HK-IN-PACE Heart Rhythm Refresher Course 2014 -
Module 2
Heart Failure and CRT

Novel Device Functions for CRT Optimization and Heart Failure Monitoring

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Novel Device Functions for CRT Optimization

1. QuickOpt – St Jude
2. Smart Delay – Boston Scientific
3. Adaptive CRT - Medtronic
St Jude QuickOpt – Automatic AV Optimization

Utilization of P wave duration to estimate optimal AV delay

**Short P Wave Example**

Optimal AV delay = AS + D
= 50 + (110) = 160

**Long P Wave Example**

Optimal AV delay = AS + D
= 120 + (80) = 200

**Paced AV delay = AS + Δ**

AS = Duration of sensed P wave

Δ = added interval allowed for ventricular filling (80 or 110 ms)

- P < 100 ms → D = 110 ms
- P > 100 ms → D = 80 ms

**Sensed AV delay**

- P < 100 ms → AS + 60 ms
- P > 100 ms → AS + 30 ms

*International Journal of Cardiology 170 (2013) 118–131*
St Jude QuickOpt – Automatic VV Optimization

Utilization of interventricular conduction delay to estimate VV timing

$$V_{V_{opt}} = 0.5 \times (\Delta + \varepsilon)$$

$\Delta$ is related to the intrinsic depolarization
$\varepsilon$ is a correction term depending on wave front velocity

Example:

$\Delta = 40 \text{ ms (RV sensed before LV)}$
$\text{IVCD}_{LR} = 60 \text{ ms}$  $\text{IVCD}_{RL} = 50 \text{ ms}$

In this case, it takes longer to depolarize from Left to Right
$\varepsilon = \text{IVCD}_{LR} - \text{IVCD}_{RL} = 60 - 50 = 10 \text{ ms}$

$V_{V_{opt}} = 0.5 \times (\Delta + \varepsilon) = 0.5 \times (40 + 10) = 50/2 = 25$

We get: LV first, V-V = 25 ms

$\text{IVCD}_{LR} \rightarrow \text{Time to activate RV by LV pacing}$

$\text{IVCD}_{RL} \rightarrow \text{Time to activate LV by RV pacing}$

$\Delta \rightarrow \text{Interventricular conduction delay (Intrinsic RV sensing before LV)}$

$\varepsilon \rightarrow \text{IVCD}_{LR} - \text{IVCD}_{RL}$
QuickOpt vs Empiric programming or one-time optimization using a non-IEGM method

**Similar heart failure clinical composite score (Packer) (CCS)**

* at 12 months (in unselected group of CRT candidates)

<table>
<thead>
<tr>
<th></th>
<th>Treatment</th>
<th></th>
<th>Control</th>
<th></th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HF CCS</strong></td>
<td><strong>n</strong></td>
<td><strong>%</strong></td>
<td><strong>n</strong></td>
<td><strong>%</strong></td>
<td></td>
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<tr>
<td>Improved</td>
<td>298</td>
<td>71.29</td>
<td>245</td>
<td>68.82</td>
<td>0.2514</td>
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<tr>
<td>Unchanged</td>
<td>23</td>
<td>5.50</td>
<td>17</td>
<td>4.78</td>
<td></td>
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<tr>
<td>Worsened</td>
<td>97</td>
<td>23.21</td>
<td>94</td>
<td>26.40</td>
<td></td>
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<tr>
<td><strong>Total</strong></td>
<td>418</td>
<td>100</td>
<td>356</td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>

Abraham WT, Gras D, Yu CM et al. Results from the Freedom Trial: assess the safety and efficacy of frequent optimization of cardiac resynchronization therapy. HRS 31st ASS Denver 2010

Packer M. Proposal for a new clinical end point to evaluate the efficacy of drugs and devices in the treatment of chronic heart failure. J of Cardiac Failure 2001; 7, 2: 176-182
Response-HF Trial (VV Optimization)

