The Fundamentals of Cardiac Resynchronization Therapy (CRT) in the Patient with Congestive Heart Failure
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Disclosures
Consultant: Medtronic

Congestive Heart Failure
Chronic, progressive clinical syndrome that develops due to structural or functional cardiac disorders.

Results in failure of the heart to pump enough oxygen-rich blood to meet the needs of the body.

Heart Failure - Patient Education
Information available to the public
Also called: Cardiac failure, CHF, Congestive heart failure, Left-sided heart failure, Right-sided heart failure

- Heart failure is a condition in which the heart can’t pump enough blood to meet the body’s needs.
- Heart failure does not mean that the heart has stopped or is about to stop working.
- It means that the heart is not able to pump blood the way it should.
- It can affect one or both sides of the heart.

NIH: National Heart, Lung, and Blood Institute

Heart Failure - Patient Education continued
- The weakening of the heart’s pumping ability causes
  - Blood and fluid to back up into the lungs
  - The buildup of fluid in the feet, ankles and legs - called edema
  - Tiredness and shortness of breath

- Common causes of heart failure are:
  - coronary artery disease,
  - high blood pressure
  - diabetes.

NIH: National Heart, Lung, and Blood Institute

Heart Failure - Patient Education continued
- It is more common in people:
  - 65 years old or older
  - African Americans
  - people who are overweight
  - people who have had a heart attack
  - Men have a higher rate of heart failure than women.

- The doctor will diagnose heart failure by doing a physical exam and heart tests.
- Treatment includes treating the underlying cause of your heart failure, medicines, LVAD and heart transplant if other treatments fail.
ACC/AHA/HRS - Indications for CRT - Class I recommendations*

- LVEF < 35%
- Sinus Rhythm
- Left Bundle Branch Block (LBBB)
- QRS duration ≥ 150 ms
- NYHA Class II, III, or ambulatory IV symptoms
- Guideline-Directed Medical Therapy (Level of Evidence A: for NYHA Class III/IV; Level of Evidence B: for NYHA Class II).

*Patients are on chronic, optimal medical therapy and have a reasonable expectation of survival with good function for > 1 year.
Cardiac Resynchronization Therapy (CRT)- Patient Education

What is CRT and how can it help your heart?
If you have heart failure and have developed arrhythmia, you may be a candidate for cardiac resynchronization therapy (CRT)

- Arrhythmias are irregular heart rhythms can be caused by a variety of reasons,
  - including age,
  - heart damage,
  - medications
  - and genetics.

In heart failure patients CRT, or biventricular pacing, is used to help improve the heart’s rhythm and the symptoms associated with the arrhythmia.

Cardiac Resynchronization Therapy (CRT)- Patient Education

Who is a Candidate for CRT?
- CRT is for heart failure patients with moderate to severe symptoms and whose left and right heart chambers do not beat in unison.
- CRT is not effective for everyone and is not for those with mild heart failure symptoms, diastolic or who do not have issues with the chambers not beating together.
- It is also not suitable for patients who have not fully explored correcting the condition through medication therapies.
- To date, studies show CRT to be equally effective for both men and women.
**Case Study- CRT**

2005: 51 y.o. male with ischemic cardiomyopathy with ICD for primary prevention, EF 15%.
- Patient at the time thought he was able to function well. Walk, golf, ride bike, etc...
- But when inquiring about quantity and quality of his activities found each of these activities were more suited to someone much older than him. He golfed but wore out early, ride about 3 miles on his bike, etc…
- Recently had progressive CHF, AF with rapid ventricular response. AV node ablation done and biventricular (CRT-D) implanted.

**Case Study- CRT continue**

Today: 61 years old and his EF is 35-40%.
- Chronic AF - 100% biventricular paced
- Can walk up inclines/ hills
- Bike 25 miles without stopping
- Golf 18 holes
- Swim/ sail
- Enjoy his grandchildren

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**BLOCK HF Trial**

CRT for Indicated Patients with AV Block and Systolic Dysfunction

- Evidence from the landmark BLOCK HF trial, which was published in the New England Journal of Medicine in April 2013, showed that RV pacing is superior to RV pacing for some patients with atrioventricular (AV) block and systolic dysfunction. Study patients exhibited a 27% relative risk reduction with RV pacing.
- Based on these results, in April 2014, the FDA approved new indications for CRT-D and CRT/P devices for patients that meet the following criteria:
  - AV block*
  - NYHA Class I, II, III heart failure
  - LVEF ≤ 50%
  - Optimal medical therapy (OMT)**

*AV block (AV block) that is expected to require a high percentage of ventricular pacing that cannot be managed without algorithms to minimize high ventricular pacing.
**OMT established before implant if indicated, and should be done post-implant.

