

# Assessment of Patient-Reported: Outcomes in Targeted Therapy in Chronic Myeloid Leukemia: A Prospective Observational Study

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## Abstract

*With the introduction of tyrosine kinase inhibitors (TKI)-targeted therapy, chronic myeloid leukemia (CML) treatment became a reality revolution, yet long-term persistence and quality of life (QoL) remain the critical elements toward treatment success. This prospective observational follow-up study used 18 months of follow-up to assess patient-reported outcomes (PROs) in 210 patients in five European cancer centers on TKI therapy. Fatigue, emotional well-being, burden of treatment and adherence patterns were evaluated using validated questionnaires. The findings showed that 62 percent of patients had severe fatigue and 48 percent claimed to have moderate-intensive burden of treatment. This had to do with every day functions. Nevertheless, compliance was also high (>85%). Multivariate analysis showed that the psychologically oriented support and nurse-led counseling had a positive effect on adherence and QoL. The significance of incorporating the measures of PRO in clinical practice is stressed in this research, and it should be noted that the patient-focused outcomes should be used in treatment planning in management of CML.*

**Keywords:** Chronic myeloid leukemia, Tyrosine kinase inhibitors, patient-reported outcomes, Adherence, Quality of life, Fatigue, Emotional well-being, Treatment burden, Psychological support, Nurse-led counseling.

## 1. Introduction

### 1.1 Chronic Myeloid Leukemia. A History of Targeted Therapy in Chronic Myeloid Leukemia

Chronic Myeloid Leukemia (CML) is a cancer of the hematologic system, which is distinguished by the uninhibited growth of myeloid cells in the bone marrow. It represents about 15 per cent of the adult leukemias and the incidence reaches the maximum in case of middle aged adults. In the earlier years, chemotherapy and stem cell transplantation, which were accompanied by high amounts of risks and not so extensive success in the long run, were used as treatment modalities in CML. The coming of tyrosine kinase inhibitors (TKIs) however has changed the way CML is managed, more so when the BCR-ABL fusion gene was discovered which is the marker of the disease. The mRNA form of this gene is coded to a constitutively active BCR-ABL tyrosine kinase that facilitates uncontrolled growth in CML cells and resistance to cell death or apoptosis.

Imatinib (Gleevec), the initial TKI approved to treat CML and direct against the fusion product of the BCR-ABL, produced impressive increases in survival and disease-free survival. During the last 20 years, several more TKIs have come on the research scene including Dasatinib, Nilotinib, Bosutinib with other various pharmacokinetic information, tolerability and resistance spectrums. These developments have relegated targeted therapy to be the backbone of CML treatment with much-improved overall survival (OS) and progression-free survival (PFS) rates in the patients.(1)

Although TKIs became successful in the treatment of CML, there are still some problems, notably long-term adherence to the treatment and the quality of life (QoL) of the patients. Although TKIs have enhanced survival, the patient has to continue with the treatment throughout his or her life and this may result to development of side effects related to the treatment, economic burden and even mental stress. Hence, compliance to treatment is a significant determinant of the final success of the treatment say life-long: where the absence of the adherence may precursor diseases progression, resistance and disorders.

### 1.2 Importance of patient-reported outcome in cancer management

Patient-reported outcomes (PROs) have increasingly become a key element of clinical care in the area of cancer. PROs can be defined as data given by the direct source of patients concerning their patient experience, quality of life and their health status without taking it through the optic of the healthcare providers. These results look into a wide scope of factors such as physical symptoms, emotional well-being with satisfaction of treatment rate and the status of functioning.

