Endocardial left ventricle pacing for CRT

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KardioCentrum

NA HOMOLCE HOSPITAL

Agenda

- Why we need LV endocardial pacing ?
- LV endocardial pacing approaches, results and limitations
- Leadless LV endocardial pacing

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Why we need LV endocardial pacing ?

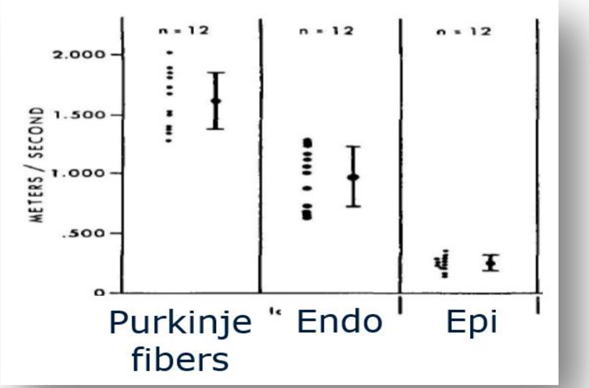
- ***90-98% success rate with CS epicardial LV pacing***
  but there are still implantation failures despite major improvements in the technology (Failure of LV lead implantation (7%)[1]
- ***Limitation due to the CS anatomy*** (small veins, tortuous veins, valves….)
- ***Limitation due to LV lead implantation complications***
  - CS dissection (1.3%) [1] coronary vein perforation (1.3%) [1]
  - High pacing threshold (acute and chronic)
  - Phrenic nerve stimulation (short and long terms)
  - LV lead dislodgement (short and long terms) (5.7%) [1]
  - Epicardial or non optimal pacing site ⟶ non response to CRT
  - X-rays exposure (patient, physician and staff)
  - In hospital-Death (0.3%) [1], 30-days mortality (0.7%) [1]

[1] Van Rees. J Am Coll Cardiol 2011; 58: 995-1000

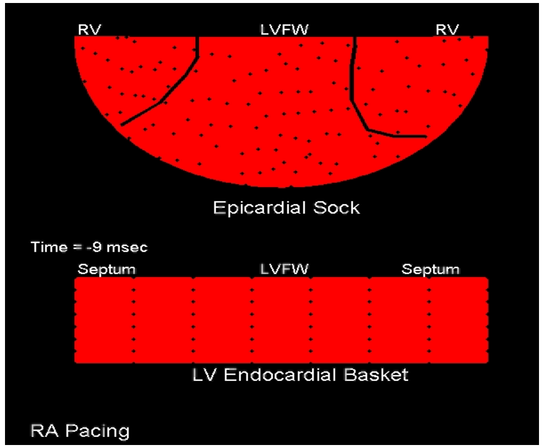
Benefits of LV Endocardial Pacing

- **Alternative to standard CRT pacing**
- **Anatomical:** Access to all regions of LV
- **Physiological:**

- Faster impulse propagation in the endocardial than in the epicardial layers providing in theory a faster LV depolarization
- More physiologic LV stimulation preserving the transmural activation and repolarization sequence



Myerburg et al., Circ. Res. 1978



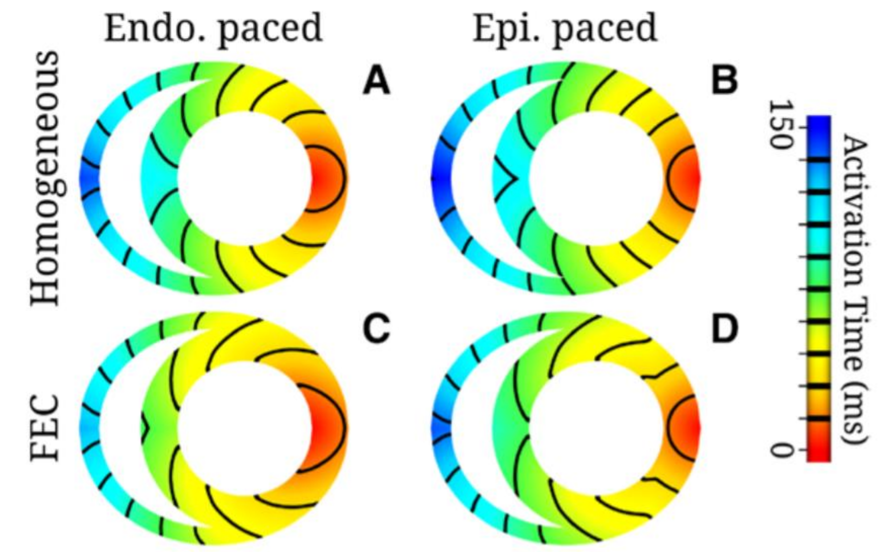


Figure 3. Activation times (ATs) for the homogeneous isotropic conduction model (**A** and **B**) and with the addition of fast endocardial conduction (FEC; **C** and **D**), solved for on the canine short-axis geometry (ecc=0.5, rLV=20.5 mm) with endocardial (**A** and **C**) and epicardial (**B** and **D**) stimuli. Note that the latest ATs for the LV and the total domain under endocardial pacing are less than those for the associated epicardial paced simulation (Table 1).

Hyde et al .: Circ Arrhythm Electrophysiol 2015 Oct:1167

Evidence of Endocardial LV Pacing

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Acute Hemodynamic Effect of Left Ventricular Endocardial Pacing in Cardiac Resynchronization Therapy

Assessment by Pressure–Volume Loops

Luigi Padeletti, MD; Paolo Pieragnoli, MD; Giuseppe Ricciardi, MD; Laura Perrotta, MD; Gino Grifoni, MD; Maria Cristina Porciani, MD; Vincenzo Lionetti, MD, PhD; Sergio Valsecchi, PhD

Background—During cardiac resynchronization therapy (CRT) device implantation, the pacing lead is usually positioned in the coronary sinus (CS) to stimulate the left ventricular (LV) epicardium. Transvenous LV endocardial pacing via transseptal puncture has been proposed as an alternative method. In the present study, we evaluated the acute hemodynamic effects of CRT through LV endocardial pacing in heart failure patients by analyzing LV pressure–volume relationships.

Methods and Results—LV pressure and volume data were determined via conductance catheter during CRT device implantation in 10 patients. In addition to the standard epicardial CS pacing, the following endocardial LV sites were systematically assessed: the site transmural to the CS lead, the LV apex, the septal midwall, the basal lateral free wall, and the midlateral free wall. Four atrioventricular delays were tested. There was a significant improvement of systolic function with CRT in all LV pacing configurations, whereas no differences in systolic or diastolic function were detected between LV epicardial and endocardial transmural sites. The optimal pacing site varied among patients but was rarely related to relatively longer activation delays, as assessed by analyzing endocardial electric activation maps. Nonetheless, positioning the pacing lead at the optimal endocardial LV site in each patient significantly improved LV performance in comparison with conventional CS site stimulation (stroke volume, 83 [79–112] mL versus 73 [62–89] mL; *P*=0.034).

Conclusions—Pacing at the optimal individual LV endocardial ... with conventional CS site stimulation. Endocardial LV pacing mi... CS pacing is not viable. (*Circ Arrhythm Electrophysiol*. 2012;5:...

Key Words: cardiac resynchronization therapy ■ endocard...

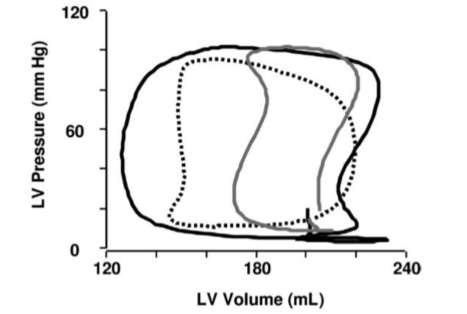


Figure 4. Example of left ventricular (LV) pressure–volume loops during atrial overdrive (**gray line**), cardiac resynchronization therapy (CRT) with standard epicardial LV pacing (epicardial coronary sinus; **dotted line**), and CRT with optimal endocardial LV pacing (**black line**).

EUROPEAN SOCIETY OF CARDIOLOGY®

Europace (2014) **16**, 873–879
doi:10.1093/europace/eut420

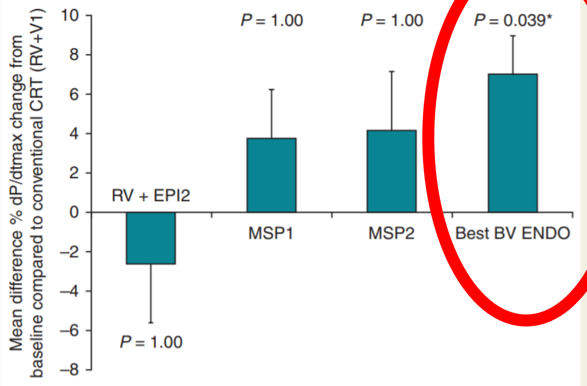
CLINICAL RESEARCH
Pacing and cardiac resynchronization therapy

A comparison of left ventricular endocardial, multisite, and multipolar epicardial cardiac resynchronization: an acute haemodynamic and electroanatomical study

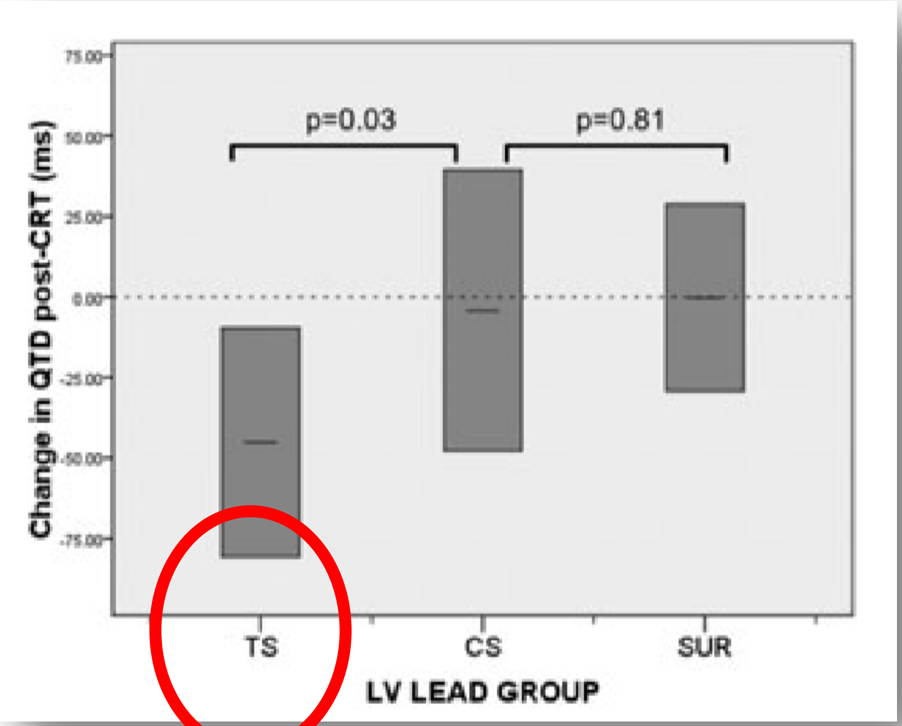
Anoop K Shetty[1,2]*, Manav Sohal[1,2], Zhong Chen[1,2], Matthew R Ginks[1,2], Julian Bostock[2], Sana Amraoui[1,2], Kyungmoo Ryu[3], Stuart P Rosenberg[3], Steven A Niederer[1], Jas Gill[1,2], Gerry Carr-White[1,2], Reza Razavi[1], and C Aldo Rinaldi[1,2]

[1]Department of Imaging Sciences, Rayne Institute, Kings College London, London SE1 7EH, UK; [2]Cardiothoracic Department, Guy's and St Thomas' NHS Foundati... Floor, East Wing, St Thomas' Hospital, SE1 7EH London, UK; and [3]Cardiac Rhythm Managem...

Received 23 September 2013; accepted after revision 9 December 2013; online publish...



Less proarrhythmogenic ventricular activation



Transseptal Left Ventricular Endocardial Pacing Reduces Dispersion of Ventricular Repolarization

PAUL A. SCOTT, M.B.CH.B.,*,† ARTHUR M. YUE, M.D.,* EDD WATTS,† MEHMOOD ZEB, M.B.B.S.,*,† PAUL R. ROBERTS, M.D.,*,† and JOHN M. MORGAN, M.D.,*,†

From the *Wessex Cardiothoracic Unit, Southampton University Hospitals NHS Trust, Southampton, UK; and †School of Medicine, University of Southampton, Southampton, UK

Background: *Cardiac resynchronization therapy (CRT) may be proarrhythmic in some patients. This may be due to the effect of left ventricular (LV) epicardial pacing on ventricular repolarization. The purpose of this study was to evaluate the effect of endocardial versus epicardial LV biventricular pacing on surface electrocardiogram (ECG) parameters that are known markers of arrhythmogenic repolarization.*

Methods: *ECG markers of repolarization (QT dispersion, QTD; T peak to end, $T_{peak\text{-}end}$; $T_{peak\text{-}end}$ dispersion, $T_{peak\text{-}end}$D; QTc) were retrospectively measured before and after CRT in seven patients with transseptal LV endocardial leads (TS group), 28 matched patients with coronary sinus (CS) LV leads (CS group), and eight patients with surgical LV epicardial leads (SUR group). All ECGs were scanned and analyzed using digital callipers.*

Results: *Compared to the CS group, the TS group CRT was associated with a significant postpacing reduction in QTD (−45.2 ± 35.6 vs −4.3 ± 43.6 ms, P = 0.03) and $T_{peak\text{-}end}$ (−24.2 ± 22.1 vs 3.4 ± 26.7 ms, P = 0.02). There was a nonsignificant post-CRT reduction in both $T_{peak\text{-}end}$D (−11.3 ± 31.0 vs 2.4 ± 28.9 ms, P = 0.27) and QTc (−50.0 ± 46.4 vs 4.4 ± 70.2 ms, P = 0.06) in the TS versus the CS group. In contrast, there were no differences between the SUR and CS groups in terms of the effect of CRT on these repolarization parameters.*

Conclusions: *CRT with (atrial transseptal) endocardial LV lead placement is associated with repolarization characteristics that are considered to be less arrhythmogenic than those generated by CS (epicardial) LV lead placement. Further work is needed to determine whether these changes translate to a reduction in proarrhythmia. (PACE 2011; 34:1258–1266)*

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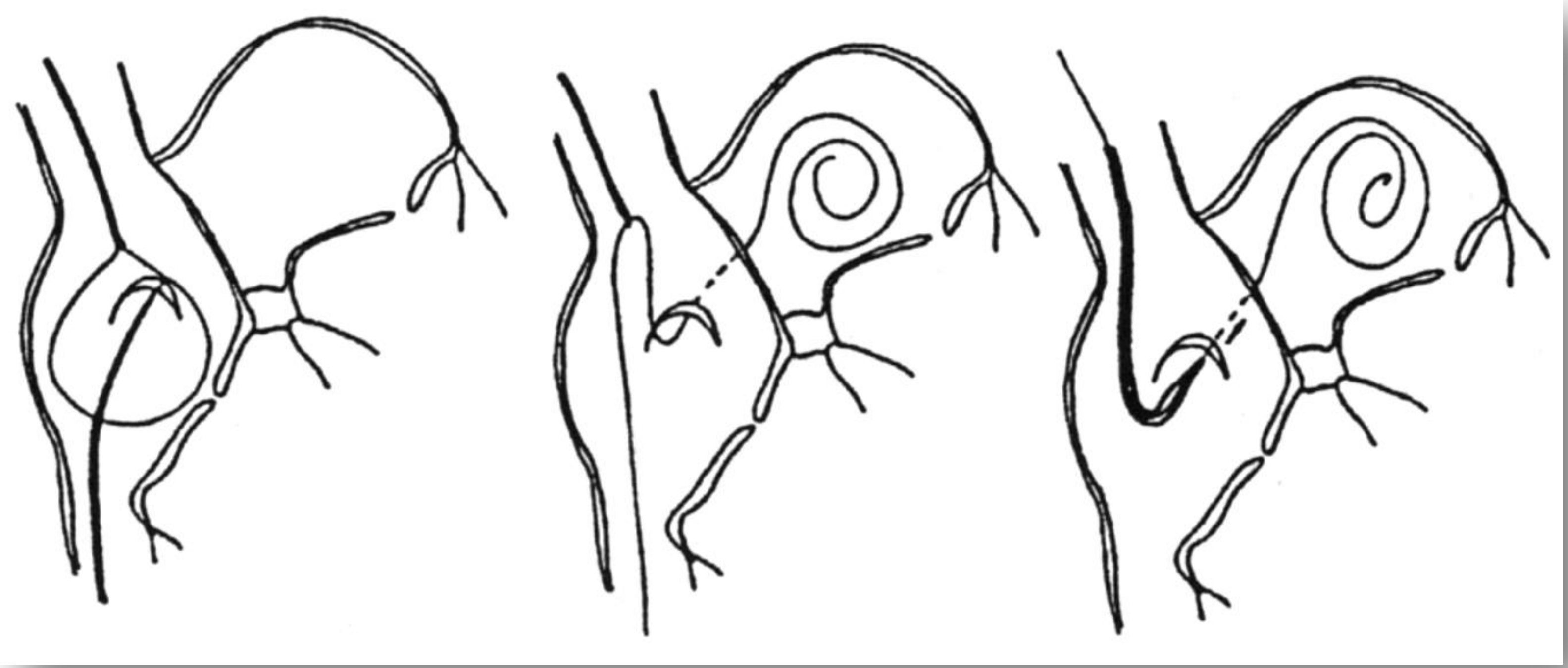
- Why we need LV endocardial pacing ?
- LV endocardial pacing approaches, results and limitations
- Leadless LV endocardial pacing

