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The value of ICT and Latex Serological tests in Screening for Toxoplasma gondii.

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Abstract

Background: Toxoplasma gondii is an intracellular zoonotic parasite responsible for infections in various warm-blooded animals and humans. This study primarily focused on evaluating the diagnostic efficacy of ICT and latex serological methods for screening Toxoplasma gondii in North Kordofan, Sudan. **Methodology:** This descriptive study was conducted in El-Obeid, North Kordofan State, Sudan, from January to May 2024. A total of 260 samples were collected from women who had experienced abortions or had a previous history of such events. A blood sample was collected from each respondent to conduct serological tests, including ICT, latex, and ELISA. **Results:** The study involved approximately 260 women to evaluate the validity of the various techniques employed. In this research, ICT and LaTeX were compared with ELIZA as the gold standard method, yielding a positive rate of 14.6% and a negative rate of 85.4% using ICT methods. However, the results from the Latex method indicated a positivity rate of 15.8%, while the negativity rate stood at 84.2%. In ELIZA, 17.3% is positive, while 82.7% is negative. The sensitivity and specificity of the techniques employed in this study are compared with the ELISA technique, as detailed in the following tests. The sensitivity achieved through the ICT technique was 84%, while the specificity reached 100% as observed in the findings. The sensitivity and specificity obtained through the latex technique were determined to be 94% and 100%, respectively. Conclusion: Both Latex and ICT demonstrate relatively better sensitivity and very good specificity, making them suitable for screening and diagnostic purposes in conflict areas.

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Keywords: Toxoplasma, Latex, ICT, ELIZA

Introduction:

Toxoplasma gondii is responsible for toxoplasmosis, which ranks among the most prevalent parasitic diseases globally. Toxoplasmosis is a parasitic disease that affects both humans and animals, classified as zoonotic in nature. In healthy individuals with competent immune systems, approximately 50% of infections are asymptomatic. However, they can also lead to a mild, self-limiting illness characterized by nonspecific signs and symptoms, including fever, malaise, headache, fatigue, and tender lymphadenopathy [1,2]. Congenital toxoplasmosis can present with significant manifestations, primarily retinochoroiditis, and may persist throughout an individual's life [3]. Toxoplasma gondii is a parasite believed to infect approximately one-third of the global population. Contaminated water and food, particularly undercooked meat, are the primary sources of acquisition, along with contact with feces from domestic or wild felines and transplacental transmission during pregnancy [4]. The prevalence of Toxoplasma gondii antibodies varies significantly across global regions, with seropositivity rates

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reported between 7% and 51%. The prevalence rate fluctuates due to variations in climate, culture, dietary practices, behaviors, personal hygiene, and cooking methods among diverse groups. A range of risk factors has been identified that contribute to the elevated prevalence rate of the disease. These include the consumption of raw or inadequately cooked meat, physical contact with cats, the intake of unwashed raw vegetables and fruits, and the drinking of contaminated water and milk [5].

Various methods exist for detecting toxoplasmosis, though some may not be financially accessible in certain healthcare environments. The current investigation sought to evaluate the effectiveness of ICT and latex serological testing in the screening of Toxoplasma gondii in North Kordofan.

Materials and Methods:

This study was conducted descriptively in El-Obeid, located in North Kordofan State of Sudan, from January 2024 to May 2024. A total of 260 samples were collected from women who had experienced abortions or had a history of abortion. Participants were chosen randomly using a straightforward random selection method, without consideration for age or other demographic factors. A carefully crafted questionnaire was developed to gather information on this matter. A venous blood sample was collected from each participant to assess serological tests, including ICT, latex, and ELISA.

Statistical Analysis: Data was initially prepared in a data sheet and subsequently entered into the statistical software package for social sciences (SPSS), Version 24, Chicago, USA. Frequencies, percentages, cross-tabulation, and chi-square tests were computed. The P-value was calculated with reference to a 95% confidence interval (95% CI). A P-value of less than 0.05 was deemed statistically significant.

Informed consent:

All participants were required to provide written ethical consent prior to the interview.

Ethical Approval:

The protocol for this study received approval from the Human Research Ethics Committee (HREC) at Prof Medical Research Centre-MRCC.

Results:

This study involved 260 women to evaluate the efficacy of various techniques, specifically ICT and latex, in comparison to the ELIZA method, regarded as the gold standard. The ICT technique identified 38 out of 260 (14.6%) as positive and 222 out of 260 (85.4%) as negative. The Latex technique yielded 41 out of 260 (15.8%) positive and 219 out of 260 (84.2%) negative results. The ELIZA method detected 45 out of 260 (17.3%) as positive and 215 out of 260 (82.7%) as negative. These findings are presented in Table 1 and Figure 1.

