Tübinger Erfahrung mit dem extravaskulären ICD

Thromboseforum 2026
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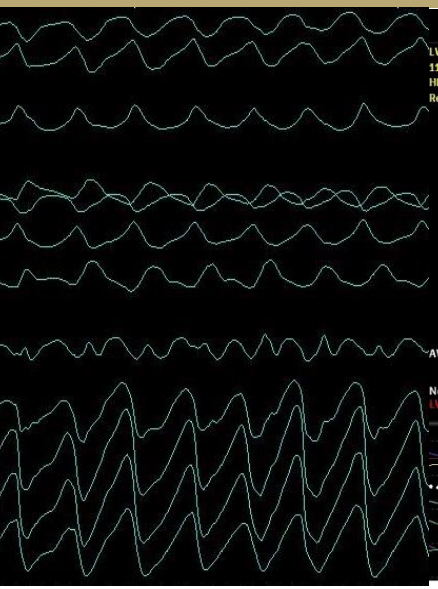

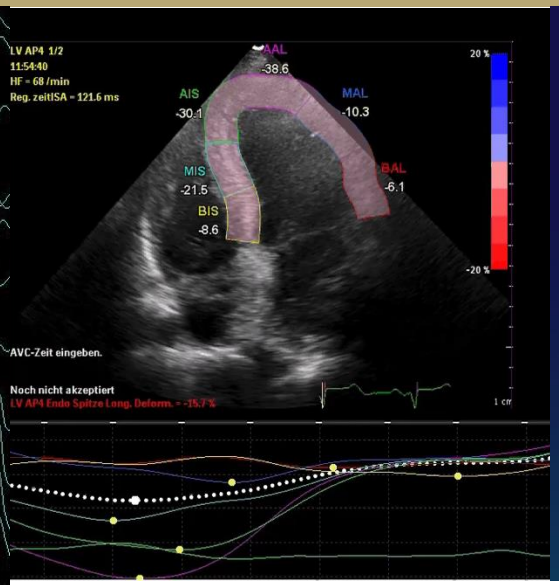

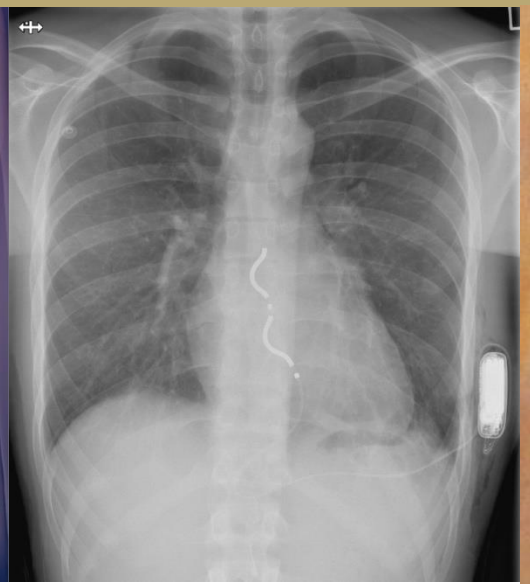

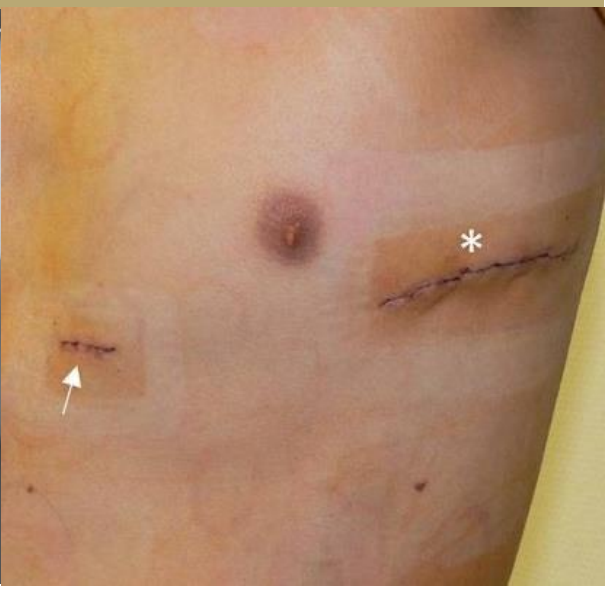

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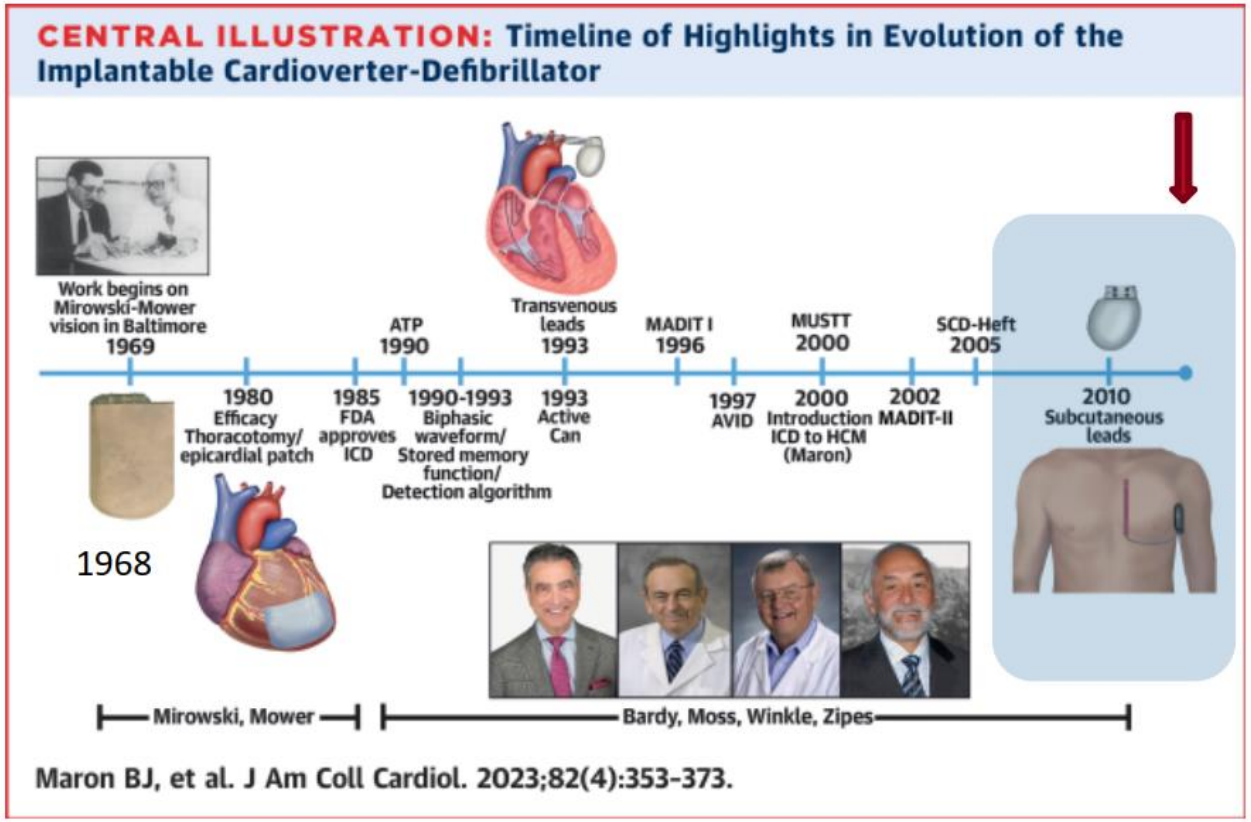
Conflicts of interest

Disclosures

Speakers‘ honoraria by
Medtronic, Abbott, AstraZeneca, Bayer, Boehringer, BMS, Novartis and Pfizer

Evolution des ICDs
Immer kleiner… Immer besser… intrakardial… extrakardial…

Significant advancements in reducing size, adding ATP, and avoiding transvenous leads



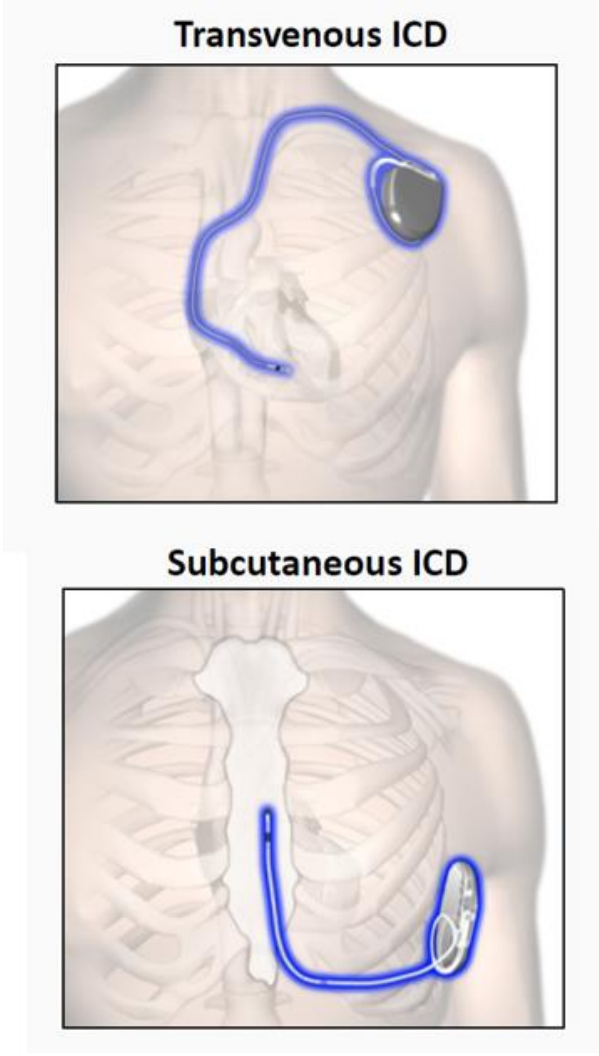
S-ICD 2009

EV-ICD 2018

Maron BJ et al., JACC 2023

WARUM brauchen wir überhaupt extrakardiale Systeme?

- Transvenous ICD have been the gold standard for sudden cardiac death prevention
- Placing leads outside the heart/vasculature may reduce complications and increase ICD accessibilty

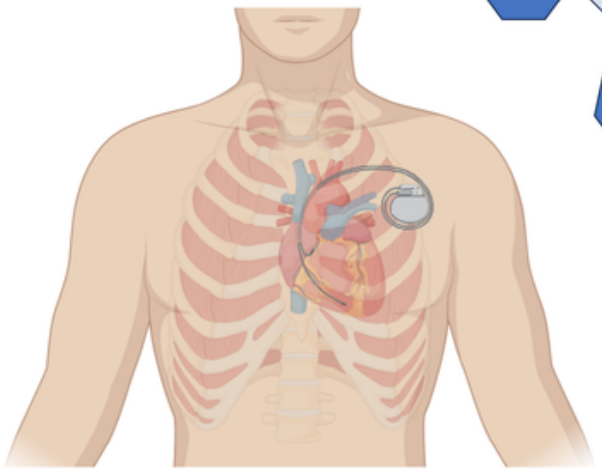


Birnie et al., JACC 2019

WARUM brauchen wir überhaupt extrakardiale Systeme? Risikostratifizierung

ICD complications are frequent ~ up to 8-10%/year

Lead issues, lead infection rates remain high



P PRIOR PROCEDURES
1: 1 prior CIED Procedure
3: ≥ 2 prior CIED Procedures

A AGE
1: 60 to 69 years
2: <60 years

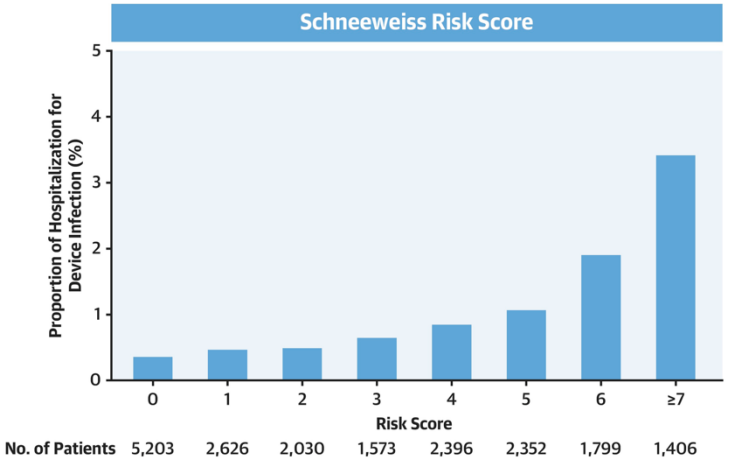
D DEPRESSED RENAL FUNCTION
1: GFR<30 ml/min

I IMMUNOCOMPROMISED
3 points

T TYPE OF PROCEDURE
2: ICD
4: CRT (new/generator change)
5: revision/upgrade

≤4	Low Risk
5-6	Intermediate Risk
≥7	High Risk

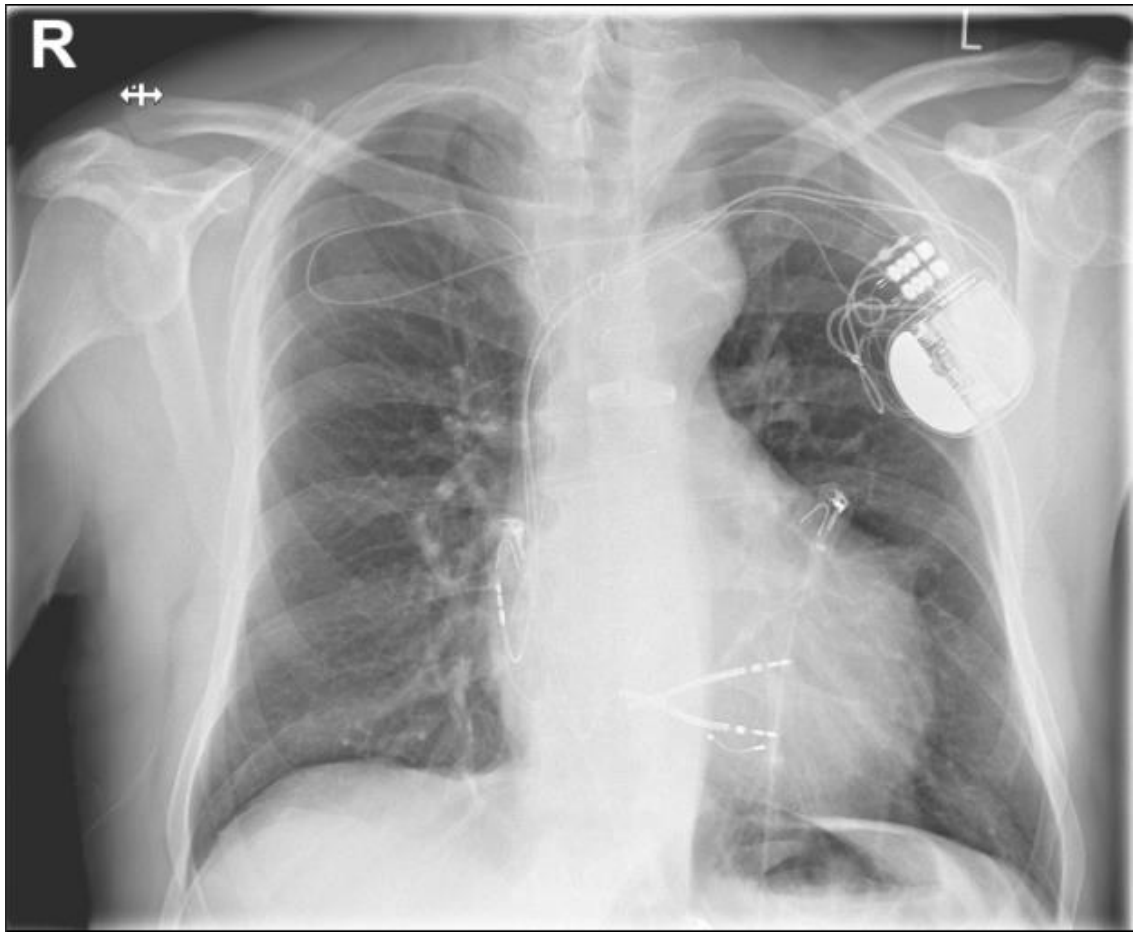
CENTRAL ILLUSTRATION: Rate of Device Infection Stratified by PADIT Infection Risk Score

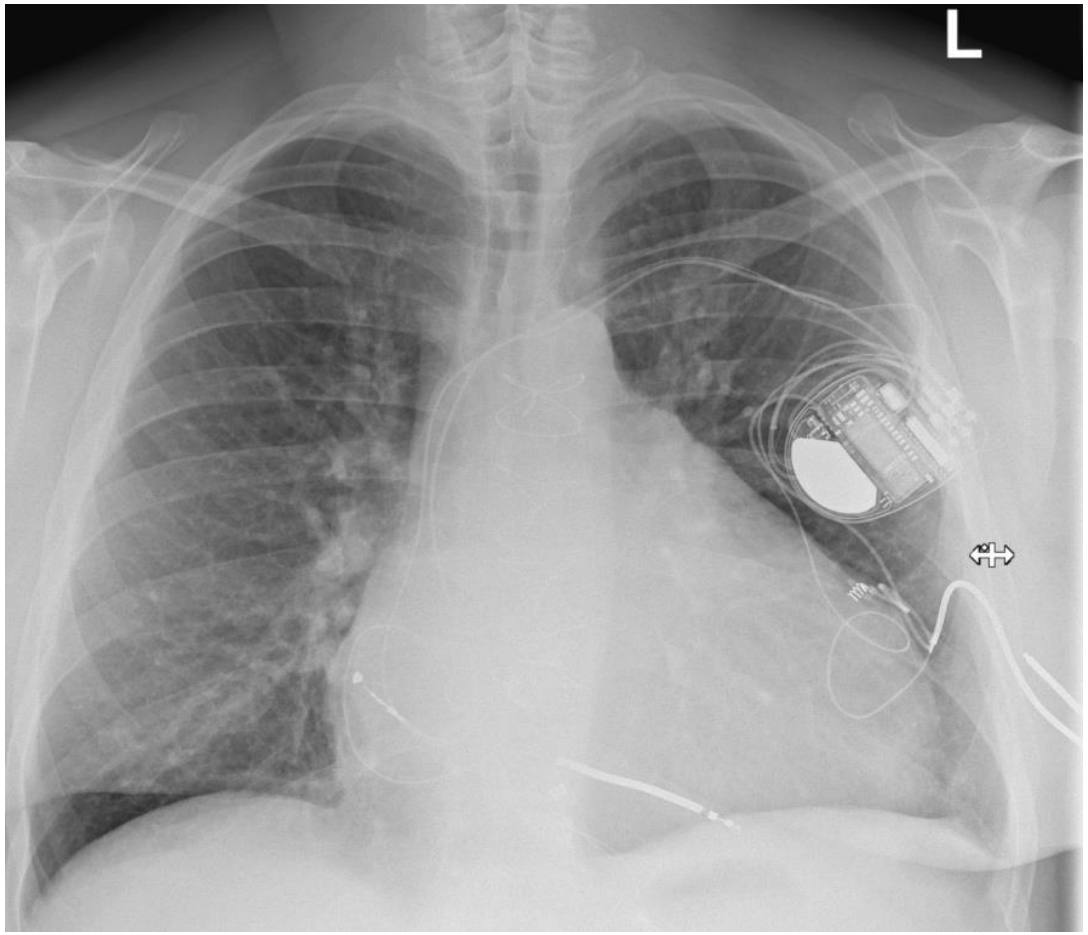


Birnie, D.H. et al. J Am Coll Cardiol. 2019;74(23):2845-54.

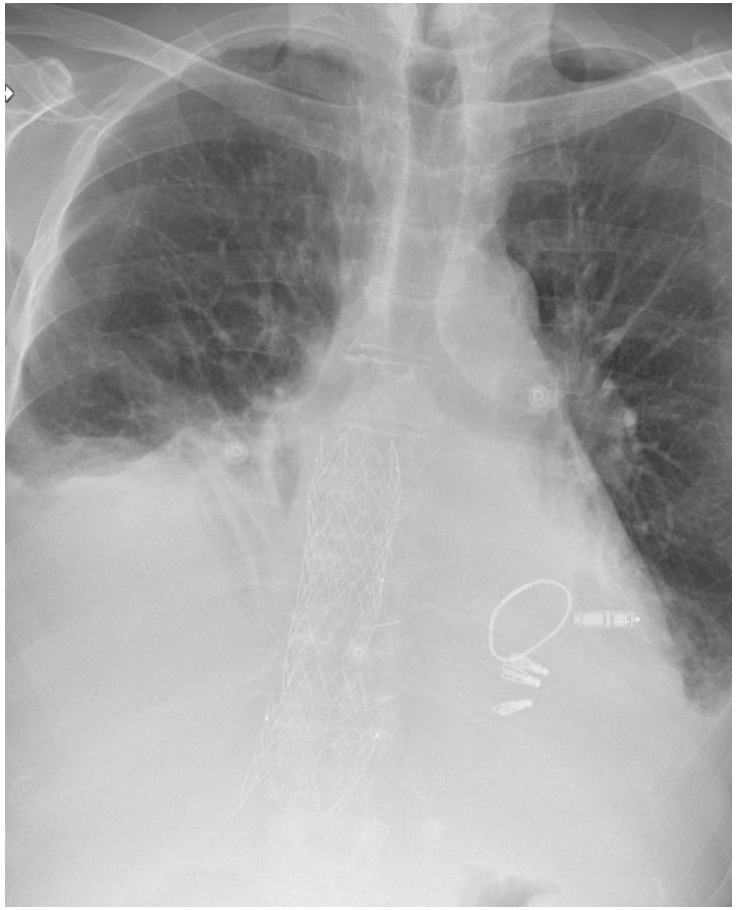
Birnie et al., JACC 2019

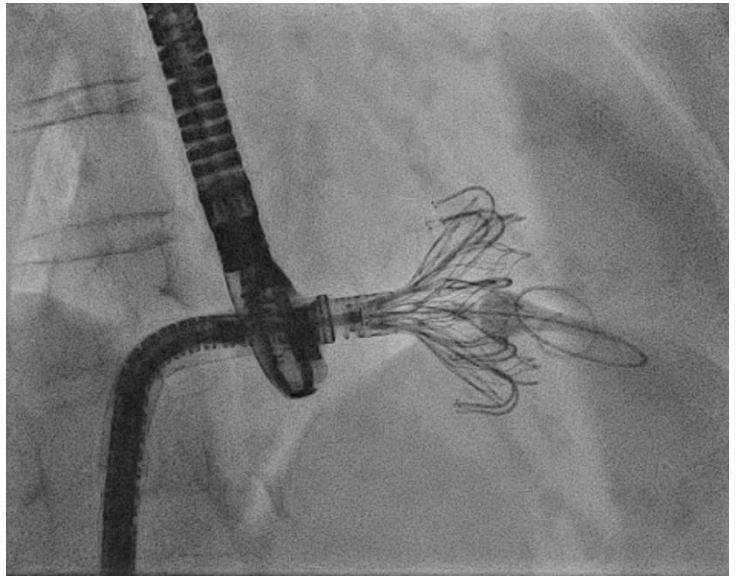
WARUM brauchen wir überhaupt extrakardiale Systeme?
Junges Patientalter - wiederholte Eingriffe - Limitationen

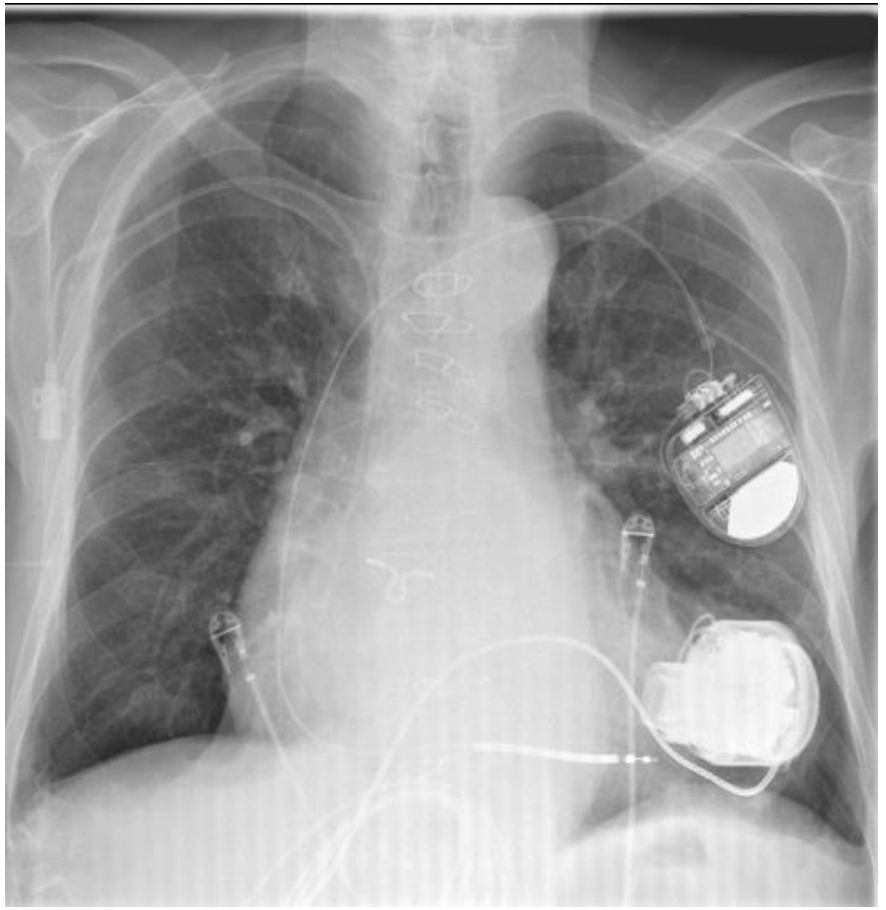




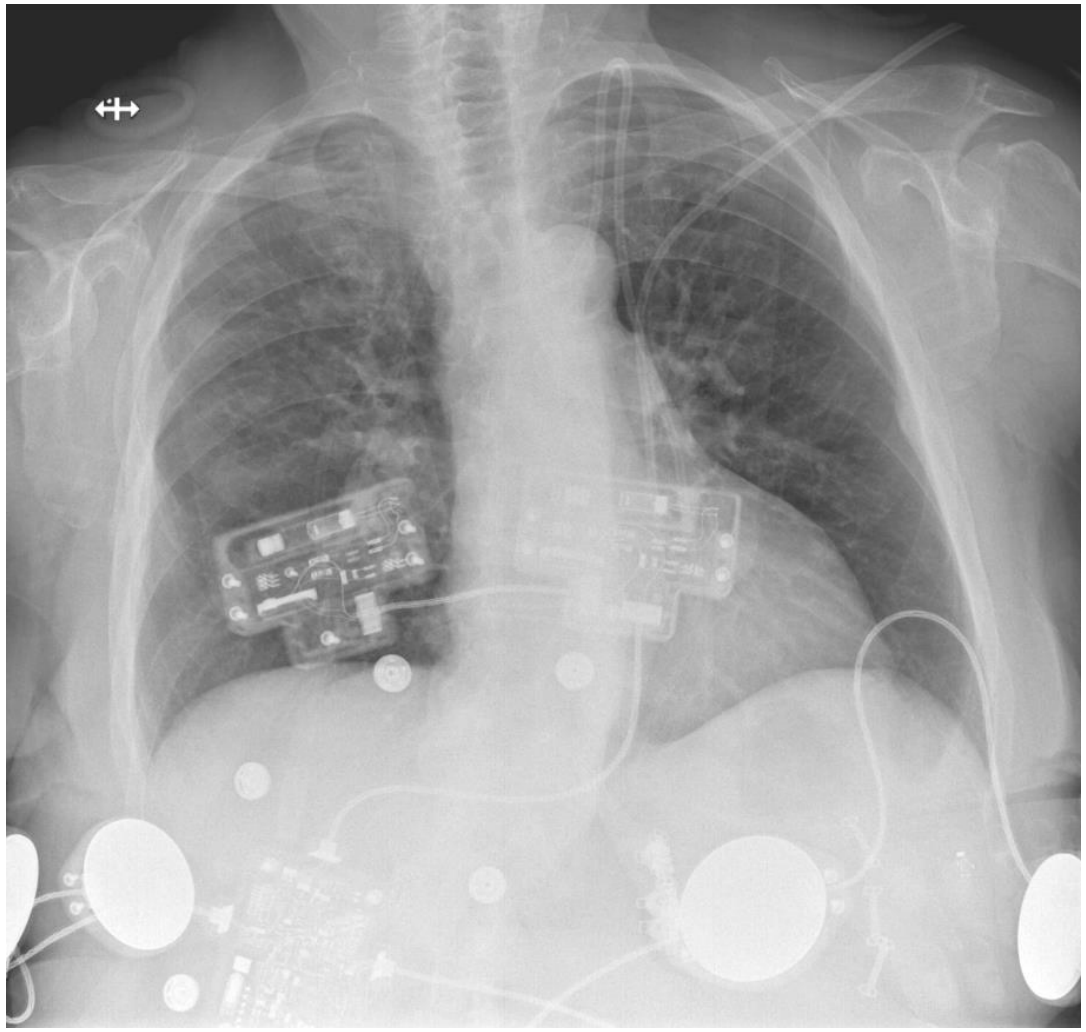
WARUM brauchen wir überhaupt extrakardiale Systeme? Innovative Klappeneingriffe, interventionelle Eingriffe an der Trikuspidalklappe, LVAD, …

