Optimizing HF and Device Therapy After Cardiac Device Implantation

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Conflict of Interest Disclosures

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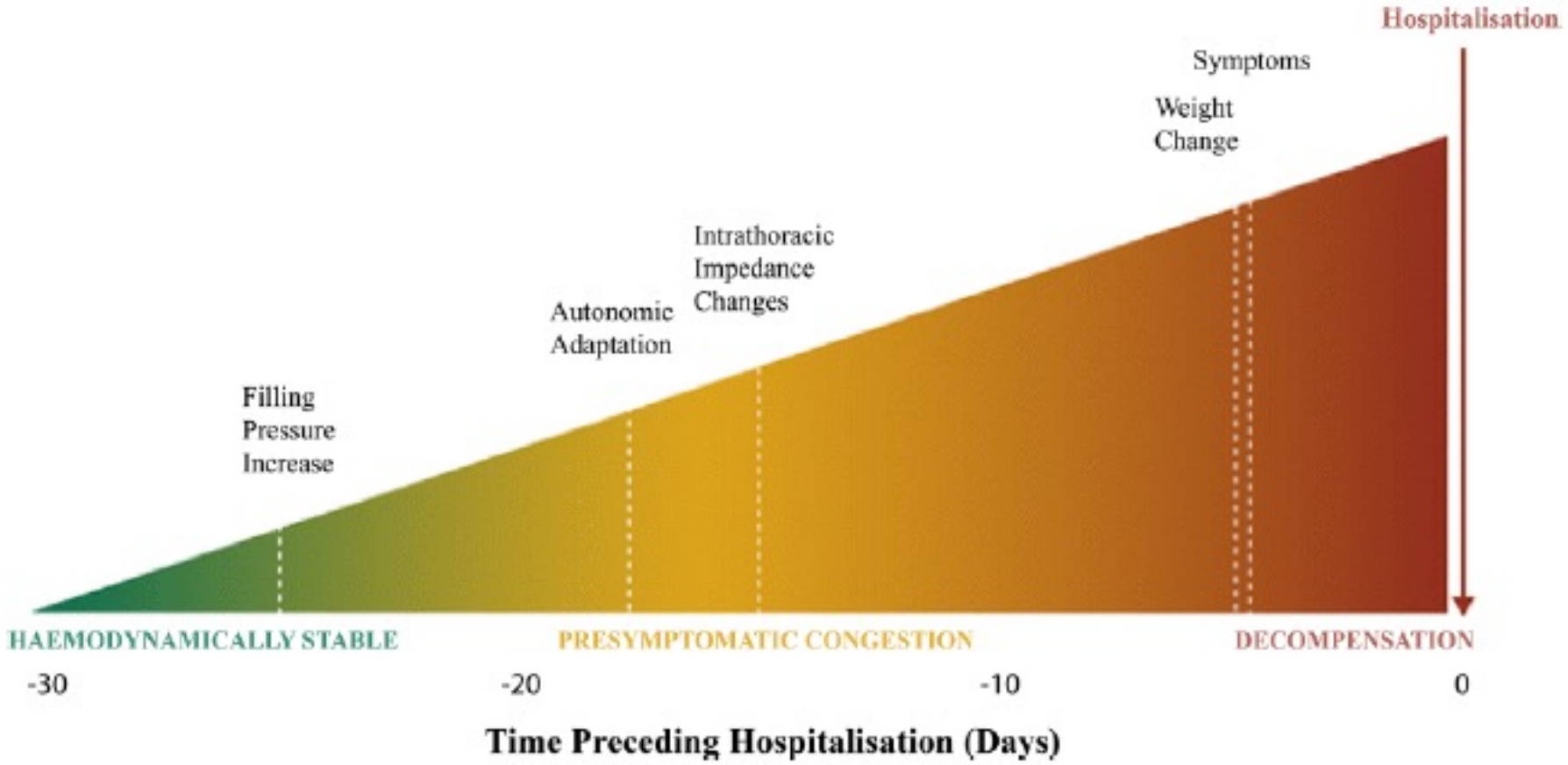
- **Speaker fees**: N/A
- **Other**: N/A

Objectives

1. Interpret CRT diagnostics and recognize opportunities for optimization
2. Discuss clinical pathways for optimization of GDMT
3. Review successful integrated HF programs for optimization in device clinics

WHAT'S NEW IN DEVICE DIAGNOSTICS?

Fig. 1 Pathophysiology of decompensated heart failure. (Reprinted from [54], with permission)



Veenis et al. Neth Heart J. 2020; 28: 3-13.

PARTNERS HF

- Observational study, 1024 patients enrolled in 100 US centres – this analysis includes 694 patients
- Inclusion: LVEF ≤ 35%, NYHA III or IV, QRS > 130 ms
- Looked at AF duration, rates during AF, OptiVol, patient activity, night heart rate, heart rate variability, %CRT pacing, ICD shocks for VT/VF
- Criteria: OptiVol > 100 or 2 of the above factors

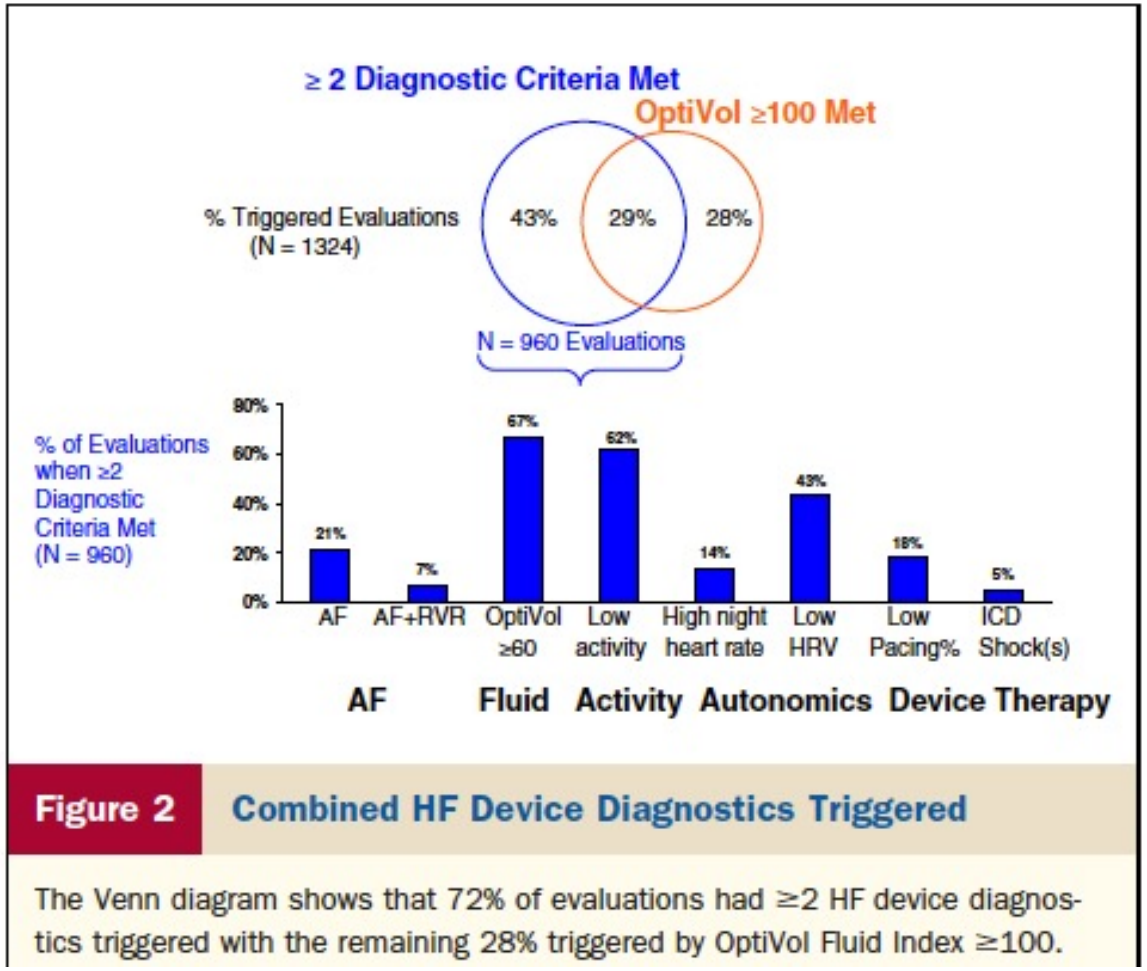


Figure 2 **Combined HF Device Diagnostics Triggered**

The Venn diagram shows that 72% of evaluations had ≥2 HF device diagnostics triggered with the remaining 28% triggered by OptiVol Fluid Index ≥100.

Whellan et al. J Am Coll Cardiol 2010; 55: 1803-10.