LV endocardial pacing approaches

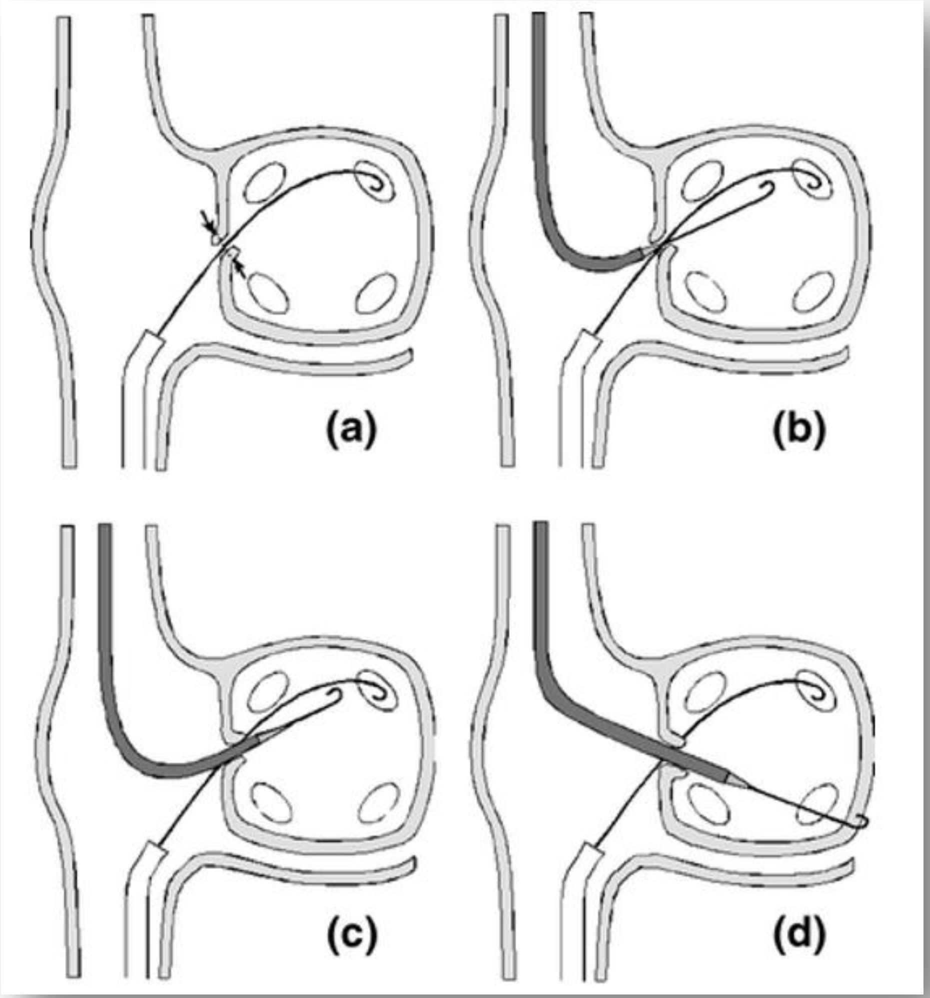
- Transseptal technique
  - **Atrial septum** (several modifications)



Jais. PACE, 1998, 21 [Part I]: 2128-31-1575

LV endocardial pacing approaches

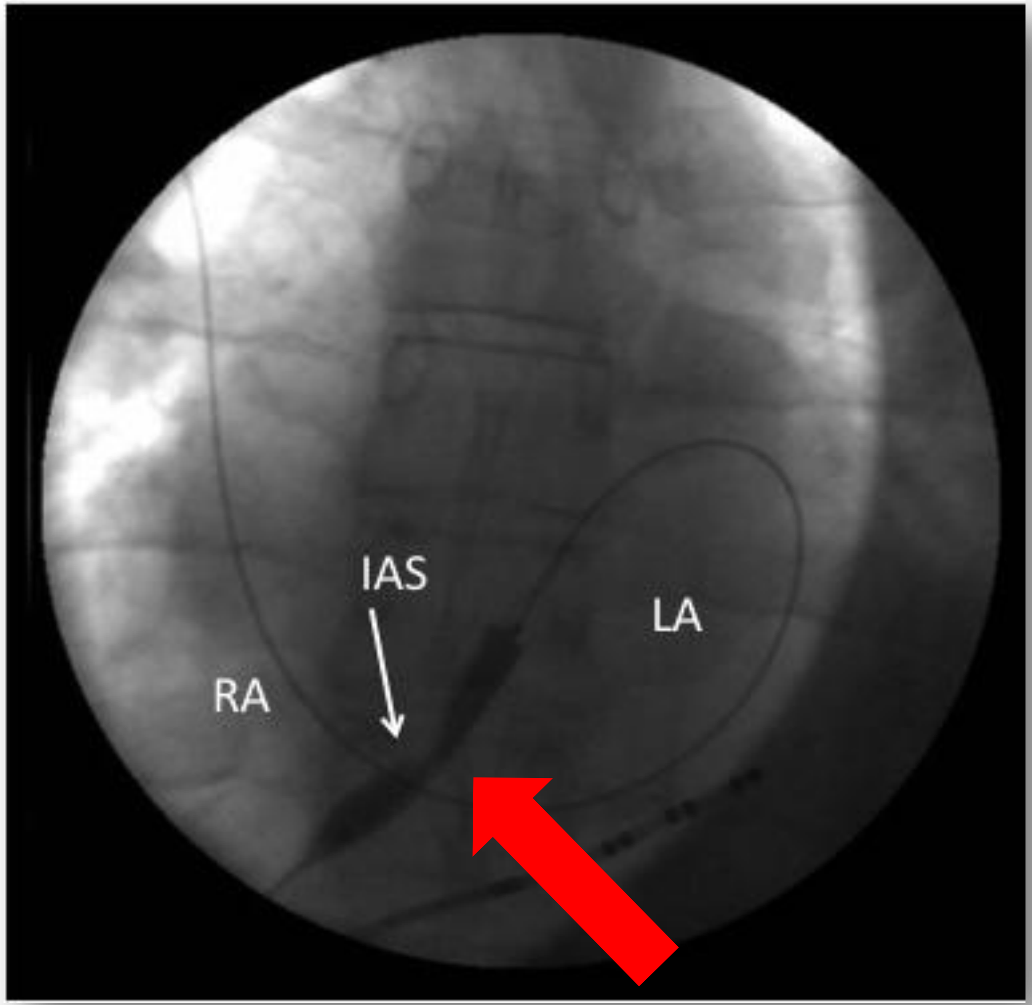
- Transseptal technique
  - **Atrial septum** (several modifications)



B.M. van Gelder, Heart Rhythm 2007;4:454–460

LV endocardial pacing approaches

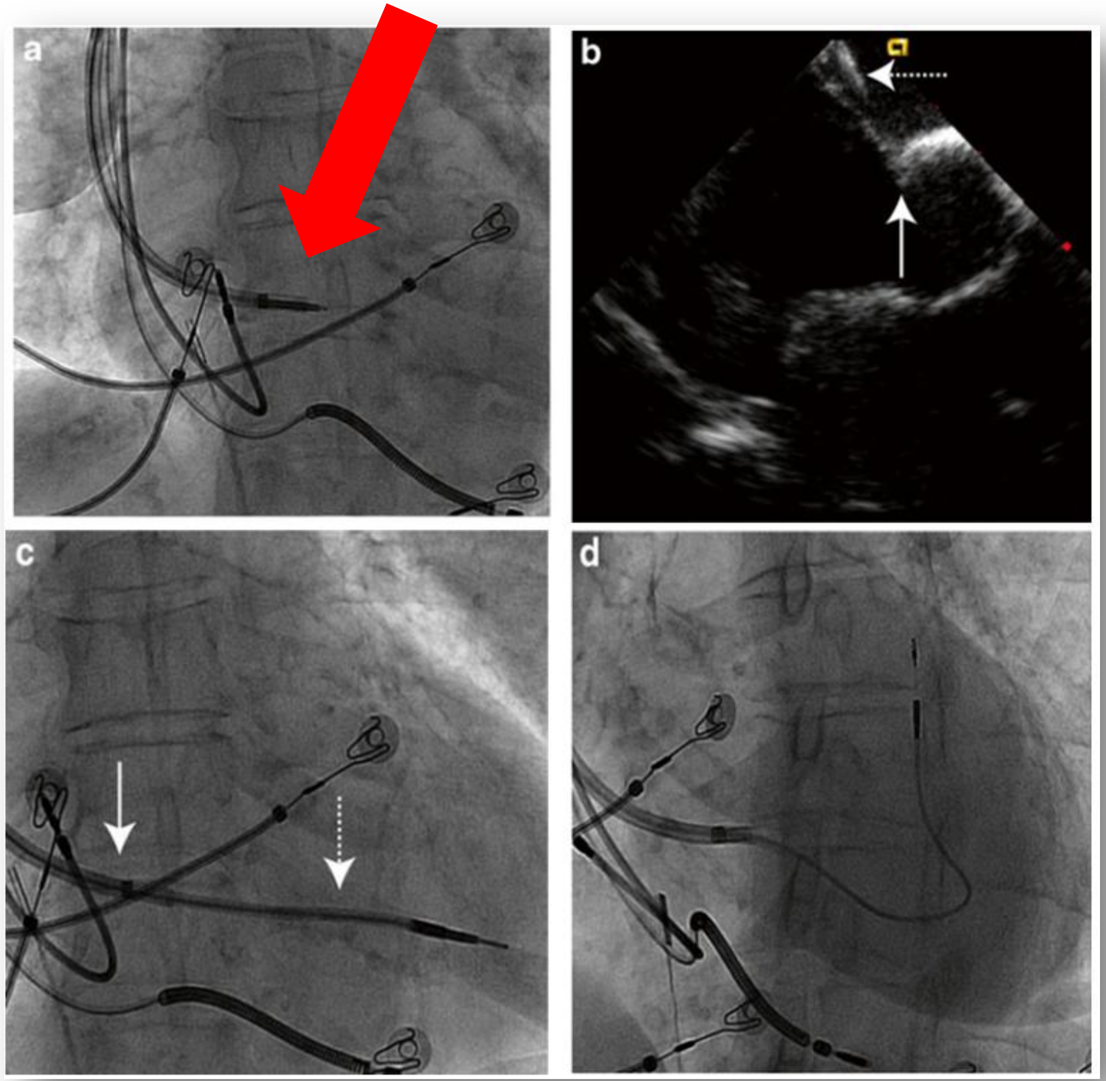
- Transseptal technique
  - **Atrial septum** (several modifications)



Neuhoff I et al: Rom J Intern Med 2016,54(2):2-4.

LV endocardial pacing approaches

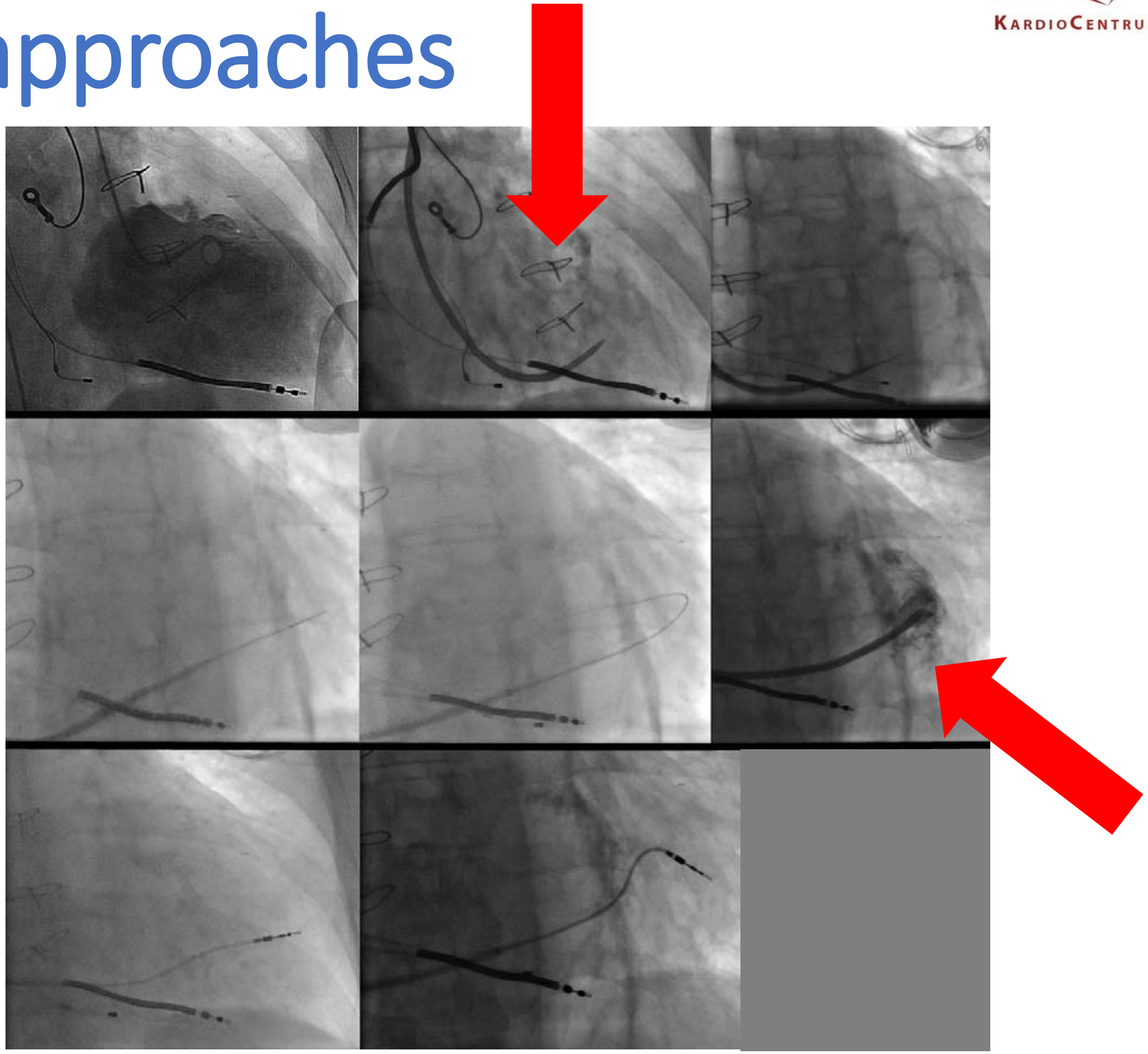
- Transseptal technique
  - **Atrial septum** (several modifications)



Bracke FA: Neth Hert J 2012,20:120.

LV endocardial pacing approaches

- Transseptal technique
  - Atrial septum (several modifications)
  - **Ventricular septum**

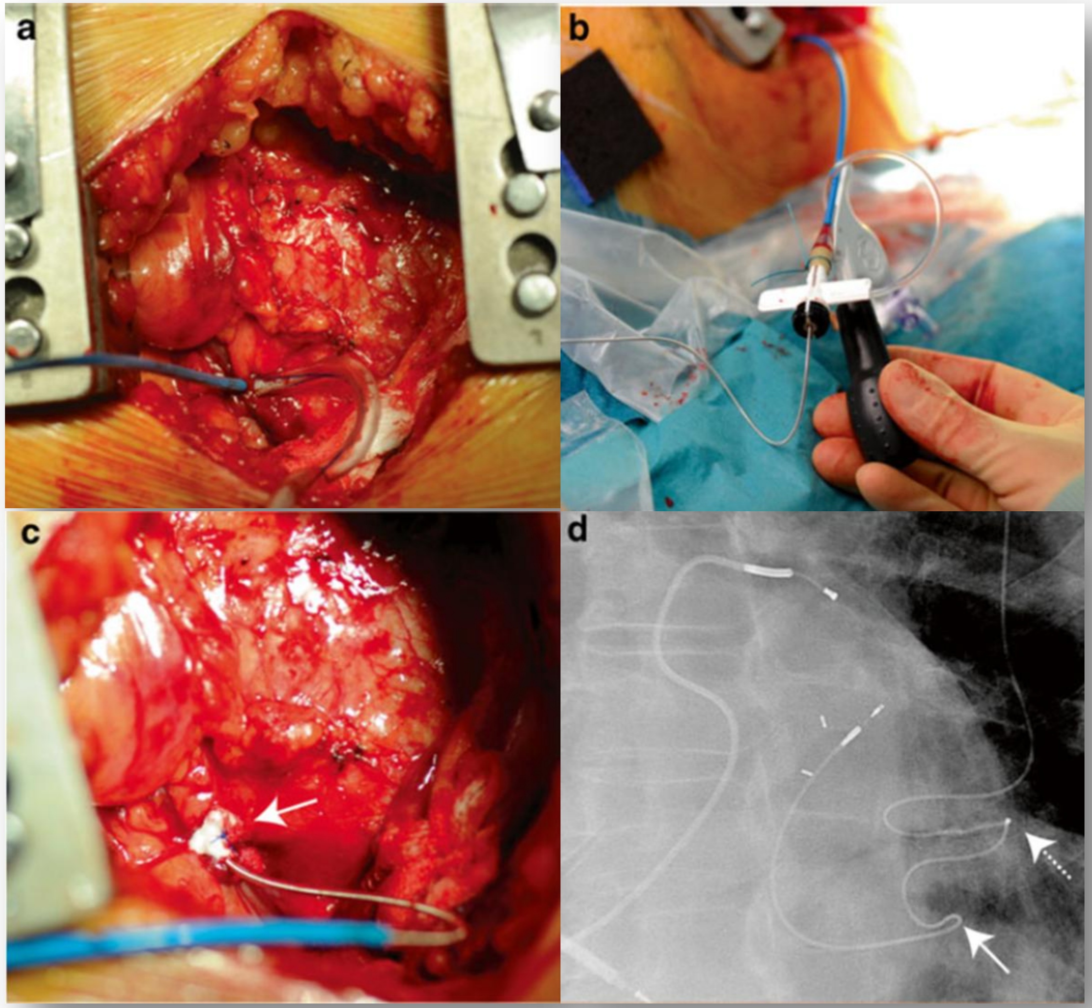


Betts et al: Circ Arrhythm Electrophysiol 2014

LV endocardial pacing approaches

- Transseptal technique
  - Atrial septum (several modifications)
  - Ventricular septum

- **Transapical technique**



Bracke FA: Neth Hert J 2012,20:122.

