New Advances & Technologies of CRT

Moamen El-Tawdy
CRM/EP product Manager
MBA

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Topics:

1.Quadripolar LV lead
2. Autovect select
3.MPP
4.SyncAV CRT
5.LV lead design

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CRT Therapy for Heart Failure Patients

CRT devices offer proven treatment for heart failure patients:

- Over 200,000 patients worldwide receive CRT devices each year[1]
- Many heart failure patients greatly benefit from CRT as it :
  - Electrically restore mechanical AV and ventricular synchrony
  - Reorganize the ventricular activation sequence
  - Coordinate septal and freewall contractions
  - Improve symptoms and enhance quality of life
  - Reverse Remoduling
  - Decrease the likelihood of disease progression & reduce the risk of death

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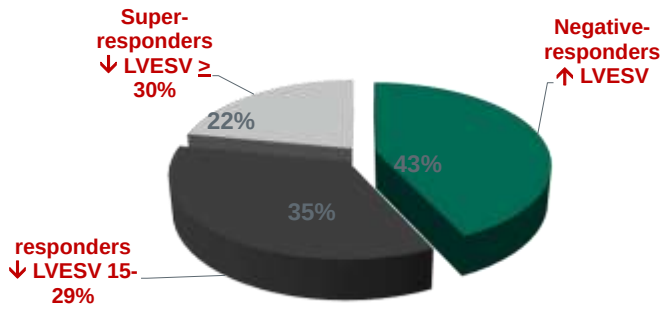
1. *Heart Rhythm Society Press Release, "CRT Consensus Set to Standardize and Improve Care for Patients Worldwide." Aug 27, 2012.*

The Varying Degrees of CRT Response



In a study (n=302), 43% of CRT patients could be classified as non-responders or negative-responders by LVESV after 6 months[1]

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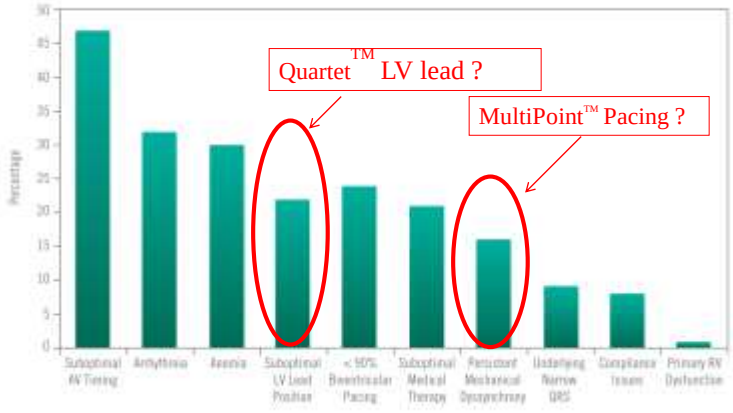
1. Ypenburg C et al. *J Am Coll Cardiol*. 2009;53(6):483-90.

Potential Reasons for Suboptimal Response in CRT

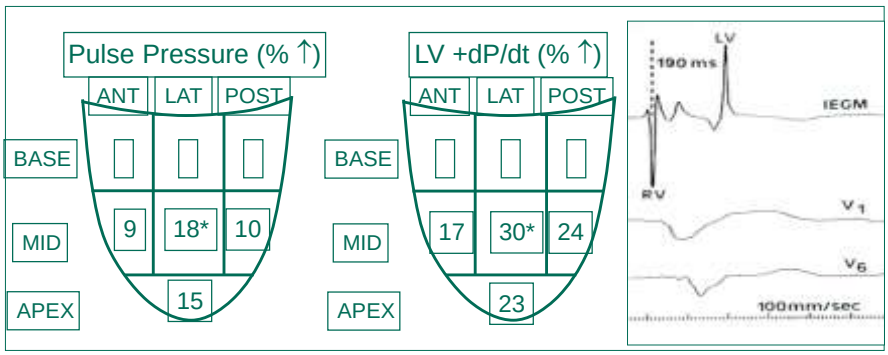
About 30% of patients fail to respond to CRT[1]



1. McAlister FA et al. *JAMA*. 2007;297:2502–14.
2. Mullens W et al. *J Am Coll Cardiol*. 2009;53:765-73.

Optimal LV lead position

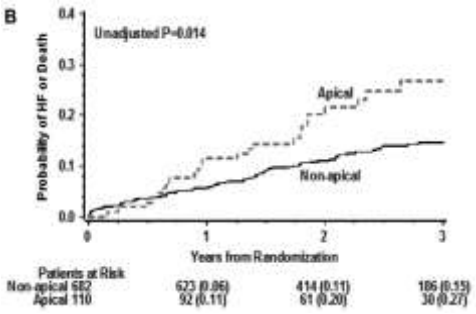
- Studies suggest that the optimal LV lead position should be at the latest activation site, to optimize CRT response.
- Lateral or posterolateral LV base, & Avoide Apical position.
- Target location : lateral or posterolateral CS vein.

