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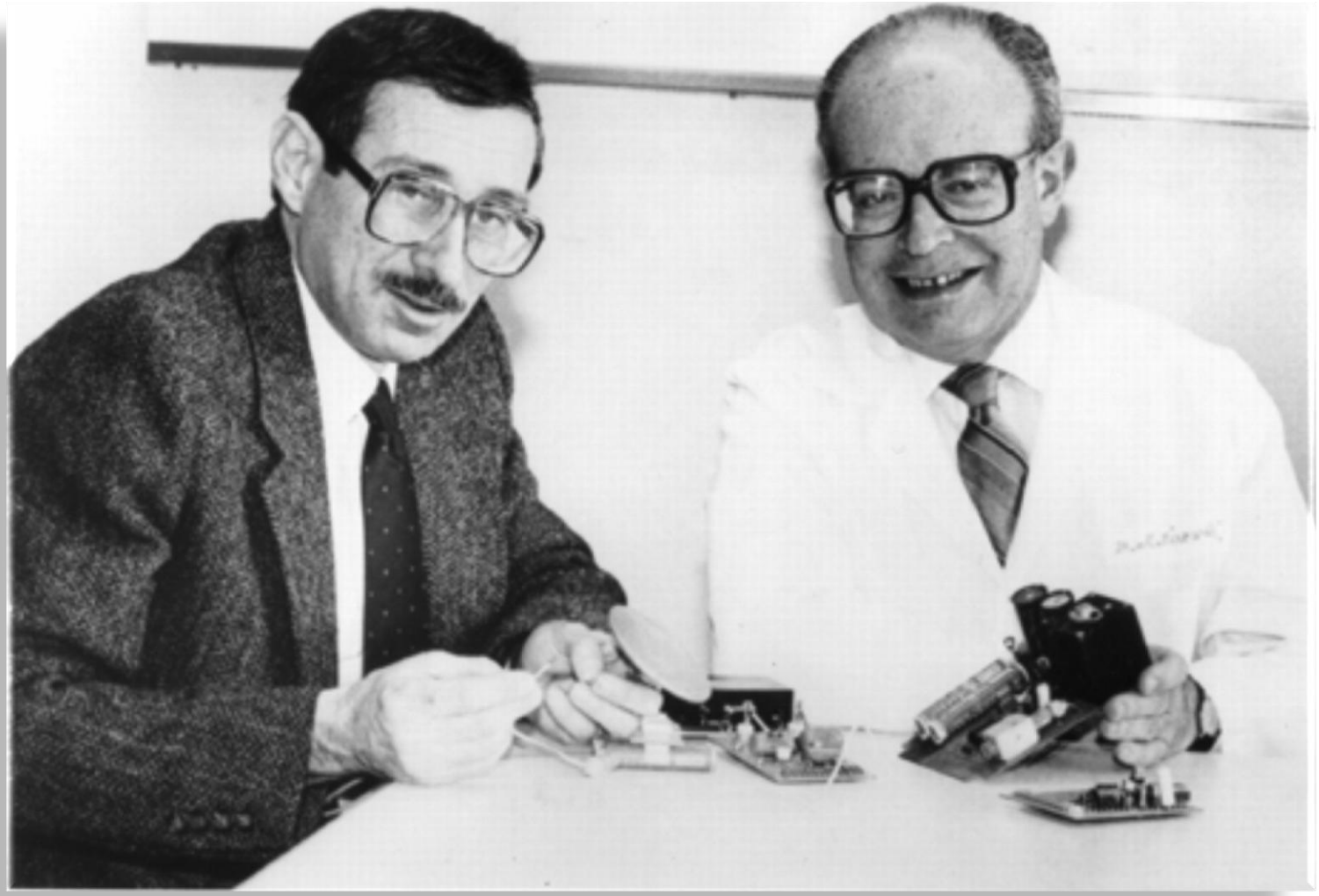
# Dysfunkce LK: ICD (skoro) vždy ano...

*Miloš Táborský*

*Brno*

*8.5.2017*

# ICD: Milník v prevenci NSS



*První implantace: J.H.Hospital, Baltimore, 1980*

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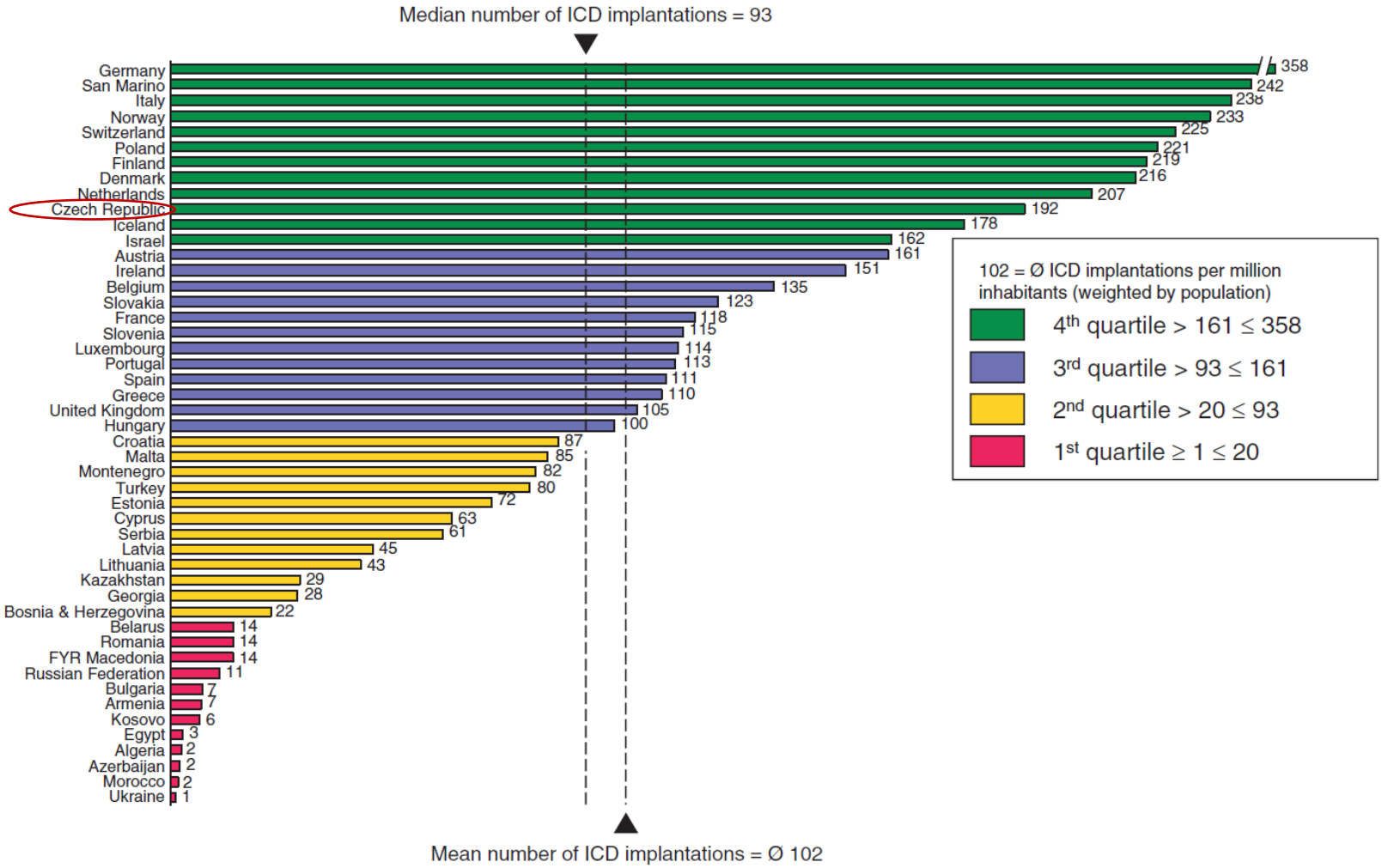
# I. Současné postavení české arytmologie v evropském kontextu

