

# Variations in the Bedside Methods of Evaluating Diabetic Peripheral Neuropathy among Patients with Type 2 Diabetes. A Challenge for Primary Health Care Physicians in Trinidad a High Prevalence Setting for Type 2 Diabetes

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**Abstract** Objective: The purpose of this study is to compare four measurements used in the diagnosis of DN, (1) symptom scoring, (2) physical examination scoring, (3) Semmes Weinstein monofilament testing, and (4) vibration sensation among patients with T2DM attending primary care facilities in North Trinidad. In addition, the study will demonstrate discrepancies between these four methods as well as estimate the prevalence of DN. Subjects and Methods: A cross-sectional survey of 14 primary care facilities chosen randomly in North Trinidad was conducted. Of the 292 patients that were screened for entry into our study, 276 met the inclusion criteria. Using four standard clinical methods ie Symptom Scoring, Physical Examination, Monofilament testing and Vibration Perception the proportion of patient with neuropathy was measured and compared. Results: The mean age of the sample population was 60.8 SD ± 11.1 with the average duration of T2DM being 10.2 SD ± 8.4 years. Additionally, there were more females than males with a female to male ratio of 2.3:1. The proportion of participants testing positive for neuropathy by Symptom Scoring, Physical Examination, Monofilament testing and Vibration Perception was 82.6%, 54%, 42.4% and 25.4% respectively. Conclusion: In conclusion the diagnosis of peripheral neuropathy can be made only after a careful clinical examination with more than 1 test, as recommended by the American Diabetes Association. However monofilament testing may in a primary care setting may not be accurate and relevant.

**Keywords** Type 2 DM, Diabetic Peripheral Neuropathy

## 1. Introduction

Diabetic Neuropathy (DN) is a heterogeneous complication which affects distinct domains of the nervous

system singly or in combination. It is the most common form of neuropathy from all causes, [1] it is estimated that as many as 60-70% of people with diabetes have some form of nerve damage.[2] Neuropathy may be painful or painless.[3] It is not only disabling in terms of pain but is an important contributor to limb loss and subsequent mortality. DN increases the risk of amputation 1.7-fold; 12-fold if there is deformity (itself a consequence of neuropathy); and 36-fold if there is a history of previous ulceration. [4-5] In fact in our setting, for the period 2000 to 2004, 800 amputations associated with Type 2 Diabetes Mellitus (T2DM) were reported [6]. The care of patients with DN has an economic impact on health care services. The annual direct expenditure was estimated as US \$668 per capita [7].

The most common form of DN is distal symmetric polyneuropathy affecting both large myelinated fibres and thin unmyelinated C fibres. The large fibres control motor strength, position, and vibration sense. Patients with DN present clinically with weakness, deep-seated pain, or numbness and prickling sensation. DN can be detected clinically by a loss of vibration perception, loss of ankle reflexes, and quantitative sensory tests, as well as by abnormalities in electrophysiology with reductions in amplitudes, delayed conduction velocities, and loss of neurons on biopsy of sural nerves. On the other hand the prevailing neuropathies leading to the greatest morbidity and mortality are those affecting the small unmyelinated C fibres. These present with pain, allodynia, loss of warm and cold thermal perception and autonomic dysfunction.

There is no gold standard for the diagnosis of DN. A combination of symptoms, signs, quantitative sensory testing, nerve conduction studies and autonomic nerve testing has been suggested. [8]. Also, the San Antonio consensus panel has recommended that at least one measurement should be performed in five different diagnostic categories. These are symptom scoring, physical examination scoring, quantitative sensory testing (QST), cardiovascular autonomic function

testing (CAFT), and electro-diagnostic studies (EDS) [9]. In the developing world including Trinidad with limited resources especially in the primary care setting the diagnosis has to be made by clinical assessment as EDS is currently unavailable. We have embarked on this study as there is no published data on the capability of traditional clinical methods for diagnosing DN in our setting in the absence of EDS. This assessment is made independent of other biomarkers of diabetic status such as HbA1C, which is often unknown at the time of assessment

The purpose of this study therefore is to compare four measurements used in the diagnosis of DN, (1) symptom scoring, (2) physical examination scoring, (3) Semmes Weinstein monofilament testing, and (4) vibration sensation among patients with T2DM attending primary care facilities in North Trinidad. In addition, the study proposes to identify differences between these four methods as well as estimate the prevalence of DN.

