Heart Rhythm 2016

Peri-Operative Decisions to Maximize CRT Response

Devi G. Nair, MD, FHRS

Director of Cardiac Electrophysiology
St. Bernard's Heart & Vascular Center
Jonesboro, AR

Disclosures: Consultant to Boston Scientific, St. Jude; Speaker for Medtronic, Pfizer, BoehringerIngelheim, Johnson and Johnson

CRM392807-AB-May2016

Factors affecting CRT

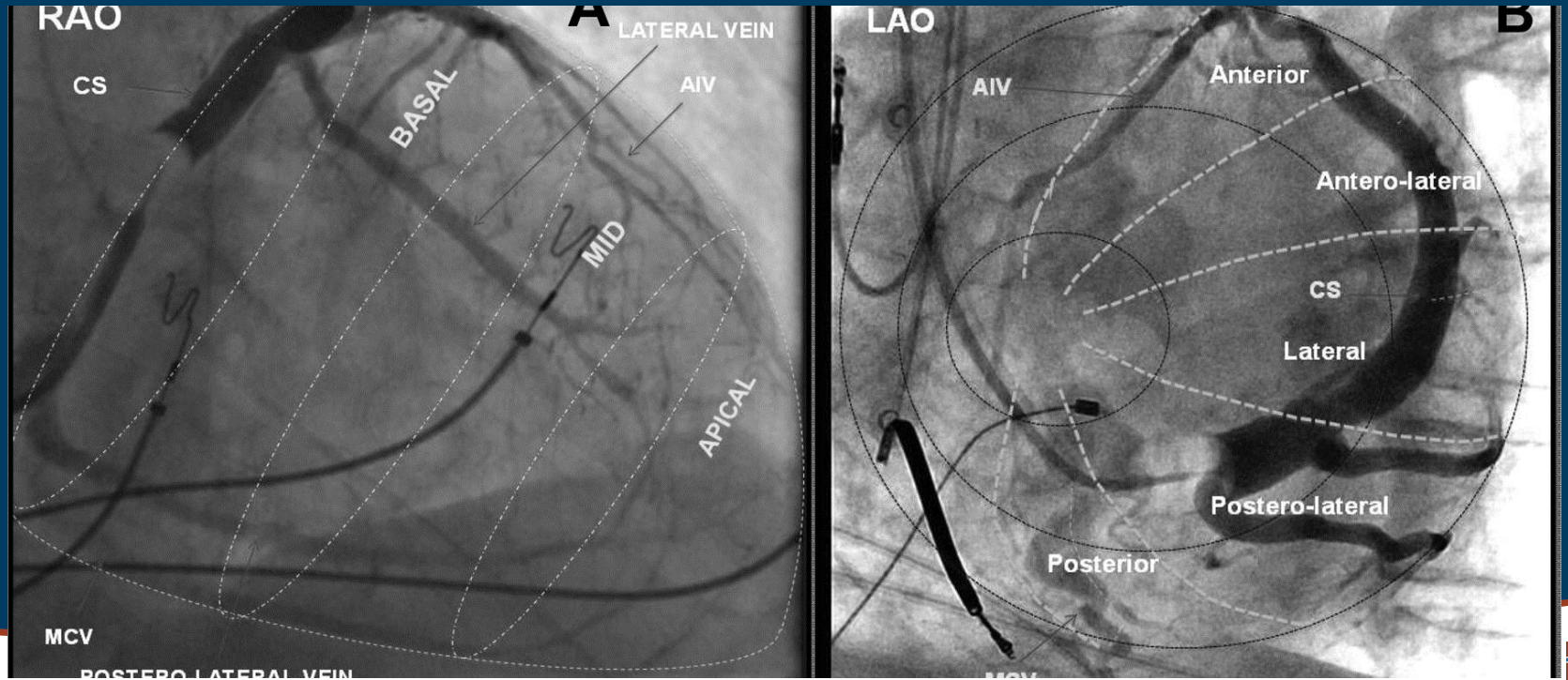
1. Patient selection
2. Patient selection
3. Patient selection
4. Patient selection
5. Patient selection
6. Patient selection
7. Patient selection
8. Patient selection
9. Patient selection
10. Patient selection

1. LV lead location
2. Programming the device
3. Pacing burden
4. Arrhythmias
5. Medications and other clinical factors

Anatomic Lead Location

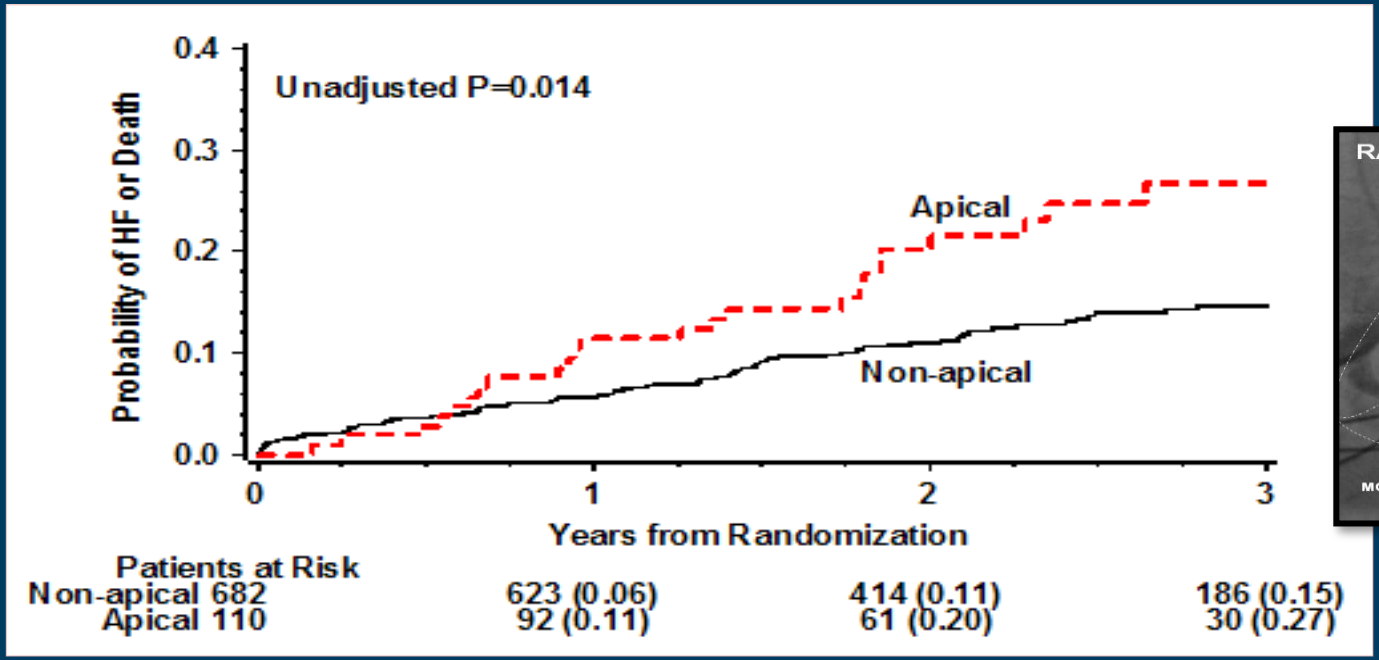
MADIT CRT STUDY

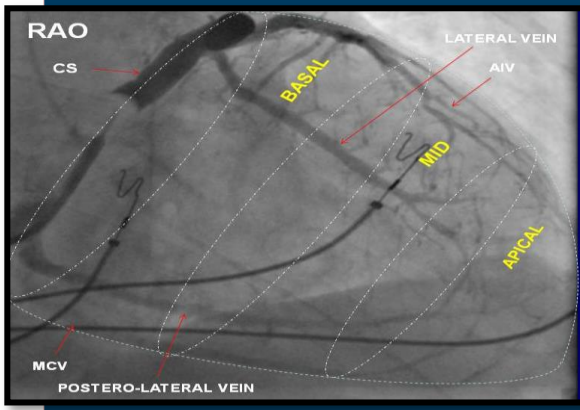
Angiographic classification of LV lead position



Jagmeet P. Singh et al. Circulation. 2011;123:1159-1166 (MADIT CRT study)

