

ORIGINAL ARTICLE

Documentation of Anti-Rabies Vaccination Could Prevent Vaccine Wastage: A Cross-Sectional Study.

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Abstract:

Objectives: To study the sociodemographic profile of re-exposure cases of animal bite, to estimate the number of patients with the documents of previous anti-rabies vaccination, to find an association of loss of documentation of previous vaccination with sociodemographic factors and factors related to animal bite and lastly to calculate the vaccine wastage due to unavailability of documents.

Methods: Data was collected using pre-designed and pre-tested questionnaire from re-exposure cases of animal bites attending the anti-rabies clinic (ARC) of SCB Medical College and Hospital, Cuttack, Odisha from January till March 2019.

Results: We found 112 cases of re-exposure meeting our inclusion criteria. Males comprised 75.9%. Re-exposure cases attending ARC after two years of previous bite comprised 44.6%. Only 33.9% were found to have kept the documents of previous vaccination and this was highly significantly associated {OR-4.00[CI 1-66-9.62]} with the fact of having bitten by animal within a period of two years. We also found nearly Rs 46,000 is lost in terms of vaccine and immunoglobulin from just one ARC during a period of three months due to loss of documentation.

Conclusion: More than two-third of the re-exposure cases of animal bites were previously completely vaccinated. Majority of cases were male children, bitten by dog and belonged to Category III bite. Failure to preserve documents of previous anti-rabies vaccines and immunoglobulins has led to a large economic and biological burden. Hence, it has become the need of the hour to have a keen look on it and prevent both biological and economic loss.

Introduction:

Human rabies transmitted by animal bites comprise a major burden in terms of morbidity and mortality throughout the world. People get exposed to animal bites once or more in their lifetime. Infectious Rabies is the 10th most common cause of death in man.¹ It takes a toll of nearly 50,000 to 60,000 deaths worldwide and nearly 30000 to 40000 are from India.² Among those who get exposed, re-exposure cases of animal bites are one where the patient must have suffered at least one or sometimes many previous exposures for which the patient seeks treatment.³ These re-exposed cases who have previously received complete pre/post exposure vaccination are administered two doses of cell culture vaccine separated by 3 days.³ Re-exposure to rabies is common in endemic areas with

an estimated incidence of nearly 50%.⁴ Each year in India nearly 17.4 million people are bitten by animals, mostly dogs.⁵ Children under 15 years of age account for 50% of bite from suspected rabid animal.⁶ Estimates reveal nearly 40% of post exposure prophylaxis is given to children of Asia and Africa aged 5-14 years.⁷ Dog mediated rabies account for 3.7 million disability adjusted life years (DALYs) and 8.6 billion USD lost annually.⁸ Guidelines of WHO technical series report (TRS) 2018 recommends complete vaccination along with immunoglobulin, if required, on loss of documentation of previous vaccination.⁹ In a developing country like India, such loss of documentation of previous vaccination and re-administering the complete dosage of anti-rabies vaccines adds up a lot more to the biological loss (anti-rabies vaccine) leading to work days loss and adding to economic burden of the country. So this study is first of its kind to have been taken up for identifying the factors associated with loss of documents, estimated vaccine wastage and provide recommendations to bring down such burden.

Objectives:

- 1) To study the sociodemographic profile of re-exposure cases of animal bite.
- 2) To estimate the number of patients with the documents of previous anti-rabies vaccination.
- 3) To find the association of loss of documentation of previous vaccination with sociodemographic factors and factors related to animal bite.
- 4) To calculate the vaccine wastage due to unavailability of documents.

Methodology:

This is a hospital based study carried out in the Anti-Rabies Clinic (ARC) of SCB Medical College and Hospital, Cuttack, Odisha. All cases of re-exposure to animal bites who reported during January till March 2019 were included as study population. Patients with exposure to animal bites and had previously been completely vaccinated with anti-rabies vaccine (ARV) either (IM/ID) or ARV with rabies immunoglobulin (RIG) for either post exposure prophylaxis or received pre-exposure prophylaxis previously were included as study subjects for re-exposure. All those cases who had not completed the previous post exposure treatment and cases with re-exposure within the period of post exposure treatment were excluded from the study. Written informed consent was taken from all the study participants and approval from institutional ethical committee (IEC) has been taken.

Results:

The total number of new cases reported during the study period were 4935, out of which 137(2.77%) were re-exposure cases.

Table1: Distribution of Re-exposure cases (N=137)

Re-exposure cases	Number	Percentage (%)
After completion of previous PEP treatment	112	81.75
Within treatment period of present PEP	4	2.91
Not completed the previous treatment	21	15.32

Patients reporting for re-exposure meeting our inclusion criteria were 112(81.75%). Cases reporting within the treatment period were four and those who did not complete the previous post exposure prophylaxis were 21.

