Evaluating the correlation of Age and Gender with the Hematological Parameters of the Chronic Myeloid Leukemia Patients

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ABSTRACT

Background: White blood cell malignancy is known as chronic myelogenous leukemia (CML), or chronic myeloid leukemia. This type of leukemia is defined by the buildup of myeloid cells in the blood and their uncontrollably elevated proliferation in the bone marrow. A proliferation of adult granulocytes (neutrophils, eosinophils, and basophils) and their progenitors is observed in CML, a clonal bone marrow stem cell illness; a distinctive increase in basophils is clinically significant. This particular form of myeloproliferative neoplasm is linked to the Philadelphia chromosome, a distinctive chromosomal rearrangement. **Methodology:** This was a cross-sectional hospital-based study carried out in Kirkuk Governorate, Iraq, from the beginning of November 2022 to May 2023 on chronic myeloid leukemia patients in the Oncology and Hematology Center. A total of 53 patients and 15 controls who were admitted and diagnosed with chronic myeloid leukemia based on complete blood count were included in the study. Incomplete data and patients who did not provide informed consent were omitted from the analysis. **Results**: A total of 53 patients were included in the study, with a mean age of 47.3±12.8 years. Mean HGB was 13.11±12.79 g/dl while HCT was 38.27±37.88%. PLT was 257.33±218.08 $x10^9$cells/mm3, WBC 4.77±4.61 $x10^9$ cells/mm3, RBC 4.77± 4.61 $x10^{12}$/L. All statistics were implemented using statistical programs. **Conclusion**: The present study predicted the median age of 47.3 years in patients from chronic myeloid leukemia; a considerable difference did not exist in various Hematological parameters of male and female CML patients. It was concluded that no important difference in correlation was observed with age. A significant difference was observed in the platelet count of these patients on the basis of gender.

Keywords: Chronic Myeloid Leukemia, BCR-ABL, Age, Gender.
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INTRODUCTION

Cancer is one of the leading causes of mortality, with one out of every eight people globally dying from one sort of cancer (1). These many varieties are distinguished by somewhat unregulated cell growth, which can penetrate bodily tissues, replace normal cells, and metastasize to distant organs (2). Cancer develops when abnormal cells divide uncontrolled and spread to other tissues in the body. The illness develops when genetic abnormalities affect the order of cell growth. Based on histological findings, the illness is categorized into five primary types: Cancer, Sarcoma, Myeloma, Leukemia, and Lymphoma (3). Cancer occurrences have been expanding lately at the global level and in Kirkuk city. Hence, numerous analysts examined diverse cancer types in order to completely understand their nature and the role of various drugs in the progression of cancer cells (4). Pancreatic cancer has been called the lord of cancer owing to its forceful and deadly behavior. Concurring to the Worldwide Organization for Investigate on Cancer (IARC)2020 insights, pancreatic cancer proceeds to contribute essentially to the around the world burden of dangerous infections, positioning as the 12th most predominant cancer (2.6% of all cancers) and the seventh most common cause of cancer mortality (4.7% of all cancers). The frequency and mortality rates of pancreatic cancer are broadly diverse; countries with tall or exceptionally tall Human Development Indexes have generally five times higher rates when compared to low or medium-sized nations. Age influences the rates for both sexes, with elderly

grown-ups over 70 having the highest rates, and individuals over 55 accounting for 90% of all frequencies of pancreatic cancer (5).

Leukemia is a malignant clonal expansion of leukocytes that directly impacts bone marrow-cell maturation and production. Diese illness develops from lymphoid or myeloid lineages and has acute (precursor cell) or chronic (mature cell) subtypes. In contrast to chronic leukemia, acute leukemia has a speedy beginning, rapid development, and a deadly end in a few weeks (6). The disease is also distinguished by a frequent rise in the number of white blood cells (WBC) and the rate of proliferation in both mature and maturing cells of a certain lineage, resulting in cell accumulation. Leukemia cells eventually replace most normal hematopoietic cells in the bone marrow, impairing normal bone marrow function. Chronic Leukemia Symptoms are frequently vague and diverse at the time of diagnosis (7).

