

# Sterile Abscess Following Hepatitis B Vaccination in a New Born- A Case Report

JISHA MYALIL LUCCA<sup>1</sup>, JUNY SEBASTIAN<sup>2</sup>, MANDYAM DHATI RAVI<sup>3</sup>, GURUMURTHY PARTHASARATHI<sup>4</sup>

## ABSTRACT

Vaccines may cause adverse events ranging from mild reactions like fever to serious events like seizures. Both the vaccine product and the process of vaccination can cause adverse events. Non-sterile abscesses are usually a program error (an event caused by an error in the transportation, storage, handling, or administration of a vaccine) that may occur due to contamination of a multi-dose vial. Sterile abscess may occur as a delayed hypersensitivity reaction due to the presence of aluminium salt as an adjuvant in the vaccine, and are classified as vaccine product related reactions. The Hepatitis B vaccine is recommended for all infants at birth and for children up to 18 years. Here, authors report a case of sterile abscess in an eight-month-old baby, after the administration of first dose of Hepatitis B Vaccination, possibly due to an error and hence classified as Immunisation error related reaction.

**Keywords:** Adverse events following immunisation, Immunisation error related reaction, Program error

## CASE REPORT

A full-term baby boy, birth weight 3.4 kg received intradermal injection of BCG on his left arm, Hepatitis B vaccine intramuscularly on right thigh and oral Polio vaccine 8 hours after birth. A month later his mother noticed a lump in the right thigh at the site of Hepatitis B injection. As the lump was asymptomatic and non-progressive, mother waited until the 6 weeks vaccination visit to consult the Paediatrician. After examining the lump, the paediatrician informed the parents that the lump may disappear within a few weeks and did not require any intervention. The baby was given subsequent doses of Pentavalent Vaccine and Inactivated Polio Vaccine (IPV) injections on his left thigh only. Baby completed all the recommended vaccinations until the age of eight months.

The lump was left untreated until eight months and later started to show progressive enlargement and became very visible. As the lump showed progressive enlargement, mother consulted the Paediatrician again and on examination, the baby showed no pain response when pressure was applied on the lump. Ultra-sonogram of the right thigh revealed a 4.3 cm × 1.5 cm irregular hypo-echoic lesion in the subcutaneous plane with Colour Doppler showing no internal vascularity. The lesion had a thick irregular wall and a small tract was seen from the lesion to the skin surface. Paediatric surgeon made a provisional diagnosis of post-injection abscess. A tissue biopsy was obtained for culture and yielded no growth. The medical history of the baby was not suggestive of any immunodeficiency status.

The final diagnosis was made as sterile abscess following vaccination. Incision and drainage procedure was performed by the pediatric surgeon after giving a prophylactic dose of an antibiotic, ceftriaxone 50 mg/Kg/day (intramuscular). The antibiotic was continued for three more days along with Ibuprofen 4 mg/kg thrice daily and mupirocin ointment twice daily for local application. The baby recovered completely on fifth day post-drainage and no recurrence was observed. The parents were educated about the importance of completing the immunisation schedule. The baby was followed until the age of one year and he received remaining vaccinations in the same immunisation clinic without any complication. However, no further vaccinations were given on the right thigh.

## DISCUSSION

The World Health Organisation (WHO) recommends that all infants should receive their first dose of Hepatitis B (Hep B) vaccine as soon

as possible after birth, preferably within 24 hours. The birth dose should be followed by two more doses to complete the primary series of Hepatitis B vaccination [1]. Adverse Events Following Immunisation (AEFIs) may occur following any vaccination including Hepatitis B. Abscess at the injection site has been a widely reported AEFI in national immunisation programs. For example, a total of 40-injection site abscess cases were reported over a period of five years from 2012 to 2017 in Netherlands's Pharmaco-vigilance program [2] and 12.2% (n=101) of injection site reactions including abscess was reported to Pharmaco-vigilance Program of India over a period of 2 years (2016 and 2017) [3]. Abscess formation following vaccination is usually an immunisation error related reaction due to the microbial contamination of the vaccine [4,5].

An AEFI is categorised as immunisation error related reaction when AEFI was caused by inappropriate handling, prescribing and administration of vaccine and thus it was preventable in nature [6]. Rarely AEFI such as sterile abscess may develop following Hepatitis B vaccination, which is a delayed hypersensitivity reaction to aluminium adjuvant present in the vaccine with a reported frequency of 0.35% to 1.18% [2,7]. An investigation done using the Vaccine Adverse Events Reporting System (VAERS) in USA, observed that all the cases of recurrent sterile abscess following vaccination were due to the aluminium salt added to vaccines as adjuvant [4], which suggests that the sterile abscess could also be a vaccine product related reaction.