- Prospective Randomized Trial. CRT non-responders N=57

- Randomized to Sequential VV (QuickOpt) vs Simultaneous VV

- Responder rate was 28.5% higher in the Sequential Group compared to the Simultaneous Group (p = 0.033)

<table>
<thead>
<tr>
<th>Per-Protocol</th>
<th>Sequential Group n = 26</th>
<th>Simultaneous Group n = 31</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responder Rate (%)</td>
<td>76.9%</td>
<td>47.4%</td>
<td>0.033</td>
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<tr>
<td>Non-Responder Rate (%)</td>
<td>23.1%</td>
<td>51.6%</td>
<td></td>
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</table>

Sequential VV optimization plays an important role in CRT non-responders

**Sensed AV offset**

\[ PAV = (SAV) + (\text{Sensed AV Offset}) \]

- **Sensed AV optimum** = a constant \( \times \) QRS + another constant
  - \( \times \) sensed AV interval
  - + another constant depending on lead position

- **Paced AV optimum** = another constant \( \times \) QRS + another constant
  - \( \times \) sensed AV interval
  - + a different constant depending on lead position

*"Sensed AV Offset" compensates inter-atrial delays*
Predictive value of SmartDelay™

Good correlation with highest achievable LV dP/dt
More accurate prediction of maximal hemodynamic response than Echo

No difference between Smart Delay vs Echo vs Fixed AV arms in LVESV at 6 months
No difference in LVEDV, LVEF, 6MW, NYHA between arms

Does not exclude utility in selected non-responder
Medtronic – Adaptive CRT Concept

1. LV only pacing is preferred over BiV pacing when A-to-RV conduction is preserved
   - Similar improvement of LV systolic function
   - Superior LV diastolic function / RV systolic function
   - Increases device longevity by minimizing RV pacing

2. BiV pacing adjusted to intrinsic electrical conduction
   - Better LV filling and higher % of BiV pacing if AV delay is adjusted to pace after the end of the P-wave and before intrinsic QRS
   - Better LV hemodynamics if VV delay is adjusted to promote intrinsic RV activation when it is sufficiently preserved

7 Medtronic Viv a XT CRT-D Manual.
8 Van Gelder et al. PACE. 2008;31:569-74.
Hemodynamic effect of LV Pacing vs BiV pacing

The LVdP/dtmax is higher in LV than in BiV pacing provided that LV pacing is associated with ventricular fusion caused by intrinsic activation.

LV Pacing → Achieves higher dP/dT than BiV pacing
If intrinsic conduction is preserved to allow ventricular fusion

Table 2. Values of dP/dt max for Baseline, LV, and BiV Pacing at Four AV Intervals and Subdivided for AV2 With and Without Fusion

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Baseline</th>
<th>LV Pacing</th>
<th>BiV Pacing</th>
<th>p Value</th>
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</thead>
<tbody>
<tr>
<td>AV1</td>
<td>34</td>
<td>813 ± 197</td>
<td>996 ± 194*</td>
<td>960 ± 208$</td>
<td>0.0009</td>
</tr>
<tr>
<td>AV2</td>
<td>34</td>
<td>813 ± 197</td>
<td>959 ± 195†</td>
<td>957 ± 189‡</td>
<td>0.88</td>
</tr>
<tr>
<td>AV3</td>
<td>34</td>
<td>813 ± 197</td>
<td>918 ± 181‡</td>
<td>921 ± 183‡</td>
<td>0.79</td>
</tr>
<tr>
<td>AV4</td>
<td>34</td>
<td>813 ± 197</td>
<td>880 ± 175</td>
<td>871 ± 174</td>
<td>0.42</td>
</tr>
</tbody>
</table>

