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ORIGINAL ARTICLE

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The demographic and clinical profile of patients with leprosy reactions at Rizal Medical Center, Philippines, from 2018 to 2022

Perfil demográfico e clínico de pacientes com reações hansênicas no Centro Médico Rizal, Filipinas, entre 2018 e 2022

Perfil demográfico y clínico de pacientes con reacciones leprosas en el Centro Médico Rizal, Filipinas, entre 2018 y 2022

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ABSTRACT

Introduction: hansen's disease, also known as leprosy, is an infection caused by *Mycobacterium leprae*. Leprosy reactions may occur before, during, or after the completion of multidrug therapy and result from changes in the immune balance between the host and *M. leprae*. These reactions are acute inflammatory episodes that primarily affect the skin and nerves and are the leading cause of morbidity and neurological disability in leprosy. Identifying the demographic and clinical profile for leprosy reactions is essential for early detection and timely management to prevent complications that may lead to long-term disability. Understanding the sociodemographic and clinical profiles of affected patients can help guide effective strategies for improving patient care and health

service delivery. **Methods:** a descriptive cross-sectional study was conducted to assess the relationship between characteristics and the occurrence of leprosy reactions among leprosy patients seen and treated at a public tertiary hospital in Pasig, Philippines, from 2018 to 2022. Secondary data were collected from medical records and hospital documents. **Results:** a total of 40 patients with leprosy were included. Most were male, resided outside the National Capital Region, and were in the 20-39 age group. Clinically, the majority were classified as lepromatous leprosy and fell under the multibacillary treatment regimen, with no extensions in treatment duration. Type I reactions were more common than type II reactions and occurred predominantly during multidrug therapy. Most patients experiencing leprosy reactions were started on prednisone 40 mg daily. The average bacteriological index showed significant improvement from pre- to post-treatment. The most frequently reported signs and symptoms included erythema and tenderness of existing lesions for type I reactions, and painful, tender nodules for type II reactions. Age, sex, leprosy spectrum, and treatment duration showed no statistically significant associations with leprosy reactions ($p > 0.05$). **Conclusion:** this study found no statistically significant associations between the sociodemographic characteristics (age and sex) and clinical characteristics (leprosy spectrum, treatment regimen classification, and treatment compliance) and the type of leprosy reaction among leprosy patients treated at a public tertiary hospital from 2018 to 2022.

Keywords: *Leprosy. Leprosy Reactions. Demographic and Clinical Profile.*

RESUMO

Introdução: a doença de Hansen, também conhecida como hanseníase, é uma infeção causada pelo *Mycobacterium leprae*. As reações hansênicas podem ocorrer antes, durante ou após a conclusão da poliquimioterapia e resultam de alterações no equilíbrio imunológico entre o hospedeiro e o *M. leprae*. Estas reações são episódios inflamatórios agudos que afetam principalmente a pele e os nervos e constituem a principal causa de morbidade e incapacidade neurológica na hanseníase. Identificar o perfil demográfico e clínico das reações hansênicas é essencial para a deteção precoce e o tratamento adequado, a fim de prevenir complicações que possam levar a incapacidades a longo prazo. Compreender os perfis sociodemográficos e clínicos dos doentes afetados pode ajudar a orientar estratégias eficazes para aprimorar os cuidados prestados e a assistência nos serviços de saúde. **Métodos:** foi realizado um estudo transversal descritivo para avaliar a relação entre as características e a ocorrência de reações hansênicas entre doentes com hanseníase atendidos e tratados em um hospital público terciário, entre 2018 e 2022, em Pasig, nas Filipinas. Foram obtidos dados

secundários a partir de prontuários médicos e de documentos hospitalares. **Resultados:** foram incluídos 40 pacientes com hanseníase. A maioria do sexo masculino, residente fora da região metropolitana, pertencente à faixa etária de 20 a 39 anos. Clinicamente, a maioria foi classificada como hanseníase virchowiana e submetida ao regime de tratamento multibacilar, sem aumento na duração do tratamento. As reações do tipo 1 foram mais frequentes do que as do tipo 2 e ocorreram predominantemente durante a poliquimioterapia. A maioria dos doentes que apresentaram reações hansênicas iniciou tratamento com 40 mg de prednisona por dia. O índice bacteriológico médio apresentou melhora significativa entre o pré-tratamento e o pós-tratamento. Os sinais e sintomas mais frequentemente relatados incluíram eritema e sensibilidade das lesões existentes às reações do tipo 1 e nódulos dolorosos e sensíveis às reações do tipo 2. A idade, o sexo, a forma clínica da doença e a duração do tratamento não apresentaram associações estatisticamente significativas com a ocorrência de reações hansênicas ($p > 0,05$). **Conclusão:** este estudo não encontrou associações estatisticamente significativas entre as características sociodemográficas (idade e sexo) e as características clínicas (forma clínica da hanseníase, regime de tratamento e adesão ao tratamento) e o tipo de reação hansênica entre doentes com hanseníase tratados num hospital público terciário entre 2018 e 2022.

