# Association of Demographic and Clinical Determinants with Treatment Response and Prognosis in a Single-Center Study with Chronic Myeloid Leukemia

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## ABSTRACT

***Background:*** Chronic Myeloid Leukemia (CML) shows a diverse clinical presentation, and its prognosis is affected by a combination of demographic and laboratory factors. Although global studies have identified several prognostic markers, detailed information specific to the Iraqi population remains limited. Understanding how local demographic trends and easily accessible laboratory measures influence treatment response is essential for customizing care in this region.

***Aim:*** To determine the influence of demographic characteristics (age, sex), disease-related factors (phase, duration), and baseline laboratory parameters ( WBC, HGB, and PLT) on treatment response and prognosis in AL-Diwaniya Iraqi patients with CML

***Methods:*** A retrospective study was conducted using routinely collected clinical data from 51 CML patients managed at Al-Diwaniya Teaching Hospital in the hematology clinic from September 2024 to March 2025. Response was mainly determined by Molecular Response, which was defined as a reduction in BCR-ABL transcript levels, as measured by RT-PCR every 3-6 months. Multivariable regression models were used to assess the independent associations between each predictor and treatment response while controlling for potential confounders.

***Results:*** PLT (Platelet count) demonstrated statistically significant associations with treatment response among the variables examined. Age, sex, disease phase, disease duration, WBC, and HGB did not reach statistical significance in this study.

***Conclusion:*** This study highlights platelet count as a significant prognostic marker, suggesting its potential utility in personalising treatment strategies and enhancing patient outcomes in limited-resource countries and as a primary assessment tool. However, the study's findings must be interpreted with caution due to limitations such as missing data and a small sample size and factors such as baseline disease burden and treatment duration, which can substantially influence response dynamics and overall outcomes, which may impact the generalisability of the results. This work provides locally relevant evidence to guide clinical practice and national policy development, contributing to better outcomes in CML management across similar healthcare contexts.

***Keywords:*** Chronic Myeloid Leukemia, Clinical Factors, Demographic Factors, Prognosis, Molecular Response, Treatment Response.

# العلاقة بين المحددات الديموغرافية والسريرية واستجابة العلاج والتشخيص في دراسة أجريت في مركز واحد لسرطان الدم النقوي المزمن

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## الخلاصة

**الخلفية:** يُظهر سرطان الدم النخاعي المزمن (CML) أعراضًا سريرية متنوعة، ويتأثر تشخيصه بمجموعة من العوامل الديموغرافية والمخبرية. على الرغم من أن الدراسات العالمية قد حددت العديد من العلامات التشخيصية، إلا أن المعلومات التفصيلية الخاصة بالسكان العراقيين لا تزال محدودة. يُعد فهم كيفية تأثير الاتجاهات الديموغرافية المحلية والمقاييس المخبرية المتاحة بسهولة على الاستجابة للعلاج أمرًا ضروريًا لتخصيص الرعاية في هذه المنطقة.

**الهدف:** تحديد تأثير الخصائص الديموغرافية (العمر، الجنس)، والعوامل المرتبطة بالمرض (المرحلة، المدة)، والمعايير المخبرية الأساسية (عدد كريات الدم البيضاء، ونسبة الهيموجلوبين في الدم، ونسبة الصفائح الدموية) على الاستجابة للعلاج والتشخيص لدى مرضى سرطان الدم النخاعي المزمن العراقيين في الديوانية.

**المنهجية:** أُجريت دراسة استعادية باستخدام بيانات سريرية جُمعت بشكل روتيني من ٥١ مريضًا بسرطان الدم النخاعي المزمن، خضعوا للعلاج في مستشفى الديوانية التعليمي في عيادة أمراض الدم، خلال الفترة من سبتمبر ٢٠٢٤ إلى مارس ٢٠٢٥. حُددت الاستجابة بشكل رئيسي من خلال الاستجابة الجزيئية، والتي عُرفت بأنها انخفاض في مستويات نسخ BCR-ABL، كما تم قياسها بواسطة تفاعل البوليميراز المتسلسل العكسي (RT-PCR) كل ٣-٦ أشهراو كل سنة. استُخدمت نماذج الانحدار متعدد المتغيرات لتقييم الارتباطات المستقلة بين كل مُتنبئ والاستجابة للعلاج، مع ضبط العوامل المُربكة المحتملة.