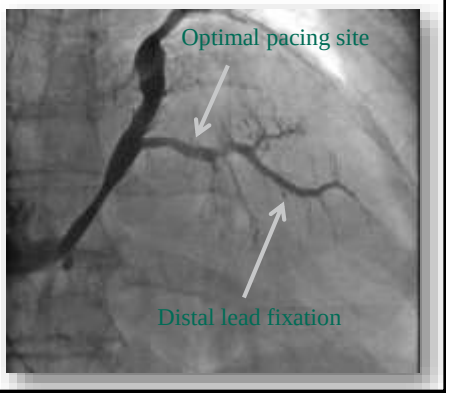


1. Causes of suboptimal lead position:

1. Lead stability Vs pacing site:

from MADIT-CRT: LV leads positioned in the apical region were associated with an unfavorable outcome, suggesting that this lead location should be avoided in CRT





2. **High pacing thresholds:** incidence rate is between 10-20% at implantation,
   - Narrow the safety margin of pacing stimulation.
   - Negatively impact on device longevity.

3. **PNS** incidence rate are at 37% of CRT patients at implant or follow-up,
   - intolerable for patients

At Implantation: Repositioning → increase procedure & fluoroscopy time

At follow-up: Surgical revision → increasing risk of infection

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Quadripolar LV lead

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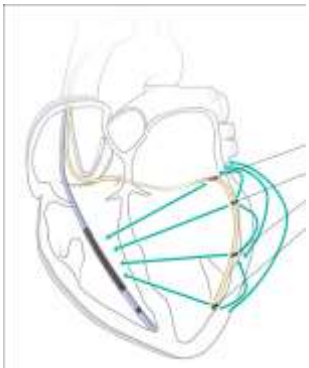
Quadripolar Pacing Technology

- 10 possible pacing configurations.
- Offers noninvasive lead repositioning options that may reduce the need for surgical revisions



Vector 1	Distal 1 to Mid 2	Distal 1	Mid 2
Vector 2	Distal 1 to Proximal 4	Distal 1	Proximal 4
Vector 3	Distal 1 to RV Coil	Distal 1	RV Coil
Vector 4	Mid 2 to Proximal 4	Mid 2	Proximal 4
Vector 5	Mid 2 to RV Coil	Mid 2	RV Coil
Vector 6	Mid 3 to Mid 2	Mid 3	Mid 2
Vector 7	Mid 3 to Proximal 4	Mid 3	Proximal 4
Vector 8	Mid 3 to RV Coil	Mid 3	RV Coil
Vector 9	Proximal 4 to Mid 2	Proximal 4	Mid 2
Vector 10	Proximal 4 to RV Coil	Proximal 4	RV Coil

The Use of a New Quadripolar Left Ventricular Pacing Lead Improves the Hemodynamic Response to Cardiac Resynchronization Therapy.
Osca Asensi J, et al. *Europace. 2011.*

- This study compared the effects of pacing from traditional vectors to vectors unique to the Quartet LV lead related to stroke volume (n=15).
- In 53% of all patients, the best stroke volume was obtained from pacing from one of the two proximal electrodes only available on the quadripolar lead.
- All of these patients were responders as they had a 10% increase in cardiac output.