## 2. Methods

We used a cross sectional study design in a population of T2DM patients currently receiving care at primary care facilities (PCF) in North Trinidad. There are 20 PCF in North Trinidad. Using random numbers 14 PCF were selected as clusters from which all T2DM patients were invited to participate in the study.

The only inclusion criterion was adult patients with T2DM. However the following exclusion criteria were applied: alcohol consumption > 14 units/week for women and > 21 units /week for men, (one unit of alcohol was defined 10mls), a history of autoimmune disorders, type one diabetes, a history of shingles, HIV positive, chronic demyelinating neuropathy (CIDN), Charcot Marie Tooth Syndrome, POEMS syndrome, a positive history of spinal cord trauma, vitamin B12 deficiency, multiple sclerosis and participants /receiving treatment with chemotherapeutic and immunotherapeutic drugs.

### 2.1. Symptom Score

Patients medical records were consecutively screened to ensure all patients satisfied the entry criteria whereupon patients were recruited after written consent. We administered by interview a 15 item questionnaire that was constructed using several published neuropathy symptom scoring systems including the Diabetic Neuropathy Symptom (DNS), the Michigan Neuropathy Screening Instrument (MNSI) and the Neuropathy Symptom Score (NSS). [10-11] The neuropathy sum score was derived using four items, neuropathic pain, paraesthesia, numbness and unsteadiness in walking. The presence of one symptom is scored as 1 point with a maximum score of 4 points. A score of 1 or higher is defined as positive for DN.

### 2.2. Monofilament Testing

The 10gm Semmes Weinstein monofilament was tested on the plantar surface of the hallux and the centre of the heel. For this examination, the patient's foot was supported (i.e., allow the sole of the foot to rest on a flat, warm surface). The filament was initially pre-stressed (4-6 perpendicular applications to the dorsum of the examiner's first finger). The filament was then applied to the dorsum of the great toe midway between the nail fold and the distal inter-phalangeal joint (DIP), without holding the toe directly. The filament is applied perpendicularly and briefly, (1 second) with an even pressure. The patient was asked to keep the eyes closed and respond "yes" if the filament was felt. Eight correct responses out of 10 applications are considered normal: one to seven correct responses indicate reduced sensation and no correct responses defines absent sensation.

### 2.3. Vibration Sensation

Vibration sensation was performed with the great toe unsupported, bilaterally, and using a 128 Hz tuning fork placed over the dorsum of the great toe on the bony prominence of the DIP joint. Patients were asked to keep the eyes closed and indicate verbally when they can no longer sense the vibration from the vibrating tuning fork.

The examiner was required to feel vibration from the hand-held tuning fork for at least 5 seconds longer on his distal forefinger than a normal subject can at the great toe (e.g. examiner's DIP joint of the first finger versus patient's toe). If the examiner felt vibration for 10 or more seconds on his or her finger, then vibration was considered decreased. A trial should be given when the tuning fork is not vibrating to be certain that the patient is responding to vibration and not pressure or some other clue. Vibration was scored as (1) present if the examiner senses the vibration on his or her finger for < 10 seconds, (2) reduced if sensed for >10 seconds or (3) absent (no vibration detection.)

### 2.4. Physical Examination Scoring

The physical examination included a foot inspection, the presence or absence of ankle reflexes which were combined with previous monofilament and vibration testing to give a cumulative score of 10. All assessments were made with the patient in a supine position and in a warm environment. Ambient air temperatures >35.

The feet were inspected for evidence of excessively dry skin, callous formation, fissures, frank ulceration or deformities. Deformities include flat feet, hammer toes, overlapping toes, Hallux Valgus, joint subluxation, prominent metatarsal heads, medial convexity (Charcot foot) and amputation. The presence of any one of these abnormalities was scored as one. The presence of ulceration was scored as one if present and zero if absent.

