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Original Article

Post-exposure prophylaxis for leprosy: evidence map

Profilaxia pós-exposição à hanseníase: mapa de evidências

Profilaxis post-exposición a la lepra: mapa de evidencia

Gabrielle Guedes Pedroso[1], Ana Carolina Vidigal Vieira Ferreira[1], Maria Luiza Quintiliano[1], Sarah Lamas Vidal[2], Gesner Francisco Xavier[2], Fernanda Moura Lanza[3], Angélica da Conceição Oliveira Coelho[1]

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Corresponding author:
Gabrielle Guedes Pedroso
guedespedrosogabrielle@gmail.com

ABSTRACT

Objective: To map evidence on post-exposure prophylaxis for leprosy through a graphical synthesis of effects and exposure levels. **Method:** Evidence map developed based on searches conducted between October 2020 and October 2021 in the VHL, Cochrane, Web of Science, Embase, PubMed, and Scopus databases. Reviews that assessed the effectiveness of post-exposure prophylaxis were included, while studies involving symptomatic participants were excluded. Critical appraisal, characterization, and graphical representation of studies were carried out. **Results:** Seven reviews were included, analyzing chemoprophylaxis, immunoprophylaxis, and their combination. Evidence showed positive or potentially positive results. Six studies presented critically low-quality evidence, and one was rated as low quality. **Conclusion:** There is favorable evidence supporting the effectiveness of the assessed intervention. However, further research with greater methodological rigor is needed.

DESCRIPTORS:
Leprosy; Post-Exposure Prophylaxis; Evidence-Based Practice.

[1] Universidade Federal de Juiz de Fora. Juiz de Fora, Minas Gerais, Brazil.
[2] Universidade Federal de Minas Gerais. Belo Horizonte, Minas Gerais, Brazil.
[3] Universidade Federal de São João del-Rei. São João del-Rei, Minas Gerais, Brazil.

RESUMO
Objetivo: Mapear evidências sobre a profilaxia pós-exposição à hanseníase por meio de síntese gráfica dos efeitos e níveis de exposição. **Método:** Mapa de evidências construído a partir de buscas nas bases BVS, Cochrane, *Web of Science*, Embase, PubMed e Scopus, realizadas entre outubro de 2020 e outubro de 2021. Foram incluídas revisões que avaliaram a eficácia da profilaxia pós-exposição, excluindo estudos com participantes sintomáticos. Procedeu-se à avaliação crítica, caracterização e representação gráfica dos estudos. **Resultados:** Sete revisões foram incluídas, analisando quimioprofilaxia, imunoprofilaxia e a combinação entre ambas. As evidências apontaram resultados positivos ou potencialmente positivos. Seis estudos apresentaram qualidade da evidência criticamente baixa, e um, baixa. **Conclusão:** Há evidências favoráveis à efetividade da intervenção avaliada. No entanto, destaca-se a necessidade de novas pesquisas com maior rigor metodológico.

DESCRITORES:
Hanseníase; Profilaxia Pós-Exposição; Prática Clínica Baseada em Evidência.

RESUMEN
Objetivo: Mapear evidencias sobre la profilaxis posexposición para la lepra mediante una síntesis gráfica de los efectos y niveles de exposición. **Método:** Mapa de evidencias elaborado a partir de búsquedas realizadas entre octubre de 2020 y octubre de 2021 en las bases de datos BVS, Cochrane, *Web of Science*, Embase, PubMed y Scopus. Se incluyeron revisiones que evaluaron la eficacia de la profilaxis posexposición, y se excluyeron estudios con participantes sintomáticos. Se realizó una evaluación crítica, caracterización y representación gráfica de los estudios. **Resultados:** Se incluyeron siete revisiones que analizaron la quimioprofilaxis, la inmunoprofilaxis y la combinación de ambas. Las evidencias mostraron resultados positivos o potencialmente positivos. Seis estudios presentaron calidad de evidencia críticamente baja, y uno, baja. **Conclusión:** Existen evidencias favorables sobre la efectividad de la intervención evaluada; sin embargo, se destaca la necesidad de nuevas investigaciones con mayor rigor metodológico.

