Research Article

A study of compliance of animal bite victims to 4 dose intradermal schedule of anti-rabies vaccine and factors affecting it

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Received: 24 February 2015
Accepted: 21 March 2015

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ABSTRACT

Background: Rabies is 100% fatal disease, but it is prevented by use of potent Anti-Rabies Vaccine (ARV). Noncompliance to vaccination schedule is one of the reasons for high number of deaths among animal bite victims. The present study is an attempt to reveal compliance of animal bite victims to 4 dose intradermal (id) schedule of Anti-Rabies Vaccine (ARV) schedule and socio-demographic factors with it.

Methods: This cross sectional study was conducted at ARV centre of government medical college, Akola, Maharashtra state of India, from 1st January 2014 to 31st December 2014. Records of all animal bite victims were studied and data regarding their compliance for completion of vaccination schedule and sociodemographic and animal related factors was analyzed.

Results: Out of these 3658 victims of animal bite, 1566 (42.81%) completed ARV schedule and remaining 2092 (57.19%) failed in it. Out of those who completed the schedule, 1484 (94.76%) didn’t delay any dose and rest 82 (5.24%) delayed one or more doses. With respect to the completion to of id ARV schedule, no significant association was observed with gender, age, place of residence and economic status of victims. But significantly higher proportion of category II bite (63.85%) and unprovoked bite (69.44%) patients exhibited poor compliance for adherence of vaccination schedule than that of category III bite (56.42%) and provoked bite (33.16%) patients respectively.

Conclusions: Poor compliance to ARV vaccination, among more than half of animal bite victims, is a serious concern in id schedule.

Keywords: Compliance, ARV, id schedule

INTRODUCTION

Rabies is the 10th biggest cause of death due to infectious diseases worldwide. The annual estimated number of animal bites in India is 17.4 million, leading to estimated 18000-20000 cases of human rabies per year which is around 36% of rabies related mortality in the world.

The reasons for this high number of deaths due to disease is attributed to lack of awareness among people about management of animal bites and also noncompliance to vaccination schedule. Rabies is 100% fatal disease, but it is prevented by use of potent Cell Cultured Vaccine (CCV) and embryonated Egg Based Vaccine (EEV) and immunoglobulin coupled with local treatment as a Post Exposure Prophylaxis (PEP). Intradermal rabies vaccination (IDRV) using selected CCVs has been established as an efficacious and economic alternative to the standard intramuscular regimens.

The present study is an attempt to reveal compliance of animal bite victims to 4 dose intradermal (id) schedule of Anti-Rabies Vaccine (ARV) schedule and socio-demographic factors with it.
METHODS

This cross sectional study was conducted at Anti-Rabies Vaccine (ARV) centre of government medical college, Akola situated at Vidarbha region of Maharashtra state of India, from 1st January 2014 to 31st December 2014. The permission from head of institute and clearance from ethical committee was obtained before starting the study.

The victims of animal bite visiting to ARV center were included in the study. Animal bite victims were classified using WHO guidelines.\(^9\)

As per this classification, category II and III patients have risk of getting rabies and require Post Exposure Prophylaxis (PEP) of ARV and/or immunoglobulin. Only these patients were included in the study.

Every such patient registered was given first dose of ARV at the time registration and advised to approach the centre on 3\(^{rd}\), 7\(^{th}\) and 28\(^{th}\) day to complete the 4 dose id schedule.

The patients referred to other centers for subsequent doses after registration were excluded from the study. Also patients came for pre exposure and re exposure cases were not included.

Records of all such patients were studied and data regarding their compliance for completion of vaccination schedule and sociodemographic and animal related factors was analyzed.

Data was entered in Microsoft excel sheet and it was analyzed with Epi info software. Percentages (%) were used to narrate the situation and Chi square test ($\chi^2$) for significance of association.

Throughout the study anonymity of all patients was maintained and privacy as well as confidentiality of the data was assured.

RESULTS

Total 3658 victims of animal bite were registered for Post Exposure Prophylaxis (PEP) during the year 2014. They were advised 4 dose id schedule of ARV (0, 3, 7, 28), first dose of which was given at the time of registration.

