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Article

Medical Error in Paediatric Vaccination: Case Report of Accidental ONCO-BCG Administration in Neonates

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ABSTRACT

Background: Medication errors involving look-alike, sound-alike (LASA) vaccines remain a critical safety concern in neonatal immunization programs, particularly in tuberculosis-endemic settings. Accidental administration of ONCO-BCG, a formulation intended for intravesical cancer therapy, in place of standard neonatal BCG vaccine, poses significant risks; however, limited data exist regarding the clinical spectrum and outcomes of such incidents. **Objective:** This study aimed to evaluate the adverse effects, clinical management, and outcomes of neonates who inadvertently received ONCO-BCG during routine immunization, with the primary focus on cutaneous, haematological, and neurological complications, as well as overall recovery. **Methods:** This retrospective observational case series included all neonates (n = 26) exposed to ONCO-BCG at a tertiary care hospital in Karachi, Pakistan. Inclusion criteria comprised all infants who received the incorrect vaccine within a two-day period; those with prior immunodeficiency or incomplete records were excluded. Data was collected from patient files, laboratory results, and direct clinical observation, with outcome measures including the incidence of adverse drug reactions, laboratory abnormalities, and recovery status. Ethical approval was obtained from the institutional review board in accordance with the Helsinki Declaration. Data analysis utilized descriptive statistics with SPSS version 25, ensuring precise quantification of clinical events. **Results:** Sixteen neonates (61.5%) developed skin lesions, three (11.5%) experienced coagulation derangement, and one (3.8%) suffered intracranial haemorrhage; no cases of disseminated tuberculosis or mortality occurred. All affected infants received chemoprophylaxis and supportive care, achieving full clinical recovery within one year of follow-up. **Conclusion**: Accidental ONCO-BCG administration in neonates led to a high rate of preventable adverse events but was effectively managed with early recognition, multidisciplinary intervention, and targeted chemoprophylaxis. Rigorous medication safety protocols and staff training are vital for preventing similar errors and safeguarding paediatric patient health.

Keywords: Neonatal Vaccination, Bacillus Calmette-Guerin Vaccine, Medication Errors, Look-Alike Sound-Alike Drugs, Chemoprophylaxis, Patient Safety, Tuberculosis Prevention

INTRODUCTION

Tuberculosis remains a pressing public health concern in many low- and middle-income countries, including Pakistan, where neonatal morbidity and mortality from the disease continue to be significant (1). As part of efforts to reduce the burden of severe childhood TB, the Bacillus Calmette-Guérin (BCG) vaccine, a live attenuated preparation of Mycobacterium Bovis, is routinely administered at birth in TB-endemic regions (2). The efficacy of neonatal BCG vaccination in preventing severe forms of TB, such as tuberculous meningitis and miliary TB, is well established, and the vaccine's safety profile is considered favorable, with adverse reactions typically limited to local injection site effects and rare occurrences of lymphadenitis or osteitis (3,4). Nevertheless, the complexity of medication management in hospital settings introduces the risk of medical errors, particularly with look-alike, sound-alike (LASA) pharmaceutical products, which may result in unintentional administration of the incorrect medication or formulation (5). Several case reports and observational studies have documented the consequences of BCG-related medical errors, including overdose and wrong-route administration, which have

resulted in both localized and systemic adverse effects (6,7). In particular, the ONCO-BCG formulation, developed for intravesical use in bladder cancer, contains significantly higher concentrations of live bacteria and is not intended for immunization; accidental administration of this formulation in place of the neonatal vaccine has been associated with serious adverse events in the pediatric population (7,8). Previous literature highlights that contributing factors in such errors often include insufficient product differentiation, packaging similarities, and lapses in safety checks at multiple points in the medication-use process (5,9). Although international recommendations emphasize strict medication safety protocols to prevent LASA-related incidents, there is a paucity of published data from South Asian healthcare settings detailing the frequency, outcomes, and management of such vaccine errors (10).

Figure 1 Image of SII ONCO-BCG packaging, manufactured by Serum Institute of India Ltd., used for educational and scientific illustration of medication error risk. No patient information is depicted.

The image shows the commercial packaging and vial of SII ONCO-BCG (Bacillus Calmette-Guérin), produced by Serum Institute of India Ltd. This formulation is intended exclusively for intravesical use in bladder cancer therapy and is clearly labeled "Not intended for immunization." In the present case, the similar packaging and labeling to standard neonatal BCG vaccine contributed to the inadvertent administration of ONCO-BCG to neonates, resulting in significant adverse reactions and highlighting the critical risk posed by look-alike, sound-alike pharmaceutical products in clinical settings.

