P632

Chronic Lymphocytic Leukemia (CLL) and Small Lymphocytic Lymphoma (SLL) Patient Demographics and Patient-Reported Burden in Ibrutinib and Non-Ibrutinib Receivers in the US: a Real-World Study

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Conclusions

Nearly half of ibrutinib receivers were reported to have Binet Stage A disease at data collection, whereas nearly half of non-ibrutinib receivers had Stage B disease.

Nearly a quarter of patients receiving ibrutinib reported experiencing no symptoms in the seven days prior to data collection, and two thirds reported only mild cancer symptoms.

In terms of patient quality of life, ibrutinib receivers scored favourably on physical, role, emotional, cognitive and social functioning, as well as reporting low symptomology including pain, nausea and vomiting and insomnia.

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Supplementary material

Disclosures

ZQ and RM are employees of J&J. NM and AS are employees of Adelphi Real World. All authors contributed to analysis and interpretation of data and reviewed and approved this poster.

The analysis described here used data from the Adelphi Real World CLL II DSP. The DSP is a wholly owned Adelphi product, of which Johnson & Johnson are one of multiple subscribers.

Background

- Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma (CLL/SLL) affect more than 200,000 people in the US annually[1] and are associated with a significant disease burden to patients[2].
- With the development of novel drugs such as Bruton's tyrosine kinase inhibitors (BTKi)[3], the overall prognosis of patients has changed dramatically, and survival outcomes have improved[4].
- Ibrutinib, the first BTKi approved by the Food and Drug Administration for treatment of patients with CLL/SLL in 2014, has since become a standard of care[5].

Objectives

- To assess patient demographics and clinical characteristics in CLL/SLL patient populations that are either receiving ibrutinib or other treatment options.
- To assess patient perspectives on disease burden within CLL/SLL patient populations receiving ibrutinib and not receiving ibrutinib.

Methods

Figure 1. Study design

Physicians were recruited to the Adelphi Real World CLL Disease Specific Programme **(DSP)**™ in the US.

Physicians completed patient record forms **(PRFs)** for their next ten consecutively consulting **CLL/SLL** patients receiving **active drug treatment** at the time of data collection.

PRFs collected data on patient **demographics**, clinical characteristics, treatment history, and physician attitudes towards treatment

- Real-world data were drawn from the Adelphi Real World CLL Disease Specific Programme™, a cross-sectional survey with retrospective data collection of hematologists and hem-oncologists in the US from October 2022 and March 2023.
- Physicians completed PRFs for consecutively consulting patients with the following quota:
  - Three patients receiving first-line (1L) active drug treatment
  - Two patients receiving 1L BTKi treatment
  - Four patients receiving second-line or later (2L+) active drug treatment
  - One patient receiving 2L+ that had previously received a BTKi and B-cell lymphoma 2 inhibitor (BCL2i)
- Patient eligibility was defined as being over the age of 18, having a confirmed CLL/SLL diagnosis with active disease, and receiving active drug treatment at the time of data collection.
- Patients were excluded if they had received a stem cell transplantation or chimeric antigen receptor T-cell therapy for any other reason than their CLL/SLL, were participating in a clinical trial at data collection, or had a diagnosis of Richter's Transformation.
- Patients for whom physicians had completed a PRF were invited to complete a patient self-completion form (PSC) that assessed patient burden using patient reported outcome measures

Limitations of the methodology

- Despite having access to medical records, physician responses to the DSP questionnaires may have been affected by recall bias.
- Data was imputed and missing values were not analyzed.

Results

Demographics and clinical characteristics

- A total of 58 physicians reported data for 103 CLL/SLL patients who also completed a PSC, split as 89 (86%) patients with a CLL diagnosis and 14 (14%) patients with SLL.
- Overall, 60% (n=62) patients were male, median (interquartile range (IQR)) body mass index (BMI) was 24.7 (23.3, 26.6), 51% (n=53) were not working due to retirement and 55% (n=57) did not have a caregiver (Table 1).
- At data collection, 28% of patients (n=29) were receiving ibrutinib (69%, n=20 at 1L) and 72% (n=74) were receiving other treatments (36%, n=27 at 1L). Common treatments for those not receiving ibrutinib at data collection were acalabrutinib monotherapy (19%, n=14), venetoclax monotherapy (15%, n=11) and venetoclax in combination with obinutuzumab (9%, n=7).
- For CLL patients at data collection, the majority of ibrutinib receivers were Binet Stage A (n=9, 43%) whereas the majority of non-ibrutinib receivers were Stage B (n=31, 46%; Table 2).
- For ibrutinib receivers, 31% (n=9) and 38% (n=11) were Eastern Cooperative Oncology Group (ECOG) score 0 and 1 respectively, whilst this was 23% (n=17) and 54% (n=40) for those not receiving ibrutinib, respectively (Table 2).

