FAKULTNÍ NEMOCNICE® OLOMOUC

Lékařská fakulta
Univerzita Palackého v Olomouci

KOMPLEXNÍ KARDIOVASKULÁRNÍ CENTRUM
FAKULTNÍ NEMOCNICE OLOMOUC

M. Táborský

Bradyarytmie 2017: Trvalá kardiostimulace a srdeční resynchronizační léčba

Historie TKS

První implantace KS v ČSSR: IKEM 1962

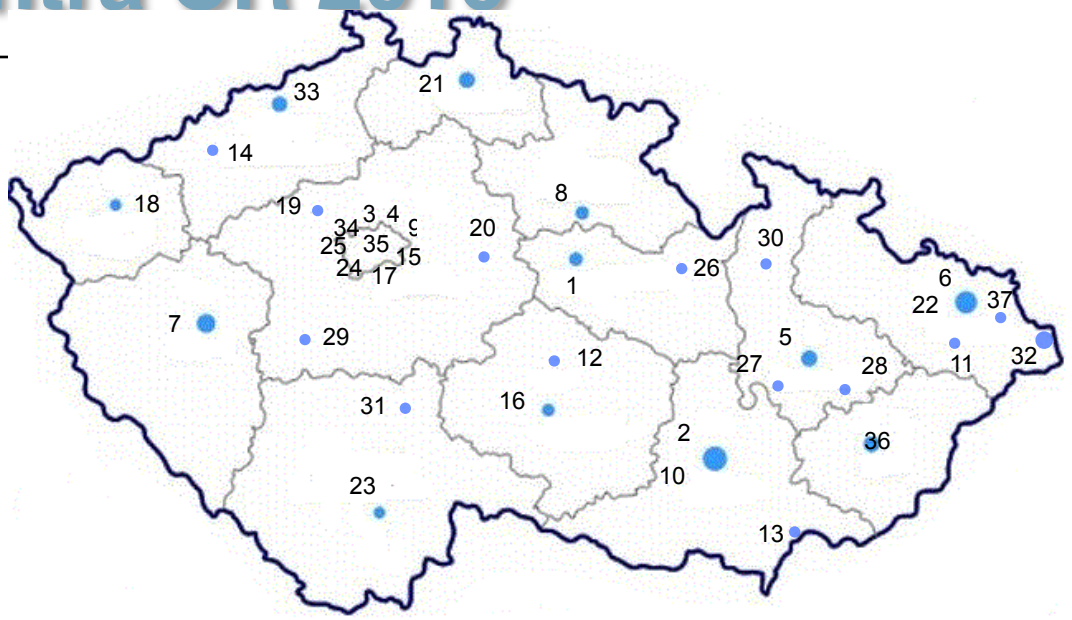
Chirurgové: Dr. Takaro (USA), Dr. Bohumil Peleška,
Prof. Bohumil Špaček

KS: Chardack – Greatbatch, VOO, frekvenčně reagující

1966: první originální český KS – Peleška, Bičík

KS centra ČR 2016

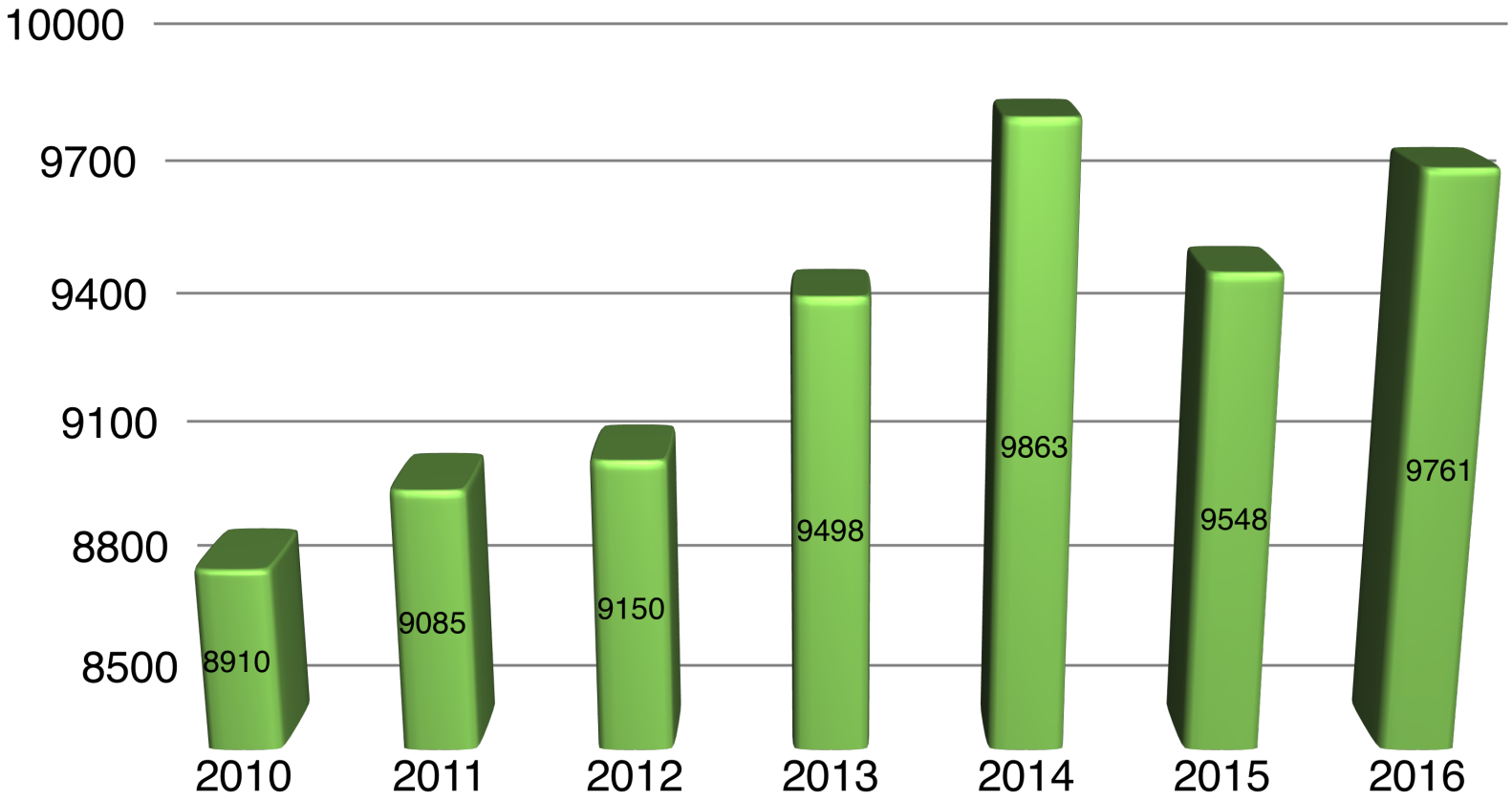
1	Kardiologické centrum AGEL a.s.
2	The University Hospital Brno – Dep. of Cardiology
3	The University Hospital Motol – Children´ Cardiocentre
4	The University Hospital Motol – Dep. of Cardiology
5	The University Hospital Olomouc – 1st Dep. of Medicine
6	The University Hospital Ostrava – Dep. of Cardiovascular Medicine
7	The University Hospital Plzeň – Dep. of Cardiology, arytmology
8	The University Hospital Hradec Králové – 1st Dep. of Internal Medicine
9	The University Hospital Královské Vinohrady – 3rd Dep. of Internal Medicine – Cardiology
10	The St. Anne's University Hospital Brno – Dep. of Cardiology
11	Hospital in Frýdek-Místek – Dep. of Internal Medicine
12	Hospital in Havlíčkův Brod – Dep. of Internal Medicine
13	TGM Hospital Hodonín – Centre of Cardiostimulation
14	Chomutov – Dep. of Internal Medicine
15	The Institute of Clinical and Experimental Medicine – Department of Cardiology
16	Jihlava – Dep. of Cardiology
17	The University Hospital Bulovka – Cardiology
18	Karlovy Vary – Kardiocentrum
19	Kladno – Dep. of Internal Medicine
20	Kolín – Dep. of Internal Medicine
21	Liberec – Cardio Centre
22	Ostrava City Hospital – Cardiology
23	Hospital in České Budějovice – Cardio Centre
24	Hospital of Merciful Sisters – Dep. of Internal Medicine
25	Hospital „Na Homolce“ – Dep. of Cardiology
26	Hospital in Ústí nad Orlicí –Dep. of Internal Medicine



27	Prostějov – Dep. of Internal Medicine
28	Přerov – Dep. of Internal Medicine
29	Příbram – Dep. of Internal Medicine
30	Šumperk – Dep. of Internal Medicine
31	Tábor – Dep. of Internal Medicine
32	Třinec – Cardio Centre
33	Ústí nad Labem – Dep. of Cardiology
34	ÚVN – Dep. of Cardiology
35	The General University Hospital in Prague – 2nd Dep. of Internal Cardiovascular Medicine
36	Zlín – Dep. of Internal Medicine
37	Havířov Hospital with Polyclinic – Dep. of Internal Medicine

Trend TKS v ČR: 2010-2016

ČASR 2016

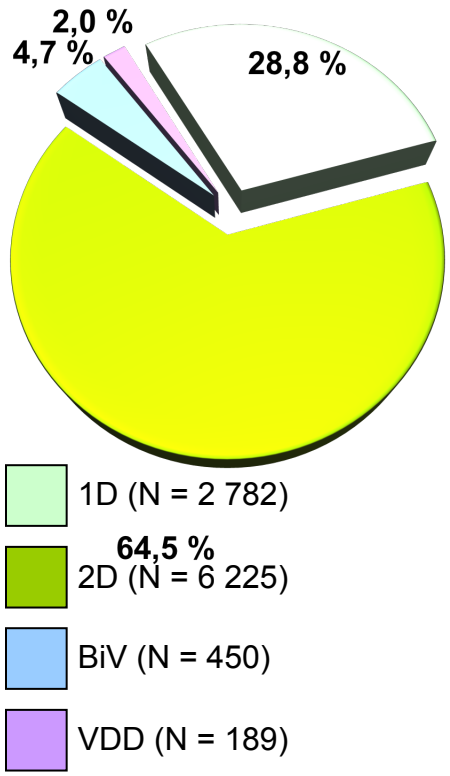


Vývoj počtu použitých KS: 2010 - 2016

Struktura typů použité stimulace 2016

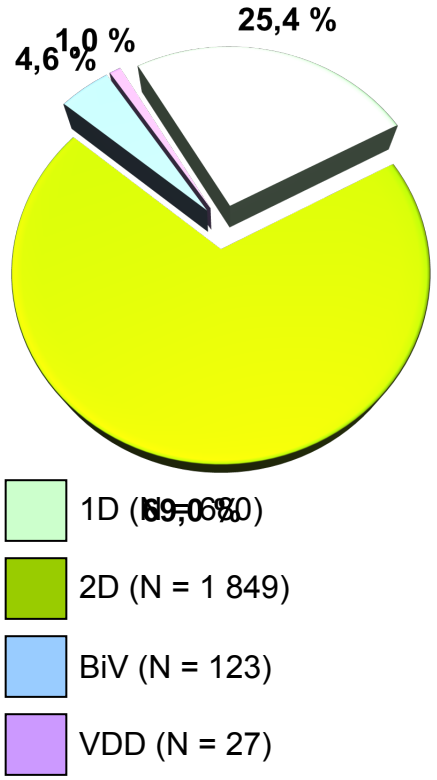
Implanted devices

N = 9 646



Explanted devices

N = 2 679

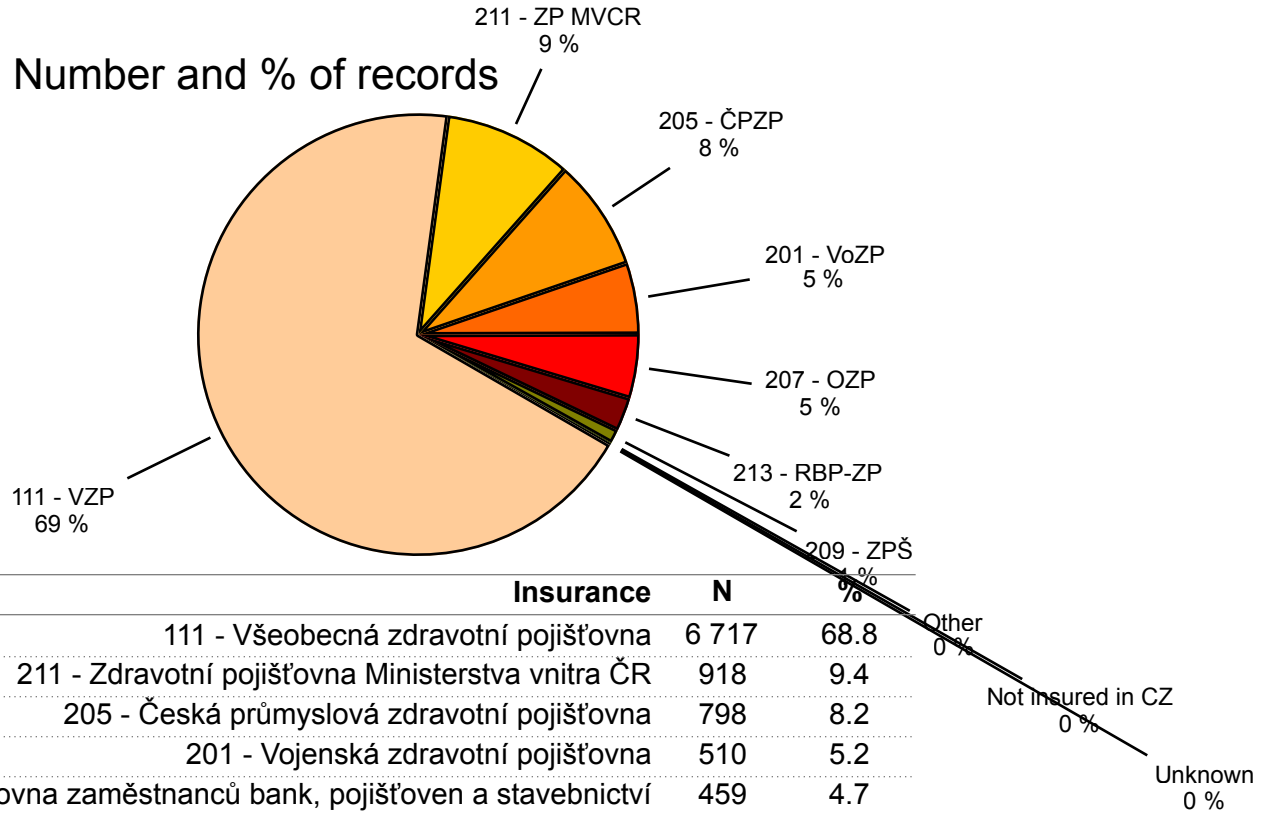


2D pacemaker is the most used device. It prevail among implanted also explanted devices.

Počty výkonů v centrech 2016

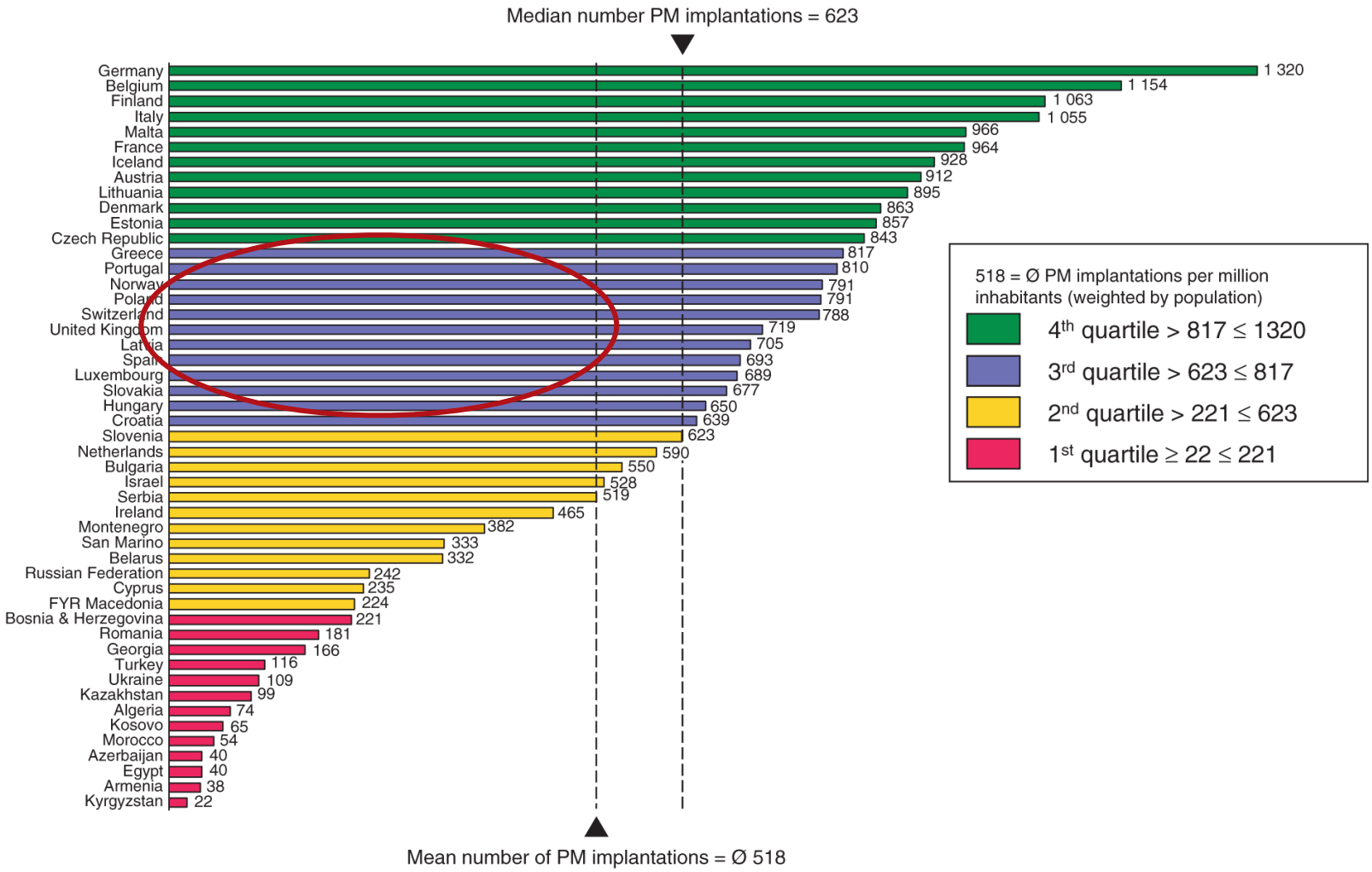
Centre/procedure type	Primo-implantation (N = 6 995)	Re-implantantation (N = 2 539)	Upgrade (N = 116)	Explantation (N = 32)	Electrode surgery (N = 53)	Other surgery (N = 26)	Total (N=9 761)
Nemocnice Na Homolce - Kardiologické odd.	412	197	4	17	3	11	644
FN Brno - Kardiologická klinika	421	152	–	–	–	–	573
FN Plzeň - Kardiologické odd.	343	175	1	2	2	1	524
IKEM Praha - Kardiologická klinika	337	111	29	10	3	1	491
FNUSA Brno - Kardiologická klinika	348	127	5	–	–	1	481
FN Ostrava - Kardiovaskulární odd.	351	100	3	–	6	–	460
Nemocnice České Budějovice - kardiocentrum	270	148	6	–	–	–	424
Liberec - Kardiocentrum	324	77	7	–	6	–	414
FNKV Praha – III.interní - kardiologická klinika	290	100	6	2	–	1	399
FN Olomouc - I. interní klinika - kardiologická	284	52	10	–	1	–	347
Třinec - Podlesí - kardiocentrum	305	34	2	–	–	–	341
VFN Praha - II.IK - Kardiologická klinika	190	122	11	–	–	–	323
Kardiologické centrum AGEL a.s.	205	84	2	–	7	1	299
FNHK - 1. IK	214	68	9	–	–	–	291
Orlickoústecká nemocnice - interní odd.	227	62	–	–	–	–	289
Zlín - Interní klinika	242	34	1	–	1	–	278
Kardiologie na Bulovce, s.r.o.	181	78	–	–	9	3	271
Městská nemocnice Ostrava - Kardiologie	196	51	4	–	1	–	252
ÚnL - Kardiologické odd.	183	68	1	–	–	–	252
ÚVN - Kardiologické odd.	132	107	4	–	5	–	248
Karlovy Vary nemocnice - Kardiocentrum	172	48	–	1	–	–	221
Kolín - Interní odd.	133	84	–	–	2	–	219
Tábor - Interní odd.	143	71	–	–	2	–	216
FN Motol - Kardiologické oddělení	146	55	9	–	–	–	210
Jihlava - Kardiologické odd.	152	39	1	–	1	–	193
Kladno - Interní odd.	123	55	–	–	–	7	185
Hodonín - Kardiostimul.centrum Nem. TGM p.o.	111	32	–	–	2	–	145
Frýdek Místek - Interní oddělení	111	30	1	–	1	–	143
Přerov - Interní odd.	106	29	–	–	–	–	135
Chomutov - Interní odd.	92	25	–	–	–	–	117
Prostějov - Interní odd.	69	44	–	–	1	–	114
Šumperk - Interní odd	81	13	–	–	–	–	94
Příbram - Interní oddělení	47	33	–	–	–	–	80
Havlíčkův Brod - Interní oddělení	41	15	–	–	–	–	56
FN Motol - Dětské kardiocentrum	13	19	–	–	–	–	32

