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DIAGNOSTIC TEST OF MOLECULAR RAPID TEST AGAINST REAL-TIME PCR ON DETECTING BCR-ABL CHRONIC MYELOID LEUKEMIA

Uji Diagnostik Test Cepat Molekuler Terhadap Real Time PCR Dalam Deteksi BCR-ABL Pada Chronic Myeloid Leukemia

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ABSTRAK

Chronic Myeloid Leukemia (CML) merupakan suatu kondisi yang ditandai oleh proliferasi abnormal sel hematopoietik yang dapat terjadi pada berbagai kelompok usia. Deteksi Breakpoint Cluster Region-Abelson (BCR-ABL) penting untuk mengidentifikasi keberadaan Kromosom Philadelphia (Ph 1 chr). Pemeriksaan Real-Time Polymerase Chain Reaction (Real-Time PCR) merupakan gold standar untuk deteksi BCR-ABL, namun memiliki keterbatasan seperti waktu pengerjaan lama dan biaya tinggi. Tes Cepat Molekuler (TCM) melalui platform GenXpert menawarkan alternatif yang lebih cepat dan praktis. Penelitian ini bertujuan mengevaluasi kinerja TCM BCR-ABL dibandingkan Real-Time PCR. Desain penelitian menggunakan pendekatan cross sectional dengan 54 sampel yang diperoleh melalui teknik consecutive sampling berdasarkan rumus Lemeshow. Hasil penelitian menunjukkan sensitivitas 91%, spesifisitas 90%, positive predictive value (PPV) 94%, dan negative predictive value (NPV) 86%. Uji Wilcoxon menunjukkan tidak ada perbedaan signifikan antara kedua metode (p=0,100). Berdasarkan hasil penelitian tersebut, TCM memiliki kinerja diagnostik yang mendekati Real-Time PCR dan berpotensi digunakan sebagai alternatif pemeriksaan cepat dan efisien pada deteksi CML.

***Kata kunci**: chronic myeloid leukemia, TCM BCR-ABL, real time PCR BCR-ABL, uji diagnostik*

ABSTRACT

Chronic Myeloid Leukemia (CML) is a condition characterized by abnormal proliferation of hematopoietic cells and can occur across various age groups. Detection of Breakpoint Cluster Region-Abelson (BCR-ABL) is essential to identify the presence of the Philadelphia chromosome (Ph 1 chr). Real-Time Polymerase Chain Reaction (Real-Time PCR) is the gold standard for BCR-ABL detection, but it has limitations such as long processing time and high cost. The Molecular Rapid Test (TCM) using the GenXpert platform offers a faster and more practical alternative. This study aimed to evaluate the performance of TCM BCR-ABL compared to Real-Time PCR. A cross-sectional design was applied with 54 samples obtained using consecutive sampling based on Lemeshow's formula. The results showed a sensitivity of 91%, specificity of 90%, positive predictive value (PPV) of 94%, and negative predictive value (NPV) of 86%. Wilcoxon test analysis revealed no significant difference between the two methods (p=0.100). In conclusion, TCM demonstrates diagnostic performance comparable to Real-Time PCR and has the potential to be used as a rapid and efficient alternative for CML detection.

Keywords: chronic myeloid leukemia, MRT BCR-ABL, real-time PCR BCR-ABL, diagnostic test

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INTRODUCTION

Chronic Myeloid Leukemia (CML) is a hematological disorder characterized by the abnormal proliferation of hematopoietic cells. This disease can occur at any age, but is most common in individuals aged 50-60 years and accounts for approximately 15% of all adult leukemia cases. The primary cause of CML is a reciprocal translocation between chromosomes 9 and 22, resulting in the Philadelphia (Ph) chromosome, which results in the fusion of the Breakpoint Cluster Region (BCR) and Abelson (ABL) genes. This results in increased tyrosine kinase activity, which plays a role in the pathogenesis of CML.[1.2]

Globally, the incidence of leukemia continues to rise. According to World Health Organization (WHO) data, in 2022, there were 486,777 cases, resulting in 305,033 deaths. Leukemia is among the top 10 causes of cancer death worldwide, with the highest incidence in Asia at 49.2%.[3.4]

