Monofilament for preventing the diabetic foot: an integrative review of the literature

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ABSTRACT

Aim: To verify, in the scientific production, the degree of reliability of the Semmens-Weinstein monofilament as a risk assessment tool for diabetic foot. Method: This is an integrative literature review conducted from consultation of the electronic databases CINAHL, MEDLINE, SCOPUS and SCIELO. Results: Six articles comprising five cross-sectional studies and one cohort study were selected. The six articles included in the review were taken from medical journals; no nursing publication was found that met the goal. Conclusion: The Semmens-Weinstein monofilament is a reliable tool which has the best performance for assessing the risk for diabetic foot and its applicability is extremely important in consultations.

Descriptors: Diabetic Foot; Peripheral Nervous System Diseases; Risk Assessment; Nursing Care.
INTRODUCTION

Diabetes mellitus (DM) is a chronic metabolic disease that is caused by anomalous metabolism of carbohydrates which results in defects in insulin secretion, thereby causing the elevation of the blood glucose level\(^1\). It can be classified in two categories: type I diabetes occurs when there is a lack of insulin in the body, requiring the use of insulin, and type II diabetes which is characterized by insufficient production of insulin or when the body cannot use it effectively\(^2\).

In Brazil, chronic non-communicable diseases account for 72.4% of the causes of deaths. Data from the Risk Factors Surveillance and Protection for Chronic Diseases obtained by telephone survey (Vigitel), collected in 2013, show that the prevalence of diabetes in the population is 6.9%. Furthermore, 12.2% of the diagnosed population of both sexes has up to eight years of schooling. When comparing the prevalence between genders, it is observed that diabetes affects more females (7.2%) than males (6.5%). In this survey, 8.5% of individuals over 45 years of age and 22.1% of those over 65 reported being diabetic\(^3\).

Data obtained by SisHiperdia (Registration and Monitoring System for Hypertensive Diabetics) show that of the more than 1.6 million registered cases of DM, 4.3% had diabetic foot and 2.2% had limbs amputated\(^4\). It is noteworthy that approximately 10 to 25% of DM patients over 70 years of age develop lesions in the lower limbs; of these, 14 to 24% have the limb amputated\(^5\).

The lower limbs are more vulnerable to the appearance of ulcers in patients with DM. Thus, professionals have been working on the need for more special care aimed at the feet of these patients. Over 10% of patients diagnosed with diabetes are prone to developing ulcers on the feet\(^6,7\).

The term diabetic foot is used to refer to the changes and complications in the feet of diabetic patients, which include the presence of infection, ulceration and/or destruction of deep tissues associated with neurological abnormalities and various degrees of peripheral vascular disease. It can be classified as neuropathic, vascular (ischemic), and mixed when it is both neuropathic and vascular\(^8\).

Risk factors for the worsening of diabetes and the emergence of foot ulcers are: age, type and time of diagnosis, inadequate control of blood glucose, smoking, alcoholism, obesity, hypertension, a history of ulcers in the feet, non-traumatic amputation, poor health education, neuropathy, non-ulcerative calluses and injuries, and the use of inappropriate footwear\(^9\).

The presence of peripheral neuropathy in diabetic patients contributes to episodes of trauma and ulcerations, causing gradual loss of protective sensitivity, and the perception of plantar pressure and temperature. The atrophy of the intrinsic muscles of the foot, due to neuropathy, can trigger osteoarticular deformities and gait changes/deambulation, which also contribute to the development of plantar ulcers\(^9,10\).

One of the obstacles for preventing diabetic foot is the lack of examinations of the feet in clinical practice, although this is already a best practice in national and international consensus. Nurses have an important role in guiding care and providing nursing consultation to patients with DM. They also have the responsibility to physically examine the feet, aimed at preventing diabetic foot\(^5\), since it is known that 85% of the problems related to the diabetic foot are capable of prevention\(^10\).