Podíl plátců ZP na nákladech trvalé kardiostimulace



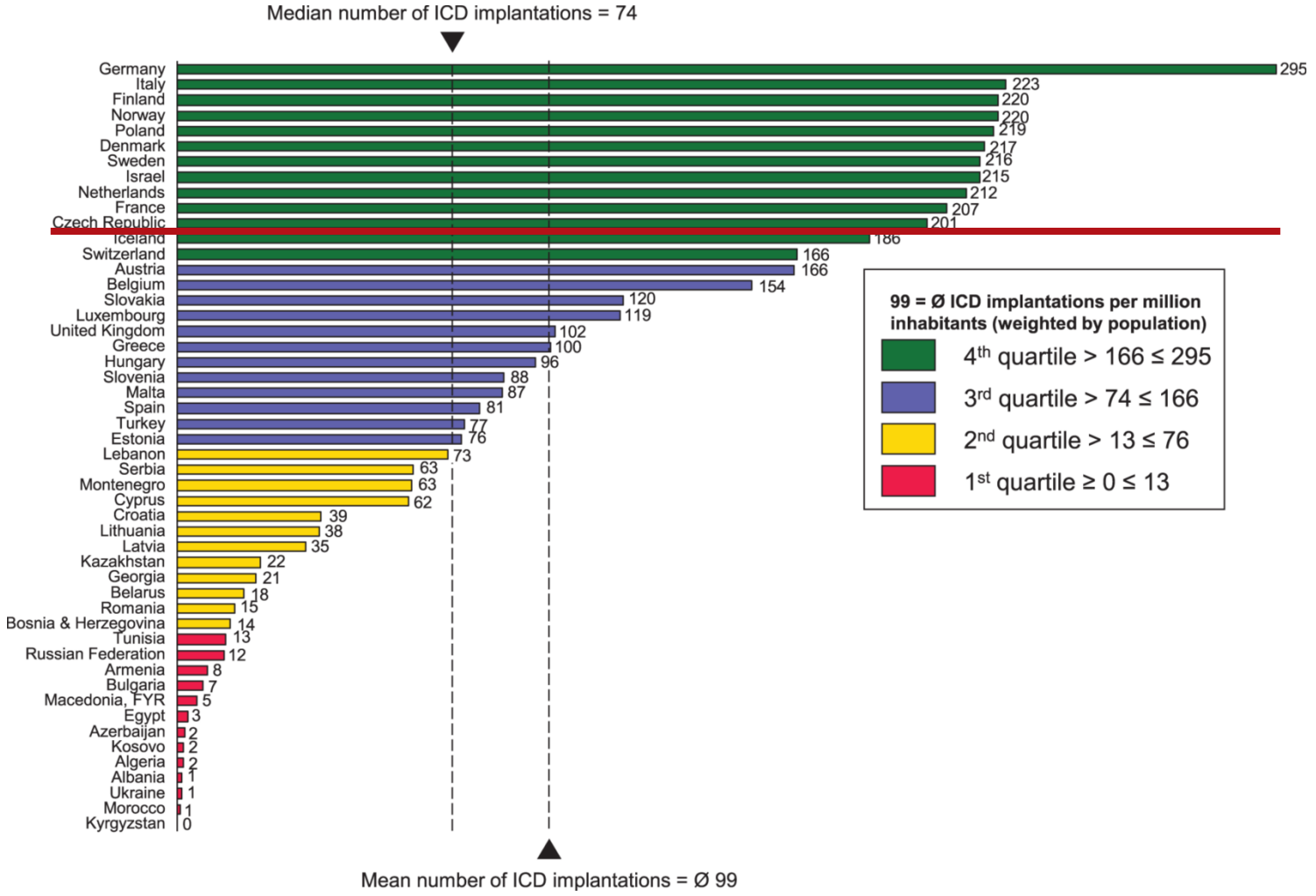
Insurance	N	%
111 - Všeobecná zdravotní pojišťovna	6 717	68.8
211 - Zdravotní pojišťovna Ministerstva vnitra ČR	918	9.4
205 - Česká průmyslová zdravotní pojišťovna	798	8.2
201 - Vojenská zdravotní pojišťovna	510	5.2
207 - Oborová pojišťovna zaměstnanců bank, pojišťoven a stavebnictví	459	4.7
213 - Revírní bratrská pokladna	241	2.5
209 - Zaměstnanecká pojišťovna Škoda	97	1.0
Other company	5	0.1
Not insured in CZ	15	0.2
Unknown	1	<0.1

Počet implantací KS /1 M obyvatel: 2016



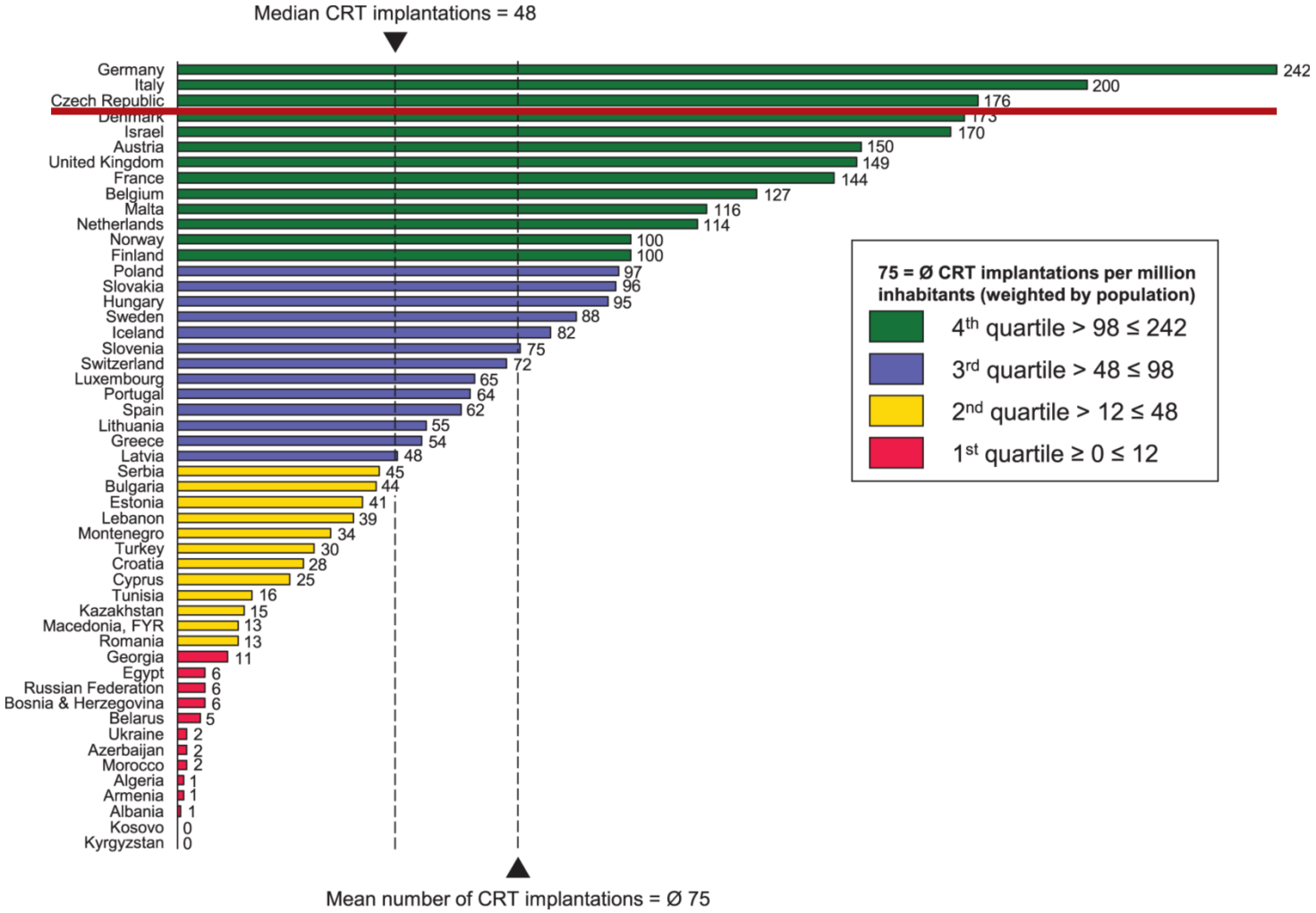
Europace. 2016 Aug;18 Suppl 3:iii1-iii79.
doi: 10.1093/europace/euw244

Počet implantovaných ICD/1M



Europace (2015) 17, iv2-iv72
doi:10.1093/europace/euv265

CRT 1 M obyvatel



Europace (2015) 17, iv2-iv72
doi:10.1093/europace/euv265

FAKULTNÍ NEMOCNICE® OLOMOUC

Lékařská fakulta
Univerzita Palackého v Olomouci

KOMPLEXNÍ KARDIOVASKULÁRNÍ CENTRUM
FAKULTNÍ NEMOCNICE OLOMOUC

Současná doporučení pro léčbu bradyarytmií

Guidelines ESC 2013

Dokument I

European Heart Journal
doi:10.1093/eurheartj/eht150

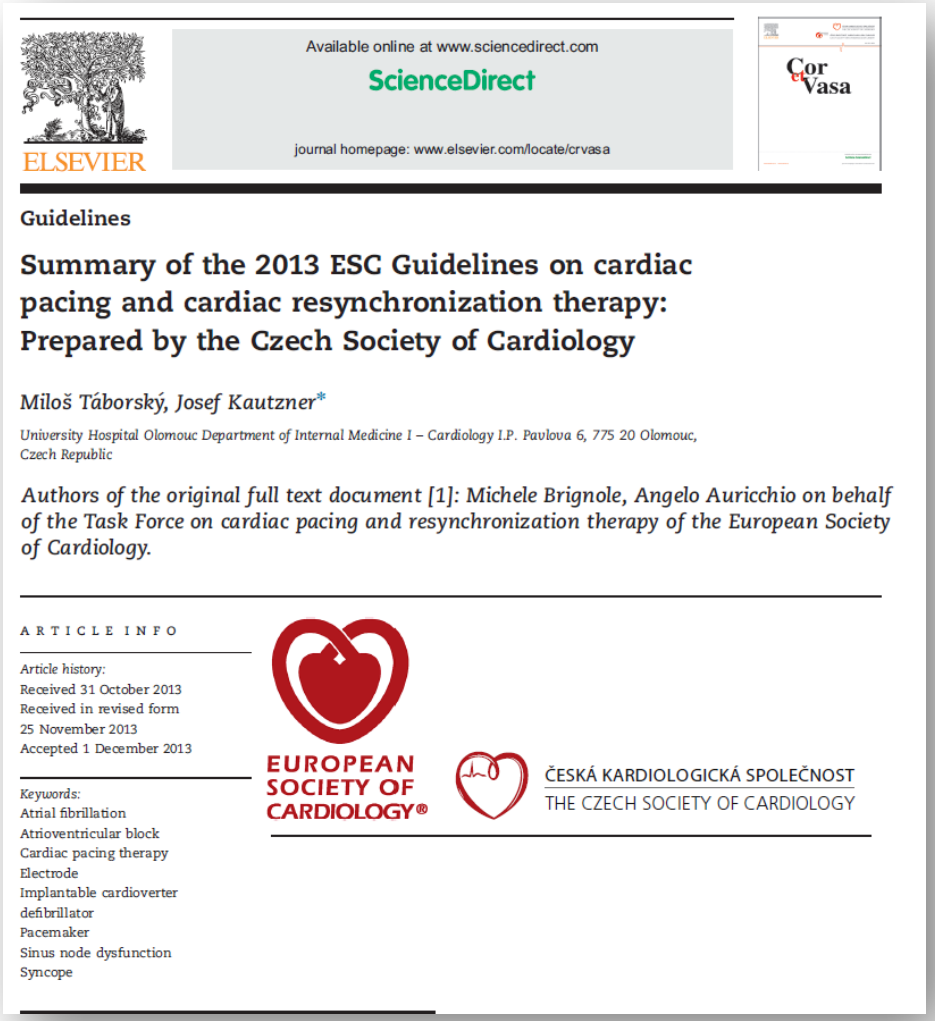
ESC GUIDELINES

2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy

The Task Force on cardiac pacing and resynchronization therapy of the European Society of Cardiology (ESC). Developed in collaboration with the European Heart Rhythm Association (EHRA).

Authors/Task Force Members: Michele Brignole (Chairperson) (Italy)*, Angelo Auricchio (Switzerland), Gonzalo Baron-Esquivias (Spain), Pierre Bordachar (France), Giuseppe Boriani (Italy), Ole-A Breithardt (Germany), John Cleland (UK), Jean-Claude Deharo (France), Victoria Delgado (Netherlands), Perry M. Elliott (UK), Bulent Gorenek (Turkey), Carsten W. Israel (Germany), Christophe Leclercq (France), Cecilia Linde (Sweden), Lluís Mont (Spain), Luigi Padeletti (Italy), Richard Sutton (UK), Panos E. Vardas (Greece)

Česká zkrácená verze



Available online at www.sciencedirect.com
ScienceDirect
journal homepage: www.elsevier.com/locate/crvasa
ELSEVIER
Cor et Vasa

Guidelines

Summary of the 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy: Prepared by the Czech Society of Cardiology

Miloš Táborský, Josef Kautzner*

University Hospital Olomouc Department of Internal Medicine I – Cardiology I.P. Pavlova 6, 775 20 Olomouc, Czech Republic

Authors of the original full text document [1]: Michele Brignole, Angelo Auricchio on behalf of the Task Force on cardiac pacing and resynchronization therapy of the European Society of Cardiology.

ARTICLE INFO

Article history:
Received 31 October 2013
Received in revised form
25 November 2013
Accepted 1 December 2013

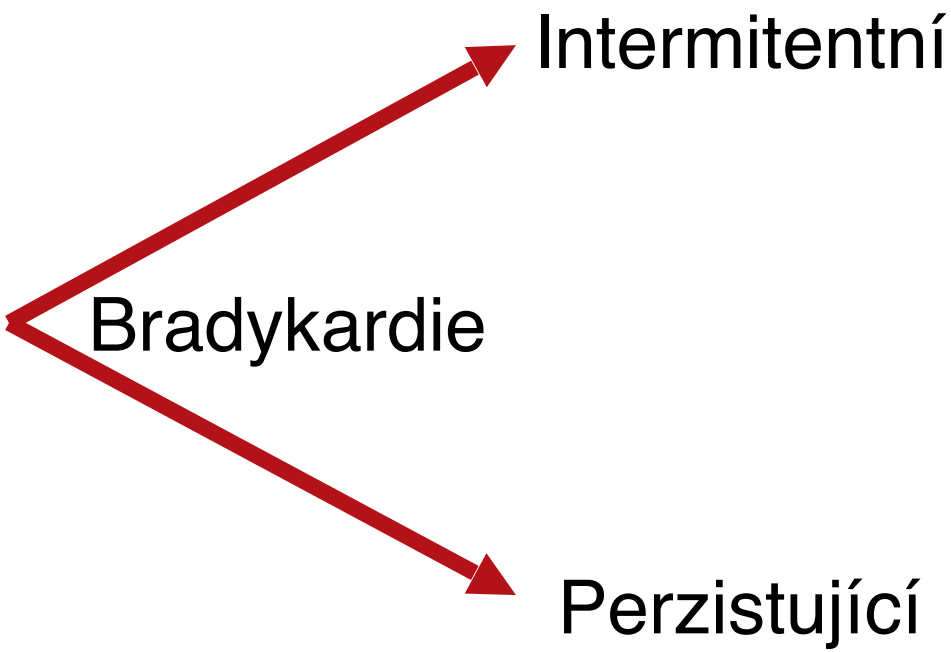
Keywords:
Atrial fibrillation
Atrioventricular block
Cardiac pacing therapy
Electrode
Implantable cardioverter defibrillator
Pacemaker
Sinus node dysfunction
Syncope

EUROPEAN SOCIETY OF CARDIOLOGY®

ČESKÁ KARDIOLOGICKÁ SPOLEČNOST
THE CZECH SOCIETY OF CARDIOLOGY

Cor Vasa 1, 2014

I: Obecné principy nových doporučení



Třídy doporučení

Classes of recommendations	Definition	Suggested wording to use
Class I	Evidence and/or general agreement that a given treatment or procedure **is beneficial, useful, effective.**	Is recommended/is indicated
Class II	**Conflicting evidence and/or a** divergence of opinion about the **usefulness/ efficacy of the given** treatment or procedure.	
Class IIa	*Weight of evidence/opinion is in **favour of usefulness/efficacy**.*	Should be considered
Class IIb	***Usefulness/efficacy is less well** established by evidence/opinion.*	May be considered
Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.	Is not recommended

Úroveň evidence

Level of evidence **A**	Data derived from multiple randomized clinical trials or meta-analyses.
Level of evidence **B**	Data derived from a single randomized clinical trial or large non-randomized studies.
Level of evidence **C**	Consensus of opinion of the experts and/or small studies, retrospective studies, registries.

