Extravaskulární způsoby implantace ICD

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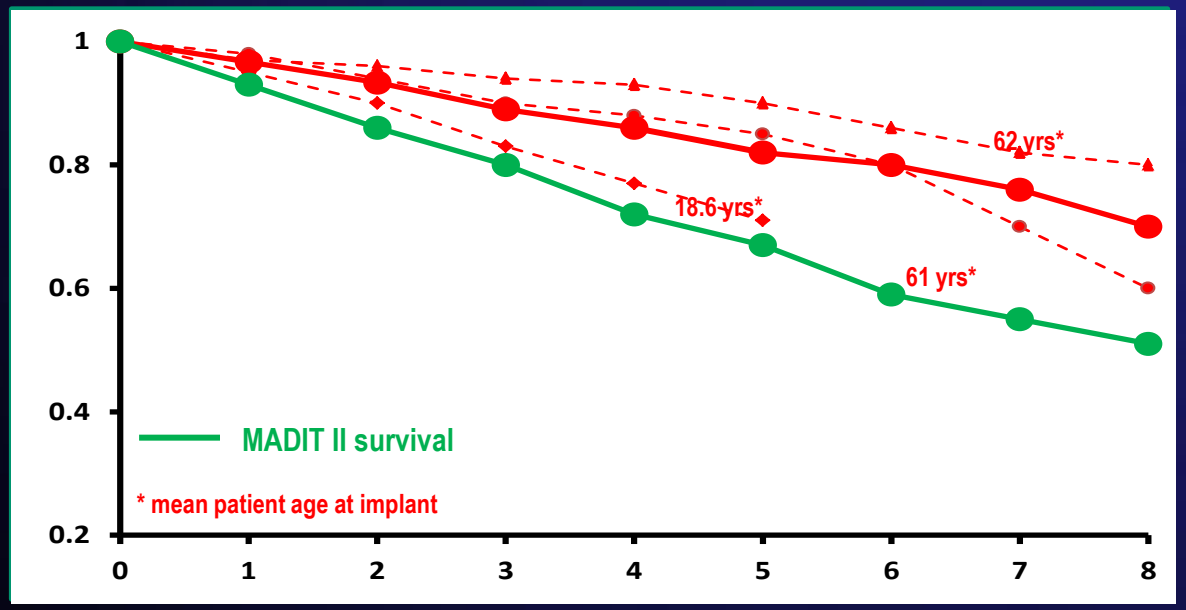
Transvenous leads survival rate

***P. Alter et al. PACE 2005*: Prospective ICD complication registry**
- Up to 30% ICD complications during mean follow-up of 4 years (conventional programming)
- Majority of ICD complication (12%) are lead-related

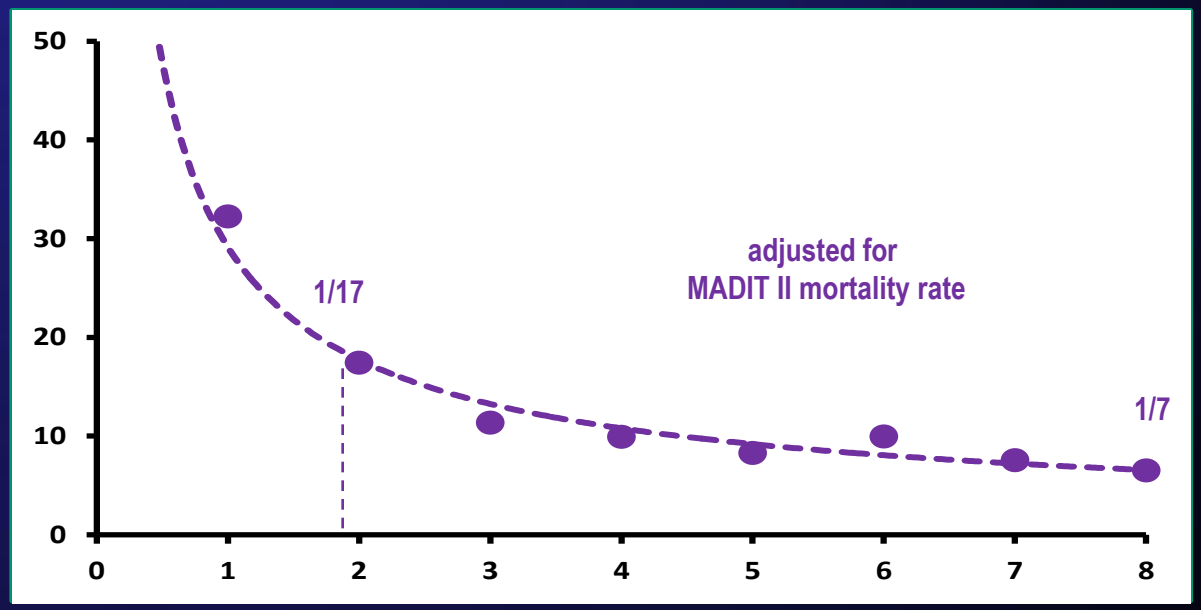
Kleemann et al. ciculation 2007
Atallah et al. circualtion 2013
Borleffs et al. Circ Arrhythmia Electrophysiol. 2009

Transvenous lead survival probability: **Increasing annual failure rate up to 20% in 10-yrs old leads***

Event-free lead function:
lead survival up to 8 years follow-up



Number Needed to Harm (NNH):
lead failure requiring intervention



* Lead failure rates depend on model/manufacturer

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Evolution of S-ICD Therapy

- Over 15 years of clinical data with *58.000 patients* implanted with an S-ICD worldwide[1]
- Rapid and incremental refinements in technology

* Than previous generation of S-ICD
** When conditions of use are met
******Concept technology***

2002 — **1st Generation**

2009

2012

2015 — **2nd Generation**

- Smaller, thinner, long er-lasting device*
- LATITUDE™ compatible[1]

2016 — **3rd Generation**

- SMART Pass[1]
- MRI compatible[1**]
- AF Monitor™ [1]

2017

Future developments
mCRM™***

- ***EMBLEM Electrode (Model 3501)***
- ***Electrode Delivery System (EDS)***
- ***2 Incision Technique Labeling***

Automated Screening Tool

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Class I Recommendation for S-ICD

11.1. Subcutaneous Implantable Cardioverter-Defibrillator

Recommendations for Subcutaneous Implantable Cardioverter-Defibrillator

References that support the recommendations are summarized in Online Data Supplement 55.

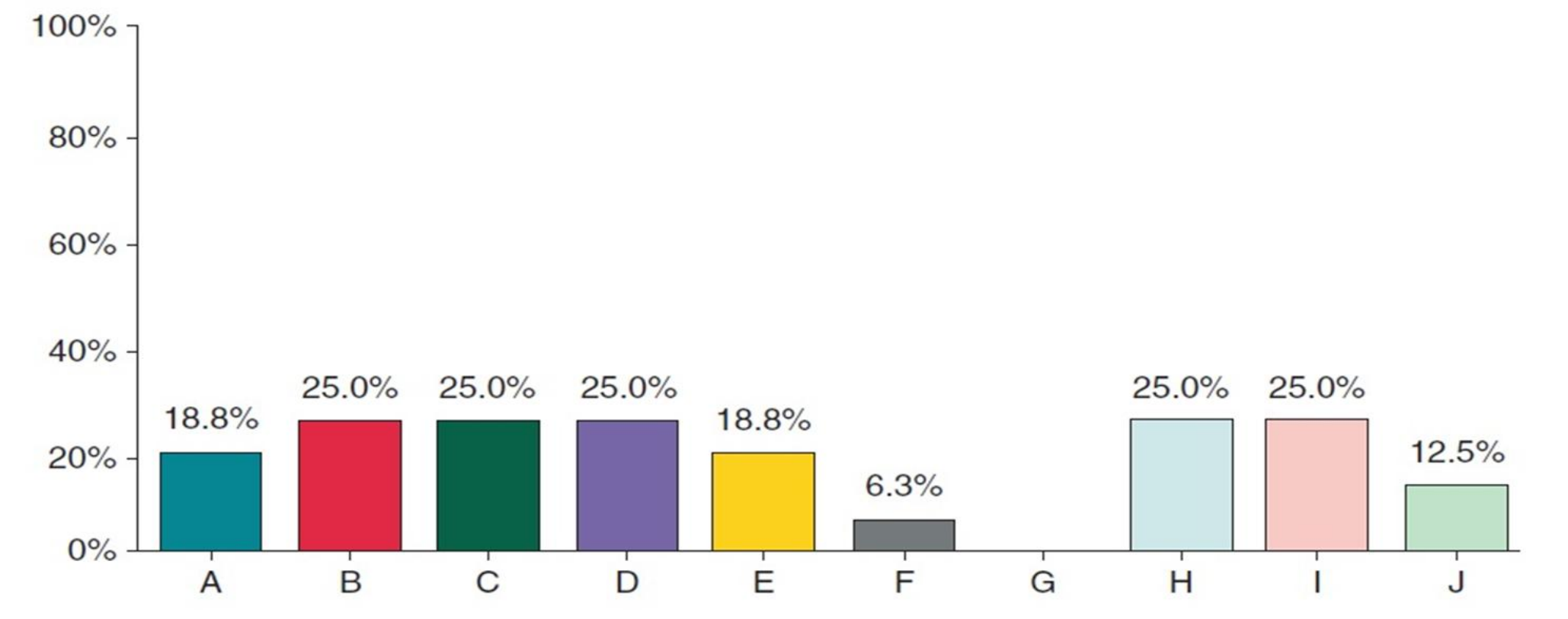
COR	LOE	Recommendations
I	B-NR	1. In patients who meet criteria for an ICD who have inadequate vascular access or are at high risk for infection, and in whom pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated, a subcutaneous implantable cardioverter-defibrillator is recommended (1-5).
IIa	B-NR	2. In patients who meet indication for an ICD, implantation of a subcutaneous implantable cardioverter-defibrillator is reasonable if pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated (1-4).
III: Harm	B-NR	3. In patients with an indication for bradycardia pacing or CRT, or for whom antitachycardia pacing for VT termination is required, a subcutaneous implantable cardioverter-defibrillator should not be implanted (1-4, 6-8).

Recommendation-Specific & Supportive

"The risk of infection appears to be lower with subcutaneous implantable cardioverter-defibrillators than with transvenous ICDs (1-4).Therefore, a subcutaneous implantable cardioverter-defibrillator may be preferred in patients who are at high risk of infection, such as those with a prior device infection, ESRD, diabetes mellitus, or who are chronically immunosuppressed."

Analýza: Proč neindikovat S-ICD

Boveda S et al: Europace 2016,18:1437.



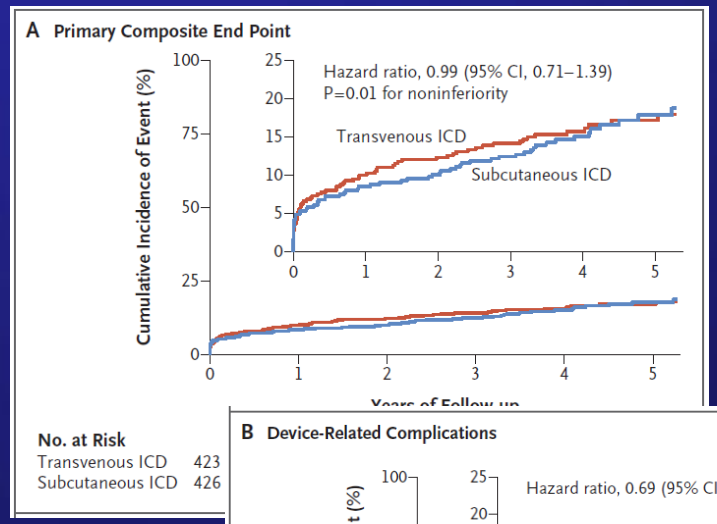
(A) not available, (B) not reimbursed, (C) price too high, (D) 'I don't believe in this system', (E) 'I've not been trained to this procedure',
(F) procedure too complex, (G) need of a surgeon, (H) lack of pacing function, (I) no patients who qualify,
(J) patients opt rather for conventional ICDs.

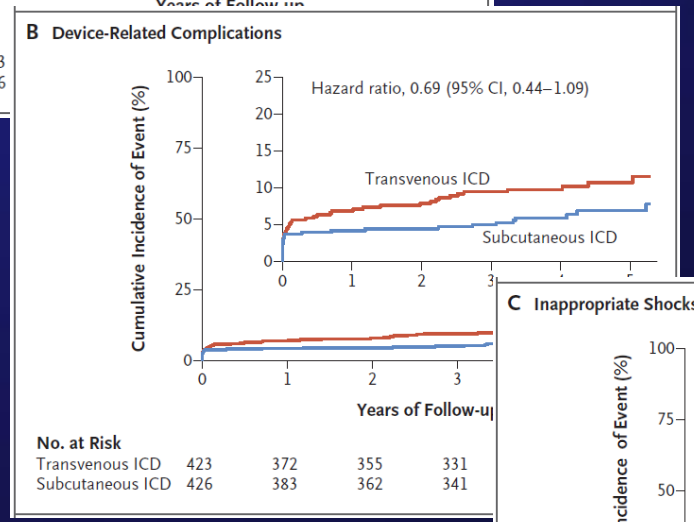
S-ICD vs TV-ICD: studie *PRAETORIAN*

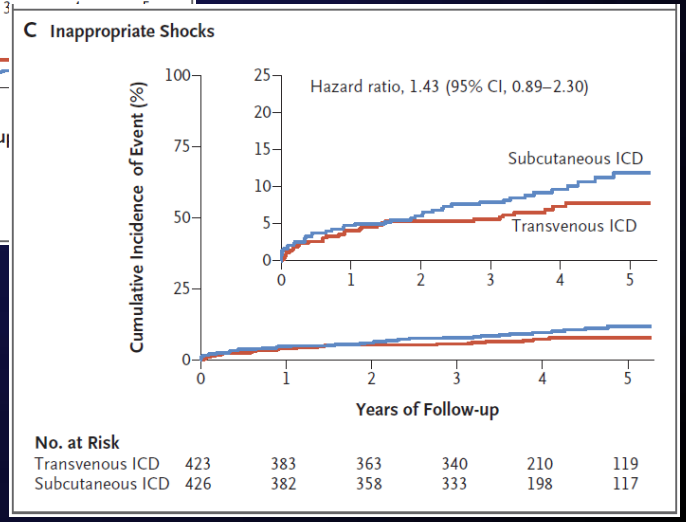
Subcutaneous or Transvenous Defibrillator Therapy

R.E. Knops, L.R.A. Olde Nordkamp, P.-P.H.M. Delnoy, L.V.A. Boersma, J. Kuschyk, M.F. El-Chami, H. Bonnemeier, E.R. Behr, T.F. Brouwer, S. Kääb, S. Mittal, A.-F.B.E. Quast, L. Smeding, W. van der Stuijt, A. de Weger, K.C. de Wilde, N.R. Bijsterveld, S. Richter, M.A. Brouwer, J.R. de Groot, K.M. Kooiman, P.D. Lambiase, P. Neuzil, K. Vernooy, M. Alings, T.R. Betts, F.A.L.E. Bracke, M.C. Burke, J.S.S.G. de Jong, D.J. Wright, J.G.P. Tijssen, and A.A.M. Wilde, for the PRAETORIAN Investigators*

Characteristic	Subcutaneous ICD (N=426)	Transvenous ICD (N=423)
Median age (IQR) — yr	63 (54–69)	64 (56–70)
Female sex — no. (%)	89 (20.9)	78 (18.4)
Diagnosis — no. (%)		
Ischemic cardiomyopathy	289 (67.8)	298 (70.4)
Nonischemic cardiomyopathy	99 (23.2)	98 (23.2)
Genetic arrhythmia syndrome	20 (4.7)	18 (4.3)
Hypertrophic cardiomyopathy	15 (3.5)	7 (1.7)
Idiopathic ventricular fibrillation	11 (2.6)	5 (1.2)
Congenital heart disease	3 (0.7)	3 (0.7)
Other†	4 (0.9)	1 (0.2)
Secondary prevention — no. (%)	80 (18.8)	84 (19.9)
Median ejection fraction (IQR) — %	30 (25–35)	30 (25–35)



