

A PILOT STUDY TO ASSESS POST VACCINATION ALLERGY INDUCED AFTER BCG VACCINATION IN INFANTS VACCINATED BY AUXILIARY NURSE-MIDWIVES IN AJMER (RAJASTHAN)

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Introduction

Since BCG Vaccination was brought under the Extended Programme of Immunisation (EPI), it has been felt necessary to assess the quality of BCG Vaccination performed by Auxiliary Nurse-midwives (ANMs) to check their cold-chain management, technique of BCG vaccination and its complications. This pilot study assesses the post-vaccination allergy and size of BCG scar when vaccinations are done by field workers compared with that done by the Assessment Team to suggest corrective actions needed for improving the quality of BCG vaccination done by ANMs.

Plan of the Study

Ajmer district in Rajasthan was selected for this study. Advance planning was done for selecting a PHC in Ajmer district and the villages under its jurisdiction for field work.

During the advance panning done in August 1988, it was observed that in the villages selected for assessment of post-vaccination allergy, among infants already vaccinated by ANMs, BCG vaccinations had actually been done in the school children but shown as done in infants below 1 year, by the ANMs. As such, it was decided that another group of 250 infants would be given BCG for this study by the ANMs/LHVs/Male workers in their respective villages following their usual technique of BCG vaccination. The comparison was therefore changed to the technique as used by ANMs, when aware that their work was being assessed, with that of the Assessment Team.

For comparison, a second group of 250 infants was first tuberculin tested by the Assessment Team with 1 TU RT 23 (with tween) to elicit

their pre-vaccination allergy for comparison later with their post-vaccination allergy and then given BCG vaccination using the same batch of BCG vaccine as used by the ANMs. The BCG Assessment Team from Delhi followed the standard cold-chain management technique of reconstitution of BCG vaccine and 0.1 ml dose of vaccine given intradermally as per the instructions given in the manual of health workers under Universal Immunisation Programme (UIP) and National Immunization Schedule as approved by the Government of India. The tuberculin reactions were read 72 to 96 hours after testing.

Both the groups i.e. those vaccinated by the ANMs and the BCG Assessment Team respectively, were re-tested with 2 TU RT 23 (with tween) at the end of 6 months after vaccination to assess the post-vaccination allergy and size of BCG scar as well as complications following vaccination, if any. (The retesting was actually planned for the end of the 4th month but due to unavoidable administrative reasons the retesting was deferred to sixth month till March 1989.)

Area of the Study

Shreenagar PHC in Ajmer District and 14 villages in the PHC area were selected and surveyed by the BCG technicians attached to the TB Centre, Ajmer by a house-to-house visit to locate infants and note down their BCG vaccination status. Out of the 14 villages surveyed, eleven were covered by the study.

Records

All the infants with their identification data were listed on a house-to-house registration form prepared for the study. The details of each infant to be included in the study were also written on

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the individual cards especially printed for the study.

Biologicals

Biologicals for the study were supplied by the BCG Vaccine Laboratory, Gundy, Madras: 1 TU RT 23 (with tween) for the pre-vaccination testing, 2 TU RT 23 (with tween) for post-vaccination testing and Freeze-dried BCG vaccine, produced by the BCG Laboratory, Madras along with the Japanese diluents. The dose of 2 TU RT 23 (with tween) in place of 5 TU RT 22 (with tween) for eliciting post-vaccination reaction was recommended by the Director, BCG Vaccine Laboratory, Madras.

The Study

The first phase of the study lasted from 19.9.88 to 28.9.88. The BCG Assessment Team visited 6 villages in Shreenagar PHC and tuberculin tested 253 infants, using 1 TU RT 23 (Batch 40. E/Jul. 1988), and later BCG Vaccinated them (using BCG Lot 137/Exp. Aug. 1989). During the period, the ANMs/LHVs/MPWs of Shreenagar PHC visited 5 villages and vaccinated 251 children using the same BCG Lot No. 137. The details of the work done by BCG Assessment Team are as follows : Vaccination coverage of the registered infants was 64 percent and mean size of pre-vaccination tuberculin reactions was 2.18 mm.

