

# TORONTO CLINICAL NEUROPATHY SCORE AND MODIFIED TORONTO CLINICAL NEUROPATHY SCORE DIAGNOSTIC TESTS IN DISTAL DIABETIC SENSORIMOTOR POLYNEUROPATHY PATIENTS

Running Head: Toronto Clinical NeuropathyScore

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**ABSTRACT--Background:** Distal diabetic sensorimotor polyneuropathy is a common complication occurred in diabetes mellitus patients. Even though the number of diabetes mellitus patients has been increasing, the prevalence is still far from its actual numbers due to diagnostic and method criteria.

**Objectives:** We aimed to determine Toronto Clinical Neuropathy (TCN) and modified Toronto clinical neuropathy (mTCN) scores in distal diabetic sensorimotor polyneuropathy patients.

**Methods:** Cross-sectional study was carried out from October 29<sup>th</sup>, 2014-June 1<sup>st</sup>, 2015 in 77 diabetes mellitus patients who visited Outpatient Clinic. Polyneuropathy diagnosis was based on TCN and mTCN scores, with gold standard of peroneal and/or sural nerve conduction velocity examination.

**Results:** Area under curve value of TCN score was 84.5% (95% CI: 74.7%-94.3%). TCN diagnostic score above 4 had sensitivity, specificity, and accuracy of 96%, 40%, 82%, respectively. On the other hand, TCN diagnostic score above 8 had sensitivity, specificity, accuracy of 72%, 80%, 74%, respectively. The AUC value of mTCN score was 81.9% (95% CI: 71.8%-92.1%). mTCN diagnostic score above 8 had sensitivity, specificity, accuracy of 63%, 75%, 66%, respectively.

**Conclusion:** TNC score above 4 could be used as a screening test, while score above 8 could be used as a diagnostic test for distal DSP.

**Keywords**---diagnostic test, distal diabetic sensorimotor polyneuropathy, mTCN score, TCN score.

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## I. INTRODUCTION

Diabetes mellitus (DM) is a group of metabolic disorders characterized by hyperglycemia as a result of impaired insulin secretion and activity.[1] 171 million people were estimated to suffer from this disease in 2000, and this number would increase to 366 million cases in 2030.[2, 3] The Indonesian Central Bureau of Statistics reported 133 million DM patients aged over 20 in 2003, with an estimated of 8.2 million and 5.5 million DM patients living in urban and rural areas, respectively.

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Diabetic neuropathy is a group of clinical syndromes affecting various neuro system, either singular or combination. The symptoms and complaints are not specific with slow progression.[4] Diabetic peripheral neuropathy (DPN) or Distal sensorimotor polyneuropathy (DSP) or Distal symmetrical polyneuropathy (DSPN) relates to peripheral nervous system and becomes a common neuropathy type occurred in DM patients. Peripheral nervous system disorder can cause protective sensation loss and impaired perception ability, particularly diabetic ulcers in the legs. DSP is a major risk factor of amputation, and significantly can cause high morbidity in DM.[5]

DSP prevalence in the United States was around 50% in chronic diabetes patients, 7 million populations with diabetic neuropathy and 2.7 million populations suffered from painful neuropathy.[4, 6] A study found 30% neuropathy prevalence in DM patients.[7] DSP condition can affect patient's life quality, both mentally and physically. DSP correlates with numbness that commonly triggers balance disorder which subsequently causes patient to easily fall down. Neuropathy is one of major three falling risk factors, particularly in DM patients, in addition to retinopathy and vestibular dysfunction. Patient with severe DSP has ulceration and amputation risks. Around 50-70% become the major cause of non-traumatic amputation. Diabetic DSP can decrease life quality, particularly pain complaints. Neuropathy pain is one of the most common disability symptoms in DSP patients. This symptom is difficult to treat and causes social distress and burden. This eventually results in higher treatment costs. In the U.S., a quarter of the total costs of diabetes care is spent on neuropathic treatment.[7]

Nerve biopsy or Electromyography (EMG) is a gold standard in making polyneuropathy diagnosis. EMG is an invasive diagnostic method that requires special tools and skills, is relatively expensive and sometimes causes patient's discomfort. A study found that combination of neuropathy symptoms, physical examination and abnormal EMG had a more accurate diagnostic score to make establish distal polyneuropathy.[8]

Toronto clinical neuropathy score (TCNS) was validated as a score in monitoring and diagnosing DSP.[9] TCNS scoring has a considerably high sensitivity and specificity. A study reported that TCNS had sensitivity 77.2% and specificity 75.6%.[10] TCNS is quite valid since it combines DSP symptom and physical examination, including sensory evaluation (pain, temperature, touch, vibration and position), reflex physiology (patellar and Achilles reflexes) and symptoms (feet, legs and ataxia symptoms).[10] Modified TCNS since TCNS results varied greatly between assessors, age and body weight. Therefore, it must be generalized in order to obtain results that can increase scoring sensitivity in early DSP diagnosis.[11] We were interested in determining if mTCNS had a better diagnostic score than TCNS in diagnosing diabetic DSP compared to EMG as the gold standard.

