Introduction

The number of patients with diabetes has been increasing worldwide, and according to the International Diabetes Federation, the global prevalence was 463 million in 2019 and is expected to reach 700 million by 2045\(^1\). Diabetes mellitus is on the rise in Japan as well. According to the National Health and Nutrition Examination Survey of 2008, the number of patients with diabetes is estimated at 10 million, and is expected to increase with the aging population\(^2\). The goals of diabetes treatment in Japan are to normalize blood glucose levels and to reduce the onset and progression of complications, as well as the rising cost of medical care. According to the 2007 National Health and Nutrition Examination

Original article

Physiotherapists’ experience of using the abbreviated diagnostic criteria for diabetic and non-diabetic patients

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Abstract

This study aimed to examine the positivity rate of the abbreviated diagnostic criteria proposed by the Diabetic Neuropathy Study Group in Japan. The medical records of the participants were retrospectively examined and classified as DPN+ for diabetes with neuropathy, DPN− for diabetes without neuropathy, and NDM for patients without diabetes. After interviewing patients for subjective symptoms, we conducted vibration sensation and Achilles tendon reflex tests. The results showed that the mean value of vibratory sensation time was 8.3 ± 2.0 seconds in the NDM, 8.5 ± 2.3 seconds in the DPN−, and 5.9 ± 2.3 seconds in the DPN+ groups. The DPN− group had a significantly longer vibratory sensation time compared to the DPN+. There were participants whose vibration sensing time, one of the diagnostic criteria, was less than 10 seconds, even in the NDM. Furthermore, participants were categorized into four groups based on age. The mean value of vibratory sensation time in DPN+ was significantly lower in NDM and DPN−, each all-age groups. Except for the NDM group of 71 years or older, there was no age-related decrease in vibratory sensation values. However, it has been shown that there are changes in neural mechanisms associated with aging, increases in sensory thresholds, and differences in vibratory sensation depending on the measurement site. It is necessary to accumulate more data to study the effect of aging on the vibration sensation and measurement site. In recent years, there have been many reports of diabetic neuropathy affecting motor function. Therefore, it seems necessary to include motor function in the physiotherapy evaluation of diabetic patients with neuropathy due to ADC.

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Vibratory sensation
Aging
Survey, the incidence of the three major complications of diabetes, neuropathy, retinopathy, and nephropathy were 11.8%, 10.6%, and 11.1%, respectively.

Diabetic neuropathy is a problem that physiotherapists should be aware of because, in serious cases, it can reduce motor function, cause foot ulcers and result in lower limb amputations. Previous studies have shown that diabetic neuropathy affects muscle strength and balance. Nomura et al. measured the knee extension muscle force (KEF) in 1442 patients with diabetes and investigated the relationship between neuropathy and age. They found no difference in KEF between patients with or without neuropathy in the 30-49 age group, but it was significantly lower in older patients with neuropathy (50-69 years and 70-87 years). Furthermore, Antonio et al. compared the swaying area as an index of balance ability and found that it was greater in patients with diabetes compared to those without. Hewston et al. reported that the incidence of falls was significantly higher in elderly patients with type 2 diabetes and that this was caused by impaired balance due to diabetic neuropathy. Therefore, physical therapists need to adequately evaluate these patients in order to plan quality physical therapy programs and manage risks.

The nerve conduction velocity testing have been used as diagnostic criteria for diabetic neuropathy, but they require and are not suitable for rehabilitation use due to considerable patient’s burden. In comparison, the abbreviated diagnostic criteria (ADC) proposed by the Diabetic Neuropathy Study Group in Japan are is simpler and conducted with devices commonly used in rehabilitation assessments, such as reflex hammers and tuning forks, which do not take up much space. On the other hand, many patients undergoing physiotherapy have a diagnosis of diabetes mellitus, but the pathogenesis and severity of the disease are unclear.

Therefore, knowing the rate of positive neuropathy with ADC in non-diabetic patients would also be important data for physiotherapy assessment. The aim of this study is to investigate the positive rate of ADC in non-diabetic patients and in diabetic patients.

**Methods**

The study included outpatients who visited Clinic A between 2015 and 2016. Patients with obvious central nervous system abnormalities, such as cerebral hemorrhage or infarction, heavy alcohol consumption, or a history of peripheral neuropathy due to bone fracture were excluded, as were patients younger than 30 years and older than 80 years of age. For the diagnosis of diabetic neuropathy, the same physiotherapist assessed all the subjects using the ADC and the results were used by the doctors to classify those with diabetic neuropathy (DPN+) and those without diabetic neuropathy (DPN−). The physicians also classified the subjects into groups without diabetes (NDM) based on blood test results.

We also investigated the effect of age by categorizing the patients into four groups: (A 1) 31-50 years, (A 2) 51-60 years, (A 3) 61-70 years, and (A 4) 71-80 years.