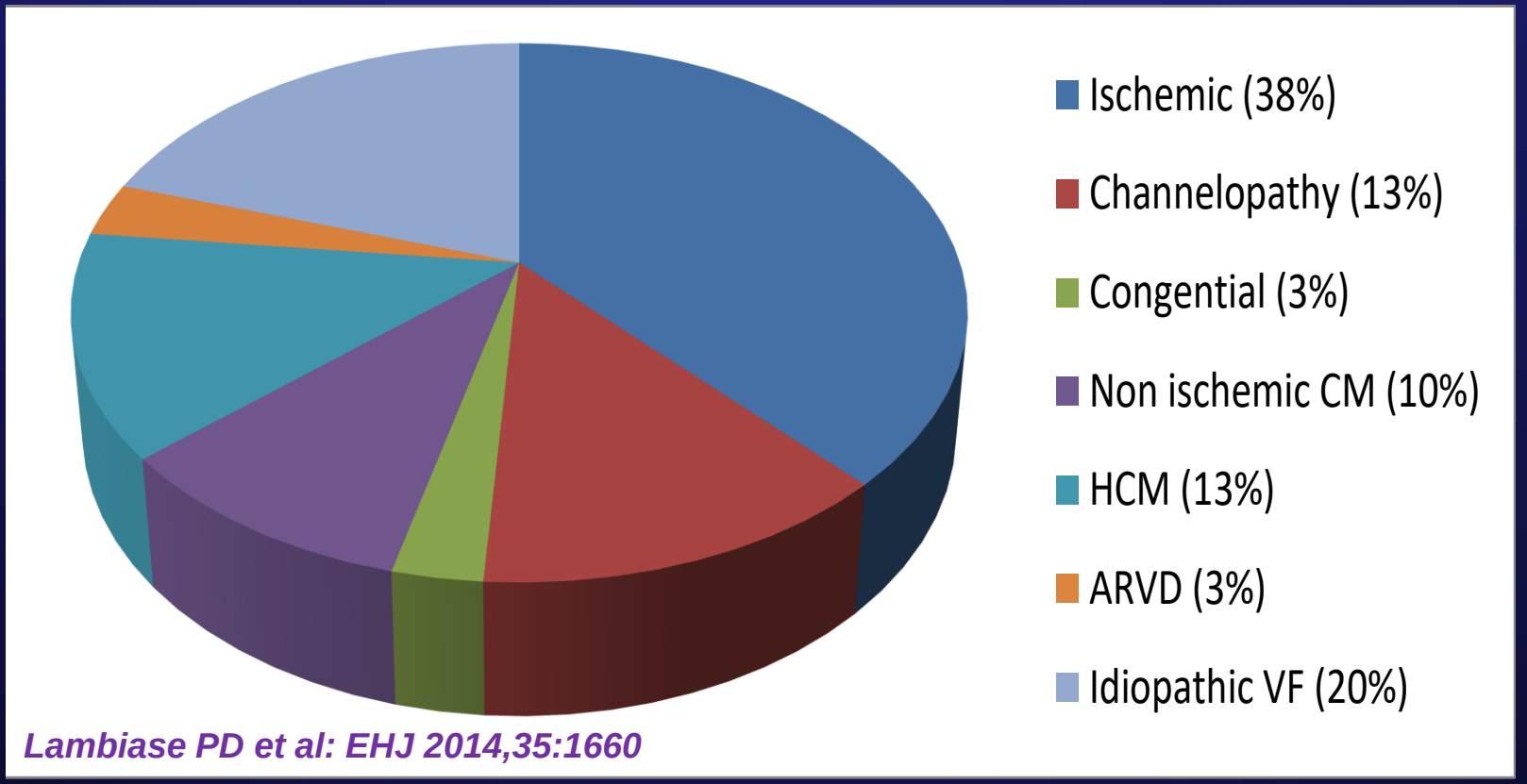




EFFORTLESS S-ICD Registr

Indikace k implantaci

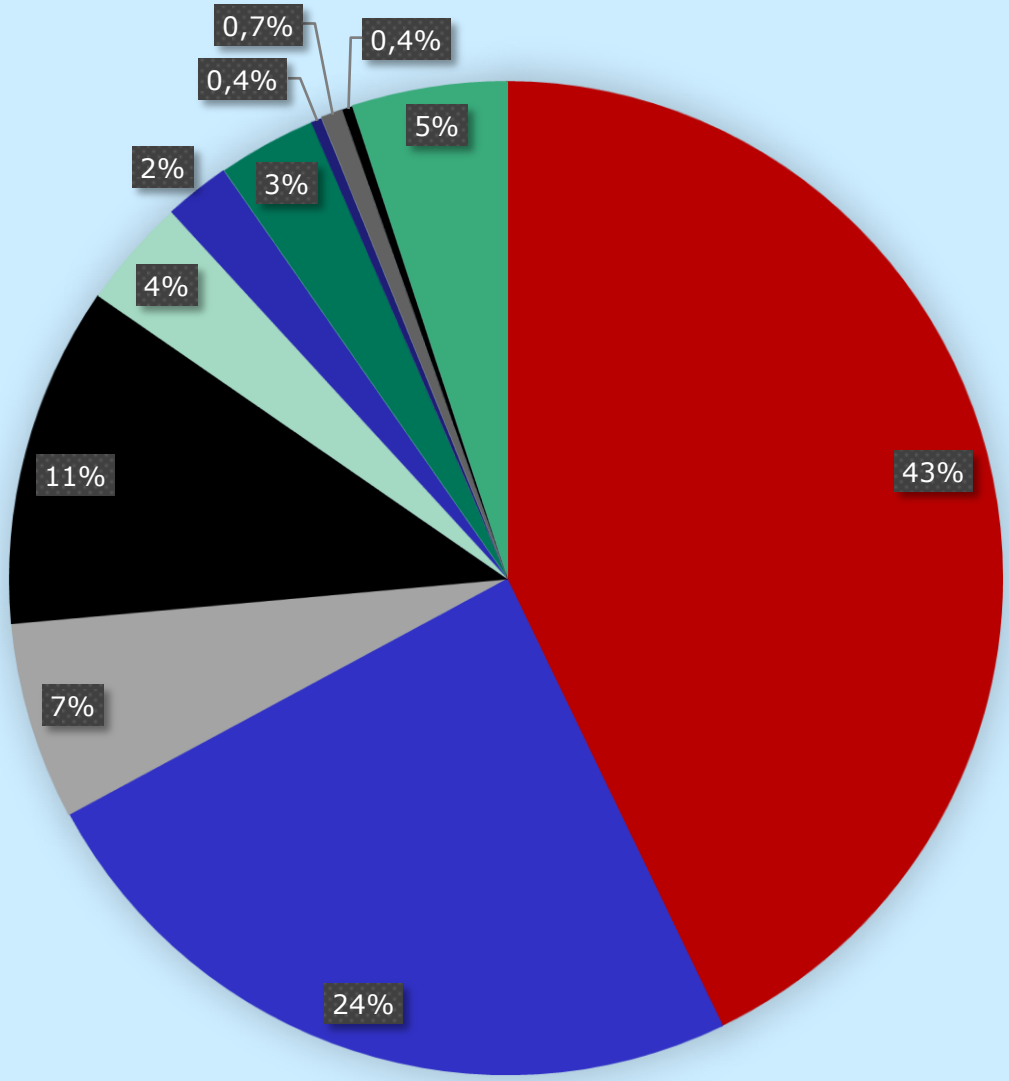
Effortless: široké spektrum indikací S-ICD ne zcela odpovídající TV



Lambiase PD et al: EHJ 2014,35:1660

Indikace S-ICD v NNH

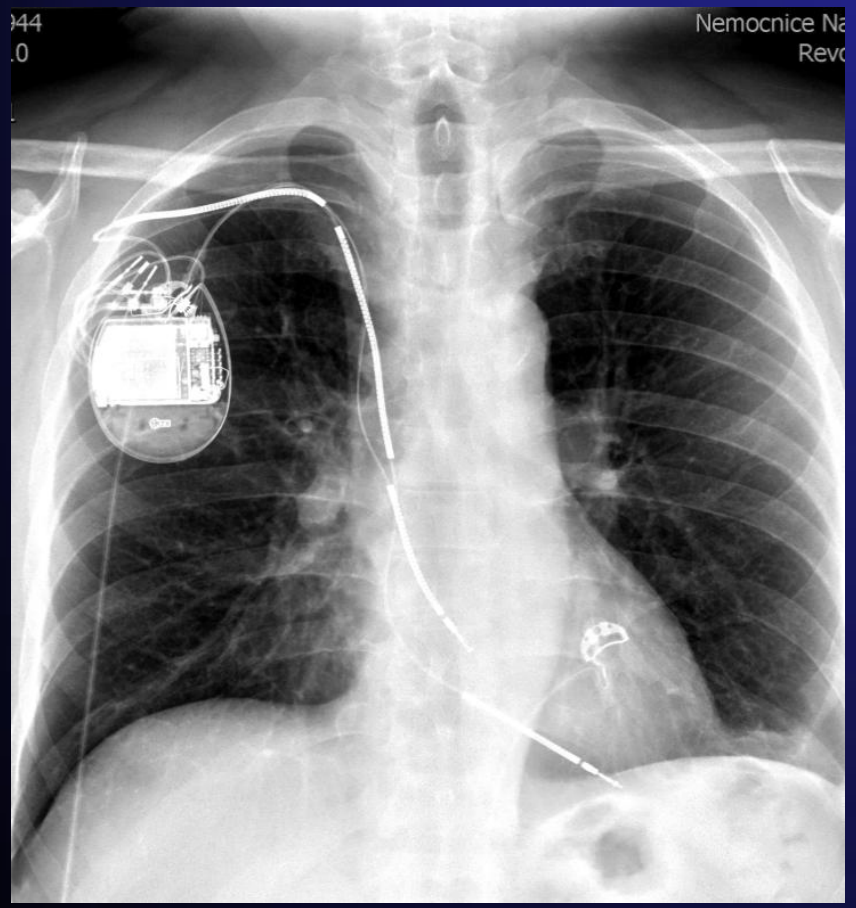
n: 280 (2023)

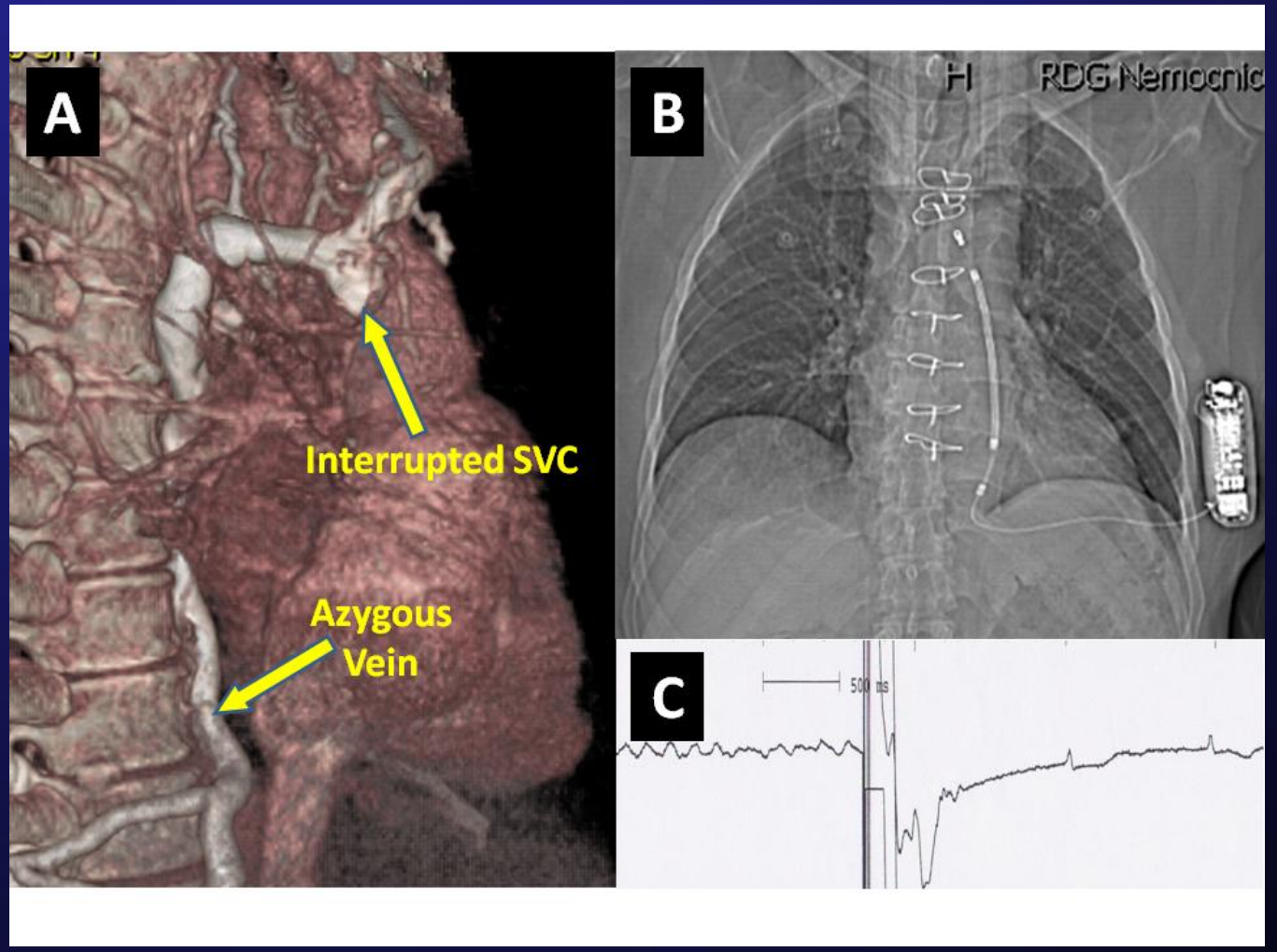


- Ischemická KMP
- Dilatační KMP
- Hypertrofická KMP
- Arytmogenní KMP, el. nestab. myokard
- Brugada syndrom
- ARVD
- Long QT
- Non-kompaktní KMP
- Ebstein
- Kawashima
- Prevence NSS bez jasné etiologie

Ideální indikace k S-ICD:

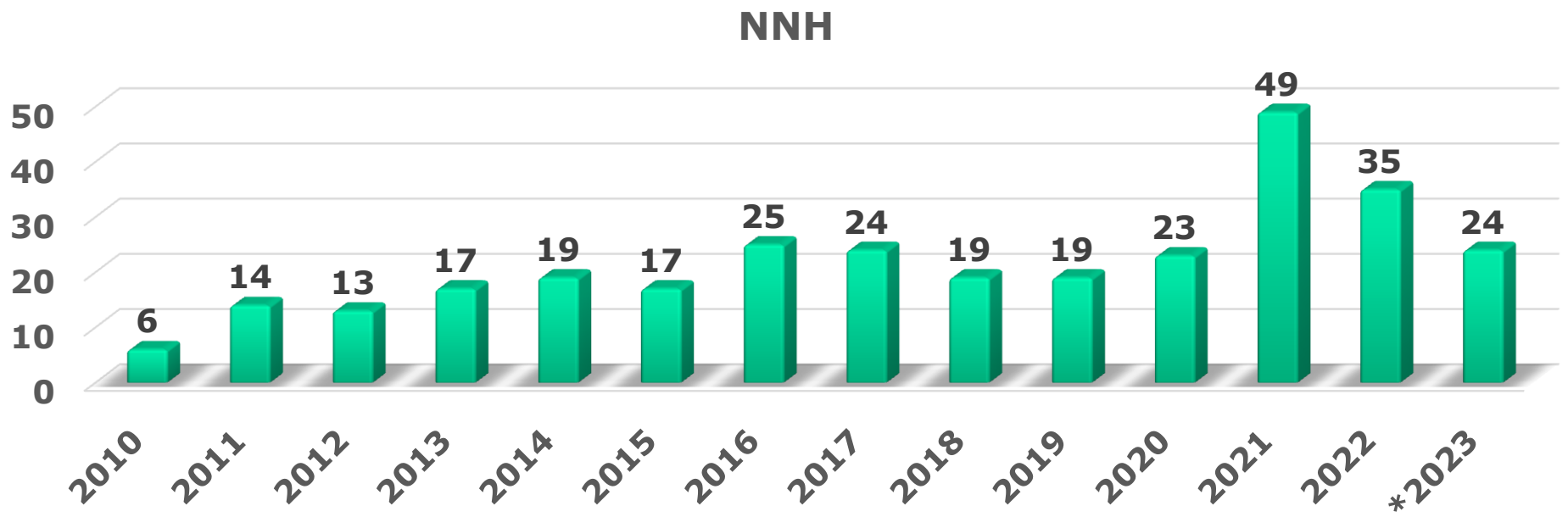
Okluze SVC po extrakci TV ICD





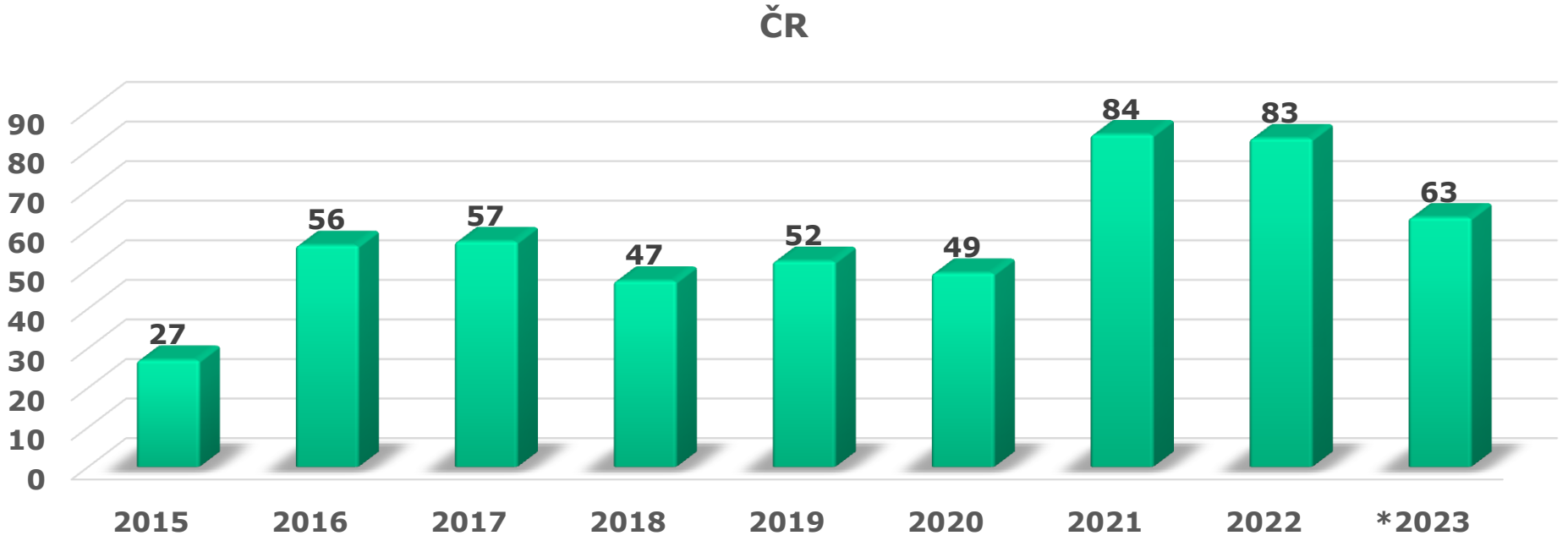
Neuzil P,Reddy VY*: Heart Rhythm 2011*

Počty implantací S-ICD v NNH



S-ICD v Nemocnici Na Homolce														
ROK	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	*2023
NNH	6	14	13	17	19	17	25	24	19	19	23	49	35	24

Počty implantací S-ICD v České republice

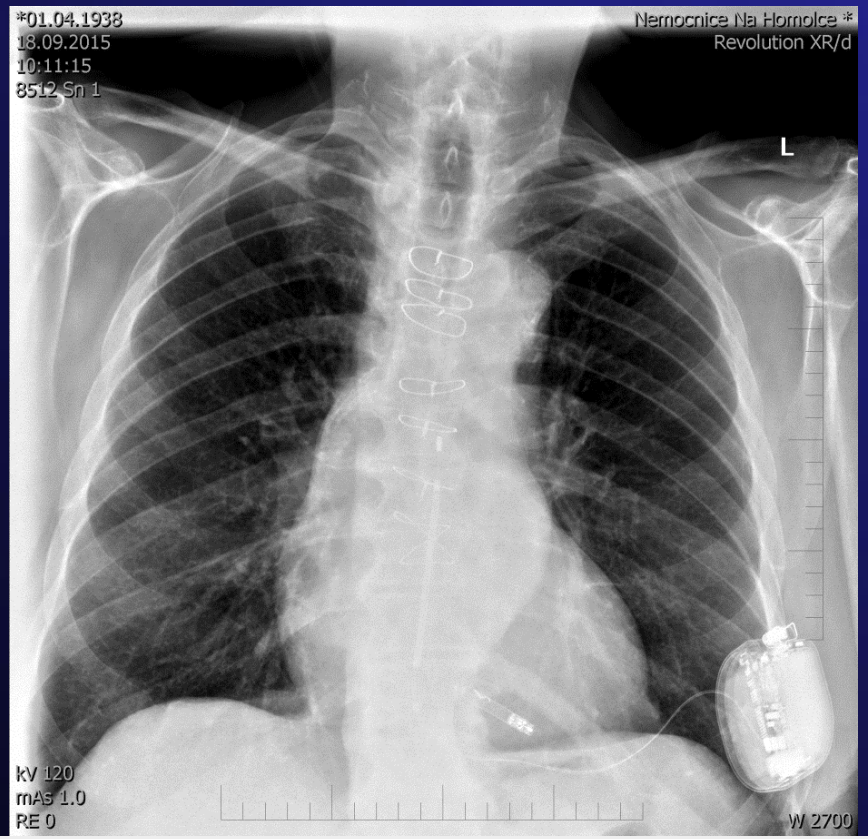


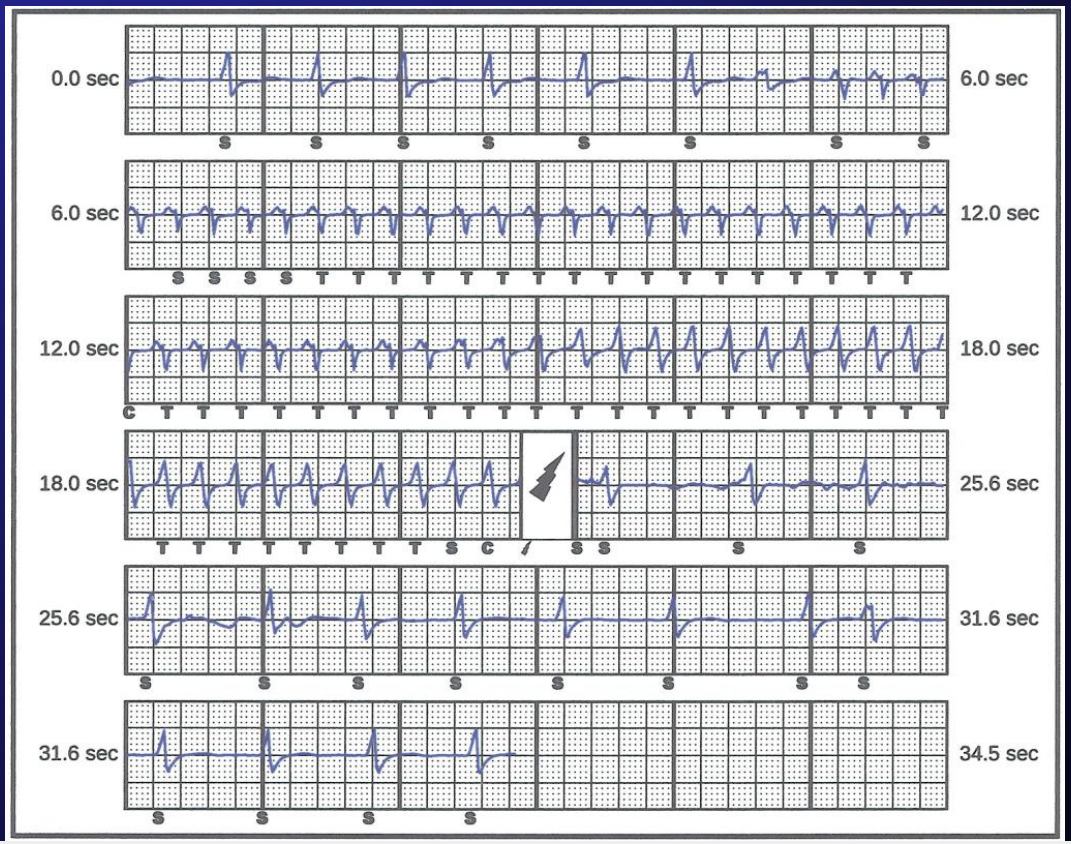
S-ICD v České republice									
ROK	2015	2016	2017	2018	2019	2020	2021	2022	*2023
ČR	27	56	57	47	52	49	84	83	63

Leadless stimulace + S-ICD:

Navzájem nekomunikující elementy

78 letý muž, ICHS - 2002 AKB, dlouhodobě perzistující FiS s pauzami, 2012 implantace LCP , 2014 incesantní KT →LVEF 35%, Katetrizační ablace KT, 2015 impl. S-ICD





EMBLEM™ S-ICD Is Designed to be Compatible with the EMPOWER™ Leadless Pacemaker

TODAY'S S-ICD

S-ICD implant today is intended to be compatible with the EMPOWER™ leadless pacemaker(began trials in 2019)

*mCRM ™ Systems, EMBLEM ™ S-ICD mCRM functionality, and EMPOWER ™ Modular Pacing Systems are in development and not approved for sale in any geography.

FUTURE S-ICD
Implantable Device Prototypes

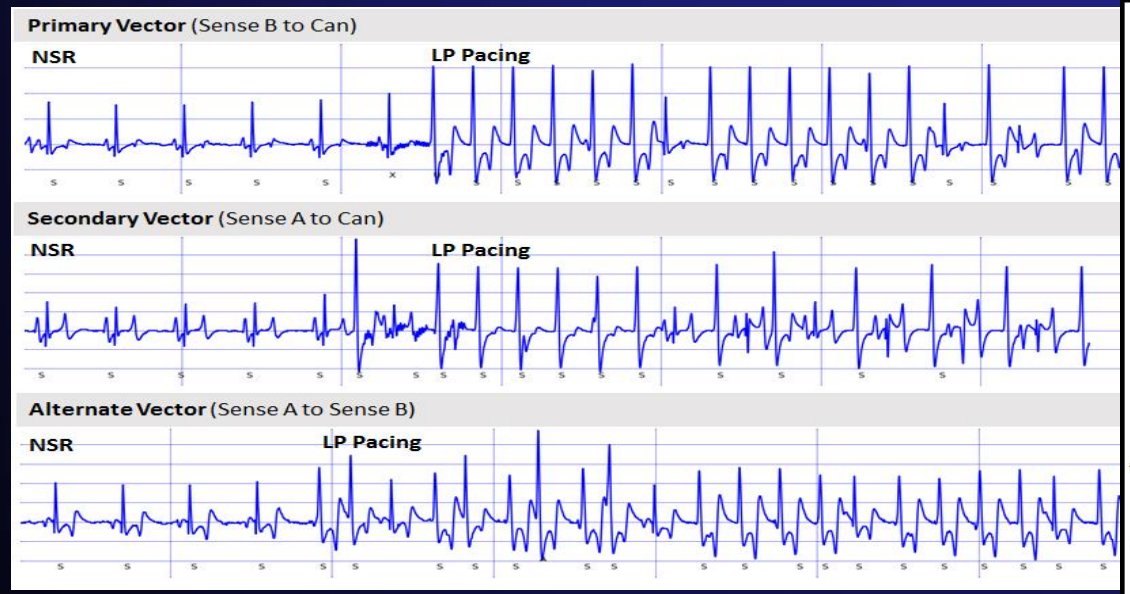
EMPOWER™ Modular Pacing & ATP System
EMBLEM™ Family of S-ICDs

MODULAR ATP & EMPOWER LP

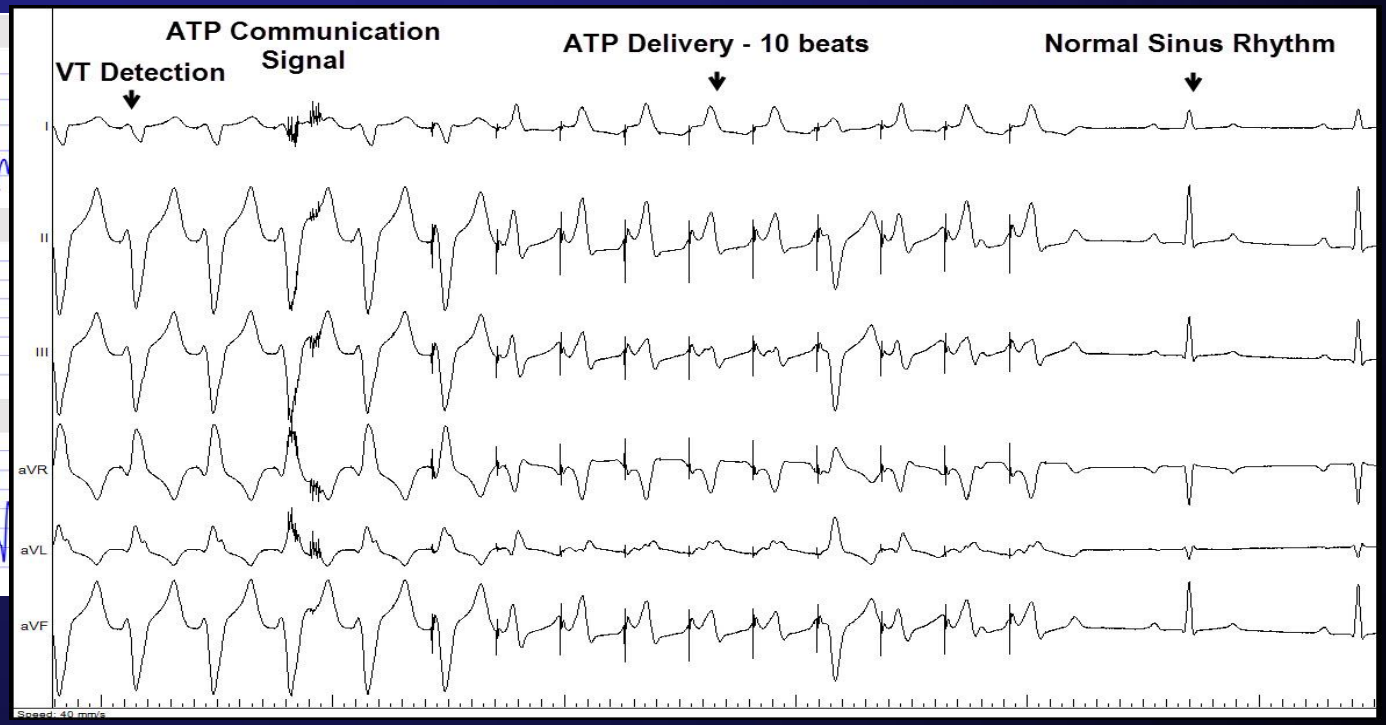
preclinical model

Tjong F.V.Y. et. al., JACC:CE,,Article in Press

S-ICD diskriminace rytmu při stimulaci



ATP terapie vydaná LCP při detekci S-ICD



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MODULAR ATP TRIAL:
Pacing Capture Threshold

