PS1595

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Impact of Adverse Events on Quality of Life in Chronic Myeloid Leukemia (CML) – Results from the Patient Survey on Humanistic Burden of Intolerance to First or Second TKIs (SHIFT) Study in the US

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FINDINGS & CONCLUSIONS

- Findings from the SHIFT study demonstrate the substantial humanistic burden of TKI-related AEs among patients with CML in the US
- Most patients had multiple persistent AEs, regardless of whether they received first or second TKI, negatively impacting physical and mental health and contributing to worse QoL
- The extent of work productivity impairment is reflected in the high proportion modifying employment due to CML and, among those employed, experiencing some work productivity loss
- QoL and work productivity were even poorer in patients experiencing a "low point" or feeling the worst in terms of their QoL, suggesting that our estimate of the humanistic burden in CML is conservative
- Treatment options with better tolerability profiles are needed to reduce AEs and help patients with CML preserve QoL

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INTRODUCTION & OBJECTIVES

- Despite extending life expectancy in patients with chronic myeloid leukemia (CML), tyrosine kinase inhibitors (TKIs) can cause adverse events (AEs)[1]
- Frequent AEs and intolerance to TKIs often result in reduced treatment adherence and medication modifications, including discontinuation and reduced quality of life (QoL)[2]
- The SHIFT study aimed to evaluate the impact of TKI-related AEs on health-related QoL in CML using patient-reported outcomes (PROs) in US clinical practice settings

METHODS

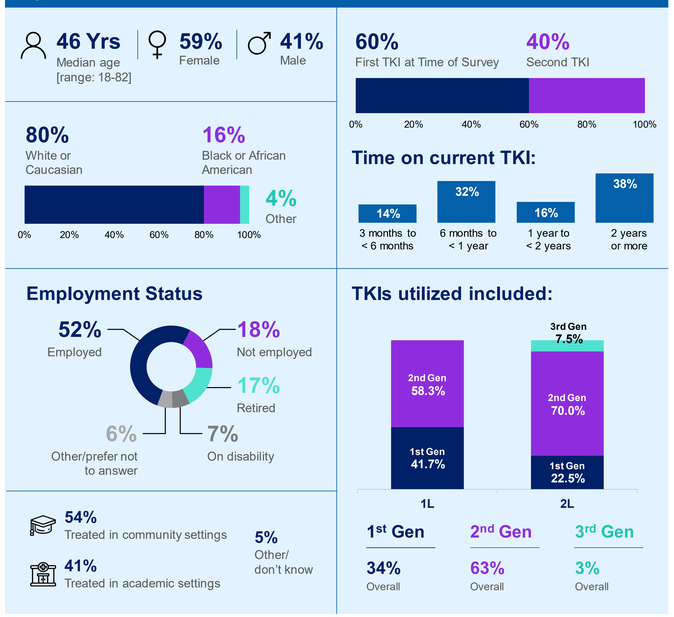
- The SHIFT study is a cross-sectional online survey conducted among patients with CML in the US from June to December 2024
- During this period, several first generation (1G; imatinib) and second generation (2G; dasatinib, nilotinib, bosutinib) ATP-competitive TKIs were indicated for newly diagnosed patients with CML; additionally, ponatinib (third generation, 3G) was considered for second treatment for CML
  - Asciminib, a selective allosteric inhibitor binding the myristoyl pocket of ABL1, was not indicated in this setting at the time of study initiation
- Eligible participants included adults (≥ 18 years old) receiving an ATP-competitive TKI for ≥ 3 months as first or second treatment for CML at the time of the survey
- Data was collected on 18 AEs using the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE)[3]
- Health-related QoL was evaluated using the Patient-Reported Outcomes Measurement Information System - Global Health (PROMIS-GH-10 v1.2; T-scores, lower score indicates worse health)[4] and the Work Productivity and Activity Impairment Specific Health Problem (WPAI:SHP; impairment percentages, higher percentages are worse) questionnaires[5]
- Patient-reported "low point(s)", defined as the time(s) since current TKI start when AEs had the most unpleasant/negative impact on QoL from the patient's perspective, was also collected
- This study was exempt by the Pearl Institutional Review Board (IRB) under 45 CFR 46.104(d)(2)