The neurological assessment of the feet can be performed with the use of three techniques recommended by the Ministry of
Health:\(^8\): evaluation of tactile sensitivity by means of the Semmens-Weinstein monofilament, evaluation of the vibration sensitivity with a pitch of 128 Hz, and evaluation of the Achilles tendon reflection.

Although the monofilament test was originally used in leprosy research, this technique has demonstrated high specificity in the diagnosis of diabetic neuropathy:\(^10,11\). Its use has been recommended by the ease of the test and its relative cost-effectiveness, in addition to the high reproducibility of the results and its ability to predict ulcerations in diabetics:\(^11\).

The early diagnosis of peripheral neuropathy associated with educational measures and encouragement of self-care of the feet can reduce the incidence of diabetic foot and the risk of amputations. It is believed that the use of the Semmens-Weinstein monofilament test in nursing consultations has a great impact in this context.

This study has the general objective to verify, in scientific production, the degree of reliability of the Semmens-Weinstein monofilament as a risk assessment tool for the diabetic foot. In addition, it will consider the following specific objectives: to verify the existence of reliable alternatives to performing a test for the loss of sensitivity of the feet; to assess and discuss the use of these tests for the early detection of neuropathy; to assess the reliability of testing for neuropathy; and to compare the functionality of other devices to the Semmens-Weinstein monofilament.

METHOD

In this study, the integrative literature review was used as a method for the preparation of the research. This method was chosen because it provides the synthesis of multiple published studies, allows general conclusions, is broader, and is a more advantageous method for enabling simultaneous inclusion of experimental or quasi-experimental research, providing opportunities for the formation of new knowledge, based on the results presented by previous research:\(^12\).

With the aim of improving the integrative review of literature works, Souza, Silva, and Carvalho:\(^13\) listed six stages of the development of the integrative review process that were followed in this work: (1) elaboration of guiding question, (2) search or sampling in the literature, (3) data collection, (4) critical analysis of the studies included, (5) discussion of the results, and (6) presentation of the integrative review.

For the elaboration of the guiding question, we used the PICO strategy (patient population, intervention, comparison, and outcomes): Is the Semmens-Weinstein monofilament test 10g the best option for the early detection of peripheral neuropathy in diabetic patients?

For the literature search, the descriptor diabetic foot (DeCS/MeSH) and the keyword monofilament were chosen. The studies considered eligible were those available in full, published in the last five years (2010–2015) in English, Portuguese, and Spanish. The articles excluded were those that mentioned monofilament as a prevention of other conditions and those that did not use a clear methodology.

The bibliographic survey was conducted in March and April 2015, by two expert reviewers individually, using the descriptor diabetic foot alone and combined with the keyword monofilament with the Boolean operator “and”. The keyword monofilament was also used alone for the search. The databases consulted were the Cumulative Index to Nursing in Allied Health Literature (CINAHL),
the Medical Literature Analysis and Retrieval System Online (MEDLINE), SciVerse Scopus and the Scientific Electronic Library Online (SciELO). The resources available for each database for retrieving publications were used to filter the time, language, and type of study.

The information obtained individually by the expert reviewers consisted of the complete references of articles, abstracts, and key words. During the search, each reviewer applied the criteria for inclusion and exclusion previously established, and read the title and abstract. To obtain the final report, all abstracts were read by at least two reviewers, and in cases of doubt about the inclusion of a study, the summary was read by a third reviewer.

All studies selected from the reading of the abstracts were obtained and read in their entirety by at least three reviewers, and then were analyzed by the instrument developed by URSI for the construction of integrative reviews.

Souza, Silva, and Carvalho (2010) recommend the use of the instrument validated by URSI, which includes the following: name of research, type of publication, methodological detailing, sample detailing, studied intervention, findings, recommendations, and conclusions. This instrument is provided in Annex A.

The studies were analyzed descriptively and presented according to language, country of origin, type of study, evaluated instrument, level of evidence, and main results.

