A Medical Chart Review of Healthcare Costs in Patients with Systemic Amyloid Light Chain Amyloidosis by Mayo 2012 Stage in the United States

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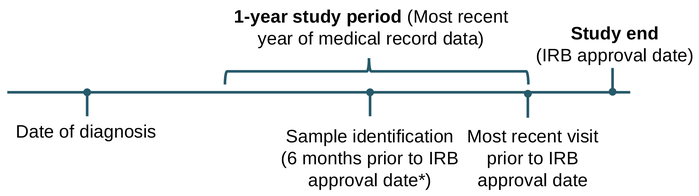
BACKGROUND & OBJECTIVE

- Systemic amyloid light chain (AL) amyloidosis is a rare (incidence of 8-14 cases per million[1-4]) but severe condition, leading to cardiac and renal dysfunction and failure[5], with significant clinical, humanistic, and economic burdens.[6]
- Burden of disease and healthcare costs associated with different stages of AL amyloidosis remain unclear, especially in light of a single ICD-10 (International Classification of Diseases) diagnosis code for all stages.
- **We aimed to estimate healthcare utilization and costs by Mayo 2012 stage (I, II, III, IV) in a prevalent population of patients with AL amyloidosis, offering a stage-specific perspective on the economic burden of the disease.**

METHODS

- Demographic, clinical, and utilization data for AL amyloidosis patients were collected via retrospective medical chart review across six U.S. hematology clinics.†
- Patients were required to be ≥18 years old with a documented diagnosis of AL amyloidosis including Mayo 2012 stage[3], have ≥1 year of available medical records, and have at least one clinic visit within 6 months prior to each site's IRB (Institutional Review Board) approval date (Figure 1).
- All patient data during the 1-year study period ranged from 11/12/2020 to 6/16/2023. No data were collected beyond each site's IRB approval date.
- We estimated total cost of clinical care over the 1-year period using utilization data available in patients' medical records (i.e., laboratory tests, medications, emergency department visits, hospitalizations, and procedures [e.g., biopsies, echocardiograms, electrocardiograms, magnetic resonance imaging]) as well as price data from the Centers for Medicare and Medicaid Services 2023 Physician Fee Schedule[7], Price Rx, and published literature adjusted to 2023 USD using the Consumer Price Index[8].
- Descriptive results were evaluated for the total sample and stratified by Mayo 2012 stage (I, II, III, IV).
- Analyses were performed using SAS® version 9.4, with descriptive analyses conducted for clinical characteristics, healthcare utilization, and costs.

Figure 1. AL Amyloidosis study population identification



*To ensure we captured a representative sample of the AL amyloidosis population and included patients with poorer outcomes to limit the impact of a survival bias, we identified patients 6 months prior to the IRB date and abstracted their most recent year of data. No inclusion/exclusion criteria were included pertaining to the date of diagnosis.

RESULTS

- The total sample included 61 patients: 15 stage I, 16 stage II, 17 stage III, and 13 stage IV (**Table 1**).
- A greater proportion of patients were male (n=37, 60.7%), non-Hispanic White (n=41, 67.2%) and had Medicare/Medicaid or private insurance (n=50, 81.9%).
- At diagnosis, all patients had ≥1 organ system involved and 28 (45.9%) had ≥2 organ systems involved. More than half of all patients had renal (n=34, 55.7%) or cardiac (n=32, 52.5%) involvement.
- Six (9.8%) patients initiated first-line therapy, and 3 (4.9%) patients had a hematopoietic stem cell transplantation during the study period. Almost all patients, 57 (93.4%) patients, had completed 1st line therapy at any point prior to their study period end.
- The mean estimated 1-year AL amyloidosis-related healthcare costs ranged from $251,412 (stage I) to $343,713 (stage IV) (**Figure 2**).
- Mean costs of high utilization (e.g., physician visits) and high cost, but less utilized (e.g., hematopoietic stem cell transplant, hospitalization) events are stratified by stage in **Table 2**.

