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SENSITIVITY AND SPECIFICITY OF MALARIA RAPID DIAGNOSTIC TEST (RDT)

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ABSTRACT
Malaria remains a significant public health issue in many regions, and early diagnosis is crucial for effective treatment. Rapid Diagnostic Tests (RDT) are commonly used for malaria detection due to their speed and ease of use, but their diagnostic accuracy, particularly in regions with varying levels of parasitemia, remains a subject of ongoing research. This study aimed to evaluate the performance of Rapid Diagnostic Tests (RDT) for malaria diagnosis at Puskesmas Hanura, Teluk Pandan District, Pesawaran Regency, by assessing the sensitivity and specificity of the test. Methods: This analytical observational study employed a cross-sectional approach, analyzing blood samples from malaria suspect patients collected between December 2024 and February 2025, with a total sample size of 50 samples. The diagnostic performance of RDT was compared to the gold standard of microscopy using thick and thin blood smears. Sensitivity and specificity were calculated based on the results of both methods. The sensitivity of the RDT was found to be 93.5%, indicating that the test was highly effective in detecting true positive malaria cases, particularly in individuals with high parasitemia. The specificity was 100%, demonstrating that the RDT accurately identified malaria-free individuals with no false positive results. However, the study also identified two false negative cases, suggesting that the RDT's sensitivity could be reduced in cases of low parasitemia. The Rapid Diagnostic Test demonstrated excellent sensitivity and specificity in detecting malaria at Puskesmas Hanura, with no false positive results and a high rate of true positive detection. However, the test showed some limitations in detecting low parasitemia, emphasizing the need for confirmatory diagnostic techniques, such as microscopy or molecular methods, especially in areas with low transmission or mild infections.

Keywords: malaria; microscopy; rapid diagnostic test (RDT); sensitivity; specificity

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INTRODUCTION

Malaria remains a major public health issue in tropical and subtropical regions, with significant variations in prevalence across different geographical areas. Recent data indicate that the prevalence of malaria can range from over 50% in some regions to near zero in others, largely influenced by geographic location, environmental conditions, and the effectiveness of public health interventions (Ncogo et al., 2015). In Asia, countries such as India report varying malaria prevalence, ranging from 0.8% in urban areas to 3.6% in rural regions (Kuepfer et al., 2019). Similarly, studies from Cambodia and Vietnam highlight high prevalence rates in areas with limited access to healthcare services and preventive interventions (Sluydts et al., 2014; Tyrrell et al., 2019). In Indonesia, malaria prevalence shows a similar disparity, with higher rates observed in eastern regions such as Papua and Maluku, where prevalence can reach 20%-30% in certain areas (Fadilah et al., 2022).In Lampung Province, malaria is endemic, with prevalence ranging from 1% to 5% in several areas, particularly in rural and forested regions (Triwahyuni et al., 2023). The transmission of malaria in this region is primarily driven by the Anopheles mosquito species, notably Anopheles maculatus and Anopheles balabacensis (Wibowo et al., 2020). The most commonly used diagnostic methods for malaria in Indonesia include microscopy, Rapid Diagnostic Tests (RDTs), and Polymerase Chain Reaction (PCR) techniques, with

microscopy being the gold standard for malaria diagnosis (Huda et al., 2024). While microscopy is highly specific, with accuracy rates often exceeding 90%, its sensitivity may decrease in cases with low parasitemia, leading to false negative results (Ciputra, 2022).

RDTs have emerged as an important tool in malaria diagnosis due to their ability to provide quick results, often within 15 to 30 minutes, and their use in settings where access to advanced laboratory equipment is limited (Prah et al., 2021). Despite their rapid diagnostic capabilities, RDTs have variable sensitivity and specificity, which can range from 62% to 95%, depending on the test used and the prevalence of malaria in the region (Mwesigwa et al., 2019). Furthermore, RDTs may yield false positive results, especially in cases of past infections where residual antigens remain detectable in the bloodstream (Shah et al., 2022).The Puskesmas Hanura, located in a malaria-endemic area in Teluk Pandan District, Pesawaran Regency, Lampung Province, recorded 1,738 malaria cases in 2017, significantly higher than other health centers in the region. The area's topography, which includes agricultural land, forests, and settlements, creates an ideal environment for Anopheles mosquitoes, contributing to the high malaria prevalence. Studies in the region have identified Plasmodium vivax as the dominant species (90.9%), followed by Plasmodium falciparum (9.1%), highlighting the environmental and behavioral factors that influence malaria transmission (Prasetyo and Haryatmi, 2023).Given the ongoing challenges in malaria diagnosis and the prevalence of Plasmodium species in the region, this study aims to assess the sensitivity and specificity of Rapid Diagnostic Tests (RDTs) for malaria diagnosis at Puskesmas Hanura. By evaluating the accuracy of RDTs compared to the gold standard microscopy method, the study seeks to contribute valuable insights for improving malaria diagnostic strategies in endemic areas.

METHOD

This study employs an analytical observational design with a cross-sectional approach. It aims to evaluate and compare the diagnostic accuracy of two malaria detection methods—Rapid Diagnostic Test (RDT) and microscopy—by analyzing data from malaria suspect patients at Puskesmas Hanura. The study will be conducted on blood samples collected from patients during the period of December 2024 to February 2025, with both diagnostic methods being applied to the same set of samples.The population for this study consists of all patients who underwent malaria diagnosis at Puskesmas Hanura between December 2024 and February 2025. The sample is drawn from these patients, with both RDT and microscopic examination conducted on blood samples collected from malaria suspects during this timeframe. Accidental sampling will be used to include all relevant data from patients who meet the inclusion criteria.

