The 6th Indonesian Symposium on Heart Failure and Cardiometabolic Disease

# AMYLOIDOSIS

## when to suspect, how to diagnose, who to treat

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# Disclosure

**Nothing to disclose** on this session

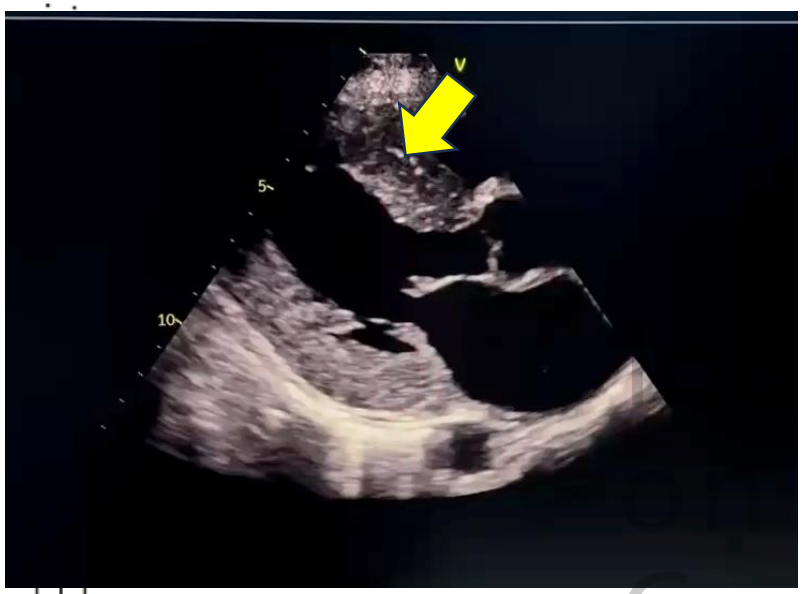
Active Scientific speaker for :

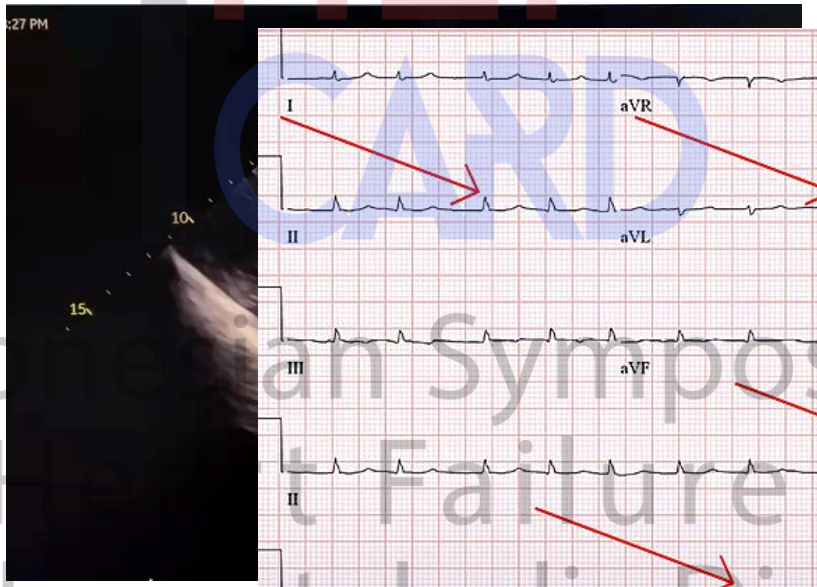
Servier, Novartis, Dexa Medica, Boehringer Ingelheim (ZPT), Bayer, Astra Zeneca, Otsuka, Menarini, Medtronic, Merck, Abbott

# The Great Mimickers

| Features | Amyloidosis | Sarcoidosis |
|---|---|---|
| General thought | Multisystem diseases that can affect organs such as the **heart** | |
| Pathology | **Infiltrative** (Extracellular amyloid fibril deposition) | **Inflammatory** (Noncaseating granulomatous inflammation) |
| Heart involvement | Common in many forms (but underdiagnosed); major cause of death | Less common but potentially serious when present |
| Biopsy findings | Amyloid deposits; Congo red stain shows apple-green birefringence under polarized light | Noncaseating granulomas |
| Treatment | **Available** (+ HF GDMT) | |
| Prognosis | Varies greatly by type and organ involvement; also time to diagnose | Many cases resolve spontaneously; some become chronic |

# Feel familiar with these echo…?





# Infiltrative Cardiomyopathy

## Cardiac Amyloidosis

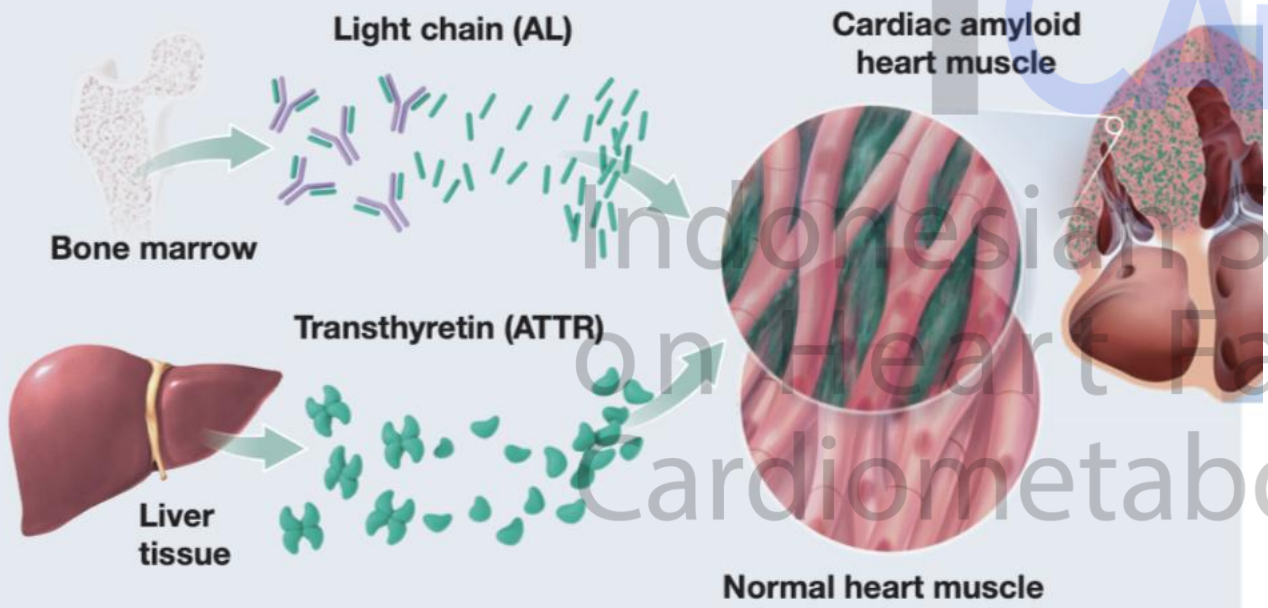
The Most Common

Anderson Fabry

## What is Cardiac Amyloidosis (CA)?

A form of restrictive infiltrative cardiomyopathy due to deposition of amyloid fibrils in the myocardium.

There are 2 common types. Similar echo features are seen in both types of CA.