Diagnosing bradyarrhythmic syncope after the initial evaluation: Most useful tests

Prolonged electrocardiogram monitoring strategy	Provocative (laboratory) test strategy
• Holter	• Carotid sinus massage
• External loop recorder	• Tilt table test
• Remote at-home telemetry	• Electrophysiological study
• Implantable loop recorder	• Exercise test

Suggested ECG monitoring techniques depending on symptom frequency

Frequency of symptoms	Suggested ECG monitoring technique
• Daily	• 24 h Holter, in-hospital telemetric monitoring
• Every 2–3 days	• 48–72 h Holter, in-hospital telemetric monitoring
• Every week	• 7 day Holter or external loop recorder
• Every month	• 14–30 days external loop recorder
• Less than once per month	• Implantable loop recorder

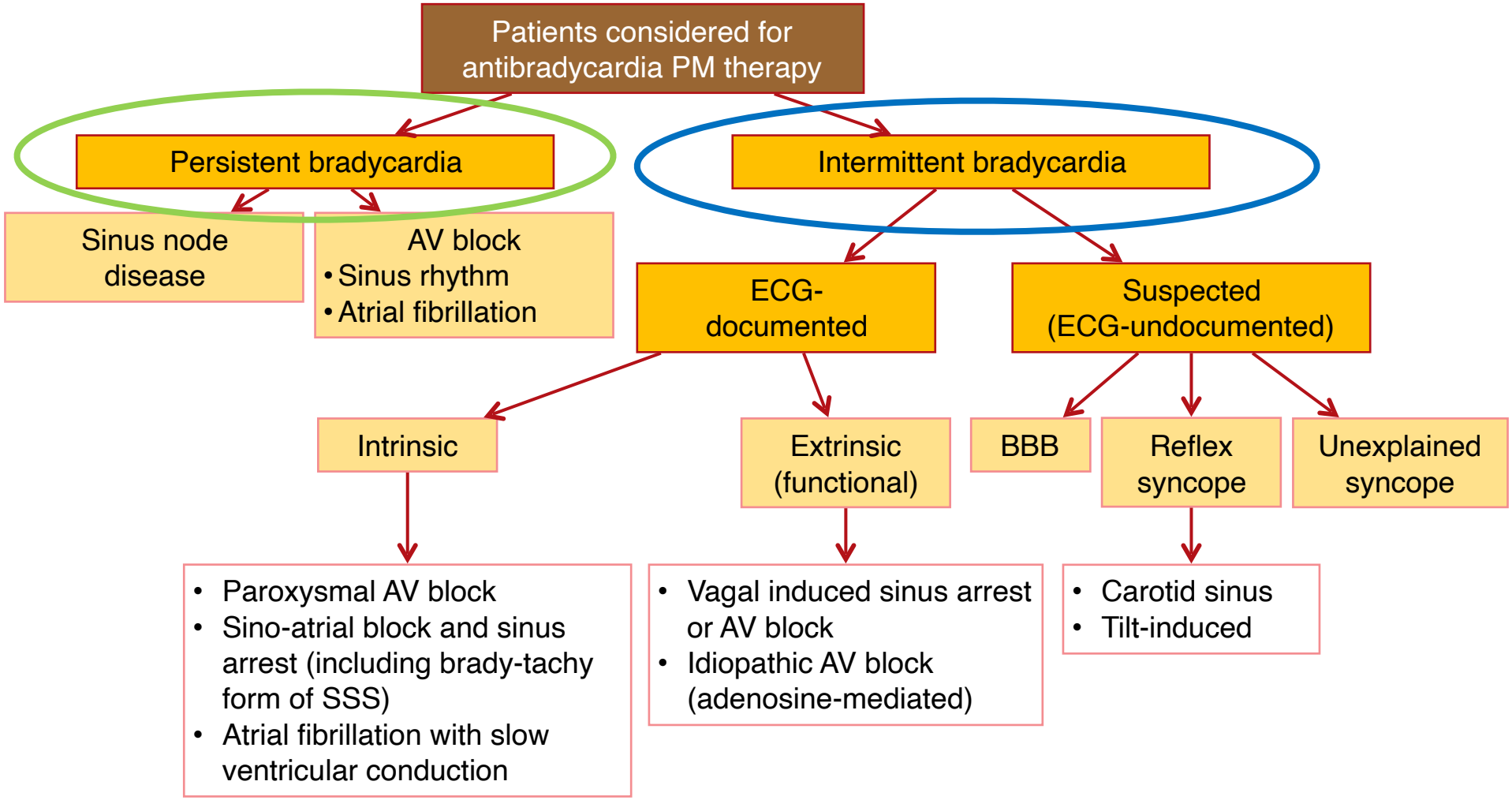
FAKULTNÍ NEMOCNICE® OLOMOUC

Lékařská fakulta
Univerzita Palackého v Olomouci

KOMPLEXNÍ KARDIOVASKULÁRNÍ CENTRUM
FAKULTNÍ NEMOCNICE OLOMOUC

II: Bradykardické indikace TKS

Classification of bradyarrhythmias based on the patient's clinical presentation



AV = atrioventricular; BBB = bundle branch block; ECG = electrocardiogram; PM = pacemaker; SSS = sick sinus syndrome.

Indication for pacing in patients with persistent bradycardia

Recommendations	Class	Level
1) Sinus node disease. Pacing is indicated when symptoms can clearly be attributed to bradycardia.	I	B
2) Sinus node disease. Pacing may be indicated when symptoms are likely to be due to bradycardia, even if the evidence is not conclusive.	IIb	C
3) Sinus node disease. Pacing is not indicated in patients with SB which is asymptomatic or due to reversible causes.	III	C
4) Acquired AV block. Pacing is indicated in patients with third- or second-degree type 2 AV block irrespective of symptoms.	I	C
5) Acquired AV block. Pacing should be considered in patients with second-degree type 1 AV block which causes symptoms or is found to be located at intra- or infra-His levels at EPS.	IIa	C
6) Acquired AV block. Pacing is not indicated in patients with AV block which is due to reversible causes.	III	C

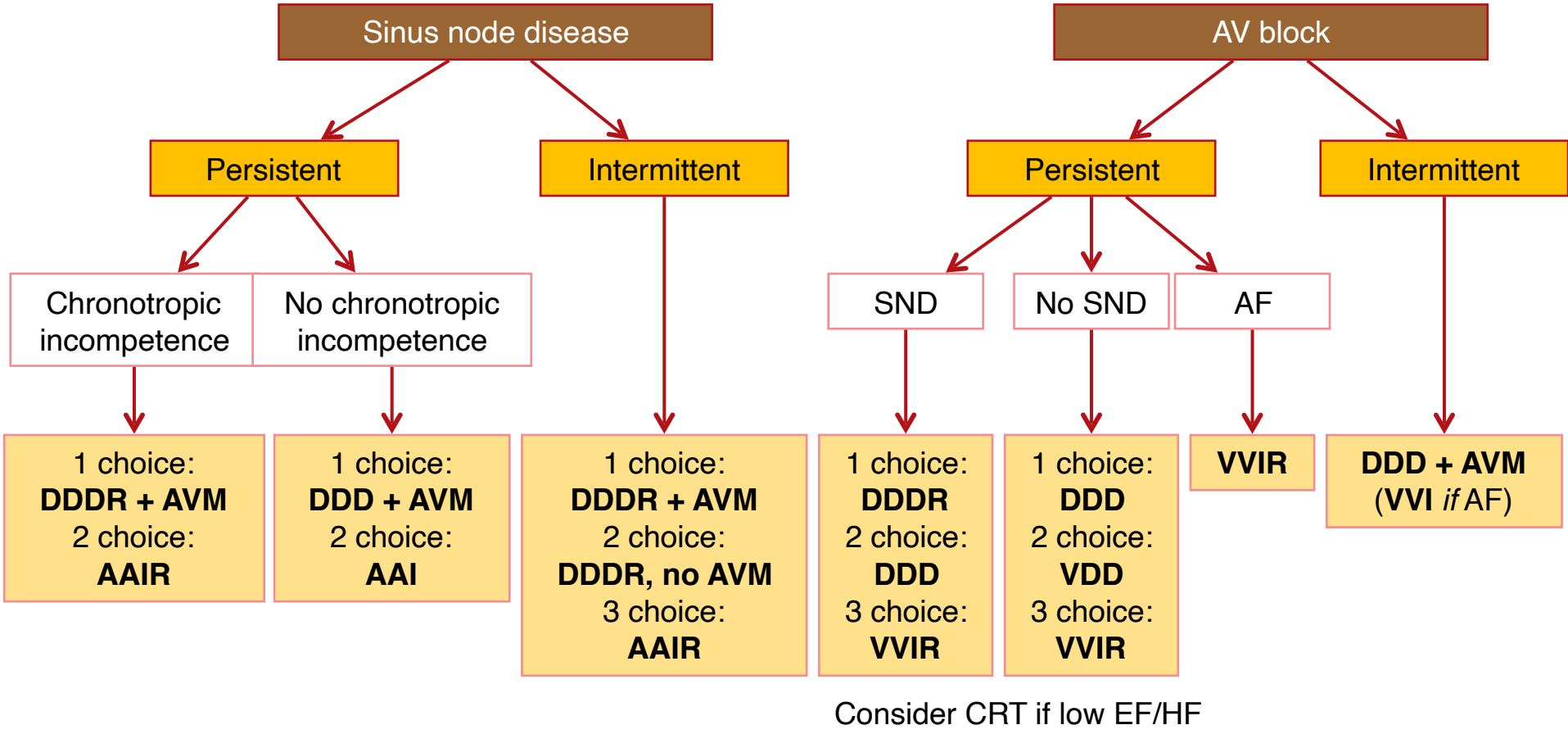
AV = atrioventricular; EPS = electrophysiological study; SB = sinus bradycardia.

Outcome of randomized controlled trials of dual-chamber versus ventricular pacing

Outcome	Dual-chamber benefit over ventricular pacing	Notes
All-cause deaths	No benefit	
Stroke, embolism	Benefit (in meta-analysis only, not in single trial)	HR 0.80. Benefit higher in SSS.
Atrial fibrillation	Benefit	HR 0.81 and 0.76. Benefit higher in SSS.
HF, hospitalization for HF	No benefit	
Exercise capacity	Benefit	Overall standardized mean improvement of 35%. No significant compared to VVIR.
Pacemaker syndrome	Benefit	Documented in up to 25% of VVI patients.
Functional status	No benefit	
Quality of life	Variable	Consistent direction of effect on quality of life, but the size cannot be estimated with confidence.
Complications	More complications with dual-chamber	Higher rate of lead dislodgment (4.25 vs. 1.4%) and inadequate pacing (1.3 vs. 0.3%).

HF = heart failure; HR, hazard ratio; SSS = sick sinus syndrome.

Optimal pacing mode in sinus node disease and AV block



Consider CRT if low EF/HF

AF = atrial fibrillation; AV = atrioventricular; AVM = AV delay management, i.e. to prevent unnecessary right ventricular pacing by means of manual optimization of AV interval or programming of AV hysteresis; SND = sinus node disease.

Choice of pacing mode/programming in patients with persistent bradycardia

Recommendations	Class	Level
7) Sinus node disease. **7A)** Dual-chamber PM with preservation of spontaneous AV conduction is indicated for reducing the risk of AF and stroke, avoiding PM syndrome and improving quality of life.	I	A (vs. VVI) B (vs. AAI)
7B) Rate response features should be adopted for patients with chronotropic incompetence, especially if young and physically active.	IIa	C
8) Acquired AV block. In patients with sinus rhythm, dual-chamber PM should be preferred to single chamber ventricular pacing for avoiding PM syndrome	IIa	A
9) Permanent AF and AV block. Ventricular pacing with rate-response function is recommended.	I	C

AF = atrial fibrillation; AV = atrioventricular; PM = pacemaker.

Indication for pacing in intermittent documented bradycardia I

Recommendations	Class	Level
1) Sinus node disease (including brady-tachy form). Pacing is indicated in patients affected by sinus node disease who have the documentation of symptomatic bradycardia due to sinus arrest or sinus-atrial block.	I	B
2) Intermittent/paroxysmal AV block (including AF with slow ventricular conduction). Pacing is indicated in patients with intermittent/paroxysmal intrinsic third- or second-degree AV block.	I	C
3) Reflex asystolic syncope. Pacing should be considered in patients ≥40 years with recurrent, unpredictable reflex syncopes and documented symptomatic pause/s due to sinus arrest or AV block or the combination of the two.	IIa	B
4) Asymptomatic pauses (sinus arrest or AV block). Pacing should be considered in patients with history of syncope and documentation of asymptomatic pauses >6 s due to sinus arrest, sinus-atrial block or AV block.	IIa	C
5) Pacing is not indicated in reversible causes of bradycardia.	III	C

AF = atrial fibrillation; AV = atrioventricular.

Indication for pacing in intermittent documented bradycardia II

Recommendations	Class	Level
6) Intermittent documented bradycardia. Preservation of spontaneous AV conduction is recommended.	I	B
7) Reflex asystolic syncope. Dual-chamber pacing with rate hysteresis is the preferred mode of pacing in order to preserve spontaneous sinus rhythm.	I	C

AV = atrioventricular.

FAKULTNÍ NEMOCNICE® OLOMOUC

Lékařská fakulta
Univerzita Palackého v Olomouci

KOMPLEXNÍ KARDIOVASKULÁRNÍ CENTRUM
FAKULTNÍ NEMOCNICE OLOMOUC

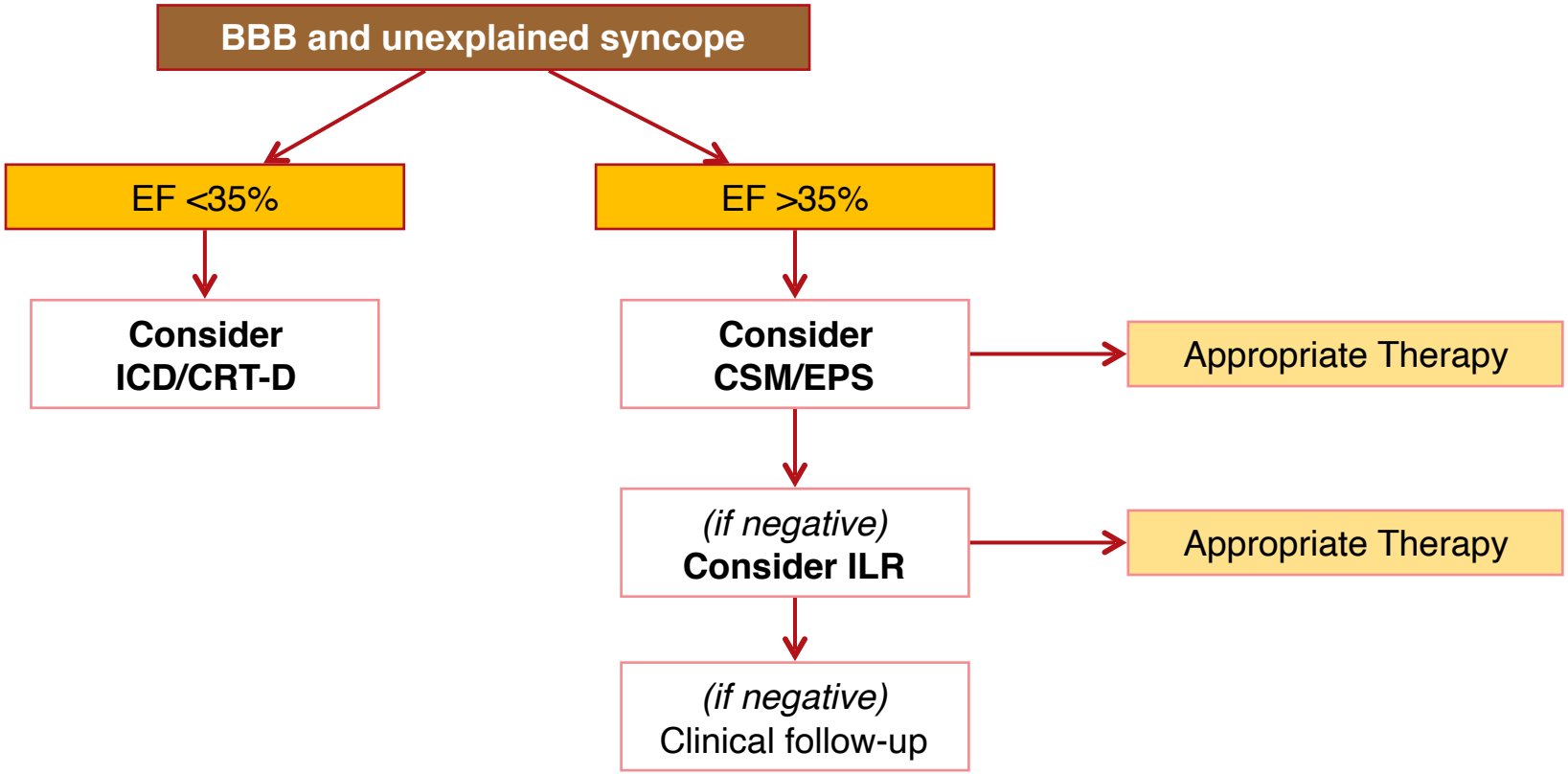
III: Indikace TKS – BBB /synkopa

Indication for cardiac pacing in patients with BBB

Recommendations	Class	Level
1) BBB, unexplained syncope and abnormal EPS. Pacing is indicated in patients with syncope, BBB and positive EPS defined as HV interval of ≥70 ms, or second- or third-degree His-Purkinje block demonstrated during incremental atrial pacing or with pharmacological challenge.	I	B
2) Alternating BBB. Pacing is indicated in patients with alternating BBB with or without symptoms.	I	C
3) BBB, unexplained syncope non diagnostic investigations. Pacing may be considered in selected patients with unexplained syncope and BBB.	IIb	B
4) Asymptomatic BBB. Pacing is not indicated for BBB in asymptomatic patients.	III	B

