Lead-less pacing: Proti

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KLINIKA KARDIOLOGIE

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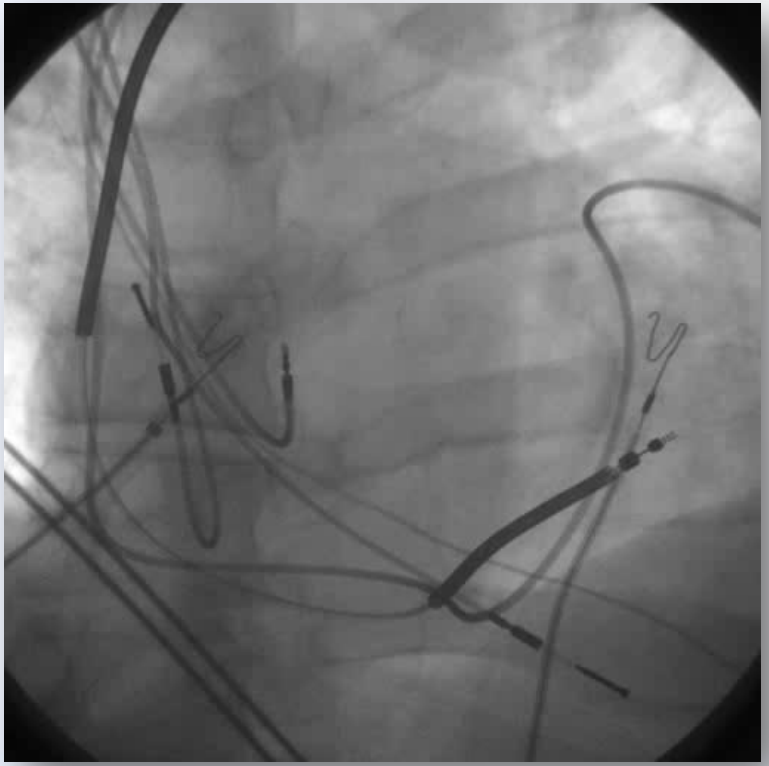
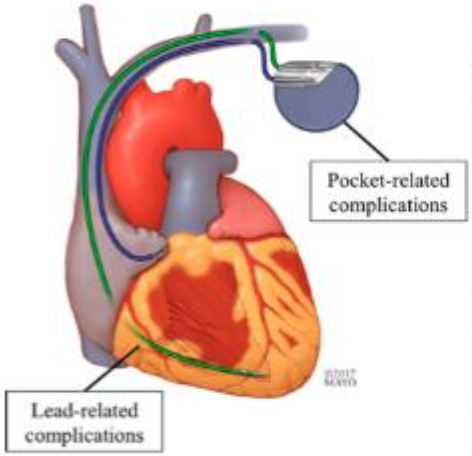
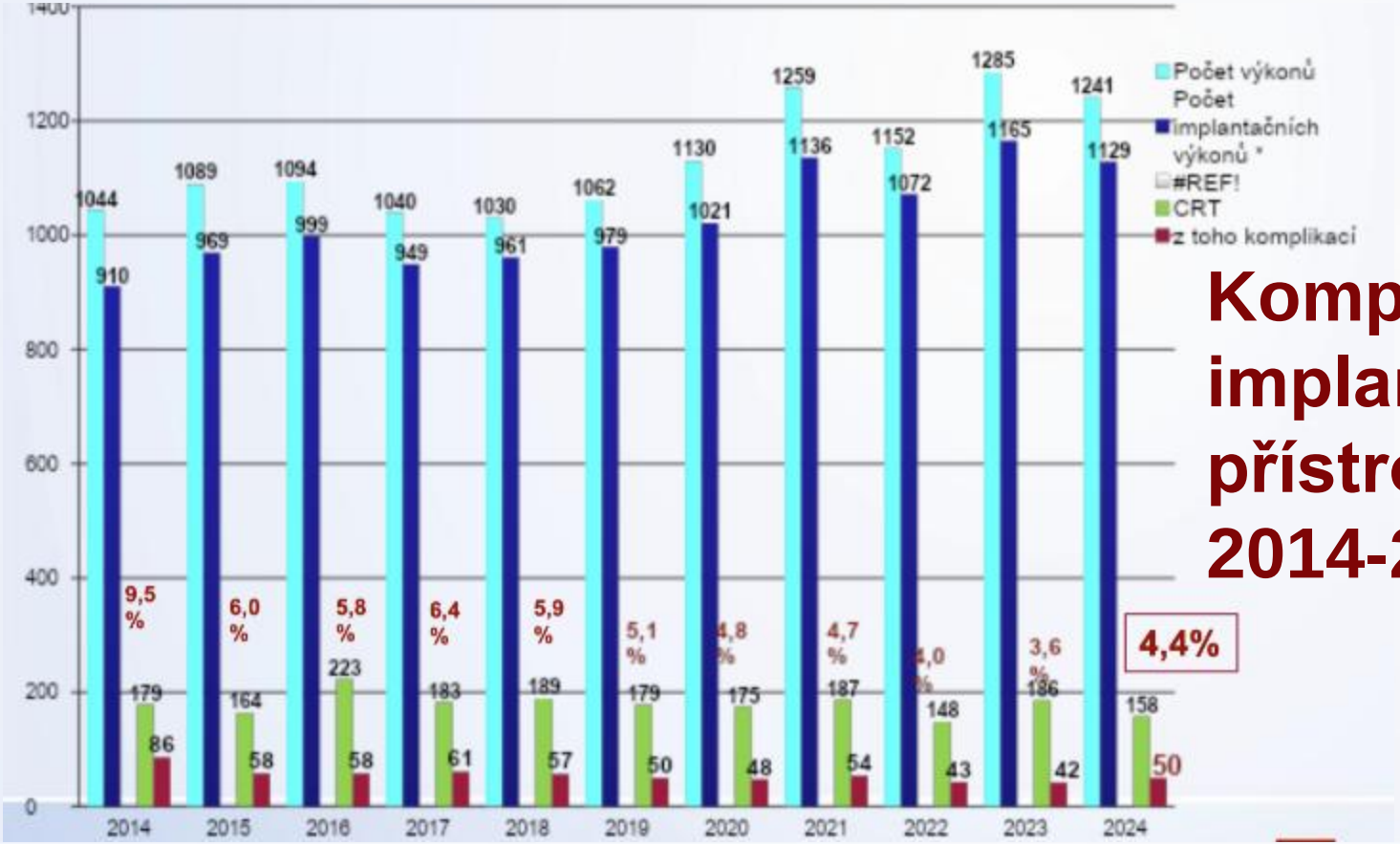
Proč „leadless“?





Transvenous pacemaker complications	Rate (%)
Immediate complications	
Pneumothorax	0.6-0.9 [3, 24]
Cardiac perforation	0.1 - 0.3 [3, 27]
Hematoma	0.2 – 0.7 [3, 26]
Intermediate complications	
Lead dislodgement	0.4 – 1.7 [3, 25]
Pocket revision because of pain	0.4 [3]
Late complications	
Lead-related re-intervention • Conductor fracture • Insulation break	1.7 - 2.4 [3, 25]
Pacemaker infections	1.8-1.9 per 1000 pacemaker years [4, 5]



Komplikace implantabilních přístrojů IKEM 2014-2024

Koncept of bezesvodové 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 the right ventricle by transvenous insertion. Since the IC pacemaker eliminates all leads, problems associated with the leads such

circuits have been improved substa
addition, the development of the e
catheter electrode has broadened t
of operative procedures to include
portion of the patient population. T
problems that still exist with cor
pacemakers are perforation or dislo
the transvenous electrode and the sh
the batteries that are presently used
tion, there is a certain physical an
logical discomfort involved with h

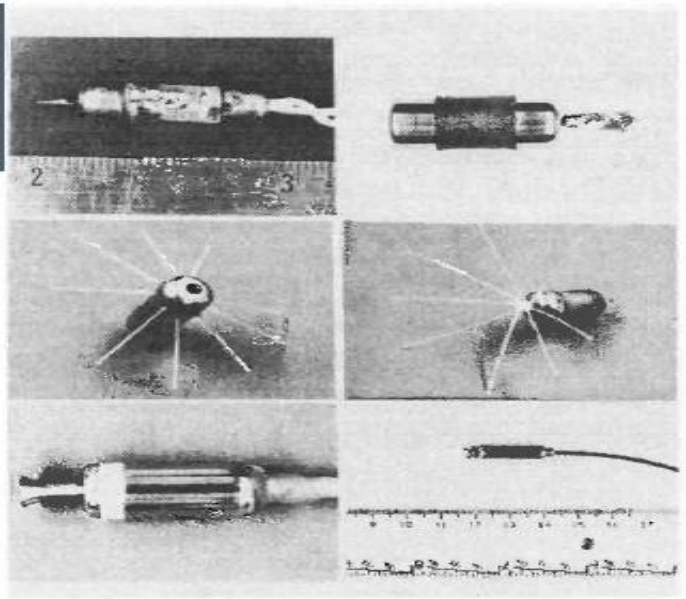


Fig. 2. Some early unsatisfactory dummy capsules used to explore attachment technique.

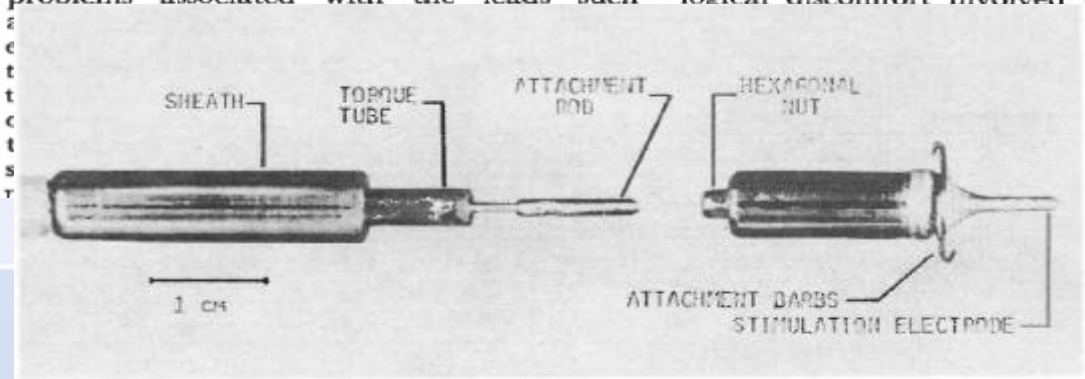


Fig. 4. Intracardiac pacemaker with catheter for transvenous insertion.