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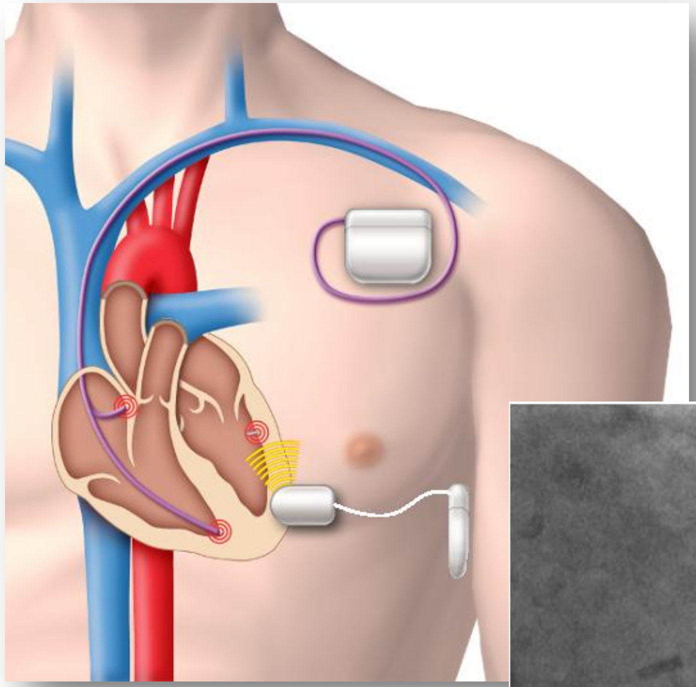
LV endocardial pacing approaches

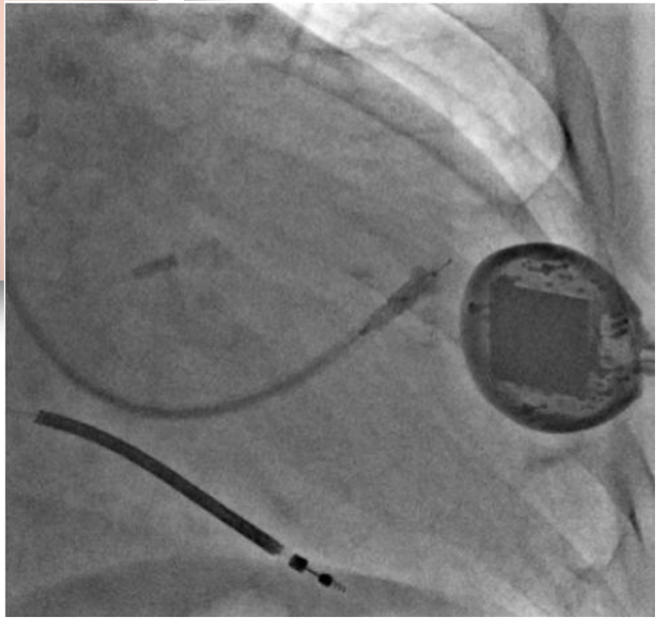
- Transseptal technique
  - Atrial septum (several modifications)
  - Ventricular septum

- Transapical technique

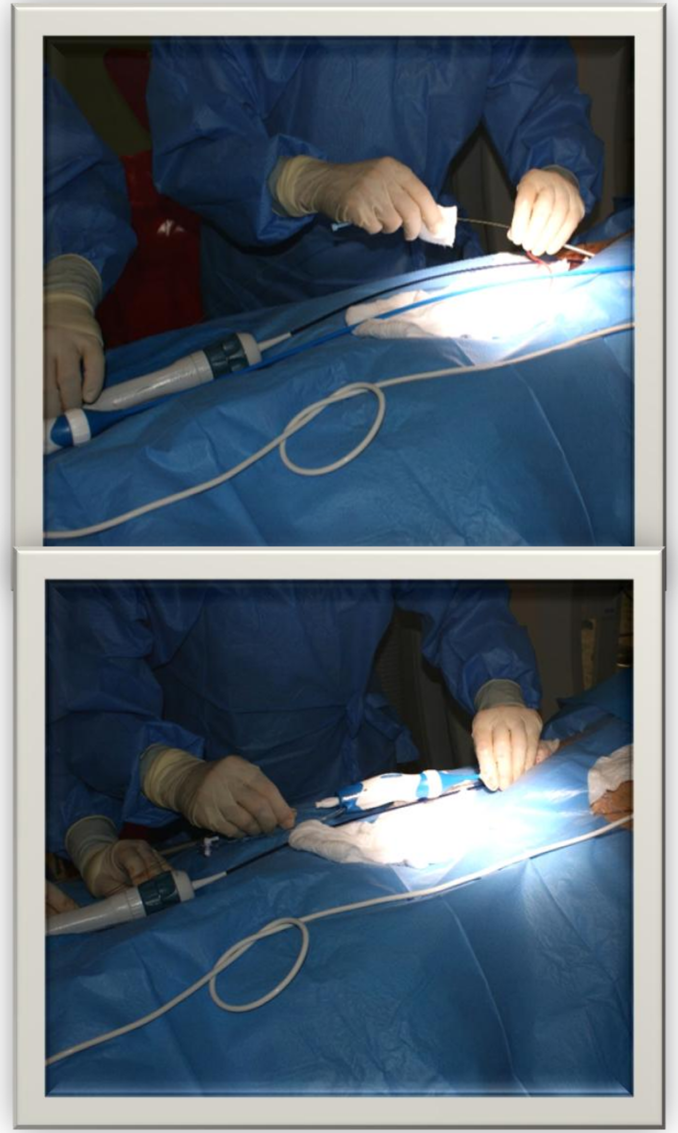
- **Retrograde approach (leadless)**

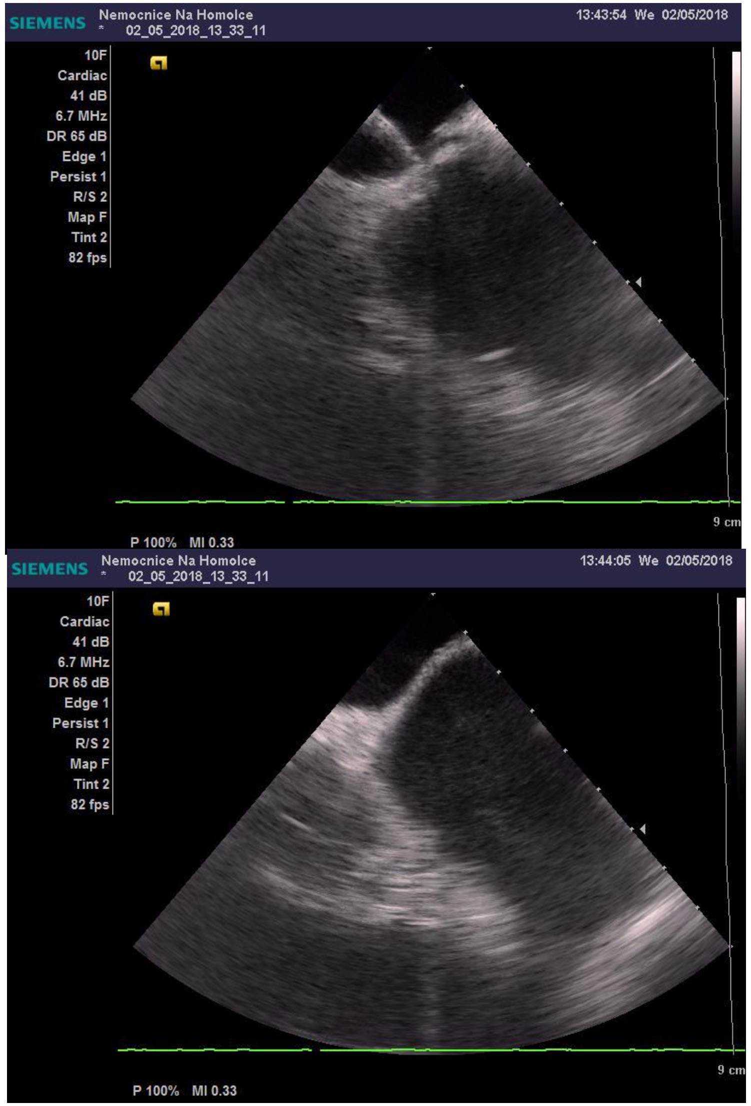
…… WiSE Technology

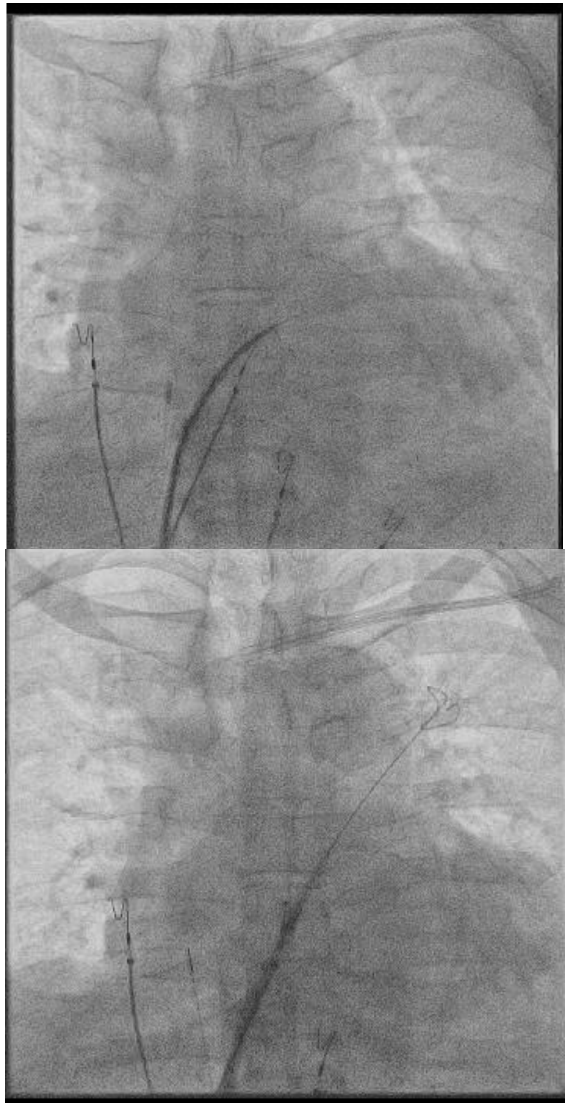




Na Homolce Hospital technique







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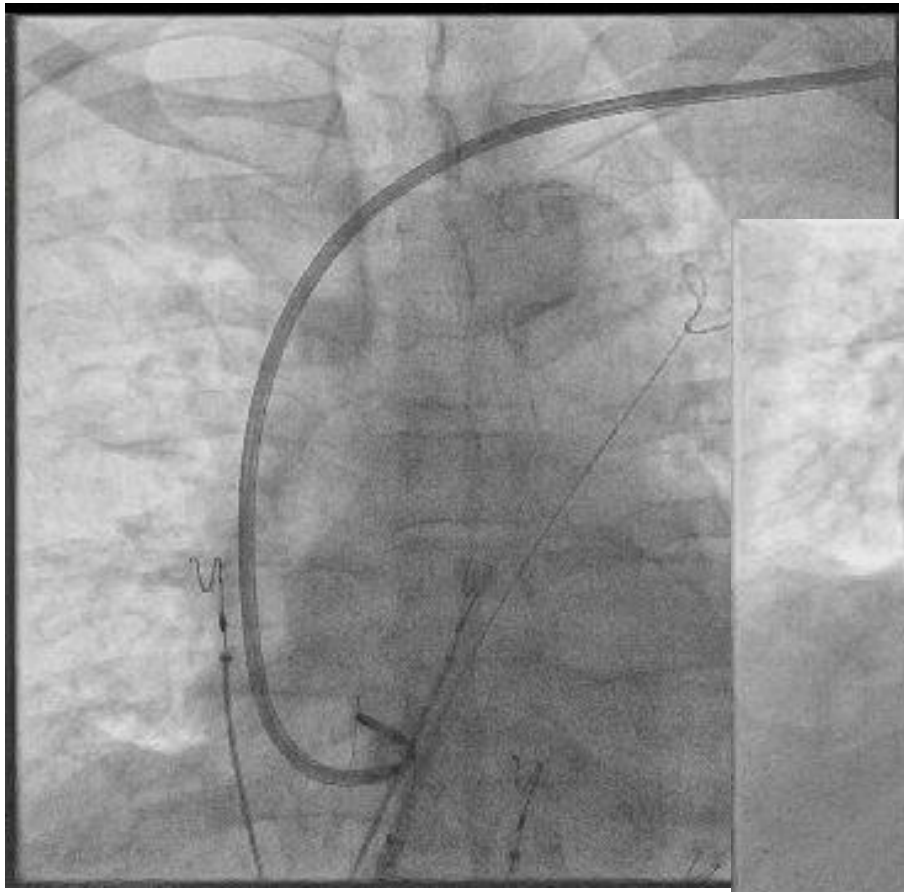

