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Real-World Treatment Patterns Among Patients with Acute Lymphoblastic Leukemia (ALL) or Lymphoblastic Lymphoma (LBL) Who Initiated an Asparaginase Treatment after the Approval of Recombinant *Erwinia* (Rylaze)

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Introduction

Recombinant *Erwinia* (Rylaze or JZP458) was approved by the United States (US) Food and Drug Administration (FDA) on June 30, 2021, for use as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma (LBL) in adult and pediatric patients 1 month and older who developed hypersensitivity to *E. coli*-derived asparaginase. There is currently limited evidence on the use of recombinant *Erwinia* outside of a clinical trial setting.

Methods

This retrospective, descriptive study used a US open claims dataset from Symphony Health. The aim of this study was to describe the treatment patterns among patients diagnosed with ALL/LBL who initiated an asparaginase treatment in the post-Rylaze approval time frame (July 1, 2021-January 31, 2023).

Index date was defined as the first date of receiving an asparaginase treatment. Patients in this study were required to have an ALL/LBL diagnosis within 365 days prior to index date, and at least 1 medical or pharmacy claim 365 days prior to and after the index. Four asparaginase molecules were included in this study, 2 *Erwinia*-derived - recombinant *Erwinia (Rylaze)* and native *Erwinia* (Erwinaze), and 2 *E. coli*-derived - pegaspargase (Oncaspar) and calaspargase pegol-mknl (Asparlas). Patients entered cohort A when they initiated their first asparaginase. Cohort B included a subset of cohort A patients who received a second different asparaginase. Patients were followed up until index treatment discontinuation, 365 days of follow-up, or January 31, 2023 (end of data), whichever came first.

Descriptive statistics were used to report patient characteristics and treatment patterns. No statistical comparisons were conducted in the analyses.

Results

Cohort A (n=1,495) included 1,370 (91.6%) pegaspargase, 85 (5.7%) recombinant *Erwinia*, 28 (1.9%) calaspargase, and 12 (0.8%) native *Erwinia*-treated patients. Among patients aged ≥18 years (n=350), 319 (91.1%), 28 (8.0%), and 3 (0.9%) patients initiated pegaspargase, recombinant *Erwinia*, and native *Erwinia* as the first asparaginase, respectively (Figure 1). Among pegaspargase- and calaspargase-treated patients, 32.2% and 10.7% developed a hypersensitivity reaction (HSR), respectively; also, 11.7% and 14.3% switched to recombinant *Erwinia*, respectively. The 3 most common comorbidities at baseline among patients in cohort A were chronic obstructive pulmonary disease (9.5%), obesity (10.2%), and liver disease (7.8%) and in patients specific to recombinant *Erwinia* were obesity (14.1%), liver disease (11.8%), and diabetes (9.4%).

Cohort B (n=203), representing 13.6% of patients in cohort A who started a second asparaginase treatment, included 168 (82.8%) recombinant *Erwinia*, 19 (9.4%) calaspargase, 13 (6.4%) native *Erwinia*, and 3 (1.5%) pegaspargase-treated patients. Near half (46.8%) of cohort B patients had an HSR after they initiated an *E. coli*-derived asparaginase before they switched to the second asparaginase. Of the patients who switched to recombinant *Erwinia*, most were <18 years old (n=139, 82.8% [Figure 2]). The top 3 comorbidities at baseline among all patients in cohort B were same as cohort A.

Of patients in cohort B, the majority (78.8%) switched from pegaspargase to recombinant *Erwinia*. Within this subgroup, a 1:6 dose replacement ratio was observed within 21 days of the switch with administrations most common on Mondays, Wednesdays, and Fridays.

Discussion/Conclusions

This observational study describes treatment patterns of asparaginase in patients with ALL/LBL in the 18 months after the approval of recombinant *Erwinia*. The majority of initial asparaginase was pegaspargase, with recombinant *Erwinia* as the second asparaginase. However, recombinant *Erwinia* was observed as the initial treatment in 5.7% of patients, with nearly one-third of those patients being ≥18 years of age. Recombinant *Erwinia* dosing usage appeared to align with the dosing schedule (Monday/Wednesday/Friday) approved by the FDA in November 2022 with 1 dose of pegaspargase replaced with 6 doses of recombinant *Erwinia*. Limitations of this study included the nature of the database used, containing mostly outpatient data, and the relatively short study time frame. Future studies with additional data are needed to fully understand the real-world asparaginase use patterns in these patient populations.

Disclosures Maese: *Jazz Pharmaceuticals:* Consultancy, Speakers Bureau. **Latimer:** *Aetion:* Current Employment. **Nerney:** *Aetion:* Current Employment. **Cao:** *Jazz Pharmaceuticals:* Current Employment, Current holder of *stock options* in a privately-held company. **Stricherz:** *Jazz Pharmaceuticals:* Current Employment, Current holder of *stock options* in a privately-held company. **Murphy:** *Jazz Pharmaceuticals:* Current Employment, Current holder of *stock options* in a privately-held company. **Chen:** *Jazz Pharmaceuticals:* Current holder of *stock options* in a privately-held company, Ended employment in the past 24 months. **Su:** *Jazz Pharmaceuticals:* Current Employment, Current holder of *stock options* in a privately-held company. **Ni:** *Jazz Pharmaceuticals:* Current Employment, Current holder of *stock options* in a privately-held company. **Prince:** *Aetion:* Current Employment. **Poole:** *Jazz Pharmaceuticals:* Current Employment, Current holder of *stock options* in a privately-held company.