**النتائج:** تُسلّط هذه الدراسة الضوء على تعداد الصفائح الدموية كمؤشر تشخيصي هام، مما يُشير إلى فائدته المُحتملة في تخصيص استراتيجيات العلاج وتحسين نتائج المرضى في البلدان محدودة الموارد، وكأداة تقييم أولية. مع ذلك، يجب تفسير نتائج الدراسة بحذر نظرًا لبعض القيود، مثل نقص البيانات وصغر حجم العينة، وعوامل أخرى مثل عبء المرض الأساسي ومدة العلاج، والتي قد تؤثر بشكل كبير على ديناميكيات الاستجابة والنتائج الإجمالية، مما قد يؤثر على إمكانية تعميم النتائج. يُقدّم هذا العمل أدلةً محليةً ذات صلة لتوجيه الممارسة السريرية وتطوير السياسات الوطنية، مما يُسهم في تحسين نتائج إدارة سرطان الدم النخاعي المزمن في سياقات رعاية صحية مُماثلة.

**الكلمات المفتاحية:** سرطان الدم النقوي المزمن؛ العوامل السريرية؛ العوامل الديموغرافية؛ التشخيص؛ الاستجابة الجزيئية؛ الاستجابة للعلاج

## INTRODUCTION

The Philadelphia chromosome is a feature of a clonal myeloproliferative neoplasm that results in the synthesis of the BCR-ABL1 fusion protein [1].

The emergence of agents that inhibit tyrosine kinase activity (TKIs) has significantly changed the management of CML, greatly enhancing the results for patients, and making the disease a long-term and controllable condition [2]. Despite these worldwide advances, genetic, environmental, and socio-economic determinants can introduce variability in clinical presentation, treatment response, and prognostic factors among populations.

Specific local information regarding the epidemiology and prognostic factors of CML is scarce in Iraq, as in the majority of developing nations. Specialty treatment approach development and the quality of patient management are advanced by the understanding of unique clinical and demographic features that affect treatment response and prognosis within this population. This contrast occurred in the original thesis that served as the basis for this information, which identified work that offers region-based insights into CML.

To fill this knowledge gap, this study will look at the effect on treatment response of some clinical and demographic factors among Iraqi CML patients. Specifically, we will look at the correlations between the molecular response of treatment and patient sex, age, phase of disease at diagnosis, duration of illness, and selected laboratory results (WBC, HGB, and PLT).

Through the analysis of these variables, we seek to identify potential prognostic indicators and contribute to a greater understanding of CML in this sample, ultimately assisting with better patient stratification and individually tailored treatment strategies.

## MATERIALS AND METHODS

### Study Design and Patient Population

A retrospective study was used to investigate clinical and demographic information among a sample of patients with Chronic Myeloid Leukemia (CM in Diwaniya, Iraq. All 51 patients included in this study are treated with TKIs according to the standard treatment protocols for chronic myeloid leukemia (CML). Treatment decisions were made by the attending hematologists based on the European LeukemiaNet (ELN) recommendations and the availability of medications in Iraq. Patients' inclusion criteria included all who were 12 years and older. TKI-treated patients. TKI contraindications, pregnancy, and lactation were the exclusion criteria from the study.

### Data Collection

Clinical and laboratory records were utilized for data extraction. The key variables considered for this analysis were:

- **Demographic Information:** Age and Sex.
- **Disease Characteristics:** Disease phase (Chronic, Accelerated, Blast) at the time of assessment, and Duration of disease (in years).
- **Laboratory Parameters:** molecular response (percentage), WBC count, HGB level, and PLT count.