Out of these 3658 victims of animal bite, 1566 (42.81%) completed ARV schedule and remaining 2092 (57.19%) failed in it. Out of those who completed the schedule, 1484 (94.76%) received all subsequent doses on prescribed days (3, 7, 28) and rest 82 (5.24%) delayed one or more doses of the vaccine. Out of those who didn’t complete the schedule, 1561 (74.62%) missed one or two doses after registration but remaining 531 (25.38%) never returned for follow up i.e. they missed all three subsequent doses (Table 1).

### Table 1: Compliance for completion of 4 dose id schedule of ARV.

| Compliance for completion of 4 dose id schedule of ARV | Completed without any delay | Completed but one or more dose delayed | Total |
|-------------------------------------------------------|-----------------------------|----------------------------------------|-------|
| Schedule completed (Good compliance)                   | 1484 (94.76%)               | 82 (5.24%)                             | 1566 (42.81%) |
| Schedule not completed (Poor compliance)               |                             |                                        |       |
| Missed one or two doses                                | 1561 (74.62%)               |                                        |       |
| Missed all three doses                                 | 531 (25.38%)                |                                        |       |
| Total patients registered                              | 3658 (100%)                 |                                        |       |

Regarding the individual dose of ARV, 82.97%, 70.07%, 46.17% received 2\(^{nd}\), 3\(^{rd}\) and 4\(^{th}\) dose respectively showing gradual decrease in compliance to subsequent doses. Among those who received, 1.88%, 3.31% and 33.39% delayed 2\(^{nd}\), 3\(^{rd}\) and 4\(^{th}\) dose respectively. Average delay for 2\(^{nd}\), 3\(^{rd}\) and 4\(^{th}\) dose was 2.21, 4.45, 3.71 days within the range of 2-3, 2-11 and 2-13 days respectively (Table 2).

### Table 2: Compliance for individual dose of ARV.

| Received | Delayed |
|----------|---------|
| Dose II  | 3035 (82.97%) | 57 (1.88%) |
| Dose III | 2563 (70.07%) | 85 (3.31%) |
| Dose IV  | 1689 (46.17%) | 564 (33.39%) |

With respect to the completion to of ARV schedule, it was observed that higher proportion of males (57.31%), rural residents (58.74%) and BPL people (58.09%) tended to default than females (56.81%), urban dwellers (56.68%) and APL people (56.85%) respectively. But statistically this difference was not found significant ($P >0.05$) (Table 3).

Significantly greater proportion of literate patients (44.08%) of animal bite adhered to ARV schedule than that of illiterate patients (36.96%). Regarding age-wise distribution, 56.04% of those less than 15 years of age, 60.27% of those in the age group of 15-45 years and 52.75% of those above 45 years of age were defaulters as they missed one more subsequent doses of ARV. This difference in the compliance among different age groups was proved significant by Chi square test ($\chi^2 = 12.61, P <0.05, df = 2$) (Table 3).

Significantly higher proportion of category II bite (63.85%) and unprovoked bite (69.44%) patients exhibited poor compliance for adherence of vaccination schedule than that of category III bite (56.42%) and provoked bite (33.16%) patients respectively. Similarly 66.74%, 52.73% and 8.11% victims of pet, stray and wild animal bite didn’t adhere to recommended ARV schedule. Statistically this association was also found significant ($\chi^2 = 142.80, P <0.05, df = 2$) (Table 4).
Among those who received all four doses of ARV, 82 (5.24%) delayed one or more subsequent doses of vaccine. Comparatively higher proportion of females (6.79%), rural (8.85%), APL (8.06%) and illiterate (7.88%) patients did not receive one or more doses of ARV on prescribed dates than that of males (4.76%), urban (4.11%), BPL (4.64%) and literate (4.75%) patients respectively. This difference observed for compliance was statistically significant. Similarly age group was also revealed significant association (P <0.05) with the adherence to ARV schedule among those who completed it (Table 5).