RESULTS

Patient Characteristics

A total of 271 patients participated in the study **(Figure 1)**

Figure 1: Patient characteristics



High Number of Persistent AEs Experienced by Patients with CML

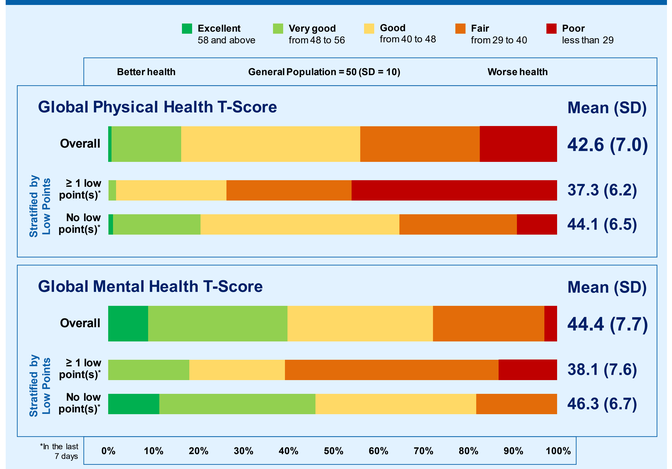
- In the 7 days prior to the survey, patients reported a median of 3 AEs (range 0-14; 41% experiencing 4 or more). Most experienced chronic (i.e., long-lasting, 80%) AEs
- Most common AEs included fatigue (54%), joint pain (34%), muscle pain (30%), problems with memory (22%), and anxiety (21%) **(Figure 2)**
- The majority (77%) experienced at least one "low point" since starting their TKI (23% in the last 7 days; 55% outside the last 7 days); "low point(s)" were most common in the first 3 months of treatment (55%)

Poorer Health-Related QoL of Patients with CML than General Population

- Mean (SD) PROMIS Global Physical Health (GPH) and Global Mental Health (GMH) T-scores in the last 7 days were reported at 42.6 (7.0) and 44.4 (7.7), respectively, reflecting poorer global health than the general population (mean of 50 [10]) **(Figure 3)**
  - Almost half (44%) and one-third (28%) reported a fair-to-poor rating for GPH and GMH, respectively
- In patients who reported at least one "low point" in the 7 days prior to being surveyed, GPH and GMH T-scores were worse than those who did not experience "low points", at 37.3 (6.2) and 38.1 (7.6), respectively **(Figure 3)**

Figure 2: Distribution of PRO-CTCAE scores by AE

Figure 3: Distribution of PROMIS Global Physical Health and Global Mental Health T-scores

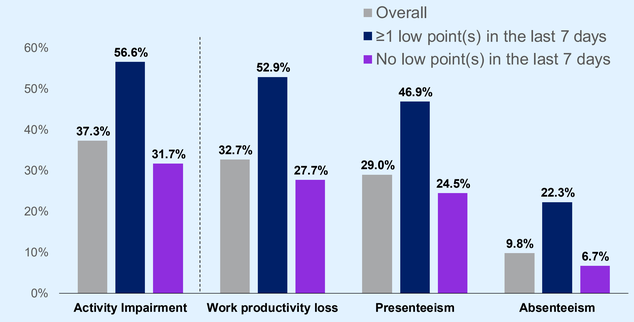


Extent of Work Productivity and Activity Impairment in Patients with CML

- Mean percent activity impairment due to CML was 37.3% **(Figure 4)**
- More than half (53.5%) had a change in employment due to CML: 14% from full-time to part-time, 13% from full-time to unemployed, 10% took early retirement, 7% stopped working temporarily/reduced workload
- Among those employed:
  - 80% reported some productivity loss (overall work impairment) due to CML, with a mean percent work productivity loss of 32.7%
  - Presenteeism (impairment while working) and absenteeism (work time missed) had a mean percent of 29.0% and 9.8%, respectively
- All productivity impairment percentages were worse among patients with at least 1 "low point" in the 7 days prior to being surveyed

Figure 4: Work Productivity and Activity Impairment Specific Health Problem – impairment percentages

WPAI: Average outcome due to CML – overall and stratified by low point(s)



LIMITATIONS

- Patients with more severe disease, male patients, and older patients may be under-represented; therefore the impact of AEs/intolerance on the overall humanistic burden may be underestimated
- Evaluation of humanistic burden is limited to the time of survey completion and findings may not be generalizable to the overall population of patients with CML in the US
- Confirmation of diagnosis by a medical professional or through medical charts was not required for patient eligibility

REFERENCES

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