

REVIEW ARTICLE

Challenges of pharmacological treatment for leprosy: a systematic review

Desafíos del tratamiento farmacológico de la lepra: una revisión sistemática

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ABSTRACT

Leprosy is a chronic, transmissible infectious disease of ancient origin that primarily affects the skin, mucous membranes, and peripheral nerves, potentially leading to disability and death. Despite advances achieved through multidrug therapy (MDT), deficiencies in public health systems persist, particularly in developing countries. The aim of the present study is to identify the achievements and challenges of pharmacological treatment for leprosy in order to advance toward its eradication. A systematic literature review was conducted following the PRISMA methodology, using searches in the scientific databases PubMed and Web of Science, and selecting studies published between 2020 and 2025 related to the pharmacological treatment of leprosy. A total of 18 studies were analyzed, addressing current treatment approaches, management in specific cases, and both challenges and advances in pharmacological therapy. The findings indicate that, although MDT remains the treatment of choice and is effective for leprosy, significant weaknesses in health systems persist, leading to difficulties in the acquisition of medications, limited accessibility to health services, delayed diagnosis, and poor treatment adherence.

Keywords: Leprosy; *Mycobacterium leprae*; Drug treatment; Polychemotherapy.

RESUMEN

La lepra es una enfermedad infecciosa crónica transmisible, muy Antigua, que afecta principalmente piel, mucosas y nervios periféricos y pudiendo llevar a discapacidad y la muerte. A pesar de los logros en el tratamiento Poliquimioterapia (PQT), persisten deficiencia en los sistemas de salud pública, especialmente en países de tercer mundo. El objetivo del presente estudio es identificar los logros y desafíos del tratamiento farmacológico de la lepra que permita avanzar hacia su erradicación. Se realizó una revisión sistemática de la literatura, siguiendo la metodología PRISMA, mediante búsquedas en las bases de datos científicas PubMed y Web of Science, seleccionando estudios publicados entre 2020 y 2025 relacionados con el tratamiento farmacológico de la Lepra. Se analizaron 18 estudios que abordan el tratamiento de la lepra en la actualidad, tratamiento en algunos casos específicos, desafíos y logros en el tratamiento farmacológico. Se concluye que, aunque la PQT constituye el tratamiento farmacológico de elección y efectivo en la lepra, aún existen debilidades en el sistema de salud que conllevan a dificultad en la adquisición de fármacos, la accesibilidad a los servicios de salud, al diagnóstico tardío y poca adherencia al tratamiento.

Palabras clave: Lepra; *Mycobacterium leprae*; Tratamiento farmacológico; Poliquimioterapia.



INTRODUCTION

Leprosy is a chronic infectious transmissible disease caused by *Mycobacterium leprae*, first described in 1873 by Gerhard Armauer Hansen; therefore, it is also known as Hansen's disease (Evia, 2021). It is a very ancient disease that dates back several centuries before Christ. It has a worldwide distribution, with higher prevalence in developing countries under low socioeconomic conditions such as poor sanitation, malnutrition, low levels of education, and overcrowding, and is considered one of the neglected and underserved diseases (Prada et al., 2025).

Approximately 720,000 new cases are reported annually worldwide, while two million people with this condition present disabilities caused by the disease itself. India, Brazil, Nepal, Madagascar, and Mozambique account for 88% of all new leprosy cases (Aliaga-Samanez et al., 2025). Other studies indicate that leprosy was introduced into Ecuador with the arrival of the Spanish in the Americas around September 24, 1493. Between 2013 and 2014, 144 cases were recorded, of which 43 were new cases; in 2021, the Ministry of Public Health (MSP) reported 51 cases. However, there are no updated data for subsequent years (Polanco et al., 2024; Galarza, 2024).