To diagnose CML, BCR-ABL testing is crucial because it is the primary molecular marker indicating the presence of genetic abnormalities characteristic of this disease. BCR-ABL testing is performed using the Real-Time Polymerase Chain Reaction (Real-Time PCR) method. This method allows for measurement of BCR-ABL transcript levels with high accuracy and sensitivity, making it the gold standard for CML diagnosis. However, this method has several limitations, such as a long processing time and high cost.[5]

In medicine, diagnostic tests play a crucial role in supporting disease diagnosis. Diagnostic tests aim to compare the predicted results of a test with the gold standard, which in the case of CML is Real-Time PCR.[6.7]The main parameters in diagnostic tests include sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). Sensitivity indicates the diagnostic tool's ability to detect disease, while specificity describes its ability to confirm that a sample is not diseased. PPV measures the probability that a person is truly diseased if their test result is positive, while NPV indicates the probability that a person is truly not diseased if their test result is negative.[8]

As an alternative to Real-Time PCR, the Molecular Rapid Test (TCM) using the GeneXpert system offers a faster and more efficient method for detecting BCR-ABL. A study by Permana (2024) showed that TCM is more effective for testing with fewer than 10 samples, with a lower unit cost than Real-Time PCR.[9]

This study aims to evaluate the sensitivity, specificity, PPV, and NPV of the BCR-ABL Molecular Rapid Test (TCM) was compared with Real-Time Polymerase Chain Reaction (Real-Time PCR) as the gold standard to ensure that this method is equivalent to Real-Time PCR in providing reliable results for clinical decision making.[10]

METHODS

This research is a diagnostic study with a cross-sectional study approach. The population in this study was all patients diagnosed with Chronic Myeloid Leukemia (CML) at a hospital in Bandung between January and November 2024. The sample was selected using a consecutive sampling method, namely patients undergoing BCR-ABL examination at the Molecular Biology Laboratory of the Hospital's Clinical Laboratory Installation. The specimen used was whole blood with EDTA anticoagulant. The sample size was calculated using the Lemeshow formula,

$$n = \frac{Z^2 \; x \; P \; x \; (1-P)}{d^2}$$

$$n = \frac{1{,}96^2 \; x \; 0{,}15 \; x \; (1-0{,}15)}{0{,}1^2}$$

$$n = \frac{3{,}8416 \; x \; 0{,}1275}{0{,}01}$$

$$n = 48{,}98 \approx 49 \text{ subjek penelitian}$$

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which produced 49 samples, then 10% was added to anticipate data loss, so that the total samples used were 54 samples.

The inclusion criteria in this study include patients examined during this study period. Meanwhile, the exclusion criteria were insufficient blood sample volume for examination.

The variables in this study consisted of the independent variable, the BCR-ABL examination method using the Molecular Rapid Test (TCM), and the dependent variable, the BCR-ABL examination results using the TCM method, which were categorized as positive or negative. These results were then compared with the examination results using the *Real-Time* PCR (qRT-PCR) is the gold standard. Furthermore, to assess the diagnostic performance of the TCM method, evaluative parameters such as sensitivity, specificity, PPV, and NPV were analyzed, calculated based on the agreement between TCM and qRT-PCR results. BCR-ABL examination in this study was carried outTwo methods were used. Real-time DNA amplification uses fluorescence to detect and quantify the amount of BCR-ABL transcripts. This method is known for its high sensitivity and is the gold standard for diagnosing CML.[11]Meanwhile, the Molecular Rapid Test (TCM) uses the GeneXpert system, which uses a nested PCR method, allowing the entire process, from RNA extraction to amplification, to be performed in a single automated cartridge. This makes the test faster and more practical than Real-Time PCR.[12].

Diagnostic evaluation is performed by determining the sensitivity, specificity, PPV, and NPV. Sensitivity was calculated as the ratio between the number of CML positive patients detected by TCM to the total number of positive patients based on Real-Time PCR, while specificity was calculated as the ratio of the number of negative patients detected by TCM compared to the total number of negative patients based on Real-Time PCR.[8] PPV describes the probability that a patient actually has CML if the TCM test result is positive, while NPV indicates the probability that a person actually does not have CML if the TCM test result is negative.[6].

