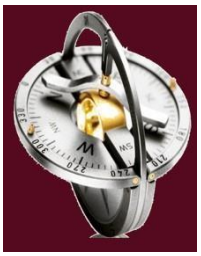
International Journal of Medicine
ISSN (P): 1468-3814; ISSN (e): 2667-7008

https://theinternationalmedicine.com/



Volume: 7(12) 2025

Original Research

Clinical usefulness of minimum sites for sensory testing by monofilament and comparing with nerve conduction test in leprosy neuropathy in eastern Nepal

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Received: 11 Nov 2025 / Accepted: 04 Dec 2025

Abstract

Background: Early detection of nerve function impairment enhances the chances of nerve function recovery following adequate treatment and is a key intervention for prevention of disabilities ***Objectives:*** To assess the sensory impairment on 40 sites in leprosy pts with neuropathy by SW monofilament for sensory testing in six nerves in four limbs and compare impact of each and combinations of sites for impairment by monofilament testing with Nerve conduction study (NCS) as gold standard ***Methods:*** Cross-sectional study was conducted in 61 leprosy pts visiting Dermatology OPD of BPKIHS. Using standard monofilament (MF), sensory testing on 40 sites on six nerves each in 4 limbs was done. Impairment on each site and combinations of site was assessed and compared with NCS (gold standard). For descriptive data, mean, median mode, SD, proportion, percentage, Sensitivity (Sn), Specificity (Sp), PPV and NPV was ca lculated. ***Results:*** Sn and Sp of SW MF for tibial was 96% & 42.9%, Deep peroneal (DPN) 94.4% & 86%, sural 90.6% & 100, Radial cutaneous (RC) 83.3% & 84% and Ulnar 75% & 70.6% and Median 40% & 67.7% respectively. Hypothenar eminence + dorsal of little finger for ulnar, dorsum middle finger + distal thumb for median, dorsum 1st metacarpal head for RC, bulb 5th metatarsal head + planter 1st toe for tibial, Dorsolateral base of 5th metatarsal for sural, 1st web space dorsum foot for DPN had Sn and Sp of 90.6 & 93.1%, 87% & 92.1%, 93.1% & 89.3%, 92.3% &88.6%, 97.8% &100% and 100 %& 93.3 % respectively. ***Conclusion:*** Sensitivity and Specificity of single site and combination of site was good and thus recommending these minimum points for touch pressure sensory impairment in leprosy pts.

Keywords: *Semmes-Weinstein (SW) monofilament, Nerve function impairment.*

Introduction

Every year, thousands of patients develop nerve damage as a result of leprosy (1). The globally reported number of new cases in 2015 was 2, 11,973, 2.9 new cases per 100,000 people. South-East Asian Region (SEAR) accounted for 74% of the global new case load; number of new cases with grade-2 disability (G2D) was 8572. The Global Leprosy Strategy 2016-2020: “Accelerating towards a leprosy-free world 2" was released in April 2016, where 3 key targets have been agreed by all National programs: a) G2D among children diagnosed with leprosy reducing to zero; b) the reduction of new leprosy cases with G2D to <1 case per million populations; and c) no countries with legislation allowing discrimination on the basis of leprosy. (2)

Nerve function impairment (NFI) can lead to permanent disability for the sufferer and increased risk of stigma (3). Early detection of NFI enhances the chances of nerve function recovery following adequate treatment and is a key intervention for prevention of disabilities (4). Nerve function assessment (NFA) is recommended for all newly diagnosed patients of leprosy (5) and also as a part of the follow -up, especially during reactional episodes (6). The main issue of importance lies in the sensitivity, reliability, and reproducibility of any standard assessment method. In 1970, Nylon monofilament (MF) was advocated where use of standardized, graded, nylon monofilaments was accepted as a liable, quick, safe and reproducible method to evaluate touch pressure sensory impairment (TPSI) at the skin sites innervated by the respective peripheral nerves (7). Assessments using MF testing using three standard test sites for each nerve show impaired sensory nerve function impairment in 41%. The proportion of nerve showing impairment ranged between 18% and 28% where sural nerve showed maximum impairment (28%) followed by ulnar (23%), median (17%) and radial cutaneous (23%). Overall, 23% of sensory nerves showed impairment by MF testing using 3 test sites for each nerve (8).

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DOI: 10.61336/im/25-12-10

Nerve conduction test is used as the gold standard for assessing the peripheral neuropathy that is expensive and difficult to operate in a primary care clinic, whereas MF test is a simple, portable and inexpensive feasible tool for identifying loss of protective sensation at every level of clinical setting. Personnel can be trained quickly in its use and results are quantifiable for comparison at various stages of the disease and over time (9). The number of testing sites varied in different study ranging from one to twenty, and the criteria for determining protective sensation, specificity or sensitivity are different in different studies (14, 15,16). Marahatta et al (2016) tested 8 sites (ulnar 3, median 3, radial cutaneous 1 and sural 1) 10, Koelewijn et al (2003) tested 20 sites (ulnar 4, median 6 and posterior tibial 10). Pawar et al (2016) compared 30 sites with 38 sites and concluded that the addition of two extra test sites on the ulnar nerve resulted in the detection of TPSI in an additional 29%. Similarly, for the median and posterior tibial nerves, the addition of one test site each detected TPSI in an additional 15% and 16% nerves respectively. The study showed that the addition of five test sites divided over three nerves, the ulnar, median and posterior tibial nerves, improved the detection of TPSI by 20% (17). Dorsal Sensory Impairment (SI) was detected in 43% of tested sites on the hands and 64% on the feet, whereas SI was detected only in 27% of the palmar and 53% of the plantar aspects. The difference between the frequency of SI on the palmar/plantar aspect and the dorsum was greater on the hands than on the feet. In the limbs, where no palmar/plantar SI was present, dorsal SI was detected in up to18% of hands and 6% of feet (18).

