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Stage B Heart failure

Diagnosis & Treatment

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Context & objectives

Context

- Heart failure is a common condition in older adults that is a leading cause of morbidity and mortality
- Identifying and treating early-stage (e.g., stage B) HF prior to the development of symptoms can improve patient outcomes
- HF is often initially diagnosed in the acute setting due to overt symptoms
- PCPs have a significant opportunity to identify and treat stage B HF

Objectives

- Understand the stages of heart failure
- Recognize the risks and prevalence of early-stage heart failure
- Understand how to diagnose stage B heart failure
- Review management of early-stage heart failure

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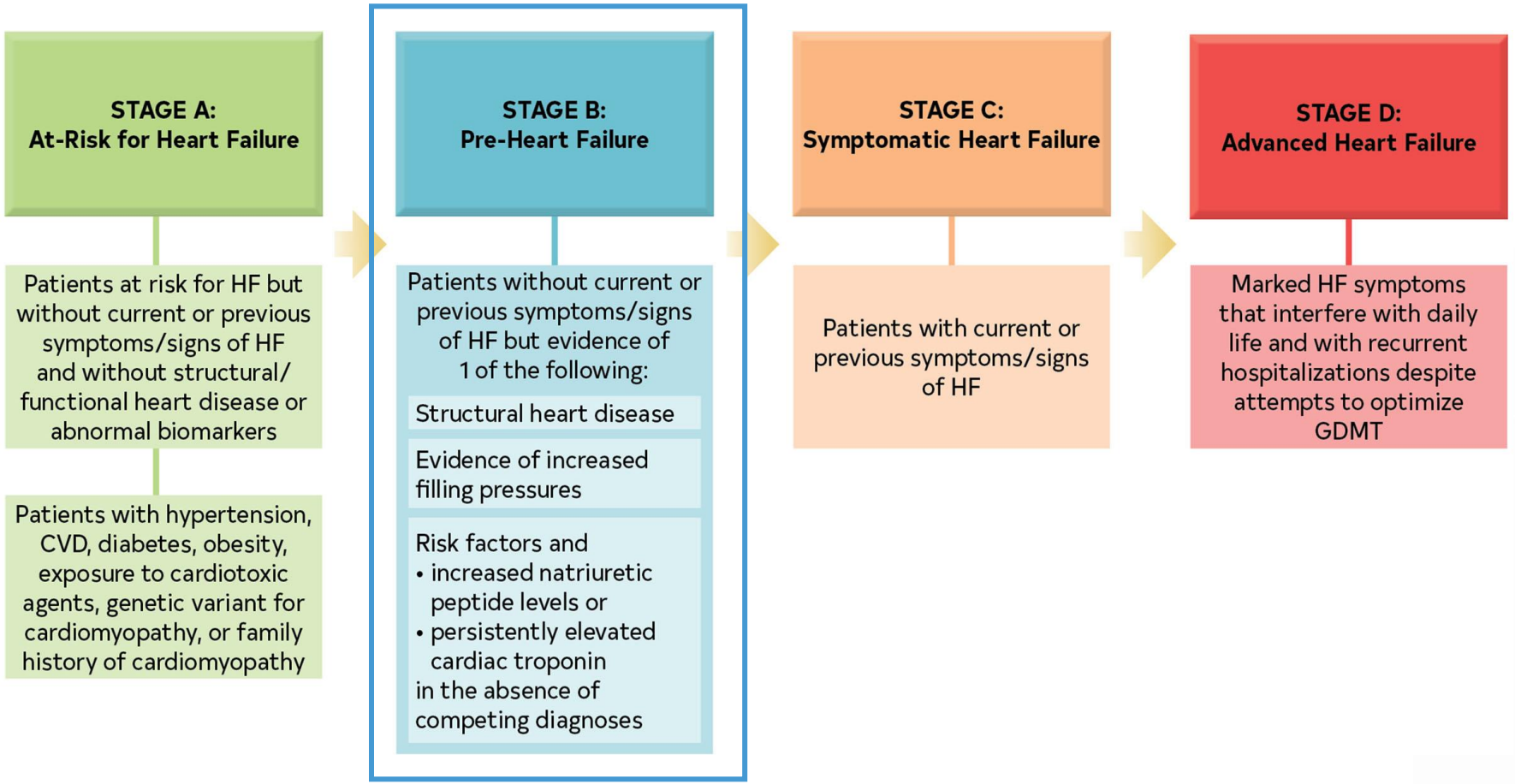
ACC/AHA/HFSA
HF Guideline 2022
Top 10 Take Home Messages

9. Primary prevention is important for those at risk for HF (Stage A) or pre-HF (Stage B). Stages of HF were revised to emphasize the new terminologies of “at risk” for HF for Stage A and Pre-HF for Stage B.

Heart failure is a progressive disease with asymptomatic disease at stage B

AHA/ACC guidelines show heart failure is progressive with opportunity to intervene early



- The AHA/ACC guidelines support diagnosing heart failure when it is asymptomatic (e.g., stage B)
- Early identification deepens understanding of the patient's risk and creates opportunity to reduce risk of progression

Source: 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines

Stage B Heart Failure: A Closer Look

Stages	Definition and Criteria
Stage A: At Risk for HF	At risk for HF but without symptoms, structural heart disease, or cardiac biomarkers of stretch or injury (eg, patients with hypertension, atherosclerotic CVD, diabetes, metabolic syndrome and obesity, exposure to cardiotoxic agents, genetic variant for cardiomyopathy, or positive family history of cardiomyopathy).
Stage B: Pre-HF	No symptoms or signs of HF and evidence of 1 of the following:
	*Structural heart disease** Reduced left or right ventricular systolic function Reduced ejection fraction, reduced strain Ventricular hypertrophy Chamber enlargement Wall motion abnormalities Valvular heart disease
	*Evidence for increased filling pressures** By invasive hemodynamic measurements By noninvasive imaging suggesting elevated filling pressures (eg, Doppler echocardiography)
	Patients with risk factors and *Increased levels of BNPs** *or* *Persistently elevated cardiac troponin* in the absence of competing diagnoses resulting in such biomarker elevations such as acute coronary syndrome, CKD, pulmonary embolus, or myopericarditis
Stage C: Symptomatic HF	Structural heart disease with current or previous symptoms of HF.
Stage D: Advanced HF	Marked HF symptoms that interfere with daily life and with recurrent hospitalizations despite attempts to optimize GDMT.

BNP indicates B-type natriuretic peptide; CKD, chronic kidney disease; CVD, cardiovascular disease; GDMT, guideline-directed medical therapy; and HF, heart failure.

* For thresholds of cardiac structural, functional changes, elevated filling pressures, and biomarker elevations, refer to Appendix 3.

Too much of a good thing?