## Data in Asia – South East Asia

- Not widely recognize in scientific literature  **underdiagnosed**
- Late diagnosis  high mortality
- Regional practice variations across South East Asia :
  1. Limited access to health care
  2. Mostly developing countries
  3. Poor availability of specific test
  4. Lack of expertise





Lin W, et al. Clin Cardiol.2022

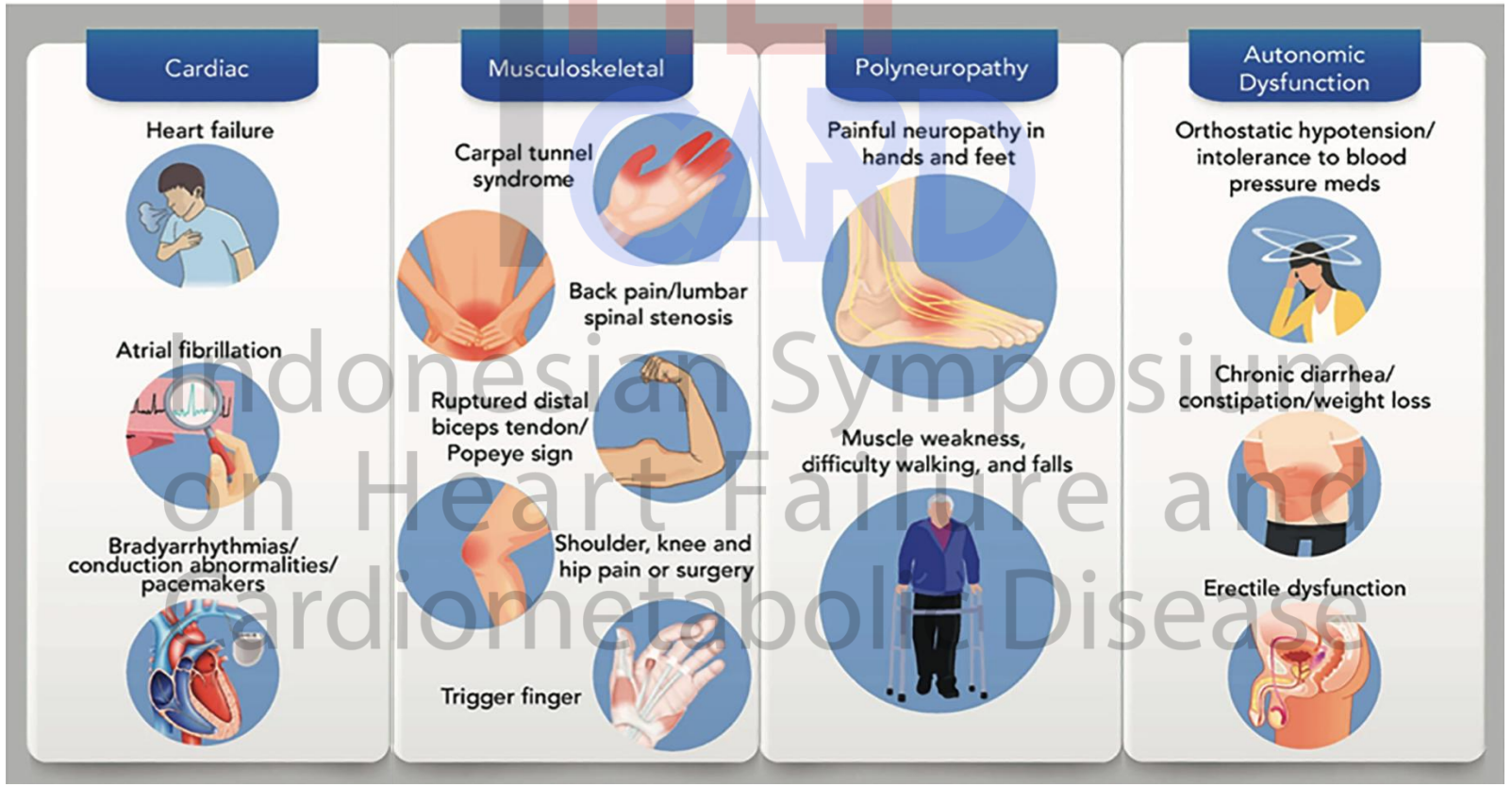
| PAST... | PRESENT |
| --- | --- |
| ✓ AL most frequent CA type | → ATTR most frequent CA type |
| ✓ Single phenotype of RCM, concentric LV thickness and low ECG voltages | → Heterogeneous phenotype: diverse LVEF, LV thickness and ECG findings |
| ✓ Thought to be a rare disease | → Not SO rare |
| ✓ Biopsies always needed for diagnosis (Invasive) | → Non-invasive diagnosis possible in many patients |
| ✓ No/Few treatments | → New treatments available |





Gonzalez-Lopez E, et al. Eur Heart J.2025

# Clinical Manifestations








Kittleson M M, et al.Am J Coll. 2023

# Diagnostic Guidance (ESC Myocardial WG Position Paper 2021)

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- Heart failure in ≥ 65 years
- Aortic stenosis in ≥ 65 years
- Hypotension or normotensive if previously hypertensive
- Sensory involvement, autonomic dysfunction
- Peripheral polyneuropathy
- Proteinuria
- Skin bruising
- Bilateral carpal tunnel syndrome
- Ruptured biceps tendon
- Subendocardial/transmural LGE or increased ECV
- Reduced longitudinal strain with apical sparing
- Decreased QRS voltage to mass ratio
- Pseudo Q waves on ECG
- AV conduction disease
- Possible family history

**SUSPECT**

Screen if

Left ventricle wall thickness ≥ 12 mm
&
≥ 1 Red Flag or Clinical Scenario


**Echocardiography**

Unexplained LV thickness (≥12 mm) plus 1 or 2:

1. Characteristic echocardiography findings (≥2 of a, b, and c have to be present)
   a. Grade 2 or worse diastolic dysfunction
   b. Reduced tissue Doppler s', e', and a' waves velocities (<5 cm/s)
   c. Decreased global longitudinal LV strain (absolute value <−15%).
2. Multiparametric echocardiographic score ≥8 points.
   a. Relative LV wall thickness (IVS+PWT)/LVEDD >0.6 (3 points)
   b. Doppler E wave/e' wave velocities >11 (1 point)
   c. TAPSE ≤19 mm (2 points)
   d. Global longitudinal LV strain ≤−13% (1 point)
   e. Systolic longitudinal strain apex to base ratio >2.9 (3 points)

**Cardiac magnetic resonance**

Characteristic findings (a and b have to be present):

a. Diffuse subendocardial or transmural LGE
b. Abnormal gadolinium kinetics*
c. ECV ≥0.40% (strongly supportive, but not essential/diagnostic)

# Why we need red flags for cardiac amyloidosis ?

- Increase clinicians awareness
- It is assumed to be rare
  - Under appreciated cause of HFpEF (30% of HFpEF patient were cardiac amyloidosis)
  - In Fact : **75% patients saw >3 physicians before diagnosis made** and **diagnosed more than 6 mo**
  - **Cardiologist** are the **most common specialist to make misdiagnosis** – most commonly HCM
- It is though to be untreatable
  - Treatment exist and are very effective if diagnosed early

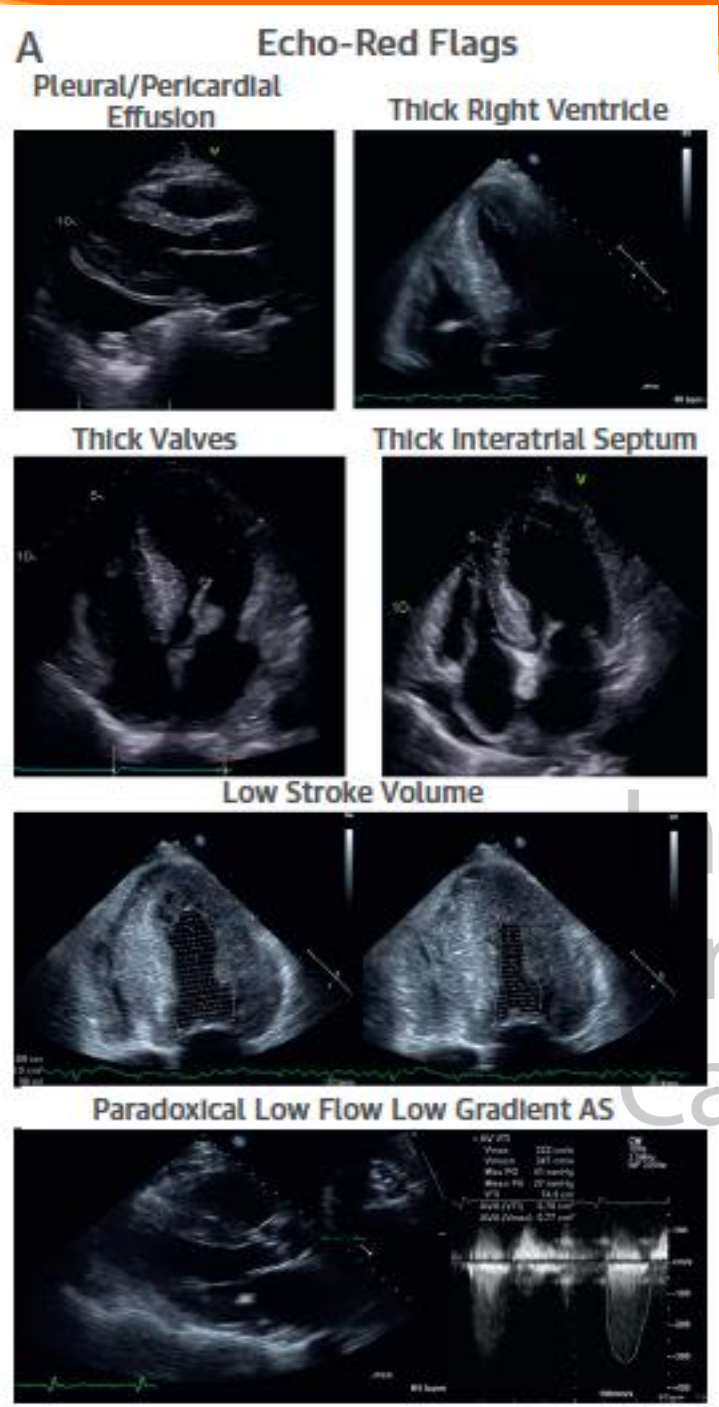
The **earlier** we diagnosed, the **better** the outcome !!



