Technology in Heart Failure and 2021 Guideline Updates

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Disclosures

- Kim Salo, CNP - No disclosures
- Jessica Zweifel, CNP - No disclosures

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Objectives

- Discuss 2021 update to the 2017 guidelines
- Identify new medications for use in patients with HFrEF
- Explore how technology plays a role in monitoring and treating patients with heart failure
- Identify specific types of monitoring devices/programs

2017 ACC/AHA/HFSA Focused Update for the Management of Heart Failure

Yancy, et al. JACC 70(6) 2017; 776-803

-Provides guidelines for heart failure with preserved ejection fraction, anemia, and hypertension management

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Recommended Therapies for HFpEF

COR	LOE	Recommendations	Comment/Rationale
I	B	Systolic and diastolic blood pressure should be controlled in patients with HF*p*EF in accordance with published clinical practice guidelines to prevent morbidity (164, 165).	2013 recommendation remains current.
I	C	Diuretics should be used for relief of symptoms due to volume overload in patients with HF*p*EF.	2013 recommendation remains current.
IIa	C	Coronary revascularization is reasonable in patients with CAD in whom symptoms (angina) or demonstrable myocardial ischemia is judged to be having an adverse effect on symptomatic HF*p*EF despite GDMT.	2013 recommendation remains current.
IIa	C	The use of beta-blocking agents, ACE inhibitors, and ARBs in patients with hypertension is reasonable to control blood pressure in patients with HF*p*EF.	2013 recommendation remains current (Section 9.1 in the 2013 HF guideline).
IIb	B-R	In appropriately selected patients with HF*p*EF (with EF ≥45%, elevated BNP levels or HF admission within 1 year, estimated glomerular filtration rate >30 mL/min, creatinine <2.5 mg/dL, potassium <5.0 mEq/L), aldosterone receptor antagonists might be considered to decrease hospitalizations (83, 166, 167).	NEW: Current recommendation reflects new RCT data.
See Outline Data Supplement C.			
III: No Benefit	B-R	Routine use of nitrates or phosphodiesterase-5 inhibitors to increase activity or QoL in patients with HF*p*EF is ineffective (171,172).	NEW: Current recommendation reflects new RCTs.
See Outline Data Supplement C.			
III: No Benefit	C	Routine use of nutritional supplements is not recommended for patients with HF*p*EF.	2013 recommendation remains current.

Hypertension

COR	LOE	RECOMMENDATIONS	COMMENT/RATIONALE
I	B-R	In patients with increased risk, stage A HF, the optimal blood pressure in those with hypertension should be less than 130/80 mm Hg (189-193).	NEW: Recommendation reflects new RCT data.
See Online Data Supplements E and F.			
I	C-EO	Patients with HF*r*EF and hypertension should be prescribed GDMT titrated to attain systolic blood pressure less than 130 mm Hg (191).	NEW: Recommendation has been adapted from recent clinical trial data but not specifically tested per se in a randomized trial of patients with HF.
See Online Data Supplements E and F.			
I	C-LD	Patients with HF*p*EF and persistent hypertension after management of volume overload should be prescribed GDMT titrated to attain systolic blood pressure less than 130 mm Hg (9, 167, 169, 170, 195-199).	NEW: New target goal blood pressure based on updated interpretation of recent clinical trial data.
See Online Data Supplements E and F.			

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Anemia

COR	LOE	RECOMMENDATIONS	COMMENT/RATIONALE
IIb	B-R	In patients with NYHA class II and III HF and iron deficiency (ferritin <100 ng/mL or 100 to 300 ng/mL in transferrin saturation is <20%), intravenous iron replacement might be reasonable to improve functional status and QoL (173, 174).	NEW: New rationale consistent with therapeutic benefit.
See Online Data Supplement D.			
III: No Benefit	B-R	In patients with HF and anemia, erythropoietin-stimulating agents should not be used to improve morbidity and mortality (176).	NEW: Current recommendations reflects new evidence demonstrating absence of therapeutic benefit.
See Online Data Supplement D.			

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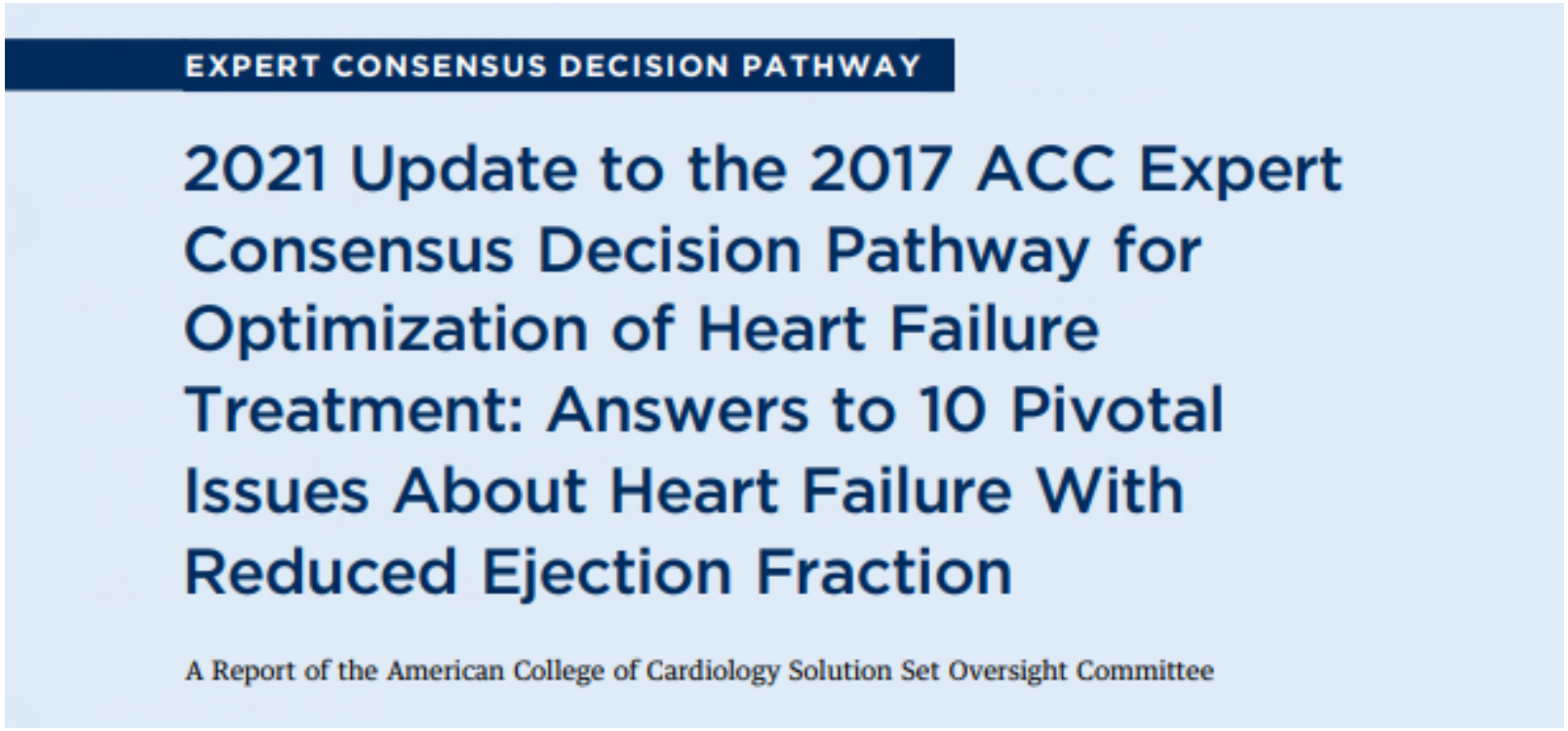

-Update on HFrEF medications

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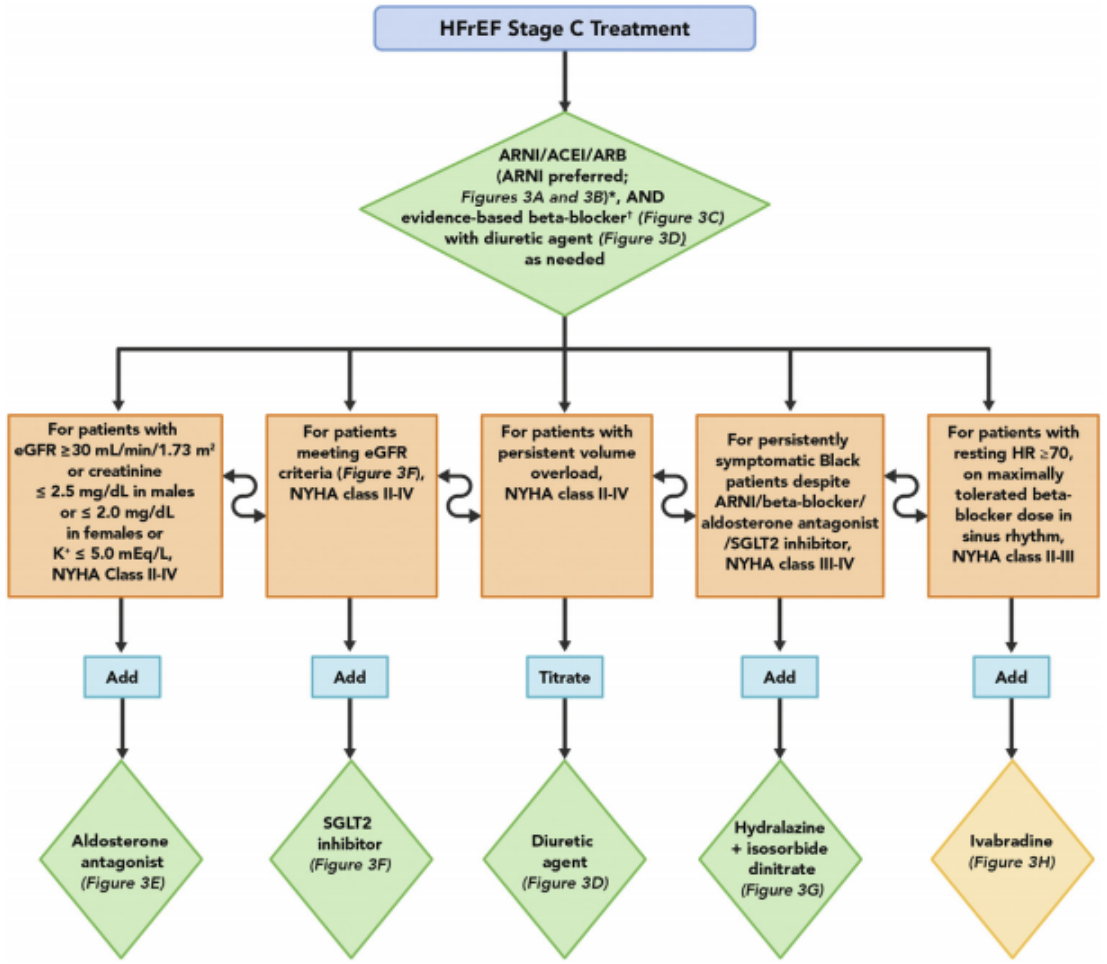
Maddox et al. JACC. 2021; in press

FIGURE 2 Treatment Algorithm for Guideline-Directed Medical Therapy Including Novel Therapies



*ACEI/ARB should only be considered in patients with contraindications, intolerance or inaccessibility to ARNI. In those instances, please consult Figure 3 and text for guidance on initiation.

†Carvedilol, metoprolol succinate, or bisoprolol.

ACEI = angiotensin-converting enzyme inhibitors; ARNI = angiotensin receptor-neprilysin inhibitors; ARB = angiotensin receptor blocker; eGFR = estimated glomerular filtration rate; HFrEF = heart failure with reduced ejection fraction; HR = heart rate; K⁺ = potassium; NYHA = New York Heart Association; SGLT2 = sodium-glucose cotransporter-2.

Green color identifies a Class I therapy from clinical practice guidelines, whereas yellow color indicates a Class II therapy.

