

# Evolving Baseline Risk in Patients With Transthyretin Amyloid Cardiomyopathy: A Systematic Literature Review of Clinical Trials

This is a plain language information of the poster presentation by Masri A, et al, presented at the American Heart Association Scientific Sessions 2024, 16 – 18 November 2024; Chicago, IL, US



## WHAT IS ATTR – CM ?

- Transthyretin amyloid cardiomyopathy, or ATTR-CM for short, is a type of heart disease that occurs when the transthyretin, or TTR, protein misfolds and forms amyloid fibrils. These amyloid fibrils then accumulate in the heart muscle, leading to thickening and stiffening of the heart walls, thereby reducing its ability to pump blood effectively.



## WHY DID THE INVESTIGATORS CONDUCT THIS ANALYSIS?

- More people know about ATTR-CM now, doctors are also able to diagnose the condition sooner than before, and there is currently one approved medicine for treating this condition. Therefore, it is possible that the patient population is changing, and patients are being diagnosed at earlier stages.
- Hence, the investigators wanted to explore if the participants in recent clinical trials of ATTR-CM may have less advanced disease than those in the earlier clinical trials. This is shown by their better heart failure symptoms, lower levels of a protein called NT-proBNP that shows reduced progression of heart disease, and higher kidney function as measured by eGFR, which shows better kidney function



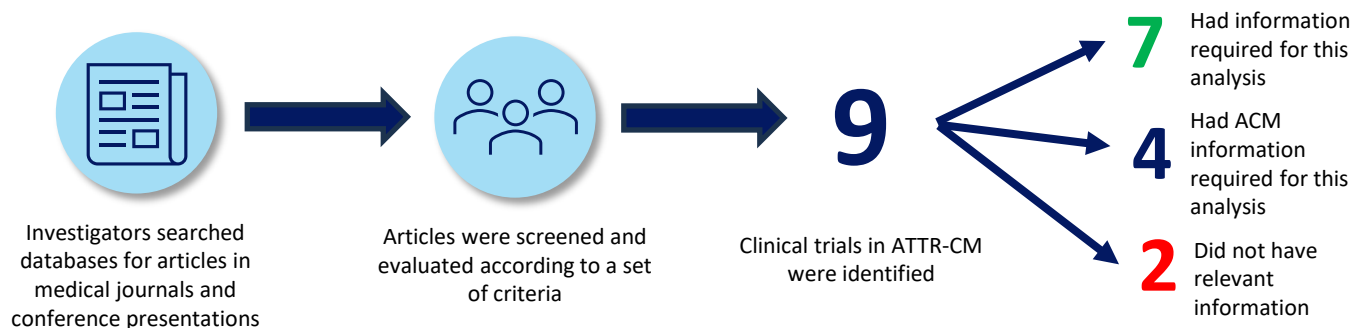
## WHAT WAS THE PURPOSE OF THIS ANALYSIS?

- In this analysis, investigators wanted to report the trends in disease characteristics and the outcome of death due to any cause or **all-cause mortality** (ACM in short) of participants with ATTR-CM enrolled in clinical trials.



## HOW WAS THIS ANALYSIS DONE?

- Investigators reviewed many published articles of clinical studies in ATTR-CM, a process called as **systematic literature review** to summarize and assess characteristics of participants who are enrolled in ATTR-CM clinical trials at baseline i.e. prior to receiving any treatment in these trials



- Names of the clinical trials (start and end of study period) analyzed were Fx1B-201 (2008-2010), ATTR-ACT (2013-2015), AG10-202 (2018), ATTRibute-CM (2019-2020), APOLLO-B (2019-2021), HELIOS-B (2019-2021), HELIOS-B monotherapy (2019-2021), INOCARD (2022)

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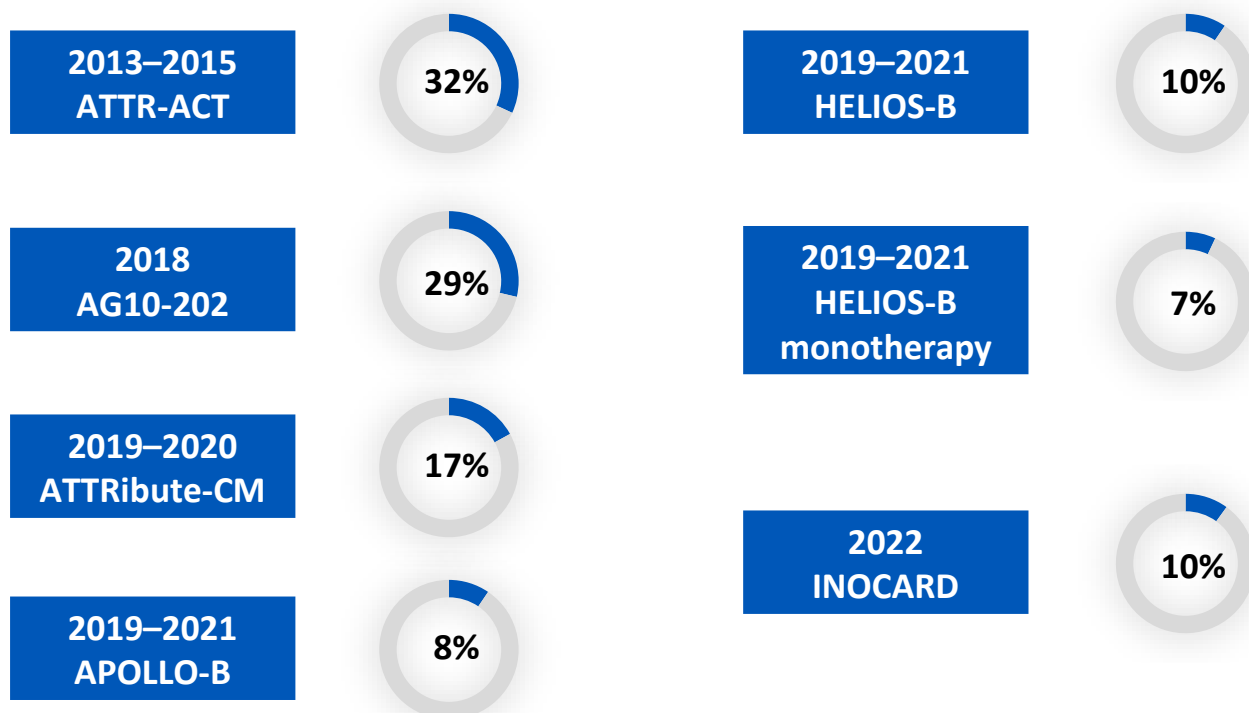
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## WHAT WERE THE KEY FINDINGS?

