Diagnosing Diseases by Measurement of Electrical Skin Impedance

A Novel Technique

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ABSTRACT: Recently, we have seen the development of diagnostic tools based on the rationale that the measurement of electrical impedance of specific dermal zones might reflect the occurrence of pathological states in corresponding internal organs. Studies published lately have shown the diagnostic potential of this technique. We set out to evaluate the accuracy of this tool in diagnosing cancer. Our study group was composed of cancer patients visiting the Oncology clinic for a routine follow-up. All patients underwent conventional medical history and physical examination by a physician. We evaluated a device manufactured by Medex Screen Ltd. The device analysis was carried out by a physician who was blinded to the previous diagnosis. A third researcher compared the “conventional” diagnosis with the Medex device output using standard statistical analysis. Overall, 125 cancer patients were included in the study. When comparing Medex Screen diagnostic technique with the conventional methods of diagnosis for the various disorders we found a sensitivity of 76.2%, 78.7%, and 92.9% and a specificity of 95.0%, 90.7%, and 90.4% for lung, breast, and prostate cancer, respectively. Existence of metastatic disease or specific treatment did not affect the diagnostic properties of the described device. Although the exact mechanism is not entirely clear, measurement of electrical impedance of dermal-visceral zones has the potential to serve as a diagnostic and perhaps a screening tool for neoplastic pathologies. Further research should be conducted to create more evidence to support or dispute the use of this technique as a reliable diagnostic tool.

KEYWORDS: skin impedance; screening; diagnostic tool; cancer; neuroreflexology

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INTRODUCTION

An early detection of disease is considered to be effective in reducing mortality. This is particularly difficult yet important in asymptomatic persons, either high-risk or average-risk individuals. In this regard, the value of routine health examination of asymptomatic persons has been well established as part of a routine checkup.\(^1\)\(^,\)\(^3\) The identification of proper tests for preventive medicine is a matter of extensive research based on a systematic review of evidence of clinical effectiveness.\(^3\)

Recently, a novel diagnostic procedure was introduced based on analysis of data obtained by measuring the skin electrical impedance of predetermined dermal–visceral zones (DVZs) on the human body.\(^4\)\(^–\)\(^6\) The rationale behind the system is that single internal organs display corresponding representative zones on the trunk and on the limbs, whose physical parameters are strictly related with the presence of pathological processes. Thus, any pathological condition affecting an internal organ might induce electrophysiological changes in the corresponding DVZs.\(^7\)\(^–\)\(^9\)

The first report on such a technique (Medex Screen diagnostic technique) described the results obtained by blind assessment of patients referred to an Internal Medicine department service and suffering from a heterogeneous group of diseases. In 150 patients a good correlation was found between the formal clinical diagnosis and the results of the measurement of electrical skin impedance.\(^4\) The technique was found to be accurate in diagnosis disease in respiratory, gastrointestinal, cardiovascular, and genitourinary organs. In a recent second report, the technique was found to diagnose well-established immunological diseases (both systemic autoimmune and allergic disorders) in 108 patients.\(^5\) Another recent study demonstrated the ability of Medex Test to detect with high accuracy the presence of liver disorders and to determine the necro-inflammatory grade.\(^6\)

As cancers are a major health burden and a classic disorder in which prompt diagnosis is crucial for definitive cure, we set out to validate the new Medex Screen diagnostic technique in cancer patients in a day hospital setting.

METHODS

The study was undertaken at the division of oncology, Sheba Medical Center. We evaluated a device manufactured by Medex Screen Ltd. (Arad, Israel). The major components of the Medex Test consist of a special skin impedance measurement device used to take various measurements of the DVZs on the human body (expressed as KOhm), which are then processed by the device software.\(^10\) Once the data are processed, the Medex device can determine if pathological states are present in the examined internal organs.
Study Population

This was a blinded, single center, retrospective, and comparative study. Patients diagnosed with cancer and undergoing follow-up and disease status assessment were screened for potential participation in the study.

The study group included patients with an established diagnosis of cancer of various primary organs, either treated or nontreated. Diagnosis was established in all patients by means of tissue sample demonstrating the neoplastic disease. Exclusion criteria were represented by local skin damage in the evaluated areas, patients with missing limbs, and pregnant women. All the patients and the controls were asked to sign an informed consent and the study was approved by the ethical committee of Sheba Medical Center.

