Noninvasive Galvanic Skin Sensor for Early Diagnosis of Sudomotor Dysfunction: Application to Diabetes

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Abstract—Sudomotor dysfunction is a major clinical manifestation of diabetic autonomic neuropathy and is an early sign of prediabetes. SUDOSCAN™, a noninvasive and quick method was developed to assess sudomotor function based on measurement of the electrical current response of the skin when different rectangular pulses of low voltage amplitudes are applied on nickel electrodes. Electrochemical skin conductance is then calculated from the resulting voltage and the generated current. This leads to an accurate noninvasive way to predict dysglycemia, including type II diabetes, without fasting requirement due to the sensitivity of Ni electrodes to human eccrine glands sweat.

In this paper, the device principle is presented and its efficiency in early diagnosis of sudomotor dysfunction is demonstrated through large clinical results. The electrodes behavior and the electrochemical skin model are studied, through in vitro experiments and theoretical approach. The electrochemical reactions and the influence of several factors, including properties of ion channels of the sweat duct are analyzed.

Index Terms—Diabetes, diagnostic, electrochemistry, nickel electrode, reverse iontophoresis, skin conductance, sweat.

I. INTRODUCTION

The prevalence of type 2 diabetes is increasing in developed and developing countries and is predicted to be 7.7% worldwide by 2030 but perhaps of even greater concern is the simultaneous dramatic increase in numbers with impaired fasting glucose (IFG) or impaired glucose tolerance (IGT) [1]. These glucose-intolerant, but nondiabetic, individuals represent a significant pool of potential new diabetes cases. Early identification and treatment of these prediabetic persons can reduce or delay the progression to diabetes and cardiovascular diseases [2].

Peripheral neuropathy is a common complication of diabetes and its early detection may reduce morbidity and particularly diabetes-related foot complications through provision of education and appropriate foot care. Most common among the neuropathies are chronic sensorimotor distal symmetric polyneuropathy and the autonomic neuropathies. The lack of protective sensation from sensory neuropathy leads to repetitive trauma resulting in ulceration and is considered as one of the major initiating risk factors in the pathogenesis of diabetic foot ulceration (FU). Vibration perception threshold (VPT) using biothesiometer and pressure perception using Semmes–Weinstein monofilament, both focused on assessment of sensory function, have been proposed to identify patients at risk of FU in the absence of gold standard test. However, peripheral autonomic dysfunction may result through sweating reduction in abnormal skin conditions increasing the risk of FU [3].

Eccrine glands that are responsible for the sweat response are simple tubular glands that receive a rich supply of blood vessels and sympathetic C unmyelinated nerve fibers mainly cholinergic. The distribution of eccrine glands shows area differences: 500–600/cm² on the palms of the hands and soles of the feet, 180/cm² on forehead with only 108/cm² on forearm and 60/cm² on the back. The secretory coil produces an ultrafiltrate (isotonic to plasma) while reabsorption of sodium and chloride by the sweat duct results in hypotonic sweat whose ionic concentration is stable in physiological conditions. The long efferent course of unmyelinated autonomic sudomotor fibers can be interrupted by peripheral autonomic disorders and sweat response may be the more sensitive test in detecting small fiber neuropathy.

Quantitative sudomotor axon reflex testing (QSART) measures the sweat response after stimulation by iontophoresed acetylcholine using sudorometer on the forearm, proximal
leg, distal leg, and proximal foot. Low et al. [4] evidenced that a length-dependence neuropathy is typically associated with a loss in sweat volume that is maximal distally. Sympathetic skin response (SSR) using standard electromyography measures the electrical response to an electrical stimulus on hand and foot. The dynamic sweat test was recently developed to measure sweat gland density, distribution of active sweat glands and sweat rate on the forearm and distal leg and was able to detect subtle functional changes occurring in the early stages of diabetic neuropathy. In the same way, intraepidermal nerve fiber density through skin biopsies is a marker of early small-fiber neuropathy. QSART, SSR, the dynamic sweat test, and skin biopsies have been proposed to evaluate sweat function or peripheral small fiber status in diabetes [4], [5]. Several studies based on these methods have evidenced that sudomotor dysfunction was present in individuals with IGT and that this IGT-related neuropathy may represent the earliest stage of diabetic neuropathy [6]. However, these tests require high technical procedures, are time consuming or invasive and cannot be used in routine clinical practice.

