Pacing the left ventricle with quadripolar spiral leads

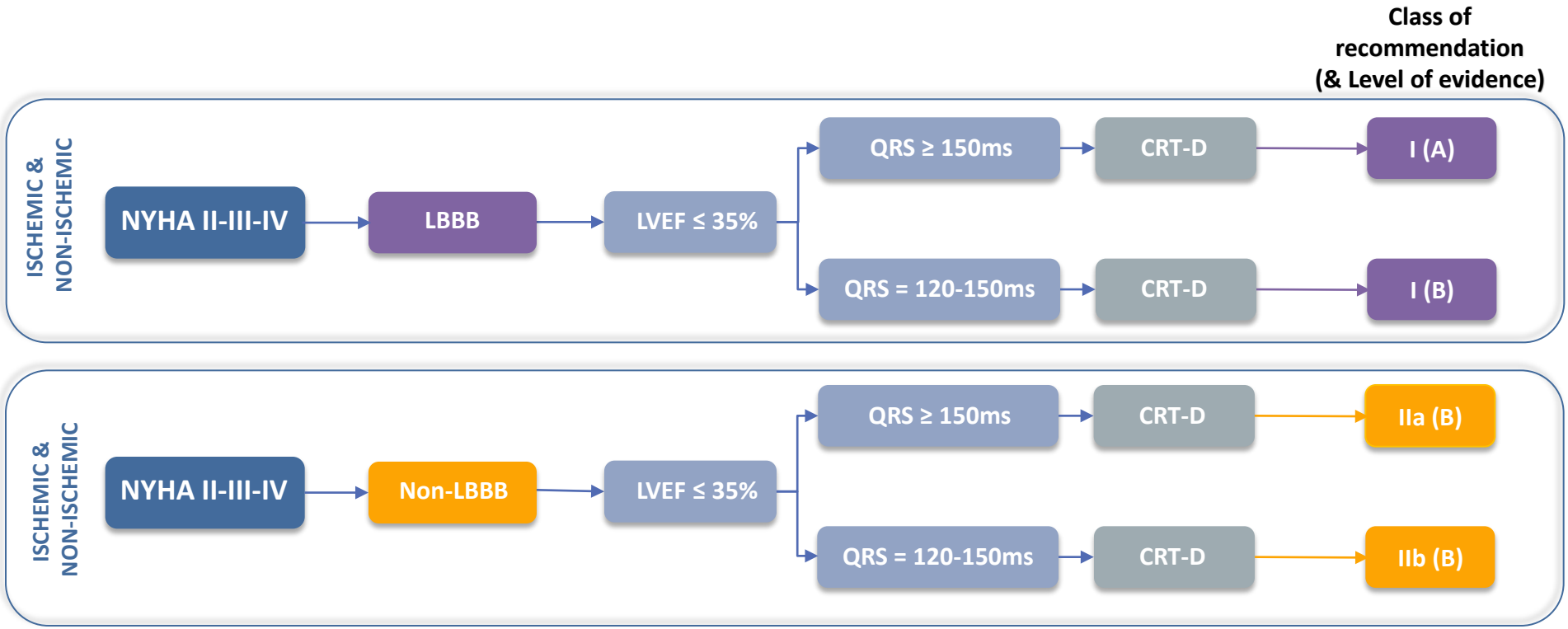
A. Reggiani

Symposium: New technologies for the heart

Advances in Cardiac Arrhythmias Turin 24.10.2014

CRT indications

CRT indications in chronic HF patients in sinus rhythm with OPT* and life expectancy >1 year



Class I = Is recommended

Class IIa = Should be considered

Class IIb = May be considered

*OPT: Optimal Medical Treatment.

1. 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy - European Heart Journal doi:10.1093/eurheartj/eht150

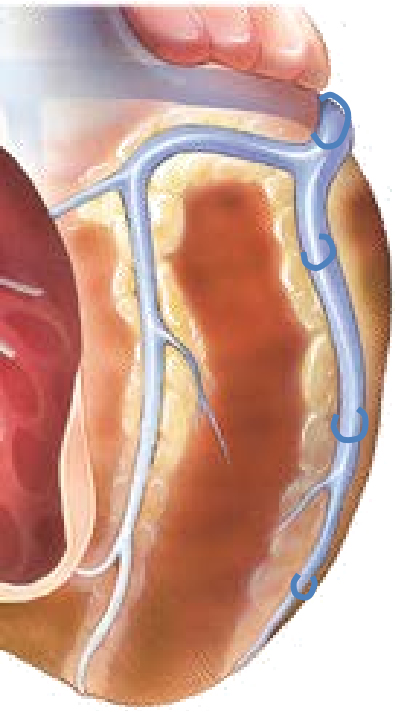
ESC Guidelines 2013: Choice of Pacing Mode

3 recommendations are provided regarding the choice of pacing mode and CRT optimization, **including one on non-apical pacing**:

	Class of recommendation (& Level of evidence)
1. **The goal of CRT should be to achieve BiV pacing** as close to 100% as possible	IIa (B)
2. **Apical position of the LV lead should be avoided when possible**	IIa (B)
3. **LV lead placement may be targeted at the latest activated LV segment**	IIb (B)

1. 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy - European Heart Journal doi:10.1093/eurheartj/eht150

What are the current LV Lead Challenges?



	Challenges			
	Threshold[1]	Stability	PNS[2]	Patient Outcome[3]
Non-Apical	Worse capture (poor electrode-myocardial contact)	Higher risk of dislodgement	Better	Better
Apical	Better capture (close electrode-myocardial contact)	Lower risk of dislodgement	Worse	Worse

Non-Apical pacing locations, which shown to have better clinical outcomes, may be harder to achieve in the implant setting.

1. Dan Blendea, MD, PhD, Variability of coronary venous anatomy in patients undergoing cardiac resynchronization therapy: a high-speed rotational venography study, Heart Rhythm, Vol 4, No 9, September 2007.
2. Occurrence of phrenic nerve stimulation in cardiac resynchronization therapy patients: the role of left ventricular lead type and placement site.
3. 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy - European Heart Journal doi:10.1093/eurheartj/eht150

ESC Guidelines 2013: Non-apical pacing reference MADIT-CRT Sub-analysis

Study: Left Ventricular Lead Position and Clinical Outcome in MADIT-CRT Trial
Singh J. et al., Circulation, 2011[1]

- 799 patients evaluated for final LV lead location
- Patients NYHA Class I/II, EF ≤ 30%, QRS ≥ 130ms
- Average follow-up of 2,4 years
- **Per protocol, coronary venograms and chest x-rays at the time of device implantation**
- LV lead location **classified by core laboratory** at University of Rochester Medical Center

MADIT-CRT Sub-analysis
Angiographic Classification of LV Lead Position

- **MADIT-CRT protocol included:**
  - Preimplantation coronary venous angiograms in at least 2 orthogonal views
  - Postprocedural chest x-rays (anteroposterior and lateral views) before discharge

- LV lead position was **determined by Core Laboratory at University of Rochester Medical Center** based on the review of venous angiograms and x-rays

- **LV lead location was classified** according to:
  - Short axis: anterior, lateral, or posterior position
  - Long axis: basal, midventricular, or apical region

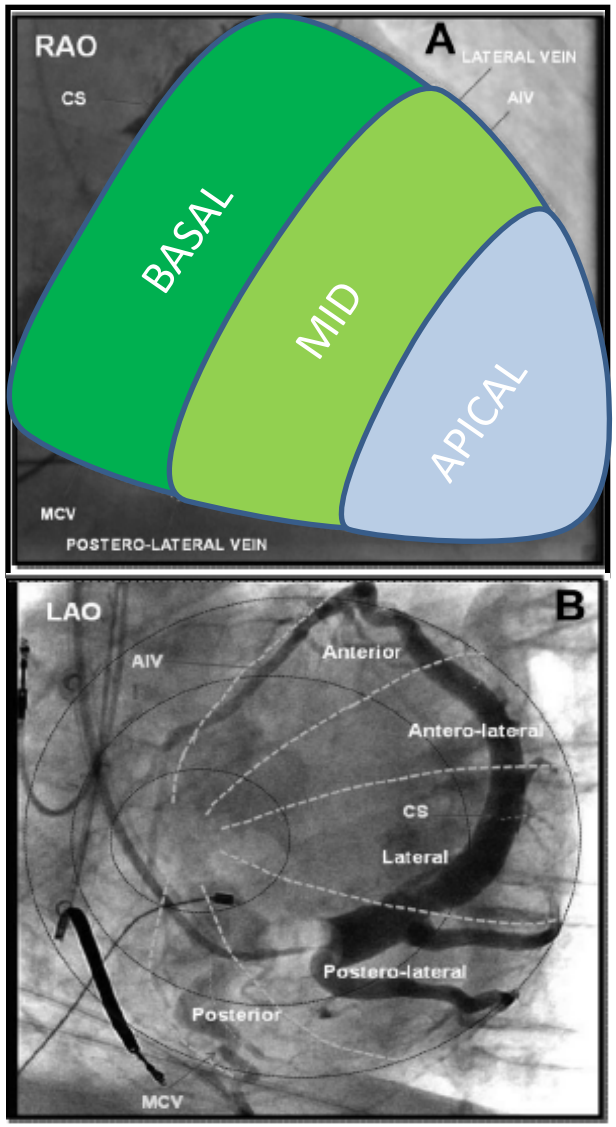


Figure: Angiographic Classification of LV Lead Position[1]

1. Page 1160, Figure 1, Singh JP et al. Left ventricular lead position and clinical outcome in the multicenter automatic defibrillator implantation trial-cardiac resynchronization therapy (MADIT-CRT) trial. Circulation 2011;123:1159–1166.