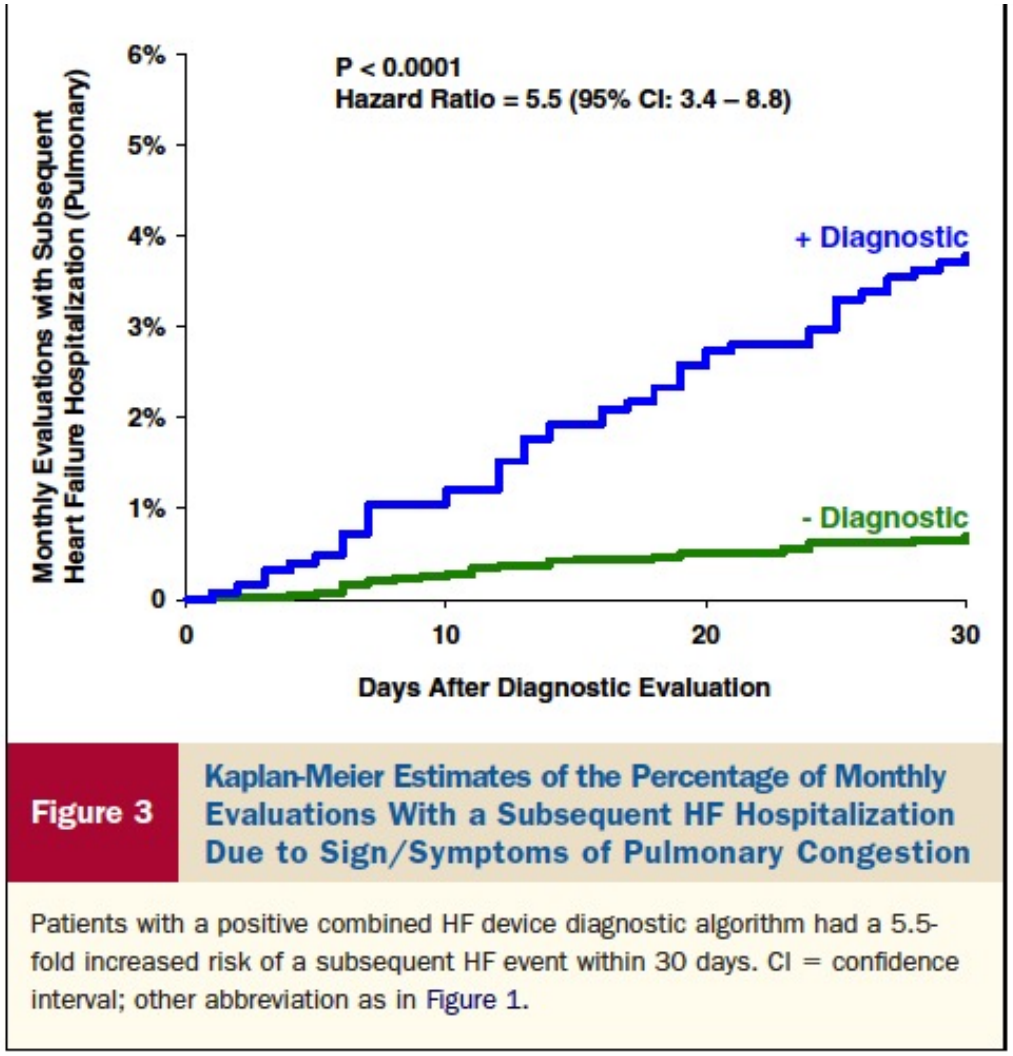
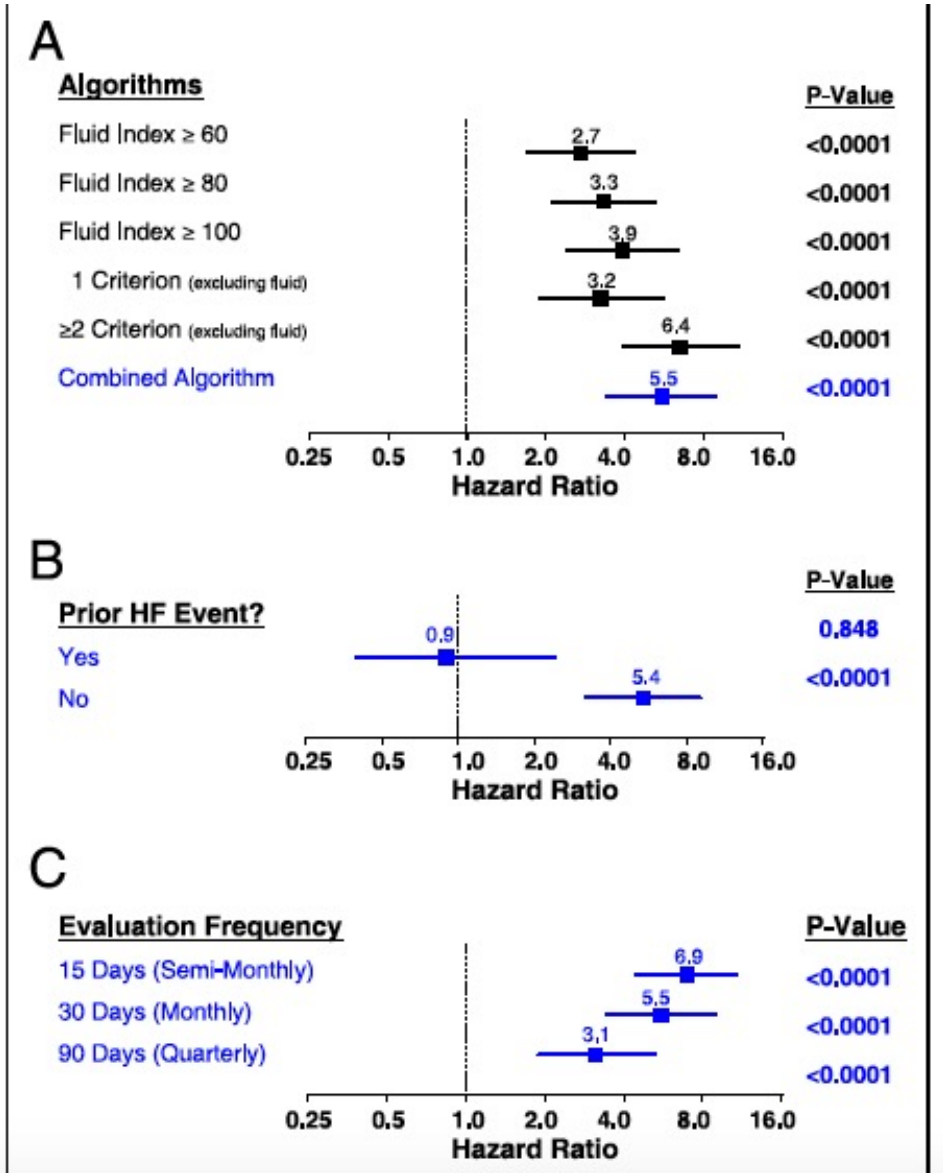


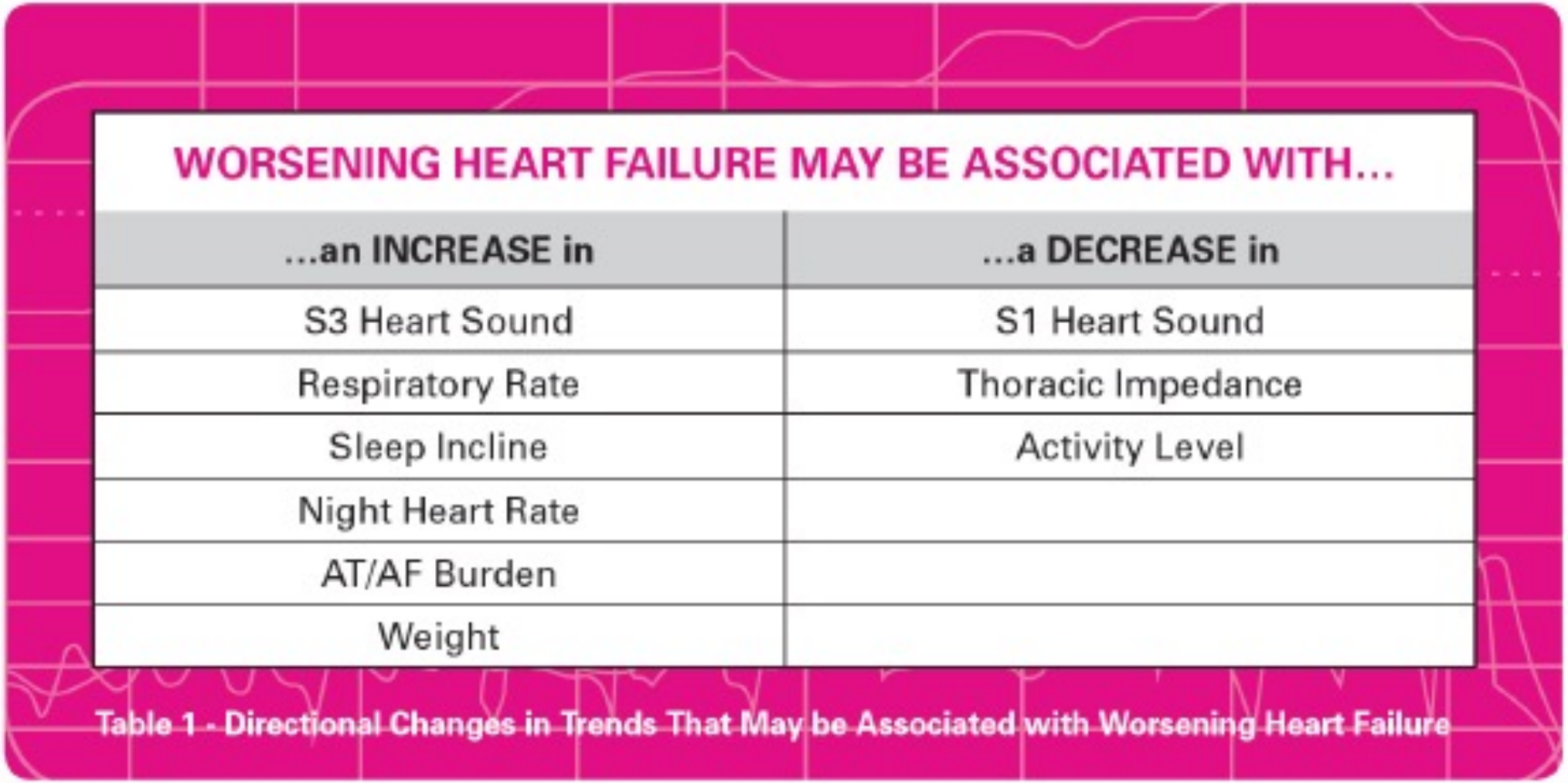
Figure 3 Kaplan-Meier Estimates of the Percentage of Monthly Evaluations With a Subsequent HF Hospitalization Due to Sign/Symptoms of Pulmonary Congestion

Patients with a positive combined HF device diagnostic algorithm had a 5.5-fold increased risk of a subsequent HF event within 30 days. CI = confidence interval; other abbreviation as in Figure 1.



Whellan et al. J Am Coll Cardiol 2010; 55: 1803-10.

Heart logic



WORSENING HEART FAILURE MAY BE ASSOCIATED WITH…	
…an INCREASE in	…a DECREASE in
S3 Heart Sound	S1 Heart Sound
Respiratory Rate	Thoracic Impedance
Sleep Incline	Activity Level
Night Heart Rate	
AT/AF Burden	
Weight	

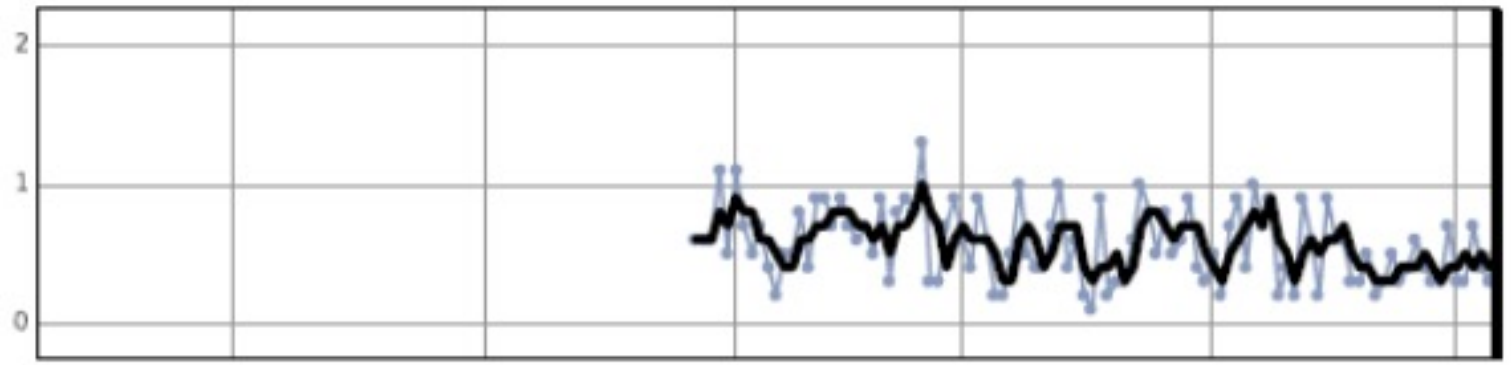
Table 1 - Directional Changes in Trends That May be Associated with Worsening Heart Failure

Activity Level

May 06, 2017

0.5

hour(s)



AT/AF Burden

May 06, 2017

23.4

hour(s)

