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Original Research Article

Adverse Events Following Immunization by BCG Vaccine among Adults: A Prospective Study in a District of West Bengal, India

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Abstract

Background: Tuberculosis is still a worldwide public health problem. Highest number of TB patients are in India. As per National immunization Schedule, BCG vaccine is given to infants at birth or otherwise within one year. But one trial in India has shown that 80% effective over 20 years of follow up.

Objectives: i) to describe the socio-demographic characteristics of the adults who were given BCG vaccine in a district of West Bengal, India, ii) to assess the AEFI after BCG vaccination among them and iii) to find out the association of AEFI and socio-demographic characteristics, if any.

Materials & Methods: It was a observational longitudinal study conducted in a district of West Bengal, India from February 2025 to August 2025, Complete enumeration technique was used and ultimately 12308 study subjects were included in the study. Data were collected initially by the ANMs using one Pretested, predesigned interviewer-administered schedule was used for data collection while the follow up was done by the ASHAs through house to house visit.

Results: Majority of the study subjects were of less than sixty years of age (66.7%). Female vaccines (54.3%) were more than males. Almost all of the participants were Hindu (97.9%). Total 12308 persons were vaccinated. Out of which 1105 vaccines faced any of the AEFIs. AEFI was found more in senior citizens (97.4%) and the difference was statistically significant ($p< 0.001$). ASHA workers followed up the vaccines by house to house visit on 2nd, 14th, 28th, 32nd and 84thday. Any AEFI occurred in 95% of the vaccines at 2nd day after immunization, 84.6% on day 14 and 83.1% on day 28. Redness and papule developed in 89% cases, while 95.4% had local tenderness. Subsequently pustule developed in 84.6% cases followed by development of abscess on 28th day. Ulcer developed in 80.7% cases whereas scar was seen in 76% study subjects,

Conclusion: Many minor AEFI developed among the vaccines which is similarly seen in infants. Further such study should be undertaken in different parts of the country to get the total picture of the country.

Keywords: Adverse events following immunization, BCG Vaccine, Prospective study, Adults.

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Introduction

Tuberculosis is still a public health problem in the world though before more than 100 years the causative organism was discovered. Highly effective MDT has been available as well as immunization programme against the disease is continuing. Globally in 2024, an estimated 10.7 million people fell ill with TB (incident cases) and 1.23 million died from the disease. The TB incidence rate (new cases per 100 000 population per year) was 131 (95% UI: 122–141) and the case fatality rate was 11.5% [1].

Globally India is the highest TB burden country. As a signatory of the United Nations Sustainable Development Goals, India, has committed to the achievement of the 'End TB' targets by 2025. The incidence for 2022 was 199 per lakh population, with 16% decline as compared to 2015 (237 per lakh population). The TB mortality was 23 per lakh population, with 18% decline as compared to 2015 (28 per lakh population) [2]. BCG vaccine was discovered almost hundred years back. According to National Immunization Schedule now BCG is given to infants at birth or otherwise within one year, to prevent Milliary TB and TB meningitis. The first BCG vaccine prospective trial in India showed that it was 80% effective over 20 years of follow up [3].

TB prevalence in India generally follows an increasing trend with age, with the highest burden observed in the elderly. In 65 years or above age group highest overall burden is found in, who are also at significantly higher risk for recurrent TB episodes. Retrospective data analysis of this community-based trial revealed that BCG revaccination in a community offered modest protection against the development of TB disease at the end of 15 years which, however, requires further evaluation4. Findings from our study show that BCG vaccination was associated with an almost halving of the risk of tuberculosis during a 40 year period after vaccination. Duration of BCG protection against tuberculosis and change in effectiveness with time since vaccination in Norway: a retrospective population-based cohort study [5]. Thorough literature search could reveal a few studies on adult BCG vaccination.

Adult BCG vaccination has been associated with a reduction in overall mortality, even in populations where tuberculosis is not prevalent. This non-specific protection is particularly relevant in regions with high burdens of infectious diseases, as it contributes to a general improvement in health outcomes. [6]

Under this circumstances, a study was conducted to describe the socio-demographic characteristics of the adults who were given BCG vaccine in Bankura district, West Bengal, India, ii)to assess the AEFI after BCG vaccination among them and iii) to find out the association of AEFI and socio-demographic characteristics, if any.

Materials & Methods

It was a descriptive observational study with longitudinal design. The study setting was all government Immunization clinics in Bankura District, West Bengal viz. sixteen blocks and one municipality. The study population was comprised of all adults immunized by BCG vaccine attending the immunizations clinics of Bankura health district comprising of 16 CD blocks. The study was conducted from February 2025 to August 2025, No sampling method was used, the complete enumeration of all beneficiaries was used instead. Total number of study subjects were 12308.Inclusion criteria were individuals more than eighteen year of age meeting any of the criteria i) People who are reported to have at least one episode of TB in past 5 years , ii)individuals aged 60 years or above**,** iii) individuals with history of tobacco smoking ,iv)Close contacts of TB patients v) individuals with history of diabetes and vi) Individuals with a Body Mass Index of less than 18 kg per sq.mts[7] The exclusion criteria were those patients who did not give consent to be included in the study.

