BCG vaccinaton scars of childen under five years in a tertiary care hospital

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(Key words: BCG vaccine, BCG scar, revaccination, tuberculosis, protective efficacy)

Abstract

Objective To study the BCG vaccination scars of under 5 year old children who were admitted to a tertiary care hospital

Design Cross sectional descriptive study

Setting Ward 3, Lady Ridgeway Hospital for Children (LRH)

Method All children between 6 and 60 months of age, admitted to ward 3 LRH from October 15th to December 30th 2006, were included in the study. The interviewer-administered questionnaire and examination of the child for BCG scar were the methods used to collect the data.

Results: Of 1010 patients admitted to ward 3 LRH during the study period, 923 were analysed. BCG vaccine had been given to all patients. Whilst 821 (89%) patients had the BCG scar, 102 (11%) did not have it. Among patients with the BCG scar, 20% had received BCG vaccine in non tertiary care hospitals, whereas in patients with absent BCG scar, this figure was 35% ($p=0.003$; $p<0.05$). In the Child Health Development Record (CHDR), the BCG scar column had been marked in only 554 (64%). Among 102 patients with absent BCG scar, revaccination was not indicated in 20 (21%) because the BCG scar had been marked as positive in the CHDR. However, 96 had not been revaccinated. Common reasons for non revaccination were: unawareness of mothers regarding absent BCG scar (38.5%) and postponement of revaccination (24%).

Conclusion There was a significant number of patients with absent BCG scars indicating need for larger scale studies.

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Introduction

The main benefit of BCG vaccination is that there is a 50-80% protective effect against disseminated TB, TB meningitis or miliary TB which occur more often in under 5 year old children[1,2]. Absent BCG scar is a common occurrence. In our unit we diagnosed TB meningitis in two patients who had no BCG scar though BCG had been given at birth. There are controversies regarding the practice of repeat BCG vaccination in children without BCG scar. Hence, we decided to perform this study.

Objectives

To study the BCG vaccination scars of under 5 year old children who were admitted to a tertiary care hospital by assessing:

1. the proportion of patients without a BCG scar.
2. whether revaccination was done in the case of absent BCG scar and if not, the reasons for non revaccination.
3. whether any relationship exists between maternal education and revaccination.
4. whether there is any association between absent BCG scar and the category of hospital/clinic where the BCG was given.

Method

A cross sectional descriptive study was carried out in ward 3, Lady Ridgeway Hospital for Children, Colombo (LRH). This hospital is the premier children's hospital in Sri Lanka getting a considerable number of patients from all over the island.

All children between 6 and 60 months of age, admitted to ward 3 for a period of 2½ months from October 15th to December 30th 2006, were included in the study.

A pretested interviewer-administered questionnaire and examination of the child to look at the BCG scar were the methods used. Interviewers were house officers and medical students who were trained to collect data and examine to look for the BCG scar. Data analysis was done using SPSS-14 software

Results

Ward 3, LRH had 1010 in-ward patients between 6 and 60 months of age from 15th October to 30th December 2006. Out of this, 923 patients were included in the analysis .Others were excluded due to unavailable or incomplete data. Out of 923 patients, 102 (11%) patients did not have the BCG scar. Tables 1 & 2 show the distribution of patients, according to age and gender, in children with and without BCG scars.

Table 1
Distribution of patients according to age & gender in children with BCG scars

Age Group (months)	BCG scar +			
	Male	Female	Total	
			No	%
6-12	126	79	205	25.0
13-24	123	97	220	26.8
25-36	100	75	175	21.3
37-48	64	54	118	14.4
49-60	57	46	103	12.5
Total	**470 (57%)**	**351 (43%)**	**821**	**100**

Table 2
Distribution of patients according to age & gender in children without BCG scars

