

LITERATURE REVIEW

RELATIONSHIP BETWEEN BCG VACCINATION HISTORY AND THE INCIDENCE OF LEPROSY IN CHILDREN: A LITERATURE REVIEW

Hubungan Antara Riwayat Vaksin BCG dan Kejadian Kusta Pada Anak: Sebuah Tinjauan Literatur

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ABSTRACT

Background: Globally, 9,052 new cases of leprosy in children were reported, with a corresponding rate of 4.5 per million child population. Children are believed to be the most vulnerable group to *M. leprae* infections due to their immature immunity. **Purpose:** This study aims to determine the relationship between the history of BCG vaccination and leprosy incidence in children. **Methods:** This study used a literature review method that involved a systematic search. The data sources were obtained using several databases, namely Google Scholar, Proquest, Science Direct, and Pubmed. Keywords were built using the PICOS protocol and Boolean Operators, so the keywords used were "relationship" AND "BCG vaccine" AND "leprosy" AND "children". The research selection and search procedures were explained using the PRISMA 2020 method and research included in this study following the inclusion and exclusion criteria that have been set. **Results:** There were eight studies suitable for inclusion in this literature review. Five articles concluded that there was a relationship between the history of BCG vaccine and the incidence of leprosy in children, while three articles concluded that there was no relationship between the two variables. **Conclusion:** The BCG vaccine is useful as an effort to prevent the transmission and spread of leprosy in children. Children who do not receive BCG immunization are more susceptible to leprosy than those who receive immunization. The BCG vaccine has a protective effect to prevent children from contracting and transmitting leprosy to other people.

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ABSTRAK

Latar belakang: Secara global, 9052 kasus baru pada anak dengan kusta dilaporkan dari 4,5 per juta populasi anak. Anak-anak diyakini sebagai

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kelompok yang paling rentan terhadap infeksi *M. leprae* karena kekebalannya yang belum matang. **Tujuan:** Penelitian ini bertujuan untuk mengetahui hubungan antara riwayat vaksin BCG dengan penyakit kusta pada anak. **Metode:** Penelitian ini menggunakan metode studi literatur yang melibatkan pencarian secara sistematis. Sumber data diperoleh dengan menggunakan beberapa database yaitu Google Scholar, Proquest, Science Direct, dan Pubmed. Kata kunci dibentuk menggunakan protokol PICOS dan Operator Boolean, sehingga kata kunci yang digunakan adalah "relationship" AND "BCG vaccine" AND "leprosy" AND "children". Pemilihan penelitian dan prosedur pencarian dijelaskan dengan menggunakan metode PRISMA 2020 dan studi yang dimasukkan dalam kajian penelitian ini sesuai dengan kriteria inklusi dan eksklusi yang telah ditetapkan. **Hasil:** Ditemukan 8 penelitian yang sesuai untuk dimasukkan dalam tinjauan literatur ini. Lima artikel menyimpulkan bahwa ada hubungan antara riwayat pemberian vaksin BCG dengan kejadian kusta pada anak, sedangkan tiga artikel menyimpulkan bahwa tidak ada hubungan antara kedua variabel tersebut. **Simpulan:** Pemberian vaksin BCG bermanfaat sebagai upaya pencegahan penularan dan penyebaran kusta pada anak. Anak yang tidak mendapat imunisasi BCG lebih mudah terkena penyakit kusta dibandingkan dengan anak yang mendapat imunisasi. Vaksin BCG memiliki efek perlindungan untuk mencegah anak tertular dan menularkan penyakit kusta kepada orang lain.

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INTRODUCTION

Leprosy is a long-lasting contagious illness triggered by a bacterium called *Mycobacterium leprae*. This bacterium primarily affects various parts of the body, such as the skin, peripheral nerves (nerves outside the brain and spinal cord), mucous membranes of the upper respiratory tract (nose and throat), and eyes (1). Leprosy is a neglected tropical disease among 20 other diseases that cause health, social, and economic problems (2). If the range of disorders arising from leprosy are not effectively managed, they have the potential to result in disability for the affected person, consequently impeding their capacity to achieve higher levels of productivity (3). Hampered productivity will have an impact on the family economy and become a stigma in society due to limited public understanding and excessive fear of leprosy (4).

