Complications from BCG Vaccination

BCG vaccine is comparatively safe vaccine. The rate of adverse reactions following BCG immunizations is low [5, 6]. Local reaction (erythema, induration, papule formation, abscess and discharging ulcer), regional lymphadenopathy, soft tissue granulomas, disseminated disease and osteomyelitis are the various complications associated with it. Out of these BCG adenitis and local reactions are the commonest. [7-9]. Serious complications like disseminated disease are mainly seen in immunocompromised states [10-12]. Commonly affected lymph nodes in BCG lymphadenitis are Ipsilateral axillary, supraclavicular and lower cervical lymph node group. There are two types of lymphadenitis associated with BCG vaccine [13, 14]. First is nonsuppurative type, with benign course and spontaneous resolution within few weeks. (Figure) [15]. Second is suppurrative type which has signs of suppuration and if left untreated, it ill rupture and require local care and there may be secondary bacterial infection and scar formation [16].

Materials and methods:

This analytic prospective follow up study was conducted over a period of 5 years from 2011 to 2016, in a tertiary care centre. During the first 2 year of the study all the 13 children who presented to us with BCG adenitis were enrolled as cases after getting consent from the parents. There were 8 male and 5 female patients. BCG lymphadenitis was diagnosed based on the following criteria: isolated axillary or supraclavicular lymph node enlargement, BCG vaccination on the ipsilateral arm and the absence of local or systemic signs of inflammation [17]. At enrolment details of each case were recorded which included epidemiological data, vaccination dataanthropometry, general physical, systemic (including features of active tuberculosis) and local examination (Table 1). In local examination details of BCG adenitis including age at vaccination, appearance of lymph node, size of swelling, time interval for complete resolution of lymphadenitis, and there may be secondary bacterial infection and scar formation [16].

Results:

Children with spontaneous rupture took minimum time duration...... for regression of lymph node and those who underwent to needle aspiration took the maximum time. However those who had spontaneous rupture required local wound care for 1-3 months. None of the patient developed any clinical features suggestive of active tuberculosis during the followup.

Conclusion:

So we recommend close clinical follow up for active tuberculosis and conservative management only.

Objectives:

To study the effectiveness of various modalities of BCG lymphadenitis management of Bacillus Calmette-Guérin (BCG) Lymphadenitis.

Methods:

This study was conducted at tertiary care centre in Himachal Pradesh, over a period of 5 years. 13 children in the age group presenting to were divided into 3 categories, Group 1 6 cases, who had firm swelling of Nodes and were subjected to no intervention. Group 2 had 4 children with fluctuant swelling and underwent needle aspiration. There were 4 children in group 3, who had self rupture, and managed with local care. Children in all the categories were followed every 3 months during first year or till the regression/ healing of BCG lymphadenitis and every 6 monthly there after till the end of study. All the subjects were followed for the development clinically for active tubercular disease.

Results:

Children with spontaneous rupture took minimum time duration...... for regression of lymph node and those who underwent to needle aspiration took the maximum time. However those who had spontaneous rupture required local wound care for 1-3 months. None of the patient developed any clinical features suggestive of active tuberculosis during the followup. Therefore children with spontaneous rupture were followed till duration 3 months.

Conclusion:

So we recommend close clinical follow up for active tuberculosis and conservative management only.

**ABSTRACT**

Objectives: To study the effectiveness of various modalities of BCG lymphadenitis management of Bacillus Calmette-Guérin (BCG) Lymphadenitis.

Methods: This study was conducted at tertiary care centre in Himachal Pradesh, over a period of 5 years. 13 children in the age group presenting to were divided into 3 categories, Group 1 6 cases, who had firm swelling of Nodes and were subjected to no intervention. Group 2 had 4 children with fluctuant swelling and underwent needle aspiration. There were 4 children in group 3, who had self rupture, and managed with local care. Children in all the categories were followed every 3 months during first year or till the regression/ healing of BCG lymphadenitis and every 6 monthly there after till the end of study. All the subjects were followed for the development clinically for active tubercular disease.

Results: Children with spontaneous rupture took minimum time duration...... for regression of lymph node and those who underwent to needle aspiration took the maximum time. However those who had spontaneous rupture required local wound care for 1-3 months. None of the patient developed any clinical features suggestive of active tuberculosis during the followup.

Conclusion: So we recommend close clinical follow up for active tuberculosis and conservative management only.

**KEYWORDS:** Bacillus Calmette-Guérin: lymphadenitis; management

**Introduction**

BCG lymphadenitis is not a uncommon problem in paediatric age group. It has incidence of 100 to 1000 cases per million vaccinations[1]. It is a cause of concern to the parents and treatment dilemma for the treating doctor. Literature suggests different types of treatment modalities for managing it. There is no consensus regarding its management weather to do active intervention like needle aspiration, incision drainage, excision or conservative management. It is a common practice to investigate the child with BCG lymphadenitis for active tuberculosis. Our aim is to find the effectiveness of various modalities of BCG lymphadenitis management. We will also study the effectiveness of clinical observation for active tuberculosis. Child will only be investigated if any clinical features of active tuberculosis appear.

