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Factors contributing to activity limitations in Leprosy patients in Sitanala Leprosy Village, Indonesia

Endonezya Sitanala Lepra Köyü'ndeki Lepra hastalarında aktivite kısıtlılıklarına katkıda bulunan faktörler

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Abstract

Background and Design: To investigate the association between sociodemographic variables, illness duration, leprosy types, comorbidities, and World Health Organization disability grading system for leprosy with daily activity limitations in people with leprosy who had completed multidrug therapy.
Materials and Methods: A cross-sectional study was conducted in Sitanala Leprosy Village, Tangerang, Indonesia, in April 2018. Sociodemographic data and leprosy baseline characteristics were obtained from patients with leprosy who had completed multidrug therapy. The Screening of Activity Limitation and Safety Awareness scale was used to measure limitations in performing daily functional activities.
Results: A total of 205 people were included in the study, of which 39 (19%) had eye disabilities, 178 (86.8%) had hand disabilities, and 187 (91.2%) had foot disabilities. A total of 135 (65.8%) people had mild-to-moderate functional limitation, and 33 (16%) had severe-to-very severe functional limitation. The proportion of unemployed individuals was higher among those with severe-extreme limitation compared to those without significant limitation (p=0.01). Individuals with eye disability had a higher risk of having severe-extreme activity limitation compared to those without eye disability (p=0.008). A dose-response association of hands and foot disabilities with activity limitation was found; the adjusted odds ratio (OR) of the association of hands and foot disabilities with mild-moderate activity limitation was 3.03 (p=0.012), and the association was greater with severe-extreme activity limitation (adjusted OR; 20.38, p=0.006).
Conclusion: Severe disability is associated with functional activity limitations. The findings of the present study can guide healthcare providers in designing appropriate prevention and intervention services for patients with leprosy-related disabilities.
Keywords: Disability, impairment, leprosy, SALSA scale

Öz

Amaç: Çoklu ilaç tedavisini tamamlamış lepralı kişilerde sosyodemografik değişkenler, hastalık süresi, lepra türleri, komorbiditeler ve Dünya Sağlık Örgütü'nün lepra için engellilik derecelendirme sistemi ile günlük aktivite kısıtlamaları arasındaki ilişkiyi araştırmaktır.
Gereç ve Yöntem: Endonezya'nın Tangerang kentindeki Sitanala Lepra Köyü'nde Nisan 2018'de kesitsel bir çalışma yapıldı. Sosyodemografik veriler ve lepra temel özellikleri, çoklu ilaç tedavisini tamamlamış lepralı hastalardan elde edildi. Günlük fonksiyonel aktivitelerin gerçekleştirilmesindeki sınırlamaları ölçmek için Aktivite Sınırlamalarının Taranması ve Güvenlik Farkındalığı ölçeği kullanıldı.
Bulgular: Çalışmaya 39'u (%19) göz, 178'i (%86,8) el, 187'si (%91,2) ayak engeli olmak üzere toplam 205 kişi dahil edildi. Toplam 135 (%65,8) kişide hafif-orta derecede fonksiyonel kısıtlılık ve 33 (%16) kişide şiddetli-çok şiddetli fonksiyonel kısıtlılık vardı. Şiddetli-aşırı kısıtlılığı olanlarda işsizlerin oranı anlamlı kısıtlılığı olmayanlara göre daha yüksekti (p=0,01). Göz engeli olan bireylerin, göz engeli olmayanlara göre ciddi-aşırı aktivite kısıtlılığına sahip olma riski daha yüksekti (p=0,008). El ve ayak engelleri ile aktivite kısıtlılığı arasında bir doz-yanıt ilişkisi bulundu; hafif-orta aktivite kısıtlılığı ile el ve ayak engeli ilişkisinin düzeltilmiş olasılık oranı (OR) 3,03 (p=0,012) ve ciddi-aşırı aktivite sınırlaması ile ilişki daha büyüktü (düzeltilmiş OR; 20,38, p=0,006).
Sonuç: Şiddetli sakatlık, fonksiyonel aktivite sınırlamaları ile ilişkilidir. Bu çalışmanın bulguları, sağlık hizmeti sağlayıcılarına lepra ile ilgili engelli hastalar için uygun korunma ve tedavi hizmetleri tasarlamada rehberlik edebilir.
Anahtar Kelimeler: Engellilik, özürlülük, SALSA ölçeği

