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Quality Assurance Assessment for Malaria Rapid Diagnostic Test in Ngoma District, Eastern Province of Rwanda: A Cross-sectional Prospective Study

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Abstract: Currently, malaria rapid diagnostic tests (mRDTs) are increasingly used for the diagnosis of malaria, particularly in communities where microscopy-based diagnosis is not practical. However, the diagnostic accuracy of mRDTs performed by community health workers (CHWs) remains unknown. This study was conducted to determine the accuracy of mRDT results performed by CHWs in Ngoma district, eastern province of Rwanda. This was a cross sectional prospective study. A total of 420 blood samples of patients self-reported to CHWs for malaria diagnosis were collected and analyzed by CHWs using mRDT, and quality control tests were performed by using microscopy as a reference test. The study was conducted from 22 April to 08 July 2021. Among the 420 patients, 234 (55.71%) were females, and 186 (44.29%) were males. Malaria test positivity was 2.62% by using mRDT and 1.67% by using microscopic tests. The sensitivity and specificity of mRDT were 85.71% and 98.78%, respectively. The negative predictive value, positive predictive value and accuracy of mRDTs were 99.75%, 54.54% and 98.57%, respectively. The sensitivity of mRDT was below the WHO recommended sensitivity (>95%), although the specificity (98.78%) was within the WHO recommended specificity (>=90). There was substantial agreement between the mRDT and malaria microscopic test results, k=0.642. mRDTs continue to be an appropriate choice for malaria diagnosis in the absence of microscopy.

Keywords: Quality Assurance, Malaria Rapid Diagnostic Test, Microscopy, Sensitivity, Specificity, Accuracy

1. Introduction

Internationally, malaria is a major public health problem. In 2014, the World Health Organization (WHO) reported that on average, 3.3 billion people were at risk of malaria [1]. In 2020, the WHO indicated that 229 million cases of malaria occurred worldwide, 215 million cases of malaria (94%) occurred in Africa, and 409000 deaths globally occurred due to malaria in 2019 [2]. Eastern and southern provinces are the most vulnerable regions to malaria in Rwanda. The number of cases tripled in the eastern province (from 460,460 in 2013–2014 to 1.4 million in 2015–2016) and doubled in the southern province (from 554,035 in 2013–2014 to over 1.1 million in 2015– 2016) [3]. The highest prevalence of malaria in Rwanda was observed in the eastern part and estimated to be 11.11% [4]. The WHO recommends parasitological confirmation through microscopy or malaria rapid diagnostic tests (mRDTs) for each suspected patient [5], and the WHO recommends that