Therefore, this study was planned to assess the sensory testing by using Semmes-Weinstein MF on the 20 sites in six nerves each in upper and lower extremities and then evaluated the impact of each site and combinations of sites for testing. The result was compared with the nerve conduction test as a gold standard.

OBJECTIVES

Primary Objective:

1. To assess the sensory impairment (SI) in leprosy patients with neuropathy by using Semmes-Weinstein monofilament (MF) for sensory testing on the 20 sites in six nerves each site in upper and lower extremities

Secondary Objective:

1. To evaluate the impact of each site and combinations of sites for MF testing for detection of sensory impairment (SI)
2. To compare the impact of each site and combinations of sites of for sensory impairment by MF testing with nerve conduction test as the gold standard

RESEARCH HYPOTHESIS

Sensory testing on the dorsal aspect of extremities may improve assessment of sensory impairment in Leprosy neuropathy

Materials and Methods

Study Design: Cross sectional study in all patients of leprosy with neuropathy visiting the leprosy clinic of Dermatology and venerology at B.P. Koirala institute of Health science, Dharan were included in the study

Duration Of Study: 1 year (September, 2017 - August, 2018).

Setting: Dermatology OPD and/or leprosy clinic, department of dermatology and venerology, BPKIHS, Dharan, Nepal
INCLUSION CRITERIA: Leprosy patients in the age group of 15-75 years either newly detected or previously treated, having at least one nerve with nerve function impairment were recruited.

Exclusion Criteria: Patients not giving consent for enrollment or Amputation of the limb or resorption of limb involving the test sites.

Ethical Clearance: The study was initiated only after approval by the Institutional Ethical Review Committee and PG Protocol committee of BPKIHS, Dharan. The study was performed in accordance with the principles established in the Declaration of Helsinki.

Conflict Of Interest: None.

Sampling Technique: Purposive sampling method i.e. involving the patients who gave voluntarily consent to participate in the study. Informed written and understood consent was obtained from all the study participant.

Estimated Sample Size: Based on the sensitivity of 74% of all sites of SI testing by MF (Pedro et al, Lepr Rev 2016) 28, and those of nerve conduction study (NCS) of 93.5% (NCS 99%, Van Brakel et al, PLoS Negl Trop Dis 2008 29), and 88% Khambati et al, Lepr Rev 2009 8), an average sensitivity of NCS of 93.5% was taken with power 80%, alpha error 5% and 2 sided

Formula

$$n = \frac{\left(z_{1-\frac{\alpha}{2}} \sqrt{2\pi_0(1-\pi_0)} + z_{1-\beta} \sqrt{\pi_1(1-\pi_1) + \pi_2(1-\pi_2)} \right)^2}{(\pi_2 - \pi_1)^2}$$

$$\pi_0 = \frac{(\pi_1 + \pi_2)}{2}$$

Where,

π_1 : Sensitivity of the new test
π_2 : Sensitivity of the reference test
α : Significance level
$1-\beta$: Power

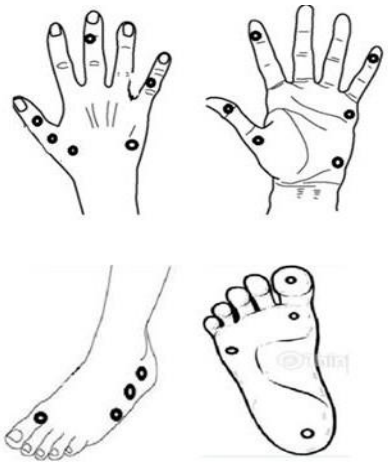
A total of 55 patients was needed, however, to consider 10% error extra 6 patients were included, i.e. a total of 61 patients

METHODS: Sixty-one leprosy patients in the age group of 15-75 years were recruited in the study after the consent. These patients were either newly detected or previously treated leprosy patients with at least one nerve with nerve function impairment.
The sex, age, duration of leprosy, types of leprosy, bacteriological index, treatment received and reactions was obtained from each patient.

The Semmes-Weinstein (SW) MF test and NCS were conducted in all patients (either newly detected or previously treated) with at least one nerve with nerve function impairment. Twenty sites in six nerves, each site in upper and lower extremities were assessed (total 40 sites)

Sites for sensory testing

Nerve	sites
Ulnar nerve	5
Median	4
Radial cutaneous nerve	3
Posterior tibial nerve	4
Sural	3
Deep peroneal nerve	1
Total	20 x 2 = 40



Investigation:
Touch sensibility testing using monofilaments (MF)
Touch sensibility was tested using Semmes-Weinstein (SW) monofilaments. Each examiner was provided with 2 filaments to use throughout the study period and they were instructed to use their own MF. The blue 2 gm MF for the hand and the purple 10gm force for the foot were considered for sensory testing. The patient was explained and was demonstrated prior to the examination and ensured that the procedure was fully understood. Hands and feet were examined one by one. Points on the same hand or foot were tested in random order. The SW monofilament was pressed perpendicular to the test site with enough pressure to bend the MF for 1 second. The patient was ask ed to close the eyes and to answer “Yes or No”, when felt or not felt the press of the MF respectively. If a stimulus is not felt for the first time, the point was tested again after having tested some other points. In this case, the result of the second test was recorded.
Nerve conduction study (NCS)

