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Novel device therapies: "Subcutaneous, Leadless, and his Bundle and more"

Paul A. Friedman, MD
Mayo Clinic
Rochester, MN USA

Evolution of Pacemakers

CENTRAL ILLUSTRATION An Overview of the History of Cardiac Pacing

Paradigm Shifts in Cardiac Pacemakers

1950s
AC-powered pacemakers tethered to an extension cord (Furman)

1950s
Battery-powered transistorized "wearable" pacemakers (Lillehei/Bakken)

1958
First fully implantable pacemaker (Elmqvist/ Senning)

2015
Implantable pacemaker—basic system had not evolved significantly

Fundamental Paradigm Hasn't changed for 50 years! Now many new approaches

Mulpuru…Friedman JACC 2017

Leads and Tricuspid Regurgitation

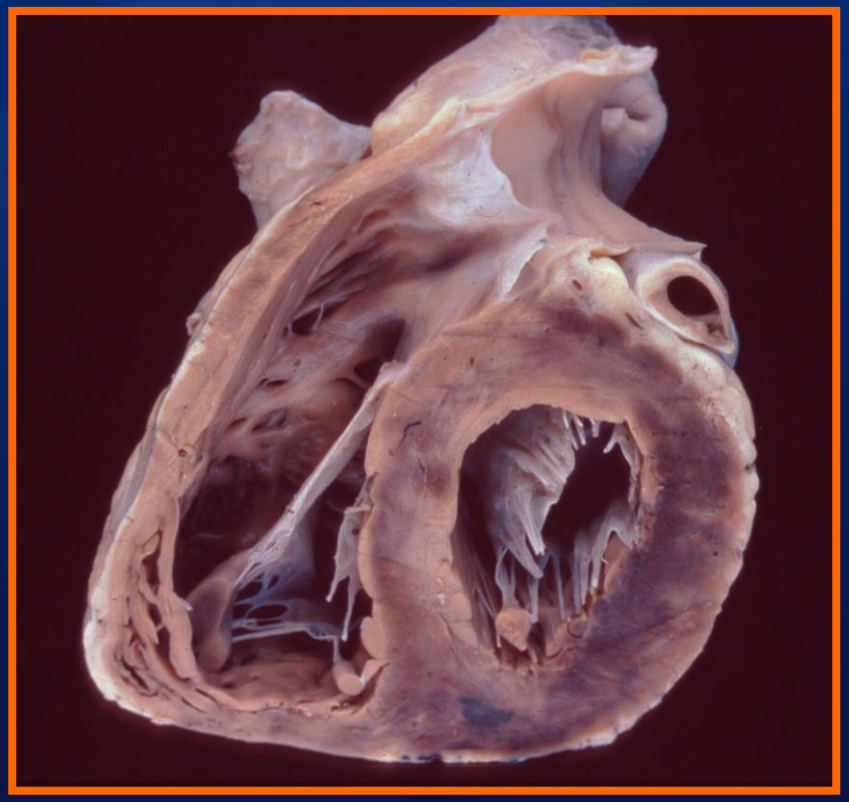

Photo courtesy of W. Edwards, MD
Dept. Pathology, Mayo Clinic

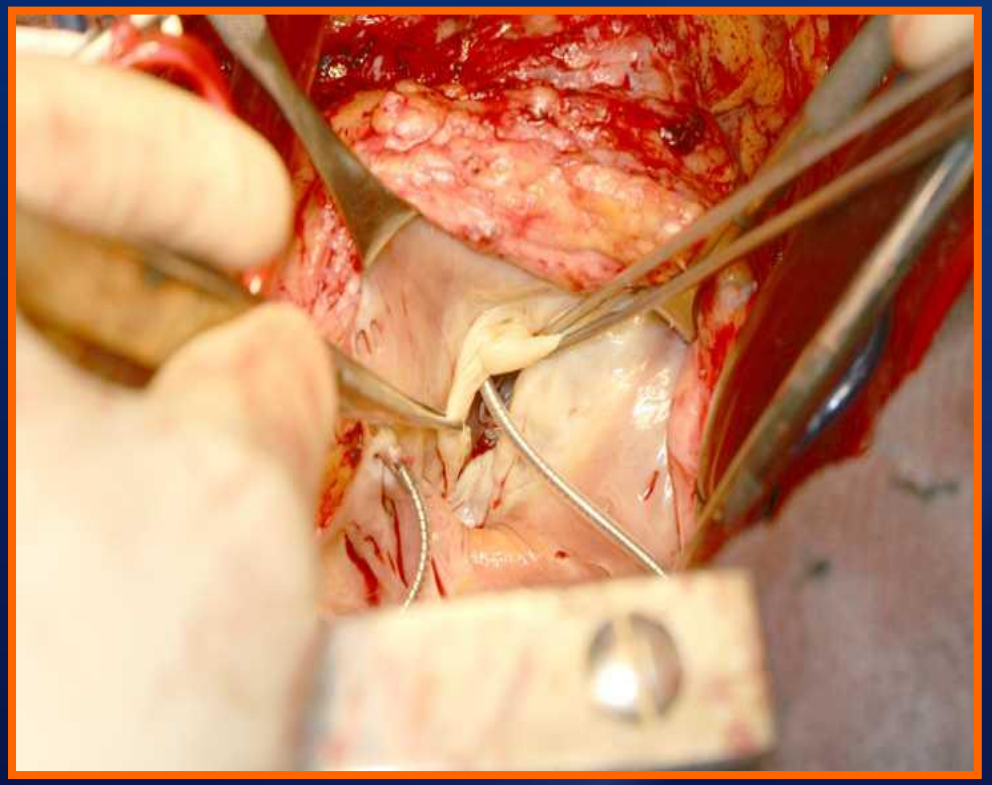

Photo courtesy of Dr Sundt
Mayo Clinic, CV Surgery

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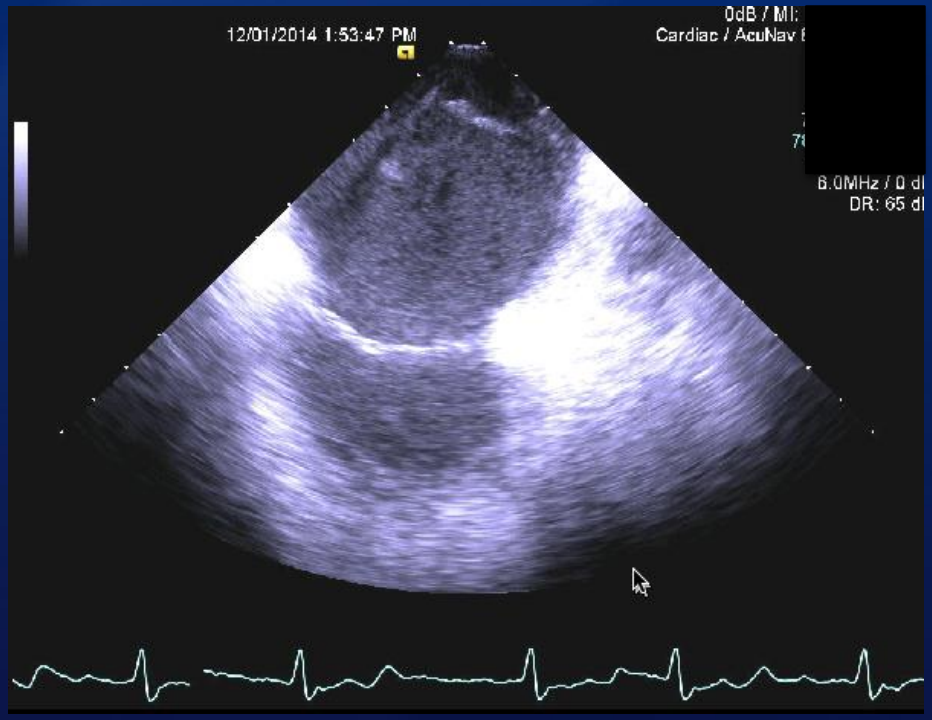
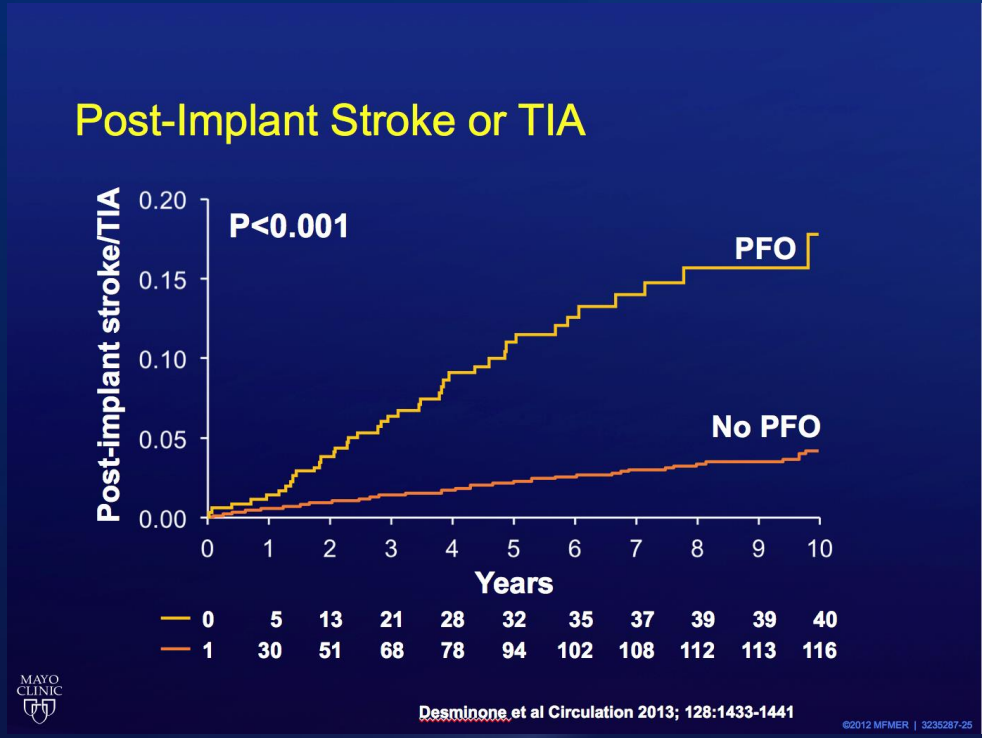
Stroke Risk with PFO and Transvenous Leads





Mobile thrombi: 30% leads on intracardiac imaging

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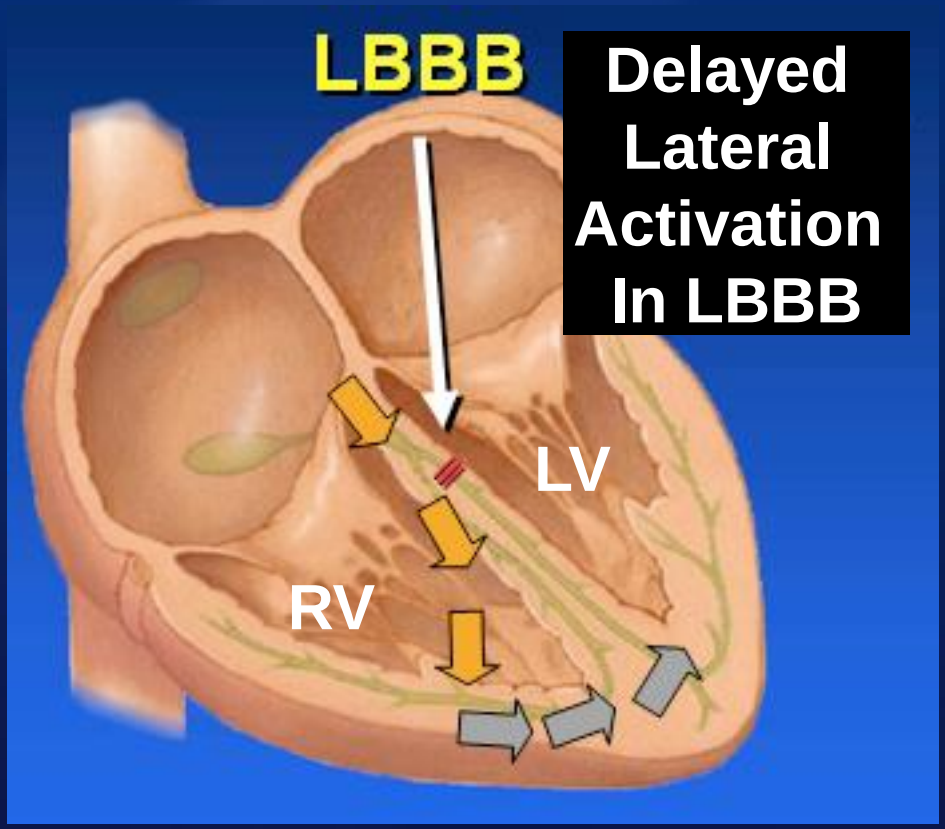
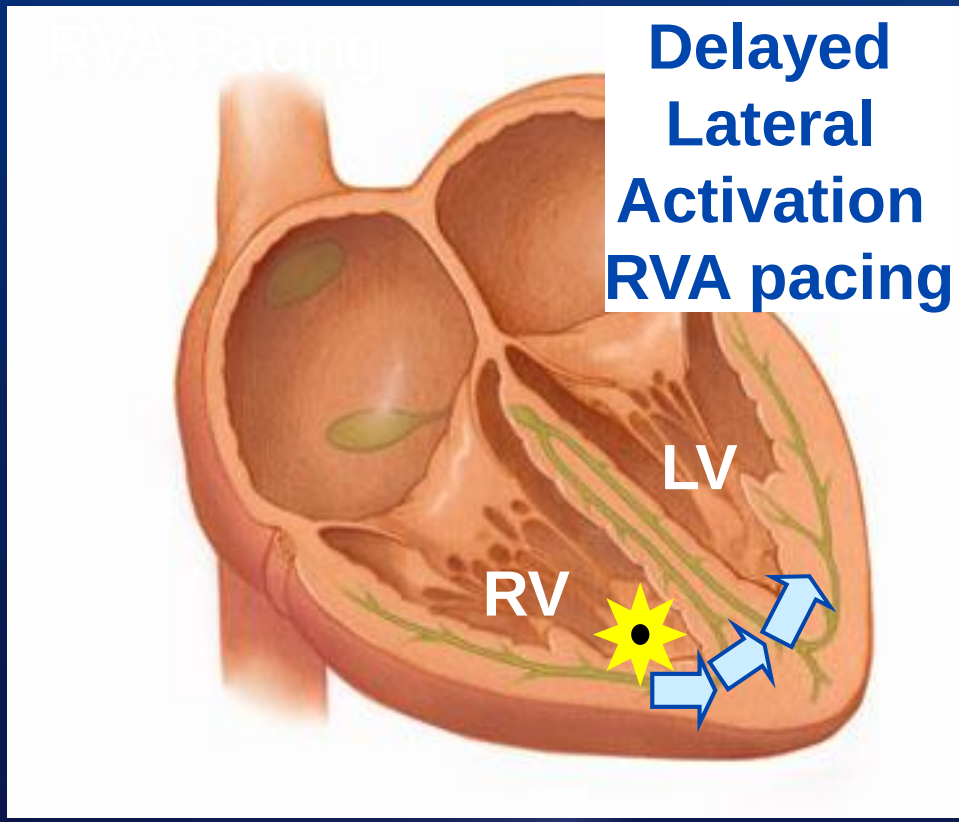
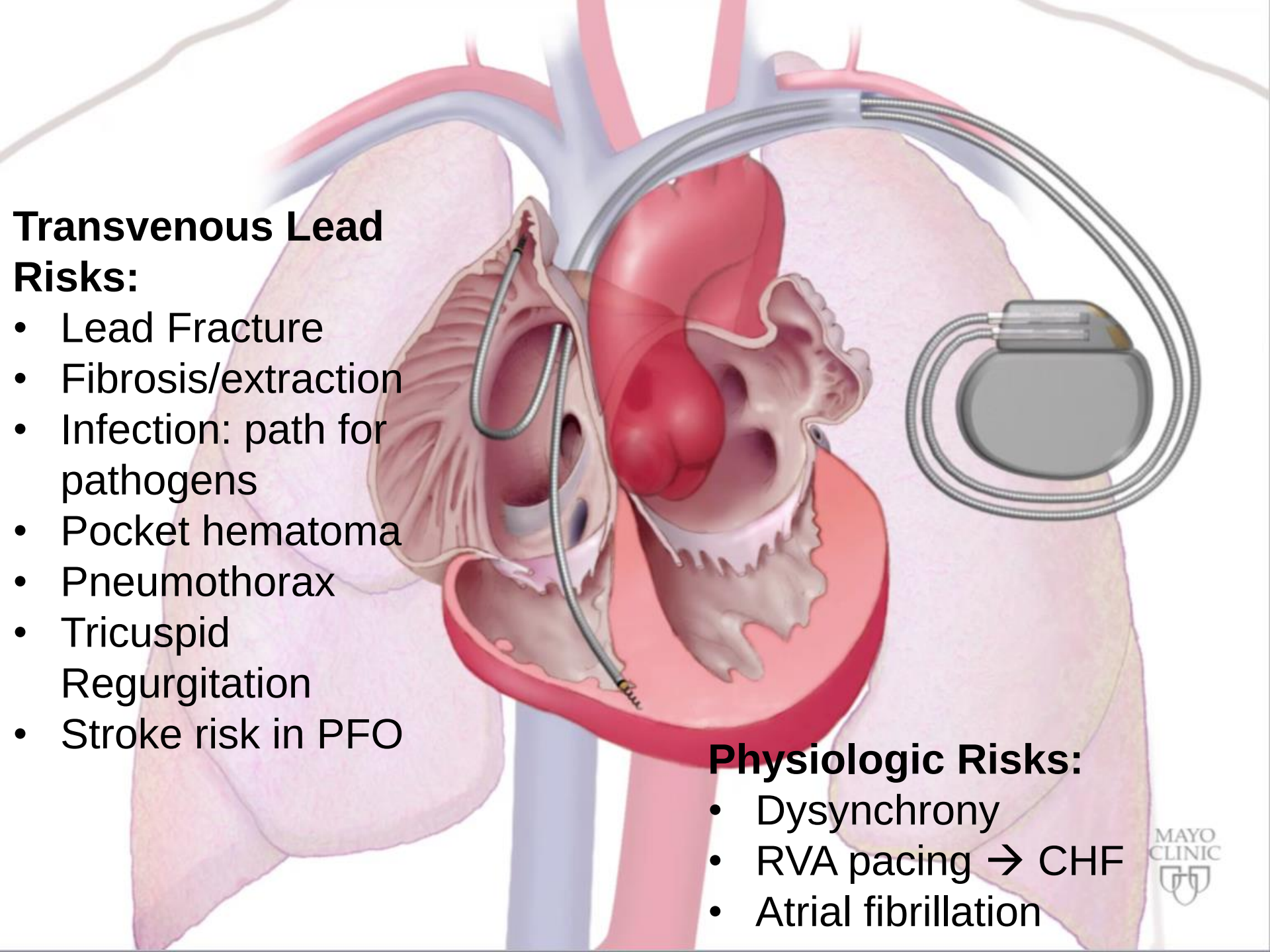
Right Ventricular Apical Pacing: Increased Mortality, Heart Failure, Hospitalizations, AF





