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Original Article

Proper Bacillus Calmette-Guérin (BCG) Scar Formation and Administration in Children under 2 years in a Tertiary Care Hospital

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ABSTRACT

Background: Bacillus Calmette-Guérin (BCG) vaccine is considered to be one of the most crucial vaccines for the immunity of Tuberculosis (TB) in the pandemic and endemic areas. Dose is administered to the children under 5 years of age in the right deltoid area of the arm. It has been determined that the number of individuals who have scar formation are less susceptible to infections and diseases in their later life. In Pakistan there is a lack of data that determines the proper administration of the BCG vaccine with scar formation.

Methodology: A cross sectional study was conducted at Railway General Hospital, Rawalpindi for a period of 6 months from December 2019 to March 2020. Total number of 359 infants, less than 4 years of age were included in the study. Location and presence of BCG scar was noted and different questions regarding the Knowledge of the BCG vaccine administration, knowledge of mother regarding the BCG vaccine, her education and the scar site were included.

Results: Out of 359 infants, 90 percent (323 individuals) of the mothers had the information that they had to administer the injection. Among these 359 infants scar was found to be in around 78 percent (--280) of infants at the correct right deltoid muscle of the arm, whereas the remaining 22 percent (79 infants) had no scar or the scar formation was not in the right deltoid area, it was either in the right triceps or biceps of the body. Among these 22 percent infants the dose was found to be administered in biceps of 76 percent (--60) infants, in triceps around 9 (--7) percent and in the remaining 15 percent (--12) there was no scar formation.

Conclusion: Our finding suggests that most of the mothers are aware of BCG vaccination and the BCG is present and at the correct site for most children, however quite a few being unaware and having an improper or no scar raises a concern.

Key words: BCG vaccine, BCG Scar, Tuberculosis, Deltoid, Health care providers.

Introduction

Mycobacterium tuberculosis (Mtb), the pathogenic agent leading to tuberculosis (TB), is still a primary source of mortality and morbidity in underdeveloped countries. In the global context, TB is indirectly linked with poverty which leads to overburdening of a nation and control of TB is eventually a question of human rights. In some areas with a high burden of TB, existing strategies for TB control are currently overwhelmed by the rising numbers of cases of TB occurring in parallel with or the HIV/AIDS pandemic. Emerging mycobacterial drug resistance is further complicating the situation.

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After decades of steady decline, the incidence of TB is also increasing in industrialized countries, mainly as the result of outbreaks in particularly vulnerable groups[1].

According to a rough estimate in the next 25 years it can lead to a mortality of over 40 million people with major involvement of over 36 million only in the developing countries[2, 3]. To have a full grasp and eradicate this problem World Health Organization (WHO) has set guidelines and keep on reviewing them on regular basis for the early detection and accurate treatment strategies to eradicate this disease and keep it under control[4,5,6].

The Bacillus Calmette-Guérin (BCG) immunization protects against tuberculosis and other bacterial contaminations. Globally and in Pakistan BCG is the most commonly used vaccine[7, 8]. This vaccine is still administered globally to infants in over two-third countries of the World as basic component of

childhood immunization programme[9]. This vaccine comprises of live attenuated strains of Mycobacterium bovis and after intradermal administration the BCG vaccine induces a localized immune response[10]. This reaction pathologically results in an ulcer formation that requires a few weeks to heal thus leaving a permanent indented scar at the site of injection[11, 12]. It is also inferred that skin lesions obey simple dose-response functions; if the amount of vaccination is halved, the scar size will be reduced by about 1 mm[13, 14, 15]. In addition, low viability vaccines result in smaller scars than high viability vaccines[16].

In Pakistan there is reemergence of Tuberculosis again due to unknown reasons[17, 18]. After the persistent and continuous efforts of multiple governments and WHO this disease was about to be eradicated from Pakistan but the cases are again increasing despite being an important component in the Extended Program of Immunization (EPI) [19,20].

Tuberculosis (TB) is considered to be a grave public health issue and BCG immunization continues to be an important part of tuberculosis prevention strategies, especially in children[21]. BCG scarring is an indirect marker for vaccination and an important indicator of immunization program[22]. Despite all this, scar absence ranges in around one fourth of the infants in the world[23, 24]. In different studies, there are also significant differences in tuberculin conversion after BCG vaccination. In addition to protection from severe forms of tuberculosis, BCG also has a beneficial effect on the survival of children who are not associated with tuberculosis[25]. Studies suggesting an association between BCG scarring and reduced infant mortality in underdeveloped nations have revitalized the importance of BCG scarring[26]. It remains unclear how much scar damage is true and whether scar-negative babies need to be monitored[27, 28].

Material and Methods

This cross-sectional study was conducted in the immunization unit of the Railway General Hospital after being approved by the Ethical Review Board. Our study population included infants who presented in the immunization unit from 1st December 2019 to 31st March 2020. Only subjects whose parents agreed to participate in the study were recruited. A total number of 359 cases were selectively included in the sampling experiment.

Premature babies, babies whose weight was less than 2 kg, babies infected with HIV, families with tuberculosis or current medical conditions were excluded from the study. All study subjects received 0.1 ml of BCG by a single trained nurse on the right arm just above the deltoid intradermal injection with a 26-gauge needle and tuberculin tube .All immunized babies were visually tested for the presence of BCG lesion by one of the investigators. At the same time, the baby was administered oral polio and hepatitis B vaccination according to the Extended Programme of Immunization Schedule (EPI). The data was collected for the purposive study by asking a set of different questions from the mothers of the infants and also determining the size, site and location of the BCG scar in the infants. The mother was asked about her own education, her knowledge of prior vaccination to their child and its related information. Then with informed consent the size, site and location of the scar was analyzed for the study.