Chronic Myeloid Leukemia (CML) is a hematopoietic malignancy arising from a molecular modification in single pluripotent hematopoietic stem cells that constantly create the myeloid progeny (8). CML is typically caused by the Philadelphia-Chromosome or hyperdiploidy with more than 50 chromosomes (9). The breakpoint cluster region and Abelson's (BCR-ABL) fusion genes result from a translocation between chromosomes 9 and 22 (q34;q11). P210, an oncoprotein located in the cytoplasm, stimulates tyrosine kinase and activates signals that transform hematopoietic stem cells into leukemic cells. This amplifies tyrosine kinase action and plays a crucial role in the pathogenesis of leukemia. Risk factors for CML include low socioeconomic status, exposure to benzene and formaldehyde, and high doses of ionizing radiation among atomic bomb survivors, in addition to leukemia-related variables. Other risk factors for CML include alcohol misuse, obesity, weight gain in maturity, and exposure to food industry preservatives and pesticides (10;11).

The disease advances through three phases: chronic, fast, and blast crises, during which the leukemic clone loses the ability to differentiate (12;13). The most common clinical signs are fever, anemia, profuse sweating, splenomegaly, anorexia, easy satiety, weight loss, and weariness (14). Some individuals exhibit hyper viscosity, spontaneous bruising or bleeding, gout, priapism, vertigo, and hearing loss (15). Examination of blood film reveals neutrophilia with a left shift and repeated eosinophilia and basophilia. Philadelphia chromosomes have been revealed in around 90–95% of patients in cytogenetic studies, and in roughly half of the Philadelphia-chromosome-negative patients, BCR-ABL-mutation (which can be major, minor, or micro, depending on the breakpoint on BCR) could yet be reported using molecular techniques (16).

Two prognostic grading methods exist to differentiate patients with CML based on their risk. The core was established during chemotherapy and considers factors such as patient age, spleen size, platelet count, and blast percentage in peripheral blood (17). Patients receiving interferon treatment may see an increase in eosinophils and basophils in their peripheral blood (18;19). Research on age as a prognostic factor for hematological parameters in CML patients is scarce. Although it has been observed that individuals under 40 years old have higher levels of leukocytosis and anemia, this relationship has not been widely researched (20).

METHODOLOGY

Fifty-three patients in total (26 males and 27 females) and 15 controls (6 males and 9 females), whose ages ranged between 20 and 80, were admitted to the Oncology and Hematology Centers and were chosen for the study. On their initial presentation, all CML patients newly diagnosed on a complete blood count (CBC), aged >20 years, were included. Any case of CML that had formerly received chemotherapy and patients who were not compliant with taking part or had insufficiency in diagnostic criteria were excluded from the study. Informed consent was obtained from the patients, who had completely concealed the data. The age and gender of the patients were among the demographic data that were recognized. A complete blood count was performed in the pathological laboratory of the Oncology and Hematology Center, including hemoglobin (HB g/dL), white blood cells (WBC $x10^9$/L), hematocrit (HCT%), and platelets (PLT $x10^9$/L).

1. SAMPLING AND DATA COLLECTION

All the necessary data was collected by the medical staff; a detailed questionnaire was designed, including name, age, sex, signs and symptoms, family history, duration of disease, and period of treatment. Peripheral blood samples were collected from the vein by a single-use sterile syringe and kept in an EDTA tube and a Jell tube, using 2 mL for the CBC test.

2. Complete BLOOD COUNT (CBC) TEST

CBC was analyzed directly after the collection of blood by using an Automatic hematology analyzer (Swelab Alfa). The CBC investigation looked at different parts of the blood, like white blood cells, hemoglobin, red blood cells, and platelets. Patients with CML have an increased white blood cell count, often to very high levels, a decreased red blood cell count, and a possible increase or decrease in the number of platelets depending on the severity of the person's CML.

3. STATISTICAL TEST

In this study, the t-test was used to compare variables between the patient group and the control group. Two types of tests were applied: a test for equal variance of samples, which compares means between the two, groups when the variance between them is assumed to be equal; a Test for unequal variance of samples, when the variances could not be assumed to be equal. Statistical analysis was also used to evaluate the data, including calculating P values and standard deviations. The level of statistical significance was set at a value less than 0.05.