V Therapy

RV Rate during AT/AF

Max

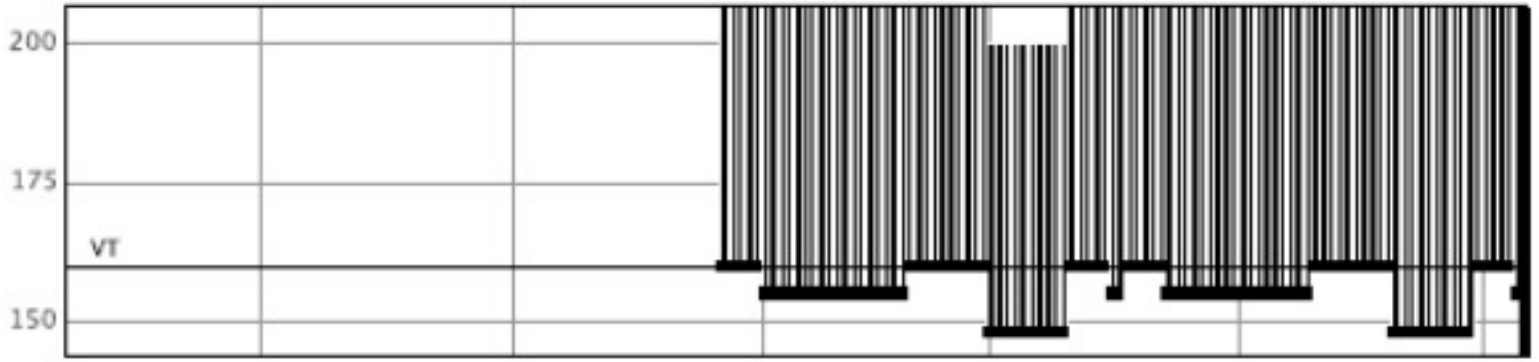
Mean

May 06, 2017

222

155

bpm



Daily Value 3 Day Average

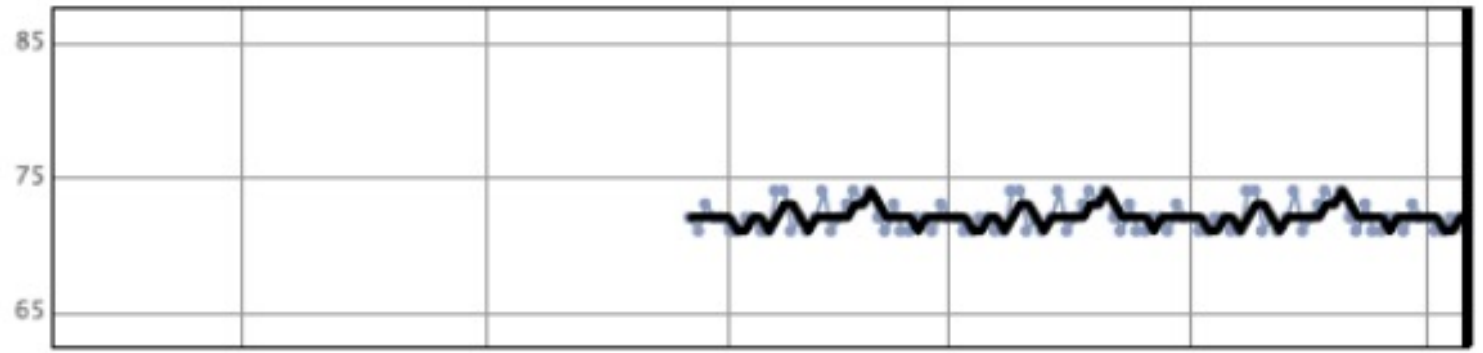
Dec 01, 2016 Jan 01, 2017 Feb 01, 2017 Mar 01, 2017 Apr 01, 2017 May 01, 201

Mean Heart Rate

May 06, 2017

71

bpm

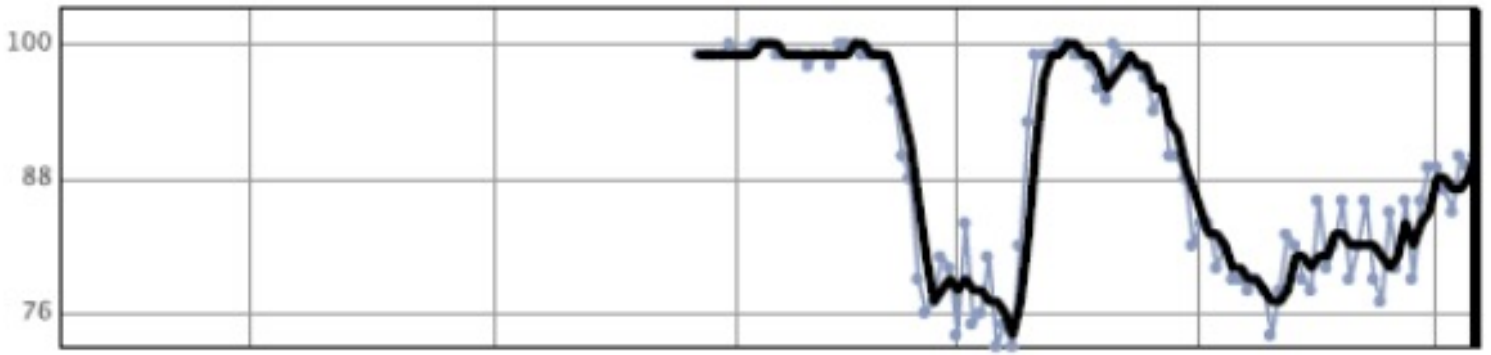


% LV Paced

May 06, 2017

90

%

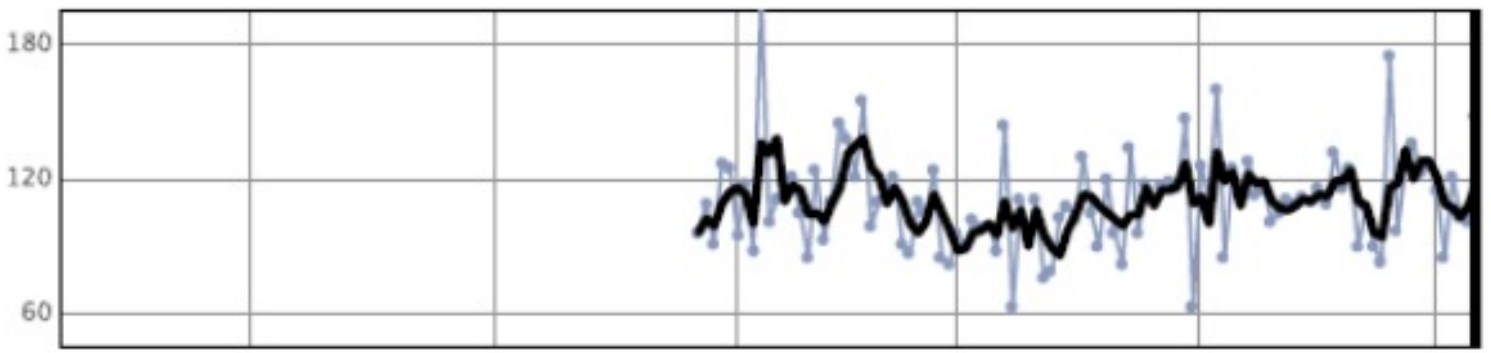


Heart Rate Variability (SDANN)

May 06, 2017

148

ms



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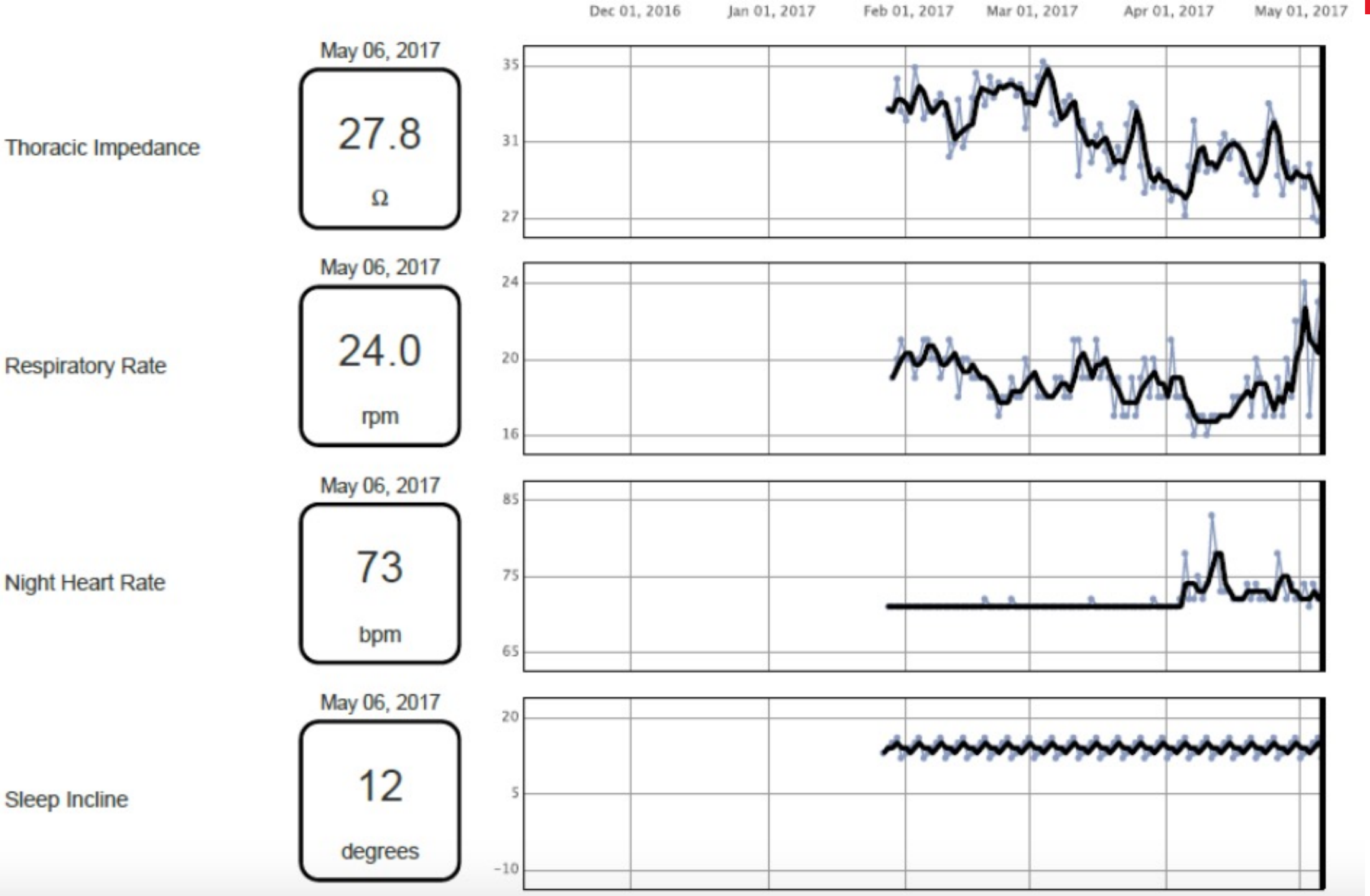
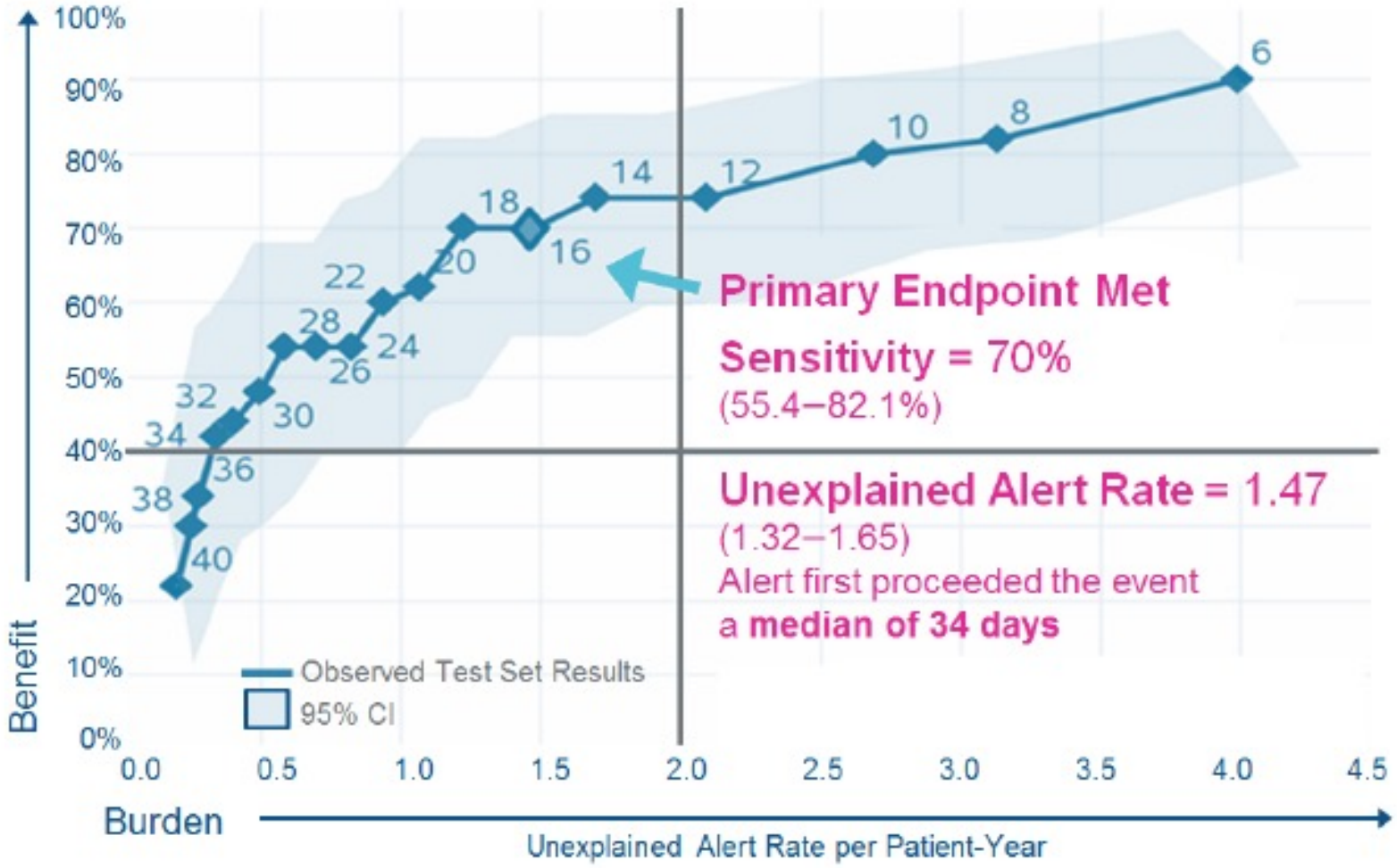