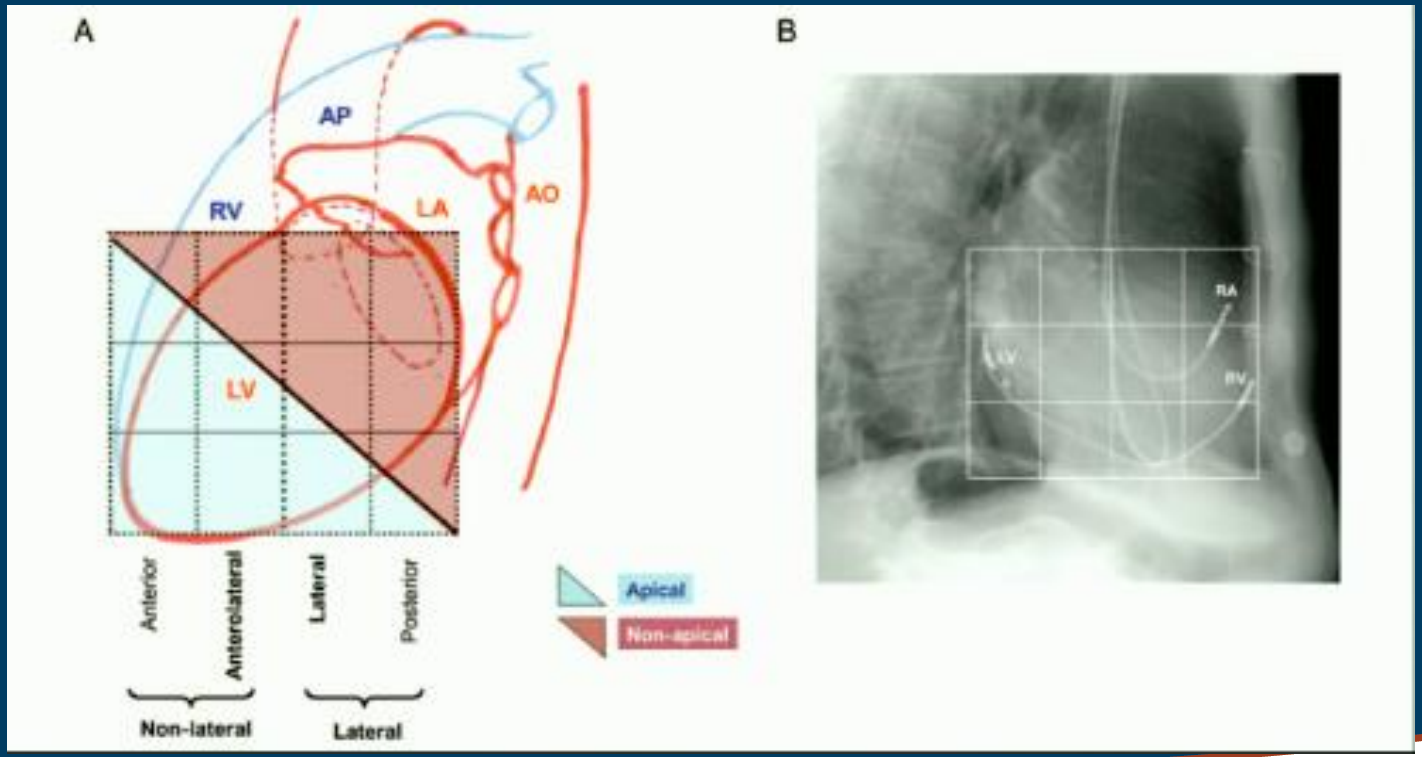
Apical lead locations are associated with worse outcome





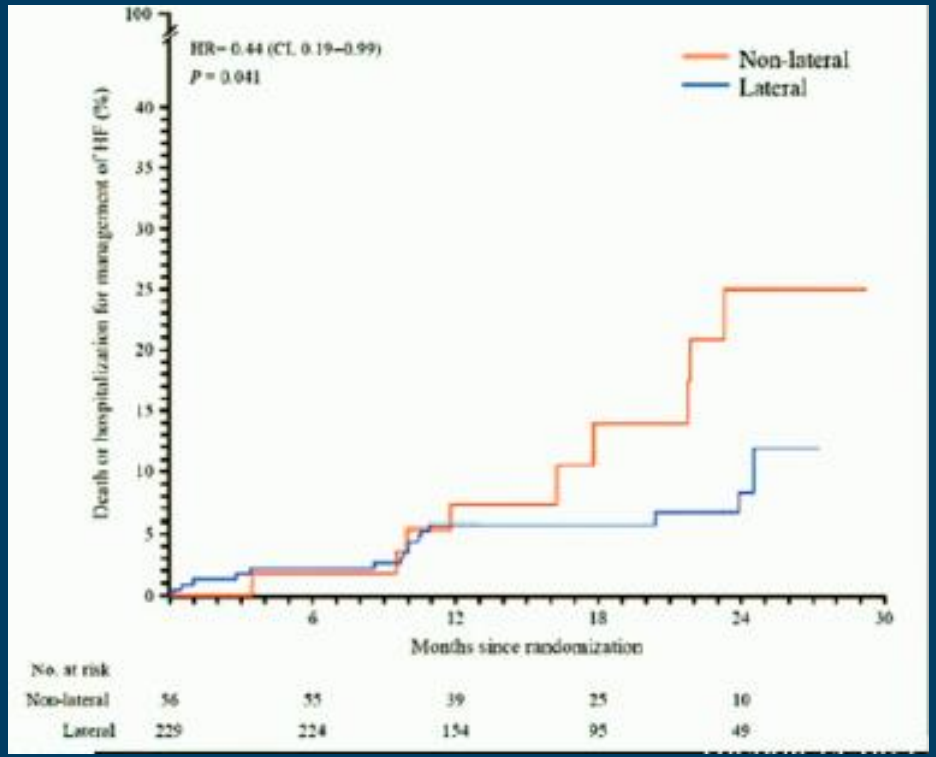
Jagmeet P. Singh et al. Circulation. 2011;123:1159-1166 (MADIT CRT study)

