# Comparing the Accuracy of the Electro Interstitial Scan-Body Composition (EIS-BC) Device between a BC Module and a Valid Assessment of BC and between an EIS Module and a Standard Assessment of Heart Rate Variability

John E. Lewis[1], Angelica B. Melillo[1], Evan Long[1], Yaima Alonso[2], Elizabeth Ko[2], Soyona Rafatjah[2], Janet Konefal[1], and Judi M. Woolger[2]

[1]Department of Psychiatry and Behavioral Sciences and [2]Department of Medicine University of Miami Miller School of Medicine, Miami, FL 33136

## ABSTRACT

The Electro Interstitial Scan-Body Composition (EIS-BC) device consists of two modules: (1) the BC module and (2) the EIS module. The objective of this study was to compare the BC module to a standardized, valid assessment of BC and to compare the EIS module to a standardized assessment of heart rate variability (HRV). Fifty subjects between 20 and 62 years of age were assessed for body composition by the BC module (total body water, fat-free mass, and fat mass) on one hand and dual x-ray absorptiometry (DXA; total fat mass and fat-free mass). On the second hand, spectrum analysis of the EIS module and HRV as measured by a standard HRV device (ES Teck PEMS) to estimate sympathetic nervous system activity were assessed. Height, weight, blood pressure (BP), and pulse were also measured. The results of the study indicated that the correlation between DXA and EIS-BC body fat percent measurements was very high ($r=.92$, $p < 0.001$). The correlation between the EIS spectrum analysis and HRV variables was also very high ($r=.76$, $p < 0.001$), suggesting that the high conductivity ratio has predictive capability on the sympathetic nervous system activity. The results of the study suggest that the EIS-BC device has a significant level of reliability in estimating body composition and sympathetic nervous system activity.

# INTRODUCTION

Body fat percentage is the fraction of the total body mass that is fat tissue.  This index is often used as a means to monitor progress during a diet or as a measure for such activities as bodybuilding.  As a measure of health, it is more accurate than body mass index (BMI) because it directly measures body composition, and men and women have separate body fat guidelines. However, it is less popular than BMI because the techniques used to measure body fat percentage typically require equipment and skills that are not readily available in most clinical settings.  For example, a skin fold caliper is a device that is simple to use and not overly expensive, but it will not be found in the typical clinical practice, nor will the average clinician know how to use it.  A dual x-ray absorptiometry (DXA) machine will typically only be found in hospital and research settings, is very expensive, and takes some level of specialized training to operate.

During the past twenty years, the United States has fallen to a pervasive obesity epidemic (Lewis & Schneiderman, 2006).  In 1980, fewer than 47% of Americans were overweight and less than 15% were obese (BMI > 30).  Today, approximately 67% of Americans are overweight and over 27% are obese (Flegal et al., 2002; Mokdad et al., 2001).  Given the enormous public health cost of obesity, using an accurate, easy-to-use, relatively low-cost, and rapid assessment of body composition is warranted.

The Module BC of the electro Interstitial Scan-Body Composition (EIS-BC) device uses bio impedance analysis (BIA; Ivorra, 2003; Schoeller, 2000) and bio impedance spectrometry (BIS; Cox-Reijven & Soeters, 2000; Rigaud, Morucci, & Chauveau, 1996; Schoeller, 2000) to assess body composition.  The module BC uses several algorithms to calculate body composition analysis and is also based on standard methodologies in BIA and BIS (Brodie et al., 1998; Chumlea et al., 2002; Rigaud et al., 1996; Schoeller, 2000).

