25TH NATIONAL & 11TH INTERNATIONAL ANNUAL CONGRESS
ON RESEARCH AND TECHNOLOGY OF IRANIAN MEDICAL SCIENCES STUDENTS
URMIA UNIVERSITY OF MEDICAL SCIENCES, URMIA, IRAN

Diagnostic Accuracy of the Direct Agglutination Test for Human Visceral Leishmaniasis: A Systematic Review

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Citation:
Javadi F, Khaghanzadeh N. Diagnostic Accuracy of the Direct Agglutination Test for Human Visceral Leishmaniasis: A Systematic Review. *Iranian biomedical journal*. Supplementary (12-2024): 111.

ABSTRACT

Introduction: Visceral leishmaniasis (VL) is a tropical parasitic disease caused by the species of the genus *Leishmania infantum*. It is a potentially fatal disease with challenging diagnostic characteristics. Parasitological testing of bone marrow, spleen, or lymph node aspirations is the gold standard for diagnosing VL. This invasive test requires skilled clinical and sophisticated laboratory staff and appropriate facilities, and its sensitivity varies based on the tissue sampled. Direct agglutination test (DAT), a simple, accurate, and reliable method, has been widely used for serodiagnosis of VL over the last three decades. The present systematic review aimed to evaluate the diagnostic accuracy of DAT for serodiagnosis of human VL.

Search Strategy: Electronic databases, including MEDLINE (via PubMed), Scopus, and Web of Science, as well as SID and Magiran (two Persian scientific search engines), were searched from November 2012 to March 2024. We determined the pooled sensitivity and specificity rates of DAT for the diagnosis.

Results: Of the 796 records identified in the mentioned electronic databases and after examining reference lists of articles, 30 met inclusion criteria and were enrolled in the systematic review. Pooled sensitivity and specificity rates of DAT were 96% (95% CI: 90-98) and 95% (95% CI: 88-98), respectively. The combined estimate of the diagnostic odds ratio for DAT was high (467 [CI 95%: 114-1912]), indicating a strong association in diagnostic test accuracy for DAT.

Conclusion and Discussion: Based mainly on evidence gained by infection with VL, our analysis shows that DAT is a valuable tool for diagnosing human VL with high sensitivity and specificity. It is a simple, accurate, and efficient serological test recommended for the diagnosis of human VL in endemic areas.

Keywords: Agglutination tests, Humans, Systematic review, Visceral leishmaniasis

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[DOI: 10.61186/ibj.25th-11th-IACRTIMSS]