

Emoclinic Symposium

SUTLE SPONDE DEL TICINO





ICD convenzionale

***‘Inside or Outside of the Heart
Where Do We Go From Here?’***

Dr. NC. Dajelli Ermolli

ICD e sICD

- **Ineleggibilità all'impianto per fallimento dello screening**
 - 7-15% dei pz
 - CM ipertrofica, c. congenite
- **Pacing antibradicardico**
 - 4-21% dei candidati all'ICD può beneficiare del pacing
 - rilievo clinico dubbio (pacing VD dannoso!)
- **Pacing antitachicardico**
 - efficace nell'interrompere TV anche rapide (~40%)
 - utilità controversa (sovrastimata?) soprattutto nei pz in prevenzione primaria
 - inutile in alcune condizioni (FV)
- **Assenza di resincronizzazione**
- **Costi**
 - Dispositivo + sostituzioni
 - Costi complicanze

Suitability for subcutaneous defibrillator implantation: results based on data from routine clinical practice

Mihály K de Bie,¹ Joep Thijssen,¹ Johannes B van Rees,¹ Hein Putter,² Enno T van der Velde,¹ Martin J Schalij,¹ Lieselot van Erven¹

Cumulative end-point occurrence

Suitability for S-ICD

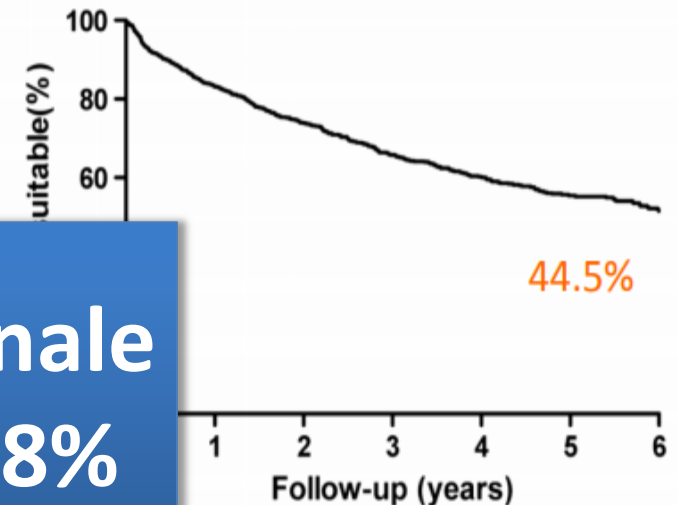


Table 2 Predictors of the unsuitability for an S-ICD

Parameter	Univariate analysis	p Value	Multivariate analysis	p Value
Age (per 10 years)	1.22 (1.13 to 1.32)	<0.01	1.10 (0.99 to 1.24)	NS
Male gender	1.14 (0.90 to 1.45)	0.26		
Secondary versus primary prevention	1.94 (1.62 to 2.34)	<0.01	2.15 (1.74 to 2.67)	<0.01
Ischaemic versus non-ischaemic cardiomyopathy	1.07 (0.88 to 1.30)	0.49		
Congenital versus acquired	0.80 (0.58 to 1.09)	0.15	1.17 (0.77 to 1.76)	NS
Renal clearance (per 20 ml/m ²)	0.91 (0.87 to 0.96)	<0.01	0.99 (0.91 to 1.08)	NS
LVEF (per 10%)	0.96 (0.90 to 1.01)	0.14	0.97 (0.89 to 1.05)	NS
NYHA class III/IV versus I/II	1.57 (1.20 to 2.04)	<0.01	1.66 (1.25 to 2.20)	<0.01
History of atrial fibrillation	1.58 (1.27 to 1.96)	<0.01	1.24 (0.95 to 1.61)	NS
QRS (per 30 ms)	1.36 (1.23 to 1.50)	<0.01	1.30 (1.16 to 1.45)	<0.01
Antiarrhythmic medication	1.20 (0.95 to 1.51)	0.13	0.95 (0.72 to 1.24)	NS

A scene from the movie Rocky. Rocky Balboa, played by Sylvester Stallone, is in a boxing ring, looking determined and slightly bruised. He is wearing red and white striped boxing trunks. His opponent, a larger man in red boxing trunks, is in the background, ready to fight. The word "Oversensing" is written in white, italicized font across the center of the image.

Oversensing

United Kingdom national experience of entirely subcutaneous implantable cardioverter-defibrillator technology: important lessons to learn

