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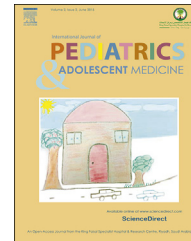


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ORIGINAL RESEARCH ARTICLE

BCG related complications: A single center, prospective observational study



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Abstract *Background and objectives:* Although the BCG vaccine is usually a safe vaccine, a number of complications can occur, such as adverse local reactions, regional lymphadenitis, osteomyelitis and disseminated infection in immunocompromised children, with lymphadenitis being the most common complication. Our objective to describe the associated clinical characteristics and outcomes.

Materials and methods: This was a prospective observational study conducted over two year's period.

Results: 100 patients were enrolled with (62%) males and (38%) females. 93 cases (93%) have nodes involvement with a total of 103 nodes was reported as follow: Axillary, supraclavicle, cervical with number of 75(72.8%), 23(22.3%), 5(4.9%) respectively. (55.3%) resulted in suppuration, and (44.7%) with non-suppurative. Only 3 cases (3%) had severe disease with dissemination, (88.3%) had small size nodes (< 3 cm), and (11.7%) with large size nodes (>3 cm). (88%) had self-limited disease, and node disappears between (8–168 weeks).

Conclusion: In the Majority of BCG related lymphadenitis is a benign condition with spontaneous healing. Also there is Increase incidence of association between BCG vaccine and serious disseminated infections in immunodeficiency cases.

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1. Introduction

Bacillus Calmette–Guerin (BCG) is a live attenuated vaccine derived from a strain of *Mycobacterium bovis* with a characteristics residual virulence, has been used to prevent tuberculosis since 1921 [1].

The World Health Organization (WHO) has recommended BCG vaccination as part of the global Expanded Program for

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Immunization (EPI). Since Saudi Arabia has an annual tuberculosis (TB) incidence rate of 15 cases/100,000 people, the national immunization Program still includes neonatal BCG vaccination [2]. As of to date the BCG vaccine strain which is use to vaccinate babies in Saudi Arabia is Dannish Strain. Although the BCG vaccine is usually a safe vaccine, a number of complications can occur, such as adverse local reactions, regional lymphadenitis, osteomyelitis and disseminated infection in immunocompromised children, with lymphadenitis being the most common complications [3].

We conducted this study to describe children with BCG vaccine related complications and highlight their presentation, course and treatment options.

2. Materials and methods

This study was conducted at King Fahad Medical City –Children’s Specialized Hospital, Riyadh. The hospital provides all levels of care for Riyadh City region as well as a referral center from all over the Kingdom of Saudi Arabia. All children who were referred to pediatric infectious disease clinics with any BCG vaccine complications were enrolled, date included between June 2011 and June 2013. All children had received the same type of vaccine (Danish strain) at birth administered intradermally at the governmental Centers. We used a standardized case report form with different variables. And all patients were followed prospectively till one year from their initial presentation with documented progress.

Data were presented as numbers (percentages), and median [minimum – maximum].

3. Results

A total of 100 children referred to infectious diseases Clinics as case of BCG vaccine related complications. Of whom 62 children (62%) were males and 38 (38%) were females (Table 1). (92%) were immunocompetent while only 8% were immunocompromised: 4 (4%) IL12 deficiency, 2 (2%) CGD, 1 (1%) SCID, 1 (1%) HIV, respectively.

Table 1 Children characteristics (No: 100 children).

Gender: number (%)	
Male	62 (62)
Female	38 (38)
Median age at starting symptoms (weeks)	8 [3–46]
Median age at presentation (weeks)	16 [6–48]
Type of complication: number (%)	
Regional lymphadenitis	90 (90)
Disseminated (BCG iosis)	3 (3)
Local reaction (ulcer, discharge, abscess)	7 (7)
Immune status: number (%)	
Immunocompetent	92 (92)
Immunocompromised	8 (8)

Data are presented as number (%) and median [minimum–maximum].

Age at observed symptoms ranged between 3 and 46 weeks with a median of 8 weeks. While the time of initial presentation to the hospital was (6–48) weeks with a median of 16 weeks. 93 children (93%) have nodes involvement with a total of 103 nodes was reported as follow: Axillary, supraclavicle, cervical with number of 75 (72.8%), 23 (22.3%), 5 (4.9%) respectively. 91 (88.3%) of the nodes had small size (< 3 cm) while 12 nodes (11.8%) with large size (>3 cm).

57 cases (55.3%) resulted in suppuration, of which 50 cases (87.7%) the abscess ruptured, of which 2 (4%) complicated by superimposed bacterial infection. 46 cases (44.7%) were non suppurative lymphadenitis (Table 2). Node disappears between (8–168 weeks) with a median of 32 weeks. Delayed nodes healing was mostly observed in immunocompromised children.

Out of the 100 children; 16 (16%) have local reaction at BCG site in form of discharge scars or subcutaneous abscess or ulceration, Nine of them with associated lymph node and seven with only local complications. and 3 (3%) had severe disease with dissemination (BCGiosis) (Table 1), and all were immunocompromised with Interleukin-12 (IL 12) deficiency disease.

The treatment given for these children was assisted as follow: 84 children (84%) had no treatment due to self-limited disease, while 16 (16%) end with treatment as follow: 11 (9%) with antituberculus treatment, 2 (2%) with surgical intervention, and 3 (3%) with both medical and surgical intervention.

4. Discussion

In this study, we explored a common but relatively under recognized problem of post BCG lymphadenopathy.

Post BCG vaccination complications are well recognized [4]. Mild adverse reactions are considered as part of the normal reaction [4]. The reported incidence of these events worldwide is 0.1–17% [5].

The explanation is not fully clear for the noted increase in BCG related complications [6,7]. The frequency of the lymphadenitis after vaccination correlates with the type of vaccine used. Teo et al [8] had demonstrated an increase in the incidence of lymphadenitis after the introduction of Danish strain (SSI) type in the United Kingdom. Using this

Table 2 Node characteristics (No: 103 nodes).

Node involved: number (%)	
Axillary	75 (72.8)
Supraclavicle	23 (22.3)
Cervicle	5 (4.9)
Type of the node complication: number (%)	
Suppurative	57 (55.3)
Ruptured	50 (87.7)
Non ruptured	7 (12.3)
Non suppurative	46 (44.7)
Disseminated (BCG iosis)	3 (3)
Local reaction (ulcer, discharge, abscess)	16 (16)
Size of the node: number (%)	
<3 cm	91 (88.3)
>3 cm	12 (11.7)

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