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CASE REPORT

Local Cutaneous Complication after Bacilli Calmette-Guerin Vaccine: Unusual Location

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Background

Bacille Calmette-Guerin (BCG) vaccine may cause some cutaneous complications at the injection site. Their management is still unclear [1].

Thigh swelling is a symptom of various benign and malignant conditions. Differential diagnosis is not easy, particularly if the causative disorder has not previously been reported.

This case highlights the importance of considering BCG induced infection in the differential diagnosis of thigh swelling occurring in infants.

Case Reports

Patient 1

A 16-month-old healthy Tunisian girl presented with left thigh painful swelling that was noticed by her parents 13 months prior to presentation. The swelling slowly increased in size.

She had no past medical history and no history of trauma. There were no associated systemic signs or symptoms and no lymphadenopathy.

At presentation, there was a circular erythematous swollen area of 5 cm diameter with indurated margins (Figure 1). A needleaspiration of the lesion was performed and 5 ml pus was collected. Incision and drainage of the abscess were performed during the same procedure. A Gram stain and routine bacterial culture were negative. Because of the persistence of the lesion and the no improvement after needle aspiration and drainage, a surgical excision was conducted.

Histopathology revealed necrotising granulomas.

A chest X-ray and complete screening by a pediatrician did not reveal any abnormalities. Dermatological examination demonstrated the absence of skin scarring in the left upper arm above the deltoid muscle.

Based on the clinical features and the histology, the diagnosis BCG-itis was strongly suspected. No treatment with isoniazid or other antituberculosis drugs was considered to be required. A complete healing was observed within 2 months. No relapse has been observed after 12 months of follow-up.

Patient 2

A 5-months-old boy presented with an inflammatory lesion on her left thigh. He was in excellent general health, and there was no fever.

A skin examination revealed a 4-cm ulceration covered by a blackish crust with infiltrated edge (Figure 2). Lymph nodes were not enlarged. Further physical examination was unremarkable. Bacteriological skin samples were negative. After 4 days of 'watchful waiting' we noted a fistulization of the lesion. A skin biopsy was then performed. Histopathology revealed a normal epidermis with a mid-dermal necrotizing granulomatous reaction pattern with abundant histiocytes, there were no other inflammatory cells.

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Figure 1: A circular erythematous swollen area with indurated margins of the left thigh.

Figure 2: An ulceration covered by a blackish crust with infiltrated edge.

diagnosis BCG-itis was strongly suspected. No treatment with isoniazid or other antituberculosis drugs was considered to be required. The lesion was disinfected and treated by local application of antiseptics agents to prevent secondary bacterial infection. The lesion was completely cleared within 3 months. No relapse has been observed after 24 months of follow-up.

Discussion

Mycobacterium tuberculosis remains an important problem worldwide [2]. Especially in developing countries with a high incidence of tuberculosis. In Tunisia, as per World Health Organization recommendations, the BCG vaccine is given to all healthy neonates [3]. The technique involves the intradermal injection of 0.05 mL of the vaccine into the left upper arm. The type of vaccine administered in our country is M. bovis (French [Pasteur] strain 1173-P2). A correct intradermal BCG vaccination commonly leads to a local reaction at the site of the vaccination. Approximately 2 weeks after the vaccination, a small infiltrated papule develops at the injection site. After about 6-12 weeks this lesion attains

a size of about 10 mm, which then ulcerates and slowly heals with scarring [4].

Besides this normal reaction at the injection site, BCG vaccination may also cause several other cutaneous reactions. Adverse reactions arising from the use of BCG vaccine are reported in 1-10% of vaccines in literature but seem to be underreported [1].

Specific cutaneous reactions, as occurred in our patients, are caused by the attenuated M. bovis from the vaccine, and mimic true cutaneous tuberculosis caused by a 'natural' mycobacterial infection. This is called BCG-itis in existing literature [5].

In addition to ulceration and abscess formation, rare adverse reactions to BCG vaccination include keloid formation and regional lymphadenitis.

Localized abscesses without regional lymphadenopathy in immunocompetent hosts, such as our patients, are relatively uncommon [6].

Adverse reactions to BCG vaccine are usually seen within the first 6 months of vaccination but can occur even 12 months later [7].

The pathogenesis for developing an adverse reaction to BCG vaccination is not clear, and causes might include: subcutaneous application of the vaccine, number of viable bacilli, changes of strain in current immunization regimes [8], the type of the injected strain or the type of preparation [1,9]. The administration technique, and the underlying immunodeficiency [10,11] may also increase their frequency.

Thus, in the cases presented here, it is possible that abscess formation was the result of injection at a non-recommended site and/or subcutaneous, instead of intradermal, inoculation.

Differential diagnosis of a thigh swelling in an infant includes a number of different conditions ranging from a variety of infections to tumours.

Differential diagnosis with cutaneous tuberculosis is fundamental in patients from endemic areas.

The left thigh is a non-recommended site of BCG vaccine, so it is not easy for clinicians to diagnose any complication related to the administration of this vaccine in this location. Therefore, health professionals should consider BCG as possible cause of thigh swelling in infants. The clinical diagnosis must always be confirmed by histopathology and microbiological cultures.

In our hospital, BCG vaccine is given to all healthy newborns as soon as possible after birth intradermally in the left upper arm. At the same time, 0.5 mL of hepatitis B vaccine is injected intramuscularly in the left thigh. All these injections used to be given by one experienced nurse at the same time. A review of the medical records revealed that all of these infants were vaccinated by the same nurse. The only reasonable explanation is that the BCG vaccine was confused with the hepatitis B vaccine, and inadvertently injected intramuscularly into the left thigh instead of an intradermal administration into the left upper arm. The absence of skin scarring in the left upper arm above the deltoid muscle in our patients raised the possibility of inadvertent injection of the BCG vaccine intramuscularly into the left thigh instead of the intradermal administration into the left upper arm.

In our cases, A diagnosis of abscess caused by BCG was not suspected initially. However, histopathology was the key to establishing the final diagnosis in our patients.

Treatment of cutaneous complications after BCG vaccine is unclear. The majority of reactions to the vaccine are localized and self-limited, and in most cases observation for 4 - 6 months is usually sufficient [3].

There are variable recommendations for management of post BCG abscess and suppurative lymphadenitis. In literature anti-tuberculosis drugs are not recommended for routine treatment of local complications because of the low penetration of anti-tuberculosis drugs into the abscess cavity and pyrazinamide resistance of *M. bovis* strains [8,12]. Early drainage is recommended for abscess formation [8]. Needle aspiration is the management of choice, although this is not always effective [11]. Some authors suggest isoniazid injection after aspiration may be useful, but there are limited data in literature [8,13,14]. Finally, the management of BCG-induced abscess with erythromycin is highly controversial [15].

In our cases, no treatment with isoniazid or other antituberculosis drugs was considered to be required. In contrast to ours first case, the lesion did not resolve after needle aspiration and surgical excision was required, the second case was managed conservatively.

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