Effectiveness of Semmes–Weinstein monofilament examination for diabetic peripheral neuropathy screening in Ahvaz, Iran

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Abstract: Foot care prevention programs can reduce the occurrence of foot ulcerations and amputations. This investigation evaluated Effectiveness of Semmes–Weinstein monofilament examination for diabetic peripheral neuropathy screening in Ahvaz, Iran. In this quasi-experimental design 150 patients with diabetes mellitus were recruited by purposive sampling. All patients were tested for sensory neuropathy using Semmes-Weinstein Monofilament Examination. In the next phase nerve conduction velocity was examined. The sensitivity of Semmes-Weinstein Monofilament 10 g was 38.5-61.5% at sites 1-8, whereas the specificity was 77.5-95.5%. Monofilament was found to be simple, cheap and useful method and suitable for detection of sensory neuropathy in clinical examinations. Hence, we recommend screening of patients for neuropathy as soon as they are diagnosed with diabetes.

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1. Introduction

Diabetic Peripheral Neuropathy (DPN) is one of the most prevalent Complications of diabetes mellitus (DM), which can lead to noticeable morbidity and mortality, foot ulcers and amputation among the diabetic patients (Harklessa et al. 2006, Nather et al. 2008). Hence, the identification of individuals who are prone to neuropathy would result in a decrease in amputation and morbidity (Boyko et al. 1999, Levin 1996, Pliskin et al. 1994). Studies have shown that 11 percent of patients suffer from neuropathy when being diagnosed to have DM and Fifty percent of patients with DM are afflicted with it after 25 years suffering from the disease. More than 50000 amputations take place annually in the USA, for which the peripheral neuropathy is responsible in 85 percent of cases (Pham et al., 2000, Pop-Busui et al., 2007).

DPN is not always obvious clinically and it has a sub-clinical state in most cases. Therefore, if a given physician just suffices to mental symptoms during the routine checkups, the diagnosis of DPN would be inevitably delayed which would accordingly influence the treatment and prognosis of the disease (Kamei et al. 2005).

Diabetic neuropathy affects the patients' quality of life and prognosis of the disease. In addition, it can lead to sudden death, orthostatic hypotension, and lower limb amputation. In other words, recovery from these complications can be attained through early screening and diagnosis of DPN. Also, diagnosing sensory neuropathy among patients helps us to give them comprehensive training about taking care of foot and manner of wearing shoes so that the progression of diabetic foot complication would be hampered by doing such interventions (Nather et al. 2008). Thus, early diagnosis and treatment of DPN is critical when doing outpatient checkups. According to the American Diabetics Association (1996), the diagnosis of DPN requires the follow-up of these cases: a) clinical manifestations, b) clinical examinations, c) electro-diagnostic studies, d) sensory tests, and e) autonomic performance tests (Nather et al. 2008). Nonetheless, conducting electro-diagnostic studies, including nerve conduction tests or electromyography as screening tests at outpatient settings are difficult and expensive. So, the diagnosis of DPN is carried out by combining 4 of the 5 aforementioned methods. Among the quantitative sensory tests, the old and new monofilaments

including the Semmes-Weinstein Monofilament Examination (SWME) alongside other sensory tests have attracted a lot of attention as appropriate, accessible and cheap methods for early screening of DPN(Abbott et al. 2002, Dimitrakoudis and Bril 2002, Dyck et al. 2000, Perkins and Bril 2003, Tesfaye et al. 1996, Valk et al. 2000).

This test is a simple method which is used for identifying the amount of sensory neuropathy and predicting the likelihood of having diabetic foot ulcers in patients with DM so that the costs and complications that are imposed on the society due to this disease would be minimized.

Although by virtue of sensation it is easy to use SWM, the use of this test has yielded different results in different parts of the world. However, no universal standard instruction does exist with regard to how and where to use the monofilaments or interpret their results. As the SWM is the best option for clinical diagnosis due to being cheap and safe and being able to predict the likelihood of having the risk of diabetic foot ulcers or the consequent amputation and the reduction of psychological problems followed by an early diagnosis among susceptible patients alongside the increase in the quality of life (Modawal et al. 2006, Rahman et al. 2003), and considering the novelty of this method in our country, we decided to determine the sensitivity and specificity of SWM in patients referring to the Diabetic Clinic of Golestan Hospital in Ahvaz,Iran.