Source: [2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines]

Effect of 2022 ACC/AHA/HFSA Criteria on Stages of Heart Failure in a Pooled Community Cohort[1]

METHODS

- 11,618 participants from 3 longitudinal cohorts categorized into 4 HF stages according to the 2013 and 2022 HF criteria
  - MESA (Multi-Ethnic Study of Atherosclerosis)
  - CHS (Cardiovascular Health Study)
  - FHS (Framingham Heart Study)
- Cox proportional hazards regression used to assess predictors of progression to symptomatic HF and adverse clinical outcomes associated with each HF stage

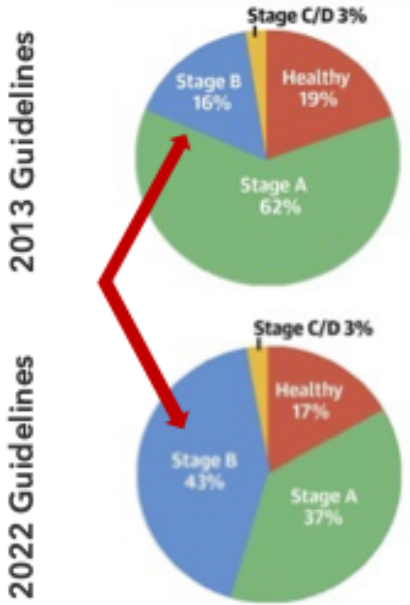
RESULTS

- Compared to the classification/definition originally described in 2013, the **2022 ACC/AHA/HFSA approach resulted in a higher proportion of individuals with stage B HF (increase from 15.9% to 43.2%)** with disproportionate shifts involving women, Hispanic and Black individuals
- Despite 2022 criteria designating a greater proportion of individuals as stage B, the relative risk of progression to symptomatic HF remained similar (HR: 10.61; 95% CI: 9.00-12.51; P < 0.001)

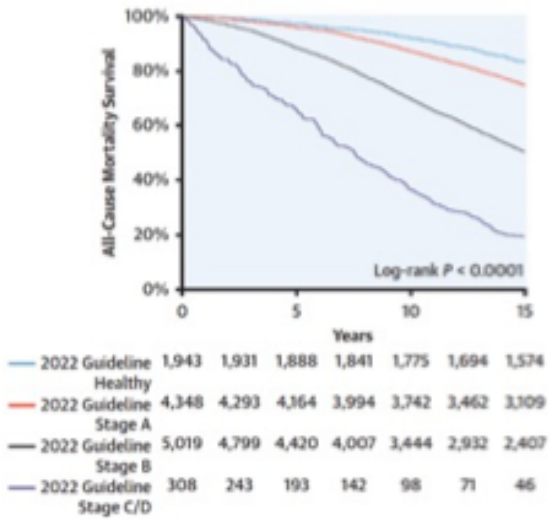
Predictors of HF Stage Progression with 2022 Guideline Definitions

Progression of Stage A to C/D		Progression of Stage B to C/D	
• Age	• Prevalent MI	• Age	• Prevalent MI
• BMI	• Prevalent CHD	• Male gender	• Prevalent CHD
• Smoking	• Log_e BNP	• BMI	• LVH
• Diabetes	• Log_e Troponin	• Smoking	• Log_e BNP
		• Diabetes	• Log_e Troponin
		• Hypertension	

Comparative Prevalence of HF Stages based on Guidelines



All-Cause Mortality Across Stages of HF

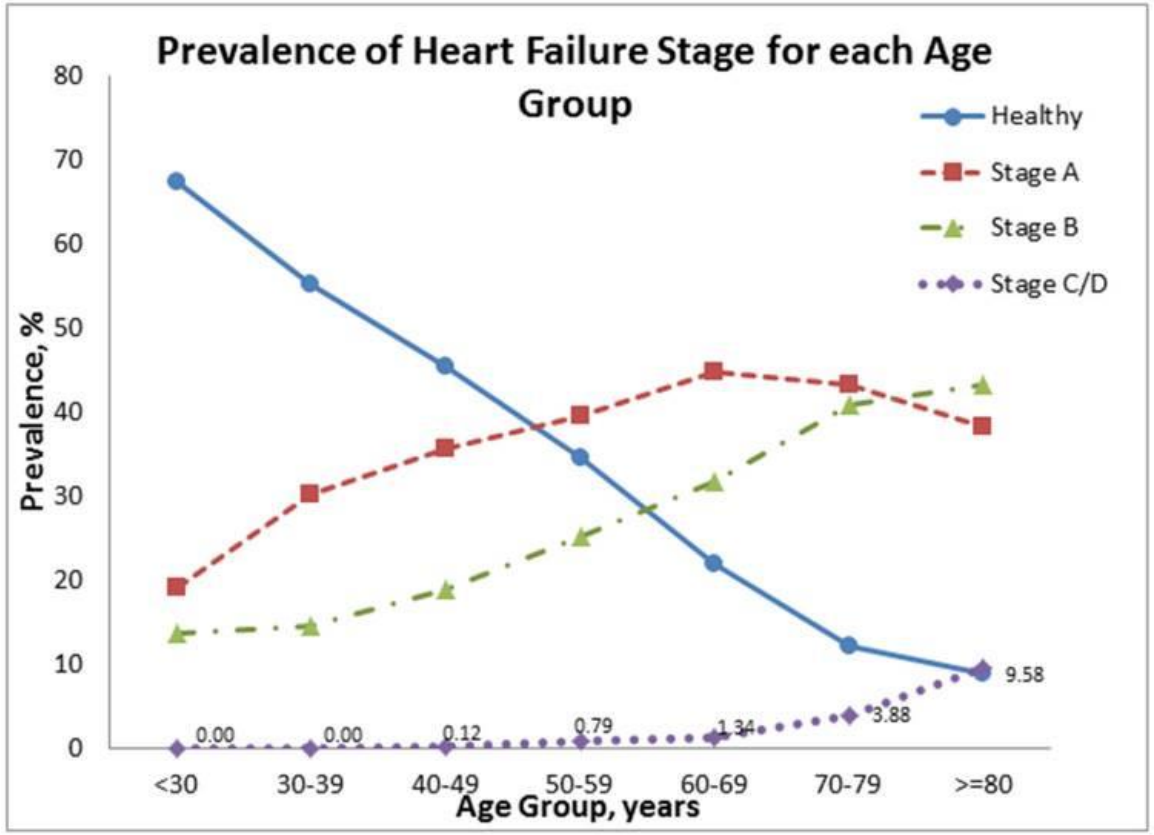


Implementation of 2022 ACC/AHA/HFSA resulted in a more prominent shift from stage A to stage B among females. In both sexes, the shift was mainly from study participants in stage A heart failure.

9

(1) Mohebi R, et.al. JACC. 2023 Jun 13;81(23):2231-2242. doi: 10.1016/j.jacc.2023.04.007.

Stage B heart failure has high prevalence, increasing with age



- The Framingham Heart Study showed prevalence of stage B to be
  - 65-74yo: 37.7%
  - ≥75yo: 42.9%
- Lifetime incidence of symptomatic heart failure (e.g., stage C/D) in a large community sample was 26% (Folsom et al, n= 13,462)

Jorge et al. The Prevalence of Stages of Heart Failure in Primary Care: A Population-Based Study – ScienceDirect. J of Cardiac Failure, 2016.
Xanthakis et al. Prevalence, Neurohormonal Correlates and Prognosis of Heart Failure Stages in the Community - PMC JACC Heart Fail. 2016.
Shah et al. Heart Failure Stages Among Older Adults in the Community: The Atherosclerosis Risk in Communities Study – PMC. Circulation. 2018.
Folsom et a. American Heart Association's Life's Simple 7: Avoiding Heart Failure and Preserving Cardiac Structure and Function – PMCAm J Med. 2015.
Ammar et al. Prevalence and prognostic significance of heart failure stages: application of the American College of Cardiology/American Heart Association heart failure staging criteria in the community – PubMed. Circulation. 2007.

