Real-World Health Care Utilization and Costs in Patients With Newly Diagnosed AL Amyloidosis

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INTRODUCTION

- Amyloid light chain (AL) amyloidosis is a rare, progressive, and typically fatal disease caused by extracellular deposition of misfolded immunoglobulin light chains (LCs)[1]
- Soluble toxic aggregates and deposited fibrils (amyloid) lead to progressive failure of vital organs, including the heart, kidneys, and nervous system, causing significant morbidity and mortality[2,3]
- The economic burden of AL amyloidosis has not been well characterized[4]
- The objective of this study was to estimate all-cause health care utilization and costs among patients with newly diagnosed AL amyloidosis in a real-world setting

METHODS

Study Design and Data Source

- Retrospective, longitudinal cohort study using 2007-2015 Truven Health MarketScan® Commercial and Medicare Supplemental databases
  - Covering approximately 65 million commercially insured patients and their dependents, and 5.3 million Medicare-eligible retired employees

Study Population

- Adults ≥18 years of age with newly diagnosed AL amyloidosis were identified if they
  - Had ≥1 inpatient or ≥2 outpatient claims consistent with AL amyloidosis (*International Classification of Diseases, Ninth Revision, Clinical Modification* [*ICD-9-CM*] code 277.30 or 277.39; *International Classification of Diseases, Tenth Revision, Clinical Modification* [*ICD-10-CM*] code E85.4x, E85.8x, or E85.9x) in any diagnosis field during the identification period between January 1, 2008 and December 31, 2014
  - Underwent 1 AL amyloidosis-specific treatment (e.g., chemotherapy, hematopoietic stem cell transplantation [HSCT]) on or after the first amyloidosis diagnosis (index date: the first date of amyloidosis diagnosis)
  - Did not receive a diagnosis of AL amyloidosis in the year before the index date (1-year disease-free period)
  - Were enrolled continuously for 1 year before their index date (baseline), and were followed until end of enrollment or 12/31/2015

Study Measures

- For all identified patients, actual health care utilization (i.e., outpatient, inpatient, and pharmacy use) and costs within 1 year after index date were reported
- For patients whose follow-up duration was ≥2 years, annualized health care utilization and costs in each follow-up year were reported

Statistical Analysis

- Means, standard deviations (SD), and relative frequencies and percentages for continuous and categorical data, respectively, were reported
- Cost estimates were converted to 2015 US dollars using the Consumer Price Index to adjust for inflation
- Data transformations and statistical analyses were performed using SAS® version 9.4 (SAS Institute, Cary, NC)

RESULTS

- The overall study sample included 2,018 patients with newly diagnosed AL amyloidosis
  - Mean (SD) age was 63.8 (12.8); 45.9% were women; all US regions were represented, and most patients had commercial insurance and PPO plans (**Table 1**)
  - In the year following diagnosis, 64.6% (n=1,303) of patients were admitted to the hospital ≥1 time, and 16.6% (n=335) were admitted ≥3 times (**Table 2**)
  - 37.9% (n=764) of patients had ≥1 emergency department (ED) visit (includes both emergency room and urgent care visits, but excludes ED visits resulting in hospital admission). The mean (SD) number of non-ED outpatient service visits was 48.0 (37.1) times per year. 81.0% (n=1,635) underwent chemotherapy for AL amyloidosis (**Table 2**)
  - Among admitted patients, mean (SD) hospital length of stay was 16.9 (22.1) days

Table 1. Demographic Characteristics and Insurance Type for Patients With Newly Diagnosed AL Amyloidosis by Duration of Follow-Up

Characteristic	With 2+ Years' Follow-up	All
N, (%)	887 (44.0)	2,018
Age, years, mean (SD)	63.3 (13.6)	63.8 (12.8)
Female, n (%)	426 (48.0)	926 (45.9)
Region, n (%)		
Midwest	252 (28.4)	554 (27.5)
Northeast	188 (21.2)	416 (20.6)
South	292 (32.9)	703 (34.8)
West	155 (17.5)	345 (17.1)
Database, n (%)		
Commercial	469 (52.9)	1,112 (55.1)
Medicare supplement[a]	418 (47.1)	906 (44.9)
Plan type, n (%)		
PPO	413 (46.6)	1,014 (50.2)
Other	474 (53.4)	1,001 (49.8)