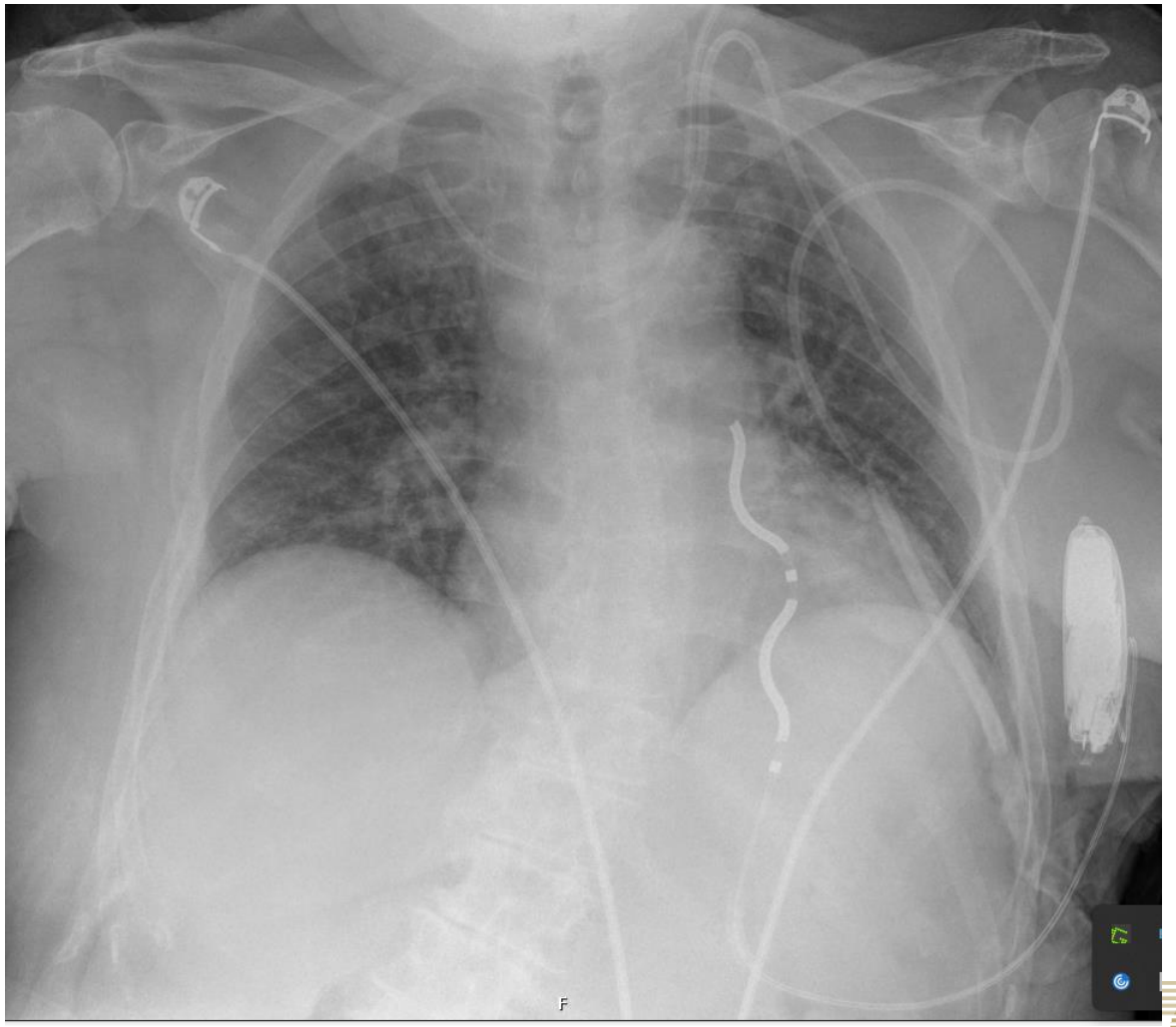




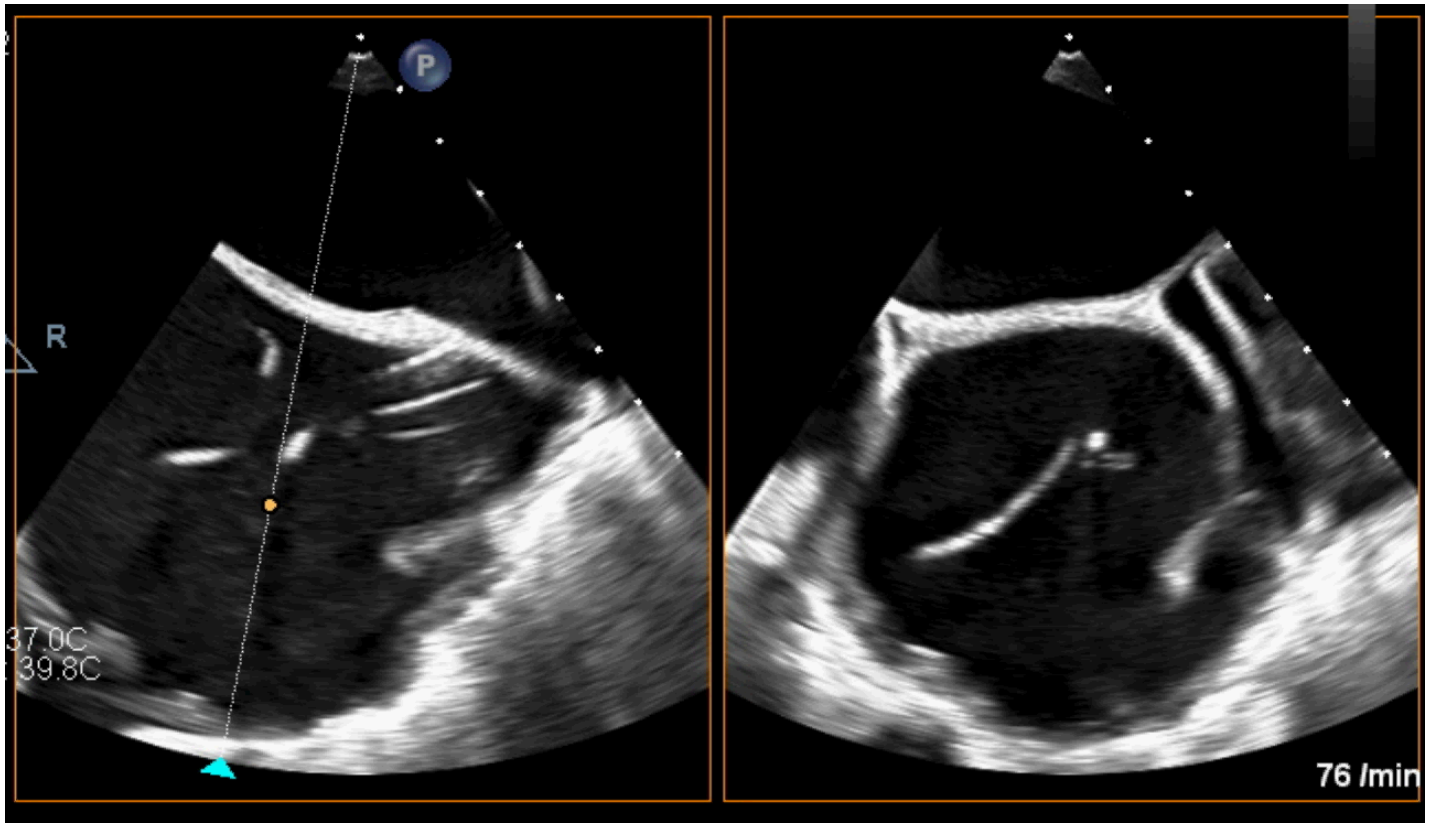


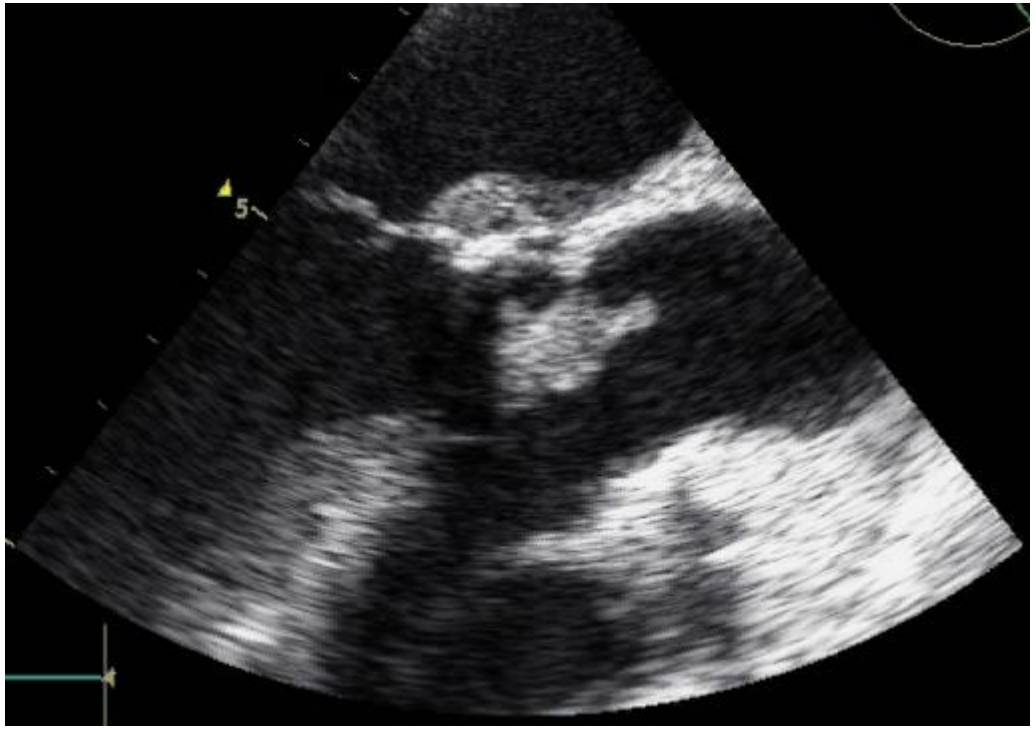
WARUM brauchen wir überhaupt extrakardiale Systeme?
Limitierte Venenzugänge – Dialyse – Ernährung - …



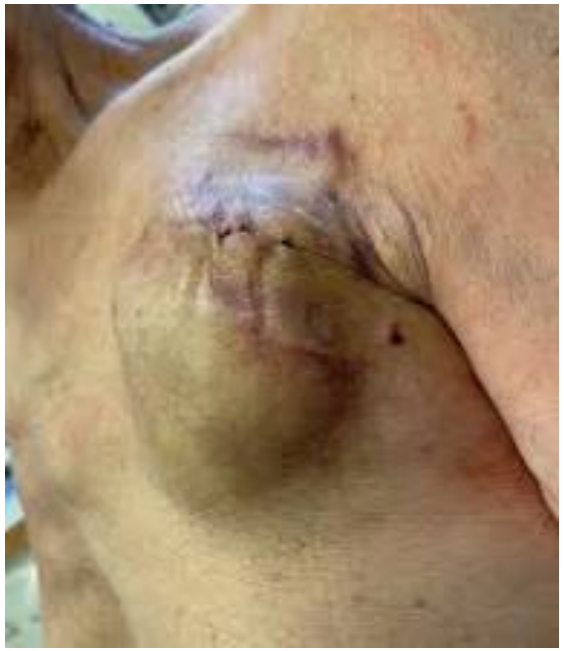


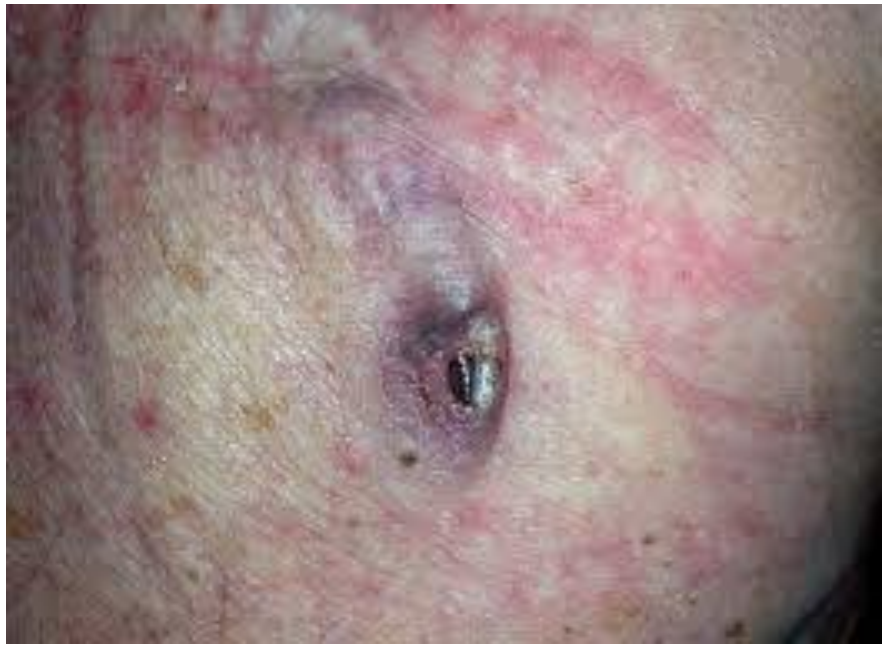
WARUM brauchen wir überhaupt extrakardiale Systeme? Sondenendokarditis, Endokarditis, ...

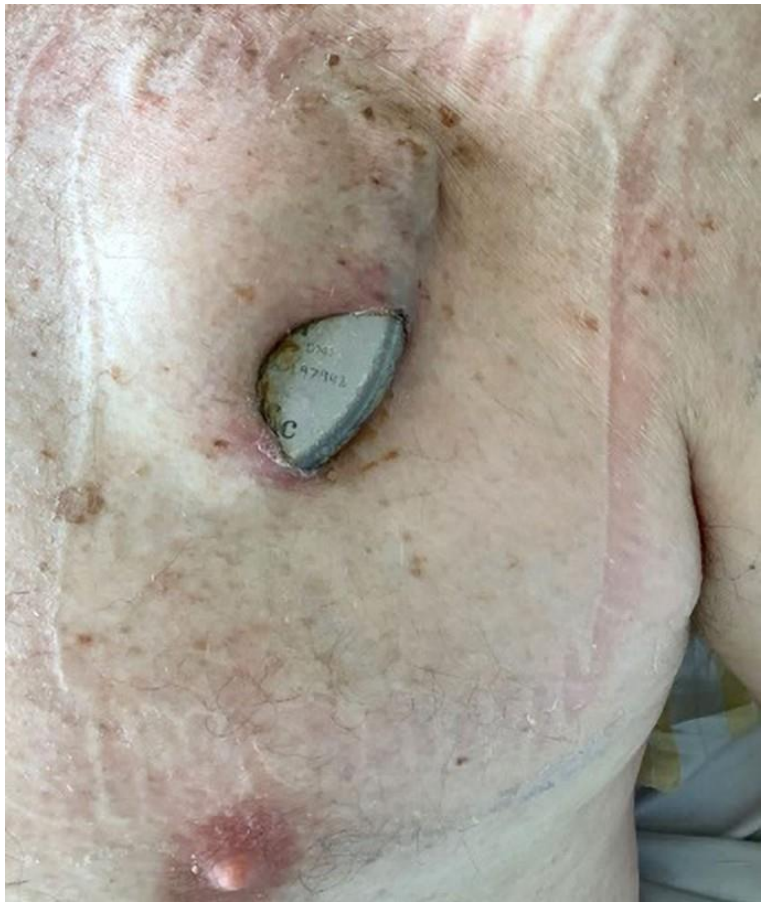




WARUM brauchen wir überhaupt extrakardiale Systeme?
Perforationen, Hämatome, Wundheilungsstörungen

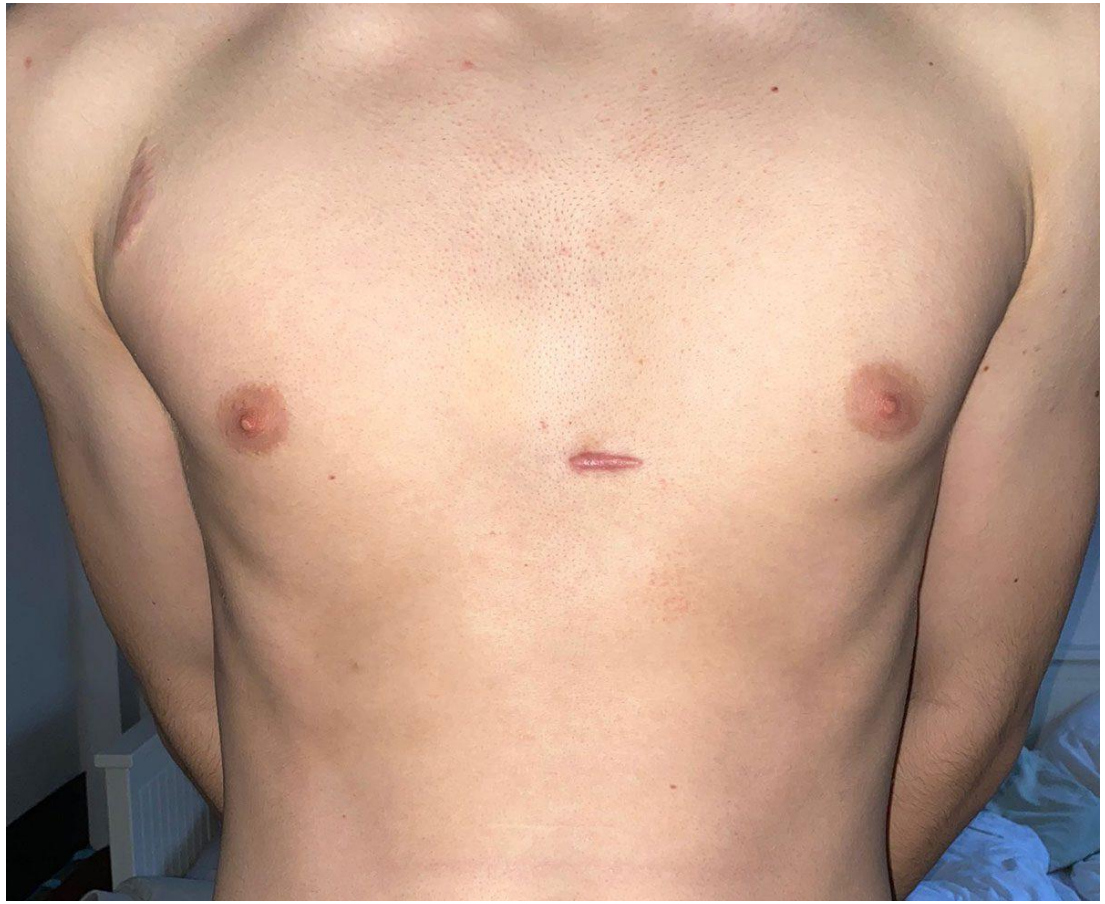


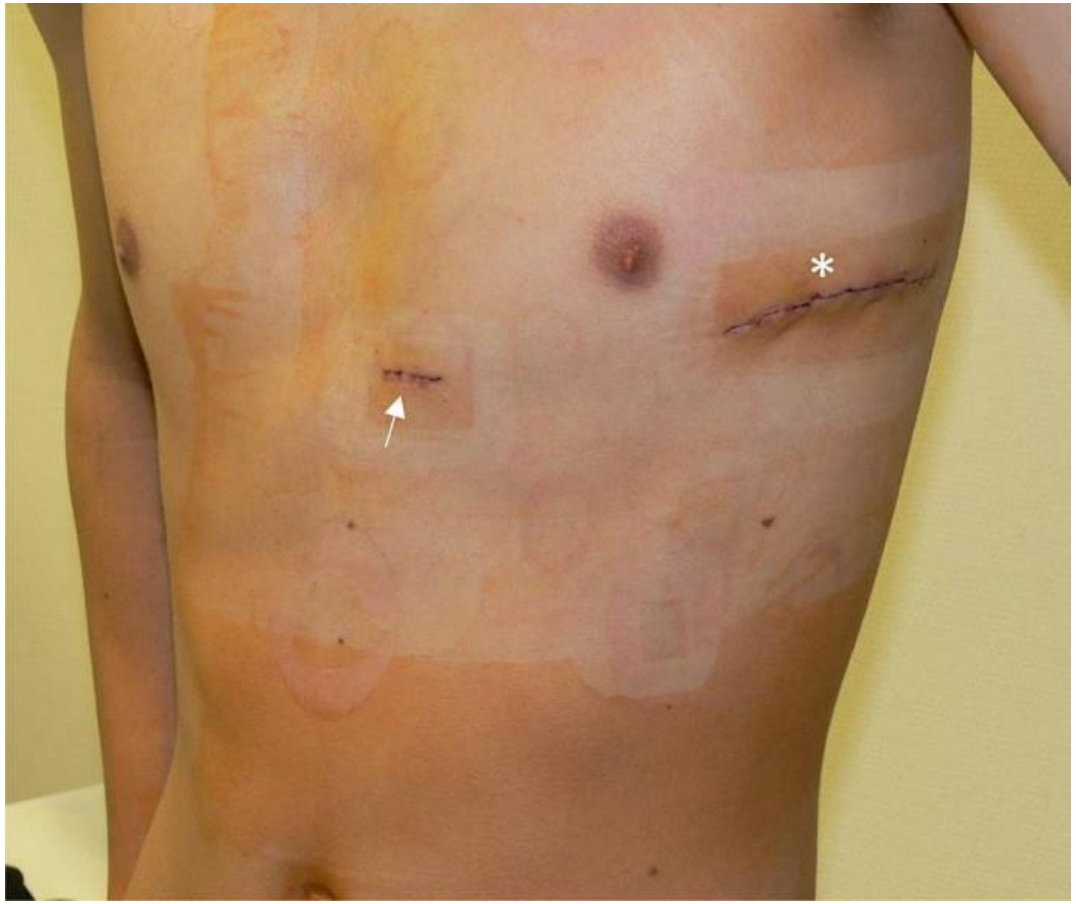




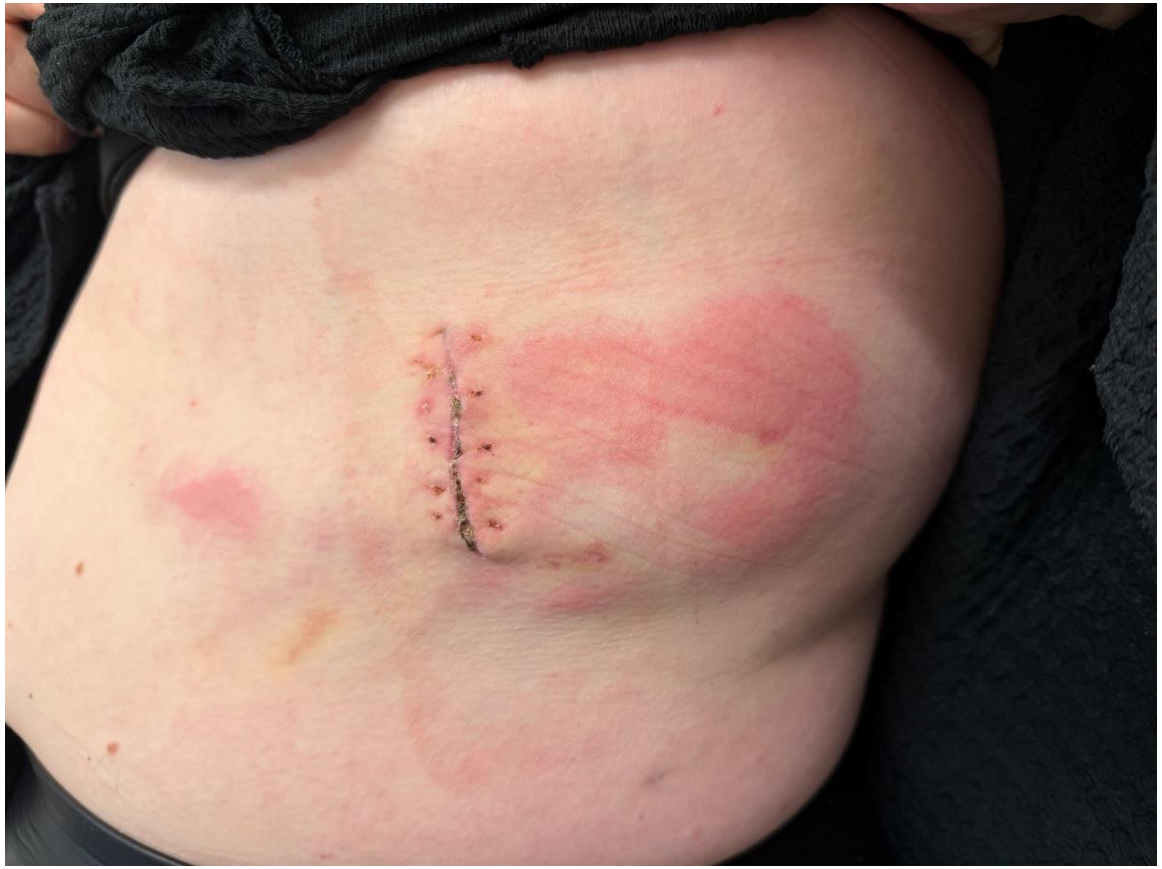
Thieme, 2023

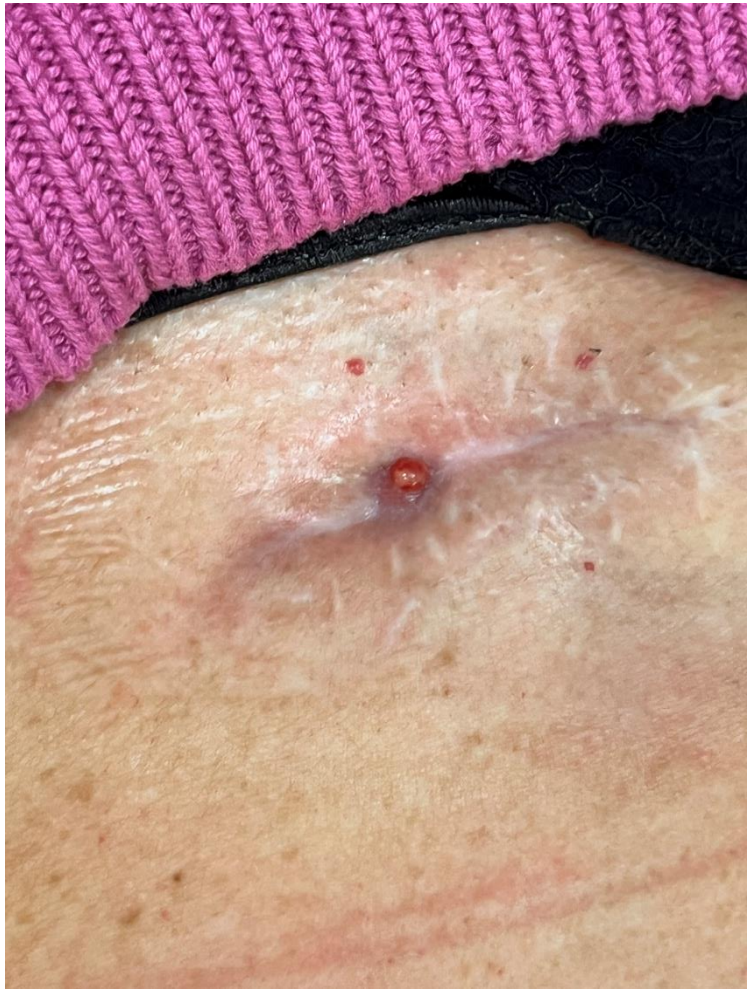
WARUM brauchen wir überhaupt extrakardiale Systeme?
Chirurgische Vorteile bei extrakardialen Systemen?





WARUM brauchen wir überhaupt extrakardiale Systeme?
Chirurgische Vorteile bei extrakardialen Systemen?
Auch hier können Komplikationen auftreten….





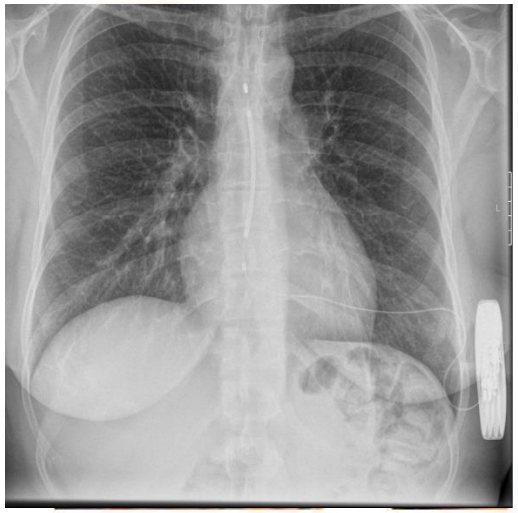
Der subkutane ICD – S-ICD

The system did not provide ATP or pacing – currently under development as modular system – higher rate of inedaquate shocks

First Extravascular System, Subcutaneous Lead and Defibrillator

https://www.nejm.org/doi/full/10.1056/NEJMoa2401807#

Long-term safety and efficacy data available



5-year PAS study results published Aug 2023

- Defibrillation efficacy: 92% 1st shock, 98% total
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- Need for pacing at 5 years: 1.6%
- Screening ineligibility: 14.3% in PAS
- SMART PASS ↓IAS by 68%, 5-year IAS: 15.8% in PAS, annual IAS 2.4% in EFFORTLESS

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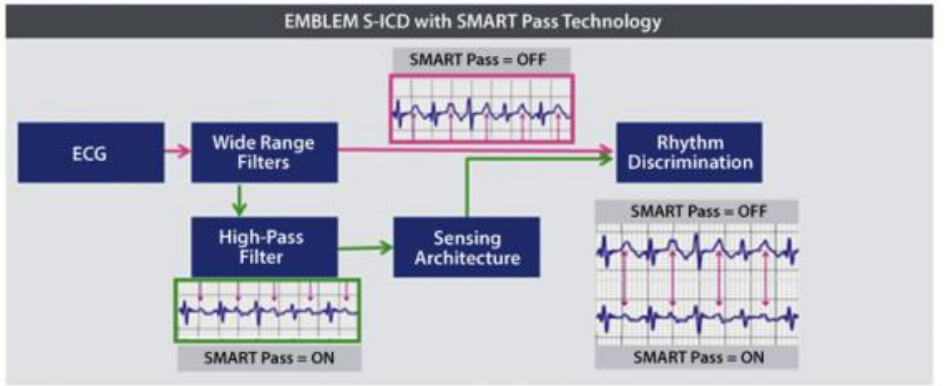

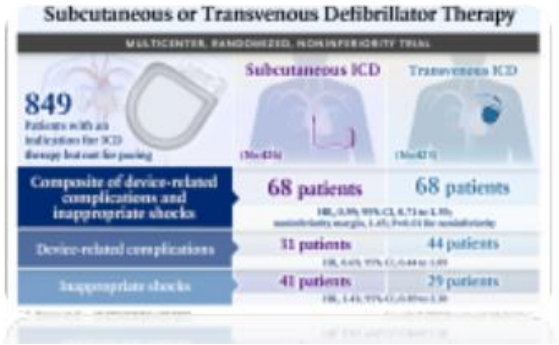

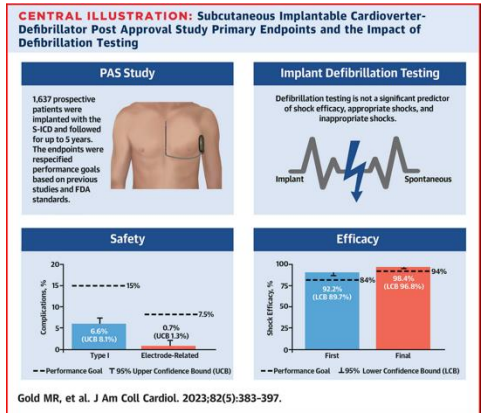

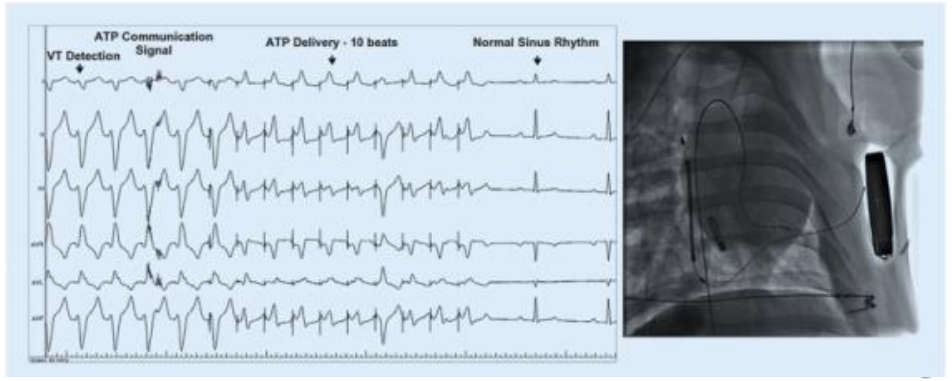

Bardy et al, NEJM, 2010, Boersma et al, JACC, 2017, Knops et al, NEJM, 2020, Gold et al, Circulation, 2021

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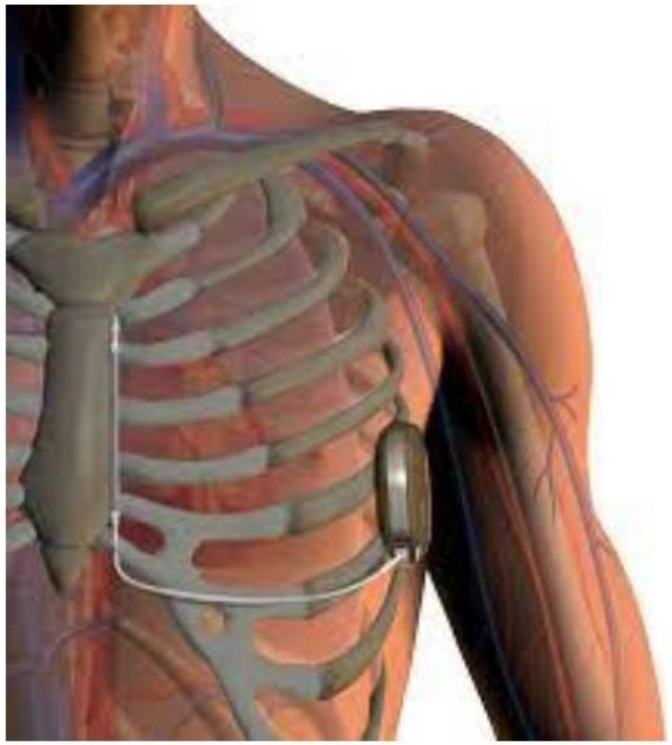

