

# Effectiveness of Semmes Weinstein 10 gm monofilament in diabetic peripheral neuropathy taking nerve conduction and autonomic function study as reference tests

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## ABSTRACT

**Context:** Diabetic peripheral neuropathy (DPN) if detected early can reduce the burden on the health system and prevent the development of diabetic foot ulcers and amputation. **Aim:** To study the effectiveness of Semmes Weinstein 10 gm monofilament in detecting DPN taking nerve conduction studies (NCS) and autonomic function testing (AFT) as reference tests. **Settings and Design:** Observational and comparative cross-sectional study conducted in the Physiology department AIIMS, Bhopal in collaboration with the Medicine department of the institute. **Methods and Material:** A total of 72 diagnosed type-2 diabetes mellitus patients were examined using Semmes Weinstein 10 gm monofilament, DPN was confirmed using NCS (Nihon Kohden Neuropack XI machine) and autonomic neuropathy was confirmed using AFT (Ewing's battery and Power lab) with heart rate variability (HRV). Diagnostic value of Semmes Weinstein 10 gm monofilament taking NCS and AFT as reference test was calculated. **Statistical Analysis Used:** Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) were calculated using the standard formula. **Results:** Sensitivity, specificity, PPV, and NPV using monofilament are 69.23%, 20%, 69.23% and 20% respectively taking NCS as reference test and 70.59%, 0, 92.30%, and 0 respectively taking AFT as reference test. **Conclusions:** Semmes Weinstein 10 gm monofilament is not the ideal screening test for the diagnosis of DPN. Sole clinical use of monofilament should be discouraged.

**Keywords:** Autonomic function testing, diabetic peripheral neuropathy, heart rate variability, nerve conduction study, Semmes Weinstein 10 gm monofilament examination

## Introduction

India is considered to be the diabetes capital of the world and cases are rapidly rising. Diabetes mellitus is associated with many chronic complications and diabetic peripheral neuropathy (DPN) is one of the most frequent complications. In clinical practice, the

presence of symptoms and signs of peripheral nerve dysfunction in people with diabetes after excluding the other cause is called DPN.<sup>[1]</sup> It is the most prevalent chronic complication of diabetes and glucose control has been considered very important in the prevention of diabetic neuropathy.<sup>[2]</sup> Besides glucose control, early diagnosis of DPN would help in the timely management of complications and would prevent further morbidity and mortality.

DPN may be diagnosed by an assessment of pinprick test, vibration, ankle reflex, thermal sensation, position, and joint

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sensation. Various scales had been mentioned in the literature which is based on various symptoms and signs.<sup>[3]</sup> However, all these tests are highly subjective, time-consuming, and not repeatable. Nerve conduction studies (NCS) were considered to be the objective test to diagnose DPN which is considered to play an important role in diagnosis, in clinical practice as well as research.<sup>[4]</sup> However, NCS are mainly helpful in the diagnosis of large fibre neuropathy and small fibre neuropathy cannot be diagnosed by NCS. Recent studies opined that electrophysiological testing is rarely needed for screening and they were recommended only when the diagnosis is in doubt or is in atypical presentation.<sup>[1]</sup> It is time-consuming, requires a specialist operator, is uncomfortable for patients, and has a poor interobserver agreement.<sup>[5]</sup> There are some other objective tests like DPN check where the sural nerve is assessed and the time required is short, however, validation is scant and it is uncomfortable for the patients.<sup>[6]</sup> All these tests mainly assess large fiber function.

Diabetes also results in autonomic neuropathy, which can be detected by autonomic function testing (AFT, Ewing's battery of tests) and heart rate variability (HRV). Decreased HRV is found in asymptomatic DPN patients.<sup>[1,7-9]</sup> Sudoscan and neuropad have been used to assess autonomic function. These tests are non-invasive and easy to perform. Besides these tests, some other recently available tests are punch skin biopsy, quantitative sudomotor axon reflex test (QSART), and corneal confocal microscopy, which are mainly used for research purposes. These tests assess small fiber function and punch skin biopsy and QSART is considered to be the gold standard test.<sup>[5]</sup> However, these tests are cumbersome, time-consuming, not feasible to do in every patient and the facility may not be available in many institutes.