Digital Nihon Kohden Machine (NM-420S, H636, Japan) was used for nerve conduction studies in all patients at the Neuro-electrophysiology laboratory of Physiology department, BPKIHS. The physiologist was blinded for the clinical findings of the patient. Sensory parameters, such as sensory conduction velocities and amplitudes of the sensory nerve action potentials (SNAP) of the all six nerves bilateral was measured according to standard procedures. Additionally, Motor conduction velocities, distal motor latencies, and distal compound muscle action potential amplitudes were studied. The room temperature was maintained at thermo neutral zone (26 ± 2 ^{0}C) to avoid any environmental variation. The patient was explained to relax and comfortable in the laboratory set up prece ding the NCV recording. The functional impairment of the nerves was done based on standard criteria **(Marahatta et al, 2016).** Nerve conduction test was considered as the gold standard for the diagnosis of sensory impairment for each test point level.

Outcome measures: Touch pressure sensory impairment, sensory nerve conduction impairment, the agreement between testers and recommendation of the minimum point for TPSI in leprosy patients. Touch pressure sensory impairment was defined as a reduction by 2 or more points in the sensory score of any nerve’s distribution.

Statistical Analysis
After completion of the study, data were entered in Microsoft Excel 2007 and converted it into the Statistical Package for Social Science (SPSS) Version 10.0. For descriptive data analysis, mean, median, mode, standard deviation, proportion, and percentage were calculated. The sensory nerve conduction study was used as a gold standard to calculate Sensitivity and Specificity of the SW monofilament test for SI at each site and then to evaluate the impact of each site and combinations of sites.

Results

A total of 61 patients were included in the study. The mean age of the study population was 42.52+/-16.3 The majority of the population i.e. 23 (37.7%) patients belonged to the age group of 29-44 years, followed by 13 (21.3%) belonged to the age group of 59-74 years. Maximum number of patients 43 (70.5%) were male and 18 (29.5%) were female. Most of them were farmer 30 (49.1%) followed by housewife and student 9 (14.7%), laborer 6 (9.8%), unemployed 4 (6.5%) and driver 3 (4.9%). Family history was positive in 10 (16.4%) of patients. (Table 1)
Touch sensation testing using MF was altered maximally in sural nerve (78.7%), posterior tibial nerve (73.8%), ulnar (62.3%) respectively.
Table 2: Table showing frequency of all impaired parameters of sensory nerve action potential (SNAP) (n=61)

Parameter	Median	Ulnar	Radial	Tibial	Sural	Deep peroneal
Amplitude	19	33	29	24	37	17
Duration	5	8	8	3	7	3
Latency	9	2	3	2	3	2
CV	6	8	9	8	5	3

In the sensory nerve conduction study, amplitude was the most frequently affected parameters of SNAP followed by conduction velocity (Table 2).

Sensory Nerve Conduction study
On nerve conduction study, maximum impairment was seen in sural nerve 37 (60.7%) followed by ulnar nerve 33 (54.1%) and radial cutaneous nerve 29(47.5%) (Table 3)

Table 3: Sensory Nerve Conduction study (n=61)

Characteristics	Category	No.	Percentage
Median	Normal	42	68.9
	Impaired	19	31.8
Ulnar	Normal	28	45.9
	Impaired	33	54.1
Radial cutaneous	Normal	32	52.5
	Impaired	29	47.5
Posterior tibial	Normal	37	60.7
	Impaired	24	27.9
Sural	Normal	24	39.3
	Impaired	37	60.7
Deep peroneal	Normal	44	72.1
	Impaired	17	27.9

Diagnostic accuracy of clinical test

For the calculation of diagnostic accuracy, nerve wise sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of MF test were calculated and nerve conduction study was taken as gold standard. Sensitivity was high for most nerves ranging from 75% to 96.2%, except for median nerve whose sensitivity was 40%. Maximum sensitivity was for tibial nerve, i.e. 96.2%, but specificity was low, i.e. 42.9% where maximum specificity and PPV was seen for sural nerve i.e.100%. NPV was highest for deep peroneal nerve i.e. 97.4% and least for ulnar nerve, i.e. 52.2%. P value was statistically significant for ulnar, radial, tibial, sural and deep peroneal nerve respectively (Table 4).

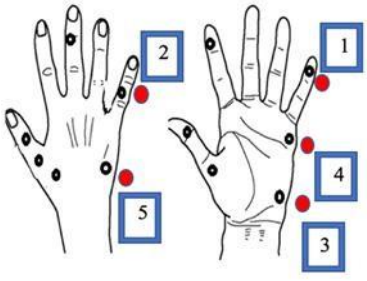
Table 4: Cross tabulation of Monofilament testing and Nerve conduction study (NCS)

Characteristics	Sensitivity	Specificity	PPV	NPV	P value
Median	40	67.7	54.5	53.8	.358
Ulnar	75	70.6	86.8	52.2	.01
Radial	83.3	84	88.2	77.8	.00
Tibial	96.2	42.9	55.6	93.8	.00
Sural	90.6	100	100	61.5	.00
Deep peroneal	94.4	86	73.9	97.4	.00