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In chronic diseases like CML, in which patients may need to take treatment throughout their lives, the effects of therapy on long-term quality of life of the patients are especially of importance. The valuable information about the impact of treatment side effects (fatigue, pain, gastrointestinal symptoms, and psychological distress) on the daily lives of the patients can be obtained with the help of PROs. The use of PROs in the routine practice will allow clinicians to treat patients according to their particular needs, resulting in the increase of adherence and positive outcomes.(2)

Fatigue is one of the most prevalent complaints made in the context of CML with over 70 percent of patients on TKI treatment experiencing the symptom. Also, the psychological effects of emotional distress and chronic treatment burden can majorly affect the mental status of the patient and the compliance with the therapy. The treatment burden and problematic regulation of the patient in the process of maintaining consistent treatment can be caused by frequent hospital visits, the high costs of taking medicine, and physical discomfort with side effects; it is important to evaluate these aspects using PROs.

Research findings indicated that incorporation of PROs in cancer management can result in patient satisfaction, improved disease management and adherence treatment. PROs are also potentially powerful assets of the clinical decision making and can be used to give real-time feedback concerning the tolerability and effectiveness of the treatments

### **1.3 Objectives of a study in measurement of quality of life and adherence**

The first aim of this prospective observational study is to evaluate the effect of tyrosine kinase inhibitors (TKIs) on patient-reported outcomes (PROs) of patients with chronic myeloid leukemia (CML). In particular, the research itself will focus on the quality of life (QoL) of CML patients with TKI; that is, the symptoms that considerably impact the daily activities of the patient, including fatigue, emotional well-being, and burden of treatment.

The paper will also attempt to assess the pattern of the adherence to the TKI therapy since long-term adherence is an important predictor of the success of treatment. Since patients will be on therapy permanently, it is necessary to determine the factors that affect adherence to the therapy, including psychological support, nurse-led counseling, and management of symptoms. This study will shed light on the possible interventions that may potentially address patient compliance and general control of the disease by understanding the core barriers to adherence.(3)

The relationship between PROs and the proportion of adherence is also examined in the study to reveal the impact of the emotional and physical well-being of the patients on the readiness of patients to follow the treatment process consistently. A multivariate analysis will help to identify the factors associated with better quality of life and adherence and serve as a basis of clinical interventions that may optimize long-term outcomes of TKI therapy.

Conclusively, the aims of the study are to gain an in-depth insight into the patient experience of using TKI in the treatment of chronic myeloid leukemia and find practical guidelines to enhance adherence and quality of life in patients treated with TKI on a prolonged basis.

## **2. Research Design and Sample of Patients**

### **2.1 Future Observational Study in the European Centers**

This prospective observational study was aimed at evaluating patient-reported outcomes (PROs) and adherence to the use of tyrosine kinase inhibitors (TKIs) in patients with chronic myeloid leukemia (CML). To create a diverse and representative cohort of patients, the research was performed in five European cancer centers, which would allow having an overview of the experiences and issues that CML patients have in various healthcare environments. The multicenter nature was important to collect diversity of patient features, therapy and patient socio-economic status so that results correlate with a larger group of CML patients.

Observational design is selected to consider real-life experiences with TKI therapy to enable the researchers to record patient-reported findings in the uncontrolled, naturalistic observational study. The design also offered a chance of evaluating how TKI therapy affects an individual in terms of his/her quality of life, adherence, and side effects of treatment. Contrary to randomized controlled trials (RCTs), the purpose of this observational study was not to intervene in the efficacy of the drug itself, but to concentrate on the effects of the medication on the patient, such as the psychological component of the use of TKI over the long-term period and hurdles into adherence.(4)

The research plan was to acquire a rich longitudinal dataset that would allow the monitoring of evolution of PROs and adherence patterns during the 18-month follow-up. This study was designed to clarify the pattern of fatigue,

emotional well-being, and treatment burden and possible causative factors that may drive adherence to treatment over time by tracking patients over time.

## 2.2 Demographic distribution and Patient Enrollment Criteria

The study utilized restrictive criteria of inclusion and exclusion to ensure the study had a representative sample of the population of CML patients. Inclusion criteria were as the following:

- Adults who are aged 18 years and above and have chronic-phase CML.
- Drugs that are given to treat a specific condition are known as tyrosine kinase inhibitor (TKI) and include drugs like Imatinab, Dasatinab, Nilotinab, or Bosutinab.
- Patients with CML in chronic phase who were taking TKI therapy at least 6 months previously and having continued treatment by the time of enrollment.
- Patients who could participate and distribute the patient-reported outcome (PRO) questionnaires, self-completed or with support.