The incubation period of leprosy averages 1 to 5 years for paucibacillary forms and 8 to 12 years for multibacillary forms. In general, close and prolonged contact with untreated patients, especially multibacillary patients, who are of greatest epidemiological importance is considered necessary for transmission. The main routes of bacilli elimination and entry into the body are the upper respiratory tract and possibly non-intact skin. In recent years, studies have also shown that hunting and consumption of armadillos may be an important factor in the possible origin of leprosy (Polanco et al., 2024).

The development of the disease and its clinical presentation depend on the patient's immune status as well as genetic susceptibility and resistance factors of the host. This condition primarily affects the skin, mucous membranes, and peripheral nerves, and is one of the leading causes of non-traumatic peripheral neuropathies worldwide (Evia, 2021; Contreras, 2024).

Currently, three classifications from the World Health Organization (WHO, 2025) are in use, among which one provides guidance regarding the therapeutic regimen to be used. Patients are classified into two major groups: Paucibacillary (PB) leprosy—patients with five or fewer skin lesions and negative bacilloscopy; and Multibacillary (MB) leprosy—patients with six or more skin lesions or positive bacilloscopy.

WHO (2025) recommendations consist of multidrug therapy (MDT), which involves a supervised monthly dose and a daily self-administered dose, combining two to three drugs: rifampicin, clofazimine, and dapsone. Paucibacillary patients may receive six doses within nine months, while multibacillary patients receive twelve doses within a maximum of eighteen months. If interruptions exceed these periods, treatment is considered discontinued and must be restarted (Guerra & Gómez 2020).

Currently, leprosy treatment has significantly improved, helping to eliminate the disease as a public health problem in many countries. However, further studies are still needed to develop new treatments. Additionally, weaknesses in healthcare systems contribute to delays in diagnosis and prolonged treatment (Osorio et al., 2020).

In general, pharmacological treatment of leprosy continues to face several barriers, including late diagnosis, limited availability of treatment, especially in developing countries, frequent adverse effects, restricted access to healthcare services, lack of updated training among healthcare professionals, and scarcity of national and international publications (Serna, 2023). Therefore, the aim of this study is to identify the challenges of pharmacological treatment of leprosy in order to contribute to its eradication.

METHODOLOGY

A systematic literature review was conducted using a non-experimental methodological approach and a descriptive-explanatory design, in accordance with the PRISMA 2020 guidelines (Page et al., 2020).

The research question was structured following the PICO model, which allowed for a clear delimitation of the components of the review. These are detailed below in Table 1:

Table 1. PICO framework used for the literature review.

Element	Description
P (Population)	Patients with leprosy (paucibacillary and multibacillary)
I (Intervention)	Pharmacological treatment (rifampicin, clofazimine, dapsone, new drugs)
C (Comparator)	Difficulties in drug acquisition, access to healthcare services, early diagnosis, and treatment adherence
O (Outcome)	Updates to public health programs and new treatment strategies

Search strategy

The search was conducted in the scientific databases PubMed and Web of Science. The following search query was used: (TITLE-ABS-KEY (“Leprosy” OR “Mycobacterium leprae”)) AND (TITLE-ABS-KEY (“Pharmacological treatment” OR “Rifampicin” OR “Clofazimine” OR “Dapsone”)) AND (PUBYEAR > 2019 AND PUBYEAR < 2026) AND (LANGUAGE (English) OR LANGUAGE (Spanish) OR LANGUAGE (Portuguese)).

Eligibility criteria

The criteria for article selection are detailed in Table 2:

Table 2. Inclusion and Exclusion Criteria.