## II. METHODS

There were 77 subjects fulfilled DM type 2 criteria with DSP diagnosis who visited Endocrine Outpatient Unit of Dr. Soetomo Teaching Hospital, Surabaya, Indonesia, from October 2014-June 2015. The inclusion criteria were DM type 2 subjects with DSP diagnosis aged 20-60 who signed informed consent. The study protocol was approved by the ethics committees of Dr. Soetomo Teaching Hospital, Surabaya, Indonesia.

It is a diagnostic test study to determine diagnostic score (sensitivity, specificity, Positive predictive value (PPV), Negative predictive value (NPV), accuracy and Likelihood ratio (LR) of TCNS and mTCNS to have early diagnose of DSP in DM patients compared to the gold standard of EMG examination. Data of score comparison was analyzed using 2x2 contingency table to obtain sensitivity, specificity, PPV and NPV in each confidence interval and LR value.

### III. RESULTS

#### Demographic data

There were 77 DM subjects with DSP diagnosis, consisting of 27 males (35.1%) and 50 females (64.9%; Table 1). The subjects' average age was  $51.90 \pm 5.619$  (Table 2). The largest sample distribution belonged to age group of 51-60 with 45 subjects (58.4%), followed by age group of 41-50 with 29 subjects (37.7%) and 3 subjects in the age group of 31-40 (3.9%; Table 1).

#### Clinical data

We measured height, body weight, Body mass index (BMI), Peripheral neuropathy (PNP) symptom onset, DM onset and hypertension history. The subjects' average height was  $157.23 \pm 7.287$  cm, with the tallest and the shortest subjects were 181 cm and 145 cm, respectively (Table 3). The subjects' average weight was  $61.17 \pm 9.908$  kg, with the biggest and the lowest weight were 100 kg and 43 kg, respectively (Table 4). There were 32 overweight subjects (42%), 4 underweight subjects (5%) and 41 normal subjects (53%; Table 1).

Most subjects had polyneuropathy symptom in 0-12 months onset (54 subjects, 70%), followed by 12 subjects with >12-24-month onset (16%) and 11 subjects with >24-month onset (14%; Table 1). Most subjects suffered from DM with 0-5-year duration (45 subjects, 58.4%), followed by 18 subjects with >5-10-year duration (23.4%), 11 subjects with >10-20-year duration (14.3%) and 3 subjects with >20-year duration (3.9%; Table 1). There were 33 subjects with hypertension history (42.9%) and 44 subjects without hypertension history (57.1%; Table 1).

#### EMG examination

There were 57 subjects with EMG polyneuropathy (74%) and 20 subjects without PNP (26%; Table 1)

#### TCNS diagnostic score on EMG

TCNS has cut-off point of 4. Score 0-4 indicates normal condition, while score above 4 indicates neuropathy symptoms[9]. There were 67 PNP DM subjects with TCNS cut-off point 4 (87%) and 10 subjects with normal cut-off point (13%; Table 1).

Cross-tabulation between TCNS cut-off point 4 and EMG results showed similar diagnosis: 67 patients with PNP DM diagnosis measured by TCNS and 55 patients with positive PNP DM diagnosis measured by EMG. Of 10 subjects with normal diagnosis measured using TCNS, 8 subjects (80%) were diagnosed not having PNP measured using EMG (Table 5). The diagnosis score of TCNS cut-off point 4 was as follows: sensitivity 96% (55/57, 95% CI: 92%-100%); specificity 40% (8/20, 95% CI: 19%-61%); PPV 82% (55/67, 95% CI: 73%-91%); NPV 80% (8/10, 95% CI: 55%-100%); prevalence 74% (57/77);  $LR+ = 96/(1-40) = 1.61$ ;  $LR- = (1-96)/40 = 0.09$ ; accuracy 81.8% [(55+8)/77 x 100%].

