# **ORIGINAL ARTICLE**

# Post BCG Vaccination Lymphadenitis Management: Experience at KFH Hospital Albaha, KSA

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#### ABSTRACT

Aim: To collect the data and assess the outcome of management of post BCG vaccination

lymphadenitis.

Study design: Prospective observational.

Study Duration: One year

Inclusion criteria: Patients coming in follow up till the resolution of lymphadenopathy were included in

the study.

**Exclusion criteria:** Patients with incomplete follow up were excluded from the study.

**Material and methods:** In a prospective observational study medical record of 48 patients presented in outpatient department of pediatric surgery during one year from 1<sup>st</sup> July 2011 to30 June 2012 was maintained on a detailed proforma. Twenty five patients presented with suppurative lymphadenitis and twenty three with non suppurative lymphadenitis. Thirty two patients (66.66%) were followed up without any treatment except aspiration if needed. Fourteen (29.16%) patients with acid fast bacilli culture positive were given INH treatment for three months. Two patients (4.16%) were added on rifampicin due to nonresponse to INH only.

**Results:** Thirty one were males and seventeen were females. Left axilla was involved in 36(75%) patients followed by supraclavicular region. All patients have good outcome resulting in resolution of lymphadenopathy in 2 to 4 month follow up period. Nine out of 48 patients are still on follow up and improving. Surgical excision was not required at all in our study.

**Conclusion:** Post BCG vaccination lymphadenitis is significant cause of morbidity in infant, incidence of which is relatively more in KSA. Majority of patients can be managed by reassurance and counseling to parents, with needle aspiration and follow up. There is no role of surgery or antibiotics in these cases except proven acid fast bacilli culture.

Key words: BCGitis, Management, Outcome

## INTRODUCTION

Bacillus calmeete-Guerin is alive attenuated vaccine which is recommended by WHO as a part of global expanded program of immunization. Itis a safe vaccine but it can lead to lymphadenitis which may be suppurative and nonsuppurative. There are lot of controversies about management of lymphadenitis. In this study we are presenting our one year experience of post BCG vaccination lymphadenitisstarting from 1<sup>st</sup> July 2011 to 30<sup>th</sup> June 2012 at King Fahad Hospital Albaha. All the patients with post BCG vaccination lymphadenitis which were referred to pediatric surgical outpatient departmentand followed up completely during this period were included in the study. The emphasis is on consensus about management protocol, how can we reduce these complications and role of surgery if it is needed or not.

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#### MATERIALS AND METHODS

This is observational prospective study. Medical record of all patients presenting from 1<sup>st</sup> July 2011 to 30<sup>th</sup> June 2012 at outpatient department of pediatric surgery KFH Albaha was maintained on detailed proforma especially emphasizing on age, sex, mode clinical presentation, sites, hematological, microbiological investigations, mountoux test, chest radiograph, treatment and outcome Forty eight patients presented during this period, 9 out of 48 are still on treatment or follow up .Twenty five patients presented with suppurative lymphadenitis and twenty three with non suppurative lymphadenitis. Almost all patients were full term and not having any known immunodeficiency disorder. Males were predominant and age ranging from less than one month to more than one year. All patients with suppurative lymphadenitis having acid fast bacilli culture positive on aspiration were put on INH treatment for three monthand with negative cultures were observed in follow up without any treatment or 2<sup>nd</sup> aspiration if needed. Patients with non suppurative but having erythematous skin changes were kept in follow-up

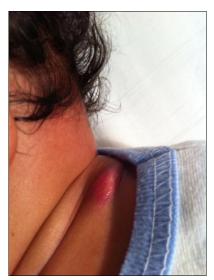
without any treatment and were given treatment with INH only if swelling size was increasing rapidly. Those with non suppurative lymphadenitis without any skin changes were observed in follow up without any treatment. (See algorithm). All patients were followed until improvement.