Table 1. Demographics and patient characteristics

	Mayo 2012 stage				
	Stage I	Stage II	Stage III	Stage IV	All Patients
N	15	16	17	13	61
Age at study start (years), mean (SD)	63.5 (12.4)	63.6 (5.5)	65.3 (9.4)	72.4 (6.9)	65.9 (9.4)
Age at diagnosis (years), mean (SD)	60.0 (11.5)	58.7 (7.6)	62.0 (9.7)	70.3 (8.1)	62.4 (10.1)
Race/Ethnicity, n (%)					
Non-Hispanic White	10 (66.7)	11 (68.8)	10 (58.8)	10 (76.9)	41 (67.2)
Non-Hispanic Black	3 (20.0)	4 (25.0)	1 (5.9)	1 (7.7)	9 (14.8)
Hispanic	0 (0)	0 (0)	1 (5.9)	0 (0)	1 (1.6)
Asian	2 (13.3)	0 (0)	2 (11.8)	0 (0)	4 (6.6)
Other	0 (0)	1 (6.3)	3 (17.6)	2 (15.4)	6 (9.8)
Female, n (%)	7 (46.7)	5 (31.3)	6 (35.3)	6 (46.2)	24 (39.3)
Current insurance					
Private insurance	7 (46.7)	9 (56.3)	3 (17.6)	2 (15.4)	21 (34.4)
Medicare/Medicaid	6 (40.0)	5 (31.3)	8 (47.1)	10 (76.9)	29 (47.5)
Unknown	2 (13.3)	2 (12.5)	6 (35.3)	1 (7.7)	11 (18.0)
Duration of disease* (yrs), mean (SD)	4.5 (3.0)	5.8 (4.4)	4.1 (3.7)	3.1 (1.9)	4.5 (3.5)

*Time from diagnosis to date of last clinic visit or date of death.

Figure 2. Total mean (SD) disease-related costs in 2023 US Dollars

Median estimated AL amyloidosis-related healthcare costs (USD) during the 1-year study period were: $95,253 (interquartile range [IQR] $2,869-497,504) for stage I, $190,796 ($5,249-499,470) for stage II, $414,677 ($28,365-533,081) for stage III, and $523,504 ($191,830-526,596) for stage IV.

RESULTS (CONTINUED)

Table 2. Estimated disease-related healthcare costs (2023 US Dollars) during study period

	Mayo 2012 stage				
	Stage I	Stage II	Stage III	Stage IV	All Patients
N	15	16	17	13	61
Total chemotherapy costs, mean (SD)	220,363 (275,134)	206,096 (263,876)	274,624 (257,951)	324,643 (228,642)	253,967 (255,669)
Total other costs, mean (SD)	31,049 (92,422)	52,198 (102,399)	47,562 (105,841)	19,070 (23,335)	38,646 (88,768)
Dialysis (n=4)	3,240 (12,549)	4,540 (13,191)	2,859 (11,787)	0 (0)	2,784 (10,948)
Hematopoietic stem cell transplant (n=3)	22,650 (87,721)	21,234 (84,936)	19,985 (82,400)	0 (0)	16,709 (74,077)
Physician visits (n=61)	904 (733)	910 (844)	956 (744)	1,169 (709)	977 (750)
Emergency department visits (n=17)	46 (180)	523 (1,065)	533 (1,339)	751 (1,004)	457 (1,017)
Inpatient hospitalizations (n=20)	1,409 (4,092)	11,697 (28,655)	11,186 (22,380)	12,306 (20,966)	9,155 (21,230)

Limitations

- This study was conducted in six centers of excellence among prevalent patients; findings may not be generalizable to the broader population of patients with AL amyloidosis.
- Healthcare services provided outside clinics (e.g., imaging, hospitalizations) were only captured if incorporated into the clinic's medical records; as such, utilization and costs may be underestimated.
- Given the high early mortality rate in stage III/IV disease, selection bias may be more significant in these subgroups due to the 1-year observation period inclusion criteria. Therefore, the real-world proportion of patients with significant cardiac/renal involvement, many of whom have stage III/IV disease, may be higher than represented in this study.
- Cost of care was estimated based on utilization data in the medical records, which may result in imprecise cost calculations. Reasonable assumptions supported cost calculations (e.g., using chemotherapy start/end dates in lieu of detailed dose data).

CONCLUSIONS

- This is the first study of AL amyloidosis that reports cost of care among prevalent patients stratified by Mayo 2012 stage.
- Prevalent patients with AL amyloidosis have higher continuing cost of care at each stage, with stage IV patients having the highest AL amyloidosis-related costs. The higher cost of chemotherapy treatment among Stage IV patients may be reflective of the limited alternative treatment options in this patient population due to severity of disease.
- Total costs of chemotherapy, emergency department visits, and inpatient hospitalizations increased by stage, with stage IV having the highest costs. Total costs of physician visits, dialysis, and stem cell transplants did not vary greatly across stages.
- These data describe the significant and continued burden faced by patients with AL amyloidosis and the health care system for the years beyond initial diagnosis and after completion of front-line treatment.

FOOTNOTES

† Atrium Health, Boston Medical Center, City of Hope, Karmanos Cancer institute, Mayo Clinic, and Memorial Sloan Kettering.

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