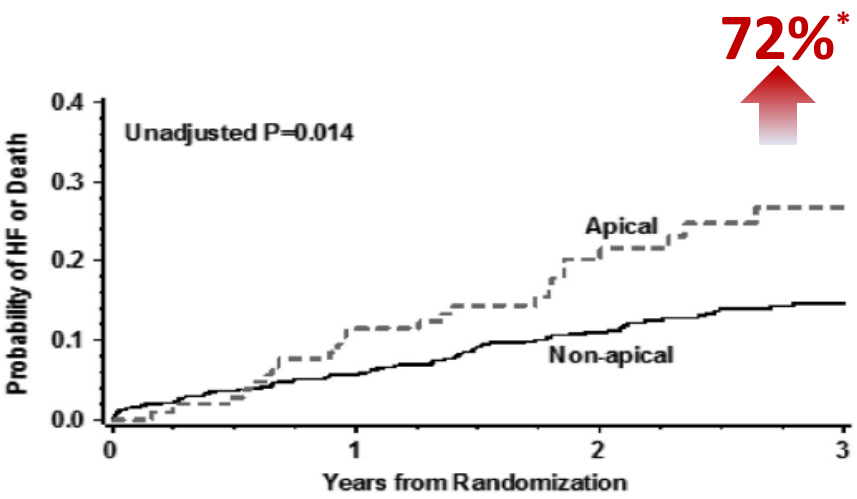
ESC Guidelines 2013: Non-apical pacing reference MADIT-CRT Sub-analysis

Study: Left Ventricular Lead Position and Clinical Outcome in MADIT-CRT Trial
Singh J. et al., Circulation, 2011[1]

Results	Apical vs Non-Apical
Death or HF event	**72% increased risk** (p=0.019*)
Death	**Risk multiplied by 2.91** (p=0.004*)

Conclusion

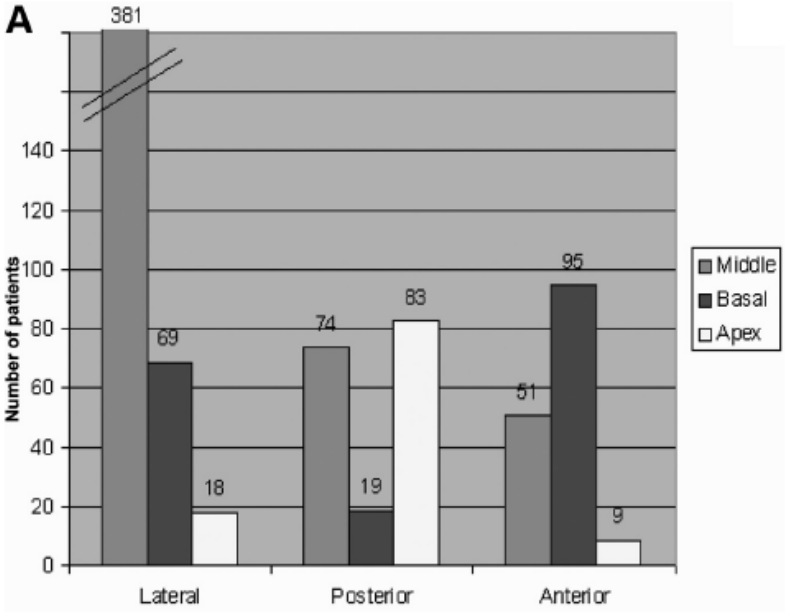
LV leads positioned in the apical region were associated with an unfavorable clinical outcome, suggesting that this lead location **should be avoided** in CRT.



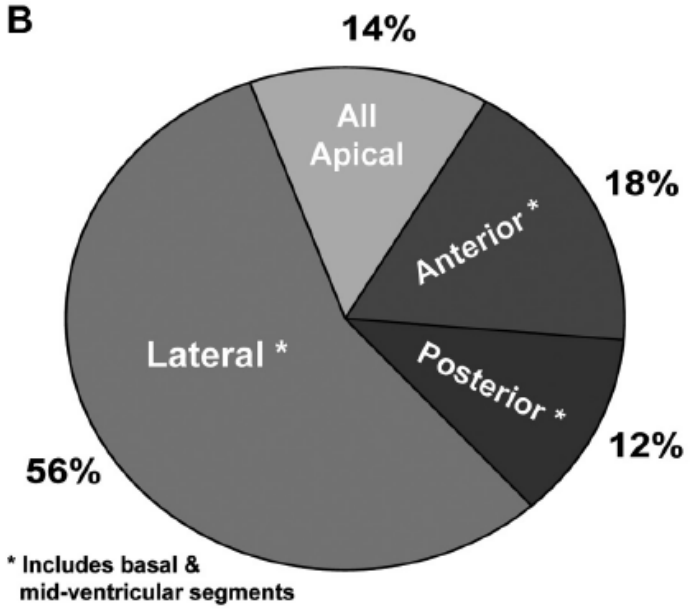
1. Singh JP et al. Left ventricular lead position and clinical outcome in the multicenter automatic defibrillator implantation trial-cardiac resynchronization therapy (MADIT-CRT) trial. Circulation 2011;123:1159–1166. *Adjusted significant p-value

MADIT-CRT Sub-analysis
Results of Classification of LV Lead Position

Figures: Distribution of LV lead location[1]



Distribution along the long and short axes of the heart



Distribution of apical vs non-apical location

- The 3 most predominant segmental lead locations were along the lateral-mid (38%), anterior-basal (12%), and postero-apical (10%) segments

1. Page 1161, Figure 2, Singh JP et al. Left ventricular lead position and clinical outcome in the multicenter automatic defibrillator implantation trial-cardiac resynchronization therapy (MADIT-CRT) trial. Circulation 2011;123:1159–1166.

REVERSE trial
Results of Classification of LV Lead Position

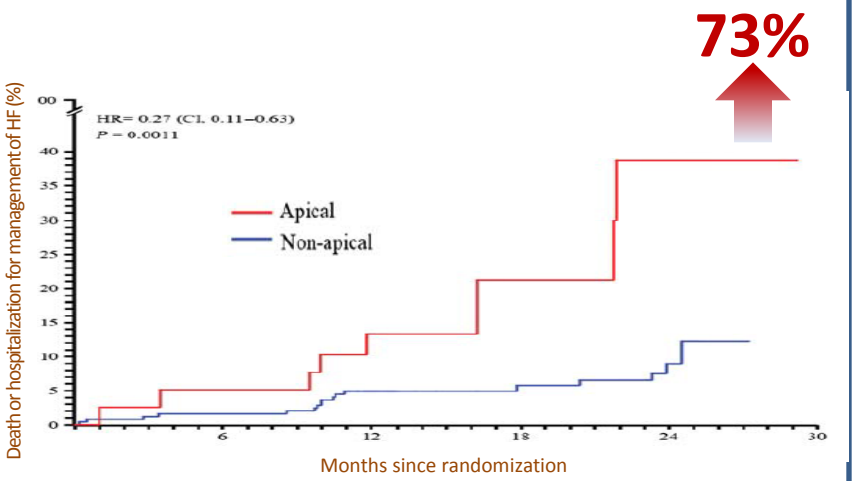
Study: Sites of LV and RV lead implantation and response to CRT observations from REVERSE trial. Thebault C et al., European Heart Journal, 2012[1]

- 346 patients included in analysis
- Patients NYHA Class I/II, EF ≤ 40%, QRS ≥ 120ms
- Average follow-up of 12,6 months
- **Per protocol, antero-posterior and lateral chest roentgenograms before discharge**
- LV lead location **determined by core laboratory** at Rennes University Medical Centre

REVERSE trial
Results of Classification of LV Lead Position

Study: Sites of LV and RV lead implantation and response to CRT observations from REVERSE trial. Thebault C et al., European Heart Journal, 2012[1]

Results	Apical vs Non-Apical
Death or HF hosp.	**73% increased risk** (p=0.001)
Echo responders*	**Significantly lower** (P=0.016)
QRS duration change	**Not significant** vs **Significant**
RV lead location	**No significant difference**



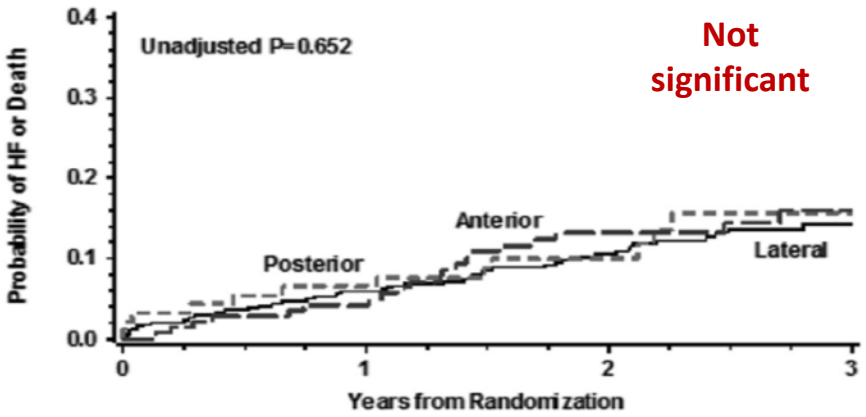
Conclusion

More favourable outcome of CRT (LV reverse remodelling, death or first HF hosp., long-term change in QRS duration) was observed when the LV lead tip was implanted in the lateral wall, **away from the apex**, while the **position of the RV lead tip was indifferent**.

