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Reliability of rapid diagnostic tests in diagnosing pregnancy and infant-associated malaria in Nigeria

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KEYWORDS
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Summary
Background: The effective management of maternal and infant malaria requires rational and prompt diagnosis. This study aims to determine the diagnostic efficiency of malaria RDT in infants and pregnant women.
Methods: The study was conducted on infants ($n = 200$), pregnant women ($n = 80$) and non-pregnant women ($n = 100$) who were recruited from two hospitals in Lagos, Nigeria. *Plasmodium falciparum* infections were assessed in the febrile subjects by microscopic examinations of blood smears and by RDT.
Results: The lowest (44.3%) and the highest (83.3%) sensitivity (SS) values were recorded in the infants and pregnant women, respectively. Other diagnostic parameters, including the specificity (SP, 97.5%), positive predictive value (PPV, 92.1%) and negative predictive value (NPV, 72.8%), in the infants were greater than the values recorded in non-pregnant (SP = 77.5%, PPV = 83.9%, NPV = 70.5%) and pregnant women populations (SP = 65.6%, PPV = 78.4%, NPV = 72.4%). The diagnostic efficiency of malaria RDT exhibited higher sensitivity in women in early gestational stages (1st trimester = 78.6% and 2nd trimester = 88.0%) compared with those in the 3rd trimester (71.4%). The sensitivity of malaria RDT (100.0%) was significantly higher in the multigravid women than in the primigravida (78.6%) and secundigravida women (77.8%, $P < 0.05$). The sensitivity of the RDT significantly increased with the intensity of the malarial parasites ($P < 0.05$).
Conclusion: Malaria is endemic in the study populations. Malaria RDT can serve as a first-line of diagnosis for pregnant women in early gestational stages and

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multigravid women and can aid the differential diagnoses of other diseases due to its high specificity in infants.

Introduction

Malaria is a disease that is caused by apicomplexan parasites and threatens the lives of millions in sub-Saharan Africa. It has been estimated that approximately 125 million pregnant women reside in malaria-endemic areas, and 32 million of the women in these regions were at risk for malaria toward the end of last decade [1,2]. The hallmark of pregnancy-associated malaria is the presentation of placentally sequestered malaria parasite infection of the erythrocytes mediated by VAR2CSA (a member of the *P. falciparum* erythrocyte membrane protein 1 (PfEMP-1) family) [3,4]. In addition to placental parasitemia, other adverse effects of maternal malaria include maternal anemia, infant anemia and low birth weight, which can pose significant threats associated with maternal, infant and fetal death [5,6]. The disease is also being implicated as one of the major childhood killers in Africa [7]. In cases of cerebral malaria, this disease causes a high mortality rate, and 5—30% of surviving children are left with a neurological disability [8].

Microscopic examinations of stained blood smears have always been the reference standard for malaria diagnosis in resource-poor endemic areas of sub-Saharan Africa. However, this method is often compromised by poor infrastructure [9], which has prompted the need for individuals with expertise in microscopy. Other problems associated with the microscopic diagnosis of malaria parasites include poor sensitivity [10], sub-standard reagents, poor microscope maintenance, and the time-consuming nature of the process [11].

The effective management of malaria in more susceptible pregnant women and infant populations requires quick and efficient diagnoses. The World Health Organization has further reiterated the role of timely, the accurate and accessible detection of malaria parasites in reducing the malaria burden [12]. There has been wide-spread advocacy for the use of rapid diagnostic test kits (RDTs) for malaria parasites for the management of malaria in endemic areas, and some studies conducted in these areas have reported that the sensitivities of RDTs are better than that of microscopy [13,14]. Therefore, RDTs should be made a supplementary diagnostic tool to aid evidence-based decision-making in malaria treatment [15]. This diagnostic approach is simple, heat-stable and can detect malaria parasites at low levels of parasitemia [16]. One shortcoming on the use of malaria parasite RDTs that can detect histidine-rich protein 2 (HRP-2) is the problem of high false positive rates due to the detection of the HRP-2 antigen circulating in the blood more than two weeks after the infected erythrocytes have been cleared from the blood stream [17]. Moreover, false-negative results of rapid diagnostic tests for *P. falciparum* have been reported to be associated with the deletion of the histidine-rich repeat region of the hrp2 gene [18].

This study assessed the performance of malaria parasite RDTs in pregnant women and infants, which are two malaria-susceptible population groups in Nigerian urban cities.

Methods

Study area and subjects

The study subjects were recruited from two hospitals in Lagos State, Nigeria between May and August of 2014. Lagos is a mega-city in the southwestern part of Nigeria. Lagos is one of the most densely populated cities in Nigeria. The poor drainage systems characteristic of many areas in the city and the large expanse of land covered with water are the strongest predisposing factors in the city. The subjects included non-randomly recruited febrile infants, pregnant and non-pregnant women who presented themselves at the hospitals for medical consultation.

Sample size determination

The sample size was determined based on a malaria prevalence of 50.0%, which is the prevalence level that has been suggested to provide a reasonable sample size for epidemiological studies [19]. Due to resource limitations, 0.08 (8%) precision was used. The minimum sample sizes computed for the infants and adult women (pregnant and non-pregnant) were 150. The totals numbers of infants and adult women participant who were recruited were 200 and 180, respectively.