CASE REPORT

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Management of Bacille Calmette-Guérin Vaccine Adverse Event: Case Report

Bacille Calmette-Guérin Aşısı İstenmeyen Etki Yönetimi: Olgu Sunumu

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Abstract

Bacillus Calmette-Guérin (BCG) vaccine is used worldwide as an important preventive vaccine against tuberculosis. It is a safe vaccine with a low incidence of serious side effects. However, some adverse events may be observed. An 8-month and 6-day-old male infant was presented to the well-child clinic. The patient was vaccinated with BCG when he was two months old. Two months after the vaccination, an induration occurred on the left shoulder and persisted for approximately 5 mm in size. Over the past week, induration and redness had gradually increased, and one day before the presentation, it had grown outward with a small amount of pus. There was no accompanying lymphadenopathy. There were eczematous lesions on the trunk, arms and face. Immunodeficiency was excluded by medical history, physical examination and laboratory tests. Conservative treatment was preferred and it was observed to heal with scar formation in a short period.

Keywords: BCG, vaccine adverse event, vaccination

Öz

Bacillus Calmette-Guérin (BCG) aşısı tüm dünyada tüberkülozu önlemek için kullanılan önemli bir aşıdır. Ciddi yan etki insidansı düşük, güvenli bir aşıdır. Ancak bazı istenmeyen etkiler görülebilir. Sekiz ay 6 günlük erkek bebek, çocuk sağlığı izlem polikliniğine başvurdu. Olguya, iki aylıkken BCG aşısı yapılmıştı. Aşıdan iki ay sonra, sol omuzda yaklaşık 5 mm boyutunda bir endürasyon oluşmuştu. Son bir haftadır endürasyon ve kızarıklık giderek artmış ve başvurudan bir gün önce az miktarda irinle birlikte dışarı doğru büyümüştü. Eşlik eden lenfadenopati yoktu. Gövde, kollar ve yüzde ekzematöz lezyonları vardı. Anamnez, fizik muayene ve laboratuvar testleri ile immün yetmezlik dışlandı. Konservatif tedavi tercih edildi ve kısa sürede skar oluşturarak iyileştiği görüldü.

Anahtar kelimeler: Aşı istenmeyen etki, aşılama, BCG

Introduction

Despite being a preventable and curable disease, 1.5 million people die from tuberculosis (TB) every year (1). It is particularly risky in children under five years of age because it can develop into a disseminated miliary form and meningitis (2). Bacillus Calmette-Guérin (BCG) vaccine is used worldwide as an important preventive vaccine against TB (1,3). The BCG coverage is also important for overall infant health. The studies have demonstrated that BCG protects against a range of non-TB infections, reducing all-cause mortality risk (4).

The national vaccination program in our country includes the BCG vaccine (5). It is a safe vaccine with a low incidence of serious side effects (5,6). However, some adverse events may be observed (3,5,6). The present case aims to explain the management of the vaccine adverse events after BCG vaccination.

Case Report

An 8-month and 6-day-old male infant was admitted to the well-child clinic due to increasing swelling on the left shoulder where the BCG vaccination was administered. It was

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performed in the second postnatal month. In the postnatal fourth month, redness began at the vaccination site and was followed by induration that persisted, approximately 5 mm in size. Over the past week, induration and redness had gradually increased, and one day before the presentation, they had grown outward with a small amount of pus (Figure 1). Medical history: 39 gestational week, 2810 g, born by caesarean section. No problems after birth. In the fourth postnatal month, eczematous rash appeared on the cheeks after wearing woollen clothing. Over time, itchy rashes spread throughout the body and were diagnosed as eczema. He was exclusively breastfed for five and a half months, and then he started complementary feeding. He had no food allergies. He had no other illnesses and had never been hospitalized. Physical examination: Weight 8200 g [23rd percentile; -0.27 standard deviation score (SDS)], height 72 cm (56th percentile; 0.17 SDS), head circumference 44.8 cm (36th percentile; -0.35 SDS). There was an induration measuring approximately 12x15 mm in size on the left arm, with a crust measuring 5x6 mm (Figure 2). There was no pain, fever, lymphadenopathy, or hepatosplenomegaly. He had eczematous lesions on his trunk, arms and face. Laboratory tests: leukocytes 9.03×10^9/L, lymphocytes 5.62×10^9/L, neutrophils 2.2×10^9/L, monocytes 0.74 × 10^9/L, eosinophils 4.9×10^9/L, and basophils 0.03×10^9/L. T cell subsets were normal: CD3 54%, CD4 40%, CD8 11%, CD19 35%, CD16+CD56+ 10%. Total immunoglobulin (Ig) E was 26.6 U/mL (0-29), IgA was 0.35 g/L, IgG was 4.16 g/L, IgM was 0.37 g/L, and (anti-HBs) was 749.24 IU/L (positive). Immune deficiency was ruled out. Conservative treatment was preferred. Within approximately ten days, the scab, redness, and induration subsided. It healed, leaving scar tissue. The child is now 20 months old, and the eczematous lesions have disappeared over time, with no additional pathology developing during follow-up.

