ORIGINAL RESEARCH ARTICLE

Post-Exposure Rabies Vaccine Compliance and Reasons for Non-Adherence - A Mixed Method Study in Puducherry

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ABSTRACT

Background: Among the people who die annually of rabies worldwide, the majority either did not receive post-exposure prophylaxis (PEP), or received PEP after substantial delays or were administered PEP according to schedules that deviated from WHO recommendations. This study focuses on post-exposure rabies vaccine compliance and on the reasons for non-adherence.

Methods: A mixed-method study was done among people exposed to animal bite who visited a PHC during January to December 2022. The participant list was taken from the register maintained at PHC and the data was collected by semi-structured questionnaire followed by in-depth interview.

Results: The major cause for noncompliance with the ARV vaccination was failure to remember ARV schedule (52.4%), followed by lack of awareness of animal bite (19.6%) poor knowledge of ARV completion (16.2%), lack of time and access (9.4%) and choice of native treatment (2.4%). On multivariate analysis of the factors influencing rabies vaccine compliance, age, area of residence and socio-economic status were found to be statistically significant.

Conclusion: The study results highlight the importance of imparting health education to increase vaccine compliance to prevent rabies.

Keywords: Anti rabies vaccination, Compliance, non-adherence, Animal bite

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Introduction

Rabies, a vaccine-preventable yet fatal disease, continues to pose a significant public health problem. Worldwide, 59,000 fatalities occur annually due to dog-mediated rabies. India accounts for 36% of the world's rabies deaths, causing approximately 18,000-20,000 deaths every year. India, being a signatory to the World Health Organization's (WHO) initiative towards zero deaths from dog-mediated rabies by 2030, suffers from a high mortality rate.² Despite vaccine availability, a majority (80%) of human rabies deaths occurred can be attributed to either lack of Post Exposure Prophylaxis (PEP), delayed vaccination or incomplete course of PEP, deviated from WHO recommendations.^{3,4} WHO has introduced the cost-effective, shortened intradermal regimen for rabies PEP to reduce visits, and increase availability and vaccine compliance.⁵ The current study aims to investigate compliance with anti-rabies vaccination (ARV) among patients exposed to animal bites and seeking treatment at a primary health centre in rural Puducherry. By employing a mixed-method approach, the study focuses on the factors influencing adherence to the ARV regimen as well as a comprehensive deeper understanding of the reasons behind the non-compliance. As with increasing dog menace, the review of the literature showed a significant gap in the lack of information on compliance with ARV from Puducherry. Hence this necessitates the need for understanding the situation in Puducherry.

The study was conducted to assess the compliance to PEP among patients vaccinated for animal bites at a rural primary health centre in Puducherry and also to explore the reasons for non-compliance with Anti Rabies Vaccination.

METHODOLOGY

The study was conducted in a rural primary health centre at Puducherry, using an explanatory sequential mixed methods study design in which the quantitative phase cross sectional survey followed by the qualitative phase (in-depth interviews). The study was carried out for a period of three months, from January 2023 to March 2023, after getting approval from the institutional ethics committee. (No: EC/06/2023, dated (17.4.2023) The study participants were patients who had been vaccinated for animal bites at the Primary Health Centre, based on the animal bite register in the previous year from January 2022 to December 2022.

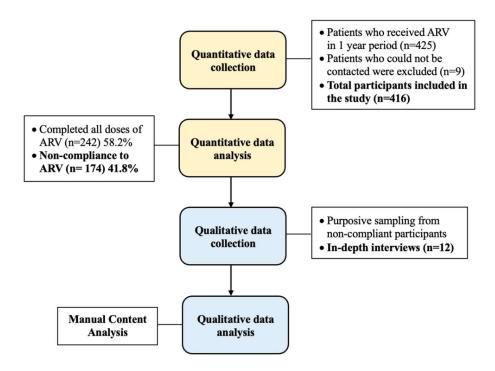


Figure 1: Visual diagram showing explanatory mixed methods study design

Phase 1: Quantitative Survey: In the quantitative phase, we conducted a cross-sectional survey among animal bite patients visited the PHC in the last one year, using a pre-designed, semi-structured questionnaire. After obtaining permission from the PHC medical officer, the list of eligible patients and their contact details was obtained from the animal bite register. During our study period, a total of 425 individuals were registered in animal bite register for

