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Risk factors for disability in leprosy patients: a cross-sectional study

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ABSTRACT

Background: The disability in leprosy is caused by *M. leprae* invasion and infiltration into the skin and the mucous membrane that results in nerve damage and deformities, loss of sensation, paralysis, and ocular manifestation. The risk of disability can be influenced by several factors, including the type of leprosy, disease duration, the number of nerves affected, leprosy reactions, gender, age, type of treatment, socioeconomic factors, and leprosy case detection methods. This study aimed to evaluate the risk factor of disability in leprosy patients.

Methods: It was a cross-sectional retrospective analytical study to discover the correlation between risk factors with the grade of disability in leprosy patients who were treated in Dermatovenerology Outpatient Clinic Dr. Soetomo General Hospital Surabaya from 2017 to 2019.

Result: This study found a total of 275 leprosy patients with disabilities, consisting of 76 patients (27,6%) with grade-1 disability and 199 patients (72,4%) with grade 2 disability. There was a statistically significant correlation between age (p=0,025), duration of disease (p=0,001), and multidrug therapy (MDT) history (p=0,001) with the incidence of disability. Gender, bacterial index, type of leprosy, and leprosy reaction were not significantly related to disability.

Conclusion: This study showed that age, duration of disease, and the history of MDT treatment were related to the incidence of disability. The longer the disease's duration despite the patient having received MDT, the more risk of the patient having a disability.

Keywords: disability, infectious disease, leprosy, multidrug therapy, neglected disease.
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BACKGROUND

Leprosy often causes disability and deformity but rarely causes death.[1] The disability in leprosy is caused by the invasion and infiltration of the skin and mucosa by *M. leprae*, which results in nerve damage and deformity, sensory loss (anesthesia), and ocular manifestations.[2] There were 9,795 new cases of grade-2 disability (G2D) globally in 2019, and there were 1,121 cases in Indonesia.[3]

The risk of disability can be influenced by several factors, including the type of leprosy, duration of disease, number of affected nerves, the occurrence of leprosy reactions, gender, age, type of treatment, socioeconomic factors, education, ethnicity, occupation, and the method of leprosy case-finding.[4] The efficacy of the leprosy treatment control program can be well assessed by determining the level of disability before and after treatment.[5] The primary disorders result from the causative process, and the primary disease causes the secondary disorders.[2] The primary disorders of leprosy include the thickening and nodules of the skin and subcutaneous tissue, eye changes, loss of sensibility, and motor paralysis of the hands, feet, and eyes. The secondary disorders include ulceration, contractures, and vision loss.[6] The World Health Organization disability assessment system has three grades (G0D, G1D, and G2D) and has been used for many years as a reference to determine individual and community level physical rehabilitation activities. Grade-1 disability (G1D) is characterized by the impaired sensation of the feet or hands and visual disturbance but no severe impact. Grade-2 disability(G2D) includes the deformity of the feet and hands, while the eyes have severe visual disturbances.[7]

This retrospective study analyzed the risk factors of leprosy patients' disability at the Leprosy Division Dermato-Venereology Outpatient Clinic RSUD Dr. Soetomo in 2017-2019. Knowing about the risk factor for disability is essential in the disability prevention program for leprosy.

METHODS

It was a cross-sectional retrospective analytical study to determine the correlation between risk factors and the grade of leprosy patients' disability treated in Leprosy Division Dermato-Venereology Outpatient Clinic RSUD Dr. Soetomo Surabaya for three years, from January 2017 to December 2019. The inclusion criteria were all patients recorded in the medical record with a diagnosis of leprosy

with a disability. The patient with no loss of sensitivity or visible deformity was excluded in this study.

The variables of disability grade (G1D and G2D), gender, age, disease duration, bacterial index, type of leprosy, leprosy reaction, and history of MDT were considered in this study. The assessment of the disability grade of leprosy was performed according to the classification of WHO. Grade 1 is indicated by a loss of sensitivity without visible deformity, and grade 2 is characterized by a visible deformity. Grade 0 with no loss of sensitivity or visible deformity. The diagnosis of leprosy was determined based on WHO criteria. Patient with leprosy showing one or more of the following features, such as hypopigmented or erythematous skin lesions with loss of sensation, involvement of the peripheral nerves by definite thickening of the nerve, and skin smear positive for acid-fast bacilli. Patients were classified into MB type when presented with more than five lesions with or without positive bacterial index, and PB type presented with less than five lesions with negative bacterial index.