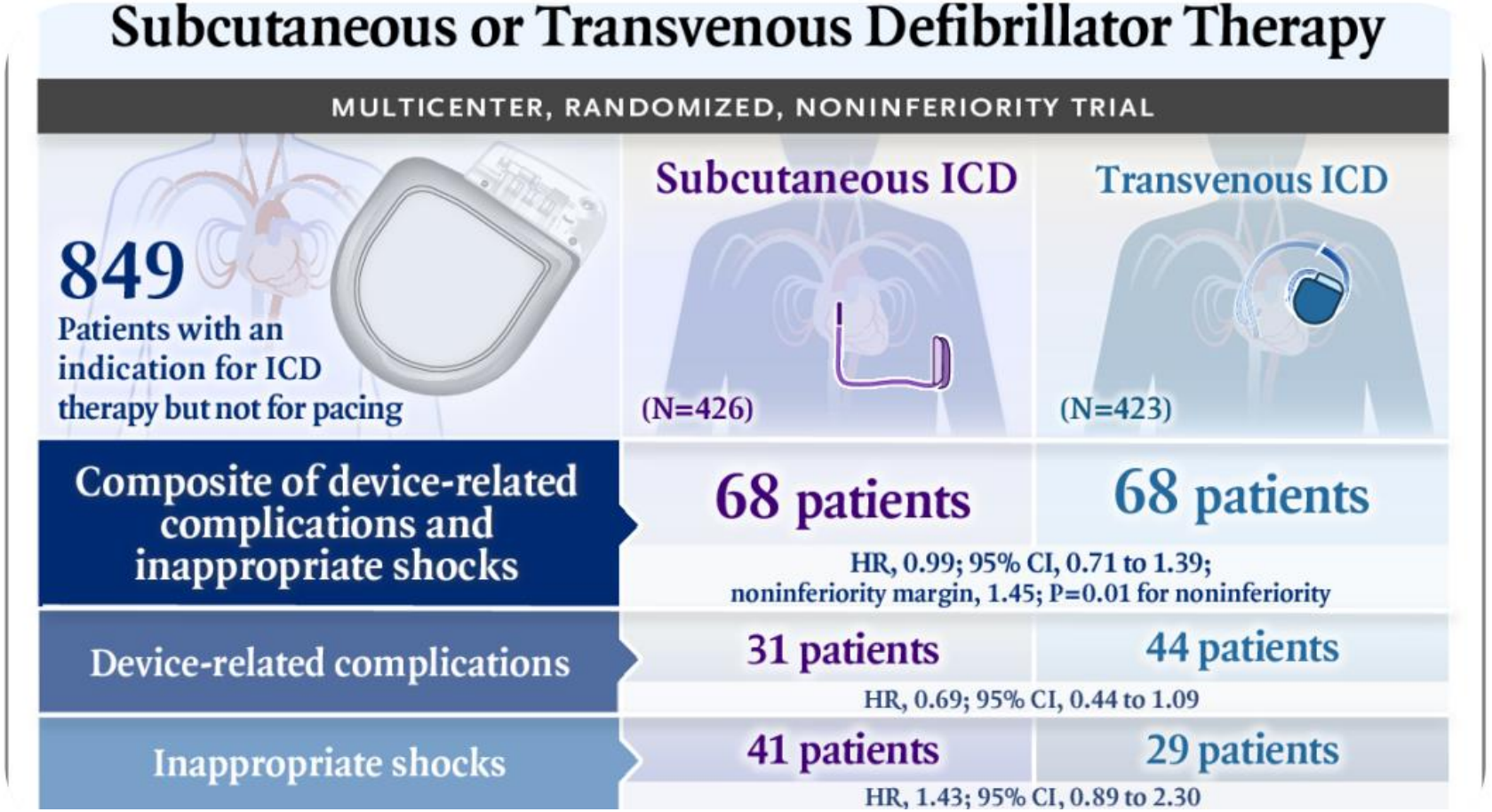

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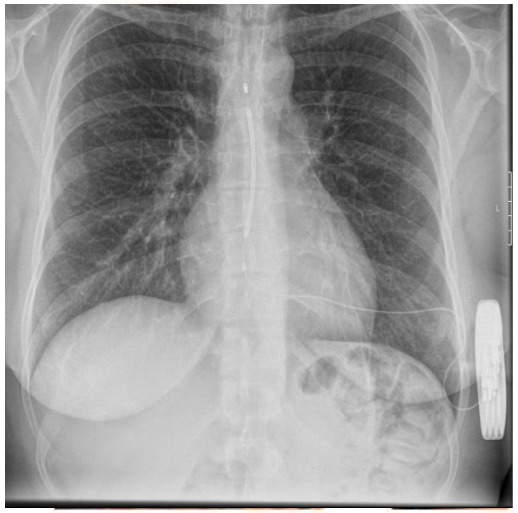

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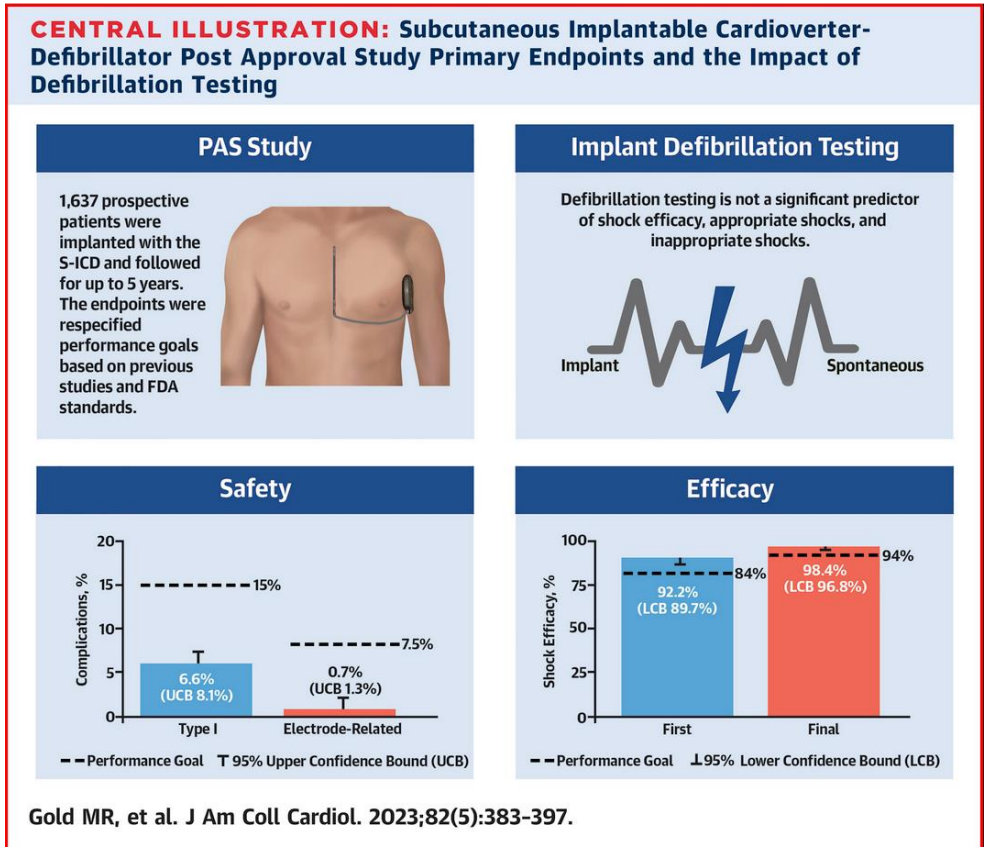

Gold MR, et al. J Am Coll Cardiol. 2023;82(5):383-397.

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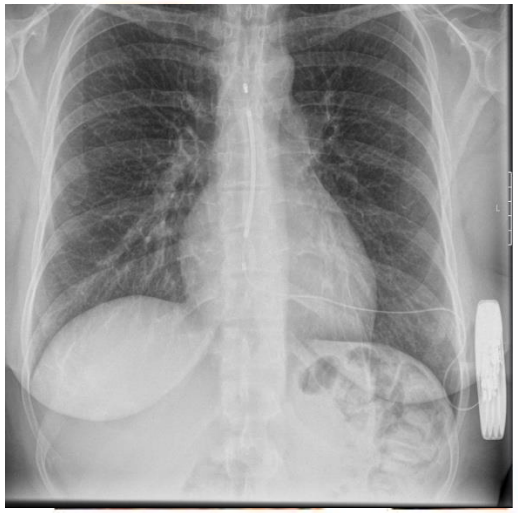

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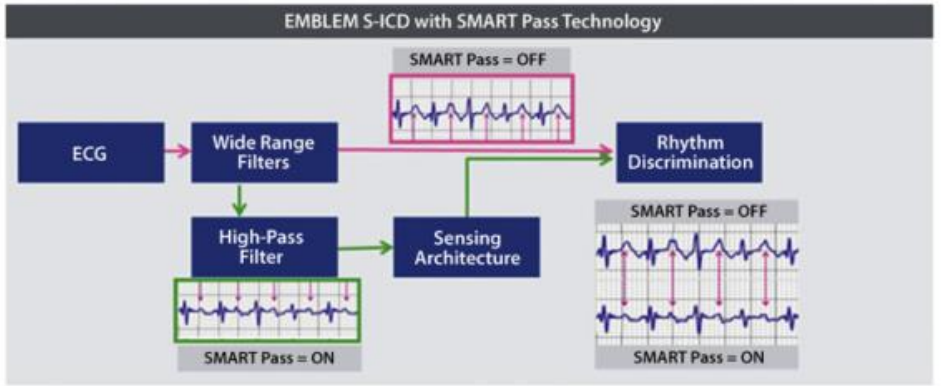

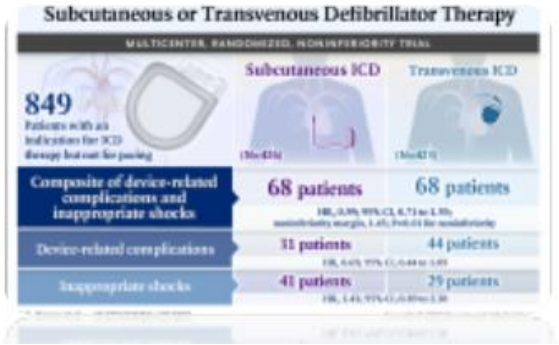

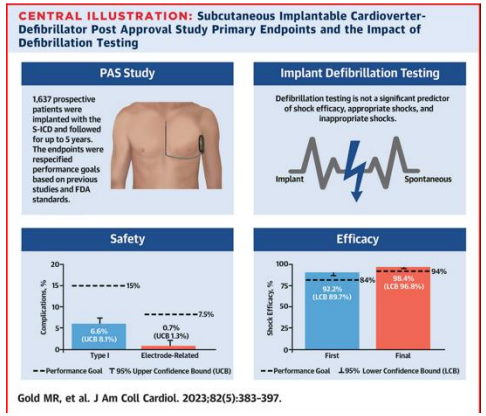

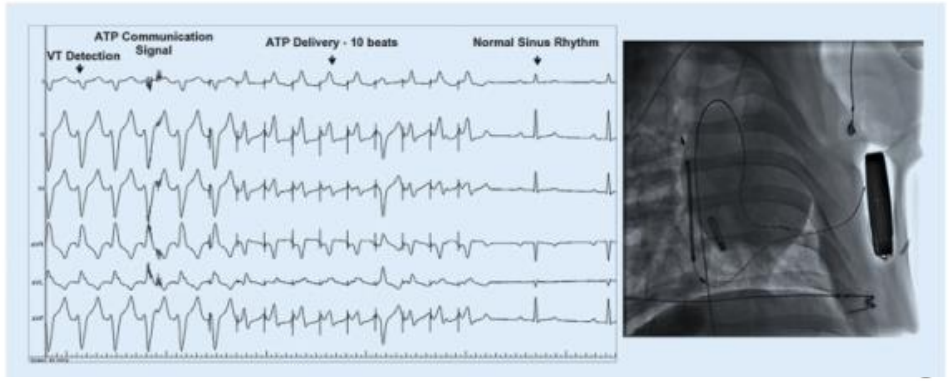

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ATP and pacing via modular system

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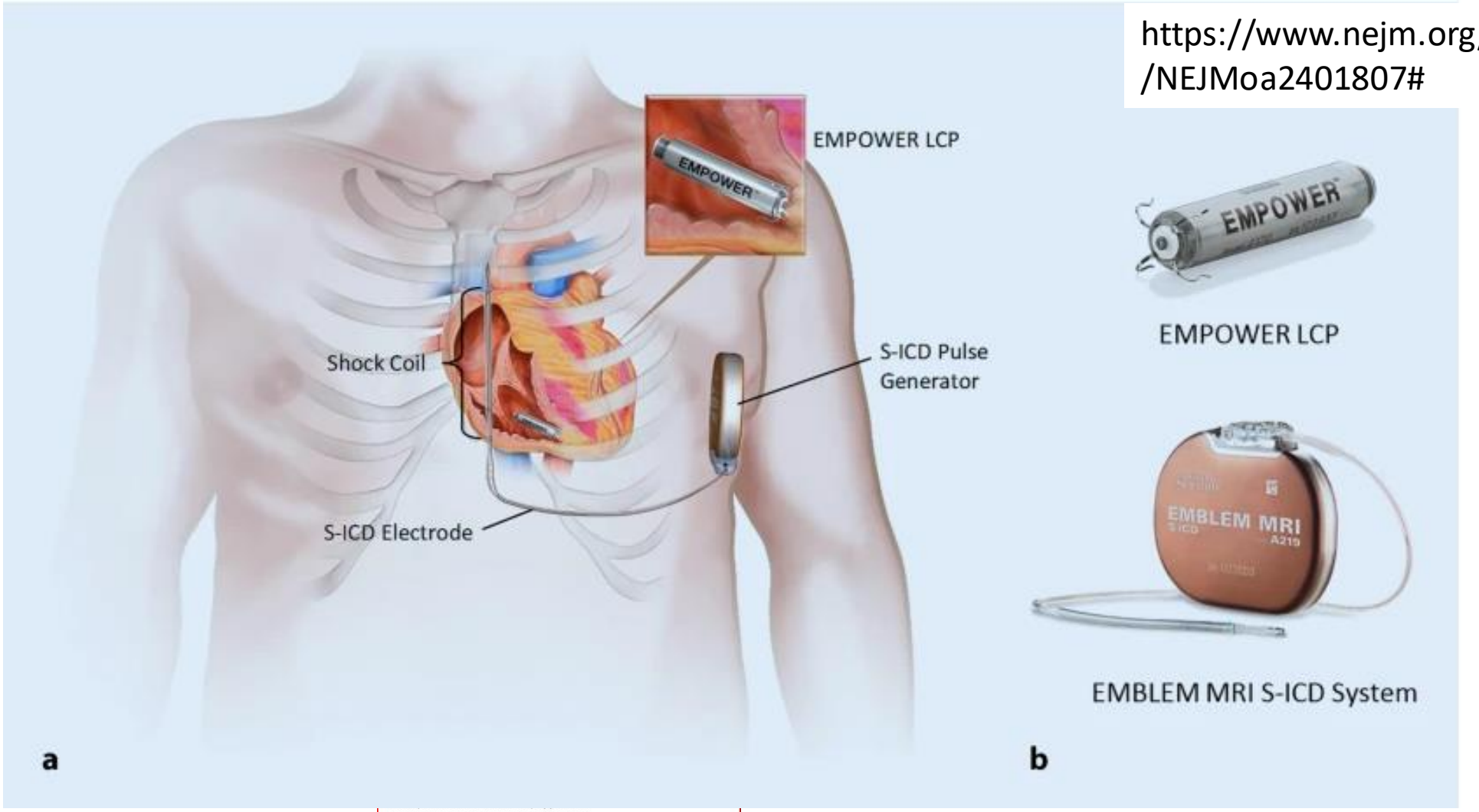

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The extravascular vision - Next generation single-chamber ICD

Provide a solution with the benefits of a single chamber transvenous ICD

via a simple, single device solution for protection from SCD

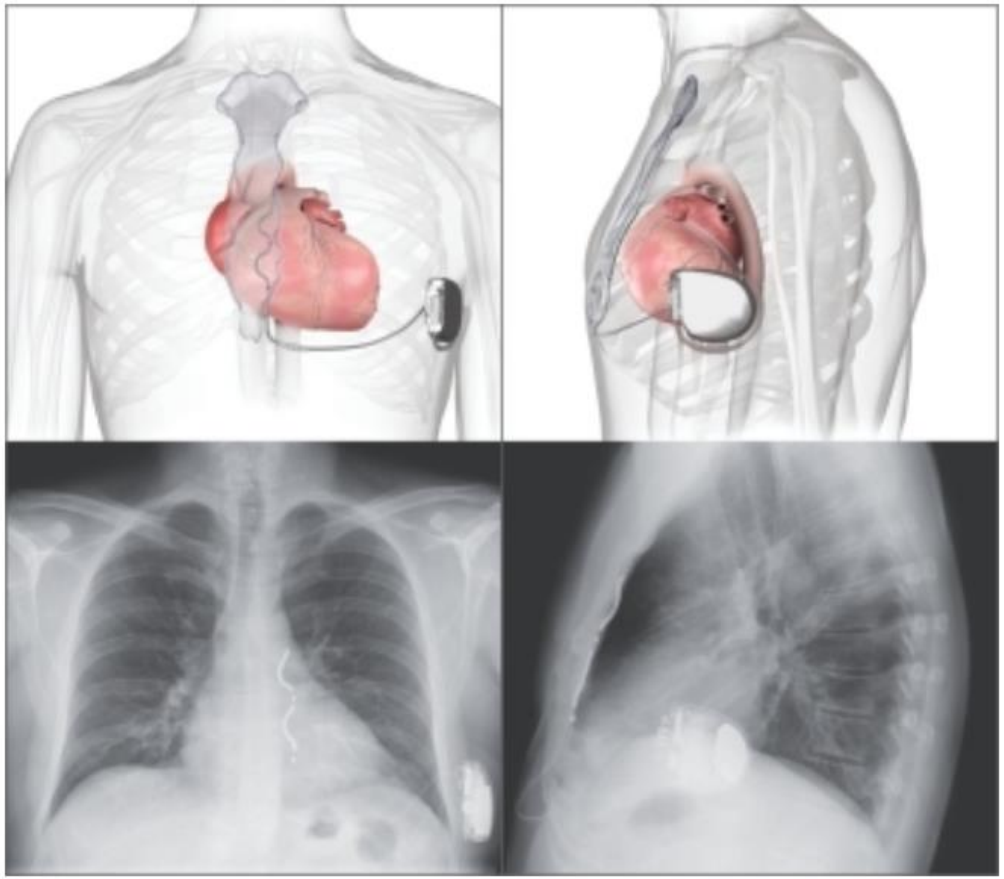
ATP

Post Shock Pacing

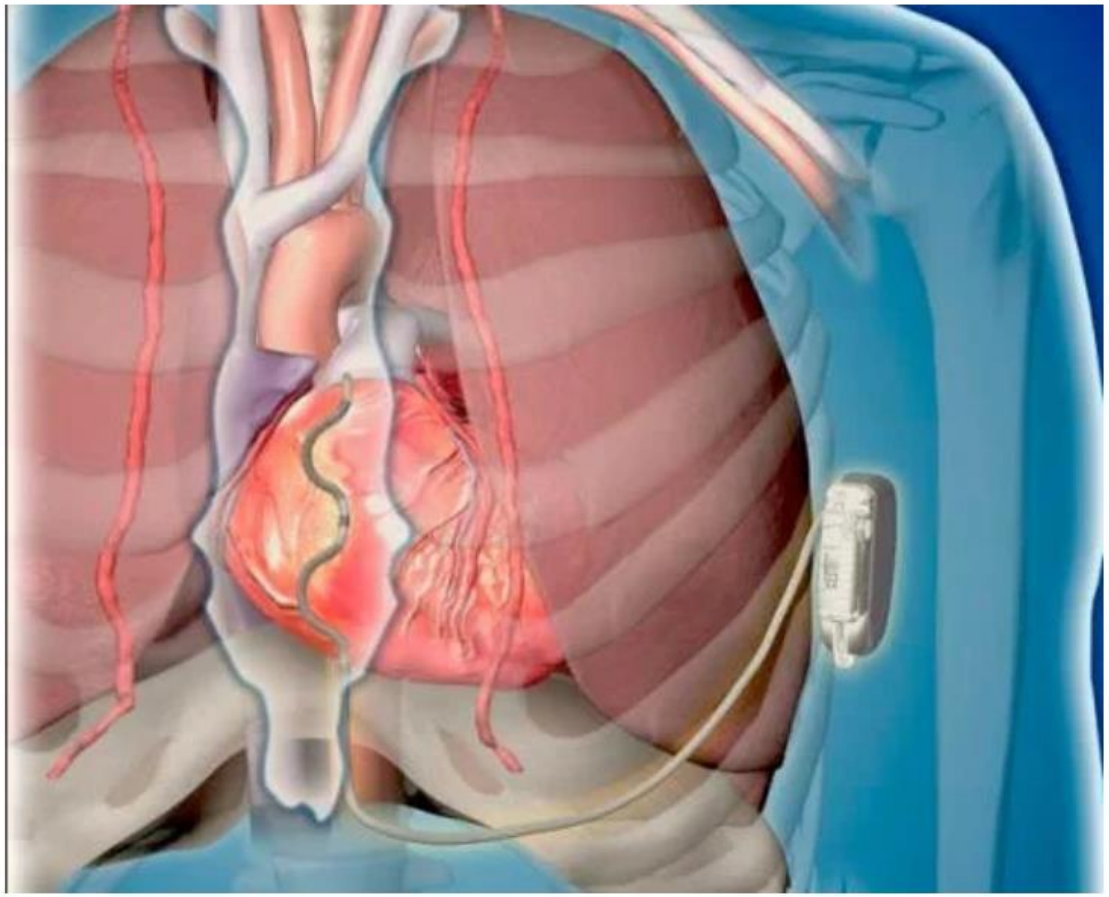
Pause Prevention Pacing

Extravascular ICD – EV-ICD

Implanting the lead substernally, directly above the right ventricle, allowing for sensing/backup pacing and lower DFT



Pause prevention, ATP, post-shock pacing



Generator implanted in the left mid-axillary region

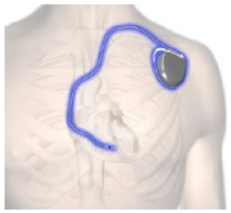
Friedman P et al. N Engl J Med2022;387:1292-1302

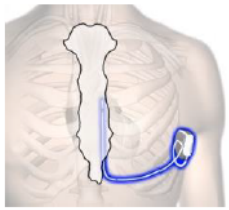
EV-ICD – Implantation

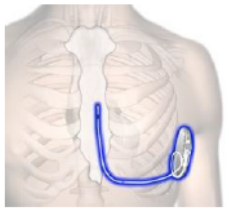
Friedman P. *N Engl J Med* 2022; 387: 1292-1302

Medtronic

Im Vergleich – transvenös, subkutan, extravaskulärer ICD
EV-ICD – best of both worlds?







Feature	Transvenous ICD[1]	Extravascular (EV) ICD[2] (substernal)	Subcutaneous ICD[3] (over the ribs/sternum)
Lead placement	**Intravascular**	**Extravascular (under the sternum)**	**Subcutaneous (over the ribs/sternum)**
Generator size	**33 cm^3**	**33 cm^3**	**60 cm^3**
Projected longevity†	**11-13 years**	**11.7 years**	**7.3 years**
Defibrillation	✓	✓	✓
Post-shock pacing	✓	✓	✓
Asystole support pacing	✓	✓	X
Antitachycardia Pacing (ATP)	✓	✓	X

† Projected battery longevities as reported in the approved device labeling.[1-3]

1. Medtronic Cobalt™ XT VR ICD MRI SureScan™ Model DVPA2D4 device manual.
2. Medtronic, Aurora EV-ICD™ MRI SureScan™ DVEA3E4 device manual.
3. Boston Scientific. User's Manual: Emblem™ S-ICD and Emblem™ MRI S-ICD. 2021. Accessed on April 10, 2024.

Medtronic

Im Vergleich – transvenös, subkutan, extravaskulärer ICD

	Transvenous ICD[a]	Subcutaneous ICD[b]	Extravascular ICD[c]
Lead location	Endovascular/endocardial	Parasternal (subcutaneous)	Anterior mediastinum (substernal)
Potential for cardiac injury/perforation	Present	Absent	Present
ICD generator location	Pectoral	Left midaxillary region	Left midaxillary region
Maximum delivered energy	40 J	80 J	40 J
ATP	Available	Not available	Available
Chronic pacing therapy	Available as chronic pacing therapy	Not available	Available as short-duration pause prevention pacing
Postshock pacing	Available	Available	Available
Generator volume	33 cc	60 cc	33 cc
Generator mass	79 g	130 g	77 g

Abbreviations: ATP, antitachycardia pacing; EV ICD, extravascular implant tor; M ce imaging; S-ICD, subcutaneous ICD.

[a] Cobalt™ XT single-chamber ICD (Medtronic plc).

[b] Emblem™ MRI S-ICD (Boston Scientific).

[c] EV ICD is not approved and Pivotal data are not available.

EV ICD Pivotal Study

Effectively terminated life-threatening rhythms with ATP and shocks while safely outside the vascular space[1]

Medtronic EV ICD Pivotal Study

Primary safety objective met

92.6% patients free from major system or procedure-related complications at 6 months*, in line with S-ICD IDE[2] and transvenous ICD studies[3-8]

Successful defibrillation

98.7% defibrillation success rate at implant meeting primary efficacy objective, 18/18 (100%) conversion of spontaneous episodes†

70%

ATP-terminated episode success rate†, avoiding 33 shocks in 7 patients

*Kaplan-Meier estimate. †Through average 10.6-month follow-up.

1. Friedman P, et al. NEJM. In press August 28, 2022. 2. Weiss R, et al. Circulation. 2013;128:944-53. 3. Bardy GH, et al. NEJM. 2005;352:225-37. 4. Sweeney MO, et al. Heart Rhythm. 2010;7:1552-60. 5. Curtis AB, et al. NEJM. 2013;369:579. 6. Linde C, et al. JACC. 2008;52:1834-43. 7. Gold MR, et al. JACC. 2015;65:2581-8. 8. Auricchio A, et al. Heart Rhythm. 2015;12:926-36.

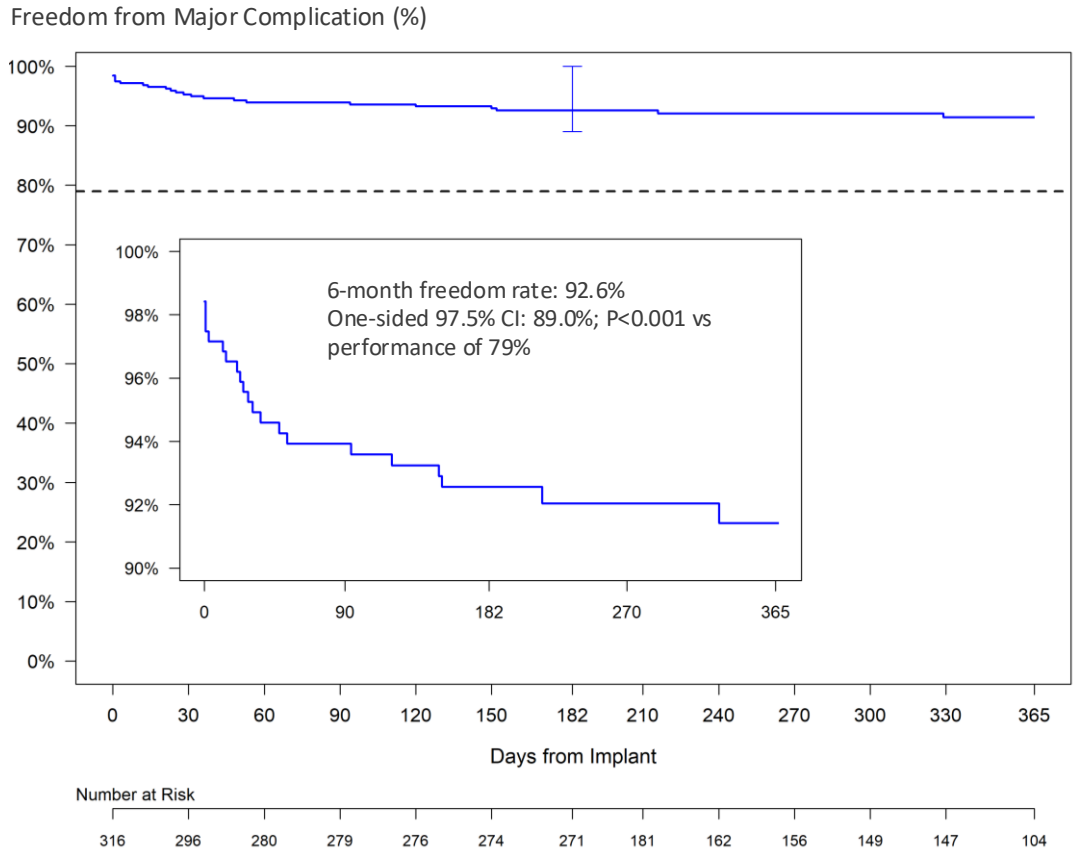
The New England Journal of Medicine

Conclusion – In this prospective global study, we found that an extravascular ICD can be implanted safely and can detect and terminate induced ventricular arrhythmias at the time of implant.

EV ICD freedom from major complication rate in-line with S-ICD IDE and transvenous ICD studies

Medtronic EV ICD Pivotal Study

- 92.6% of patients (Kaplan-Meier estimate) free from major complication at 6 months (p<0.001 compared to the safety performance goal of 79%)[1]
  - **S-ICD IDE study: 92.1%[2]**
  - **Transvenous ICD studies: 85.4%-93.8%[3-8]**
- Adverse events to 6 months; 25 events in 23 patients
  - System revision required: 18
  - No revision required: 7
- No major intraprocedural or unique complications due to EV ICD
- No reports of mediastinitis, sepsis, or endocarditis related to EV ICD
- No procedure or system related deaths



1. Friedman P, et al. NEJM. In press August 28, 2022. 2. Weiss R, et al. Circulation. 2013;128:944-53. 3. Bardy GH, et al. NEJM. 2005;352:225-37. 4. Sweeney MO, et al. Heart Rhythm. 2010;7:1552-60. 5. Curtis AB, et al. NEJM. 2013;369-579. 6. Linde C, et al. JACC. 2008;52:1834-43. 7. Gold MR, et al. JACC. 2015;65:2581-8. 8. Auricchio A, et al. Heart Rhythm. 2015;12:926-36.

Medtronic

Primary Safety Endpoint Adverse Events

- 25 events in 23 Patients
- No cardiac injury during implant
- No unique complications related to EV ICD procedure/system

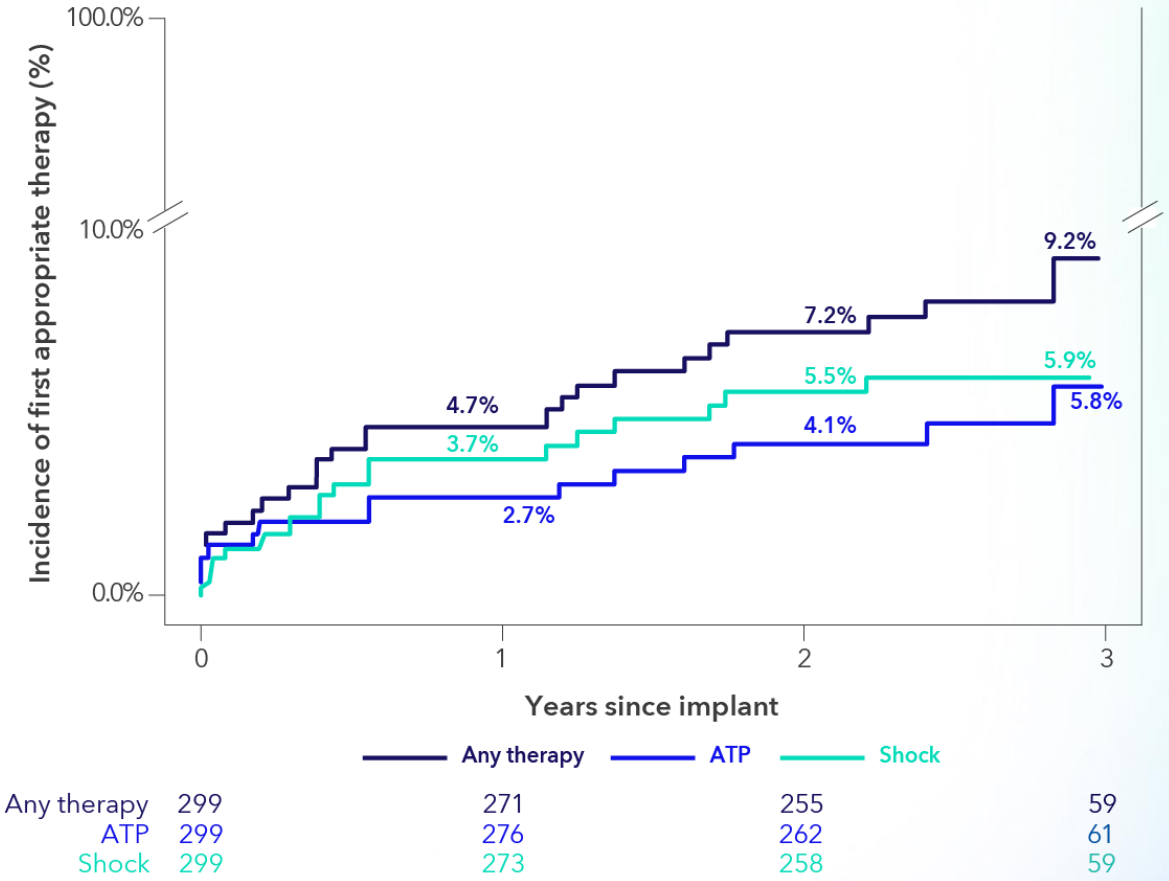
System revision required	**18**
Lead dislodgement	9
Infection	5
Discomfort/haematoma	2
Lead reposition/oversensing	1
Device lockup	1
No revision required	**7**
Wound related	3
Hospitalization for inappropriate shock	3
Lead dislodgement	1

EV ICD Pivotal Study long-term results[1]

Appropriate therapy through three years

Effective termination of VT/VF with 9.2% of patients receiving appropriate ATP or shock by three years follow-up

100% (27/27) discrete† shock success of spontaneous episodes



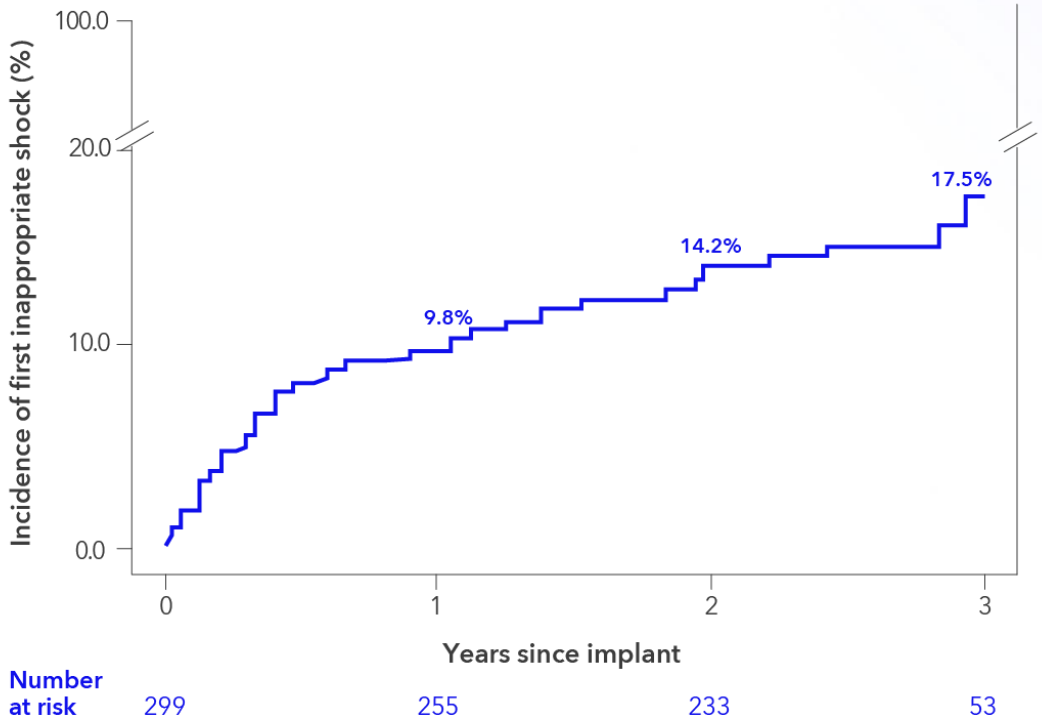
† Discrete episodes are defined as less than or equal to two events within 24 hours.