Pacing the RV induces a LBBB pattern—that delays lateral wall activation.

DOI: 10.1016/j.jacc.2009.06.006
Indian Pacing Electrophysiol J. 2012 May-Jun; 12(3): 102–113.



Transvenous Lead Risks:

- Lead Fracture
- Fibrosis/extraction
- Infection: path for pathogens
- Pocket hematoma
- Pneumothorax
- Tricuspid Regurgitation
- Stroke risk in PFO

Physiologic Risks:

- Dysynchrony
- RVA pacing → CHF
- Atrial fibrillation

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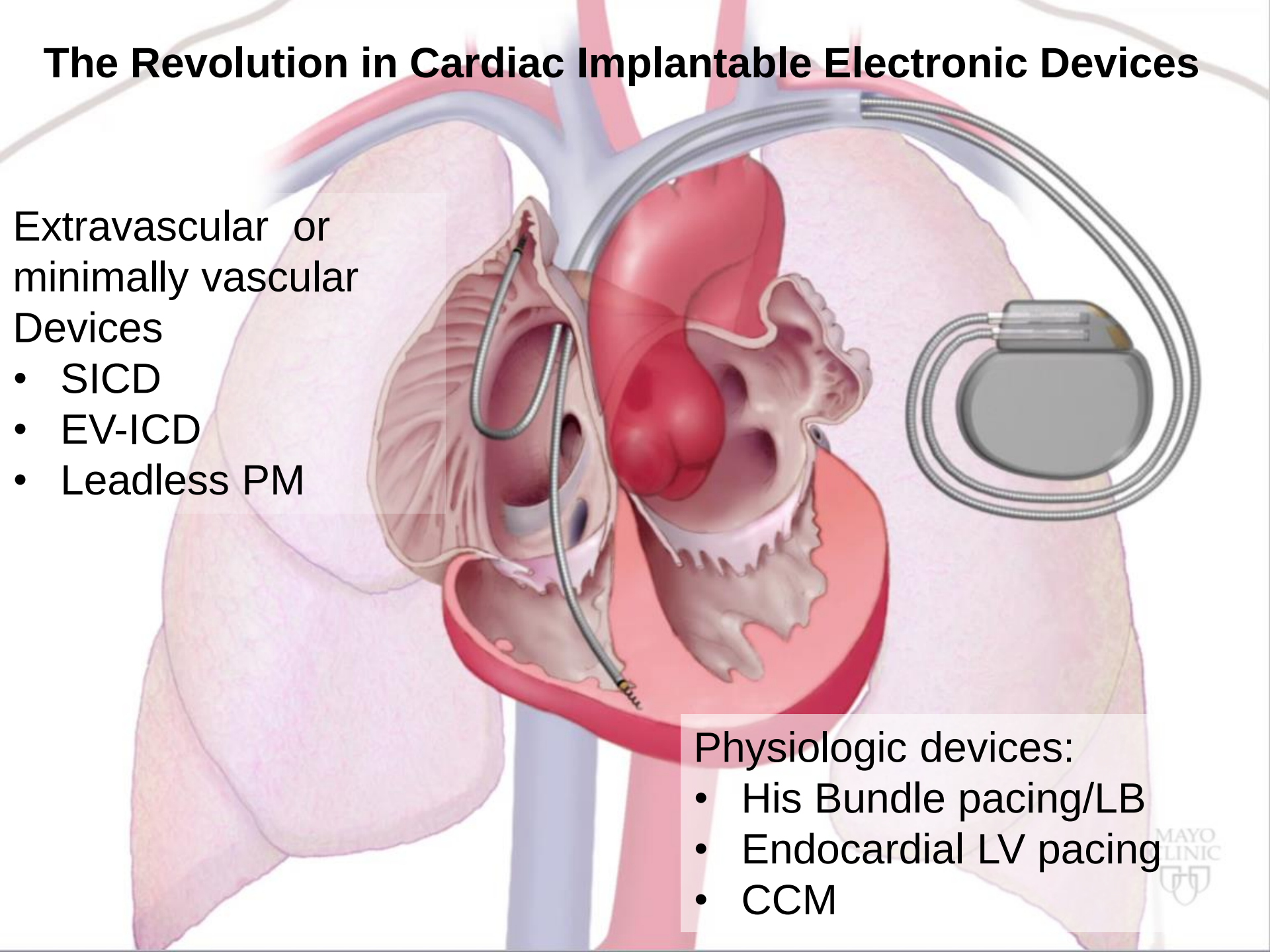
The Revolution in Cardiac Implantable Electronic Devices

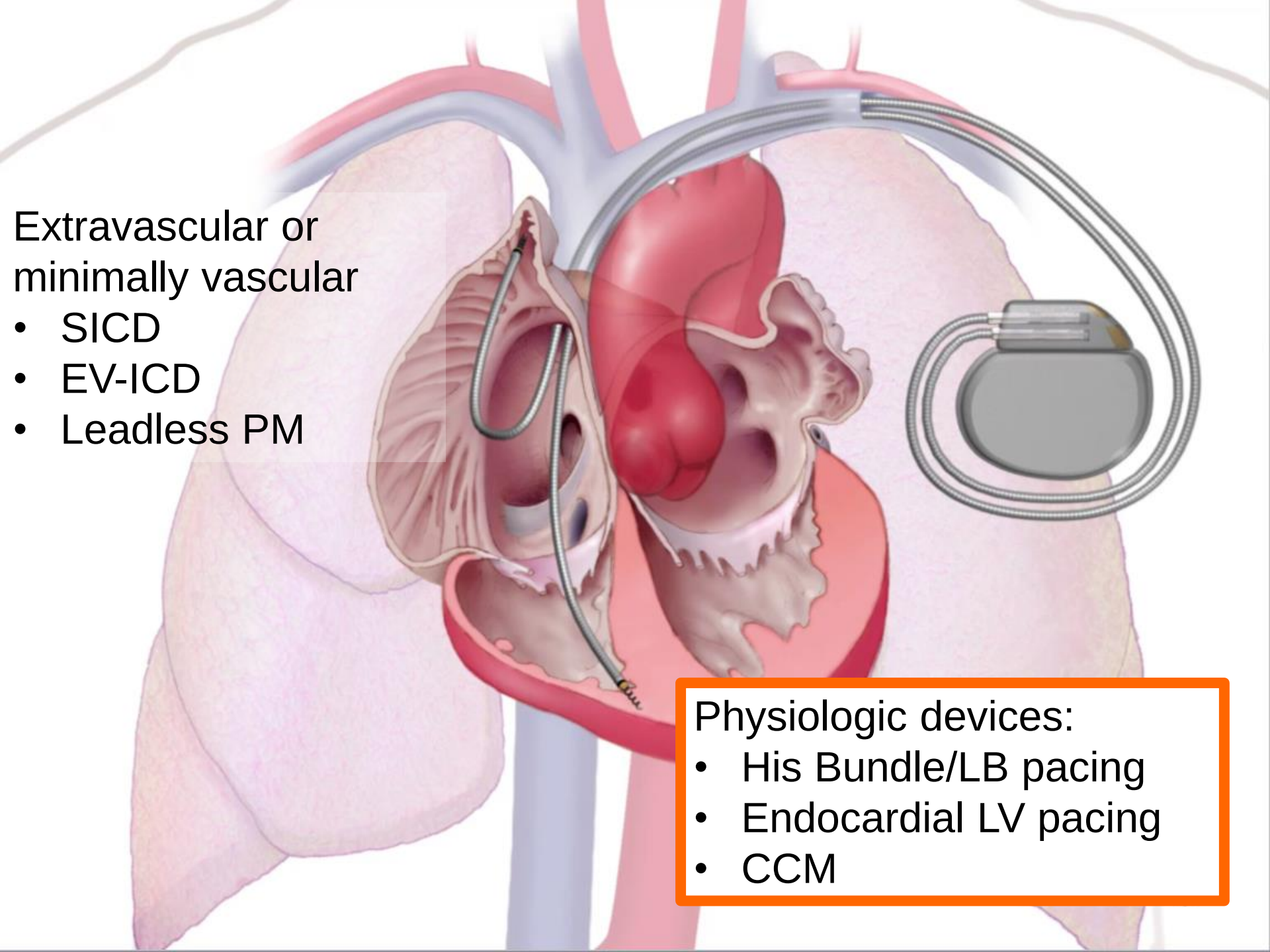


Extravascular or minimally vascular Devices

- SICD
- EV-ICD
- Leadless PM

Physiologic devices:

- His Bundle pacing/LB
- Endocardial LV pacing
- CCM



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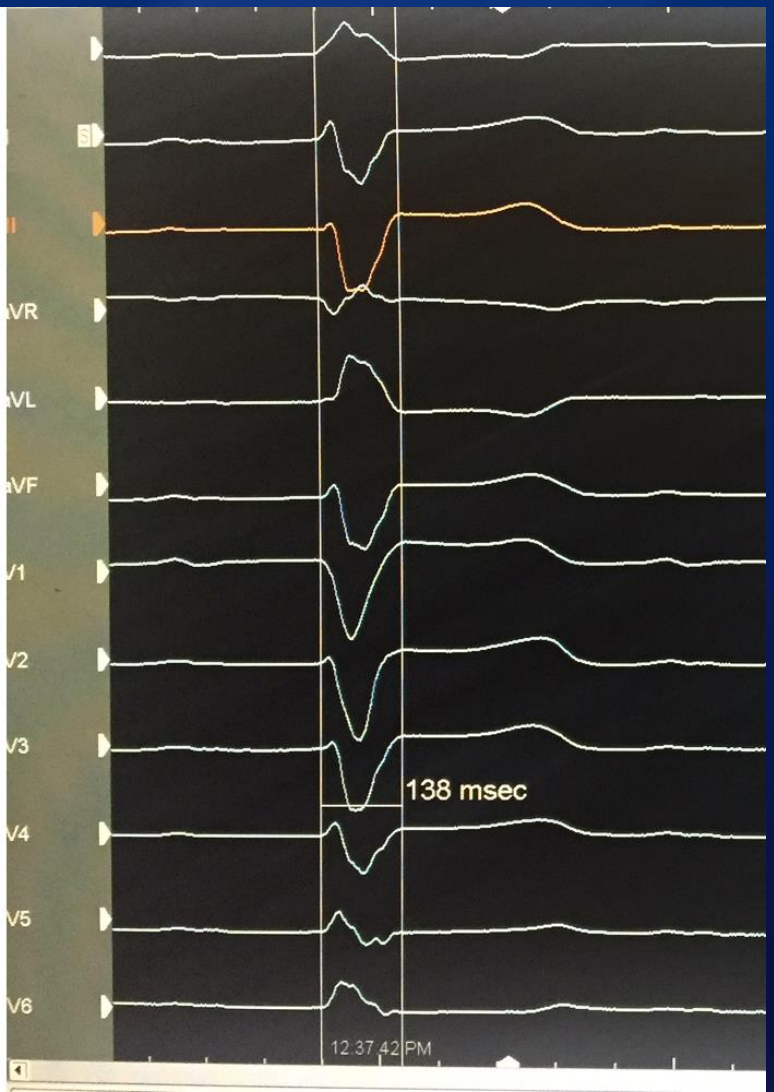
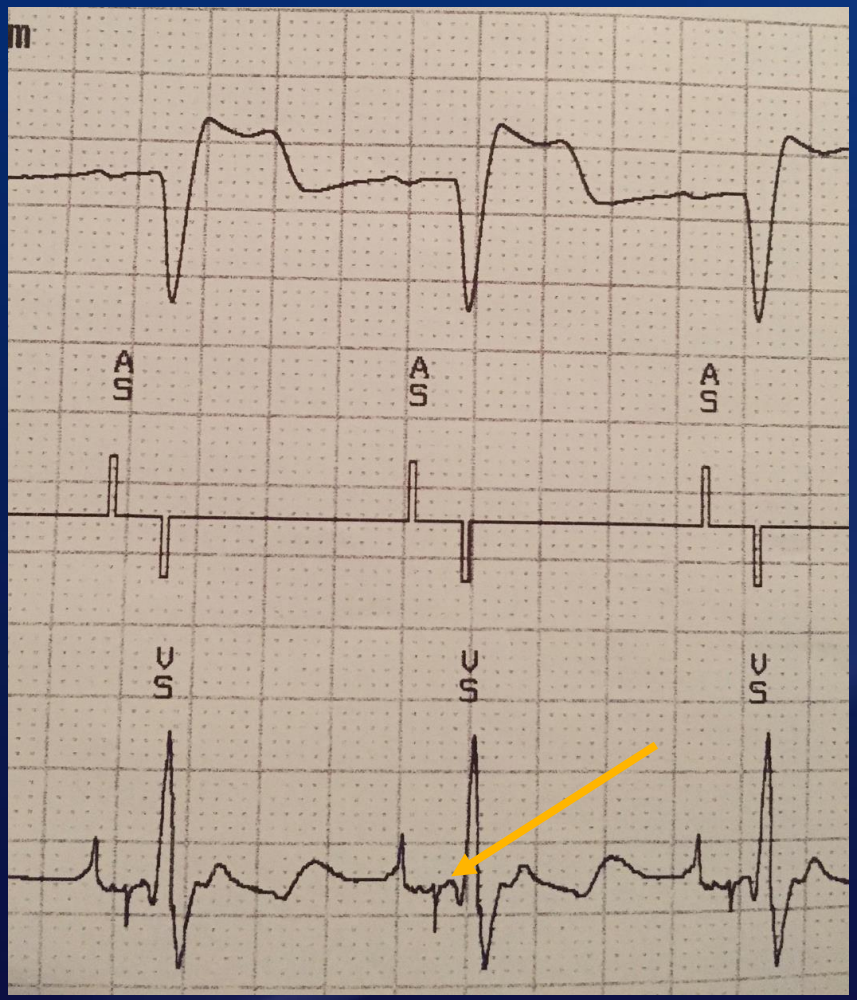
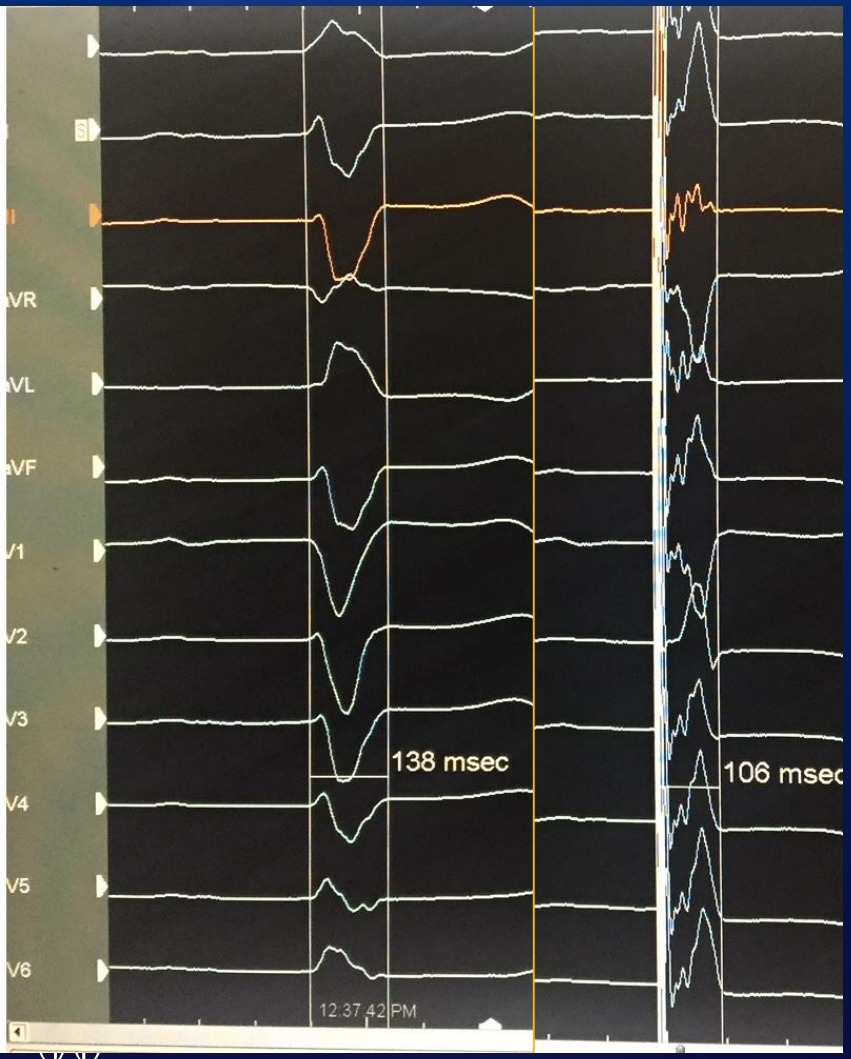
Patient with LBBB, low EF, CRT lead cannot be placed