RESULTS

The survey of the databases generated 59 articles related to the study. After application of the previously defined exclusion and inclusion criteria and analysis of the titles related to the theme, an initial sample was obtained with 24 articles whose summaries were read and analyzed according to the research objectives, resulting in a final sample of six articles.

For data collection, the items selected in the final sample were listed one (1) to six (6), according to the year of publication, in an ascending order. They are identified by presenting the bibliographic reference prepared in Picture 01 below:

The sample comprised five cross-sectional studies and one cohort study. Note that the six articles included in the review were taken from medical journals; however, no publication was identified in nursing journals.

The selected articles were written in two languages, English and Portuguese, following the inclusion criteria of the study. As can be seen in Table 1, 84% of the articles were written in English and 16% of the articles in Portuguese.

<table>
<thead>
<tr>
<th>LANGUAGE</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nº</td>
<td>%</td>
</tr>
<tr>
<td>English</td>
<td>5  84</td>
</tr>
<tr>
<td>Portuguese</td>
<td>1  16</td>
</tr>
<tr>
<td>TOTAL</td>
<td>6  100</td>
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</tbody>
</table>

Source: prepared by the authors.

From the data presented above and in order to characterize the sample, the data reported were those relating to the identification of the original country of the articles, presented in Table 2.

The United States was the country that produced articles with the theme proposed in this study. It is noticeable that there is a scarcity of published studies using monofilament for the early detection of peripheral neuropathy. However, to date there have been no national publications on the reliability of...
Figure 1 - Flowchart Explanatory of the selection of articles to form the sample. Lauro de Freitas, 2015.

Source: prepared by the authors.
Picture 1 - List of articles that were part of the sample. Lauro de Freitas, 2015.

<table>
<thead>
<tr>
<th>ARTICLE</th>
<th>TYPE</th>
<th>AUTHOR</th>
<th>YEAR</th>
<th>EQUIPMENT/TOOLS</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Cross-sectional study</td>
<td>FERREIRA, M. C., VIEIRA, S. A. T., de CARVALHO, V. F.</td>
<td>2010</td>
<td>PSSD</td>
</tr>
<tr>
<td>3</td>
<td>Cross-sectional study</td>
<td>ELLAWAY, P. H., CATLEY, M.</td>
<td>2012</td>
<td>Electric Perception Threshold Test and Semmes-Weinstein</td>
</tr>
<tr>
<td>4</td>
<td>Retrospective Cohort Study</td>
<td>KATON, J. G., REIBER, G. E., NELSON, K. M.</td>
<td>2013</td>
<td>Semmens-Weinstein</td>
</tr>
<tr>
<td>6</td>
<td>Cross-sectional study</td>
<td>HIRE, J. M., RAMADORAI, U. E., CONTRACTOR, S., JACOBS, J. M., BOJESCU, J. A., ABELL, B. E.</td>
<td>2014</td>
<td>Angiocatheter 24g x 0.75</td>
</tr>
</tbody>
</table>

Source: prepared by the authors.

Picture 2 - Equipment / tools used for diagnosis of peripheral neuropathy. Lauro de Freitas, 2015.

<table>
<thead>
<tr>
<th>ARTICLE</th>
<th>TYPE</th>
<th>AUTHOR</th>
<th>YEAR</th>
<th>EQUIPMENT/TOOLS</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Cross-sectional study</td>
<td>FERREIRA, M. C., VIEIRA, S. A. T., de CARVALHO, V. F.</td>
<td>2010</td>
<td>PSSD</td>
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<tr>
<td>3</td>
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<td>2014</td>
<td>Angiocatheter 24g x 0.75</td>
</tr>
</tbody>
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Source: prepared by the authors.
the Semmens-Weinstein test for the purpose of early detection of peripheral neuropathy. According to the results, it can be noted that 84% of the samples are of foreign origin.