Palavras-chave: *Hanseníase. Reações Hansênicas. Perfil Demográfico e Clínico.*

RESUMEN

Introducción: la enfermedad de Hansen, también conocida como lepra, es una infección causada por *Mycobacterium leprae*. Las reacciones leprosas pueden producirse antes, durante o después de completar el tratamiento multifarmacológico y son consecuencia de alteraciones del equilibrio inmunológico entre el huésped y *M. leprae*. Estas reacciones son episodios inflamatorios agudos que afectan principalmente a la piel y a los nervios y constituyen la principal causa de morbilidad y discapacidad neurológica en la lepra. Identificar el perfil demográfico y clínico de las reacciones leprosas es esencial para la detección precoz y el tratamiento oportuno, con el fin de prevenir complicaciones que puedan conducir a una discapacidad a largo plazo. Comprender los perfiles sociodemográficos y clínicos de los pacientes afectados puede ayudar a orientar estrategias eficaces para mejorar la atención al paciente y la prestación de servicios sanitarios. **Métodos:** se llevó a cabo un estudio transversal descriptivo para evaluar la relación entre las características clínicas y la aparición de reacciones leprosas en pacientes con lepra atendidos y tratados en un hospital público terciario en Pasig, Filipinas, entre 2018 y 2022.

Se recopilaron datos secundarios a partir de historias clínicas y documentos hospitalarios. **Resultados:** se incluyó a un total de 40 pacientes con lepra. La mayoría eran hombres, residían fuera de la región de la capital y pertenecían al grupo de edad de 20 a 39 años. Desde el punto de vista clínico, la mayoría fueron clasificados como lepra lepromatosa y se les aplicó el régimen de tratamiento multibacilar, sin prolongar su duración. Las reacciones de tipo 1 fueron más frecuentes que las de tipo 2 y se produjeron principalmente durante la terapia multifarmacológica. A la mayoría de los pacientes que experimentaron reacciones leprosas se les administró una dosis inicial diaria de 40 mg de prednisona. El índice bacteriológico medio mostró una mejora significativa entre el momento previo y el posterior al tratamiento. Los signos y síntomas notificados con mayor frecuencia incluyeron eritema y sensibilidad en las lesiones existentes para las reacciones de tipo 1 y nódulos dolorosos y sensibles para las reacciones de tipo 2. La edad, el sexo, el espectro de la lepra y la duración del tratamiento no mostraron asociaciones estadísticamente significativas con la aparición de reacciones leprosas ($p > 0,05$). **Conclusión:** este estudio no encontró asociaciones estadísticamente significativas entre las características sociodemográficas (edad y sexo) y las características clínicas (espectro de la lepra, régimen de tratamiento y adherencia al tratamiento) y el tipo de reacción leprosa en pacientes con lepra tratados en un hospital público terciario entre 2018 y 2022.

Palabras clave: *Lepra. Reacciones Leprosas. Perfil Demográfico y Clínico.*

INTRODUCTION AND RELEVANCE

Hansen's disease, or leprosy, is an illness caused by the bacterium *Mycobacterium leprae*. The organism multiplies very slowly, and symptoms may not appear for many years, sometimes taking up to two decades to develop[1]. According to the World Health Organization (WHO), the disease spreads through droplets released from the nose and mouth, and infection typically requires prolonged, close contact with an untreated individual for several months[2]. Leprosy primarily affects the nerves, skin, eyes, and the inner lining of the nose[1]. Clinically, it is often identified by characteristic findings such as loss of sensation in skin patches, enlargement or tenderness of nerves, or the detection of acid-fast bacilli on slit skin smears or biopsy samples[3]. If left untreated, nerve damage can lead to complications affecting the eyes, hands, and feet, involving both soft tissues and bone, ultimately resulting in deformity and the stigma long associated with the disease[3]. Early detection, proper management, and contact tracing are essential in preventing transmission and reducing the risk of disability.