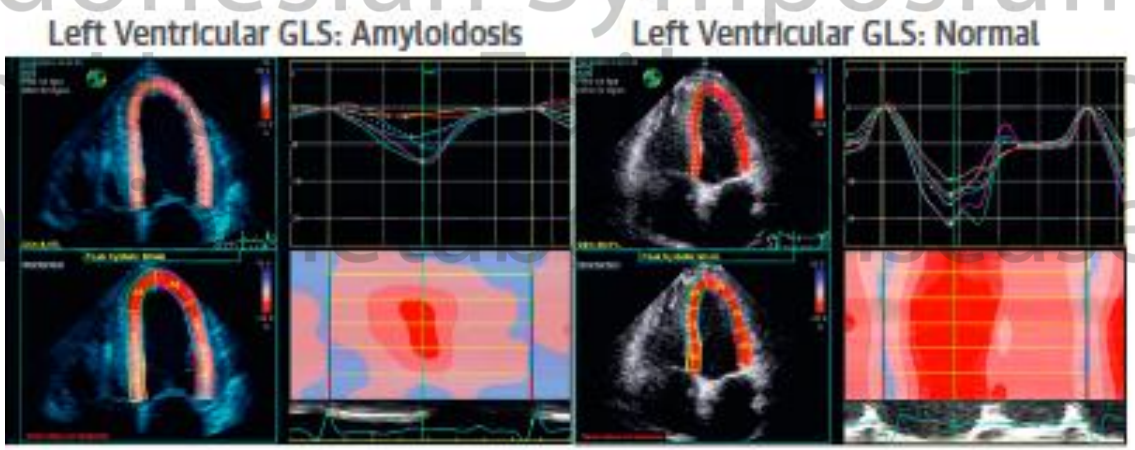


Grogan M, et al.Heart 2017

# First Hint after clinical findings is Echocardiography





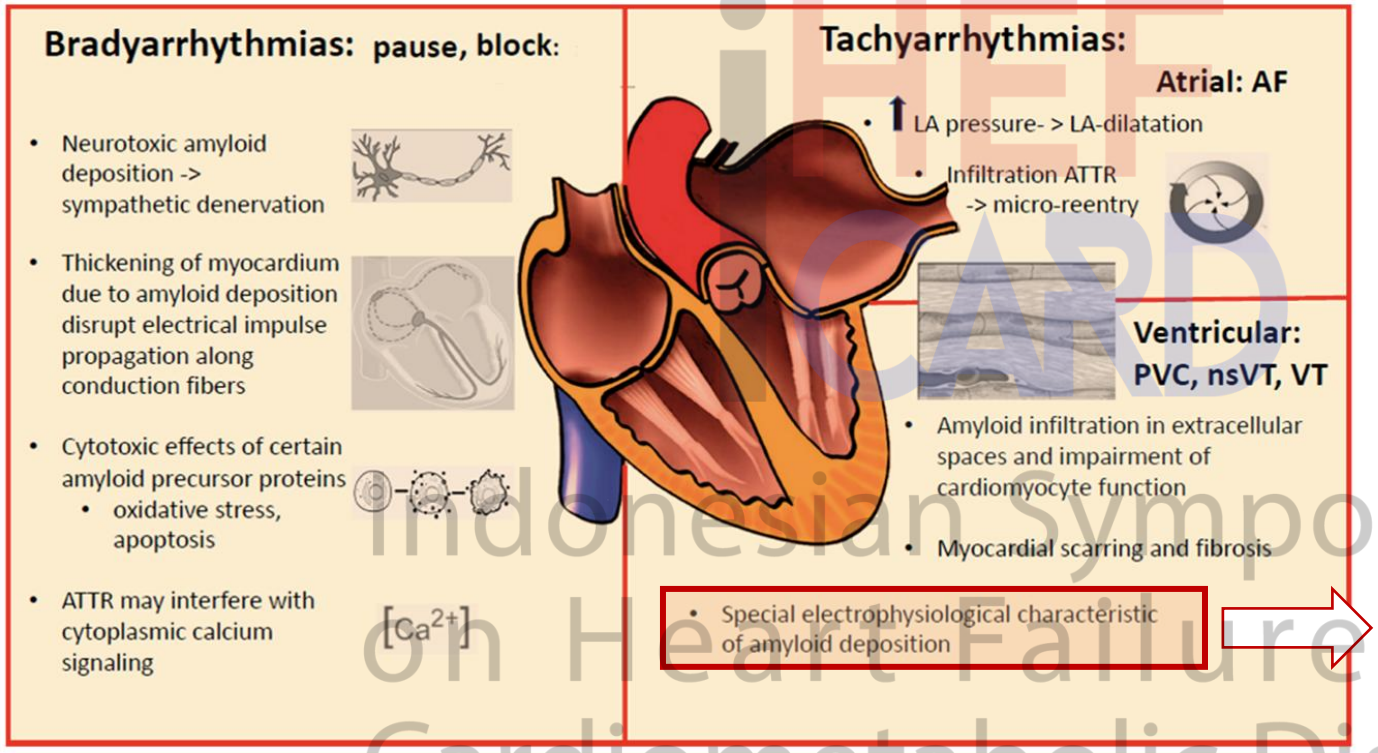



esp. LVH with LV wall thickness ≥ 12 mm – unlikely due to HTN only

**Apical sparing pattern**
sensitivity 93%
specificity 82%

P Garcia Pavia, et al. Eur Heart J. 2021

# It is not uncommon arrhythmia as manifestation




- ✓ Thick heart + low voltage **(classic)**
- ✓ Pseudo-infarction pattern, despite normal coronary arteries **(very common)**
- ✓ AF in ATTR **(very common)**
- ✓ Progressive conduction system disease **(common)**, but not post infarction/degenerative
- ✓ EPS : Extensive atrial scar substrate / "voltage–mass discordance"

**Figure 1.** Main pathophysiologic factors causing arrhythmias in cardiac amyloidosis.LA: left atrium; AF: atrial fibrilation; PVC: premature ventricular contraction; nsVT: nonnonsustained ventricular tachycardia; VT: ventricular tachycardia; arrow means elevated.





Laptseva N, et al. J. Clin. Med. 2023, 12, 2581
Teresi L, et al. Electrocardiographic Patterns and Arrhythmias in Cardiac Amyloidosis. 2024.

