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Lékařská fakulta
Univerzita Palackého v Olomouci

KOMPLEXNÍ KARDIOVASKULÁRNÍ CENTRUM

Kontroverze náhlé smrti u pacientů

Miloš Táborský

Sympózium ČAAK

Karlovy Vary, 3.12. 2017

Sudden Cardiac Death 2017

- Sudden cardiac death remains amajor public health problem
- Annually accounting for an estimated **350,000 deaths in the US**
- **700,000 in Europe**
- 4–5 million around the globe.

Expectations x reality

- The dawning of the new millennium saw the prophylactic implantable defibrillator (**ICD**) firmly established as the **major primary prevention modality to make a major impact on the burden of SCD.**
- But the overall impact of the ICD on this major public health problem has been modest.
- Among patients with the most common forms of SCD high-risk conditions such as ischemic and non-ischemic cardiomyopathies, improved health care provider awareness and consistency in diagnosis and treatment of heart failure, **may have lowered rates of ICD therapies.**

Markers of SCD:

- The limited effectiveness of the left ventricular ejection fraction **(LVEF)** as a risk stratification tool has nowbeen identified as a major stumbling block.
- Based on identification of severely reduced LVEF, we continue to implant this device in significant numbers of patients, **yet only a minority, in the range of 1–5%** per year, have need for the potentially life-saving therapies the ICD is capable of delivering.
- **NNT with a primary prevention ICD in order to save one life, in the range of 20–99 per year depending on the population studied, is not acceptable.**

LVEF Role in 2017

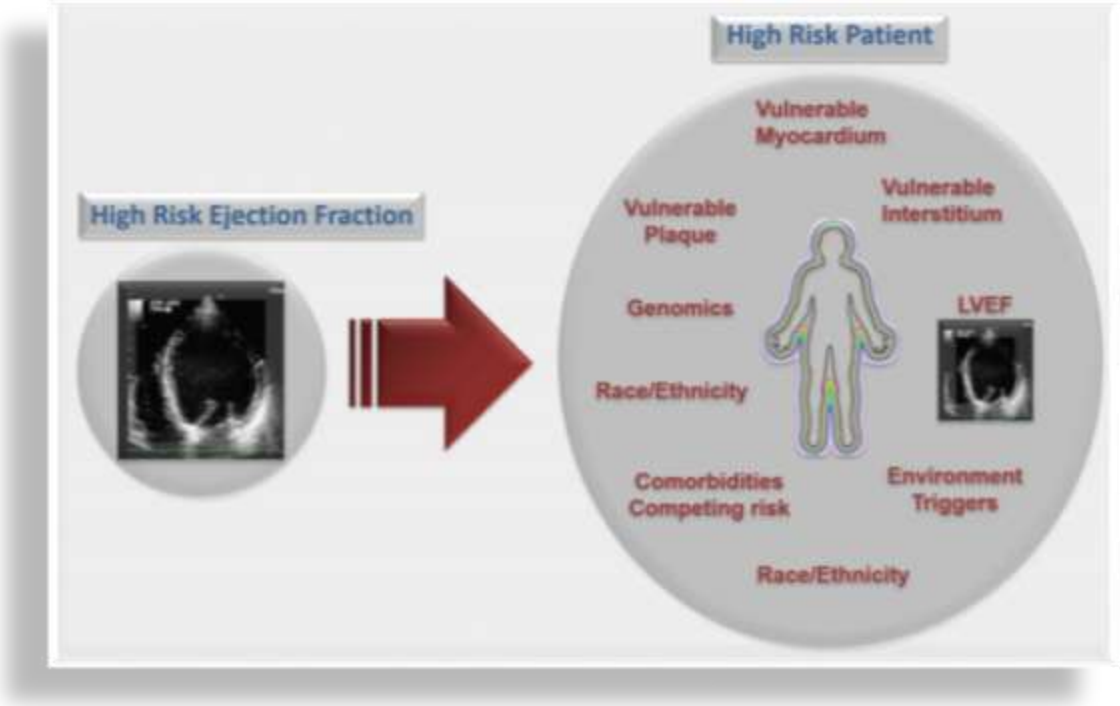
- Large majority, approximately **70% of all SCDs occur in subjects with LVEF over 35%**; and at least half of all individuals that suffer SCD have preserved LVEF.

- As a result, it is now well-recognized that **LVEF measurement has both limited sensitivity and specificity as a tool for SCD clinical risk stratification**.

- Overall, the recognition that the field of SCD prediction needs to extend beyond the LVEF, represents progress based on objective evidence.

Change in SCD perception

- The identification of SCD has transitioned from a focus on the “high-risk ejection fraction” to the broader concept of the “high-risk patient”.



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Organizace péče o pacienty s oběhovou zástavou: Narůstající význam managementu KT

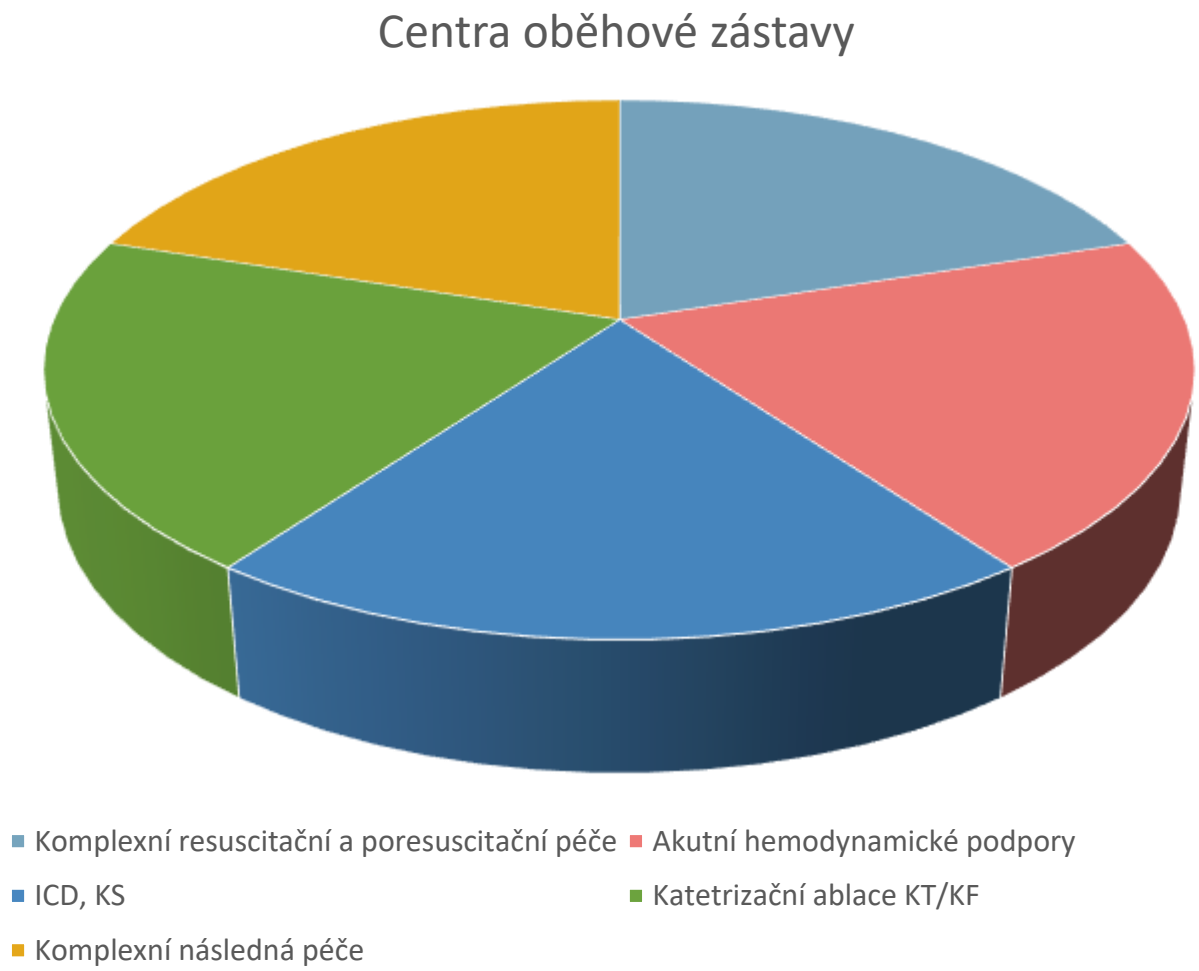
Centra péče o nemocné po srdeční zástavě

Mezioborová spolupráce zahrnující kardiology,
lékaře urgentní medicíny, anesteziology, intenzivisty,
neurology, rentgenology a další specialisty

Centrem péče o nemocné po srdeční zástavě musí být rovněž zajištěna další specializovaná péče (např.
implantace kardiostimulátoru-defibrilátoru)

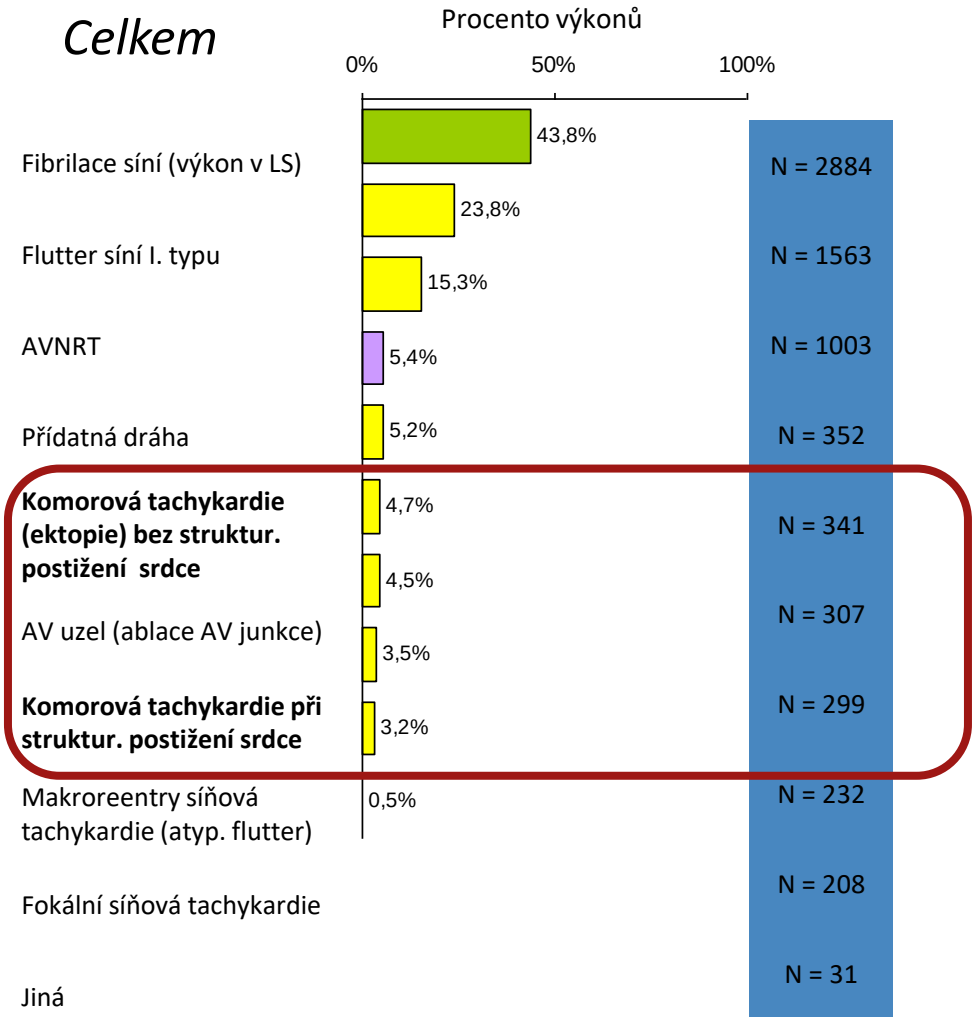
Nově: Intervenční management KT

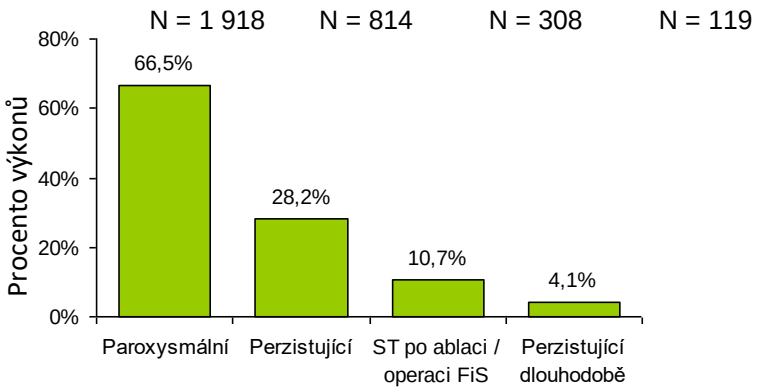
Update 2018


Centra oběhové zástavy
Komplexní resuscitační a poresuscitační péče
Akutní hemodynamické podpory
ICD, KS
Katetrizační ablace KT/KF
Komplexní následná péče

Registr katetrizačních ablací pro arytmie ČR 2016

Spektrum výkonů





Fibrilace síní (N = 2 884)

Báze: všechny výkony 2016 (N = 6 557)