"Leprosy reactions" are acute inflammatory episodes that may occur at any point during the course of leprosy – before, during, or even after treatment – and may present as medical emergencies in an otherwise slowly progressive disease[4]. Two major types of leprosy reactions are recognized: type I (reversal reaction) and type II or Erythema Nodosum Leprosum (ENL). These reactions affect 30-50% of all leprosy patients[4]. Type I reaction is a delayed-type hypersensitivity response to bacillary antigens, whereas type II is an immune complex–mediated process. Type I reactions present with redness, swelling, and tenderness of existing skin lesions, along with nerve pain, swelling, and loss of function; new lesions may also appear. Type II reactions typically occur in crops, with new lesions emerging as older ones subside. These lesions may range from small papules to large nodules and may be found superficially or deep in the skin, and are often painful and tender. Unlike type I, type II reactions are commonly associated with systemic symptoms such as high fever[5]. Additional manifestations may include inflammation of the eyes (uveitis), muscles (myositis), joints (arthritis), lymph nodes (lymphadenitis), and testes (orchitis)[6]. Leprosy reactions may recur frequently and contribute to long-term morbidity[7,8]. Although the immunologic mechanisms underlying these reactions are not fully understood, understanding their onset and management is crucial to preventing disability[9]. If inadequately managed or diagnosed too late, leprosy can lead to irreversible peripheral nerve damage, resulting in lifelong impairment for patients and a significant burden for families and communities[10].

Globally, an estimated 1-4 million people live with leprosy-related disabilities, ranging from Grade 1 to Grade 2[11]. The WHO classifies leprosy as a neglected tropical disease, as it disproportionately affects disadvantaged communities characterized by poverty, overcrowding, poor housing, inadequate sanitation, and limited access to healthcare[12]. Worldwide, the disease accounts for approximately 21,100 disability-adjusted life years (DALYs)[13]. Leprosy remains present in more than 120 countries, with over 200,000 new cases reported annually[2]. In the Philippines, 1,005 new cases were recorded in 2022, indicating that local transmission persists[14]. Data on the national prevalence and incidence of leprosy reactions remain limited. Still, disease patterns are consistent with those observed in other endemic regions: type I reactions are commonly associated with borderline forms of leprosy. In contrast, type II reactions are typically seen in lepromatous leprosy.

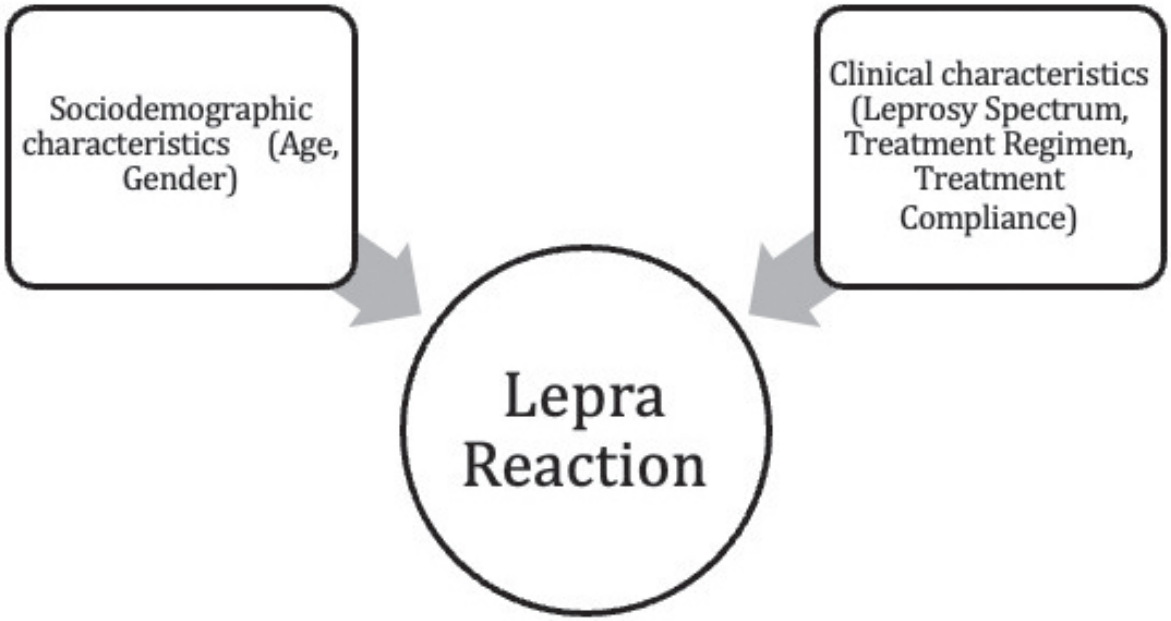
Epidemiological assessment is essential for monitoring ongoing transmission, understanding disease trends, evaluating the impact of public health interventions, and designing targeted strategies to reduce disease burden[15]. By identifying incidence and prevalence in a given population, appropriate measures can be implemented to reduce transmission and improve access to necessary services.