1. Thebault C et al. Sites of left and right ventricular lead implantation and response to cardiac resynchronization therapy observations from the REVERSE trial. Eur Heart J 2012;33:2662–2671. *Defined as proportion of patients whose LVESVi had decreased by ≥15% at 12 months

Results on Posterior, Anterior, or Lateral pacing MADIT-CRT and REVERSE Sub-analysis

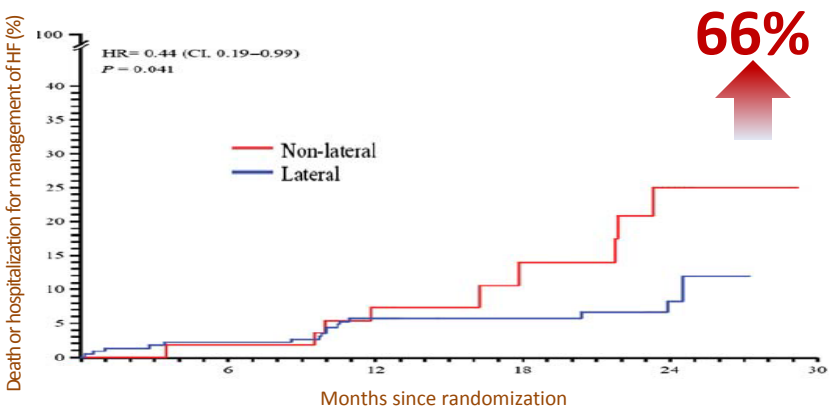
MADIT-CRT Sub-analysis[1]



Conclusion

The extent of CRT **benefit was similar** for leads in the **anterior, lateral, or posterior position**, excluding the apical lead positions

REVERSE Sub-analysis[2]



Conclusion

Lateral LV position was associated with a **significantly lower risk** of HF hospitalization or of all-cause mortality than non-lateral position (p=0.04)

- Discordant results might be explained by **different methodologies and proportions of leads placed in lateral positions** (59% in MADIT-CRT vs 80.4% in REVERSE recommended pacing site by protocol)
- ESC Guidelines: largely empirical practice is to pace lateral or posterolateral vein when possible

1. Page 1163, Figure 3A and 3B, Singh JP et al. Left ventricular lead position and clinical outcome in the multicenter automatic defibrillator implantation trial-cardiac resynchronization therapy (MADIT-CRT) trial. Circulation 2011;123:1159–1166. 2. Thebault C et al. Sites of left and right ventricular lead implantation and response to cardiac resynchronization therapy observations from the REVERSE trial. Eur Heart J 2012;33:2662–2671

Non-apical pacing
Additional literature review

Study: Impact of segmental left ventricle lead position on cardiac resynchronization therapy outcomes[1]. Merchant F. M. et al., Heart Rhythm, 2010[1]

- 115 patients in single center prospective study
- Symptomatic HF, EF ≤ 35%, QRS ≥ 120ms, LBBB
- Average follow-up of 15,1 months
- **Per protocol, posteroanterior (PA) and lateral CXRs before discharge**
- LV lead location **determined by investigator blinded** to the outcome data

1. Merchant FM, Heist EK, McCarty D, Kumar P, Das S, Blendea D, Ellinor PT, Mela T, Picard MH, Ruskin JN, Singh JP. Impact of segmental left ventricle lead position on cardiac resynchronization therapy outcomes. Heart Rhythm 2010;7: 639–644. *Adjusted significant p-value

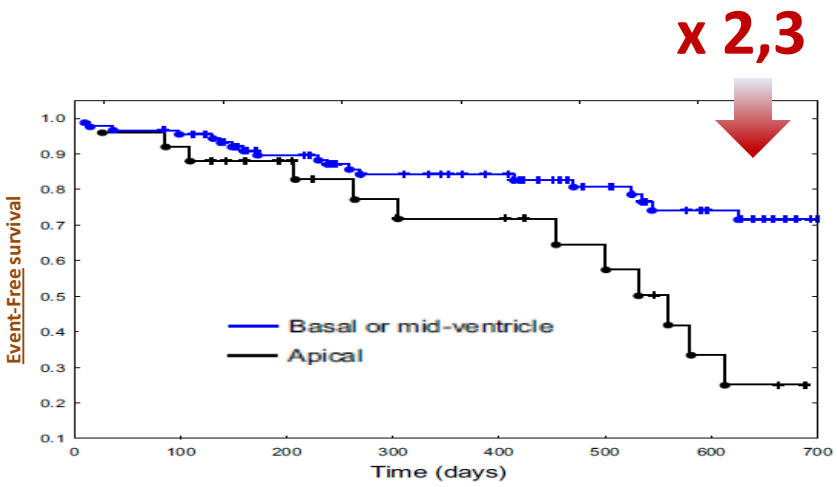
Apical vs Non-Apical pacing
Additional literature review

Study: Impact of segmental left ventricle lead position on cardiac resynchronization therapy outcomes[1]. Merchant F. M. et al., Heart Rhythm, 2010[1]

Results	Apical vs Non-Apical
HF hosp., cardiac transplantation, or all-cause mortality	**Risk multiplied by 2.3** (p=0.006*)

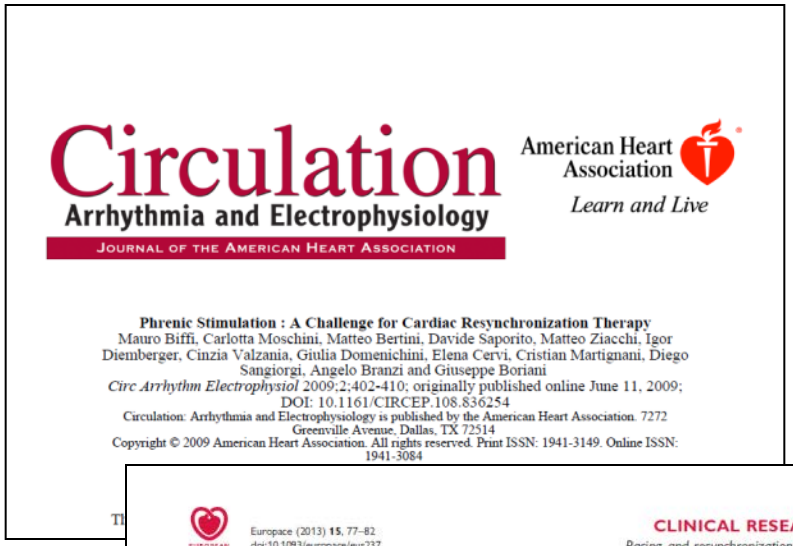
Conclusions

Apical LV lead placement is associated with **worse CRT outcomes**. Preferential positioning of LV leads in the **basal/ midventricle segments may improve outcomes.**



1. Merchant FM, Heist EK, McCarty D, Kumar P, Das S, Blendea D, Ellinor PT, Mela T, Picard MH, Ruskin JN, Singh JP. Impact of segmental left ventricle lead position on cardiac resynchronization therapy outcomes. Heart Rhythm 2010;7: 639–644. *Adjusted significant p-value

Phrenic Nerve Stimulation



Circulation
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Phrenic Stimulation : A Challenge for Cardiac Resynchronization Therapy

Mauro Biffi, Carlotta Moschini, Matteo Bertini, Davide Saporito, Matteo Ziacchi, Igor Diemberger, Cinzia Valzania, Giulia Domenichini, Elena Cervi, Cristian Martignani, Diego Sangiorgi, Angelo Branzi and Giuseppe Boriani

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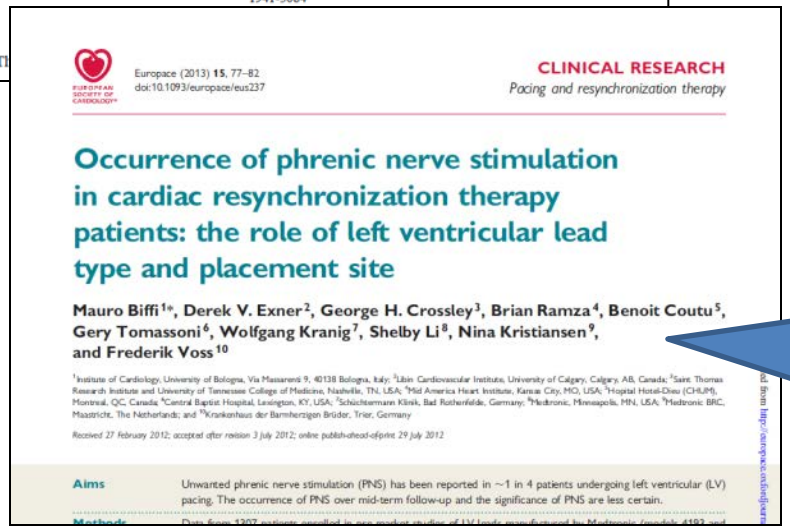

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doi:10.1093/europace/eus237

CLINICAL RESEARCH
Pacing and resynchronization therapy

Occurrence of phrenic nerve stimulation in cardiac resynchronization therapy patients: the role of left ventricular lead type and placement site

Mauro Biffi[1]*, Derek V. Exner[2], George H. Crossley[3], Brian Ramza[4], Benoit Coutu[5], Gery Tomassoni[6], Wolfgang Kranig[7], Shelby Li[8], Nina Kristiansen[9], and Frederik Voss[10]

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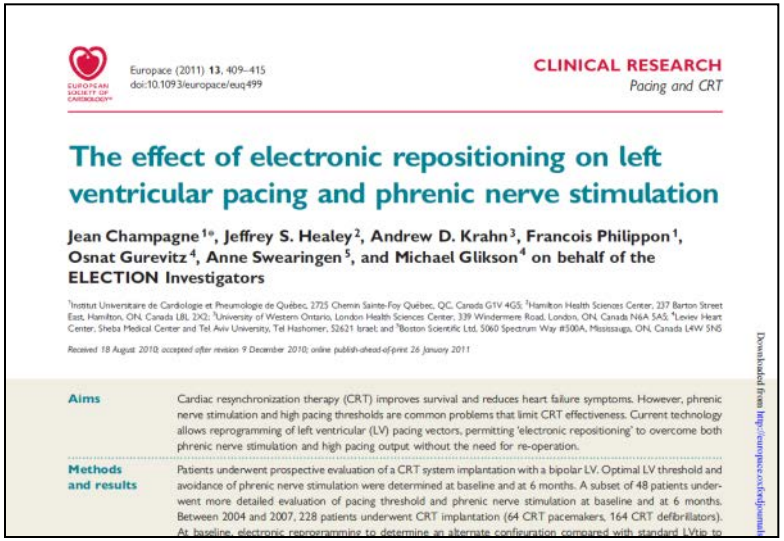
Aims Unwanted phrenic nerve stimulation (PNS) has been reported in ~1 in 4 patients undergoing left ventricular (LV) pacing. The occurrence of PNS over mid-term follow-up and the significance of PNS are less certain.

