RESEARCH PAPER

Treatment Accessibility, Medication-Related Burden, and Patient-Reported Outcomes Among Patients with Chronic Myeloid Leukemia Receiving BCR-ABL Tyrosine Kinase Inhibitor Therapy: A Multidimensional Observational Study.

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Received: 20th July 2026

Revised: 25th Aug 2026

Accepted: 10th November 2026

Available Online: 13th November 2026

Abstract

Introduction: Chronic myeloid leukemia (CML) is effectively managed with BCR::ABL1 tyrosine kinase inhibitors (TKIs); however, long-term therapy may impose treatment-related and medication burdens that affect patients' quality of life. Understanding patients' experiences with treatment accessibility, medication-related burden, treatment-related knowledge, monitoring requirements, and quality of life is therefore important for comprehensive CML care.

Objective: To assess treatment accessibility, medication-related burden, treatment understanding, monitoring, and quality of life among patients with CML receiving BCR::ABL1 TKI therapy.

Methods: This observational study was conducted among 390 patients with CML receiving TKI therapy. Sociodemographic, disease- and treatment-related characteristics, accessibility, financial burden, treatment knowledge, monitoring, and patient-reported outcomes were assessed. Quality of life was evaluated using the EORTC QLQ-C30. Multivariable linear regression identified factors associated with global health status/quality of life.

Results: The mean age was 43.4 ± 15.6 years, and 53.3% were male. Imatinib was the most commonly used TKI (70.0%). TKI medication was reported to be always available by 92.1% of patients, while 77.2% reported insurance/PM-JAY coverage. However, 52.1% reported no financial assistance, and mean monthly treatment expenditure was ₹6,580.2 ± 1,600.3. Poor or very poor understanding of BCR::ABL1, TKI treatment, and monitoring was reported by 57.4%. On the EORTC QLQ-C30, mean global health status/quality of life was 46.6 ± 15.5; emotional functioning was particularly impaired (39.7 ± 18.3), while fatigue was the most prominent symptom (54.0 ± 17.6). Significant or severe side effect/cost burden was reported by 23.4%. Significant side effect and cost burden was independently associated with poorer global quality of life (β=−.383; P<.001), whereas better understanding of BCR::ABL1, TKI treatment, and monitoring was associated with better quality of life (β=.131; P=.006).

Conclusions: Despite favorable treatment accessibility, substantial treatment-related burden persisted. Addressing treatment toxicity, financial burden, and patient understanding may improve patient-centered CML care.

Keywords: chronic myeloid leukemia; BCR-ABL, tyrosine kinase inhibitors; quality of life; treatment burden; financial burden; patient-reported outcomes.

How to cite this article: Md Rabiul Parwana1 Yogesh Kumar Singh2* Sourav Debnath3 Prachi Saban4 Natasha Modi5.. Treatment Accessibility, Medication-Related Burden, and Patient-Reported Outcomes Among Patients with Chronic Myeloid Leukemia Receiving BCR-ABL Tyrosine Kinase Inhibitor Therapy: A Multidimensional Observational Study.. Int J Drug Deliv Technol. 2026;16(90s):2008-2017. DOI: 10.25258/ijddt.16.90s.201.

Introduction

Chronic myeloid leukemia (CML) is a myeloproliferative neoplasm driven by the BCR::ABL1 fusion gene, resulting from the t(9;22)(q34;q11.2) translocation and constitutive

tyrosine kinase activity. The introduction of BCR::ABL1 tyrosine kinase inhibitors (TKIs) has transformed CML into a manageable chronic disease, with treatment goals extending beyond hematologic and molecular response to include individualized therapy, long-term safety and tolerability, management of comorbidities, and preservation of quality of life [1–3].

Despite their effectiveness, prolonged TKI therapy may impose a substantial treatment burden, including adverse effects, treatment interruptions, monitoring requirements, medication and investigation costs, travel expenses, and difficulties accessing treatment. These factors may influence adherence, treatment persistence, and patients' overall well-being, particularly in settings where patients bear substantial out-of-pocket costs [4,5].

