CZECH SOCIETY OF CARDIOLOGY

An international symposium to commemorate the 20th anniversary of the first CRT implants in the Czech Republic

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Alternative techniques for LV lead implant

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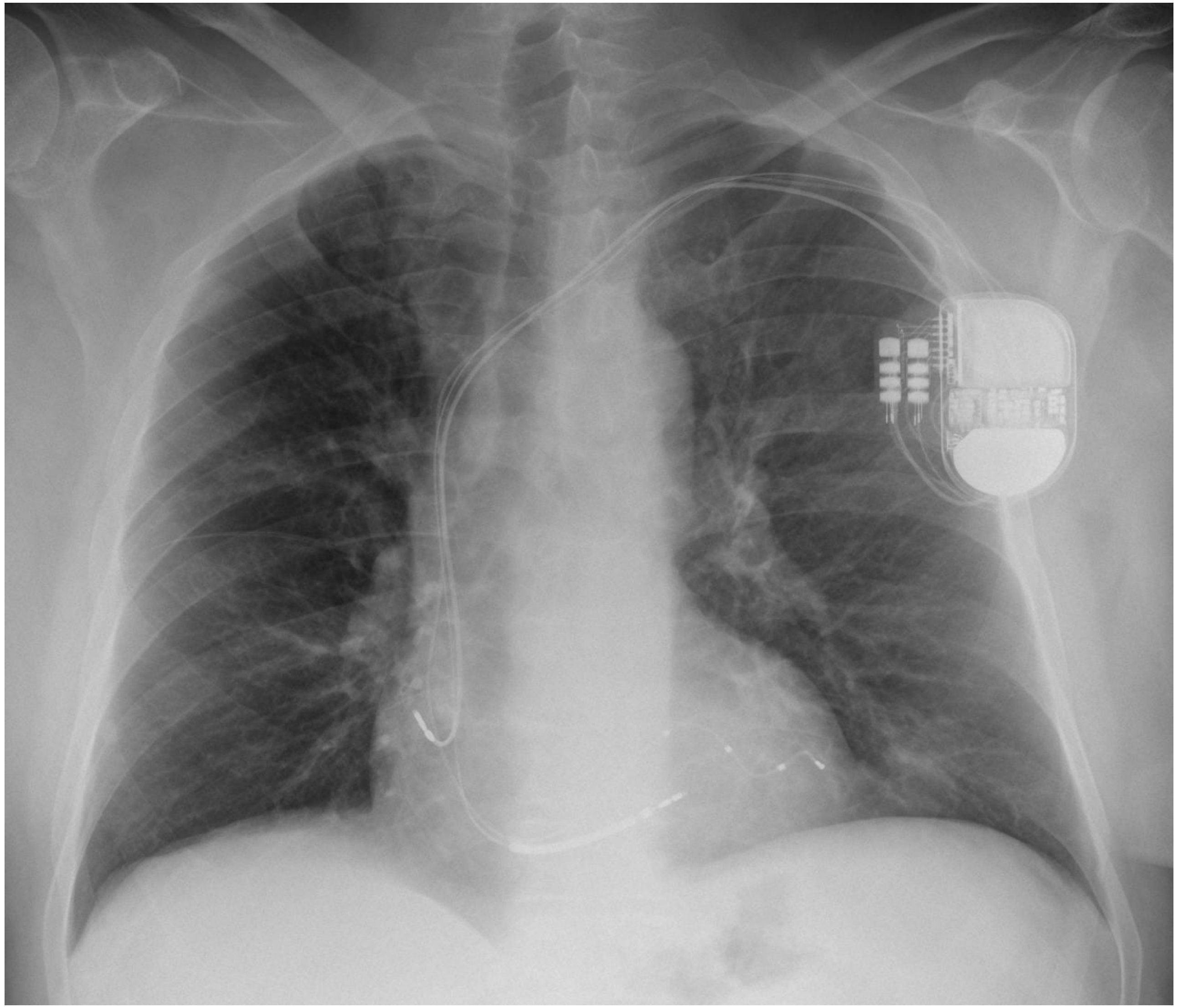
Gold standard of LV lead implantation

Transvenous epicardial LV pacing via CS



LV lead implant success rate

- LV lead transvenous implant success rate varies from 89 % to 98 %[1, 2].

- Leon et al.[2] published results of more than 2,000 implants in MIRACLE **(MIRACLE, MIRACLE ICD, and InSync III)** studies. 1,903 out of 2,078 patients **(i.e. 91.6%)** were successfully implanted in this group, of which 35 (i.e. 1.8%) required more than one procedure.

- **CARE-HF study** overall procedural **success rate 95,6 %** (390 from 404 pt). 89,5 % pt by first implant, 9,2 % second attempt a 1,3 % pt third attempt[1].

1. Gras D, Bocker D, Lunati M *et al. Europace* 2007; 9(7):516-522.

2. Leon AR, Abraham WT, Curtis AB *et al. J Am Coll Cardiol* 2005;46(12):2348-2356.

Success vs. experience

- In the **MIRACLE[2] patient group,** the experience of the implanting doctor predicted successful completion of implantation. The success of the **first 5 implants was 89.5% in all implant centers, increased to 94.6% for the next 5 implants**, and remained at 93.4% for all other cases.
- In **CARE-HF[1]**, the success of the first procedure depended on the experience of the implant center**: it reached 90% in high-volume centers, and only 82% in small centers.**
- Further work confirms that the success rate of implantation is **highest in high-volume centers**, and after the introduction of **OTW technique, 98%** was in one high-volume center in 400 patients[3].
- Bulava et al. (2007)[4] reported a 98% first attempt success rate and the overall transvenous success rate, for CS lead placement, was 99%.

1. Gras D, Bocker D, Lunati M *et al. Europace* 2007; 9(7):516-522. 2. Leon AR, Abraham WT, Curtis AB *et al. J Am Coll Cardiol* 2005;46(12):2348-2356. 3. Leon AR, Delurgio DB, Mera F. *J Cardiovasc Electorophysiol* 2005;16(1):100-105. 4. Bulava A, Lukl J. *Europace* 2007;9:523-527

Causes of LV lead implant failure

	Comment
Absence of venous access	Stenosis or complete oclusion access vein (v. subclavia)
Accesing the coronary sinus	Prominent Eustachian valve, Thebesian valve; extreme RA dilatation
Absence of lateral CS branch	Gracile branches, absence of lateral branches
Mechanical instability of the LV lead	Unstable LV lead position, repeated LV lead dislocation
High pacing threshold	Extensive scar at the target area, epicardial fat tissue
Phrenic nerve stimulation	Absence of the lead location without phrenic nerve stimulation

Causes of LV lead implant failure

- **Ve skupině MIRACLE** byla nejčastějším důvodem selhání implantace 1. neúspěšná kanylace koronárního sinu (39,4 % neúspěšných procedur), 2. časná dislokace nebo nestabilita LK elektrody (33,7 %) a 3. nemožnost zavedení elektrody do cílové větve (29,7 %)[2].
- Podobně i ve **studii CARE-HF**[1] byla nejčastějším důvodem selhání implantace LK elektrody 1. neúspěšná kanylace koronárního sinu (42,8 %), následovaná 2. nedosažením stabilní polohy elektrody (32,6 %), 3. nemožností zavedení elektrody do cílové větve (12,2 %), vysokým stimulačním prahem (8,2 %) a výčet důvodů neúspěšné implantace byl zakončen neovlivnitelnou stimulací bráničního nervu (4,1 %).

1. Gras D, Bocker D, Lunati M *et al. Europace* 2007; 9(7):516-522.

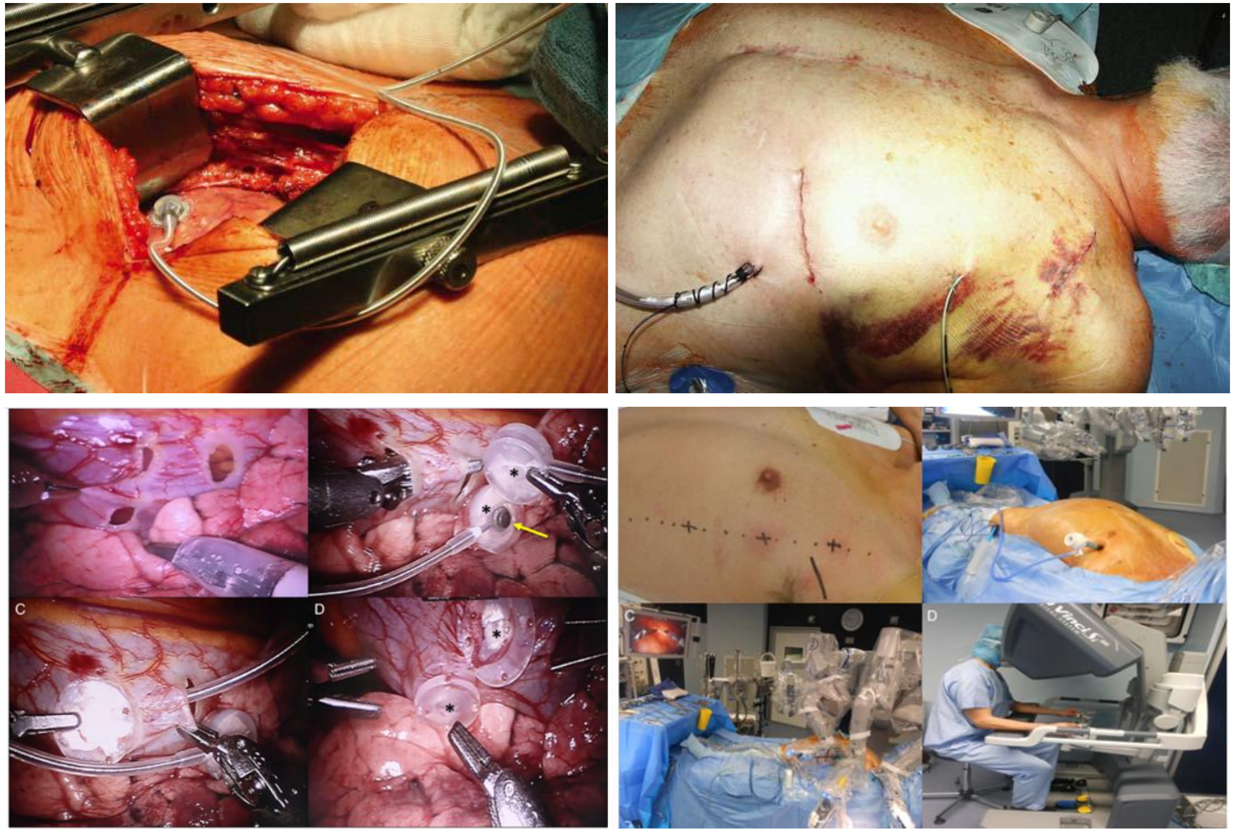
2. Leon AR, Abraham WT, Curtis AB *et al. J Am Coll Cardiol* 2005;46(12):2348-2356.

