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Targeted therapy in chronic myeloid leukemia with imatinib: A retrospective hospital-based study in Georgia

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Abstract: Chronic myeloid leukemia (CML) was the first oncological disease for which targeted therapy, specifically the tyrosine kinase inhibitor (TKI) Imatinib, was introduced. This study aimed to evaluate clinical, laboratory, and cytogenetic outcomes in CML patients treated with Imatinib. A retrospective hospital-based study was conducted involving 219 patients at the LTD Medinvest Institute of Hematology and Transfusiology in Georgia, between 2003 and 2018. The analysis included clinical and laboratory parameters, cytogenetic responses, and survival outcomes. Kaplan–Meier survival analysis was used, with treatment responses assessed at 3, 6, and 12 months. During the study, 30 patients (13.7%) died. After three months of therapy, hematological indicators improved in all patients. At six months, 82.3% achieved cytogenetic improvement, increasing slightly to 83.5% after twelve months. Kaplan–Meier analysis showed higher survival rates among patients who started treatment during the chronic phase. No significant differences in treatment outcomes were observed between patients receiving 400 mg and 600 mg doses of Imatinib. Overall, Imatinib proved effective in managing CML, leading to improved hematological and cytogenetic responses and reducing mortality. These findings highlight the importance of early diagnosis and prompt initiation of targeted therapy, especially in resource-limited healthcare settings.

Keywords: *Chronic myeloid leukemia, Clinical haematology, Imatinib therapy, Retrospective hospital-based study, Targeted cancer treatment, Treatment outcomes.*

1. Introduction

Chronic myeloid leukemia is the first cancer disease that is clinically and diagnostically associated with its expression, causing molecular damage, an abnormal hybrid gene, BCR-ABL1 expression (National Comprehensive Cancer Network, 2017).

BCR-ABL1 is a molecular product of the Philadelphia chromosome, found in more than 95% of patients with CML, and its detection is necessary for diagnosing and monitoring patients under treatment (A. Hochhaus et al., 2017; National Comprehensive Cancer Network, 2017; Saleem & Yusoff, 2016). This hybrid gene encodes a multiply ten times activated ABL1 tyrosine kinase, which is detected with activation of RAS/MAPK, JAK-STAT, PI3K, and Myc vital signal-sending cascades and promotes growth and proliferation of leukemic cells (Arber et al., 2017; A. Hochhaus et al., 2017; Hoelzer et al., 2016; National Comprehensive Cancer Network, 2017; NCCN, 2017a, 2017b; Seiter, 2017). Therefore, these patients are subject to targeted, anti-tyrosine kinase therapy. In particular, treatment with BCR-ABL inhibitors such as Imatinib (Gleevec), Nilotinib (Tasigna), and Dasatinib (Sprycel) (Arber et al., 2017; A. Hochhaus et al., 2017; Hoelzer et al., 2016; National Comprehensive Cancer Network, 2017; NCCN, 2017a, 2017b; Seiter, 2017).
In Druker et al. (2001) had created and innovated in clinical practice the medicine STI 571 which obtaining the name Imatinib(Gleevec) (National Cancer Institute, 2018), and is the first drug to target

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the BCR-ABL tyrosine kinase protein specifically (American Cancer Society, 2021). In order to avoid complications related to effective treatment, prognosis, resistance, and recurrence, minimal balance monitoring of diseases is critical during the treatment process of the disease (Foroni et al., 2011; Moore, Rempfer, & Press, 2013). The most effective and sensible method is real-time polymerase chain reaction (Bauer & Romvari, 2012; Foroni et al., 2011; Moore et al., 2013).

Currently, the international scale of BCR-ABL1 monitoring is introduced, where the percentage of transcript correlation is used with the full amount of ABL1 gene transcripts. This scale is based on two critical points: transcript standard 100% and 0.1%, which represent the major molecular response, indicating a decrease in transcripts across three logarithmic ranges. Estimation of treatment is carried out according to full hematological response, complete cytogenetic response, and major molecular response, which correspond to decreases of 1-2, 2-3, and 3-4 logarithmic ranges from the standard background of 100% BCR-ABL1 transcripts. The full molecular response, defined as when BCR-ABL1 transcript detection is unable, is considered the healing rate and is indicated by a decrease of 4-5 logarithmic ranges (0.01%-0.0001%) of the transcript (Bauer & Romvari, 2012).