LV-BiV

AV2 fusion 21 800 ± 228 983 ± 213 957 ± 202 +26.5 ± 71.9
AV2 no fusion 13 835 ± 139 919 ± 164 957 ± 174 −38.0 ± 58.4
Synchronized LV pacing produces acute LV and systemic hemodynamic benefits similar to BiV pacing. LV pacing at an appropriate atrioventricular interval prior to the RV sensed impulse provides superior RV hemodynamics compared with BiV pacing. (J Cardiovasc Electrophysiol, Vol. 18, pp. 497-504, May 2007)

LV pacing improved RV dP/dtmax, preserved RV cycle efficiency and stroke volume

Based on LV dP/dtmax, the optimal atrioventricular interval could be estimated by subtracting 30 msec from the intrinsic atrial to sensed RV interval.

N=17. CHF. LVEF = 30 ± 1% Wide QRS (138 ± 25 msec)

Synchronized LV pacing produces acute LV and systemic hemodynamic benefits similar to BiV pacing. LV pacing at an appropriate atrioventricular interval prior to the RV sensed impulse provides superior RV hemodynamics compared with BiV pacing. (J Cardiovasc Electrophysiol, Vol. 18, pp. 497-504, May 2007)
Adaptive LV Pacing – How was the optimal AVI derived?

LV Pacing based on AVI estimated from Ap-RVs → Similar improvement of LVEF, reduction of LVESV, MR area vs BiVp & reduction of diastolic filling time vs BiVp

A pace to RV sensing interval best correlate with Echo derived optimal AV interval

<table>
<thead>
<tr>
<th>Parameter</th>
<th>AV_opt by LVEF</th>
<th>AV_opt by LVESV</th>
<th>AV_opt by LVEF and LVESV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ap-RVs</td>
<td>0.47 (y = 0.52x + 32, P = 0.0004)</td>
<td>0.56 (y = 0.70x + 0.71, P &lt; 0.0001)</td>
<td>0.66 (y = 0.61x + 16, P &lt; 0.0001)</td>
</tr>
<tr>
<td>QRSs</td>
<td>0.40 (y = 0.71x + 50, P = 0.004)</td>
<td>0.22</td>
<td>0.40 (y = 0.55x + 85, P = 0.005)</td>
</tr>
<tr>
<td>RVs - LVs</td>
<td>0.04</td>
<td>0.002</td>
<td>0.26</td>
</tr>
<tr>
<td>LVp - RVs</td>
<td>0.27</td>
<td>0.15</td>
<td>0.03</td>
</tr>
</tbody>
</table>

N= 55 SR PR <300ms

Europace (2011) 13, 1464–1470
Adaptive LV Pacing – How was the optimal AVI derived?

LV Pacing at AVI at 70% of Ap-RVs results in best LVEF, LVESV, LVEDV, MR area, LVOT VTI and DFT vs BiV Pacing

Figure 2 Echocardiographic parameters of left-ventricular function during bi-ventricular pacing, left-ventricular pacing at atrio-ventricular delays ranging from 40 to 95% of the intrinsic atrio-ventricular interval and without ventricular pacing (AAI). LVEF, left-ventricular ejection fraction; LVESV, left ventricular end-systolic volume; LVEDV, left-ventricular end-diastolic volume; MR area, area of the mitral regurgitant jet; LVOT VTI, velocity-time integral of the left-ventricular outflow; LVDF, left-ventricular diastolic filling time. *P < 0.05 vs. AAI, #P < 0.05 vs. bi-ventricular.
Adaptive LV Pacing – How was the optimal AVI derived?

If A-RVs >133.3ms: AV Optimum = 70% of A-RVs
If A-RVs <133.3ms: AV Optimum = 40ms prior RVs

Intrinsic RV completes biventricular activation

Optimal AV delay correlates with Ap-RVs

(R = 0.66, P <0.0001)
Adaptive BiV Pacing – How was the optimal AVI derived?

