Leadless pacing: Kdy, komu a jak?

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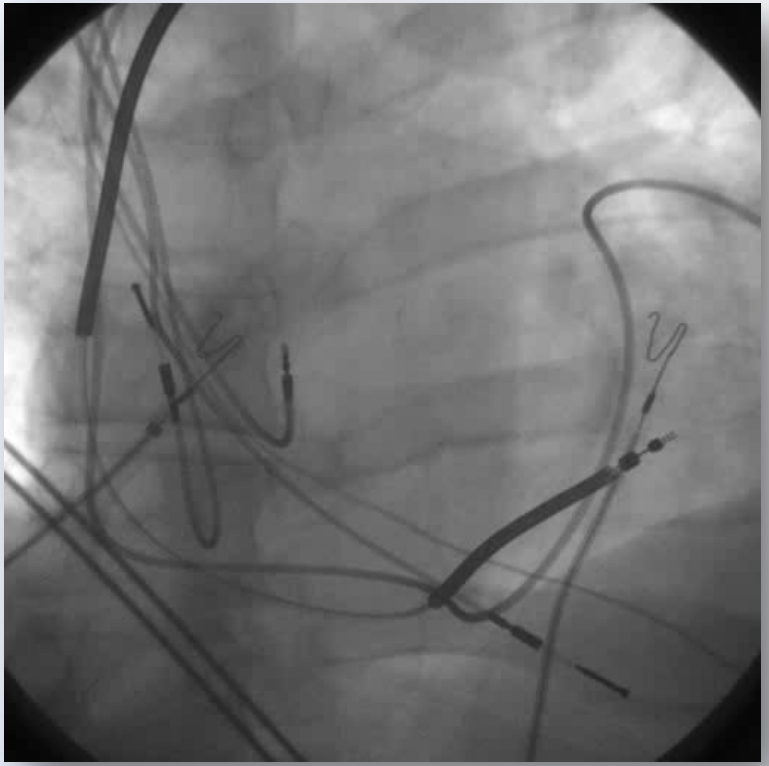
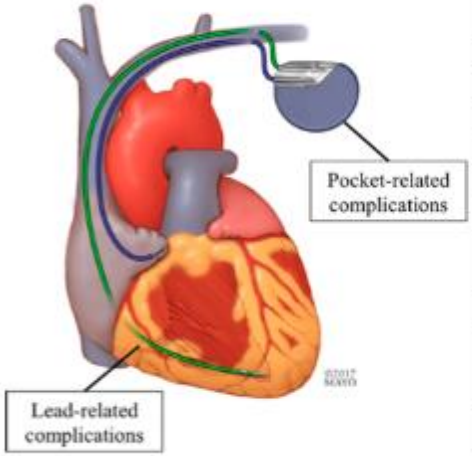
Proč „leadless“?





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]

Koncept není nový…

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

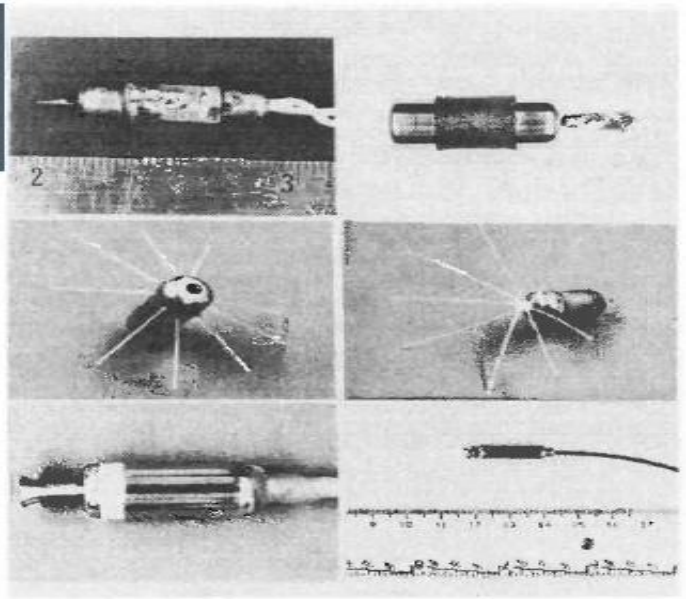


Fig. 2. Some early unsatisfactory dummy capsules used to explore attachment technique.

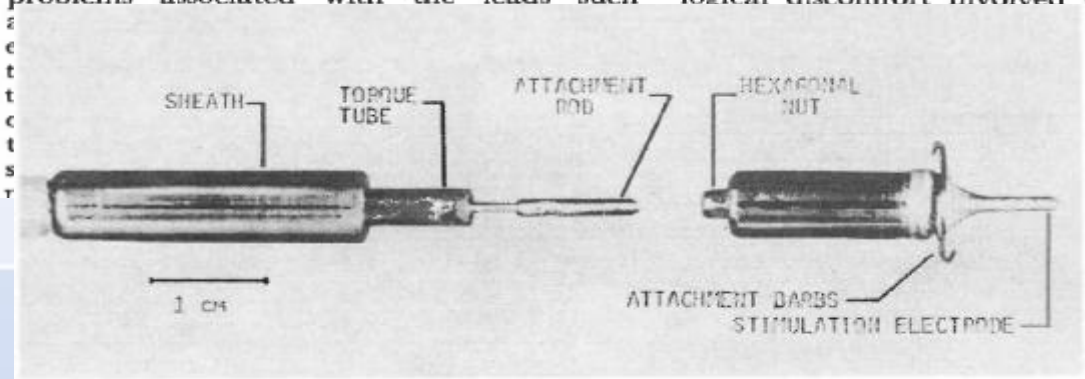


Fig. 4. Intracardiac pacemaker with catheter for transvenous insertion.

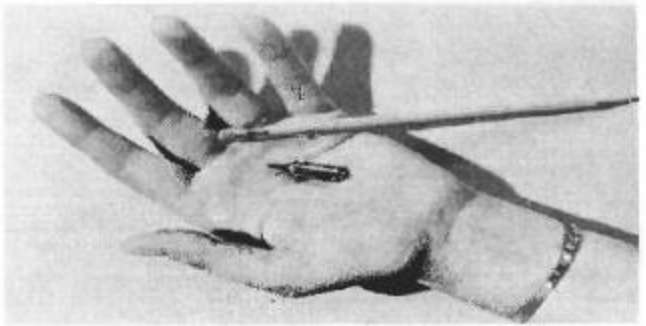


Fig. 8. Nuclear-powered intracardiac pacemaker.

Nicméně uplynulo 20 let …

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.