Heart Failure Stages Among Older Adults in the Community:

The Atherosclerosis Risk in Communities (ARIC) Study

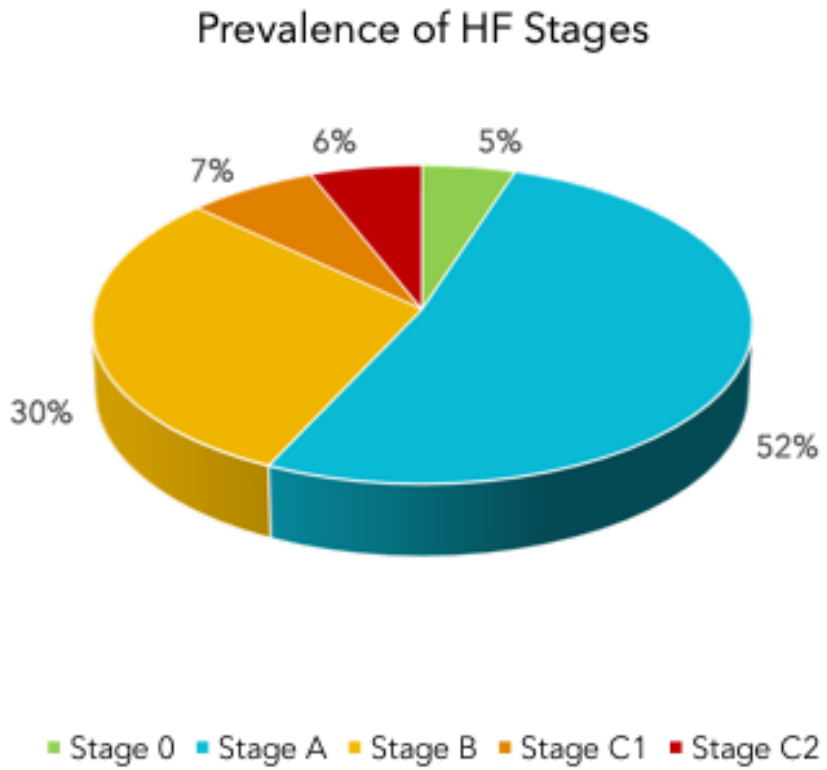
METHODS:

HF stages were classified in 6,118 participants in the ARIC study (67–91 years of age) at the fifth study visit as follows:

- **Stage 0:** Healthy
- **Stage A**: Asymptomatic with HF risk factors but no cardiac structural or functional abnormalities),
- **Stage B**: Asymptomatic with structural abnormalities, defined as left ventricular hypertrophy, dilation or dysfunction, or significant valvular disease)
- **Stage C_1**: Clinical HF without prior hospitalization
- **Stage C_2**: Clinical HF with earlier hospitalization

RESULTS:

- Using the traditional definitions of HF stages, only 5% of examined participants were free of HF risk factors or structural heart disease
- Worse HF stage was associated with a greater risk of incident HF hospitalization or death at a median follow-up of 608 days.
- LVEF was preserved in 77% and 65% in Stages C1 and C2, respectively.
- Incorporation of longitudinal strain and diastolic dysfunction into the Stage B definition reclassified 14% of the sample from Stage A to B and improved the net reclassification index (P=0.028) and integrated discrimination index (P=0.016).
- Abnormal LV structure, systolic dysfunction and diastolic dysfunction were each independently and additively associated with risk of incident HF hospitalization or death in Stage A and B participants.



Shah et al. Heart Failure Stages Among Older Adults in the Community: The Atherosclerosis Risk in Communities Study - PubMed

Stage B Heart Failure is associated with significant progression to clinical heart failure (Stage C or worse)[1]

Stage B has worse long-term outcomes compared that of Stage A

METHODS

- Population-based random sample of 2042 Olmstead County, Minnesota residents aged 45+.
- Cohorts of residents included:
  - 32% (672) with Stage A heart failure
  - 28% (582) with Stage B heart failure with preserved ejection fraction (HFpEF)
  - 3% (61) with Stage B heart failure with reduced ejection fraction (HFrEF)

RESULTS

- Over a median follow- up period of 10.6 years, those with Stage B heart failure has a significantly increased risk of the following when compared to those with Stage A heart failure.
  - Mortality
  - Development of Stage B heart failure
  - Occurrence of cardiac events