On the other hand, higher proportion of category II bite (8.03%) and unprovoked bite (5.33%) patients tended to delay one or more doses than that of category III bite (4.97%) and provoked bite (4.74%) patients respectively among those who successfully completed the vaccination. Similarly 66.74%, 52.73% and 8.11% victims of pet, stray and wild animal bite received one or more doses late. Statistically this association between all these three animal related factors (nature of bite, category of bite, and type of animal ) and receiving all doses in time was not found statistically significant (P >0.05) (Table 6).

**Table 3: Compliance to 4 dose id schedule of ARV by socio-demographic factors.**

| Schedule completed (n=1566) | Schedule not completed (n=2092) | Total (n=3658) |
|-----------------------------|--------------------------------|---------------|
| **Distribution of animal bite patients according to their gender** | | |
| Male                        | 1198 (42.69%)                  | 1608 (57.31%)  | 2806 \( \chi^2 = 0.07, P >0.05 \) |
| Female                      | 368 (43.19%)                   | 484 (56.81%)   | 852 |
| **Distribution of animal bite patients according to their place of residence** | | |
| Urban                       | 1193 (43.32%)                  | 1561 (56.68%)  | 2754 \( \chi^2 = 1.18, P >0.05 \) |
| Rural                       | 373 (41.26%)                   | 531 (58.74%)   | 904 |
| **Distribution of animal bite patients according to their literacy status** | | |
| Illiterate                  | 241 (36.96%)                   | 411 (63.04%)   | 652 \( \chi^2 = 11.08, P <0.05 \) |
| Literate                    | 1325 (44.08%)                  | 1681 (55.92%)  | 3006 |
| **Distribution of animal bite patients according to their age** | | |
| <15                         | 604 (43.96%)                   | 770 (56.04%)   | 1374 \( \chi^2 = 11.08, P <0.05 \) |
| 15-45                       | 619 (39.73%)                   | 939 (60.27%)   | 1558 |
| >45                         | 343 (47.25%)                   | 383 (52.75%)   | 726 |
| **Distribution of animal bite patients according to their economic status** | | |
| BPL                         | 1149 (43.15%)                  | 1514 (56.85%)  | 2663 \( \chi^2 = 0.45, P >0.05 \) |
| APL                         | 417 (41.91%)                   | 578 (58.09%)   | 995 |

**Table 4: Compliance to 4 dose id schedule of ARV by animal related factors.**

| Schedule completed (n=1566) | Schedule not completed (n=2092) | Total (n=3658) |
|-----------------------------|--------------------------------|---------------|
| **Distribution of animal bite patients according to category of bite** | | |
| Cat II                      | 137 (36.15%)                   | 242 (63.85%)   | 379 \( \chi^2 = 7.66, P <0.05 \) |
| Cat III                     | 1429 (43.58%)                  | 1850 (56.42%)  | 3279 |
| **Distribution of animal bite patients according to type of biting animal** | | |
| Pet                         | 466 (33.26%)                   | 935 (66.74%)   | 1401 \( \chi^2 = 142.80, P <0.05 \) |
| Stray                       | 1032 (47.27%)                  | 1151 (52.73%)  | 2183 |
| Wild                        | 68 (91.89%)                    | 6 (8.11%)      | 74 |
| **Distribution of animal bite patients according to type of bite** | | |
| Provoked                    | 253 (30.56%)                   | 575 (69.44%)   | 828 \( \chi^2 = 65.65, P <0.05 \) |
| Unprovoked                  | 1313 (46.40%)                  | 1517 (53.60%)  | 2830 |
Table 5: Association between delay in completion of 4 dose id schedule of ARV and socio-demographic factors.

