

MEASURING THE HUMAN ENERGY FIELD: STATE OF THE SCIENCE

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GASEOUS DISCHARGE VISUALIZATION (GDV) BIOELECTROGRAPHY IN PATIENTS WITH HYPERTENSION (PILOT STUDY)

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ABSTRACT

Objectives

The purpose of this study was to compare the Gas Discharge Visualization images (GDV gram) and Heart Rate Variability (HRV) of healthy adults and patients hospitalized for hypertension. A second purpose was to compare the effect of low energy laser plus medication (LEL+M) with medication alone in the hypertensive patients.

Subjects

Twenty-four healthy young adults (control group) and 26 patients hospitalized for hypertension at the St. Petersburg Military Medicine Hospital (diseased group).

Methods

Subjects completed a screening questionnaire, underwent a physical examination and measurements of sitting blood pressure, static unfiltered and filtered GDV grams, dynamic GDV grams, and five-minute measurements of HRV in each of three positions. The diseased group underwent inpatient treatment for three weeks with 10 low energy laser treatments to the back and neck plus usual medical treatment, or medical treatment alone.

Results

The control group blood pressure was $117/75 \pm 9/7$ (Mean \pm SD), and the Diseased Group blood pressure was $145/88 \pm 21/11$, (Control vs. Diseased systolic $p = 0.02$ /diastolic $p = 0.0004$). All patients had an ejection fraction ≥ 45 percent. The Control Group was younger and had a lower body mass index than the diseased group. Six GDV indices were statistically different between the Control and Diseased Groups at baseline: Left and Right Hand Fractality, Left and Right Hand GDV Health Index, Right Hand Entropy, and Right Hand JS (RJS). RJS averaged -0.56 ± 0.8 for the

control group and -0.15 ± 0.6 for the Disease Group (controls vs. Disease Group, $p = 0.01$). Most of HRV indices differed significantly between Control and Diseased Groups.

LEL+M decreased systolic and diastolic blood pressure ($151/93 \pm 16/10$ to $127/81 \pm 5/6$, systolic $p < 0.0001$, diastolic $p = 0.0005$), and decreased LJS (-0.162 ± 0.4 to -0.704 ± 0.5 , $p = 0.001$) but not RJS. LEL+M decreased SDNN msec2, (45.6 ± 19.3 vs. 37.9 ± 19.6 , $p = 0.03$), decreased CV percent (5.6 ± 3.0 to 4.7 ± 2.8 , $p = 0.01$), decreased RMSSD msec2 (37.4 ± 38.6 vs. 28.8 ± 36.7 , $p = 0.034$) during the background test. Medication treatment did not reduce blood pressure mm Hg ($140/83 \pm 25/11$ to $132/83 \pm 14/8$, systolic $p = 0.16$, diastolic $p = 0.89$) nor Js of either hand (LJS - 0.522 ± 0.8 to -0.605 ± 0.5 , $p = 0.45$); it did reduce normalized area and increase fractality. Medication treatment increased RMSSD, msec2 (30.538 ± 26.0 vs. 57.2 ± 64.6 , $p = 0.045$, increased PNN50, percent (4.5 ± 5.5 vs. 14.5 ± 16.5 , $p = 0.02$) and decreased VLF percent (45.4 ± 17.7 vs. 31.8 ± 19.7 , $p = 0.02$), during the background test.

Conclusions

GDV and HRV indices differed between Control and Diseased Groups at the baseline examination. Inpatient treatment altered some, but not all GDV and HRV measures in each treatment group. The LEL+M normalized blood pressure and LJS, a global GDV measure of health status. The pattern of HRV changes suggests that low energy laser treatment increased parasympathetic and decreased sympathetic activity of these hypertensive patients.