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Introduction

Indonesia, being the country with the third most leprosy cases after India and Brazil, has a significant burden in handling leprosy. In 2019, the leprosy prevalence was 0.74 cases per 100,000 population, and new case findings were 6.51 cases per 100,000 population, where 17,439 new cases of leprosy were reported. A province is declared to have achieved elimination if the prevalence rate is <1 per 10,000 population. In Indonesia, 26 provinces have successfully achieved elimination. However, leprosy elimination has not been attained in several regions, such as in North Sulawesi, South Sulawesi, Gorontalo, West Sulawesi, Maluku, North Maluku, West Papua, and Papua. Moreover, the grade 2 disability (i.e., visible deformity) rate is used as the indicator to show success in early case detection. In 2019, the grade 2 disability rate was 4.18 per 1,000,000 population, which tended to decrease compared to 7 years earlier. This number illustrates the increased success of case-finding activities[1].

Disabilities of the eyes, hands, and feet in leprosy are influenced by various factors, including sociodemographic and clinical factors. In 2019, the systematic review and meta-analysis by de Paula et al.[2] found an association of physical disability with male sex, multibacillary leprosy type, incidence of leprosy reactions, and lepromatous presentation. In addition, other factors such as low education and nervous system involvement affect the development of disabilities[3]. On the contrary, comorbidities such as smoking, alcoholism, and diabetes do not appear to affect the incidence of disability development[4]. Some studies have demonstrated a significant correlation of leprosy-related ocular complications with increased age, illness duration, decreased visual function, and vision <3/60, but not with disease classification[5,6].

The Screening of Activity Limitation and Safety Awareness (SALSA) is a diagnostic tool used to assess the extent to which disability due to leprosy affects activity limitations. SALSA is a cross-cultural tool that assesses three domains, namely, mobility, self-care, and work. This simple questionnaire has been applied widely to evaluate activity limitations. Several studies have used this questionnaire to measure the level of function and activity limitations in patients with leprosy. Furthermore, SALSA has been utilized by service providers in designing an appropriate intervention[7,8].

The present study aimed to investigate factors that influenced disability in patients with leprosy and assess the use of the SALSA scale for evaluating activity limitations in patients with leprosy who had completed leprosy treatment.

Materials and Methods

Design and sampling

The study was approved by the University Indonesia Faculty of Medicine, Ethics Committee (approval number: 0310/UN2.F1/ETIK/2018).

We conducted a cross-sectional study to investigate factors that influenced disability in patients with leprosy. This study was a part of the Katamataku project that involved multidisciplinary departments, namely, the Departments of Dermatology and Venereology, Ophthalmology, and Medical Rehabilitation. The study population included all patients with leprosy living in residential areas around the Sitanala Hospital (previously Leprosy Hospital), Tangerang. Participant recruitment was conducted on April 23-24, 2018. A total of 250 patients were recruited. The inclusion criteria were as follows: (1) Patients (all ages) who had completed monotherapy or multidrug treatment, (2) had been declared released from treatment at the Sitanala Hospital based on the patient's statement, (3) had given consent to participate in the study, and (4) were willing to comply to the research procedure. Individuals who had severe mental disorders or difficulty communicating according to the research team's assessment were excluded.

Physical impairments were assessed using World Health Organization (WHO) disability grading. The eyes, hands, and feet score is an indicator of severity impairment. Scores ranging from 0 to 2 were used to assess organ impairment separately. The assessment of activity limitations due to disabilities was assessed using the SALSA scale. SALSA is a 20-item questionnaire that can be filled out in 10 min. A SALSA score indicates the difficulties encountered in daily living activities; the higher the value, the greater the level of activity limitations. The SALSA scale was categorized into five groups: 10-24, "no significant limitation"; 25-39, "mild limitation"; 40-49, "moderate limitation"; 50-59, "severe limitation"; and 60-80 "extreme limitation."

Statistical Analysis

Continuous data distribution was assessed using histograms. Data with normal distribution are presented as means and standard deviations, whereas non-normal distribution data are presented as median (minimum-maximum). Categorical data are presented as proportions. The chi-square or Kolmogorov-Smirnov test was used to compare activity limitations with categorical variables. Furthermore, continuous variables were tested using ANOVA or Kruskal-Wallis test. The associations between disabilities and activity limitations were analyzed using multinomial logistic regression. In the multivariate analysis, associations for these variables were adjusted for all demographics and characteristics if they had p-values <0.25 in the bivariate analysis. The results are presented as odds ratios (ORs) with 95% confidence intervals (CIs). Significance was defined as $p<0.05$. Data were managed and analyzed using STATA version 16 (StataCorp, College Station, TX, USA). However, not all datasets for each participant are complete; thus, the samples analyzed for each variable may differ from the total sample size.