**Optimum AV Delay:**

- **For paced P**
  - ==> 30ms after end of P wave & 50ms before onset of intrinsic QRS
- **For sensed P**
  - ==> 40ms after end of P wave & 50ms before intrinsic QRS

The ventricular pacing configuration (RV->LV, LV->RV or LV) and V-V pace delay are updated every minute based on AVI and QRS width measurements.

ECG based AV optimization improves mitral inflow pattern/ A-V synchrony.

J Cardiovasc Electrophysiol, Vol. 21, pp. 1226-1232, November 2010
Adaptive LV/BiV Operation

Assess intrinsic conduction every minute. Extends the AV delay up to 300 ms

Normal AV Conduction

- HR $\leq 100$
- AS-VS $\leq 200$
- AP-VS $\leq 250$

LV Capture confirmed by LVCM

Adaptive LV pacing

Optimises AV delay to pre-pace the LV to synchronise with intrinsic RV activation

Prolonged AV Conduction

Adaptive BiV pacing

Adaptive BiV pacing automatically optimises AV delay / VV delay / BiV pacing configuration
Adaptive CRT

Determines the pacing method based on the intrinsic conduction assessment and heart rate

Adaptive LV Conditions:
1. HR ≤ 100 bpm
2. Intrinsic AV conduction normal (AS-VS ≤ 200 ms or AP-VS ≤ 250 ms)
3. LV capture confirmed by LVCM

Suspend Conditions:
1. Evidence of tachyarrhythmia
2. Incompatible device operation which affects patient's rhythm

- e.g. LV capture mx, threshold test
AdaptivCRT® Response Analysis

12% Absolute Higher Response Rate was Achieved with AdaptivCRT Compared to Historical CRT Trials.

OBJECTIVE:
- Compare AdaptivCRT response rates to Historical trials

OVER 1,300 CRT-D PATIENTS STUDIED:
- AdaptivCRT Cohort; n = 318 patients
- Historical Cohort; n = 1,003 patients

COMPARISON METHOD:
- Propensity Score allows comparison with historically matched patients
- Compensates for differences in baseline patient characteristics across trials

RESULTS:
- A 12% Higher Response Rate was achieved with AdaptivCRT Compared to Historical CRT Trials.

Note: Differences between the clinical composite scores of the Historical and AdaptivCRT cohorts were averaged across the subgroups.

1 Singh JP, Shen J, Chung ES. Clinical response with Adaptive CRT algorithm compared with echo guided AV optimization: a propensity score analysis of multi-center trials. Presentation at European Society of Cardiology Congress August 2012.
Clinical outcomes with synchronized left ventricular pacing: Analysis of the adaptive CRT trial

1. LV Pacing $\geq$50% was independently associated with a ~50% decreased risk of death or heart failure hospitalization compared with LV Pacing <50% (Heart Rhythm 2013;10:1368–1374; HR 0.49; 95% CI 0.28–0.85; P =0.012)

2. In patients with normal AV conduction: adaptive CRT → lower risk of death or CHF hospitalization by ~ 50% (HR 0.52; 95% CI 0.27–0.98; P =0.044)
AdaptivCRT® is Non-Inferior to Echo Optimisation at 6 months.

**OBJECTIVE:**
- Comparison between AdaptivCRT algorithm and Echo optimisation

**METHODS:**
- Prospective, multicenter, randomised, double blinded worldwide IDE clinical
- Rigorous and consistent echo protocol in control arm with optimisations at 1 & 6 months (AoVTI/iterative method)
- Follow-up at 6 months and 12 months

**PRIMARY END POINT (6 Months):**
1. Clinical Composite Score (non-inferiority)
2. Cardiac Performance/Aortic VTI (non-inferiority)

**RESULTS:**
- AdaptivCRT algorithm was safe and at least as effective as BiV pacing with comprehensive echo optimisation across a variety of primary and secondary end points

1. **Outcome of Packer Clinical Composite Score Analysis**
   - Non-inferiority P < 0.001