Komplexní ablační management KT

IKEM

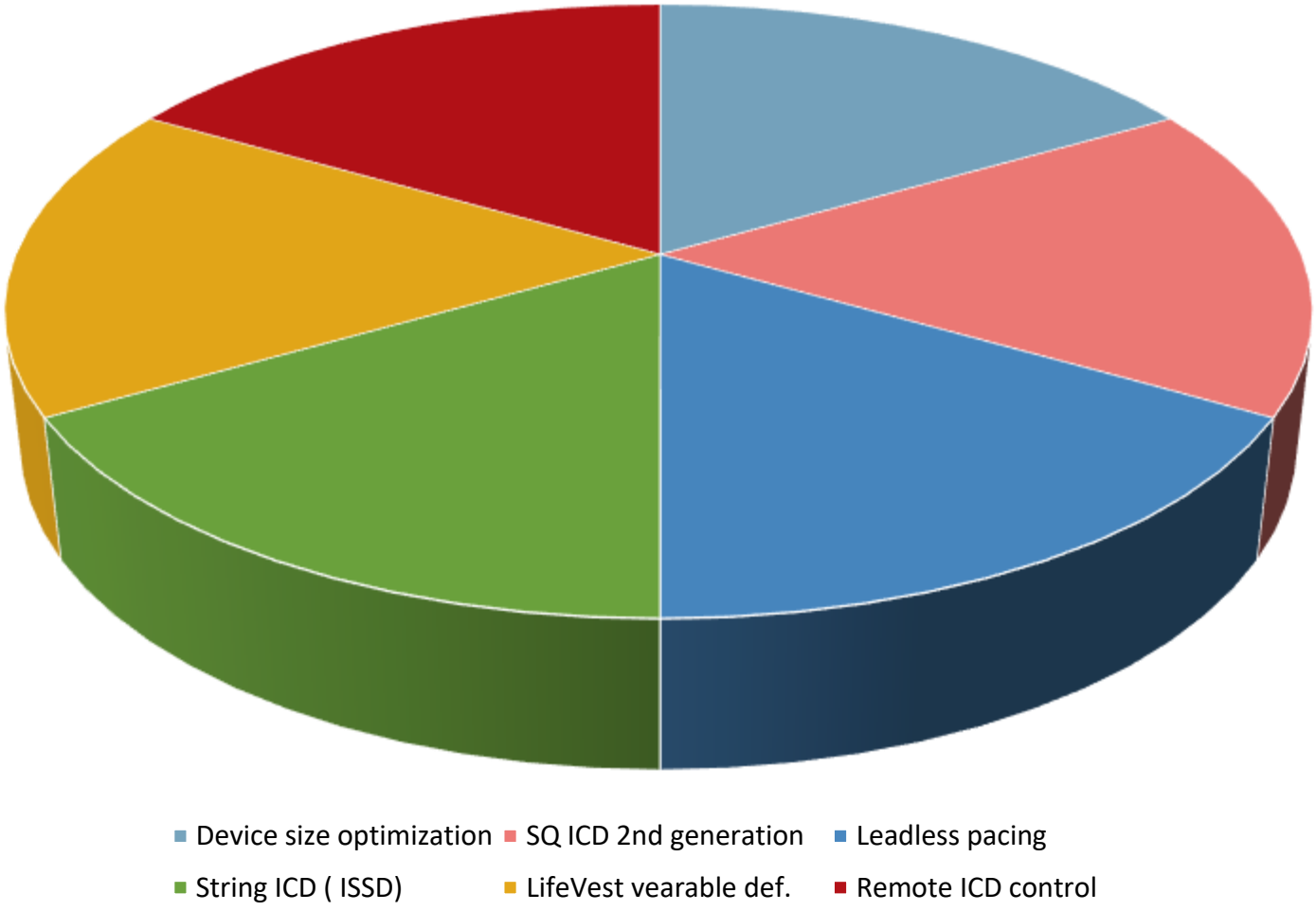
NNH

České Budějovice

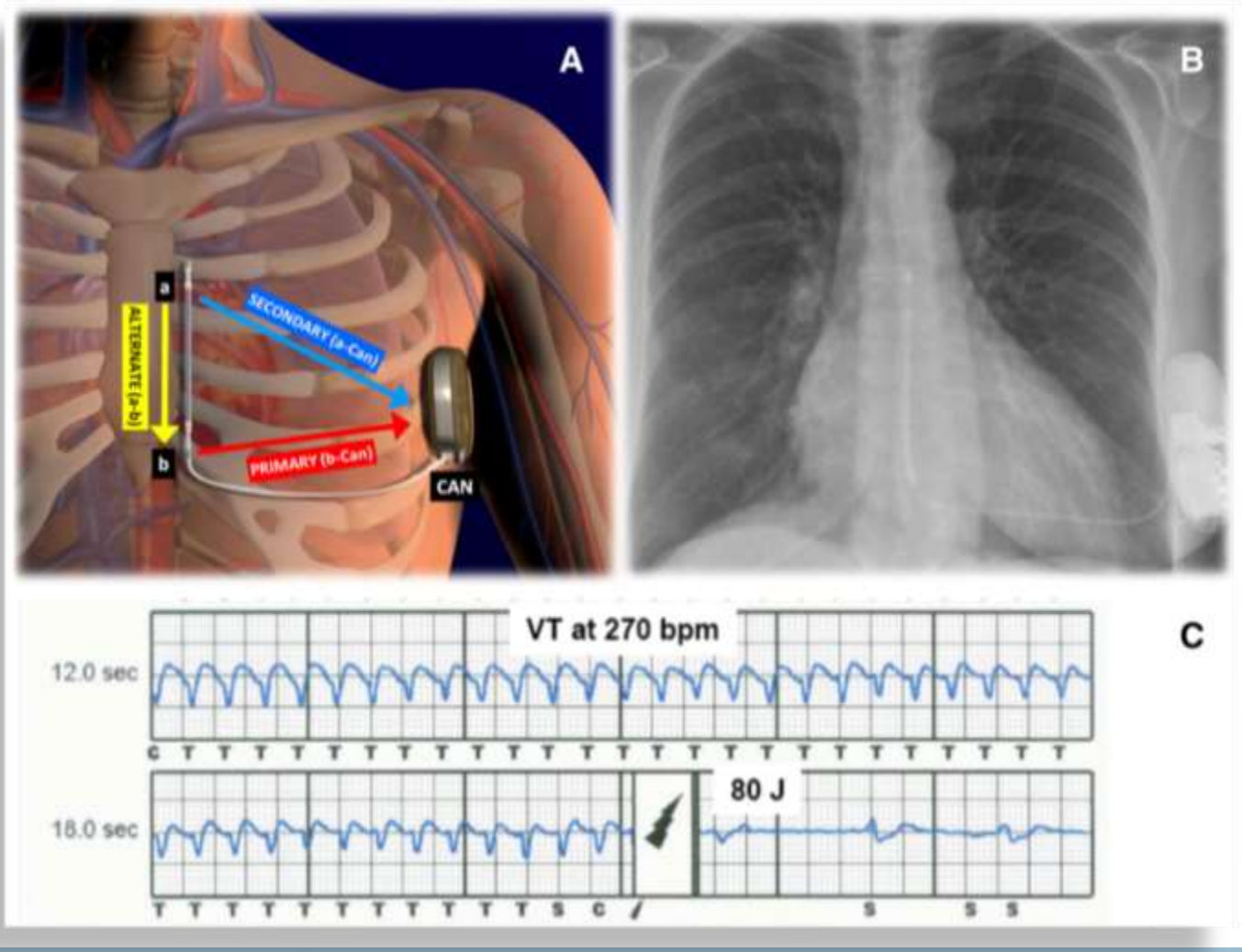
FNUSA

Olomouc

SCD: Technology improvement



SQ ICD Concept



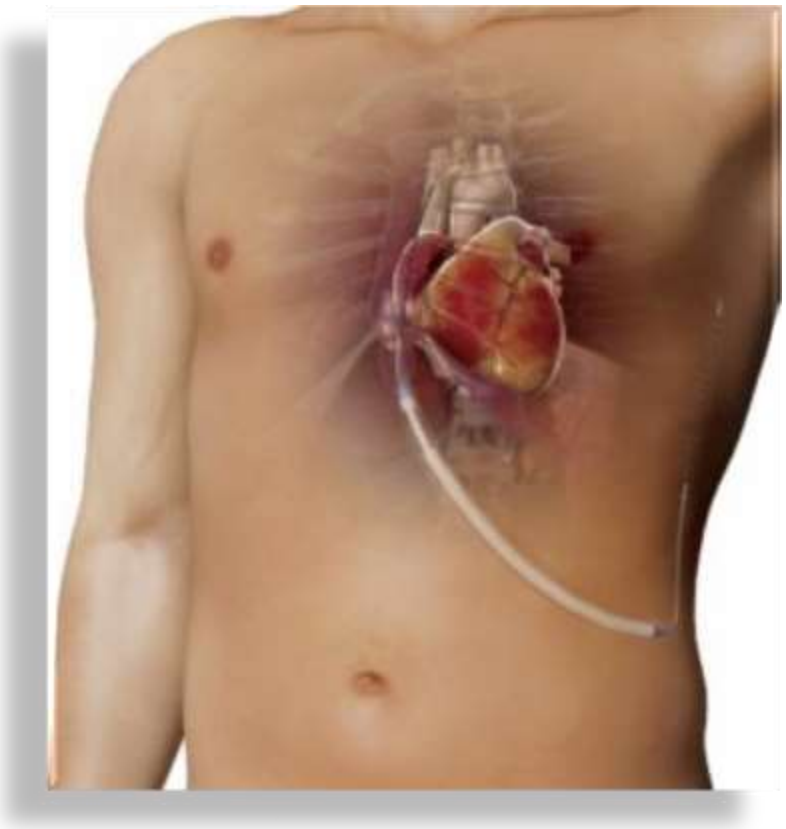
Burke M C: Safety and efficacy of the totally subcutaneous implantable defibrillator: 2-year results from a pooled analysis of the IDE study and EFFORTLESS registry, J. Am. Coll. Cardiol. 65 (2015) 1605–1615.

ESC Guidelines 2015: SQ ICD Indications

Recommendations	Class[a]	Level[b]	Ref.[c]
Subcutaneous defibrillators should be considered as an alternative to transvenous defibrillators in patients with an indication for an ICD when pacing therapy for bradycardia support, cardiac resynchronization or antitachycardia pacing is not needed.	IIa	C	157, 158
The subcutaneous ICD may be considered as a useful alternative to the transvenous ICD system when venous access is difficult, after the removal of a transvenous ICD for infections or in young patients with a long-term need for ICD therapy.	IIb	C	This panel of experts

European Heart Journal (2015) 36, 2793–2867
doi:10.1093/eurheartj/ehv316.

Implantable string subcutaneous defibrillator (ISSD)



https://cardiacrhythmnews.com/hrs-2017-new-implantable-string-subcutaneous-defibrillator-shows-promise-for-sudden-cardiac-death-prevention/

Wearable defibrillator: How to ensure it for patients in the CR ?

Recommendation	Class[a]	Level[b]	Ref.[c]
The WCD may be considered for adult patients with poor LV systolic function who are at risk of sudden arrhythmic death for a limited period, but are not candidates for an implantable defibrillator (e.g. bridge to transplant, bridge to transvenous implant, peripartum cardiomyopathy, active myocarditis and arrhythmias in the early post-myocardial infarction phase).	IIb	C	167, 168

European Heart Journal (2015) 36, 2793–2867
doi:10.1093/eurheartj/ehv316

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Narůstající role katetrizačních ablací