New cases in children indicate recent transmission, Globally the three countries in a row that accounted for 74.5% of new leprosy cases detected worldwide in 2021 were Brazil, India, and Indonesia. Based on the data, out of 143 countries that reported, 36 reported 0 new cases, 58 reported <100 new cases, 36 reported 101-1000 new cases, and 10 countries reported 1001-10,000 new cases. Brazil, India, and Indonesia each continue to report more than 10,000 new cases.

The trend in the number of new child cases detected globally is decreasing, where in 2011 it was 12.3 per million and in 2021 it was 4.5 per million child population. An increase in the number of cases of children was observed in 2021 when compared with 2020 (a total of 8,642 cases) (5).

A particular focus on children as an effort to reduce disability and reduce transmission is one of the core areas of intervention of the global leprosy strategy 2021-2030, recently published by the World Health Organization. Case detection in children is considered a problem indicator of recent transmission of infection in the community (6). Children are considered to be the most vulnerable group to *Mycobacterium leprae* infections because of their immature immunity, especially if children do not get essential vaccines (7). Bacillus Calmette-Guerin vaccination is known to have intervened in producing some protection against leprosy. Previous studies have found that BCG vaccination offers partial immunity against *Mycobacterium leprae* (8). However, the degree of protective effect of BCG varies greatly with each study (both observational studies and clinical trials) (9).

One of the main problems in studying the relationship between the BCG vaccination and leprosy is the lack of consistent and conclusive evidence. While some studies have suggested a

partial protective effect of BCG vaccination against leprosy in children, others have not found the significant association. This inconsistency may be due to various factors, including differences in the study design, population characteristics, and the complex nature of leprosy transmission. Another challenge is the limited effectiveness of BCG vaccination in preventing leprosy. Even in studies that have shown the protective effect, the reduction in risk is typically modest (10). This finding highlights the need for additional preventive strategies and interventions to control leprosy in children.

Furthermore, there are global challenges in the implementation of BCG vaccination programs. Access to healthcare services, including vaccination programs, is unequal in many parts of the world. This leads to disparities in BCG vaccination coverage, leaving certain populations at a higher risk of leprosy and other infectious diseases (11). To address these challenges, it is crucial to continue research on the relationship between BCG vaccination and leprosy, as well as to explore other preventive measures.

Based on the description, the authors are interested in further examining the relationship between BCG vaccination history and the incidence of leprosy in children by using the literature review method conducted to identify and interpret all research results that are relevant to the research question and the phenomenon determined by comparing the data found.

METHODS

This study used a literature review method, where data sources were obtained using search engines through several accessible electronic databases, namely Google Scholar, Proquest, Science Direct, and Pubmed. The search process of the research followed the PICOS protocol (Population-Intervention-Comparison-Outcome-Study Design). As for the description of the PICOS used in this study: (P) leprosy in children, (I) BCG vaccination history, (C) non-leprosy, (O) relationship between BCG vaccination history and the incidence of leprosy in children, (S) study design was cross-sectional, case-control and cohorts. Boolean Operators were used as the tool to construct keywords when performing a search. Keywords adapted to the PICOS rule to obtain relevant research, therefore the keywords used were "relationship" AND "BCG vaccine" AND "leprosy" AND "children".

Research selection and search procedures were explained using the PRISMA 2020 method (The Preferred Reporting Items for Systematic Review and Meta-Analysis) to seek and identify research transparently and systematically. Determination of research to be included according to the inclusion and exclusion criteria that have been set. The inclusion criteria used in this study were: (i) articles published in the last 10 years (2014-2023), (ii) full-text articles published and freely accessible, (iii) articles using Indonesian and English, (iv) the article is not a literature review, systematic review, and meta-analysis, (v) not the type of gray literature article; books, dissertations, theses, etc. Exclusion criteria in this study were: (i) the article did not discuss about the relationship between BCG vaccination history and leprosy in children.