Early detection and management of leprosy reactions are especially important, as these reactions can lead to complications that impair quality of life and result in long-term disability. Therefore, this study aims to characterize the demographic and clinical profiles of leprosy patients and to report the frequency and clinical patterns of reactional episodes observed at Rizal Medical Center, in the Philippines, from 2018 to 2022.

METHODOLOGY

Framework and variables

Figure 1 – Framework and variables.



Source: Created by the author.

Study design and population

A descriptive cross-sectional study design was used to determine the sociodemographic and clinical characteristics and the occurrence of leprosy reactions among patients with leprosy seen and treated at a public tertiary hospital in Pasig, Philippines, from 2018 to 2022, using secondary data from medical records and other hospital documents.

Participants were selected via random sampling until at least the minimum computed sample size was met. A population of 96 unique patients with leprosy was identified from historical data after surveying the census of leprosy consults seen at the Dermatology Department from 2018 to 2022. Based on an assumed 95% confidence level, Zα / 2 (critical value at the desired level of significance) = 1.96, Zβ (critical value at the desired power of the test) = 0.842, and δ (expected difference in proportions or frequencies between groups = 0.07, a minimum of 40 patients were required for this study.

Data collection

A list of patients with leprosy was taken from the departmental census. Only the records and electronic and/or physical charts of patients who were included in the study were retrieved. The age, sex, spectrum of leprosy, classification of treatment regimen, history of leprosy reaction, bacteriological index (pre- and post-treatment), extension of treatment, prednisone dose, and signs and symptoms of reaction were extracted from the records and entered in individual data collection forms. The extracted data was encoded in an Microsoft Excel file.

Ethical considerations

This study was approved by the Institutional Review Board of the Rizal Medical Center with the code 2024-D-#004-RP-FB.IV. The investigator requested a waiver of informed consent from the IRB as the study did not adversely affect the rights of patients, there was no increased risk for the patients, the investigator utilized measures to anonymize the patient's identity, only data needed in the study were collected, there was no communication with the patients, and it was not feasible to get written consent from each patient.

Data analysis

The demographic and clinical profile will be reported as percentages and means. The chi-square test of independence will be used to assess the significance of associations between patients' sociodemographic and clinical profiles and the type of leprosy reaction. If one cell crosstabulation is found to contain a value less than 5, Fisher's Exact Test will be used instead.

A *p-value* of < 0.05 will be considered statistically significant. IBM SPSS version 26 and Microsoft Excel were used in data analysis.

RESULTS

A total of 40 patients with leprosy were included in the study. The majority of patients fall within the 20-39 age group (47.50%), followed by the 40-59 age group (32.50%). A higher prevalence of leprosy was identified among males (80.00%) compared to females. In terms of geographic location, the majority of cases were reported from areas outside the national capital region (NCR) (45.00%), followed by the NCR 2nd District (40.00%). The NCR 4th District had the lowest incidence (15.00%) [Table 1]. Rizal Medical Center is committed to being the end-referral medical center for the Eastern NCR and CALABARZON, which may explain the geographic distribution of most cases in this study.

Table 1 – Sociodemographic profile of patients with leprosy (n = 40).