# Pozice ČR v dostupnosti ICD: 2015




*M.J. Pekka Raatikainen: Europace (2016) 18, iii1–iii79, doi:10.1093/europace/euw244*

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I. INTERNÍ KLINIKA KARDIOLOGICKÁ
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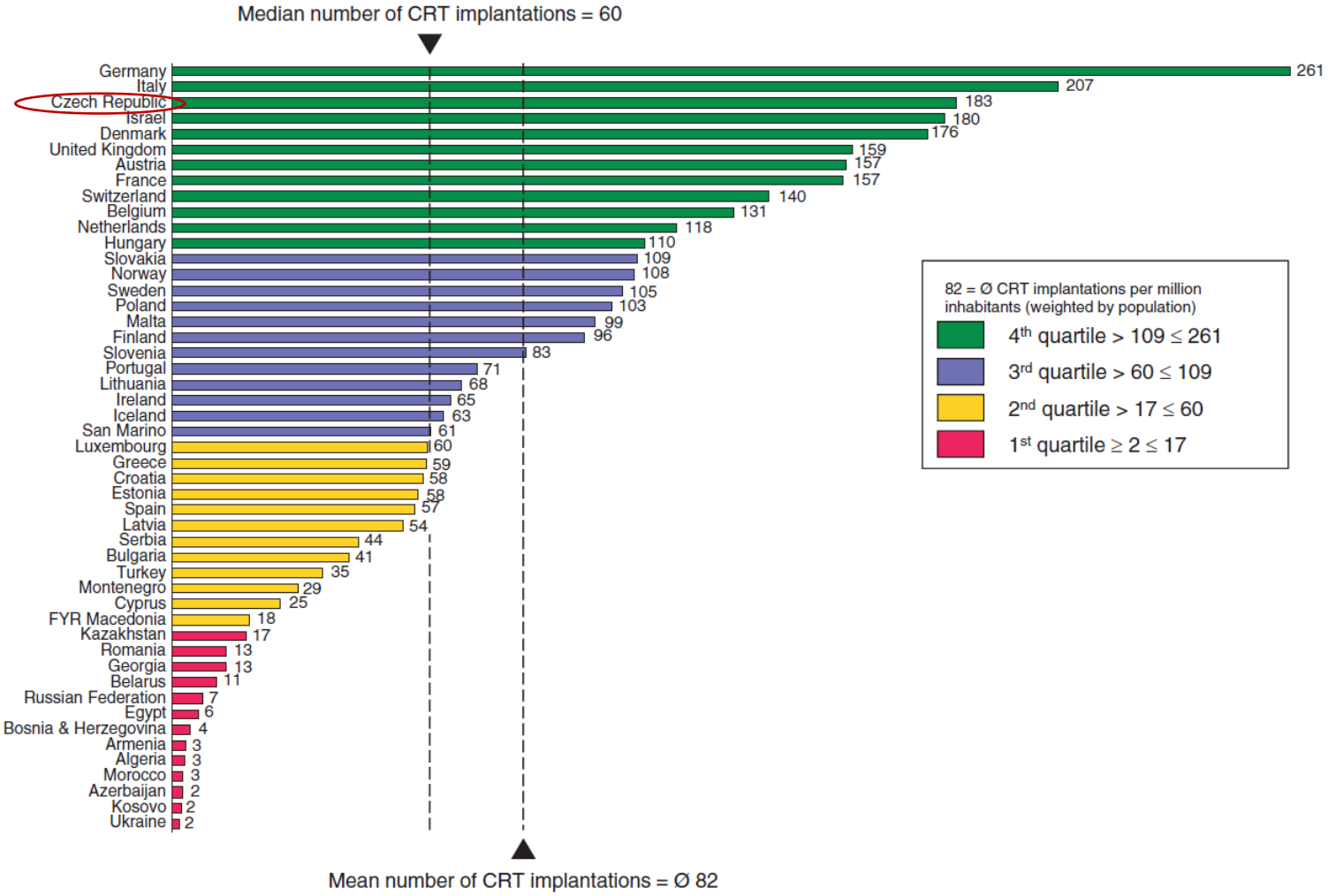
# Resynchronizační terapie: ČR leader problematiky




*M.J. Pekka Raatikainen: Europace (2016) 18, iii1–iii79, doi:10.1093/europace/euw244*

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# II: Sekundárně preventivní indikace ICD

# ICD: Sekundární prevence

| Recommendations | Class[a] | Level[b] | Ref.[c] |
|---|---|---|---|
| ICD implantation is recommended in patients with documented VF or haemodynamically not tolerated VT in the absence of reversible causes or within 48 h after myocardial infarction who are receiving chronic optimal medical therapy and have a reasonable expectation of survival with a good functional status >1 year. | I | A | 151–154 |
| ICD implantation should be considered in patients with recurrent sustained VT (not within 48 h after myocardial infarction) who are receiving chronic optimal medical therapy, have a normal LVEF and have a reasonable expectation of survival with good functional status for >1 year. | IIa | C | This panel of experts |
| In patients with VF/VT and an indication for ICD, amiodarone may be considered when an ICD is not available, contraindicated for concurrent medical reasons or refused by the patient. | IIb | C | 155, 156 |