| Schedule delayed (n=82) | Schedule not delayed (n=1484) | Total (Schedule completed) (n=3658) |
|-------------------------|-------------------------------|-------------------------------------|
| Distribution of animal bite patients according to their gender | | |
| Male | 57 (4.76%) | 1141 (95.24%) | 1198 | $\chi^2 = 2.35$, P < 0.05 |
| Female | 25 (6.79%) | 343 (93.21%) | 368 | |
| Distribution of animal bite patients according to their place of residence | | |
| Urban | 49 (4.11%) | 1144 (95.89%) | 1193 | $\chi^2 = 12.87$, P < 0.05 |
| Rural | 33 (8.85%) | 340 (91.15%) | 373 | P < 0.05 |
| Distribution of animal bite patients according to their literacy status | | |
| Illiterate | 19 (7.88%) | 222 (92.11%) | 241 | $\chi^2 = 4.02$, P < 0.05 |
| Literate | 63 (4.75%) | 1262 (95.25%) | 1325 | |
| Distribution of animal bite patients according to their age | | |
| <15 | 39 (6.46%) | 565 (93.54%) | 604 | $\chi^2 = 4.66$, P < 0.05 |
| 15-45 | 32 (5.17%) | 587 (94.83%) | 619 | |
| >45 | 11 (3.21%) | 332 (96.79%) | 343 | |
| Distribution of animal bite patients according to their economic status | | |
| BPL | 60 (4.64%) | 1233 (95.33%) | 1293 | $\chi^2 = 5.31$, P < 0.05 |
| APL | 22 (8.06%) | 251 (91.94%) | 273 | |

DISCUSSION

Total 3658 victims of animal bite were registered for Post Exposure Prophylaxis (PEP) during the year 2014. They were advised 4 dose intradermal (id) schedule of ARV (0, 3, 7, 28), first dose of which was given at the time of registration.

Gradual decrease in the compliance was noted as 82.97% patients approached to ARV centre for 2nd dose, 70.07% for 3rd dose and only 46.17% for 4th dose. Such an adverse compliance for subsequent doses of ARV was also recorded by various studies in India and in other countries. Only 80.7%, 60.3% and 35.3% patients at Mandya, Karnataka received 2nd, 3rd and 4th dose respectively while at Behrampur, Odisha these figures were 87.9%, 77.5% and 60.3% respectively. The highest dropout to 4th dose in all these studies, including present one, is a serious concern and to some extent it may be attributed to comparatively longer i.e. 21 days interval between 3rd and 4th dose.

Out of 3658 exposed patients, less than half (42.82%) completed the immunization schedule by receiving all prescribed doses of ARV. Rest 57.18% didn’t complete the schedule keeping them susceptible to rabies. Among those who were noncompliant, 1561 (74.62%) missed one or two doses and remaining 531 (25.38%) didn’t receive even a single dose after registration. Similarly almost half of the animal bite victims failed to complete 4 dose id schedule of ARV in Karnataka, India as well as in Abidjan, France. Even among re-
exposure cases to whom 2 doses were advised 21.6% complete the schedule.13

Among 3658 animal bite victims studied, maximum were males (76.71%) and majority belonged to urban area (75.29%). It may be related to more outdoor activity of males as compared to females and urban location of ARV centre where the study was conducted respectively. Very less, and that too insignificant, difference regarding the completion of ARV schedule was observed between males (57.31%) and females (56.81%) as well as between urban (56.68%) and rural (58.74%) residents as well as between BPL (56.85%) and APL people (58.09%). It revealed the fact that gender, place of residence and economic status were not risk factors for not being adhered to ARV schedule. Consistent findings were also put forward by Vinay M et al.10 and Rohki KR et al.17 who also observed statistically insignificant association.

Majority of animal bite victims in the present study were in the age group of 15-45 years (42.59%) followed by those under the age of 15 years (37.56%) and rest were above the age of 45 years (19.85%). 39.73% of those in the age group of 15-45 years, 43.96% of those less than 15 years of age and 48.36% of those above 45 years of age successfully received all four doses. This difference in the compliance among different age groups was proved significant by Chi square test ($\chi^2 = 12.61, P <0.05, df = 2$) similar to that reported by Vinay M et al. in their both studies.10,12

Maximum were victims of stray animal bite (59.68%), followed by pet animal (38.30%) and only 2.02% were attacked by wild animals. Vaccination dropout rates were the highest (66.74%) for patients of pet animal bite and the least (only 8.11%) for wild animal and those for stray animal (52.73%), they were in between these two. This difference in the dropout rates among the victims of pet, stray and wild animal bites was found statistically significant. Wild animal bites are usually severe and people have a great fear of wild animals. On the contrary, people are not that much serious about pet animals and their bites are many a times milder one. These might be reasons for favorable and adverse compliance among wild, pet and stray animal bite victims respectively. Both the studies by Vinay M et al.10,12 revealed significantly better compliance among the stray animal bite victims than that of pet animal bite victims, again in accordance with the present study findings.