	2018 (n = 1)	2019 (n = 4)	2020 (n = 4)	2021 (n = 15)	2022 (n = 16)	TOTAL
	Frequency (%)					
Age, years						
0-19	0	1 (25.00)	1 (25.00)	2 (13.33)	1 (6.25)	5 (12.50)
20-39	1 (100.00)	3 (75.00)	1 (25.00)	8 (53.33)	6 (37.50)	19 (47.50)
40-59	0	0	1 (25.00)	5 (33.33)	7 (43.75)	13 (32.50)
≥ 60	0	0	1 (25.00)	0	2 (12.50)	3 (7.50)
Sex						
Male	1 (100.00)	3 (75.00)	4 (100.00)	13 (86.67)	11 (68.75)	32 (80.00)
Female	0	1 (25.00)	0	2 (13.33)	5 (31.25)	8 (20.00)
Location						
NCR 2nd District	0	1 (25.00)	1 (25.00)	7 (46.67)	7 (43.75)	16 (40.00)
NCR 4th District	1 (100.00)	0	0	3 (20.00)	2 (12.50)	6 (15.00)
Outside NCR	0	3 (75.00)	3 (75.00)	5 (33.33)	7 (43.75)	18 (45.00)

Source: Created by the author.

The clinical profile of leprosy patients reveals that the majority of the patients are classified as lepromatous-lepromatous (LL) at 70.00% [Table 2]. Borderline-lepromatous (BL) cases constitute 20.00%, while borderline- tuberculoid (BT) and borderline-borderline (BB) types are less common, each at 5.00%. Regarding treatment regimens, a vast majority were treated with the multidrug regimen (MB) (95.00%), while only 5.00% received the paucibacillary (PB) regimen. Treatment duration was not typically extended; 87.50% of patients completed their treatment within the standard period. Concerning leprosy reactions, 55% of patients experienced no reaction, while type I and type II reactions were observed in 25% and 20% of patients, respectively.

Table 2 – Clinical profile of patients with leprosy (n = 40).

	Frequency (%)
Spectrum of leprosy	
TT (*tuberculoid*)	0
BT (*borderline-tuberculoid*)	2 (5.00)
BB (*borderline-borderline*)	2 (5.00)
BL (*borderline-lepromatous*)	8 (20.00)
LL (*lepromatous-lepromatous*)	28 (70.00)

	Frequency (%)
Treatment regimen classification	
PB (*paucibacillary*)	2 (5.00)
MB (*multibacillary*)	38 (95.00)
Treatment duration	
Extended	5 (12.50)
Not extended	35 (87.50)
Type of reaction	
No reaction	22 (55.00)
Type I	10 (25.00)
Type II	8 (20.00)

Source: Created by the author.

The average bacteriological index (BI) for leprosy patients shows a significant improvement from pre-treatment to post-treatment assessments. At the start, 22.50% of patients had a BI of 0, which increased to 55.00% after treatment, indicating a substantial reduction in bacterial load [Table 3]. The number of patients with higher BI values decreased notably post-treatment, with those in the 0.10-0.50 range dropping from 22.50% to 7.50%.

Conversely, the proportion of patients with a BI in the higher ranges (e.g., 1.01-1.50, 1.51-2.00) reduced post-treatment. The disappearance of patients in the highest BI ranges (e.g., 4.51-5.00, 6.00) further reflects the effectiveness of the treatment regimen in reducing bacterial counts.

Table 3 – Average bacteriological index of patients with leprosy.

	(n = 40)	
	Pre-treatment	**Post-treatment**
	Frequency (%)	
Average bacteriological – Index		
0	9 (22.50)	22 (55.00)
0.10-0.50	9 (22.50)	3 (7.50)
0.51-1.00	5 (12.50)	8 (20.00)
1.01-1.50	2 (5.00)	3 (7.50)
1.51-2.00	6 (15.00)	3 (7.50)
2.01-2.50	1 (2.50)	1 (2.50)
2.51-3.00	2 (5.00)	0
3.01-3.50	1 (2.50)	0

	(n = 40)	
	Pre-treatment	Post-treatment
	Frequency (%)	
Average bacteriological – Index		
3.51-4.00	1 (2.50)	0
4.01-4.50	2 (5.00)	0
4.51-5.00	0	0
5.01-5.50	0	0
5.51-6.00	2 (5.00)	0
6.00	0	0

Source: Created by the author.

Age, sex, spectrum of leprosy, and treatment duration do not show significant associations with leprosy reactions, as indicated by *p-values* > 0.05 [Table 4].

A higher frequency of leprosy reactions, particularly type I, was observed among males, though this did not reach statistical significance.

Table 4 – Association of sociodemographic and clinical characteristics with leprosy reaction in Rizal Medical Center from 2018 to 2022.