In earlier trials, more participants had **NHYA Class III** (indicating more severe disease with significant limitation in physical activity) compared with more recent trials



Compared with earlier trials, recent clinical trials showed a trend of:

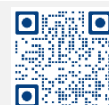


Lower **NT-proBNP levels**, an indicator of heart health (higher number means worse heart function)



Higher **eGFR**, an indicator of kidney health (higher number means better kidney function)

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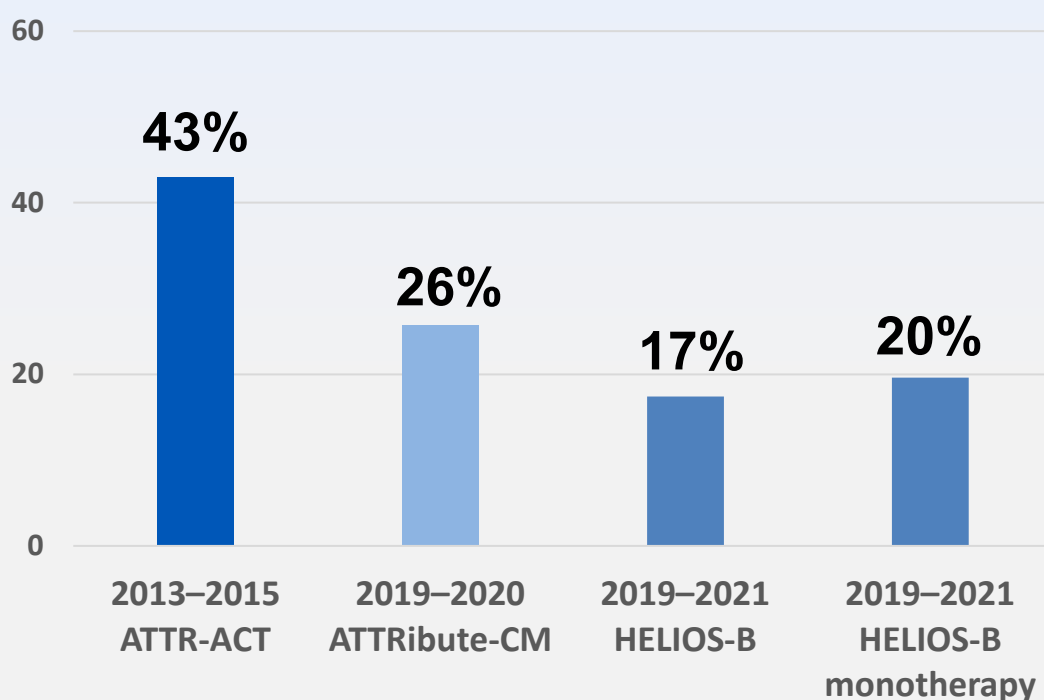


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## WHAT DO THE RESULTS MEAN?

- Recent clinical trials in ATTR-CM appear to have enrolled participants with less severe disease, which could lead to better outcomes compared to those in older studies.
- As more people become aware of ATTR-CM and get diagnosed earlier, often with less severe disease (or amyloid buildup), it is important to evaluate the benefits of new treatments for people with ATTR-CM that are more representative of today's patient population.



## GLOSSARY

- **All-cause mortality (ACM):** Death due to any reason or all causes, including because of heart issues. It also includes participants who received heart transplant, or implantation of devices (known as cardiac mechanical assist device) in the participant's heart to improve its function.
- **Estimated glomerular filtration rate (eGFR):** A test that measures how well your kidneys filter waste and toxins from your blood.
- **NT-proBNP:** A protein that can detect heart failure. Higher levels of BNP hormone mean the heart has to work harder to pump blood around the body.
- **New York Heart Association (NYHA) class:** Grouping or classification of people with heart failure according to how limited their physical activities are. Higher class means the physical activities are more limited.
- **Placebo:** Sugar or dummy pill without any medication.
- **Systematic literature review:** A research method that includes collecting, evaluating, summarizing, and presenting findings on a topic from across multiple trials.

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