RESULTS

A total of 53 patients diagnosed with chronic myeloid leukemia were selected for this study, with a mean age of 47.3±12.5, as illustrated in Figure (1). The distribution of the patients based on gender is illustrated in Figure (2). The percentages of males are 47% compared to females, which is 53%. This percentage can help give an accurate idea of the development of the recovery percentage based on gender. Figure (3) illustrates the percentage of smokers, which is 26%, or about 2/3, compared to non-smokers. Eighty-three percent of the persons in this study were married, Figure (4).

The most important variable used in this study is based on a family history of cancer types. The collected data showed that 13% of the persons had risk factors for CML; however, 21% had the same risk but with different organs affected by cancer in some relatives of patients. While more than 2/3 of the individuals in the population were without any risk based on their family history. Figure (5) illustrated the mentioned percentages. Moreover, 68% of the population did not suffer from chronic diseases during the treatment period. Figure (6) patients are described according to their chronic diseases (hypertension and diabetes).

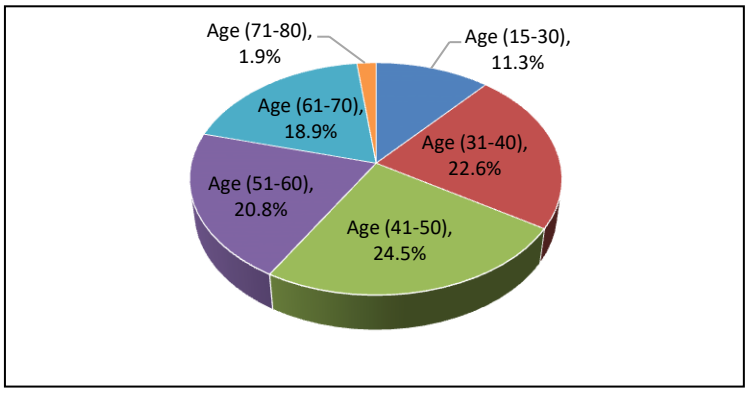

Figure (1): Distribution of the patient group based on age.

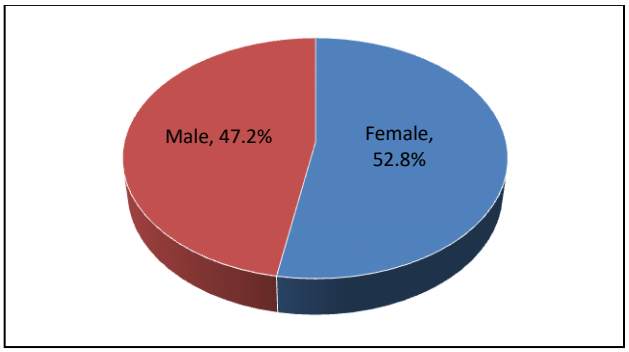

Figure (2): Distribution of the patient group based on gender.

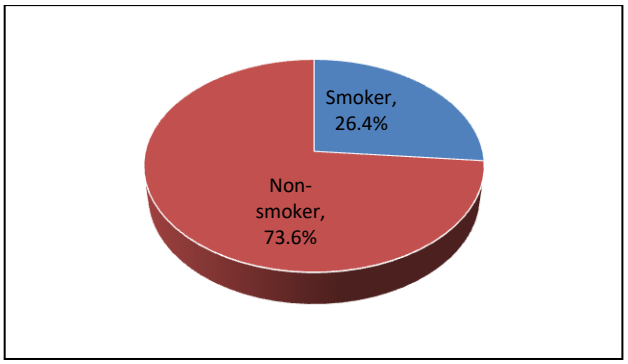

Figure (3): Distribution of the patient group related to the smoker versus non-smoker.

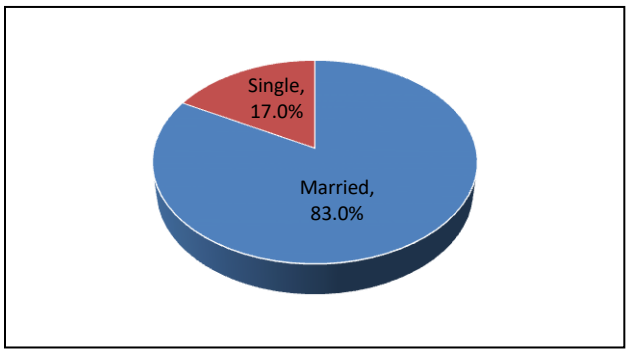

Figure (4): Distribution of the patient group based on marital status.

