

Evaluation of a vaccine composed of a new *Leishmania*-specific hypothetical protein in the protection against visceral leishmaniasis

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In this work, the effect of vaccination of a newly described *Leishmania infantum* antigenic protein has been studied in BALB/c mice infected with this parasite species. The LiHyD protein was characterized after a proteomic screening performed with the sera from dogs suffering visceral leishmaniasis (VL). Its recombinant version was expressed, purified and administered to BALB/c mice in combination with saponin. As a result of vaccination and ten weeks after challenge using an infective dose of *L. infantum* stationary promastigotes, vaccinated mice showed lower parasite burdens in different organs (liver, spleen, bone marrow and footpads´ draining lymph nodes) than mice inoculated with the adjuvant alone or the vaccine diluent. Protected mice showed anti-*Leishmania* IgG2a antibodies and a predominant IL-12 driven IFN- γ production (mainly produced by CD4+ T cells) against parasite proteins whereas unprotected controls showed anti-*Leishmania* IgG1 antibodies and parasite mediated IL-4 and IL-10 responses. Vaccinated mice showed an anti-LiHyD IgG2a humoral response and their spleen cells were able to secrete LiHyD specific IFN- γ , IL-12 and GM-CSF cytokines before and after infection. The protection was correlated to the *Leishmania*-specific production of nitric oxide. Altogether, the results indicate that the new LiHyD protein could be considered in vaccine formulations against VL.

Keywords: Visceral leishmaniasis; vaccine; LiHyD; *Leishmania*, immune response.

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