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Original Article

Safety and Clinical Effectiveness of Rabies Post-Exposure Prophylaxis Following Animal Bites

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ABSTRACT

Introduction: Rabies remains a fatal but preventable zoonotic disease, particularly in high-burden countries such as India. Effective post-exposure prophylaxis comprises immediate wound washing, anti-rabies vaccination, and passive immunization for Category III exposures. Although modern biologicals are generally safe and effective, real-world evaluation remains essential. This study assessed victim characteristics, prophylaxis practices, adverse reactions, treatment adherence, and clinical outcomes among patients attending an Anti-Rabies Clinic.

Material and Methods: This prospective observational study was conducted at the Anti-Rabies Clinic, Kempegowda Institute of Medical Sciences Hospital, Bengaluru, among 312 consecutive Category III animal bite victims. Sociodemographic, clinical, and post-exposure prophylaxis (PEP) details were recorded. Participants received standard WHO-recommended PEP and were monitored for adverse reactions until Day 28 and clinical outcomes for six months. Data were analysed descriptively using IBM SPSS Statistics version 27.0, with categorical variables expressed as frequencies and percentages.

Results: Among 312 Category III animal bite victims, 44.7% were aged 18–59 years and 68.9% were males. Dogs accounted for 93.6% of bites, predominantly stray dogs (70.5%). All participants received complete post-exposure prophylaxis, with Rabivax-S (76.9%) and rabies monoclonal antibody (76.6%) being most commonly used. Mild local and systemic adverse reactions were observed, pain (18.9%) being the commonest. All participants completed treatment and six-month follow-up, with no suspected rabies cases or rabies-related deaths, confirming the safety and clinical effectiveness of rabies post-exposure prophylaxis.

Conclusion: The study demonstrated that complete rabies post-exposure prophylaxis, including wound care, vaccination and passive immunization, was safe, well tolerated and clinically effective. All participants completed treatment and follow-up, with only mild adverse reactions and no suspected rabies cases or deaths, confirming effective rabies prevention following bites.

Keywords*: Post-Exposure Prophylaxis, Rabies Vaccines, Animal Bites, Adverse Reactions, Treatment Outcome.*

INTRODUCTION

Rabies is an acute viral zoonotic disease that is almost universally fatal once clinical manifestations appear; however, it is entirely preventable when appropriate post-exposure prophylaxis (PEP) is initiated promptly following exposure [1,2]. Rabies continues to pose a significant public health challenge in many low- and middle-income countries, particularly across Asia and Africa, with India accounting for a substantial proportion of the global burden of human rabies [1,3]. Dog bites are responsible for nearly all human rabies exposures, making canine-mediated transmission the predominant source of infection worldwide [1]. Despite sustained national rabies control efforts and improved availability of modern cell culture vaccines and passive immunization products, millions of individuals exposed to animal bites require rabies PEP each year, emphasizing the ongoing need for effective preventive strategies [1,2].

Rabies post-exposure prophylaxis comprises immediate and meticulous wound cleansing, administration of anti-rabies vaccine, and passive immunization with rabies immunoglobulin (RIG) or rabies monoclonal antibody (RMAb) for individuals sustaining Category III exposures, in accordance with World Health Organization recommendations [1,2]. Prompt and appropriate administration of these interventions effectively prevents rabies by inhibiting viral progression before involvement of the central nervous system [1]. Modern cell culture rabies vaccines and passive immunization products have consistently demonstrated excellent safety profiles, with adverse events being predominantly mild, transient, and self-limiting. The most frequently reported reactions include pain, erythema, or swelling at the injection site, accompanied occasionally by mild systemic symptoms such as fever, headache, or malaise [2,4].

