049: FINDINGS OF BCG SCAR SURVEY IN BANGALORE CITY


TB is widely prevalent in India. As disease surveys are too expensive and difficult, the assessment of TB situation in developing countries is preferably done by subjecting a representative sample of children without BCG scar to tuberculin testing. Prior to a tuberculin survey in school children of Bangalore city, a cluster sample, household survey was undertaken during September-November 1995 with the objectives of ascertaining the proportion of children aged 5-7 years with BCG scar and also to find the proportion among them attending schools. It was also decided to include 12-23 months old children to ascertain the recent BCG vaccination coverage in the city among the targeted population under UIP.

From 2100 identified localities of Bangalore city, each of which was considered as a cluster, 60 clusters were selected for the study by simple random sampling. One fifth of the selected clusters were from slums. From the selected households in each cluster, inquiries were made about the presence of children of the required age groups of 12-13 months and 5-7 years. From every cluster, 7 children each from both the age groups were registered and their BCG scar status recorded. Information on BCG vaccination status of children was obtained from immunization cards. In case of their non-availability, the information was collected by oral questioning.

The results of the survey showed BCG scar was identified in 71% and 74% of the children aged 12-23 months and 5-7 years respectively. The scar could not be identified in 20% of the children vaccinated according to the information culled from immunization cards. The results revealed that 38% of the children aged 12-23 months received BCG vaccination at private health agencies, 60% at Government Health Institutions and the remaining 2% were vaccinated by outreach services. The scar identification was higher among those vaccinated by private health agencies compared to those vaccinated at government institutions. Almost all children (99%) aged 5-7 years were attending schools.

It appeared that BCG vaccination coverage was higher than the observed BCG scar rates. Private health agencies played an important role in the immunization programme. A lower scar identification in children vaccinated at Government Health Institutions suggests a need to examine the vaccination technique and cold chain management observed in these institutions. The high proportion of children attending schools is an encouraging factor for carrying out studies targeted at 5-7 years age group in schools.

Key Words: Cluster, Survey; BCG scar; Immunization Card; BCG Vaccination;

050: BCG-DO WE HAVE TO CONTINUE TO USE, YES?


The TB prevention trial and efficacy of BCG vaccines used in Chingleput is a world famous study. The write up on the first report of this study in 'Indian Express' proclaimed “ TB vaccine is worthless says ICMR”. Following this, the Government of India changed its policy. When the second report came 'Indian Express' again hit the headlines saying “TB vaccine is worthless says ICMR”. Why this controversy? This controversy is basically due to ignorance about BCG, etiopathogenesis of TB, genesis of the trial and mis-interpretation of the latest report on findings of Chingleput BCG trial.

The childhood forms of TB occur by dissemination through blood vessels and lymphatics. In adults, few virulent TB bacilli in healed lesions can flare up any time in the future, breakdown into pulmonary disease leading to adult type of pulmonary TB. BCG is given for: 1) Prevention of primary disease; 2) Reduction of haematogenous dissemination and 3) Prevention of flaring up of old healed TB lesions of primary complexes in the lungs. Only the adult type of Pulmonary TB is responsible for maintaining the transmission of infection in the community. The mass BCG campaign in 1951 was started all over the country with the objective of controlling TB in the community, but the BCG trials conducted globally showed varying protection rates ranging from 0-80%. The Chingleput trial was a result, of the concern of planners, policy makers and TB workers. The findings showed no protection against adult forms of TB. The prevention of dissemination and producing childhood forms of TB was not studied in this trial.
ICMR in its Bulletin clearly states BCG vaccine interferes with the haematogenous spread of tubercle bacilli which could otherwise result in fatal forms of TB like TB meningitis and miliary TB. Therefore, GOI revised its policy of giving BCG to all children within 1st year of age through UIP. The GOI’s decision to continue vaccination of children has prevented millions of children from dying of serious forms of TB or from becoming mentally and physically handicapped. The reduction in above forms of TB have been noticed by the present day practicing physicians. Ironically, the recently published second report of the trial showed that BCG confers more benefits to children and it provides some protection against adult forms of TB, which is due to endogenous reactivation.