DESCRIPTORES:
Lepra; Profilaxis Posexposición; Práctica Clínica Basada en la Evidencia.

INTRODUCTION

Leprosy is an infectious disease whose etiological agent is *Mycobacterium leprae* (M. *leprae*), and it affects mainly the skin and peripheral nerves. Its diagnosis is essentially clinical and epidemiological. Leprosy treatment is free of charge and consists of the administration of three drugs (rifampicin, dapsone, and clofazimine). Treatment should begin soon after diagnosis[1].

Leprosy remains a public health concern on a global scale. In 2023, there was a 5% increase in the detection of new cases, totaling 182,815 reported cases. Of the newly identified cases, 9,729 were grade two physical disabilities, accounting for more than 5% of all newly identified cases. Additionally, 10,322 new cases were identified in children, which is an indicator of recent transmission and highlights the need to improve disease control measures[2].

To reduce the chain of transmission, the World Health Organization launched a global strategy for combating leprosy in 2021-2030. Expectations are that by 2030 the strategy will achieve a reduction of 70% in the number of cases registered annually, 90% of cases with grade two physical disability and 90% of new cases detected. It is also expected that 120 countries will not report new cases. To achieve

these goals, the proposed actions involve the optimization of existing tools, contact tracing, the use of post-exposure prophylaxis (PEP), and the active search for cases, in addition to the introduction of new tools such as diagnostic tests, vaccines and an improved preventive regimen[3].

The term "PEP" can be used to refer to both chemoprophylaxis and immunoprophylaxis. Chemoprophylaxis involves medication administration, typically used in leprosy treatment, to individuals who have been in contact with an untreated infectious case but have not yet developed the disease, aiming to prevent its onset, and it has proven to be effective. This intervention has been studied and implemented in some regions as an additional strategy to reduce the transmission chain of the disease [4-5]. Regarding immunoprophylaxis, the Bacillus Calmette-Guérin (BCG) vaccine, initially developed against the tuberculosis bacillus, also provides protection against leprosy[6]. The enhanced protective effect of the combination of chemoprophylaxis and immunoprophylaxis is noteworthy[7].

Despite the advances proposed for leprosy control, epidemiological data show the need for improvement in disease control actions. Chemoprophylaxis together with immunoprophylaxis, when offered to contacts of leprosy cases who have not yet developed the disease, has been shown to be an important strategy for reducing transmission of the disease. There are studies on the effectiveness of PEP. However, there are still challenges in the use of these measures.

OBJECTIVE

To map evidence on PEP for leprosy through a graphical synthesis of effects and exposure levels.

METHODOLOGY

Study design

This is an evidence map. This methodology consists of a synthesis that provides a systematic overview of the literature regarding a specific area or theme, seeking to identify, describe, characterize, and graphically represent what is already known. The map allows the organization of scientific knowledge based on the association of interventions, themes and their outcomes of interest. Furthermore, it allows the identification of knowledge gaps[8,9].

Inclusion and exclusion criteria

To create the map, a systematic literature search was performed. Inclusion criteria based on the PICO anagram were used for this purpose. Thus, reviews that assessed contacts of leprosy cases, as well as the general population without clinical signs of the disease, were included in the study. We sought to compare individuals who received PEP with those who did not receive PEP and its influence on the onset or absence of leprosy. Concerning study design, systematic reviews were included. Initially, the exclusion criterion adopted was the use of PEP in contacts who had clinical signs of leprosy.

Search strategy

The search strategy, based on the inclusion criteria, aimed to locate published studies on the subject regardless of the date of publication, as we sought to identify all available evidence. The search occurred between October 2020 and October 2021, and was repeated using the free full-text filter. The search was initially applied to PubMed and CINAHL to identify articles and keywords on the topic. Based on the terms and texts identified in this search, a complete strategy was prepared by a librarian according to each database. The databases searched were Virtual Health Library (VHL), Cochrane, Web of Science, Embase, PubMed, and Scopus. In addition, the reference lists of studies included in the review were assessed.