Although the efficacy of rabies PEP under recommended protocols has been conclusively established, there remains a need for real-world evidence regarding its implementation, safety, and clinical outcomes in routine healthcare practice [2,4]. Information on the sociodemographic characteristics of animal bite victims, patterns of PEP administration, adverse events following immunization, and treatment outcomes is essential for evaluating adherence to standard recommendations and strengthening pharmacovigilance activities.[4] Such evidence is particularly valuable in countries with a high rabies burden, where large numbers of animal bite victims receive PEP annually [3]. Therefore, the present study was undertaken to describe the sociodemographic profile and characteristics of animal bite victims, document the pattern of rabies post-exposure prophylaxis administered, and evaluate the safety and clinical effectiveness of rabies post-exposure prophylaxis among animal bite victims attending an Anti-Rabies Clinic.

MATERIALS AND METHODS

This prospective observational study was conducted over three months, at the Anti-Rabies Clinic of the Preventive Medicine Unit, Kempegowda Institute of Medical Sciences Hospital and Research Centre, Bengaluru. All consecutive animal bite victims attending the clinic during the study period were screened for eligibility. A total of 312 participants who fulfilled the eligibility criteria and provided written informed consent were enrolled. Approval from the Institutional Ethics Committee was obtained before commencement of the study. Patients presenting with Category III animal exposures and requiring complete rabies post-exposure prophylaxis according to the institutional protocol were included. Individuals who declined consent, did not initiate post-exposure prophylaxis, or had incomplete treatment or follow-up records were excluded.

After obtaining informed consent, information regarding sociodemographic characteristics, the biting animal, site and type of wound, and first-aid measures undertaken before hospital presentation was recorded using a structured case record form. Details of the post-exposure prophylaxis administered were also documented. All participants received standard rabies post-exposure prophylaxis in accordance with the prevailing national and World Health Organization recommendations. Management included immediate and thorough wound washing with soap and running water, administration of anti-rabies vaccine through the intramuscular route, and passive immunization using equine rabies immunoglobulin, human rabies immunoglobulin, or rabies monoclonal antibody, as clinically indicated. Passive immunization was infiltrated into and around the wounds according to the recommended technique. Additional treatment, including tetanus prophylaxis, antibiotics, analgesics, and wound dressing, was provided whenever required.

Participants were prospectively monitored for local and systemic adverse reactions throughout the vaccination schedule up to Day 28. Adverse reactions reported or observed during follow-up visits were documented and managed according to standard clinical practice. The participants were subsequently followed for six months through scheduled telephonic interviews and, when required, home visits. Clinical effectiveness was assessed based on survival and the absence of clinical features suggestive of rabies during the follow-up period.

Categorical variables were summarized using frequencies and percentages. As the study was descriptive in nature and did not involve comparison between treatment groups, no inferential statistical tests were applied. The sociodemographic characteristics, details of animal exposure, pattern of rabies post-exposure prophylaxis, adverse reactions, and six-month clinical outcomes were analysed descriptively. Statistical analysis was performed using IBM SPSS Statistics for Windows, version 27.0 (IBM Corp., Armonk, NY, USA).

RESULTS

Table 1: Sociodemographic characteristics of the study participants (N = 312)

Characteristics		**Frequency (n)**	**Percentage (%)**
Age group	<18 years	96	30.7%
	18 to 59 years	139	44.7%
	≥60 years	77	24.6%
Gender	Male	215	68.9%
	Female	97	31.1%
Educational status	Illiterate	17	5.4%
	Primary school	58	18.6%

	Middle school	47	15.1%
	High school	35	11.2%
	Pre-University Course	72	23.1%
	Graduate/Postgraduate	83	26.6%
Socioeconomic status (Modified BG Prasad)	Upper	28	9.0%
	Upper middle	83	26.6%
	Lower middle	82	26.3%
	Upper lower	64	20.5%
	Lower	55	17.6%

Among the 312 participants, 139 (44.7%) were aged 18–59 years, followed by 96 (30.7%) aged below 18 years and 77 (24.6%) aged 60 years or older. Males constituted the majority, accounting for 215 (68.9%) participants. Regarding education, 83 (26.6%) were graduates or postgraduates and 72 (23.1%) had completed pre-university education. Most participants belonged to the upper-middle 83 (26.6%) or lower-middle 82 (26.3%) socioeconomic classes. (Table 1)