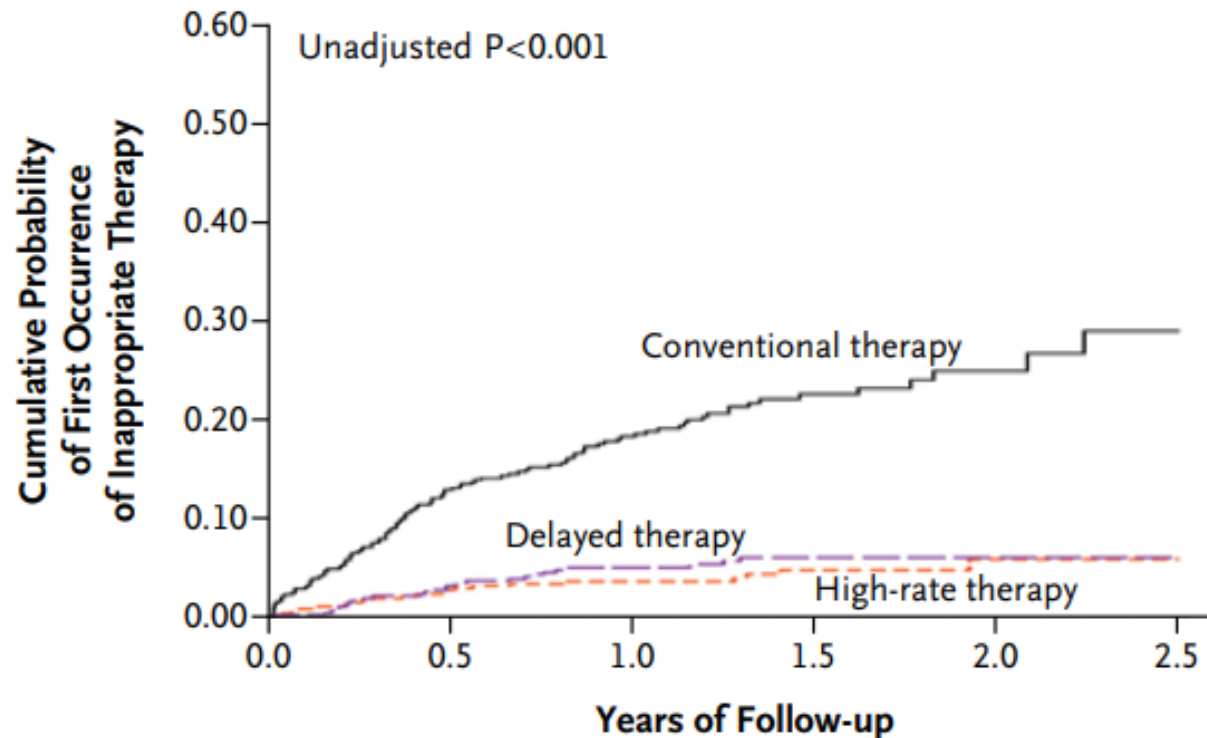
Table 1 Published S-ICD case series

	Jarman et al. ⁵	Current study	Aydin et al. ⁶	Köbe et al. ⁷	Olde Nordkamp et al. ⁸	Dabiri Abkenari et al. ⁴	Bardy et al. ³
Number of patients	16	111	40	69	118	31	55
Patients age [median (range)/mean \pm SD]	23 (10–48)	36 (10–87)	42 \pm 15	46 \pm 16	50 \pm 14	53 \pm 16	56 \pm 13
Ischaemic or idiopathic dilated cardiomyopathy	0%	18%	45%	52%	57%	71%	85%
Mean/median follow-up duration (months)	9	12	8	7	18	9	10
Patients with re-interventions	19%	16%	13%	4%	14%	10%	11%
Patients with inappropriate shocks	25%	15%	5%	4%	13%	16%	9%

The 11 patients who received inappropriate shocks due to T-wave over-sensing were significantly younger than patients who did not (24 ± 10 vs. 37 ± 19 years; $P = 0.02$) (Table 3). Underlying pathologies were tetralogy of Fallot in three, Ebstein's anomaly in one, hypertrophic cardiomyopathy in three, CPVT in three, and long QT syndrome in one.

0.01). All inappropriate shocks occurred subsequent to the introduction of a new software upgrade in October 2009 designed to reduce inappropriate shocks due to T-wave over-sensing.

Reduction in Inappropriate Therapy and Mortality through ICD Programming



No. at Risk

Conventional therapy	514	420 (0.13)	305 (0.18)	149 (0.22)	56 (0.25)	8 (0.29)
High-rate therapy	500	454 (0.03)	339 (0.04)	191 (0.05)	70 (0.06)	17 (0.06)
Delayed therapy	486	445 (0.03)	342 (0.05)	177 (0.06)	82 (0.06)	13 (0.06)



***Gli elettrocatteteri degli ICD
si rompono spesso***

Quanto durano gli elettrocateri?

100

● Aass (2002), n=80

Methods and Results— A total of 990 consecutive patients who underwent first implantation of an implantable cardioverter-defibrillator between 1992 and May 2005 were analyzed. Median follow-up time was 934 days (interquartile range, 368 to 1870). Overall, 148 defibrillation leads (15%) failed during the follow-up. The estimated lead survival rates at 5 and 8 years after implantation were 85% and 60%, respectively. The annual failure rate increased progressively with time after implantation and reached 20% in 10-year-old leads ($P<0.001$). Lead defects affected newer as well as older models. Patients with lead defects were 3 years younger at implantation and more often female. Multiple lead implantation was associated with a trend to a higher rate of defibrillation lead defects ($P=0.06$). The major lead complications were insulation defects (56%), lead fractures (12%), loss of ventricular capture (11%), abnormal lead impedance (10%), and sensing failure (10%).

Conclusions— An increasing annual lead failure rate is noted primarily during long-term follow-up and reached 20% in 10-year-old leads. Patients with lead defects are younger and more often female.

Clinical Outcome

During the median follow-up of 934 days (interquartile range, 368 to 1870) 207 patients (21%) died: 115 patients (55%) died from congestive heart failure, 4 (2%) from sudden death, 18 (9%) from other cardiovascular death, and 27 (13%) from noncardiac causes. In 45 patients (21%), the cause of death remained unknown. Seven patients underwent heart transplantation.

A systematic review of ICD complications in randomised controlled trials versus registries: is our 'real-world' data an underestimation?

Vivienne A Ezzat, Victor Lee, Syed Ahsan, Anthony W Chow, Oliver Segal, Edward Rowland, Martin D Lowe, Pier D Lambiase

Table 1 Baseline characteristics of the included studies

		Trial	Year	N	Mean Follow-up (months)
1	Calkins <i>et al</i> ²³	SCV vs cephalic approach	2001	71	18
2	Deisenhofer <i>et al</i> ²⁴	Dual vs single chamber	2001	92	8
3	Kron <i>et al</i> ⁸	AVID	2001	539	27
4	Bänsch <i>et al</i> ²⁵	CAT	2002	50	66
5	Moss <i>et al</i> ²⁶	MADIT	2002	742	20
6	Vollman <i>et al</i> ²⁷	6944 vs 6942	2003	542	11
7	Bänsch <i>et al</i> ²⁸	1+1	2004	102	12
8	Bokhari <i>et al</i> ²⁹	CIDS subset	2004	60	67
9	Hohnloser <i>et al</i> ³⁰	DINAMIT	2004	310	30
10	Kadish <i>et al</i> ¹¹	DEFINITE	2004	229	29
11	Bänsch <i>et al</i> ³¹	Quick-ICD	2007	190	12
12	Reddy <i>et al</i> ³²	SMASH-VT	2007	128	22
13	Almendral <i>et al</i> ¹⁰	DATAS	2008	334	15
14	Russo <i>et al</i> ³³	INTRINSIC RV	2009	1530	11
15	Steinbeck <i>et al</i> ⁷	IRIS	2009	415	37