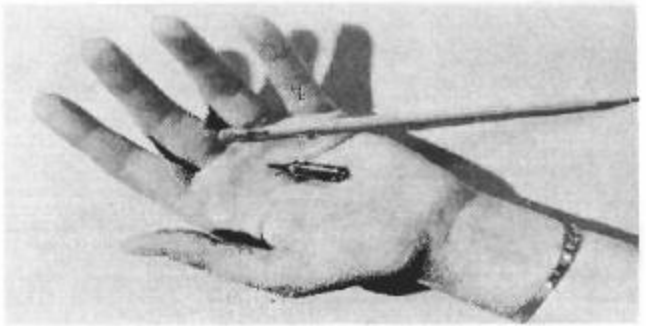
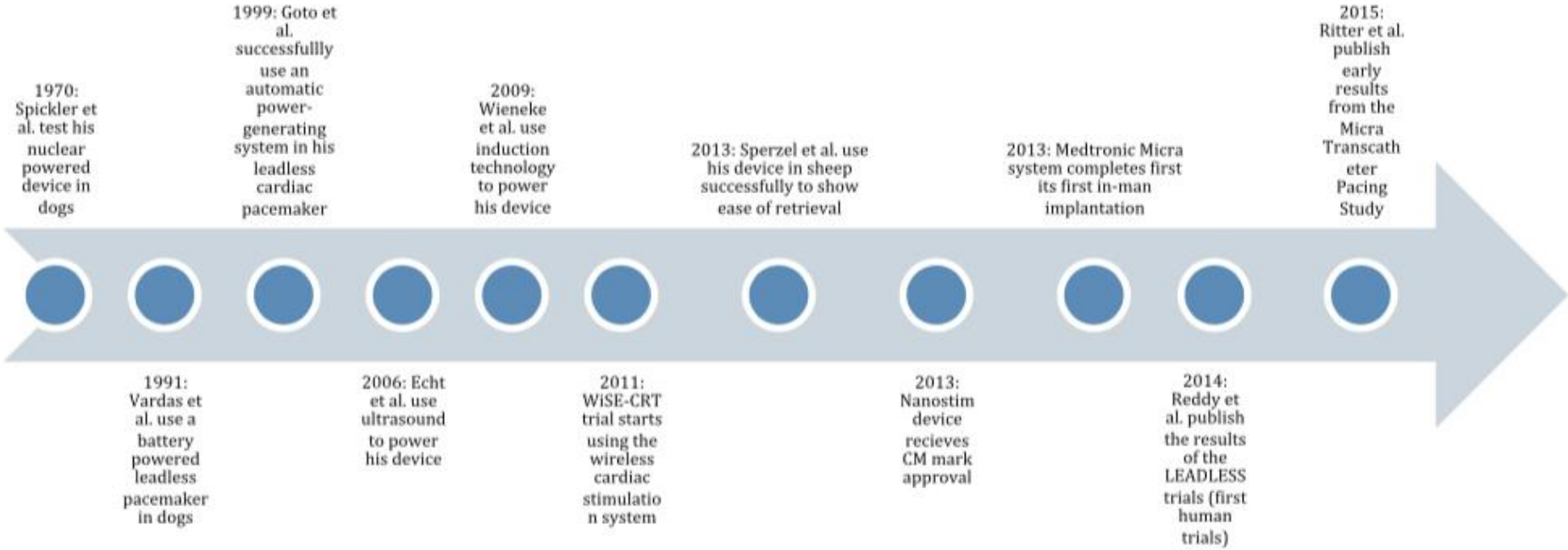


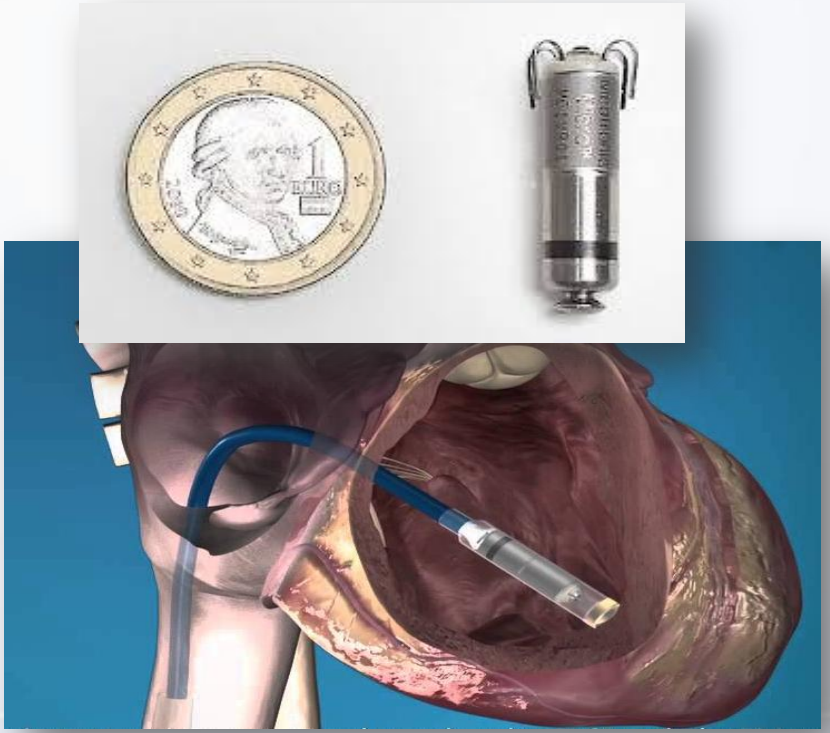
Fig. 8. Nuclear-powered intracardiac pacemaker.

Od té doby uběhlo dlouhé období..



H.M. Seriwala et al. / Journal of Cardiology 67 (2016) 1–5

Současné systémy



Permanent Leadless Cardiac Pacing
Results of the LEADLESS Trial

Vivek Y. Reddy, MD; Reinoud E. Knops, MD; Johannes Sperzel, MD; Marc A. Miller, MD; Jan Petru, MD; Jaroslav Simon, MD; Lucie Sediva, MD; Joris R. de Groot, MD, PhD; Fleur V.Y. Tjong, MD; Peter Jacobson, BS; Alan Ostrosff, MS; Srinivas R. Dukkipati, MD; Jacob S. Koruth, MD; Arthur A.M. Wilde, MD, PhD; Josef Kautzner, MD, PhD; Petr Neuzil, MD, PhD

Background—Conventional cardiac pacemakers are associated with several potential short- and long-term complications related to either the transvenous lead or subcutaneous pulse generator. We tested the safety and clinical performance of a novel, completely self-contained leadless cardiac pacemaker.

Methods and Results—The primary safety end point was freedom from complications at 90 days. Secondary performance end points included implant success rate, implant time, and measures of device performance (pacing/sensing thresholds and rate-responsive performance). The mean age of the patient cohort (n=33) was 77±8 years, and 67% of the patients were male (n=22/33). The most common indication for cardiac pacing was permanent atrial fibrillation with atrioventricular block (n=22, 67%). The implant success rate was 97% (n=32). Five patients (15%) required the use of >1 leadless cardiac pacemaker during the procedure. One patient developed right ventricular perforation and cardiac tamponade during the implant procedure, and eventually died as the result of a stroke. The overall complication-free rate was 94% (31/33). After 3 months of follow-up, the measures of pacing performance (sensing, impedance, and pacing threshold) either improved or were stable within the accepted range.

Conclusions—In a prospective nonrandomized study, a completely self-contained, single-chamber leadless cardiac pacemaker has shown to be safe and feasible. The absence of a transvenous lead and subcutaneous pulse generator could represent a paradigm shift in cardiac pacing.

Clinical Trial Registration—URL: http://clinicaltrials.gov. Unique identifier: NCT01700244.

(*Circulation*. 2014;129:1466-1471.)

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A Leadless Intracardiac Transcatheter Pacing System

Dwight Reynolds, M.D., Gabor Z. Duray, M.D., Ph.D., Razali Omar, M.D., Kyoko Soejima, M.D., Petr Neuzil, M.D., Shu Zhang, M.D., Calambur Narasimhan, M.D., Clemens Steinwender, M.D., Josep Brugada, M.D., Ph.D., Michael Lloyd, M.D., Paul R. Roberts, M.D., Venkata Sagi, M.D., John Hummel, M.D., Maria Grazia Bongiorni, M.D., Reinoud E. Knops, M.D., Christopher R. Ellis, M.D., Charles C. Gornick, M.D., Matthew A. Bernabei, M.D., Verla Laager, M.A., Kurt Stromberg, M.S., Eric R. Williams, B.S., J. Harrison Hudnall, B.S., and Philippe Ritter, M.D., for the Micra Transcatheter Pacing Study Group*

ABSTRACT

BACKGROUND

A leadless intracardiac transcatheter pacing system has been designed to avoid the need for a pacemaker pocket and transvenous lead.

METHODS

In a prospective multicenter study without controls, a transcatheter pacemaker was implanted in patients who had guideline-based indications for ventricular pacing. The analysis of the primary end points began when 300 patients reached 6 months of follow-up. The primary safety end point was freedom from system-related or procedure-related major complications. The primary efficacy end point was the percentage of patients with low and stable pacing capture thresholds at 6 months (≤2.0 V at a pulse width of 0.24 msec and an increase of ≤1.5 V from the time of implantation). The safety and efficacy end points were evaluated against performance goals (based on historical data) of 83% and 80%, respectively. We also performed a post hoc analysis in which the rates of major complications were compared with those in a control cohort

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*A complete list of investigators in the Micra Transcatheter Pacing Study Group is provided in the Supplementary Appendix, available at NEJM.org.

This article was published on November 9, 2015, at NEJM.org.

DOI: 10.1056/NEJMoa1511643

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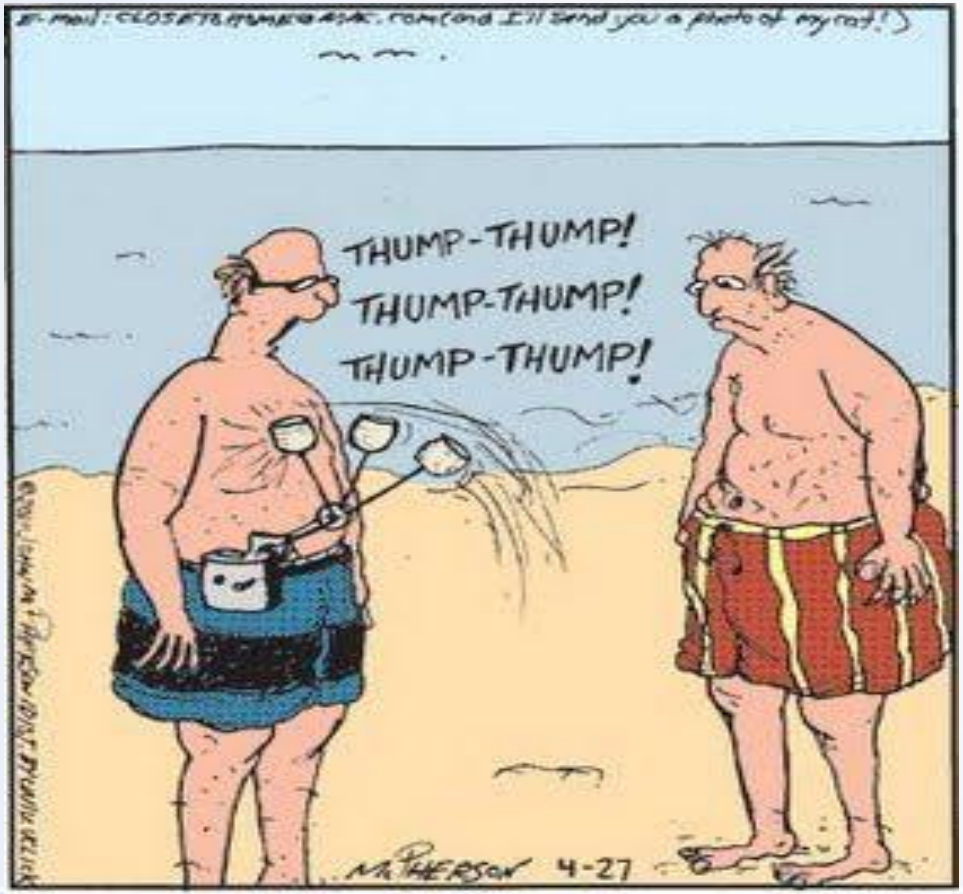
Leadless (bezesvodový) PM: potenciální benefity

- Snížená invazivita
  - Bez chirurgie
  - Méně komplikací
  - Menší radiační zátěž
  - Lepší kosmetický efekt

- Zlepšená výkonnost
  - Jednodušší výkon
  - Femorální přístup
  - Bez spojovacích komponent
  - MRI kondicionální

- Cost/effectiveness
  - Snížená délka hospitalizace
  - Méně akutních a chronických komplikací

Snížená invazivita, méně komplikací



"They said I wouldn't survive the surgery to implant a regular pacemaker."