After diagnostic evaluation, statistical analysis was performed to compare the results of TCM examination and *Real-Time* PCR. A descriptive univariate test was conducted to determine the distribution of %IS values from the TCM and Real-Time PCR test results. This analysis aims to describe the characteristics of the data before further statistical testing is carried out. Then, the data distribution was first tested using the Kolmogorov-Smirnov normality test to determine whether the data were normally distributed or not. If the data were normally distributed, the analysis was carried out using parametric statistical tests, whereas if the data were not normally distributed, a non-parametric statistical test (Wilcoxon test) was used. Differences in the results of the TCM and Real-Time PCR tests were tested using statistical methods appropriate to the data distribution to see if there were significant differences between the two methods.

This study has obtained ethical approval from the Ethics Committee of the Bandung Ministry of Health Polytechnic, with ethics review number 18/KEPK/EC/XII/2024. All patient data in this study will be kept confidential and will be used only for research purposes.

RESULTS

A total of 54 samples were examined using both methods, and their distribution and frequency were calculated. The data are presented in Table 1.

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Table 1. Distribution Data and Frequency Results of TCM and PCR Results

Results	N (TCM)	Percentage (%) (TCM)	N (PCR)	Percentage % (PCR)
Negative	21	39	22	41
Positive	33	61	32	59
Total	54	100	54	100

Table 1 shows that 54 samples were tested for BCR-ABL using the TCM tool. Twenty-one (39%) samples were negative and 33 (61%) were positive. The results were interpreted automatically by the GeneXpert system, based on a fluorescence signal algorithm. Meanwhile, examination using Real-Time PCR showed that 32 samples (59%) tested positive, while 22 samples (41%) tested negative. The results of the Real-Time PCR examination were plotted against a standard curve, consisting of five standard kit inserts with concentrations of 10^3 to 10^7, one negative control (NTC), and a curve of 10 samples. The comparison of the results of these two methods was then analyzed through a diagnostic test.

Table 2. Table 2 x 2 Diagnostic Test of TCM examination against Real Time PCR

Check up result		TCM		
		Positive	Negative	Total
*Real Time*PCR	Positive	30 (a)	2 (b)	32
	Negative	3 (c)	19 (d)	22
Total		33	21	54

Information :
a= Samples with TCM GenXpert (+) and Real Time PCR (+)
b= Samples with TCM GenXpert (-) and Real Time PCR (+)
c= Samples with TCM GenXpert (+) and Real Time PCR (-)
d= Samples with TCM GenXpert (-) and Real Time PCR (-)
n= Total

The data in Table 2 illustrates the results of the diagnostic test analysis to evaluate the performance of the TCM method compared to Real-Time PCR. Diagnostic test analysis was conducted to evaluate the performance of the TCM method compared to Real-Time PCR. Based on the results of the examination of 54 samples, the distribution of results shows that 30 samples were detected positive by both TCM and Real-Time PCR (true positive), while 2 samples showed positive results in TCM, but negative in Real-Time PCR (pseudo-positive). In addition, there were 3 samples that were negative in TCM, but positive in Real-Time PCR (pseudo-negative), and 19 samples were declared negative by both methods (true negative).

Based on these data, sensitivity, specificity, PPV, and NPV were calculated using diagnostic test formulas. Sensitivity was calculated as the ratio of the number of samples detected positive by TCM and Real-Time PCR compared to the total number of true positive samples, namely true positives (a) plus false negatives (c). These results indicate that the TCM method has a sensitivity of 91%, meaning it is able to detect 91% of positive CML cases that are also detected by Real-Time PCR.

Next, specificity was calculated as the ratio between the number of samples detected negative by both methods (true negatives (d)) compared to the total number of true negative samples, namely true negatives (d) plus false positives (b). From these results, it is known that the TCM method has a specificity of 90%, which means it is able to correctly identify 90% of negative samples.

In addition, a PPV calculation was performed, which is the probability that a patient actually has CML if the TCM test result is positive. From these results, it can be concluded that if the TCM test result is positive, there is a

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94% probability that the patient actually has CML.

Meanwhile, the NPV was calculated to determine the probability that the patient truly does not have CML if the TCM test result is negative. These results indicate that if the TCM result is negative, there is an 86% probability.

Before statistical analysis was carried out, a descriptive univariate test was carried out to determine the distribution of %IS values from the examination results using TCM and Real-Time PCR.

Table 3. Descriptive Univariate Test

IS % Value	N	Min	Max	Mean
TCM	54	0.00	113.71	19.46
*Real Time*PCR	54	0.00	114.71	17.47

The results of the descriptive univariate test are presented in Table 3. The analysis shows that the average %IS value for the TCM test was 19.46%, with a minimum range of 0.00% and a maximum range of 113.71%. Meanwhile, the average %IS value for the Real-Time PCR test was 17.47%, with a minimum range of 0.00% and a maximum range of 114.71%.