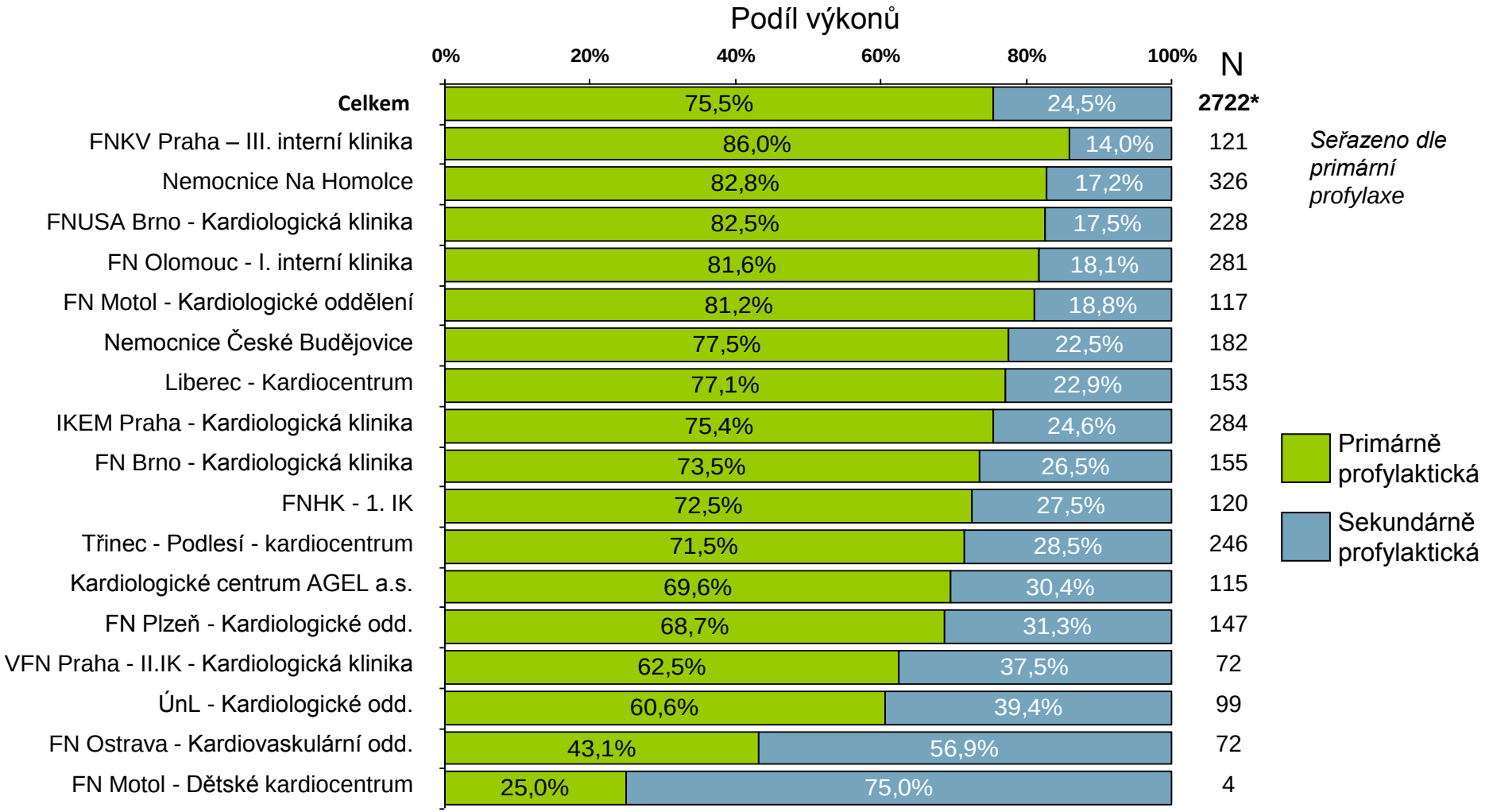
*European Heart Journal (2015) 36, 2793–2867*
*doi:10.1093/eurheartj/ehv316*

# Sekundární prevence: Jasná indikace ICD

| Trial | N | Total mortality | | | Arrhythmic mortality | | |
|---|---|---|---|---|---|---|---|
| | | Events | Hazard ratio | 95% CI | Events | Hazard ratio | 95% CI |
| AVID[153] | 1016 | 80 | 0.62 | 0.47–0.81 | 24 | 0.43 | 0.27–0.66 |
| CIDS[151] | 659 | 83 | 0.82 | 0.61–1.10 | 30 | 0.68 | 0.43–1.08 |
| CASH[152] | 191 | 37 | 0.83 | 0.52–1.33 | 7 | 0.32 | 0.15–0.69 |
| Cumulative | 1866 | 200 | 0.72 | 0.60–0.87 | 61 | 0.50 | 0.37–0.67 |

*AVID = Antiarrhythmic drugs Versus Implantable Defibrillator; CASH = Cardiac Arrest Study Hamburg; CI = confidence interval; CIDS = Canadian Implantable Defibrillator Study. P value for heterogeneity = 0.306.*
*European Heart Journal, doi:10.1093/eurheartj/ehv316*

# Sekundární x primárně preventivní indikace ICD




*Zdroj: Registr ICD ČASR ČKS*

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# III. Doporučené postupy ESC/ČKS a AHA/ACC/HRS

# VT and SCD ESC Guidelines 2015

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

**ESC GUIDELINES**

## 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death

**The Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC)**

**Endorsed by: Association for European Paediatric and Congenital Cardiology (AEPC)**

**Authors/Task Force Members: Silvia G. Priori*(Chairperson) (Italy) Carina Blomström-Lundqvist*(Co-chairperson) (Sweden) Andrea Mazzanti† (Italy), Nico Blom[a] (The Netherlands), Martin Borggrefe (Germany), John Camm (UK), Perry Mark Elliott (UK), Donna Fitzsimons (UK), Robert Hatala (Slovakia), Gerhard Hindricks (Germany), Paulus Kirchhof (UK/Germany), Keld Kjeldsen (Denmark), Karl-Heinz Kuck (Germany), Antonio Hernandez-Madrid (Spain), Nikolaos Nikolaou (Greece), Tone M. Norekvål (Norway), Christian Spaulding (France), and Dirk J. Van Veldhuisen (The Netherlands)**