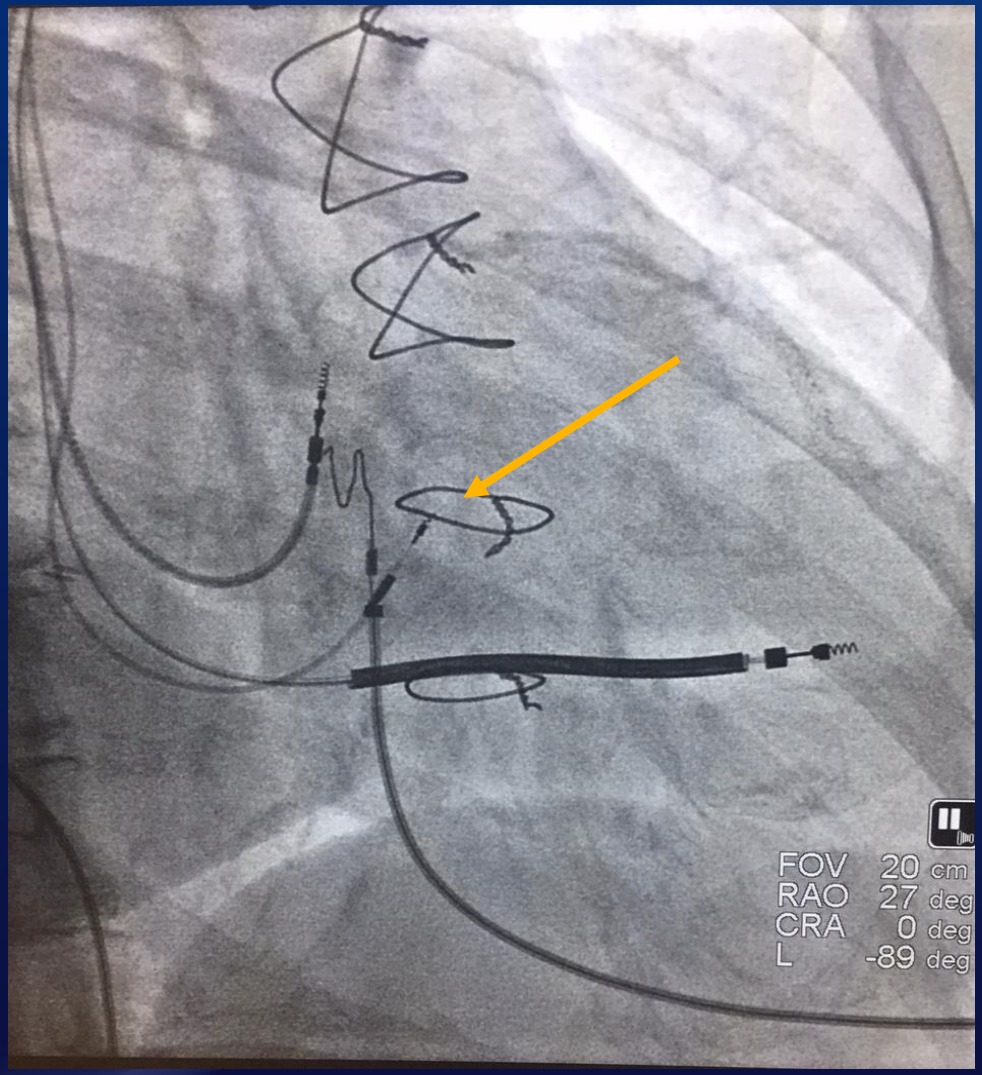




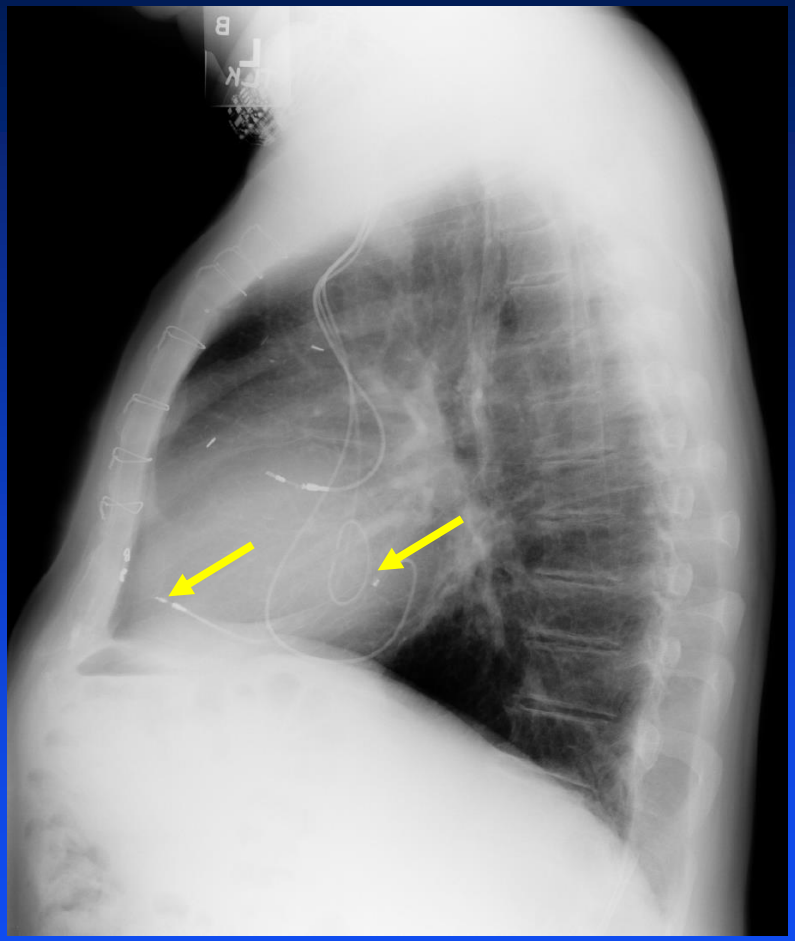
Courtesy Dr. Krishna Kancharla

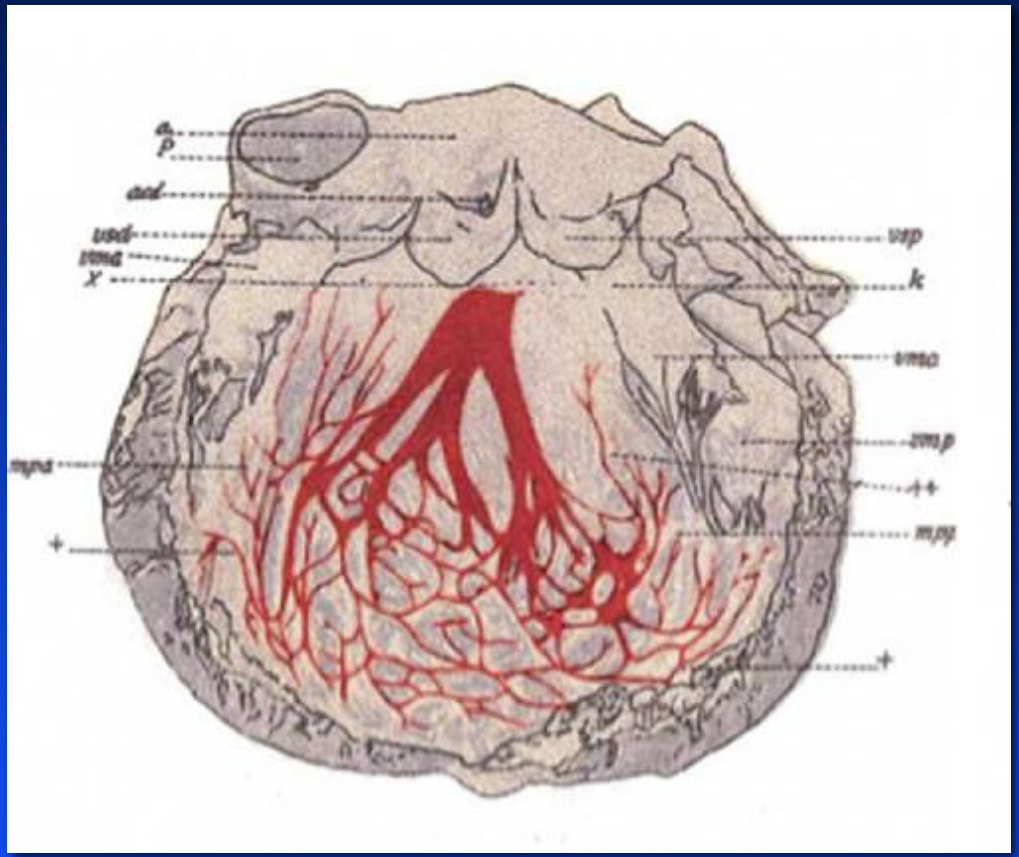
Patient with LBBB, low EF, CRT lead cannot be placed





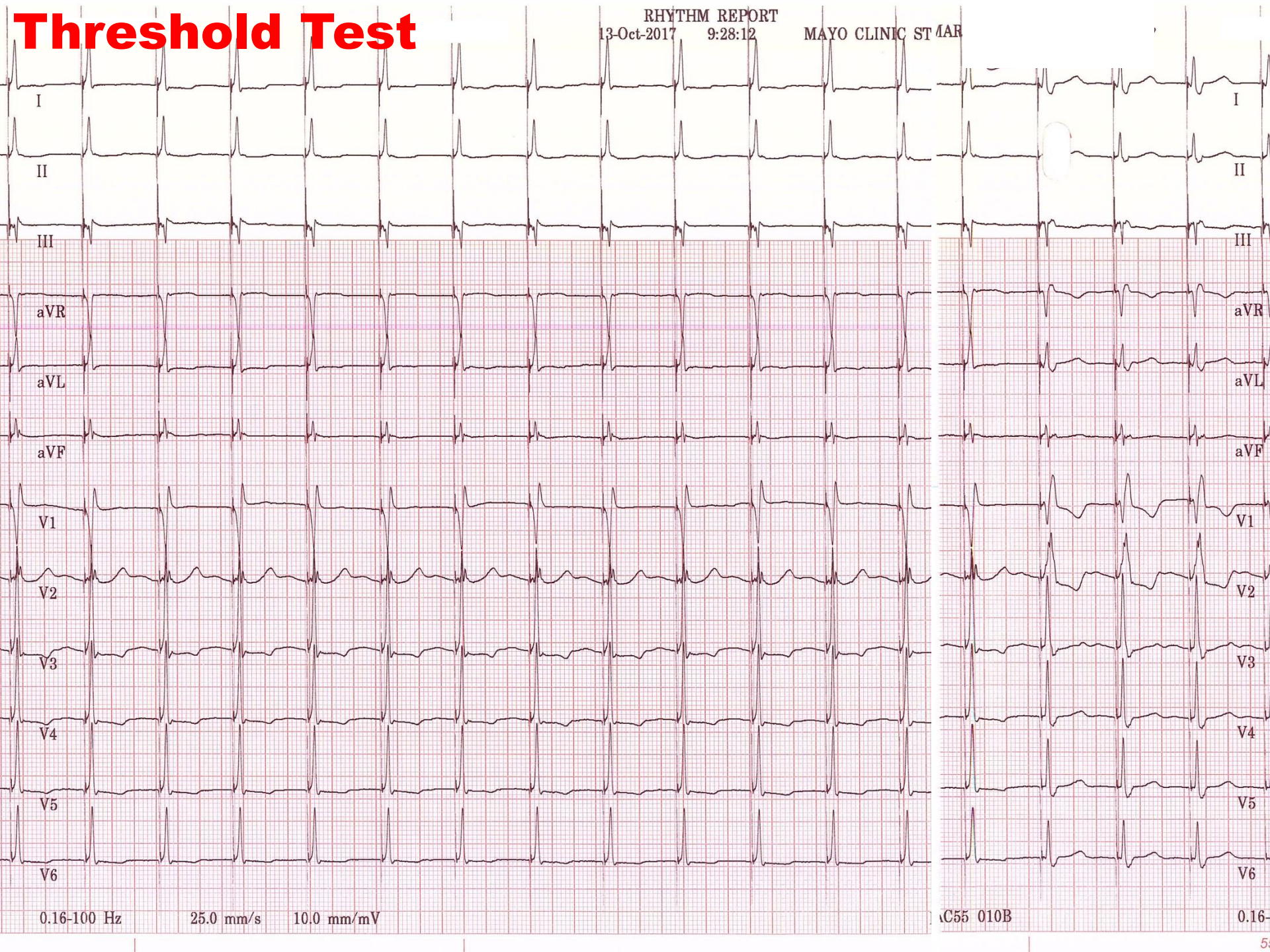
Resynchronization:
Two sites vs. Thousands