**Key Words:** BCG; Chingleput Study; BCG Policy.

---

**051: A COMPARATIVE STUDY OF TUBERCULIN REACTION TO 1 TU AND 2 TU OF PPD RT 23**


Most tuberculin surveys in India have used 1TU PPD RT23 with Tween 80 as per WHO guidelines. The NTI, Bangalore, has proposed a nation wide study to estimate the ARTI in different parts of the country. Some experts including the IUALTD have suggested use of 2TU of PPD RT23 with Tween 80 for the proposed survey since they believe reactions with 1TU dose are softer and inexperienced readers are prone to commit errors in reading the soft reactions. Hence it was thought a comparative study of the use of the 2 doses of tuberculin would be appropriate. The objectives of the study were (i) to compare the tuberculin reaction sizes of 1TU and 2TU doses of PPD RT23 with Tween 80 for the proposed survey since they believe reactions with 1TU dose are softer and inexperienced readers are prone to commit errors in reading the soft reactions. Hence it was thought a comparative study of the use of the 2 doses of tuberculin would be appropriate. The objectives of the study were (i) to compare the tuberculin reaction sizes of 1TU and 2TU doses of PPD RT23 with Tween 80 (ii) to decide which of the two doses has a better correlation between reading of the standard reader and (iii) newly trained readers and to compare the rates of unpleasant skin reactions to either dose.

The study was conducted in 5-9 year old school children in the year 1998 in Anekal taluk of Bangalore district. The study was conducted using a double blind design wherein each child was subjected to dual testing with the two doses of PPD RT23 with tween 80. The tuberculin vials and child cards all were pre-coded for the dose to be given on a particular arm. Therefore, the sites of injection for the two tests were randomized. The same tester performed all the tests in the study. As per standard procedure the reactions were read on the 3 day by palpating the induration and measuring its maximum transverse diameter by a standard reader and two trained readers- Reader I and Reader II separately and were also recorded independently. The presence or absence of unpleasant skin reactions at the test site like oedema, bullae, vesicles and necrosis were recorded at the same time. Children among whom injection of either of the 2 doses was unsatisfactory and children whose reactions could not be read by all the 3 readers were excluded from analysis. Data analysis was done using SPSS and Epi-Info software packages.

In all 609 children without BCG scar were registered for the study. The data of 537 children was analysed after excluding those with unsatisfactory tests and those whose reactions could not be read by all the three modes.

The frequency distribution of tuberculin reaction sizes to 1 TU among children without BCG scar showed a bimodal distribution and a clear demarcation for identification of the children probably infected with M. tuberculosis was observed at 17 mm. However such a demarcation could not be observed with 2 TU dose. The distributions of reactions to 1TU as read by Readers I and II were statistically similar to that of the standard reader. The frequency distributions of reaction size to 2 TU as read by the 3 readers were also similar. There was high degree of correlation between Standard Reader, Reader I and Reader II for reaction sizes for both 1 TU and 2 TU. Reactions ≥ 17 mm were termed as large reactions while those 10-16mm in size were termed as moderate reactions. A significant proportion of children with moderate reaction to 1 TU showed large reaction to 2 TU. Almost all the children with unpleasant skin reaction to the 2 TU dose had similar reactions to 1 TU as well.

The results obtained in this study do not support the hypothesis favoring a shift over to the use of 2 TU dose of PPD RT23 with Tween 80 for TB surveys in India.

**Key Words:** Surveys; PPD RT23 with Tween80; Epidemiology.

---

**052: TUBERCULIN TEST**


At last an article that puts to rest all ambiguity and speculation shrouding the interpretation of tuberculin test results. The author cautions that the tuberculin test only
detects the presence or absence of tuberculous infection and that the test should not be the sole investigation for diagnosing TB even in children.

The tuberculin, 1 TU of PPD RT23 with Tween 80 is recommended for use in India as it is more specific in our situation. This was originally prepared by SSI, Copenhagen and freeze-dried form supplied to BCG Laboratory, Guindy which reconstitutes and supplies the tuberculin to other parts of India. Other tuberculin preparations available in the market may not be standardized. Intradermal injection of 0.1 mm of 1TU PPD RT23 is administered conventionally on the volar aspect of left forearm using a standard tuberculin syringe and the induration at the test site read 48-96 hours later. A satisfactory test should raise a flat pale pea size weal with clear pits of hair follicles and there should be no leakage of tuberculin.

The tuberculin test is based on the principle that individuals harboring tuberculous infection develop delayed type hypersensitivity reaction at the test site. The window period for the sensitization to occur following infection takes 4-8 weeks. Not all tuberculin reactions are attributed to infection with tubercle bacilli. The reaction may also be attributable to non-specific sensitivity due to infection with environmental mycobacteria or BCG induced tuberculin sensitivity. The essence of interpretation of the test is that larger the size of the induration, higher is the probability of it being due to infection with tubercle bacilli. Also other circumstances including the purpose for which the test is administered is to be taken into account while interpreting the test results. Reaction sizes of 15 mm and above indicate infection with tubercle bacilli while those less than 5 mm suggest absence of any type of mycobacterial infection except in those with severe degree of immune suppression. Reactions with indurations between 10-14 mm could be due to cross sensitivity induced by environmental mycobacteria, BCG induced tuberculin sensitivity or infection with tubercle bacilli. It is more likely to be due to infection with tubercle bacilli in case the child has had contact with a smear positive case of pulmonary TB. Induration between 5-9 mm are often due to non-specific sensitivity or BCG induced tuberculin sensitivity. However, in an immuno compromised child it could be attributable to infection with tubercle bacilli. When the test is used for screening apparently healthy children for TB, before subjecting them to further investigations, a lower cut-off level may be considered to denote infection, while a higher cut-off level may be used when the test is performed for deciding on the provision of chemoprophylaxis.

