

Measurement of Electrical Skin Impedance of Dermal-Visceral Zones as a Diagnostic Tool for Inner Organ Pathologies: A Blinded Preliminary Evaluation of a New Technique

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Abstract

Background: As complementary and alternative medicine is gaining popularity among health consumers, diagnostic screening tools based on neuroreflexology are also being developed. These techniques, which are based on the rationale that measurement of electrical impedance of specific dermatomes reflects corresponding internal organ pathologies, have not yet been the subject of conventional scientific research.

Objectives: To determine the effectiveness of a neuroreflexology-based screening test, specifically the Medex device (Medex Screen Ltd.), for diagnosing patients undergoing conventional internal organ assessment, in a hospital setting.

Methods: Patients admitted to an internal medicine department, who met the inclusion criteria and agreed to participate, underwent conventional medical evaluation that included past medical history and physical examination. Another examination was conducted by a second physician using the Medex device to determine internal organ pathologies. A third researcher compared the actual "conventional" diagnosis with the Medex device output using standard statistical analysis.

Results: Overall, 150 patients participated in the study. Correlation was significant for all categories ($P < 0.01$) except for blood and lymphatic disease. A high sensitivity (>70%) was measured for cardiovascular, respiratory, gastrointestinal and genitourinary diseases. The highest measure of agreement, as represented by the Cohen-Kappa factor, was found for respiratory disease (0.57).

Conclusions: Although the exact mechanism is not entirely clear, measurement of electroskin impedance of dermal-visceral zones has the potential to serve as a screening tool for inner organ pathologies. Further research should be conducted to create more evidence to support or dispute the use of this technique as a reliable diagnostic tool.

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The value of the routine health examination of asymptomatic persons, in which a predetermined battery of tests and physical examination procedures are performed as part of a routine checkup, is well established [1,2]. It is now common practice among health professionals to recommend routine testing as effective preventive medicine, with the intention that early diagnosis and treatment of illness will lead to improved prognosis.

The choice of tests has become the focus of much debate. In an effort to examine these issues, public health services in the United States commissioned task forces to develop recommendations for clinicians on the appropriate use of preventive interventions, based on a systematic review of evidence of clinical effectiveness [3].

For medical tests to be suitable as screening diagnostic tools they would have to be: a) highly sensitive in order not to miss patients with the screened disease; b) highly specific with low false-positive rates; c) low adverse effects or complication rates; d) economically cost-efficient (while taking into account non-diagnosed complications and economic implications); and e) available and easy to use. Indeed, some medical tests have proved themselves and are being used as screening tools, such as colonoscopy for early detection of colon cancer, Papanicolaou (PAP) smear for cervical cancer, and mammography for breast cancer. Other tests are being used for screening, although their effectiveness is questionable (such as prostatic specific antigen for prostate cancer, chest X-ray for lung cancer, and stress test for ischemic heart disease).

As complementary and alternative medicine is gaining momentum with increasing numbers of people seeking non-conventional therapies [4], new screening techniques are also being developed. One of them, which has gained popularity in various settings throughout the world, is derived from the field of neuroreflexology. This system is based on the selection and analysis of data obtained from measuring the skin's electrical impedance of predetermined dermal-visceral zones on the human body. The rationale behind the system is that each internal organ has a representative dermal zone on the trunk and limbs, the physical parameters of which are in correspondence with the physiology of the organs represented by them, so that any pathology affects and changes the zones' absolute and relative parameters [5–8]. The same rationale is lately being used for various other non-invasive diagnostic tests such as measuring cardiac output through whole-body electrical bioimpedance [9].

This method, sponsored by various commercial companies, is currently used by medical organizations in Israel and throughout the world primarily as a screening test for internal

organ pathologies. However, it is considered as “alternative” medicine, and has yet to be the subject of conventional scientific research. As medical researchers, we have approached this controversial field with both skepticism and concern, but with the aim of putting conventional evidence-based medicine techniques into use in order to evaluate the reliability of this method as a scientific medical tool. The objectives of the present study were to determine the effectiveness of this screening test, specifically the Medex device (Medex Screen Ltd.), for diagnosing patients undergoing conventional internal organ assessment as part of their standard medical diagnosis, in a hospital setting.