Category II bite victims (10.36%) were comparatively very low than that of category III (89.64%). Adherence to immunization schedule was significantly higher among category III (43.58%) bite victims than that of category II (36.15%). As among category II bite victims bleeding is absent, wound is very mild or absent, it heals quickly without any scar marks, motivation to receive subsequent doses may not be maintained compared to that among category III bite victims who have significant bleeding at the time of animal bite, wound is large, it heals slowly with the formation of scab and scar. Compliance for vaccination might be the reflection of sustained motivation for vaccination among the animal bite victims. Different studies had different observations. Similar to the present study results, Vinay M et al.10 observed significantly better compliance among CAT III bite victims than that of CAT II, but their another study12 documented exactly opposite finding i.e. significantly higher dropouts among CAT III bite victims than that of CATIII. Again Mohammed et al.14 didn’t observe any significant association between category of bite and compliance to vaccination schedule, totally different findings that observed in all these studies.

Among all patients, maximum had unprovoked animal bite (77.36%) and only (22.64%) gave history of provoked bite. Comparison with respect to nature of bite revealed significantly higher dropouts among provoked bite victims (69.44%) than that among the unprovoked bite victims (53.60%). Such significant different dropout rates were also revealed by Satpathy M et al. at Beh rampur, Odisha.11 In case of provoked bites, people might have opinion that biting animal is not rabid and vaccination is not that much essential. This might be responsible for higher dropouts among provoked bite victims than that among the unprovoked bite victims.

Out of those who successfully completed 4 dose id schedule of ARV, majority (94.76%) of them completed it without delaying any dose, but few (5.24%) patients delayed one or more doses. Statistical association of various factors with delaying of doses among those who completed the schedule was also studied. It was observed that animal related factors viz. type of biting animal (whether pet, stray or wild), category of bite (whether II or III) and nature of bite (whether provoked or unprovoked) were not significantly associated with the receiving the doses of ARV strictly as on the prescribed dates. On the contrary, all these animal related factors had a significant impact for dropouts (missing one or more doses) to ARV schedule. Similarly patient related factors viz. gender, place of residence, and economic status, which didn’t show significant association with the completion of vaccine schedule, were proved to be significantly associated with delay in receiving one or more doses of vaccination among those who completed the schedule. In both the situations, to complete the schedule at all or to complete the schedule without delay, age groups and literacy status of patients made statistically significant difference.

When all doses are considered together, irrespective of schedule completed or not, delay in the receipt of individual dose of vaccine went on increasing as revealed by the fact that 1.88%, 3.31% and 33.39% received 2nd, 3rd and 4th dose later than the prescribed.

As compared to the 2nd and 3rd dose, compliance to the fourth dose was very poor as it is missed by more than half (53.83%) of the patients and among those who
received it, almost one third received it 7-13 days late. This worst compliance may be attributed to relatively a longer interval (21 days) between 3rd and 4th dose as compared to that between 1st and 2nd (3 days) and 3rd and 4th dose (7 days).

CONCLUSION

Poor compliance to ARV vaccination (4 dose id schedule), among more than half of animal bite victims, is a serious concern in id schedule. Again compliance to the fourth dose was the poorest one. Patient related factors like age, sex, place of residence, economic status are not significantly associated with completion of id schedule of ARV, but animal related factors viz. type of biting animal, category of bite and nature of bite showed statistically significantly association. On the contrary, sociodemographic factors made significant difference for delaying the doses among those who successfully completed the schedule and animal related factors proved to be insignificant.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the institutional ethics committee

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DOI: 10.5455/2394-6040.ijcmpmh20150517
Cite this article as: Malkar VR, Joge US. A study of compliance of animal bite victims to 4 dose intradermal schedule of anti-rabies vaccine and factors affecting it. Int J Community Med Public Health 2015;2:156-61.