Spectrum analysis of heart rate variability (HRV), particularly high frequency (HF) and low frequency (LF), is considered an accurate, non-invasive indicator of the functioning of the autonomic nervous system, including its vagal and sympathetic components, according to internationally-recognized guidelines for clinical use (Kleiger et al., 1991; Malik et al., 1996; Malik & Camm, 1993; Malliani et al., 1991; Merri et al., 1990; Pomeranz et al., 1985; Scherer et al., 1993). Given the strong relationships between reduced HRV and increased mortality after an acute heart attack (Bigger et al., 1992; Casolo et al., 1992; Ewing, 1991), and between HRV and the occurrence of coronary heart disease and mortality (Tsuji et al., 1994; Tsuji et al., 1996) and that various forms of coronary heart and cardiovascular disease comprise the spectrum of the leading killer throughout the world, an accurate and rapid assessment of HRV is warranted. In addition, 24-hour Holter recorded electrocardiograms are typically used to study HRV, but this method is difficult to apply for studies with large sample sizes (Sinnreich et al., 1998).

Therefore, this type of study is likely to be significantly different from what is typically provided to patients who need their autonomic nervous system checked or want to have their body composition measured. The EIS-BC device that will be used in the study will provide another option for assessing autonomic nervous system indicators and body composition. Thus, the purpose of this study is a cross-sectional comparison of the EIS-BC and DXA on body composition (total fat-free mass and fat mass) and a spectrum analysis of the electro scan gram (ESG graphics from the EIS measurements) and HRV measured by a standard device (ES Teck PEMS). The EIS-BC device has never been compared to the ES Teck PEMS for spectrum analysis of HRV or DXA for body composition, so we cannot hypothesize specific outcomes for this study, but rather we are executing a formative, pilot study to determine if hypotheses can be generated for future studies.  The primary outcomes for this study will body composition, i.e., primarily fat mass, and spectrum analysis of HRV for 5 minutes.

# METHODS

## Study Participants

All participants (N=50) were recruited by referrals at the University of Miami Miller School of Medicine campus during 2009. The study was conducted with the approval of the Institutional Review Board for human subjects' research and participants signed informed consent before commencing in the study. The sample comprised of 40% males (n=20) and 60% females (n=30) with a mean age of 32.3 years (SD=10.2; R=20, 62). The racial/ethnic distribution of the sample was as follows: 42% Hispanic (n=21), 38% white (n=19), 12% black (n=6), 6% Asian/Pacific Islander (n=3), and 2% of other origin (n=1).

## Study Design

Potential participants 18 years of age and over were identified as those who expressed an interest in having their body composition and HRV assessed. Subjects were not enrolled in the study if they: (1) were unable to consent to the study; (2) were undergoing external defibrillation; (3) had erratic, accelerated, or mechanically-controlled irregular heart rhythms; (4) had arterial fibrillation/flutter; (5) had atrioventricular block; (6) had dermatological lesions or excessive hair that would be in contact with the placement of the electrodes on the EIS-BC device; (7) had any implanted electronic device; (8) were just prior to, during, or after menstruation; (9) were suffering from acute fever; (10) were using diuretics; (11) had prior renal or heart failure; (12) had excessively used alcohol or stimulants (amphetamines) 12 hours before the examination; (13) had diarrhea; (14) had engaged in intense physical activity or the use of a sauna 8 hours before the examination; (15) had edema; and/or (16) were pregnant.

## Outcomes and Assessments

Criteria used to select the study assessments included: (1) appropriateness for the population; (2) ease of administration and scoring; (3) the investigators' experience administering these measures; and (4) employment of measures involving a multi-method (i.e., self-report and physical measures) approach to enhance the validity of the overall assessment. Each participant completed a basic demographics and medical history questionnaire at the baseline assessment. Blood pressure (BP), heart rate (HR), and height and weight to calculate body mass index (BMI) were collected prior to EIS-BC and DXA assessments. Then, subjects were assessed with the EIS-BC device assessment for ESG spectrum analysis, HRV measurements, and body composition in the Integrative Medicine Clinic, and then taken to the Pediatric Clinical Research Laboratory for the DXA scan. The entire assessment took less than 1 hour for each participant. Subjects were compensated $10 for the participation in the study once all assessments were completed.