	No reaction (n = 22)	Type I (n = 10)	Type II (n = 8)	Test statistic	*p-value*
	Frequency (%)				
Age, years					
0-19	3	1	1	5.967	0.388
20-39	7	6	6		
40-59	10	2	1		
≥ 60	2	1	0		
Sex					
Male	15	10	7	4.269	0.094
Female	7	0	1		
Spectrum of leprosy					
BT	1	0	1	5.042	0.518
BB	2	0	0		
BL	3	4	1		
LL	16	6	6		
Treatment regimen classification					
PB	2	0	0	1.068	1.000
MB	20	10	8		
Treatment duration					
Extended	2	1	2	1.606	0.470
Not extended	20	9	6		

Source: Created by the author.

Prednisone intake is predominantly at a higher dosage, with 66.67% of patients taking 40 mg daily [Table 5]. Additionally, the average bacteriological index (BI) has decreased post-treatment, with the percentage of patients with a BI of 0 increasing from 22.22% pre-treatment to 44.44% post-treatment. This reduction indicates a positive response to the treatment, reflecting the effectiveness of the multidrug therapy (MDT) in reducing bacterial load among patients with leprosy reactions.

In terms of reaction, most leprosy reactions occurred during MDT (72.22%), suggesting that these reactions are more likely to arise during treatment than before or after its completion.

Table 5 – Clinical profile of patients with leprosy reaction (n = 18).

	Frequency (%)	
Prednisone intake		
< 20 mg daily	0	
20 mg daily	2 (11.11)	
30 mg daily	4 (22.22)	
40 mg daily	12 (66.67)	
	Pre-treatment	**Post-treatment**
	Frequency (%)	
Average bacteriological index		
0	4 (22.22)	8 (44.44)
0.10-0.50	3 (16.67)	2 (11.11)
0.51-1.00	4 (22.22)	6 (33.33)
1.01-1.50	1 (5.56)	2 (11.11)
1.51-2.00	3 (16.67)	0
2.01-2.50	0	0
2.51-3.00	0	0
3.01-3.50	0	0
3.51-4.00	0	0
4.01-4.50	1 (5.56)	0
4.51-5.00	0	0
5.01-5.50	0	0
5.51-6.00	2 (11.11)	0
6.00	0	0
	Frequency (%)	
In reaction		
Before MDT	0	
During MDT	13 (72.22)	
After MDT	5 (27.78)	

Source: Created by the author.

It can be observed in Table 6 that for type I leprosy reaction, the most commonly reported sign and symptom was that existing lesions became more erythematous. For type II leprosy reaction, painful and tender lesions were the most common sign and symptom experienced by patients, followed by fever, anorexia, and malaise.

Table 6 – Usual signs and symptoms experienced by patients with leprosy reaction.

	Frequency (%)
Type I Lepra signs and symptoms	
Existing lesions become erythematous	9 (90.00)
Neuritis (nerve tenderness, new anesthesia and/or motor loss)	1 (10.00)
Edema of hands and feet	0
Sudden loss of nerve function (claw hand, foot drop, facial palsy)	0
Type II Lepra signs and symptoms	
Painful and tender lesions	7 (87.50)
Fever, anorexia, or malaise	3 (37.50)
New erythematous dermal and/or subcutaneous nodules	2 (25.00)
Arthralgias, myalgias	2 (25.00)

Source: Created by the author.

DISCUSSION

Because leprosy reactions are closely linked to morbidity and disability as leprosy progresses, numerous studies have examined the sociodemographic and clinical characteristics of patients who develop these acute episodes. In this study of 40 patients – most of whom were males aged 20-39 and classified as having lepromatous leprosy with no treatment extensions – no significant associations were identified between these variables and the occurrence of leprosy reactions. Although most cases occurred among adults, this finding showed no significant association. These results differ from those of Scollard et al., who reported an increased risk of leprosy reactions with advancing age, noting a trend toward more complications – including leprosy reactions – among older individuals[4].

Male patients accounted for the highest proportion (80%, 32 patients), yet sex was not significantly associated with leprosy reactions. This contrasts with Scollard et al.[4], who reported that sex does not significantly influence the incidence of leprosy, regardless of reaction status. However, studies by Ramadhona, Supriyanto and Martini[10] and Antunes et al.[16] suggest that

the higher number of male leprosy patients may be associated with stress. Stress can alter immune function by modifying lymphocyte proliferation, T-cell activation, antigen processing, macrophage activity, Th1/Th2 balance, and cytokine release such as IL-6[16]. These immune shifts may act as triggers for type I leprosy reactions, which aligns with this study's observation of a higher frequency of type I reactions (25%, 10 patients) compared with type II reactions (20%, 8 patients).

