Sensitivity and specificity of traditional testing methods to detect sensory impairment in the skin lesions of leprosy compared to Semmes–Weinstein monofilaments

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Summary

Objective: To determine the sensitivity and specificity of traditional testing methods to detect sensory deficit in the skin lesions of leprosy in comparison to Semmes Weinstein (SW) nylon monofilaments.

Design: After ethical clearance and written informed consent from study subjects, a consecutive series of 50 patients aged >12 years with leprosy skin lesions, who attended our institution, were evaluated in this cross sectional study.

Results: 74 skin lesions of 50 patients were evaluated. Considering the monofilament test result as the gold standard, the sensitivity to detect sensory impairment was 95.9% for the ballpoint pen, 97.3% for a sterile needle and 100% for cotton wool, and cold and warm water.

Limitation: Paucity of cases in the lepromatous spectrum of disease and the probable absence of early lesions of disease in the study group were the study limitations.

Conclusions: The cotton wool and ballpoint pen methods are easy to perform in the field and have comparable sensitivity and specificity to the blue Semmes

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Weinstein nylon monofilament to detect sensory impairment in skin lesions, especially in tuberculoid cases.

Keywords: Semmes Weinstein nylon monofilament, sensory impairment, cotton wool, ballpoint pen, sterile needle, warm water, cold water

Introduction

Despite the elimination of leprosy as a problem of public health importance, new cases continue to be reported.¹ Early diagnosis and treatment is the recommended strategy to break the chain of disease transmission.¹ Leprosy is diagnosed by the cardinal signs proposed by WHO.² Patients having one of the three signs (asymptomatic hypopigmented or erythematous skin lesion with sensory impairment; thickened peripheral nerve with sensory impairment over the area supplied by the nerve; acid fast bacilli positivity in skin smear studies) are diagnosed to have leprosy. Hence detection of defective sensory perception is significant in diagnosing leprosy.

Peripheral centres generally use the tip of a ballpoint pen (to test light touch), while many tertiary referral centres make use of cotton wool (for light touch), as well as the point of a sterile needle (for pain), and cold (25 °C) and warm water (40 °C–45 °C as per various studies) in test tubes (for temperature), to detect sensory impairment.^{3,4} But these traditional methods are not standardised.

Semmes Weinstein nylon monofilaments (SW filaments) are considered as sensitive and objective tools to detect sensory impairment in leprosy.⁵ The standard SW filament set comprises of precisely calibrated six monofilaments that are of equal length. They are colour coded and calibrated to produce varying forces of pressure when applied on the surface of skin (Table 1).⁵

Villarroel, *et al.* in their study on cutaneous sensation of leprosy lesions, documented the monofilaments to have a sensitivity and a specificity of 81.7% and 96.1%, respectively while thermal sensory testing to have sensitivity of 90.2% and 92.2%, respectively for warm and cold water and 100% specificity for both. But they employed a thermal sensory analyser to perform the testing. The size and cost of thermal sensory analysers rule out their routine use. The authors concluded their study with the opinion that smaller and cheaper devices that can assess thermal perception need to be developed and at present monofilaments have adequate validity as a diagnostic tool in leprosy.³

In a study comparing the ballpoint pen with the monofilaments to detect sensory perception of hands and feet, the former was found to be less reliable.⁶ Sensory nerve function impairment affecting hands and feet in leprosy is denoted as Grade1 disability. Prompt detection of Grade1 disability and the adoption of protective life style practices may prevent progression to Grade2 disability in those affected. Hence, testing specified points (corresponding to the nerves supplying the area) in hands and feet with SW nylon monofilaments (the green filament exerting 0.05 gm force for hands and the purple filament exerting 2 gm force for feet) is recommended.⁵

Saunderson and Groenen, in their study of 594 leprosy patients identified sensory loss in a typical skin patch as the most important sign of early leprosy.⁷ This observation points to the importance of accurate detection of sensory deficit in the skin patch of suspected leprosy cases. But SW filaments, considered as the objective tool to detect sensory deficit are not easily available; moreover a certain level of expertise is needed for sensory testing using them.

Table 1. Pressure imparted by Semmes Weinstein nylon monofilaments on application on skin surface

Colour of filament	Pressure on surface of skin on application of filament
Green	0.05 gm
Blue	0.2 gm
Purple	2 gm
Red	4 gm
Orange	10 gm
Light red	300 gm

Sensory testing with them is time consuming as well. Hence examining all skin lesions of leprosy for sensory impairment with SW filaments becomes less practical, especially in a field setting. There is a dearth of studies comparing the efficacy of traditional methods to detect sensory impairment in skin lesions of leprosy with that of SW filaments.