Study selection and critical assessment

After searching the databases, all identified citations were grouped and sent to the Rayyan QCRI platform, and duplicates were removed. The titles and abstracts were assessed by two independent reviewers, and disagreements were resolved through discussion. Potentially relevant studies were selected for full reading. Subsequently, the studies that met the inclusion criteria were analyzed and categorized. Evidence quality assessment was performed by two reviewers using the Measurement Tool to Assess Systematic Reviews (AMSTAR) 2[10].

Matrix preparation and characterization worksheet

The studies were characterized, and a matrix listing the interventions and their respective outcomes, using the Microsoft Excel 2013 program, was prepared. Study data were organized in a characterization worksheet, which can be viewed in the supplementary material. The spreadsheet contains the identification number previously established for each article and its title. Moreover, three intervention groups were noted in the spreadsheet: chemoprophylaxis, immunoprophylaxis, and their combination. Each group of study subjects was divided into subgroups according to the corresponding interventions, i.e., the “chemoprophylaxis” group was divided according to each drug used in this intervention. Likewise, the “immunoprophylaxis” group was divided into subgroups corresponding to each vaccine described in the reviews assessed. The “immunoprophylaxis + chemoprophylaxis” group was not subdivided because only the association between BCG and rifampicin was identified.

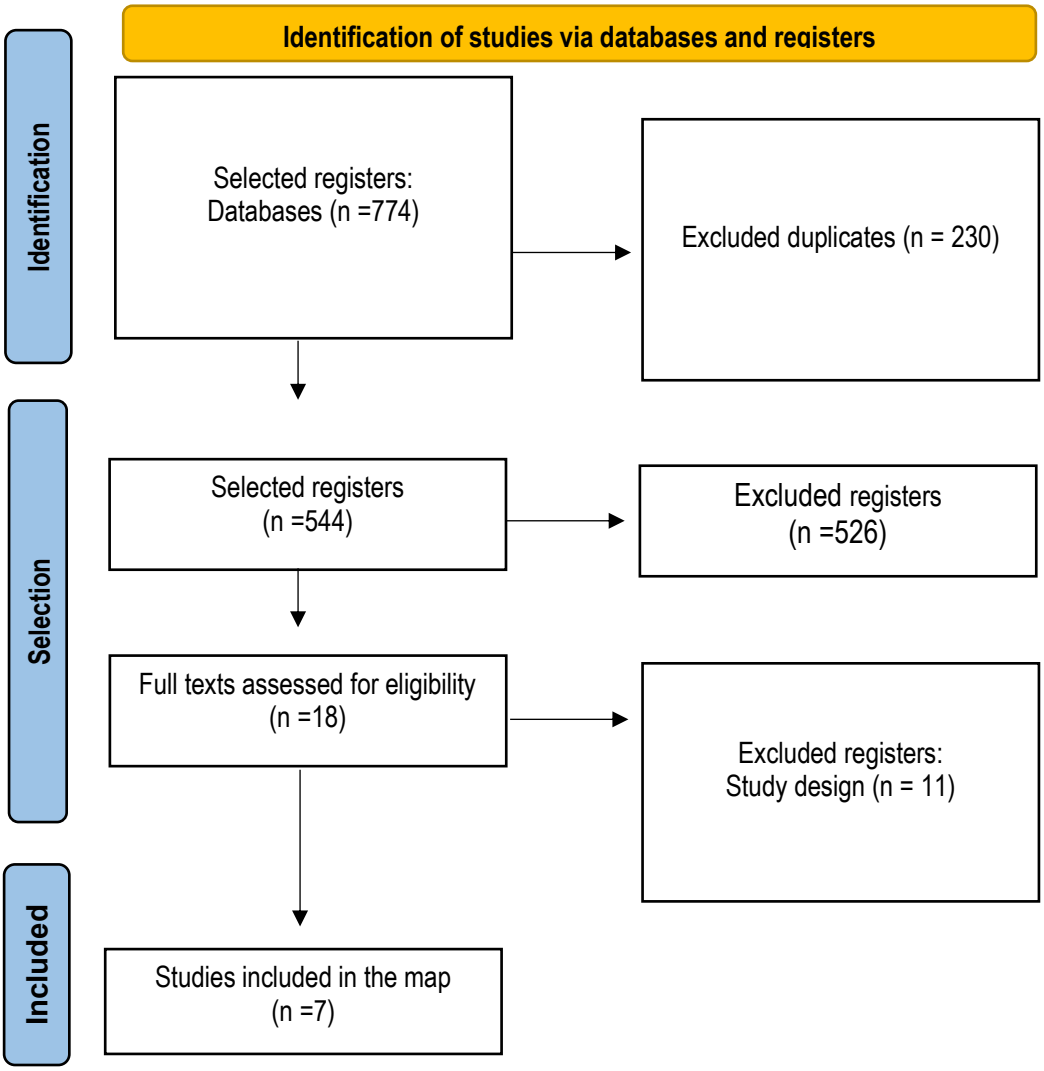
Outcomes were divided into two groups: one for cases in which participants were contacts and the other for cases that mentioned no contact. The first group was divided into three subgroups: contacts of leprosy cases, contacts under 15 years of age, and household contacts. The second group was divided into four subgroups: general population, schoolchildren, individuals with vaccination scars, and individuals without vaccination scars. The criterion for dividing the groups and subgroups was based on the heterogeneity observed in the description of the reviews.

