Moderne ICD-Therapie: Sind intravasale Elektroden noch nötig?

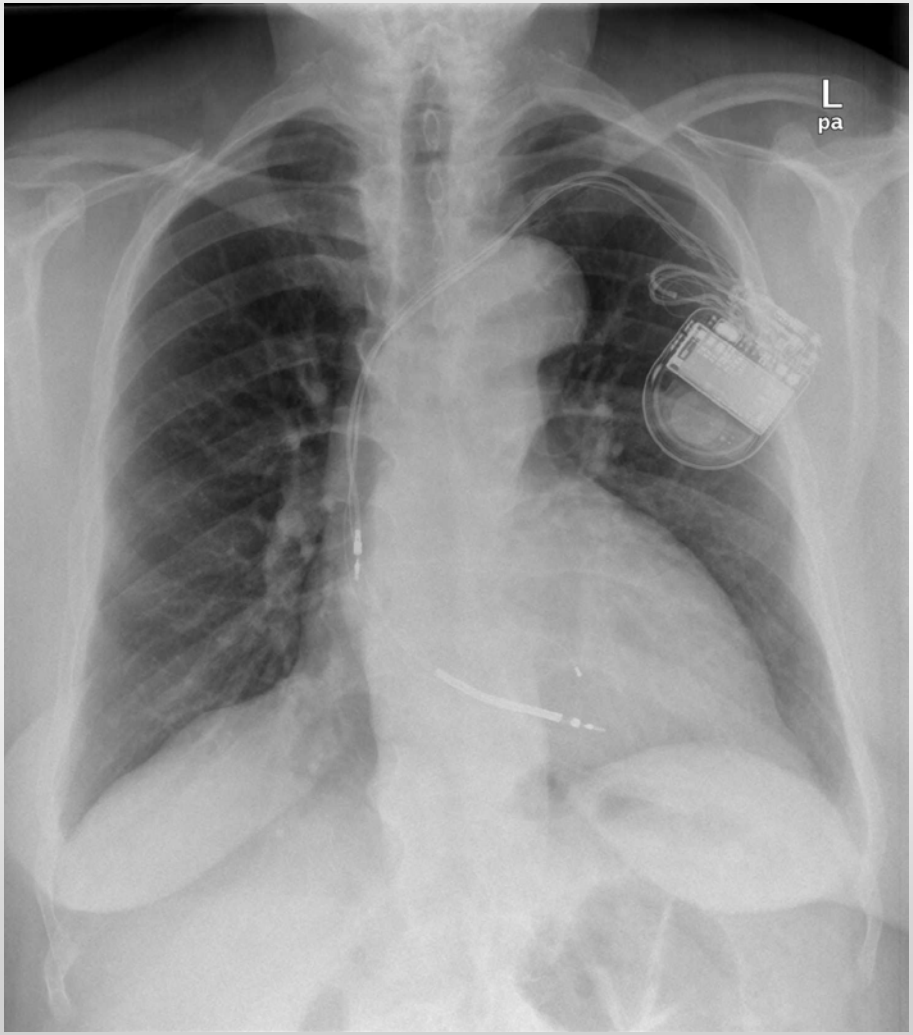
Professor Dr. med. Joachim Winter
Augusta Krankenhaus Düsseldorf-Rath

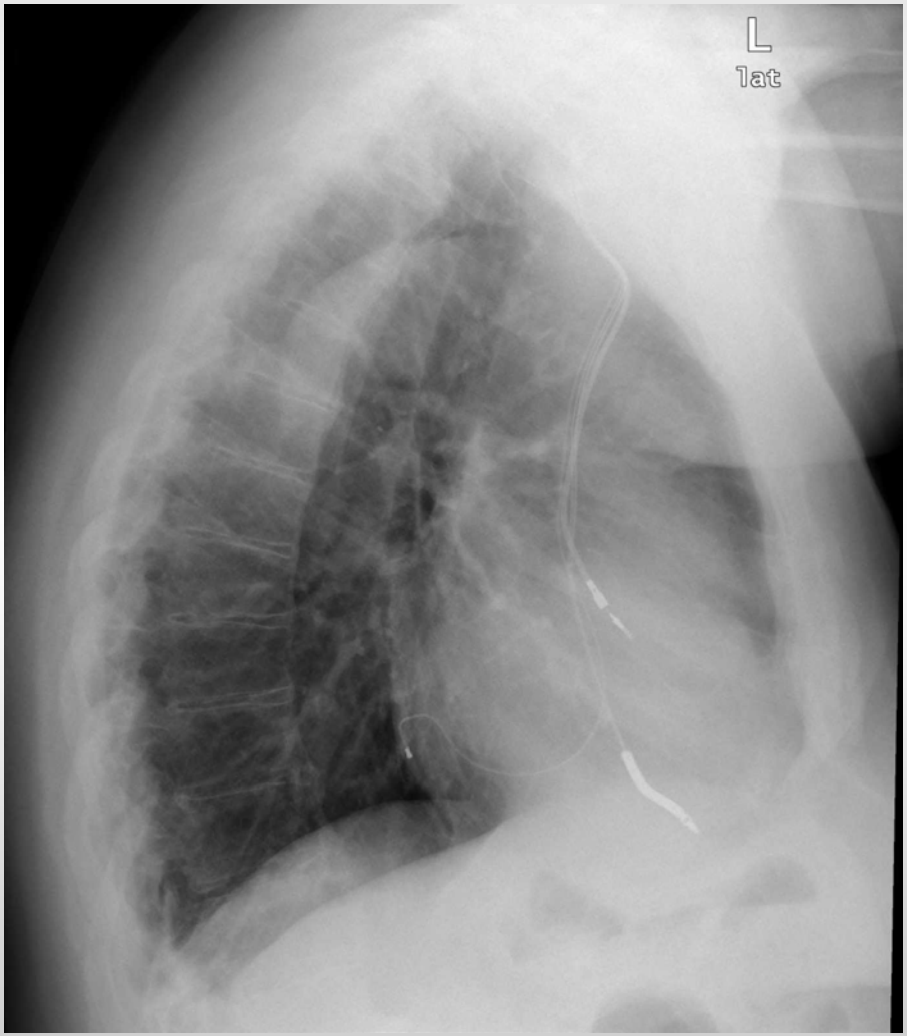
Die Achillesferse der ICD-Therapie

- **Elektrodenfehlfunktionen und -brüche**
- **Stenosen und Verschlüsse des zuführenden Venensystems**
- **Elektrodenfehllagen**
- **Infektionen / Endokarditis**
- **Risiko der Elektrodenextraktionen**

Pat.: R.R. *08.09.1939

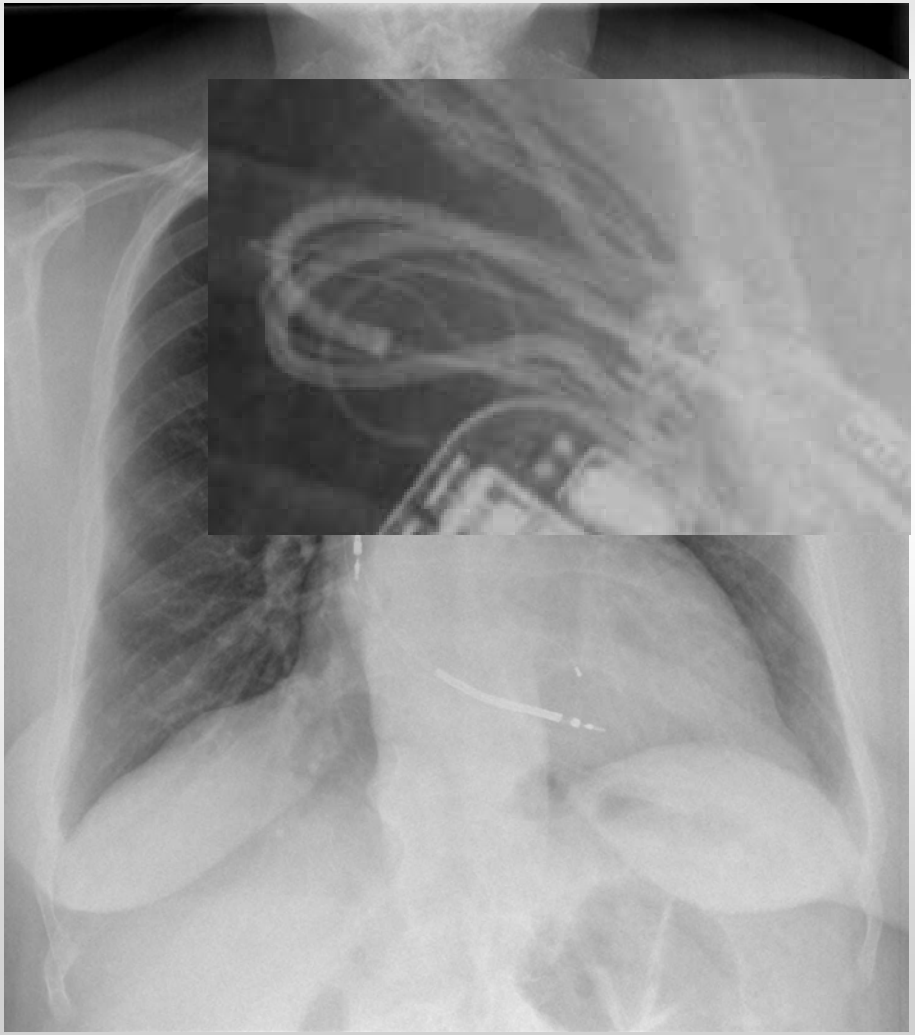
Erstimplantation 2004 Revision 2011



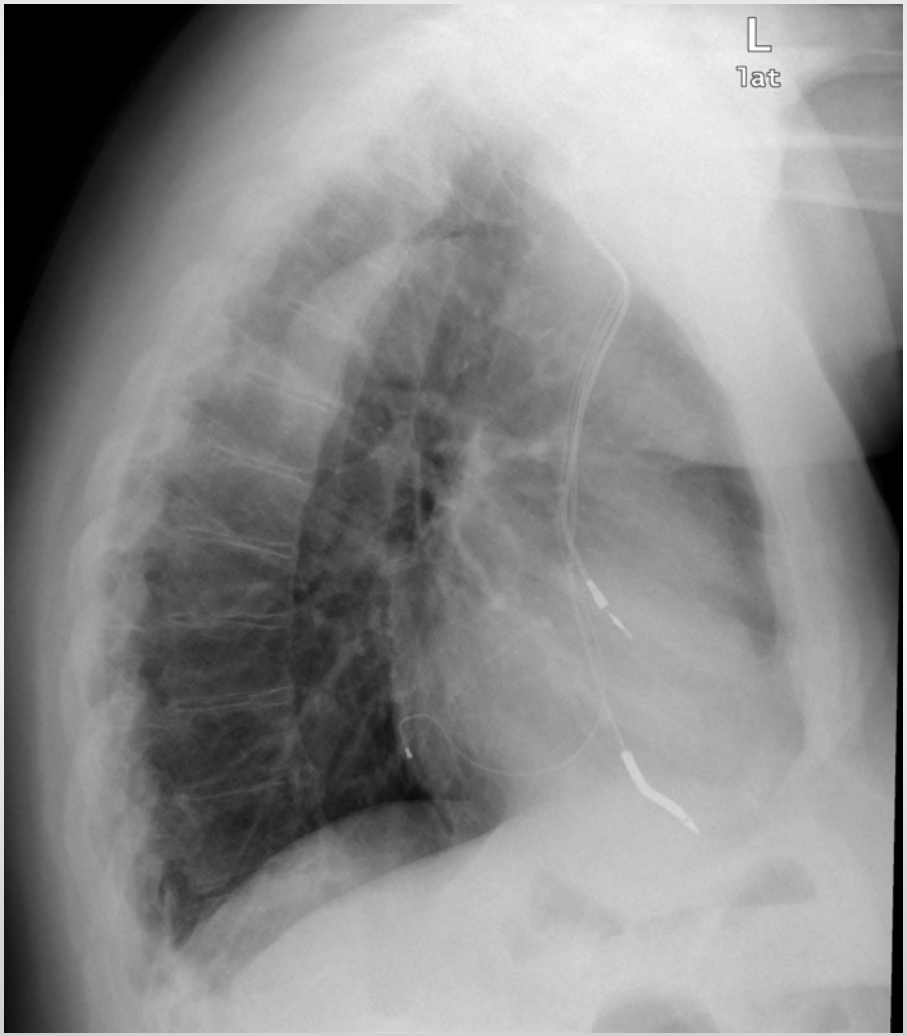


Pat.: R.R. *08.09.1939

Erstimplantation 2004

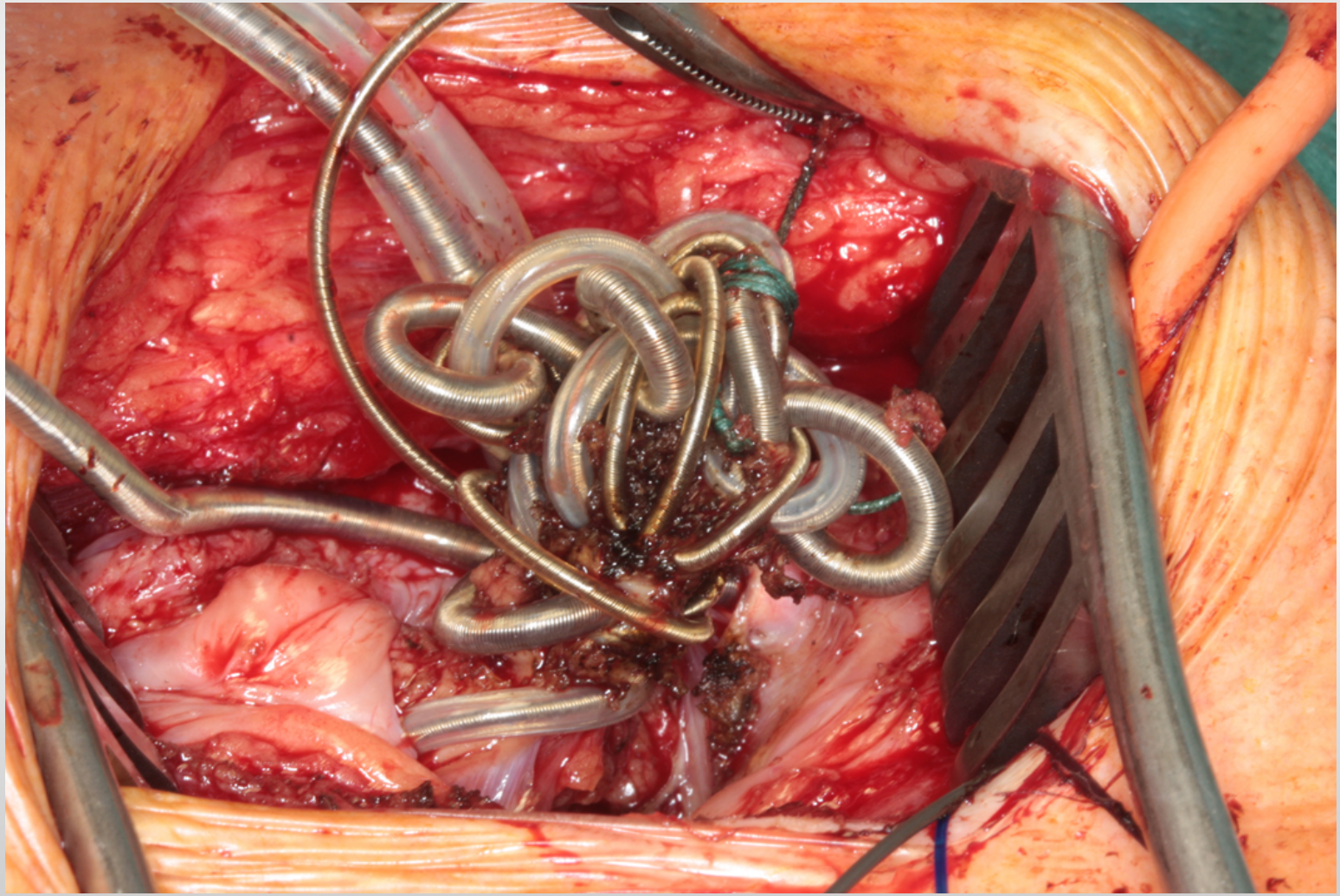


Revision 2011



Pat.: R.R. *08.09.1939

Erstimplantation 2004 Revision 2011

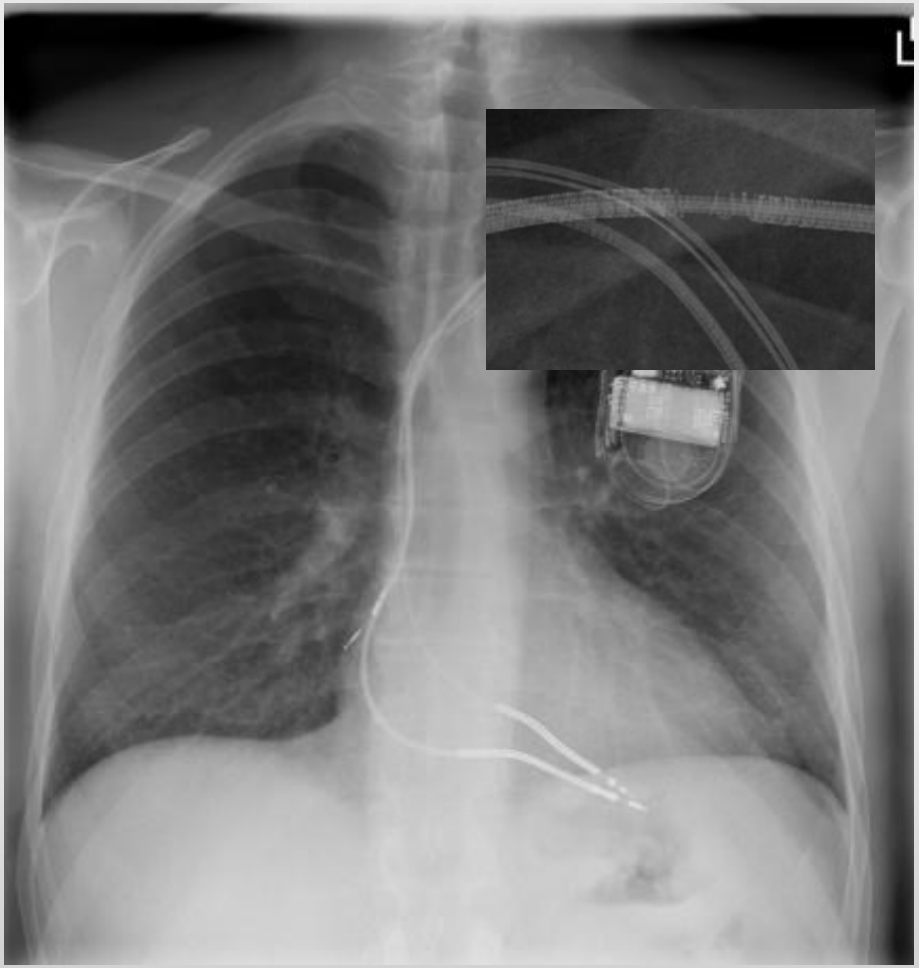


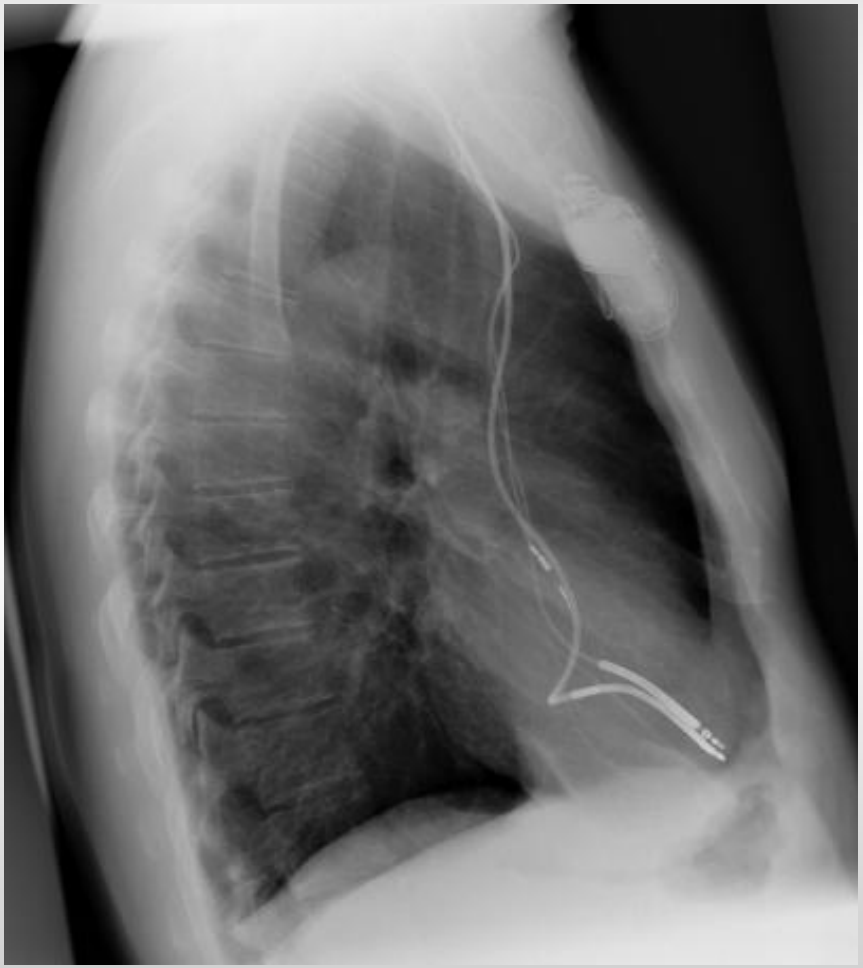
Pat.: R.R. *08.09.1939

Erstimplantation 2004 Revision 2011

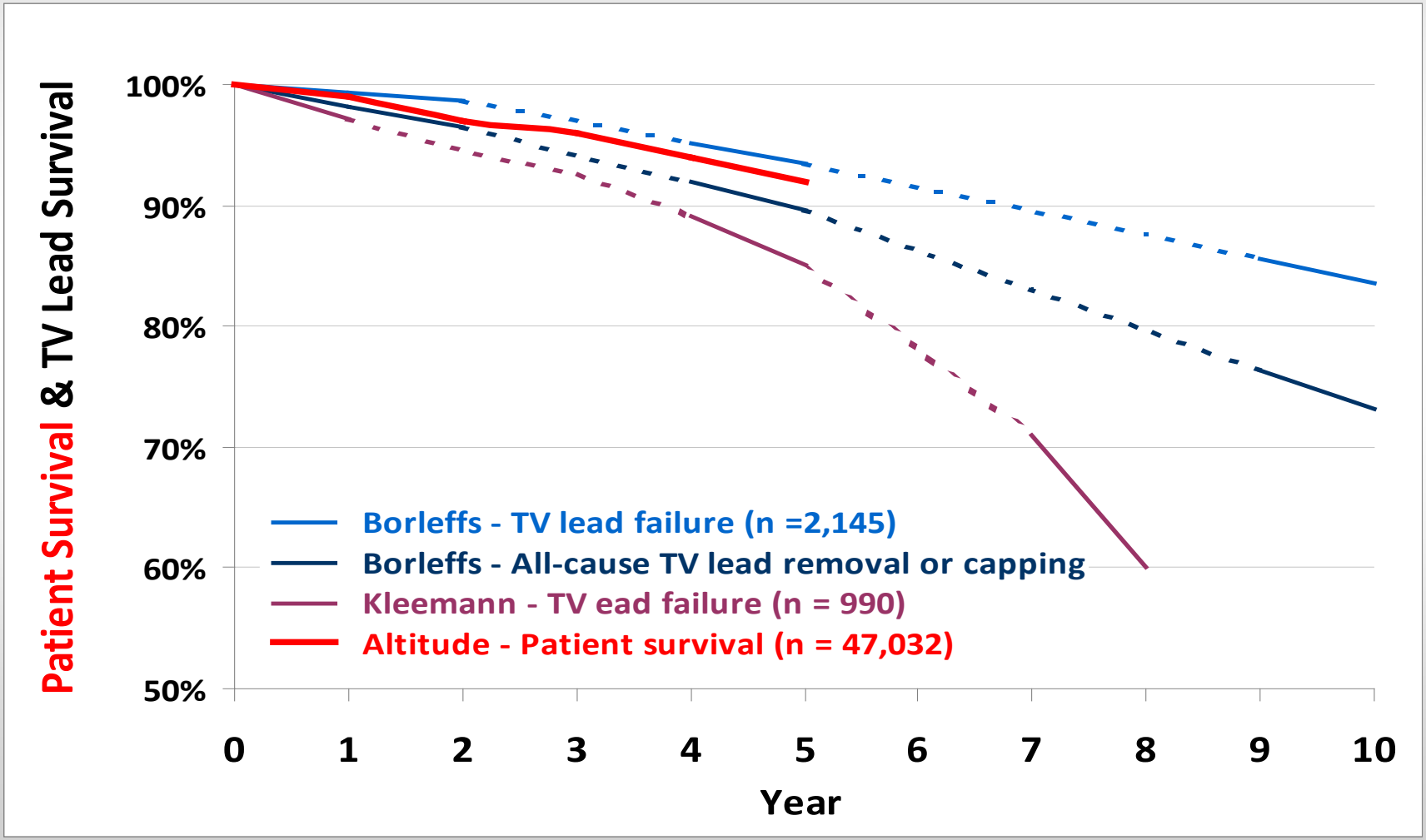
Pat.: V.M. *25.12.1955

Implantation 05.07.1995 Zusätzliche Pace-Sense Elektrode 03.02.2000
Zusätzliche ICD Elektrode 26.08.2004