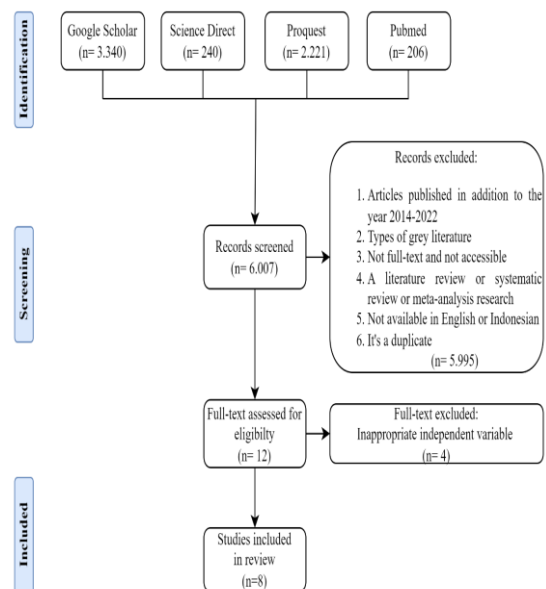


Figure 1. PRISMA Flow Chart

All titles and abstracts were screened based on the criteria of publications published in the last 10 years, type of research article, and in Indonesian and English. Full-text and open-access articles were examined for eligibility criteria. The inclusion criteria were children aged less than 15 years and the article discussed the history of BCG vaccination. The authors carried out data extraction and synthesized the information obtained from each study as described in the table. The preparation of tables in data synthesis followed the information requirements according to the PICOS framework, which describes: (i) the researcher, (ii) the country, (iii) methods, and (iv)

findings. Research was presented to analyze the relationship between a history of the BCG vaccine and leprosy in children.

RESULTS

Research Quality

Data search results based on keywords that have been set were shown in Figure 1. In total, 6,007 studies were identified and entered the screening stage.

After screening based on the inclusion criteria set, 5,995 studies were excluded, and 12 studies were obtained for full-text screening. As a result of the full-text screening based on the established exclusion criteria, a total of 4 studies were excluded. The reasons underlying the exclusion of these four studies because the studies did not discuss about the relationship between BCG vaccination history and leprosy in children. Thus, eight studies were used in compiling the literature review.

Study Characteristic

The results of a review of eight articles that were included in the synthesis stage to study the relationship between BCG vaccination history and leprosy in children are shown in Table 1. The research included in this study was research conducted in Indonesia, Brazil and India. Judging from eight articles found, five articles used a case-control study design, while the other three used cross-sectional study design. Based on research reports, various results were found about relationship between vaccine BCG history and leprosy in children, five of them concluded that there is a relationship between BCG vaccination history and the incidence of leprosy in children, whereas three articles concluded that there is no relationship between the two variables.

DISCUSSION

The BCG vaccine is primarily known for its use in preventing tuberculosis (TB). However, it has also been used as an immunoprophylactic measure against leprosy which is a chronic infectious disease caused by the bacterium *Mycobacterium leprae*. The vaccine is typically administered at birth or during early childhood. In regions with a high burden of leprosy, the BCG

vaccine is given to prevent severe forms of the disease in children who may be exposed to leprosy bacteria. In some studies, the BCG vaccine shows its effect in preventing leprosy. A study conducted in Indonesia in leprosy endemic areas found statistically significant differences ($p= 0.04$) between BCG vaccination of children with leprosy in endemic areas and children without leprosy in non-endemic areas of leprosy. This study suggests leprosy infection can be prevented and protected because of the effect of the vaccination received (12).