Table 5: Sensitivity, specificity, PPV, NPV of the individual site and combination of site of the nerves on comparing with NCV of Hand

Point	Ulnar			
	Sn	Sp	PPV	NPV
1	85.7	73.4	64.5	92.3
2	84.4	76.5	82.4	90.8
3	85.7	72.3	61.3	93.3
4	84.2	72.1	74.2	93.3
5	84.8	73.6	65.6	92.4
1+2	90.6	93.1	93.5	90
1+3	90.3	90	90.3	90
1+4	92.6	82.4	80.6	93.3
1+5	87.9	92.6	93.5	86.7
2+3	90.6	93.1	93.5	90
2+4	90.6	93.1	93.5	90
2+5	87.9	92.6	93.5	86.7
3+4	90.3	90	90.3	90
4+5	87.9	92.6	93.5	86.7
1+2+3	90.6	93.1	93.5	90
1+2+4	90.6	93.1	93.5	90
1+2+5	87.9	92.6	93.5	86.7
1+3+4	90.6	93.1	93.5	90
1+3+5	87.9	92.6	93.5	86.7
1+4+5	87.9	92.6	93.5	86.7
2+3+4	90.6	93.1	93.5	90
2+3+5	87.9	92.6	93.5	86.7
2+4+5	87.9	92.6	93.5	86.7
3+4+5	87.9	92.6	93.5	86.7
1+2+3+4	90.6	93.1	93.5	93.1
1+2+4+5	87.9	92.6	93.5	86.7
1+3+4+5	87.9	92.6	93.5	86.7
2+3+4+5	87.9	92.6	93.5	86.7
1+2+3+4+5	87.9	92.6	93.5	90

1. volar surface of the distal phalanx of little finger
2. dorsal surface of distal phalanx of little finger
3. hypothenar eminence
4. 5th metacarpal head on volar aspect
5. dorsal surface of hand



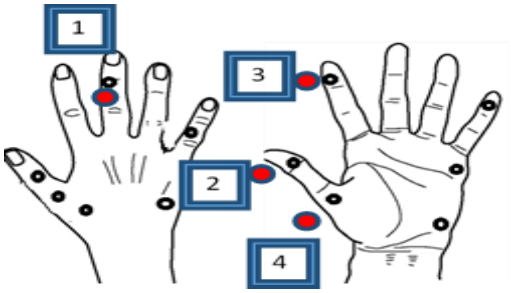
Maximum sensitivity, specificity, PPV, and NPV were seen in combination of 1st + 2nd point, 2nd +3rd point, 2nd + 4th point, 3rd + 4th point, 1st + 2nd +3rd point, 1st + 2nd +4th point, 1st + 3rd +4th point, 2nd +3rd +4th point, 1st + 2nd +3rd +4th point which were 90.6%, 93.1%, 93.5%, and 90% respectively.

Median nerve

Table 6: Sensitivity, specificity, PPV, NPV of individual site and combination of site of median nerve on comparing with NCV of Hand

Point	Median			
	Sn	Sp	PPV	NPV
1	64.7	56.8	60.9	94.7
2	73.3	58.7	65.4	89.3
3	73.3	60	60.9	92.5
4	66.6	60	64.2	90.3
1+2	87	92.1	87	92.1
1+3	90.5	90	82.6	94.7
1+4	87	92.1	87	92.1
2+3	90.5	90	82.6	94.7
2+4	89.5	94.7	82.6	94.7
3+4	90.9	92.3	87	94.7
1+2+3	87.5	92.1	91.3	92.1
1+2+4	87.5	92.1	87	92.1
1+3+4	87.5	92.1	91.3	92.1
2+3+4	90.9	92.3	87	94.7
1+2+3+4	88	97.2	95.7	92.1

1. dorsum of middle phalanx of middle finger
2. distal phalanx thumb volar aspect
3. distal phalanx index finger volar aspect
4. thenar eminence

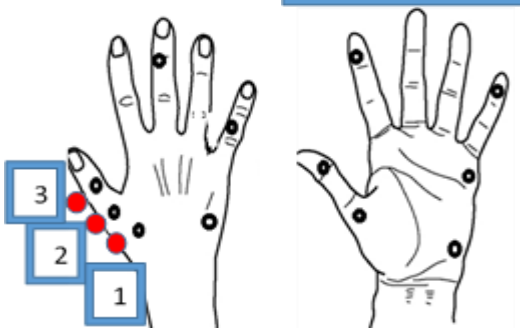


Maximum sensitivity, specificity, PPV, and NPV were 90.9%, 92.3%, 87%, and 94.7% respectively in combination of 3rd + 4th point and 2nd + 3rd +4th point

Table 7: Sensitivity, specificity, PPV, NPV of the individual site and combination of site of radial cutaneous nerve on comparing with NCV of Hand

Point	Radial			
	Sn	Sp	PPV	NPV
1	88.2	84.8	90.3	86.5
2	88.2	84.8	90.3	86.5
3	93.1	89.3	93.5	90
1+2	88.7	85.2	93.7	91.4
1+3	93.1	89.3	94.4	91.1
2+3	89.3	85.5	94.4	91.1
1+2+3	88.7	85.2	94.4	91.1

1. over anatomical snuff box
2. midpoint between anatomical snuff box and metacarpal head
3. over dorsum of the thumb at 1st metacarpal head