Probably of clinical heart failure development at 10 years

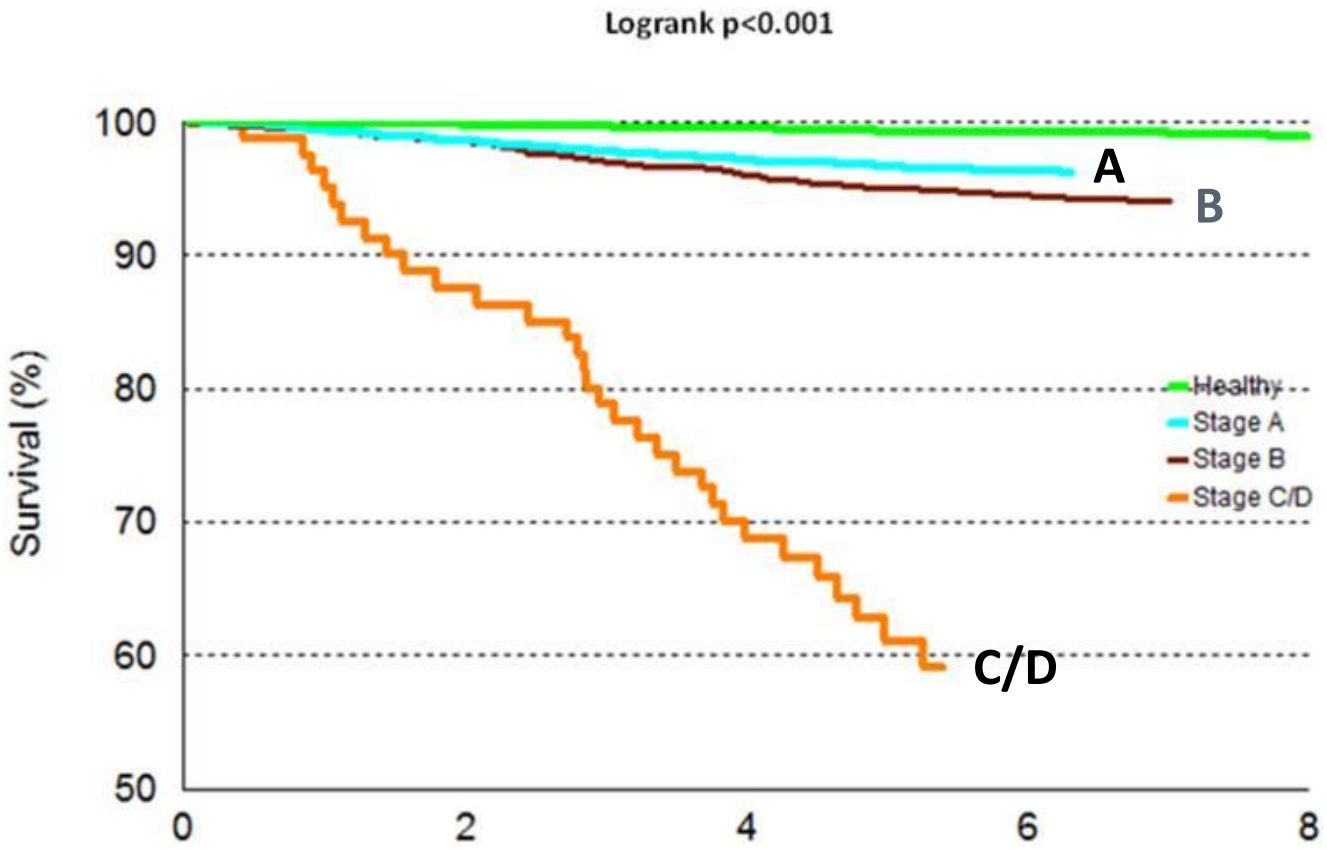
8%
from Stage A

18%
from Stage B HFpEF

62%
from Stage B HFrEF

Ammar et al. Prevalence and prognostic significance of heart failure stages: application of the American College of Cardiology/American Heart Association heart failure staging criteria in the community – PubMed. Circulation. 2007.

Mortality increases with early-stage heart failure



- The Framingham Heart Study (n=6,770) showed increase in mortality across stages
- Mortality hazards ratios (95% CI):
  - Stage A: 1.97 (1.24 – 3.13)
  - Stage B: 2.07 (1.29 – 3.34)
  - Stage C/D: 7.83 (4.61 – 13.28)

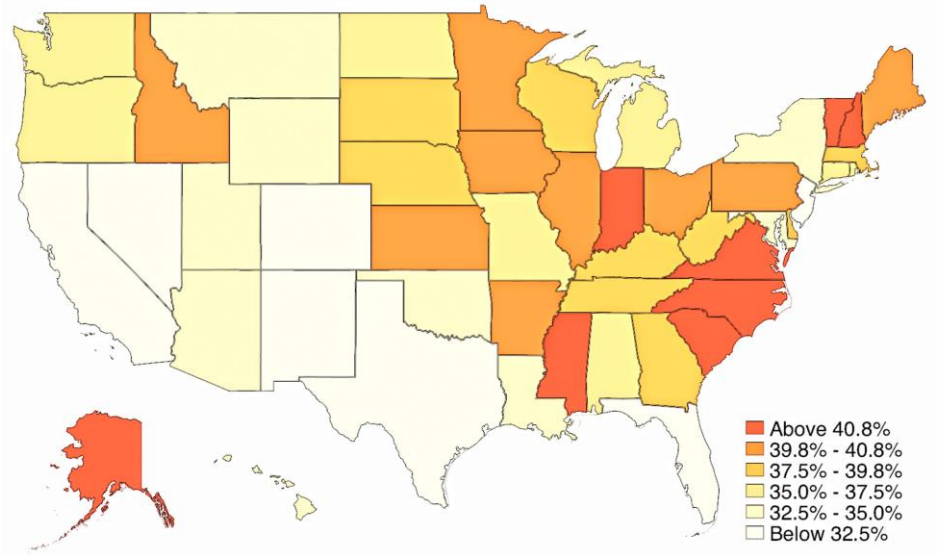
Xanthakis et al. Prevalence, Neurohormonal Correlates and Prognosis of Heart Failure Stages in the Community. JACC Heart Fail. 2016. Prevalence, Neurohormonal Correlates and Prognosis of Heart Failure Stages in the Community - PMC

Diagnosis of early-stage heart failure creates opportunity to improve outcomes

Early diagnosis of heart failure can help avoid hospitalization

- 38% of new heart failure diagnoses are made in the acute care setting (n=959K, Sandhu et al)
- 46% had potential heart failure symptoms in the prior 6 months
- Rate of acute care diagnosis (vs outpatient) varies by state

Variation in acute care diagnosis by state, adjusted for patient level risk factors



Young et al. Progression of Preclinical Heart Failure: A Description of Stage A and B Heart Failure in a Community Population - PMC. 2022.
Xanthakis et al. Prevalence, Neurohormonal Correlates and Prognosis of Heart Failure Stages in the Community - PMC JACC Heart Fail. 2016.
Wang et al. Diagnosis of Nonischemic Stage B Heart Failure in Type 2 Diabetes Mellitus: Optimal Parameters for Prediction of Heart Failure – ScienceDirect. JACC: Cardiovascular Imaging. 2018
Sandhu et al. Disparity in the Setting of Incident Heart Failure Diagnosis | Circulation: Heart Failure. Circulation: Heart Failure. 2021

Why Early Diagnosis in Stage B Matters

➢ Prevention of Symptomatic Heart Failure (Stage C)

•Structural heart disease (e.g., left ventricular dysfunction, LVH, or prior MI) is already present, but patients are symptom-free.
•Without treatment, progression to symptomatic heart failure is inevitable in many patients.
•Early guideline-directed medical therapy (GDMT) can halt or slow progression.

➢ Reduction in Mortality & Hospitalization

•ACE-I, ARBs, ARNIs, and beta-blockers in Stage B patients with reduced ejection fraction (HFrEF, LVEF ≤ 40%) reduce the risk of death and hospitalization by up to 30-40% in clinical trials.
•Statins and blood pressure control lower cardiovascular risk in patients with CAD and LVH.

➢ Structural Heart Changes Are Often Irreversible

•Once cardiac remodeling progresses (e.g., dilation, fibrosis), reversing damage is difficult.
•Early pharmacologic intervention can prevent or slow these structural changes.

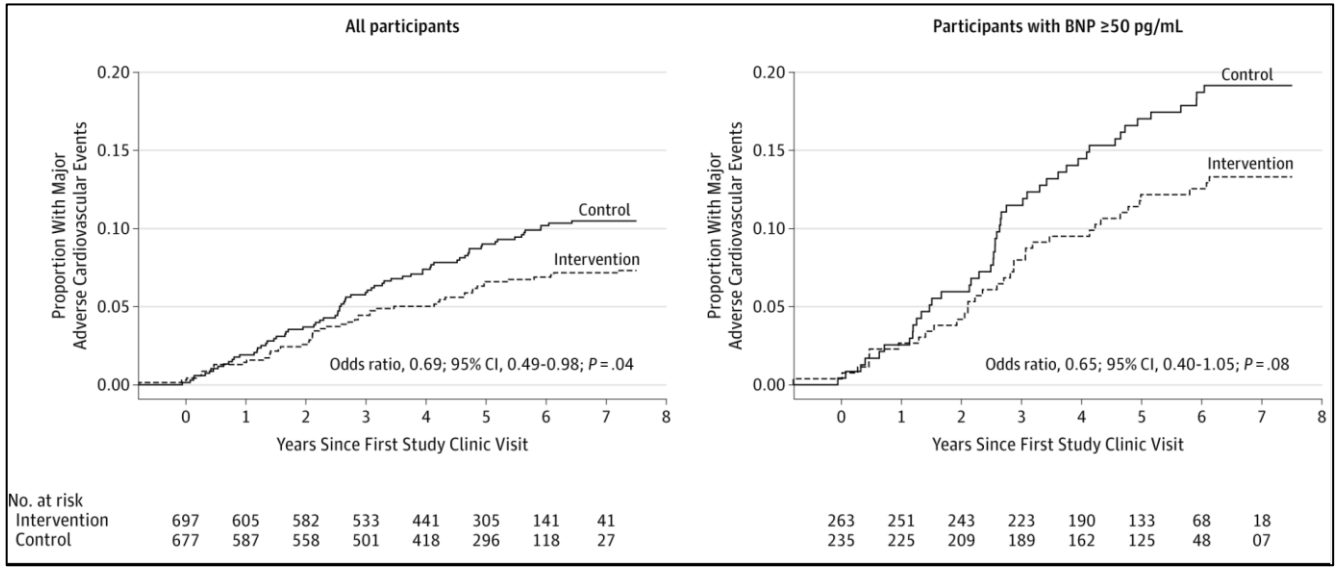
➢ Avoids the High Cost of Late-Stage Treatment