Adherence to daily TKI therapy is essential for sustained disease control but may be influenced by treatment toxicity, financial burden, medication accessibility, forgetfulness, treatment complexity, patient understanding, social circumstances, and communication with health care professionals [6]. Consequently, assessment of treatment burden requires consideration of both patient-level and health-system factors.

Patient-reported outcomes (PROs) provide information that may not be fully captured by routine clinical and laboratory assessments. Symptoms such as fatigue, pain, gastrointestinal disturbances, sleep problems, and emotional difficulties may persist despite adequate disease control. Incorporating PROs into CML care can therefore provide a more comprehensive assessment of treatment-related symptoms and health-related quality of life [7-9].

Contemporary CML management increasingly emphasizes patient-centered care, integrating treatment goals, comorbidities, toxicity, accessibility, affordability, adherence, and quality of life with molecular disease control [2,10]. However, real-world studies evaluating these interconnected dimensions simultaneously remain limited.

Therefore, this study aimed to evaluate treatment accessibility, medication-related burden, treatment-related knowledge and monitoring, and patient-reported health-related quality of life among patients with CML receiving BCR::ABL1 TKI therapy. We also aimed to identify factors independently associated with global health status/quality of life, thereby providing a multidimensional assessment of the patient experience and identifying potentially modifiable factors relevant to patient-centered CML care.

Materials and Methods

Study Design

This study was designed as a cross-sectional observational study to evaluate treatment accessibility, medication-related burden, treatment-related knowledge and monitoring, and patient-reported health-related quality of life among patients with chronic myeloid leukemia (CML) receiving BCR-ABL tyrosine kinase inhibitor (TKI) therapy. The study used a multidimensional approach incorporating sociodemographic, disease-related, treatment-related, socioeconomic, accessibility, and patient-reported outcomes.

Study Setting and Study Period

The study was conducted among patients with CML receiving TKI therapy at the Department of Oncology at National Institute of Medical Sciences and Research from October 2024 to September 2026. Patients were recruited from outpatient and inpatient oncology clinic.

Study Population

The study population comprised patients diagnosed with CML who were receiving BCR-ABL TKI therapy at the study center. The final analytic sample consisted of 390 patients. Clinical and treatment characteristics included disease duration, disease phase, BCR-ABL status, current TKI, treatment duration, previous TKI exposure, and prescribed TKI dose.

Eligibility Criteria

Patients with a documented diagnosis of CML who were receiving BCR-ABL TKI therapy at the time of assessment were eligible for inclusion. Participants were required to be able to provide information on their sociodemographic, disease, treatment, accessibility, and medication-related characteristics and to complete the EORTC QLQ-C30 questionnaire. Patients who had a diagnosis other than CML, were not receiving TKI therapy, were unable to provide reliable study information or complete the questionnaire, or declined or withdrew informed consent were excluded.

Sample Size

The sample size was calculated using the single-population proportion formula:

$$n = \frac{Z^2 p(1-p)}{d^2}$$

where n is the required sample size, Z is the standard normal deviate corresponding to a 95% confidence level (1.96), $p$is the anticipated proportion of patients experiencing treatment-related financial burden (52.75%), and $d$is the desired absolute precision (5%).

A previous Indian study of 400 patients with chronic myeloid leukemia receiving imatinib reported that 52.75% of patients perceived their treatment as financially burdensome, considering medication costs, investigations, travel and accommodation expenses, and loss of working days [11].

Accordingly:

$$n = \frac{(1.96)^2(0.5275)(1-0.5275)}{(0.05)^2}$$

$$n = \frac{(1.96)^2(0.5275)(0.4725)}{0.0025}$$

$$n = 382.9$$

Thus, the minimum required sample size was approximately 383 patients.

Data Collection

Data were collected using a structured study data form containing sociodemographic, clinical, treatment, accessibility, financial, social, and treatment-monitoring variables. Sociodemographic variables included age, sex, education, marital status, occupation, monthly family income, and socioeconomic status. Disease and treatment variables included duration since diagnosis, disease phase, BCR-ABL result, current TKI, treatment duration, TKI dose, and previous TKI therapy.