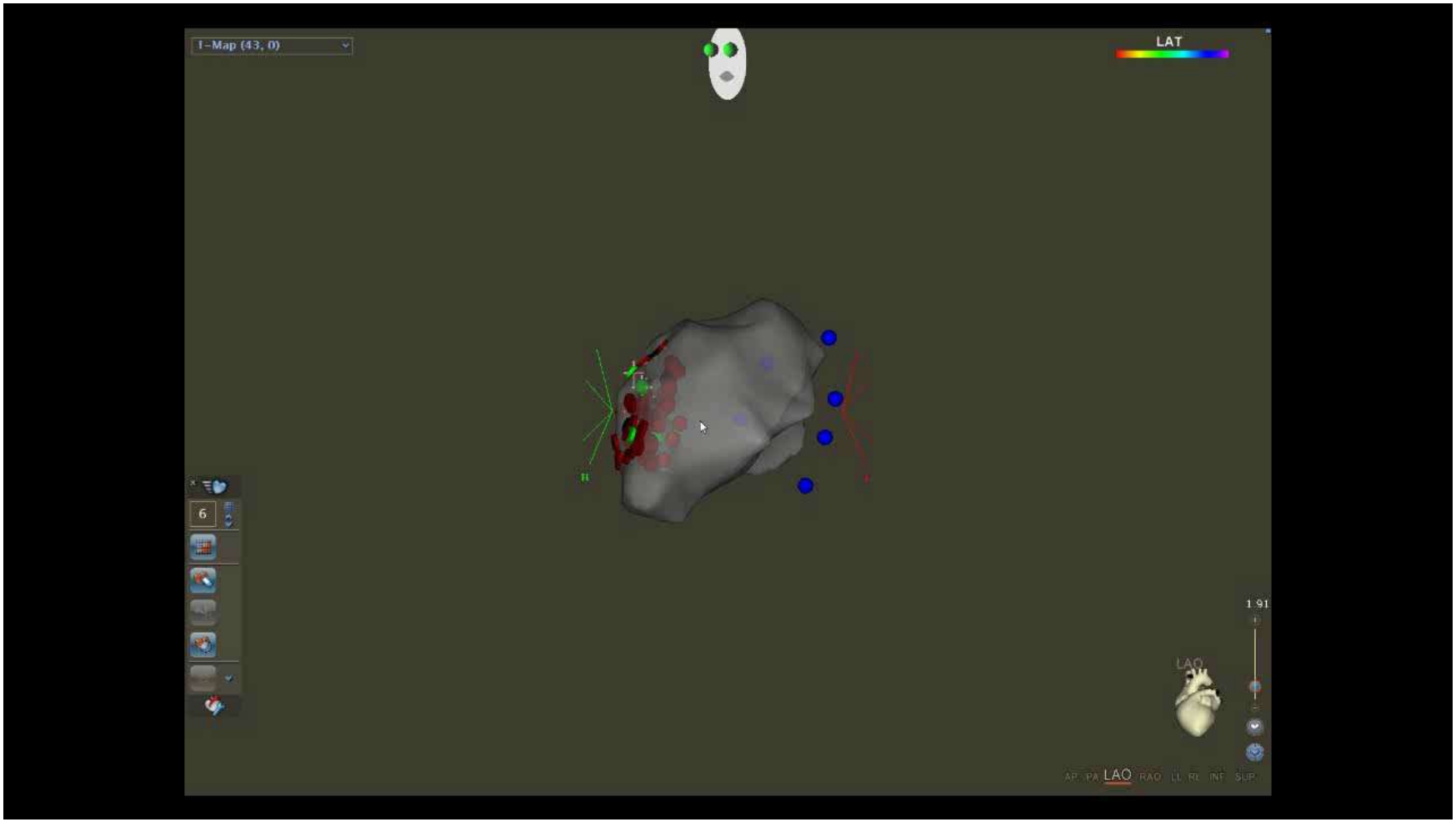
Komplikace přístrojové léčby

Catheter ablation to prevent sudden cardiac death

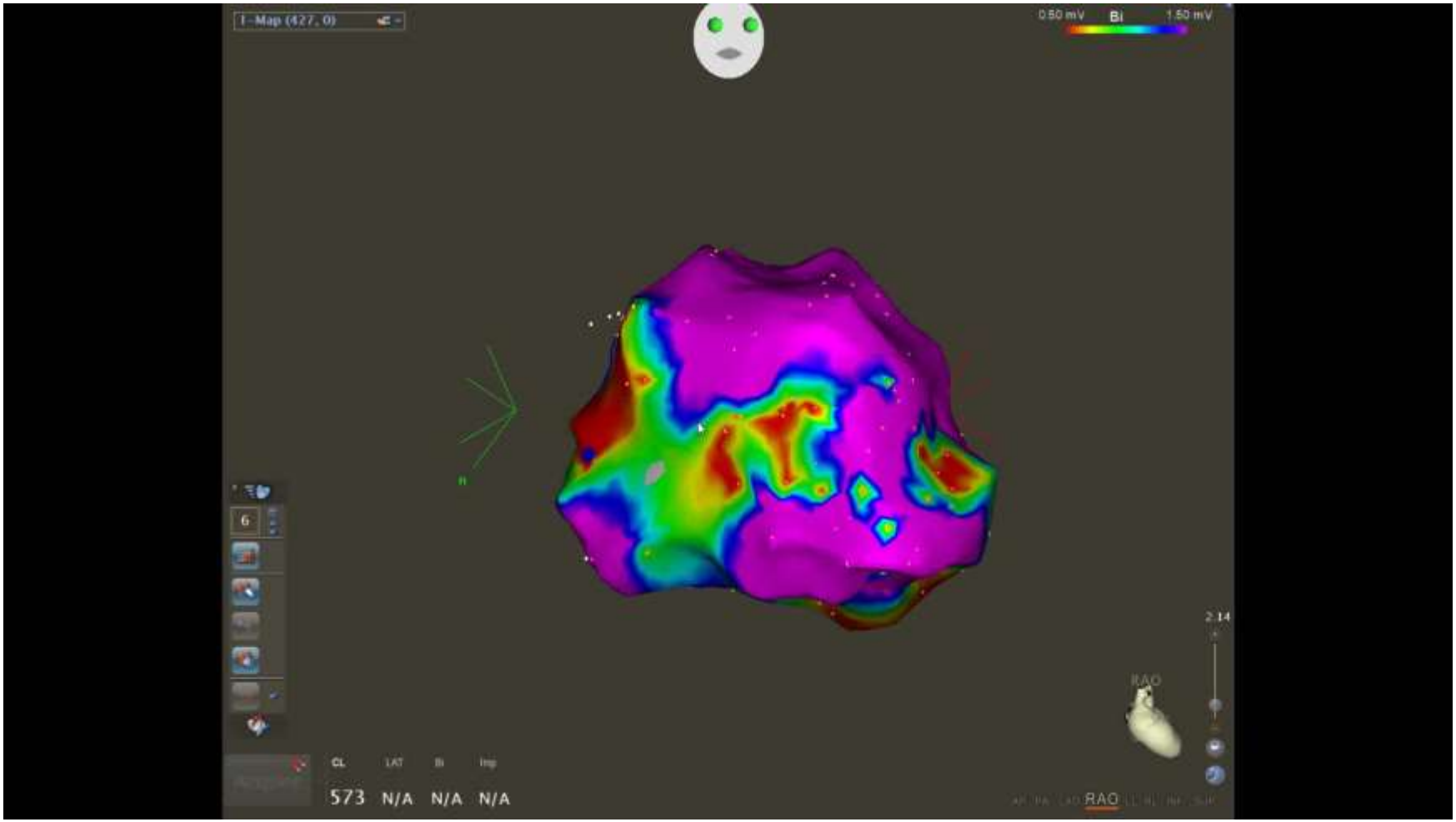
CA can decrease the likelihood of SCD in the following arrhythmia categories:

1. **idiopathic ventricular fibrillation** (VF) that is usually triggered by premature ventricular beats originating in the Purkinje fibres;
2. **VF in subjects with structural heart disease**, especially after myocardial infarction, that is triggered by premature ventricular beats from surviving **Purkinje fibres**;
3. **Brugada syndrome** in which modification of an epicardial substrate in the right ventricular outflow tract might be themost promising strategy;
4. **Recurrent monomorphic ventricular tachycardias** in the setting of structural heart disease;
5. **Ventricular preexcitation** in which CA appears to be a method of choice in high risk patients, regardless of the presence or absence of symptoms.

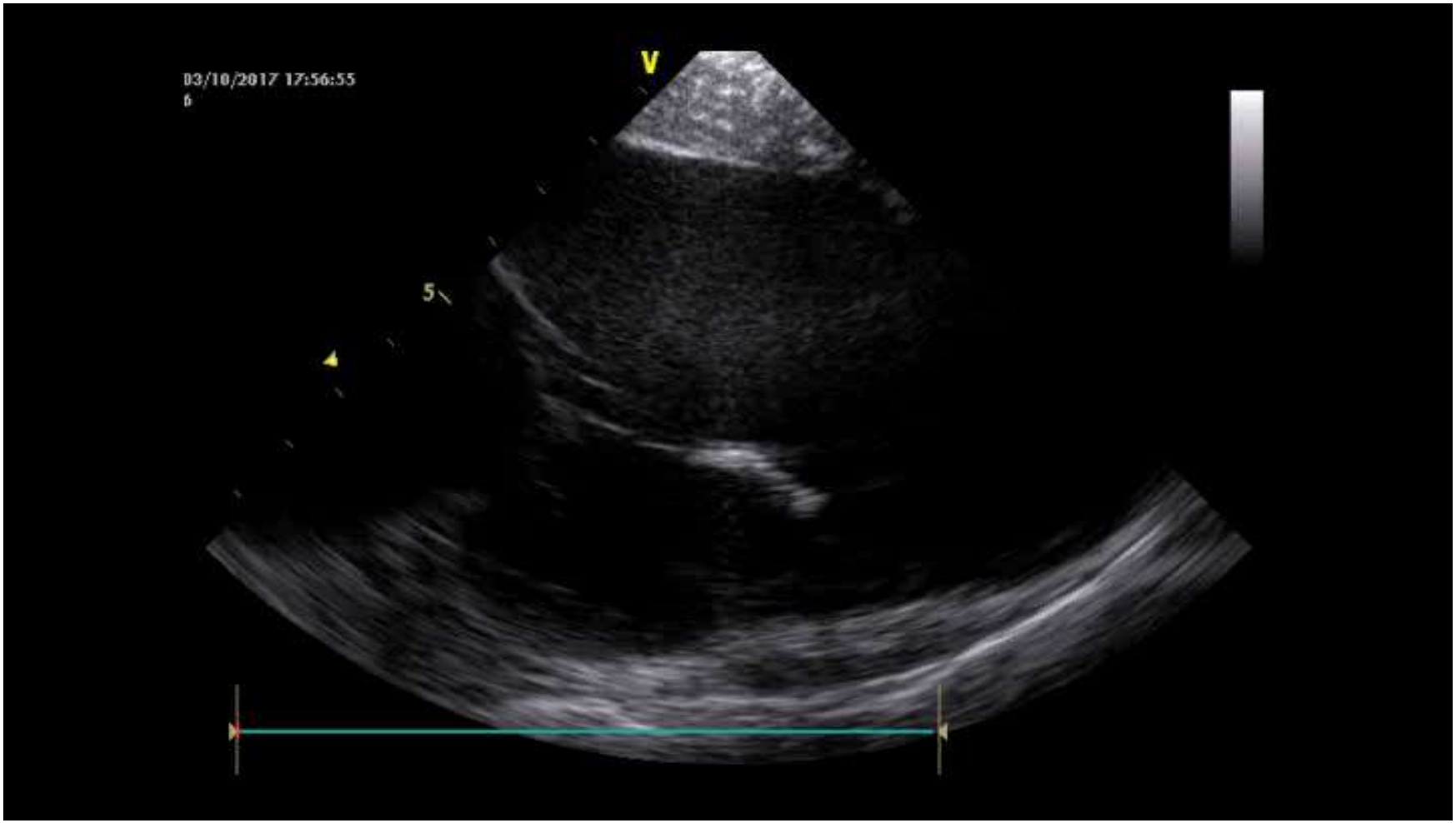
42 y, F, DCM, ICD storm (21 ICD discharges/day)



