CLINICAL INVESTIGATIONS LD TECHNOLOGY PRODUCTS

Abreu D.S. Bioimpedance and chronoamperometry as an adjunct to prostate-specific antigen screening for prostate cancer. Cancer Management and Research 2011:3 109–116

Link to your paper on PubMed: http://www.ncbi.nlm.nih.gov/pubmed/21629833

Abstract

Background: Bioimpedance is an electrical property of living tissue that has been shown to be a safe technique when used in a number of biomedical applications. The aim of this research was to assess the utility of bioimpedance measurement as a rapid, cost-effective, and noninvasive adjunct to digital rectal examination and PSA in differentiating tumor from normal prostatic tissue.

Methods: Three hundred men were examined for signs and symptoms of prostate disorders. 147 patients with a digital rectal examination indicating a positive result underwent a prostate-specific antigen (PSA) test. A biopsy was advised for 103 of the men, of whom 50 completed the study. Before undergoing biopsy, an examination with the EIS (electro interstitial scan) system using bioimpedance and chronoamperometry was performed. In reference to the biopsy results (negative or positive), a statistical analysis of the EIS data and PSA was conducted using receiver operating characteristic curves to determine the specificity and sensitivity of each test.

Results: The PSA test had a sensitivity of 73.9% and specificity of 51.9% using a cutoff value > 4 and a sensitivity of 52.2% and specificity of 81.5% using a cutoff value ≥ 5.7 and $P = 0.03$.
The delta of the electrical conductivity (DE) of the left foot-right foot pathway had a sensitivity of 62.5% and specificity of 85.2%, with a cutoff value ≤ -5 and $P = 0.0001$.
Algorithms comprising the delta of electrical conductivity and PSA showed a sensitivity of 91.5% and a specificity of 59.3%, with a cutoff value ≤ -10.52 and $P = 0.0003$.

Conclusion: The EIS system had a very good specificity of 85.2%. However, the sensitivity of 62.5% would be a problem. Using a PSA reference > 4.1 ng/mL, the adjunctive use of bioimpedance and chronoamperometry provided by EIS technology could raise the sensitivity from 73.9% to 91.5% and the specificity from 51.9% to 59.3% in prostate cancer screening.

CLINICAL INVESTIGATIONS COMPLETED . Accepted for publication in "Psychology Research and Behavior Management".

Bioimpedance application in Selective Serotonin Reuptake Inhibitor (SRI) treatment monitoring

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Abstract

Background:
Bioimpedance has been shown to be a safe technique when used in a number of biomedical applications. In this study, we use a device named Electro Interstitial Scan (EIS) performing bioimpedance measurements to follow up the effect of SSRI treatment in depressed subjects.

Method and material :
Fifty nine subjects (Age 47 from 17 to 76 years old and 38 women) diagnosed with major depression disorder by psychiatric assessment at the Botkin Hospital according to DSM-IV and CGI (Clinical Global Impression) were recorded with the EIS System before undergoing anti depressant SSRI treatment.
Then, SSRI treatment follow-up was undertaken on one hand with the EIS bioimpedance measurements (electrical conductivity and dispersion α parameter) and on the other hand by treatment responses based on Hamilton Depression Scale (Ham-D) and CGI each 15 days

during 60 days.

At day 45, 2 groups where constituted: group 1: group with treatment response and group 2: group with non treatment response. At day 60, 2 groups where constituted: group 3: group with treatment response and group 4: group with non treatment response

Results:
Comparing the group 1 and 2 , electrical conductivity measurement of the pathway between the 2 disposable forehead electrodes has a specificity of 72 % and a sensitivity of 85.3% ($p< 0.0001$) with a cutoff > 4.32µSi . Comparing the group 3 and 4, electrical conductivity of the same pathway has specificity of 47.6 % and a sensitivity of 76.3% ($p< 0.16$) with a cutoff > 5.92µSi.
Comparing the group 1 and 2, electrical dispersion α parameter of the pathway between the 2 disposable forehead electrodes has a specificity of 80 % and a sensitivity of 85.2% ($p< 0.0001$) with a cutoff > 0.678. Comparing the group 3 and 4, electrical dispersion α parameter of the same pathway has specificity of 100 % and a sensitivity of 89.5% ($p< 0.0001$) with a cutoff > 0.692.

Conclusion
The EIS electrical conductivity measurement of the forehead pathway has a high specificity and sensitivity at D+ 45 comparing the patients' response group and non response group. The specificity and sensitivity decrease at D+60.
The EIS electrical dispersion α parameter of the forehead pathway has a high specificity and sensitivity at D+ 45 comparing the patients' response group and non response group. The specificity and sensitivity raise at D+60.
The practitioners could therefore have available in the EIS System, a non-invasive, low-cost system that is easy to use in the office and that could offer major depression disorder treatment monitoring in adjunct to DSM-IV questionnaires and CGI .