Figure 1. Distribution of patients using each formulation by age in cohort A

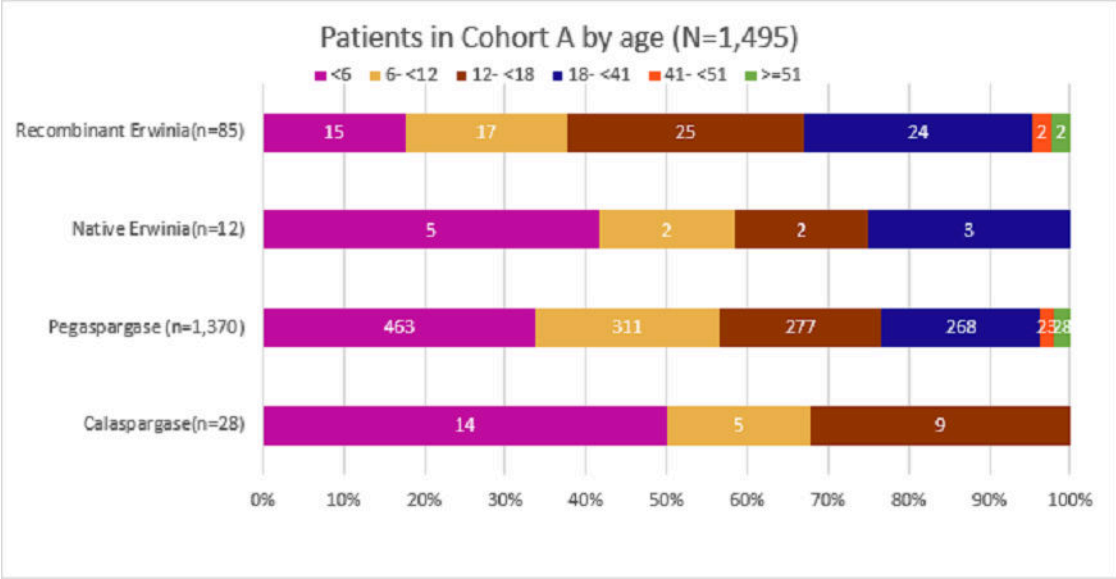

Figure 2. Distribution of patients using each formulation by age in cohort B

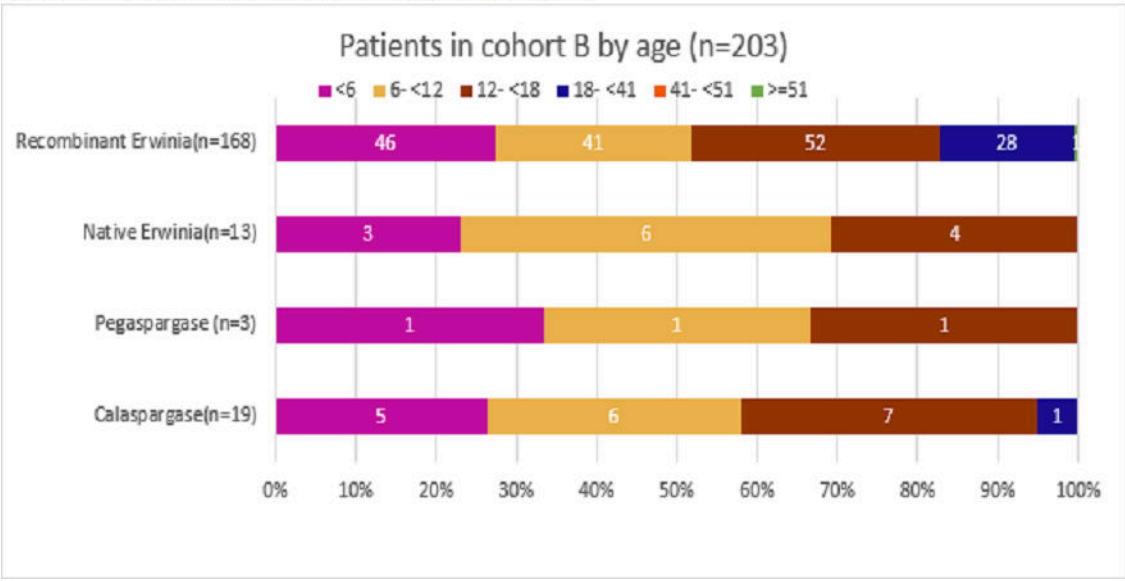

Figure 1

https://doi.org/10.1182/blood-2023-172591