#### **RESULTS**

A total of 48 patients with post BCG lymphadenitis were managed in pediatric surgery outpatient department. Thirty one (64.58%) was males and seventeen (35.41%) were females (Table1). Majority (52.08%) of patients presented at age ranging from 1 to 4 months (Table 2). Most common site of involvement was left axilla (75%) followed by left supraclavicular region (Table 3). At the time of presentation twenty three patients(47.91%) have non suppurative lymphadenitis (without skin changes n-18 with skin changes, n-8) and twenty five patients (52.08%) have suppurative lymphadenitis(Table 4). In suppurative cases fine needle aspiration done and pus sent for acid fast bacilli culture which was positive in 11 cases and negative in 14 cases (Table 5).Fourteen patients (29.16%) received INH treatment for three months; two patients were put on rifampicin+ INH due to non-response to INH. Thirty two patients (66.66%) were followed up without any treatment (Table5). All patients were under monthly follow up and showed resolution of lymphadenitis in 2 to 4 month follow up period. Nine patients are still under follow-up. Chest-Ray, mountouxt test and hematological investigations were not helpful.



Nonsuppurative lymphadenitis in axilla



Suppurative lymphadenitis in supraclavicular area

Table 1: Sex distribution

Gender	n=	%age
Male	31	64.58
Female	17	35.41

Table 2: Age distribution

Age	n=	%age
< one month	4	8.33
1-4 month	25	52.08
> 4-7 month	14	29.16
7-12 months	4	8.33
> 12 month	1	2.08

Table 3: Sites of lymphadenitis

Site	n=	%age
Left axilla	36	75
Left supraclavicular	8	16.66
Left upper armleft axilla	4	8.33

Table 4: Type of lymphadenitis

Types	n=	%age
Suppurative	25	52.08
AFB+ve	11	22.91
AFB-ve	14	29.16
Non suppurative (without skin changes 15 &with skin changes 8)	23	47.91

Table 5: Treatment

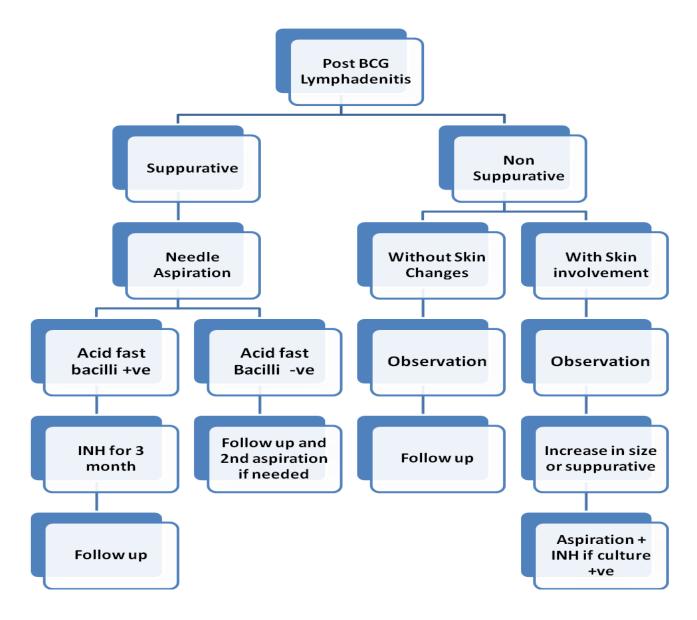
Types of treatment	n=	%age
Observation	32	66.66
INH (ISONIAZIDE)	14	29.16
Rifampicin+INH	2	4.16

Table 6: Types of Intervention

Intervention	n=	%age
Fine needle aspiration	25	52,08
No intervention	23	47.19

# **ORIGINAL ARTICLE**

Algorithm of Management of Post BCG Vaccination Lymphadenitis (Based on our experience)



# **DISCUSSION**

BCG vaccination can lead to swelling at site of vaccination followed by regional lymphadenopathy which is usually self-limiting and needs no treatment. Timing of normal reaction after BCG vaccination may varies from 2 weeks to eight weeks and it may be delayed up to eight month and even more. Excessive reaction to BCG vaccination may lead to suppurative lymphadenitis which may need aspiration and may result in sinus or fistula formation if not treated properly and timely. We did not find any patient with sinus or fistula formation which may be due to early presentation and management with aspiration. The advantage of needle aspiration is

prevention of spontaneous perforation and sinus formation<sup>3</sup>.