Lebensdauer der ICD Elektroden



Pat.: G.K. *18.11.1930

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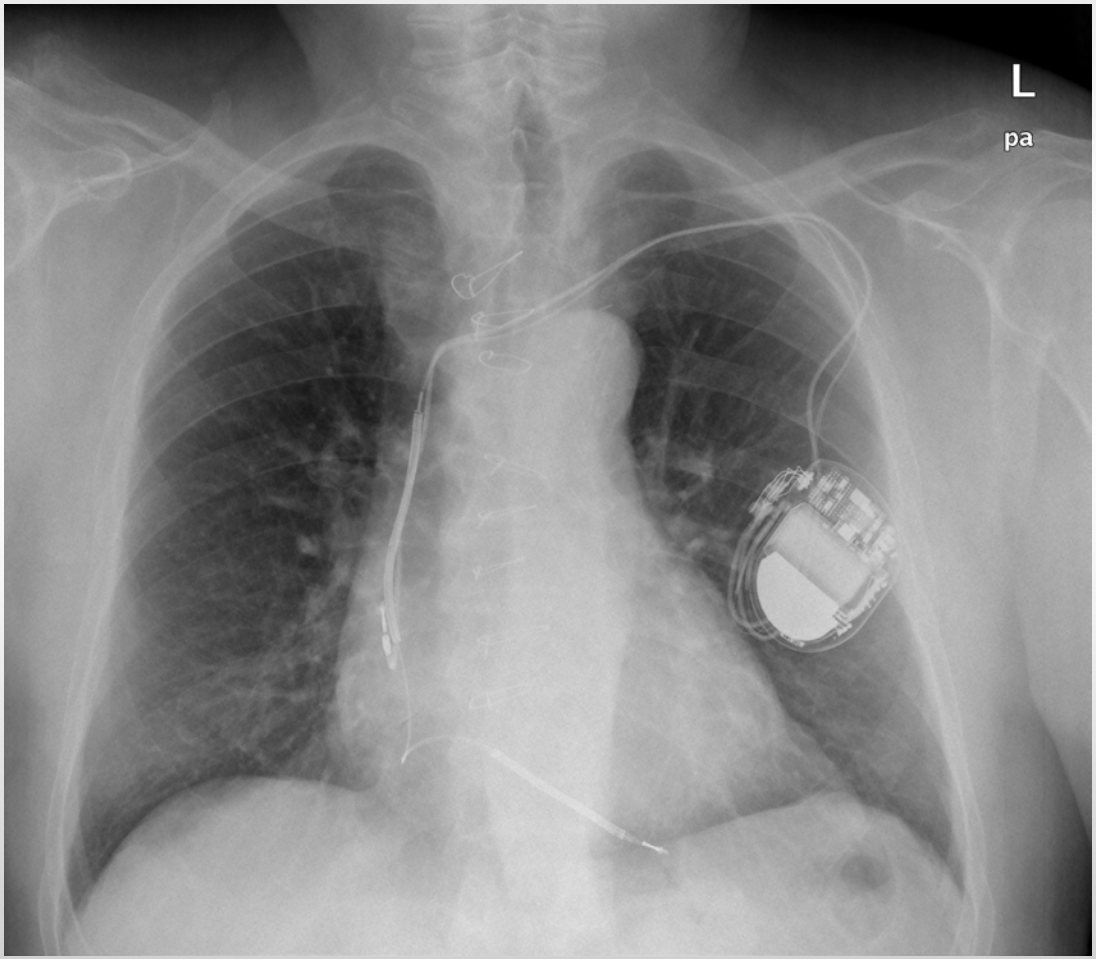
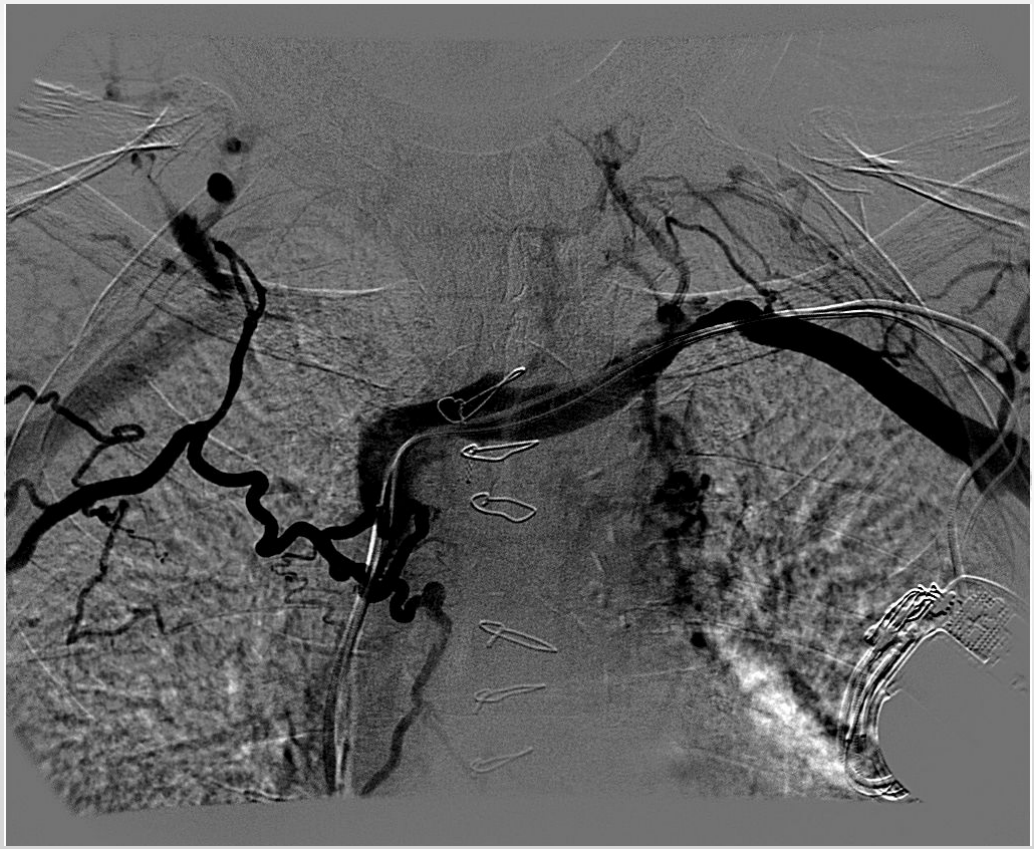
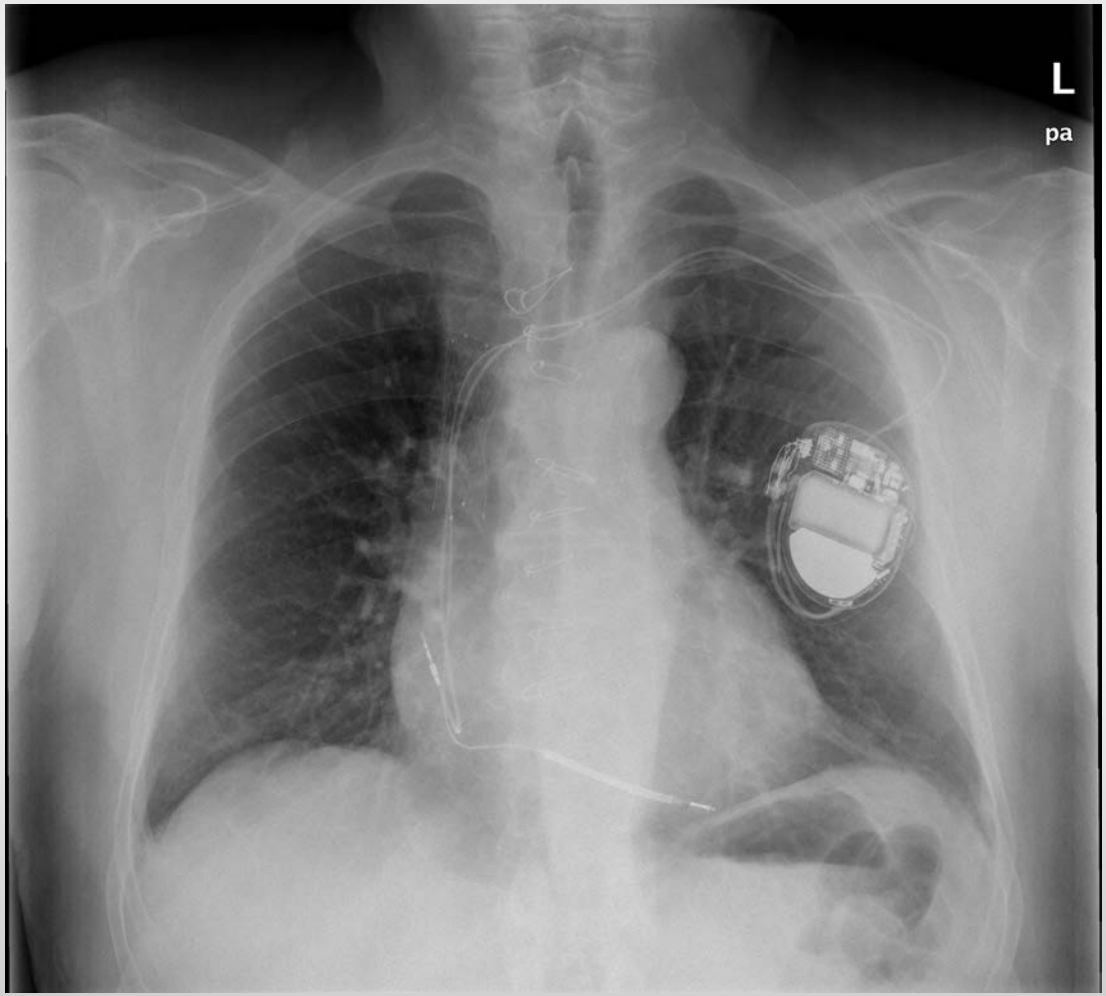
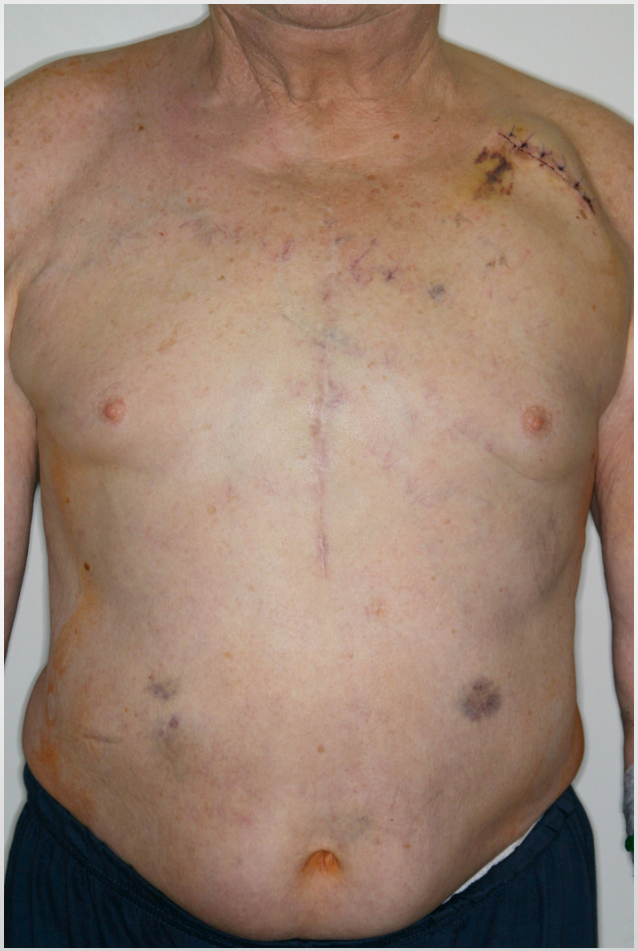




