VANDERBILT HEALTH | Specialty Pharmacy

Real-World Outcomes of Patients Receiving Oral Specialty Therapy for the Treatment of Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia at an Integrated Health System in the United States

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Purpose

Evaluate treatment outcomes (adherence, persistence, switching and discontinuation of therapy) in patients on an oral oncolytic therapy for CLL/SLL at an integrated health-system specialty pharmacy (IHSSP) focused on patient outcomes.

Study Design and Setting

Single-center, retrospective cohort analysis of data collected from electronic medication records and specialty pharmacy management system

Vanderbilt Health System outpatient oncology and hematology clinics from 1/1/19 – 6/30/22 with patients having a minimum of 6 months of follow-up

Study Methods

Inclusion and Exclusion Criteria

Inclusion: Patients prescribed acalabrutinib, ibrutinib, or venetoclax for treatment of CLL/SLL

Exclusion: Clinical trial participation, off-label use, lost to follow-up, received a stem cell transplant, or transferred care outside of VUMC

Sample

157 patients were identified for inclusion

12 patients were excluded (off-label indication [n=2], lost to follow-up [n=1], stem cell transplant [n=1], and transferred care outside of VUMC [n=5])

145 patients included for analysis

Outcome Measures

1) Adherence (calculated as proportion of days covered [PDC]); **2)** Persistence (defined as a >30-day gap in treatment); **3)** Therapy discontinuation or switch; **4)** Reasons for discontinuation or switch in therapy

Data Analysis

Patients with 3+ fills were included in the adherence and persistence analyses. PDC was calculated as the number of days with medication available between the date of the first fill and the last fill in the study period. Excess supply from overlap was carried forward and truncated at the date of the last fill.

Results

Table 1. Baseline Demographics (n=145)

Characteristic	n (%)
Age (at start of medication use), median [IQR]	69 [60-76]
Male	96 (66)
Female	49 (34)
White	130 (90)
Black	7 (5)
Duration of disease in years (at start of medication use), median [IQR]	6 [2-10]
Medicare insurance	74 (51)
CLL/SLL Treatment	**n (%)**
Ibrutinib	77 (53)
Venetoclax	46 (32)
Acalabrutinib	22 (15)
Comorbid Conditions	**n (%)**
Hypertension	74 (51)
GERD	45 (31)
Atrial fibrillation/arrhythmia	26 (18)
Cerebrovascular disease	7 (5)
Headache	7 (5)
Migraine	3 (2)
Genetic Testing	**n (%)**
Del (13q)	77 (53)
Del (11q)	24 (17)
Del (17p)	15 (10)
No testing available	46 (32)

CLL = Chronic Lymphocytic Leukemia; SLL = Small Lymphocytic Leukemia; VSP = Vanderbilt Specialty Pharmacy

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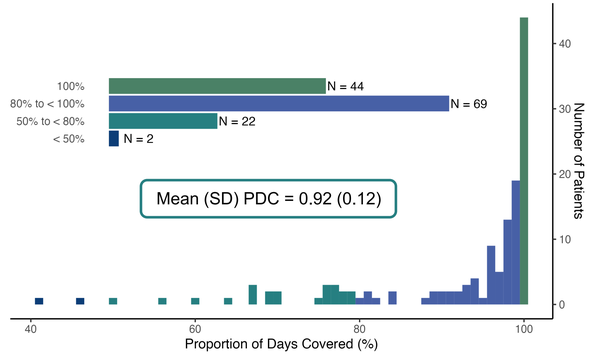
Conclusion

- In a population of patients initiating CLL/SLL therapy through an integrated health-system specialty pharmacy, adherence to therapy was high (mean PDC = 92%).
- Adverse effects contributed to 36% of therapy discontinuations and 72% of therapy switches, indicating a continued opportunity for specialty pharmacists to help manage and mitigate adverse effects.

