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# Diagnostic test using monofilament compared to electroneuromyography (ENMG) for detection of peripheral neuropathy in leprosy at Sanglah General Hospital, Bali-Indonesia

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## ABSTRACT

**Introduction:** Leprosy is a chronic granulomatous infection caused by *M. leprae* with high affinity to Schwann cell. Primary concern of leprosy is disability due to progressive nerve damage so that patients and their families are sometimes faced with social stigma and discrimination. This can be caused by late detection and treatment of nerve damage. Electroneuromyography (ENMG) as the gold standard for nerve damage detection has limitations in terms of cost and operational procedures, so there is a need for simpler and cheaper method such as monofilament test. This study aims to determine the validity of monofilament test compared to ENMG for the detection of peripheral neuropathy in leprosy.

**Method:** Study design using analytic method with cross-sectional approach, a total 40 patients including paucibacillary and multibacillary

type of leprosy who met inclusion and exclusion criteria were recruited by consecutive-sampling. All subjects undergo monofilament test at Dermato-Venereology Clinic of Sanglah General Hospital Denpasar and electroneuromyography test at Neurology Clinic of Sanglah General Hospital Denpasar from December 2018 to February 2019. The data was analyzed to determine sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV).

**Result:** The result of this study revealed that monofilament test had an overall sensitivity of 67.2% and specificity of 77.5%. High sensitivity and specificity were found in the sural nerve (85.7% and 75%) and radial nerve (82.7% and 80%)

**Conclusion:** monofilament test can be considered for early detection of peripheral neuropathy, especially for sural and radial nerve.

**Keywords:** leprosy, peripheral neuropathy, monofilament test.

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## INTRODUCTION

Leprosy is a chronic granulomatous bacterial infection that attacks the skin, peripheral nerves, and upper respiratory tract mucosa. This disease is rarely found in developed countries, but is still a major health problem in developing countries like Indonesia. The main problem that becomes a concern to people affected by leprosy is physical disability due to progressive nerve damage and tends to settle down so that patients and their families are sometimes faced with social stigma and discrimination by the surrounding community. Risk factors for the occurrence of various leprosy defects, including age factors, leprosy reaction, high bacterial index, multiple nerve enlargement, and late diagnosis and treatment.

Worldwide leprosy incidence in 2014 was 213,899 cases, around 81% of which came from the three main endemic countries such as India, Brazil, and Indonesia. Indonesia ranks third for finding new cases of leprosy worldwide after Brazil and India, which amounted to 17,025 cases. Indonesia is the highest contributor to new multibacillary

(MB) type of leprosy in Southeast Asia, which is 14,213 cases or 83.4%.<sup>1</sup> The highest number of new cases in Indonesia is in 4,132 cases.<sup>2</sup> Number of new cases of disability due to leprosy in Southeast Asia still quite high, which is around 8,572 cases in 2015. Indonesia itself in 2016 reported a rate of 2 leprosy defects of 5.27 per 1,000,000 residents, with the highest number in North Maluku province (13.49 per 1,000,000 residents). The disability rate due to leprosy in the province of Bali in 2016 was around 0.71 per 1,000,000 residents.<sup>4</sup>

*Mycobacterium leprae* (*M. leprae*) is obligate intracellular with low virulence and has high affinity, especially in Schwann cells.<sup>4</sup> Leprosy stigmatizes the community, so leprosy patients not only suffer from the disease, but are kept away or excluded by society due to visible disabilities. Most of the problems with leprosy defects occur due to *M. leprosy* which attacks peripheral nerves causing peripheral neuropathy.<sup>5</sup>

Peripheral neuropathy in leprosy involves sensory nerves, motor nerves, and autonomic

nerves. Clinical manifestations can occur if more than 30% damage to peripheral nerve fibers.<sup>6</sup> Diagnosis of nerve damage early is sometimes difficult to know through clinical examination. Additional examinations with electroneuromyography (ENMG) and monofilament can be used to detect nerve damage in leprosy.