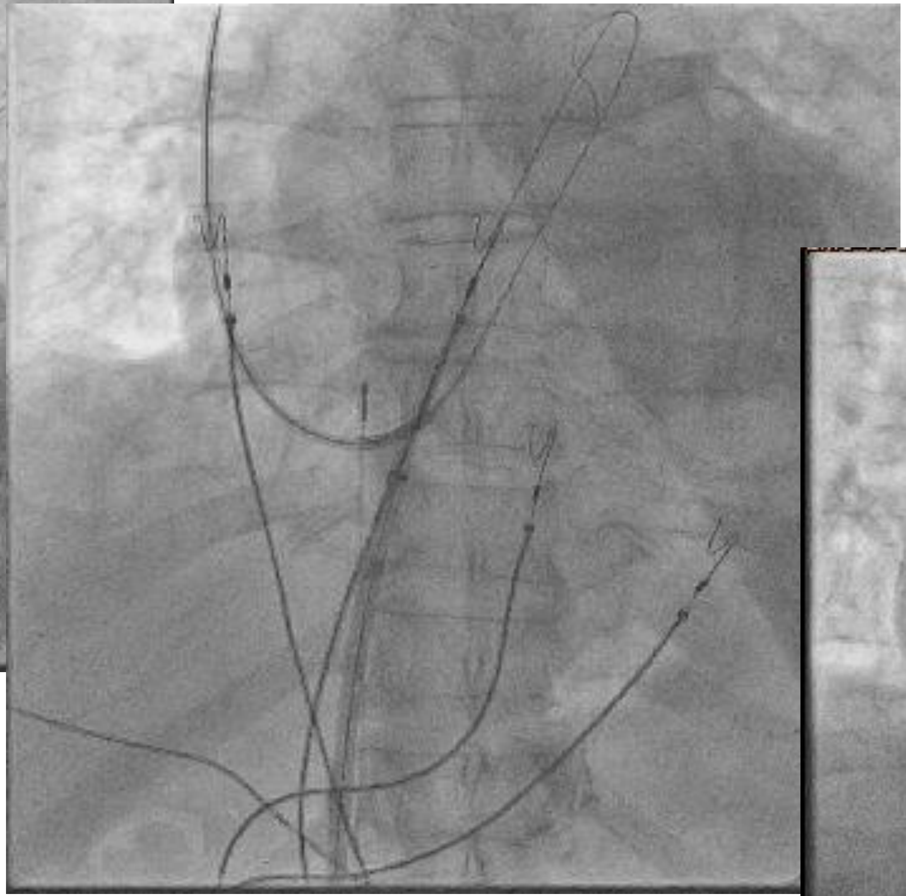

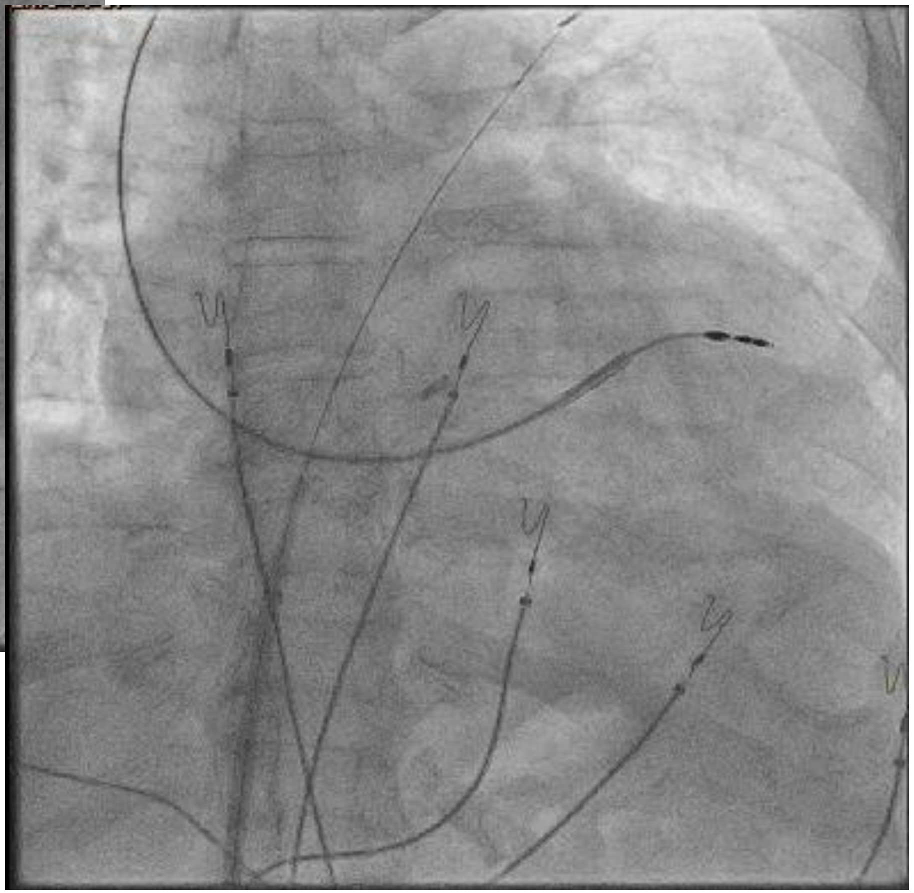

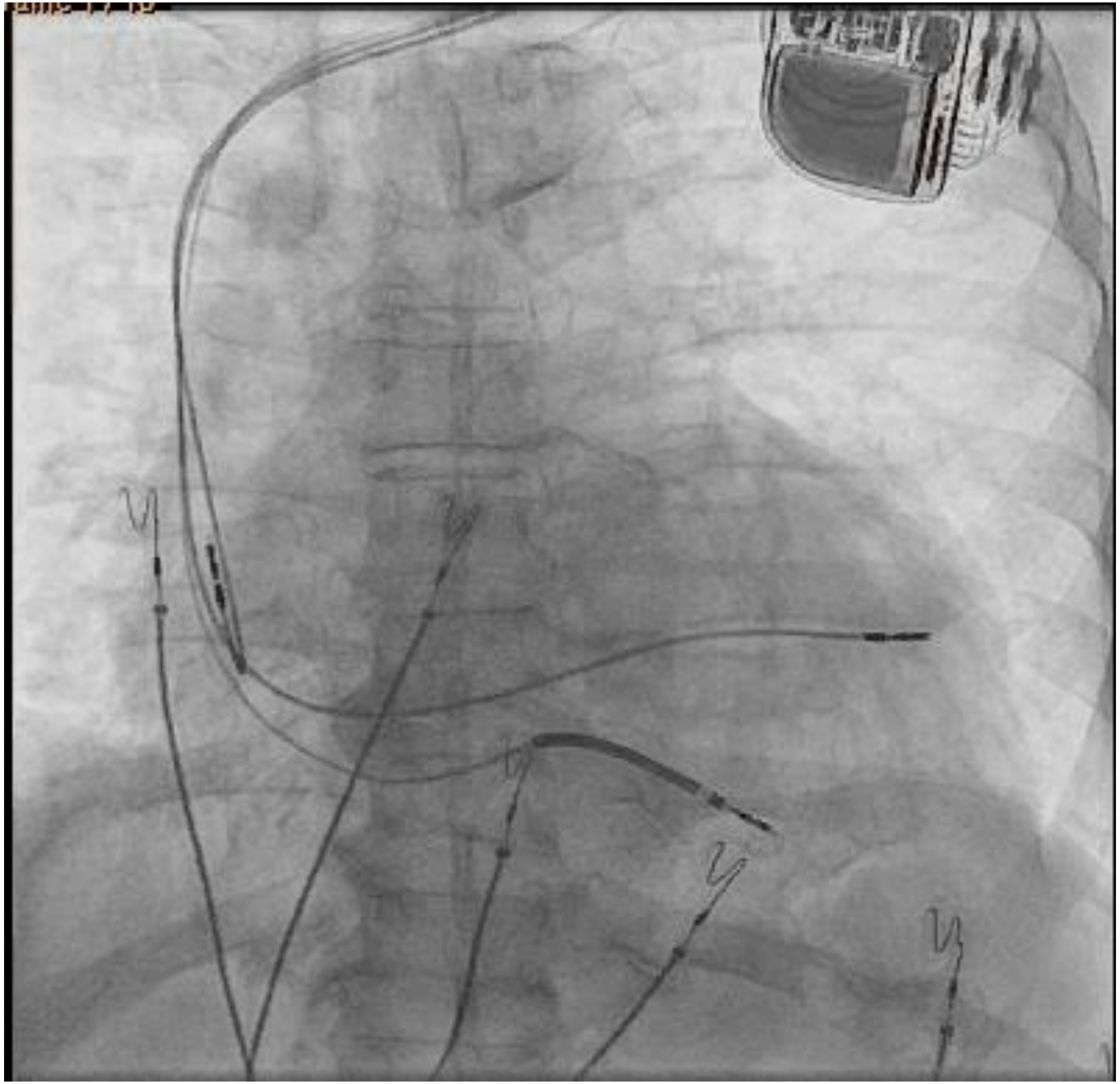

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Endocardial left ventricular pacing for cardiac resynchronization: systematic review and meta-analysis

James Hugo Phillimore Gamble*, Neil Herring, Matthew Ginks, Kim Rajappan, Yaver Bashir, and Timothy Rider Betts

- to assess the relative benefits and risks of LV endocardial pacing
  - Long-term thromboembolic (TE) events
  - Rate of response to endocardial CRT
- 23 studies published 1999-2016
- no randomised, single centre
- Procedural success rate > 95%

Trans-atrial septal technique	20
Trans-ventricular septal technique	2
Transapical technique	1

Table 2 Summary features of included studies and patients

Parameter	Result	Proportion of patients with data available
Studies	23	
Patients included	384	
Median patients per study (range)	8 (1–136)	
Proportion of male patients	66%	93%
Age (years)	66.2 (61.9–70.5)	97%
EF (%)	26.4 (23.8–29.0)	91%
NYHA class	3.0 (2.8–3.2)	98%
CHADS-VASc score	3.4 (2.9–4.0)	47%

Gamble JHP et al : Europace 2018,20:77

16 6

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

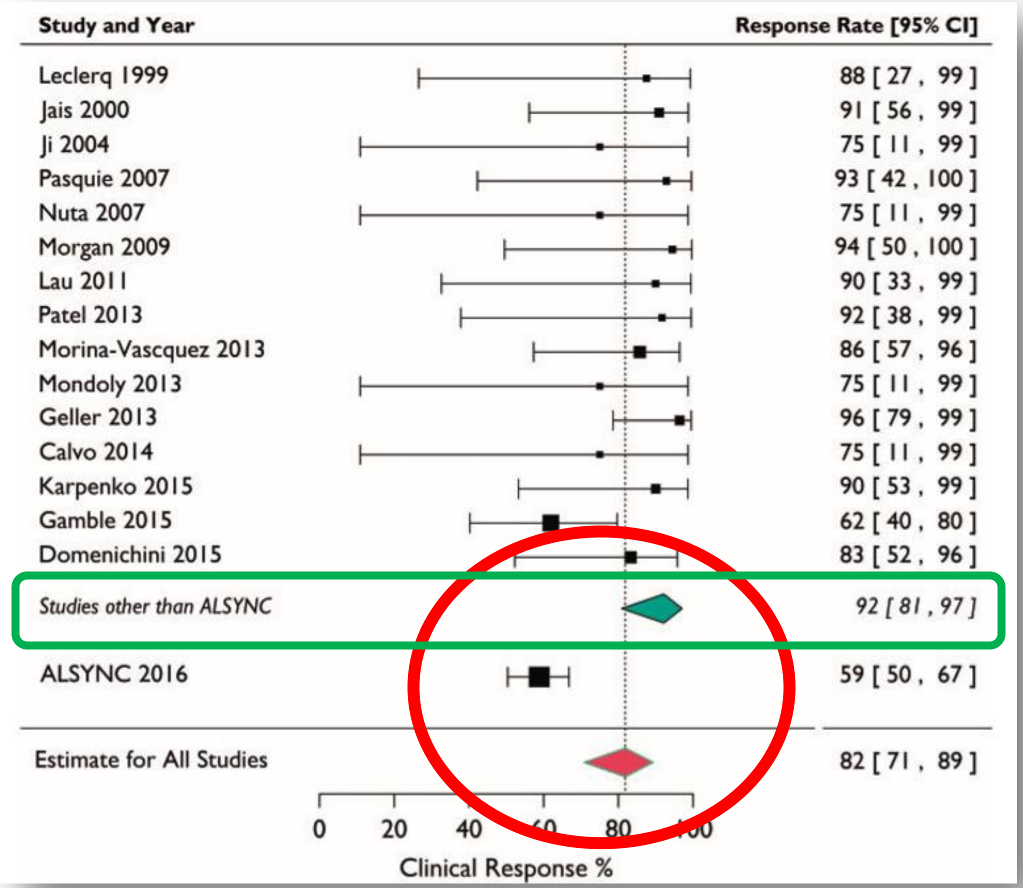
TAS, trans-atrial septal; TVS, trans-ventricular septal; TVA, trans-apical. Follow up given as mean with standard deviation where available. When range is given this is minimum to maximum.

Gamble JHP et al : Europace 2018,20:77

Response to endocardial CRT

- **Clinical response**
- 262 patients
- 191 (73%) ≥ 1 decrease in NYHA
- **82%** (95% CI 71-89%)

- **Echocardiographic response** > 5% in EF
- 171 patients
- **64,3%** (56,8-71,2)



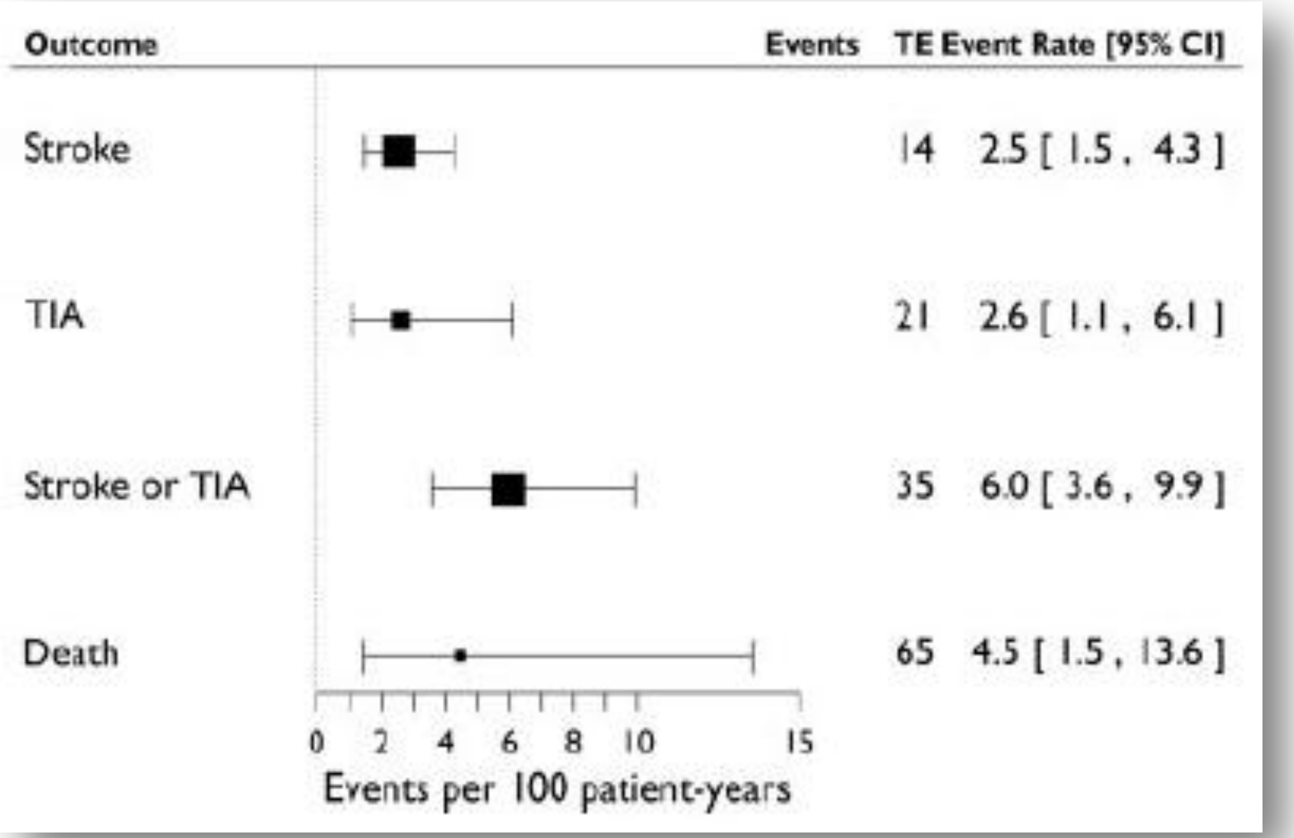
Gamble JHP et al : Europace 2018,20:77

TE complications of endocardial CRT

- Relatively small numbers of events
- 13/23 (57%) reporting no events

- **Event rates:**
  - **TIA, stroke 6%/year**
  - **Death 4,5%/year**

- Related to level of INR
- No significant diferences between techniques

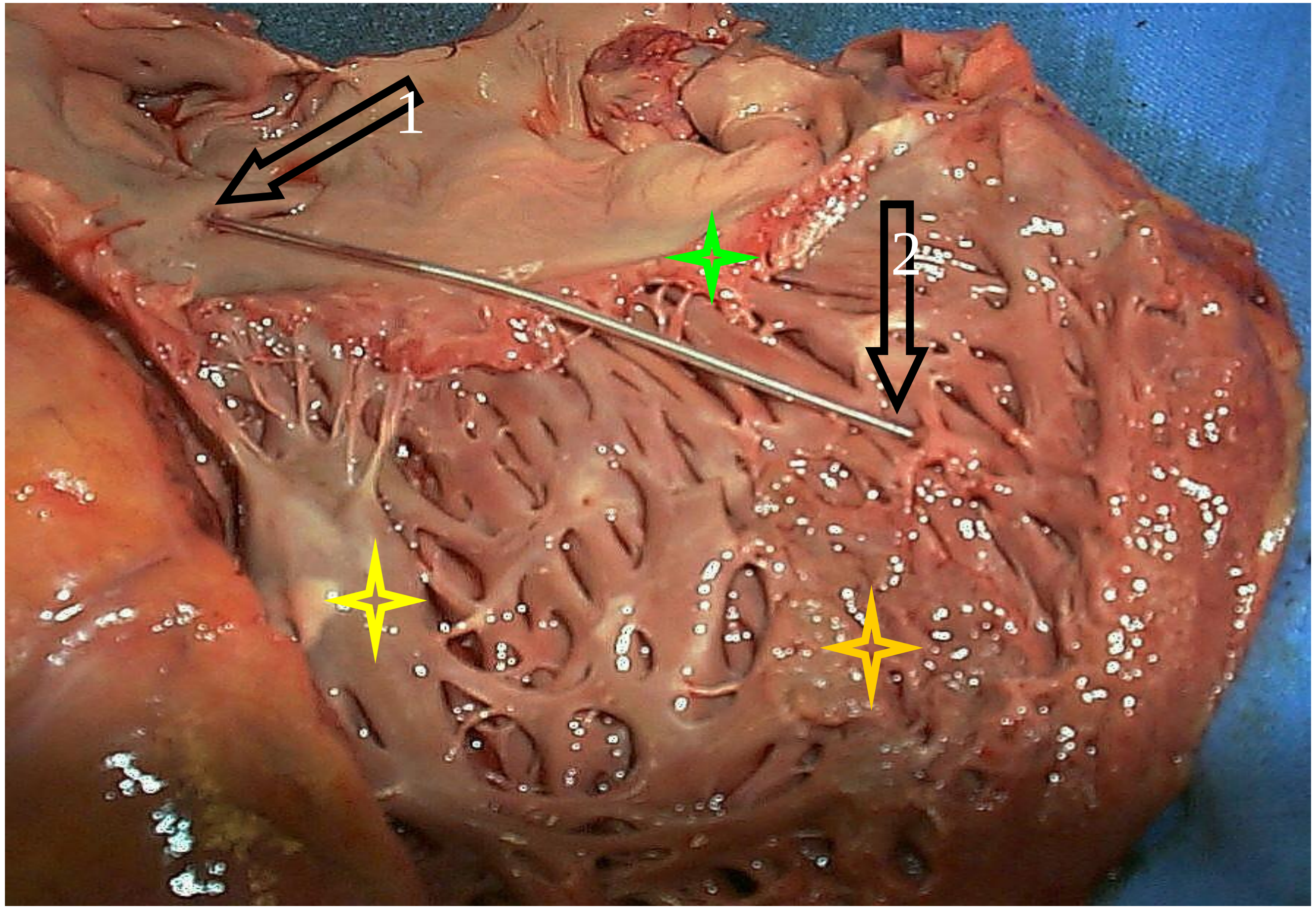


Gamble JHP et al : Europace 2018,20:77

Transseptal LV Lead Placement

- Risk of infection exists !
- ALSYNC study: 2/118

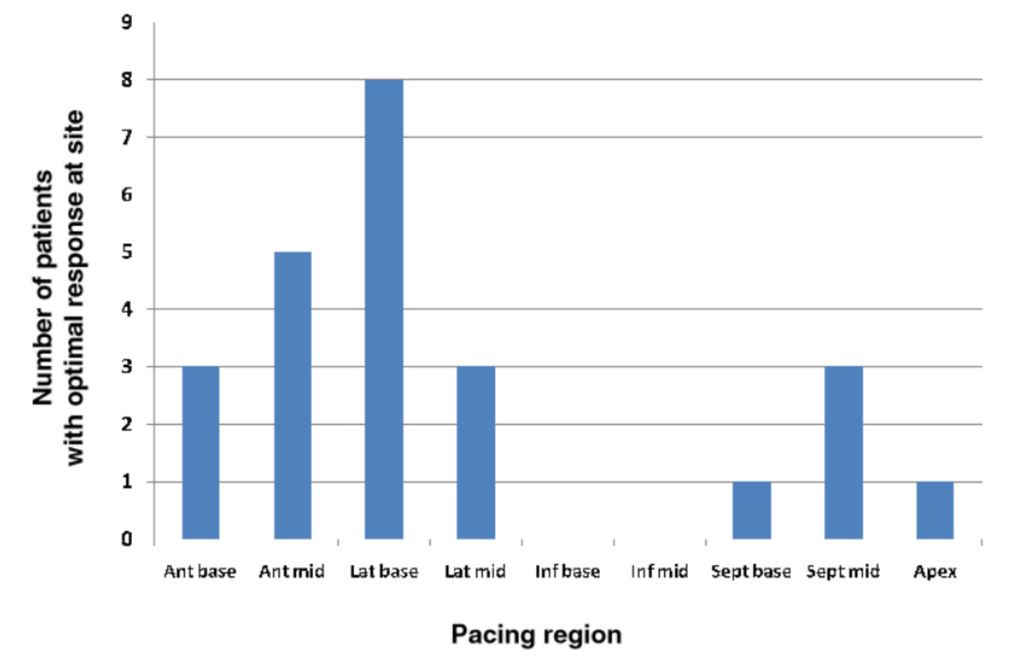
- Risk of mitral regurgitation ?



