BACKGROUND

Prior studies have reported that ibritinib, a Bruton’s tyrosine kinase inhibitor (BTKI), is the only targeted therapy to demonstrate significant progression-free survival and overall survival benefit in multiple phase 3 studies for chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL). There is variability within the prescribing information for dosing, with restrictions on dose reduction and management of different types of adverse events. In clinical trials, efficacy outcomes were similar for patients with cardiac AEs and those without cardiac AEs.

OBJECTIVE

Describe the dosing patterns and compare the TTNT following the first incident AE between patients with CLL/SLL who did and did not have DR of 1L ibritinib

RESULTS

Among 680 patients and 16,233 incident AEs, the incidence of cardiac AEs was 14% (without DR) and 33% (DR). Patients with DR had significantly lower costs compared with patients without a DR.

CONCLUSIONS

In this real-world analysis, patients with DR following an incident AE had longer TTNT than patients without DR. However, patients with DR had significantly lower costs compared with patients without a DR.

For additional information or to obtain a PDF of this poster

References

SUPPLEMENTAL METHODS

- Data were identified and compiled with HIPAA-compliant, non-identifiable patient data stored in a secure database.

Study Design and Population

- Patients were required to have ≥90 days of follow-up post-ibrutinib initiation (with or without agents used in combination during this period) to ensure single-agent use.
- The identification of 1L treatment was established based on a washout period of 12 months (baseline period) without any use of antineoplastic agents.
- Patients using CYP3A inhibitors during the baseline period were excluded.

- The following characteristics were included in adjusted models:
  - Baseline variables: age, sex at birth, region, race, year of initiation of 1L ibrutinib, time between the first CLL diagnosis observed in the data and initiation of 1L therapy, diagnosis of any DSM-5 mental comorbidity, diagnosis of infection, diagnosis of musculoskeletal pain, number of admissions, number of hospitalizations, and number of emergency department visits.
  - Time-varying variables (evaluated during each 30-day cycle post-index): DR indicator, cumulative number of unique incident AEs, total all-cause medical costs.

LIMITATIONS

- Study Design and Population
  - Claims data may contain omissions and inaccuracies, but this was expected to equally affect all cohorts and thus should not impact conclusions.

- SUPPLEMENTAL METHODS
  - The analyses were conducted in a cohort of commercially insured and Medicare Advantage patients and may not be generalizable to patients with other types of insurance (eg, Medicaid) or uninsured patients.
  - Current study with fixed durations that may have had a treatment-free interval lasting more than 12 months, actual second-line therapy could have been misclassified as 1L therapy in the current study.
  - A 12-month washout period for antineoplastic agents prior to the initiation of 1L therapy was imposed to ensure that therapy for CLL was captured; however, for regimens with fixed durations that may have had a treatment-free interval lasting more than 12 months, actual second-line therapy could have been misclassified as 1L therapy in the current study.

- Data were de-identified and comply with HIPAA; therefore, no institutional review board approval was needed.

SUPPLEMENTAL FIGURE

Figure S1. Study Population Selection–Patients With CLL Treated 1L With 420 mg Starting Dose of Single-Agent Ibrutinib Without Use of CYP3A Inhibitors During Baseline

- Patients treated with 1L ibrutinib with dose reduction anytime during LOT
  - Patients treated with 1L ibrutinib with dose reduction anytime during LOT
  - Patients without dose reduction anytime during LOT
  - Patients treated with 1L ibrutinib with dose reduction anytime during LOT
  - Patients with a dose reduction after a clinical event
  - Patients with an incident clinical event during LOT
  - Patients with dose reduction anytime during LOT
  - Patients without dose reduction anytime during LOT
  - Patients with dose reduction anytime during LOT
  - Patients without dose reduction anytime during LOT
  - Patients with dose reduction anytime during LOT