Vaccine induced injection site reactions due to Hepatitis B vaccine usually occur approximately one month after vaccination [5]. Possible explanations for injection site reactions could be either due to previous T-cell response to a killed bacteria in a vaccine, or the patient has a bacterial infection which can cause a T-cell response to the vaccine [7]. The route of administration also plays a vital role in the abscess formation, particularly Intramuscular (IM) injection. There are many reports of sterile abscess following IM administration of vaccines [8,9].

The major contributing factor for abscess formation is improper injection technique [9,10]. Rarely, sterile abscess may be caused by the inherent property of the vaccine itself. Aluminium salts added as adjuvants in the vaccine cause a slow escape of antigen from the site of injection, thereby lengthening the duration of contact between the antigen and immune system. Hypersensitivity to a vaccine component especially aluminium salt added as an adjuvant can be one of the possible explanations of sterile abscess following

vaccination [4,7,8]. Aluminium containing vaccines can cause a nodule at the injection site which can last for several weeks for 5-10% of vaccinated persons. In rare instances, the nodule may become inflammatory and can turn into an abscess. Nodules persisting more than six weeks may indicate the delayed type hypersensitivity reactions to the aluminium component in the vaccine [9,10]. Here, in this case, the baby received Hepatitis B vaccine (each dose of 0.5 mL contains Purified HBsAg >10 microgram, Aluminium hydroxide gel equivalent to AL +++ 0.25 mg and Thiomersal IP 0.025 mg).

Previous studies have reported that abscess formation is commonly noted if the quantity of aluminium present in the vaccine is more than 0.17 mg [5] Subcutaneous administration of aluminium salt containing vaccines can result in cyst, necrotic breakdown and sterile abscess formation. WHO's vaccine safety basics learning manual suggests, to administer the aluminium containing vaccines intramuscularly and not subcutaneously to ensure the safety of vaccination [8,11]. The recommended primary treatment of abscesses includes drainage of the abscess and systemic plus local applications of antibiotics.

Causality assessment of the AEFI was performed according to the user manual for the WHO classification [11]. This case satisfied the eligibility criteria for AEFI, as Hepatitis B vaccine was the only vaccine administered before the event and the diagnosis of sterile abscess met the Brighton collaboration case definition [12]. Based on the algorithm, causality of the event was classified as 'consistent causal association to vaccination' with the sub-class 'immunisation error related reaction'. Sterile abscess due to a delayed hypersensitivity reaction to aluminium salt adjuvant present in the vaccine may be unlikely in this case, as there was no recurrence of sterile abscess following administration of further doses of vaccines with similar components including aluminium salt. Previously published case reports have described the recurrence of sterile abscess following the administration of vaccines containing aluminium salts as adjuvants [13,14]. Hence the reaction may be an immunisation error related reaction due to an error in the injection technique. The possible injection technique error occurred, in this case, may be the non-deep injection of Hepatitis B [8]. Vaccinators need to undergo continuous education and training to minimise immunisation error related reactions as these AEFIs may negatively influence the parent's confidence in immunisation.

## CONCLUSION

The occurrence of sterile abscess, in this case, maybe attributed to an error in the immunisation process. In view of the high risk of VPDs in the community, parents need to be educated and counselled to complete the immunisation schedule with possible precautions to avoid recurrence of AEFIs.

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### PARTICULARS OF CONTRIBUTORS:

1. Assistant Professor, Department of Pharmacy Practice, Imam Abdulrahman Bin Faisal University, Dammam, Saudi Arabia.
2. Lecturer, Department of Pharmacy Practice, JSS College of Pharmacy, JSS Academy of Higher Education and Research, Mysuru, Karnataka, India.
3. Professor, Department of Paediatrics, JSS Medical College and Hospital, JSS Academy of Higher Education and Research, Mysuru, Karnataka, India.
4. Professor, Department of Pharmacy Practice, JSS College of Pharmacy, JSS Academy of Higher Education and Research, Mysuru, Karnataka, India.

### NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Gurumurthy Parthasarathi,  
Professor, Department of Pharmacy Practice, JSS College of Pharmacy, Jagadguru Shri Shivarathreeshwara  
Academy of Higher Education and Research, S S Nagara, Mysuru-570015, Karnataka, India.  
E-mail: Partha18@gmail.com

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