Bacillus Calmette-Guérin (BCG) is a live attenuated vaccine which mainly prevents the severe form of childhood tuberculosis, routinely administered at birth as part of the World Health Organization global expanded immunisation programme. It is a live attenuated vaccine derived from Mycobacterium bovis. It is named after French bacteriologist Albert Calmette and veterinarian Camille Guérin. [2]. In August 1948, the first BCG vaccinations were conducted in India. The work on BCG had started in India as a pilot project in two centres in 1948. In 1949, the BCG vaccination was extended to schools in almost all States of India [3]. With the expanded immunisation programme and since 1985 the universal programme of immunisation, the coverage status of BCG vaccination in India has been very good [4].
months) underwent spontaneous regression and when interval early appearance of lymph node after BCG vaccination (mean 3.66 supraclavicular and axillary lymphadenitis [18]. Children who had 92.3% of axillary, 3.8% supraclavicular and 3.8% with both involvement. Cases were categorized in three groups as already mentioned. First group had 6 cases, 2nd and 3rd group had 3 and 4 cases respectively. Average interval between BCG vaccination and appearance of swelling was mean 3.66 months, 7 months and 6.4 months in 1st, 2nd and 3rd group respectively. None of the cases had signs of inflammation at presentation or during follow up. Almost half of the cases (46%) settled spontaneously and mean time taken for complete resolution in them was 8 months. Needle aspiration done in 23% of children, spontaneous rupture occurred in 31% of the children and they took average 11 months and 6.7 months for complete resolution respectively. Though the fluctuation settled immediately after aspiration in the 2nd group but complete resolution of lymph node took longer time and needed no repeat aspiration. One child in group 2 developed sinus after aspiration which healed within next 3 months. At presentation as well as at follow up all the cases were clinically scrutinized actively for tuberculosis. None were found to have any clinical features of tuberculosis. Each child followed its centile on height and weight parameters at subsequent visits.

Discussion:
Our study group had solitary left axillary lymphadenopathy in 76.9% children, left supraclavicular in 15.4% while 1 (7.6%) child had both left supraclavicular and left axillary lymphadenopathy these results were comparable to study by Mostafa behjati from Iran who reported 92.3% of axillary, 3.8% supraclavicular and 3.8% with both supraclavicular and axillary lymphadenitis [18]. Children who had early appearance of lymph node after BCG vaccination (mean 3.66 months) underwent spontaneous regression and when interval between BCG vaccination and appearance of lymph node was longer, they require needle aspiration (mean 7 months) or spontaneous rupture (6.4 months). Majority of the children in our study group had BCG adenitis with no features of suppuration and settled spontaneously with mean period of 8 months. 23% of children had BCG adenitis with fluctuation and were subjected to needle aspiration and mean time taken for resolution with minimal scarring was 11 months. 31% of children had spontaneous rupture of their lymph nodes and it took mean period of 6.7 months for resolution in them. Out of 3 groups, children who had spontaneous rupture, took minimum time for resolution but they had unsightly discharging wound, which required frequent hospital visits for 1 to 3 months for local wound care. The children in the second group who underwent needle aspiration took longest period with mean of 11 months for the resolution of the lymph node although the fluctuation settled in them immediately after aspiration. First group who had spontaneous resolution took intermediate period for resolution with mean of 7.8 months. Investigations for active tuberculosis were to be planned in only those children who had clinical features of active tuberculosis. None of the children had clinical evidence of active tuberculosis at presentation or follow up of 3 to 5 years, hence they were not subjected to any investigations. There was no significant difference in the scar size among the children in second and third group.

Conclusion
We suggest close follow up without any active intervention for the children with BCG lymphadenitis along with reassurance and effective counselling of the care takers regarding the disease condition. Any child presenting with BCG adenitis, need not to be investigated for active tuberculosis unless there are features suggesting of it. A drawback of our study was the small study group. So further large trials are needed, before giving the general recommendations.

Table: Details and outcome of children with BCG adenitis

<table>
<thead>
<tr>
<th>Group</th>
<th>Total/ Mean</th>
<th>Axillary (%)</th>
<th>Supraclavicular (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>6(46)</td>
<td>8</td>
<td>3.7</td>
</tr>
<tr>
<td>II</td>
<td>10</td>
<td>7.0</td>
<td>2.8X2.8</td>
</tr>
<tr>
<td>III</td>
<td>10</td>
<td>6.0</td>
<td>3.0X3.0</td>
</tr>
<tr>
<td>Total</td>
<td>18(100)</td>
<td>9.33</td>
<td>5.7</td>
</tr>
<tr>
<td></td>
<td>10(76.9)</td>
<td>2.7X2.7</td>
<td>10(76.9)</td>
</tr>
</tbody>
</table>

Discussion
Our study group had solitary left axillary lymphadenopathy in 76.9% children, left supraclavicular in 15.4% while 1 (7.6%) child had both left supraclavicular and left axillary lymphadenopathy these results were comparable to study by Mostafa behjati from Iran who reported 92.3% of axillary, 3.8% supraclavicular and 3.8% with both supraclavicular and axillary lymphadenitis [18]. Children who had early appearance of lymph node after BCG vaccination (mean 3.66 months) underwent spontaneous regression and when interval
References


3. Madras: Tamil Nadu State Archive, Health Department, no. 809, 1950. Undated press note (but the note is accompanied by a covering letter dated 28 May 1948)

4. Udani PM