In addition to this information, we collected the following: the effects of the intervention; the database in which the study was identified; the study's identification number; the country in which the study was conducted; the place and year of publication; the type of review; and the design of the primary study and review. Also included were the degree of reliability of the study, the link to the full text, and its citation. Information from the matrix and characterization worksheet was used to prepare the map. The graphical representation was prepared using Tableau software. Interventions whose description of the primary study in the review did not include all the items established for constructing the spreadsheet were excluded.

RESULTS

From the database search, 774 articles were identified. After removing duplicates, 544 documents remained for assessing titles and abstracts. Of these, 18 articles were selected for full-text reading, and 11 were excluded because they did not meet the inclusion criteria, leaving seven articles for analysis, as shown in Figure 1.

Figure 1 - Research results, study selection and inclusion process



After selecting the studies, they were characterized by the type of intervention and outcome. We identified 45 associations between nine types of interventions and seven outcomes. The seven evidence reported in the studies indicates that 32 associations had positive effects and 13 had potentially positive effects related to the use of BCG, rifampicin, rifampicin + BCG, BCG + M. *leprae*, the Indian Cancer Research Centre (ICRC) vaccine, and the *Mycobacterium* W vaccine. Among the evidence assessed, there was a greater number of studies related to the use of rifampicin and a lower number of studies related to *Mycobacterium* W vaccine and ICRC vaccine when compared to the use of BCG and chemoprophylaxis using other medications. Using the AMSTAR 2, one review showed a low level of reliability for the reported evidence, and six reviews had a critically low level. Chart 1 describes the summary of available evidence.

Chart 1 - Summary of evidence. Juiz de Fora, Minas Gerais, Brazil, 2022

Id	Title	Author and year of publication	Location of primary studies	Assessed interventions	Main findings	Evidence confidence level
1	Chemoprophylaxis in contacts of patients with leprosy: systematic review and meta-analysis	Reveiz; Buendía; Telléz, 2009[12]	Bangladesh, Myanmar, India	Chemoprophylaxis using rifampicin, dapsone, acedapsone and rifampicin, ofloxacin, and minocycline regimen.	Chemoprophylaxis is effective in reducing new cases of leprosy and should be recommended by clinical guidelines and public health policies.	Critically low
2	Leprosy	Smith; Sauderson, 2009[13]	Bangladesh, Malawi, Brazil, India	Immunoprophylaxis using BCG, BCG + M. *leprae*, ICRC vaccine and *Mycobacterium* w vaccine and chemoprophylaxis using rifampicin.	Single-dose rifampicin was able to significantly reduce the proportion of diagnosed contacts. The vaccines reported in this review showed positive results for reducing leprosy.	Critically low