- **Clinical response:** Response measured by molecular response, which is divided into (major molecular response, deep molecular response, complete molecular response, deep molecular response, relapse).
- The time point for molecular response recording the patients is at least 3 months if the diagnosis is not more than 1 year, or 3-6 months if the duration of disease is more than one year, duration of disease for all patients is at least one year or more, no less than one year

## Molecular Response

Molecular response to therapy in CML patients is assessed by monitoring the reduction in BCR-ABL1 transcript levels over time, expressed as a percentage on the International Scale (IS). Table 1. Subsequent monitoring categorizes response based on specific BCR-ABL1 % (IS) thresholds. These response criteria are critical for guiding treatment decisions and predicting long-term outcomes in CML patients receiving tyrosine kinase inhibitor (TKI) therapy.

Table 1:Molecular response category [3]

| Response Type | Definition (BCR::ABL1 IS) | Time Point |
|---|---|---|
| **Early Molecular Response (EMR)** | ≤10% | 3 and 6 months |
| **Major Molecular Response (MMR)** | ≤0.1% **or** ≥3-log reduction from standardized baseline (if qPCR IS not available) | ~12 months |
| **Deep Molecular Response (DMR)** | **MR4.0:** ≤0.01% **or** **MR4.5:** ≤0.0032% 1 | ≥18 months |

1. **MR4 (Molecular Response 4.0):** A **4-log reduction** (10,000-fold decrease) in BCR::ABL1 transcript levels from the standardized baseline, corresponding to **BCR::ABL1 (IS) ≤0.01%**. **MR4.5 (Molecular Response 4.5):** A **4.5-log reduction** (~32,000-fold decrease) in BCR::ABL1 transcript levels from the standardized baseline, corresponding to **BCR::ABL1 (IS) ≤0.0032%**. **MR5 (Molecular Response 5.0):** A **5-log reduction** (100,000-fold decrease) in BCR::ABL1 transcript levels from the standardized baseline, corresponding to **BCR::ABL1 (IS) ≤0.001%**.

## BCR-ABL1 Transcript Detection

### Sample Collection and Preparation

Preparation: Whole blood samples were collected into tubes containing appropriate anticoagulants (e.g., EDTA) to prevent clotting and preserve nucleic acid integrity. Samples are then processed to extract RNA, which serves as the template for subsequent real-time PCR amplification. The GeneXpert system automates this process, including RNA isolation, reverse transcription, and PCR amplification within a self-contained cartridge[4].

### BCR-ABL1 Detection and Quantification

The detection and quantification of BCR-ABL1 fusion transcripts were performed using the Xpert BCR-ABL Ultra G2 assay (Assay Version 1), an in vitro diagnostic test designed for use on the GeneXpert Dx System (Software Version 6.4).

This assay targets the major breakpoint (p210) transcripts of BCR-ABL1. The GeneXpert system automates the entire process from sample preparation to real-time PCR amplification and detection, providing quantitative results. The principle of the assay relies on real-time quantitative PCR (RT-qPCR), which measures the amount of BCR-ABL1 mRNA relative to a control gene (ABL). The cycle threshold (Ct) values for both BCR-ABL1 and ABL are determined, and these values are used to calculate the BCR-ABL1 % on the International Scale (IS). The IS provides a standardized method for reporting BCR-ABL1 levels, allowing for consistent monitoring of molecular response across different laboratories and studies [5].

## Statistical Analysis

A retrospective study was conducted using routinely collected clinical data, applying multivariable regression models; statistics were calculated for both continuous and categorical data types. Associations between categorical variables and treatment response were assessed using Chi-square tests (Sex, Disease Phase vs.

Treatment Response). Differences in continuous variables across treatment response groups were evaluated using one-way ANOVA (Age, Duration of Disease, WBC, HGB, PLT vs.

Treatment Response). Post-hoc Analysis (Tukey HSD) was used to identify specific differences among groups when ANOVA showed a significant result for PLT.