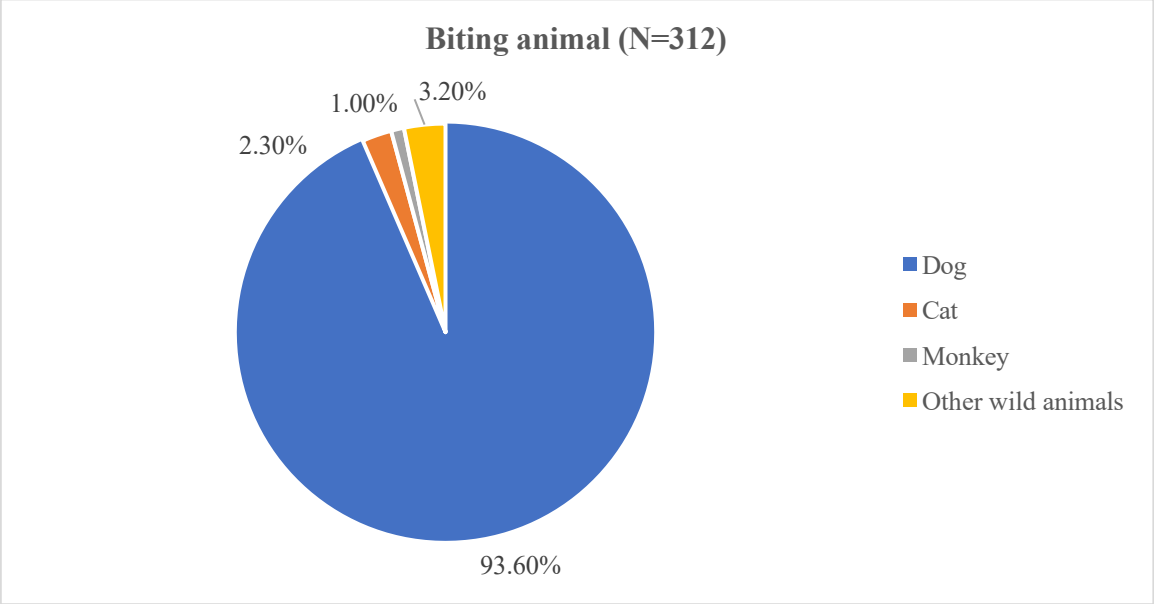

Figure 1: Distribution of study participants according to the biting animal

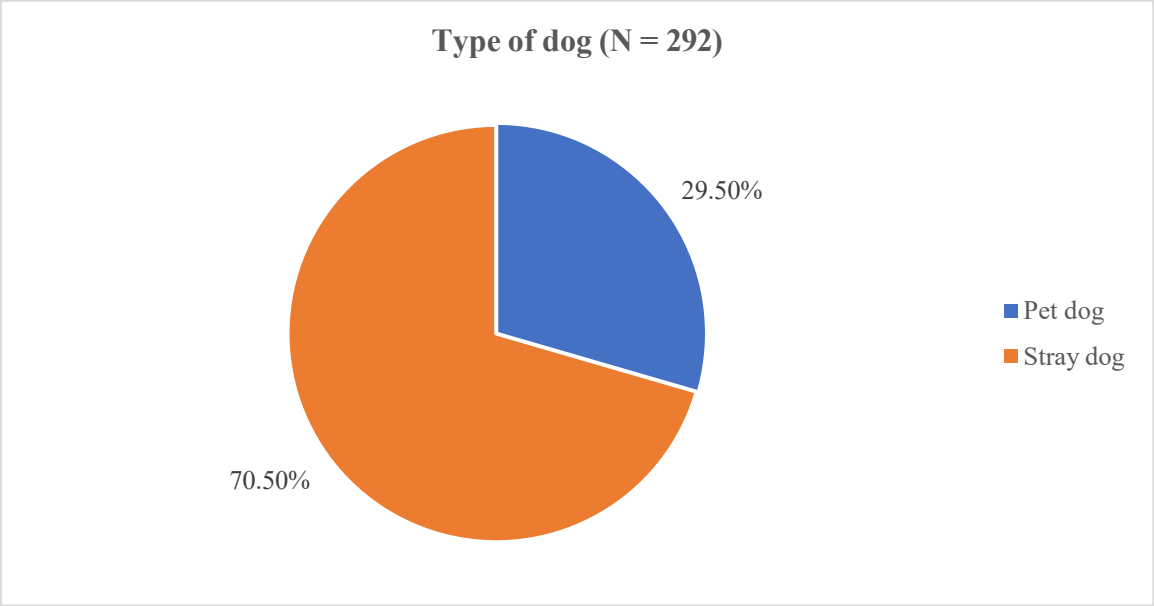

Figure 2: Distribution of study participants according to the type of dog

Dogs were responsible for the majority of animal exposures, accounting for 292 (93.6%) cases. Other exposures included wild animals in 10 (3.2%), cats in 7 (2.3%), and monkeys in 3 (1.0%) participants. Among the 292 dog-bite cases, 206 (70.5%) involved stray dogs, while 86 (29.5%) were caused by pet dogs. (Figure 1 & 2)