## Data Analysis

Data were analyzed using SPSS 15 (SPSS Inc., Chicago, IL) for Windows. Frequency and descriptive statistics were calculated on all variables. We used Pearson product-moment correlation to estimate the relationship: (1) between body fat percentage on the EIS-BC and DXA and (2) ESG HF spectrum analysis and HRV LF spectrum analysis of sympathetic nervous system activity. Linear regression was also used to estimate the predictability of ESG HF spectrum analysis on sympathetic nervous system activity. We used chi-square to classify subjects into body fat categories according to the American Council on Exercise for women and men on both the EIS-BC and DXA assessments. For women, essential fat is 10-13%, athlete is

14-20%, fitness is 21-24%, average is 25-31%, and obesity is 32% or greater. For men, essential fat is 2-5%, athlete is 6-13%, fitness is 14-17%, average is 18-24%, and obesity is 25% or greater. We used $\alpha = 0.05$ as the criterion for statistical significance.

## RESULTS

### Clinical Measurements

Mean systolic BP was 117.2 mm Hg (SD=12.7, R=96, 142), mean diastolic BP was 75.1 mm Hg (SD=12.3, R=38, 100), mean HR was 68.8 beats per minute (SD=9.7, R=41, 90), mean height was 66.7 inches (SD=4.3, R=59, 75), mean weight was 159.4 pounds (SD=41.5, R=98, 258), and mean BMI was 25.1 $kg/m^2$ (SD=6.2, R=18.4, 48.7) for the total sample.

### Body Composition

The EIS-BC measurements were as follows: fat free mass (M=115.8 pounds, SD=30.1, R=71.6, 180.9), fat mass (M=43.6 pounds, SD=22.5, R=23.3, 128.1), and percent body fat (M=26.8%, SD=8.2, R=12.2, 50.5). The mean percent body fat according to DXA was 26.5% (SD=11.0, R=8.6, 53.5). The correlation between EIS-BC percent body fat and DXA body fat was r=0.92 ($p<0.001$). According to the EIS-BC body fat percentage, subjects were classified as following: (1) athlete (n=4, 8%), fitness (n=9, 18%), average (n=20, 40%), and obese (n=17, 34%). According to the DXA body fat percentage, subjects were classified as following: (1) athlete (n=8, 16%), fitness (n=11, 22%), average (n=15, 30%), and obese (n=16, 32%). According to chi-square ($\chi^2[9]=46.3$, $p < 0.001$), the frequency or proportion of those classifications was disparate between the EIS-BC and the DXA assessments. For example, DXA classified 8 subjects in the athlete category, whereas EIS-BC only classified 4 subjects in the athlete category, and only 2 subjects were classified as an athlete according to both devices.

**HRV and Autonomic Nervous System Activity**

The correlation between ESG HF spectrum analysis and HRV LF spectrum analysis variable was $r=0.76$ ($p < 0.001$). Utilizing ESG HF spectrum analysis as the independent variable and the HRV LF as the dependent variable in a linear regression, the model is statistically significant ($F[1, 49]=63.8$, $p < 0.001$). The adjusted $R^2$ value is 0.56. Finally, ESG HF spectrum analysis is a significant predictor of HRV LF spectrum analysis, according to the t test ($t=8.0$, $p < 0.001$).

## CONCLUSIONS

The results of the study suggest that the EIS-BC and DXA measurements are comparable in their estimates of body fat percentage, when continuous data are correlated with one another. However, when body fat percentage is classified according to the American Council on Exercise for each assessment method, the EIS-BC and DXA categorize 18 (36%) of the sample differently. Thus, some caution is warranted in interpreting the results of the continuous data as a completely reliable measurement between EIS-BC and DXA. Regarding HRV and autonomic nervous system activity, the results strongly indicate that ESG HF is a statistically significant predictor of HRV LF. A significant correlation was found between the two variables and a high amount of variance was explained in autonomic nervous system functioning (i.e., HRV LF) by ESG HF. All subjects completed every assessment with reporting any adverse event, and the assessments were completed in a timely fashion.

## REFERENCES


Bigger JT, Fleiss JL, Rolnitzky LM, et al. The ability of several short-term measures of RR variability to predict mortality after myocardial infarction. *Circulation* 1993;88:927-934.