•Stage C & D HF often leads to hospitalizations, costly procedures (e.g., ICDs, LVADs), and intensive management.
•Stage B treatment is much more cost-effective than managing advanced HF

St. Vincent's Screening to Prevent Heart Failure (STOP-HF) Trial

Objective:
To evaluate whether a screening and intervention program using B-type natriuretic peptide (BNP) levels can prevent heart failure (HF) and left ventricular dysfunction in at-risk patients

Study Design:
- **Type:** Prospective, open-label, cluster-randomized controlled trial
- **Participants:** Adults at risk for heart failure (e.g., those with hypertension, diabetes, or cardiovascular risk factors) but without a history of heart failure (1374 participants)
- **Intervention Group:** BNP screening combined with collaborative cardiology care if BNP ≥ 50 pg/mL
- **Control Group:** Standard primary care without BNP screening



Key Findings:
- BNP screening and early intervention led to a **significant reduction in the incidence of left ventricular dysfunction and clinical heart failure**.
- Patients in the intervention group received earlier cardiovascular interventions, such as intensified medical therapy and lifestyle modifications.
- The approach demonstrated **improved outcomes without increasing healthcare utilization costs**.

Why is this important????

Using strategies to identify those high-risk, asymptomatic heart failure patients with evidence of cardiovascular damage can allow for a more intensive, targeted approach and slow the progression to symptomatic heart failure

Ledwidge M, Gallagher J, Conlon C, et al. Natriuretic Peptide–Based Screening and Collaborative Care for Heart Failure: The STOP-HF Randomized Trial. *JAMA*. 2013;310(1):66–74. doi:10.1001/jama.2013.7588

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Approach to stage B heart failure diagnosis

AHA/ACC guidelines: Stage B heart failure is present when there are **no symptoms / signs of HF** and one of the following:

Structural heart disease

- Reduced LV or RV systolic function
- Reduced EF, low global longitudinal strain (GLS)
- Ventricular hypertrophy
- Atrial or ventricular chamber enlargement
- Wall motion abnormalities
- Valvular heart disease

Increased filling pressures

- By echocardiogram
- By invasive hemodynamic measurements
- New noninvasive devices

Risk factors + positive labs

- Presence of risk factors (e.g., HTN, CAD, PVD, CVD, obesity, DM)

Plus

- Elevated BNP/proBNP or troponin in the absence of alternative diagnosis (e.g., ACS, CKD, PE, anemia)
- BNP >= 35 or NT-pro-BNP > 125

Source: 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines
Shavelle et al. Abstract 16544: A Multicenter Validation of a Noninvasive Brachial Cuff-ECG System for Estimation of Elevated Left Ventricular End Diastolic Pressure | Circulation. Circulation 2023.
Borlaug et al. Heart Failure With Preserved Ejection Fraction: JACC Scientific Statement – ScienceDirect. JACC 2023.
Verbrugge et al. Heart failure with preserved ejection fraction in patients with normal natriuretic peptide levels is associated with increased morbidity and mortality | European Heart Journal | Oxford Academic. European Heart Journal 2022.

AHA/ACC thresholds for structural heart disease and evidence of increased filling pressures

Morphology	• LAVI ≥29 mL/m^2 • LVMI >116/95 g/m^2 • RWT >0.42 • LV wall thickness ≥12 mm
Ventricular systolic function	• LVEF <50% • GLS <16%
Ventricular diastolic function	• Average E/e′ ≥15 for increased filling pressures • Septal e′ <7 cm/s • Lateral e′ <10 cm/s • TR velocity >2.8 m/s • Estimated PA systolic pressure >35 mm Hg
Biomarker	• BNP ≥35 pg/mL* • NT-proBNP ≥125 pg/mL*

AF indicates atrial fibrillation; BNP, brain natriuretic peptide; CKD, chronic kidney disease; GLS, global longitudinal strain; HF, heart failure; LAVI, left atrial volume index; LVMI, left ventricular mass index; NT-proBNP, natriuretic peptide tests; PA, pulmonary artery; RWT, relative wall thickness; and TR, tricuspid regurgitation.

Usually, higher cutoff values are recommended for the diagnosis of HF in these patients. Natriuretic peptide cutoffs selected for population screening for pre-HF (stage B HF) may be <99% reference limits and need to be defined according to the population at risk. *Cutoffs provided for natriuretic peptide levels may have lower specificity, especially in older patients or in patients with AF or CKD.

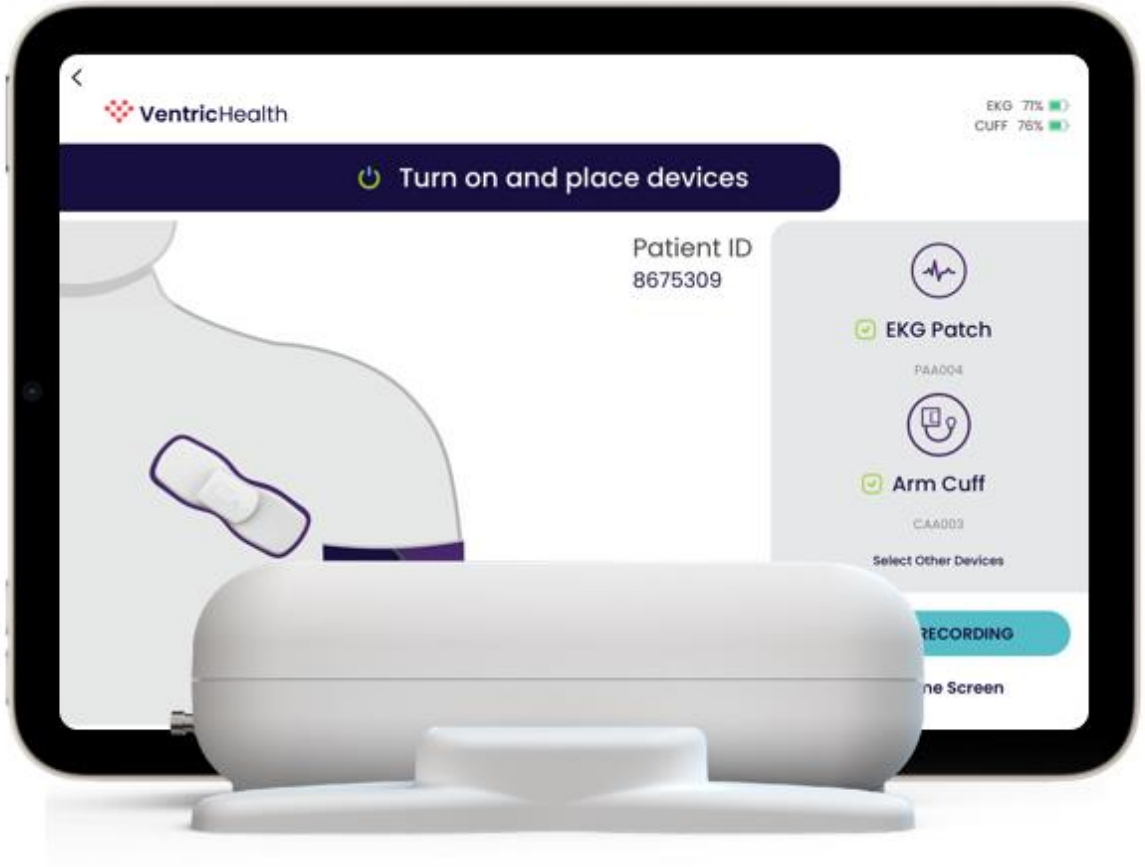
Source: 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines Appendix 1.