Table 2: Distribution of study participants according to the site and type of bite wound (N = 312)

Characteristics		Frequency (n)	Percentage (%)
Site of bite*	Upper limb	118	37.8%
	Lower limb	132	42.3%
	Other sites†	82	9.3%
Type of wound	Abrasion	143	45.8%
	Laceration	116	37.2%
	Puncture wound	53	17.0%

*Multiple responses were possible for the site of bite; therefore, percentages may exceed 100%.
†Other sites included the head and neck, trunk, and genital region.

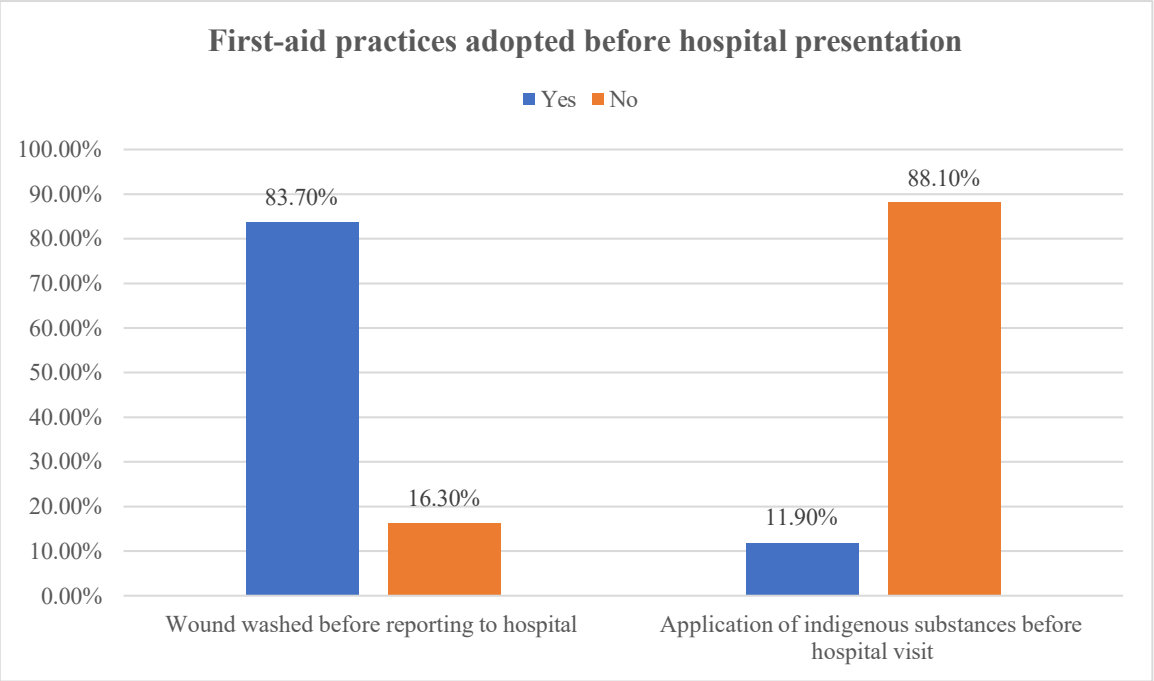

Figure 3: First-aid practices adopted before hospital presentation among the study participants (N = 312)