the ARV vaccine in the primary health centre. Among them, 9 participants were excluded from the study as they could not be contacted by phone even after three attempts at different times. The final sample size included in our study was 416 participants. All the participants were contacted over the phone and after obtaining informed oral consent, their demographic characteristics, details of animal bites were collected. Their compliance with PEP including the

ARV regimen were asked by phone and were cross checked with the details available in the animal bite register.

Operational definitions: Post-exposure prophylaxis consists of extensive washing with water and soap for at least 15 minutes and local treatment of the wound as soon as possible after a suspected exposure, with a course of rabies vaccine that meets WHO standards and administration of rabies immunoglobulin, if indicated based on wound category.¹

The WHO classification of wounds, based on the severity of exposure was utilized.⁶ The Category 1 wounds included touching or feeding animals, animal licks on intact skin, Category2 included nibbling of uncovered skin, minor scratches or abrasions without bleeding, and Category 3 covered single or multiple transdermal bites or scratches, contamination of mucous membrane or broken skin with saliva from animal licks, exposure due to direct contact with bats.

Under National Rabies Control Programme, the updated Thai Red cross regimen which involves injecting reconstituted vaccine on two sites with 0.1 ml per site intradermally over the deltoid region on days 0,3,7 and 28 is followed at the PHC.4 The patients who have taken all the doses of the on specified dates were considered to be compliant and those patients who missed one or more than one dose were considered to be non-compliant.

Statistical Analysis of Quantitative Data: The collected quantitative data were entered in Microsoft Excel 2016 and were analyzed using a Statistical Package for the Social Sciences for Windows (SPSS), version 28.0 Descriptive variables were expressed as frequency and percentages and the association between the variables was analyzed using the chisquare test. Bivariate and multivariate logistic regression was done to find out the statistically significant determinants. The 'p' value of less than 0.05 was considered statistically significant. A total of ten independent variables were included in the regression model. Compliance and noncompliance to ARV were taken as dependent variables. Age, gender, residence, educational qualification, socioeconomic status, type of animal, ownership, vaccination status, site of the bite, category of bite, and immediate action after bite were considered as independent variables. We have used the Enter method for multivariate analysis and included all the independent variables in the model, irrespective of their significance.

Phase 2: Qualitative interview: For the qualitative part, the patients who were non-compliant with the ARV regimen in the quantitative part were included in the study. The female principal investigator who had undergone training in qualitative research, conducted a one-to-one in-depth interview, each lasting for about 30 minutes. Purposive sampling was utilized to select the study participants and we achieved data saturation by the 12th interview with no additional new information. Informed consent was ob-

tained from the participants before each interview and the interviews were audio-recorded using mobile phones with their permission. We interviewed at the participant's convenient timings, using an interview guide, containing open-ended questions to explore the reasons for non-compliance of ARV with sufficient probes being added, based on the interview process. The investigator checked the validity of the participant's responses by de-briefing after each interview.

Qualitative data analysis: The verbatim of the participants were translated into English transcripts using the audio recordings. Manual content analysis of the transcripts was done. Descriptive codes were derived and similar codes merged into categories and developed into broad themes. The codes were crosschecked by the first two authors and verified by the fourth author to increase the validity of the study findings. Any discrepancies that arise were settled by mutual discussion.