Table 1 illustrates the distribution of study subjects by positive and negative results for Toxoplasma gondii across the different techniques employed.

Techniques	Negative	Positive	Total
ICT technique	222	38	260
Latex technique	219	41	260
ELIZA technique	215	45	260

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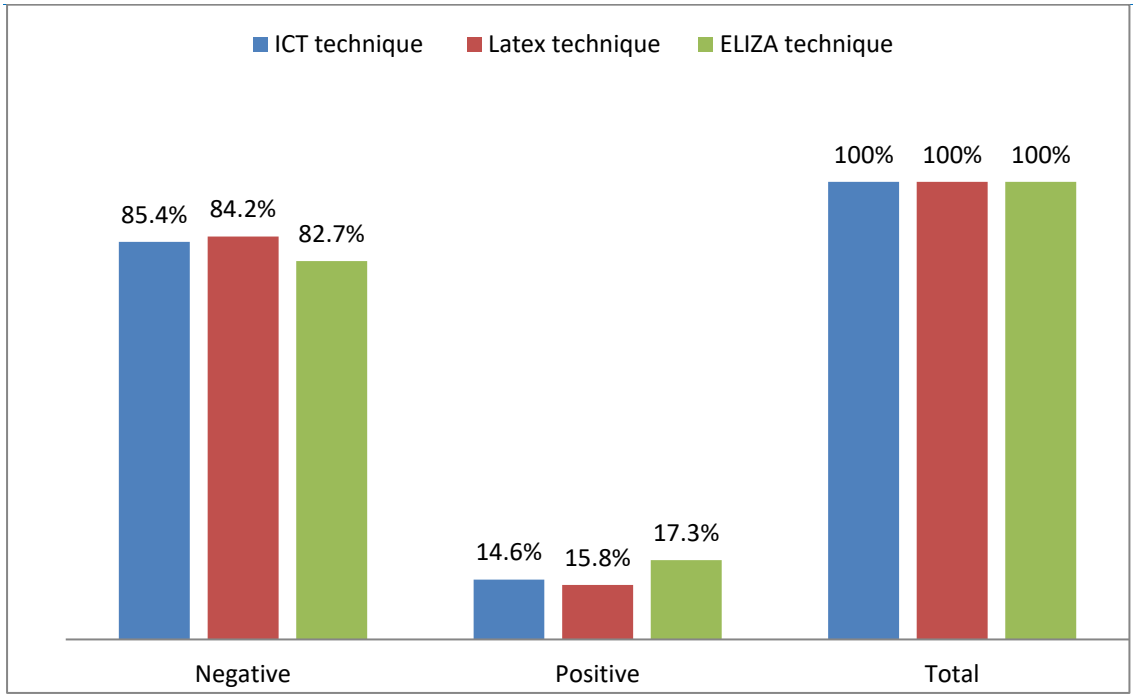

Figure 1. Distribution of study subjects based on the positivity and negativity of Toxoplasma gondii across various techniques employed.

Assuming ELISA as the gold standard technique, the sensitivity and specificity of the techniques employed in this study are compared with the ELISA technique as follows: The sensitivity using the ICT technique was 84%, while the specificity reached 100%, as shown in Table 2. The sensitivity and specificity obtained through the latex technique were 94% and 100%, respectively, as demonstrated in Table 3.

Table 2: Rates of sensitivity and specificity for ICT in comparison to ELISA

		ELISA IgG/IgM		
ICT		-ve	+ve	Total
	-ve	212(81.5%)	10(3.8%)	222(85.4%)
	+ve	3(1.2%)	35(13.5%)	38(14.6%)
	Total	215(82.7%)	45(17.3%)	260(100%)

Sensitivity = 84 % and specificity = 100%

Table 3: Rates of sensitivity and specificity for Latex compared to ELISA

		ELISA		
LATEX		-ve	+ve	Total
	-ve	208(80.0%)	11(4.2%)	219(84.2%)
	+ve	7(2.7%)	34(13.1%)	41(15.8%)
	Total	215(82.7%)	45(17.3%)	260(100%)

Sensitivity = 94% and specificity = 100%

Discussion

The situation in Sudan is dire, marked by a significant breakdown of the national health system. A number of diagnostic methods remained nonfunctional because of insufficient reagents or inadequate maintenance. As a result, numerous diagnostic laboratories have been deprived of access to more precise and sensitive techniques like ELISA. The current investigation assessed LATEX and ICT

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techniques, utilizing ELIZA as the benchmark for diagnosing Toxoplasma gondii.