Reverse Trial

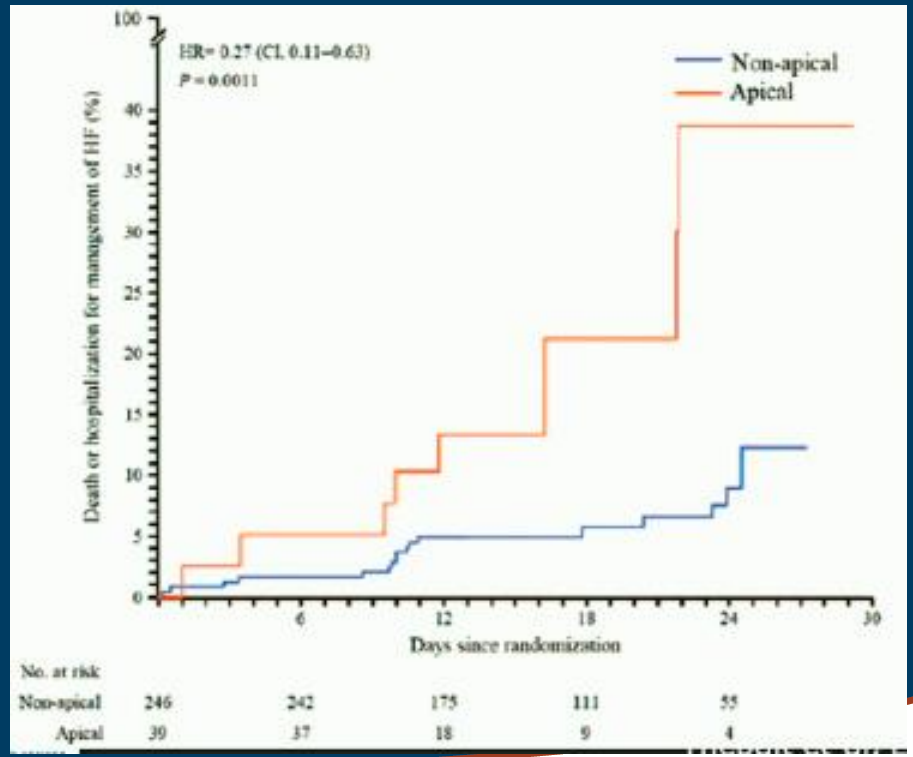


Thebalt et al, EHJ 2012

Lateral lead position better



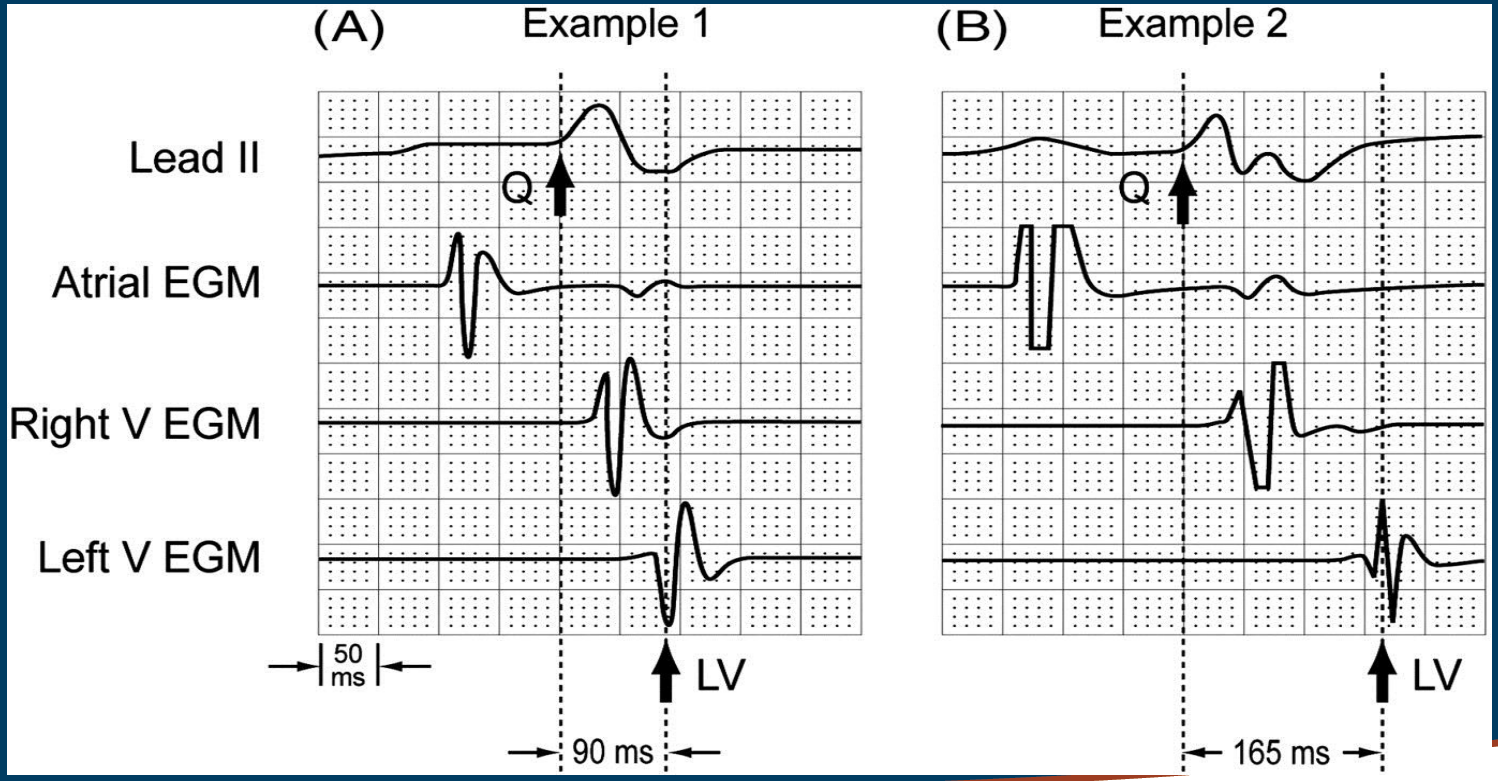
Apical lead positions worse



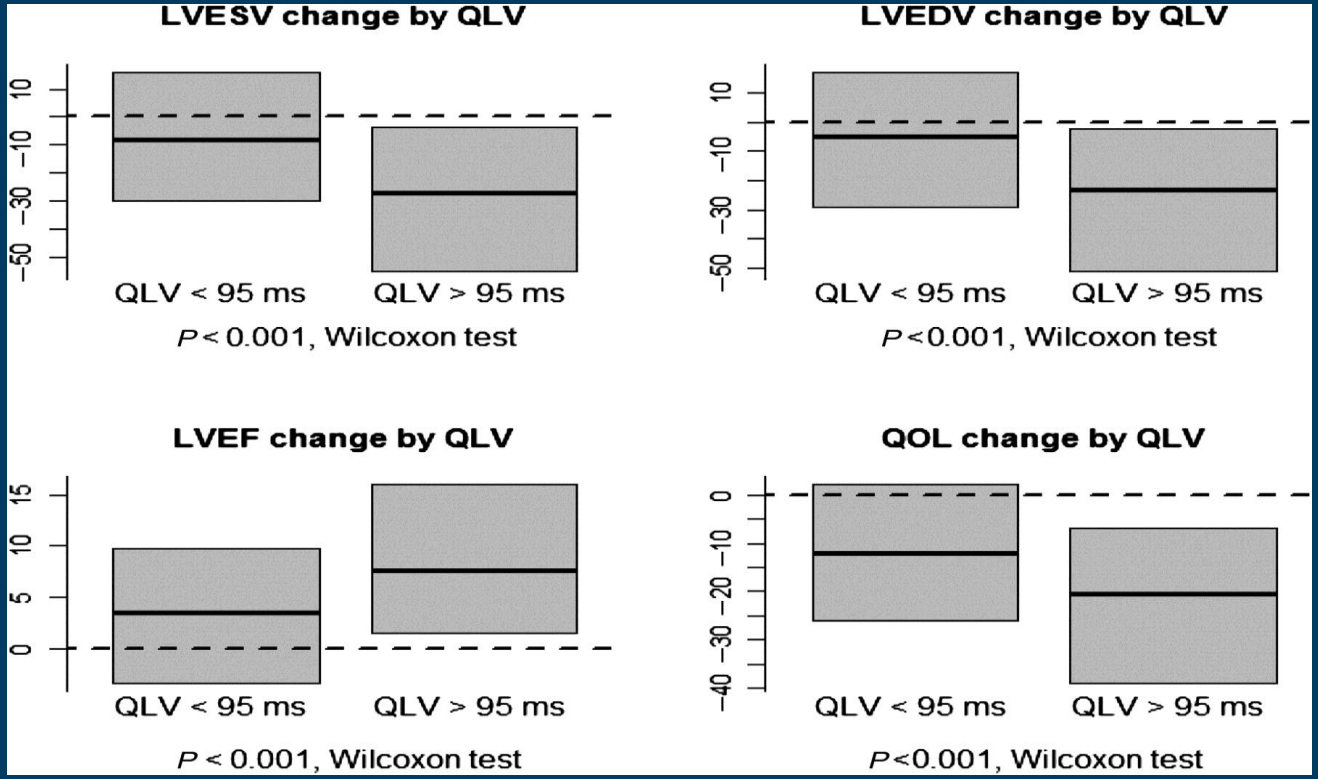
Thebalt et al, EHJ 2012

Electrical Lead Positioning

QLV Measurement

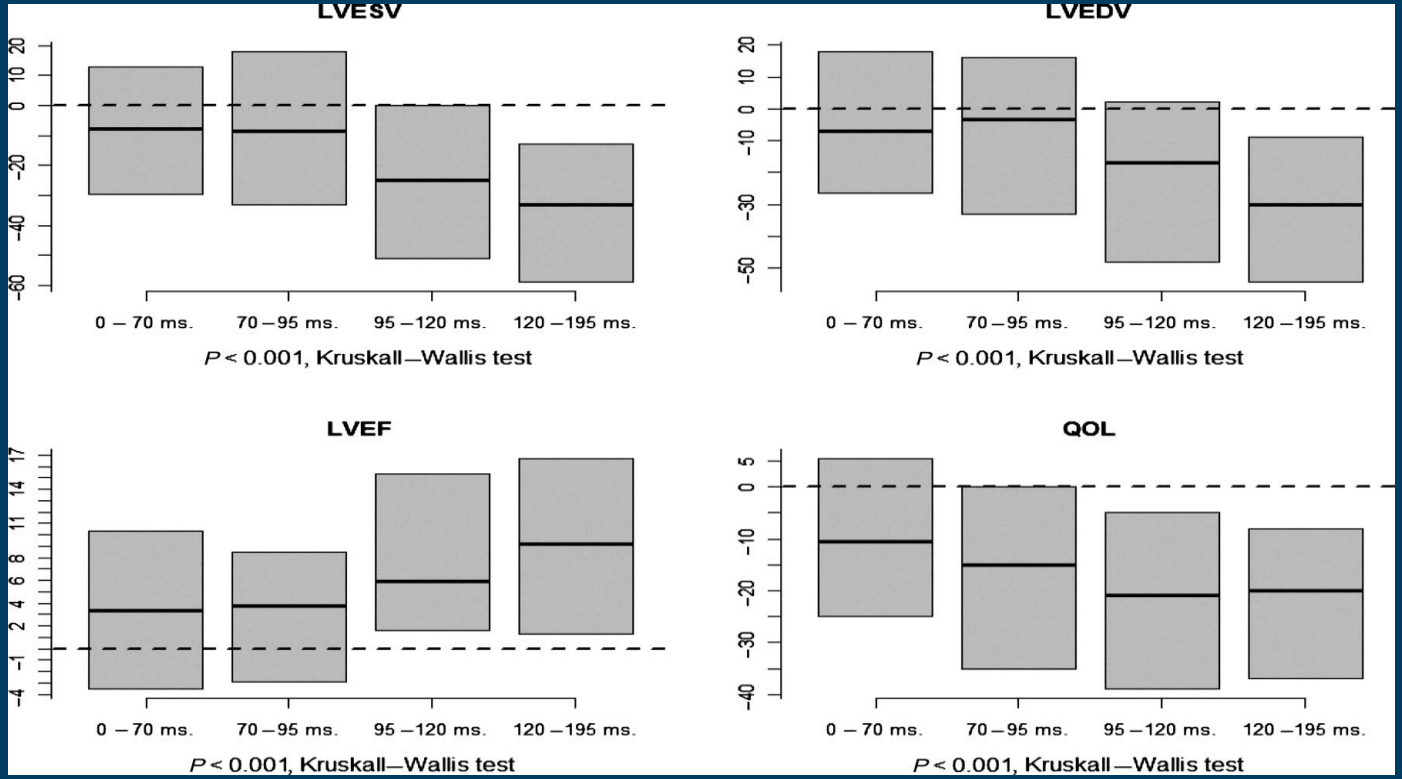


Michael R. Gold et al. Eur Heart J 2011;32:2516-2524



Michael R. Gold et al. Eur Heart J 2011;32:2516-2524

Comparisons of the changes in left ventricular end-systolic volume, left ventricular end-diastolic volume, ejection fraction, and quality of life from implant baseline to 6 months for the QLV quartiles.