ENMG examination is the gold standard for early detection of nerve damage. This examination can be used to identify mononeuropathy or polyneuropathy, determine axonal type neuropathy, demyelinating type, or axonal-demyelinating type, confirm early diagnosis of neuropathy and early detection involvement of damaged nerves so that the risk of leprosy defects can be minimized. The weakness of ENMG is that not all health service facilities have these tools because the price is high and requires trained personnel.<sup>7</sup>

Another modality to check nerve conduction function is to use a monofilament test. Monofilament tests are said to be more sensitive than using cotton and pins or pens in assessing nerve function disorders and monitoring the development of nerve function, so that they can play a role in early diagnosis of peripheral neuropathy. This examination is easier to do, does not require a long examination time, is cheaper, and does not require experts compared to ENMG examination. Marahatta et al. reported that monofilament sensitivity was quite low in detecting nerve damage due to leprosy, which was between 38.46 - 68.75%.<sup>8</sup> Other studies by Villarroel et al. reported that monofilament tests were quite sensitive (87.1%) to detect the amount of nerve damage in leprosy.<sup>9</sup>

Based on these problems, it takes a tool that is cheap, easy to do and does not require too long an examination as an alternative ENMG examination for the detection of peripheral neuropathy in leprosy, therefore the aim of this study is to provide a proper comparison regarding sensitivity, specificity, negative predictive value, and positive predictive value monofilament test for detection of peripheral neuropathy in leprosy in Sanglah General Hospital compared to ENMG as the gold standard.

## METHOD

Study design using analytical observational study with a cross-sectional approach with a diagnostic test procedure, which aimed to compare sensitivity, specificity, positive predictive value and negative predictive value of monofilament and electroneuromyography (ENMG) tests for the detection of peripheral neuropathy in leprosy. The study conducted at Dermatology and Venereology Outpatient Clinic of Sanglah General Hospital

Denpasar for two months, starting in December 2018 to February 2019. Monofilament examinations are carried out at the Morbus Hansen Subdivision at Dermatology and Venereology Outpatient Clinic of Sanglah General Hospital Denpasar, while ENMG examinations are conducted at the Neurology Outpatient Clinics, Subdivision of Neurophysiology of Sanglah General Hospital Denpasar.

The population in this study were leprosy patients and leprosy reactions without neuritis, aged 18-80 years, willing to be participating in this study after receiving a signed informed consent, and having a good general condition. Exclusion criteria in this study were patients with other systemic conditions such as chronic kidney failure, coronary heart disease, systemic lupus erythematosus (SLE), diabetes mellitus, chronic liver disease, thyroid disease, multiple sclerosis, malignancy and HIV infection. Have experienced neuropathy such as Guillain Barre Syndrome (GBS), carpal tunnel syndrome, and cervical root syndrome.

Monofilament examination is an examination performed for the detection of peripheral neuropathy through assessment of sensory nerve function, carried out using the Brazilian Semmes-Weinstein monofilament tool model Estesiometro Sorri-Bauru produced in 2016. This tool consists of 5 different colors, green (0.07 gm), blue (0.2 gm), purple (2 gm), dark red (4 gm), orange (10 gm), and pink (300 gm), depending on the score and the weight of the pressure produced by each monofilament yarn. Patients are said to have peripheral neuropathy if they cannot feel green monofilament threads on the location of their hands and instep and blue at the location of the soles of the feet. ENMG examination is an examination performed for the detection of peripheral neuropathy through assessment of nerve delivery speed and electrical muscle activity, carried out using the 2015 German Dantex 6 Ch Amp Keypoint Electroneography, the results of the examination were interpreted by a clinical expert neuro-physiology.

Statistical analysis in this study used SPSS statistical software program assistance (Version 25.0; SPSS Inc, Chicago, IL, USA). The diagnostic test procedure uses calculations of sensitivity, specificity, positive predictive value, negative predictive value, on monofilament examination compared with ENMG in detecting peripheral neuropathy in leprosy.