# HF ESC Guidelines 2016

European Heart Journal (2016) **37**, 2129–2200
doi:10.1093/eurheartj/ehw128

**ESC GUIDELINES**

## 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

**The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC)**

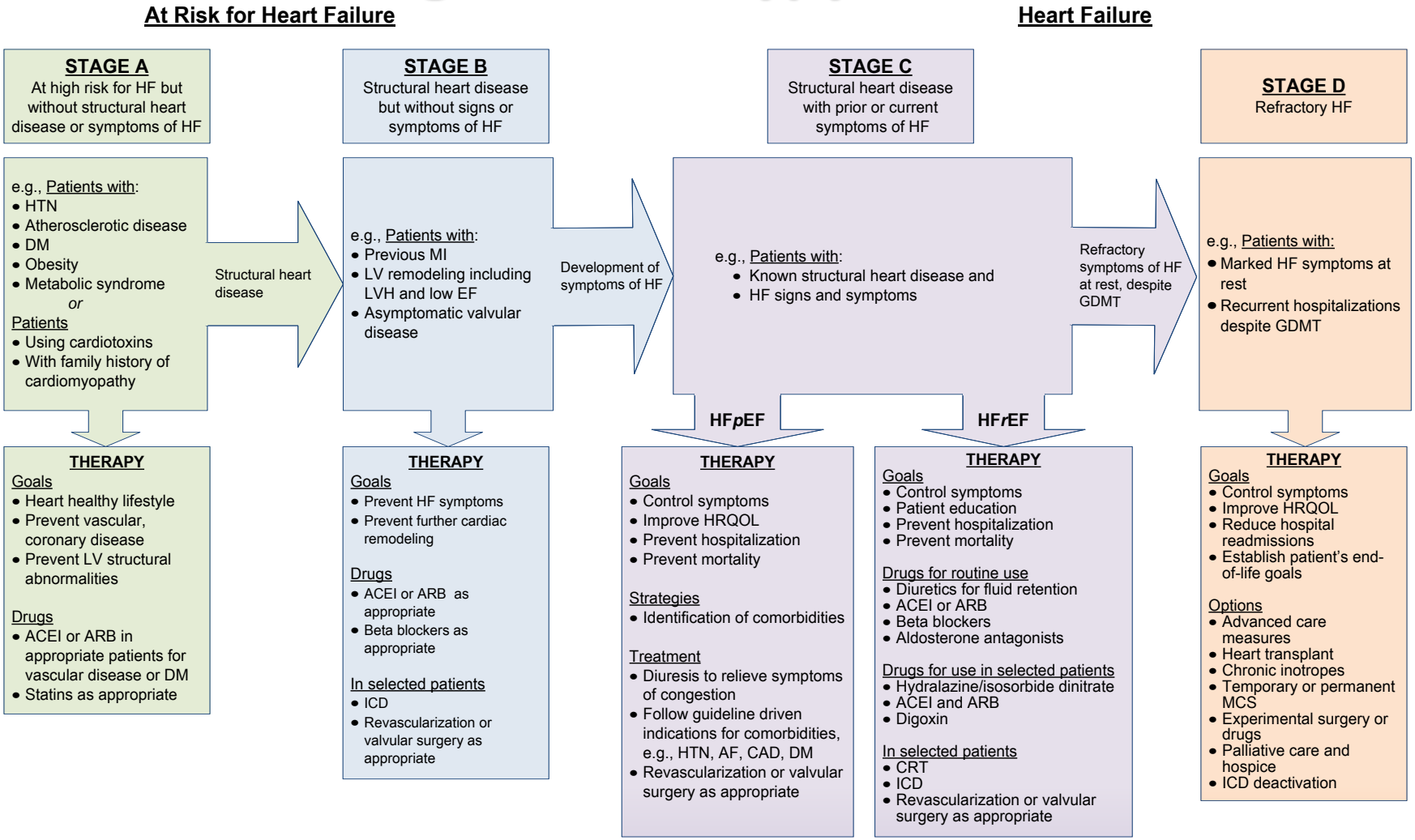
**Developed with the special contribution of the Heart Failure Association (HFA) of the ESC**

**Authors/Task Force Members: Piotr Ponikowski* (Chairperson) (Poland), Adriaan A. Voors* (Co-Chairperson) (The Netherlands), Stefan D. Anker (Germany), Héctor Bueno (Spain), John G. F. Cleland (UK), Andrew J. S. Coats (UK), Volkmar Falk (Germany), José Ramón González-Juanatey (Spain), Veli-Pekka Harjola (Finland), Ewa A. Jankowska (Poland), Mariell Jessup (USA), Cecilia Linde (Sweden), Petros Nihoyannopoulos (UK), John T. Parissis (Greece), Burkert Pieske (Germany), Jillian P. Riley (UK), Giuseppe M. C. Rosano (UK/Italy), Luis M. Ruilope (Spain), Frank Ruschitzka (Switzerland), Frans H. Rutten (The Netherlands), Peter van der Meer (The Netherlands)**

**Document Reviewers: Gerasimos Filippatos (CPG Review Coordinator) (Greece), John J. V. McMurray (CPG Review Coordinator) (UK), Victor Aboyans (France), Stephan Achenbach (Germany), Stefan Agewall (Norway), Nawwar Al-Attar (UK), John James Atherton (Australia), Johann Bauersachs (Germany), A. John Camm (UK), Scipione Carerj (Italy), Claudio Ceconi (Italy), Antonio Coca (Spain), Perry Elliott (UK), Çetin Erol (Turkey), Justin Ezekowitz (Canada), Covadonga Fernández-Golfín (Spain), Donna Fitzsimons (UK), Marco Guazzi (Italy),**

*P. Ponikowski: European Heart Journal (2016) 37, 2129–2200*

# USA guidelines: Kategorie, fenotypy a léčba SS




*Guidelines ACCF/AHA 2013*

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# IV. Primárně preventivní indikace ICD

# PP indikace ICD u pacientů s dysfunkcí LK

| Recommendations | Class[a] | Level[b] | Ref.[c] |
|---|---|---|---|
| ICD therapy is recommended to reduce SCD in patients with symptomatic HF (NYHA class II–III) and LVEF ≤35% after ≥3 months of optimal medical therapy who are expected to survive for at least 1 year with good functional status: | | | |
| – Ischaemic aetiology (at least 6 weeks after myocardial infarction). | I | A | 63,64 |
| – Non-ischaemic aetiology. | I | B | 64,316, 317 |

## NYHA IV

| Recommendation | Class[a] | Level[b] | Ref.[c] |
|---|---|---|---|
| ICD implantation should be considered for primary and secondary prevention of SCD in patients who are listed for heart transplant. | IIa | C | 320, 321 |

| Recommendations | Class[a] | Level[b] | Ref.[c] |
|---|---|---|---|
| CRT is recommended to reduce all-cause mortality in patients with an LVEF ≤35% and LBBB despite at least 3 months of optimal pharmacological therapy who are expected to survive at least 1 year with good functional status: | | | 322–326 |
| – With a QRS duration >150 ms | I | A | 313, 314, 327–329 |
| – With a QRS duration of 120–150 ms | I | B | 313, 314 |
| CRT should or may be considered to reduce all-cause mortality in patients with an LVEF ≤35% without LBBB despite at least 3 months of optimal pharmacological therapy who are expected to survive at least 1 year with good functional status: | | | 326 323–325 |
| – With a QRS duration >150 ms | IIa | B | 313, 314 |
| – With a QRS duration of 120–150 ms | IIb | B | 313, 314 |