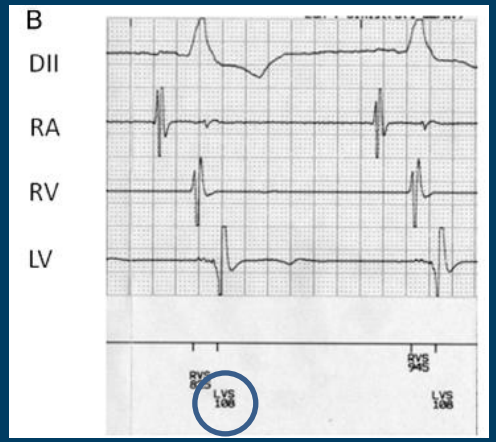


Michael R. Gold et al. Eur Heart J 2011;32:2516-2524

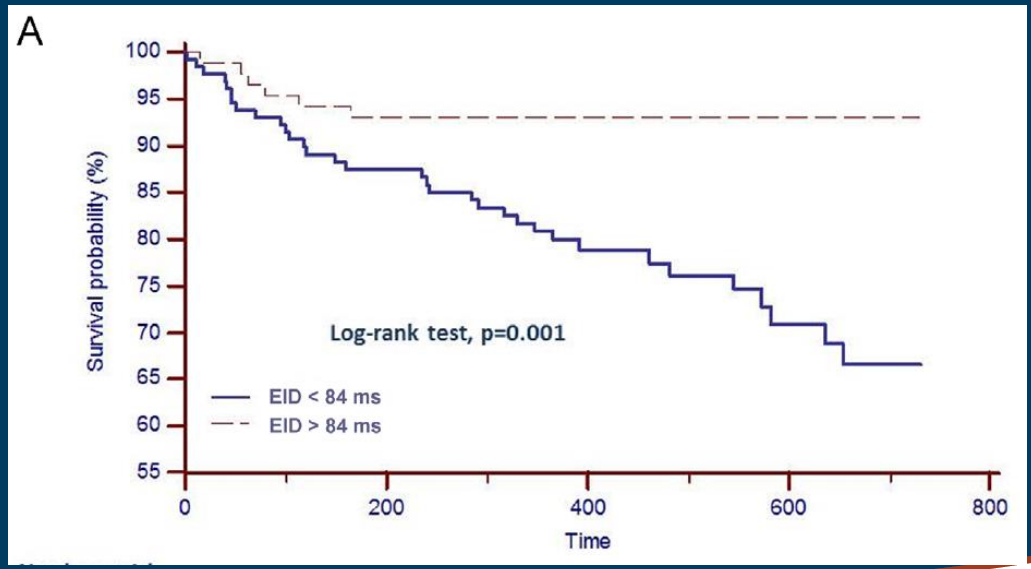
European Heart Journal

RV - LV Delay

- Pacing at LV sites with increased RV-LV delay improved mortality and cardiovascular hospitalization.[1]



LVS
100ms

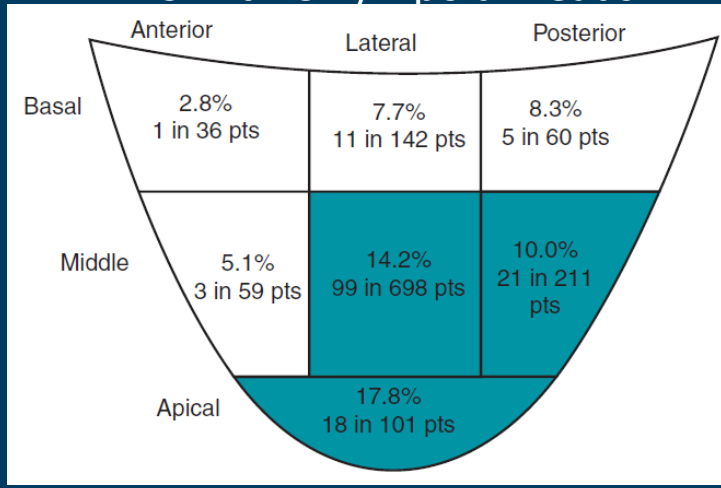


Stabile G et al. Heart Rhythm 2015;12:2221-29.

Phrenic Nerve Stimulation

	PNS occurrence	Re-intervention or CRT abandonment
Unipolar and bipolar leads[1-2]	11.6% – 12.9%	1.6% – 2.1%
Quadripolar leads[3-5]	7.2% – 13.5%	0.0% – 0.4%

PNS with Uni/Bipolar Leads[1]

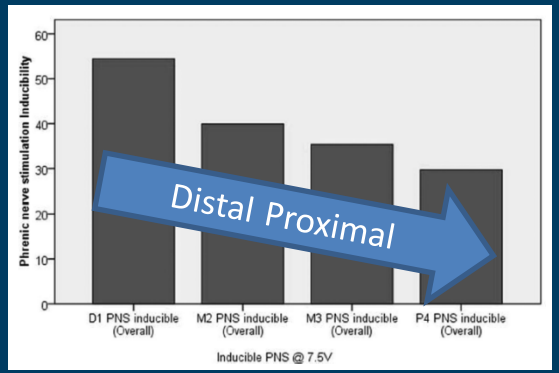


1. Biffi M et al. Europace 2013;15:77-82.
2. Goetze S et al. J Interv Card Electrophysiol 2013;38:1-9
3. Tomassoni G et al. J Cardiovasc Electrophysiol 2013;24:449-56
4. Crossley G et al. Heart Rhythm 2015;12:751-58
5. Mittal S et al. J Am Coll Cardiol. 2016;67 (13 Suppl):824

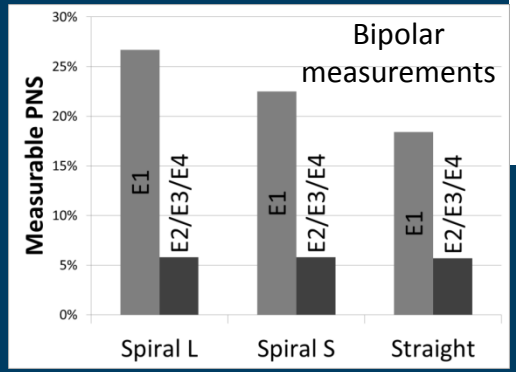
Phrenic Nerve Stimulation

- Quadripolar leads provide more options to avoid PNS
- PNS is less frequent with proximal electrodes

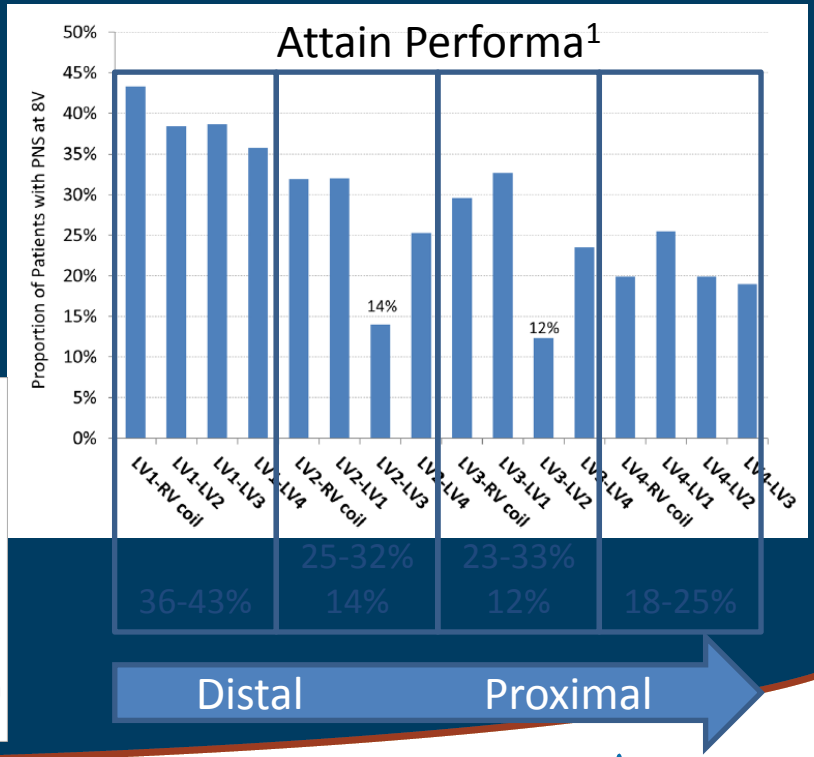
Quartet[2]



Acuity X4[3]



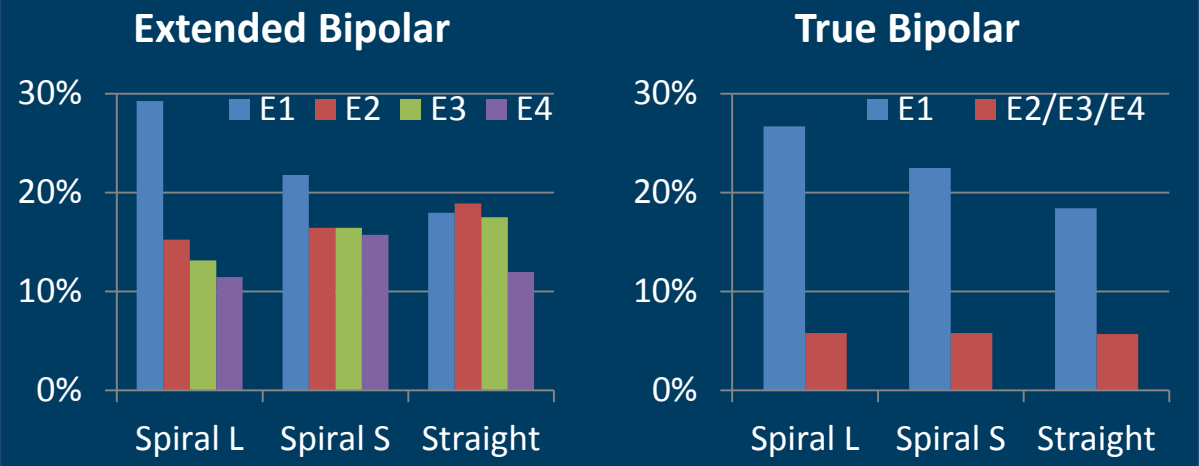
Attain Performa[1]