Dec 01, 2016
Jan 01, 2017
Feb 01, 2017
Mar 01, 2017
Apr 01, 2017
May 01, 2017
Thoracic Impedance
May 06, 2017
27.8
Ω
35
31
27
Respiratory Rate
May 06, 2017
24.0
rpm
24
20
16
Night Heart Rate
May 06, 2017
73
bpm
85
75
65
Sleep Incline
May 06, 2017
12
degrees
20
5
-10

Multisense trial

- 974 patients, international, multi-center, non-randomized study
- Objective: to evaluate multi-sensor based algorithm for early detection of worsening HF
- Criteria: Recent HFH
- Amended criteria: NYHA II-IV within the last 6 months
- Clinical events committee was blinded to sensor readings
- Endpoint 1: Sensitivity for detecting HFE > 40%
- Endpoint 2: Unexplained alert rate per patient-year < 2
- Development set: first 531 pts
- Test set: 443 pts

Boehmer J et al. J Am Coll Cardiol HF 2017; 5: 216-25.

Multisense trial



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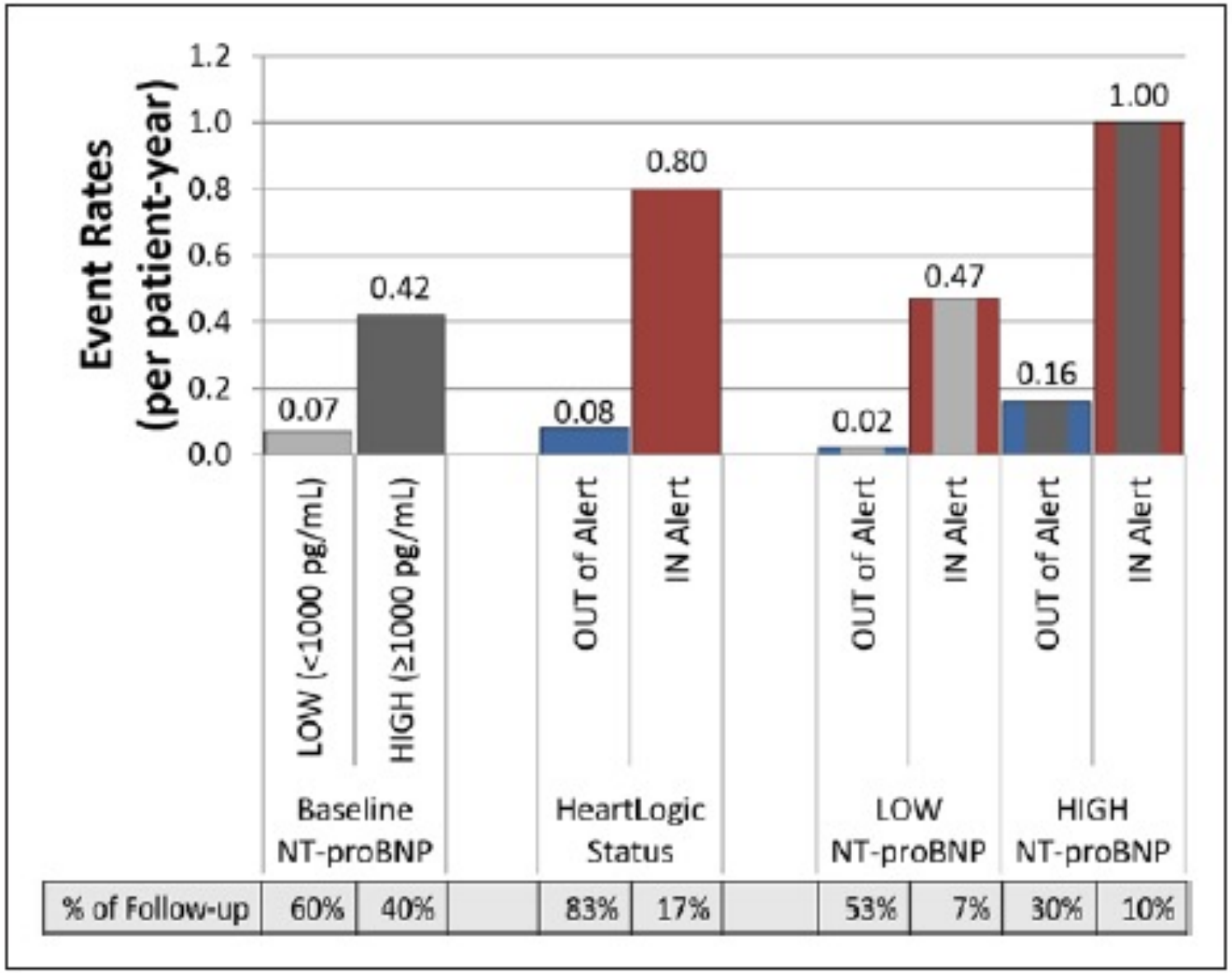
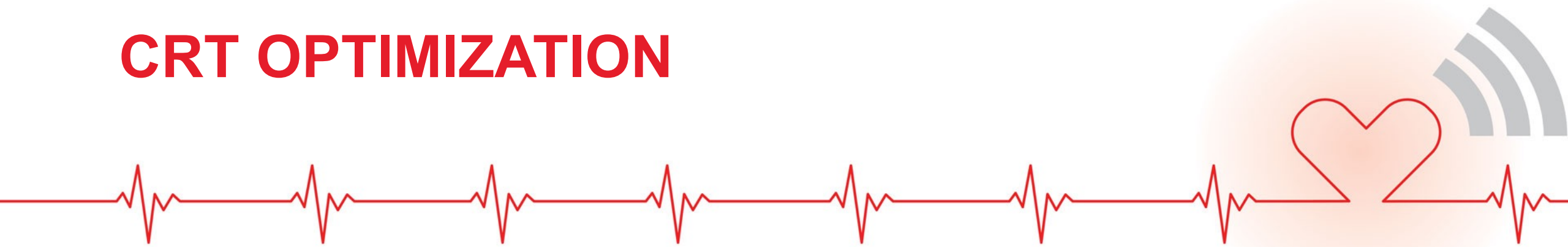


Gardner R et al. Circ Heart Fail 2018; 11: 1-10.