(Table-1)

Table 2: Sociodemographic profile of study subjects (N=112)

Sl no	Characteristics	Number	Percentage (%)	
1	Age	≤5 years	10	8.9
		6-15 years	27	24.1
		16-40 years	50	44.6
		41-60 years	19	17
		>60 years	6	5.4
2	Gender	Female	27	24.1
		Male	85	75.9
3	Religion	Hindu	106	94.6
		Muslim	6	5.4
4	Socio Economic Status	Lower	86	76.8
		Others	26	23.2
5	Residence	Rural	90	80.4
		Urban	22	19.6
6	Literacy Status	Literate	82	73.2
		Illiterate	30	26.8

The mean age of the re-exposed cases was 27.07 ± 18.18 years. Males accounted for 75.9% and females comprised 24.1% of the study population. The subjects mainly belonged to low socio-economic status 76.8%. Majority (44.6%) were adults aged between 16-40 years followed by children less than 15 years who accounted for 33% and rest aging >40 years were 22.4%. Majority of the study subjects were Hindus 94.6% followed by Muslims 5.4%. People from rural i.e 80.4% formed a major chunk of ARC attendance. Among the study subjects, 73.2% had either formal or primary education. (Table-2)

Table 3: Factors related to previous and present animal bite cases among the study subjects.

Sl no	Characteristics	Number	Percentage (%)	
1	Years since last bite	≤ 1 year	41	36.6
		1-2 years	21	18.8
		>2 years	50	44.6
2	Documents of previous vaccination	Present	38	33.9
		Absent	74	66.1
3	Suspected rabid animal in last bite	Yes	18	16.1
		No	94	83.9
4	Category of last bite/scratch	II	33	29.5
		III	79	70.5
5	Cause of present bite/scratch	Cat	31	27.7
		Dog	78	69.6
		Monkey	3	2.7
6	Category of present bite	II	19	17
		III	93	83
7	Aware of keeping documents of previous vaccination	Yes	79	70.5
		No	33	29.5

Among the re-exposed cases who were bitten for less than or equal to 1 year comprised of 36.6%, those bitten between 1-2 years back were 18.8% and cases with bite >2 years back were 44.6%. Among the re-exposure cases, 29.5% were previously treated for category II exposure and 70.5% were previously treated for category III. However, 16.1% cases of re-exposure stated of being bitten by suspected rabid animal. The present distribution of cases according to the WHO categorization reveals 83% as category III and rest as category II exposure. Dogs comprised of 69.6% of bites followed by cats 27.71% and monkeys 2.7%. Although, 70.5% of cases were aware of keeping the documents, only 33.9% kept the documents and rest 66.1% lost them. (Table -3)

Table 4: Association of various factors with preservation of documents of previous anti-rabies vaccination (N=112)

Sl no	Characteristics		Document present	Document lost	P value	OR CI
1	Age	≤5 years	6(60)	4(40)	0.06	3.28
		>5years	32(31.4)	70(68.6)	-	0.86-12.43
2	Gender	Females	9(33.3)	18(66.7)	0.94	1.03
		Males	29(34.1)	56(65.9)	-	0.41-2.59
3	Religion	Hindu	35(33)	71(67)	0.39	2.02
		Others	3(50)	3(50)	-	0.38-10.57
4	Socio Economic Status	Lower	27(31.4)	59(68.6)	0.30	1.6
		Others	11(42.3)	15(57.7)	-	0.65-3.94
5	Residence	Rural	31(34.4)	59(65.6)	0.81	1.12
		Urban	7(31.8)	15(68.2)	-	0.41-3.05
6	Literacy Status	Illiterate	8(26.7)	22(73.3)	0.32	1.58
		Literate	30(36.6)	52(63.4)	-	0.62-4.00
7	Years since last bite	≤2 years	29(46.8)	33(53.2)	<0.001*	4.00
		>2 years	9(18)	41(82)	-	1.66-9.62
8	Suspected rabid animal in last bite	Yes	9(50)	9(50)	0.11	0.44
		No	65(69.1)	29(30.9)	-	0.16-1.24
9	Category of last bite/scratch	II	13(39.4)	20(60.6)	0.43	0.71
		III	25(31.6)	54(68.4)	-	0.30-1.65
10	Aware of keeping documents	Yes	29(36.7)	50(63.3)	0.33	0.64
		No	24(72.7)	24(72.7)	-	0.26-1.57

*Significant at $p < 0.05$, OR-odds ratio, CI- confidence interval at 95%.

Out of all the factors taken into consideration, only those who were bitten within a period of two years kept the documents of previous anti-rabies vaccination and this association was found to be highly significant { $p < 0.001$, OR=4[CI= 1.66-9.62]}.