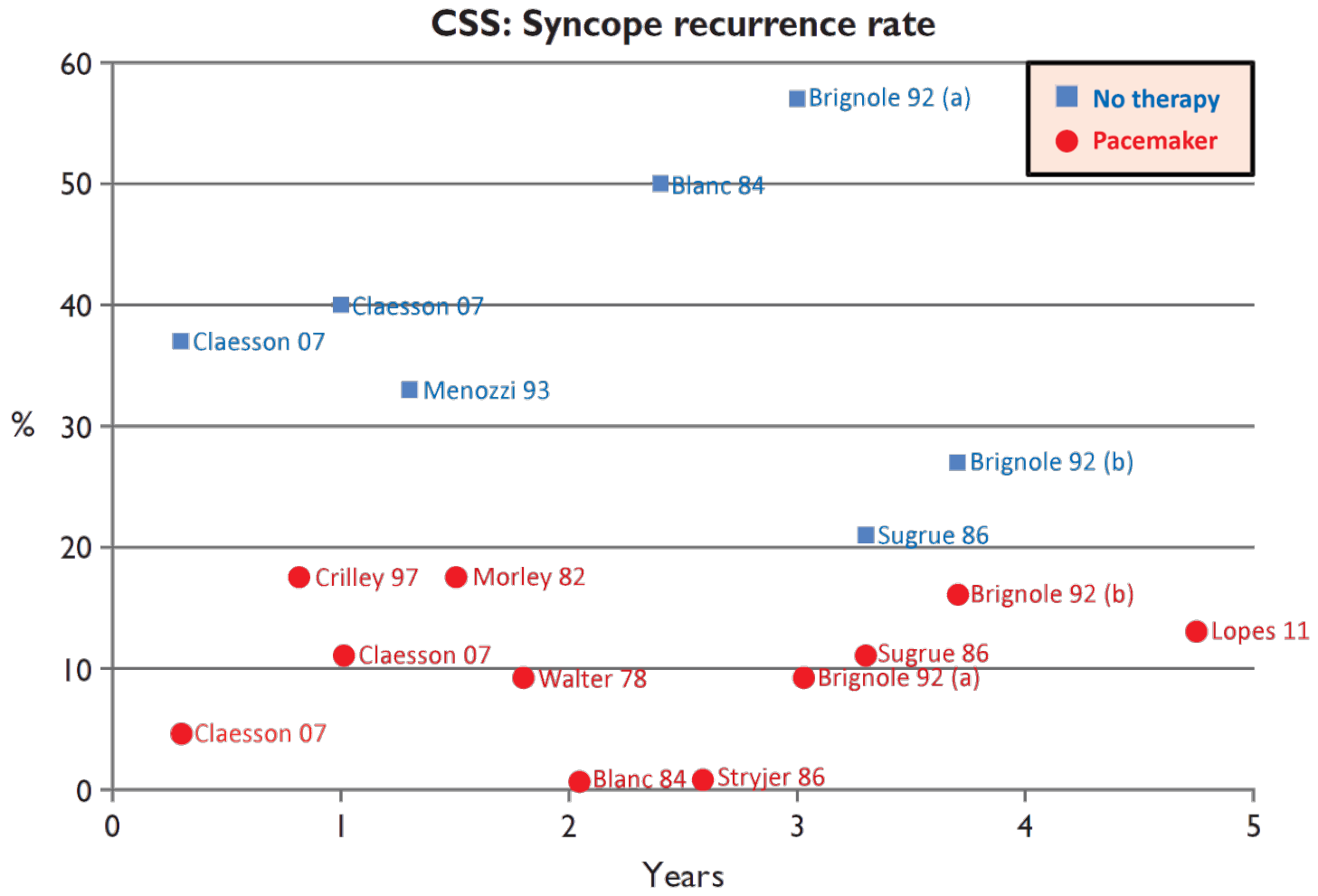
BBB = bundle branch block; EPS = electrophysiological study.

Therapeutic algorithm for patients presenting with unexplained syncope and bundle branch block (BBB)



CRT-D = cardiac resynchronization therapy and defibrillator; CSM = carotid sinus massage; EF = ejection fraction; EPS = electrophysiological study; ICD = implantable cardioverter defibrillator; ILR = implantable loop recorder.

Recurrence of syncope in untreated and paced patients affected by carotid sinus syndrome (CSS).



Brignole et al.

Indication for cardiac pacing in patients with undocumented reflex syncope

Recommendations	Class	Level
1) Carotid sinus syncope. Pacing is indicated in patients with *dominant cardioinhibitory carotid sinus syndrome* and recurrent unpredictable syncope.	I	B
2) Tilt-induced cardioinhibitory syncope. Pacing may be indicated in patients with tilt-induced cardioinhibitory response with recurrent frequent unpredictable syncope and age >40 years after alternative therapy has failed.	IIb	B
3) Tilt-induced non-cardioinhibitory syncope. Cardiac pacing is not indicated in the absence of a documented cardioinhibitory reflex.	III	B

BBB = bundle branch block; EPS = electrophysiological study.

Choice of pacing mode

Recommendations	Class	Level
4) Carotid sinus syncope. In patients with carotid sinus syndrome, dual-chamber pacing is the preferred mode of pacing.	I	B
5) Tilt-induced cardioinhibitory syncope. In patients with cardioinhibitory vasovagal syncope, dual-chamber pacing is the preferred mode of pacing.	I	C
6) Lower rate and rate hysteresis should be programmed in order to achieve back-up pacing function which preserves native heart rhythm and AV conduction.	IIa	C

BBB = bundle branch block; EPS = electrophysiological study.

Indication for cardiac pacing in patients with unexplained syncope

Recommendations	Class	Level
1) Unexplained syncope and positive adenosine triphosphate test. Pacing may be useful to reduce syncopal recurrences.	IIb	B
2) Unexplained syncope. Pacing is not indicated in patients with unexplained syncope without evidence of bradycardia or conduction disturbance.	III	C
3) Unexplained falls. Pacing is not indicated in patients with unexplained falls.	III	B

BBB = bundle branch block; EPS = electrophysiological study.

IV: Srdeční resynchronizační léčba

3 okruhy indikací:

- 1. CRT – SR
- 2. CRT – AF
- 3. CRT – upgrade /HF brady

Inclusion criteria, design, endpoints, and main findings of the randomized clinical trials evaluating cardiac resynchronization therapy in heart failure patients and sinus rhythm

Trial (ref)	No.	Design	NYHA	LVEF	QRS	Primary endpoints	Secondary endpoints	Main Findings
MUSTIC-SR	58	Single-blinded, crossover, randomized CRT vs. OMT, 6 months	III	<35 %	≥150	6MWD	NYHA class, QoL, peak VO_2LV volumes, MR hospitalizations, mortality	CRT-P improved 6MWD, NYHA class, QoL, peak VO_2, reduced LV volumes and MR and reduced hospitalizations
PATH-CHF	41	Single-blinded, crossover, randomized RV vs. LV vs. BiV, 12 months	III-IV	NA	≥150	Peak VO_2, 6MWD	NYHA class, QoL hospitalizations	CRT-P improved NYHA class, QoL and 6MWD and reduced hospitalizations
MIRACLE	453	Double-blinded, randomized CRT vs. OMT, 6 months	III-IV	≤35%	≥130	NYHA class, 6MWD , QoL	Peak VO_2 LVEDD, LVEF, MR clinical composite response	CRT-P improved NYHA class, QoL and 6MWD and reduced LVEDD, MR and increased LVEF
MIRACLE-ICD	369	Double-blinded, randomized CRT-D vs. ICD, 6 months	III-IV	≤35%	≥130	NYHA class, 6MWD , QoL	Peak VO_2 LVEDD, LVEF, MR clinical composite response	CRT-D improved NYHA class, QoL, peak VO_2
CONTAK-CD	490	Double-blinded randomized CRT-D vs. ICD, 6 months	II-III-IV	≤35%	≥120	NYHA class, 6MWD , QoL	LV volume, LVEF composite of mortality, VT/VF, hospitalizations	CRT-D improved 6MWD, NYHA class, QoL, reduced LV volume and increased LVEF
MIRACLE-ICD II	186	Double-blinded, randomized CRT-D vs. ICD, 6 months	II	≤35%	≥130	Peak VO_2	VE/VCO_2, NYHA, QoL, 6MWD, LV volumes and EF, composite clinical endpoint	CRT-D improved NYHA, VE/CO_2 and reduced LV volumes and improved LVEF
COMPANION	1520	Double-blinded randomized OMT vs. CRT-P / or vs. CRT-D, 15 months	III-IV	≤35%	≥120	All-cause mortality or hospitalization	All-cause mortality, cardiac mortality	CRT-P and CRT-D reduced all-cause mortality or hospitalization
CARE-HF	813	Double-blinded randomized OMT vs. CRT-P 29.4 months	III-IV	≤35%	≥120	All-cause mortality or hospitalization	All-cause mortality, NYHA class, QoL	CRT-P reduced all-cause mortality and hospitalization and improved NYHA class and QoL
REVERSE	610	Double-blinded, randomized CRT-ON vs. CRT-OFF, 12 months	I-II	≤40%	≥120	% worsened by clinical composite endpoint	LVESV index, heart failure hospitalizations and all-cause mortality	CRT-P/CRT-D did not change the primary endpoint and did not reduce all-cause mortality but reduced LVESV index and heart failure hospitalizations.
MADIT-CRT	1820	Single-blinded, randomized CRT-D vs. ICD, 12 months	I-II	≤30%	≥130	All-cause mortality or heart failure hospitalizations	All-cause mortality and LVESV	CRT-D reduced the endpoint heart failure hospitalizations or all-cause mortality and LVESV. CRT-D did not reduced all-cause mortality
RAFT	1798	Double-blinded randomized CRT-D vs. ICD 40 months	II-III	≤30%	≥120	All-cause mortality or heart failure hospitalizations	All-cause mortality and cardiovascular death	CRT-D reduced the endpoint all-cause mortality or heart failure hospitalizations. In NYHA III, CRT-D only reduced significantly all-cause mortality

CARE-HF = Cardiac Resynchronization-Heart Failure; CONTAK-CD = CONTAK-Cardiac Defibrillation; COMPANION = Comparison of Medical Therapy, Pacing and Defibrillation in Heart Failure; CRT-D = cardiac resynchronization therapy with defibrillator; CRT-P = cardiac resynchronization therapy pacemaker; LV = left ventricular; LVEDD = left ventricular end-diastolic dimension; LVEF = left ventricular ejection fraction; LVESV = left ventricular end-systolic volume; MADIT-CRT = Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy; MIRACLE = Multicenter InSync Randomized Clinical Evaluation; MIRACLE-ICD = Multicenter InSync Implantable Cardioverter Defibrillator; MR = mitral regurgitation; MUSTIC = Multisite Stimulation in Cardiomyopathies; MUSTIC-SR = Multisite Stimulation in Cardiomyopathies in Sinus Rhythm patients; NYHA = New York Heart Association; PATH-CHF = Pacing Therapies in Congestive Heart Failure trial; QoL = quality-of-life score; RAFT = Resynchronization-Defibrillation for Ambulatory Heart Failure Trial; VE/VCO_2= minute ventilation/minute volume carbon dioxide production; VF = ventricular fibrillation; VO_2 = volume of oxygen; VT = ventricular tachycardia; 6MWD = 6-min walk distance.

Indications for cardiac resynchronization therapy in patients in sinus rhythm

Recommendations	Class	Level
1) LBBB with QRS duration >150 ms. CRT is recommended in chronic HF patients and LVEF ≤35% who remain in NYHA functional class II, III and ambulatory IV despite adequate medical treatment.*	I	A
2) LBBB with QRS duration 120–150 ms. CRT is recommended in chronic HF patients and LVEF ≤35% who remain in NYHA functional class II, III and ambulatory IV despite adequate medical treatment.*	I	B
3) Non-LBBB with QRS duration >150 ms. CRT should be considered in chronic HF patients and LVEF ≤35% who remain in NYHA functional class II, III and ambulatory IV despite adequate medical treatment.*	IIa	B
4) Non-LBBB with QRS duration 120–150 ms. CRT may be considered in chronic HF patients and LVEF ≤35% who remain in NYHA functional class II, III and ambulatory IV despite adequate medical treatment.*	IIb	B
5) CRT in patients with chronic HF with QRS duration <120 ms is not recommended.	III	B

CRT = cardiac resynchronization therapy; HF = heart failure; LBBB = left bundle branch block; LV = left ventricular; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association.
**Patients should generally not be implanted during admission for acute decompensated HF. In such patients, guideline-indicated medical treatment should be optimized and the patient reviewed as an out-patient after stabilization. It is recognized that this may not always be possible.*

Indications for cardiac resynchronization therapy in patients with permanent atrial fibrillation

Recommendations	Class	Level
1) Patients with HF, wide QRS and reduced LVEF: **1A)** CRT should be considered in chronic HF patients, intrinsic QRS ≥120 ms and LVEF ≤35% who remain in NYHA functional class III and ambulatory IV despite adequate medical treatment*, provided that a BiV pacing as close to 100% as possible can be achieved.	IIa	B
1B) AV junction ablation should be added in case of incomplete BiV pacing.	IIa	B
2) Patients with uncontrolled heart rate who are candidates for AV junction ablation. CRT should be considered in patients with reduced LVEF who are candidates for AV junction ablation for rate control.	IIa	B

*AV = atrioventricular; CRT = cardiac resynchronization therapy; HF = heart failure; ICD = implantable cardioverter defibrillator; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association. *Patients should generally not be implanted during admission for acute decompensated HF. In such patients, guideline-indicated medical treatment should be optimized and the patient reviewed as an out-patient after stabilization. It is recognized that this may not always be possible.*

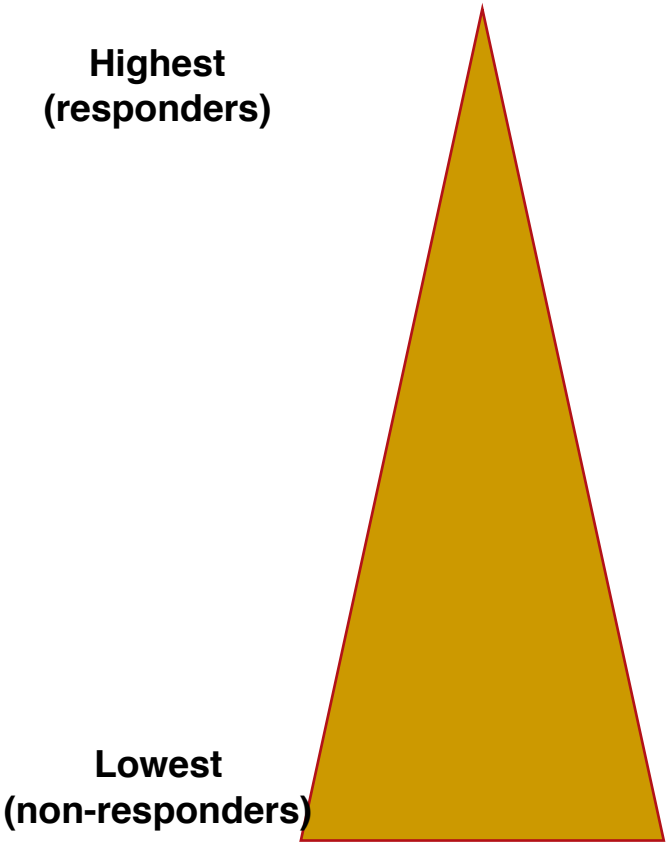
Indication for upgraded or de novo cardiac resynchronization therapy in patients with conventional pacemaker indications and heart failure

Recommendations	Class	Level
1) Upgrade from conventional PM or ICD. CRT is indicated in HF patients with LVEF <35% and high percentage of ventricular pacing who remain in NYHA class III and ambulatory IV despite adequate medical treatment.*	I	B
2) *De novo* cardiac resynchronization therapy. CRT should be considered in HF patients, reduced EF and expected high percentage of ventricular pacing in order to decrease the risk of worsening HF.	IIa	B

CRT = cardiac resynchronization therapy; HF = heart failure; ICD = implantable cardioverter defibrillator; LVEF = left ventricular ejection fraction; PM = pacemaker; NYHA = New York Heart Association.
**Patients should generally not be implanted during admission for acute decompensated HF. In such patients, guideline-indicated medical treatment should be optimized and the patient reviewed as an out-patient after stabilization. It is recognized that this may not always be possible.*

Clinical factors influencing the likelihood to respond to CRT

Magnitude of benefit from CRT



Wider QRS, left bundle branch block, females, non-ischaemic cardiomyopathy

Males, ischaemic cardiomyopathy

Narrower QRS, non-left bundle branch block

Choice of pacing mode (and cardiac resynchronization therapy optimization)

Recommendations	Class	Level
1) The goal of CRT should be to achieve BiV pacing as close to 100% as possible since the survival benefit and reduction in hospitalization are strongly associated with an increasing percentage of BiV pacing.	IIa	B
2) Apical position of the LV lead should be avoided when possible.	IIa	B
3) LV lead placement may be targeted at the latest activated LV segment.	IIb	B

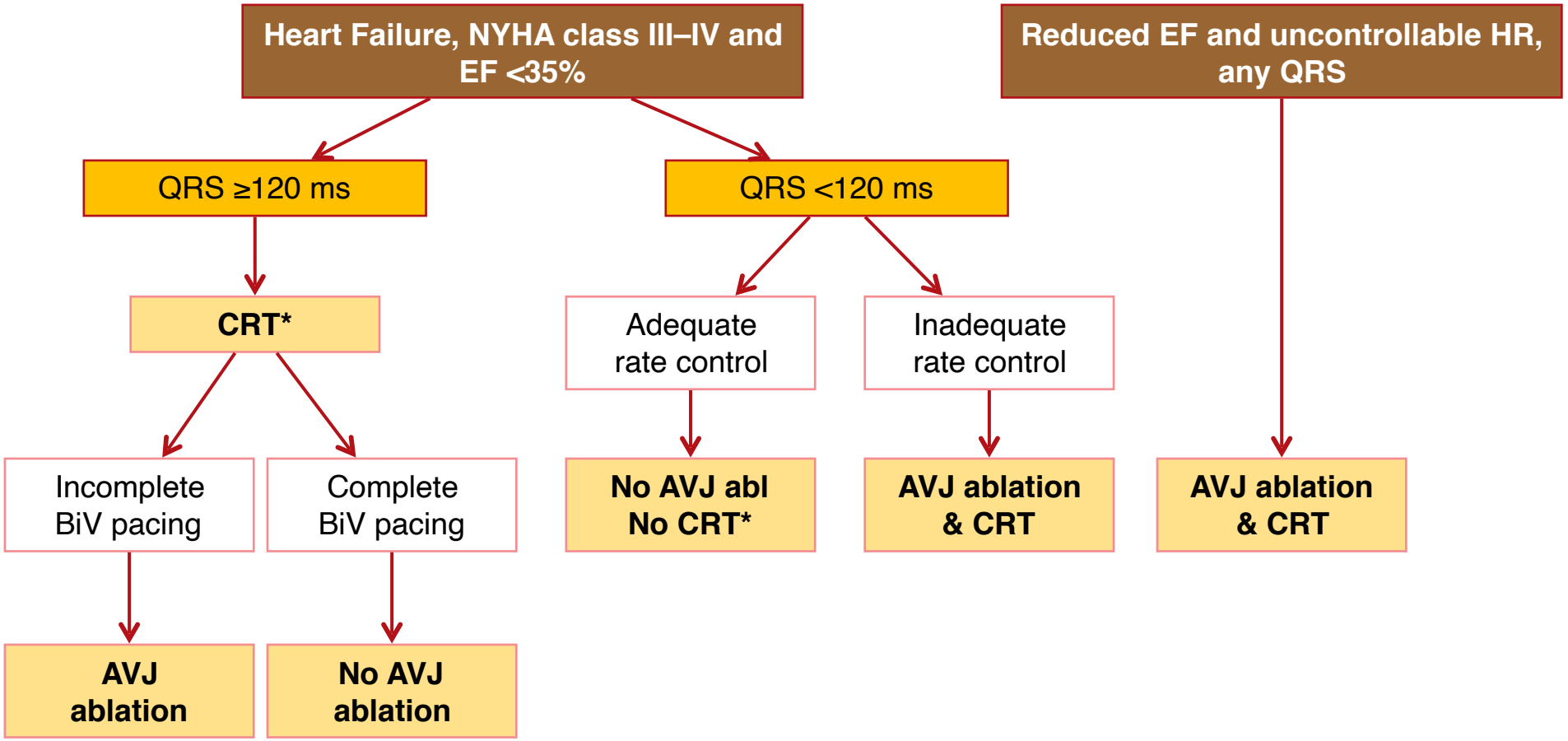
CRT = cardiac resynchronization therapy; LV = left ventricular.