Tawara

Threshold Test



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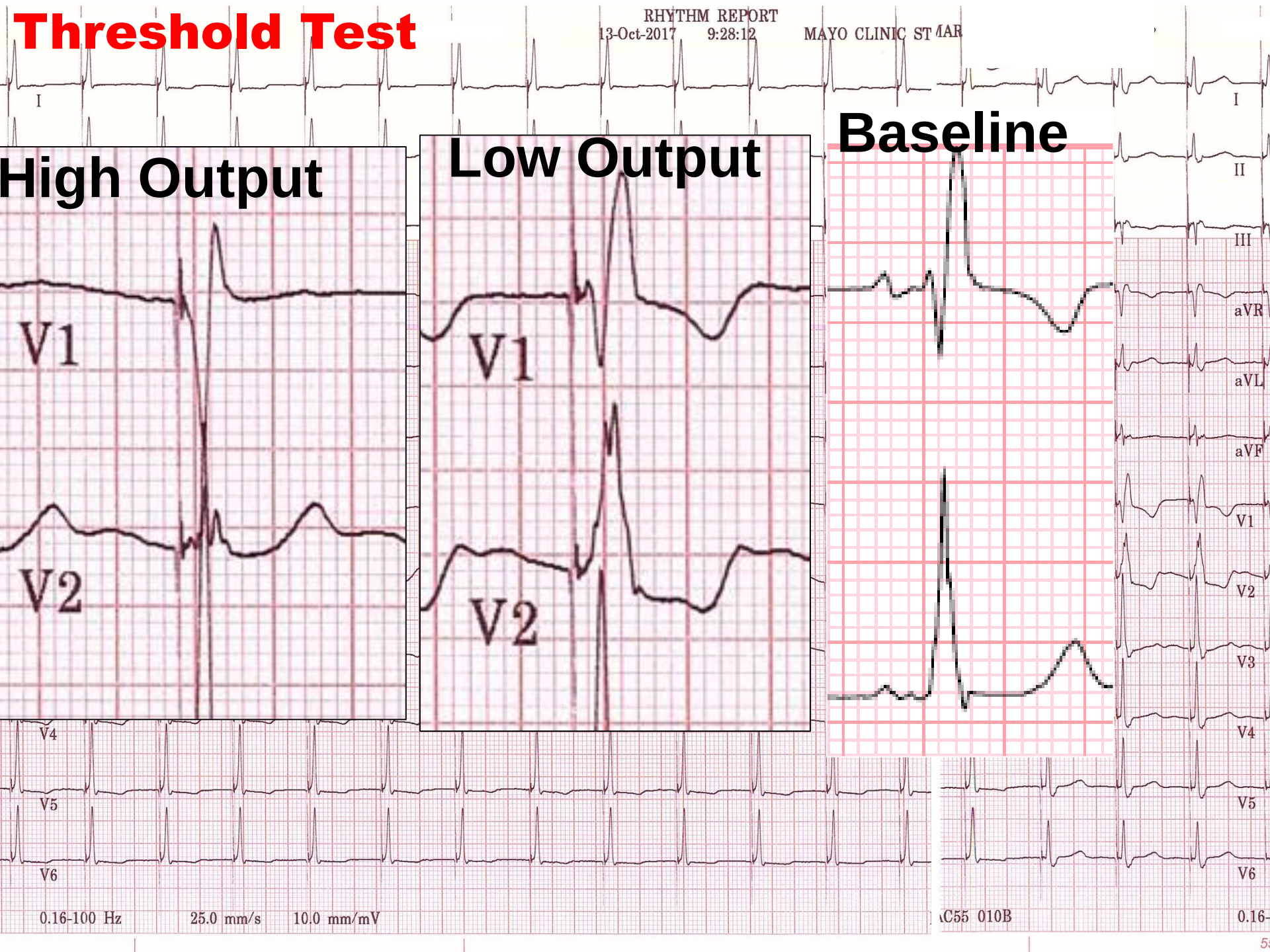
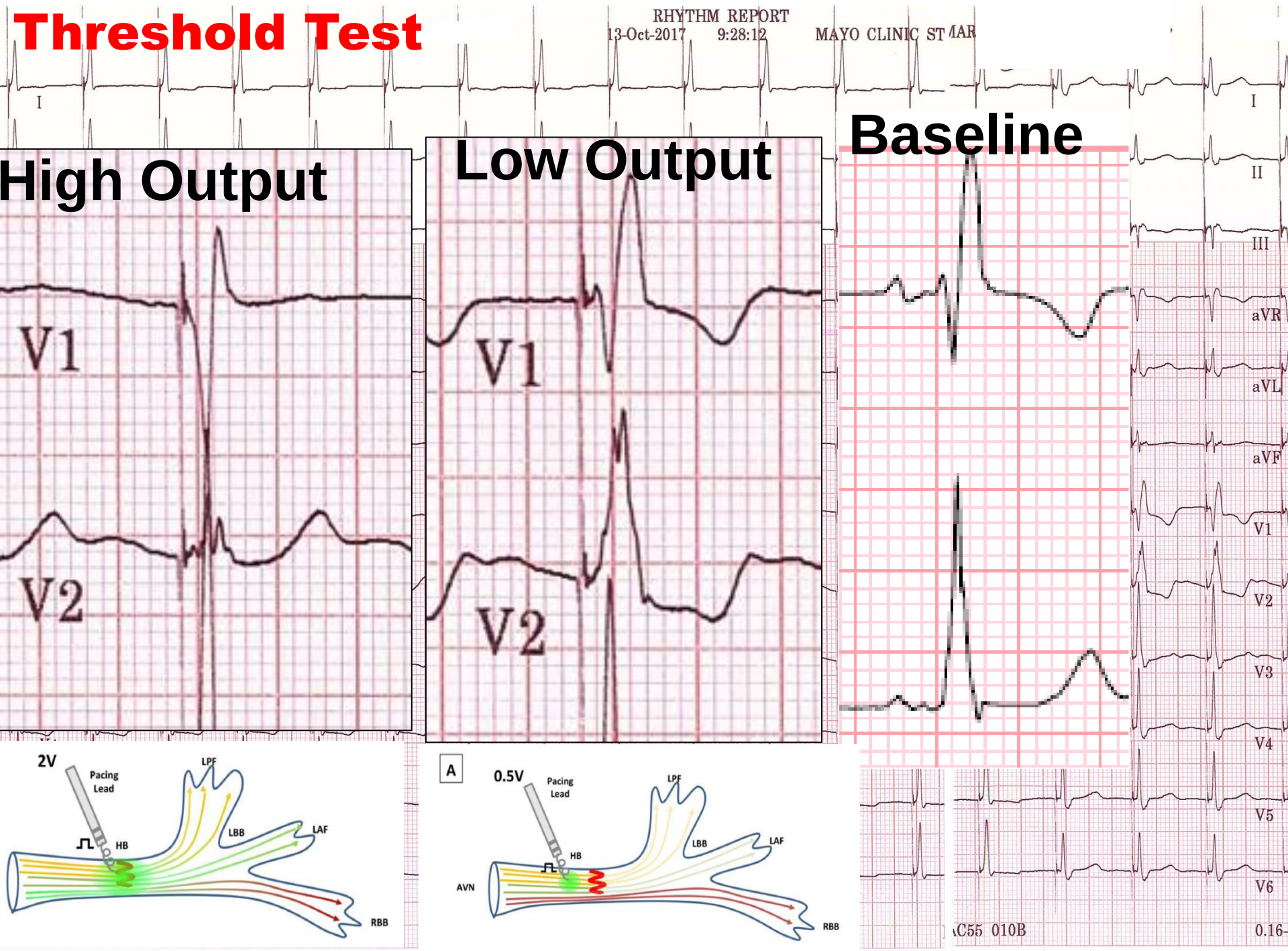
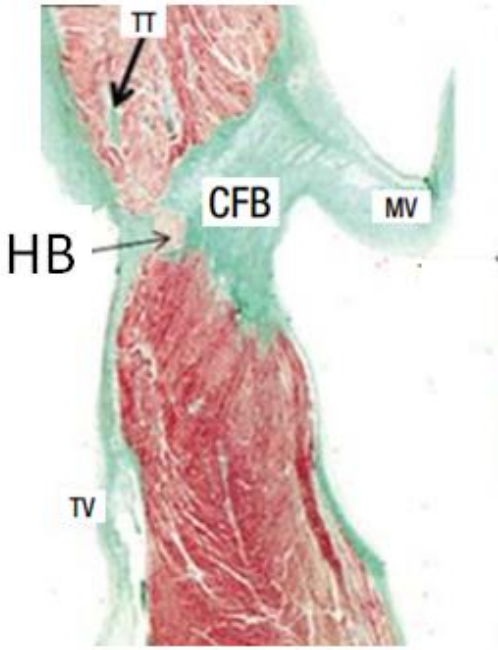


Threshold Test

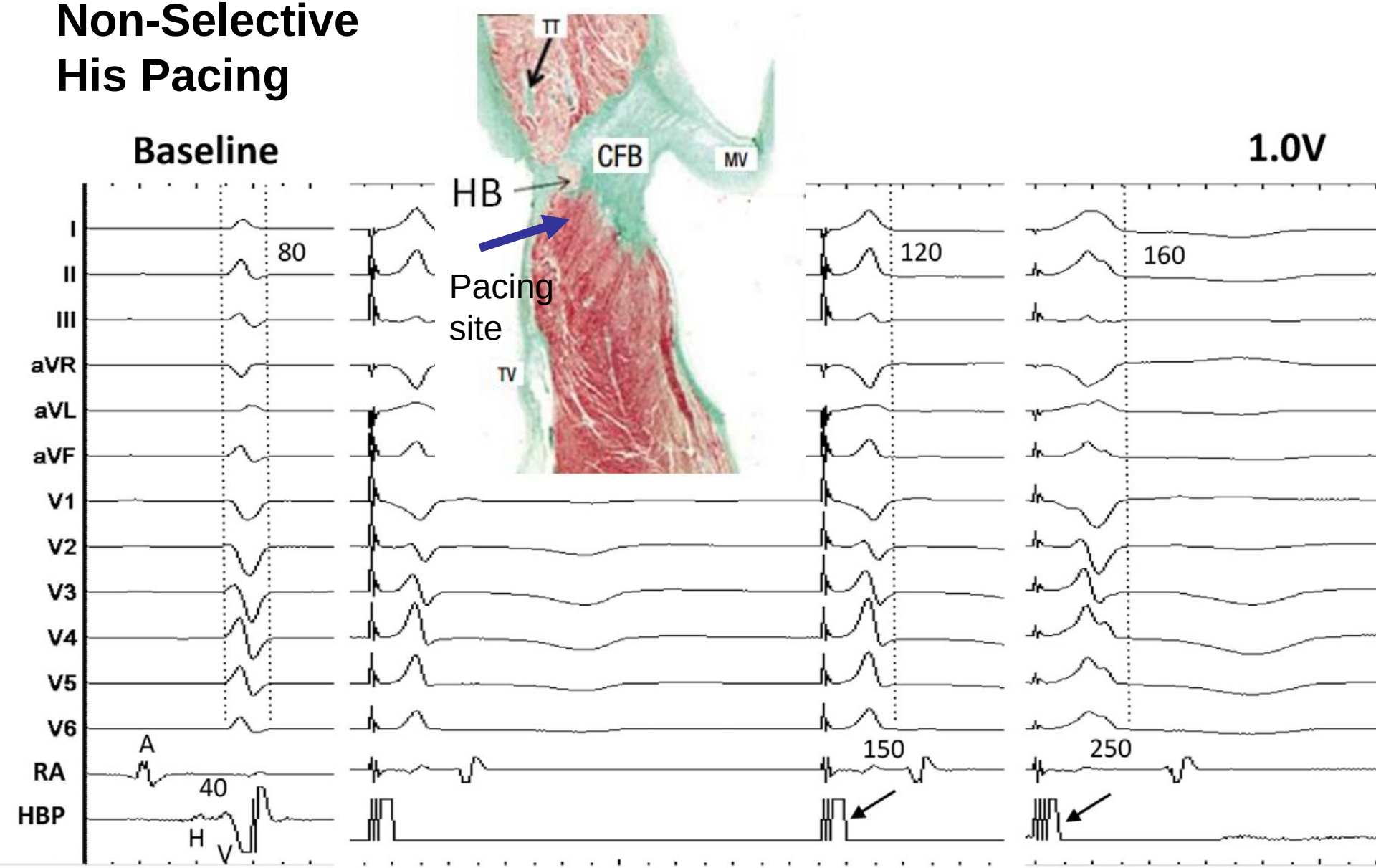


Selective His Pacing

- Stim-QRS = native His-QRS (depending on lead position and if normal HP conduction)
- Local V EGM not directly captured (S-V = H-V); difference usually < 10 msec
- QRS same as native (if nl)
- Usually: single capture threshold
  - At high output may have non-selective pacing (fusion)