Treatment accessibility and medication-related burden were assessed through drug availability, insurance/PM-JAY coverage, financial assistance, investigation expenditure, travel costs, and monthly treatment expenditure. Employment, family, and social impact were assessed using job loss, family support, and changes in social activities.

Assessment of Treatment Knowledge, Monitoring, and Satisfaction

Patients' understanding of BCR-ABL, TKI treatment, and monitoring was assessed using an ordinal response scale ranging from very poor to excellent. Treatment monitoring was assessed according to the reported regularity of CBC, BCR-ABL PCR, and physician visits. Satisfaction with treatment efficacy was categorized as very poor, poor, moderate, good, or excellent. Patients also reported the degree of burden related to treatment side effects and cost, categorized as mild/acceptable, moderate, significant, or severe.

Assessment of Health-Related Quality of Life

Patient-reported health-related quality of life was assessed using the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (EORTC QLQ-C30) [12]. The questionnaire comprises functioning domains, symptom domains/items, and a global health status/quality-of-life scale. Scores are transformed to a 0-to-100 scale. Higher scores indicate better functioning and health-related quality of life for functioning and global health domains, whereas higher scores indicate greater symptom or financial burden for symptom and financial items.

The primary patient-reported outcome for the regression analysis was the global health status/quality-of-life score of the EORTC QLQ-C30.

Socioeconomic Status

Socioeconomic status was assessed using the Modified Kuppuswamy Socioeconomic Scale, with higher scores indicating higher socioeconomic status. Participants were classified into 5 socioeconomic classes according to their total socioeconomic score: Class I (Upper), 26–29; Class II (Upper-middle), 16–25; Class III (Middle), 11–15; Class IV (Lower-middle), 5–10; and Class V (Lower), <3–4 [13].

Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics [version 31]. Categorical variables were summarized using frequencies and percentages. Continuous variables were summarized using mean (SD) and median (range), as appropriate. The final analysis included 390 participants.

For the primary multivariable analysis, global health status/quality of life was treated as a continuous dependent variable. A multiple linear regression model using the Enter method was performed to examine independent associations between global QoL and age, sex, disease duration, treatment duration, drug availability, financial assistance, understanding of BCR-ABL/TKI treatment and monitoring, physician visits, and significant side effect and cost burden. Categorical predictors were entered according to prespecified reference categories. The reference categories were female sex, unavailable drug, no insurance/financial assistance, and missed physician visit. Regression coefficients were reported as unstandardized B coefficients, standard errors, standardized β coefficients, 95% confidence intervals, and P values. Model fit was assessed using R^2 and adjusted R^2, and overall model significance was assessed using the F statistic. Multicollinearity was assessed using tolerance and variance inflation factor (VIF) statistics. Statistical significance was defined as a 2-sided $P<.05$.

Ethics Approval

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Institutional Ethics Committee, Nims University Rajasthan, Jaipur, India (Approval No. NIMSUR/IEC/2024/1279)

Results

Participant Characteristics

A total of 390 patients with chronic myeloid leukemia (CML) were included in the analysis. The mean (SD) age was 43.4 (15.6) years, with a median age of 42.5 years (range, 2–80 years). There were 208 male patients (53.3%) and 182 female patients (46.7%). Most patients had secondary education (130 [33.3%]) or higher secondary education (106 [27.1%]), while 41 (10.5%) had no formal education. The majority were married (358 [91.8%]). Private employees (117 [30.0%]) and homemakers (109 [27.9%]) constituted the largest occupational groups. The most common monthly family income category was ₹50,000–₹99,999 (171 [43.8%]).

Job loss was reported by 10 patients (2.6%). Family support was reported as strong by 245 patients (62.8%) and good by 121 (31.0%), while 24 (6.2%) reported limited support. Social activities were unchanged in 134 patients (34.4%), slightly reduced in 142 (36.4%), moderately reduced in 101 (25.9%), and reduced a lot in 13 (3.3%).

Regarding socioeconomic status, 12 patients (3.1%) were classified as upper class (Class I), 58 (14.9%) as upper-middle class (Class II), 171 (43.8%) as middle class (Class III), 101 (25.9%) as lower-middle class (Class IV), and 48 (12.3%) as lower class (Class V).

