Use of Real-World Claim Databases to Assess Prevalence of Comorbid Conditions Relevant to the Treatment of Chronic Myelogenous Leukemia Based on National Comprehensive Network Treatment Guidelines

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Abstract

This study assessed the prevalence of comorbid conditions relevant to tyrosine kinase inhibitor treatment choice per National Comprehensive Cancer Network guidelines among chronic myelogenous leukemia (CML) patients in the US real-world setting. The results of the analysis provide real-world evidence that the prevalence of relevant comorbid conditions is substantial among CML patients and therefore needs to be considered throughout various health care decision-making processes related to CML.

Background: The National Comprehensive Cancer Network (NCCN) guidelines state that based on toxicity profiles, 1 second-generation tyrosine kinase inhibitor (TKI) indicated for first-line therapy (ie, dasatinib, nilotinib) may be preferred over the other for treatment of chronic myelogenous leukemia (CML) patients with certain comorbidities. This study assessed the prevalence of comorbid conditions relevant to TKI treatment choice among CML patients in the US real-world setting. **Patients and Methods:** Patients who had CML and initiated TKI treatment were identified from the MarketScan Commercial and Medicare databases (January 1, 2006, to June 30, 2013). Demographics and prevalence of comorbid conditions relevant to TKI treatment choice per NCCN guidelines (heart disease, arrhythmia, diabetes, pancreatitis, pleural effusion, lung disease) were assessed among the overall study population and among subgroups. **Results:** The median age of the CML study population newly initiated on TKI treatment (ie, imatinib, dasatinib, or nilotinib; n = 2296) was 56 years. Approximately 41% of the CML study population had at least 1 comorbid condition that may influence the choice of TKI treatment as recommended by NCCN guidelines. The most prevalent comorbid condition was heart disease (23%), followed by diabetes (18%) and lung disease (13%). The prevalence of comorbid conditions relevant to TKI treatment choice varied among patients of different age groups, gender, and US regions. **Conclusion:** The results of this analysis provide real-world evidence that the prevalence of relevant comorbid conditions is substantial among CML patients in the US managed care setting and therefore needs to be considered throughout various health care decision-making processes related to CML.

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Introduction

Chronic myelogenous leukemia (CML) is a progressive cancer of bone marrow stem cells with an incidence of 1 to 2 cases per 100,000 adults.[1] An acquired reciprocal translocation in the Philadelphia chromosome resulting in the formation of a BCR-ABL protein with constitutively activated tyrosine kinase activity plays a central role in the pathogenesis of CML.[2,3] The development and introduction of multiple targeted therapies inhibiting BCR-ABL tyrosine kinase activity has substantially improved the outcomes

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of patients with CML and provide many therapeutic options to treat CML.[2,3]

Imatinib was the first tyrosine kinase inhibitor (TKI) approved by the US Food and Drug Administration for first-line treatment of CML.[4] National Comprehensive Cancer Network (NCCN) guidelines currently recommend 3 TKI, imatinib, dasatinib, and nilotinib, for first-line treatment of CML patients.[3] Dasatinib and nilotinib are second-generation (2G) TKI and are relatively stronger inhibitors than imatinib of BCR-ABL tyrosine kinase activity.[2,3] Randomized clinical trials have shown superior clinical responses for patients with CML treated with dasatinib and nilotinib compared to imatinib-treated patients.[3,5,6]

On the basis of toxicity profiles of the 2G-TKI, certain comorbid conditions may influence the decision-making process of choosing the most appropriate treatment for a particular CML patient.[3] The NCCN guidelines state, "Nilotinib may be preferred for patients with a history of lung disease or deemed to be at risk of developing pleural effusions. Alternatively, dasatinib may be preferred in patients with a history of arrhythmias, heart disease, pancreatitis, or hyperglycemia."[3] There is a paucity of data on the prevalence of comorbid conditions among CML patients that are relevant to TKI treatment choice, as mentioned in the NCCN guidelines. To address this need, the objective of this study was to assess the prevalence of the comorbid conditions relevant to TKI treatment

Table 1 Demographics of Study Populations With Chronic Myelogenous Leukemia

Characteristic	Overall Study Population (N = 2296)	Commercially Insured (n = 1789)	Medicare Insured (n = 507)
Age (Years)			
Mean	56	50	76
Standard deviation	15	11	7
Median	56	52	76
Gender			
Male	1307 (57%)	995 (56%)	312 (62%)
Female	989 (43%)	794 (44%)	195 (38%)
Region			
Northeast	326 (14%)	241 (13%)	85 (17%)
North Central	696 (30%)	511 (29%)	185 (36%)
South	868 (38%)	712 (40%)	156 (31%)
West	375 (16%)	298 (17%)	77 (15%)
Health Plan Type			
Comprehensive	273 (12%)	50 (3%)	223 (44%)
EPO	26 (1%)	25 (1%)	1 (0.2%)
HMO	313 (14%)	244 (14%)	69 (14%)
POS	145 (6%)	132 (7%)	13 (3%)
PPO	1362 (59%)	1177 (66%)	185 (36%)
POS with capitation	7 (0.3%)	7 (0.4%)	0 (0%)
CDHP	60 (3%)	57 (3%)	3 (1%)
Index TKI			
Dasatinib	359 (16%)	298 (17%)	61 (12%)
Imatinib	1652 (72%)	1263 (71%)	389 (77%)
Nilotinib	285 (12%)	228 (13%)	57 (11%)
CCI Score			
Mean	2.9	2.7	3.6
Standard deviation	1.6	1.4	2.0
Median	2.0	2.0	3.0
CCI Group			
CCI = 0	47 (2%)	41 (2%)	6 (1%)
CCI = 1-2	1254 (55%)	1086 (61%)	168 (33%)
CCI = 3-4	712 (31%)	501 (28%)	211 (42%)
CCI ≥5	283 (12%)	161 (9%)	122 (24%)

Abbreviations: CCI = Charlson Comorbidity Index; CDHP = consumer-driven health plan; EPO = exclusive provider organization; HMO = health maintenance organization; POS = point of service; PPO = preferred provider organization; TKI = tyrosine kinase inhibitor.