Can ELISPOT replace the tuberculin skin test for latent tuberculosis?

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CRD summary
The author concluded that the ELISPOT assay was more sensitive than the tuberculin skin test in detecting *Mycobacterium tuberculosis* infection. The results of the review did not allow calculation of comparative data on sensitivity for the two tests and so the conclusions are unlikely to be reliable.

Authors' objectives
To review the evidence on use of interferon gamma release assay (ELISPOT test) in diagnosis of latent tuberculosis prior to initiation of anti-tumor necrosis factor (TNF)-alpha treatment and to examine the agreement with the tuberculin skin test.

Searching
MEDLINE, EMBASE and The Cochrane library were searched from 1990 to 2009. Search terms were reported. Reference lists of retrieved studies were screened to identify additional relevant studies. The review was restricted to studies published in English.

Study selection
Primary studies that compared the accuracy of ELISPOT with tuberculin skin test in adults prior to anti-TNF-alpha therapy were eligible for inclusion. Studies conducted in populations where tuberculosis was endemic were excluded.

Participants in the included studies were patients with rheumatic disease, rheumatoid arthritis, tuberculosis and healthy controls. Both studies were conducted in low-incidence populations. Antigens used in the ELISPOT test were ESAT-6, CFP-10 and PPD. Both studies compared the ELISPOT test to the Mantoux tuberculin skin test. One study used a diagnostic accuracy design using the Mantoux test as the reference standard; the other study examined agreement between the two tests.

The author did not state how studies were selected for inclusion in the review.

Assessment of study quality
Study quality was assessed using QUADAS.

The author did not state how many reviewers performed the quality assessment.

Data extraction
Data were extracted on sensitivity, specificity and agreement between the ELISPOT and Mantoux test.

The author did not state how many reviewers extracted data.

Methods of synthesis
A narrative synthesis was presented.

Results of the review
Two cross-sectional studies were included (n=317).

The diagnostic accuracy study reported sensitivity of 94% and specificity of 100%. The other study reported an agreement between the ELISPOT test and Mantoux test of 73%.
Authors' conclusions
The ELISPOT assay was more sensitive than the tuberculin skin test in detecting *Mycobacterium tuberculosis* infection, particularly in patients who took immunosuppressant medication or those with previous BCG vaccination.

CRD commentary
The review addressed a clear objective. Inclusion criteria were defined in terms of index test, participants and comparator test/reference standard, but were lacking for study design and outcomes. The literature search was adequate for published studies, but restriction of the review to studies published in English risked language and publication biases. It was unclear how many reviewers were involved in each stage of the review, but given that the review only had one author it was unlikely that appropriate steps were taken to minimise bias and errors in the review process. The author stated that study quality was formally assessed, but no results of the quality assessment were reported (some methodological aspects of the studies were discussed in the text). A narrative synthesis was appropriate given the differences between studies, but findings were not clearly reported and were difficult to interpret. The results of the review did not allow calculation of comparative data on sensitivity for the two tests and so the author's conclusions are unlikely to be reliable.

Implications of the review for practice and research
The author did not state any implications for practice.

Research: The author stated that further studies were needed into cost-effectiveness of ELISPOT and tuberculin skin test in routine clinical practice.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.