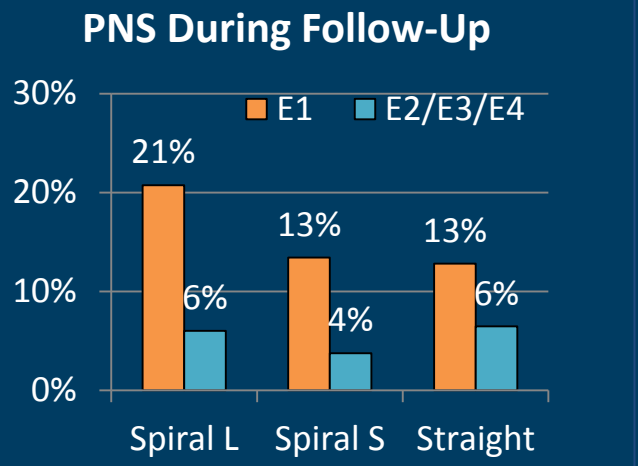
1. Crossley G et al. Heart Rhythm 2015;12:751-58
2. Oswald H et al. PACE 2015;38:942-50
3. Mittal S et al. J Am Coll Cardiol. 2016;67 (13 Suppl):824

Phrenic Nerve Stimulation in NAVIGATE X4

Testing at Maximum Output



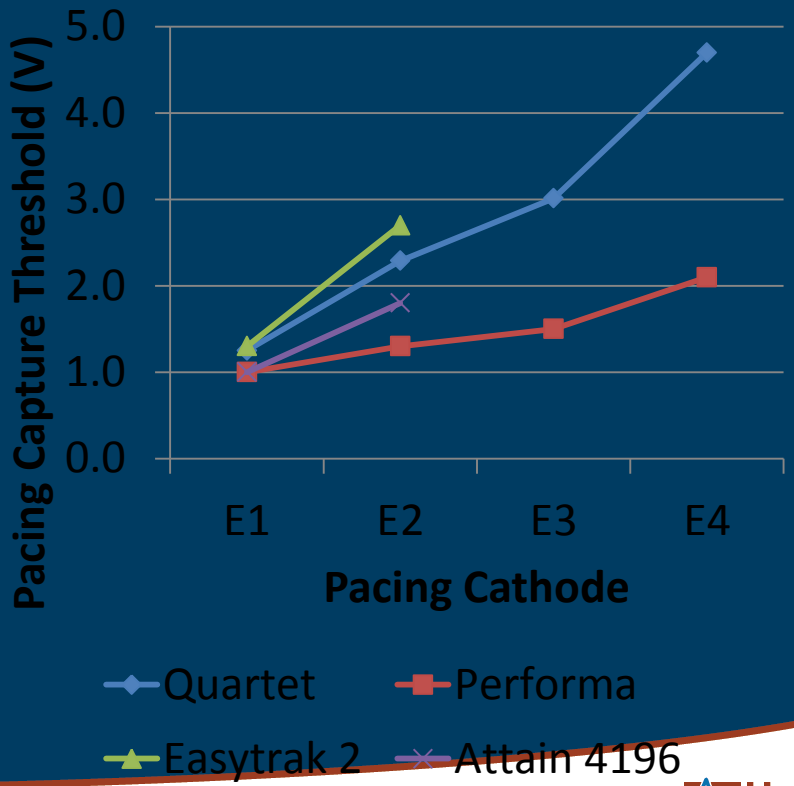
Clinical Observation of PNS



- Pacing from proximal electrodes reduces the rate of PNS during acute testing as well as reduces clinical observations of PNS

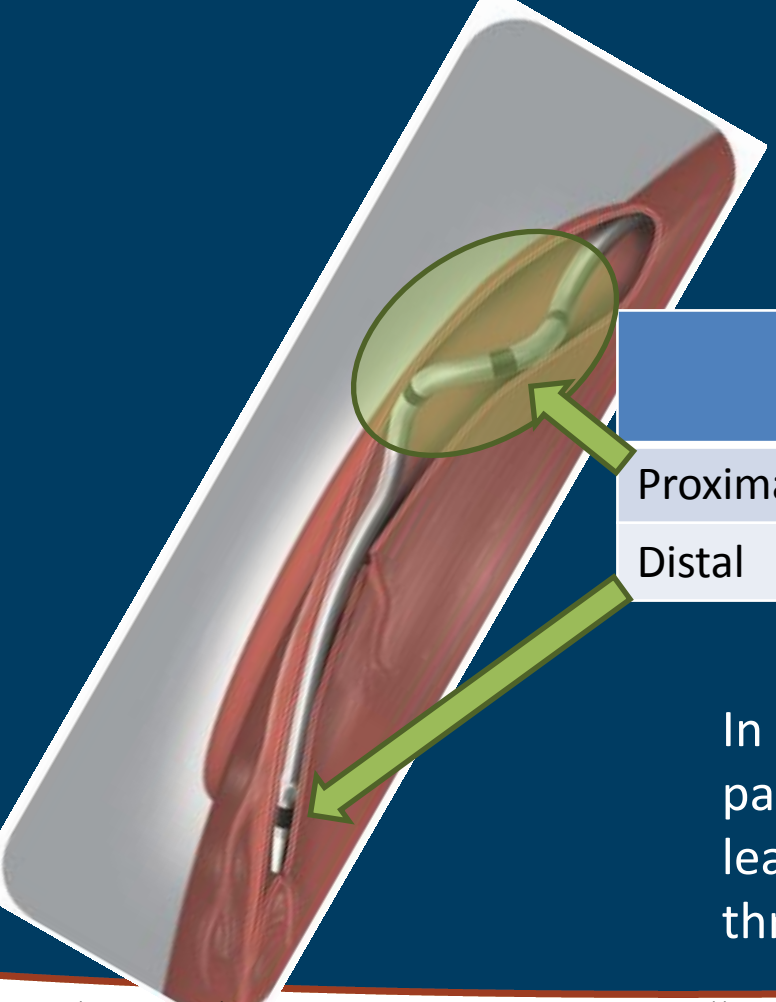
Pacing Capture Thresholds

- Pacing capture thresholds are lowest with the distal electrode, and increase with longer spacing



1. Tomassoni G et al. J Cardiovasc Electrophysiol 2013;24:449-56
2. Crossley G et al. Heart Rhythm 2015;12:751-58
3. Easytrak 2 Physician's Manual 2004 355898-004.
4. Attain Ability 4196 Clinical Study Summary 2008 M932891A001

Pacing Performance



	Spiral L		Spiral S		Straight	
	V_{th}	Use	V_{th}	Use	V_{th}	Use
Proximal	0.9V	78%	0.9V	76%	1.2V	65%
Distal	1.3V	22%	1.2V	76%	1.0V	35%

In contrast to prior bipolar[1-2] or quadripolar leads[3-5], pacing from the proximal electrodes of the spiral leads was performed without an increase in pacing thresholds[6]

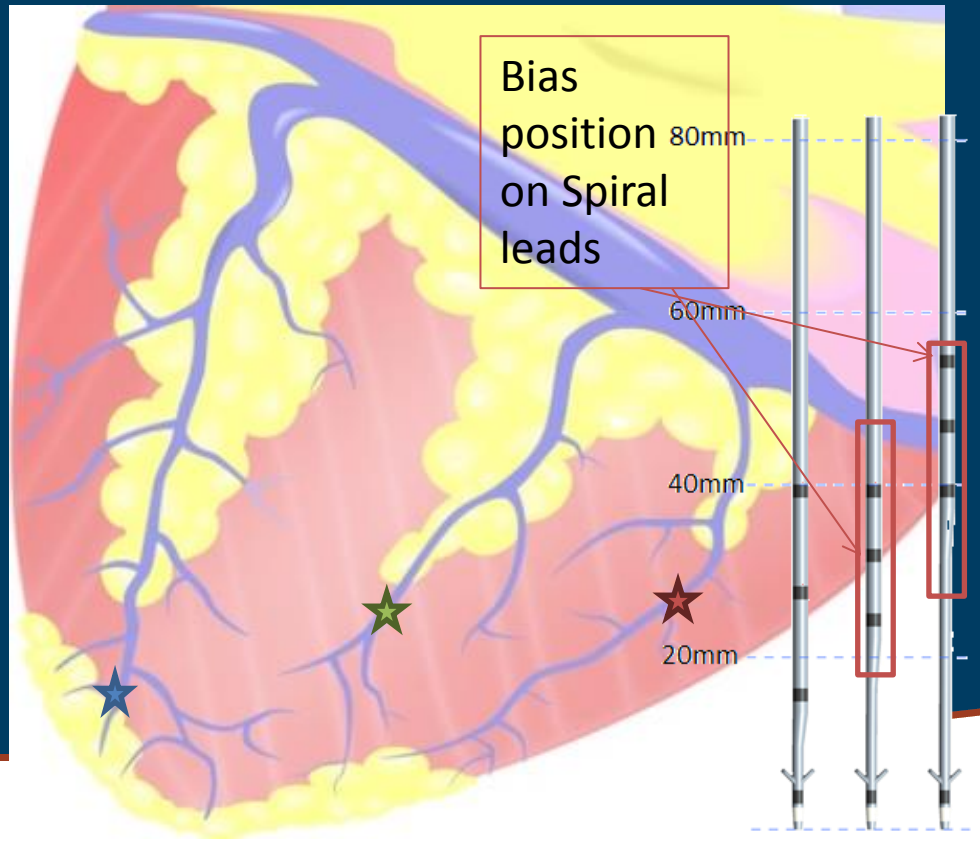
1. Champagne J et al. Europace 2011;13:409-15
2. Klein N et al. Europace 2012;14:826-32.
3. Tomassoni G et al. J Cardiovasc Electrophysiol 2013;24:449-56
4. Oswald H et al. PACE 2015;38:942-50.
5. Crossley G et al. Heart Rhythm 2015;12:751-58
6. Mittal S et al. J Am Coll Cardiol. 2016;67 (13 Suppl):824