Discussion

The BCG vaccine is a live attenuated bacterial vaccine derived from Mycobacterium bovis. In our country, the vaccine is administered intradermally into the left deltoid region when children are 2 months old (5). In individuals who have not previously been exposed to TB bacilli, approximately 3-4 weeks after vaccination, an induration approximately 5 mm in diameter forms at the vaccination site. The induration is bluish-red in colour and drains by the 6th week. This ulcerative lesion forms a crust by the 8th week and heals within a few weeks, leaving scar tissue (3,5,7). Scarring generally occurs 12 weeks after vaccination, although it has been reported that this period may be 6 months or longer (7,8). Sometimes, within a week after vaccination, induration and oozing pus can be observed at the vaccination site. This early reaction is called the "Koch phenomenon" and demonstrates that the child may have been previously infected with TB (5).

Adverse events following BCG vaccination are mostly local reactions: Abscess, injection site reaction (ulceration), suppurative/non-suppurative lymphadenopathy, and keloid. These are dependent on the skill and method of vaccine administration, the vaccine strain and dose used, gender, age, and the individual's immune status (1,3,5)

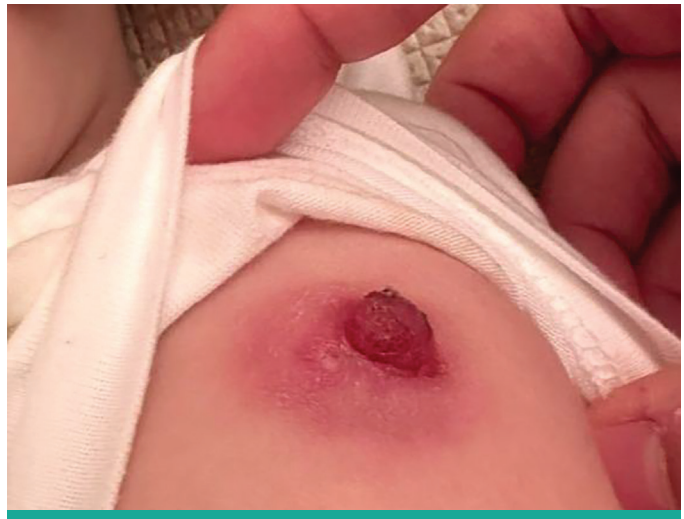

Figure 1. Clinical image showing a protruding swelling at the vaccination site

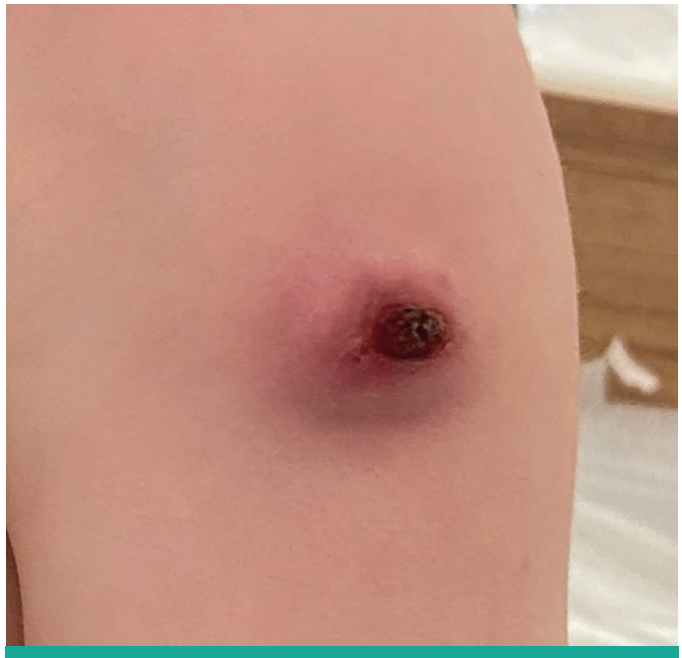

Figure 2. Clinical appearance of the lesion as observed at the time of presentation

BCGitis is a general term for local inflammatory reactions caused by the BCG vaccine. There is also ipsilateral regional lymph node enlargement (3,9). BCG lymphadenitis occurs in 1-2% of cases. It typically develops as a result of an exaggerated immune response to the attenuated mycobacterial strain in the vaccine. As a result of the excessive local immune response, the lesion is characterised by axillary, cervical, or supraclavicular lymphadenopathy, redness, and tenderness near the arm where the vaccine was administered. Physical examination may reveal local swelling and lymphadenopathy. The diagnosis is typically based on clinical findings. Ultrasound or needle aspiration biopsy may be used. Lymphadenitis can present in two forms: non-suppurative or suppurative (3,5,9,10).