The lower limb was the most commonly affected site, reported in 132 (42.3%) participants, followed by the upper limb in 118 (37.8%). Other sites, including the head and neck, trunk, and genital region, were involved in 82 (26.3%) participants. Abrasions were the most frequent wound type, observed in 143 (45.8%) participants, followed by lacerations in 116 (37.2%) and puncture wounds in 53 (17.0%). (Table 2)

Table 3: Details of rabies post-exposure administered among the study participants (N = 312)

Post-exposure prophylaxis component		Frequency (n)	Percentage (%)
Wound management at the anti-rabies clinic*	Wound washing with soap and running water	312	100.0%
	Wound irrigation	312	100.0%
	Wound dressing	64	20.5%
Anti-rabies vaccination	Vaccine administered by intramuscular route	312	100.0%
Brand of anti-rabies vaccine administered	Rabivax-S	240	76.9%
	Abhayrab	25	8.0%
	Vaxirab-N	11	3.5%
	Brand not documented	36	11.5%
Passive immunization administered	Rabies monoclonal antibody	239	76.6%
	Equine rabies immunoglobulin	69	22.1%
	Human rabies immunoglobulin	4	1.3%

Site of passive immunization administration	Local infiltration into and around the wound only	292	93.6%
	Local infiltration with additional systemic administration	20	6.4%
Additional treatment provided*	Antibiotics	240	76.9%
	Tetanus prophylaxis	230	73.7%
	Analgesics	130	41.7%
	Wound dressing	64	20.5%

*Multiple additional treatments could be provided to the same participant; therefore, the percentages may exceed 100%. Rabies monoclonal antibody - Rabishield; Equine rabies immunoglobulin - Equirab; Human rabies immunoglobulin - Berirab-P

Before reporting to the hospital, 261 (83.7%) participants had washed the wound, whereas 51 (16.3%) had not undertaken wound washing. Indigenous substances had been applied to the wound by 37 (11.9%) participants, while 275 (88.1%) reported no such application before seeking medical care. (Figure 3)

All participants received wound washing, wound irrigation, and intramuscular anti-rabies vaccination. Rabivax-S was the most commonly administered vaccine brand, used in 240 (76.9%) participants. Rabies monoclonal antibody was the predominant passive immunization product, administered to 239 (76.6%), and local wound infiltration alone was performed in 292 (93.6%). Antibiotics and tetanus prophylaxis were provided to 240 (76.9%) and 230 (73.7%) participants, respectively. (Table 3)

Table 4: Distribution of local and systemic adverse reactions following rabies post-exposure prophylaxis (N = 312)

Type of adverse reaction*		**Frequency (n)**	**Percentage (%)**
Local reactions	Pain at the administration/infiltration site	59	18.9%
	Erythema	51	16.3%
	Itching	41	13.1%
	Localized swelling	21	6.7%
Systemic reactions	Headache	37	11.9%
	Myalgia/body ache	37	11.9%
	Fever	31	9.9%
	Malaise	25	8.0%
	Nausea	15	4.8%

*Multiple adverse reactions could occur in the same participant; therefore, the percentages may exceed 100%.