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Maddox et al. JACC. 2021; in press

TABLE 1 Starting and Target Doses of Select GDMT and Novel Therapies for HF (choice and timing of each therapy and in whom they should be added discussed in the text)*

	Starting Dose	Target Dose
Beta-Blockers		
Bisoprolol	1.25 mg once daily	10 mg once daily
Carvedilol	3.125 mg twice daily	25 mg twice daily for weight <85 kg and 50 mg twice daily for weight ≥85 kg
Metoprolol succinate	12.5–25 mg daily	200 mg daily
ARNIs		
Sacubitril/valsartan	24/26 mg–49/51 mg twice daily	97/103 mg twice daily
ACEIs		
Captopril	6.25 mg 3× daily	50 mg 3× daily
Enalapril	2.5 mg twice daily	10–20 mg twice daily
Lisinopril	2.5–5 mg daily	20–40 mg daily
Ramipril	1.25 mg daily	10 mg daily
ARBs		
Candesartan	4–8 mg daily	32 mg daily
Losartan	25–50 mg daily	150 mg daily
Valsartan	40 mg twice daily	160 mg twice daily

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Aldosterone antagonists		
Eplerenone	25 mg daily	50 mg daily
Spironolactone	12.5–25 mg daily	25–50 mg daily
SGLT2 inhibitors		
Dapagliflozin	10 mg daily	10 mg daily
Empagliflozin	10 mg daily	10 mg daily
Vasodilators		
Hydralazine	25 mg 3× daily	75 mg 3× daily
Isosorbide dinitrate†	20 mg 3× daily	40 mg 3× daily
Fixed-dose combination isosorbide dinitrate/hydralazine‡	20 mg/37.5 mg (1 tab) 3× daily	2 tabs 3× daily
Ivabradine		
Ivabradine	2.5–5 mg twice daily	Titrate to heart rate 50–60 beats/min. Maximum dose 7.5 mg twice daily

*Digoxin remains indicated for HFrEF, but there are no contemporary data to warrant additional comment in this document. The reader is referred to already available guideline statements (3).
†Isosorbide mononitrate is not recommended by the ACC/AHA/HFSA guideline.
‡The ACC/AHA/HFSA guideline considers either the fixed-dose combination or the separate combination of isosorbide dinitrate and hydralazine as appropriate guideline-directed

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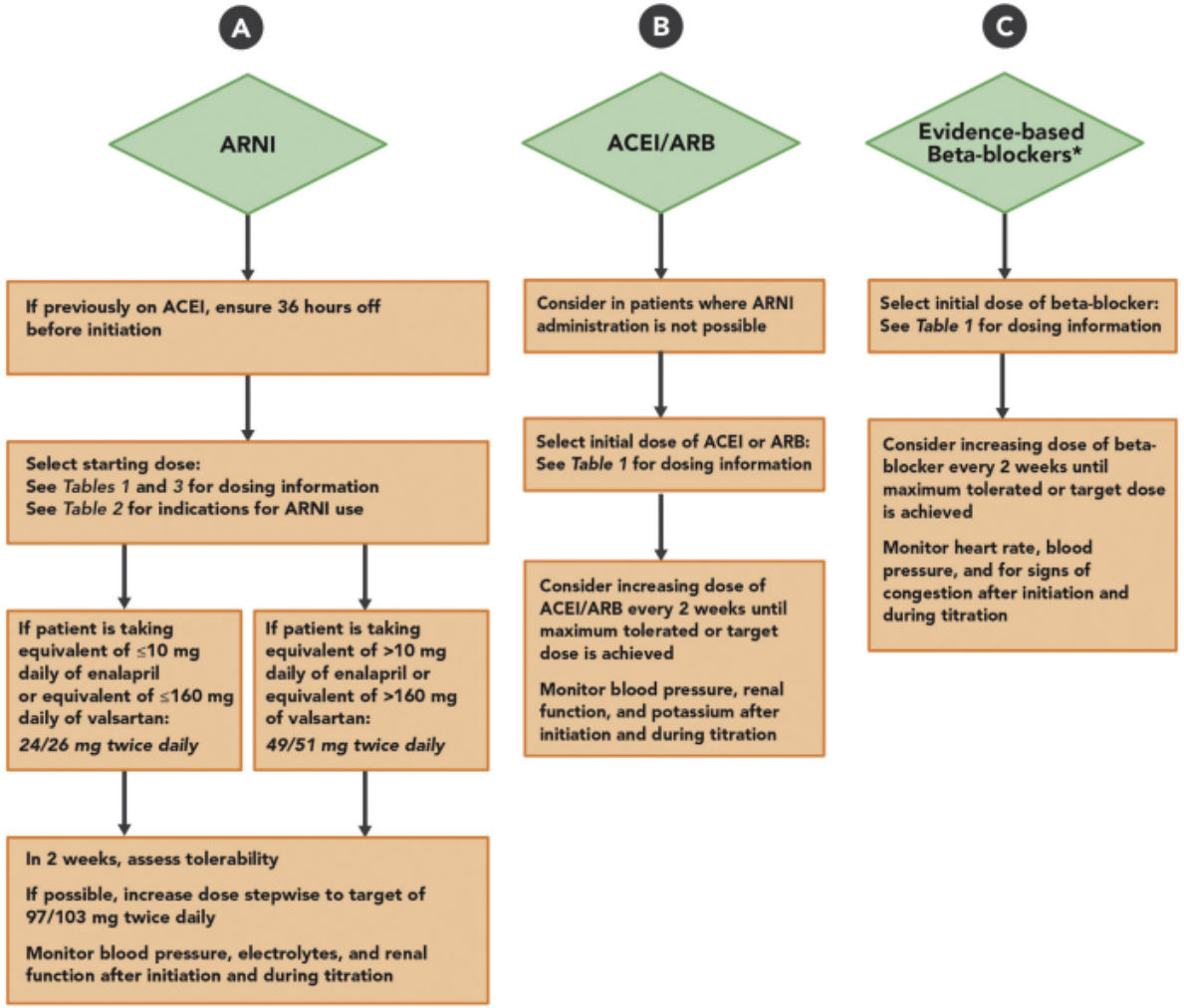
Maddox et al. JACC. 2021; in press

FIGURE 3 Guideline-Directed Medical Therapy Including Novel Therapies in the Expert Consensus Decision Pathway for Chronic Heart Failure



ACEI = angiotensin-converting enzyme inhibitors; ARNI = angiotensin receptor-neprilysin inhibitors; ARB = angiotensin receptor blocker; eGFR = estimated glomerular filtration rate.

*Carvedilol, metoprolol succinate, or bisoprolol.

ARNIs are the preferred agents, but for patients in whom ARNI administration is not possible, an ACEI/ARB is recommended.

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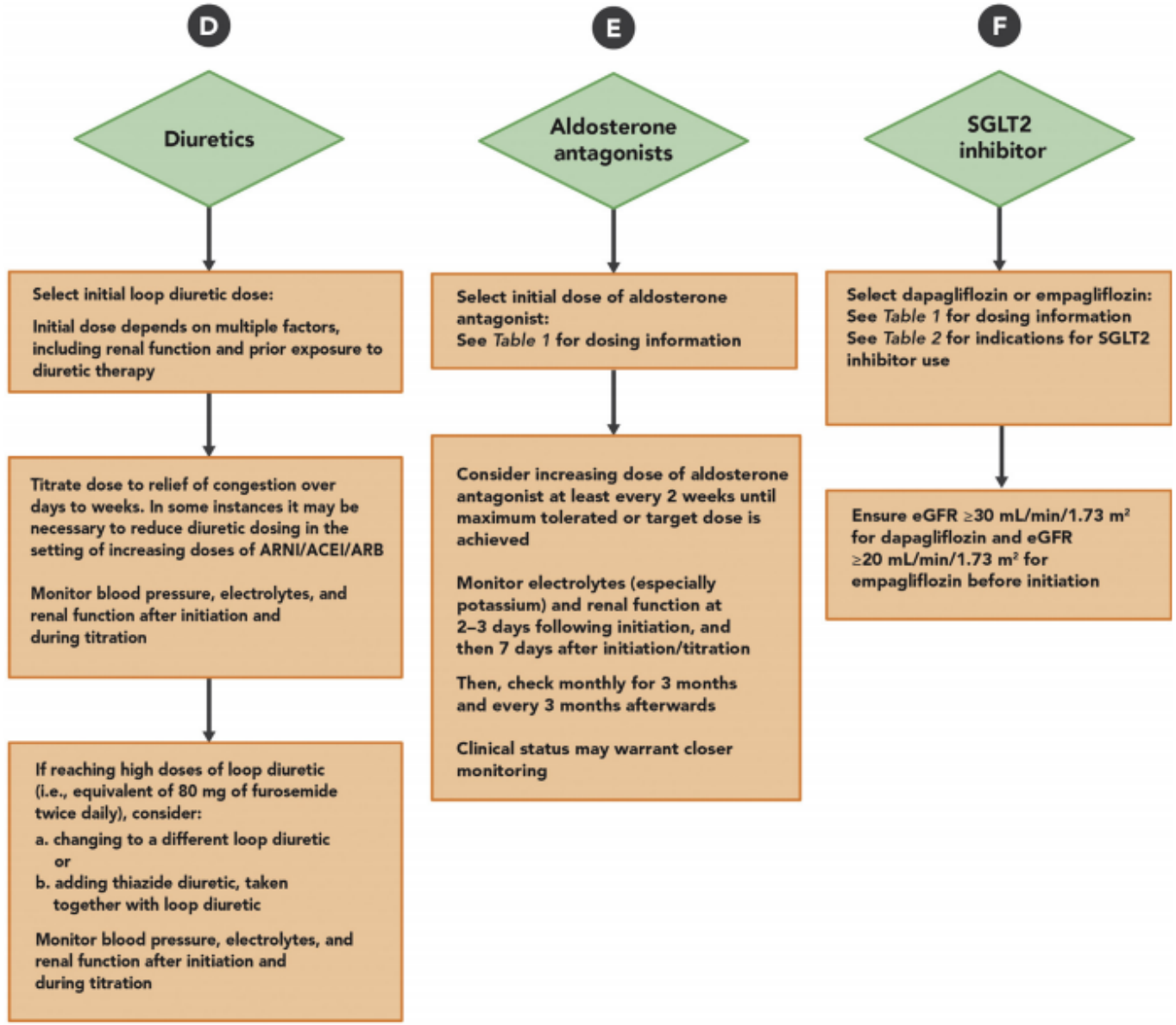
FIGURE 3 Continued



ACEI = angiotensin-converting enzyme inhibitors; ARNI = angiotensin receptor-neprilysin inhibitors; ARB = angiotensin receptor blocker; eGFR = estimated glomerular filtration rate; SGLT2 = sodium-glucose cotransporter-2.

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FIGURE 3 Continued

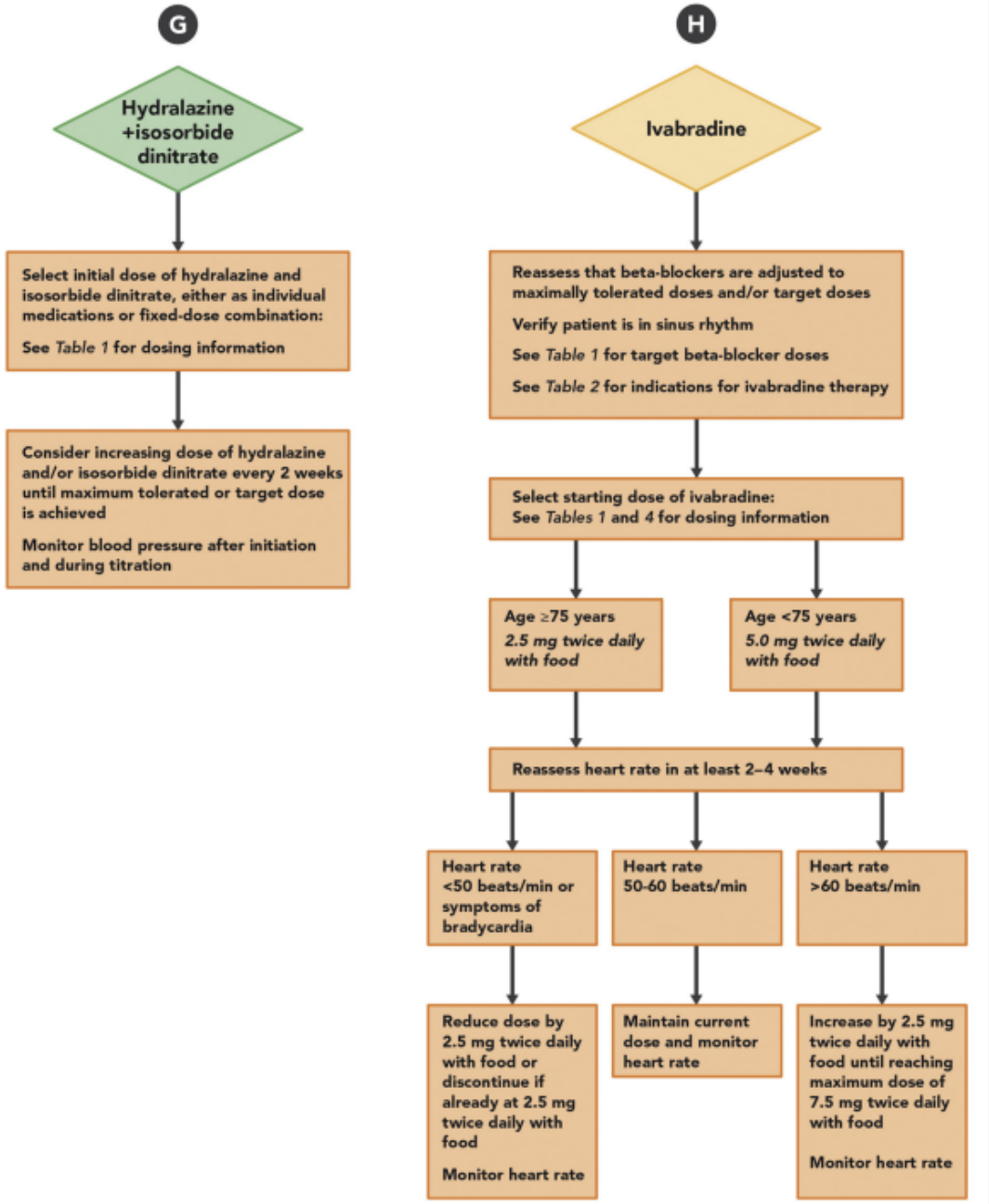

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TABLE 2 Indications for ARNI, Ivabradine, and SGLT2 Inhibitor Use