Methods Data from 1307 patients enrolled in one pivotal study of LV leads manufactured by Medtronic (models 4193 and



Europace (2011) **13**, 409–415
doi:10.1093/europace/euq499

CLINICAL RESEARCH
Pacing and CRT

The effect of electronic repositioning on left ventricular pacing and phrenic nerve stimulation

Jean Champagne[1]*, Jeffrey S. Healey[2], Andrew D. Krahn[3], Francois Philippon[1], Osnat Gurevitz[4], Anne Swearingen[5], and Michael Glikson[4] on behalf of the ELECTION Investigators

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Received 18 August 2010; accepted after revision 9 December 2010; online publish-ahead-of-print 26 January 2011

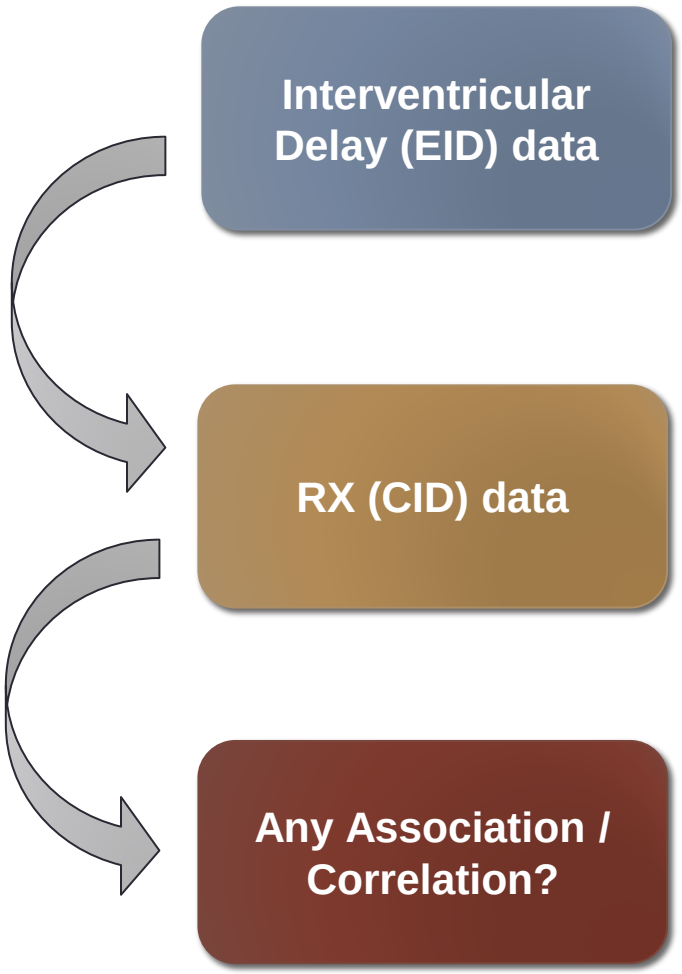
Aims Cardiac resynchronization therapy (CRT) improves survival and reduces heart failure symptoms. However, phrenic nerve stimulation and high pacing thresholds are common problems that limit CRT effectiveness. Current technology allows reprogramming of left ventricular (LV) pacing vectors, permitting 'electronic repositioning' to overcome both phrenic nerve stimulation and high pacing output without the need for re-operation.

Methods and results Patients underwent prospective evaluation of a CRT system implantation with a bipolar LV. Optimal LV threshold and avoidance of phrenic nerve stimulation were determined at baseline and at 6 months. A subset of 48 patients underwent more detailed evaluation of pacing threshold and phrenic nerve stimulation at baseline and at 6 months. Between 2004 and 2007, 228 patients underwent CRT implantation (64 CRT pacemakers, 164 CRT defibrillators). At baseline, electronic reprogramming to determine an alternate configuration compared with standard LVtip to

"Phrenic nerve stimulation occurred in 13% of patients undergoing LV lead placement and was **more common** at mid-lateral/posterior, and **LV apical sites**."*

*Occurrence of phrenic nerve stimulation in cardiac resynchronization therapy patients: the role of left ventricular lead type and placement site.

CRT More Registry
447 Pts with EID data, 240 Pts with EID & CID data

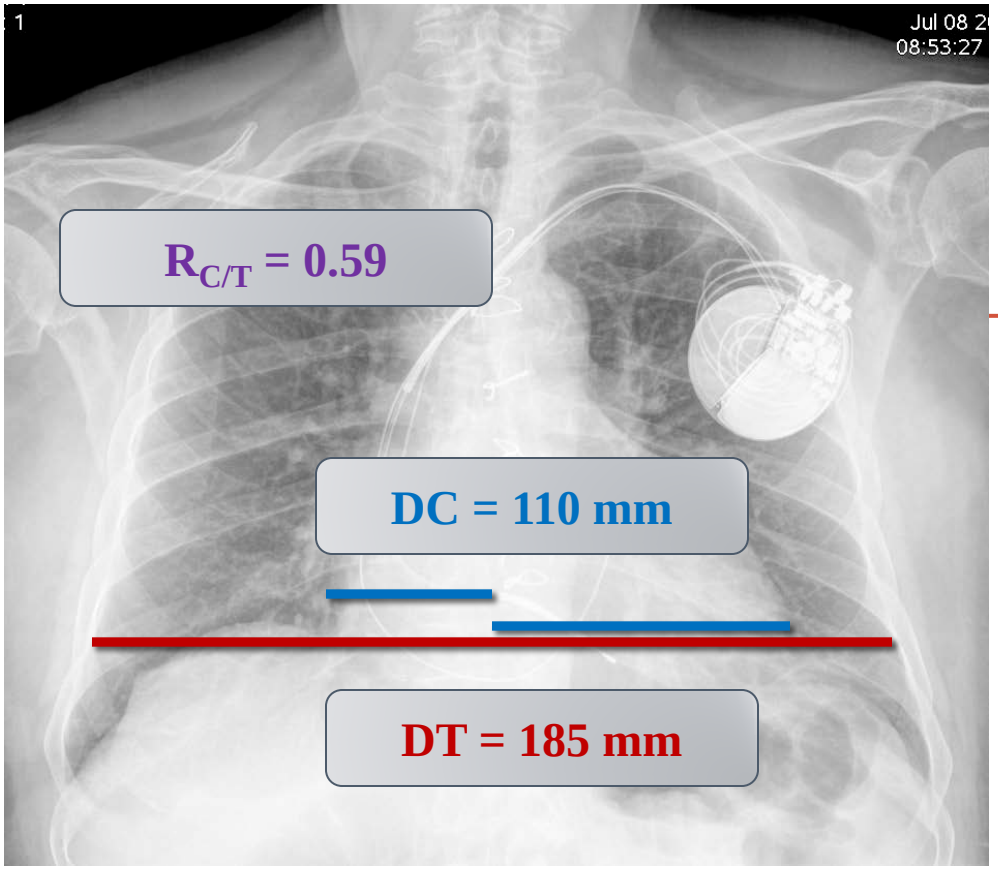


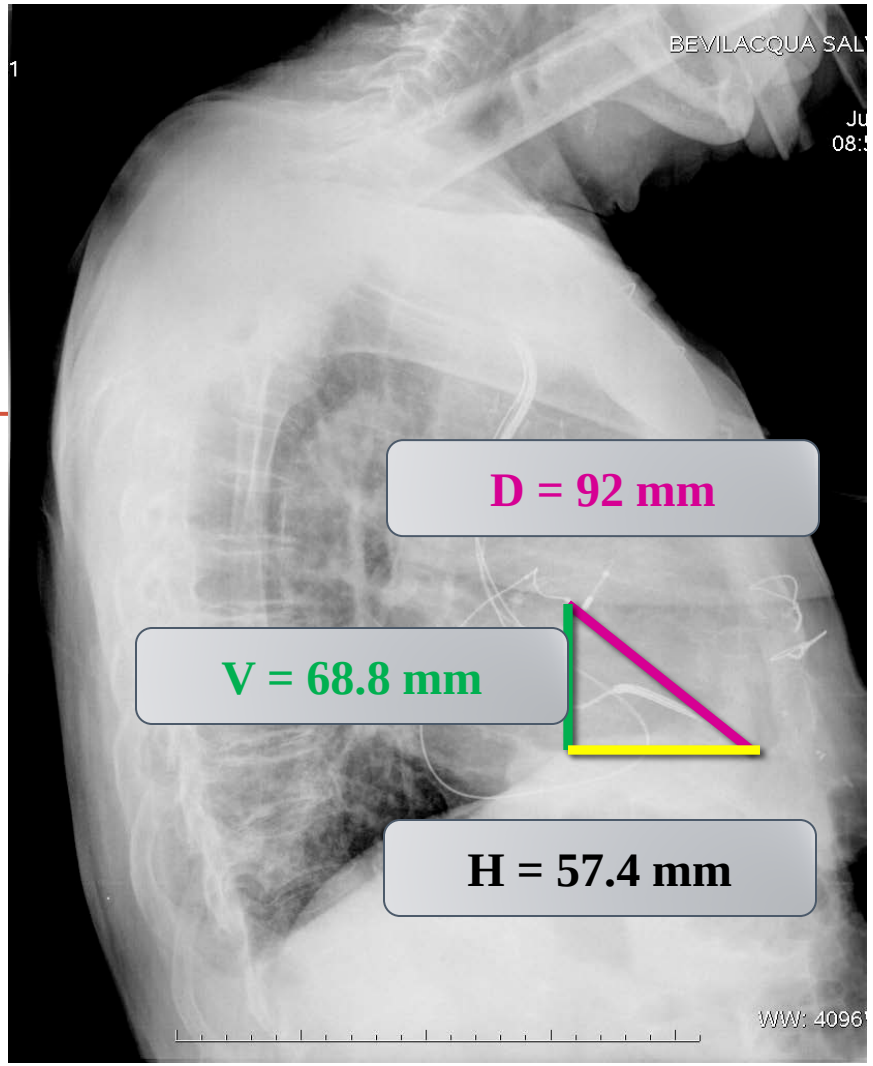
At the end of the implantation procedure, the electrical inter-lead distance (EID), defined as the time interval between spontaneous peak R-waves of the same QRS complex detected at the RV and LV pacing sites, was automatically measured by the device and printed on an electrocardiographic recording.