all mRDT sensitivities (compared to microscopy as the "gold standard") should be above 95% and a minimum specificity of at least 90% for all malaria species [6, 7]. mRDTs accounted for 71% of the diagnostic tests performed in sub-Saharan Africa in 2014 [8]. A study conducted between 2009 and 2015 in 19 sub-Saharan countries revealed that the prevalence of malaria using microscopy tests was 24.4%, while the prevalence of malaria using mRDT was 30.3% [9]. During a study conducted in Nigeria for evaluating and comparing the performance of microscopy as the gold standard test with four other malaria rapid diagnostic test (mRDT) kits (carestart, SB Bioline, LabAcon and Global kits), their respective sensitivities of mRDTs were 83.7%, 86.5%, 84.9% and 86.5%, while their respective specificities were 96.00%, 95.80%, 95.30% and 95.40%. It was concluded that mRDT kits could not replace microscopy [10]. Another study carried out in 2020 in Nigeria aimed to compare the sensitivity and specificity of mRDTs (carestart TM) with microscopy as the gold standard and found that mRDTs had a sensitivity and specificity of 29% and 89%, respectively. These low values of sensitivity were significantly associated with parasite density ($pv < 0.001$), and other mRDT kits that could detect malaria parasites at low density were recommended [11]. Another similar study conducted in Nigeria for assessing the performance of mRDTs in febrile under-five children at a tertiary health facility level demonstrated that mRDTs' sensitivity, specificity, positive and negative predictive values were respectively 40.3%, 89.6%, 81.8%, and 56.5%, respectively and it was recommended that febrile children with positive mRDT results would be confirmed as having malaria while those with negative mRDT results would be retested again using microscopy [12]. Another study conducted in Sierra Leone in 2020 revealed different prevalences of malaria in children under five years of age by using mRDTs and microscopy (52.67% and 40.05%, respectively), and the overall sensitivity and specificity of mRDTs were 85.52% and 69.23%, respectively; these values were lower than the values recommended by the WHO (95% and 90%, respectively) [13, 6]. Other studies assessed the application and accuracy of malaria diagnosis by mRDT among pregnant women in Nigeria. Both the sensitivity and specificity of mRDTs were 75% and 25%, respectively [14]; therefore, they were far lower than the recommended values of sensitivity and specificity (95% and 90%, respectively) [6, 7]. Another study examined the performance of mRDTs among HIV-positive individuals in Nigeria, and the overall sensitivity of mRDT was 58%, while the specificity was 97%. It was recommended to monitor the quality of mRDTs for malaria diagnosis among HIV coinfected persons [15]. Furthermore, a comparative study comparing the performance of three brands of mRDTs, namely, SD Bioline, Paracheck and Acon, found that their sensitivity and specificity were SD Bioline (86.3%, 99.6%), Paracheck (50%, 97.7%) and Acon (66.7%, 100%), respectively, and they recommended that mRDT quality should be strongly monitored during the transportation and storage process [16]. Similarly, a longitudinal study conducted in Tanzania in 2011, in which the accuracy and impact of mRDTs were assessed, the sensitivity of mRDT was 88.6%, while the specificity of mRDTs was 88.2% [17]. These sensitivity and specificity values were high, yet they were lower than the recommended values of sensitivity and specificity [6, 7]. It was argued that the low values of mRDTs (low sensitivity and specificity) were largely influenced by fever and parasite density. The authors recommended that the use of mRDTs should be coupled with supportive supervision to improve the treatment of both malaria and non-malaria fevers and prevent the waste of anti-malaria drugs for malaria false positive patients [18]. Other studies have shown that false-positive results for mRDTs occur because the Plasmodium falciparum histidine rich protein-2 (pfHRP-2) antigen remains in the bloodstream for some months after an infection is cleared, which in turn could lead to overtreatment and the misdiagnosis of the true cause of symptoms [19]. False-negative (FN) results of mRDTs were found to be influenced by either parasite density, which is below the mRDT limit of detection, typically in the range of 200 parasites/μL [20], or non-Plasmodium falciparum malaria, which is not detected by commonly used pfHRP2-based mRDTs, or adverse storage conditions of mRDTs, where they are denatured by heat or humidity [21].

In 2008, the Rwanda Ministry of Health (MOH) piloted and scaled up the mRDTs (by community health workers) as recommended by WHO's Roll Back Malaria program (source) in most of the regions as a way to expand and strengthen malaria diagnostic capacity throughout the country [22]. In Rwanda, community health workers (CHWs) are the first point of contact with healthcare services for those with fever or a history of fever. Binome community health workers (a woman and a man) were trained to perform mRDT on all suspected malaria cases and provide anti-malaria drugs to symptomatic individuals in their villages [23]. In 2018, research was carried out in Kayonza District (Eastern Province of Rwanda), and the performance of HRP-2-based mRDT and microscopy-based malaria tests were compared. This study found that the sensitivity of mRDT was 95.0%, while the specificity was 59.2% among 264 suspected patients [24], and despite the extensive training of CHWs, the observed value for the specificity was below the acceptable levels. Moreover, little is known about the accuracy and predictive value of mRDT in the diagnosis of malaria infection at the community level, where asymptomatic people are more likely to have lower parasitaemia than in clinical settings [25]. Therefore, this study aimed to respond to this knowledge gap through an assessment of the accuracy, sensitivity, specificity and predictive values of histidine rich protein-2 (RHP-2)-based mRDTs in the Ngoma district, eastern province of Rwanda, by comparing mRDT results performed by CHWs with malaria microscopic test results performed by qualified laboratory technicians at health centers (HCs) to assure or safeguard the performance of mRDTs.

2. Method

2.1. Research Design and Target Population

This was a cross-sectional prospective study. All patients self-reported to CHWs for malaria diagnosis from 22 April to

08 July 2021 in Ngoma district who were willing to participate in this study were included. Patients who had recovered from malaria within the past three weeks were not included in this study because it was revealed that malaria antigen can be found in blood for 3 weeks after completion of treatment, which could increase false positive results [17]. Patients who were taking anti-malaria drugs were not included in this study.