With courtesy of Prof. Christophe Leclercq

Not just about the delivery, but where to pace

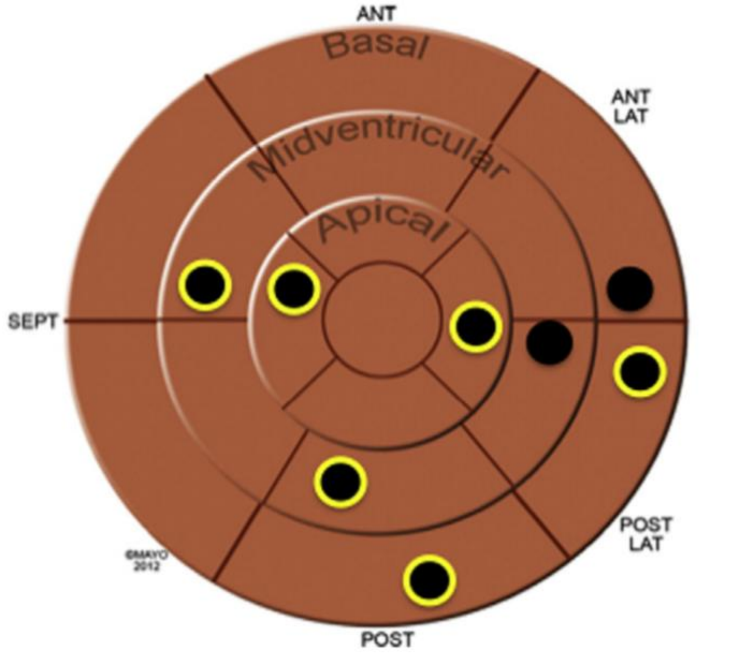
- very, very individual …. scar related ?! …. CMR benefit ??



Distribution of LV Pacing Sites Yielding Optimal LV Systolic Function

D.D. Spragg, J Am Coll Cardiol 2010:56, 774-81

Best endocardial position (LVendo)



J.M. Behar, J Am Coll Cardiol EP 2016;2:799–809

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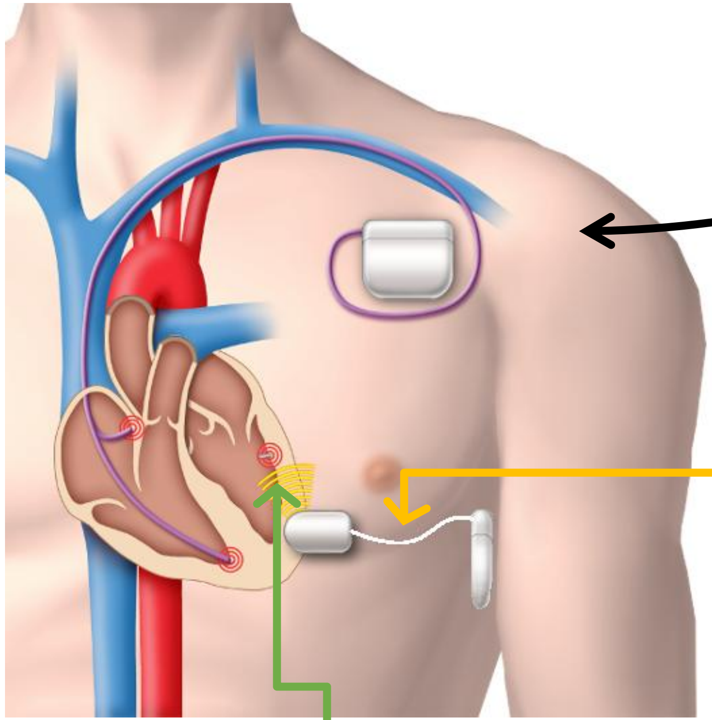
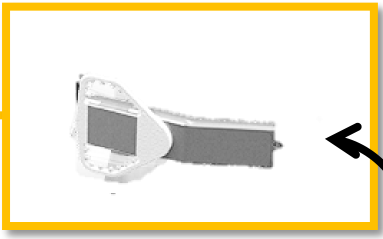
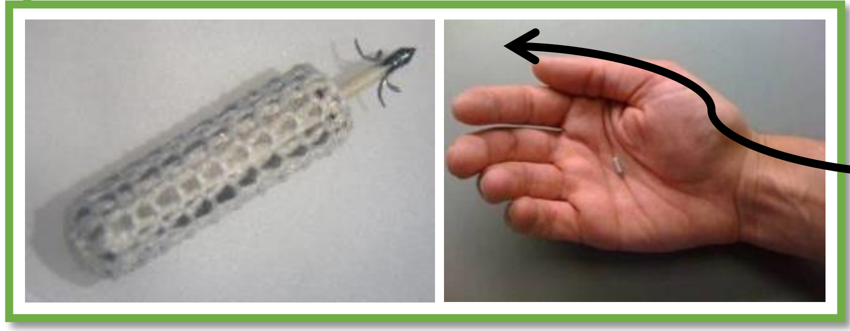
Leadless LV endocardial pacing - **WiSE** Technology







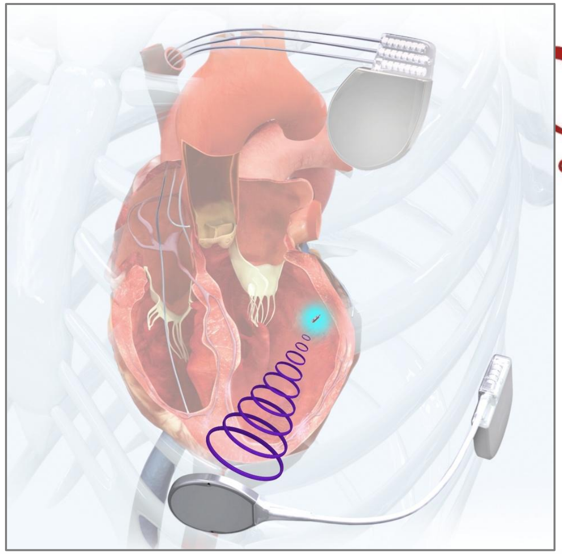
ebr SYSTEMS

Conventional Device ("Co-Implant")
Provides RA and RV Pacing
(Pacemaker, ICD, CRT-p, CRT-D)

EBR's System Provides Synchronized Left Ventricular Pacing

- Phased Array Ultrasound Transmitter is Implanted in Intercostal Space
- Receiver Electrode (RE) is Implanted in LV Endocardially. Converts ultrasound energy to electrical pulse.

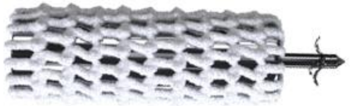
WiSE Technology



Small Size

Designed for LV placement while diminishing need for chronic anticoagulation

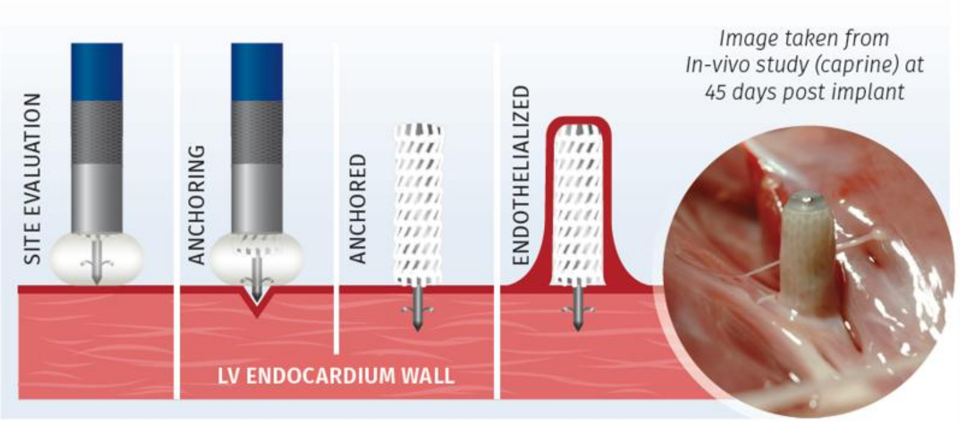
LENGTH OF BODY: **9.1mm**
DIAMETER: **2.7mm**
WEIGHT: **0.12 grams**
VOLUME: **0.05 cc**

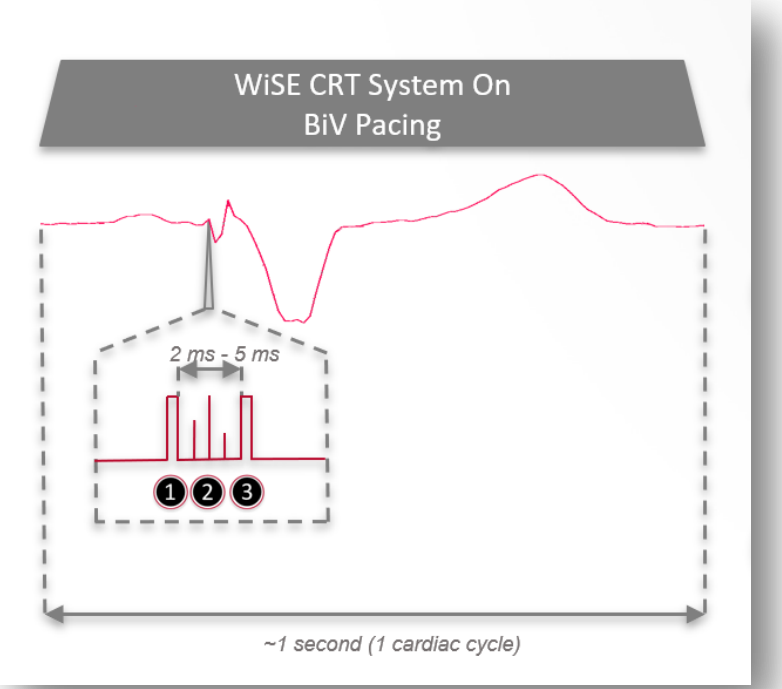


Secure Attachment

Endothelialises for a low risk of thromboembolic events

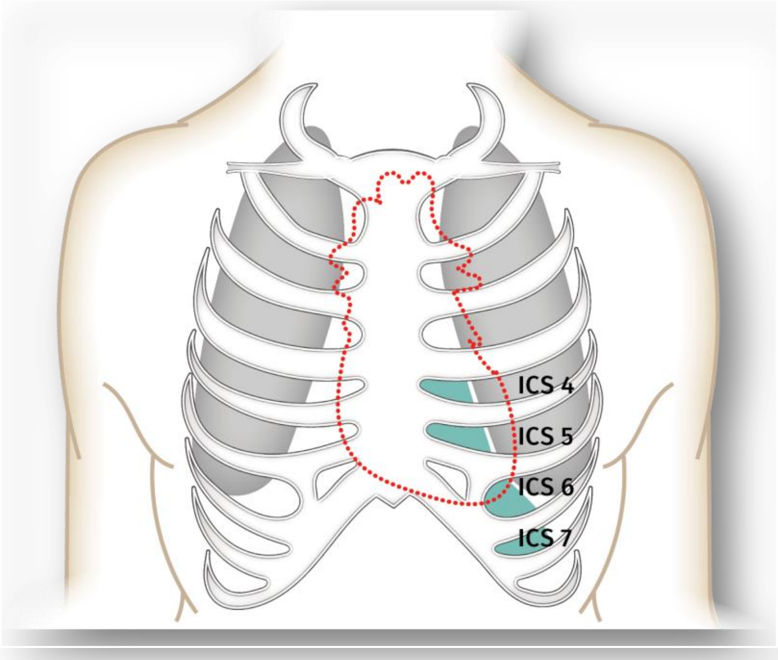
- Anchors onto endocardial wall with 5 nitinol tines
- Passive device with no need for replacement
- Full endothelialisation in animal testing at 30 to 45 days^





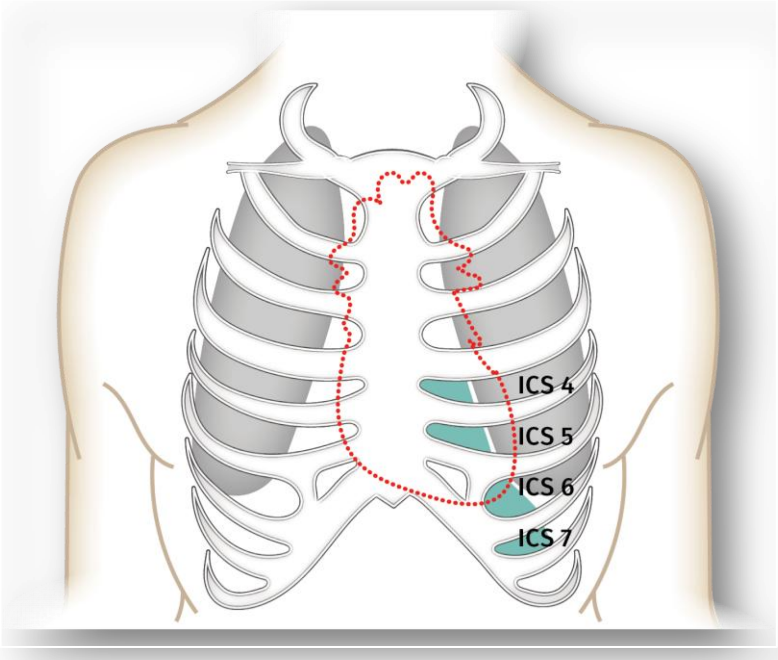
Echt DS, Moore D, Cowan M, Valli VE, Whitehair JG, Willis NP. Heart Rhythm 2010; S451-2.