European Heart Journal Advance Access published June 4, 2015

European Heart Journal
doi:10.1093/eurheartj/ehv214

CLINICAL RESEARCH
Arrhythmia/electrophysiology

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

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Received 9 February 2015; revised 30 March 2015; accepted 4 May 2015

Micra Major Complications (N=726)

	Within 30 days	30 days – 6 Mos	> 6 Mos	Events (Patients, %)
Total	24	6	2	32 (29, 4.0%)
Cardiac Perforation/Effusion	10	1	0	11 (11, 1.5%)
AV Fistula/Pseudoaneurysm	5	0	0	5 (5, 0.7%)
Cardiac Failure	0	4	2	6 (6, 0.8%)
Elevated Thresholds	2	0	0	2 (2, 0.3%)
Pacemaker Syndrome	1	1	0	2 (2, 0.3%)
Acute MI	1	0	0	1 (1, 0.1%)
Deep Vein Thrombosis	1	0	0	1 (1, 0.1%)
Metabolic Acidosis	1	0	0	1 (1, 0.1%)
Presyncope	1	0	0	1 (1, 0.1%)
Pulmonary Embolism	1	0	0	1 (1, 0.1%)
Syncope	1	0	0	1 (1, 0.1%)

S rostoucí praxí klesá počet komplikací

(Micra Postapproval Registry)

- M792/795 (99.6%) úspěšná implantace
- 30 dní, 13 větší komplikace (1.51 %)

Table 3 Components of Major Complications for Post-Approval and Investigational Studies

Major Complication Criterion	30-Day Event Rate: Post-Approval (n = 795) No. (Patients, %)	30-Day Event Rate: Investigational (n = 726) No. (Patients, %)	Odds Ratio (Post-Approval vs Investigational) (95% CI)
Total Major Complications	13 (12, 1.51%)	24 (21, 2.89%)	0.58 (0.27, 1.25)*
Death	1 (1, 0.13%)	1 (1, 0.14%)	0.91 (0.06–14.66)
Hospitalization	4 (4, 0.50%)	9 (8, 1.10%)	0.45 (0.14–1.51)
Prolonged hospitalization	9 (8, 1.01%)	16 (14, 1.93%)	0.52 (0.22–1.24)
System revision	2 (2, 0.25%)	3 (3, 0.41%)	0.61 (0.10–3.65)
Loss of device function	0 (0, 0%)	2 (2, 0.28%)	NE

CI = confidence interval; NE = not estimable.

*Adjusted analyses for baseline characteristics (P = 0.16). Unadjusted results were similar (0.52, 95% CI: 0.25-1.05).

Roberts PJ, et al. Heart Rhythm 2017;14:1375–1379

Another halt for St. Jude Medical's European Nanostim trial

MAY 26, 2015 BY BRAD PERRIELLO LEAVE A COMMENT

St. Jude Medical (NYSE:STJ) once again asked physicians in a European clinical trial to stop implanting its Nanostim leadless pacemaker this year after reports of series adverse events, including perforation of the heart and dislodgment of the device.

In 1 case reported to the FDA's adverse events database, the device became dislodged and traveled into the pulmonary artery, where it was later removed.

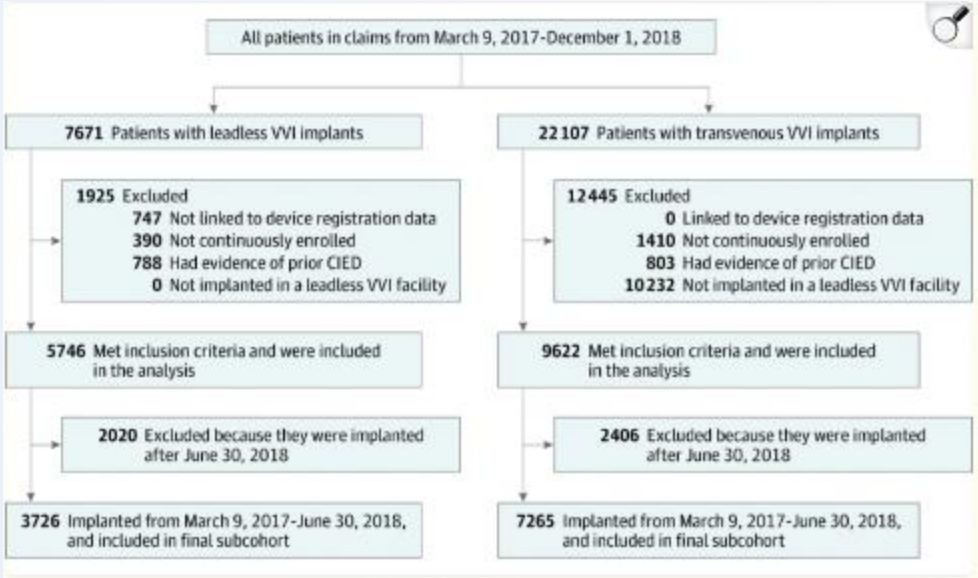
The company 1st paused enrollment in its European post-market trial in April 2014, reporting 6 instances of perforation, including 2 patient deaths, out of more than 200 implants. According to a letter St. Jude sent to physicians in February, after that trial resumed in June 2014, there were another 2 cases of perforation or excess fluid around the heart, 1 of which required an invasive intervention.

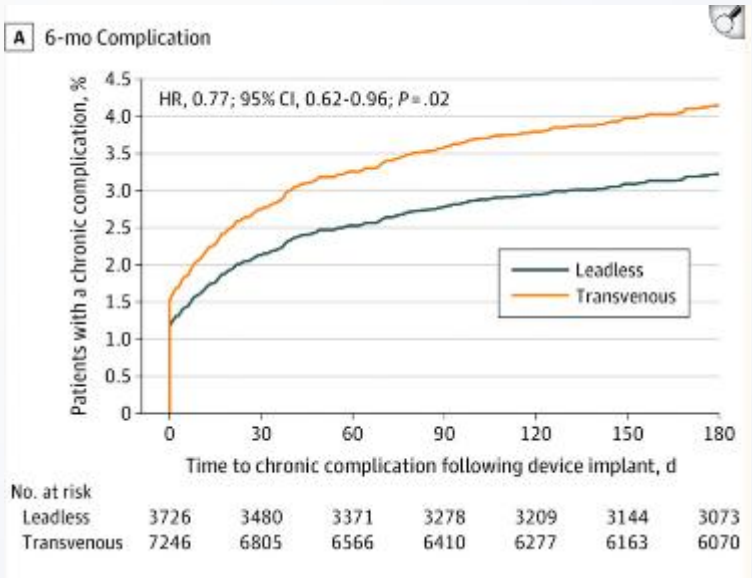
That trial halted again Jan. 5 of this year, according to the letter.* Between Feb. 4, 2014, and the 2nd pause of the European trial, the IDE trial showed 5 incidents of perforation or pericardial effusion, 4 of which required invasive intervention, and 6 dislodgments.

All told since the end of the 1st pause last June, among a total of 415 patients in both trials, there were 7 incidents of perforation or pericardial effusion, 5 requiring intervention, and 6 dislodgments, according to the letter.

http://www.massdevice.com/another-halt-st-jude-medicals-nanostim-trial/

Porovnání komplikací LCP vs konvenční stimulace





Measure	Unadjusted event, No. (%)		
	Leadless VVI (n = 5746)	Transvenous VVI (n = 9662)	P value
Overall complications	484 (8.4)	707 (7.3)	.02
Embolism and thrombosis	202 (3.5)	286 (3.0)	.07
Deep vein thrombosis	145 (2.5)	176 (1.8)	.003
Events at puncture site	79 (1.4)	31 (0.3)	<.001
Arteriovenous fistula	40 (0.7)	<10[a]	<.001
Vascular aneurysm	49 (0.9)	21 (0.2)	<.001
Cardiac effusion and/or perforation	47 (0.8)	38 (0.4)	<.001
Device-related complication[b]	81 (1.4)	347 (2.6)	<.001

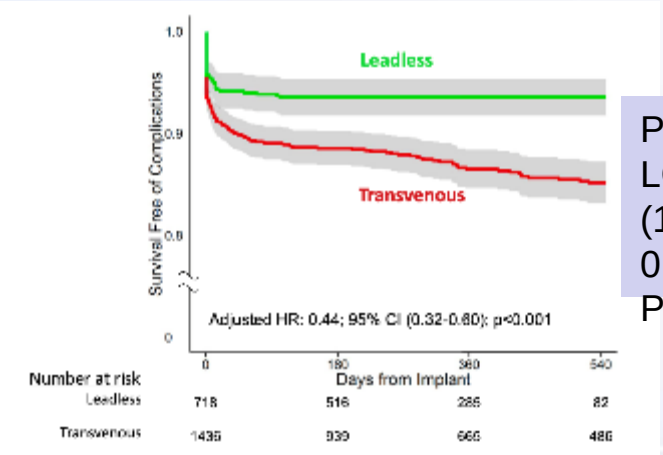
Piccini JP, et al. JAMA Cardiol 2021;6(10):1–9.

Komplikace LCP vs transvenózní system (propensity match)

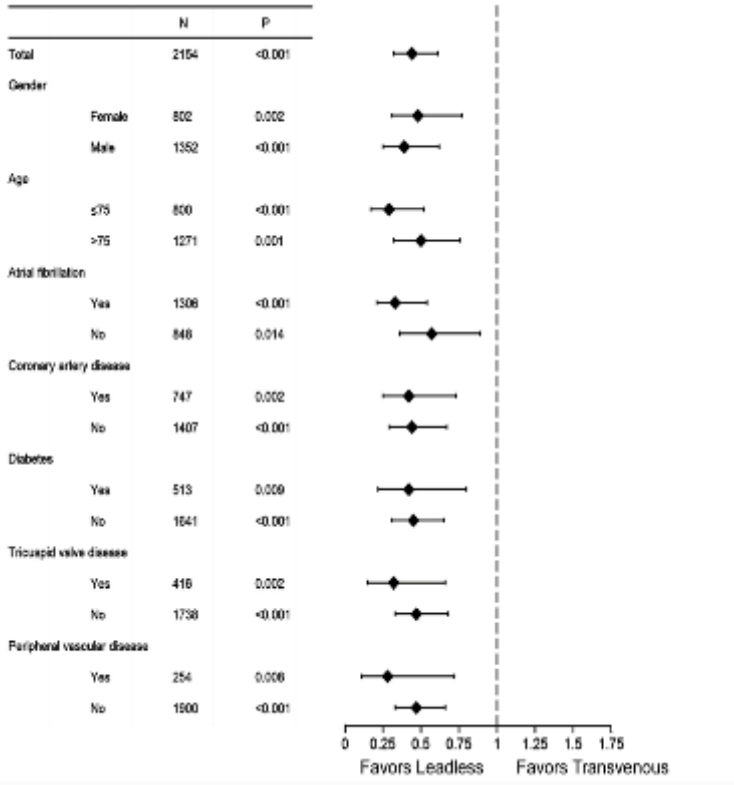
Table 1 Baseline demographic characteristics of propensity score–matched patients

Characteristic	Patients with leadless pacemaker (n = 718)	Patients with transvenous pacemaker (n = 1436)	P
Age (y)	75.6 ± 11.9	76.1 ± 12.3	.39
Follow-up (d)	323 (197–489)	408 (167–547)	<.001
Sex: male	447 (62.3%)	905 (63.0%)	.77
Atrial fibrillation	425 (59.2%)	881 (61.4%)	.36
Coronary artery disease	262 (36.5%)	485 (33.8%)	.23
Diabetes mellitus	178 (24.8%)	335 (23.3%)	.49
Hyperlipidemia	476 (66.2%)	970 (67.5%)	.55
Hypertension	557 (77.6%)	1146 (79.8%)	.25
Tricuspid valve disease	150 (20.9%)	266 (18.5%)	.21
Peripheral vascular disease	91 (12.7%)	163 (11.4%)	.41

Values are presented as mean ± SD, as median (interquartile range), or as n (%).