Serious adverse events following BCG vaccination are rare; BCG osteitis affecting the epiphysis of long bones (0.01-300 per million doses), may occur 4-24 months after vaccination. Disseminated BCG disease (0.19-1.56/1,000,000) is seen particularly in children with uncontrolled HIV infection or immunodeficiency on average 8 months after vaccination. (1,3,6).

The previous studies demonstrated that local complications (injection site reactions, suppurative/non-suppurative lymphadenitis) following BCG vaccination can be managed using various strategies (9-13). The efficacy of anti-tuberculous therapy in treating local complications of BCG is unclear (13). In a study investigating adverse events after BCG vaccination, one-third of children were referred with injection site reactions, which were mostly managed conservatively, and almost all resolved completely, supporting the generally adopted “watch and wait” approach for this type of adverse event. Two-thirds of children were referred with lymphadenitis following BCG vaccination; in half of these cases, there was evidence of suppuration. There is no clear consensus regarding the management of suppurative BCG lymphadenitis (13). Needle aspiration, surgical drainage, and anti-TB therapy could be administered in the management of these events (9-13). The high risk of complications, especially in children with suppressed immune systems, should be taken into consideration (3,10,14).

In conclusion, following BCG vaccination, some adverse events may be observed. The presented case was considered a local vaccine adverse event. We performed conservative treatment (watch and wait) due to the absence of lymphadenopathy discharge or abscess, and immunodeficiency, and the formation of a crust. Spontaneous healing was seen within a short period (approximately 10 days) by forming a scar.

Ethics

Informed Consent: Written and verbal informed consent was obtained from the patient’s parent(s).

Footnotes

Financial Disclosure: The author declared that this study received no financial support.

References

1. World Health Organization. WHO position papers on BCG vaccines. [Internet] Available from: https://www.who.int/teams/immunization-vaccines-and-biologicals/policies/position-papers/bcg
2. Tapaç NN, Alabaz D. Tüberküloz epidemiyolojisi; dünya (Dünya Sağlık Örgütü verileri) ve Türkiye verileri. Alabaz D (editör). Çocukluk çağında tüberküloz enfeksiyonlarına güncel yaklaşım. 1. baskı. Ankara: Türkiye Klinikleri, 2025:4-10.
3. Alabaz D. Bacillus Calmette-Guérin aşısının komplikasyonları. Alabaz D (editör). Çocukluk çağında tüberküloz enfeksiyonlarına güncel yaklaşım. 1. baskı. Ankara: Türkiye Klinikleri, 2025:31-35.
4. Stougaard SW, Benn CS, Aaby P, Nielsen S, Schaltz-Buchholzer F. Using real-life data to model the impact of increasing BCG vaccination coverage and scar prevalence on all-cause infant mortality. Ann Epidemiol. 2023;86:90-97.e7.
5. Çuhacı Çakır B, Duyan Çamurdan A. BCG aşıları. Gökçay G (editör). Aşılar. 1. baskı. Ankara: Türkiye Klinikleri, 2021:52-59.
6. Okuno H, Satoh H, Morino S, Arai S, Ochiai M, Fujita K, et al. Characteristics and incidence of vaccine adverse events after Bacille Calmette-Guérin vaccination: a national surveillance study in Japan from 2013 to 2017. Vaccine. 2022;40(33):4922-4928.
7. Huang CY, Chi H, Chang L, Chiu NC. Typical time courses and appearance of skin reactions at the site of BacillusCalmette-Guérin vaccination for infants inoculated at 5-8 months of age. Vaccine. 2023;41(8):1529-1535.
8. Faridi MM, Krishnamurthy S. Abortive reaction and time of scar formation after BCG vaccination. Vaccine. 2008;26(3):289-290.
9. Ladeira I, Carvalho I, Correia A, Carvalho A, Duarte R. BCGitis in children. Rev Port Pneumol. 2014;20(3):172-173.
10. Elsidig N, Alshahrani D, Alshehri M, Alzahrani M, Alhajjar S, Aljummah S, et al. Bacillus Calmette-Guérin vaccine related lymphadenitis in children: management guidelines endorsed by the Saudi Pediatric Infectious Diseases Society (SPIDS). Int J Pediatr Adolesc Med. 2015;2(2):89-95.
11. Çiftçi E, İnceli HB, Özdemir H, Haskoloğlu Ş, Doğu F. Local abscess due to BCGitis. J Pediatr Inf. 2022;16(4):295.
12. Venkataraman A, Yusuff M, Liebeschuetz S, Riddell A, Prendergast AJ. Management and outcome of Bacille Calmette-Guérin vaccine adverse reactions. Vaccine. 2015;33(41):5470-5474.
13. Al Waili B, Al Mufarajii N, Al Hashmi S, Al Ajmi A, Al Sukaiti N. Bacillus Calmette-Guérin vaccine-related complications in children in Oman. Ann Saudi Med. 2021;41(1):24-30.