CIED implantation:
Is it a just beginning of problems?

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Conflict of interest

Nothing to disclosure

Yes or No?

Multiple choices?

Short-answer question or essay question?

Great job !!!

or

Oh My God !!!

The emerging use of Cardiac Implantable Electronic Devices (CIED)

- ✓ Resuscitation of the Heart in Ventricular Standstill by External Electric Stimulation.

  Zoll PM. *N Engl J Med.* **1952**;*247:768–771*

- ✓ Elmqvist and Senning implanted the first cardiac pacemaker (PM) by thoracotomy.

  Elmqvist R, Senning A. 24–27 June **1959**

- ✓ Termination of Malignant Ventricular Arrhythmias with an Implanted Automatic Defibrillator in Human Beings.

  Mirowski M, et al.*N Engl J Med.* **1980**;*303:322–324*

Prevalence of infections in use of CEIDs
- USA -

In the United States, **from 1996 to 2003**

Implantations; 0.49-fold

Infections; 3.1-fold

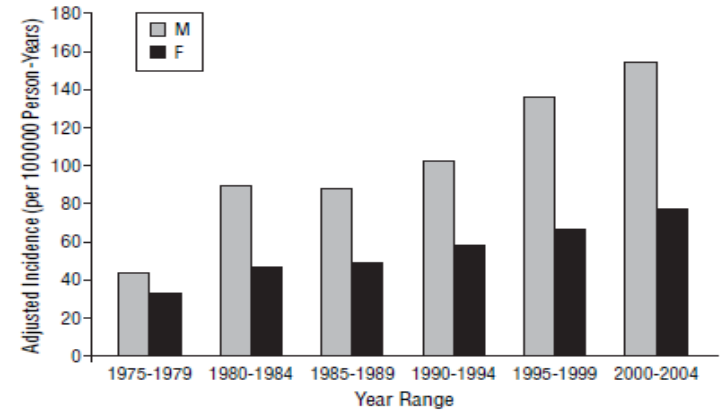
Year	CRT-D	CRT-P	AICD	Pacemaker	Other
1997	0 (0)	0 (0)	26,922 (2,333)	144,765 (5,416)	50,918 (2,735)
1998	0 (0)	0 (0)	28,260 (2,255)	147,695 (5,949)	41,387 (1,955)
1999	0 (0)	0 (0)	32,944 (3,168)	155,182 (6,438)	46,595 (2,711)
2000	0 (0)	0 (0)	39,334 (2,698)	164,845 (6,054)	49,488 (2,436)
2001	0 (0)	0 (0)	47,962 (3,988)	188,358 (7,096)	55,435 (3,092)
2002	1,623 (220)	734 (104)	66,528 (5,670)	188,224 (7,534)	67,593 (4,752)
2003	18,761 (1,714)	6,697 (536)	62,200 (4,190)	182,597 (6,590)	70,089 (2,643)
2004	32,737 (2,760)	7,325 (644)	66,545 (4,416)	178,816 (6,528)	60,118 (3,200)

Zhan C, et al. *J Gen Intern Med. 2007;23(suppl 1):13–19*

Between **2004 and 2006**

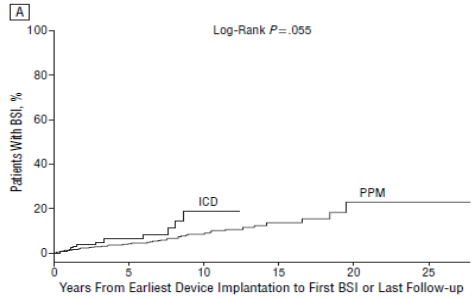
Implantations; 12% increase

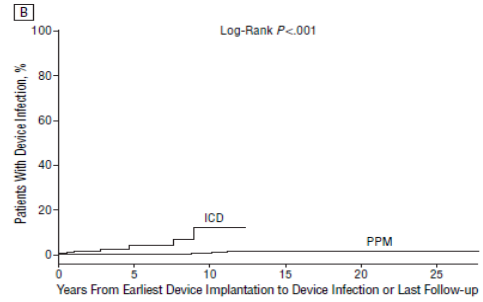
Infections; 57% increase

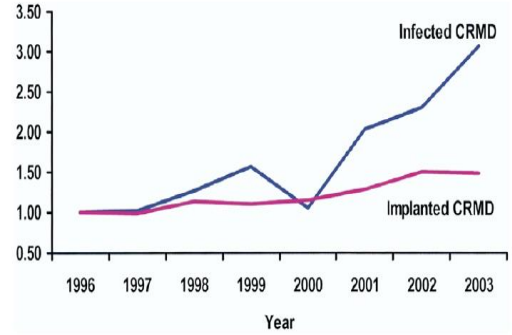


Uslan DZ, et al. *Arch Intern Med. 2007;167:669–675*

Prevalence of infections in use of CEIDs







- ✓ Infection rate; ICDs > PMs
- ✓ Hospitalizations; ICDs > PMs

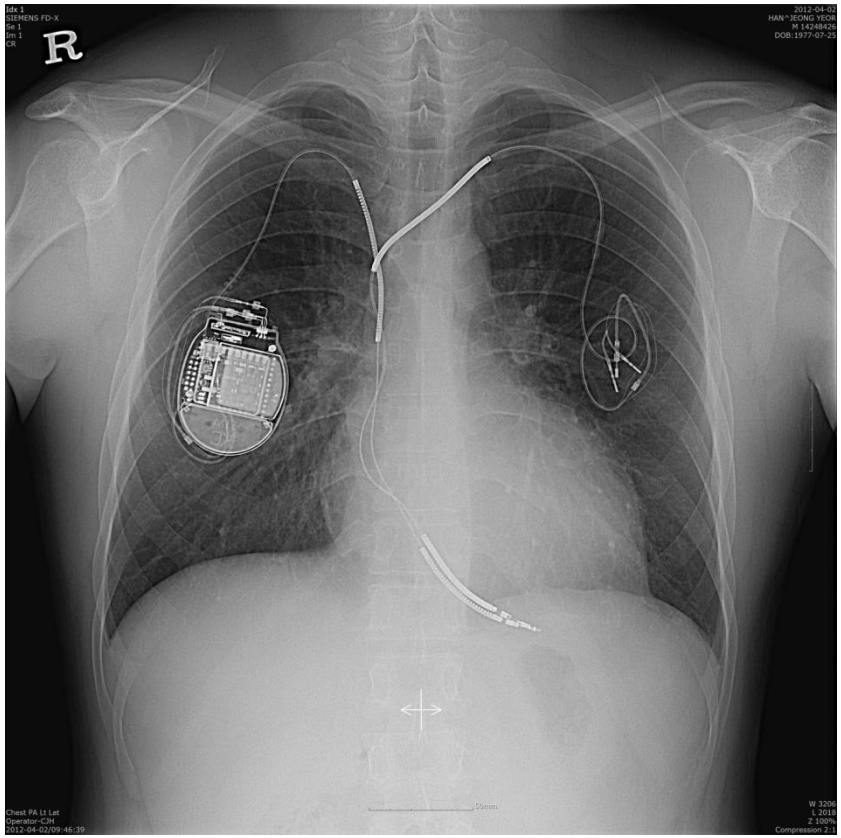
- ✓ Longer lengths of stay
- ✓ Five-fold risk of in-hospital death
- ✓ High rates of one-year mortality even after the removal

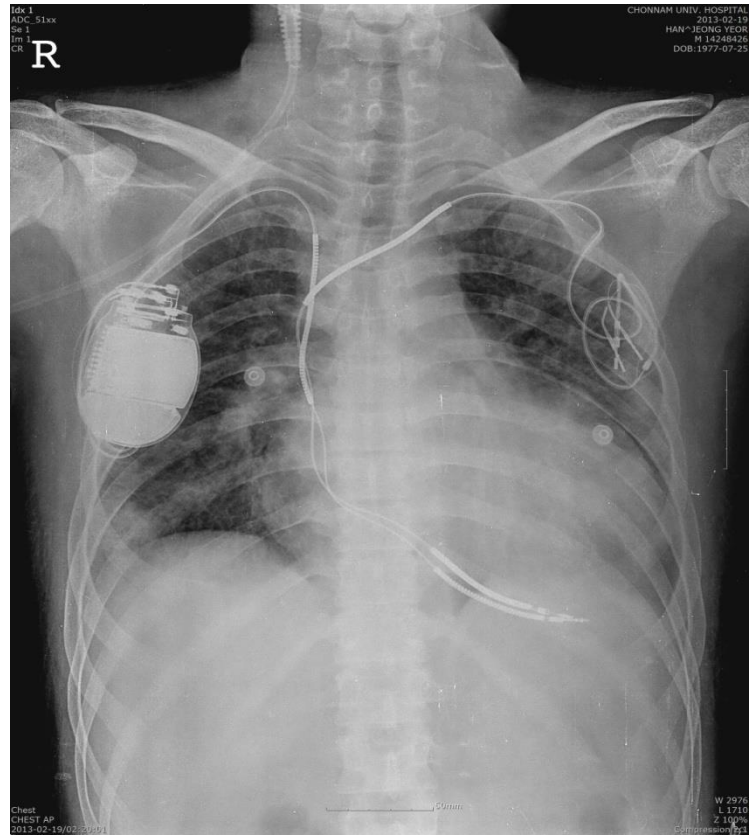
Tarakji K, et al. *Heart Rhythm. 2010;7:1043–1047*