## RESULT

### Study Participant

The sex distribution in this study obtained more men than women, 24 people (60%) and 16 people

**Table 1 Study participant characteristics**

Characteristics	n=40
<b>Age (Mean ± SD) (years)</b>	40.58 ± 14.61
17-25	7 (17.5%)
26-35	11 (27.5%)
36-45	7 (17.5%)
46-55	8 (20%)
56-65	4 (10%)
>65	3 (7.5%)
<b>Gender (n,%)</b>	
Male	24 (60%)
Female	16 (40%)
<b>Leprosy type (n,%)</b>	
Multibacillary	30 (75%)
Paucibacillary	10 (25%)
<b>History of leprosy reaction (n,%)</b>	
ENL	13 (32.5%)
RR	1 (2.5%)
Never	26 (65%)
<b>Duration of disease (n,%)</b>	
<1 year	15 (37.5%)
>1 year	6 (15%)

**Table 2 Peripheral neuropathy based on ENMG examination**

Variable	n=40
<b>Nerve involvement (n,%)</b>	
Median nerve	36 (90%)
Ulnar nerve	38 (95%)
Radial nerve	40 (100%)
Common peroneus nerve	26 (65%)
Posterior tibial nerve	34 (85%)
Sural nerve	36 (90%)
<b>Number of nerve involvement (n,%)</b>	
2	1 (2.5%)
3	1 (2.5%)
4	6 (15%)
5	11 (27.5%)
6	21 (52.5%)
<b>Distributive pattern (n,%)</b>	
Right side only	2 (5%)
Left side only	0 (0%)
Right and left side	38 (95%)

(40%) respectively. The age characteristics of the research subjects showed that the youngest age was 19 years, and the oldest age was 80 years. The average age in the study subjects was 40.58 ± 14.61 years,

with the most age group being aged 26-35 years as many as 11 people (27.5%), and at least age above 65 years as many as 3 people (7.5%) (Table 1).

Based on the type of leprosy, it was found that the multibacillary type of leprosy was the most common type, 30 people (75%), and the remaining types were paucibacillary as many as 10 people (25%). In this study, several subjects had a history of leprosy reactions, erythema nodosum leprosum (ENL) of 13 people (32.5%) and history of reversal reactions (RR) of 1 person (2.5%), whereas without a history of leprosy reaction are 26 people (65%). The duration of leprosy is generally <1 year, which is in 15 patients (37.5%) (Table 1).

### Peripheral neuropathy pattern in ENMG and monofilament examination

Based on the results of ENMG, the total number of nerves examined were 6 nerves consisting of the median nerve, ulnar nerve, radial nerve, communal peroneus nerve, posterior tibial nerve and sural nerve. The most affected number of nerves is 6 nerves (total) of 21 people (52.5%), while the number of nerves is the least affected are 2 nerves and 3 nerves, each with 1 person (2.5%). The nerves that are mostly affected by peripheral neuropathy are as many as 40 radial nerves (100%), 38 ulnar nerves (95%), median and sural nerves, respectively 36 people (90%). But the communal peroneus nerve is the nerve that is least affected by peripheral neuropathy, which is as many as 26 people (65%). The pattern of distribution of peripheral neuropathy in the most subjects was right and left side as many as 38 people (95%), but only 2 people (5%) with right distribution (Table 2).

Meanwhile, based on the results of the monofilament test. The number of nerves most affected is 5 nerves as many as 17 people (42.5%), while the number of nerves is the least affected are 2 and 3 nerves, each of which is 2 people (5%) and 3 people (7.5%) respectively. The nerves that were mostly affected by peripheral neuropathy were radial nerves, 38 people (95%). The pattern of distribution of peripheral neuropathy in the most subjects was right and left side as many as 38 people (95%), but only 2 people (5%) with right distribution (Table 3).

### Comparison of diagnostic testing between monofilament and ENMG for detecting peripheral neuropathy in leprosy

The overall value diagnostic test of the monofilament test has a sensitivity of 67.2%, specificity of 77.5%, positive predictive value (PPV) of 89.9% and negative predictive value (NPV) of 44.1% (Table 4).