Included studies	Excluded studies
Publications between 2020 and 2025	Duplicate publications or those outside the established time frame
Written in Spanish, English, or Portuguese	Written in languages other than Spanish, English, or Portuguese
Full-text availability for analysis	Articles requiring paid access to full text
Original articles addressing one or more of the following aspects:	Studies conducted exclusively in animal models
• Current pharmacological treatment of leprosy • Adverse drug reactions related to treatment • Treatment in specific clinical cases • Challenges and barriers in the implementation of pharmacological treatment • Recent therapeutic advances and achievements in combating the disease	
Studies focused on combination therapies involving drugs not directly related to the objective of this review	

Selection process

The process of identification, evaluation, and selection of the studies included in this review is presented in Figure 1. Initially, 145 records were identified from two scientific databases. After removing 15 duplicates, 130 titles and abstracts were screened, of which 70 were excluded for not meeting the preliminary criteria. Subsequently, full texts were sought for 60 studies, of which 14 could not be retrieved. Of the remaining 46 articles assessed in full text, 28 were excluded. As a result, 18 studies met all the established methodological criteria and were included in the final analysis.

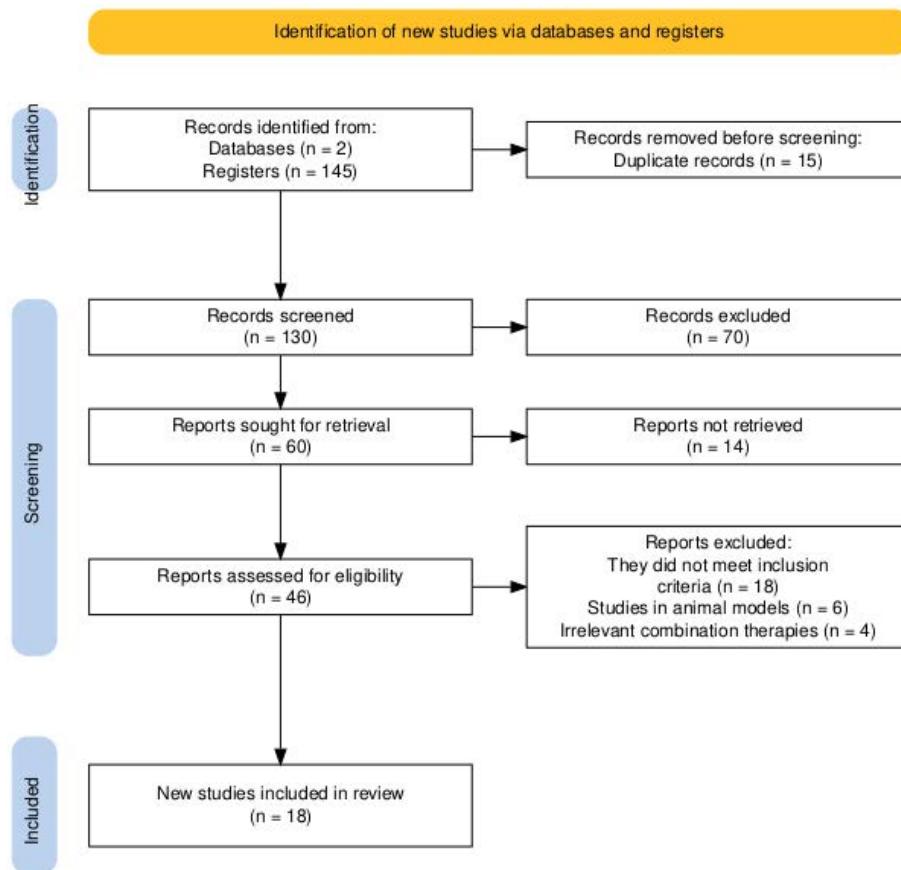


Figure 1. Article selection process according to the PRISMA framework.

Content analysis, bias assessment, and study limitations

The content of the selected studies was qualitatively analyzed through a critical reading approach aimed at identifying therapeutic recommendations, pharmacological foundations, prescribing criteria, adverse effects, and clinical applicability across different scenarios. The extracted information was systematized in a thematic analysis matrix, which enabled comparisons between studies and the identification of points of agreement or discrepancy in clinical guidelines and the available scientific evidence.