Features of alternative LV pacing methods

	In clinical practice since	Access	Pacing site	System components for LV pacing	Invasiveness / fitting into hospital workflow
sEPI	Before CRT era	Surgical / full sized-, mini-, robotic-thoracotomy	Epicardial-like CS side branches	Only standard epicardial pacing lead	Under general anaesthesia, transition of pts to surgical team and waiting list
TIAsLV	1997	Percutaneous venous, atrial septal puncture and sheet guiding, passing mitral valve	Endocardial with lead	Only standard endocardial pacing lead with active fixation	Longer procedure but with the same team and waiting list
TALV	2007	Surgical / minithoracotomy	Endocardial with lead	Only standard endocardial pacing lead with active fixation	Under general anaesthesia, transition of pts to surgical team and waiting list
TIVsLV	2011	Percutaneous venous, ventricular septal perforation and sheet guiding	Endocardial with lead	Only standard endocardial pacing lead with active fixation	Longer procedure but with the same team and waiting list
WiSE	2012	Percutaneous femoral, artery puncture, trans-aortic sheet guiding	Endocardial without lead	Subcutaneous battery, subcutaneous transmitter, receiver-electrode implanted	Longer procedure but with the same team and waiting list

Surgical techniques for epicardial lead implantation

- **STERNOTOMY** – CONCOMITANT CARDIAC SURGERY (REVASCULARIZATION, VALVE REPAIR/REPLACEMENT)
- **MINI-THORACOTOMY**
- VIDEO-ASSISTED THORACOSCOPY APPROACH **(VATS)**
- **ROBOTICALLY ENHANCED** TELE-MANIPULATION SYSTEMS



COMPARISON OF THE STANDARD ENDOVASCULAR VERSUS SURGICAL APPROACH

- Mair et al. (2005) reported on 80 patients with epicardial LV leads for BiV pacing implanted using **3 different techniques (mini-thoracotomy, a VATS approach and a robotically enhanced tele-manipulation system)**. They reported that acute and **3-month LV lead thresholds were satisfactory in 79 patients (99%).** Two lead displacements were observed. Five patients who underwent the robotic procedure needed a conversion to thoracotomy because of a technical failure of the robotic system (2 patients) or massive pleural adhesions (3 patients). There were no severe adverse events related to any of the techniques used.
- Garikipati et al. (2014) compared endovascular and epicardial groups in patients with HF. Epicardial leads were placed using a **minimally invasive, robot-assisted thoracoscopic approach.** The primary end point was a decrease in the LV end-systolic volume index at 6 months. The secondary end points included 30-day mortality rate, measures of clinical improvement, 1-year electrical lead performance, and 1-year survival rate. They concluded that **there were no differences in echocardiographic and clinical outcomes.**
- Mair et al. (2005) reported that surgically placed epicardial leads had **excellent long-term results and a lower LV-related complication rate compared to CS leads.** Additionally, they found that the **mini-thoracotomy approach was a safe and reliable technique that offered 100% accuracy** relative to lead placement on the intended target and could have potential benefits as the primary implantation method for a substantial subset of patients.

1. Mair H, *et al. Heart Surg Forum* 2003;6:412–7.

2. Garikipati NV, *et al. Am J Cardiol* 2014;113:840-844.

3. Mair H, *et al. Eur J Cardiothorac Surg* 2005;27:235–242.

COMPARISON OF THE STANDARD ENDOVASCULAR VERSUS SURGICAL APPROACH

- On the other hand, Koos et al. (2004) found significantly different outcomes in patients who underwent a limited left thoracotomy (n=25) compared to a coronary sinus approach (n=56). After one year, patients who underwent surgical LV lead placement had **less improvement in LV EF and peak functional capacity and worse survival.**

- The finding that epicardial LV leads were more likely to be placed anteriorly may explain the reduction in ventricular remodelling seen in this study.

Koos R, Sachweh J, Meuris B *et al. Am J Cardiol* 2004;94:59-63.

Our experiences

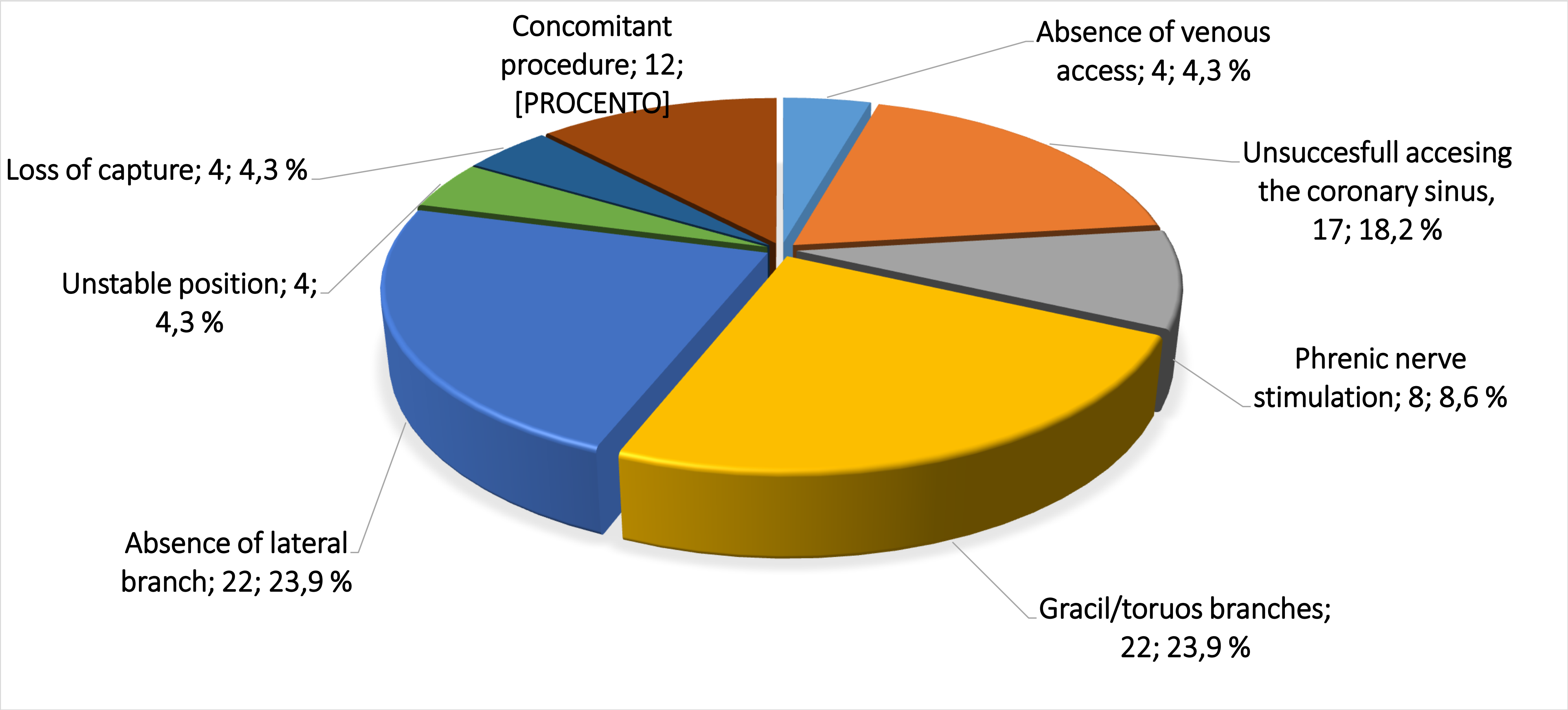
- 2008-2014 = 1488 endovasal procedures (České Budějovice n = 712, Olomouc n = 776).
- 92 pt indication to epicardial lead implantation. 12 pt concomitant implantation.
- The overall procedural success of endovasal implantation has been achieved 94,6 % (České Budějovice 98,04 %, Olomouc 91,9 %, p < 0,0001).

Primary and secondary endpoints

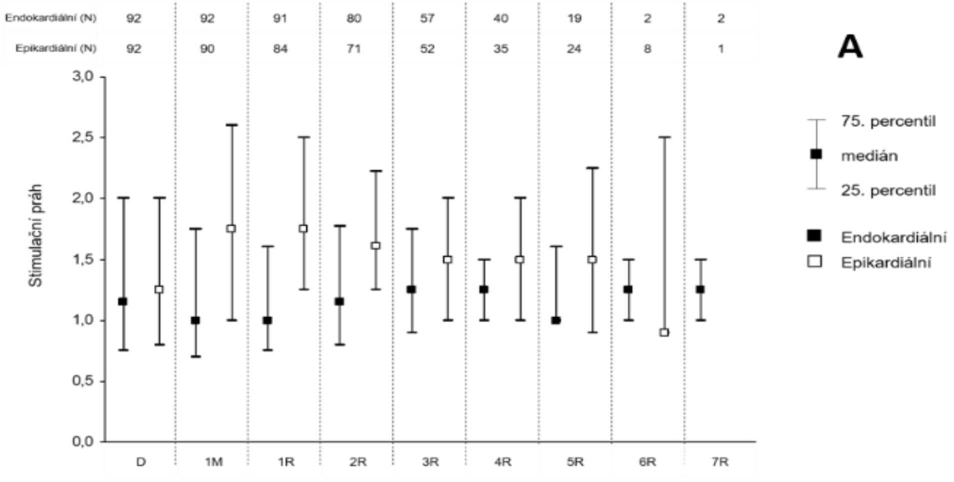
- Investigate the **middle-term electrical parameters of the epicardial LV leads** and compare them to the endovasally implanted leads.
- Determine whether the stimulation parameters of epicardial leads implanted surgically can be **affected by various clinical and demographic factors**.

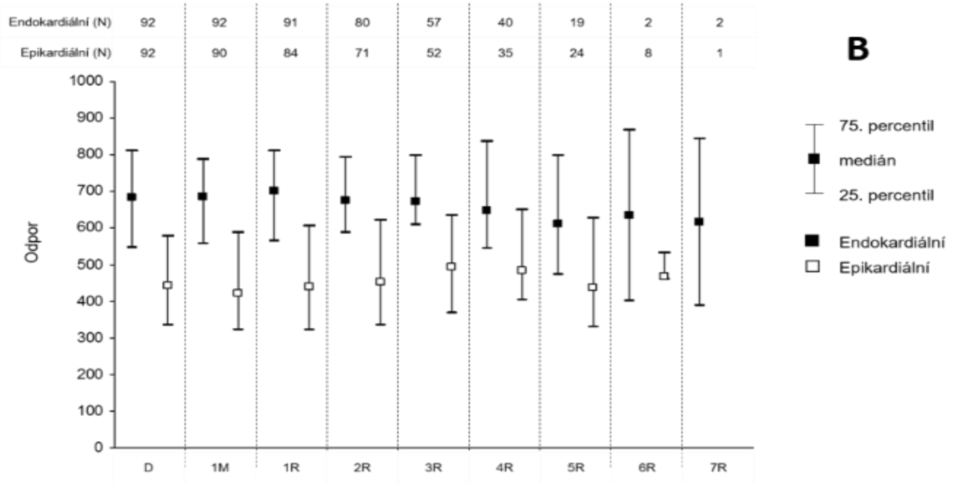
- Identify the main **reasons for the failure** of endovasal LV leads implantation.
- Compare the **resynchronization effect** in the group with endovasal and epicardial LV leads in terms of clinical and echocardiographic response.
- Compare the **safety** of implantation of SRL devices with the introduced electrode endovasally and epicardially.

