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Short communication

Performance of commercially available serological diagnostic tests to detect *Leishmania infantum* infection on experimentally infected dogs

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ABSTRACT

Leishmania infantum (syn. Leishmania chagasi) is the etiological agent of a widespread serious zoonotic disease that affects both humans and dogs. Prevalence and incidence of the canine infection are important parameters to determine the risk and the ways to control this reemergent zoonosis. Unfortunately, there is not a gold standard test for *Leishmania* infection. Our aim was to assess the operative validity of commercial tests used to detect antibodies to *Leishmania* in serum samples from experimental infections. Three ELISA tests (LEISCAN® Leishmania ELISA Test, INGEZIM® LEISHMANIA, and INGEZIM® LEISHMANIA VET), three immunochromatographic tests (INGEZIM® LEISHMACROM, SNAP® Leishmania, and WITNESS® Leishmania), and one IFAT were evaluated. LEISCAN® Leishmania ELISA test achieved the highest sensitivity and accuracy (both 0.98). Specificity was 1 for all tests except for IFAT. All tests but IFAT obtained a positive predictive value of 1, while the maximum negative predictive value was achieved by LEISCAN® Leishmania ELISA Test (0.93). The best positive likelihood ratio was obtained by INGEZIM® LEISHMANIA VET (30.26), while the best negative likelihood ratio was obtained by LEISCAN® Leishmania ELISA Test (0.02). The highest diagnostic odds ratio was achieved by LEISCAN® Leishmania ELISA Test (729.00). The largest area under the ROC curve was obtained by LEISCAN® Leishmania ELISA Test (0.981). Quantitative ELISA based tests performmed better than qualitative tests ("Rapid Tests"), and the test best suited to detect *Leishmania* in infected dogs and to provide clinically useful information was LEISCAN® Leishmania ELISA Test. This and other results point also to the need of revising the status of IFAT as a gold standard for the diagnosis of leishmaniasis.

1. Introduction

In terms of global disease burden, leishmaniases are the second parasitic diseases among those caused by protozoa, just after malaria. Transmitted by sand flies, they are present in most ecozones and the impact may be underrated: 360 million people at risk; prevalence 14 million; 2 million annual incidence; 60,000 annual deaths; and 2.4 million DALYs lost (Desjeux, 2004). In humans, visceral leishmaniasis —the most severe form with a 90% mortality if left untreated— is caused by species of the *Leishmania donovani* complex: *L. donovani* in the Palearctic and *L. infantum* (=*L. chagasi* (Mauricio et al., 2000)) in both the Palearctic and the Neotropical ecozones. The dog, which also suffers from the disease, is the main reservoir of *L. infantum* (Moreno and Alvar, 2002; Dantas-Torres, 2007), and in enzootic regions infection may reach 67–80% (Berrahal et al., 1996; Solano-Gallego et al., 2001). There is a serious concern about the introduction of leishmaniasis into non-enzootic areas due to travelling.

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