Risk factors for CIEDs infections

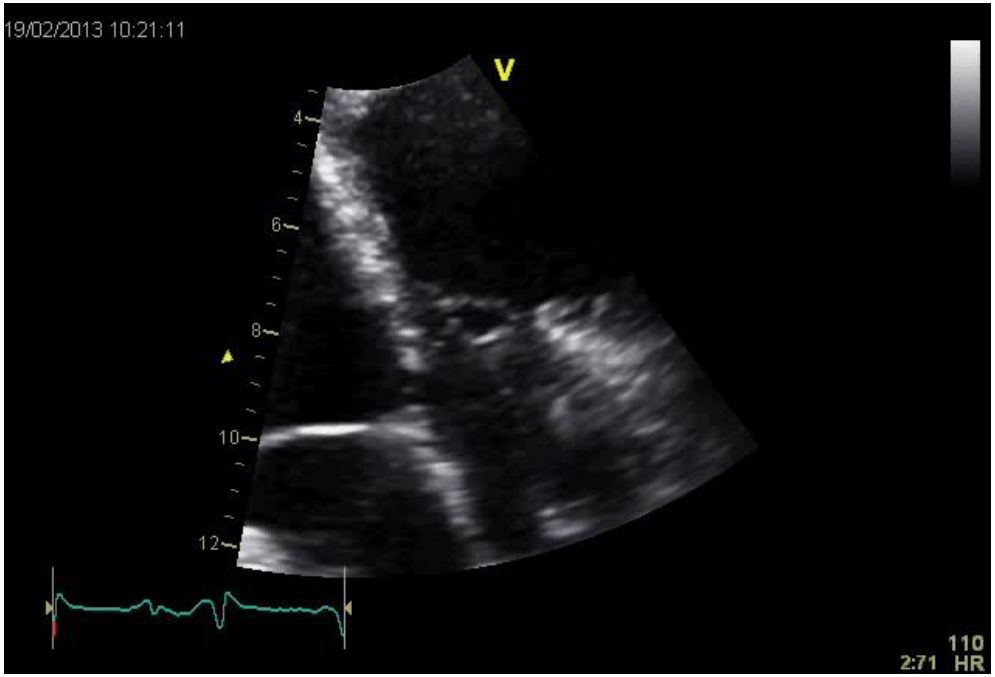
- ✓ Immunosuppression (diabetes, CRF, steroid therapy and/or immunosuppressive therapy, malignancy)
- ✓ No periprocedural antimicrobial prophylaxis
- ✓ Fever less than 24 hours before implantation
- ✓ Vitamin K – antagonist therapy
- ✓ Postoperative hematoma
- ✓ Generator replacement
- ✓ Preprocedural temporary pacing
- ✓ Need for acute repositioning of a lead
- ✓ Presence of abandoned leads
- ✓ Operator experience
- ✓ Duration of procedure
- ✓ Number of implanted leads

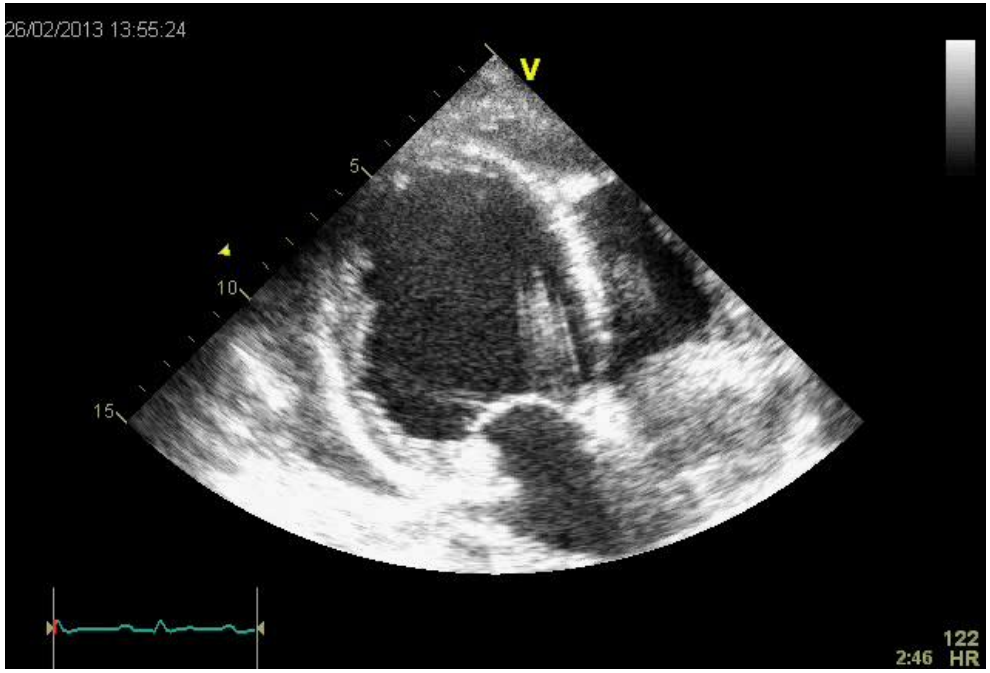
32Y, M, ICD. Secondary prevention for DCMP VT





32Y, M, ICD. Secondary prevention for DCMP VT – Vegetation around lead





AHA Scientific Statement

Update on Cardiovascular Implantable Electronic Device Infections and Their Management

A Scientific Statement From the American Heart Association

Endorsed by the Heart Rhythm Society

- ✓ **Once the diagnosis of CIED infection is made**
- ✓ **Removal of both the device and the lead**
- ✓ **High risk of relapse due to retained hardware, even in case of demonstrated valvular endocarditis without definite involvement of the leads or the device, and in case of persisting or relapsing SAB**

Baddour LM, et al. *Circulation. 2010;121:458–477.*

CIEDs infections

✓ **Superficial or incisional pocket site infection**

Device involvement (-)

→ **No indication to remove** it, oral antibiotic therapy

Baddour LM, et al. *Circulation. 2010;121:458–477.*

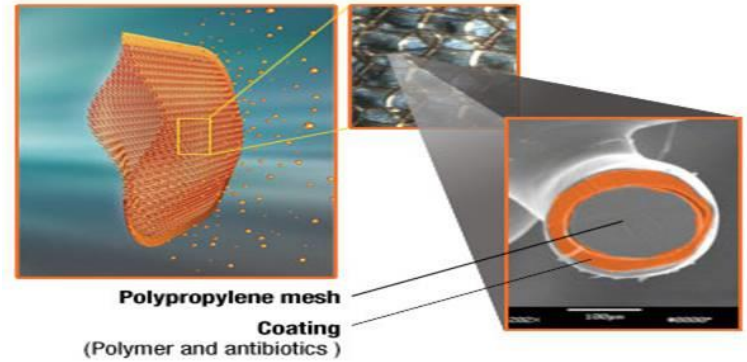
✓ **Reimplantation**

; **No sooner than 72 hours after negative blood cultures**

Must be delayed by 2 weeks in case of demonstration of infectious involvement of a native valve

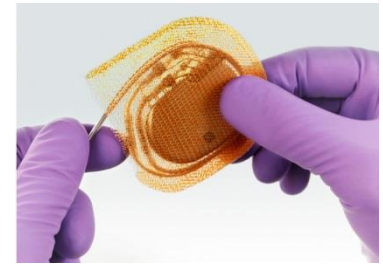
Tarakji K, et al. *Heart Rhythm. 2010;7:1043–1047.*

CIEDs infections



- ✓ **Implanting the device with a polymer mesh**

  → Releases minocycline and rifampin, in addition to standard systemic antimicrobial prophylaxis (cephalosporin or vancomycin).



- ✓ ***Conclusions:*** *CIED procedures that utilized an antibacterial envelope had a high rate of CIED implantation success (>99%). Although the follow-up to date is short, there was also a* ***low rate of infection (<0.50%) in this population at high risk for CIED infection****.*

Bloom HL, et al. *Pacing Clin Electrophysiol.* 2011;34:133–142.

Safety is the first priority

From WWW.google.com

Safety in the use of CEIDS

- ✓ CIEDs beget an intrinsic risk of **mechanical failure**
- ✓ A sharp increase in manufacturer **recalls**

Table 1. Current ICD Advisories Included in the Survey and Associated Risk

Company/Device*	Date of Advisory	Advisory Issue†	Current Risk of Failure, %†
Medtronic Marquis ICD	February 2005	Accelerated battery depletion caused by internal battery short	0.01
Guidant Ventak Prizm 2 DR ICD	June 2005	Short circuit caused by wire insulation problem within lead connector block	0.1
Guidant Ventak Prizm AVT, Vitality AVT, and Contak Renewal AVT ICDs	June 2005	Random memory error, limiting delivery of therapies	0.0095
Guidant Contak Renewal 3, 4, Renewal 3, 4 AVT, and Renewal RF ICDs	June 2005	Magnetic switch faulty, impairing delivery of therapies	0.009
St Jude Photon DR, Photon Micro VR/DR, and Atlas VR/DR ICDs	October 2005	Memory chip affected by atmospheric radiation, which can impair pacing and delivery of therapies	0.167
ELA Alto ICD	August 2001	Migration of metal, which can impair pacing and delivery of therapies	2.6‡ 0.1§

Abbreviation: ICD, implantable cardioverter-defibrillator.
*Predominantly subpopulation of listed devices affected by advisory.
†Data obtained from physician communications and public statement releases such as those from Medtronic[10] and Guidant.[11] The current risk of failure represents the number of failures divided by the number of devices implanted at the time of advisory disclosure.
‡Manufactured between April and July 2003.
§Manufactured between August 2003 and August 2004.