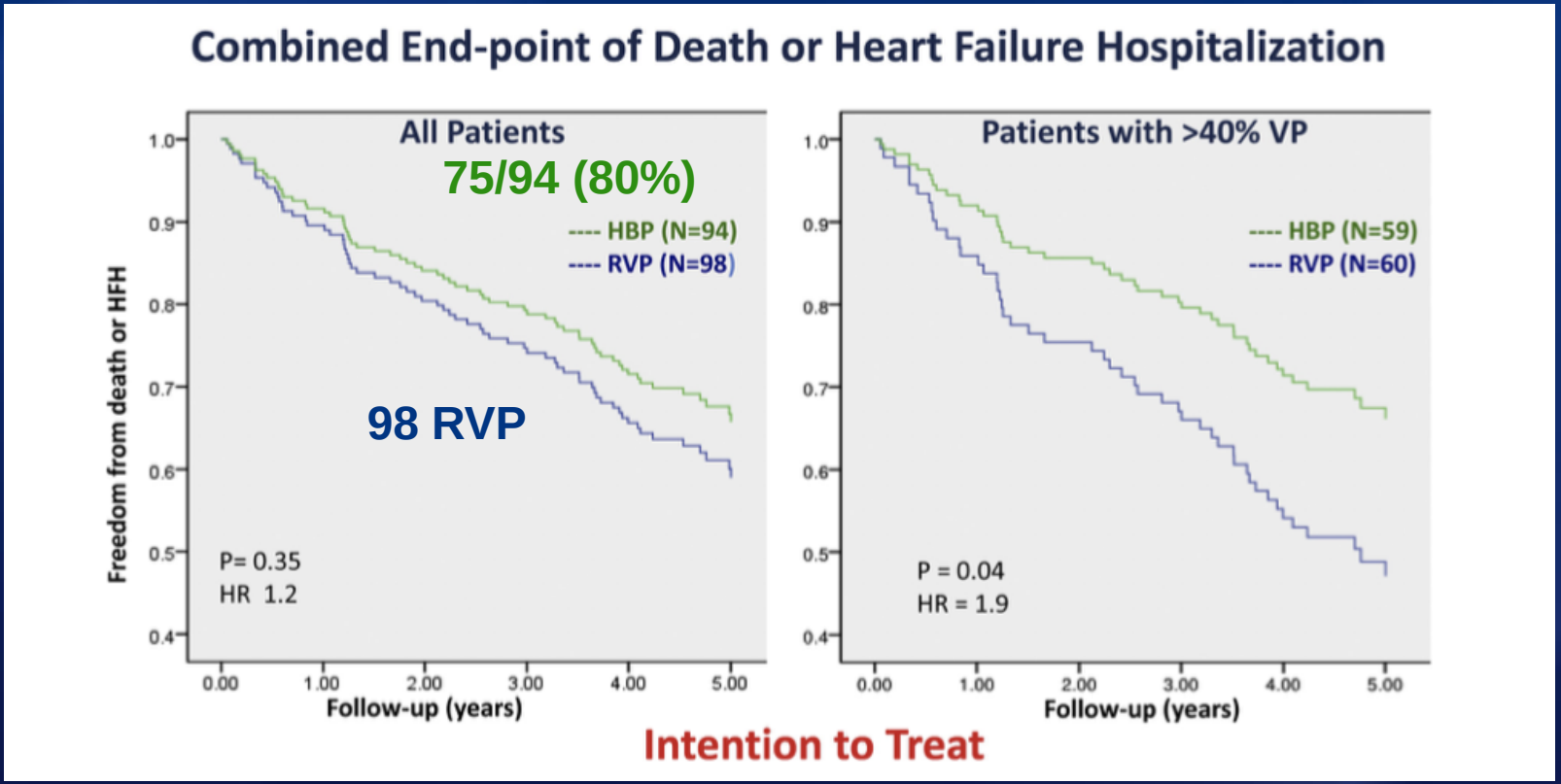


Non-Selective His Pacing



Vijayrman et al. Heart Rhythm 2018;15:460–468

RV Pacing vs. His Bundle Pacing



- Non-randomized, two different hospitals, showed promise for Long term HBP

Sharma HRJ 2015

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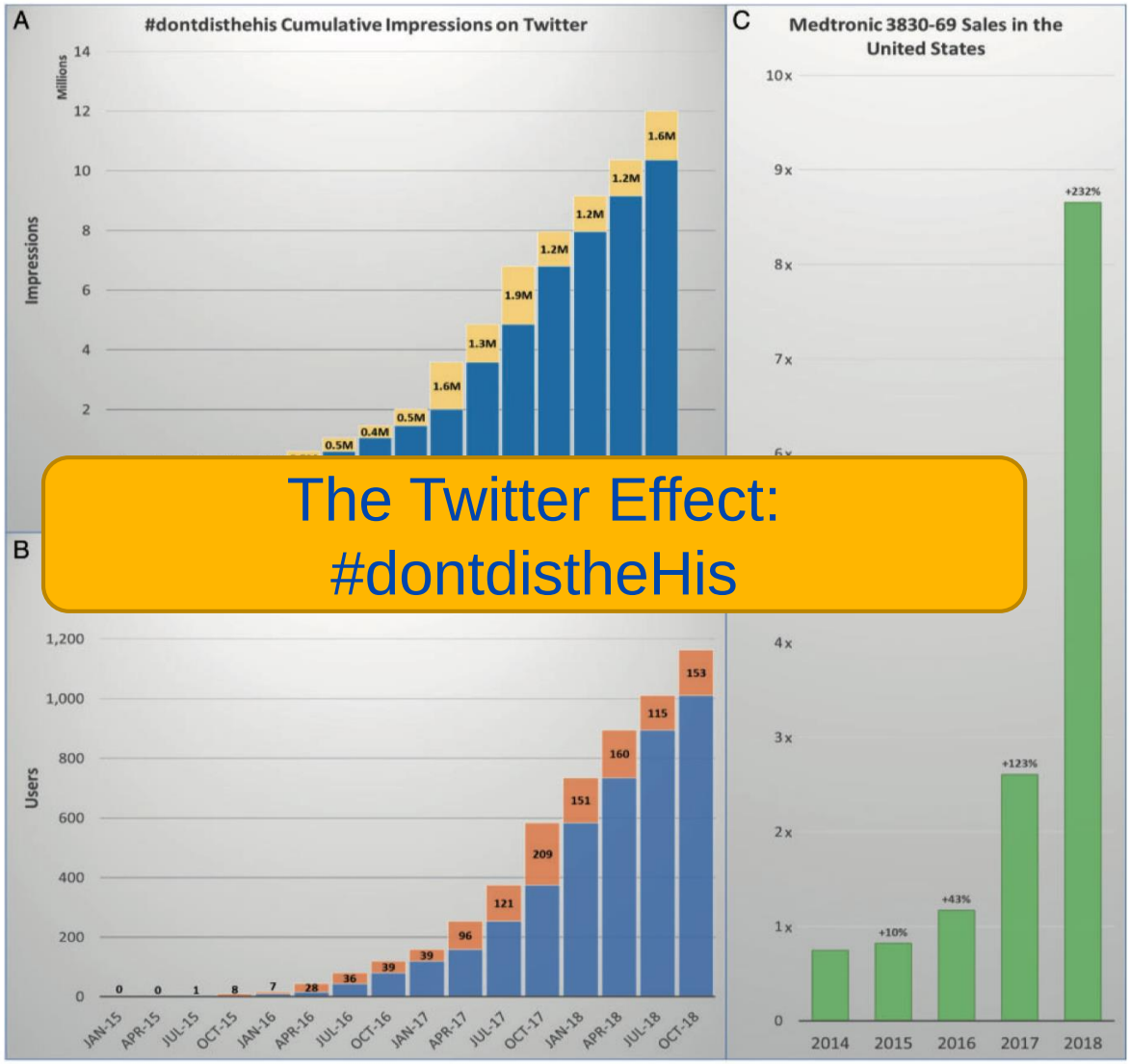
His-bundle pacing: impact of social media

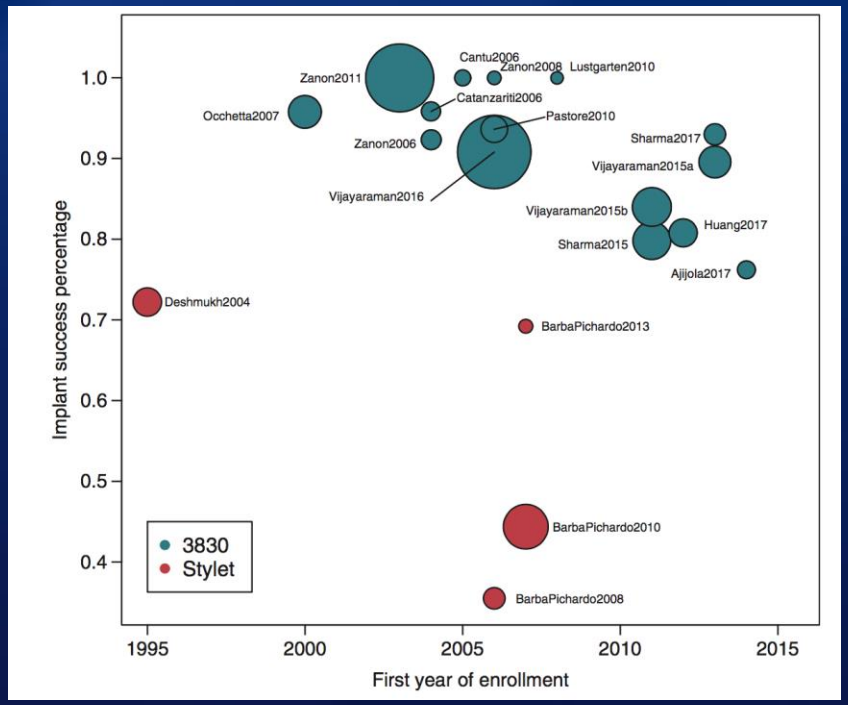
Dominik Beer[1], Gopi Dandamudi[2], John M. Mandrola[3], Paul A. Friedman[4], and Pugazhendhi Vijayaraman [1]*

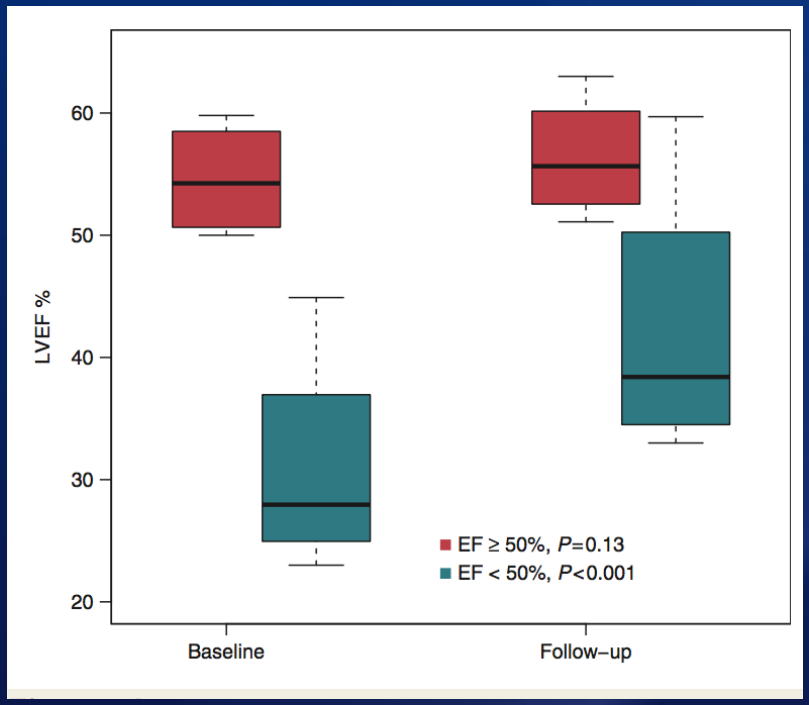
Europace (2019) 21, 1445–1450 doi:10.1093/europace/euz169



The Twitter Effect: #dontdistheHis

Meta-analysis: 26 studies, 1438 patients





Amongst 26 studies, the implant success rate averaged 84.8% and LVEF improved by an average of 5.9% during follow-up. Them mean threshold was 1.8V, varying pulse width. There is a need for uniformity.

Zanon et al Europace (2018)0, 1–8doi:10.1093/europace/euy058

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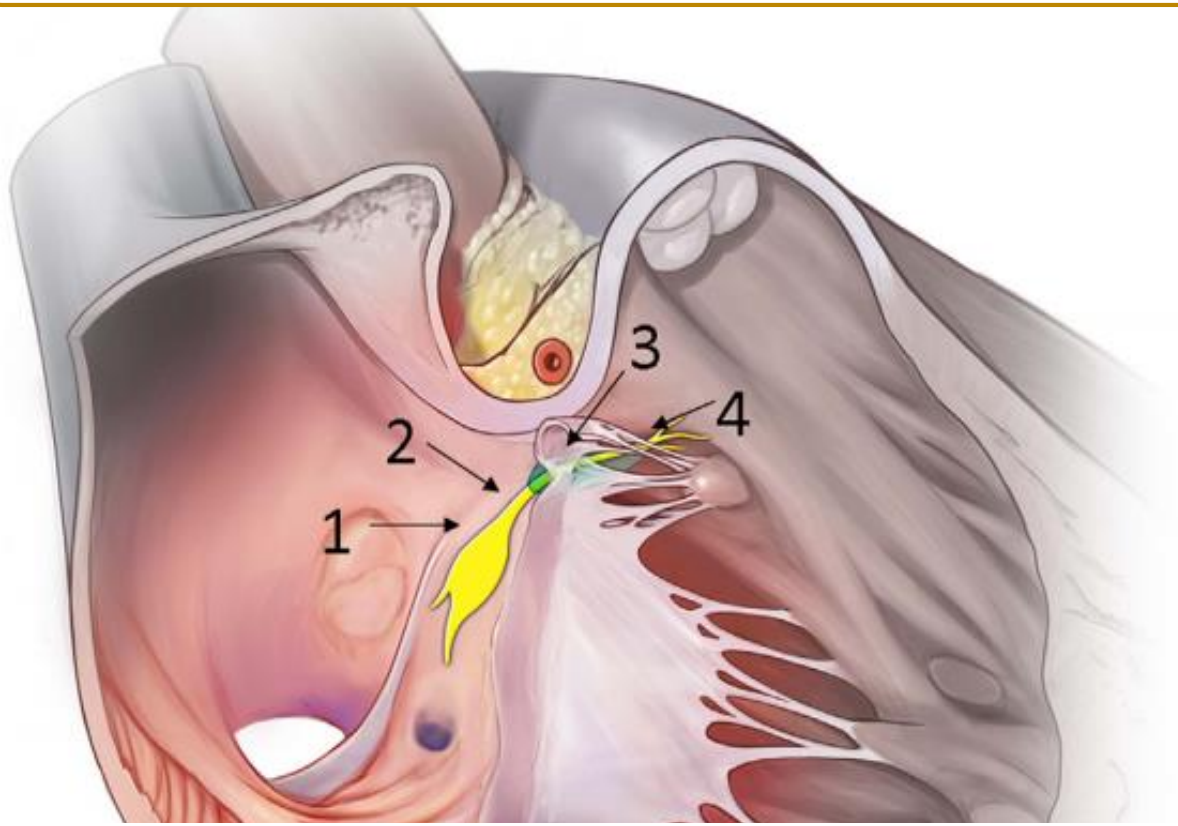
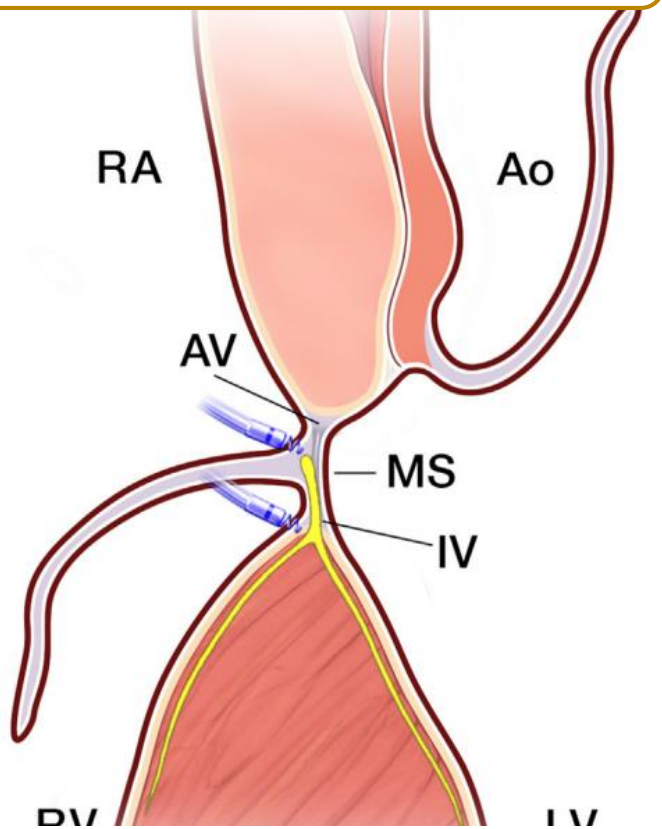
Pacing at Site of Thin Tissue and Proximal Conduction



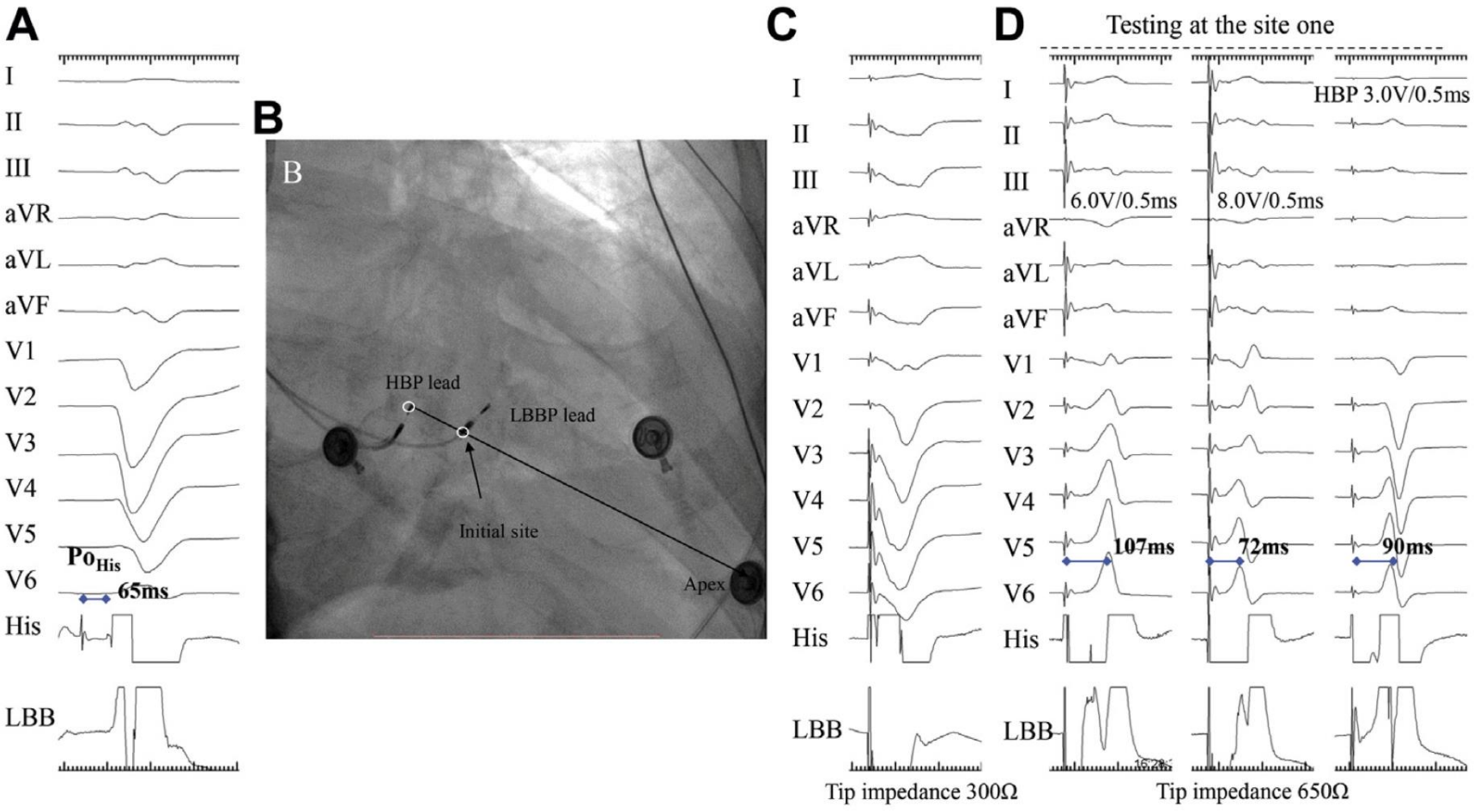


- **Thresholds are higher (up to 20% fail implant, 30% rise post implant)**
- **R waves smaller**
- **Dislodgment risk greater (8%)**
- **Autocapture thresholds / threshold more difficult**