In this setting we compared the sensitivity and specificity of traditional methods to detect sensory impairment in skin lesions of leprosy with that of Semmes Weinstein monofilaments.

Methodology

STUDY DESIGN: CROSS SECTIONAL STUDY

Fifty patients aged more than 12 years and manifesting skin lesions of leprosy (diagnosed as per clinical evaluation, skin smear study and histology analysis), who attended the Dermatology department of a tertiary care centre from 1.6.2019 were included consecutively in the study (irrespective of duration of treatment), after clearance from the Institutional ethics committee and written informed consent from individual patient.

Patients not willing to participate in the study and patients with peripheral neuropathy due to other causes such as hereditary neuropathies, Type 2 diabetes, trauma and carpal tunnel syndrome, were excluded.

According to a previous study, the sensitivity and specificity of SW monofilaments is 81.7% and 96.1% in detecting sensory nerve function impairment.⁸ Taking an accuracy of 15%, the sample size was determined as a minimum of 50.

In this cross sectional study, a pre-set proforma was used to collect data pertaining to patient characteristics, evolution of disease, and clinical features.

Site, morphology and number of skin lesions and enlarged nerves were noted for each individual case. Skin smear and histopathology findings were documented. Patients were grouped according to the Ridley–Jopling classification of leprosy as per clinical, histological and skin smear findings. The treatment required by the patients was recorded.

Skin lesions of leprosy were tested using cotton wool (for uniform assessment cotton was passed through aluminium rod of 2 cm length and 1 cm inner diameter, care was taken to touch and not to stroke the cotton across the skin), the 0.7 mm tip of a Reynolds Brite ballpoint pen (keeping the testing hand supported to make it more stable, skin touched gently with the tip of pen kept perpendicular to the surface of skin so as to produce just a slight movement of skin, taking care not to stroke or produce deep dent), a sterile needle prick (touched lightly on the skin without causing bleeding) with 23 gauge needle, and warm and cold water at 42 °C and 25 °C (measured using digital thermometer) respectively in 10 mm Cresil glass test tubes. The Semmes Weinstein monofilament testing was performed with green and blue filaments, providing 0.05 gm and 0.2 gm force respectively.⁵ Each filament was applied perpendicularly

Table 2. Age and gender distribution of study group

Gender	Age distribution of study group				Total
	12–20 years	21–40 years	41–60 years	Above 60 years	
Male	7 (20.6%)	11 (32.4%)	10 (29.4%)	6 (17.6%)	34 (100%)
Female	3 (18.8%)	8 (50%)	5 (31.3%)	0 (0%)	16 (100%)
Total	10 (20%)	19 (38%)	15 (30%)	6 (12%)	50 (100%)

to the specified site with mild pressure until it formed a 'C' curve. The approximate time of contact with the skin during each application was kept as one second.

Sensory testing was carried out starting from the normal skin on the opposite side to the leprosy lesion, followed by nearby normal skin and then on skin lesion itself. If the stimulus was felt as less than that in normal skin or if the patient pointed to a site 2 cm away as the site of application of particular stimulus, it was considered as hypoaesthesia. Anaesthesia was defined as complete absence of perception of the stimulus. Inability or reduced ability to appreciate the stimulus applied by the blue monofilament was taken as evidence of anaesthesia and hypoaesthesia respectively, to the SW filament testing. The same examiner evaluated all the patients and a single set of monofilaments was used throughout the study.

In patients with multiple skin lesions, (affecting different body parts and of different morphologies), representative lesions for each body area (face, trunk, upper limb and lower limb) and for each particular morphology were tested for sensory impairment and the results were documented.

Throughout the sensory testing, the patient's view of the skin being tested was blocked. Motor nerve function impairment was diagnosed when the power recorded by voluntary muscle testing was <5 on the Medical Research Council scale.^{5,9}

The data were entered into Microsoft Excel and analysed with SPSS Version 18. Sensitivity and specificity of sensory impairment detected by traditional methods were compared with that of blue SW monofilament (which was adopted as the gold standard).

Results

The study population comprised of 50 patients with skin lesions diagnostic of Hansen's disease (Table 2). Ages ranged from 10 years to 75 years (mean 38.4, standard deviation 16.3). Males outnumbered females with a male:female ratio of (2.1:1).

Duration of disease in study participants ranged from 2 weeks to five years (mean 1.57 years $\pm$ 1.23 years).