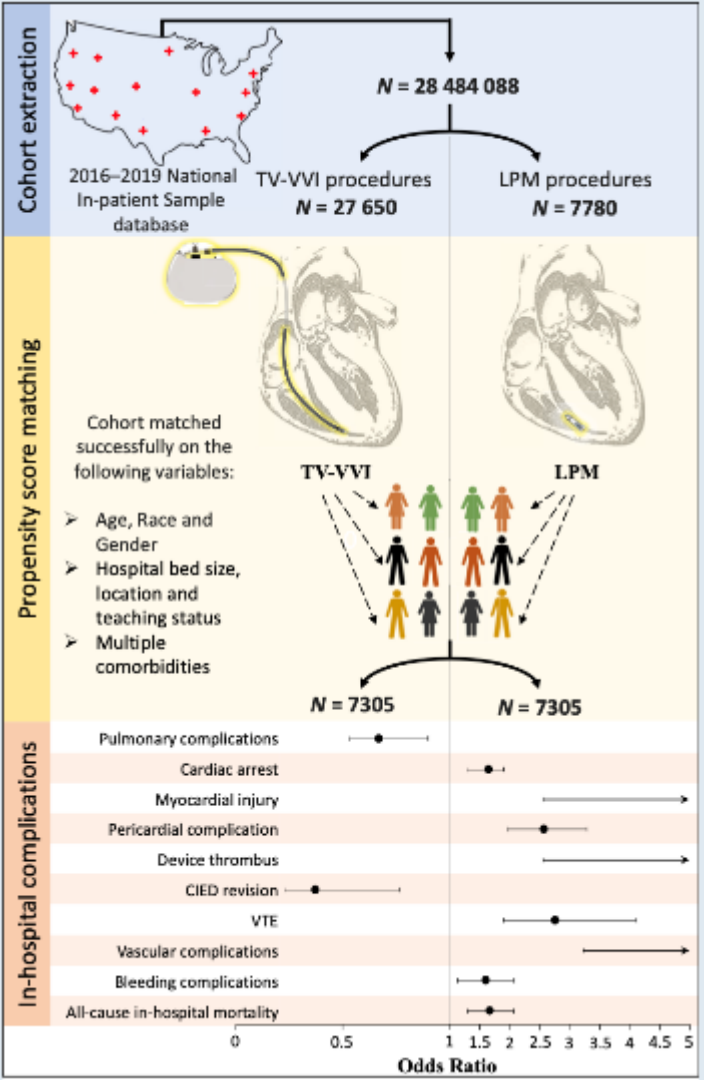


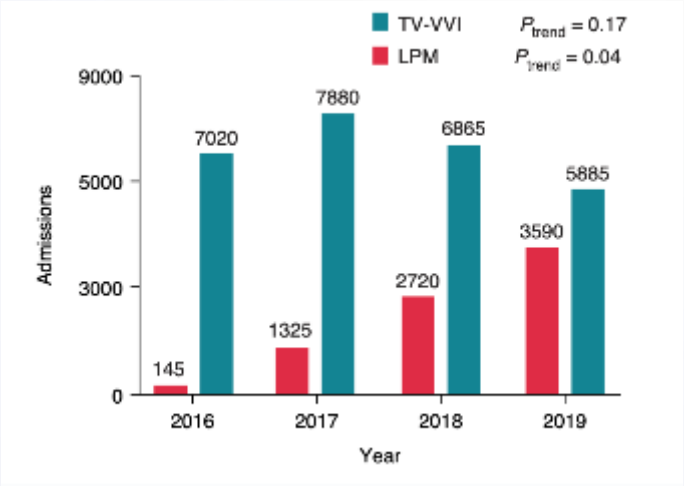
Perforace srdce: LCP vs TVS (1.53% vs 0.35%; P 5 .005)



Cantillon DJ, et al. Heart Rhythm 2018;15:1023–1030

Porovnání komplikací LCP vs konvenční stimulace



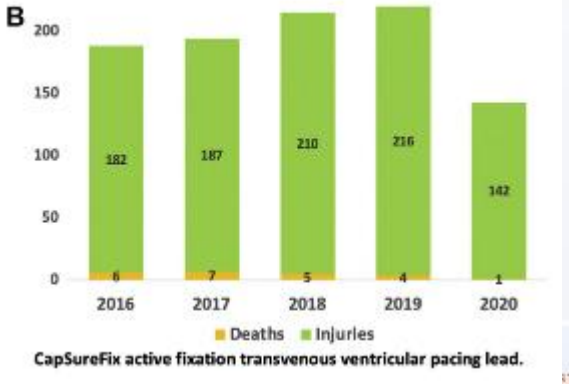


Al Deen Alhuarrat M, et al. Europace (2023) **25**, 1–9

Hlavní rizika spojená s implantací LCP

	Micra LICP	CapSureFix	*P* value
No. of major adverse events*	363	960	—
Major adverse event			
Death	96 (26.4)	23 (2.4)	<.001
Tamponade	287 (79.1)	225 (23.4)	<.001
Perforation without tamponade	61 (16.8)	731 (76.1)	<.001
Rescue thoracotomy	99 (27.3)	50 (5.2)	<.001
Repair RV tear	75 (20.7)	15 (1.6)	<.001
Repair PA tear	2 (0.5)	—	.075
Drainage only	24 (6.6)	35 (3.6)	.029
Pericardiocentesis without thoracotomy	190 (52.3)	195 (20.3)	<.001
Cardiopulmonary resuscitation	79 (21.8)	11 (1.1)	<.001
Shock/hypotension	80 (22.0)	56 (5.8)	<.001

Micra leadless intracardiac pacemaker.

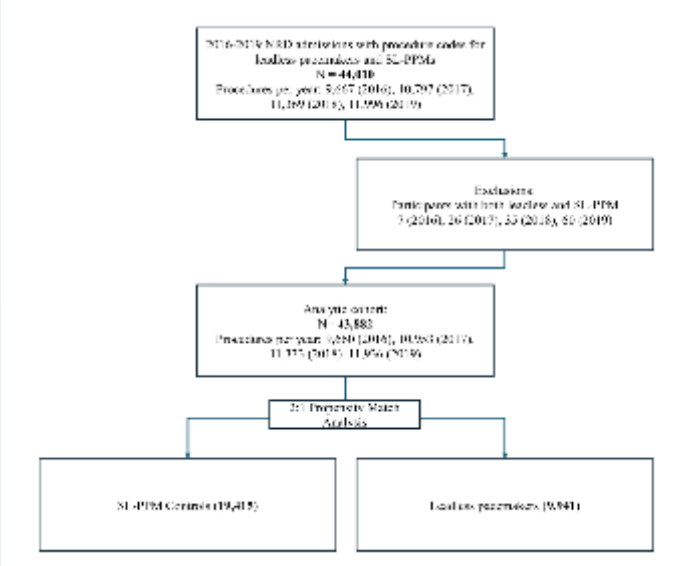


CapSureFix active fixation transvenous ventricular pacing lead.

Databáze MAUDE 2016-2020
Větší nežádoucí kardiovaskulární události do 30 dní po implantaci

Hauser RG, et al. Heart Rhythm 2021;18:1132–1139

Komplikace LCP vs TVS (National Readmissions Database)

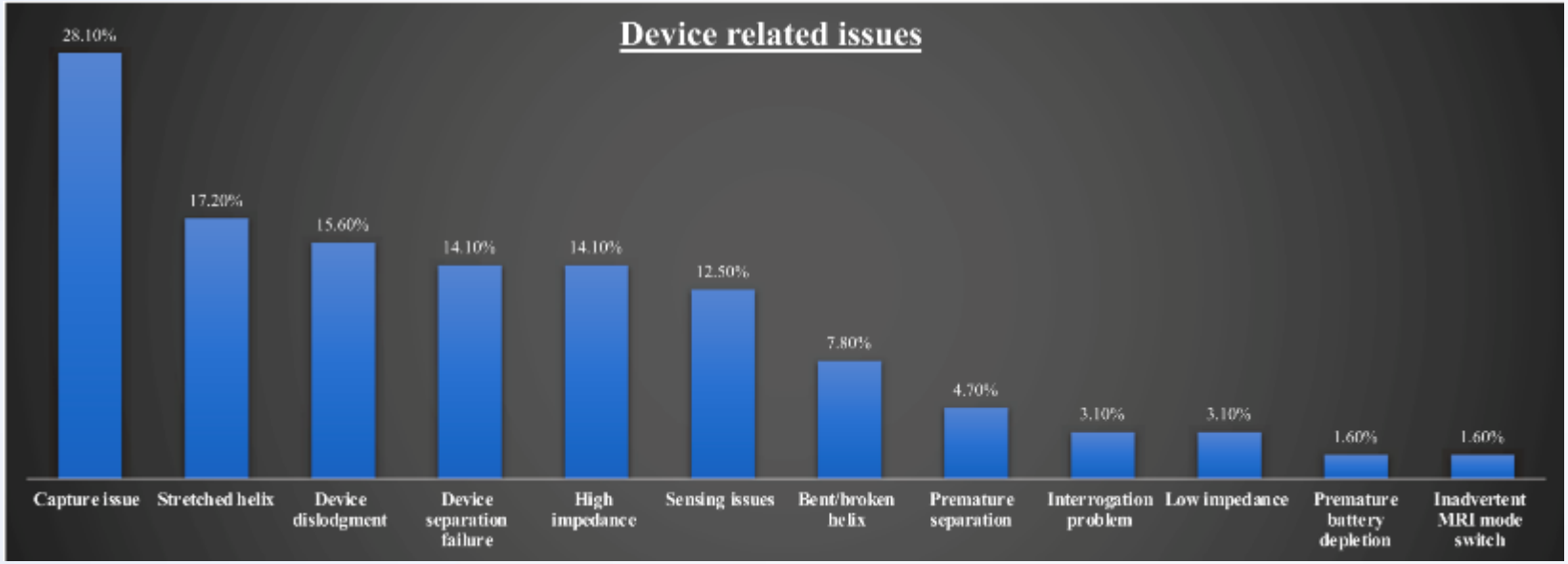


N = 29 356	Total cohort (N = 29 356)	PScore-matched single-lead controls (n = 19 415)	Micra pacemaker (n = 9941)	p-value[a]	Standardized difference
Tamponade					
Yes	179 (0.59)	67 (0.35)	112 (1.1)	< 0.001	0.09
Open approach					
Yes	1 (0.003)	0 (—)	1 (0.009)	—	0.01
RV repair					
Yes	13 (0.04)	3 (0.02)	10 (0.10)	0.001	0.04
Perforation[b]					
Yes	184 (0.62)	68 (0.36)	116 (1.1)	< 0.001	0.09
Defined as presence of tamponade or RV repair[b]					
Cardiac arrest					
Yes	878 (3.0)	393 (2.1)	485 (4.9)	< 0.001	0.16
Hypotension					
Yes	2288 (7.9)	1202 (6.3)	1086 (11.3)	< 0.001	0.09
Cardiogenic shock					
Yes	1036 (3.5)	450 (2.3)	586 (5.9)	< 0.001	0.18
Post-procedural shock					
Yes	9 (0.03)	3 (0.02)	6 (0.06)	0.08	0.02
VF arrythmia					
Yes	310 (1.1)	149 (0.81)	161 (1.7)	< 0.001	0.08
VT arrythmia					
Yes	1518 (5.1)	796 (4.1)	722 (7.2)	< 0.001	0.14
Pericardiocentesis					
Yes	188 (0.63)	68 (0.36)	120 (1.2)	< 0.001	0.09
Pericardial window					
Yes	82 (0.28)	36 (0.19)	46 (0.48)	< 0.001	0.05