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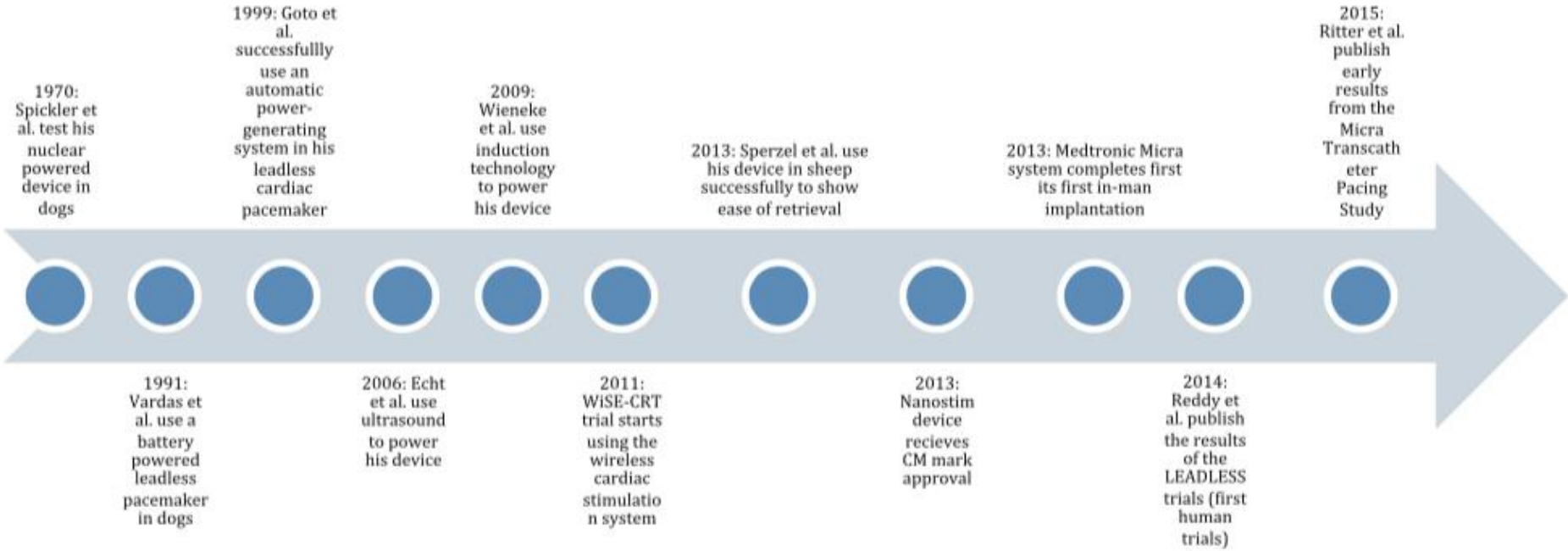
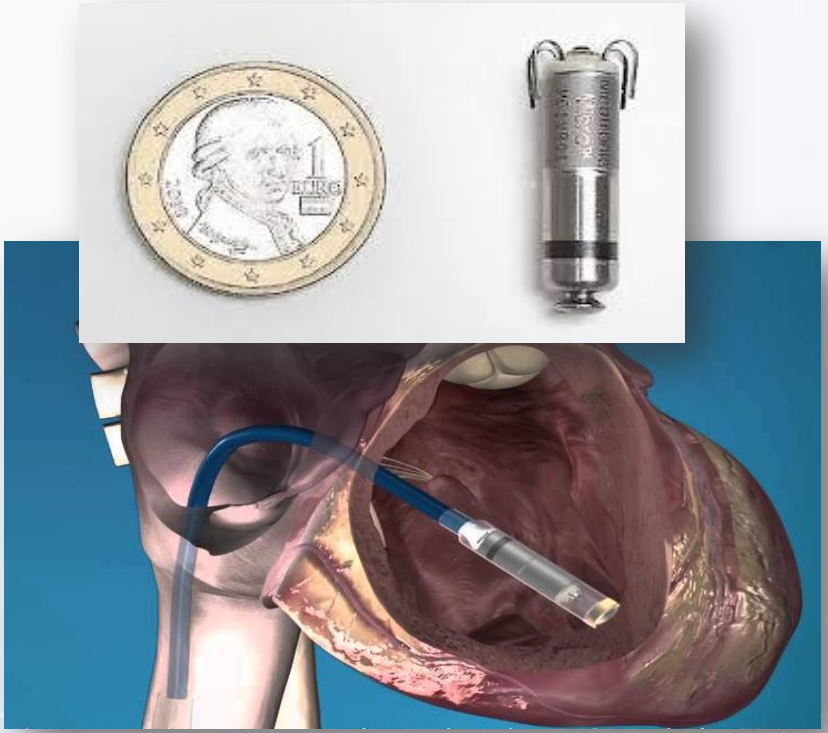
Časová linie vývoje LPC



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

2 druhy leadless stimulátorů



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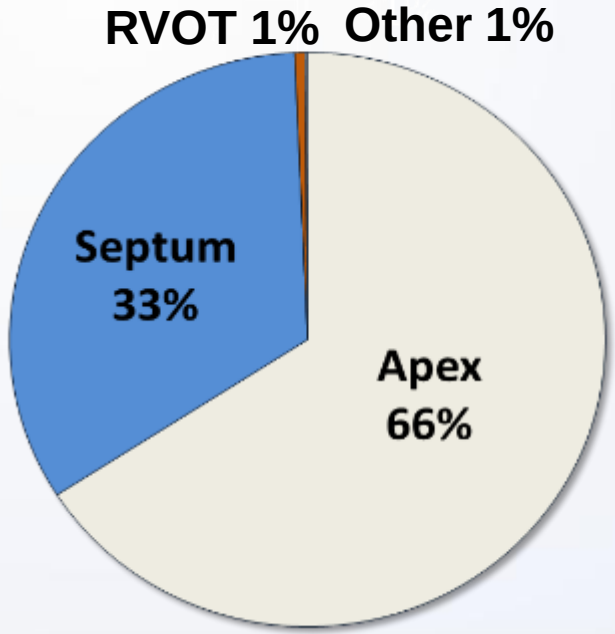
Received 9 February 2015; revised 30 March 2015; accepted 4 May 2015

Implantace Micra v klíčové studii

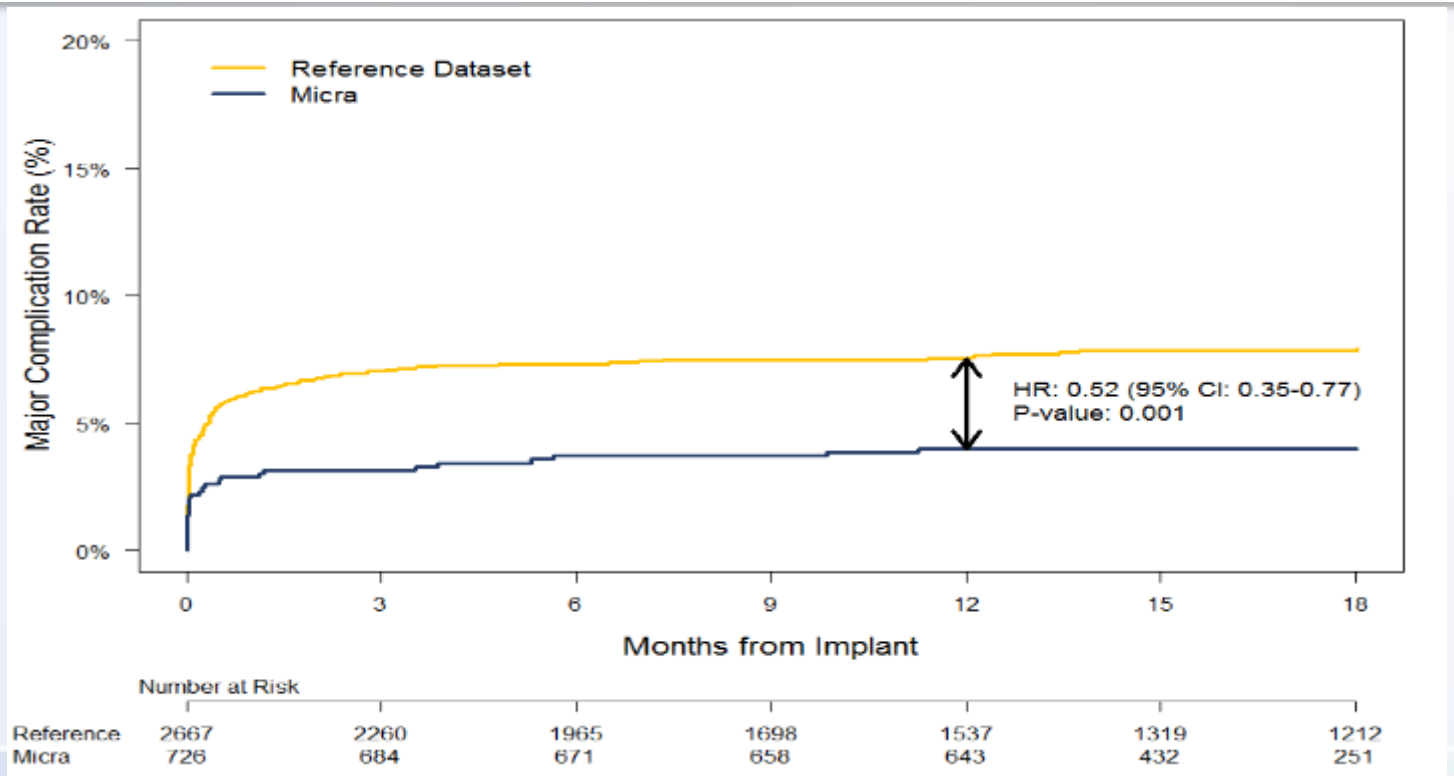
- 99.2% implant success (719 of 725 attempts) with 94 implanters
- Median implant time was 28 min introducer in to introducer out
  - 22 min after 1st 10 implants