Table 1. Patient Demographics

		All patients (n=103)	Patients receiving ibrutinib at data collection (n=29)	Patients not receiving ibrutinib at data collection (n=74)
Age, median (IQR)		68.0 (63.0, 72.0)	65.0 (62.5, 68.5)	70.0 (62.5, 73.0)
Time since CLL/SLL diagnosis (months), median (IQR)		n=68 20.3 (10.3, 34.9)	n=16 5.8 (3.4, 34.7)	n=52 21.3 (11.7, 35.1)
Sex, n (%)	Male	62 (60)	18 (62)	44 (59)
BMI, median (IQR)		24.7 (23.3, 26.6)	25.8 (23.7, 28.0)	24.3 (23.0, 26.3)
Employment status, n (%)	Not working due to retirement	53 (51)	9 (31)	44 (59)
	Working full-time	26 (25)	7 (24)	19 (26)
	Homemaker	8 (8)	4 (14)	4 (5)
	Working part-time	9 (9)	7 (24)	2 (3)
	On long-term sick leave	5 (5)	2 (7)	3 (4)
	Unknown	2 (2)	0 (0)	2 (3)
Caregiver status, n (%)	Patient has a caregiver	45 (44)	10 (34)	35 (47)
	Patient does not have a caregiver	57 (55)	19 (66)	38 (51)
	Unknown	1 (1)	0 (0)	1 (1)

Table 2. Patient Clinical Characteristics

		All patients (n=103)	Patients receiving ibrutinib at data collection (n=29)	Patients not receiving ibrutinib at data collection (n=74)
CLL Stage (Binet) at Data Collection, n (%)		n=89	n=21	n=68
	Stage A	30 (34)	9 (43)	21 (31)
	Stage B	37 (42)	6 (29)	31 (46)
	Stage C	22 (25)	6 (29)	16 (24)
SLL Stage (Ann Arbor) at Data Collection		n=14	n=8	n=6
	Stage 1	5 (36)	4 (50)	1 (17)
	Stage 2	6 (43)	3 (38)	3 (50)
	Stage 3	3 (21)	1 (13)	2 (33)
	Stage 4	0 (0)	0 (0)	0 (0)
ECOG Score at Data Collection, n (%)	0	26 (25)	9 (31)	17 (23)
	1	51 (50)	11 (38)	40 (54)
	2	21 (20)	7 (24)	14 (19)
	3	5 (5)	2 (7)	3 (4)
Symptoms at Data Collection*, n (%)	Lymphocytosis	49 (48)	7 (24)	42 (57)
	Fatigue	47 (46)	17 (59)	30 (41)
	Painless swelling in the neck, armpit, stomach or groin	24 (23)	9 (31)	15 (20)
	Splenomegaly	24 (23)	6 (21)	18 (24)
	Painful swelling in the neck, armpit, stomach or groin	19 (18)	5 (17)	14 (19)

Patient Quality of Life - EORTC QLQ-C30

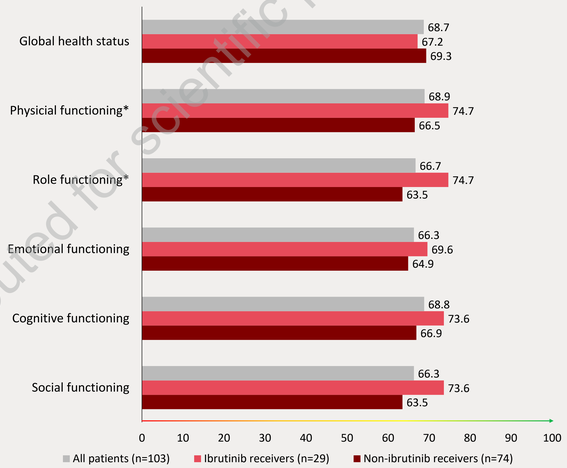
Functional Scores

- Patients receiving ibrutinib at data collection reported mean EORTC QLQ-C30 functional scores across the physical (74.7), role (74.7), emotional (69.6), cognitive (73.6) and social (73.6) domains, indicating high functioning (Figure 2).

