Interest of Sudoscan in the detection of diabetic peripheral neuropathy

W Douali *, Fel Jaafari, S Rafi, G El Mghari and N El Ansari

Endocrinology, diabetology, metabolic diseases and nutrition department CHU Mohamed VI Marrakech.

World Journal of Advanced Research and Reviews, 2022, 16(01), 590–594

Publication history: Received on 06 September 2022; revised on 12 October 2022; accepted on 15 October 2022

Article DOI: https://doi.org/10.30574/wjarr.2022.16.1.1034

Abstract

Introduction: Disturbance of pain sensation is considered one of the major initial risk factors for diabetic foot ulcers. Sweat dysfunction leading to abnormal skin conditions, including dryness and fissures, may increase the risk of foot ulcer. The objective of this study was to evaluate the Sudoscan, a new rapid, non-invasive, quantitative method for early detection of diabetic peripheral neuropathy by measuring sweat electrical conduction (SEC).

Patients and methods: We conducted this study on 85 type 2 diabetic patients. The data of the study were collected through a questionnaire, clinical examination (DN4, monofilament) and sudoscan for SEC.

Results: We recruited 85 patients, the average age of the subjects was 58.32 ± 10.89 years. 77.6% were women and 22.4% were men. A significant proportion (67%) of our study population had a duration of diabetes of less than 10 years. Among 85 patients 40% had a positive DN4 and only 17.2% of the participants had a positive monofilament test. 52.9% of the patients had a moderate dysfunction of the electrical conduction of sweat (SEC) and only 29.4% had a severe dysfunction, and 17.6% of the patients had a normal conduction we did not objectify a significant correlation between the sudoscan and the other tests notably the DN4 and the monofilament.

Conclusion: The Sudoscan is a reproducible technique, with a high specificity, it is a simple test for the detection of neuropathy diabetic peripheral allowing an early prevention of foot lesions.

Keywords: Type 2 diabetes; Diabetic peripheral neuropathy; Electrical conduction of sweat; DN4; Mono filament

1. Introduction

Diabetes is the leading cause of neuropathy worldwide. The most common form is symmetrical distal predominantly sensory polyneuropathy (DSP). The estimate of its prevalence is variable depending on the criteria used (symptomatic forms or not) and the tools used (none: clinical diagnosis only, monofilament, instrumental quantitative exploration of sensitivity or electroneuromyogram). It is estimated that it reaches about 30% of diabetic subjects at the time of diagnosis [1] with extremes ranging from 8 to 54% in type 1 diabetes and 13 to 46% in type 2 diabetes [2].

The SUDOSCAN is a rapid, non-invasive test that provides an accurate assessment of sweat gland function reflecting the state of the autonomic nervous system.

With quantitative and reproducible results, SUDOSCAN allows physicians to detect peripheral neuropathy early and to follow up on the evolution of the disease and to evaluate the effectiveness of the treatment for a better management of the patients.

*Corresponding author: W Douali
Endocrinology, diabetology, metabolic diseases and nutrition department CHU Mohamed VI MARRAKECH.

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The aim of this study was to demonstrate the value of sudoscan in the detection of diabetic neuropathy.

2. Patients and methods

This was a prospective cross-sectional study conducted during the month of Ramadan 2021 and included type 2 diabetic patients followed at the endocrinology and diabetology department of the CHU Mohammed VI.

The collection of information concerning the participants’ sociodemographic data (age, sex, occupation, level of education), history, duration of diabetes and its treatment, and associated complications was carried out by a physician during face-to-face directed interviews using a predefined questionnaire containing closed questions.

The clinical examination was performed by the attending physician and allowed to specify the different clinical parameters: weight and height, BMI, blood pressure, GPI, DN4 and monofilament test.

The Sudoscan device is a device that consists of a computer and 4 electrodes on which patients place their bare hands and feet, it offers a stimulation of the sweat glands that evaluates small nerve fibers and the results were obtained in 3 minutes.

The electrical conduction of sweat (ECS) and expressed in microsiemens (µS), the threshold values are as follows: >60 µS: No dysfunction; 40-60 µS: moderate dysfunction; <40 µS: severe dysfunction; these threshold values were defined based on previous studies [3, 4].

The data were entered and coded on Excel 2017 under numerical coding, to obtain the description of the study population and to perform a uni-variate analysis. The descriptive analysis consisted of the calculation of absolute and relative frequencies for qualitative variables, and central tendency and dispersion values for quantitative variables (mean, standard deviation or extended median).

The bivariate analysis used the usual techniques of comparing means and comparing percentages. The Student t test was used to compare two means on two independent samples. The threshold of statistical significance was set at 0.05.