KEY WORDS GDV, bioelectrography, HRV, hypertension, low energy laser

GLOSSARY

- CG - Control Group
- DG - Disease Group
- LTG - Laser Treatment Group
- MTG - Medication Treatment Group
- LEL+M - low energy laser plus medication
- GDV - Gaseous Discharge Visualization
- HRV - Heart Rate Variability

HRV INDICES

- RRNN - Average length of R-R intervals measured over short-term period (< 5 minutes)
- SDNN - Standard Deviation of the NN values (NN denotes a single normal-beat to normal-beat interval).
- RMSSD - The square root of the mean of the sum of the squares of differences between adjacent NN intervals.
- pNN50 - The proportion derived by dividing NN50 by the total number of NN intervals (where NN50 count is number of pairs of adjacent NN intervals differing by more than 50 msec in the entire recording).

CV percent - Coefficient of Variation = $SDNN/RRNN \times 100$ percent
TP, msec2 - Total Power of the spectrum
LF, msec2 - Power in the low frequency range (0.04–0.15 Hz)
HF, msec2 - Power in the high frequency range above 0.15 Hz
LF, nu - Power of Low-frequency wave measured in normalized units
HF, nu - Power of High-frequency wave measured in normalized units
LF/HF - Low/High Frequency components Ratio

GDV INDICES

FC - Form Coefficient
NORM - Normalized Area
AvBr - Average Brightness
ENT - Entropy
FRACT - Fractality
AnInd - GDV Anxiety Index
H ind - GDV Health Index
JS - JS Integer

INTRODUCTION

Hypertension is an important public health problem in developed countries: The Framingham Study showed that almost one-half of their study population had blood pressures greater than 140/90. Hypertension is readily detectable but if untreated, may lead to end organ damage such as cardiac enlargement, myocardial infarction, impaired renal function, or cerebrovascular accidents. Although the number of undiagnosed and/or untreated patients has been reduced significantly, in 90 to 95 percent of cases the etiology of hypertension is still largely unknown.¹

The regulation of arterial pressure involves interrelated mechanisms, including the peripheral and/or central nervous system as well as renal, hormonal, and vascular factors. Heart Rate Variability is a measure of the variation of both instantaneous heart rate and RR intervals.² A recent task force concluded that HRV has considerable potential to assess the role of autonomic nervous system fluctuations in normal healthy individuals and in patients with various cardiovascular and noncardiovascular disorders.²

HRV has been studied in patients with hypertension. Studies typically show a decrease in HRV in essential hypertension and an inverse relationship between disease severity and magnitude of the HRV change.^{3,4} More detailed studies showed a direct relationship between the low-frequency (LF) component and LF/HF ratio with the severity of hypertension.⁵

Gaseous Discharge Visualization (GDV) bioelectrography is an imaging method that captures the interaction of an induced brief high voltage electromagnetic impulse with a human subject's 10 fingertips. Studies performed in Russia suggest that GDV images reflect influences of an autonomic

nervous system. The performance of GDV bioelectrography compared to HRV in a well-characterized study population has not been tested.

The purpose of this study was to compare the Gas Discharge Visualization images (GDV gram) and Heart Rate Variability (HRV) of healthy adults and patients hospitalized for hypertension. A second purpose was to compare the effect of low energy laser plus medication (LEL+M) with medication alone in the hypertensive patients.

METHODS

Test measures were performed between January, 2002 and March 2002. The study design was approved by responsible authorities in the St. Petersburg Medical Military Academy and St. Petersburg State Technical University. Verbal informed consent was obtained from all subjects in advance of performing the procedures.

Study Population Selection:

Control Group Subjects: The Control Group subjects were recruited from third year, highly physically trained medical students who attended classes at the Physiotherapy Department of the St. Petersburg Medical Military Academy. They were on no medications and reported no chronic diseases, specifically no cardiovascular diseases or diseases which affect the cardiovascular system such as hypertensive encephalopathy of any etiology, impaired renal function, pheochromocytoma, obesity, thyroid diseases, head injuries, toxemia of pregnancy, thrombotic and hemorrhagic stroke, dissecting aortic aneurysm, malignancies, or recent operations.

Disease Group: The Disease Group (DG) patients were recruited from patients aged 30–80 years admitted to the Internal Medicine Ward of St. Petersburg Medical Military Academy Hospital with a diagnosis of moderate to severe hypertension. Patients with current or past malignancies were excluded.