Brodie D, Moscrip V, Hutcheon R. Body composition measurement: a review of hydrodensitometry, anthropometry, and impedance methods. *Nutrition* 1998; 14:296-310.

Casolo GC, Stroder P, Signorini C, et al. Heart rate variability during the acute phase of myocardial infarction. *Circulation* 1992;85:2073-2079.

Chumlea W, Guo S, Kuczmarski R, Johnson C, Heymsfield S, Lukaski H, Friedl K, Hubbard V. Body composition estimates from NHANESIII bioelectrical impedance data. *Int J Obesity* 2002; 26:1596-1609.

Cox-Reijven, PL, Soeters PB. Validation of bio-impedance spectroscopy: Effects of degree of obesity and ways of calculating volumes from measured resistance values. *Int J Obesity* 2000; 24(3):271-280.

Ewing DJ. Heart rate variability: an important new risk factor in patients following myocardial infarction. *Clin Cardiol* 1991;14:683-685.

Flegal KM, Carroll MD, Ogden CL, Johnson CL. Prevalence and trends in obesity among US adults, 1999-2000. *JAMA* 2002 October 9; 288(14):1723-7.

Ivorra, A. (2003). Bioimpedance monitoring for physicians: An overview. Available at: http://www.ldteck.com/1PDF/7.%20%20Bioimpedance_for_physicians_rev1.pdf. Accessed: March 16, 2009.

Kleiger RE, Bigger JT, Bosner MS, et al. Stability over time of variables measuring heart rate variability in normal subjects. *Am J Cardiol* 1991;68:626-630.

Lewis J, Schneiderman N. Nutrition, physical activity, weight management, and health. *Revista Colombiana de Psiquiatría* 2006; 35(Supplement):157S-175S.

Malik, M., Bigger, J., Camm, A., Kleiger, R., Malliani, A., Moss, A., Schwartz, P. Heart rate variability: Standards of measurement, physiological interpretation, and clinical use**.** *Eur Heart J* 1996; 17:354-381.

Malik M, Camm AJ. Components of heart rate variability: what they really mean and what we really measure. *Am J Cardiol.* 1993;72:821-822.

Malliani A, Pagani M, Lombardi F, Cerutti S. Cardiovascular neural regulation explored in the frequency domain. *Circulation.* 1991;84:1482-1492.

Merri M, Farden DC, Mottley JG, Titlebaum EL. Sampling frequency of the electrocardiogram for the spectral analysis of heart rate variability. *IEEE Trans Biomed Eng.* 1990;37:99-106.

Mokdad AH, Bowman BA, Ford ES, Vinicor F, Marks JS, Koplan JP. The continuing epidemics of obesity and diabetes in the United States. *JAMA* 2001 September 12; 286(10):1195-200.

Pomeranz B, Macaulay RJB, Caudill MA, et al. Assessment of autonomic function in humans by heart rate spectral analysis. *Am J Physiol* 1985;248:H151-H153.

Rigaud B, Morucci J, Chauveau N. Bioelectrical impedance techniques in medicine. Part I: Bioimpedance measurement. Second section: impedance spectrometry. *Crit Rev Biomed Eng* 1996; 24:257-351.

Scherer P, Ohler JP, Hirche H, Höpp H-W. Definition of a new beat-to-beat parameter of heart rate variability. *PACE Pacing Clin Electrophysiol.* 1993;16:939.

Schoeller D. Bioelectrical impedance analysis. What does it measure? *Ann NY Acad Sci* 2000; 904:159-162.

Sinnreich, R, Kark, J, Friedlander, Y, Sapoznikov, D, Luria, M. Five minute recordings of heart rate variability for population studies: repeatability and age-sex characteristics. *Heart* 1998;80:156-162.

Tsuji H, Larson MG, Venditti FJ, et al. Impact of reduced heart rate variability on risk for cardiac events: the Framingham heart study. *Circulation* 1996;94:2850-2855.

Tsuji H, Venditti FJ, Manders ES, et al. Reduced heart rate variability and mortality risk in an elderly cohort: the Framingham heart study. *Circulation* 1994;90:878-883.