Cut-off point refers to as a boundary value between normal and abnormal, or between positive and negative test results. Cut-off point determination includes a bargaining process since increased sensitivity will cause decreased specificity in the similar data, and vice versa. Receiver operating curve (ROC) is a way to determine diagnostic test's cut-off point. It describes a bargaining process between sensitivity and specificity in the form of a graph. Sensitivity and specificity are represented on y-axis and x-axis, respectively. The higher the sensitivity, the lower the specificity, and vice versa. The closer the ROC to the diagonal line, the worse the results. The best cut-off point is the farthest point on the upper left of diagonal line.

ROC line of TCNS was far from the diagonal line, with the area under curve (AUC) value of 84.5% (95%CI: 74.7%-94.3%). ROC procedure also obtained some alternative cut-off points of TCNS along with sensitivity value. Specificity value was calculated using Microsoft Excel. The software helped to find optimal cut-off point that was obtained from the intersection of sensitivity and specificity curves. The point was between score 7.5 and 8.5. Nevertheless, this scoring had no decimal score, therefore we took optimal value of 8.

There were 41 subjects with TCNS cut-off point 8 who suffered from PNP DM (58.4%) and 32 normal subjects (41.6%; Table 1). Cross-tabulation between TCNS cut-off point 8 and EMG results showed similar diagnosis: 45 patients with PNP DM diagnosis measured using TCNS, 41 patients with positive PNP DM diagnosis measured using EMG (91.1%). Of 32 subjects with normal diagnosis measured using TCNS, 16 subjects (50%) were diagnosed not having PNP measured using EMG (Table 6). The diagnosis score of TCNS cut-off point 8 was as follows: Sensitivity 72% (41/57, 95% CI: 60%-84%); specificity 80% (16/20, 95% CI: 62%-98%); PPV 91% (41/45, 95% CI: 83%-99%); NPV 50% (16/32, 95% CI: 33%-67%); prevalence 74% (57/77);  $LR+ = 72/(1-80) = 3.60$ ;  $LR- = (1-72)/80 = 0.35$ ; accuracy 74% [(41+16)/77 x 100%].

#### **mTCNS diagnostic score on EMG**

ROC line of mTCNS was far from the diagonal line, with the AUC value of 81.9% (95%CI: 71.8%-92.1%). ROC procedure also obtained some alternative cut-off points of mTCNS along with sensitivity value, followed by specificity measurement using Microsoft Excel. The software helped to find optimal cut-off point that was obtained from the intersection of sensitivity and specificity curves. The point was between score 7.5 and 8.5 (Table 7). Nevertheless, this scoring did not have decimal score, therefore we took optimal value of 8.

There were 41 subjects with mTCNS cut-off point 8 who suffered from PNP DM (53%) and 36 normal subjects (47%; Table 1). Cross-tabulation between mTCNS cut-off point 8 and EMG results showed similar diagnosis: 41 patients with PNP DM diagnosis measured using mTCNS, 36 patients with positive PNP DM diagnosis measured using EMG (87.8%). Of 36 subjects with normal diagnosis measured using mTCNS, 15 subjects (41.6%) were diagnosed not having PNP measured using EMG. The diagnostic score of mTCNS cut-off point 8 was as follows: sensitivity 63% (36/57, 95% CI: 51%-76%); specificity 75% (15/20, 95% CI: 56%-94%); PPV 88% (36/41, 95% CI: 78%-98%); NPV 42% (15/36, 95% CI: 26%-58%); prevalence 74% (57/77);  $LR+ = 63/(1-75) = 2.53$ ;  $LR- = (1-63)/75 = 0.49$ ; accuracy 66.2% [(36+15)/77 x 100%].

#### **IV. DISCUSSION**

The subjects' average age was  $51.9 \pm 5.619$ , with most subjects belonged to age group of 51-60 (58.4%). This finding was consistent with a study conducted in India found that diabetic neuropathy subjects' average age was  $50.44 \pm 10.35$ . [12] On the other hand, a study in Sri Lanka found subjects' average age was  $62.1 \pm 10.8$ . [5]

There were 77 subjects, consisting of 27 males (35.1%) and 50 females (64.7%). The study consistent with the Sri Lankan study that obtained samples consisting of 37.1% of male and 62.9% of females. [5] The largest sample distribution belonged to age group of 51-60 with 45 subjects (58.4%), followed by age group of 41-50 with 29 subjects (37.7%) and 3 subjects in the age group of 31-40 (3.9%). It was consistent with a multi-center study conducted in the United Kingdom that reported diabetic neuropathy increased along with age. [13]

There were 32 overweight diabetic polyneuropathy subjects with BMI above 25 (42%) and 33 diabetic polyneuropathy subjects with hypertension (43%). There were 45 subjects with DM duration ranged from 0 to 5 years (59%). This study consistent with a study that reported correlation between diabetic neuropathy and modified cardiovascular risk factor, such as BMI and hypertension.[14] A study reported that age, diabetes duration and overweight correlated with increased diabetic neuropathy prevalence.[15]