Table 2 Complications

	Patients, n	All events, n (%)
Calkins <i>et al</i> ²³	71	2 (2.8)
Deisenhofer <i>et al</i> ²⁴	92	10 (10.9)
Kron <i>et al</i> ⁸	539	68 (12.6)
Bänsch <i>et al</i> ²⁵	50	14 (28)
Moss <i>et al</i> ²⁶	742	18 (2.4)
Vollman <i>et al</i> ²⁷	542	64 (11.8)
Bänsch <i>et al</i> ²⁸	102	20 (19.6)
Bokhari <i>et al</i> ²⁹	60	21 (35)
Hohnloser <i>et al</i> ³⁰	310	25 (8.1)
Kadish <i>et al</i> ¹¹	229	13 (5.7)
Bänsch <i>et al</i> ³¹	190	3 (1.6)
Reddy <i>et al</i> ³²	128	0
Almendral <i>et al</i> ¹⁰	334	30 (9.0)
Russo <i>et al</i> ³³	1530	71 (4.6)
Steinbeck <i>et al</i> ⁷	415	76 (18.3)
Kuck <i>et al</i> ³⁴	107	15 (14.0)
Varma <i>et al</i> ³⁵	1339	81 (6.0)
Cheng <i>et al</i> ³⁶	16	1 (6.3)
Event rate, % (95% CI)		9.1 (6.4 to 12.6)

Efficacy and Safety of Automatic Remote Monitoring for Implantable Cardioverter-Defibrillator Follow-Up The Lumos-T Safely Reduces Routine Office Device Follow-Up (TRUST) Trial

Table 2. Actionable Evaluations

Actionable Evaluations	HM		Conventional		P
	n	%	n	%	
Clinically significant reprogramming changes	247	78.4	135	72.6	0.158
Initiation or uptitration of antiarrhythmic medications	69	21.9	55	29.6	0.068
Lead/generator revision	14	4.4	6	3.2	0.639

Note that a single patient follow-up could have >1 classification (eg, reprogramming and drug initiation). Thus, in the HM group, 325 actionable items occurred in 315 follow-up encounters, and in the conventional group, 196 items occurred in 186 encounters.

(14+6)/1339=1,4% in 11 mesi

Risultati registri

Parameter	OPTIMUM	SCORE	SJ4	TOTAL
Enrollment years	2006–2009	2007–2012	2009–2010	—
Enrolled (n)	5929	3357	1534	10 820
Unique leads (n)	6016	3416	1573	11 005
Median follow up (y)	3.5	2.3	2.7	3.0

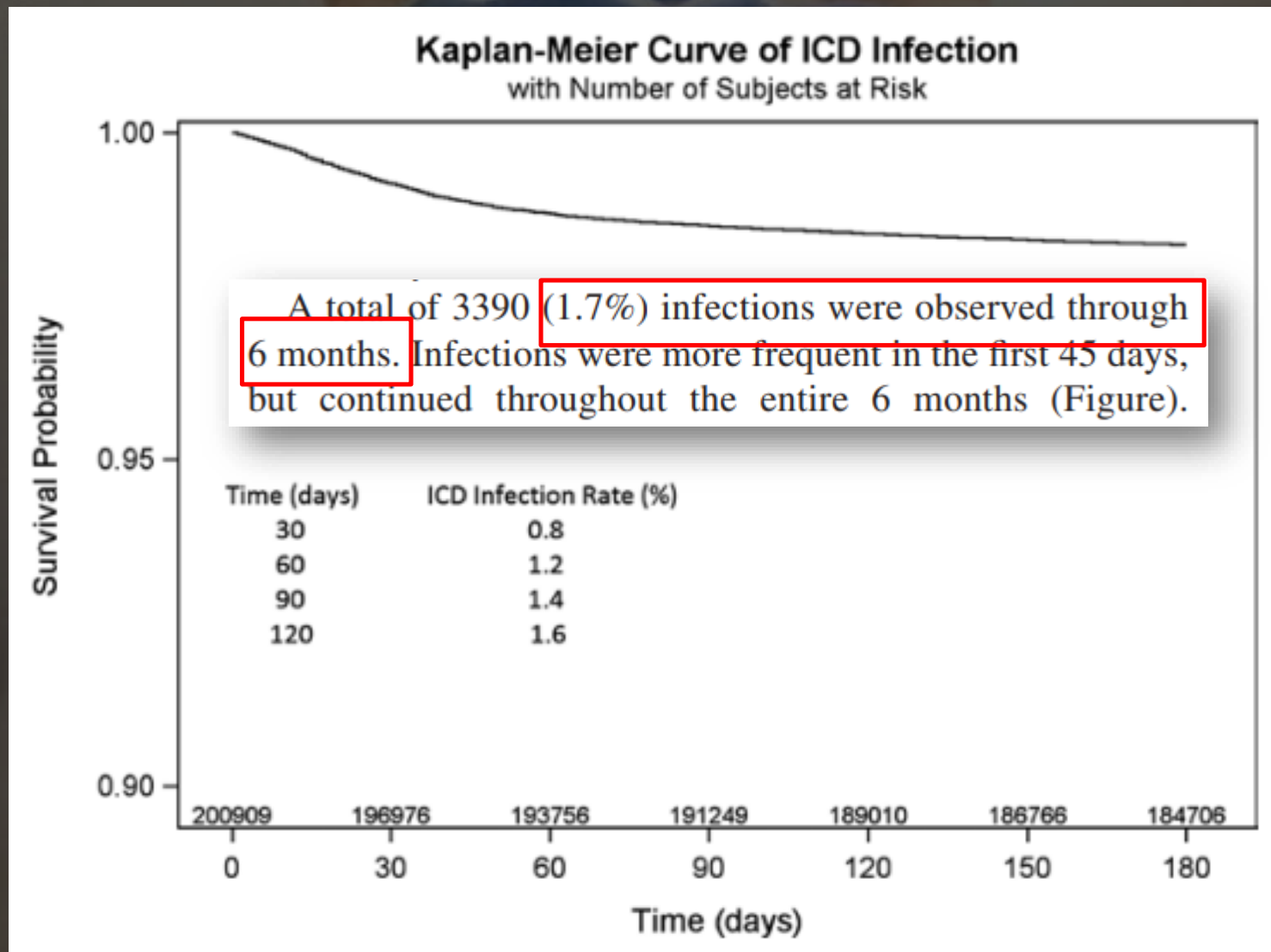
End point	Fallure rate (%)	Freedom from fallure at 5 y (%)
All-cause mechanical fallure	0.35	99.4
Conductor fracture	0.22	99.6
Insulation abrasion	0.07	99.9
Externalized conductor	0	100