1. Friedman P, et al. *Circulation*. 2025;151:322–332.

EV ICD Pivotal Study long-term results[1]

Inappropriate shock rate from the investigational Pivotal Study device

- Inappropriate shock rate of 9.8% was observed at one year follow-up†; the rate slows after six months
- P-wave oversensing was the most common cause of inappropriate shock (51% of episodes)



† Kaplan-Meier estimate.

1. Friedman P, et al. *Circulation*. 2025;151:322–332.
2. Swerdlow C, et al. *JACC Clin Electrophysiol*. 2024;10:1896–1912.
3. Aurora EV-ICD™ MRI SureScan™ DVEA3E4 Device Manual.

The EV ICD Pivotal Study inappropriate shock performance is not representative of the commercial system performance.

- Aurora EV-ICD has the **Smart Sense** discrimination algorithm which showed a 29% projected reduction in the number of patients with inappropriate detection in preclinical validation.[2]
- **Repositioning** the lead at implant to meet P-wave and R-wave criteria may reduce cardiac oversensing[3] and the risk of inappropriate shock.
- **Reprogramming** the device parameters for sensing and detection discrimination may prevent inappropriate shock.[1]

Enlighten: The EV-ICD Post Approval Registry is evaluating the real-world performance of the Aurora EV-ICD™ system. Results of the commercial system are shown in subsequent slides.

Real-World Safety and Efficacy of the Extravascular ICD through Six Months: Outcomes from the Enlighten Study Post Approval Registry

Crozier I. Real-world safety and efficacy of the extravascular ICD through six months: Outcomes from the Enlighten study post approval registry; late-breaking results. Presented at: APHRS 2025; November 13, 2025; Yokohama, Japan.

Objective: assess the real-world safety s performance of the Aurora EV-ICD system through 6 months

Study design and methods

- Enlighten is a global, multicenter, prospective, post-market registry study assessing safety and performance of the Aurora EV-ICD system through the life of the device
- Characterize periprocedural outcomes
- Update on primary endpoint: Rate of chronic (> 30 days), system-related major complications† at 6 months (excluding infections and infestations)
- Rate of appropriate and inappropriate therapy at 6 months including a characterization of shock and ATP therapy
- Summary data is provided through all available follow-up
- 6-month rates were determined with the Kaplan-Meier method

Enlighten Study by the numbers

786 patients with an implant attempt

112 centers

168 implanters

23 countries

†Major complication defined as a complication that results in: death, permanent loss of device function due to mechanical or electrical dysfunction of the device, hospitalization, extension of a hospitalization by ≥48 H, or system revision

Baseline characteristics

Characteristic	Enlighten (N=786)	Pivotal[1] (N=316)
Mean age ± SD (years)	49.0 ± 15.2	53.8±13.1
Female	225 (28.6%)	80 (25.3%)
Secondary Prevention[†]	268 (34.1%)	57 (18.0%)
NYHA Functional Class III or IV	58/784 (7.4%)	23 (7.3%)
Mean BMI ± SD (kg/m^2)	27.4 ± 5.8 (N=779)	28.0 ± 5.6
Mean LVEF ± SD (%)	44.8 ± 16.0 (N=708)	38.9 ± 15.4
Cardiomyopathy	526/786 (66.9%)	266 (84.2%)
Ischemic	165/786 (21.0%)	127 (40.2%)
Non-ischemic	222/786 (28.2%)	103 (32.6%)
Hypertrophic	146/786 (18.6%)	41 (13.0%)
Primary/idiopathic electrical disease	133/784 (17.0%)	24 (7.6%)
Atrial fibrillation	109/786 (13.9%)	45 (14.2%)

[†]Determined based on history of cardiac arrest, ventricular fibrillation, or sustained ventricular tachycardia (Enlighten only)

[1]Friedman P, Murgatroyd F, Boersma LVA et al; *Circulation*. 2025 Jan 28: 151(4):322-332.

Baseline Charakteristika Tübinger Kohorte

Characteristic	All patients (n=41, 100%)
Mean age ± SD (years)	38,2 ± 15,5
Female	19 (46,3)
Secondary Prevention	21 (51,2)
NYHA III or IV	4 (9,7)
Mean LVEF ± SD (%)	53 ± 15,2
Cardiomyopathy	
Ischemic	4 (9,8)
Non-ischemic	12 (29,3)
Hypertrophic	11 (26,8)
ARVC	4 (9,8)
Idiopathic electrical disease	2 (4,9)
Brugada	4 (9,8)
Long QT	4 (9,8)
Atrial fibrillation	2 (4,9)

Our patients were younger,

had more often a secondary prevention indication,

showed better LVEF,

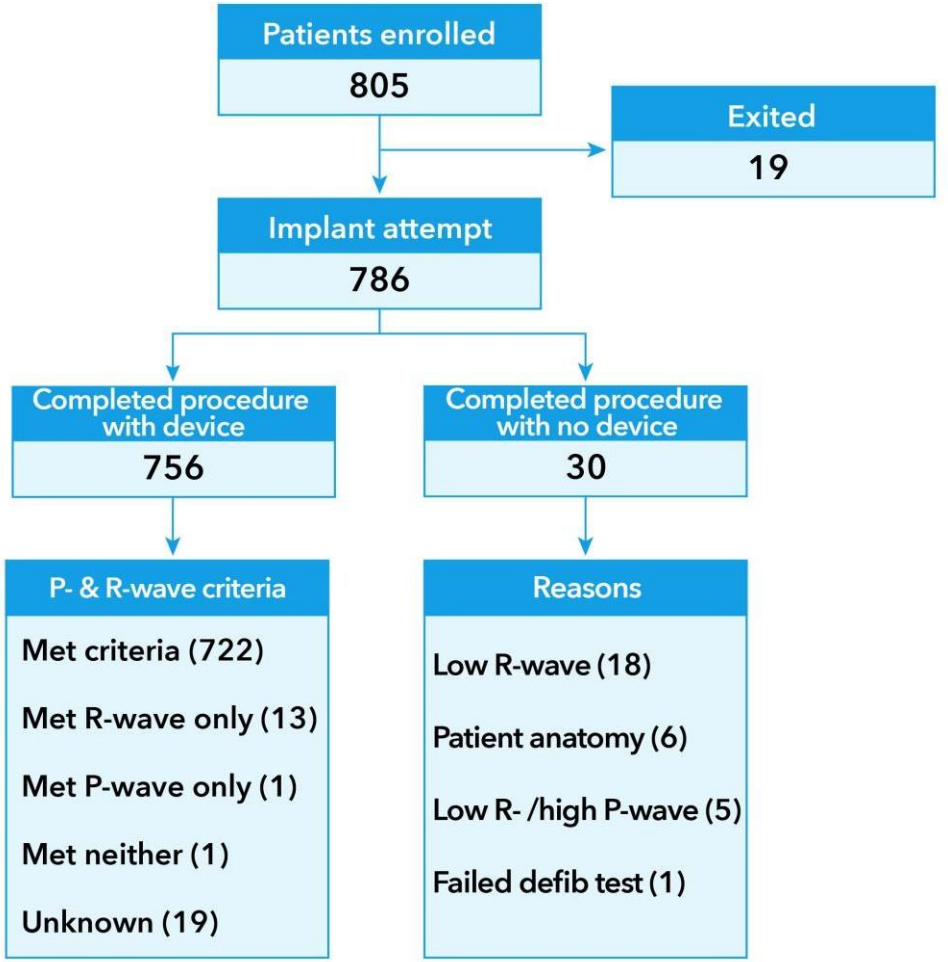
better NYHA class, and

similar underlying diseases

Implant procedure

- 99.2% (780/786) tunneling and lead placement success
- 96.2% (756/786) completed the procedure with a device
- Mean procedure time (1st incision to final suture) was 81.0±38.2 min
- Mean R-wave amplitude at implant was 2.9±1.6 mV (N=731 reported)
- 98.0% (722/737 reported) met P- and R-wave criteria†

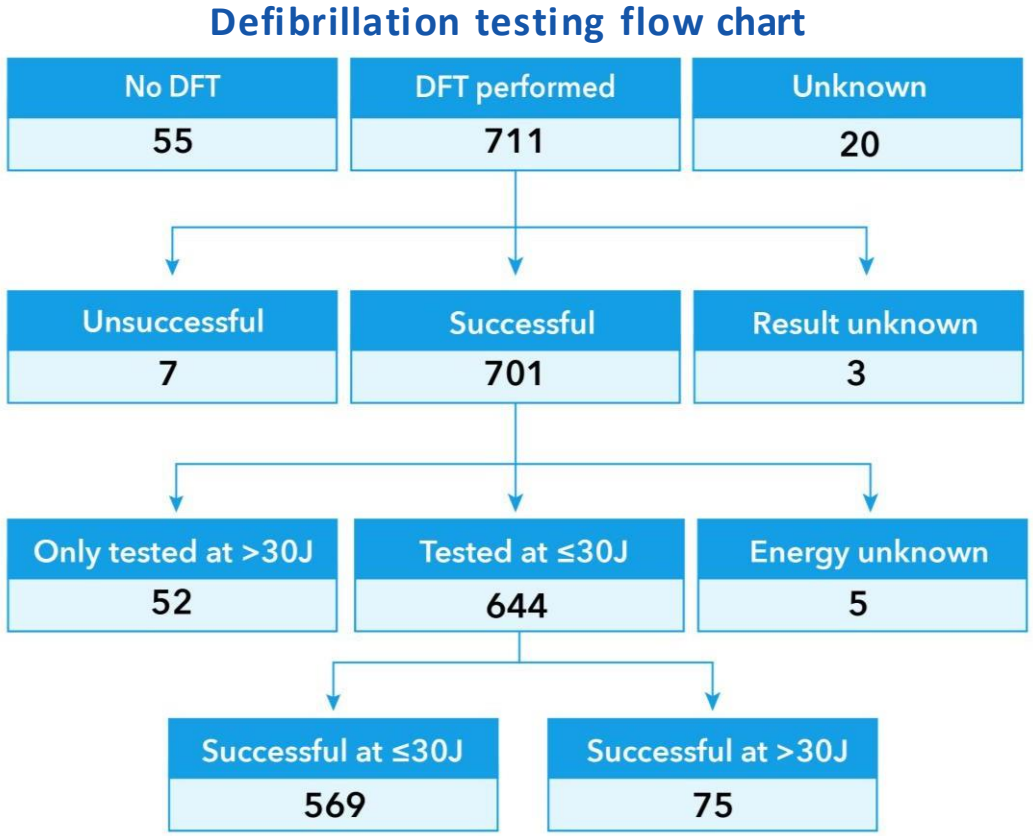
Enlighten Study patient flow chart



†R-wave amp ≥1mV; P-wave not present, P-wave at which no longer sensed ≤0.2mV or sensitivity ≤0.3mV and ratio of R-wave ≥10

Defibrillation testing

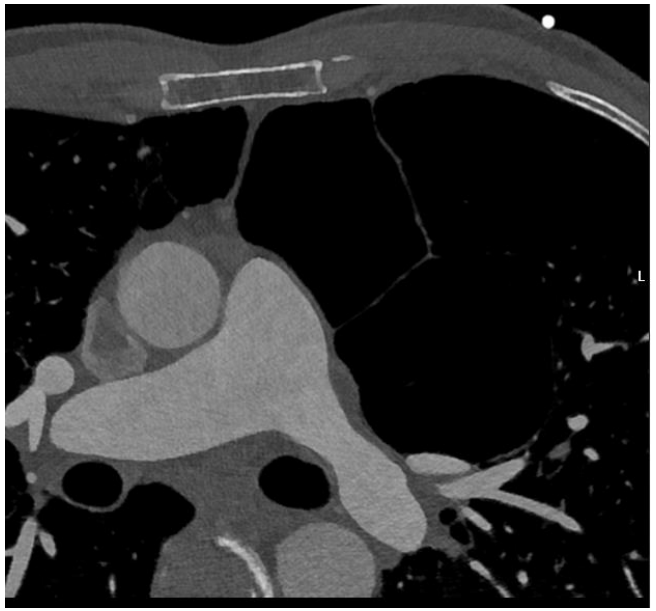
- 99.0% (701/708 reported) defibrillation testing success when performed at implant
- Mean energy successful was 31.2±4.3J
- 88.4% (569/644 reported) of those tested at ≤30J were successful

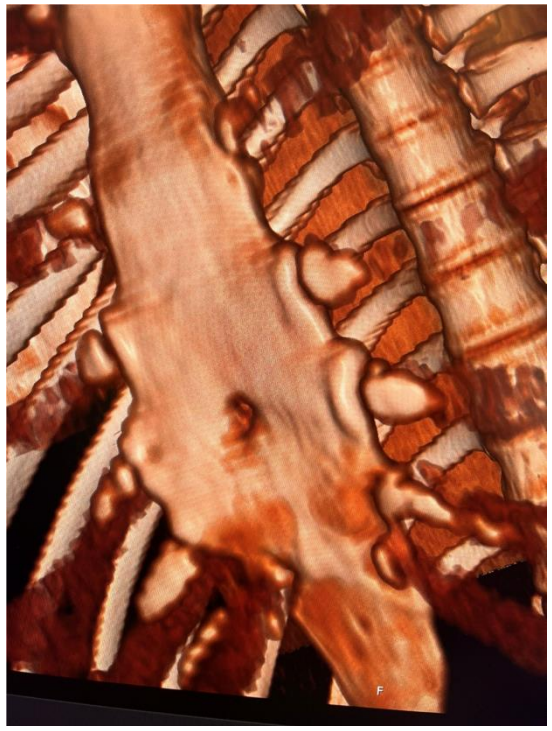


*Defibrillation testing was performed per physician discretion/standard of care

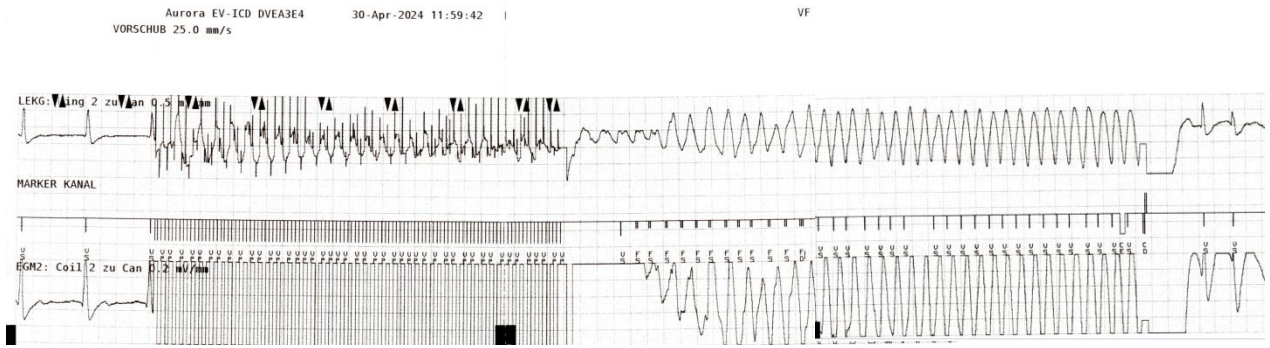
Charakteristika der Implantation Tübinger Kohorte

Characteristic	All patients (n=41, 100%)
Implant success rate	37 (90,2)
Transvenous VVI-ICD	4 (9,8)
DFT success rate	39 (95,1)





Implant success rate was 90,2%, 4 patients were switched to transvenous VVI-ICD 2 due to low sensing, 1 because of large pulmonal bullae newly developred and 1 due to foramen sternale
DFT success rate intraoperative 95,1%,2 remaining patients successfull DFT after 4 weeks
Mean R-wave during implant was 2,1 ± 1,7 mV
No P-wave detectable during implantation



Intraprocedural complications

- Six intraprocedural major complications† related to the system and/or procedure. All resolved without any lasting effects
  - Prolonged hospitalization to repeat defibrillation test (N=2), re-position device (N=2), replace lead due to lead movement (n=1)
  - Pneumothorax (N=1); prolonged hospitalization to monitor patient and no intervention required
- No procedures required emergency surgical intervention

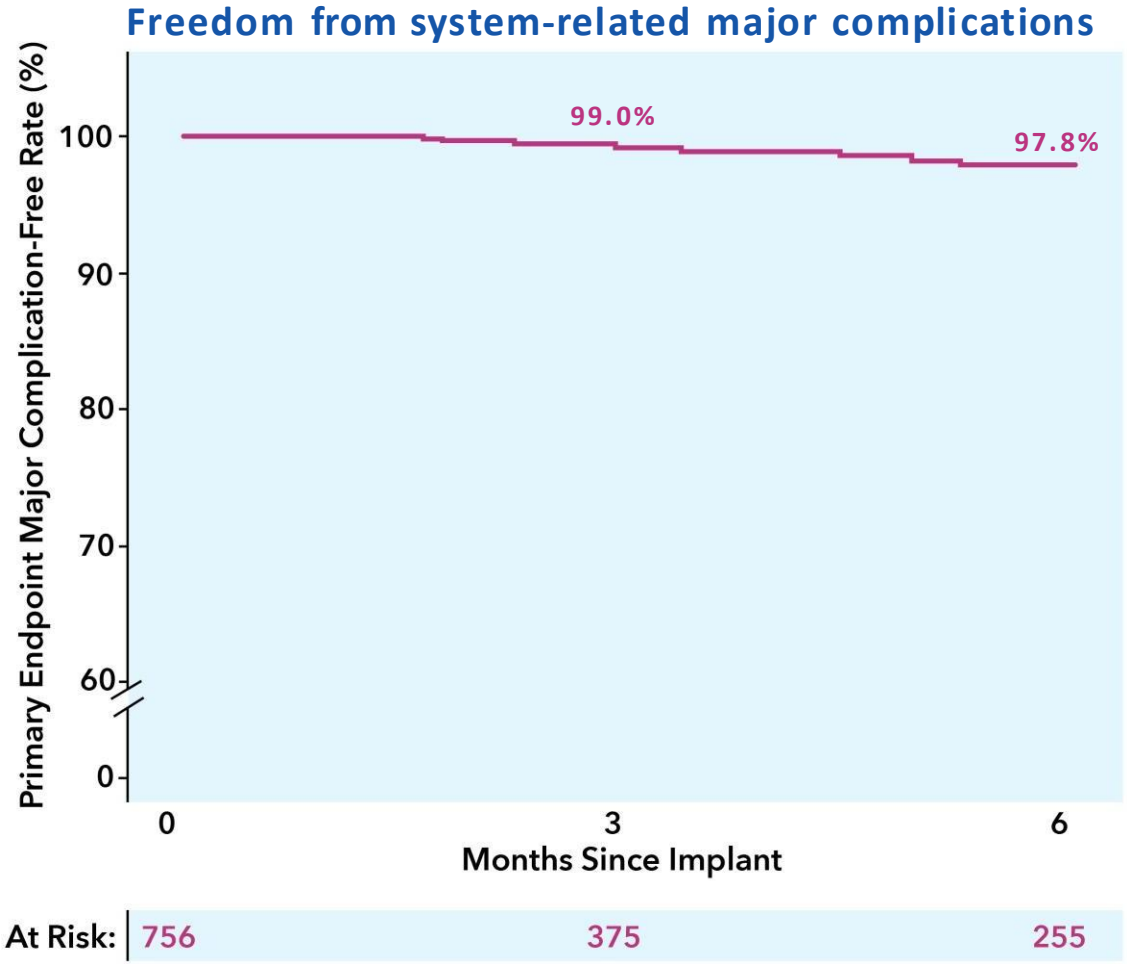
Tübinger Kohorte:

- **Keine intraoperativen Komplikation**
- **bisher alle Eingriffe in ITN und Atemmanöver/Atemstopp**
- **nun erste Eingriff in Analgosedierung und sternaler Blockade und Rektusscheidenblock (Rectus Sheath Block) als effektives Regionalanästhesieverfahren geplant**

†Defined as death, permanent loss of device function due to mechanical or electrical dysfunction of the device, hospitalization, prolonged hospitalization by 48 hours or more, or system revision

Primary endpoint

- Primary endpoint[†] will be assessed at 5 years
- 97.8% freedom from chronic system-related major complications at 6 months (**Figure**)
  - In line with Pivotal (98.0% at 6 months)
- 8 system-related major complications in 8 patients:
  - Inappropriate shock delivery [‡] (N=5)
  - Lead dislodgement (N=2)
  - Implant site pain (N=1)



[†]Pre-determined endpoint with the FDA: defined as chronic (>30 days) system-related major complications (excluding infections s infestations)
[‡]Not inclusive of all inappropriate shocks that occurred, only those that met the definition of the primary endpoint

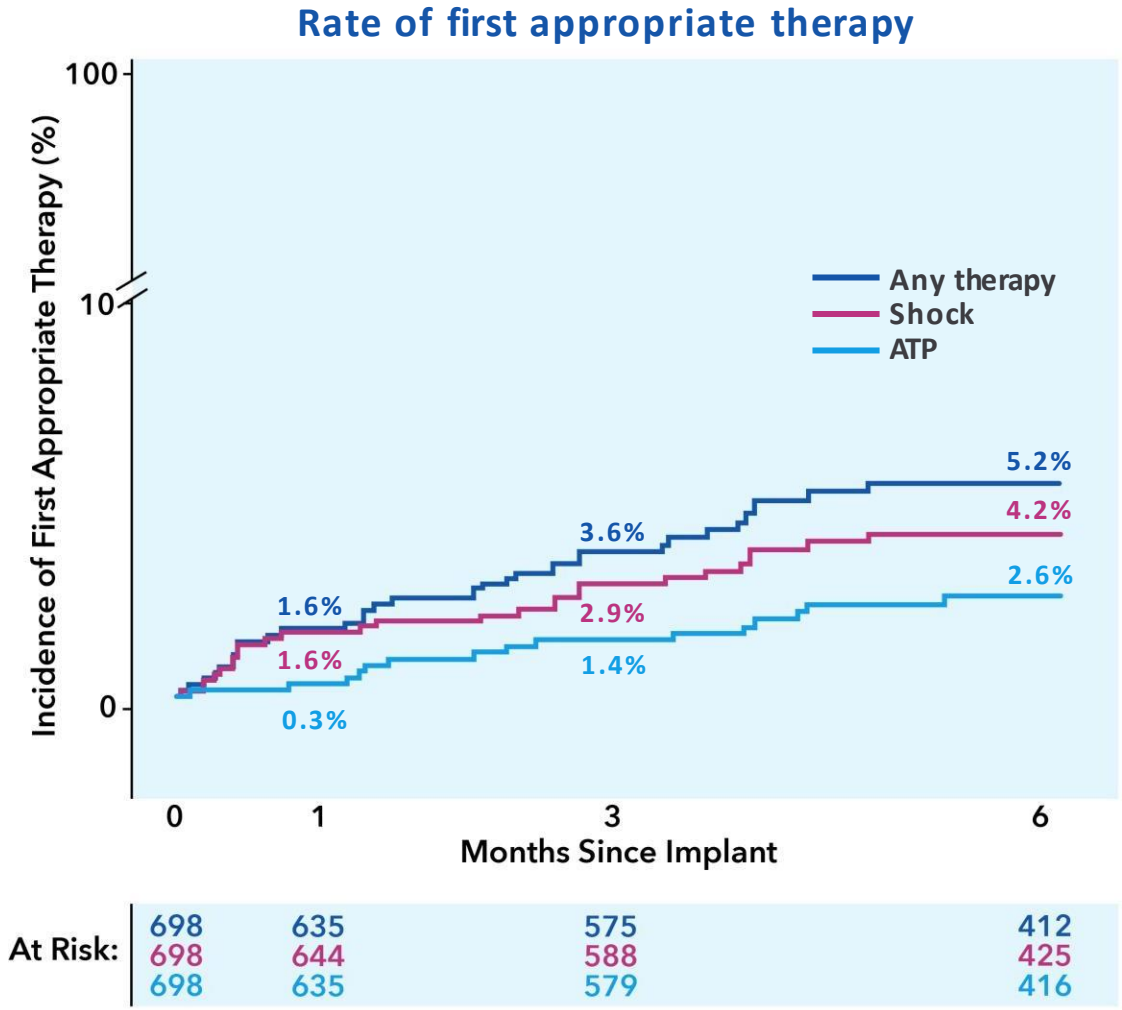
Infections

- 11 of 786 (1.4%) patients with an implant attempt had a major system- and/or procedure-related infection (10 resolved, 1 pending)
  - System explanted (N=6)
  - Antibiotics only (N=3)
  - Wound or pocket revision (N=2)
- No cases of mediastinitis, sepsis, or endocarditis related to the system and/or procedure

Appropriate therapy

- 5.2% rate of first appropriate therapy at 6 months (**Figure**)
- 195 total appropriately treated episodes in 44 patients through mean of 7.9 months follow-up:

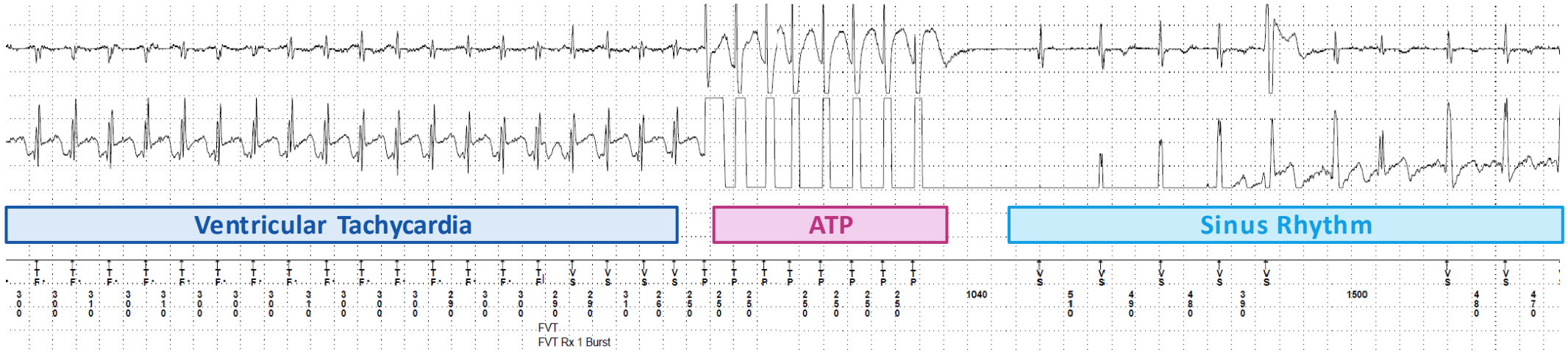
- 100% (47/47) shock success for discrete spontaneous VT/VF episodes
- 95.7% (45/47) first shock success (one episode required 2 shocks; one episode required 3)



Characterization of ATP

- 66.9% adjusted† ATP success rate (60.3% raw success rate) through a mean of 7.9 months follow-up
- 44 shocks avoided in 17 patients because of ATP through all follow-up
- No patients had ATP programmed ‘Off’ after receiving ambulatory therapy

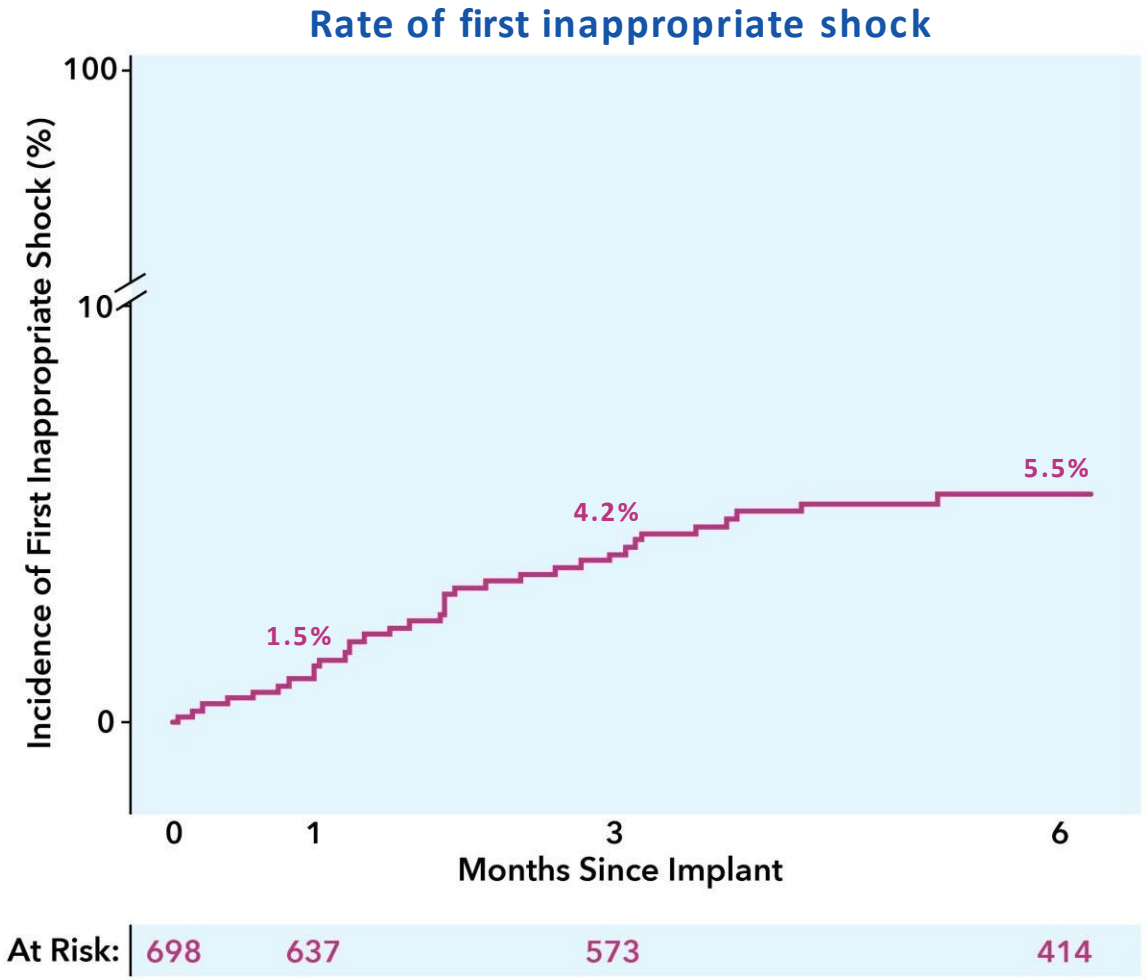
Example of a successful ATP



†Adjusted using Generalized Estimating Equations (95% CI: 48.2%, 81.4%)

Inappropriate shock

- 5.5% rate of first inappropriate shock at 6 months (**Figure**)
- 66 total inappropriate shocks in 43 patients through a mean of 7.9 months follow-up
- 32.1% lower rate than what was observed in Pivotal (8.1% rate at 6 months[1])

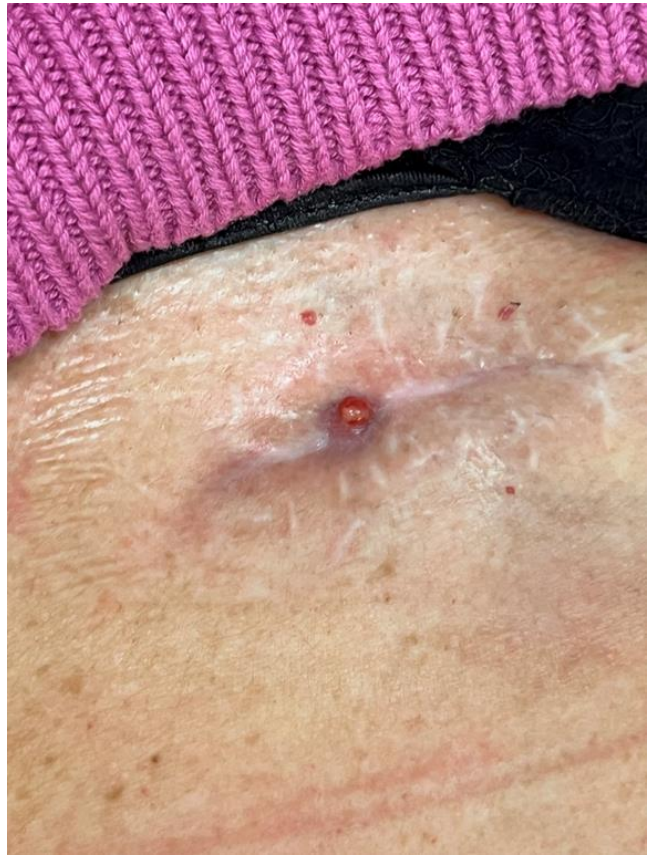


[1]Friedman P, Murgatroyd F, Boersma LVA et al; *Circulation*. 2025 Jan 28: 151(4):322-332.