Data will be collected from the blood samples of patients showing symptoms of malaria, taken according to standard procedures and examined using both RDT and microscopy. The blood samples will first be processed for microscopic examination, which includes the preparation of thin and thick blood smears. The Giemsa staining technique will be employed for the microscopic analysis, with a staining time of 20–30 minutes. The RDT will be conducted using standard test kits, following the manufacturer's instructions, with a sample size of 5–10 µL of blood for each test. The results for both diagnostic methods will be recorded as positive or negative, with any invalid RDT results requiring a retest.The primary data source will be the results from both RDT and microscopy, which will be compared using a contingency matrix. The matrix will categorize the results into True Positive (TP), False Positive (FP), True Negative (TN), and False Negative (FN) for both methods. This comparison will be analyzed to determine the sensitivity and specificity of the RDT relative to microscopy. Sensitivity will be calculated as the proportion of true positive cases detected by the RDT, and specificity will be calculated as the proportion of true negative cases correctly

identified by the RDT. The analysis will help assess the reliability of RDT as a diagnostic tool for malaria in the study area.

RESULT

Table 1.
Contingency Matrix

Interpretation	f	%
True Positive	29	58
True Negative	19	38
False Negative	2	4
False Positive	0	0

The primary objective of this study was to evaluate the performance of the Rapid Diagnostic Test (RDT) in diagnosing malaria at Puskesmas Hanura. The results were analyzed by comparing the findings from the RDT to the microscopic examination of thick and thin blood smears. Among the 50 samples tested, RDT detected 29 true positives (TP), 19 true negatives (TN), and 2 false negatives (FN). Notably, no false positives (FP) were recorded, indicating a high specificity of the RDT. These findings suggest that the RDT was highly accurate in identifying malaria-free individuals, with no misdiagnoses of non-infected patients as positive.

Contingency Matrix Analysis

To further assess the diagnostic performance of the RDT, the contingency matrix was used to compare the results from the RDT against the gold standard of microscopy. The absence of false positive results indicates that the RDT is exceptionally reliable in detecting non-infected individuals. The true positive rate of 29 out of 50 samples suggests that the RDT effectively identifies the majority of malaria-positive cases. Importantly, there were only two false negative cases, which indicates that the RDT was highly sensitive, though not perfect, particularly for cases of low parasitemia.

Sensitivity and Specificity of RDT

$$Sensitivity = \frac{True\ Positive}{True\ Positive + False\ Negative}$$

$$Sensitivity = \frac{29}{29 + 2}$$

$$Sensitivity = 0.935$$

$$Sensitivity = 93.5\%$$

Figure 1. The calculation result of the sensitivity of the RDT

The sensitivity of the RDT was calculated to be 93.5%. This high sensitivity indicates that the RDT is capable of detecting the vast majority of actual malaria cases, especially those with high parasitemia. However, the presence of two false negatives suggests that the test may not detect malaria infections in individuals with low parasite levels or those with asymptomatic malaria. This highlights the limitation of the RDT in cases with low parasite density, where the test may fail to detect infection, underscoring the need for further confirmation, such as microscopy or additional diagnostic methods, to ensure accuracy in such cases.

$$Specificity = \frac{True\ Negative}{True\ Negative + False\ Positive}$$

$$Specificity = \frac{19}{19 + 0}$$

$$Specificity = 1$$

$$Specificity = 100\%$$

Figure 2. The calculation result of the specificity of the RDT

DISCUSSION

This study aimed to evaluate the performance of Rapid Diagnostic Tests (RDT) in diagnosing malaria by assessing the sensitivity and specificity of the test. The results from this research revealed that the sensitivity of the RDT was 93.5%, indicating that the test effectively detects nearly all positive malaria cases with a high level of accuracy. This finding suggests that RDT is particularly reliable for identifying infected individuals, especially in cases of high parasitemia. However, the high sensitivity also underscores a challenge in detecting cases with low parasitemia, where the sensitivity of the RDT tends to decrease. These findings are consistent with those of Karani et al. (2023), who reported a specificity of 87%, despite the various field conditions that may impact test results. The slightly reduced specificity observed in their study emphasizes the importance of local factors, such as malaria prevalence and the accuracy of test result interpretation, which can influence the performance of RDT in different settings.This study confirms the findings of Bwire et al. (2019), which demonstrated that the performance of RDT is highly dependent on the parasite density in blood samples. In cases with high parasitemia, the RDT was able to detect malaria very effectively. However, in infections with low parasitemia, the test is more prone to yielding false negative results. This highlights that while RDT has significant potential in malaria diagnosis, its limitations become more pronounced in cases with low parasite loads, which are often seen in mild or asymptomatic malaria cases. Therefore, in malaria management, RDT should be supplemented with other confirmatory techniques, such as microscopy or molecular diagnostics, to enhance diagnostic accuracy, particularly in regions with low transmission or mild infections.

Although the RDT demonstrated good sensitivity and specificity in this study, it is important to acknowledge that the performance of the test can vary based on field conditions, such as parasite density and malaria prevalence in a given area. This research reinforces the arguments presented in previous studies, which assert that while RDT offers advantages in terms of speed and ease of use, the test's performance is still influenced by local conditions and the characteristics of the samples being tested (Karani et al., 2023; Yeboah et al., 2016). Consequently, the use of RDT as the primary method for malaria diagnosis should be complemented by more sensitive confirmatory tools to ensure more accurate detection, especially in areas with low parasitemia or regions experiencing a decline in malaria cases.

CONCLUSION

The sensitivity of the RDT was recorded at 93.5%, indicating that this method has an excellent ability to detect positive malaria cases. The specificity of the RDT was recorded at 100%, demonstrating that the RDT is highly effective in identifying individuals who are not infected with malaria.

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