3 stage procedure

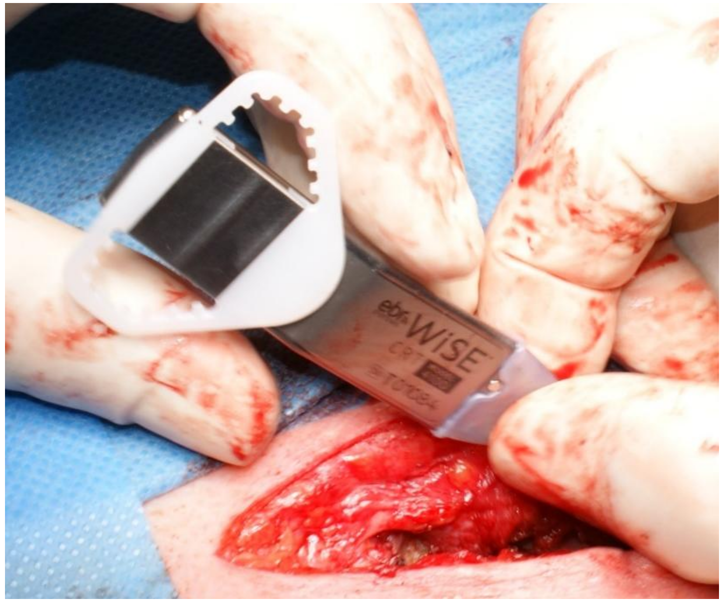


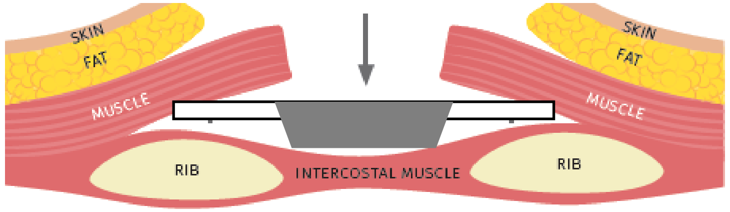
Acoustic window screening

3 stage procedure



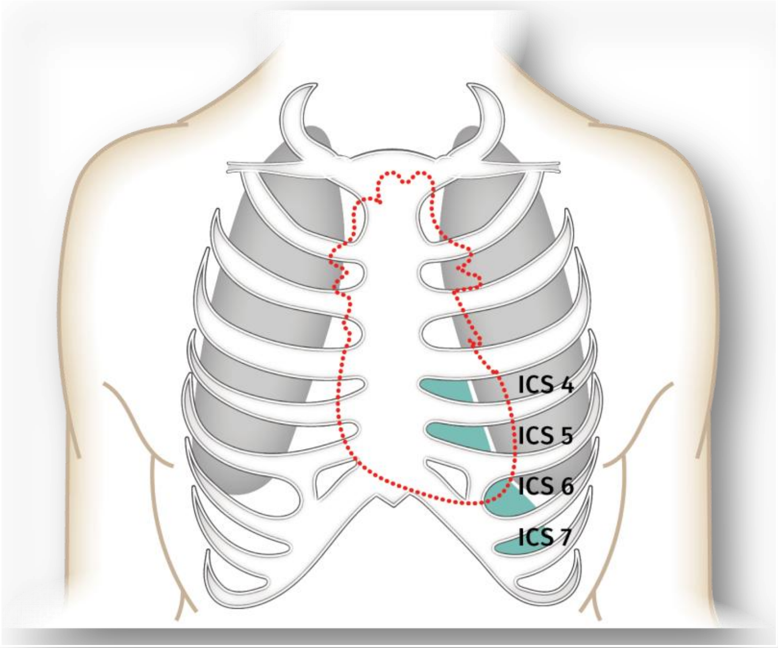
Acoustic window screening





Transmitter Implant

3 stage procedure

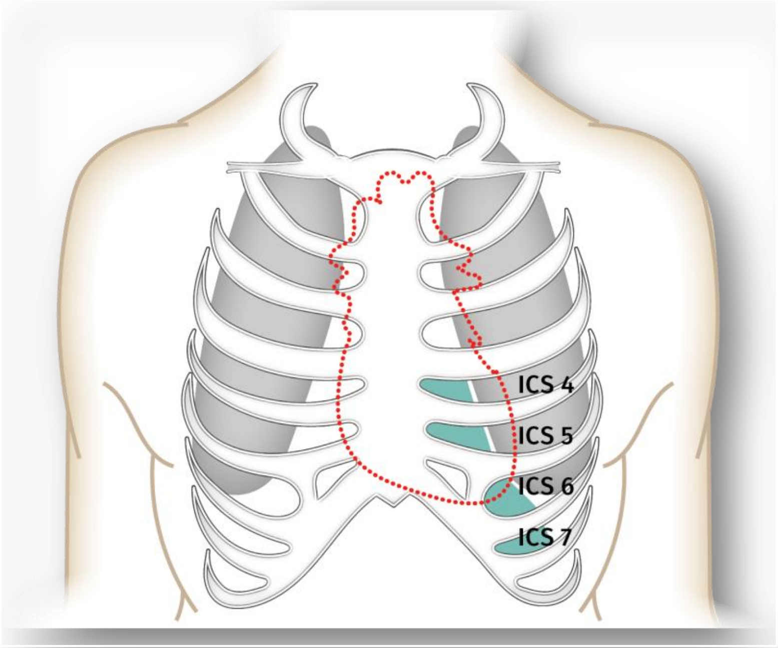


Acoustic window screening

Transmitter Implant

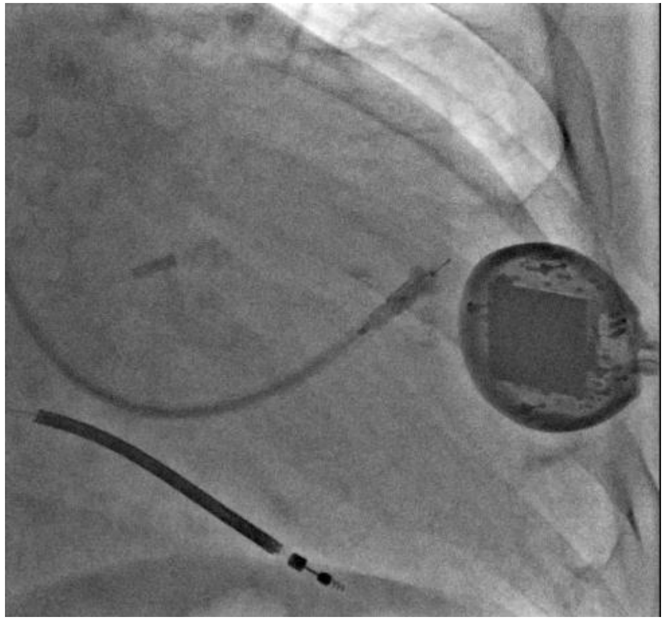
3 stage procedure

- 12 Fr steerable Sheath with a balloon “bumper” to minimize trauma to endocardium
- 8Fr delivery catheter for electrode
- Electrical connection to the RE cathode for site evaluation (local EGM, test capture threshold using lab stimulator)

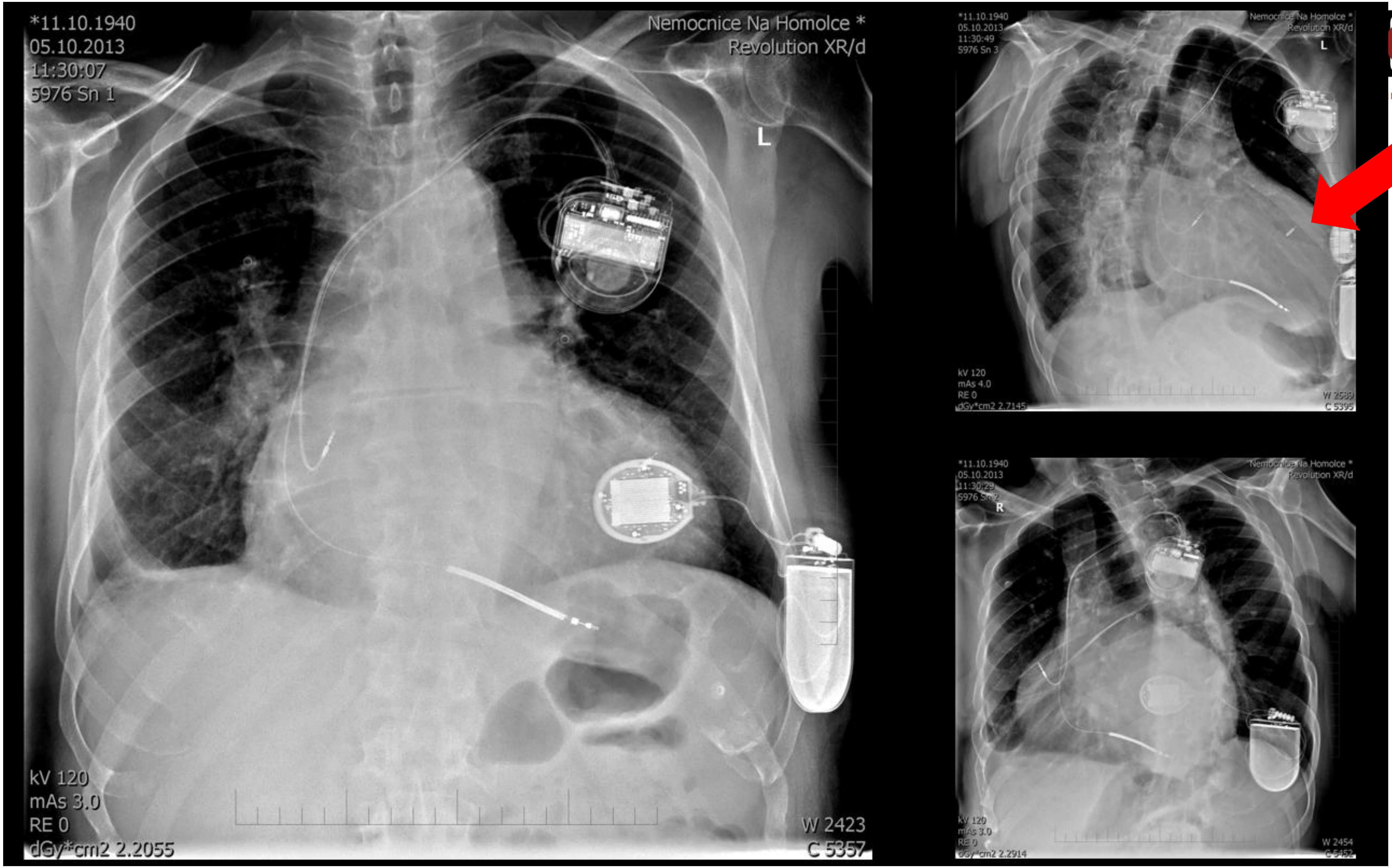


Acoustic window screening

Transmitter Implant



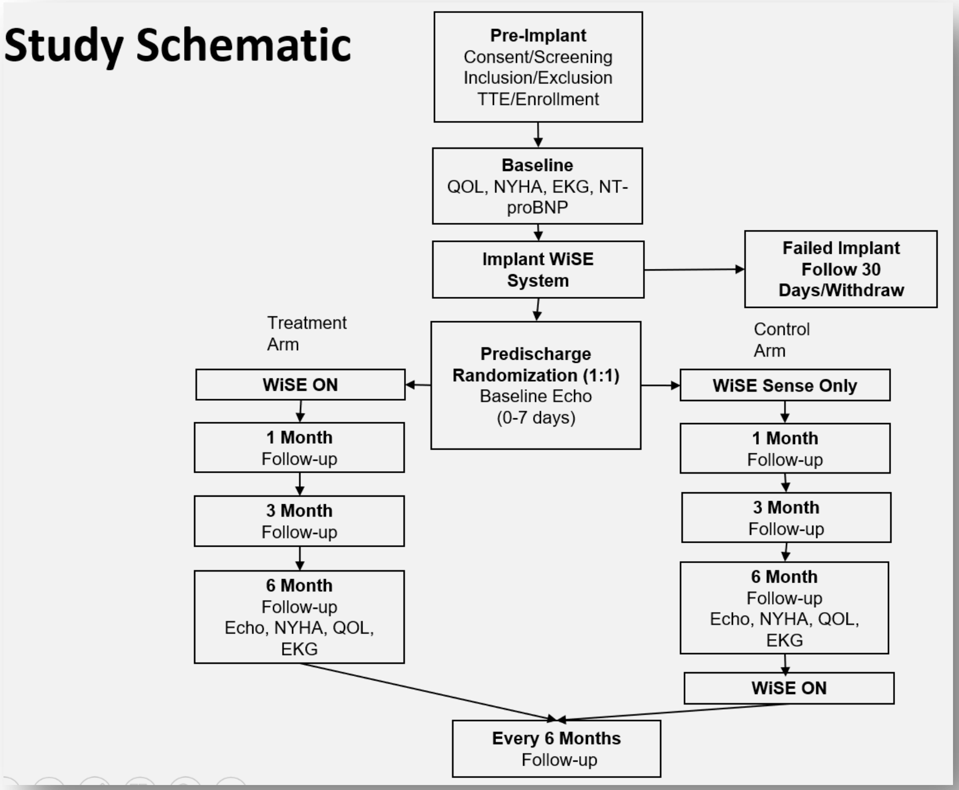
Electrode delivery


*11.10.1940
05.10.2013
11:30:07
5976 Sn 1
Nemocnice Na Homolce *
Revolution XR/d
L
kV 120
mAs 3.0
RE 0
dGy*cm2 2.2055
W 2423
C 5357
*11.10.1940
05.10.2013
11:30:49
5976 Sn 3
Nemocnice Na Homolce *
Revolution XR/d
L
kV 120
mAs 4.0
RE 0
dGy*cm2 2.7145
*11.10.1940
05.10.2013
Nemocnice Na Homolce *
Revolution XR/d
R
kV 120
mAs 3.0
RE 0
W 2454

WiSE Technology

- First in Human: WiSE-CRT 13 pts
- CE Study: SELECT LV 34 pts (12 pts in NNH)
- Post-CE Mark Registry > 100 pts

- SOLVE CRT - ongoing
  - 350 non CRT responders, 45 Centers
    - Prospective, two-arm, randomized 1:1
    - double blind, multi-center trial



Cardiac Resynchronization Therapy With Wireless Left Ventricular Endocardial Pacing

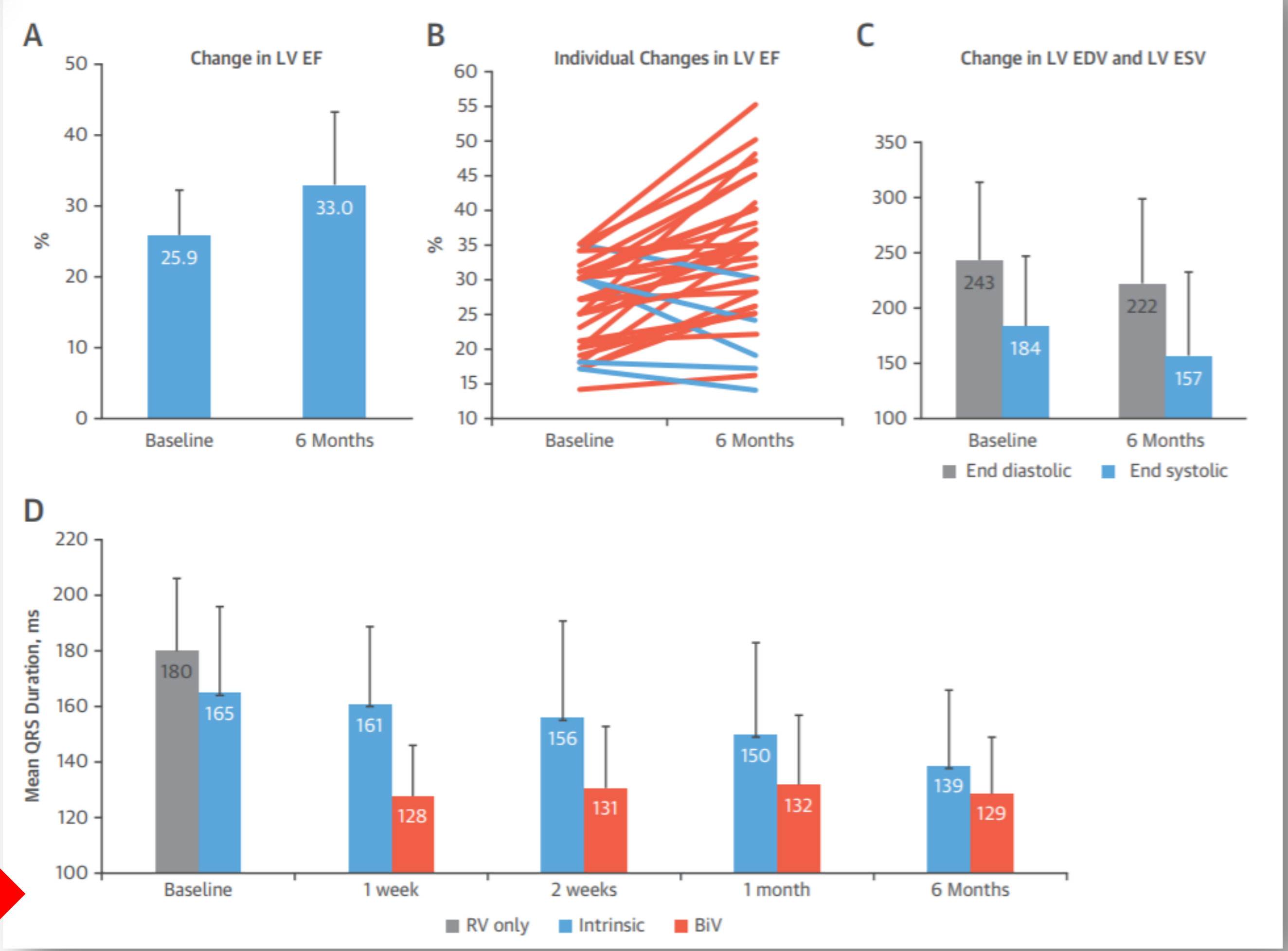
The SELECT-LV Study

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]

- 34/35 (97%) implantation success

- **6M follow-up:**
- 94% of patients (who failed conventional CRT) achieved resynchronization
- 85% of pts with clinical response
- 66.7% pts ≥ 1 NYHA class
- 66% of pts with increase of EF ≥5%
- Signs of LV remodelation !!

FIGURE 2 Change in Echocardiographic and Electrocardiographic Parameters From Baseline to 6 Months



Reddy et al. JACC VOL. 69, NO. 17, 2017 MAY 2, 2017:2119 – 2 9

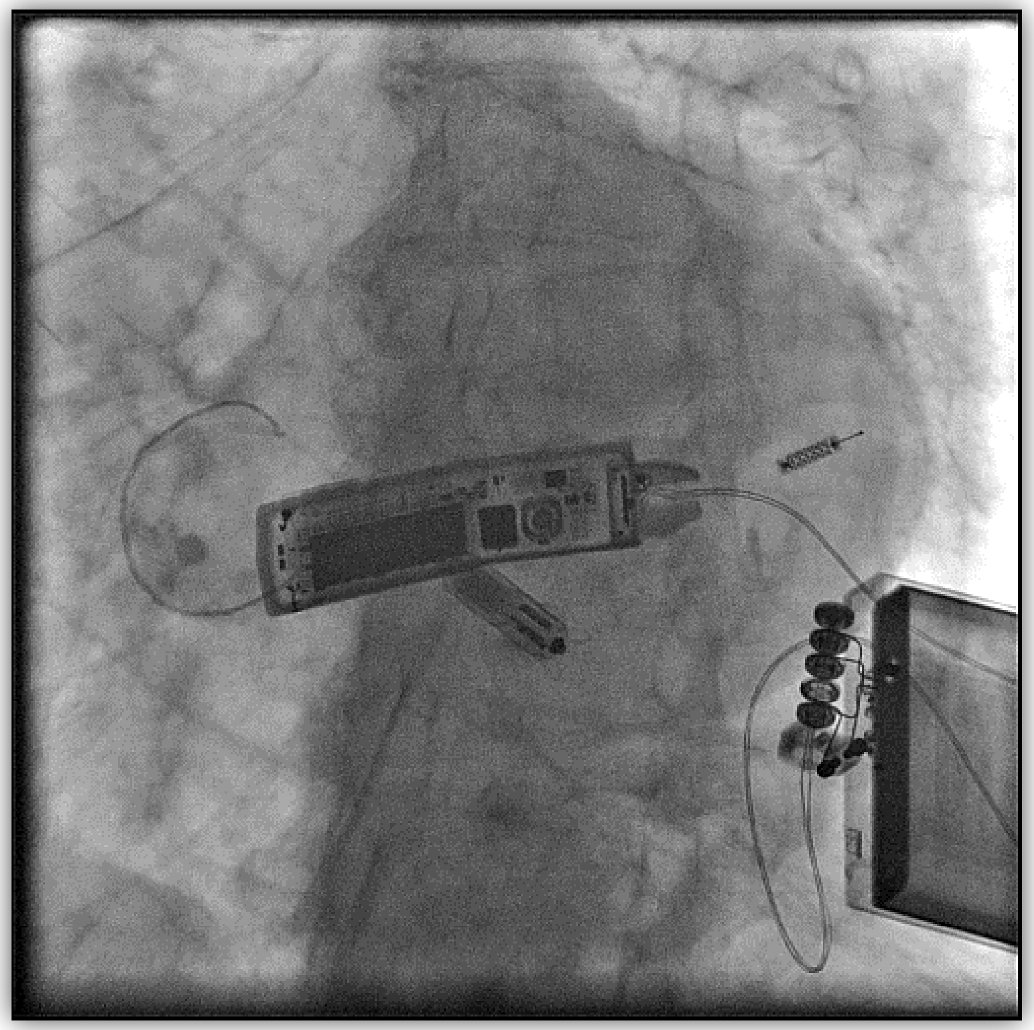
WiSE Technology – Concl.