RESULTS

The mean age of the participants was 33.6±19.49 years. Of the total 416 respondents, about 129 participants (31%) were in the age group of 41-59 years and the majority 262 were Males (63%). About 172 participants (41.3%) had completed their primary education and only 34 participants (8.2%) were illiterates. As per the modified BG Prasad scale, the majority of 182 participants (43.8%) belonged to the Middle class and 179 (43%) belonged to the upper middle class. (Table 1)

Table 1: Socio-demographic details of the study participants (N=416)

Variable	Participants (%)			
Gender				
Male	262(63)			
Female	154(37)			
Residence				
Rural	303(72.8)			
Semi urban	63(15.2)			
Urban	50(12.0)			
Age category				
Under 5 years	29(7.0)			
6-19 years	94(22.6)			
20-59 years	248(59.6)			
>60 years	45(10.8)			
Education				
Illiterate	34(8.2)			
Primary	172(41.3)			
Secondary	147(35.3)			
Graduate	63(15.2)			
Socioeconomic status*				
Class I	30(7.2)			
Class II	179(43.0)			
Class III	182(43.8)			
Class IV	25(6.0)			

^{*}As per Revised Modified BG Prasad Scale October 2023)7

Table 2: Baseline characteristics of participants on animal bite: (N=416)

Variable	Participants (%)			
	i ai deipants (70)			
Type of animal bite	2.45(22.2)			
Dog	345(82.9)			
Cat	71(17.1)			
Vaccination status of animal				
Vaccinated	99(23.8)			
Not vaccinated	112(26.9)			
Unknown	205(49.3)			
Site of bite				
Upper Limb	107(25.7)			
Lower Limb	309(74.3)			
Category of wound				
Category 1	55(13.2)			
Category 2	361(86.8)			
Immediate action				
Wound wash with soap & water	104(25.0)			
Wound wash with water	153(36.8)			
Did nothing	159(38.2)			
Number of ARV doses taken				
4 doses	242(58.2)			
3 doses	74(17.7)			
2 doses	64(15.4)			
1 dose	36(8.7)			

As seen in Table 2, the majority of 345 ARV recipients (82.9%) were exposed to dog bites, followed by cat bites (16.9%) in 70 patients. As per WHO wound classification, the majority of 361 animal bites (86.8%) were classified as category 2 exposure, necessitating PEP. About 104 participants (25%) reported that they had washed their wounds immediately with soap and water after animal bite whereas 159 participants (38.2%) did not clean the wound in PEP. Encouragingly, more than half of the participants (58.2%) were successfully compliant with four doses of ARV, 17.7% of patients managed to complete three doses, 15.4% finished two doses and 8.7% received only one dose of ARV. In multivariate analysis, among all the factors influencing rabies vaccine compliance, the factors namely age, area of residence, and socio-economic status were found to be statistically significant (p-value < 0.001). (Table 3)

In our study, the major reasons for noncompliance with the ARV vaccination were forgetfulness regarding the next dose followed by a lack of importance to complete the full course of ARV for other types of animal bites.

Table 3: Bivariate and multivariate Analysis of Factors Influencing Rabies Vaccine Compliance