Keywords: Major depression disorder, SSRI treatment response, Bioimpedance, EIS (Electro Interstitial Scan) system, electrical conductivity, dispersion α parameter.

CLINICAL INVESTIGATIONS COMPLETED .SUBMITTED FOR PUBLICATION

New marker using the bioimpedance technology in Attention Deficit/Hyperactivity Disorder (ADHD) Children screening in adjunct to conventional diagnostic methods

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Abstract

Background:
Bioimpedance has been shown to be a safe technique when used in a number of biomedical applications. In this study we used a device named Electro Interstitial Scan (EIS) performing bioimpedance measurement and we compared the results of conductivity measurements at the level of forehead electrodes between a diagnosed ADHD children group and no ADHD group.

Method and material:
112 children were undergoing for psychiatric examination for diagnostic of ADHD and then an examination with E.I.S (Electro Interstitial Scan) system was performed in the Dr Caudal 'office. In reference to the psychiatrist opinion and diagnostic, 2 groups were constituted:
Group 1: 60 Children supposed non ADHD children from the psychiatrics according to the DSM-IV and not undergoing for any treatment. (Mean age 8.7 years old and 27 girls).
Group 2: 52 Children diagnosed ADHD from the psychiatrics according to the DSM-IV and further examinations and not undergoing for any treatment. (Mean age 8 years old and 14 girls)

Statistical analysis was performed to compare the conductivity measurements at the level of the forehead electrodes using Independent T-tests and receiver operating characteristic curve to determine the specificity and sensitivity of the test.

Results:
Independent samples t-test results:
The mean of the 2 pathways at ADHD group was M=33.11µSi (from 2 to 113µSi) was significantly ($p<0.001$) higher than the mean of 2 pathways at the control group
M
=2.75µSi (from 1.75 to 27.4µSi).
Receiver operating characteristic curve results:

The parameter mean of conductivity of the pathway between the forehead electrodes has a specificity of 98% and sensitivity of 80 % and p=0.0001 (Upper 95% CI) using a cutoff value at 7.4 µSi.

Conclusion
The EIS marker with the conductivity measurements of the forehead pathway has a high specificity and high sensitivity and the practitioners would have a non-invasive, low-cost system, easy to use in the office, that could offer adjunct in the conventional diagnosis of ADHD children and also in treatment monitoring and, from this result, provide intervention sooner.

Comparing the accuracy of ES-BC, EIS and ES Oxi results versus the recognized standardized assessment.

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ABSTRACT

Background and Purpose: The Electro Sensor Complex (ESC) is software displaying data of combination of 3 devices using bioelectric impedance and spectrophotometry techniques: (1) ES-BC to assess body composition, (2) EIS to assess sympathetic system activity, and (3) ES Oxi to assess cardiac output. The objective of this study was to compare the: ES-BC to dual

energy x-ray absorptiometry (DEXA) on body composition, EIS to a standardized assessment of heart rate variability (HRV), as an indicator of sympathetic system activity, and ES Oxi to BioZ Dx, which uses impedance cardiography, as a standardized assessment of cardiac output.

Patients and Methods: The study was conducted in 2 waves. The first wave was performed for the evaluation of the ES- BC and EIS: Fifty subjects between 20 and 62 years of age were assessed for fat mass evaluation by the ES-BC module and dual x-ray absorptiometry (DEXA), and for sympathetic system level activity by spectrum analysis of the EIS measurement and spectrum results of the Heart Rate Variability (HRV) analysis. . The second wave was performed for the evaluation of the ES Oxi device: Fifty one subjects between 18 and 65 years of age were assessed for cardiac output by the E.S Oxi device on one hand and impedance cardiography device (BioZ) on the other hand.

Results:
First wave, using SPSS 15 (SPSS Inc., Chicago, IL) for Windows:
For percent body fat, the correlation between DXA and ES-BC, the body fat percent measurements was r=.92, p < 0.001.
For sympathetic system level activity, the correlation between the EIS HF spectrum analysis results and HRV LF spectrum analysis results was r=.76, p < 0.001.
Second wave, using SPSS 18 (SPSS Inc., Chicago, IL) for Windows:
For cardiac output, the correlations between the ES Oxi and the BioZ Dx were very high (r=0.693 (p < 0.0001) at baseline, r=0.79 (p < 0.0001) after the first exercise stage, and r=0.86 (p < 0.0001) after the second exercise stage, respectively.