Data obtained from secondary data in medical record files and electronic medical records and entered into a data collection sheet to be analyzed using the Statistical Package for Social Science (SPSS) version 21. The correlation between variables and incidence of disability was analyzed by using Spearman's rho correlation test. Variables suspected as risk factors of the disability were analyzed using logistic regression.

RESULT

There were 1,132 leprosy patients, including 345 patients with disabilities. Two hundred seventy-five leprosy patients with disabilities met the study inclusion criteria, and 70 patients were excluded because the required data were not found. A hundred and fifty-two patients (55.3%) were new patients, and 123 patients were previously-treated (44.7%). The number of G1D cases was 76 patients (27.6%), and G2D was more dominant, with as many as 199 patients (72.4%) (Table 1).

The disability in the feet of as many as 148 patients (53.8%), hands of 120 patients (43.6%) and eyes of 7 patients (2.5%). In patients with G1D, the feet were dominant in 42 patients (15.3%), and G2D was also in the feet of as many as 106 patients (38.5%). Clinical examination found the highest number of patients with ulcers was 95 patients (34.5%), followed by claw hand was 57 patients (20.7%), and anesthesia was 40 patients (14.6%).

Male patients were more than female, with as many as 202 (73.4%) versus 73 (26.6%) patients, respectively. The majority were in the 25-44 years group (42.18%), with G1D and G2D being 31 (40.79%) and 85 (42.71%) patients, respectively. One-hundred and forty-four patients (52.36%) had the disease for more than 12 months. Most G1D patients had the disease for less than 6 months, as many as 43 patients (56.58%). On the other hand, G2D patients were more than 12 months, as many as 125 patients (62.81%). In this study, 147 patients (53.45%) had a negative bacterial index, 37 patients (48.68%) with G1D, and 110 patients (55.28%) with G2D. Two-hundred and fifty-three patients (92%) had multibacillary (MB) leprosy type, which was 70 patients (92.11%) and 183 patients (91.96%) of G1D and G2D, respectively.Male patients were more than female, as many as 202 (73.4%) versus 73 (26.6%) patients, respectively. The majority were in the 25-44 years group (42.18%) with G1D and G2D were 31 (40.79%) and 85 (42.71%) patients, respectively. One-hundred and forty-four patients (52.36%) had the disease for more than 12 months. Most G1D patients had the disease for less than 6 months, as many as 43 patients (56.58%). On the other hand, G2D patients were more than 12 months, as many as 125 patients (62.81%). In this study, 147 patients (53.45%) had a negative bacterial index, 37 patients (48.68%) with G1D, and 110 patients (55.28%) with G2D. Two-hundred and fifty-three patients (92%) had multibacillary (MB) leprosy type, which was 70 patients (92.11%) and 183 patients (91.96%) of G1D and G2D, respectively.

The majority of the patients did not have a leprosy reaction, as many as 187 patients (68%), whereas 57 patients (75%) and 130 patients (65.33%) with G1D and G2D, respectively. One hundred and twenty-five patients (45.5%) had received MDT therapy. The majority were 106 patients (53.27%) with G2D, while G1D was only 19 patients (25%). Patients who had not received MDT were 101 patients (36.72%), 48 patients (63.16%) with G1D, and 53 patients (26.63%) with G2D.

This study analyzed the correlation between variables such as gender, age, duration of disease, bacterial index, type of leprosy, leprosy reaction, and MDT treatment history. The bivariate analysis showed that age, duration of disease, and MDT treatment history had a p-value <0.05, so it had a statistically significant positive correlation with the incidence of disability in leprosy patients. Table 2 presents the multivariable logistic regression analysis results to identify risk factors for disability among leprosy patients. This study showed a high probability of disability in leprosy patients with risk factors aged less than 15 years and more than 24 years old with a disease duration of more than 12 months and being on therapy or after receiving MDT treatment, which was 90.9%.

DISCUSSION

This study showed that the deformity of patients with G1D and G2D were dominant on the feet, as many as 42 patients (15.3%) and 106 patients (38.5%), respectively. The most common deformity was an ulcer, found in 95 patients (34.5%). Bungin's 2019 study in Samarinda showed that the most frequent complaint was the presence of hands and feet ulcers. The most common complaint of G1D is loss of sensation (anesthesia) in the hands or feet.[8] Tropical ulcers were the most frequent deformity found in the study by Mangala in 2015-2018, as many as 37,6%.[4] Similar to our study, the most common deformity was an ulcer, found in 95 patients (34.5%).

