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Research Article

A Longitudinal Study on Safety and Clinical Efficacy of Rabies Biologicals for Post Exposure Prophylaxis Among the Vulnerable Elderly Population at the Anti-Rabies Clinic, Bangalore

Ravish H S[1], G Gouri Vijay[2], Navyashree N S[3], Divya Bharathi G[4]

[1]Professor, [2,3,4]Department of Community Medicine, Kempegowda Institute of Medical Sciences (KIMS), Bangalore, India
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Corresponding Author:
Ravish H S, Department of Community Medicine, Kempegowda Institute of Medical Sciences (KIMS), Bangalore, India
E-mail Id:
drravishhs@rediffmail.com
Orcid Id:
https://orcid.org/0000-0002-8518-3285
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A B S T R A C T

Introduction: Animal exposures are a public health problem that occurs largely in the underserved populations where there is close habitation of human and dog populations. The elderly are more vulnerable to animal bites, often unable to defend themselves, and require immediate post-exposure prophylaxis (PEP), which is effective in preventing rabies. The present study was conducted to study the safety and clinical efficacy of post-exposure prophylaxis among this vulnerable group.

Methodology: All the elderly individuals who came for post-exposure prophylaxis to the anti-rabies clinic were included in the study after obtaining written informed consent. The details on socio-demographic profile and characteristics of animal bites and PEP provided were recorded. A safety assessment was done by recording the adverse drug reactions (ADRs), both local & systemic, immediately & subsequently up to day 28. Likewise, all the patients were followed up to 6 months after PEP to know their health status and for the clinical efficacy of PEP.

Results: The study included 54 subjects with category III exposure, aged between 60 and 97 years. All the subjects were provided post-exposure prophylaxis as recommended by NCDC, India. Among the study subjects, 12 (22.2%) reported ADRs such as pain (14.8%), itching (3.7%), erythema (1.9%), and malaise (1.9%), which were mild and resolved without any complications. All the study subjects were healthy and alive at the end of 6 months.

Conclusion: The post-exposure prophylaxis provided was safe and clinically effective in preventing rabies among the elderly in category III animal exposures and supports its continued usage in this vulnerable group.

Keywords: Safety, Clinical efficacy, Rabies biologicals, Post exposure prophylaxis, Elderly

Introduction

Animal exposure is a public health problem, posing an imminent threat of rabies to over 3.3 billion people worldwide.[1] These exposures occur mostly in the underserved populations, both in urban and rural areas.[2] The most common animal exposures across the globe are by dogs and cats, most commonly seen in Africa and Asia, where a close habitation of large human and dog/cat populations exists.[3]

Therefore, in these countries, whenever there is an exposure to an animal that is suspected or confirmed to be rabid or when there is doubt about the circumstances that led to the exposure, post-exposure prophylaxis (PEP) should be initiated immediately and completed to prevent rabies.[4]

The PEP consists of a thorough wound wash with soap and water, followed by the application of a virucidal agent to reduce the viral inoculum, a complete course of post-exposure anti-rabies vaccination to induce antibodies that prevent the risk of the virus entering the peripheral nerves, and a timely infiltration of rabies immunoglobulin (RIG) to neutralize the virus at the wound site.[5, 6]

In India, an estimated 9.1 million animal bites occur annually, with an annual incidence of animal bites of 0.66%; the majority of animal bites are from dogs (0.56%), affecting the poor and vulnerable across all the age groups. 7 The multi-centric study across the country done by the Association for Prevention and Control of Rabies in India (APCRI) with the technical and operational support from the WHO, with the objective of determining the treatment-seeking behavior of animal bite victims, showed that 7.4% of all the animal bites in the field survey and 11.4% in the health care facility study were elderly.[8,9]

The elderly are more vulnerable to animal bites, often unable to defend themselves, and require immediate post-exposure prophylaxis (PEP), which is effective in preventing rabies. 10 The present study was conducted to study the safety and clinical efficacy of post-exposure prophylaxis among this vulnerable elderly population.

Materials and Methods

The study was initiated after getting the clearance from the Institutional Ethics Committee, Kempegowda Institute of Medical Sciences, Bengaluru, ref. no. KIMS/IEC/A333/M/2025 dated 14.10.2025. It was a longitudinal study from July 2025 to March 2026 at KIMS Hospital and Research Center, Bangalore, India. The study included 54 elderly individuals who were category III animal bite victims and presented to the anti-rabies clinic for PEP.

Sample size

The sample size was calculated based on the incidence of adverse events (AEs) in subjects with category III exposures who received PEP in a recent study, i.e., 16.7%.[11]

n = sample size; Z = level of confidence according to the standard normal distribution; for a level of confidence of 95%, it is 1.96; p = 16.7% (AE); q = 1-p (83.3%); d = 10% (absolute precision). The sample size was 54.