Methods

Measurement

In this study we evaluated a device manufactured by Medex Screen Ltd. (Arad, Israel). The major components of the Medex device comprise a special skin impedance measurement device used to take various measurements of DVZs on the human body (in KOhm), which are then processed by the device software (patent number US 10/210,223 “Non-invasive method for internal diseases diagnosis”). Once the data are processed the Medex device can determine if there are any pathologies in the internal organs examined. Before testing, the DVZs are cleaned with 70% ethyl alcohol solution to avoid possible effects of sebum or humidity on the skin that could affect the test results. Measurements were performed using the skin electrode on 24 predetermined zones on the hands and feet. The measurements are repeated twice. First a baseline measurement is taken and these values are considered to be normative values for the individual. Then, transcutaneous electrical stimulation of other specific skin areas is performed. The response of these areas is supposedly different between normal and abnormal conditions. A second measurement is done, and any differences are recorded and analyzed in comparison to the first set of values. The electrical stimulation is performed with a very short-lasting electrical current of 20 microA (voltage of 5 V). This very low electric current is considered completely safe with no damage to the skin. A software program processes the collected information with the help of a previously built correlative algorithm and produces an output of a suggested diagnosis.

Study population

The study population comprised 150 patients who were admitted to an internal medicine department for various health problems. All study subjects underwent conventional medical assessment as part of their standard medical examination. The subjects were selected according to the following inclusion and exclusion criteria. Patients included in the study were over the age of 18 and willing to participate; they signed the written informed consent. Those excluded were comatose patients, patients in terminal stages of disease and on intra-

venous opiate treatment, patients with missing limbs, and pregnant women.

Patient examination and evaluation

Demographic and medical information acquired from the patients and from their medical charts including previous medical history, as well as a physical examination, were recorded on pre-study case report forms. This information comprised clinically significant abnormalities of all body systems including main and concurrent diseases and relevant past medical history. All subjects had undergone a conventional physical examination by an authorized physician participating in the study. The examination included an evaluation of all body systems. Any clinical significant abnormalities were recorded on the appropriate case report forms. Diagnosis of preexisting medical conditions was categorized according to 12 categories [Table 1].

Table 1. Categories of illness and number of patients diagnosed by conventional methods

| Categories | N |
|--|-----|
| Eyes/Ears/Nose/Throat | |
| Complete blindness, retinopathy, deafness, Meniere's disease and primary carcinoma | 9 |
| Central nervous system | |
| Stroke, meningitis/encephalitis, encephalopathy | 27 |
| Blood/Lymph | |
| Abnormalities in red blood cells, thrombocytes and leukocytes, including leukemia and lymphoma | 29 |
| Skin/Hair | |
| Skin diseases and conditions, including autoimmune, infectious, malignant and atopic etiologies | 9 |
| Cardiovascular | |
| Ischemic heart disease, congestive heart failure, infectious disease, hypertension, vascular pathologies including thrombosis and vasculitis | 102 |
| Respiratory | |
| Obstructive and restrictive disease, infectious (pneumonia), pulmonary embolism, malignancy | 36 |
| Gastrointestinal | |
| Inflammatory bowel disease, malignant (primary and secondary), hepatic and biliary disease (hepatitis, cirrhosis) | 37 |
| Musculoskeletal | |
| Conditions affecting the muscles and bones, including osteomyelitis, myositis, rhabdomyolysis, paresis/plegia conditions | 25 |
| Endocrine | |
| Diabetes mellitus, thyroid, adrenal and other endocrine-related conditions | 49 |
| Allergic | |
| Autoimmune disease without a predominant effect on one of the other categories, allergic reactions | 7 |
| Drug/Alcohol abuse | |
| Major adverse drug effect, alcohol abuse without a predominant hepatic or encephalopathic condition | 21 |
| Genitourinary | |
| Urinary or genital infection, carcinoma (prostate, bladder or genital), pelvic floor abnormalities | 35 |

N represents number of patients diagnosed of the 147 patients analyzed in the study (three patients were omitted due to missing data).