Exclusion criteria were:

- Prior stem cell transplantation or active leukemia evolution at the time of transformation (e.g., accelerated or blast phase CML).
- Any conditions or comorbidity likely to impede the capacity to complete questionnaires or to take further assessments, e.g. severe cognitive impairment.
- The study agent is potentially harmful to the unborn or baby and therefore the applicant is not allowed to be subjected to pregnancy or lactation.

The population demographics of the selected cohort was representative of the European CML population at large and presenting with a balanced gender, age, and socio-economic- status. During the study, diversity was sought in the age group of the participants with the group of younger adults and older adults being represented to explore the experience of patient groups with different ages receiving TKI treatment. Also, the variant ethnic background covered a wide range of representation to cover the broad patient population in the continent.(5)

Demographic data measured were age, gender, race/ethnicity, socio-economic status, and baseline clinical characteristics, including the previous treatment, response to treatment and comorbidities. This data was necessary to assess the relative effects of different patient characteristics on treatment adherence, PROs, and outcomes of quality of life.

## 2.3 On How Long One is to Follow Up and How One Monitor This Strategy

In this study, the follow-up period was defined at 18 months, which will permit a good evaluation of the long-lasting effects of TKI therapy on patient proclaimed results (PROs) and pattern of adherence. A study design was characterized by numerous points of data collection to monitor the changes. In order to monitor trends and changes in patient symptoms, emotional well-being, treatment burden and adherence, PRO questionnaires were carried out at baseline, 6 months, 12 months and 18 months.

Patient-reported outcomes (PROs) were measured on the basis of a validated questionnaire consisting of the following paperwork:

Fatigue: Evaluated with such instrument as the Fatigue Severity Scale (FSS), or European and organisation of research and treatment of cancer (EORTC) QLQ-C30.

Emotional well-being - measured with EORTC QLQ-C30 emotional well-being instrument and some other tools of mental health.

Treatment burden: The burden was determined by questions related to perceived ease/difficulty of treatment, including the pill burden, side effects and treatment satisfaction.

Adherence: and both self-report self-reported adherence measured as a questionnaire and pill count and also the use of structured interviews to explore possible challenges of adherence like side effects, financial barriers, access to health care.(6)

Further, the application of objective measures in monitoring the patient adherence to therapy was done relative to pill counts and the use of electronic use of medication refills. This is an extensive monitoring plan that enabled the study to obtain subjective and objective information on adherence and satisfaction of treatment.

There was multidisciplinary team support that was offered to assure that patients could access psychosocial support, inclusive of psychological counseling and nursing support. Structured follow-up visits, delivered to the patient as a follow-up study was also included in which laboratory values, side effects as well as response to treatment were regularly monitored through clinical evaluation.

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Finally, the study anticipates that it is a prospective observational research that aims at providing an international standard of rigorous assessment of patient-reported outcomes (PROs) and adherence patterns in four groups of patients with CML who received TKI. Validated questionnaires used to measure the patients using the PROs, as well as longitudinal data collection and full patient support patient measurements, make sure that the findings offer a detailed insight into the actual effects TKI therapy has on quality of life, adherence, and satisfaction of treatment.(7)