Prior to the measurements, the room temperature was set at 26-28 °C in the summer and 22-24 °C in the winter. According to a previous study, the sensation of the foot diminishes immediately after walking, so the test was carried out after 15 to 30 minutes of rest. We used the ADC proposed by the Diabetic Neuropathy Study Group in Japan to determine diabetic neuropathy in all participants. After interviewing patients for subjective symptoms (only existing symptoms were used), we conducted vibratory sensation and Achilles tendon reflex tests, in that order. The vibration test was conducted in the supine position. The duration of vibratory sensation was measured with a stopwatch from the medial malleoli of each leg using a 128 Hz tuning fork, and the right and left mean values were calculated. An aluminum C 128 tuning fork (Yufu Seiki G-157 A) with a total length of 21 cm was used as the vibration sensor. A sensing time of 10 seconds or greater was considered normal, and less than 10 seconds was considered abnormal. The Achilles tendon reflex was performed in the Babinski limb position or on all fours. A 22 cm long Babinski reflex hammer (Aizen Corporation) was used. The Achilles tendon reflex was considered normal when it was observed and abnormal when it was not. Patients who fulfilled at least two of the following criteria were diagnosed with DPN: concerns about bilateral sensory symptoms in their toes and the soles of their feet, bilateral diminished or absent Achilles tendon reflexes, and bilateral decreased vibratory sensations in the medial malleoli. Written and oral explanations of the purpose of the study and the publication of data were provided to the participants by their attending physicians, and consent was obtained from all of them. This study was approved by the Research
Ethics Committee of Health Science University (No.01).

Data analysis

EZR (Easy R) was used for the statistical analysis. Tukey as a multiple comparison test among the three groups. χ²-test was used for the frequency of subjective symptoms, Achilles tendon reflex, and vibration sensation abnormalities in the ADC, and Statistical significance was set at P<0.05.

Results

A total of 270 patients were included in this study, and 54 were classified as NDM, 81 as DPN−, and 135 as DPN+. The ADC positivity rate for all participants was 50.4%. The DPN− group was significantly younger than both the NDM and DPN+ groups. The DPN− group had a significantly longer disease duration compared to the DPN+. (Table 1)

Table 1 Characteristics of the study participants stratified by the three groups

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>NDM</th>
<th>DPN−</th>
<th>DPN+</th>
</tr>
</thead>
<tbody>
<tr>
<td>61.4 ± 12.8</td>
<td>56.0 ± 12.2*</td>
<td>60.6 ± 10.9</td>
<td></td>
</tr>
<tr>
<td>Sex (male/female)</td>
<td>23 / 31</td>
<td>58 / 23</td>
<td>93 / 42</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>24.0 ± 3.7</td>
<td>27.1 ± 22.9</td>
<td>25.2 ± 4.1</td>
</tr>
<tr>
<td>Duration of diabetes (years)</td>
<td>NA</td>
<td>8.1 ± 6.8</td>
<td>14.1 ± 9.3†</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>NA</td>
<td>7.5 ± 1.9</td>
<td>7.9 ± 1.7</td>
</tr>
</tbody>
</table>

BMI: Body mass index, HbA1c: Hemoglobin A1c

The tukey as a multiple comparison test among the three groups.

*: P<0.05 DPN− vs DPN+, NDM
†: P<0.05 DPN+ vs DPN−

As for the subjective symptoms, there was a significant difference between the three groups, which were present in 9% of the NDM group (n = 5), 26% of the DPN− (n = 21), and 61% of the DPN+ (n = 82). Achilles tendon reflexes were significantly different among the groups as well, prevalent in 7% of the NDM group (n = 4), 20% of the DPN− (n = 16), and 87% of the DPN+ (n = 117). With respect to vibrational sensation, 72% of the NDM group (n = 39) were reported as abnormal, compared to 67% of the DPN (n = 54) and 93% of the DPN+ group (n = 126). (Table 2)

<table>
<thead>
<tr>
<th>Subjective symptoms</th>
<th>NDM</th>
<th>DPN−</th>
<th>DPN+</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>49</td>
<td>60</td>
<td>53</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>5</td>
<td>21</td>
<td>82</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>α</td>
<td>9%</td>
<td>26%</td>
<td>61%</td>
<td></td>
</tr>
</tbody>
</table>

χ²-test was used for the frequency of subjective symptoms, Achilles tendon reflex, and vibration sensation abnormalities.

The vibratory sensation time among the three groups was 8.3 ± 2.0 seconds for NDM, 8.5 ± 2.3 seconds for DPN−, and 5.9 ± 2.3 seconds for DPN+. The DPN− had a significantly longer vibratory sensation time than the DPN+. The median for each group was 8.1 (max-min: 3.9-12.8) for NDM, 8.3 (3.6-12.4) for DPN− and 5.5 (2.2-13.1) for DPN+. (Figure 1)

Figure 1 The results of the vibratory sensation time stratified by the three groups

The tukey as a multiple comparison test among the three groups

*: P< 0.05 DPN+ vs DPN−.