Treatment Group Assignment: The Disease Group was divided into two treatment groups: Low Energy Laser treatment group (LTG) and the conventional Medication treatment group (MTG). Patients assigned to the LTG had a primary diagnosis of Stage I or II Hypertension (Blood Pressure $\leq 180/100$ mm Hg), no evidence of end organ damage and no other co-morbid (cardiovascular and non-cardiovascular) diseases. Patients assigned to the MTG had Stage III Hypertension (Blood Pressure $\geq 180/100$ mm Hg) or had other cardiovascular events such as primary disease, had evidence of end organ damage, or refused treatment with the Low Energy Laser.

Study Design: Diseased subjects underwent baseline evaluation (“Baseline”) within three to four days of hospital admission, but before treatment was started. Follow-up examination (“Post Treatment”) occurred two weeks after initiating Laser treatment (typically after two weeks or seven to 10 laser treatment sessions). Follow-up examination for the MTG occurred after three weeks of inpatient medical therapy.

Control subjects were examined once ("Baseline").

Test sequence: All examinations were performed in the following sequence between 9:30 A.M. and 1:30 P.M. with the subjects seated in a quiet room with temperature 22–24°C. All subjects had completed breakfast by 9:00 A.M. and did not have lunch until after the test sessions:

1. Subject characteristics were obtained only at baseline evaluation.
2. Sitting Blood Pressure (Systolic and Diastolic) was measured by sphygmomanometry at the baseline and post-treatment examinations.
3. Static GDV measurements of the 10 fingers of the Right and Left hand were captured first without the filter and then with the polyethylene filter. Dynamic GDV measurements of the fifth Right and Left digits were then captured for 30 seconds.
4. Three sequential short-term (five minutes) HRV measurements were performed.

Subject Characterization: The demographic characteristics (age, sex, height, weight, BMI, smoking habits, alcohol intake, office blood pressure measurement) were obtained from every subject in this study. Diseased patients also answered the questions about clinical history (primary disease, duration of primary disease, co-morbid diseases).

Blood Pressure: Sitting sphygmomanometric blood pressure was measured after 15 minutes of rest at the test center. Patients had received their scheduled antihypertensive medications during the blood pressure measurement.

GDV Measurement: Registration of both dynamic and static GDV images were implemented using the GDV Compact device developed by Kirlioniks Technologies International Ltd (Russia). GDV Capture software was used for capturing and saving black and white GDV images in .bmp format. GDV Processor software was used to process both static and dynamic images. Both software programs were provided by the manufacturer of GDV device.

The patients were seated at the table with a GDV device directly in front of them. The tester trained subjects in the placement of the finger pad on the dielectric plate. For each digit registration, the light shield sleeve was opened, so the trainer would verify correct finger placement. Static images were captured following a 0.5 second stimulus period. The dynamic images were captured during a 30 second stimulus period. To capture both static and dynamic GDV images, high-voltage impulses were applied using alternating current with a frequency of 50 Hz and voltage of 220 V. The amplitude of generated high-voltage impulses was up to 5 kV, impulse frequency was 1024 Hz, and duration of single impulse was 10 microseconds.

Processing GDV images enabled derivation of static and dynamic parameters. Static parameters are:

The JS Integer (JS [Integral Area Coefficient]) is defined as the logarithm of the area of BEO-gram area of fingers of a particular study subject, normalized according to the area of the inner oval of a

healthy subject. This parameter represents the deviation of measured BEO-gram value from the “ideal image” and reflects the global health of a particular subject. The area of the “ideal” image is the area of the test-object or the average area of all the subjects in a group of healthy subjects. Measurements must be registered on the same GDV device. JS values of (-0.6 / + 0.3) are considered by the manufacturer as indicative of a “good health status.” The distribution of values for this parameter varies with age: “Good health status” for individuals 20 years old and less - (- 0.6 / +1.3), 20–60 years old - (- 0.6 / + 1.0), 60 years old and more - (- 0.6 / + 0.6).

The GDV Health Index is defined as the filtered GDV JS parameter.