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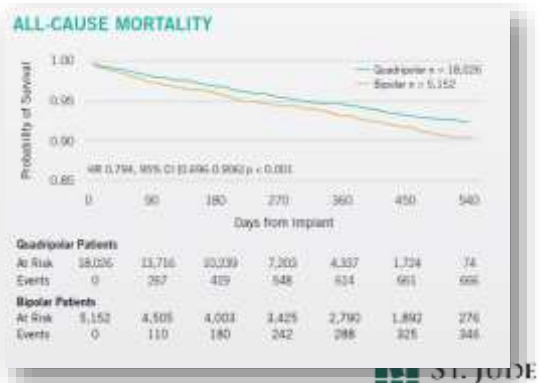
HRS 2014 abstract

- Patients with quadripolar LV leads may receive **more effective CRT than those with bipolar LV leads.**
- 18% Relative reduction in all cause mortality: (n = 23,178) at 8 months Follow up when compared to bipolar CRT systems1



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Turakhia M, et al. Reduced Mortality with Quadripolar versus Bipolar Left Ventricular Leads in Cardiac Resynchronization Therapy. HRS 2014. San Francisco, California. May 7-10, 2014

- Quartet™ LV lead enable LV pacing at the preferred site without compromising lead stability for better management of heart failure patients.
- No re-interventions duo to PNS
- No re-interventions for high threshold or loss of capture
- 98.8% success rate in implantation
- Decreased implant times and fluoroscopic exposure[3,4]
- More basal pacing opportunities with increase in acute haemodynamics & response rate.

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Access from CRT Toolkit: AutoVect Select

"Perform Auto VectSelect"

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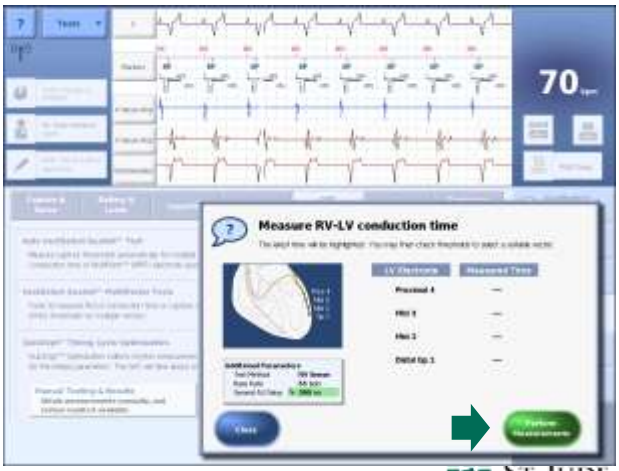
RV-LV Conduction Test

Step 2: Press “Perform Measurements”



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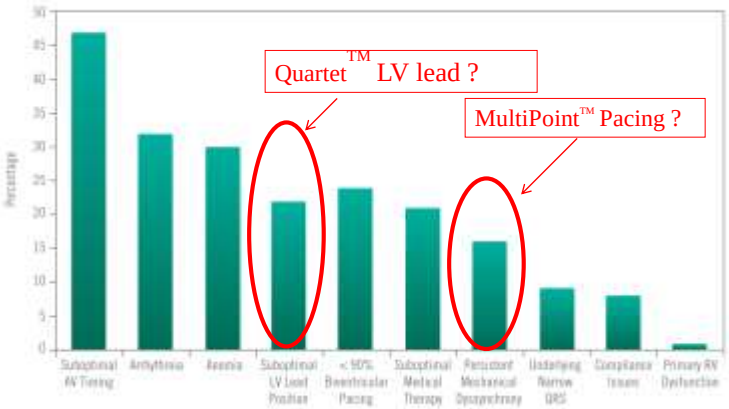


1. McAlister FA et al. *JAMA*. 2007;297:2502–14.
2. Mullens W et al. *J Am Coll Cardiol*. 2009;53:765-73.

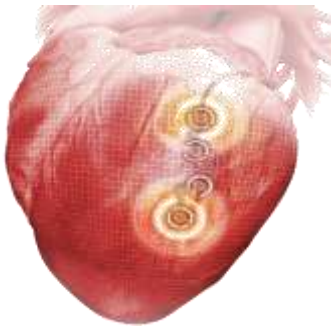
Goals of MultiPoint™ Pacing Technology

Pacing from TWO LV sites is designed to capture more tissue to improve:

The dual pulses from MultiPoint™ pacing

- Capture a larger area of the myocardium
- Improve transventricular activation time[1]
- Improve hemodynamics[2]
- Offer resynchronization throughout the LV[3]

▪ resulting in a more uniform ventricular contraction, which may enhance the response of both CRT responders and non-responders



MultiPoint™ Pacing allows pacing from two LV sites through just one CRT lead.