**Table 2 -** Distribution of studies according to country of origin of the article. Lauro de Freitas, 2015.

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>NO.</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>2</td>
<td>32</td>
</tr>
<tr>
<td>Brazil</td>
<td>1</td>
<td>17</td>
</tr>
<tr>
<td>Netherlands</td>
<td>1</td>
<td>17</td>
</tr>
<tr>
<td>Israel</td>
<td>1</td>
<td>17</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>1</td>
<td>17</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>6</strong></td>
<td><strong>100</strong></td>
</tr>
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*Source: prepared by the authors.*

Picture 2 shows the different types of methods used and tested as possible tools for the clinical examination for the early detection of peripheral neuropathy.

Three articles used the monofilament as a test for diagnosing loss of peripheral sensitivity, one article used the PSSD technique (Pressure-Specified Sensory Device), one used the test of electrical perception threshold to compare their results to the Semmens-Weinstein monofilament in order to compare the reliability of the tests, and one used an angiocatheter as the equipment to test peripheral sensitivity as a possible replacement for the monofilament.

Article 01 aimed to determine the intra-rater reliability, inter-rater reliability and normal reference score of the Semmens-Weinstein test of the feet of healthy individuals. It was concluded that the measurements of the Semmens-Weinstein (SW) monofilament of the plantar side of the feet are reliable when measured by a single researcher. The SW is able to detect changes in real sensory limits; however, it is not clear whether the SW monofilament is sufficiently stable to be used in research.

Article 02 determined and compared the skin sensitivity thresholds in the feet of diabetic patients with ulcers in one of the lower limbs. It was clear that the PSSD can be more accurate than the test with the SW monofilament, as it does not differentiate members with and without ulcers as the PSSD does. Thus, PSSD is reliable and useful to perform accurate diagnosis of sensitivity loss in diabetic patients in a demonstrable quantitative way.

Article 03 compared the reliability of the electrical perception threshold testing (EPT) and SW of cutaneous sensibility in a neurologically healthy population, resulting in small changes in the limits of 95% between the various dermatomes for both methods, and no relationship between the size of the gap, the evaluations, and the average magnitude of a measure for any dermatome by any of the methods.

Article 04 determined whether the status of diabetes is associated with increased risk of peripheral neuropathy using the SW monofilament as a sensitivity test. The results suggested that DM is associated with a risk almost twice higher for peripheral neuropathy.

Article 05 studied the meaning, hitherto unexamined, of false-positive responses. It was proven that false-positive responses in the SW test are common in diabetic patients with and without a history of ulceration and may be an important factor in evaluating the results.

Article 06 tested the functionality of an angiocatheter to replace the SW monofilament, in the case of unavailability. It was concluded that the angiocatheter can complement the range of tools for the examinations provided by health care; however, the SW 10g remains the gold standard.
DISCUSSION

Different studies have been conducted on the diabetic foot. It is apparent that the most frequently tested method is still the Semmens-Weinstein monofilament, and it can be concluded that the measurements are reliable when measured by a single researcher. In addition, the normal sensory score is between 3.22 and 4.08\(^\text{(14)}\), which is reliable and easy to handle. However, recent research shows the attempt to find another technique to replace the monofilament in the event of failure, or which could be safer; and also concern in terms of the reliability of the results of the SW monofilament as a prevention for diabetic foot.

The comparative analysis of the EPT and SW test, as two tests that can evaluate different skin sensitivity modes, shows that there are small differences within a 95% limit between them. The ICC (intraclass correlation coefficient) ranged from 0.46 to 0.61 for the Semmens-Weinstein test and 0.67 to 0.81 for the EPT, concluding that the individual at risk would benefit by performing the two tests, since one complements the other\(^\text{(15)}\).