Family physicians play an important role not only in diagnosis of diabetes mellitus but also in monitoring the complications of diabetes mellitus. DPN is a frequent complication of diabetes mellitus and if remained undiagnosed can result in diabetic foot which may cause lower limb amputation. This complication can be prevented by recognition of the condition in the early stages when the patient is asymptomatic. This is where family physician has their role to play. In busy clinical settings like in India where family Physicians especially in primary health care setting are overburdened, there should be a rapid screening test available to diagnose this condition.

The 10 gm Semmes Weinstein monofilament examination (SWME) is a non-invasive, low-cost, simple, and accurate handheld calibrated nylon thread that buckles once it has delivered a force of 10 g. It provides a standardized measure of a patient's ability to sense a point of pressure.<sup>[10,11]</sup> This test is used to detect light touch sensation. Many studies have used this test and they have found it useful however contradiction exists among different authors regarding its use. Some authors have found it to be inconsistent and had not recommended this test.<sup>[5]</sup> In India, studies about the use of monofilament are scant. There are very few studies where NCS was taken as a reference test, however, we did not come across any study

where AFT was taken as a reference test. Diabetes mellitus patient may present with autonomic neuropathy even before development of abnormal nerve conduction test.<sup>[5]</sup> Hence, we endeavored to undertake this study where we made an attempt to find the role of 10 gm SWME in diagnosis of DPN including autonomic involvement.

The main aim of this study was to perform 10 gm SWME, nerve conduction study, and AFT on a suspected case of DPN and to estimate sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) for 10 gm SWME concerning AFT and nerve conduction study.

## Subjects and Methods

This was an observational and comparative cross-sectional study conducted amongst 72 diagnosed type-2 diabetes mellitus patients of either sex. Standard diagnostic criteria were used to diagnose diabetes.

### Inclusion criteria

- Age 18–50 years
- Diabetes duration >1 year.

The study was conducted by the Physiology Department in collaboration with Medicine Department. The study was conducted between March 2020 to July 2021.

### Exclusion criteria were as follows

- Patients with end-stage renal disease
- Chronic alcoholics
- Cancer patients
- Patients on neurotoxic medications affecting B-12 absorption
- Newly diagnosed case of Diabetes mellitus.

The study was undertaken after due approval from the Institutional Human Ethics Committee of AIIMS, Bhopal. Due consent was obtained from patients and they were asked to visit the physiology department where history taking, clinical examination, 10 gm SWME, NCS, and AFT testing were done. All the tests were performed in the laboratory with optimum temperature and ambiance.

### SWME 10 gm monofilament test is performed by the standardized method as follows

A 10 gm SWME was applied by testing the plantar aspect of the great toe, third, fifth metatarsal heads (Total site 3). The patient has to say “yes” every time, he senses monofilament on their foot. If the patient fails to sense the monofilament even after it bends the test is said to be insensate.<sup>[12]</sup>

### Autonomic function testing

It was done using Ewing's battery of tests and the standard protocol was followed.<sup>[13]</sup>

- Immediate heart rate and blood pressure response to standing (30:15 R-R ratio)
- Blood pressure response to isometric exercise (hand grip test)
- Valsalva ratio
- Heart rate variation with respiration.

These parameters were assessed using Power Lab and Lab Chart 8 by Ad Instrument using Motorized tilt table (Medica Podium) and B. P measurement using Diamond model no. BPDG 124).<sup>[14]</sup>

### Heart rate variability

HRV recording and assessment were done on Power lab (AD Instruments P Ltd, Castle Hill Australia). ECG was sampled at 1000 Hz for 5 min with the Power Lab acquisition system. The recording was started once the patient becomes stable in a quiet room with a comfortable temperature. HRV recording was analyzed with both frequency-domain and time-domain analyses.

Before AFT testing and HRV recording, patients were instructed to abstain from any type of exercise, eating and drinking anything, having caffeine, at least 2 h before the scheduled time for the test.