2. Material and Methods

A quasi-experimental design and purposive sampling were conducted. This research was conducted from 2009 to 2010 on 150 patients suffering from DM, type II, without the diabetic foot ulcers who had referred to the Diabetes Clinic of Golestan Hospital in Ahvaz.

The research sample was determined through purposive sampling by suing the following statistical formula:

$$n=\frac{\left(z_{1-\alpha/2}+z_{1-\beta}\right)^2\left[p_1(1-p_1)+p_2(1-p_2)\right]}{(p_1-p_2)^2}=148\cong 150$$

In this formula which has been adopted from previous studies, the amounts are $\alpha=0.05$ ، $\beta=0.2$ ، $p_1=0.86$ ، $p_2=0.96$ (Miranda-palma et al. 2005).

The patients who had the following criteria entered the study: (a) Patients who had a stable clinical situation and were able to cooperate with the researcher, (b) Patients who were able to have verbal communication, (c) those who were interested to participate in the study.

The patients, who had the following conditions, were excluded from the study: (a) patients who suffered from psychological problems, (b) patients who had the history of neuropathy due to other reasons like hereditary-acquired neuropathy or Guillain-Barré Syndrome, (c) pregnant women, (d) patients who had the history of brain stroke, (e) patients who had callous or any other complications in their feet, (f) and patients who were under neuropathy treatment

The 5.07 gram Semmes- Weinstein Monofilament Test

The monofilament test was conducted on the patients' both feet of by two researchers who had received the required training about the application of the monofilament under the supervision of an endocrinologist. This test was done at eight points in each foot (the dorsal aspect of the first, second, third, fourth, and fifth digits; the dorsal aspect of medial, central, and lateral aspect of mid foot) by the monofilament Semmes- Weinstein (5.07/10g). The way of doing the test was as follows:

The monofilament was accidentally placed on palm of patient's hand while his/her eyes were closed and the patient answered the following questions:

- Do you feel the monofilament placed at your palm?
- Which part of your hand is touched by the monofilament?

After making sure about this point that the patient has understood the manner of doing and responding the questions, we tested the monofilaments on the sole of both feet while the patient had closed his/her eyes.

1- The monofilament was placed on the patient's skin on which there was no callus and it was pressed to the extent that it was bent. 2) The patient was asked if s/he feels something on the foot sole; in which part of the foot is that sensation felt: left or right. 3) The test was repeated three times for each point. 4) If the patient answered wrongly two or more times after three rounds of tests on any given point, that point was recorded as positive. 5) These acts were repeated for other points too (Forouzandeh et al. 2005, Kamei et al. 2005, Mayfield and Sugarman 2000, Modawal et al. 2006). Both feet were tested for 5 to 10 minutes. The total time for implementing the intervention lasted for 8 months which started in November, 2009 and finished in June, 2010.

Diagnostic Criteria for DPN: In order to diagnose the diabetic neuropathy, the nerve conduction velocity (standard test) was also done. The doer of the nerve conduction velocity was quite blind about the clinical examination. For identifying the sensitivity and specificity, the results of the

monofilament examination were compared with the nerve conduction velocity as the gold test. The neural conduction tests have been recommended by medical studies as the gold test for assessing and validating the screening tests of diabetic neuropathy (Forouzandeh et al. 2005, Mason et al. 1999, Shin et al. 2000).

The neuropathy was approved through conducting the neural conduction test which was done by a neurologist when there was disturbance in two or more nerves and in symmetrical mode. The set applied here for taking neuromuscular graph was the Biomed, model 3520 belonging to the Negar Andisheh Company.

Data analysis: The data analysis was performed using the SPSS software Ver.16. The Sensitivity and specificity of the SWME were measured. The data were presented as means and standard deviations, and percentiles.

Ethical Considerations: After the approval of the study at the Ethics Committee of Jundishapur Medical Sciences University, Ahvaz, Iran, informed consent was taken from the patients for participating in the study. Also, the patients received enough information about the safety of this method and their freedom for entering into or exiting the study.

3. Results

Among 150 patients participating in the study, there were 47 male (31.3%) and 103 female (68.7%). The average age of the patients was 55.71 years (SD= 8.95 years) and the mean of their disease duration was 7.7 years (SD = 6.1 years). We assessed sensitivity and specificity of 10-g monofilament in terms of neuropathy trace as follows:

At least one point out of 16 points on both feet should be reported as insensate; at a minimum, two points out of 16 points on both feet should be reported as insensate; no less than 8 points out of 16 points on both feet should be reported as insensate. We found that the sensitivities of the monofilament ranged from 38.5 to 61.5 % while the specificities ranged from 77.5 to 95.5 percent (Tables 1-2).