1. Theis C. et al. The relationship of bipolar left ventricular pacing stimulus intensity to cardiac depolarization and repolarization in humans with cardiac resynchronization devices. Journal of Cardiovascular Electrophysiology Vol. 20, No. 6, June 2009, 645-649.
2. Pappone, C., Calovic Z., Vicedomini G., Cuko, A., McSpadden, L. C., Pyiu, K., ... Santinelli, V. (2015). Improving cardiac resynchronization therapy response with multipoint left ventricular pacing: Twelve-month follow-up study. Heart Rhythm. 12(6):1250-8.
3. Rinaldi CA, Leclercq C, Kranig W, Kacet S, Betts T, Bordachar P, ..., Naqvi TZ. (2014). Improvement in acute contractility and hemodynamics with multipoint pacing via a left ventricular quadripolar pacing lead. J Interv Card Electrophysiol., 40(1), 75-80.
4. Thibault B, Dubuc M, Karst E, Andrade J, Dyrda K, Guerra PG, ..., Khairy P. (2014). Design of an acute dP/dt hemodynamic measurement protocol to isolate cardiac effect of pacing. J Card Fail., 20(5), 365-72.

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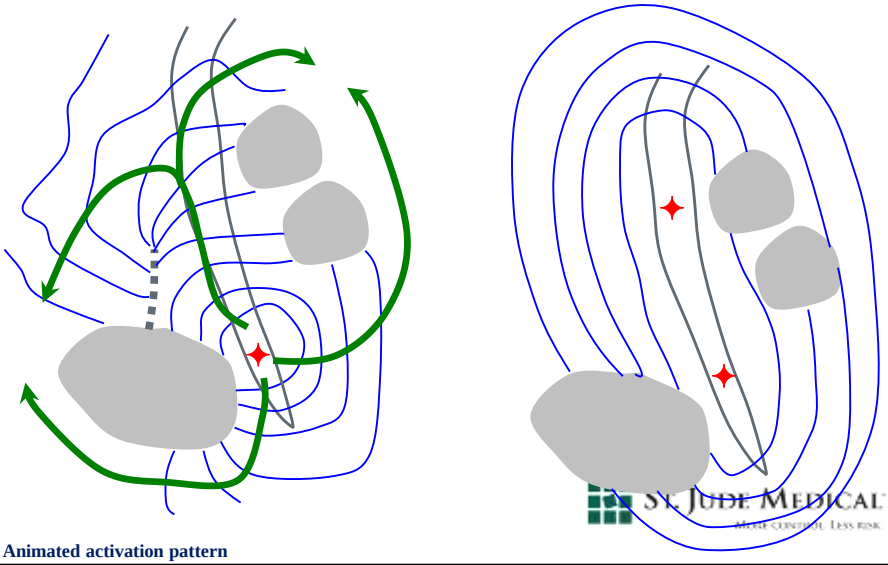
Possible Patterns of Wavefront Propagation* with conventional LV Pacing vs. MPP in HF, Scarred Heart



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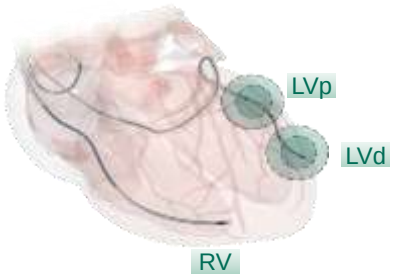
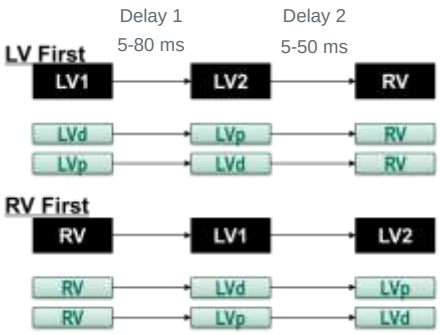
*** Animated activation pattern**

MultiPoint™ Pacing Technology Programming Options

Pacing Sequences and Delay

- Allows LV first or RV first
- Delays between pulses are programmable





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MultiPoint™ Pacing, Hemodynamics, and CRT Response

Improved Hemodynamics:

- MultiPoint™ pacing improved acute systolic function over single-site pacing in 80% of patients in a study assessing acute hemodynamics with dP/dtmax[1]
- MultiPoint™ pacing reduced mechanical dyssynchrony on echo tissue Doppler imaging in more patients than single-site pacing alone[2]

Improved CRT Response :

After 3 months, 73% of traditional CRT patients and 89% of patients treated with MultiPoint™ pacing were classified as responders[3]

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1. Thibault B et al. *Heart Rhythm* 2011; 8: S291.
2. Rinaldi CA et al. *J Am Coll Cardiol* 2012; 59: E918.
3. Pappone C et al. *HRS 2013 Poster Session PO02*. May 9, 2013.