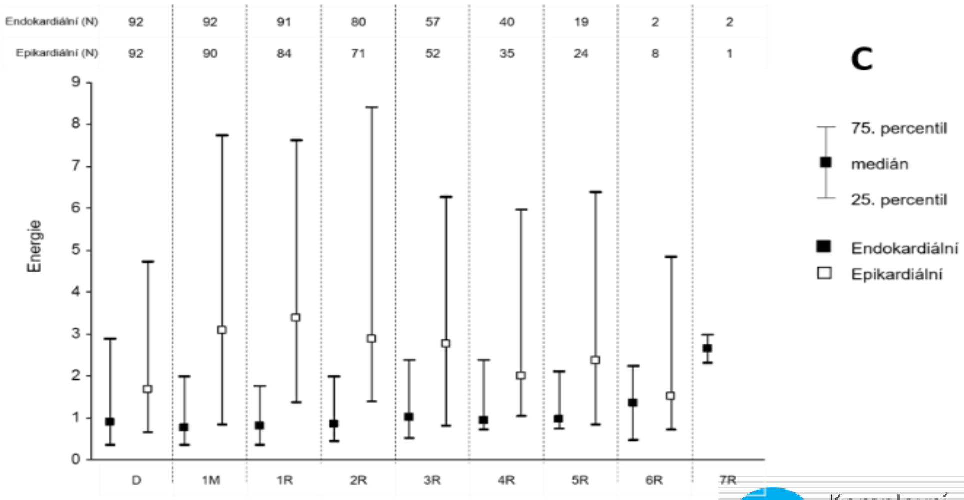
Causes of LV lead implant failure



Comparison of the pacing threshold, impedance and impulse energy

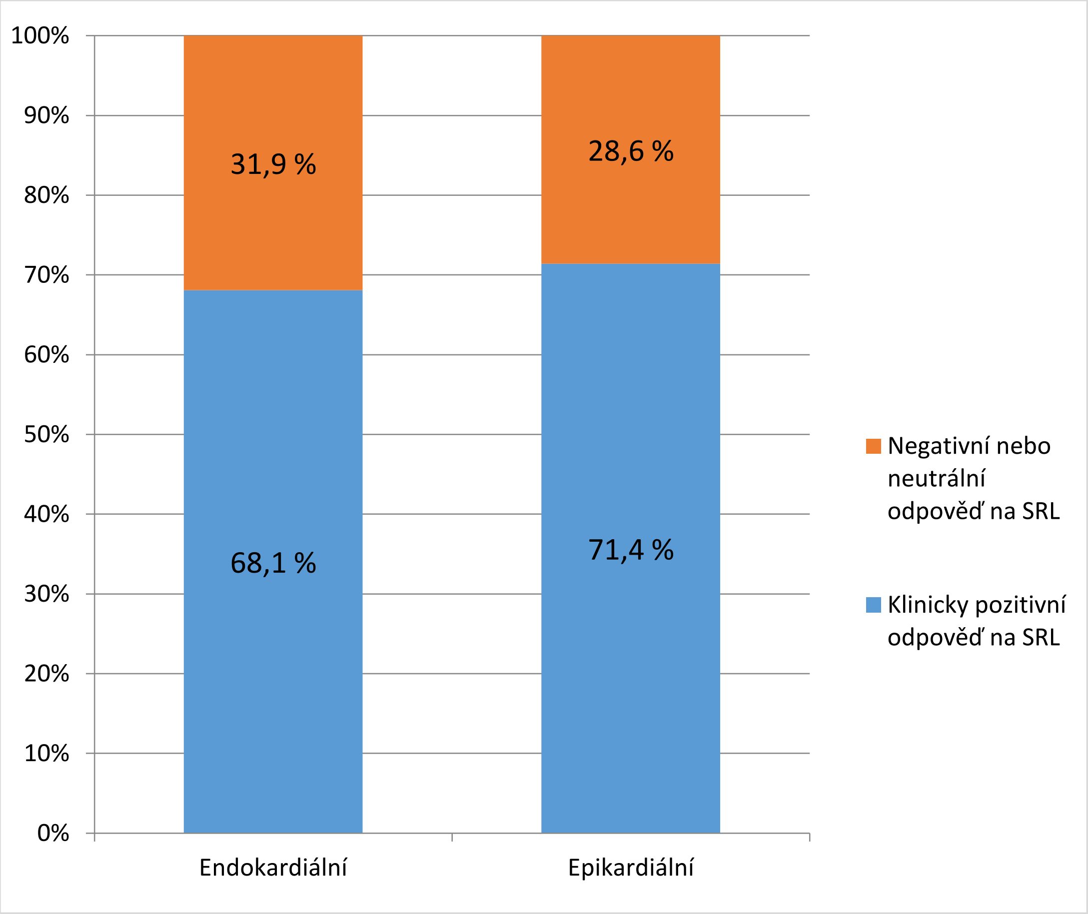


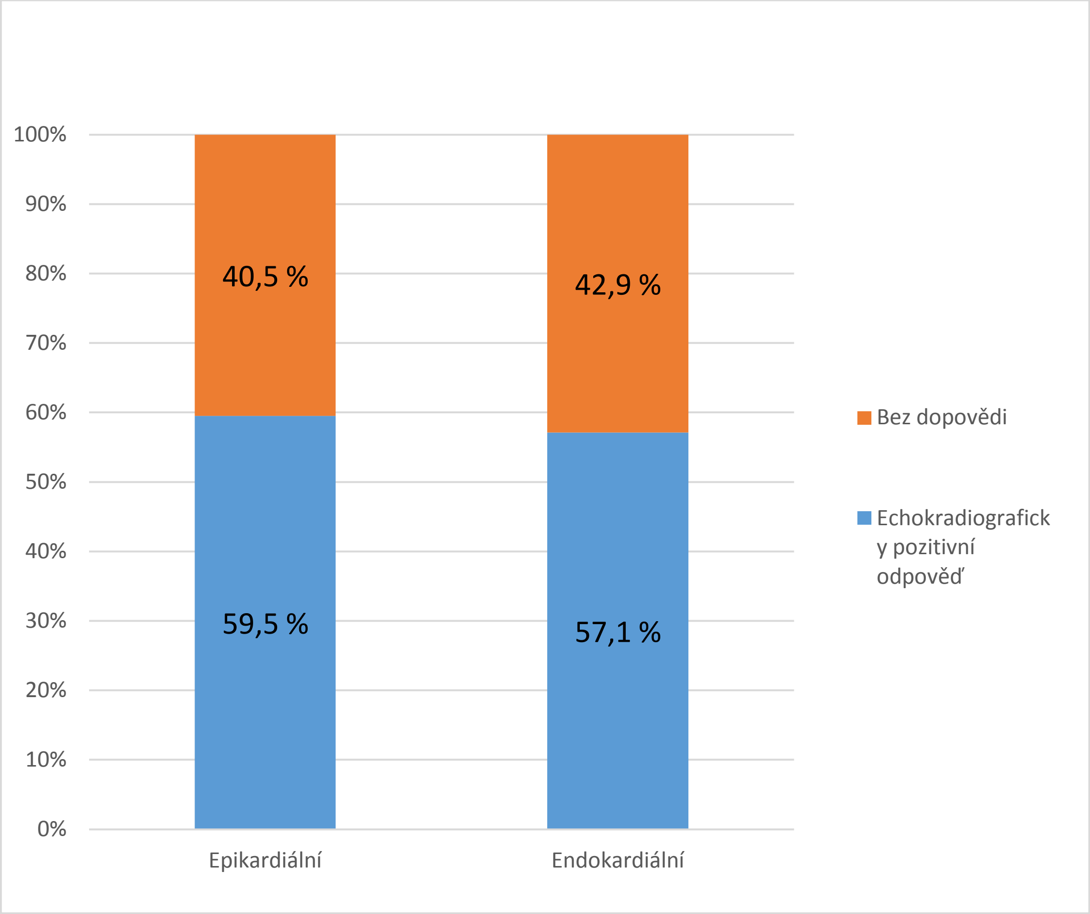




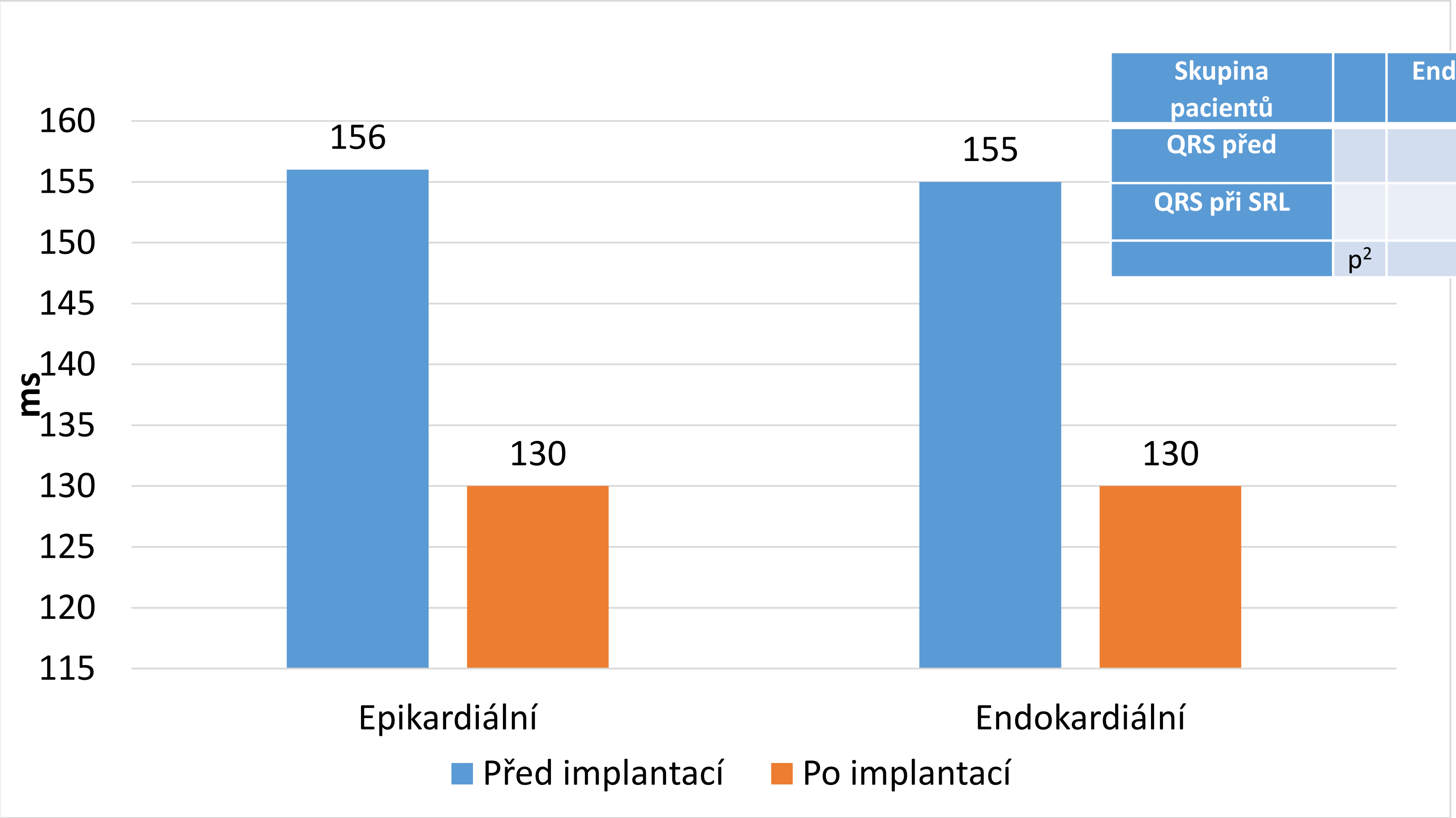
Charakteristiky	Propuštění Geometrický průměr (95% CI)	1 měsíc Geometrický průměr (95% CI)	1 rok Geometrický průměr (95% CI)	2 roky Geometrický průměr (95% CI)	3 roky Geometrický průměr (95% CI)	p^1
Stimulační práh						
Endokardiální	1,13 (0,98; 1,31)[ab]	1,06 (0,91; 1,22)[a]	1,09 (0,93; 1,26)[ab]	1,21 (1,05; 1,39)[ab]	1,25 (1,10; 1,42)[b]	0,015
Epikardiální	1,26 (1,06; 1,49)[a]	1,62 (1,37; 1,93)[b]	1,57 (1,39; 1,79)[b]	1,54 (1,37; 1,73)[b]	1,44 (1,27; 1,64)[ab]	0,006
P^2	0,370	< 0,001	< 0,001	0,010	0,119	
Stimulační odpor						
Endokardiální	657 (607; 712)	673 (625; 726)	695 (644; 750)	674 (623; 730)	679 (619; 743)	0,534
Epikardiální	468 (420; 521)	465 (419; 516)	474 (429; 523)	478 (432; 529)	480 (434; 531)	0,966
P^2	< 0,001	< 0,001	< 0,001	< 0,001	< 0,001	
Energie						
Endokardiální	1,0 (0,7; 1,3)[ab]	0,8 (0,6; 1,1)[a]	0,8 (0,6; 1,1)[ab]	1,1 (0,8; 1,4)[ab]	1,1 (0,8; 1,5)[b]	0,021
Epikardiální	1,8 (1,1; 2,8)[a]	3,0 (1,9; 4,7)[b]	2.7 (1.9; 3.9)[b]	2.6 (1.9; 3.6)[ab]	2,2 (1,5; 3,1)[ab]	0,007
p^2	0,030	< 0,001	< 0,001	< 0,001	0,004	

