

Social Determinants of Health-Related Disparities in the Diagnosis of Transthyretin Cardiac Amyloidosis

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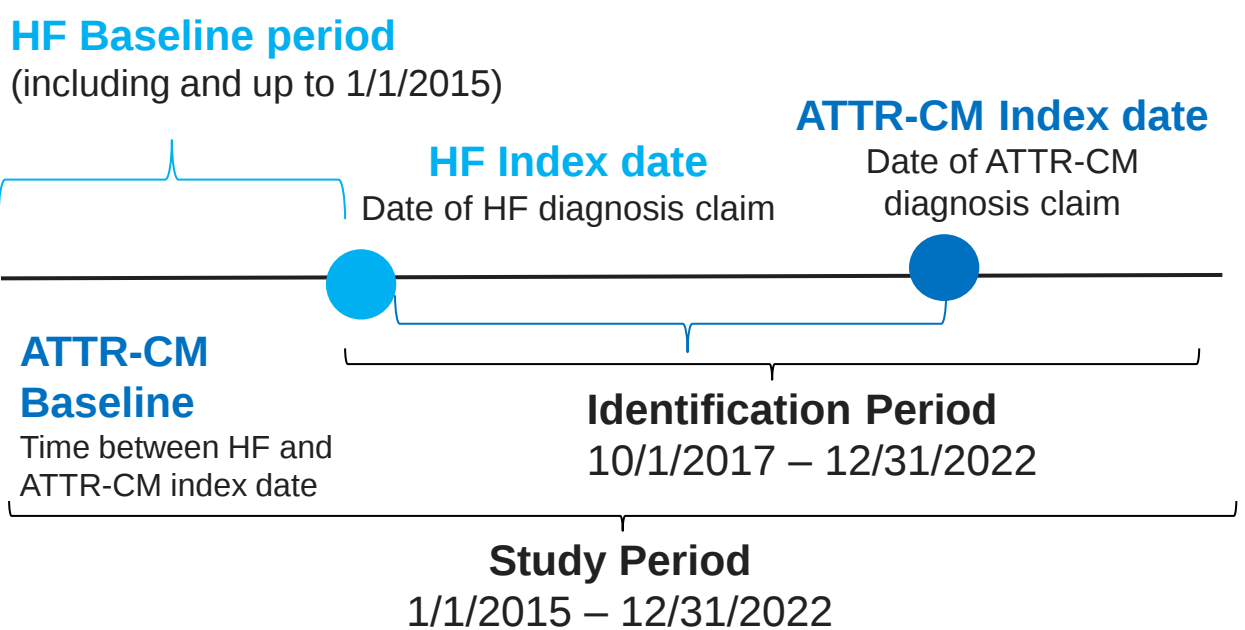
INTRODUCTION

- Social determinants of health contribute to outcome disparities. Yet, their impact on time to diagnosis in Transthyretin Cardiac Amyloidosis (ATTR-CA), particularly transthyretin amyloid cardiomyopathy (ATTR-CM), remains unexplored.
- Currently, no other studies have examined the impact of social determinants of health (SDoH) in ATTR-CM.
- In this study, we described SDoH among Medicare fee-for-service enrolled patients with hereditary (hATTR-CM) or wild-type ATTR-CM (ATTRwt-CM) and the mean time from first heart failure (HF) diagnosis to ATTR-CM diagnosis, stratified by SDoH variables.

METHODS

- Study Design:** Noninterventional, retrospective cohort study. Details in **Figure 1**.
- Data Source:** De-identified administrative claims data from the Centers for Medicare and Medicaid Services Medicare.
- Diagnosis Identification:** International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes.
- Eligibility criteria inclusive of the cohort definitions are detailed in **Figure 2**.
- Outcomes:**
 - ❖ Time from HF diagnosis to ATTR-CM diagnosis will be described in months.
 - ❖ SDoH variables: Socioeconomic status defined by social vulnerability index (SVI), race, geographic location, household count.
- Statistical Analysis:** Categorical variables will be summarized by percentages. Continuous variables will be summarized by mean.

Figure 1: Study Design



RESULTS

Figure 2 – Summary of cohort identification

All patients enrolled during the Study Period (1/1/2015 – 12/31/2022)
N=14,194,960

Included (n=8,375)

- ≥1 claim for HF¹ or cardiomyopathy¹ during the identification period (10/1/2017 – 12/31/2022)
- ≥1 claim for ATTRwt-CM¹ hATTR-CM^{1,2} or Organ-limited amyloidosis¹ during the identification period
- ≥2 claims for ATTRwt-CM, hATTR-CM, or organ-limited amyloidosis after HF diagnosis on distinct service dates with a minimum 30-day interval between claims of the same ATTR type³
- Medicare and no Medicare Advantage enrollment Part A, B and/or D coverage
- Age ≥65 years
- Continuous enrollment in Medicare parts A, B, and D between HF and ATTR-CM index date
- ≥12 months of continuous pre-HF index enrollment for Medicare Parts A/B and D
- SDoH variables of interest documented

Excluded (n=1,643)

