



Investigating BCG Vaccine-Related Adverse Events Following BCG Vaccination in Children Referred to Healthcare Centers in Tehran and Alborz, Iran

Roxana Mansour Ghanaiee,¹ Fariba Shirvani,¹ Abdollah Karimi,¹ Ahmad Reza Shamshiri,² Foroughalsadat Pourheidari,³ Fariba Rasanezhad,⁴ Yasaman Aminpour,⁵ Zhilla Mohammadi,⁶ Seyedeh Mahsan Hoseini-Alfatemi^{*}

¹Pediatric Infections Research Center, Research Institute for Children's Health, Shahid Beheshti University of Medical Sciences, Tehran, Iran

²Research Center for Caries Prevention, Dentistry Research Institute, Tehran University of Medical Sciences, Tehran, Iran

³Head of Communicable Disease Control, East Tehran Health Center, Tehran, Iran

⁴Non-Communicable Disease Research Center, Alborz University of Medical Sciences, Karaj, Iran

⁵Clinical Research Development Unit, Imam Ali Hospital, Alborz University of Medical Sciences, Karaj, Iran

⁶Dietary Supplements and Probiotic Research, Alborz University of Medical Sciences, Karaj, Iran

Abstract

Introduction: Bacillus Calmette-Guérin (BCG) vaccination is routinely administered at birth to prevent severe tuberculosis. Although BCG is generally safe, adverse events may occur. Therefore, this study aimed to describe reported adverse events following BCG vaccination among children referred to healthcare centers in Tehran and Alborz Provinces during one year of follow-up.

Methods: This registry-based prospective descriptive cohort study included 976 children enrolled between September 2022 and February 2024. Participants attending healthcare centers in Tehran and Alborz were followed for one year, with assessments every four months. To this end, parent-reported and clinically documented adverse events were recorded using Rabbit. Finally, SPSS 23 was used for data analysis.

Results: Among 976 participants, 492 (50.4%) were boys and 484 (49.6%) were girls. Diarrhea (4.20%, n=41), skin rash (2.15%, n=21), and fever (1.74%, n=17) were the most frequently reported adverse events. However, decreased milk intake (1.02%, n=10) and lymphadenopathy (0.61%, n=6) were less common. All reported events were transient and resolved without hospitalization. Ultimately, no cases of disseminated BCG infection, osteitis, or vaccine-related mortality were observed during the follow-up.

Conclusion: Reported adverse events during the follow-up were uncommon, mild, and self-limited. Given that this descriptive study lacked diagnostic confirmation and a comparison group, no causal relationship could be established between the reported events and BCG vaccination, requiring larger studies to evaluate rare BCG-related complications.

Keywords: Bacillus Calmette-Guérin vaccine, Child, Infant, Immunization, Adverse effects

*Corresponding Author:

Seyedeh Mahsan Hoseini-Alfatemi,

Email: mahsan.hoseinialfatemi@gmail.com

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Introduction

The Bacillus Calmette-Guérin (BCG) vaccine is one of the oldest and most widely used vaccines worldwide and is routinely administered at birth in countries with a high burden of tuberculosis. It provides effective protection against severe forms of childhood tuberculosis, including miliary tuberculosis and tuberculous meningitis, and has an established safety profile. Various vaccines, including coronavirus disease 2019 vaccines, influenza vaccines, and the BCG vaccine, have been associated with the adverse effects of varying frequency and severity. Although most vaccine-related adverse events are mild and self-limiting, rare but serious adverse reactions have also been reported,¹⁻⁴ including serious complications (e.g., disseminated

BCG infection), particularly in children with underlying immunodeficiency disorders.⁴⁻⁷

It should be noted that most BCG-associated adverse events are mild and self-limiting, including local ulceration, regional lymphadenopathy, low-grade fever, and transient skin reactions. In contrast, disseminated BCG infection is an uncommon but potentially life-threatening complication that is primarily observed in children with primary immunodeficiency, especially severe combined immunodeficiency and disorders affecting the interleukin-12/interferon-gamma pathway.^{8,9} Previous research has estimated the incidence of disseminated BCG infection at approximately one case per 100,000 vaccinated children, whereas local complications occur more frequently.⁸

