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Analyzing factors of leprosy patients' adherence to treatment in Sukasari Sub-district, Subang

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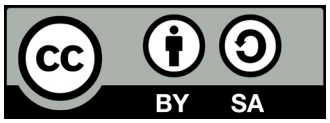

ABSTRACT

Background: Indonesia is currently contributing to the third highest incidence of leprosy in the world. Leprosy sufferers who do not undergo regular treatment have risk in transmitting the disease to others. Moreover, it may also cause disability problems and social impacts.
Objective: This study aims to analyse relationships between drug side effects, subject characteristics and adherence to treatment of leprosy patients.
Method: This was an observational analytic study with a cross-sectional research design with a sample of 115 leprosy patients. This study was conducted at four Puskesmas (Community Health Centre) of Sukasari sub-district, Subang from October to December 2021. Its data was collected by using a questionnaire consisting of patient characteristics; the MMAS-8 questionnaire was used to assess levels of the adherence and the side effects. Then the data were analysed by Chi-Square and Fisher's Exact test, with a significance level of 0.05.
Results: The results of this study revealed that 60 (52.2%) of the subjects were categorized in the medication adherence with a score of 0 and 22 (19.1%) of them were relatively high adherence with a score of 1-2. Most of the 93.9% of subjects experienced drug side effects while undergoing the leprosy treatment. There was no significant relationship between drug side effects (p=0.442), genders (p=0.848), ages (p=0.275), education levels (p=0.134), types of occupations (p=0.847) and adherence to treatment of leprosy patients.
Conclusion: Several factors such as drug side effects, ages, genders, education levels and occupations were not significantly related to medication adherence in the leprosy patients.

Latar Belakang: *Indonesia saat ini merupakan negara penyumbang kasus kusta tertinggi ketiga di dunia. Penderita kusta yang tidak menjalani pengobatan secara teratur beresiko menularkan kepada orang lain, selain itu juga menimbulkan masalah kecacatan dan dampak sosial.*
Tujuan: *Tujuan penelitian ini adalah untuk menganalisis hubungan antara efek samping obat dan karakteristik subjek dengan kepatuhan berobat penderita kusta.*
Metode: *Penelitian ini merupakan penelitian analitik observasional dengan desain penelitian cross sectional dengan sampel 115 pasien kusta. Penelitian ini dilakukan di empat Puskesmas Kecamatan Sukasari, Subang pada bulan Oktober-Desember 2021. Pengumpulan data menggunakan kuesioner yang terdiri dari karakteristik pasien, kuesioner MMAS-8 digunakan untuk menilai tingkat kepatuhan minum obat dan efek samping. Data dianalisis dengan uji* Chi-Square *dan* Fisher's Exact*, dengan tingkat signifikansi 0,05.*
Hasil: *Hasil penelitian ini menunjukkan sebanyak 60 subjek penelitian (52,2%) termasuk dalam kategori patuh minum obat dengan skor kepatuhan 0, diikuti sebanyak 22 (19,1%) mempunyai tingkat kepatuhan cukup tinggi dengan skor kepatuhan 1-2. Sebagian besar 93.9 % subjek mengalami efek samping obat selama menjalani pengobatan. Didapatkan tidak ada hubungan yang signifikan antara efek samping obat (p=0,442), jenis kelamin (p=0,848), usia (p=0,275), tingkat pendidikan (p=0,134), maupun jenis pekerjaan (p=0,847) dengan kepatuhan*

berobat pasien kusta.
Kesimpulan: *Beberapa faktor seperti efek samping obat, umur, jenis kelamin, tingkat pendidikan, dan pekerjaan tidak berhubungan bermakna dengan kepatuhan minum obat penderita kusta.*