Mortalita LCP vs TVS:5.3% vs. 1.9%, p < 0.001)

Parulkar A, et al. JCE 2025; 36:1538–1547

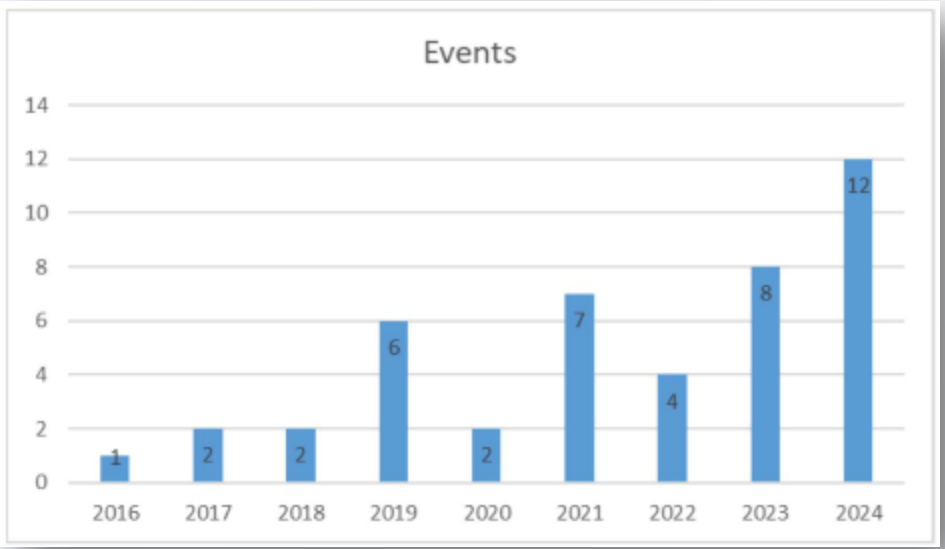
Nežádoucí účinky spojené s LCP Aveir



MAUDE database, 2022-2023, 64 událostí
8 závažných událostí – 5 tamponád (7.8%), 2 vedoucí k úmrtí, 3 setrvalé komorové arytmie (3,1%)

Garg J, et al. J Cardiovasc Electrophysiol. 2023;34:1469–1471.

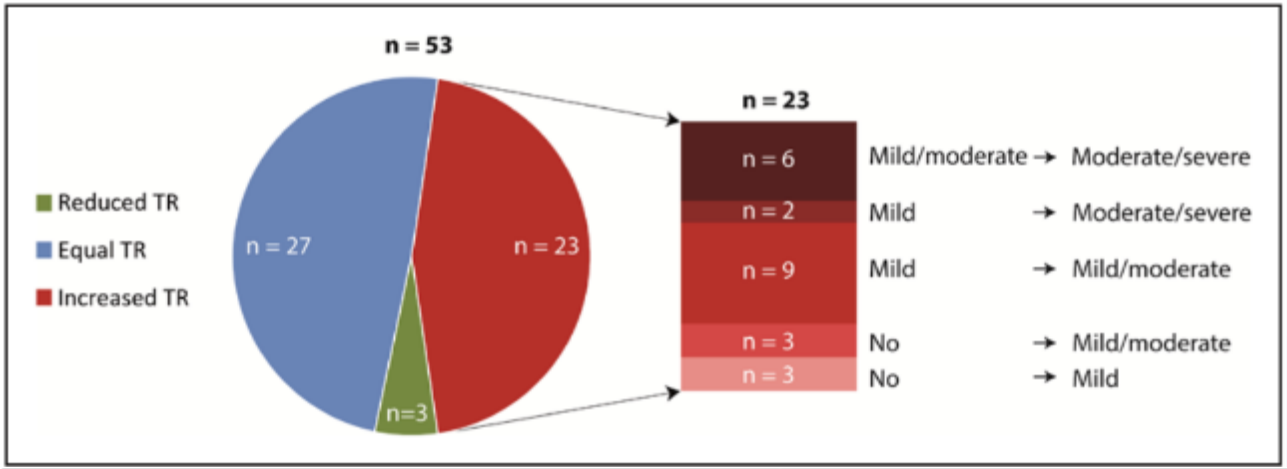
Periproceduralní poškození trikuspidální chlopně



- 2025: FDA's Manufacturers and User Facility Device Experience (MAUDE) database
- 44 případů nežádoucích účinků spojených s trikuspidální chlopní od 2016
- Micra (*n* = 40; 90%) and Aveir (*n* = 4; 10%)
- MACE u 16 (36%) – úmrtí 5, srdeční selhání 5, 11 – intervence na mi chlopni
- Zhoršení MR u 67%

Bahbah A, et al. JICE 2025; 68:1703–1705

Progrese trikuspidální a mitrální regurgitace



28 Nanostim
25 Micra
+12 měsíců FU – echo

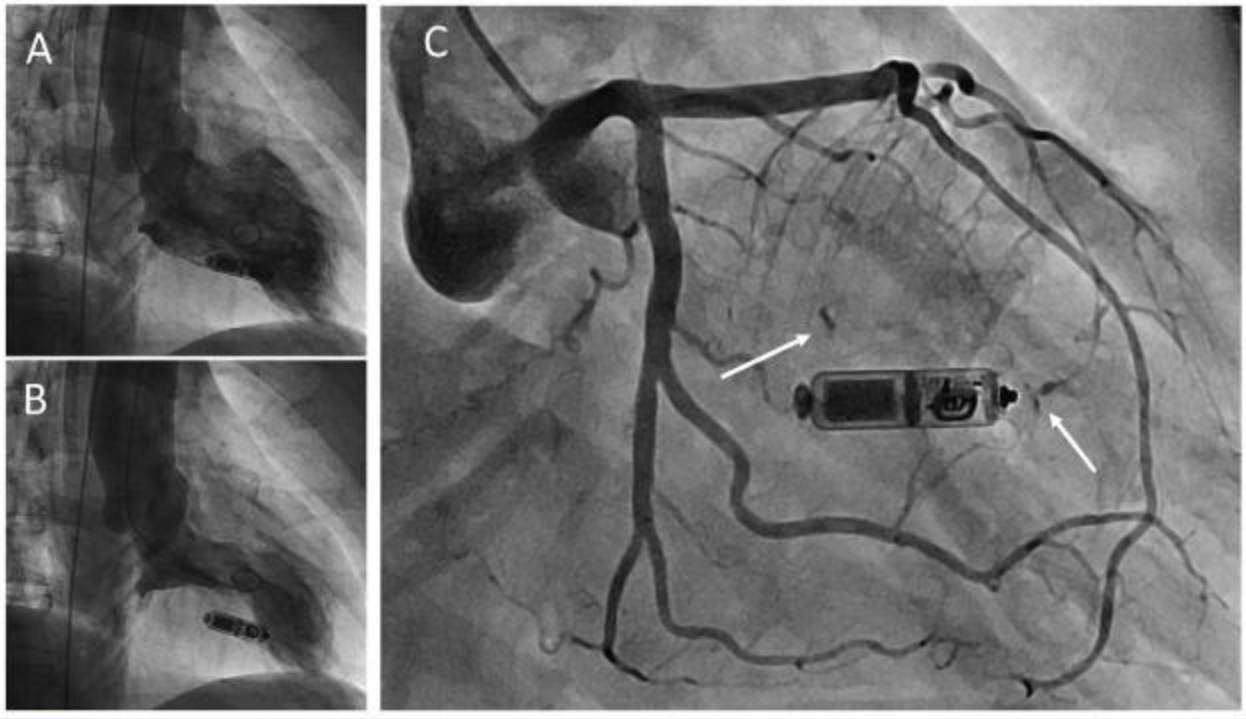
Septální pozice častěji TR (p =0.03)
Zvýšení MR u 38% (p=0.006)

Redukce fce PK a LK

	LPs (n=53)			Conventional DDD Pacemakers (n=53)			*P* Value
TV Disease	**Baseline**	**FU**	***P* Value**	**Baseline**	**FU**	***P* Value**	**0.395**
No	6 (11%)	1 (2%)	<0.001	10 (19%)	2 (4%)	0.02	
Mild regurgitation	26 (49%)	18 (34%)		27 (51%)	31 (59%)		
Mild-to-moderate regurgitation	14 (26%)	20 (38%)		12 (23%)	16 (30%)		
Moderate-to-severe regurgitation	7 (13%)	14 (26%)		4 (8%)	1 (2%)		
Severe regurgitation	0 (0%)	0 (0%)		0 (0%)	3 (6%)		