Variables	Compliance to ARV		uOR (95%CI)	aOR (95%CI)	P value
	Yes (%) (n=242)	No (%) (n=174)	_ ` `		
Age*					
0-5 years	24 (9.9)	5 (2.9)	1	1	
6-19 years	78(32.2)	16 (9.2)	1.01 (0.38-3.06) p	0.82 (0.24-2.84)	0.755
20-59 years	133(55)	115(66.1)	0.24 (0.09-0.65)*	0.19 (0.06-0.60)	0.005*
More than 60 years	7(2.9)	38(21.8)	0.04 (0.01-0.14) *	0.037* (0.01-0.14)	0.000*
Gender					
Male	157(64.88)	105(60.34)	0.82 (0.55-1.23)	0.89 (0.55-1.45)	0.648
Female	85(35.12)	69(39.66)	1	1	
Educational Qualification					
Illiterate	14(5.79)	20(11.5)	1	1	
Primary	100(41.32)	72(41.4)	0.33 (0.14-0.77) *	0.50 (0.16-1.59)	0.238
Secondary	85(35.12)	62(35.6)	0.65 (0.35-1.19)	0.65 (0.32-1.32)	0.229
Graduate	43(17.77)	20(11.5)	0.64 (0.34-1.19)	0.73 (0.36-1.45)	0.368
Socio Economic Status *					
Class I	11(4.6)	19(10.92)	1	1	
Class II	104(42.9)	75(43.10)	2.40 (1.08-5.33) *	3.06 (1.23-7.66)	0.017^{*}
Class III	114(47.1)	68(39.08)	2.90 (1.30-6.45) *	3.83*(1.53-9.58)	0.004*
Class IV	13(5.4)	12(6.9)	1.87 (0.64-5.51)	2.52 (0.74-8.60)	0.139
Type Of Animal					
Dog	209(86.36)	136(78.16)	1.77 (1.06-2.96) *	1.79 (0.87-3.69)	0.114
Cat	33(13.64)	38(21.84)	1	1	
Ownership Of Animal					
Pet	130(53.72)	81(46.6)	1.33 (0.90-1.97)	0.92 (0.08-10.98)	0.949
Stray	112(46.28)	93(53.4)	1	1	
Vaccination Status of Animal					
Vaccinated	67(27.7)	32(18.4)	1		
Not vaccinated	66(27.3)	50(28.7)	0.63 (0.36-1.10)	0.94 (0.46-1.94)	0.874
Not known	109(45)	92(52.9)	0.57 (0.34-0.94) *	0.93 (0.08-10.87)	0.955
Category of Bite					
Category 1	32(13.2)	23(13.2)	1	1	
Category 2	210(86.8)	151(86.8)	1.0 (0.56-1.78)	0.96 (0.49-1.87)	0.892
Site Of Bite					
Upper Limb	62(25.6)	45(25.9)	1	1	
Lower Limb	180(74.4)	129(74.1)	0.98 (0.63-1.54)	1.18 (0.70-2.01)	0.538
Residence*	• •	. ,	•		
Rural	158(65.3)	145(83.33)	1	1	
Urban	84 (34.7)	29(16.7)	0.38 (0.23-0.61) *	2.42* (1.41-4.18)	0.001^{*}

^{*}p value< 0.05 was considered as statistically significant; uOR – Unadjusted Odds Ratio; aOR - Adjusted OR; CI – Confidence Interval

Table 4: Perceived reasons for the non-compliance of ARV by the respondents: (n=12)

Theme	Categories	Codes
Challenges for ARV	Failure to remember the ARV schedule	 Forgot to take next dose
Course Completion		 Missed dose due to lack of reminders
		 Lost OP card and forgot the due date
	Lack of awareness of animal bites	 Perception that ARV is only for dog bite
		 ARV not considered as necessary
		 Belief that cat bite pose no risk
	Poor knowledge of ARV completion	 Perception that 1 dose is adequate for protection
		 Misconception that small bite doesn't need full
		vaccination
		 Belief that full vaccination was not necessary for
		certain animal bites
	Lack of time and access to continue ARV	masmy to community that to marriage
		 Discontinued due to travel constraints
		 Limited access due to vaccination timing of
		healthcare facilities
	Choice of native treatment	Preferring native treatment
		 Perception that home remedies are more effective
		 Family members or relatives' advice
		 Influence of cultural beliefs on treatment decision

The participants perceived that continued vaccination was unnecessary after receiving one or a few doses including lack of time and accessibility due to school or work commitments. Other reasons included returning to their native place and opting for native treatment. Manual content analysis of the transcripts were done in the form of themes, categories and codes (Table 4). The results of the qualitative study are described based on the following themes.

Failure to remember the ARV schedule: The most common reason stated by the participants for not completing all the doses of ARV was that they forgot the next dose as per the schedule. They were provided with dates of their next visits on a slip of paper and some missed their doses as they did not remember those dates. This was stated by 52.4% of the participants. The following statements in italics indicate the direct quotes of the participants.