Geometrical distance between RV and LV leads was determined on chest X-rays in postero-anterior and lateral views, at maximal inspiration, typically on the day after device placement. The inter-lead distance (ID) was measured on a digital radiology workstation, together with the thoracic and cardiac widths. The ID values were divided by the cardio-thoracic ratio in order to take into account the relative differences in cardiac and thoracic sizes among patients, thus providing corrected inter-lead distances (CID): the direct (DCID) and the horizontal (HCID) corrected RV–LV electrode tip separation

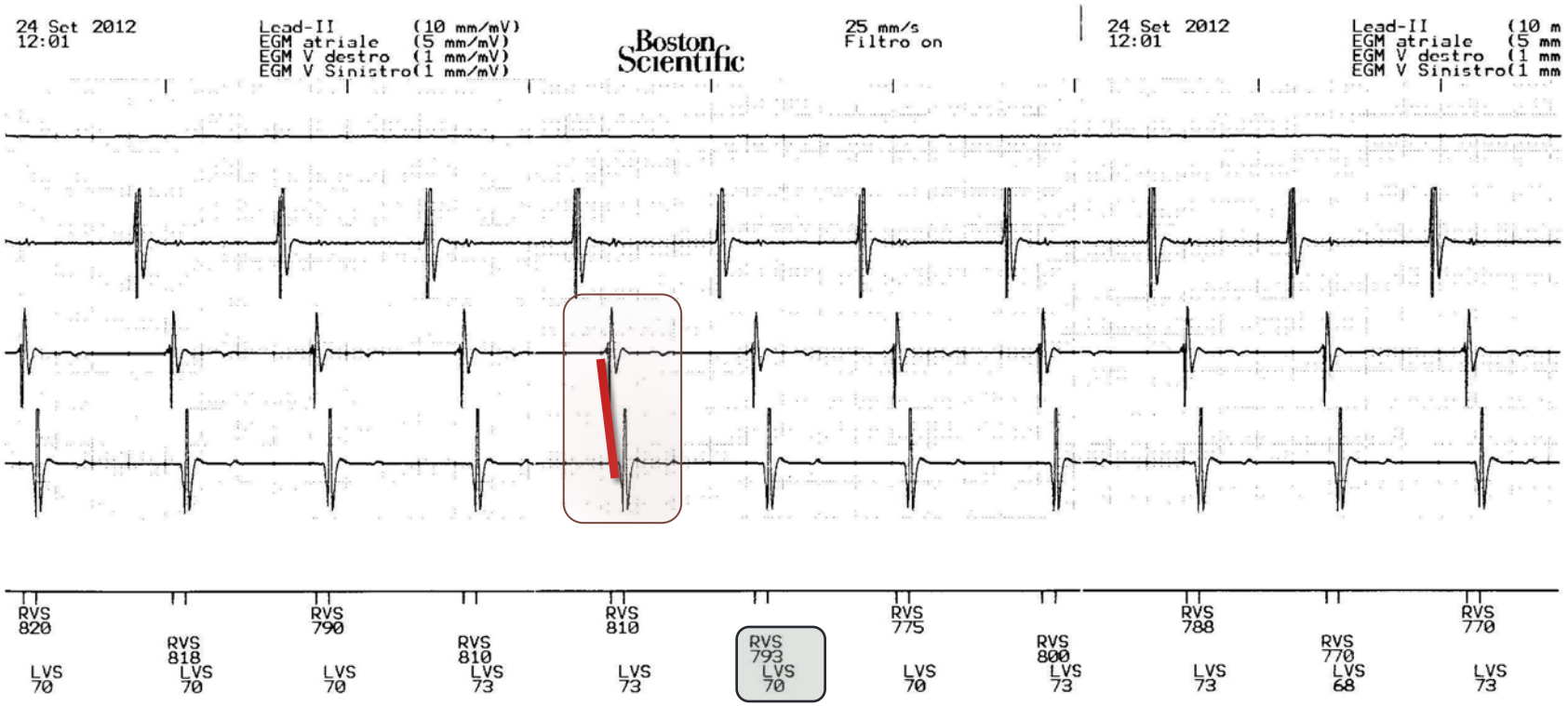
Both interventricular lead distance and spontaneous interventricular conduction time have been reported to predict the response to CRT and can be evaluated during the implantation procedure. The aim of our study was to evaluate the geometrical characteristics of interventricular electrical delay in an unselected population of patients with left bundle branch block (LBBB) undergoing CRT

RX (CID) data





Interventricular Delay (EID) data



Sensing Configuration

LV tip/LV Ring

CID Results

n (%)	Anteriore / Antero-laterale	Laterale	Posteriore / Postero-laterale	Totale
Basale	24 (10%)	23 (10%)	6 (3%)	53 (22%)
Media	31 (13%)	91(40%)	39 (16%)	161 (67%)
Apicale	0 (0%)	13 (5%)	13 (5%)	26 (11%)
Totale	55 (23%)	127 (53%)	58 (24%)	240 (100%)

RV position	RVA	RVS
n (%)	179 (75%)	61 (25%)

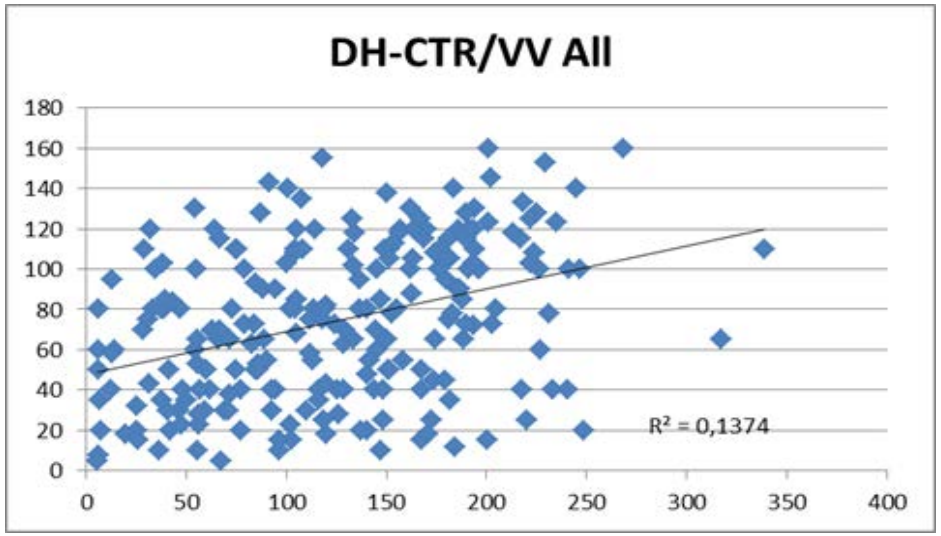
EID

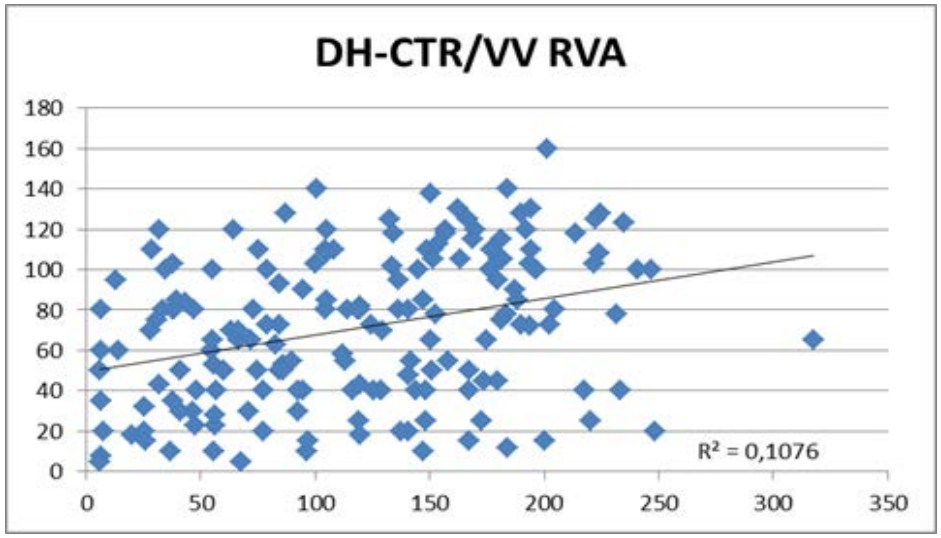
EID (mean)	76 ± 37 ms	Pt 240
EID (RV septal)	81 ± 37 ms	P=0.035 vs RV apical
EID (RV apical)	73 ± 37 ms	
EID (LV lat)	82 ± 32 ms	P=0.001 vs ant lat
EID (LV post lat)	83 ± 33 ms	P=0.001 vs ant lat
EID (LV antero lat)	56 ± 38 ms	
EID (LV basal)	72 ± 39 ms	
EID (LV med)	76 ± 38 ms	
EID (QRS > 158 ms)	85 ± 40 ms	P=0.001 vs QRS<158
EID (QRS < 158 ms)	69 ± 34 ms	

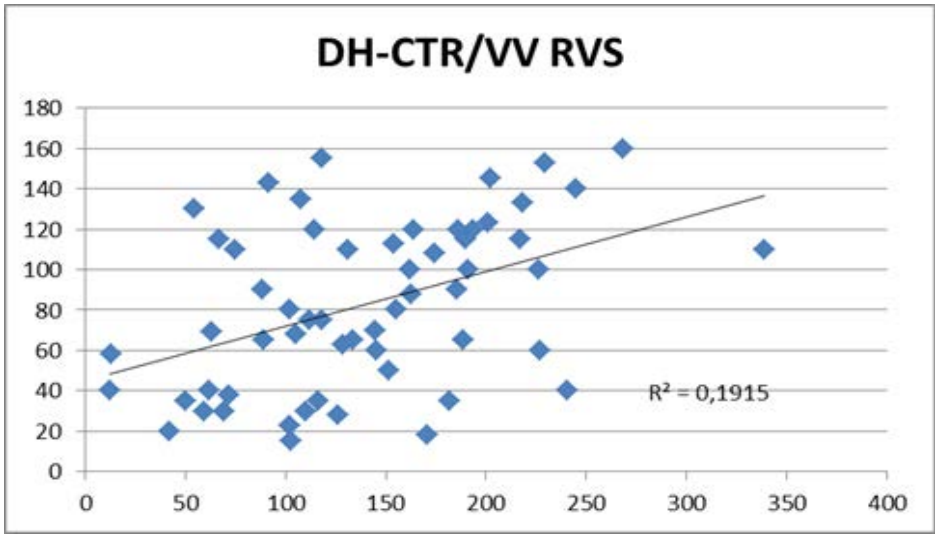
Association VV & CID

n (%)	HCID	DCID	EID	*p*
HCID ≥ 126 mm			87 ± 38 ms	
HCID < 126 mm			63 ± 35 ms	*p* < 0,001
DCID ≥ 155 mm			84 ± 39 ms	
DCID < 155 mm			64 ± 35 ms	*p* < 0,001
EID ≥ 76 ms	148 ± 70 mm	166 ± 55 mm		
EID < 76 ms	104 ± 63 mm	143 ± 52 mm		*both p* < 0,001