Gould PA, et al. *JAMA. 2006;295:1907–1911*

Safety in the use of CEIDS

Table 2. Advisory Device Replacement Population Characteristics (n = 533)

	Data
Total replacements, No.	533
Device manufacturer, %	
Medtronic	72
Guidant	27
St Jude	0.9
ELA	0.1
Patient age, mean (SD), y	64 (13)
Male, %	77
Secondary prevention indication for ICD, %	66
Previous appropriate shock, %	45
Pacing dependency, %	21

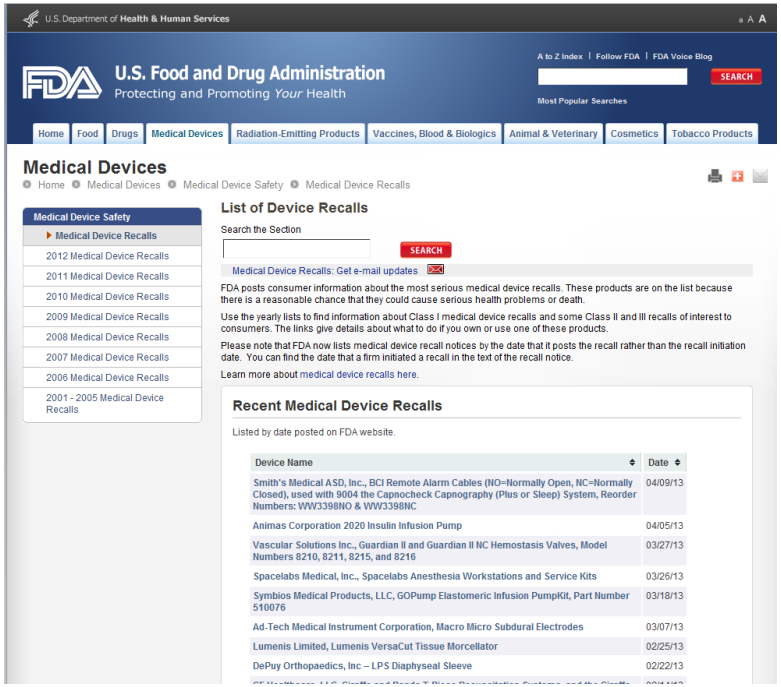
Table 3. Summary of Number of Advisory Devices and Number Replaced at Participating Implanting/Follow-up Centers

Site	No. of Advisory Devices	No. (%) Replaced	Devices Implanted/2 y*
1	229	14 (6)	317
2	138	62 (45)	407
3	378	61 (16)	439
4	131	30 (23)	428
5	248	21 (8)	359
6	153	24 (16)	312
7	90	33 (37)	297
8	130	47 (36)	693
9	59	23 (39)	170
10	94	22 (23)	213
11	15	2 (13)	22
12	410	90 (22)	699
13	196	32 (16)	380
14	63	0	149
15	53	24 (45)	0
16	177	21 (12)	449
17	351	27 (8)	405
Total	**2915**	**533** (18.3)	**5289**

Gould PA, et al. *JAMA. 2006;295:1907–1911*

Safety in the use of CEIDS

- ✓ **US FDA classifies medical device recalls; class I, II, III**
- ✓ FDA and the HRS have set guidelines for advisories



① Advisory has been issued

② Patients with an affected device must be contacted

③ Physicians have to choose the best management strategy
-- Estimates of rate of possible malfunction
-- Likely effect of the issue on specific patients (eg, pacemaker dependency)
-- Individual center's procedural risk associated with the replacement

http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm
Carlson MD, et al. *Heart Rhythm. 2006;3:1250–1273*

Safety in the use of CEIDS

- ✓ Three management strategies are possible:
  - ***Replacing all the recalled devices***
  - ***Replacing a few devices***
  - ***Not replacing any device***

- ✓ According to several analyses…
- ✓ Mean percentage of replaced devices, in different countries, is
  - lower than 20%
  - complications rate ranges from 0.62% to 8.1%

Safety in the use of CEIDS

- ✓ When a device is returned to the manufacturer;
  Laboratory technicians and engineers assess all its functions and perform an **analysis** through a series of diagnostic tests that verify the performance of defibrillation, pacing, sensing, memory, and recording functions.

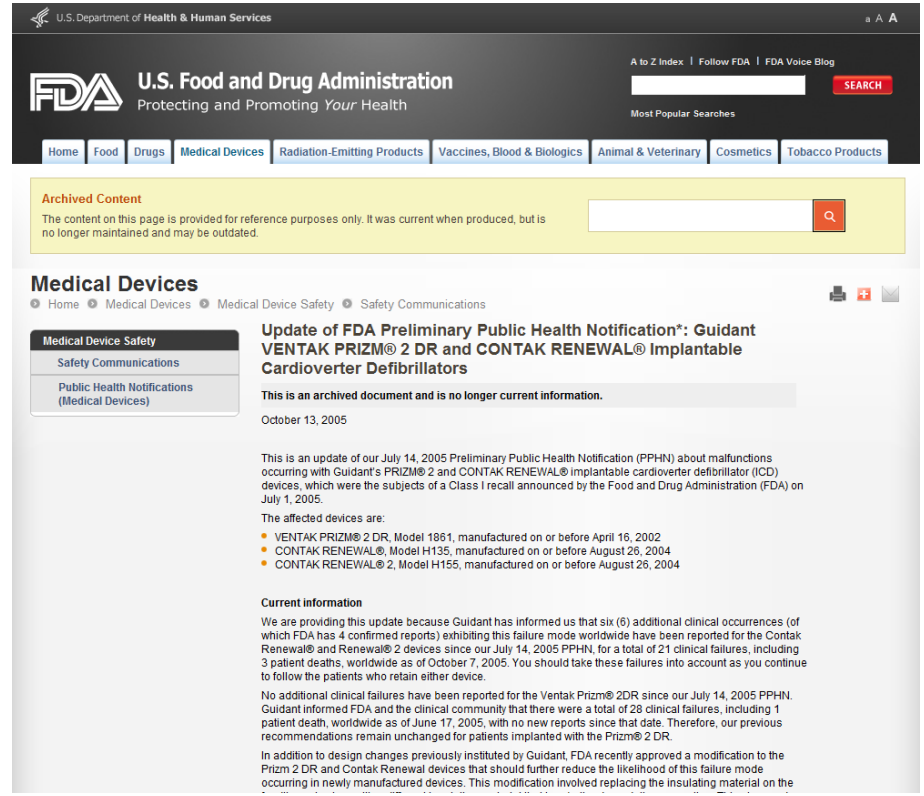
- ✓ **Test results are compared to original manufacturing records** and design intent. **Companies should inform the regulatory authorities** of each significant event that poses potential risk to patients' health, and **periodically publish a performance report**, indicating the overall incidence of malfunctions that have occurred for each product

Safety in the use of CEIDS

✓ July 2005,

✓ **FDA class I recall:**

Boston Scientific (formerly Guidant) about a potential short circuit that might have affected the **Prizm ICD** (model 1861), manufactured on or before 16 April 2002, and about a potential deterioration in the wire insulator within the lead connector block, affecting the **Renewal I** (model H135) and **Renewal II** (model H155) CRT-D, manufactured on or before 26 August 2004

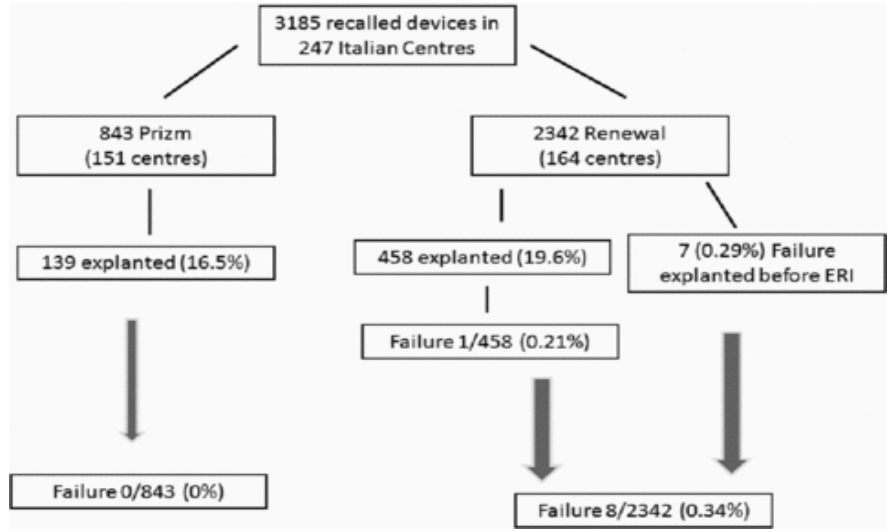


Safety in the use of CEIDS

Table I.