The risk of bias was addressed through a descriptive assessment, considering factors such as methodological quality, study type, level of reported evidence, and clarity in the presentation of results. However, among the main limitations of this review is the absence of a formal assessment of the methodological quality of all included studies, as well as the potential exclusion of grey literature or relevant works not indexed in the consulted databases. Additionally, since the review was restricted to publications in Spanish, English, and Portuguese, there is a potential language bias associated with the exclusion of studies in other languages.

RESULTS AND DISCUSSION

Table 3 presents a thematic synthesis of the 18 studies included in this systematic review, organized into four categories: author and year of publication, country of origin, central topic addressed, and main conclusions. The studies mainly originate from Latin American countries—such as Colombia, Ecuador, Brazil, Mexico, and Peru—where leprosy remains a significant public health issue. Research from Europe (Spain and England) is also included. The most frequent central themes revolve around pharmacological treatment, particularly multidrug therapy with rifampicin, dapsone, and clofazimine; additional aspects include treatment adherence, barriers to medication access, delayed diagnosis, and the exploration of new therapeutic strategies, including immunomodulators and vaccines.

Table 3. Studies included on pharmacological treatment of leprosy (n = 18).

Authors (year)	Country	Central topic	Main conclusions
Ascanio et al. (2020)	Colombia	Outpatient approach to leprosy treatment	Highlights the need to strengthen health services
Polanco et al. (2024)	Ecuador	Pharmacological treatment and comprehensive follow-up	Delays in access to medications pose a risk of therapeutic failure
Ramón et al. (2024)	Ecuador	Persistence of challenges such as resistance and adverse reactions	New drugs, vaccines, and biological therapies are under investigation
Almada et al. (2023)	Spain	Role of the healthcare team in treatment adherence	Educational interventions improve patient knowledge and adherence
Contreras (2024)	Colombia	Use of genetic biomarkers as therapeutic innovation	New treatments such as immunomodulators are proposed
Evia (2021)	Mexico	Delayed diagnosis and limited access to comprehensive care	Timely treatment prevents disabilities and reduces stigma
Guerra & Gómez (2020)	El Salvador	Multidrug therapy as standard treatment	Need for vaccine development is identified
Lima (2024)	Ecuador	Multidrug therapy as an effective therapeutic proposal	Timely treatment improves patients' quality of life
Osorio et al. (2020)	Peru	Delays in treatment initiation	Strengthening the healthcare system is required
Torres et al. (2023)	Colombia	Deficiencies in access and timeliness of treatment	Need to improve healthcare system response
Domínguez & Olmedo (2024)	Paraguay	Importance of appropriate treatment to reduce disease burden	Therapeutic regimen includes dapsone, rifampicin, and clofazimine
Rivera et al. (2020)	Costa Rica	Barriers to early treatment initiation	Accessibility to care and treatment is key for disease control
de Melo et al. (2021)	Brazil	MDT-based multidrug therapy	Continuous training of healthcare personnel is essential
Prada et al. (2025)	Mexico	Effectiveness of multidrug treatment	Barriers to timely and effective treatment persist
Aguilera et al. (2021)	Chile	Impact of delayed diagnosis on therapeutic failure	Primary healthcare quality is crucial for clinical outcomes
Cavalcante et al. (2020)	Brazil	Deficiencies in healthcare networks as a therapeutic obstacle	Public policies ensuring equitable access to medications are needed
Verdugo (2024)	Ecuador	Inequality in access to approved treatments	Promotes research and development of new therapeutic alternatives
Borah (2023)	England	Persistence of leprosy despite available therapies	Emphasizes the need for vaccines and new therapeutic strategies

Table 4 presents a quantitative analysis of the main clinical recommendations identified. One of the most recurrent proposals was strengthening public health programs, mentioned in 67% of the studies (n = 12), highlighting an unmet structural need in the therapeutic management of leprosy. Likewise, multidrug therapy (MDT)—based on rifampicin, dapsone, and clofazimine—remains the standard treatment, reported in 9 studies (50%). Difficulties in drug acquisition appear in 8 studies (44%), while poor adherence to treatment and limited access to healthcare services were identified in 28% of the studies (n = 5). Finally, 8 studies (44%) suggest the development or incorporation of new drugs and technologies, indicating an interest in improving the efficacy and tolerability of current treatments.