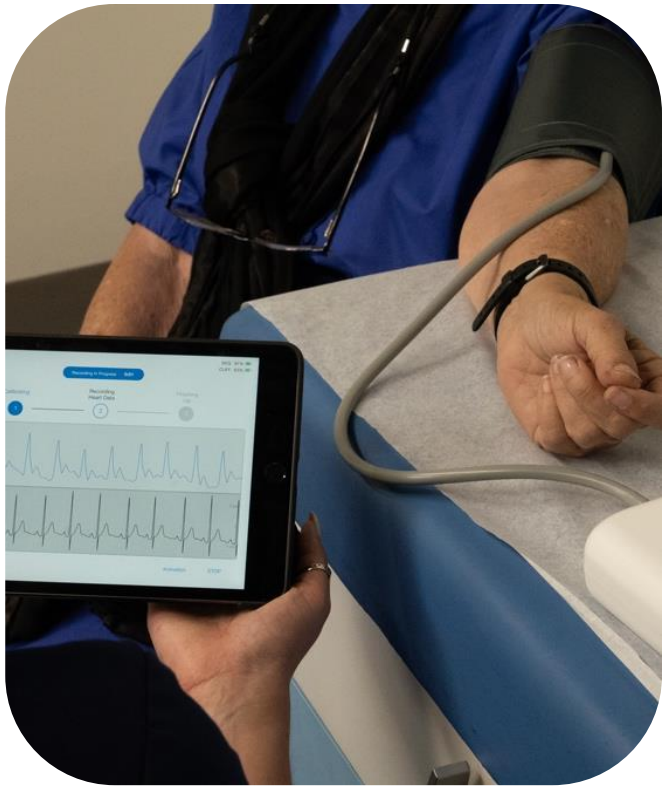
Diagnosis of Stage B: The Poor Man's Guide

- LVEF < 50% or RV dysfunction
- Presence of any LVH or LA enlargement
- Grade 1 diastolic dysfunction or greater
- Dilated IVC
- Moderate or severe mitral regurgitation
- Aortic stenosis
- BNP ≥ 35 or NT-pro-BNP ≥ 125
- *And*……..Unable to elicit HF symptoms

Evaluating Filling Pressures (LVEDP) Noninvasively: The Vivio System™

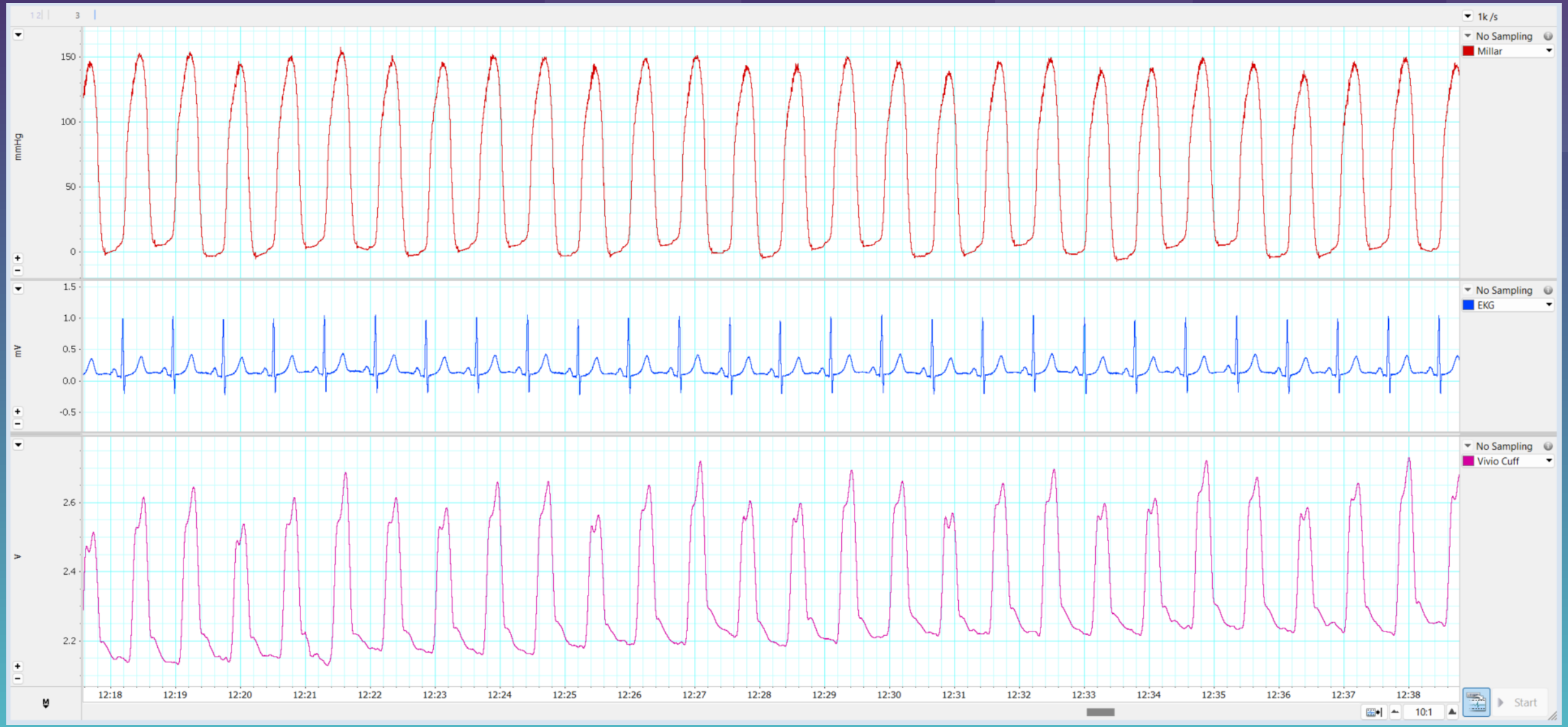
A five-minute non-invasive test estimating elevated LVEDP to enable heart failure diagnosis





The Vivio System™ is FDA cleared.