Correlation VV & HCID







Conclusion

There is an association between longer CIDs and greater EID *but* no correlation between them

Maximizing CID at implantation will not ensure optimal EID and vice versa

Many other factors, besides the lead position, may impact the overall electrical delay so an optimal anatomic site may not reflect the site with maximal electrical delay

Conventional lateral or postero-lateral LV segments might be preferred for lead positioning, as they are generally areas of late activation

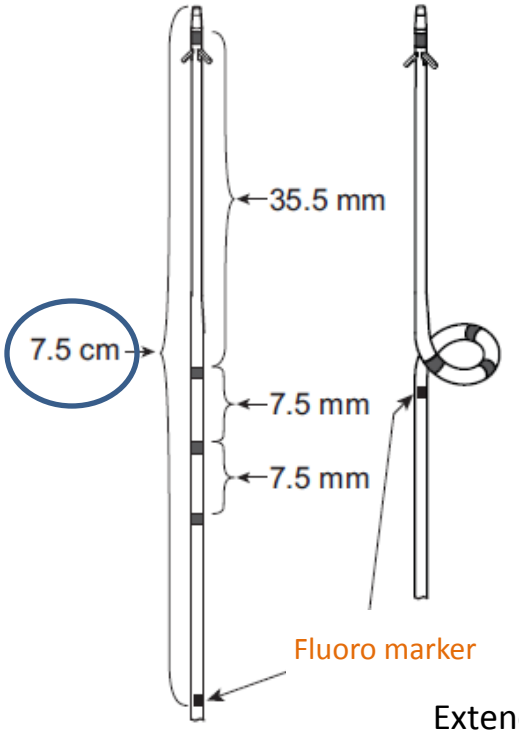
CRT : the challenges

- To position and to achive the stabilisation of the lead
- To pace basal/mid-ventricle with lower threshold
- To maximize the distance between left and right poles

Quadripolar leads designed to obtain basal LV pacing

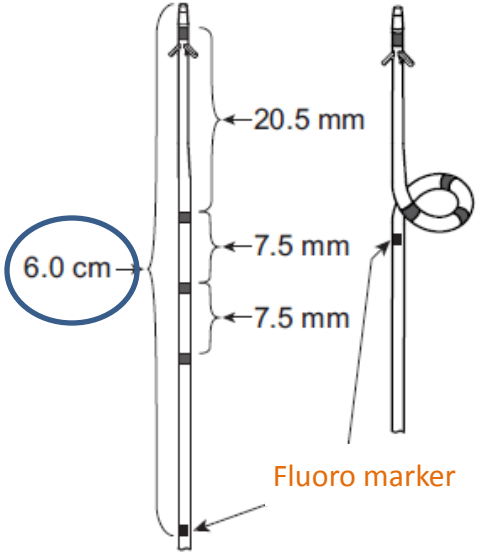
A **Fluoroscopic marker** indicates the proximal end of the spiral fixation on the 3D spiral models.

Spiral L

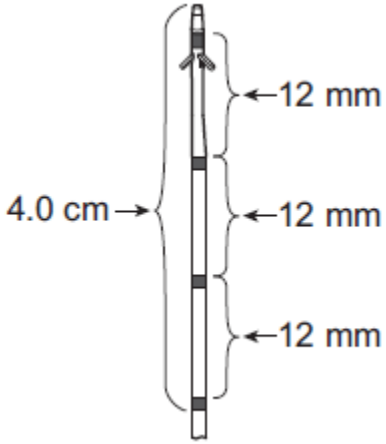


Extended straight tip with even spaced electrodes along a 3D spiral

Spiral S

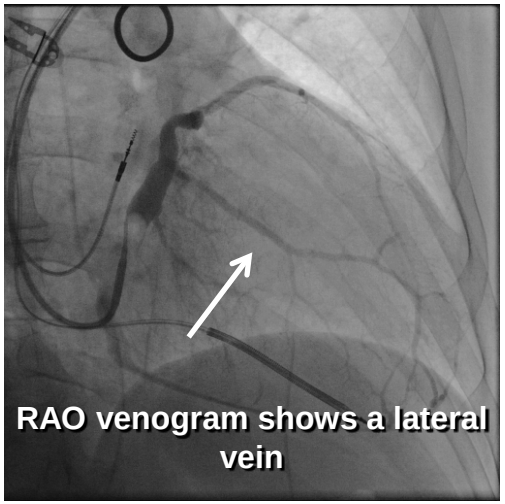


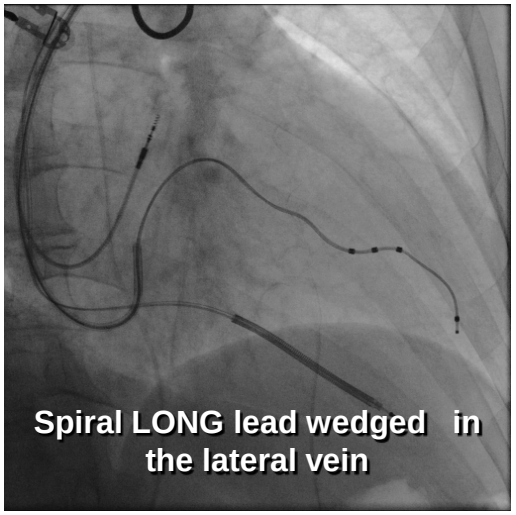
Straight

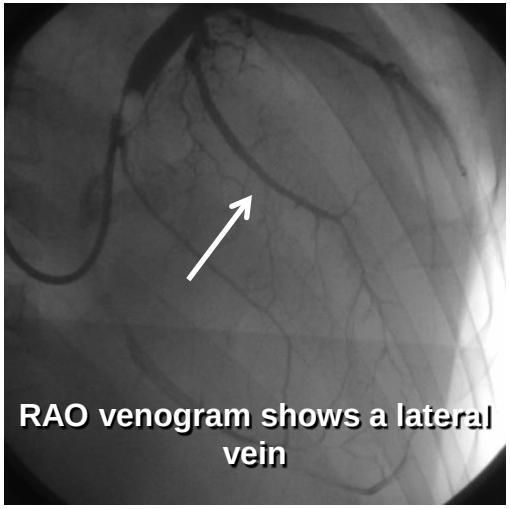


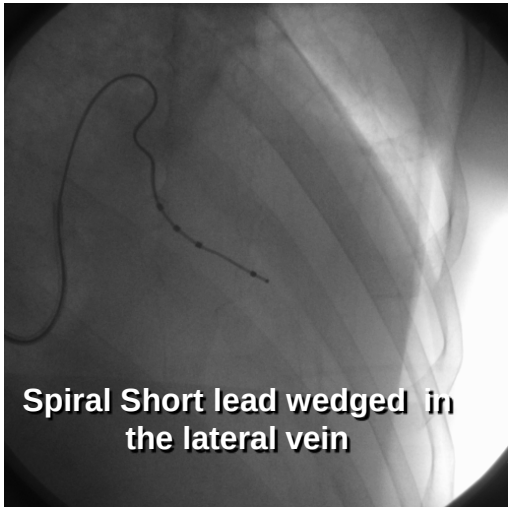
Straight lead body with even spaced electrodes

Different electrode spacing to accommodate individual anatomy and **pace at target location**



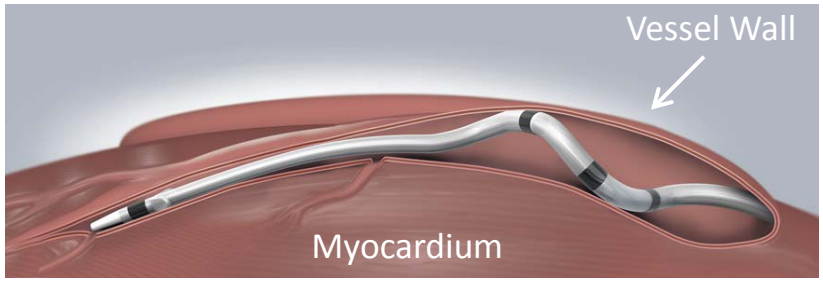




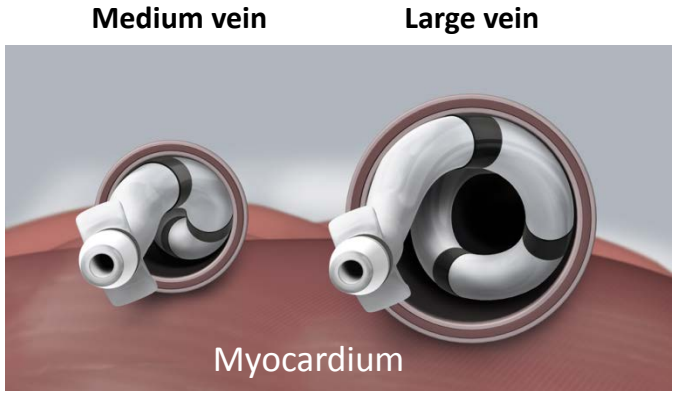


Optimize stability and electrode contact with the myocardium to minimize pacing capture thresholds (PCT) in a non-apical location

Side View



Cross Section



LILAC Acute Human Clinical Study Final Report

Spiral Electrodes with PCT≤ 2.5V[3]

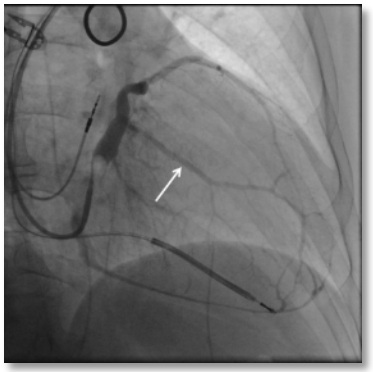
# of Electrodes	≥1	≥2	All 3
wedged	**87%**	63%	35%
unwedged	81%	47%	13%

- **More than 80% of patients** had at least one vector option in the spiral with PCT ≤2.5V in an unwedged, basal position (n = 46).

