Sociodemographic Disparities in Tafamidis Treatment and Clinical Outcomes Across the United States

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Introduction

- ATTR-CM is a progressive, often fatal cardiomyopathy caused by TTR deposition in the heart[1]
- ATTR-CM treatment is most effective when initiated early, yet access to treatment may not be equitable[2]
- Using a large, real-world US cohort, this study examines inequities in the initiation of tafamidis, the only approved therapy available during the study period, and outcomes based on sex, race, and socioeconomic factors to help inform clinical practice, payer policy, and targeted interventions to improve equity in the care of patients with ATTR-CM

OBJECTIVE:
To evaluate potential differences in tafamidis treatment patterns and clinical outcomes by sex, race, and socioeconomic factors using a large, real-world US cohort

ATTR-CM, transthyretin amyloid cardiomyopathy; TTR, transthyretin.
1. Ruberg FL, et al. *J Am Coll Cardiol*. 2019;73(22):2872-2891. 2. Maurer MS, et al. *N Engl J Med*. 2018;379(11):1007-1016.

Methods

- This was a **retrospective cohort analysis** using the Komodo Healthcare Map® (1/2016 to 6/2024)
- **Adults ≥18 years of age with ATTR-CM** (≥2 claims with an ATTR-CM diagnosis code [E85.0, E85.1, E85.2, E85.4, E85.82] occurring on separate days and ≥2 claims for a cardiac-related ICD-10-CM code) were followed from diagnosis to the end of follow-up (defined as the earliest of enrollment end, study end, or death)
- Patients were **excluded** if they had >1 claim (on separate days) for multiple myeloma or light chain amyloidosis, or HSCT any time during the study period, tafamidis use or ATTR-CM diagnosis any time before the index date (to ensure a newly diagnosed population), unknown sex, or <6 months of enrollment before the index date
- Outcomes included **time from diagnosis to tafamidis initiation** and **time from diagnosis to first CV-related hospitalization** (CVH; based on inpatient admission with a medical claim for a CV-related ICD-10-CM diagnosis code) or death, were stratified by sex and race, and estimated with Kaplan-Meier
  - **Pairwise comparisons** were generated across sex and race groups (both overall and stratified by ATTR-CM subtype and Social Deprivation Index [SDI]) from Cox proportional hazards models of time to tafamidis initiation and time to CVH or death using least squares means
    - Least squares means estimate adjusted survival outcomes by averaging over all other model covariates (ie, sex, race, SDI, ATTR-CM type, year of diagnosis, age at diagnosis, region, insurance type, loop diuretic dose at index, and select comorbidities)
    - SDI is a composite measure of area-level deprivation as it relates to social determinants of health, including poverty, education, employment, housing, transportation, and other household characteristics, used to quantify levels of disadvantage and inequities in small areas of the US; scores range from 1 to 100, with a higher score indicating higher social vulnerability
    - Comparisons are presented using HRs and nominal P values

ATTR-CM, transthyretin amyloid cardiomyopathy; HSCT, hematopoietic stem cell transplantation; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

Patient Characteristics

- A total of 11,311 patients with ATTR-CM were included in the analysis[a]
  - Collectively, 52.0% were White, 29.6% were Black, 18.4% were other/unknown race, 63.9% were male, and 91.3% had ATTRwt-CM
- Black patients were younger (mean [SD], 71.1 [12.6] years vs 76.1 [10.3] years), had higher rates of ATTRv-CM (12.6% vs 6.0%), and had a higher degree of social deprivation (SDI 81-100, 39.7% vs 12.5%) than White patients, respectively

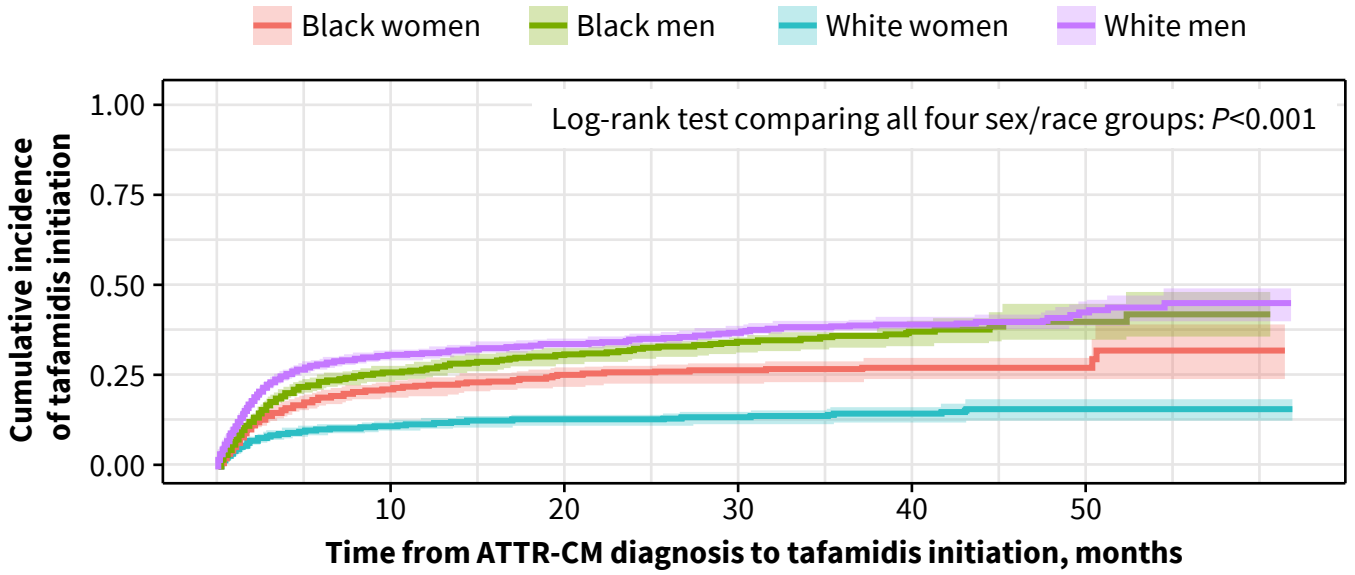
Baseline Demographics and Patient Characteristics by Sex and Race