The GDV Anxiety Index is the absolute magnitude of difference of the Integral Area Coefficients (JS) of BEO-grams created using GDV images captured with and without filter taking corresponding dispersion. The GDV Anxiety Index is graded on a zero to ten scale with two to four defined as normal by the manufacturer. Values of zero to two were defined as below normal levels of anxiety, four to eight defined as increased levels of anxiety, and eight to ten defined as evidence of distress or altered state of consciousness.

Dynamic parameters are:

The Form Coefficient is defined as “ $FC = aL^2/S$ ” (relative units), where L is the length of the perimeter (external contour) of the BEO-gram, and S is the area of the BEO-gram. FC describes the degree of irregularity of the BEO-gram’s external contour relative to the BEO-gram area.

The Normalized Area is defined as “ $NA = S'/S1$ ” (relative units), where S' = BEO-gram area, and $S1$ = inner oval area.

The Average Brightness (relative units) is defined as
$$PJ = \sum_{i=0}^n d[i]i / \sum_{i=0}^n d[i];$$

where i – brightness, i belongs to (0,250), i = 0 – min brightness, i = 250 – max brightness, N – number of levels of brightness, d[i] - number of pixels of the image of the specified level of brightness.

The Entropy is defined as “ $E = - \sum P_i \ln P_i$ ” (relative units), where p_i is a normalized function having the meaning of probability density, $p = 0$ showing the total regularity of system (in this case Entropy=0), i – horizontal line, n_i - number of horizontal lines, $P_i = n_i/360$ – probability, showing how many times curve of perimeter of external contour of the BEO-gram crosses particular horizontal line ($i_1, i_2, i_3 \dots$), R - radius of BEO-gram, α - angle between Radius of BEO-gram and axis x; $\alpha \in (0, 360)$. Entropy is a measure of disorder of the BEO-gram.

The Fractality is defined as “ $FrC = 2\Pi L/R_{av}$ ” (relative units), where $R_{av} = (R_1 + R_2 + \dots + R_n)/n$, L - length of perimeter of BEO-gram, R_{av} - average radius of each level of brightness of BEO-gram, n - number of levels of brightness of BEO-gram, Π - constant number = 3,14. Fractality evaluates the degree of irregularity of the BEO-gram’s external contour relative to its area.

Heart Rate Variability: Heart rate variability was registered using NeuroSoft Software developed by NeuroSoft Company (Ivanovo, Russia). Short-term (five minutes) HRV assessment occurred in a dim, quiet room with subjects resting in the supine position for five to ten minutes before the start

of the HRV test. Four leads were attached: right hand, left hand, right ankle, left ankle. The first five-minute *Background test* (B) was performed in the supine position with regular quiet tidal Breathing. The second five-minute *Deep Breathing test* (I) was also performed in the supine position with slow, controlled Deep Breathing rate of six breaths per minute (five second inhalation time and five second exhalation time). The third five-minute *Ortho test* occurred after subjects resumed regular tidal Breathing and as they changed their position from supine to standing.

Heart Rate (HR) was calculated using the following formula: $HR \text{ (Heart Rate)} = 60 \times 10^3, \text{ msec/R-R, sec}$, where R-R is the average length of R-R intervals for each group.

The standard deviation of R-R intervals (SDNN) and the root-mean square of successive differences in R-R intervals (RMSSD) were used as time domain measures of R-R interval variability.

Total power (TP, 0.003–0.4 Hz) and power of high-frequency (HF, > 0.15 Hz) and low-frequency bands (LF, 0.04–0.15 Hz) were calculated. Powers were determined in absolute and normalized units (n.u.). The n.u. were calculated using these two formulas:

$$LF, \text{ n.u} = LF / (TP - VLF) \times 100$$

$$HF, \text{ n.u} = HF / (TP - VLF) \times 100$$

LF/HF-ratio and mean values of systolic and diastolic blood pressure were calculated.

Echocardiogram: Echocardiograms were recorded using the hospital's ultrasound imaging system and values extracted from the clinical report.