Indications for Use of an ARNI
■ HFrEF (EF ≤40%)
■ NYHA class II-IV HF
■ Administered in conjunction with a background of GDMT for HF in place of an ACEI or ARB

TABLE 3 Dose Adjustments of Sacubitril/Valsartan for Specific Patient Populations

Population	Initial Dose
High-dose ACEI *> Enalapril 10-mg total daily dose or therapeutically equivalent dose of another ACEI*	**49/51 mg twice daily**
High-dose ARB *> Valsartan 160-mg total daily dose or therapeutically equivalent dose of another ARB*	
De novo initiation of ARNI *Low- or medium-dose ACEI* *≤ Enalapril 10-mg total daily dose or therapeutically equivalent dose of another ACEI*	**24/26 mg twice daily**
Low- or medium-dose ARB *≤ Valsartan 160-mg total daily dose or therapeutically equivalent dose of another ARB*	
ACEI/ARB naive	
*Severe renal impairment** *(eGFR <30 mL/min/1.73 m²)*	
Moderate hepatic impairment (Child-Pugh Class B)	
Elderly (age ≥75 years)	

*This population was not studied in the PARADIGM-HF trial. The statement is consistent with FDA-approved labeling indications.

ACEI = angiotensin-converting enzyme inhibitor; ARB = angiotensin receptor blocker; ARNI= angiotensin receptor-neprilysin inhibitor; eGFR = estimated glomerular filtration rate; FDA = Food and Drug Administration; PARADIGM-HF = Prospective Comparison of ARNI with ACEI to Determine Impact on Global Mortality and Morbidity in HF.

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Maddox et al. JACC. 2021; in press

TABLE 4 Contraindications and Cautions for Sacubitril/Valsartan, Ivabradine, and SGLT2 inhibitors

A) Sacubitril/Valsartan

Contraindications	Cautions
■ Within 36 hours of ACEI use ■ History of angioedema with or without an ACEI or ARB ■ Pregnancy ■ Lactation (no data) ■ Severe hepatic impairment (Child-Pugh C) ■ Concomitant aliskiren use in patients with diabetes ■ Known hypersensitivity to either ARBs or ARNIs	■ Renal impairment: – Mild-to-moderate (eGFR 30-59 mL/ min/1.73 m^2): no starting dose adjustment required – Severe* (eGFR <30 mL/min/ 1.73 m^2): reduce starting dose to 24/26 mg twice daily; double the dose every 2-4 weeks to target maintenance dose of 97/103 mg twice daily, as tolerated ■ Hepatic impairment: – Mild (Child-Pugh A): no starting dose adjustment required – Moderate (Child-Pugh B): reduce starting dose to 24/26 mg twice daily; double the dose every 2-4 weeks to target maintenance dose of 97/103 mg twice daily, as tolerated ■ Renal artery stenosis ■ Systolic blood pressure <100 mm Hg ■ Volume depletion

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Maddox et al. JACC. 2021; in press

PARADIGM-HF

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 SEPTEMBER 11, 2014 VOL. 371 NO. 11

Angiotensin–Neprilysin Inhibition versus Enalapril in Heart Failure

John J.V. McMurray, M.D., Milton Packer, M.D., Akshay S. Desai, M.D., M.P.H., Jianjian Gong, Ph.D., Martin P. Lefkowitz, M.D., Adel R. Rizkala, Pharm.D., Jean L. Rouleau, M.D., Victor C. Shi, M.D., Scott D. Solomon, M.D., Karl Swedberg, M.D., Ph.D., and Michael R. Zile, M.D., for the PARADIGM-HF Investigators and Committees*

Entresto (sacubitril/valsartan)

- Neprilysin is a neutral endopeptidase that degrades several endogenous vasoactive peptides
  - Natriuretic peptides, bradykinin, adrenomedullin
- Inhibition increases levels of these substances
  - Decreases vasoconstriction, Na retention, maladaptive remodeling
- Combined inhibition of RAAS and neprilysin had effects that were superior to either alone in experimental studies
  - ACEI and neprilysin associated with high angioedema rates early clinical trial
- LCZ696 consists of neprilysin inhibitor sacubitril and ARB-valsartan

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McMurray et al. NEJM 371(11) 2014: 993-1003

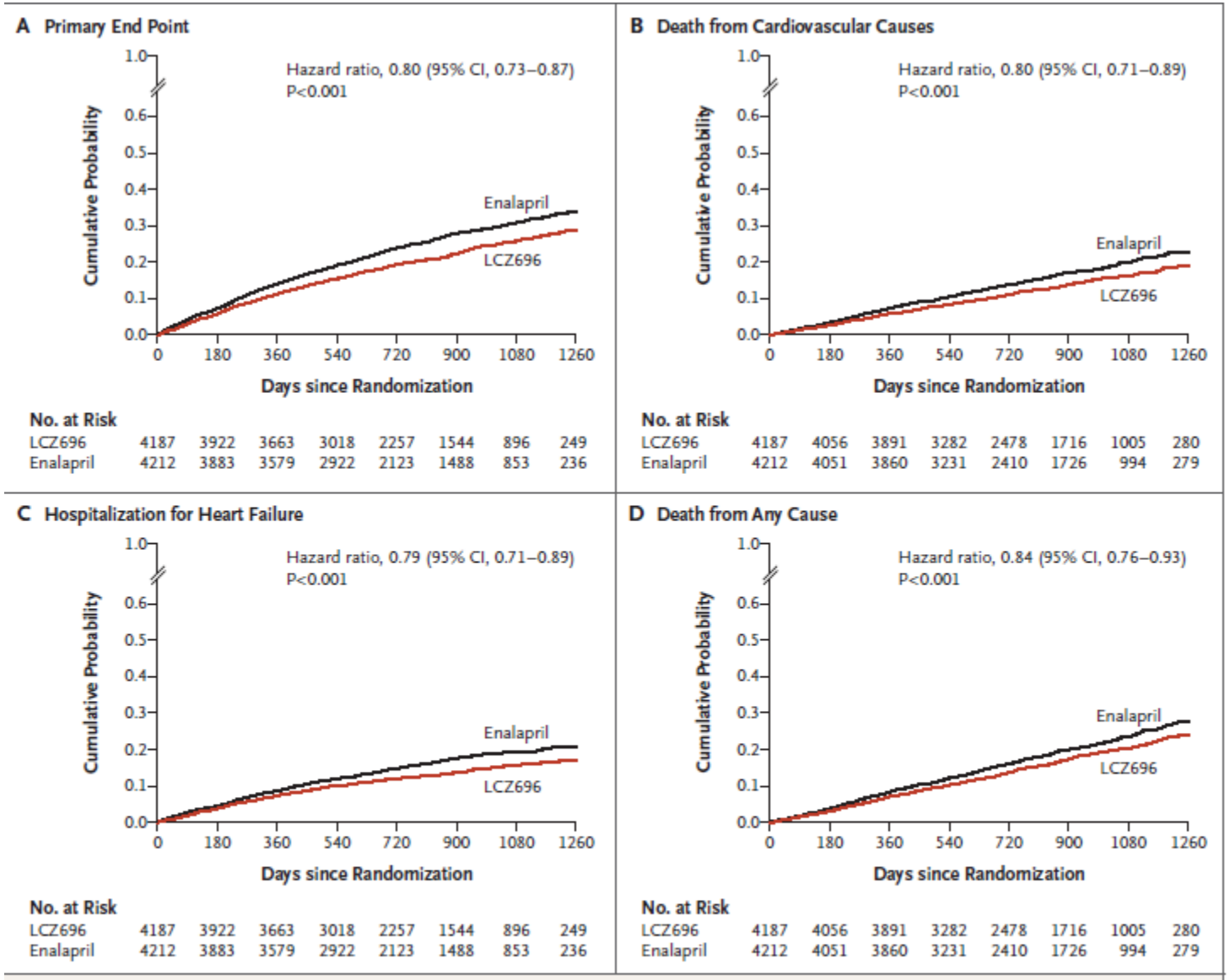

Figure 2. Kaplan–Meier Curves for Key Study Outcomes, According to Study Group.

Shown are estimates of the probability of the primary composite end point (death from cardiovascular causes or first hospitalization for heart failure) (Panel A), death from cardiovascular causes (Panel B), first hospitalization for heart failure (Panel C), and death from any cause (Panel D).

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Conclusions

- Inhibition with both angiotensin II receptor and neprilysin was more effective in reducing the risk of death from CV causes or HF hospitalization than ACEI with enalapril
- Also superior to reducing death from any cause and reducing symptoms and limitations of HF
- Benefit early in trial in setting of GDMT
- LCZ696 was associated with hypotension
  - No increased discontinuation
  - No significant increase in angioedema or renal complications
- Now on market as Entresto (sacubitril/valsartan)
  - Combined with ARB to prevent upregulation of RAAS
  - Goal dose 97/103mg (200mg)bid
- Contraindicated with hypersensitivity to ACEI or history of angioedema, ACEI within last 36 hours, pregnancy
- On going studies looking at sacubitril/valsartan in other populations
  - HFpEF, Post-MI, Anti-hypertensive, ADHF

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McMurray et al. NEJM 371(11) 2014: 993-1003

COR	LOE	RECOMMENDATIONS	COMMENT/RATIONALE
I	ACE I: A ARB: A ARNI: B-R	The clinical strategy of inhibition of the reninangiotensin system with ACE inhibitors (*Level of Evidence: A*) (128-133), OR ARBs (*Level of Evidence: A*) (134-137) , OR ARNI (*Level of Evidence B-R*) (138) in conjunction with evidence-based beta blockers (9, 139, 140), and aldosterone antagonists in selected patients (141, 142), recommended for patients with chronic HFrEF to reduce morbidity and mortality.	NEW: New clinical trial data prompted clarification and important updates.
I	ARNI: B-R	In patients with chronic symptomatic HF*r*EF NYHA class II or III who tolerate an ACE inhibitor or ARB, replacement by an ARNI is recommended to further reduce morbidity and mortality (138).	NEW: New clinical trial data necessitated this recommendation.

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III: Harm	B-R	ARNI should not be administered to concomitantly with ACE inhibitors or within 36 hours of the last dose of an ACE inhibitor (148, 1149).	NEW: Available evidence demonstrates a potential signal of harm for a concomitant use of ACE inhibitors and ARNI.
III: Harm	C-EO	ARNI should not be administered to patients with a history of angioedema.	NEW: New clinical trial data.

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Considerations

- Although not previously laid out in the focus guidelines, aggregate clinical experience suggests that de novo ARNI is safe and effective
  - Direct to ARNI is now recommended
  - De novo initiation may not be best for all patients (hypotension, advanced CHF)

- Entresto may cause naturesis in some patients
  - Diuretics may need adjustment
  - Recommend follow up labs similar to assessing ARB/ACEI's and aldosterone inhibitors
- Would caution in patients that cannot tolerate ACEI due to hypotension or renal function
- Note patients with GFR <30 were not included in the trial.

