

Consistency Analysis Between SUDOSCAN Examinations and Electromyography Results in Patients with Diabetes

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Objective: To evaluate the consistency between SUDOSCAN examinations and electromyography (EMG) results in patients with diabetes.

Methods: A total of 326 patients with diabetes (201 males and 125 females) who were hospitalized in the endocrinology ward of the Affiliated Hospital of Nanjing University of Chinese Medicine (Jiangsu Province Hospital of Chinese Medicine) from June 2020 to February 2021 were selected as participants. All the patients were tested using a SUDOSCAN conductance analyzer for electrical skin conductivities and EMG for nerve conduction. The differences and consistencies between the results of the two examinations were analyzed. McNemar's test was used to analyze the differences between the results, and Cohen's kappa test was utilized to test the consistencies.

Results: A total of 174 patients had abnormal SUDOSCAN results, and 152 patients had normal SUDOSCAN results. The EMG results of 299 patients were abnormal, and the EMG results of 27 patients were normal. The McNemar test result was $P = 0.000$, and the differences between the results of the SUDOSCAN and EMG examinations were statistically significant ($P < 0.01$). No significant consistency was found between the SUDOSCAN and EMG results, meaning that the consistency between the two examination results was not statistically significant ($P = 0.868$, $P > 0.05$). The difference between the results was statistically significant ($P < 0.05$), and the consistency was poor ($\text{kappa} = 0.005$).

Conclusion: Differences existed between the SUDOSCAN examination and EMG results, and the results of the two examination methods were inconsistent, indicating that SUDOSCAN examinations cannot replace EMG examinations for DSPN.

Keywords: diabetes mellitus, SUDOSCAN, electromyogram, consistency

Introduction

With the ever-changing population structure and the huge development of the economy, the prevalence of diabetes mellitus (DM) has increased. As the disease progresses, several complications can emerge. The most common chronic complication of DM is diabetic neuropathy, which increases the risk of cardiovascular disease, peripheral arterial disease, amputation, and mortality,¹ frequently resulting in severe physical symptoms and psychological issues among patients. Neuropathy occurs in 60–70% of patients with diabetes and involves both the central and peripheral nerves. Peripheral neuropathy is the more common strand and has various clinical manifestations.²

According to the latest classification standard of the Diabetic Branch of the Chinese Medical Association, diabetic peripheral neuropathy (DPN) can be divided into three main types: (1) diffuse neuropathy, including distal symmetric polyneuropathy (DSPN) and autonomic neuropathy, (2) mononeuropathy, and (3) radiculopathy.³ Distal symmetric polyneuropathy—a chronic symmetrical length-dependent sensorimotor polyneuropathy—is the most representative

and common type in patients with type-1 DM (T1DM) and type-2 DM (T2DM). In clinical practice, five physical examinations, namely, ankle reflex testing, acupuncture pain sensing, tuning fork vibration, pressure sensing, and temperature sensing, as well as nerve conduction studies (NCSs), such as electromyography (EMG), are used to screen for DSPN, with NCSs the current gold standard for DSPN diagnosis.⁴

However, these commonly adopted detection methods demonstrate certain defects in clinical practice. For example, EMG has a long examination time, is complicated, depends on the technical level of the examiner, requires patient cooperation, and tends to be affected by the environment, while some patients cannot tolerate the process. Meanwhile, the examiner's subjective assessment greatly affects some physical examinations, including tuning fork vibration sensing, acupuncture sensing, and ankle reflex testing. Therefore, there is an urgent need to devise a simple, convenient, rapid, non-invasive, quantitative, and objective instrument with good sensitivity and repeatability for accurate DSPN screening.