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**Block HF case study**

79 y.o male with history of paroxysmal A Fib was on medical management with Sotolol, no anti-coagulation (CHA2DS2VASc score 2)

6/2014: Had a syncopal episode and an electrophysiology work up with no conclusive finding so a Linq loop recorder was implanted.

Loop recorder finding showed periodic rapid AF with median rates of 122 bpm and maximum 158 bpm. Rate dependent LBBB. Was admitted switched to Dofetilide (Tikosyn) 9/2014 and anti-coagulation.

Continued to have breakthrough AF with rapid rates but for shorter lengths of time.

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**Block HF case study continue**

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Block HF case study continue

Medical management continued with ongoing monitoring until 7/2015

Block HF case study continue

7/2015: AV Node ablation was done and a CRT-P device was inserted.
Continue anticoagulation and small amount of beta blocker (Metoprolol 25 mg) was continued.

HRS Guidelines

ACC/AHA/HRS 2012 Practice Guidelines for Device Therapy in Patients with Ventricular Dysynchrony and Heart Failure

CRT Devices

Modification of systolic function (amplifying LV function: LVEF < 30%), NYHA class (I to IV), LBBB morphology, intraventricular conduction delay, and previous AMI are associated with CRT in post-MI heart failure.

Recent data (DACOR, DIAMOND, COMPANION, CAPACITY studies) have suggested that the benefit of CRT is dependent on QRS duration, with a significant benefit associated with CRT in patients with QRS > 150 ms, but not in patients with QRS < 150 ms. The DIAMOND CRT study demonstrated that CRT was also beneficial in patients with LBBB and QRS 150 ms.

Recent meta-analyses of CRT trials have suggested that the benefit of CRT is dependent on QRS duration, with a significant benefit associated with CRT in patients with QRS > 150 ms, but not in patients with QRS < 150 ms.

HRS Guidelines

ACCF/HRS/AHA/ASE/HFSA/SCAI/SCCT/SCMR 2013 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy

Stratification of ejection fraction (separating LVEF < 30% from LVEF 31% to 35%), NYHA class (class I through ambulatory class IV), QRS morphologies (considering LBBB QRS morphologies separate from non-LBBB QRS morphologies) were selected based on data from recent clinical trials.

Recent data from the MHLV (Multi-center Heart Failure Long-term Evaluation) study and the DIAMOND CRT study have suggested that the benefit of CRT is dependent on QRS duration, with a significant benefit associated with CRT in patients with QRS > 150 ms, but not in patients with QRS < 150 ms.

Clinical response to CRT is dependent on QRS morphology, with the greatest response for patients with LBBB and QRS > 150 ms. There is also evidence that patients with RBBB morphology may not demonstrate benefit from CRT.

Recent data from the MADIT-CRT (Multi-center Automatic Defibrillator Implantation Trial–Cardiac Resynchronization Therapy) study have suggested that CRT was associated with a 41% reduction in the risk of heart-failure events, particularly in patients with a QRS duration of >150 ms.

MADIT-CRT was limited to patients with ischemic cardiomyopathy (NYHA class I or II) and non-ischemic cardiomyopathy (NYHA class II only), so no conclusions can be made for non-ischemic patients with class I heart failure based on the results of this study.

Scenarios modified by QRS duration, QRS morphology, NYHA class, type of heart disease, LVEF, need for inotropic support, other clinical indications for CIED therapy with anticipated frequent need for RV pacing, and timing post-MI or revascularization. In the setting of an LVEF < 35% with a narrow QRS and planned ICD or pacemaker implantation, CRT implantation was rated Appropriate regardless of NYHA class.

This is consistent with prior studies implicating the deleterious consequences of RV pacing, specifically suggesting that >40% RV pacing results in a higher risk of heart failure, particularly in the setting of a normal LVEF.

Challenges to lead placement

- Coronary sinus access
- Angulation and tortuosity
- Size of vessels
- Absence of a postero-lateral vein
- Instability of the lead
- Diaphragmatic stimulation
- Infarct myocardium
- Epicardial lead placement?

New Lead systems allow multiple vectors to stimulate the left ventricle

- 4 Unipolar
- 4 Extended Bipolar
- 9 Bipolar

Ventricular Dysynchrony and Cardiac Resynchronization

- Ventricular Dysynchrony
  - Electrical: Inter- or Interventricular conduction delays typically manifested as left bundle branch block
  - Structural: Disruption of myocardiol collagen matrix impairing electrical conduction and mechanical efficiency
  - Mechanical: Regional wall motion abnormalities with increased workload and stress—compromising ventricular mechanics

- Cardiac Resynchronization
  - Therapeutic intent of atrial synchronized biventricular pacing
    - Modification of interventricular, intraventricular, and atrial-ventricular activation sequences in patients with ventricular dysynchrony
    - Complement to optimal medical therapy

http://www.hrsonline.org/Practice‐Guidance/Clinical‐Guidelines‐Documents/2012‐Expert‐Consensus‐Statement‐on‐CRT