3	Effectiveness analysis of single dose Rifampicin-post-exposure prophylaxis (SDR-PEP) as a preventive intervention for Leprosy transmission: a systematic review of randomized controlled trials	Asyura *et al*., 2021[14]	Bangladesh, Myanmar, India	Chemoprophylaxis using rifampicin and combination of chemoprophylaxis and immunoprophylaxis using BCG + rifampicin.	The review results indicate that the prophylactic use of rifampicin is a promising strategy and should be guaranteed on a large scale. It is suggested that the strategy approach be divided into stages in order to ensure continuity of intervention broadly.	Critically low
4	The State of Affairs in Post-Exposure Leprosy Prevention: A Descriptive Meta-Analysis on Immuno- and Chemo-Prophylaxis	Schoenmakers *et al*., 2020[6]	Uganda, Myanmar, Brazil, India, Indonesia, Bangladesh, Morocco, Marquesas Islands, Tanzania, Nepal, Sri Lanka	Immunoprophylaxis using BCG, BCG + M. *leprae*, ICRC vaccine, *Mycobacterium* w vaccine and chemoprophylaxis using rifampicin and dapsone.	There has been progress regarding the use of chemoprophylaxis and immunoprophylaxis. However, there is a need for more studies to assess interventions in different settings, using triage strategies and specific approaches for each type of contact.	Critically low
5	A systematic review of the importance of chemoprophylaxis and immunoprophylaxis in subclinical case of leprosy that can reduce the incidence and the transmission of leprosy	Mulianto *et al*., 2020[15]	Indonesia, Brazil	Chemoprophylaxis using rifampicin and combination of chemoprophylaxis and immunoprophylaxis using BCG and rifampicin.	Immunoprophylaxis and chemoprophylaxis are important interventions to reduce the development of leprosy, and are essential, especially for people who have regular contact with individuals affected by the disease.	Critically low

6	Chemoprophylaxis is effective in the prevention of leprosy in endemic countries: a systematic review and meta-analysis. MILEP2 Study Group. Mucosal Immunology of Leprosy	Smith; Smith, 2000[4]	India, Korea, Uganda, Philippines	Chemoprophylaxis using rifampicin, dapsone and acedapsone.	Chemoprophylaxis is effective in reducing leprosy detection. However, the development of studies that assess new drugs is recommended.	Critically low
7	Effectiveness of rifampicin chemoprophylaxis in preventing leprosy in patient contacts: a systematic review of quantitative and qualitative evidence	Ferreira *et al.* 2017[16]	Indonesia, Bangladesh, Myanmar, Marquesas Islands, Kiribati Islands, Marshal Islands, Micronesia	Chemoprophylaxis using rifampicin and rifampicin ofloxacin, and minocycline regimen an association of chemoprophylaxis and immunoprophylaxis using BCG and rifampicin.	Chemoprophylaxis is effective in reducing new cases of leprosy. The single dose of rifampicin was more effective in the first years of follow-up. The use of BCG associated with rifampicin is more effective when compared to each intervention used separately. Rifampicin, ofloxacin, and minocycline can be used to reduce the detection of new cases of leprosy.	Low

After synthesizing existing evidence, assessing the association between interventions and outcomes, and assessing the reliability of the evidence reported in the selected studies, the evidence map was created. A graphical representation can be accessed through the following link: https://public.tableau.com/app/profile/bireme/viz/ProfilaxiaHanseniase/evidence-map.

DISCUSSION

Based on the map elaboration, most of the evidence assessed showed positive results for the use of PEP to leprosy. However, of the seven reviews included in the study, four assessed primary studies conducted in India, which is expected because the country has the highest detection rate of new cases of leprosy in the world and has the largest scientific production on the subject[2-17].

In 2014, the leprosy post-exposure prophylaxis (LPEP) program was launched to assess contact tracing and the provision of preventive measures for leprosy in eight countries, including Brazil. The

program showed a decline in the number of leprosy cases, demonstrating the importance of contact tracing and preventive treatment for reducing the chain of transmission of the disease[18].

At the national level, the *PEP-Hans Brasil* program was established within the scope of the Unified Health System (In Portuguese, *Sistema Único de Saúde* - SUS) and complements the evidence of the LPEP program to assess the operability of single-dose rifampicin[5,18]. However, in 2020, the Brazilian National Coordination for the Incorporation of Technologies in the SUS (In Portuguese, *Comissão Nacional de Incorporação de Tecnologias no SUS* - CONITEC) recommended the exclusion of rifampicin in a single dose as a prophylactic measure for contacts of leprosy cases since the project was completed in 2018. According to the CONITEC report (2020), more studies are needed on chemoprophylaxis and on the monitoring and assessment of individuals who received such an intervention so that the measure can be implemented[19].