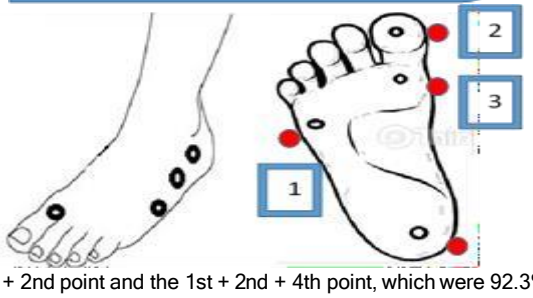


Maximum sensitivity, specificity, PPV, and NPV were seen for 3rd point, which were 93.1%, 89.3%, 93.5%, and 90% and combination of 1st +3rd point, which were 93.1%, 89.3%, 94.4%, and 91.1% respectively

Table 8: Sensitivity, specificity, PPV, NPV of individual site and combination of site of posterior tibial nerve on comparing with NCV of feet

Point	Post tibial			
	Sn	Sp	PPV	NPV
1	61.9	67.5	73.4	68.7
2	48	61.1	66.2	63.5
3	68.9.	74.2	84.3	79.4
4	73.5	79.3	87.9	83.4
1+2	92.3	88.6	85.7	93.9
1+3	85.7	87.9	85.7	87.9
1+4	67.4	86.8	96.4	48.5
2+3	61.4	94.1	96.4	48.5
2+4	60.5	88.9	92.9	48.5
3+4	86.2	83.6	92.9	48.5
1+2+3	61.4	94.1	96.4	48.5
1+2+4	92.3	88.6	85.7	93.9
1+3+4	83.4	81.9	96.4	45.5
2+3+4	60	93.8	96.4	45.5
1+2+3+4	71.4	86.3	96.4	45.5

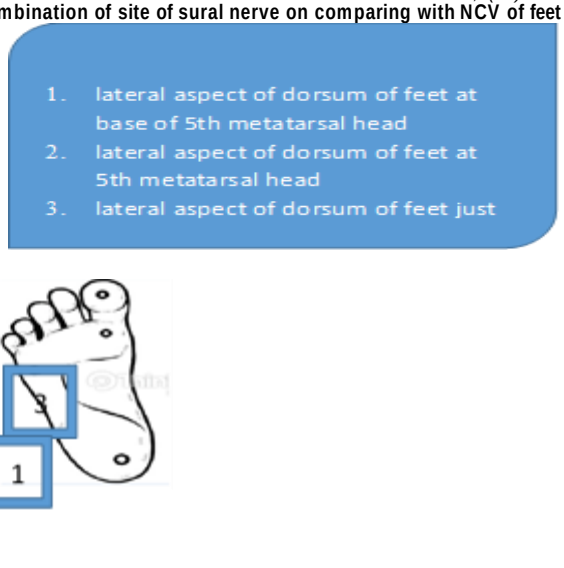
1. bulb of the feet 5th metatarsal head
2. planter surface of 1st toe
3. bulb of the 1st metatarsal head
4. heel



Maximum sensitivity, specificity, PPV, and NPV were seen in combination of 1st + 2nd point and the 1st + 2nd + 4th point, which were 92.3%, 88.6%, 85.7%, and 93.9% respectively

Table 9: Sensitivity, specificity, PPV, NPV of the individual site and combination of site of sural nerve on comparing with NCV of feet

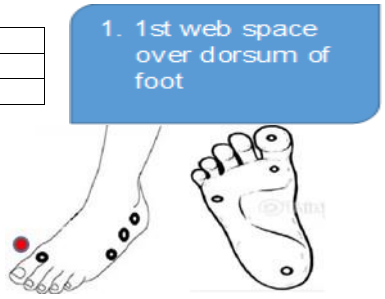
Point	Sural			
	Sn	Sp	PPV	NPV
1	97.8	100	100	93.8
2	95.7	93.3	97.8	87.5
3	95.7	93.3	97.8	87.5
1+2	95.7	100	97.8	87.5
1+3	95.7	100	97.8	87.5
2+3	95.7	100	97.8	87.5
1+2+3	95.7	100	97.8	87.5



Maximum sensitivity, specificity, PPV, and NPV was seen for 1st point which was 97.8%, 100%, 100%, and 93.8% respectively

Table 10: Sensitivity, specificity, PPV, NPV of individual site and combination of site of deep peroneal nerve on comparing with NCV of feet

Point	Deep peroneal			
	Sn	Sp	PPV	NPV
1	100	93.3	94.7	100



Discussion

Leprosy is a neglected tropical disease with devastating impact in the patient life because of the potential deformities, disabilities and morbidity associated with it. Early detection of NFI is key, enhances the nerve function recovery following adequate treatment (19, 20) and is a key intervention for prevention of disabilities (4). Early detection of the NFI is, therefore, a vital component of programs for the prevention of disability (Koelewijin et al, 2003) 15. Nerve function assessment (NFA) is recommended for newly diagnosed patients (5) as a part of the follow up and during reactional episodes (6).