97.4% of patients experienced
PCTs ≤2.0 volts (0.4 ms pulse width)[7] (n=151)

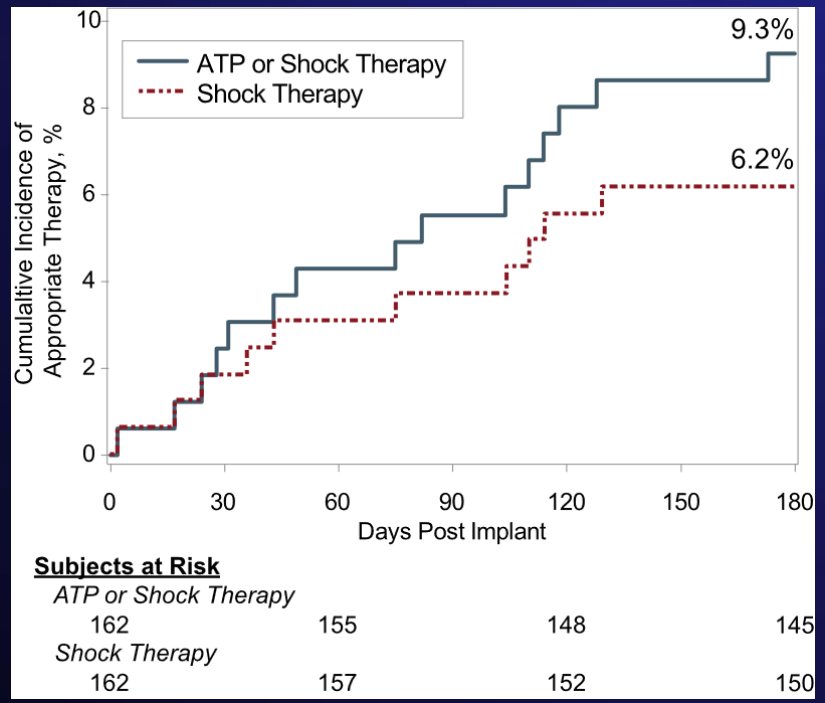
- EMPOWER LP PCTs across patients in the 6-month endpoint cohort were 0.56±0.49 V
- EMPOWER LP's 6-month PCT was similar to 6-month PCTs from other LP systems

	6-month PCT
Nanostim*	88%[9]
Micra**	98.3%[10]

* Nanostim PCT endpoint[9]: <2.0V at 0.5 ms and R-wave >5mV
** Micra PCT endpoint[10]: ≤2.0 V at a pulse width of 0.24 msec and an increase of ≤1.5 V from the time of implantation

MODULAR ATP TRIAL:
Successful ATP Therapy – 61,3%

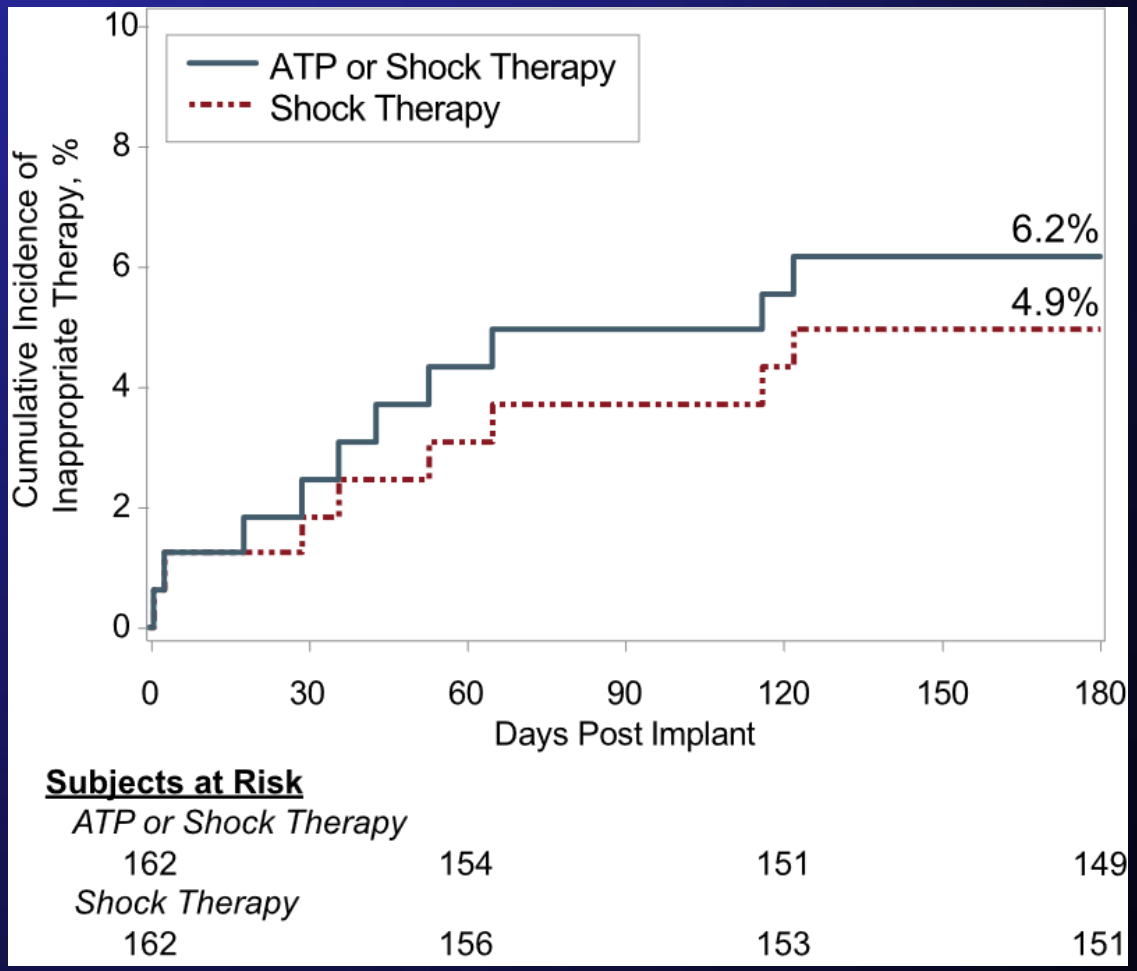
- ATP delivered in 31 episodes in 13 patients[7]
- Appropriate therapy rate[7] = 9.3%
- Appropriate shock rate[7] = 6.2%



- ATP accelerated arrhythmia in 3 episodes[7]
- Episodes post ATP failure[7]:
  - Terminated by shock (9 episodes from 4 patients)
  - Self-terminated (after 2 ATP bursts (1 episode))
  - Arrhythmia stabilized to a rate below the conditional zone (2 episodes from 2 patients)
- ATP therapy provided by EMPOWER was similar to ATP success rates in other large ICD trials (46 – 72%)
  & similar to the EV ICD (70%)
  - However, the ATP or pause prevention pacing in the EVl ICD caused pain or discomfort in some patients, leading to the therapy being turned off or the device explanted.

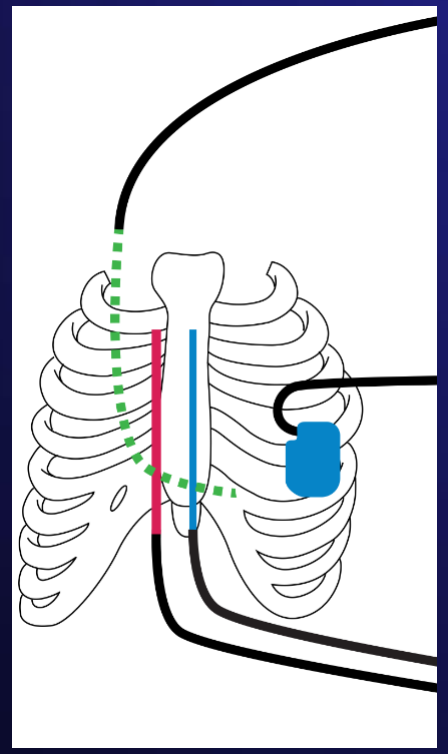
MODULAR ATP TRIAL:
Inappropriate Shock & Therapy

- Inappropriate therapy occurred in 14 patients with 36 episodes.
  - 67% of the episodes were cardiac oversensing of slow VT
- Risk of inappropriate therapy = 6.2%
- Risk of inappropriate shock = 4.9%
- Most inappropriate shocks were delivered to slower ventricular arrhythmias, this finding may be attributable to patient selection and device programing.
- No inappropriate episodes due to oversensing of pacing.
- At 6 months, the substernal ICD experienced an inappropriate shock rate of 8.5%.

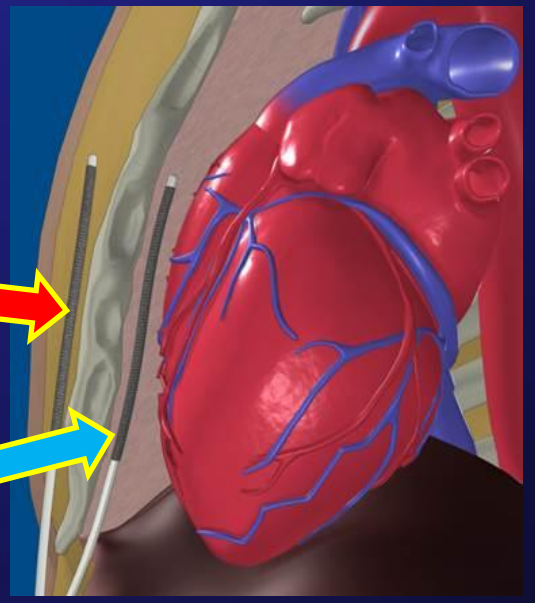


Substernální poloha elektrody:
Pro optimalizaci terapie EV-ICD

Experimentální srovnávací studie u prasečího biomodelu
(11 prasat, 39.3 ± 9.5 kg)



1. **Transvenózní:**
   Cívka (5.7 cm) v pravé komoře
2. **SubQ: Cívka (8 cm) parasternálně**
3. **Substernální :**
   Cívka (8 cm) ve střední sternální čáře zavedené subxiphoidálně



Heart Rhythm, 2016; 13 (AB26-03) supplement

AURORA EV ICD™:

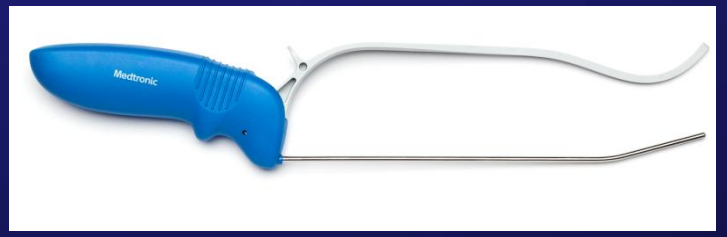
EV-ICD Systém

1. Aurora EV-ICD™ MRI SureScan™
2. Epsila EV™ MRI SureScan (Defibrillation Lead)
   Custom Implant Tools:
3. Epsila EV™ Sternal Tunneling Tool
4. Epsila EV™ Transverse Tunneling Tool
5. SafeSheath® II Hemostatic Peel-away Introducer System

1.

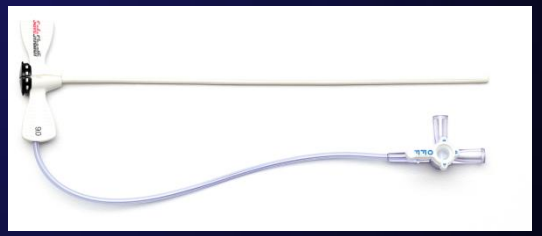
2.

3.



4.

5.



AURORA EV ICD™:

EV-ICD Systém

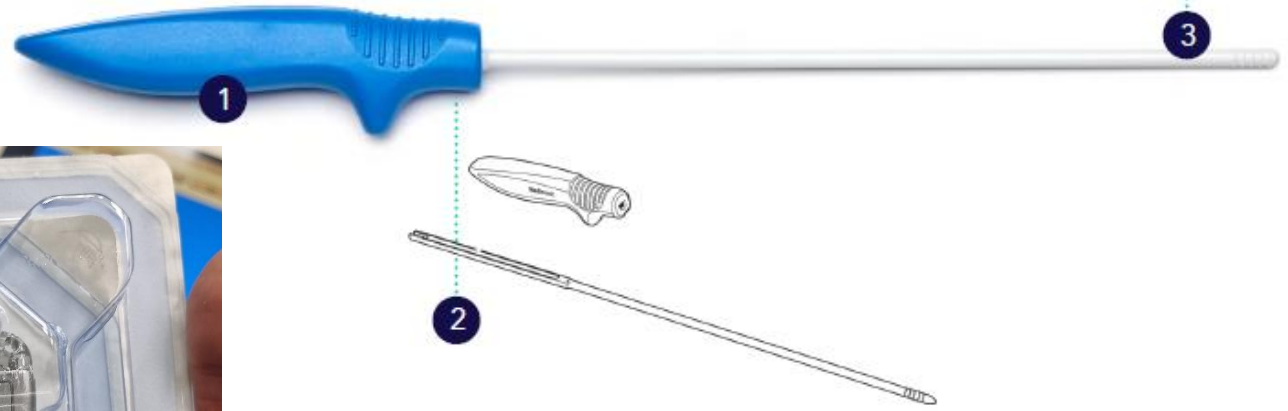
Epsila EV™ Transverse Tunneling Tool

Model EAZ201

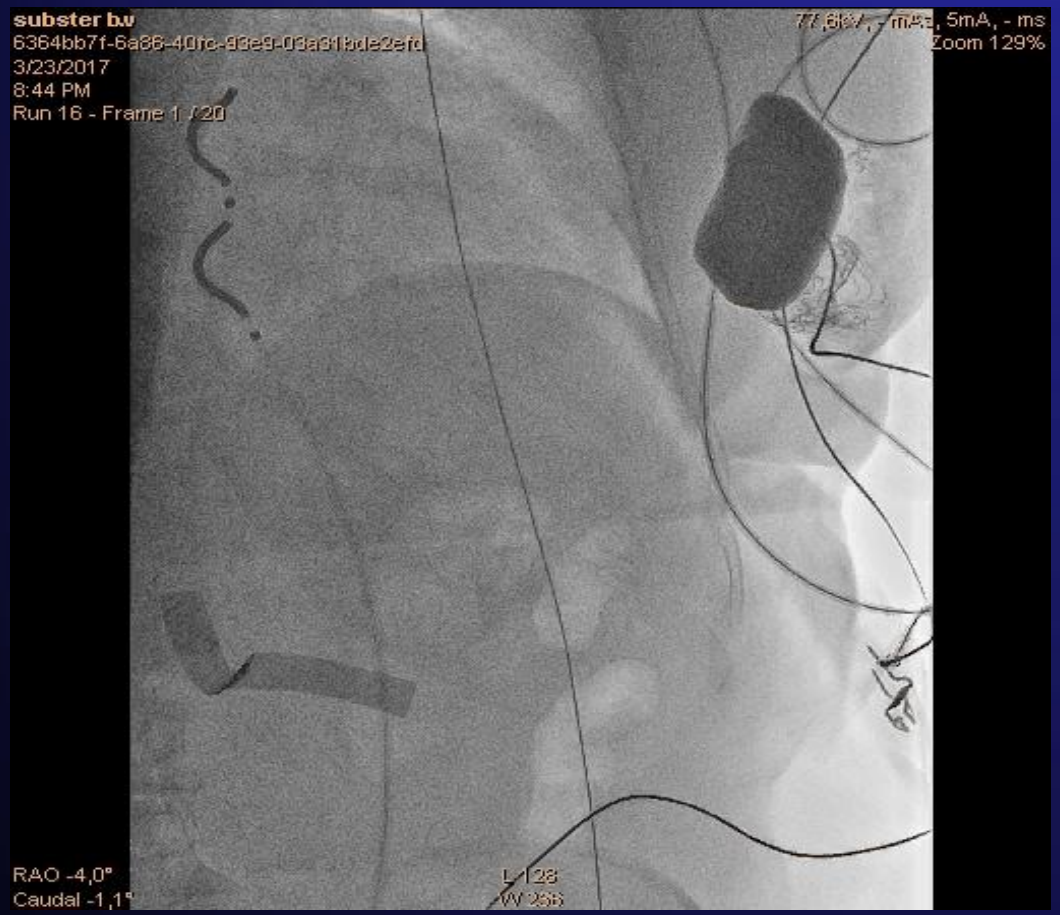
1 Handle

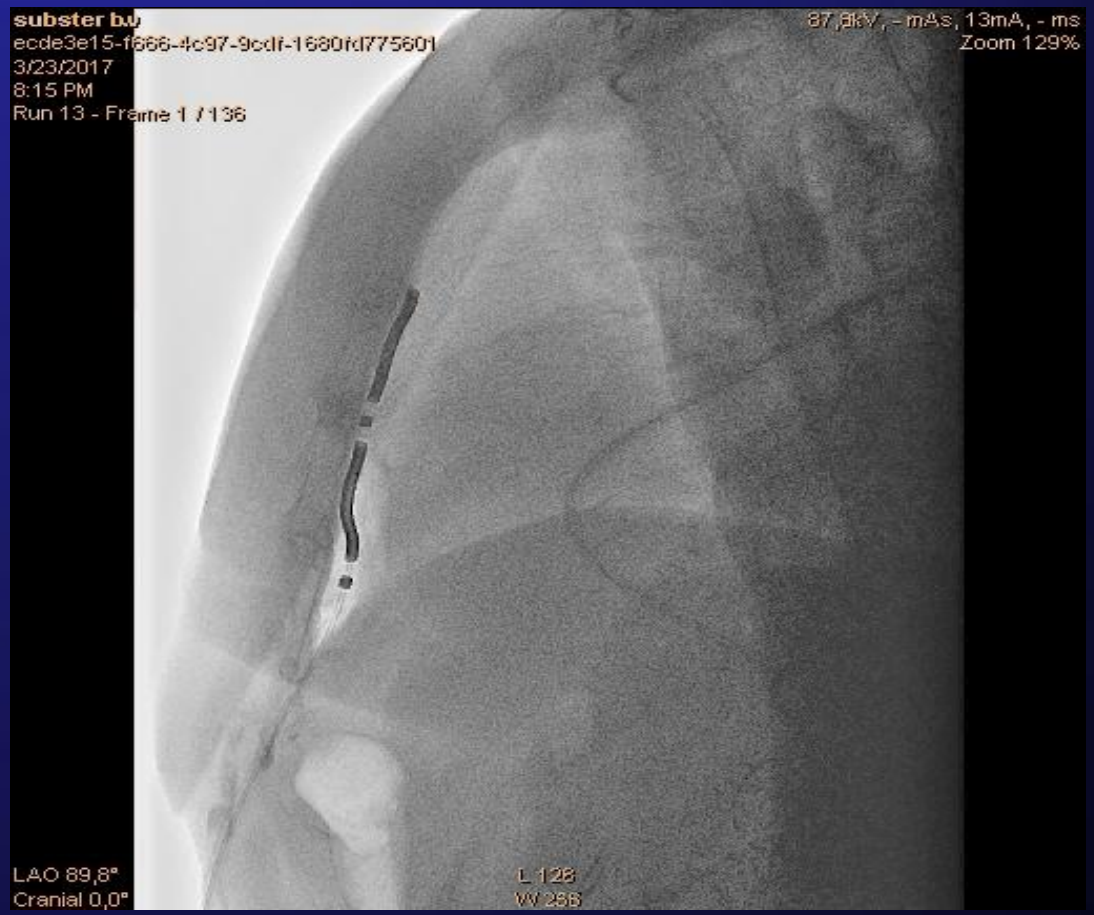
2 Channel for lead delivery

3 Tunneling rod



Pacing and Defibrillation Performance of Mediastinal vs Subcutaneous Electrodes





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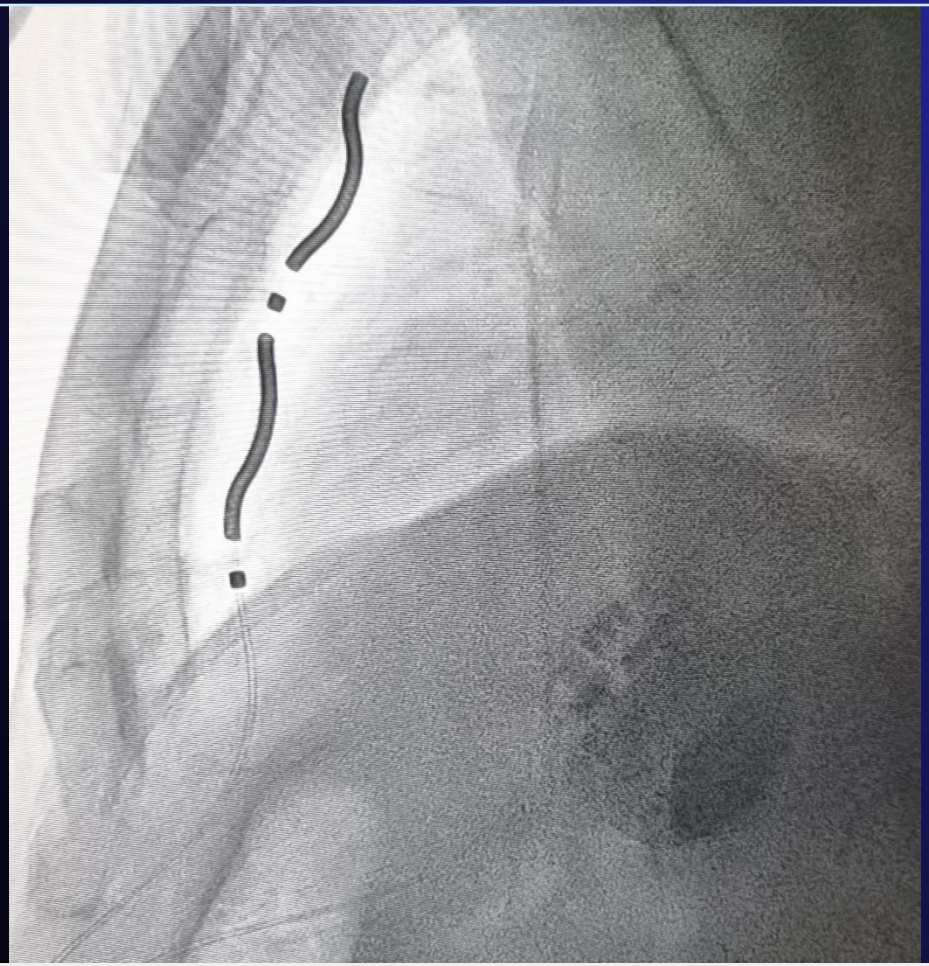
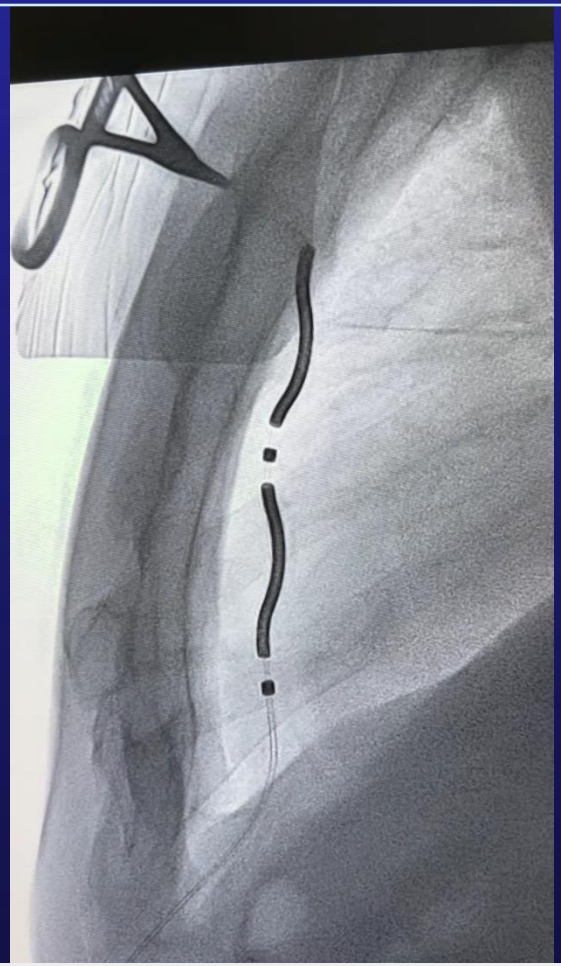
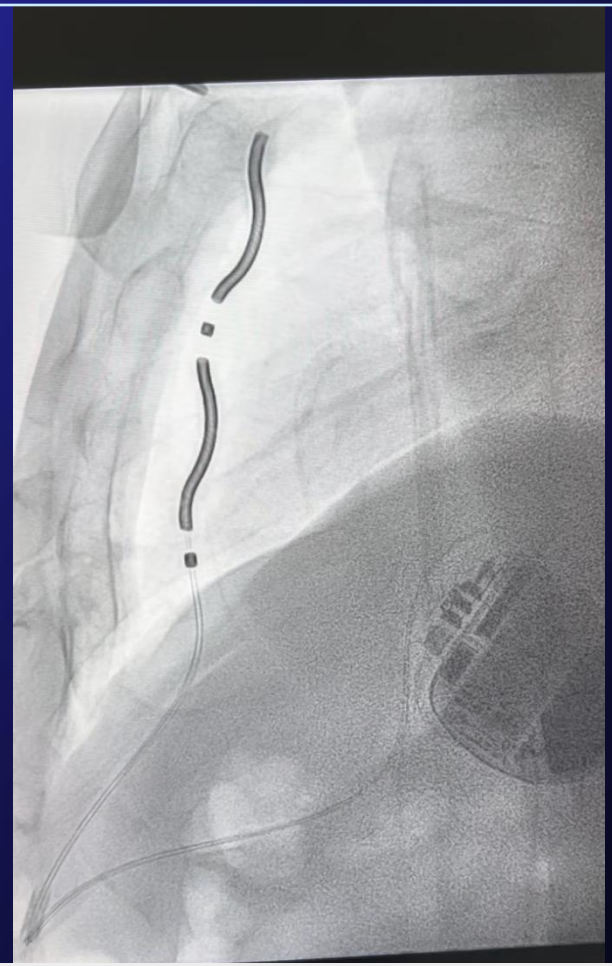
EV ICD: Elektroda Epsila

Pean na RTG indikuje úroveň bifurkace







EV ICD : Srovnání komplikací

EV ICD / TV ICD / S ICD

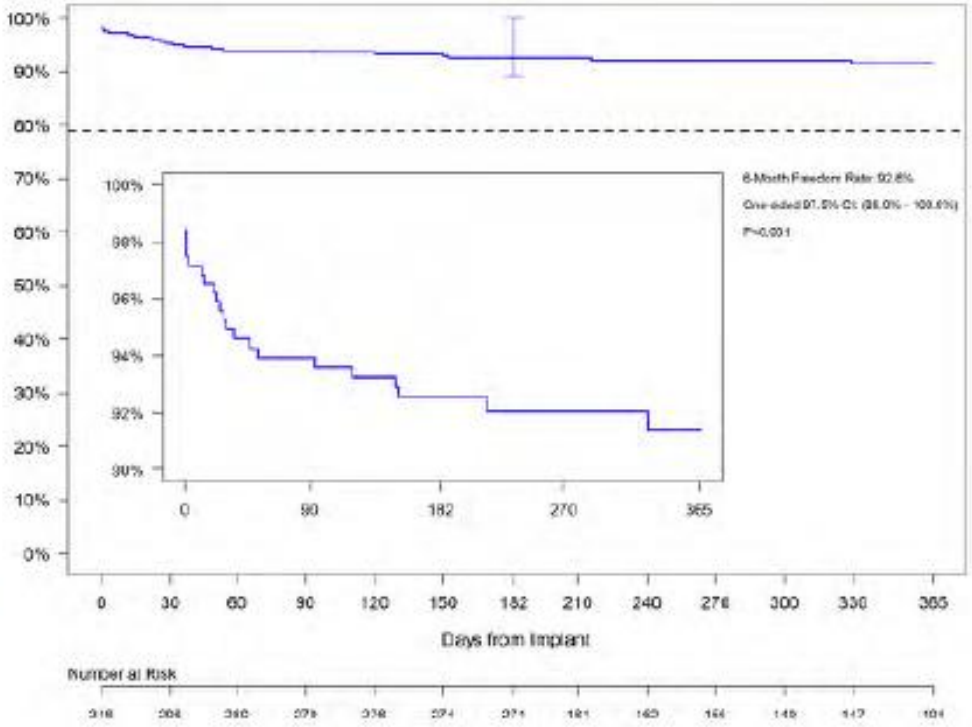
EV ICD freedom from major complication rate is in line with S-ICD IDE and transvenous ICD studies

The rate of EV ICD freedom from system or procedure-related complications[1] is in line with the rates observed in transvenous ICD studies[2-7] and the S-ICD IDE study.[8]

EV ICD[1]	Transvenous ICDs[2-7]	S-ICD[8]
92.6%	85.4 %–93.8%	92.1%

- No statistical difference was observed in the freedom from major complications by BMI tertiles (ranging from 17.9 to 45.6 kg/m^2)[9]
- No major intraprocedural complications[1]
- No unique complications due to EV ICD[1]
- No reports of mediastinitis, sepsis, or endocarditis related to EV ICD[1]

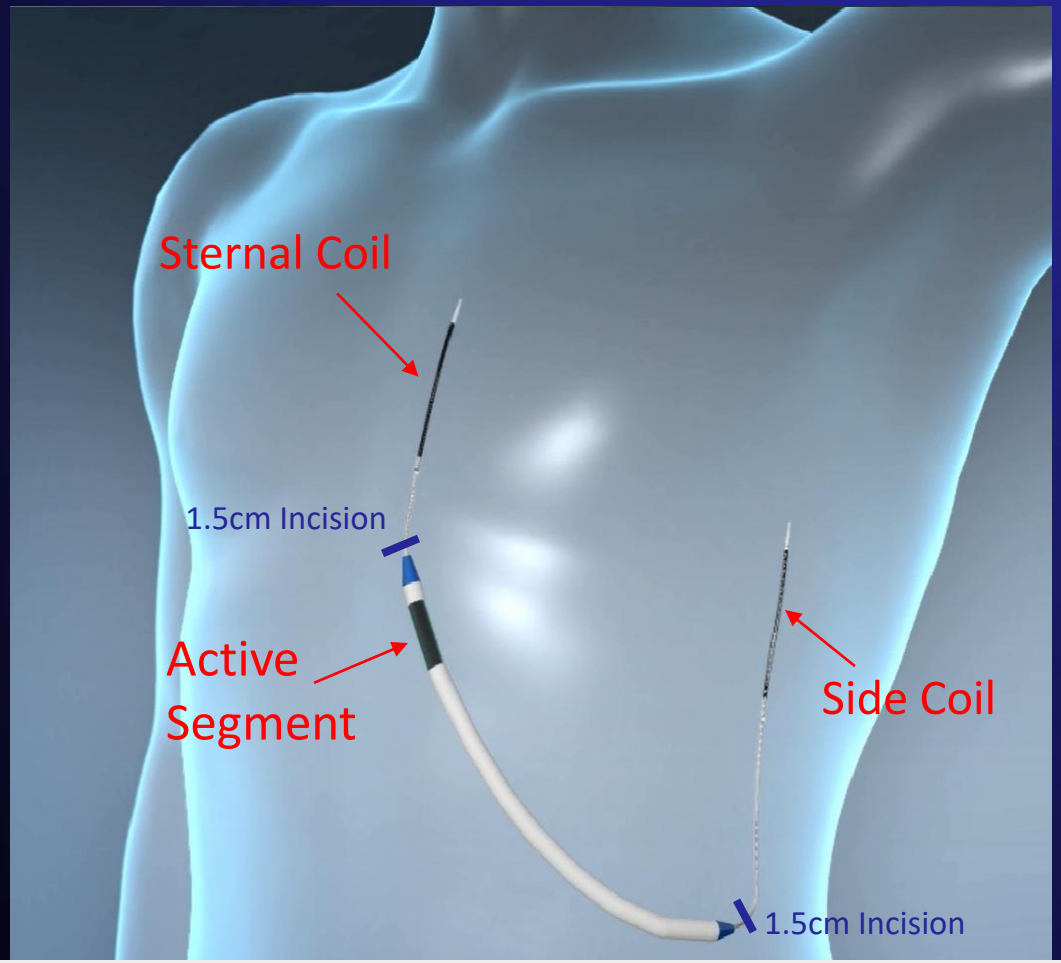
EV ICD freedom from major complication (%)[1]



[1] Friedman P, et al. *N Engl J Med*. 2022;387:1292-1302.
[2] Bardy GH, et al. *N Engl J Med*. 2005;352:225-237.
[3] Sweeney MO, et al. *Heart Rhythm*. 2010;7:1552-1560.
[4] Curtis AB. *N Engl J Med*. 2013;369:579.
[5] Linde C, et al. *J Am Coll Cardiol*. 2008;52:1834-1843.
[6] Gold MR, et al. *J Am Coll Cardiol*. 2015;65:2581-2588.
[7] Auricchio A, et al. *Heart Rhythm*. 2015;12:926-936.
[8] Weiss R, et al. *Circulation*. 2013;128:944-953.
[9] Leclercq C, et al. Efficacy and Safety of the Extravascular Implantable Cardioverter Defibrillator by Body Habitus. Late Breaking Clinical Trial Presentation at APHRS 2022. Singapore and online.