Clinical and echocardiographic response to CRT



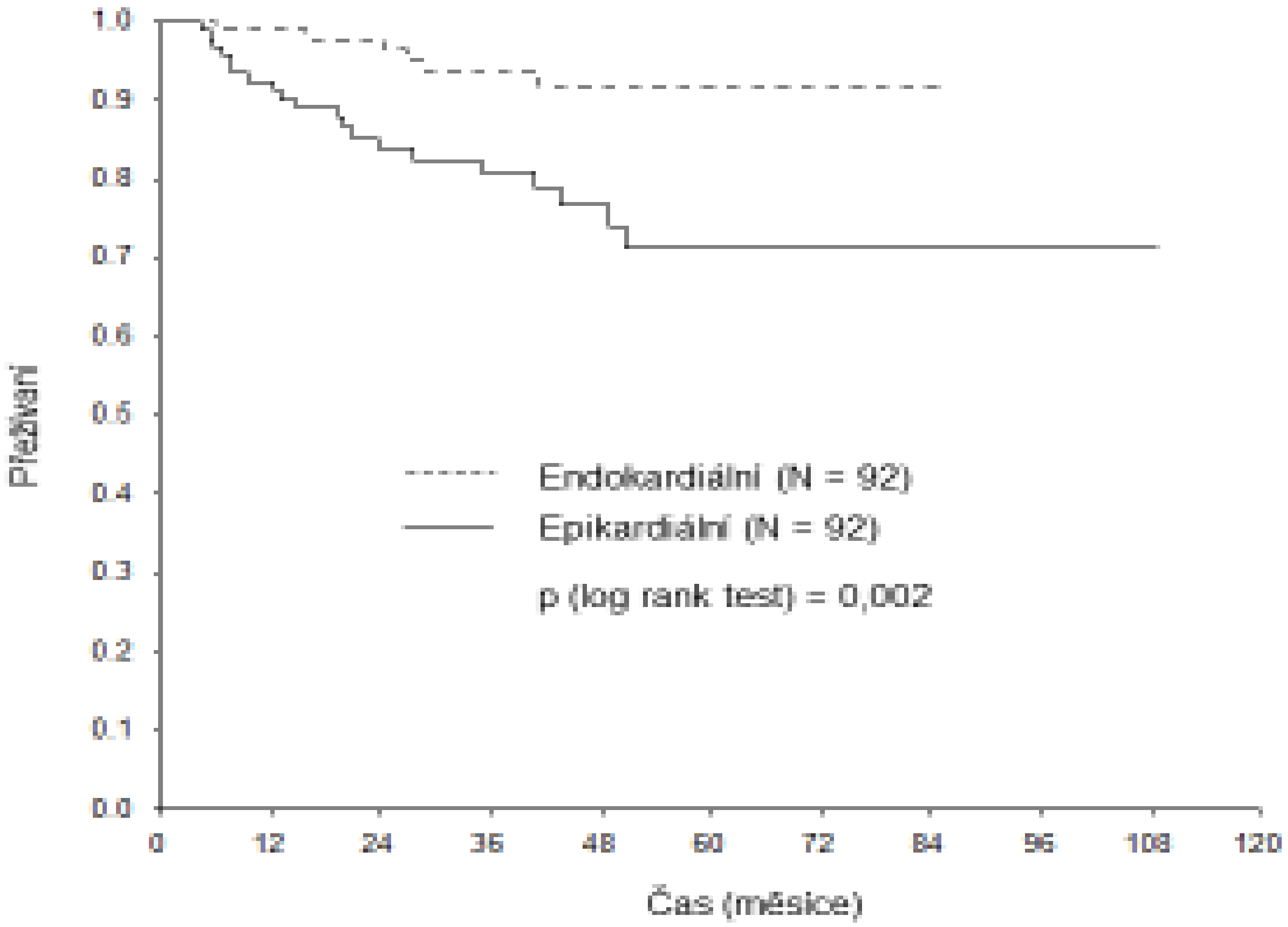


Change in QRS duration before a after CRT implantation

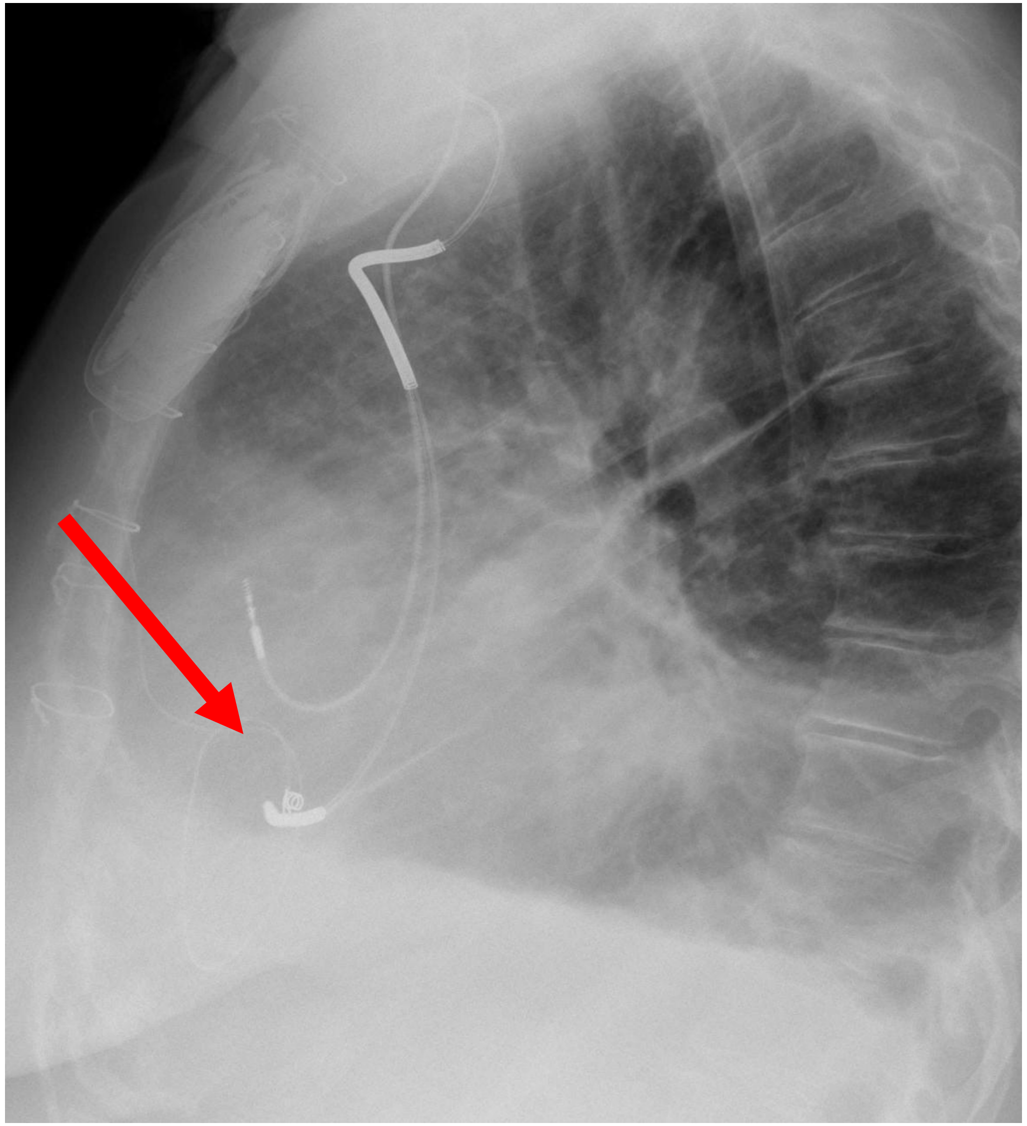


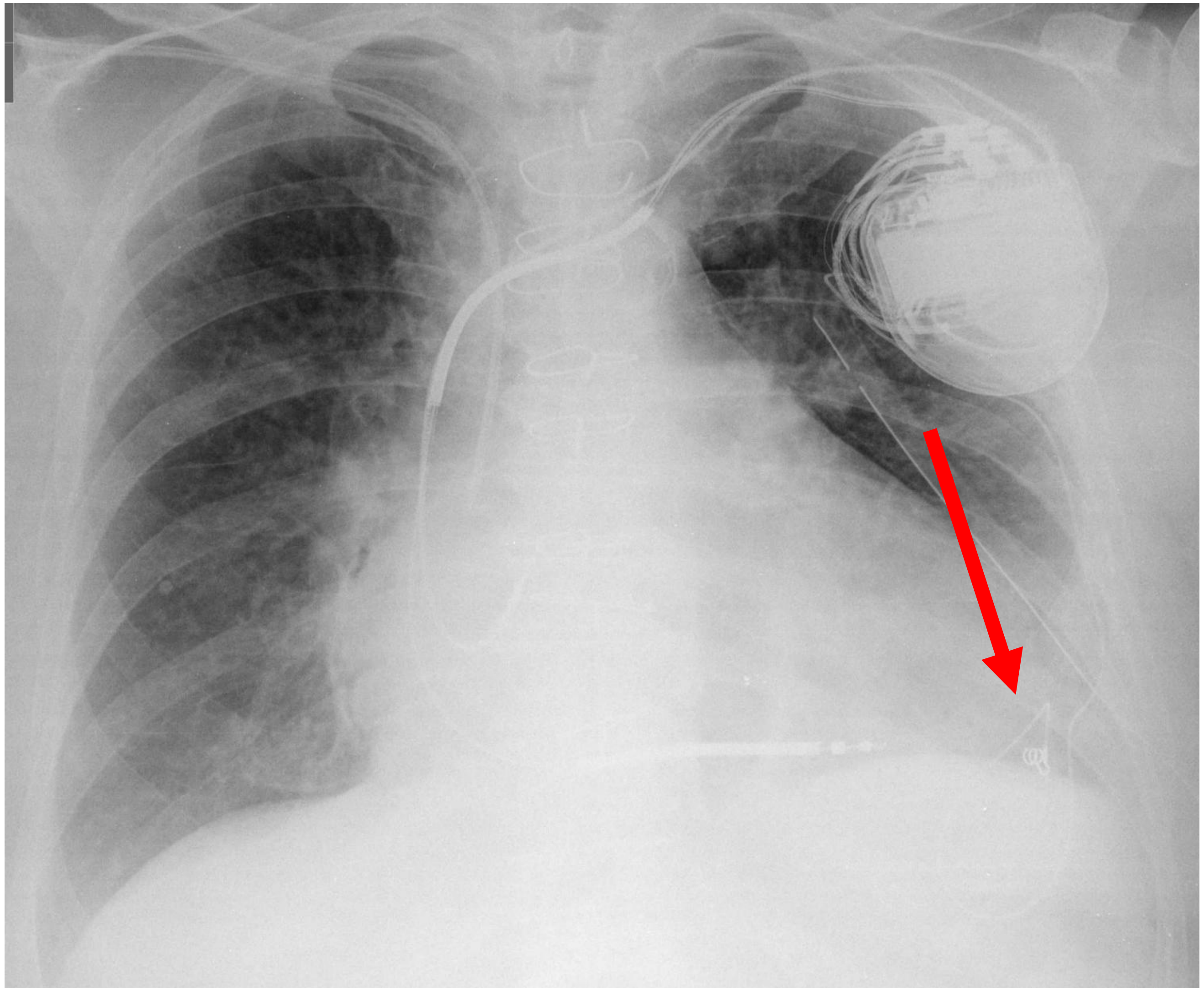
Skupina pacientů		Endokardiální (N = 92)	Epikardiální (N = 92)	P[1]
QRS před		155 (130; 200)	156 (125; 186)	0,740
QRS při SRL		130 (115; 160)	130 (115; 165)	0,207
	p[2]	<0,001	<0,001	