More pacing options
3 electrode spacing configurations

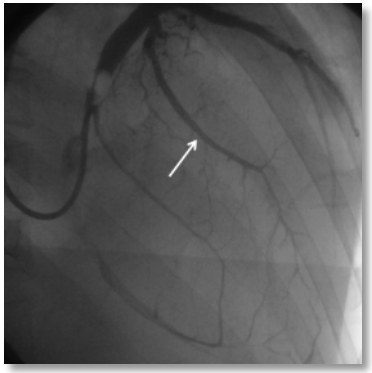
The Acuity™ X4 family of LV leads offers different electrode spacing to **accommodate individual anatomy** and to help you **pace at your target location**

Long veins



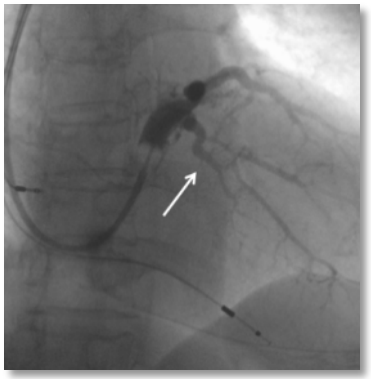
ACUITY™ X4 Spiral L

Short veins



ACUITY™ X4 Spiral S

Narrow or tortuous veins

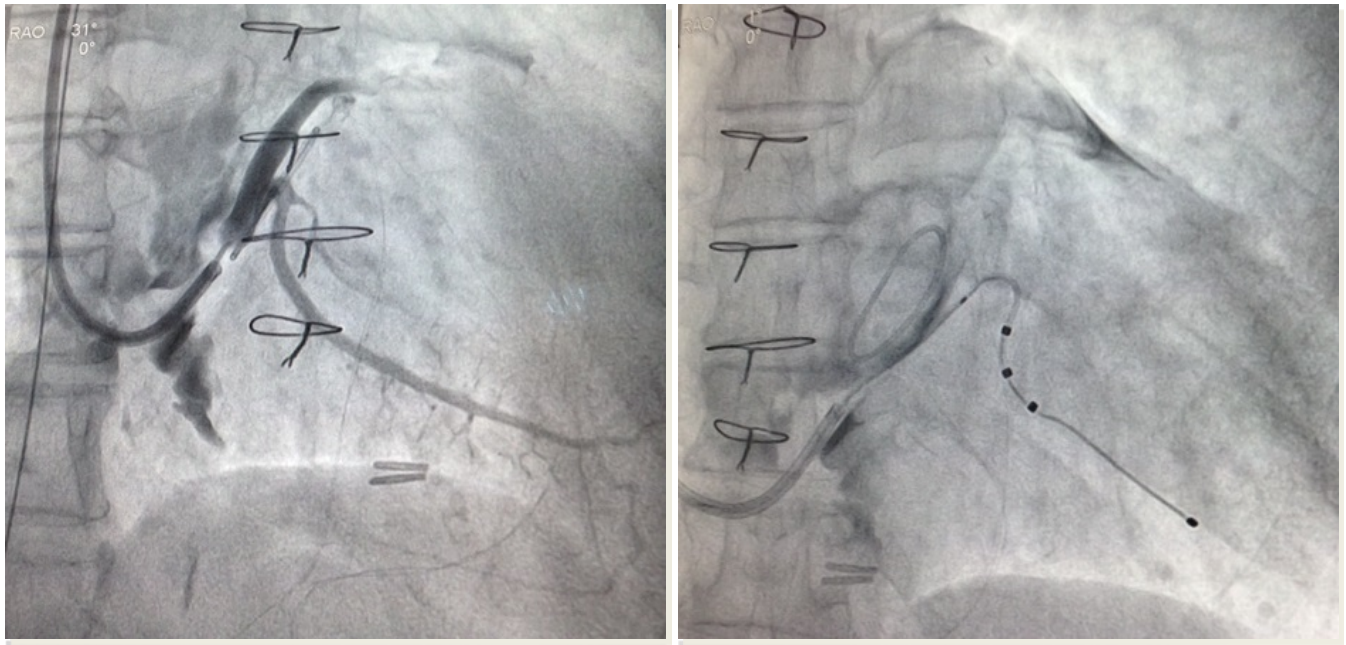


ACUITY™ X4 Straight

Photos taken by Boston Scientific

Case Report (Spiral X4 long)

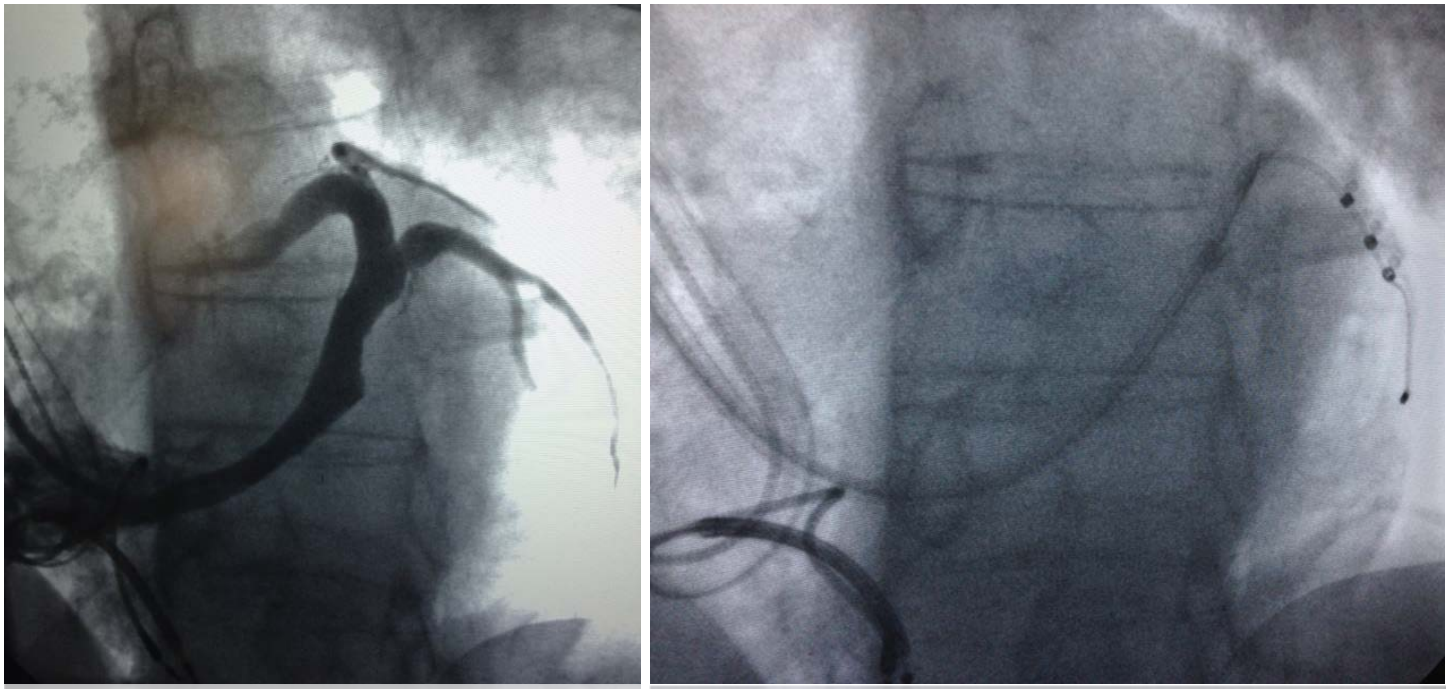
- **Implated device model:** Boston Scientific X4 CRT-D
- **Implated LV Lead:** ACUITY™ X4 Spiral Long



Case courtesy of Dott. Rovaris - San Gerardo Hospital - Monza, Italy

Case Report (Spiral X4 long)

- **Implated device model:** Boston Scientific X4 CRT-D
- **Implated LV Lead:** ACUITY™ X4 Spiral Long



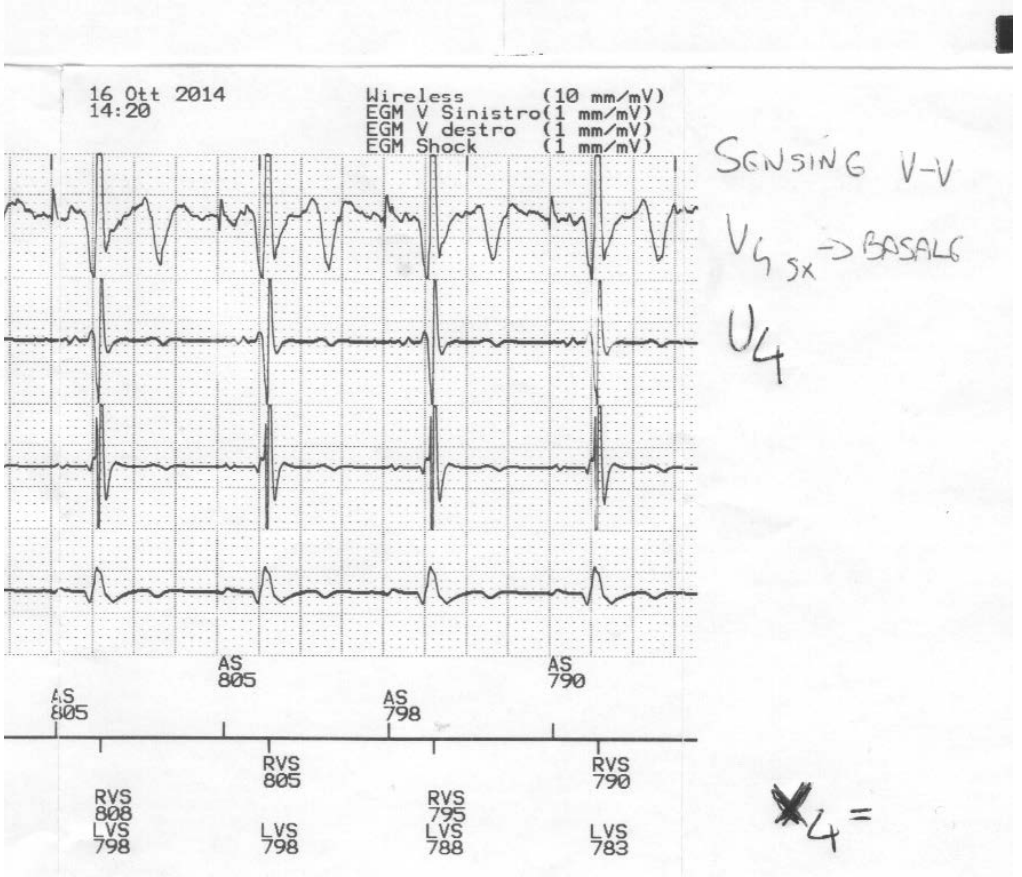
Case courtesy of Dott. Anaclerio - Policlinico - Bari, Italy