### Nerve conduction study

Test was done using Nihon Kohden Neuropack X1 Machine. Nerves tested were median, ulnar, common peroneal, tibial, and sural nerves. The parameters recorded were distal latencies, amplitudes of compound motor action potentials (CMAP), duration of CMAP, F wave latencies, and conduction velocities in motor nerves. In sensory nerves, latencies and amplitudes of the sensory nerve action potentials (SNAP) and their conduction velocities were documented. H reflex (tibial nerve) was also recorded. Standard procedures were followed.<sup>[15]</sup>

### Interpretation of NCS and AFT

Depending on NCS parameters test was labeled as normal or abnormal. Standard guidelines were followed for interpretation.<sup>[15,16]</sup>

AFT will be labeled as normal or abnormal based on the AFT test battery and HRV. Standardized guidelines are followed for interpretation.<sup>[14]</sup>

Statistical analysis was done using the Statistical Package for the Social Sciences (SPSS) statistical software. A categorical or

Table 1: Formula to calculate sensitivity, specificity, PPV, NPV		
10 gm SWME	Reference test (NCS/AFT)	
	Positive	Negative
Positive	True positive (a)	False positive (b)
Negative	False negative (c)	True negative (d)
Sensitivity= $a/a+c \times 100$		PPV= $a/a+b \times 100$
Specificity= $d/b+d \times 100$		NPV= $d/c+d \times 100$

nominal variable would be summarized by count or percentage, numerical variable by mean and SD (normal distributed). Sensitivity, specificity, PPV, and NPV were calculated.

## Results

A study was done on 72 diagnosed patients of diabetes mellitus of either sex (mean age  $\pm$  SD, 50.44 years  $\pm$  9.55). The basic characteristics of the patients are shown in Tables 1 and 2.

Out of these 94% (68), patients had abnormal NCS findings. Mixed involvement (sensory and motor) is mainly seen in 74% (53) patients whereas pure sensory is in 10% (7) patients and the pure motor is in 11% (8) patients. Mixed involvement (axonal and demyelinating) was seen in 60% (43) and pure axonal in 35% (25) patients. The peroneal nerve is the most common bilaterally involved motor nerve whereas the sural nerve is the most common bilaterally involved sensory nerve. Asymmetrical involvement is also seen.

Based on HRV and AFT testing, 72% (52) had diabetic autonomic neuropathy whereas 28% (20) were without neuropathy. Sympathetic involvement was seen in 39% (28) patients based on HRV.

Categorization of the patients based on SWME 10 gm monofilament, NCS, and AFT with HRV is shown in Table 3. The diagnostic value of SWME 10 gm monofilament testing taking AFT and NCS as reference tests is shown in Table 4.

## Discussion

The study aimed to find the effectiveness of SWME 10 gm monofilament in DPN taking NCV and AFT as reference tests.

Table 2: Characteristics of patients		
	Mean $\pm$ SD	Range (minimum to maximum)
Age (years)	50.44 $\pm$ 9.55	22-60
Weight (kg)	68.73 $\pm$ 12.66	43-97
Height (CM)	160.95 $\pm$ 10.50	132 to 189
BMI (kg/m <sup>2</sup> )	26.55 $\pm$ 4.40	14.9-39.4

BMI=basal metabolic index

Table 3: Categorization of patients based on different methods		
Names of methods	Abnormal	Normal
SWME 10 gm monofilament	72% (52)	28% (20)
NCS	94% (68)	6% (4)
AFT with HRV	72% (52)	28% (20)

Table 4: Diagnostic value of SWME 10 gm monofilament testing taking AFT and NCS as reference test								
	Sensitivity (%)		Specificity (%)		PPV (%)		NPV (%)	
Reference test	AFT	NCS	AFT	NCS	AFT	NCS	AFT	NCS
Monofilament test	70.59	69.23	0	20	92.30	69.23	0	20

Sensitivity of monofilament SWME taking NCS and AFT as reference tests were around 70%. Specificity as well as NPV taking AFT as reference test was 0%. Specificity as well as NPV taking NCS as reference test was 20%. PPV value taking AFT and NCS as reference test was 92% and 70%, respectively.