Similar to three studies conducted in Gresik, Indonesia, which found a relationship between the history of receiving the BCG vaccine and the incidence of leprosy in children (13–15). Prior BCG vaccination is shown to be a strong predictor, which means that the children who did not undergo BCG immunization have an OR exp (B) of 22,164 times to contract leprosy (14). A study explains that access to health services is still an obstacle to administering the BCG vaccine (13), in line with research that mentions leprosy transmission factors in children can be seen from the coverage of the BCG vaccine program that is imperfect (16). The study conducted found a statistical relationship, but in the study 26 people who had leprosy and had a history of BCG vaccination, more than respondents who did not have a history of BCG vaccination but had leprosy. So there were doubts about the relationship between the two variables and it was concluded that it was necessary to re-vaccinate BCG to protect against leprosy bacteria (17). However, one of the preventive measures to help stop the transmission of leprosy infection in endemic areas is BCG vaccination which can increase the cellular immune response (18).

Table 1

Characteristics of Reviewed Study

Researcher	Country	Method	Findings
(Nuraeni, 2018)	Indonesia	Case-Control; 13 Cases and 52 Controls	There is no relationship between the history of the BCG vaccination and the incidence of leprosy in children ($p=0.70$). It was found that the number of child leprosy sufferers who had a history of vaccination was almost the same as those who did not have a history of vaccination.
(Endaryanto, Prakoeswa, & Prakoeswa, 2020)	Indonesia	Cross-Sectional; 173 Cases of maternal leprosy and the leprosy cases among children	There is a relationship between the history of BCG vaccination and the incidence of leprosy in children living in endemic areas ($p=0.04$).
(Sarkar et al., 2020)	India	Cross-Sectional; 137 pediatric leprosy patients	There is a relationship between the history of BCG vaccination and the incidence of leprosy in children ($p=0.03$). The proportion of MB leprosy was statistically significant in the unvaccinated group compared to the vaccinated group.
(Rodrigues et al., 2020)	Brazil	Case-Control; 40 Cases and 164 Controls	There is no relationship between a history of BCG immunization and the incidence of leprosy in children under 15 years ($p=0.06$). It was found that the number of child leprosy sufferers who had a history of vaccination was almost the same as those who did not have a history of vaccination.
(Haerani, Pramuningtyas, Mahmudah, & Prakoeswa, 2021)	Indonesia	Case-Control; 34 Cases and 34 Controls	There is a relationship between a history of BCG vaccination and the incidence of leprosy ($p=0.00$). It was found that 26 people had leprosy and had a history of BCG vaccination, more than respondents who did not have a history of BCG vaccination but had leprosy. This study concluded that BCG revaccination is needed to protect against leprosy bacteria
(Prakoeswa et al., 2021)	Indonesia	Case- Control; 30 Cases and 30 Controls	There is a relationship between the history of BCG vaccination and the incidence of leprosy in children ($p=0.02$). The strongest risk predictor factor was the absence of previous BCG vaccination in children
(Sato et al., 2022)	Brazil	Cross-Sectional; 236 Social contacts	There is no relationship between a history of BCG immunization and positive cases of leprosy in children under 15 years ($p=0.67$). It was found that the number of child leprosy sufferers who had a history of vaccination was almost the same as those who did not have a history of vaccination.

Table 1

Continued

Researcher	Country	Method	Findings
(Arifin et al., 2022)	Indonesia	Case-Control; 18 Cases and 18 Controls	There is a relationship between the history of BCG vaccine and the incidence of leprosy in children ($p=0.02$). From the results of an analysis of the status of the BCG vaccine in Gresik Regency in 2019, both cases and controls found 23 children (69.40%) did not have the BCG vaccine because their access to health services was limited.

A study examining the effectiveness of the BCG vaccine in children in India found a relationship between the history of BCG vaccination and the incidence of leprosy in children ($p= 0.02$). This study also found that PB leprosy was most common in the age group <12 years and the proportion of MB leprosy was statistically significant in the unvaccinated group compared to the vaccinated group (19). These results are in line with studies conducted from four leprosy endemic in Brazil showing that more leprosy sufferers who had not received the BCG vaccine were detected as MB-type leprosy patients compared to PB-type leprosy patients. In addition, BCG vaccination protection was effective against leprosy even in the multibacillary form (20).