After univariate analysis was carried out, the data were tested using the Kolmogorov-Smirnov normality test to determine whether the data were normally distributed or not.

Table 4. Normality Test

	Kolmogorov-Smirnov		
	Statistics	df	Sig
TCM	0.279	54	0,000
*Real Time*PCR	0.260	54	0,000

The results of the Komogorov-Smirnov normality test are shown in Table 4. The test results show that the significance value for TCM and Real-Time PCR is 0.000 each, which is less than 0.05, so it can be concluded that the data is not normally distributed.

Because the data were not normally distributed, statistical analysis was performed using the Wilcoxon test, which is a non-parametric test to see whether there was a significant difference between the results of the examination using TCM and Real-Time PCR.

Table 5. Wilcoxon

	TCM with Real-Time PCR
Z	-1,646
Asymp. Sig. (2-tailed)	0.100

The Wilcoxon test results in Table 5 show that the Asymp. Sig. (2-tailed) value is 0.100, which is greater than 0.05, so it can be concluded that there is no significant difference between the results of the TCM and Real-Time PCR examinations.

DISCUSSION

In this study, a diagnostic test was conducted on TCM results against Real-Time PCR results. Diagnostic testing is a method for determining whether a person has a disease or not, based on the presence of signs and symptoms. This test is a crucial component of laboratory testing aimed at detecting, confirming, and monitoring disease. The accuracy of the test results in approaching the true value will determine the degree of certainty of the disease or whether a person is in a normal condition. One disease that requires accurate diagnostic testing is Chronic Myeloid Leukemia (CML).[7]

The accuracy, sensitivity, and ease of use of a method for diagnosing CML can influence treatment decisions and the patient's prognosis. The hallmark of this disease is the presence of chromosomeThe Philadelphia (Ph) chromosome produces the BCR-ABL fusion gene and triggers the production of the BCR-ABL fusion protein. Therefore, BCR-ABL testing is the primary method for identifying the presence or absence of the Philadelphia chromosome.[2.13]

The method currently used in BCR-ABL testing is*Real-Time*PCR, which is recommended by the National Comprehensive Cancer Network (NCCN) as the gold standard because it has very high analytical sensitivity, which is 100 to 1000 times more

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sensitive than FISH.[14.15]In addition, the National Institutes of Health Consensus Group recommends the use of the International Scale (IS) for BCR-ABL monitoring to allow for broader use of test results across laboratories. This IS scale is a system based on the IRIS clinical trial (100%IS), where a 3-log decrease from baseline is considered a major molecular response (MMR; MR3; 0.1%IS).[15]

In this study, from a total of 54 samples examined, the TCM method showed 33 positive samples and 21 negative samples, while *Real-Time* PCR showed 32 positive samples and 22 negative samples. The slightly higher positivity of TCM results compared to Real-Time PCR is consistent with previous research, which stated that the GeneXpert detection limit was 12 neoplastic cells (95.2% confidence), which is equivalent to detecting 1 leukemia cell in 10^5 white blood cells. This resolution is very similar to other Real-Time PCR methods.[16]

System based cartridge in TCM shows a linear relationship between ΔCt (BCR-ABL Ct – ABL Ct). GeneXpert generates the BCR-ABL ratio from the threshold cycle (Ct) value using the delta Ct method, with the final result being categorized into three categories: positive, negative, or invalid. A difference of up to 20 Ct values can be found between ABL and BCR-ABL, resulting in a minimum measurable ratio of 0.00001%. Meanwhile, in the Real-Time PCR assay, one sample showed a larger bias, likely due to separate reactions for BCR-ABL and ABL detection.[16,17]

Technology the innovative GeneXpert on the Xpert® BCR-ABL Ultra p190 allows the entire testing process, from RNA isolation, reverse transcription, to Real-Time PCR, to be performed automatically in a single, sealed cartridge.[12] In contrast, in BCR-ABL testing using Real-Time PCR, the isolation and PCR processes are performed in separate stages, so the results can be lower because RNA molecules are inherently susceptible to degradation. Other factors that influence the success of Real-Time PCR testing include initial sample handling, storage conditions, and sample transportation.[18]

