

Research Paper: Reliability of Semmes-Weinstein Monofilaments and Tuning Fork on Pressure and Vibration Sensation Measurements in Diabetic Patients



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Citation Bagherzadeh Cham M, Mohseni-Bandpei MA, Bahramizadeh M, Kalbasi S, Biglarian A. Reliability of Semmes-Weinstein Monofilaments and Tuning Fork on Pressure and Vibration Sensation Measurements in Diabetic Patients. Iranian Rehabilitation Journal. 2019; 17(1):1-8. <http://dx.doi.org/10.32598/irj.17.1.1>

doi <http://dx.doi.org/10.32598/irj.17.1.1>



Article info:

Received: 20 Oct 2018

Accepted: 23 Jan 2019

Available Online: 01 Mar 2019

Keywords:

Pressure sensation, Vibration sensation, Observer variations, Diabetes Mellitus

ABSTRACT

Objectives: Sensory neuropathy is the major cause of ulceration in diabetic patients. Periodical sensory examination is an appropriate method to detect neuropathy and decrease the risk of diabetic foot ulcer. Semmes-Weinstein Monofilaments (SWM) and tuning fork on/off test are widely used to assess pressure and vibration sensitivity. The present study evaluated the inter- and intra-rater reliability of SWM and tuning fork to measure pressure and vibration sensations in diabetic patients.

Methods: Following ethical approval, 34 diabetic patients without foot ulceration were recruited. Feet kit SWM and tuning fork were used for pressure and vibration sensation evaluation, respectively. Measurements were performed twice on the first session with an hour interval to assess within-day reliability and the third one was demonstrated 7 days later to assess between-days reliability.

Results: Within-day Intra-class Correlation Coefficient (ICC) analysis indicated excellent levels of inter- and intra- rater reliability (ICC>0.75) for feet kit SWM in all foot regions and 128 Hz and 256 Hz tuning forks. Excellent between-days intra-rater reliability (ICC>0.75) was also obtained for SWM; however, the ICC of tuning fork was moderate. Between-days inter-rater reliability of SWM and tuning fork were high and poor, respectively.

Discussion: The obtained results indicated that SWM and tuning fork seemed to be highly reliable to measure pressure and vibration sensations in diabetic patients. However, further studies are required to support the results of current study.

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Highlights

- Semmes–Weinstein monofilaments are reliable to measure pressure sensation in diabetic patients.
- The tuning fork is reliable to measure vibration sensations in diabetic patients.

Plain Language Summary

Sensory neuropathy is one of the main causes of foot ulcer in diabetic patients. Thus, diabetic patients should be regularly evaluated for sensory perception. One of the simplest ways of sensory evaluation is to examine the pressure sensation by monofilaments and vibration sensation by tuning fork. These two tools (monofilaments and tuning fork) should have sufficient accuracy and reliability to evaluate sensory perception in diabetic patients. In this study, the reliability of these two tools was evaluated for sensory evaluation of diabetic patients and the results showed that they have sufficient reliability in several sessions (intervals of about 7 days). Also, these tests were performed by several experts that showed no significant differences in the obtained results.

1. Introduction

Peripheral Sensory Neuropathy (PSN) is the main risk factor for foot ulceration and lower extremity amputations in diabetic patients [1]. Peripheral neuropathy involves sensory, motor and autonomous systems and causes decreased pressure sensation, increased vibration perception threshold, foot deformities, and dry skin [1].

Previous research recognized sensory neuropathy as the major cause of ulceration in diabetic patients [1, 2]. Approximately 50% of diabetic patients experience peripheral neuropathy and more than 50% of them experience symptomatic neuropathy [3]. Early diagnosis of PSN is important in diabetic patients to prevent diabetic foot problems. Periodical sensory examinations are appropriate to detect neuropathy and decrease the risk of diabetic foot ulcer. According to the Polish Diabetes Society, diabetic patient's feet should be examined at every medical visit [4].

Nerve conduction velocity is a gold standard test to detect neuropathy [5]. This test is a complex, costly, and time consuming method and not suitable for clinical evaluations [6]. The ideal instrument for neuropathy examination should be easily accessible, simple to use, and reliable with high sensitivity and specificity. Several instruments are frequently used to screen peripheral neuropathies such as monofilaments, tuning fork, and biothesiometry [3, 6].

Previous studies demonstrated that Semmes-Weinstein Monofilament (SWM) and tuning fork are appropriate tools for the clinical evaluation of pressure and vibration

sense, respectively [1, 3, 5-8]. Monofilaments and tuning fork are non-invasive, available and easy to use instruments [5, 6, 9]. Monofilaments, often called SWM, are calibrated, single fiber nylon threads, identified by values ranging from 1.65 to 6.65 that generate reproducible buckling stress. The higher the value of the monofilament, the stiffer and more difficult it is to bend [5]. Monofilaments are used to detect the pressure sensation in neuropathic patients [10]. Reliability of SWM in healthy and elderly people was evaluated by the previous studies [4, 11-13].