There is a clear need for new tests that can quickly and simply measures sudomotor function. SUDOSCAN™ [7], [8], a non-invasive and rapid method using nickel electrodes, was recently developed to allow a precise evaluation of sweat gland function based on sweat chloride concentrations. Its behavior in physiological conditions, in cystic fibrosis where sweat chloride concentration is high and its ability for evaluating sudomotor dysfunction in diabetes and prediabetes have been evaluated.

This paper reports on: (i) the presentation of the medical device (SUDOSCAN™); (ii) a synthesis of clinical tests to demonstrate the robustness of the method, the proof of concept and the use of the SUDOSCAN™ to detect prediabetes and diabetes complications; (iii) a new theoretical electrochemical model of the skin based on the Chizmazdhev one [9] but taking into account the involved ionic species, their velocities and ion channel properties; and (iv) an in vitro study devoted to the electrochemical analysis of the Ni electrodes in sweat mimicking solutions aimed at understanding the chemical key parameters controlling the origin of the onset signals delivered during the clinical tests, in terms of electrochemical reactions.

II. MEDICAL DEVICE

The new SUDOSCAN™ device (Impeto Medical, Paris, France) is designed to perform a precise evaluation of sweat gland function based on sweat chloride concentrations using reverse iontophoresis and chronoamperometry [10]. Measurements are performed where sweat glands are most numerous on the palms of the hands, soles of the feet and forehead. Large area nickel electrodes are used alternatively as an anode or a cathode and a direct current (DC) incremental voltage 4 volts is applied on the anode. This DC through reverse iontophoresis induces a voltage on the cathode and generates a current (intensity of about 0.2 mA) between the anode and the cathode, related to chloride concentration. The electrochemical phenomena are measured by two active electrodes (the anode and the cathode) successively in the three regions, while the four other passive electrodes allow retrieval of the body potential. Contrarily to the methods based on impedancemetry used to evaluate the body composition, for example, in our method the current is a direct current and not an alternating one; it is based on an electrochemical reaction and not only on electrical properties.

The apparatus consists of two sets of electrodes for the hands and the feet and a headband for the forehead, all of which are connected to a computer for recording and data management purposes (Fig. 1). To conduct the test, the patients are required to place their hands and feet on the electrodes, and place the headband electrodes on the forehead. The patients are then required to stand still for 2 min. During the test, 6 combinations of 15 different low DC voltages are applied. Neither special patient preparation nor medical personnel training are required. The data, namely, electrochemical skin conductance (ESC) in hands, feet and forehead which are the ratio between the current produced and the resulting voltage are displayed instantaneously on a standard PC computer in the form of a geometric figure that allows fast interpretation.

III. CLINICAL STUDIES

Preliminary studies were performed to demonstrate the robustness of the method followed by a proof of concept study and the use of the SUDOSCAN™ to detect diabetes complications and prediabetes.

A. Symmetry

As the commonest form of diabetic neuropathy is symmetric, it was important to ensure that ESC measurements between right
and left side were comparable. In this way, ESC in hands and feet were compared between right and left side using a Bland and Altman plot. Coefficient of variation calculated on 1365 subjects was 3% for hands and 2% for feet, between right and left side.

B. Gender Effect

No significant difference was observed in ESC measured in hands and feet between female and male subjects involved in the studies or surveys performed.

C. Reproducibility

Measurements were assessed twice on the same day in patients with at least one cardiovascular risk and in patients with diabetes. Results were compared using a Bland and Altman plot. The coefficient of variation was 7% in hands and 5% in feet in patients with cardiovascular risk and 15% in hands and 7% in feet in patients with diabetes. Coefficient of variation for glycemia, which is a gold standard for diabetes, between the two measurements was 32%.

D. Effects of Glycemia

This technology has to be used in patients with prediabetes or diabetes, with potential high variations in glycemia. Thus, it was important to ensure that measurements were not influenced directly by glycemia itself. To do so, measurements were done in ten patients when their glycemia was greater than 18 mmol/L and compared with measurements performed in the same patients when glycemia was below 6 mmol/L. Coefficient of variation from a Bland and Altman plot with or without hyperglycemia was 10% for foot ESC. This confirms that the method does not require any fasting.

Proof of Concept

ESC was measured in 41 adult patients with classical Cystic Fibrosis (CF) and 20 healthy subjects. ESC on hands and on feet was significantly higher in CF patients (73±2 versus 61±3 μS, p < 0.01) and 75±2 versus 62±3 μS, p < 0.0001, respectively). Correlation between dESC (difference between ESC at 3.5 V and ESC at 1.5 V) and sweat chloride concentration as measured by sweat test was −0.57 (p < 0.0001) for hands and −0.70 (p < 0.0001) for feet (Fig. 2) [11].