Given this knowledge gap, there is an urgent need to better understand the clinical impact, contributing factors, and management strategies surrounding inadvertent administration of high-potency ONCO-BCG vaccine in neonates within TB-endemic, resource-constrained environments. Such insights are critical to inform the design of safer immunization systems and strengthen institutional policies aimed at minimizing preventable harm. This case report aims to address this gap by presenting the clinical presentation, adverse outcomes, and multidisciplinary management of neonates who were mistakenly administered ONCO-BCG instead of standard neonatal BCG vaccine at a tertiary care hospital in Pakistan, with the objective of elucidating the systemic vulnerabilities that led to the incident and offering recommendations for prevention and practice improvement.

CASE PRESENTATION

Between 14th and 16th April 2016, an incident occurred at a tertiary care hospital in Karachi, Pakistan, involving the accidental administration of ONCO-BCG, a formulation intended exclusively for intravesical use in bladder cancer patients, to twenty-six neonates in place of the standard neonatal BCG vaccine. The affected infants, aged 2 to 4 days, included 13 males and 13 females, all of whom were scheduled for routine immunization for tuberculosis prevention, as per national guidelines (1). The error was traced to the pharmacy department, where vials of ONCO-BCG—similar in appearance and labeling to the neonatal BCG vaccine—were inadvertently dispensed to the maternity ward satellite pharmacy. Subsequent lapses in standard cross-checking protocols allowed the error to progress unrecognized through to the point of administration by the nursing staff (2).

The ONCO-BCG formulation administered was approximately 80 times more potent than the recommended neonatal dose, resulting in a range of adverse drug reactions among the affected infants. Clinical monitoring revealed that sixteen neonates developed various forms of skin lesions, including papules, pustules, indurations, and erythema at the injection site. Axillary lymphadenopathy was observed in one infant, while three developed coagulation derangements, of which one experienced intracranial bleeding manifested by fever, cough, irritability, and focal seizures. Laboratory evaluation of the most severely affected neonate demonstrated hypocalcemia, anemia, and a normal coagulation profile, while neuroimaging confirmed the presence of a left subdural hematoma and minimal subarachnoid hemorrhage. Other complications included post-circumcision bleeding and factor deficiencies; all responded to supportive management with vitamin K, calcium supplementation, antibiotics, antiepileptic therapy, and, where indicated, transfusions (3,4). Importantly, none of the neonates developed clinical or disseminated tuberculosis during the follow-up period.

Upon recognition of the error, a multidisciplinary team comprising pediatric infectious disease specialists, pharmacists, nursing supervisors, and hospital ethics committee members was convened to guide immediate and long-term management. Parents and guardians of all affected neonates were promptly informed, and the hospital assumed responsibility for the costs of care and follow-up for one year. All neonates were initiated on chemoprophylaxis with isoniazid (10 mg/kg/day) and rifampicin (15 mg/kg/day) for at least three months, as a precautionary measure due to the high-dose exposure. Throughout the follow-up period, clinical and laboratory monitoring was performed at regular intervals, with no mortality observed and resolution of all adverse events except for one persistent skin lesion that eventually resolved with topical therapy and antibiotics (5). Hospital leadership undertook an internal review to identify system vulnerabilities, reinforce safety protocols, and implement preventive measures, including enhanced product labeling, segregated storage of LASA products, and mandatory double-checks for all high-risk medications prior to dispensing and administration (6).

Declarations

Informed consent for publication of this case report was obtained from the parents or guardians of all involved neonates. Ethical approval for the study was granted by the hospital's

institutional review board in accordance with national and international guidelines for clinical case reporting. The authors declare that there are no conflicts of interest relevant to this case report, and no external funding was received to support this work. All authors contributed substantially to the conceptualization, data collection, analysis, and manuscript preparation. Data supporting the findings of this case report are available from the corresponding author upon reasonable request.

RESULTS

A total of 26 neonates (13 males, 13 females; age range: 2–4 days) inadvertently received an intradermal dose of ONCO-BCG, estimated to be approximately 80 times the standard neonatal BCG vaccine potency, during a routine immunization session over a two-day period. All infants were monitored for adverse drug reactions, clinical complications, and laboratory abnormalities, with follow-up conducted for up to one-year post-exposure.

Out of the 26 affected neonates, 16 (61.5%) developed skin lesions at the injection site. Of these, 15 (93.8%) progressed to papule formation, while 3 (18.8%) developed pustules, 3 (18.8%) exhibited induration, and 2 (12.5%) experienced localized erythema. Axillary lymphadenopathy was observed in one neonate (3.8%). Coagulation derangements were identified in three neonates (11.5%), with clinical manifestations including post-circumcision bleeding in two cases and intracranial hemorrhage in one case. Notably, the infant with intracranial hemorrhage presented with fever, cough, irritability, and focal seizures, and neuroimaging revealed a left subdural hematoma and minimal subarachnoid hemorrhage. Laboratory investigations in this infant showed significant hypocalcemia (serum calcium: 6.5 mg/dL), acute anemia (hemoglobin: 6.3 g/dL), and a normal coagulation profile (INR: 1.2; platelet count: 427 109/L). Factor XIII deficiency was excluded based on a normal activity level (102%; normal range: 70–100%). All infants with coagulation disorders responded favorably to supportive management, including vitamin K and transfusion as indicated.

