New devices in current practice and on the horizon

CRT

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Disclosures

Institutional research and educational funding: Abbott, Biotronik, Biosense Webster, Boston, Medtronic, St. Jude Medical
Cardiac Resynchronization Therapy

- Primary nonpharmacologic therapy for drug refractory HF & ventricular dyssynchrony
- 20-30% of HF patients have BBB

Cardiac Resynchronization Therapy

- 10% unsuccessful LV lead placement

- Surgical epicardial LV lead placement via mini-thoracotomy or video-assisted thoracoscopic surgery (VATS)

- 30-40% of patients are nonresponders

Novel Approaches to CRT

What alternatives are available?

- Vector Selection / Quadripolar Leads
- Multisite Pacing
- Transseptal LV Endocardial Pacing
- LV Leadless Endocardial Pacing
- MR in CRT-Patients
Vector Selection

• Ideal lead location may not always be feasible

• Newer leads allow multiple options for LV pacing

• Pacing at optimal vs suboptimal site can increase acute hemodynamic response by up to 10%

Rinaldi C, Burri H, A review of multisite pacing to achieve CRT, Europace Jan 2015;17 (1) 7-17
Seger M, Hanser F, Dichtl W, et al. Non-invasive imaging...
Europace 2014;16:743-749
Multi Site Pacing

- Stimulation of the LV from more than one location
- Goal of providing more complete resynchronization
- Multi-vein Pacing vs Multi-polar Pacing

Multi Side Pacing

Rationale:
Multi side pacing delivers two pacing pulses on the LV via a quadripolar lead, thus allowing to capture at once a larger area of the myocardium.

- St. Jude Medical Quadra Assura MP (CE mark June 2013)
- BIOTRONIK Ilivia 7 HF-T QP (CE mark Jan 2016*)
- Medtronic Amplia Quad CRT-D (CE mark Febr 2016)

* Market Launch exp. September 2016
Multiside pacing trials

Thibault 2013: Invasive hemodynamics; MSP improved acute systolic function in 72% patients vs. conventional CRT.

Rinaldi 2013: Post implant echocardiographic evaluation; 64% reduction in dyssynchrony with MSP vs. conventional CRT.

Pappone 2013: Monitoring of pressure volume loops during implant; MSP significantly improved acute LV hemodynamic parameters as compared with conventional CRT.

Rinaldi, Burri, Thibault, Curnis, et al.
A review of multisite pacing to achieve cardiac resynchronization therapy Europace Jan 2015, 17 (1) 7-17.
Multi Site Pacing

12-month follow-up in 22 pts.: Improvement in
- Dyssynchrony
- Hemodynamics
- QRSd

- Longer term data is still needed

- Tommasoni, Heart Rhythm Meeting 2016
Mainly dependent on LV lead location and capture:

- Endocardial >>> Epicardial
- Faster impulse propagation

Transeptal LV Endocardial Pacing

- LV endocardial pacing via a transseptal bipolar active fixation lead
- Access to all regions of the LV
- Lower rate of lead dislodgement
- Faster impulse propagation

Limitations

- Thromboembolic Risk
- Technically difficult
- MV insufficiency
- Infection management

A: Septum punctured and proximal segment of a guidewire placed in the LA
B: Sheath was introduced into the left atrium along the guidewire / lead advanced into LA
ALSYNC Trial (ALternative site cardiac reSYNCHronization)

- 138 patients with criteria for CRT
- 40% ischemic cardiomyopathy
- 50% AF
- 78% prior failed CRT attempt
- 22% nonresponder at 6 months
- 75% NYHA FC III-IV

ALSYNCE Trial (ALternative site cardiac reSYNCHronization) Trial Results

- Endocardial LV lead placement success rate → 89.4%
- Freedom from complications → 82.2% at 6 months
  - Implantation site hematoma (early)
  - Aortic puncture at transfemoral implantation
  - 6 neurologic events
  - Only one death was procedural related (pneumo/hemothorax)

ALSYNCG Trial (ALternative site cardiac reSYNCHronization) Trial Results

Also at 6 months

- NYHA FC improved in 59% of patients
- LVESV improved in 55% of patients by 15% or more
- 33% of patients showed improvement of MR by ≥1 class

LV Leadless Pacing System

- Implantable wireless pacing system converts ultrasound energy to electrical energy
- Electrode, transmitter and battery
- Co-implanted with a pacemaker, ICD, or existing CRT device

LV Leadless Pacing System

1) Conventional PM generates an electric pacing pulse

2) Pulse generator picks up electrical activity by PM

3) Pulse generator sends ultrasonic pulse to reciever-electrode causing left ventricle to pace

LV Leadless Pacing System

Long-term (6 months) Experience of Clinical Efficacy and Clinical Events from Two Centers in 22 patients

- BiV pacing achieved in 100, 91 and 94% of pts at 1, 6 and 12m
- Mean ejection fraction increased
- Mean NYHA reduced
- Mean end systolic / diastolic volumes reduced

➢ Two-center experience in limited number of pts has demonstrated feasibility, utility and long term outcome of endocardial LV pacing to achieve CRT
➢ WiSE CRT shows promising efficacy in pts unable to benefit from conventional CRT, non responders / upgrades

Neuzil, Heart Rhythm Congress 2016
# Possibilities with Leadless Technology

## Applications of leadless technology

| Dual Chamber Nanostim | - 2 Discrete devices: Right Atrium and Right Ventricle  
- Beat to Beat Communication  
- Chronically retrievable |
|-----------------------|----------------------------------------------------------------------------------------------------------|
| Leadless ICD/PM       | - Leadless ICD system with device-to-device communication to Nanostim  
- Nanostim device paces, senses, and delivers ATP therapy |
| Leadless CRT          | - Evaluate leadless options for CRT therapy delivery  
- Applicable to low and high voltage |
| Pediatric Leadless    | - Miniaturize present leadless pacemaker  
- Fully retrievable  
- Reduce complications from venous adhesions |
| Temporary Pacing      | - Utilize Nanostim for temporary pacing  
- Avoid surgical pocket  
- Retrievability makes this attractive |
# CRT-D and MRI conditions

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Adapted from Auricchio, EHRA Webinar 2016
Image Quality of Cardiac Magnetic Resonance Imaging in Patients With an Implantable Cardioverter Defibrillator System Designed for the Magnetic Resonance Imaging Environment

Cardiac MRI can offer diagnostic information in most cases (175 pts)
Summary

• Multiple different approaches for CRT are evolving which will hopefully improve response rates.
• Allows individualized therapy for each patient.
• Results are promising, but longer term and larger studies are still needed.
• The ability to provide CRT-D patients with access to MRI scans is a significant, necessary advancement.
Thank you!