The graduated tuning fork and tuning fork on/off tests are available in every dialectology clinic. Tuning fork test determines the ability of subjects to discriminate vibration sensation. Limited studies evaluated the reliability of graduated tuning fork for the detection of fracture- and immune-mediated polyneuropathies; however, the tuning fork on/off test reliability was overlooked [14, 15]. Previous studies demonstrated that SWM and tuning fork are appropriate tools to clinically evaluate pressure and vibration senses, respectively [1, 3-7]. Reliability of SWM and tuning fork on/off tests are important in the evaluation of periodic clinical sensation. The present study aimed to determine the within- and between-subject intra- and inter-rater reliability of pressure and vibration senses measurements with SWM presented with a 6-piece foot kit and 128 and 256 Hz tuning fork in diabetic patients.

2. Methods

Study participants

Thirty-four patients with type 2 diabetes, aged 40-60 years were recruited from Taban diabetic center, Tehran City, Iran. Participants with skin ulcer or scar in the test-

ing site, vascular diseases (absence of at least one foot pulse) and other causes of neuropathy such as alcoholism, thyroid disease, lumbar or cervical radiculopathy, inflammatory and infection diseases were excluded [16]. Neuropathy severity was assessed by the Toronto Clinical Neuropathy Score (TCNS) to maintain the patient's condition during the two test sessions.

TCNS consists of 13 items; 6 items focusing on symptoms, two items testing reflexes and 5 items assessing sensation. Symptom and sensation items answered as yes or no are given scores 0 and 1, respectively. Normal reflex item is scored 0, reduced reflex item is scored 1 and the lack of reflex item is scored 2. The maximum achievable score is 13 [17]. Participants' demographic data were recorded at the first session. The study was approved by the Medical Ethics Committee of the University of Social Welfare and Rehabilitation Sciences, Tehran, Iran. All subjects provided their informed consent and signed the consent form.

Equipment

Six feet kit SWM (North Coast Medical Inc.; USA) consisting of sizes 2.83, 3.61, 4.17, 4.56, 5.07, and 6.10 was used to evaluate the pressure sensation of foot plantar surface [18]. Four regions of both feet including heel, medial and lateral of forefoot and hallux were examined by SWM [18]. Moreover, 128 Hz and 256 Hz tuning fork (Surgicon; Germany) were employed to evaluate vibration sensation in the hallux region of both feet [9, 19].

Study procedure

Each participant was examined twice on the same day with an hour interval by one examiner in respect of inter- and intra-rater reliability. The third measurement was demonstrated 7 days later to assess between-days reliability [4, 18]. First and second examination sessions were conducted in the same room and under the same condition. The testing protocol was described briefly for all participants and a simple test was performed on the patient's hand to become familiarize with monofilament and tuning fork test in the first session.

The patients were requested to remove shoes and socks, lay on the bed and close eyes; then, they were instructed to say "yes" each time they felt the pressure of monofilament. Both examiners randomly selected SWM size and foot region for pressure sensation test. Examiners placed the monofilament on the plantar surface of the foot and pressed it to bend into a C-shape for approximately 11/2 seconds. Pressure sensation tests were repeated three

times at each foot region with each monofilament [20, 21]. After an hour interval, the second measurement was performed using SWM and tuning fork.

Vibration testing by 128 Hz and 256 Hz tuning fork on/off method was applied to the hallux of both feet. The patient was requested to report the lack/existence of vibration [5]. Vibration sensation test was repeated three times for both tuning fork frequencies, while vibration was randomly off in one test. To evaluate the between-days reliability of kit SWM for feet and tuning fork, a similar protocol was performed with a 7 days interval.

Statistical analysis

Descriptive statistic were used to describe the demographic data. Intra-class Correlation Coefficients (ICC) and Standard Error of the Mean (SEM) were calculated to evaluate within- and between-subject inter- and intra-rater reliability of SWM and tuning fork test. Based on Rosner's classification, $ICC \geq 0.75$ represent excellent, $0.4 \leq ICC < 0.75$ indicate fair to good, and < 0.4 demonstrate poor reliability [22]. Statistical analyses were performed using SPSS.

3. Results

Thirty-four patients (11 men and 23 female) were included in the study. The study participants' demographic data are listed in Table 1. Neuropathy severity was similar in both sessions among all study participants based on TCNS ($P > 0.05$). The ICC analysis results suggested excellent levels of inter- and intra-rater reliability ($ICC \geq 0.75$) with respect to SWM in all regions of feet and both tuning fork frequencies (Tables 2 and 3).