There are an increasing number of treatments and sophisticated tests to combat the impact of diabetes. Failure to meet these in early prevention impacts the quality of life of patients\(^\text{(16)}\). As for equipment/instruments that were used as alternatives to the SW monofilament studies, the PSSD stood out for being a more accurate piece of equipment, capable of differentiating members with and without injury. Therefore, it is a test that can complement the SW test to be performed at screening, in order to evaluate the loss of sensitivity, since the p value was less than 0.001 for all tests performed with this equipment, showing statistical significance\(^\text{(17)}\). It was also identified that the angiocatheter 24g X 0.75 can replace SW monofilament in the event of lack of funds to purchase it, for the examination and early detection of diabetic foot risk, having a reliability with higher values at 0.98 (p<0.001). However, the gold standard remains the SW monofilament with a reported sensitivity and specificity of 0.95 to 0.82 for the diagnosis of loss of sensation, proving its efficiency and reliability\(^\text{(18,19,20)}\).

The objective is the increased use of a systematic evaluation of individuals with the SW monofilament test, aiming at maintaining the preventive measures for complications. The use of the SW test would be sufficient for the diagnosis of patients at risk of neuropathy during routine primary care consultations. Individuals at risk should understand the implications of the loss of protective sensation and the importance of having daily foot care\(^\text{(6,9,21)}\).

No study related to the prevention and/or treatment provided to a patient who loses sensitivity to the SW monofilament, referring to the monitoring performed on this patient, has been found until now\(^\text{(22)}\).

This study reinforces the need for units for the specialized treatment of patients with diabetes, where the risk of developing peripheral neuropathy is valued; it creates a system for classifying the risk and/or the development of diabetic foot; and it requires places in which to plan and implement programs for prevention and early detection of these diseases in order to avoid frequent amputations of the lower limbs\(^\text{(23)}\).

CONCLUSION

The results of this study achieved the proposed objectives, concluding that the SW monofilament test is reliable for the early detection of diabetic foot. It is of utmost im-
portance to its applicability in consultations given to diabetic patients, and may also be supplemented with other tests, such as PSSD, in order to obtain an even more specific result regarding the existence of peripheral neuropathy.

The study provided knowledge of new equipment, such as PSSD and angiocatheter 24g X 0.75, which assist the SW monofilament in a reliable manner and can be performed together or even replace it.

Although the reliability of the SW test has been tested and approved for the early detection of peripheral neuropathy, its applicability has still been neglected given the increasing diagnoses of diabetic foot, which can be seen through the high index of diabetic foot and amputations of the lower limbs as a result of peripheral neuropathy.

In addition to stimulating foot care and promoting educational activities about diabetes diseases, nurses should examine and apply the SW monofilament test, since it remains the gold standard due to its low cost and easy and reliable handling. It can contribute to the prevention of peripheral neuropathy and its consequences, enabling awareness among these individuals for the development of self-care and promotion of quality of life.

Although the SW monofilament test has been potentially able to identify the risk for diabetic foot, further studies should be conducted in order to ascertain the impact of early diagnosis of peripheral neuropathy on the prevention of diabetic foot, considering the current scenario of the Brazilian public policies for health. In this context, it is necessary to know how to predict this risk, when considering the use of the SW monofilament test individually or combined with other techniques, such as the PSSD, from the first consultation in the basic health network.

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All authors participated in the phases of this publication in one or more of the following steps, in accordance to the recommendations of the International Committee of Medical Journal Editors (ICMJE, 2013): (a) substantial involvement in the planning or preparation of the manuscript or in the collection, analysis or interpretation of data; (b) preparation of the manuscript or conducting critical revision of intellectual content; (c) approval of the versión submitted of this manuscript. All authors declare for the appropriate purposes that the responsibilities related to all aspects of the manuscript submitted to OBJN are yours. They ensure that issues related to the accuracy or integrity of any part of the article were properly investigated and resolved. Therefore, they exempt the OBJN of any participation whatsoever in any imbroglios concerning the content under consideration. All authors declare that they have no conflict of interest of financial or personal nature concerning this manuscript which may influence the writing and/or interpretation of the findings. This statement has been digitally signed by all authors as recommended by the ICMJE, whose model is available in http://www.objnursing.uff.br/normas/DUDE_eng_13-06-2013.pdf

Received: 08/03/2015
Revised: 04/27/2016
Approved: 04/27/2016