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CRT Device follow up Clinic/Plan

- 1 week post implant wound check
  - Evaluation of the incision
  - Full interrogation of the CRT-D or CRT-P device
  - Education and confirm set up of the remote monitoring system
  - Review clinic booklet & follow up

Information for a CRT-ICD Device

- VT/VF information:
  - Treated events
  - Monitored Events
  - Therapy: ATP, Shocks
- Percent pacing: Atrial and Ventricular, Bi-ventricular
- Alert notifications
- Histograms
- Programming information
- Lead function: Trends
- Battery, estimated longevity, alerts/observations
- Atrial arrhythmias:
  - Atrial Tachycardia's, Atrial Fibrillation, Supraventricular Tachycardia's

CCHVC CRT Device Follow up

- Routine follow up 1st year:
  - 1 week post
  - 6 weeks with CHF and/or EP physician
  - 3 months: remote follow up
  - 6 months: remote follow up
  - 9 months clinic visit
- After the patient is routinely checked 3x yearly but remote home monitoring and seen in clinic yearly*

* Patient is seen with any physician of CHF follow up

Available Diagnostics

- Weight
- Blood Pressure
- Respiratory Rate
- Activity Levels
- Heart Rates
- Heart Rate Variability
- Atrial Burden
- Arrhythmias
Device Reports

Partner HF Criteria

<table>
<thead>
<tr>
<th>Diagnostic parameter</th>
<th>Criterion for a positive diagnosis</th>
<th>Score (2 or more)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optivol Fluid Index</td>
<td>&gt;60</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;100</td>
<td></td>
</tr>
<tr>
<td>AT/AF Duration</td>
<td>&gt;6 hours and not persistent AT/AF</td>
<td></td>
</tr>
<tr>
<td></td>
<td>U rate during AT/AF &gt;240 bpm and nonvetricular rate &gt;24 bpm</td>
<td></td>
</tr>
<tr>
<td>Patient activity</td>
<td>Average &lt;1 hour over 1 week (85% -95%)</td>
<td></td>
</tr>
<tr>
<td>Night heart rate</td>
<td>&gt;95 bpm for 7 consecutive days</td>
<td></td>
</tr>
<tr>
<td>Heart rate variability</td>
<td>&lt;60% for 7 consecutive days (HR footprint)</td>
<td></td>
</tr>
<tr>
<td>CRT % Pacing</td>
<td>&gt;90% for less of 7 days</td>
<td></td>
</tr>
<tr>
<td>Shocks</td>
<td>1 or more shocks</td>
<td></td>
</tr>
</tbody>
</table>

Non-Responders

- Lead placement
- Compliance: Medications, dietary, activity
- Programming parameters
- Arrhythmias: Atrial fibrillation, ventricular arrhythmias, PVC burden

CRT Response Rates

One-third of patients do not experience the full benefit of CRT1-6

Potential Reasons for Suboptimal CRT Response

A Significant Percentage of Patients Do Not Achieve Optimal BiV Pacing %

In a cohort of >80,000 patients, 40.7% exhibited less than 98% BiV pacing

Outcomes Improved in Patients with Near 100% BiVentricular Pacing

Early data showed decline at <93% BiV pacing; Recent, larger cohort data at <98.5% BiV pacing

Reasons for < 100% pacing
- Atrial fibrillation
- PVCs
- Competitive AV nodal conduction

Influences on CRT pacing percentages
- Non-sustained VT
- Slow VT
- PVC’s
- Atrial fibrillation with rapid ventricular response
- Patient changes after initial implant and programming. Ventricular remodeling after optimal therapy implemented.
- Patient non-compliance
- Activity

Way to promote Bi-ventricular pacing
- VSR: ventricular sense response
- LV offset
- Bi-V Trigger

Alerts
- Percent pacing < 90% (programmable)
- Weight gain
- Heart rates in A fib, 100 bpm for a designated period of time.
- # of hours in Atrial fibrillation
- Shocks from CRT-D devices
- Lead integrity alerts
Future Innovations

- Smarter algorithms to insure Bi-ventricular pacing
- Patient engagement/APP’s that provide feedback to patients about their device/health/goals

Patient Education Information

Take Aways

1. Why did the patient get this device prevention of CHF or for treatment of CHF?
2. What is the patient perception of their disease and medical available to help them. Educate!
3. Bi-ventricular pacing %?
4. Look for the Non-responder: Why are they not responding to therapy?
5. Is this a pacemaker or an ICD? What feature could help this patient?
6. Technology is changing rapidly what is not now available maybe in the near future.

Thank you

Resources

- Tavazzi L. Eur Heart J 2000;21:1211‐1214