Type I reactions involve a type IV hypersensitivity response wherein the immune system recognizes *M. leprae* antigens, leading to renewed cell-mediated activity. Type II reactions, on the other hand, arise from immune complex formation between bacterial antigens and antibodies, with tissue deposition and inflammation mediated by neutrophils and macrophages. These reactions are often seen in patients with high bacterial loads and involve inflammatory cytokines[16].

Most patients in this study were classified as having lepromatous leprosy (70%, 28 patients), were placed under the multibacillary (MB) treatment regimen (95%, 38 patients), and showed good treatment compliance (87.5%, 35 patients). Despite this, none of these factors were significantly associated with leprosy reactions. These findings differ from those of Hungria et al.[17], who reported that MB patients are more likely to experience leprosy reactions. Other studies have similarly found that reactions are more common among MB patients, particularly during MDT[18]. Antunes et al.[16] also reported that MB cases increase with age, suggesting that in populations with declining transmission, later-onset infection and prolonged incubation periods may contribute to the predominance of MB disease. Patients with lepromatous leprosy have unstable immune responses, placing them at higher risk for both type I and type II reactions as bacterial loads rise.

A positive bacterial index (BI) was found in 77% of patients (31 individuals), but BI was not significantly associated with leprosy reactions in this study. This differs from several studies reporting that patients with positive BI are more likely to develop leprosy reactions due to higher antigen loads, which trigger stronger immune responses, especially type II reactions[16].

Most patients with leprosy reactions were treated with prednisone 40 mg daily (66.67%, 12 patients). An initial prednisolone dose of 0.5 mg/kg/day is typically recommended, which corresponds to approximately 30-40 mg/day for most adults[2]. Treatment patterns observed in this study reflect standard practice, especially for type I reactions, where corticosteroids are the mainstay of therapy.

Direct comparison with previous studies is limited, as the present study did not find statistically significant associations between sociodemographic or clinical variables and leprosy reactions. Several factors may explain these discrepancies:

the limited sample size, which reduces statistical power; the single-institution population, which may not represent broader epidemiologic trends; and the retrospective nature of the study, which limits the completeness and accuracy of available data. Additionally, the data collection period (2018-2022) coincided with the COVID-19 pandemic, which may have affected patient follow-up, healthcare access, and the documentation of reactions.

No statistically significant associations were detected. A higher frequency of type I leprosy reactions was seen among male patients, though this did not reach statistical significance. A larger sample size and prospective study design may be needed to further clarify whether these observed trends represent true associations. The lack of statistically significant findings ($p > 0.05$) is likely due to the study's limited power and heterogeneity of clinical presentations.

The study population demonstrates a marked over-representation of severe disease, with 70% classified as lepromatous leprosy and 95% as multibacillary cases. This distribution is consistent with the setting of a tertiary referral center, where more complicated and advanced cases are preferentially managed. Consequently, the observed frequency of leprosy reactions in this cohort may be overestimated compared with that in the general leprosy population. Furthermore, the findings should be interpreted with caution, as they cannot be readily generalized to all patients with leprosy, particularly those with paucibacillary forms, who are underrepresented in this sample. These factors limit the study's external validity and should be explicitly acknowledged when contextualizing the results.

LIMITATIONS

This study has several limitations that should be considered when interpreting the findings. First, the small sample size ($n = 40$) substantially limits statistical power, reducing the ability to detect true associations between sociodemographic or clinical variables and the occurrence of leprosy reactions. Second, the single-center design creates potential sampling bias, as the patient population may not be representative of the broader leprosy population in other regions of the Philippines where epidemiologic patterns, access to care, or clinical presentations may differ.

The retrospective nature of the study also introduces multiple constraints, including incomplete or missing clinical documentation, variability in physician assessment, and limitations in confirming symptom onset or accurately classifying leprosy reaction episodes. Important immunologic or microbiologic markers were also unavailable for many patients, preventing a deeper analysis of host immunity, bacterial load, and risk of reaction. Additionally, the study did not employ multivariable adjustment, making it difficult to account for confounding factors such as symptom duration before consultation, nutritional status,

comorbidities, or treatment adherence outside hospital records.

