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Full Length Research Paper

Evaluation of the test relab essentials toxoplasma latex® in the biological diagnosis of toxoplasmosis in Abidjan (Cote D'Ivoire)

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Abstract

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Screening for toxoplasmosis during pregnancy is vital for child protection. However, the associated tests are still expensive and borne by households in Côte d'Ivoire. It is therefore necessary to provide the healthcare system with reliable and accessible tests. The aim of this study was to evaluate the test Relab Essentials Toxoplasma agglutination Latex® in the diagnosis of toxoplasmosis in Abidjan. From 4 october to 4 november 2023, a descriptive cross-sectional study was conducted at the parasitology-mycology laboratory of the teaching hospital of Cocody. A serum bank of 369 non-pregnant girls aged between 5 and 18 years was examined. For each serum stored at -20°C, toxoplasma serology was carried out by agglutination using the Relab Essentials Toxoplasma Latex® and by immunoenzymatic test, considered to be the reference method, using the Mini Vidas® device, in accordance with the manufacturers' instructions. The diagnostic performance of this test was evaluated on the basis of sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio (PLR), negative likelihood ratio (NLR), and the Youden index. The mean age of the 369 girls was 10.8 years (+/- 3.96), with a predominance of girls with secondary education. The seroprevalence of toxoplasmosis using the ELISA technique was 13.8%, compared with 5.9% for the agglutination test. The test Relab Essentials Toxoplasma Latex® had a relatively low sensitivity of 33.3% and a good specificity of 98.4%. The positive and negative predictive values were 77.7% and 90.2% respectively. In addition, the Youden index, which reflects the accuracy of the test, was 0.32, indicating that the Relab test was not effective. The Relab Essentials Toxoplasma test Latex® performed unsatisfactorily. It cannot be recommended for the diagnosis of toxoplasmosis in Côte d'Ivoire.

Keywords: Diagnosis of toxoplasmosis - Rapid test - Relab Essentials Toxoplasma Latex® - Côte d'Ivoire.

INTRODUCTION

Toxoplasmosis is a widespread zoonosis caused by Toxoplasma gondii, an obligate intracellular protozoan parasite. Transmission in humans can result from the ingestion of oocysts shed by infected felids and of cysts from undercooked meat of infected animals (Dupont et *al*. 2021). It is one of the most widespread parasitoses in the world. Its global seroprevalence is around 30% to 50%, but varies considerably from region to region due to differences

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in climate, diet, hygiene and host susceptibility (Dubey, 2010 ; Dard, 2016 ; Pamatika et *al*., 2022 ; Jean-Pierre et *al*, 2022). This infection is generally asymptomatic. The interest in studying toxoplasmosis lies in its severity in pregnant women and immunocompromised patients (Peyron et *al*, 2016 ; Anofel, 2017; Abbas et *al*, 2019). In the immunocompromised, the risk predominates in those who are immune, i.e. who have already been in contact with *T. gondii* and whose cysts are present in the tissues (Hosseini et *al*., 2020). As for pregnant women, the major risk is represented by transmission of the parasite to the foetus, leading to possible foetopathies. This risk is only recorded in cases of primary maternal infection during pregnancy (Messerer, 2015). Consequently, there is a need to prevent the condition in non-immunised women. This prevention involves hygienic and dietary measures and regular (monthly) monitoring of toxoplasma serology (Paquet et *al*., 2016). Several serological methods are available. However, ELISA (Enzyme Linked Immuno Sorbent Assay) and IFI (Indirect Immunofluorescence) techniques, the reference methods recommended because they give reliable and robust results, are costly and require a laboratory infrastructure that is not always accessible in our day-to-day practice (Yéngué et al, 2022). Furthermore, as part of the prenatal check-up, toxoplasma serology is not subsidised, leaving this costly test to be borne by the family budget and, at the same time, posing the problem of accessibility in our poor country context. As a result, toxoplasmosis serology is not systematically performed by pregnant women. Foetuses are then exposed to the risk of congenital toxoplasmosis. Simple, reliable and affordable diagnostic methods that do not require complex equipment should be researched and made available. In response to this concern, several rapid diagnostic tests have been proposed, including the test Relab Essentials Toxoplasma Latex®. In Côte d'Ivoire, diagnostic methods depend on the category of health centre. While in university centres, diagnosis is made using immunoenzymatic methods, in primary care health centres, which receive the largest number of patients, toxoplasma serology is performed using rapid tests based on agglutination methods. However, many rapid agglutination tests are marketed and used without prior evaluation of their diagnostic performance. This is the case with the *Relab Essentials Toxoplasma Latex* test. This is the purpose of this study, which aimed to evaluate the *Relab Essentials Toxoplasma Latex* test in the diagnosis of toxoplasmosis in Côte d'Ivoire.