Micra větší komplikace (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%)

O 48% méně větších komplikací v porovnání s registrem transvenozních kardiostimulátorů



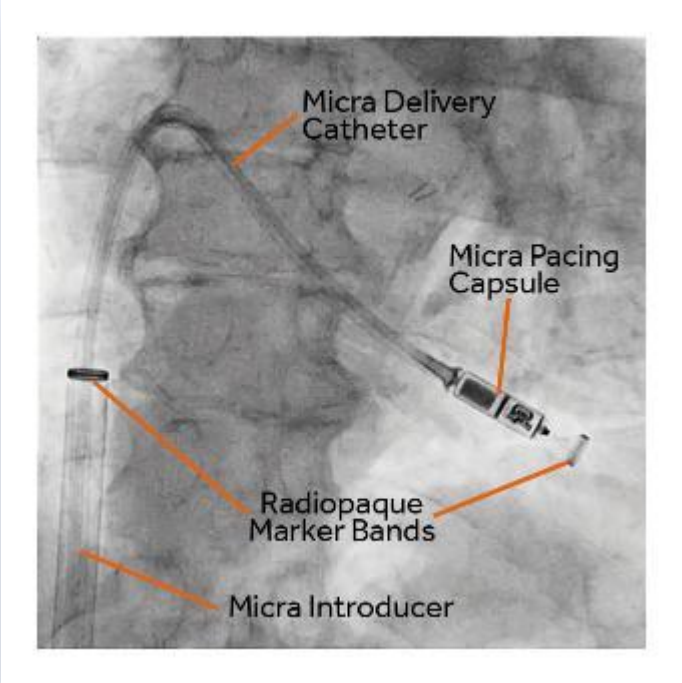
To adjust for differences in patient populations, propensity matching to a subset of the historical control confirmed a reduction in major complications with Micra (HR: 0.46; 95% CI: 0.30-0.72; P-value <0.001).

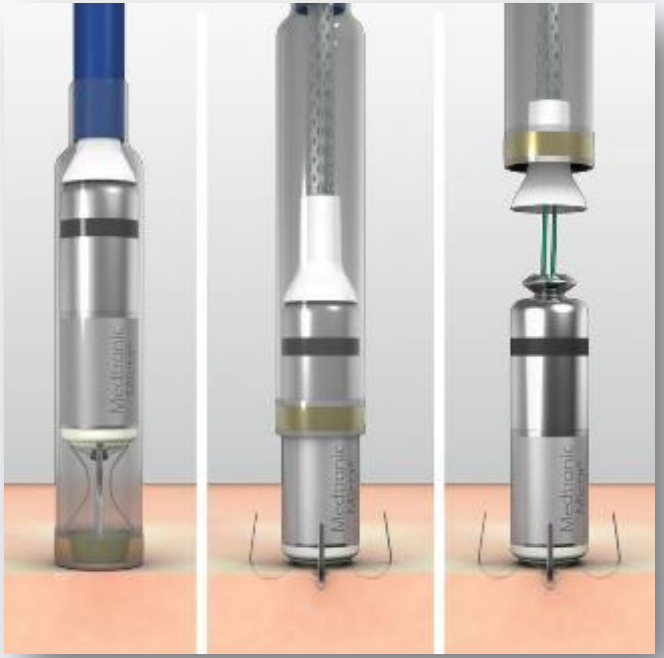
Jak?