Charakteristika nach Implantation Tübinger Kohorte

Characteristic	All patients (n=41, 100%)
Adequate therapy during 2 ys FU	4 (9,7)
ATP	5 (12,2)
ICD-shock	1 (2,4)
Pacing	0 (0)
Complications during surgery	0 (0)
Complications after 4 weeks	0 (0)
Complications after 2 years FU	2 (4,9)
Superficial wound necrosis	2 (4,9)
Wound infection	0
Allergic reaction	1 (2,4)
Explantation	2 (4,9)
P-Oversensing causing nadequate ICD-shock	1 (2,4)

- **2 minor wound necrosis**
- **2 explantations (one due to recurrent wound necrosis, one due to patient‘s request**



Conclusions of real world data

Preliminary evidence from a large real-world cohort with more than a third secondary prevention patients, the Aurora EV-ICD has demonstrated:

- **A high implantation success rate s low rate of chronic complications through 6 months**
  - 99.2% achieved tunneling and lead placement success
  - 96.2% completed the procedure with a device
  - 97.8% freedom from system-related major complications at 6 months
  - Low rate of major infection (1.4%), none resulting in mediastinitis, sepsis, or endocarditis
- **Effective appropriate therapy**
  - 5.2% rate of first appropriate therapy at 6 months
  - 100% shock success for discrete spontaneous episodes
  - 66.9% GEE-adjusted ATP success rate (60.3% raw success rate) avoiding 44 shocks in 17 patients
- **Reduced inappropriate shock rate compared to Pivotal[1]**
  - 5.5% inappropriate shock rate at 6 months versus 8.1% in Pivotal (32% reduction)
  - 34.8% reduction in proportion of inappropriate shocks caused by PWOS compared to Pivotal

[1]Friedman P, Murgatroyd F, Boersma LVA et al; *Circulation*. 2025 Jan 28: 151(4):322-332.

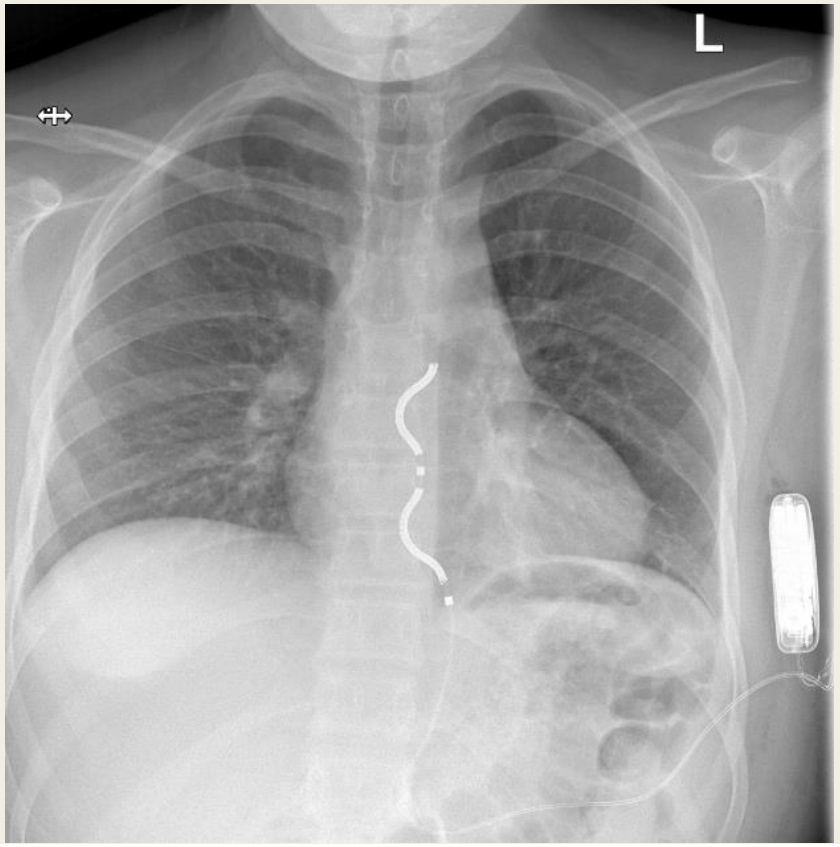
Tübinger Kohorte

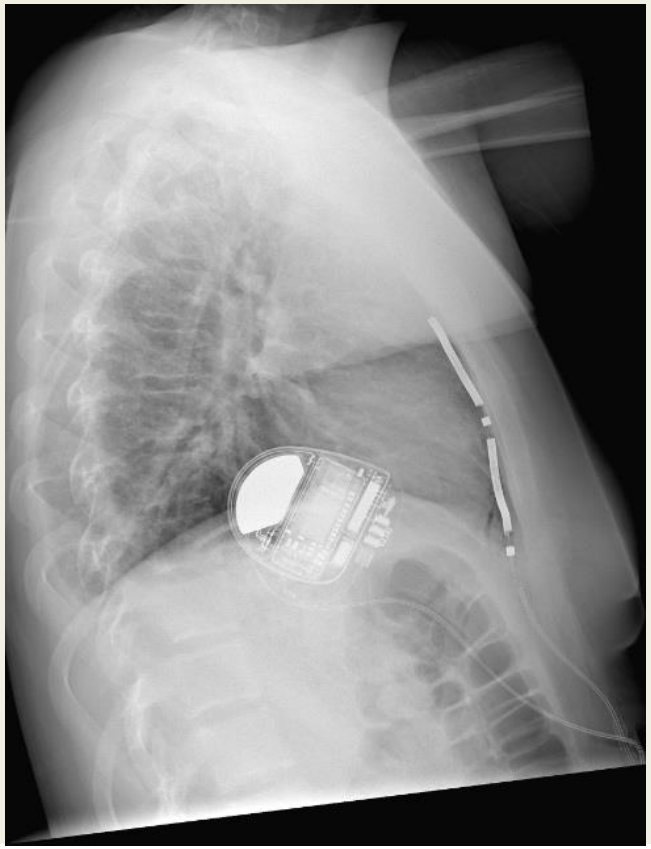
- Spiegelt im Wesentlichen das Real WorldScenario anderer Zentren wieder, unser FU sind 2 Jahre im Gegensatz zu 6 Monaten
- Besonderheit: Versorgung von Kindern und Jugendlichen in unserem Zentrum im Alter von 6, 12, 14 und 17 Jahren

Tübinger Kohorte entspricht im Wesentlichen dem Real World Scenario anderer Zentren, unser FU umfasst 2 Jahre im Gegensatz zu 6 Monaten

- **Besonderheit: Versorgung von Kindern und Jugendlichen in unserem Zentrum im Alter von 6, 12, 14 und 17 Jahren**

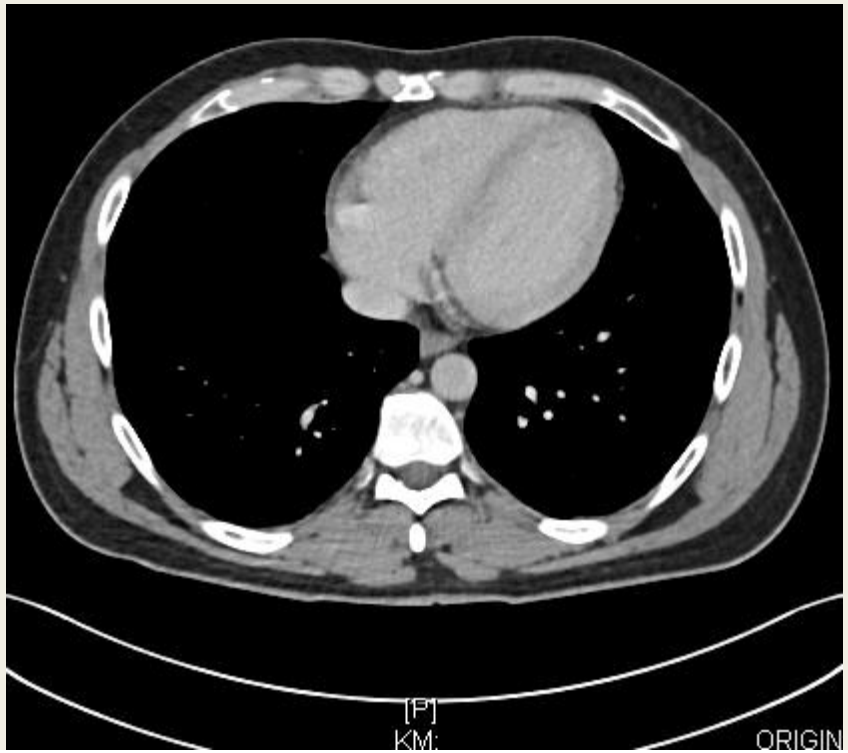
Schulkinder, Adoleszenz/junge EW

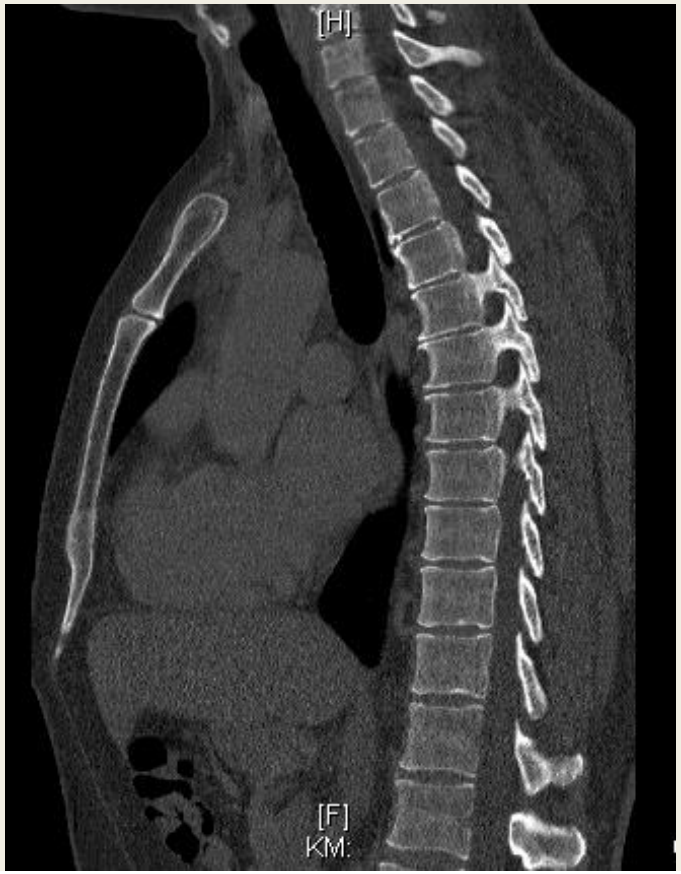




Tachykardie-Therapie

EV-ICD: Präoperatives Screening: cMRT oder CT





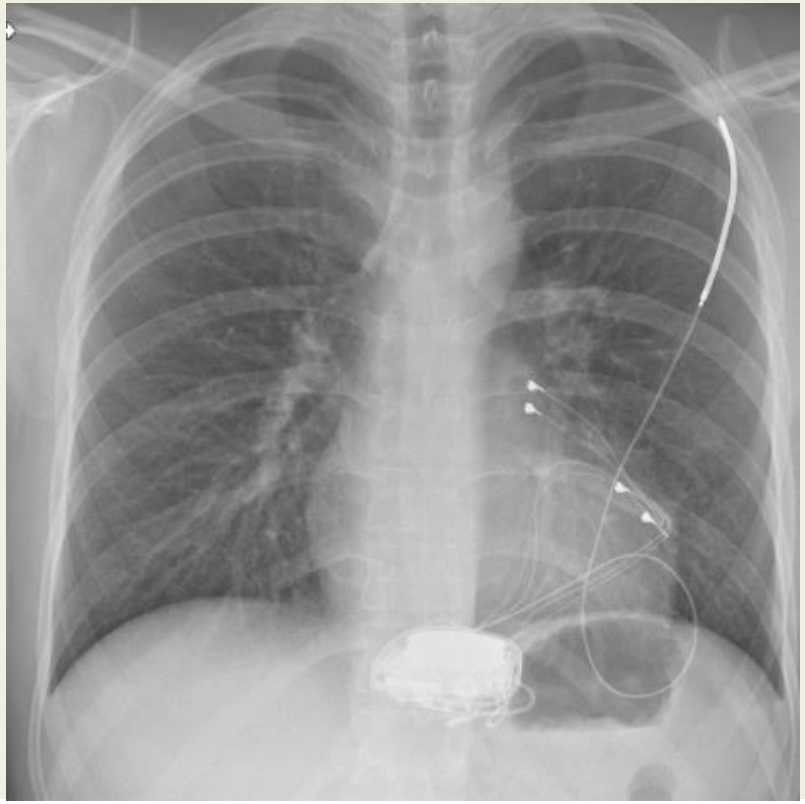
Tachykardie-Therapie

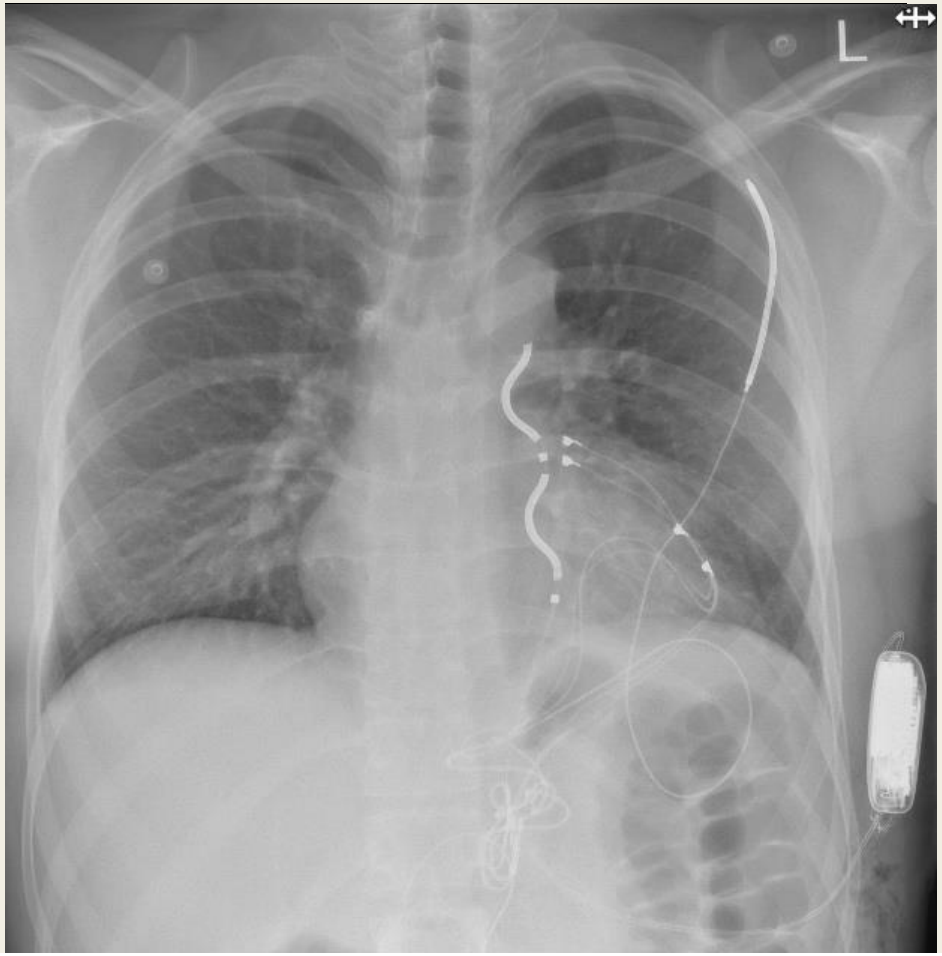
EV-ICD

- Bei jungen Patienten ohne antibradykarden Pacingbedarf
- Insbesondere Ionenkanalerkrankungen, CMP (Shockbox)
- Schonung der venösen Gefäßzugänge
- Gute Batterielaufzeit, kleineres Aggregat im Vgl. zu S-ICD
- Antitachykardes Pacing und Asystolieschutz möglich, Schock mit 40J
- Monitorzone und Algorithmen (Wavelet), Größe und Batterielaufzeit wie transven. ICD
- MRT-tauglich

Wann ist der EV-ICD nicht sinnvoll?

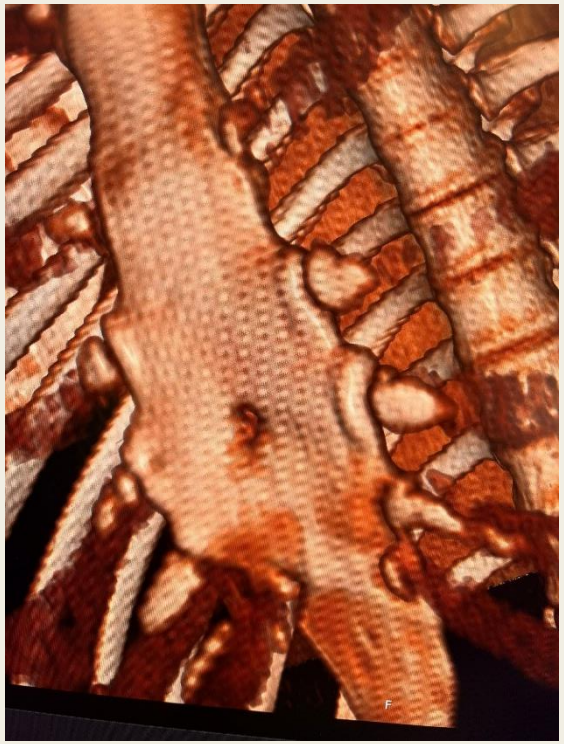
EV-ICD: Keine sternalen Voreingriffe

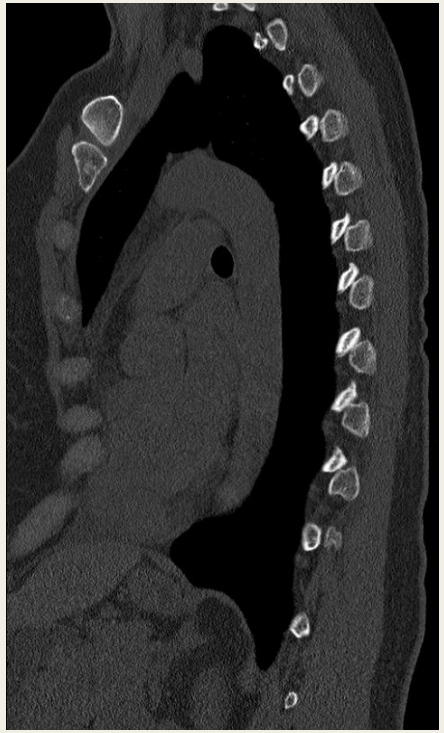


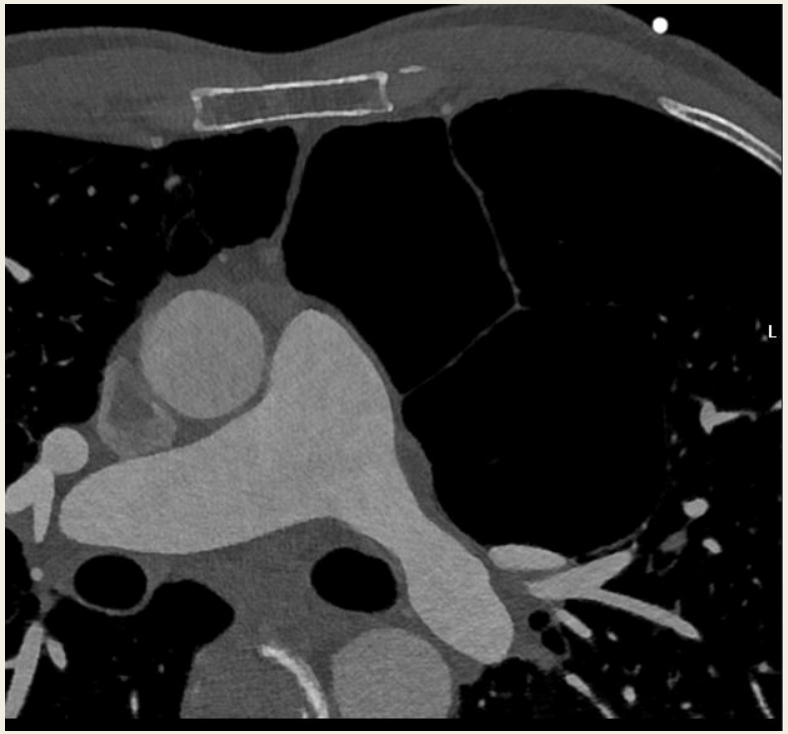


Wann ist der EV-ICD nicht sinnvoll?

Anatomische Herausforderungen







Ggf. Körpergröße

> 200cm

Body Mass Index

< 40

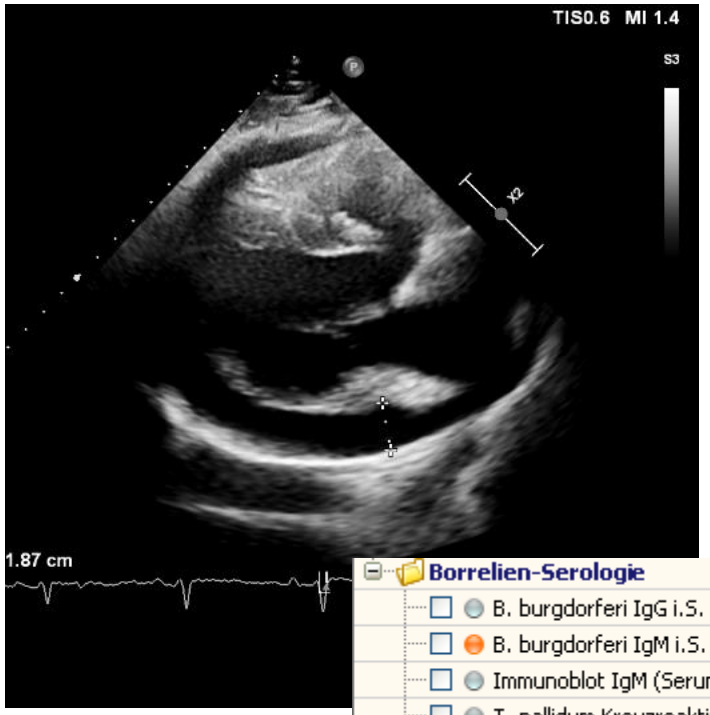
Challenges during clinical course of disease

1. P-Wellen-Oversensing due to newly developed atrial flutter/fibrillation in HOCM patient - PWOS is a unique challenge for the EV-ICD that can result in double counting and inappropriate therapies – **Only no P-Wave is a good P-Wave!**
2. Impedance changes due to pericardial effusion caused by Lyme carditis

Impedance changes due to pericardial effusion caused by Lyme carditis

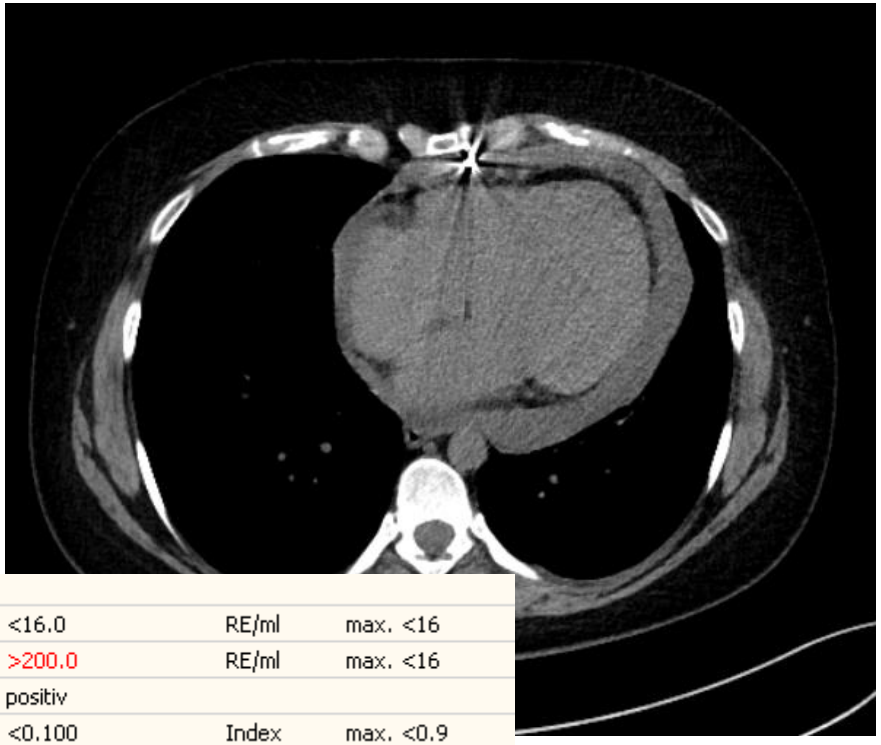
Patient with HOCM and acute borreliosis

Newly developed pericardail effusion – drop of impedance with alarming signal of EV-ICD



Cause of pericardial effusion

- **Dressler?**
- **Hemorrhagic?**
- **Perforation?**
- **Inflammatory?**
- **Infections?**



Borrelien-Serologie				
B. burgdorferi IgG i.S.	<16.0	<16.0	RE/ml	max. <16
B. burgdorferi IgM i.S.	>200.0	>200.0	RE/ml	max. <16
Immunoblot IgM (Serum)	positiv	positiv		
T. pallidum Kreuzreaktivität	<0.100	<0.100	Index	max. <0.9

Impedance changes due to pericardial effusion caused by Lyme carditis

Patient with HOCM and acute borreliosis

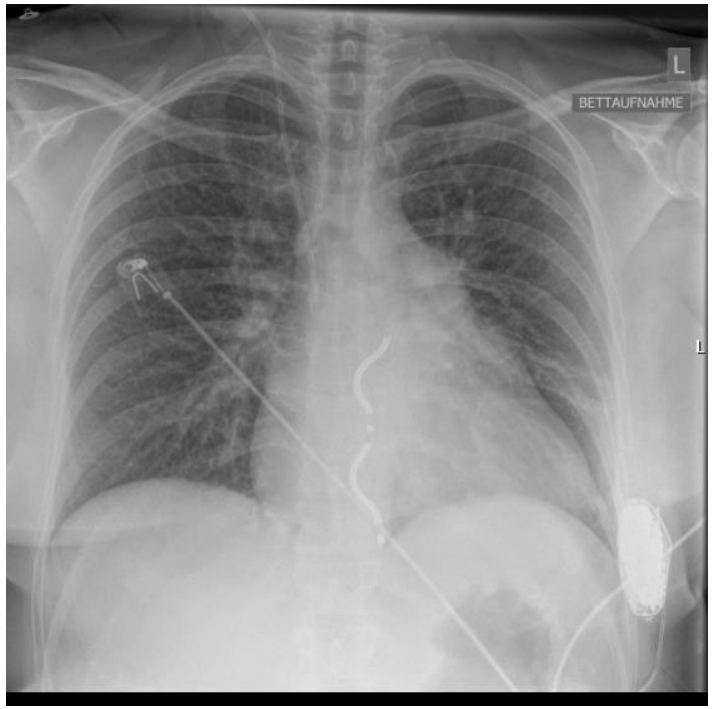
Chest X-ray during course of the disease

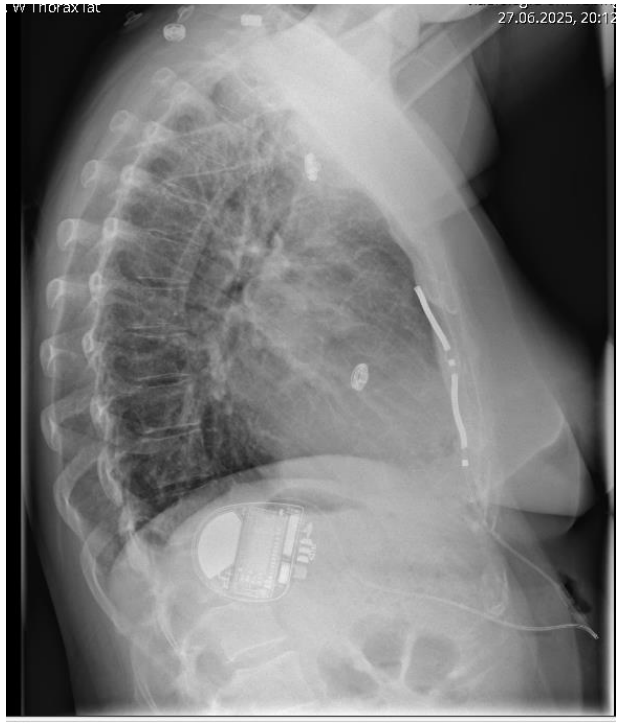
Impedance changes due to pericardial effusion caused by Lyme carditis