Beurskens DEG, et al. Circ Arrhythm Electrophysiol. 2019;12:e007124

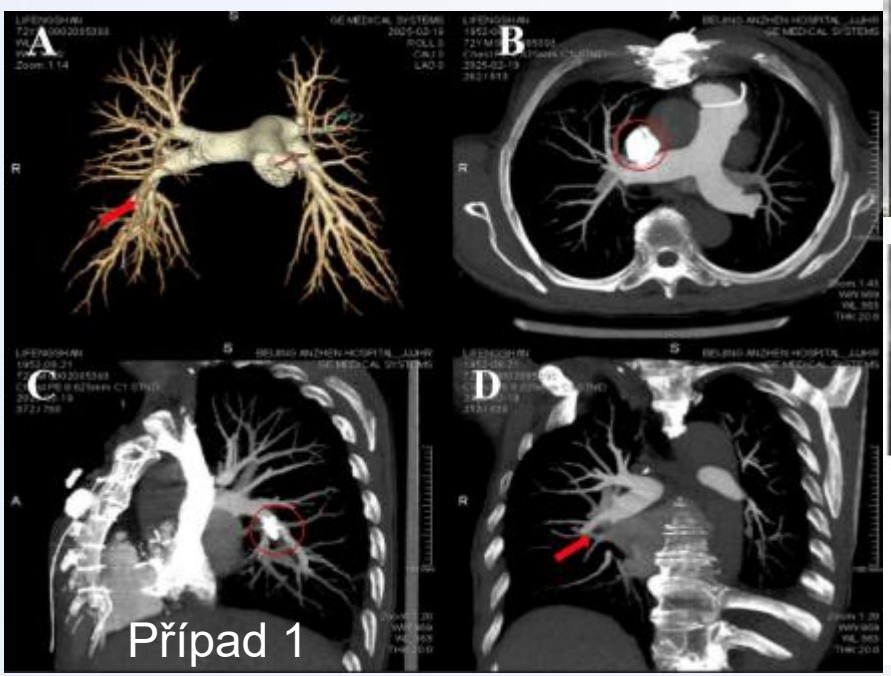
Poranění koronárních tepen

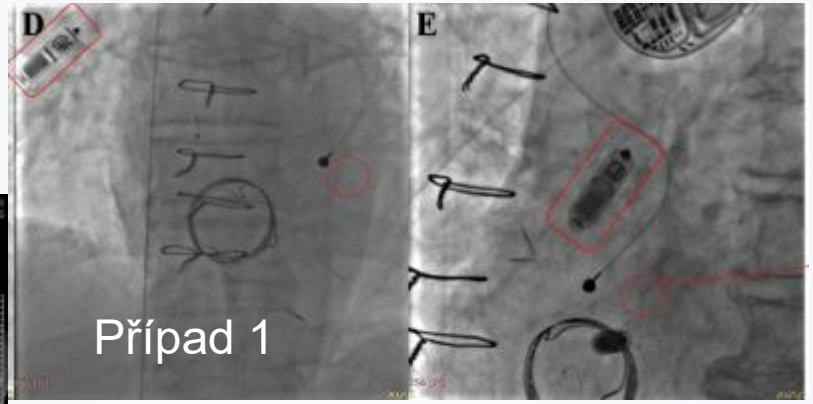


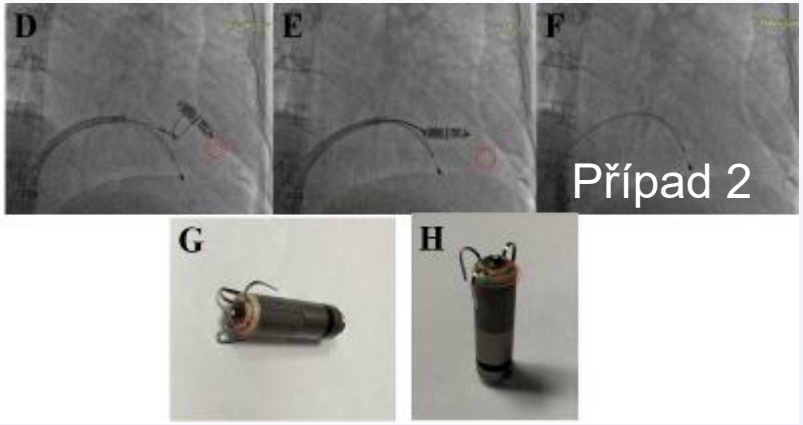
73-letá žena
2 pozice LCP
Bolest na hrudi po
Týdnu
Takotsubo
KMP, poškození
septálních větví LCA

Fukaya H, et al. Circ J 2020; **84:** 530

Dislokace při fraktuře kotviček







Shen *et al. BMC Cardiovascular Disorders* (2025) 25:756

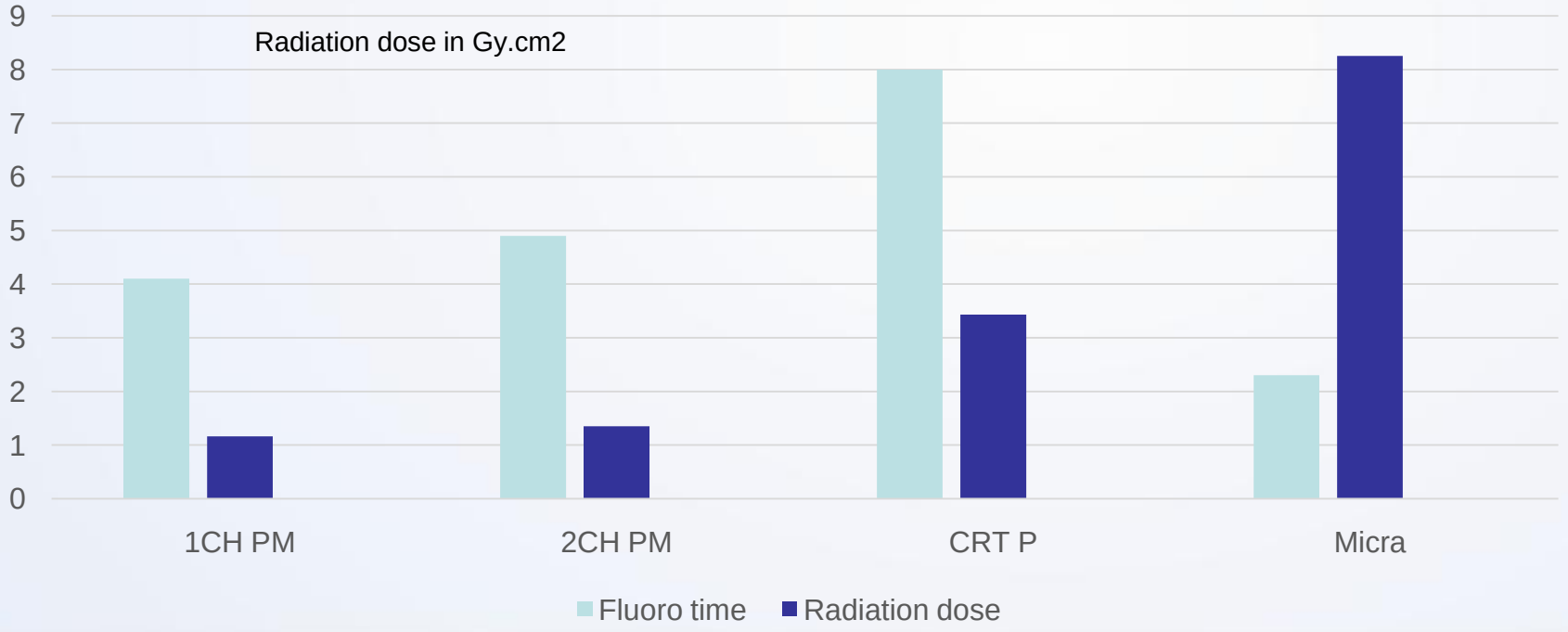
Nižší radiační zátěž?

Micra Transcatheter Pacing Study

reverse anticoagulation effects in 16 patients (11%). The mean implant time was 37 ± 21 min (range: 11–154 min) with an average fluoroscopy time of 9 ± 7 min. The majority of attempts were successful upon initial device positioning (59%) or two positioning (22.1%), but the maximum number of attempts in a single patient was 18 deployments (mean ± SD, 2 ± 2). A second device was used in two implants, due to unacceptable electrical measurements.

Ritter P, et l. European Heart Journal
doi:10.1093/eurheartj/ehv214

Radiační zátěž (IKEM 1-6/2020)



2020-2025: fluoro 4.1±4.1 min, dose 7.4 ± 15 Gy.cm2

Zlepšená výkonnost

Neočekávaná dysfunkce baterií (Nanostim)

Circulation
Volume 137, Issue 22, 29 May 2018; Pages 2408-2410
https://doi.org/10.1161/CIRCULATIONAHA.117.030371

RESEARCH LETTER

Battery Malfunction of a Leadless Cardiac Pacemaker

Worrisome Single-Center Experience

Sergio Richter, MD, Michael Döring, MD, Micaela Ebert, MD, Kerstin Bode, MD, Andreas Müssigbrodt, MD, Philipp Sommer, MD, Daniela Husser, MD, and Gerhard Hindricks, MD

Patient No.	Age, y/Sex	Early Implant (Until April 2014)	LCP Performance at Implant/Last Regular FUp								LCP Failure	Time to Last FUp or LCP Failure, mo
			Sensing, mV		Threshold, V/ms		Impedance, ohm		Cell Voltage, V			
1	81/f	Yes	8.0	7.0	0.5/0.4	0.5/0.4	710	500	3.30	3.28	Yes	36.6
2	73/m	Yes	4.0	5.0	1.25/1.0	1.25/1.0	520	480	3.30	3.27	Yes	30.2
3	71/m	Yes	12.0	NA	0.3/0.4	0.5/0.4	620	690	3.30	3.24	Yes	35.2
4	84/f	Yes	4.0	8.0	1.25/0.4	1.5/0.4	520	410	3.30	3.24	No	38.8
5	83/m	Yes	6.0	12.0	1.25/0.4	0.5/0.4	700	810	3.30	3.29	Yes	37.5
6	85/f	Yes	6.0	11.0	0.4/0.4	2.0/0.4	800	400	3.30	3.20	Yes	37.9
7	84/m	Yes	NA	NA	0.5/0.4	0.5/0.4	730	550	3.30	3.25	Yes	44.6
8	72/m	Yes	7.0	6.5	2.0/0.4	1.0/1.0	500	380	3.30	3.00	No	42.6
9	82/m	Yes	7.5	NA	1.0/0.4	0.5/0.4	630	460	3.30	3.27	No	31.5
10	80/m	No	10.0	12.0	1.0/0.4	0.5/0.4	500	350	3.30	3.30	No	18.3
11	79/f	No	12.0	12.0	1.0/0.4	0.5/0.4	830	430	3.30	3.30	No	11.9
12	75/f	No	NA	NA	1.0/0.4	0.5/0.4	500	410	3.30	3.17	No	17.7
13	69/m	No	8.0	12.0	0.8/0.4	0.75/0.4	520	830	3.30	3.30	No	16.7
14	53/f	No	5.5	7.0	0.5/0.4	0.5/0.4	750	500	3.30	3.30	No	12.9

Found 4 result(s) for your search

I have a Nissan Micra. 06 plate. The problem is that the battery keeps going flat. I have had two new batteries in less