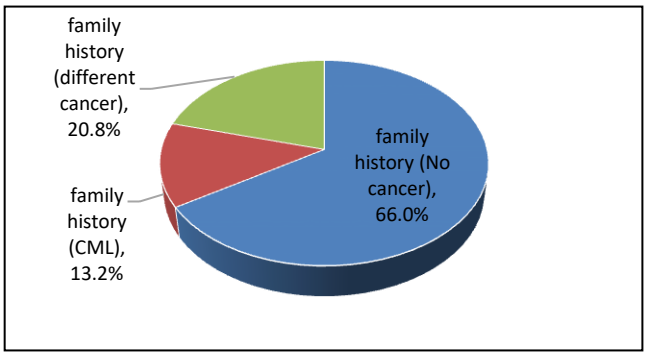

Figure (5): Distribution of the patient group based on familial history of cancer types.

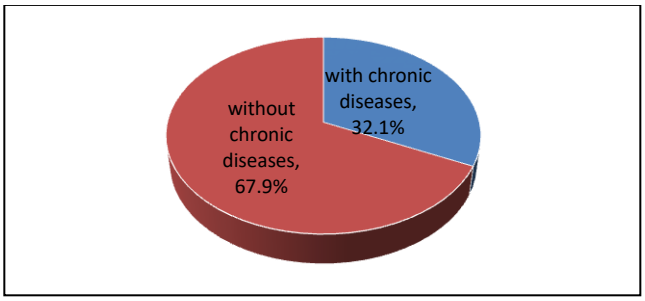

Figure (6): Distribution of the patient group with chronic disease.

The main symptoms that were recorded for all patients (patient group) were fatigue, fever, abdominal discomfort, night sweats, and splenomegaly. Table (1) shows the clinical characteristics of patients under consideration. It is clearly seen that all of the patients have abdominal discomfort. Moreover, most of them suffer from splenomegaly, while almost half of them showed fatigue during the test, and they lost weight**.** The table presents categorical data with counts for clinical characteristics among male and female individuals. Fatigue was the only factor that showed a statistically significant difference between males and females (p = 0.0017). The remaining variables were not statistically significant, meaning there was no significant difference between the sexes in these symptoms.

Table (1): Clinical characteristics of the CML patients (n = 53)

Clinical characteristics	**(%)**		**Chi-square**	**d_f**	***P*- Value**
	Female	**Male**			
Splenomegaly	47	42	0.000	1	**1.00**
Fatigue	40	13	9.898	1	**0.0071**
Lose weight	25	26	0.177	1	**0.674**
Fever	6	8	0.026	1	**0.872**
Night sweats	2	6	0.408	1	**0.523**
Abdominal discomfort	100	100	0.000	1	**1.000**

To determine whether a treatment has a real effect on the patient population, several methods are used in the current research. These methods depend on the obtained results and the details of the assumptions. The first method is a manual comparison of the means of the two groups, where the means are directly compared based on a simple definition of statistical criteria. The results in Table (3) show that almost all means fall within the normal ranges mentioned in Table (2). However, this method does not provide a true picture and cannot be applied to individual results. The aim of this research is to evaluate the results of the patient population compared to the normal range for complete blood counts.

Table (2): Normal range for CBC

Statistics	**Group**	**WBC $\times 10^9$cell/L**	**RBC $\times 10^{12}$ cell/L**	**HGB g/dL**	**PLT $\times 10^9$ cell/L**	**HCT %**
Male	Max.	11.0	4.7	16.5	317	48.6
	Min.	4.5	6.1	13.0	135	38.3
Female	Max.	11.0	5.4	16.0	371	44.9
	Min.	4.5	4.2	12.0	157	35.5
Independent t-test		0.000	0.651	0.282	0.271	0.466
***P* _value**		**1.000**	**0.583**	**0.805**	**0.813**	**0.687**