All-cause mortality



Apical epicardial LV lead position





Conclusion

- The worrying finding was that the mortality of patients with epicardial LV electrode was significantly higher, both in the short and medium term. This is due to the suboptimal (too apical and anterior) position of the epicardial LV lead.
- Epicardial LV leads have a higher pacing threshold and lower impedance, leading to more energy pacing impulse, independent of patient clinical or demographic characteristics.
- The resynchronization effect in terms of clinical and echocardiographic response in surviving patients with epicardial LV electrode is comparable to patients with endovasally implanted leads.

Endocardial LV lead implant techniques

Features of alternative LV pacing methods

	In clinical practice since	Access	Pacing site	System components for LV pacing	Invasiveness / fitting into hospital workflow
TIAsLV	1997	Percutaneous venous, atrial septal puncture and sheet guiding, passing mitral valve	Endocardial with lead	Only standard endocardial pacing lead with active fixation	Longer procedure but with the same team and waiting list
TALV	2007	Surgical / minithoracotomy	Endocardial with lead	Only standard endocardial pacing lead with active fixation	Under general anaesthesia, transition of pts to surgical team and waiting list
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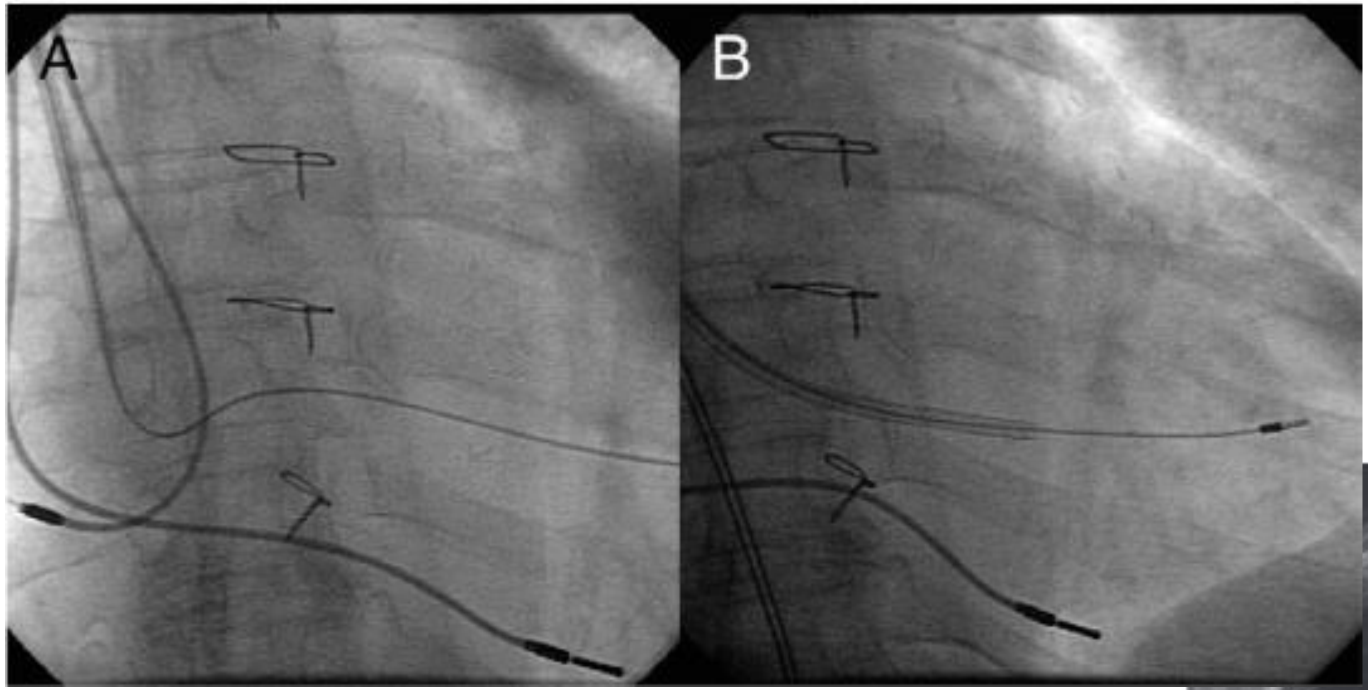
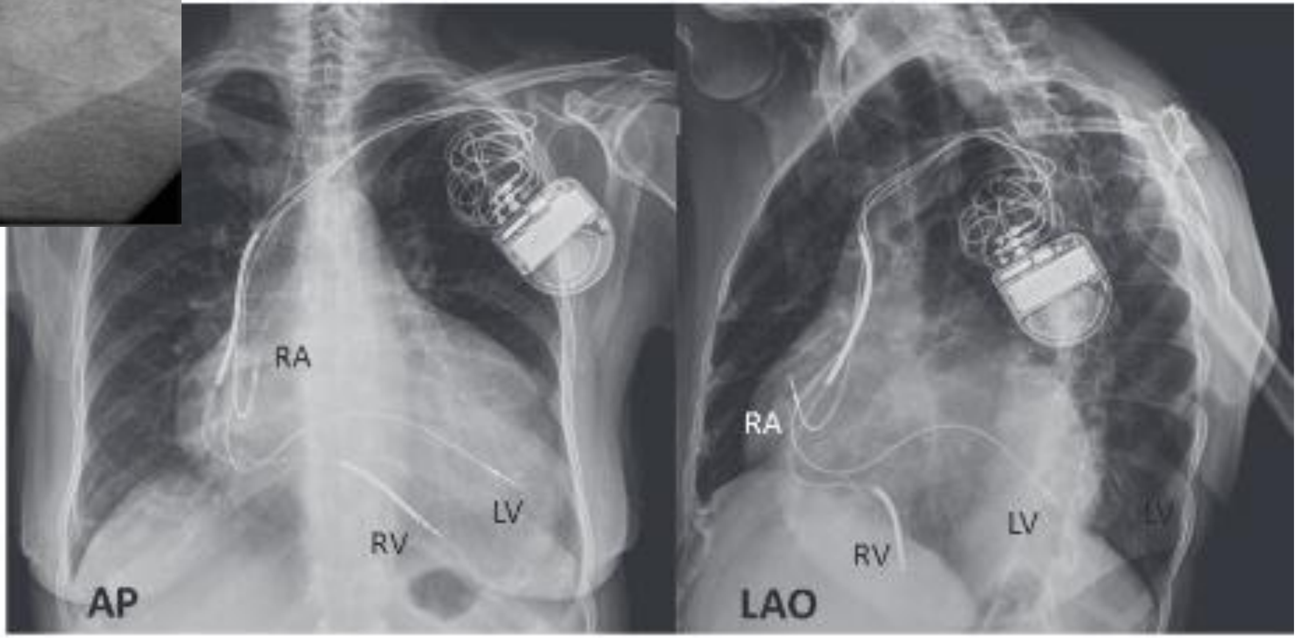
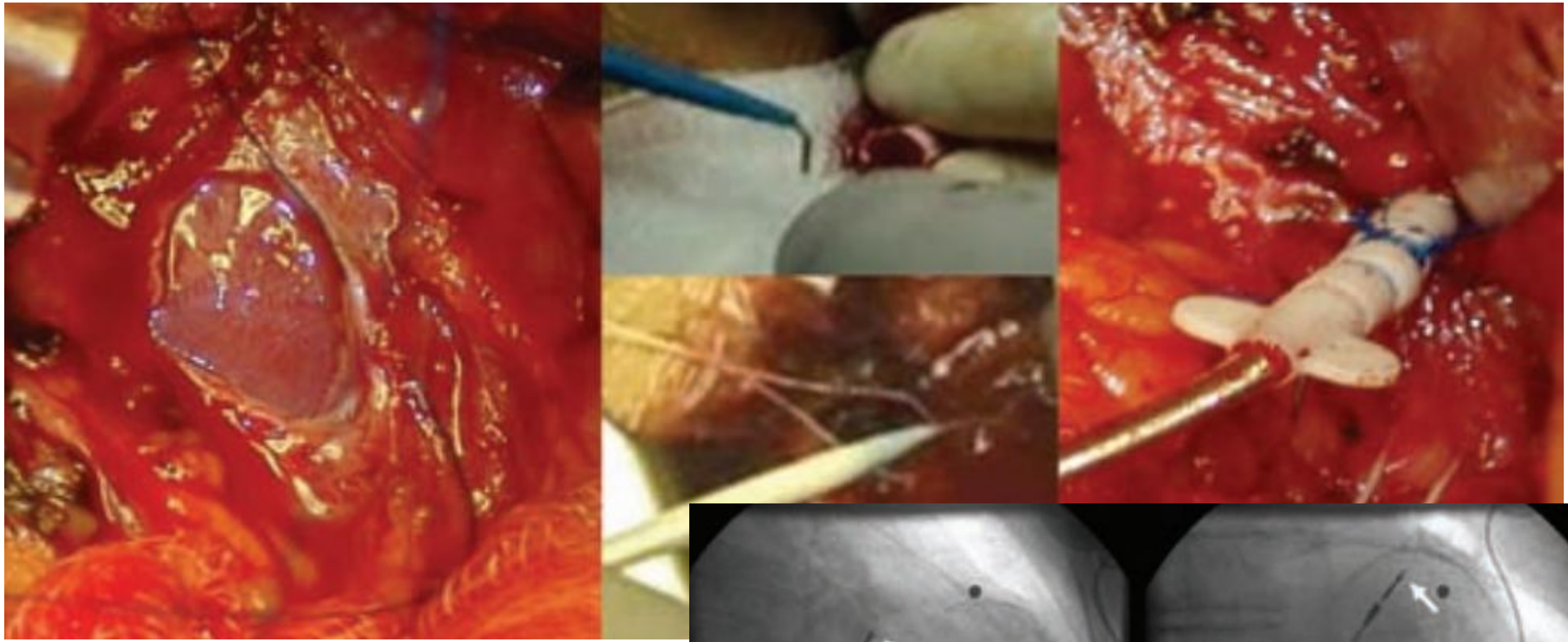
WiSE	2012	Percutaneous femoral, artery puncture, trans-aortic sheet guiding	Endocardial without lead	Subcutaneous battery, subcutaneous transmitter, receiver-electrode implanted on the LV-endo wall	Longer procedure but with the same team and waiting list