Results

Subject characteristics and their associations with activity limitations

Of the 205 individuals, 61% were men. Among all individuals, the mean age was 52.7±10.6 years. Most individuals (95%) had household member(s) with leprosy. Demographic characteristics are shown in Table 1.

Of the 205 individuals included in the study, 18% (n=37) had no significant activity limitation, 66% (n=135) had mild or moderate activity limitations, and 16% (n=33) had severe or extreme activity limitations. The prevalence of eye, hand, and foot disabilities were 19%, 87%, and 91%, respectively (Table 2).

Based on the WHO disability grading, from 205 individuals, 19% had eye disability, 86.8% had hand disability, 91.2% had foot disability, 96.1% had either hand or foot disability, and 81.95% had both hand and foot disability.

The proportion of unemployed individuals was higher among those with severe-extreme limitations than in those without significant limitation (72.7% vs 40.5%, p=0.01). Other sociodemographic characteristics were not associated with the grade of activity limitations (Table 3).

The median leprosy duration was 5 years (minimum: 1 month, maximum: 53 years). At the treatment initiation, 70% of the individuals had multibacillary leprosy, and 30% had paucibacillary leprosy. Leprosy reactions were experienced by 44% of the individuals. The most common comorbidities found were hypertension (25%) and diabetes (7%). No association was found between clinical characteristics and grade of activity limitations (Table 4).

Association between disabilities and activity limitations

Compared with individuals without eye disability, those with eye disability had a higher risk of severe-extreme activity limitations (crude OR, 6.48; 95% CI, 1.63-25.67, p=0.008), but no higher risk of mild-moderate activity limitations (p=0.163). The association between eye disability and severe-extreme activity limitations was strengthened when adjusted for ethnicity, employment status, marital status, presence of any comorbidities, and treatment dropout (adjusted OR for severe-extreme activity limitations, 13.27; 95% CI, 2.93-60.13, p=0.001). A dose-response association of hand and foot disabilities with activity limitations was found; the adjusted OR of the association of hand and foot disabilities with mild-moderate activity limitations was 3.03 (95% CI, 1.27-7.22, p=0.012), and the association was greater with severe-extreme activity limitations (adjusted OR, 20.38; 95% CI, 2.39-174.06, p=0.006) (Table 5).

Table 1. Demographic characteristics

Demographic characteristics	Total, (n)	n (%)	Mean (SD)
Sex	205	-	-
Male	-	125 (61.0)	-
Female	-	80 (39.0)	-
Age (years)	166	-	52.7 (10.63)
Education	205	-	-
High school graduates	-	24 (11.7)	-
Non-high school graduates	-	181 (88.3)	-
Employment status	205	-	-
Employed	-	105 (51.2)	-
Unemployed	-	100 (48.8)	-
Monthly income[a]	97		-
<1.5 million (IDR)	-	68 (70.1)	-
≥1.5 million (IDR)	-	29 (29.9)	-
Marital status	201		-
Married	-	171 (85.1)	-
Unmarried	-	30 (14.9)	-
Ethnicity	205		-
Javanese	-	55 (26.8)	-
Sundanese	-	81 (39.5)	-
Betawinese	-	42 (20.5)	-
Others	-	27 (13.2)	-

SD: Standard deviation, [a]: Among employed individuals, IDR: Innate defense regulators

Table 2. Prevalence of activity limitations according to the SALSA scale (n=205)

Limitation	n	%
No significant limitation	37	18.1
Mild limitation	103	50.2
Moderate limitation	32	15.6
Severe limitation	22	10.7
Extreme limitation	11	5.4

SALSA scale: 10-24, no significant limitation; 25-39, mild limitation; 40-49, moderate limitation; 50-59, severe limitation; 60-80, extreme limitation. SALSA: The Screening of Activity Limitation and Safety Awareness