Disability in leprosy patients was more in male patients (73.4%). Gender was not significantly related to disability in this study (p>0.05). A 2015 retrospective study in India showed that disability in male patients with G1D and G2D was more dominant than in females (62.73% vs. 37.27%, p=0.031).[7] A study by Monteiro in 2001-2012 concluded that male was a risk factor for G2D disability with a total of 490 patients (p=<0.001). The high incidence of disability in males is related to the high prevalence of leprosy and the vulnerability

to work-related trauma.[9,10]

This study's correlation between age and disability was significant (p=0.025). Age less than 15 years and over 24 years old were more at risk of disability. There is a high burden in the productive age group associated with G2D.[11] A study by Sarkar et al. stated that age was not significantly related to disability, but in contrast to the study by Naik in 2015, which showed that there was a correlation between disability and age, the majority of disabilities occurred at the age of 19 to 60 years (60.69%), and only 0.58% were under 14 years.[6] A retrospective study by Mani in 2017-2018 showed that age was also not significantly a risk factor.[12] Age is directly related to the disease duration, so elderly patients can increase the potential of disability due to the chronic nature of leprosy.[2] A retrospective study by Mani in

Table 1. Association of variables and grade of disability in leprosy patients.

Variables	Grade 1 Disability *n*(%)	Grade 2 Disability *n*(%)	Total *n*(%)	*p*-Value	r
Gender				0.95	0.003
Male	56(73.68)	146(73.37)	202(73.45)		
Female	20(26.32)	53(26.63)	73(26.55)		
Age (years old)				0.025*	0.135
<15	1 (1.32)	4(2,01)	5 (1.82)		
15-24	21 (27.63)	28 (14.07)	49 (17.82)		
25-44	31 (40.79)	85 (42.71)	116 (42.18)		
45-60	17 (22.37)	60 (30.15)	77 (28)		
>60	6 (7.89)	22 (11.05)	28 (10.18)		
Duration of disease (months)				0.001*	0.355
<6	43(56.58)	46(23.12)	89(32.36)		
7-12	14(18.42)	28(14.07)	42(15.27)		
>12	19(25)	125(62.81)	144(52.36)		
Bacterial Index				0.535	0.038
Negative	37(48.68)	110(55.28)	147(53.45)		
1+	9(11.84)	12(6.03)	21(7.64)		
2+	13(17.10)	36(18.09)	49(17.82)		
3+	14(18.42)	29(14.57)	43(15.63)		
4+	2(2.63)	11(5.53)	13(4.73)		
>4+	1(1.32)	1(0.5)	2(0.73)		
Leprosy type				0.639	0.028
PB	5(6.58)	11(5.53)	16(5.82)		
MB	70(92.11)	183(91.96)	253(92)		
Other	1(1.3)	5(2.51)	6(2.18)		
Leprosy Reaction				0.108	0.097
Type 1	6(7.89)	17(8.54)	23(8.36)		
Type 2	13(17.11)	52(26.13)	65(23.64)		
No reaction	57(75)	130(65.33)	187(68)		
MDT Treatment History				0.001*	0.317
Pre-MDT	48(63.16)	53(26.63)	101(36.72)		
On treatment	9(11.84)	40(20.1)	49(17.82)		
Post-MDT	19(25)	106(53.27)	125(45.45)		

***Spearman test results are significant if p<0.05**

Table 2. Multivariate analysis of risk factors for leprosy disability.

Variable	*p*-Value	OR	(95% CI)
Age (years old)			
<15	0.717	1.599	0.126-20.302
15-24	0.027	3.826	1.168-12.535
25-44	0.178	2.137	0.708-6.445
45-60	0.979	0.984	0.313-3.098
>60			
Duration of disease (months)			
<6	0.001	5.255	2.474-11.162
7-12	0.025	2.865	1.141-7.197
>12			
MDT Treatment History			
Pre-MDT	0.008	2.792	1.307-5.961
On treatment	0.459	0.688	0.256-1.852
Post-MDT			

OR: odds ratio; **CI**: confidence interval; **MDT**: multidrug therapy

2017-2018 showed that age was also not significantly a risk factor.[12] Age is directly related to the disease duration so that that elderly patient can increase the potential of disability due to the chronic nature of leprosy.[2]

There was a significant correlation between the duration of the disease and disability in leprosy patients. Duration of more than 12 months increased the risk of disability in this study. The study by Shumet in Ethiopia showed the duration of symptoms of the disease is 6-12 months (p=0,017), and above 24 months (p=0,005) with sensory loss, nerve damage, and reversal reactions can progress to disability.[13] The shorter the duration of active disease, the minor deformity develops later due to better medication control and less involvement of nerves and other body tissues.[1] The most crucial factor in preventing disability in leprosy patients is early diagnosis and adequate treatment of neurological disorders. For the prevention of secondary disability of leprosy, G1D assessment is the foremost to be worked on.[2]