   ![Bar chart showing outcomes](chart)

   - AdaptivCRT: 74% Improved, 12% Unchanged, 14% Worsened
   - Echo control: 73% Improved, 16% Unchanged, 11% Worsened

Adaptive CRT is Non-Inferior to Echo optimization in terms of CHF composite scores

**AdaptivCRT vs Echo Optimization**
- N=522
- NYHA Class III/IV
- QRS \(\geq 120\) ms
- LVEF \(\leq 35\%\)

Adaptive CRT Trial

Adaptive CRT reduces RV pacing by 44% vs Echo Optimization arm

Novel Device Functions for CRT Optimization

1. Device-based – automatic CRT optimization has been proven non-inferior to echo-based optimization in acute hemodynamic and long term CHF endpoints.

2. LV based pacing algorithm improves hemodynamic outcome/ interventricular synchrony and prolongs device longevity by minimizing RV pacing.

3. No improvement on CHF/mortality endpoint vs echo-based optimization.

4. Not suitable for AF patients.
Novel Device Functions for Heart Failure Monitoring

1. Thoracic Impedance Monitoring
2. CHF Remote Monitoring
3. Invasive PAP Monitoring
Medtronic OptiVol®: Thoracic Impedance Monitoring

Heart Failure Exacerbation

Fluid Retention

Decrease in Impedance

OptiVol® Fluid Management is a feature in Concerto® and InSync Sentry® CRT-Ds and Virtuoso® DR/VR ICDS.
OptiVol fluid index is an accumulation of the difference between the daily and reference impedance.

\[ P = \text{Program} \]
\[ I = \text{Interrogate} \]

Fluid Index

Thoracic impedance

Review
Daily Impedance
graph first
Abraham WT. Superior Performance of Intrathoracic Impedance-Derived Fluid Index versus Daily Weight Monitoring in Heart Failure patients. Results of the Fluid Accumulation Status Trial. Late Breaking Clinical Trials. HFSA Conference 2009.
St Jude CorVue™ Congestion Monitoring

Normal: Dry: High Impedance  Congested: Wet: Low Impedance

Impedance measurement every 2 hours → Daily Impedance Average (Divided/12)
First 12-14 days measurement → Baseline reference impedance

The typical range of impedances in clinical study => 800 to 1600 ohms
Medtronic OptiVol - MIDHeFT Study

Impedance Trend -
Reflects Fluid Balance & PCWP

33 patients with NYHA Class III/IV HF and 5 patients without HF

Impedance drop precedes CHF symptom onset by 15.3±10.6 days

Impedance drop: ~77% sensitive in detecting fluid overload

Medtronic OptiVol - MIDHeFT Study
Thoracic Impedance prior to hospitalization

Patients who Were NOT Hospitalized

Patients who Were Hospitalized

Days Prior to Admission

Days After Implant

Days Before Hospitalization

Impedance (%)

Reference Baseline

Impedance Reduction

Duration of Impedance Reduction

More Fluid

Less Fluid

Symptoms Onset

Impedance Decline

Fluid Index Threshold Crossing – Predicts Mortality / CHF Hospitalization

OptiVol® and Mortality Risk

Threshold Crossing of OptiVol® Impedance Identified Patients with Significant Long-Term Mortality Risk


![Graph showing the relationship between time and all-cause mortality with early and no early threshold crossings.]

The Kaplan-Meier survival analysis for all-cause mortality stratified by the presence or absence of early intrathoracic impedance threshold crossings.