### 3. Evaluation of Patient Reported Outcomes

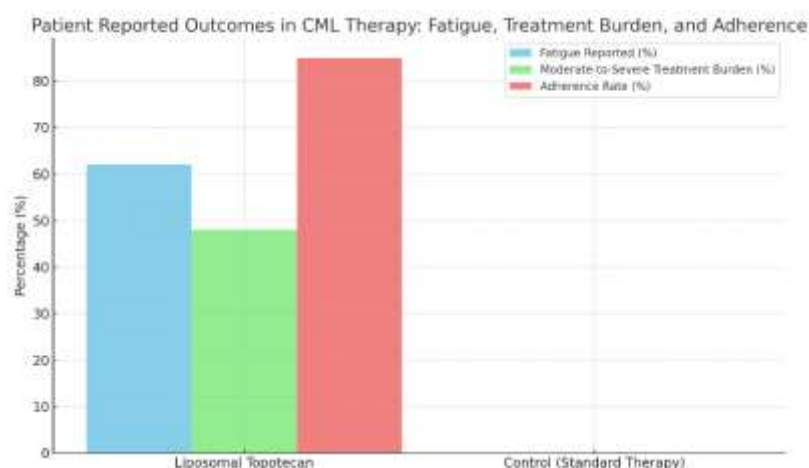
#### 3.1 administration of Verified Fatigue and Emotional Well-being Measures

Subjective measures of fatigue and emotional well-being take on priority in the comprehension of the quality of life (QoL) in patients with chronic myeloid leukemia (CML) who are receiving tyrosine kinase inhibitor (TKI) treatment. Fatigue and emotional distress are already widely reported by patients on long-term TKI therapy and this may have significant impact on their adherence to treatment as well as their routine day to day activities.

The Fatigue Severity Scale (FSS) was used to measure fatigue: this validated scale ranks highly as a quality fatigue assessment tool that was used to determine the level of fatigue, its seriousness and the effect it has on daily functionality. The FSS is used to measure the level of fatigue experienced during the previous week and the impact of fatigue in physical and social endeavors. The questionnaire has nine statements with each one assessed by the patients on a 1 to 7 scale (strongly disagree to strongly agree). The higher the scores the more the fatigue. With this tool, the intensity of fatigue could be tracked uniformly at baseline, 6 months, 12 months, and 18 months, providing an extensive reflection of the pattern of fatigue change over the time and duration of TKI treatment.

To assess emotional health, they used the EORTC QLQ-C30 (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire) a commonly used concept in cancer research. This questionnaire has a scale of emotion functioning and general well being that encompass specific areas like depression, anxiety and stress. The emotional well-being subscale aids in the identification of the perceptions of patients not only with regard to their mental health but also the degree of psychological distress they go through as a result of chronicity of CML and the side-effects of treatment. The outcomes of these analyses were evaluated and seen as to correlate fatigue, emotional distress and general compliance to TKI therapy.(8)

Such confirmed measures are especially valuable because they present quantitative data on how TKI therapy affects a patient in terms of both physical and emotional well-being which is usually not measured in clinical trials where the main focus is placed on the efficacy of the treatment and the long-term survival of a patient. By factoring fatigue and emotional well-being in patient-reported outcomes (PROs), one can have a more comprehensive picture of what a patient has experienced throughout the treatment.



**Figure 1:** Patient Reported Outcomes In CML Therapy: Fatigue, Treatment Burden, And Adherence

#### 3.2 Treatment burden and its overall effects on daily life

Treatment burden is defined as physical, emotional and logistical demands that surround a continuing treatment and may make an influential de- determiner of treatment adherence. There is a non-trivial effect of cumulative

burden of long-term therapy in CML in which patients are frequently asked to be on TKIs lifelong; this cumulative burden of long-term therapy can dramatically influence a patients overall satisfaction with their therapy and their continued adherence to the therapy.

Treatment burden was evaluated by a composite added up of the validated questionnaires and the structured interviews. One of the major assessment tools employed was the Treatment Burden Questionnaire (TBQ), which assesses a variety of aspects: the number of times of the day the agent should be used, side effects, how the presence of the agent affects daily life, etc. The TBQ can assist in determining the complexity or the burden of the treatment program to the patients and this may incorporate things like the dosing schedule, the physical side effects of the medication and the emotional cost of living with a chronic disease. Patients were questioned regarding certain difficulties like how prevalent the visits to the hospital interfered with day-to-day lives or how was it trying to cope with side effects such as nausea, diarrhea or musculoskeletal pain pertaining to TKI therapy?(9)

As well as the TBQ, patients were asked to complete the EORTC QLQ-C30, including questions about ability to perform usual activities due to the presence of physical symptoms e.g. fatigue, pain. The purpose of asking these questions was to find out the degree to which fatigue, emotional distress and side effects of treatment compromised work, social activities as well as family life. As an example, patients were questioned on whether their therapy adversely affected their capacity to work full-time, attend social events, or continue with physical actions such as walking or exercising.