# RESULTS

## Descriptive Statistics of the Study

A total of 51 patients with Philadelphia chromosome-positive CML were included in this study. The median age was 47 years (range: 14–77), with a mean age of 47.0 ± 14.0 years, and the majority were male (56.9%). At assessment, 49 patients (96.1%) were in the chronic phase, while 2 patients (3.9%) were in the blast phase, both of whom presented with relapse. The median disease duration was 8 years (range: 1–26), with a mean of 9.7 ± 7.9 years. Baseline laboratory values showed a mean WBC of 15.3 ± 29.6 $\times 10^9$/L, hemoglobin of 11.7 ± 1.4 g/dL, platelet count of 214 ± 86 $\times 10^9$/L, and BCR-ABL1 transcript levels averaging 6.65 ± 17.1% (IS). Comorbidities were present in a subset of patients, most commonly hypertension (15.7%) and diabetes mellitus (9.8%). Regarding treatment, imatinib was the most frequently used TKI (27 patients, 52.9%), followed by nilotinib (12 patients, 23.5%) and bosutinib (12 patients, 23.5%). Table2.

Table 2: Baseline Characteristics of the Study

| Characteristic | n (%) or Mean ± SD (Range) |
|---|---|
| **Age (years)** | 47.0 ± 14.0 (14–77) |
| **Sex** | |
| **– Male** | 29 (56.9%) |
| **– Female** | 22 (43.1%) |
| **Disease Phase at Assessment** | |
| **– Chronic** | 49 (96.1%) |
| **– Blast** | 2 (3.9%) |
| **Duration of Disease (years)** | 9.7 ± 7.9 (1–26) |
| **Baseline Laboratory Values** | |
| **– WBC ($\times 10^9$/L)** | 15.3 ± 29.6 (2.7–203.5) |
| **– Hemoglobin (g/dL)** | 11.7 ± 1.4 (8–14) |
| **– Platelet Count ($\times 10^9$/L)** | 214 ± 86 (34–486) |
| **– BCR-ABL1 (% IS)** | 6.65 ± 17.1 (0–100) |
| **Comorbidities** | |
| **– Hypertension** | 8 (15.7%) |
| **– Diabetes Mellitus** | 5 (9.8%) |
| **– Ischemic Heart Disease** | 2 (3.9%) |
| **Current TKI Therapy** | |
| **– Imatinib** | 27 (52.9%) |
| **– Nilotinib** | 12 (23.5%) |
| **– Bosutinib** | 12 (23.5%) |

## Association of Demographic and Clinical Factors with Treatment Response

## Sex vs. Response

The Chi-square test did not demonstrate a statistically significant correlation between sex and treatment response. (Chi2 = 1.50, p-value = 0.8270).. The distribution of responses by sex is shown in Table 3, Figure 1.

Table 3: Distribution of Response by Sex (Counts)

| SEX.1 | Loss major response | complete response | deep response | major response | relapse |
|---|---|---|---|---|---|
| **FEMALE** | 3 | 5 | 4 | 3 | **7** |
| **MALE** | **3** | **6** | **4** | **8** | **8** |

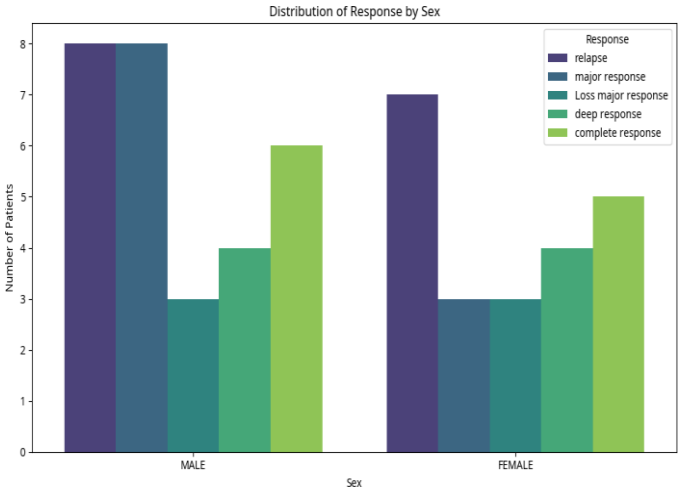


Figure 1: Distribution of Response by Sex

## Phase vs. Response

No statistically significant association was found between the disease phase at the assessment and treatment response (Chi2 = 7.65, p-value = 0.4684). While blast phase patients exclusively showed relapse, the statistical significance was not met, likely due to the small sample size of patients in advanced phases. The distribution of responses by disease phase is presented in Table 4, Figure 2.