OFISSER: Identify Patients at Risk

- Frequent or sustained OptiVol® threshold crossings identify high-risk patients

Changes in Intrathoracic Impedance Are Associated with Subsequent Risk of Hospitalizations for Acute Decompensated Heart Failure:
Clinical Utility of Implanted Device Monitoring without a Patient Alert

ROY S. SMALL, MD; WILLIAM WICHEMEYER, MD; ROBIN GERMAIN, MD; BOBBI HOPPE, MD; JOHN ANDRILLI, DO; PETER A. BRADY, MD; MELODY LABEAU, JORDI KOCHER, MS; SHANTANU SARKAR, PhD; DOUGLAS A. HETTRICK, PhD; AND W. H. WILSON TANG, MD, FAAAA

ADHF Hospitalization Rate (yr)

![Graph showing intrathoracic impedance fluid index threshold crossings and days with intrathoracic impedance fluid index above threshold.]


Thoracic Impedance Monitoring Reduces CHF Hospitalization by 58%

Reducing Hospitalizations

Practical Experience by a High Volume Heart Failure Clinic in the OFISSER Study

Primary Findings
- Patients hospitalized less often
- Fewer patients hospitalized
- Patients hospitalized for less time

Impact on Reduction of Heart Failure Hospitalization
- 0.15 patients per year reduction with use of OptiVol®
- 58% reduction in Hospitalization Admission Rate
  - Defined as hospitalization that occurred within 12 months

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Thoracic Impedance Monitoring:

1. Correlates well with PCWP/ Fluid balance
2. Detection bf CHF symptom onset by ~ 2 weeks
3. Fluid index threshold crossing predicts CHF hospitalization/ CHF readmission/ mortality
4. Fluid index guided Rx reduces CHF hospitalization
CHF Remote Monitoring
BIOTRONIK Home Monitoring® vs. Other Remote Monitoring Systems


1 Stationary patient devices require continuous 110/220 V mains connection.
2 Carelink® and Merlin@home PCN® to offer limited cellular capability in select stationary patient communicators starting in 2010.
Medtronic CareLink® Monitor

CardioSight®

1. Using the secure Medtronic CareLink Clinician Website, clinic staff can preschedule up to six automatic device checks for each patient – without having to make appointments or coordinate calendars with patients.

2. The device automatically “wakes up” at the scheduled time and communicates with the Medtronic CareLink Monitor, which is plugged into a standard phone line and an electrical outlet. Data are transmitted wirelessly from the device to the monitor as the patient sleeps.

3. Data are sent automatically from the Medtronic CareLink Monitor to a secure server via the phone line.

4. The clinician reviews the patient’s device data on the secure website.
IN-TIME: The Influence of Implant-Based Home Monitoring on the Clinical Management of Heart Failure Patients with an Impaired Left Ventricular Function

Study Design

664 pts. with ICD/CRT-D chronic HF ≥ 3 months NYHA II/III, EF ≤35%

Home Monitoring arm 333

Standard Care 331

Follow-up: 12 months

Primary composite endpoint: Death, HF hospitalization, NYHA, global self assessment score (= Modified Packer Score)

Major secondary endpoints: All-cause mortality, number of HF hospitalizations and length(s) of stay

IHD 69%
Mean age 66±9 years
CRT-D 58%; PPM 42%

Hindricks G et al. The Influence of Implant-Based Home Monitoring on the Clinical Status of Heart Failure Patients with an Impaired Left Ventricular Function ESC 2013
Result at 12 months:

Telemonitoring Arm vs Control Arm:

1. Reduces worsening of clinical status by ~1/3

   (Packer Score = Mortality, CHF hospitalization, NYHA class global self assessment) (18.9% vs 27.5%; RRR 31%; p<0.05)

2. Lowers all-cause mortality by ~ 60%

   (3.4% vs 8.7%; HR 0.35; 95% CI 0.172-0.735; p = 0.004)

First RCT to demonstrate a significant reduction in all-cause mortality in heart failure patients with implant-based remote monitoring

Hindricks G et al. The Influence of Implant-Based Home Monitoring on the Clinical Status of Heart Failure Patients with an Impaired Left Ventricular Function ESC 2013
CHF Remote Monitoring – Trials

1. TRUST Trial: Reduces cardiac resources utilization by 45% in 1y and enables early detection of arrhythmia/ silent events