Proportion of Explanted Devices Stratified Per Center Volume. The Center has been Classified on the Basis of the Volume of Impacted Devices (>30; 10–30; <10 Units Per Center)

Impacted Devices Per Center	# Centers	Total Devices Impacted	Total Devices Explanted	Mean % Explanted Per Center	P Value
>30	19	1349	221 (16%)	16.7%	
10–30	74	1269	278 (22%)	21.3%	0.092
<10	154	567	98 (17%)	14.6%	



In absence of underestimation of the events, a lower incidence than expected could resize the dimension of the problem, justifying the concept of a more frequent follow-up of patient with respect to the choice of an immediate device explant

Perrotta L, et al. *PACE* 2011;34:998-1002

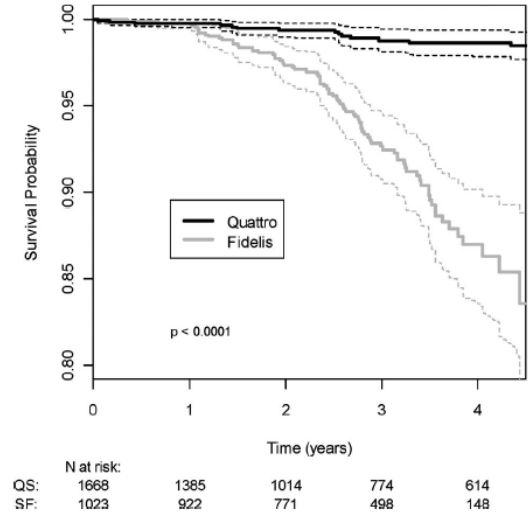
Safety in the use of CEIDS

- ✓ Medtronic **Sprint Fidelis** implantable cardioverter-defibrillator leads are **prone to fracture**, which caused **inappropriate shocks and a few reported deaths.** When compared with Medtronic Sprint Quattro leads, they showed a significantly higher fracture rate (2.81%/year vs 0.43%/year, *P , 0.0001).*

Table 2. Fidelis and Quattro Lead Status and Failure Rates

	Fidelis (n=1023)	Quattro (n=1668)
Active, n (%)	683 (66.8)*	1290 (77.3)
Failed, n (%)	80 (7.8)*	23 (1.4)
Removed from service, n (%)	240 (23.5)	323 (19.4)
Died	145 (14.2)†	245 (14.6)
Replaced/abandoned	61 (6.0)*	24 (1.4)
Transplanted	10 (1.0)	14 (0.8)
Infection	12 (1.2)	23 (1.3)
Deactivated	12 (1.2)	17 (1.0)
Lost or followed up elsewhere, n (%)	20 (2.0)	32 (1.9)
Average follow-up, y	2.78*	3.18
Implant time, y	2844	5309
Failure rate, %/y	2.81*	0.43

*$P<0.0001$; †$P=0.76$.



Hauser RG, et al. *Circulation. 2011;123:358–363.*

Safety in the use of CEIDS

- ✓ During the study, no deaths occurred as the result of lead failure.
- ✓ Overall, 42% of lead failures (42 of 103) were associated with inappropriate shocks, including 37 Fidelis pace-sense conductor fractures
- ✓ Interestingly, **the failure rate was higher** for **younger patients**, for **women**, and for patients affected by **channelopathies** or by **hypertrophic cardiomyopathy**: these findings support once more the **need for risk stratification** in choosing whether to replace a lead or not

Hauser RG, et al. *Circulation. 2011;123:358–363.*

Safety in the use of CEIDS

	Sprint Fidelis		Quattro Secure	
	Failure Rate	95% CI	Failure Rate	95% CI
HCM	74.0	(36.9, 132.4)	3.2	(0.1, 17.7)
ARVD and channelopathies	68.7	(25.2, 149.4)	0.0	(0.0, 58.1)
Female	39.1	(25.8, 56.9)	2.9	(0.6, 8.4)
Ischemic HD	27.1	(19.6, 36.7)	4.4	(2.5, 7.2)
Idiopathic VT/VF	26.3	(3.2, 94.9)	0.0	(0.0, 14.2)
DCM	17.1	(9.3,28.6)	5.7	(2.1, 12.4)

HD indicates heart disease; VT, ventricular tachycardia; VF, ventricular fibrillation; and DCM, dilated cardiomyopathy.

Hauser RG, et al. *Circulation. 2011;123:358–363.*

Safety in the use of CEIDS

- ✓ In 1994,
- ✓ **Teletronics Accufix active fixation** leads were subjected to recall because of the risk of **fracture and protrusion of the J retention wire**, which had caused **pericardial tamponade**, **perforation of the right atrium**, e**mbolization** to the pulmonary circulation, and **a few deaths**.
- ✓ **Of the potentially affected leads, 13% were extracted, but the risk of fatal and of life- threatening complications were much higher for extraction than for leaving the lead in place**, especially for elderly patients, while the risk of lead fracture and complications were lower in the elderly.

Safety in the use of CEIDS

TABLE 3. WWR Reported Accufix Injuries Related to J Retention Wire

Injury	n
Death	6
Pericardial tamponade (nonfatal)	19
Pericardial effusion without tamponade	5
Atrial perforation with pericarditis	3
Embolism of J-wire fragment	4
Tricuspid valve perforation and insufficiency	1
Aorta–right atrial fistula	1
Right atrial thrombus with pulmonary thromboembolism	1

Total injuries=40.

Conclusion; Low, ongoing risk of injury.
Extraction associated risk is higher than conservative management approach.

Kay GN, et al. *Circulation.* 1999;100:2344–2352

Jones SO 4th, et al. Heart Rhythm. 2008;5(4):520-5

Efficacy and safety in the use of CEIDS

- ✓ In fact, for both leads and devices, **the decision to replace an element subject to recall is still uncertain**, as it depends on several variables, among which the most important are the estimated rate of device failure, the arrhythmic risk, and the mortality rate of device replacement.

- ✓ In most cases, **a conservative strategy with short (3-month) follow-up may prove to be safer than an attempt to replace the potentially affected element**, either because the effective failure rate can be overestimated, or because of the low benefit/risk ratio for the replacement strategy.

Amin MS, et al. ***JAMA. 2006;296:412–420***
Priori SG, et al ***J Cardiovasc Electrophysiol. 2009;20:164–170***

Patient-focused perspectives such as quality of life, patient satisfaction/acceptability

- ✓ Clinicians are usually unaware of the **psychosocial impact of implanted PMs and ICDs,** as they focus their attention mainly on the technical aspects of device functions rather than on psychosocial factors.

- ✓ For this reason, a better understanding of factors likely to contribute to patients' perception of their own health would be help in their management, and in the training of clinicians and nurses.

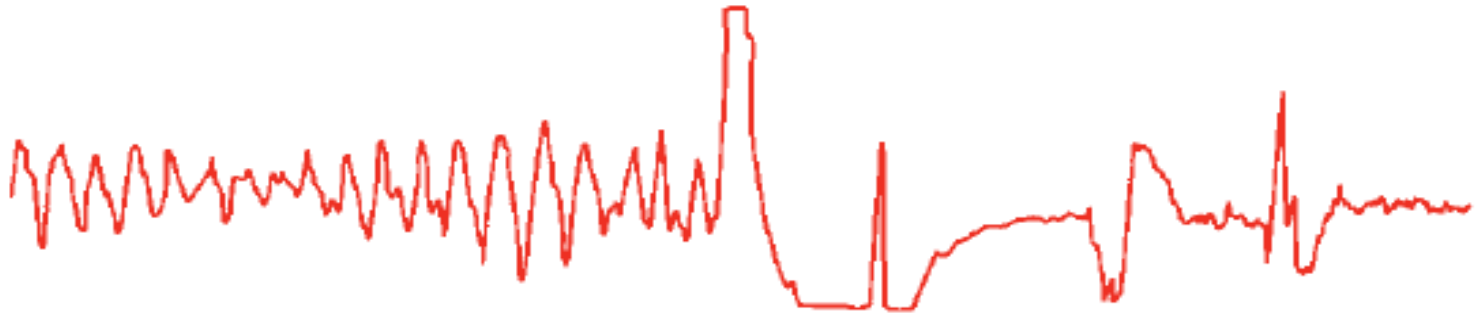
Patient-focused perspectives such as quality of life, patient satisfaction/acceptability

- ✓ One of the first studies to assess differences in psychosocial adaptation, QOL, and incidence of affective disorders between patients with PMs and those with ICDs (shock and no-shock groups) found no difference in scores such as the Hospital Anxiety and Depression (HAD) scale or Short Form 36 QOL measurement.

- ✓ However, **ICD patients who had experienced a shock** reported more **limitation in their leisure time activities** than patients in the other two groups (ICD without shock and PM) and were particularly **concerned about the battery running out** or about **possible technical failures of their device**. A greater demand for a support team in the shocked ICD group than in the non-shocked ICD group or the PM group was also reported.

Duru F, et al. *Heart*. 2001;85:375–379.

Ethical aspects of deactivating implanted cardiac devices



Endless shock, Endless pacing

Patient-focused perspectives such as quality of life, patient satisfaction/acceptability

- ✓ **Deactivation of ICDs** in patient nearing end of life is a controversial and debated issue, which is becoming increasingly topical. In this regard, the **Heart Rhythm Society, in its 2008 consensus statement on CIEDs**, affirmed that "The primary aim behind the rationale for deactivation must always be to **respect the patient's right to live, or at least to die with dignity,** while limiting any therapeutic action that increases the patient's level of stress, pain or anxiety."