MATERIALS AND METHODS

Study areas

A cross-sectional study was conducted from October 4 to November 4, 2023, at the Parasitology Mycology laboratory of the university hospital of Cocody to evaluate the performance of the test Relab Essentials Toxoplasma Latex® in the diagnosis of toxoplasmosis in Côte d'Ivoire.

Study population

The study population was represented by a serum bank of the Parasitology-Mycology laboratory of the university hospital of Cocody, made up of sera obtained from a previous survey on the seroprevalence of toxoplasmosis among girls aged 5 to 18 years. The sera were stored at -20°C since the first study, i.e. for approximately one month.
Using Schwartz's formula and a prevalence of toxoplasmosis in Côte d'Ivoire of 60% with a 5% margin of error, the population size was 369. We therefore included 369 serums for which the data required for the study were available.

Laboratory examination

For each serum included, toxoplasmosis serology was performed using two methods:
-1st method: the Immunoenzymatic method, which served as the reference technique. It was performed using the Mini VIDAS® automated system (Biomerieux SA; Series No. 410416) according to the manufacturer's instructions, to detect two isotypes of anti-toxoplasmic immunoglobulins, namely IgG and IgM.
-2nd method: the test to be evaluated, i.e., the Relab Essentials Toxoplasma Latex test. This is a plate agglutination test for the qualitative detection of anti-Toxoplasma antibodies. Latex particles coated with *Toxoplasma gondii* antigen are agglutinated when mixed with samples containing anti-Toxoplasma antibodies. According to the manufacturer, Atlas Médical, the sensitivity is 100% and the specificity is 98.5%. In this study, kits from batch "AA0306" and reference "B06R-0033-P-0100" were used, according to the operating procedure described by the manufacturer.

Methodological limitations

One of the limitations of this study is that it did not use a third diagnostic test to arbitrate in cases of discordant results between the two tests used. In cases of discordant results, our judgement was in favour of the immunoenzymatic test taken as the reference test.
Furthermore, given that toxoplasmosis is mainly diagnosed in Côte d'Ivoire as part of prenatal screening, it would have been interesting to evaluate the Relab Essentials Toxoplasma Latex test on serum samples from pregnant women. However, toxoplasmosis is also problematic in several categories of immunocompromised individuals (transplant recipients, AIDS patients, etc…). The performance of the test must therefore be relevant to all sections of the population.

Data analysis

Statistical analysis was performed with EPI-INFO version 3.5.4. Quantitative data were expressed as mean and standard deviation, and qualitative variables were expressed as proportions. To assess the diagnostic performance of the test Relab Essentials Toxoplasma Latex®, sensitivity, specificity, predictive values, and likelihood ratios were calculated using Immunoenzymatic method as the reference test.

Ethical considerations

During the establishment of the biobank, the patients included were informed of the possibility of conducting further studies with their blood samples. It was on this basis that they agreed to participate. This study was conducted in accordance with the rules of confidentiality and prior consent.

RESULTS

The mean age of the 369 girls whose sera were included in this study was 10.8 years (+/- 3.96). Children under the age of 10 accounted for 46.9% of cases.

Serological data and diagnostic performance of the test Relab Essentials Toxoplasma Latex®

Using the immunoenzymatic technique on the Biomérieux's Mini Vidas® device, 51 sera were positive for toxoplasmosis, giving a seroprevalence of 13.8% (95 % CI : 10.3 % – 17.3 %), compared with 22 sera for the Relab Essentials Toxoplasma test Latex® (5.9% ; 95 % CI : 3.5 % - 8.4 %).
Of the 51 sera that tested positive using the immunoenzymatic technique, IgG was detected exclusively in 49 sera (96.1%). Only 2 sera simultaneously presented anti-Toxoplasma IgG and IgM.
Compared with the Immunoenzymatic test, the test Relab Essentials Toxoplasma Latex® had a sensitivity of 33.3%, a specificity of 98.4%, a positive predictive value (PPV) of 77.2% and a negative predictive value (NPV) of 90.2%. Likelihood ratios were also determined. The Positive Likelihood Ratio (PLR) was 16.5, while the Negative Likelihood Ratio (NLR) was 0.68.
The Youden index, which measures the effectiveness of the test, was 0.32.
Table 1 shows the cross-tabulation of the results of the immunoenzymatic test and the test Relab Essentials Toxoplasma Latex® used to calculate the performance indicators.

DISCUSSION

A widespread disease, the prevalence of toxoplasmosis varies from one country to another, and within the same country from one region to another. Because of its harmful effects on the foetus, screening for toxoplasmosis during pregnancy is strongly recommended. However, in Côte d'Ivoire, the diagnostic test is neither subsidised nor covered by the state. As a result, many pregnant women do not undergo the test. There is therefore a need to find simple diagnostic methods that make this examination financially accessible. It was with this in mind that this study evaluating the Relab Essentials Toxoplasma agglutination test Latex® was carried out.