Case Report (VV measurement)

SENSING V-V

$V_{1\ Sx}$ -> APICALE

V_1



SENSING V-V

$V_{4\ Sx}$ -> BASALE

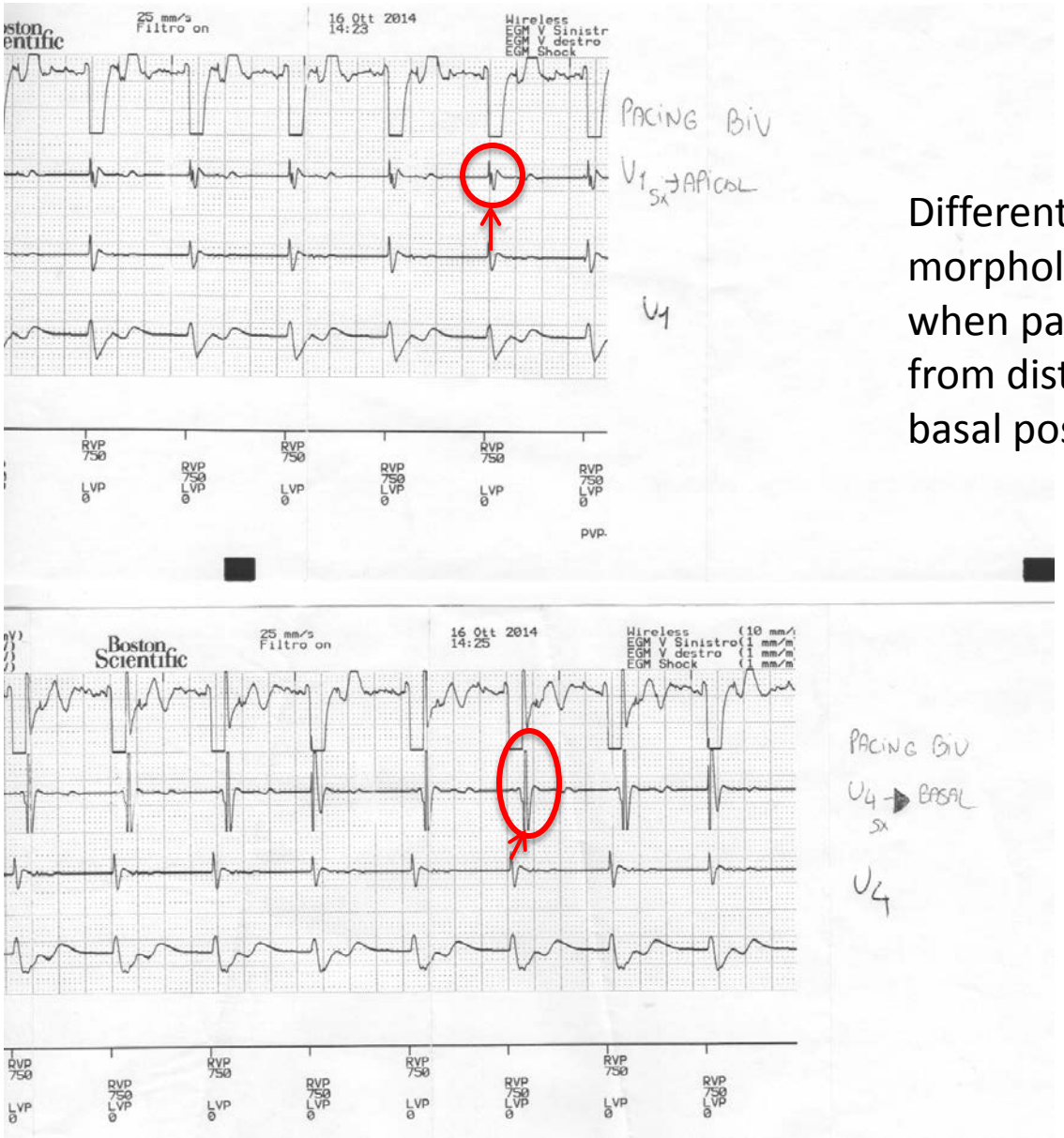
V_4

V_4 =

No difference in VV measurement (≈ 10 msec) between RV-LV, when LV pole is in distal or in basal position.

Possible explanation is the RV lead is placed in medium septal position and LV lead is placed in a lateral not wedget position.

Case Report (EGM during biv pacing)



Different delay and morphology in LV EGM when pacing come from distal position or basal position

Future developments

1) Autoreprogramming to pace the most delayed vector
2) Multi site pacing

Dynamic RV-LV Delay

- *Automatically re-programs to vector with longest RV-LV delay*

E1 => E2 → E2 => E3

Multi Site Pacing

- *Activate 2 or more electrodes simultaneously*

E1 & E2

3) At implant: selection of the appropriate vessel in order to maximize VV distance by mapping with an «electronic» guidewire

QLV GuideWire

- *Same .014" wire used for lead delivery*
- *Real-time QLV display*
- *1 electrode at tip*

4) Automatic tests performed by the device (sensing, delays, thresholds and PNS)

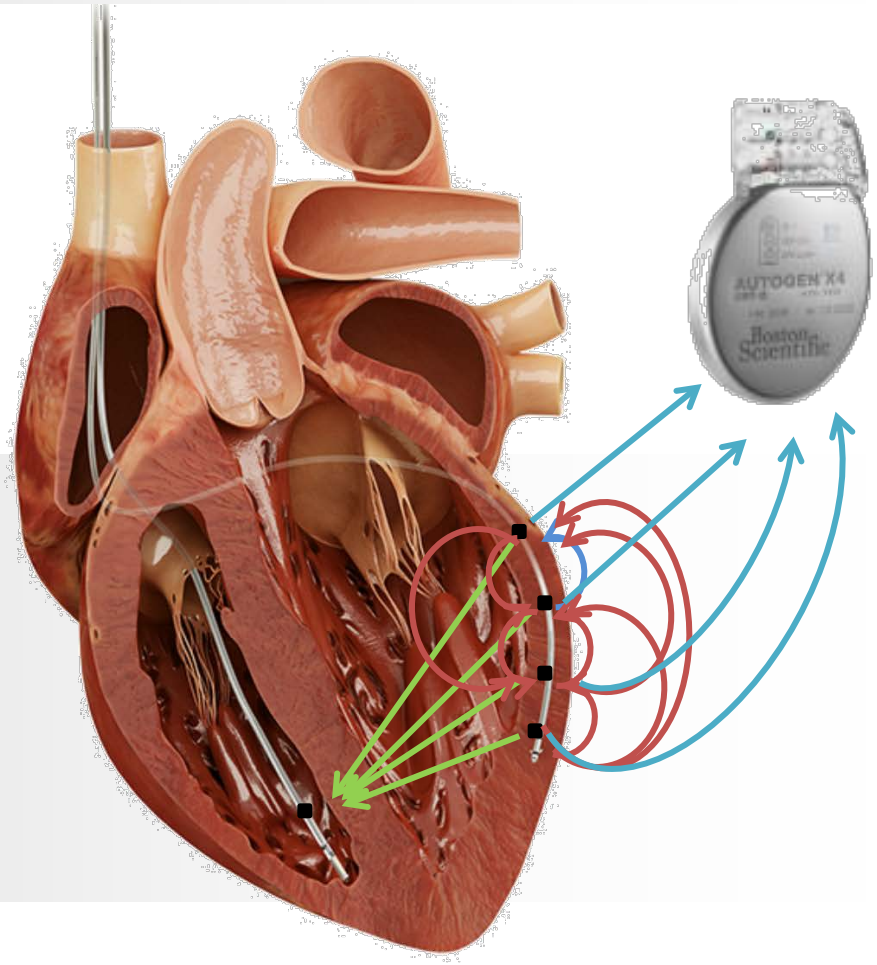
More pacing options
17 Vectors available

The X4 CRT-D System offers **17 vectors for maximum flexibility** when choosing lead position

17

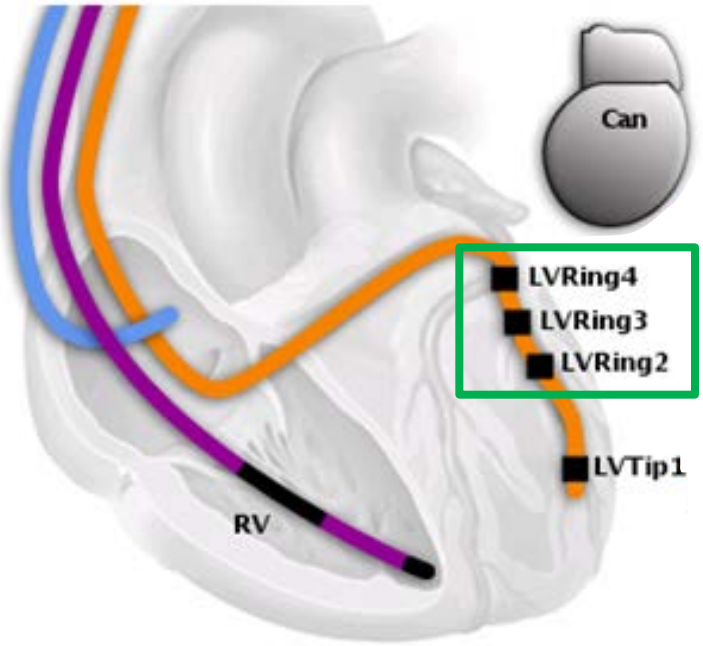
vectors for patient optimization

- 9 Bipolar
- 4 Extended Bipolar
- 4 Unipolar



More pacing options
Non-Apical pacing options

The X4 CRT-D System offers **12 proximal vectors** to help manage PNS and thresholds while still **pacing from a Non-Apical location**



Vector Options by Cathode

Cathode	Boston Scientific
LVRing4	4
LVRing3	4
LVRing2	4
LVTip1	5