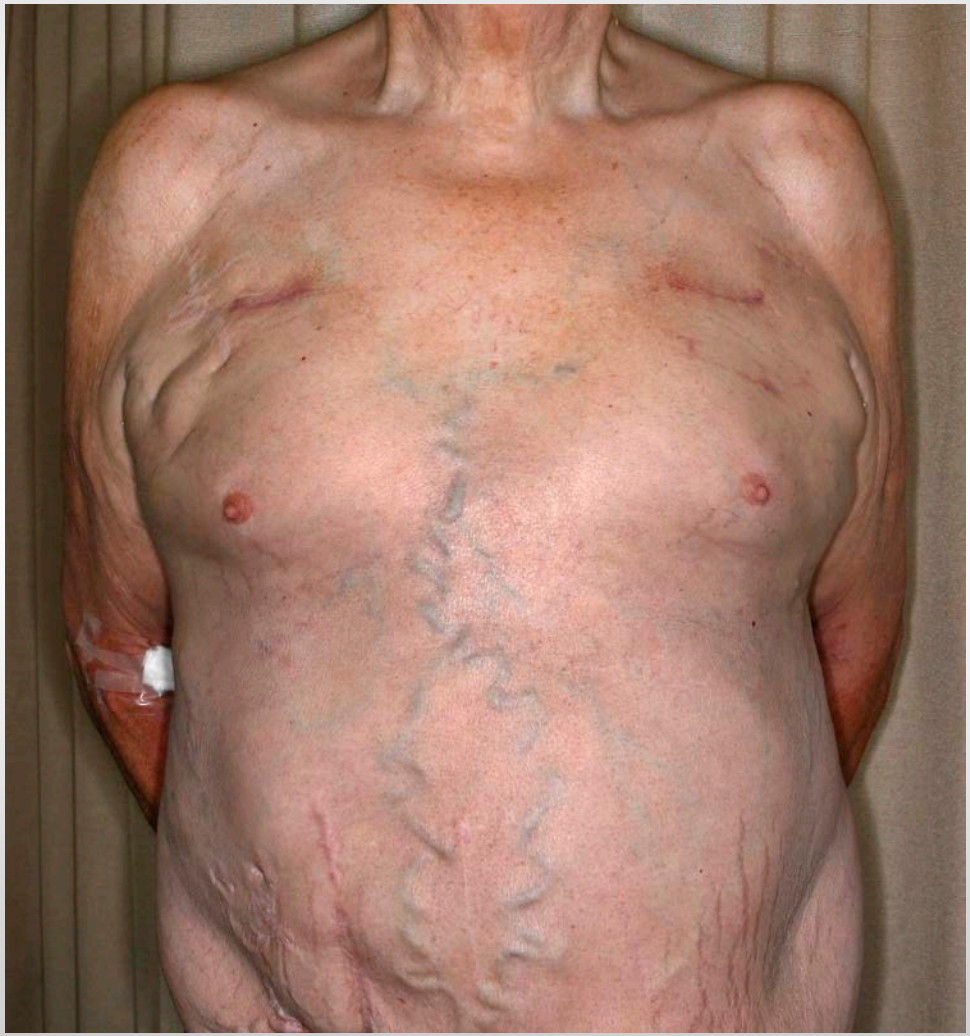
Pat.: G.K. *18.11.1930

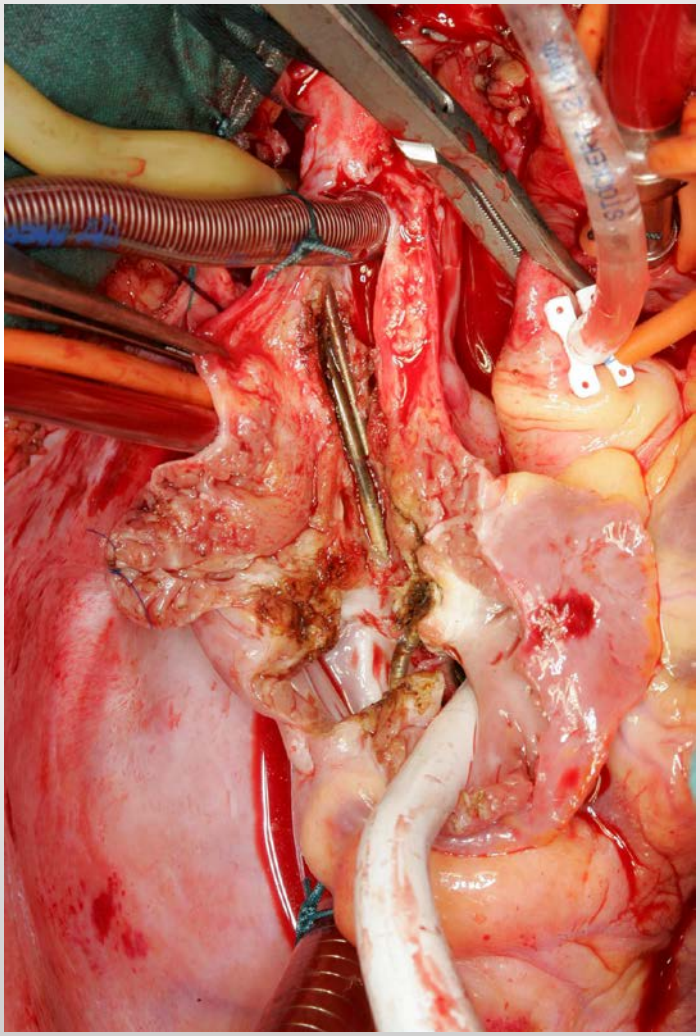


Pat.: G.K. *18.11.1930



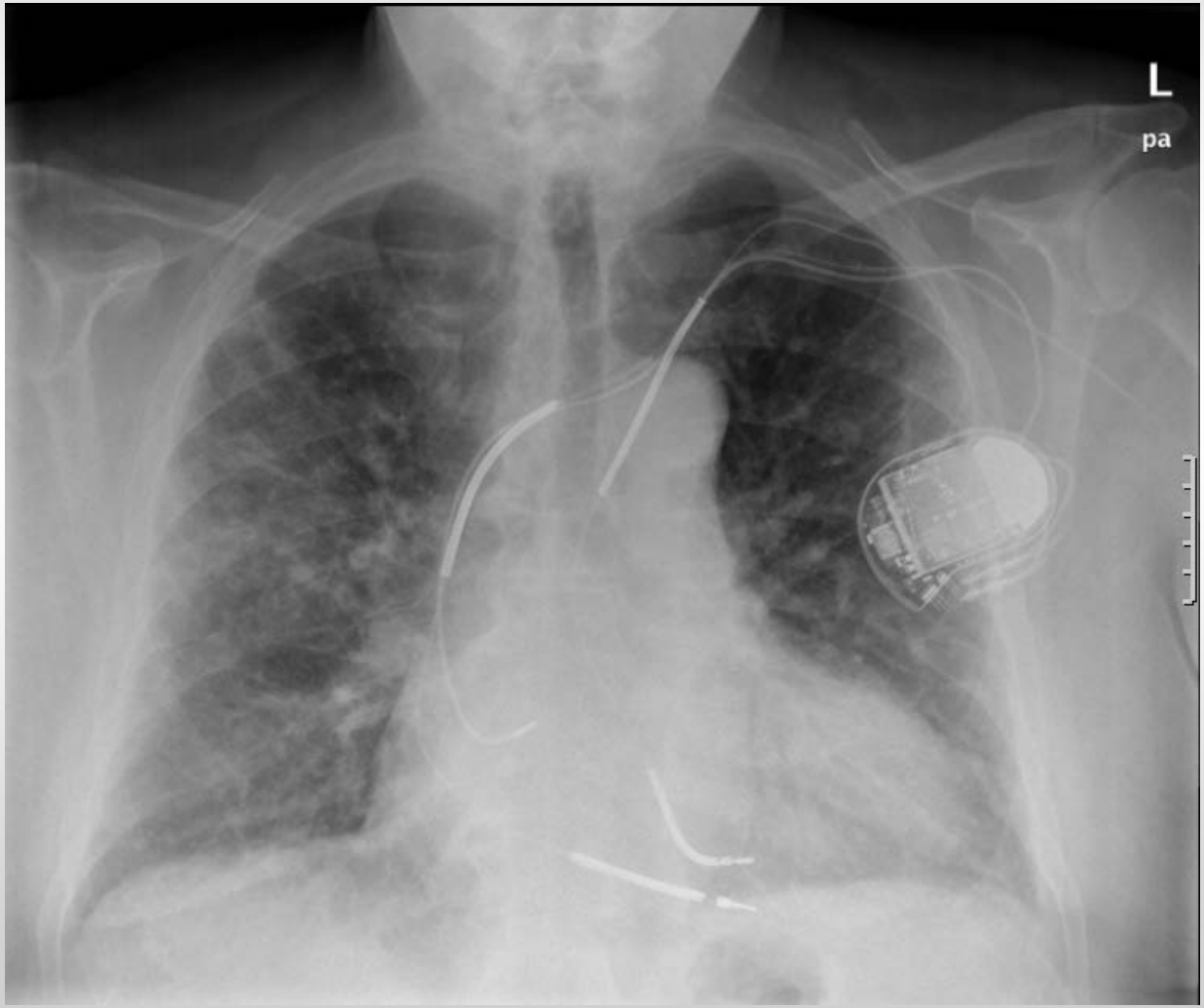
Pat.: K.T. *22.09.1949

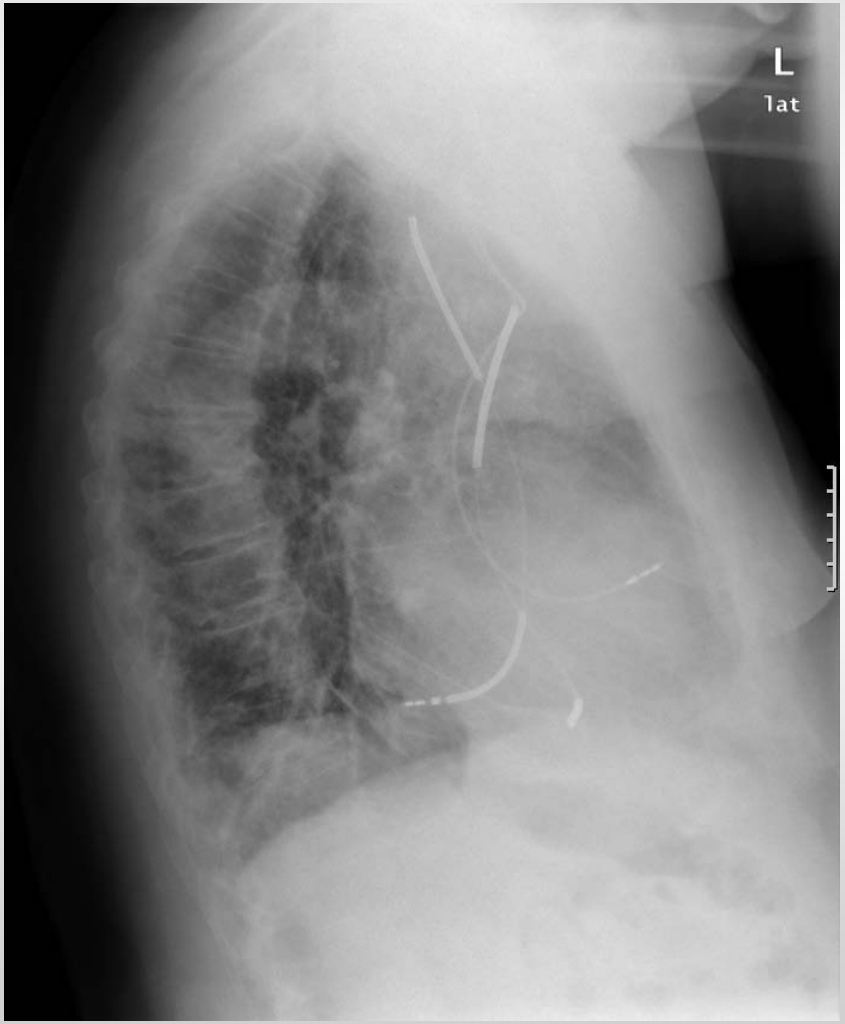




Pat.: B.F. *27.06.1929

Implantation 02.08.2006 zusätzliche ICD-Elektrode 01.03.2011





Pat.: B.F. *27.06.1929

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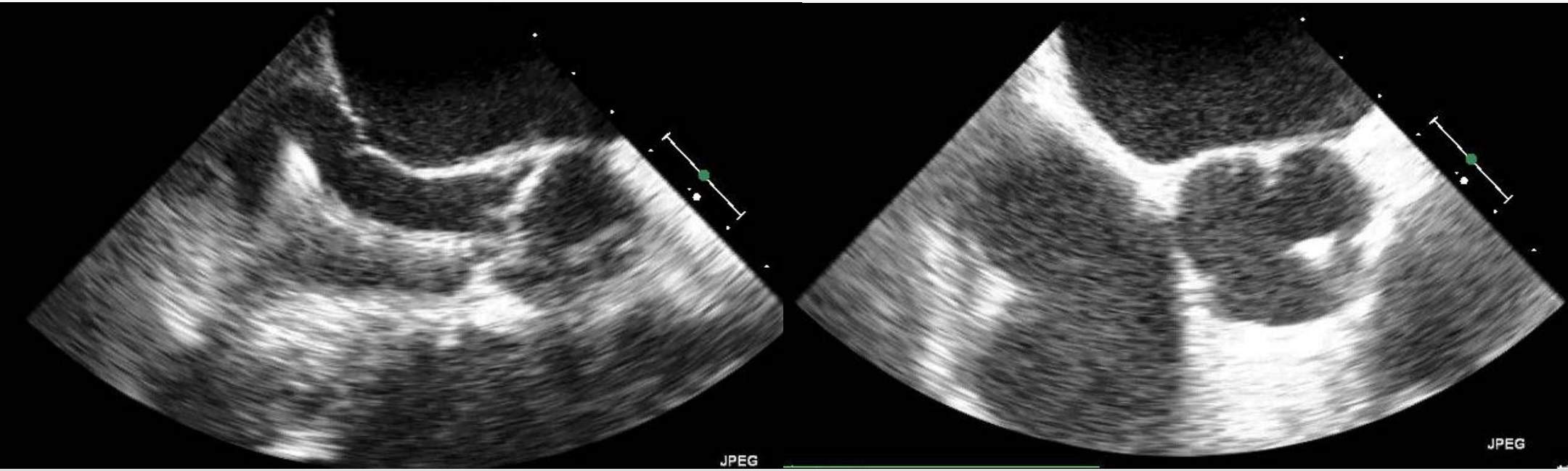
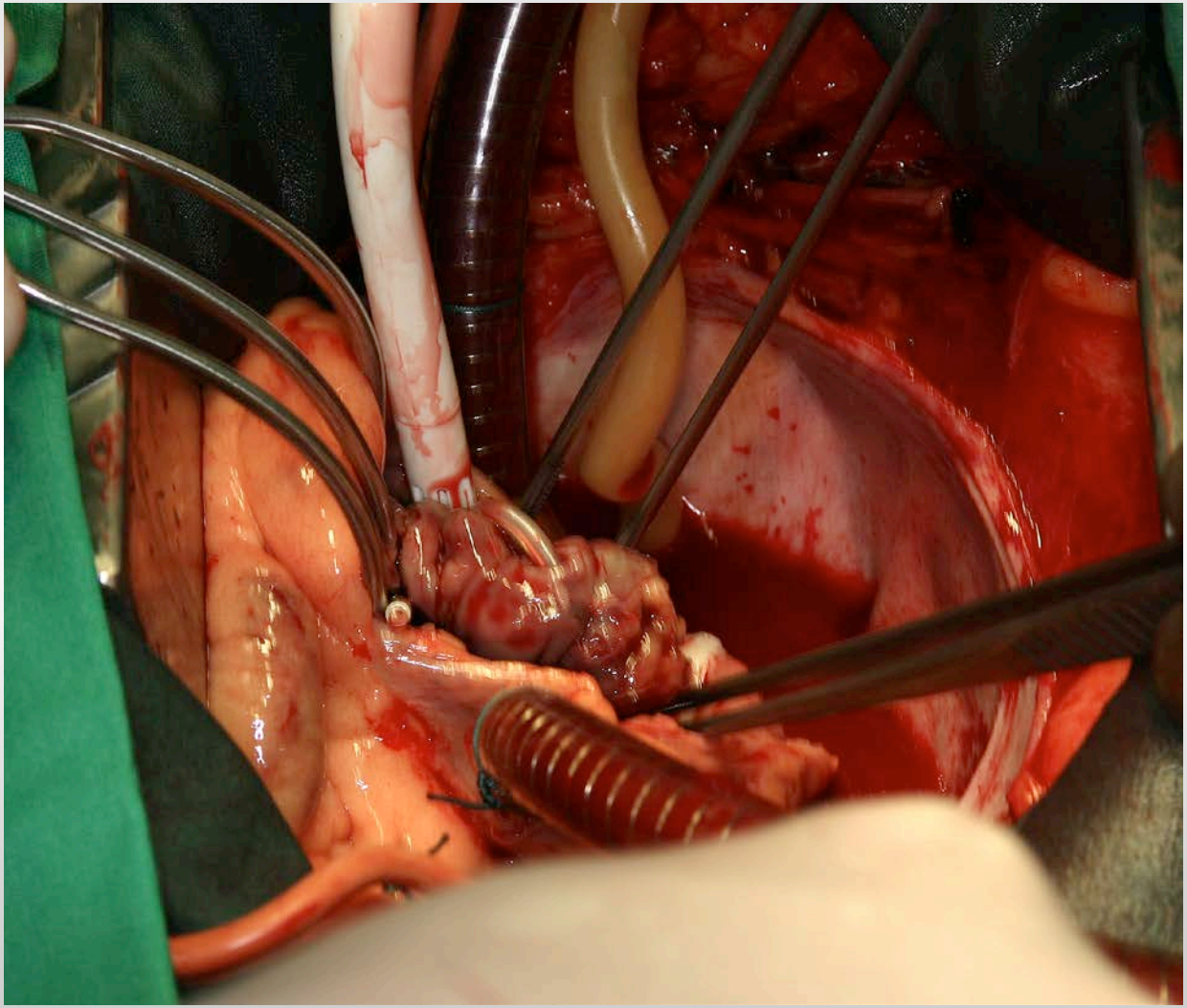


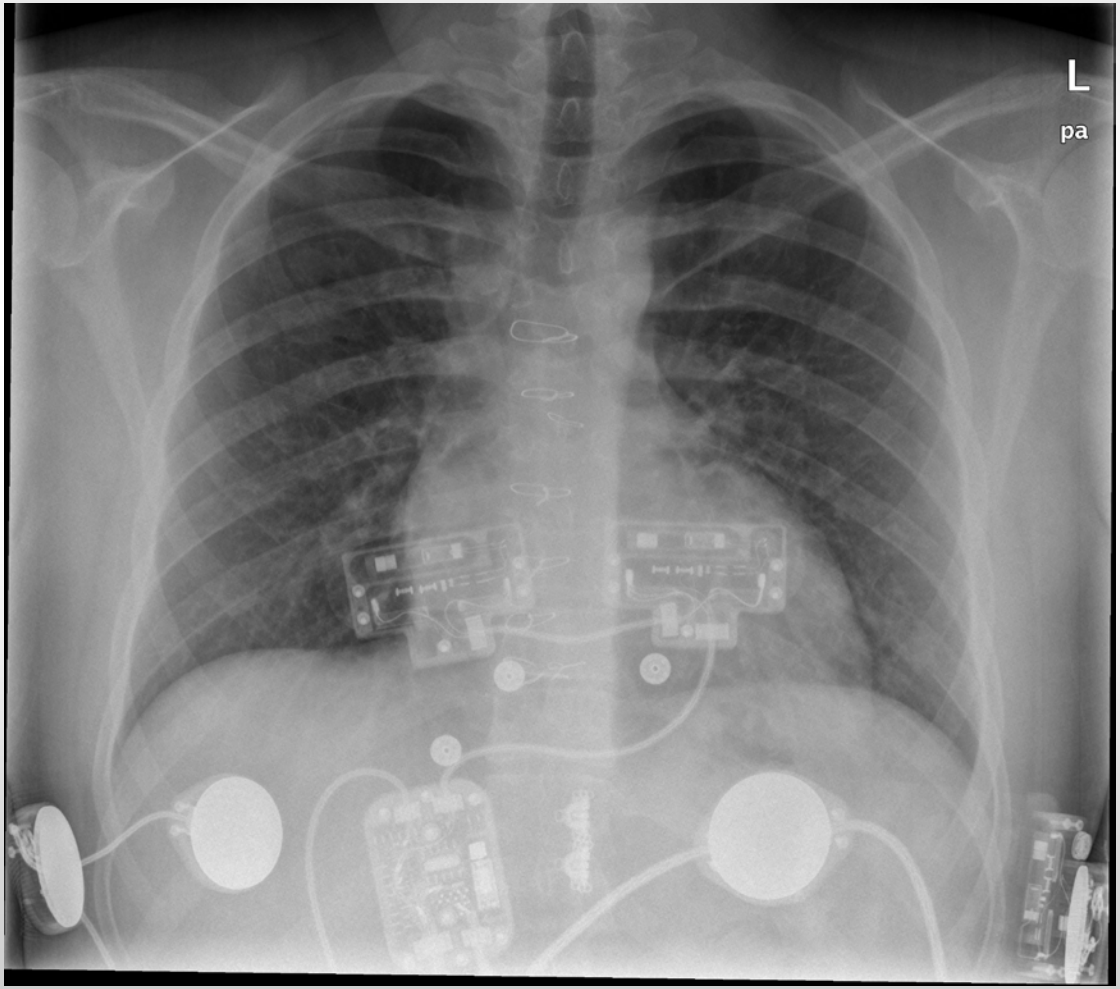
Pat.: K.R. *22.09.1949

Das „Super-Breitband-Antibiotikum“

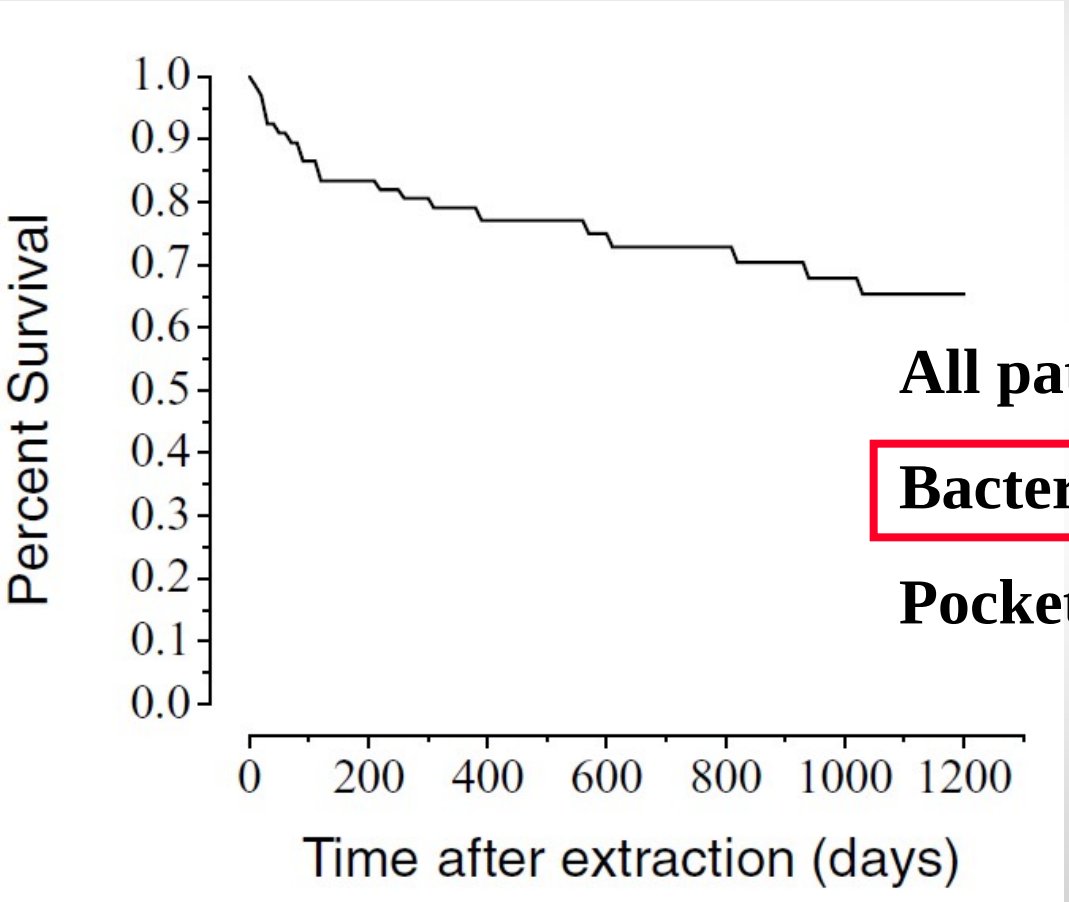
Pat.: K.E. *04.07.1942



LifeVest
Wearable Defibrillator



High Mid-Term Mortality Following Successful Lead Extraction for Infection



All patients (67 pts): **30% mortality**

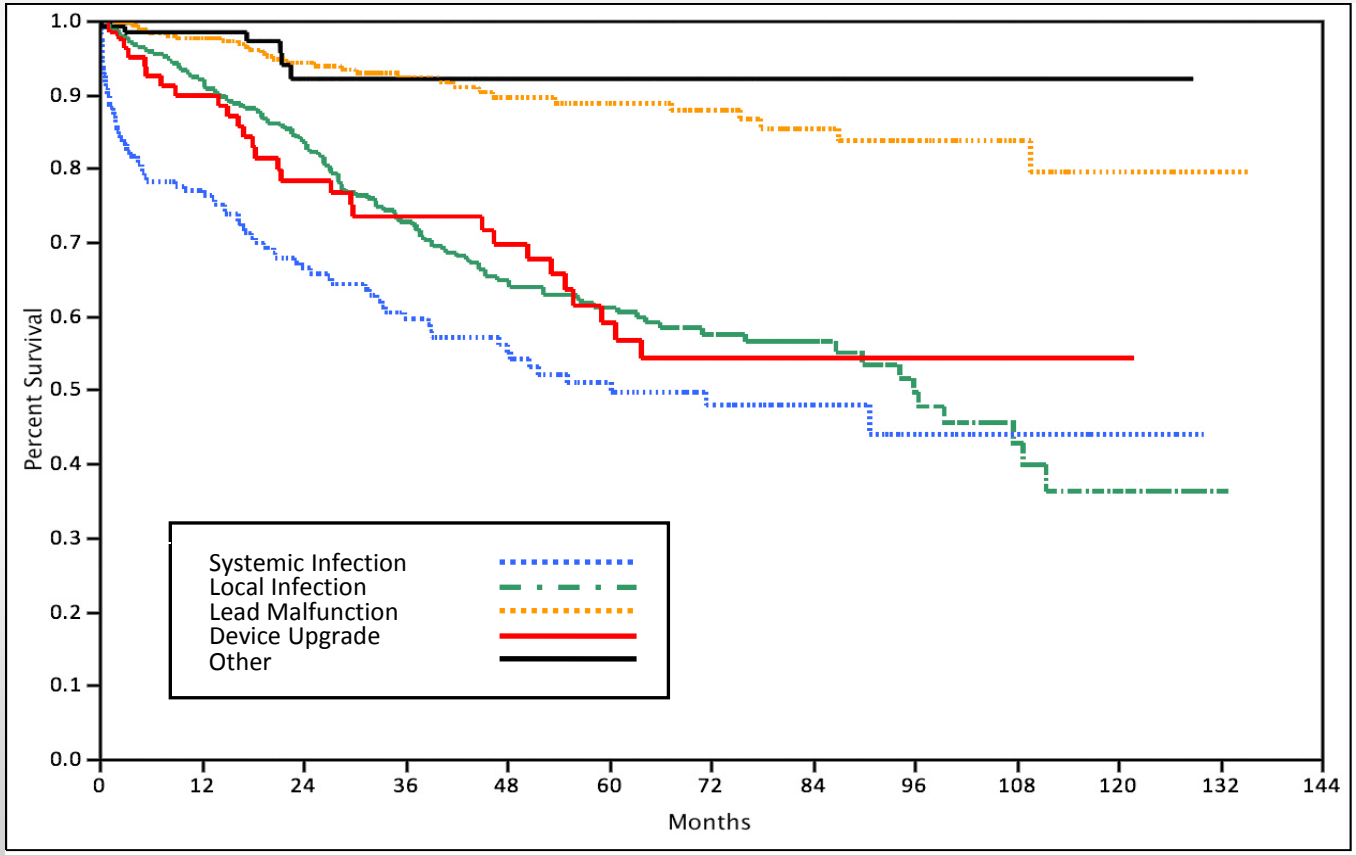
Bacteremia (34 pts): **44% mortality**

Pocket infection (33 pts): **15% mortality**

Hendrikson et al.: PACE, 34, 32, 2011

Long-Term Mortality Following Transvenous Lead Extraction

Overall Kaplan-Meier survival curves according to TLE indication



Courtesy Melanie Maytin, Brigham & Women‘s Hospital, Boston, MA

Lead Extraction in the Contemporary Setting: The LExICon Study

An Observational Retrospective Study of Consecutive Laser Lead Extractions

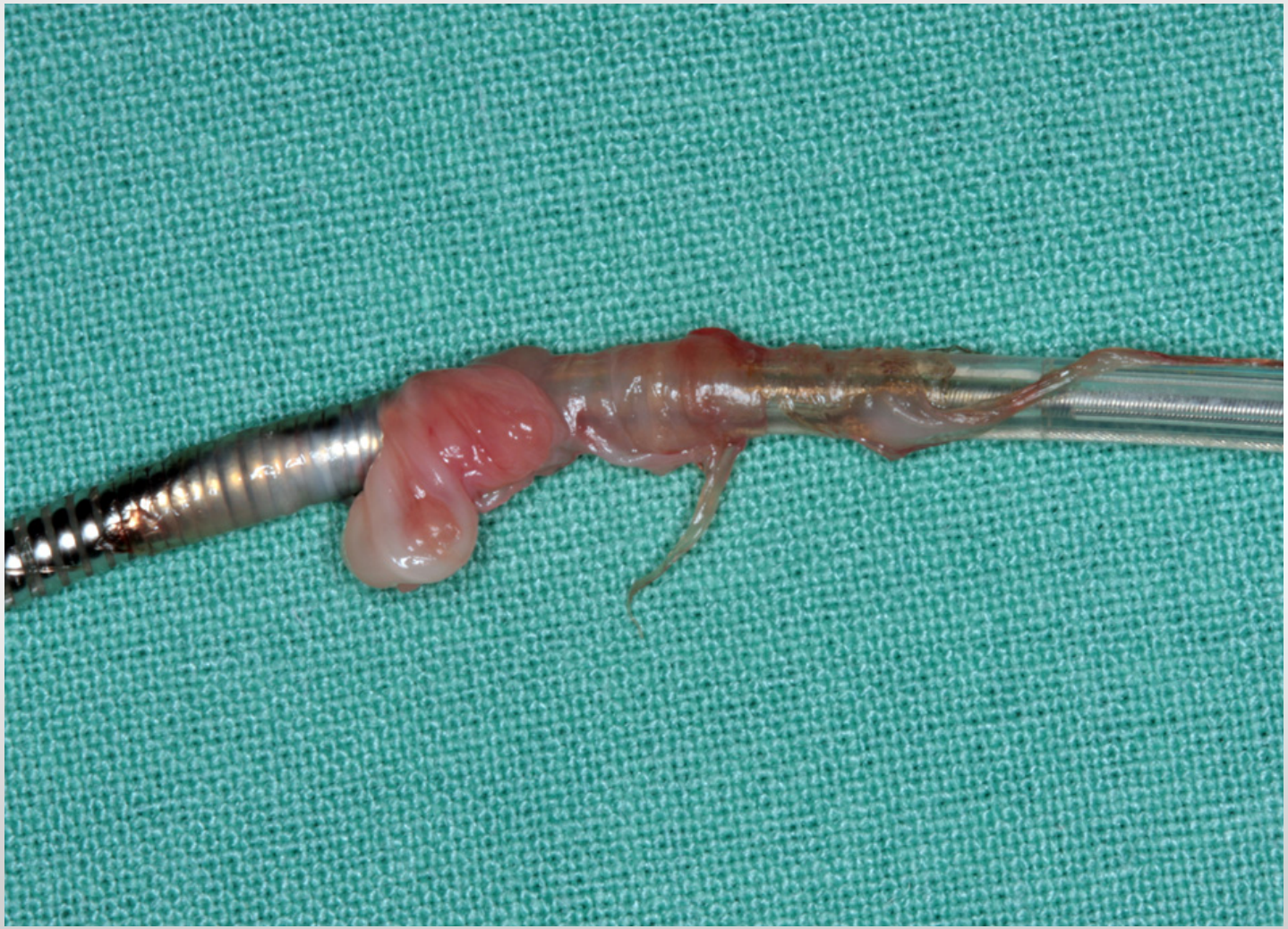
- **1449 konsekutive Patienten: Alter 63,4±17,06 Jahre**
- **2405 Elektroden:**

  1684 SM-Elektroden, 703 ICD-Elektroden, 18 unbekannt
  1226 aktive, 832 passive und 347 unbekannte Fixierung
  Mittlere Implantationsdauer 81,2 Monate

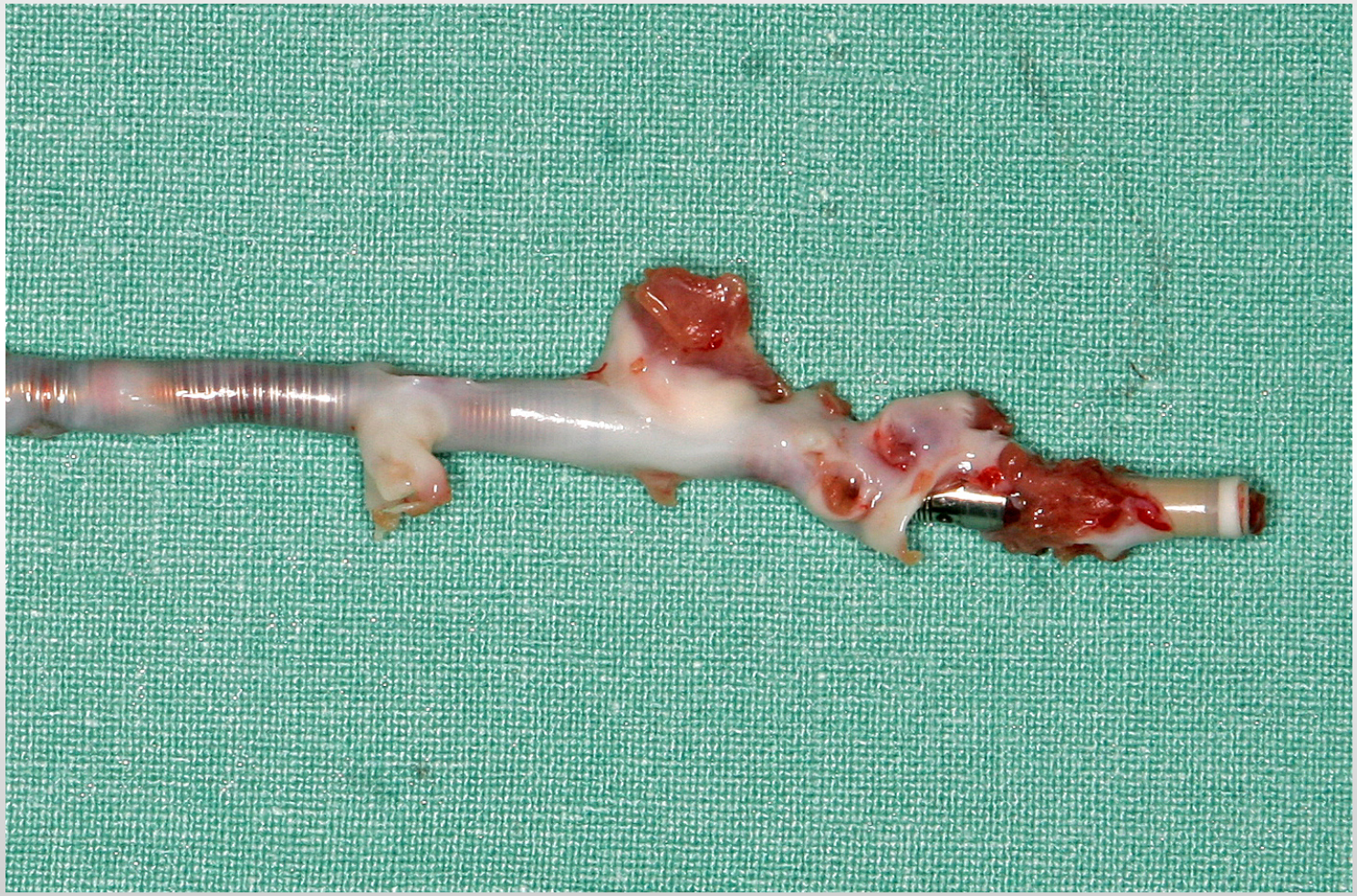
- **96,5% der Elektroden konnten komplett extrahiert werden.**
- **4 Patienten (0,28%) verstarben an den Folgen des Eingriffs.**

Wazni et al.: J Am Coll Cardiol 55, 579, 2010

Pat.: L.S. *22.01.1970



Pat.: K.G. *05.04.1947



Pat.: B.H. *08.06.1922

Pat.: V.M. *25.12.1955

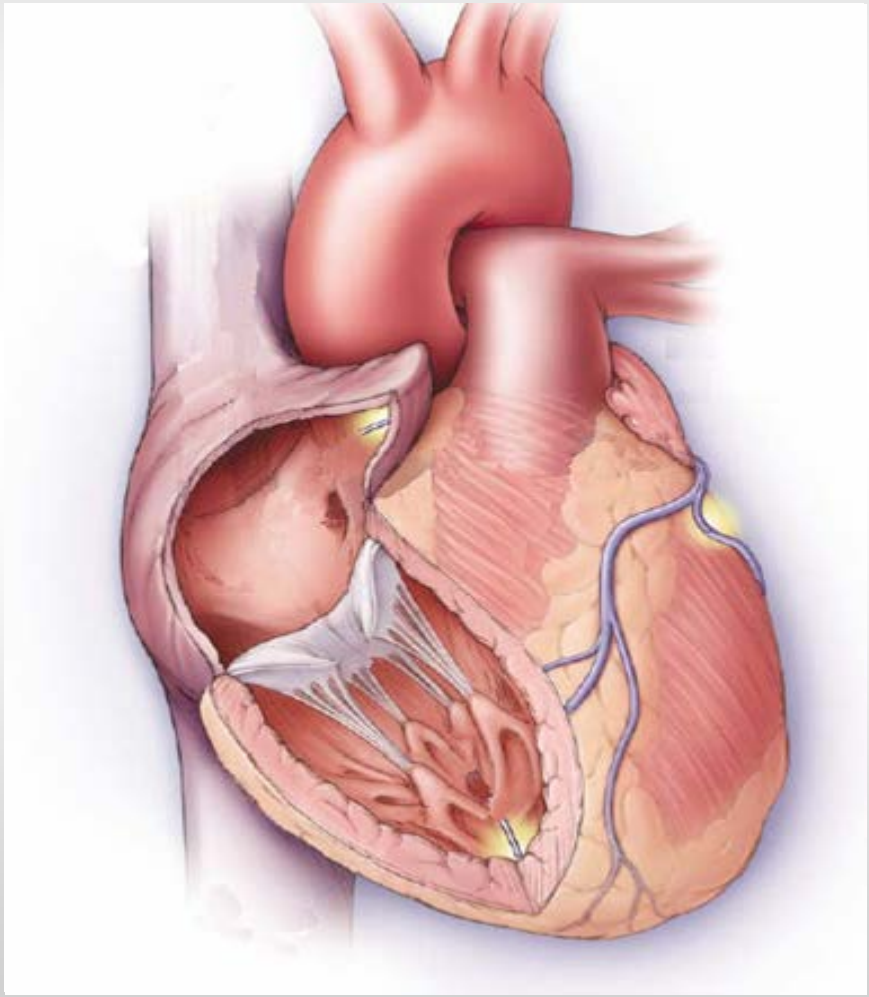
Implantation 05.07.1995 Explantation 15.8.2012

Die Lösung?

