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Rapid Diagnostic Tests and ELISA for diagnosing Chronic Chagas Disease: Systematic revision and meta-analysis

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
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ABSTRACT

Objective

To determine the diagnostic validity of the enzyme-linked immunosorbent assay (ELISA) and Rapid Diagnostic Tests (RDT) among individuals with suspected chronic Chagas Disease (CD).

Methodology

A search was made for studies with ELISA and RDT assays validity estimates as eligibility criteria, published between May and August 2020 on PubMed, Web of Science, Scopus, and LILACS. This way, we extracted the data and assessed the risk of bias and applicability of the studies using the QUADAS-2 tool. The bivariate random effects model was also used to estimate the overall sensitivity and specificity through *forest-plots*, ROC space, and we visually assessed the heterogeneity between studies. Meta-regressions were made using subgroup analysis. We used Deeks' test to assess the risk of publication bias.

Results

43 studies were included; 27 assessed ELISA tests; 14 assessed RDTs; and 2 assessed ELISA and RDTs, against different reference standards. 51.2 % of them used a non-comparative observational design, and 46.5 % a comparative clinical design ("case-control" type). High risk of bias was detected for patient screening and reference standard. The ELISA tests had a sensitivity of 99% (95% CI: 98-99) and a specificity of 98% (95% CI: 97-99); whereas the Rapid Diagnostic Tests (RDT) had values of 95% (95% CI: 94-97) and 97% (95% CI: 96-98), respectively. Deeks' test showed asymmetry on the ELISA assays.

Conclusions

ELISA and RDT tests have high validity for diagnosing chronic Chagas disease. The analysis of these two types of evidence in this systematic review and meta-analysis constitutes an input for their use. The limitations included the difficulty in extracting data due to the lack of information in the articles, and the comparative clinical-type design of some studies. This article was funded through the Universidad de Boyacá.

ATTACHMENTS

[Protocolo RS Chagas.pdf](#)

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Rapid Diagnostic Tests, ELISA, diagnosing Chronic, Chagas Disease, Systematic revision, meta-analysis

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MATERIALS TEXT

Bases de datos PubMed, Web of Science, Scopus, and LILACS; hojas, esferas, packages (meta4diag: Binomial-normal with probit, and metandi and IGS: Binomial-normal with logit); (R DTApplots program), R 1.3 *software* (DTApplots, bamdit::plotcompare and meta4diag::meta-regression), Stata 15 (metandi), midas and JAGS

1 Protocol and registration

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