Data collection

We enrolled 54 elderly subjects with category III animal exposures who signed the written informed consent to participate in the study. A detailed history was recorded, including the socio-demographic profile and the details of animal exposure, such as the type of animal and whether the attack was provoked or unprovoked. Bites inflicted on a person attempting to feed or handle an apparently healthy animal were regarded as provoked. An unprovoked attack indicates that the animal was more likely to be rabid. Simultaneously, a history of current or past medical issues, past medications, and allergies to any medicines was also noted.

A detailed clinical examination was conducted to evaluate all the wounds present in the study subjects. The number and site of the wounds (viz., upper limb, lower limb, head, neck, trunk, and abdomen) and their severity (viz., abrasions, lacerations, and punctures) were recorded.

Post-exposure prophylaxis was provided to all the study subjects according to the National Rabies Control Programme (NRCP) guidelines by the NCDC, Government of India. It included thorough wound wash with soap and running water for 10–15 minutes, irrespective of any wound care given before presentation to the hospital, and a complete course of intramuscular anti-rabies vaccination by the Essen regimen, i.e., one dose each, on days 0, 3, 7, 14, and 28.

A simultaneous infiltration of ERIG/RmAb was done on day "0" in a single dose not exceeding the recommended dosage for the body weight, i.e., 40 IU/kg body weight for ERIG/cocktail of 2 monoclonal antibodies and 3.33 IU/kg body weight for a single monoclonal antibody into all the wounds, as was anatomically feasible, i.e., until it oozes out of the wound, indicating the successful infiltration. Any remaining volume was injected deep intramuscularly away from the site of vaccination. For multiple or extensive wounds, the calculated dose of ERIG/RmAb was diluted with normal saline as was clinically required and infiltrated to cover all the wounds.

Assessing safety & clinical efficacy: All the patients were assessed for AEs following PEP. The subjects were observed for an hour to record possible immediate solicited local AEs such as pain, erythema, pruritus, and induration and/or systemic reactions like shivering, malaise, asthenia, faintness, dizziness, headache, myalgia, arthralgia, nausea, abdominal pain, and hypersensitivity or allergic reactions

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such as urticaria, rash, and anaphylaxis. Follow-up cards indicating the dates for the next doses of vaccination were issued to all the patients to note down unsolicited late AEs such as itching, fever, serum sickness, arthralgia, and any others. These cards were checked during subsequent hospital visits on days 3, 7, 14, 28, and 180. The causality and severity of the AE were adjudicated by the principal investigator. The AEs were graded as mild (Grade 1)—with noticeable discomfort without interference with daily activities; moderate (Grade 2)—which interferes with daily activities; and severe (Grade 3)—which prevents daily activities.

All the study subjects were followed up via phone calls every month after complete PEP, and at the end of 6 months, they were called to the hospital to confirm their health and survival status. The survival of the exposed persons after the completion of the rabies PEP and beyond the usual incubation period of the disease, i.e., six months, is an indicator of the clinical efficacy of the treatment.

The data collected was statistically analyzed using MS Excel and the IBM-SPSS statistics software package version 21.0. The frequency and percentages were computed for analyzing the ADRs among the study subjects.

Results

The present study included 54 elderly subjects with category III animal exposures representing both sexes and with the age range of 60-97 years; most of them belonged to 60-69 years (63%), followed by 70-79 years (26%), 80-89 years (5.5%), and >90 years (5.5%). The majority of the bites were from dogs (83.3%), followed by cats (12.9%) and monkeys (3.8%); most of the exposures (66.6%) were unprovoked.

The animal bites in the study subjects were present on lower limbs (64.8%), upper limbs (31.4%), head, neck, and face (3.7%), and trunk (3.7%), and some had bites on multiple sites (3.7%). The most common type of wound was abrasions (75.9%), followed by lacerations (35.2%) and punctured wounds (12.9%). (Table 1).

ERIG/RmAb was infiltrated locally into or around the wound in all the subjects. Additionally, in some patients, the remainder after local infiltration was administered deep intramuscularly at a site away from the anti-rabies vaccination (Table 2). Among the 54 study subjects, 12 (22.2%) reported minor ADRs. The common local ADRs were pain at the injection site, erythema, and itching, and the systemic ADR was malaise (Table 3). All the ADRs were mild in nature and subsided spontaneously and completely, without any complications. Some (7.4%) patients had applied irritants like lime, turmeric, and coffee powder before coming to the clinic, but none of them reported any ADRs after PEP. None of the study subjects reported a severe ADR or an ADR leading to discontinuation of the study. In the present study, all the subjects were healthy and alive throughout the period of 6 months after receiving PEP, thereby proving the clinical efficacy of PEP among the elderly.