In addition, factor X deficiency was observed in one neonate, and another developed deficiency of factors VII, IX, and X, all of which are vitamin K-dependent; both responded to vitamin K therapy. Rifampicin, part of the anti-tuberculosis chemoprophylaxis regimen, was considered as a potential contributor to coagulopathy in vitamin K-deficient patients. No cases of clinical or disseminated tuberculosis, osteomyelitis, or other severe complications were reported during the follow-up period. One infant developed a persistent weeping skin lesion on the left big toe, requiring biopsy, topical therapy, and antibiotics, with full resolution achieved over three months. No mortality occurred among the cohort.

All affected neonates were initiated on chemoprophylaxis with isoniazid (10 mg/kg/day) and rifampicin (15 mg/kg/day) for three months, as agreed upon by the hospital's multidisciplinary team. Clinical and laboratory follow-up was performed at regular intervals for one year, during which all acute complications were managed successfully, and no long-term sequelae were observed. The hospital assumed all costs associated with treatment and follow-up care.

Table 1. Clinical and Laboratory Findings in Neonates Following Accidental ONCO-BCG Administration (N = 26)

Clinical Finding	Cases (%)
Total neonates affected	26 (100)
Skin lesions (any type)	16 (61.5)
Papule	15 (57.7)
Pustule	3 (11.5)
Induration	3 (11.5)
Erythema	2 (7.7)
Axillary lymphadenopathy	1 (3.8)
Coagulation derangement (any type)	3 (11.5)
Post-circumcision bleeding	2 (7.7)
Intracranial hemorrhage	1 (3.8)
Factor X deficiency	1 (3.8)
Combined factor VII, IX, and X deficiency	1 (3.8)
Persistent weeping skin lesion	1 (3.8)
Osteomyelitis	0 (0.0)
Clinical/disseminated TB	0 (0.0)
Mortality	0 (0.0)

Table 1. Clinical and laboratory outcomes among neonates exposed to high-dose ONCO-BCG. Percentages are calculated out of the total cohort (N=26).

Although formal inferential statistics (such as p-values or effect sizes) could not be applied given the single-group nature and descriptive context of this event, the observed frequency and spectrum of adverse reactions underscore the clinical significance of the incident. The incidence of skin lesions (61.5%) and the presence of coagulation disorders (11.5%), including one case of intracranial hemorrhage, highlight the potential for serious complications with inadvertent high-dose BCG exposure in neonates.

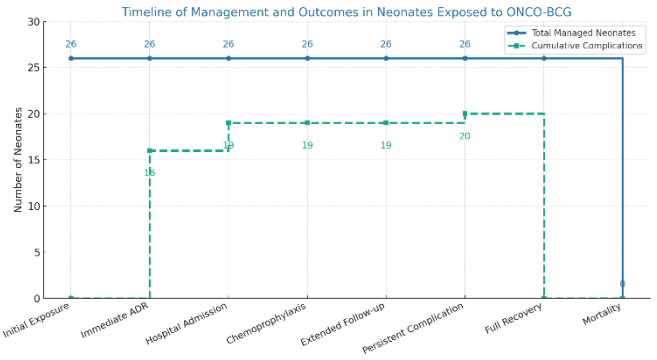

Figure 2 Management and Outcomes

All affected neonates demonstrated complete or near-complete resolution of adverse events with timely, multidisciplinary intervention. The absence of clinical tuberculosis, osteomyelitis, or mortality throughout follow-up supports the effectiveness of early chemoprophylaxis and supportive care.

DISCUSSION

The inadvertent administration of ONCO-BCG, a highly concentrated formulation intended for intravesical use in bladder cancer, to neonates in place of the standard BCG vaccine underscores a critical, yet under-recognized, medication safety

issue within pediatric immunization programs in TB-endemic regions. This incident resulted in a substantial rate of adverse drug reactions, including cutaneous lesions, coagulation disturbances, and one instance of intracranial hemorrhage, although no cases of disseminated tuberculosis or mortality were observed over extended follow-up. These findings are consistent with previous reports in the literature, which document that while BCG overdose or administration errors can cause significant local and systemic complications, early recognition and prompt multidisciplinary intervention often lead to favorable outcomes (3,5,8).