Patient with HOCM and acute borreliosis

Chest X-ray during course of the disease

Postoperative 07/2025



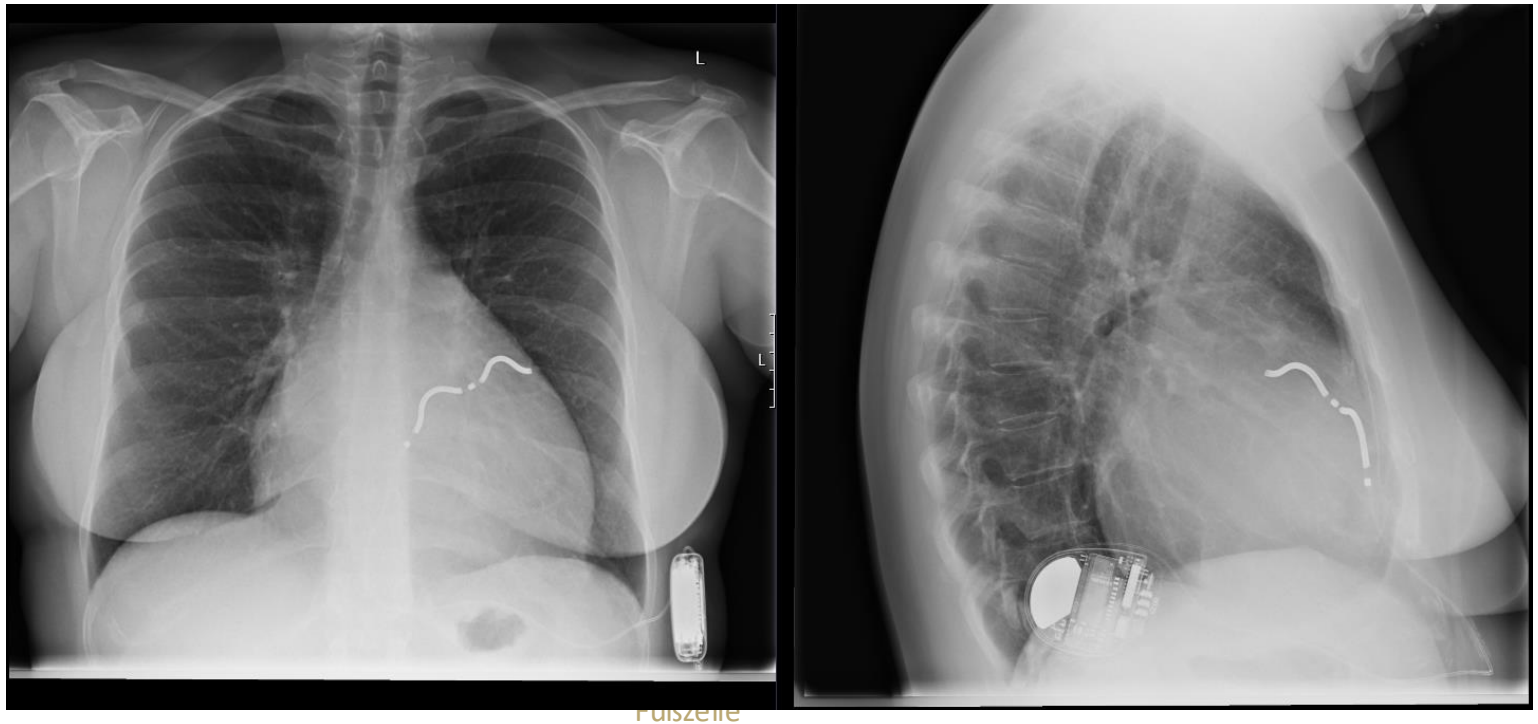


Impedance changes due to pericardial effusion caused by Lyme carditis

Patient with HOCM and acute borreliosis

Chest X-ray during course of the disease

After alarming signal 09/2025

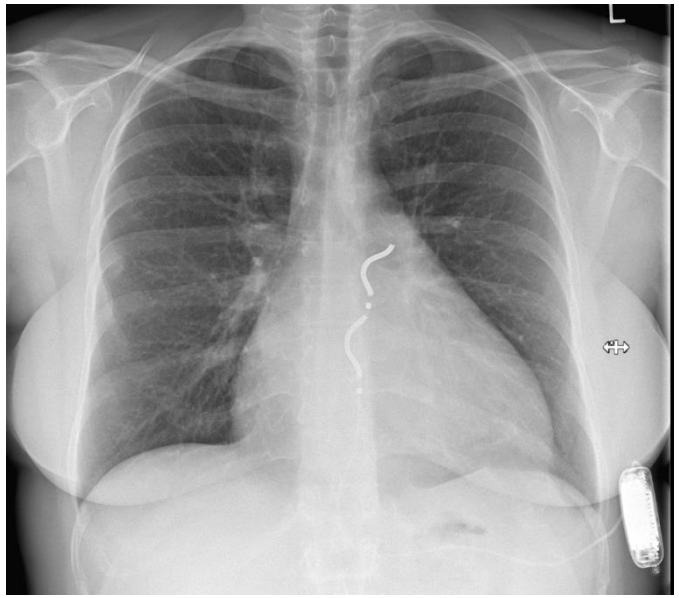


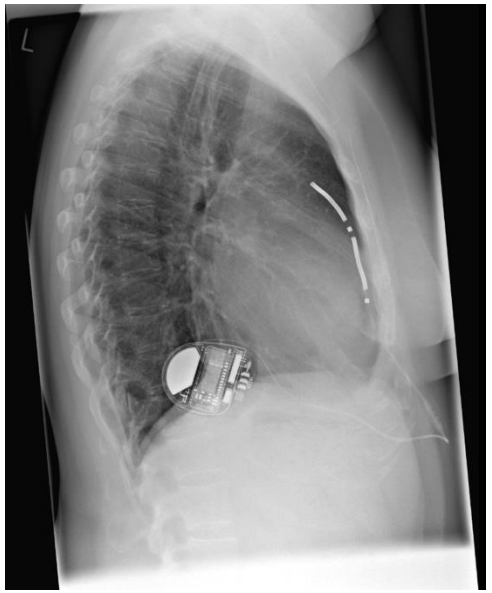
Impedance changes due to pericardial effusion caused by Lyme carditis

Patient with HOCM and acute borreliosis

Chest X-ray during course of the disease

6 Weeks after doxycyclin therapy





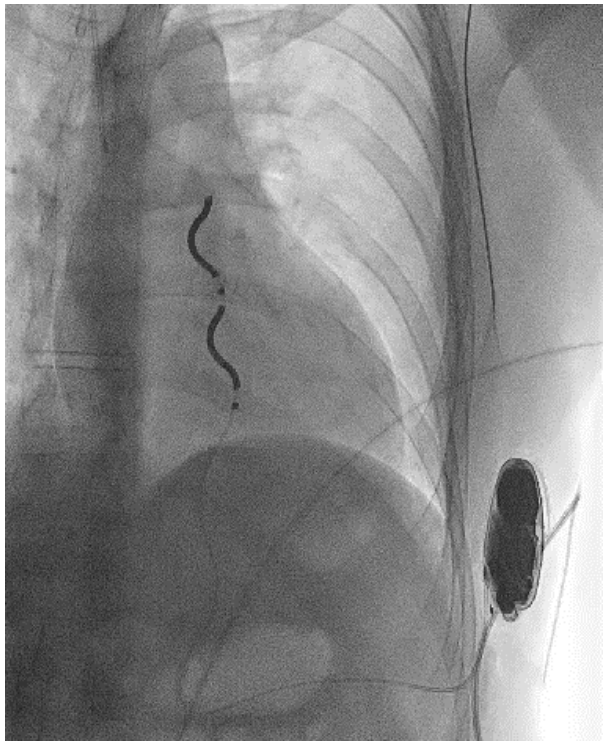
Normalization von X-Ray

Normalization of impedance values after pericardial effusion was resolved

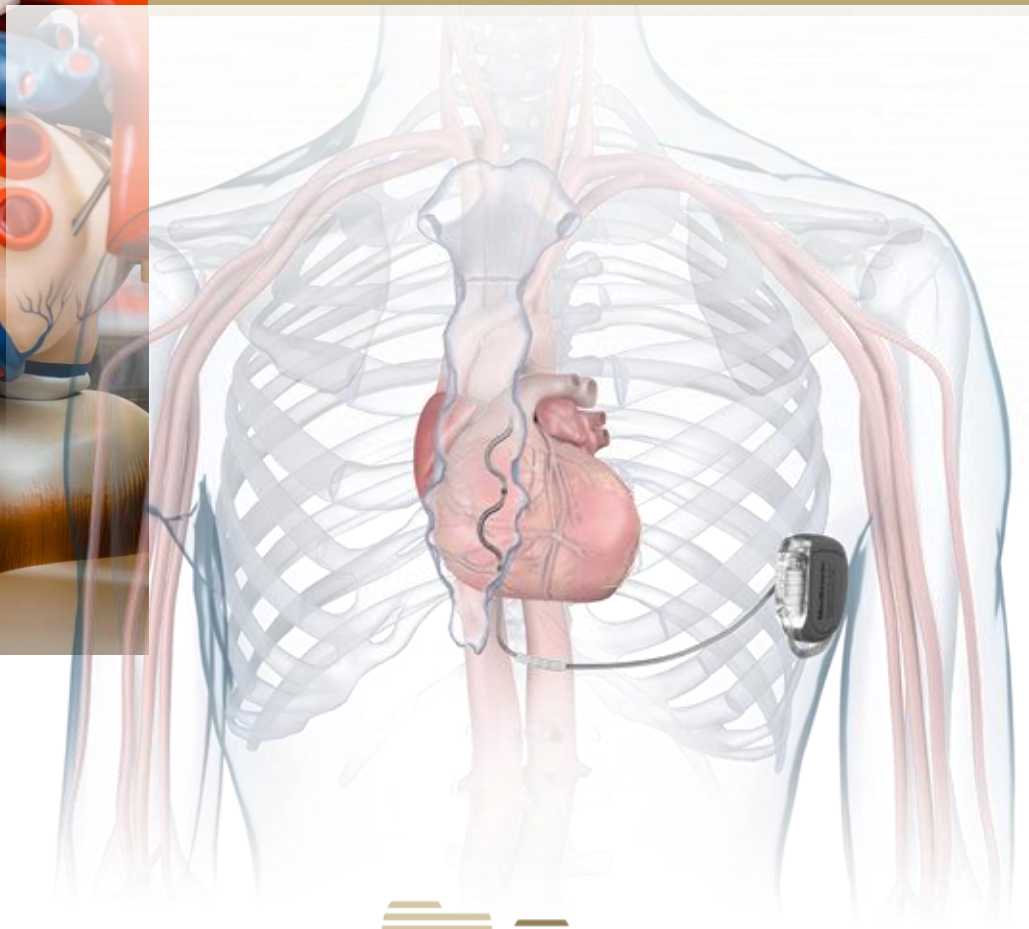
Zusammenfassung

ICDs save lives, and new technologies are evolving to avoid leads in the vasculature

- Transvenous ICDs save lives, but they have non-negligible short- and long-term complications associated with increased morbidity and mortality
- Extravascular ICD systems were developed to avoid the vasculature
- S-ICD has proven 5+ years safety and efficacy established
- EV-ICD has completed its pivotal trial achieving initial safety and efficacy
- IAS rates, reliable pacing/ATP needs further attention
- Longer-term studies are warranted to continue to assess extravascular ICD systems and their benefits and to develop reliable pacing, and ATP features



Thank you!

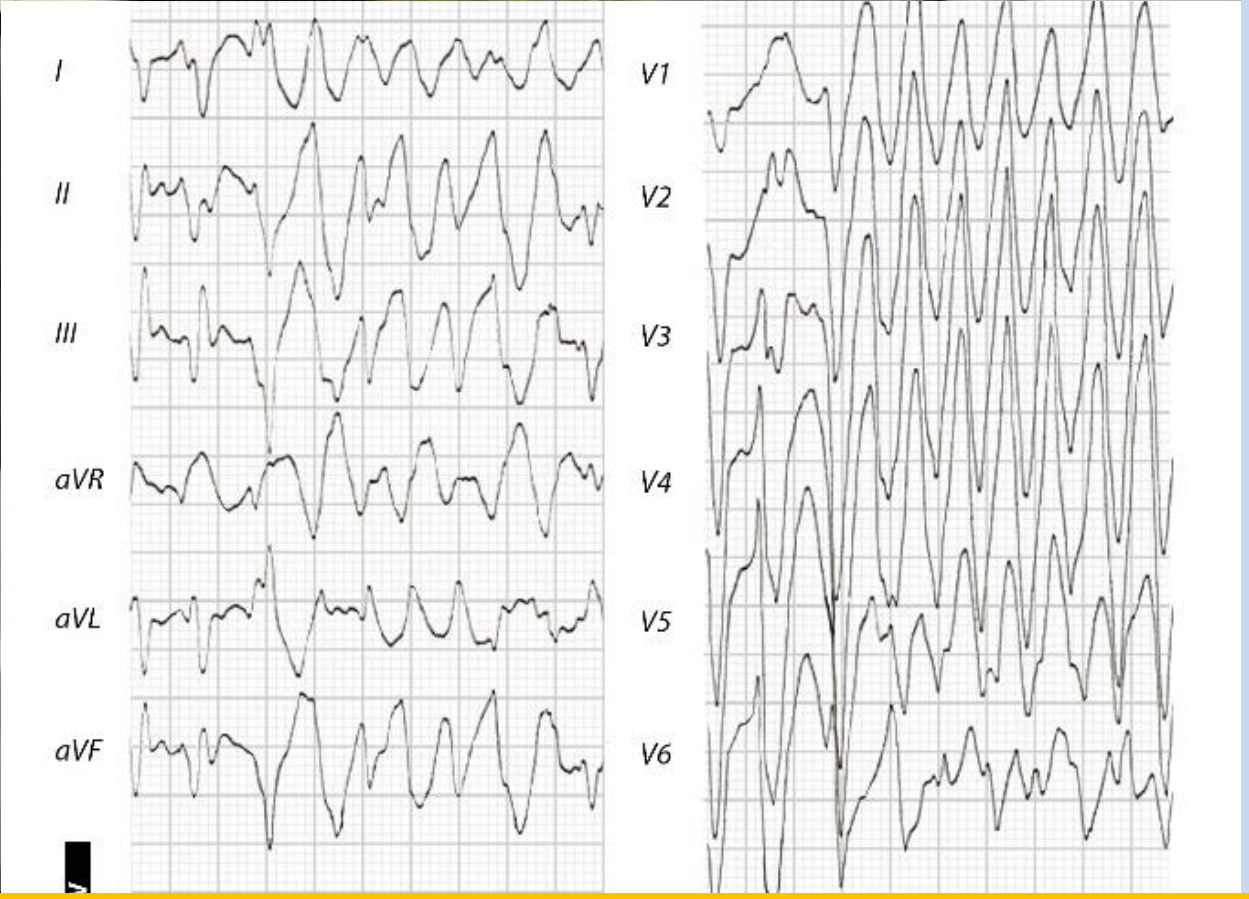


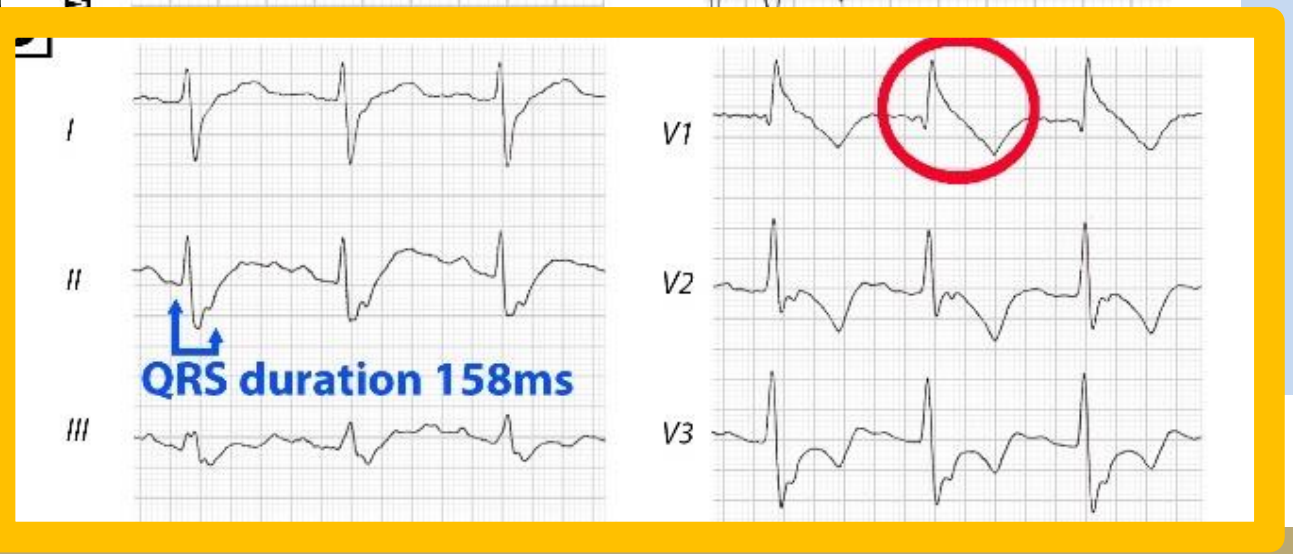
Universitätsklinikum Tübingen

Case report #1

Family history with one case of electrical storm and one suspected case of sudden cardiac death – implications for the family members and allele carriers?

- Counseling of a 36 years old father of an 8 months old girl being admitted with cardiogenic shock due to electrical storm.
- Father “healthy”, no medication, no history of syncope, no cardiac symptoms, no palpitations, good body condition, exercises regularly, no sleeping disorders.



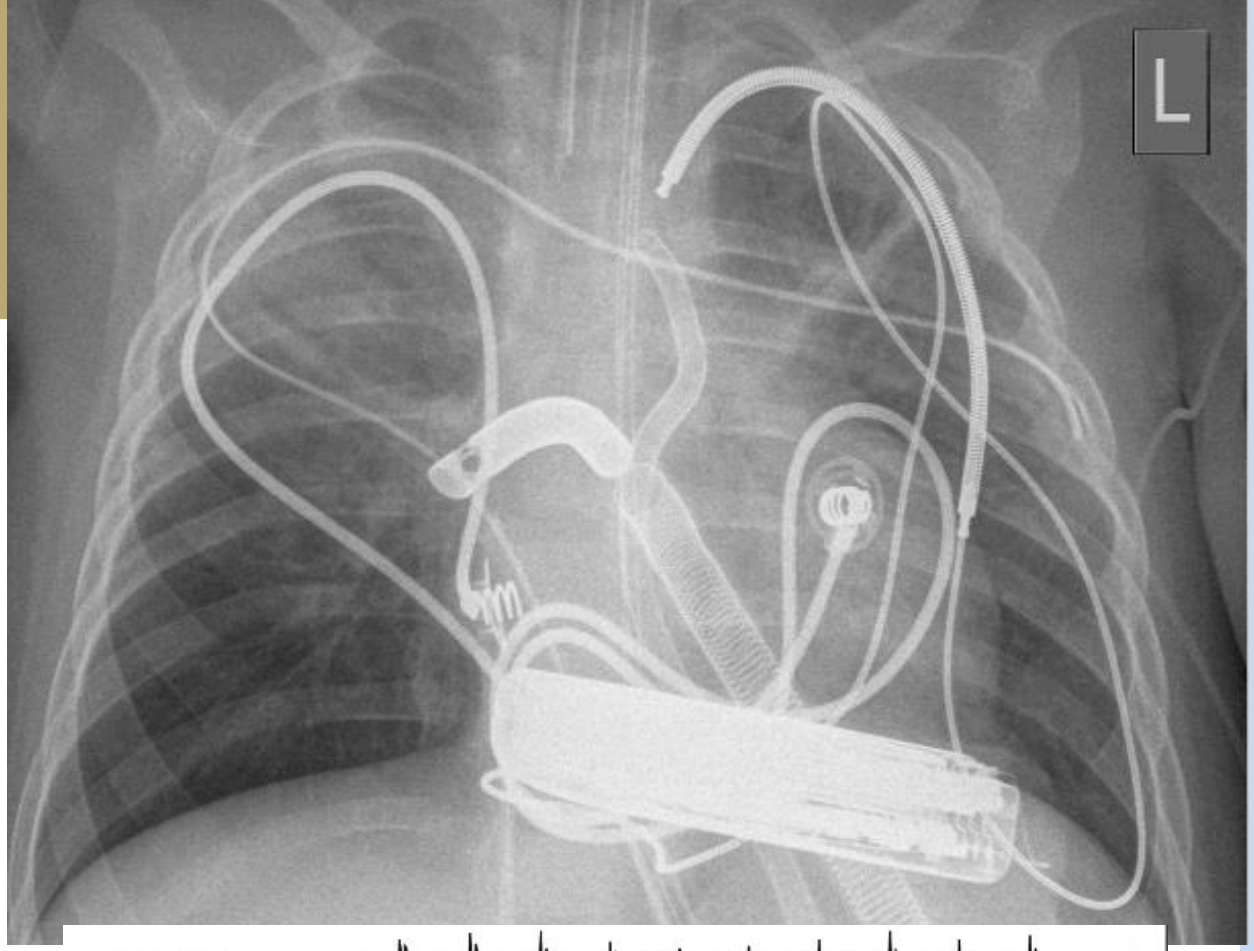


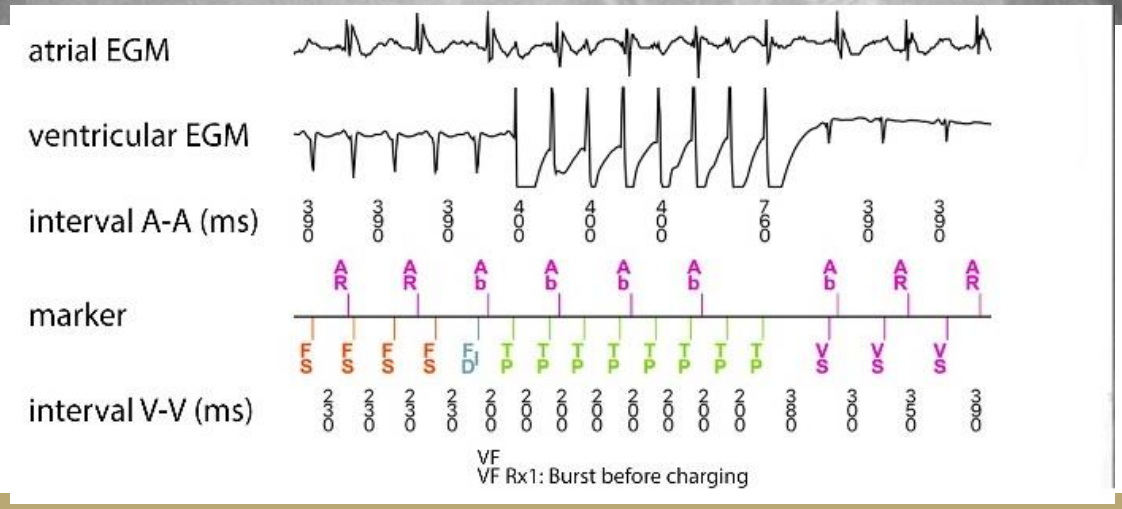
Family history

Acute SARS-CoV-2 Infection Reveals a Novel Pathogenic SCN5A Variant Causing Electrical Storm in an 8-Month-Old Infant: Implications for the Whole Family

Symptomatic index patient - daughter

- Cardiac arrest during an acute febrile infection due to VF
- In the paediatric ICU recurrent VTs (“electrical storm”) persistent despite external defibrillations, hypothermia, and drug therapy with amiodarone and metoprolol necessitating ECLS
- **Acute SARS-CoV-2 infection**
- **No myocarditis**
- ECG pattern of elevated ST segments resembled Brugada syndrome
- SCN5A channelopathy

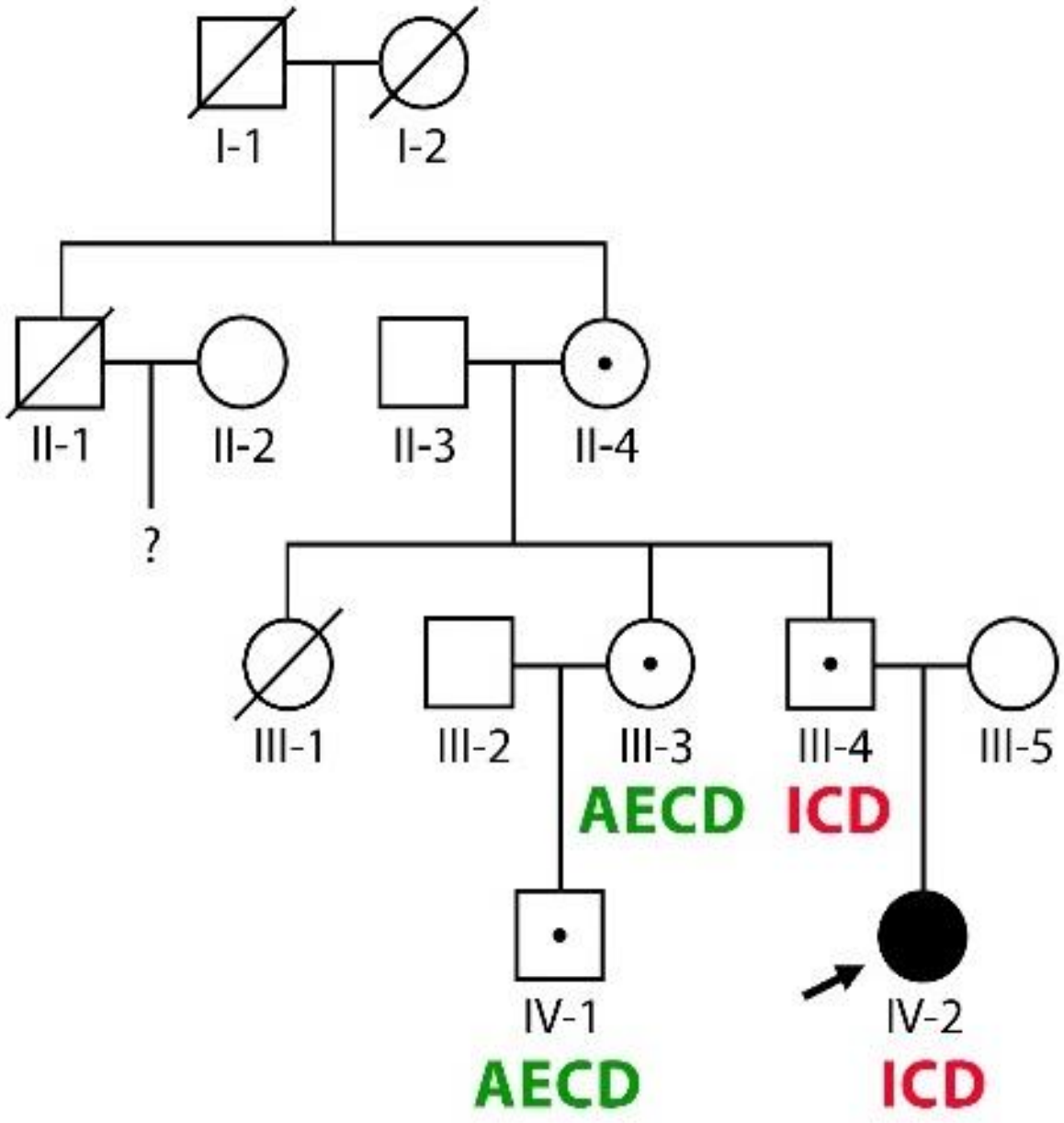




Family history

Critical clinical course of daughter

- Quinidine therapy reduced arrhythmia but caused bradycardia and QRS widening
- An extracardiac dual-chamber pacemaker-defibrillator with pleural shock coil was implanted for secondary prevention.
- Intraoperative VT/VF could not be induced.
- The patient was discharged five weeks later with minimal motoric delay.
- Nine months post-event the ICD terminated VT during another febrile infection by antitachycardia pacing.

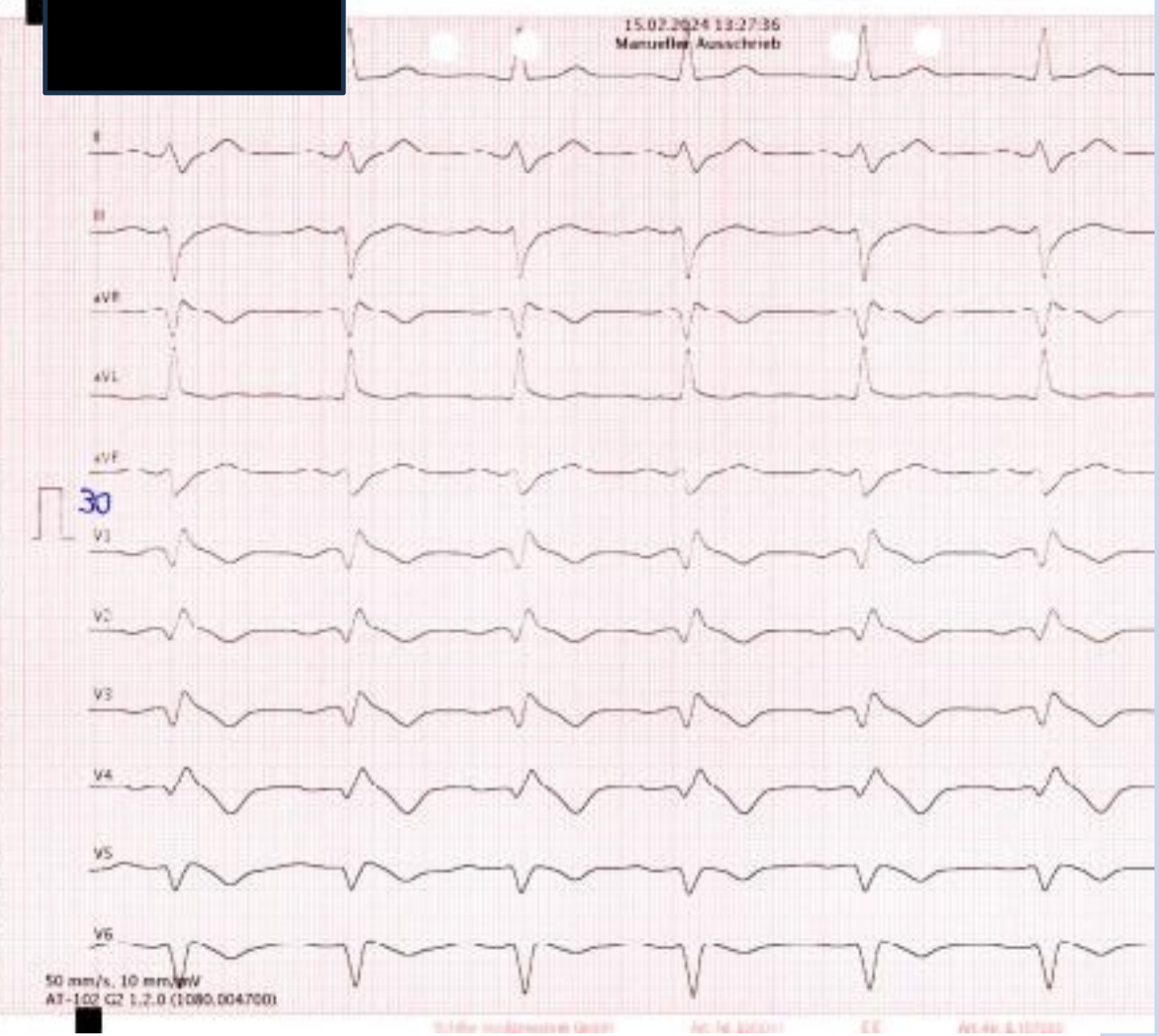


Family history

Implications for the Whole Family

Allele Carrier - father

- Genetic testing identified a novel pathogenic heterozygous nonsense variant (c.1978C>T, p.Gln660Ter) in the SCN5A gene (OMIM ID: *600163; MANE select transcript: ENST00000423572.7) in the index patient and four family members
- Family history revealed one sudden cardiac death (58 years, II-1) and one neonatal death unrelated to heart disease (III-1).
- Two relatives (IV-1, III-3) with the variant were clinically unremarkable and received automated defibrillators. The asymptomatic grandmother (II-4) declined preventive measures.
- This case unmasked a previously unknown risk of sudden cardiac death inherited across three generations in a single family. SCN5A carrier status enabled tailored measures to mitigate life-threatening arrhythmias.