According to European LeukemiaNet, it is essential to monitor the desired dynamics of treatment mentioned above stages once every three months (Baccarani et al., 2006).

Targeted therapy is the future of the global healthcare industry, which may substitute chemotherapy treatment for patients with myeloid leukemia worldwide. In 2001, the FDA approved treatment with Imatinib for patients with CML who have the Philadelphia chromosome (National Cancer Institute, 2018).

Despite the fact that targeted therapy with Imatinib is approved in more than 100 countries (Novartis, 2017) of low and middle-income countries, it is limited for patients, for example, in Bosnia and Lithuania (Kurtovic-Kozaric et al., 2017). In Brazil, targeted therapy with Imatinib is also limited to a minority of patients (Funke et al., 2005).

In Georgia, targeted therapy with Imatinib started in 2003 at LTD Medinvest-Institute of Hematology and Transfusiology, and unfortunately, not all patients can have the full treatment.

Late results of targeted therapy effectiveness are not yet thoroughly examined. In common cases, it influences small investment, to include patients with CML in Imatinib Program. Therefore, all studies with Imatinib have vital importance so that governments and international organizations will draw attention to the matter of targeted therapy program's investment. In particular, within countries of severe socio-economic condition.

2. Hypothesis and Objectives

The aim of this retrospective hospital-based study is to analyze clinical-laboratory and cytogenetic data of chronic myeloid leukemia in the dynamics of Imatinib treatment and to determine risk factors. This study hypothesizes that the clinical-laboratory and cytogenetic data improve during Imatinib treatment. The second aim is to determine if treatment with different dosages of Imatinib has the same effect.

3. Methods

This study is based on information from patients' paper records at the LTD Medinvest Institute of Hematology and Transfusiology (Tbilisi, Georgia).

3.1. Population and Sample

All patients aged 16 years or more with CML Ph^+ newly diagnosed between 2003-2018 are included in this study.

As Imatinib usage in children is not universal, younger patients were excluded. All patients were treated with a single daily dose of 400 mg or 600 mg of Imatinib according to the European LeukemiaNet guidelines (Baccarani et al., 2006). The initial sample consisted of 232 patients; however, only 219 were considered eligible, as shown in Figure 1.

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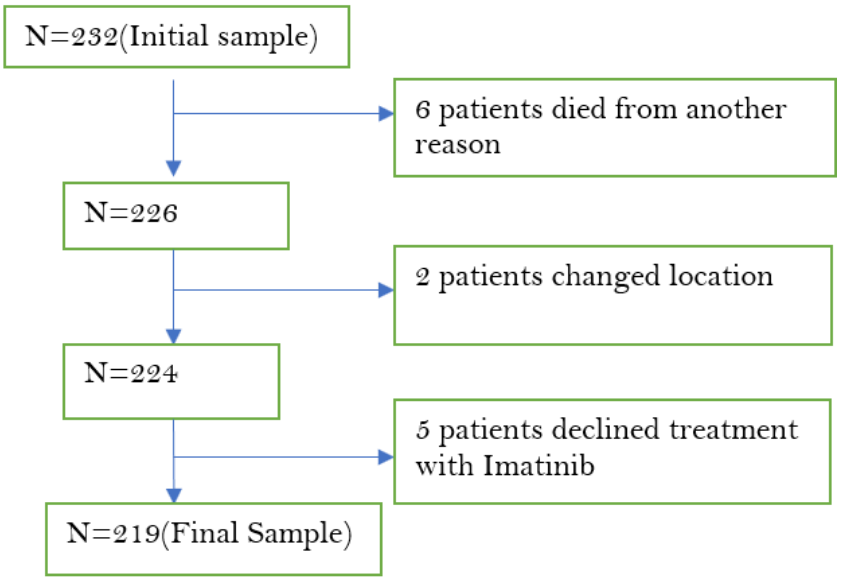

Figure 1.
PRISMA of the process of composing the studied sample.

3.2. Data Collection

Chronic Myeloid Leukemia patient's paper records were identified and imported into Excel. Data extracted from each patient included: registration year, age, gender, Imatinib doses, death year, and death reason. Clinical laboratory test results at the beginning of treatment and after 3 months of treatment included erythrocytes ($x10^{12}$/L), leukocytes ($x10^{9}$/L), platelets ($x10^{9}$/L), myeloblasts (%), promyelocytes (%), eosinophils (%), and basophils (%). Cytogenetic and BCR-ABL1% results were recorded after 6 and 12 months.