Zaváděcí systém - Micra

Medtronic, USA

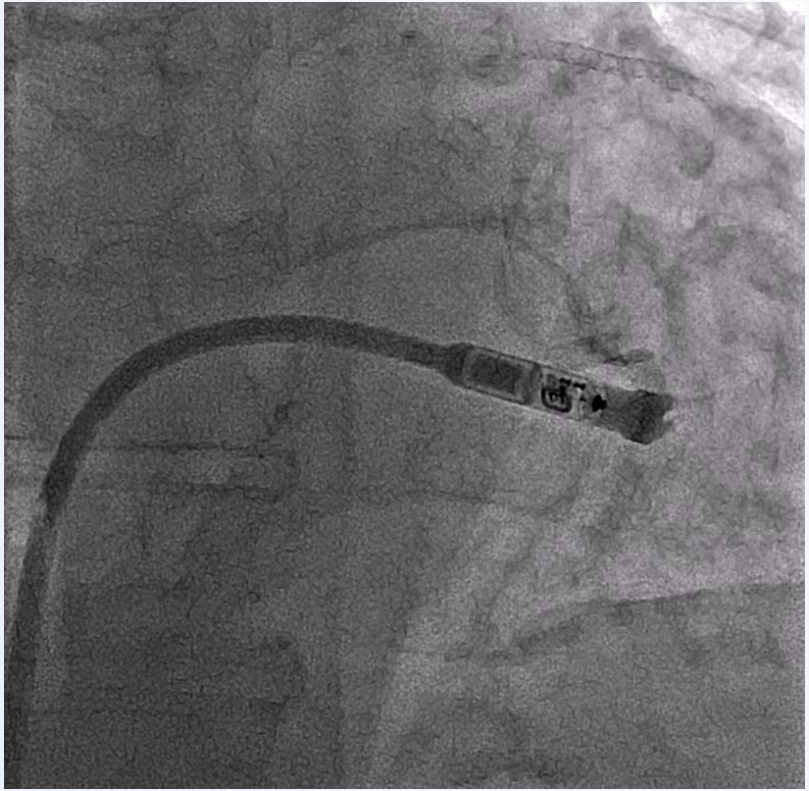
Princip fixace

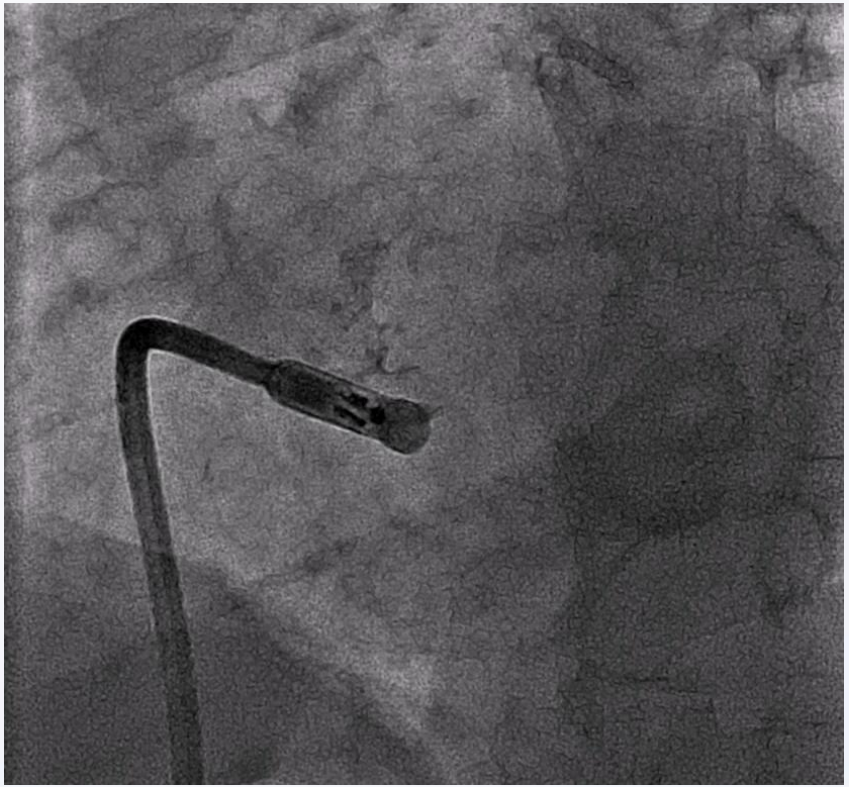




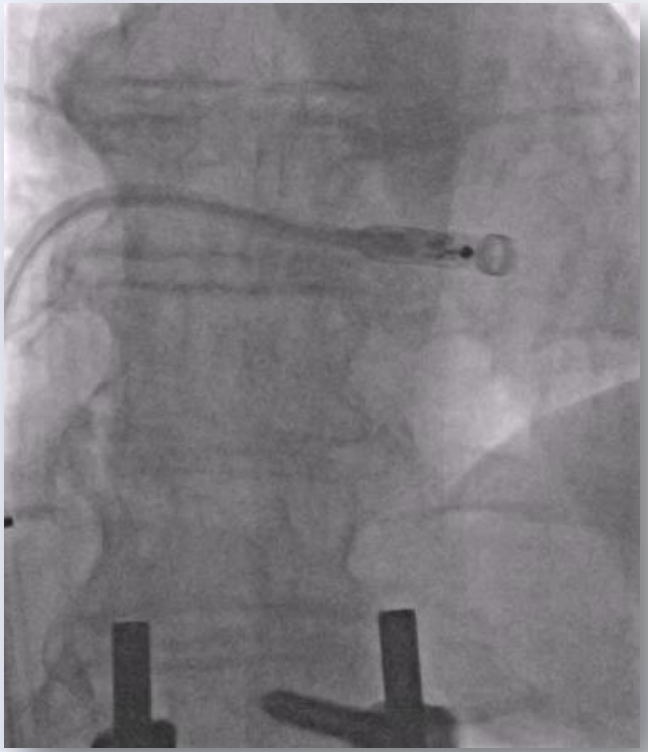
Medtronic, USA

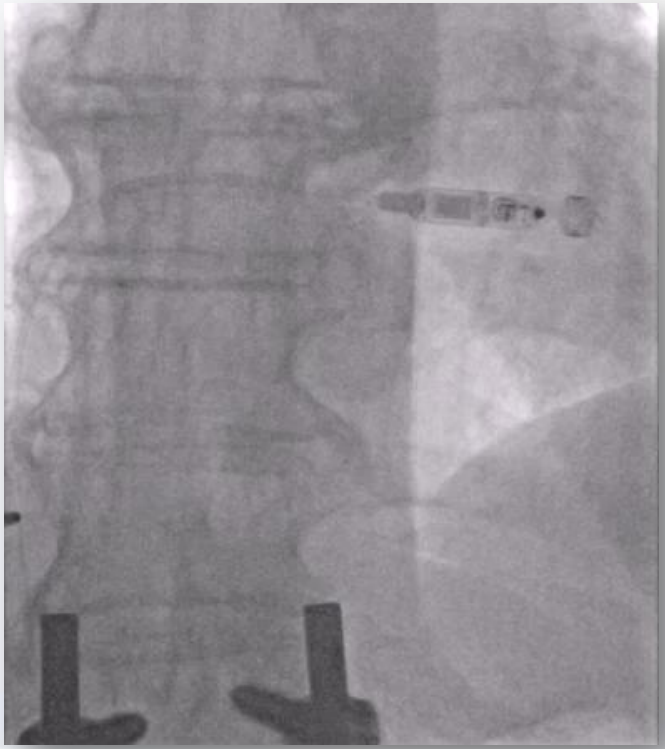
Zavedení LCP na septum PK