Ajmalin testing revealed a typical type 1 ECG

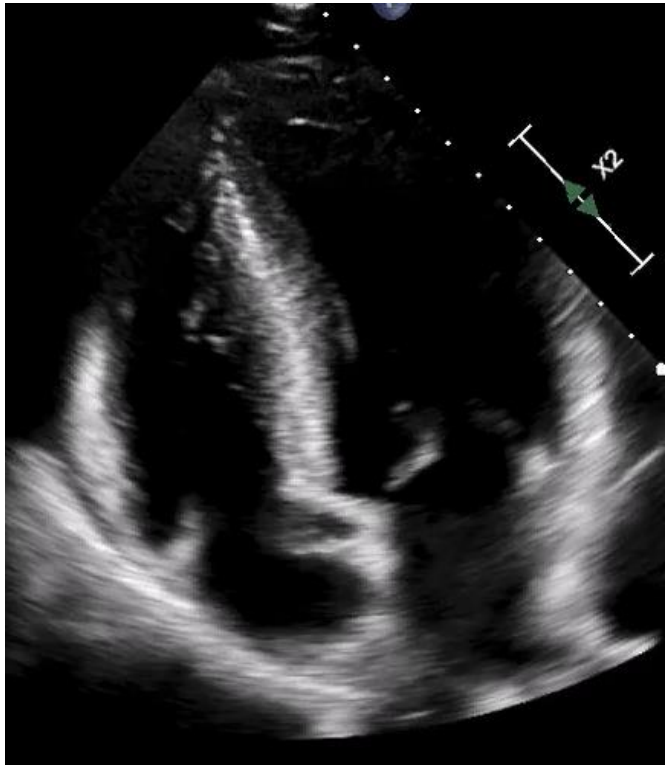
Case report #1

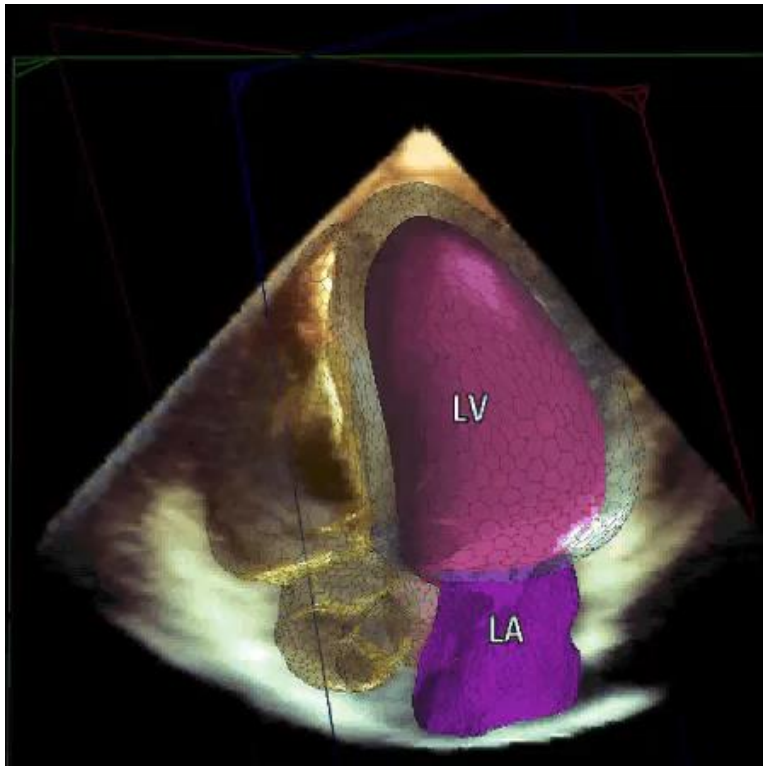
36 year old asymptomatic male with positive family history and positive ajmaline test – low risk patient pattern for SCD and indication for ICD

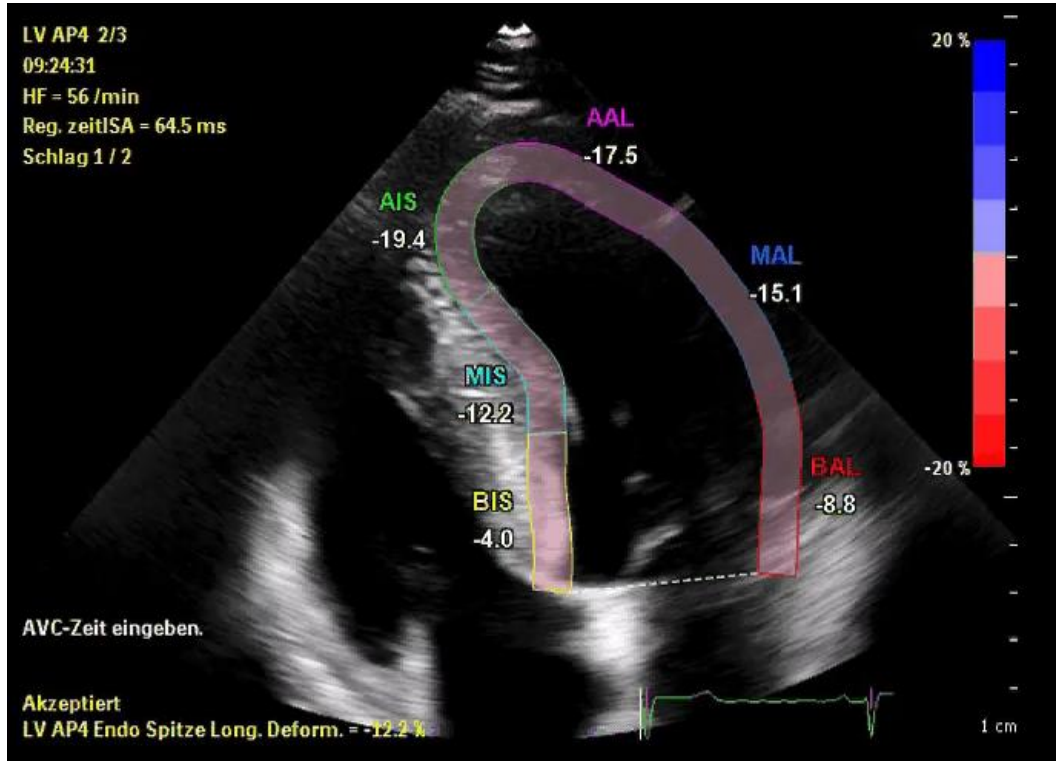
Brugada patients are known to have higher rates of unsuccessful internal defibrillations and inadequate shock therapy.

So far, only limited data exist on the safety and efficacy of the novel EV-ICD in this patient population.

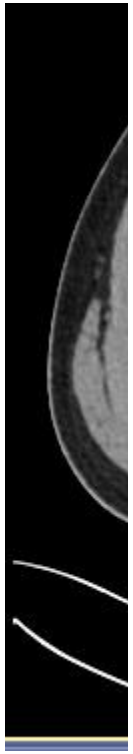
36 year old male with Brugada syndrome, normal systolic LV function, LA slightly enlarged, mild hypertrophy of LV, mild diastolic impairment, pathologic strain analysis

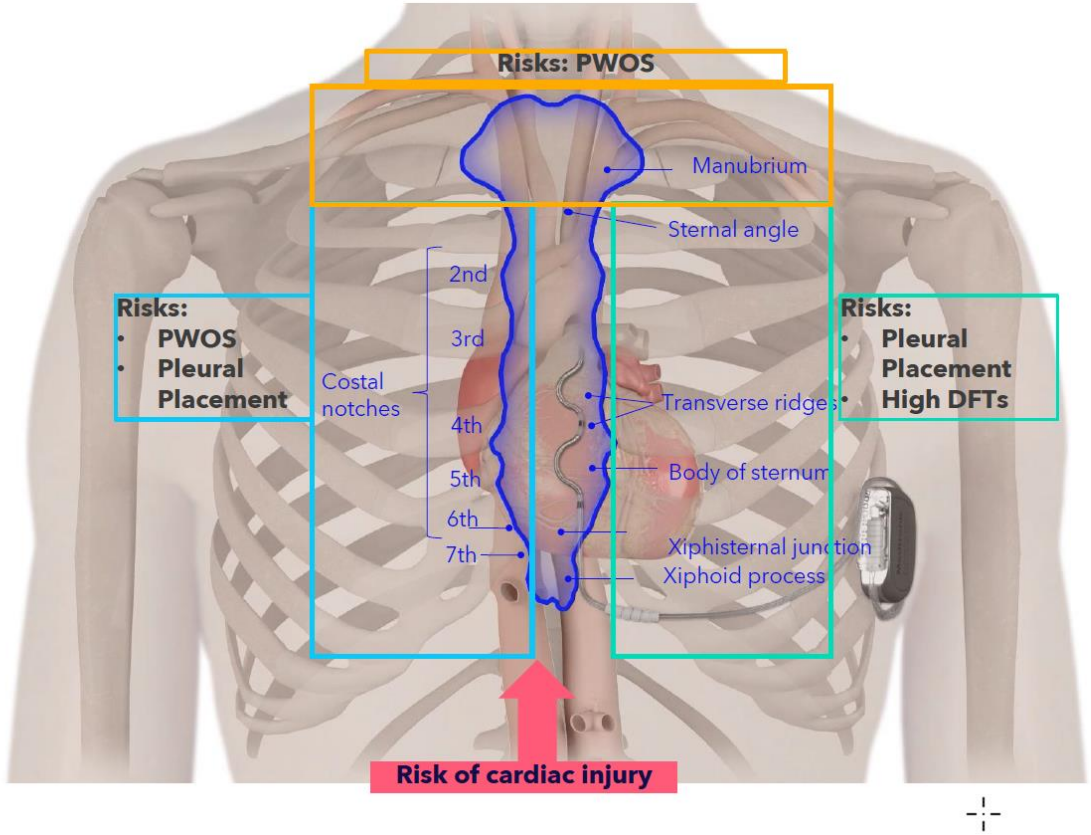


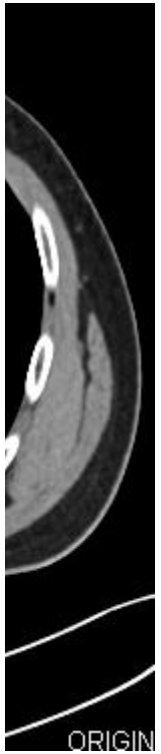


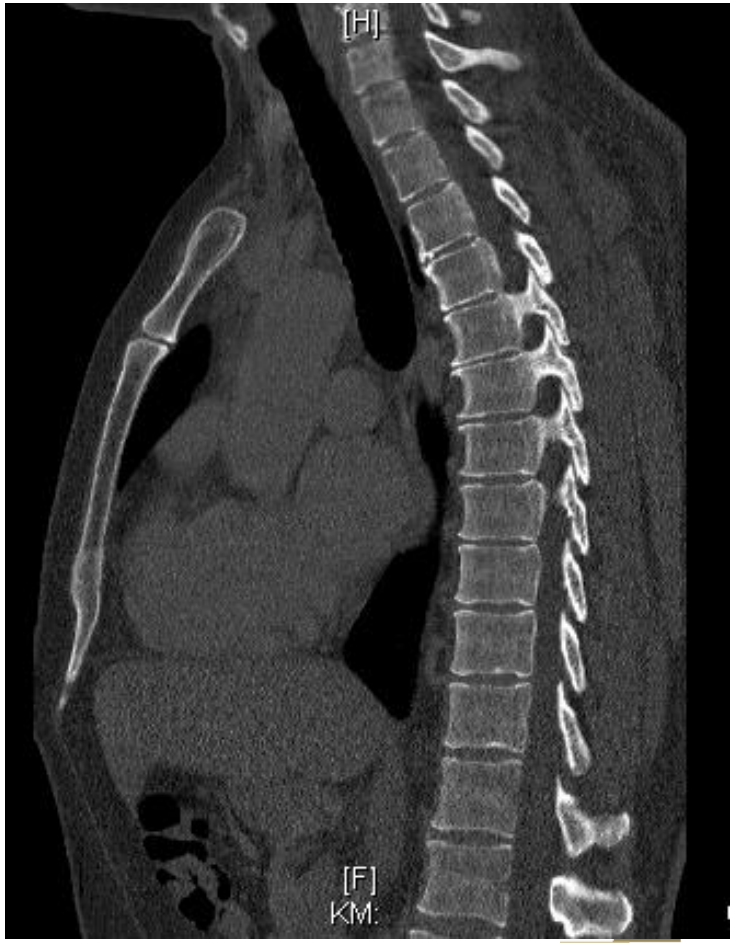


CT scan to evaluate chest and heart anatomy

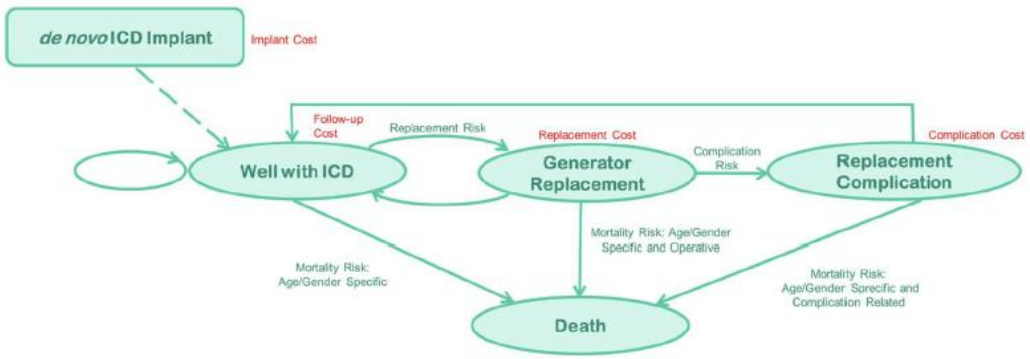




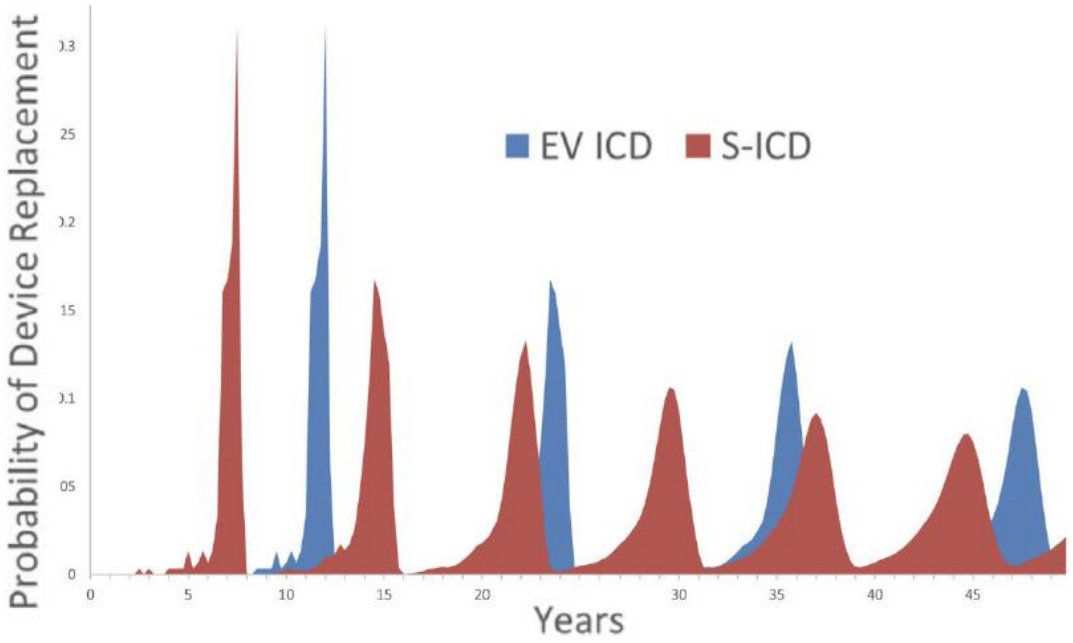




Impact of exended battery longevity of EV-ICD



Markov Model

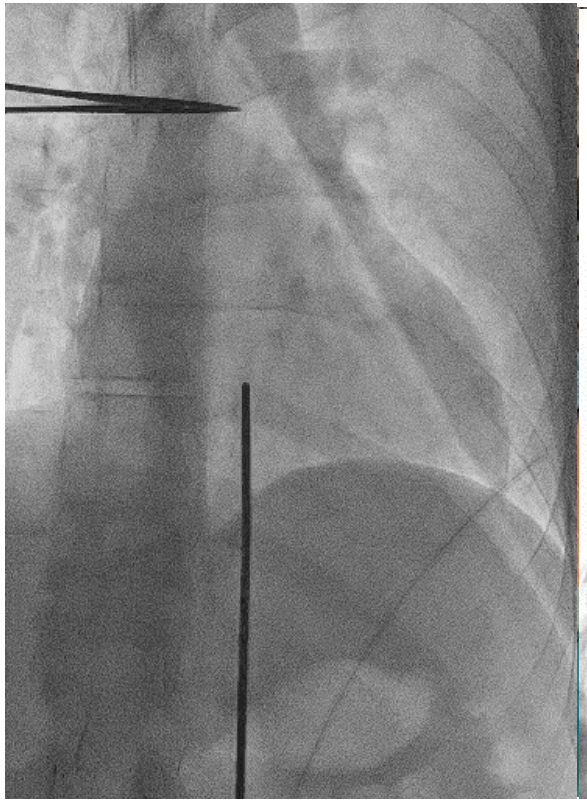
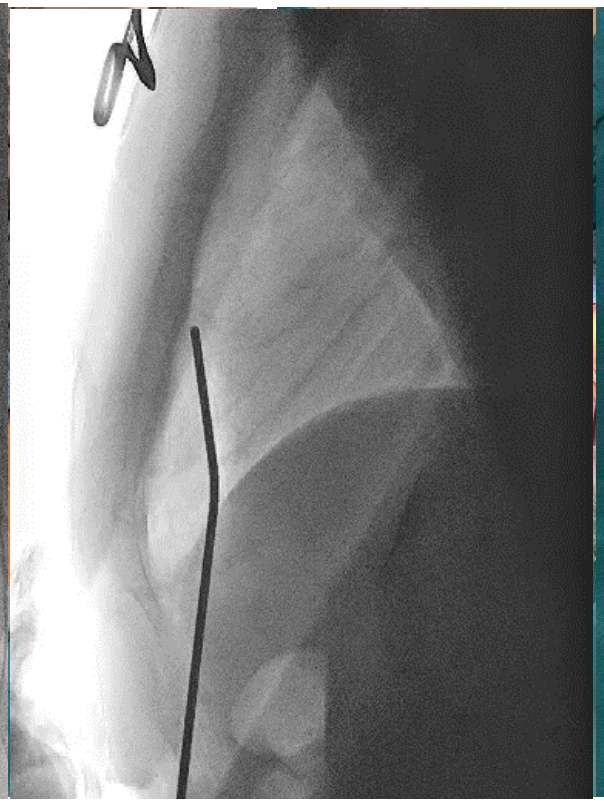
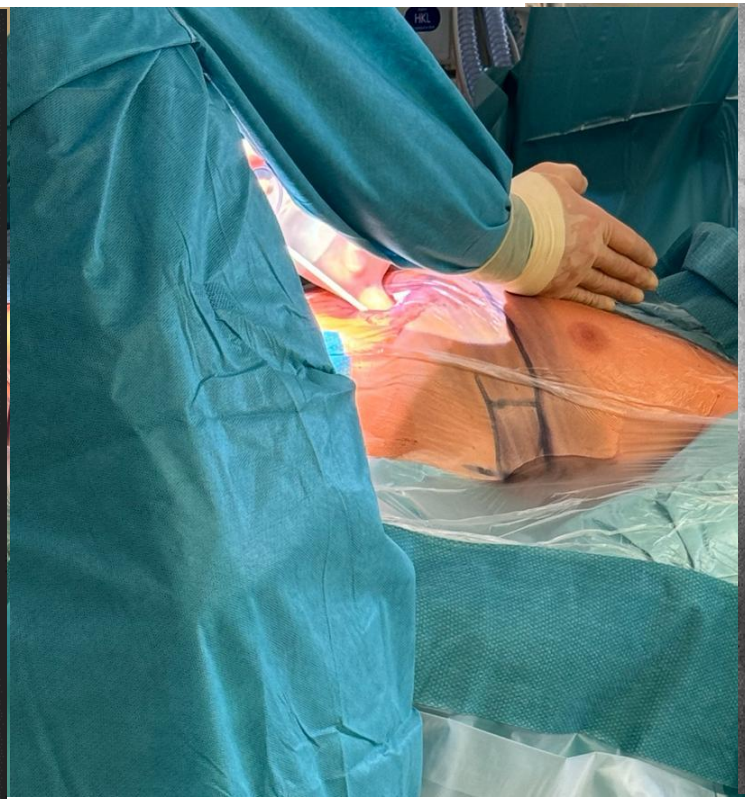
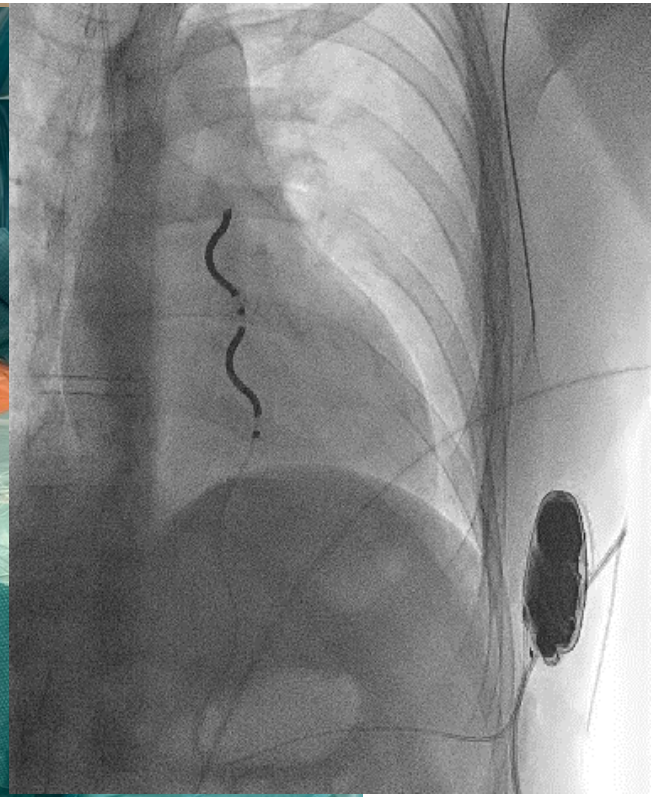


	US	France	Australia	Japan	
Replacement surgeries					
S-ICD	3.2	3.6	3.6	3.6	
EV ICD	1.8	2.0	2.0	2.0	
Difference	1.4	1.6	1.6	1.6	
Undiscounted costs					
S-ICD	$112 990	€ 91 531	AUD 194 871	¥20 551 666	
EV ICD	$79 341	€ 66 072	AUD 135 685	¥15 069 873	₩62 269 173
Difference	$33 649	€ 25 458	AUD 59 186	¥5 481 793	₩25 959 274

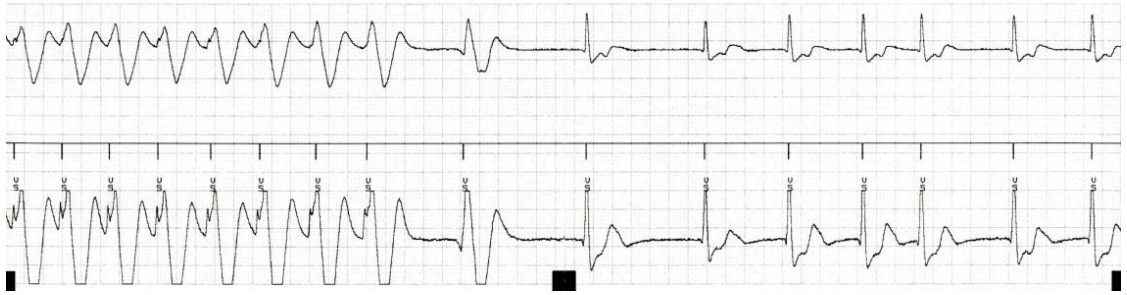
The longer projected battery life of the EV ICD has the potential to meaningfully reduce long-term morbidity and healthcare resources related to generator changes from the perspective of multiple diverse healthcare systems.

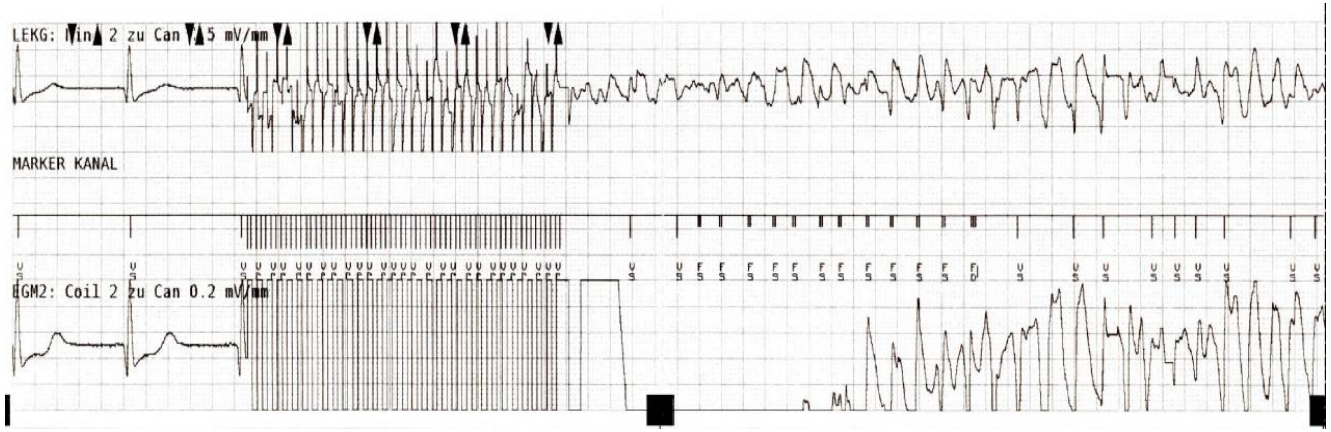
Knight et al
J. Cardiovasc. Electrophysiol. 2024;35:230–237.

EV-ICD implant
Defibrillation threshold testing (DFT) during implantation of the EV-ICD is recommended

Intraprocedural challenges
EV-ICD: DFT not successful during surgery





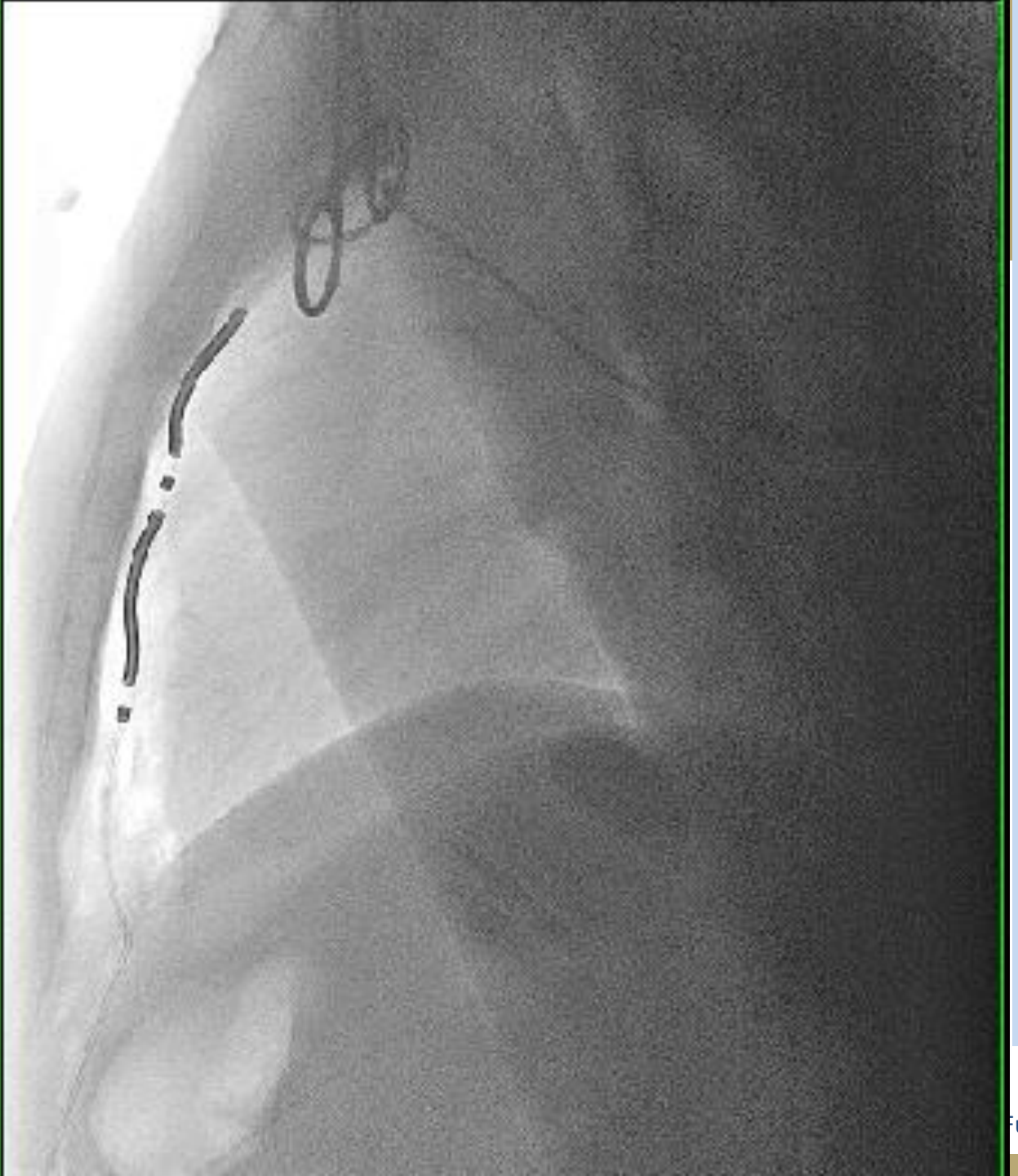
- Successful implantation of an EV-ICD on April 8, 2024 (Aurora EV-ICD MRI SureScan DVEA3E4, Medtronic)
- No P- Waves
- R-Wave between 2.1-2.9 mV
- Pacing at high 10 V setting
- Intraprocedural stable rhythm, after inducing VF twice spontaneous termination of the VF
- Third induced VF could not be terminated by the EV-ICD with up to 40 J in 3 attempts, ATP not successful resulting in internal frustrating DFT testing up to 40 J
- only external defibrillation with 360 J was successful

Question #4

Intraoperative trouble shooting due to ineffective shock of induced VF in asymptomatic Brugada patient and indication of EV-ICD for primary prevention.