The current investigation has demonstrated that ICT exhibits a sensitivity of 84% and a specificity of 100%. A prior investigation has demonstrated that immunochromatography technology The detection sensitivity for low IgG titers in the absence of IgM, as well as for specific anti-Toxoplasma IgM, was found to be 100%. The results affirm the impressive sensitivity of Toxoplasma ICT IgG-IgM® in identifying both specific anti-Toxoplasma IgG and IgM, underscoring the value of this rapid test as a primary or secondary Toxoplasma serological test for pregnant women [6]. The sensitivity and specificity of the ICT and Architect IgG assays were evaluated through a prospective panel comparison. The ICT test demonstrated a sensitivity of 100%, while the Architect test showed a sensitivity of 92.1% with a cutoff set at 1.6 IU/ml. The results of the low-IgG-titer serum indicated that the sensitivity of ICT was superior to that of Architect. The specificity recorded was 98.7% for ICT and 99.8% for Architect IgG. The ICT test proves to be effective in identifying IgM in the absence of IgG, demonstrating both sensitivity and specificity at 100%. It successfully differentiates between nonspecific IgM and specific Toxoplasma IgM. The sensitivity and specificity of IgM on Architect are 96.1% and 99.6%, respectively, with a cutoff set at 0.5 arbitrary units [AU]/ml. In conclusion, this novel test addresses the shortcomings of automated screening methods, which do not provide sufficient sensitivity for IgG and exhibit a lack of specificity for IgM, including rare instances of false-positive IgM results [7].

This study shows that the Toxoplasma ICT IgG-IgM test can be effectively utilized as a point-of-care diagnostic tool for Toxoplasma gondii infection. This presents a chance to enhance maternal-fetal care through the utilization of existing approaches, diagnostic tools, and medications. This infection carries significant, enduring implications for those affected and their families. The current study indicates that a straightforward, affordable point-of-care test is now accessible to aid in reducing morbidity and disability, lowering costs, and facilitating gestational screening. It also offers new options for improved prenatal care in low- and middle-income countries [8].

The findings of the current study reveal that the Latex technique demonstrates a sensitivity of 94% and a specificity of 100%. Previous reports indicated comparable results; the latex test demonstrated a sensitivity of 94% and a specificity of 100% when evaluated against an indirect immunofluorescence assay. In comparison to an enzyme-linked immunosorbent assay, the latex test demonstrated 86% sensitivity and 100% specificity. In the evaluation of samples displaying nonspecific polar staining through the immunofluorescence assay, the enzyme-linked immunosorbent assay demonstrated a 50% false-positive rate, while the latex agglutination test produced no false-positive results. Consequently, the latex agglutination test proved to be an effective approach for regular serological screening for antibodies to T. gondii [9]. The application has demonstrated a sensitivity range of 72 to 85% for confirming congenital toxoplasmosis during the third month of life. When paired with serological methods, the sensitivity rises to 94%, while maintaining a specificity of 100% [10].

A meta-analysis revealed the use of different samples in the standardization of techniques such as serum, total blood, colostrum, and amniotic fluid. The flow cytometry, lateral flow immunoassay, and qPCR techniques demonstrated 100% sensitivity, while the ELISA, western blotting, qPCR, and RE-LAMP techniques reached 100% specificity. The assessment of the likelihood ratio revealed that the qPCR and LAMP techniques demonstrated greater accuracy. The meta-analysis revealed that ISAGA and western blotting exhibit low sensitivity values, while LIASON, ELFA, and ELISA, utilizing a silica bioconjugate, demonstrate low specificity values as well. A diverse array of methods demonstrates elevated levels of sensitivity and specificity. Therefore, the choice of the method will be based on the conditions and its financial viability [11].

In conclusion, both Latex and ICT demonstrate relatively better sensitivity and very good specificity, making them suitable for screening and diagnostics in conflict areas. Acknowledgment

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Authors' contribution

-Bbdallah MMM: Conception, Data collection, Analysis, Approval of the final version

-Ahmed NA: Conception, Consultation, Critical revision

Conflict of interest:

Authors declare No conflict of interest.

Data Availability:

Data for this study can be obtained from the corresponding authors.

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