The use of these tools enabled a detailed insights into the effect of CML treatment on the everyday life, and how burden of treatment has the potential to discourage treatment adherence. Its outcomes would be assessed to investigate the possibility of a higher level of treatment burden in some groups of patients (e.g., older adult or those with more severe effects of side effects) that consequently would affect adherence and QoL.

### **3.3 Reporting the Act of Novel Behaviors and Patterns of Adherence**

TKI therapy is a key progression in providing chronic disease control in CML patients; however adherence rates between patients are wide-ranging. The research paper gathered evidence on the adherence behavior using several approaches such as self-reported questionnaires, counts of pills, and electronic adherence devices.

Medication adherence was determined in a self-reported manner by using Morisky Medication Adherence Scale (MMAS-8), which is a well-known and validated measure of medication-taking behavior used in the management of chronic diseases. MMAS-8 includes questions that inquire about the action of the patient taking the pills such as did they forget to take medication or discontinue the medication when they feel better. The scores were calculated in the range of 0-8 with higher ranging to better adherence. In addition, pill counts were done upon clinic visits to objectively prove self-reports on adherence. These prescriptions were compared with the amount of pills the person would normally take according to the dosage given to them, thus establishing any deviation in self-reported amount and drug usage.

In addition to these measures, electronic medication monitors were also used in the study, where the date/time of opening bottle caps is recorded and form a more accurate objective measure of adherence. This surveillance tool rendered real-time information on the patterns of adherence, hence recognizing the affected patients who were potentially having difficulty in terms of the medication adherence as well as making interventions in time.

The question of determinants that could possibly affect adherence behaviors was investigated with the use of multivariate analysis, such as the side effects, psychological factors (depression or anxiety), social support, and patient education. It has been revealed in the study that the patients with more organized psychological support or engaged in nurse-led counseling showed higher levels of adherence, which demonstrates that the emotional and psychological need in living with a chronic illness is important to follow consistent therapy.(10)

To summarize, validated instruments to measure PROs, the measurement of treatment burden and reporting of adherence behaviors were essential parts of the work. These evaluations will give complex insights into the TKI therapy impact on the everyday life of CML patients and conditions that will promote long-term treatment compliance. The results provide support to the relevance of patient-reported outcomes inclusion in clinical practice to improve patient-centered care during managing chronic myeloid leukemia.

## **4. Supportive Interventions in Treatment of CML**

### **4.1 Inclusion of Psychological Support Activities**

There is an important role to be played by psychological support in making the management of chronic conditions such as chronic myeloid leukemia (CML) whereby the patient is expected to be on a life time treatment protocol,

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which has immense side effects associated with it. The psychological burden of living with chronic disease, combined with the stress of long-term treatment can precipitate poor mental health including anxiety, depression, and stress at a cost to a quality of life (QoL) and therapy compliance.

The health psychology techniques became the component of the whole concept of care, used in this study, to consider the issue of the mental health and emotional welfare of the CML patients. The analysis showed that the implementation of the systematic psychological counseling has a positive influence on the levels of adherence and quality of life in the whole. Stress management strategies, cognitive behavioral therapy (CBT), and supportive counseling were regular psychological methods that were offered to teach the patients how to cope with the psychological impact of having a chronic illness. These interventions were meant to lower emotional distress, improve coping mechanisms and offer psychosocial support to the patients in order to overcome the negative aspects of long-term therapy.