Among the study group there were seven (14%) cases of Tuberculoid (TT), 38 (76%) cases of Borderline Tuberculoid (BT), two cases (4%) each of Borderline Lepromatous (BL) and Lepromatous (LL) and one of (2%) Indeterminate leprosy. Skin lesions were distributed on the face, trunk, upper limbs and lower limbs. The different types of lesions observed were hypopigmented or asteatotic patches, plaques and infiltrated plaques (Table 3). None of the study participants showed nodular lesions or vague, shiny hypopigmented macules of leprosy. Ear lobe infiltration was noted in two LL cases.

Seven patients (14%) required PB treatment and the others (86%) needed MB treatment.

Seventy four skin lesions in 50 study participants were evaluated for sensory perception. All patients showed normal perception of stimuli on normal skin, on the opposite side of the body, and on nearby normal skin, when tested with cotton wool, tip of a ballpoint pen, sterile needle,

Table 3. Distribution and morphology of leprosy skin lesions

Sites affected	Morphological type			Total
	Hypopigmented and/ or asteatotic patch	Plaque	Infiltrated plaque	
Face	6 (66.7%)	2 (22.2%)	1 (11.1%)	9 (100%)
Trunk	7 (58.3%)	3 (25%)	2 (16.7%)	12 (100%)
Upper limb	24 (85.7%)	3 (10.7%)	1 (3.6%)	28 (100%)
Lower limb	19 (76%)	6 (24%)	0 (0%)	25 (100%)
Total	56 (75.7%)	14 (18.9%)	4 (5.4%)	74 (100%)

water at different temperatures and the blue monofilament (0.2 gm). Only 20/50 (40%) patients were able to perceive the green filament (0.05 gm) on non-lesional skin. In all 20 patients (all BT) who were able to perceive green filament in non lesional skin, anaesthesia was recorded in lesions. None of the patients who failed to feel the green filament in non-lesional skin was able to feel it in lesional skin.

69/74 leprosy lesions tested (93.2%) showed hypoaesthesia or anaesthesia to all modalities of testing (cotton wool, ballpoint pen, sterile needle, water at different temperatures and the blue monofilament) (Table 4).

Two cases who showed normal perception to the ballpoint pen stimulus, the lesions were located on upper limbs. One was, 31 year old female with BT and the lesion was found to be anaesthetic to all other stimuli. The second patient was sixty year old female of BL spectrum, whose upper limb lesion showed hypoaesthesia for all methods except testing by ballpoint pen.

The face lesion of one 22 year old female patient with BT showed normal sensory perception to both ballpoint pen and sterile needle stimuli; but hypoaesthesia was noted to testing by temperature, cotton and blue monofilament (Table 4).

Among the 74 lesions tested with blue filament, 62 (83.8%) were anaesthetic, 11 (14.9%) hypoaesthetic and one (1.4%) had normal sensory perception (Table 5).

On analysing the cutaneous sensation (normal/ hypoaesthesia/ anaesthesia) as assessed by different methods, we observed cotton wool (87.8%) and water at different temperatures (83.8%) to have greater concordance (than sterile needle and ballpoint pen) with the same recorded by blue filament (Table 6).

But all traditional methods were found to have good sensitivity to differentiate sensory impairment from normal sensory perception (Table 7).

The sensitivity to detect sensory impairment was 95.9% for tip of ballpoint pen, 97.3% for sterile needle and 100% for cotton wool and cold and warm water when compared to blue monofilament (Table 7). No significant variation was documented in sensitivity of different testing methods to detect sensory impairment with respect to morphology or site of the lesions.

Since all testing methods except cotton wool identified the normal sensory perception in the lone lesion that showed normal perception of blue filament, specificity to detect sensory impairment was 100% for all traditional methods except cotton wool.

Discussion

We observed all traditional methods to have high sensitivity (95.9% for tip of ballpoint pen, 97.3% for sterile needle and 100% for cotton wool and cold and warm water) to detect sensory impairment in lesional skin of leprosy in comparison to blue SW filament. Moreover all stimuli had 100% specificity in making this distinction except cotton wool, which failed to identify

Table 4. Sensory perception of skin lesions of leprosy to different modalities of testing

Site of lesion	Sensory testing method																	
	Ballpoint pen		Cotton wool		Sterile needle		Warm water		Cold water		SW filament-blue							
	Normal	Reduced/Absent	Normal	Reduced/Absent	Normal	Reduced/Absent	Normal	Reduced/Absent	Normal	Reduced/Absent	Normal	Reduced/Absent						
Face (9)	1	8	0	0	2	7	1	4	4	0	2	7	0	2	7	0	3	6
Upper limb (28)	2	21	5	0	3	25	0	16	12	0	5	23	0	5	23	0	7	21
Trunk (12)	1	6	5	0	3	9	1	5	6	1	1	10	1	1	10	1	1	10
Lower limb (25)	0	11	14	0	0	25	1	6	18	0	3	22	0	3	22	0	0	25
Total (74)	4	46	24	0	8	66	3	31	40	1	11	62	1	11	62	1	11	62