Implantable Subcutaneous String Defibrillator (ISSD)

monolitní přístroj a elektrody



Configuration:

1. A unitary (integrated) and flexible structure ("string") having two shocking coils and an active part ("active segment")
2. Implanted subcutaneously

Feasibility questions:

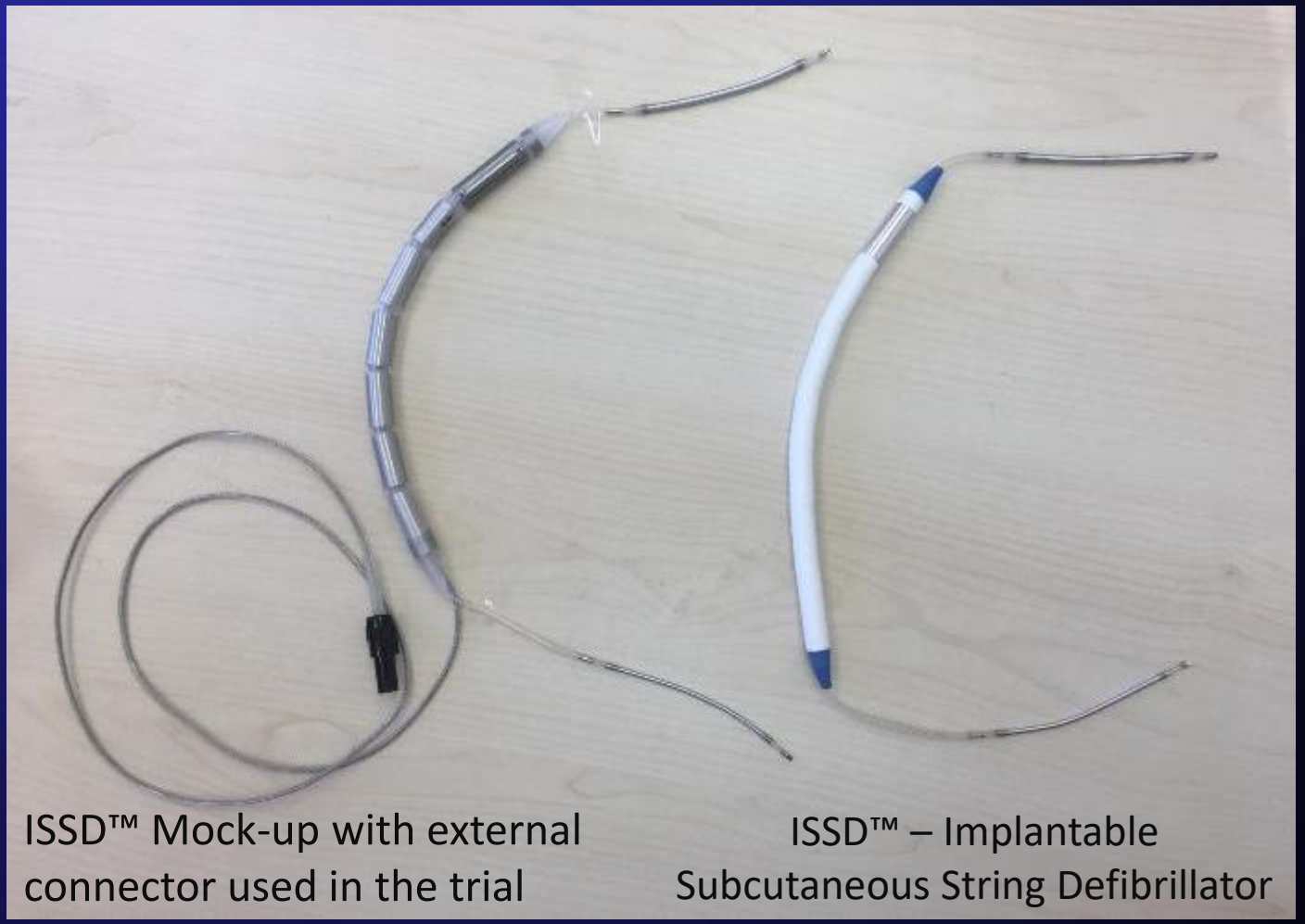
1. Can this configuration defibrillate?
2. How complex is the implant procedure?

Implantable Subcutaneous String Defibrillator (ISSD)

Ověřovací studie

- Use a passive ISSD™ Mockup
  - Same size and placement
  - Connects via cable to:
    1. External defibrillator
    2. External sense signal recorder

- Acute DFT study
  - ICD patients, pre-implant



ISSD™ Mock-up with external connector used in the trial

ISSD™ – Implantable Subcutaneous String Defibrillator

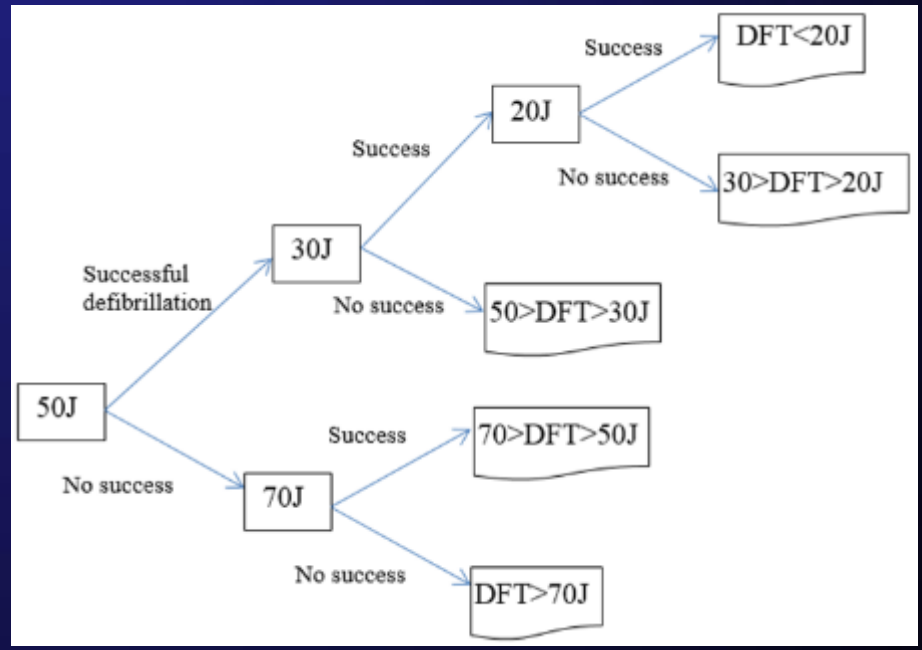
Implantable Subcutaneous String Defibrillator (ISSD)

Ověřovací studie

- 22 ICD implant patients
- 18 male, 4 females
- 91% primary prevention patients

	AVG	STD	Min	Max
Age	69.5	8.9	46	87
BMI	26.9	3.5	20.6	34.1
LVEF	28.9	8.2	10	50

- 18% non ischemic cardiomyopathy
- 14% with prior cardiac surgery



Implantable Subcutaneous String Defibrillator (ISSD)

Ověřovací studie

ISSD™ Mockup fully implanted

Fluoro of ISSD™ fully implanted*

DFT statistics: 25.8J ± 10.7J

successful shock (J)	Number of pts*
20J	7
30J	4
50J	7

* 4 patients excluded from results due to lead misplacements

1. LÉKAŘSKÁ FAKULTA Univerzita Karlova

NEMOCNICE NA HOMOLCE

KARDIOCENTRUM

	TV-ICD	S-ICD	EV-ICD
Umístění	Intravaskulárně	Subkutánně	mediastinum
Účinnost defi	Výborná	Výborná	**Výborná**
Bolestivost výboje	Nižší (20– 40 J)	Nejvyšší (65 – 80 J)	Střední (40 – 60 J)
Možnosti stimulace	Ano	Ne	**Dočasná ano**
ATP	Ano	Ne	**Ano**
resynchronizace	Ano	Ne	Ne
Riziko infekce	Vysoké	Nejnižší	**Nízké**
Riziko cévních komplikací	ano	Ne	**Ne**
extrakce	Obtížná	Snadná	**Snažší**
Vhodní pacienti	Potřebují pacing, ATP, CRT	Mladí, bez potřeby stimulace, infekce, přístup	Bez potřeby CRT, ale s potřebou ATP nebo dočasné stimulace
Kosmetika	Diskrétní	Méně estetické	Diskrétní
Riziko neadekv.výbojů	Nízké	Mírně vyšší	Nízké
zkušenosti	Mnoho let zkušeností	Cca 10 let zkušeností	Nová technologie

Extravaskulární ICD

1. Emancipace subutánní defibrilace: široká platforma rozvíjejích se ICD systémů mimo srdeční dutiny

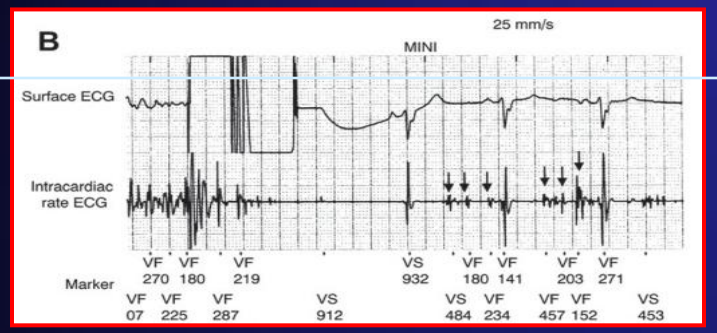
2. Data studie Praetorian prokazují ve shodě s observační studií Effortless velmi malý podíl neadekvátních ICD terapií s velmi dobrým rofilem efektivity ICD terapie

3. EV-ICD spektrem indikovaných nemocných přiblížil extravaskulární systém implantabilních defibrilátorů „standardním“ indikacím

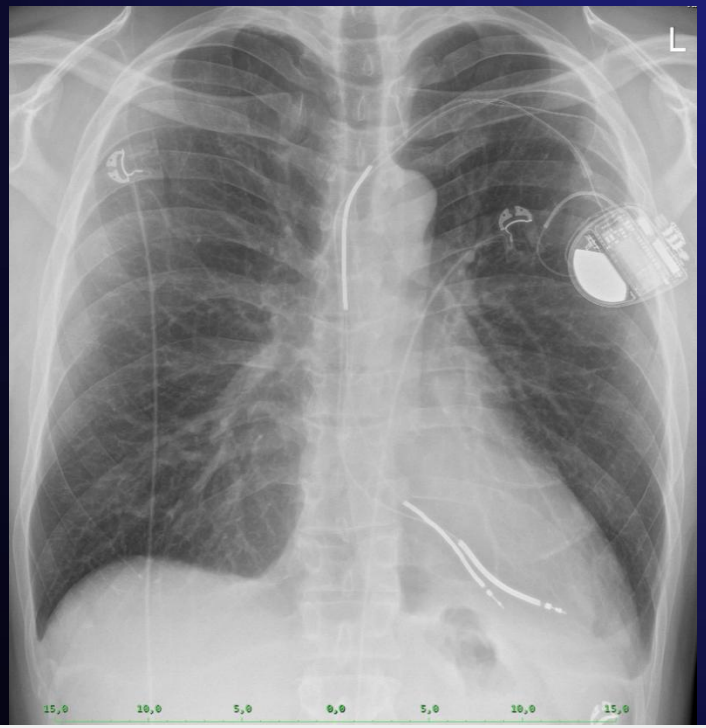
4. S-ICD systém integrovaný s Leadless KS nabízí plnou šíři funkcí standardního ICD s velkou výhodou LBBAP pozice v budoucnosti

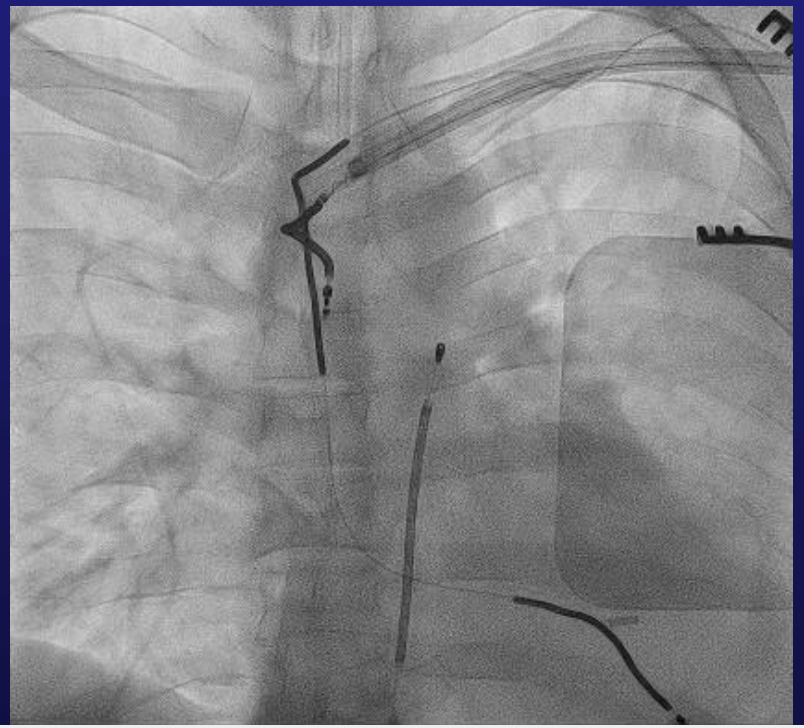
Interakce elektrod a S-ICD:

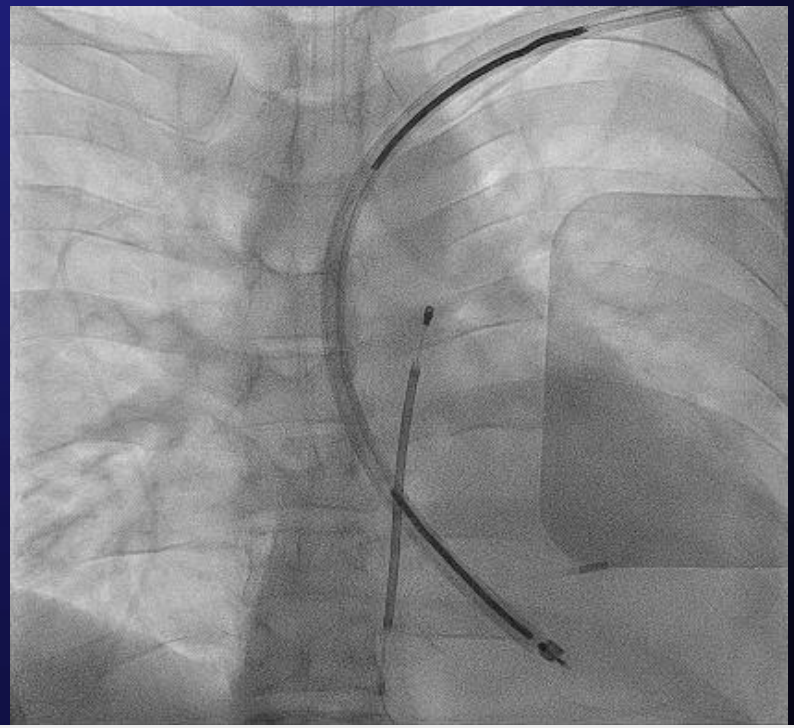
Okluze SVC po extrakci TV ICD



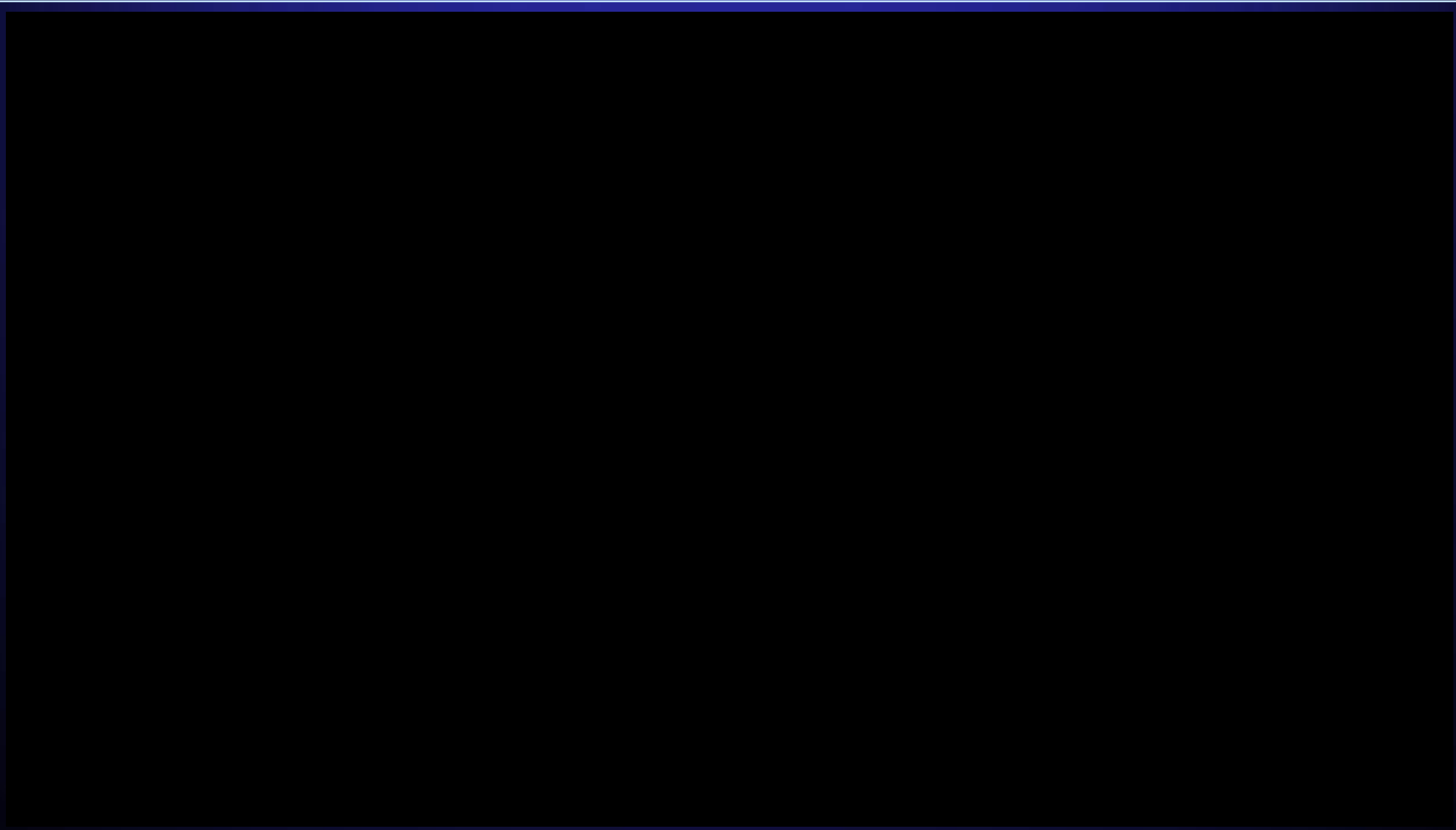
IEKG VVICD prokazuje neadekvátní oversensing, vedoucí k falešné detekci VF



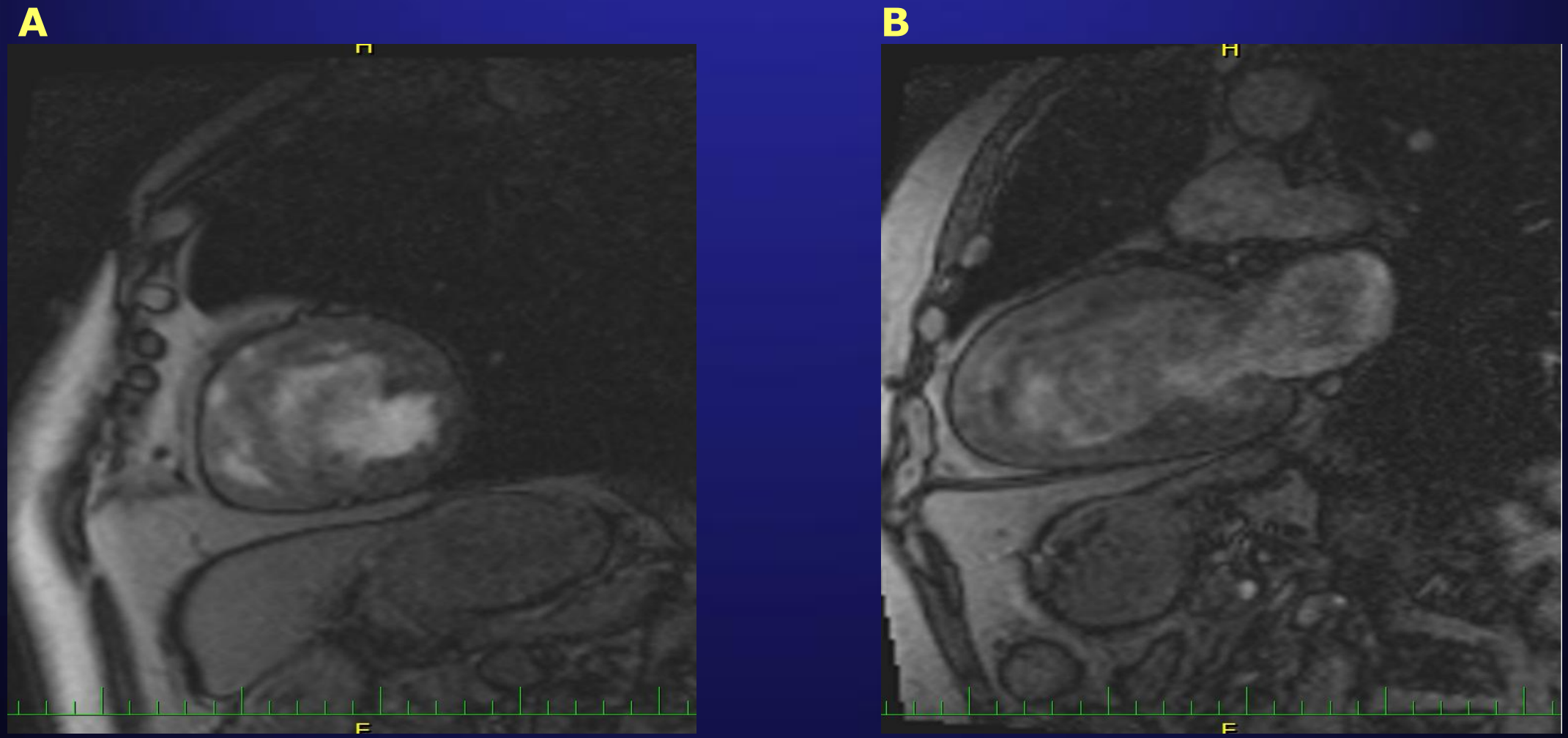




AURORA EV ICD™: Animace



Cardiac MRI: EMBLEM -SICD



FLASH 2D, gradient ECHO transversal axis; A) mild artefacts; B) long axis – no artefacts (EMBLEM S-ICD in mid-axilar line)

Keller/Neuzil/Reddy et al: Europace 2015 ;17:761-6

Vývoj EV-ICD terapie:

5 klinických studií, 80+ center, 400 + pacientů

Feasibility

2012–2014

Pre-clinical studies

Proof-of-concept

Jan–Nov 2015

ASD

Defibrillation feasibility

SPACE

Pacing and sensing feasibility

Epsilon-Shaped Substernal Lead

May 2016–June 2017

ASD2

- Evaluated lead design
- Gathered electrograms for algorithm development

Jul–Dec 2018

EV-ICD Pilot Study

- Chronic first-in-human
- Provided data for Pivotal readiness

First in-human

Sept 2019–present

EV-ICD Pivotal Study

- Worldwide clinical [redacted]

The New England Journal of Medicine

ORIGINAL ARTICLE

Efficacy and Safety of an Extravascular Implantable Cardioverter–Defibrillator

Thompson AE, et al. J Cardiovasc Electrophysiol. 2022;33:1085-1095.