The SUDOSCAN tool is a non-invasive device for evaluating the secretion function of sweat glands. Specifically, it is used to measure the ability of sweat glands to release chloride ions through the electrochemical reactions between the ions in the sweat and the nickel in the electrodes. The generated voltage and current values, ie, the electrical skin conductivity (ESC) values (unit = μS), are adopted to draw a curve to calculate the slope. The lower the chloride ion concentration, the lower the ESC value, and the worse the sweating function.⁵

Sweat glands are innervated by small unmyelinated sympathetic nerve fibers, meaning that the SUDOSCAN instrument can detect the function of the smallest autonomic sympathetic nerves in the body and assess the degree of peripheral neuropathy through the skin's conductivity on the palms of the hand and the soles of the feet.⁶ Furthermore, the operation of the tool is simple and convenient, the instrument occupies a relatively small area, the normal reference range is not affected by the sex of the patient,⁷ and the tool has good repeatability.⁸ It has been reported that the sensitivity and specificity of the SUDOSCAN tool in detecting DPN are 78–87.5% and 76.2–92%,^{9,10} respectively, indicating that the tool has good potential diagnostic value for this condition.¹¹ However, whether SUDOSCAN tool also has high diagnostic performance for DSPN is worth exploring and studying. Therefore, a comparative test was conducted between the SUDOSCAN tool and EMG to verify whether the SUDOSCAN tool could replace EMG. The sample size included in this study was relatively large, which provides persuasive value. If this method possesses high specificity, sensitivity, and consistency, such a simple and convenient instrument should be promoted.

Ascertaining whether SUDOSCAN results and EMG examination results demonstrate good consistency is crucial. In the present study, SUDOSCAN and EMG instruments were adopted to compare and analyze the results of the examinations of patients with diabetes, with the overall aim of ascertaining whether SUDOSCAN examinations can replace EMG examinations and providing an evidence-based basis for the early prevention and treatment of DSPN.

Data and Methods

Study Participants

The clinical data of patients with T1DM and T2DM who were hospitalized in the Endocrinology Department of Nanjing University of Chinese Medicine (Jiangsu Province Hospital of Chinese Medicine) from May 2020 to February 2021 were collected, and 326 cases for patients who underwent both SUDOSCAN and EMG examinations were selected (201 male and 125 female patients). The average age of the patients was 59 years (51–70 years), and the average duration of DM was 10 years (2–15 years). This study complied with the Declaration of Helsinki.

Inclusion and Exclusion Criteria

The inclusion criteria included i) patients who met the World Health Organization's 1999 diagnostic criteria for DM¹² and ii) patients who underwent a SUDOSCAN-based sweat function examination alongside an EMG examination during hospitalization, with standardized examination procedures and complete examination results. The exclusion criteria included i) patients with other types of DM, ii) patients with acute complications of DM, iii) patients with acute stress states (eg, severe infection, trauma, surgery), iv) patients with severe cardiovascular and cerebrovascular diseases, v) patients with a history of narcotic and psychotropic medication and a recent history of alcoholism, vi) patients with

peripheral neuropathy due to other causes (eg, chemotherapy, radiotherapy, or neurological diseases, such as Guillain-Barre syndrome), and vii) patients equipped with a pacemaker.

Study Methods

Sweat Function Testing

The patients were tested using a SUDOSCAN electrical conductivity analyzer (Impeto Medical, France). The device consisted of two sets of electrodes for the feet and hands, with both sets connected to a computer for data recording and analysis. The entire examination was non-invasive and required no special preparation, with the patients required to place their palms and soles on the electrodes during the procedure. The ESC values for the hands and feet were automatically calculated. Those with ESC values of $>60 \mu\text{S}$ for both hands ESC (HESC) and feet ESC (FESC) were considered to have normal sweat function (152 patients),¹³ while those with HESC or FESC values of $<60 \mu\text{S}$ were considered to have abnormal sweat function (174 patients).¹³

