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Review

Vaccines for visceral leishmaniasis: A review

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ABSTRACT

Visceral leishmaniasis, which is also known as Kala-Azar, is one of the most severely neglected tropical diseases recognized by the World Health Organization (WHO). The threat of this debilitating disease continues due to unavailability of promising drug therapy or human vaccine. An extensive research is undergoing to develop a promising vaccine to prevent this devastating disease. In this review we compiled the findings of recent research with a view to facilitate knowledge on experimental vaccinology for visceral leishmaniasis. Various killed or attenuated parasite based first generation vaccines, second generation vaccines based on antigenic protein or recombinant protein, and third generation vaccines derived from antigen-encoding DNA plasmids including heterologous prime-boost *Leishmania* vaccine have been examined for control and prevention of visceral leishmaniasis. Vaccines based on recombinant protein and antigen-encoding DNA plasmids have given promising results and few vaccines including Leishmune®, Leishtec, and CaniLeish® have been licensed for canine visceral leishmaniasis. A systematic investigation of these vaccine candidates can lead to development of promising vaccine for human visceral leishmaniasis, most probably in the near future.

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Contents

1. Introduction

Infectious diseases like malaria, tuberculosis, filariasis, visceral leishmaniasis, leprosy, and HIV infection pose enormous burden on world health. Hence it is necessary to control these diseases and their outbreaks. Leishmaniasis has been elected by the World Health Organization (WHO) among the category-1 diseases described as emerging and uncontrolled diseases and its prevention is majorly based on three parameters including

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control of vector, animal reservoir control and research and development of potential vaccine candidates. Instead of extensive research and execution of various programs by health system, the prevalence of visceral leishmaniasis has increased particularly in Indian subcontinent (Abdian et al., 2011; John et al., 2011; Matlashewski et al., 2011; Stockdale and Newton, 2013). Inefficient antileishmanial drugs, unavailability of human leishmania vaccine, diversity and complexity of leishmania parasite, varied response with geographical distribution, complexity and severity of diseases, emergence of resistance due to improper use of medicines and unawareness of general public resulted in this prevalence. Current treatment strategies for visceral leishmaniasis are greatly hampered by cost of available drugs and emergence of resistance to antileishmanial drugs. Hence it is necessary to understand immunology of visceral leishmaniasis to develop an effective vaccine against this severe ailment (Jain and Jain, 2013; Kaye and Aebischer, 2011; Nagill and Kaur, 2011).

Leishmaniases comprises a group of diseases caused by protozoan parasite belonging to genus *Leishmania*. Based on the main clinical symptoms, these complex diseases may be classified into three groups, namely; visceral leishmaniasis, cutaneous leishmaniasis and mucocutaneous leishmaniasis. Visceral leishmaniasis is the most severe form of leishmaniasis, which may be fatal if not treated and is caused by parasite *Leishmania donovani* and *Leishmania infantum* (also known as *Leishmania chagasi*). Transmission of visceral leishmaniasis occurs by the bite of a sand fly belonging to genus *Phlebotomus* and *Lutzomiya* (De Oliveira et al., 2009; Van Griensven and Diro, 2012). Life cycle of *Leishmania* parasite along with strategy to control infection is presented in Fig. 1. Visceral leishmaniasis exists in two forms, zoonotic and anthroponotic, caused by *L. infantum* and *L. donovani*, respectively. The zoonotic form of disease exists in the Mediterranean region and American continent whereas the anthroponotic form is prevalent in Asian and African continents including India, Nepal, Bangladesh and East Africa (Van Griensven and Diro, 2012). Around 350 million populations are at risk of contracting this parasitic infection and about 1.6 million new cases are likely to occur per annum. Visceral leishmaniasis is fatal in 85–90% untreated patients (Stockdale and Newton, 2013). Visceral leishmaniasis is one of the fatal diseases in the Indian subcontinent due to increasing resistance to conventional drugs, inadequate treatment and HIV–leishmania co-infection; hence it is necessary to develop novel drugs/drug delivery systems/vaccine targets to fulfill the needs of visceral leishmaniasis therapy. Additionally cost of treatment as well as drug identification and development, restricts commercial production of antileishmanial agents. Further toxicity, long treatment course and limited efficacy are other confinement of antileishmanial therapy. Hence scientists are focusing on the immunotherapy and immunochemotherapy for control and treatment of visceral leishmaniasis (Roatt et al., 2014; Kumar et al., 2015; Islamuddin et al., 2015; Jain et al., 2015a, 2015b).