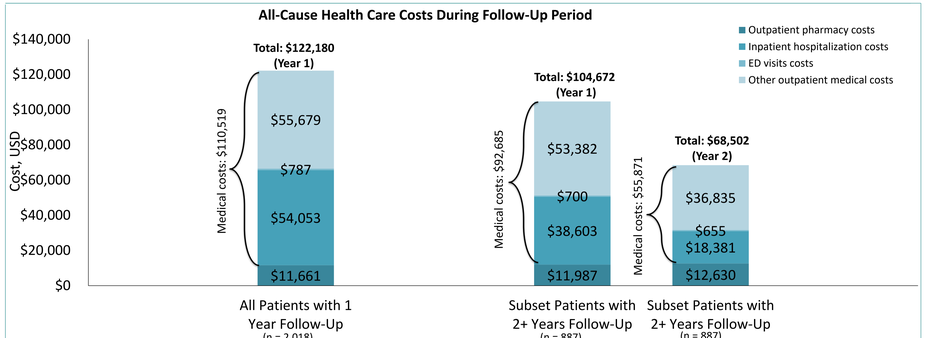
AL, amyloid light chain; PPO, preferred provider organization.
[a]A Medicare supplement insurance (Medigap) policy, sold by private companies, can help pay some of the health care costs that original Medicare does not cover, such as copayments, coinsurance, and deductibles.

Table 2. Post-Index Utilization of Inpatient and Outpatient Hospital Services for Patients With Newly Diagnosed AL Amyloidosis

	All	With 2+ Years' Follow-up	
	Post Year 1 n = 2,018	Post Year 1 n = 887[a]	Post Year 2 n = 887[a]
No. inpatient hospital admissions, mean (SD)	1.32 (1.67)	1.05 (1.27)	0.57 (1.14)
0, n (%)	715 (35.4)	344 (38.8)	604 (68.1)
1, n (%)	667 (33.1)	325 (36.6)	157 (17.7)
2, n (%)	301 (14.9)	126 (14.2)	79 (8.9)
3+, n (%)	335 (16.6)	92 (10.4)	47 (5.3)
Total days of stay, n (mean) [SD]	1,303 (16.9) [22.1]	543 (12.5) [15.6]	283 (10.4) [14.2]
No. of ED visits, mean (SD)	0.78 (2.10)	0.73 (2.23)	0.63 (1.66)
0, n (%)	1,254 (62.1)	577 (65.1)	607 (68.4)
1, n (%)	441 (21.9)	189 (21.3)	164 (18.5)
2, n (%)	173 (8.6)	57 (6.4)	58 (6.5)
3+, n (%)	150 (7.4)	64 (7.2)	58 (6.5)
Non-ED outpatient services, mean (SD)	48.0 (37.1)	49.2 (35.6)	39.7 (36.1)
AL amyloidosis treatment (chemotherapy based or HSCT), n (%)	1,635 (81.0)	599 (67.5)	486 (54.8)

AL, amyloid light chain; ED, emergency department; HSCT, hematopoietic stem cell transplantation.
[a]This sample size is the overall patient sample with 2+ years of follow-up, looking at post year 1 and post year 2, respectively.
Mean (SD) total annual all-cause health care costs were $122,180 (159,074), with $11,661 (23,543) accrued from outpatient pharmacy costs and $110,519 (154,625) from inpatient hospital admissions, ED visits, and outpatient medical costs (**Figure 1**).

Figure 1. Post-Index All-Cause Health Care Costs[a] for Patients with Newly Diagnosed AL Amyloidosis During the Follow-Up Period.



[a] Costs were adjusted to 2015 US dollars.

- Among a subgroup of patients with newly diagnosed AL amyloidosis who had ≥2 years of follow-up (n=887)
  - Hospital admissions declined from 61.2% in the first year after diagnosis to 31.9% in the second year, and use of AL amyloidosis chemotherapy-based treatment declined from 67.5% to 54.8% (**Table 2**)
  - Total costs declined from $104,672 in the first year after diagnosis to $68,502 in the second year

DISCUSSION AND CONCLUSIONS

- Patients with AL amyloidosis required substantial use of health care resources and incurred substantial costs
  - More than half of the patients with newly diagnosed AL amyloidosis were admitted to the hospital in the year following diagnosis; the average length of stay was more than 2 weeks
  - Patients visited laboratories, offices, and other outpatient sites almost 4 times per month
  - The total cost of this care was more than $120,000 per patient per year
- Among a subgroup of patients with ≥2 years of follow-up, health care costs decreased over time
  - This decline in cost may be due to decreased hospital admissions over the 2-year period; however, the cost may have increased in the final stages of life as suggested in previous studies[5]
- New therapies aimed at improving organ response have the potential to reduce disease burden and health care utilization
- Limitation
  - Our cost estimates include direct health care costs only and do not take into account important indirect costs associated with caregiver burden, loss of productivity, or reduced quality of life

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