How would you proceed?

a) Try to fix ineffective shocks by programming other algorhitms
b) Re-locate aggregate for more favorable coil-aggregate positioning
c) Transfer to TV-ICD
d) Transfer to S-ICD
e) Implant loop recorder

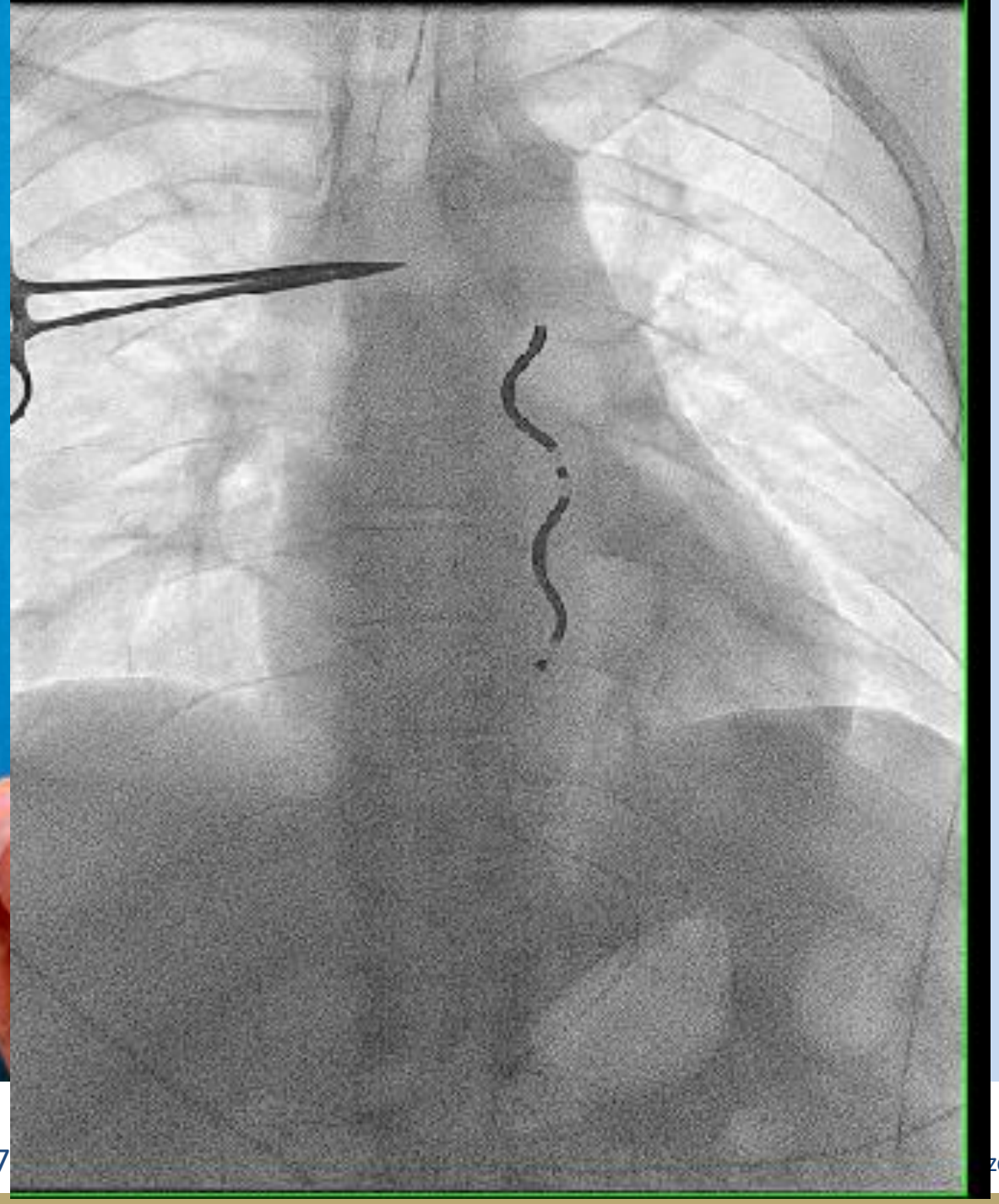


Trouble shooting in the hybrid surgery room

1. **Check for lead and aggregate location clinically and in X-ray**

Answer:

No lead dislocation, correct aggregate position regarding heart silhouette „triangle of lucency“, correct angle between coil and device in regards of heart base and apex



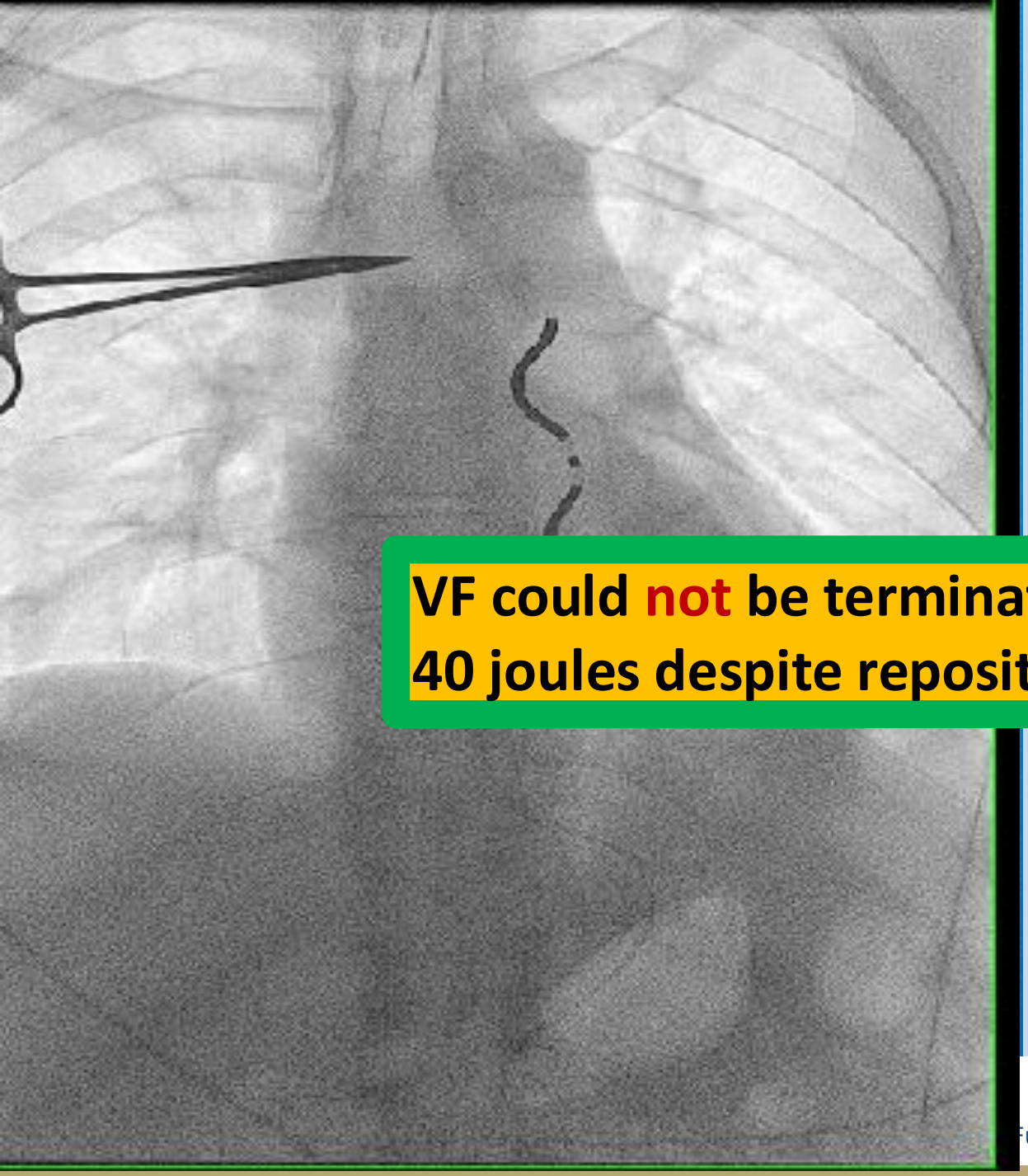
Trouble shooting in the hybrid surgery room

2. Check for air trapped substernally in X-ray or in the pocket of the device

Answer:

Massage air out of tissue carefully, flush pocket and tissue with sterile NaCl solution with 50 ml, press tissue against pocket during DFT

Use TYRX for pocket stability



Trouble shooting in the hybrid surgery room

3. Check for good aggregate contact with tissue/fascia/muscle, re-evaluate anatomy, consider repositioning aggregate submuscular

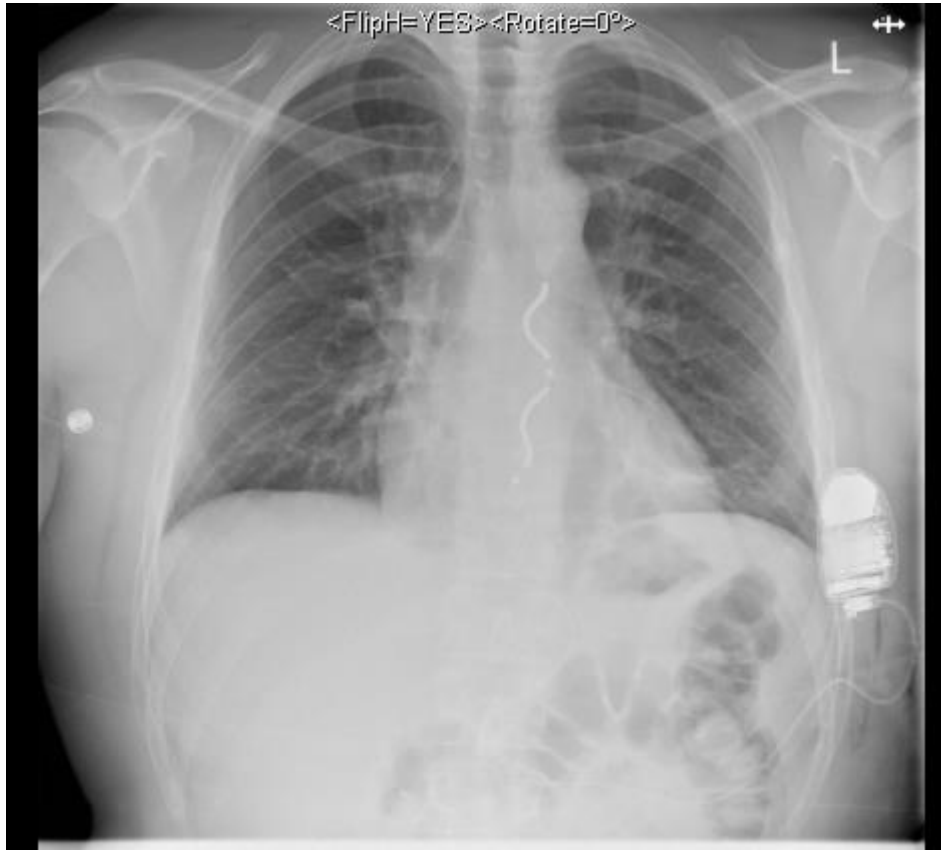
VF could not be terminated by the device with up to 40 joules despite repositioning of the generator.

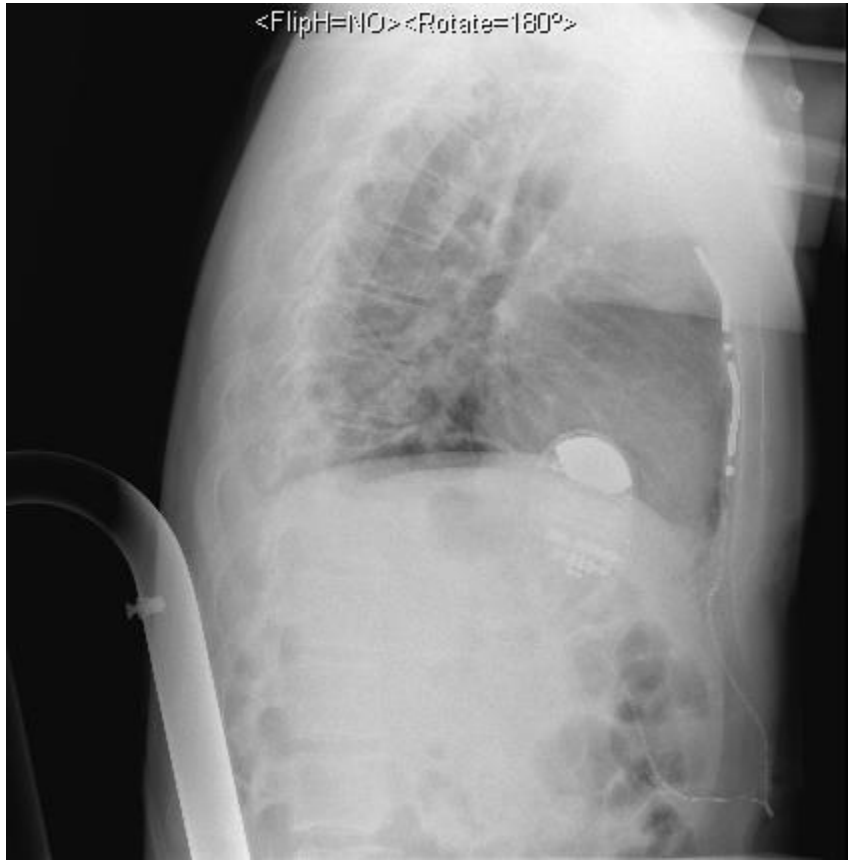
submuscular if anatomy in subcutaneous approach seems unfavorable

Use TYRX for pocket stability

Here: We relocated the aggregate to a submuscular position

X-ray post surgery

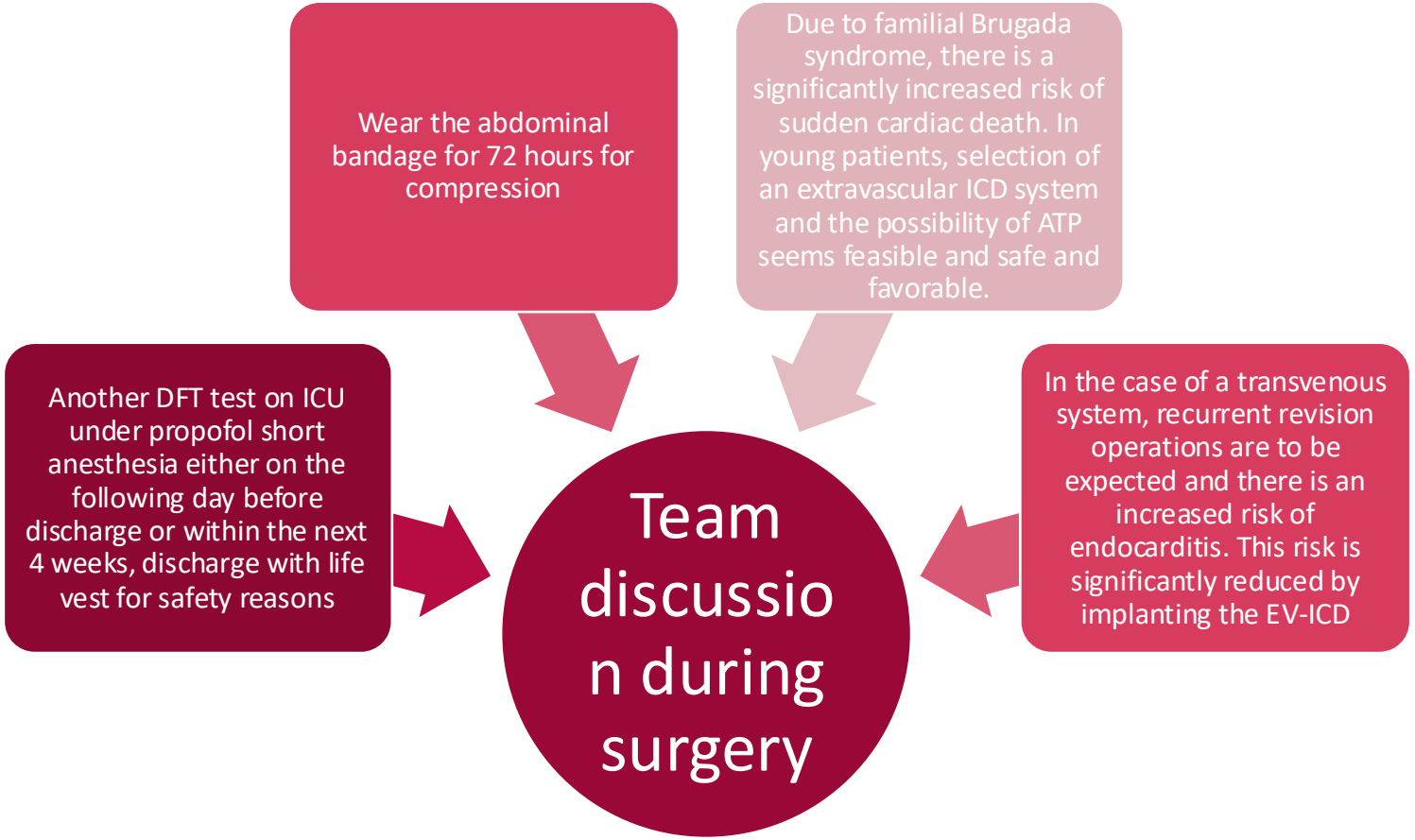




Question #5

Would you switch to a transvenous approach if intraoperative DFT is failing in this Brugada patient with primary prevention EV-ICD implantation - keeping in mind his daughter‘s clinical course of disease and his life time risk of device associated complications of transvenous systems.

Trouble shooting and discussing prior back up plans due to inefficent VF termination by shock during procedure



Be aware of challenges and discuss back-up plan prior to procedure to provide best patient care

- How to deal with low r-waves?
- How to handle high DFTs during implant? What if shock remains inefficient?
- When is switching the procedure a good option?
- How to manage pericardial or intrapleural placement?
- Discuss programming options and procedural options in sensing and detection challenges
- No P- wave is the best P-wave
- Anatomical challenges may be no problem
- Deep sedation and intubation might be changed to conscious sedation in some procedures

Decision to discharge patient on the first post-surgery day with life vest and perform DFT after 3 weeks under improved wound conditions

- **Three weeks after surgery we successfully repeated DFT testing on our ICD proving shock efficacy with 30 J.**

- BS might be associated with elevated DFT. In our case although initial DFT testing failed repeated testing after wound healing proved safe function of the EV-ICD.
- EV-ICD can be a reliable treatment to prevent SCD in BS even if intraoperative conditions seem challenging.
- Patient had no episodes of oversensing in 9 month FU

Stimulationsanteil RA/LV/RV/VP [%]		0	0
Batterie			
Status	10,4 Jahre		
Spannung [V]		gemessen am	
Impedanz [Ω]			
Letzte Ladung [Datum]	30.04.2024	Dauer [s]	13
Programmierung			
Betriebsart	0V0		
Interventionsfrequenz [/min]	40		
Max. Synchronfrequenz [/min]			
Hysteresefrequenz [/min]			
Ruhefrequenz [/min]			
Max. Sensorfrequenz [/min]			
Magnetfrequenz [/min]			
Parameter	**RA**	**RV**	**LV**
Impulsamplitude [V]		high	
Impulsdauer [ms]			
Empfindlichkeit [mV]		0,150	-
Messwert	**RA**	**RV**	**LV**
Reizschwelle Amplitude [V]			
Reizschwelle Dauer [ms]			
Wahrnehmung [mV]		1,7	-
Stimulationsimpedanz [Ω]		2,47	
Stimulationsanteil [%]	0	0	0

Decision to discharge patient on the first post-surgery day with life vest and perform DFT after 3 weeks under improved wound conditions

- **Three weeks after surgery we successfully repeated DFT testing on our ICD proving shock efficacy with 30 J.**

[redacted]

Gerät: Aurora EV-ICD DVEA3E4
Seriennummer: EVX600213S

Untersuchungsdatum: 30-Apr-2024 11:26:16
SW041 Software-Version 8.4 (8.1)
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EP-Studie Episoden-Bericht Seite 1

Letzte Abfrage: 30-Apr-2024 11:26:16

Letzte Episode

Episode #6: 30-Apr-2024 11:24:53

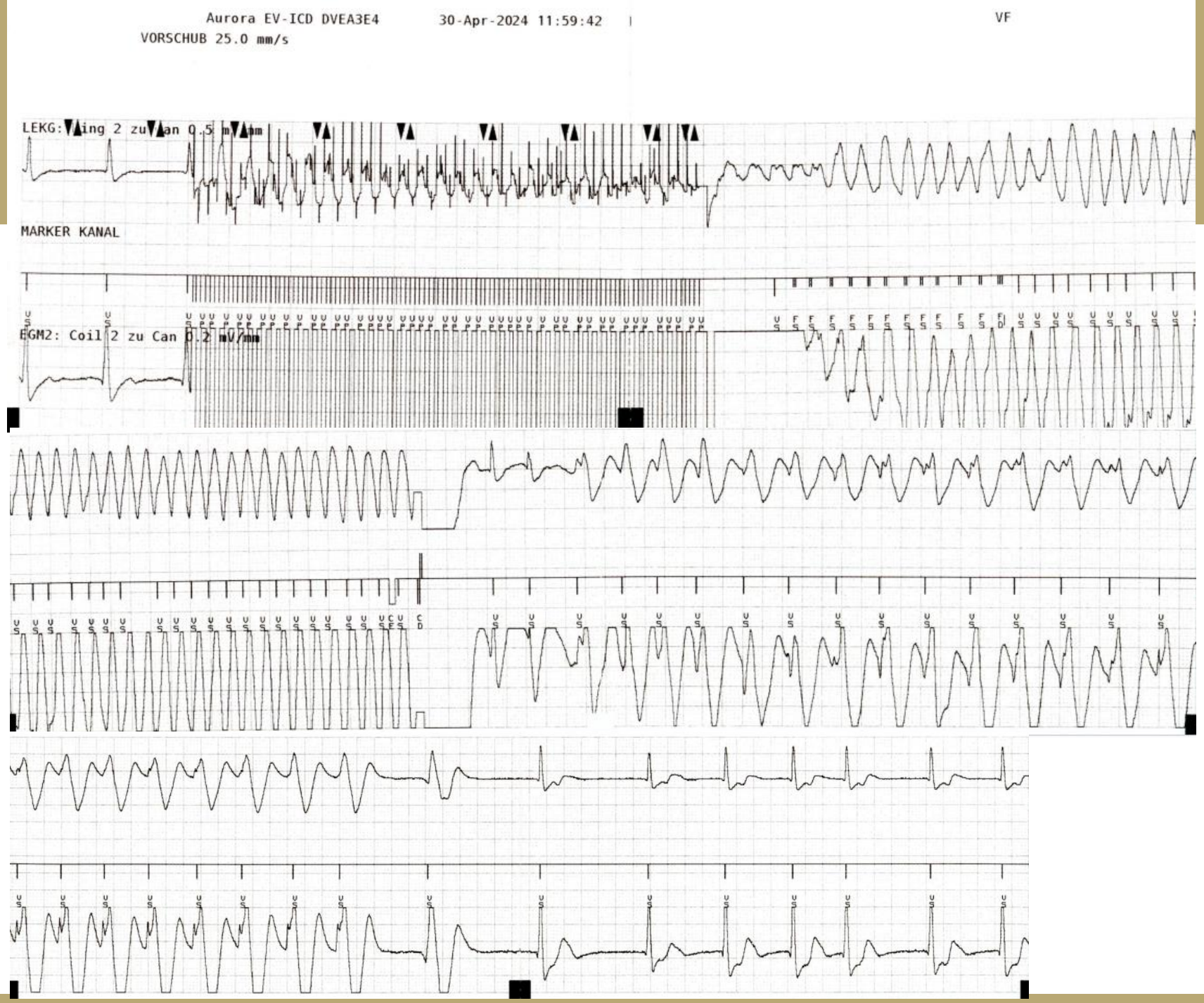
Art	VF (induziert)
Durchschnittlicher V. Zyklus	180 ms
Letzte Therapie	VF Rx1: Defib., Erfolgreich
VT/VF-Dauer	9 Sek

Letzte HV-Therapie

30-Apr-2024 11:24:59

Energie	0.1 - 30 J
Ladezeit	6.3 Sek
Abgegebene Energie	31 J
Impedanz	57 Ohm

Stimulationsanteil RA/LV/RV/VP [%]		0	0
Batterie			
Status	10,4 Jahre		
Spannung [V]		gemessen am	
Impedanz [Ω]			
Letzte Ladung [Datum]	30.04.2024	Dauer [s]	13
Programmierung			
Betriebsart	0V0		
Interventionsfrequenz [/min]	40		
Max. Synchronfrequenz [/min]			
Hysteresefrequenz [/min]			
Ruhefrequenz [/min]			
Max. Sensorfrequenz [/min]			
Magnetfrequenz [/min]			
Parameter	**RA**	**RV**	**LV**
Impulsamplitude [V]		high	
Impulsdauer [ms]			
Empfindlichkeit [mV]		0,150	-
Messwert	**RA**	**RV**	**LV**
Reizschwelle Amplitude [V]			
Reizschwelle Dauer [ms]			
Wahrnehmung [mV]		1,7	-
Stimulationsimpedanz [Ω]		2,47	
Stimulationsanteil [%]	0	0	0


Aurora EV-ICD DVEA3E4
30-Apr-2024 11:59:42
VF
VORSCHUB 25.0 mm/s
LEKG: Ring 2 zu Can 0.5 mV/mm
MARKER KANAL
EGM2: Coil 2 zu Can 0.2 mV/mm

Successful DFT after 3 weeks on our ICU under improved wound conditions

Hengl, Thomas 6
Gerät: **Aurora EV-ICD DVEA3E4**
Seriennummer: **EVX600213S**

Untersuchungsdatum: **30-Apr-2024 11:26:16**
SW041 Software-Version 8.4 (8.1)
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Wahrnehmungstestbericht **Seite 1**

Wahrnehmungstest

	Testwert	Permanent
Betriebsart	OVO	OVO

Letzte Wahrnehmungsmessung

30-Apr-2024
Amplitude der R-Zacke 2.1 mV

Wahrn.polarität

R-Zacke Ring 1 zu Ring 2

Remote monitoring for Aurora EV-ICD devices

CareLink Network

Aurora EV-ICD device is available on CareLink Network

Key feature: CareAlerts™ notifications

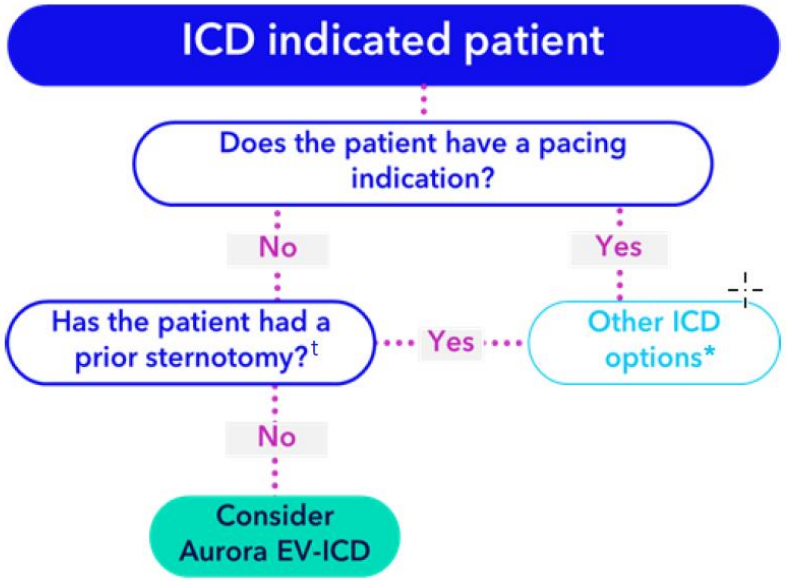
Patient Monitoring

MyCareLink™ patient monitor is the remote monitoring option compatible with the Aurora EV-ICD device

Conclusion: Think twice before switching EV-ICD to TV-ICD due to intraprocedural challenges
Think even more in Brugada syndrome patients!

Aurora EV-ICD Indications

Patient indication tree



[t] Prior sternotomy may indicate risk for cardiac perforation
* Not designed to be a chronic pacing device

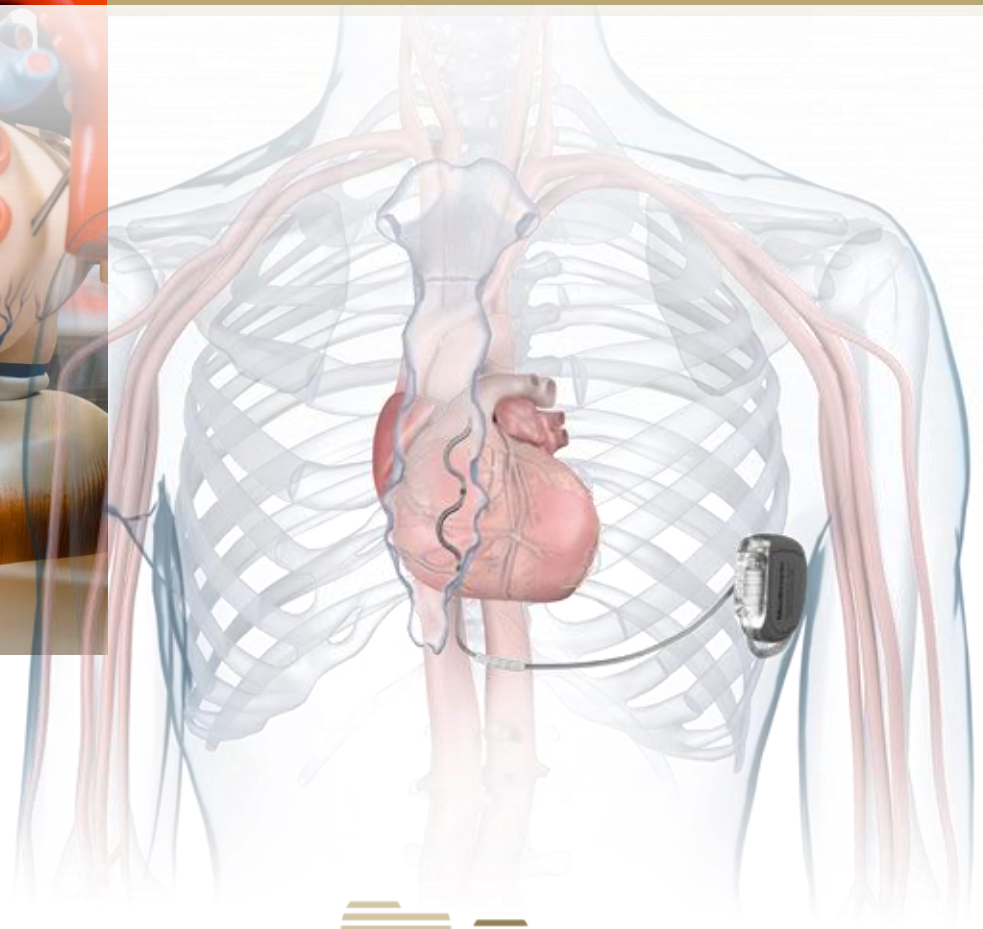
Quality of life considerations

- Need for ATP
- Device size /longevity (e.g.: need more than 1 device)
- Need for preserved vasculature

For patient-specific recommendations such as primary and secondary preventions, refer to current clinical guidelines from the European Society of Cardiology (ESC), American Heart Association (AHA), American College of Cardiology (ACC), and Heart Rhythm Society (HRS) and the device manual.

Medtronic

Thank you!



Medtronic

CareLink™ Network

Website für Ärztinnen und Ärzte zur Überwachung kardialer Geräte von Medtronic

Zugang zu CareLink

Universitätsklinikum Tübingen

EV-ICD implantation at the University Hospital Tübingen, Germany

13 patients implanted with EV-ICD

2 ICM, 3 NICM, 5 HOCM, 1 Long QT- syndrome, 2 Brugada syndrome patients

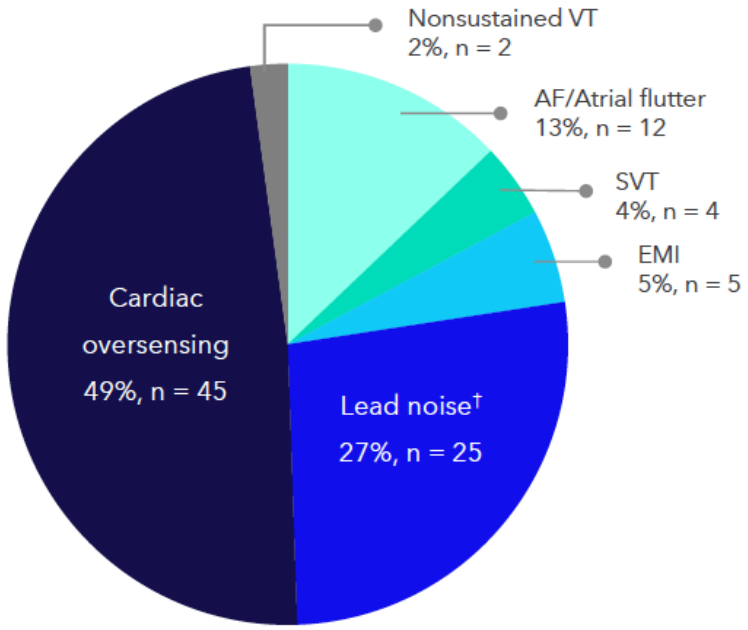
first 5 implants with cardiothoracic surgeon, good team approach

no intraprocedural complications

All deeply sedated intubated lead was advanced substernally during breathing manuveurs safe substernal tunneling	No infections, no system explantation	1 local tissue necrosis of substernal access site of 2 mm, sterile, no signs of infection, wound necrosis after excessive physical training, we relocated the lead under rectus fascia with effective wound healing	No appropriate or inappropriate therapy delivered by EV-ICD, no ATP or shock	0.1 mV p-waves in 1 case of a female patient with severe scoliosis and body height of 148 cm no P-wave oversensing 2 pts with oversensing due to muscular activity, after adapting of programming episode number decreased significantly	No patient died

Programming and implantation features of EV-ICDs can address many reasons of inappropriate shock

Reasons for inappropriate shocks in the EV ICD Pivotal Clinical Study (episodes through 17.1+/-6.4 months)[1]



Repositioning the lead at implant to meet P-wave and R-wave criteria may reduce cardiac oversensing[2] and the risk of inappropriate shock

→ **33%** reduction in the number of patients with inappropriate shock due to P-wave oversensing from the first half to the second half of the study implants‡[3]

Utilizing Smart Sense, a novel algorithm in the commercial device, may prevent an inappropriate shock when oversensing is present

→ **29%** projected reduction in the number of patients with inappropriate detection with Smart Sense in preclinical validation§[4]

Enlighten: The EV-ICD Post Approval Registry will evaluate the real-world performance of the system.

† Myopotential oversensing excluding P-wave, T-wave, or EMI.

Modified from Friedman P, et al. Chronic Safety and Performance of the Extravascular ICD: Results from the Global EV ICD Pivotal Study. Presented as a Late Breaking Clinical Trial at HRS 2023. New Orleans, LA.
Friedman P, et al. *N Engl J Med*. 2022;387:1292–1302.
Swerdlow CD, et al. Performance of a Novel P-wave Oversensing Rejection Algorithm to Reduce Inappropriate Detections in the Extravascular ICD, Oral Presentation at HRS; May 20, 2023.

Contraindications

1. If implanted with a unipolar pacemaker, a device delivering dual-chamber or triple-chamber pacing, and/or a device delivering antitachyarrhythmia therapies
2. If incessant ventricular tachycardia (VT) or ventricular fibrillation (VF) exists
3. If the patient's primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF
4. If symptomatic bradycardia exists
5. If tachyarrhythmias with transient or reversible causes exist
6. The Epsila EV Model EAZ101 sternal tunneling tool is contraindicated for use in patients with a prior sternotomy.