## CRT-SR

## CRT-AF

| Recommendations | Class[a] | Level[b] | Ref.[c] |
|---|---|---|---|
| CRT should be considered to reduce all-cause mortality in patients with chronic HF, QRS ≥120 ms and LVEF ≤35% who remain in NYHA functional class III/ambulatory class IV despite at least 3 months of optimal pharmacological therapy who are expected to survive at least 1 year with good functional status, provided that biventricular pacing as close as possible to 100% can be achieved. | IIa | B | 330, 331 |
| AV junction ablation should be considered in case of incomplete biventricular pacing. | IIa | B | 332, 333 |

| Recommendations | Class[b] | Level[c] | Ref.[d] |
|---|---|---|---|
| CRT-D is recommended to reduce all-cause mortality in patients with a QRS duration ≥130 ms, with an LVEF ≤30% and with LBBB despite at least 3 months of optimal pharmacological therapy who are expected to survive at least 1 year with good functional status. | I | A | 148, 322, 323, 325, 327, 329 |
| CRT-D may be considered to prevent hospitalization for HF in patients with a QRS duration ≥150 ms, irrespective of QRS morphology, and an LVEF ≤35% despite at least 3 months of optimal pharmacological therapy who are expected to survive at least 1 year with good functional status. | IIb | A | 148, 327–329, 334 |

## NYHA II

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

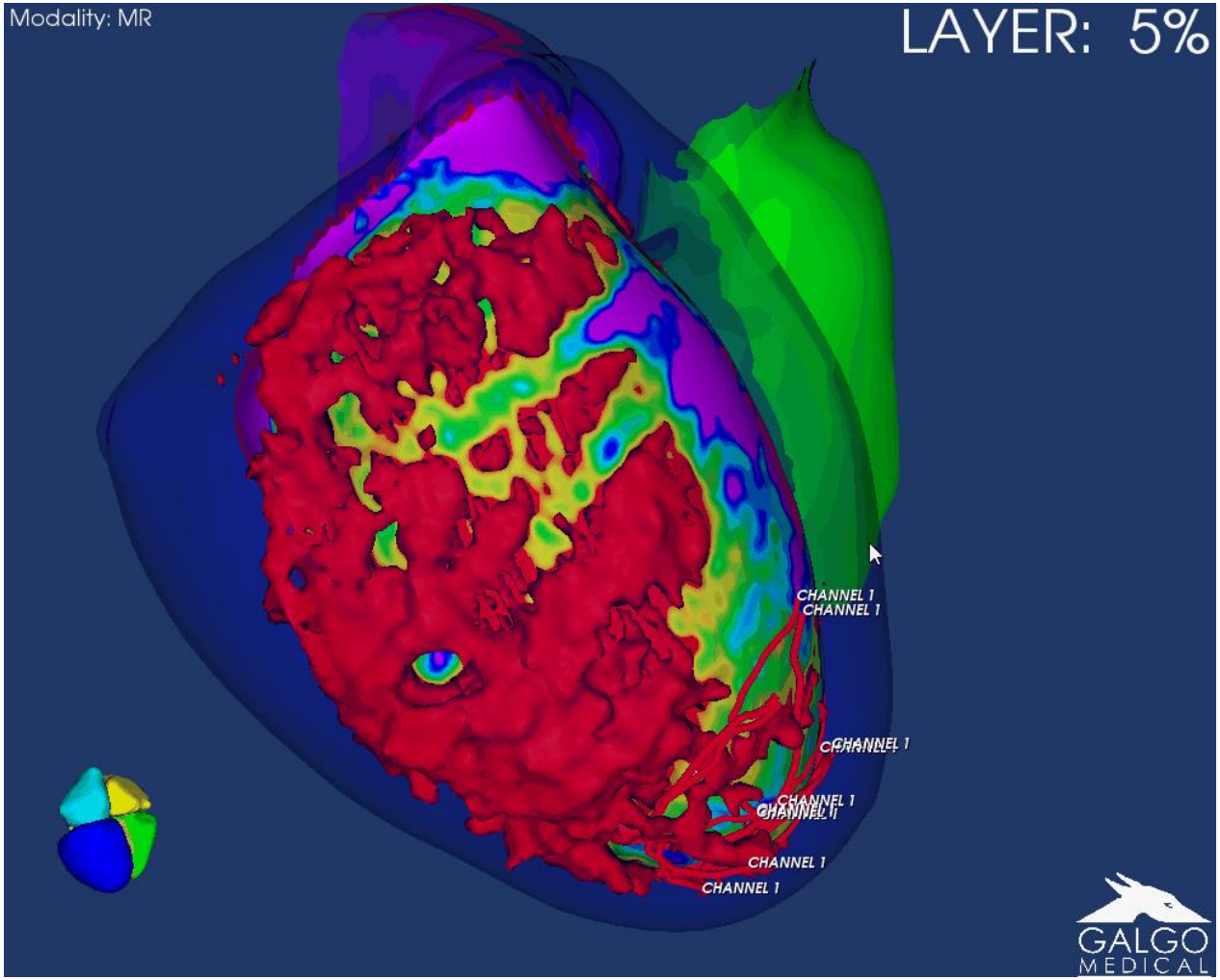
# Kontroverze PP indikace ICD I: Stratifikace rizika NSS

- EF LK stále jako „zlatý standard“
- Opuštění parametrů neinvazivní kardiologie (mTWA…)
- MRI – LA a stanovení perijizevnaté zóny – pomalejší, než se čekalo …
- Neexistují specifické biochemické markery NSS

# Kontroverze PP indikace ICD II: Substrát 2017 x 1990

1. D-PCI = standard léčby AIM
2. Standardní léčba po IM
3. Moderní léčba srdečního selhání
4. Nová antidiabetika u pacientů s KV onemocněními
5. Intenzivnější sledování pacientů
6. Využití m-Health technologií