The Sokal score (Baccarani et al., 2013) was used to calculate the RR for the identification of CML patients as low risk, intermediate risk, and high risk.

3.3. Statistical Analysis

Patients' results from Excel were imported into the SPSS 21 statistical package for analysis. Patients were categorized based on sex and age groups: 16-40, 41-60, and 61 and above, according to disease stages: Chronic, Accelerated, and Blastic phases. Clinical and laboratory data from patients at the start of treatment and three months post-treatment with Imatinib were statistically processed. Patient treatment outcomes were compared based on RR classification (low, intermediate, high). Results of Imatinib 400 or 600 mg treatments were analyzed according to clinical and laboratory data.

BCR-ABL1 percentage data were analyzed according to the European LeukemiaNet recommendation (Baccarani et al., 2013). After 6 months, Optimal <1%, warning 1-10%, failure >10 %, and after 12 months, optimal <0.1%, warning>0.1-1%, and failure >1%. A p-value <0.05 was considered significant. Survival analysis was done by the Kaplan-Meier method.

4. Results

Results of the study and treatment of 219 patients diagnosed with CML were analyzed. 54.3% of patients were women, and 45.7% were men. The patients' ages ranged from 16 to 40 years for 30.6%, 41 to 60 years for 49.3%, and over 61 years for 20.1%. Most of the patients were in the Chronic phase – 94.1%, in the Accelerated phase – 5.5%, and only 0.5% were in the blastic phase. During treatment, 13.7% of patients died, while 86.3% are still alive (Table 1).

The majority of patients before treatment had splenomegaly, erythrocytopenia, leukocytosis, and platelet counts, which were within the normal range in most cases, with a left shift in the leukocyte differential. The number of myeloblasts and promyelocytes was insignificantly increased; similarly, the numbers of eosinophils and basophils were also insignificantly increased.

After 3 months of treatment with Imatinib, all mentioned data improved, in particular, the number of leukocytes, which in most cases reverted to the norm or developed leukopenia. After 3 months of treatment, the change in all clinical-laboratory data is reliable ($P<0.05$). (Table 2).

Table 1.
Chronic Myeloid Leukemia Patients' Characteristics.

Variable	N	%
Gender		
Female	119	54.3
Male	100	45.7
Age (years)		
16-40	67	30.6
41-60	108	49.3
61+	44	20.1
Disease Phase		
Chronic	206	94.1
Accelerated	12	5.5
Blastic	1	0.5
Death		
Yes	30	13.7
No	189	86.3

Table 2.
Chronic Myeloid leukemia patient's clinical laboratory test results: at the beginning and after 3 months of treatment.

Variable	Results at the beginning of the treatment		Results after 3 months		t	P-value
	Mean	SD	Mean	SD		
Erythrocytes	33.041	0.53	34.120	0.51	-2.77	0.006
Leukocytes	133.274	100.69	62.900	8.41	18.56	0.000
Platelet	356.237	188.91	232.973	115.56	9.49	0.000
Myeloblasts	2.4	3.17	0.015	0.12	10.63	0.000
Promyelocyte	2.087	2.85	0.010	0.14	10.4	0.000
Eosinophils	4.015	2.33	2.34	2.46	7.56	0.000
Basophils	3.746	2.77	0.585	0.84	16.44	0.000
Spleen	5.617	5.45	0.1402	0.86	15.24	0.000

According to the Relative Risk Sokal-Score, low was 30.1%, intermediate 42%, and high 27.9% (table 3). The relevant differences between these three groups were noticeable, according to the number of leukocytes and spleen size. Other statistical data in these three groups were not significantly different.

Table 3.
Calculation of the Relative Risk of Chronic Myeloid Leukemia Patients by the Sokal-Score Calculator.

Relative Risk	N	%
Low	66	30.1
Intermediate	92	42.0
High	61	27.9
Total	219	100,0

Analyses of clinical-laboratory data of patients treated with Imatinib 400 or 600 mg dosage have shown that data of patients treated with both dosages after 3 months have significantly improved, except for the index of erythrocytes, and the results were not statistically different from each other. Table 4.

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Table 4.
Correlation between Chronic Myeloid Leukemia Patients' Clinical Laboratory Test Results and Imatinib Doses.