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Indications for Use of Ivabradine

- HFrEF (EF ≤35%)
- On maximum tolerated dose of beta-blocker
- Sinus rhythm with a resting heart rate ≥70 beats/min
- NYHA class II or III HF

TABLE 5 Recommended Starting Dose of Ivabradine

Population	Initial Dose
Maximally tolerated beta-blocker dose with persistent resting heart rate ≥70 beats/min	5 mg twice daily with meals
History of conduction defects Age ≥75 years	2.5 mg twice daily with meals

B) Ivabradine

Contraindications	Cautions
■ HFpEF	■ Sinus node disease
■ Presence of angina with normal EF	■ Cardiac conduction defects
■ Hypersensitivity	■ Prolonged QT interval
■ Severe hepatic impairment (Child-Pugh C)	
■ Acute decompensated HF	
■ Blood pressure <90/50 mm Hg	
■ Sick sinus syndrome without a pacemaker	
■ Sinoatrial node block	
■ 2nd or 3rd degree block without a pacemaker	
■ Resting heart rate <60 beats/min	
■ Persistent AF or flutter	
■ Atrial pacemaker dependence	

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Maddox et al. JACC. 2021; in press

Ivabradine-SHIFT Trial

Ivabradine and outcomes in chronic heart failure (SHIFT): a randomised placebo-controlled study

*Karl Swedberg, Michel Komajda, Michael Böhm, Jeffrey S Borer, Ian Ford, Ariane Dubost-Brama, Guy Lerebours, Luigi Tavazzi, on behalf of the SHIFT Investigators**

Summary

Background Chronic heart failure is associated with high mortality and morbidity. Raised resting heart rate is a risk factor for adverse outcomes. We aimed to assess the effect of heart-rate reduction by the selective sinus-node inhibitor ivabradine on outcomes in heart failure.

Lancet 2010; 376: 875–85

Published Online
August 29, 2010
DOI:10.1016/S0140-

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Background

- Beta-blockers have demonstrated to reduce morbidity and mortality beyond what is achieved by RAAS alone
- Some benefits thought in part to be linked to heart rate reduction
- BB may have other undesired effects of reduced myocardial contractility
- Heart rate found to be a risk factor for mortality and CV outcomes

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Swedberg et al. Lancet 376; 2010:875-885

Conclusion

- Ivabradine substantially and significantly reduced major risks associated with HF when added to guideline-based and evidenced-based treatment
- Mainly a result of a favorable effect on HF events (death due to HF and admissions)
- Found that SHIFT patients with HR higher than median received greater event-reducing benefit

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Swedberg et al. Lancet 376; 2010:875-885

Indications for Use of an SGLT2 Inhibitor

- HFrEF (EF ≤40%) with or without diabetes
- NYHA class II–IV HF
- Administered in conjunction with a background of GDMT for HF

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Maddox et al. JACC. 2021; in press

C) SGLT2 Inhibitors

Contraindications	Cautions

■ Not approved for use in patients with type I diabetes due to increased risk of diabetic ketoacidosis
■ Known hypersensitivity to drug
■ Lactation (no data)
■ On dialysis
	■ For HF care, dapagliflozin, eGFR <30 mL/min/1.73 m^2
	■ For HF care, empagliflozin, eGFR <20 mL/min/1.73 m^2
	■ Pregnancy
	■ Increased risk of mycotic genital infections
	■ May contribute to volume depletion. Consider altering diuretic dose if applicable
	■ Ketoacidosis in patients with diabetes:
	  ■ Temporary discontinuation before scheduled surgery is recommended to avoid potential risk for ketoacidosis
	  ■ Assess patients who present with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level
	■ Acute kidney injury and impairment in renal function: consider temporarily discontinuing in settings of reduced oral intake or fluid losses
	■ Urosepsis and pyelonephritis: evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated
	■ Necrotizing fasciitis of the perineum (Fournier's gangrene): rare, serious, life-threatening cases have occurred in both female and male patients; assess patients presenting with pain or tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise

*This population was not studied in PARADIGM-HF. The statement is consistent with FDA-approved labeling indications.

ACEI = angiotensin converting enzyme inhibitor; AF = atrial fibrillation; ARB = angiotensin receptor blocker; EF = ejection fraction; eGFR = estimated glomerular filtration rate; ESRD = end-stage renal disease; FDA = Food and Drug Administration; HF = heart failure; HFpEF = heart failure with preserved ejection fraction; PARADIGM-HF = Prospective Comparison of ARNI with ACEI to Determine Impact on Global Mortality and Morbidity in HF; SGLT2 = sodium-glucose cotransporter-2.

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Maddox et al. JACC. 2021; in press

SGLT2 Inhibitors

- Sodium-glucose co-transporter inhibitor
  - SGLT1-is the primary transporter for glucose and galactose in the GI tract, reduces postprandial glucose levels
  - SGLT2-lowers renal threshold for glucose and increases urinary glucose excretion by interfering with renal filtered glucose glucose across tubular lumen
    - Decreasing fasting and post-prandial blood glucose levels
- Most SGLT2 have some SGLT1 effect
- SGLT2-currently 4 FDA approved
  - Empagliflozin (Jardiance)
  - Dapagliflozin (Farxiga)

FIGURE 2 Overview of Described Effects of SGLT2 Inhibitors

Favorable effects
Reduction of pre-load (diuretic effects)
Reduction of afterload (blood pressure, arterial stiffness)
Improvement of mitochondrial efficiency
Delay of decline in eGFR
Delay of micro- and macroalbuminuria
Weight loss
Reduction in epicardial adipose tissue
Improvement in glycemia
Reduction in uric acid

Unfavorable effects
Amputations (in particular toe, metatarsal)
Volume depletion/Hypotension
Diabetic ketoacidosis
Fractures
Urinary and genital infections

Favorable and unfavorable effects that have been reported for sodium-glucose co-transporter (SGLT2) inhibitors. eGFR = estimated glomerular filtration rate.

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Zelniker et al. JACC. 2018: 72 (15), 1852

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 NOVEMBER 21, 2019 VOL. 381 NO. 21

Dapagliflozin in Patients with Heart Failure and Reduced Ejection Fraction

J.J.V. McMurray, S.D. Solomon, S.E. Inzucchi, L. Køber, M.N. Kosiborod, F.A. Martinez, P. Ponikowski, M.S. Sabatine, I.S. Anand, J. Bělohlávek, M. Böhm, C.-E. Chiang, V.K. Chopra, R.A. de Boer, A.S. Desai, M. Diez, J. Drozdz, A. Dukát, J. Ge, J.G. Howlett, T. Katova, M. Kitakaze, C.E.A. Ljungman, B. Merkely, J.C. Nicolau, E. O'Meara, M.C. Petrie, P.N. Vinh, M. Schou, S. Tereshchenko, S. Verma, C. Held, D.L. DeMets, K.F. Docherty, P.S. Jhund, O. Bengtsson, M. Sjöstrand, and A.-M. Langkilde, for the DAPA-HF Trial Committees and Investigators*

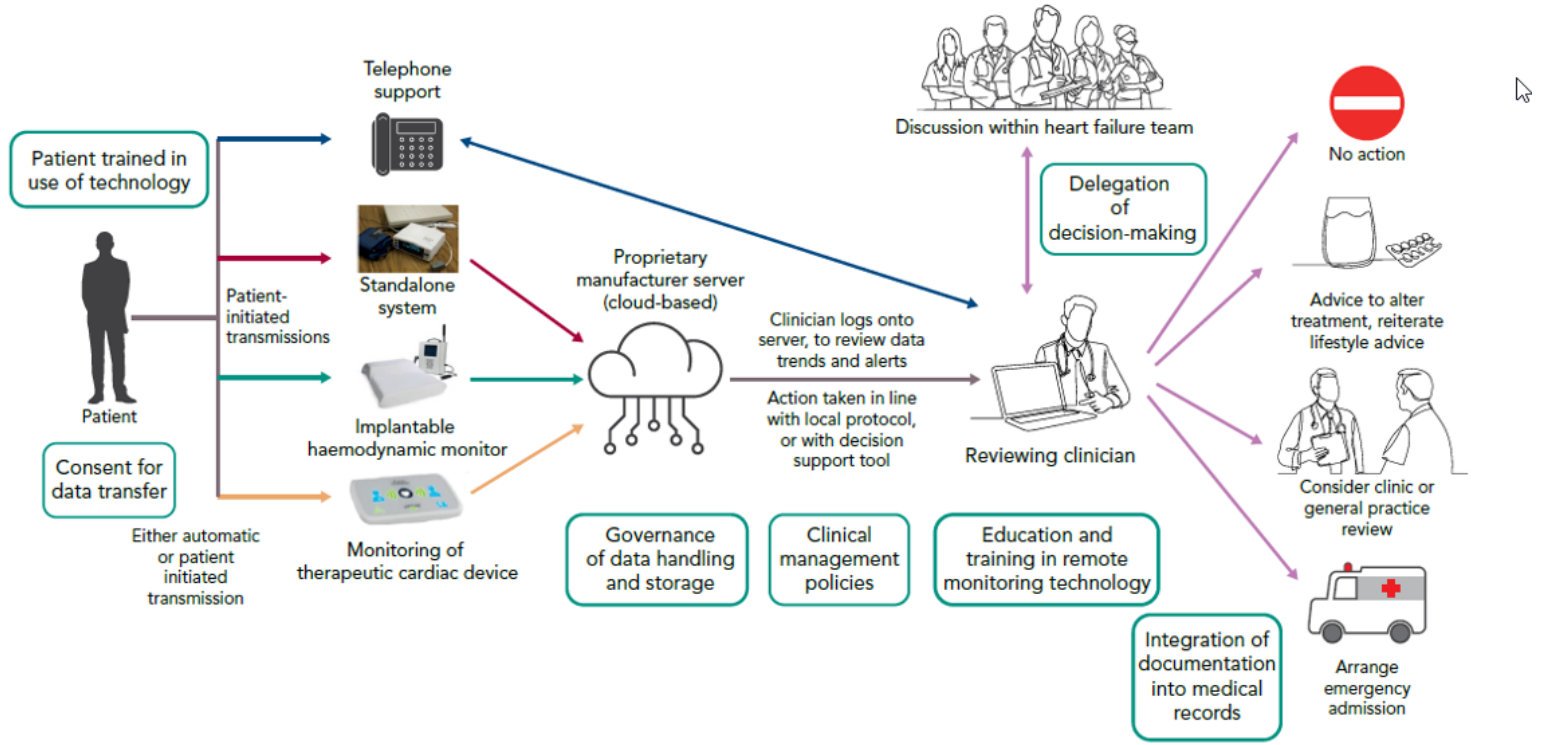
The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 OCTOBER 8, 2020 VOL. 383 NO. 15

Cardiovascular and Renal Outcomes with Empagliflozin in Heart Failure

M. Packer, S.D. Anker, J. Butler, G. Filippatos, S.J. Pocock, P. Carson, J. Januzzi, S. Verma, H. Tsutsui, M. Brueckmann, W. Jamal, K. Kimura, J. Schnee, C. Zeller, D. Cotton, E. Bocchi, M. Böhm, D.-J. Choi, V. Chopra, E. Chuquiure, N. Giannetti, S. Janssens, J. Zhang, J.R. Gonzalez Juanatey, S. Kaul, H.-P. Brunner-La Rocca, B. Merkely, S.J. Nicholls, S. Perrone, I. Pina, P. Ponikowski, N. Sattar, M. Senni, M.-F. Seronde, J. Spinar, I. Squire, S. Taddei, C. Wanner, and F. Zannad, for the EMPEROR-Reduced Trial Investigators*

Technology in Heart Failure



Boxes show key considerations for a remote monitoring clinical service. Arrows indicate the actions taken.

Cardiac Failure Review 2019;5(2):86–92.

