The analysis of adverse reactions in patients who have undergone PET revealed local symptoms such as pain and systemic reactions of mild fever. The symptoms were of short duration and in no case made it necessary to seek medical intervention. Similar type of reactions were recorded when HDC vaccine is used in patients earlier[7]. The PET consisted of six injections of Abhayrab and ERIG for patients of Class III bite category.

The patients showed steep rise in antibody titres during short period with three inoculations who had no antibody titres prior to first immunization. The passive immunisation did not interfere with active immunization as shown in the results of sero-conversion studies of patients on 14 and 30 dpv. 100% sero-conversion was observed on 14 dpv. The results accomplish the observations made earlier with purified vero cell culture vaccine[5]. All the patients tolerated PET and the immunogenecity of the vaccine was established by serological assay performed on serum samples collected on different days during PET course.

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An immunogencity study of a newly introduced purified vero Cell rabies vaccine (*Abhayrab*) manufactured in India

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Abstract

Purified Vero cell culture rabies vaccine *"Abhayrab"* manufactured by Human Biologicals Institute, Ooty, India was subjected for immunogenicity studies. Pre-exposure study was undertaken on 60 healthy volunteers (Group I) with vaccination on days 0, 7 and 21. A group of 75 patients of category II (Group II), 67 of category III (Group III) were given post-exposure prophylaxis and 88 patients of category III were administered with rabies immunoglobulins (Group IV) along with post-exposure prophylaxis as per World Health Organization (WHO) recommendations with a booster on day 90. The volunteers and patients vaccinated showed very few adverse side effects. The blood samples collected from volunteers (Group I) on days 14, 35 and 365 and patients (Group II-IV) on days 14, 30, 90 and 365 showed geometric mean titres (GMT) of > 0.5 IU/ml. The study indicated new rabies vaccine manufactured in India was found to be safe and immunogenic.
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Keywords : Post-exposure rabies treatment; Rabies tissue culture vaccine; Rabies in India

1. Introduction

Rabies is endemic in India where approximately 5,000,000 persons undergo post-exposure rabies vaccination annually. The exact number of human rabies deaths is not known since rabies is not a reportable disease in India. Estimates range from 15,000 to 30,000 deaths annually [1]. Sheep brain derived Semple type rabies vaccine is still being manufactured and utilized for the majority of exposed patients in India, even though this vaccine has been discouraged by the World Health Organization (WHO) [2]. The high cost of tissue culture vaccine and inertia have been the main barrier to the replacement of Semple vaccine by WHO recommended post-exposure rabies prophylaxis (PEP), utilizing tissue culture derived products [3]. Fortunately, Indian manufacturers have now rallied to the challenge and several "home grown" tissue culture rabies vaccines are appearing on the potentially large public and private sector Indian market. Vero cell culture based Rabies vaccine *Abhayrab,* manufactured by the Human Biologicals Institute (HBI) at Ooty, is to the best of our knowledge, the first new product which has undergone an independent immunogenicity study.

The Vero cell line was first described by Yasumura in 1962. This resilient high-yield permanent cell line is derived from *Cercopithecus aethrops* (African Green Monkey) kidney cells. It has a long and successful history of being used in production of rabies and polio vaccines worldwide [4]. Introduction of a Vero cell rabies vaccine into Thailand, along with the economical intradermal Thai Red Cross post-exposure vaccine schedule, was instrumental in abolishing the use of animal brain tissue derived rabies vaccines by the late 1980s in that country. Vero cell derived rabies vaccines are now being manufactured in France, Columbia, China and India. *Abhayrab* is grown on a Vero cell line utilizing the L. Pasteur 2061 strain of rabies virus. It is inactivated with *ß propiolactone* (BPL), lyophilized and reconstituted in 0.5 ml of physiological saline. It is manufactured under good manufacturing practices (GMP) and fulfills WHO recommendations for potency. It was licensed by the Drugs Controller General of India (DCGI) in 1999 and has been marketed throughout the country since that time. Before the initiation of the current trial, a simulated post-exposure prophylaxis study was done in 40 healthy volunteers. They were administered *"Abhayrab"* intramuscularly into the deltoid muscle on days 0, 3, 7, 14 and 30. Estimation of Rabies neutralizing antibody titers revealed geometric mean titres (GMT) > 0.5 IU/ml in all individuals on days 14, 30, 90 and 365 (unpublished data).

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