2.2. Sample Size

Sample size was calculated by using the statistical formula of Cochran (1963: 75) for calculating sample size for infinite population. It says that for a large population for which the variability in proportion is unknown, it is assumed that the maximum variability is equal to 50% (p =0.5), and at the 95% confidence level with ±5% precision, the determination of the needed sample size is as follows: $n = \frac{z^2 p(1-p)}{e^2}$, where the critical value of the desired confidence level z =1.96 the desired level of precision e=0.05, proportion p= 0.5 [26]. Therefore, the desired sample size $n = \frac{1.96^2 \text{ X } 0.5(1-0.5)}{0.05^2} = 384$. By adding the rate of no respondent of 10% (38), the needed sample size, n, becomes 422 malaria suspected patients. In the end, only 420 malaria suspected patients were considered in this study.

2.3. Study Site

The study was conducted in Ngoma district, one of the six high malaria burden districts in the eastern province of Rwanda, which has the highest malaria prevalence of 11.11% [3, 4]. The number of cases of malaria tripled in the eastern province of Rwanda (from 460,460 in 2013–2014 to 1.4 million in 2015– 2016) [3]. The Ngoma district borders the Kayonza and Rwamagana districts in the north, the Bugesera district in the southwest, and the Kirehe district in the southwest. It also borders the country of Burundi in south. It has an area of 861 km² with 15 health centers (HCs).

2.4. Materials and Data Collection Procedures

A total of 109 binomes (CHWs) were randomly selected to take a blood sample and perform mRDT. A sample for thick blood smear for malaria microscopic testing was also taken by the CHWs, and the slides were taken to a health center (HC) for processing by qualified microscopists. At HC, thick blood smears were stained using a solution of 10% Giemsa, left for 30 minutes and then washed in buffered water at pH 7.2. Blood smears were examined using 100x high-power fields [27], and malaria parasite density was counted by using the formula developed by the WHO, where parasites/µL blood = (No parasites counted x 8000 white blood cells/µL)/No white blood cells counted [28]. The results of malaria microscopic tests and mRDT results were collected using a data collection form created using Epi info. Laboratory technicians at HCs were trained by Kibungo referral hospital on how to diagnose malaria using microscopy and how to calculate malaria parasite density before the study; similarly, 15 data collectors were trained on how to collect data by using a data collection form created in Epi info. Smart phones were used to collect all data.

2.5. Data Analysis Procedure

An mRDT-positive case was defined by the presence of *P. falciparum* or a pan-positive test line, while an mRDT-negative case was defined by the absence of *P. falciparum* and a pan-test line. The results of mRDT were compared with the results of the malaria microscopic test, and the accuracy, sensitivity, specificity positive and negative predictive value of mRDT (RHP-2 based) are presented in terms of percentages. Cohen's kappa test was performed to determine the level of agreement between mRDT and malaria microscopic test results. The sensitivity and specificity of mRDT (RHP-2-based) kits were compared to the WHO recommended value, which is greater than 95% for sensitivity and greater than or equal to 90% for specificity.

2.6. Ethical Considerations

Before starting data collection, ethical clearance was sought from the Institute Review Board of University of Rwanda/College of Medicine and Health Science and Kibungo Referral Hospital independent ethics committee. Before patients provided blood samples, they signed consent forms voluntarily. To ensure confidentiality of patients who provided samples, the names of patients were removed from the data set, and every patient was represented by his/her unique code auto generated by Epi info. To ensure the security of the data set, it was protected with a password and stored in a laptop protected with a password.

3. Results

3.1. Sociodemographic Characteristics of the Studied Population

Among 420 patients who were considered in this research, 234 (55.71%) were females, and 186 (44.29%) were males. The minimum age was 18 years, while the maximum age was 91 years. The mean age was 34.32 years with a standard deviation of 14.01, as shown in Table 1 below.