In our study, the age of the leprosy patients ranged from 15 to 72 years with mean age of 42.52 +/- 16.3 years. The patient between age group 29 - 44 years were found to have more affected with leprosy. This was in concordance with the findings reported by Villrroel et al, Manandhar et al, Badhan et al and Khambati et al (MF Villrroel et al 2007 21; Khambati F et al, 2009 8; Manandhar U et al, 2013 22; Badhan R et al, 2014 23). Out of 61 patients, 43 (70.5%) were males and 18 (29.5%) were females with a ratio of 2.38: 1. This was in concordance with the findings reported by van Brakel et al, Gupta et al, Pathak et al, and Khambati et al (13, 8, 24, 25). In our study, we had patients with different occupations, most of them were farmer 30 (49.1%) followed by housewife and student 9 (14.7%), laborer 6 (9.8%), unemployed 4 (6.5%) and driver 3 (4.9%). It could be due to the fact, farmers are from low socio-economic status and there is a link between low socioeconomic status and increase incidence of leprosy. The rate of illiteracy and social stigma was also more in this group, which correlates with the findings of Singh et al and Nardi et al who observed a link between low socio-economic status and increased incidence of leprosy (30,31) also our country being agricultural countries most of them were farmers by occupation. In our study family history was positive in 10 (16.4%) which was higher than a study done by Nair SP which showed 5.44% of familial cases (32) and 9.5% in a study done by Salodkar and Kalla (33) It coul d be explained by the fact that close contact is one of the common modes of transmission of leprosy, so lack of contact tracing may be one of the reasons for underreporting of familial cases.

Touch sensation testing by monofilament:

MF test is a simple, easy and inexpensive tool for identifying loss of protective sensation and it can be one of the valid and standard screening tests for sensory nerve function impairment (13).

In our study while testing touch sensation by MF, out of 61 patients sural nerve showed maximum impairment in 48 (78.7%) followed by posterior tibial nerve in 45 (73.8%), ulnar nerve in 38 (62.3%), radial cutaneous nerve in 34 (55.7%), deep peroneal nerve in 23 (37.70%) and median nerve in 22 (36.1%) respectively. According to a study done by WH van Brakel and Khawas in western Nepal most commonly affected nerve by function impairment was the posterior tibial followed by ulnar nerve with 3.23% of nerve impaired (26). In another study done by Khambati et al also showed sural nerve impairment in maximum 28% patients followed by 23% in radial nerve and 23% in median nerve (8). In another study done by Marahatta et al the sural nerve showed maximum impairment in 14.9%, followed by radial nerve in 12.1%, ulnar nerve in 9.1% and median nerve in 6.8% (16). A study done by Pawar et al ulnar nerve was impaired in 56%, median nerve in 26% and posterior tibial nerve in 54% (17). Sural nerve is earliest nerve to be involved in leprosy and has got less propensity to ca use deformity.

Sensory nerve conduction study:

In the nerve conduction study, sural nerve was found to be most frequently impaired in 37 (60.7%) amongst all nerves. It was followed by ulnar in 33 (54.1%), radial nerve in 29 (47.5%), posterior tibial nerve in 24 (39.3%), median nerve in 19 (31.8%) and deep peroneal nerve in 17 (27.9%) respectively. It was in concordance with study done by Marahatta et al where sural nerve shows maximum impairment in 21.6%, followed by ulnar nerve in 17.6%, radial nerve in 16.2% and median nerve in 9.5% (16). Sensory nerve action potential (SNAP) amplitude was affected in all patients and was most affected parameter in the nerve conduction study. Amplitude represents a summation of the activity of the axons within the nerve trunk.

Monofilament testing in comparison with Nerve conduction study (NCS)

An effective diagnostic test requires an acceptable sensitivity and specificity. To find the accuracy of monofilament test, we calculated sensitivity (Sn), specificity (Sp), positive predictive value (PPV) and negative predictive value (NPV) where NCS was taken as gold standard. In our study, the tibial nerve has maximum sensitivity 96.2% but specificity was very low 42.9% followed by the deep peroneal nerve, which had sensitivity of 94.4% and specificity of 86%, sural nerve had sensitivity of 90.6% and specificity 100%, radial cutaneous nerve had sensitivity of 83.3 % and specificity of 84%, ulnar nerve had sensitivity of 75% and specificity of 70.6% and median nerve had sensitivit y of 40% and specificity of 67.7%. In a study done by Khambati et al, sensitivity for the ulnar nerve was 44% and specificity was 88%, radial cutaneous nerve sensitivity was 39% and specificity was 90%, sural nerve sensitivity was 36% and specificity was 93%, and median nerve sensitivity was 35% and specificity was 93% (8). Another study done by Marahatta et al sural nerve showed maximum sensitivity of 68.75% and speci ficity of 100%, followed by median nerve whose sensitivity was 42.85% and specificity was 97.01%, radial cutaneous nerve sensitivity was 41.66% and specificity was 93.4% and ulnar nerve sensitivity was 38.46% and specificity was 96.72 % (16). In a systematic review done by Dros J et al in diabetic patient for detection of diabetic neuropathy by MF had a sensitivity ranging from 41% to 93% and specificity ranging from 68% to 100% (27). In our study also, maximum sensitivity and specificity was seen in sural nerve followed by deep peroneal nerve, radial cutaneous nerve and ulnar nerve. This could be explained as nerve over the dorsum aspect of the limbs are earliest to involve and lesser propensity to affect their day to day activities so patients are not bothered about it. The high sensitivity of posterior tibial nerve coul d be explained by the fact that in heel one of the testing sites patients were not able to detect touch sensation by MF due to hyperkeratosis. The PPV and NPV for deep peroneal nerve was 73.9% / 97.4% (p=0.00), ulnar nerve 86.2% / 52.2% (p=0.01), median nerve 54.5% / 53.8% (p=0.358) and posterior tibial nerve 55.6%/93.8% (p=0.00), respectively. It was in discordance with the study done by Marahatta et al where PPV and NPV for sural nerve was 100% and 92.06% respectively, ulnar nerve 71.42% and 88.05%, median nerve 60% and 94.20%, and radial nerve 55.55% and 89.23% respectively. (16). In our study, sural, radial cutaneous nerve and ulnar nerve showed PPV of greater than 86%, which increased the chance of detecting sensory impairment.