Chronic myelogenous leukemia (CML) caused significant anemia (Hgb < 12 g/dl), significant thrombocytosis (platelets > 450 × 10^9/L), and significant leukocytosis (WBC > 50 × 10^9/L) (22) as significant adverse pretreatment prognostic factors. The normal ranges of the CBC count for both male and female that are considered in this research are listed in the Table (2), while the actual ranges obtained from the lab test and the results of statistical analysis for both groups (control group n = 15 and the patient group n = 53) are listed in Table (3)**.**

Table (3) Statistics analysis of complete blood count for the two groups (control and patients)

Variable	Group	WBC (×10^9 cell/L)	RBC (×10^{12} cell/L)	HGB(g/dL)	PLT (×10^9 cell/L)	HCT(%)
Max.	Control	9.10	5.35	14.80	331.00	48.2
	patients	31.90	7.95	17.40	526.00	55.40
Min.	Control	4.90	4.12	10.7	181	22.5
	patients	2.90	3.25	7.70	30.00	26.30
Mean.	Control	6.89	4.77	13.11	257.33	37.88
	patients	7.76	4.61	12.79	218.08	38.27
St.D	**Control**	**1.28**	**0.37**	**1.29**	**43.64**	**8.22**
	patients	**4.92**	**0.98**	**1.97**	**87.49**	**6.72**
St. Error means	**Control**	**0.33**	**0.10**	**0.33**	**11.27**	**2.12**
	patients	**0.68**	**0.14**	**0.27**	**12.02**	**0.92**

In Table (4) introduced the results of the parameters obtained from a t-test of two groups, with the assumption that the variances of both groups are equal. It is clearly seen that the t-statistic for all CBC tests are less than t-critical, and p-values are greater than the estimated significance level ($\alpha = 0.05$). Therefore, the result is not significant, and the test shows meaningless results.

As mentioned above, t-statistics are obtained according to Equation 4.4 (unequal variance assumed). The results are listed in Table (5). It is obvious that the t-test value, t-critical, df, and *p*-value were significantly changed compared to those in the Table (4) (equal variances assumed). It can be seen that all *p*-values are greater than α, except for PLT, which means that the null hypotheses cannot be rejected for all, but for PLT, alternative hypotheses can be accepted. Moreover, this result is also satisfactory with the t-statistic compared to the t-critical; now one can say that the PLT count is significantly different between the control and experienced group, i.e., there is a small effect of the treatment program on the PLT.

Table (4): t-Test: Two-Sample Equal Variances Assumed

Statistics' parameter	WBC ×10^9 cell/L	RBC ×10^{12} cell/L	HGB g/dL	PLT×10^9 cell/L	HCT %
t-statistic	0.67	0.51	0.59	1.67	0.19
Pooled Variance	19.43	0.80	3.42	6434.44	49.93
d_f	66	66	66	66	66
P-value (2-tail)	0.50	0.54	0.56	0.10	0.85
Mean difference	0.87	0.13	0.32	39.26	0.39
St. Error difference	**1.29**	**0.26**	**0.54**	**23.46**	**2.07**

Table (5): t-Test: Two-Sample Unequal Variances Assumed

Statistics' parameter	WBC $\times 10^9$ cell/L	RBC $\times 10^{12}$ cell/L	HGB g\dL	PLT $\times 10^9$ cell/L	HCT %
t-statistic	1.15	0.96	0.75	2.38	0.17
t-critical	2.00	2.00	2.03	2.01	2.09
d_f	66	61	35	47	20
***P*-value (2-tail)**	**0.25**	**0.34**	**0.46**	**0.02**	**0.87**

DISCUSSION

Fifty-three patients (26 males and 27 females) admitted to the hematology and oncology center were chosen for the study. On initial presentation, all of them with Chronic Myeloid Leukemia (CML), moreover, the mentioned patients can be considered as patients under chronic phase diagnosis and have undergone treatment by Tyrosine Kinase Inhibitor (TKI), any case of CML who formerly received chemotherapy and patients not compliant to take part or having insufficiency in diagnostic criteria were debarred from the study. The patients were asked for permission to use their information without telling them what the information would be used for. The researchers looked at information about the patients' age, male or female, and ethnic background. A complete blood picture was performed in a pathological laboratory.