Rapid and accurate diagnostic tests are essential in the management of CML patients. TCM offers a more practical and efficient solution, but it is still necessary to ensure that the sensitivity,The specificity, PPV, and NPV obtained are equivalent to Real-Time PCR so that they can be relied upon in clinical decision making.[10]. Based on the results of this study, the sensitivity values were 91%, specificity 90%, PPV 94%, and NPV 86%, which were calculated based on the diagnostic test table.[19]

Sensitivity measures the ability of a diagnostic method to detect disease, calculated from the ratio of true positive samples (a) to total positive samples (a+c). In this study, the sensitivity of BCR-ABL examination using TCM against Real-Time PCR was 91%, which means TCM was able to detect 91% of Philadelphia type CML (Ph+). Meanwhile, specificity measures the ability of the diagnostic method to determine that a sample is not diseased. The calculation of specificity is done by the ratio of true negative samples (d) compared to the total negative samples (b+d). The specificity result in this study was 90%, which means TCM can identify patients who do not have Philadelphia type CML (Ph+) with 90% accuracy.[8]

The PPV value (94%) indicates that if the TCM result is positive, there is a 94% probability that the patient actually has Philadelphia-type CML (Ph+). Conversely, the NPV value (86%) indicates that if the TCM result is negative, there is an 86% probability that the patient actually does not have CML. Errors in the NVP values are likely caused by pre-analytical factors,

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such as sample collection, storage, and handling.[6,8,15]

After the diagnostic test results were known, a statistical test was performed to determine the significant differences between the TCM and Real-Time PCR results. The normality test results indicated that the data were not normally distributed, so a Wilcoxon test was performed. Of the 54 samples tested, a significance value of 0.100 was obtained, which is greater than 0.05. Therefore, it can be concluded that there is no significant difference between the TCM and Real-Time PCR results. This indicates that TCM has ideal diagnostic value and can be used as an alternative to Real-Time PCR, which is the gold standard.[6]

These findings not only confirm the diagnostic value of TCM, but also provide a basis for reviewing its advantages, limitations, and potential applications in clinical practice.The strength of this study is the use of two BCR-ABL testing methods, namely the Molecular Rapid Test (TCM) and Real-Time PCR, both of which have been clinically approved. Although the results of the statistical analysis showed that the differences were not statistically significant, this comparison still provides practical contributions, especially in helping hospitals determine the efficient unit cost of BCR-ABL testing and determine the turnaround time (TAT) of BCR-ABL testing through TCM. In addition, the cross-sectional design and sufficient sample size are also strengths of this study, and the use of GeneXpert as an automated system shows potential for implementation in laboratories with limited resources.

However, this study also has several limitations. First, it did not stratify patients based on age, even though age can influence the clinical manifestations of CML and BCR-ABL levels. Second, this study did not include data on leukocyte or routine blood tests, which could have been supporting factors in interpreting molecular results. Third, the %IS results from the Real-Time PCR assay showed a very wide range, which can lead to variability in interpretation, especially in borderline cases.

The practical implications of this study suggest that TCM BCR-ABL may be a viable alternative to *Real-Time* PCR in detecting the BCR-ABL fusion gene in CML patients, especially in healthcare facilities that require rapid processing and simpler operations. With accuracy approaching the gold standard, TCM has the potential to be adopted as a routine diagnostic tool in CML management, while accelerating clinical decision-making at various levels of care. Impact on clinical decisions, especially in monitoring therapy with tyrosine kinase inhibitors (TKIs). qRT-PCR is used to determine whether patients achieve a major molecular response (MMR, MR3) or a deep molecular response (DMR, MR4.5 or lower), which is a benchmark in evaluating the success of therapy.[14]

CONCLUSION

Based on the research results, it can be concluded that the Molecular Rapid Test (TCM) shows comparable diagnostic accuracy to Real-Time PCR in detecting the BCR-ABL gene in Chronic Myeloid Leukemia (CML) patients with 91% sensitivity, 90% specificity, 9% PPV, and 8% NPV. These findings suggest that TCM can be a faster and more practical diagnostic alternative for CML, especially in healthcare facilities with limited resources.

Future research is recommended to involve a more diverse population, including patients with different disease stages and other supporting clinical data. Furthermore, follow-up studies with designs that consider the prevalence of cases and healthy controls will provide a more comprehensive picture of TCM's diagnostic performance in clinical practice.

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