Table 1: Sociodemographic characteristics of the study participants (N=390)

Variable	Category	n	%
Age, (years)	Mean ± SD; median (range)	43.4 ± 15.6	42.5 (2–80)
Sex	Male	208	53.3
	Female	182	46.7
Education	No Formal Education	41	10.5
	Primary Education	15	3.84
	Secondary Education	130	33.3
	Higher Secondary	106	27.1
	Graduate	80	20.5
	Post Graduate	18	4.6
Marital status	Married	358	91.8
	Unmarried	32	8.2
Occupation	Private employee	117	30.0
	Homemaker	109	27.9
	Business	71	18.2
	Student/Unemployed	25	6.4
	Government employee	25	6.4
	Farmer	20	5.1
	Self-employed	19	4.9
	Retired	4	1.0
Monthly family income	<₹20,000	48	12.3
	₹20,000–₹49,999	101	25.9
	₹50,000–₹99,999	171	43.8
	₹1,00,000–₹2,49,999	58	14.9
	≥₹2,50,000	12	3.1
Job loss	Yes	10	2.6
	No	380	97.4
Family support	Strong	245	62.82
	Good	121	31.02
	Limited	24	6.15
Social activities	No changed	134	34.35
	Slightly reduced	142	36.41
	Moderately reduced	101	25.89
	Reduced a lot	13	3.33
Socioeconomic status	Upper (Class I)	12	3.1
	Upper-Middle (Class II)	58	14.9
	Middle (Class III)	171	43.8
	Lower-middle (Class IV)	101	25.9
	Lower (Class V)	48	12.3

Values are presented as frequency (n) and percentage (%); percentages are based on the total sample of 390 patients

Disease and Treatment Characteristics

The mean (SD) duration since diagnosis was 96.5 (51.5) weeks, with a median of 100 weeks (range, 2–179 weeks), whereas the mean (SD) current treatment duration was 50.4 (40.9) weeks, with a median of 35 weeks (range, 2–175 weeks). BCR-ABL was detected in 341 patients (87.4%). Most patients were in the chronic phase (374 [95.9%]), while 11 (2.8%) and 5 (1.3%) were in the accelerated and blast phases, respectively.

Imatinib was the most frequently used TKI (273 [70.0%]), followed by dasatinib (61 [15.6%]), bosutinib (40 [10.3%]), and nilotinib (16 [4.1%]). Most patients received 400 mg once daily (253 [64.9%]). Previous TKI exposure was absent in 289 patients (74.1%).

Table 2: Disease and treatment characteristics

Variable	Category / summary	n / mean ± SD	% / median (range)

Duration since diagnosis, (weeks)	Mean ± SD; median (range)	96.5 ± 51.5	100.0 (2–179)
Current treatment duration, (weeks)	Mean ± SD; median (range)	50.4 ± 40.9	35.0 (2–175)
BCR-ABL result	Detected	341	87.4
	Not detected	49	12.6
Disease phase	Chronic phase	374	95.9
	Accelerated phase	11	2.8
	Blast phase	5	1.3
TKI name	Imatinib	273	70.0
	Dasatinib	61	15.6
	Bosutinib	40	10.3
	Nilotinib	16	4.1
Dose	400 mg once daily	253	64.9
	100 mg once daily	71	18.2
	300 mg twice daily	66	16.9
Previous TKI	None	289	74.1
	Imatinib	44	11.3
	Nilotinib	29	7.4
	Dasatinib	28	7.2

Categorical variables are presented as n (%). Continuous variables are presented as mean ± standard deviation (SD) and median (range). Treatment duration is reported in weeks. TKI = tyrosine kinase inhibitor; BCR-ABL = breakpoint cluster region-Abelson.

Treatment Accessibility and Medication-Related Burden

Most patients reported that their medication was always available (359 [92.1%]), whereas 31 (7.9%) reported that drugs were sometimes unavailable. Insurance/PM-JAY coverage was reported by 301 patients (77.2%), while 89 (22.8%) had no such coverage. Financial assistance was unavailable for 203 patients (52.1%), whereas 115 (29.5%) received insurance-based assistance and 72 (18.5%) received other forms of assistance.