The article concludes making a reference to the interpretation of a repeat tuberculin test, the invalidity of BCG test and also about newer tuberculins.

Key Words: Tuberculin Test; Induration Size; Infection; Tubercle Bacilli; Non Specific Sensitivity; BCG induced Sensitivity.

053: PROTECTIVE EFFECT OF BCG AMONG CHILDREN VACCINATED UNDER UNIVERSAL IMMUNIZATION PROGRAMME


A case control study was undertaken by NTI, Bangalore to assess the protection offered by BCG vaccination against TB rendered under the UIP, as there was no scientific data pertaining to the Indian context available in the country.

This study was conducted among children aged 1-14 years with suspicion of TB, attending pediatrics department of 2 hospitals in Bangalore, namely St. Martha's Hospital and Vani Vilas Children Hospital, Bangalore. Only the children residing within 30 kms radius from the city were registered into the study and subjected to detailed clinical examination and investigations. The presence of BCG scar was taken as evidence of vaccination. Modified Steagen Jones scoring method was adopted for diagnosing TB. Children with score of ≥ 4 were labeled as controls.

A total of 118 age-sex matched case-control pairs were identified and the final analysis was confined to 113 cases and 109 controls after excluding children with doubtful BCG scar. A low protective effect of BCG vaccination at 31% (not significant, statistically) was observed against TB – all forms combined, among children vaccinated under the UIP. The protective efficacy against extra-pulmonary TB was observed to be higher than for pulmonary TB but it was not statistically significant. Inadequate matching with respect to socio-economic status and deficiencies in vaccine administration could be some of the limitations of the study. The protective effect of BCG vaccine against TB meningitis and miliary TB could not be specifically evaluated in this study owing to small
numbers. The authors conclude by stating that it would be appropriate to conduct further studies on protection rendered by BCG vaccination against TB meningitis and other severe forms of TB. Nevertheless, till such time the current BCG vaccination policy needs to be adhered to.

Key Words: BCG; Protective Effect.

054: TUBERCULIN SENSITIVITY AMONG CHILDREN VACCINATED WITH BCG UNDER UNIVERSAL IMMUNIZATION PROGRAMME


The information on the tuberculin sensitivity in BCG vaccinated children under the UIP in India, was fairly limited. So, the large volume of data available from the nation-wide tuberculin survey was analyzed to compare tuberculin sensitivity patterns in children with and without BCG scar and also to study their trends with age.

The database comprised of 45,988 children 1-9 years of age with BCG scar and 54,227 children without BCG scar residing in selected rural areas of northern, eastern and western zones of India. The children were subjected to tuberculin testing using 1 TU PPD RT 23 with Tween 80 procured from BCG laboratory, Guindy. Trained personnel performed the tuberculin test using Mantoux technique. The maximum transverse diameter of induration was measured after about 72 hours. The readers were blinded to the BCG scar status at the time of reading the reactions. About 45-60% of the BCG vaccinated children elicited reactions <5 mm in size and about 70-80% had reactions <10 mm. Therefore, in the majority of children (showing tuberculin reaction of <10 mm), BCG-induced tuberculin sensitivity does not interfere with the interpretation of the tuberculin test. The study also revealed that a proportion of reactions among BCG vaccinated children in 5-9 mm, 10-14 mm and 15-19 mm range may be attributable to BCG vaccination. Therefore, reactions between 10-14 mm and especially 15-19 mm among the vaccinated children are to be interpreted carefully. However, 19 mm was observed as the upper limit for BCG induced tuberculin sensitivity and all reactions > 20 mm in size may be considered to be due to infection with tubercle bacilli, irrespective of the BCG vaccination status.

Considering that BCG induced tuberculin sensitivity depends on various factors like dose and type of vaccine, age and technique of vaccination, time gap between vaccination and tuberculin testing and also on racial factors, the findings of this study may not particularly be applicable to settings in other countries.

Key words: Infection; Tuberculin Test; BCG Vaccination.

Total: 6