CRT OPTIMIZATION

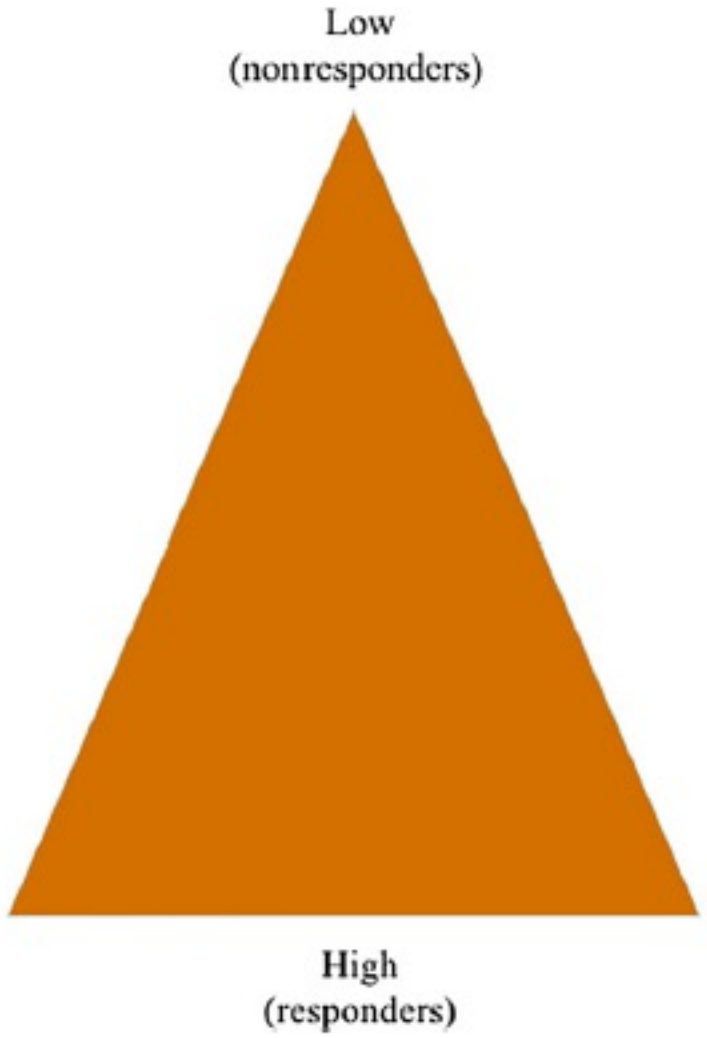


Patient case

- 66M advanced ischemic cardiomyopathy (EF<20%), NYHA IIIb, ICD in-situ, wide LBBB
- Other co-morbidities: DM (A1c: 12%) and significant PAD
- Underwent CRT upgrade during HFH – initially felt to be a non-responder but within 6 months, SBP improved by 20 mm Hg and functional class improved to NYHA II
- Able to optimize his meds further: Ramipril 5 mg BID, Spironolactone 25 mg daily, Furosemide 80 mg BID, Empagliflozin 25 mg daily, intolerant of BB
- Does well for ~ 1 year and then returns with worsening volume overload
- Device interrogation reveals that his Bi-V pacing %age has dropped from 98% to 70%

- What is on your differential for this sudden drop in Bi-V pacing?

Appropriate patient selection



QRS (120–130 ms)
non-LBBB morphology

Ischemic cardiomyopathy
males

QRS >150 ms
LBBB morphology
nonischemic
cardiomyopathy
females

Tolosana JM et al. Heart Failure Clin 13 (2017): 233-240.

Varying definitions of CRT non-response

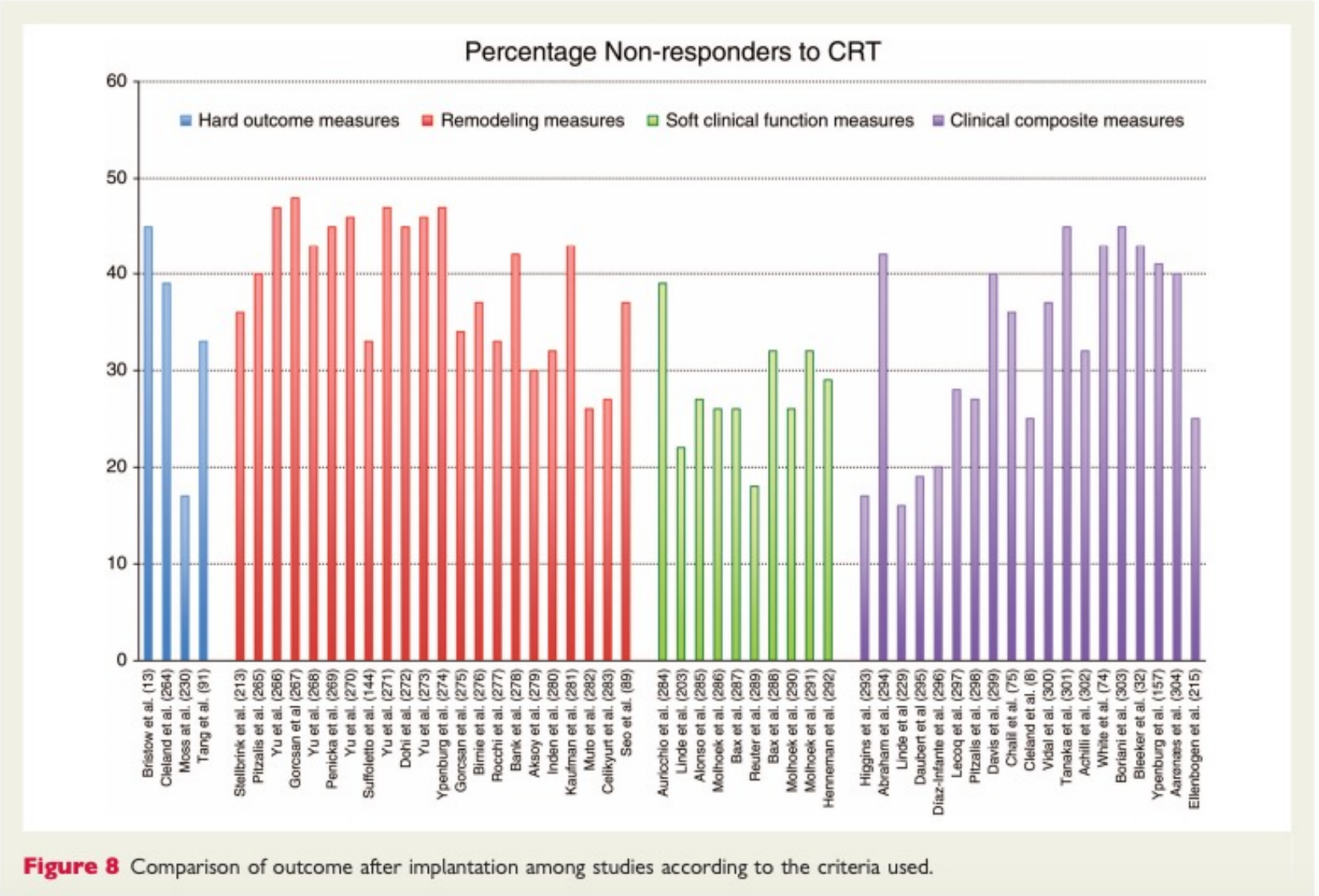
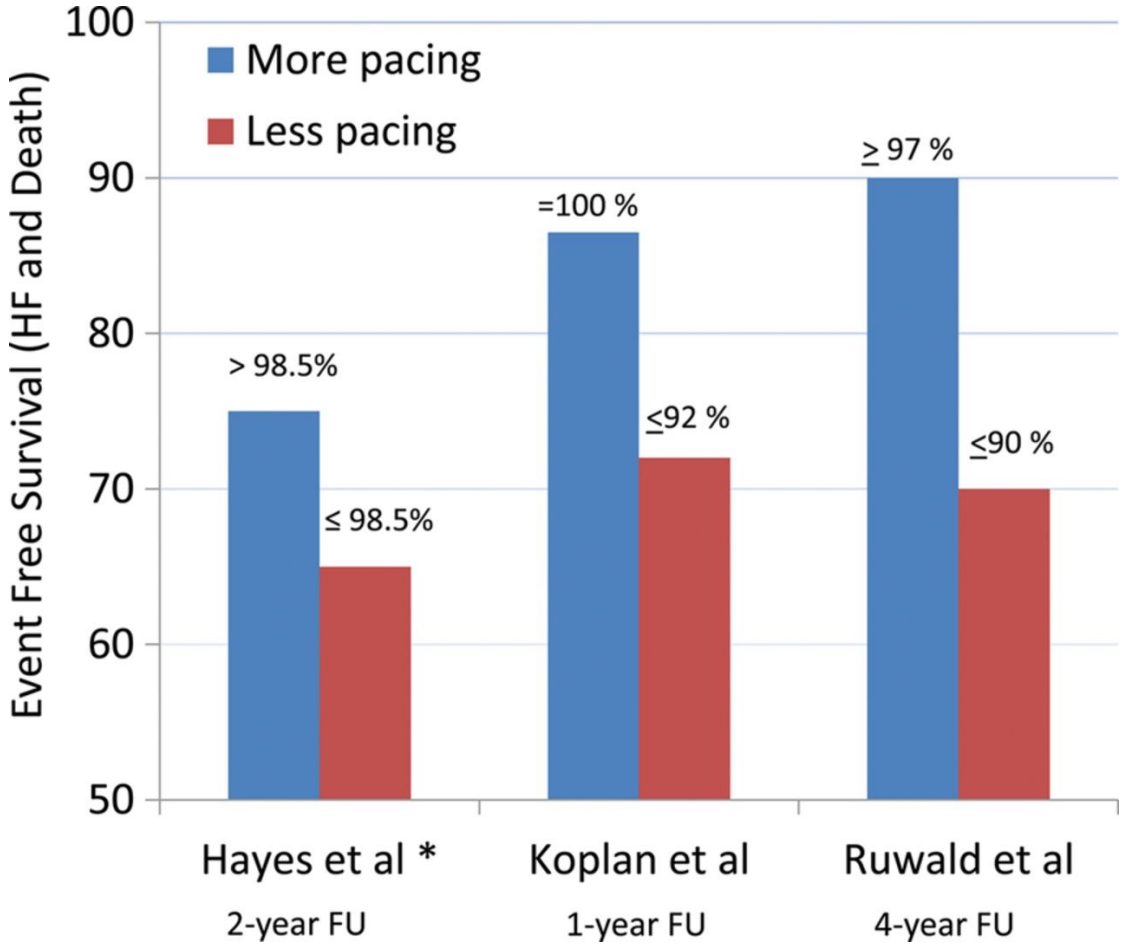


Figure 8 Comparison of outcome after implantation among studies according to the criteria used.

EHRA/HRS Consensus Statement on CRT in HF. Europace 2012; 14: 1236-86.