Table 4. Quantitative summary of clinical recommendations in the reviewed studies (n = 18)

Category	(n) (%)
Difficulty in drug acquisition	8 44%
Limited access to healthcare services	5 28%
Poor treatment adherence	5 28%
Multidrug therapy (MDT)	9 50%
Strengthening public health programs	12 67%
Development of new drugs or technologies	8 44%

Current treatment of leprosy: multidrug therapy (MDT)

Currently, the WHO (2025) recommends that leprosy treatment be based on MDT, combining rifampicin, clofazimine, and dapsone, with a limited duration and without the use of any drug as monotherapy (de Melo et al., 2021; Lima, 2024). Treatment duration for paucibacillary patients is 6 months, which may extend up to 9 months, while for multibacillary patients it is 12 months, extendable up to 18 months. If interruptions exceed these periods, treatment is considered discontinued and must be restarted (Guerra & Gómez 2020; Domínguez & Olmedo, 2024).

Before initiating treatment, a comprehensive evaluation should be performed, including complementary tests such as liver and renal function tests and complete blood count, which should be repeated every three months. Patients should be informed about the treatment and its adverse effects, the importance of timely diagnosis and treatment of iron deficiency anemia, and the need for laboratory monitoring. Additionally, anti-anemic therapy is recommended according to patient needs (e.g., folic acid 5 mg daily; ferrous sulfate or fumarate with meals), along with comprehensive medical follow-up (Guerra & Gómez 2020).

From a therapeutic standpoint, paucibacillary leprosy is treated with dapsone 100 mg daily for six months (self-administered) and rifampicin 600 mg as a single supervised monthly dose for six months. In pediatric patients, dapsone 50 mg daily or 1 mg/kg for six months and rifampicin 450 mg or 12-15 mg/kg monthly are recommended (Evia, 2021).

Multibacillary patients are treated with dapsone 100 mg daily and clofazimine 50 mg daily for one year (self-administered), in addition to rifampicin 600 mg and a monthly booster dose of clofazimine 300 mg. In pediatric patients, dapsone 50 mg daily or 1 mg/kg, clofazimine 50 mg every other day or 0.5 mg/kg/day, and rifampicin 450 mg monthly combined with 150 mg of clofazimine are administered for one year, like adult regimens (Evia, 2021).

Adverse drug reactions and treatment in special cases

In the event of an adverse reaction to dapsone, it should be discontinued immediately, continuing treatment with multibacillary regimen drugs (clofazimine and rifampicin). In paucibacillary cases, dapsone should be replaced with clofazimine 50 mg/day for six months combined with monthly rifampicin. Hemolytic anemia is a possible adverse reaction associated with both rifampicin and dapsone; in patients with glucose-6-phosphate dehydrogenase deficiency, dapsone may cause severe hemolysis. Other adverse effects of dapsone include dermatitis, rash, liver dysfunction, headache, psychosis, and peripheral neuropathy (de Melo et al., 2021).

Treatment during pregnancy follows the same regimen, with particular attention to anemia caused by dapsone, which may compound physiological anemia of pregnancy. Maternal leprosy has been associated with low birth weight, and clofazimine may cause transient skin pigmentation in infants due to its excretion in breast milk (Evia, 2021).

In cases of co-infection with tuberculosis, rifampicin dosing should follow tuberculosis treatment guidelines (600 mg daily for at least 6 months). After completing TB treatment, rifampicin may continue in multibacillary cases. No changes are required for HIV co-infected patients, although a higher frequency of reactions may occur; monthly rifampicin does not interfere with antiretroviral therapy (Evia, 2021).