TCNS above 4 had sensitivity 96%, specificity 40%, PPV 84%, NPV 80%, LR+ 1.61, LR- 0.09 and accuracy 82%. Sensitivity 96% indicated TCNS cut-off 4 ability in determining DM polyneuropathy as much as 96%. Specificity 40% indicated lower ability in determining the absence of polyneuropathy. PPV 84% indicated that if TCNS cut-off 4 showed polyneuropathy, EMG results also possibly had polyneuropathy as much as 84%. NPV 80% indicated that if TCNS cut-off 4 obtained normal value, EMG results also possibly had 80% normal value. Accuracy 82% indicated TCNS cut-off 4 conformity with EMG as much as 82%.

TCNS above 8 had sensitivity 72%, specificity 80%, PPV 91%, NPV 50%, LR+ 3.60, LR- 0.35 and accuracy 74%. Sensitivity 72% indicated TCNS cut-off 8 ability in determining DM polyneuropathy as much as 72%. Specificity 80% indicated high ability in determining the absence of polyneuropathy. PPV 91% indicated that if TCNS cut-off point 8 showed polyneuropathy, EMG results also possibly showed polyneuropathy as much as 91%. NPV 50% indicated that if TCNS cut-off point 8 showed normal value, EMG results also possibly showed normal value as much as 50%. Accuracy 74% indicated TCNS cut-off 8 conformity with EMG as much as 74%.

mTCNS score above 8 had sensitivity 63%, specificity 75%, PPV 88%, NPV 42%, LR+ 2.53, LR- 0.49 and accuracy 66%. Sensitivity 63% indicated mTCNS cut-off 8 ability in determining DM polyneuropathy as much as 63%. Specificity 75% indicated high ability in determining the absence of polyneuropathy. PPV 88% indicated that if mTCNS cut-off 8 showed polyneuropathy, EMG results also possibly showed polyneuropathy as much as 88%. NPV 42% indicated that if mTCNS cut-off 8 showed normal value, EMG results also possibly showed normal value as much as 42%. Accuracy 66% indicated mTCNS cut-off 8 conformity with EMG as much as 66%.

It could be inferred that TCNS cut-off 4 was more appropriate for screening test since it had high sensitivity value (96%) and low specificity value (40%). On the other hand, TCNS cut-off 8 (sensitivity 72%, specificity 80%) and mTCNS cut-off 8 (sensitivity 63%, specificity 75%) could be utilized as diagnostic tests since they had a higher specificity value. LR+ value obtained by TCNS cut-off 4 (1.61) indicated comparison between PNP DM patients with positive TCNS and non-PNP DM patients with positive TCNS proportion was 1.61. LR- value obtained by TCNS cut-off 4 (0.09) indicated comparison between PNP DM patients with negative TCNS and non-PNP DM patients with negative TCNS proportion was 0.09. A study reported that a strong positive diagnostic score gave LR score higher than 1, while a strong negative strong gave LR score closer to 0. On the other hand, a moderate score gave LR score around 1. The strongest positive diagnostic score was obtained by TCNS cut-off 8 (LR+ 3.60, LR- 0.35).

## V. CONCLUSION

TCNS above 4 was more appropriate for screening test since it had high sensitivity value (96%). TCNS above 8 could be utilized as diagnostic test since it had high specificity value (80%). TCNS had higher diagnostic score than mTCNS.

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**TABLES**

Table 1. Subject's characteristics by sex

| Variables             | n  | percentage(%) |
|-----------------------|----|---------------|
| Sex                   |    |               |
| Male                  | 27 | 35.1          |
| Female                | 65 | 64.9          |
| Age group             | 77 | 100.0         |
| 31–40                 | 3  | 3.9           |
| 41–50                 | 29 | 37.7          |
| 51–60                 | 45 | 58.4          |
| BMI                   |    |               |
| Underweight           | 4  | 5.2           |
| Normal                | 41 | 53.2          |
| Overweight            | 32 | 41.6          |
| Polyneuropathy onset  |    |               |
| 0-12 months           | 54 | 70.1          |
| >12-24 months         | 12 | 15.6          |
| >24 months            | 11 | 14.3          |
| DM duration           |    |               |
| 0-5 years             | 45 | 58.4          |
| >5-10 years           | 18 | 23.4          |
| >10-20years           | 11 | 14.3          |
| >20 years             | 3  | 3.9           |
| Hypertension history  |    |               |
| With                  | 33 | 42.9          |
| Without               | 44 | 57.1          |
| EMG results           |    |               |
| PNP                   | 57 | 57            |
| Non-PNP               | 20 | 26.0          |
| TCNS cut-off point 4  |    |               |
| PNP DM                | 67 | 87            |
| Normal                | 10 | 13            |
| TCNS cut-off point 8  |    |               |
| PNP DM                | 45 | 58.4          |
| Normal                | 32 | 41.6          |
| mTCNS cut-off point 8 |    |               |
| PNP DM                | 41 | 53            |
| Normal                | 36 | 47            |