- ✓ More recently, the **European Heart Rhythm Society** issued a consensus statement on the subject of ICDs deactivation in patients with irreversible or terminal illness. In this document, the members of the EHRA committee have discussed the ethical, legal and technical aspects of this issue, following the **"key principles of liberal democratic societies, which include respect for the diversity of values and cultures, equal rights for all individuals, and preservation of fundamental human rights."**

Wilkoff BL, et al. *Europace*. 2008;10:707–725
Padeletti L, et al. *Europace*. 2010;12:1480–1489

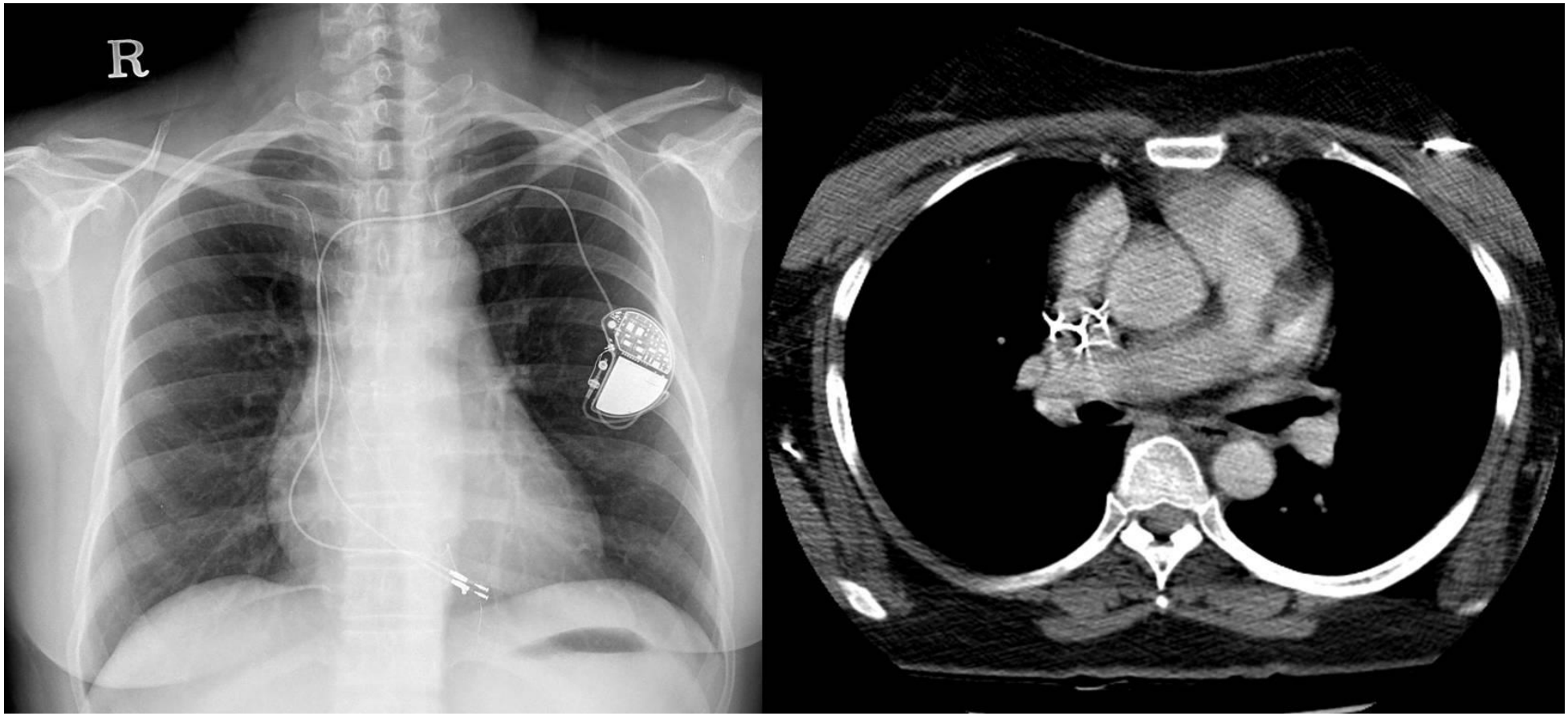
50Y, F

- C/C
  - Swollen face and neck
- P/I:
  - 1982: VVI PM (1st) for SSS
  - 1986: 2nd PM (Teletronics, OPTIMA MP) for lead fracture
  - 1992: 3rd PM (Teletronics, TEMPO VR 1102, VVIR) for recurrent lead fracture

50Y, F

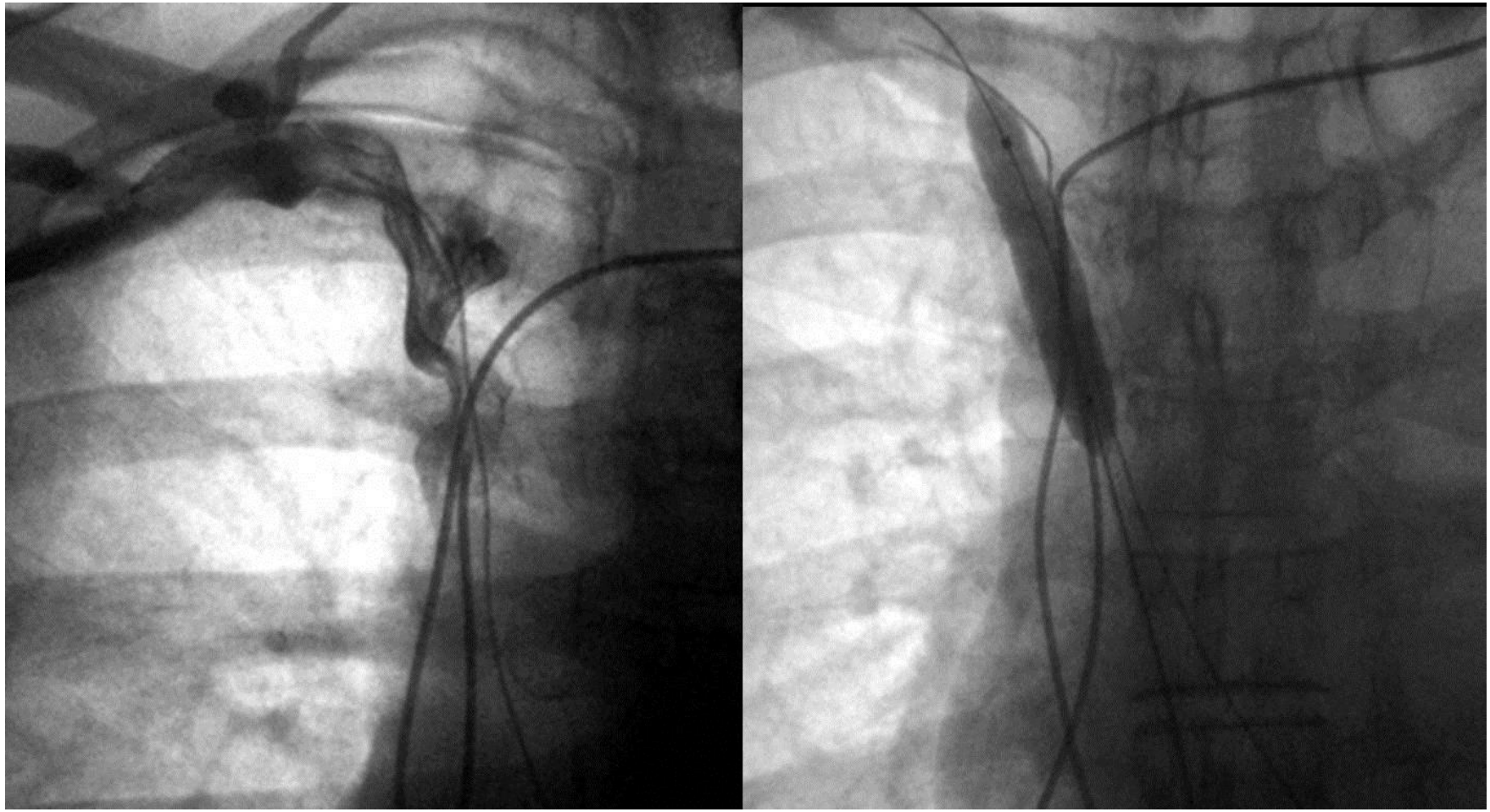
- P/I
  - 1999: 4th PM for power depletion
  - 2000: Painful swelling of right clavicular area
    (Osteomyelitis of right clavicle)
    5th pacing lead through left subclavian vein
  - 2003: Swollen face and neck
    Thrombolysis with 1,500,000 unit urokinase
    Heparin and warfarin
  - Jan. 2004: Intense facial and arm swelling