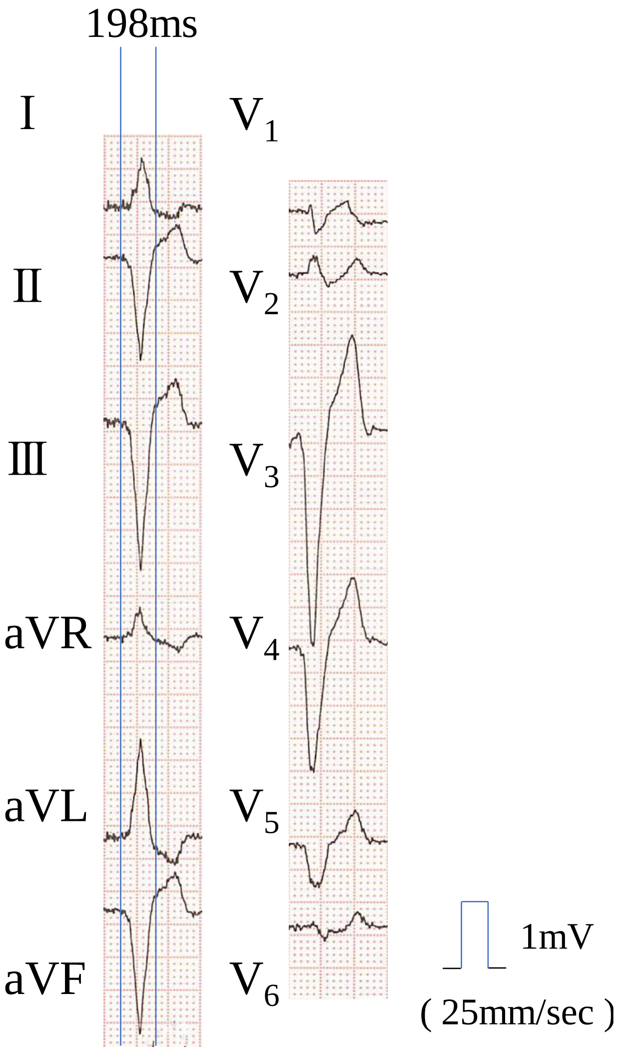
- **Chronic anticoagulation is not required !!!**

- Improvement in battery longevity by
  - Programming
  - Transmitter development
  - Electrode development
  - Battery development

Completely leadless biventricular pacing

- 75-year old female, history of MVP, TVP, MAZE (2015)
- Persist Afib reccurence, extreme LA dilation, Afib considered to be permanent
- 2016 intermit. AV block episodes - MICRA implantation
- FU revealed high rate of pacing (71%) with LV dysfunction (EF 25%)
- 2018 WiSE implantation



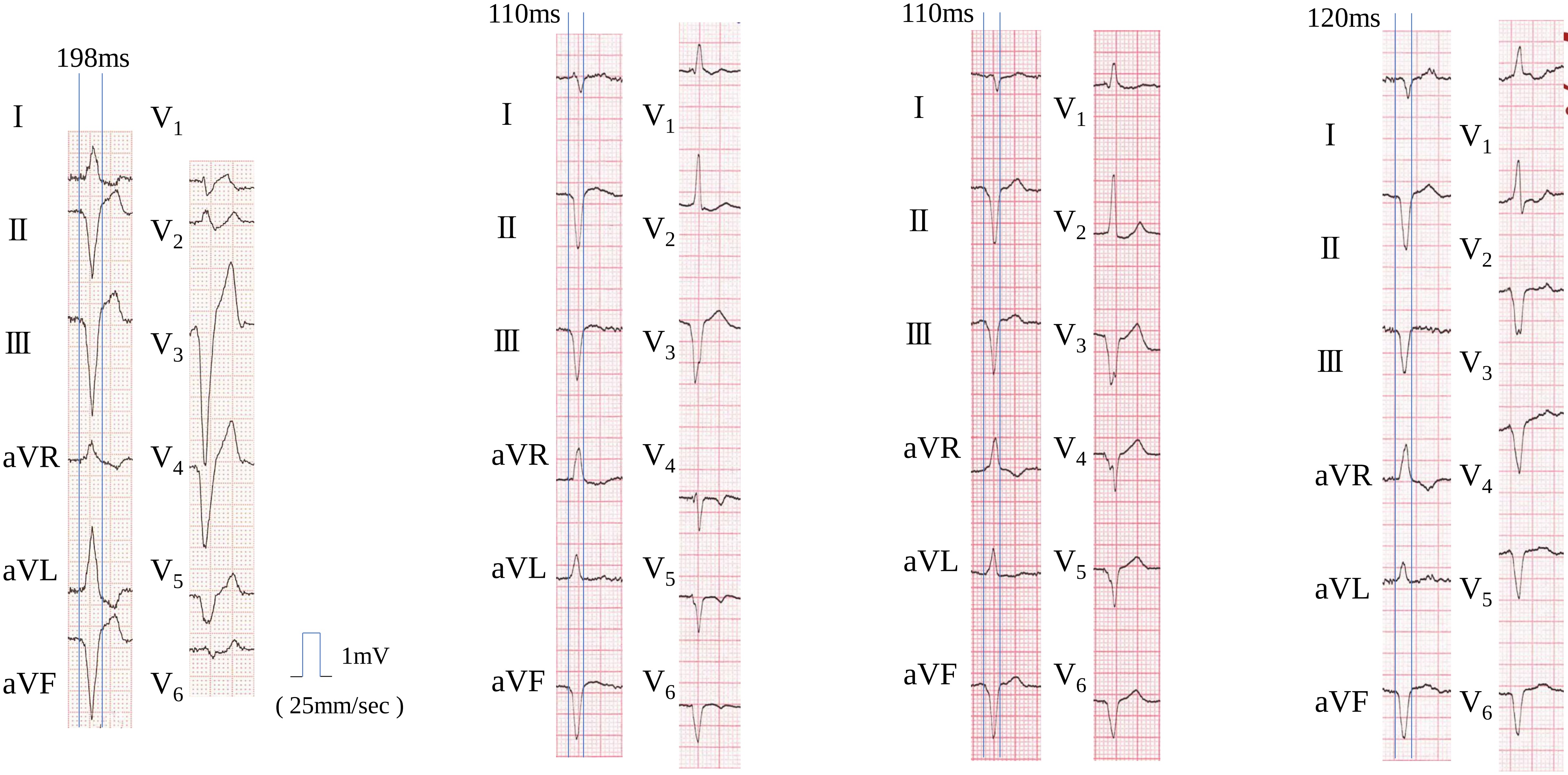


BL (RV pacing)

1W after

3M after

6M after



BL (RV pacing)   1W after   3M after   6M after

Conclusions

- Endocardial LV pacing is very attractive alternative for CRT, with advantage of more physiological electrical activation

- Limitations are mainly represented by the risk of TE events and level of anticoagulation remains a crucial challenge

- RCTs trial are needed for the evaluation of this technique to assess the feasibility, the safety and the clinical efficacy (increase in responders rate)

- Leadless LV endocardial (WiSE technology) development

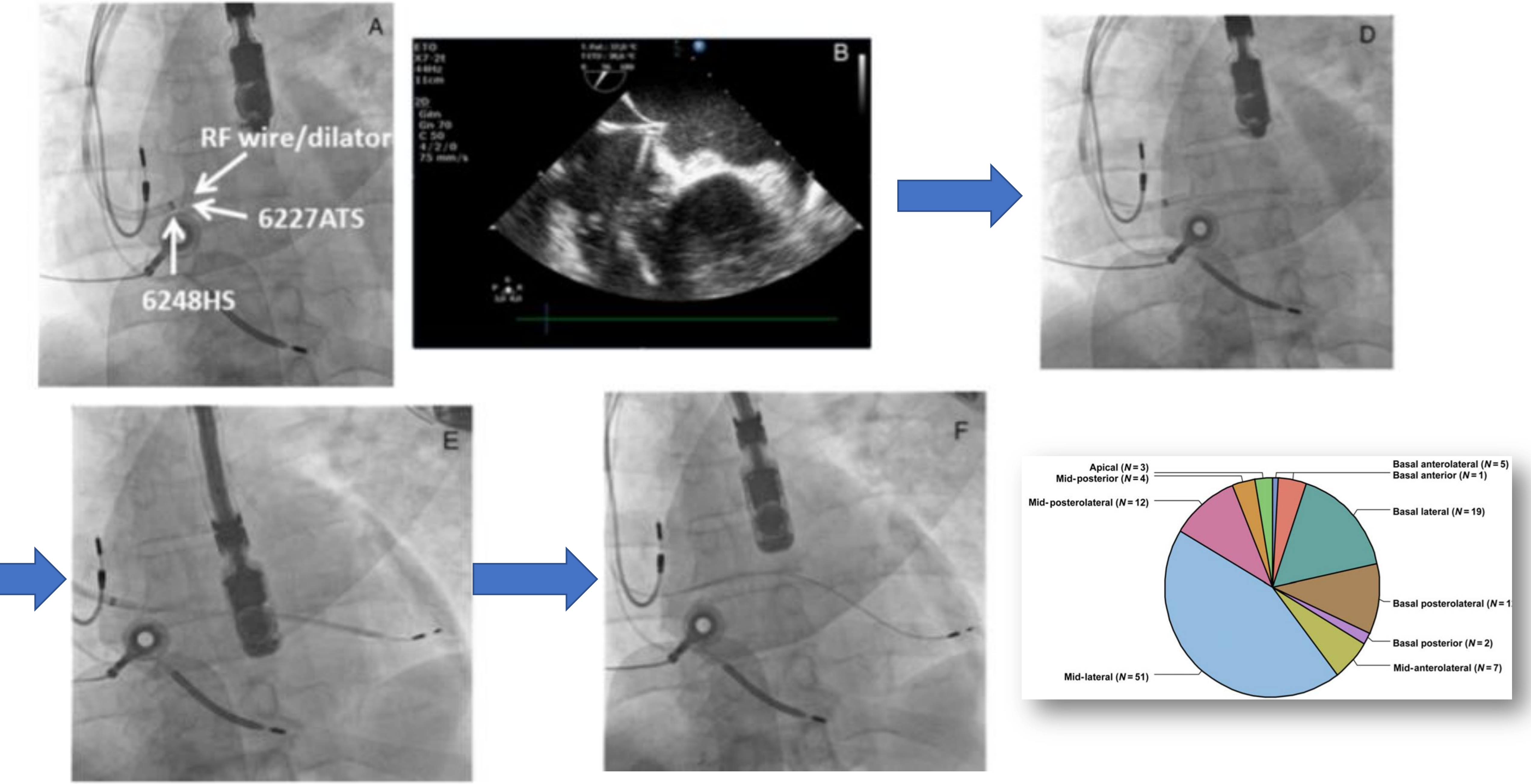
ALSYNC trial (Alternate Site Cardiac ResYNChronization)

- Prospective, multicentre (18) investigation of CRT-indicated patients, who had failed or were unsuitable for conventional CRT

- Evaluate safety and performance of novel atrial transseptal left ventricular (LV) endocardial lead delivery system, implant procedure via superior access, RF puncture, SelectSecure® Model 3830 lead

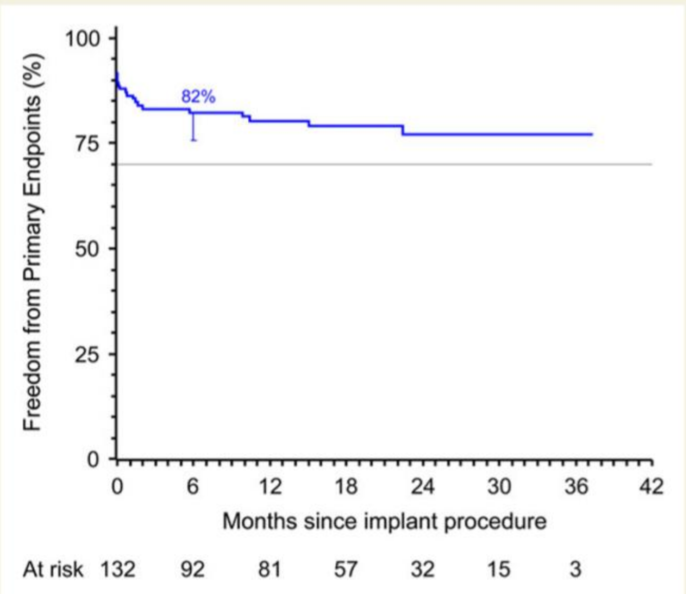
- 138 patients
- Mean FU: 17 ± 10 months

JM Morgan et al., European Heart Journal (2016) 37, 2118–2127



JM Morgan et al., European Heart Journal (2016) 37, 2118–2127

ALSYNC trial – main results



- successful implantation in 118 patients (89,4%)
  - 90 pts …. failed CS implants
  - 28 pts … prior CRT non-responders

- At 6-month **82.2%** of the patients remained free of complications related to implantation or presence of an LVEP lead

- 59% achieved an improvement of at least one NYHA class

JM Morgan et al., European Heart Journal (2016) 37, 2118–2127

ALSYNC trial – main results

Table 3 **Echocardiographic indices and clinical outcomes**

	Baseline (n = 118)	6 months (n = 105)	Change	*P*-value*	Response definition	Response rate for all patients (n = 118)
LVESV	149 ± 79 mL	121 ± 74 mL	29 ± 60 mL reduction	<0.0001	≥15% relative reduction	55%
					≥30% relative reduction	33%
LVEF	29 ± 10%	36 ± 12%	7 ± 10% increase	<0.0001	≥5% absolute increase	64%
Mitral regurgitation	Moderate/ severe: 41%	Moderate/ severe: 30%		0.035	≥1 class improvement	33%
NYHA class	I/II/III/IV: 3%/ 20%/69%/7%	I/II/III/IV: 19%/ 51%/28%/2%		<0.0001	≥1 class improvement	59%
Six-minute walking test	332 ± 117 m	388 ± 135 m	47 ± 87 m increase	0.004	≥60 m increase	44%

LVESV: left ventricular end-systolic volume; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; CRT: cardiac resynchronization therapy.
**P*-value from repeated-measures linear or multinomial regression model.

JM Morgan et al., European Heart Journal (2016) 37, 2118–2127

ALSYNC trial – main results

Table 3 **Echocardiographic indices and clinical outcomes**

	Baseline (*n* = 118)	6 months (*n* = 105)	Change	*P*-value*	Response definition	Response rate for all patients (*n* = 118)	Response rate for non-responders with prior CRT (*n* = 31)
LVESV	149 ± 79 mL	121 ± 74 mL	29 ± 60 mL reduction	<0.0001	≥15% relative reduction	55%	47%
					≥30% relative reduction	33%	5%
LVEF	29 ± 10%	36 ± 12%	7 ± 10% increase	<0.0001	≥5% absolute increase	64%	61%
Mitral regurgitation	Moderate/ severe: 41%	Moderate/ severe: 30%		0.035	≥1 class improvement	33%	43%
NYHA class	I/II/III/IV: 3%/ 20%/69%/7%	I/II/III/IV: 19%/ 51%/28%/2%		<0.0001	≥1 class improvement	59%	52%
Six-minute walking test	332 ± 117 m	388 ± 135 m	47 ± 87 m increase	0.004	≥60 m increase	44%	42%

LVESV: left ventricular end-systolic volume; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; CRT: cardiac resynchronization therapy.
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NYH	ement	59%	52%
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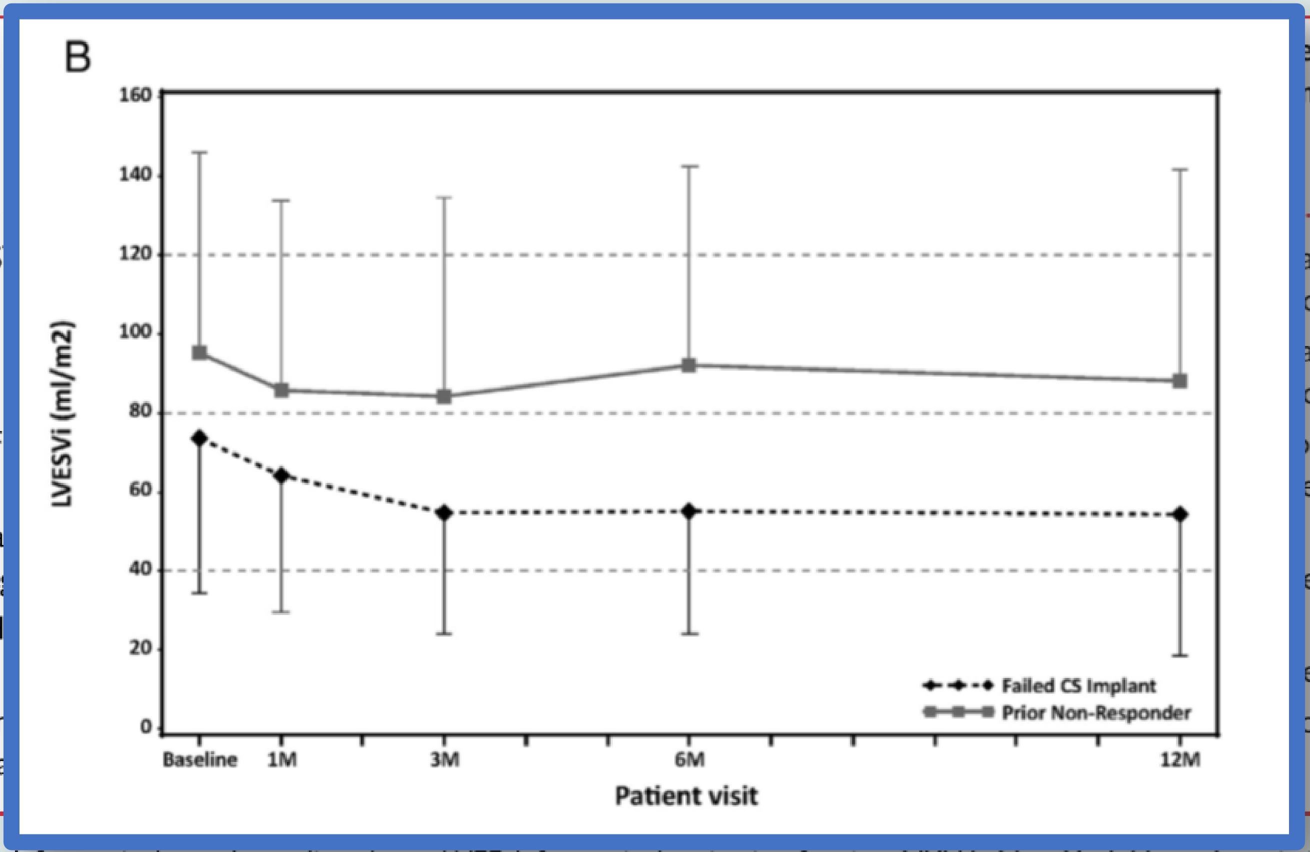

