Infantile BCG Revaccination with an Inappropriate Technique: Malpractice: Case Report

BEBEKLİK DÖNEMİNDE HATALI TEKNİKLE BCG RAPEL AŞILAMASI: UYGULAMA HATASI

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Abstract

In this paper, we aimed to report 5 infants who received the second dose of BCG vaccine (instead of measles vaccine) by mistake via an inappropriate application. Measles vaccine solvent (5 ml sterile water) was used for BCG vaccine preparation and 0.5 ml of this solution was injected to the left deltoid region as a subcutaneous injection. Only 1 case had a cold abscess at the site of the injection after 2 months of vaccination and improved with a retracted scar within 4 months. No case had severe adverse reactions during the 6 months of follow-up period. BCG revaccination of 5 infants by subcutaneous administration did not result in lymphadenitis.

Key Words: BCG vaccine, malpractice

Özet

Bu makalede, hatalı uygulama ile, kızamık aşısı yerine ikinci doz BCG aşısı yapılmış 5 bebeğin izlemi rapor edilmiştir. Kızamık aşı çözücüsü (5 ml steril su) BCG aşı hazırlanmasında kullanılmış ve bu çözeltinin 0.5 ml'si sol deltid bölgeye subkutan olarak yapılmış. Sadece 1 vakada aşıdan 2 ay sonra enjeksiyon bölgesinde soğuk abse gelişmiş ve çöküntü skar dokusu bırakarak 4 ay içinde iyileşmiştir. Vakalarda 6 aylık izlem döneminde ciddi yan etki gözlenmemiştir. Bebeklik döneminde deri altına yapılan BCG rapel aşılaması lenfadenit ile sonuçlanmamıştır.

Anahtar Kelimeler: BCG aşısı; malpraktis, uygulama hatası

Turkiye Klinikleri J Pediatr 2007, 16:62-64

Program errors result from errors and accidents in vaccine preparation, handling, or administration; they may lead to a cluster of events associated with immunization. They are preventable and detract from the overall benefit of the immunization schedules thus, the identification and close follow-up of patients involved are of great importance.[1,2]

The official recommendation of the World Health Organization is that children under 1 year of age who did not receive BCG earlier should be given 1 dose (0.05 ml) of BCG vaccine, as an intradermal injection. If the injection is administered too deeply or an overdose is given, possible severe injection site reactions, large ulcers and abscesses may appear.[3-6] Therefore, in this report we present the follow-up data of 5 infants 10 months of age, who received subcutaneous injections of the second dose BCG vaccine, prepared incorrectly by mistake.

Reports

Five healthy children (2 girls and 3 boys), aged 10 months, had received a subcutaneous injection of BCG vaccine instead of measles vaccine by mistake at a primary healthcare center (Table 1). Measles vaccine solvent (5 ml sterile water) was used for BCG vaccine preparation and 0.5 ml of this solution was injected to the left

Geliş Tarihi/*Received:* 03.05.2006 **Kabul Tarihi/*Accepted:*** 20.07.2006

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deltoid region. Normally 1 mg lyophilized BCG vaccine is diluted with 1 ml BCG solvent and 0.05 ml vaccine is administered intradermally. After vaccination of these 5 infants, the nurse became aware of the error and all infants were examined and antituberculous prophylaxis was recommended. The parents of 2 infants refused prophylaxis and 3 children took prophylaxis (isoniazid once a day 5 mg/kg) for 6 months. All cases were followed-up every 2 months over a 6 months period (Table 1).

Four infants had received prior BCG vaccine when they were 2 months of age. Only 1 infant had received BCG vaccine 1 month before the wrong BCG injection. In 1 case, 0.2 x 0.2 cm hyperemia was observed at the injection site on the first day of vaccination and it disappeared within 2 days. He used isoniazid for 6 months. A cold abscess was detected in another case at the side of injection after 2 months of vaccination and it improved with a rectracted scar within 4 months. This case did not use antituberculous chemotherapy for prophylaxis or treatment of the abscess.

One infant with mild malnutrition developed slight hyperemia (0.3 x 0.3 cm) at the injection site 3 weeks after improper BCG injection and it lasted 1 day. She received isoniazid prophylaxis for 6 months and no other adverse reactions of BCG vaccine were observed.