INTRODUCTION

Indonesia currently faces a double burden due to the emergence of non-communicable diseases and infectious diseases that cannot be controlled, including leprosy. Leprosy is a chronic infectious disease caused by *Mycobacterium leprae* bacteria which mainly attack the skin, mucous membranes, and peripheral nerves. Leprosy needs to be managed properly to avoid damage to the skin, nerves, limbs, and eyes. Leprosy may cause various health problems and remain a problem in some countries. Data from World Health Organization (WHO) suggests that the incidence of leprosy is expected to continuously increase.[1] Countries in the Southeast Asia Region have been recorded to experience the highest cases of leprosy, and currently Indonesia is a country that contributes to the 3rd highest incidence of leprosy in the world after Brazil and India.[2] Based on data from the Ministry of Health, West Java Province is on the 2nd highest case in Indonesia, with a number of 1.832 people after East Java Province (3.373 people). In West Java, Subang Regency is on the 3rd highest leprosy cases after Karawang Regency and Indramayu Regency.[2,3]

Epidemiological data reported that the productive age group is the most affected by the leprosy. A study by Raposo et al. indicated that leprosy cases were found in the productive age group with men being the highest leprosy survivors.[4] The same results were also obtained by other studies demonstrating that the highest leprosy was found in the productive age group. At productive age, it implies that those who are still in prime condition and productive activities have a greater risk of transmission of it. Types of occupations such as farmers and construction workers are risky occupations of getting afflicted by this disease.[5]

Regular and thorough treatment of leprosy sometimes causes various problems, and this is due to several factors such as medication adherence and side effects. Medication adherence is a behaviour which a patient undergoes all procedures or rules for using drugs given by a doctor. Before administering the drug, the doctor can identify histories of the patient or his/her family who is a key person in the patient's life. If the leprosy patients do not undergo medication regularly, the *Mycobacterium leprae* bacteria will be reactivated so that new symptoms will appear on the skin's nerves which can worsen their situation and cause disability and socio-economic impacts.[6,7] A study of Wiyarni concluded that 62.3% of leprosy patients did not comply with taking medication.[8] One of main factors of leprosy patients in not complying the medication was the drug side effects. A study by Afifah found that patients who experienced side effects of leprosy drugs had affected medication adherence and resulted in treatment dropout.[9] Likewise, a study by Rukua et al. in Sampang Regency noted that medication adherence of leprosy patients was influenced by the presence or absence of drug side effects. This study pointed out that 96.8% of the subjects experienced drug side effects.[10] However, this was not in line with a study by Suki et al. demonstrating that leprosy patients who experienced drug side effects did not affect the medication adherence.[11]

Based on the problems above, there are several factors such as ages, types of occupation, and genders affecting the medication adherence; there are still pros and cons related to side effects with the medication adherence in leprosy patients. The researchers are interested in researching factors related to medication adherence of leprosy patients, especially in Subang, West Java. In addition, there is still a lack of research conducted in the area which becomes the high prevalence of leprosy sufferers.

METHODS

Research design

This study was an analytical observational study with a cross-sectional design, conducted in Subang Regency, West Java, Indonesia in October-December 2021. The subjects of this study was collected by a consecutive non-random sampling that met the inclusion and exclusion criteria; they were leprosy patients who came for treatment at the leprosy polyclinic of four Puskesmas (the community health centre) in Sukasari sub-district, Subang, West Java

Research population and samples

The research samples in this study were calculated by the Lameshow formula with a prevalence of 37.7% of medication adherence and with an accuracy rate of 0.05. A number of 115 subjects were involved in this study. Its inclusion criteria were male and female leprosy patients aged 15-64 years currently undergoing treatment, communicating well, and willing to give informed consent. Its exclusion criteria were patients who had undergone treatment > 2 years and had a history of drug withdrawal.

Materials and research instruments

The data were collected by using an interview technique of the subjects conducted by the researchers accompanied by the health centre staffs. The data were collected by using a questionnaire to determine the sociodemographic characteristics (age, gender, education, type of occupation) of the subjects, as well as the side effects felt by them. The Morisky Medication Adherence Scale -8 (MMSA-8) in this study was modified as changes were made to the scoring system.[12] The MMSA-8 was used as a reference. The Indonesian version of the MMSA-8 questionnaire was used for data collection purposes in this study.[13] The medication adherence questionnaire consisted of 8 questions which were given a score for each question. A score of 0 was if the answer was no; a score of 1 was if the answer was yes. Based on the adherence scores, it was categorized as obedient if the score = 0, and it was categorized as non-adherence if the score was 1 or above. The non-adherence category was then divided into groups named relatively high, average, low, and very low with scores 1-2, 3-4, 5-6, and 7-8 respectively.