Clinical Evidence of improved outcomes with MultiPoint™ Pacing

11 completed clinical studies, N = 1,148 pts	15 published manuscripts and > 50 abstracts to date
Pappone, et al. (n = 44) MPP™ technology improved acute LV hemodynamic parameters and mid- and long-term LV reverse remodeling compared to conventional CRT[1-3]	**Rinaldi, et al.** (n = 52) MPP technology was acutely safe, and a proportion of MPP technology pacing configurations resulted in a significant reduction in echocardiographic dyssynchrony[12-13]
Zanon, et al. (n = 29) MPP technology increased hemodynamic response compared with BiV pacing at any LV site and improved 1-yr CRT response[4-6]	**Pappone, et al.** (n = 8) Multipoint LV pacing may provide additional improvement to LV function in patients receiving conventional CRT [14]
Park, et al. (n = 8) MPP technology resulted in better electrical and structural reverse remodeling after 6 months compared to using conventional bipolar lead[7]	**Menardi, et al.** (n = 10) CRT with MPP technology improved both endocardial and surface electrical parameters and hemodynamics in comparison with conventional CRT[15]
Forleo, et al. (n = 436) MPP technology was programmable in 97% of patients; at follow-up QRS was reduced and EF improved with MPP technology relative to conventional BiV[8]	**Shetty, et al.** (n = 15) MPP technology may give some degree of hemodynamic benefit, and delivery via a single lead may be as efficacious as pacing with multiple LV leads[16]
Osca, et al. (n = 25) In comparison to conventional CRT, MPP technology decreased further LV dyssynchrony indexes and resulted in an additional improvement in EF and in CO[9]	**Tomassoni, et al.** (n = 502) Wider cathode spacing and near-simultaneous intraventricular timing delays provide best MPP technology response at 87% and 'superresponse' at 54% (52 patients)[17]
Thibault, et al. (n = 19) MPP technology improved acute LV dP/dt_{Max} compared with BiV pacing using a pacing protocol designed to isolate changes due to cardiac effects[10-11]	

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SyncAV™ CRT

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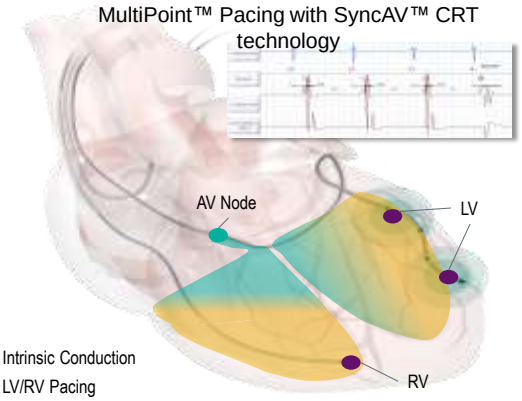
SyncAV™ CRT Dynamically Tailored to the patient's beat[1]

- New dynamic timing feature for quadripolar CRT devices
- Individualize and dynamically adjust timing (AV Delays) based on intrinsic patient rhythm
- Drive fusion with intrinsic rhythm for improved electrical synchrony and narrower QRS[1]
- Can complement Multipoint™ Pacing



1. Wisnoskey BJ, Cranke G, Cantillon DJ, and Varma N. "Feasibility of Device-Based Electrical Optimization via Application of the Negative AV Hysteresis Algorithm during Cardiac Resynchronization Therapy (CRT)." Heart Rhythm. 2016; 13 (5S): S443

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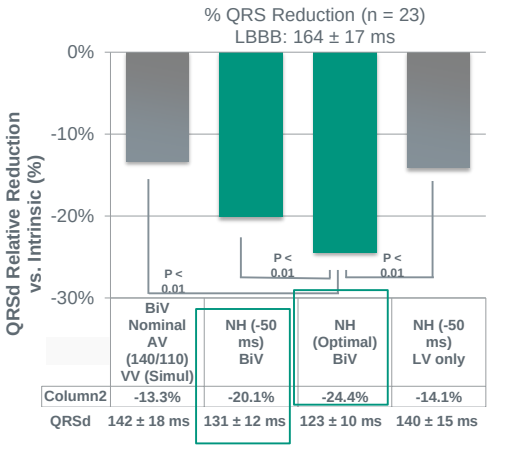
QRS Reduction with SyncAV™ CRT technology