Investigation expenditure was ₹500–₹1,500 for 128 patients (32.8%), ₹1,500–₹2,500 for 86 (22.1%), ₹2,501–₹3,500 for 78 (20.0%), and greater than ₹3,500 for 98 (25.1%). Travel costs were less than ₹500 for 72 patients (18.5%), ₹500–₹1,000 for 169 (43.3%), ₹1,001–₹2,500 for 86 (22.0%), and greater than ₹2,500 for 63 (16.2%). The mean (SD) monthly treatment expenditure was ₹6,580.2 (₹1,600.3), with a median of ₹6,000 (range, ₹4,900–₹10,000).

Table 3: Treatment accessibility and medication-related burden

Variable	Category / summary	n / mean ± SD	% / median (range)
Drug availability	Always available	359	92.1
	Sometimes unavailable	31	7.9
Insurance/PM-JAY	Yes	301	77.2
	No	89	22.8
Financial assistance	No financial assistance	203	52.1
	Insurance	115	29.5
	Other assistance	72	18.5
Investigation expenditure	₹500 - ₹1,500	128	32.8
	₹1,500 - ₹2,500	86	22.1
	₹2,501 - ₹3,500	78	20.0
	>₹3500	98	25.1
Travel cost	<₹500	72	18.5
	₹500 - ₹1000	169	43.3
	₹1,001 - ₹2500	86	22.0

	>₹2,500	63	16.2
Monthly treatment expenditure	Mean ± SD; median (range)	6580.2 ± 1600.3	6000.0 (4900.0 – 10000.0)

Values are presented as n (%) for categorical variables and mean ± SD with median (range) for monthly treatment expenditure. Treatment accessibility variables reflect the categories recorded in the study dataset. PM-JAY = Pradhan Mantri Jan Arogya Yojana.

Treatment Knowledge, Monitoring, and Satisfaction

Understanding of BCR-ABL, TKI treatment, and monitoring was rated as very poor in 98 patients (25.1%) and poor in 126 (32.3%), indicating that 224 patients (57.4%) had poor or very poor understanding. Moderate, good, and excellent understanding was reported by 74 (19.0%), 69 (17.7%), and 23 (5.9%) patients, respectively.

Regular CBC, BCR-ABL PCR, and physician visits were reported by 314 patients (80.5%); 65 (16.7%) sometimes missed monitoring, and 11 (2.8%) frequently missed it. Satisfaction with treatment efficacy was rated as good or excellent by 148 patients (38.0%). Side effects and cost were considered mild/acceptable by 163 patients (41.8%), moderate by 136 (34.9%), significant by 72 (18.5%), and severe by 19 (4.9%).

Table 4: Treatment knowledge, monitoring, and satisfaction

Variable	Category	n	%
Understanding of BCR-ABL, TKI treatment and monitoring	Very poor	98	25.1
	Poor	126	32.3
	Moderate	74	19.0
	Good	69	17.7
	Excellent	23	5.9
Regular CBC, BCR-ABL PCR and physician visits	Regular	314	80.5
	Sometimes missed	65	16.7
	Frequently missed	11	2.8
Satisfaction with treatment efficacy	Very poor	40	10.3
	Poor	100	25.6
	Moderate	102	26.2
	Good	138	35.4
	Excellent	10	2.6
Side effects and cost	Mild/acceptable	163	41.8
	Moderate	136	34.9
	Significant	72	18.5
	Severe	19	4.9

Values are presented as frequency (n) and percentage (%), based on the patients' responses for each variable. CBC = complete blood count; PCR = polymerase chain reaction; TKI = tyrosine kinase inhibitor.

Patient-Reported Quality of Life

Patient-reported quality of life was assessed using the EORTC QLQ-C30. Mean (SD) scores were 56.7 (12.1) for physical functioning, 59.0 (12.9) for role functioning, 39.7 (18.3) for emotional functioning, 48.1 (19.3) for cognitive functioning, and 49.7 (18.4) for social functioning.