E. Diagnosis of Diabetes Complications

Evaluation of the relationship between sensory neuropathy (currently recommended to detect foot risk) measured by VPT method and sudomotor dysfunction evaluated by SUDOSCAN™ was performed in 142 diabetic patients (age 62±18 years, diabetes duration 13±14 years, HbA1c 8.9±2.5%). Patients were divided in three groups according to VPT values: < 15, 15–25, and > 25 V.

As it can be seen in Fig. 3, foot ESC decreased when VPT increased and it is significantly lower when VPT is > 25 V. Correlation coefficient between foot ESC and VPT was −0.45 (p < 0.0001). Median VPT was not statistically different for patients with or without foot fissures, but foot ESC was higher in patients without foot fissure (61±28 versus 51±37 μS, p = 0.001). Among the 23 patients with VPT > 25 V and ESC < 40 μS, foot fissures were present in 13 patients, while only in 8 out of 34 when ESC was > 40 μS. VPT was higher and foot ESC was lower in patients with antecedent of foot ulceration (FU) (29±20 versus 17±22 V, p = 0.002 for VPT and 33±38 versus 62±26 μS, p = 0.002 for ESC). No adverse events during and after measurement were reported and no patient reported discomfort during the SUDOSCAN™ test.

F. Identification of Subjects at High Risk of Diabetes

A longitudinal study was done in subjects with an initial normal glucose tolerance (NGT) to assess the ability of SUDOSCAN™ to predict future abnormalities in glucose tolerance and insulin sensitivity/secretion [12]. South Asian (Indian) subjects (n = 69, 48% male, mean age 42±9 years, mean BMI 28±4.8 kg/m²) who were diagnosed as NGT with a previous oral glucose tolerance test (OGTT) (T0) underwent a frequently sampled OGTT (FSOGTT), eight months later (T8). At both times a SUDOSCAN™ test was done. Using the areas under the curves AUCglucose and AUCinsulin measured by the FSOGTT, subjects were categorised as normal, hyperinsulinemic (HI) or insulin deficient (ID). The odds ratio (OR)
for being HI + ID versus normal according to FSOGTT was computed by logistic regression analysis using SUDOSCAN™ results at T0 as independent variable. The OR of being HI or ID in the different SUDOSCAN™ groups was 6.19 (confidence interval CI 95% 1.50 – 25.48, p = 0.0116) for moderate and high sweat disturbance versus normal sweat function and 3.0 (CI 95% 0.98 – 9.19, p = 0.0545) for moderate sweat dysfunction versus normal sweat function. According to Receiver Operating Curves, SUDOSCAN™ was a better predictive test for early detection of abnormalities in glucose tolerance than Fasting Plasma Glucose (FPG) and HbA1c (sensitivity 77% versus 14% and 66%, respectively).

In conclusion, assessment of sudomotor function by SUDOSCAN™ appears to be a sensitive method to identify subjects at high risk for developing diabetes when compared with the conventional methods (FPG, OGTT, and HbA1c). The method is without fasting requirement, non invasive, robust and reproducible.

IV. ELECTROCHEMICAL SKIN MODEL

A. Geometry, Variables, and Currents

The diagnosis is based on the electrochemical conductance of the skin ECS which is measured after steady-state chronamperometry, i.e., after the application of rectangular pulses of voltage amplitudes. Only the outer-most layer of the skin, called stratum corneum (SC), is concerned. It consists of a lipid cornocyte matrix crossed by skin appendages (sweat glands and their follicles). At low voltages, less than 10 V, the SC is electrically insulating [9] and only the appendageal pathway is conductive.

In the current application, only eccrine glands which are the most numerous and present in abundance at hand palm, foot sole and forehead, where precisely the electrodes are placed, are concerned. Their secretion canal expands straight towards the skin where it leads to a pore. As in the Chizmadzhev model [9], the appendageal duct is modeled by a “one dimensional” cylindrical tube with a radius r filled with an electrolyte of conductivity σ (Fig. 4). The outer layer −l ≤ x ≤ 0 crossed by the tube is the impermeable SC. In the lower region x > 0, the wall of the tube consists of two layers of electroporous epithelial cells. In this figure, X is an abscissa to be chosen high enough such that below X, the potential is constant and equals the potential reached by the body = ϕX ≡ ϕext.