The diagnostic performance of this test was evaluated on the basis of sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio (PLR), negative likelihood ratio (NLR), and the Youden index.

Sensitivity

In this study, the overall prevalence according to the immunoenzymatic method (reference method) was 13.8%, compared to 5.9% for the test Relab Essentials Toxoplasma Latex®. The sensitivity of the Relab® test was therefore 33.3%. This sensitivity is too low given the high risk toxoplasmosis for the mother-child pair. As it stands, this test would not be recommended for the diagnosis of toxoplasmosis in Côte d'Ivoire. Indeed, the inclusion of a test in the diagnostic arsenal requires good performance. Thus, to adopt a new diagnostic test, either non-inferiority studies are conducted compared to existing tests, or studies are performed to demonstrate the additional value of this test over existing tests. This added value may be financial, in the sense of a reduction in the cost of the test and making it more accessible. It can also be technical, i.e. easy to perform, faster result turnaround, early diagnosis, etc.
However, financial and technical benefits should not be the most important factors. Indeed, what is expected of a test is its ability to diagnose the disease for which it has been developed, with a view to optimizing patient care.
Given the very low sensitivity of the Relab Essentials Toxoplasma Latex® test, its use as it stands would lead to missed diagnoses of many seropositive women, with potentially disastrous consequences for several reasons:
-Economic reason: For seropositive women, this test could classify them as naïve to toxoplasmosis, leading to monthly serological controls until delivery. This would increase the cost of pregnancy, which would be borne by households in an already poor country, even though this test was designed to address the issue of financial accessibility.
-Health reason: For a non-immune pregnant woman who is undergoing toxoplasmic seroconversion, the Relab Essentials Toxoplasma Latex® test could incorrectly classify her as negative, causing doctors to fail to take appropriate measures, potentially leading to fetal infection and all the consequences that may arise.
The 33.3% sensitivity found in this study was significantly lower than the 100% sensitivity claimed by the manufacturer. This discrepancy supports the idea that all tests must be evaluated before their implementation in a given region. Don't rely solely on the manufacturer's information.
In our research, we did not find any studies evaluating the Relab Essentials Toxoplasma Latex® test. However, studies conducted in other countries have used other rapid tests with better sensitivities. For example, Hounto et *al*. in Benin (2013) observed a sensitivity of 95% for the immuno-

Table 1 : Cross-tabulation between immunoenzymatic test and Relab Essentials Toxoplasma Latex® test results.

Test ELISA	Relab Essentials Toxoplasma Latex®		TOTAL
	Positive	Negative	
Positive	17	34	51
Negative	5	313	318
TOTAL	22	347	369

combs® test (Hounto et *al*., 2014). With the ICT IgG-IgM test Rym in Tunisia and Begeman in US found good sensitivity (Rym et *al*., 2021 ; Begeman et *al*, 2017). As for Yéngué et *al*. in Cameroon (2020), they also noted a low sensitivity for the rapid test (Yéngué et *al*., 2022).

Specificity, PPV, and NPV

The rapid test used in our study had a specificity of 98.4%. This is a good specificity, which suggests that for patients without toxoplasmosis, the test Relab Essentials Toxoplasma Latex® has a high probability of being negative. This result is not surprising. Given the low sensitivity of the test, it is fair to say that it tends to be negative regardless of the patient's status. Moreover, the positive predictive value (PPV) and negative predictive value (NPV) were 77.2% and 90.2%, respectively. These are relatively low values, which do not support relying on the results of this test. Indeed, the test indicators suggest that it would miss many cases of toxoplasmosis. Yéngué et *al*. (2022) in Cameroon and Hounto et *al*. (2014) found specificities of 91% and 100%, respectively. For Yéngué, predictive values were also poor, with a PPV of 80% and a NPV of 20%.

Youden Index

The Youden index measures the accuracy of the diagnostic method. It lies between 0 and 1. A value of 1 indicates a perfect diagnostic method, while 0 indicates an ineffective method. In this study, the Youden index was 0.32, indicating that the test Relab Essentials Toxoplasma Latex® is not effective in diagnosing toxoplasmosis in Côte d'Ivoire. It is not recommended. Yengué et *al*. (2022) found a better Youden index of 0.6.

CONCLUSION

This study demonstrated that the diagnostic performance indicators of the test Relab Essentials Toxoplasma Latex®, compared with our reference method, were unsatisfactory. It showed a sensitivity of 33.3%, a specificity of 98.4% and the Youden index was 0.32. In light of these characteristics, the Relab® test is not recommended for the diagnosis of toxoplasmosis in our routine practice in Côte d'Ivoire. However This significant discrepancy requires confirmation through other studies using the same test but, for example different batches, different sera, etc. This study suggests that health authorities should evaluate the various tests to be used in the country under real-world conditions, independently of the data provided by the manufacturer, before granting marketing authorisation. Furthermore, laboratories should only use approved tests.

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