PA086

Real-World Burden of Comorbidities 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 fibril deposits (amyloid) lead to progressive failure of vital organs, including the heart, kidneys, and nervous system, causing significant morbidity and mortality[2,3]

OBJECTIVE

- To estimate the burden of comorbidities among patients with newly diagnosed AL amyloidosis in a real-world setting

METHODS

Study Design and Data Source

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

Study Population and Time Frame

- Adults (≥18 years of age) with newly diagnosed AL amyloidosis were identified if they
  - Had ≥1 inpatient claim 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 an AL amyloidosis–specific treatment (eg, chemotherapy, hematopoietic stem cell transplantation [HSCT]) on or after the first amyloidosis diagnosis (index date)
  - Did not have a diagnosis of AL amyloidosis in the year before the index date (1-year disease-free period)
  - Were enrolled continuously for 1 year before (baseline) their index date and were followed up until end of enrollment or December 31, 2015

Study Measures

- We measured demographic characteristics; frequency of AL amyloidosis-related, Charlson Comorbidity Index (CCI), Healthcare Cost and Utilization Project[4] chronic conditions; and other comorbidities (defined as patient having ≥1 claim with a relevant *ICD-9-CM* or *ICD-10-CM* code) for patients during the 1-year baseline period

Statistical Analysis

- Descriptive statistics were reported by length of follow-up
- All analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC)

RESULTS

- 2018 patients with newly diagnosed AL amyloidosis were included in the study; 307 were enrolled for <6 months, 309 for 6-<12 months, 515 for 12-<24 months, and 887 for 24+ months (**Table 1**)
  - Mean (SD) age was 63.8 (12.8) years; 46% of the patients were women

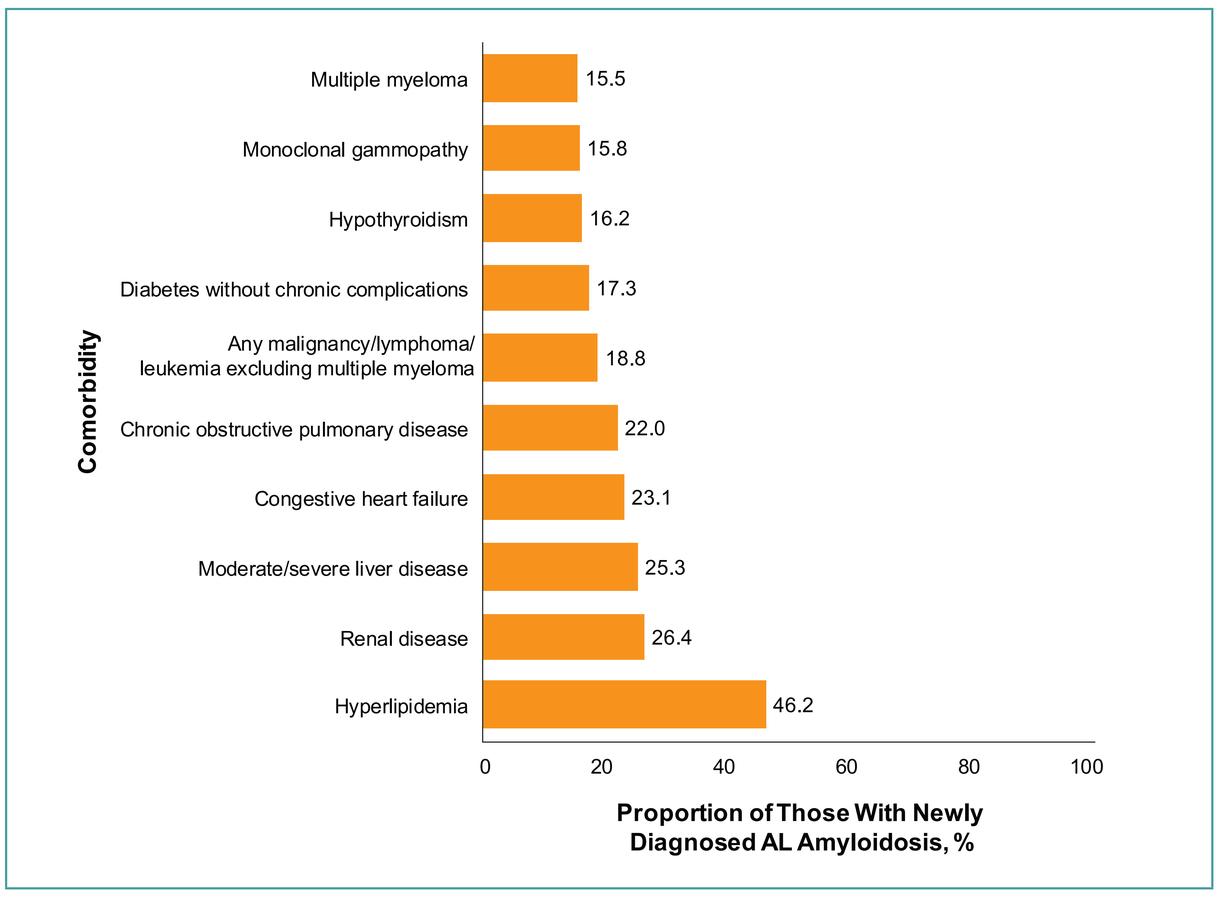
Table 1. Demographic Characteristics and Comorbidities for Patients With Newly Diagnosed AL Amyloidosis