Table 4: Distribution of Response by Disease Phase (Counts)

| phase.1 | Loss major response | complete response | deep response | major response | relapse |
|---|---|---|---|---|---|
| **Blast phase** | 0 | 0 | 0 | 0 | **2** |
| **Chronic** | **6** | **11** | **8** | **11** | **13** |

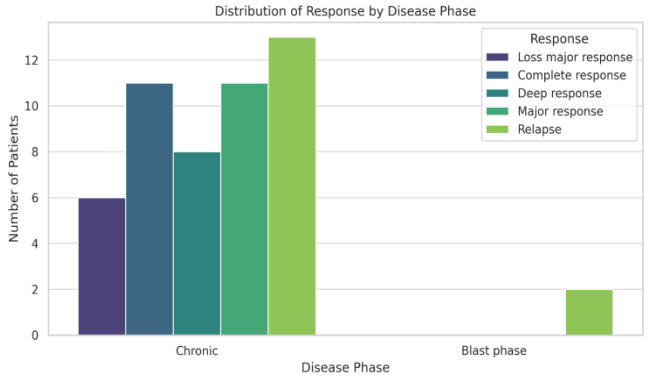


Figure 2: Response by Disease Phase

## Age vs. Response

ANOVA results indicated no statistically significant association between age and treatment response (F = 0.86, p-value = 0.4701). This implies that age, within the observed range, does not significantly predict treatment response Figure 3.

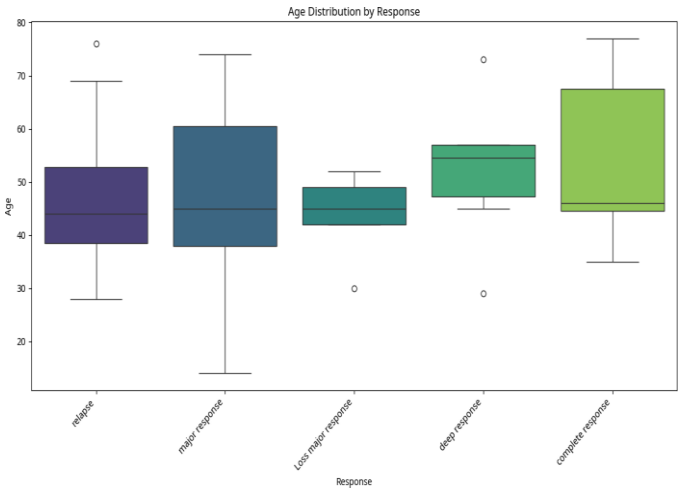


Figure 3: box plots illustrating the relationship between Age and treatment response, respectively

## Duration of Disease vs. Response

Similarly, the ANOVA for duration of disease showed no statistically significant association with treatment response (F = 0.15, p-value = 0.9320).

## Association Between Laboratory Parameters (WBC, HGB, PLT) and TKI Therapy & Clinical Response

The ANOVA results demonstrate that WBC and HGB levels did not differ significantly across response categories (p > 0.05) with small effect sizes (Î·Â² < 0.16). In contrast, Figure 4 platelet counts differed significantly with clinical response (p = 0.002) with moderate effect sizes. Table 7 for the Tukey post-hoc test showed that Patients in complete or major response categories had higher platelet counts than those in relapse.

Table 5, showing the baseline white-blood-cell (WBC), hemoglobin (HGB), and platelet (PLT) counts, was compared across clinical response categories. One-way ANOVA is shown in Table 6 and Tukey post-hoc tests were used to assess differences.