Furthermore, the discussion of discordant findings relative to previous studies (e.g., Scollard et al.[8], Hungria et al.[17], Antunes et al.[16]) is limited by insufficient integration of the underlying immunologic and epidemiologic mechanisms. Differences in immune responses across the Th1–Th2 spectrum, variability in antigenic load, and environmental or genetic factors affecting host immunity likely contribute to disparities between studies. These important mechanistic factors could not be thoroughly explored due to the restricted dataset and lack of detailed immunologic measurements.

Lastly, the study period overlapped significantly with the COVID-19 pandemic, which may have influenced healthcare-seeking behavior, continuity of leprosy follow-up, and completeness of documentation – further affecting data reliability.

CONCLUSION

In summary, this study found no statistically significant associations between sociodemographic factors (age, sex) or clinical characteristics (leprosy classification, treatment regimen, treatment duration, compliance, and bacterial index) and the occurrence of leprosy reactions among patients with leprosy seen at a public tertiary hospital from 2018 to 2022. Although trends – particularly a higher frequency of type I reactions among male patients – were observed, these did not reach statistical significance. The absence of significant findings is likely influenced by the study's small sample size, retrospective design, and limited variability within the population.

Despite these limitations, the study highlights important clinical observations, including the predominance of lepromatous leprosy, multibacillary treatment, and frequent reactions during MDT, underscoring the need for continued vigilance in monitoring for leprosy reactions. Future research using larger, multicenter cohorts and prospective designs is recommended to more accurately determine the demographic and clinical profile for leprosy reactions and to support improved clinical management aimed at preventing disability.

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APPENDIX

Sociodemographic and clinical profile of patients with leprosy (n = 40).

	2018 (n=1)	2019 (n=4)	2020 (n=4)	2021 (n=15)	2022 (n=16)	TOTAL
	Frequency (%)					
Age, years						
0-19	0	1 (25.00)	1 (25.00)	2 (13.33)	1 (6.25)	5 (12.50)
20-39	1 (100.00)	3 (75.00)	1 (25.00)	8 (53.33)	6 (37.50)	19 (47.50)
40-59	0	0	1 (25.00)	5 (33.33)	7 (43.75)	13 (32.50)
≥ 60	0	0	1 (25.00)	0	2 (12.50)	3 (7.50)
Sex						
Male	1 (100.00)	3 (75.00)	4 (100.00)	13 (86.67)	11 (68.75)	32 (80.00)
Female	0	1 (25.00)	0	2 (13.33)	5 (31.25)	8 (20.00)
Location						
NCR 2nd District	0	1 (25.00)	1 (25.00)	7 (46.67)	7 (43.75)	16 (40.00)
NCR 4th District	1 (100.00)	0	0	3 (20.00)	2 (12.50)	6 (15.00)
Outside NCR	0	3 (75.00)	3 (75.00)	5 (33.33)	7 (43.75)	18 (45.00)
Spectrum of leprosy						
TT	0	0	0	0	0	0
BT	0	0	0	0	2 (12.50)	2 (5.00)
BB	0	0	0	0	2 (12.50)	2 (5.00)
BL	1 (100.00)	0	0	6 (40.00)	1 (6.25)	8 (20.00)
LL	0	4 (100.00)	4 (100.00)	9 (60.00)	11 (68.75)	28 (70.00)
Treatment regimen classification						
PB	0	0	0	0	2 (12.50)	2 (5.00)
MB	1 (100.00)	4 (100.00)	4 (100.00)	15 (100.00)	14 (87.50)	38 (95.00)
Treatment duration						
Extended	1 (100.00)	2 (50.00)	0	1 (6.67)	1 (6.25)	5 (12.50)
Not extended	0	2 (50.00)	4 (100.00)	14 (93.33)	15 (93.75)	35 (87.50)

	2018 (n=1)	2019 (n=4)	2020 (n=4)	2021 (n=15)	2022 (n=16)	TOTAL
	Frequency (%)					
Type of reaction						
No reaction	0	0	2 (50.00)	7 (46.67)	13 (81.25)	22 (137.50)
Type I	0	3 (75.00)	2 (50.00)	5 (33.33)	0	10 (62.50)
Type II	1 (100.00)	1 (25.00)	0	3 (20.00)	3 (18.75)	8 (50.00)