Chest X-ray and CT scan



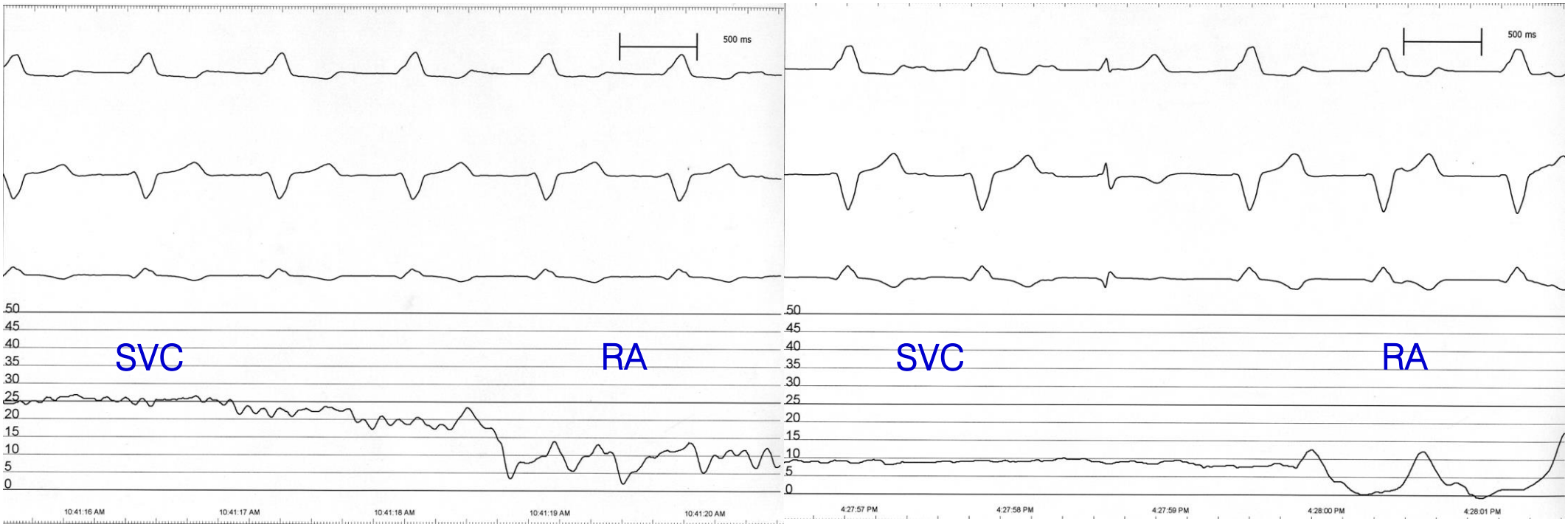
Park HW et al. JCE 2005;16:221-3

Cavogram and balloon venoplasty



Park HW et al. JCE 2005;16:221-3

Pressure tracing
– Before and after venoplasty –



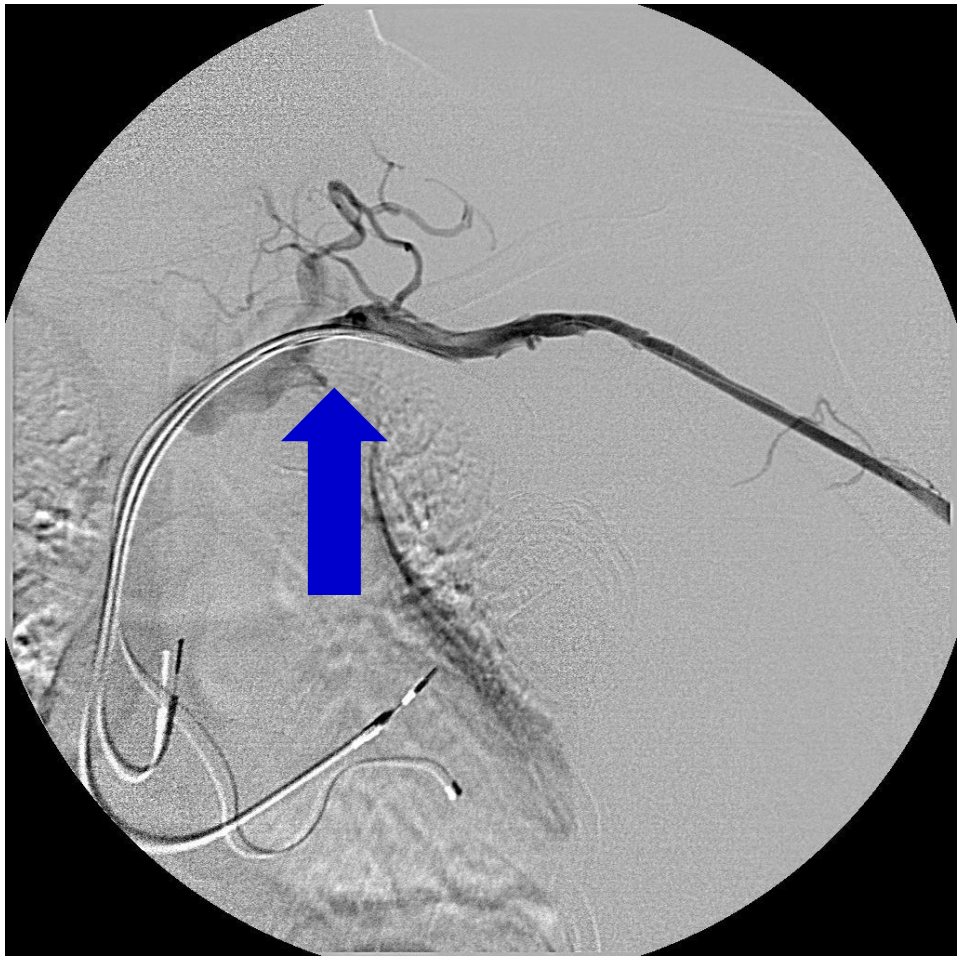
The patient required venous stenting because of recurred SVC syndrome.

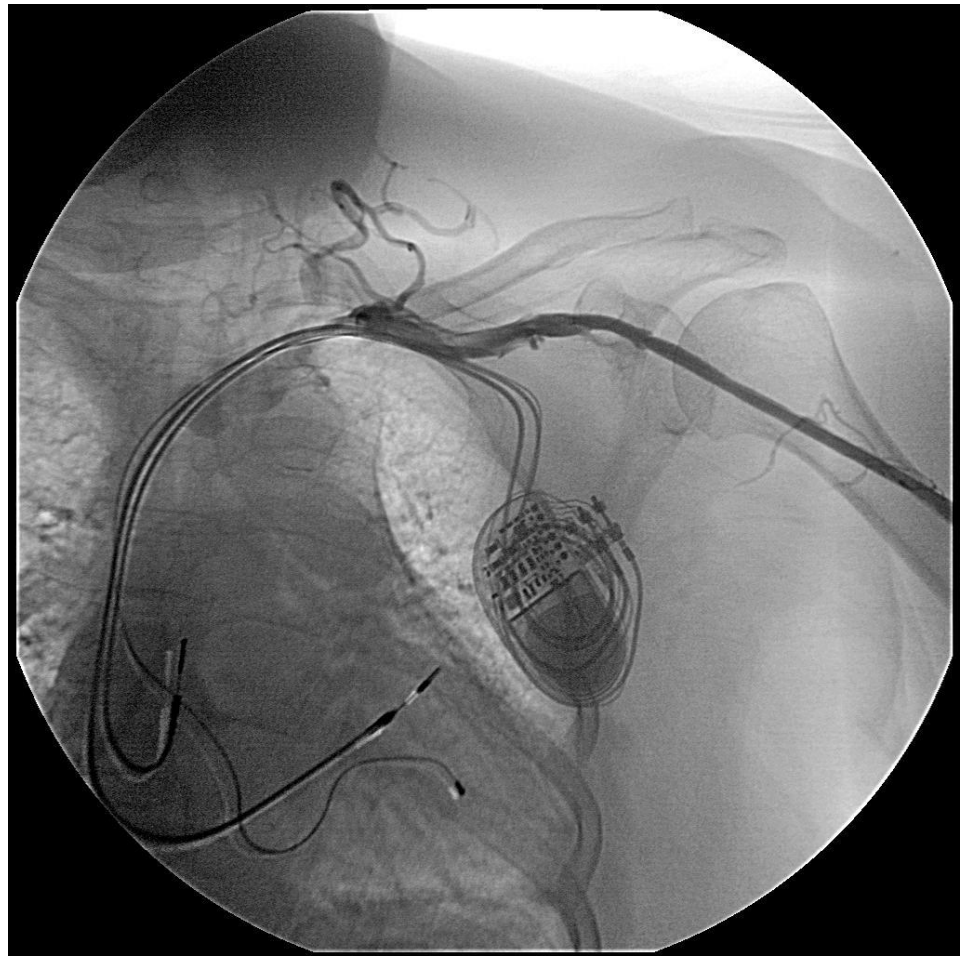
Park HW et al. JCE 2005;16:221-3

62Y, F

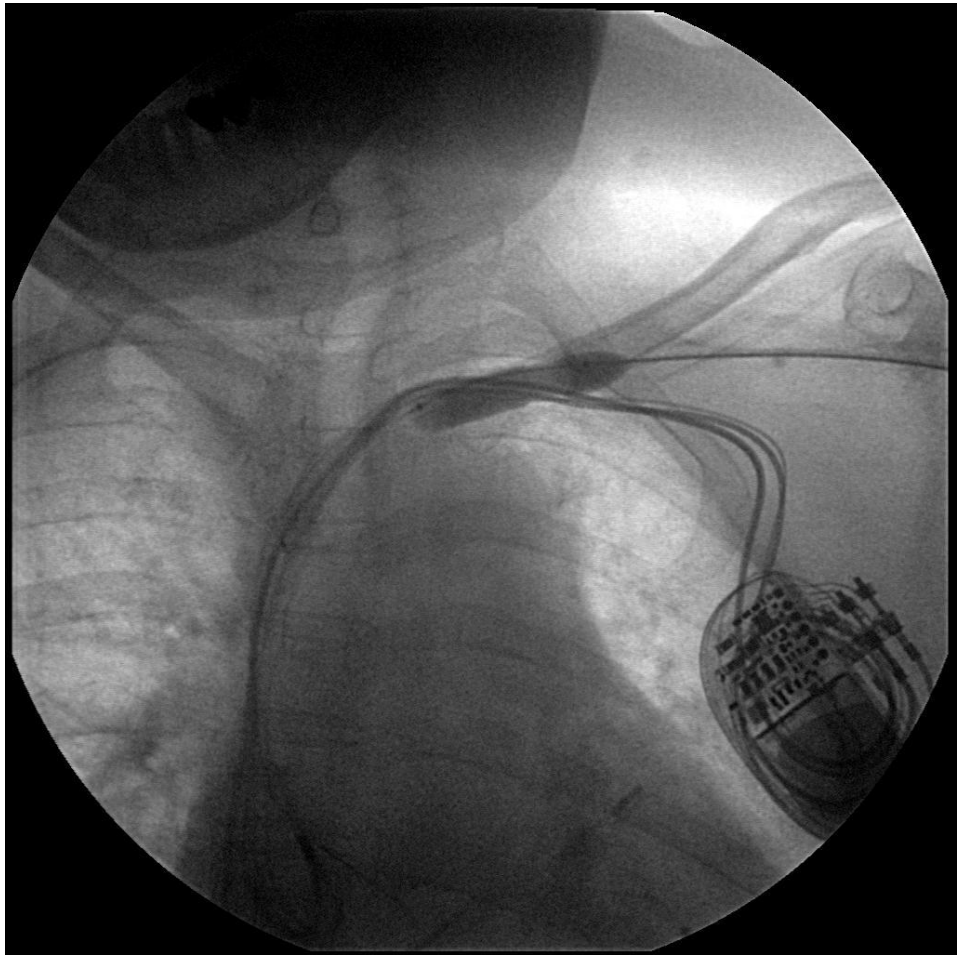
- C/C
  - Swollen face, neck and left arm
- P/I:
  - 2003; DCMP
  - 2005; CRT–P
  - 2006; Swollen face, neck and left arm

