Incidence of First-Line and Second-Line Myelodysplastic Syndrome in a US Commercial Claims Database

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Background: The myelodysplastic syndromes (MDS) include a group of malignancies characterized by myeloid stem cell origin and increasing incidence with age. Although treatment is available with hypomethylating agents (HMAs), 80% of patients fail to achieve remission and nearly all patients eventually develop chemoresistant disease. The incidence of MDS 1st-line HMA treatment failures has not been previously reported.

Methods: We examined US commercial health insurance claims data to estimate the annual incidence of MDS and the number of MDS patients potentially eligible for 2nd-line therapy. We conducted a retrospective cohort study of patients with an MDS-associated medical claim (ICD-9-CM diagnosis code 238.7x) in the identification (ID) period (calendar year 2009). The subgroup of newly diagnosed patients had no prior MDS diagnosis in the pre-ID period (calendar year 2008); patients newly treated with HMA had a claim for HMA in the ID but not pre-ID periods. Using expert input, we defined MDS patients as potential candidates for 2nd-line therapy if they used an HMA in the ID period and stopped for \geq 2 months, switched to another HMA, or remained on the first HMA for >7 months. MDS incidence rates were stratified by age (\leq 49, 50-64, 65-74, and \geq 75 years) and sex.

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Results: We identified 9,209 patients with an MDS-associated claim. There were 4,151 patients newly diagnosed with MDS, yielding an overall MDS incidence of 69.9/100,000 enrollees (**Table**). Incidence was slightly higher among women (75.7/100,000) than men (63.1/100,000). Women between the ages of 50 and 64 years had the highest incidence (111.5/100,000) among all newly diagnosed patients stratified by age and sex.

The incidence of newly treated MDS patients was 2.8/100,000 enrollees. Among this group, incidence was higher among men (3.6/100,000) than women (2.1/100,000), and when stratified by age and sex the incidence was highest among men aged 75 years or older (10.5/100,000). For each 100,000 enrollees, there were 3 new 2nd-line therapy candidates.

Conclusions: The estimated incidence of MDS in the United States was 69.9 per 100,000 insured enrollees in 2009, similar to results found in other epidemiological databases (Cogle et al, Blood 2011; Goldberg et al, J Clin Oncol 2010). The incidence of MDS patients identified as eligible for 2nd-line therapy was 3/100,000. In this commercially insured patient population we estimate that approximately 9,500 people per year in the United States may be candidates for 2nd-line therapy for MDS. These data can be used to inform population-based estimates that would include Medicare patients in addition to those commercially insured of the medical and economic burden of disease faced by MDS patients.

Gender	Age Group, years	Newly	Newly Treated	Potential 2 nd Line
		Diagnosed	Patients	Treatment
		Patients		Candidates
Female	All ages	75.7	2.1	2.0
	<u>≤</u> 49	56.6	0.1	0.0
	50-64	111.5	2.1	1.1
	65-74	101.2	4.0	5.3
	≥75	68.5	4.4	4.4
Male	All ages	63.1	3.6	4.1
	≤49	29.6	0.2	0.1
	50-64	86.5	2.5	3.8
	65-74	106.1	8.5	8.5
	≥75	97.1	10.5	11.7
All	All ages	69.9	2.8	3.0

Table: Incidence of MDS Stratified by Age and Gender

Note: Results are expressed as number of cases per 100,000 enrollees.