- ≥1 claim for:
 - Light chain amyloidosis¹
 - Multiple myeloma¹
 - Heart or liver transplant
 - Treatment for multiple myeloma⁴

Overall (n=6,732)

Subgroups⁵

- hATTR-CM (n=388)
- Organ limited amyloidosis (n=3,967)
- ATTRwt-CM (n=1,465)

1. ICD-10-CM-diagnosis code: HF (I50), cardiomyopathy (I42, I43) ATTRwt-CM (E85.82), hATTR-CM (E85.0, E85.1, E85.2), organ-limited amyloidosis (E85.4), light chain amyloidosis (E85.81), multiple myeloma (C90.0)

2. Since no exact ICD-10-CM-diagnosis code is available for hATTR-CM, used a proxy code listed in footnote 1

3. Within 6 months before the ATTR-CM diagnosis claim date

4. Melphalan, cyclophosphamide, bortezomib, lenalidomide, thalidomide, bendamustine, pomalidomide, carfilzomib, ixazomib, daratumumab, venetoclax, elotuzumab

5. Subgroup analysis performed among patients with ≥1 claim for select comorbid conditions of interest such as cardiovascular, nervous system and renal.

Overall cohort (Table 1)

- Socioeconomic status ranged from 24.5% to 25.5%, grouped as lowest 25th percentile, 25th to 50th percentile, 50th-75th percentile and greater than 75th percentile.
 - The highest SVI indicates the most vulnerable, while the lowest indicates the least vulnerable
- 85% of participants were of white race.
- 78% resided in urban geographic locations.
- 40% reported a household income greater than \$100,000.
- 45% had a household size of 3+ persons.

Results for subgroups are presented in Table 1

Table 1: Demographic and socioeconomic characteristics

Characteristic	Overall ¹	Subgroups ²			
	N=6,732	ATTR-CM Baseline N=5,820	Hereditary ATTR-CM N=388	Organ-Limited Amyloidosis N=3,967	Wild-Type ATTR-CM N=1,465
Socioeconomic status³					
Lowest: ≤ 25th percentile	25.5%	25.6%	25.5%	25.1%	26.9%
Low: >25th and ≤ 50th percentile	24.5%	24.4%	20.6%	24.6%	24.9%
High: >50th and ≤ 75th percentile	25.2%	25.0%	24.0%	25.2%	24.7%
Highest: >75th percentile	24.8%	25.0%	29.9%	25.0%	23.5%
Race⁴					
White, Non-Hispanic	85.0%	84.9%	69.1%	84.9%	89.4%
Black, Non-Hispanic	11.1%	11.2%	26.8%	10.7%	8.3%
Asian/Pacific Islander	1.1%	1.1%	<11	1.3%	<11
Hispanic/Latino	2.0%	2.0%	3.4%	2.1%	1.2%
Other	0.9%	0.9%	<11	1.1%	<11
Geographic location⁵					
Rural	22.0%	21.4%	15.5%	21.8%	21.9%
Urban	78.0%	78.5%	84.5%	78.2%	78.0%
Household income⁶					
\$0-\$49,999	26.4%	26.6%	31.2%	28.2%	21.2%
\$50,000-\$99,999	33.4%	33.6%	27.1%	34.5%	32.8%
\$100,000+	40.2%	39.8%	41.8%	37.3%	46.1%
Household Count⁶					
1 person	23.5%	23.7%	24.5%	24.3%	21.7%
2 persons	31.9%	31.7%	29.4%	31.5%	32.7%
3+ persons	44.7%	44.7%	46.1%	44.2%	45.6%

1. The overall cohort denotes individuals diagnosed with heart failure. The SDoH variables were used based on the date of first heart failure diagnosis

2. ATTR-CM baseline represents the period between a beneficiary's heart failure index date and ATTR-CM index date, excluding both dates. The baseline period is limited to beneficiaries with more than 1 comorbidity claim within the specified timeframe.

3. The Social Vulnerability Index (SVI) is a tool developed by the Centers for Disease Control (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) that utilizes uses 16 U.S. census variables to assist local officials in identifying communities requiring support before, during, or after disasters. SVI rankings range from least vulnerable (lowest SVI) to most vulnerable (highest SVI). Beneficiaries were linked to the SVI by zip code when a zip code was available.

4. Race/ethnicity is determined based on a combination of the race a beneficiary has historically reported to the Social Security Administration.