Low Energy Laser Treatment: Low Energy Laser Treatment was performed by physical therapists at the clinical research site utilizing a laser device. The device head (2 cm diameter) delivered a wave length of 890 nm with energy delivered to a target tissue over a period of time equals 7 Joules. A treatment session consisted of application of the laser device for one to two minutes to 16 separate sites. No erythema or other skin changes occurred at the site of device application. Patients received seven to ten treatments, one treatment a day, weekdays only. The treatment protocol ended when blood pressure control was considered satisfactory.

Medication Treatment: The study coordinators were not provided with specific treatment regimens for the patients in either the LTG +M or the MTG. Most subjects from the LTG group typically did not take antihypertensive medications prior to hospitalization, so low energy laser treatment for them was the only treatment. For several subjects from the LTG, the typical treatment was to continue previous antihypertensive medications and to add Laser treatment. For the MTG, the typical treatment regimen at St. Petersburg Medical Military Hospital consisted of a combination therapy beginning with a diuretic (hydrochlorothiazide, furosemide, spironolactone) and an agent from one of four drug classes:

1. Antiadrenergic Agents:
 - L-Adrenergic Receptors Blockers (prazosin, doxazosin)
 - B-Adrenergic Receptors Blockers (propranolol, metoprolol)
2. Vasodilators (hydralazine, nitroprusside)
3. Angiotensin-Converting Enzyme Inhibitors (Captopril, Enalapril)
4. Calcium Channel Antagonists (nifedipine, verapamil)

Dosage was increased until blood pressure control was achieved and decreased if unacceptable side effects occurred. Typically, a three-week hospitalization was required to establish an appropriate medication treatment regimen.

Statistical Analysis

Data were analyzed with the Statistica 5.0 software developed by Statsoft company (Russia) for the descriptive analyses. Chi square test was used to compare dichotomous variables. Due to the small sample size and skewed distribution of the study population, nonparametric statistics analyses were used to compare continuous variables for the Control vs. Disease Group. Three nonparametric alternatives to the unpaired t-test for independent samples were used for comparisons:

The Wald-Wolfovitz Runs test assesses the hypothesis that two independent samples were drawn from two populations that differ in some respect, i.e., not just with respect to the mean, but also with respect to the general shape of the distribution. The null hypothesis is that the two samples were drawn from the same population. In this respect, this test is different from the parametric t-test which strictly tests for differences in locations (means) of two samples.

The Mann-Whitney U test assumes that the variable under consideration was measured on at least an ordinal (rank order) scale. The interpretation of the test is essentially identical to the interpretation of the result of a t-test for independent samples, except that the U test is computed based on rank sums rather than means. The U test is the most powerful (or sensitive) nonparametric alternative to the t-test for independent samples; in fact, in some instances, it may offer even greater power to reject the null hypothesis than the t-test.

The Kolmogorov-Smirnov test assesses the hypothesis that two samples were drawn from different populations. Unlike the parametric t-test for independent samples or the Mann-Whitney U test, which test for differences in the location of two samples (differences in means, differences in average ranks, respectively), the Kolmogorov-Smirnov test is also sensitive to differences in the general shapes of the distributions in the two samples; i.e., to differences in dispersion, skewness, etc. Thus, its interpretation is similar to that of the Wald-Wolfovitz runs test.

A value of $P < 0.05$ was considered statistically significant. The results are expressed as Mean \pm SD or number of cases and percentages.

RESULTS

I. Baseline Differences (Diseased vs. Control Groups):

Sixty-nine subjects were initially recruited for the study: The final study population consisted of 24 Control subjects and 26 Disease subjects. Eighteen subjects from Control and Disease Groups were excluded from the final data. Fifteen patients from the DG were excluded from data analysis because of absent follow-up data: Three patients were transferred to another hospital, eight declined follow-up examination, three patients were excluded because GDV or HRV measurements did not meet quality criteria, and data for one diseased subject was inadvertently deleted. Three healthy controls were excluded from the final analysis because of an incomplete baseline evaluation.

