Effects of BCG Vaccination on Evolution of Leprosy

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Abstract

Background: BCG vaccine is considered to have immunoprophylactic potential in leprosy. However controversy exists about the extent of prophylaxis it provides. In view of this, a study was undertaken to see the evolution of disease in established cases of leprosy who were already vaccinated with BCG and to compare it with the cases of leprosy who were not vaccinated with BCG.

Methods: 114 newly diagnosed cases of leprosy were studied. Patients were divided into two groups-BCG vaccinated and non-vaccinated. Clinical diagnosis of leprosy was confirmed by bacteriological and histopathological studies in each case. All patients were given standard anti leprosy treatment and were evaluated monthly for a minimum period of one year.

Results: All the cases were males in the age group of 20 to 50 years. 25.4% of cases had received BCG vaccine and 74.6% were not vaccinated for the same. No significant difference was observed in the incidence of different types of leprosy in vaccinated and non-vaccinated groups. 25.9% cases in non-vaccinated group developed lepra reaction as compared to 13.8% in vaccinated group. The incidence of deformities and disabilities in vaccinated group was only 10.3% as against 18.8% in non-vaccinated group. The rate of bacillary clearance appeared faster in vaccinated group.

Conclusions: Although there is no significant difference in the pattern of different types of leprosy in BCG vaccinated and non-vaccinated cases, there is reduction in the incidence of reactions as well as deformities and disabilities in BCG vaccinated cases as compared to non-vaccinated cases.

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Key Words : BCG Vaccine; Leprosy

Introduction

BCG vaccine is considered to have immunoprophylactic potential against leprosy[1]. However controversy exists about the extent of prophylaxis it provides against leprosy. BCG vaccine along with killed Mycobacterium leprae as also other cultivable mycobacteria is currently under trial for immunoprophylaxis and immunotherapy in leprosy [1]. In view of these, a study was undertaken to see the evolution of disease in established cases of leprosy who were already immunized with BCG and to compare it with cases of leprosy who were not immunized with BCG.

Material and Methods

The study was conducted at a Leprosy Centre in a tertiary care military hospital. All newly diagnosed cases of leprosy admitted during the period from Jan 2000 to Aug 2001 were studied. Besides history taking and general, physical and systemic examination each patient underwent a detailed evaluation of skin lesions, nerve involvement and evidence of lepra reactions, deformities and disabilities. Slit skin smear for acid fast bacillus leprae (AFB(L)) and skin biopsy were done in all cases in addition to routine haematological and biochemical investigations. Other investigations were done as indicated. History of BCG vaccination was confirmed by

the observation of scar for the same. Patients were divided into two groups-those already vaccinated with BCG (vaccinated group) and those not vaccinated with BCG (Non-vaccinated group). All patients were given standard therapy as per recommendation of National Leprosy Eradication Programme (NLEP) as institutional cases. Patients were evaluated monthly for a minimum period of one year. The results were compiled and data analysed.

Results

A total of 114 cases were studied. All cases were males in the age group of 20 to 50 year, 64 (56.1%) being in 3rd decade, 40 (35.1%) in 4th decade and 10 (8.8%) in 5th decade. Of these, 29 (25.4%) cases were vaccinated with BCG while 85 (74.6%) were not vaccinated (Table-1). Borderline tuberculoid leprosy was the commonest in both groups (37.9% in vaccinated and 45.9% in non-vaccinated) followed by tuberculoid (17.2% and 14.1%), borderline lepromatous (13.8% and 14.1%), indeterminate (10.3% and 12.9%), lepromatous (13.8% and 9.5%) and neuritic leprosy (3.5% in each) cases (Table-2). No significant difference was thus noted in the pattern of different types of leprosy in the two groups. 17 (20%) cases in non-vaccinated group developed Type I lepra reaction as compared to 4 (13.8%) in vaccinated group. The incidence of Type II reaction in non-vaccinated group was in 5 (5.9%) cases as compared to none in vaccinated group (Table-3). The incidence of deformities and disabilities (WHO grade II)

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Table 1

Age incidence of leprosy cases

Age group (years)	Number (Percent)		
	Total	BCG Vaccinated	Non-Vaccinated
< 20	-	-	-
20-29	64 (56.1)	11	53
30-39	40 (35.1)	12	28
40-49	10 (8.8)	06	04
50 and above	-	-	-
Total	114 (100)	29 (25.4)	85 (74.6)

 $\chi^2 = 9.03$, df = 2, p = 0.01**Table 2**

Pattern of different types of leprosy

Types of leprosy	Number (percent)		
	Total	BCG Vaccinated	Non-Vaccinated
I	14 (12.3)	3 (10.3)	11 (12.9)
TT	17 (14.9)	5 (17.2)	12 (14.1)
BT	50 (43.9)	11 (37.9)	39 (45.9)
BB	1 (0.9)	1 (3.5)	-
BL	16 (14.0)	4 (13.8)	12 (14.1)
LL	12 (10.5)	4 (13.8)	8 (9.5)
N	4 (3.5)	1 (3.5)	3 (3.5)
Total	114 (100)	29 (100)	85 (100)