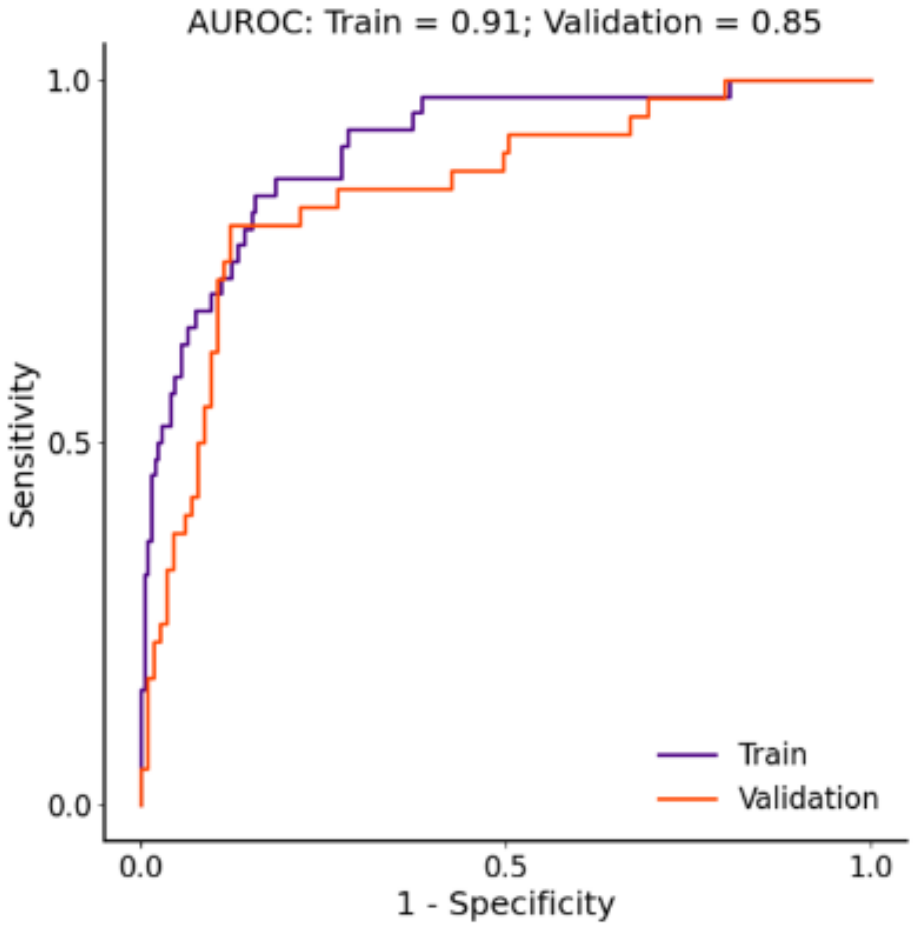
LabChart Data Intro



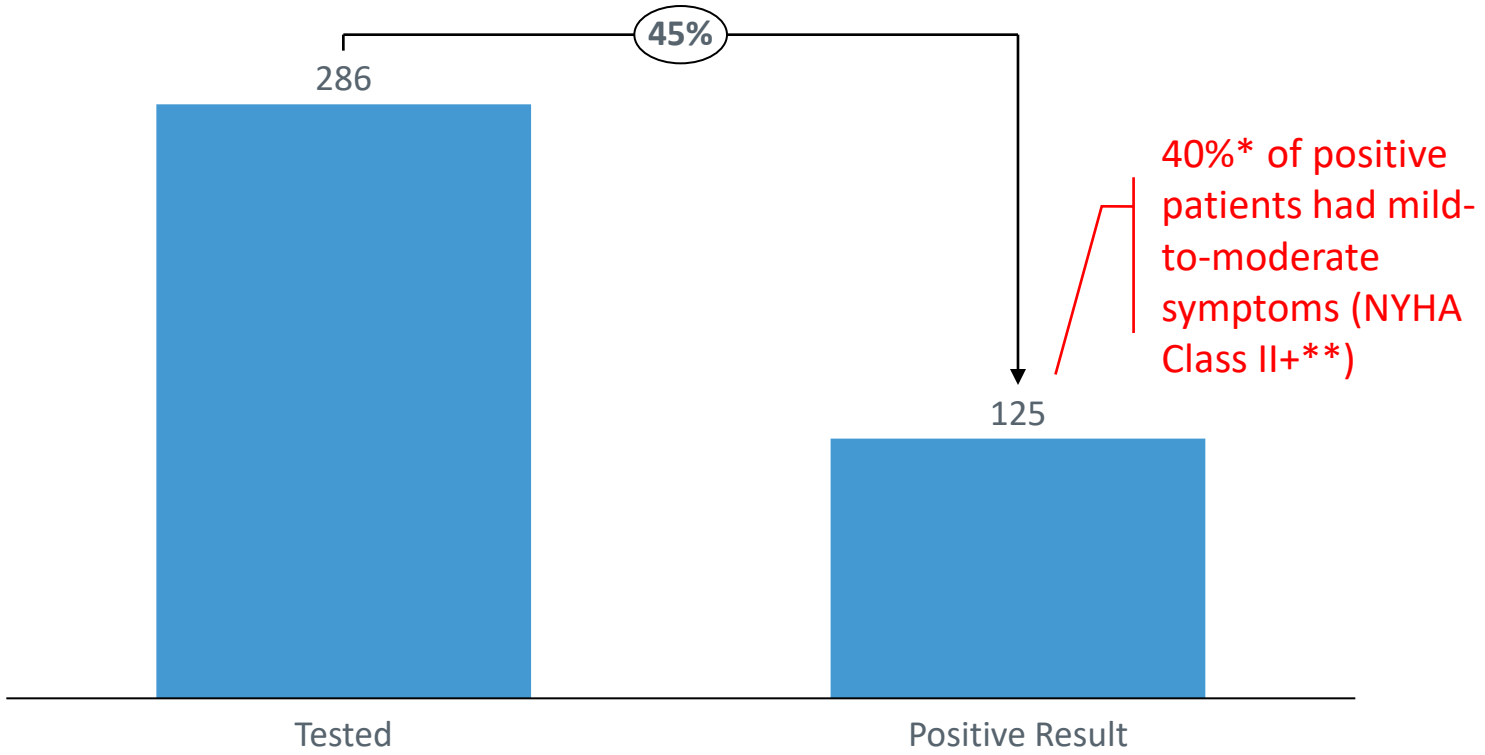
The Ventric Vivio Data: 2023 AHA Scientific Sessions

A Multicenter Validation of a Noninvasive Brachial Cuff-ECG System for Estimation of Elevated Left Ventricular End Diastolic Pressure

- 728 patients were enrolled from 7 medical centers in the USA
- Invasive LVEDP measurements were conducted using Millar catheters
- Sensitivity of 0.80 (95% CI: 0.64 - 0.91) and a specificity of 0.83



Early results from screening DM & CKD patients at an agilon market show 45% positive for heart failure, with 40% of those patients Stage C