Age Group (months)	BCG scar -			
	Male	Female	Total	
			No	%
6-12	22	12	34	33.3
13-24	23	16	39	38.2
25-36	07	08	15	14.7
37-48	05	06	11	10.8
49-60	01	02	03	03.0
Total	**58 (57%)**	**44 (43)**	**102**	**100**

The mean age of the study population was 26.7±16.3 months. While the mean age of patients with BCG scars was 27.5±15.4 months, the mean age for patients with absent BCG scars was 20.9±13.4 months. There was a significant number of patients with absent BCG scars in the younger age groups (<24 months) than in the older age groups. (X^2 test p=0.002; p<0.005)

The patients with BCG scars category had 57% boys and 43% girls. Similarly 57% of patients with absent BCG scars were boys and 43% were girls. There was no gender variation in the presence or absence of BCG scars (X^2 test p=0.51; p>0.05).

All patients had been given the BCG vaccine. This was confirmed by referring to the Child Health Development Record (CHDR). Among them only 7 (0.8%) patients received delayed vaccination (mostly after 2 weeks) and all of them had BCG scars. The main reason for delay in vaccination was stay in the special care baby units. In this study, 369 children had the old form of CHDR which does not have the column to mark the BCG scar. The new type of CHDR has been available island-wide only since end of year 2003. However, only in 554 (64 %) of CHDR the column had been marked.

Among patients with BCG scars, 20% had been vaccinated in non tertiary care hospitals whereas for patients without BCG scars this figure was 35% (p=0.003;p<0.005). (Tertiary care hospitals are Teaching General Hospitals and Provincial General Hospitals).

The mean maternal education was grade 10.15 ± 2.9 in the study population. When we grouped the educational level (table 3), the mode and median educational levels were grade 11(G.C.E.O/L) in both BCG scar positive and negative patients.

Table 3
Presence or absence of BCG scars according to maternal educational levels

Maternal education	BCG scar +	BCG scar -
Grade <5	64 (07.8%)	15 (14.7%)
Grade 6-10	248 (33.0%)	28 (27.5%)
G.C.E.O/L	311 (37.9%)	31 (30.3%)
G.C.E.A/L	181 (22.2%)	26 (25.5%)
Graduate	17 (02.1%)	02 (02.0%)
Total	**821 (100 %)**	**102 (100%)**

Among the patients with BCG scars, 14 had developed BCG scar due to revaccination.

Out of 102 patients with absent BCG scar, 96 (94%) had not been revaccinated while 6 patients had not developed BCG scar even after revaccination. Revaccination had not been indicated in 20 (20%) because the BCG scar had been marked as positive in the CHDR. In 76 (75%) we were unable to get the BCG scar information by referring to the CHDR because either BCG scar column had not been marked or there was no BCG column to mark BCG scar in the old form of the CHDR.

There was a significant association between the reasons for non revaccination and poor maternal education, defined as educational level <grade 10 (p= 0.006; p<0.05). Reasons for non revaccination in absent BCG scar patients are given in table 4.

Table 4
Reasons for non revaccination in absent BCG scar patients

Reason	No	%
Mother unaware of absent BCG scar and no details about BCG scar in CHDR	37	38.5
Mother aware about absent BCG scar, but didn't seek advice and no details about BCG scar in CHDR	16	16.5
Mother went for revaccination, but revaccination postponed and no details about BCG scar in CHDR.	23	24.0
BCG scar marked as positive in CHDR so that repeat BCG vaccine had not been given	20	21.0
Total	**96**	**100**

Common reasons for postponement of revaccination were: mothers being asked to bring their babies after about 1 year and minor illness like upper respiratory tract infection.

In this study, there were no patients who were diagnosed to have TB during their hospital stay or in the past. However, among 923 patients 11 patients were found to have a close contact history of TB. All the patients with contact history of TB were screened for TB.