In this study, although most of the patients were MB-type leprosy, the bacterial index examination was mostly negative because most of the patients had finished the treatment (RFT). Based on a study by Sales, the initial bacterial index was not associated with future problems after therapy. This study is related to the study of Sharma et al., the type of leprosy and the bacterial index did not affect the incidence, development, or regression of neurological disorders.[14] A study by Jha et al. showed that 36.12% of patients had a difference between the bacterial index and the clinical type of leprosy.[15] The type of leprosy with multibacillary (MB) has the most type (92%). Patients with G1D and G2D with Multibacillary (MB) type leprosy were 70 (92,11%) and 183 (91,96%) patients, respectively. The correlation between the type of leprosy and disability in this study was not significant (p>0.05). A study by Sarkar et al. in 2012 showed that disability in MB patients was more significant than in PB patients (31.6% vs. 10%, p= 0.001).[16] Borderline and lepromatous leprosy have a high risk compared to indeterminate and tuberculoid types, which have a very low risk of deformity. The deformity is common in lepromatous patients due to extensive nerve involvement.[2,6]

Disability grade-1 and 2 in leprosy patients were more commonly found in patients without leprosy reactions (68%), type 2 reactions in 65 patients (23.6%), and type 1 reactions in 23 patients (8.4%). Leprosy reactions in this study were not associated with disability (p>0.05). Similar to our study, Domple reported that patients with G1D and G2D were 61.9% (p=0,64) more likely to have no reaction.[17] The study by Santos stated that the majority of cases of disability (2,043; 86.7%) did not have leprosy reaction.[18] Another study noted higher disability in patients with type 2 versus type 1 reactions of 61.9% and 36.4% (p=0.069), respectively.[19] The study by Sales showed a lack of association between type 1 and 2 reactions to worsening disability among patients on treatment at a referral center. Leprosy reactions cause nerve damage and, if not treated early, can lead to disability.[14,20] Leprosy reactions in borderline leprosy patients produce acute nerve damage, which can sometimes be fully recovered with appropriate treatment.[1]

This study showed that the history of MDT was significantly related to disability. Patients on treatment and post-MDT can increase the potential for disability. Nerve damage leading to disability and deformity can occur before, during treatment, and post-release from treatment.[14,21,22] In a 2012 study by Kumar, the incidence of high disability after completion of MDT treatment increased (OR 3.05; 95% CI 1.10 – 8.48) standardized by age and delay in treatment.[23] Sales reported that 40% of patients experienced worsening disability after completing treatment at the end of the observation period. Patients worsened one year after treatment by 9% and after five years by 30%.[14] Lack of active follow-up after completion of treatment is common and exacerbates existing disability.[11]

In a study in Indonesia, G2D that occurs up to 5 years after RFT has increased from 31% to 49%. In the study by Haefner in a hyperendemic area of Brazil, the majority of disabilities (783/858; 91.3%) occurred in patients who had completed treatment.[24] The occurrence of disability in leprosy indicates a lack of leprosy control management. Follow-up on patients after RFT should be systematically integrated into health services to ensure management of disease and patient morbidity; increase awareness about the disease, and seek help immediately if sequelae related to leprosy

appear later.[6,24]

This study had limitations because it used retrospective data contained in the medical record and involved only one tertiary level hospital. Most of the patients were referred with a diagnosis of MB type of leprosy. Many medical records were incomplete in identifying risk factors such as bacterial index, type of leprosy, duration of treatment, and history of MDT treatment, so not all leprosy patients with G1D and G2D were included in this study.

CONCLUSION

In this study, we conclude that there was a correlation between risk factors of age, duration of disease, and history of MDT treatment with the incidence of disability in leprosy patients. The disability was not significantly related to gender, bacterial index, type of leprosy, and leprosy reaction. Early detection, management, and education are urgently needed to prevent the disability. Self-care and recognition of early symptoms of disability can be followed up immediately to reduce the occurrence of disability that affects the patient's quality of life.

CONFLICT OF INTEREST

No conflict of interests was declared.

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This study did not receive a specific grant from any institution.

ETHICS APPROVAL

This study has received ethical approval from the Hospital Ethics Committee RSUD Dr. Soetomo Surabaya (0440/LOE/301.4.2/IV/2021).

AUTHOR CONTRIBUTION

All authors contributed to the study, including conceptual framework, design, data collection, and data analysis to report study results for publication.

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