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## Safety of purified chick embryo cell rabies vaccine administered in previously vaccinated animal handlers working in a biological park

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### Abstract

**Background:** Wild animal handlers are at continuous risk of exposure to rabies. They have to be protected against rabies by pre-exposure rabies vaccination and regular booster doses.

**Methodology:** The study was conducted in a biological park in Karnataka during October 2018. Animal handlers working in the various capacities at the park and having taken three primary doses of anti-rabies vaccine as pre-exposure prophylaxis were the study subjects. The booster dose of anti-rabies vaccine was administered by a team of trained vaccinators. After the vaccination all the subjects were observed for any adverse reactions for thirty minutes; subsequently the subjects were followed up for any adverse drug reactions through telephone for a period of 30 days.

**Results:** The study included 198 subjects with a mean age of 38.1 + 12 years. Only 8 adverse reactions were reported from 8 subjects immediately following vaccination. The adverse reactions were itching 3 (1.5%) & redness 5 (2.5%); which subsided without any complications. None of the subjects developed systemic or delayed adverse reactions.

**Conclusion:** Booster dose rabies vaccination with purified chick embryo cell rabies vaccine is safe in previously vaccinated animal handlers.

**Keywords:** Safety, anti-rabies vaccine, animal handlers, pre-exposure prophylaxis, booster dose

### Introduction

Rabies is a neglected viral zoonotic disease causing acute encephalitis which is almost always fatal. The disease is caused by single stranded RNA virus belonging to genus *Lyssavirus* of the family *Rhabdoviridae* [1]. The disease is transmitted by the saliva of rabid animals and generally enters the body via infiltration of virus-laden saliva from a rabid animal to other animals/humans through bites, scratches, licks on broken skin and mucous membrane. All Carnivores species including wild animals serve as natural reservoirs of the virus [2].

The South East Asia Region of World Health Organization's (WHO) has a high burden of rabies than in any other part of the World, due to a large human animal interaction. It is estimated that more than 1.4 billion people in this region are at risk of rabies infection. Therefore, it is a major public health and economic problem throughout the region as approximately 1.5 million US dollars is spent every year for rabies post exposure prophylaxis [3, 4]. India is also a rabies endemic country, where animal bites to humans are a major public health problem and an estimated 17.4 million animal bites occur annually which accounts to an incidence of 1.7 %. An estimated 20,000 human rabies deaths occur in India every year [3, 4, 5].

Therefore, in rabies endemic country like India, every animal bite is potentially suspected as a rabid animal bite, more so, all exposures to wild animals must be considered as high risk in countries enzootic for rabies [6].

The wild animal handlers are at significant risk of exposure to rabies every day, which is a significant occupational hazard. Timely and correct post exposure prophylaxis (PEP) consisting of proper wound wash with soap & running water, administration of full course of rabies vaccines (ARV) and local infiltration of rabies immunoglobulin (RIG)/Rabies monoclonal antibodies (Rmab) in all category III exposures is effective in preventing rabies, even after high-risk exposure [3]. The facilities for post exposure prophylaxis is not always available/accessible and even if it is available these biologicals are costly; leading to delay in availing PEP [4].

Therefore, WHO has recommended, pre-exposure prophylaxis (PrEP) for all high risk group using cell culture vaccines; which includes administration of three doses of anti-rabies vaccine (ARV) by either intra muscular or intra dermal route. Administration of correct pre-exposure prophylaxis & timely booster doses eliminates the need of rabies immunoglobulin (RIG) & reduces the required number of ARV to 2 doses [4].

Therefore, it is important that all the animal handlers receive pre-exposure prophylaxis with timely booster doses in order to prevent rabies in this high risk group. The present study was undertaken to assess the safety of booster dose of ARV administered by intradermal (ID) route in animal handlers, who were previously vaccinated with three doses of ARV as pre exposure prophylaxis and working in various sections of a biological park.

### Material and Methods

The study was conducted after obtaining permission from the concerned authorities of the biological park. It was conducted during October – December, 2018. A total of 198 animal handlers working in various capacities at different sections of the biological park and having taken three doses of pre-exposure prophylaxis ARV were included in the study, after obtaining their informed consent.

