

CLINICAL INVESTIGATIONS EIS SYSTEM

Botkin 2006

Summary

Clinical investigations were conducted at the S.P. Botkin Hospital from May 20, 2006, to September 1, 2006, in order to evaluate a galvanic skin responses measurement device named Electro Interstitial Scan (E.I.S), we performed drug administration studies. The EIS system is measuring the electrical conductivity (inverse of the resistance) of the skin and displays 3 parameters:

- SDESG segments values (conductivity)
- EPA-SPA segments values (dynamic process to get the conductivity values)
- HF/VLF ratio (High conductivity values / very low conductivity values ratio)

Two hundred fifteen (215) test subjects (Age 54 ± 16) were recorded with the EIS System.

These patients presented affections diagnosed by conventional examinations (hypothyroidism, hypertension, atherosclerosis or thrombosis risk, and Major depression) and were undergoing no treatment.

The treatments corresponding to the diseases were decided by the conventional examinations results, and a follow-up being undertaken on one hand with the EIS System and on the other hand by conventional methods.

Hypothesis

Could the drugs 'administration affect the autonomic responses estimated from the 3 measured parameters of the EIS system and therefore the EIS can be used in adjunct in treatments' follow up?

The hypothesis was validated according to the raw data analysis:

Thyroid treatment monitoring

The findings show that SDESG and TSH has a significant negative correlation to each other ($r = -0.975$, $p = 0.005$). It shows that, TSH shares approximately 95.1% (that is $(-0.975)^2 \times 100\%$ or $0.951 \times 100\%$) of its variability with TSH. Thus, a high value of SDESG corresponds to low TSH or low value of SDESG corresponds to high TSH.

The findings show that EPA-SPA and TSH has a significant positive correlation to each other ($r = 0.926$, $p = 0.024$). It shows that, TSH shares approximately 85.7% (that is $(0.926)^2 \times 100\%$ or $0.857 \times 100\%$) of its variability with TSH. Thus, a high value of EPA-SPA corresponds to high TSH or low value of SDESG corresponds to low TSH.

Beta blockers treatment monitoring

The findings show that SDESG and Diastolic Pressure has a significant positive correlation to each other ($r = 0.975$, $p = 0.005$). It shows that, Diastolic Pressure shares approximately 95.1% (that is $(0.975)^2 \times 100\%$ or $0.951 \times 100\%$) of its variability with SDESG. Thus, a high value of SDESG corresponds to high Diastolic Pressure or low value of SDESG corresponds to low Diastolic Pressure.

The findings show that ESGHF/VLF and Diastolic Pressure has a significant positive correlation to each other ($r = 0.977$, $p = 0.004$). It shows that, Diastolic Pressure shares approximately 95.4% (that is $(0.977)^2 \times 100\%$ or $0.954 \times 100\%$) of its variability with ESGHF/VLF. Thus, a high value of ESGHF/VLF corresponds to high Diastolic Pressure or low value of ESGHF corresponds to low Diastolic Pressure.

ACE inhibitors treatment monitoring

The findings show that EPA-SPA and Diastolic Pressure has a significant negative correlation to each other ($r = -0.892$, $p = 0.042$). It shows that, Diastolic Pressure shares

approximately 79.6% (that is $(-0.892) \times 100\%$ or $0.796 \times 100\%$) of its variability with EPA-SPA at hypertension 2B. **Anticoagulant treatment monitoring**

The findings show that SDESG and PI has a significant positive correlation to each other ($r = 0.998$, $p < 0.001$).

The findings show that EPA-SPA and PI has a significant positive correlation to each other ($r = 0.961$, $p = 0.009$).

The findings indicate that ESG HF/VLF and PI has a significant positive correlation to each other ($r = 0.994$, $p = 0.001$).

SSRI treatment monitoring

The findings indicate that there were a significant positive correlations between SDESG and the treatment Response at D+30 ($\rho = 0.484$, $p < 0.001$) and D+4560 ($\rho = 0.557$, $p < 0.001$).

The findings indicate that there were a significant positive correlations between EPA-SPA and the treatment Response at D+45 ($\rho = 0.709$, $p < 0.001$) and D+60 ($\rho = 0.804$, $p < 0.001$).

Caudal 2007

Summary

Clinical trials were conducted at the office of Dr. Frederique Caudal, pediatrician and specialist in Attention-Deficit/Hyperactivity Disorder (ADHD) in children.

Symptoms of this disorder are related, in the current literature, to a low level of cerebral neurotransmitters, but what's about the autonomic nervous system?

The diagnosis of ADHD children is almost symptomatic, which leads to the dramatic possibility of error and treatment (Ritalin®, or SSRI or catecholamine's) with medications associated with numerous side effects in particular for the age of the population.