Some evidence included in the map describes the use of dapsone, acedapsone, and the rifampicin, ofloxacin, and minocycline regimen as a form of leprosy chemoprophylaxis. Dapsone is studied as a prophylactic agent used for long periods of time and in weekly or fortnightly doses[6]. Despite the efficacy of dapsone as a prophylactic agent, the need for long-term use may induce the emergence of drug resistance[20].

From the preparation of this map, a greater number of associations related to the use of rifampicin was observed, which may be associated with the citation of the same primary study in the different assessed reviews. The COLEP study, conducted in Bangladesh, for instance, was cited in most reviews. It demonstrated the possibility of reducing the development of clinical leprosy by 57% through the use of a single dose of rifampicin[21].

The effect of the intervention was greater in the contacts farther away from the index case, which can be explained by the possibility that the infection had already developed among closer contacts, hindering the desired effect with only one or two doses of the drug[21-22]. In contrast, the effectiveness of rifapentine, used in a single dose, has been proven in household contacts and, like rifampicin, it has been considered for the eradication of leprosy in China[23].

Contact tracing and the strengthening of PEP constitute cost-effective strategies in both the short and long term. In this context, the identification of individuals at higher risk of developing the disease is recommended[24–25].

In addition to chemoprophylaxis, the studies included in the present map demonstrated positive results regarding the use of immunoprophylaxis. The BCG vaccine is already administered to contacts without signs and symptoms at the time of assessment, according to their vaccination status, regardless

of the operational classification of the index case[26]. This strategy is feasible because immune responses play a crucial role in disease progression and in the clinical manifestations of leprosy[27].

In a double-blind study conducted in southern India, the efficacy of four vaccines was assessed and compared with placebo. The vaccines assessed were: BCG, which provided 34.1% protection; BCG combined with heat-killed M. *leprae*, which provided 64% protection; ICRC vaccine, which showed 65.5% protection; and *Mycobacterium* w vaccine, currently known as *Mycobacterium* indicus pranii, which conferred 25.7% protection. However, despite the demonstrated efficacy of these vaccines, few studies have focused on the use of PEP[5].

In the context of PEP, the combination of chemoprophylaxis and immunoprophylaxis is emphasized because they work together to improve the intervention. The first reduces the emergence of new cases more quickly, while the second reduces them over the long term[28]. Therefore, the administration time of the two strategies should be considered, as BCG cannot be administered at the same time as antibiotics, which is possible from a killed microorganism vaccine, such as Lepvax. Despite the positive effects of the ICRC vaccine, studies have concentrated on only one geographical location[13,22].

Study limitations

This study has limitations, such as the small number of systematic reviews on the subject and the quality of the evidence found for inclusion in the map. These factors indicate the need to conduct new reviews in which the authors clearly describe the methodological trajectory of the review so that they can support the formulation of public policies. The low level of quality is attributed to the failure to follow guidelines for planning reviews, especially in older studies[28]. It is believed that the lack of some information included in the AMSTAR 2 tool, such as the description of the funding of each primary study in the review and reasons for the exclusion of each register, may be related to each journal's publication standards, which sometimes limit the length of the manuscript.

Another limitation relates to the study search period, which was conducted in 2020. Although new evidence may have been published after this period, it was not possible to update the search, as the evidence map had already been finalized and published in VHL. This limitation should be taken into account when interpreting the presented results.

Contributions to nursing, health, or public policy

It is important to highlight that this is the first evidence map in the field of leprosy, contributing to public health by providing a graphical overview of the available knowledge, which facilitates evidence-based decision-making in healthcare. Moreover, it is worth mentioning that the topic of PEP for leprosy has been identified as a research priority by the Ministry of Health[29].

CONCLUSIONS

In light of the data presented, it was possible to conclude that there are studies that prove the effectiveness of PEP in leprosy. However, it is evident that there is a need for improvements in the methodological description of these studies so that they can be used as support in the implementation of this intervention.

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