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Title Assessment of laboratory medicine procedures related to the diagnosis of leishmaniasis

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Aim

The objective of this work is to assess the tests used to detect Leishmania DNA and serum antibodies in the diagnosis and follow-up of leishmaniasis by specifying their indications and the techniques used.

Conclusions

The conclusions of HAS are:

- **The detection of *Leishmania* DNA by gene amplification (PCR) is indicated:**
  - when (cutaneous, mucosal and visceral) leishmaniasis is suspected in order to establish the diagnosis;
  - in the follow-up of immunosuppressed patients with a visceral form.

This test is carried out on blood or bone marrow samples when the visceral form is suspected and on lesion samples for the cutaneous or mucosal forms (biopsy, aspiration, scraping, swabs, etc.). A quantitative result is obtained on blood samples and a qualitative result is obtained for all other samples. Visceral forms are followed up approximately every three months in immunosuppressed patients. Serology is not useful during the follow-up period.

- **Serum should be collected for detection of antileishmanial antibodies to diagnose visceral or mucosal leishmaniasis.**

The initial diagnosis is performed using the immunofluorescence (IFI) or enzyme-linked immunosorbent assay (ELISA) technique. In the event of a positive result, this is then confirmed using the "Western blot" immunoblotting method. The agglutination technique (AGG) should no longer be used in first-line testing. Serum antibody testing is not useful in follow-up.
The sequence of the testing for serum antibodies and DNA is not clearly established for the forms in which these two tests are used: visceral form and mucosal form; nevertheless, they appear to be carried out at the same time.

Methods

The method used is a short assessment procedure that involves:

- performance of a critical analysis of the literature reviews (good practice guidelines, technological assessment reports, meta-analyses and systematic reviews) identified by a systematic literature search and then selected using specific criteria; thus two meta-analyses and two good practice guidelines were selected;
- collection of the reasoned views of the professional bodies involved in the subject (laboratory medicine and infectious diseases) and of the national centre of reference for this parasitic disease;
- a survey of the biomedical laboratories using the gene amplification technique ("PCR") to detect *Leishmania* DNA in order to estimate the number of patients who have been diagnosed through gene amplification in France in recent years.

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