The development of various vaccine candidates including live or killed parasites, defined leishmanial antigenic proteins as well as antigenic salivary proteins of sandfly vector with successful results obtained in animal experiments strongly supports the opportunity for developing vaccine against visceral leishmaniasis as well as other forms of leishmaniasis (Lee et al., 2012; Alvar et al., 2013). In the following sections we will discuss various vaccine candidates, which have shown some promising results against experimental visceral leishmaniasis, along with the role of immune responses in the treatment and control of visceral leishmaniasis.

2. Immune responses in leishmaniasis

Leishmania parasites are transmitted by the bite of infected sandfly, reside in host macrophages and cause infection due to its ability to evade and attenuate microbicidal function of host by modulation of innate and adaptive immunological

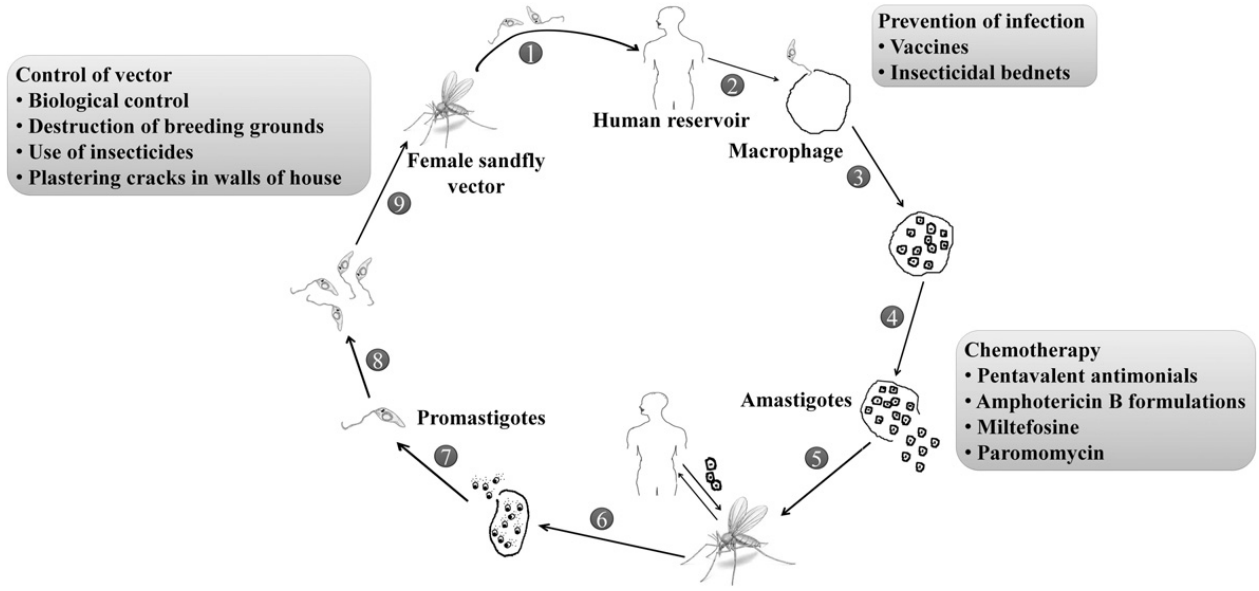

Fig. 1. Life cycle of visceral leishmaniasis parasite and potential strategies for control of infection. 1) Transfer of flagellate promastigotes form of *Leishmania* parasite by the bite of sandfly vector to human; 2) invasion of macrophages by promastigote; 3) transformation of promastigotes into amastigotes form; 4) multiplication of amastigotes within macrophages which infects new cells; 5) transfer of amastigotes into vector during human bite; 6) release of amastigotes in the midgut of sandfly; 7) transformation of amastigotes into promastigotes; 8) multiplication of promastigotes; and 9) migration of promastigotes to pharyngeal valve.

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