	Results at the beginning of the treatment				Results after 3month				400		600	
Imatinib Dose	**400**		**600**		**400**		**600**		**t**	**P-value**	**T**	**P-value**
Variable	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**				
Erythrocytes	3.36	0.50	3.26	0.55	3.46	0.50	3.38	0.52	-1.67	0.10	-2.19	0.03
Leukocytes	122.96	102.02	140.21	99.58	6.39	9.89	6.22	7.29	10.61	0.00	15.36	0.00
Platelet	346.77	214.13	362.60	170.47	230.12	102.15	234.89	124.10	5.71	0.00	7.56	0.00
Myeloblasts	2.06	2.94	2.61	3.30	0.01	0.11	0.02	0.13	6.15	0.00	8.68	0.00
Promyelocyte	1.71	2.62	2.36	2.99	0.00	0.00	0.02	0.18	6.01	0.00	8.55	0.00
Eosinophils	4.33	2.25	3.81	2.36	2.16	1.92	2.46	2.77	7.31	0.00	4.36	0.00
Basophils	3.25	1.94	4.08	3.16	0.51	0.70	0.64	0.92	11.70	0.00	12.40	0.00
Spleen	5.16	5.18	5.91	5.62	0.06	0.39	0.19	1.06	9.21	0.00	12.12	0.00

The analysis of BCR-ABL1 showed that after 6 months, the optimal result was observed in the majority of patients, accounting for 82.3% (Table 5). After 12 months, the condition also improved, with the optimal effect reaching 83.5% (Table 6).

Table 5.
Chronic myeloid Leukemia patients' Cytogenetic, BCR-ABL1 (%) results after 6 months.

		Frequency	Percent	Valid Percent	Cumulative Percent
Optimal	<1%	65	29.7	82.3	82.3
Warning	1-10%	6	2.7	7.6	89.9
Failure	>10%	8	3.7	10.1	100.0
	Total	79	36.1	100.0	
Missing	System	140	63.9		
Total		219	100.0		

Table 6.
Chronic myeloid Leukemia patients' Cytogenetic BCR-ABL1 (%) results after 12 months.

		Frequency	Percent	Valid Percent	Cumulative Percent
Optimal	<0.1%	66	30.1	83.5	83,5
Warning	>0.1-1%	6	2.7	7.6	91,1
Failure	>1%	7	3.2	8.9	100,0
	Total	79	36.1	100.0	
Missing	System	140	63.9		
Total		219	100.0		

According to the survival functions of chronic myeloid leukemia, life expectancy is high in patients diagnosed in the chronic phase (Figure 2).

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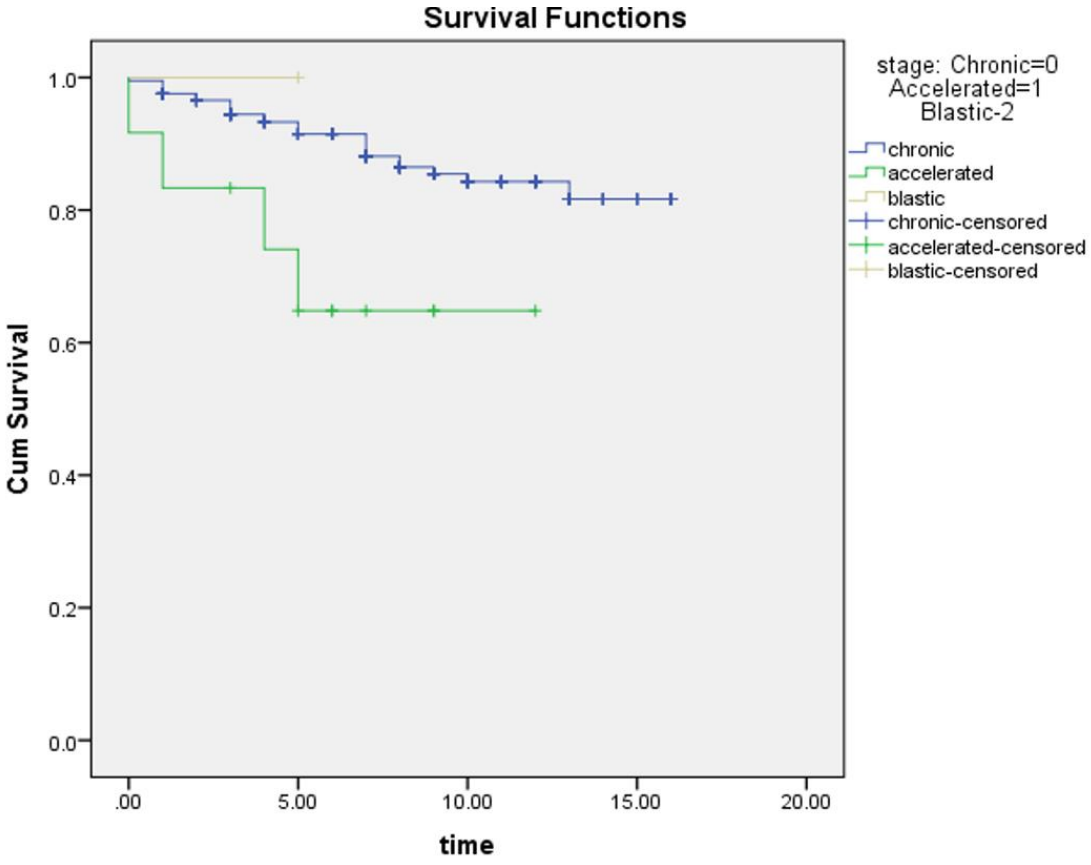