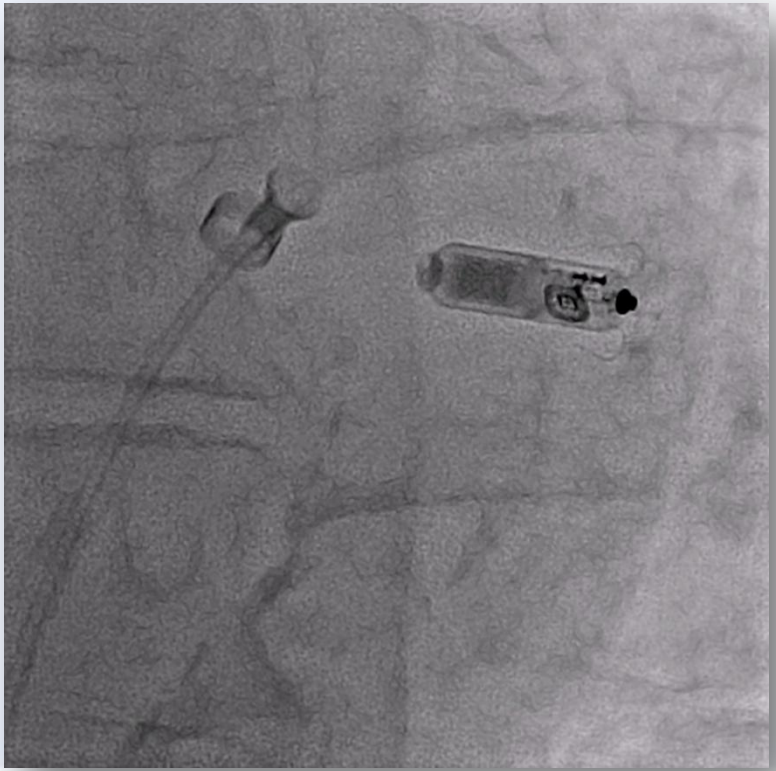


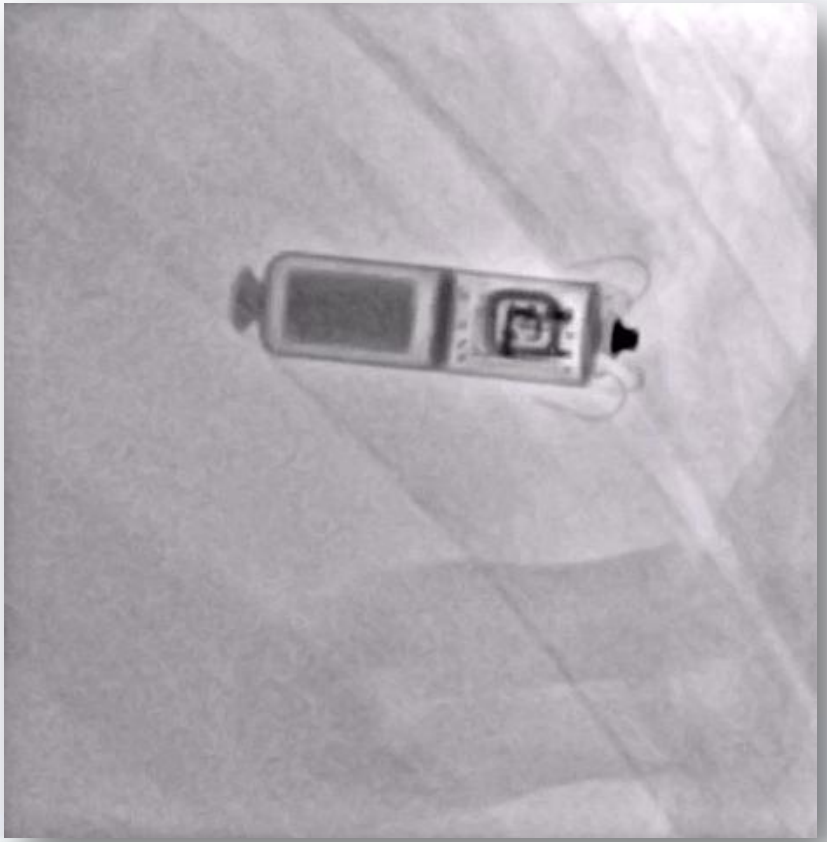
Ukotvení LCP na septu



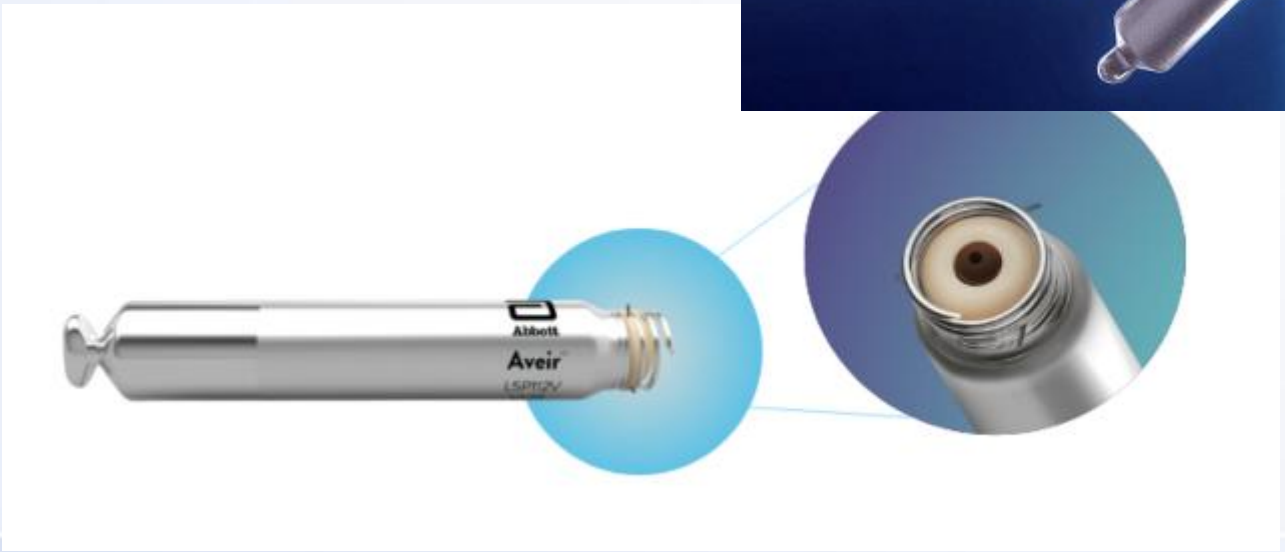


Tahový test

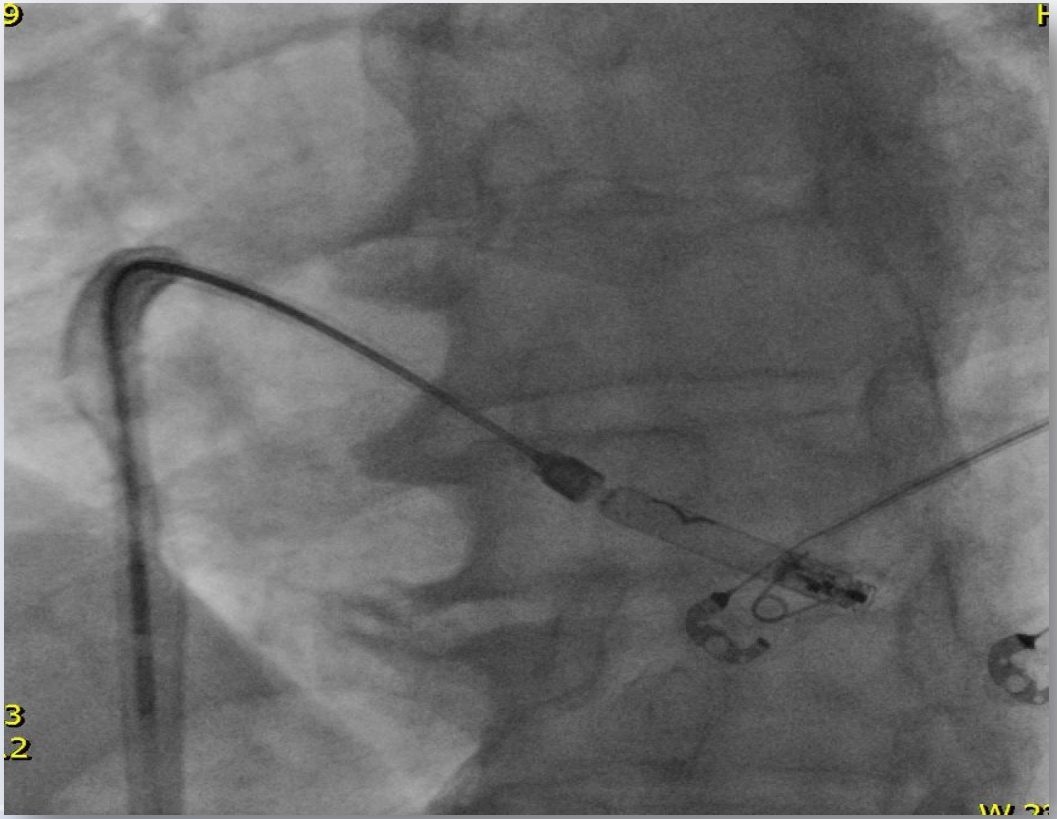




AVEIR VR/DR



Pozice v hrotu PK



Komu implantovat?