Challenges in pharmacological treatment

Leprosy remains a significant public health problem, particularly affecting populations in disadvantaged socioeconomic conditions. Although Ecuador has been declared free of leprosy, recent studies show its persistence in vulnerable communities (Polanco et al., 2024; Galarza, 2024).

Living conditions and cultural factors contribute to disease persistence, with leprosy still perceived as highly contagious and disfiguring, leading to stigma and social isolation. Additional challenges include drug resistance and adverse reactions, complicating treatment and potentially leading to prolonged and less effective regimens (Almada et al., 2023; Verdugo, 2024).

Pharmacological treatment is generally outpatient-based, with follow-up by healthcare teams as a cornerstone of treatment adherence (Ascanio et al., 2020). Continuous training of healthcare personnel is essential to improve care quality, monitoring, and adherence (de Melo et al., 2021; Cavalcante et al., 2020).

Health system weaknesses include limited drug availability in primary care and extended treatment durations due to system inefficiencies. Improving drug procurement for neglected diseases remains a critical challenge (Polanco et al., 2024; Torres et al., 2023).

Although effective multidrug therapy exists, millions still suffer from leprosy, underscoring the urgent need for new therapeutic strategies and better management of available resources. Poor healthcare management—rather than limited financial resources—is often a key barrier (Osorio et al., 2020; Borah, 2023; Prada et al., 2025).

Public health programs should therefore focus on improving healthcare access, drug availability, treatment adherence, and reducing stigma, adopting a comprehensive approach that integrates medical therapy, rehabilitation, and public health strategies (Ramón et al., 2024; Rivera et al., 2020; Aguilera et al., 2021).

Advances in pharmacological treatment

The study of genetic markers has enhanced understanding of susceptibility and resistance to leprosy, identifying genes involved in immune response. This opens new therapeutic possibilities, including immunomodulators, which may be key for developing more effective prevention and treatment strategies (Contreras, 2024).

New therapies are under investigation, including drugs such as bedaquiline and delamanid, as well as therapeutic vaccines and biological therapies aimed at improving patient outcomes. Nanotechnology also offers promising advances in drug delivery systems (Evia, 2021).

According to Guerra & Gómez (2020), the *Bacillus Calmette-Guérin* (BCG) vaccine administered at birth reduces the risk of leprosy and should continue to be used in high-prevalence countries. A specific leprosy vaccine, LepVax (LEP-F1 + GLA-SE), composed of the LEP-F1 antigen and a glucopyranosyl lipid adjuvant (GLA), has shown reduced disease severity in armadillos and has been tested in healthy humans, demonstrating safety and tolerability.

CONCLUSIONS

Multidrug therapy (MDT), combining rifampicin, clofazimine, and dapsone, constitutes the treatment of choice and has proven effective in leprosy. However, persistent weaknesses in healthcare systems continue to be identified, leading to difficulties in drug acquisition, limited access to healthcare services, delayed diagnosis, and poor treatment adherence. Various studies highlight the need to develop new treatment strategies, including innovative pharmacological approaches that incorporate immunological therapies and the use of nanotechnology.

At present, it is essential to ensure proper management of available resources and treatments through the strengthening of training in healthcare management and public health programs. Such efforts would contribute to advancing toward the eradication of leprosy and improving the quality of life of patients affected by the disease.

Further studies should focus on the development and clinical evaluation of novel therapeutic strategies, including immunotherapies, vaccines, and nanotechnology-based drug delivery systems. It is also essential to investigate health system factors—such as access, adherence, and resource management—through longitudinal and multicenter studies, particularly in high-burden regions. These efforts will contribute to improving treatment outcomes and advancing toward the global goal of leprosy eradication.

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The authors declare no conflicts of interest.

Author Contributions:

The authors were responsible for all aspects of the study, including conceptualization, methodology, analysis, and writing.

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