Akurasi diagnostik tes monofilamen untuk saraf medianus, ulnaris, radialis, peroneus, tibialis posterior dan suralis dapat dilihat pada tabel 5.6. Pada

**Table 3** Peripheral neuropathy based on monofilament examination

Variable	n=40
<b>Nerve involvement (n,%)</b>	
Median nerve	27 (67.5%)
Ulnar nerve	32 (80%)
Radial nerve	38 (95%)
Common peroneus nerve	26 (65%)
Posterior tibial nerve	26 (65%)
Sural nerve	37 (92.5%)
<b>Number of nerve involvement (n,%)</b>	
2	2 (5%)
3	3 (7.5%)
4	10 (25%)
5	17 (42.5%)
6	8 (20%)
<b>Distributive pattern (n,%)</b>	
Right side only	2 (5%)
Left side only	0 (0%)
Right and left side	38 (95%)

**Table 4** Overall diagnostic accuracy of monofilament compared to ENMG

		ENMG		Sensitivity	Specificity	NPV	PPV
		Positive	Negative				
Monofilament test	Positive	242	27	67.2%	77.5%	89.9%	44.1%
	Negative	118	93				

**Table 5** Specific accuracy for each nerve tested with monofilament compared to ENMG

Nerve	Sensitivity	Specificity	Positive Predictive Value (PPV)	Negative Predictive Value (NPV)
Median nerve	50.8%	88.2%	94.1%	32.6%
Ulnar nerve	69.2%	86.7%	95.7%	39.4%
Radial nerve	82.7%	80%	98.4%	23.5%
Common peroneus nerve	53.3%	71.4%	70.6%	54.3%
Posterior tibial nerve	55.4%	70.8%	81.6%	40.5%
Sural nerve	85.7%	75%	88.9%	69.2%

penelitian ini, sensitivitas paling tinggi didapatkan melalui tes monofilamen pada saraf suralis (85,7%), diikuti saraf radialis (82,7%), ulnaris (69,2%), tibialis posterior (55,4%), peroneus (53,3%), dan medianus (50,8%). Spesifisitas pemeriksaan paling tinggi yaitu pada saraf medianus (88,2%), diikuti saraf ulnaris (86,7%), radialis (80%), suralis (75%), peroneus (71,4%), dan tibialis posterior (70,8%). Nilai prediksi positif (NPP) dari paling tinggi ke paling rendah berturut-turut adalah saraf radialis

(98,4%), ulnaris (95,7%), medianus (94,1%), suralis (88,9%), tibialis posterior (81,6%) dan peroneus (70,6%). Nilai prediksi negatif (NPN) paling tinggi didapatkan melalui tes monofilamen pada saraf suralis (69,2%), diikuti saraf peroneus (54,3%), tibialis posterior (40,5%), ulnaris (39,4%), medianus (32,6%), dan radialis (23,5%) (Table 5).

The diagnostic accuracy of monofilament tests for the median, ulnar, radial, peroneus, posterior and sural nerve can be seen in table 5. In this study,

the highest sensitivity was obtained through monofilament test on sural nerve (85.7%), followed by radial nerve (82.7%), ulnar (69.2%), posterior tibialis (55.4%), peroneus (3.3%), and median nerve (50.8%). The highest specificity of examination was the median nerve (88.2%), followed by ulnar nerves (86.7%), radial (80%), sural (75%), peroneus (71.4%), and posterior tibialis (70.8%). Positive predictive value from highest to lowest respectively are radial nerve (98.4%), ulnar (95.7%), median (94.1%), sural (88.9%), tibialis posterior (81.6%) and peroneus nerve (70.6%). The highest negative predictive value was obtained through monofilament test on sural nerve (69.2%), followed by peroneus nerve (54.3%), posterior tibialis (40.5%), ulnar (39.4%), median (32.6%), and radial (23.5%) (Table 5).

## DISCUSSION

The validity of a test or measuring instrument can be assessed through sensitivity, specificity, positive predictive and negative predictive value. This study showed that the monofilament test had a sensitivity of 67.2%, specificity of 77.5%, PPV of 89.9% and NPV of 44.1% compared to ENMG. This is in accordance with a study by Dross et al. which reported that monofilament tests had sensitivity between 41 - 93% and specificity between 68-100%.<sup>10</sup> Other studies also showed that monofilament had a higher specificity than sensitivity, one of which was research by Marahatta et al. who compared nerve palpation examinations, voluntary muscle tests and monofilament tests in the detection of peripheral neuropathy in leprosy.<sup>8</sup> The study reported that monofilament tests had sensitivity between 38.46% - 68.75% and specificity between 93.54 - 100%, besides that it was said that monofilament tests were the most specific test compared to nerve palpation and voluntary muscle test. Villarroel et al. reported a sensitivity of monofilament tests of 81.7% and a specificity of 96.1% in the detection of peripheral neuropathy in 82 patients diagnosed with leprosy and 26 patients with other diseases.<sup>9</sup>