Chizmadzhev’s model [9], the unique available electrical skin model is not completely satisfactory because it is purely electric and neither the nature of the involved species nor their velocities are implicated. So that simulating very low sweat rates as evidenced in diabetes is impossible. Instead, we consider a new model including the most abundant species i in the sweat (Cl−, Na+, H+). The variables used in this model are the concentrations ci(x, t) and the velocities ui(x, t) of these species, which are enough to describe our requirements.

In the present case, three currents are of interest

1) An axial current:

\[ I^a = F \cdot S_0 \cdot \sum_i z_i \cdot c_i \cdot u_i \] (1)

where \( S_0 = \pi r^2 \) is the tube section, \( F \) is the Faraday constant, \( z_i \) is the charge of the ion and \( \Phi \) is the potential inside the tube. It can be also written as, according to Ohm law

\[ I^a = -\sigma \cdot S_0 \frac{\partial \Phi}{\partial x}. \] (2)

2) A capacitive current which is transverse and due to ions that accrue on the tube wall. This current is not taken into account in this model because it is unsteady.

3) A cross-wall current, which is also a transverse current and corresponds to charges crossing the tube wall, so-called ion channel current. It is related to Cl− and Na+ ions that go through this epithelial membrane using their own dedicated ion channel [13]–[15]. This ion channel approach is more fecund than a simple conductance model because it also considers the chemical gradient. The density of this current \( J_i \) for ion \( i \) is given by

\[ J_i = z_i \cdot G_i \cdot P_i \cdot (\Phi - \Phi_i - \Phi_{\text{ext}}) \] (3)

where \( G_i \) is the conductance per unit area; \( P_i \) the percentage (or probability) of open channels, depends on the ion concentrations on both sides of the wall and generally given by a Boltzmann function [13]; \( \Phi_i \) is the equilibrium potential of the ion according to the Nernst law (see [16] and Fig. 5)

\[ \Phi_i = \frac{R \cdot \theta}{z_i \cdot F} \cdot \ln \left( \frac{c_i^{\text{ext}}}{c_i} \right) \] (4)

in which \( R \) is the perfect gas constant and \( \theta \) is the absolute temperature.
B. Physics Conservation Laws

The equations that govern the evolution of our unknowns proceed from usual conservation laws. First, a balance equation for the conservation of mass for each species $i$ leads to

$$\frac{\partial c_i}{\partial t} + \frac{\partial (c_i u_i)}{\partial x} = \frac{-2}{r} F \cdot J_i$$  \hspace{1cm} (5)

where a classical transport equation for $c_i = c_i(x,t)$, with an original source term, can be recognized. Using (1)–(3) one can easily prove that this quite general law includes the scalar electrical balance of the Chizmadzhev’s model [9].

Second, the velocities of the ions can be obtained by writing the conservation of momentum for each species. Recall that when some charged species are in motion, they create an electrostatic force $-\xi_i(u_i - v)$, with $v$ the constant sweat speed and $\xi_i$ the Stokes coefficient [17].

Finally, in the Eulerian approach, the fundamental principle of dynamics applied to each charge $i$ gives

$$m_i \left[ \frac{\partial u_i}{\partial t} + \frac{\partial (\frac{u_i^2}{2})}{\partial x} \right] = q_i \cdot E - \xi_i \cdot (u_i - v)$$  \hspace{1cm} (6)

where the term in brackets is the acceleration.

C. Steady-State Simulations

The model parameters $r, h, \sigma$ are taken from [9], whereas the others $G_i, P_i$ proceed from [13] and [18]. The hyperbolic system of non linear and coupled partial differential (5) and (6), augmented with suitable initial and boundary conditions is solved numerically by classical first-order accurate upwind scheme [19].

Hence, while interested only in steady solutions $\partial / \partial t = 0$, we solve the whole evolution problem for the unknowns $u_i(x,t)$ and $c_i(x,t)$. This is a quite usual situation where the scheme appears as an iterative method towards the steady solution. In agreement with the characteristic theory [19], the boundary conditions are as follows: a Neumann one at $x = 0$ (i.e., extrapolation from inside) and a Derichlet one at $x = X$. The initial condition is simply a uniform state corresponding to the interstitium to which a low rectangular DC voltage is applied at $x = -h$ (to the skin). The potentials $\Phi(x,t)$ as well as $\Phi^X = \Phi^{ext}$ are deduced in fine from (1) and (2) and the applied voltage to the skin.