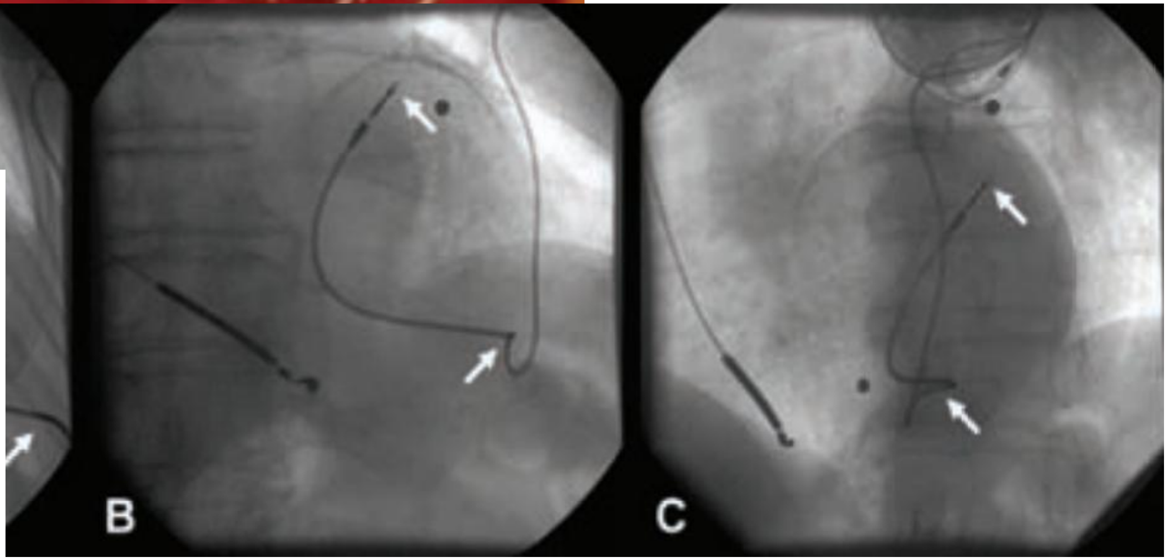
Trans-interatrial septal endocardial lead





Transapical endocardial LV lead





The Heart Surgery Forum #2009-1039
12 (3), 2009 [Epub June 2009]
doi: 10.1532/HSF98.20091039

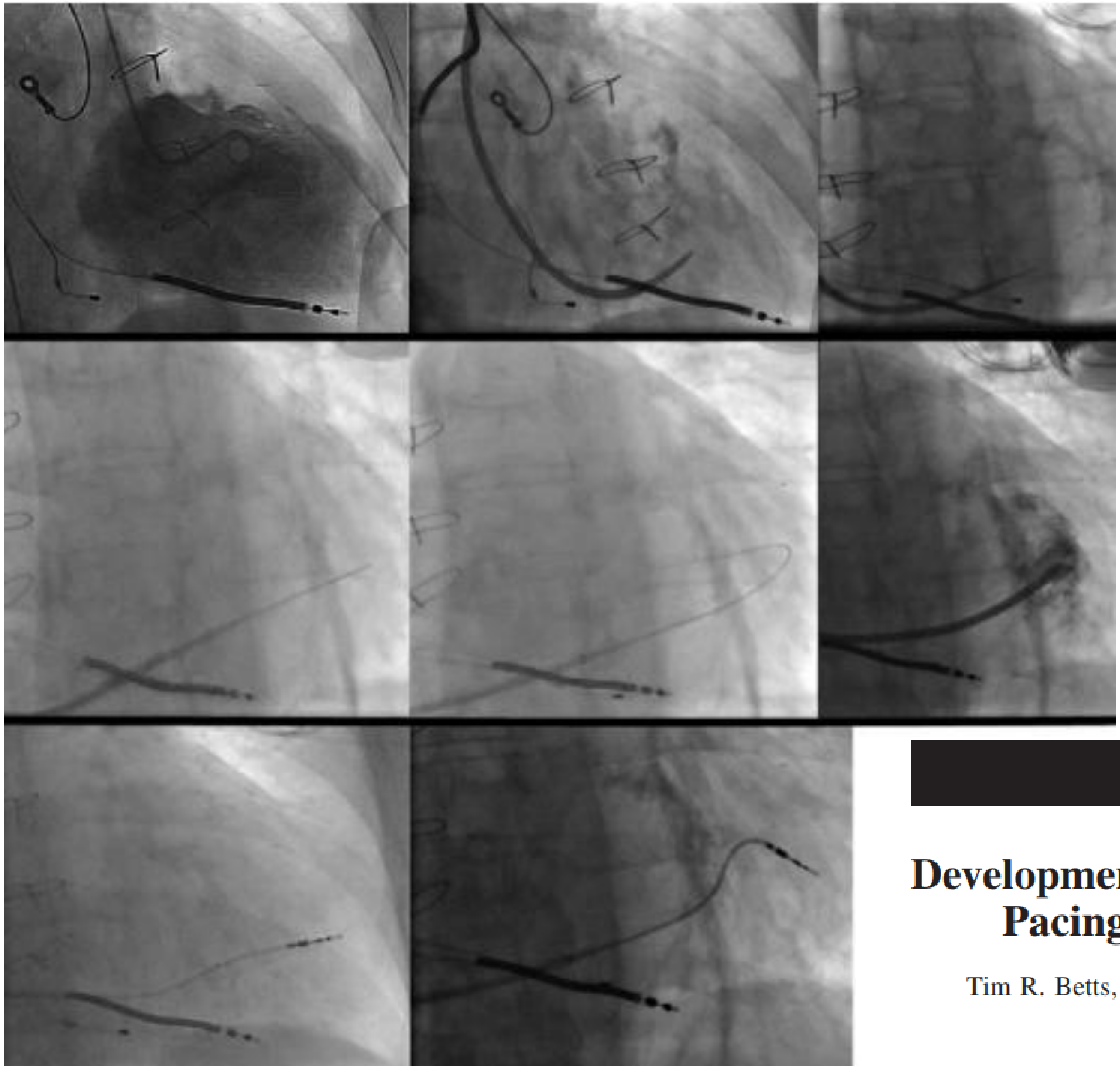
Online address: http://cardenjennings.metapress.com

A Novel Approach for Endocardial Resynchronization Therapy: Initial Experience with Transapical Implantation of the Left Ventricular Lead

Imre Kassai,[1] Attila Mihalcz,[1] Csaba Foldesi,[1] Attila Kardos,[1] Tamas Szili-Torok[2]

[1]Gottsegen Gyorgy Hungarian Institute of Cardiology, Budapest, Hungary; [2]Department of Clinical Electrophysiology, Thoraxcentre, Erasmus MC, Rotterdam, the Netherlands

Transseptal Endocardial LV lead implant



Original Article

Development of a Technique for Left Ventricular Endocardial Pacing via Puncture of the Interventricular Septum

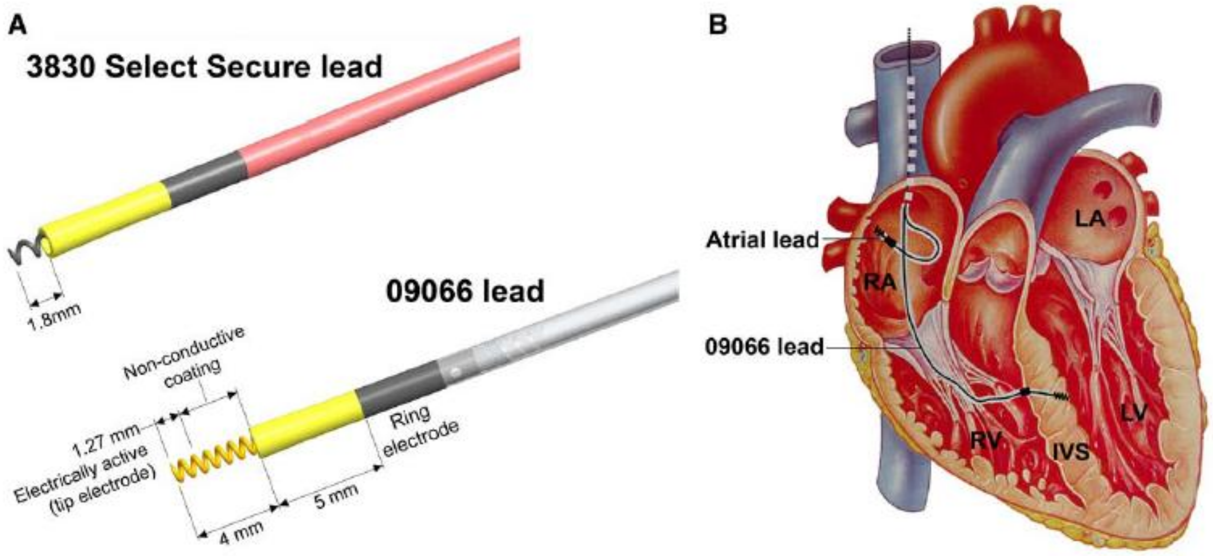
Tim R. Betts, MD, FRCP; James H.P. Gamble, BMBCh, MRCP; Raj Khiani, MBBS, MRCP; Yaver Bashir, DM, FRCP; Kim Rajappan, MD, MRCP

