

Inadvertent Intramuscular Administration of High Dose Bacillus Calmette Guerin Vaccine in a Pre-term Infant

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ABSTRACT

This case report examined the natural course of reaction after accidental intramuscular administration of high dose Bacille Calmette-Guérin (BCG) vaccine into the anterolateral aspect of thigh of a pre-term infant as a part of routine vaccination instead of intra-dermal injection into the arm. There is no consensus on the best management of this complication, although in this case healing was prolonged but was spontaneous without anti-tubercular chemotherapy.

Keywords: Bacille Calmette-Guérin, tuberculosis, vaccination

Introduction

The World Health organization (WHO) has recommended Bacillus Calmette Guerin (BCG) vaccination as a part of the global expanded program for immunization (EPI) for tuberculosis. BCG is a live attenuated vaccine derived from a strain of *Mycobacterium bovis*. The efficacy of currently available BCG vaccines ranges from 60% to 90%.^[1,2] BCG vaccine is a safe vaccine, but a number of complications have been reported such as localized ulceration, regional lymphadenitis, osteomyelitis, lupoid reactions, eczema vaccinatum, hypertrophic scars and keloid formation, disseminated infection and death following vaccination.^[3]

A number of factors such as age of the child, technique of vaccination, the BCG strain, the dose, potency, viability and immunogenicity of the vaccine, and prior exposure to mycobacterial antigen are implicated in the pathogenesis of various complications.^[3] All the complications so far reported have been due to the routine intradermal vaccination or the intravesicular BCG therapy for treatment of superficial bladder tumors.

Here, we report a case of pre-term infant who was administered 10 times the normal dose of BCG vaccine intramuscularly due

to negligence of the health care worker. To the best of our knowledge, this is the first case of its kind reported in the world.

Case Report

A preterm male baby weighing 1.6 kgs, born at 32 weeks of gestation was not given BCG vaccination at birth. When he turned 2 kgs at 2 months of age, he was given 1 full vial of BCG vaccine (10 times the usual dose) intramuscularly into the right thigh, instead of the usual dose of 0.1 ml intradermally in the arm. After 5 months of injection, he developed a swelling in the right thigh. The infant did not have any other symptoms such as fever, weight loss, refusal of feeds or inability to thrive.

On physical examination, there was a swelling in the right anterolateral thigh, measuring 4 cm × 5 cm, which was non-tender with diffuse margins in the intramuscular plane. There were no palpable lymph nodes except for the sub-occipital lymphnodes, which was considered insignificant. Other systemic examinations were within normal limits. Developmental milestones were delayed by 2 to 3 months because the infant was born pre-term.

Routine blood investigations like complete blood count, ESR were unremarkable. Chest X-ray was normal. Magnetic Resonance Imaging (MRI) of the right thigh showed an intramuscular abscess in the vastus intermedius muscle measuring 7.5 cm × 2.8 cm.

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The swelling was managed surgically. A wide bore needle was inserted into the abscess, and about 30 ml of non-reactive pus was aspirated. A small trans-incision over the swelling was done, and loculi were broken. Scrapings from the wall of the abscess cavity was sent for histopathology, which showed chronic inflammatory cell infiltration admixed with epithelioid cells, langhans, and foreign body giant cells and areas of necrosis suggestive of granulomatous lesion. Gram stain and Ziehl Neelsen stain of the pus did not show any organisms. Culture and sensitivity for aerobic bacteria showed no growth. Culture done on Lowenstein Jensen medium for Mycobacteria was also negative after 2 months of incubation. Post-procedure, the infant was treated with amoxycillin and clavulanic acid 325 mg, twice a day, for 5 days. Since the culture for Mycobacteria was negative, the baby was not started on anti-tubercular drugs. Post-procedure, the wound continued to discharge pus for about 5 to 6 months forming a sinus, which later healed with a puckering scar. On follow-up after 1 year, there was no discharge, and the child was healthy.

Written, informed consent was taken from the parents to report this case.

Discussion

Bacille Calmette-Guérin (BCG) has been used extensively as a vaccine against human tuberculosis for over 70 years. BCG vaccine is an attenuated, live culture preparation of the Bacillus of Calmette and Guerin (BCG) strain of *Mycobacterium bovis* used to prevent infection with *Mycobacterium tuberculosis*.^[4]

Adverse reactions to BCG vaccination are rare, provided that correct immunization techniques are used and that those to be vaccinated are properly selected. Fewer than one in 1000 people vaccinated develop significant local reactions, and serious disseminated disease develops in fewer than one in a million. Most of the complications were abnormal primary complexes, either lesions at the injection site or, more commonly, suppurative lymphadenitis. Lesions at the injection site were either ulcers, subcutaneous abscesses, or necrotic lesions due to excessive delayed hypersensitivity reactions. Abscesses at the injection site occur more commonly than lymphadenopathy.^[5] Other complications were localized or generalized non-fatal persisting BCG infection, fatal disseminated BCG infection, and post-BCG syndrome, principally keloid scarring.^[6,7] Infectious complications include ulcers and abscesses at the site of injection, regional lymphadenitis, and more distant lesions, such as osteitis and disseminated disease (BCG-osis).^[8]

Various case reports of inadvertent vaccination so far reported are—inadvertent usage of BCG vaccination instead of PPD,^[9] inadvertent BCG injections into the fore arm,^[10] inadvertent intramuscular injection of BCG into already tuberculin sensitive patient,^[9] and inadvertent intravenous administration of BCG during intravesicular BCG therapy.^[11]

Only 2 case reports exist related with inadvertent “intramuscular” injection of BCG. In both cases, severe and prolonged local reactions developed.^[10,11] Former was inadvertent intramuscular injection of BCG-vaccine into an already tuberculin-sensitive individual.^[10] However, latter was a 60-year-old male with bladder transitional cell carcinoma. Following intramuscular administration, systemic symptoms including fever and headache developed with normal chest X-ray who was treated with anti-tuberculosis drugs successfully.^[11]

In this case, we observed that the course in case of accidental injection of high dose BCG vaccine in a pre-term infant was benign but prolonged (52 weeks), suggesting that, in accidental events, such as the one reported here, a prolonged and appropriate follow-up should be implemented.

There has been no case report so far published, where BCG was given intramuscularly into the anterolateral aspect of the thigh of an infant. Such a case of negligent inadvertent vaccination leads to immense dilemma regarding the complications that might occur and the management aspects regarding starting anti-tubercular drugs. Since there were no formulated guidelines or any previous reports of such a case, it became a herculean task to monitor the infant and to decide on the treatment options for tuberculosis. This made the necessity to report this case so that this may instigate experts to come up with proper regulations regarding administration of vaccines and penalty for negligence on part of the health care providers. Guidelines regarding management of such cases should be formulated and included in the national policy.

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