Table 5. Cutaneous sensation assessed by different methods with reference to the blue Semmes Weinstein nylon monofilament

Sensory perception by blue Semmes Weinstein nylon monofilament*	Ballpoint pen		Cotton wool		Sterile needle		Warm water		Cold water	
	N	↓	N	↓	N	↓	N	↓	N	↓
Normal sensation by blue filament	0	0	0	0	0	0	0	0	0	0
Upper limb (0)	0	0	0	0	0	0	0	0	0	0
Trunk (1)	1	0	0	1	0	0	1	0	1	0
Lower limb (0)	0	0	0	0	0	0	0	0	0	0
Total (1)	1	0	0	1	0	0	1	0	1	0
Face (3)	1	2	0	2	1	2	0	2	1	0
Hypoaesthesia by blue filament	1	6	0	2	5	7	0	3	4	4
Upper limb (7)	0	1	0	1	0	1	0	0	1	1
Trunk (1)	0	0	0	0	0	0	0	0	0	0
Lower limb (0)	2	9	0	5	6	10	0	5	6	6
Total (11)	0	5	1	0	6	3	0	6	0	6
Face (6)	1	15	5	1	20	9	12	19	0	19
Upper limb (21)	0	5	5	1	9	4	6	1	9	9
Trunk (10)	0	12	13	0	25	1	19	3	22	3
Lower limb (25)	1	37	24	0	60	21	40	6	56	6
Total (62)	4	46	24	8	66	31	40	11	62	11
Grand total (74)										

*Number in brackets shows the number of lesions in each category. N: normal, ↓: reduced; 0: absent.

Table 6. Concordance between cutaneous sensation documented by individual traditional method and blue Semmes Weinstein nylon monofilament.

Cutaneous sensation as assessed by blue filament	Concordance rate for ballpoint pen	Concordance rate for cotton wool	Concordance rate for sterile needle	Concordance rate for warm water	Concordance rate for cold water
Normal sensation (1)	1/1 (100%)	0/1 (0%)	1/1 (100%)	1/1 (100%)	1/1 (100%)
Hypoaesthesia (11)	9/11 (81.8%)	5/11 (45.5%)	10/11 (90.9%)	5/11 (45.5%)	5/11 (45.5%)
Anaesthesia (62)	24/62 (38.7%)	60/62 (96.8%)	40/62 (64.5%)	56/62 (90.3%)	56/62 (90.3%)
Total (74)	34/74 (45.9%)	65/74 (87.8%)	51/74 (68.9%)	62/74 (83.8%)	62/74 (83.8%)

Table 7. Sensitivity of traditional method to detect sensory impairment in skin lesions of leprosy in comparison to Semmes Weinstein nylon blue monofilament

* Site of lesion	Sensory testing method				
	Ballpoint pen	Cotton wool	Sterile needle	Warm water	Cold water
Face (9)	8 88.9%	9 100%	8 88.9%	9 100%	9 100%
Upper limb (28)	26 92.9%	28 100%	28 100%	28 100%	28 100%
Trunk (11)	11 100%	11 100%	11 100%	11 100%	11 100%
Lower limb (25)	25 100%	25 100%	24 96%	25 100%	25 100%
Total (73)	70 95.9%	73 100%	71 97.3%	73 100%	73 100%

*Number in brackets shows the total number of lesions in each category detected to have sensory impairment by blue monofilament. The lone lesion that showed normal sensory perception to blue Semmes Weinstein filament is excluded from this table.

the normal sensory perception in the single lesion that manifested neither anaesthesia nor hypoaesthesia to testing by blue filament.

Cotton wool (87.8%) and water at different temperatures (83.8%) showed greater concordance with blue filament with respect to the grades of sensory impairment (Table 6) in comparison to ballpoint pen (45.9%) and sterile needle (68.9%). But this may not have much practical implication since when hypoaesthesia and anaesthesia were considered together all these methods have high sensitivity in making a diagnosis of leprosy (Table 7).