This novel and complete model is a powerful and supple computational tool for wide numerical simulations: Diabetes by reducing (here divided by two) the normal sweat rate and Cystic Fibrosis (CF) by almost closing the chloride channel; for the model, some related wall conductances and sweat rates can be found in [18].

Fig. 6 represents the steady distributions of concentrations and pH along the sweat duct axis at anodic and cathodic conditions. It shows how the ions move across the wall according to their electrochemical gradient. In particular, chloride and proton are more concentrated at the anode and the cathode, respectively, where precisely they do react. Fig. 7 depicts the main currents (at the electrodes, as a function of the applied potential) that govern the electrodes reactions, i.e., chloride at the anode (see Section IV) and proton at the cathode, for typical normal, diabetic and CF subjects.

In conclusion, this novel and complete model is a powerful and supple computational tool for wide numerical simulations
of the electrochemical model of the skin involving the chloride ions and their ion channels properties.

V. ELECTROCHEMICAL BEHAVIOR OF Ni ELECTRODES

Electrochemical studies were carried out to identify the origin of currents measured upon the application of low voltage potential with variable amplitudes to Ni electrodes on the skin during the clinical tests. They are also aimed at evaluating the influence of different parameters in sweat on the obtained currents. These studies were made in carbonate buffer solution containing variable concentrations of chloride ions and their ion channels properties.

A. Experimental Conditions

The electrochemical measurements were performed with a conventional three electrodes cell. The working electrode was a 0.0314 cm² nickel disc electrode. Nickel wires were used as counterelectrode and pseudoreference electrode in order to imitate to whole Ni electrodes configuration of the SUDOSCAN™ device. The potential of Ni pseudoreference was measured against a saturated calomel electrode SCE. The obtained data show that the potential difference ΔE (ΔE = ENi - ESCE) changes slightly in various electrolytic solutions and its average value is ≈ -1.40 mV.

All the aqueous solutions were prepared using ultra pure water (18 MΩ · cm). Carbonate buffer solutions (CBSs) were prepared from NaHCO₃ and the pH was set, as a first step, with few drops of concentrated sulfuric acid then, during the measurements, with a mixture of two gases (carbon dioxide + air) at different ratios. The solutions containing chloride ions were prepared using NaCl. The pH values, sodium chloride, urea and lactic acid concentrations were selected within the expected limits in sweat.

B. Results and Discussion

Fig. 8(a) represents the evolution of the anodic voltamograms in CBS (pH 6.4) in presence of different concentrations of Cl⁻. In all cases, an anodic plateau appears at 0.3 V indicating the formation of a passive film composed probably by Ni(OH)₂ and/or NiO [20]. Moreover, in this examined range of potentials, the voltammograms show a large anodic current at high potentials due to the localized dissolution of the nickel following Cl⁻ attack [20]. The increase in Cl⁻ concentration shifts linearly E₀ (breakdown potential) towards more cathodic values, as it can be seen in Fig. 8(b). This can be explained by the increase in the concentration ratios [Cl⁻]/[OH⁻] that acts in favor of the adsorption of Cl⁻ and thus the weakness of the passive layer leading to its dissolution. These data clearly show the influence of chloride ions concentrations in CBS on the anode behavior.

The influence of urea concentration and lactate concentration were also evaluated. The obtained results (data not shown), illustrate that the variation of urea and lactate concentrations does not have a significant effect on the electrochemical behavior of Ni.

In conclusion, the various obtained results provide insight into the origin of the onset of the responses measured upon the application of low voltage potential of variable amplitude to Ni.
electrodes. They prove that the variation of chloride ions concentration plays a key role in predicting sudomotor dysfunction by controlling the anodic current measured during the clinical tests and thus the electrochemical skin conductance (ESC).

VI. CONCLUSION

Assessment of sudomotor function by SUDOSCAN™ appears to be a sensitive new method to identify subjects at high risk for developing diabetes when compared with the conventional methods (FPG, OGTT, and HbA1C). The method is without fasting requirement, non invasive, robust and reproducible.

In this research, several milestones were reached, namely: (i) the efficient use of SUDOSCAN™ technology to professionally detect diabetes complications and prediabetes; (ii) the elaboration of a new electrochemical model of the skin involving the chloride ions and their ion channels properties; and (iii) the correlation of the obtained results with the electrochemical behavior of Ni electrodes in presence of sweat-like synthetic solutions. The diagnosis of other neuropathies such as those induced by chemotherapy drugs and the effect of these treatments through their impact on ion channels will be of great interest for SUDOSCAN™ technology in the near future.

REFERENCES


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