Table 5: Descriptive statistics by clinical response

| Response | n | WBC (mean Â± SD) | HGB (mean Â± SD) | PLT (mean Â± SD) |
|---|---|---|---|---|
| Loss major response | 6 | 9.23 Â± 1.94 | 11.23 Â± 0.59 | 204.83 Â± 84.15 |
| complete response | 11 | 7.73 Â± 1.74 | 11.80 Â± 1.16 | 248.64 Â± 73.55 |
| deep response | 8 | 7.08 Â± 2.12 | 12.01 Â± 0.58 | 224.46 Â± 18.65 |
| major response | 11 | 7.46 Â± 3.21 | 11.78 Â± 1.39 | 267.91 Â± 82.88 |
| relapse | 15 | 33.43 Â± 51.07 | 11.43 Â± 2.05 | 148.53 Â± 84.87 |

Table 6: One-way ANOVA results by clinical response

| Parameter | F | p-value | Î·Â² |
|---|---|---|---|
| **WBC** | **2.19** | **0.084** | **0.160** |
| **HGB** | **0.39** | **0.816** | **0.033** |
| **PLT** | **4.87** | **0.002** | **0.298** |

Table 7 Tukey HSD post-hoc comparisons for PLT by clinical response

| Group 1 | Group 2 | Mean diff | p-value |
|---|---|---|---|
| Loss major response | complete response | 43.80 | 0.7820 |
| Loss major response | deep response | 19.63 | 0.9886 |
| Loss major response | major response | 63.08 | 0.4752 |
| Loss major response | relapse | -56.30 | 0.5388 |
| complete response | deep response | -24.17 | 0.9577 |
| complete response | major response | 19.27 | 0.9745 |
| complete response | relapse | -100.10 | 0.0136 |
| deep response | major response | 43.45 | 0.7282 |
| deep response | relapse | -75.93 | 0.1633 |
| major response | relapse | -119.38 | 0.0021 |

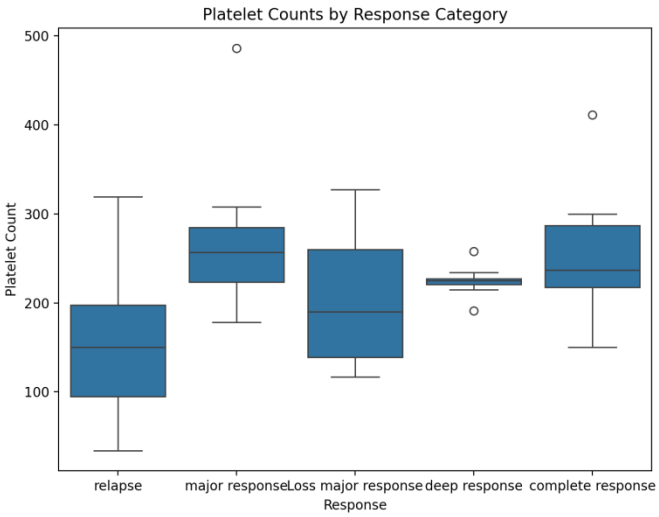


Figure 4 boxplot visualizes the distribution of platelet counts across different response categories

## DISCUSSION

This study aimed to identify demographic and clinical factors influencing treatment response and prognosis in AL-Diwaniya Chronic Myeloid Leukemia (CML) patients. the results highlight the significant role of PLT counts as prognostic indicators, while other factors such as age, sex, duration of disease, WBC, and HGB did not show a statistically significant association with treatment response in this study, but the baseline disease burden and treatment duration may confound the observed molecular responses.