Table 1. Sensitivity and specificity of 10 g monofilament according to the number of insensate

Testing site	Sensitivity	specificity
Semmes-weinstein 10g≥1/16	61.5	77.5
Semmes-weinstein 10g≥2/16	59	79.3
Semmes-weinstein 10g≥8/16	38.5	95.5

Data are %

Table 2. The sensitivities of the monofilament

patients	*EMG-NCV*		*Semmes-weinstein 10 gr*	
	abundance	percentile	**abundance**	percentile
One point*				
neuropathy	39	26	20	13
No-neuropathy	111	74	130	87
total	150	100	150	100
Two points†				
neuropathy	39	26	18	12
No-neuropathy	111	74	132	88
total	150	100	150	100
Eight points ‡				
neuropathy	39	26	15	10
No-neuropathy	111	74	135	90
total	150	100	150	100

* Cutoffs of ≥1 insensate sites of 16
†Cutoffs of ≥2 insensate sites of 16
‡ Cutoffs of ≥8 insensate sites of 16

4. Discussions

We applied the Semmes-Weinstein monofilament at eight points on each foot in this study. This test is one of the most important tests in clinical examination. The sensitivity of this test was 38.5-61.5 % and its specificity was 77.5-95.5% in screening the diabetic neuropathy. The almost moderate sensitivity indicates that unusual cases and numb points can be diagnosed only in highly severe neuropathy. The use of this test in our study showed that the Semmes-Weinstein 10 gram monofilament can be effective in tracing and screening the decreased of protective sense of diabetic foot. Nonetheless, those complications which are often something impossible to be diagnosed with reflexive or vibrating tests are barely diagnosed by the monofilament test. So, using this test alongside the above methods is more effective in screening the neuropathic cases. Other studies also recommended that the likelihood of screening and early diagnosis of peripheral neuropathy by using a mixture of different methods, especially a combination of monofilament with clinical examinations or clinical symptoms or sensory tests is a little increased (Abouaesha et al. 2001, Olmos et al. 1995).

Nozomu kamei (2005) tested the sensitivity and specificity of two types of monofilaments, through which the sensitivity and specificity of the SWM 10 gram was 30% and 92%, respectively. This amount was lower with respect to the sensitivity of monofilament in our study but higher with regard to its specificity which can be attributed to the number of samples, type of sampling and other characteristics of patients, including the level of HbA1c, controlling of diet and duration of DM, medications regiments (Kamei et al. 2005).

We got a sensitivity and specificity of 38.5-61.5% and 77.5-95.5% for the Semmes-Weinstein 10 gram monofilament. However, a sensitivity and specificity of 32.5-47.5% and 73.8-92.9% (Dyck et al. 2000, Valk et al. 2000) and 65-86% and 58-71% (Abbott et al. 2002, Dimitrakoudis and Bril 2002) have been reported in other studies.

The prevalence of diabetic neuropathy has been between 9.33 to 14 percent based on the positive results of the SWMF 10 gram. These findings are different from other studies' findings, including Foruzandeh's study, in which the prevalence of diabetic neuropathy was 23.9 percent based on the positive results of the monofilament test. This discrepancy can be due to the number of samples participating in the study, the type of sampling and the number of examined points (Forouzandeh et al. 2005).

Considering this point that the monofilament test has been used a lot for tracing neuropathy recently, no definite information exists about the optimal use of this test for screening the numbness of foot and accordingly the diabetic foot ulcers. Although lots of studies have used monofilaments for screening purposes, no precise data is available about the application of a standard method for monofilament up to now (Mayfield and Sugarman 2000).

A limitation with this study, the number of participants in this study was relatively small and a prospective study with sufficient power is performed to compare monofilament with other testing modalities, definitive conclusions cannot be drawn.

Conclusion

The use of monofilament alone or alongside with other methods and criteria for screening neuropathy is an easy, useful and accessible way. Following due diagnosis, therapeutic measures and required trainings, this method can prevent the great number of complications of neuropathy, especially ulcers and amputation of the diabetic foot.

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