Keine Elektrode

auf oder im

Herzen



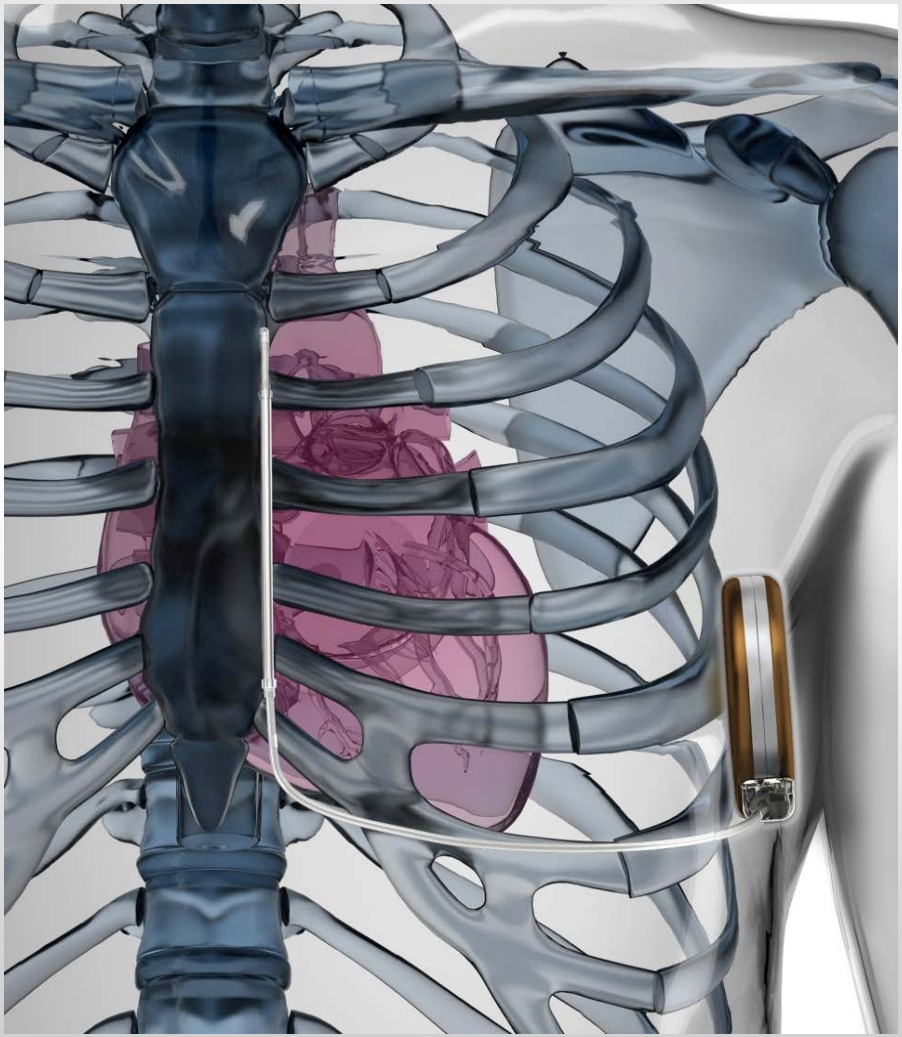
Vergleich intra- und postoperativer Komplikationen transvenöser versus subcutaner ICD-Systeme

Transvenöses ICD-System

- **Pneumothorax/ Haematothorax**
- **Elektrodenfehllagen im linken Ventrikel/Coronarvenöses System**
- **Ventrikelperforation**
- **Elektrodendislokationen**
- **Elektrodenbrüche ?**
- **Taschenprobleme: Haematome, Schmerzen, Perforationen, Infektionen**
- **Bewegungseinschränkungen im Schultergelenk: "frozen schoulder"**
- **Verschlüsse und Stenosen des Venensystems**
- **Risiko der Extraktion**
- **Endokarditis**

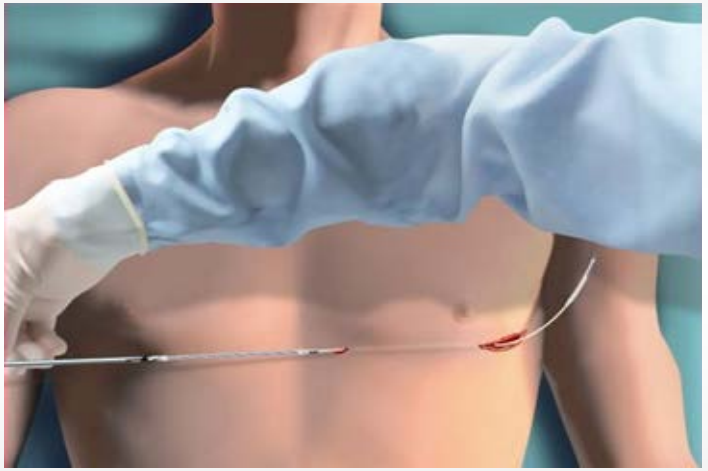
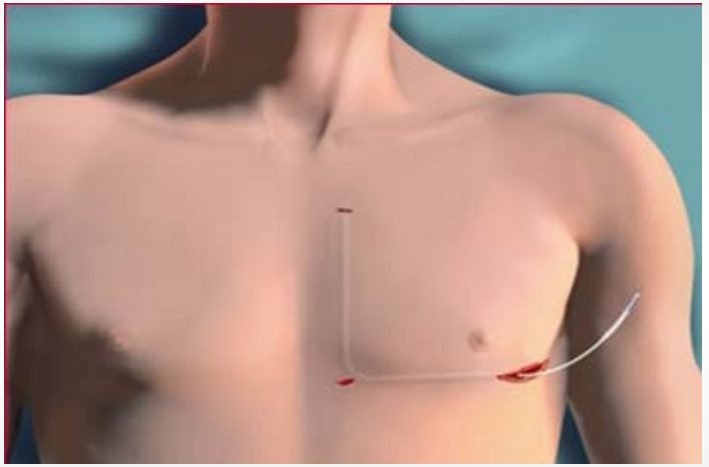
Der subcutan implantierbare Cardioverter/Defibrillator

“eine reine Schockbox”



- **Größe: 78,2 x 68,5 x 15,7 mm**
- **Volumen: 70 cm^3**
- **Gewicht: 145 g**
- **3 Sensing-Vektoren**
- **Maximale Energie: 80 J**
- **Reversed polarity programmierbar**
- **1 oder 2 Zonen programmierbar**
- **Post-shock pacing 30 s**
- **Funktionszeit: ~ 5 Jahre**

S-ICD Implantation

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

111 patients: 19 pts (17%) required 20 re-operations:

- **11 pts infection**
  - **4 pts device removal for infection**
  - **7 pts superficial infection (only antibiotics)**
- **9 pts device erosion with chronic pain**
  - **2 pts device removal**
  - **7 pts device repositioning**

11.7% Pocket problems

- **5 pts T-wave oversensing**
  - **5 pts device explantation (1 pt with infection)**
- **1 pt electrode movement**

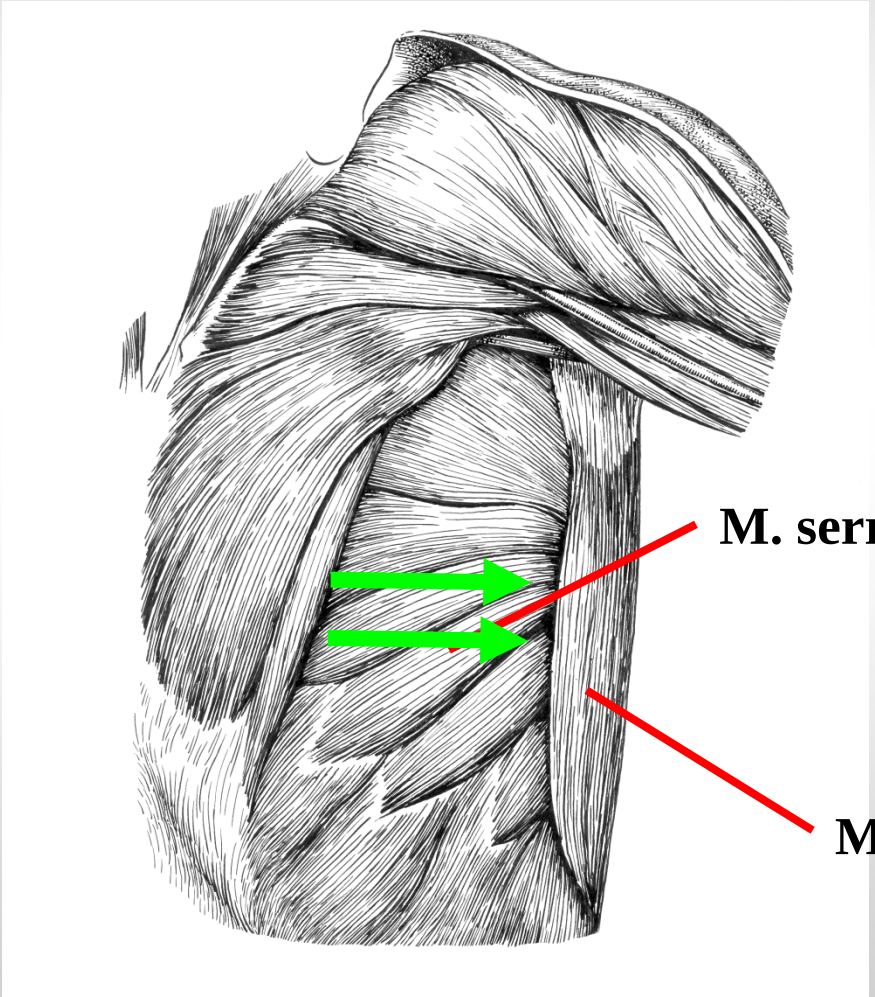
5.4% Lead problems

- **2 pts premature battery depletion**

Jarman et al.: Europace Advance Access published February 28, 2013

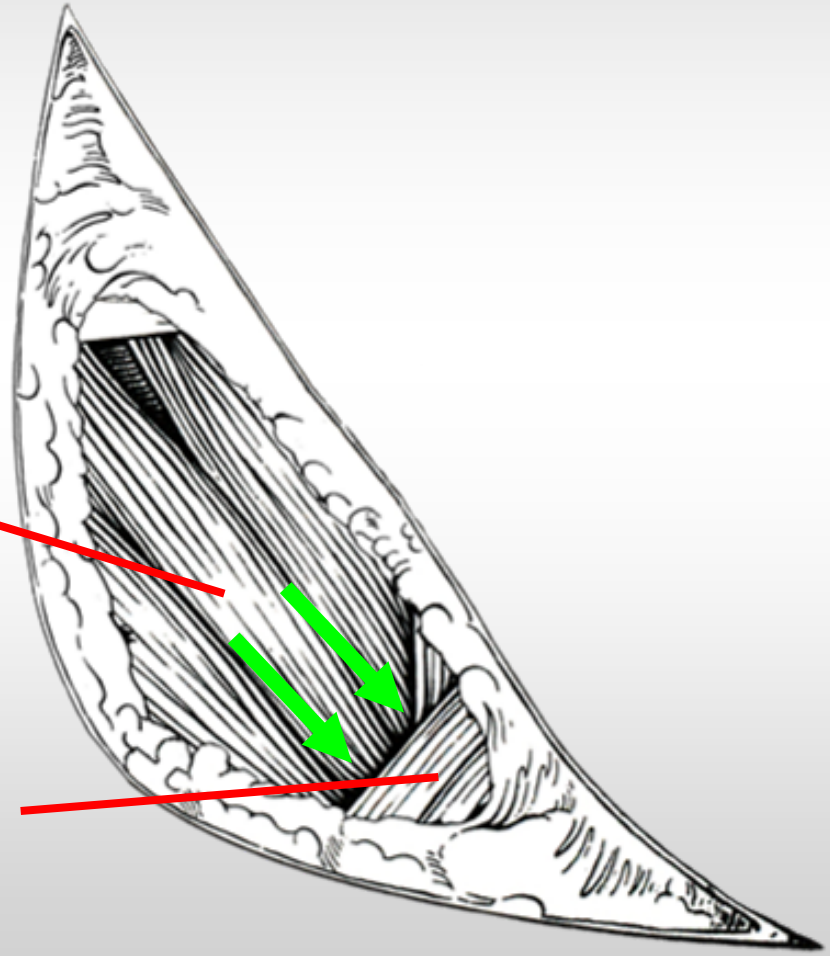
Vollständig subkutan? implantierbares Cardioverter/Defibrillator-System (S-ICD)

Intermuskuläre S-ICD-Implantation



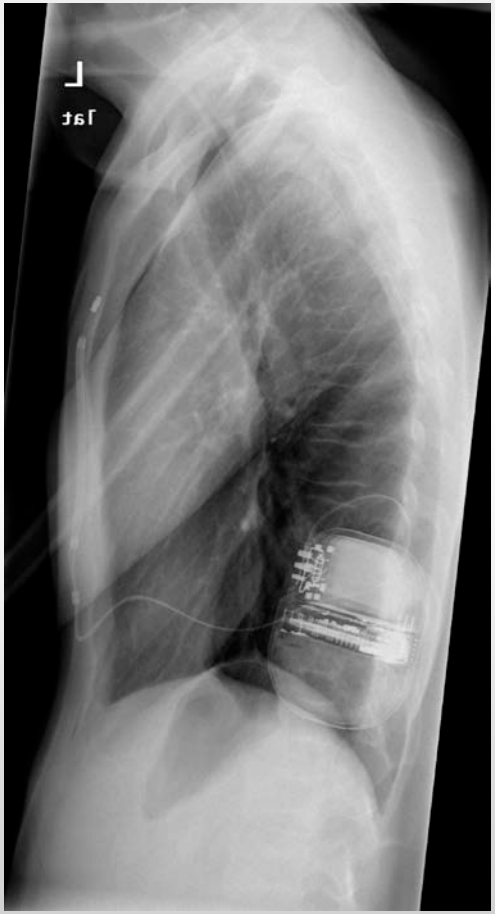
M. serratus anterior

M. latissimus dorsi



Pat.: F.R. *01.11.1997

Brugada-Syndrom, S-ICD Implantation 17.07.2011



S-ICD Indikationen

- **Erste Wahl:**
  - **Kein venöser Zugang zum rechten Ventrikel möglich**
  - **Ionenkanalstörungen**
  - **Dialysepatienten?**
  - **Hohes Endokartisrisiko**
  - **Nach Explantation infizierter transvenöser Systeme**
- **Engere Wahl:**
  - **Junge Patienten, Lebenserwartung > 10 Jahre**
  - **Bridge-to-Transplantation**
- **Keine Indikation:**
  - **Herzinsuffizienz mit LSB (CRT-Indikation)**
  - **Bradykardien mit Stimulationsbedarf**
  - **Überstimulierbare monomorphe VTs (ATP)**
  - **Körpergewicht < 35 kg**

S-ICD System: Personal Experiences

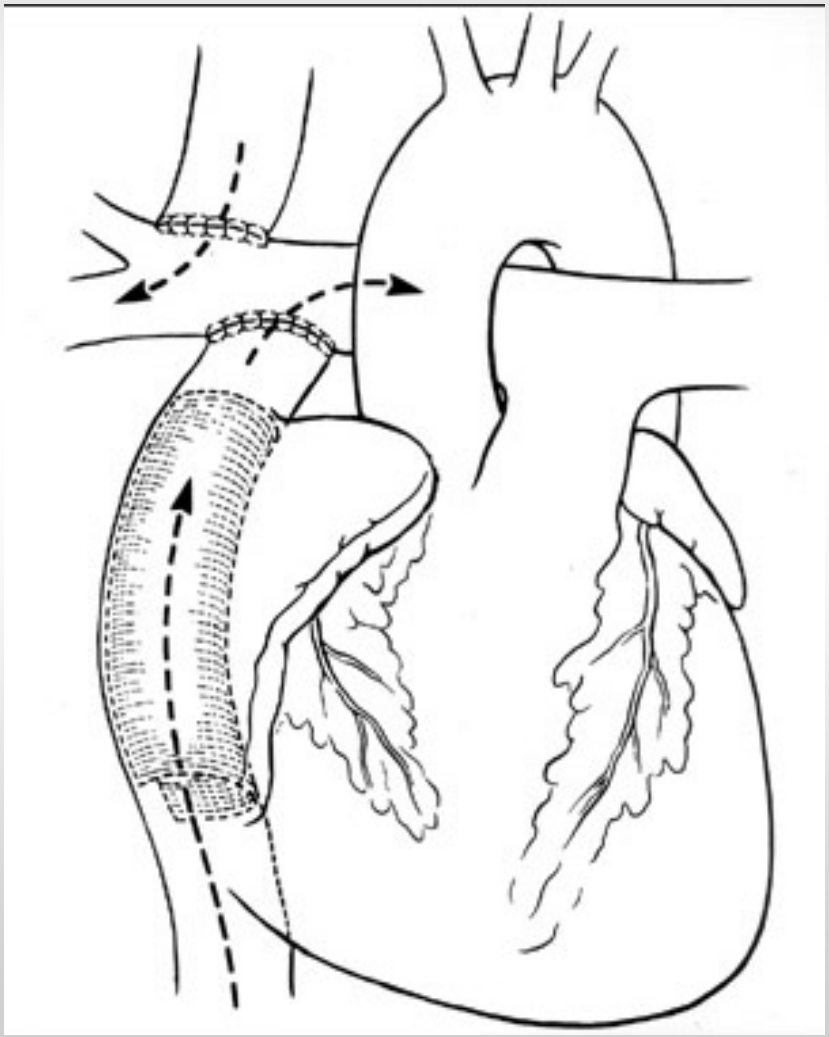
Contraindications:

- Bradycardia pacing
- ATP
- CRT-Indication
- Body weight < 30 kg

Advantages:

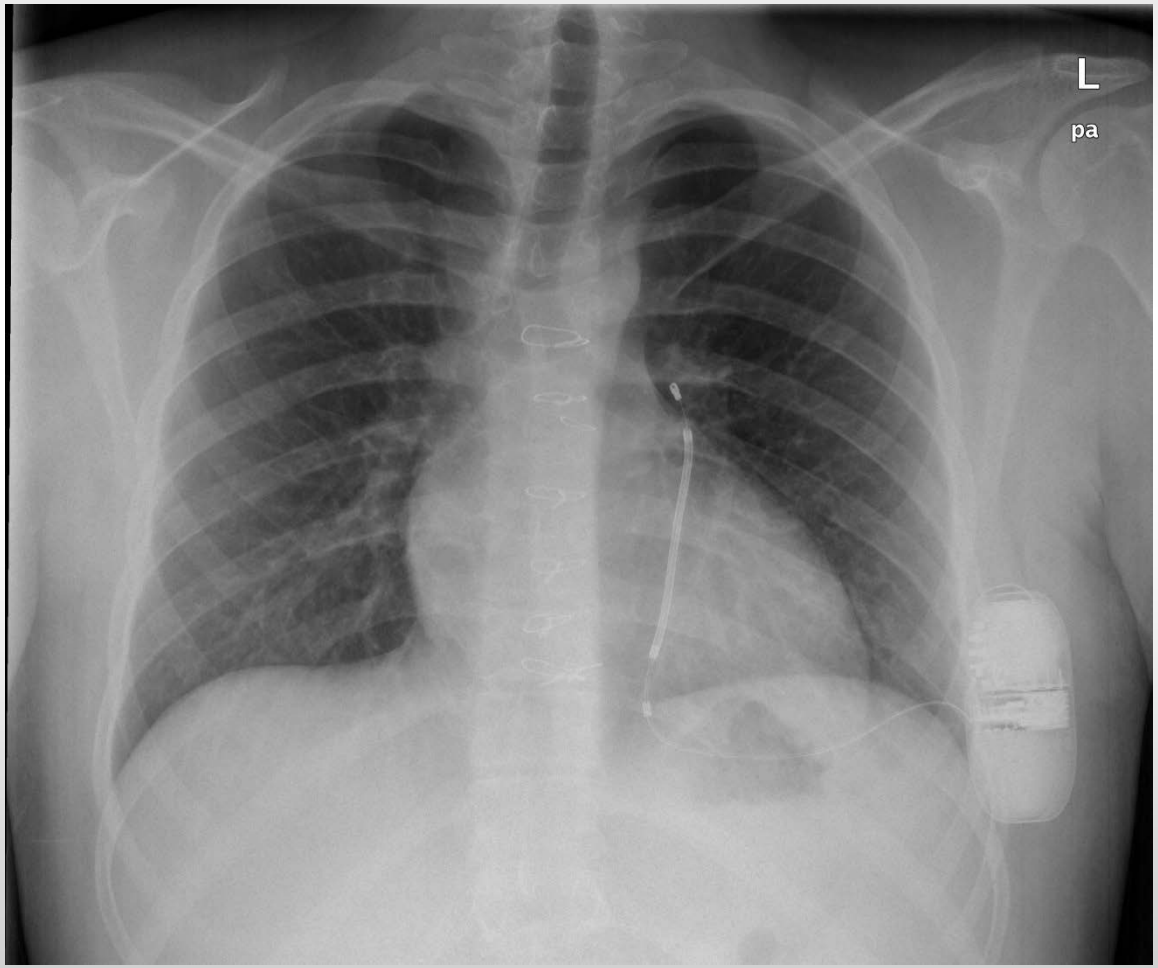
- Implanted without access to venous system
- Vasculature is preserved
- Any infection is not life threatening
- If required, explantation is simple