Discussion

This study showed that most patients with leprosy had physical disabilities (96%). We demonstrated an association between activity limitations and disabilities of the eyes, hands, and feet in patients with leprosy in a leprosy village in Indonesia. Among all sociodemographic factors, employment status was associated with activity limitations and disabilities. No associations of other demographic or clinical characteristics with activity limitation or disability were found. Most patients were men (61%; women, 39%). Neither activity limitation nor disability was associated with education level, age, or marital status. We also found a null association of activity limitation or disability with illness duration, leprosy reactions, corticosteroid medication, and neuritis. Eye disability and hand disability were found to be significantly associated with severe-extreme limitations (p=0.008 and 0.022, respectively). Hand disability was also significantly associated with mild-moderate limitations (p=0.026). Hand, foot, and eye disabilities were significantly associated with severe-extreme limitations (p=0.005).

Among all sociodemographic variables measured in this study, employment status was the factor associated with activity limitations in patients with leprosy. The unemployment rate was higher in individuals with severe limitations than in those without limitation or had mild-moderate limitations. Most of the patients in the present study were men (61.0%), which was in line with the results of Reis et al.[9] in 2017 (61.3%) and de Paula et al.[2] in 2019. Such disproportion might be due to the lifestyle of men who expose themselves to greater risk of infection. Men often ignore leprosy symptoms and seek health services when they are at more advanced stages and had severe clinical manifestations; therefore, this might contribute to the prevalence of physical disability in men being almost twice more likely than that in women[4,9].

The proportion of unemployed individuals was higher among those with severe-extreme limitations than among those without significant limitation (72.7% vs 40.5%, p=0.01). This result was in line with the finding of Dixit and Dhiman[10] in 2019, who stated that disability had a direct bearing on employability (p=0.009). The study found that most patients with severe disabilities were unemployed and patients with any disabilities were either self-employed or in some form of job. Disability-related activity limitations might encourage patients to change their occupation from jobs that require greater physical effort to low physical effort, or stop working entirely[4,9].

In the present study, marital status was not associated with activity limitations (p=0.205). This result was not in line with the previous report

of Dixitand Dhiman[10]. The previous study demonstrated that significant proportions of patients were single, separated, divorced, or widow. In Indonesia, van Brakel et al.[11] also reported higher proportions of separated, divorced, or widowed patients among women. However, our result was in line with those of Nardi et al.[12] in 2012, which showed no difference in percentages of disability among patients with leprosy who had a partner compared to their counterparts without a partner[1,2,9]. This difference in the results might be explained by the difference in study settings and sociocultural practices.

In the present study, age was not significantly associated with activity limitations (p=0.974). This result was not consistent with the findings of Govindharaj et al.[13] in 2020 and Nardi et al.[12] in 2012, which indicated that older persons suffered more limitations in activities. Reis et al.[9] also found that 40% of the patients aged 29-55 years and 50% of the patients aged 56-86 years presented activity limitations. The study showed a decline in limitations with increasing age. On the contrary, Barbosa demonstrated a null relationship between the SALSA score and age range[9].

In the present study, education level was also not significantly associated with disabilities and activity limitations. In 2018, Santana et al.[3] reported that a low educational level was associated with a 40% higher probability for developing disabilities. The knowledge of the disease and understanding of the guidelines and preventive and therapeutic measures influence the self-care ability, which is essential to achieve preventive actions[3].

Compared with individuals without eye disability, those with eye disability had a higher risk of having severe-extreme activity limitations but no higher risk of mild-moderate activity limitations. Singh et al. found that 39.4% of patients with leprosy suffered from eye disability, with bilateral eye defect more common than unilateral defect. Lagophthalmos, keratitis, corneal opacity, and uveal involvement were the types of abnormalities identified. van Brakel et al.[11] also found a substantial proportion (39%) of patients with visible impairment in Indonesia. They also found a high proportion of visual impairment (67.5%, 81 eyes)[14]. Ocular impairment might affect patient's activities the most because it is directly related to activities that patients can perform. Severe visual impairment and blindness contribute to ocular disability. The presence of blindness combined with other forms of deformity would significantly reduce the quality of life and lead to "double-handicap" conditions. Other than steroid treatment in leprosy reactions, blindness can be influenced by factors such as the leprosy type, illness duration, late management of eye disorders, and social barriers caused by ignorance[14]. However, this study did not find an association between steroid administration and other factors.