Subject characteristics:

Table 1 shows the baseline subject characteristics of the Control Group and the Disease Group.

Table 1. Baseline Study Population Characteristics

Variable	All subjects Mean	SD*	Control Mean	Group SD	Disease Mean	Group SD	P - value
Number	50		24		26		
Age (years)	36	17.3	21	2.5	50	13.8	< 0.0001
Height (cm)	171	8.2	174	6	168	24	< 0.0001
Weight (kg)	75	11.5	70	8	74	15	< 0.0001
Heart Rate (beats/min)	67	12	59	14	72	13	0.0008
Blood Pressure (mm Hg)							
Systolic	132	22	117	9.1	145	21.7	< 0.0001
Diastolic	82	12	75	7.5	88	11.4	< 0.0001
Body Mass Index (kg/m ²)	25.7	4.2	22.8	1.8	28.3	4.2	< 0.0001
Gender							
Male	72		83		62		0.08
Female	28		17		38		
Smoking status							
Current smoker (%)	30		33		27		0.56
Not current smoker (%)	70		66		73		
Alcohol intake							
Any (%)	18		8		27		0.08
None (%)	72		92		73		

*SD (here and below) = Standard Deviation

The Control Group averaged 21 years old (range 19–28), and the Disease Group averaged 50 years old (range 29–81), $p < 0.0001$. BMI, kg/m² in Control and Disease Groups averaged 22.8 ± 1.8 vs. 28.3 ± 4.2 , $p < 0.0001$. Twenty-two healthy controls (92 percent) and four diseased subjects (15 percent) had normal weight (BMI ≤ 25.9 kg/m²). Two healthy controls (8 percent) and 22 diseased subjects (85 percent) had overweight (BMI > 25.9 kg/m²). The blood pressure averaged $117/75 \pm 9/7$ in the Control Group and $145/88 \pm 21/11$ in the Disease Group, $p = 0.03/0.0005$ (See Table 1).

Baseline diseased subjects characteristics:

Thirteen of the 26 Disease subjects were in the LTG +M, and 13/26 were in the MTG. The admitting diagnosis for the cardiovascular Disease Group was uncontrolled Hypertension (N = 19) and Hypertension plus Ischemia (N = 7). The LTG +M were younger than MTG (42.6 ± 9.4 vs. 56.7 ± 14.1 , $p = 0.006$). Heart Rate was not different between treatment groups at baseline examination. Baseline Diastolic blood pressure of the LTG +M was higher than of the MTG (93.1 ± 9.7 vs. 83 ± 11.1 , $p = 0.02$). EF, percent was higher in the LTG +M than in the MTG (68 ± 5 vs. 60 ± 7 , $p = 0.004$). The other baseline characteristics were not different in the two Groups (See Table 2).

GDV indices:

The mean JS Integer for both Left and Right Hands in the Control Group was more negative and more close to normal values than in the Disease Group. The Right Hand JS Integer (RJS) averaged -0.56 ± 0.8 for the control group and -0.15 ± 0.6 for the cardiovascular Disease Group (Controls vs. Disease Group, $p = 0.01$ according to Wald-Wolfowitz Runs test). The Left Hand JS Integer (LJS) averaged -0.55 ± 0.8 for the control group and -0.34 ± 0.7 for the cardiovascular Disease Group (Control vs. Disease Group, $p = 0.77$ according to Wald-Wolfowitz Runs test).

Wald-Wolfowitz Runs test showed a significant difference for Left Hand Fractality and Left Hand GDV Health Index in the two study groups. Left Hand Fractality averaged 2.44 ± 0.4 for the control Group and 2.25 ± 0.3 for the cardiovascular Disease Group (Control vs. Disease Group, $p = 0.02$). Left Hand GDV Health Index averaged 0.08 ± 0.6 for the Control Group and 0.37 ± 0.4 for the Disease Group (Control vs. Disease Group, $p = 0.01$ according to the Wald-Wolfowitz Runs test and $p = 0.05$ according to the Mann-Whitney U test).