"When I went to a shop, a stray dog which was lying near the shop bit me. Then I went to PHC. They gave me an injection for the dog bite and told me to come back after 3 days. I went again and took the second injection, but after that, I forgot to go to the hospital. Then I remembered it only after some 20 days So I did not go again."

"I came late night from my relative's house. Three dogs chased my bike. Suddenly one dog jumped and bit me. I went to the PHC near my house. They gave me a TT injection and asked me to come on the next day. I went the next day, and they gave me a dog bite injection and told me to return after 3 days. I went correctly after 3 days, but later I forgot to go, and when I remembered it was very late, so I left"

Lack of awareness of animal bites: Some of the participants (19.6%) felt that ARV injection has to be taken only for dog bites and need not be taken for other animal bites. They perceived that only TT injection is necessary for any other animal bites.

"My cat which is 8 months old bit me. My cat will not

go anywhere, it will remain in the house only and it's healthy. So, at first, I didn't think I needed an injection. But then, my neighbour advised me to take the injection. So, I went to nearby PHC where they gave me TT and one dog bite injection. Then I forgot to go".

"We have a pet cat at home. It bit me when I was playing with it. I got scratches. So, I went to PHC to put TT. There they advised me to take dog-bite injections. I was confused about why to take an injection for a dog bite when I had a cat bite. They told me that it was the same. Then they gave me dates for injections. I took 2 doses."

Poor knowledge of ARV completion: The perception that the vaccine was no longer needed was the next most common reason for the non-compliance with ARV. This was found to be in about 16.2 % of the participants. Some of the quotations include:

"A stray dog near my house bit me. My neighbour told me that I should take TT. So, my son took me to the hospital. There the nurse told me that along with TT, I should take another injection for a dog bite. She gave me another injection and told me that I had to take a few more injections for dog bites on specified dates. But I did not go again as I thought it was not needed.

"I went to hospital for a dog bite. They gave me an injection for a dog bite and told me to come for the remaining injections. But the bite area was very small. So, I thought many injections might not be needed and I did not take my other injections".

"Usually monkeys roam around our house. One day a monkey came to our house and when I tried to chase it out, it bit me. Then I went to a nearby hospital. They gave me a dog bite injection and asked me to come for other doses as per the dates. But I was healthy only. So, I thought it was not needed for me and I didn't go."

Lack of time and access to continue ARV: Many participants stated that they could not take their vaccination due to lack of time and went back to the

workplace or hostel. This was stated by 9.4% of the participants. Some quotations include:

"When I went to my home for my holidays, I had a dog bite. I took TT and one dose of a dog bite injection. Then I went back to my hostel after my holidays. So, I could not continue the rest of my injections."

"I came for the weekend to my home. A stray dog near my house bit me. I went to a nearby hospital and took an injection. But I work at Karaikal so I come home only on weekends. So, I could not continue my injections on the specific dates".

Choice of native treatment: Apart from the above reasons, some participants gave other reasons like they started taking native treatment. It was reported by 2.4 % of the participants.

"I took 2 doses of injections at PHC. Then, one of my relatives told me about home remedies for dog bites. He told me to drink 'kashayam' for 48 days, eat food without salt and oil, and avoid non-vegetarian food. So, I did not take other injections"

DISCUSSION

The study was done among those people who had an exposure and have approached one of the Primary Health Centre in Puducherry. The study showed a 42.8% non-compliance rate to completion of ARV. The results of our study are similar to a study conducted by Sundaram et al at Coimbatore where the non-compliance to the ARV was 40%.4 Our study found that a total of 58.2% were compliant with the full course of ARV. Many studies have also reported the same finding.^{8,9} Remaining have skipped the schedule due to the lack of awareness. This was similar to a study conducted by Wadde et al at Bangalore, in which the factors related to noncompliance were found to be forgetfulness, cost incurred, distance from the hospital, and loss of wage cost incurred, distance from the hospital, and loss of wages3. In our study the other reason for non-compliance was found to be that the participants went for work as they would not get their pay if they come to the hospital for taking the vaccination.

