Adjuvant action from *Agaricus blazei* murill in a vaccine candidate to protect against murine visceral leishmaniasis.

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The development of effective prophylactic strategies to prevent leishmaniasis has become a high priority. No less important than the choice of an antigen, the association of an appropriate adjuvant is necessary to achieve a successful vaccination. However, few effective adjuvants that can be used against leishmaniasis exist on the market today; therefore, the research aiming to identify new adjuvants could be considered relevant. In this context, the present study evaluated purified fractions derived from *Agaricus blazei* as Th1 adjuvants through *in vitro* assays of their immune stimulation of spleen cells derived from naive BALB/c mice. The water extract of the mushroom were fractionated, and the obtained fractions were used to stimulate spleen cells derived from naive BALB/c mice. Then the production of IFN-γ, IL-4 and IL-10 was evaluated. Two of the tested six fractions (F2 and F4) were characterized as polysaccharide-rich fractions, and were able to induce high levels of IFN-γ, and low levels of IL-4 and IL-10 in the spleen cells. The efficacy of adjuvant action against *L. infantum* was evaluated in BALB/c mice, with these fractions being administered together with a recombinant antigen, LiHyp1, which was previously evaluated as a vaccine candidate, associated with saponin, against visceral leishmaniasis (VL). The associations between LiHyp1/F2 and LiHyp1/F4 were able to induce an *in vivo* Th1 response, which was primed by high levels of IFN-γ, IL-12, and GM-CSF, by low levels of IL-4 and IL-10; as well as by a predominance of IgG2a antibodies in the vaccinated animals. After infection, the immune profile was maintained, and the vaccines proved to be effective against *L. infantum*. The immune stimulatory effects in the BALB/c mice proved to be similar when comparing the F2 and F4 fractions with a known Th1 adjuvant (saponin), though animals vaccinated with saponin did present a slight to moderate inflammatory edema on their hind footpads. The F2 and F4 fractions appear to induce a Th1-type immune response and, in this context, they could be evaluated in association with other protective antigens against *Leishmania*, as well as in other diseases models.

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