Development of a Unique Vaccine endowed with Multiple Therapeutic properties

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Abstract

Many years back, I developed a vaccine against leprosy, which has both immuno-prophylactic and laudable therapeutic properties. It cures ugly leprosy patients to normal beings without any ugly blemishes or scars, so much so that it is difficult to consider the cured person as having ever suffered from leprosy. It received the approval of Drugs Controller General of India and US FDA. It is passed on to a company for making it available to public. The vaccine is based on a cultivable atypical mycobacteria. The gene sequence of this mycobacteria is now known. It has been named as Mycobacterium indicus pranii (MIP). Pran is my family name and nii is the National institute of immunology, of which I was the Founder Director, where the final vaccine development took place. MIP is also highly effective for treatment of Category-II, "Difficult-to-treat" Tuberculosis. It is a potent invigorator of immune response. The company making it, is marketing it under different names for Psoriasis and some cancers It is being employed by the Department of Dermatology, All India Institute of Medical Sciences, New Delhi for impressive treatment of ugly ano-genital warts. We are using MIP as adjuvant in the recombinant anti-hCG Birth Control vaccine currently under development. A totally unforeseen application of MIP has been for treatment for Covid-19 patients as reported in 2 recent publications.

Leprosy is caused by Mycobacterium leprae, a mycobacteria isolated by Armauer Hansen in Norway in 1873. He was unable to grow it in any of the many media that he tried. His thesis is one of the shortest on record. The majority (~99%) of humans can resist infection of M. leprae successfully, and do not become leprosy patients. The few who become victim to the disease manifest a spectrum ranging from a single lesion with few if any bacteria, classified as tuberculoid (TT) to multibacillary lepromatous leprosy (LL) with multiple lesions loaded with M. leprae. This spectrum is a reflection of the existence of complete or variable degrees of immune response against M. leprae in patients manifesting the different forms of leprosy. Our first task was to learn of what goes wrong or is deficient in humans who become victims of the disease. After learning this, the next task obviously was to see whether anything can be done to prevent

humans contracting the disease. Nature of immune deficit in leprosy Those who contract leprosy have T cells that are unable to react against some key antigen(s) of M. leprae. Their immune system is otherwise fairly normal, and they respond normally to cholera or typhoid vaccines.T lymphocytes generate the signal for macrophages to prevent the proliferation of

phagocytosed M. leprae. Table 1 gives data clearly supporting the role of T cells in this process. In this experiment, monocytederived macrophages from either TT leprosy patients or those suffering from the LL form of the disease were infected with M. leprae derived from patients. Radioactive thymidine (3 Hthymidine) was used as a precursor in the medium. It was incorporated into DNA by M. leprae engulfed in macrophages derived from either LL or TT leprosy patients. However, if T cells derived from TT patients were also included in culture, the incorporation of 3 H-thymidine by M. leprae was restricted, whereas T lymphocytes derived from LL patients lacked this property. Can anything be done to restore this deficiency?

This was the basic requirement of an eventual vaccine against leprosy. Vaccines are usually made using the killed or attenuated forms of infecting microorganisms. Such a homologous approach was illogical for leprosy, as the basic defect in LL patients is their inability to respond to key antigen(s) of M. leprae. Therefore, a heterologous approach was adopted.Search for an atypical Mycobacterium sharing antigens with M. leprae Whereas M. leprae is noncultivable, a candidate for a vaccine against leprosy has to be cultivable in one medium or another to enable its production on a large scale for public use. We collected 16 cultivable, atypical mycobacteria from various sources, some already named and classified, others lying in various atypical collections. Each of them was coded and investigated for its ability to cause blast transformation of T cells from not only TT but also LL patients.

Their ability to generate cytokines influencing macrophage function as investigated. The ensemble of these investigations led to the shortening of the list of 16 to 5 mycobacteria. These were M. vaccae, M. phlei, M. gordonae, ICRC bacillus, and Mycobacterium w (Mw). To confirm their closeness to M. leprae, lepromin-like preparations were made of these five atypical mycobacteria and evaluated alongside lepromin prepared from M. leprae in TT and LL patients to evoke M. leprae lepromin-like responses in leprosy patients. An atypical mycobacteria (Mw) appeared to possess these molecular traits. Could Mw serve as a vaccine? Can it convert leprominnegative leprosy patients to lepromin-positive status?

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