Summary of current evidence for CRT optimization

Parameter	Standard (current practice)	CRT optimization	Additional clinical benefit (compared to standard)
LV lead position	Posterolateral	• Avoid apical • Target latest activated area	Benefit likely (less hospitalization for HF) Benefit likely (one RCT more responders, less hospitalization for HF)
AV delay	Fixed empirical AV interval 120 ms (range 100–120 ms)	• Echo-Doppler: shortest AV delay without truncation of the A-wave (Ritter's method) or change in LV systolic function	• Uncertain or mild (one small RCT and several observational positive)
		• Device-based algorithms (SmartDelay, QuickOpt)	• Uncertain (two RCTs negative)
VV delay	Simultaneous BiV	• Echo: residual LV dyssynchrony	• Uncertain or mild (one RCT showed mild benefit)
		• Echo-Doppler: largest stroke volume	• Uncertain (one RCT negative, one controlled positive)
		• ECG: narrowest LV-paced QRS; difference between BiV and preimplantation QRS	• Unknown (no comparative study)
		• Device-based algorithms (Expert-Ease, Quick-Opt, Peak endocardial acceleration)	• Uncertain (three RCTs negative)
LV pacing alone	Simultaneous BiV	n.a.	Non-inferior

AV = atrioventricular; BiV = biventricular; CRT = cardiac resynchronization therapy; DTI = tissue Doppler imaging; HF = heart failure; LV = left ventricular; n.a. = not available; RCT = randomized controlled trial; VV = interventricular delay.

Indication for atrioventricular junction (AVJ) ablation in patients with symptomatic permanent atrial fibrillation (AF) and optimal pharmacological therapy



*Consider ICD according to guidelines

BiV = biventricular; CRT = cardiac resynchronization therapy; EF = ejection fraction; HR = heart rate; ICD = implantable cardioverter defibrillator; NYHA = New York Heart Association.

Summary of evidence for upgrading from conventional pacemaker or implantable cardioverter defibrillator to cardiac resynchronization therapy devices

Studies	No. of patients	Echo, ESD (%)	Echo, EF (%)	QoL scores (%)	NYHA class (%)	Clinical outcome
RCT, cross-over design, upgraded CRT vs RV						
Hoijer	10	-2	–	Improved	–	Patient's preference: 90% CRT ($P = 0.01$)
Leclercq	32	-4	0	-44	-16	Fewer hospitalizations (4 vs. 17, $P = 0.001$)
van Gerlop	36	-9	+18	-10	-16	Responders, clinically relevant: 53%
Delnoy	40	-31	+30	-19	-26	–
Total	***118***	***-6***	***+17***	***-22***	***-18***	**–**
Observational studies, post-CRT upgrading vs. pre-CRT						
Leon	20	-8	+44	-33	-29	Fewer hospitalizations: –81%
Baker	60	–	+26	-31	-29	–
Valls	14	-8	+17	–	-24	–
Eldadah	12	–	+16	–	–	–
Shimano	18	–	+23	–	-35	Fewer hospitalizations: –81%
Laurenzi	38	-5	+41	-68	-36	Responders, clinically relevant: 84%
Vatankulu	26	-13	+18	–	–	–
Total	***188***	***-7***	***+28***	***-43***	***-31***	
Controlled studies, upgraded CRT vs. de novo CRT*						
Marai	25 vs. 73	-1 vs. -1	+1 vs. +1	–	-0.3 vs. -0.7	NYHA ≥1 class: 76 vs. 42% ($P = 0.01$)
Foley	58 vs. 336	–	+10 vs. +4	Similar	Similar	Responders: 47 vs. 46% Mortality: 27 vs. 26%
Paparella	39 vs. 43	–	+10 vs. +8	–	-1.2 vs. -1.1	Hospitalization: –81 vs. –77% Non-responders: 9 vs. 10%
Frohlich	70 vs. 102	-7 vs. -6	+10 vs. +10	–	–	NYHA ≥1 class: 53 vs. 51% Responders: 56 vs. 56%
EU survey	692 vs. 1675	–	–	–	-1.0 vs. -1.0	At 1-year follow-up: similar mortality (8.6 vs. 7.9%), hospitalization (23 vs. 27%), improved quality of life (27 vs. 20%) and complications (11 vs. 10%)
Total	***884 vs. 2229***	**–**	**–**	**–**	**–**	

**Differences from baseline.*
CRT = cardiac resynchronization therapy; ESD = end-systolic diameter; EF = ejection fraction; ICD = implantable cardioverter defibrillator; NYHA = New York Heart Association; PM = pacemaker; QoL = quality of life; RCT = randomized controlled trial; RV = right ventricle.

Summary of evidence of RCTs of de novo CRT implantation compared with RV apical pacing in patients with conventional indication for anti-bradycardia pacing

Studies	No. of patients	Echo, ESD (%)	Echo, EF (%)	QoL scores (%)	NYHA class (%)	Clinical outcome
Patients with moderate/severe systolic dysfunction, CRT vs RV						
HOBIPACE	30	-9	+22	-19	-24	Patient's preference: 67% CRT, 7% RV (P = 0.0002)
COMBAT	60	-24	-21	-47	-24	Worsening HF or hospitalization: 3 vs. 8 patients
BLOCK HF	691	–	–	–	–	Significant 28% reduction in the combined primary endpoint of mortality, heart-failure related urgent care, and increase in LV end-systolic volume
Patients with preserved systolic function, CRT vs RV						
Albertsen	50	–	+5	–	-17	–
PACE	177	-22	+13	No difference	–	Hospitalization for HF: 6 vs. 7% (ns)
PREVENT-HF	108	-5	+7	–	–	Worsening of HF: 6 vs. 14% (ns)

CRT = cardiac resynchronization therapy; ESV = end-systolic volume; EF = ejection fraction; ICD = implantable cardioverter defibrillator; NYHA = New York Heart Association; PM = pacemaker; QoL = quality of life; RCT = randomized controlled trial; RV = right ventricular; ns = not significant.

Indication for concomitant implantable cardioverter defibrillator (cardiac resynchronization therapy and defibrillator)

Recommendations	Class	Level
1) When an ICD is planned,* a CRT is recommended when indicated.	I	A
2) When a CRT is planned, implantation of CRT-D device should be considered in patients with clinical conditions listed in *Table 17*.	IIa	B

CRT = cardiac resynchronization therapy; CRT-D = CRT and defibrillator; CRT-P = CRT and pacemaker; ICD = implantable cardioverter defibrillator.
**According to present ICD guidelines.*

Klinická doporučení pro výběr biventrikulárního kardiostimulátoru/ defibrilátoru v primární prevenci

Faktory upřednostňující biventrikulární defibrilátor	Faktory upřednostňující biventrikulární kardiostimulátor
Předpoklad přežití >1 rok	Pokročilé srdeční selhání
Stabilní srdeční selhání - NYHA II	Závažné ledvinné selhání nebo potřeba dialýzy
Ischemická choroba srdeční	Jiné závažné ko-morbidity
Nízké a střední rizikové skóre ze studie MADIT (0-2 z následujících RF): třída NYHA > II,věk >70 let, přít.FIS, QRS > 0,12, urea > 9,23 mmol/l	Celková zesláblost
Chybění komorbidit	Kachexie

Comparative results of CRT-D vs. CRT-P in primary prevention

	CRT-D	CRT-P
Mortality reduction	Similar level of evidence but CRT-D slightly better	Similar level of evidence but CRT-P slightly worse
Complications	Higher	Lower
Costs	Higher	Lower

CRT-D = cardiac resynchronization therapy and defibrillator; CRT-P = cardiac resynchronization therapy and pacemaker.

ECHO-CRT Studie

ORIGINAL ARTICLE

Cardiac-Resynchronization Therapy in Heart Failure with a Narrow QRS Complex

Frank Ruschitzka, M.D., William T. Abraham, M.D., Jagmeet P. Singh, M.D., Ph.D., Jeroen J. Bax, M.D., Ph.D., Jeffrey S. Borer, M.D., Josep Brugada, M.D., Ph.D., Kenneth Dickstein, M.D., Ph.D., Ian Ford, M.D., Ph.D., John Gorcsan III, M.D., Daniel Gras, M.D., Henry Krum, M.B., B.S., Ph.D., Peter Sogaard, M.D., D.M.Sc., and Johannes Holzmeister, M.D., for the EchoCRT Study Group*

ABSTRACT

BACKGROUND

Cardiac-resynchronization therapy (CRT) reduces morbidity and mortality in chronic systolic heart failure with a wide QRS complex. Mechanical dyssynchrony also occurs in patients with a narrow QRS complex, which suggests the potential usefulness of CRT in such patients.

METHODS

We conducted a randomized trial involving 115 centers to evaluate the effect of CRT in patients with New York Heart Association class III or IV heart failure, a left ventricular ejection fraction of 35% or less, a QRS duration of less than 130 msec, and echocardiographic evidence of left ventricular dyssynchrony. All patients underwent device implantation and were randomly assigned to have CRT capability turned on or off. The primary efficacy outcome was the composite of death from any cause or first hospitalization for worsening heart failure.

RESULTS

On March 13, 2013, the study was stopped for futility on the recommendation of the data and safety monitoring board. At study closure, the 809 patients who had undergone randomization had been followed for a mean of 19.4 months. The primary outcome occurred in 116 of 404 patients in the CRT group, as compared with 102 of 405 in the control group (28.7% vs. 25.2%; hazard ratio, 1.20; 95% confidence interval [CI], 0.92 to 1.57; P=0.15). There were 45 deaths in the CRT group and 26 in the control group (11.1% vs. 6.4%; hazard ratio, 1.81; 95% CI, 1.11 to 2.93; P=0.02).

CONCLUSIONS

In patients with systolic heart failure and a QRS duration of less than 130 msec, CRT does not reduce the rate of death or hospitalization for heart failure and may increase mortality. (Funded by Biotronik and GE Healthcare; EchoCRT ClinicalTrials.gov number, NCT00683696.)

From the Clinic for Cardiology, University Hospital Zurich, Zurich, Switzerland (F.R., J.H.); the Division of Cardiovascular Medicine, Ohio State University Medical Center, Davis Heart and Lung Research Institute, Columbus (W.T.A.); Cardiac Arrhythmia Service, Massachusetts General Hospital, Harvard Medical School, Boston (J.P.S.); the Department of Cardiology, Leiden University Medical Center, Leiden, the Netherlands (J.J.B.); the Division of Cardiovascular Medicine and Howard Gilman and Ron and Jean Schiavone Institutes, State University of New York (Downstate College of Medicine, New York (J.S.B.); Cardiology Department, Thorax Institute, Hospital Clinic, University of Barcelona, Barcelona (J.B.); University of Bergen, Stavanger University Hospital, Stavanger, Norway (K.D.); Robertson Centre for Biostatistics, University of Glasgow, Glasgow, United Kingdom (I.F.); University of Pittsburgh, Pittsburgh (J.G.); Nouvelles Cliniques Nantaises, Nantes, France (D.G.); Monash Centre of Cardiovascular Research and Education in Therapeutics, Melbourne, VIC, Australia (H.K.); and Aalborg University, Aalborg, Denmark (P.S.). Address reprint requests to Dr. Holzmeister at the Clinic for Cardiology, University Hospital Zurich, Raemistr. 100, CH-8091 Zurich, Switzerland, or at johannes.holzmeister@usz.ch.

Drs. Ruschitzka and Holzmeister and Drs. Abraham and Singh contributed equally to this article.

*Participating centers and investigators in the Echocardiography-Guided Cardiac Resynchronization Therapy (EchoCRT) study are listed in the Supplementary Appendix, available at NEJM.org.

This article was published on September 3, 2013, at NEJM.org.

N Engl J Med 2013.
DOI: 10.1056/NEJMoa1306687

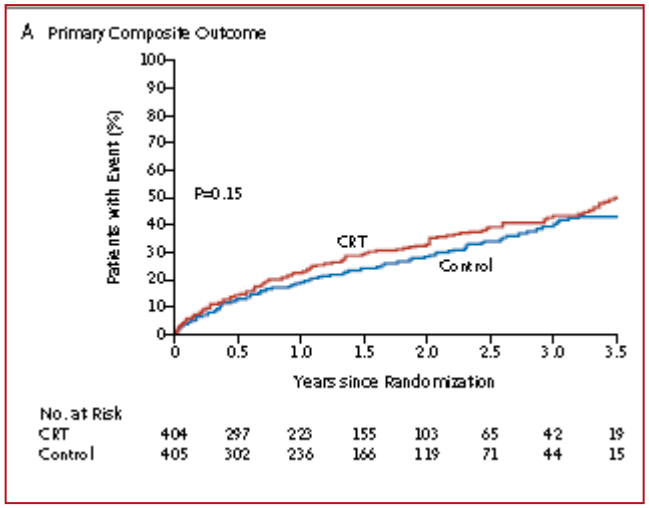
Ruschitzka F. NEJM 2013

KOMPLEXNÍ KARDIOVASKULÁRNÍ CENTRUM
FAKULTNÍ NEMOCNICE OLOMOUC

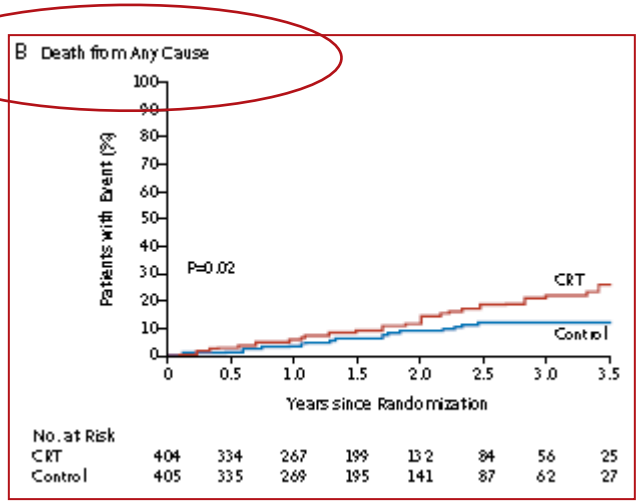
Lékařská fakulta Univerzity Palackého v Olomouci

I. INTERNÍ KLINIKA KARDIOLOGICKÁ
FAKULTNÍ NEMOCNICE OLOMOUC

ECHO-CRT Studie



Primární kompozitní endpoint:
Úmrtí nebo hospitalizace pro srdeční selhání



FAKULTNÍ NEMOCNICE® OLOMOUC

Lékařská fakulta
Univerzita Palackého v Olomouci

KOMPLEXNÍ KARDIOVASKULÁRNÍ CENTRUM
FAKULTNÍ NEMOCNICE OLOMOUC

V: Další indikační skupiny

Indications for pacing therapy in paediatric patients and congenital heart disease

Recommendations	Class	Level
1) **Congenital AV block.** Pacing is indicated in high degree and complete AV block in symptomatic patients and in asymptomatic patients with any of the following risk conditions: ventricular dysfunction, prolonged QTc interval, complex ventricular ectopy, wide QRS escape rhythm, ventricular rate <50 b.p.m., ventricular pauses >three-fold the cycle length of the underlying rhythm.	I	C
2) **Congenital AV block.** Pacing may be considered in asymptomatic patients with high degree and complete AV block in absence of the above risk conditions.	IIb	C
3) **Postoperative AV block in congenital heart disease.** Permanent pacing is indicated for postoperative advanced second degree or complete AV block persisting >10 days.	I	B
4) **Postoperative AV block in congenital heart disease.** Permanent pacing should be considered for persistent, asymptomatic post-surgical bifascicular block (with or without PR prolongation) associated with transient, complete AV block.	IIa	C
5) **Sinus node disease.** Permanent pacing is indicated for symptomatic sinus node disease, including brady-tachy syndrome, when a correlation between symptoms and bradycardia is judged to be established.	I	C
6) **Sinus node disease.** Permanent pacing may be useful for asymptomatic resting heart rate <40 b.p.m. or ventricular pauses lasting >3 sec.	IIb	C

AV = atrioventricular

Indication for cardiac pacing in patients with hypertrophic cardiomyopathy

Recommendations	Class	Level
1) Left ventricular outflow tract obstruction. Sequential AV pacing with short AV interval may be considered in selected patients with resting or provocable LV outflow tract obstruction and drug-refractory symptoms who: **a)** have contraindications for septal alcohol ablation or septal myectomy;	IIb	B
or **b)** or are at high risk of developing heart block following septal alcohol ablation or septal myectomy.	IIb	C
2) For patients in whom there is an indication for an ICD, a dual-chamber ICD should be considered	IIa	C

AV = atrioventricular

Pacing in pregnancy

Recommendations	Class	Level
Implantation of permanent pacemakers (preferably one chamber) should be considered with echocardiographical guidance, especially if the foetus is beyond 8 weeks gestation in selected women with symptomatic complete AV block.	IIa	C

Klíčová úloha ICE

Indication for pacing for first-degree atrioventricular block

Recommendations	Class	Level
Permanent pacemaker implantation should be considered for patients with persistent symptoms similar to those of pacemaker syndrome and attributable to first-degree atrioventricular block (PR >0.3 s).	IIa	C