Mechanic's Assistant chat

Answered by martin jones in 22 hours • 10 years ago

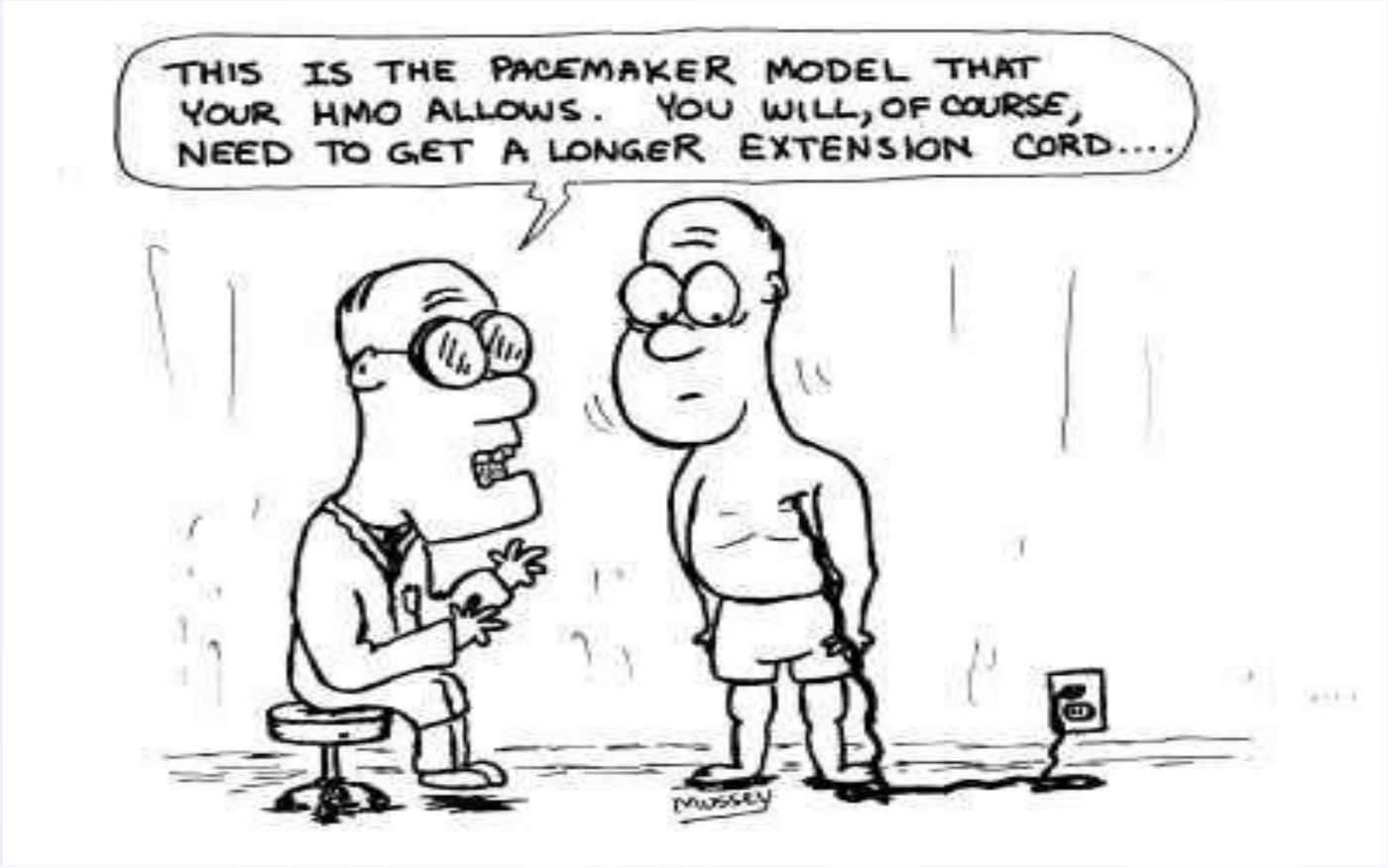
martin jones

25 years as a mechanic and mot tester, owned own business for 10…

★★★★★ **942** satisfied customers

Specialities include: Audi, Car, Citroen, Ford, UK Car, UK Nissan, Vauxhall

Výhodná efektivita za vynaložené peníze


THIS IS THE PACEMAKER MODEL THAT YOUR HMO ALLOWS. YOU WILL, OF COURSE, NEED TO GET A LONGER EXTENSION CORD....
MUSSEY

Cost effectiveness analysis

	Pacemaker type		
	Conventional ($n=244$)	Leadless ($n=159$)	p-value
Men	60.2%	59.1%	0.8217
Women	39.8%	40.9%	
Mean age	83.31	79.15	0.000
Age >75 years	82.8%	78.6%	0.296
AH	76.2%	80.5%	0.312
DM	29.5%	35.2%	0.229
IC	32.0%	24.5%	0.108
COPD	16.4%	17.6%	0.750
CI	17.6%	21.4%	0.881
CM	27.9%	48.4%	0.000
CRF	34.8%	17.6%	0.000
Arteriopathy	8.6%	7.5%	0.705
Valvulopathy	38.1%	42.1%	0.651

AH, arterial hypertension; DM, diabetes mellitus; IC, ischaemic cardiopathy; COPD, chronic obstructive pulmonary disease; CI, cardiac insufficiency; CM, cardiomyopathy; CRF, chronic respiratory failure.

Table 3. Cost-effectiveness analysis.

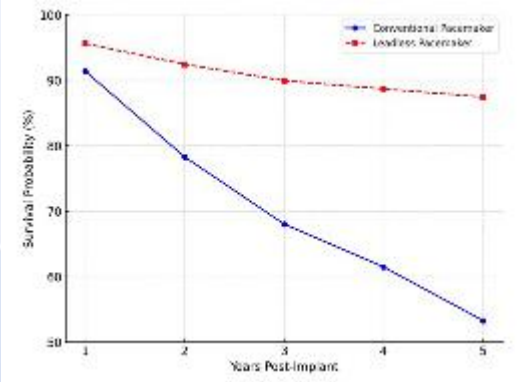
Pacemaker	GLYs	Cost (€)	Incremental GLYs	Incremental cost (€)	ICER
Leadless	4.54	10,773.29	0.99	6,200.75	6,263.38
Conventional	3.55	4,572.54			

GLY, gained life year; ICER, incremental cost-effectiveness ratio.

Table 4. Cost-utility analysis.

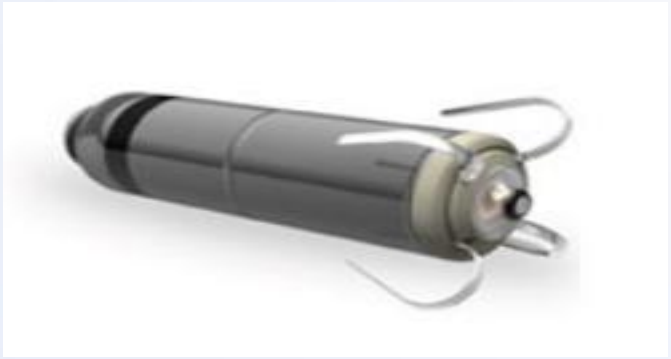
Pacemaker	QALYs	Cost (€)	Incremental QALYs	Incremental cost (€)	ICER
Leadless	3.38	10,773.29	1.19	6,200.75	5,210.71
Conventional	2.19	4,572.54			

QALY, quality-adjusted life year; ICER, incremental cost-effectiveness ratio.



Lago-Quinteiro JR, et al. Annals of Medicine 2025, VOL. 57, NO. 1, 2512108

Cost - Effectiveness



=

Your ticket to Low-Cost Luxury

THE GREAT ALL NEW *Pacemaker*

CHICAGO - NEW YORK

$34.50

Soon, your *Pacemaker* ticket will mean more ... low-cost luxury. For this fine ... an exciting transformation.

Yes, the *Pacemaker* will be gleamingly, luxuriously new. And as always, it will be yours from end to end at New York Central's regular low coach fares.

Soon, the *Pacemaker* will streak ... over the famous Water Level Route... linking New York and Chicago on a schedule almost as fast as the 20th Century Limited.

And the *Pacemaker* is not alone! For today, all over New York Central, world's largest fleet of post-war coaches brings you air-conditioned travel that's *fare*-conditioned, too!

New **Custom Built Coaches!**
Air-conditioned, with deep, lean-back seats, wide windows, fluorescent lights, and many another luxury that 5,000 Central passengers said they wanted.

New **"King Size" Dining Cars!**
Each so spacious it needs a separate kitchen car to prepare those delicious meals which you select from the *Pacemaker's* special money-saving menu.

New **Luxury Lounge Cars!**
Both a Tavern Lounge and an Observation Car will be yours for a change of scene . . . music, refreshments, a quiet game or chat on the all-coach *Pacemaker*.

NEW YORK CENTRAL

The Scenic Water Level Route

LCP v Evropě: EHRA survey

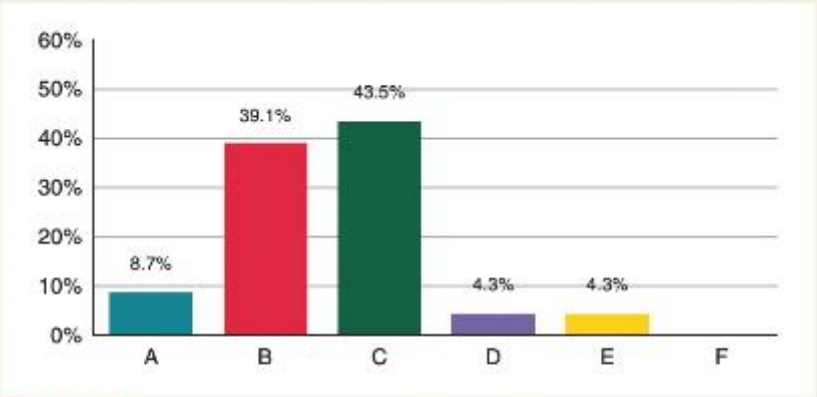


Figure 1 Proportion of respondents to the question: 'How many patients were equipped with a LLPM during the last 12 months in your centre?' Each bar represents one possible answer. A, None; B, <10 patients; C, 10–29 patients; D, 30–49 patients; E, 50–100 patients; and F, >100 patients. LLPM, leadless pacemaker.

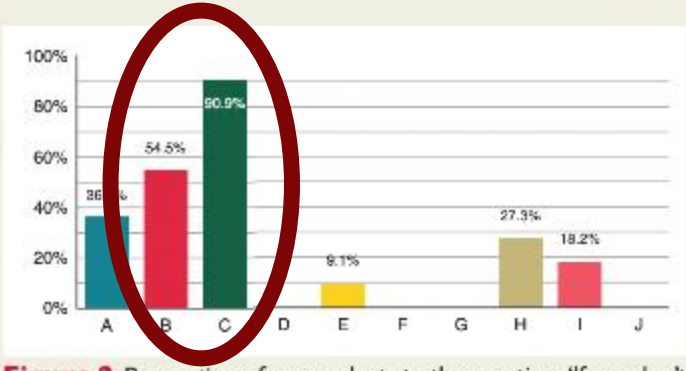
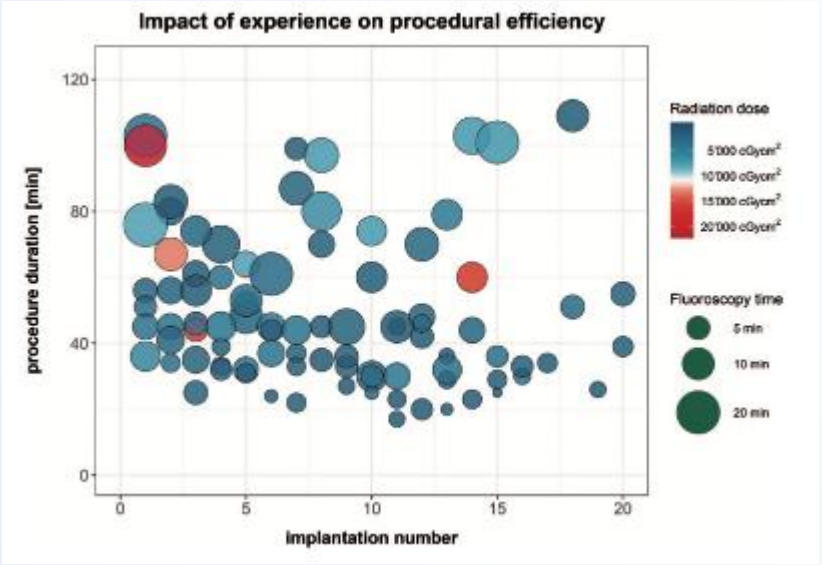


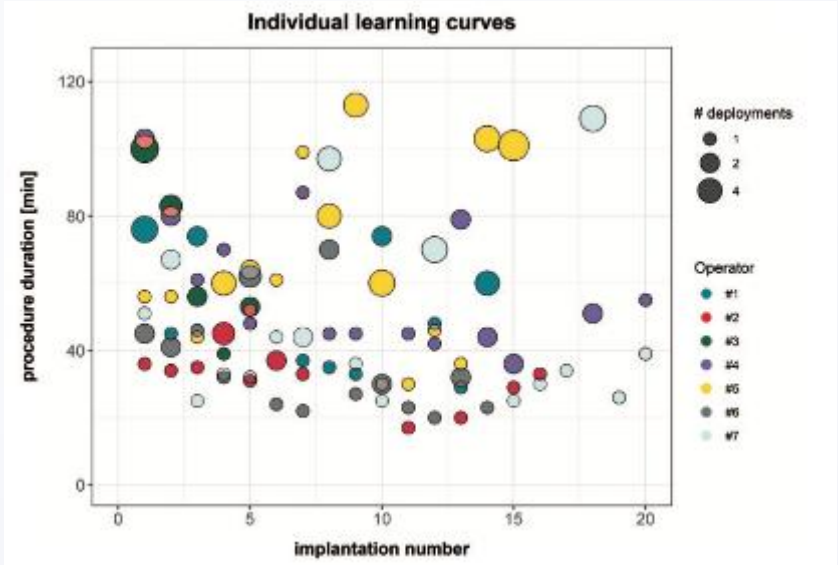
Figure 2 Proportion of respondents to the question: 'If you don't implant leadless pacemakers in your centre, the reasons are (multiple answers)?' A, Not available; B, not reimbursed; C, price too high; D, 'I don't believe in this system'; E, 'I've not been trained to this procedure'; F, procedure too complex; G, need for a surgical back-up; H, lack of dual chamber or CRT pacing function; I, no patients who qualify; J patients rather opt for a conventional pacemaker. CRT, cardiac resynchronization therapy.