Likewise, the frequency and pattern of reported adverse events following BCG vaccination vary among countries because of differences in vaccine substrains, vaccination techniques, surveillance systems, and population characteristics.^{9,10} Importantly, population-based vaccination registries play an important role in monitoring vaccine safety, estimating the frequency of reported adverse events, and supporting public health decision-making. Specifically, these registries provide valuable real-world data regarding vaccine safety during routine immunization programs.¹¹

Several studies from Iran and other countries have investigated severe BCG-related complications, particularly among hospitalized children and patients with primary immunodeficiency disorders.^{8,10,12-16} However, prospective registry-based studies describing reported adverse events among routinely vaccinated children in the general population remain limited, indicating that information regarding the frequency and spectrum of post-vaccination events in healthy children is still insufficient.

Hence, the present registry-based prospective descriptive cohort study seeks to describe the frequency and pattern of reported local and systemic adverse events during one year of follow-up among children who received routine BCG vaccination and were referred to healthcare centers affiliated with Tehran and Alborz Universities of Medical Sciences. Considering that the study is observational and descriptive, its objective is to characterize reported post-vaccination events rather than establish causal relationships between BCG vaccination and the observed outcomes.

Materials and Methods

Study Design

This registry-based prospective descriptive cohort study was conducted using data obtained from the main registry project, "Registration of BCG Vaccine Side Effects in Children," which began in September 2022 and concluded in February 2024. In addition, the study included 976 children who attended health centers in Tehran (Ershad, East of Tehran - Besat o Nabi, Kamalinejad, Shahid Safdari, and Pour Hedayat) and the Alborz University of Medical Sciences for their two-month vaccination. All children were monitored for one year to assess potential side effects related to the BCG vaccine (the strain used is the Pasteur strain).

Four follow-up visits were performed every four months, either by phone or in person; the first visit occurred immediately after the injection, followed by visits at 2 months, 6 months, 10 months, and 14 months post-injection. The child was referred to Mofid Children's Hospital in cases of severe complications or the need for hospitalization. A consecutive registry-based sampling strategy was used, and all eligible children presenting to the participating centers during the study period were invited to participate.

Inclusion and Exclusion Criteria

Inclusion criteria consisted of all children aged two months

who attended the participating health centers during the study period and whose parents agreed to participate in follow-up assessments. However, exclusion criteria included refusal by parents or legal guardians to participate in the study and non-Iranian nationality.

Sampling Method

A consecutive registry-based sampling strategy was employed. All eligible children who presented to the participating centers during the study period were invited to participate.

Definition of Complications

Complications were defined as any parent-reported or clinically documented adverse event occurring during the follow-up period. In this study, reported complications were categorized as local (e.g., lymphadenopathy) or systemic (e.g., fever, diarrhea, skin rash, and decreased milk intake). It should be noted that severity grading was not performed because all recorded events were mild and self-limited.

Furthermore, no diagnostic investigations were routinely conducted to determine whether the reported events were causally related to BCG vaccination. Events were recorded based on parental reports and/or clinical observations during the follow-up. Thus, the registry was designed to document post-vaccination adverse events rather than establish vaccine causality.

Statistical Analysis

Data were analyzed using IBM Statistical Package for the Social Sciences (SPSS) statistical software, version 23. Means were used to describe quantitative variables, while frequencies and percentages were employed to describe qualitative variables.

Results

Demographic Data

This study evaluated 976 children referred to participating health centers. Among them, 50.4% ($n = 492$) were boys and 49.6% ($n = 484$) were girls. The study flowchart showing participant enrollment, follow-up, and the proportion of children with at least one reported adverse event is presented in [Figure 1](#). The mean age and weight of participants at each follow-up stage are provided in [Table 1](#). A total of 976 children were enrolled in the registry, and all participants completed the scheduled follow-up assessments. No participants were lost to follow-up or excluded after enrollment. Therefore, all enrolled children were included in the final analysis.