Among symptom scales and single items, mean (SD) scores were 54.0 (17.6) for fatigue, 47.4 (16.1) for nausea/vomiting, 50.3 (19.8) for pain, 48.4 (23.8) for dyspnea, 52.7 (27.4) for insomnia, 52.1 (28.9) for appetite loss, 51.2 (29.2) for constipation, 43.1 (24.6) for diarrhea, and 50.1 (25.6) for financial difficulties. The mean (SD) global health status/QoL score was 46.6 (15.5), indicating relatively poor overall QoL in the study population (**Fig**.

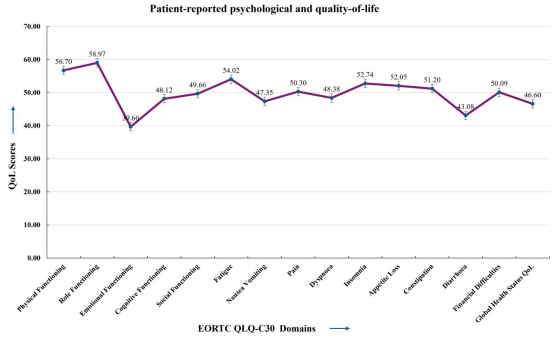

Figure 1. Patient-reported Psychological and quality of life

Factors Associated with Global Health Status/Quality of Life

A multivariable linear regression model was used to examine factors associated with global health status/QoL. The model was statistically significant ($F_{9,380}$=10.139; P<.001) and explained 19.4% of the variance in global QoL (adjusted R^2=0.175).

Better understanding of BCR-ABL, TKI treatment, and monitoring was independently associated with higher global QoL (B=4.112; standardized β=0.131; 95% CI, 1.192–7.031; P=.006). In contrast, significant side effect and cost burden was strongly associated with lower global QoL (B=−14.067; standardized β=−0.383; 95% CI, −17.456 to

−10.678; P<.001), representing the strongest standardized association in the model.

Sex, disease duration, treatment duration, drug availability, financial assistance, and physician visits were not independently associated with global QoL (all P>.05).

Table 5: Multivariable linear regression analysis of factors associated with global health status/quality of life (EORTC QLQ-C30)

Predictor	B	SE	Standardized β	95% CI for B	p-value
Age (years)	0.069	0.046	0.070	−0.022 to 0.160	0.134
Sex	−2.730	1.451	−0.088	−5.583 to 0.123	0.061
Disease duration (weeks)	−0.012	0.017	−0.040	−0.046 to 0.022	0.489
Treatment duration (weeks)	−0.008	0.022	−0.022	−0.052 to 0.035	0.701
Drug availability	−0.595	2.686	−0.010	−5.875 to 4.686	0.825
Financial assistance	−1.439	1.457	−0.046	−4.304 to 1.426	0.324
Understanding of BCR-ABL, TKI treatment and monitoring	4.112	1.485	0.131	1.192 to 7.031	**0.006**
Physician visit	−1.537	1.821	−0.039	−5.118 to 2.045	0.399
Significant side effect and cost burden	−14.067	1.724	−0.383	−17.456 to −10.678	**<0.001**

B indicates unstandardized regression coefficient; SE, standard error; β, standardized regression coefficient; CI, confidence interval; TKI, tyrosine kinase inhibitor; BCR-ABL, breakpoint cluster region–Abelson. The dependent variable was global health status/quality of life (EORTC QLQ-C30). Reference categories were female sex, drug unavailability, no insurance/financial assistance, and missed physician visit. Boldface indicates statistically significant associations at P<.05.

Discussion

We evaluated treatment accessibility, medication-related burden, treatment knowledge and monitoring, and patient-reported quality of life among 390 patients with CML receiving BCR::ABL1 TKI therapy. The principal findings were that overall global health status/quality of life was relatively poor, with substantial impairment in emotional, cognitive, and social functioning and moderate symptom burden. More than half of the patients reported poor or very poor understanding of BCR-ABL, TKI treatment, and monitoring, despite most reporting regular disease monitoring. In multivariable analysis, significant side effect and cost burden was the strongest factor associated with poorer global quality of life, whereas better understanding of BCR-ABL, TKI treatment, and monitoring was independently associated with better quality of life.