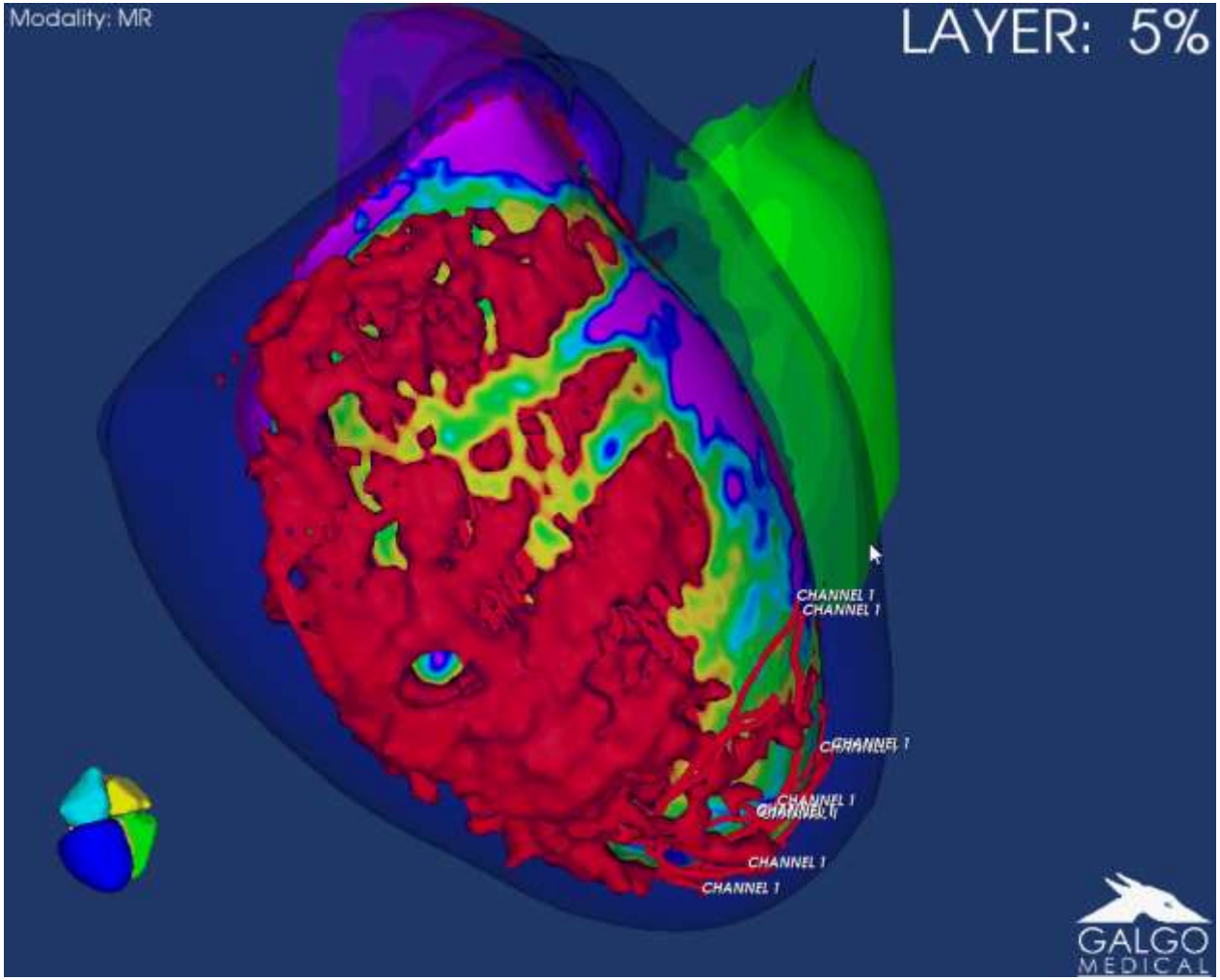
VT ablation in complex CAD substrate



Role of ICE in VT ablation

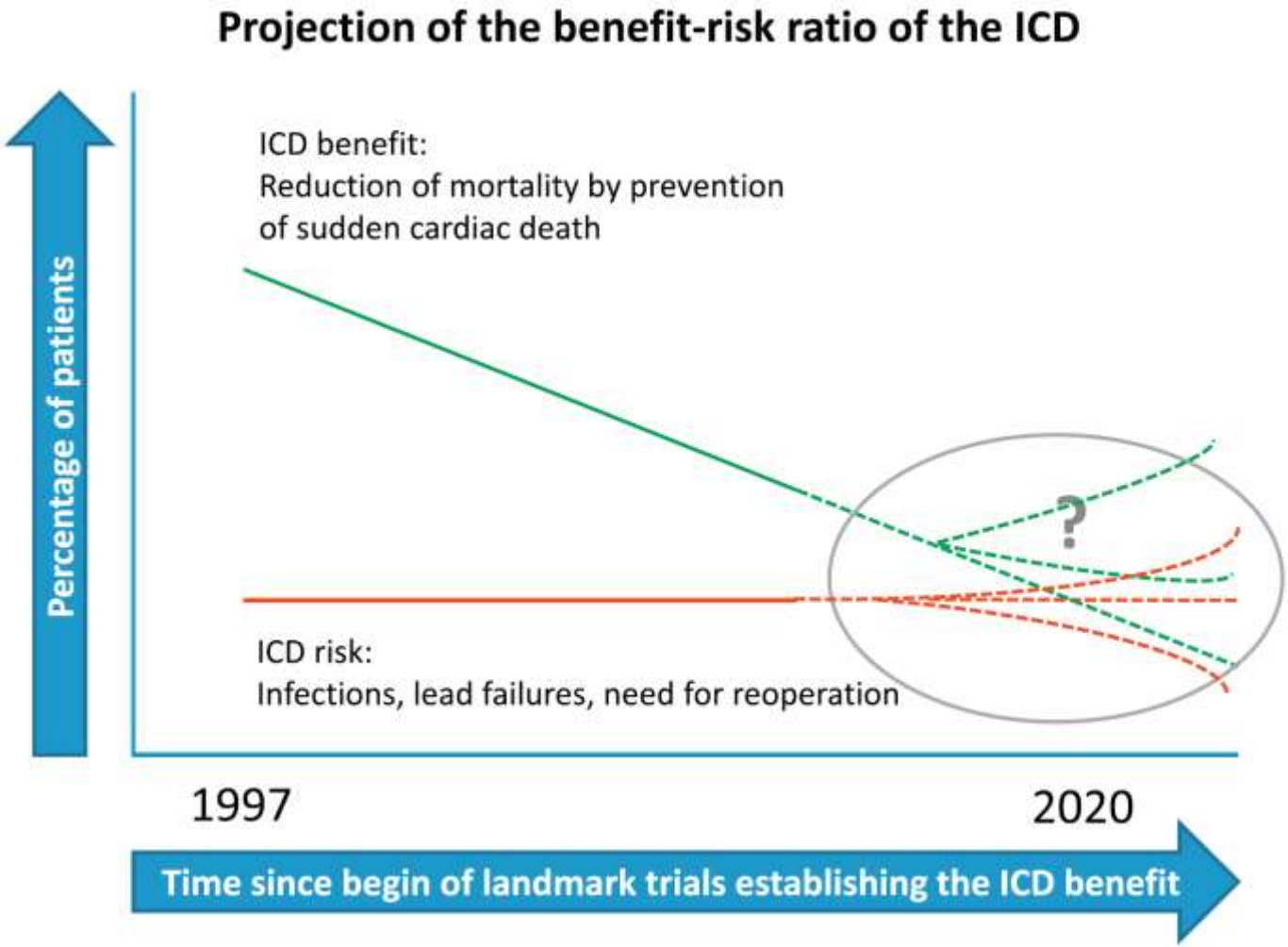


Sudden cardiac death: The role of imaging



http://www.galgomedical.com/products/adas

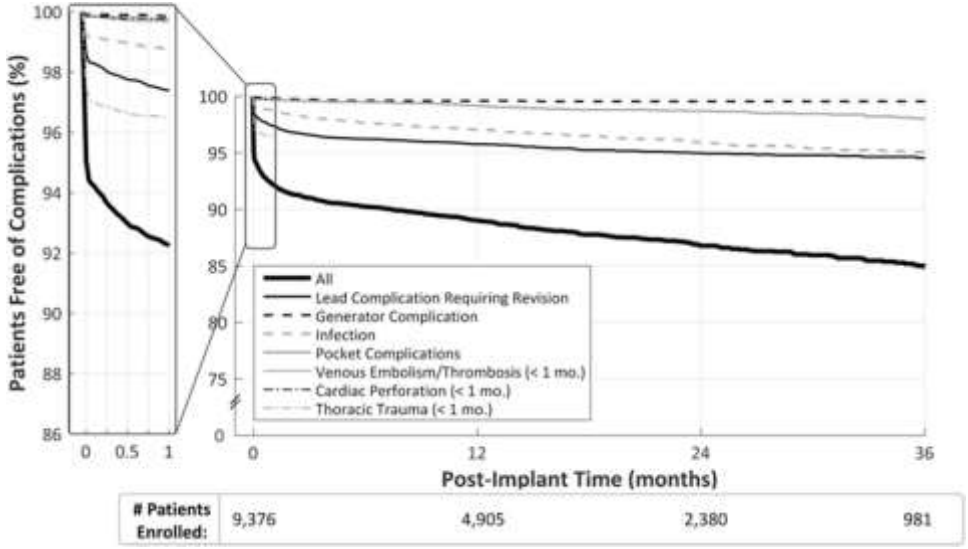
Change in benefit-risk ratio



Dagres N et al. International Journal of Cardiology 237 (2017) 34–37
http://dx.doi.org/10.1016/j.ijcard.2017.03.053

Complications and Health Care Costs Associated With CIEDS Therapy

- Among 72,701 TVP implantations (mean age 75 ± 12 years, 55% men, 13% single chamber) with 1.5 ± 1.1 years of follow-up, acute complications (0 to 1 month) occurred in 7.7% of single- and 9.1% of dual-chamber TVPs and longterm complications (1 to 36 months) in 6.4% and 5.9% of single- and dual-chamber TVPs, respectively.
- The net 3-year event rates were approximately 15% and 16%. The incidence and incremental cost of complications are considerable.
- Most common acute complications include thoracic trauma (3.71%, $70,114), leads requiring revision (3.51%, $9,296), and infection (1.15%, $80,247). Long-term complications are attributed to leads (2.84%), infection (2.42%), and pocket (0.96%).
- Claims data suggest that TVP complications are more common than previously reported, affecting nearly 1 in 6 patients by 3 years and contributing to considerable incremental U.S. health care cost.



Cantillon DJ: JACC: Clinical Electrophysiology, 2017, http://dx.doi.org/10.1016/j.jacep.2017.05.007

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Pohled na náhlou smrt u neischemických kardiomyopatií

DANISH Study

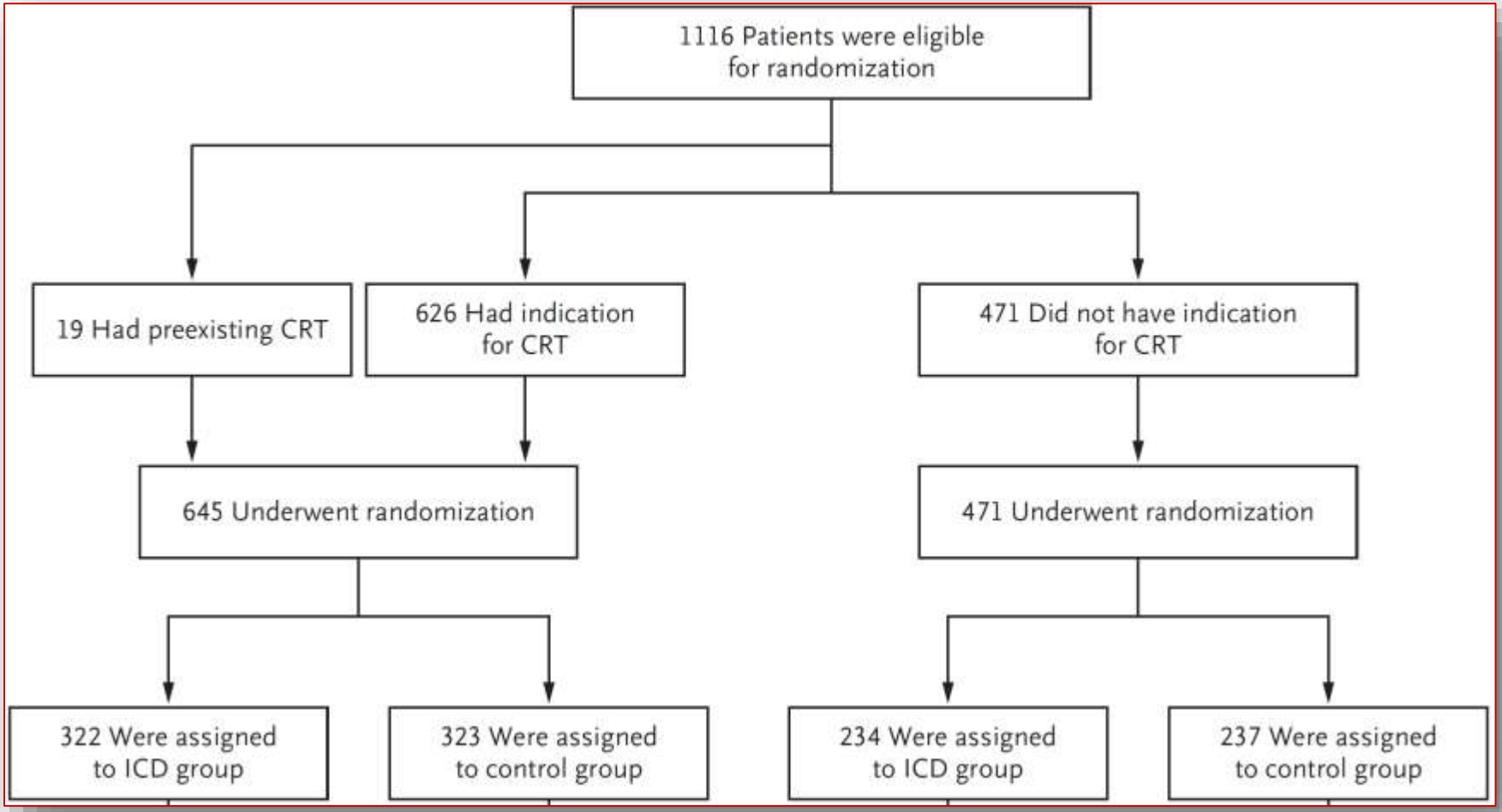
The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 SEPTEMBER 29, 2016 VOL. 375 NO. 13

Defibrillator Implantation in Patients with Nonischemic Systolic Heart Failure

Lars Køber, M.D., D.M.Sc., Jens J. Thune, M.D., Ph.D., Jens C. Nielsen, M.D., D.M.Sc., Jens Haarbo, M.D., D.M.Sc., Lars Videbæk, M.D., Ph.D., Eva Korup, M.D., Ph.D., Gunnar Jensen, M.D., Ph.D., Per Hildebrandt, M.D., D.M.Sc., Flemming H. Steffensen, M.D., Niels E. Bruun, M.D., D.M.Sc., Hans Eiskjær, M.D., D.M.Sc., Axel Brandes, M.D., Anna M. Thøgersen, M.D., Ph.D., Finn Gustafsson, M.D., D.M.Sc., Kenneth Egstrup, M.D., D.M.Sc., Regitze Videbæk, M.D., Christian Hassager, M.D., D.M.Sc., Jesper H. Svendsen, M.D., D.M.Sc., Dan E. Høfsten, M.D., Ph.D., Christian Torp-Pedersen, M.D., D.M.Sc., and Steen Pehrson, M.D., D.M.Sc., for the DANISH Investigators*

Study Design



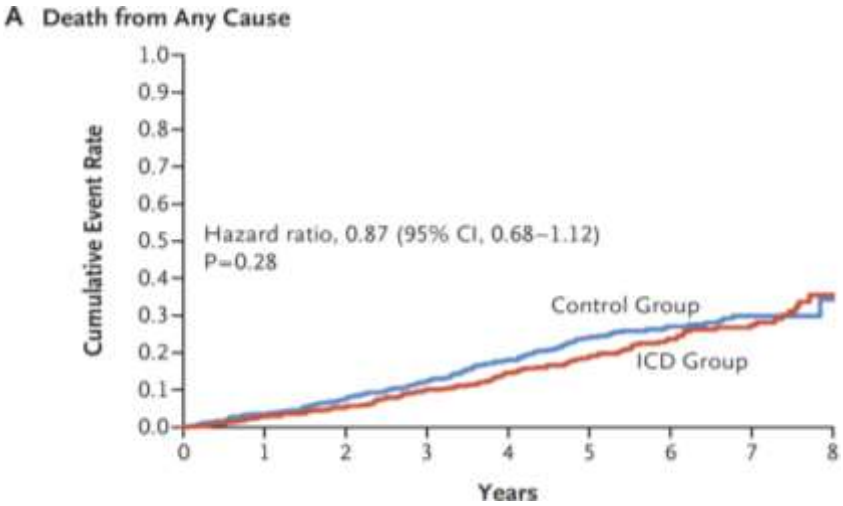
Køber L, Thune JJ, Nielsen JC, et al. Defibrillator implantation in patients with nonischemic systolic heart failure. N Engl J Med 2016; DOI:10.1056/NEJMoa1608029.