Gli ICD si possono infettare

Rates of and Factors Associated With Infection in 2009 Medicare Implantable Cardioverter-Defibrillator Implants

Results From the National Cardiovascular Data Registry



Rates of and Factors Associated With Infection in 200 909 Medicare Implantable Cardioverter-Defibrillator Implants

Results From the National Cardiovascular Data Registry

Table 3. Multivariable Predictors of ICD Infection

Effect	OR (95% CI)	P Value
Clinical characteristics		
Previous valvular surgery	1.525 (1.375–1.692)	<0.0001
Cerebrovascular disease	1.172 (1.076–1.276)	.0003
Chronic lung disease	1.215 (1.125–1.312)	<0.0001
Renal failure-dialysis	1.342 (1.123–1.604)	.0012
Procedure factors		
Reimplantation		
No	Reference	
Yes-device upgrade, malfunction, manufacturer advisory	1.354 (1.196–1.533)	<0.0001
Yes-battery change	1.090 (0.992–1.198)	
Adverse events	2.692 (2.304–3.145)	<0.0001
Medications		
Warfarin	1.155 (1.060–1.257)	0.001
C-statistic for model 0.676.		

Rate, causes, and impact on patient outcome of implantable device complications requiring surgical revision: large population survey from two centres in Italy

Follow-up
27 mesi

Table 3 Numbers of device-related complications requiring surgical revision per procedure-year of observation according to type of initial procedure

Procedures	N of procedures (procedure years)	Cardiac tamponade, n (procedure-year)	Pneumothorax, n (procedure-year)	Device infection, n (procedure-year)	Non-septic pocket erosion, n (procedure-year)	Pocket haematoma, n (procedure-year)	Lead dislodgement, n (procedure-year)	Lead failure, n (procedure-year)	Generator malfunction, n (procedure-year)	Total, n (procedure-year)
Pacemaker implantation	959 (1643)	0 (0.00%)	7 (0.43%)	1 (0.06%)	2 (0.12%)	0 (0.00%)	13 (0.79%)	4 (0.24%)	1 (0.06%)	28 (1.70%)
ICD implantation	310 (518)	0 (0.00%)	3 (0.58%)	0 (0.00%)	0 (0.00%)	1 (0.19%)	5 (0.97%)	9 (1.74%)	0 (0.00%)	18 (3.47%)
CRT device implantation	242 (423)	3 (0.71%)	2 (0.47%)	7 (1.65%)	2 (0.47%)	6 (1.42%)	14 (3.31%)	6 (1.42%)	0 (0.00%)	40 (9.46%)
Elective generator replacement	1034 (1758)	–	–	17 (0.97%)	4 (0.23%)	8 (0.46%)	–	–	0 (0.00%)	29 (1.65%)
Pacing system upgrade	126 (231)	0 (0.00%)	2 (0.87%)	5 (2.16%)	2 (0.87%)	2 (0.87%)	3 (1.30%)	0 (0.00%)	0 (0.00%)	14 (6.06%)
All procedures	2671 (4573)	3 (0.07%)	14 (0.31%)	30 (0.66%)	10 (0.22%)	17 (0.37%)	35 (0.77%)	19 (0.42%)	1 (0.02%)	129 (2.82%)

Table 4 Lead-related complications requiring surgical revision according to type of lead

Lead type	n (%)	Dislodgement, n (%)	Failure, n (%)
Atrial leads	1216	11 (0.9)	0 (0.0)
Active fixation	278 (22.9)	2 (0.7)	0 (0.0)
Passive fixation	938 (77.1)	9 (1.0)	0 (0.0)
Right ventricular leads	964	7 (0.7)	4 (0.4)
Active fixation	181 (18.8)	1 (0.6)	1 (0.6)
Passive fixation	783 (81.2)	6 (0.8)	3 (0.4)
High-voltage ICD leads	591	3 (0.5)	15 (2.5)
Active fixation	281 (47.5)	1 (0.3)	9 (3.2)
Passive fixation	310 (52.5)	2 (0.6)	6 (1.9)
Coronary sinus leads	379	14 (3.7)	0 (0.0)
All leads	3150	35 (1.1)	19 (0.6)

Risultati sottocutanei

	Bardy et al. (15) (n = 55)	Dabiri Abkenari et al. (16) (n = 31)	Aydin et al. (18) (n = 40)	Jarman et al. (22) (n = 111)	Olde Nordkamp et al. (17) (n = 118)	Köbe et al. (20) (n = 69)	Weiss et al. (21) (n = 330)	Lambiase et al. (24) (n = 472)	Burke et al. (23) (n = 883)
Age, yrs	56 ± 13	53 ± 4	42 ± 15	33	NA	46 ± 16	52 ± 16	49 ± 18	50 ± 17
Male	80	77	70	NA	75	72	74	72	72.5
Follow-up	10 ± 1 months	286 days	229 days	12.7 ± 7.1 months	18 ± 7 months	217 ± 138 days	330 days	558 days	651 ± 345 days
Ischemic cardiomyopathy	37 (67.0)	18 (58.0)	9 (22.5)	15 (14.0)	45 (38.0)	11 (15.9)	137 (41.4)	166 (37.0)	330 (37.8)
LVEF	35 ± 14	38 ± 15	47 ± 15	NA	41 ± 15	46 ± 16	36 ± 16	42 ± 19	39 ± 18
Primary prevention	43 (78.0)	21 (67.0)	17 (42.5)	55 (50.0)	71 (60.0)	41 (59.4)	262 (79.0)	282 (63.0)	610 (69.9)
Inappropriate shocks	5 (9.0)	5 (16.0)	2 (5.0)	17 (15.0)	15 (13.0)	3 (4.0)	41 (13.0)	32 (7.0)	14 (2.5)
Appropriate therapy (% successful)	3 (100.0)	4 (100.0)	4 (96.4)	13 (100.0)	8 (100.0)	3 (100.0)	21 (95.2)	33 (100.0)	111 (98.2)
Complications									
Infection	2 (3.6)	1 (3.2)	0	11 (9.9)	7 (5.9)	1 (1.4)	18 (5.6)	11 (2.3)	14 (1.5)
Lead migration	6 (10.9)	2 (6.4)	0	0	3 (2.5)	0	0	4 (0.8)	7 (0.8)
Device erosion	0	0	0	2 (1.8)	2 (1.7)	0	0	4 (0.8)	12 (1.4)
Hematoma	0	0	0	0	0	1 (1.4)	0	1 (0.2)	4 (0.4)

