Real-World Persistence and Time to Next Treatment With Ibrutinib Treatment in Patients With Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Including Patients At High Risk for Atrial Fibrillation or Stroke

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BACKGROUND

Ibrutinib, a once-daily Bruton's tyrosine kinase inhibitor (BTKi), has been used to treat chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) in clinical practice. As such, this study describes the real-world persistence and time to next treatment (TTNT) with ibrutinib in patients with CLL/SLL, including patients at high risk for atrial fibrillation (AF) or stroke. The analyses were descriptive, and no adjustments were made for differences in baseline characteristics between the patient cohorts. The main endpoint was the persistence of treatment for >120 days. The analyses were descriptive, and no adjustments were made for differences in baseline characteristics between the patient cohorts. The main endpoint was the persistence of treatment for >120 days.

OBJECTIVE

The objective of this study was to describe the real-world persistence and time to next treatment (TTNT) with ibrutinib in patients with CLL/SLL, including patients at high risk for AF or stroke. The analyses were descriptive, and no adjustments were made for differences in baseline characteristics between the patient cohorts. The main endpoint was the persistence of treatment for >120 days. The analyses were descriptive, and no adjustments were made for differences in baseline characteristics between the patient cohorts. The main endpoint was the persistence of treatment for >120 days.

METHODS

Data Source

Electronic health records from the US Medicare health claims with recorded genotyping-identified database were used to select patients with CLL/SLL, with ibrutinib as a new treatment, and who were included in the database on or after February 14, 2014. The database also contained elements derived from structured electronic health records (EHRs) from de-identified patients with CHARGE-AF and CHA2DS2-VASc risk scores.

Study Design

A retrospective cohort design was used. The date of the first event observed in the data, and the end of clinical activity was the date of the last event observed in the data. A total of 7,585 eligible patients (12,564 lines of therapy) were eligible for the study. Among the overall patient population and across treatment lines and treatment types, 36% of patients were ≥75 years, sex, hypertension, diabetes mellitus, stroke/ transient ischemic attack + 0.349 × antihypertensive medication + 0.237 × diabetes = 1.7 + 0.349 × antihypertensive medication + 0.237 × diabetes + 0.264 × obesity + 0.227 × acute coronary syndrome + 0.178 × chronic obstructive pulmonary disease + 0.151 × obesity + 0.131 × chronic obstructive pulmonary disease + 0.113 × hypertension + 0.107 × diabetes mellitus.

Study Measures

The analysis was performed as a single cohort without a washout phase of ≥120 days. The study focused on the initiation of 1L on or after February 14, 2014. The clinical benefit of ibrutinib over other regimens was seen across all types of therapy (in months).

Study Population

The sample selection criteria are presented in Figure 1. The following elicitation of baseline risk of AF/AF-related stroke was calculated using the following formula: CHARGE-AF score = 1 × hypertension + 1 × diabetes + 1 × stroke/transient ischemic attack + 1 × atrial fibrillation (AF) + 1 × age ≥75 years + 1 × female gender. A total of 7,585 eligible patients (12,564 lines of therapy) were eligible for the study. Among the overall patient population and across treatment lines and treatment types, 36% of patients were ≥75 years, sex, hypertension, diabetes mellitus, stroke/ transient ischemic attack + 0.349 × antihypertensive medication + 0.237 × diabetes = 1.7 + 0.349 × antihypertensive medication + 0.237 × diabetes + 0.264 × obesity + 0.227 × acute coronary syndrome + 0.178 × chronic obstructive pulmonary disease + 0.151 × obesity + 0.131 × chronic obstructive pulmonary disease + 0.113 × hypertension + 0.107 × diabetes mellitus.

RESULTS

Baseline Characteristics

Among eligible patients (12,564 lines of therapy) were eligible for the study. Among the overall patient population and across treatment lines and treatment types, 36% of patients were ≥75 years, sex, hypertension, diabetes mellitus, stroke/ transient ischemic attack + 0.349 × antihypertensive medication + 0.237 × diabetes = 1.7 + 0.349 × antihypertensive medication + 0.237 × diabetes + 0.264 × obesity + 0.227 × acute coronary syndrome + 0.178 × chronic obstructive pulmonary disease + 0.151 × obesity + 0.131 × chronic obstructive pulmonary disease + 0.113 × hypertension + 0.107 × diabetes mellitus.

DISCUSSIONS

This is the largest cohort of patients treated with ibritinib in a US community oncology setting, and includes a comprehensive clinical benefit analysis. The results of this study highlight the importance of assessing the impact of TTNT with ibritinib in real-world patients with CLL/SLL.