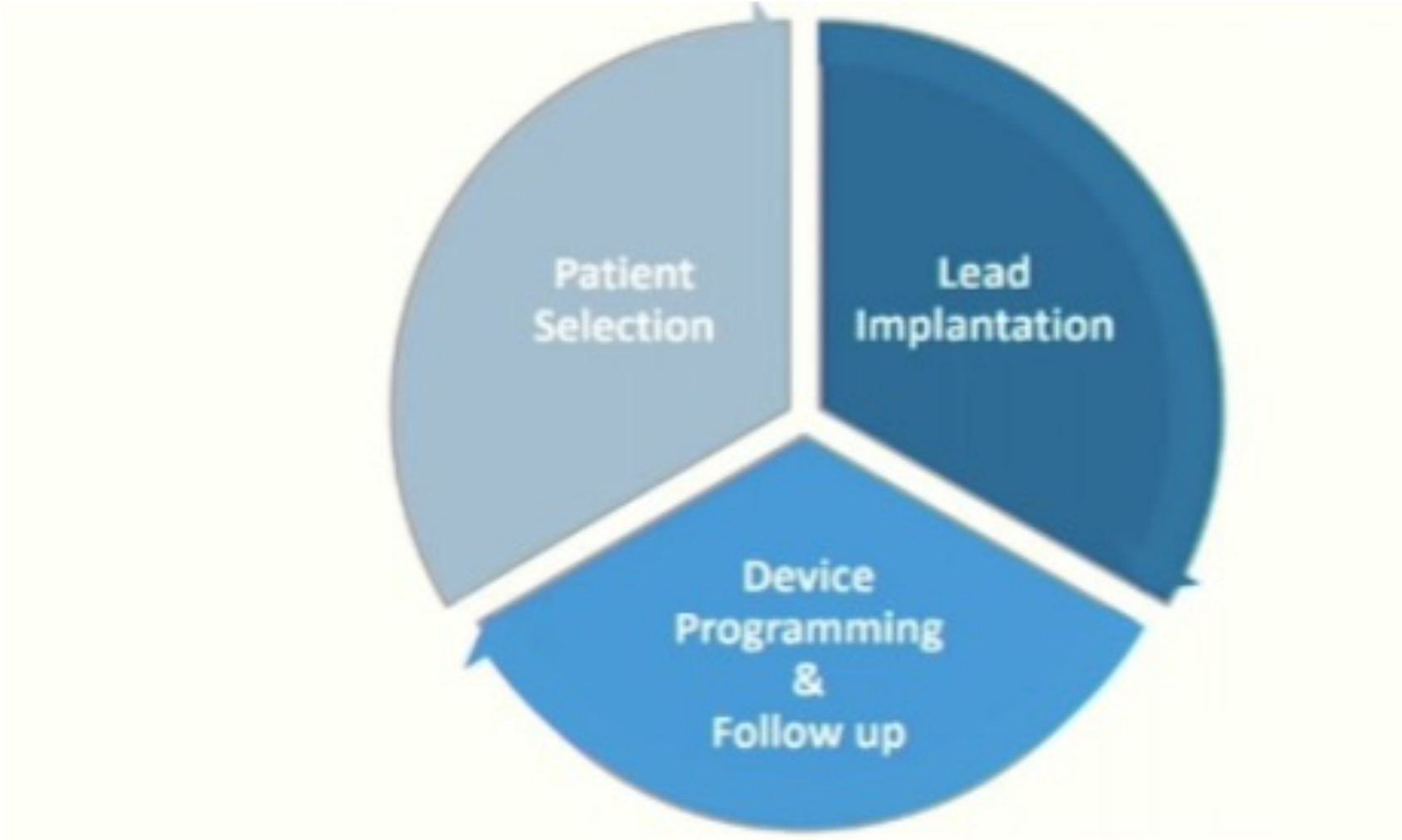
More biventricular pacing is better



Lubitz SA et al. Eur Heart J 2015; 36: 407-09.

CRT non-responder

- Look for rhythm issues
- AV or VV optimization
- Medical optimization
- Reassess LV lead position
- Alternative pacing modalities



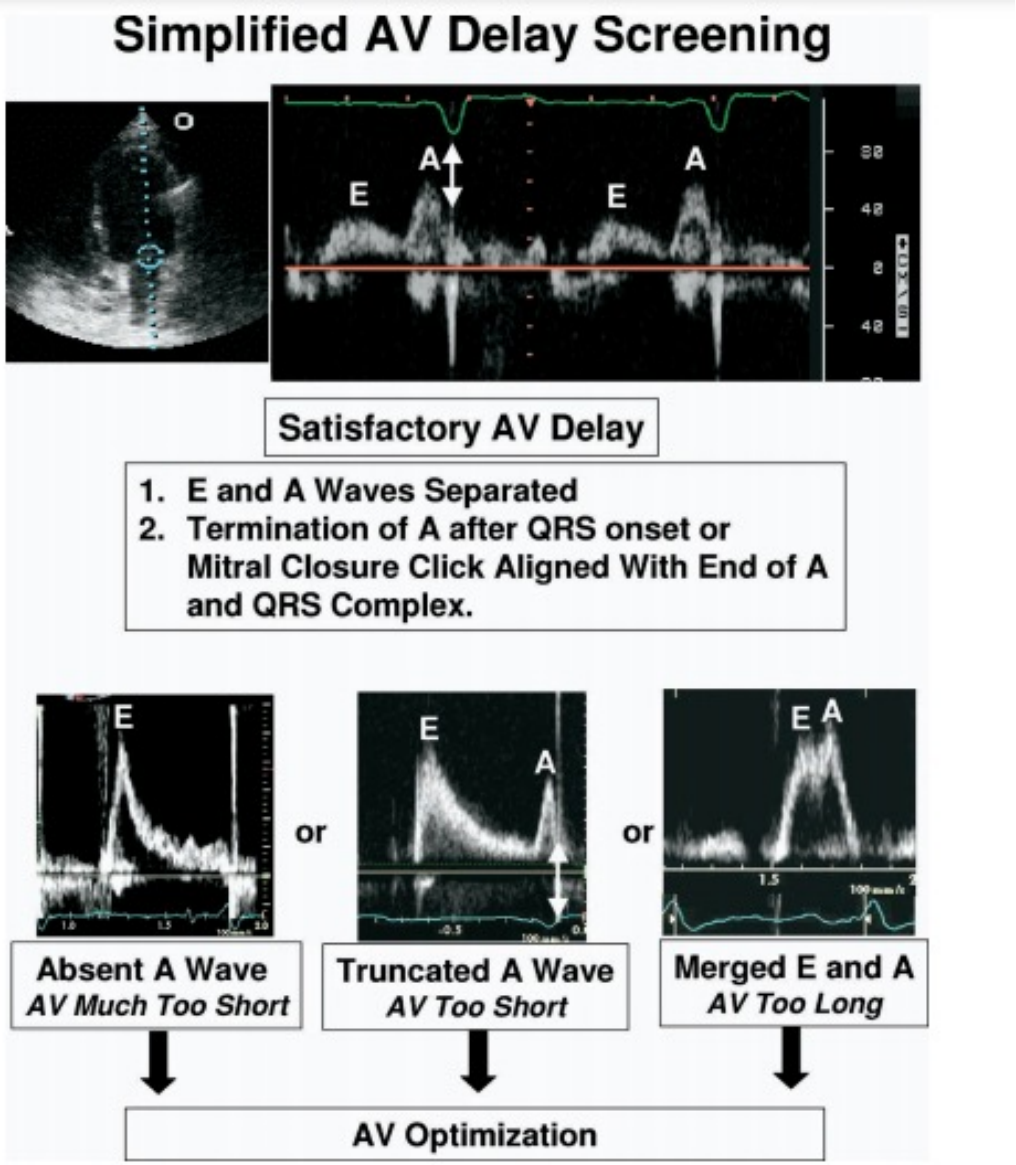
Courtesy of Dr. Jagmeet Singh

Making use of device diagnostic data

Diagnostic data	Description and rationale
Ventricular pacing (VP)	Estimate of the percentage of paced ventricular events • Should be >95% (ideally near to 100%)
Biventricular (BiVP), right (RVP), and left ventricular pacing (LVP)	Dedicated counters available in some devices • May indicate VP without resynchronization (%RVP < %BiVP)
Biventricular pacing via resynchronization algorithm	Counter for LVP after RV sensing • LV capture questionable
Ventricular sensing (VS)	Estimate of the percentage of sensed ventricular events • Should be close to 0% • VS episodes (continuous ventricular sensing) may indicate intrinsic AV conduction (programmed AV delay too long) or atrial undersensing with intrinsic AV conduction
Premature ventricular complexes (PVCs)	Number of PVCs and per cent of ventricular events that are PVCs • PVCs reduce the time in effective CRT; should be suppressed • May represent atrial undersensing with intrinsic AV conduction, ventricular oversensing (QRS, T wave) or ventricular exit block
Mode switch, atrial high rate episodes, AT/AF episodes	Number of AF episodes and percentage of time in mode switch • May explain non-response to CRT • May represent inappropriate mode switch due to atrial oversensing (resulting in VVI pacing with pacemaker syndrome)
VT/VF	Evaluate for triggers of VT/VF events (e.g. atrial fibrillation)
Non-sustained VT	High grade non-sustained VT may result in significant loss of BiV pacing • Can represent ventricular oversensing or atrial undersensing

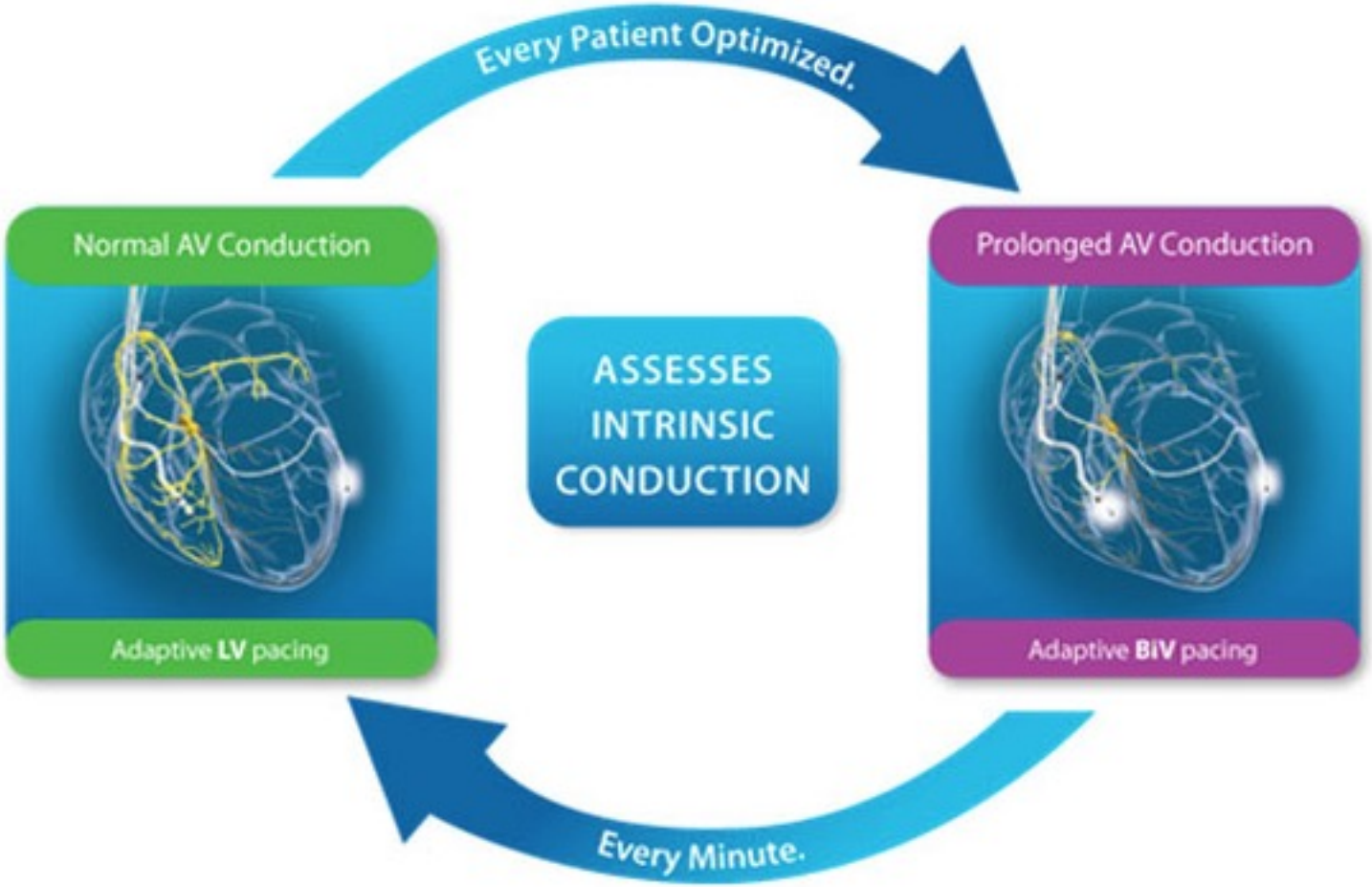
EHRA/HRS Consensus Statement on CRT in HF. Europace 2012; 14: 1236-86.