Compared with people who did not experience significant limitations, those with hand disabilities had a greater chance of experiencing mild-

Table 3. Association between sociodemographic characteristics and activity limitation

	No limitation	Mild-moderate limitations	Severe-extreme limitations	p
	(n=37)	(n=135)	(n=33)	
Sex				0.727
Male	23 (62.2)	80 (59.3)	22 (66.7)	-
Female	14 (37.8)	55 (40.7)	11 (33.3)	-
Age (years)[a]	52.3 (10.91)	52.3 (10.56)	55 (10.73)	0.974
Education				0.834
High school graduates	3 (8.1)	20 (14.8)	1 (3.0)	-
Non-high school graduates	34 (91.9)	115 (85.2)	32 (97)	-
Employment status				**0.01**
Employed	22 (59.5)	74 (54.8)	9 (27.3)	-
Unemployed	15 (40.5)	61 (45.2)	24 (72.7)	-
Marital status				0.205
Married	28 (75.7)	114 (87.0)	29 (87.9)	-
Unmarried	9 (24.3)	17 (13.0)	4 (12.1)	-
Ethnicity				0.148
Javanese	10 (27.0)	40 (29.6)	5 (15.2)	-
Sundanese	16 (43.2)	55 (40.7)	10 (30.2)	-
Betawinese	5 (13.5)	25 (18.5)	12 (36.4)	-
Others	6 (16.2)	15 (11.1)	6 (18.2)	-
Household members with leprosy				0.999
Yes	36 (97.3)	127 (94.8)	30 (90.9)	-
No	1 (2.7)	7 (5.2)	3 (9.1)	-
Duration of leprosy (years)[b]	5 (0.08-44)	5 (0.25-48)	6 (0.5-53)	0.929

Independent categorical variables were analyzed using chi-square or Kolmogorov-Smirnov test, where appropriate. Independent continuous variables were analyzed using One-Way ANOVA or Kruskal-Wallis test, where appropriate. Bold numbers indicate significance. [a]: Data are presented as mean (standard deviation). [b]: Data are presented as median (minimum-maximum)

moderate limitations by 2.75 times and very severe limitations by 11.85 times. Interestingly, foot disability alone was not significantly associated with activity limitations. It appears that individuals did not experience significant limitations if they had foot disability and not hand disability. A dose-response association was seen in patients with hand and foot disability. They had a 2.64 higher risk for mild-moderate limitations and

Table 4. Association between patients' characteristics and activity limitations

	No limitation	Mild-moderate limitations	Severe-extreme limitations	p
	(n=37)	(n=135)	(n=33)	
Leprosy classification				0.107
Paucibacillary leprosy	6 (16.2)	43 (32.1)	12 (37.5)	-
Multibacillary leprosy	31 (83.8)	91 (67.9)	20 (62.5)	-
Treatment dropout				0.208
Yes	2 (5.6)	22 (16.9)	6 (18.2)	-
No	34 (94.4)	108 (83.1)	27 (81.8)	-
Leprosy reactions				0.869
Yes	14 (41.2)	59 (46.1)	14 (43.8)	-
No	20 (58.8)	69 (53.9)	18 (56.2)	-
Medication with corticosteroid				0.548
Yes	28 (75.7)	92 (69.7)	21 (63.6)	-
No	9 (24.3)	40 (30.3)	12 (36.4)	-
Neuritis				0.305
Yes	22 (59.5)	94 (70.7)	20 (60.6)	-
No	15 (40.5)	39 (29.3)	13 (39.4)	-
BCG vaccination				0.837
Yes	9 (26.5)	36 (31.6)	9 (32.1)	-
No	25 (73.5)	78 (68.4)	19 (67.9)	-
Presence of comorbidities				0.17
Yes	13 (35.1)	42 (31.1)	16 (48.5)	-
No	24 (64.9)	93 (68.9)	17 (51.5)	-

Independent categorical variables were analyzed using chi-square or Kolmogorov-Smirnov test, where appropriate. Independent continuous variables were analyzed using One-Way ANOVA or Kruskal-Wallis test, where appropriate. Bold numbers indicate statistical significance. [a]: Data are presented as mean (standard deviation) [b]: Data are presented as median (minimum-maximum)