The sensitivity variation of the monofilament test is influenced by various factors, among others, there is still no definite standard in the use of monofilament, which includes the number of areas examined, the exact location of the examination, and other tests used as a comparison. Other factors reported to influence are filament age and environmental factors such as the effects of humidity or humidity and temperature on monofilament threads.<sup>9,10</sup>

The results showed that the sensitivity of the monofilament test in detecting the highest peripheral neuropathy was found in the sural nerve and radial nerves, which were 85.7% and 82.7% respectively. Marahatta et al. also reported a greater sensitivity

of monofilament tests on sural nerve (68.75%) and radial (41.66%).<sup>8</sup> High sensitivity value for the sural nerve can be caused because these nerves have a lower sensitivity threshold compared to other nerves. Donaghue et al. reported a lower current sural nerve threshold perception than posterior tibial nerve ( $p < 0.0001$ ).<sup>11</sup> Also, through ENMG examination it was found that the sural and radial nerves were indeed the most common abnormalities in the study subjects. This is findings were supported by a study by Khambati et al. which reported that the most detected peripheral neuropathy in sural and radial nerves experience interference through monofilament tests in 28% and 18% of subjects. Nerve conduction examination also showed that the sural and radial nerves had the most disorders, 72% and 47% subjects.<sup>11</sup>

Sensitivity examination of monofilament tests of low detection median nerve can be influenced by several factors such as work and daily activities. Jobs such as farmers, construction workers, or jobs or activities that often use the thumb, index finger and middle finger such as typing or holding ball-points or pencils continuously can cause callus or thickening of the skin thus increasing the sensory threshold in the area.<sup>5</sup>

Examination of the sural nerve which innervates the lateral part of the lower limb is often overlooked because the nerve disorder sometimes only causes mild functional impairment in patients. Wexler et al. recommend that sural nerve examination be included as a routine examination because lesions and sensory disorders often occur in this area.<sup>13</sup> This is supported by Khambati et al. who reported that sensory disturbances in the sural nerve occur in about 28% of new cases multibacillary type leprosy. *M. leprae* is easier to invade non-myelinated and thinner myelinated nerve fibers, such as C nerve fibers and A $\delta$  nerve fibers.<sup>14</sup> The sural nerve is a sensory nerve that is included in type C nerve fibers which are not small in size (0.3-1.5 in diameter nm) for temperature, pain, and pressure perceptions.<sup>15,16</sup>

The combination of monofilament tests with other examinations such as voluntary muscle test and nerve palpation is reported to increase the sensitivity of the examination. Khambati et al. reported a sensitivity of monofilament tests of 38% in the detection of peripheral leprosy neuropathy, but when combined with voluntary muscle test and nerve palpation, sensitivity increased to 40% and 72% respectively.<sup>12</sup>

The limitation of this study is the relatively small size sample that causes the results of this study to have low strength generalizability towards population.

## CONCLUSION

The sensitivity of the monofilament test was highest in the sural nerve (85.7%) and radial nerve

(82.7%). The sensitivity of the monofilament test was low in the ulnar nerve (69.2%), posterior tibial (55.4%), peroneus (53.3%) and median (50.8%). Monofilament tests can be used to detect peripheral neuropathy, especially in the sural and radial nerves, less sensitive to other nerves. Monofilament examination will be a very good modality used in detecting peripheral neuropathy in leprosy when ENMG examination cannot be performed.

### CONFLICT OF INTEREST

The author declares there is no conflict of interest regarding all aspect of this study.

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### ETHICAL ASPECT

Current study has been approved by Ethical Committee Faculty of Medicine Universitas Udayana/Sanglah General Hospital with ethical clearance reference number 2359/UN14.2.2.VII.14/LP/2018.

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