Data on the Side Effects of Bacillus Calmette-Guérin Vaccination

This study investigated complications such as fever, skin rash, decreased breastfeeding, hepatomegaly, lymphadenopathy, diarrhea, and bone involvement in children. The results are presented in [Table 2](#).

According to the findings, none of the reported

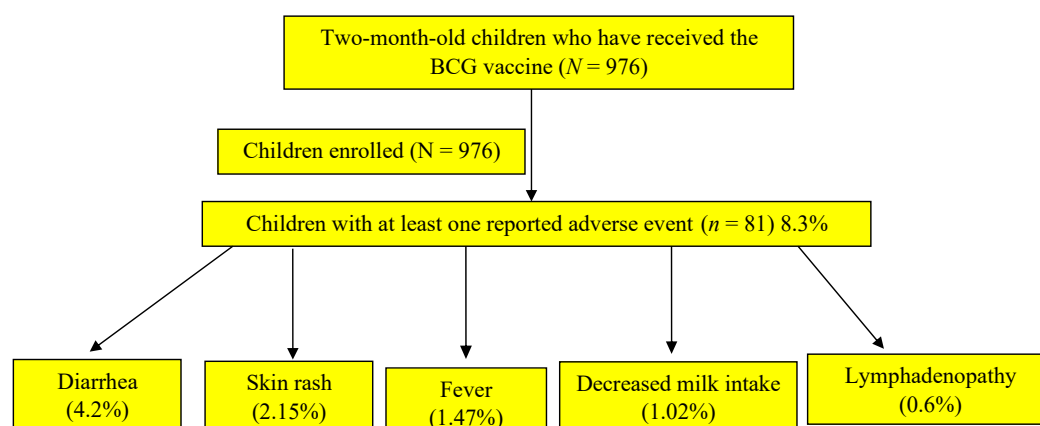


Figure 1. Study Flowchart and Reported Adverse Events. Note. BCG: Bacillus Calmette-Guérin

Table 1. Age and Weight Distribution of Children Participating in the Study at the Four Stages

Mean	2 Months Old	6 Months Old	10 Months Old	14 Months Old
Mean age (months)	2	6.1	10.3	14.4
Mean weight (g)	5170	7500	8990	10460

cases of fever were persistent. Additionally, the cases of skin rash were not continuous or widespread. In three cases of diarrhea, the incidence occurred during two consecutive stages. Moreover, there were five reports of lymphadenopathy, four of which were axillary and one unspecified. Likewise, three cases were unilateral, while two were bilateral. No instances of hepatomegaly, bone involvement, or fatalities were reported. Further, none of the cases required hospitalization for vaccine-related complications. Overall, 81 children experienced at least one reported adverse event during the follow-up. Given that no diagnostic investigations or comparison group were available, these events should be interpreted as observations occurring after vaccination rather than confirmed vaccine-related complications.

Discussion

The present registry-based prospective cohort study demonstrated that reported adverse events following BCG vaccination were uncommon and generally mild. In addition, diarrhea, skin rash, and fever were the most frequently reported events, all of which resolved spontaneously without hospitalization or specific treatment. No cases of disseminated BCG infection, osteitis, or vaccine-related mortality were observed during the one-year follow-up period. Considering that this study was descriptive and lacked diagnostic confirmation and a comparison group, these findings should be interpreted as reported post-vaccination events rather than confirmed vaccine-associated adverse reactions. Furthermore, without diagnostic evaluation or an unvaccinated comparison population, it is impossible to determine whether the reported events were causally related to BCG vaccination or coincidentally occurred during infancy.