The ankle reflexes were examined using an appropriate reflex hammer (Queen square). The ankle reflexes were elicited in the sitting position with the foot dependent and the patient relaxed. For the reflex, the foot was passively

positioned and dorsiflexed slightly to obtain optimal stretch of the muscle. If the reflex was obtained, it was graded as present. If the reflex was absent, the patient is asked to perform the Jendrassic maneuver (i.e., hooking the fingers together and pulling). Reflexes elicited with the Jendrassic maneuver alone are designated "present with reinforcement." If the reflex is absent, even in the face of the Jendrassic it was recorded as absent.

The monofilament test was scored as previously (ie normal = 0 , reduced = 0.5 and absent =1). Finally the vibration sense was scored similarly (Present=0, Reinforced =0.5 and Absent= 1). Therefore the aggregated score for the physical examination assessment was ten.

All data collected were analyzed using SPSS version 16. The study protocol was approved by the Ethics Committee of the University of the West Indies.

### 3. Results

The study sample consisted of all T2DM patients attending 14 randomly selected primary care facilities in Trinidad. From these clusters 292 patients were screened for entry into the study of which 276 satisfied the inclusion criteria and were used in the analysis. The mean age was 60.8 (SD  $\pm$ 11.1) years and ranged from 31 to 88 years with an interquartile range of 52-68 years, table 1. There were more females 195 (70.7%) than males 81 (29.3 %) resulting in a female to male ratio of 2.3:1. There was a greater percentage of patients with a family history of diabetes 221 (80.1%), indicating a strong hereditary pattern. The average duration of DM was 10. 2 years (SD  $\pm$ 8.4) and ranged from, 5 to 58 years.

**Table 1.** characteristics of the sample.

Characteristic of sample	n (%)
Age	
0 – 45	21( 7.6 )
45 -60	111(40.2 )
$\geq$ 60	144 (52.2 )
Total	276 (100)
Gender	
Male	81(29.3)
Female	195(70.7)
Total	276 (100)
Duration of Diabetes	
$\leq$ 4.9 years	21(7.6 )
5- 15 years	114 (40.2)
$\geq$ 15	144(52.2)
Family history of Diabetes	
Positive Family history	221(80.1)
Negative Family history	55 (19.9)

Approximately a third of all patients (93, 33.7%) reported having one cardinal symptom of DN i.e. numbness or pain or paraesthesia or unsteadiness on walking. In addition 48 (17.4%) had no symptoms, 56(20.3%) had two symptoms, 63(22.8%) had three symptoms and 16(5.8%) reported four symptoms. Using the symptom score criteria only - having at

least one cardinal symptom- 228(82.6%) participants have a probable diagnosis of DN and should have further evaluation. In addition using this criterion alone the prevalence of DN in our sample was 83%. In order to access the internal consistency of our 4-item subscale we calculated a Chronbach's alpha. The Chronbach's alpha for the symptom subscale was 0.8 indicating high reliability.

**Table 2.** number and percentage of patients with only one of the four cardinal symptoms of DN.

Symptom	n (%)
Numbness	35 (12.7)
Pain	26 (9.4)
Unsteadiness	19 (6.9)
Paraesthesia	13 (4.7)
None	16(5.8)

Using monofilament testing 25.4% of patients was positive for DN. However using vibration sensation 42.4% of patients were positive for DN and 54% by physical examination, table 3.

