs with only a small increase in pulse generator size.

Physicians tend to believe that patients would resist any increase in pulse generator size. However, a recent study by Wild et al. (14) found that 90% of patients thought that ICD and pacemaker longevity was more important than size. The vast majority of patients preferred a larger device that could reduce the number of potential replacement

Longevità e capacità della batteria

CAPACITA' (Ah)



Boston Scientific

New generation device batteries

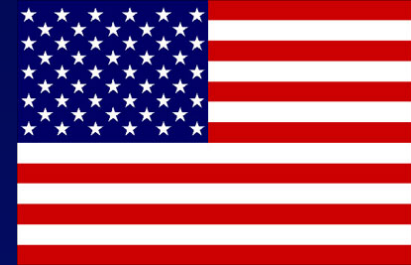
- ◉ Litio / Diossido di Manganese (invece che ossido di Vanadio)
- ◉ Costruite in proprio
- ◉ Nuova chimica e maggior capacità (2 Ah)
- ◉ Nuova modalità di calcolo della durata residua basata sul consumo reale, la capacità residua, il voltaggio medio (3.1 BOL-2.9 ERI)



Le nuove batteria Boston Scientific garantiscono durate elevate con tempi di carica dei condensatori stabili per tutta la vita di servizio del device

DURATA DEI DISPOSITIVI – BSCI MnO2

Real-World Device Longevity LATITUDE Jan 2012

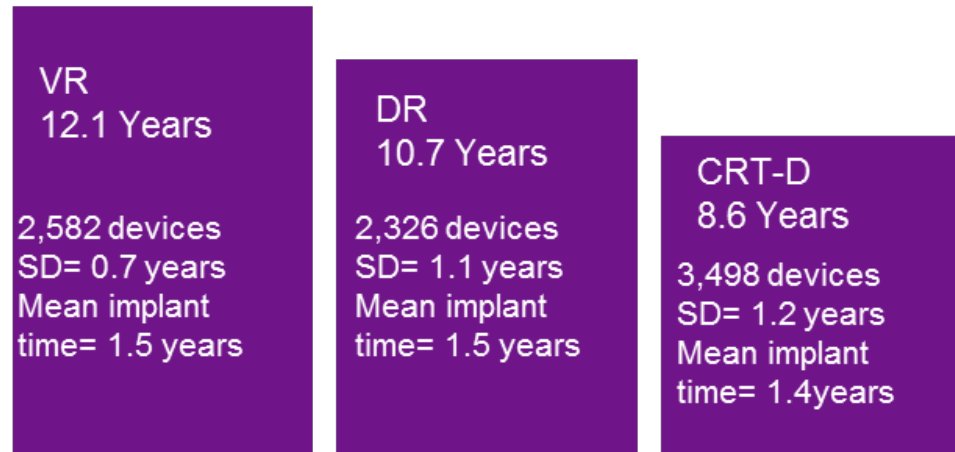


Real-world

Over 67,000 devices

- ~12.5 year projected longevity TELIGEN VR
- ~11 year projected longevity TELIGEN DR
- ~8.7 year projected longevity COGNIS CRT-D