Sharma et al HRJ 2015; Bhatt…Mittal JACC 2018

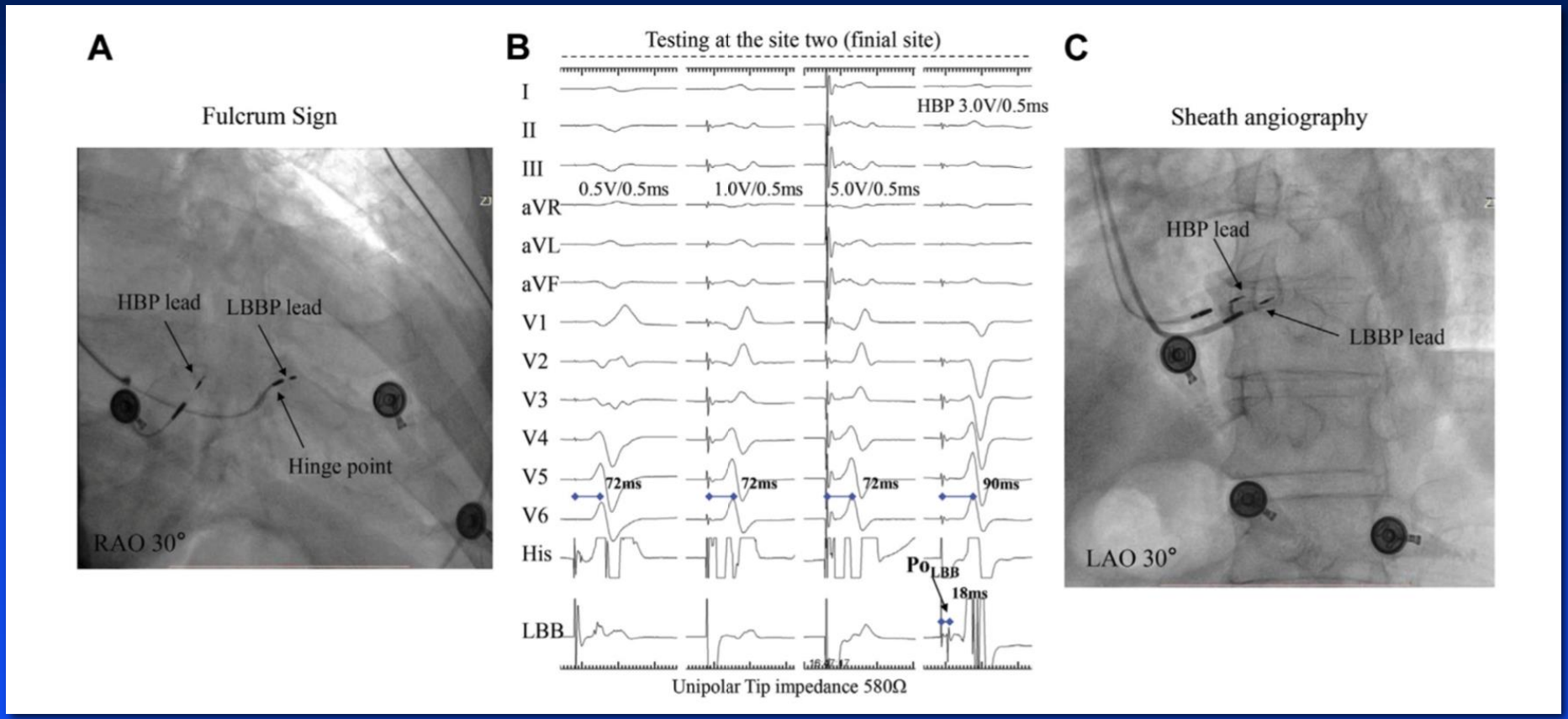
We found the His Bundle…CHB

LBBB pacing



https://doi.org/10.1016/j.hrthm.2019.06.016
VIJAYARAMAN. DOI: 10.19102/icrm.2019.100504

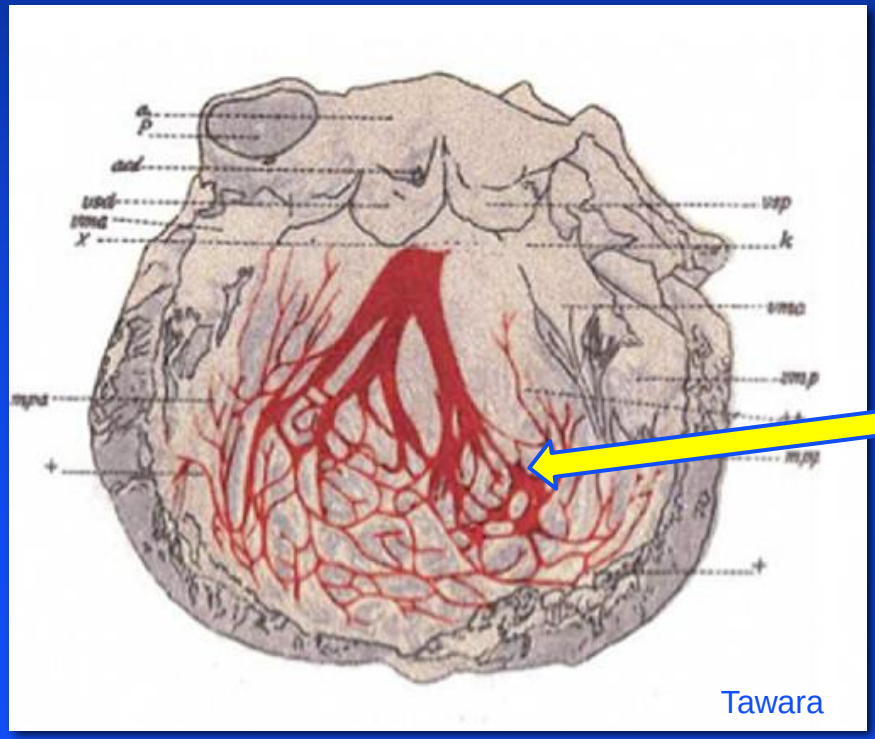
Testing LB Pacing



https://doi.org/10.1016/j.hrthm.2019.06.016
VIJAYARAMAN. DOI: 10.19102/icrm.2019.100504

New Electrical Device Therapies for CHF

- His Bundle pacing
- **Leaded Endocardial CRT**
- Leadless Endocardial CRT
- Cardiac Contraction Modulation



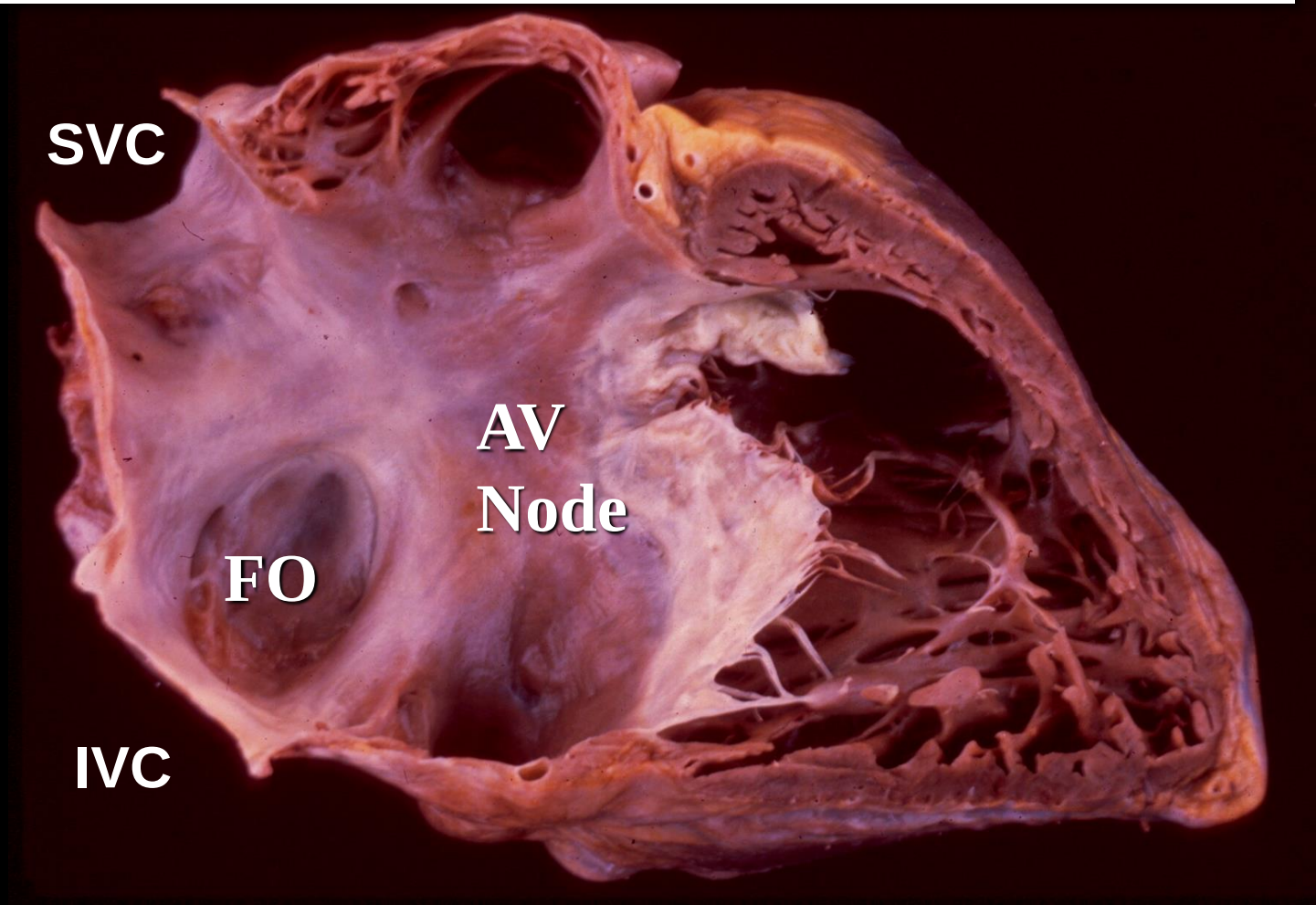
Pace here instead of His

- **Physiologic**
- **?easier**
- **Lower risk of block**

Multicenter prospective observational long-term follow-up study of endocardial cardiac resynchronization therapy using the Jurdham procedure

Heart Rhythm 2019;16:1453–1461

Benjamin Elencwajg, MD,*†‡ Néstor López-Cabanillas, MD,*†‡ Avi Fischer, MD, FHRS,*†‡ Alberto Negrete, MD,§ Jorge Marin, MD,¶ Lorena Delgado, MD,*†‡ Michael Glikson, MD, FHRS,‖ Luis Molina, MD,** Seth Worley, MD, FHRS,†† Jaime Arnez, MD,‡‡ Fernando Vidal, MD,§§ Paul A. Friedman, MD, FHRS,¶¶ on behalf of the Jurdham Group



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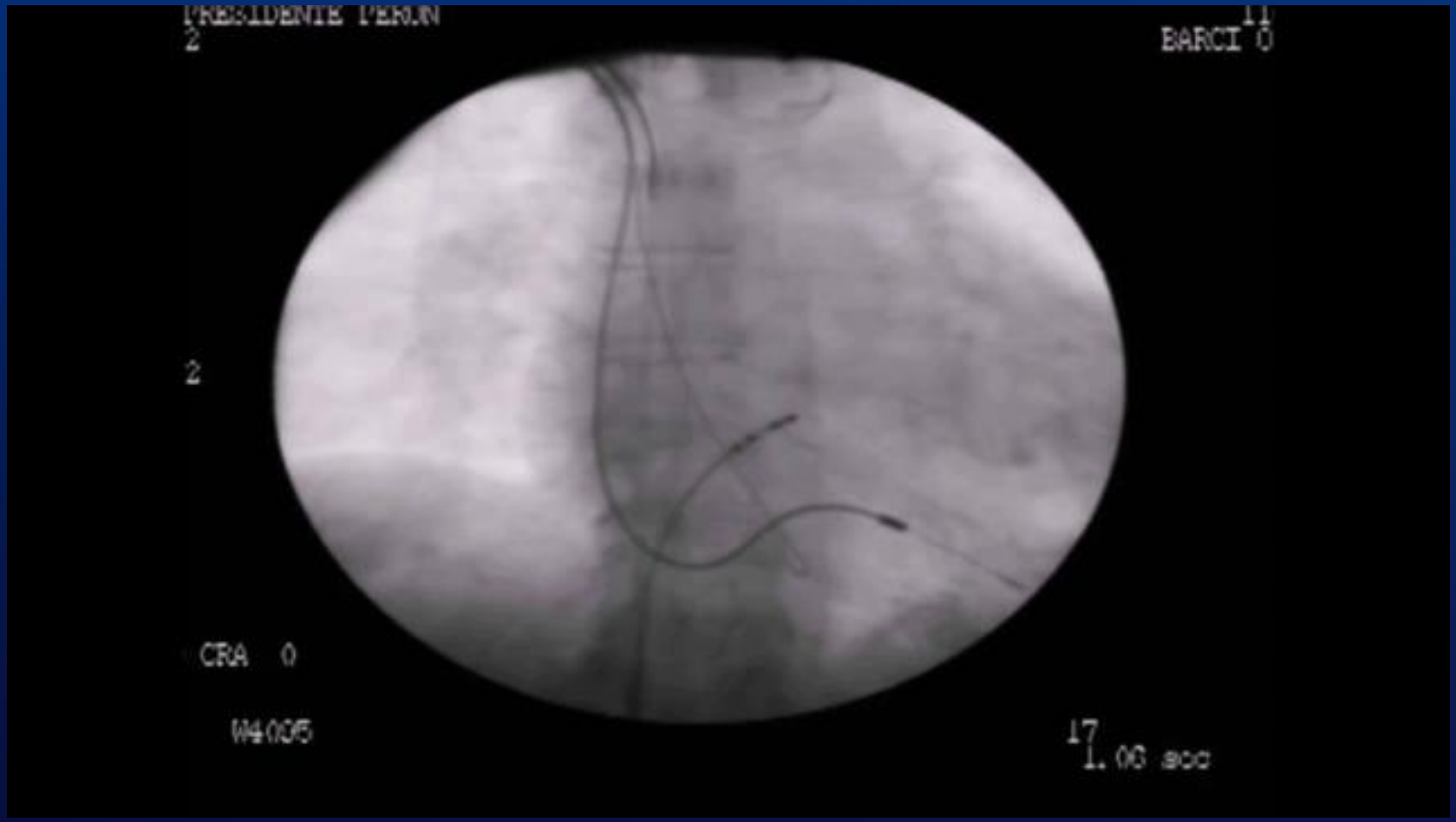
JURDHAM Procedure