- Coronary venous angiography -
  - for selecting the most suitable lead for the appropriate branch anatomy .
  - segmental classification of the coronary veins and tributaries in relation to the LV wall

ACUITY X4 Lead Design

ACUITY X4 leads are designed for anatomical variation:

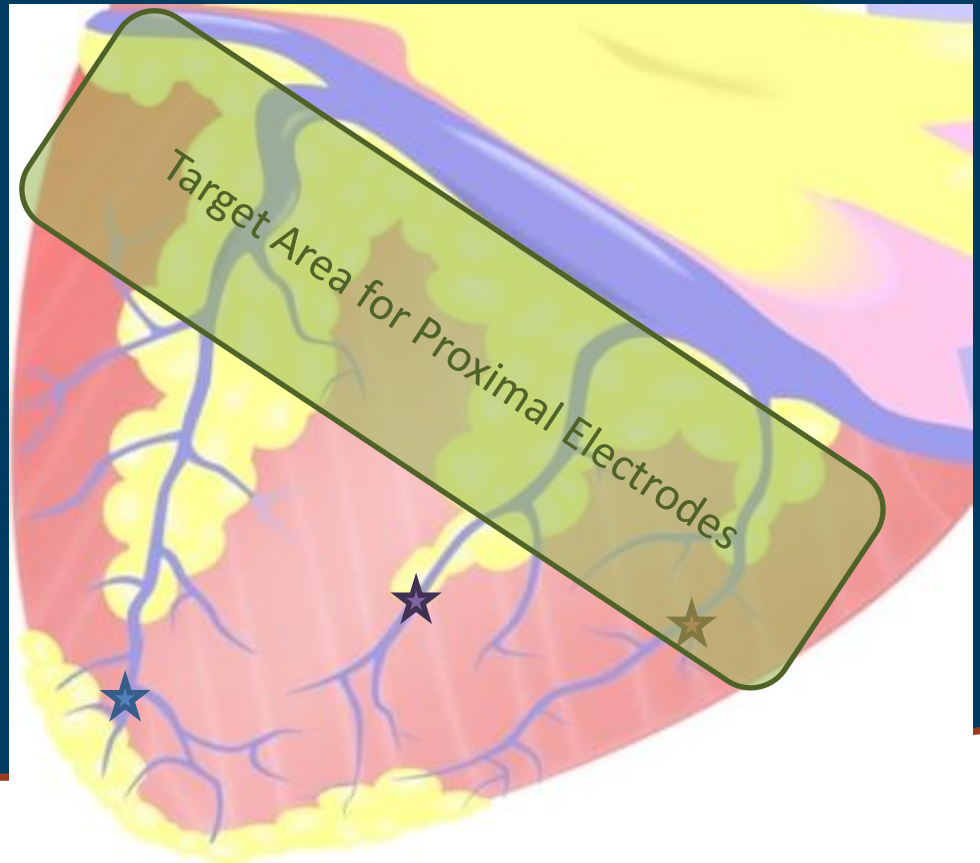
- Spiral L has 40mm spacing for long veins
- Spiral S has 25mm spacing for mid-ventricular termination
- Straight leads are designed for short and narrow vessels



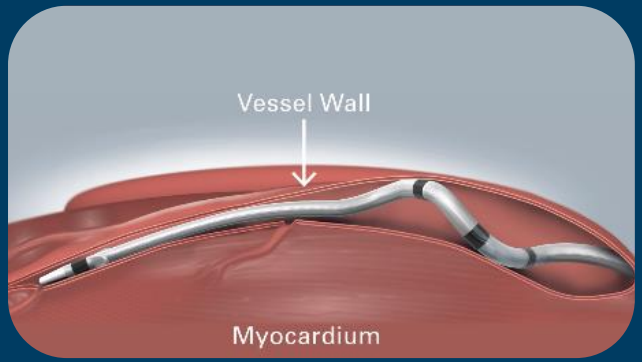
ACUITY X4 Lead Design

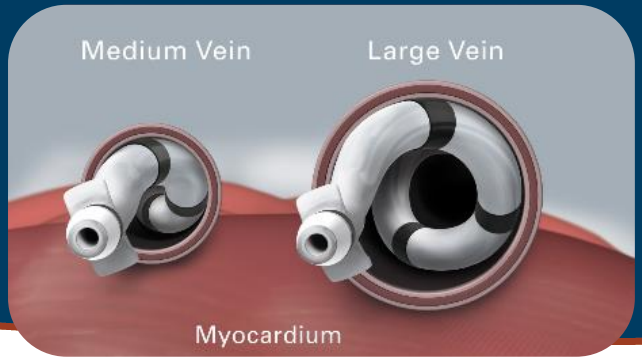
ACUITY X4 leads are designed for anatomical variation:

- Spiral L has 40mm spacing for long veins
- Spiral S has 25mm spacing for mid-ventricular termination
- Straight leads are designed for short and narrow vessels