The age of the population ranges between 20 and 80 years, with a slight female predominance. The age groups illustrated in Figure(1) clearly show that the most frequent age was older than 50 years old, which was 42%, compared to 58% who were less than 50 years old. The mean age of the patients was 47.3±12.8 years, which is higher than the highest mean found in the literature by 5.4 years. The means found in the literature range between 39 years and 41.8 years (21; 22; 23; 24; 25; 26).

Effect of Gender Risk, this section aimed to evaluate the association of hematological parameters with gender, 53% of females versus 47% of males included in this assessment, having a mean age of 48.9±14.6 and 45.5±13.6 years, respectively. As previously shown in Table (1), the active symptoms that were recorded for all patients were fatigue, fever, abdominal discomfort, night sweats, and splenomegaly. Regarding this section, the effect of gender on these symptoms, and from Figure (1), it is clear that males were predominant over females in terms of fatigue. This agrees with some research (22;32).

The maximum, minimum, mean ±SD and standard error mean of variables were recorded for the leucocyte and red blood count, hemoglobin level, platelet, and hematocrit percentage. Moreover, two assumptions (equal and unequal variance) of the t-test were applied for comparison purposes of the differences in means between the two groups. Comparing the different variables showed that there are no significant differences were seen related to age, this is consistent with some research (24;25), however, some studies (22;25;26) found that the male were predominance over females for the middle age (35-54 years), and less pronounced in older populations (26), while (29) concluded that female patients were older at diagnosis than male patients.

The mean of leucocyte was 7.52±4.1 and 8.03±5.78 $\times 10^9$ cell/L, for female and male respectively, and the platelet mean was 223±82 213±95×109 cell/L for female and male respectively, in these two tests statistic result showed meaningless results related to gender this agrees with many studies' conclusion (24; 29; 30; 31) in other words, one can accept the null hypothesis and there are no gender effect on the treatment type, this is not surprisingly because the treatment generally with Imatinib mesylate improved the leucocyte count to normal level (26), keeping in mind that the treatment time is normalized automatically because Imatinib mesylate had been reported as a rapid and dramatic resolution within 2 weeks after initiation of Imatinib mesylate treatment, while the treatment time for all patients in the current work were treated for a long time.

The same neglected effect of gender can be concluded for platelet count, where the t-value was 0.41, which is greater than the t-critical of 2.01, ** and the *p*-value was 0.69, which is greater than the significance level ($\alpha = 0.05$). This agrees with the previous studies (26) about the treatment with Imatinib mesylate.

The important differences were among the red blood count, hemoglobin count, and the percentages of hematocrit ($P = 0$ for all, which is less than the significance level), and absolute t-values are greater than the t-critical of 2.02, 2.05, and 2.01, respectively. (24) concluded that there is a significantly low proportion of males compared to females related to thrombocytosis, however in the current study the thrombocytosis for male compared to female (526×10^9 L), and also low hemoglobin for female vis males agrees with (28), however, opposite conclusion can be found in (24; 29) moreover, (27) found that the comparisons between females and males in based on the race, they found that the Whites are more consistent then the Blacks and Asian, and the males are larger in risk but shorter in latency, (28) also accepted this hypothesis.

Another simple and accurate method were applied, where the percentages of the individual values out of the normal ranges had been calculated, the results show that the females are get less benefit from the treatment specially regard the RBC (74%) Anemia, HGB (68%) Hemoglobinopathy, and HCT (68%) Table 8, where these values were less than the lesser amount of normal count (thrombocytopenia). Moreover, females' PLT also benefits less from the treatment than males. The good finding is that the females benefit less from the treatment regarding CBC.

Effect of Age Risk In this section, the effect of age on the treatment program was held on, in order to get an accurate judgment in obtaining the results, the patients' age was divided into five groups limited to ten years for each group (21-30), group (31-40), group (41-50), group (51-60), and group (61-70). Therefore, as an active way, the CBC parameters were checked as an independent variable that affects a dependent variable, which is the age group. Group age (61-70) differs from all other groups ($P = 0.03, 0.03, 0.05$) with group age (31-40), group age (41-50), and group age (51-60), respectively. As a conclusion related to this section for those aged 61- 70, one can reject the null hypothesis, i.e., the group age (61-70) has a higher incidence, and the leucocyte count is the main factor that is affected by age. This mentioned group age can agree with some studies found in the literature. (28) found that the group age (55-75) shows slow response to the treatment compared to other groups, moreover, (29) concluded that the predominance of age group is depending on gender, they found that males under 55 years are more affecting than female, while the female older than 55 years have a higher incidence. Further, (31) introduced a lower group age, where, at group age (40-60), CML mostly occurs. However, (33) concluded that no important difference in correlation was observed with age.