On evaluation; 66% of cases who lost the documents were administered with 0.1 ml each on 2 sites as i.d of purified vero cell rabies vaccine (PVRV) for 4 visits amounting to nearly loss of 60 ml of PVRV in a period of 3 months. On extrapolating the given figures; anti rabies vaccine wastage in a year could be as high as 240 ml in our set-up. Each vial of PVRV supplied by Govt. of Odisha costs around Rs 325 in the market and contains 1ml for intradermal use. So a total loss of Rs 19,500 in the study period (January to March 2019) from one ARC of Odisha could be prevented by just an easy way to preserve the documents, most likely in a digital form.

Out of the 74 subjects who lost the document; 61 belonged to category III which implied administration of rabies immunoglobulin (RIG) also. On calculating, a sum total of 284 ml of ERIG was administered to the 61 cases. Each vial of ERIG contains 5ml which costs around Rs 465 in the market. Hence nearly Rs 26,500 of ERIG is overused from just one ARC which could have been saved for other cases of category III.

On interviewing the study subjects, 87(77.7%) were of an opinion of having some kind of service at our OPD to track their documents and 71(63.4%) specifically mentioned the OPD tickets to be scanned and a copy to be preserved at the health centre for any future reference.

Discussion:

Our study found three-fourths of re-exposure cases being males. Similar studies by Mohanty S et al¹⁰ at ARC of MKCGMCH, Berhampur, Odisha revealed 61.3% males whereas a similar study on re-exposure by Mahendra B J et al¹¹ at Mandya found 72.5% males. Our study found nearly 4 out of 10 cases were children which was similar to the findings of Mohanty S et al¹⁰ and Mahendra B J et al¹¹. This could probably be explained due to the vulnerability, playfulness and less defensiveness of younger children. We found majority i.e 50(44.6%) belonged to age group of 16-40 years and children less than 15 years comprised 37(33%) of the study population which was similar to the study conducted by Mohanty S et al.¹⁰ A study based on the case record analysis in Delhi also revealed that males constituted 78%.¹² Among those who attended ARC, people from rural areas formed a major chunk i.e 90 (80.4%) as was found by MK Sudarshan et al¹³ where 76% of victims were from rural areas. We also found nearly three-fourths of animal bite cases were of low SES which was a little lesser than the findings of MK Sudarshan et al¹³ where they found nearly 90% of the people belonging to poor and low income level. Rural people having higher chances of close proximity to stray and unvaccinated animals could be a reason for higher prevalence of animal bite cases among the rural mass.

Study illustrates 7 out of 10 cases were bitten by dogs, which is a little lower than the findings by Mahendra B J et al¹¹ and Mohanty S et al¹⁰ where nearly 9 out of 10 cases were bitten by dogs. We found 83% of the victims presently having category III bite which was a slightly higher than the findings of Mahendra B J et al¹¹ i.e 76.6%. Nearly 45% of the subjects had re-exposure after 2 years from the last bite, mostly by dogs. Consequently, the key to the success in containment of rabies lies in successful control of canine rabies and stray dog population.

Out of all the factors taken into account; only those who were bitten for less than equal to two years kept the documents. Rest all the study subjects irrespective of age, gender, marital status, animal being suspected rabid, awareness of keeping the document etc. lost the documents leading to complete re-vaccination and ERIG administration as the case may be. This adds up to a major economic burden on the health care system.

We found an economic loss of nearly Rs 20,000 from overuse of PVRV due to loss of documents in just a period of 3 months from 1 ARC of Odisha which throws light on the major economic burden it adds up annually, if all ARC centres are taken into consideration. On extrapolating the losses; anti rabies vaccine wastage in a year could be as high as 240 ml in our set-up. This could be prevented by just an easy way to preserve the documents, most likely in a digital form.

Over use of ERIG and its side-effects are yet to be apprehended but as found in our study Rs 26500 could have been saved by mere preservation of documentation of previous anti-rabies vaccination. Annually; assuming the trend remains the same, Government is facing a huge loss of nearly Rs 80,000 each year from just 1 ARC. So it is highly recommended to preserve the documents of anti-rabies vaccination with the health centre (most likely in digital form) and providing them with a unique ID for future reference. It was also opined by majority of re-exposure cases attending the ARC to keep a copy of the prescription at the health facility as well as to specifically illustrate the importance of preserving the documents to all cases.

Conclusion:

Countries such as Thailand and Philippines have mandated local guidelines of administering boosters six months after the previous PEP or PrEP in subjects experiencing re-exposure. In Sri Lanka it is twelve months and in a study conducted by MK Sudarshan et al³ showed antibody levels above 0.5 IU per ml upto the end of third month. However, no final guidelines have been yet recommended by WHO expert committee and hence recommendations are further awaited. TRS 2018 guidelines prompts the importance of documentation of anti-rabies vaccination, hence steps must be taken and awareness must be created for proper preservation of these documents and thereby decreasing the biological as well as economic burden on the country.

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