Data analysis

The data were presented descriptively in percentages. Chi-square and Fisher's test were performed to analyse the relationships between the subject characteristics, the drug side effects, and the medication adherence. The significance level used was 0.05. Statistical tests were carried out by using SPSS version 25. This research protocol was ethically approved by the Research Ethics Commission of the Faculty of Medicine Universitas Trisakti with No. 11/KER-FK/IX/2021.

RESULTS

The socio-demographic of the subjects is displayed in Table 1. Of 115 subjects, 108 subjects experienced side effects of drug combination during the leprosy treatment, so the prevalence of side effects was 93.9%. 107 (93%) subjects were included in the adult age group, and 71 subjects (61.7%) were male. Based on the level of education, 62 subjects (53.9%) had a low educational background. Then based on their occupations, 74 subjects (64.3%) were included in occupations with high risk for leprosy infection transmission. This study found that only 60 subjects (52.2%) were categorized in medication adherence, and 93 subjects received a combination of dapsone, rifampicin, and clofazimine. Red urine was the most common side effect obtained from this study, experienced by 96 subjects (83.5%), and darker skin colour was experienced by 83 subjects (72.2%). Furthermore, 41 subjects had undergo medication for 6-12 months.

Data of the medication adherence based on the score of the modified MMSA-8 questionnaire demonstrates that 60 subjects (52.2%) had a score of 0, meaning the subjects always took their medication. Also, 22 subjects (19.1%) had a score of 1-2 and only 8 subjects (7%) had a score of 7-8, meaning that these subjects had very low adherence. The higher the adherence score, the higher the subject's non-adherence of medication (Table I).

Fisher's test results pointed out that there was no significant relationship between drug side effects, ages, and medication adherence with p=0.442 and p=0.275. The results of the Chi-square test also indicated that there was no significant relationship between gender and medication adherence with p=0.848. Likewise, the results of the bivariate analysis showed that there was no significant relationship between education or occupation and medication adherence with p=0.134 and p=0.847 (Table 2).

DISCUSSION

Treatment for leprosy requires a long period of treatment and t combination of drugs is prescribed depending on the type of leprosy. Medication adherence is a key to successful treatment, and this is greatly influenced by various factors including drug side effects, ages, education and others. Non-adherence will cause various problems such as

Table 1. Subject characteristics (n=115)

Variable	n (%)
Age (year)	
Teenagers (13-<18)	8 (7)
Adult (≥18)	107 (93)
Gender	
Man	71 (61.7)
Woman	44 (38.30
Occupation	
at risk	74 (64.3)
No risk	41 (35.7)
Education	
Low	62 (53.9)
High	53 (46.1)
Medication adherence	
Yes	60 (52.2)
No	55 (47.8)
Drug side effects	
No	7 (6.1)
Yes	108 (93.9)
Types of side effects	
Red urine	96 (83.5)
Red stool	2 (1.7)
Skin rash	28 (24.3)
Skin colour dark	83 (72.2)
Medication adherence score	
Score 0	60 (52.2)
Score 1-2	22 (19.1)
Score 3-4	15 (13.0)
Score 5-6	10 (8.7)
Score 7-8	8 (7.0)
Type of drug consumed	
Dapsone + Rifampicin	22 (19.1)
Dapsone + Rifampicin + Clofazimine	93 (80.9)

treatment resistance or even physical disability complications in leprosy patients. Combination of several drugs (multidrug) in leprosy has been recommended by the World Health Organization since 1981; WHO data reported that the side effects of multi-drug therapy (MDT) were rare and mild; although, severe and fatal side effects can also occur, especially the administration of rifampicin and dapsone drugs. Serious side effects of dapsone can result in haemolytic anaemia, agranulocytosis, methemoglobinemia, hepatitis, and dapsone syndrome. Serious side effects of rifampicin are thrombocytopenia, hepatitis, flu-like syndrome, and acute kidney failure. Treatment with clofazimine generally causes mild side effects, such as skin discoloration, ichthyosis, and gastrointestinal discomfort.14-16 Haemolytic anaemia and hepatitis are the most common side effects; it is estimated that around 72% of side effects occur in the first two months of treatment.[15,16]