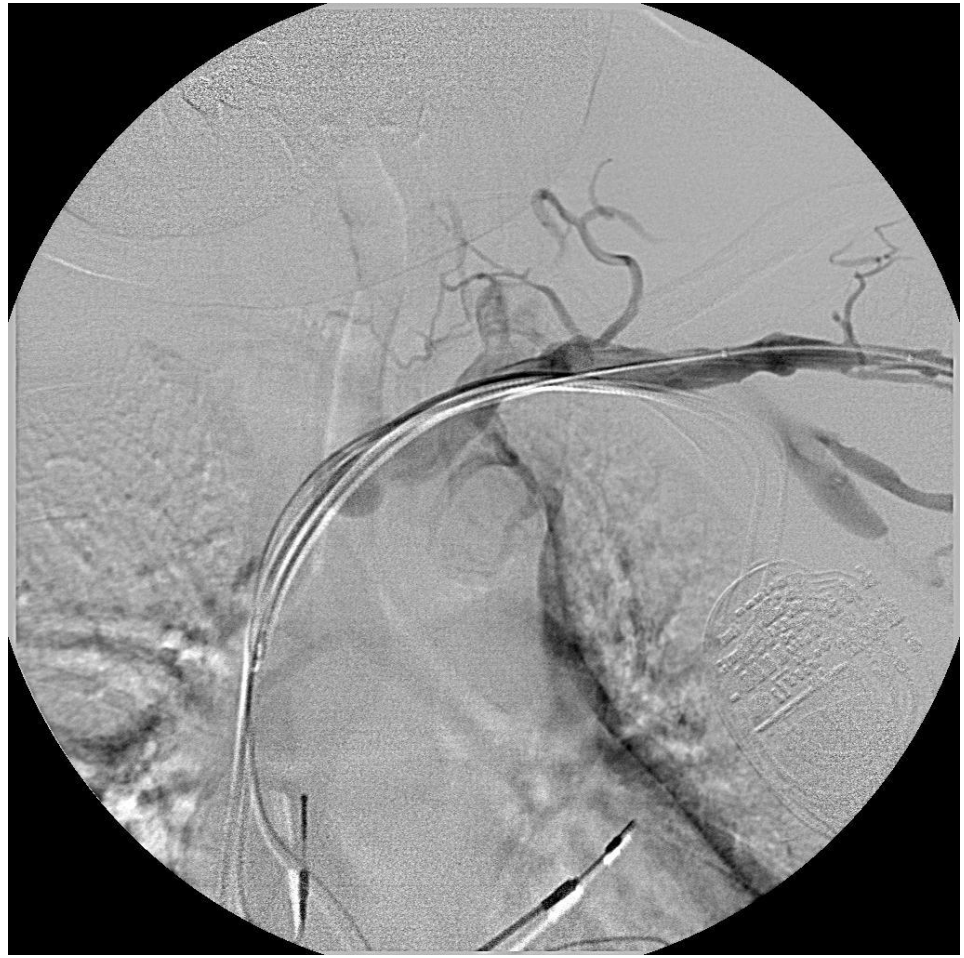
Venogram of left subclavian vein





Venoplasty



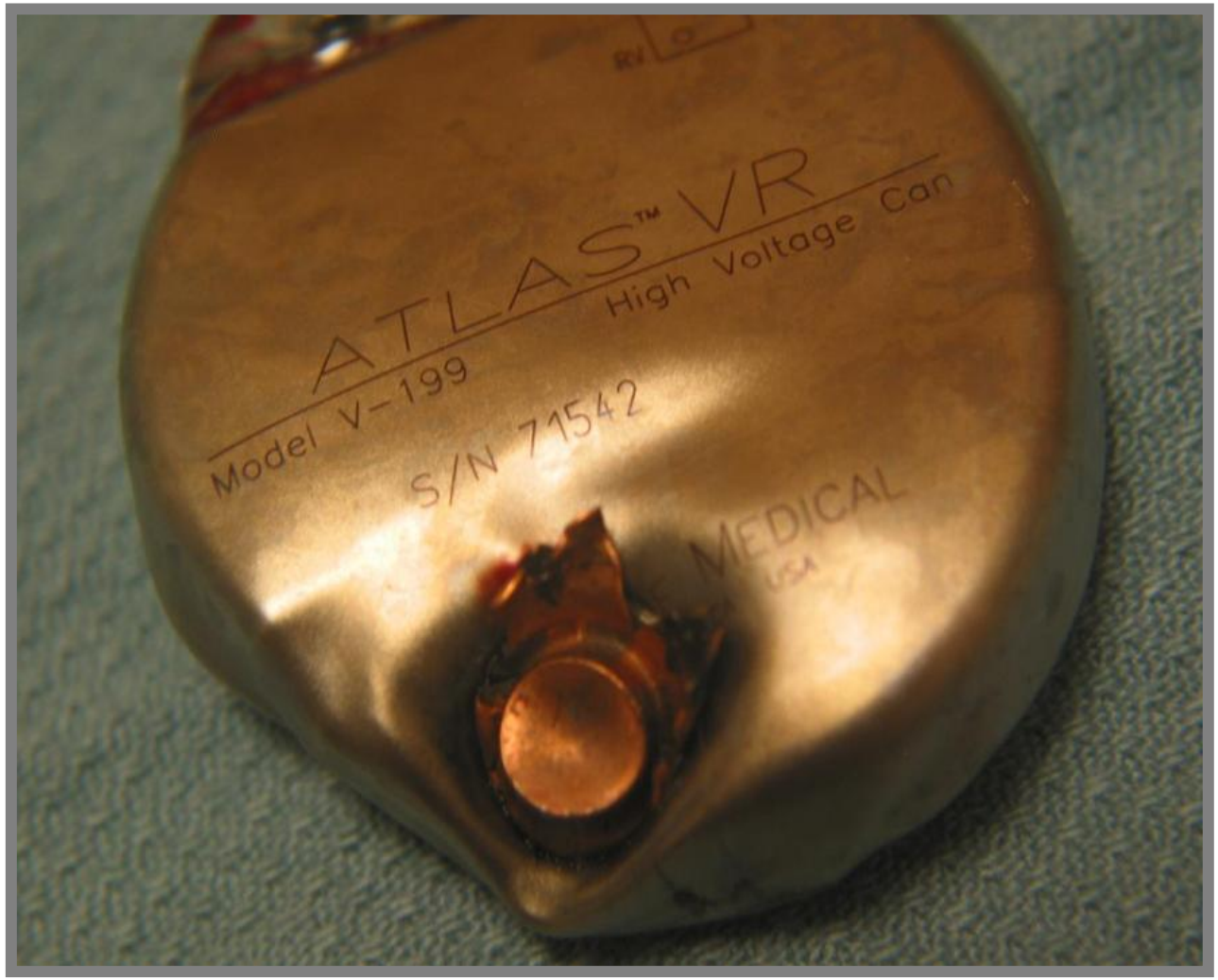


Thrombosis or venous stenosis

- ✓ Lead removal is recommended in patients with clinically **significant thromboembolism events** associated with thrombus on a lead or a lead fragment
- ✓ Lead removal is recommended in patients **with bilateral subclavian vein or superior vena cava occlusion precluding implantation of a needed transvenous lead**
- ✓ Lead removal is recommended in patients with **planned stent deployment in a vein already containing a transvenous lead**, to avoid entrapment of the lead
- ✓ Lead removal is recommended in patients with **superior vena cava stenosis or occlusion with limiting symptoms**
- ✓ Lead removal is recommended in patients with ipsilateral venous occlusion preventing access to the venous circulation for required placement of an additional lead when there is a contraindication for using the contralateral side (e.g., contralateral AV fistula, shunt or vascular access port, mastectomy)

Body Guard Saves Lives !!!

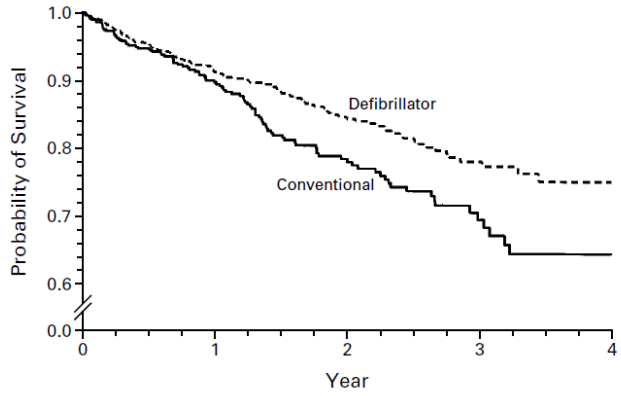
ICD saves lives !!!