Indication for prevention and termination of atrial tachyarrhythmias

Recommendations	Class	Level
***De novo* indications.** Prevention and termination of atrial tachyarrhythmias does not represent a stand-alone indication for pacing	III	A

Summary of randomized clinical studies of specific algorithms for prevention and termination of atrial tachyarrhythmias in patients with conventional brady indications and atrial tachyarrhythmias/fibrillation

Trial	Study design	Algorithm/s	No. of patients	Effect on AF burden	Clinical result
ADOPT	Parallel	Rate-adaptive pacing at high rest rate	288	25% decrease in symptomatic AF burden ($P = 0.005$)	No change in quality of life, hospitalizations and adverse events
PIRAT	Cross-over	Post-mode switch overdrive pacing	37	No change in AT episodes, AT burden	No change in number of symptoms and quality of life
ATTEST	Parallel	Atrial preference Atrial rate stabilization Post-mode switch overdrive pacing ATP therapy	324	No difference in AT/AF burden and frequency	Not assessed
PIPAF	Cross-over	SR overdrive Post-extrasystolic pause suppression Acceleration after premature atrial beats	28	No change in mode-switch episodes and % A/V pacing	No difference in symptom score
PAFS	Cross-over	Rate-smoothing, Rate stabilization	182	No change	No change in episode number, quality of life, or symptoms
AOPS	Cross-over	Rate-adaptive pacing at high rest rate	99	No change in mode-switch episodes	No change in symptoms of arrhythmia
POT	Cross-over	Atrial preference Atrial rate stabilization Post-mode switch overdrive pacing ATP therapy	85	72% decrease in AF burden with preventive algorithms, no further reduction with ATP therapy	Not assessed
SAFARI	Parallel	Combination of six triggered and continuous overdrive prevention pacing therapies	240	Slight reduction in AF burden (0.08 h/day, $P = 0.03$)	Not assessed
ASSERT	Parallel	Atrial overdrive pacing	2343	No difference in device-detected AT	No difference in symptomatic and asymptomatic AT. No difference in stroke, hospitalization and death

AF = atrial fibrillation; AT = atrial tachyarrhythmias; ATP = anti-tachycardia pacing; SR = sinus rhythm

FAKULTNÍ NEMOCNICE® OLOMOUC

Lékařská fakulta
Univerzita Palackého v Olomouci

KOMPLEXNÍ KARDIOVASKULÁRNÍ CENTRUM
FAKULTNÍ NEMOCNICE OLOMOUC

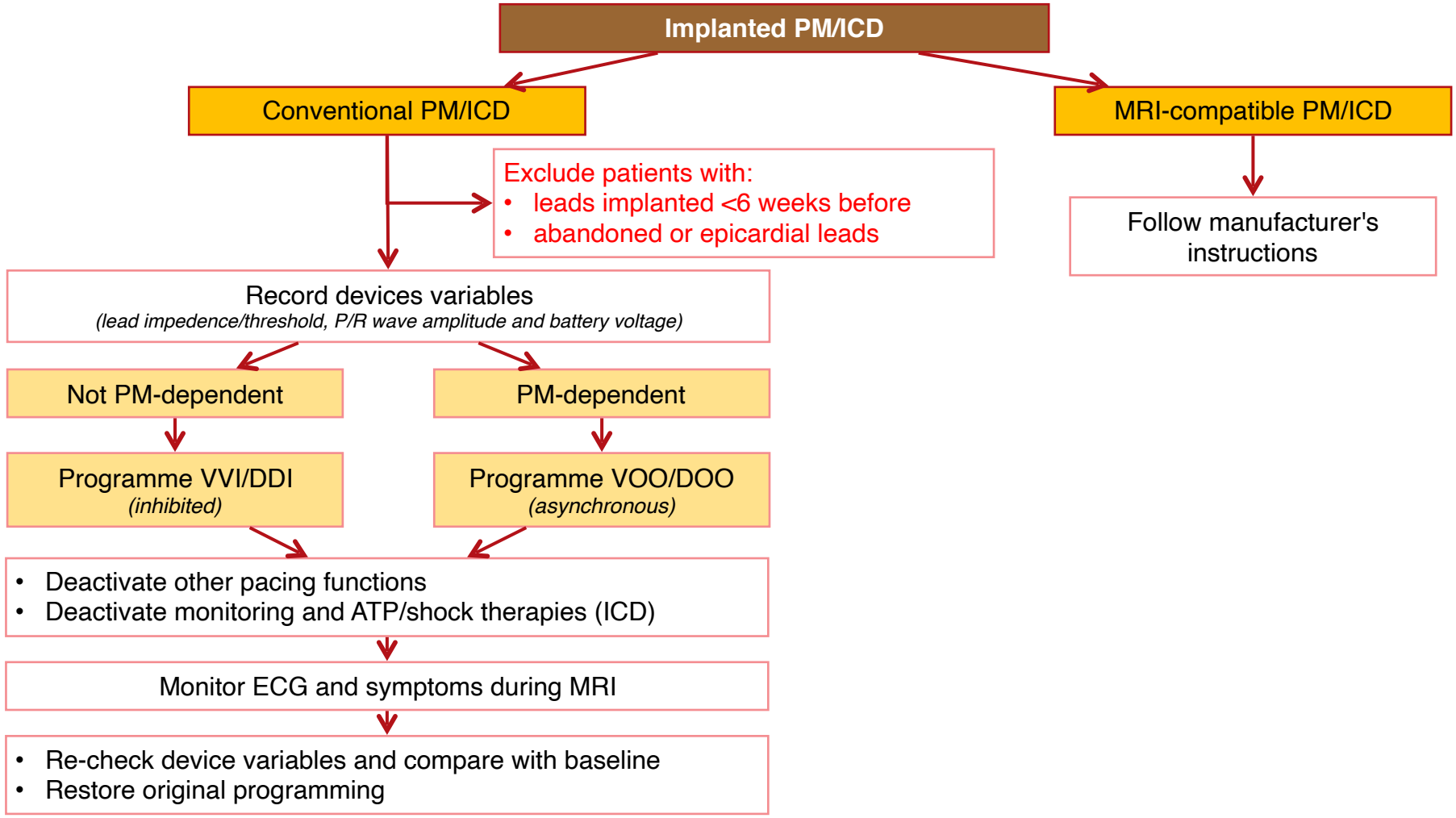
VI: Implantáty a MRI

Magnetic resonance in patients with implanted cardiac devices

Recommendations	Class	Level
1) Conventional cardiac devices. In patients with conventional cardiac devices, MR at 1.5 T can be performed with a low risk of complications if appropriate precautions are taken (see additional advice).	IIb	B
2) MR-conditional PM systems. In patients with MR-conditional PM systems, MR at 1.5 T can be done safely following manufacturer instructions.	IIa	B

MRI = magnetic resonance imaging; PM = pacemaker

Safety precautions for magnetic resonance imaging (MRI) in patients with conventional cardiac devices.



ATP = anti-tachycardiac pacing; ECG = electrocardiogram; ICD = implantable cardioverter defibrillator; PM = pacemaker. Adapted from Nazarian et al.

FAKULTNÍ NEMOCNICE® OLOMOUC

Lékařská fakulta
Univerzita Palackého v Olomouci

KOMPLEXNÍ KARDIOVASKULÁRNÍ CENTRUM
FAKULTNÍ NEMOCNICE OLOMOUC

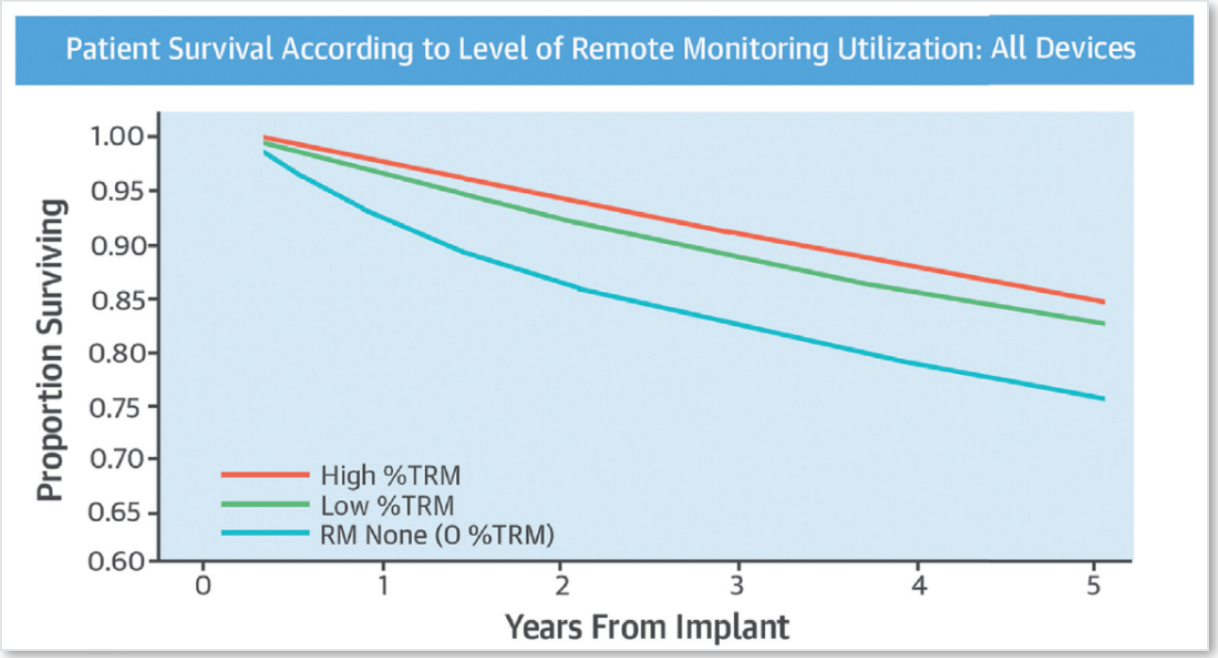
VII: Dálková monitorace pacientů s KS a ICD

Remote management of arrhythmias and device

Recommendations	Class	Level
Device-based remote monitoring should be considered in order to provide earlier detection of clinical problems (e.g. ventricular tachyarrhythmias, atrial fibrillation) and technical issues (e.g. lead fracture, insulation defect).	IIa	A

High rate of transmission (>75%) is associated with a mortality benefit for all devices

- Registry of 269,471 US patients using SJM Merlin
- Improved survival associated with remote monitoring with all devices graded to level of adherence
- Only 25% of patients had „high transmission“ >75%



Varma et al.; Relationship Between Level of Adherence to Automatic Wireless Remote Monitoring and Survival in Pacemaker and Defibrillator Patients; JACC 2015

HRS Consensus Statement recommends remote monitoring & interrogation for all devices (class 1A)

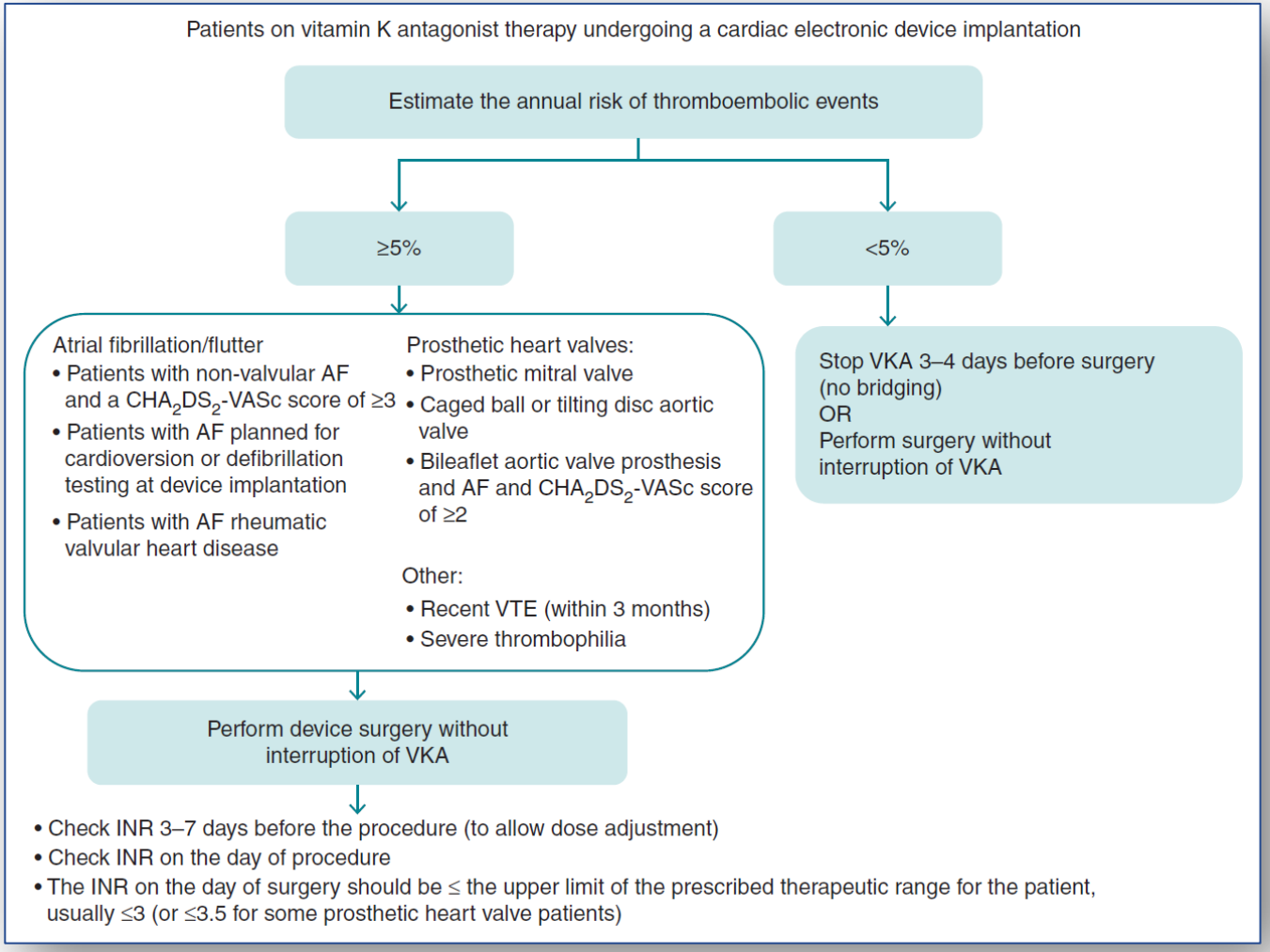
- New Class 1A recommendation for remote interrogation and monitoring of all device patients (including IPGs)
- The consensus paper highlighted also the recent findings (Varma et al) regarding the "dose dependency" of remote monitoring, ie. the higher the transmission success the greater the survival advantage.

HRS Remote Monitoring Consensus Statement Recommendations

Device Follow-up Paradigm	Class of Recommendation	Level of Evidence
A strategy of remote CIED monitoring and interrogation, combined with at least annual IPE, is recommended over a calendar-based schedule of in-person CIED evaluation alone (when technically feasible).	I	A
All patients with CIEDs should be offered RM as part of the standard follow-up management strategy.	I	A

Slotwiner et al.; HRS Expert Consensus Statement on Remote Interrogation and Monitoring for Cardiovascular Electronic Implantable Devices; Heart Rhythm 2015

Algorithm for peri-device surgery anticoagulation for patients on a VKA (note exceptions to operating without interruption of VKA include sub-pectoral implants and lead extraction). AF, atrial fibrillation; VKA, vitamin K antagonist; VTE, venous thromboembolism.



Sticherling C., et al. Europace. 2015;17,1197-1214.

VII: Komplikace trvalé kardiostimulace

Závažné	Méně klinicky závažné
Perforace PK s tamponádou	Hematom v kapse KS
Disekce koronárního sinu	Penetrující elektroda
Implantace EL do LK	Displacement elektrod
Bakteriální endokarditis	Porucha izolace EL
Rozsáhlý hematom (kapsa + TH)	Vrcholový/plášťový PNO
Rozsáhlý pneumothorax	Twiddlers sy…

Doporučené postupy pro extrakci KS/ICD/CRT

Absolutní indikace infekce:

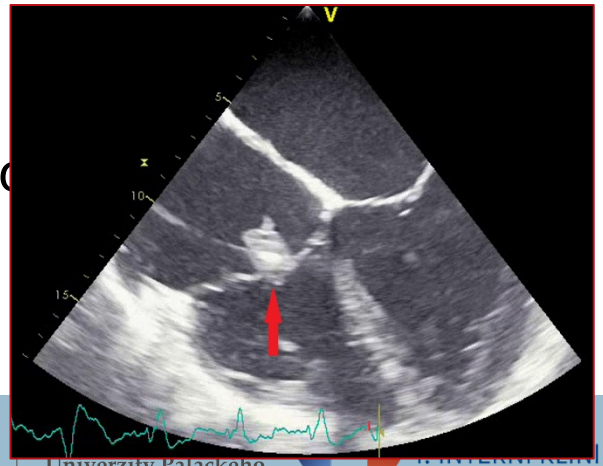
Class I

1. Complete device and lead removal is recommended in all patients with definite CIED system infection, as evidenced by valvular endocarditis, lead endocarditis or sepsis. (Level of evidence: B)
2. Complete device and lead removal is recommended in all patients with CIED pocket infection as evidenced by pocket abscess, device erosion, skin adherence, or chronic draining sinus without clinically evident involvement of the transvenous portion of the lead system. (Level of evidence: B)
3. Complete device and lead removal is recommended in all patients with valvular endocarditis without definite involvement of the lead(s) and/or device. (Level of evidence: B)
4. Complete device and lead removal is recommended in patients with occult gram-positive bacteremia (not contaminant). (Level of evidence: B)

VIII: Reimplantace po extrakci

- Reimplantace je u nemocnych léčených pro infekci KS/BiV přistroje zdrojem vyznamnych pot. problémů.
- Proto by mělo byt rozhodnuti reimplantovat přistroj pečlivě zváženo a indikace opětovně přehodnocena.
- Nový KS nebo CRT přístroj by měl byt implantován na odlišne misto, než byl explantovaný infikovany system.
- Optimalni načasovani reimplantace neni znamo.
- U pacientů dependentnich na stimulaci je nutno ponechat transvenozni dočasnou stimulaci až do reimplantace.
- 2015 Guidelines ESC pro infekční endokarditidu (Guidelines on infective endocarditis) doporučuji vyhýbat se dočasnée stimulaci, pokud je to možné

- 3 specializovaná centra: NNH, IKEM a Olomouc



FAKULTNÍ NEMOCNICE® OLOMOUC

Lékařská fakulta
Univerzita Palackého v Olomouci

KOMPLEXNÍ KARDIOVASKULÁRNÍ CENTRUM
FAKULTNÍ NEMOCNICE OLOMOUC

IX: Lealess pacing

Inovativní technologie kardiostimulace

První studie bezelektrodové stimulace

J. ELECTROCARDIOLOGY, 3 (3-4) 325-331 (1970)

Special Article

Totally Self-Contained Intracardiac Pacemaker*

J. WILLIAM SPICKLER, PH.D., NED S. RASOR, PH.D.†, PAUL KEZDI, M.D.
S. N. MISRA, M.D., K. E. ROBINS, P.E., AND CHARLES LeBOEUF, P.E.