Leprosy is known to affect all age groups, from

Table 2. The relationship between side effects, ages, genders, education, occupations, and medication adherence

Variable	Medication adherence			p
	Yes n (%)	No n (%)	Total n (%)	
Drug side effects				
No	5 (71.4)	2 (28.6)	7 (100)	0.442[f]
Yes	55 (50.9)	53 (49.1)	108 (100)	
Age				
Teenager	6 (75)	2 (25)	8 (100)	0.275[f]
Adult	54 (50.5)	53 (49.5)	107 (100)	
Gender				
Man	38 (53.5)	33 (34)	71 (100)	0.848[c]
Woman	22 (50)	22 (50)	44 (100)	
Education				
Low	28 (45.2)	34 (54.8)	62 (100)	0.134[c]
High	32 (60.4)	21 (39.6)	53 (100)	
Occupation				
At risk	38 (51.4)	36 (48.6)	74 (100)	0.847[c]
No risk	22 (53.7)	19 (46.3)	41 (100)	

[f]=fisher [c]=chi-square

children to the elderly. Based on the data on the characteristics of the subjects of this study, most leprosy patients were in the adult age group and even in the productive age group. This might be because in the productive age group the risk of transmission was greater through their daily activities and interactions in their work environment. It is known that transmission occurs through airborne and prolonged skin contact, and it was revealed that leprosy was mostly found in the young and productive age group, although it may attack children and the elderly.[17-19] A study by Zuraida and Nurhidayah found that most leprosy patients were male, with an age range of 20-50 years.[20] Similarly, a study in Denpasar obtained data of leprosy patients who seek treatment at the hospital polyclinic, dominated by the age of 16-35 years.[21] Leprosy in the child age group is associated with an immature immune system. The incubation period for leprosy varies from 40 days to 40 years, although the average incubation period for this disease is 3-5 years. This causes the leprosy to be identified at the age of 15-60 years.[22] Based on genders, there were more men with leprosy than women. In line with previous studies, men had an increased risk to suffer from leprosy; this might be due to a lack of health concerns compared to women who are usually very concerned and proactive in maintaining their skin health.[17,19,23] In addition, men are more exposed to various outdoor activities, so there can be an increase in exposure and the risk of transmission.

In this study, most of the subjects were included to the low-education group. The level of education was closely related to the economic level. This implies that most of the subjects fall into the low economic group which may affect the understanding of the disease and the patient's concern about its treatment method. Lack of knowledge about leprosy and wrong public belief about leprosy which this disease is caused by a curse or witchcraft make leprosy difficult to cure.[24] In this study, it was found that the level of education was not related to adherence medication of leprosy patients in Subang. However, another study concluded that the level of education affected the adherence; most patients who dropped out of drugs had a low level of education. Understanding the disease and medication adherence is strongly influenced by the level of education. Various interventions, both through cognitive and behavioural approaches, need to be performed by health workers and patients' families so that the level of knowledge and awareness of patient

recovery is increased.

Based on the types of occupations in this study, most of the subjects worked as farmers, construction workers, and transportation workers, having higher risk of transmission for leprosy. Dirty work environments and soil-related work are proper breeding grounds for *Mycobacterium leprae*. This can be exacerbated by poor personal hygiene. A study by Marsanti et al. reported that poor personal hygiene practices increased the risk of leprosy transmission.[25] Bad personal hygiene factors such as unhealthy behaviour and a dirty home environment are considered conditions that allow the transmission and proliferation of leprosy germs in the house.