Table 1.Details of exposure among study subjects

(n = 54)

Details of exposure	Frequency	Percentage
Biting animal:		
Dog	45	83.3
Stray	28	62.2
Pet	17	37.8
Cat	7	12.9
Monkey	2	3.8
Circumstance of bite:		
Provoked	18	33.4
Unprovoked	36	66.6
Type of wound:*		
Abrasion	41	75.9
Laceration	19	35.2
Punctured wound	7	12.9
Site of Exposure:*		
Lower limb	35	64.8
Upper limb	17	31.4
Head, neck, and face	2	03.7
Trunk	2	03.7
Multiple sites	2	03.7
Wound wash practiced:		
Yes	52	96.3
No	2	03.7

*Multiple responses

Table 2.Usage of rabies immune biologicals

(n = 54)

Rabies immune biologicals	Frequency	Percentage
Anti-rabies vaccine used:		
PCECV	12	22.2
PVRV	42	77.8
Passive Immunization given:		
Single monoclonal antibody	28	51.8
Cocktail of 2 monoclonal antibodies	16	29.7

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Equine rabies immunoglobulin	10	18.5
Site of RIG/RmAb administration:		
Local	49	90.7
Local and systemic	05	09.3

PCECV Purified chick embryo cell vaccine; PVRV purified vero cell rabies vaccine

Table 3.Adverse reactions following post exposure prophylaxis (n = 54)

Types of adverse reactions*	Frequency	Percentage
Local:		
Pain	8	14.8
Itching	2	03.7
Erythema	1	01.8
Systemic:		
Malaise	1	01.8
Total	12	22.2

*Multiple response.

Discussion

Animal exposures continue to be a major public health and economic problem throughout the Southeast Asian region. Improved PEP services with safe and effective immune biologics in the healthcare system, particularly for the vulnerable populations, will lead to the prevention, control, and eventually elimination of the disease by 2030, which has been set in line with the Sustainable Development Goals (SDG) 3.3 to end neglected tropical diseases by 2030.[12-15]

The present study showed that the subjects were representative of both sexes and varied age groups among the elderly. The incidence of ADRs was found to be 22.2%, and all were mild in nature and subsided spontaneously without any complications. These findings are similar to other studies conducted previously. A study conducted at the anti-rabies clinic in Bangalore, including eighty-six subjects who were provided PEP with different anti-rabies vaccines along with ERIG, showed that the ADRs were 7.7%. The common ADRs were erythema at the site of injection, itching at the site of injection, pain at the site of injection, and induration at the site of injection, and all of them subsided without any complications.[16]

Another study evaluated the safety of PEP using a monoclonal antibody cocktail along with an anti-rabies vaccine in 159 patients with severe animal bites. The adverse events were reported in 10.7% of cases, predominantly mild and local, with no systemic or severe reactions observed. No cases of rabies occurred during six months of follow-up.[17]

Similarly, another open-label, postmarketing study conducted at the anti-rabies clinic in the southern part of India, where PEP was provided to all the study participants as per the national guidelines, showed that a total of 19 (6.2%) ADRs were reported. All the ADRs were local reactions, namely pain (2.6%), erythema (1.4%), tenderness (1%), induration (0.6%), and swelling (0.6%). All reported ADRs were mild (Grade 1 severity) and resolved completely with symptomatic treatment.[18]

In another study, the PEP was provided using the human monoclonal antibody with a complete course of anti-rabies vaccination among 199 subjects, showing that all the ADRs that were reported were found to be mild, with no serious AE reported during the study period.[19]

In our study, all the subjects recovered completely and were alive at the end of the study period of 6 months after receiving PEP, proving the clinical efficacy of PEP. The clinical efficacy of PEP was consistent with the results of other studies. A study from Bangalore, India, with 717 subjects having category III animal exposures showed that all the study subjects recovered completely and were alive at the end of the study period of 6 months after receiving PEP, proving the clinical efficacy of PEP.[20]

Our study was limited by logistical issues that prevented the follow-up of the biting animals to ascertain if they were rabid. Likewise, the Rabies Virus Neutralizing Antibody (RVNA) analysis for the immunogenicity of the anti-rabies vaccine could not be done due to the costs involved. However, as the maximum incubation period of rabies is 6 months, the survival status of all the study subjects beyond 6 months was indicative of the clinical efficacy of the PEP administered.

In conclusion, this study provides robust evidence of the safety and clinical efficacy of PEP among the elderly with category III animal exposures and supports its continued usage to prevent rabies in this vulnerable group.

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