Indikace LCP

- Potřeba stimulace - VVI(R) mode (fibrilace síní s potřebou stimulace, intermit. AVB při SR)
- Nově typ AV Micra i režimu VDD(R)
- Nemožnost transvenózního přístupu
- Riziko fraktury elektrod endovazálních el.
- Polymorbidita nemocného
- Starší nemocní
- Vysoké riziko infekce stimulačního systému (hemodialýza, atd)

Recommendations for using leadless pacing (leadless pacemaker)

Recommendations	Class[a]	Level[b]
Leadless pacemakers should be considered as an alternative to transvenous pacemakers when no upper extremity venous access exists or when risk of device pocket infection is particularly high, such as previous infection and patients on haemodialysis.[45,47–50,450]	IIa	B
Leadless pacemakers may be considered as an alternative to standard single-lead ventricular pacing, taking into consideration life expectancy and using shared decision-making.[45,47–50]	IIb	C

Soubor (2017-2021) – 2 implantující

V současnosti 3 implantující, z toho 2 noví, počet cca 40/rok

Počet pacientů	60
Muži	66,6 %
Ženy	33,3 %
Věk – průměr	73,7 roku
Věk – SD	± 9,9 roku

Indikace	počet	procento
AVB III. stupně	24	40,0
bradykardie	21	35,0
SSS	6	10,0
rate control	5	8,3
ostatní	4	6,7

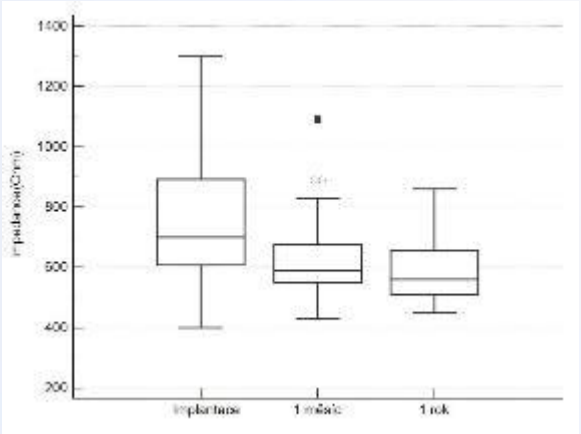
Výsledky – implantační výkon

2 implantující, poměr 21:39 implantací

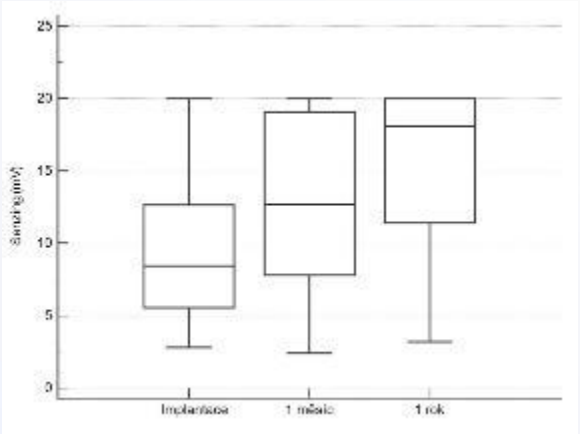
	Průměr	SD	Spearmanovo ρ	p
Implantační čas	63,5 min	± 27,5 min	- 0,0575	0,67
Skiaskopický čas	4,1 min	± 3,6 min	- 0,4817	< 0,0001
Dávka RTG záření	1396,8 μGy.m^2	± 3248,6 μGy.m^2	- 0,6454	< 0,0001

Výsledky – stimulační parametry

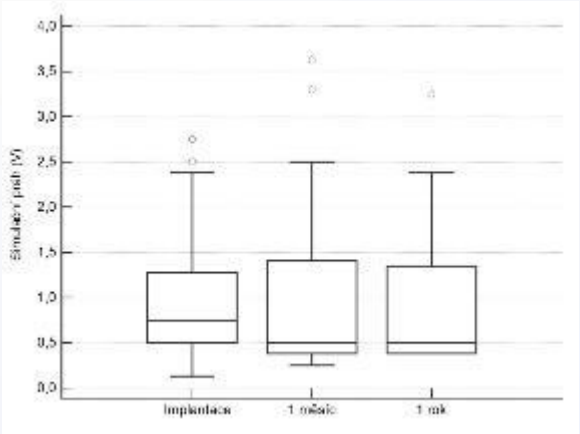
Impedance



Senzing



Stimulační práh



Výsledky - komplikace

Prvních 20 výkonů:

3 komplikace (5%)

- 1x krvácení z třísla
- 1x srdeční tamponáda
- 1x dislokace v rámci pravé komory

Následujících 40 výkonů

- 1x přechodná asystolie
- 37 případů: umístění LCP na první pokus

Data z poslední doby

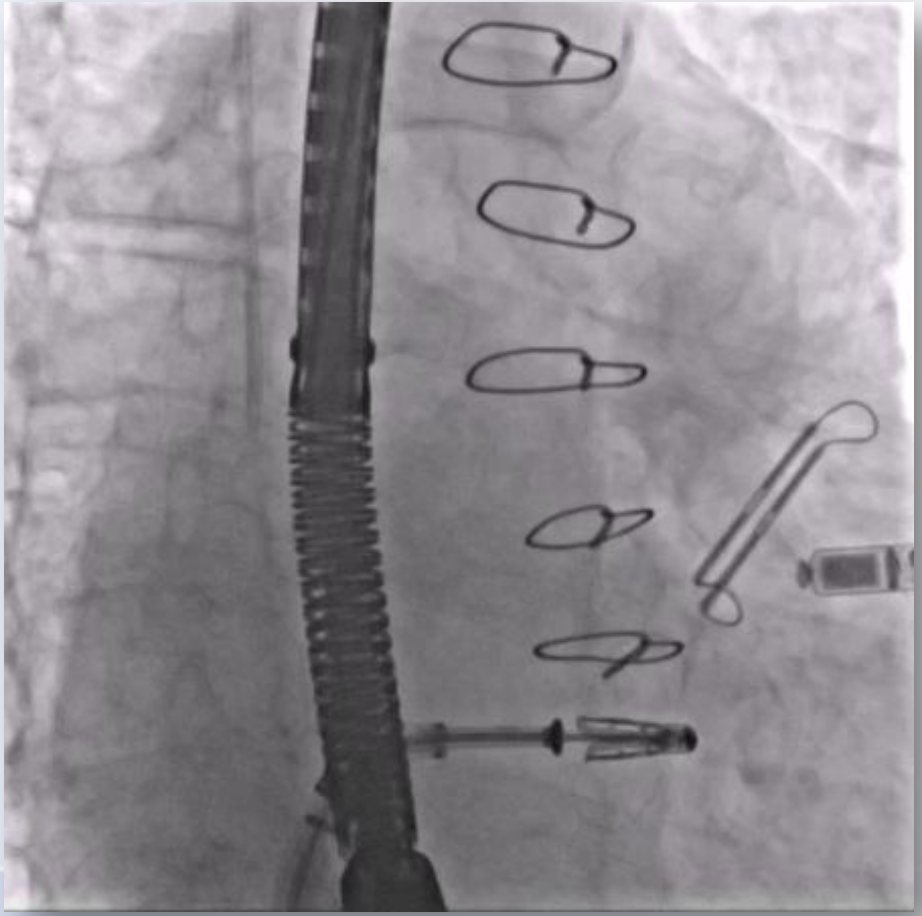
Leden 2020 do srpen 2025 / 3 lékaři

156 pacientů (91 mužů, 65 žen, průměrný věk 73,9 ± 10,2 let)

154 pacientů midseptum PK, 1 x LK (TGV korigovaná), 1 x apex PK

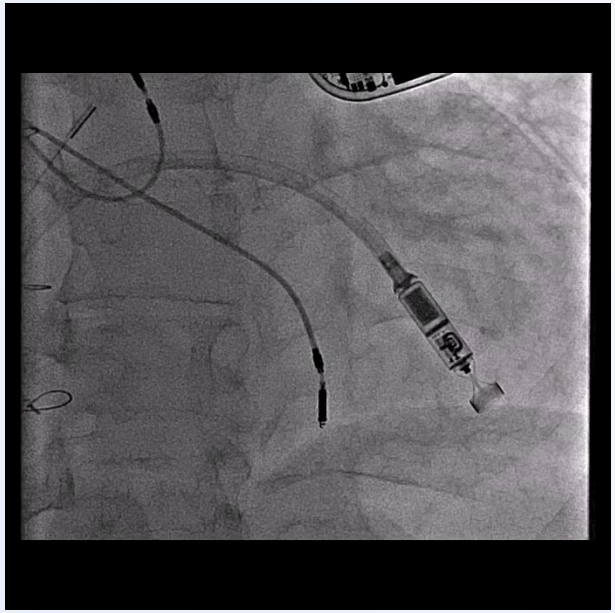
Kdy implantovat?

