INTRODUCTION

• Clinical trial data obtained for patients with myelodysplastic syndromes (MDS) may not be representative of the general MDS patient population; many patients are ineligible for inclusion in clinical trials.
• Fewer than 5% of cancer patients participate in trials.
• Clinical trials involve carefully controlled, idealized conditions and selective patient populations; healthcare decision-makers increasingly use real-world evidence to guide policy development.
• Although a number of MDS post-marketing studies have been conducted, few have assessed treatment effectiveness during off-label use or in the general population. Characteristic real-world studies may help address this knowledge gap (Figure 1).

The GE Centricity EMR Database

The GE Centricity™ EMR Database (GE Healthcare IT, Princeton, NJ, USA) contains clinical practice records for patients and is both de-identified and compliant with the Health Insurance Portability and Accountability Act (HIPAA) of 1996.

Patients with MDS can be identified by searching for specific ICD-9-CM diagnosis codes indicative of MDS (codes 238.72–75).

Several approaches were developed, applied, and evaluated to refine this initial selection to exclude patients with a lower likelihood of MDS.

METHODS

EMR Database Participants

The GE Centricity™ EMR Database is an ambulatory EMR system that is generally representative of the US population and contains records from single-physician offices to large practices and networks.
• It contains 38 million patient records across 49 states.
• It includes > 30,000 participating clinicians, two-thirds of whom are primary care physicians; the remainder are specialists.
• The EMR database has a slight bias toward black, female, and older patients compared with the general US population.

Patient Identification

• Patients suspected to have MDS with records entered into the database between Jan 1, 2006 and Feb 24, 2014 were identified by searching for individuals with > 1 recorded ICD-9-CM diagnosis code indicative of MDS (codes 238.72–75).
• Several approaches were developed, applied, and evaluated to refine this initial selection to exclude patients with a lower likelihood of MDS.
• Cohorts were compared with MDS patients in the SEER Program.

Patient Treatment History

• History of supportive and active treatments was also assessed.
• Supportive treatment was defined as hematopoietic growth factor, erythropoiesis-stimulating agents, iron-chelating therapy, or transfusions.
• Active, disease-modifying treatment was defined as lenalidomide, azacitidine, or decitabine.

RESULTS

Identifying the Initial Cohort

• 6,945 individuals (the Initial Cohort) with ≥ 1 ICD-9-CM diagnostic code indicative of MDS (codes 238.72–75) were identified (Figure 2).
• Baseline characteristics for patients in the Initial Cohort are presented in Table 1.
• In the Initial Cohort, 31% of patients received supportive treatment and 8% received active treatment.
• Only 9% of patients received transfusions, however, transfusions are not accurately represented in EMR databases.

Table 2. Treatment Patterns of the Final Cohort by Age and Comorbidity

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Final Cohort</th>
<th>SEER MDS Cohort*</th>
<th>SEER Non-MDS Cohort*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>60–69</td>
<td>70–79</td>
<td>≥ 80</td>
</tr>
<tr>
<td>n (%)</td>
<td>1,794 (34.8)</td>
<td>1,592 (33.8)</td>
<td>2,062 (42.8)</td>
</tr>
<tr>
<td>Supportive treatment</td>
<td>1,794 (34.8)</td>
<td>1,592 (33.8)</td>
<td>2,062 (42.8)</td>
</tr>
<tr>
<td>Active treatment</td>
<td>682 (13.2)</td>
<td>54 (12.7)</td>
<td>164 (18.4)</td>
</tr>
<tr>
<td>Transfusions</td>
<td>555 (10.8)</td>
<td>47 (11.1)</td>
<td>102 (11.4)</td>
</tr>
</tbody>
</table>

LIMITATIONS

• A potential limitation of EMR studies is that procedures occurring outside the EMR system, such as transfusions, may be underestimated.
• Data that would be entered into the physician notes or appear on a patient report are difficult to extract from the GE Centricity EMR database, or any database for that matter.

CONCLUSIONS

• This study developed an approach to identify a large, real-world cohort of MDS patients in the GE Centricity EMR database; these criteria can inform other investigators involved in cancer outcomes research.
• Using this approach, based on clinical and diagnostic features associated with MDS diagnosis, a final cohort of patients with baseline characteristics and treatment patterns comparable to patients in the SEER Program was identified.
• Our identified cohort can be useful in the further characterization of treatment patterns and outcomes of MDS patients.
• MDS patients aged ≥ 60 years or with comorbidities were more likely to receive only supportive treatment.

The cohort included a significant number of patients aged ≥ 60 years, who could support additional analyses to inform physicians with older MDS patients.

REFERENCES