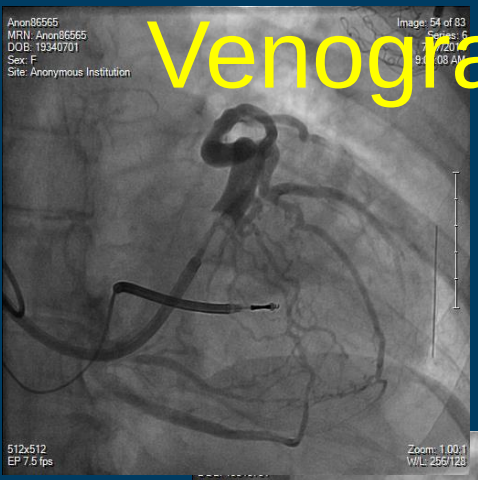


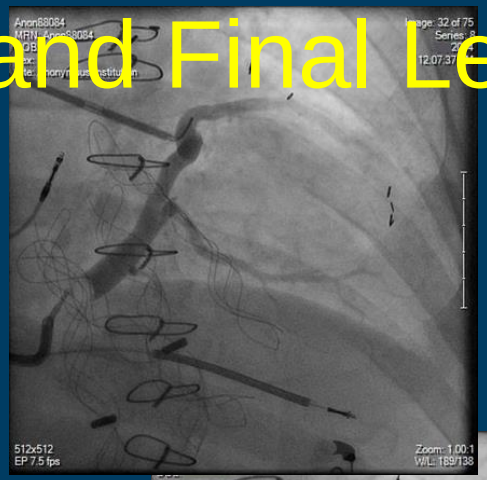
Lead Bias

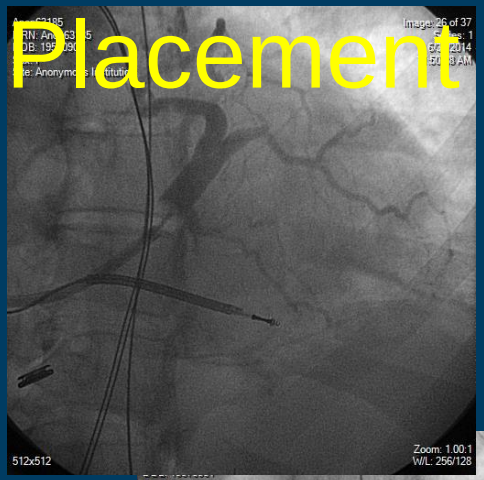


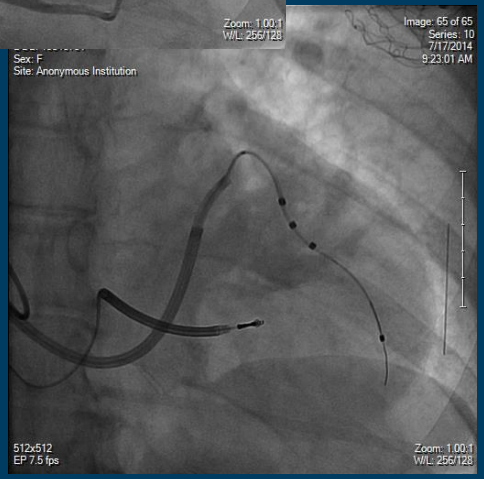


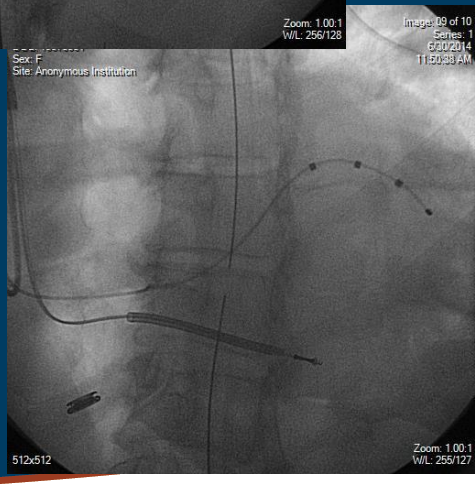
Venograms and Final Lead Placement











Spiral L

Spiral S

Straight

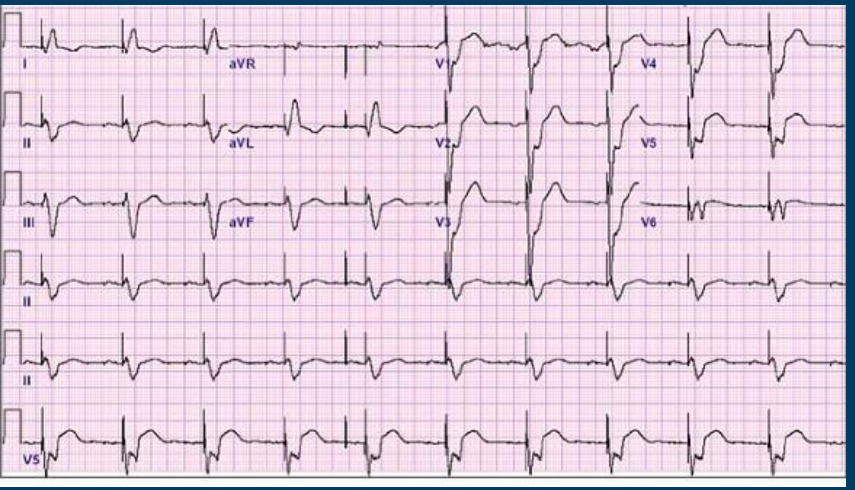
Heart Rhythm 2016

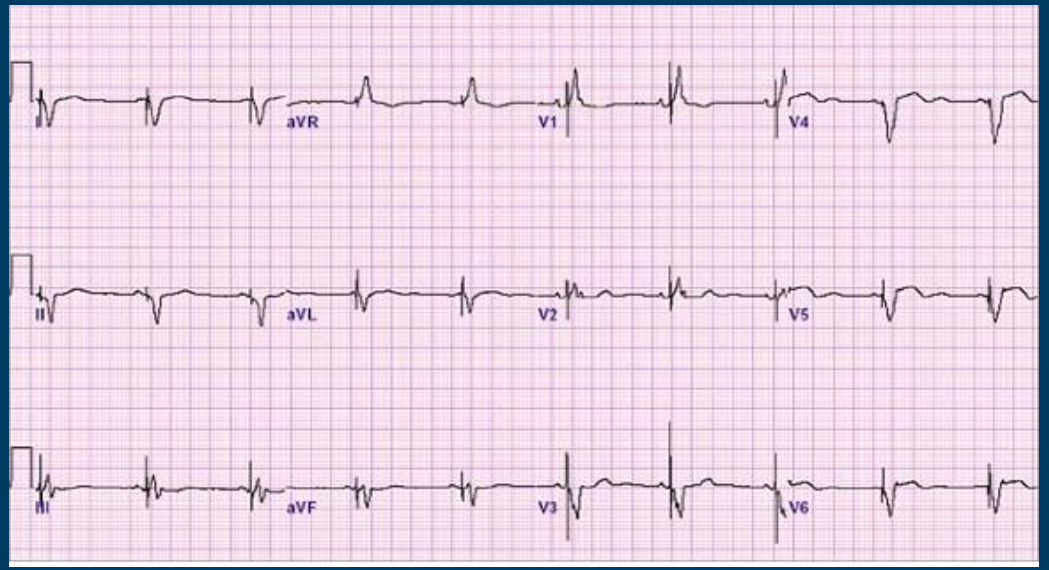
Suneet Mittal et al. J Am Coll Cardiol. 2016;67 (13 Suppl):824

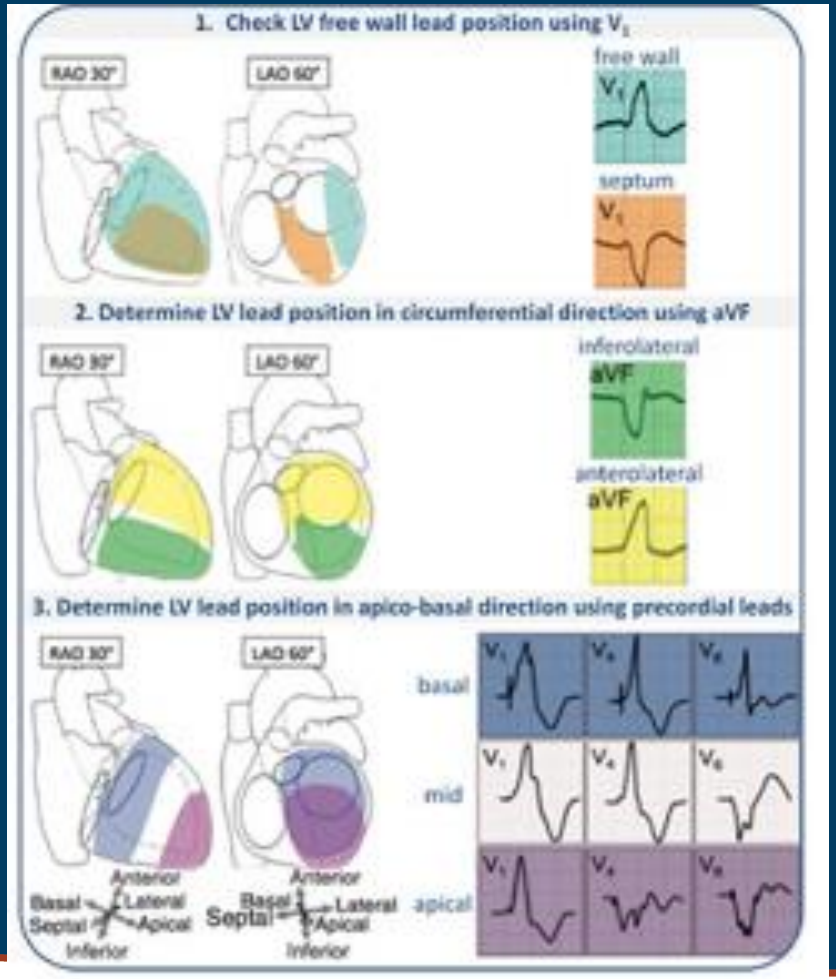
Techniques and Tools to Enable Targeted LV Lead Implantation

- Anatomical lead position
- Relationship with intrinsic ventricular activation
- Proximity to scar tissue
- Concordance with the segment of mechanical dyssynchrony

The surface EKG to ensure Bi-V capture







Verifying lead position with 12 lead ECG

van Deursen, et al, J Electrocardiol, 2014. 47(2): p. 202-11.

The Holy Grail of CS Lead Placement

1. Good anatomic location
   - AVOID apical location
2. Good pacing threshold
   - Ensure LV capture and good battery longevity
3. No phrenic nerve capture
   - Ideally none @ 10V on the table, choosing electrode with a good safety margin
4. Good lead stability
   - Doing a venogram and choosing the right LV lead
5. Programming device to being patient specific
   - AV / VV timing

ACUITY™ X4 Quadripolar LV Leads

Indications

This Boston Scientific lead is indicated for use as follows: Intended for chronic, left-ventricular pacing and sensing via the coronary venous system when used in conjunction with a compatible pulse generator. The Boston Scientific ACUITY X4 lead is a steroid0eluting (dexamethasone acetate) IS4 quadripolar lead.

Contraindications

Use of this Boston Scientific lead is contraindicated for the following patients: Patients with a hypersensitivity to a maximum single dose of 0.54 mg dexamethasone acetate.

Warnings

Read the manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. Such damage can result in patient injury or death. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. When using a right ventricular (RV) pace/sense lead in conjunction with this left coronary venous pace/sense lead, it is recommended that a polyurethane- insulated lead be used. Lead fracture, dislodgment, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both. Although pliable, the lead is not designed to tolerate excessive flexing, bending or tension. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. Use caution handling the lead terminal when the Connector tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats and clamps. Do not contact any other portion of the lead terminal, other than the terminal pin, even when the lead cap is in place. When implanting a system which uses both a DF4-LLHH/LLHO2 and IS4-LLLL3 lead, ensure that the leads are inserted and secured in the appropriate ports. Only use the Connector Tool for electrical connections to pacing system analyzers or similar monitors. Take care to obtain appropriate electrode position. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents.

Precautions

Refer to the lead product labeling for cautions specific to clinical considerations, sterilization and storage, handling, implanting hospital and medical environments, and testing the lead. Failure to observe these cautions could result in incorrect lead implantation, lead damage and/or harm to the patient.

Potential Adverse Events

Potential adverse events include, but are not limited to the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation /lead tip)hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, procedure-related, and component failure. In rare cases severe complications or device failures can occur.