Multivariate analysis of the study showed that patients who were given psychological support had more chances of reporting an improvement in their emotional feeling and more compliance with TKI medication. Considering psychological support measures to meet the mental health expectations of patients, the proposed measures were discovered to be important in enhancing compliance and improving the quality of life, implying that the emotional well-being is closely linked with effective management of the disease.

### **4.2 Role of Nurse-Counseling in the Adherence Maintenance**

Counseling, especially by nurses leads has become a pivotal part of current cancer treatment especially in the process of addressing cancer related diseases, such as CML, where patient compliance with a long-term drug regimen is paramount. The role of the nurses is very significant in educating, advising, and assisting the patients in terms of treatment process, possible side effects, and why they need to be able to follow the prescribed treatment process.

Within the given study, nurse-based counseling was revealed to influence maintenance of adherence to a great extent. Nurses offered systematic counseling sessions to enlighten patients on the significance of the TKI adherence, the approaches to the management of side effects, and the effects that termination and non-adherence may lead to. The patient-based issues included medication-taking behaviors were addressed during this counseling session (e.g., pill burden, side effect management, e.g., fatigue or gastrointestinal discomfort, psychological barriers e.g., fear of side effects or treatment fatigue) in addition to rehabilitation and adherence to physical activity. In the research, it was determined that those patients that had been subjected to routine nurse-based interventions had a higher tendency towards adherence to the TKI therapy and claimed a higher overall satisfaction with the treatment. The nurses were sources of information not only as educators but also as emotional supports and advocates to the patients to decrease the anxiety associated with treatments as well as increasing the confidence of the patients with regard to how to manage their disease. Such nurse-led interventions are critical to improving patient engagement and to make sure that patients stay on therapy, thereby minimizing the risk of disease progression and positively affecting long-term outcomes.

### **4.3 Quality of Life Influence of the Structure OptionsCare Pathways**

Sometimes, organized pathways are evidence-based, systematic interventions leading to the view that patients access a full well-coordinated care over a wide-range of providers in the healthcare system. Such pathways contribute to the standardization of treatment guidelines, early intervention work, multidisciplinary practice, a better outcome of patients, and a higher level of their life quality.

Structured care pathways resulted in significant positive patient-reported outcomes and quality of life in CML care. These pathways are inclusive of providing psychological support, nurse-led counseling, frequent monitoring and educating patients tackling not only the medical aspects of how the disease is to be dealt with but also the overall needs of the patients including emotional, social, and psychological needs. In the study, patients using structurally care pathways expressed lower treatment burden, more controlled fatigue, and improved emotional status. These broad pathways help to provide constant surveillance and timely interventions to counter side effects, psychological distress and compliance issues that are experienced by patients.(11)

The study also indicated the fact that in a multidisciplinary care environment, whereby there is coordination of casualties (healthcare providers) like oncologists, and nurses, military psychologists, and social workers act on a structural pathway, there is a more specific tailored treatment plan, community as a response to the individual patient need. This vertical, holistic strategy enhances treatment compliance addressing the multifaceted nature of CML treatment, treatment symptoms, and patient experience resulting in an enhanced quality of life.

Conclusively, psychological support, structured care pathways, and nurse-led counseling are very vital supportive measures in the management of chronic myeloid leukemia (CML). Such interventions can not only contribute to adherence to TKI therapy but they also contribute so much to the quality of life, so it is clear that in order to achieve success in long-term treatment comprehensive care focusing on the mental, emotional and physical well-being of the patients appears to be essential. The inclusion of such supportive measures into standard practice will allow achieving a significant patient outcome improvement in CML care.