Dynamic pacing delays resulted in improvement in QRS duration

1

- Study Detail:
  - Methods:
    - Compared QRS reduction in N = 23 patients utilizing Neg-Hys (predicate version of SyncAV™ CRT feature
  - Results:
    - Using a delta value of -50ms, fusion pacing was achieved and provided a 20% improvement in QRS width
    - Methodology improved QRS duration over traditional fixed AV delays and LV only pacing
    - Incremental QRS narrowing can be achieved by fine-tuning delta value, programmable only in SJM™ SyncAV feature

1. Wisnoskey BJ, Cranke G, Cantillon DJ, and Varma N. "Feasibility of Device-Based Electrical Optimization via Application of the Negative AV Hysteresis Algorithm during Cardiac Resynchronization Therapy (CRT)." Heart Rhythm. 2016; 13 (5S): S443

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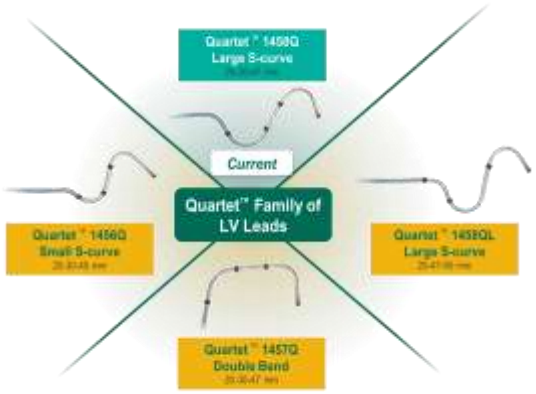
Multiple quadripolar lead options to the right target vein to deliver MultiPoint™ Pacing



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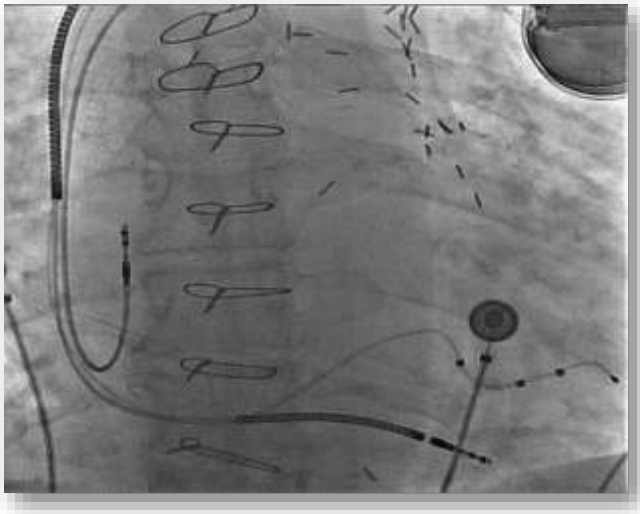

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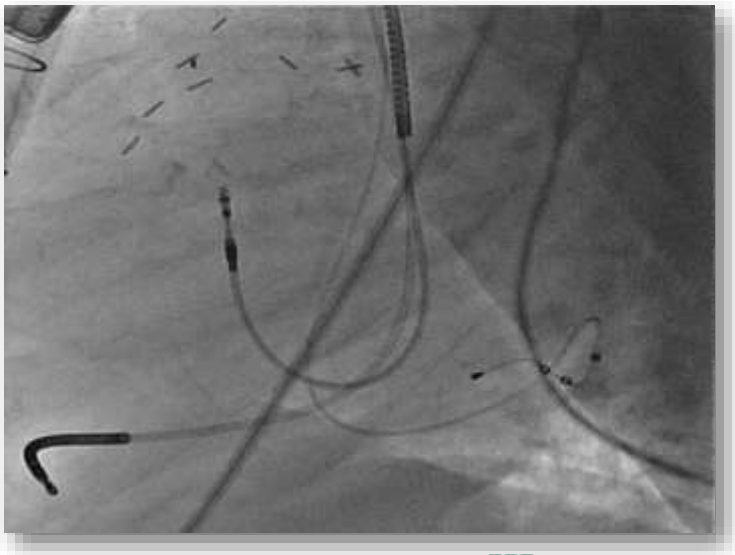