Table 1. *Descriptive presentation of the studied population.*

Variables	Frequency (n=420)	Percentage
Age group in years		
18 - 24	136	32.38
25- 44	194	46.19
45-64	72	17.14
65 and above	18	4.29
Gender		
Female	234	55.71
Male	186	44.29

3.2. Comparison of mRDT Results with Malaria Microscopic Results

Malaria positivity was found to be 2.62% by using mRDT and 1.67% by using microscopy, as shown in Table 2. No

cases of panpositivity were found during this study, and all positive cases were due to *P. falciparum*. The average malaria parasites density obtained by microscopy was 451.8 with a range of 40-1200 parasites/µL.

Table 2. *Test positivity of mRDT and malaria microscopic tests.*

Variables	Frequency (n=420)	Percentage
Malaria rapid diagnostic test (mRDT) results		
Negative	409	97.38
Positive	11	2.62
Malaria microscopic test results		
Negative	413	98.33
Positive	7	1.67

In this study, the malaria microscopic test was used as a reference test. The frequencies of mRDT false positive and negative results are summarized in Table 3.

Table 3. *Comparison of mRDT results to malaria microscopic test results.*

Variables	Frequency (n=420)	Percentage
mRDT results status		
True negative	408	97.14
True positive	6	1.42
False negative	1	0.23
False positive	5	1.16

In this study, mRDT had a sensitivity of 85.71% and 98.78% specificity, a negative predictive value of 99.75%, a positive predictive value of 54.54%, and a Cohen's kappa test K of 0.642. One false negative mRDT was observed with a microscopic malaria parasite density of 1200 parasites/µl.

During this study, by using logistic regression, as shown in Tables 4 & 5, it was found that having malaria parasite density equal to or greater than 100/µl was significantly associated with mRDT sensitivity > 95% with P-V= 0.006 at 95% CI (2.6397 342.6845) and OR of 30.07. This means that malaria parasite density equal to or greater than 100/µl was 30.07 times more associated with a sensitivity > 95% than malaria parasite density less than 100/µl. However, specificity was not statistically associated with malaria parasite density.

Table 4. *Association between sensitivity of mRDT and malaria parasites density.*

Variables	Sensitivity of mRDT			
	>95%	<=95%	Statistical tests	
	(n: 392)	(n=28)	cOR at 95% CI	P.value
Malaria parasites density				
Malaria parasites density < 100/ µl	391	26	Ref(1)	
Malaria parasites density > =100/ µl	1	2	30.07 (2.26-342.6)	0.006

Table 5. *Association between specificity of mRDT and malaria parasites density.*

Variables	Specificity of mRDT			
	> =90%	<90%	Statistical tests	
	(n: 392)	(n=28)	cOR at 95% CI	P.value
Malaria parasites density				
Malaria parasites density < 100/ µl	389	28	1	
Malaria parasites density > =100/ µl	3	0	1	

4. Discussion

This study provided information concerning the diagnostic accuracy of mRDT performed by CHWs in Ngoma district. In this study, malaria positivity by using mRDT was slightly higher than malaria positivity by using microscopy. This finding agreed with several studies conducted by Ekom et al, Oliver et al and Mohamed et al [29, 9, 13], which reported higher malaria prevalences of 75%, 30.3% and 52.67% by using mRDTs compared to malaria prevalences of 60%, 24.4% and 40.05% reported by using malaria microscopic tests, respectively.

In this study, mRDT had a sensitivity of 85.71%, which was below the sensitivity recommended by the WHO (> 95%) and a specificity of 98.78%, which is within the recommended WHO value [6]. The observed sensitivity of 85.71% is higher than other sensitivities found in different studies: Isa et al, Ekom et al and Rose et al found sensitivities of 40.3%, 75%, 50%, 66% [12, 29, 16] but lower than those found in other studies (Niyibizi et al, Vyankatesh et al and Phoebe et al.) [24, 30, 17], demonstrating the wide range of mRDT sensitivities. A low mRDT sensitivity can be a problem for patient care given

that some patients who require antimalarial treatment (false negatives) will be missed. Indeed, in this study, mRDT sensitivity >95% was found to be associated with malaria parasite density equal to or greater than 100/µl, a finding that is in agreement with what was found by Bisoffi et al and Nwajei et al [31, 11]. This limitation of the current mRDTs led to the development of a newer generation of highly sensitive mRDTs aimed at increasing the capability of mRDTs to detect low parasite density infections [32, 33]. In addition to parasite density, several other factors are known to affect the sensitivity of mRDTs, including storage and transportation conditions, which influence denaturation of mRDT kits and adherence to the protocol by the end user (Matthew et al, Rennie et al, Francois et al) [34-36]. In this study, the association between the sensitivity and skills of end users, physical storage and transportation conditions was not investigated.