CONCLUSION

The present study predicted a mean age of 47.3±12.8 years in patients suffering from chronic myeloid leukemia. Furthermore, no significant correlation existed in various hematological parameters with increasing age in these patients. However, a significant difference was observed in the platelet count of these patients on the basis of gender.

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ETHICAL APPROVAL

Before participating in the project, each patient received detailed information about the study and signed an informed consent form according to the acceptance of the Iraq, Kirkuk, and Health Directorate.

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تقييم العلاقة بين العمر والجنس مع المتغيرات الدموية لدى مرضى سرطان الدم النخاعي المزمن

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الخلاصة

خلفية عن الموضوع: تُعرف الأورام الخبيثة في خلايا الدم البيضاء باسم سرطان الدم النقوي المزمن (CML)، أو سرطان الدم النخاعي المزمن. يتم تعريف هذا النوع من سرطان الدم من خلال تراكم الخلايا النقوية في الدم وانتشارها المرتفع بشكل لا يمكن السيطرة عليه في نخاع العظم. لوحظ تكاثر الخلايا المحببة البالغة (العدلات، والحمضات، والقاعدات) وأسلافها في سرطان الدم النخاعي المزمن، وهو مرض الخلايا الجذعية النسيلي لنخاع العظم. الزيادة المميزة في الخلايا القاعدية مهمة سريريًا. يرتبط هذا الشكل المحدد من الأورام التكاثرية النقوية بكروموسوم فيلادلفيا، وهو إعادة ترتيب كروموسومي مميز، **الهدف من الدراسة**: أجريت هذه الدراسة بهدف تحديد العلاقة الارتباطية بين العمر والجنس مع المتغيرات الدموية لدى المرضى المقبولين في مركز الأورام وأمراض الدم في محافظة كركوك، العراق، **الطرق ومواد العمل**: كانت هذه دراسة مقطعية على مستوى المستشفيات أجريت في محافظة كركوك، العراق من بداية نوفمبر 2022 إلى مايو 2023 على مرضى سرطان الدم النخاعي المزمن في مركز الأورام وأمراض الدم. تم تضمين ما مجموعه 53 مريضا و شخص اصحاء 15 تم تشخيصهم على أنهم سرطان الدم النخاعي المزمن عن طريق تعداد الدم الكامل. في الدراسة تم حذف البيانات غير الكاملة والمرضى الذين لم يقدموا موافقة مستنيرة من البيانات، النتائج: تم تضمين ما مجموعه 55 مريضا في الدراسة بمتوسط عمر 47.3 ± 12.8 سنة. كان متوسط HGB 13.11 ± 12.79 جم / ديسيلتر بينما كان HCT 38.27 ± 37.88٪. كان PLT 257.33 ± 218.08 10^9 × خلية / مم ^{3}، WBC 4.77 ± 4.61 × 10^9 خلية / مم ^{3}، RBC 4.77 ± 4.61 × 10^{12} / لتر. تم تنفيذ جميع الإحصائيات باستخدام برامج الإحصاء، **الاستنتاجات**: تنبأت الدراسة الحالية بأن متوسط العمر هو 47.3 سنة في المرضى الذين يعانون من سرطان الدم النخاعي المزمن، ولم يكن هناك فرق كبير في مختلف معايير أمراض الدم لدى مرضى سرطان الدم النخاعي المزمن من الذكور والإناث. لم يستنتج هناك وجود علاقة فرق مهمة مع تقدم العمر. وقد لوحظ وجود اختلاف كبير في عدد الصفائح الدموية لهؤلاء المرضى على أساس الجنس.

الكلمات المفتاحية: ابيضاض الدم النقوي المزمن، BCR-ABL، العمر، الجنس.