3. Results

Table 1 Descriptive data of the study

| The variables                       | number | %    |
|-------------------------------------|--------|------|
| **Gender**                          |        |      |
| Female                              | 66     | 77.65% |
| male                                | 19     | 22.35% |
| **Diabetes Duration**               |        |      |
| <10 years                           | 57     | 67%   |
| >10 years                           | 28     | 33%   |
| HTA                                 | 38     | 44.7% |
| Nephropathy                         | 9      | 10.6% |
| Heart disease                       | 17     | 20%   |
| Diabetic Retinopathy                | 25     | 29.4% |
| DN4 positive                        | 34     | 40%   |
| Positive monofilament test          | 15     | 17.6% |
| Sudoscan: Severe dysfunction        | 25     | 29.4% |
| Moderatedysfunction                 | 45     | 52.9% |
| No malfunction                      | 15     | 17.6% |
We recruited 85 patients, the average age of the subjects was 58.32 ± 10.89 years. 77.6% were women and 22.4% were men.

A significant proportion (67%) of our study population had a duration of diabetes of less than 10 years.

**Table 2 Analytical data of the study**

| Variables              | No malfunction | Moderate to severe dysfunction | P   |
|------------------------|----------------|-------------------------------|-----|
| DN4 positive           | 7 (20.5%)      | 27 (79.4%)                    | 1.1 |
| Positive monofilament  | 7 (46.6%)      | 8 (53.4%)                     | 1.8 |

Among 85 patients 40% had a positive DN4 and only 17.2% of participants had a positive monofilament test.

We found that the majority of patients (52.9%) had a moderate dysfunction of the electrical conduction of sweat (CES) and only 29.4% had a severe dysfunction, while patients with a normal conduction represent only 17.6% of patients.

In our study, we did not observe a significant correlation between the Sudoscanner and other tests including DN4 and monofilament.

**4. Discussion**

Diabetic neuropathy (DNP) is the most common complication of diabetes and is of great clinical importance, primarily because of pain and the possibility of ulceration in the lower extremities. Early detection of neuropathy is essential in the medical management of this complication. [5].

In patients with peripheral neuropathy (PN), small fibers (autonomic system - sweating) and thermal and tactile sensitivity are affected first, followed by involvement of large fibers, exhibiting altered vibratory sensation that eventually alters electromyographic (EMG) patterns. Therefore, dysfunction of the sweating reflex in small distal fibers is one of the first changes detected in these patients [5].

The diagnosis of DPN is usually made on the basis of signs and symptoms and usually includes the use of several scores such as the Neuropathy Disability Score (NDS), the Neuropathy Symptoms Score (NSS), the Michigan Neuropathy Instrument (MNI) and the Neuropathic Pain 4 Questions (DN4). These methods are easy to perform and are reproducible, sensitive, and adequate for use in a screening program [6].

There are many confirmatory tests, including nerve conduction velocity (EMG) measurements and biothesiometry or skin biopsy. However, the most commonly used are the measurement of altered sensation with a tuning fork vibrating at 128 Hz and/or pressure with the Semmes-Weinstein monofilament [7]. The monofilament test (MFT) is widely accepted and recommended by all scientific societies because of its validity, predictive risk, efficacy and simplicity. Feng et al [8] reported that the monofilament test (MFT) has a sensitivity of 57% to 93%, a specificity of 75% to 100%, a positive predictive value (PPV) of 36% to 94%, and a negative predictive value (NPV) of 84% to 100% compared to EMG nerve velocity measurement.

Although electrophysiological measurements are more objective and reproducible, they are limited in that they only detect dysfunction on the basis of the presence of thicker and faster (myelinated) fibers and show their involvement later. Therefore, EMG is a specific test, although not very sensitive [5].

Recently developed noninvasive techniques are more reproducible and reliable for detecting early small fiber dysfunction. One of these new techniques is the sudoscan, which involves the measurement of dermal electrochemical conductance (DEC) or sudomotor dysfunction index and has been evaluated by well-designed studies that support its use as a screening test [9-10].

The SUDOSCAN measures the capacity of the sweat glands to release chloride ions in response to an electrical stimulus on the palms of the hands and soles of the feet, the areas with the highest density of sweat glands [11].
Our study found a significant rate of DAC dysfunction (82.5%).

Among 85 patients, 52.9% had moderate dysfunction, while 29.4% had severe dysfunction, which is consistent with another study published in 2014 whose objective is to show the interest of sudoscan in the detection of symmetrical distal polineuropathy with a rate of 67%.

In another study of 75 individuals, [12] also described similar results with the sudoscan with a sensitivity of 87%, and a specificity of 76% in contrast to another study [5] which only found 14.4%.

We did not find a significant correlation between the Sudoscan and other tests such as the DN4 and the monofilament, contrary to another study published in 2019 which found a significant correlation between the results of the Sudoscan and the DN4, monofilament and the Neuropathy Disability Score (NDS), [5] which is in line with another study published in 2011 [13] the main limitation of our study was the small sample size.

5. Conclusion

In conclusion, in routine clinical practice, the sudoscan is feasible, with moderate sensitivity but high specificity [5]. It is also easy to use and interpret and requires little training, making it a good screening test in populations with diabetes and pre-diabetes. It may also be useful for screening general populations at risk for neuropathy.

Compliance with ethical standards

Acknowledgments

I thank all the authors of this article.

Disclosure of conflict of interest

No conflict of interest.

Statement of ethical approval

The present research work does not contain any studies performed on animals/humans subjects by any of the authors.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.
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