# The CMR (Sensitivity 85%; Specificity 90%)

**Characteristic of CMR findings**

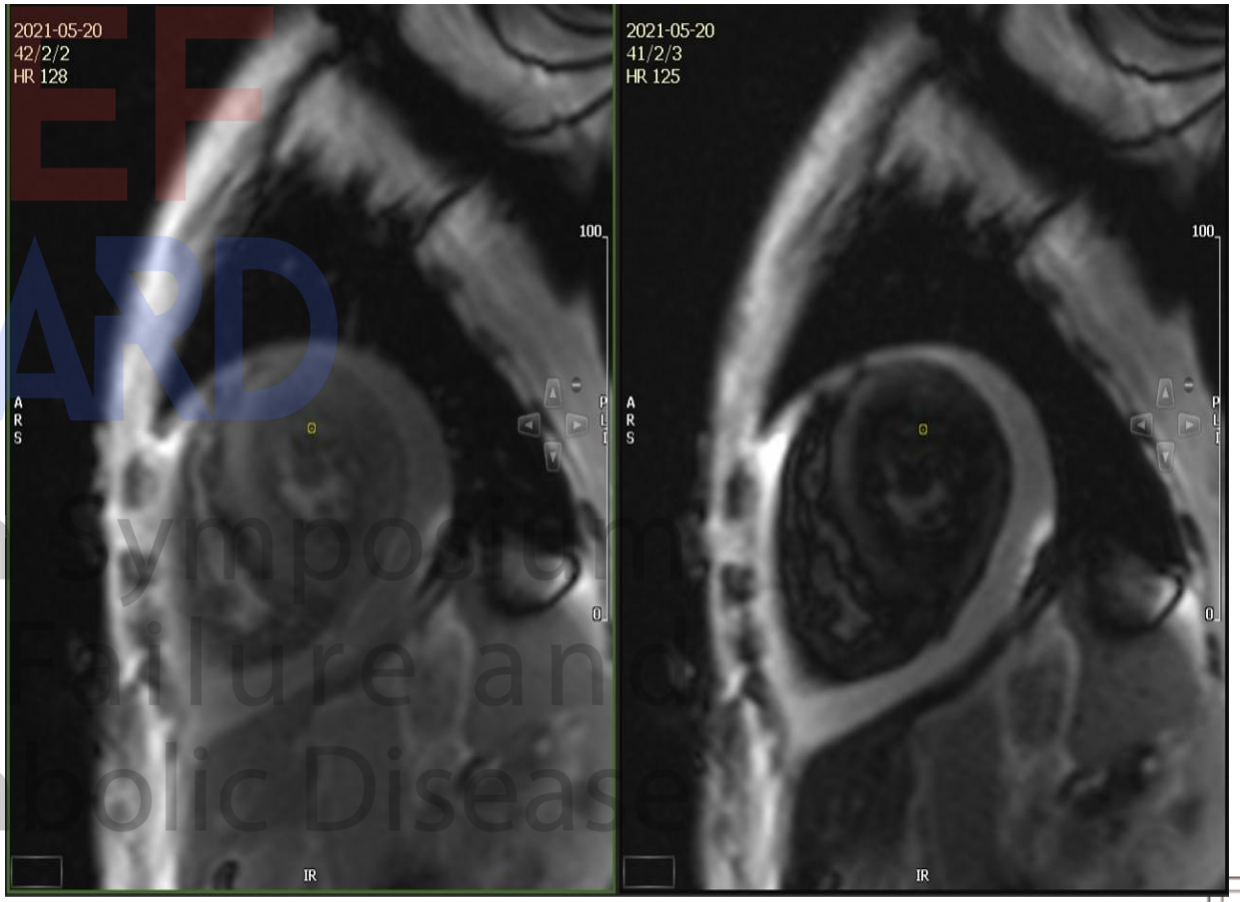
(a and b have to be present)

a) Diffuse subendocardial or transmural LGE

b) Abnormal gadolinium kinetics

c) ECV ≥ 0.40% (strongly supportive, but not essential/diagnostic)

**CMR is definitely worth to be assessed**





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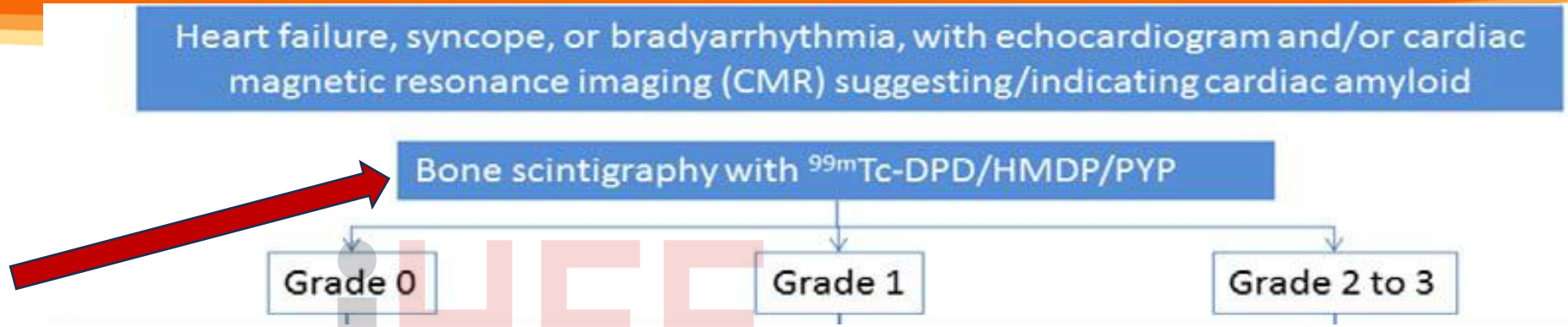
# HOW TO DIAGNOSE?








Gillmore et al.Circulation 2016

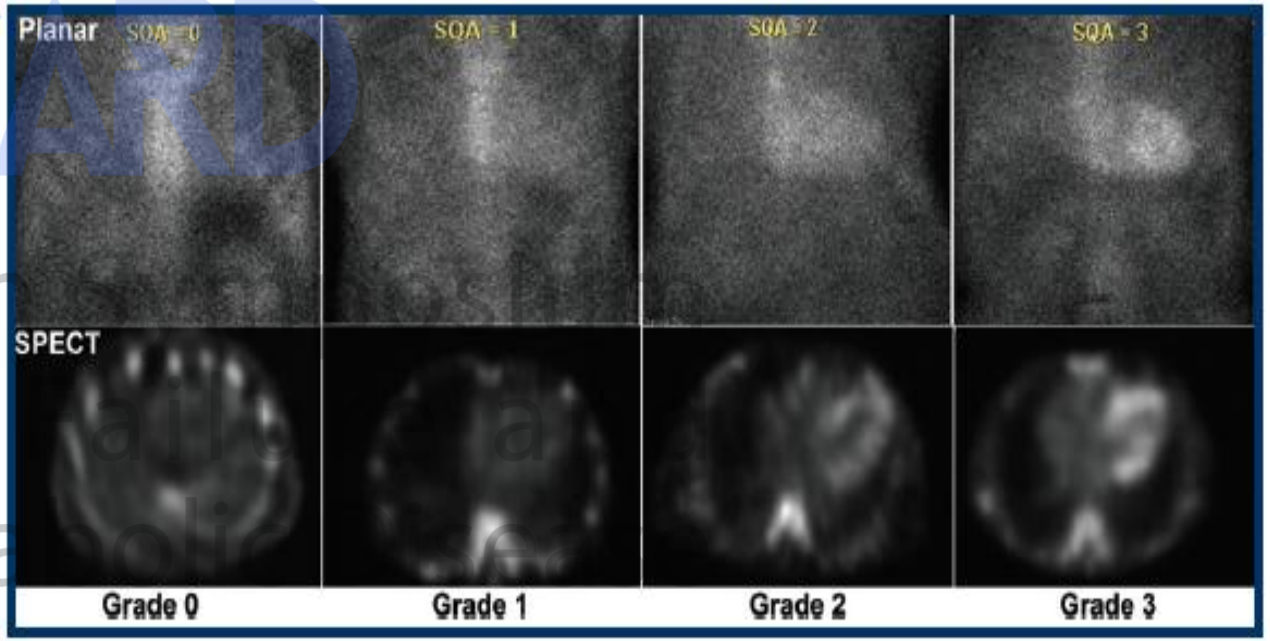
# Nuclear Bone Scintigraphy

- Most common use is $^{99}$Tc PYP / DPD
- Calcium in amyloid deposits binds to phosphates in the radiotracer

