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BRIEF COMMUNICATION

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Sensitivity and specificity of a rapid diagnostic test for chronic Chagas disease at a referral center in Brazil - can it be included as a standard serological diagnostic test in the clinical practice of a referral center?

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Abstract

Introduction: Chagas disease (CD) is a neglected tropical disease. In the chronic phase of CD, the diagnosis is essentially serologic. Conventional reactions are currently in use. More recently, the use of rapid diagnostic testing (RDT) is indicated when conventional techniques are not available. Objective: To evaluate the sensitivity and specificity of RDTs for chronic CD diagnosis. Methodology: Individuals under suspicion of CD were evaluated using ELISA, Chemiluminescence (ChLIA) and RDT tests. Results: The RDT showed 95.1% sensitivity and 96.7% specificity, respectively. Conclusion: The findings of the present study showed that RDT used in the diagnosis of CD at a referral center in Brazil were not able to detect all CD cases when compared to Elisa and ChLIA.

Key word: Chagas disease, rapid test, ELISA, chemoluminescence, sensitivity, specificity.

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Introduction

Chagas disease (CD) is considered a neglected tropical disease by the World Health Organization, with an estimated 6-7 million people infected worldwide(1). Nowadays, with the control of vectorial transmission and blood transfusion implemented in the late 1990s, in most endemic countries, the new challenges of CD are the control of congenital transmission and the identification of the million people infected by trypanosoma cruzi (T. cruzi). Integrated surveillance and health interventions are now targeted at this large contingent of already infected patients (2).

In the chronic phase of CD, the diagnosis is essentially serologic and must be performed using a test with high sensitivity in conjunction with another having high specificity, and both must be reactive (3). Conventional reactions such as the enzyme-linked immunosorbent assay (ELISA) test, indirect immunofluorescence (IFI), indirect hemagglutination (IHA) and, chemiluminescence (ChLIA) are currently under use (4). More recently, the use of rapid diagnostic testing (RDT) are indicated in order to improve the diagnosis in remote areas in which conventional techniques are not available (5).

The aim of this study was to evaluate the sensitivity and specificity of RDTs for CD used at a referral center in Brazil.

Methods

This is an observational retrospective study including patients that underwent CD diagnosis test from July 2018 to December 2020. People under suspicion of disease were evaluated in the immunodiagnostic sector of Evandro Chagas

National Institute of Infectious Diseases (INI) of Oswaldo Cruz Foundation (Fiocruz), Rio de Janeiro, Brazil, using ELISA (Wiener lab - Chagatest and DiaSorin lab - CHAG0560/96 Wells), ChLIA (Abbott - Architect i1000s) and RDT (Bioline - SD Chagas Ab, Abbott Alere - Chagas Ab Rapid and OnSite - Chagas Ab Combo) tests. CD diagnosis was confirmed when both Elisa and ChLIA were reactive. This study was approved by the INI-Fiocruz Research Ethics Committee (number CAAE:35748820.1.0000.5262) on September 2, 2020 and was carried out in accordance with the 1964 Declaration of Helsinki and its later amendments.

Sensitivity and specificity analysis were used to assess the performance of the RDTs. Sensitivity was determined by the proportion of those with positive RDT result out of those who had positive CD diagnosis by both Elisa and ChLIA. Specificity was determined by the proportion of those with negative RDT result out of those who had negative CD diagnosis by both Elisa and ChLIA.

Results

During the study period, 1182 CD serological tests were performed. Three hundred ninety-nine patients underwent simultaneously ELISA, ChLIA, and RDT. Three hundred eight patients presented both Elisa and ChLIA reactive, and 91 non-reactive (Table 1). Among individuals with positive reactive tests, 293 present a RDT positive (95.1% sensitivity). Among individuals with non-reactive tests, 88 presented a RDT negative (96.7% specificity).

Table 1. Elisa and ChLIA vs RDTs diagnostic test results for CD diagnosis (n=399)

	Elisa and ChLIA	
RDTs	Positive (n=308)	Negative (n=91)
Positive	293	3
Negative	15	88
	Sensitivity=95.1% (293/308)*100	Specificity=96.7% (88/91)*100

Discussion

The INI-Fiocruz is a reference center for CD that provides diagnostic interpretation for patients referred from blood banks, primary and secondary care units, private health services, or by spontaneous demand, offering integral and multidisciplinary clinical care for patients with CD(6).

Due to the low parasitemia in the chronic phase of the disease, the diagnosis of T. cruzi infection is performed using serological or molecular methods, with serological methods being the preferred choice for the diagnosis of chronic CD(7). Current guidelines developed by the World Health Organization, Pan American Health Organization, and Brazilian and Argentine consensus advise the use of at least two serological tests based on different principles for a conclusive diagnosis (1),(3),(8),(9).

Current diagnostic methods based on serology are highly accurate in detecting T. cruzi infections. However, serological tests are not always available, making difficult the CD diagnosis in some areas. In this setting, the use of RDT for CD diagnosis can emerge as a feasible alternative for diagnosis of CD. However, its inclusion as a standard test to be used in routine diagnostics services needs further investigation.

The lack of information about the diagnostic kits used for each patient should be acknowledged as a limitation of the study, considering that different kits may provide discordant results. Therefore, this result should be interpreted with caution considering that better or worse performance for the RDTs can be found depending on the diagnostic kit.

To conclude, the findings of the present study showed that RDTs used in the diagnosis of CD at a referral center in Brazil were not able to detect all chronic CD cases when compared to Elisa and ChLIA. Therefore, RDTs should not be used for standard serological diagnosis of chronic CD in the same way as conventional tests that have already been previously validated. However, RDTs should be used as secondary alternative tests for confirmation of chronic Chagas disease in epidemiological field studies and diagnosis in remote areas.

Conflict of interest

None to declare.

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Authors' contributions

All authors wrote the draft, reviewed the manuscript, and approved the final version.

Ethical Statement

This study was approved by the INI-Fiocruz Research Ethics Committee (number CAAE:35748820.1.0000.5262) on September 2, 2020 and was carried out in accordance with the 1964 Declaration of Helsinki and its later amendments. The need for informed consent was waived considering the retrospective nature of the study.

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