Title: EVALUATION OF ADHERENCE TO INTRA-DERMAL AND INTRA-MUSCULAR ANTI-RABIES VACCINATION REGIMES AT A GOVERNMENT TERTIARY HEALTH CARE CENTRE

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EVALUATION OF ADHERENCE TO INTRA-DERMAL AND INTRA-MUSCULAR ANTI-RABIES VACCINATION REGIMES AT A GOVERNMENT TERTIARY HEALTH CARE CENTRE

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ABSTRACT

Objective : To compare adherence to Intra-Dermal (ID) and Intra-Muscular (IM) anti-rabies vaccination regimes.

Design and Setting : It is a Hospital Record based study conducted at Anti Rabies Vaccination Clinic of a government tertiary health care centre at Mumbai, Maharashtra. 5 years ID data was collected. One year ID data for year 2012 was compared with year 2007 for adherence and vaccine cost separately. Pearson's Chi-square test was applied to test significance.

Results: Adherence to IM was just 40% as compared to 93.6% with ID route. Cost evaluation of both routes also proved ID route to be cheaper than IM route with saving of Rs. 11,73,600 in a year.

Conclusion: ID route is distinctly superior to IM route in terms of adherence as well as cost.

Key words: Intra-Dermal anti-rabies vaccination, Intra-Muscular anti-rabies vaccination, Adherence to treatment, Cost evaluation

Introduction

Rabies is an acute viral disease which causes fatal encephalomyelitis in virtually all the warm blooded animals including man. As per WHO recommendations, the production and use of nervous tissue vaccine has been stopped since December 2004 in our country which had fairly good adherence. Modern Cell Culture Vaccines (CCV) are now being used for post-exposure prophylaxis (PEP). Higher cost of intra-muscular administration of CCV is a limiting factor for its wider use. To overcome this problem, WHO has recommended use of efficacious, safe and feasible intradermal (ID) route for inoculation of CCVs.1 Intradermal administration of these vaccines require only 1-2 vials of vaccine to complete a full course of PEP, thereby reducing the volume used and the direct cost of vaccine by at least 60% depending on the vaccine type; compared with standard intramuscular vaccination.² One Indian study has also observed that, Post-exposure rabies vaccination when administered intra-dermal in 0.1-ml doses using the two-site method is safe and highly immunogenic.3

Though intra-dermal route is cheaper and safe, Indian data on its adherence are inadequate. Adherence is the act of taking a treatment exactly as prescribed. It implies a strong collaboration between the patient and the health care provider. Adherence is crucial for the success of PEP. Hence current study was carried out with the objective of comparing adherence of cases receiving PEP by Intra-muscular (IM) and Intra-dermal routes and to evaluate the performance of the ID route in terms of cost as well.

Methodology

It is a Hospital Record based study conducted at Anti Rabies Vaccination Clinic (ARVC) of a government tertiary health care centre at Mumbai, Maharashtra. Intra-dermal vaccination in this clinic was started from July 2008. For comparison, 5 years ID vaccination data from July 2008 to June 2013 was included. On the other hand one year record of IM vaccination was taken from year 2007 as it included all cases who received CCV latest by IM route only.

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ID regimen followed in this clinic is Updated Thai Red Cross (TRC) schedule. This involves injection of 0.1ml of reconstituted vaccine per ID site and on two such ID sites per visit (one on each deltoid area, an inch above the insertion of deltoid muscle) on days 0, 3, 7 and 28. For ID administration, PCECV (Purified Chick Embryo Cell Vaccine) and PVRV (Purified Vero Cell Rabies Vaccine) were used. IM vaccinated cases had followed standard WHO intramuscular regimen on days 0, 3, 7, 14 and 28; and they received PCECV.

IM vaccination data was taken for the sole purpose of comparison. All animal bite cases, which were prescribed full PEP schedule, comprised the study population. Data regarding age and gender were also included.

To overcome the disparity in duration of record studied, one year ID data for year 2012 was compared with year 2007 for adherence and vaccine cost separately. Pearson's Chi-square test (2 sided p values) was applied to test the relationship of categorized independent and dependent variables. Odds ratio and 95% confidence interval were calculated. Stata SE 12.1 was used to analyse data.

Results

9689 cases that received ID vaccine in five years and 1075 cases that received IM vaccine in one year comprised the study population. 2414 cases in 2012 received ID vaccine. Figure 1 shows comparison of adherence to IM and ID routes.

Adherence to IM was just 40% as compared to 93.6% with ID route. Statistically also it is very highly significant.

Yearly data of ID administration also showed adherence to the PEP in the range of 84-95% (Figure 2).





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The adherence to ID route thus, was sustainably higher over a period of 5 years.

Cost evaluation of one year of IM route (Year 2007) and ID route (Year 2012) was done. The hospital cost for one vial of either PCECV or PVRV was Rs. 200. If similar usage of both vaccines is assumed, a saving of Rs. 11,73,600 in a year is evident on account of less dose requirement.

Adherence in the adults aged 18-60 years, was higher as compared to paediatric and geriatric population in the current study. It was statistically very highly significant. Also, significantly better adherence was observed in males as compared to females.

Discussion

Rabies is a 100% fatal but at the same time, 100% preventable disease.⁴ India alone is estimated to have 20,000 deaths due to human rabies every year.^{5,6} Adherence to PEP is crucial for reducing death rate. According to WHO – Association for Prevention and Control of Rabies in India (APCRI) survey on Rabies burden (2004), 73.9% of rabies deaths were among partially completed CCV cases.⁶ In the current study it has been observed that adherence with ID route is distinctly higher than that of IM route. Poor adherence to IM route has also been proved previously in the WHO-APCRI Pan-India study.⁶ In this study, 43.6% of cases receiving CCV by IM route completed full schedule which is similar to the observation in the current study.

Constant high adherence can also be seen when year wise data was analysed. But, in two studies from India where updated TRC is given in government hospitals, the completion/compliance rate to full course or taking 4 doses of vaccine including the one on day 28 was found to be 38.5% in Mandya⁷ and 75.5% in North

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Kerala⁸. Nevertheless, statistically significant high adherence with the ID route, when compared with IM route; strongly provides evidence that ID route is the best in terms of adherence in the current study.

It is also clear that not just in terms of adherence but also in terms of cost; ID route is far cheaper than IM route^{1.9}. This was the obvious finding in the current study, as only one fifth of dose is required to be given by ID route.

More adults completed the PEP as compared to paediatric and geriatric population. Poor adherence in children was observed in one more study group. It reports that, exposed children do not receive timely and complete PEP, and a much higher proportion of young children contract and die of unrecognized rabies than estimates from Asia.¹⁰ The completion of the ID PEP schedule was higher among patients aged more than 45 years in one of the Indian study.¹¹ Still, in depth reasons for this disparity have to be evaluated further. High adherence in males indicates better health seeking behaviour in them.

One more issue faced in some anti-rabies clinic is supply of vaccine. Though in some centres it is provided free of cost to all, the stock available is always very scarce as compared to demand. Many poor people are asked to buy injections of the vaccine, which costs about Rs. 200 - 300 per dose¹². Thousands of poor people cannot afford this expense and they go home without taking the injection. Considering all above facts, it's high time for the centres where IM route is practiced to shift to ID route for anti-rabies vaccine administration.

Key Message:

Looking at the drastic difference in performance of IM and ID route for PEP anti-rabies vaccination, ID

route is far superior to IM route in terms of adherence as well as cost.

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