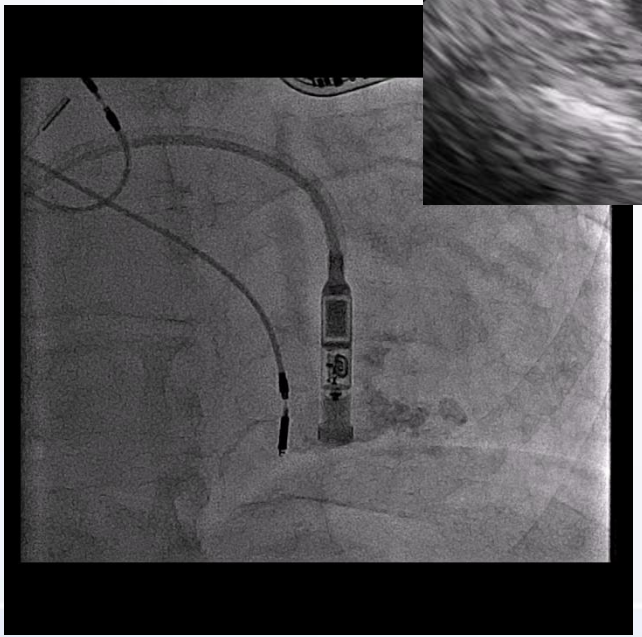
- Kdykoliv, kdy je vhodná indikace, vybavení a operatér se zkušeností