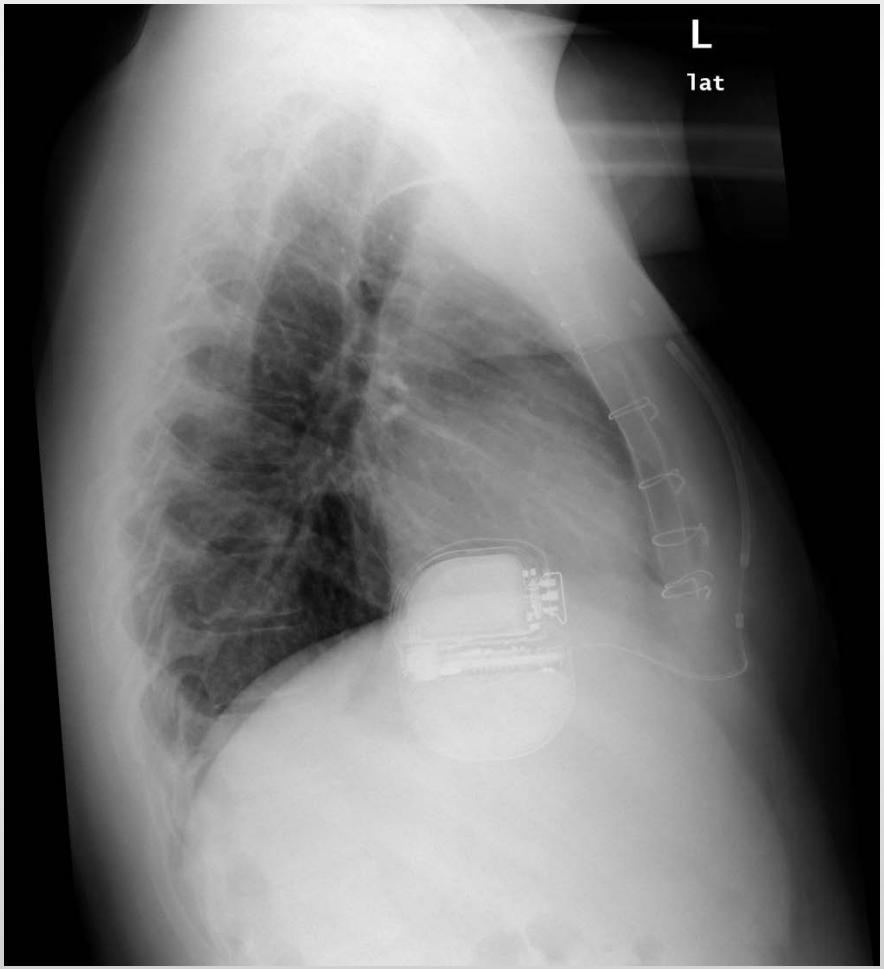
Fontan-Operation
TCPC



Pat.: H.R. *30.01.1989

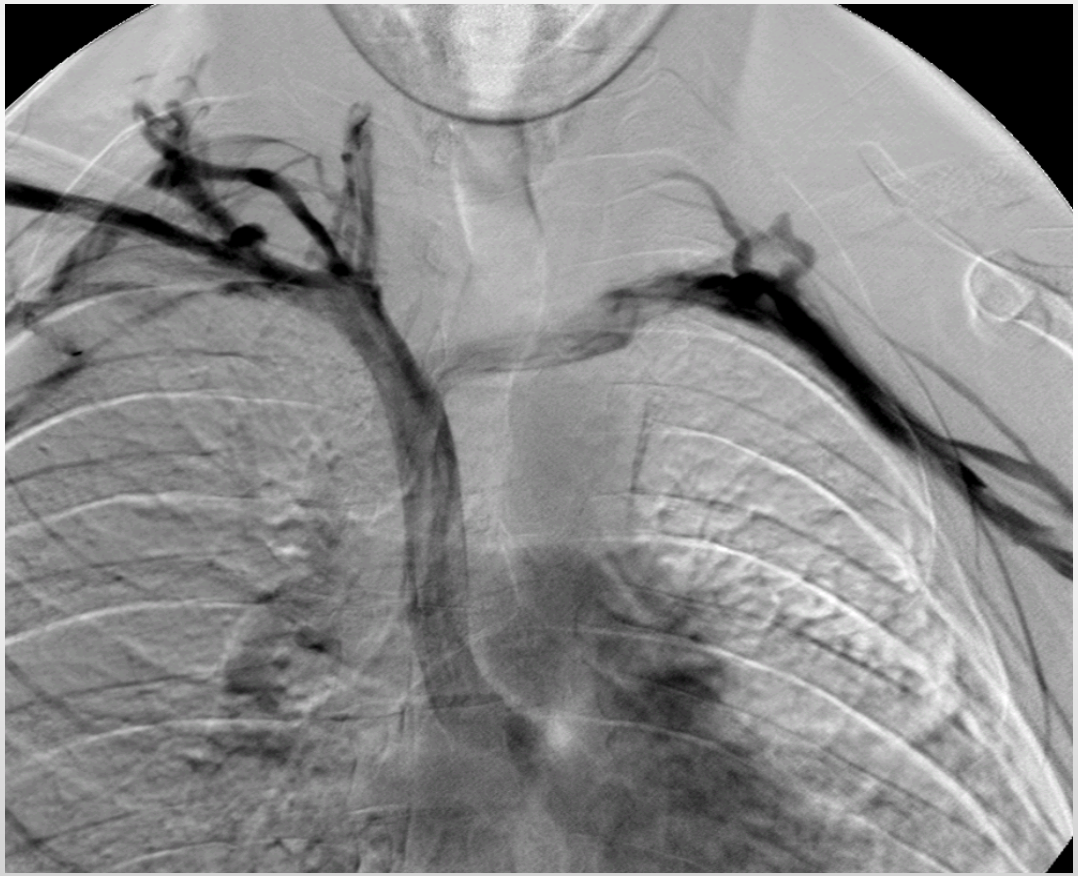
AV septal defect with hypoplastic RV and VSD, surgical reconstruction 1995, 2003 Fontane Procedure(TCPC). 02.06.2010 VF, CPR

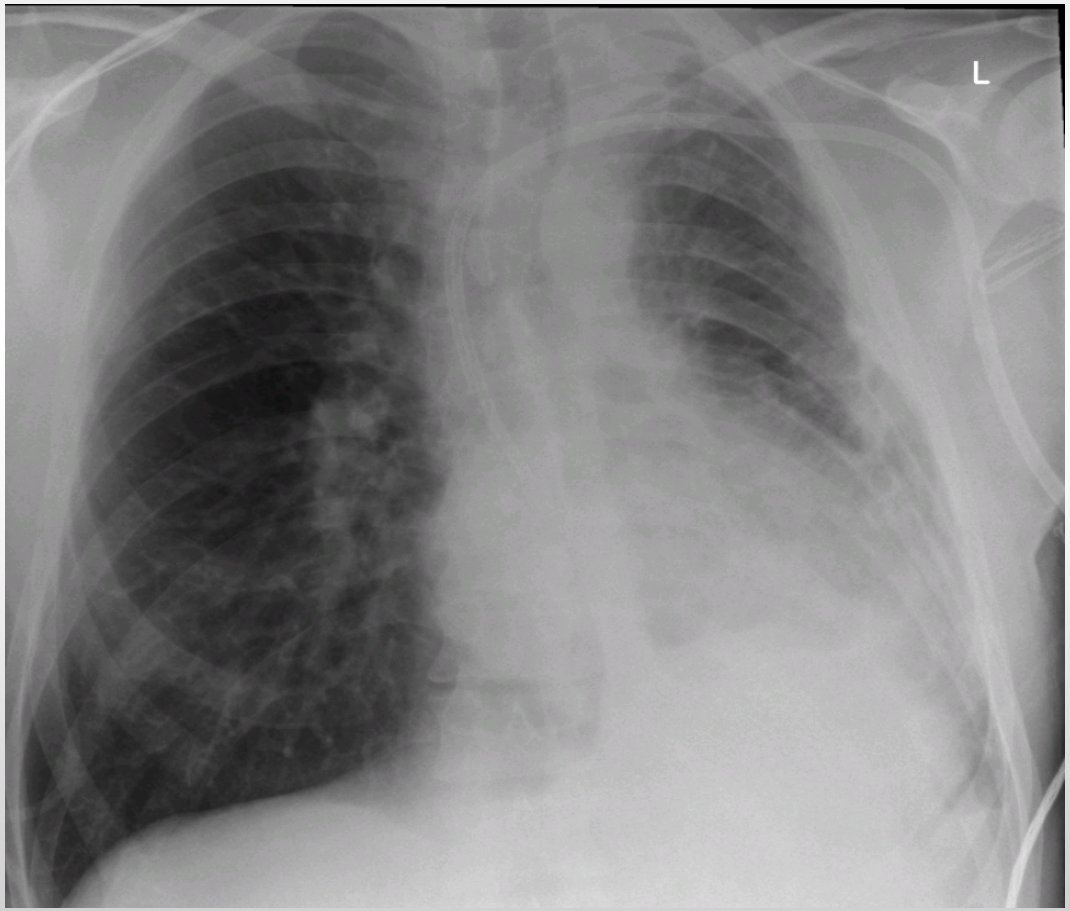




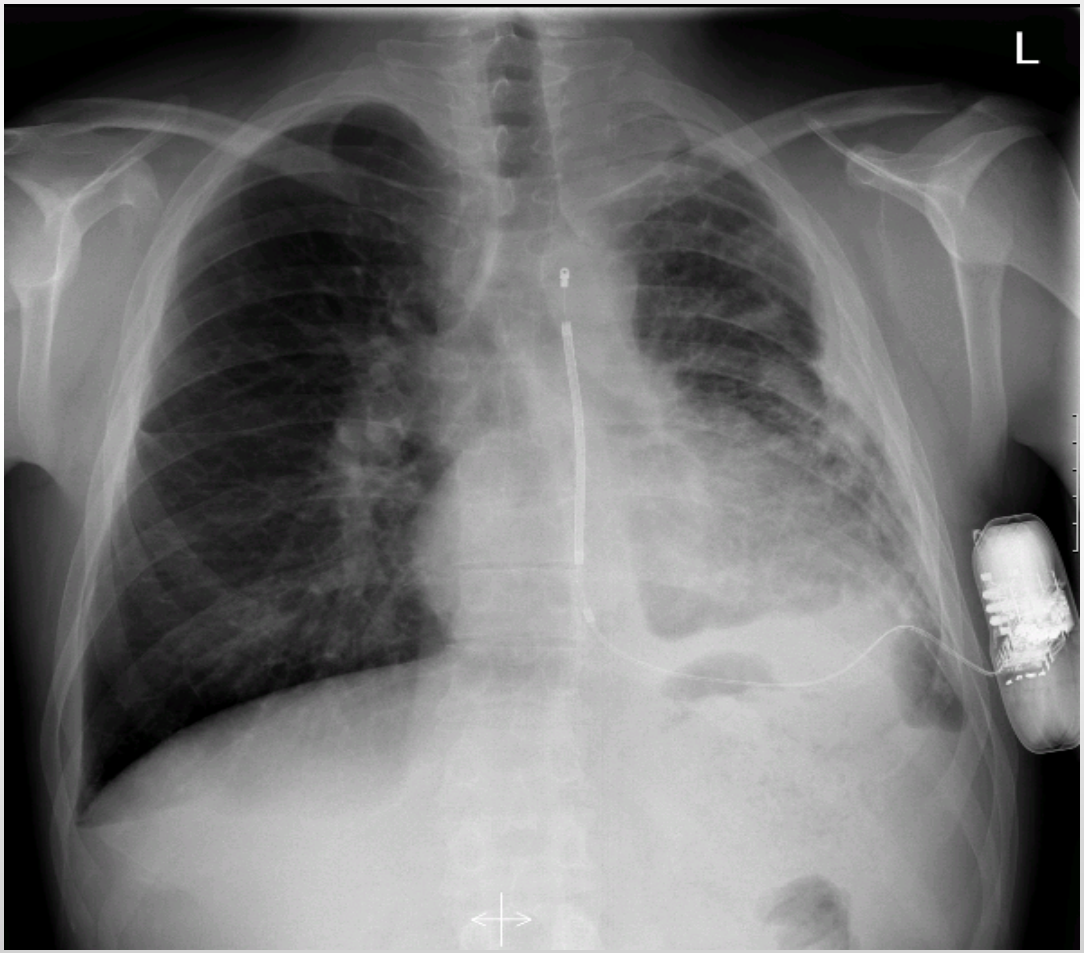
Pat.: A.P. *11.11.1978

TGA, Mustard procedure 1979, multiple shunts for renal dialysis





Pat.: A.P. *11.11.1978



Results of a Multicenter Retrospective Implantable Cardioverter-Defibrillator Registry of Pediatric and Congenital Heart Disease Patients

- 443 patients
- Median age 16 yrs (range 0-54 yrs)
- Congenital Heart Disease 46%
- Unclear length of follow-up
- Implant dates 1992 – 2004
- Lead problems in 15% (68/443)

Berul et al.: JACC, 51, 1685, 2008

Results of a Multicenter Retrospective Implantable Cardioverter-Defibrillator Registry of Pediatric and Congenital Heart Disease Patients

	No. of Complications
Acute Complications (Perioperative or Within 30 Days of Implant)	
Lead dislodgement	13
Inability to defibrillate or unacceptable DFT	9
Bleeding or pocket hematoma	8
Infection	7
Unsuccessful transvenous lead placement	6
Electrical storm	5
Hemothorax or pneumothorax	4
EMD/PEA	4
Skin erosion	3
SVC syndrome	2
Skin burns	2
Pneumonia and ileus	1
Total acute complications	64 (in 55 patients)

Berul et al.: JACC, 51, 1685, 2008

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Prevalence of Asymptomatic Upper Extremity Venous Obstruction in 302 Patients Undergoing First Implantation of Cardioverter Defibrillator

Abnormal Bilateral Venogram Findings in 302 Patients (n=22, 7.3%)

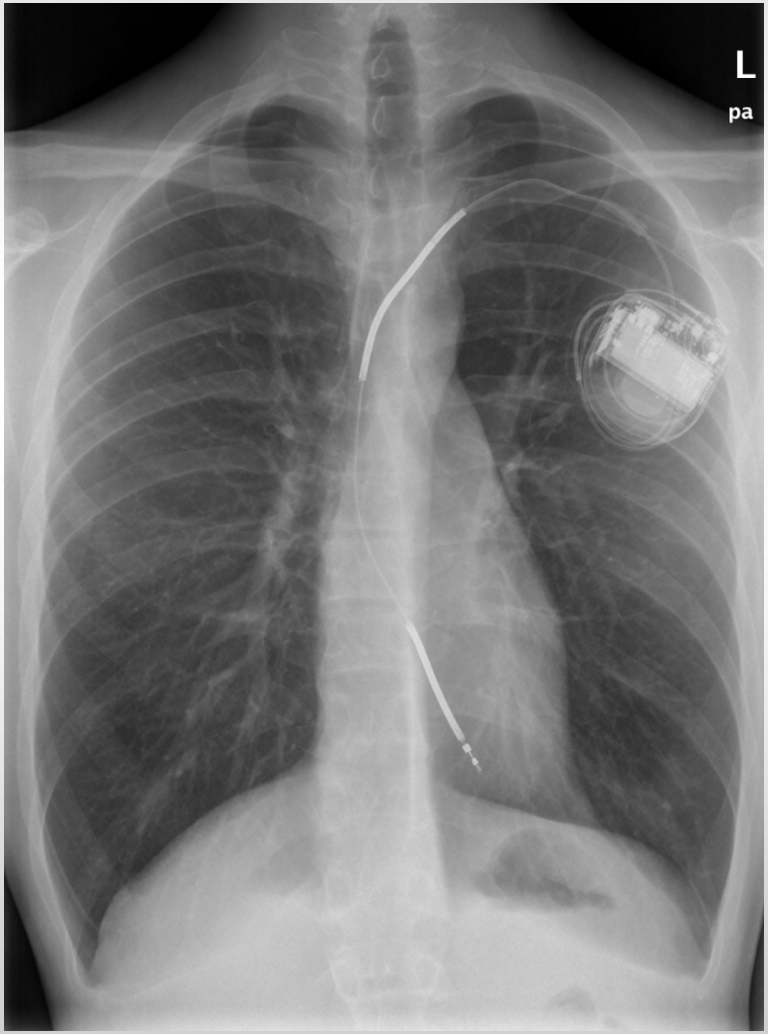
Upper vein obstruction (n = 20, 6.6%)

	Left Side	Right Side	Total
Obstruction			
Subclavian vein	4	9	13 (59%)
Axillary vein	2	2	4 (18%)
Brachiocephalic vein	1	1	2 (9%)
Subclavian and brachocephalic vein	1	0	1 (5%)
Persistent left superior vena cava	2		2 (9%)
Total	10	12	22 (100%)

Linhart et al.: PACE 34,684,2011

Pat.: D.M. *12.09.1983

Implantation 07.09.2007



Revision 02.12.2009

Incidence of venous obstruction Following insertion of an ICD

A study of systematic contrast venography on patients presenting for their first elective ICD generator replacement

- **105 consecutive patients**
- **Bilateral contrast venography 47 ± 12 months after first single chamber ICD-implant**

Moderate stenosis (50-75% diameter reduction): 10%

Severe stenosis (< 75 % diameter reduction): 6%

Total occlusion: 9%

= 25%

- **Risk factors: Dual-Coil-Electrode**
  PM-implant prior to ICD-implant

Lickfett et al.: Europace 6, 25, 2004

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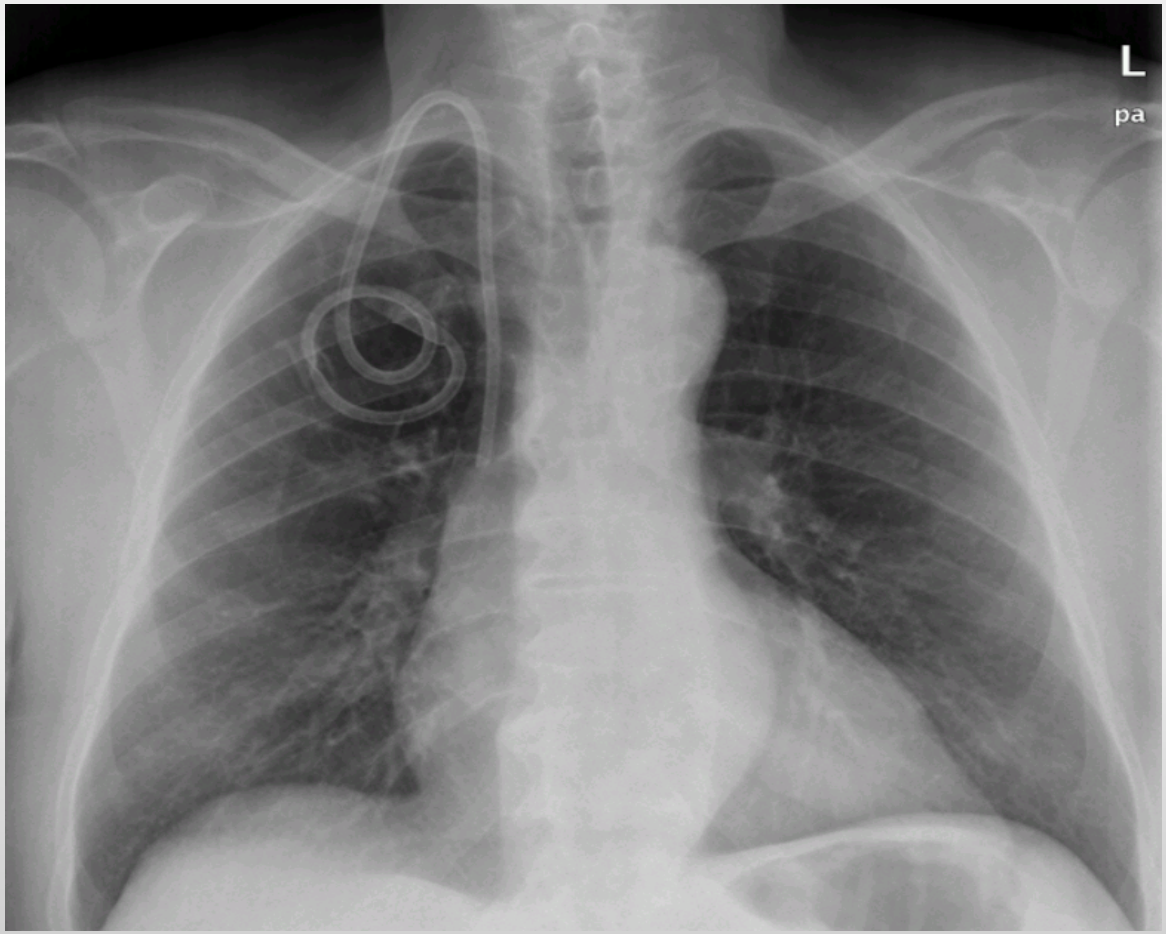
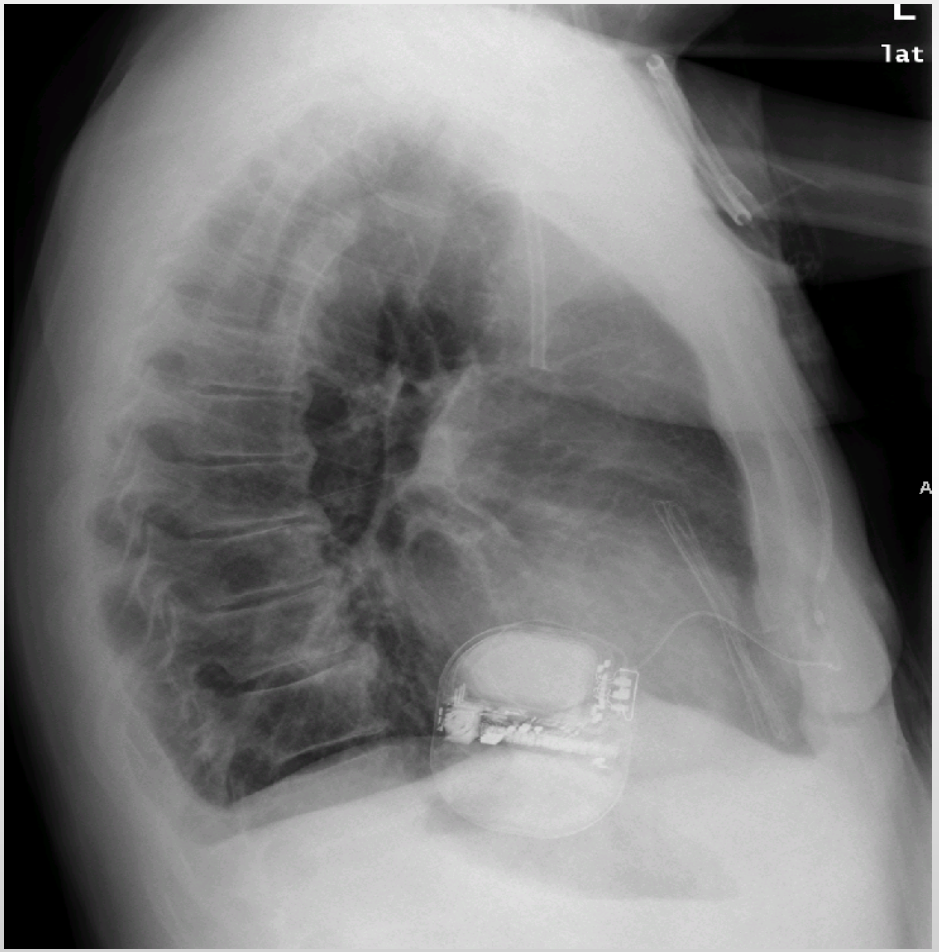
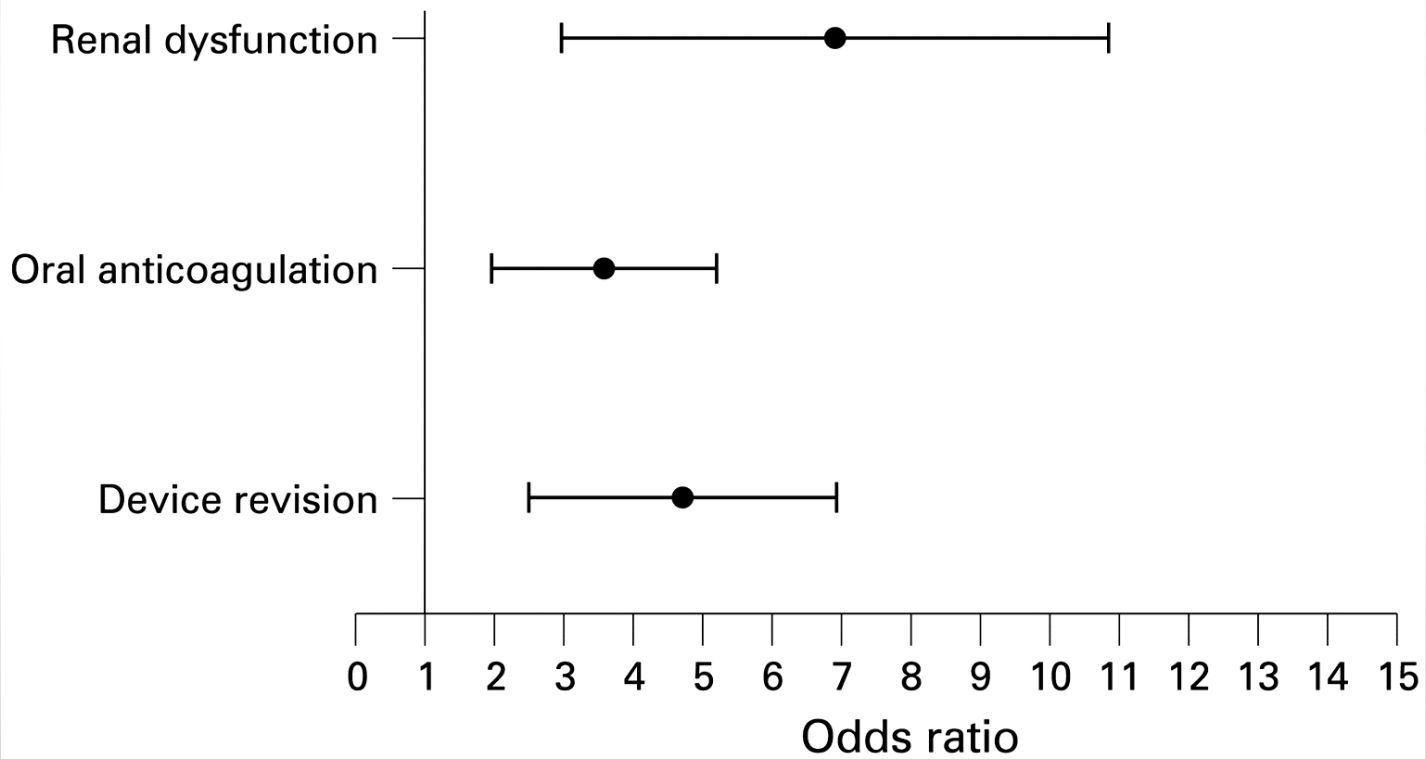
Pat.: B.W. *18.12.1939

Demers-Katheter right, Occlusion of left subclavian V.