**Diagnostic of ATTR CA :**
**Grade 2 or 3 scan (confirmed by SPECT)**
**Negative monoclonal lab testing**

**Table 2. Semi-quantitative Visual Grading of Myocardial $^{99m}$Tc-PYP Uptake by Comparison to Bone(rib) Uptake**

| Grade | Myocardial $^{99m}$Tc-PYP Uptake |
|---|---|
| Grade 0 | no uptake and normal bone uptake |
| Grade 1 | uptake less than rib uptake |
| Grade 2 | uptake equal to rib uptake |
| Grade 3 | uptake greater than rib uptake with mild/ absent rib uptake |




**Always confirm myocardial uptake with SPECT ⍰ reduce False positive**

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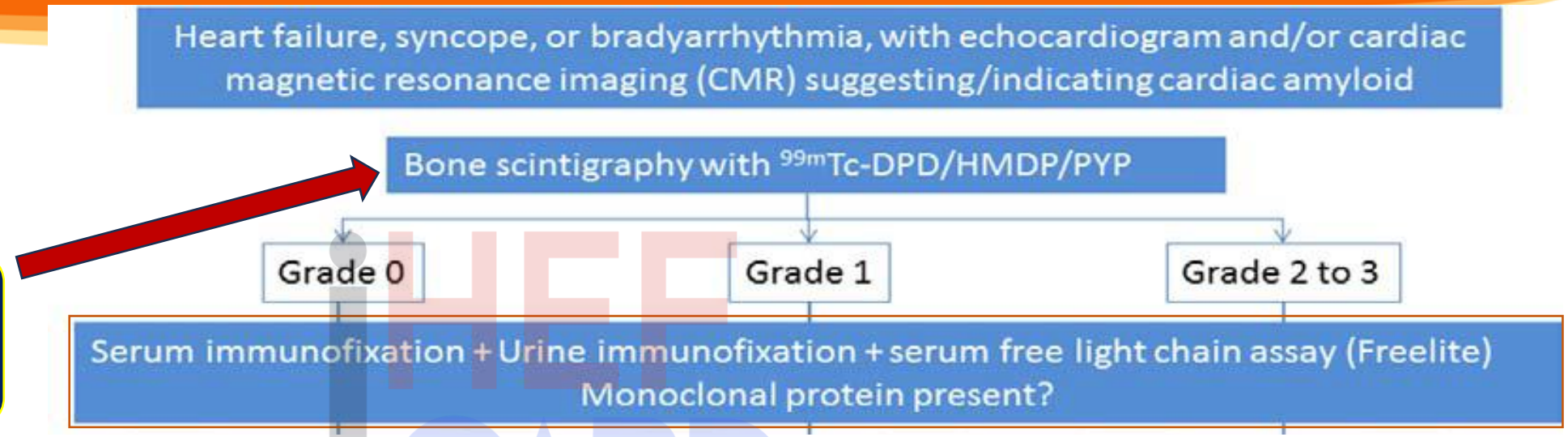
# HOW TO DIAGNOSE?








Gillmore et al.Circulation 2016

# Endomyocardial Biopsy (EMB)

- Appropriate in certain cases:
  - ✓ Suspected combined systemic AL with cardiac ATTR
  - ✓ AL or other types of amyloidosis with suspected cardiac involvement
- Biopsy of the involved organ is highly recommend compare abdominal fat pad





P Garcia Pavia, et al. Eur Heart J. 2021

# Genetic testing in ATTR cardiac amyloidosis

- Hereditary form of ATTRv is caused by variants in the TTR gene and is transmitted as an autosomal dominant

| Variant | Frequency | Penetrance | Typical Age of Onset (y) | Cardiac Phenotype | Neurologic Phenotype | Race and/or Nationality | Country/Location |
|---|---|---|---|---|---|---|---|
| Val122Ile | 3.5% in Blacks | 37.4% with carpal tunnel syndrome, polyneuropathy, cardiomyopathy, or heart failure by age 75 y[103] | Late 60s | +++ | + | Black and Caribbean Hispanics/West African ancestry | Worldwide |
| Val30Met (early onset) | Most common variant currently worldwide | >90% | <40 | + | +++ | Portuguese, Japanese, Swedish | Portugal, Sweden, Japan, Brazil, Cyprus, and Majorca |
| Val30Met (late onset) | 1 per million in Japan | >60% | >50 | ++ | ++ | Worldwide | Worldwide |
| Thr60Ala | 1% in County Donegal, Ireland. | >90% | >50 | +++ | ++ | Irish | Ireland, England, United States |
| Leu111Met | <1% of all *TTR* variants | >90% | 30-40 | +++ | + | Danish | Denmark |
| Ile68Leu | <1% of all *TTR* variants | >90% | 55 | +++ | + | Italian, German | Italy, Germany |
| Ser77Tyr | <1% of all *TTR* variants | >90% | 55 | ++ | ++ | French, German, American | United States, France, Spain |
| Glu89Gln | <1% of all *TTR* variants | >90% | 55 | ++ | ++ | Italian | Italy |
| Gly47Glu | <1% of all *TTR* variants | >90% | 45 | ++ | +++ | Italian | Italy, German |
| Ile84Ser | <1% of all *TTR* variants | Unknown | 40 | ++ | +++ | Swiss, German | United States |
| Phe64Leu | <1% of all *TTR* variants | Unknown | >50 | ++ | +++ | Italian | Italy, United States |
| Leu58His | <1% of all *TTR* variants | Unknown | >50 | ++ | +++ | German | United States, Germany |
| Ser50Arg | <1% of all *TTR* variants | Unknown | >40 | ++ | +++ | Asian, Mexican | Japan, Mexico |
| Gly47Ala | <1% of all *TTR* variants | Unknown | >40 | + | +++ | German, Italian, French, Mexico | Germany, Italy, France |
| Val20Ile | <1% of all *TTR* variants | Unknown | 60s | ++ | + | German[104] | Germany |

+ = less common; ++ = common; +++ = more common.





Kittleson M M, et al.Am J Coll. 2023

# Rare Form of cardiac amyloidosis

| Amyloidosis type | Protein | Hereditary | Frequency of heart involvement | Median survival from diagnosis (months) | Usual extracardiac signs |
|---|---|---|---|---|---|
| AL | Immunoglobulin light chain | No | 70% | 24<br>6 (if HF at diagnosis and not treated) | Nephropathy, proteinuria, autonomic dysfunction, polyneuropathy, macroglossia, spontaneous bruising, liver involvement |
| ATTRwt | Transthyretin | No | 100% | 57 | CTS, LSS, ruptured biceps tendon |
| ATTRv | Transthyretin | Yes | 30–100%<br>Depending on the mutation | 31 (Val142Ile)<br>69 (non-Val142Ile) | Polyneuropathy, orthostatic hypotension, vitreous opacities, gastrointestinal problems |
| AA | Serum amyloid A | No | 5% | 133 | Renal impairment (95%), proteinuria, hepatomegaly, gastrointestinal problems |
| AFib | Fibrinogen α | Yes | Rare | 180 | Renal impairment, proteinuria |
| AApoAI | Apolipoprotein A-I | Yes | Rare<br>Depending on the mutation | No data.<br>Probably >120 | Primarily renal impairment, proteinuria, hepatosplenomegaly, adrenal insufficiency, dysphonia due to laryngeal involvement |
| AApoAII | Apolipoprotein A-II | Yes | Rare<br>Depending on the mutation | No data | Primarily renal impairment, proteinuria |
| AApoAIV | Apolipoprotein A-IV | No | Unknown | 79 | Primarily renal impairment |
| Aβ2M | β2-microglobulin | No | 80% | No data | Long-term dialysis, CTS, joint problems |
| AGel | Gelsolin | Yes | 5%<br>Primarily conduction disease | Near normal life expectancy | Corneal lattice dystrophy, cutis laxa, drooping eyelids, paresthaesia, proteinuria (rare) |