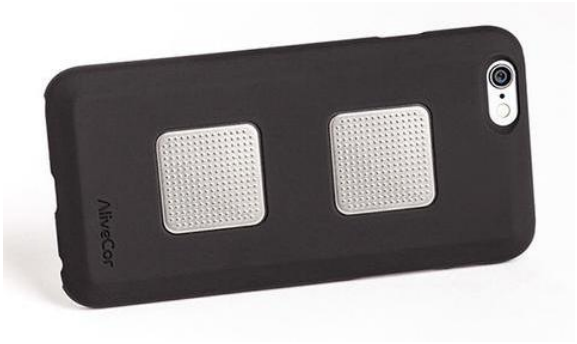
# Komplexní substrát komorových arytmií




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

# Monitoring v EP

- Přechod od implantátů k sofistikovaným externím monitorům

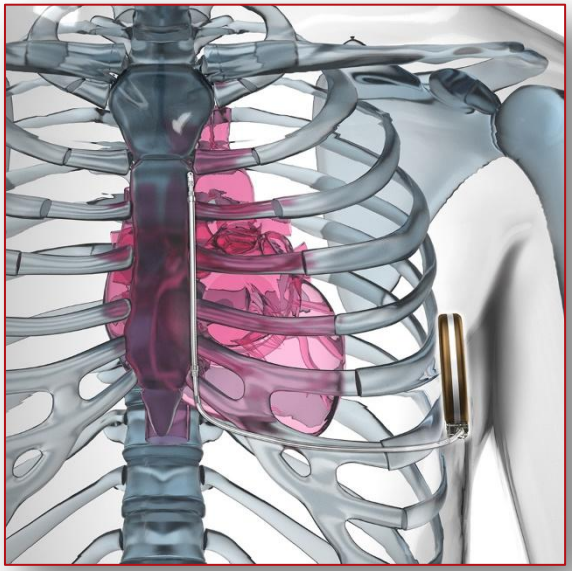





*https://alivecor.com/*

# Indikace SQ ICD 2017

| 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*

# Wearable defibrilátor: Řešení přechodného období

| 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 |

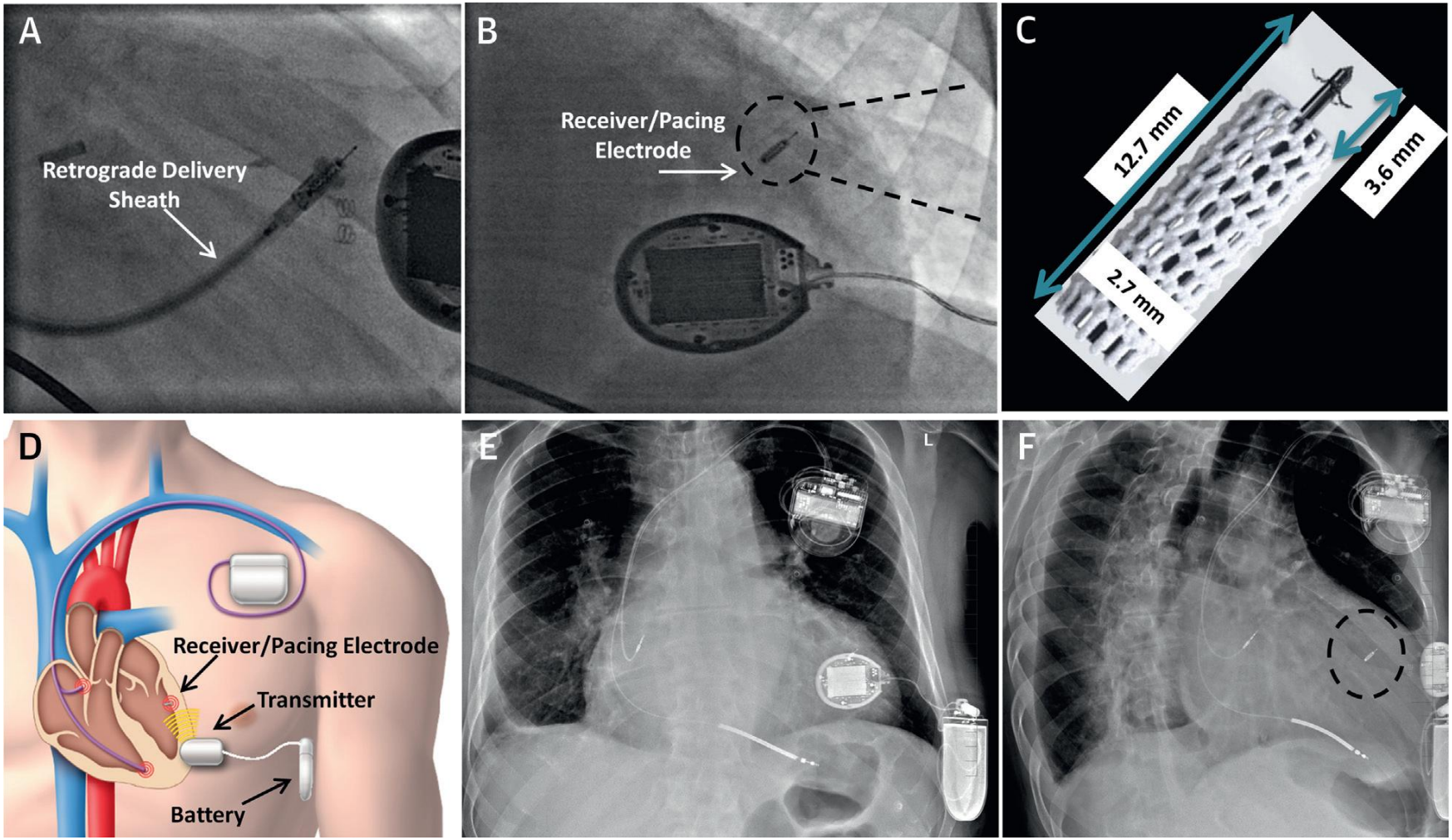
*European Heart Journal (2015) 36, 2793–2867*
*doi:10.1093/eurheartj/ehv316*

# Public defibrillation AED

| Recommendations | Class[a] | Level[b] | Ref.[c] |
|---|---|---|---|
| It is recommended that public access defibrillation be established at sites where cardiac arrest is relatively common and suitable storage is available (e.g. schools, sports stadiums, large stations, casinos, etc.) or at sites where no other access to defibrillation is available (e.g. trains, cruise ships, airplanes, etc.). | I | B | 173, 174 |
| It may be considered to teach basic life support to the families of patients at high risk of SCD | IIb | C | This panel of experts |

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

# Nové technologie: Wireless Endocardial Left Ventricular Pacing – CRT-D




*Reddy V.Y. : J Am Coll Cardiol 2017;69:2119–29*

# Clinical Efficacy Endpoints and Response to CRT

| Parameter | Baseline | 6 Months | Change | p Value | Response Definition | Response Rate at 6 Months (%) |
|---|---|---|---|---|---|---|
| LVESV, ml (n = 25) | 183.8 ± 62.9 | 157.0 ± 75.7 | −26.8 ± 45.1 | 0.007 | ≥15% relative reduction | 52 |
| LVEDV, ml (n = 25) | 243.1 ± 70.7 | 222.4 ± 77.0 | −20.6 ± 41.5 | 0.02 | ≥10% relative reduction | 40 |
| LVEF, % (n = 32) | 25.9 ± 6.4 | 33.0 ± 10.3 | +7.1 ± 8.0 | <0.0001 | ≥5% absolute increase | 66 |
| NYHA functional class I/II/III/IV | 3/24/73/0 | 24/67/3/6 | +0.8 ± 0.8 | | ≥1 class improvement | 67 |
| Global assessment | | | Markedly improved: 42.4%<br>Moderately improved: 27.3%<br>Mild improvement: 6.1%<br>No change: 15.2%<br>Slightly worse: 0.0%<br>Moderately worse: 3.0%<br>Markedly worse: 6.1% | | Markedly or moderately improved | 70 |