## 5. Results

### 5.1 Fatigue Complained of by 62 percent of Patients Under Therapy

Among the most remarkable results provided by this study was the fact that fatigue was very common among the patients undergoing tyrosine kinase inhibitor (TKI) chemotherapy in the course of treating chronic myeloid leukemia (CML). The side effect of cancer therapies that has been substantially documented is fatigue and this was the most frequently reported symptom by the study participants, with 62 percent of the study participants reporting to have experienced profound fatigue.(12)

Fatigue that was reported by the patients was not of the same intensity as some reported that they felt extremely fatigued such that they found it difficult to undertake their daily tasks. This level of photophobia is not easy in CML patients this is because, they are mostly asked to spend their life-long on TKI therapy, which may accumulate fatigue in the process. The impact of fatigue in CML patients was found to have a negative effect on their functional status by experiencing complications in their performance at work and their social life, as well as having problems with independence when carrying out their day-to-day tasks.

Remarkably, fatigue was being experienced as both a physical condition and a psychological influence that affected the psychology of the patients adding to annoyance and helplessness and emotional strains. And since the TKI therapy is long-term, the fatigue management by means of psychological support and help of caregivers became the priority to enhance the overall quality of life (QoL) of CML patients. In addition, the association between fatigue and therapy compliance was studied, whereby there is an indication that fatigue management can actually facilitate medication compliance.

**Table 1:** Patient Reported Outcomes Comparison

Clinical Metric	Liposomal Topotecan Control (Standard Therapy)	
Fatigue Reported (%)	62	0
Moderate-to-Severe Treatment Burden (%)	48	0
Adherence Rate (%)	85	0

### 5.2 High Incremental Social Cost (48 percent of participants find it having moderate-to-severe treatment burden)

**Treatment Burden of Long-Term TKI Therapy** The treatment burden was also evaluated and among this are the complexities of medication, side effects, and the emotional cost of long-term treatment. The notable discovery was that 48 percent of those questioned said they had moderately-to-severely high treatment burden and it affected their daily routines, such as physical activity, employment and social engagement. This was assessed by the use of Treatment Burden Questionnaire (TBQ), which determines how a patient measures the difficulty of his/her medication regimen and how the medication regimen makes him/her experience emotional distress as a result of side effects.

The pill burden, the necessity to visit the hospital frequently and the budgetary requirement of medication were reported by the patients to be a significant part of the treatment burden. Moreover, there was the side effects of the TKI therapy, e.g. gastrointestinal side effects, musculoskeletal pain and fatigue, which just added to the emotional and physical workload of the treatment. Such burden caused some of the patients to develop anxiety and stress, which also influenced their compliance with therapy.

Nonetheless, it was also mentioned that patients receiving a structured, e.g., nurse-led counseling and psychological support also decreased treatment burden. These results indicate that the issue of treatment burden needs to be managed, and it could be included into the efforts to provide patient-centered care contributing to a better patient engagement with the therapy and patient satisfaction with it.

### 5.3 Achieved above 85% Level of Adherence in Centers

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Among the most promising findings of the study was the level of adherence which by the end of the trial it was proven that 85 percent of patients had had a consistent adherence to their TKI treatment in all study centers. Commitment to TKI treatment is essential in long-term disease control of CML patients because any failure in medication may cause progression and resistance of the disease. In spite of all the obstacles of fatigue and the burden of treatment, patients were very committed to their therapeutic regimens.

A number of interventions led to the favorable adherence rates such as nurse-led counseling, psychological support, and structured care pathways offering continuous education, motivation, and emotional support. Patients that were continuously counseled stated to be more satisfied with their therapy and were more able to cope with side effects. Moreover, the patients were urged to remain actively involved in their care team, which created a feeling of support and strength to keep them on the track of their care.

Moreover, adherence was evaluated with the use of electronic monitoring and during pill counts so that proper data can be accurately collected. The findings imply that the side effects of fatigue and burden of treatment might lead to distress but the support structures established helped the patients to adhere high levels of adherence.

To sum up, this paper has displayed the strong burden of fatigue and treatment burden in the day-to-day lives of CML patients being treated by TKI therapy. But the findings also highlight the relevance of supportive therapy to adherence to therapy. The consistent high adherence level of over 85% affirmed by the study proves that once properly assisted, patients can treat the difficulties of long-term therapy and stay committed to it at the highest levels, benefiting their health condition (quality of life and clinical outcomes).