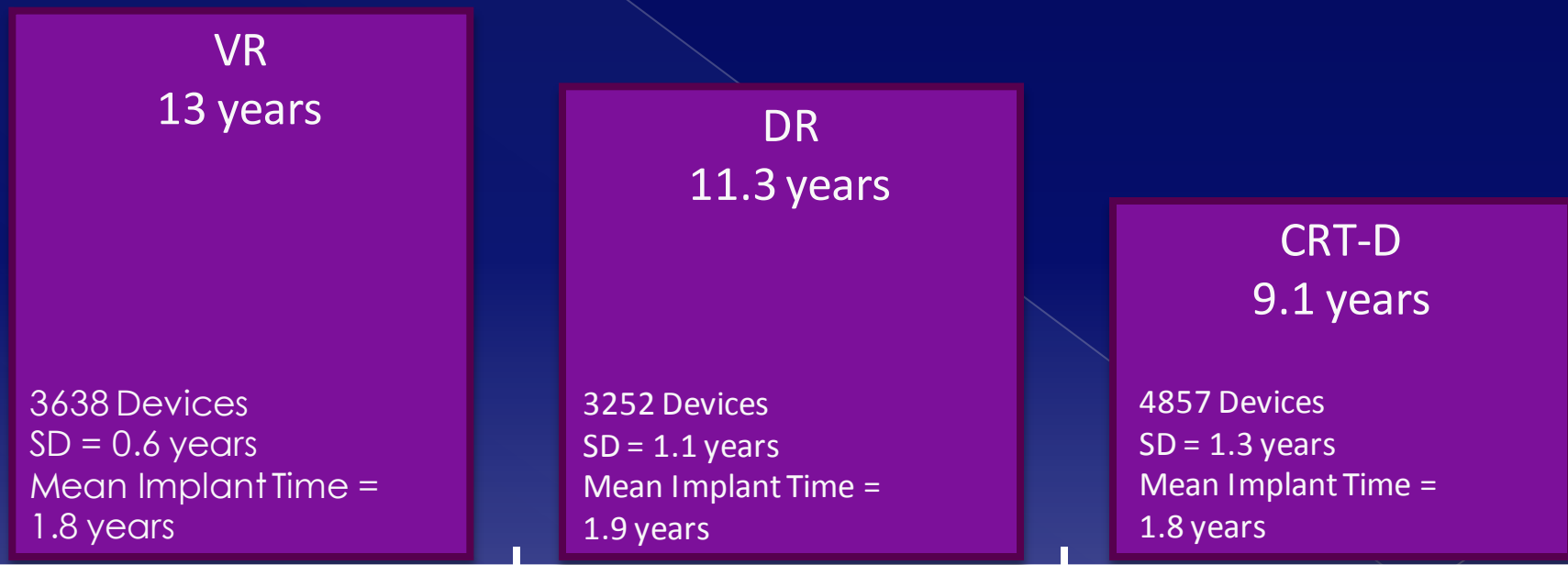
Calculated Longevity from LATITUDE™



Analysis of aggregate LATITUDE patient management data from over 8,406 patients as of January 2nd 2012 Data on file

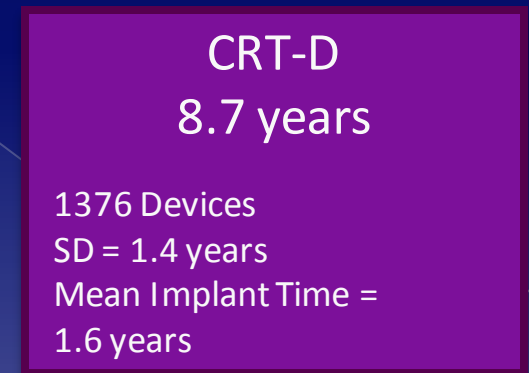
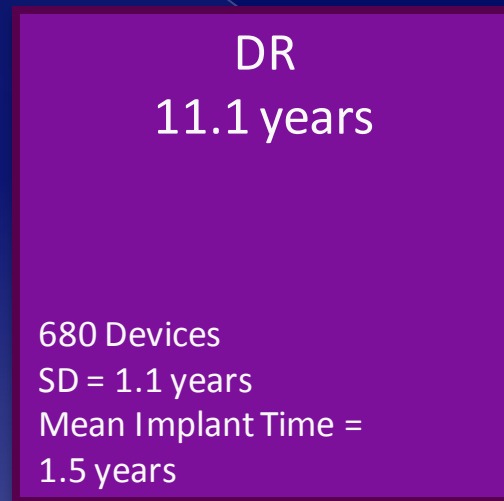
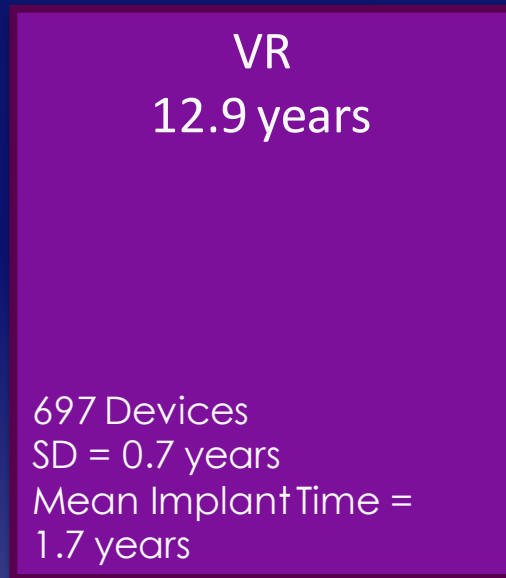
DURATA DEI DISPOSITIVI – BSCI MnO2

Real-World Longevity from Latitude
8406 patient devices
Aug 2012



DURATA DEI DISPOSITIVI – BSCI MnO2

Real-World Longevity from Latitude
1863 patient devices
Aug 2012



Conclusioni

- ◉ La durata delle batterie è il principale fattore che influenza la longevità di un ICD, ma non il solo
- ◉ L'esperienza degli ultimi 15 anni ci porta a considerare longevo un dispositivo che ha una vita di servizio superiore a 5-6 anni
- ◉ I rischi di complicanze sui pazienti aumentano anche del 10% nelle sostituzioni (oltre 25% alla quinta sostituzione)
- ◉ Device che durino oltre 10 anni ridurrebbero notevolmente il rischio di complicanze legate alle sostituzioni
- ◉ Le tecnologie attuali ci permettono di ottenere batterie che offrono una durata superiore ai 10 anni

GRAZIE

Il nuovo dispositivo BSCI MnO₂

In momento di “paying review