ECHO optimization



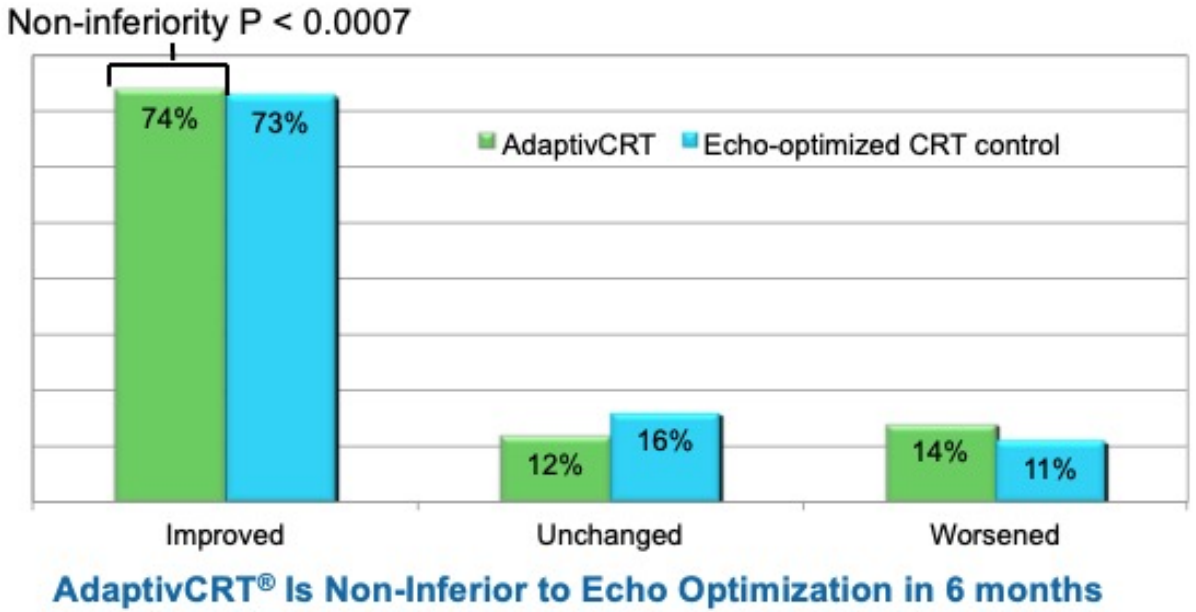
Gorcsan J et al. 2008 ASE guidelines for CRT optimization

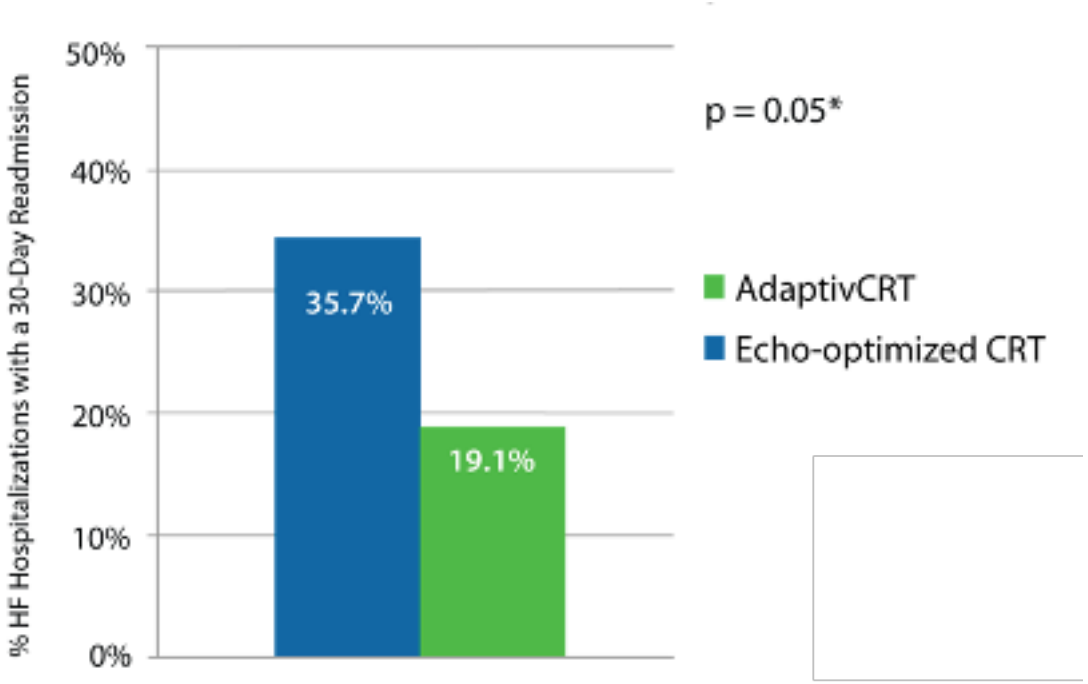
AdaptivCRT



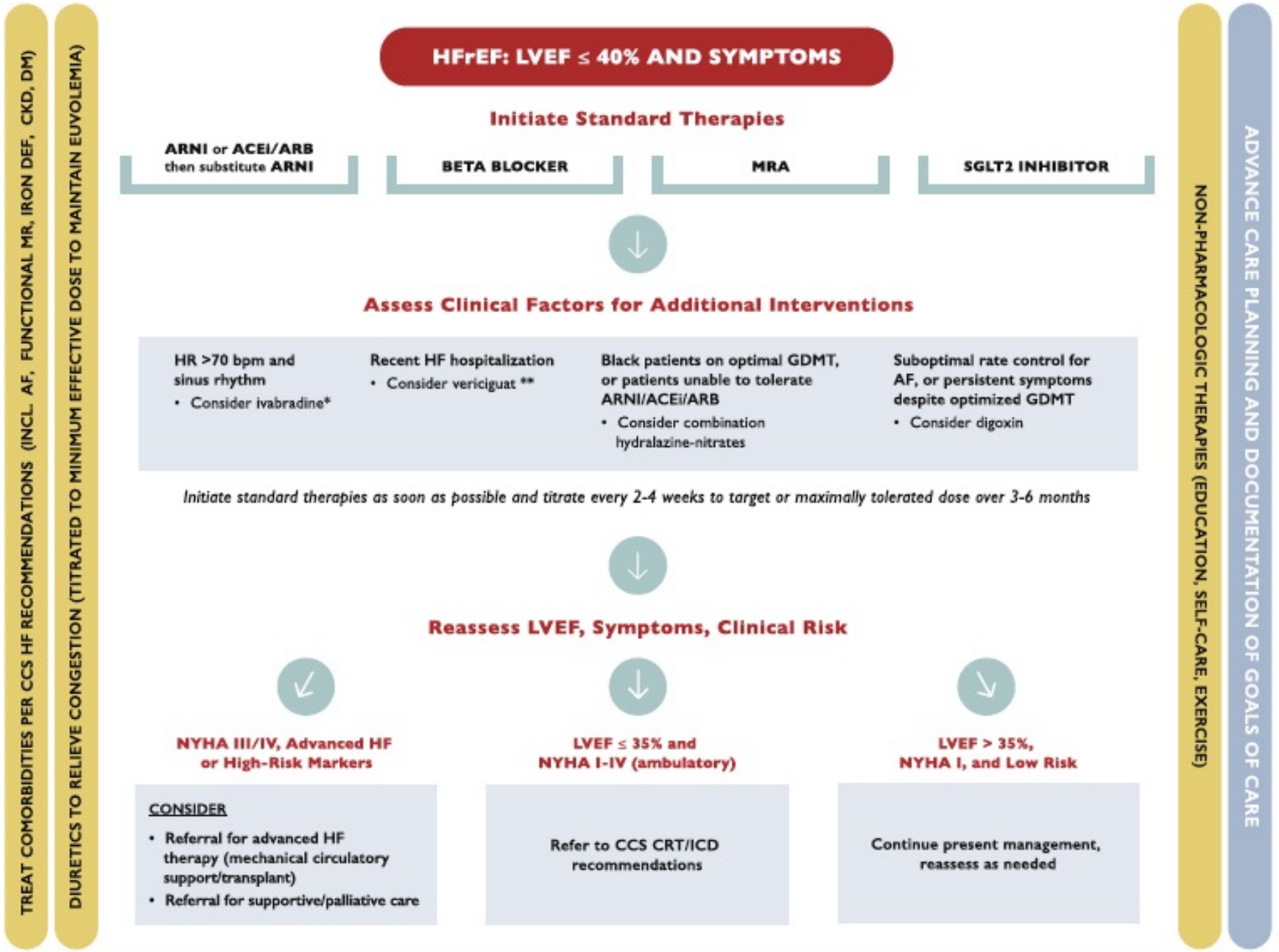
Courtesy of Medtronic Academy

AdaptivCRT trial





Starling RC et al. JACC Heart Fail 2015; 3(7): 565-72.



2021 CCS HF guidelines

HOW ARE CENTERS OPTIMIZING HF THERAPIES IN THE DEVICE CLINIC?

CRT-HF Clinic

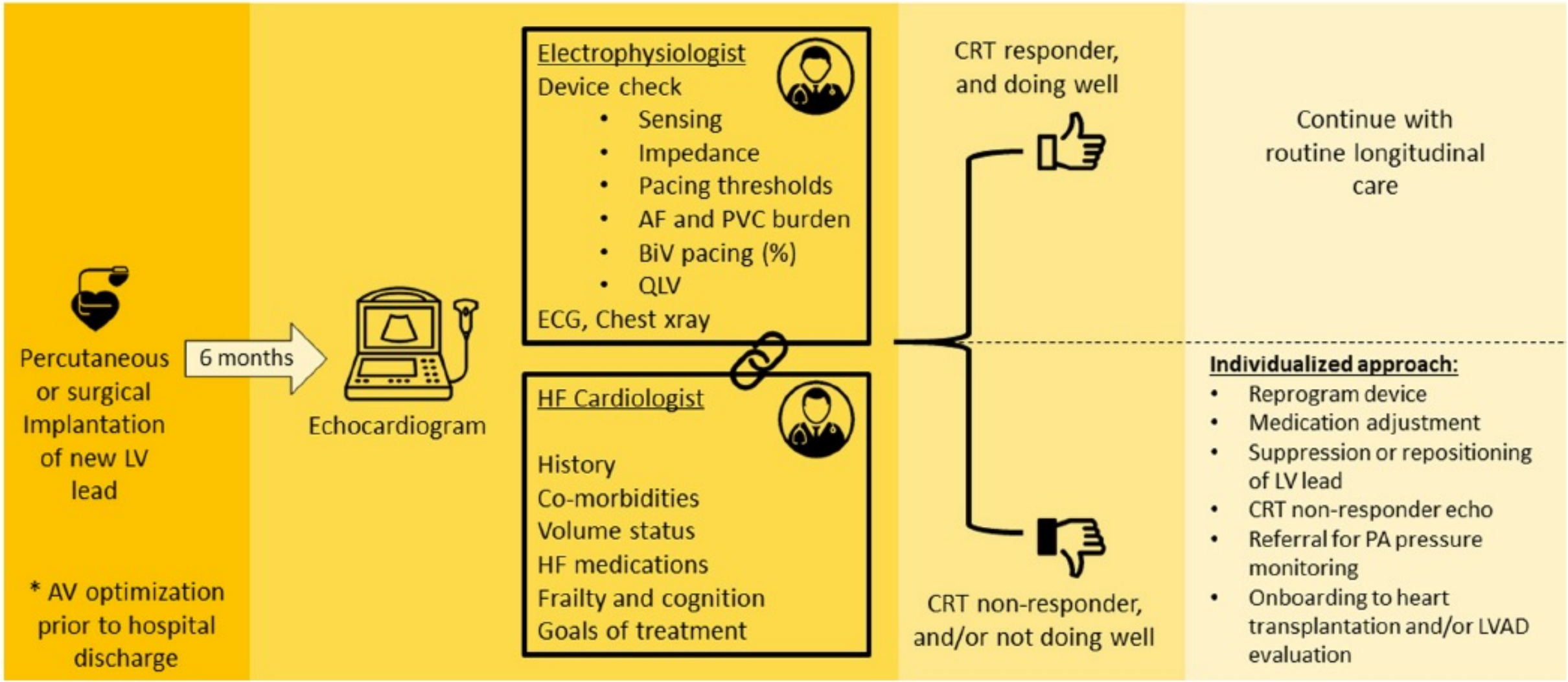


Fig 1. CRT-HF clinic workflow.