We encountered 48 cases of post BCG lymphadenitis in one year period which is relatively higher than studies from other countries What is the reason for increase number in our country, it is still a question mark .Pathogenesis of lymphadenitis has been attributed to various factors in literature such as age of child, technique of vaccination, BCG strain, dose, patency, viability, immunogenicity of vaccine and prior exposure to mycobacterium antigen<sup>4</sup>. Study done in King Saud University concluded that change of strain of BCG vaccine (BCGSSI strain) has

contributed to increase incidence of lymphadenitis<sup>5</sup>. Zafar et al has reported 43 cases of post BCG lymphadenitis in 3 years period<sup>6</sup>. A study from Medina Saudi Arabia has described 156 patients of lymphadenitis in 4 years period<sup>7</sup>. In our study majority (52.08%) of patients presented between one month and four month of age which is comparable with study from Iran in which 53% patients presented between during 1 to 4 month of age<sup>8</sup>. Age at the time of presentation ranged from 2 to 9 month in a study by Abdul Hameed F et al<sup>7</sup>. In a study by Zafar Nazir and Sagib Hamid the most of the cases presented within 8 weeks and few cases developed lymphadenitis even 1 to 5 years after vaccination<sup>6</sup>. We also have one case who presented at 2 year of age. The studies on these children failed to demonstrate significant nutritional or immune deficiency. Our patients were mostly full term and not having any known immune deficiency disorders. In our study males were predominant (64.58%). In a study from Iran there was no statistically significance difference between male and female gender<sup>8</sup>. Lymphadenitis usually occurs in axilla of vaccination side but may involve supraclavicular region if BCG vaccine is given relatively more in superior part of deltoid3. We found left axilla to be most common site (75%) followed by left supraclavicular region which is comparable with study by bdulhameed F D et al and Zafar Nazir et al<sup>6</sup>. We managed 25 cases of suppurative lymphadenitis and 23 cases of non suppurative lymphadenitis (Figure 1 & 2). Out of nonsuppurative cases 15 were without skin changes and 8 were with skin changes(table4).Incidence of suppurative lymphadenitis was also higher in Korea(41.2%)<sup>10</sup> and Zimbabwe(62%)<sup>11</sup>. But low incidence of suppurative lymphadenitis has been reported in Hamadan Iran (0.54%)<sup>12</sup>. Brazil (0.3%)<sup>1</sup> South Africa  $(0.18\%)^{14}$  and Turkey  $(0.3\%)^{15}$ . According to another study suppurative lymphadenitis develops in 30% to 80% cases<sup>16</sup>

There are different protocols mentioned for management of post vaccination BCG lymphadenitis, from no treatment to medical and surgical treatment <sup>17</sup>.We managed non suppurative lymphadenitis and suppurative with negative culture report for acid fast bacilli (66.66%) with observation and follow-up only except that needle aspiration was repeated in some cases (see Algorithm). Suppurative cases with positive acid fast bacilli culture (22.91%) were given INH treatment for 3 months only. Patients with nonsuppurative lymphadenitis were followed up without treatment but put on INH treatment if size of swelling was increasing along with skin changes (see algorithm). According to one study medical treatment is effective only in early stage of disease 18. Another study describes that surgical excision is the treatment of choice for fluctuant enlarged lymph node<sup>19</sup>.No surgery was required even in a single case in our study. Majority (66.66%) of patients improved with observation and needle aspiration only.

## CONCLUSION

We BCG conclude that post vaccination lymphadenitis is significant cause of morbidity in infants, the number of which is increasing especially in KSA. Majority of patients can be managed with reassurance and counseling with the parents, needle aspiration and follow-up. There is no role of antibiotics or surgery in these cases except INH which may be given in acid fast bacilli culture positive patients to fasten the rate of recovery. There is need of ametaanalytical study in KSA to find etiological factors to prevent this disease and make a uniform protocol for management of post BCG lymphadenitis so that morbidity can be reduced in such cases.

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