Pain at the administration or infiltration site was the most frequently reported local reaction, occurring in 59 (18.9%) participants, followed by erythema in 51 (16.3%) and itching in 41 (13.1%). Among systemic reactions, headache and myalgia/body ache were each reported in 37 (11.9%) participants. Fever occurred in 31 (9.9%), malaise in 25 (8.0%), and nausea in 15 (4.8%) participants. (Table 4)

Table 5: Six-month clinical outcomes following rabies post-exposure prophylaxis among the study participants (N = 312)

Clinical outcome	**Frequency (n)**	**Percentage (%)**
Completed prescribed post-exposure prophylaxis	312	100.0%
Completed follow-up up to Day 28 for adverse reactions	312	100.0%
Available for clinical follow-up at 6 months	312	100.0%
Remained healthy without clinical features s/o rabies	312	100.0%
Developed clinically suspected rabies	0	0.0%
Rabies-related mortality	0	0.0%
All-cause mortality during follow-up	0	0.0%

All 312 (100.0%) participants completed the prescribed post-exposure prophylaxis, Day 28 safety follow-up, and six-month clinical follow-up. At six months, every participant remained healthy without clinical features suggestive of rabies. No participant developed clinically suspected rabies, and no rabies-related or all-cause mortality was recorded during the follow-up period. (Table 5)

DISCUSSION

Despite the established effectiveness of rabies post-exposure prophylaxis (PEP), real-world evidence regarding its safety, implementation, and clinical outcomes remains essential, particularly in high-burden settings. This prospective observational study was conducted for 3 months, at the Anti-Rabies Clinic, Kempegowda Institute of Medical Sciences Hospital and Research Centre, Bengaluru, after ethics approval. A total of 312 consecutive Category III animal bite victims who provided written informed consent were enrolled; those who declined consent, did not initiate PEP, or had incomplete treatment or follow-up records were excluded. Sociodemographic details, animal exposure characteristics, wound profile, first-aid practices, and PEP received were recorded using a structured case record form. Participants received standard wound care, intramuscular anti-rabies vaccination, and indicated passive immunization with rabies immunoglobulin or monoclonal antibody. Additional treatment was provided as required. Adverse reactions were monitored until Day 28, and clinical effectiveness was assessed over six months through survival and absence of suspected rabies.

Adults aged 18–59 years constituted the largest proportion of participants in the present study (44.7%; 139/312), followed by those aged <18 years (30.7%; 96/312) and ≥60 years (24.6%; 77/312). Comparable adult predominance was reported by Haradanhalli RS et al. (2016), where 70.5% were aged 14–65 years, and Hens M et al. (2024), who observed 50.7% in the 15–45-year age group [5,6]. In contrast, Fotedar N et al. (2025) exclusively evaluated children (mean age: 9.4 years), while Huang S et al. (2019) reported a single pediatric case, indicating that anti-rabies clinics cater to all age groups, although children remain particularly vulnerable [7,8]. A marked male predominance was observed (68.9% males vs. 31.1% females), consistent with Fotedar N et al. (70.9% males), Haradanhalli RS et al. (72.6%), and Hens M et al. (70.3%), reflecting greater male involvement in outdoor activities and occupational exposure [7,5,6].

Educational attainment was relatively high, with graduates/postgraduates comprising 26.6% and illiterates only 5.4%. Hens M et al. reported formal education in 67.4% but illiteracy/informal education in 32.6%, whereas Fotedar N et al. described 43.0% of participants as school-going children [6,7]. Socioeconomically, the upper-middle (26.6%) and lower-middle (26.3%) classes predominated. Fotedar N et al. similarly reported a predominantly middle-class cohort (67.8%), whereas Nadal D et al. (2023) and Hens M et al. highlighted that the greatest rabies burden and mortality occur among socioeconomically disadvantaged rural populations with limited healthcare access [7,9,6].

Dogs were the predominant source of exposure in the present study, accounting for 93.6% (292/312) of cases, followed by wild animals (3.2%), cats (2.3%), and monkeys (1.0%). Similar findings were reported by Fotedar N et al. (2025), with 96.6% dog bites, and Haradanhalli RS et al. (2016), with 79.2% dog bites [7,5]. Hens M et al. (2024) further highlighted that domestic dogs are responsible for approximately 99.0% of human rabies infections globally [6]. Among dog-bite cases, stray dogs accounted for 70.5% of exposures compared with 29.5% from pet dogs, a higher proportion than reported by Fotedar N et al. (48.8% stray) and Hens M et al. (56.5% stray), emphasizing the importance of controlling both stray and inadequately managed owned dogs [7,6].