Patient Examination and Evaluation

Patients were subjected to a medical examination by authorized oncologists before the Medex Test was performed. A prestudy case report form for all subjects was recorded with medical information including main current disease, comorbidity illness, current medications, and relevant past medical history.

Technicians that were trained by Medex Screen personnel performed the Medex Test measurement. Before testing, the DVZs are cleaned with 70% ethyl alcohol solution to avoid possible effects of sebum or humidity on the skin, which could affect the test. Measurements were carried out by using skin electrode on 24 predetermined zones on the hands and feet. Skin measurement points were established according to neuroreflexology areas on the wrists, arms, ankles, and foot. Each measurement was repeated twice. First, a baseline measurement was performed; the recorded values were considered to be normative values for the individual. Then, transcutaneous electrical stimulation of other specific skin areas was performed. A second measurement was performed, and any differences were recorded and analyzed in comparison to the first set of values. The measurements were performed with an electrical current of 20 µA (voltage of 5 V). This very low electric current, is safe and does not display any damage to the skin during the short time of testing. A software program processes the collected information with the help of previously built correlative algorithm, and produces an output of suggested diagnosis.

The Medex Test technicians were unaware of the patient’s diagnoses. The results of Medex Test assessment have been compared to data from the conventionally accepted tests and the patients’ charts, in order to determine the accuracy of the Medex Test device. Software analysis was done at the Medex Screen Company’s headquarters by a second investigator that was blinded to the medical charts and physical examination details. The diagnosis determined by the Medex software was printed as a written report. A third investigator, also blinded to the actual process conducted previously, compared the actual “conventional” diagnosis and the Medex device output.
Statistical Analysis

Statistical analysis was conducted using the SPSS for Windows 10.0 program (SPSS Inc., Chicago, IL). The Medex Test diagnosis was statistically compared to the results obtained from the conventional diagnosis 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, sensitivity and specificity for the Medex Test diagnosis were calculated using the conventional diagnosis as the gold standard. In order to analyze the affect of treatment and disease activity on the test results, we performed linear regression models where the result of the Medex Test was considered the dependent variable. P value for the Cohen–Kappa test <0.01 was considered significant.

RESULTS

Overall, 125 participants were included in the study, 65 were female and 60 males. Of these, 28 were patients with prostate cancer, 22 were patients with lung cancer, 45 were patients with breast cancer, and 30 were patients with various other neoplastic disorders (cervix, endometrial, colon, renal, larynx, pancreas, seminoma, gastric, urinary bladder, and menigioma). Each of the participating patients had only one neoplastic disease. Of the study’s population 36.8% had metastatic disease while 78.4% were undergoing therapy—either chemotherapy, radiotherapy, hormonal therapy, or were receiving narcotics. Demographic and treatment data for the study’s population and for the major cancer groups are described in Table 1.

When comparing Medex Screen diagnostic technique with the conventional method diagnostic technique for the various neoplastic disorders we found a sensitivity of 76.2%, 78.7%, and 92.9% and a specificity of 95.0%, 90.7%.

<table>
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<th>TABLE 1. Diagnosis and characteristics of patients included in the study</th>
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<tr>
<td>Number of patients 125</td>
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<td>Average age (years) 63.2</td>
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<td>Gender M:F 60:65</td>
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<tr>
<td>Metastatic disease 46 (36.8%)</td>
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<td>Chemotherapy 53 (42.4%)</td>
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<td>Tumor location Overall Prostate Lung Breast Other</td>
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and 90.4% for lung, breast, and prostate cancer, respectively (Table 2). A high measure of agreement was found, as represented in the Cohen–Kappa method ($P < 0.01$).

In the linear regression model performed to analyze the affect of disease severity and treatment for the primary neoplastic disease we used the presence of metastatic lesions as a degree of disease severity and either chemotherapy, radiotherapy, or hormonal therapy independently. In all linear regression models the independent variables were not found to be significant in affecting the dependent variable—accuracy of the Medex device.