Sensitivity, specificity, PPV and NPV of individual site and combination of sites:

The number of testing sites varied from one to twenty, and the criteria for determining protective sensation, specificity or sensitivity are different in different studies (Koelewijn et al 2003; Marahatta et al 2016. Marahatta et al 2016 tested 8 sites, Koelewijn et al 2003 tested 20 sites, ulnar 4, median6 and posterior tibial 10. Pawar et al 2016 compared 30 sites with 38 sites over the distribution of six nerves.

In our study, we compared the sensitivity (Sn), specificity (Sp), PPV, and NPV of each site and combination of the sites for detection of sensory impairment and this is the first study as per our literature search where the impact of each site and combination of the site has been studied. For ulnar nerve individual site i.e. 1st site (volar surface of the distal phalanx of little finger), 2nd site (dorsal surface of distal phalanx of little finger), 3rd site (hypothenar eminence), 4th site (5th Metacarpal head on volar aspect), and 5th site (dorsal surface of hand) had sensitivity ranging from 84.2% to 85.7% with an average of 84.96%, while specificity ranged from 72.1% to 76.5% with an average of 73.58%, PPV ranged from 61.3% to 82.4 with an average of 61.3% and NPV ranged from 90.8% to 92.4% with an average of 92.42%. While combination of 1st site (volar surface of the distal phalanx of little finger) + 2nd site (dorsal surface of distal phalanx of little finger) and 2nd site (dorsal surface of distal phalanx of little finger) + 3rd site (hypothenar eminence) had 90.6% sensitivity, 93.1% specificity, 93.5% PPV and 90% NPV. While 3rd site (hypothenar eminence) + 4th site (5th Metacarpal head on volar aspect) had 90% sensitivity, 90% specificity, 93.5% PPV and 90% NPV. So, taking 2 sites of hand had good sensitivity, specificity, PPV and NPV than taking multiple 3, 4 or 5 sites for sensory testing for ulnar nerve.

For median nerve, individual site i.e. 1st site (Dorsum of middle phalanx of middle finger), 2nd site (distal phalanx thumb v olar aspect), 3rd site (distal phalanx index finger volar aspect), and 4th site (thenar eminence) had sensitivity ranging from 64.7% - 73.3% with an average of 69.47%, while specificity ranged from 56.8% - 60% with an average of 58.87%, PPV ranged from 60.9% - 65.4 with an average of 62.85% and NPV ranged from 89.3% - 94.7% with an average of 91.7% respectively. While, combination of 3rd site (distal phalanx index finger volar aspect) + 4th site (thenar eminence) has 90.9% sensitivity, 92.3% specificity, 87% PPV and 94.7% NPV respectively. So, taking 2 sites of hand has good sensitivity, specificity, PPV and NPV than taking multiple 3 or 4 sites for sensory testing for median nerve.

For radial cutaneous nerve, individual site i.e. 1st site (over anatomical snuff box), 2nd site (midpoint between anatomical snuff box and 1st site), 3rd site (over dorsum of the thumb at 1st metacarpal head) had sensitivity ranged from 88.2% - 93.1% with an average of 89.83%, while specificity ranged from 84.8% - 89.3% with an average of 84.3%, PPV ranged from 90.3% - 93.5 with an average of 91.36% and NPV ranged from 86.5 - 90% with an average of 87.66% respectively. While combination of site 1st +3rd had 93.1% sensitivity, 89.3%.

For posterior tibial nerve individual site i.e. 1st site (bulb of the 5th metatarsal head planter aspect), 2nd site (planter surface of 1st toe), 3rd site (bulb of 1st metatarsal head volar aspect), and 4th site (heel) had sensitivity ranged from 48% to 73.5% with an average sensitivity of 63.05%, while specificity ranged from 61.1% to 79.3% with an average of 70.52%, PPV ranged from 66.2% to 87.9% with an average of 77.95% and NPV ranged from 63.5% to 83.4% with an average of 73.75%. While combination of 1st site (bulb of the 5th metatarsa l head planter aspect) + 2nd (planter surface of 1st toe) had 92.3% sensitivity, 88.6% specificity, 85.7% PPV and 93.9% NPV respectively. So, combination of 2 sites had good sensitivity, specificity, PPV and NPV as compared to individual site and combination of 4 sites.