The lower limb was the most commonly affected site (42.3%), followed by the upper limb (37.8%). Comparable distributions were observed by Fotedar N et al. (42.2% and 35.3%, respectively) and Haradanhalli RS et al. (44.2% and 42.1%), while Hens M et al. reported leg involvement in 50.7% [7,5,6]. Lower-limb predominance likely reflects easier anatomical accessibility, whereas bites involving the head, neck, and hands require urgent management because of their higher risk. Abrasions were the commonest wound type (45.8%), followed by lacerations (37.2%) and puncture wounds (17.0%). Fotedar N et al. reported a similar distribution with abrasions (44.6%), whereas Haradanhalli RS et al. found lacerations (47.4%) to be most frequent [7,5]. Hens M et al. observed that 89.1% of fatal rabies cases had Category III wounds, and Nadal D et al. (2023) emphasized that such wounds require immediate rabies immunoglobulin and post-exposure prophylaxis, highlighting the greater clinical significance of deep lacerations and puncture wounds [6,9].

In the present study, 83.7% (261/312) of participants had washed their wounds before reaching the hospital, while 16.3% (51/312) had not. Haradanhalli RS et al. (2016) reported a considerably lower wound-washing rate of 57.9% (55/95), whereas Hens M et al. (2024) observed that many rural patients neglected wound cleansing and instead relied on traditional remedies [5,6]. Nadal D et al. (2023) emphasized that immediate washing with soap and running water for approximately 15 minutes is the most effective first-aid measure to reduce viral inoculum. Indigenous substances were applied by 11.9% (37/312) of participants in the present study[9]. Nadal D et al. discouraged such practices because of contamination risks, while Hens M et al. reported widespread use of traditional plant remedies in rural Ethiopia, often delaying timely post-exposure prophylaxis (PEP) [9,6]. At the anti-rabies clinic, 100% (312/312) of participants underwent professional wound washing and irrigation, while 20.5% (64/312) required wound dressing. Nadal D et al. recommended thorough wound cleansing with antiseptics and avoidance of primary suturing whenever possible, whereas Hens M et al. highlighted inadequate wound-care facilities in resource-limited rural settings [9,6].

All participants (100%; 312/312) received anti-rabies vaccination using the intramuscular Essen regimen. Rabivax-S was administered to 76.9% (240/312), Abhayrab to 8.0% (25/312), and Vaxirab-N to 3.5% (11/312). Similarly, Fotedar N et al. (2025) used the Essen regimen, administering purified Vero cell vaccine to 65.1% (188/289) and purified chick embryo cell vaccine to 34.9% (101/289), while Haradanhalli RS et al. (2016) predominantly used purified chick embryo cell vaccine (81.1%; 77/95) [7,5]. Huang S et al. (2019) reported successful substitution of purified Vero cell vaccine after anaphylaxis to human diploid cell vaccine [8]. In contrast, Nadal D et al. advocated the WHO one-week intradermal regimen to improve cost-effectiveness, whereas Hens M et al. described continued use of obsolete nerve-tissue vaccines in rural Ethiopia [9,6]. For passive immunization, rabies monoclonal antibodies were used in 76.6% (239/312), equine rabies immunoglobulin in 22.1% (69/312), and human rabies immunoglobulin in 1.3% (4/312). Comparable findings were reported by Fotedar N et al., with monoclonal antibodies in 67.1% (194/289) and equine rabies immunoglobulin in 10.0% (29/289) [7]. Haradanhalli RS et al. reported exclusive use of equine (93.7%) and human (6.3%) rabies immunoglobulins, reflecting practice before monoclonal antibodies became widely available [5]. Hens M et al. noted complete unavailability of passive immunization products in rural Ethiopia, while Nadal D et al. endorsed monoclonal antibodies as safe and scalable alternatives [6,9]. Local infiltration into and around the wound alone was performed in 93.6% (292/312), whereas 6.4% (20/312) required additional systemic administration. Similar proportions were reported by Fotedar N et al. (92.7% local infiltration alone) and Haradanhalli RS et al. (86.2%) [7,5]. Nadal D et al. emphasized that adequate local wound infiltration is the cornerstone of passive immunization, with minimal benefit from unnecessary systemic administration [9].