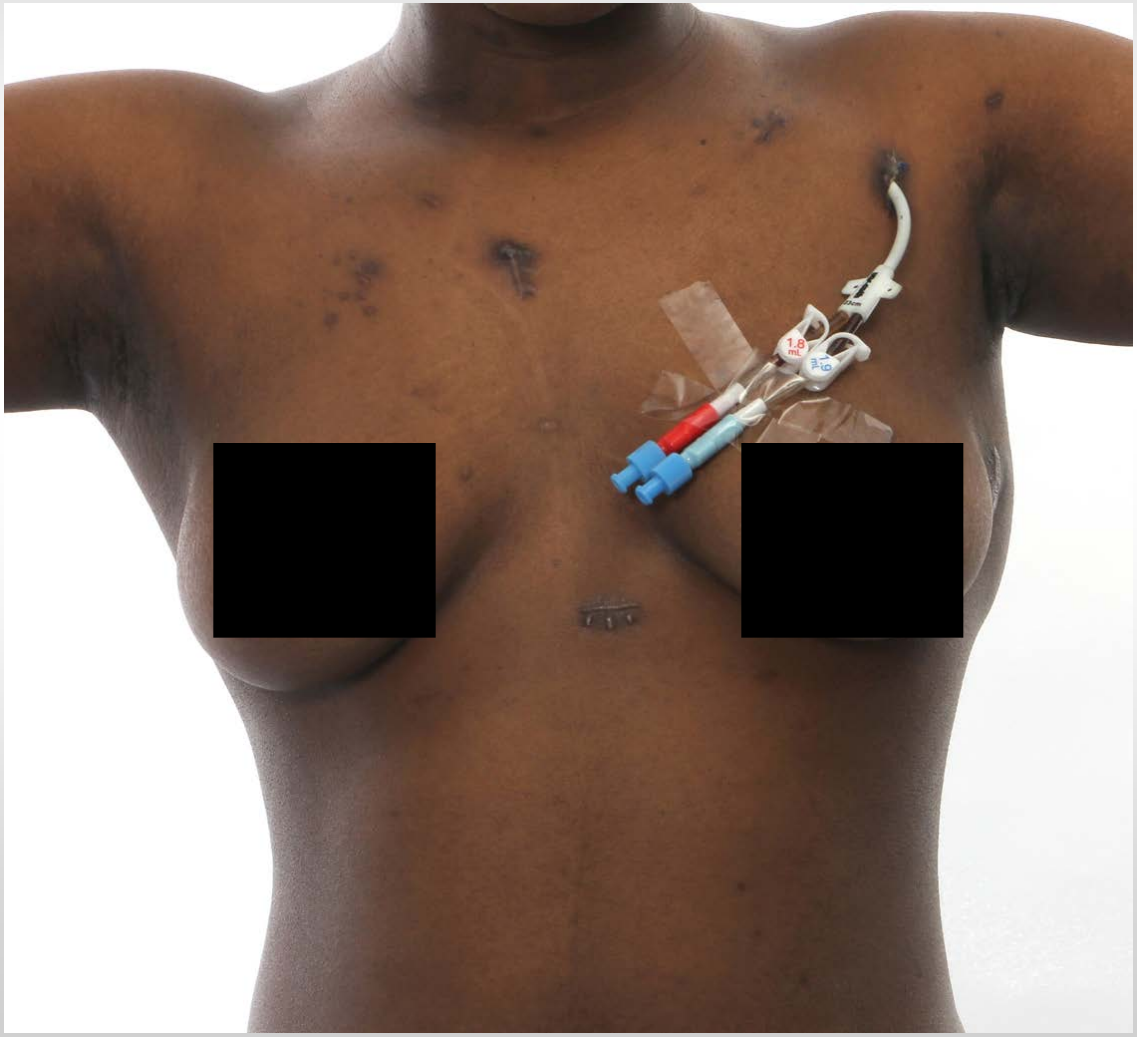
Risk factors and time delay associated with cardiac device infections: Leiden device registry

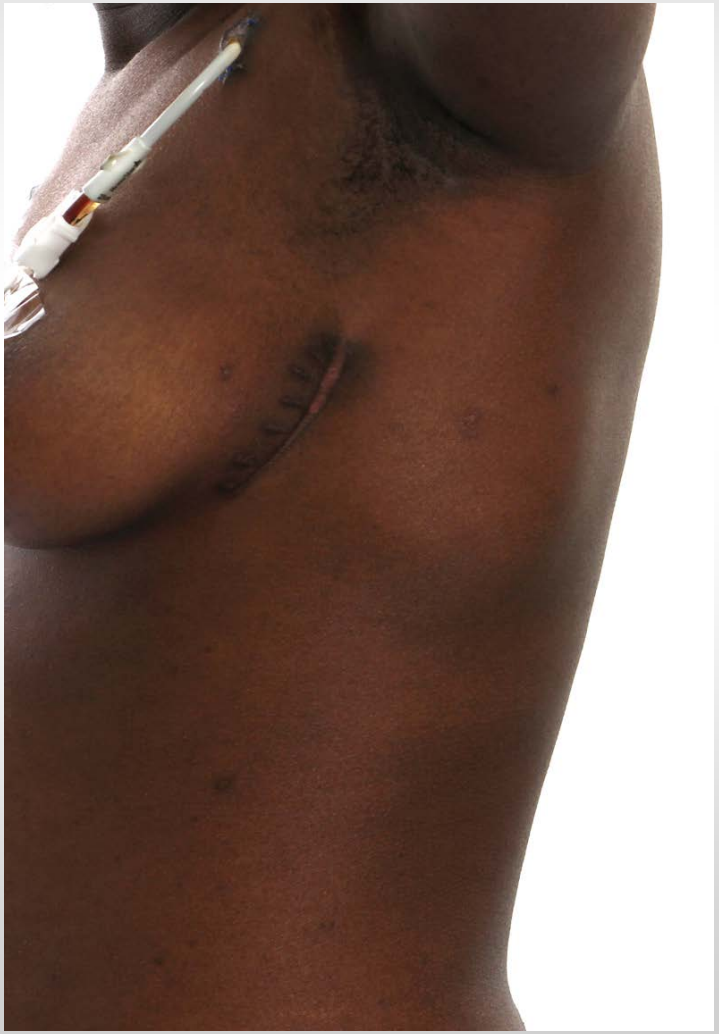


Lekkerkerker et al.: Heart 95, 715, 2009

Pat.: D. L. *13.02.1995

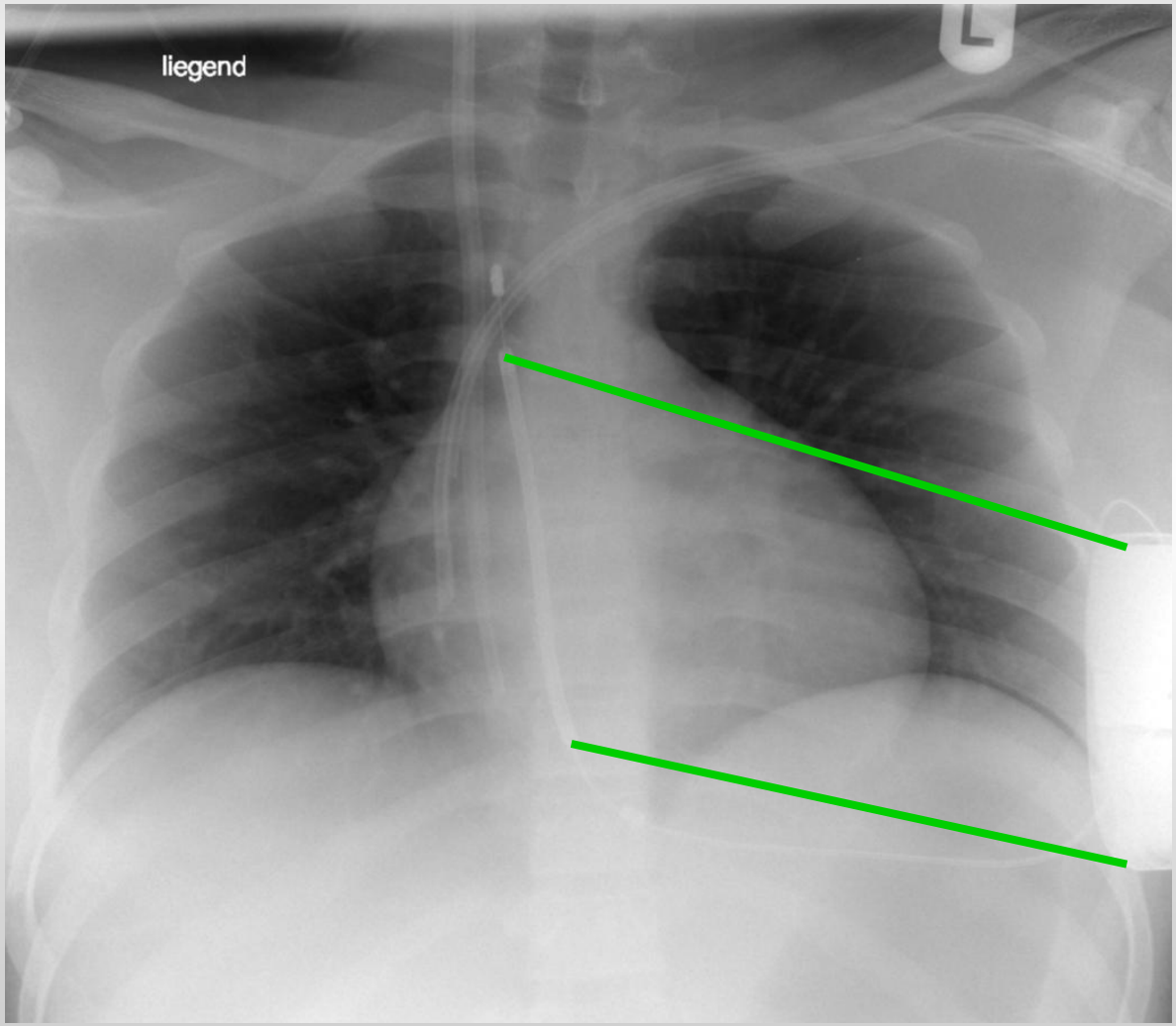
Implantation 22.02.12





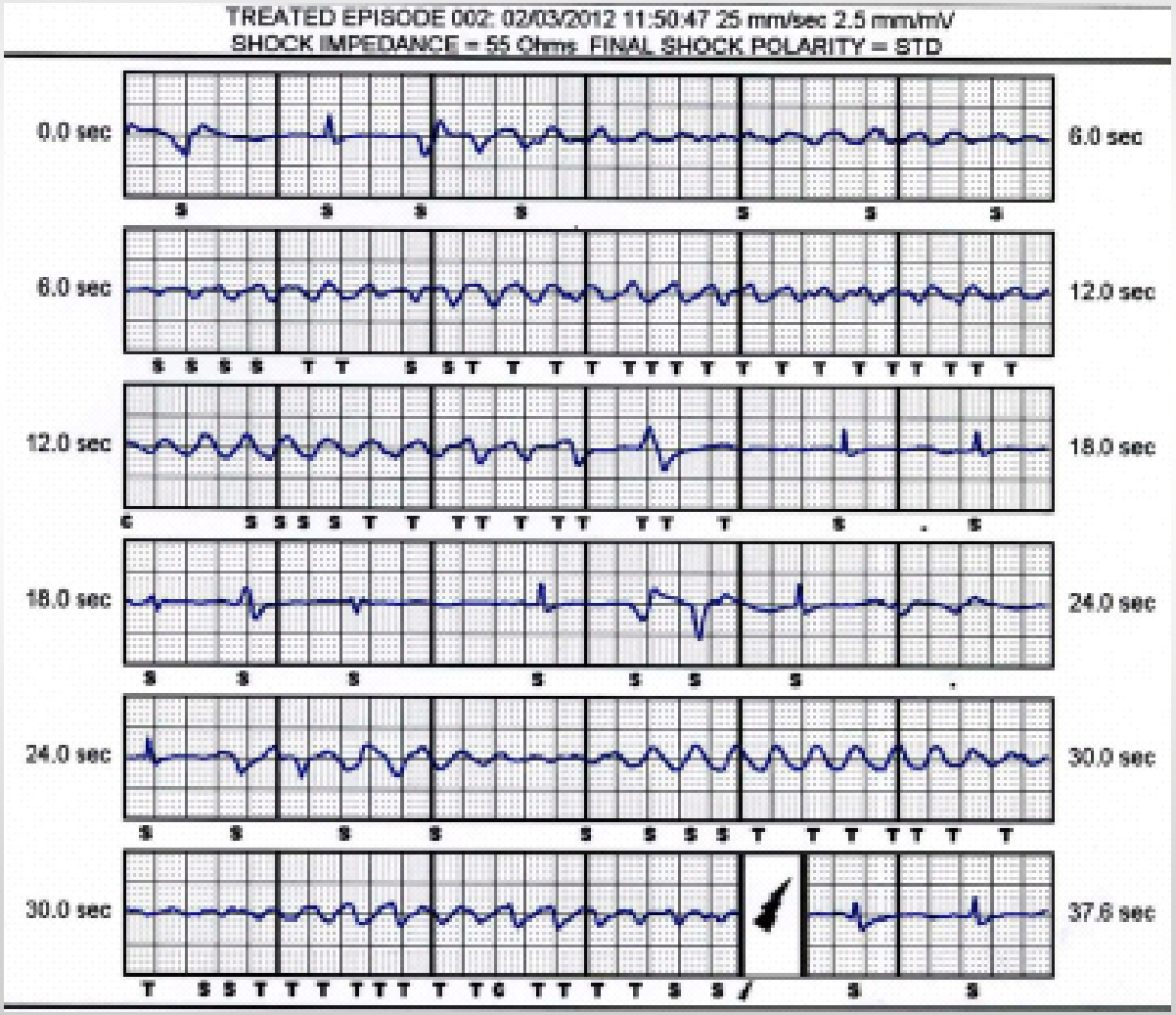
Pat.: D. L. *13.02.1995

Long QT-Syndrome, CPR 23.01.12, ECLS, S-ICD Implantation 22.02.12



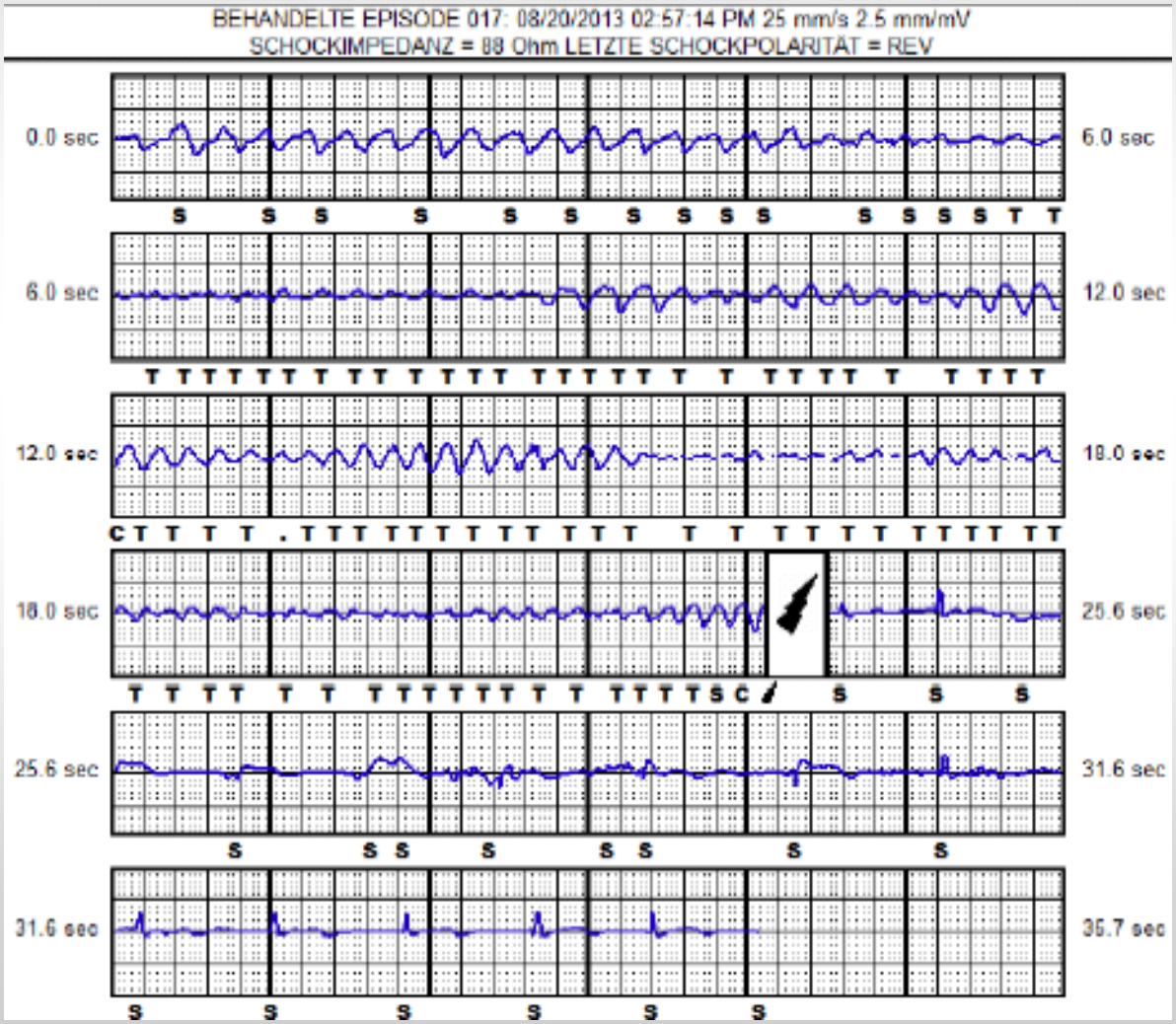
Pat.: D. L. *13.02.1995

Implantation 22.02.12, 02.03.12 Torsade de pointes



Pat.: D. L. *13.02.1995

Implantation 22.02.12, 20.08.13 VF



S-ICD System: Personal Experiences

Contraindications:

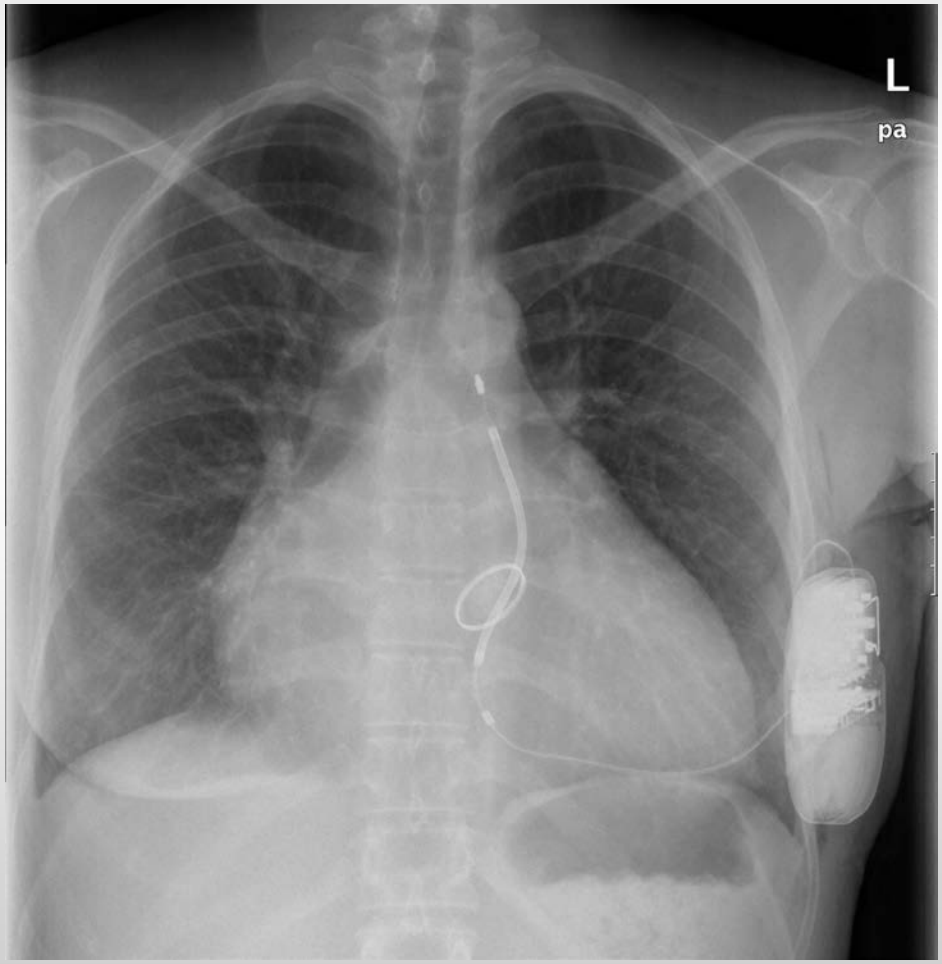
- Bradycardia pacing
- ATP
- CRT-Indication
- Body weight < 30 kg

Advantages:

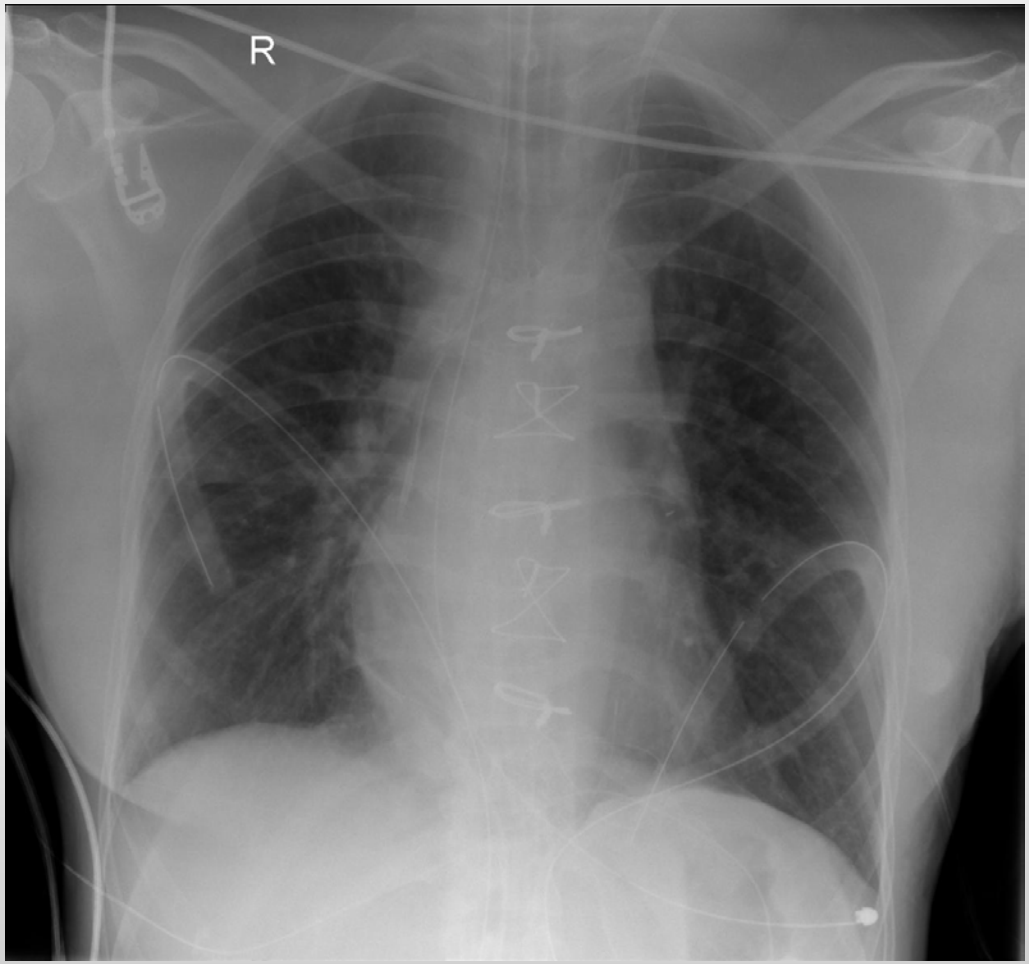
- Implanted without access to venous system
- Vasculature is preserved
- Any infection is not life threatening
- If required, explantation is simple