Electromyography Examination

A Dantec (Denmark) EMG/evoked potential instrument (model: Dantec Keypoint 9031A070) was used to test motor conduction velocity (MCV), motor nerve action potential (MNAP), and sensory conduction velocity (SCV). The instrument also tested the sensory nerve action potential (SNAP) of the median nerve and ulnar nerve in the upper limbs, the MCV and MNAP of the common peroneal nerve and tibial nerve in the bilateral lower limbs, the SCV and SNAP of the superficial peroneal nerve and sural nerve in the bilateral lower limbs, and the F waves of the median, ulnar, tibial, and common peroneal nerves in the bilateral lower limbs. The testing environment temperature was controlled within the range of 20°C – 26°C , and the patient's skin temperature was maintained at 29°C – 32°C . The method and the normal values were selected with reference to a previous study.¹⁴ Patients with abnormal conduction parameters in at least one or more nerves were regarded as having abnormal EMG results. Among all the patients, 299 had abnormal EMG results, and 27 had normal EMG results.

Statistical Processing

The data were processed and analyzed using SPSS 22.0 statistical software. The patients with HESC and FESC values of $>60 \mu\text{S}$ were allocated to the normal sweat function group, while those with values of $<60 \mu\text{S}$ were allocated to the abnormal sweat function group. All the patients were also divided into the EMG normal group and the EMG abnormal group based on the nerve conduction parameter results. A paired fourfold table was established to analyze the differences between the results of the two examinations using a paired Chi-squared test (ie, the McNemar test), with a P value of <0.05 considered statistically significant. Cohen's kappa consistency test was used to analyze the consistency between the results obtained via the two examination methods, with a kappa of >0.75 indicating good consistency and a kappa of <0.4 indicating poor consistency.

Results

Analysis of the Differences Between the results of the Two Examinations

Among the 326 patients, 174 had abnormal SUDOSCAN results, and 152 had normal SUDOSCAN results. Additionally, 299 had abnormal EMG results, and 27 had normal EMG results. The McNemar test result was $P = 0.000$, suggesting that the differences between the results of the SUDOSCAN and EMG examination were statistically significant ($P < 0.01$) (Table 1).

Analysis of the Consistency Between the Results of the Two Examinations

The consistency rate of the SUDOSCAN and EMG results was 53.07%, with the kappa value of the consistency test = 0.005, indicating poor consistency between the results. No significant consistency was found between the SUDOSCAN and EMG results, meaning the consistency between the two examination results was not statistically significant ($P = 0.868$, $P > 0.05$) (Table 2).

Table 1 Paired Fourfold Table McNemar Test for SUDOSCAN and EMG Examination

			Electromyogram		Total	P
			The Abnormal Group	The Normal Group		
SUDOSCAN	The abnormal group	The number of cases Percentage	160 92%	14 8.0%	174 100%	0.000 (<0.01)
	The normal group	The number of cases Percentage	139 91.4%	13 8.6%	152 100%	
Total		The number of cases Percentage	299 91.7%	27 8.3%	326 100%	

Table 2 Consistency Test of Results of SUDOSCAN and Electromyogram

Diagnostic Method	Electromyogram		Sensitivity (%)	Specificity (%)	Consistency Rate (%)	Kappa Value	P value
	The Abnormal Group	The Normal Group					
SUDOSCAN			53.51	48.15	53.07	0.005	0.868 (>0.05)
The abnormal group	160	14					
The normal group	139	13					

Discussion

This study compared and analyzed the results of specific SUDOSCAN and EMG examinations. Few similar studies have been conducted in China to date. The results indicated that there was some inconsistency between the SUDOSCAN and EMG examination results. The sensitivity and specificity of the SUDOSCAN DSPN-diagnosis examination were 53.51% and 48.15%, respectively; therefore, the sensitivity and specificity were not high. The consistency rate between the SUDOSCAN and EMG examination results was 53.07%, with a kappa value of 0.005 ($P > 0.05$). Overall, the consistency between the two examination results was poor, indicating that the SUDOSCAN examination could not replace the traditional EMG examination.