Gorodeski EJ et al. PLoS ONE 14(9): e0222610.

Hamilton approach

Arrhythmia Devices Clinic Questionnaire

Please take a few minutes to let us know how you have been feeling since we last saw you in our clinic:

	YES	NO	DON'T KNOW
Since we last saw you, have you been more short of breath than usual?	☐	☐	☐
Since we last saw you, have you had to sleep on more pillows than usual to help with your breathing?	☐	☐	☐
Since we last saw you, have you been awakening at night feeling short of breath?	☐	☐	☐
Since we last saw you, have your feet or abdomen been more swollen?	☐	☐	☐
Since we last saw you, did you require adjustment of your water pill?	☐	☐	☐
Is there anything you would like to ask about your device today?	☐	☐	☐

Please specify:_____

- Who looks after your heart failure, or adjusts your water pill? (please circle)

Cardiologist Family Doctor Heart Function Clinic Don't know

For use by health care practitioner:

1. Questionnaire reviewed with patient? ☐
2. Results documented in clinic visit chart? ☐
3. Action taken? ☐

Courtesy of Dr. Healey

Hamilton approach

- Med reconciliation done at each PPM/ICD visit
- Opportunity for medication optimization:
  - At that visit
  - Communicated to general cardiologist
  - Liaison with HF clinic
  - Referral to DMOC (device medication optimization clinic)

- DMOC
  - Run by HF/EP NP as well as 3 EP physicians (one dually trained)
  - Able to provide frequent follow-ups in the short-term as an outpatient

Courtesy of Dr. Healey

Calgary Integrated Care Pathway (ICP): Process Road Map

1. CIED Clinic Encounter

- If patient has last documented LVEF < 40% → CIED nurse completes ICP checklist
- If patient qualifies → patient consent in CIED clinic
- If patient consents → send consent to ICP clinic and give patient information

2. Triage For Potential Integrated Care Pathway Enrolment

- Every week, ICP clinic nurse will triage potential enrolments
- Key exclusion at this step → patients of cardiologists who opted out of ICP participation

3. Pre-Assessment Patient Contact

- Re-affirmation of consent for participation
- Over the phone medication reconciliation completed
- Ensure patient has weight scale and blood pressure cuff (with ability to detect heart rate)
- Appointment for initial assessment made

4. Initial Assessment in Integrated Care Pathway

- Remote visit, according to institution guidelines

5. Follow-up Care

- Determined on an as needed basis

6. Integrated Care Pathway Exit

- Patients discharged from ICP after maximally targeted doses of guideline directed medication reached
- Continue with follow-up care through primary cardiologist

Integrated Care Pathway (ICP):
Eligibility Checklist & Next Steps

1. If your patient has LV ejection fraction < 40% at last assessment, please complete the following medication checklist:

Is you patient on the following medications at maximally-tolerated doses:

- ❑ Beta-Blocker (bisoprolol, metoprolol, or carvedilol)
- ❑ Mineralocorticoid receptor antagonist (spironolactone, or eplerenone)
- ❑ Angiotensin receptor/neprilysin inhibitor (Sacubitril/valsartan or "Entresto")
- ❑ SGLT-2 inhibitor (Dapagliflozin, or empagliflozin)
- ❑ Ivabradine (*if on all other agents and HR in sinus rhythm > 70*)

2. If your patient is not on **ALL** these medications, please refer for ICP clinic

Is the stable CIED patient with NYHA II, III, or IV and EF < 40% on maximally tolerated guideline directed medical therapy (GDMT) for optimizing heart function?

Is the patient already on GDMT :

- Beta-blockers
  - Carvedilol, Bisoprolol, or Metoprolol
- Angiotension Receptor Neprilysin Inhibitors (ARNI) – instead of ACE-I
  - Sacubitril/Valsartan
- Mineralocorticoid Receptor antagonist (MRA)
  - Spironolactone or Eplerenone
- Sodium-Glucose Cotransporter-2 (SGLT2) Inhibitors
  - Dapagliflozin, Canagliflozin, Empagliflozin

NO → Patient did not tolerate GDMT in past or is unwilling to try

YES → If resting HR > 77 BPM then is the patient already on Ivabradine?

YES → Continue with usual CIED and other cardiology follow up

NO → Is the patient already followed by a heart function clinic

NO → Please fax letter to primary cardiologist regarding optimizing therapy and follow their response

YES → Continue with usual CIED and other cardiology follow up

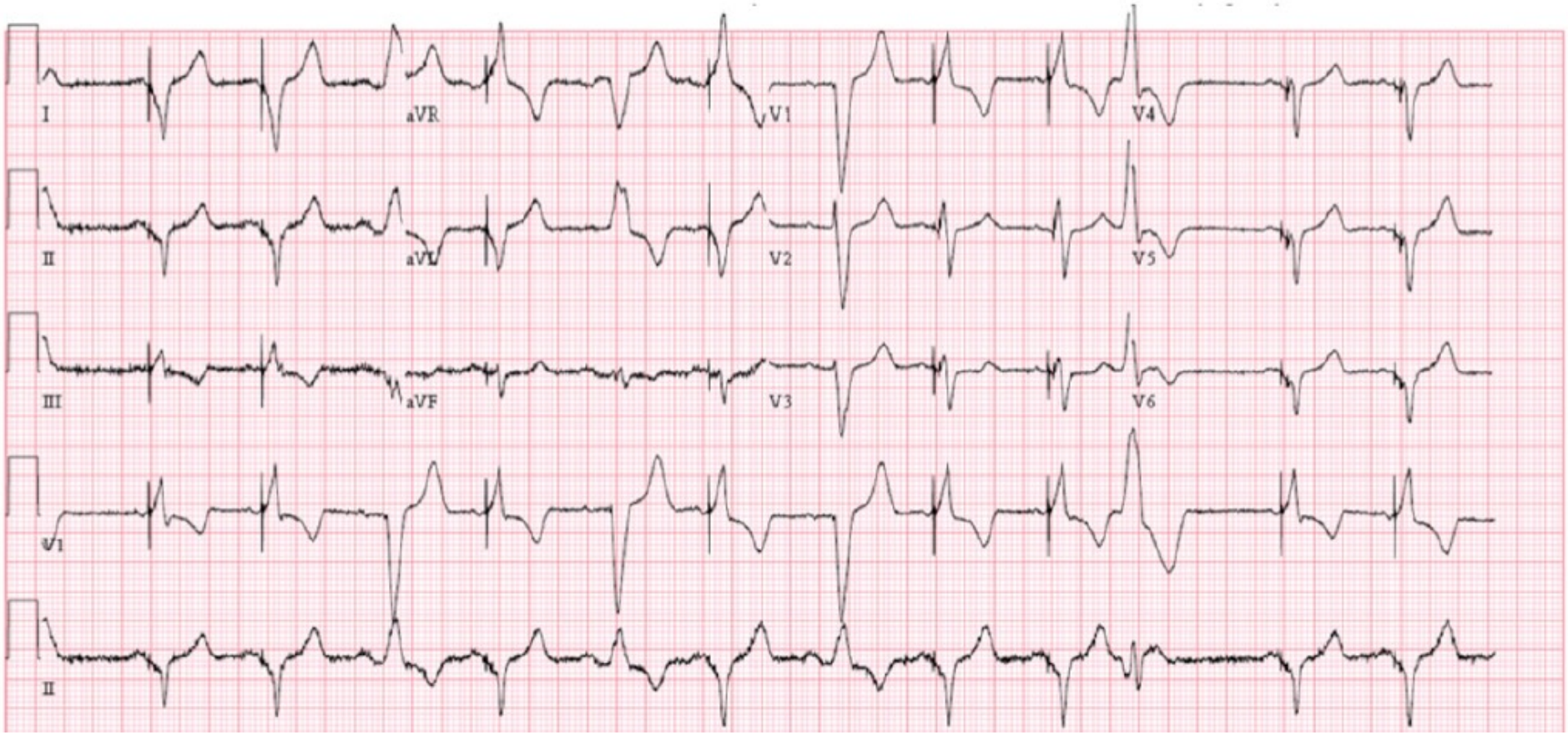
If patient does not have a primary cardiologist then please refer for CIED CFC Integrated Care Pathway

Vancouver approach

- VGH/SPH device clinics are running a medication optimization clinic within the device clinic as a QI initiative
- Clinical assistant screens patient charts prior to device clinic visit to identify patients who could use medication optimization
- Physicians receive a notification (email, printed, in EMR) about potential patients to be approached (including which meds, renal function, LVEF etc.)
- Physicians then can do one of the following:
  - Direct medication optimization with labs/imaging PRN
  - Referral to HF clinic
  - Referral to pharmacy led service
  - Referral to IM/general cardiology

Courtesy of Dr. Hawkins

Back to the case



- Loaded with Amiodarone and placed on 200 mg daily with dramatic reduction in his PVC burden and improved BiV pacing %age with subsequent improvement in HF symptoms
- Recently also transitioned to Entresto 49/51 mg BID and feels great!

Take home points

- Pay attention to device diagnostics – they may pre-empt clinically evident HF
- Don’t miss an opportunity to further optimize a CRT device – we should be aiming for 100% Bi-V pacing
- Common causes of loss of Bi-V pacing include: AF, PVCs, long AV delays, loss of Bi-V pacing with exercise, LV lead issues
- Remember to optimize meds including ARNI and SGLT2 inhibitors
- For those who cannot be converted from CRT non-responders to responders – consider early referral to HF clinic for consideration of advanced therapies

Questions/comments

MANAGE HF

- 2700 pts, randomized, open-label study comparing HeartLogic ON to OFF
- Inclusion: adult pts with ICD or CRT-D with NYHA II/III HF AND: 1 of the following 3:
  - HFH in the last year OR unscheduled outpatient visit for IV diuretics in the last 3 months OR NT-proBNP>600
- Primary outcome: All-cause mortality and HFH
- Secondary outcomes: All cause mortality, HFH, risk of multiple HFH, change in NYHA class, QOL, NT-proBNP, medication status
- Estimated completion data is January 2025

AdaptivCRT®: Operation