Between-days intra-rater reliability of SWM was excellent, except for right medial forefoot and left lateral forefoot ($ICC = 0.73$) (Table 2). Between-days intra-rater ICC of both tuning fork frequencies were moderate ($0.4 \leq ICC < 0.75$) (Table 3). Between-days inter-rater reliability of SWM was high, except for medial forefoot of both feet ($ICC = 0.62$ and 0.46 , respectively) (Table 2), and it was poor by tuning fork (Table 3).

Within-day intra-rater ICC values of pressure sensation with all sizes of SWM were 0.93 (right heel, medial forefoot and hallux) to 0.89 (left lateral of forefoot); within-day inter-rater reliability were 0.92 (right hallux) to 0.79 (right Heel). Between-days intra-rater reliability range were 0.91 (left heel) to 0.73 (right lateral forefoot and left medial forefoot) and inter-rater ICC were 0.84 (left heel) to 0.46 (left medial forefoot).

Table 1. Participants' demographic characteristics

| Variable | Mean±SD | Minimum | Maximum |
|------------------------------------|-------------|---------|---------|
| Age, y | 51.64±6.52 | 40 | 60 |
| Weight, kg | 72.67±8.85 | 56 | 93 |
| Height, cm | 166.55±7.64 | 155 | 180 |
| Body mass index, kg/m ² | 26.22±2.98 | 21.46 | 32.37 |
| Disease duration, y | 11.70±5.80 | 3 | 30 |

Iranian Rehabilitation Journal

Within-day intra-rater reliability range of vibration sensation with both tuning fork frequency was 0.92 (256 Hz in right hallux) to 0.82 (128 Hz in right hallux), and inter-rater ICC was 0.92 (256 Hz in left hallux) to 0.76 (128 Hz in right hallux). Between-days intra-rater reliability range was 0.71 (128 Hz in right hallux) to 0.46 (128 Hz in left hallux) and inter-rater ICCs were 0.47 (256 Hz in left hallux) to 0.18 (128 Hz right hallux).

4. Discussion

High levels of within- and between-days inter-rater reliability were detected for the SWM in the present study. Our result was in line with other studies that reported

high inter-rater reliability [11, 12, 18, 23]. However, it was in contrast with Rozentel et al. and Collins et al. studies that documented low inter-rater reliability [13, 24].

Examiner professionalism was important in measuring pressure sensation by SWM and affected the level of data reliability [12, 25]. Robert et al. study demonstrated that a professionally trained examiner positively affected inter-rater reliability. Examiners of the current study (M.B, A.M) were expert to evaluate pressure and vibration sensation by SWM and tuning fork and were trained by a professional neurologist [25].

Table 2. ICC and SEM for inter-and intra-rater reliability of measuring pressure sensation with Semmes-Weinstein monofilaments

| Reliability | Area | Right Foot | | | | | | | | Left Foot | | | | | | | |
|--------------|-------------|------------|-------|-----------------|-------|------------------|-------|--------|-------|-----------|-------|-----------------|-------|------------------|-------|--------|-------|
| | | Heel | | Medial Forefoot | | Lateral Forefoot | | Hallux | | Heel | | Medial Forefoot | | Lateral Forefoot | | Hallux | |
| | | ICC | SEM | ICC | SEM | ICC | SEM | ICC | SEM | ICC | SEM | ICC | SEM | ICC | SEM | ICC | SEM |
| Within day | Intra-rater | 0.93 | 0.151 | 0.93 | 0.427 | 0.91 | 0.550 | 0.93 | 0.702 | 0.91 | 0.866 | 0.90 | 1.168 | 0.91 | 0.980 | 0.91 | 0.876 |
| | Inter-rater | 0.79 | 2.012 | 0.88 | 1.154 | 0.83 | 0.999 | 0.93 | 0.191 | 0.86 | 0.317 | 0.80 | 2.096 | 0.83 | 2.108 | 0.88 | 1.095 |
| Between days | Intra-rater | 0.89 | 1.687 | 0.73 | 0.54 | 0.75 | 0.92 | 0.78 | 0.812 | 0.90 | 0.727 | 0.78 | 0.703 | 0.73 | 1.08 | 0.89 | 0.574 |
| | Inter-rater | 0.78 | 1.842 | 0.62 | 2.136 | 0.83 | 0.924 | 0.75 | 0.807 | 0.84 | 0.646 | 0.46 | 2.971 | 0.76 | 0.339 | 0.78 | 2.113 |