Boveda S, et al. Europace (2018) 20, 555–559

Další faktory

Zkušenost operatéra je klíčová





Variables	Univariate analysis		Multivariate analysis	
	OR (95% CI)	P-value	OR (95% CI)	P-value
Patient-related factors				
Age	1.00 (0.95–1.05)	0.90	–	–
Male gender	1.35 (0.53–3.44)	0.53	–	–
Body mass index	1.02 (0.93–1.12)	0.70	–	–
LVEF	1.03 (0.98–1.08)	0.20	–	–
AF-related implantation indication	2.08 (0.88–4.94)	0.10	2.07 (0.86–4.99)	0.11
Procedure-related factors				
Experience first operator	1.09 (1.00–1.19)	0.045	1.09 (1.00–1.19)	0.05
Experience second operator	0.99 (0.96–1.03)	0.66	–	–
Therapeutic anticoagulation	1.49 (0.61–3.64)	0.38	–	–

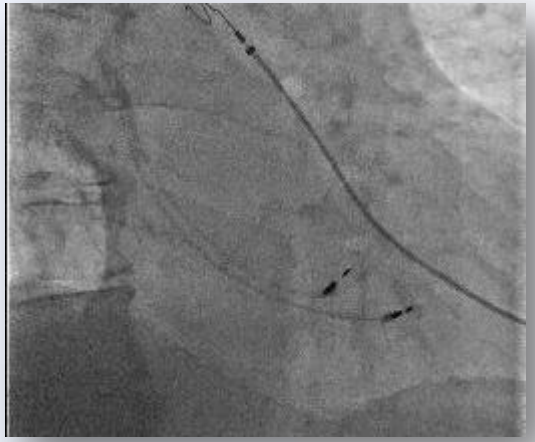
Haeberlin A, et al.
Europace (2020) 22, 939–946

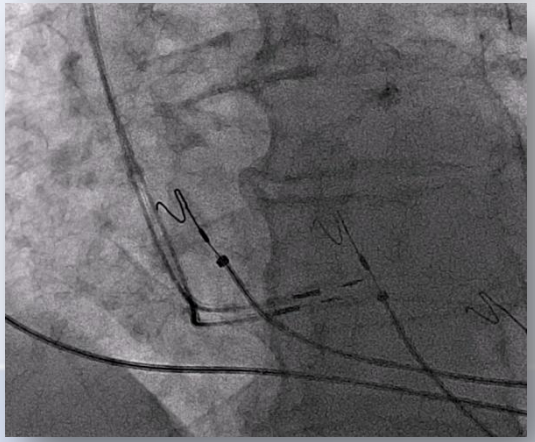
Minimální počet implantací a trénink (Francie)

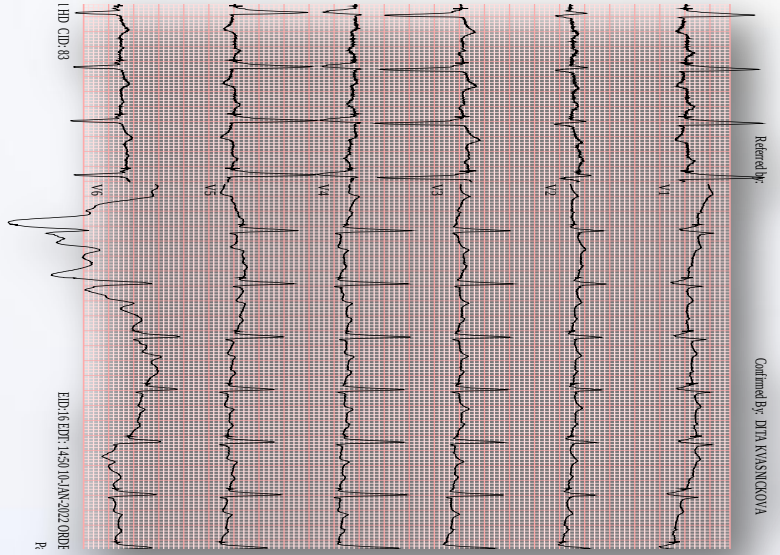
- Ne vice než 2 operatéři/ centrum
- Minimální roční počet implantací – 20
- Kvalifikovaný elektrofyziolog
- Zkušenost s ovládáním ohybatelných zavaděčů a řiditelných katetrů

Defaye P, et al. Arch Cardiovasc Dis (2018) **111**, 53—58

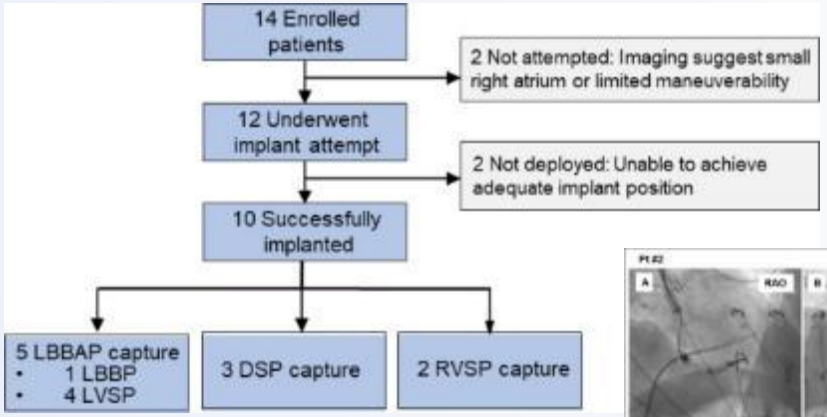
Fyziologická stimulace

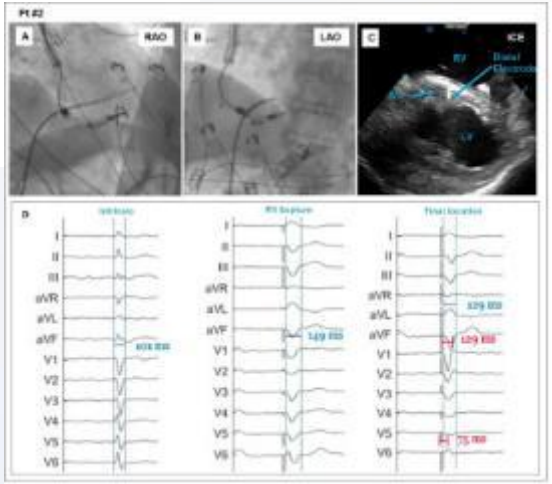


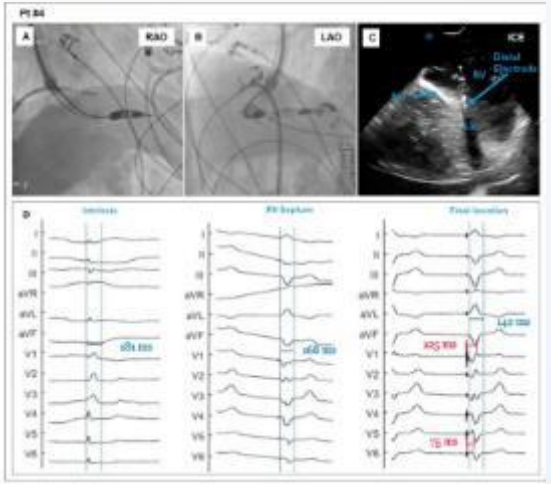




First-in-human LCP CSP trial

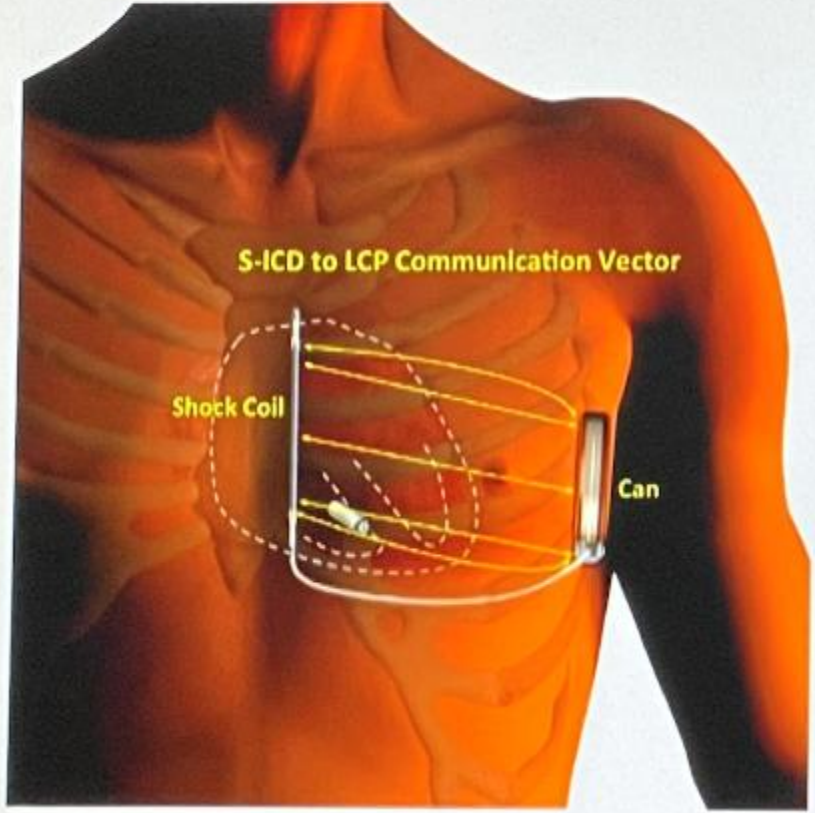




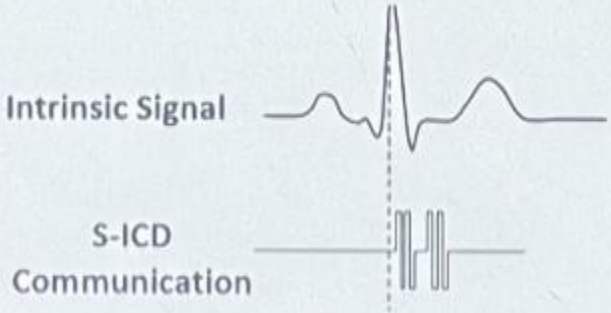


Reddy VY, et al. Heart Rhythm 2025;22:2010–2017)

Modular CRM (mCRM)



- All EMBLEM™ S-ICDs can be upgraded and paired with EMPOWER™
- Utilizes existing morphology-based S-ICD algorithms
- Uni-directional device-device communication from S-ICD → LP
- Specific conductive communication protocol



- Coupled to R-wave
- Voltage and pulse width similar to existing lead impedance measurement
- Built-in redundancy

Závěry

- Leadless stimulace je inovace přinášející změnu paradigmatu stimulace, ale….
- V současnosti jsou indikace omezeny především na jednodutinovou indikaci
- Je potřeba více dat o bezpečnosti, trvanlivosti a dlouhodobé účinnosti v běžném životě
- Hlavní překážkou je cena přístroje
- Vývoj pokračuje směrem k fyziologické stimulaci a modulárním systémům, ale před námi je dlouhá cesta…