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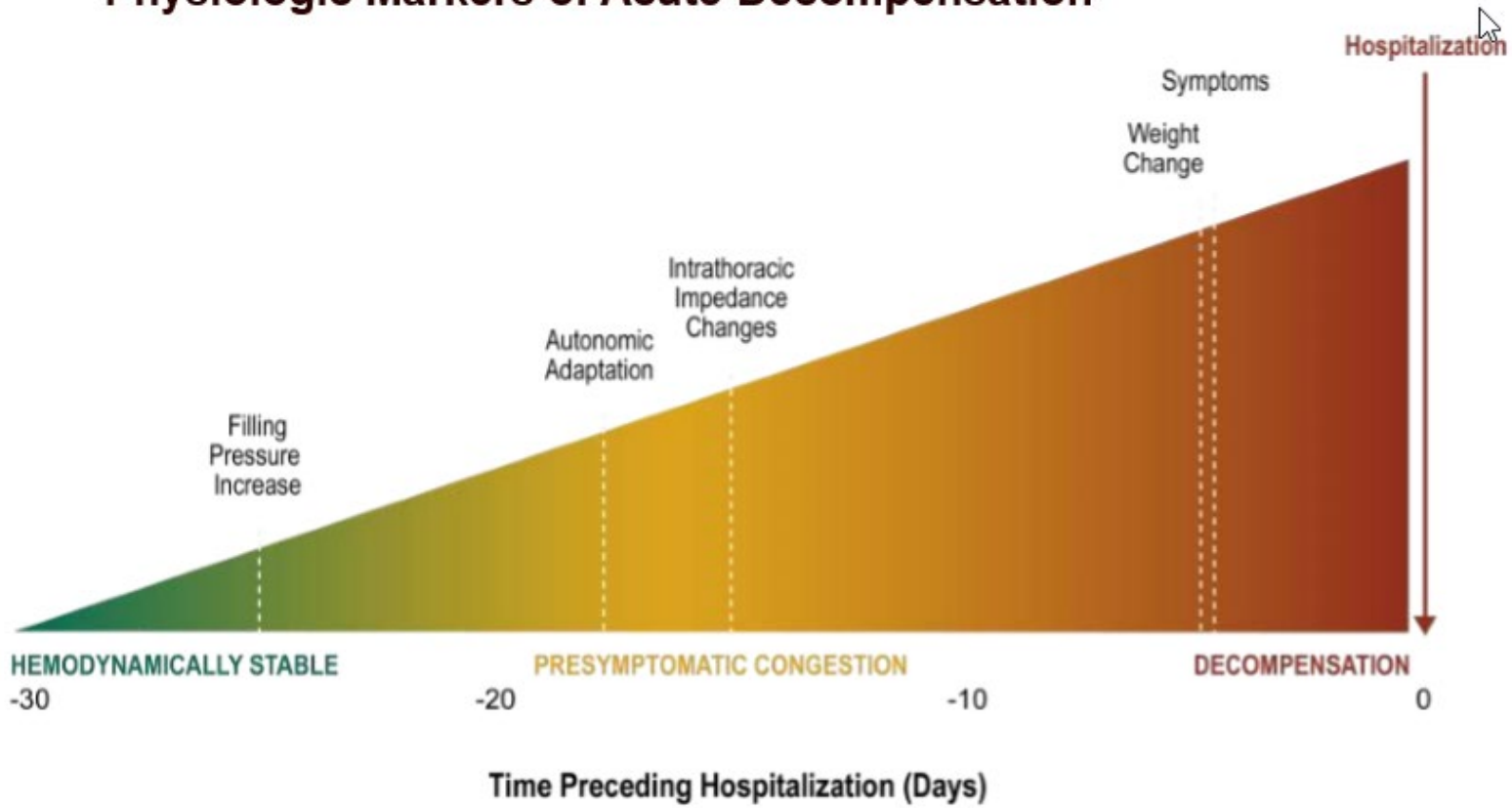
Problem

- Cases
  - > 1 million new cases of heart failure (HF)/year.
  - Prevalence of HF will increase 46% (> 8 million) from 2012 to 2030
  - Lifetime risk of developing HF is 20-45% for Americans > 45 years of age
- Cost
  - $31 billion/year (2012), projected $70 billion by 2030
  - Most common cause of hospitalizations in people > 65 years, mean estimated cost of$23,000 per hospitalization
- Morbidity
  - Primary reason for 12-15 million office visits
  - 30-day readmission rates 18.5-24.8%
    - 34.5% of re-admissions related to heart failure
    - 13.1% pulmonary causes
    - 8.9% renal causes
- Mortality
  - Despite improvements in monitoring and treatment, diagnosis of HF can still carry a mortality rate of 50% in 5 years.

Yancy et al. JACC. 2013;62(16):1495-1539. Jessup et al. JACC. 2009;53(15):1343-82. Hunt et al. JACC. 2005; 46:1-82. Benjamin et al. Circ. 2017;135:e146-e603 Braunwald. JACC Heart Failure 2013; 1(1): 1-20

- **Physiologic Markers of Acute Decompensation**



Graph adapted from Adamson PB, et al. Curr Heart Fail Reports, 2009.

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Medtronic Cardiocom

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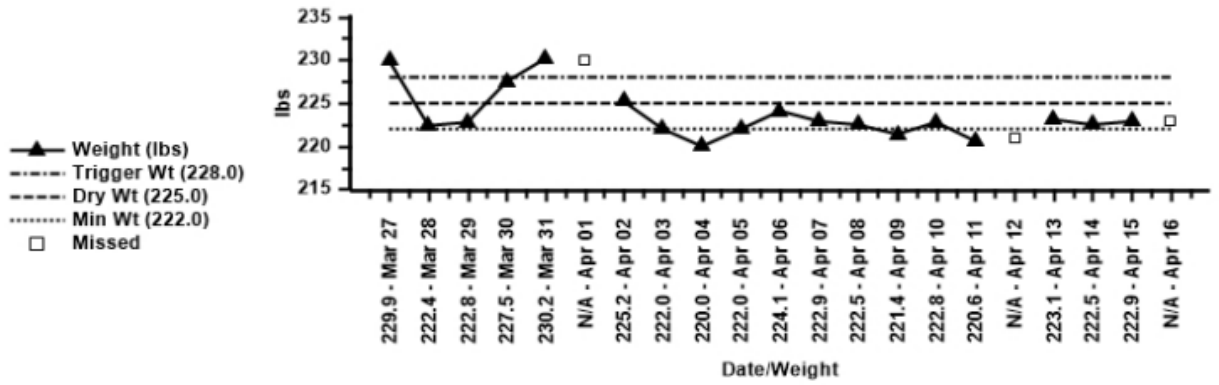
Cardiocom

- Patients high risk for re-admission, poor adherence, isolated
- Answer pre-determined questions
  - Feeling more short of breath?
  - Ankles or feet more swollen?
  - Dizzy or lightheaded?
  - Miss any medications?
- Weigh (with/without BP)
- Device transmits data
- RN reviews all “alerts” and assesses trends
  - Diuretic protocol
- Discusses with provider and determines plan

Medtronic https://www.medtronic.com/us-en/healthcare-professionals/services/medtronic-care-management-services.html

Highest Wt: 230.2 lbs Lowest Wt: 220.0 lbs Average Wt: 223.6 lbs



NA - Missed Day H - Hospital A - Away From Home NH - Nursing Home ER - Emergency Room

Medication *This List May Not Be Complete And Must Be Verified*

Metolazone	2.5 mg	PRNas directed	Torsemide	10 mg	qd	

Provider Comments

Symptom Detail *Markers Indicate Symptomatic Response*	Mar 27	Mar 28	Mar 29	Mar 30	Mar 31	Apr 01	Apr 02	Apr 03	Apr 04	Apr 05	Apr 06	Apr 07	Apr 08	Apr 09	Apr 10	Apr 11	Apr 12	Apr 13	Apr 14	Apr 15	Apr 16
Woke up during the night SOB					●																
More short of breath lying down					●																
Needed extra pillows last night					●																
Slept sitting up last night					●																
Ankles or feet are more swollen					●																
Stomach feels more bloated					●									●	●	●		●			
More tired than usual					●																
Avoided normal activities yesterday					●																

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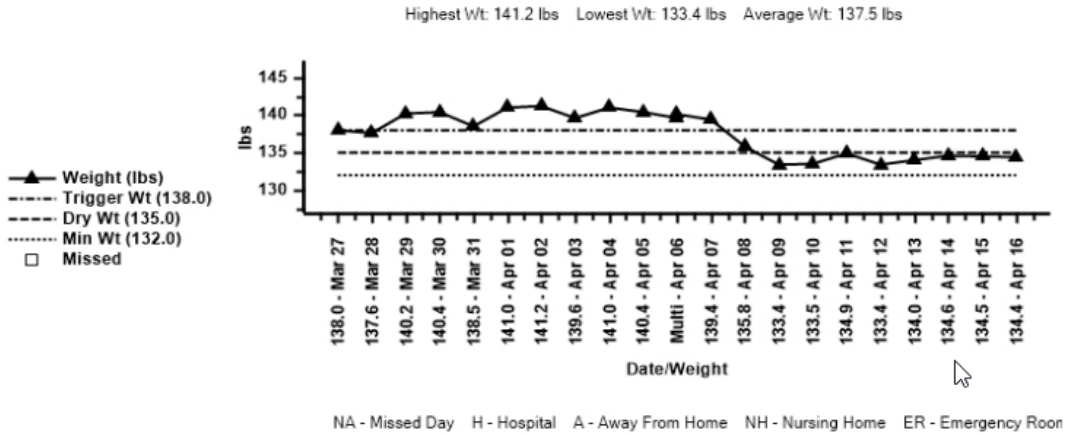
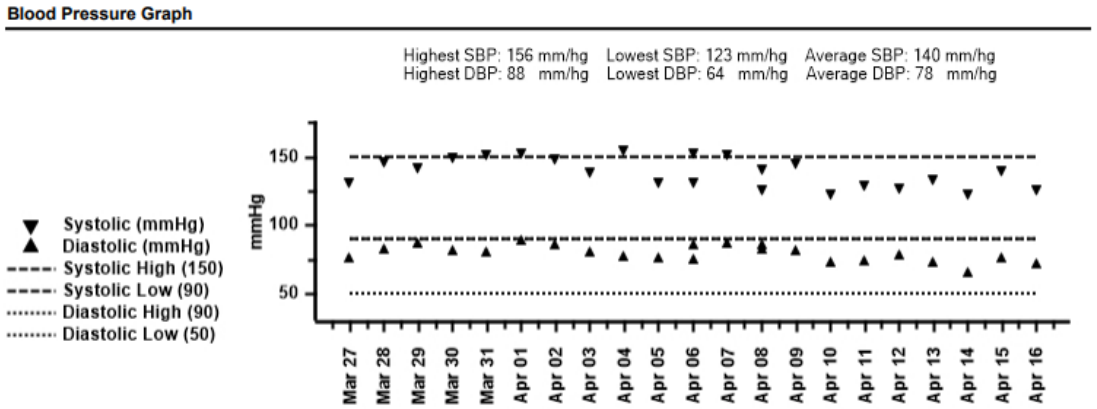
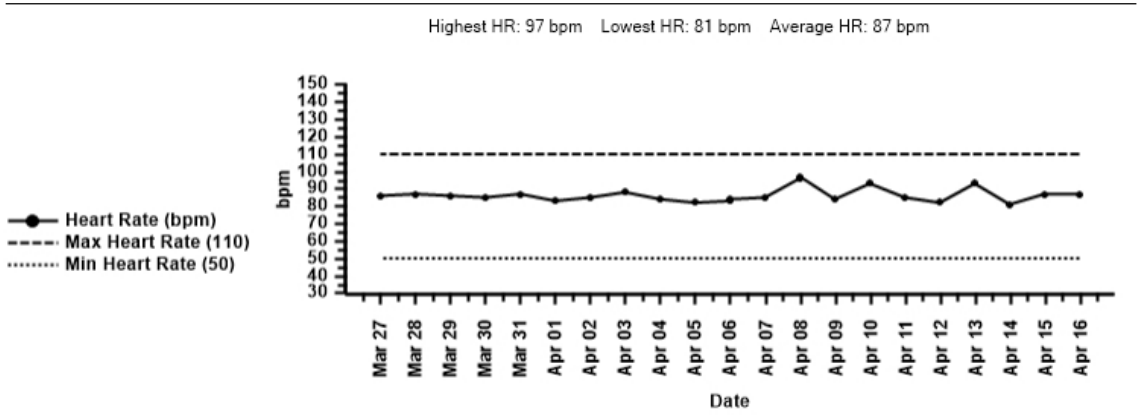
Weight