2. ECOST Trial: Reduces risk of ICD shock delivery by 71%

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**Figure 1** The TRUST trial. Home Monitoring (HM) reduced cardiac-resource utilization [scheduled and unscheduled clinic and hospital visits (including responses to HM event notifications)] by 45% in 1 year (left) yet enabled early detection of arrhythmias (middle) and silent events (right). Compiled with permission from Varma et al.\textsuperscript{11}
CHF Remote Monitoring – Trials

1. COMPASS Trial: Reduces number of follow up visits by 36%
2. ECOST Trial: Reduces major adverse events

**Figure 2** The COMPAS trial. Major adverse events (MAEs) were unchanged but face-to-face visits were reduced. Compiled with permission from Mabo et al.¹²

**Figure 3** The ECOST trial. Cumulative survival free from major adverse events in the intention to treat (A) and per-protocol (B) population.
2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy

The Task Force on cardiac pacing and resynchronization therapy of the European Society of Cardiology (ESC). Developed in collaboration with the European Heart Rhythm Association (EHRA).

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Classa</th>
<th>Levelb</th>
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</thead>
<tbody>
<tr>
<td>Device-based remote monitoring should be considered in order to provide earlier detection of clinical problems (e.g. ventricular tachyarrhythmias, atrial fibrillation) and technical issues (e.g. lead fracture, insulation defect).</td>
<td>IIa</td>
<td>A</td>
</tr>
</tbody>
</table>

2012 EHRA/HRS expert consensus statement on cardiac resynchronization therapy in heart failure: implant and follow-up recommendations and management

Remote monitoring and follow-up in addition to in-clinic follow-up is recommended. Patients should be encouraged to initiate a remote transmission if new symptoms or concerns arise.
PAP Sensor and System (CardioMEMS)

Post implant: Aspirin + Plavix x 1 month
Followed by aspirin alone

External Measurement System

Patient Database

*See appendix for information on implant techniques*
PAP Sensor and System (Champion Trial)

CHF Patients
NYHA III

550 Pts w/ CM Implants
All Pts Take Daily readings

Treatment
270 Pts
Management Based on
PAP + Traditional Info

Control
280 Pts
Management Based on
Traditional Info

Primary Endpoint: rate of HF Hospitalization

26 (9.6%) Exited < 6 Months
15 (5.6%) Death
11 (4.0%) Other

26 (9.6%) Exited < 6 Months
20 (7.1%) Death
6 (2.2%) Other

Secondary Endpoints included:
- Change in PAP at 6 months
- No. of patients admitted to hospital for HF
- Days alive outside of hospital
- QOL

Target PAP:
PAP Systolic 15 – 35 mmHg
PAP diastolic 8 – 20 mmHg
PAP mean 10 – 25 mmHg

PAP was managed to target pressures by physicians with titration of HF medications.

Compared to the control group, patients managed with PAP had persistently lower mean PA pressures, lower CHF Hospitalization rate.

**CHAMPION Trial: PAP Mean Change from Baseline**

![Graph showing mean change from baseline with PAP treatment](image)

**Figure 3:** Cumulative heart-failure-related hospitalisations during entire period of randomised single-blind follow-up (A), and freedom from first heart-failure-related hospitalisation or mortality during the entire period of randomised follow-up (B).

Summary

1. Device-based automatic CRT Optimization is non-inferior to echo-optimization and is more time-efficient. No long term data in CHF/ Mortality endpoint.

2. LV-based pacing algorithm improves inter/intra-ventricular hemodynamic/synchrony/reduces CHF in patients with preserved AV conduction. It minimizes RV pacing induced dyssynchrony and prolongs device longevity

3. Device-based CHF monitoring allows pre-symptomatic detection of CHF/ arrhythmia, prediction of CHF hospitalization/ mortality and guides early medical intervention to reduce CHF admissions /morbidities