Characteristics	White men (n=4125)	Black men (n=1857)	White women (n=1752)	Black women (n=1489)
Age at diagnosis				
Mean (SD), years	76.5 (9.6)	70.3 (12.2)	75.1 (11.6)	72.2 (13.0)
ATTR-CM type, n (%)[b]				
ATTRwt-CM	3899 (94.5)	1614 (86.9)	1628 (92.9)	1309 (87.9)
ATTRv-CM	226 (5.5)	243 (13.1)	124 (7.1)	180 (12.1)
SDI, n (%)				
1-20	1202 (29.3)	265 (14.3)	429 (24.7)	172 (11.6)
21-40	1002 (24.4)	266 (14.4)	431 (24.8)	188 (12.7)
41-60	773 (18.9)	284 (15.3)	335 (19.3)	207 (13.9)
61-80	629 (15.3)	319 (17.2)	304 (17.5)	311 (20.9)
81-100	495 (12.1)	719 (38.8)	237 (13.7)	608 (40.9)

[a]Only White and Black patients were included were included for the remaining analyses due to the small sample size and heterogeneity of other groups; patients of other races were excluded (n=2088).
[b]To be considered ATTRv-CM, a patient was required to have ≥2 heredofamilial amyloidosis codes (on separate days) during the identification period. If a patient had ATTRwt-CM codes and 0-1 heredofamilial amyloidosis codes during the identification period, the patient was considered ATTRwt-CM.
ATTR-CM, transthyretin amyloid cardiomyopathy; ATTRv-CM, variant transthyretin amyloid cardiomyopathy; ATTRwt-CM, wild-type transthyretin amyloid cardiomyopathy; SD, standard deviation.

Tafamidis Initiation

Cumulative Incidence of Tafamidis Initiation by Sex and Race



	At risk, n				
Black women	701	399	205	90	30
Black men	852	437	220	100	35
White women	977	592	332	163	63
White men	1766	1007	541	255	89
	Events, n				
Black women	279	304	309	311	311
Black men	430	475	491	498	501
White women	174	189	192	195	197
White men	1136	1203	1237	1253	1260

- After diagnosis, women had a significantly lower cumulative incidence of tafamidis initiation compared with men (*P*<0.001)
  - Within 3 months of diagnosis, the cumulative incidence of tafamidis initiation was 9.9% among women versus 19.9% among men; within 12 months, this gap persisted (14.5% vs 28.5%)
- White patients had a greater cumulative incidence of tafamidis initiation within 3 months of diagnosis compared with Black patients (18.3% vs 16.0%)
- Stratified by both race and sex, White men had the highest cumulative incidence of tafamidis initiation (31.0%), followed by Black men (26.7%), Black women (22.0%), and White women (11.4%) within 12 months of diagnosis
- Pairwise contrasts of race and sex for time to tafamidis initiation demonstrated that White women had the longest time to tafamidis initiation compared with all other groups[1]