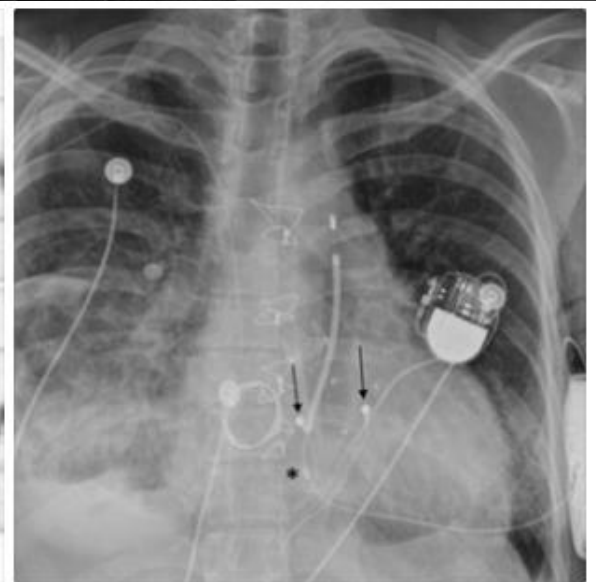
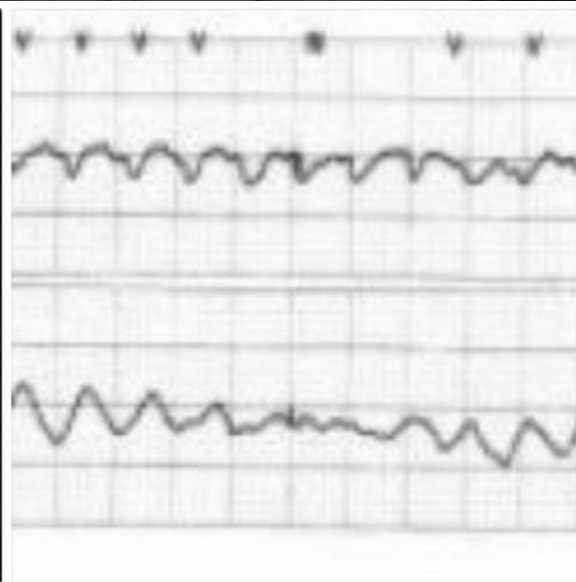
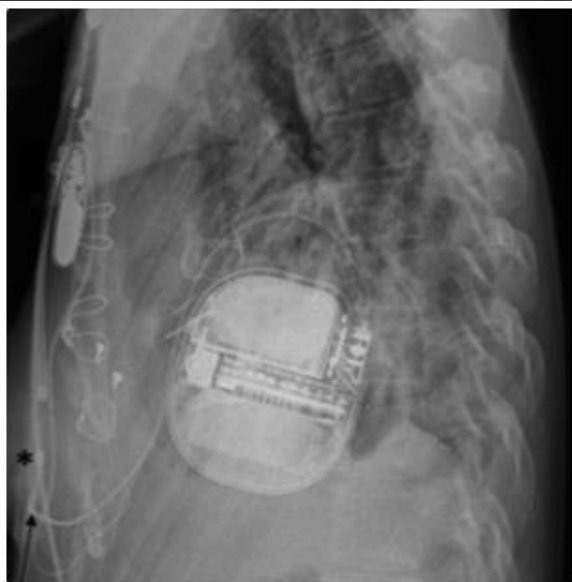
Rischi nell'estrazione

Publication	Number of leads	Complete procedural success (%)	Major complications (%)	Procedural mortality (%)
Byrd <i>et al.</i> ¹⁴	2,561	90.0	1.9	0.8
LExICon study ²¹	2,405	96.5	1.4	0.28
Brunner <i>et al.</i> ²⁴	5,521	96.8	1.8	0.4
Maytin <i>et al.</i> ⁴⁸	577 (Riata®)	99.1	0.87	0.17
Epstein <i>et al.</i> ⁸²	2,274 (ICD)	98.8	0.82	0.31
Bongiorni <i>et al.</i> ⁹⁵	2,062	98.4	0.7	0.3



*Si puo mettere un
pacemaker se serve*

Cross-talking





***Gli ICD hanno più
complicanze***

Rate, causes, and impact on patient outcome of implantable device complications requiring surgical revision: large population survey from two centres in Italy

Follow-up
27 mesi

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Rate, causes, and impact on patient outcome of implantable device complications requiring surgical revision: large population survey from two centres in Italy

*Follow-up
27 mesi*

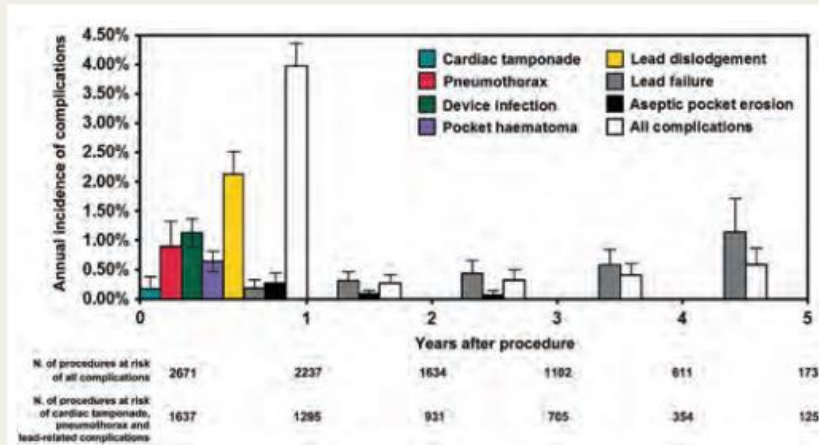


Figure 2 Annual incidence of device-related complications.