Symptom Scores

- Ibrutinib receivers at data collection reported mean EORTC QLQ-C30 symptom scores in the fatigue (36.0), nausea & vomiting (24.7), pain (28.7), dyspnea (20.7), insomnia (31.0), appetite loss (26.4), constipation (26.4) and diarrhea (21.9) domains, indicating low symptomology (Figure 3).

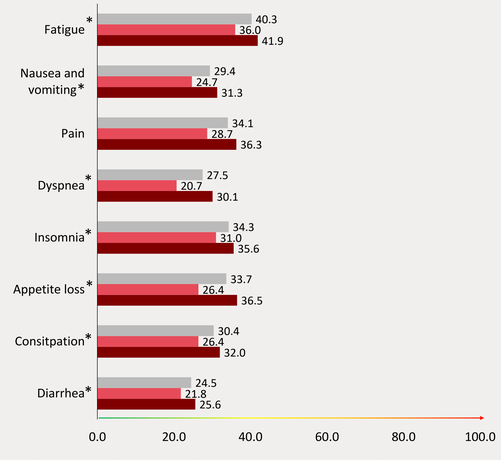
Figure 2. EORTC QLQ-C30 Functional Scores



*The EORTC scale is 0 – 100, with a **lower** scores representing a **low** functioning (worse) and a **higher** scores representing a **high** functioning (better)*

*Base size: All patients (n=102); Ibrutinib receivers (n=29); Non-ibrutinib receivers (n=73)

Figure 3. EORTC QLQ-C30 Symptom Scores



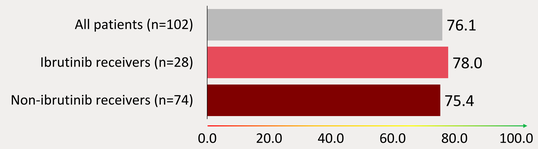
*The EORTC scale is 0 – 100, with a **lowers** score representing a **low** symptomatology (better) and a **higher** scores representing a **high** symptomatology (worse).*

*Base size: All patients (n=102); Ibrutinib receivers (n=29); Non-ibrutinib receivers (n=73)

Patient Quality of Life – EQ-5D Visual Analogue Scale (VAS)

- On the EQ-5D VAS, ibrutinib receivers reported a mean score of 78.0, whilst non-ibrutinib receivers reported a mean score of 75.4, with a greater VAS score indicating better perceived health status (Figure 4).

Figure 4. EQ-5D VAS Scores

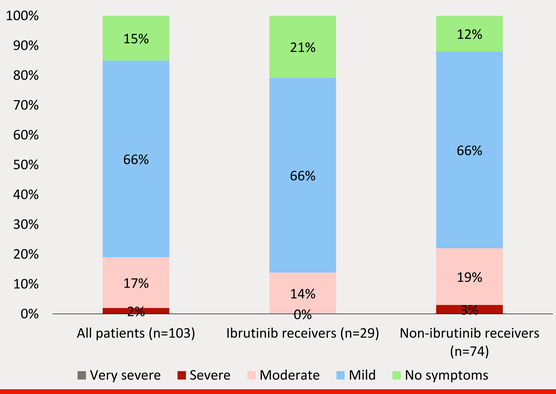


*The EQ-5D VAS ranges from 100 to 0, **higher** values indicate **better** perceived health status. A clinically meaningful score change is regarded as one of 7 points or more.*

Patient Quality of Life – PGI-S

- For patients receiving ibrutinib at data collection, 21% reported having no cancer symptoms in the past seven days, whilst 12% of non-ibrutinib receivers reported having no cancer symptoms (Figure 5).

Figure 5. PGI-S Scores



References

1. Shadman, M., Jama. 2023; 329(11), pp.918-932.
2. Wawrenu, C. et al., Curr Med Res. 2020; 36(9) pp.1481-1495
3. Smolewski, P. and Robak, T., Acta Haematologica. 2021; 144(4), pp.365-387
4. Tadmor, T. et al, Anticancer Research. 2024; 44(5), pp.2109-2115
5. Kim, M.S. and Prasad, V., Cancer. 2020; 126(19), pp.4270-4272

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