

Evaluation of a vaccine composed by a *Leishmania infantum* hypothetical protein plus saponin against tegumentary and visceral leishmaniasis

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Leishmaniasis represents a spectrum of diseases caused by protozoan parasites of the genus *Leishmania* that affect million people in several countries in the world. Due to difficulties found in implementing effective prophylactic methods and in the treatment of the disease, the development of alternative measures, such as vaccines, is attractive. Experimental vaccine candidates have been tested to prevent leishmaniasis, but no commercial vaccine has proved to be effective against more than one parasite species. The aim of this study was evaluate the immunogenicity and protective efficacy of a new hypothetical protein, specific and conserved in *Leishmania spp.*, named LiHyT, added with saponin, against visceral and tegumentary leishmaniasis. The DNA sequence of LiHyT was cloned and the recombinant protein was expressed and purified. BALB/c mice were vaccinated with LiHyT plus saponin and infected with *L. infantum*, *L. major* or *L. braziliensis*. The immune response generated was evaluated before and 10 weeks after infection, as well as the parasite burden in spleen, liver, bone marrow, draining lymph node and lesion. The vaccination induced a Th1 response, which was characterized by the production of IFN- γ , IL-12 and GM-CSF, as well as by high levels of IgG2a antibodies, after in vitro stimulation. After challenge, vaccinated mice that were infected with *L. major* or *L. braziliensis* showed significant reduction in footpads swelling, as well as of the parasite burden in this tissue. All the immunized animals, infected with different species of *Leishmania*, demonstrated a significant decrease of the parasite load in the organs evaluated, when compared to the control groups (saline and saponin). The anti-*Leishmania* Th1 response was maintained after infection, being the IFN- γ production based mainly on CD4+ T cells. In conclusion, we described that only one conserved *Leishmania* specific hypothetical protein could compose a good vaccine against several species of *Leishmania spp.*

Keywords: Visceral leishmaniasis; tegumentary leishmaniasis; hypothetical proteins; vaccine; Th1 immune response.

Financial Support: Programa de Pós-Graduação em Ciências da Saúde: Infectologia e Medicina Tropical, Faculdade de Medicina, UFMG. FAPEMIG. CAPES. CNPq.