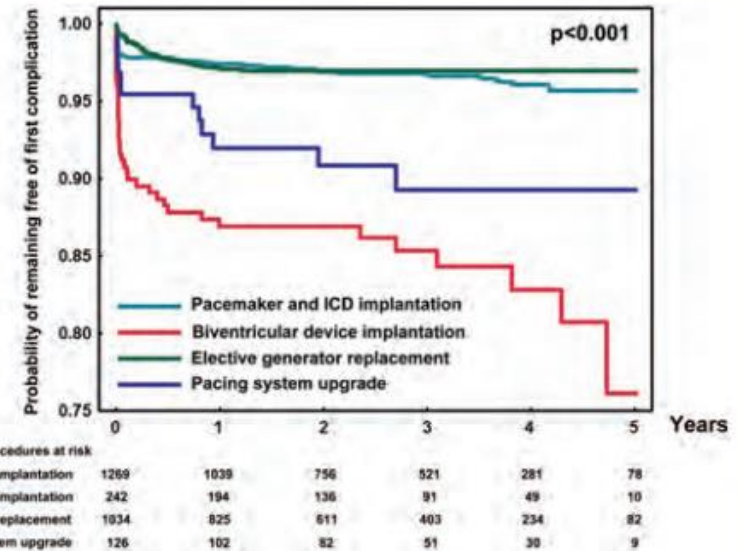


Figure 3 First complication-free survival according to type of initial procedure.

Conclusion

Cardiac resynchronisation therapy implantation was the procedure with the highest risk of complications requiring surgical revision. Complications were associated with substantial clinical consequences and a significant increase in the number and length of hospitalizations.

United Kingdom national experience of entirely subcutaneous implantable cardioverter-defibrillator technology: important lessons to learn

Table 1 Published S-ICD case series

	Jarman et al. ⁵	Current study					
Number of patients	16	111					
Patients age [median (range)/mean ± SD]	23 (10–48)	36 (10–87)					
Ischaemic or idiopathic dilated cardiomyopathy	0%	18%					
Mean/median follow-up duration (months)	9	12					
Patients with re-interventions	19%	16%	13%	4%	14%	10%	11%
Patients with inappropriate shocks	25%	15%	5%	4%	13%	16%	9%

Re-operations

Nineteen patients (17%) underwent 20 re-operations, among whom the device was permanently explanted in 10 (9%). Infection led to explant in four (4%) patients, and in seven (6%) other patients apparently superficial infection was noted and managed conservatively with antibiotics. T-wave over-sensing in multiple vectors, with inappropriate shock therapy, led to explant in five (5%) patients (one also suffering infection). Device erosion with chronic pain led to permanent explant in two (2%) patients and repositioning in seven (6%) patients. One lead was also repositioned for T-wave over-sensing. In a further two (2%) patients, unexpected early battery depletion required generator replacement, and this problem is now the subject of a Medical Device Alert from the UK Medicines and Healthcare products Regulatory Agency (MDA/2011/067 issued 14 June 2011).

Implantation and follow-up of totally subcutaneous versus conventional implantable cardioverter-defibrillators: A multicenter case-control study

Follow-up 10 mesi

Table 1 Clinical parameters of 69 S-ICD patients and

Sex
Male
Female
Age (years)
Ejection fraction (%)
Indication for device
Primary prevention
Secondary prevention
Monomorphic VT
Polymorphic VT
Ventricular fibrillation
Underlying heart disease
Dilated cardiomyopathy
Coronary artery disease
Hypertrophic cardiomyopathy
Congenital heart disease
Electrical heart disease
Other
Anesthesia
General
Local
Implantation time (minutes)
Programming (shock delivery) (bpm)
Days in hospital

Table 2 Adverse events of S-ICD and conventional ICD patients

	69 S-ICD patients (n)	69 control patients (n)
Periprocedural adverse events		
Pericardial effusion	0	1
Hematoma requiring revision	1	0
Early lead revision	0	1
Follow-up adverse events		
Infection requiring revision	1	1
Late lead revision	0	1
Late system revision	1	0
Follow-up		
Inappropriate episode	3	0
I-wave oversensing		
Inappropriate episode	2	1
oversensing		
Inappropriate episode	0	2
supraventricular		
Appropriate episode	3	9
Software reset	1	0

ICD = implantable cardioverter-defibrillator; S-ICD = subcutaneous implantable cardioverter-defibrillator.

*Change to conventional system due to ventricular tachycardia storm.

Dipendono dai pazienti



mechanical valve implantation

METHODS The authors analyzed 1,160 patients who underwent S-ICD or TV-ICD implantation in 2 high-volume hospitals in the Netherlands. Propensity matching for 16 baseline characteristics, including diagnosis, yielded 140 matched pairs. Clinical outcomes were device-related complications requiring surgical intervention, appropriate and inappropriate ICD therapy, and were reported as 5-year Kaplan-Meier rate estimates.