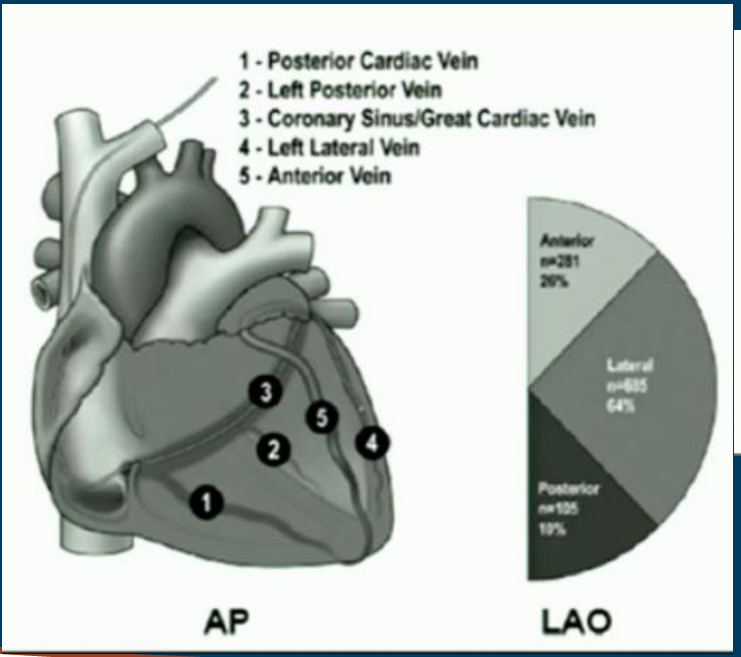
Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev. A)

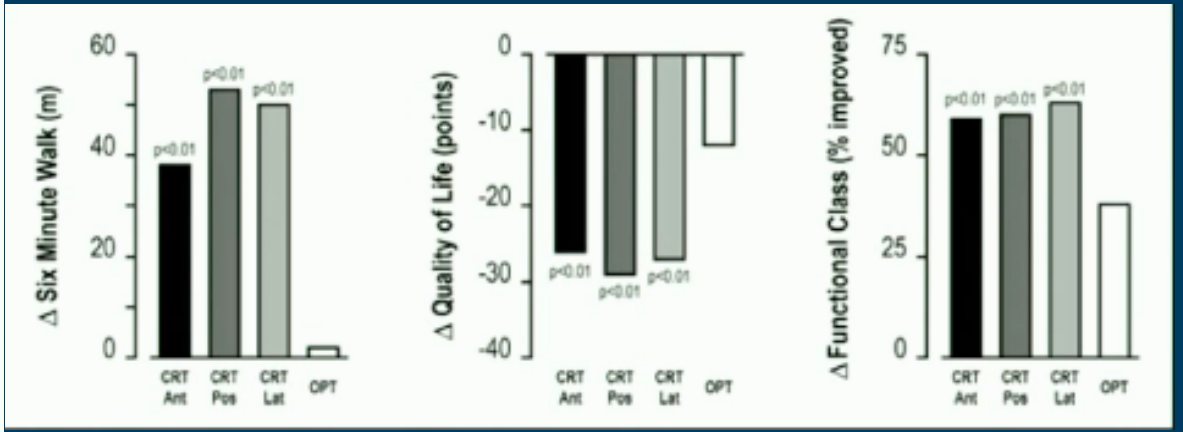
THANK YOU

BACK UP SLIDES

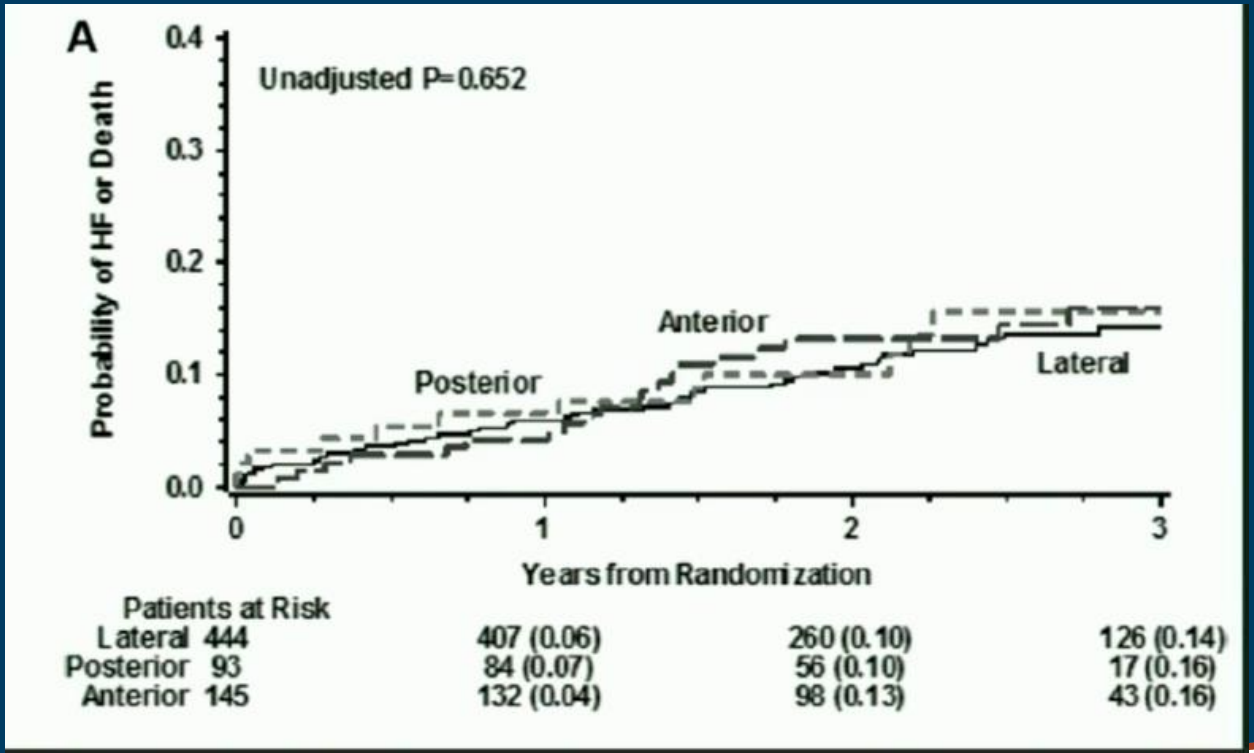
Anatomical Lead position

Functional outcomes in Companion Trial





Saxon et al. JCE 2009

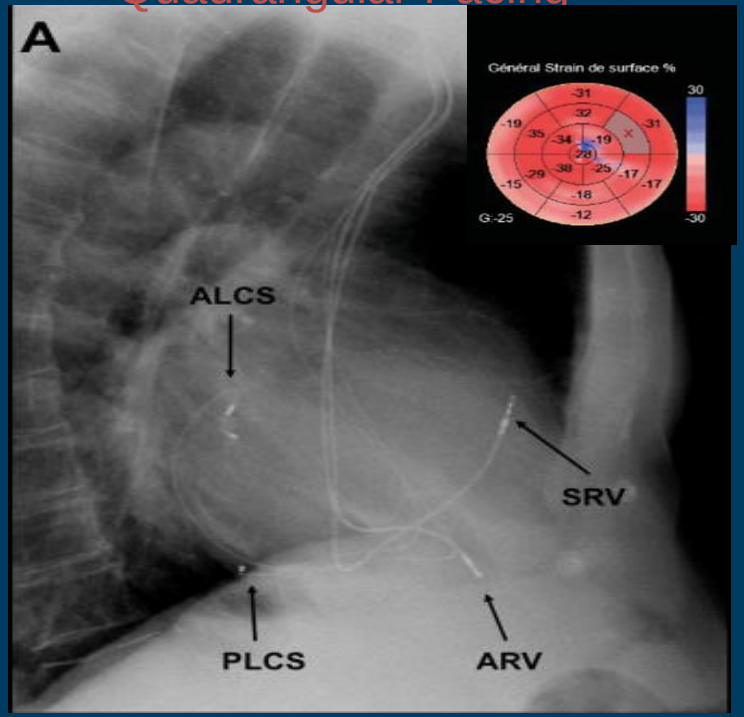


Jagmeet P. Singh et al. Circulation. 2011;123:1159-1166 (MADIT CRT study)

Recruiting & Synchronizing in Non-responders

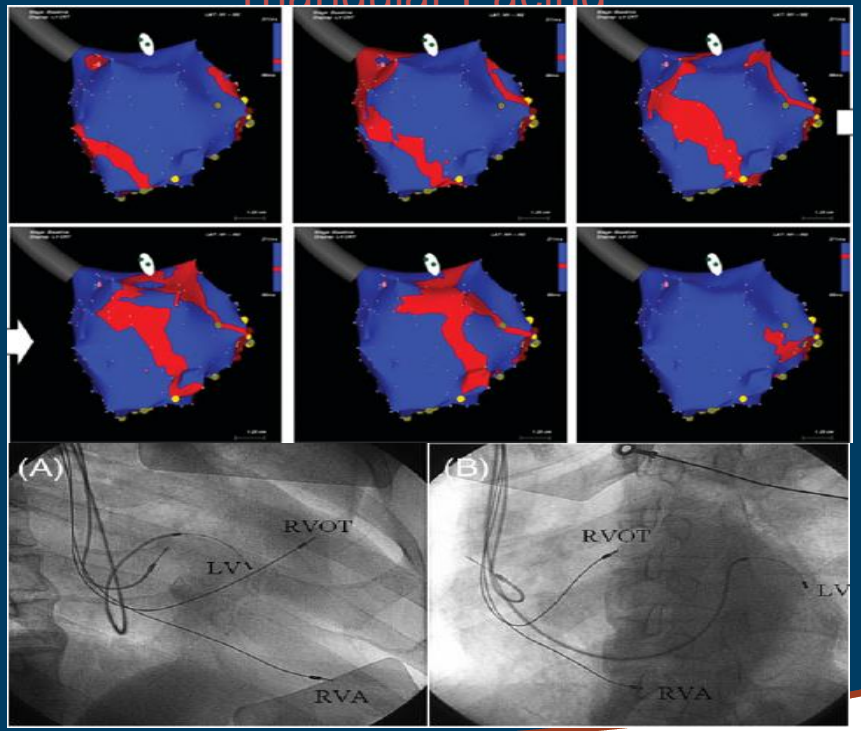
Triangular & Quadrangular Pacing

Quadrangular Pacing



Clementy N et al: EHJ 2011

Triangular Pacing



Yoshida et al: EHJ 2007;28:2610-19

Heart Rhythm 2016