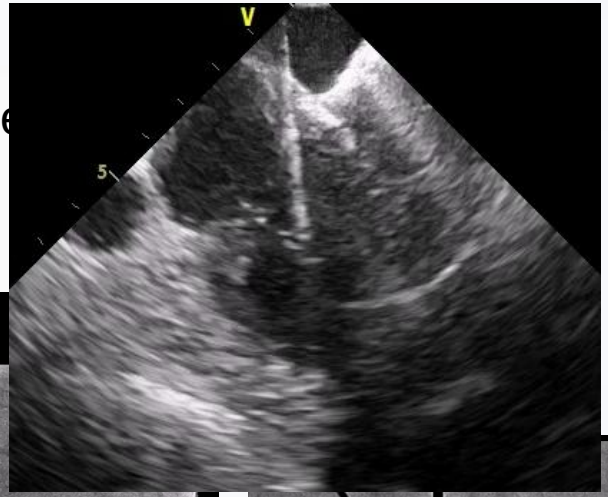


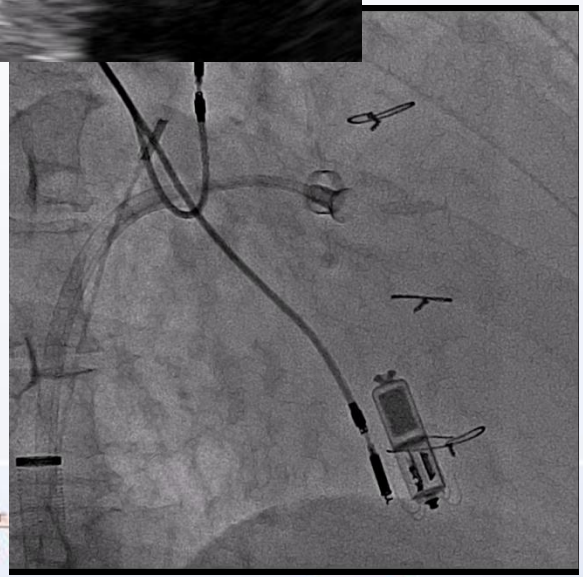
LCP lze kombinovat s Triclipem

- April 21th 2021, Micra implantation, ICE guide



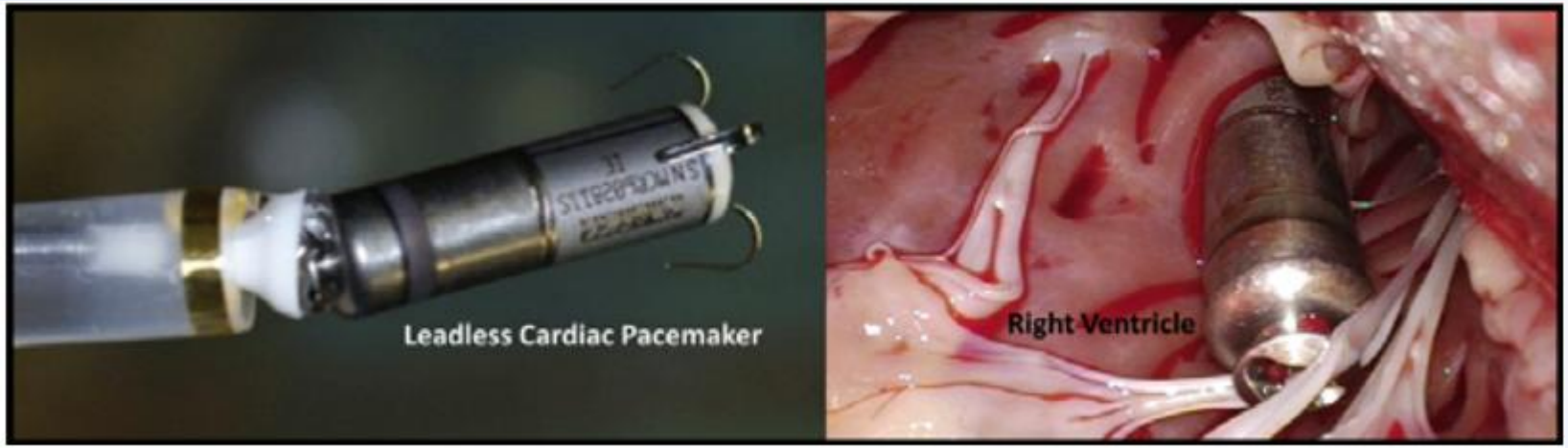






Přímá implantace za vizuální kontroly

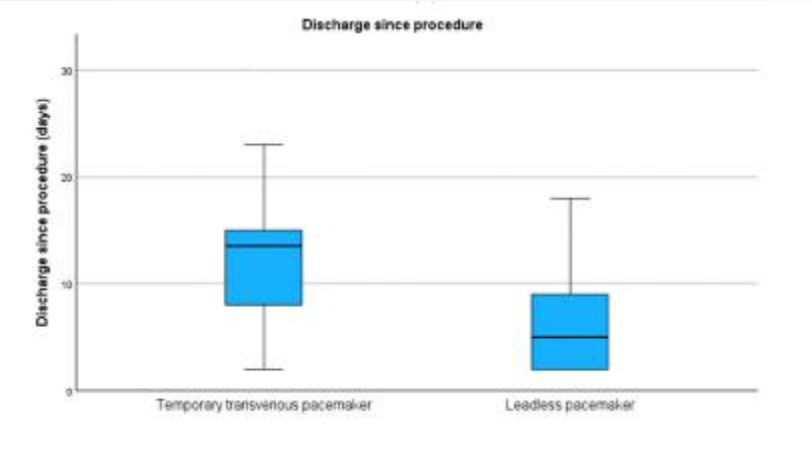
- 15 pts, implantace během KCH výkonu

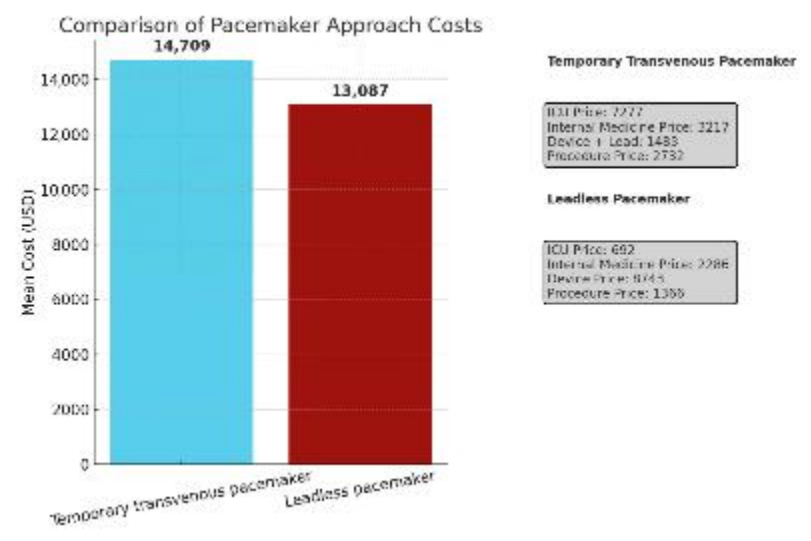


Shivamurthy P, et al. J Thorac Cardiovasc Surg 2022;163:1818-25

Implantace během extrakce systému pro akutní infekci

- 87 pts, 45 LCP během extrakce systému, 42 pts implantace externalizovaného systému a následně permanentního systému
- LCP kratší pobyt na JIP a kratší hospitalizace
- Počet infekcí za 1 rok srovnatelný





Solomon A, et al J. Clin. Med. 2025, 14, 5450

Implantace po chlopenních intervencích

Type of intervention	All patients (*n* = 78)	Micra VR (*n* = 40)	Micra AV (*n* = 38)
AVR	7	3	4
TVR	6	1	5
MVR	3	1	2
Multiple valve	20	13	7
CABG	3	1	2
CABG + valve	5	3	2
s/p OHT	2	1	1
Replacement of aorta/ aortic root	4	1	3
TAVR	25	13	12
TMVR	1	0	1
Mitraclip™	2	2	0

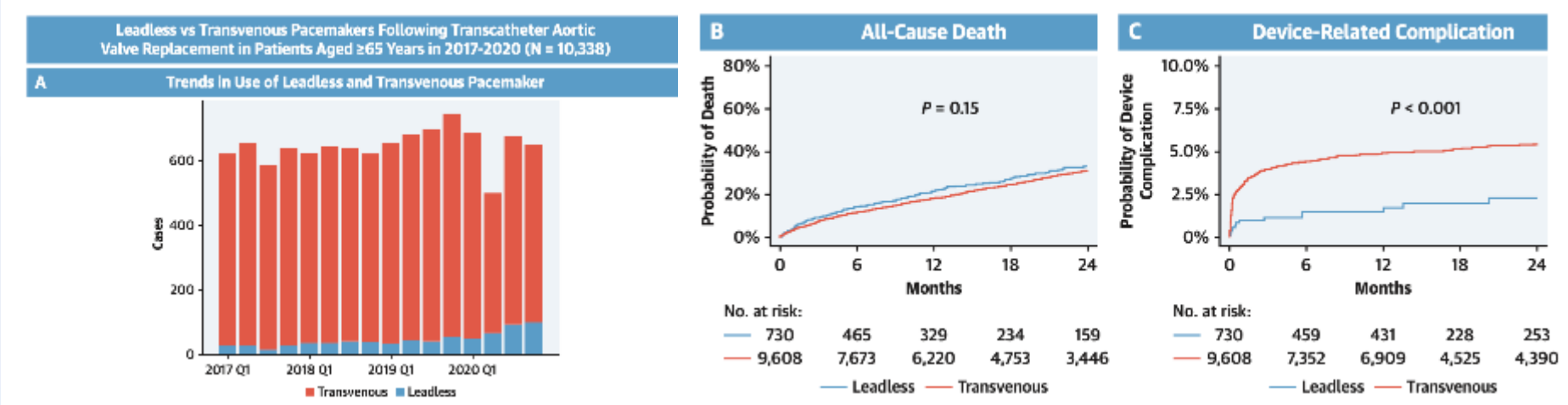
	LVEF drop (*n* = 21)	LVEF stable (*n* = 57)	*p* Value
Gender (M %)	13 (61.9%)	28 (49.1%)	.32
Age	71.2 ± 15.3	64.8 ± 18.4	.16
DM	5 (23.8%)	14 (24.6%)	.95
Hypertension	12 (57.1%)	31 (54.4%)	.83
CAD	5 (23.8%)	16 (28.1%)	.71
Hx of PCI	1 (4.7%)	3 (5.3%)	.93
Hx of CABG	3 (14.3%)	8 (14.0%)	.98
Paroxysmal Afib	6 (28.6%)	16 (28.1%)	.97
Permanent Afib	5 (23.8%)	8 (14.0%)	.31
ESRD	7 (33.3%)	18 (31.6%)	.88
Hx of HFrEF	11 (52.3%)	11 (19.3%)	<.01
Hx of HFpEF	3 (14.3%)	9 (15.8%)	.87
Follow-up time (year)	1.1 ± 0.9	1.3 ± 1.2	.38
Mean time between cardiac procedure and Micra LP implant (days)	8.3 ± 7.9	7.0 ± 8.1	.54

Micra VR	Postprocedural	Last follow-up	*p* Value
R waves (mV)	10.9 ± 5.3	10.3 ± 5.3	.27
Impedance (ohms)	636.0 ± 192.1	531.8 ± 134.8	<.001
Capture threshold @ 0.24 ms	0.5 V ± 0.2	0.7 V ± 0.4	<.001
RV pacing burden (%)	69.9 ± 38.8	50.3 ± 39.5	.01
LVEF (%)	54.1 ± 11.9	48.8 ± 11.9	.003
Micra AV	**Postprocedural**	**Last follow-up**	***p* Value**
R waves (mV)	11.2 ± 5.0	11.4 ± 5.3	.85
Impedance (ohms)	740.1 ± 230.7	537.9 ± 106.9	<.001
Capture threshold @ 0.24 ms	0.5 V ± 0.3	0.6 V ± 0.4	.22
RV pacing burden (%)	78.9 ± 35.3	45.0 ± 42.1	<.001
LVEF (%)	56.1 ± 9.0	54.6 ± 9.7	.06

Huang J, et al. J. Cardiovasc. Electrophysiol. 2023;34:2216–2222

Leadless po TAVI

(730 leadless vs 9,608 transvenózních PM)



Kdy neimplantovat?

- Není-li vhodná indikace, vybavení a operatér se zkušeností

Kontraindikace implantace

- Mechanická trikuspidální chlopeň
- Preexistující funkční stimulační nebo defibrilační elektroda
- Kavální filtr (lze implantovat shora)
- Hypersensitivita k dexamethason acetatu
- Nepříznivá anatomie
- Pacemakerový syndrom
- Pre-existující těžká plicní hypertenze

Lee JZ, et al. Trends Cardiovasc Meed 28(2018)130–141

Závěry

- „Leadless“ stimulace přináší změnu paradigmatu v kardiostimulaci
- Indikace jsou zatím omezeny na poměrně malý počet pacientů (méně než 10%)
- Hlavní indikací je riziko infekce, opakovaná infekce, nemožnost zavedení elektrod shora, riziko fraktury elektrod, polymorbidita
- Přístroj lze implantovat i při výměně systému pro infekci nebo u chlopenních a vrozených vad