Local adverse reactions following post-exposure prophylaxis (PEP) were generally mild and self-limiting in the present study. Pain at the injection or infiltration site was the most common local reaction, occurring in 18.9% (59/312) of participants, followed by erythema (16.3%; 51/312), itching (13.1%; 41/312), and localized swelling (6.7%; 21/312). Similar findings were reported by Fotedar N et al. (2025), who observed pain in 13.1% (38/289), erythema in 7.6% (22/289), itching in 6.2% (18/289), and swelling in 5.9% (17/289) [7]. Haradanhalli RS et al. (2016) reported a lower overall incidence of local adverse events (7.5%), including pain (2.5%), itching (2.3%), erythema (2.1%), and induration (0.6%) [5]. Huang S et al. (2019) described a rare severe injection-site swelling following human diploid cell vaccine, suggesting that serious local reactions are uncommon with modern vaccines [8].

Systemic adverse events were also infrequent and transient. Headache and myalgia/body ache each occurred in 11.9% (37/312), followed by fever (9.9%; 31/312), malaise (8.0%; 25/312), and nausea (4.8%; 15/312). Fotedar N et al. reported lower frequencies of body ache (5.2%), fever (3.5%), and malaise (1.7%), while Haradanhalli RS et al. documented no systemic adverse reactions [7,5]. Huang S et al. reported an isolated case of acute anaphylaxis in a two-year-old child, whereas Hens M et al. (2024) highlighted that obsolete nerve-tissue vaccines are associated with frequent systemic and neurological adverse effects [8,6]. These findings support the favorable safety profile of modern cell-culture vaccines.

All participants (100%; 312/312) completed the prescribed PEP schedule and Day-28 follow-up. At six months, 100% remained healthy, with 0% clinically suspected rabies, 0% rabies-related mortality, and 0% all-cause mortality. Comparable outcomes were reported by Fotedar N et al., with 100% survival among 289 children, and Haradanhalli RS et al., where all 95 participants remained healthy one year after PEP [7,5]. In contrast, Hens M et al. reported that only 65.2% (90/138) received post-exposure vaccination, resulting in 46 rabies deaths, largely due to delayed treatment and reliance on traditional remedies [6]. Their multivariable analysis demonstrated that PEP reduced the risk of rabies death by 94.2% (AOR=0.058; p=0.001), while each day of treatment delay increased mortality risk by 15% (AOR=1.15; p=0.002).

Supportive care in the present study was comprehensive, with antibiotics administered to 76.9% (240/312), tetanus prophylaxis to 73.7% (230/312), analgesics to 41.7% (130/312), and wound dressing to 20.5% (64/312). Nadal D et al. (2023) similarly recommended tetanus prophylaxis, antibiotics for contaminated wounds, meticulous wound care, and prompt passive immunization [9]. Overall, the present findings closely align with those of Fotedar N et al., Haradanhalli RS et al., and Nadal D et al., confirming that standardized wound management, modern cell-culture vaccines, and appropriate passive immunization are safe, well tolerated, and highly effective in preventing human rabies [7,5,9]. Differences compared with Hens M et al. primarily reflect disparities in healthcare access, vaccine availability, and delays in treatment in resource-limited settings [6].

CONCLUSION

The study demonstrated that complete rabies post-exposure prophylaxis, comprising appropriate wound care, anti-rabies vaccination and passive immunization, was safe, well tolerated and clinically effective among Category III animal bite victims. Adverse reactions were mild and predominantly local or transient systemic symptoms. All participants completed treatment and follow-up, and none developed suspected rabies or died during six months of observation. These findings support the timely and appropriate administration of complete post-exposure prophylaxis as an effective strategy for preventing rabies following animal bites.

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