The nerves mainly examined via EMG are larger myelinated A-alpha class nerve fibers. The sweat function of the sweat glands detected via the SUDOSCAN instrument is innervated by the sweat nerve—a branch of the sympathetic nerve of the autonomic nervous system and a small nerve belonging to class-C unmyelinated fibers, which are vulnerable due to their slenderness and unmyelinated sheath.¹⁵

Sweat nerve damage is an early manifestation of nerve damage in many peripheral neuropathies, including autonomic dysfunction. Patients with diabetic autonomic neuropathy often present with abnormal sweat function.¹⁶ The palms and soles of the human body are the areas with the most densely and maximally distributed sweat glands. When the C-fibers innervating these areas are damaged, sweat secretion is diminished. Early damage to the small fibers is associated with painful diabetic neuropathy and foot ulcers.¹⁷

Meanwhile, the ESC value correlates well with skin nerve fiber density.¹⁸ Therefore, it can be suggested that the SUDOSCAN tool mainly examines small nerve fibers in the autonomic nervous system. While the SUDOSCAN and EMG methods both detect the function of different nerve fibers, each has its own advantages and disadvantages and cannot effectively replace one another; however, they can be used in conjunction in a complementary manner.

The results of the present study suggested that the SUDOSCAN tool cannot be recommended as a diagnostic tool for DSPN. The examination failed to identify all types of DPN, rendering it largely applicable for screening autonomic neuropathy. However, the SUDOSCAN tool can compensate for the lack of rapid and non-invasive

detection methods for small nerve and autonomic nerve functioning in clinical practice. This is because the tool has the advantage of providing a rapid, non-invasive, simple, convenient, objective, and quantitative evaluation of the function of the peripheral small nerve fiber, making it applicable for detecting sweat nerve fiber dysfunction.¹⁹ Furthermore, the tool offers a potentially reliable method for detecting autonomic nerve dysfunction and could assist in the early detection of skin dryness and ulcers caused by sweat dysfunction.²⁰ The resulting preventive treatment would potentially reduce or delay disease progression and any related complications, such as lower extremity ulcers and amputations.²¹

Previous research has also indicated that there is a certain correlation between the sweat function of patients with diabetes and cardiovascular autonomic neuropathy.¹⁸ The typical symptoms of DPN include limb numbness, pain, and paresthesia.²² However, the early diagnosis of this condition has always been challenging, especially in patients without clear clinical symptoms.²³ Previous studies have demonstrated that the SUDOSCAN instrument may be a more sensitive tool for patients with asymptomatic DPN,²⁴ implying that the tool has certain clinical value and significance.

The strength of the present study is that it directly compared the consistency of the results of the SUDOSCAN and EMG detection methods. Few similar studies have been conducted in China. The results indicated that the SUDOSCAN instrument should not be recommended as a diagnostic tool in DSPN. Our study's limitation is that it did not further explore why the two methods were inconsistent.

Conclusion

Differences existed between the SUDOSCAN and EMG results, and the results of the two examination methods were inconsistent, indicating that SUDOSCAN examinations cannot replace EMG examinations for DSPN.

Abbreviations

DPN, Diabetic Peripheral Neuropathy; DSPN, Distal symmetric polyneuropathy; T1DM, Type 1 diabetes mellitus; T2DM, Type 2 diabetes mellitus; NCS, Nerve conduction examination; ESC, Electrical skin conductivities; WHO, World Health Organization; MCV, motor nerve conduction velocity; MNAP, motor nerve action potentials; SCV, sensory nerve conduction velocity; SNAP, sensory motor nerve action potentials.

Data Sharing Statement

All data generated or analysed during this study are included in this article. Further enquiries can be directed to the corresponding author.

Ethics Approval and Consent to Participate

I confirm that I have read the Editorial Policy pages. This study was conducted with approval from the Ethics Committee of Jiangsu Province Hospital of Chinese Medicine, Affiliated Hospital of Nanjing University of Chinese Medicine. Written informed consent was obtained from all participants.

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Disclosure

The authors declare that they have no competing interests.

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