NCS was found abnormal in the majority of patients. Sensory-motor involvement was seen commonly and the pattern was predominantly mixed, that is, axonal and demyelinating. Bilateral Peroneal motor nerve and Sural sensory nerve was most commonly involved. The majority of patients had diabetic neuropathy based on HRV and AFT testing with the sympathetic system being maximally involved. Similar results were also obtained in other studies.<sup>[7,17,18]</sup>

A 10 gm SWME is considered to be a simple, inexpensive, portable test and can be a useful tool for quick outpatient department (OPD) assessment to assess loss of protective sensation. There have been various studies in which sensitivity, specificity, PPV, and NPV of 10 gm monofilament had been compared.<sup>[7,19-22]</sup> The range of sensitivity in these studies was 41–98% whereas the range of specificity was 55–100% which was not in accordance with our study. Our range of sensitivity was around 70% and specificity was 0–20% taking NCS and AFT as reference tests.

Wide variation has been found by various authors.<sup>[19,20,23]</sup> It may be due to the variability in testing procedure, lack of standard procedure, reference standard, variability in application site of monofilament, variation in the population to be studied, thick sole, patient cooperation, and also because of certain monofilaments that did not buckle at 10 gm.<sup>[24]</sup> Moreover, intra-observer and inter-observer variations occur and hence they have a disadvantage of subjective variation.<sup>[5]</sup> This could be a reason for decreased specificity of our study which is the ability of the test to identify correctly those who do not have the disease (True negative).

A diagnostic test may be considered effective if it is having an acceptable sensitivity and specificity. Our study considers this test as not the ideal screening test which is also recommended by some authors.<sup>[20,25,26]</sup> It may be useful for routine screening of asymptomatic newly diagnosed diabetes mellitus which has been also recommended in NICE guidelines.<sup>[27]</sup>

In literature, we came across studies where no significant difference in the effectiveness of 3, 4, and 10-site SWME testing for DPN was observed, however, three sites on each foot were considered sufficient to screen for diabetic neuropathy.<sup>[28]</sup> We have followed three sites for the present study.

One of the uniqueness of this study here was we had taken NCS as well as AFT as reference tests. NCS mainly assess large fiber function while AFT assesses small fiber function. Large fiber function is assessed clinically with 10 gm SWME. Small fiber function is earlier to be affected. This is the reason that nerve conduction study may be normal in DPN patients.<sup>[1]</sup> This may be the reason for more positive predictive value and less

specificity when the diagnostic value of 10 gm SWME taking AFT as reference test with that of NCS as reference test.

Various studies had used it along with vibration perception threshold and ankle reflex testing, pinprick sensation, and thermal sensation. It was found to increase diagnostic value when 10 gm SWME is combined with these tests.<sup>[1,20,25,26]</sup> We also recommend that it should not be used alone.<sup>[23,29]</sup>

Should we recommend family physician to use 10 gm SWME?

DPN is the commonest problem and family physicians play an important role in the early diagnosis of the condition. The family physician should always prefer a detailed clinical examination to diagnose the DPN in time to avoid future complications.

## Conclusion

Thus, to conclude we suggest that sole clinical use of monofilament alone is not recommended. It is always recommended to be used with other clinical methods which improve the sensitivity and specificity of the test. NCS and AFT should be done when the diagnosis is in doubt.

## Key points

- DPN is one of the frequent complications of diabetes mellitus.
- Role of 10 gm SWME is evaluated in the study taking NCS and AFT as a reference test.
- Sensitivity, specificity, PPV, and NPV using monofilament are 69.23%, 20%, 69.23%, and 20%, respectively taking NCS as reference test and 70.59%, 0, 92.30%, and 0, respectively taking AFT as reference test.
- Sole use of 10 gm SWME is not recommended.

Take home message

- Family physician should not rely on 10 gm SWME, always prefer detailed clinical examination.

Novelty

- NCS as well as AFT were taken as the reference tests.

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## Conflicts of interest

There are no conflicts of interest.

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