Note that patients could be diagnosed with more than one disease, but each disease was assigned to one category.

DVZ = dermal-visceral zone

Statistical analysis

Statistical analysis was conducted using the SPSS for Windows 10.0 program. The Medex test diagnosis was statistically compared to the results obtained from the conventional diagnostic methods. The statistical analysis estimated agreement between the Medex test diagnosis and the results of the conventional diagnostic examinations. A standard measure of agreement (Cohen-Kappa) between two binary variables was estimated. In addition, all measures of agreement (sensitivity and specificity) for the Medex test diagnosis were calculated using the conventional diagnosis as the gold standard. *P* values <0.01 were considered significant.

Results

Overall, 150 patients participated in the study of whom 4 had missing data (incomplete medical information) and were omitted from the analysis. The average age of the study participants – 90 males and 56 females – was 63.8 years. Categories of illness and number of patients diagnosed by conventional methods, for each category, are summarized in Table 1. Comparison between the conventional and the Medex test diagnosis was done only when more than 10 patients were diagnosed for each category. Table 2 summarizes the sensitivity, specificity, Cohen-Kappa measure of agreement and *P* value for each defined category. Correlation was significant for all categories (*P* < 0.01) except for blood and lymphatic disease. A high sensitivity (>70%) was measured for cardiovascular, respiratory, gastrointestinal and genitourinary diseases, with the highest sensitivity measured for cardiovascular disease (85.3%). The highest measure of agreement, as represented by the Cohen-Kappa factor, was measured for respiratory disease (0.57).

Discussion

Preventive medicine and CAM are two fields in healthcare that are gaining momentum in the modern medical era. Indeed, it was only a question of time until CAM, or as it is sometimes referred to – “non-conventional” medicine, would be put to use as a screening tool.

As scientists, we set out to explore this new non-conventional medicine-based method, using conventional evidence-based research tools. Exploring the efficacy of alternative medicine-based therapies and diagnostic tools has been the focus of many large-scale studies undertaken in recent years, and has yielded some interesting results. To name just a few, *Echinacea purpurea* was found to be ineffective for the prevention of rhinovirus common cold [10], acupuncture is not more effective than other conventional and “alternative” treatments for chronic low back pain [11], and reviewing data from double-blind control studies found the effect of intercessory prayer on healthcare outcomes to be inconclusive [12,13].

In this study we set out to explore the efficacy of a diagnostic tool based on measuring electrical skin impedance of DVZs for inner organ pathologies. As we analyzed the data, we

Table 2. Sensitivity and specificity of the Medex test method to predict diagnosis, as compared to conventional gold standard methods

| Diagnosis | Sensitivity (%) | Specificity (%) | Kappa* | <i>P</i> |
|------------------------|-----------------|-----------------|--------|----------|
| Central nervous system | 18.5 | 98.3 | 0.24 | <0.001 |
| Blood/Lymph | 6.9 | 99.1 | 0.09 | 0.04 |
| Cardiovascular | 85.3 | 52.3 | 0.39 | <0.001 |
| Respiratory | 80.6 | 82.7 | 0.57 | <0.001 |
| Gastrointestinal | 81.1 | 45.0 | 0.18 | 0.005 |
| Musculoskeletal | 48.0 | 88.4 | 0.36 | <0.001 |
| Endocrine | 51.0 | 81.4 | 0.34 | <0.001 |
| Drug/Alcohol abuse | 9.5 | 99.2 | 0.14 | 0.009 |
| Genitourinary | 72.4 | 69.7 | 0.35 | <0.001 |

* Cohen-Kappa is the measure of agreement. Kappa equals 0 when the agreement equals that expected by chance.