Table 2. Subjects' characteristics by average age

|                   | <b>Subjects</b> |         |         |
|-------------------|-----------------|---------|---------|
|                   | Mean±SD         | Minimum | Maximum |
| <b>Age (year)</b> | 51.90±5.619     | 36      | 60      |

Table 3. Subjects' characteristics by height

|                    | <b>Subjects</b> |         |         |
|--------------------|-----------------|---------|---------|
|                    | Mean±SD         | Minimum | Maximum |
| <b>Height (cm)</b> | 157.23±7.287    | 145     | 181     |

Table 4. Subjects' characteristics by weight

|                    | <b>Subjects</b> |         |         |
|--------------------|-----------------|---------|---------|
|                    | Mean±SD         | Minimum | Maximum |
| <b>Weight (kg)</b> | 61.17±9.908     | 43      | 100     |

Table 5. Cross-tabulation (2x2 table) of TCNS cut-off point 4 and EMG

|                            |              | <b>EMG</b> |         |       |
|----------------------------|--------------|------------|---------|-------|
|                            |              | PNP DM     | Non-PNP | Total |
| <b>TCNS cutoff point 4</b> | PNP DM       | 55         | 12      | 67    |
|                            |              | 82.1%      | 17.9%   | 100%  |
|                            | Normal       | 2          | 8       | 10    |
|                            |              | 20%        | 80%     | 100%  |
|                            | <b>Total</b> | 57         | 20      | 77    |
|                            |              | 74%        | 26%     | 100%  |

Table 6. Cross-tabulation (2x2 table) of TCNS cut-off point 8 and EMG

|                            |              | <b>EMG</b> |         |       |
|----------------------------|--------------|------------|---------|-------|
|                            |              | PNP DM     | Non-PNP | Total |
| <b>TCNS cutoff point 8</b> | PNP DM       | 41         | 4       | 45    |
|                            |              | 91.1%      | 8.9%    | 100%  |
|                            | Normal       | 16         | 16      | 32    |
|                            |              | 50%        | 50%     | 100%  |
|                            | <b>Total</b> | 57         | 20      | 77    |
|                            |              | 74%        | 26%     | 100%  |

Table 7. mTCNS sensitivity and specificity from some alternative cut-points

| No. | Cut-off Point | Sensitivity | Specificity |
|-----|---------------|-------------|-------------|
| 1   | 1.00          | 1.00        | 0.00        |
| 2   | 2.50          | 1.00        | 0.05        |
| 3   | 3.50          | .98         | 0.30        |
| 4   | 4.50          | .93         | 0.50        |
| 5   | 5.50          | .84         | 0.50        |
| 6   | 6.50          | .81         | 0.60        |
| 7   | 7.50          | .77         | 0.70        |
| 8   | 8.50          | .63         | 0.75        |
| 9   | 9.50          | .58         | 0.90        |
| 10  | 10.50         | .40         | 0.95        |
| 11  | 11.50         | .33         | 1.00        |
| 12  | 12.50         | .30         | 1.00        |
| 13  | 13.50         | .25         | 1.00        |
| 14  | 14.50         | .21         | 1.00        |
| 15  | 15.50         | .18         | 1.00        |
| 16  | 16.50         | .16         | 1.00        |
| 17  | 17.50         | .14         | 1.00        |
| 18  | 18.50         | .12         | 1.00        |

Table 8. Cross-tabulation (2x2 table) of mTCNS cut-off point 8 and EMG

|                                 |        | EMG    |         | Total |
|---------------------------------|--------|--------|---------|-------|
|                                 |        | PNP DM | Non-PNP |       |
| <b>mTCNS<br/>cutoff point 8</b> | PNP DM | 36     | 5       | 41    |
|                                 |        | 87.8%  | 12.2%   | 100%  |
|                                 | Normal | 21     | 15      | 36    |
|                                 |        | 58.4%  | 41.6%   | 100%  |
| Total                           |        | 57     | 20      | 77    |
|                                 |        | 74%    | 26%     | 100%  |