SUMMARY

Recent developments in miniature long-life power sources and electronics, such as nuclear batteries and integrated circuits make feasible a new generation of pacemakers, the intracardiac pacemaker (IC), i.e., a completely self-contained pacemaker implanted inside

circuits have been improved substantially. In addition, the development of the endocardial catheter electrode has broadened the choice of operative procedures to include a larger portion of the patient population. Two major problems that still exist with conventional pacemakers are perforation or dislocation of the transvenous electrode and the short life of

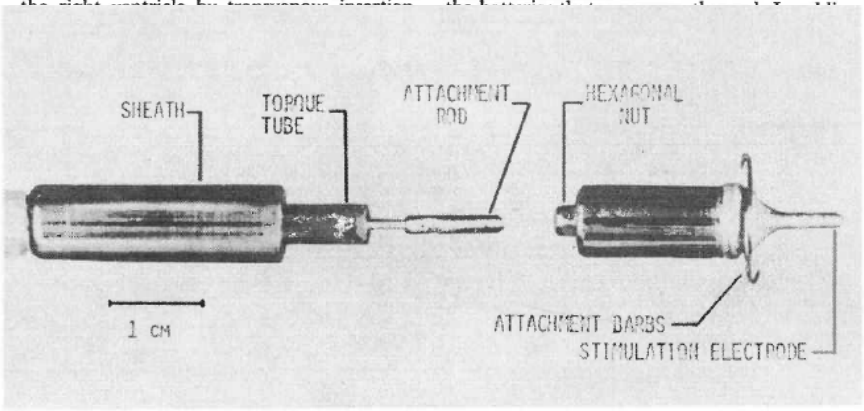


Fig. 4. Intracardiac pacemaker with catheter for transvenous insertion.

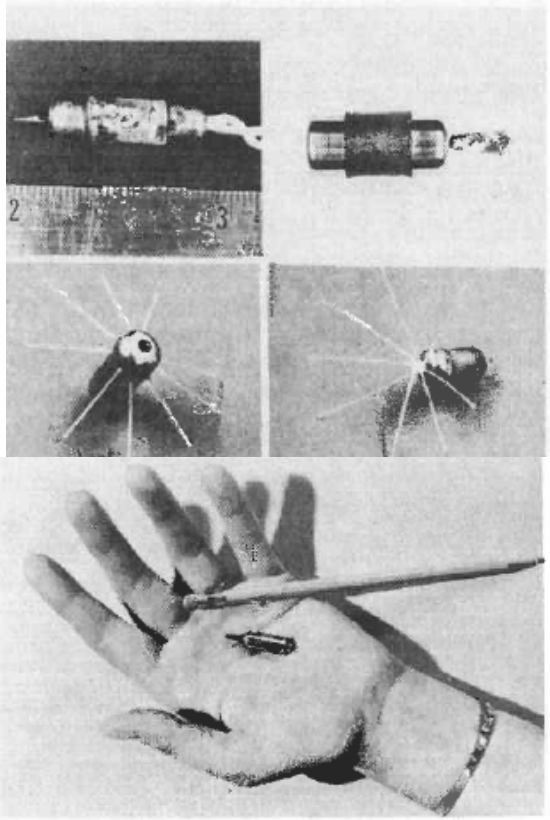
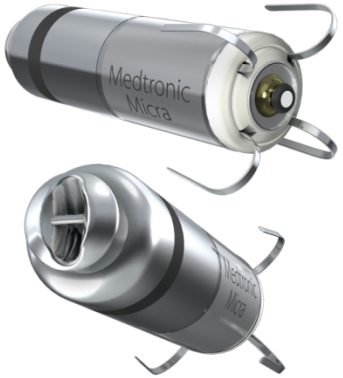


Fig. 8. Nuclear-powered intracardiac pacemaker.

2 technologie vyvíjené v EU /USA

- MICRA, Medtronic , INC



N Engl J Med 2016;374:533-41.
DOI: 10.1056/NEJMoa1511643

NANOSTIM, SJM, IN

N Engl J Med 2015; 373:1125-1135.
DOI: 10.1056/NEJMoa1507192

LEADLESS II Study

Percutaneous Implantation of an Entirely Intracardiac Leadless Pacemaker

Vivek Y. Reddy, M.D., Derek V. Exner, M.D., M.P.H., Daniel J. Cantillon, M.D., Rahul Doshi, M.D., T. Jared Bunch, M.D., Gery F. Tomassoni, M.D., Paul A. Friedman, M.D., N.A. Mark Estes, III, M.D., John Ip, M.D., Imran Niazi, M.D., Kenneth Plunkitt, M.D., Rajesh Banker, M.D., James Porterfield, M.D., James E. Ip, M.D., and Srinivas R. Dukkipati, M.D., for the LEADLESS II Study Investigators*

ABSTRACT

BACKGROUND

Cardiac pacemakers are limited by device-related complications, notably infection and problems related to pacemaker leads. We studied a miniaturized, fully self-contained leadless pacemaker that is nonsurgically implanted in the right ventricle with the use of a catheter.

METHODS

In this multicenter study, we implanted an active-fixation leadless cardiac pacemaker in patients who required permanent single-chamber ventricular pacing. The primary efficacy end point was both an acceptable pacing threshold (≤2.0 V at 0.4 msec) and an acceptable sensing amplitude (R wave ≥5.0 mV, or a value equal to or greater than the value at implantation) through 6 months. The primary safety end point was freedom from device-related serious adverse events through 6 months. In this ongoing study, the prespecified analysis of the primary end points was performed on data from the first 300 patients who completed 6 months of follow-up (primary cohort). The rates of the efficacy end point and safety end point were compared with performance goals (based on historical data) of 85% and 86%, respectively. Additional outcomes were assessed in all 526 patients who were enrolled as of June 2015 (the total cohort).

RESULTS

The leadless pacemaker was successfully implanted in 504 of the 526 patients in the total cohort (95.8%). The intention-to-treat primary efficacy end point was met in 270 of the 300 patients in the primary cohort (90.0%; 95% confidence interval [CI], 86.0 to 93.2, P=0.007), and the primary safety end point was met in 280 of the 300 patients (93.3%; 95% CI, 89.9 to 95.9; P<0.001). At 6 months, device-related serious adverse events were observed in 6.7% of the patients; events included device dislodgement with percutaneous retrieval (in 1.7%), cardiac perforation (in 1.3%), and pacing-threshold elevation requiring percutaneous retrieval and device replacement (in 1.3%).

CONCLUSIONS

The leadless cardiac pacemaker met prespecified pacing and sensing requirements in the large majority of patients. Device-related serious adverse events occurred in approximately 1 in 15 patients. (Funded by St. Jude Medical; LEADLESS II ClinicalTrials.gov number, NCT02030418.)

Characteristic	Primary Cohort (N=300)	Total Cohort (N=526)
Procedural characteristics§		
Duration of implantation — min		
Total: sheath insertion to removal	50.0±27.3	46.5±25.3
Procedure: insertion of delivery catheter to removal	30.4±18.2	28.6±17.8
Duration of fluoroscopy — min	14.9±9.4	13.9±9.1
Device repositioning — no. of patients/total no. (%)		
None	199/289 (68.9)	354/504 (70.2)
1	53/289 (18.3)	89/504 (17.7)
2	24/289 (8.3)	39/504 (7.7)
>2	13/289 (4.5)	22/504 (4.4)
Final device position in right ventricle — no. of patients/total no. (%)		
Apex	140/289 (48.4)	192/504 (38.1)
Apical septum	5/289 (1.7)	96/504 (19.0)
Outflow, septum, or other	144/289 (49.8)	215/504 (42.7)
Missing data	0/289	1/504 (0.2)

Total	22	20	6.7	40	34	6.5
Cardiac perforation						
Cardiac tamponade with intervention	1	1	0.3	5	5	1.0
Cardiac perforation requiring intervention	1	1	0.3	1	1	0.2
Pericardial effusion with no intervention	2	2	0.7	2	2	0.4
Vascular complication						
Bleeding	2	2	0.7	2	2	0.4
Arteriovenous fistula	1	1	0.3	1	1	0.2
Pseudoaneurysm	1	1	0.3	2	2	0.4
Failure of vascular closure device requiring intervention	0	0	0	1	1	0.2
Arrhythmia during device implantation						
Asystole	1	1	0.3	1	1	0.2
Ventricular tachycardia or ventricular fibrillation	1	1	0.3	2	2	0.4
Cardiopulmonary arrest during implantation procedure	0	0	0	1	1	0.2
Device dislodgement	5	5	1.7	6	6	1.1
Device migration during implantation owing to inadequate fixation	0	0	0	2	2	0.4
Pacing threshold elevation with retrieval and implantation of new device	4	4	1.3	4	4	0.8

DOI: 10.1056/NEJMoa1507192

MICRA Study

Early performance of a miniaturized leadless cardiac pacemaker: the Micra Transcatheter Pacing Study

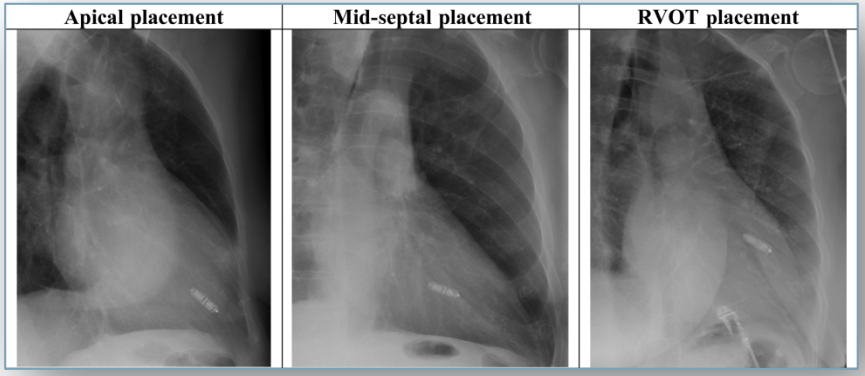
Philippe Ritter[1]*, Gabor Z. Duray[2], Clemens Steinwender[3], Kyoko Soejima[4], Razali Omar[5], Lluís Mont[6], Lucas VA Boersma[7], Reinoud E. Knops[8], Larry Chinitz[9], Shu Zhang[10], Calambur Narasimhan[11], John Hummel[12], Michael Lloyd[13], Timothy Alexander Simmers[14], Andrew Voigt[15], Verla Laager[16], Kurt Stromberg[16], Matthew D. Bonner[16], Todd J. Sheldon[16], and Dwight Reynolds[17], Micra Transcatheter Pacing Study Group

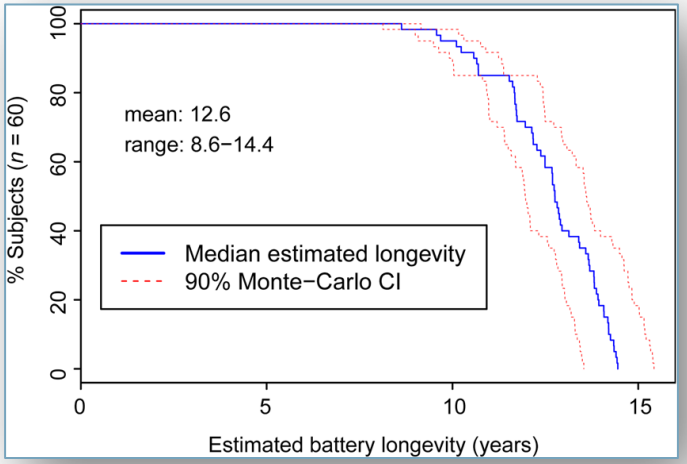
[1]Hôpital Cardiologique du Haut-Lévêque, CHU Bordeaux, Université Bordeaux, IHU LIRYC, Bordeaux, France; [2]Clinical Electrophysiology Department of Cardiology, Medical Centre, Hungarian Defence Forces, Budapest, Hungary; [3]Department of Cardiology, Linz General Hospital, Johannes Kepler University School of Medicine Linz, Linz, Austria; [4]Department of Cardiology, Kyorin University Hospital, Tokyo, Japan; [5]Electrophysiology and Pacing Unit, National Heart Institute, Kuala Lumpur, Malaysia; [6]Hospital Clínic, Universitat de Barcelona, Catalonia, Spain; [7]St Antonius Ziekenhuis, Nieuwegein, the Netherlands; [8]Academisch Medisch Centrum (AMC), Amsterdam, the Netherlands; [9]New York University, New York, NY, USA; [10]State Key Laboratory of Cardiovascular Disease Fuwai Hospital, National Center for Cardiovascular Disease, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China; [11]Division of Electrophysiology, Department of Cardiology, CARE Hospitals and CARE Foundation, Hyderabad, India; [12]The Ohio State University, Columbus, OH, USA; [13]Emory University Hospital, Atlanta, GA, USA; [14]Catharina Ziekenhuis, Eindhoven, the Netherlands; [15]University of Pittsburgh Medical Center UPMC Presbyterian, Pittsburgh, PA, USA; [16]Medtronic plc, Mounds View, MN, USA; and [17]Cardiovascular Section, University of Oklahoma Health Sciences Center, OU Medical Center, Oklahoma City, OK, USA

Received 9 February 2015; revised 30 March 2015; accepted 4 May 2015; online publish-ahead-of-print 4 June 2015

See page 2520 for the editorial comment on this article (doi:10.1093/eurheartj/ehv261)

Aims	Permanent cardiac pacing is the only effective treatment for symptomatic bradycardia, but complications associated with conventional transvenous pacing systems are commonly related to the pacing lead and pocket. We describe the early performance of a novel self-contained miniaturized pacemaker.
Methods and results	Patients having Class I or II indication for VVI pacing underwent implantation of a Micra transcatheter pacing system, from the femoral vein and fixated in the right ventricle using four protractible nitinol tines. Prespecified objectives were >85% freedom from unanticipated serious adverse device events (safety) and <2 V 3-month mean pacing capture threshold at 0.24 ms pulse width (efficacy). Patients were implanted ($n = 140$) from 23 centres in 11 countries (61% male, age 77.0 ± 10.2 years) for atrioventricular block (66%) or sinus node dysfunction (29%) indications. During mean follow-up of 1.9 ± 1.8 months, the safety endpoint was met with no unanticipated serious adverse device events. Thirty adverse events related to the system or procedure occurred, mostly due to transient dysrhythmias or femoral access complications. One pericardial effusion without tamponade occurred after 18 device deployments. In 60 patients followed to 3 months, mean pacing threshold was 0.51 ± 0.22 V, and no threshold was ≥2 V, meeting the efficacy endpoint ($P < 0.001$). Average R-wave was 16.1 ± 5.2 mV and impedance was 650.7 ± 130 ohms.
Conclusion	Early assessment shows the transcatheter pacemaker can safely and effectively be applied. Long-term safety and benefit of the pacemaker will further be evaluated in the trial.
Clinical Trial Registration	ClinicalTrials.gov ID NCT02004873.





European Heart Journal (2015) ***36****, 2510-2519*
doi:10.1093/eurheartj/ehv214

KOMPLEXNÍ KARDIOVASKULÁRNÍ CENTRUM
FAKULTNÍ NEMOCNICE OLOMOUC

Lékařská fakulta Univerzity Palackého v Olomouci

I. INTERNÍ KLINIKA KARDIOLOGICKÁ
FAKULTNÍ NEMOCNICE OLOMOUC

Indikace bezelektrodové stimulace

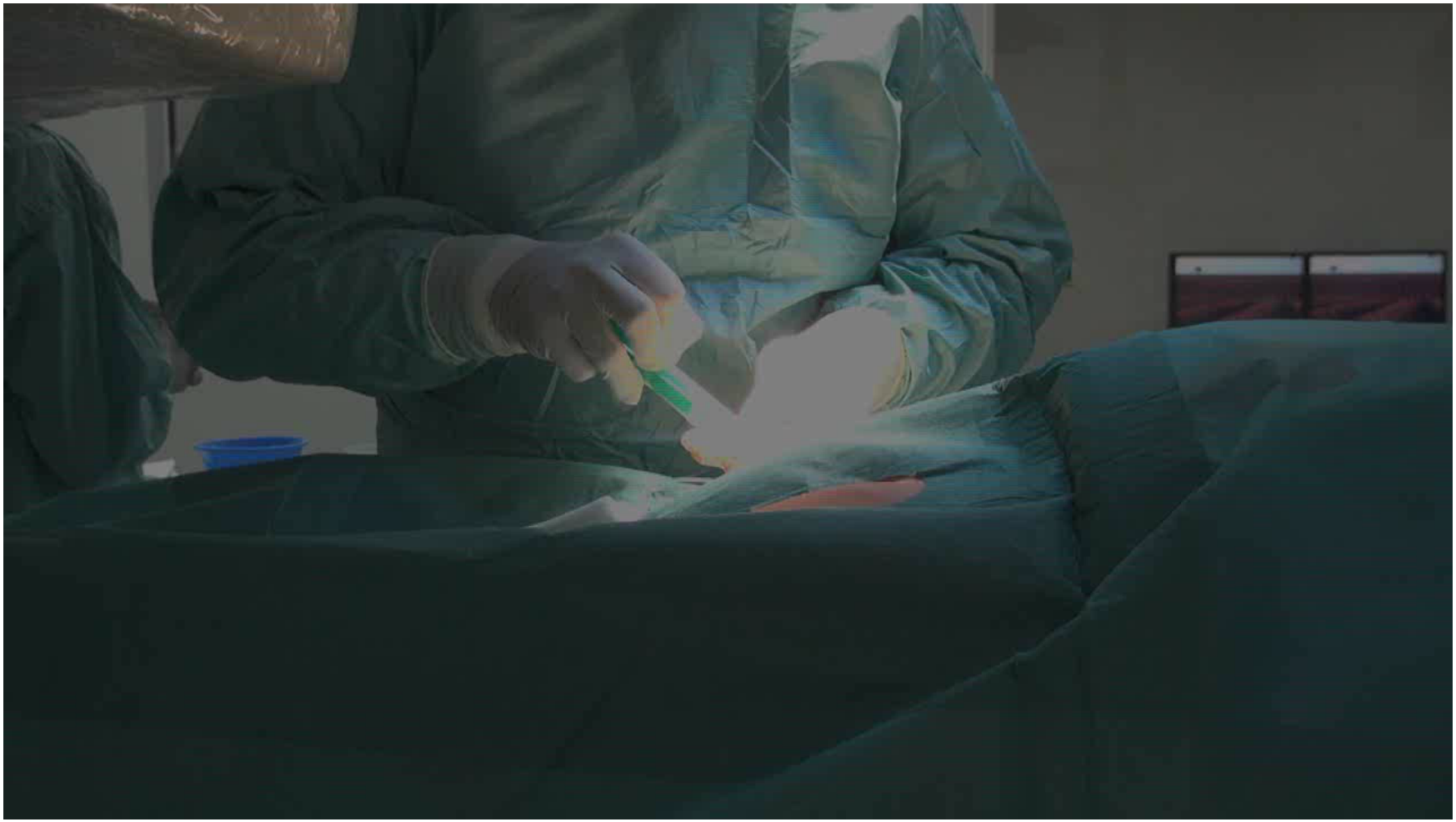
- Indikace VVI/VVIR stimulace dle Doporučených postupů ESC/ČKS
- Pacienti s velmi obtížným žilním přístupem pro konvenční typ stimulace
- Pacienti po závažné komplikaci TKS (bakteriální endokarditis, extrakce KS pro infekční komplikace, extrakce KS pro mechanickou poruchu elektrody, závažné krvácivé komplikace aj.)
- Pacienti po srdeční transplantaci s indikací intermitentní stimulace