*Values are mean ± SD or %.*
*LVEDV = left ventricular end-diastolic volume; LVESV = left ventricular end-systolic volume; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association*

# Device- or Procedure-Related Adverse Events (n = 35)

| | |
|---|---|
| <24 h | 3 (8.6%) |
| VF during catheter contact with LV endocardium | 1 |
| Electrode embolization to lower extremity | 1 |
| Femoral artery fistula (required surgical repair) | 1 |
| 24 h to 1 month | 8 (22.3) |
| Acute CVA (AF noncompliant with anticoagulation) | 1 |
| Femoral pseudoaneurysm | 2 |
| Pocket hematoma (generator) | 1 |
| Suspected infection (generator site) | 3 |
| Death (following VF during initial implant procedure) | 1 |
| 1 to 6 months | 3 (8.6) |
| Defective transmitter circuitry | 3 |

*Values are n (%) or n.*
*AF = atrial fibrillation; CVA = cerebrovascular accident; LV = left ventricular; VF = ventricular fibrillation.*

# Katetrizační ablace KT jako metoda první volby ?

- SMASH –VT
- Marchlinski
- V-TACH …

- "*we are not there yet*" and ICD implantation cannot be deferred in these patients but potentially questioned. Available data do not allow conclusion on the impact of primary VT ablation on mortality and further studies are warranted…

*Di Biase l. J Cardiovasc Electrophysiol 2013 ,24(5):530-3*

# 5-year risk of SCD using the HCM Risk-SCD model

**Probability** $_{\text{SCD at 5 years}}$ **= 1-0.998** $^{\exp(\text{Progostic index})}$

where Prognostic index = [0.15939858 x maximal wall thickness (mm)] – [0.00294271 x maximal wall thickness$^2$ (mm$^2$)] + [0.0259082 x left atrial diameter (mm)] + [0.00446131 x maximal (rest/Valsalva) left ventricular outflow tract gradient (mm Hg)] + [0.4583082 x family history SCD] + [0.82639195 x NSVT] + [0.71650361 x unexplained syncope] – [0.01799934 x age at clinical evaluation (years)].

Hranice: 5 leté riziko SCD ≥ 5 % a předpoklad přežití > 1 rok


European Heart Journal (2014);35:2733–2779 - doi:10.1093/eurheartj/ehu284

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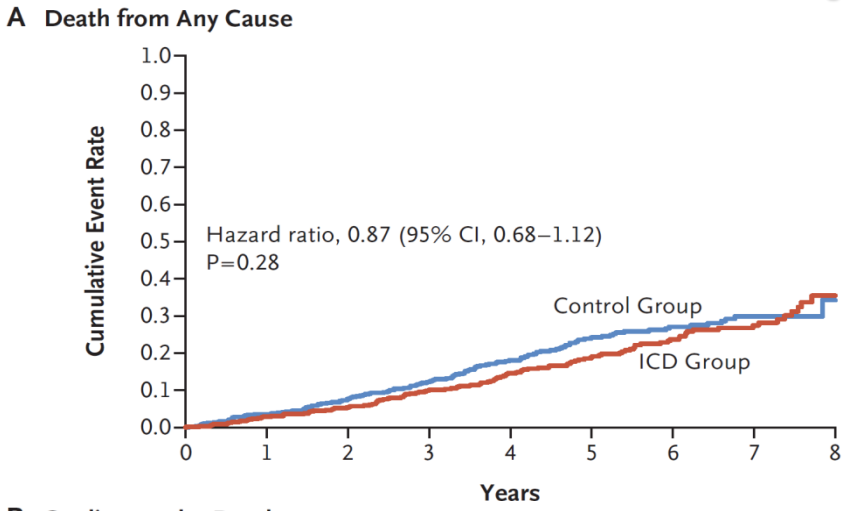
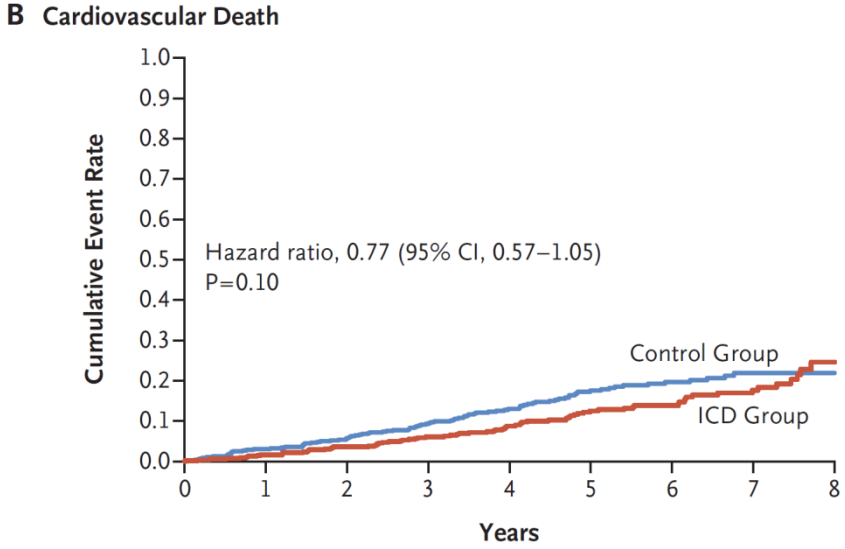
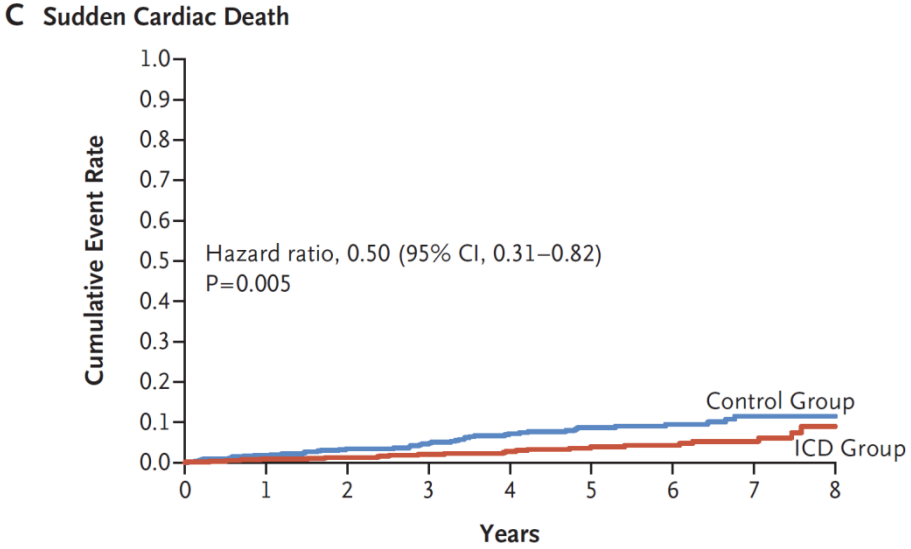
# IV: Co se pravděpodobně bude měnit v PP indikacích ICD ?