 $\chi^2 = 3.9$, df = 6, p = 0.69

were in 16 (18.8%) cases in non-vaccinated group as compared to 3 (10.3%) in vaccinated group (Table-4) and included claw hand / wasting / weakness of muscles of hand (12.9% in non-vaccinated and 6.9% in vaccinated), foot drop (7.1% and 3.4%), lagophthalmos (3.5% and none) and trophic ulcers (8.2% and none) (Table-4). The rate of bacillary clearance appeared faster in vaccinated group as compared to non-vaccinated group (Table-5).

Discussion

Following observation of Fernandez in 1939 that BCG vaccination was able to convert lepromin negativity into positivity in lepromatous leprosy patients, this vaccine has been focus of attention [2]. Long term results of studies conducted in different countries show that BCG vaccine offered variable protection against leprosy i.e. in 80% cases in Uganda [3], 56% cases in Venezuela [4], 20% cases in Burma [5] and in 24% cases in south India [1]. The reason for this regional variation in the efficacy in prevention of leprosy is not clear. Several explanations have been hypothesized like different strains of *M. leprae*, different strains of BCG, presence of mycobacteria in the environment, immunogenetic characteristics of the population etc[6]. BCG alone and alongwith killed *M. Leprae* are under trial for immunoprophylaxis and immunotherapy of leprosy [7,8]. However, not much is known about the course of leprosy in cases already immunized with BCG.

Table 3

Incidence of lepra reactions in leprosy cases

Types of lepra reaction	Number (percent)			
	Total	BCG Vaccinated	Non-Vaccinated	p value
Type-I	21 (18.4)	4 (13.8)	17 (20.0)	0.45
Type-II	5 (4.4)	-	5 (5.9)	0.18
Total	26 (22.8)	4 (13.8)	22 (25.9)	

Table 4

Incidence of deformities and disabilities in leprosy cases

Types of deformities & disabilities	Number (percent)			
	Total	BCG Vaccinated	Non-Vaccinated	p value
Claw hand/ Wasting/ Weakness hand	13 (11.4)	2 (6.9)	11 (12.9)	0.37
Foot drop	7 (6.1)	1 (3.4)	6 (7.1)	0.48
Lagophthalmos	3 (2.6)	-	3 (3.5)	0.30
Trophic ulcer	7 (6.1)	-	7 (8.2)	0.11
Total	19 (16.7)*	3 (10.3)	16 (18.8)*	

*Some patients had more than one disability

Table 5

Rate of bacillary clearance in multi bacillary leprosy cases

Types of leprosy	Mean bacillary index (BI)				
	Base line	3 months	6 months	9 months	12 months
BCG vaccinated	3.8	3.8	2.8	2.4	2.4
Non-vaccinated	4	4	3.5	2.8	2.5

In the present study, which was conducted on Armed Forces personnel, most cases were in 3rd and 4th decades which was proportional to the age structure of the services. Only 25.4% of leprosy cases were in BCG vaccinated group as against 74.6% in non-vaccinated group, the difference being statistically highly significant, indicating that less number of BCG vaccinated individuals developed leprosy. However, this study revealed no significant difference in the pattern of types of leprosy developing in BCG vaccinated and non-vaccinated. Similar findings were observed in a study from Pakistan involving 562 cases of leprosy, 124 among them vaccinated for BCG and 438 not vaccinated [9].

In the present study it was observed that incidence of Type I and Type II lepra reactions were comparatively less (13.8%) in BCG vaccinated than in non-vaccinated group (25.9%) though it is not found statistically significant. This lower incidence of reactions may be because of the immunomodulatory effect of BCG vaccine. This study also revealed lower incidence of deformities and disabilities in BCG vaccinated (10.3%) as compared to those in non-vaccinated (18.8%). This could be directly due to the lower incidence of lepra

reactions in vaccinated cases and also because of the vaccine induced immunomodulation.

In this study, rate of bacillary clearance in multibacillary cases appeared faster during the period of observation. However, more prolonged observation is required to reach any conclusion. Enhanced bacterial clearance following combined chemotherapy and immunotherapy with BCG vaccine has been reported by other workers [7,10] also.

To conclude, the results of the present study show that although there is no significant difference in the pattern of different types of leprosy in BCG vaccinated and non-vaccinated, there is reduction in the incidence of lepra reactions and deformities and disabilities and probably faster bacillary clearance in BCG vaccinated as compared to non-vaccinated cases. However studies involving larger number of cases and observation for more prolonged period are required to confirm the latter finding.

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