The relatively low global health status/QoL score in our cohort (mean, 46.6) is consistent with previous evidence showing that patients with CML receiving TKI therapy may continue to experience impaired HRQoL despite effective disease-directed treatment

[3,6]. In a large cross-sectional study of 828 patients with CML receiving TKIs, Jiang et al. reported that patients with higher treatment-related out-of-pocket expenses had poorer physical and mental HRQoL [8]. Similarly, Efficace et al. demonstrated that HRQoL remains an important concern among patients receiving long-term imatinib, with younger patients and women experiencing greater limitations in some domains [3]. Our findings extend this evidence by using the EORTC QLQ-C30 and by examining treatment accessibility, perceived treatment burden, and patient understanding within the same clinical cohort.

The pattern of QLQ-C30 scores also provides insight into the nature of the burden experienced by our patients. Emotional functioning was the lowest functioning domain (mean, 39.7), followed by cognitive and social functioning, while fatigue was the most prominent symptom domain (mean, 54.0). These findings are clinically relevant because CML patients may remain in long-term treatment while experiencing persistent symptoms that are not necessarily reflected by conventional hematologic or molecular assessments [4,7,14]. In an observational study of patients receiving imatinib, Efficace et al. found that fatigue was independently and consistently associated with poorer physical and mental HRQoL, emphasizing the importance of patient-reported symptoms in CML care [4]. Patient-reported adverse effects have likewise been associated with interference in daily life and quality of life among patients receiving oral TKIs [7].

A major finding of our study was the strong association between significant side effect and cost burden and poorer global QoL. This variable had the largest standardized coefficient in the regression model ($\beta=-0.383$; $P<.001$), suggesting that the perceived burden arising from treatment toxicity and financial demands was more strongly associated with QoL than the demographic and treatment-access variables included in the model. This finding is consistent with the study by Jiang et al., in which higher annual out-of-pocket expenditure was independently associated with poorer HRQoL across multiple SF-36 domains [8]. It is also consistent with evidence from other cancers demonstrating an association between financial strain and poorer quality of life [9].

Our findings are particularly relevant in the Indian context. Gupta et al., in a 400-patient Indian study of patients receiving imatinib, reported that 52.75% of patients perceived financial burden related to drug and investigation costs, travel, hospital stays, and loss of working days; treatment interruptions and missed doses were also reported [10]. In our cohort, medication availability itself was relatively high, with 92.1% reporting that drugs were always available, and 77.2% reported insurance/PM-JAY coverage. Nevertheless, monthly treatment expenditure remained substantial, with a mean expenditure of approximately ₹6,580, and 52.1% reported no financial assistance. Thus, access to medication should not be equated with absence of treatment-related financial burden. Patients may obtain their medication consistently while still experiencing financial strain from treatment, investigations, travel, and other indirect costs.

Interestingly, neither drug availability nor financial assistance was independently associated with global QoL in our multivariable model. This may reflect the relatively high availability of medication in this cohort and the fact that these variables measure access rather than the patient's overall perception of treatment burden. In contrast, the combined measure of significant side effect and cost burden directly captured the patient's experience of treatment and demonstrated a strong association with QoL. This distinction is important: objective access to therapy and subjective treatment burden are related but not interchangeable constructs [8-10]. The present findings therefore support assessment of the patient's perceived treatment burden rather than relying solely on whether medication is available or whether financial assistance exists.

Another important finding was the association between understanding of BCR-ABL, TKI treatment, and monitoring and better global QoL ($\beta=0.131$; $P=.006$). More than half of the participants reported poor or very poor understanding, despite 80.5% reporting regular CBC, BCR-ABL PCR, and physician visits. This apparent discrepancy suggests that regular contact with health services does not necessarily translate into adequate understanding of the disease and its treatment. Previous Indian evidence has also identified suboptimal patient awareness as an important challenge in TKI-based CML care [10]. Qualitative evidence similarly indicates that inadequate treatment knowledge, information needs, and difficulties managing treatment may influence adherence and patients' treatment experiences [11].