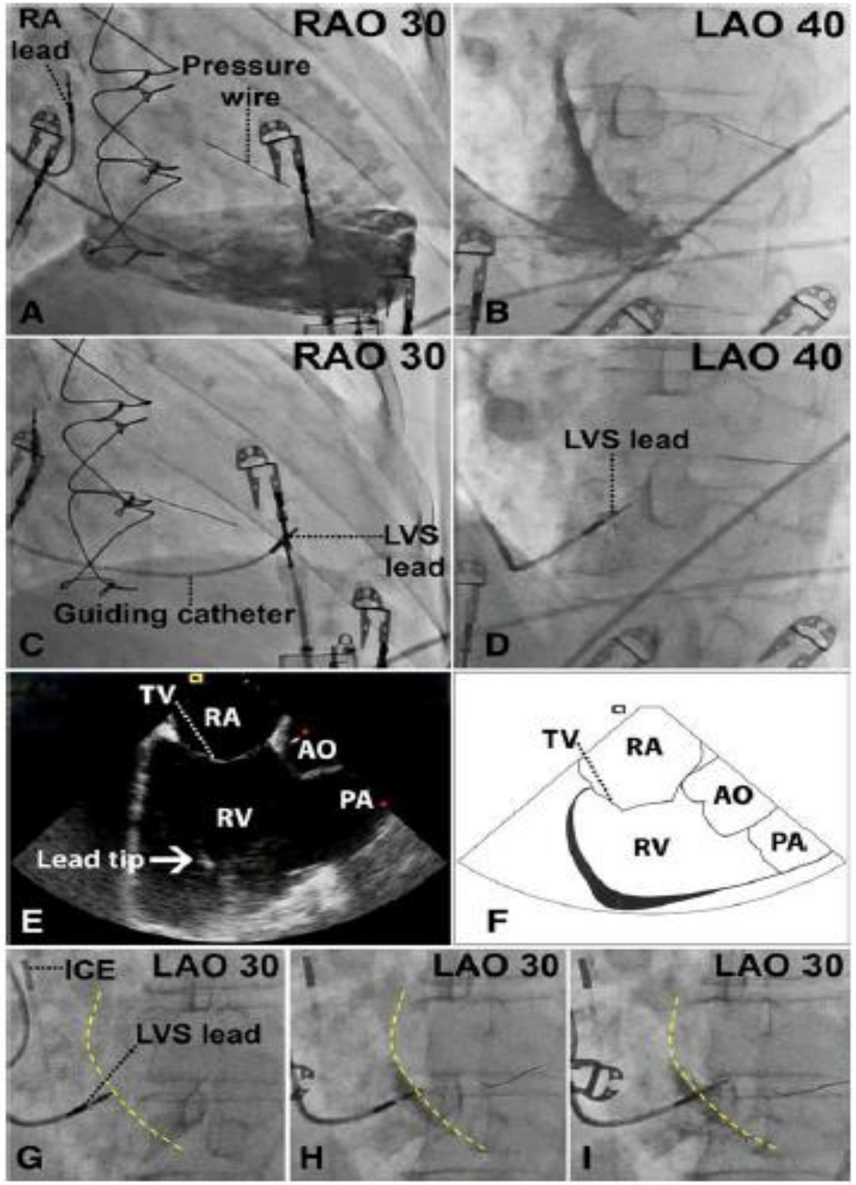
(Circ Arrhythm Electrophysiol. 2014;7:17-22.)

Transseptal Endocardial LV Pacing

Feasibility and Acute Hemodynamic Effect of Left Ventricular Septal Pacing by Transvenous Approach Through the Interventricular Septum

Masih Mafi-Rad, MD; Justin G.L.M. Luermans, MD, PhD; Yuri Blaauw, MD, PhD; Michel Janssen, BSc (MT); Harry J. Crijns, MD, PhD; Frits W. Prinzen, PhD; Kevin Vernooy, MD, PhD

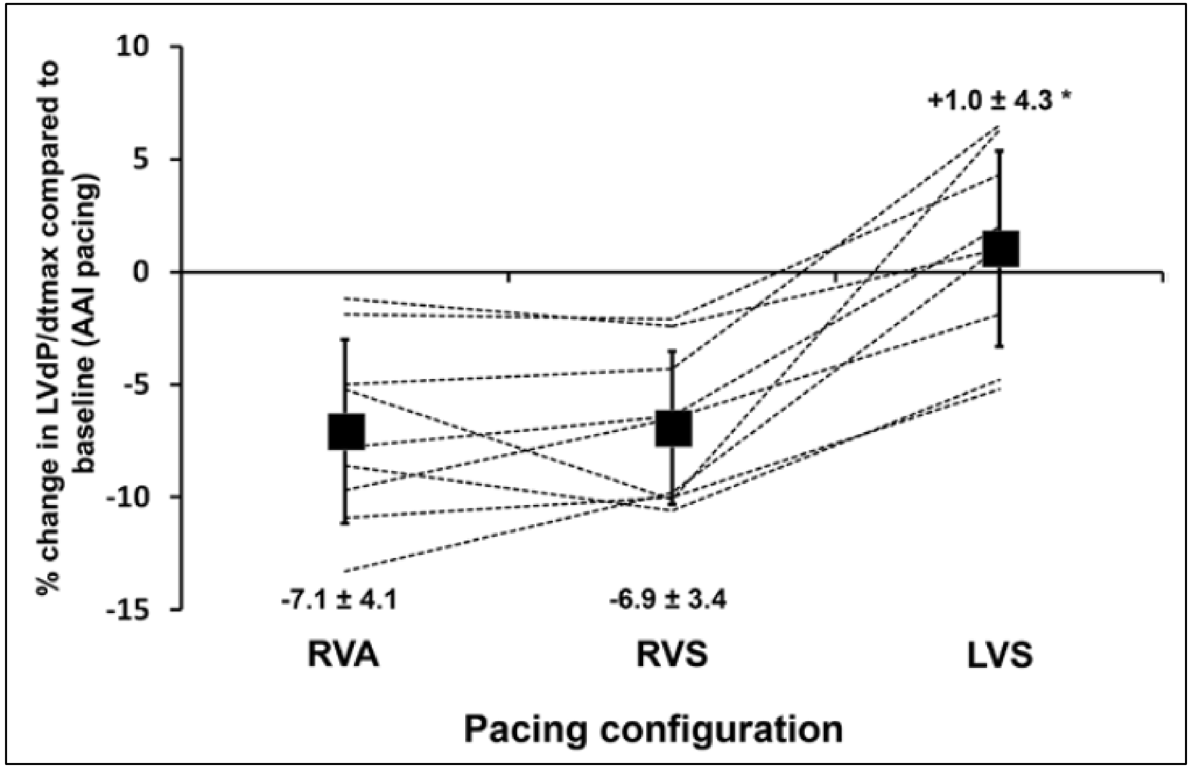




(*Circ Arrhythm Electrophysiol*. 2016;9:e003344. DOI: 10.1161/CIRCEP.115.003344.)

Transseptal Endocardial LV Pacing

Acute hemodynamical effect
Change in LVdP/dt max



(*Circ Arrhythm Electrophysiol*. 2016;9:e003344. DOI: 10.1161/CIRCEP.115.003344.)

Wireless LV endocardial pacing

Europace (2014) **16**, 681–688
doi:10.1093/europace/eut435

CLINICAL RESEARCH
Pacing and resynchronization therapy

Feasibility, safety, and short-term outcome of leadless ultrasound-based endocardial left ventricular resynchronization in heart failure patients: results of the Wireless Stimulation Endocardially for CRT (WiSE-CRT) study

Angelo Auricchio[1]*, Peter-Paul Delnoy[2], Christian Butter[3], Johannes Brachmann[4], Lieselot Van Erven[5], Stefan Spitzer[6], Tiziano Moccetti[1], Martin Seifert[3], Thanasie Markou[2], Karolyi Laszo[6], and François Regoli[1], for the Collaborative Study Group

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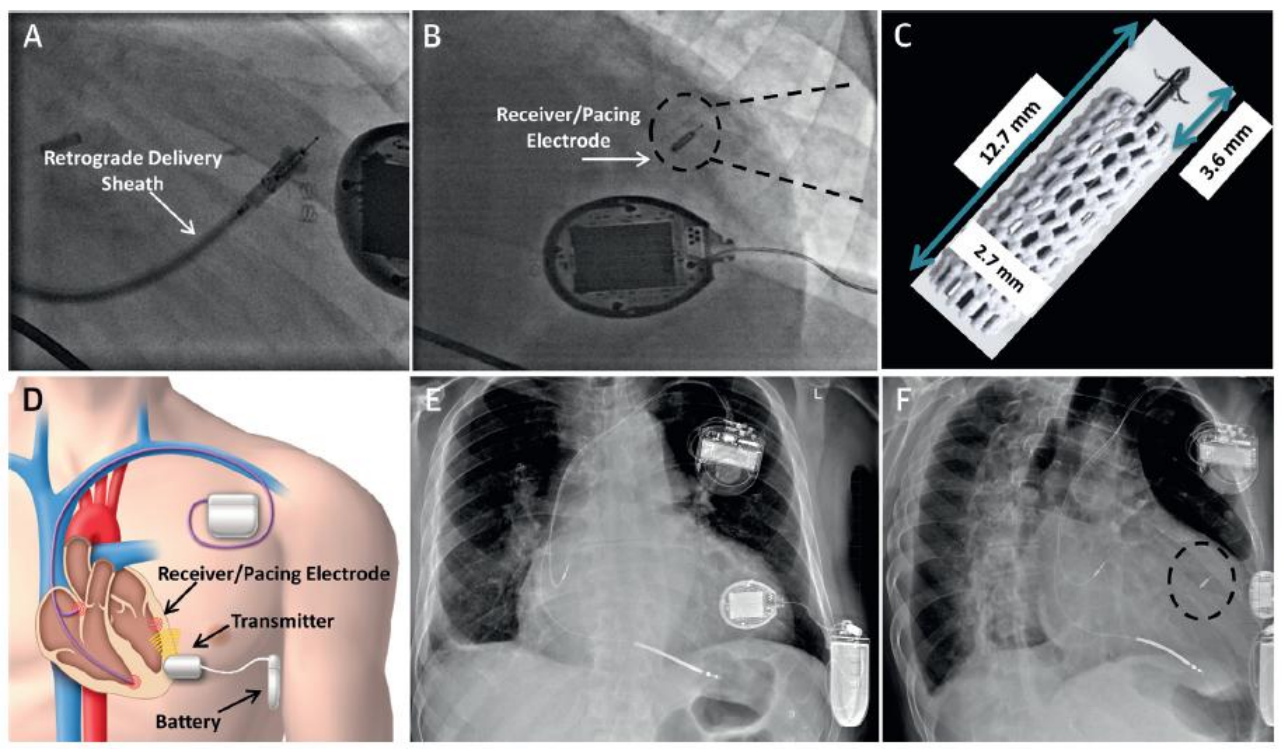
Cardiac Resynchronization Therapy With Wireless Left Ventricular Endocardial Pacing

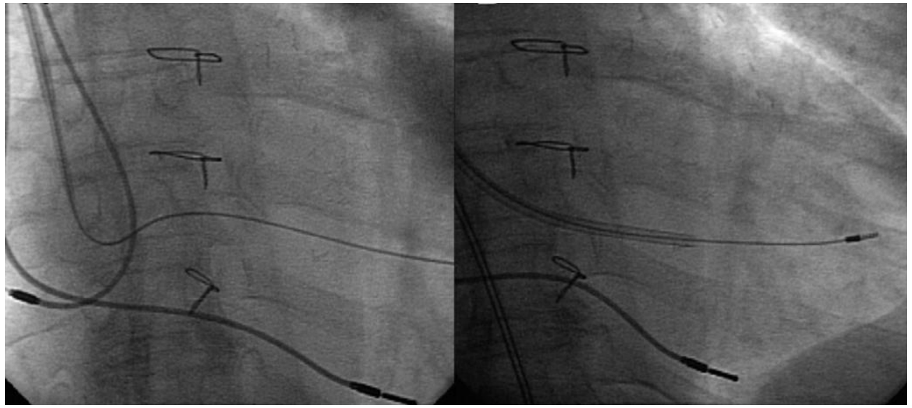
The SELECT-LV Study

Vivek Y. Reddy, MD,[a] Marc A. Miller, MD,[a] Petr Neuzil, MD,[b] Peter Søgaard, MD,[c] Christian Butter, MD,[d] Martin Seifert, MD,[d] Peter Paul Delnoy, MD,[e] Lieselot van Erven, MD,[f] Martin Schalji, MD,[f] Lucas V.A. Boersma, MD,[g] Sam Riahi, MD, PhD[c]



Advantages of LV Endocardial Stimulation

- **Choice of the site of stimulation**
  - Optimization of capture threshold
  - Absence of the phrenic nerve stimulation
  - Incidence of the lead dislodgment is lower



- **Monitoring of the cardiac function by a sensor imbedded in the stimulating lead**
- **More physiologic and might be less arrhythmogenic than epicardial stimulation**
- **Higher response to CRT by endocardial LV stimulation?**

Limiting factors for LV endocardial pacing

- Trombembolic complication
  - Long-term anticoagulation therapy, warfarin vs. NOAC, new lead materials?
- Interaction with the mitral valve
  - Increased risk of insufficiency
  - Higher risk of mitral valve endocarditis (systemic embolization)
- Risk associated with extraction of the CRT system
  - Risk of systemic embolization of vegetations, throbi or fibrotic material surrounding the lead

European Society of Cardiology

Endocardial left ventricular pacing for cardiac resynchronization: systematic review and meta-analysis

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Received 28 June 2016; editorial decision 28 October 2016; accepted 31 October 2016; online publish-ahead-of-print 10 January 2017

Aims Endocardial left ventricular (LV) pacing for Cardiac Resynchronization Therapy has been proposed as an alternative to conventional LV lead placement via the coronary sinus. In order to assess the relative benefits and risks of this technique, we have performed a meta-analysis of published reports.