A study conducted in Bangalore by Domple et al found that 77.0% of people had completed the intradermal rabies vaccination where the main obstacles found were missing pay, misplacing dates, expenses, and the hospital's distance. In another study conducted at Karnataka by Anadhraj R et al found that 50.3% of participants had taken all four doses in accordance with the Updated Thai Regimen. Transportation issues, wage loss, the inaccessibility of rabies biologicals in peripheral centers, participant negligence, and dates that were forgotten were identified as the reasons for non-compliance, which was similar to our study. In the sum of the property of the property

In our study, the most common bites were from dogs (82.3%). Many other studies have reported the same finding. 12-18 In our study it was found that the most

common site of bites were lower limb bites accounting for about 74.3 % of the bites as it is the most easily approachable part for an animal bite. These findings were similar to many studies conducted by Massodi et al (55.6%), Nimale et al (65%), Gujalwar et al (65%) and Basir MF et al (57.8%). 19-22 In our study the vaccination status of the animals is 49.3% as the majority of the animal bites were from stray dogs and stray cats.

In our study, we found that age, area of residence, and socio-economic status were found to be the statistically significant determinants influencing rabies vaccine compliance. This can be attributed to the fact that people residing in urban areas have easier access to healthcare facilities and those from the upper and upper middle classes tend to seek medical attention earlier. These findings were similar to the studies conducted by Sachdeva et al in Haryana.²³ Most of the participants did not know the importance of wound washing, as only 25% of the participants had washed their wounds with soap and water before the visit to the primary health centre. This is consistent with other research that found low levels of wound cleansing following exposure. The noncompliance of ARV is still high and the reasons found out were that majority of the participants forgot to continue the schedule. The importance of wound washing after the bite is not known by some of the participants.

According to the study conducted by Lungten et al, health education interventions have been proven effective in enhancing knowledge, perception, and dog bite safety behaviour among school children.²⁴ Provision of health education materials have improved the public awareness of rabies and the vaccination of their pet dogs.²⁵ Integration of text message reminders were also shown to increase the compliance to ARV.²⁶

The strength of the study is that it was a mixedmethod study, which enabled us to explore the underlying reasons for the incomplete vaccination course.

The main limitation of our study is that our sample included individuals who visited a single Primary Health Centre, and henceforth the findings may not be generalizable. Secondly, we could not assess compliance among patients with category III bites, as they have been referred to the ARV Clinic at the nearest government hospital due to the non-availability of Rabies Immunoglobulin at the Primary Health Centre.

CONCLUSION

Poor ARV vaccine compliance was observed as only half of the population had completed the full course of the ARV regimen. Failure to remember the ARV schedule, lack of awareness of the necessity of ARV for other animal bites, inadequate knowledge about the benefits of vaccine course completion, time constraints, and accessibility issues were the perceived

challenges for the non-adherence of ARV.

RECOMMENDATIONS

Health education materials on animal bites which is not given at the PHC can be given to all ARV beneficiaries to increase their knowledge and compliance with vaccination. A vaccine reminders system, such as SMS or phone calls, can be implemented to remind individuals about upcoming vaccination schedules. Digitalization of animal bite registers and follow-up of ARV recipients to complete the ARV schedules can be established. Healthcare workers are to be trained to communicate effectively the importance of rabies vaccination and address the concerns of animal bite patients. Misconceptions related to rabies vaccination should be identified and addressed. Pet vaccination campaigns at regular intervals to increase awareness and accessibility to pet vaccination. Availability of rabies immunoglobulin should be ensured at the Primary Health Centre to manage patients with category III bites at the Primary care level.

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