The specificity of 98.78% identified in the present study was higher than other specificities found in other studies by Niyibizi et al, Anthony et al, Henry et al and Isa et al of 59.2%, 89%, 97% and 89.6%, respectively [24, 11, 15, 12]. This satisfactory specificity was not associated with malaria parasite density and is very important because it helps to differentiate other malaria-like illnesses from malaria, and health care providers will be able to administer the right medications. In the present study, the positive predictive value and negative predictive value were 54.54% and 99.75%, respectively, and compared to another study conducted in Nigeria, the positive predictive value and negative predictive value were 81.8% and 56.5%, respectively. The negative predictive values seem to be nearly equal, but the positive predictive values are slightly different [12]. This very low positive predictive value (54.54%) reported in the present study was due to high false positive results of mRDT. False positive results of mRDT were found to be associated with a high level of rheumatoid factors in patients [37] and the persistence of HRP-2 antigens in blood for up to 61 days after completion of treatment [19], which is another limitation of mRDTs. However, in the larger scheme of things, treatment of false positive cases is less detrimental compared to lack of treatment of the false negatives, although it contributes to overuse of antimalarials and appropriate treatment of missed non-malaria cases. Therefore, a confirmatory test is needed in case of doubtful positive mRDT results.

Overall, the accuracy of mRDTs in this study was 98.57%, implying that mRDT kits used in this study gave correct results either positive or negative at the level of 98.57%, and a Cohen's Kappa test k is equal to 0.642, meaning that there was good concordance with microscopy. Given that the majority of malaria cases are diagnosed at the community level by CHWs using mRDTs, these results demonstrate that the use of mRDTs by CHWs is appropriate and helps increase the trust of the population toward health care services provided by CHWs. However, continued supportive supervision and quality assurance of mRDTs is important to ascertain the quality of case management of malaria.

5. Conclusion

As the diagnostic accuracy of mRDTs performed by CHWs remains unknown, this study aimed to assess the accuracy, sensitivity, specificity and predictive values of histidine rich protein-2 (RHP-2)-based mRDTs in the Ngoma district, eastern province of Rwanda, by comparing mRDT results performed by CHWs with malaria microscopic test results performed by qualified laboratory technicians at health centers (HCs) to assure or safeguard the performance of mRDTs.

In this study the accuracy, sensitivity, specificity, negative predictive value, and positive predictive value of mRDTs were found to be 98.57%, 85.71%, 98.78%, 99.75%, and 54.54% respectively, and Cohen's kappa test k was found to be 0.642.

Overall, the accuracy of mRDTs in this study was acceptable, and the results were well correlated with the microscopy results. This implies that the use of mRDTs by CHWs in Ngoma district is appropriate. The continued supportive supervision and quality assurance of mRDTs is important to ascertain the quality of case management of malaria in the community, especially given that the majority of malaria cases are managed in the community. Additional studies should assess the effect of skills of CHWs; storage and transportation conditions on the sensitivity and the specificity of mRDTs.

Declarations

Ethics Approval and Consent to Participate

Before starting data collection, ethical clearances were sought from the Institute Review Board of University of Rwanda/College of Medicine and Health Science and Kibungo Referral Hospital independent ethics committee. Before patients provided blood samples, they signed consent forms voluntarily. To ensure confidentiality of patients who provided samples, the names of patients were removed from the data set, and every patient was represented by his/her unique code auto generated by Epi info. To ensure the security of the data set, it was protected with a password and stored in a laptop protected with a password.

Consent for Publication

Not applicable.

Competing Interests

The authors declare that they have no competing interests.

Availability of Data and Materials

The dataset used and analyzed during the current study is available from the corresponding author on reasonable request.

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Biography

Metuschelah Habimana is a pharmacist, who is holder of Master's of Science in Field Epidemiology and Laboratory Training Program *(MSc Field Epi)* gained from University of Rwanda in School of Public Health, and he is interested in conducting operations researches. He has an experience of almost 5 years in supply chain and logistics management of health products in hospital setting and 3 years of experience working in retail pharmacies in Rwanda.