ICD x Control Group

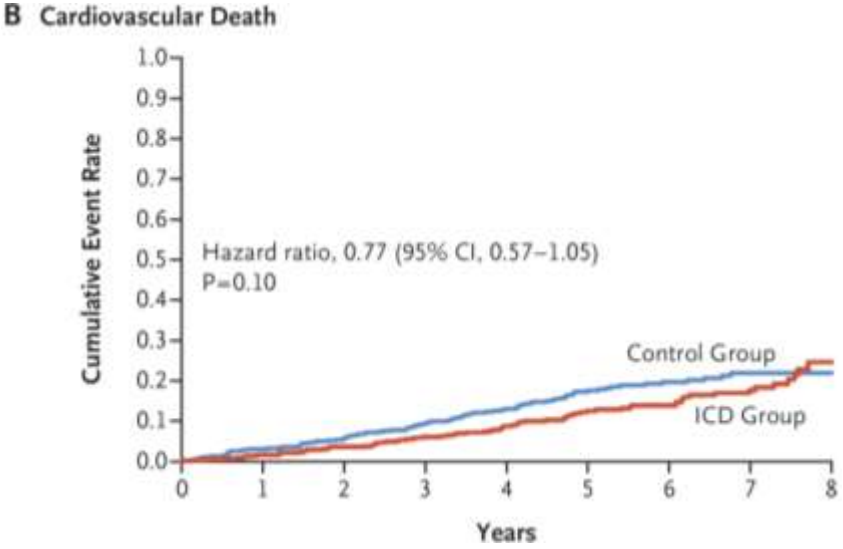
Outcome	ICD Group† (N=556)	Control Group† (N=560)	Hazard Ratio (95% CI)	P Value
	no. of patients/total no. (%)			
Death from any cause	120 (21.6)	131 (23.4)	0.87 (0.68–1.12)	0.28
Cardiovascular death	77 (13.8)	95 (17.0)	0.77 (0.57–1.05)	0.10
Sudden cardiac death	24 (4.3)	46 (8.2)	0.50 (0.31–0.82)	0.005
Other cardiovascular death	53 (9.5)	49 (8.8)	1.03 (0.70–1.52)	0.89
Noncardiovascular death	43 (7.7)	36 (6.4)	1.12 (0.72–1.76)	0.60
Resuscitated cardiac arrest or sustained VT	26 (4.7)	25 (4.5)	1.03 (0.59–1.79)	0.91
Cardiac arrest	11 (2.0)	14 (2.5)	0.79 (0.36–1.75)	0.56
Sustained VT requiring medical intervention or electrical conversion	16 (2.9)	14 (2.5)	1.12 (0.54–2.30)	0.76
			Odds Ratio (95% CI)	
Device infection	27 (4.9)	20 (3.6)	1.38 (0.73–2.63)	0.29
CRT‡	15/322 (4.7)	18/323 (5.6)	0.83 (0.38–1.78)	0.60
No CRT‡	12/234 (5.1)	2/237 (0.8)	6.35 (1.38–58.87)	0.006
Serious device infection§	15 (2.7)	13 (2.3)	1.17 (0.51–2.69)	0.69
CRT‡	9/322 (2.8)	11/323 (3.4)	0.82 (0.29–2.20)	0.65
No CRT‡	6/234 (2.6)	2/237 (0.8)	3.09 (0.54–31.56)	0.24
Bleeding requiring intervention	1 (0.2)	0	—	—
Pneumothorax	11 (2.0)	6 (1.1)	1.86 (0.68–5.08)	0.22
Inappropriate shocks	33 (5.9)	0	—	—

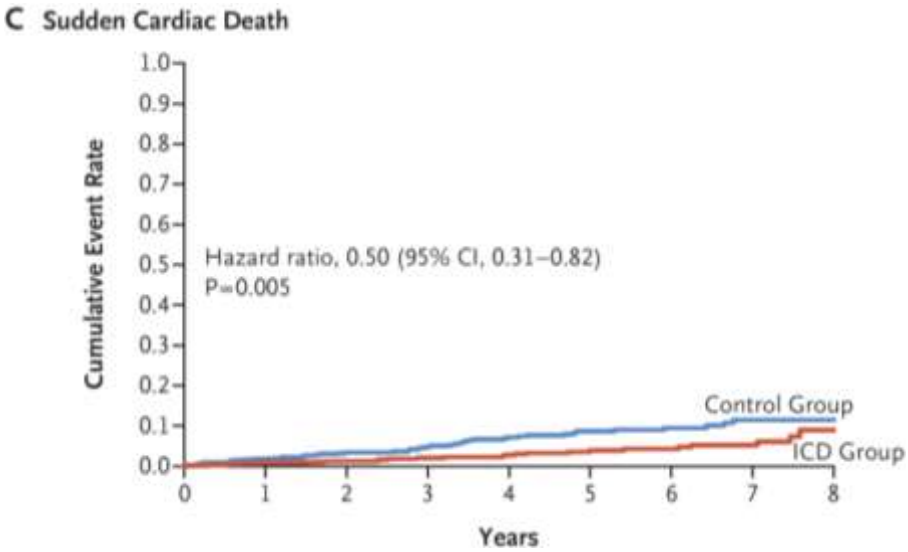
Køber L, Thune JJ, Nielsen JC, et al. Defibrillator implantation in patients with nonischemic systolic heart failure. N Engl J Med 2016; DOI:10.1056/NEJMoa1608029.

DANISH Study Results



REVISIt SCD Study

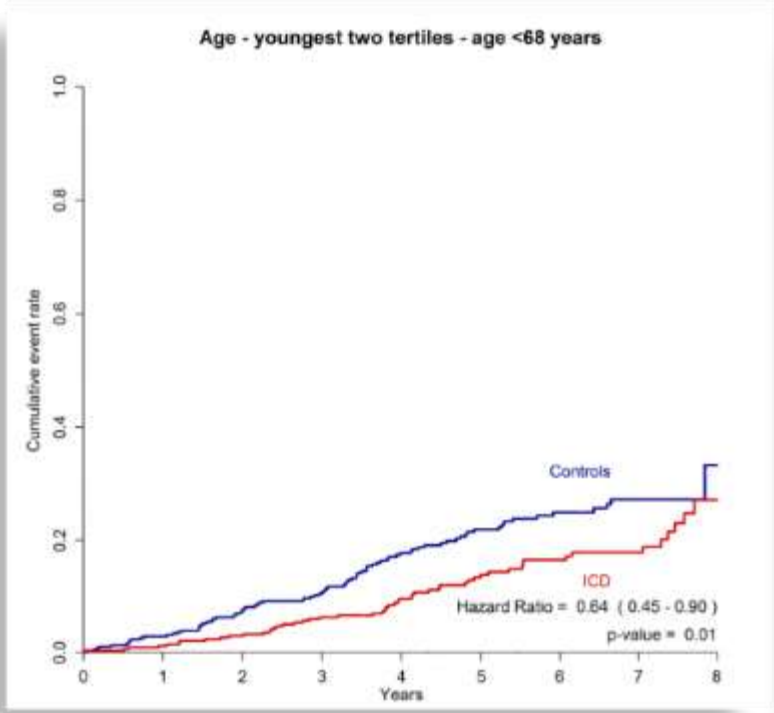


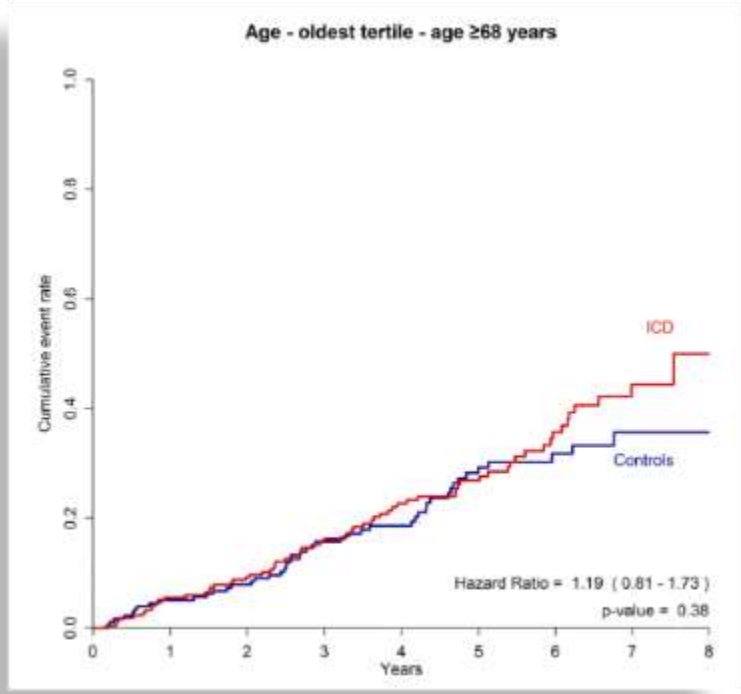


Køber L, Thune JJ, Nielsen JC, et al. Defibrillator implantation in patients with nonischemic systolic heart failure. N Engl J Med 2016; DOI:10.1056/NEJMoa1608029.

Should we implant ICD to older pts with NICM ???

Subgroup	ICD Group	Control Group	Hazard Ratio (95% CI)	P Value	P Value for Interaction
	no. of events/total no.				
Age					0.009
<59 yr	17/167	34/181	0.51 (0.29–0.92)	0.02	
≥59 to <68 yr	36/173	50/202	0.75 (0.48–1.16)	0.19	
≥68 yr	67/216	47/177	1.19 (0.81–1.73)	0.38	





Køber L, Thune JJ, Nielsen JC, et al. Defibrillator implantation in patients with nonischemic systolic heart failure. N Engl J Med 2016; DOI:10.1056/NEJMoa1608029.

Contra :

EDITORIAL

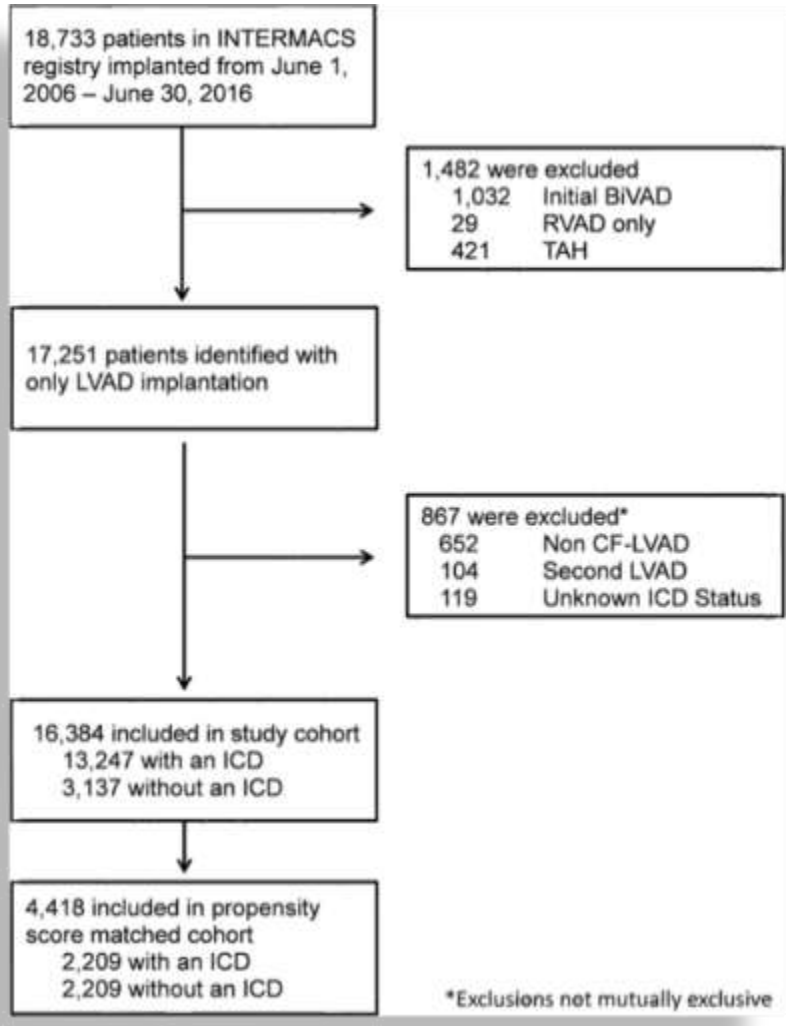
Does Anyone Really Believe the Results of the DANISH Trial?—Implanting an ICD in Nonischemic Cardiomyopathy Patients

J. ROD GIMBEL, M.D.,* and JUDITH MACKALL, M.D.†

From the *Columbia-St. Mary's Hospital, Cardiology, Milwaukee, Wisconsin; and †Division of Cardiology University Hospitals Cleveland Medical Center, Case Western Reserve University, Cleveland, Ohio