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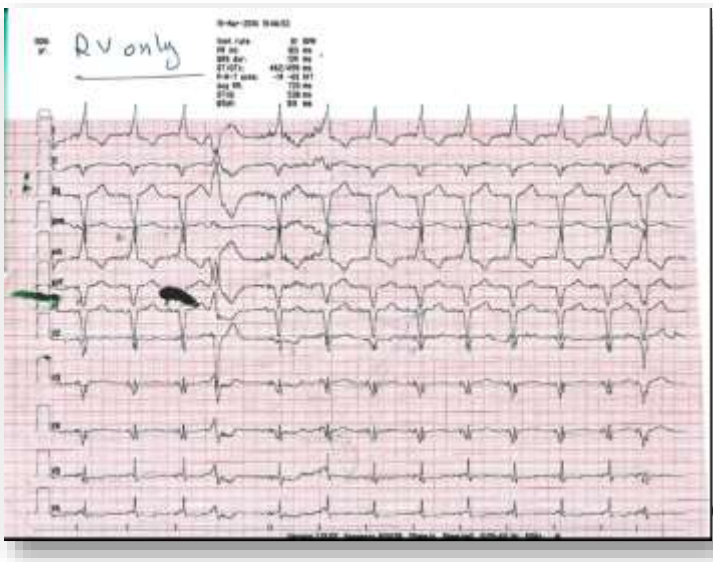
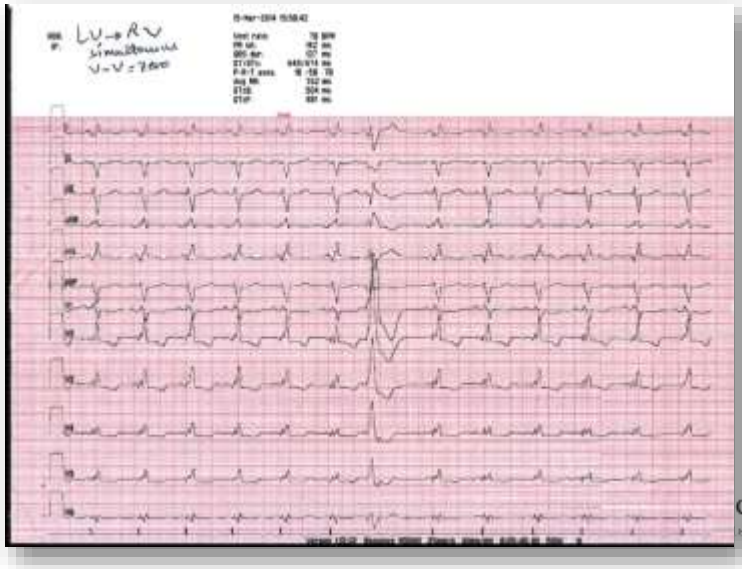
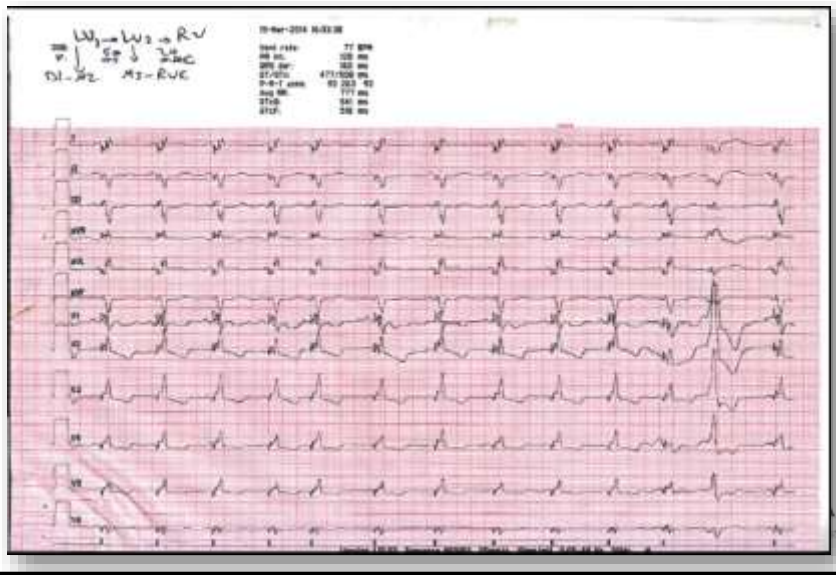
RV only Pacing



Conventional BiV pacing



MPP on



Thank you for your attention