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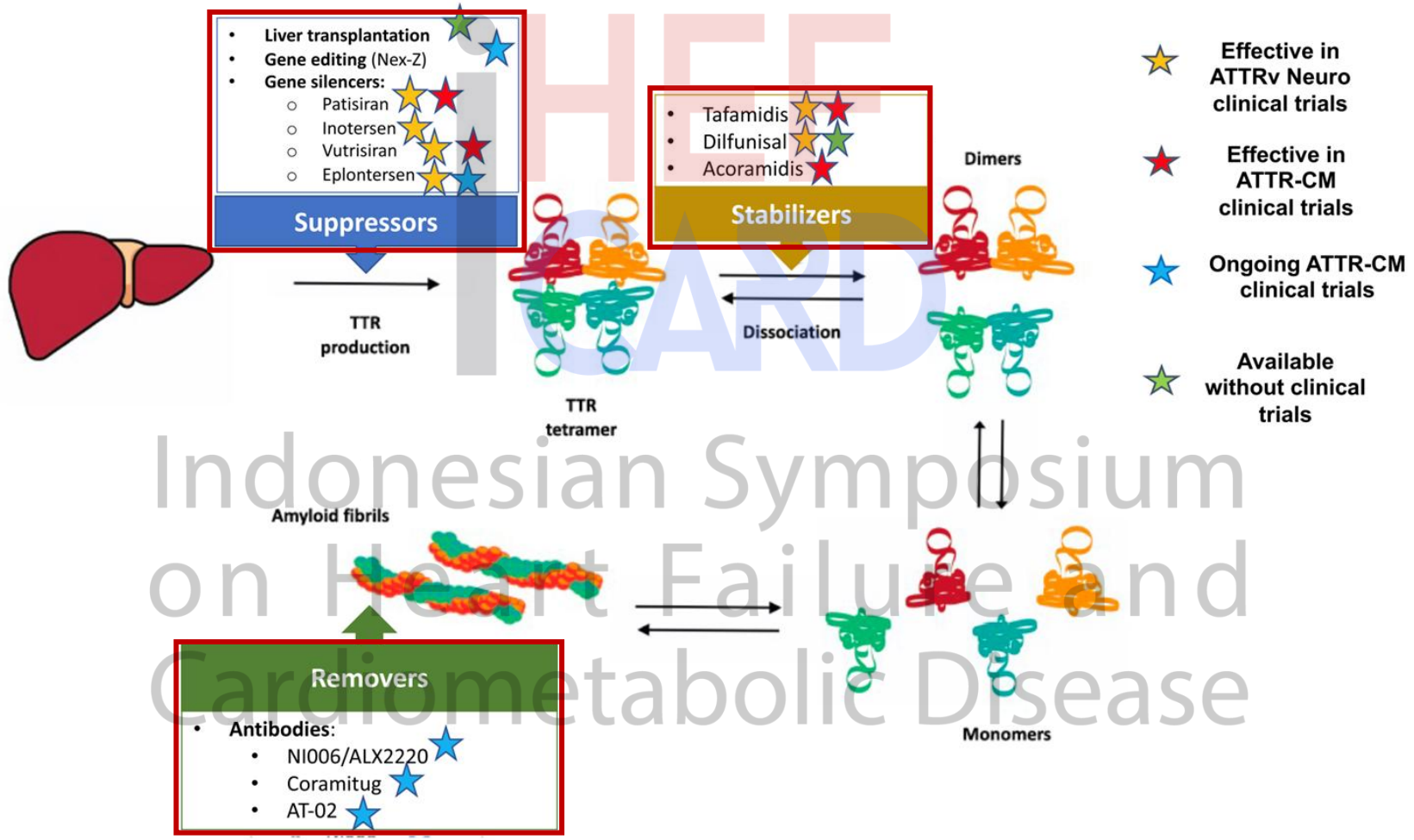
# Treatment of Cardiac Amyloidosis

- Specific Cardiac Amyloidosis
- Non specific Cardiac Amyloidosis

# Specific treatment





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# **Specific treatment –** suppressor / gen silencer

| | Mechanism of action | Route | Trial and *n* | Key inclusion criteria | Key exclusion criteria | Concomitant therapy | Primary endpoint | Results and status |
|---|---|---|---|---|---|---|---|---|
| Vutrisiran | Gene silencer (siRNA, 2nd generation) | SC Q3 months | HELIOS-B Phase III (*n* = 655) | • 18–85 years<br>• Invasive and non-invasive diagnosis of ATTR-CM<br>• HF: previous admission or clinical evidence of HF | • NYHA IV<br>• NYHA III at high risk<br>• eGFR <30 mL/min/1.73 $m^2$<br>• Polyneuropathy PND III or IV | • Tafamidis allowed<br>• Diflunisal not permitted | Composite of all-cause mortality and recurrent CV events at 33–36 months in the overall population and in monotherapy (patients not on tafamidis at baseline) | Results positive |
| Eplontersen | Gene silencer (ASO, 2nd generation) | SC Q1 month | Cardio-TTRansform Phase III (*n* = 1443) | • 18–90 years<br>• Invasive and non-invasive ATTR-CM diagnosis<br>• IVS >12 mm<br>• NYHAs I–III | • Liver or heart transplantation<br>• Previous treatment with gene silencers<br>• Current treatment with diflunisal | • Tafamidis allowed<br>• Gene silencers not permitted. | Composite of CV mortality and recurrent CV clinical events | Recruitment completed. Results expected in mid 2026 |
| Nexiguran ziclumeran (NTLA-2001) | Gene Silencer (CRISPR) | IV once | MAGNITUDE Phase III (*n* = 765) | • Medical history of HF<br>• HF symptoms optimally managed and clinically stable within 28 days<br>• NTproBNP ≥1000 or ≥2000 pg/mL in AF | • NYHA class IV<br>• Polyneuropathy stage IV<br>• RNA silencer within previous 12 months<br>• Liver failure<br>• eGFR <30 mL/min/1.73 $m^2$ | • Stabilizers allowed<br>• Gene silencers not permitted | Composite outcome of CV mortality and CV events | Recruiting |





Gonzalez-Lopez E, et al. Eur Heart J.2025

# **Specific treatment –** stabilizer tetramer

| | Mechanism of action | Route | Trial and *n* | Key inclusion criteria | Key exclusion criteria | Concomitant therapy | Primary endpoint | Results and status |
|---|---|---|---|---|---|---|---|---|
| Tafamidis | Stabilizer | Oral | ATTR-ACT Phase III ($n = 441$) | • 18–90 years<br>• Invasive diagnosis of ATTR-CM<br>• IVS >12 mm<br>• History of HF: previous HF admission or volume overload requiring diuretics<br>• NTproBNP >600 pg/mL<br>• Distance on 6MWT >100 m | • NYHA IV<br>• eGFR < 25 mL/min/1.73 $m^2$<br>• Liver transaminase >2 times upper limit<br>• Severe malnutrition (mBMI <600) | • Diflunisal not permitted | Hierarchical all-cause mortality and frequency of CV-related hospitalizations | Positive<br>Drug approved in several countries |
| Acoramidis | Stabilizer | Oral | ATTRibute-CM Phase III ($n = 632$) | • 18–90 years<br>• Invasive or non-invasive diagnosis of ATTR-CM<br>• History of HF: previous HF admission or volume overload requiring diuretics<br>• NTproBNP >300 pg/mL<br>• Distance on 6MWT >150 m | • Likely heart transplantation within a year<br>• ALT/AST >2 times and bilirubin >3 times the upper limit<br>• NTproBNP > 8500 pg/mL<br>• eGFR <15 mL/min/1.73 $m^2$ | • Tafamidis allowed after initial 12 months<br>• Diflunisal not permitted | Part A: 6MWT at 12 months<br>Part B: hierarchical combination of mortality, CV hospitalizations, NTproBNP, and 6MWT | Part A: not positive<br>Part B: positive<br>Drug approved by FDA and under evaluation by EMA |





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# Treatment of Cardiac Amyloidosis