- Initial phase of this screening work has focused on higher risk patients than the more expanded set in the guidelines
- Screening is identifying a significant number of patients who have Stage B and Stage C heart failure
- In addition to the clinical impact of improving cardiovascular outcomes and quality of life, this has improved risk adjustment accuracy and is estimated to significantly reduce hospital days

*Extrapolated from 9/17 – 10/31 data; Nov-Dec. coding review not yet complete
**Based on patients with a recorded KCCQ-12 Score

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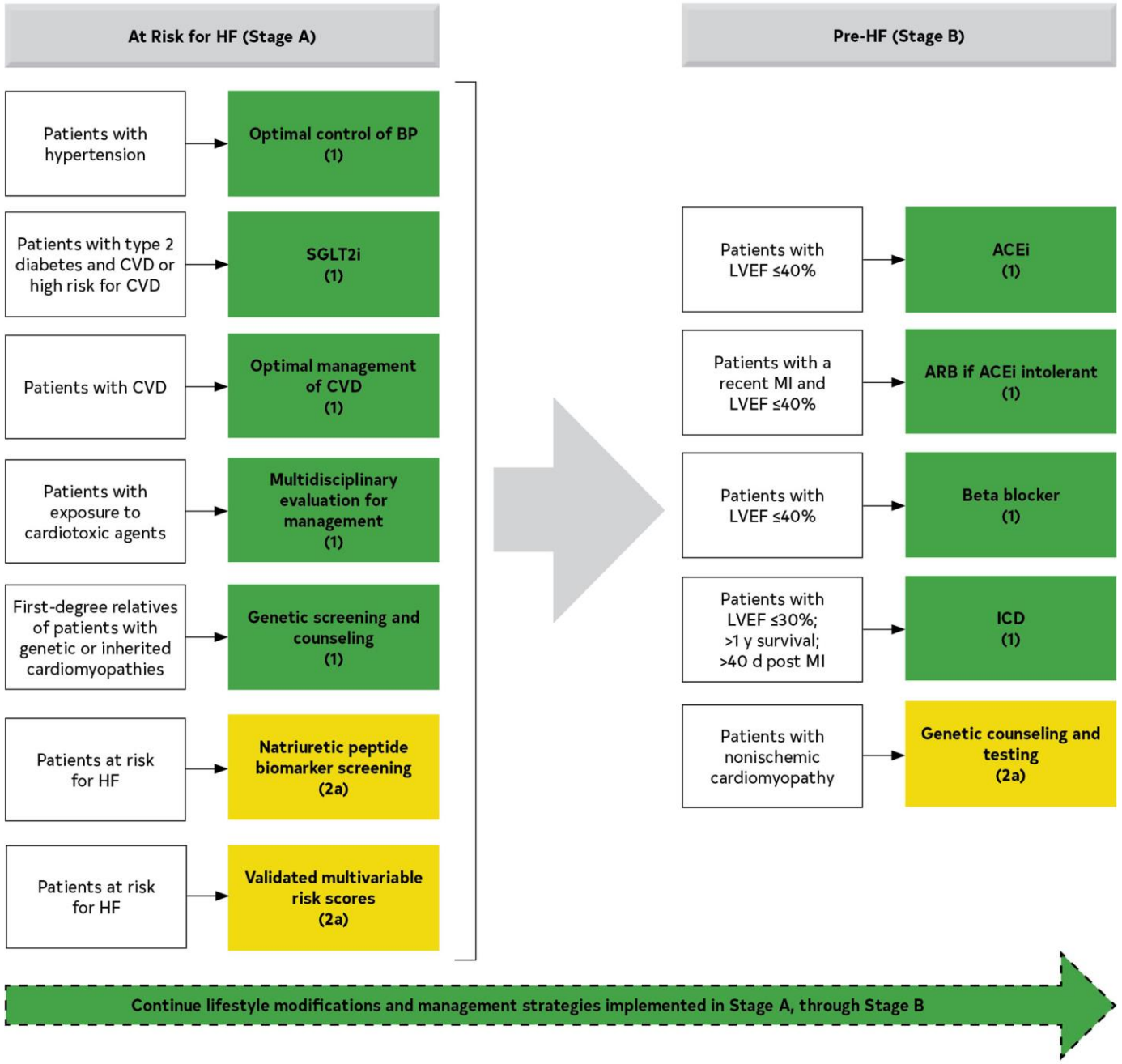
Management of stage B heart failure is tailored to risk factors and LVEF

Clinical Pearl: If the diagnosis of stage B heart failure was made based on positive BNP/pro-BNP in the setting of risk factors, **consider an echo to guide therapy based on EF**



Source: 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines

Is it really Stage B or is it Stage C:

- Heart failure symptoms can often be subtle or masquerade as other organ systems
  - Fatigue
  - Shortness of breath
  - Abdominal pain or bloating
  - Early satiety
  - Edema
- Ask for specific examples
  - Can you walk to the mailbox?
  - Do you stop after every aisle in the store?

Documenting/Coding Stage B Heart Failure

- Based on CMS ICD-10 indexing "Stage B heart failure" codes to "I50.9 – Heart Failure, Unspecified" [1]
  More specific codes can be used if the documentation matches:
    - I50.1 "Stage B left ventricular heart failure" (e.g., elevated LVEDP, left sided echo finding)
    - I50.22 "Stage B systolic heart failure", "Stage B heart failure with reduced ejection fraction"
    - I50.32 "Stage B diastolic heart failure", "Stage B heart failure with preserved ejection fraction"
- Documentation stating only "Pre-Heart failure" (not Stage B heart failure), would produce *no code* to capture because there is no indexing for this verbiage.
- If a provider stated both (e.g., "Stage B – pre-HF") in most cases medical coders would evaluate for any additional information as MEAT for the Stage B heart failure.
    - Subsequently, if the encounter does not include the necessary MEAT for Stage B heart failure, further documentation/clarification would be needed to meet documentation requirements
        - M - Monitoring signs, symptoms, disease progression, disease regression
        - E - Evaluating test results, medication effectiveness, response to treatment
        - A - Assessing/Addressing ordered tests, discussion, review records, counseling
        - T - Treating medications, therapies, other modalities

1. CMS 2023 Coding Guidelines Updates. https://www.cms.gov/files/zip/2023-code-tables-tabular-and-index-updated-01/11/2023.zip; File name "icd10cm_index_2023", p 573.
2. ICD-10 Coordination and Maintenance Committee Meeting March 7-8, 2017 Diagnosis Agenda – pg 47-51 (Focused on Heart Failure Staging)
3. Heidenreich PA, et al.. Circulation. 2022 May 3;145(18):e895-e1032. doi: 10.1161/CIR.0000000000001063. Epub 2022 Apr 1

STAGE B HEART FAILURE – Take Home Points

- Stage B HF refers to structural changes in the heart and/or elevated filling pressures that predispose patients to developing symptomatic HF
- Early identification & treatment of these changes with management of risk factors and targeted GDMT can prevent/delay the development of HF and improve QoL and decrease mortality
- Screening programs work best in high-risk patients with targeted tools
- HF symptoms can often be mis-attributed to other issues obesity, GI symptoms, dependent edema -> screen carefully. When in doubt, check BNP or other screening tools

Questions?

CME Survey