The frequency of reported adverse events in the present

study (0.61–4.20%) is comparable to that reported in previous studies, where adverse events following BCG vaccination ranged from 1.6% to 34%, depending on the study population, vaccine strain, surveillance method, and diagnostic criteria.^{17–19} Marciano et al estimated that local BCG-related complications occur in approximately one per 2,500 vaccinated children.²⁰ Although the reported frequency in our study was higher, all observed events were mild, transient, and required no specific treatment.

Our findings are consistent with those of previous population-based studies, indicating that most adverse events following BCG vaccination are mild and self-limiting. Mild local reactions and regional lymphadenopathy are considered expected responses after vaccination and generally resolve without intervention.²¹ Similarly, Yamoah et al found that fever, skin rash, diarrhea, injection-site reactions, and several nonspecific symptoms were among the commonly mentioned adverse events following BCG vaccination.²² Differences in the observed frequency of adverse events across countries may be explained by variations in vaccine strains, vaccination techniques, vaccine storage conditions, surveillance systems, and host genetic characteristics.²³

Transient diarrhea was the most frequently reported event in our study. Unlike persistent diarrhea accompanied by fever and weight loss, which has been described in disseminated BCG infection.²⁴ In the present study, diarrhea resolved spontaneously within a few days and therefore cannot be considered evidence of vaccine-related disease. Additionally, lymphadenopathy was uncommon (0.61%), which is in line with the findings of the multicenter study performed by Nissen et al²⁵ but considerably lower than rates found in previous Iranian research.⁸

Importantly, no cases of purulent lymphadenitis were identified in the present study, which conforms to current World Health Organization reports, demonstrating that suppurative lymphadenitis is uncommon when vaccination is performed using standardized techniques and appropriate vaccine doses.²⁶

Based on the results, no disseminated BCG infection or osteitis was observed during the follow-up period, which corroborates the findings of previous population-based

Table 2. Complications of BCG Vaccination

Complications of the Vaccine	Number of Reported Cases (%)	2 Months Old	6 Months Old	10 Months Old	14 Months Old
Fever	17 (1.74)	3	3	11	0
Skin rash	21 (2.15)	16	3	2	0
Decreased breastfeeding	10 (1.02)	3	4	3	0
Diarrhea	41 (4.20)	5	8	20	8
Lymphadenopathy	6 (0.61)	2	2	2	0
Hepatomegaly	0	0	0	0	0
Bone involvement	0	0	0	0	0
Death	0	0	0	0	0

Note. BCG: Bacillus Calmette-Guérin.

studies conducted among routinely vaccinated children. Mansour Ghanaee et al concluded that local reactions and lymph node involvement were the most common findings in Iranian children, while no cases of disseminated BCG infection or osteitis were identified.⁴

In contrast, some previous Iranian studies reported relatively high frequencies of disseminated BCG infection.^{8,27} However, direct comparison should be made cautiously because those investigations primarily included hospitalized children or patients with primary immunodeficiency disorders, thereby representing highly selected high-risk populations rather than routinely vaccinated children. Consequently, the higher rates of severe complications reported in those studies are not directly comparable with the findings of the present registry-based cohort. Nevertheless, these reports highlight the importance of considering underlying primary immunodeficiency in infants who develop severe, persistent, or unusual complications following BCG vaccination.

Overall, the findings of the present study describe the pattern of observed adverse events among routinely vaccinated children attending healthcare centers rather than high-risk hospitalized populations. Nonetheless, future multicenter studies with larger sample sizes, standardized diagnostic evaluation, and appropriate comparison groups are warranted to better estimate the incidence of rare BCG-related complications and clarify the causal relationship between reported adverse events and BCG vaccination.