Conclusion: The results of the study suggest that ES-BC, EIS, and ES Oxi demonstrate the ability to accurately assess body composition, sympathetic system activity, and cardiac output compared to standardized instruments. The ESC software displaying data from all three devices would be useful to help detect the metabolic syndrome, diabetes and its cardiovascular complications and to manage treatment follow-up in non invasive way and in 5 minutes.

Key words: Fat mass, autonomic nervous system, cardiac output, Electro Sensor Complex, ESC software, DEXA, HRV, bioimpedance cardiography.

New approach for large scale screening for the asymptomatic Hepatitis C Virus (HCV).

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Abstract

Background: Combination of technologies such as Bioimpedance and spectrophotometry has been shown to be a safe technique when used in a number of biomedical applications. The aim of this research was to assess the utility of combination of technologies as rapid, cost-effective, and noninvasive tools to detect asymptomatic chronic hepatitis C Virus in large scale.It should be used to indicate the need for further evaluation – not as a basic for diagnosis

Methods: 91 patients were undergoing for lab tests including Anti-HCV test, and Liver Panel; ALT, AST, and for an examination E.S Complex (Electro Sensor Complex) system using a combination of technologies such as the Bioimpedance and the spectrophotometry. 41 patients (group 1) were found Anti HCV test positive and 50 patients were found negative (group 2). Statistical analysis was conducted between the 2 groups using receiver operating characteristic curves to determine the specificity and sensitivity to detect C hepatitis with the ES Complex algorithm calculated from data such as the conductivity measurement and the arterial stiffness.

Results: The ES Complex algorithm using the stiffness index and delta for the conductivity value in the pathway right foot –left hand minus left hand-right foot had a sensitivity of 82.9 % and specificity of 84.8 % (cutoff > 201) and $P = 0.0001$.

Conclusion: The E.S Complex has a very high sensitivity and specificity, and it can be used at low cost and rapid screening and follow ups in large scale for asymptomatic hepatitis C virus.

Keywords: Asymptomatic hepatitis C virus screening, E.S Complex, delta of conductivity, stiffness Index.

Correlation between physiological data algorithms with the homeostasis model assessment (HOMA) and with blood glycated hemoglobin (HbA1c).

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Abstract

Background: The pathogenesis of type 2 diabetes is hypothesized to be related to two principal factors: insulin resistance and β cell function. Only blood tests and related algorithms are used to assess these factors. Physiologic data affected by these factors have never been used to screen for diabetes and prediabetes. The aim of this study was to assess the correlation of algorithms from physiologic data with the HOMA-IR and HOMA-β algorithms and HbA1C
.

Methods and material : 148 patients (117 women and 31men) mean age 39 (range 17– 62) years were included in the study and were undergoing laboratory tests including fasting blood glucose, fasting insulin plasma, HbA1c and LDL Cholesterol, blood pressure measurement and examination with the E.S Complex system.
The ES Complex system is a combination of devices managed by software, and the data obtained from the system include tissue acid base balance, arterial stiffness, autonomic nervous system level activity and body composition.
The HOMA (Homeostasis model assessment) algorithms were calculated from the fasting blood glucose and the fasting insulin plasma (HOMA-IR and HOMA-β) and ESC algorithms were calculated from the E.S Complex data.(ESC-IR, ESC-β and ESC BGC).
Statistical analysis was conducted to determine the correlation between ESC-IR (ESC-Insulin

Resistance) and HOMA-IR (HOMA-Insulin Resistance), correlation between the ESC-β (HS- β cell function) and HOMA-β (HOMA- β cell function) and correlation between the ESC-BGC (ESC-Blood Glucose Control) and HbA1c values.

Results:

The correlation between ESC-IR and HOMA-IR calculated with Spearman's coefficient of rank correlation (rho) = 0909 and $p < 0.0001$

The correlation between ESC β and HOMA-β calculated with Spearman's coefficient of rank correlation (rho) = 0876 and $p < 0.0001$

The correlation between ESC BGC and HbA1c values calculated with Spearman's coefficient of rank correlation (rho) = 0.786 and $p < 0.0001$

Conclusion: The E S Complex algorithms have a very high correlation to the HOMA algorithms and blood glycated hemoglobin (HbA1c) and therefore predictive capacity to screen insulin resistance, β cell function and blood glucose control. The ES Complex can be used as a rapid, cost-effective, and noninvasive tool in prediabetes and diabetes screening on a larger scale.The screening should be used to indicate the need for further evaluation – not as a basic for diagnosis.

Keywords: Electro Sensor Complex (ES Complex), HOMA-IR, HOMA-β, HbA1c, ESC-IR, ESC-β, ESC-BGC, large scale screening.