This study revealed that there was no relationship between occupations and medication adherence; this might be because they maintained personal hygiene and used protective equipment while working although most of them were included in the risk group for leprosy transmission. Unlike other studies, several previous researchers also concluded that some occupations such as farmers, construction workers, transportation workers have a higher risk of transmission compared to other occupations. A study conducted by Dianita stated that respondents with risky occupations had a risk of 3.13 times greater than those who have non-risk occupations.[26] In line with a study by Giantoro, it was mentioned that leprosy patients were found more in the working group compared to those who did not work; this was possible because of the exposure to the risk of transmission from the workplace/environment.[23] *Mycobacterium leprae* can live outside the human body, such as in soil or dirty environments, these germs can live for 46 days. Types of physical work that expend a lot of energy and cause physical fatigue, when followed by unhealthy living habits, can cause a decrease in body resistance and can accelerate the proliferation of leprosy germs. The work of farmers and laborers may increase the risk of being infected with leprosy by 2.28 times higher than other occupations such as employees, entrepreneurs, housewives, and students, as these jobs are categorized as low-risk jobs for being infected with leprosy.[17,19,27]

The results of the analysis of the data in this study identified that there was no significant relationship between medication adherence in the subjects and the side effects of drugs. A study by Suki et al. also revealed that there was no effect of drug side effects on medication adherence.[11] Most side effects of drug administration in leprosy patients can be tolerated and do not interfere with daily activities. Side effects of drug combination in the leprosy treatment that can be seen immediately, such as changes in urine or stool colour and changes in skin colour that can be informed by doctors and other health workers; so that, the patients do not panic and can stop their treatment. The active role of health workers in providing information of their drugs and their side effects can support the success of the treatment. Ease of access to health facilities, availability of drugs, and handling of patient complaints during treatment are the keys to successful treatment that need attention. In addition, the patient's motivation to recover, the fear of repeating treatment from the beginning if the patient drops, complications of leprosy that can cause disability and fear of being ostracized from family and society are important elements for medication adherence and successful treatment of the leprosy patients.[28,29]

In addition, the results of the data analysis showed that there was no significant relationship between age and medication adherence. This might be because most of the subjects were dominated by the adult age group and were included in the productive worker group. Another study also stated that age was not associated with medication adherence, but medication adherence was associated with duration of illness and level of knowledge.[30] Other researchers obtained results of patients in the age group less than 15 years whom their family actively involved in monitoring their medication so that they tend to comply with taking medication according to the rules.[31] Treatment of leprosy requires a long period, but the emergence of stop-taking and side effects due to drugs often causes not taking medication according to the rules, and sometimes patients will stop their treatment. Another study pointed out that there was a significant relationship between age and medication adherence.[11] This might be because adults and productive age had a higher motivation to recover. After all, this age group pays more attention to physical appearance and health compared to older people or younger ages. The physical environment of a house including

ventilation and lighting needs attention; a physical environment that is not in line with minimum health standards will increase the risk of transmitting this disease.[32]

In this study, it was concluded that there was no significant relationship between genders, occupations and medication adherence. These results are in line with other researchers, genders are not a determinant of adherence, although the incidence of leprosy is higher in men than women. This may be because men are more indifferent to health conditions, especially skin health, than women. In addition, certain types of outdoor work are dominated by men, thereby increasing the risk of being infected with leprosy due to exposure to the work environment.[7,33] Leprosy patients who are at work/productive age will be more motivated to be more obedient in taking medication for recovery; working is a source of income for the patient and the patient's family. Meanwhile, leprosy patients who do not work have more opportunities and time to maintain health, including medication adherence; this may be because of the absence of a significant relationship between leprosy patients who work or not.[11,23]

In addition to medication adherence, a factor that may affect disability in leprosy patients is the role of the family. The role of the family is very important, especially in their treatment. If a family member is sick, the family will also pay attention to the sick individual completely and provide the care needed to achieve an optimal level of health.[8,9,33] Furthermore, the active role of health workers in providing counselling, promoting health activities for leprosy, and taking action to improve patient adherence with treatment is important. The activity of recording all patient complaints during treatment because of drug side effects and other factors needs to be continued with analysis and treatment; therefore, the patient adherence will increase and can recover. From this study's implementation, it is necessary to consider other factors such as socio-cultural, health facilities, and health workers that may affect the adherence and treatment success.

CONCLUSION

It was concluded that several factors such as drug side effects, age, gender, education levels, and occupation were not significantly related to medication adherence in leprosy patients in Subang.

CONFLICT OF INTEREST

The researchers state that there is no conflict of interest in this study.

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