For sural nerve individual site i.e. 1st site (lateral aspect of dorsum of feet at base of 5th metatarsal head), 2nd site (lateral aspect of dorsum of feet at 5th metatarsal head) and 3rd site (lateral aspect of dorsum of feet just beneath the ankle) had sensitivity ranged from 95.7% to 97.8% with an average sensitivity of (96.4%), while specificity ranged from 93.3% - 100% with an average of 95.53%, PPV ranges from 97.8% - 100 with an average of 98.53% and NPV ranged from 87.5% to 93.8% with an average of 89.6%. While combination of sites had sensitivity, specificity, PPV and NPV of 95.7%, 100%, 97.8% and 87.5% respectively which was comparatively less than the 3rd site. Similarly, deep peroneal nerve single site (1st web space over dorsum of foot) had 100% sensitivity, 93.3% specificity, 94.7% PPV and 100% NPV. So, taking 2 sites for ulnar nerve, 2 sites for median nerve, 1 site for radial cutaneous nerve, 2 sites for posterior tibial nerve, 1 site for sural nerve and 1 site for deep peroneal nerve (including dorsum aspect of nerve distribution) i.e. total of 9 sites+ 9 sites (total 18 sites) for 6 nerves had an average sensitivity, specificity, PPV, and NPV of >90%. In study done by Marahatta et al testing 8 sites (Ulnar nerve - at hypothenar eminence, 5th metacarpal head and volar surface of the distal phalanx of the little finger; Median nerve - at thenar eminence, volar surface of distal phalanx of the thumb and volar surface of distal phalanx of the index finger; Radial nerve - over dorsum of the thumb at the site of motor point Sural - at dorsal lateral aspect of the foot) had overall sensitivity of 78.94%, specificity of 83.63%, PPV of 62.5% and NPV of 92% (Marahatta et al 2016).

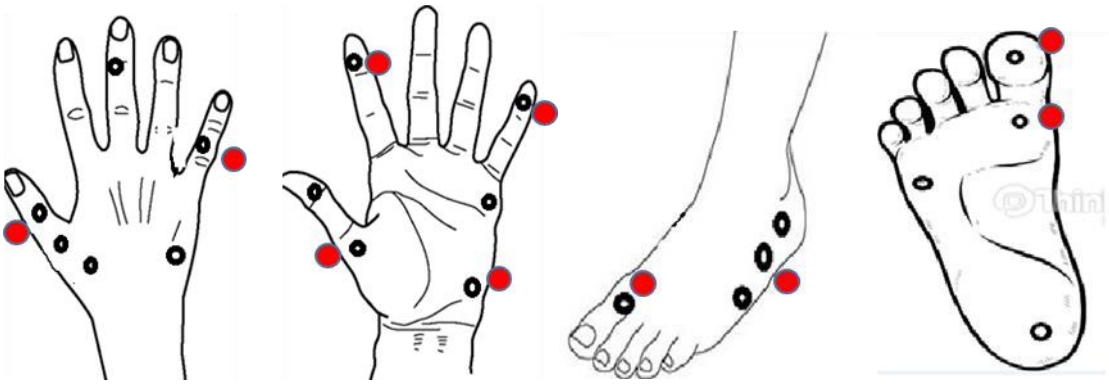
In another study done by Khambati et al testing 8 sites (Ulnar nerve - at hypothenar eminence, 5th metacarpal head and volar surface of the distal phalanx of the little finger; Median nerve - at thenar eminence, volar surface of distal phalanx of the thumb and volar surface of distal phalanx of the index finger; Radial nerve - over dorsum of the thumb at the site of motor point Sural -at dorsal lateral aspect of the foot) were tested and sensitivity ranged from 36% to 80%, maximum being for ulnar nerve whereas specificity ranged from 88% to 93% (Khambati F et al, 2009).

While Koelewijn et al tested 20 sites (ulnar 4, median 6 and posterior tibial 10 sites) where MF testing was taken as a gold standard and compared with ballpoint testing. The percentage of under diagnosis in absence of sensation with ballpoint pen was 21% for hands and 30% for feet (Koelewijn et al, 2003)15.While Pedro et al included standard testing site as per WHO where they tested 7sites on hand (Ulnar nerve - at hypothenar eminence, 5th metacarpal head and volar surface of the distal phalanx of the little finger; median nerve - at thenar eminence,

volar surface of distal phalanx of the thumb and volar surface of distal phalanx of the index finger; Radial nerve - over dorsum of the thumb at the site of motor point) and 10 sites on plantar aspect of feet where sensitivity of MF testing was 74.1% (28).

Recommendation

Two sites for ulnar nerve (volar surface of the distal phalanx of little finger or dorsal surface of distal phalanx of little finger and hypothenar eminence), median nerve (distal phalanx index finger volar aspect and hypothenar eminence) and posterior tibial nerve (bulb of the 5th metatarsal head planter aspect and planter surface of 1st toe) and single site for radial cutaneous nerve (dorsum of the thumb at 1st metacarpal head), sural nerve (lateral aspect of dorsum of feet at base of 5th metatarsal head) and deep peroneal nerve (1st web space over dorsum of foot) has good to very good sensitivity, specificity, PPV and NPV. Thus, we recommend these 9 sites in each nerve (total of 18 site) for sensory testing in leprosy neuropathy.



Limitation

1) In our study we were not able to carry out sensory nerve conduction study over each testing site i.e. over 40 sites over the distribution of 6 nerves due to unavailability of technicians.
2) The diagnosis of PNHD was made based on the clinical examination and no nerve biopsy was carried out for the confirmation of the diagnosis

Socio - Epidemiological Profile

Characteristic	Category	No	Percentage
Age	15-29	14	23
	29-44	23	37.7
	44-59	11	18
	59-74	13	21.3
Sex	Male	43	70.5
	Female	18	29.5
Education	Uneducated	17	27.9
	0-10 class	35	57.4
	>10 class	9	14.8
Occupation	Unemployed	4	6.5
	Housewife	9	14.7
	Student	9	14.7
	Driver	3	4.9
	Farmer	30	49.1
	Laborer	6	9.8
Family history	Positive	10	16.4
	Negative	51	83.6

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