**DISCUSSION**

A relatively new application based on measuring electrical properties of dermal zones representing internal organs has recently been developed by commercial companies with the aim of diagnosing internal organs pathologies, even at early stages of the disease. This application was the focus of several published studies that have demonstrated its ability to diagnose common disorders, such as respiratory, cardiovascular, and gastrointestinal pathologies in an internal medicine department setting, autoimmune and allergy disorders, and liver disorders.

In the first published report the researchers describe their experience in determining the effectiveness of this technique, specifically the Medex device (Medex Screen Ltd.), for diagnosing patients undergoing conventional internal organ assessment, in an internal medicine department setting. In a cohort of 150 patients, the authors found this diagnostic tool to be highly sensitive (>70%) in diagnosing 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). A second study set out to evaluate the reliability of the same device test in diagnosing immune-mediated diseases in a blinded single center study. In examining 78 patients and 30 matched healthy controls, a high correlation between the formal
clinical diagnosis and the results of the measurement of electrical skin impedance was reported, with a specificity of 93.3% and a sensitivity of 81.2%. In a third study the researchers addressed two questions: first, can the Medex device detect liver disease, and second, can it measure the severity of a known liver disease? While evaluating 113 patients with liver disease (hepatitis C, hepatitis B, and nonalcoholic fatty liver disease) and 85 healthy controls, the device detected with high sensitivity (85%) and specificity (94.1%) the presence of the liver disorders. For 60 patients with hepatitis C the device was also tested for its ability to diagnose grading of the disease. The Medex device grading matched the biopsy-based pathological grading of necroinflammation in 78% of hepatitis C patients.

Another attempt to use the technique of skin impedance measurement to diagnose organ pathologies was described earlier by Szopinski et al. In a double-blind comparative study the researchers conclude that electrical impedance of skin projection areas corresponding to diseased organs is increased, relative to that of healthy organ-related skin zones. Overall, sensitivity was 91.8% and specificity equaled 89.9% in 70 patients with esophagus, stomach, duodenum, biliary tract, pancreas, colon, kidneys, and urinary tract pathologies. The difference in impedance was also found to be proportional to the intensity of the pathological process.

In the current study we set out to explore the efficacy of this novel diagnostic tool using conventional evidence-based medicine techniques, comparing the studied device diagnosis to the conventional diagnosis of cancer patients. Our study population included patients with several neoplastic diseases who attended the oncology center in a major hospital, either for treatment or for follow-up. We found a high correlation when comparing the results of the Medex Test device to the conventional clinical diagnosis for all three major disease subgroups—prostate, lung, and breast carcinoma, with a higher sensitivity to diagnosing prostate cancer than lung or breast cancer and a similar specificity. We also found that the presence or absence of metastatic disease, or specific treatment, did not affect the diagnostic properties of the described device.

The overall accuracy of the Medex device to identify neoplastic pathologies, similar to the accuracy in the other described studies performed on this technique, is surprisingly high. An ideal diagnostic test for screening would first and foremost have to be highly sensitive, so that it will diagnose all diseased persons. Second, for the test to be reliable and cost-effective, it would have to be highly specific, so that persons without the disease would be negative on this diagnostic test. Considering these assumptions, many of the diagnostic tests in use for screening today 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. 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.14 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%.15 When compared to sensitivity and specificity of most screening tests, the sensitivity and specificity of the Medex Test can lead to the conclusion that this test is suitable for use as a diagnostic tool, and perhaps even a screening tool for immune pathologies.

The major weakness of this technique, for us as scientists, is the lack of understanding of its mechanism of action in pathophysiological terms. Theories concerning neural pathways that connect through reflex arch specific dermal points/areas to internal organs have been postulated. These theories have remained speculations with no clear scientific evidence published. When trying to explain our and other published results concerning the Medex device, it is conceivable that the diseased organ has different electrical and magnetic properties that by allowing an electrical current flow through it and measuring the resistance, in a specific algorithm, one might detect the pathology. This theory still remains to be proven.

In summary, we have described here our experience with a novel technique that is still relatively unexplored by scientific methods. We feel that the results presented here merit further research aimed toward a better understanding of the physiologic mechanism, and further evaluation of this tool’s potential as an accepted evidence-based diagnostic and screening test. 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.

REFERENCES


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