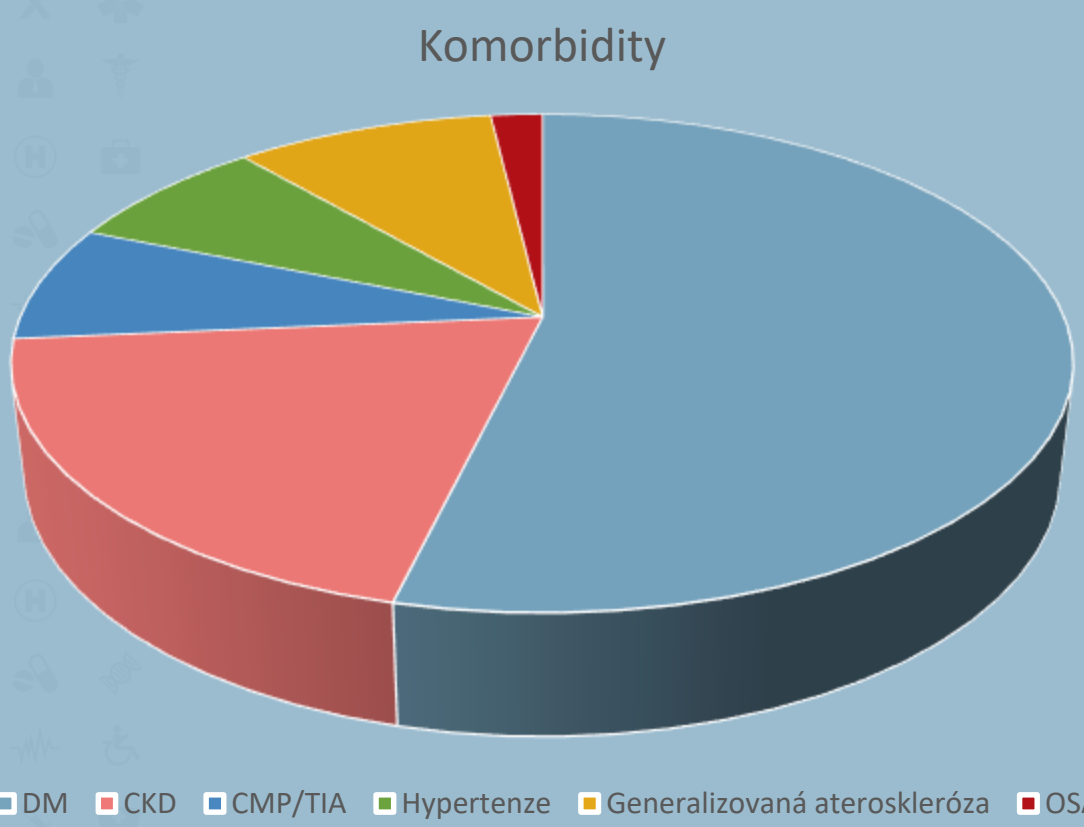
Význam ICD u pacientů s LVAD: Analýza dat Registru INTERMACS

Conclusions: Among patients with a continuous flow LVAD, the presence of an ICD was not associated with reduced mortality.

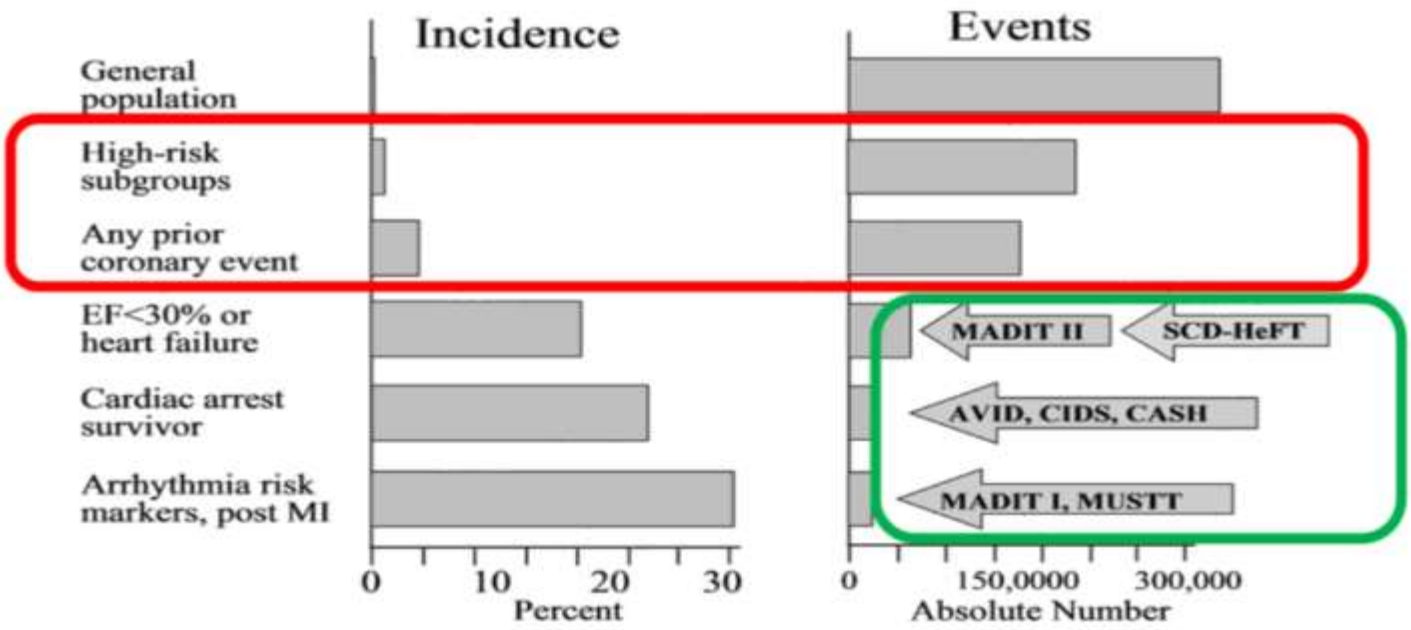


Clerin KJ: JACC: Heart Failure Dec 2017, 5 (12) 916-926; DOI: 10.1016/j.jchf.2017.08.014

Přidružená onemocnění a SCD

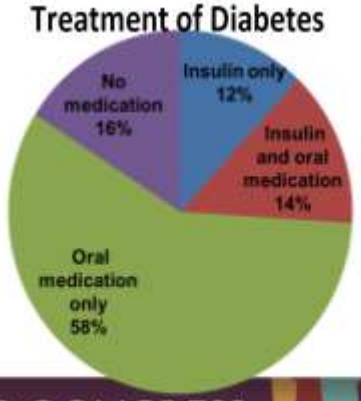


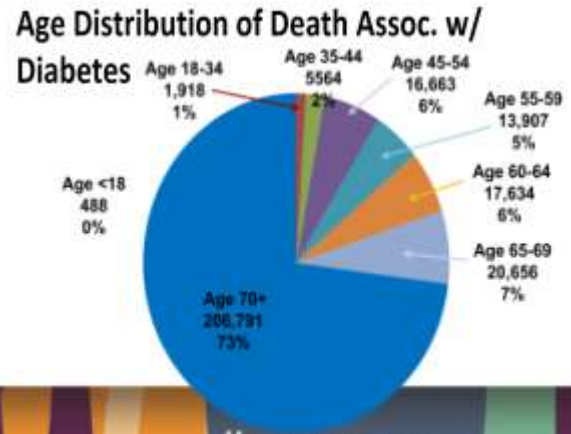
SCD in „midrange LV EF“



Diabetes a SCD

- DM affects 29 million people in the US and claims >250,000 lives/year[1,2]
- **Adults with diabetes have heart disease death rates ~2–4 times higher[2]**
- 70% of diabetes patients die from a cardiovascular cause[1]
- About 50% of the CV death in diabetes is SCD[1]





1. ESC Guidelines on Diabetes 2003
2. professional.diabetes.org/facts. 2013.
3. American Diabetes Association. Diabetes Care. 2008;31:596-615
4. Monitoring Chronic Disease Care and Outcomes among Elderly Medicare Beneficiaries with Chronic Disease, Medicare Research and Demonstration (MRAD) Contract HHSM-500-2005-000271

MADIT Studies

MADIT FAMILY OF TRIALS

- MADIT: 1996 NEJM (n=196; ↓mortality)
- MADIT-II: 2002 NEJM (n=1232; ↓mortality)
- MADIT-II LTFU: Circ 2010
- MADIT-CRT: 2009 NEJM (n=1820; ↓HF)
- MADIT-RIT: 2012 NEJM (n=1500; ↓inapp Rx & mortality
- MADIT-Diabetes: starting 2016 (n=1800; S-ICD)

PIs: Arthur J. Moss MD &
Valentina Kutyifa MD, PhD

The MADIT trials have been sponsored by Boston Scientific, but were independently conducted by the MADIT Executive Committee and the Heart Research Follow-up Program of the University of Rochester Medical Center.

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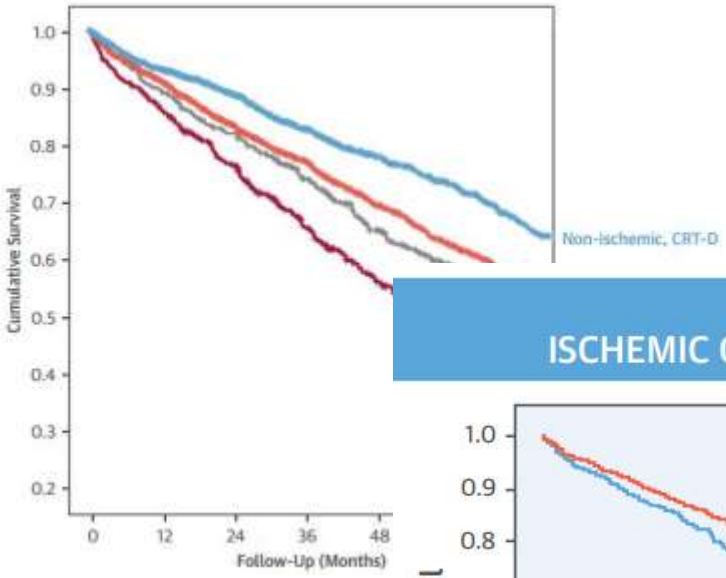
Nezávislé výzkumné aktivity ESC / EHRA

REVISit SCD Study

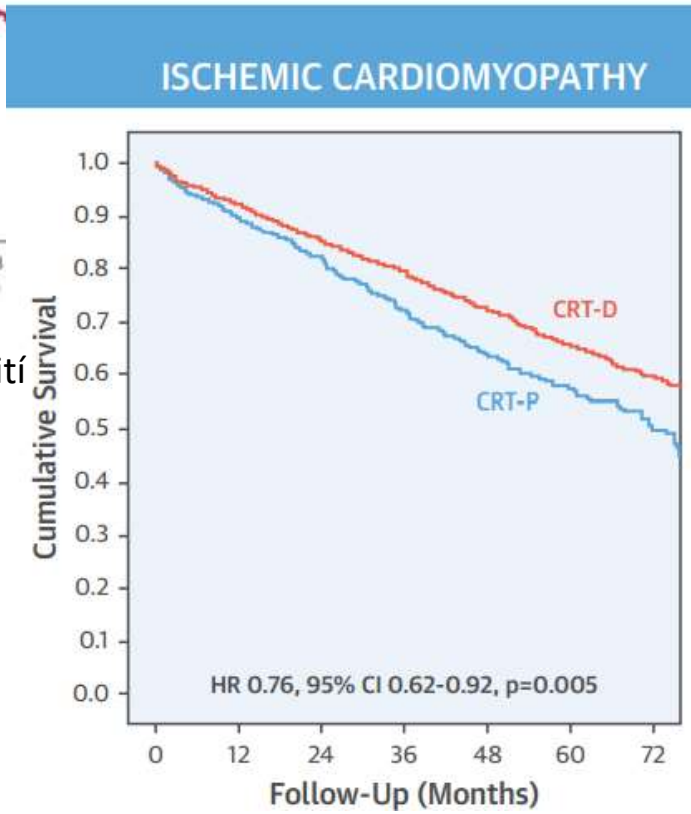
- Ultimate goal is to re-evaluate the optimal treatment strategies for prevention of sudden cardiac death (SCD) in patients with ischemic cardiomyopathy and reduced left ventricular ejection fraction and specifically to re-evaluate the role of implantable cardioverter-defibrillator (ICD).
- Current guidelines for SCD prevention are based on research from 15-20 years ago. While these recommendations were a tremendous advancement for the field, major recent advances in pharmaceuticals and medical devices require that these guidelines are updated to reflect the current state of the art.
- To achieve this, we will conduct a multinational randomised clinical trial and perform a cost-effectiveness study.