# DANISH Study: ICD u pacientů s neischemickou KMP




RESET 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.*

# RESET 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: VISZEGRAD Study

- Základní myšlenka:
  U pacientů s pokročilým srdečním selháním je prognostický význam komor. arytmií pravděpodobně nižší než max. léčba srdečního selhání – kombinace opt. farmakologické léčby + CRT
- Indikace: pacienti s neischemickou KMP s jasnou indikací CRT, bez dokumentace komor. arytmií, synkop…
- Randomizace: CRT-P x CRT-D v kombinaci s remote control

# Recentní metaanalýza PP ICD studií

- Implantable cardioverter defibrillators for primary prevention of death in left ventricular dysfunction with and without ischaemic heart disease: a meta-analysis of 8567 patients in the 11 trials:

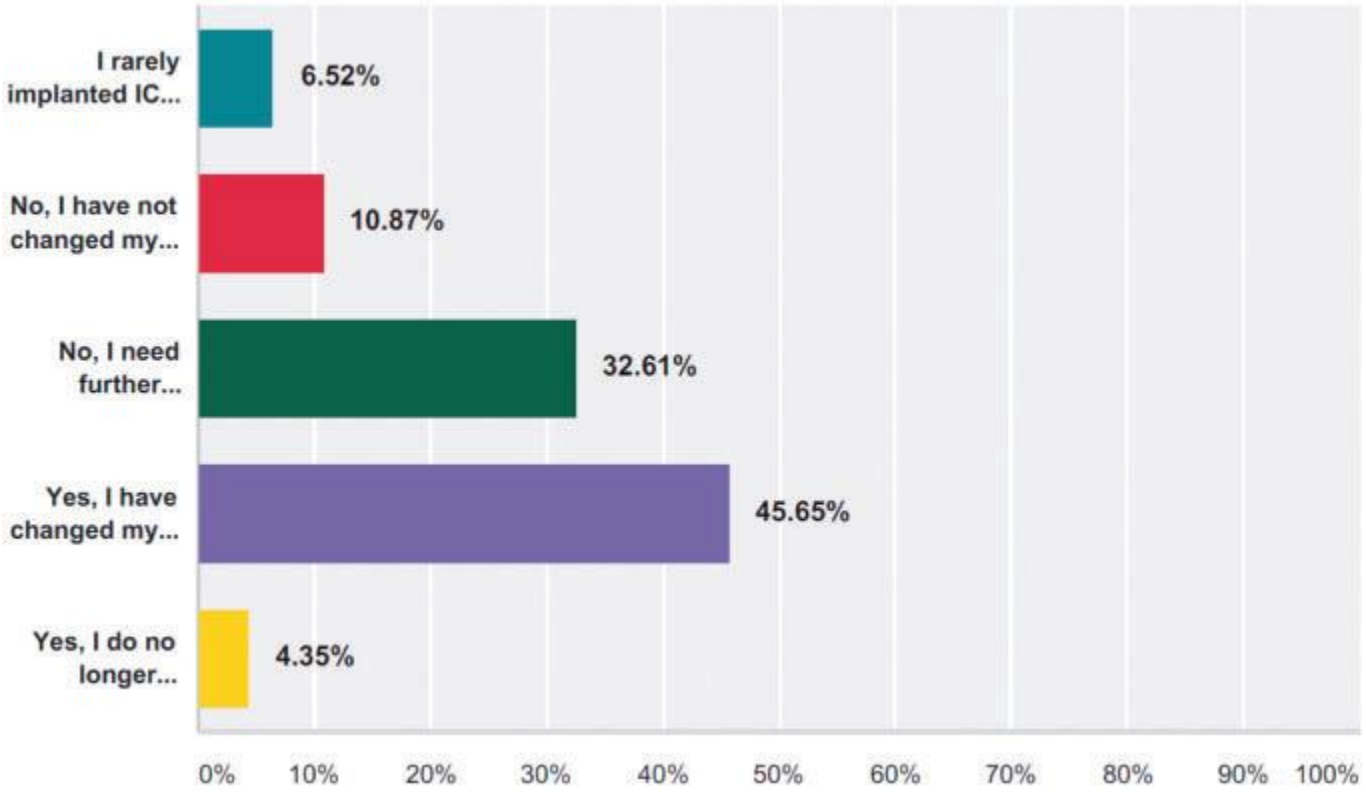
- In patients with left ventricular dysfunction, primary prevention ICDs reduce mortality.

- ICDs reduce mortality by 24% in both patients with (P = 0.03) and without IHD (P = 0.0023).

*Shun-Shin MJ: European Heart Journal (2017) 0, 1–10.*

# Reakce na DANISH Study:

- Implantable cardioverter defibrillator use for primary prevention in ischaemic and non-ischaemic heart disease—indications in the post-DANISH trial era: Results of the European Heart Rhythm Association survey




*K.H. Haugaa: Europace (2017) 19, 660–664*

# Take home message

1. Sekundárně preventivní indikace ICD – stabilní
2. PP indikace – zásadní nedostatečná a současné populaci neodpovídající riziková stratifikace NSS
3. Zlepšení – MR-LA, markery NSS, limitace komorbiditami – diabetes, renální insuficience …
4. Využití nových technologií – SQ ICD, WD …
5. Nedílná součást – moderní monitorace pacientů
6. Další vývoj v oblasti kat. ablací KT jako primární terapie

# HFA Congress 2017

- ICDs were “life-saving therapies for many but not all patients with heart failure”.
- He added that as “a doctor, you want to identify the patient who is going to benefit from such a device and, importantly, who is not”.
- “The expense and uncertainty of ICD therapy requires a more individualised, patient-centred approach. If you identify a patient who is unlikely to benefit from the ICD implantation, then you have spared a potentially unnecessary and costly procedure.” Prof. Ruschitzka states.

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