Blood Pressure



Heart Rate



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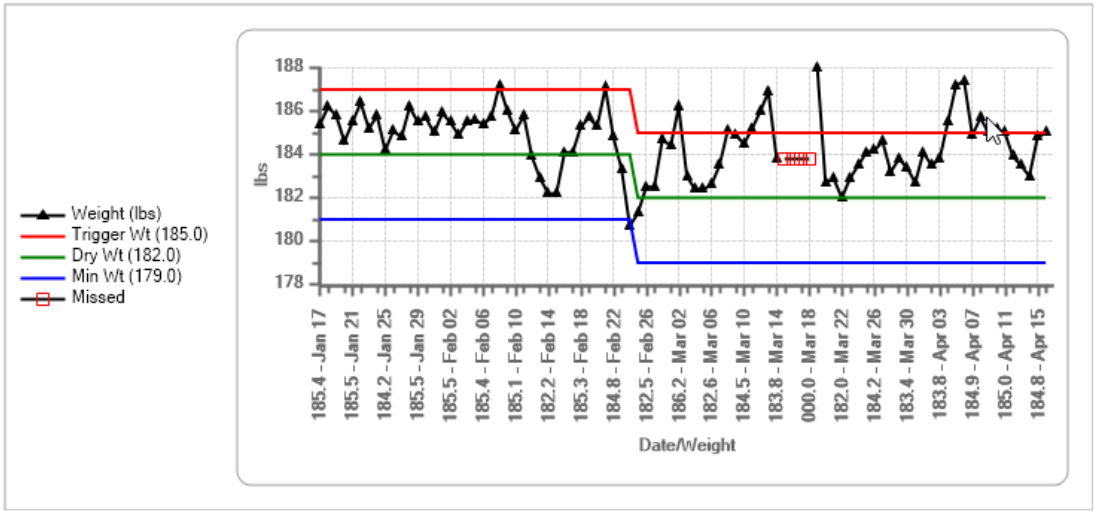
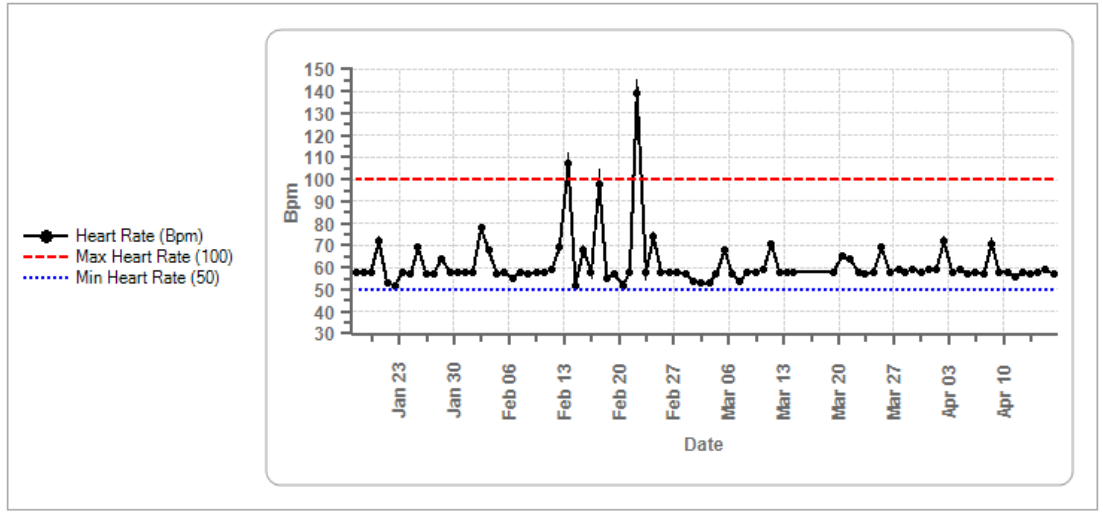
- 83 y.o. female with worsening SOB, fatigue. Treated with extra diuretic, metolazone, but symptoms continued. Heart rate typically did not vary much. Initially questioned whether heart rate was accurate. Had even higher heart rates with ongoing sx. Interrogated her pacemaker and found new a-fib with RVR.





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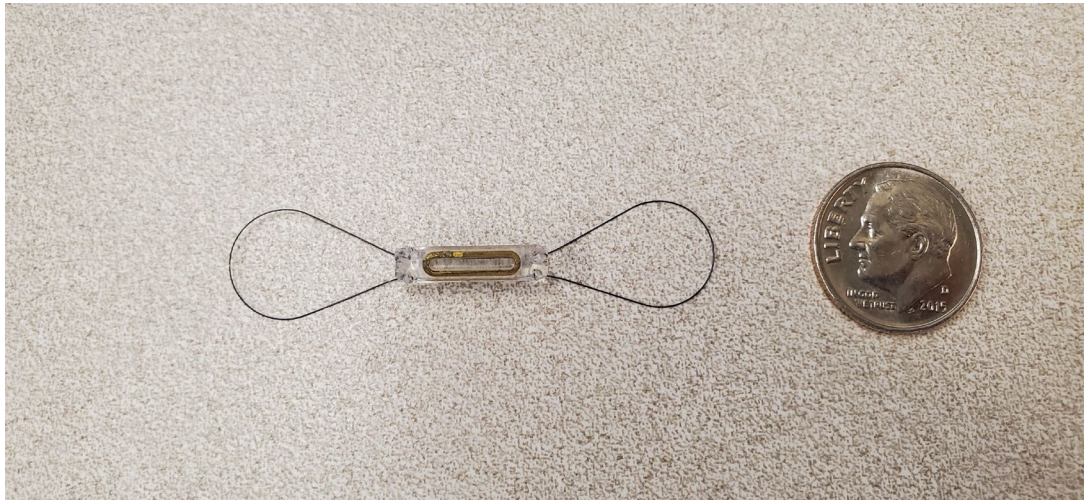
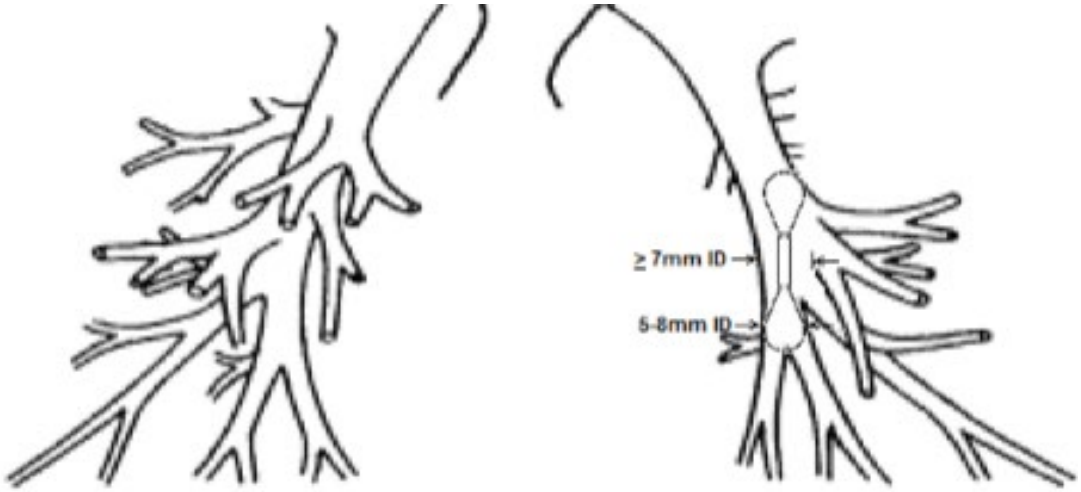
CardioMEMS



- Permanent pressure sensor implant in the pulmonary artery without batteries or replaceable parts
- Provides PA measurements and HR through electronic media
- FDA approved for NYHA III HF patients who have been hospitalized for HF in the previous year (CHAMPION trial)
  - 550 patients, demonstrated 48% reduction in HF rehospitalization at 6 months



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Background

- Patients admitted for heart failure usually because of worsening signs and symptoms of congestion
- Previous investigation have shown increases of intracardiac and PAP are apparent several days to weeks before onset of symptoms or hospitalization
- Intracardiac pressures can arise independently of weight changes
- The only FDA-approved implantable cardiac device which was found in the CHAMPION trial to reduce hospitalization and mortality rates, with a high safety profile

Findings

- Initial findings: 33% reduction in admissions to hospital for heart failure
- During open access, patients previously receiving guideline-directed management alone during randomized access (control group), access to pulmonary artery pressure monitoring resulted in a 48% reduction in heart failure hospitalizations (HFH) and a 21% reduction in all-cause admissions
- Since then, other studies have found 43-62% reduction in HFH

Lancet 2016;387:453-61
Abbott CardioMEMS HF System Clinical Evidence

Indications

- Hospitalization in the last year
- NYHA Class III symptoms (dyspnea that limited exertion with minimal effort)
- No ejection fraction requirements
- Patients should be on GDMT-ideally maximum tolerated doses
- Consideration for difficult to treat patients with cardiorenal syndrome
- Patients with concomitant lung disease where frequent office visits/hospitalizations for “shortness of breath”
- Practical considerations
  - Change in treatment philosophy
  - Treat patients prior to having symptoms
  - DAP for one month
  - Cost covered by Medicare for implant as long as done as outpatient
  - Time/cost of monitoring
  - Remote monitoring cost to patient

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Contraindications

- Contraindications:
  - Inability to take dual anti-platelet agents or anticoagulation for 1 month post-implant
- Considerations for non-selection:
  - Patients with ACC/AHA Stage D heart failure that are in need of advanced therapies such as transplant and LVAD.
  - Patients with active infection
  - Patients unable to tolerate right heart catheterization
  - Patients with history of recurrent (>1) pulmonary embolus or DVT
  - Patients with GFR <25ml/min not responsive to diuretics or are on chronic renal dialysis
  - Patients with congenital heart disease or mechanical right sided valves
  - Patients with known coagulation disorders
  - Patients with hypersensitivity or allergy to aspirin and/or clopidogrel
  - Patients with CRT implant within the last 3 months
  - If the patients BMI is greater than 35, measure chest circumference at the axillary level. If circumference is greater than 165cm, implant should not occur.

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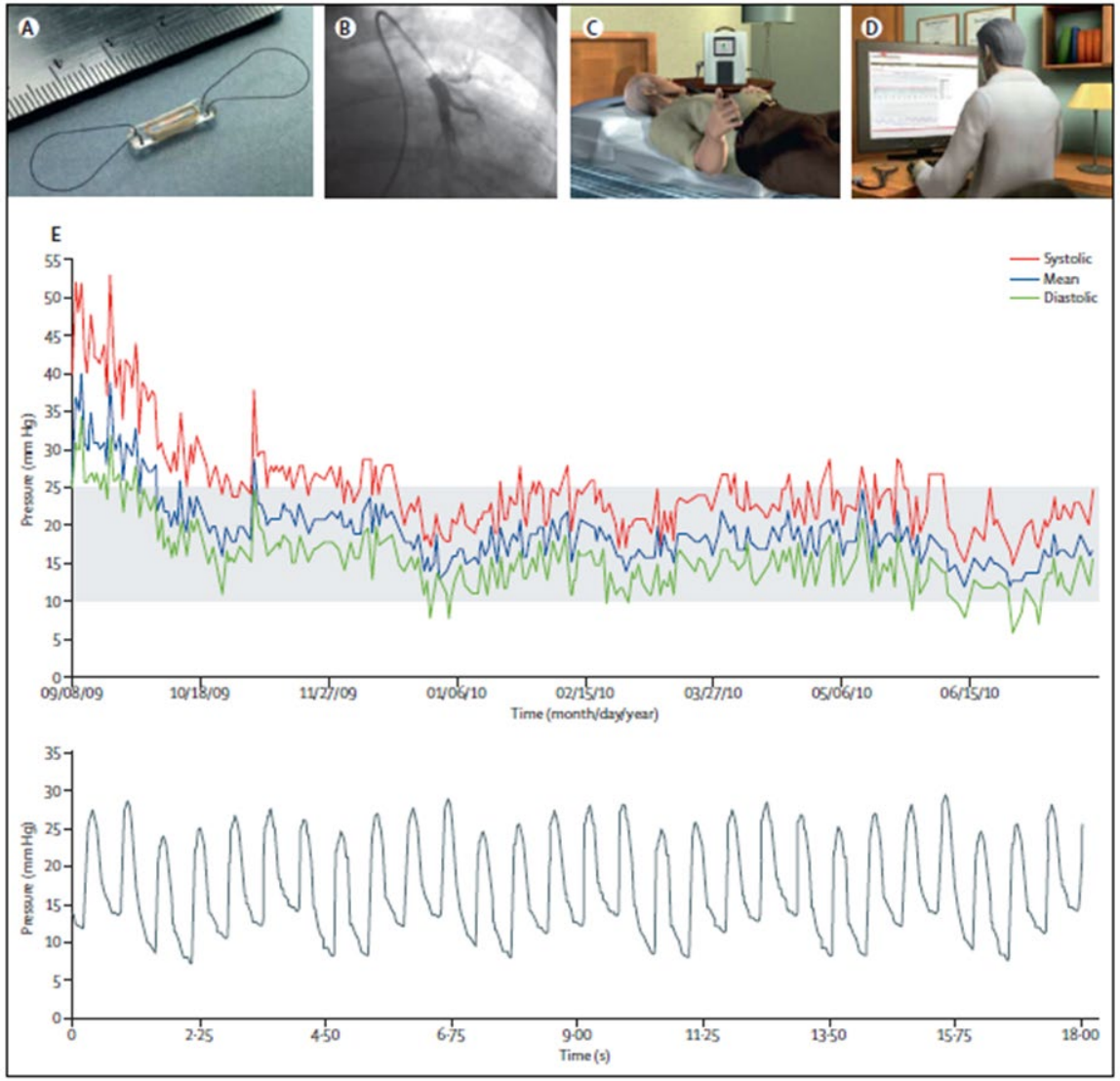

Figure 1: **Implantable haemodynamic monitoring system**
(A) CardioMEMS sensor or transmitter. (B) Transcatheter is implanted into a distal branch of the descending pulmonary artery. (C) Patient is instructed to take daily pressure readings from home using the home electronics. (D) Information transmitted from the monitoring system to the database is immediately available to the investigators for review. (E) Transmitted information consists of pressure trend information and individual pulmonary artery pressure waveforms.