The reason for using BCG as a leprosy vaccine is based on the understanding that *M. leprosy* and *M. bovis* (BCG) have numerous similar antigens with a high degree of homology (20). Leprosy is a disease characterized by impaired cell-mediated immunity (CMI) specific to the disease. CMI decreases from Pausi Baciller to Multi Baciller leprosy. Although the multidrug therapy kills the bacilli, it has no role in enhancing CMI. It cannot prevent the susceptibility to acquired infection nor effectively clear dead bacilli from the body rendering the individual to dead bacilli-related complications like reaction. Various vaccines, including BCG, have been tested to boost CMI. Vaccine studies have utilized live or killed whole mycobacterium, such as Bacille Calmette-Guérin (BCG), Indian cancer research center (ICRC) bacilli, and *Mycobacterium weither* alone or in combination with killed *Mycobacterium leprae*. Additionally, there is evidence that BCG vaccination may modify CMI, as there were fewer vaccinated individuals with advanced leprosy cases compared to unvaccinated individuals (19).

Three studies that examined leprosy in children found that there was no relationship between the history of BCG vaccination and the

incidence of leprosy in children. This happens because descriptive statistics show that the number of child leprosy sufferers who have a history of vaccination is almost the same as those who do not have a history of vaccination. In addition, other factors are more dominant in influencing the incidence of leprosy in children, such as environmental factors, family history of leprosy, history of contact (21), and duration of contact with leprosy sufferers (22–23). In line with research that found the factors related to the incidence of leprosy after adjusting for age, children who had a family history of leprosy were 8.76 times more likely to develop leprosy than children who did not have a family history of leprosy (24).

This research can be the basis for raising public awareness and improving access to BCG vaccination, especially in areas with a high leprosy burden. Policies can be implemented to ensure that all children receive the BCG vaccine according to the recommended immunization schedule. Apart from vaccination, policies can focus on public education about the symptoms of leprosy, early examination, appropriate treatment, and reducing stigmatization of leprosy sufferers. In addition, further research needs to be carried out to understand the protective mechanism of the BCG vaccine against leprosy. Policies can be encouraged to support further research involving the development of new vaccines or improving the effectiveness of existing BCG vaccines.

Research Limitations

It is important to know that literature review research is a way to combine findings from various existing studies conducted by various researchers with different methodologies. Differences in research design, sample population, sample size, and operational definitions of leprosy variables, as well as the history of BCG vaccination in children, can influence the findings. In addition, this

literature review limits the use of Indonesian and English only, so it is possible that research from other geographies was not included in the synthesis of findings. This literature review study also shows the need for further research to understand the mechanism of BCG vaccine protection against leprosy. Further research, including well-designed prospective studies, is needed to provide more robust evidence on this topic.

CONCLUSION

The relationship between BCG vaccination history and leprosy in children suggests a potential protective effect of BCG vaccine against leprosy. BCG vaccine has benefits in preventing the transmission and spread of leprosy in children. Children who were not given BCG immunization were more susceptible to developing leprosy compared to those who were given immunization. Numerous studies have explored this relationship and have found evidence supporting the idea that BCG vaccination might provide additional benefits in preventing leprosy, especially in areas where leprosy transmission was high. However, the effectiveness of BCG vaccination in preventing leprosy may vary depending on factors, such as geographic location, endemicity of leprosy, history of contact with leper, length of contact with lepers, and conditions of residence. Overall, although BCG vaccination may offer some degree of protection against leprosy, its role as a preventive measure should be considered in the broader context of a comprehensive leprosy control program.

CONFLICT OF INTEREST

All authors have no conflict of interest to declare for this study.

AUTHOR CONTRIBUTIONS

ANAMP and SM contributed equally during the conceptualization. ANAMP took part in the methodology, analysis, and writing original draft preparation. SM gives advice and suggestions by reviewing and revision this article. NMGN contributed to writing-reviewing and editing.

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