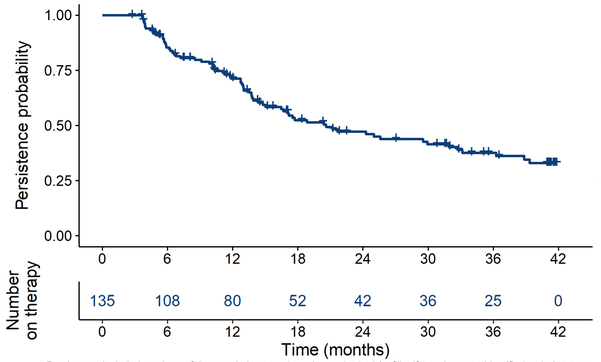
Results

Figure 1. Adherence (n = 137)



Adherence included a subset of the population as only patients who had 3+ fills. Median [IQR] PDC = 0.98 [0.9-1.0].

Figure 2. Persistence (n = 135)



72 patients (53.3%) were found to be **non-persistent** with a median time to non- persistence of 375 (IQR 180-526) days.

Reasons for non-persistence:

- Treatment progression (n=22; 31%)
- Adverse effects (n=20; 28%)
- Treatment completed (n=23; 32%)
- Patient deceased (n=4; 6%)
- Unknown (n=9; 13%)

Multiple reasons for non-persistence could be reported therefore percentages add up to >100%

Persistence included a subset of the population as only patients who had 3+ fills. If a patient was identified as being non-persistent after 2 fills, then they are considered as only having 2 fills in the persistence calculation and therefore excluded.

Table 2. Discontinuation Reasons (n = 81)

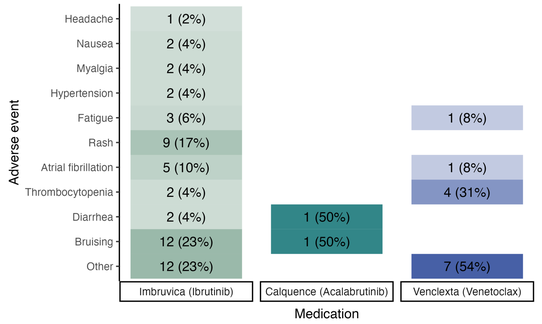
Discontinuation Reason	n (%)
Adverse events	29 (36)
Treatment completed	28 (35)
Treatment progression	25 (31)
Patient deceased	5 (6)

Includes all patients in study regardless of # of fills. Patients may have more than one reason documented for discontinuation.

Primary Adverse Events (≥10%) Leading to Discontinuation (n,%)

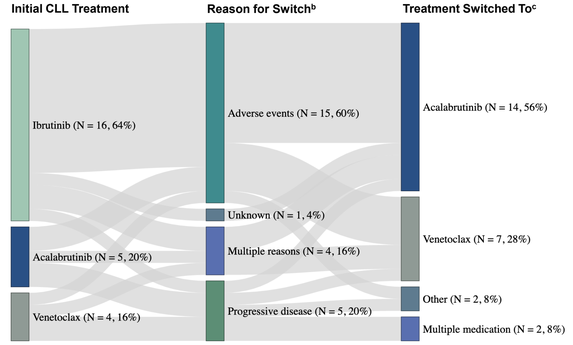
- **Ibrutinib (n=21):** atrial fibrillation (3,14); bruising (2,10); fatigue (2,10); nail splitting (2,10); rash (2,10)
- **Acalabrutinib (n=2)**: bruising (1,50); diarrhea (1,50)
- **Venetoclax (n=6)**: pancytopenia (4,66); itching (1,17); nausea (1,17)

Figure 3. Patient Reported Adverse Events for Patients who Discontinued Medication (n = 67)



Includes all adverse events experienced by patients who discontinued the study medication.

Figure 4. Medication Switches and Reasons for Switch (n = 18)[a]



[a]Numbers will not add up to 18 as some patients switched treatment more than once.

[b]Multiple reasons: No clinical response + Adverse events (n=1); No clinical response + Progressive disease (n=1); No clinical response + Adverse events + Progressive disease (n=1); Progressive disease + Adverse events (n=1)

[c]Multiple medications: Acalabrutinib + Venetoclax (n=1); Venetoclax + Obinutuzumab (n=1)