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ANALYSIS OF DIAGNOSTIC ACCURACY OF RAPID DIAGNOSTIC TEST IN CONFIRMED CASES OF MALARIA IN CHILDREN

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Abstract:

Introduction: *The adoption of artemisinin-based combination therapy (ACT) for malaria in most endemic countries, and the availability of new diagnostic tools, such as rapid diagnostic tests (RDTs), have led the World Health Organization (WHO) to recommend a modified approach to malaria management.* ***Objectives of the study:*** *The basic aim of the study is to analyse the diagnostic accuracy of rapid diagnostic test in confirmed cases of malaria in children.* ***Material and methods:*** *This cross sectional study was conducted in THQ Hospital Shahkot during March 2019 to October 2019. Participants included in the study were under-5-year-old children, either admitted in the children's ward or attending any clinic on outpatient basis.* ***Results:*** *This study recruited 270 patients. Twelve patients were excluded due to incomplete data. Two hundred and fifty-eight patients were tested using Paracheck-Pf RDT, while 167 patients were tested using thick-film microscopy. Because of 91 patients who did not have matching microscopic tests, these patients' results were excluded from the analysis. The actual patients' results included for analysis were 167.* ***Conclusion:*** *It is concluded that interpreting test results without gold standard can be challenging. The use of RDTs in the diagnosis of malaria infection offers an easy-to-use, low-cost, and rapid testing alternative*

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INTRODUCTION:

The adoption of artemisinin-based combination therapy (ACT) for malaria in most endemic countries, and the availability of new diagnostic tools, such as rapid diagnostic tests (RDTs), have led the World Health Organization (WHO) to recommend a modified approach to malaria management. The previous policy indicated the presumptive treatment for malaria of all patients with fever, unless another obvious cause was found. The increased cost of new treatments, as well as the concern for the potential selection of drug resistant *Plasmodium falciparum* strains, prompted a more selective approach [1].

The African continent bears the greatest burden of malaria, contributing 90% of the world's malaria cases and 91% of malaria deaths globally. Nigeria, Africa's most populous country, accounts for 27% of malaria cases and 24% of malaria deaths globally in 2016, making that Nigeria accounts for more cases and deaths than any other country in the world. The WHO recommends that all cases of suspected malaria should have parasitological test, supported by a quality assurance program to confirm the diagnosis of malaria [2]. Currently, the parasitological test comprises rapid diagnostic test (RDT) or microscopy. Newer tests like the nucleic acid amplification-based tests such as loop-mediated isothermal amplification or polymerase chain reaction have a limited role in the management of clinical malaria [3].

As the incidence of malaria declines, increasingly more children will present to health facilities with low levels of parasitaemia. At low levels of parasitaemia, the probability of a false-negative result is higher and this could cause delay in the initiation of treatment. On the other hand, in high transmission settings a positive RDT result does not necessarily rule out bacterial or viral co-infections, as symptomatic malaria parasitaemia is not uncommon [4]. In the era of presumptive treatment, nearly all children who presented with febrile illness received an antimalarial. In addition to clearing parasites in children with malaria, this "opportunistic presumptive treatment" probably prevented new malaria infections through post treatment prophylaxis in all children [5]. It is hypothesised that restricting ACTs to RDT-positive cases would lead to increased frequency of malaria in children since a large number of children would be denied this inadvertent prophylactic benefit and make them prone to malaria sooner and more frequently than children who receive antimalarials [6].

Objectives of the study

The basic aim of the study is to analyse the diagnostic accuracy of rapid diagnostic test in confirmed cases of malaria in children.

MATERIAL AND METHODS:

This cross sectional study was conducted in THQ Hospital Shahkot during March 2019 to October 2019. Participants included in the study were under-5-year-old children, either admitted in the children's ward or attending any clinic on outpatient basis. The patients were clinically evaluated and those suspected of having malaria (regardless of intake of antimalarial drugs or not) were selected to undergo testing by microscopy and RDT after an informed written consent has been signed by the parents/caregivers and assent obtained from the participants.

Statistical analysis

The data was collected and analysed using SPSS version 17.0. All the values were expressed in mean and standard deviation.

RESULTS:

This study recruited 270 patients. Twelve patients were excluded due to incomplete data. Two hundred and fifty-eight patients were tested using Paracheck-Pf RDT, while 167 patients were tested using thick-film microscopy. Because of 91 patients who did not have matching microscopic tests, these patients' results were excluded from the analysis. The actual patients' results included for analysis were 167. A total of 70 (41.9%) were found to be positive by microscopy and 62 (37.1%) by RDT. Thirty-four of the 70 positive results by microscopy were negative (false-negative rate of 48.6%), while 26 of the 97 negative thick-film microscopic results were positive (false-positive rate of 26.8%).

Table 01: Overall sensitivity, specificity, predictive values, and likelihood ratios of rapid diagnostic test using microscopy as the standard

	Estimated values (%)	**Percentage CI**
Prevalence	41.9	0.3441-0.4978
Sensitivity	51.4	0.39274-0.6343
Specificity	73.2	0.6308-0.8145
PPV	58.1	0.4488-0.7025
NPV	67.6	0.5769-0.7623
PLR	1.92	1.2862-2.8622
NLR	0.66	0.5176-0.8507

PPV – Positive predictive value; NPV – Negative predictive value; PLR – Positive likelihood ratio; NLR – Negative likelihood ration; CI – Confidence interval

DISCUSSION:

Although the different test sensitivity in the dry and in the rainy season may be surprising, this difference appears to be caused almost entirely by the different mean parasite density in the two seasons: if the analysis is stratified for parasite density, the sensitivity is very similar in both seasons. The overall sensitivity was lower than 95%, the minimal level recommended by the WHO [7]. However, most false negative results occurred at the lowest parasite density. Over 400 parasites/µl the sensitivity was higher than 95% and approached 100% over 4,000 parasites/µl. Leaving without treatment patients with false negative results at low parasite density might be relatively harmless. Niama-Meya *et al* in Uganda showed that the missed treatment for patients with a false negative malaria microscopy never resulted in severe disease [8].

Accurate diagnosis is of utmost importance to good malaria case management, whether the test is RDT or microscopy based. Due to high diagnostic performance capabilities of quality-assured RDT and microscopy in detecting clinical malaria, their relatively low cost, and availability, they have been considered the diagnostic tools of choice for the confirmation and management of suspected clinical malaria even in areas of low transmission [9]. The joint WHO-FIND-CDC-TDR Malaria RDT Evaluation program which has gone up to 6 test rounds offers quality standard panels to assist RDT product developers come up with RDTs with high accuracy [10]. Currently, the WHO recommended selection criteria for procurement of RDT for member states' usage, which include panel detection score (PDS) of ≥75% in low transmission areas at 200 parasites/µL, <10% false-positive rate, and <5% invalid rate in all transmission areas [11].

CONCLUSION:

It is concluded that interpreting test results without gold standard can be challenging. The use of RDTs in the diagnosis of malaria infection offers an easy-to-use, low-cost, and rapid testing alternative; however, the performance of these kits easily wanes owing to a number of factors ranging from manufacture, poor storage, and handling to usage and interpretation by end users.

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