Elencwajg … Friedman Heart Rhythm Journal 2019

Endocardial LV CRT: Jurdham Procedure EP developed without industry support

Elencwajg … Friedman Heart Rhythm Journal 2019

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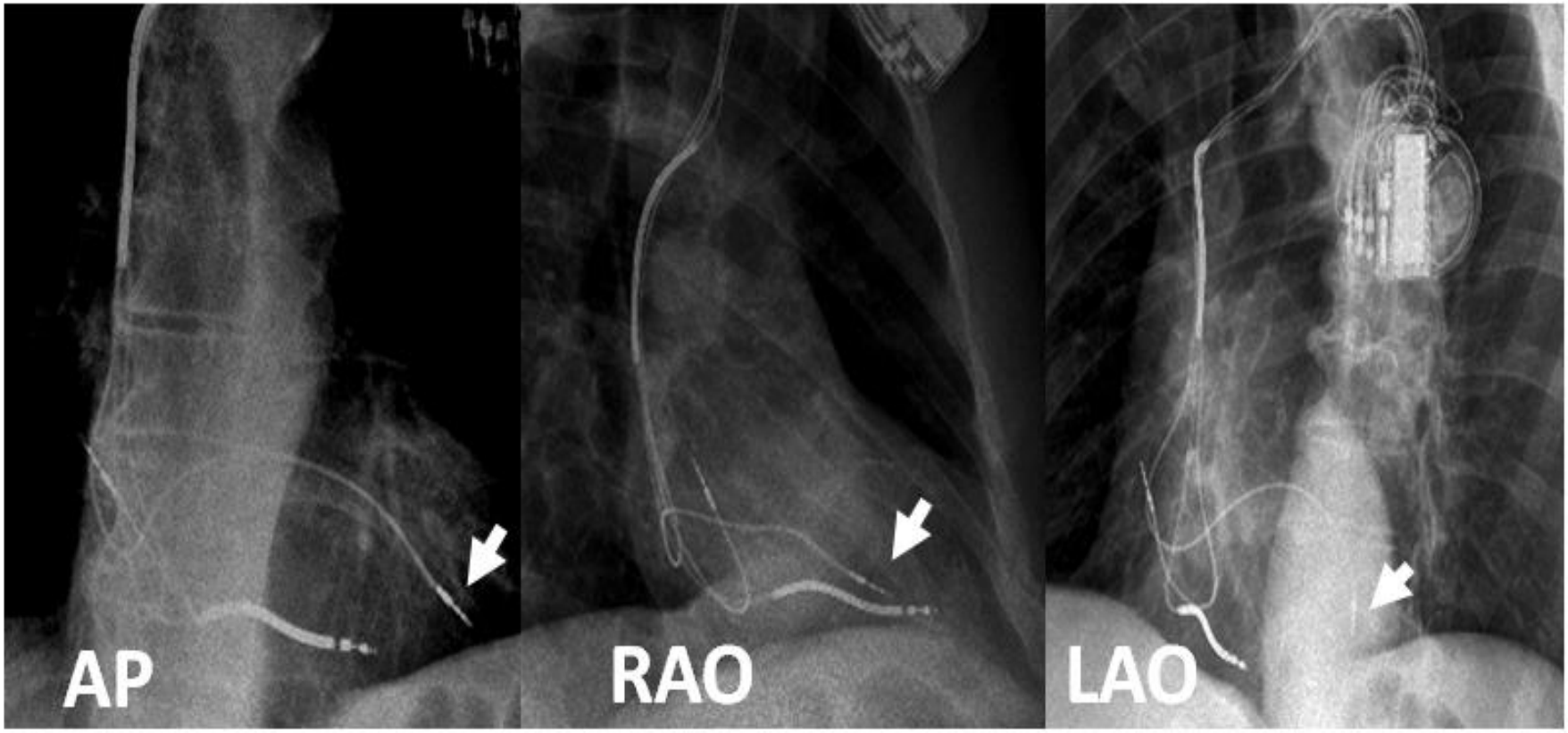
Endocardial CRT (eCRT)



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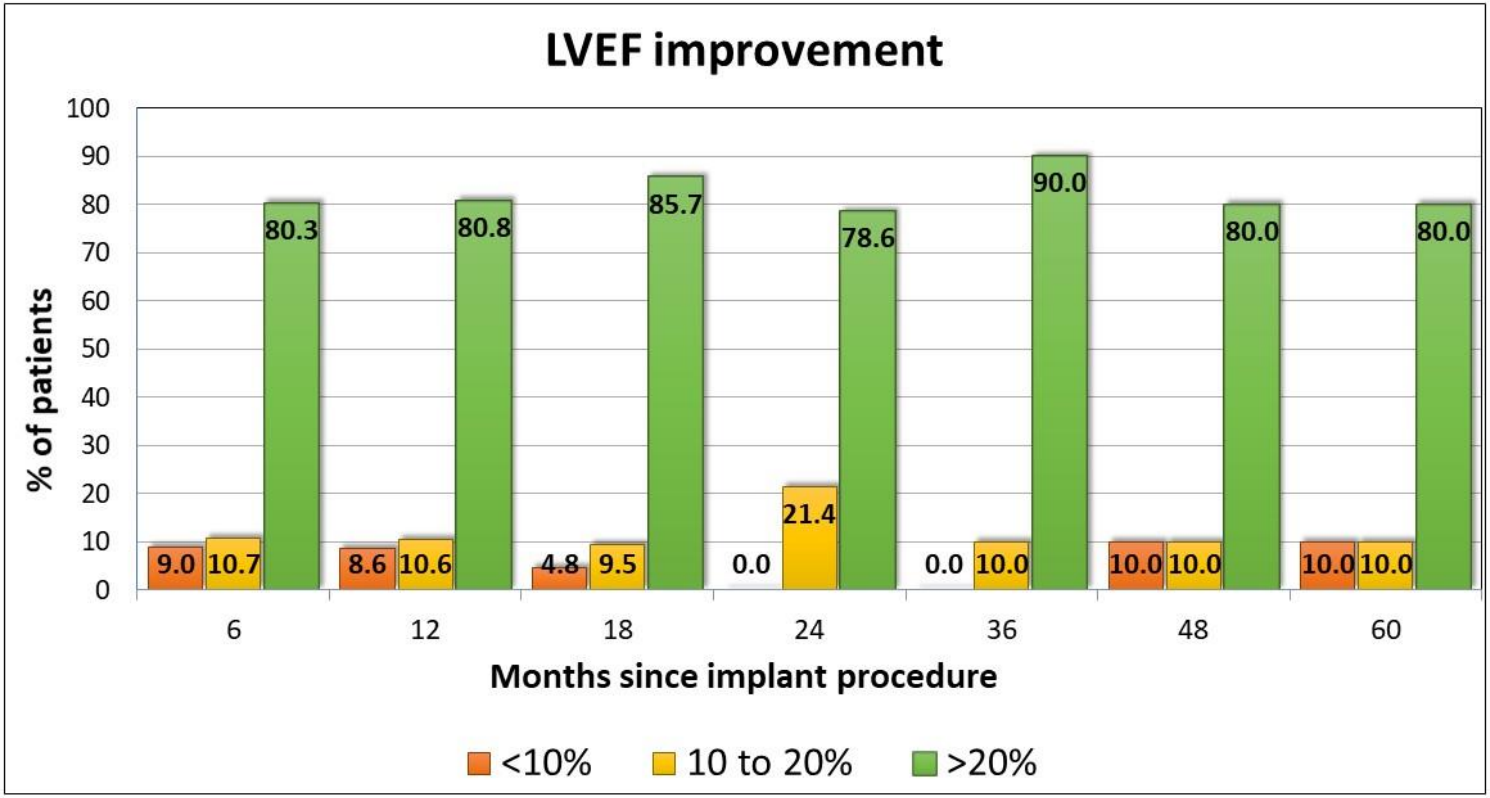
Ejection Fraction response to eCRT



88 patients; 72% failed CRT
80% NYHA III; 10% NYHA IV
Implant success 100%; FC: NYHA 2.9→1.3

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Endocardial LV Summary

- **Remarkable response rate to eCRT -- >80% super-responders (Jurdham)**
- Feasible with off the shelf tools, widely disseminated, in resource constrained environments
- Risk of stroke/TIA remains incompletely resolved issue
  - Balance with risk of CHF death/stroke
- For patients who must be anticoagulated, may be an attractive option

What if could pace the endocardial LV without a lead inside of it?

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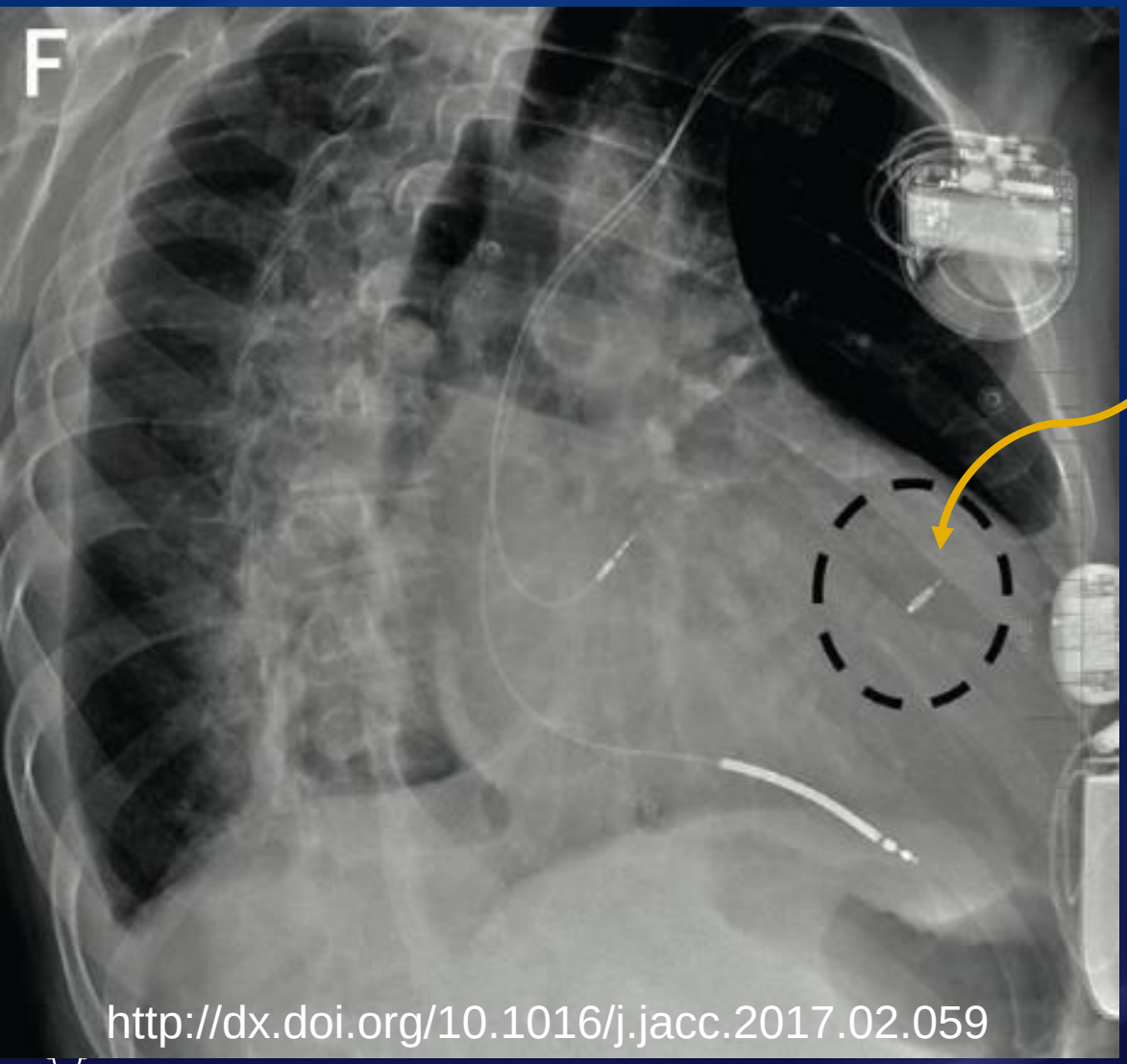
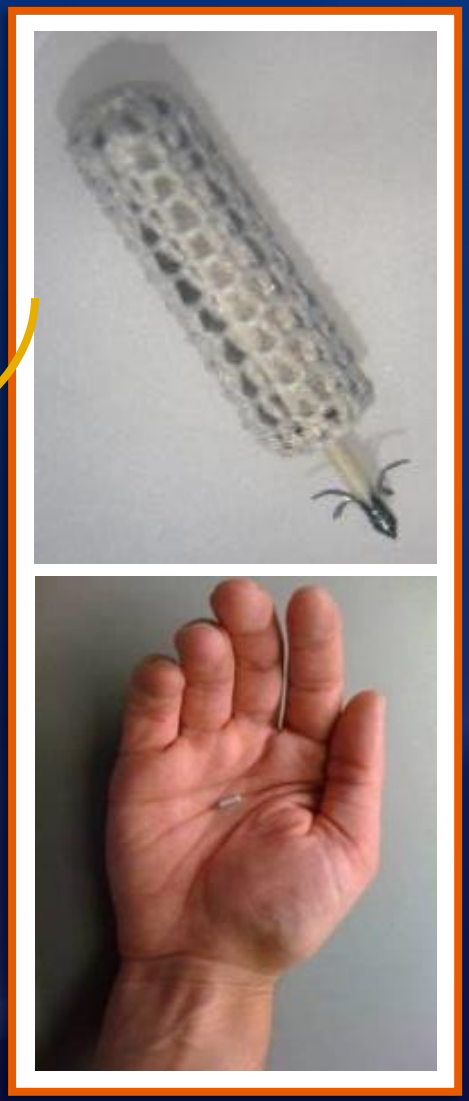
Rx: ASA + Clopidogre x 3 mo → ASA

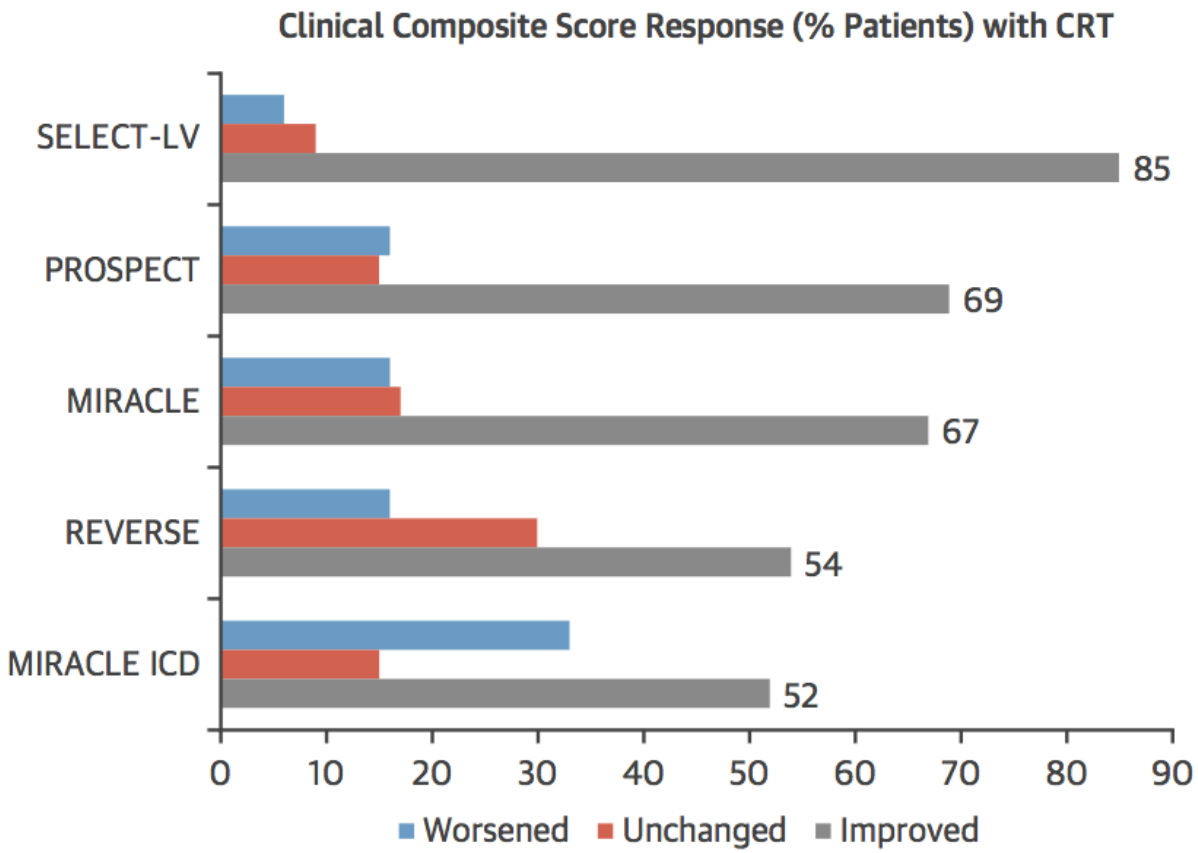




http://dx.doi.org/10.1016/j.jacc.2017.02.059

Endocardial LV pacing

FIGURE 4 **Clinical Composite Score in SELECT-LV Compared With Historical Control Subjects**



http://dx.doi.org/10.1016/j.jacc.2017.02.059

Endocardial LV Ultrasound system

- Appears very effective (as does endo-CRT)
- Likely low risk CVA
- Very promising – specially for CRT failures

- But:
  - Two stage implant technique, over two days
  - Two batteries, and ?s about battery longevity
  - Data are pending - clinical study ongoing
  - Long-term chronic US stim?