- Specific Cardiac Amyloidosis
- Non specific Cardiac Amyloidosis

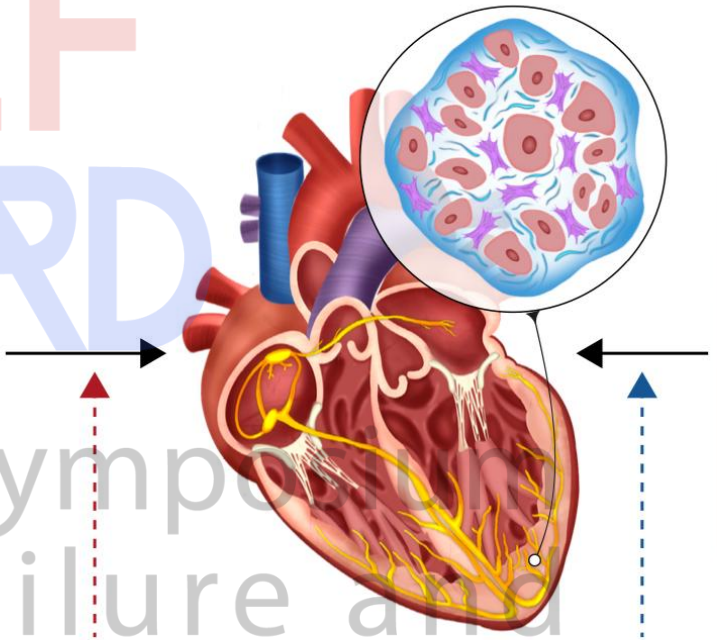
## Non-specific treatment of ATTR-CA

**Heart failure**
- Volume management
- GDMT
- Devices: CRT, ICD
- Advanced therapies

**Aortic stenosis**

**Arrhythmias**
- AV block
- Atrial fibrillation
- Sudden death

**Disease burden**




**Lack of RCTs**
**Need for better treatment algorithms**





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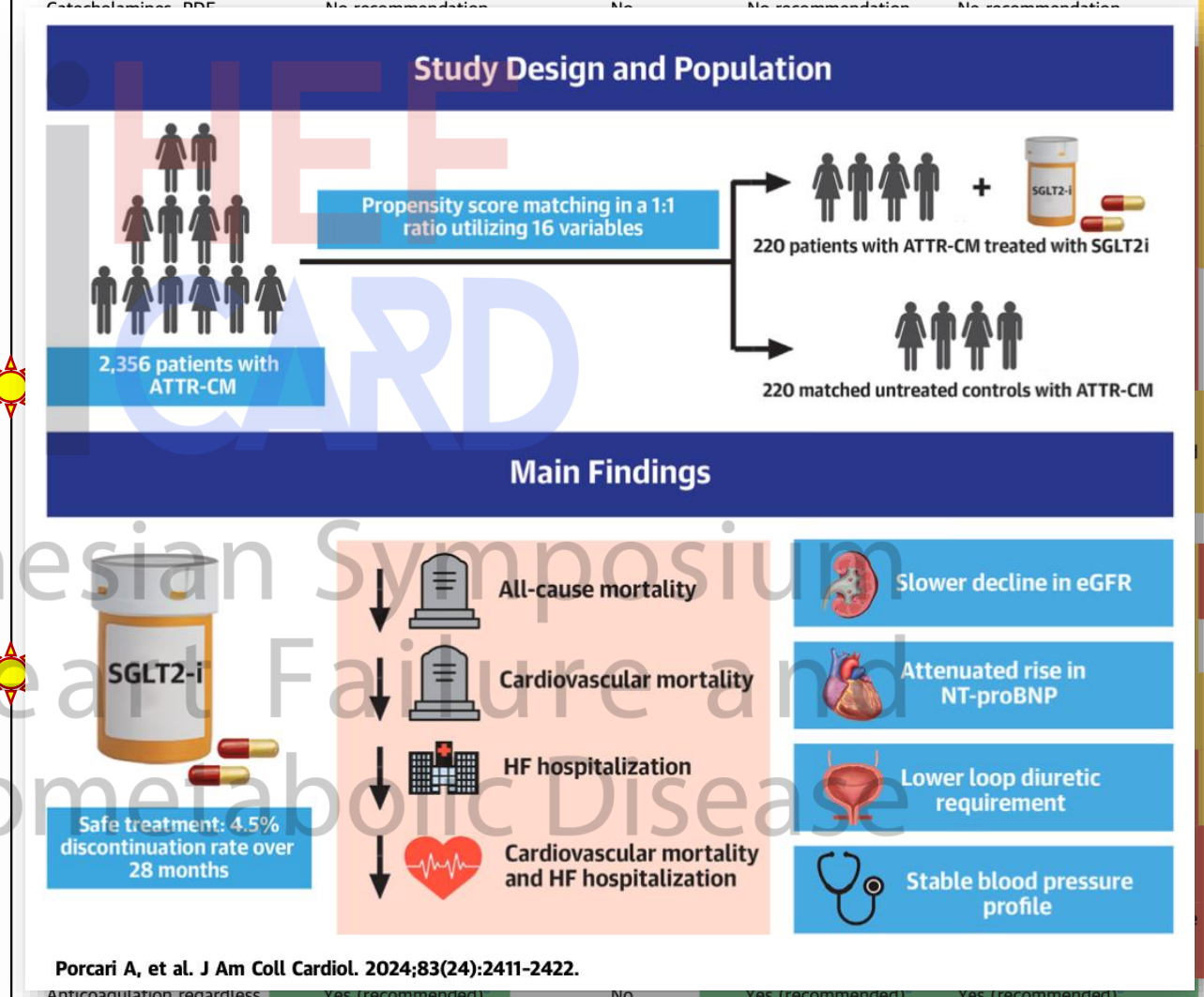
# HF GDMT in Cardiac Amyloidosis

| Drug | ESC[1] | DGK[2] | CCS/CHFS[3] | AHA[5] | JCS[6] |
|---|---|---|---|---|---|
| HF setting | | | | | |
| Loop or thiazide diuretics | Recommended[a] | Recommended[a] | Recommended[a] | Recommended, but avoid underfilling and worsening renal function from restrictive physiology[a] | Recommended[a] |
| Nitrates or carperitide (AHF) | No recommendation | No recommendation | No recommendation | No recommendation | Might be considered[a] |
| | | | | | Might be considered[a] |
| | | | | | Tolerated dosing might be considered[a] |
| | | | | | Tolerated dosing might be considered[a] |
| | | | | | No recommendation |
| | | | | | Tolerated dosing might be considered[a] |
| | | | | | Not recommended (should be avoided)[a] |
| | | | | | No recommendation |
| | | | | | Case-by-case decision (may be considered)[a] |
| | | | | | Case-by-case decision (may be considered)[a] |
| | | | | | Not recommended (should be avoided)[a] |
| | | | | | Not recommended (should be avoided)[a] |
| Anticoagulation regardless of $CHA_2DS_2$-VASc score? | Yes (recommended)[a] | No recommendation | Yes (recommended)[a] | Yes (recommended)[a] | No recommendation |
| Anticoagulation in SR? | Might be considered[a] | No recommendation | No recommendation | Might be considered[a] | No recommendation |






Rapezzi C, et al. J Am Coll Cardiol.2022

# HF GDMT in Cardiac Amyloidosis

| | |
|---|---|
| SGLT2 inhibitors | Advised |
| MRA | Advised |
| Beta-Blockers | Not advised in LVEF>40%<br>Possible in LVEF<40% |
| Sacubitril/Valsartan | Unknown/Not advised |
| ACEI/ARB | Not Advised |





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# Arrhythmia Approach in Cardiac Amyloidosis

**Table 2.** Arrhythmia risk and indication for device therapy in various forms of cardiac amyloidosis.

| | AL | vATTR | wtATTR |
|---|---|---|---|
| **Arrhythmia risk** | | | |
| Sinus node disease | +/++ | ++ | ++ |
| AV conduction disease | ++ | +++ | +++ |
| Atrial fibrillation | ++/+++ | +++ | +++ |
| nsVT/VT | +++ | ++/+++ | ++/+++ |
| SCD risk | +++ | ++ | ++ |
| **Device indication** | | | |
| PM | + | +++ | ++/+++ |
| CRT | +/++ | ++/+++ | ++ |
| ICD (primary prevention) | +/? | +/? | +/? |

+ demonstrates degree of increased arrhythmia risk or degree of device indication (+, ++ or +++); +/++ means between + and ++; ? means controversial; AL: light chain amyloidosis; vATTR: variant transthyretin amyloidosis; wtATTR: wild-type transthyretin amyloidosis; AV: atrioventricular; PM: pacemaker; CRT: cardiac resynchronization therapy; nsVT: nonsustained ventricular tachycardia; SCD: sudden cardiac death; ICD: implantable cardioverter defibrillator.