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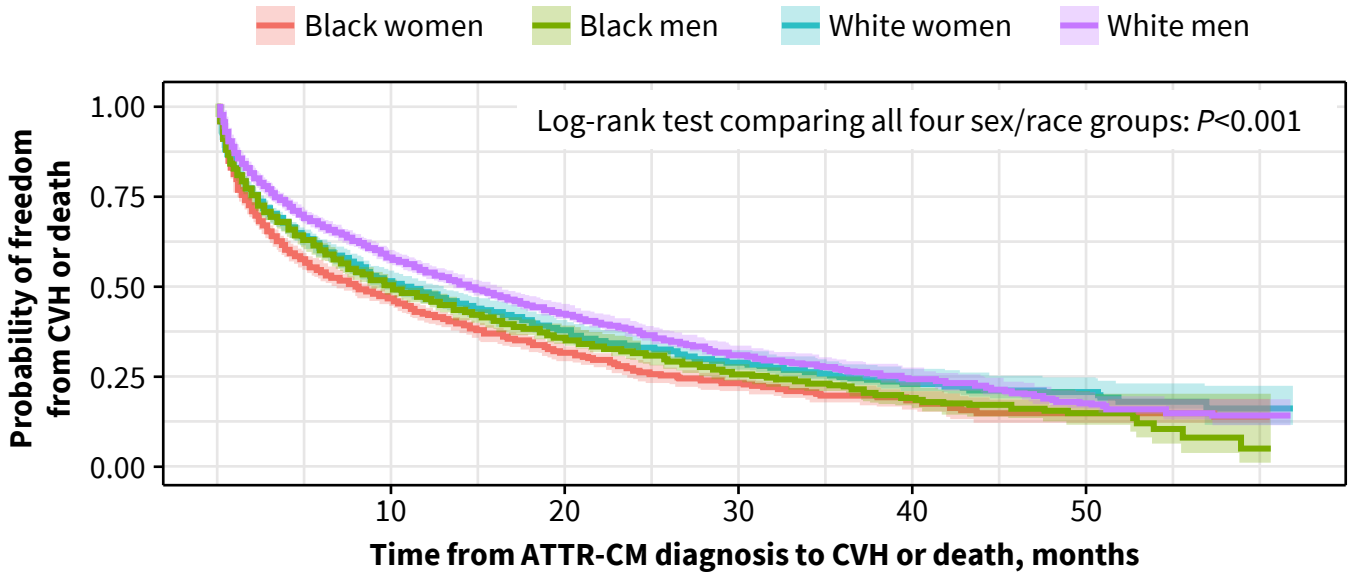
1. Data on file. BridgeBio, Inc.; 2025.

Time to Cardiovascular Hospitalization or Death

Time to CVH or Death by Sex and Race



	At risk, n				
Black women	472	203	88	32	12
Black men	658	314	133	53	18
White women	645	327	154	77	27
White men	1681	784	369	148	53
	Events, n				
Black women	722	844	886	898	903
Black men	857	999	1065	1091	1099
White women	781	921	980	1003	1009
White men	1571	1923	2096	2149	2177

- Kaplan-Meier curves demonstrated significant differences in time to CVH or death stratified by race and sex (*P*<0.001)
- Pairwise contrasts of race and sex for time to CVH or death demonstrated that both White and Black women had a greater risk of CVH or death compared with White men[1]

CVH, cardiovascular hospitalization.

1. Data on file. BridgeBio, Inc.; 2025.

Cardiovascular Hospitalization or Death by Sex and Race

Characteristics	White men (n=4125)	Black men (n=1857)	White women (n=1752)	Black women (n=1489)
Events, n (%)				
CVH	1962 (47.6)	1052 (56.7)	947 (54.1)	863 (58.0)
Death	685 (16.6)	237 (12.8)	299 (17.1)	195 (13.1)
CVH or death	2183 (52.9)	1104 (59.5)	1013 (57.8)	903 (60.6)
Median (95% CI) time to CVH or death, months	15.0 (14.0-16.0)	9.9 (8.8-12.0)	11.0 (9.6-13.0)	8.0 (6.8-10.0)
Patients free from CVH or death, % (95% CI)				
3 months	76.1 (74.8-77.4)	69.5 (67.4-71.7)	70.2 (68.1-72.4)	64.8 (62.4-67.4)
6 months	66.9 (65.4-68.4)	59.8 (57.6-62.2)	60.5 (58.2-62.9)	54.1 (51.5-56.8)
9 months	60.4 (58.8-62.0)	51.9 (49.6-54.4)	53.2 (50.8-55.8)	48.7 (46.1-51.5)
12 months	54.4 (52.8-56.1)	46.8 (44.4-49.3)	48.6 (46.1-51.2)	42.9 (40.2-45.8)

- Event-free survival at 12 months was lowest for Black women (42.9%), followed by Black men (46.8%), White women (48.6%), and White men (54.4%)
- Black women experienced the shortest median (95% CI) time to CVH or death (8.0 months [6.8-10.0]), followed by Black men (9.9 months [8.8-12.0]), White women (11.0 months [9.6-13.0]), and White men (15.0 months [14.0-16.0])

CVH, cardiovascular hospitalization.

Limitations

- As this was a claims-based analysis, the results may underrepresent undocumented variables
- Patients in the Patient Assistance Program are not captured in the Komodo Healthcare Map; therefore, patients with low SDI may be underrepresented and proportions of treated patients may be underestimated in this analysis
- Multiple ad hoc comparisons can inflate the type I error

SDI, Social Deprivation Index.

Conclusions

Sex, race, ATTR-CM type, and SDI contributed to disparities in tafamidis initiation and clinical outcomes in this large real-world US cohort of patients with ATTR-CM

Differences were observed in the factors associated with shorter or longer times to tafamidis initiation compared with clinical outcomes of CVH or death

White women were least likely to initiate tafamidis, while Black women had the poorest survival, underscoring compounded disparities in both access and outcomes

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