One Pretested, predesigned interviewer-administered schedule was used for data collection. Face to face interview by ANMs after BCG vaccination during the 30 minutes compulsory waiting period as per norm after any vaccination. The schedule was validated by five subject matter experts and pilot testing was conducted at Bishnupur TU, Bankura. During the interview exact address of the vaccinees were noted. Subsequently, ASHA workers followed up the vaccinees by house to house visit on 2nd, 14th, 28th, 32nd and 84thday. During conversation they were asked about having any of the side effects like pain, fever, swelling and ulcer. Any local reaction viz. bleeding, pus and ulcer were also looked for and such cases of case of pain, fever and swelling were given symptomatic treatment.

The study was conducted after obtaining permission from the Institutional Ethics Committee, Bankura Sammilani Medical College (No.) Informed written consent was obtained from the study participants. In case of illiterates, left thumb impression with attestation by another literate person was taken. Permission was obtained from the Chief Medical Officer of Health, Bankura Health District, Chairperson State Task Force, RNTCP, West Bengal and Director ICMR. Privacy and confidentiality of study subjects were ensured. Study technique was face to face interview and observation at the site of vaccine administration.

Data were entered in MS Excel spread sheet and checked for accuracy. Descriptive statistical analysis was performed using mean, median, standard deviation etc. Data were checked for normality using the histogram and Sapiro-Wilk test and parametric or non-parametric test was applied as applicable. Inferential analysis was performed using Chi square test using the "Jamovi software2.3.28 solid version".

Results

The mean age of the vaccinees was 50.3 ±38.7years (Range: 18 years-78 years) Majority of the study subjects were of less than sixty years of age (66.7%). Female vaccinees (54.3%) were more than males. Almost all of the participants were Hindu (97.9%). Total 12308 persons were vaccinated. Out of which 1105 vaccinees faced any of the AEFIs. All of the AEFIs were of mild type only. Highest proportion of occurrence of AEFI was found in Chhatna block (12.2%) followed by Sarenga block (9.7%), whereas lowest incidence of AE was found in Raipur (1.1%).

Among the vaccine recipient any AEFI was more common among senior citizens (97.4%) which was statistically significant ($p<0.001$). Male senior citizens were vaccinated more (37.1%) than the females (31.1%) and the difference is statistically

significant (p<001). Both male and female vaccinees almost equally faced AEFI (p = 0.64) as there was no significant difference (p>0.05) in occurrence of any AEFI according to gender. AEFI was found to be more in senior citizens (97.4%) as compared to adults below sixty years (94.1%) and the difference was statistically significant (p< 0.001) Any AEFI occurred in 95% of the vaccines at 2nd day after immunization, 84.6% on day 14 and 83.1% on day 28. Redness and papule developed in 89% cases, while 95.4% had local tenderness. Subsequently pustule developed in 84.6% cases followed by development of abscess on 28th day. Ulcer developed in 80.7% cases whereas scar was seen in 76% study subjects.

Table 1: Distribution of study subjects according to age and sex (n=12308).

Sex	Age group No. (%)		Total	X^2, df	P value
	60 years	≥ 60 years			
Male	3533 (62.9)	2087 (37.9)	5620	68.4,1	< 0.001
Female	4676(69.9)	2012(30.1)	6688		
Total	8299 (100.0)	4099(100.0)	12308		

Table no.1 shows that among the vaccines elderly males were more than the females (p< 0.001) and the difference is statistically significant

Table 2: Distribution of study subjects according to age and AEFI (n=12308).

Age group	AEFI No. (%)		Total	X^2, df	p value
	Present	Absent			
< 60 years	7895 (95.1)	314 (4.9)	8299	11.7, 1	< 0.001
≥ 60 Years	3991 (97.4)	108 (2.6)	4099		
Total	11886(100.0)	412 (100.0)	12308 (100.0)		

Table no. 2 reveals that incidence of AEFI was more among senior citizens (p<0.001) and the difference is statistically significant

Discussion

Literature search could not reveal many articles on adult BCG vaccination. The inclusion of adult BCG vaccination in public health programs carries several implications. First and foremost is the potential to reduce the burden of infectious diseases, both respiratory and non-respiratory, at the population level In England in a trial local adverse events were reported by 77.8% participants in the BCG-vaccine group and 38.1% in the placebo group on 12-18 years children [8].Villanueva Pet al found injection site abscess to be 3% in a study [9].

The most commonly reported reactions were abscess (31%), injection site reaction (27%) and lymphadenopathy/ lymphadenitis (17%) in a study at Australia among the children of 1-7 years of age [10].

In a study at Turkey the Abscess formation (30%), localized inflammation signs (45%), purulent discharge (10%), crust (10%) and eczematous lesion (5%) were found as local cutaneous complications in case of children under two years of age in Turkey [11].

A study in Australia showed at 27% developed injection site abscess and local reaction in 31%. A study conducted at Bangladesh revealed that 6th week redness was 62.7%, 52% developed ulcer and scar developed in 12% [12].

Local adverse reaction in England was found is less than the present study, In a study at Bangladesh, England and Australia which was is than our study. Abscess is found much less than as seen in the study at Australia and Turkey. The local redness developed much less in Turkey and Australia study in comparison to our study. Therefore, the pattern of AEFI in adults by BCG vaccine is like as seen in children but in varying proportions. Further multicentric study should be undertaken in different parts of the country.

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