P value is given for the Cohen-Kappa test.

found a high correlation for most of the explored pathologies when comparing the device diagnosis to conventional methods diagnosis. Thus, a reasonably high sensitivity (>70%) was found for pathologies in the cardiovascular, respiratory, gastrointestinal and genitourinary systems, in some of which a high specificity was also calculated (respiratory and genitourinary systems).

An ideal diagnostic test for screening would first and foremost have to be highly sensitive, so that it will diagnose all diseased persons. Secondly, for the test to be reliable and cost-effective, it would have to be highly specific, so that persons without the disease would show negative on this diagnostic test. Considering these assumptions, many of the diagnostic tests in use seem to be far from ideal. Thus, one of the most widely used screening tests for colorectal cancer, the fecal occult blood test (rehydrated), was found to have a sensitivity of only 50% with a specificity of 94%, when compared to the gold standard of colonoscopy [14]. Another widely used screening test is the PAP smear for cervical cancer. A meta-analysis prepared for the U.S. Agency for Health Care Policy and Research in 1999 estimated the sensitivity of this commonly performed test to be only 51% but with 98% specificity [15]. Finally, a diagnostic test that has been the subject of much professional debate with regard to its place in screening for prostate cancer, prostatic specific antigen, was found to have a sensitivity range of 18–46% and specificity of 91–98% [16].

When comparing these sensitivity and specificity figures to the ones we calculated for the Medex device, we are tempted to conclude that this test is suitable for use as a screening tool, at least for some of the pathologies explored. However, we must point out the disadvantages of the test. Firstly, we were screening for non-specific pathologies (i.e., per organ/system). When the device detected pathology, it did not state the exact problem and was accepted as correct if the patient had pathology in that same organ/system. For example, when the device detected a cardiovascular pathology, it was considered accurate if the patient had an ischemic heart disease, congestive heart failure, or a vascular pathology such as an aortic aneurysm. Furthermore, we were frustrated by the fact that, from a scientific point of view, the mechanism and physiology of this

CAM = complementary and alternative medicine

method was not well established, at least not by conventional methods. Thus, we approached this study with the recognition that we were not attempting to tackle this debatable issue, and with the view that ...some things we don't understand may still work...

The fact that we did not use gold standard diagnostic tests as a comparison to evaluate the accuracy of the Medex device was a limitation of our study. We relied on predetermined evaluations and did not establish the diagnosis based on up-to-date diagnostic criteria. However, we believe that based on past history, we can establish a reliable list of pathologies (i.e., patients with past history of a coronary artery bypass grafting or a positive coronary angiography can be assumed to have a cardiovascular pathology, namely coronary artery disease). Another limitation of our study is the fact that the device was not tested in a setting of routine screening of healthy individuals – which is what the device is ultimately intended for. Thus, we cannot comment on this tool's ability to serve as a screening diagnostic tool.

This study was considered a preliminary study, aimed at evaluating the potential of this unexplored (by conventional scientific methods) technique. We feel that the results presented here merit further research aimed at a better understanding of the physiologic mechanism, and further evaluation of this tool's potential as a widely accepted evidence-based screening and diagnostic test. Indeed, further studies are being planned for evaluating the device's accuracy compared to gold standard tests such as tissue biopsy-based diagnosis and other well-established diagnostic criteria. As shown in the results and conclusions presented here, we believe the future focus of research should be on pathologies related to cardiovascular, respiratory, gastrointestinal and genitourinary systems. However, we wish to point out that at this point, this method cannot replace formal physical examination or other well-established diagnostic tests or devices.

We conclude that although the exact mechanism is not entirely clear, measuring electroskin impedance of DVZ has the potential to serve as a diagnostic tool for inner organ pathologies. According to our preliminary results, we consider it worthwhile to conduct further research on this tool, as suggested in this discussion. Future research should enhance our understanding of the physiologic mechanism, and create more evidence to support or dispute the use of this technique as a reliable diagnostic tool.

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The trouble with the rat race is that even if you win you are still a rat.

Lily Tomlin (1939-), American actress and comedienne