	<6 Months	6-<12 Months	12-<24 Months	24+ Months	All
N, (%)	307 (15.2)	309 (15.3)	515 (25.5)	887 (44.0)	2018
Age, years, mean (SD)	64.1 (11.7)	65.0 (12.2)	63.8 (12.4)	63.3 (13.6)	63.8 (12.8)
Female, n (%)	126 (41.0)	141 (45.6)	233 (45.2)	426 (48.0)	926 (45.9)
Region, n (%)					
Midwest	83 (27.0)	84 (27.2)	135 (26.2)	252 (28.4)	554 (27.5)
Northeast	69 (22.5)	56 (18.1)	103 (20.0)	188 (21.2)	416 (20.6)
South	100 (32.6)	100 (32.4)	211 (41.0)	292 (32.9)	703 (34.8)
West	55 (17.9)	69 (22.3)	66 (12.8)	155 (17.5)	345 (17.1)
Database, n (%)					
Commercial	174 (56.7)	167 (54.0)	302 (58.6)	469 (27.0)	1112 (55.1)
Medicare supplement[a]	133 (43.3)	142 (46.0)	213 (41.4)	418 (47.1)	906 (44.9)
Plan type, n (%)					
PPO	162 (52.8)	152 (49.2)	287 (55.7)	413 (46.6)	1014 (50.2)
Other	145 (47.3)	157 (50.8)	228 (44.3)	474 (53.5)	1004 (49.8)
CCI, mean (SD)	3.9 (3.2)	3.9 (3.1)	3.3 (2.9)	2.8 (2.7)	3.3 (2.9)
HCUP chronic conditions, n (SD)	5.4 (2.5)	5.4 (2.6)	5.0 (2.5)	4.5 (2.4)	4.9 (2.5)

AL, amyloid light chain; CCI, Charlson Comorbidity Index; HCUP, Healthcare Cost and Utilization Project; 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.

- Mean (SD) CCI was 3.3 (2.9) overall, and mean (SD) number of chronic conditions was 4.9 (2.5). Patients with longer follow-up times had a lower frequency of comorbidities
- The most common AL amyloidosis–related comorbidities were renal disease (26.4%), moderate or severe liver disease (25.3%), and congestive heart failure (23.1%) (**Figure 1**)
- Other conditions observed included hyperlipidemia (46.2%), chronic obstructive pulmonary disease (22.0%), any malignancy/lymphoma/leukemia excluding multiple myeloma (18.8%), diabetes without chronic complications (17.3%), hypothyroidism (16.2%), monoclonal gammopathy (15.8%), and multiple myeloma (15.5%) (**Figure 1**)

Figure 1. Rates of common AL amyloidosis–related comorbidities and other comorbidities in patients with newly diagnosed AL amyloidosis (n = 2018).



AL, amyloid light chain

DISCUSSION AND CONCLUSIONS

- Patients with newly diagnosed AL amyloidosis experienced substantial comorbidities in the year before the diagnosis of AL amyloidosis
  - The general disease burden was high (as evidenced by the high CCI), and frequencies of comorbidities in this population were also high
- Many of the observed comorbidities, including congestive heart failure, renal disease, and liver disease, likely represented manifestations of the disease process, as did complications and morbidity secondary to undiagnosed AL amyloidosis
- High rates of hypothyroidism were consistent with rates in other studies of patients with newly diagnosed AL amyloidosis[5]
- To our knowledge, this study is the first comprehensive report of the real-world burden of comorbidities in a US population with newly diagnosed AL amyloidosis
- Multidisciplinary collaborative care may be needed to provide optimal treatment for patients with AL amyloidosis and concurrent diseases

Limitations

- The presence of comorbidities and other observed conditions was determined based on each patient's having ≥1 claim with a relevant *ICD-9-CM* or *ICD-10-CM* code, not on a clinical diagnosis; misclassification, diagnostic uncertainty, and coding errors were possible

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