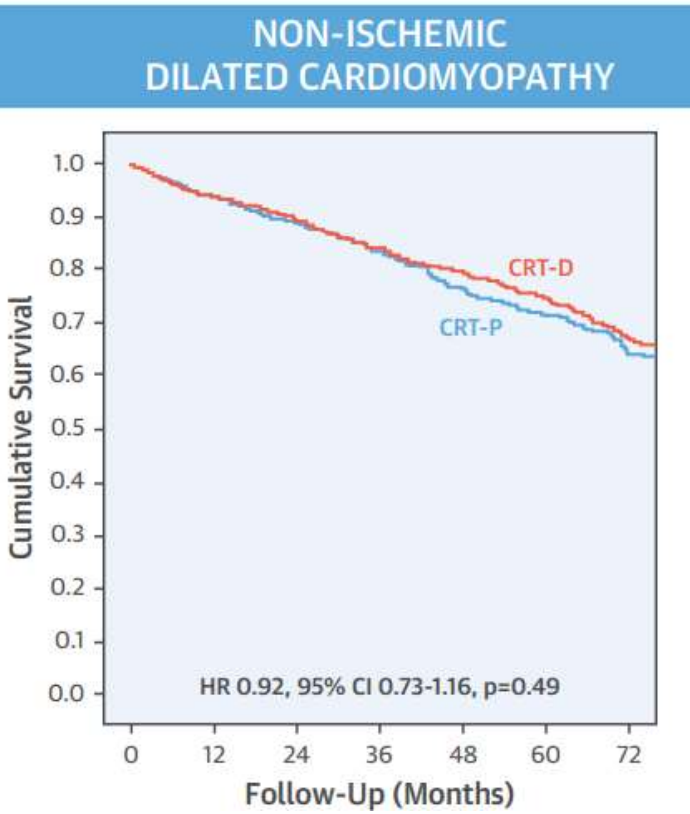
CRT-P x CRT-D Results: Substrate dependent



Neadjustované přežití

Adjustované přežití:

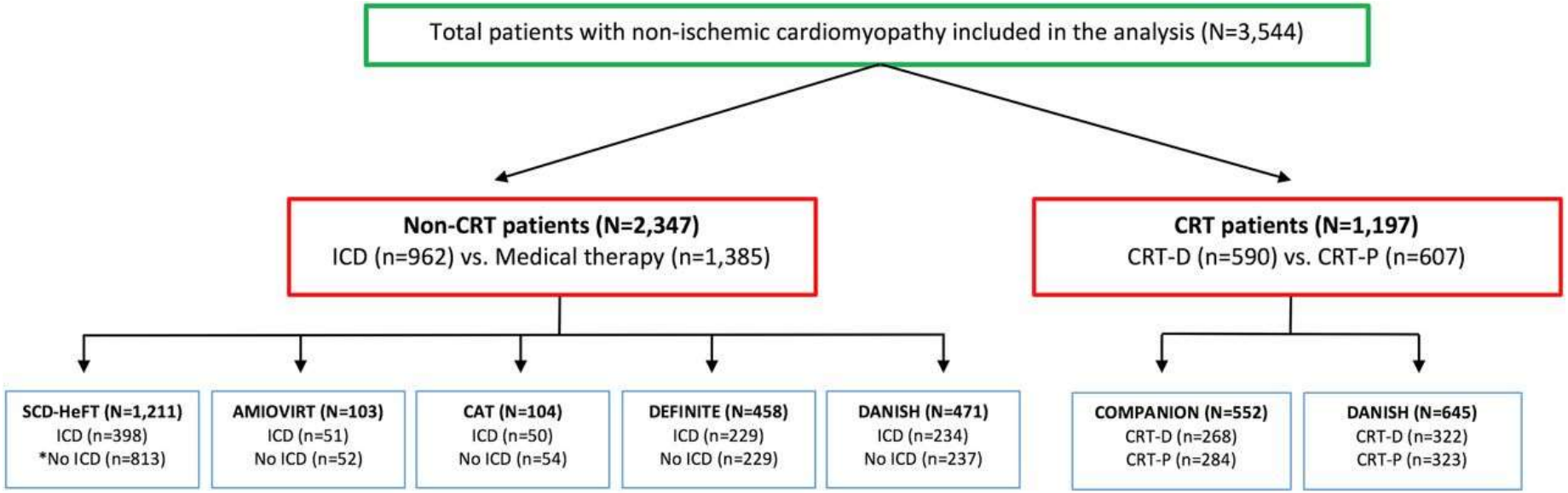




Barra S et al. J Am Coll Cardiol. 2017 Apr 4;69(13):1669-1678.

Efficacy of Implantable Cardioverter-Defibrillator Therapy in Patients With Nonischemic Cardiomyopathy

A Systematic Review and Meta-Analysis of Randomized Controlled Trials



Mahesh Anantha Narayanan: ***JACC: Clinical Electrophysiology*** *Volume 3, Issue 9, September 2017 DOI: 10.1016/j.jacep.2017.02.006*

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I. INTERNÍ KLINIKA KARDIOLOGICKÁ
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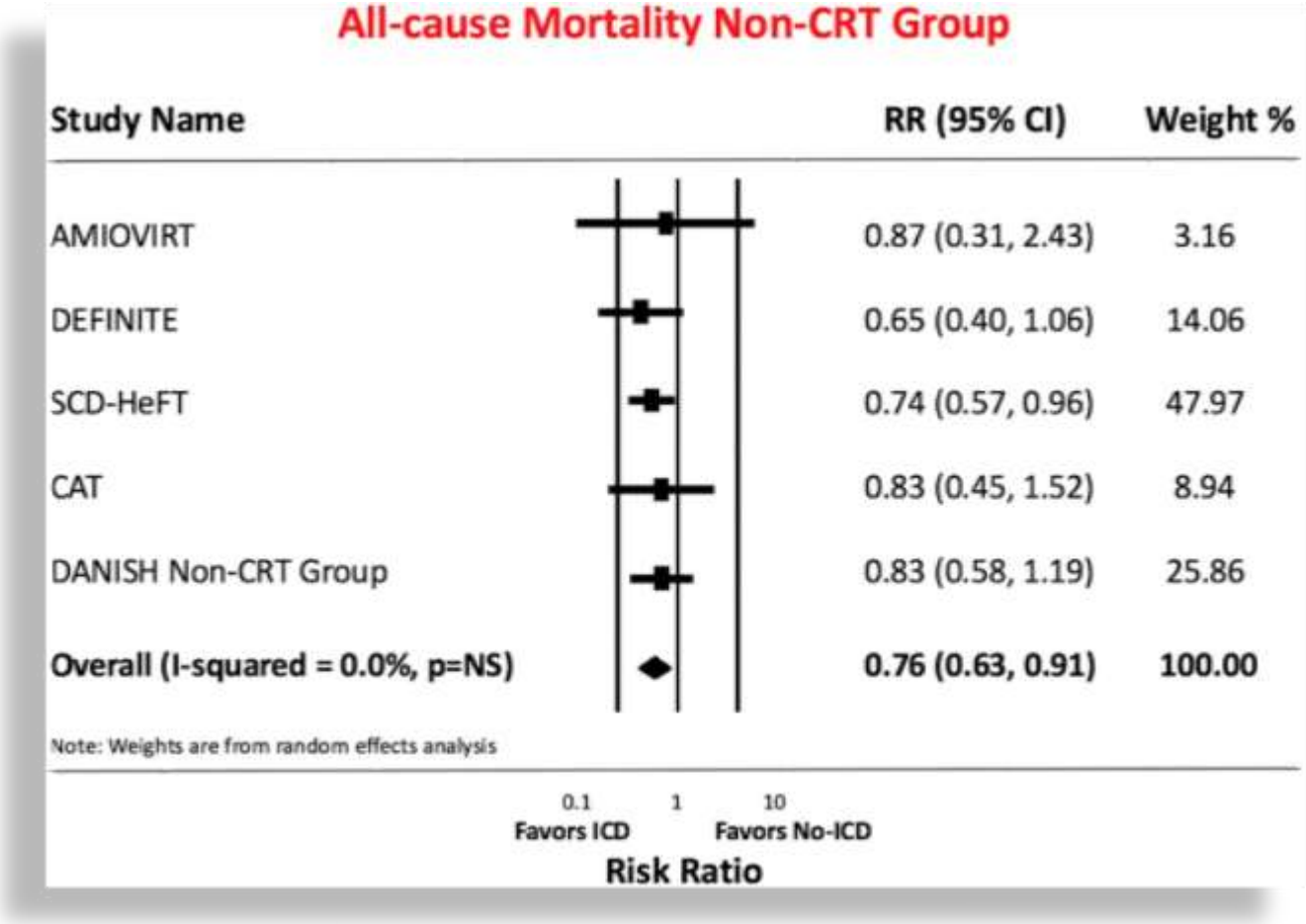
All-Cause Mortality Non-CRT



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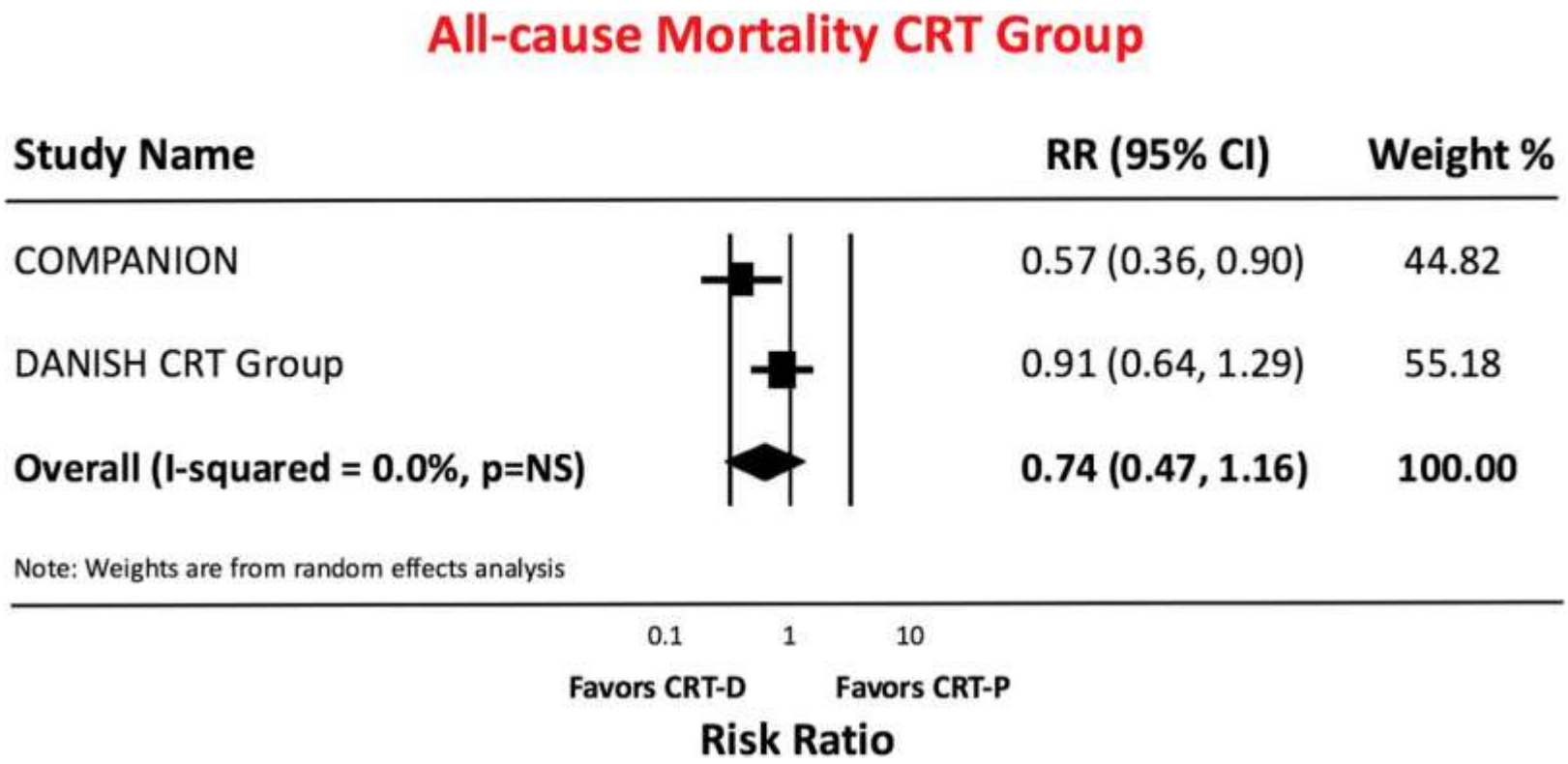
All-Cause Mortality CRT



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Visegrad CRT Study

- Hypothesis: In pts with NICM and CRT class I indication without doc. NSVT or fr. PVCs CRT-P is non inferior to CRT-D
- SR and AF pts with early AVN ablation (100 % CRT)
- Randonization 1:1: CRTP-P x CRT-D
- Daily remote monitoring
- Primary endpoint: Rehospitalization for HF, QoL, complications, morbidity and mortality
- 3 year FU
- Contact: milos.taborsky@fnol.cz