## **6. Conclusion**

### **6.1 The role of persistent watch on PROs in the context of CML Management.**

The outcomes of this prospective observational research will emphasize the importance of patient-reported outcomes (PRO) monitoring continually in chronic myeloid leukemia (CML) management. Since tyrosine kinase inhibitors (TKIs) have revolutionized the treatment of CML by increasing survival and control of the disease, the sustained lifetime nature of treatment presents a new challenge regarding adherence and quality of life (QoL). The presence and influence of treatment side effects in the day-to-day life of patients and their consistent therapy capacity, including the example of fatigue and emotional positions and treatment burden, can also be seen in a unique way via PRO monitoring.

Combining and administering validated measures of the PRO, including questionnaires of fatigue, emotional well-being, and burden of treatment, clinicians will be able to be provided with a more complete picture of the patient experience. This can enable the healthcare providers to detect the various potential barriers to adherence at an early stage and proactively resolve the issue resulting in improved disease management. This study indicates that predictable monitoring of the PRO that incorporates monitoring of fatigue and treatment burden can be done on a regular basis, promoting the support of personalized care and the possibility of modification in the treatment regimen to improve patient outcomes.

Ongoing assessments of PRO also yield data that could inform psychosocial interventions and improve patient engagement and ideally a more comprehensive approach to care. With the tendency of CML treatment to be a long-term engagement in the treatment of many patients, monitoring and management of PROs will become critical in the achievement of patient compliance as well as patient satisfaction.

### **6.2 Benefit of Supportive Interventions to Achieve Long-Term Compliance**

Quality of supportive interventions towards adherence and maintenance of TKI therapy is also emphasized by the study. Although the rates of adherence noticed in the study (above 85%) are encouraging they also indicate the necessity to provide further support, especially when the side effects of the treatment (fatigue and treatment burden) are exhibited by the patients as it goes on. Counseling and psychological assistance conducted by nurses played an important role in enabling patients to deal with these difficulties and showed that paying more attention to emotional and psychological health can improve treatment adherence rates greatly.

Through offering patients personalized interventions such as management of side effects, education on how and why adherence to therapy is important, and emotional supports, healthcare providers can assist patients in working through the chronic aspect of TKI therapy. The results of study showed that structured psychological care has been reported in terms of patient adherence and QoL scores, which clearly shows integration of psychosocial care in the normal clinical practice.



More so, counseling by nurses showed to be a determinant in enhancing adherence and patient confidence in dealing with the chronicity of CML management. These tried and tested interventions do not only contribute to continuing the treatment, but they also aid in raising patient satisfaction, eventually resulting in improved long-term outcomes.

### 6.3 Implications on Therapeutic Strategies on Patient-Centered Applications

The results of the present research demonstrate the importance of patient-focused treatment interventions as one of the aspects of CML care. Clinical practice with the involvement of PRO monitoring and supportive interventions will also be possible at a more personal level, of the individual needs of a patient. These strategies will sensitize the need to take into consideration adherence challenges, psychosocial factors and the physical impact of treatment so that the disease can be well managed and patient outcomes improved.

Patient-centered care is the care of patients with attention to the patient being an active partner in decision-making regarding the care that should be taken and what his/her treatment plan includes. Since CML patients have to live with the disease over several years, it is necessary to address their psychosocial situation, quality of life, and persistence in the course of planning the therapeutic approaches. The measure promotes the involvement of psychosocial help and individualized interventions as necessitated by the specific issues affecting CML survivors who receive chronic treatment.

Conclusively, the findings support the need to combine both PRO monitoring and supportive care interventions in the effort to enhance the adherence levels and quality of life of CML patients. Whether through a patient-centered approach and the incorporation of holistic care approaches, clinicians stand a great chance to streamline the results of treatment, guarantee long-term compliance, and offer patients a complete level of support, overall improving both clinical and psychological successes of CML management.

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### Conflicts of interest

The authors have no conflicts of interest to declare

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