ICD saves lives !!!

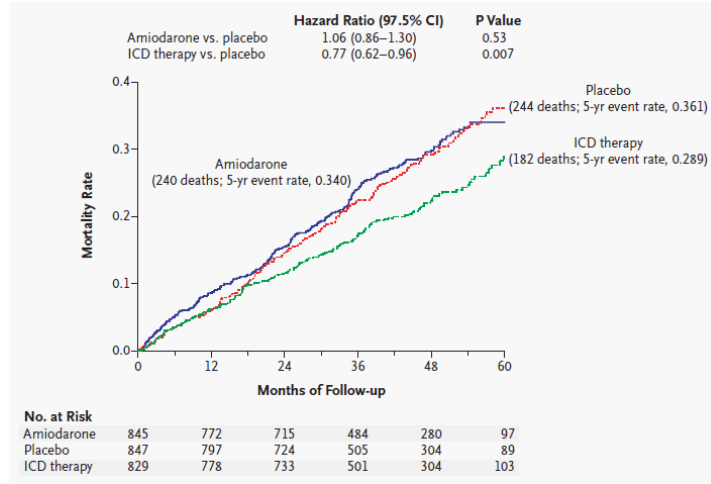
ICDs in the reduction of SCD in primary and secondary prevention

MADIT II



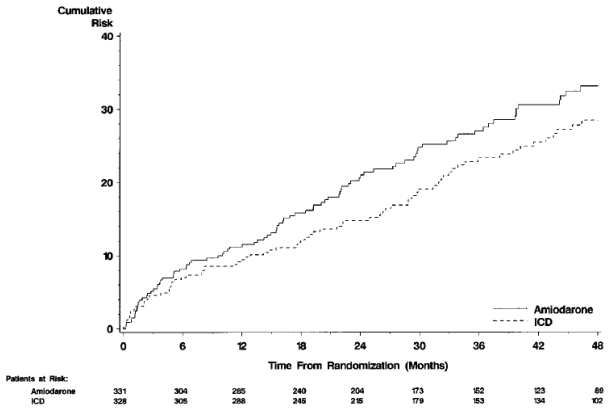
No. at Risk					
Defibrillator	742	503 (0.91)	274 (0.84)	110 (0.78)	9
Conventional	490	329 (0.90)	170 (0.78)	65 (0.69)	3

SCD-HeFT

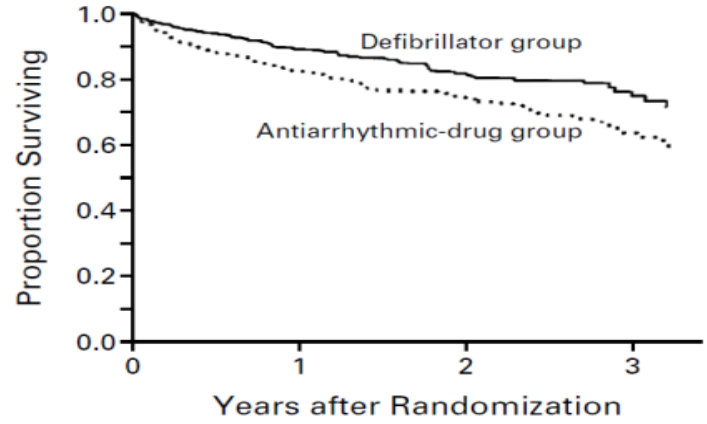


No. at Risk						
Amiodarone	845	772	715	484	280	97
Placebo	847	797	724	505	304	89
ICD therapy	829	778	733	501	304	103

CIDS



AVID



CRT-D and CRT-P can reduce overall and CV mortality and number of hospitalizations

Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION)

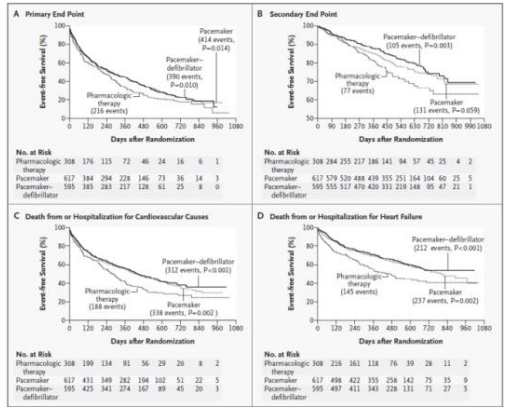
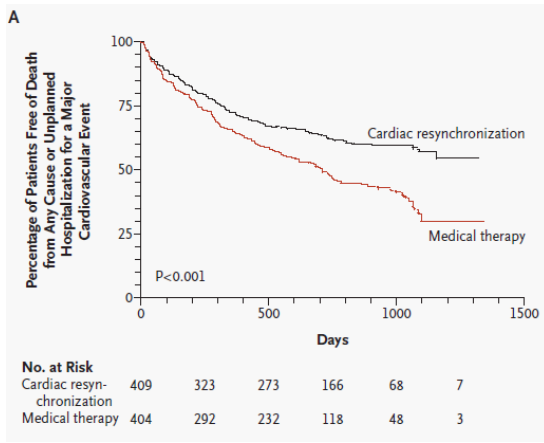


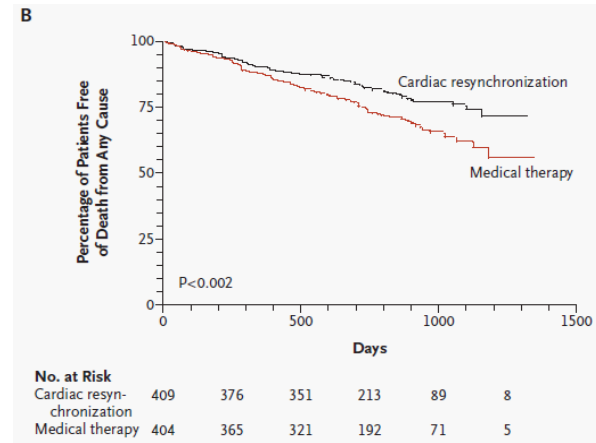
Table 2. Changes in Distance Walked in Six Minutes, Quality of Life, and New York Heart Association (NYHA) Class.

Variable	3 Months			6 Months		
	No. of Patients	Mean ±SD Change	P Value*	No. of Patients	Mean ±SD Change	P Value*
Increase in distance walked in 6 min (m)						
Optimal pharmacologic therapy	170	9±84	—	142	1±93	—
Cardiac-resynchronization therapy						
Pacemaker	422	33±99	<0.001	373	40±96	<0.001
Pacemaker–defibrillator	420	44±109	<0.001	378	46±98	<0.001
Increase in quality of life (%)†						
Optimal pharmacologic therapy	243	−9±21	—	207	−12±23	—
Cardiac-resynchronization therapy						
Pacemaker	510	−24±27	<0.001	460	−25±26	<0.001
Pacemaker–defibrillator	514	−24±28	<0.001	478	−26±28	<0.001
Improvement in NYHA class symptoms (%)						
Optimal pharmacologic therapy	242	24	—	199	38	—
Cardiac-resynchronization therapy						
Pacemaker	551	58	<0.001	489	61	<0.001
Pacemaker–defibrillator	543	55	<0.001	497	57	<0.001

Bristow MR, et al. *N Engl J Med. 2004;350:2140–2150*

CARE-HF study

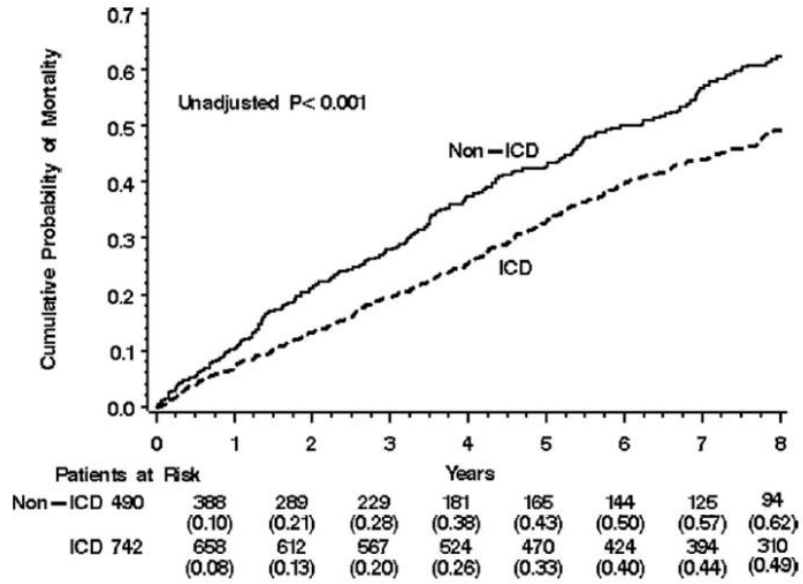




Cleland JGF, et al. *N Engl J Med. 2005;352:1539–1549*

Cost-effectiveness of CEID – MADIT II

- ✓ Advantage of the use of ICDs in preventing SCD increases further at **long-term follow-up (8 years),** while the cost-effectiveness ratio per saved discontinued life-year dramatically improves during the same period



Goldenberg I, et al. *Circulation. 2010;122:1265-1271*

"… 무서워 장 못담글까?"

CIED implantation:
Is it a just beginning of problems?

Yes!!!

Just the beginning of lots of events
which we need to overcome!!!