Among the cases with improper immunization site, no scar formation was observed at the side of injection after 6 months of follow-up. No case had fever, convulsions, loss of appetite or irritability.

Discussion

For more than 70 years, BCG vaccines have been administered safely to billions of individuals throughout in the world. BCG vaccine may uncommonly cause adverse reactions (0.1% to 2.0%), such as moderate axillary or cervical lymphadenopathy and induration and subsequent pustule formation at the injection site, which generally is not serious.[4-6] The frequency and severity of such effects depend on the dosage and method of administration, the age of the person receiving the vaccine, the substrain of the bacillus used by the manufacturer, and the presence of abnormal cellular immunity.[3-5,7,8] Adverse reactions are more common in young vaccine recipients such as infants versus older children. A study of 291 Haitian infants reported an outbreak of complications after administration of 2.0 to 2.5 times the recommended dose of BCG vaccine.[5] A modification to the current infant dose of vaccine decreased the incidence of these reactions among infants to <2%. The risk of suppurative lymphadenitis is greater among older infants and children, especially when a full dose of vaccine (0.1 ml) is given; therefore, the WHO recommends using a reduced dose (0.05 ml) in newborn. In addition, inadvertent subcutaneous injection may result in abscess formation and leads to ugly rectracted scars at the site of injection.[3-6] However, in this study with improper vaccination, only 1 case had an abscess at the site of injection 2 months after the injection that healed spontaneously. The most serious complications of BCG vaccination are disseminated BCG infection and BCG osteitis, principally in immunocompromised

Table 1. Clinical features of infants.

Case no	Age at previous BCG vaccination	BCG scar due to previous vaccination	Health status	Side effects	Use of isoniazid
1	2 mo	+	Healthy	Cold abscess 2 months after injection, then improved with retracted scar formation	-
2	2 mo	+	Healthy	-	-
3	2 mo	+	Iron deficiency anemia	0.2 x 0.2 cm hyperemia for the first 2 days of injection	+
4	8 mo	-	Mild malnutrition	0.3 x 0.3 cm hyperemia for 1 day after 3 weeks of injection	+
5	2 mo	-	Healthy	-	+

individuals, that can occur from 4 months to 2 years after vaccination and requires anti-TB therapy. In this study, no case had severe adverse reactions during the 6 months of follow up period.

Reports in the medical literature of adverse reactions due to revaccination are limited.[9,10] Reports indicated that adverse reactions to a second dose of BCG might be more frequent than reaction to a first dose; however they were still rare events and adverse reactions took place between 21 days and 9 months after BCG revaccination.[9,10] However, this is the first report 1 cases who were revaccinated under 12 months of age as far as we know. Four cases had no adverse reactions, but an abscess developed in only 1 case who did not take isoniazid prophylaxis.

Usually, small red areas at the site of injection appear 10-14 days after injection and slowly decrease in size. In 2 of our cases slight hyperemia was observed at the site of injection after BCG vaccination, 1 on the first day of injection and the other 1, 3 weeks after injection. Ninety percent to 95% of cases vaccinated with BCG develop a local reaction followed by healing and scar formation within 3 months.[1,3,4] Of 5, 3 infants had a scar from prior BCG vaccination, however, none developed scar formation after this erroneous BCG vaccination.

In this study, a cluster error was associated with a single vial of vaccine that was inappropriately prepared. To avoid schedule error, vaccines must only be reconstituted with the diluent supplied by the manufacturer; no other drugs or substances should be stored in the refrigerator of the immunization center. In addition, immunization staff must be adequately trained and closely supervised to ensure that proper procedures are followed. Although adverse reactions were rare, we monitored this schedule error in order to provide appropriate assessment and timely intervention.

In conclusion, after infant BCG revaccination by subcutaneous administration, neither disseminated BCG infection nor enlargement of lymph nodes developed. However, faulty application is known to be the most important factor for the development of adverse events; therefore, training nurses for strict intradermal injection should be maintained as it has proved to be effective in minimizing the incidence of BCG complications.

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