Pat.: A.R. *26.05.1978

S-ICD 12.8.2011



HTX 1.9.2011



Frequency and Sequelae of Retained Implanted Cardiac Device Material Post Heart Transplantation

56 of 100 HTX-Patients had a CIED in situ
Hardware was retained postoperatively in 22 pts (39%)

	Confined to the Device Pocket Only	Confined to the Central Venous System Only	Present in Both the Device Pocket and Central Venous System
Any hardware	5	7	10
Lead fragment	1	7	7
Suture sleeve only	4		
Lead fragment and ICD generator			3

Martin et al.: PACE, 37, 242, 2014

S-ICD System: Personal Experiences

Contraindications:

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- Body weight < 30 kg

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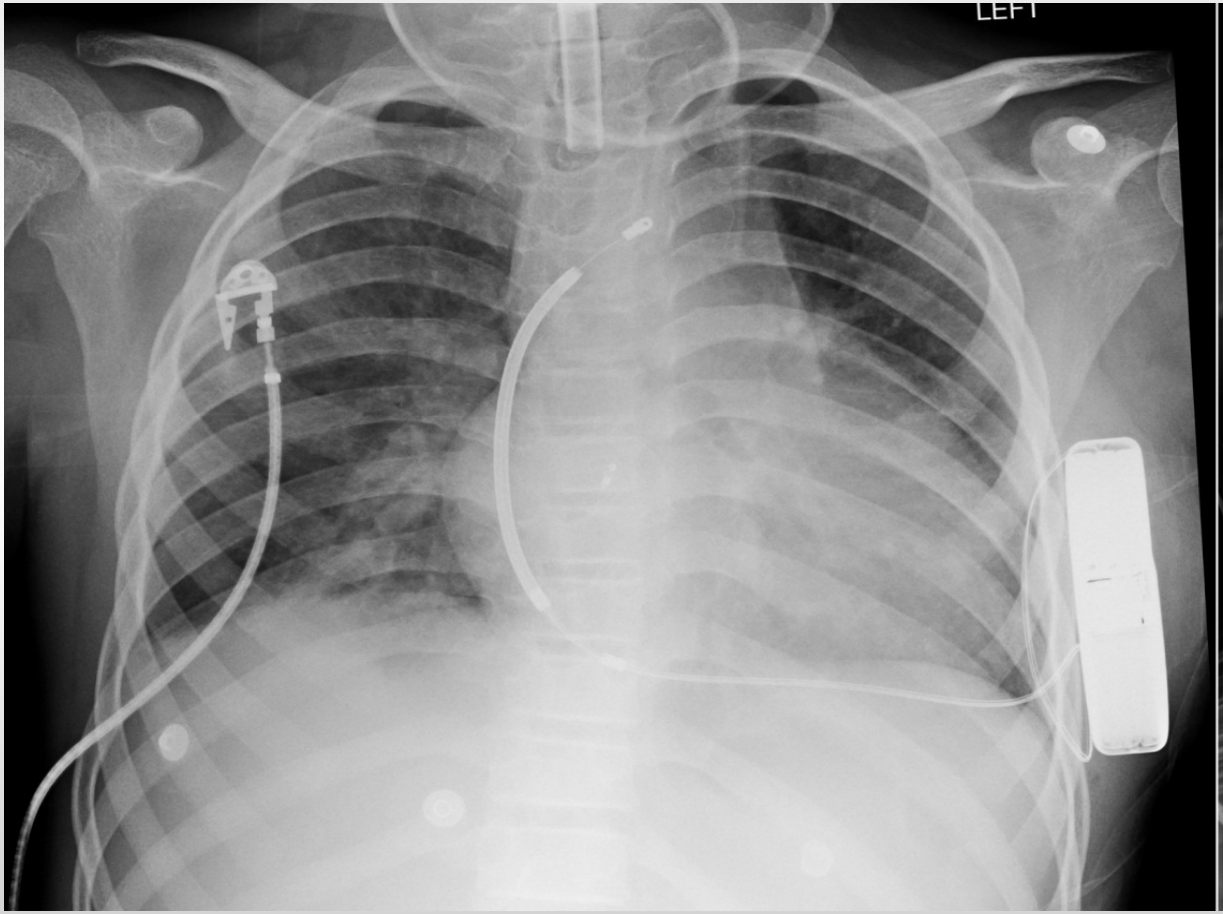
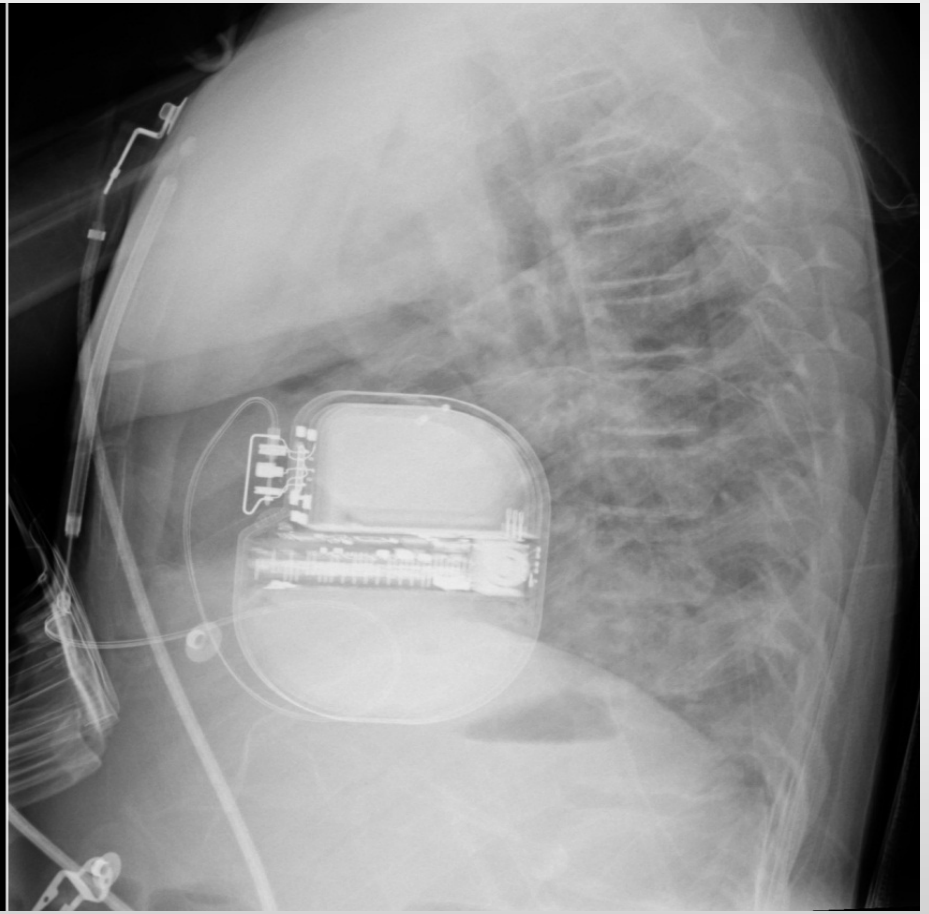
S-ICD-Implantation

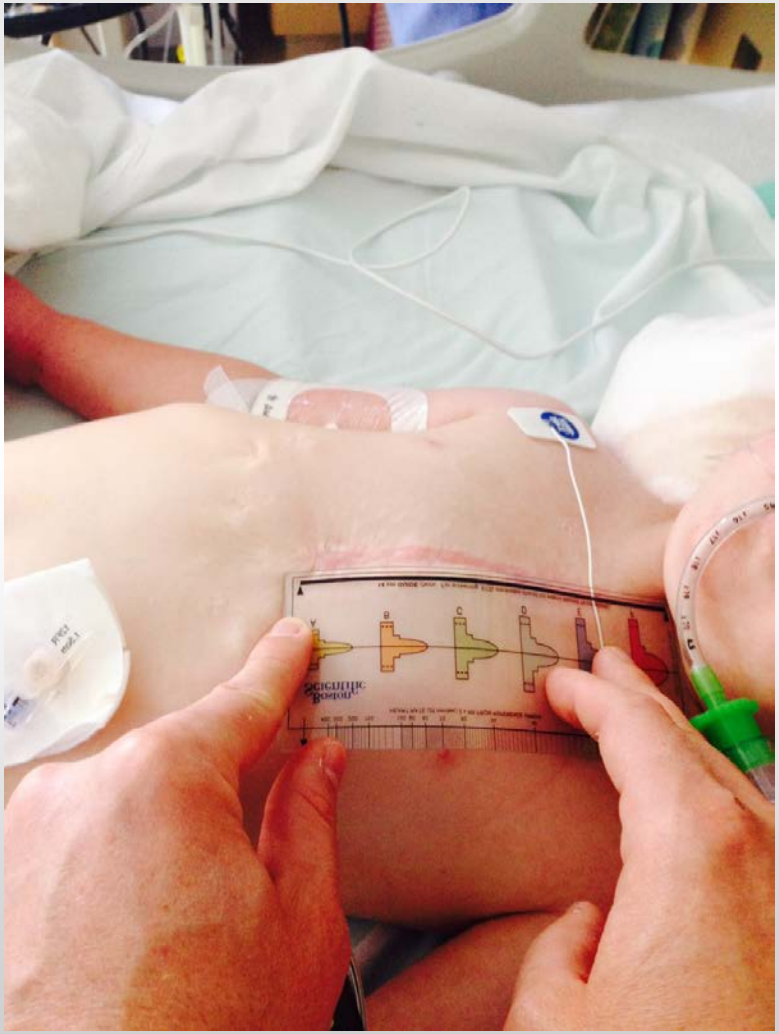
Körpergewicht > 30 kg?

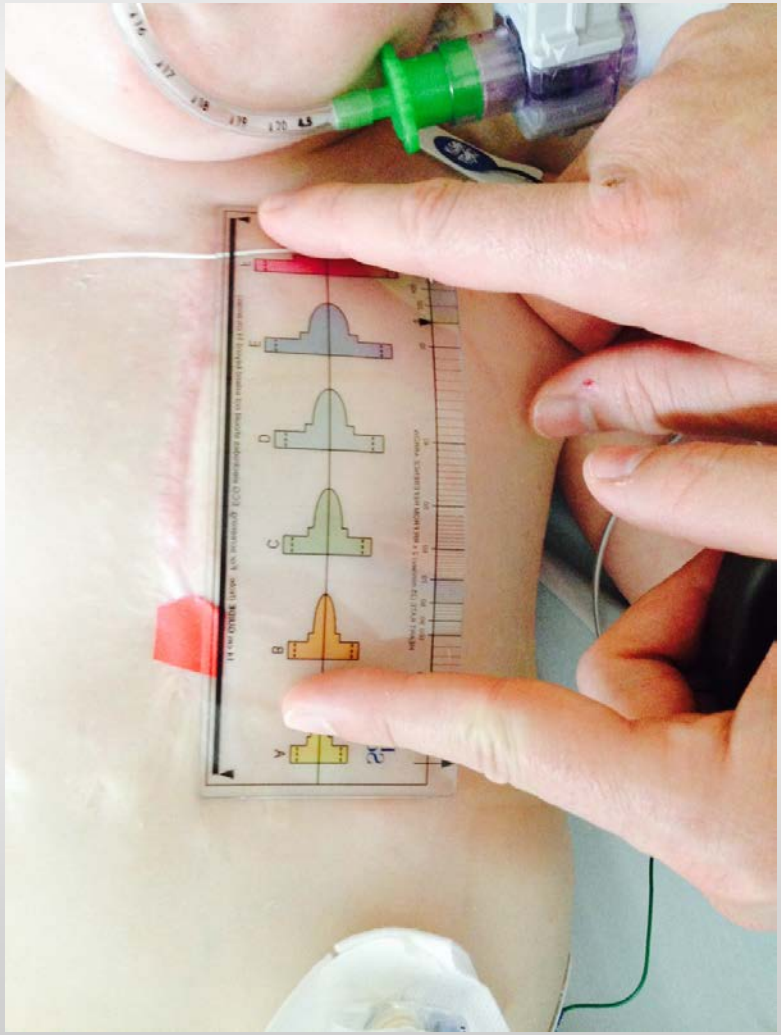




S-ICD-Implantation

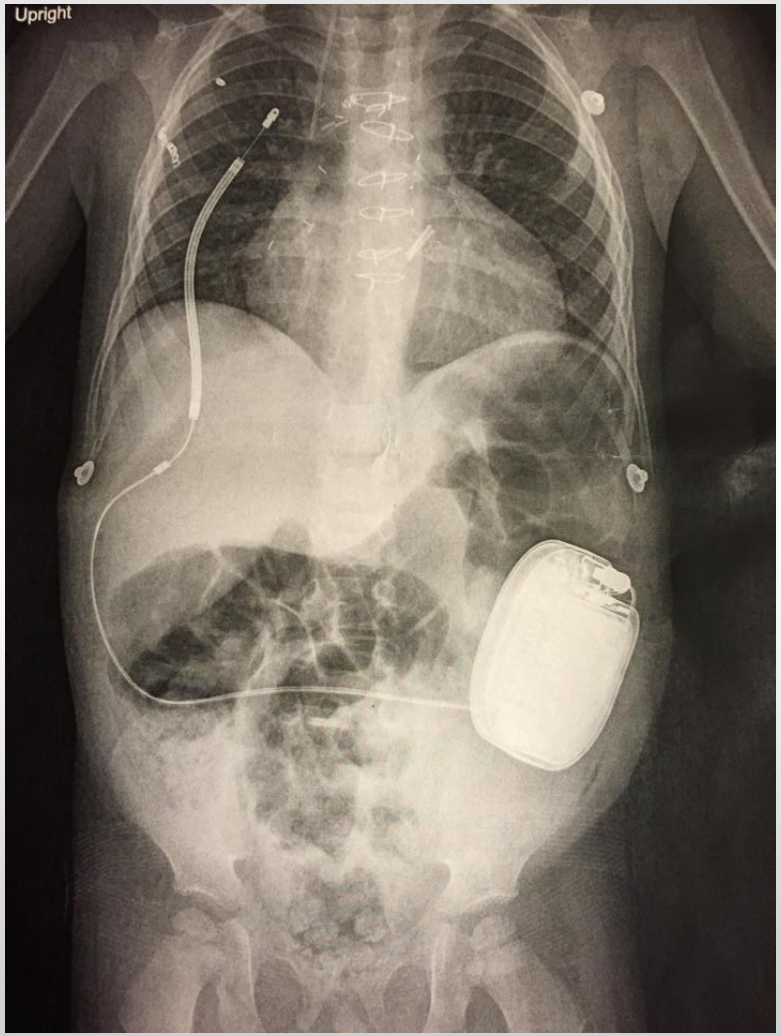
Körpergewicht < 30 kg?

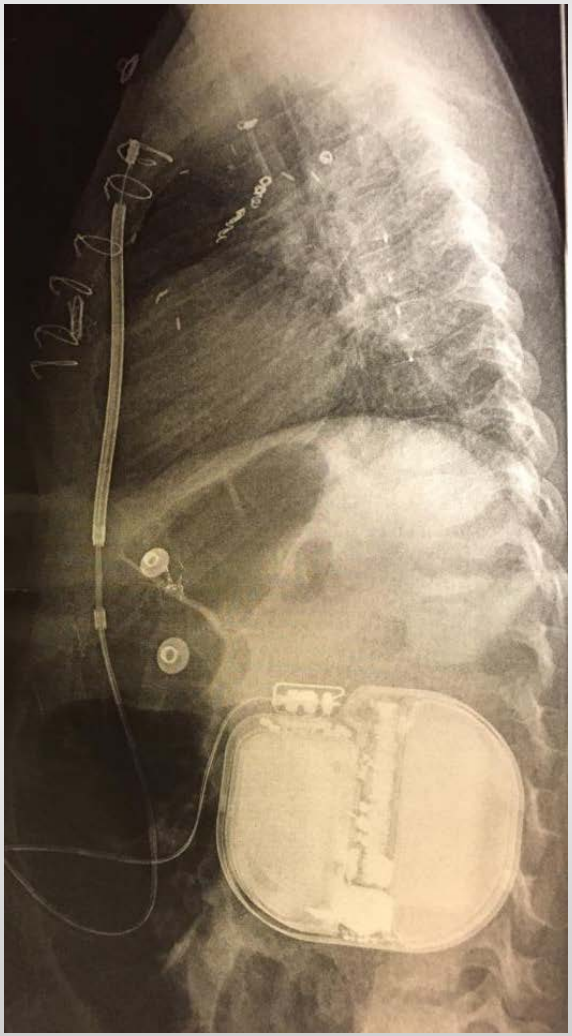




S-ICD-Implantation

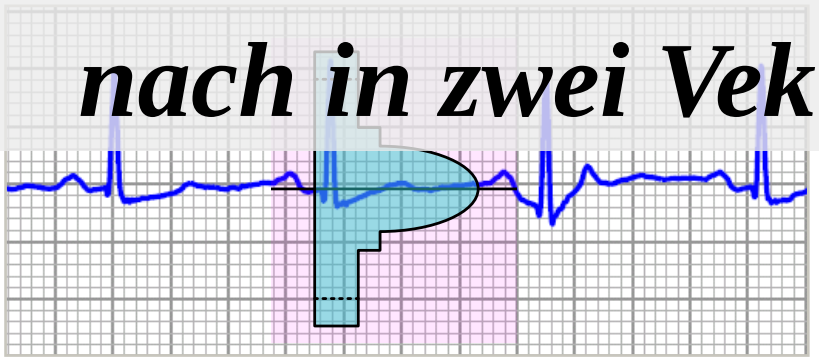
Körpergewicht < 30 kg?

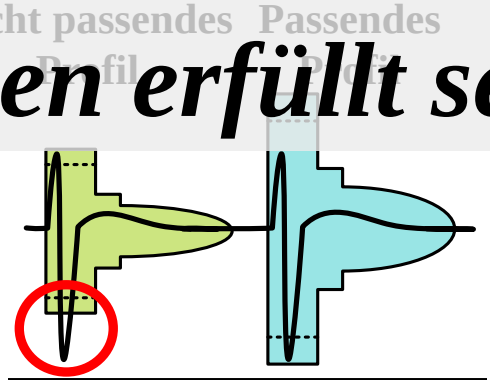


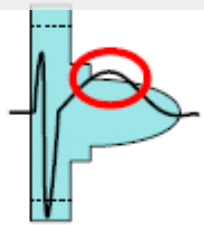


Präoperatives Screening

- ***Akribisches EKG-Screening ist die Grundvoraussetzung für eine sichere Erkennung***
- ***Die Einschlusskriterien sollten m.E. nach in zwei Vektoren erfüllt sein***







How many patients fulfil the surface electrocardiogram criteria for subcutaneous implantable cardioverter-defibrillator implantation?

„About 82,2% of patients (n=196) with a indication for a primary or secondary prevention ICD have a surface ECG that is suitable for S-ICD implantation when assessed with an S-ICD screening template.“

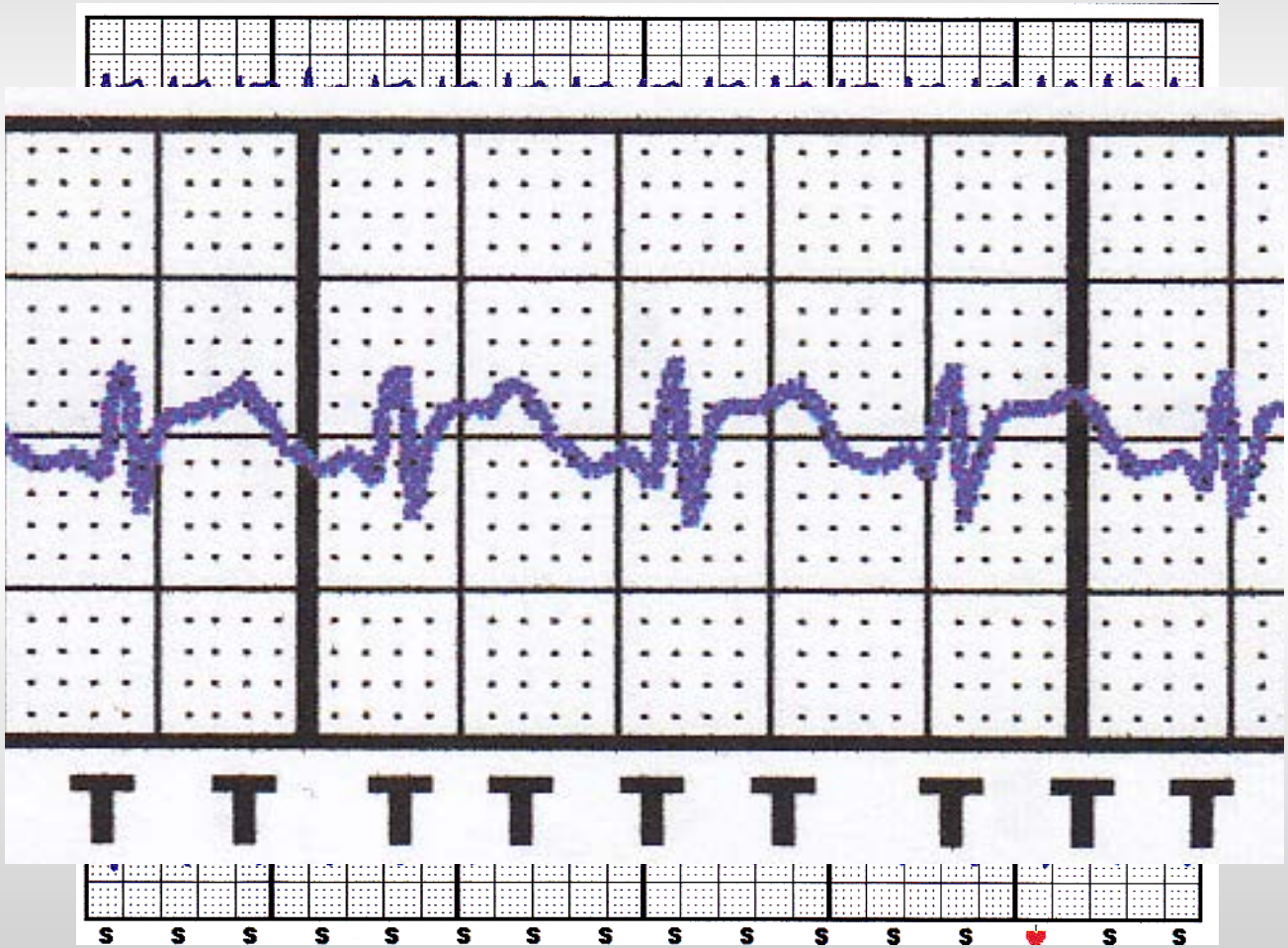
Randles et al.: Europace Advance Access published December 18, 2013

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

- **463 pts (34% of the total population of 1345 pts) receiving a single- or dual-chamber ICD**
- **Exclusion criteria: no pre-existent indication for cardiac pacing**
- **Exclusion criteria for an S-ICD during follow-up:**
  - **Atrial and/or ventricular pacing indication**
  - **Successful antitachyrdia pacing without a subsequent shock**
  - **Upgrade to a CRT-D device**
- **Median follow-up of 3.4 years**
- **55.5% are suitable for an S-ICD**

de Bie et al.: Heart, 99, 1018, 2013

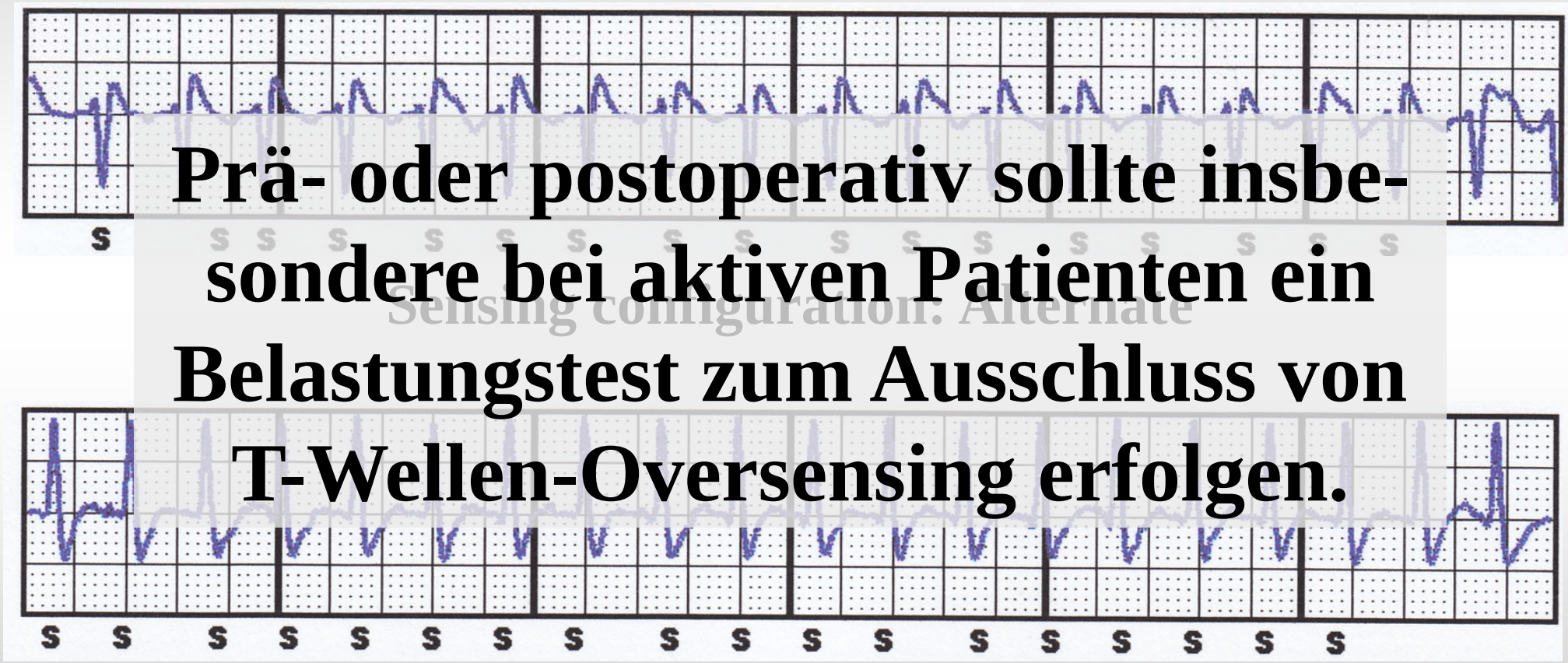
Pat.: F.R. *01.11.1997
S-ICD- Implantation 17.07.2011
Inadäquater Schock 07.09.2011