Cor et Vasa 2014: http://www.sciencedirect.com/science/article/pii/S0010865013001392

Budoucnost leadless PM

- Současná doba = 1. generace
- 2. generace : DDDR KS
  - 2 různé koncepty
  - a: VDD – sensor A aktivity – MDT
  - b: 2 PM – A+ V – SJM, Biotronik
- 3. generace: CRT – LL PM + nástupce např. WISE
- Samostatná technologie: SQ ICD + LL PM – Boston Scientific

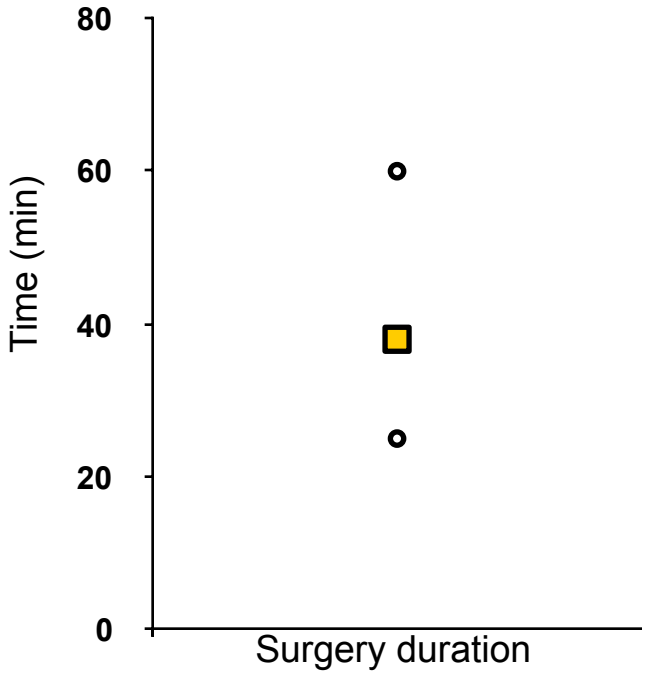
Implantace systému MICRA

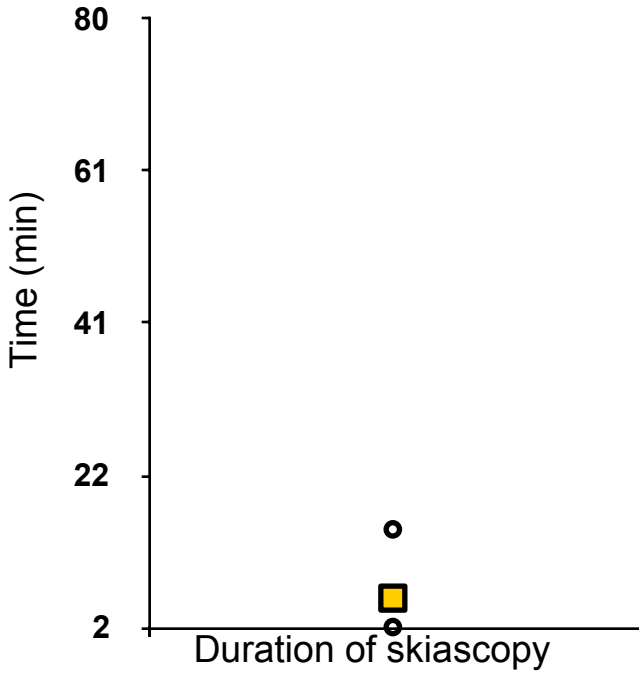


Trvání výkonu a skiaskopický čas

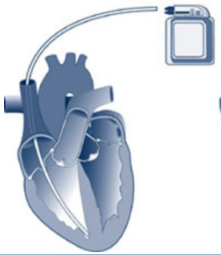
Time (minutes)	Surgery duration
N	38
5% percentile	25
Median	38
95% percentile	60

Time (minutes)	Duration of skiascopy
N	38
5% percentile	2.1
Median	5.8
95% percentile	14.6



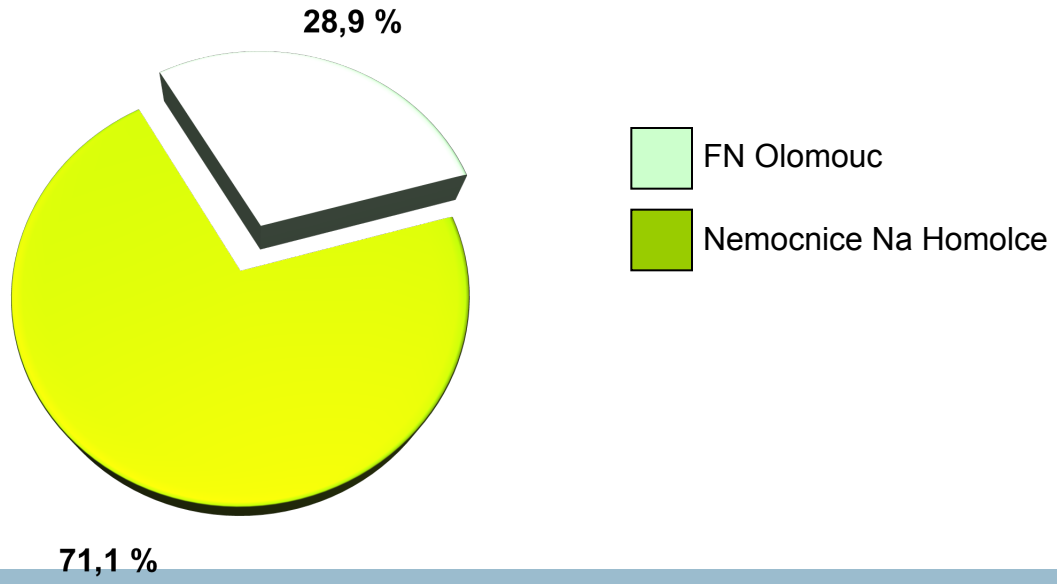


Median
(5%,95% percentile)



Počty leadless KS 2016

Centre	N	%
FN Olomouc - I. interní klinika - kardiologická	11	28.9
Nemocnice Na Homolce - Kardiologické odd.	27	71.1
Total	38	100.0



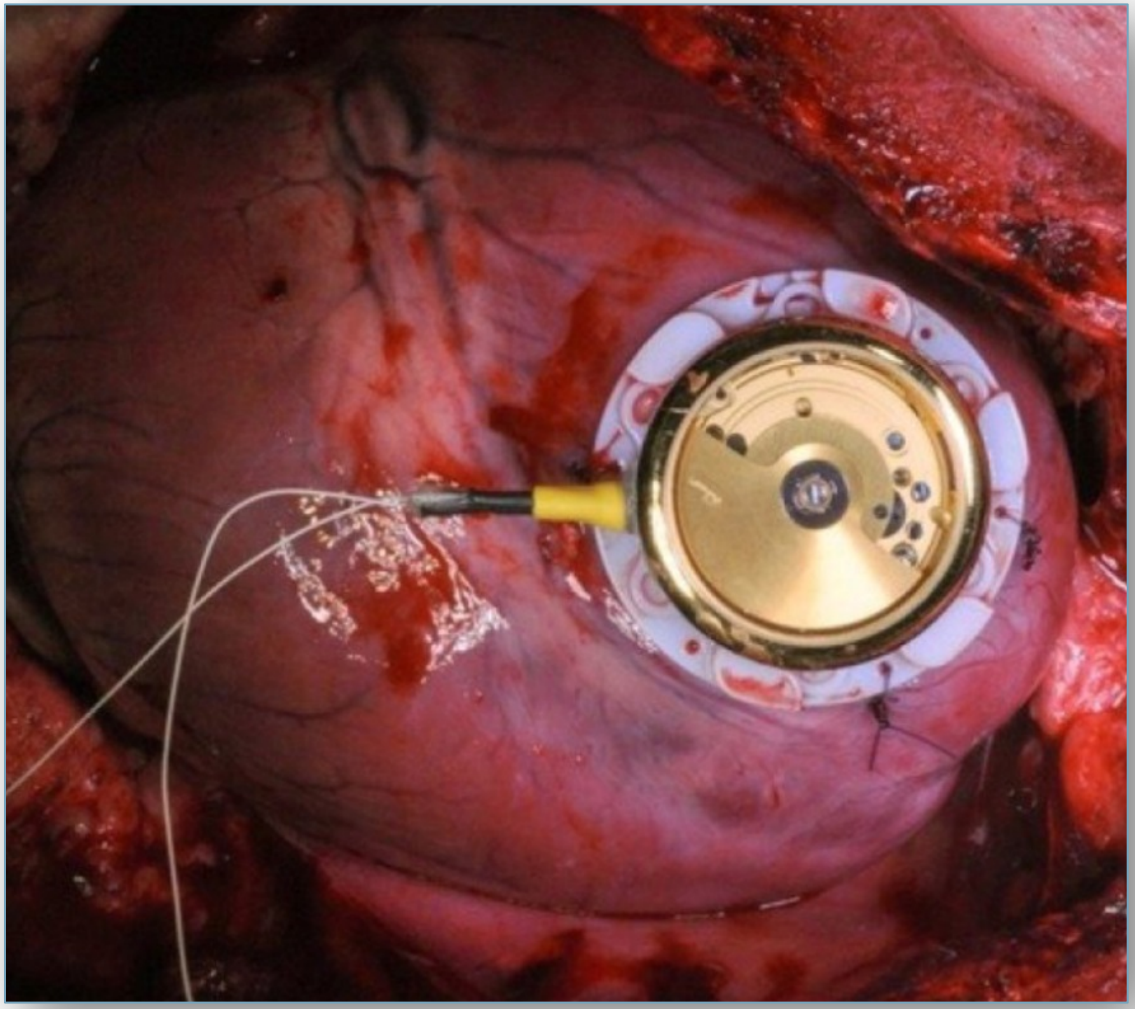
FAKULTNÍ NEMOCNICE® OLOMOUC

Lékařská fakulta
Univerzita Palackého v Olomouci

KOMPLEXNÍ KARDIOVASKULÁRNÍ CENTRUM
FAKULTNÍ NEMOCNICE OLOMOUC

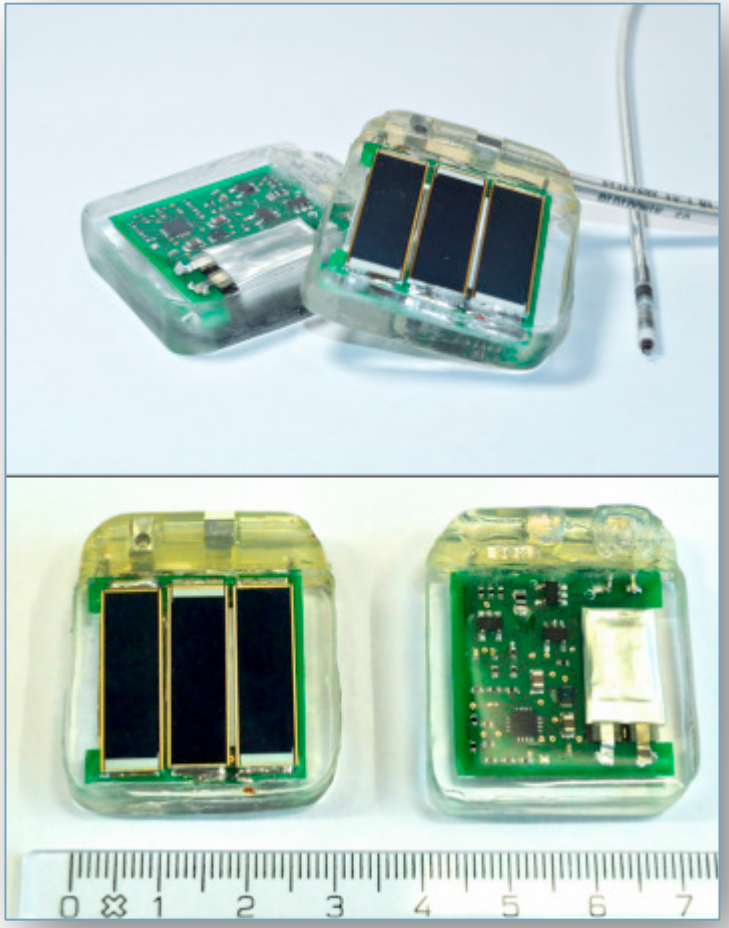
X: Alternativní technologie KS

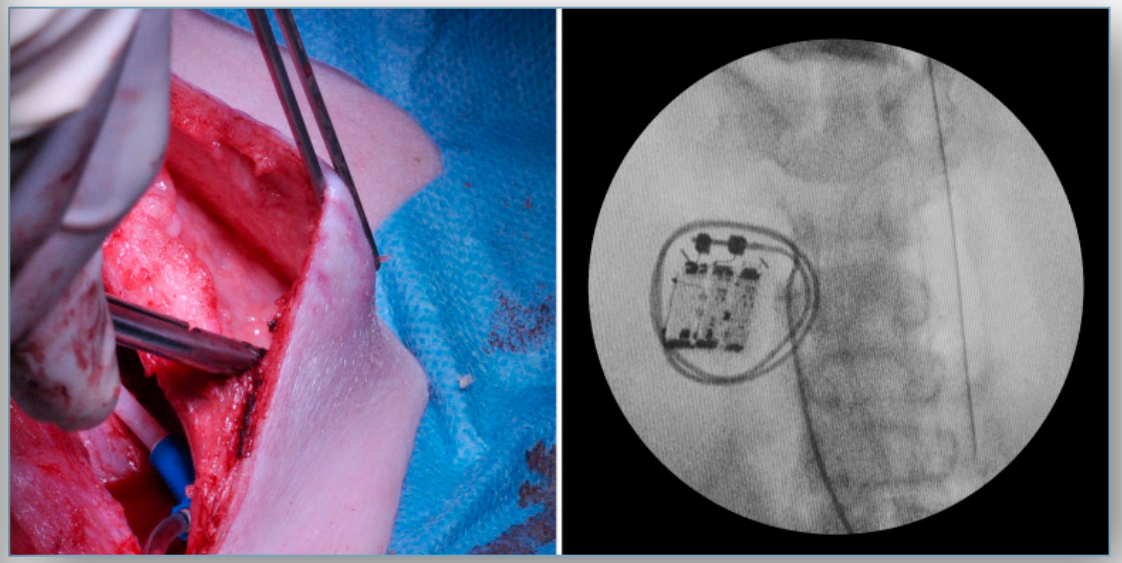
Mechanical Battery-less PM



http://www.sciencealert.com/battery-less-pacemaker-is-powered-by-heartbeats

Solar-powered cardiac pacemaker





Haeberlin A.: Heart Rhythm. 2015 Jun;12(6):1317-23. doi: 10.1016/j.hrthm.2015.02.032. Epub 2015 Mar 2.

20 let naděje …

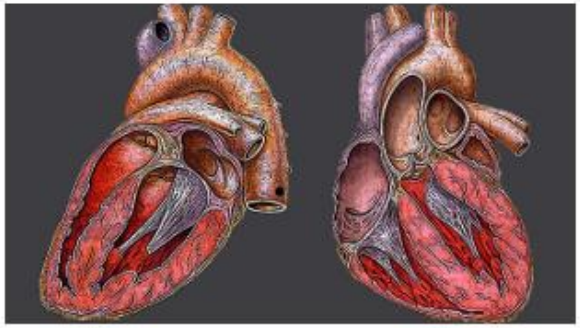
TheScientist
EXPLORING LIFE, INSPIRING INNOVATION

The Scientist » The Nutshell

New Biological Pacemaker

In guinea pigs, the insertion of a single gene can transform ordinary heart cells into pacemaker cells that regulate cardiac rhythm.

By Dan Cossins | December 18, 2012



WIKIMEDIA, HEIKENWALDER HUGO

Scientists have converted normal heart muscle cells into pacemaker cells that control heartbeat by inserting a single gene into the heart of a guinea pig. The findings, published this week (December 17) in *Nature Biotechnology*, hint at the possibility of a biological alternative to artificial pacemakers for humans with failing hearts.

A human heart is made up of around 10 billion cells, but only the 10,000 or so cells in are responsible for firing the electrical pulses that control its beat. When old age or disease result in the failure of these pacemaker cells, the downstream muscle cells that create contractions lapse into inactivity. At the moment, the typical treatment is a battery-powered pacemaker implanted into the heart.

Závěry I

Nová doporučení zavádějí novou klasifikaci bradyarytmií dle vyvolávajícího mechanismu

- persistentní bradykardie
- intermitentní bradykardie s EKG dokumentací
- susp. intermitentní bradykardie bez EKG dokumentace

Ke každé z těchto bradyarytmií uvádějí indikace k TKS

Rozdílná doporučení jsou také uvedena pro upgrade nebo „de novo“ implantaci CRT u pacientů indikovaných k trvalé kardiostimulaci z bradykardické příčiny

Závěry II

- Shrnují klíčové důkazy na podporu nových doporučení k CRT
- Uvádějí indikace CRT u pacientů se srdečním selháním a nízkou ejekční frakcí při sinusovém rytmu
- Uvádějí indikace CRT u pacientů se srdečním selháním a nízkou ejekční frakcí při fibrilaci síní
- Uvádějí klinická doporučení pro volbu mezi CRT-P a CRT-D v léčbě pokročilého srdečního selhání
- Uvádějí klinické a EKG parametry pro maximalizovaný přínos resynchronizační léčby

Milos Taborsky, MD, PhD, FESC, FACC
Professor of Cardiology
Palacky University, Olomouc, CZ
milos.taborsky@fnol.cz

KOMPLEXNÍ KARDIOVASKULÁRNÍ CENTRUM
FAKULTNÍ NEMOCNICE OLOMOUC

Lékařská fakulta
Univerzity Palackého
v Olomouci

I. INTERNÍ KLINIKA
KARDIOLOGICKÁ
FAKULTNÍ NEMOCNICE OLOMOUC