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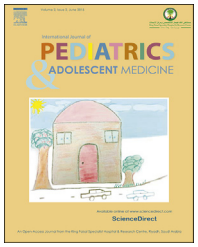

CLINICAL PRACTICE GUIDELINES

Bacillus Calmette—Guérin vaccine related lymphadenitis in children: Management guidelines endorsed by the Saudi Pediatric Infectious Diseases Society (SPIDS)

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Abstract The Bacillus Calmette—Guérin (BCG) vaccine contains live attenuated *Mycobacterium bovis*; was first used in humans to prevent tuberculosis (TB) in 1921. The World Health Organization (WHO) established the Expanded Program on Immunization in 1974 to ensure that all children have access to routinely recommended vaccines including BCG. Each year 120 million doses of BCG vaccine are administered worldwide. Intradermal BCG vaccine gives rise

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Disseminated BCG infection;
Guidelines

to a classic primary complex that consists of a cutaneous nodule at the site of injection and subclinical involvement of the regional lymph nodes, which is self-limiting and requires no treatment.

However, ipsilateral regional lymph node enlargement may follow BCG vaccine and is considered as the most common complication, some progress to suppuration. Rarely a disseminated BCG infection may develop in immunocompromised individuals resulting in a devastating outcome. Within the last decades, variable strategies have been applied in treating lymphadenitis related to BCG vaccine, ranging from observation, anti-mycobacterial therapy, aspiration, incision and drainage to lymph node surgical excision.

We are presenting these guidelines that intended to optimize and standardize management of various types of BCG related lymph adenitis in children. They are based upon the best available evidence in literature beside our experience in this field.

1. Purpose of the guidelines

To standardize a clinical practice for classification and management of BCG related lymphadenitis in children, extrapolated from the relevant literature besides our accumulative experience in this field, through evaluation of benefits and harms of alternative care options. These guidelines intended to provide an outcome with maximum benefits and minimum risks, reduce the inappropriate variation in clinical practice, eliminate the unnecessary interventions, promote efficient use of resources and support the decision making processes for the best interest of children presenting with BCG related lymphadenitis.

2. Introduction

BCG vaccine developed by Albert Calmette and Camille Guerin in France between 1908 and 1921 contained a live attenuated *Mycobacterium bovis*. Currently, there are multiple strains of BCG vaccines in use around the world produced by different manufacturers.

BCG is now used worldwide in childhood immunization programs with approximately 100 million newborns being vaccinated each year [1]. In Saudi Arabia, BCG was introduced initially for population at risks in 1964 and later for all newborns in 1970 [2].

Efficacies of BCG vaccines ranges from 0 to 80% in studies of different populations throughout the world [3]. The main role of the BCG vaccines is to protect vaccinees, especially infants and children against disseminated TB and tuberculous meningitis with an estimated efficacy of 78% and 64% respectively [4,5]. The current estimated incidence of TB in Saudi Arabia is 14/100,000 [6]. Globally the incidence of BCG adverse reaction differs between regions, ranging between 0.5—100 per 1000 vaccinations [7—9] with the most common presentation is regional lymphadenitis, mainly non-suppuartive lymphadenitis. A rare complication is a disseminated disease, in less than one in a million of vaccinated individuals [7,10].

In Saudi Arabia, a raised incidence in BCG related lymphadenitis from zero to 10.4 per 1000 vaccinations was linked to the introduction of the Danish strain(SSI 1331), currently in use since November 2005 [11], leading to more awareness about this complication [12] and raising the need to establish national guidelines with the best management approach and outcome.

3. Classification of BCG related lymphadenitis

The term BCG lymphadenitis applies when lymph node(s) have become large enough to be easily palpable and a cause of concern for the parents [13,14], likely with a diameter greater than or equal to 1 cm.

3.1. Regional BCG related lymphadenitis

The term regional lymphadenitis may apply when there is a BCG vaccine at one arm with ipsilateral regional lymph node(s) involvement. Laboratory and radiological investigations are not routinely recommended in a thriving child with unremarkable physical examination and no evidence of immunodeficiency in the family history.

The flowing features are in favor of regional BCG related lymphadenitis rather than other pathology [14—16]:

1) BCG vaccination at the ipsilateral arm.
2) Onset between 2 weeks and 6 months, most patients present within 2—4 months after BCG vaccination.
3) Child age not more than 2 years
4) Absence of systemic manifestations such as fever and weight loss.
5) Absence of tenderness over the lymph node(s).
6) Axillary lymph node is mostly involved, although supraclavicular or cervical may be involved in isolation or association with axillary lymphadenopathy.