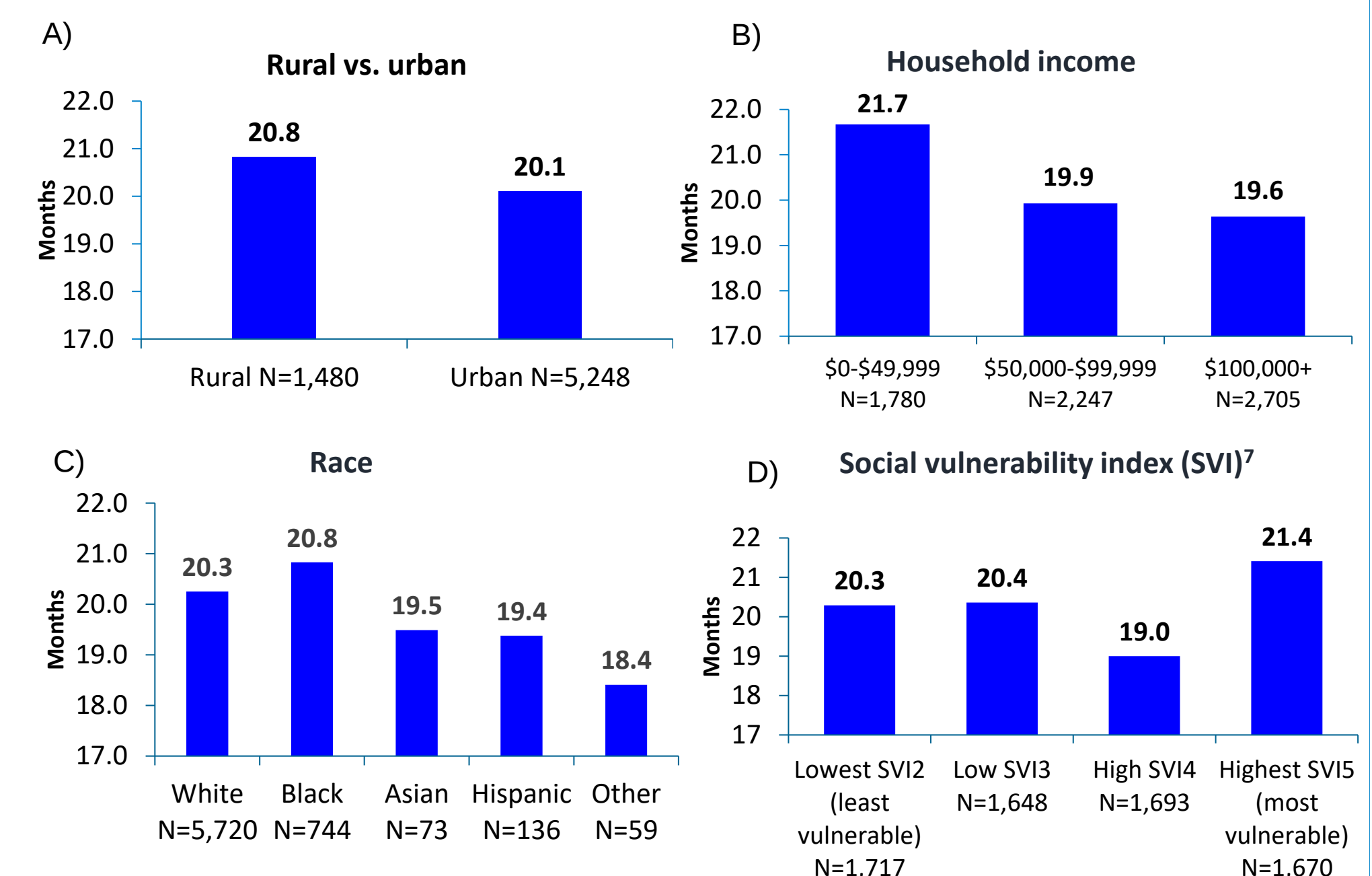
5. The Urban-Rural classification was obtained from the NCHS (National Center for Health Statistics) Urban-Rural Classification Scheme. Counties with a 2013 NCHS code between 1-3 were classified as Urban while counties with a 2013 NCHS code between 4-5 were classified as Rural.

6. Household income and household count are data sourced from Clarify Health database, reflecting the most recent information available at the time of data collection.

*counts ranging from 1-10 individuals are categorized as "<11"

Figure 3: Mean time from first heart failure diagnosis to ATTR-CM diagnosis by social determinants of health in the overall cohort

- Rural areas: 20.8 months (n=1,480) compared to urban areas 20.1 months (n=5,248).
- Lowest income group: 21.7 months to diagnosis; highest income group: 19.6 months.
- Black individuals had the longest time to diagnosis at 20.8 months (n=744), compared to 20.3 months for whites (n=5,720).
- Highest SVI group: 21.4 months to diagnosis; lowest SVI group: 20.3 months.



CONCLUSIONS

- In this descriptive analysis, although no notable differences were observed in SDoH and mean time to ATTR-CM diagnosis, it's important to underscore the significance of the largest sample sizes observed in urban areas and among white individuals.
- This study represents the first analysis of SDoH in the ATTR-CM population, underscoring the need for further research to elucidate the relationship between these factors and ATTR-CM diagnosis, while accounting for potential confounders.

REFERENCES

1. Agency for Toxic Substances and Disease Registry (ATSDR). (n.d.). Social Vulnerability Index (SVI).

2. Centers for Disease Control and Prevention. 2013. 2013 Urban-Rural Classification Scheme for Counties.

DISCLOSURES

CP, HC, and AE: Employee/stockholder of Pfizer. AC, AR, DS, and NB: Employee of Genesis Research Group, which received funding from Pfizer. SS: Employee of Clarify Health and received funding from Pfizer. KA: Has been a consultant, advisor, and/or speaker for Arbor, Attralus, Intellia, and Prothena.

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