Most of the studies involving SW filament have assessed the sensory perception pertaining to hands and feet since sensory nerve function impairment affecting these sites amounts to Grade I disability; hence testing these sites requires a more sensitive test for early detection.^{6,8} But previous authors have demonstrated the importance of accurate detection of sensory impairment in the skin lesions for early diagnosis of leprosy.⁷ The literature suggests that the threshold for normal sensation for any part of the body is 0.05 gm (green filament) except for the sole of foot where it is considered as 2 gm.⁵ Hence we adopted the inability to perceive

the stimulus applied with blue monofilament (0.2 gm) as the cut off for sensory nerve function impairment in the skin lesions of leprosy.

Adopting the blue filament rather than the green filament as the gold standard is supported by our observation of 30/50 patients (60%) failing to perceive green filament in unaffected skin. The false positivity to testing was minimised by comparing the ability to perceive sensation within lesions, with that of the corresponding area on the contralateral side, as well as on adjacent normal skin, and to document hypoaesthesia and anaesthesia when the sensory perception on lesions was less or absent respectively when compared to normal skin.

The lower sensitivity documented for ballpoint pen and sterile needle prick to detect sensory impairment of lesions on the face compared to other areas is explained by the fact that thin skin and overlapping and rich nerve supply of facial skin may mask the sensory deficit. Moreover, the tendency of the clinician to apply the tip of ballpoint pen and sterile needle more gently on face so as not to traumatise the skin might have also contributed.

The significance of the present study lies in the importance assigned to detection of sensory impairment in diagnosing leprosy.⁷ The most important and time tested strategy of prevention of transmission of leprosy is by early diagnosis and treatment of affected cases.

Traditional testing methods that assess touch, pain and temperature in suspected leprosy cases (by tip of ballpoint pen, cotton wool, pin prick and warm and cold water in test tubes, respectively) in field camps and hospitals are not standardised. When warm and cold water containing test tubes are used, the temperature imparted to skin at the point of application varies with the type of test tube used and also with the time interval between collection of water in test tubes and its application to skin. Sensory perception with the ballpoint pen, cotton wool and pin prick depend on the force with which the stimulus is applied.

Despite temperature being the early affected sensation in leprosy, Semmes Weinstein nylon monofilaments are considered as an objective and sensitive tool to detect sensory impairment, since instruments like thermal sensory analysers that can ensure proper testing of thermal sensations are not routinely available.

The paucity of BL and LL cases (who usually manifest minimal sensory impairment or normal sensation) and most of the cases belonging to tuberculoid group, may have resulted in the high rate of sensory impairment in the study. Hence the ability of different methods to distinguish minimal sensory deficit from normal perception could not be well assessed. Saunderson and Groenen, in their study noted lack of sensory impairment in skin lesions in 49% (132/248) of smear positive leprosy cases.⁷

The specificity of standardised cotton wool to differentiate sensory impairment from normal perception needs to be further evaluated in large studies including more cases belonging to different groups of the leprosy spectrum, since the former over diagnosed sensory impairment in the lone lesion that showed normal sensation with the blue filament.

The study indicates that the combination of standardised cotton wool and ballpoint pen could increase the sensitivity and specificity as well as maintaining an acceptable level of concordance with blue SW filament to detect the presence and extent of sensory impairment in skin lesions of leprosy.

Though water at different temperatures yielded comparable results to that of cotton wool in detecting sensory deficit and the extent of sensory impairment in lesional skin of leprosy, we recommend the use of standardised cotton wool over warm and cold water since the use of water at different temperatures for sensory testing may have practical difficulties in a field setting. Though sterile needle and ballpoint pen had equal specificity to detect sensory impairment,

ballpoint pen may be the preferred option over sterile needle considering the latter's potential to cause injury and the need for replacement after each use.

We suggest testing with cotton wool (100% sensitivity) which is confirmed by ballpoint pen (100% specificity) will be enough in routine clinical examination of skin lesions of leprosy and we can do away with heat and cold, needle and SW filament in the diagnosis of leprosy.

Limitation

As we had only a few cases from the Lepromatous and Indeterminate groups, the applicability of our results in these groups must be evaluated with larger studies.

Conclusion

Ballpoint pen and cotton wool stimuli are easy to perform methods in the field scenario that have comparable sensitivity and specificity to blue Semmes Weinstein nylon monofilament to detect sensory impairment in skin lesions of leprosy, especially in tuberculoid patients.

DECLARATION

The authors declare that this article has not been published in its present form in any other scientific journal.

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Competing interest statement

All authors declare that the answers to the questions on your competing interest form are all no and therefore have nothing to declare.

Details of ethics approval

Ethics committee clearance was obtained from the institutional ethics committee of Government Medical College, Kozhikode, Kerala, India on 19.2.2019.

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