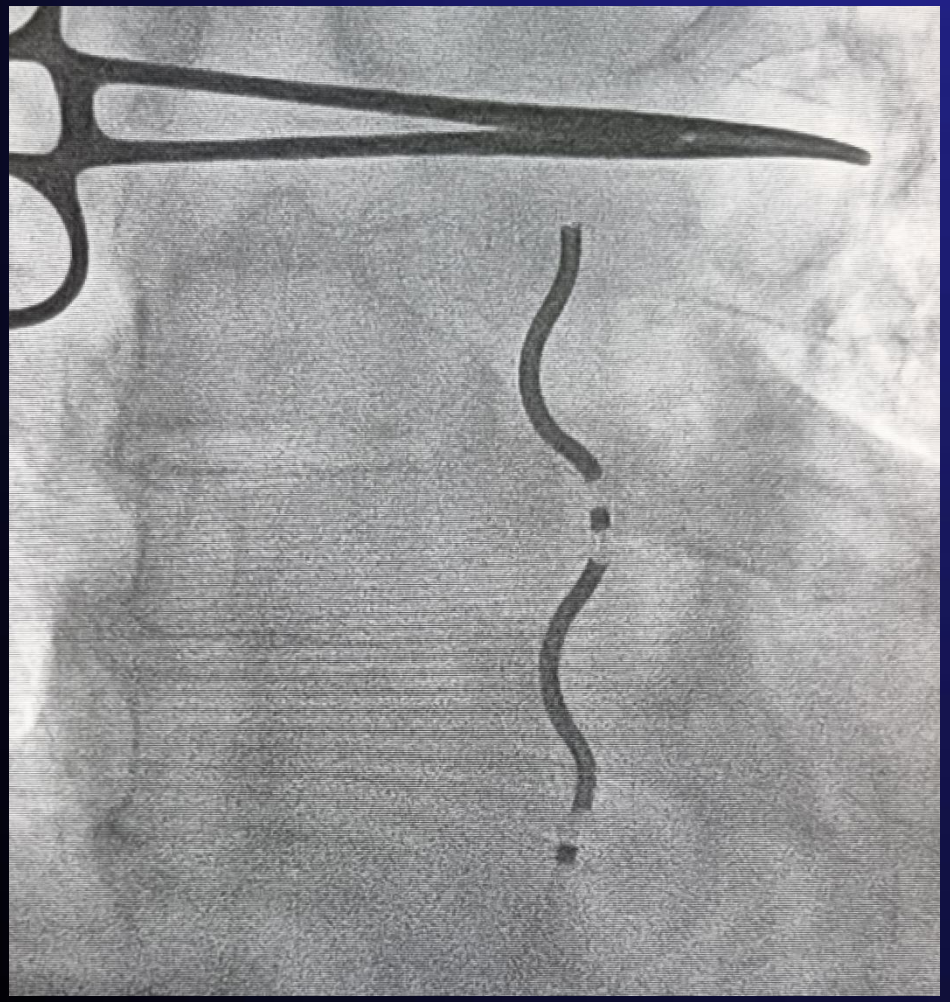
1. LÉKAŘSKÁ FAKULTA Univerzita Karlova

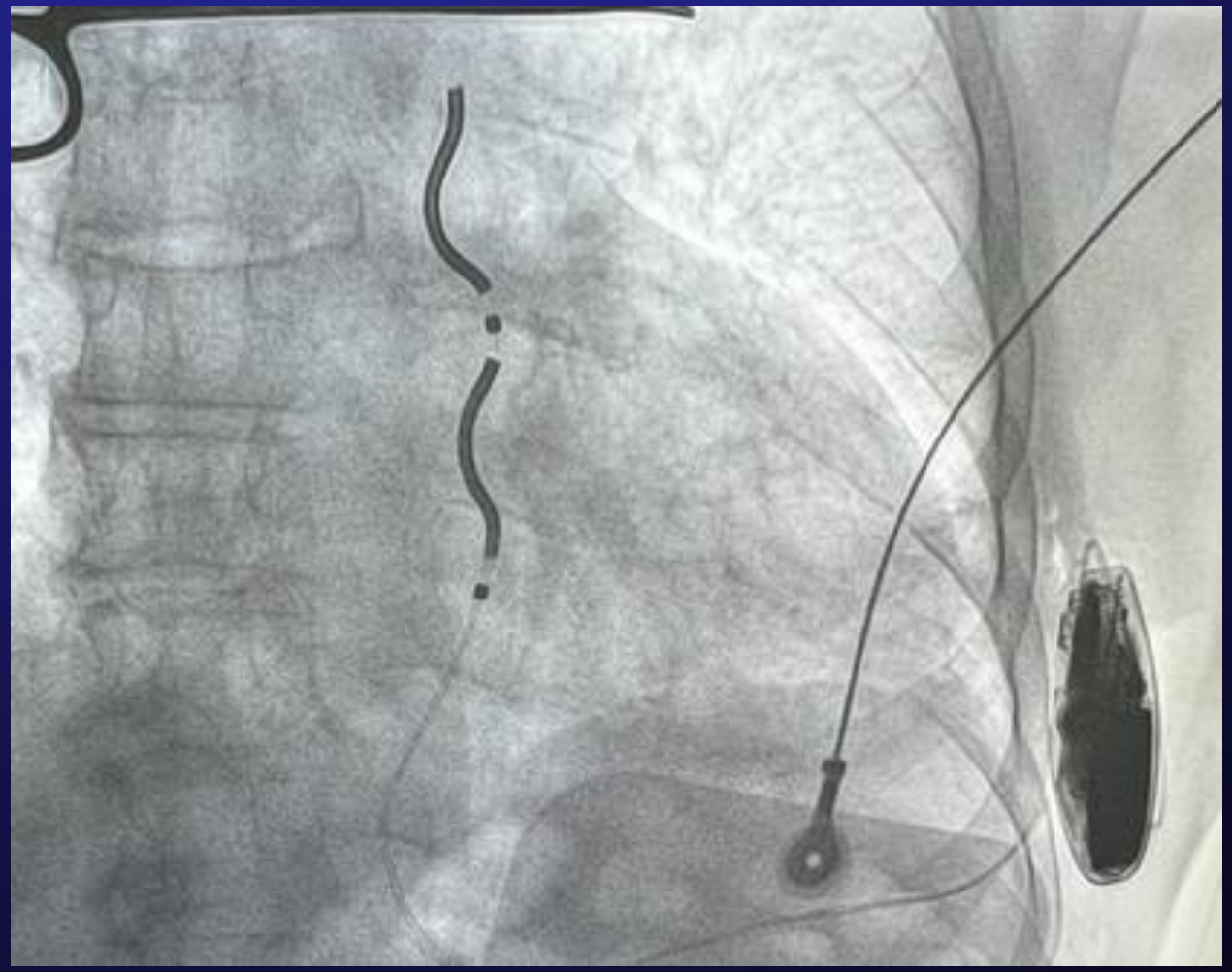
NEMOCNICE NA HOMOLCE

KardioCentrum

EV ICD: Elektroda Epsila

Pean na RTG indikuje úroveň bifurkace



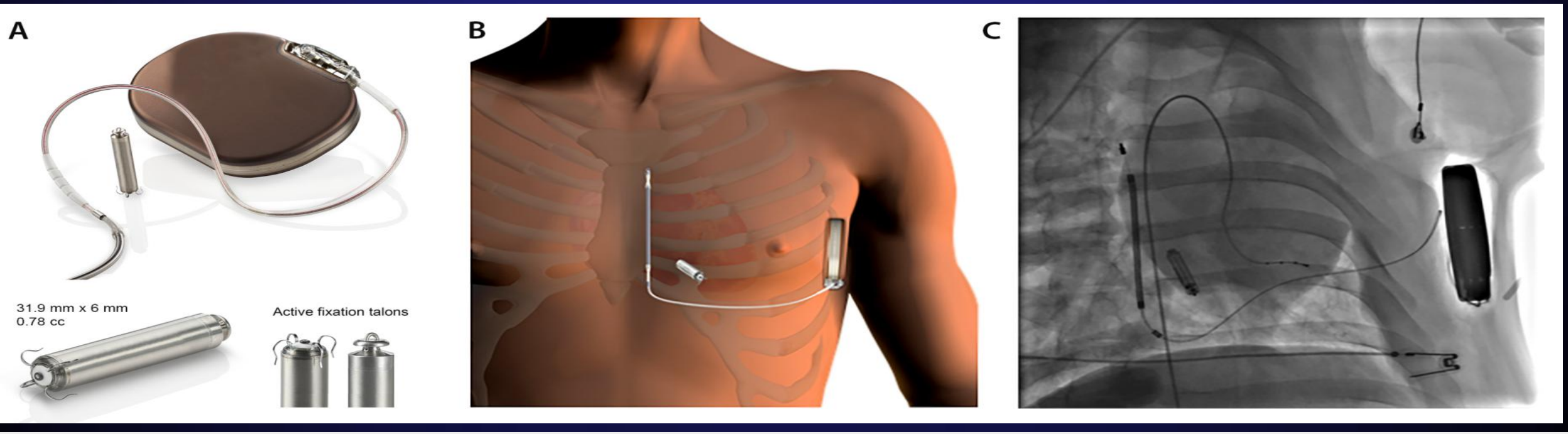


MODULAR ATP & EMPOWER LP

preclinical model

Koncept: Leadless Systém umožňuje brady pacing, ATP a defibrilaci

Tjong F.V.Y. et. al., JACC:CE,,Article in Press

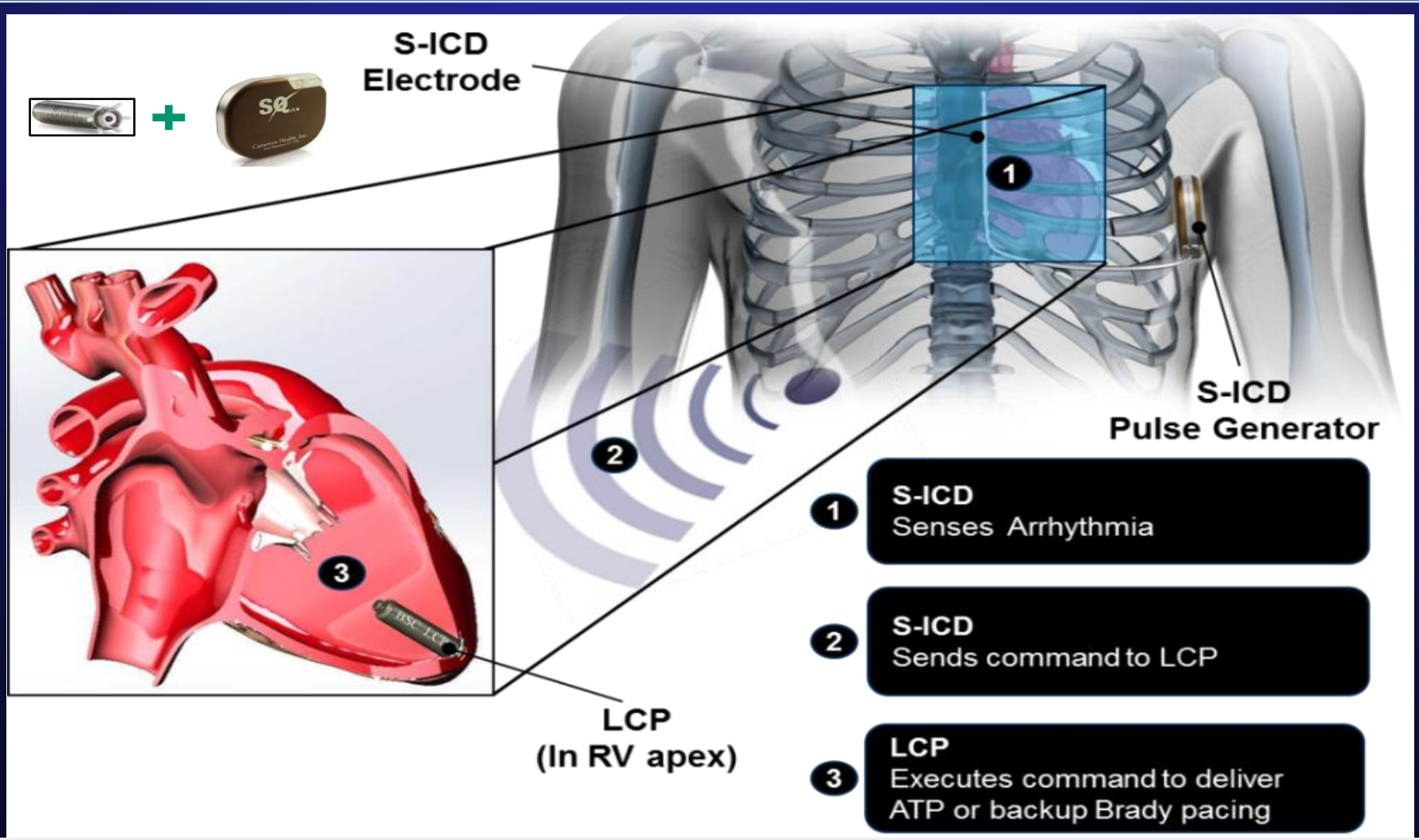


1. LÉKAŘSKÁ FAKULTA Univerzita Karlova

NEMOCNICE NA HOMOLCE

KARDIOCENTRUM

EMBLEM™ S-ICD with the EMPOWER™ Leadless Pacemaker

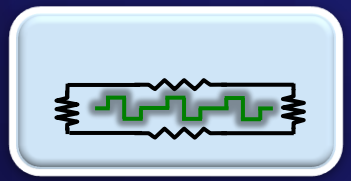


Modular ATP™ : Components

EMPOWER™

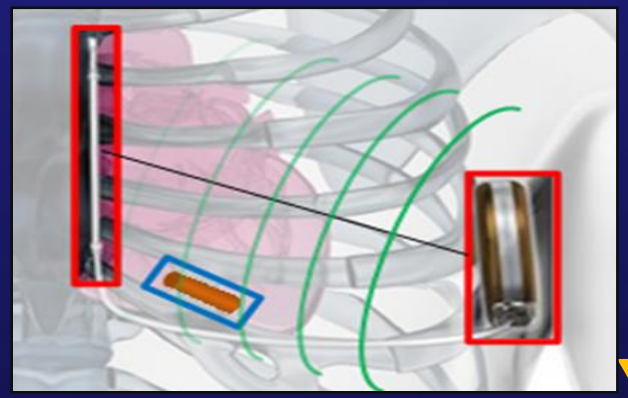
Pulse Generator

Communication Link

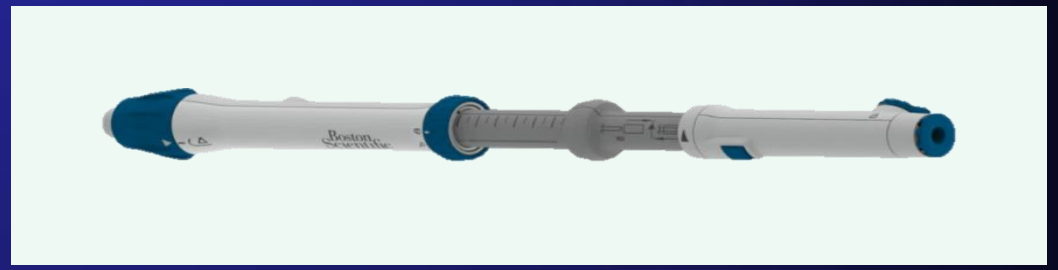


S-ICD

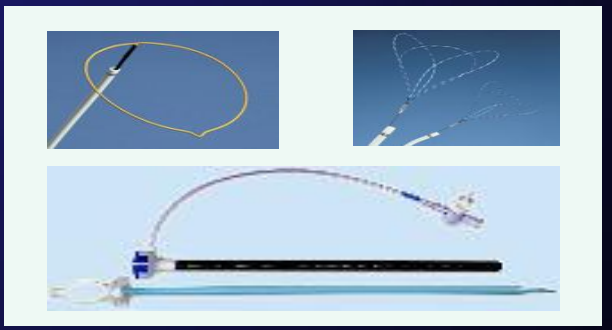
Programmers



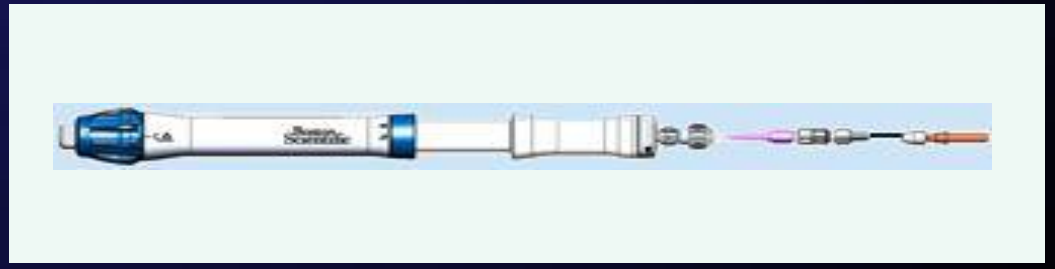
Delivery



Accessories
Accessories



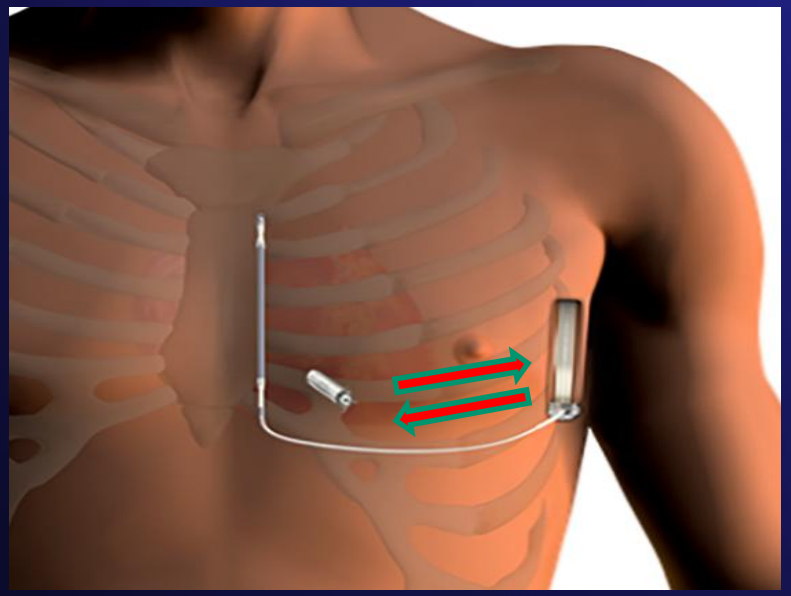
Retrieval

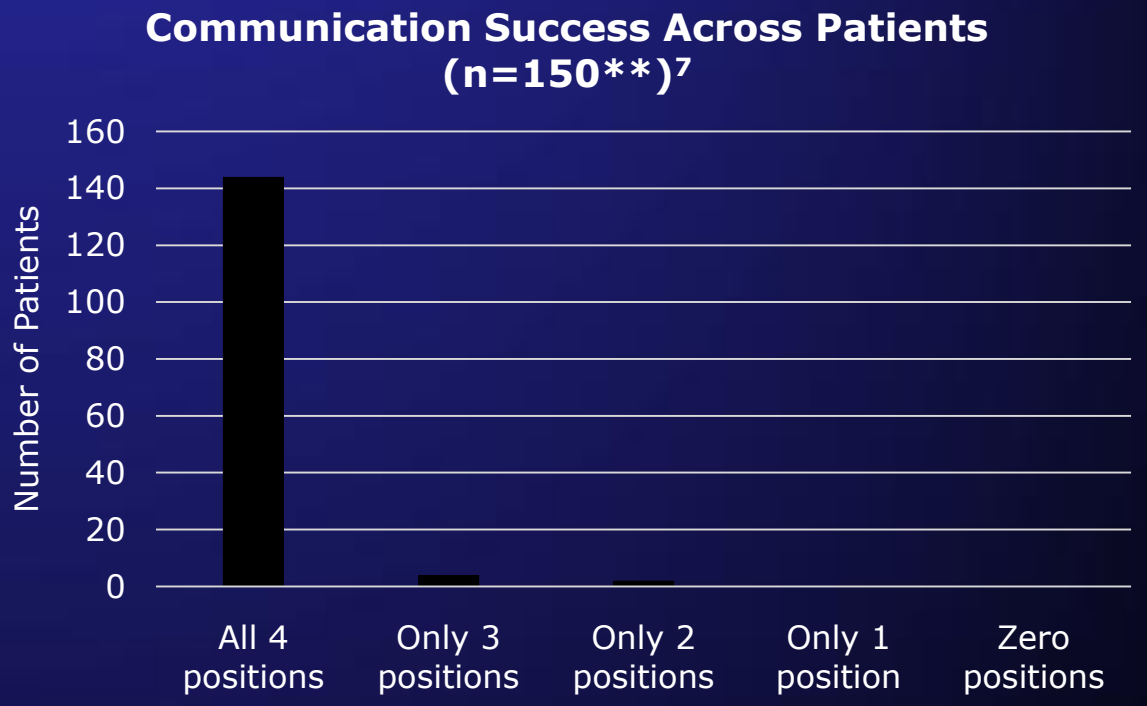


MODULAR ATP TRIAL: Communication Success

S-ICD &EMPOWER™ LP

Communication success rate
98.8% between the EMBLEM S-ICD and EMPOWER LP





No patient experienced a failure of therapy delivery due to device communication failure.