The significant association between PLT counts and treatment response, where Patients in complete or major response categories had higher platelet counts than those in relapse an interesting finding. While high platelet counts are a common feature of CML at diagnosis, and their normalization is a sign of hematologic response, the specific relationship between platelets and long-term treatment response is less commonly highlighted as a primary prognostic factor compared to molecular response. This observation warrants further investigation to understand the underlying clinical implications. It could potentially reflect a more effective suppression of the leukemic clone, leading to better control of myeloproliferation and subsequent normalization of platelet counts, or it could be an indirect marker of other biological processes influencing response. Conversely, the lack of a statistically significant association between age, sex, and duration of disease with treatment response suggests that these demographic and general disease characteristics may not be primary determinants of TKI efficacy in this study.

This aligns with some studies that show TKIs are effective across a wide range of ages and in both sexes [6]. The limited number of patients in advanced disease phases (accelerated or blast phase) has influenced the statistical power to detect associations with disease phase, although clinically, advanced phases are known to be associated with poorer outcomes [7]. The findings from this study contribute valuable localized data from Iraq, a region where such comprehensive analyses are often scarce. Understanding these region-specific factors is crucial for optimizing CML management strategies.

## CONCLUSION

The study on Chronic Myeloid Leukemia (CML) in the Iraqi population highlights platelet count as a significant prognostic marker, suggesting its potential utility in personalizing treatment strategies and enhancing patient outcomes. However, the study's findings must be interpreted with caution due to limitations such as missing data and a small sample size, which may impact the generalizability of the results. The analysis revealed that platelet counts significantly predict treatment response, with higher counts associated with complete or major responses compared to relapse. In contrast, white blood cell (WBC) and hemoglobin (HGB) levels did not significantly differ across response categories. These findings align with the known myelosuppressive effects of Bosutinib and suggest that platelet recovery may reflect marrow normalization during effective therapy. Other factors, such as age, sex, and disease duration, did not show statistically significant associations with treatment response.

The study contributes to the limited regional data on CML, emphasizing the need for localized research to optimize patient management strategies in resource-limited settings. Future research should focus on validating these findings in larger, multicenter study and incorporating cytogenetic and mutational analyses to elucidate resistance mechanisms and inform precision medicine. This work provides locally relevant evidence to guide clinical practice and national policy development, contributing to better outcomes in CML management across similar healthcare contexts.

The study contributes to the limited regional data on CML, emphasizing the need for localized research to optimize patient management strategies in resource-limited settings. Future research should focus on validating these findings in larger, multicenter cohorts and incorporating cytogenetic and mutational analyses to elucidate resistance mechanisms and inform precision medicine. This approach could contribute to the development of evidence-based clinical guidelines and policy decisions, thereby improving CML management in Iraq and similar contexts. This work provides locally relevant evidence to guide clinical practice and national policy development, contributing to better outcomes in CML management across similar healthcare contexts.

## LIMITATIONS

This study has several limitations that should be acknowledged:

**Missing data**: Certain clinical variables, such as treatment adherence data, were unavailable, potentially limiting the comprehensiveness of the analysis.

**Small sample size**: This was a single-center study, and the small sample size of patient selection may not fully represent the broader Iraqi CML population, potentially affecting generalizability.

## RECOMMENDATIONS

1-Include adherence monitoring to evaluate the impact of compliance on treatment outcomes.

2- Multi-center studies are essential to overcome small sample size limitations, enhance generalizability, and improve statistical power.

3-Investigate treatment resistance mutations and their clinical correlates to guide precision therapy.

## ACKNOWLEDGEMENT

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No external funding was obtained for this study.

## Conflict of Interest

The authors declare that there are no conflicts of interest regarding the publication of this manuscript.

## Authorship Contribution Statement

Study conception and design: Mohammed, Dr Doaa, and Dr Bassim. Data collection: Mohammed & Doaa. Statistical analysis: Mohammed. The initial draft of the paper was written by Mohammed. Critical revision and final approval: all authors

## Ethical Consideration

This study was approved by the College of Medicine, University of Al-Qadisiya, Iraq, and the Scientific & Ethical Committee of Al-Diwaniyah Teaching Hospital (No. 23). 2024-09-30 and

## Data Availability

All the data utilized in this study are accessible.

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