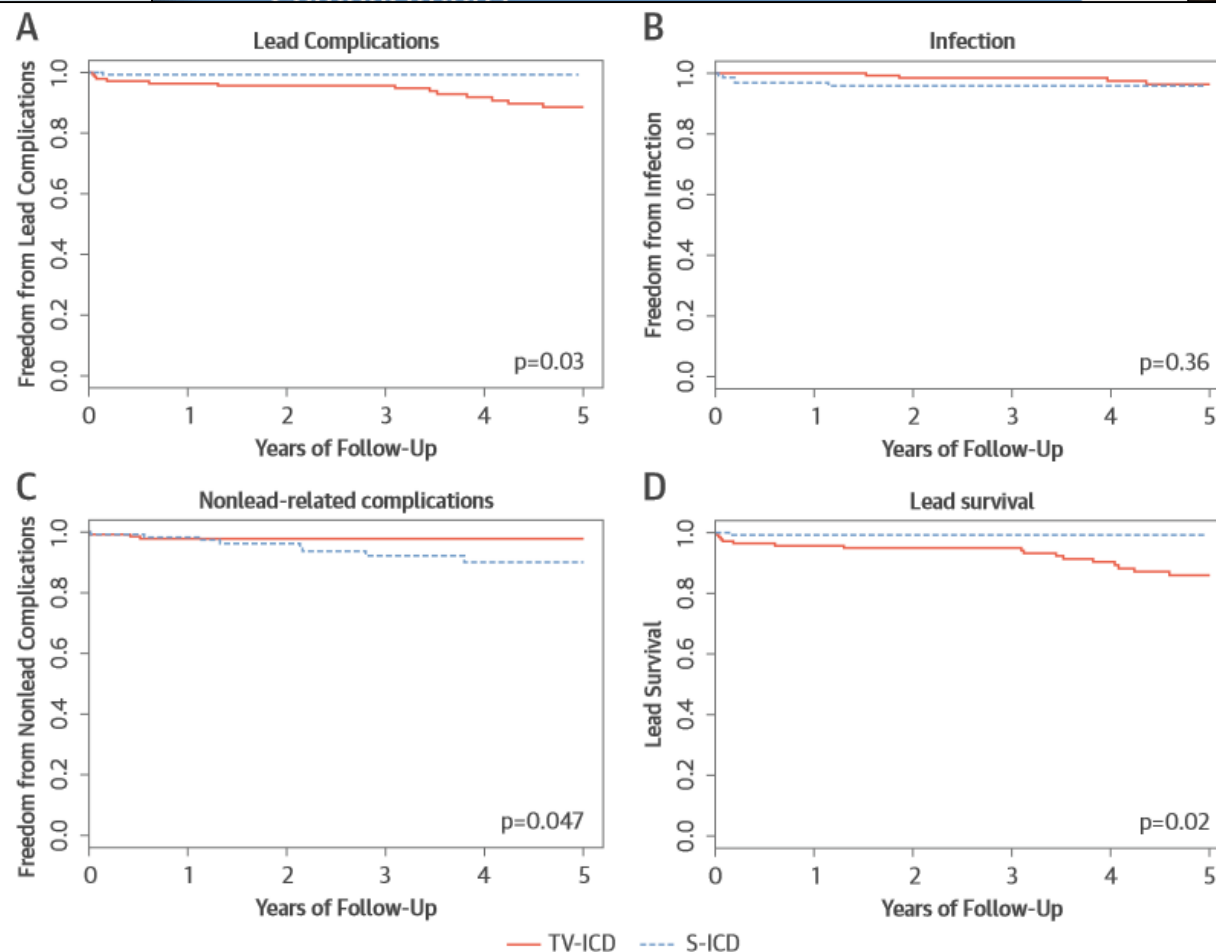
TABLE 2 Clinical Endpoints*

Complications	S-ICD	KM Rate, %
Total	14	13.7
Lead (total)	1	
Atrial lead failure		
Defibrillation lead failure	0	0
Atrial and defibrillation lead failure		
Displacement	1	0.8
Infection	5	4.1
Erosion	3	3.0
DFT failure	1	0.7
Inappropriate sensing	2	3.2
Twiddler syndrome	1	1.1
Device failure	1	1.1
Pneumothorax	0	0
Appropriate therapy	12	17.0
ATP		
Shock	12	17.0
Inappropriate shocks	20	
Oversensing	17	17.1
Supraventricular tachycardia	3	4.2
Deceased	2	
Noncardiac	1	2.0
Cardiac	1	2.0
Unknown	0	0

*Crude number of patients in the first 5 years and the adjusted for the follow-up duration.

ATP = antitachycardia pacing; DFT = defibrillation threshold testing; KM = Kaplan-Meier; other abbreviations as in Table 1.

Complications





*Chi più spende meno
spende*

Durata batteria

- **Stima ditta:** **5 aa** (1gen)
7,3 aa (2gen)
- **Sostituzione entro 5 aa** (1gen) **71%**
- **Sostituzione <1,5 aa** **9%**
Longevity of the subcutaneous implantable defibrillator: long-term follow-up of the European Regulatory Trial Cohort. Circ Arrhythm Electrophysiol, 8 (2015), pp. 1159-1163
- **ICD VVI oltre 5 aa** **74-92%** (>2006)
Longevity of implantable cardioverter defibrillators: a comparison among manufacturers and over time. Europace. 2016 May; 18(5): 710–717.
- **ICD VVI vita media** **5±1,8 aa** (1+2 gen)
“Real life” longevity of implantable cardioverter-defibrillator devices. Clinical Cardiology. 2017; 40: 759–764

Table 3 Comparison of longevity of devices implanted until December 2005 and thereafter (highlighted is the best performance in the corresponding group) according to the manufacturer and pacing mode

	Before 2006		Thereafter	
	5-year longevity (%)	6-year longevity (%)	5-year longevity (%)	6-year longevity (%)
All ICD models				
All manufacturers**	63.9	44.9	80.6	61.6
Biotronik**	44.0	10.5	81.4	42.1
Boston**	65.1	45.7	98.0	98.0
Medtronic	77.7	64.1	85.8	72.6
St. Jude Medical**	64.3	49.8	74.1	60.7
Sorin	59.8	27.8	77.5	77.5
Intermedics	0	0	n.a.	n.a.
Cameron Health	n.a.	n.a.	47.9	n.a.
VVI				
All manufacturers**	73.7	56.4	92.1	76.0
Biotronik**	59.8	15.2	89.1	45.6
Boston**	74.3	53.3	100.0	100.0
Medtronic	86.7	80.1	91.7	85.9
St. Jude Medical**	70.9	60.1	94.3	92.6
Sorin	n.a.	n.a.	80.0	80.0
Intermedics	0	0	n.a.	n.a.
Cameron Health	n.a.	n.a.	47.9	n.a.
DDD				
All manufacturers**	58.2	40.8	76.1	50.9
Biotronik**	26.6	4.2	60.0	26.3
Boston [#]	65.8	52.2	93.3	93.3
Medtronic	87.5	68.6	89.3	76.5
St. Jude Medical	54.7	46.0	78.7	35.3
Sorin	59.8	27.8	n.a.	n.a.
CRT				
All manufacturers**	47.1	21.2	66.3	43.0
Biotronik**	0	0	76.2	44.9
Boston**	43.5	17.5	97.6	97.6
Medtronic**	39.2	7.4	74.1	46.3
St. Jude Medical	61.5	30.9	45.3	26.5

n.a., not applicable, i.e. not manufactured in this period, not implanted in the two hospitals, or time point not reached; ICD, implantable cardioverter defibrillator; VVI, single-chamber ICD; DDD, dual-chamber ICD; CRT, cardiac resynchronization therapy ICD.

^{||}P = n.s., [#]P ≤ 0.05, **P ≤ 0.001.

Sostituzioni

- Rischio di infezione
- Ospedalizzazione post-procedurale occasionale
- Rischio di danneggiamento elettrocateri



Conclusioni

Chi e come sceglie?