Discussion

According to the Expanded Program of Immunization (EPI), BCG vaccine has to be administered between 12 hours after delivery and before discharge from the hospital or within 4 weeks of delivery[2]. In this study almost 99% of patients were vaccinated within one week after delivery. The remaining 1% was given BCG, at a later time due to stay in special care baby unit. In Sri Lanka, EPI coverage assessment surveys have indicated that there is almost 100% coverage for BCG[2,3]. This finding was found in our study too..

On intradermal administration of BCG vaccine a swelling appears at the site of injection. Two or three weeks later a small red slightly tender swelling develops into a small abscess which ulcerates and crusts. The crusts disappear leaving a small red swollen scar which becomes smaller, paler and sunken and remains for years[2].

Complications could develop after BCG vaccination in infants including local ulcers and regional lymphadenitis (4 to 30 per 1000 vaccinated infants), osteomyelitis (0.1 to 30 per 100,000 doses), disseminated BCG infection (0.1 per 100,000 doses) and death (0.02 per million)[4]. In our study, only one patient had BCG adenitis following vaccination.

Absence of BCG scar is commonly seen in children. This study revealed 11% of patients did not have BCG scars. Similar results were found in previous Sri Lankan studies[2,5]. The reason for non-development of scar may be

1. Faulty technique, including leaving the prepared vaccine for long periods, leaving the prepared vaccine near a flame or indirect sunlight and injecting subcutaneously instead of intradermally[2]. In our study a significant number patients with absent BCG scars were given BCG vaccine in the hospitals or clinics other than the TGH/PGH. The above mentioned factors, limited facilities and inexperienced staffs may contribute to this finding.

2. Use of vaccine which is not potent[2]. In this study, there was a significant number of patients without BCG scar who were less than 24 months of age (these children were born in the period between October 2004 and April 2006). The vaccine used during that period was imported from India (Serum institute, India) and prior to year 2004; the vaccine was imported from Denmark and Japan. (source Epidemiology unit). We do not know whether the vaccine potency was different.

3. BCG might not have been given even though an entry was made. This could happen, since the cards are usually completed before the vaccination is given. Some mothers could slip away with their babies during this procedure. This could happen if mothers' education is poor. We did not find significant association between maternal education and the absence of BCG scar (P=0.065;p>0.05).

4. The immune response system may not have been developed sufficiently immediately after delivery. There is some evidence to suggest that later immunization during infancy may confer a higher degree of immunity[6]. A study which was

conducted in 1990 in the Northern Province of Sri Lanka, revealed a significant number of infants who had been given BCG vaccine at birth but did not develop BCG scar in contrast to the babies vaccinated in the clinics at a later time[2]. However, in our study; less than 1% of patients were given BCG vaccine at a later time.

There are controversies regarding revaccination of BCG. One suggests that repeated BCG vaccinations might be effective in asthma therapy[7]. Studies have shown that BCG vaccine protects leprosy [8]. However, repeat vaccination is not recommended by WHO as there is no evidence for the efficacy of BCG revaccination[9]. Furthermore, the formation of scar is not the only indication of success of BCG vaccine. However it is the only simple & convenient way of determining success of BCG vaccine. It may take 3-6 months for the scar to form. If no scar is visible at all after 6 months one should give repeat BCG[10,11]. Such vaccination can be restricted to children up to 5 years who are most vulnerable to miliary and meningial forms of tuberculosis [12]. In Sri Lanka, The National Programme for Tuberculosis Control and Chest Diseases recommends repeat vaccination in case of absent BCG scar[4]. In our study, a significant percentage of non revaccination was found, in case of absent BCG scar. Non revaccination was mainly associated with poor maternal education.

Conclusions and recommendations

A significant number of patients did not have a BCG scar after 6 months of age. A significant proportion of patients with absent BCG scar had been vaccinated in the non tertiary care hospitals. Larger scale studies are needed to confirm these findings. Majority of patients with absent BCG scars, had not been revaccinated. It is necessary to train the health staff in peripheral hospitals and educate mothers regarding BCG vaccination and scar.

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