Methods and results A systemic search was performed using online databases to identify studies of lead-based endocardial pacing. A random-effects meta-analysis was performed, to assess the rate of complications and clinical response (defined as ≥1 decrease in NYHA class). We selected 23 studies, including 384 patients. The trans-atrial septal technique was used in 20 studies, 1 used the trans-ventricular apical technique, and 2 used the trans-ventricular septal technique. Mean age was 66 years, male 66%, EF 26%, NYHA class 3.0. Procedural success rates were over 95% in all studies. Clinical response was reported by 16 studies for 262 patients, giving a response estimate of 82% (95% CI 71–89%). There was significant heterogeneity, and response in the only large study was 59%. Thromboembolic (TE) complications were reported by all studies, over 22 ±32 months follow up. The rate of stroke was 2.5 events per 100 patient years (95% CI 1.5–4.3), and TIA 2.6 (1.1–6.1). The mortality rate was 4.5 (1.5–13.6) per 100 patient years.

Conclusion LV endocardial pacing appears to be a viable technique when conventional lead placement is not possible. Response rates were heterogeneous but comparable with conventional CRT. There is likely to be a small increase over expected rates of stroke, although included patients were high risk.

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Table 1 Studies included in the meta-analysis

First author, year	Journal	Technique	Design	Centres	Patients	Follow up (months)	Follow up	Reports clinical response	Reports echo response
Leclerq[22]	PACE	TAS	Case series	1	3	6	Unclear	Yes	No
Jais[17]	PACE	TAS	Case series	1	11	15 ±12	Systematic	Yes	No
Garrigue[21]	Am J Cardiol	TAS	Case series	1	8	10	Unclear	No	No
Ji[23]	J CV EP	TAS	Case report	1	1	3	N/A	Yes	No
Pasquie[20]	PACE	TAS	Retrospective case series	1	6	85 ±5	Systematic	Yes	No
Nuta[19]	Europace	TAS	Case report	1	1	9	N/A	Yes	No
Morgan[18]	Europace	TAS	Case series	1	8	1-32	Unclear	Yes	No
Lau[24]	J Int CV EP	TAS	Case report	1	1	6	N/A	No	No
Kassai[13]	Europace	TVA	Case series	3	23	40 ±24.5	Unclear	No	Yes
Lau[26]	PACE	TAS	Case series	1	4	6 ±1.5	Systematic	Yes	No
Wright[25]	PACE	TAS	Case series	1	3	12	Unclear	No	No
Morina-Vascquez[46]	PACE	TAS	Case series	1	14	0-54	Systematic	Yes	Yes
Mondoly[27]	PACE	TAS	Case report	1	1	6	N/A	Yes	No
Patel[28]	J Int CV EP	TAS	Case series	1	5	150	Unclear	Yes	No
Geller[29]	ESC abstract	TAS	Case series	1	28	21 ±13	Unclear	Yes	Yes
Shalaby[30]	HRS abstract	TAS	Case series	1	5	10.72	Unclear	No	Yes
Elencwajg[47]	EHRA-EP abstract	TAS	Case series	1	31	24.1 ±16.2	Unclear	No	No
Rademakers[12]	Heart Rhythm	TAS	Retrospective case series	2	51	24	Systematic	No	No
Calvo[32]	Europace	TAS	Case report	1	1	6	N/A	Yes	No
Domenichini[31]	Heart Rhythm	TAS	Case series	1	12	5.7	Unclear	Yes	No
Gamble[34]	Europace	TVS	Case series	1	21	11 ±8	Systematic	Yes	Yes
Karpenko[35]	EHRA-EP abstract	TVS	Case series	1	10	7 ±2	Unclear	Yes	No
ALSYNC[11]	EHJ	TAS	Prospective clinical trial	18	136	17 ±6	Systematic	Yes	Yes

TAS, trans-atrial septal; TVS, trans-ventricular septal; TVA, trans-apical. Follow up given as mean with standard deviation where available. When range is given this is minimum to maximum.

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ESC European Society of Cardiology

Response rates in trials of endocardial LV pacing for CRT

Stroke, TIA, stroke/TIA

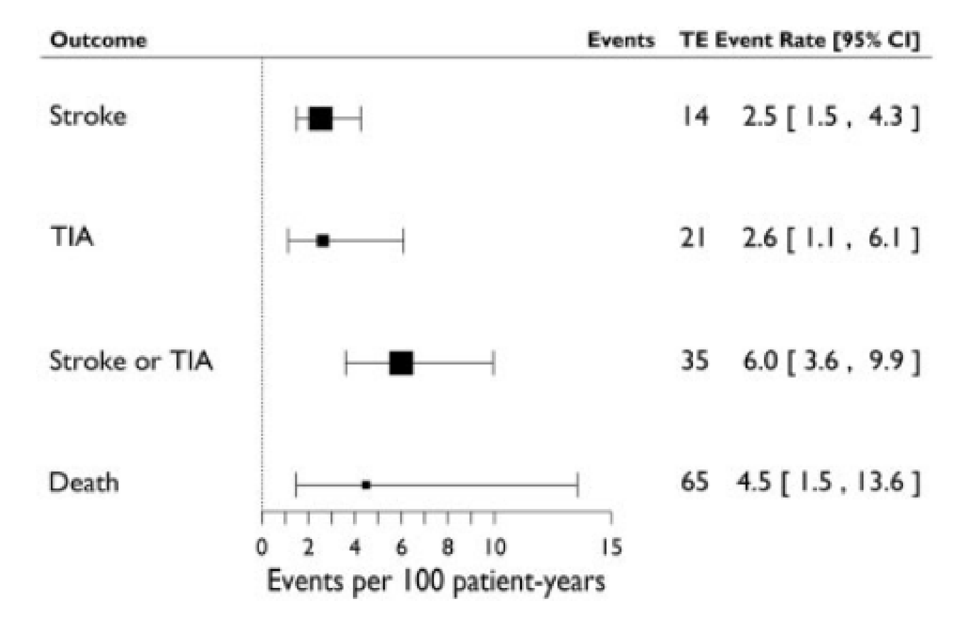
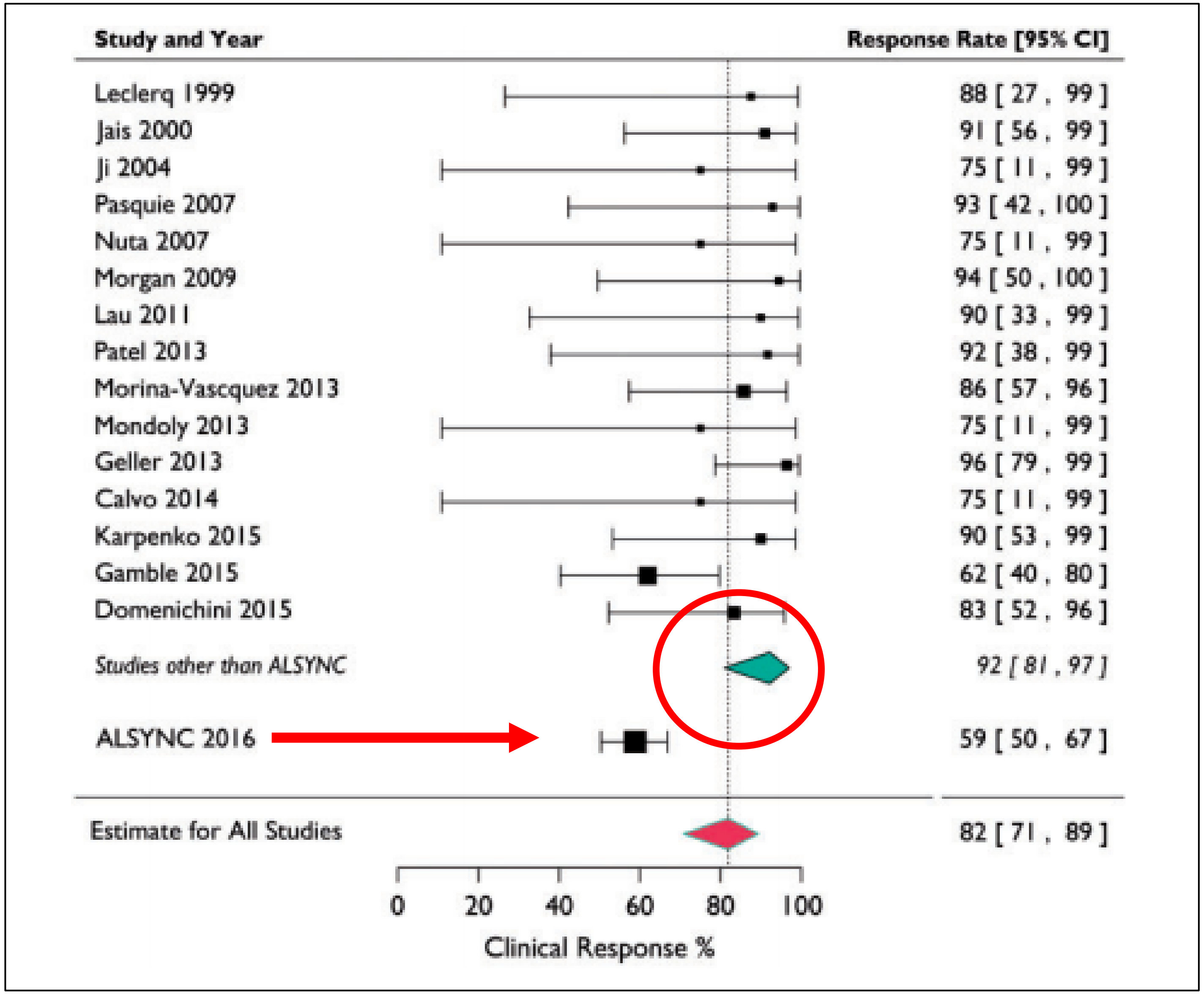


Figure 2 Summary results of the meta-analysis of adverse outcomes in trials of endocardial LV pacing for CRT, including the total number of events recorded, the event rate per 100 patient-years, and the confidence interval. TIA, transient ischaemic attach.



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Conclusions

- Surgical LV **epicardial lead** implantation still remains gold standard as alternative technique for LV lead implantation
- Very important **optimal LV lead placement** (avoid anterior and apical position)
- Alternative techniques using LV endocardial pacing still have significant limitations, primarily **trombembolic events!**
- His-bundle pacing?