Comparative analysis with international case series and reports highlights both similarities and key distinctions. For instance, Wei et al. in Taiwan reported that incorrect dilution of BCG vaccine led to a 15% incidence of skin abscesses among neonates, with all affected infants recovering after local and supportive therapy (3). Similarly, Puliyel et al. described adverse local reactions in infants following accidental BCG overdose, noting that severe complications such as disseminated disease remain rare in immunocompetent children (4). In the present study, the predominance of cutaneous lesions and the absence of systemic mycobacterial disease support the hypothesis that host immune status plays a decisive role in determining the clinical spectrum of BCG-related adverse events. Nevertheless, the occurrence of serious complications such as intracranial hemorrhage, even in the absence of overt immunodeficiency, points to the need for heightened vigilance and individualized clinical assessment in such settings. Notably, previous literature has also implicated rifampicin, used in anti-tuberculosis prophylaxis, as a potential contributor to coagulopathy in vitamin K-deficient patients, which may partially explain some of the hematological findings observed in this cohort (4).

Mechanistically, the observed adverse effects may be attributed to the significantly higher mycobacterial load delivered via ONCO-BCG, resulting in amplified local immune and inflammatory responses, as well as an increased risk of systemic toxicity. This aligns with theoretical models of vaccine-induced hypersensitivity and local tissue injury, which predict that dose-dependent effects are most pronounced in tissues with high immunological reactivity, such as the skin and mucosa. The absence of disseminated tuberculosis in all neonates, despite marked local and hematological complications, also reinforces the importance of early and adequate chemoprophylaxis, as well as the inherent resilience of the neonatal immune system under appropriate management. Furthermore, the extended follow-up in this study, which demonstrated resolution of all complications and no late sequelae, provides valuable evidence to support the effectiveness of current prophylactic and supportive protocols in managing BCG overdose events (5,8).

Clinically, this case series reinforces the critical importance of robust medication safety systems, including the identification and segregation of look-alike, sound-alike products, mandatory double-checks at all dispensing and administration points, and ongoing staff education tailored to the specific needs of pediatric and neonatal wards. The Swiss Cheese model of error causation, referenced in both this and prior analyses, remains highly relevant, as the alignment of multiple latent system failures—including pharmacy labeling, staff rotation, and lapses in routine safety checks—was instrumental in allowing this incident to occur (9,10). The hospital's comprehensive response, including transparent disclosure to families, multidisciplinary management, and assumption of treatment costs, exemplifies best practices in patient-centered care and error rectification.

However, this study is not without limitations. The small sample size, inherent to the nature of such rare adverse events, restricts the statistical power and generalizability of the findings. The reliance on observational data and lack of a control group further limit causal inference regarding the effectiveness of specific management strategies. Methodological constraints, such as retrospective data collection and potential reporting bias, must also be acknowledged. Despite these limitations, the systematic documentation of clinical outcomes, laboratory findings, and management pathways contributes valuable insights to a sparsely reported area of pediatric safety science.

Families' Perspective

From the perspective of families, the emotional distress associated with learning of a medication error in a newborn, particularly in a tertiary care setting, was significant. Parents expressed initial anxiety and concern regarding the long-term impact of the incident, but reported appreciation for the hospital's transparency, timely intervention, and continuous support throughout the follow-up period. This feedback underscores the ethical imperative for open communication and collaborative decision-making in the aftermath of medical errors.

Future research should focus on multicenter surveillance to better quantify the incidence and spectrum of BCG-related vaccination errors, as well as prospective evaluation of intervention strategies designed to minimize LASA product confusion in high-risk clinical environments. The integration of advanced technologies, such as barcode scanning and electronic verification systems, represents a promising avenue for enhancing medication safety. Additionally, qualitative research exploring patient and caregiver experiences could further inform institutional policies aimed at fostering trust and resilience following adverse events. In summary, this report advances the field by providing a detailed account of a rare but clinically significant medication error, while highlighting actionable recommendations for improving safety and patient-centered care in neonatal immunization practices (10).

CONCLUSION

This case series highlights the critical consequences of an accidental ONCO-BCG administration during routine neonatal vaccination, revealing that look-alike pharmaceutical products and lapses in medication safety protocols can lead to significant, yet largely preventable, adverse drug reactions in vulnerable pediatric populations. Despite the occurrence of local skin lesions and coagulation abnormalities—including a rare case of intracranial hemorrhage—no cases of disseminated tuberculosis or mortality were observed, and all neonates recovered fully with multidisciplinary management and targeted chemoprophylaxis. These findings underscore the urgent need for rigorous medication safety measures, vigilant cross-checking

procedures, and comprehensive staff education to prevent similar incidents in human healthcare. Clinically, this report emphasizes the importance of rapid, transparent communication with families and the implementation of best-practice management strategies for rare vaccination errors. From a research perspective, the study calls for larger, multicenter surveillance efforts and the integration of advanced technological safeguards to minimize the risk of look-alike, sound-alike medication errors in pediatric immunization programs.

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