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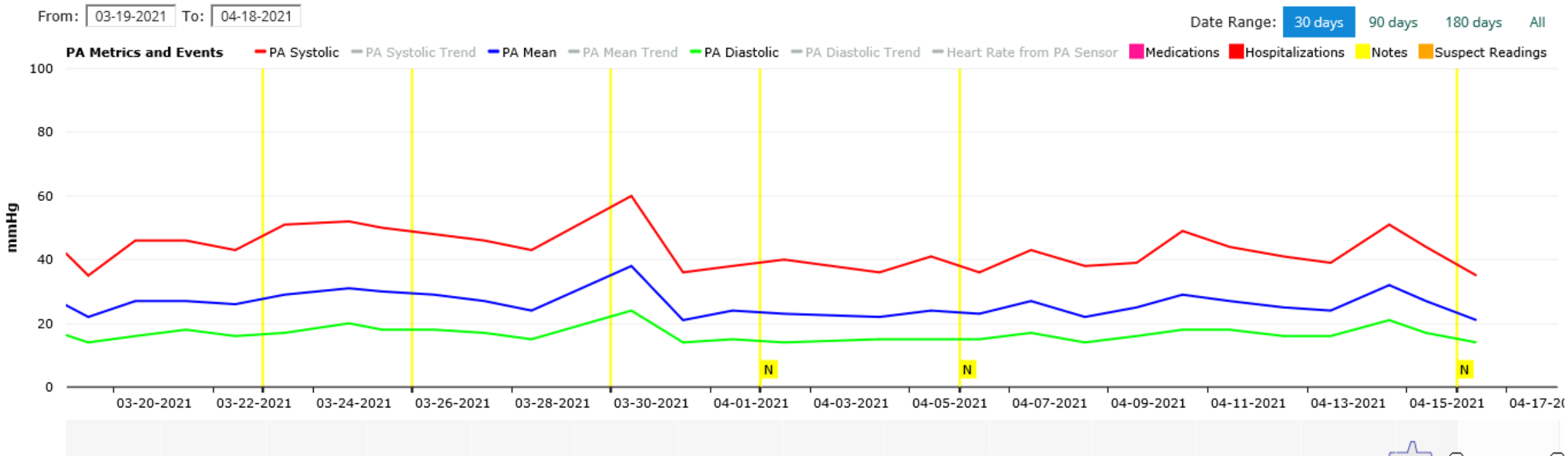
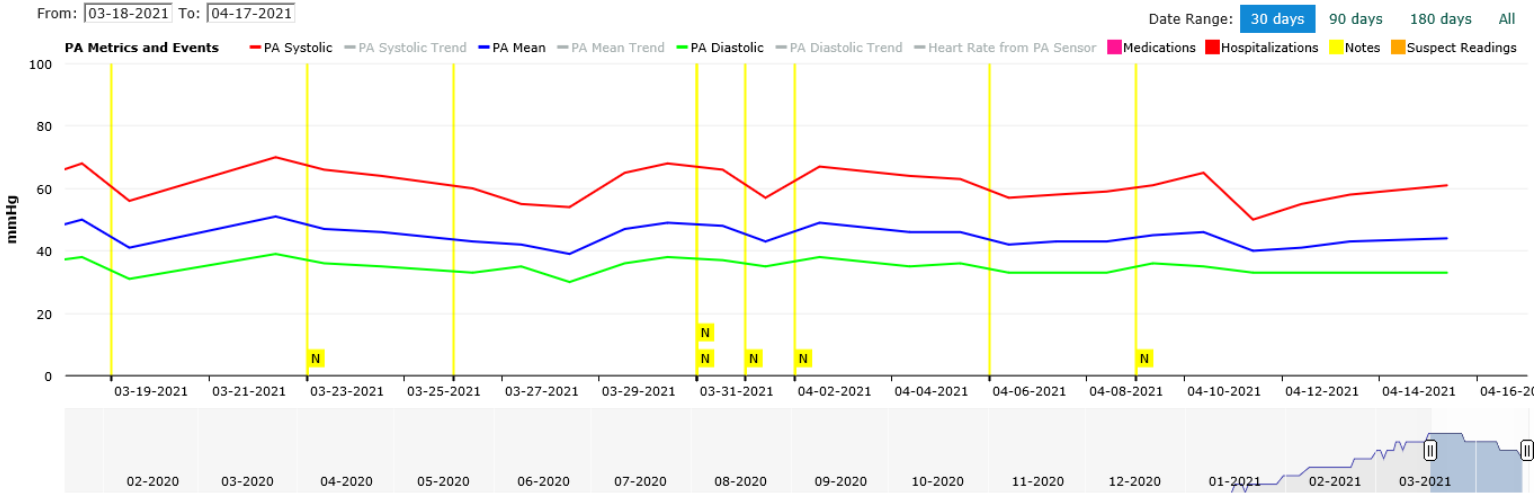
CardioMEMS / Merlin software



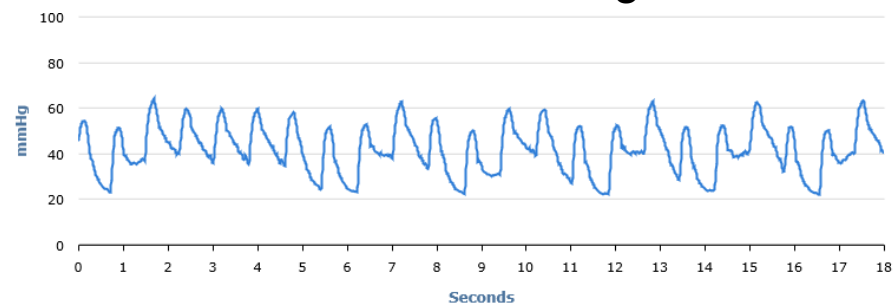
Taken on	PA Systolic	PA Diastolic	+/- Goal †	PA Mean	Heart Rate	Waveform
04-16-2021, 09:14 AM	35 mmHg	14 mmHg	n/a	21 mmHg	57 bpm	
04-15-2021, 09:16 AM	44 mmHg	17 mmHg	n/a	27 mmHg	59 bpm	
04-14-2021, 03:01 PM	51 mmHg	21 mmHg	n/a	32 mmHg	59 bpm	
04-13-2021, 11:53 AM	39 mmHg	16 mmHg	n/a	24 mmHg	63 bpm	
04-12-2021, 12:16 PM	41 mmHg	16 mmHg	n/a	25 mmHg	61 bpm	
04-11-2021, 10:33 AM	44 mmHg	18 mmHg	n/a	27 mmHg	56 bpm	
04-10-2021, 11:22 AM	49 mmHg	18 mmHg	n/a	29 mmHg	54 bpm	

Health

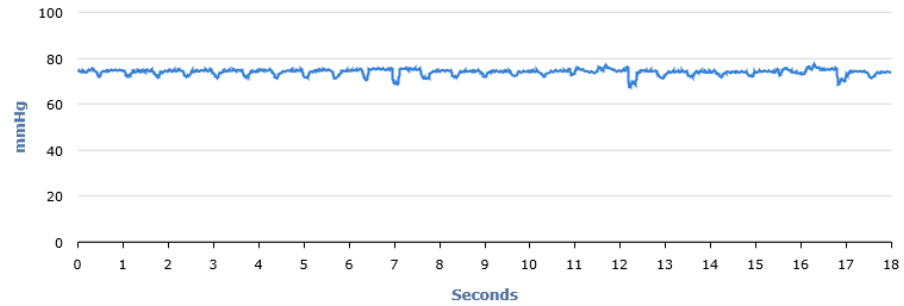


Taken on	PA Systolic	PA Diastolic	+/- Goal †	PA Mean	Heart Rate	Waveform
04-15-2021, 09:03 AM	61 mmHg	33 mmHg	n/a	44 mmHg	95 bpm	
04-13-2021, 09:02 AM	58 mmHg	33 mmHg	n/a	43 mmHg	100 bpm	
04-12-2021, 09:00 AM	55 mmHg	33 mmHg	n/a	41 mmHg	108 bpm	
04-11-2021, 09:49 AM	50 mmHg	33 mmHg	n/a	40 mmHg	121 bpm	
04-10-2021, 09:11 AM	65 mmHg	35 mmHg	n/a	46 mmHg	91 bpm	
04-09-2021, 08:49 AM	61 mmHg	36 mmHg	n/a	45 mmHg	103 bpm	
04-08-2021, 09:06 AM	59 mmHg	33 mmHg	n/a	43 mmHg	97 bpm	
04-07-2021, 08:30 AM	58 mmHg	33 mmHg	n/a	43 mmHg	111 bpm	
04-07-2021, 08:28 AM	70 mmHg	44 mmHg	n/a	54 mmHg	124 bpm	
04-06-2021, 09:11 AM	57 mmHg	33 mmHg	n/a	42 mmHg	93 bpm	
04-05-2021, 09:25 AM	63 mmHg	36 mmHg	n/a	46 mmHg	102 bpm	

Normal Reading



Suspect Reading



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Patient Profile

- 66 y.o male
- HFpEF; CAD; PAF; PPM; obesity hypoventilation syndrome; chronic hypoxemic respiratory failure; tobacco use disorder; Type II diabetes with gastroparesis; OSA; CKD 3-4
- Maintained previously on telescale for > 1 year
- Weights/symptoms didn’t always correlate. Frequently c/o shortness of breath, orthopnea, bloating
- Treated with increasing doses of diuretic, sometimes with little symptom effect, often worsening renal function

Patient Profile, continued

- Back and forth between Cardiology and Pulmonary
- Implanted 3/1/2021. PA pressures just slightly elevated – systolic 27-34 mmHg, diastolic 18-22 mmHg
- Let him trend a little higher based on RHC findings. Now – typical PA-diastolic 21-24 mmHg, feels well. Treat with extra diuretic ≥25-27 mmHg or lower if more symptomatic.
- PRN diuretic / metolazone use has drastically reduced, ≥50%
- Renal function before implant: Cr 1.5-1.7/GFR 40's; post-implant 1.3-1.4/GFR 50's

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CardioMEMS Management

- Nurse monitors Merlin website, paying attention to trends
- Assesses twice weekly
- If pressures elevated above set parameters, RN calls to assess
- Depending on assessment: no intervention, use of diuretic protocol, or other plan as determined by provider

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HeartLogic

- In the MultiSENSE trial, the HeartLogic algorithm demonstrated the capability to alert clinicians before the majority of heart failure events (HFEs) (hospitalizations or outpatient visits with IV therapies with HF as the primary diagnosis).
- Monitors for S3 and S1 heart sounds, thoracic impedance, respiratory rate, and night time heart rate and formulates an algorithmic-based number that reflects from each individual patient's baseline.
- Boston Scientific ICD's and CRT's
- HeartLogic index was able to detect 70% of impending HF events with a median 34 days warning when using the nominal threshold of 16
- Can be false alarms.
  - Anemia, faulty pacemaker lead, a-fib, PVC's, pneumonia, other things affecting thoracic impedance

Boehmer et al. A Multisensor Algorithm Predicts Heart Failure Events in Patients With Implanted Devices: Results From the MultiSENSE Study. J Am Coll Cardiol HF. 2017 Mar; 5 (3): 216–225

TABLE 1 Physiological Variables and Their Clinical Relevance

Physiological Variable	Clinical Relevance
Heart sounds	
First heart sound	Associated with ventricular contraction status
Third heart sound	Associated with early diastolic filling
Thoracic impedance	Associated with fluid accumulation and pulmonary edema
Respiration	
Respiration rate	Rapid shallow breathing patterns associated with shortness of breath
Ratio of respiration rate to tidal volume	
Heart rate	Indicator of cardiac status
Activity	Global patient status and fatigue

Boehmer et al. A Multisensor Algorithm Predicts Heart Failure Events in Patients With Implanted Devices: Results From the MultiSENSE Study. J Am Coll Cardiol HF. 2017 Mar; 5 (3): 216–225

HeartLogic, cont.