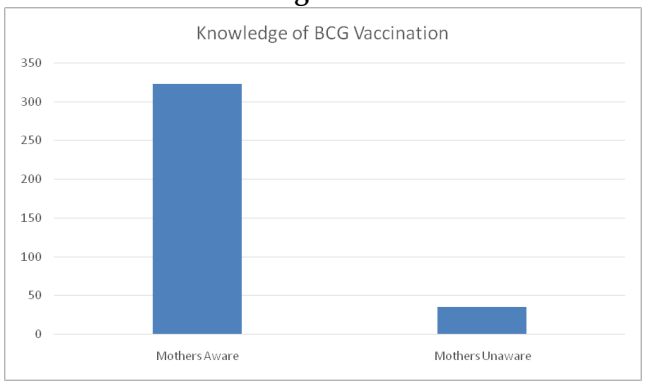
Limitations

Indicators of the BCG scarring were BCG vaccine administration, intradermal injection route, size of injection wheal

Results

The results were very interesting in the sense that the total number of infants that were included in the study was 359 infants who came for the regular vaccination in the vaccination center of the tertiary hospital. Among these 90 percent (323 individuals) of the mothers had the information and knowledge about the administration of the injection to their baby (Fig 1).

Fig 1- Comparison of BCG Vaccination knowledge among mothers



From total 359 infants the scar was found to be present in 78 percent (280 infants) at the correct right deltoid muscle of the arm, whereas the remaining 22 percent (79 infants) had either no scar or the scar was in the

triceps or biceps of the body. On further evaluation among these 22 percent infants the dose was found to be administered in biceps of 76 percent (60 infants), in triceps around 9 percent (7 individuals) and in the remaining 15 percent (12 individuals) there was no scar formation due to the vaccination in the arm (Fig 2) (Table 1).

Table 1 – Location and presence of the BCG Scar

BCG Scar	Number of babies	Percentage of babies %
BCG scar present & at right site	280	**77.9**
BCG scar present but not at correct site	67	18.6
BCG Scar Absent	12	3.34

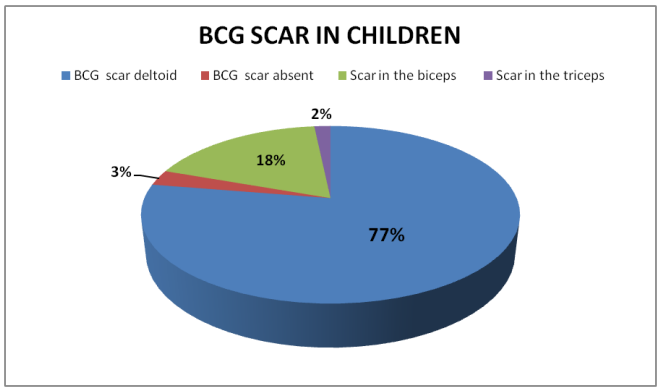


Fig 2 - Continuous variables were summarized using a pie chart

Discussion

As much research has been done in the past, the TB burden remains high in developing countries and BCG vaccination remains an important arsenal in the prevention of severe childhood TB[29]. It is one of the oldest and most commonly used vaccines despite the controversy surrounding it. BCG is generally considered to be protective against various forms of tuberculosis in infants and young children. According to WHO recommendations, the BCG vaccine should be given as soon as possible after birth and before one month of age for maximum protection.

. The BCG vaccines besides other vaccines of Extended Program of Immunization (EPI) are distributed all over Pakistan by World Health Organization (WHO) under program of EPI. All cold chain precautions are maintained by the vaccination centers of the hospital and a regular check and balance is maintained.

There is still lack of studies which suggest the protective efficacy of BCG vaccine against tuberculosis. The presence of a scar is thought to be the best sign of a successful vaccination and we used scars to confirm vaccination in our study.

The BCG vaccines has been in practice by the developed nations since 1950s but in a few countries like United States of America (USA) and Netherlands have not inculcated BCG vaccine in national scale. This can be one of the reasons studies now show reemergence of TB in the West[30].

Especially in Pakistan and generally in other developing Countries the mortality rate due to TB is very high. This is due to factors like poor health education, low socioeconomic status, over population, non-compliance and drug resistance (Unanue ER, 1983). To overcome this we need to educate the people in our community provide them with free health facilities like Health Cards so that the medical facilities are provided to everyone irrespective of their class. Besides educating the people we also need to train our health care providers as in my study we have seen that around 22 percent of the total dose administrations were not properly administered. This can be overcome if we train our healthcare providers on regular basis and keep a follow up on the infants who come for vaccinations. All these conditions are also the cause of poor governmental vision that prevails in the country like for example in the time of Covid, the living standards of people went down drastically that lead to their compromise in basic health facilities.

In another study in 2018 by Petra Zimmermann and et al, it was explained that the number of individuals who were taken into study and who lagged the scar for BCG vaccine were revaccinated and the recurrence of disease with mycobacterium species was reduces to more than half as compared to infants with a single dose of BCG who lacked the scar. This practice should also be followed in the developing countries so the disease of TB on which we have spent so much time and money should not go in vain and this disease should not emerge[31].

Although the exact depth of scar failure or the children who lack scar formation of BCG is still undetermined whether it is linked to disease or mortality in later life but one point that is very evident and it cannot be emphasized more is that, there is strong association between the presences of BCG scar with decreased childhood death and disease rate.

Competing interests

The authors of the study have no conflict of interest.

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A. Conception/Study/Designing/Planning
B. Active Participation in Active Methodology
C. Interpretation/ Analysis and Discussion