Limitations of the Study

This study had several limitations. First, the reported adverse events were based primarily on parental observations and routine clinical follow-ups, without standardized diagnostic investigations to confirm whether the events were causally related to BCG vaccination. Therefore, the findings should be interpreted as reported post-vaccination events rather than confirmed vaccine-related complications. Moreover, this was a descriptive registry-based study without an unvaccinated or comparison group. Consequently, causal relationships between the reported events and BCG vaccination cannot be established. Additionally, only descriptive statistical analyses were performed because the primary objective of the study was to describe the frequency and pattern of reported adverse events. It should be noted

that no analytical statistical comparisons or risk factor analyses were conducted in this study. Finally, although the study included 976 children with complete one-year follow-up, the sample size was insufficient to evaluate highly rare complications such as disseminated BCG infection or osteitis. Accordingly, larger multicenter studies with longer follow-ups and standardized diagnostic evaluations are needed to more accurately assess the incidence of rare BCG-associated complications.

Conclusion

In this study, diarrhea, skin rash, and fever were the most frequently observed symptoms during the follow-up, while lymphadenopathy was uncommon. In addition, no cases of disseminated BCG infection were identified. Given that this study was descriptive and lacked a comparison group, these findings should be interpreted as reported post-vaccination events rather than vaccine-attributable complications. Likewise, no causal relationship between the reported events and BCG vaccination can be established since the study was descriptive and included a comparison group. The findings therefore should be interpreted as observational rather than causal. Although no disseminated BCG infection was identified in this cohort, clinicians should remain aware of the possibility of underlying primary immunodeficiency in infants who develop severe or unusual vaccine-related complications. Decisions regarding BCG vaccination timing should be guided by national vaccination policies and specialist clinical assessment rather than by the findings of the present study.

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Artificial Intelligence Disclosure

The authors used ChatGPT (OpenAI) solely to improve the English language and readability of the manuscript. Additionally, all scientific content, study design, data analysis, interpretation of the findings, and final approval of the manuscript were performed by the authors, who take full responsibility for the content.

Authors' Contribution

Conceptualization: Roxana Mansour Ghanaee, Abdollah Karimi

Data Curation: Foroughalsadat Pourheidari, Fariba Rasanezhad, Yasaman Aminpour, Zhilla Mohammadi, Seyedeh Mahsan Hoseini-Alfatemi

Formal Analysis: Ahmad Reza Shamshiri

Investigation: Roxana Mansour Ghanaiee, Seyedeh Mahsan Hoseini-Alfatemi

Methodology: Fariba Shirvani, Seyedeh Mahsan Hoseini-Alfatemi

Project Administration: Seyedeh Mahsan Hoseini-Alfatemi

Software: Ahmad Reza Shamshiri, Seyedeh Mahsan Hoseini-Alfatemi

Supervision: Roxana Mansour Ghanaiee

Validation: Roxana Mansour Ghanaiee, Fariba Shirvani, Abdollah Karimi, Ahmad Reza Shamshiri, Foroughalsadat Pourheidari, Fariba Rasanezhad, Yasaman Aminpour, Zhilla Mohammadi, Seyedeh Mahsan Hoseini-Alfatemi

Writing-Original Draft: Seyedeh Mahsan Hoseini-Alfatemi, Roxana Mansour Ghanaiee

Writing-Review & Editing: Roxana Mansour Ghanaiee, Fariba Shirvani, Abdollah Karimi, Ahmad Reza Shamshiri, Foroughalsadat Pourheidari, Fariba Rasanezhad, Yasaman Aminpour, Zhilla Mohammadi, Seyedeh Mahsan Hoseini-Alfatemi

Competing Interests

The authors declared no conflict of interests.

Ethical Approval

The study protocol was reviewed and approved by the Ethics Committee of the Research Institute for Children's Health, Shahid Beheshti University of Medical Sciences, Tehran, Iran (ethics code: IR.SBMU.RICH.REC.1398.031).

Additionally, verbal informed consent was obtained from the parents or legal guardians of all participating children before enrollment. Likewise, all procedures were performed in accordance with the ethical standards of the institutional research committee and the principles of the Declaration of Helsinki. Participant confidentiality was also maintained throughout the study, and all data were anonymized before analysis.

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