Worsening heart failure may be associated with:

Increased:

- Respiratory Rate
- S3
- Sleep incline
- Night heart rate
- Thoracic impedance

Decreased:

- S1
- Activity

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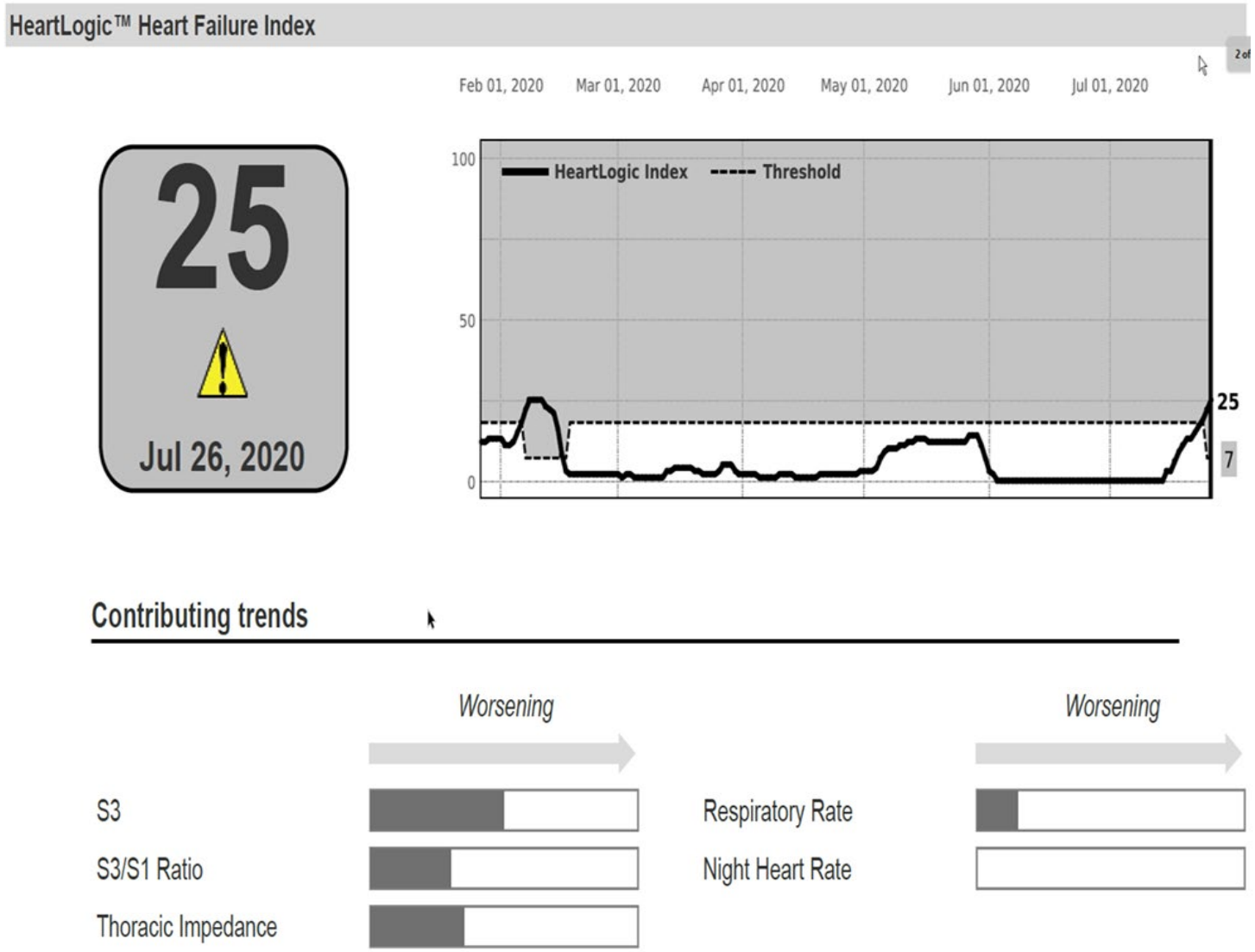
HeartLogic, cont.

- Median time from alert to an event is 34 days (in early studies).
- Treating patients before they are having actual, significant symptoms
- Our Practice: When HeartLogic Index crosses the threshold, a Heart Logic alert is issued. Alerts delivered every 7 days by Device Clinic as long as the Heart Logic Index remains above threshold.
- Alert sent to RN pool, will typically call patient and assess. May not have symptoms, but can help r/o other potential reasons for score increase (anemia, etc). RN then discusses with provider to determine plan of care.



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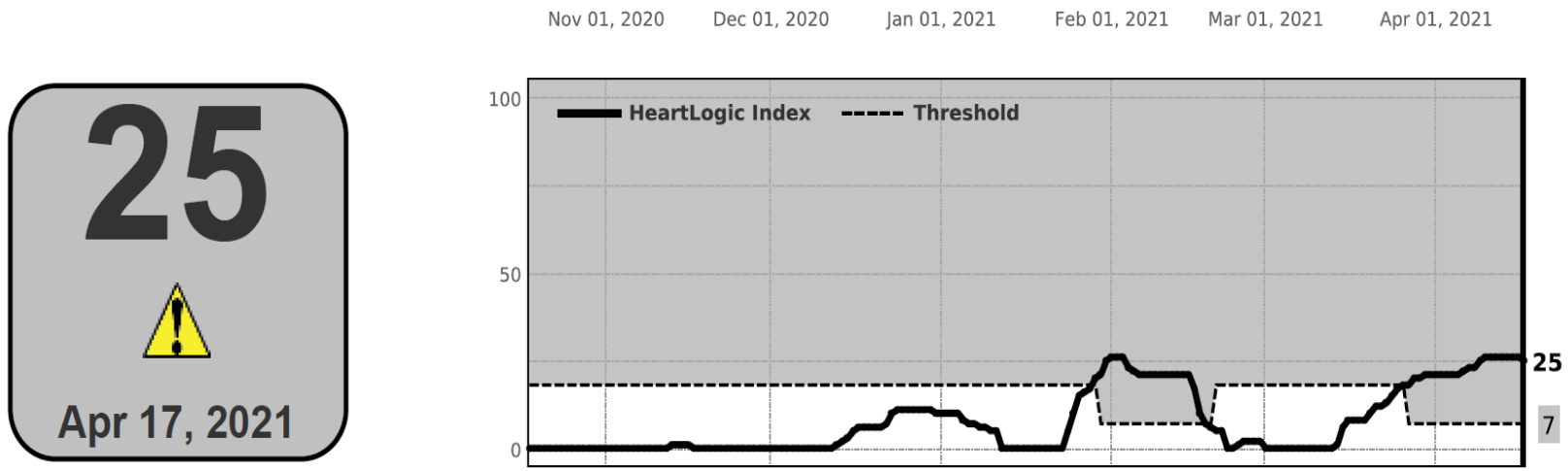
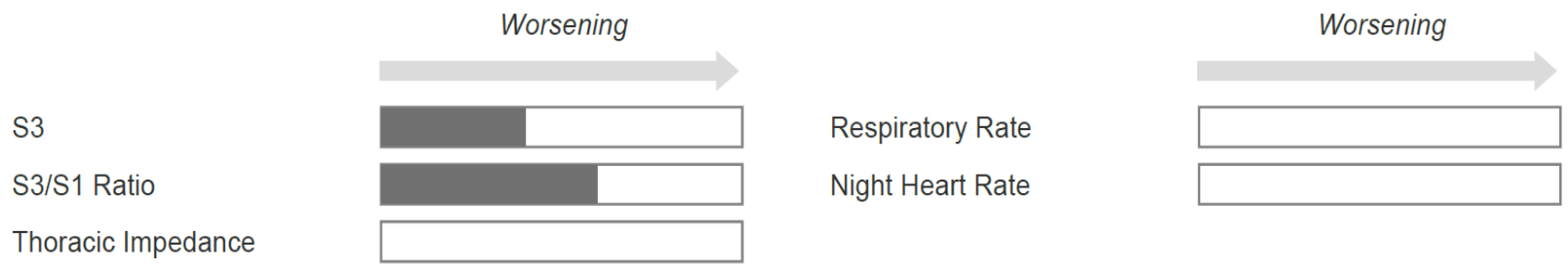
HeartLogic™ Heart Failure Index



Contributing trends



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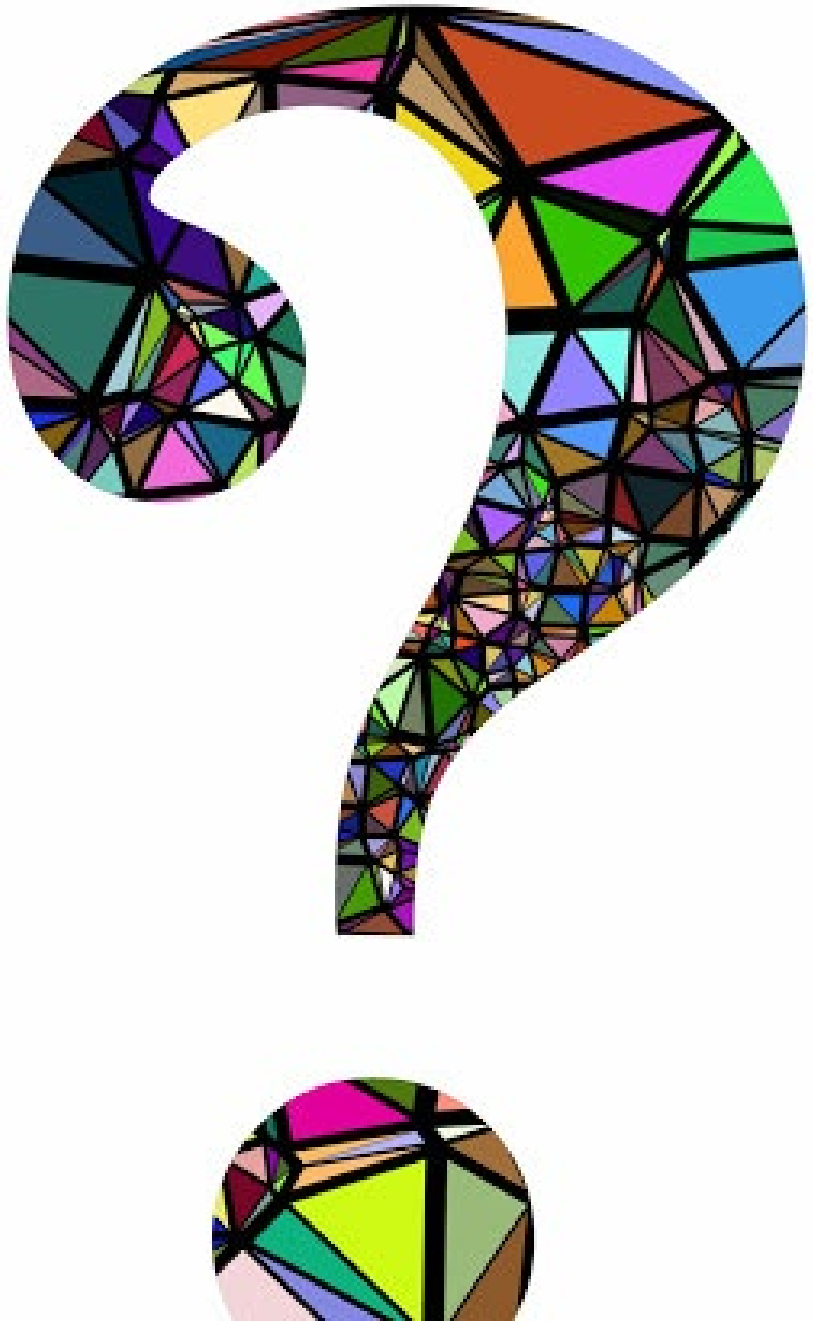

.....Questions?

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