Village	No. of Houses surveyed	No. of infants registered	No. of infants tested/ vaccinated	Mean size of Tub. reaction (in mm)
Balak Dheda	107	38	26	2.73
Kheda	185	40	26	2.27
Babaicha	229	72	55	2.04
Kayed	290	81	49	2.30
Dal	226	69	35	2.14
Gagwana	312	95	62	2.13
Total	1349	395	253	2.18

The details of the work done by the ANMs / LHVs/MPWs are as follows : The vaccination coverage of the registered infants was 53 percent

Village	No. Of houses surveyed	No. Of infants registered*	No. Of infants vaccinated
Shreenagar	422	78	45
Tihari	339	96	45
Narwar	138	68	32
Kanpura	231	51	30
Zamsar	602	182	99
Total	1732	475	251

* Pre-vaccination tuberculin testing was not done in this group.

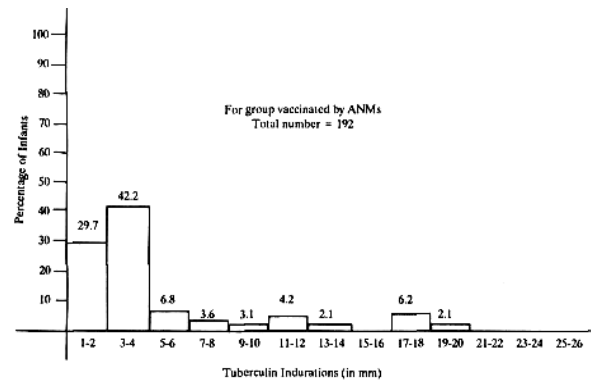
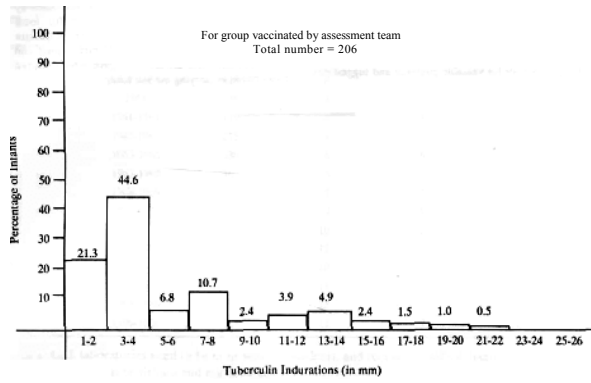
Both the groups were then re-tested with 2 TU RT 23 (with tween) (Batch 45. X. Dec. 1988). The size of BCG scars as well as tuberculin reactions were noted 72 to 96 hours after testing from 17.3.89 to 25.3.89.

Results and Discussion

Table 1 and Graph I give the comparison between the mean sizes of post-vaccination tuberculin indurations as well as of BCG scars in the infant groups vaccinated by the Assessment Team and field workers respectively. **There is practically no difference ($P > 0.05$) suggesting that cold chain and BCG vaccination technique used by ANMs (when they knew their work was being assessed) were as good as of the Assessment Team.** There was no difference also in the rates of complications following vaccination (not shown).

It has been mentioned that the mean size of pre-vaccination tuberculin induration (group vaccinated by Assessment Team) among the infants of the selected villages was 2.18 mm meaning that they were non-infected either by tubercle bacilli or environmental mycobacteria. Yet, the observed mean size of post-vaccination allergy in both the groups was below 6 mm i.e. much lower than what could be expected. Since the maximum extent of post-vaccination allergy occurs three to four months following vaccination, the possible waning of allergy, if any, that could have occurred in the two to three months that elapsed after the target timing could not have been so profound. It can, therefore, be recommended that the study be repeated in some

GARPH I
POST VACCINATION TUBERCULIN INDURATIONS WITH 2TU RT 23 (WITH TWEEN)



other population groups in order to validate the finding that the technique of properly trained field staff could be as good as desired.

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