- Clinico
- Impiantatore
- Paziente
- Dott. Google
- Costi sanitari



Chi e come sceglie?

- *Bilancio costo-beneficio da valutare correttamente anche in considerazione delle nuove generazioni di device*
- *Complicanze diverse*
- *Definizione della popolazione che potrebbe non giovare di un ICD convenzionale*
- *Contenimento dei costi*



*Vieni da me, che ti faccio
la "stessa cosa" a molto meno!*

**I problemi degli uomini
hanno tre cause:
le donne, i soldi
ed entrambi.
Johnny Carson**

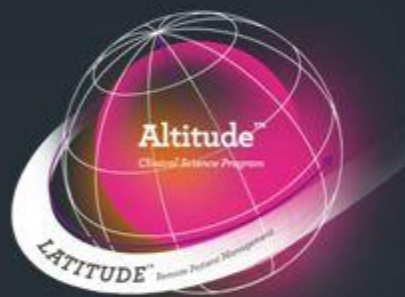
Aforismario



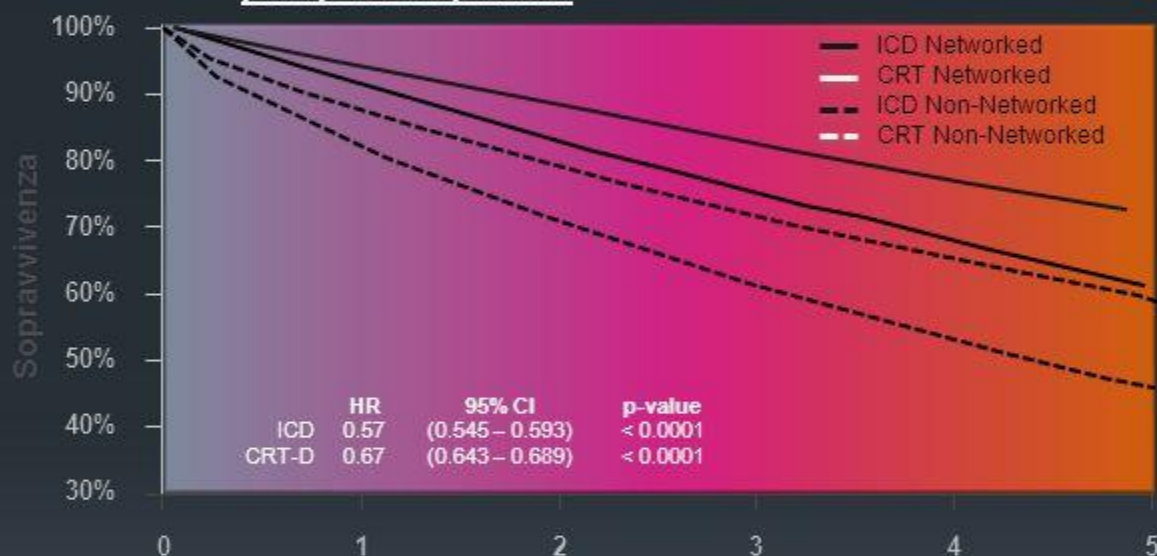
*Vieni da me,
la "stessa cosa"*

ALTITUDE™ Survival study*

I pazienti seguiti con monitoraggio remoto hanno una **riduzione relativa del rischio di morte del 50%** se paragonati ai pazienti seguiti solo in ospedale ($p < 0,0001$)



Comparazione di Sopravvivenza "On e Off the Network" per tipo di dispositivo



I pazienti con scompenso cardiaco che hanno trasmesso i dati di peso e pressione attraverso il sistema LATITUDE™ hanno goduto di una **riduzione aggiuntiva del 10% nel rischio di morte** se paragonato agli altri pazienti CRT-D nel network ($p < 0,01$) seguiti con [REDACTED]

The Entirely Subcutaneous Implantable Cardioverter-Defibrillator

Initial Clinical Experience in a Large Dutch Cohort

Follow-up 18 mesi

Table 2 S-ICD Related Adverse Events

	Patients	Episodes
Inappropriate shocks		
Total number	15 (100)	33 (100)
Number pre-software upgrade	6 (40)	7 (21)
Cause		
T-wave oversensing	9 (60)	11 (33)
Myopotentials	3 (20)	4 (12)
Double counting	1 (6.7)	15 (45)
Atrial flutter	1 (6.7)	2 (6.1)
TENS therapy	1 (6.7)	1 (3)
Complications		
Total number	16 (14)	
Cause		
Lead dislodgement	3 (2.5)	
Device dislodgement	1 (0.8)	
Infection	7 (5.9)	
Premature battery depletion	2 (1.7)	
Skin erosion	2 (1.7)	
Explantation because of need for ATP	1 (0.8)	

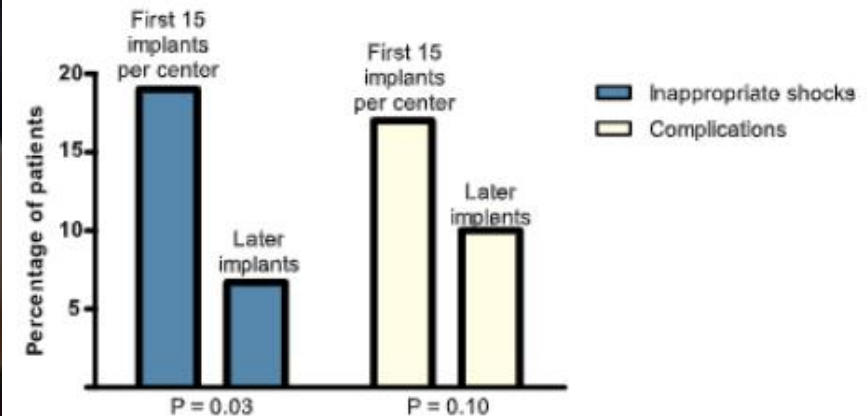


Figure 1

Comparison of Inappropriate Shock and Complication Rate Between First and Later S-ICD Implants

Inappropriate shocks and complications occurred more frequently in the first 15 patients per center who were implanted with the subcutaneous implantable cardioverter-defibrillator (S-ICD) than in subsequent patients (inappropriate shocks 19% vs. 6.7%; complications 17% vs. 10%).