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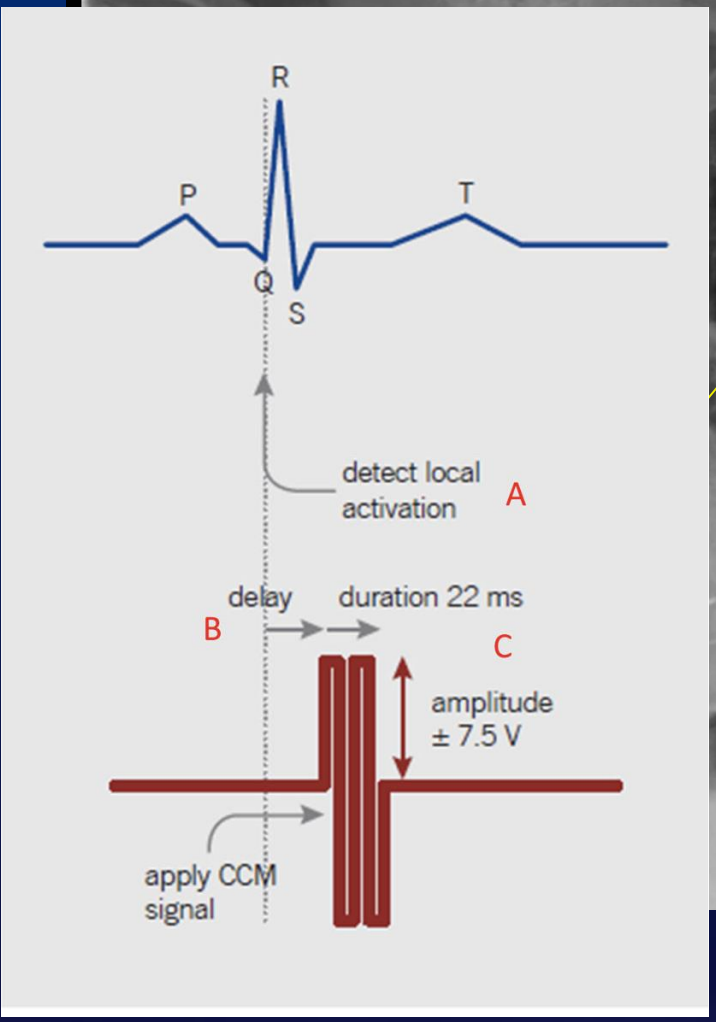
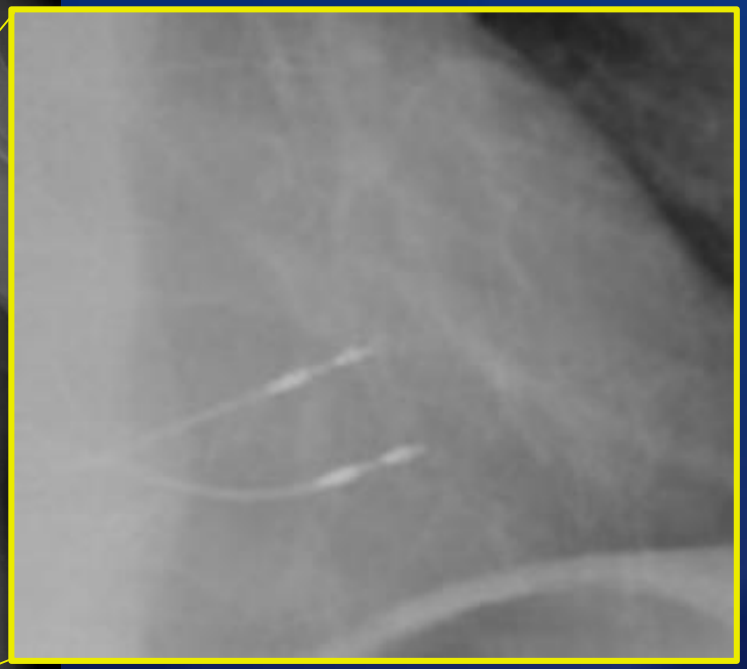
Cardiac Contraction Modulation only option for narrow QRS (<130)

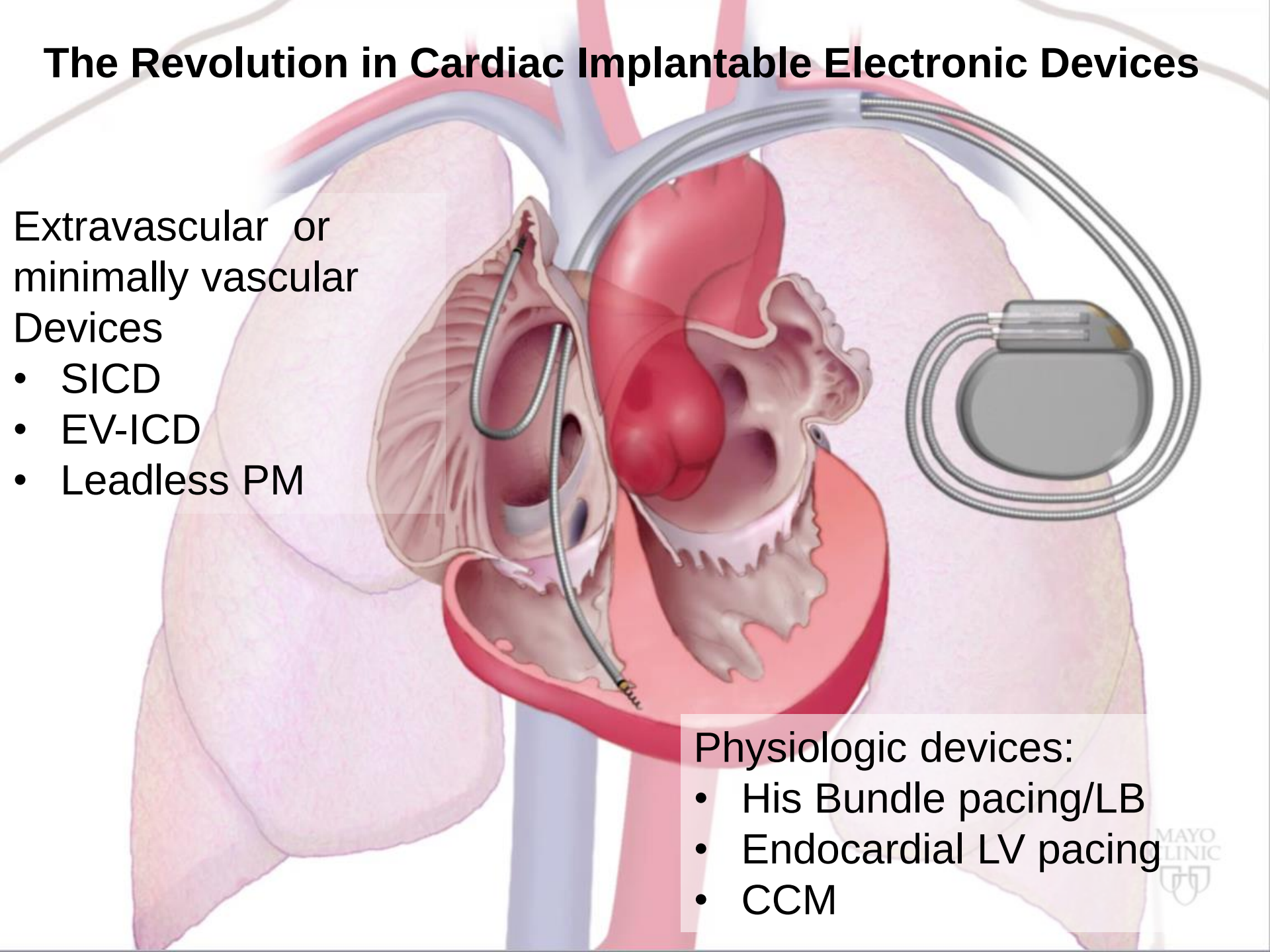




Rechargeable device
Device-device interactions

Dr. med. Dominik Traunwieser, Oberarzt der Klinik für Innere Medizin II, Kardiologie, Pneumologie und Angiologie, HELIOS Vogtland-Klinikum Plauen

The Revolution in Cardiac Implantable Electronic Devices



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Thank you

- pfriedman@mayo.edu

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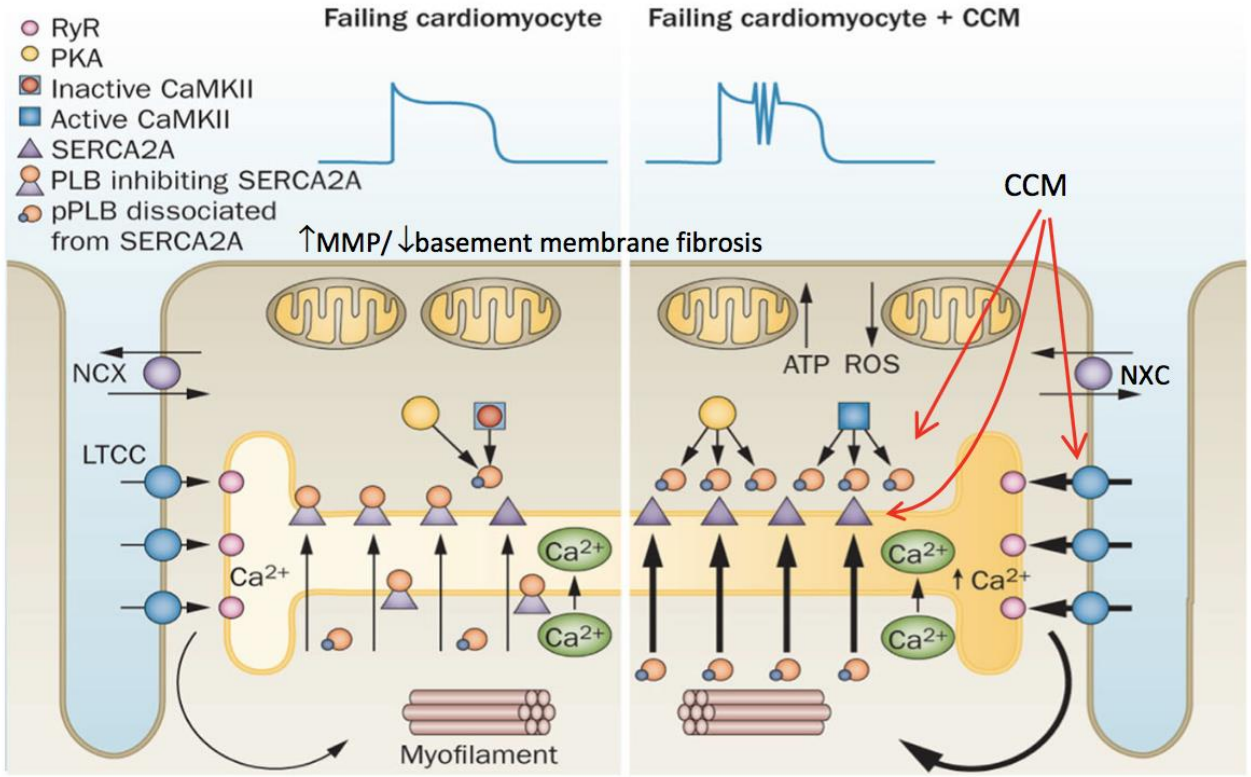
CCM Mechanisms



Upregulate SERCA Activity

Phosphorylate phospholamban, thereby detaching it from SERCA

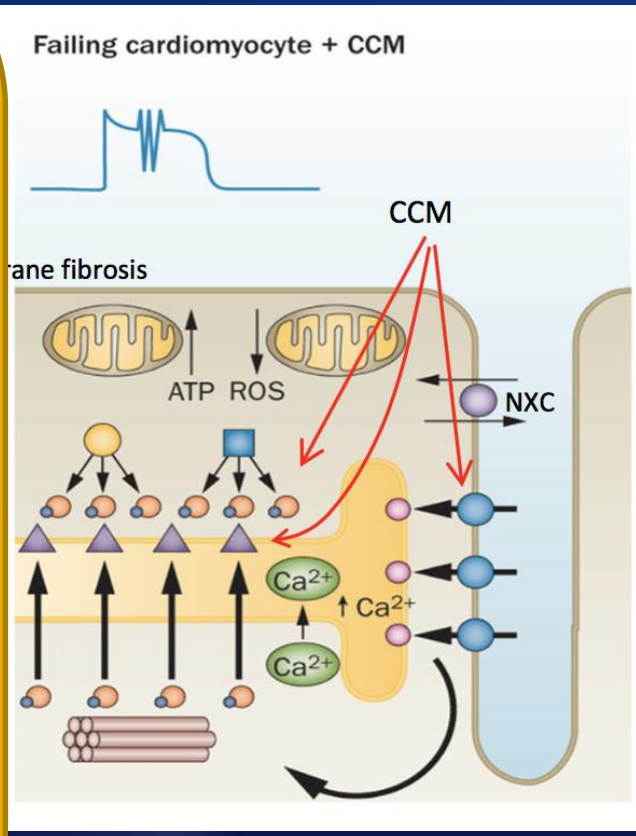
Activate LTCC currents

Normalize Na/Ca exchanger

Increase MMP; reverse pathological remodeling

CCM Mechanisms

- **Gene expression (Ca++): changes within 2 hours at site of electrodes**
- **Local and remote gene expression changes: within 3 months**
- **Revions from fetal phenotype towards normal adult, with improve Ca++ handling**
  - **Upregulation of SERCA**
  - **Phosphorylation: phospholamban**
  - **Improved Ca++ updake SR**



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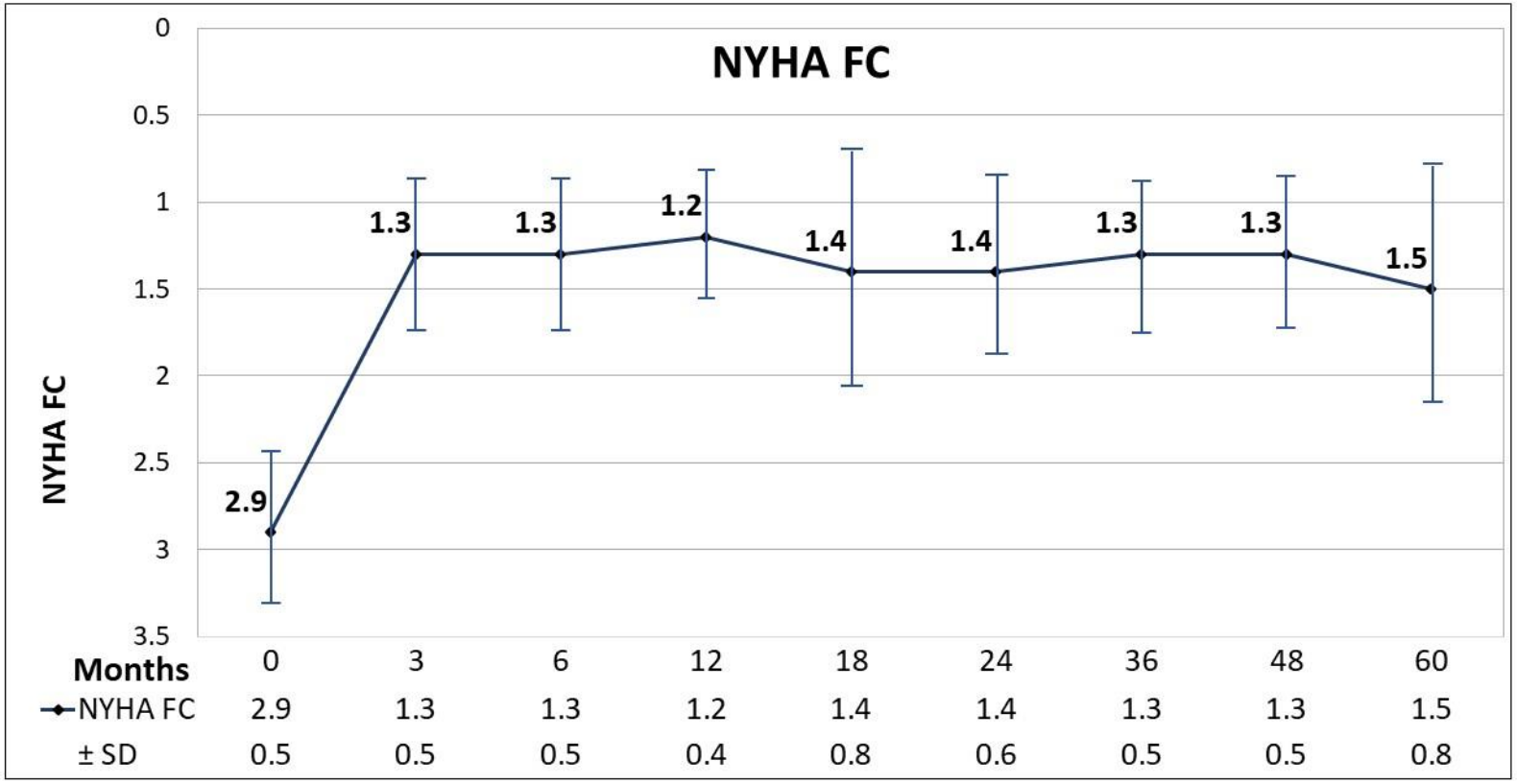
Functional Improvement to eCRT



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