Episode of inappropriate therapy: T-Wave oversensing
Sensing configuration: Secondary

Pat.: F.R. *01.11.1997

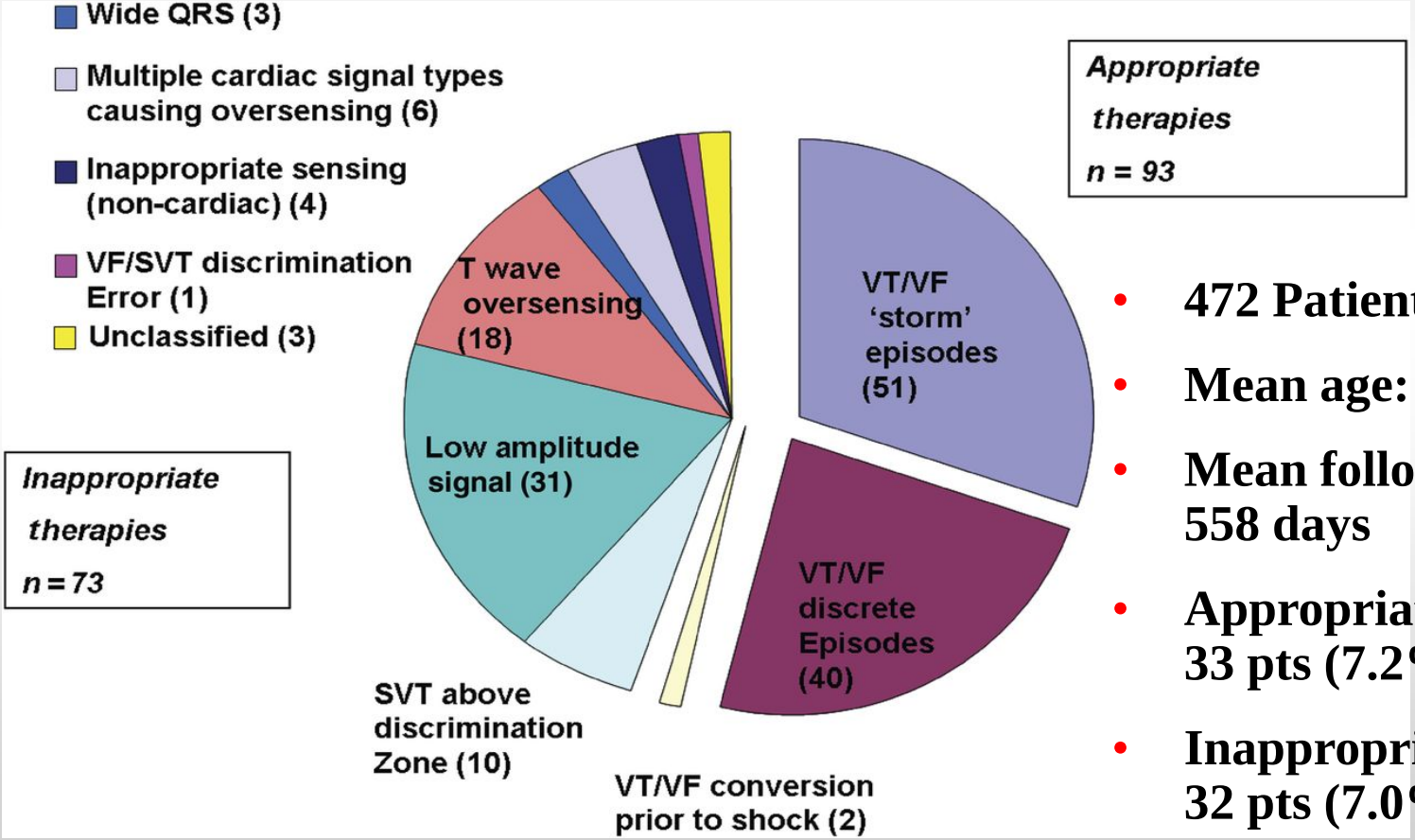
Umprogrammierung 16.09.2011



Prä- oder postoperativ sollte insbesondere bei aktiven Patienten ein Belastungstest zum Ausschluss von T-Wellen-Oversensing erfolgen.

Worldwide experience with a totally subcutaneous implantable defibrillator: Early results from the EFFORTLESS S-ICD Registry

Proportion of appropriate and inappropriate therapies and their aetiologies



- 472 Patients
- Mean age: 49 ± 18 years
- Mean follow-up: 558 days
- Appropriate therapy: 33 pts (7.2%)
- Inappropriate therapy: 32 pts (7.0%)

Lambiase et al.: European Heart Journal Advance Access published March 26, 2014

EFFORTLESS cohort: comparison with Danish Registry for procedural related outcomes

Baseline characteristics	S-ICD N = 581	TV-ICD (VR & DR) N = 784
Data Source	Effortless	Danish ICD Registry
Male Gender (%)	406 (71.4%)	622 (79%)
Age (yrs)	49.3 +/- 18.2*	62.5 +/-12.9
Follow-up time, median (range)	314 (2-365) days*	163 (154-335) days
Primary prevention (%)	367 (65.0%)*	352 (45%)
Ischemic Heart Disease (%)	202 (37.3%)*	512 (65%)

*p<0.05

- Cohorts not matched
- Shorter follow-up in the TV-ICD group compared to S-ICD

Johansen et al.: Cardiostim 2014

EFFORTLESS cohort: comparison with Danish Registry for procedural related outcomes

Type of complication	S-ICD N = 581	TV-ICD N = 784
Any complication	44 (7.6%)	90 (11,5%)*
All lead related	11 (1.9%)	37 (4,7%)*
Infection, re-intervention	11 (1.9%)	6 (0,7%)
Local infection (antibiotics)	11 (1.9%)	18 (2,3%)
Any Major (surgical intervention)	34 (5.9%)	51 (6,5%)
Any Minor (no surgery required)	10 (2.7%)	43 (5,5%)*

*p<0.05

- Short-term complication rate with S-ICD is lower compared to conventional TV-ICD
- Lead related complications less frequent with S-ICD compared to TV-ICD
- 2/3rd of S-ICD infections requiring re-intervention occurred in the first enrollment phase

Johansen et al.: Cardiostim 2014

Complications Associated with the Totally Subcutaneous Implantable Defibrillator: Results from a Pooled Analysis of 882 Patients from the IDE Study and EFFORTLESS Registry

Complication	Patients (n = 882)
Device removal for infection	14 (1.6%)
Device removal for erosion	6 (0.7%)
Pocket revision for device migration	1 (0.1%)
Hematoma requiring evacuation	4 (0.5%)
Syncope	2 (0.2%)
Premature battery depletion	5 (0.6%)
Inability to communicate with device	3 (0.3%)
Lead fracture	0 (0.0%)
Systemic blood infection or endocarditis	0 (0.0%)

Knight et al.: HRS 2014

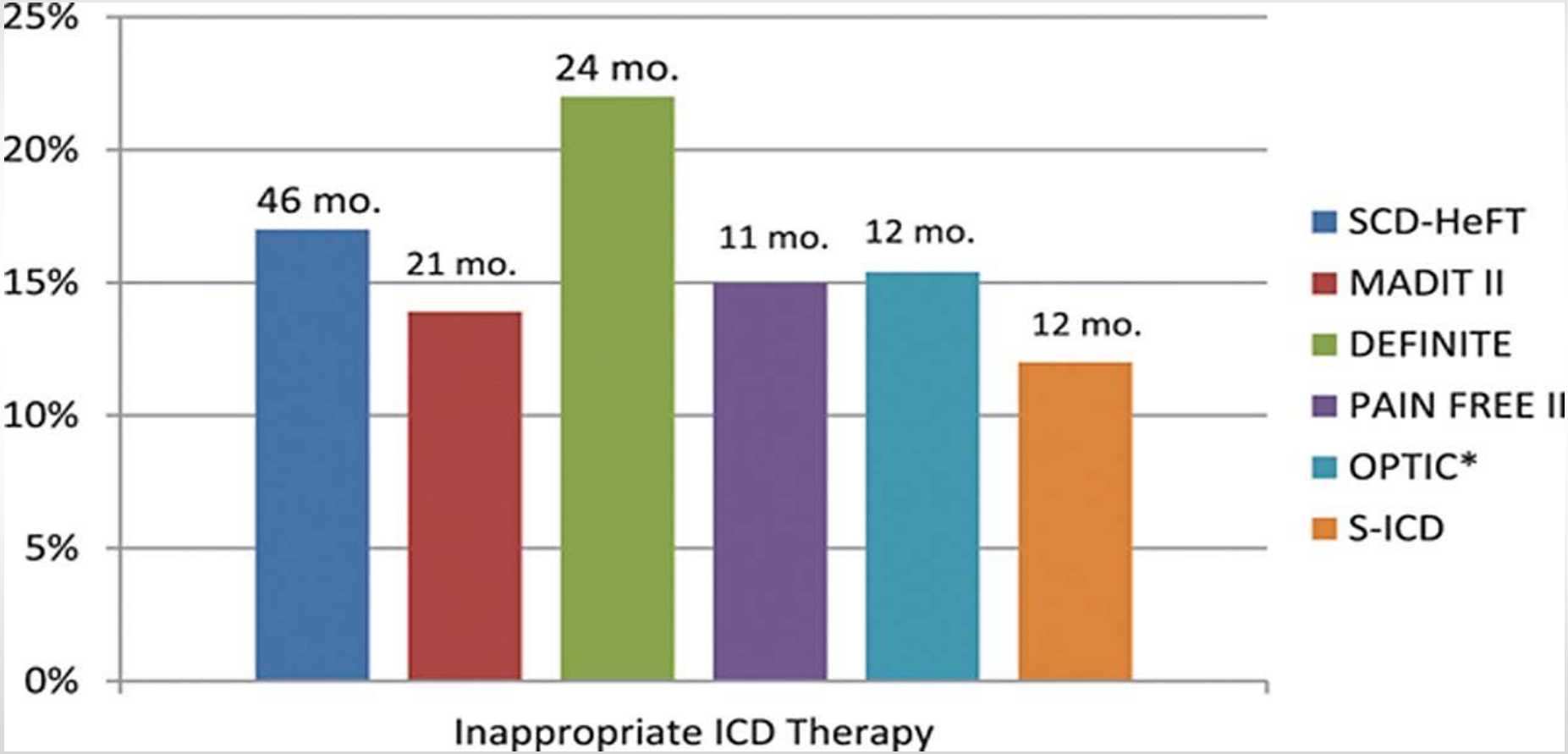
Incidence and Efficacy of Shocks with the S-ICD™ System: Pooled Long Term Results from the IDE and EFFORTLESS Studies

	Full Cohort (N=882)	Programmed Dual Zone (N=689)
Inappropriate Shocks	94 (10.7)	62 (9.0)
SVA Discrimination Error	3 (0.3)	3 (0.4)
SVA Above Shock Zone Cutoff	28 (3.2)	15 (2.2)
Oversensing	67 (7.6)	48 (7.0)
Committed shock post spont. conversion	2 (0.2)	1(0.1)

Dual-zone programming reduces the overall incidence of inappropriate shocks

Gold et al.: HRS 2014

The Subcutaneous Implantable Cardioverter Defibrillator should be considered in all ICD Patients who do not require Pacing



Comparison of inappropriate ICD therapies reported from six ICD clinical trials and the S-ICD IDE study.

Poole et al.: Circ Arrhythm Electrophysiol., 6, 1236, 2013

Incidence and Efficacy of Shocks with the S-ICD™ System: Pooled Long Term Results from the IDE and EFFORTLESS Studies

VT/VF Presentation	Pts	Episodes	Conversion Success
Patients with Inductions at Implant	771		98.6%
Discrete Spontaneous Episodes	59	111	98.2

Gold et al.: HRS 2014

Spontaneous Episodes
IDE Cohort: Discrete VT/VF Episodes

28 discrete VT/VF episodes from 16 patients

Discrete Episodes	Event Type	Patients	Episodes	EPISODES		
				Spontaneous Termination	1st S-ICD System Shock Conversion	S-ICD System Shock Conversion
28	MVT	12	19	1 (5%)	18 (95%)	18 (95%)
	PVT/ VF	6	9	0 (0%)	8 (89%)	9 (100%)

Weiss et al.: Circulation 128, 944, 2013

Shock efficacy

Shock Efficacy of Subcutaneous Implantable Cardioverter-Defibrillator for Prevention of Sudden Cardiac Death

Initial Multicenter Experience

Ali Aydin, MD; Friederike Hartel, MD; Michael Schlüter, PhD; Christian Butter, MD; Julia Köbe, MD; Martin Seifert, MD; Nils Gosau, MD; Boris Hoffmann, MD; Matthias Hoffmann, MD; Eik Vettorazzi, MSc; Iris Wilke, MD; Karl Wegscheider, PhD; Hermann Reichenspurner, MD, PhD; Lars Eckardt, MD; Daniel Steven, MD; Stephan Willems, MD

Ineffective shock delivery may occur in patients with S-ICD, even after successful intraoperative testing

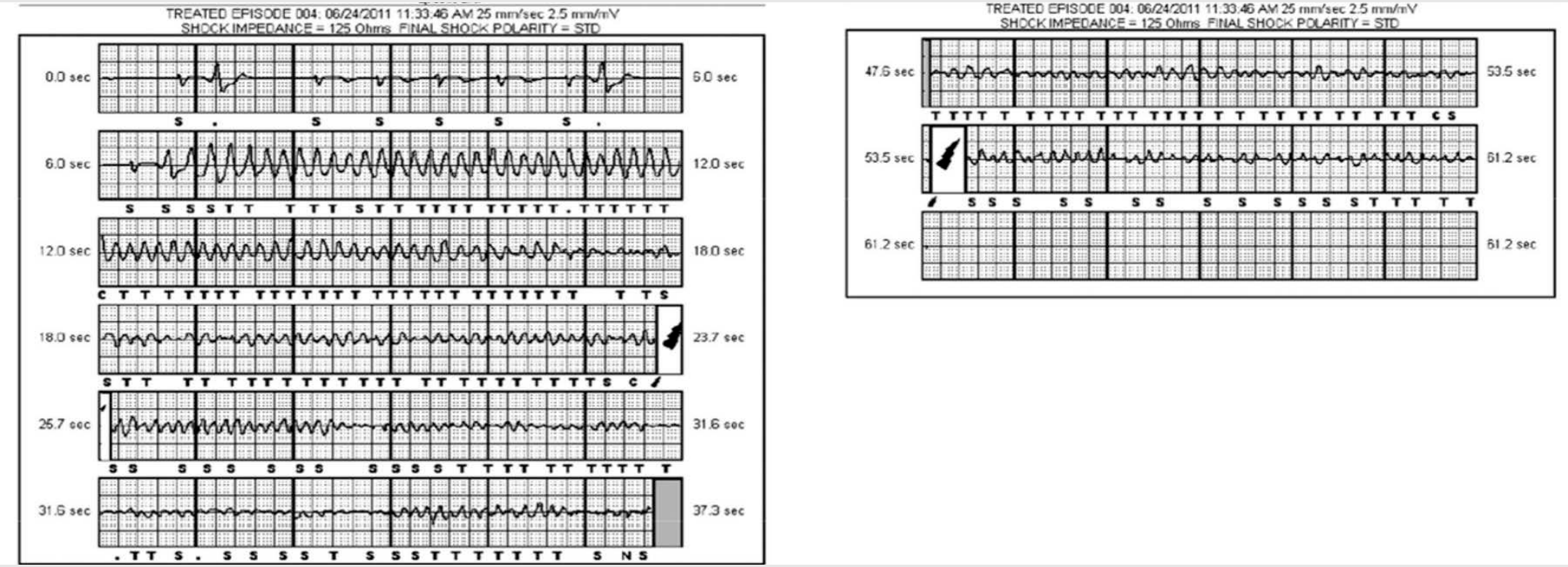
Methods and Results—Between June 2010 and July 2011, 40 consecutive patients (42±15 years; body mass index, 27±6 kg/m… left ventricular ejection fraction, 47±15%, 28…) received an S-ICD for primary (n=17) or secondary prevention… reduced left ventricular ejection fraction; testing was effective in all other patients. All episodes stored in the S-ICD were analyzed for appropriate and inappropriate detection, as well as effective shock delivery to convert ventricular … up of 229 (interquartile range, 116–305) days, 4 patients … tachyarrhythmia and subsequent shock therapy. A total of 28 shocks were delivered in these 4 patients. Mixed logistic regression modeling revealed a shock efficacy of 96.4% (95% CI, 12.8%–100%). The efficacy of first shocks, however, was only 57.9% (95% CI, 35.6%–77.4%). Four episodes were incorrectly classified as ventricular tachyarrhythmia, which led to inappropriate shock delivery in 2 patients.

Conclusions—Ineffective shock delivery may occur in patients with S-ICD, even after successful intraoperative testing. Multicenter trials are required with close monitoring of safety and efficacy end points to identify patients who may be at risk for shock failure. (***Circ Arrhythm Electrophysiol*. 2012;5:913-919.**)

Aydin et al.: Circ Arrhythm Electrophysiol, 5, 913, 2012

Shock Efficacy of Subcutaneous Implantable Cardioverter-Defibrillator for Prevention of Sudden Cardiac Death

Initial Multicenter Experience



Detection of spontaneous polymorphic ventricular tachycardia. Delivery of two 80-J shocks did not terminate ventricular tachyarrhythmia. Undersensing of ventricular fibrillation after shock delivery between 31.6 and 37.3 seconds.

Aydin et al.: Circ Arrhythm Electrophysiol, 5, 913, 2012

Shock efficacy

Spontaneous events

	Aydin	Olde Nordkamp	IDE	EFFORTLESS
n	40	118	321	450
Events (n)	21	45	38	87
Patients (n)	4	8	21	32
Detection (%)	100	100	100	100
1st conversion efficacy (%)	58 *	98	92*	84 *

**** Electrical Storm***

Aydin et al.: Circ Arrhythm Electrophysiol, 5, 913, 2012

Olde Nordkamp et al.: J Am Coll Cardiol, 60, 1933, 2012

Weiss et al.: Circulation, 128, 944, 2013

Liambase et al.: HRS 2012

S-ICD System Annualized Mortality Comparable to ICD Studies

Clinical Study	Annualized Mortality Rate
S-ICD System IDE Study	3.7%
MADIT	5.8%
MADIT II	6.2%
AVID	8.2%
SCD-HeFT	5.8%

8 Deaths

- **7 not associated with device or procedure**
- **1 unknown due to limited information from overseas death**

Weiss R et al.: Circulation, 128, 944, 2013

The **S**hockless **IMPL**ant **E**valuation (**SIMPLE**) study

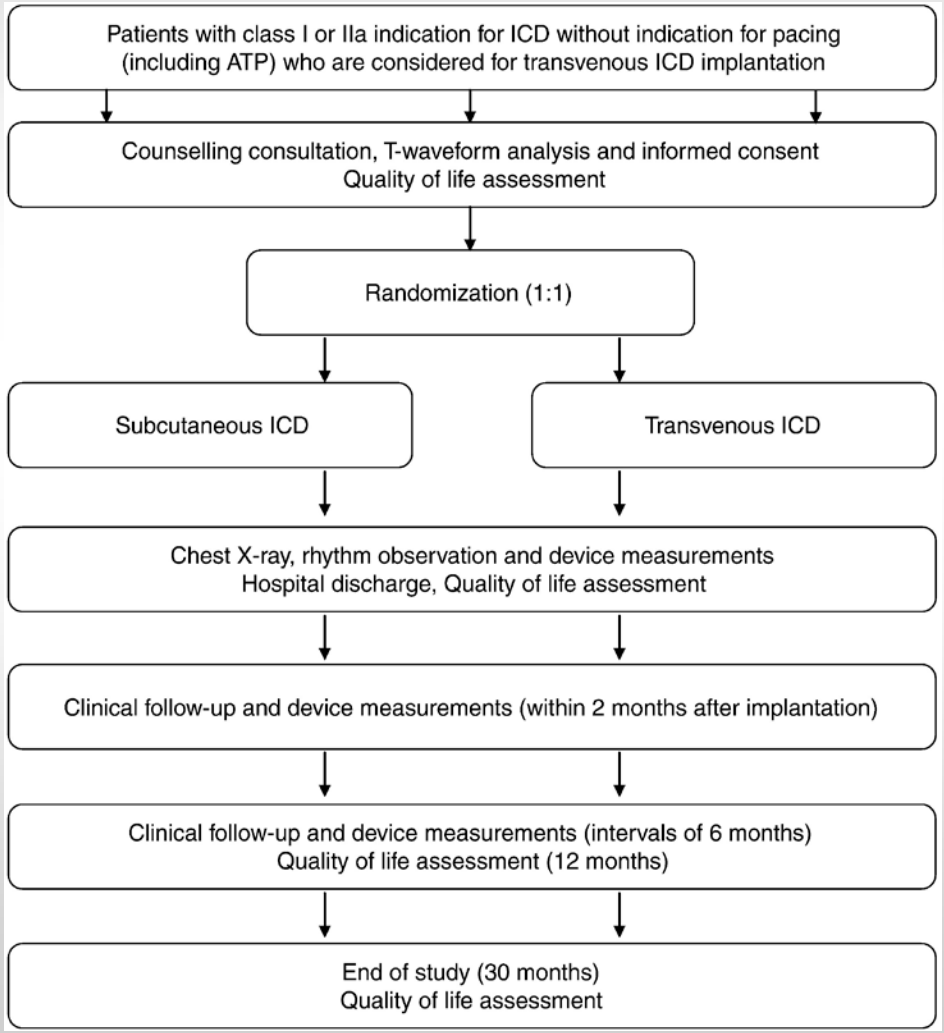
- **Routine defibrillation testing (DFT) versus no testing at the time of implant**
- **2500 patients 1:1 randomized, average length of follow-up 3.1 years**
- **Primary endpoint: Ineffective clinical shock or arrhythmic death**
- **Results:**

7.27 % no – DFT group
8.30 % DFT group } **Primary endpoint**

94.8 % no – DFT group
94.4 % DFT group } **Survival from arrhythmic death**

Healey et al.: HRS 2014

Rationale and design of the PRAETORIAN trial: A Prospective, RAndomizEd comparison of subcuTaneOus and tRansvenous ImplANtable cardioverter-defibrillator therapy



Olde Nordkamp et al.: Am Heart J, 163, 753, 2012

Zusammenfassung

- **Der S-ICD der ersten Generation stellt für ausgewählte Patienten bei den bekannten Kontraindikationen einen deutlichen Fortschritt dar.**
- **Im Vergleich zu den transvenösen Systemen hat der S-ICD eine geringere periprocedurale Komplikationsrate.**
- **Elektrodenkomplikationen sind bisher deutlich seltener. Die Gefahr einer Endokarditis bei einer Infektion besteht nicht.**
- **Taschenprobleme einschließlich Infektionen sind durch eine adäquate Implantationstechnik vermeidbar.**

Zusammenfassung

- **Die Diskriminierung und Detektion des S-ICD‘s nach akribisch durchgeführtem Screening einschließlich Belastungstests entspricht dem des transvenösen ICD.**

- **Die Rate der inadäquaten Schockabgaben ist mit den transvenösen ICD-Sytemen vergleichbar, wobei supraventrikuläre Rhythmusstörungen (2-Zonen-Programmierung) offensichtlich besser erkannt werden.**

- **Nach den vorliegenden Daten scheint die Schockeffektivität des S-ICD‘s dem transvenösen ICD nicht unterlegen zu sein.**

- **Ein randomisierter Vergleich der beiden Systeme (PRAETORIAN-Trial) steht noch aus.**

Done is better than perfect

Mark Elliot Zuckerberg

Vielen Dank für Ihre Aufmerksamkeit