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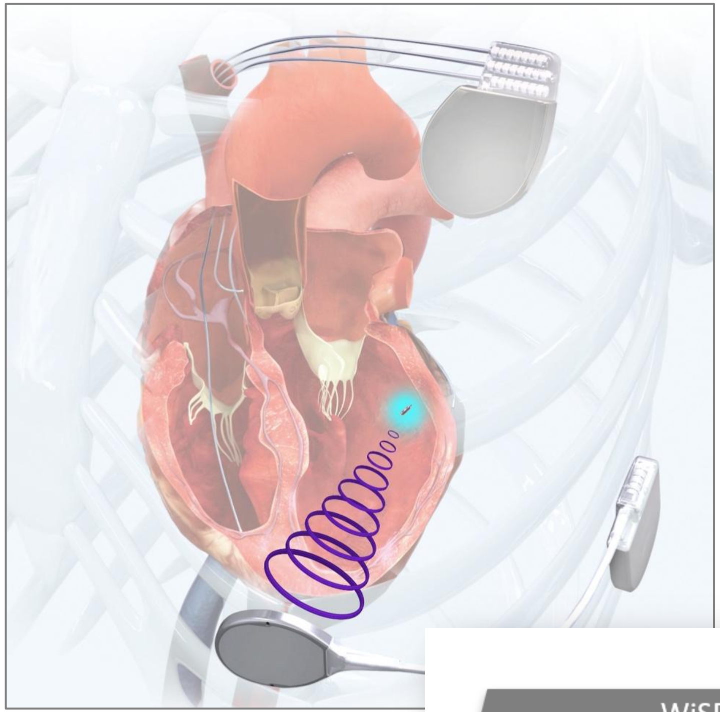
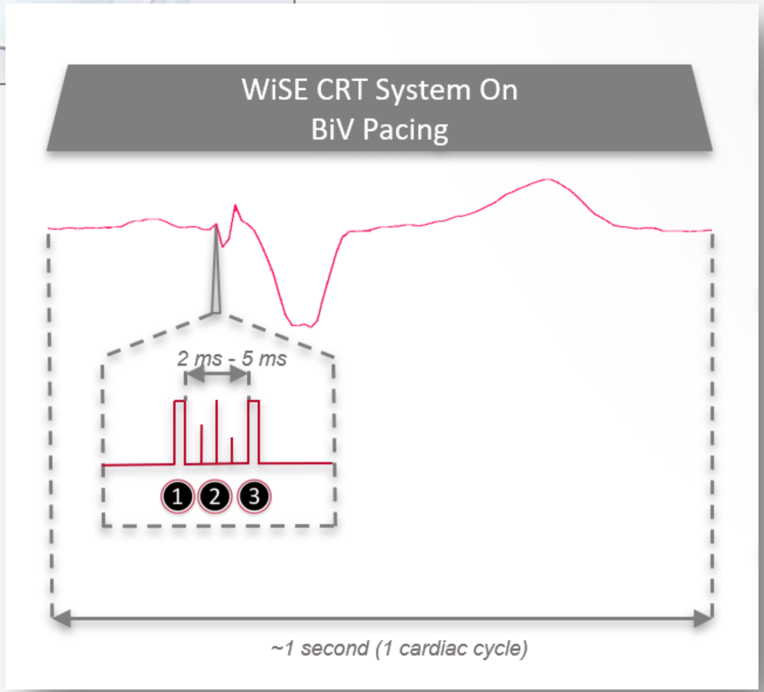
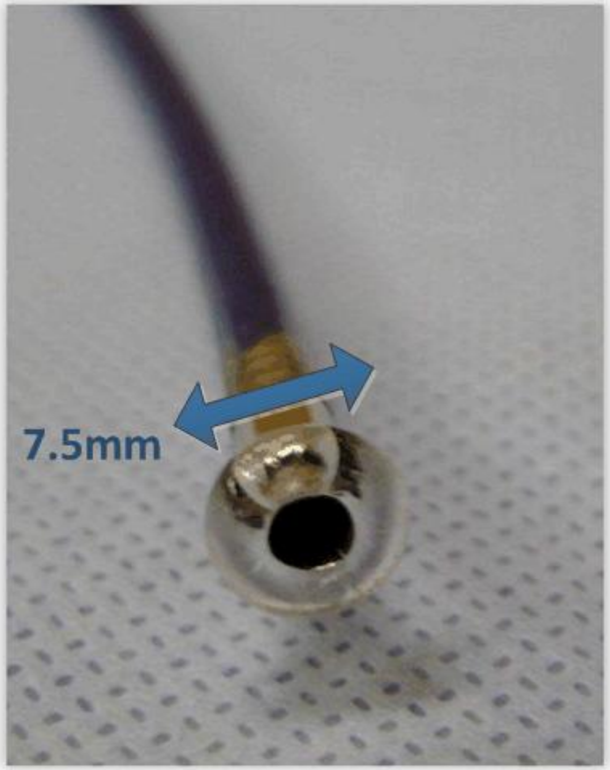
How it works

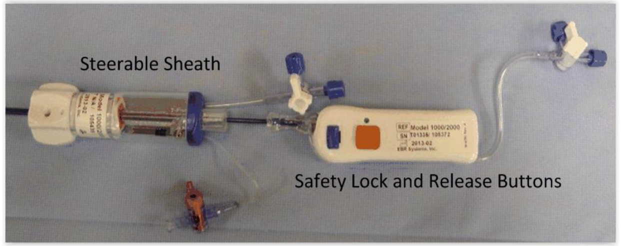




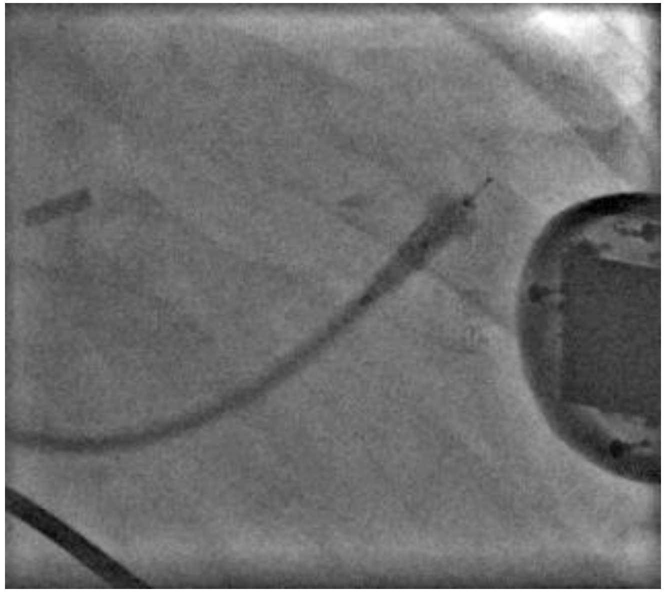
1. Detect Co-implant RV output
   - Pacemaker, ICD, or CRT
   - Pulse-width measured to discriminate RV vs. RA
2. Locate/Target *Electrode – "search"*
   - *16 µs ultrasound pulses*
   - *sensed amplitude* response discriminates position
3. Send pacing energy
   - Programmable PW 0.1-2.0ms and Transmit level
   - Typically 3ms after RV pulse, max ~12ms

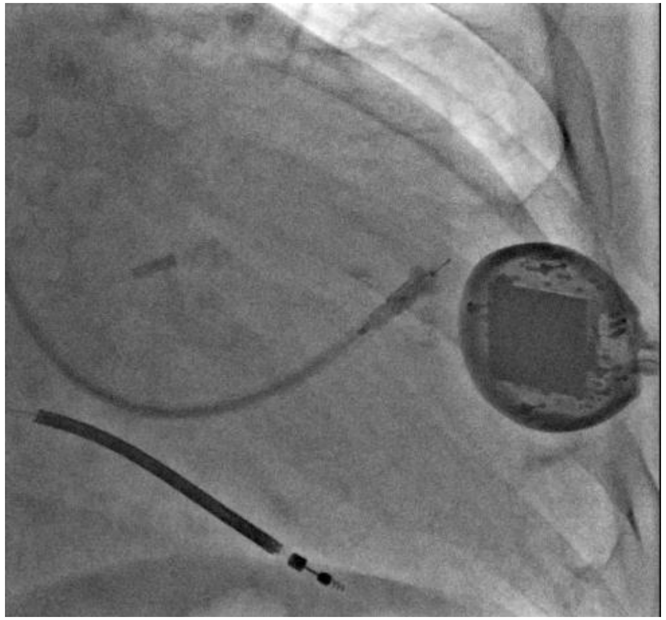
Electrode delivery





- 12 Fr steerable Sheath with a balloon "bumper" to minimize trauma to endocardium
- 8Fr delivery catheter for electrode
- Electrical connection to the RE cathode for site evaluation (local EGM, test capture threshold using lab stimulator)
- Safety/release buttons detach Electrode



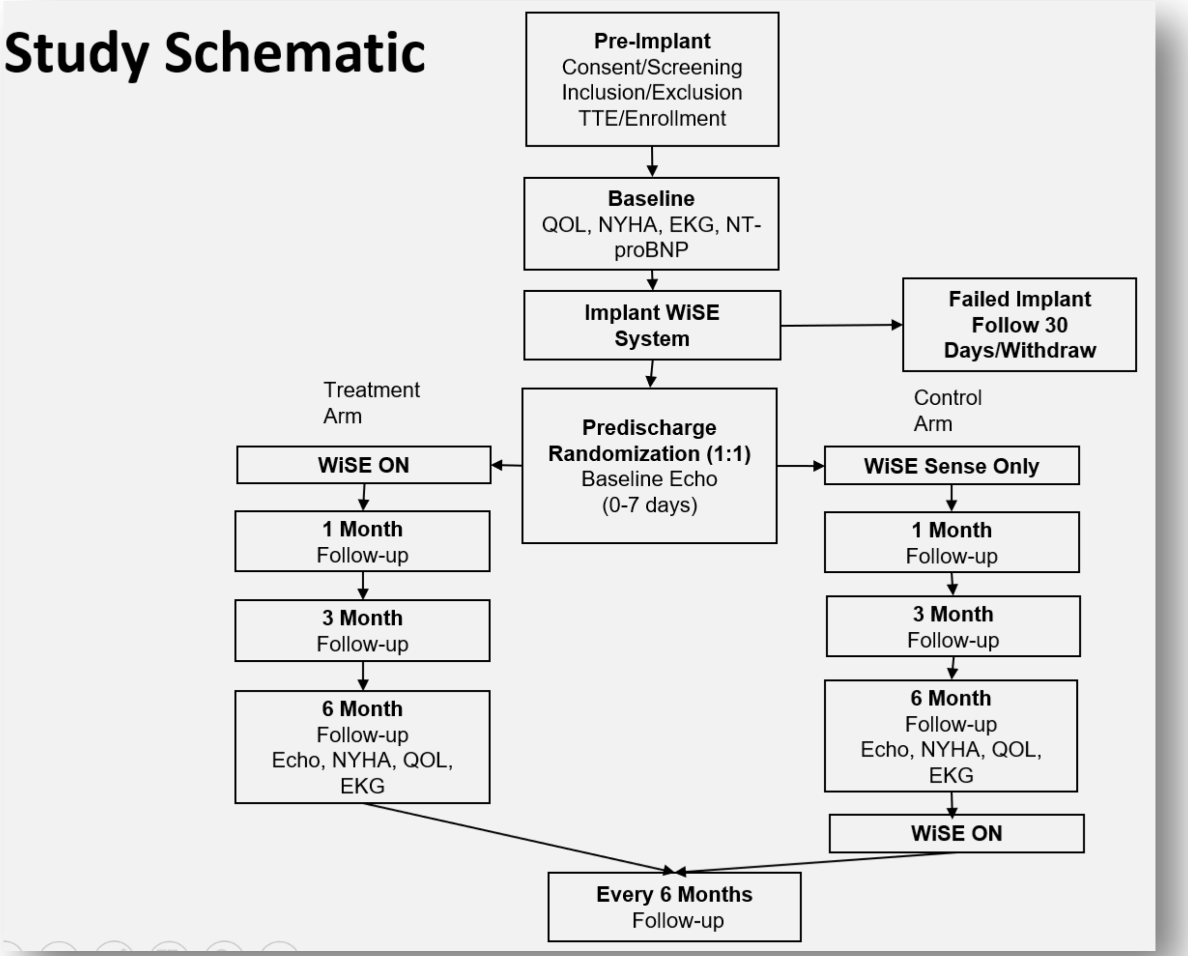


Disclosure

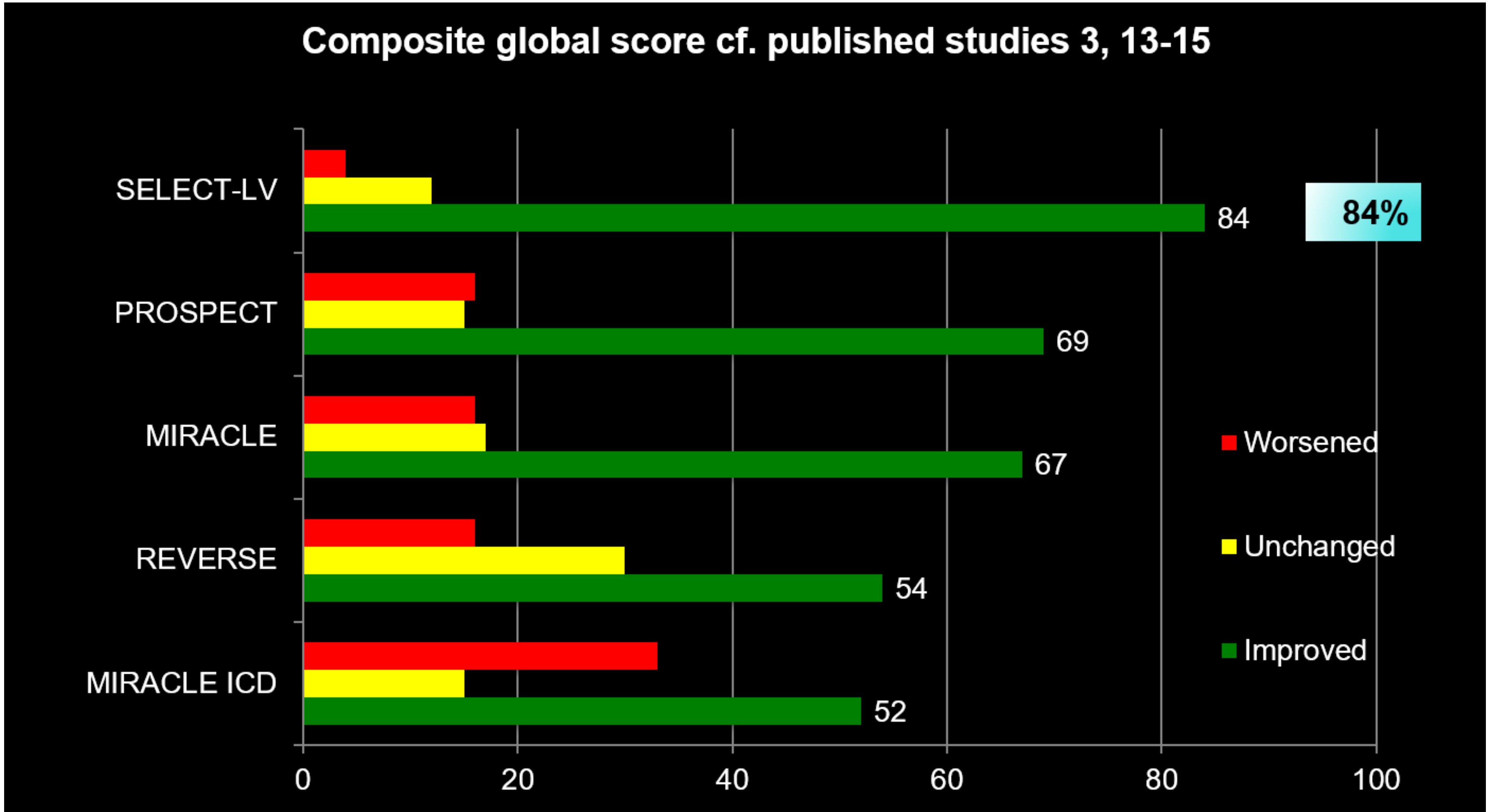
- nothing

SOLVE CRT Study

- **Randomized Control Trial**
  - Design, 350 patients, 45 Centers
    - Prospective, two-arm, randomized, double blind, multi-center trial
    - All patients get WiSE, Randomized 1:1 Sense Mode vs WiSE ON
  - Purpose
    - To demonstrate the safety and effectiveness of the WiSE system in Non-CRT Responders



SELECT-LV pts reaching 12m: Clinical Composite Score



3. Leon AR et al., JACC 2005; 46: 2348-2356.
13. Chung E et al., Circulation 2008; 117: 2608-2616.
14. Linde C et al., JACC 2008; 52: 1834-1843.
15. Young JB et al., JAMA 2003; 289: 2685-2694.