All the study subjects were given a booster dose of ARV by trained Vaccinators intra dermally in the deltoid region using an insulin syringe of 31 gauge. The vaccine used for the study was a purified chick embryo cell culture vaccine (PCEC) Rabipur, manufactured by Glaxo SmithKline Pharmaceuticals Ltd. It is WHO pre-qualified vaccine & is licensed to be used by the national authorities both by intramuscular & intradermal route for both pre & post exposure prophylaxis. [7] All the vaccine vials belonged to the batch number 3428 with an expiry date of May 2020 was used. A physician was designated to assess the tolerability/reactogenicity/safety parameters among all the vaccinated subjects. After 30 min, the data regarding safety was recorded by asking the subjects regarding any reactions and then transcribed into the case record form. Local and systemic reactions were recorded which included pain at the injection site, redness, swelling, fatigue, headache, fever, myalgia, systemic allergic reactions and any other adverse drug reactions. The adverse drug reactions were also collected through telephonic follow up in weekly intervals up to 30 days following the vaccination. The data was entered into Microsoft excel 2010 & analysed using Open Epi: Open Source Epidemiologic Statistics for Public Health. [8] Descriptive statistics like mean, standard deviation, frequency & percentages were used.

### Results and Discussions

The study included 198 subjects with a mean age of 38.1+12 years. Majority 153 (77.3%) of the study subjects were males followed by 22.7% females. Among the study subjects, 37(18.68%) of them worked as animal keepers, 20(10.1%) worked as Mahouts, and the rest of the study subjects included veterinarians 5(2.52%), vehicle drivers 5(2.52%), security guards 17(8.58%), 10(5.05%) gate keepers, administrative & other staff.

Among the study subjects, 8 immediate adverse reactions were reported from 8 different subjects. These adverse reactions included itching 3(1.5%) & redness 5(2.5%); which subsided with symptomatic treatment and without

any complications. This showed that, the anti-rabies vaccination given as pre exposure prophylaxis was safe among the animal handlers.

Therefore, anti- rabies vaccines is safe and remains the main stay of preventing rabies, using both as pre exposure and post exposure prophylaxis. PrEP is recommended for all the individuals who are at high risk of rabies exposure who includes children, animal handlers, and veterinarians [2]. ARV as pre-exposure prophylaxis leads to development of immunological memory which further leads to long lasting immunity against rabies in humans. Administration of booster dose of ARV, after pre-exposure prophylaxis produces a good anamnestic response irrespective of route of ARV administration during PrEP & booster vaccination [6, 7].

The present study showed that, PrEP with anti-rabies vaccine is found to be safe among animal handlers. Similarly, a study conducted at a tertiary care hospital in Bangalore, showed that the anti- rabies vaccine given as PEP was safe and effective in wild animal exposures, where all the subjects were healthy and alive after 1 year of follow up after complete post exposure prophylaxis [9].

A study conducted in Bangalore during the year 2012 to assess the safety of purified chick embryo cell vaccine administered by intra dermal route as pre-exposure prophylaxis in children proved to be safe and was well tolerated by the study subjects [10].

Similarly a study conducted to assess the safety of intra dermal rabies vaccination as pre exposure prophylaxis among veterinary students in Bangalore proved to be safe as there were only 38 ADRs reported from 19 subjects that were mild & self-limiting without any medication [11].

A comparative study to assess the safety of ARV used for pre- exposure prophylaxis in three high risk groups was conducted in the year 2015 at Bangalore which included children, rag-pickers & veterinarians the study results concluded that pre-exposure prophylaxis is safe & well tolerated by high risk groups [12].

Countries where serological testing for antibody titres is not easily available it is important to administer timely booster doses for individuals who are at a high risk of rabies exposure [5].

### Conclusion

Pre-exposure rabies vaccination is safe and well tolerated by intradermal route among high risk group and is an effective tool in rabies prevention for animal handlers who are at risk of exposure to rabies.

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