Laptseva N, et al. J. Clin. Med. 2023, 12, 2581

# Arrhythmia Approach in Cardiac Amyloidosis

**Table 3.** Prognostic factors in the development of clinically relevant brady- and tachyarrhythmias in cardiac amyloidosis.

| |
|---|
| **Bradyarrhythmias** |
| Potential candidates who may require cardiac pacing * |
| – PR interval >200 ms |
| – QRS duration >120 ms |
| – History of atrial fibrillation |
| – Long HV intervals in electrophysiologic testing |
| – High degree AV block |
| – ATTR cardiac amyloidosis |
| **Tachyarrhythmias** |
| Patients at risk for atrial fibrillation |
| – Left atrial dilatation |
| – Advanced interatrial block |
| – Old age |
| Potential candidates who may require ICD therapy * |
| – Increased NTproBNP and high sensitivity cTnT |
| – Decreased eGFR |
| – LGE uptake in CMR (role uncertain) |
| – nsVT (role controversial and possibly limited) |
| – Syncope (role controversial and possibly limited) |

* The list does not include conventional indications for pacemaker and ICD therapy. HV: His-Ventricle interval; AV: atrioventricular; ATTR: transthyretin amyloidosis; ICD: implantable cardioverter defibrillator; NTproBNP: N-terminal prohormone of brain natriuretic peptide; cTnT: cardiac Troponin T; eGFR: estimated glomerular filtration rate; LGE: late gadolinium enhancement: CMR: cardiac magnetic resonance imaging; nsVT: nonsustained ventricular tachycardia.

**HIGHLIGHTS**

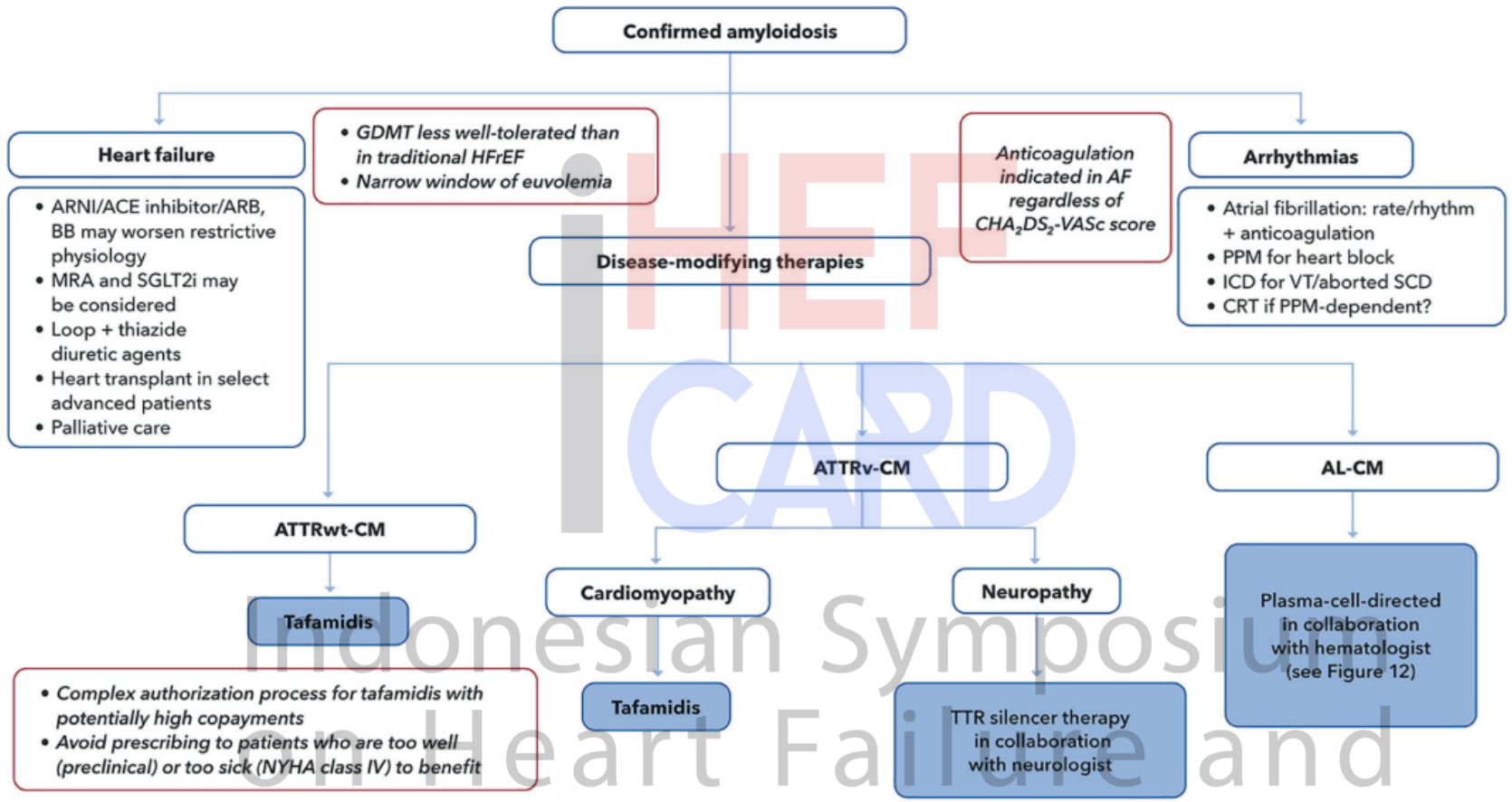
- Atrial and ventricular arrhythmias and conduction disease are common in cardiac amyloidosis.
- Atrial fibrillation may be difficult to rate control and carries a high risk of stroke.
- Implantable cardioverter-defibrillator placement for prevention of sudden cardiac death is controversial.
- New therapies are likely to change prognosis and therefore further studies are needed.





Laptseva N, et al. J. Clin. Med. 2023, 12, 2581
Giancaterino et al. JACC : 2020:351 – 6 1

**FIGURE 4** Overview of Management of Cardiac Amyloidosis




AF = atrial fibrillation; ARNI/ACE inhibitor/ARB = renin-angiotensin system inhibitors; AL-CM = amyloid monoclonal immunoglobulin light chain; ATTR = amyloid transthyretin; ATTRv-CM = variant transthyretin amyloid cardiomyopathy; ATTRwt-CM = wild-type transthyretin amyloid cardiomyopathy; BB = beta-blocker; CRT = cardiac resynchronization therapy; HFrEF = heart failure with reduced ejection fraction; GDMT = guideline-directed medical therapy; ICD = implantable cardioverter-defibrillator; MRA = mineralocorticoid receptor antagonists; NYHA = New York Heart Association; PPM = permanent pacemaker; SCD = sudden cardiac death; SGLT2i = sodium glucose cotransporter 2 inhibitor; TTR = transthyretin; VT = ventricular tachycardia.





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# Take Home Points

- Amyloidosis is a systemic disease that can present with various clinical manifestations
- Cardiac  Heart Failure and Arrhythmia
- When to suspect
  - ✓ Discrepancy between echo and clinical; suspicious arrhythmia
- How to diagnose
  - ✓ Start from Echo and/or CMR + Blood-Urine check; continue with Bone Scintigraphy, EMB, Genetic test
- Who to treat
  - ✓ ATTR-CA (specific tx, non-specific tx of HF GDMT)
- Cardiac Amyloidosis  **non-invasive dx test is available; now is treatable**
- **Early diagnosis is critical for timely treatment and improved outcomes**

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# THANK YOU

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