Real-world Treatment Patterns, Adherence and Healthcare Resource Utilization for Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Among Veterans in the United States

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Introduction

- Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) are the most common types of leukemia in adults in the US

- The US veteran population, predominantly older males, are at high risk for CLL/SLL, especially with prior exposure to Agent Orange or other herbicides during military service

- With the increasing availability of novel agents and associated improved survival, there is a need to assess the real-world evidence of CLL/SLL burden in US veterans, and the clinical and economic outcomes associated with current treatments
Objectives

• To examine the clinical burden, costs and healthcare resource utilization of US veterans with CLL/SLL
Methods

- **Study design:** Retrospective, observational study
- **Data source:** Veteran Health Administration dataset
- **Study period:** October 2014 - September 2019
- **Study population:**
  - Adults who were newly diagnosed with CLL/SLL
  - Index date: the first CLL/SLL diagnosis date during the identification period (April 2014 - July 2018)
  - Aged ≥18 years at index date
  - ≥2 diagnosis of CLL/SLL on different days during the identification period
  - Continuous enrollment of 6 months pre- and 3 months post-index date
  - ≥1 CLL/SLL treatment on or after the index date
  - No CLL/SLL treatment any time prior to the index date
Methods

Treatment regimens and patterns:

- Classified according to NCCN guidelines and identified using HCPCS and NDC codes
- 5 mutually exclusive categories of CLL/SLL treatment regimen:
  - Bendamustine-based (alone or in combination) therapy
  - Other chemotherapies
  - Ibrutinib
  - Rituximab-monotherapy
  - Other regimens
- Adherence: discontinuation and switching
- Economic outcomes: healthcare resource utilization and costs
Results: Patient Characteristics

- Of 13,664 veteran patients diagnosed with CLL/SLL, 79% were in watch-and-wait

- Final study population consisted of 2,861 patients who received ≥1 line of CLL/SLL therapy (mean duration = 465 days)

- Most patients were elderly (median age= 70 years), white (83%), and male (98%)

- Approximately 39% of veterans had concurrent use of proton pump inhibitors at baseline

| Table 1. Demographic and Clinical Characteristics of CLL/SLL Patient Population |
|---------------------------------|-------------------------------|
| **CLL/SLL Patients** (N=13,664) | **CLL/SLL Patients** (N=13,664) |
| Age at index | 70.3 (8.0) |
| Mean (SD) | Median 70 |
| Age group, n (%) | 18-34 | 9 (0) |
| 35-54 | 47 (3%) |
| 55-64 | 2,077 (15%) |
| 65+ | 11,101 (81%) |
| Sex | Male 13,429 (98%) |
| Female 235 (2%) |
| Charlson comorbidity index (CCI) | Mean (SD) 0.5 (1.0) |
| Duration of follow-up, days | Mean (SD) 1051.1 (393.7) |
| Median 1,207 |

**Baseline comorbidity, n (%)**

- Atrial fibrillation/arrhythmia (including all cardiac arrhythmias) 1,082 (8%)
- Cerebrovascular disease 133 (1%)
- Hypertension 3,267 (24%)
- Coronary artery disease (including myocardial infarction) 1,022 (7%)
- Renal disease (acute or chronic kidney disease/renal failure/dialysis) 475 (3%)
- Diabetes 2,241 (16%)
- Neutropenia 22 (0%)
- GERD 722 (5%)
- Headache 221 (2%)
- Hepatic disease 140 (1%)

**Abbreviations:** GERD, gastroesophageal reflux disease; SD, standard deviation; CLL/SLL, Chronic lymphocytic leukemia / small lymphocytic lymphoma
• Average time to treatment initiation from diagnosis to first-line therapy was 315 days

• 770 (26.9%) patients who received first-line (1L) therapy further received second-line (2L) therapy (mean duration of treatment=318 days), and 199 (7.0%) patients received third-line (3L) therapy (mean duration of treatment=229 days)

• Ibrutinib was the most common treatment regimen across all lines of therapy (1L: 39%; 2L: 55%; 3L: 43%)

Abbreviations: 1L, first-line therapy; 2L, second-line therapy; 3L, third-line therapy.
Results: Treatment Discontinuation

• Overall, treatment discontinuation rates were high across current regimens in each line of therapy (1L: 73% [mean duration: 354 days], 2L: 66% [mean duration: 241 days], 3L: 59% [mean duration: 190 days])

• Discontinuation rates were generally highest for bendamustine-based chemotherapies, with 85%, 84% and 89% discontinuing in 1L, 2L, and 3L, respectively

• Ibrutinib accounts for over half of total patient discontinuations during treatment; discontinuation rates at 60%, 60%, and 55% in 1L, 2L, and 3L, respectively

Abbreviations: 1L, first-line therapy; 2L, second-line therapy; 3L, third-line therapy.
The CLL/SLL-related hospitalization rate among veterans was 39%, with an average LOS of 7 days.

Table 2. All-Cause Health Resource Utilization

<table>
<thead>
<tr>
<th>Frequency (Per-Patient Per-Month)</th>
<th>Overall Treated (N=2,861)</th>
<th>1L (n=2,861)</th>
<th>2L (n=770)</th>
<th>3L (n=199)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outpatient visits (Mean ± SD)</td>
<td>7.69 ± 5.07</td>
<td>5.62 ± 2.74</td>
<td>6.07 ± 5.58</td>
<td>6.19 ± 3.06</td>
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<tr>
<td>Inpatient admissions (Mean ± SD)</td>
<td>0.05 ± 0.30</td>
<td>0.02 ± 0.18</td>
<td>0.07 ± 0.43</td>
<td>0.08 ± 0.37</td>
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<tr>
<td>Pharmacy visits (Mean ± SD)</td>
<td>5.74 ± 5.06</td>
<td>4.05 ± 3.06</td>
<td>4.93 ± 4.40</td>
<td>5.19 ± 4.00</td>
</tr>
<tr>
<td>Duration of hospitalization (Mean ± SD)</td>
<td>1.04 ± 3.66</td>
<td>0.64 ± 2.71</td>
<td>1.14 ± 3.78</td>
<td>1.46 ± 4.80</td>
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Results: Healthcare Costs

- Total PPPM all-cause- and CLL/SLL-related costs were $26,709 and $17,233, respectively

- Costs increased by line of therapy

- Controlling for patient clinical and demographic covariates, treatment discontinuation and treatment switching were statistically significant predictors of higher inpatient admissions and LOS of hospitalizations
Discussion

• This study evaluated the real-world utilization of treatment regimens by line of therapy in newly diagnosed CLL/SLL patients in the US. Results reflected the variation of real-world treatment patterns from clinical treatment guidelines.

• Study limitations were inherent to the use of claims databases in an observational study design.

• Future studies are needed to further understand factors associated with treatment selection and outcomes.
Conclusions

- This real-world data demonstrated significant clinical and economic burden associated with CLL/SLL among the US veterans.

- The suboptimal adherence, as reported by high treatment discontinuation rates and its impact on increasing costs and healthcare resource use, highlights the real-world unmet needs of CLL/SLL management in the veteran population.