**Table 3.** summary of point estimates of DN using four clinical measurements.

Clinical Measurement	Point estimates DN and 95% CI
Symptom Score	(228) 82.6 % (45.5-57.3)
Monofilament testing	(70) 25.4% (20.6-30.8)
Vibration	(117) 42.4% (36.2-48.8)
Physical examination	(149) 54% (48.1-59.7)

### 4. Discussion

Using four standard clinical methods we assessed patients with T2DM for the presence of DN. Our findings showed wide differences among the four methods studied, emphasizing minimal congruence among the four methods, table 3. In fact using a standard set of symptom criteria i.e. a modified diabetic neuropathy symptom score the proportion of participants with DN was as high 83%. The clinical implication of this finding may be symptom scores alone over estimates the presence of DN, and therefore is unreliable as a single method for detecting DN. This is supported by evidence that 50% of patients with peripheral neuropathy may have no symptoms [12-13]. In addition numbness appears to be the most common symptom therefore an enquiry and record of the presence of numbness is important. Further all patients who complain of numbness in the lower limb should be flagged and carefully followed as likely candidates for the development of DN. Further 25.4% of participants tested positive for DN by monofilament testing, 42.4% by vibration sensation and 54% by physical examination. In a systematic review of 173 studies Dros and colleagues demonstrated a wide range in sensitivity from

41% to 93% and specificity 68% to 100% using monofilament testing. They concluded that despite the frequent use of monofilament testing, there was little support for its accuracy in detecting neuropathy in feet without visible ulcers. [14] We found that monofilament testing was detecting the smallest proportion of participants in the study with possible DPN. The technique for testing pressure perception with the 10-g monofilament is cumbersome. In addition caution is necessary when selecting the brand of monofilament to use, as many commercially available monofilaments have been shown to be inaccurate. Single-use disposable monofilaments or those shown to be accurate by the Booth and Young study are recommended. [15] In developing countries such monofilaments may not be readily available abundantly and given their relative instability especially in hot tropical climates, monofilament testing should not be considered as an essential component in the assessment of DN.

Burns et al, is an analysis of three large cohorts studies showed that the tuning fork over estimated vibration sensation loss compared with quantitative sensory testing. Discordance between tests was associated with age, height, and body surface. Although it is a highly subjective measure the absence of vibration sensation at the great toe is significantly associated with the development of foot ulcers. [16-18] Because ankle reflex is a poor predictor of ulceration we combined it with foot inspection and vibration and monofilament testing in a composite assessment called physical examination which was predicting DN in 54% of patients.

The main limitation of the study was the unavailability of a confirmatory test such as QST. Therefore no analysis on the sensitivity and specificity of the various methods could be reported.

In conclusion the diagnosis of DN can be made only after a careful clinical examination with more than 1 test, as recommended by the American Diabetes Association. [19] Tests for this clinical examination are vibration perception (using a 128-Hz tuning fork), pressure sensation (using a 10-g monofilament at least at the distal halluces), ankle reflexes, and pinprick. [20-21] We concur with all of the test except monofilament testing. DN is associated with significant morbidity and mortality and the only intervention proven to alter its pathogenesis is glycaemic control it is important therefore for clinicians in primary care who attend to the bulk of patients with T2DM to diagnose DN early in order to limit its progression.

## Conflict of Interest Statement

This statement is to certify that all Authors have seen and approved the manuscript being submitted. We warrant that the article is the Authors' original work. We warrant that the article has not received prior publication and is not under consideration for publication elsewhere. On behalf of all Co-Authors, the corresponding Author shall bear full

responsibility for the submission. This research has not been submitted for publication nor has it been published in whole or in part elsewhere. We attest to the fact that all Authors listed on the title page have contributed significantly to the work, have read the manuscript, attest to the validity and legitimacy of the data and its interpretation and agree to its submission to CIM

The Authors of this manuscript have also certified that they comply with the Principles of Ethical Publishing. All authors agree that author list is correct in its content and order and that no modification to the author list can be made without the formal approval of the Editor-in-Chief. Named authors have satisfied the three criteria listed below and detailed in the guidelines promulgated by the International Committee of Medical Journal Editors (ICMJE), viz a vie:

1. Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
2. Drafting the article or revising it critically for important intellectual content; and
3. Final approval of the version to be published.

All authors declare no conflict of interest or competing interests under the following headings:

- (a) Financial ties
- (b) Academic commitments
- (c) Personal relationships
- (d) Religious beliefs
- (e) Institutional Affiliation

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