The absence of an independent association between physician visit attendance and global QoL is also noteworthy. Although regular monitoring is essential for appropriate CML management, attendance alone may not capture the quality of communication, understanding of treatment recommendations, or the extent to which patients participate in treatment decisions. Evidence supporting patient-centered assessment in CML emphasizes the importance of incorporating the patient's perspective and HRQoL alongside conventional disease measures [5,6].

The lack of significant associations between age, sex, disease duration, treatment duration, drug availability, financial assistance, and physician visits and global QoL should be interpreted cautiously. Previous studies have identified demographic factors such as female sex and increasing age as determinants of poorer HRQoL in some CML

populations. Jiang et al., for example, reported lower HRQoL in women and with increasing age across selected domains [8]. In our cohort, however, sex and age were not statistically significant independent predictors of global QoL. Differences in study population, HRQoL instrument, treatment characteristics, and covariate selection may account for these differences.

Our findings have several clinical implications. The results suggest that evaluation of CML treatment should extend beyond molecular response and treatment availability to include patient-reported treatment burden and quality of life. Patients reporting substantial adverse effects or financial difficulties may benefit from early supportive interventions, treatment optimization, financial assistance, and closer assessment of treatment-related concerns [4,7,14,15]. The broader consequences of CML treatment should also be considered, as previous evidence has shown that ability to work is an important determinant of quality of life among patients with CML [16]. Similarly, structured education regarding BCR-ABL monitoring, TKI therapy, adverse effects, and the importance of treatment continuity may help improve patients' understanding and potentially their treatment experience. Importantly, these findings should be interpreted as associations rather than evidence that improving knowledge or reducing treatment burden will necessarily cause an improvement in QoL.

This study has several limitations. First, the cross-sectional design precludes determination of temporal or causal relationships between treatment burden, knowledge, and QoL. Second, several variables were based on patient self-report and may therefore be affected by recall or reporting bias. Third, the financial variables assessed in this study do not represent the same construct as annual out-of-pocket TKI expenditure used in previous studies; therefore, direct quantitative comparison of effect sizes is inappropriate. Finally, the findings may not be generalizable to all patients with CML because treatment access, financial support, socioeconomic circumstances, and health care delivery vary across settings.

Conclusion

Our findings indicate that treatment-related adverse effects and financial burden are important determinants of patient-reported quality of life in CML, while better understanding of BCR-ABL, TKI treatment, and monitoring is associated with better QoL. These results reinforce the importance of integrating patient-reported outcomes, treatment-burden assessment, and patient education into routine CML care. A patient-centered approach that addresses both the effectiveness of TKI therapy and the burden experienced by patients may help optimize long-term treatment outcomes and quality of life.

Funding

The authors declare that no funds, grants, or other financial support were received for conducting this study or preparing this manuscript.

Competing Interests

The authors declare that they have no relevant financial or non-financial interests to disclose.

Acknowledgements

The authors would like to thank the patients who participated in the study and the clinical and laboratory staff of the Department of Oncology, NIMS University Rajasthan, Jaipur, India, for their valuable support in patient care and data collection.

Author Contributions

Md Rabiul Parwana: Conceptualization, methodology, data collection, data curation, formal analysis, and writing-original draft; *Yogesh Kumar Singh*: Supervision, study coordination, methodology, interpretation of results, and writing-review and editing; *Sourav Debnath:* Methodology, data interpretation, and writing-review and editing; *Prachi Saban:* Data collection, investigation, and writing-review and editing; *Natasha Modi:* Clinical/pathological interpretation and writing-review and editing. All authors read and approved the final manuscript and agreed to be accountable for all aspects of the work.

Consent to Participate

Written informed consent was obtained from all individual participants included in the study. For participants under the applicable age of consent, informed consent was obtained from their parent or legal guardian.

Consent to Publish

Not applicable. The manuscript does not contain identifiable individual information or images requiring consent for publication.

Data Availability

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request, subject to institutional and ethical restrictions.

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