To examine the effect of age, the NDM, DPN−, and DPN+ were divided into four age groups, and the vibratory sensation time was later compared. The results showed that the vibratory sensation time of the DPN+ group was significantly shorter than that of NDM and DPN−. No significant difference was found between NDM and DPN− in any age group. In all groups, we observe a tendency towards a decrease in the sensation of vibration.
with age, but A4 in the NDM group showed the greatest decrease compared to all other age groups. (Table 3)

Table 3 Effect of age on vibration sensation among the three groups

<table>
<thead>
<tr>
<th>Years</th>
<th>A1 31-50</th>
<th>A2 51-60</th>
<th>A3 61-70</th>
<th>A4 71-80</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDM</td>
<td>9.4 ± 1.9* 9.2 ± 2.3* 8.1 ± 2.0* 7.1 ± 1.5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DPN−</td>
<td>8.9 ± 2.1  8.7 ± 2.1  7.8 ± 2.3  8.9 ± 3.1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DPN+</td>
<td>6.6 ± 2.2† 6.3 ± 2.5† 5.8 ± 2.3† 5.3 ± 2.0†</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The tukey as a multiple comparison test among the three groups.

*: P<0.05 A4 vs A1, A2 A3. †: P<0.05 DPN+ vs DPN−, NDM

Discussion

This study validated the positivity rate of diabetic neuropathy by assessing with the ADC and included patients with and without diabetes. Because the original ADC requires two mandatory items, “has diabetes” and “can deny peripheral neuropathy other than diabetic neuropathy,” it is not appropriate to use the ADC for participants who do not have diabetes. On the other hand, since these diagnostic criteria were anticipated to be affected by aging, the ADC was also administered to non-diabetic participants in this study.

Our results revealed that 72% of the NDM group also felt vibrating for less than 10 seconds. In an epidemiological survey conducted in six prefectures in Tohoku using the ADC, 35.8% of participants had neuropathy11), whereas this rate was 16.2% in a survey conducted by Yokoyama et al. The prevalence of neuropathic complications varies between domestic studies. This is due to the variety of clinical presentations and the lack of international diagnostic criteria. The Michigan Neuropathy Screening Instrument (MDNS)12) and the Toronto Clinical Neuropathy Score (TCNS)13) are well-known diagnostic criteria for diabetic neuropathy. In Japan, the invasive nerve electric velocity test can be used to assess severity. But the one proposed by the Diabetes Neuropathy Association is widely used in clinical practice and is simple and easy to use. Association is widely used in clinical practice and is simple and easy to use, with a reported sensitivity of 68% and specificity of more than 70%19).

Although the MDNS, TCNS, and ADC differ in the content and evaluation of each test item, especially in terms of neurological symptoms and feet observation, there is consistency in the general idea. These criteria are mainly qualitative tests, and only the vibration sensation test is quantitative in nature and has been reported to be highly correlated with nerve conduction velocity according to previous studies10). All three methods use a C128 tuning fork for vibration testing, and the MDNS uses the on-off and the time method on the dorsal side of the hallux interphalangeal joint. However, these have not been sufficiently studied, and it has been pointed out that the threshold of detection varies with age. Our study found that the SE of the DPN+ group was approximately 6 seconds, whereas that of the DPN− and NDM groups were 8 seconds, suggesting that the vibratory sensation value is an evaluation index that increases the SE. Decorps et al. found that the thresholds of touch, vibration and pain increase with age, in comparison with the decrease in nerve conduction velocity15). The DPN+ group showed significantly lower values than the DPN− and NDM in all age subgroups.

Age did not show any effect in the NPD or NMD groups, except in the 71-80-year-old category of the latter. To obtain a cutoff value for vibration sensation, it is necessary to use the data from patients who are definitively diagnosed with neuropathy based on quantitative testing such as nerve conduction velocity. In this study, it was not possible to clarify the extent to which the effect of aging taken into consideration.

In addition, the MDNS and TCNS use the dorsal side of the hallux interphalangeal joint, which differs from the medial malleoli of the simplified diagnostic criteria. Martin et al. reported that the threshold of vibration sensation increases with age and that the percentage of abnormalities is higher in greater toe compared to the index finger16). In recent years, there have been several studies on the effect of diabetic neuropathy on locomotor activity using the simple diagnostic criteria. According to Nomura et al., knee extensor strength was shown to be affected by age17), and Kataoka et al. reported a decrease in the hallux grip strength in these patients17).

One of the limitations of this study is that nerve conduction velocity testing is said to be useful in assessing neurological deficits, and therefore future studies should be based on nerve conduction velocity testing.

In conclusion, it is possible to estimate the motor
function of patients with diabetes using simple diagnostic criteria. Future studies should focus on gathering more data on the effect of aging on vibration sensation and measurement sites.

Conflict of Interest
The authors declare no conflict of interest.

References