Iranian Rehabilitation Journal

Table 3. ICC and SEM for within-and between-days inter-and intra-rater reliability of measuring vibration sensation with both tuning fork frequencies

| Reliability | Frequency | Right Foot | | | | Left Foot | | | |
|--------------|-------------|------------|-------|--------|-------|-----------|-------|--------|-------|
| | | 128 Hz | | 256 Hz | | 128 Hz | | 256 Hz | |
| | | ICC | SEM | ICC | SEM | ICC | SEM | ICC | SEM |
| Within day | Intra-rater | 0.82 | 0.587 | 0.91 | 0.623 | 0.91 | 0.587 | 0.90 | 0.657 |
| | Inter-rater | 0.76 | 1.697 | 0.86 | 1.296 | 0.83 | 2.286 | 0.90 | 0.784 |
| Between days | Intra-rater | 0.71 | 2.986 | 0.46 | 2.546 | 0.52 | 5.763 | 0.66 | 2.021 |
| | Inter-rater | 0.44 | 3.743 | 0.18 | 2.512 | 0.42 | 5.279 | 0.47 | 1.193 |

Iranian Rehabilitation Journal

The participant's individual variation affected the reliability [26]. All studies that reported low inter-rater reliability of SWM have examined healthy people [13, 24]. Individual variation was low in healthy people; however, other studies that examined the reliability of SWM in elderly [11] or patients [12, 18, 23] reported high levels of inter-rater reliability. The present study evaluated the diabetic patients with and without neuropathy and the ICC revealed a high inter-rater reliability.

A number of monofilament, test location and examiner may affect the level of reliability. A prolonged period of the test may lead to fatigue and decreases participant's concentration. Although long-time participant's immobilization for testing decreased lower limb blood circulation and foot temperature. Decreased skin temperature is affected by plantar sensation [27].

Furthermore, increased number of tests and examiners enhanced participant's learning. Anderson et al. [12] and Roberts et al. [25] performed test-retest assessment by 5 and 9 expert and trained examiners, respectively. These studies reported high inter-rater reliability; however, Collins et al. [13] evaluated inter-rater reliability by two examiners and reported a low reliability. In the present study, 6 sizes of SWM were tested in the 4 areas of both feet by the first examiner and retested after 5 minutes by the second examiner.

A maximum time lasted approximately 5 minutes for all tests performed by each examiner. Moreover, temperature, room condition and participant's position were similar in all tests.

Test location may affect the reliability score [13]; Collins et al. indicated stronger reliability for some sub-tests [13]. Heel, metatarsal head and the plantar surface of toes (especially hallux toes) are evaluated for testing plantar

sensation in diabetic patients [28]. Previous studies argued that heel, hallux and metatarsal head were reliable testing regions [18]. In the current study, within- and between-days inter-rater reliability were excellent in all areas except for medial forefoot of both feet in between-days inter-rater reliability that was moderate.

The intra-rater reliability demonstrated high ICC in within- and between-days examination, similar to previous studies [13, 18, 23]. Only the reliability of right medial forefoot and left lateral forefoot were moderate. Collins et al. assessed the between-days intra-rater reliability in healthy people and reported good reliability for the right foot and poor-to-moderate reliability for the left foot. Individual's variation and examiner proficient affected the reliability [25, 26]. Studies demonstrated that vibration sensation test is appropriate for neuropathy diagnosis in diabetic patients [28]. Reliability of graduate tuning fork was assessed in diabetic and polyneuropathy patients [14].

There is no data available on the reliability of on/off method of tuning fork for vibration sensation evaluation in diabetic patients. Results of the present study demonstrated that within-day intra- and inter-rater reliability of tuning fork were excellent. However, between-days intra- and inter-rater reliability were moderate and poor, respectively.

An analysis of 3 cohort studies indicated that disagreement in tuning fork result was associated with age, height and the area of vibration test. In addition, the vibration sensation test by tuning fork results depended on examiner experience and were highly subjective [28]. In our study, both evaluators were expert and only the vibration sensation of hallux was examined. Percentage of the correct answer on total on/off test of each tuning fork was calculated and the personal opinion of the examiner did not affect the results.

5. Conclusion

The current study was demonstrated to investigate reliability of within- and between-days inter- and intra-rater reliability in diabetic patients by SWM and tuning fork test. The between-days inter- and intra-rater reliability of the tuning fork were low. The sensation of diabetic patients must be periodically evaluated to understand whether SWM is a reliable tool for this reason.

Ethical Considerations

Compliance with ethical guidelines

All procedures performed in studies involving human participants were in accordance with the ethical standards of the University of Social Welfare and Rehabilitation Sciences research committee and with the 2013 Helsinki declaration. Informed consent was obtained from all patients included in the study.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Authors contributions

Designing and performing tests: Masumeh Bagherzadeh Cham and Akbar Biglarian; Collecting the data and co-writing the paper: Masumeh Bagherzadeh Cham and Saeed Kalbasi; Performing the analysis: Akbar Biglarian; and Supervising the research: Mohammad Ali Mohseni-Bandpei and Mahmood Bahramizadeh.

Conflict of interest

The authors declare no conflict of interest.

Acknowledgements

The authors would like to thank the Iran National Science Foundation (INSF), Tehran, Iran for supporting this study.

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