For this reason, a new, measurable, and therefore objective marker was proposed using the Electro Interstitial Scanner (EIS) galvanic skin responses measurement device, in adjunct to the conventional diagnoses and treatment monitoring of the ADHD children. From 10.04.2006 to 05.16.2007, data from 59 children (age 12 ± 5) presenting symptoms and not undergoing treatment were recorded with the EIS System. This database was compared with another control group database (age 14 ± 6) of non-hyperactive children also recorded with the same EIS System.

Hypothesis tested

The hypothesis tested was:

- Can the EIS galvanic skin responses measurement device with reference to its ESG (Electro Scan Gram) graph be used as a marker for ADHD children and therefore as adjunct to the conventional diagnosis of ADHD children?

This hypothesis was validated by statistical analysis.

In order to determine the differences between ADHD and the control group in the values of v9/v10, v2/v4/v15/v17 and v1/v3/v16/v18 comparison of means via independent samples t-test was conducted. Table 1.1 presented the t-test results for v9/v10 scores at ADHD and the control group. It shows the number of cases per group used in the analysis, the means, the standard deviation, degrees of freedom, t value and the significance of the test (p-value). The findings in Table 1.1 indicate that the mean of v9/v10 at ADHD ($M=78.38$) was significantly ($p < 0.001$) higher than the mean of v9/v10 at the control group ($M=21.75$). Thus, the score of v9/v10 at ADHD was expected to be higher than the scores of v9/v10 at control group.

Table 1.1

Independent Sample T-test for v9/v10 between ADHD and Control

	N	Mean	Std. Deviation	DF	T	P-value
ADHD	104	78.38	30.062	224	19.309	0.000
Control	122	21.75	11.166			

Table 1.2 shows the t-test results for v2/v4/v15/v17 between ADHD and the control group. Accordingly, the mean of v2/v4/v15/v17 at ADHD ($M=52.96$) was significantly ($p=0.003$) higher than the mean of v2/v4/v15/v17 at the control group ($M=47.96$). Thus, the score of v2/v4/v15/v17 at ADHD was expected to be higher than the scores of v2/v4/v15/v17 at the control group.

Table 1.2

Independent Sample T-test for v2/v4/v15/v17 between ADHD and Control

	N	Mean	Std. Deviation	DF	T	P-value
ADHD	208	52.96	19.981	450	3.031	0.003
Control	244	47.96	47.96			

T-test results for v2/v4/v15/v17 between ADHD and the control group were presented in Table 1.3. the findings shows that the mean of v1/v3/v16/v18 at ADHD ($M=30.34$) was significantly ($p<0.001$) higher than the mean of v1/v3/v16/v18 at the control group ($M=16.75$). Thus, the score of v1/v3/v16/v18 at ADHD was expected to be higher than the scores of v1/v3/v16/v18 at the control group.

Table 1.3

Independent Sample T-test for v1/v3/v16/v18 between ADHD and Control

	N	Mean	Std. Deviation	DF	T	P-value
ADHD	208	30.34	1.016	450	12.931	0.000
Control	244	16.57	0.481			

Body Composition clinical investigation

ABSTRACT

Bioelectrical impedance analysis (BIA) is an attractive method of measuring body composition in the field, but the applicability of existing predictive equations from the peer reviews has been questioned.

Objective: The objectives were to evaluate the performance of the BC module of the EIS –BC device versus the Quantum II model of RJL device and compare the measurements results and the published BIA-based predictive equations used.

Design:

1. We compared the EIS BC device versus the RJL device for the Resistance (R) and reactance (Xc) measurement of 64 healthy subjects aged 10–70 y.o, including 35 males and 29 females.

2. We compare the results of the estimated parameters (FFM, TBW and ECW) from the EIS BC algorithms used versus the RJJ device algorithms used.

In order to compare the measurements of R, X_c, TWB, FFM and EWC between RJJ and EIS-BC paired sample t-test was performed. This test is appropriate when the objective is to compare whether two scores that are taken from the same sample are significantly different.

The mean of R at RJJ ($M=508.80$) and the mean of R at EIS-BC ($M=509.02$) do not significantly differ.

The mean of X_c at RJJ ($M=66.23$) was significantly higher ($p<0.001$) than the mean of X_c at EIS-BC ($M=62.92$)

The mean of TWB at RJJ ($M=40.80$) was significantly ($p<0.001$) higher than the mean of TWB at EIS-BC ($M=30.72$).

The mean of FFM at RJJ ($M=52.26$) was significantly ($p<0.001$) higher than the mean of FFM at EIS-BC ($M=49.59$).

The mean of EWC at RJJ ($M=40.80$) was significantly ($p<0.001$) higher than the mean of EWC at EIS-BC ($M=30.72$).

Conclusion: Test under raw data BC shows that the scores of X_c, TWB, FFM and EWC for the data RJJ were significantly higher than the scores of X_c, TWB, FFM and EWC for the data EIS-BC. Whereas, it also shows that the scores of R for both RJJ and EIS-BC data do not show significant difference.