Table 5. Association between disabilities and activity limitations

	n (%)			Crude OR (95% CI, p-value), (n=205)		Adjusted OR (95% CI, p-value), (n=195)	
Disabilities	**No limitation**	**Mild-moderate limitations**	**Severe-extreme limitations**	**Mild-moderate limitations[a]**	**Severe-extreme limitations[a]**	**Mild-moderate limitations[a]**	**Severe-extreme limitations[a]**
Eye disability	3 (8.1)	24 (17.8)	12 (36.4)	2.45 (0.70-8.64, 0.163)	**6.48 (1.63-25.67, 0.008)**	3.04 (0.82-11.22, 0.096)	**13.27 (2.93-60.13, 0.001)**
Hand disability	27 (73.0)	119 (88.2)	32 (97.0)	**2.75 (1.13-6.73, 0.026)**	**11.85 (1.42-98.59, 0.022)**	**2.89 (1.13-7.37, 0.026)**	**12.1 (1.39-105.08, 0.024)**
Foot disability	30 (81.1)	124 (91.9)	33 (100)	2.63 (0.94-7.35, 0.065)	NAb	-	-
Either hand or foot disability	33 (89.2)	131 (94.0)	33 (100)	3.97 (0.94-16.72, 0.06)	NAb	-	-
Both hand and foot disabilities	24 (64.9)	112 (83.0)	32 (97.0)	**2.64 (1.17-5.93, 0.019)**	**17.33 (2.12-141.79, 0.008)**	**3.03 (1.27-7.22, 0.012)**	**20.38 (2.39-174.06, 0.006)**
Hand, foot, and eye disabilities	2 (5.4)	24 (17.8)	12 (36.4)	3.78 (0.85-16.82, 0.08)	**9.99 (2.03-49.12, 0.005)**	4.20 (0.92-19.13, 0.063)	**16.27 (3.06-86.54, 0.001)**

OR: Odds ratio, CI: Confidence interval, OR and 95% confidence intervals were calculated using simple multinomial logistic regression. Multivariate analysis was adjusted for ethnicity, employment status, marital status, presence of any comorbidities, and treatment dropout. Bold numbers indicate significance. [a]: No significant limitation group as reference, [b]: Not available because of no reference in severe-extreme limitation group

a 17.33 higher risk for severe-extreme limitations than patients without hand and foot disability.

In leprosy, the eyes, hands, and feet are commonly affected in the advanced stages[15]. In 2019, Rathod et al.[16] found that 44.48% (n=113) of the deformities involved the hand and feet 39.76% (n=101). This result may be explained by the dependency on using the eyes, hands, and feet for mobility and other vital activities of daily living[16]. The grade of physical disabilities was associated with activity limitations. A possible explanation was that people with reduced sensitivity might end up avoiding daily activities that may cause injury, and they might change the way they do these activities[17]. Boku et al.[18] also stated that severe visible impairment was one of the risk factors for a high SALSA score, which consequently caused severe activity limitations. In 2011, Melchior and Velema[7] reported a significant association between SALSA scores and functional hand tests, indicating that hand impairments caused activity limitations.

This study was conducted on a leprosy village with a large number of samples. Therefore, the results of this study can be applied to other leprosy villages in Indonesia and even in other countries that have similar characteristics. In addition, this study confirms that SALSA can be utilized to see activity limitations in patients with leprosy.

Study Limitations

This study had some potential limitations. Recall bias might occur because the patients have lived with leprosy for decades, so they might not be able to retrieve detailed information, such as the incidence of leprosy reactions, medication history, and types of reactions. Recruiting patients with leprosy who have recently been diagnosed, who are still undergoing treatment, and working-age patients could be valuable for future research. Moreover, the use of SALSA was recommended as a tool for routine evaluation of activity limitations in a leprosy village setting. This tool can contribute to the prevention of an increase in disability in patients with leprosy.

Conclusion

Severe disability is associated with functional activity limitations. The findings of this study can support healthcare providers in designing appropriate prevention and intervention services for patients with leprosy-related disabilities.

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Ethics

Ethics Committee Approval: The study was approved by the University Indonesia Faculty of Medicine, Ethics Committee (approval number: 0310/UN2.F1/ETIK/2018).

Informed Consent: It wasn't obtained.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Concept: A.P., S.L.M., Design: A.P., S.L.M., Data Collection or Processing: A.P., S.L.M., Analysis or Interpretation: A.P., S.L.M., M.M., Literature Search: A.P., S.L.M., M.M., Writing: A.P., S.L.M., M.M.

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