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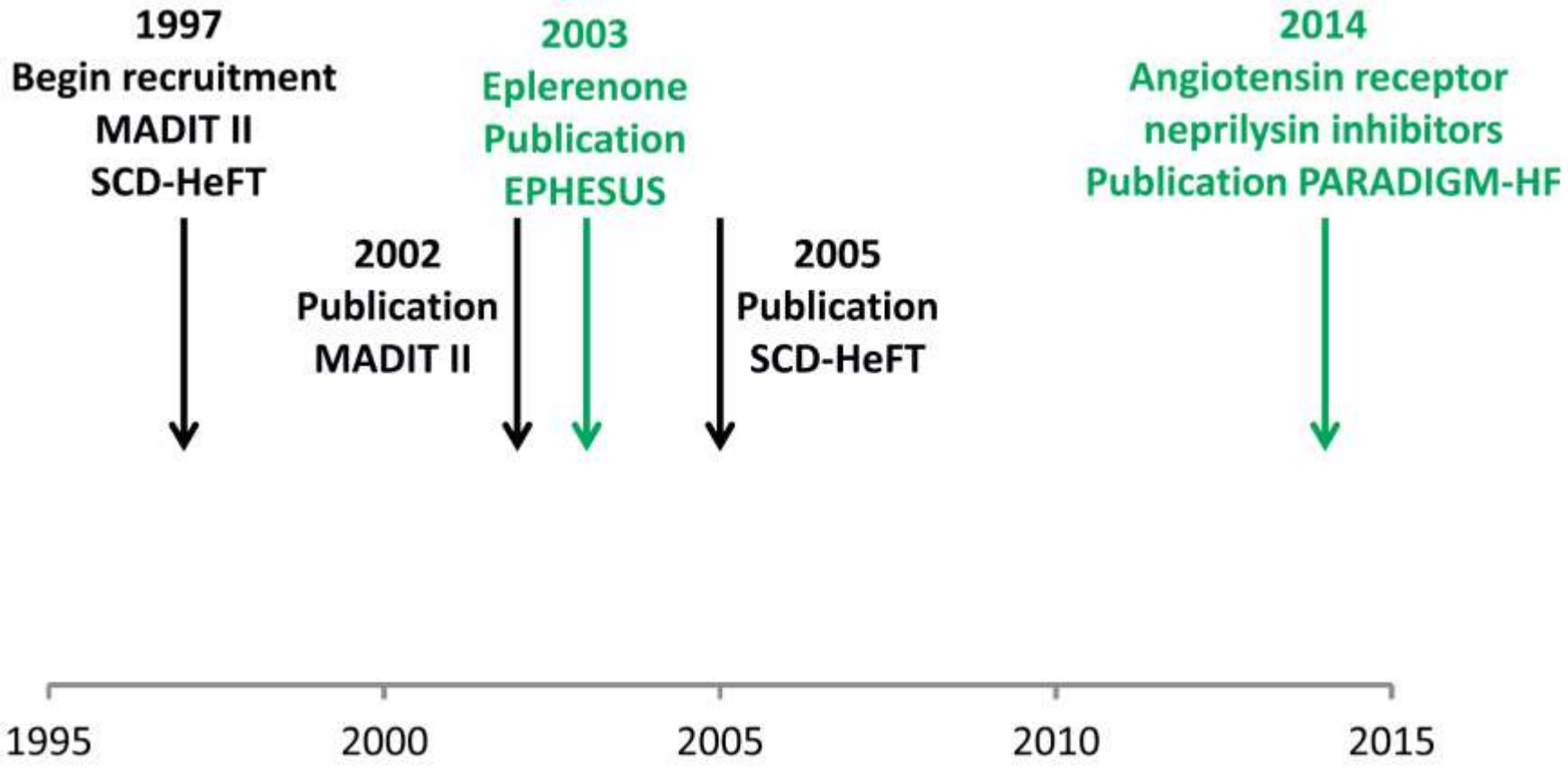
Zásadní změna: Vliv moderní farmakoterapie SS na SCD

Improvements in HF medical therapy

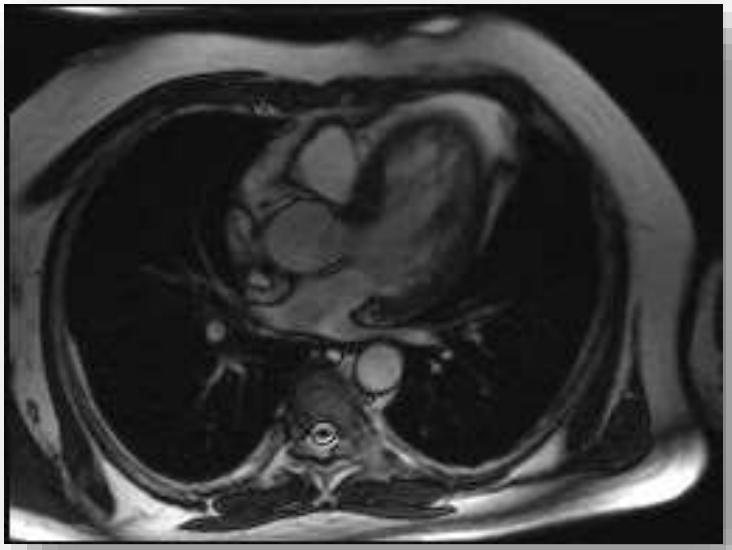


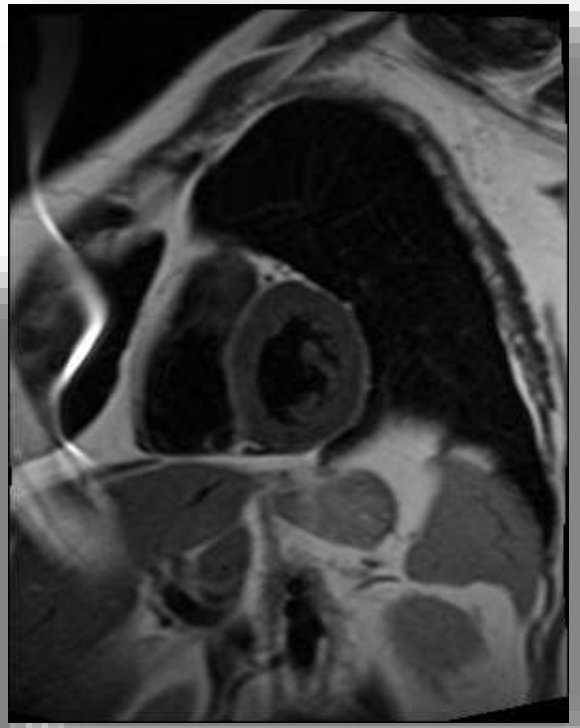
Dagres N et al. International Journal of Cardiology 237 (2017) 34–37
http://dx.doi.org/10.1016/j.ijcard.2017.03.053

Kazuistika

- 40 letý muž – referován v 5/2017 pro progresi dušnosti – NYHA III, otoky DK, palpitace, NTproBNP 12453
- Dg. neischemická KMP, difuzní porucha kinetiky , hypertrofie LK, EF LK 0,30, SR, QRS 108 ms
- 7 D EKG Holter: bez dokumentace KT/nsKT ...
- Ambulantní kardioložka pokračovala v doporučené standardní léčbě SS
- Intolerance spironolactonu → eplerenon
- Od 9/2017 zavedena léčba sacubitril valsartanem s postupnou uptitrací k cílové dávce
- 11/2017 – MR – LA + kontrolní echokardiografie

Aktuální nález: MRI-LA





MR-LA: 14.11.2017

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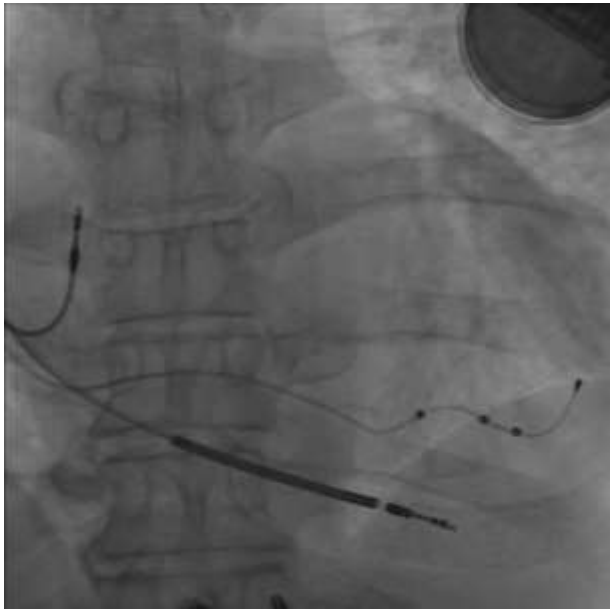
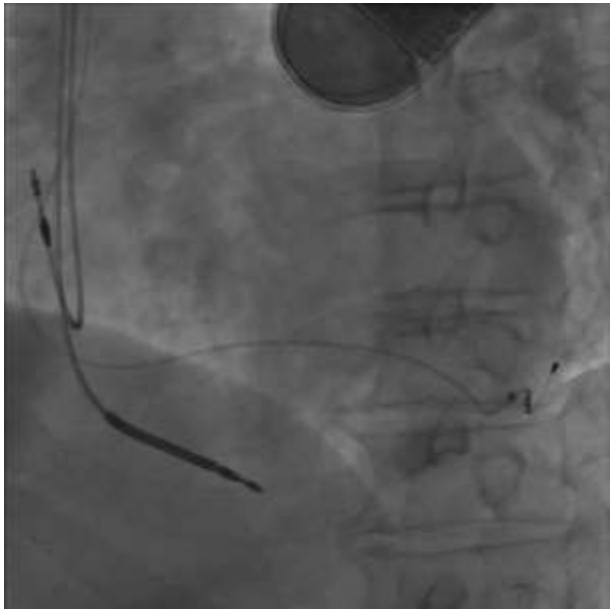
Co by měl znát akutní kardiolog z technických aspektů CRT ?

Co byste měli vědět o CRT?





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Monitoring pacientů s riziky SCD

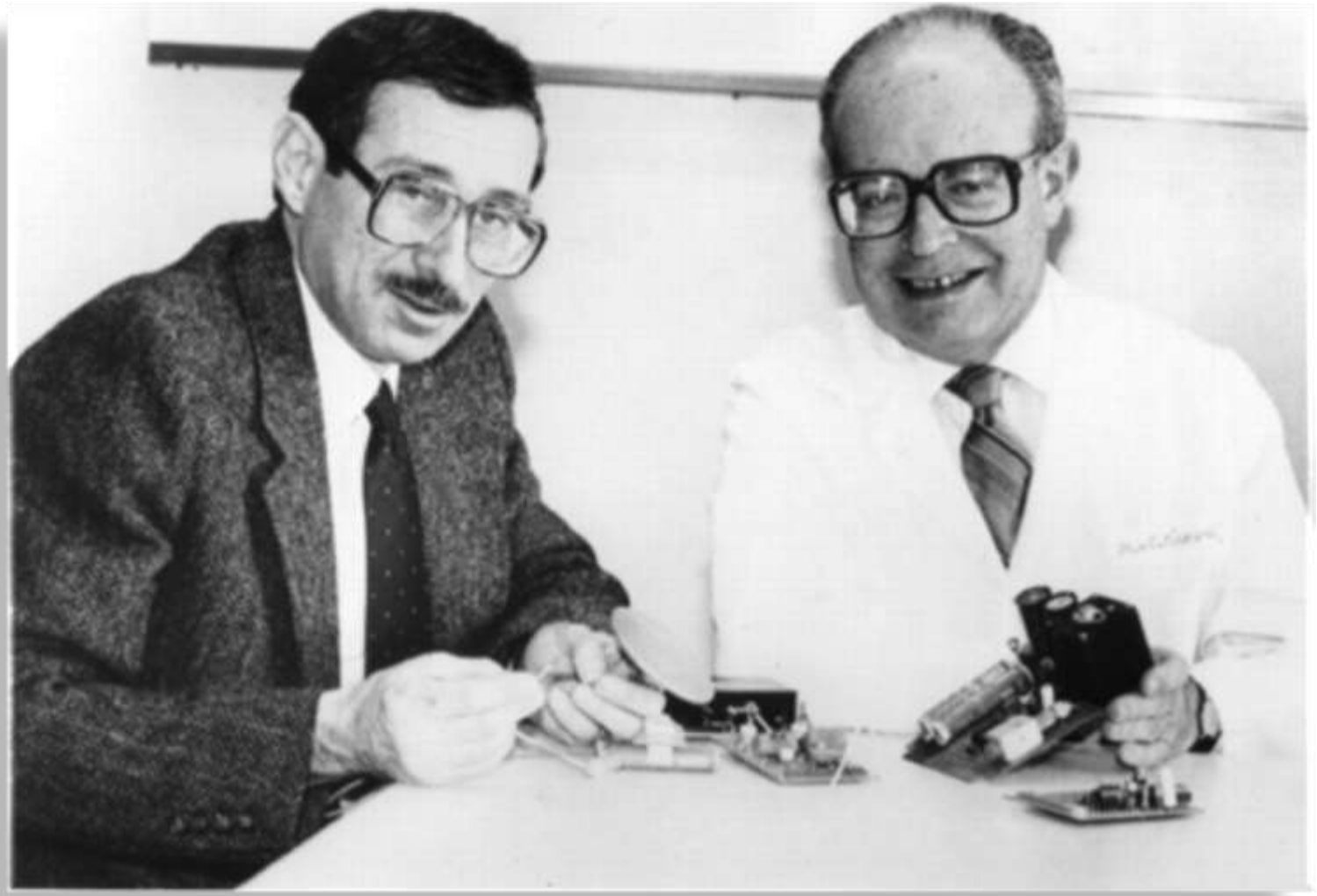
Apple Heart Study: Od FS k VES a KT

https://www.apple.com/watch/apple-heart-study/

Take home message

1. Bude nutná reevaluace PP indikací ICD u neischemických a pravděpodobně i u ischemických KMP
2. EF LK jako jediný marker SCD má v současné době nízkou prediktivní hodnotu
3. Důležité je kompletní posouzení substrátu potencionální arytmie a komorbidit pacienta
4. MR – jedna ze základních vyšetřovacích metod v arytmologii i akutní kardiologii
5. Příští desetiletí = období zásadní změny v pohledu na SCD u SS
6. Úloha ČKS: Organizace intervenční léčby komorových arytmií u akutních pacientů i v dlouhodobém horizontu
7. Moderní telemonitoring fragilních pacientů – e-Health principy

ICD: Milestone in SCD Prevention



First ICD implant worldwide: J.H. Hospital, Baltimore, 1980

The roads of God and SCD are complicated ...

Olomouc, Svatý kopeček