Figure 2.
Chronic Myeloid Leukemia patients' survival functions according to disease phases.

5. Discussion

This retrospective study, conducted at LTD Medinvest Institute of Haematology and Transfusiology, has shown that the number of CML patients was equally distributed between men and women, and the majority of patients were aged 41-60 years (49.3%).

Unlike similar research conducted in Brazil (Danielle Maria et al., 2013)' our patients were involved in the study during the accelerated and chronic phases. The treatment of patients in the chronic phase has yielded significantly better results, as also indicated in the PETHEMA group research (Francisco et al., 2010). It is noteworthy that patients in the chronic phase constitute 94.1%, which should indicate that the life expectancy of these patients is 16 years, 86.3%.

After 3 months of treatment with Imatinib, all clinical laboratory data improved, which indicates the effectiveness of the treatment.

According to RR Sokal, the difference between the groups was particularly noticeable according to the leukocytes - low 98.36±58.43, intermediate 123.39±101.03, high 185.95±115.82, and according to the spleen - low 2.26±2.69, intermediate 4.97±4.35, high 10.3±6.05. Other data do not differ significantly.

The results of Imatinib treatment for RR after 3 months coincide with other study data (Danielle Maria et al., 2013), indicating that the outcomes are not significantly different from other forms of RR.

According to some studies, treatment with high dosages of Imatinib yields better results (Gafter-Gvili et al., 2011; Sawyers et al., 2002), while, according to this study, analyses of clinical-laboratory data of patients treated with 400 or 600 mg Imatinib have shown that the rate of patients treated with both

dosages after three months does not significantly differ. Therefore, treatment with 400 mg Imatinib should prevail.

The results of BCR-ABL1 (%) have shown that after 6 months, the optimal results were obtained in 82.3%, and after 12 months, 83.5%, which coincides with the results of other researchers (Tomasz, 2014). According to IRIS and Hammersmith studies (De Lavallade et al., 2008; A Hochhaus et al., 2009), negative results are more frequent in the first 3 years of observation and then decrease. Survival analysis has shown a significant difference between patients in the chronic and accelerated phases of CML. The survival rate of patients in the chronic phase was significantly higher than that of patients who started treatment in the accelerated phase.

6. Conclusions

1. During the treatment of CML with Imatinib, survival rates are higher when treatment begins in the chronic phase.

2. CML treatment with Imatinib, after 3 months, causes a significant improvement in clinical-laboratory data (spleen size, erythrocytes, leukocytes, platelets) for the majority of patients.

3. Treatment of CML with 400 or 600mg Imatinib gives a similar result.

4. During CML treatment, the majority of patients show significant improvement in BCR-ABL1 data after 6 and 12 months.

7. Recommendations

1. The further study of different doses of activation of Imatinib for the specification of treatment dosage.
2. For the estimation of full effectiveness during Imatinib treatment, BCR-ABL1 examination should be performed for all CML patients.
3. Awareness of the efficacy of Imatinib within society and, in particular, CML patients.
4. Conducting a study on the cost-effectiveness of Imatinib to establish a program by the governments and international organizations to fully finance patients with chronic myeloid leukemia.

Transparency:

The authors confirm that the manuscript is an honest, accurate, and transparent account of the study; that no vital features of the study have been omitted; and that any discrepancies from the study as planned have been explained. This study followed all ethical practices during writing.

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