Both the Mann-Whitney U test and Kolmogorov-Smirnov test showed the significance of Right Hand Entropy, Right Hand Fractality and Right Hand GDV Health Index. Right Hand Entropy averaged 2.3 ± 0.6 for the Control Group and 2.02 ± 0.6 for the Diseased Group (controls vs. Diseased Group, $p = 0.03$ according to the Mann-Whitney U test and $p < 0.05$ according to the Kolmogorov-Smirnov test). Right Hand Fractality averaged 2.8 ± 1.6 for the Control Group and 2.26 ± 0.45 for the Disease Group (Control vs. Disease Group, $p = 0.03$ according to the Mann-Whitney U test and $p < 0.05$ according to the Kolmogorov-Smirnov test). Right Hand GDV Health Index averaged 0.07 ± 0.6 for the Control Group and 0.33 ± 0.3 for the cardiovascular Disease Group (Control vs. Disease Group, $p = 0.03$ according to the Mann-Whitney U test and $p < 0.025$ according to the Kolmogorov-Smirnov test) (See Table 3).

Table 2. Baseline Characteristics of the Hypertensive Subjects

Variable	LTG*		MTG**		P - value
	Mean	SD	Mean	SD	
Number	13		13		
Age (years)	42.6	9.4	56.7	14.1	0.006
Height (cm)	171.3	8.4	166.4	9.7	0.180
Weight (kg)	83	14.1	78.5	9.5	0.350
Heart Rate (beats/min)	74	12	71	14	0.590
Blood Pressure (mm Hg)					
Systolic	150.8	16.4	139.6	25.3	0.190
Diastolic	93.1	9.7	83.1	11.1	0.022
Body mass Index (kg/m ²)	28.1	4.6	28.6	3.9	0.780
Gender					
Male	9	69	7	54	0.420
Female	4	31	6	46	
Echocardiogram					
ESDvs (cm)	3.2	0.4	3.6	0.5	0.058
EDDvs (cm)	5.2	0.6	5.2	0.5	0.932
EF (%)	68	4.8	60	6.6	0.004
PWLv (cm)	1.0	0.2	1.1	0.2	0.121
VS (cm)	1.1	0.2	1.2	0.1	0.274
Cholesterol (mmol/l)	6.3	1.2	6.6	1.4	0.560
Adult Desirable* (%)	15		15		
Borderline** (%)	39		15		
High Risk*** (%)	46		55		
Missing data**** (%)	0		15		
Duration of primary disease (years)	5	3.2	10.8	11.3	0.090
< 1	23		15		
2 - 9	62		46		
> 10	15		39		
Smoking status					
Current smoker (%)	31		23		0.650
Not current smoker (%)	69		77		
Alcohol intake					
Any (%)	23		31		1.000
None (%)	77		69		
Primary Disease					
Hypertension (%)	100		38		0.001
Hypertension + Ischemia (%)	0		62		

*LTG - Laser Treatment Group, **MTG - Medication Treatment Group, Cholesterol: *Adult Desirable, < 5.2 mmol/l, **Borderline, 5.2 - 6.2 mmol/l, ***High Risk, > 6.2 mmol/l, ****Missing data (percent).

HRV parameters:

At the baseline examination, the mean Heart Rate in the Control and Disease Groups was 59 ± 14 beats/min and 72 ± 13 beats/min respectively, $p = 0.0008$. The K30/15 was significantly higher in the Control Group compared with the Disease Group (1.6 ± 0.3 vs. 1.2 ± 0.3 , $p < 0.0005$).

Frequency Domain measures of HRV: At the baseline examination, Frequency Domain measures of HRV were reduced in diseased patients (Table 3). Compared with normotensive controls, hypertensive patients had significantly lower total power (6612 ± 5595 msec² vs. 1653 ± 1191 msec², $p < 0.0005$), lower LF component (2474 ± 3329 msec² vs. 514 ± 522 msec², $p < 0.0005$), lower HF component (2473 ± 1940 msec² vs. 462 ± 713 msec², $p < 0.0005$).

Low-Frequency component measured in normalized units (n.u.) was significantly higher in the Disease Group compared with Control Group during the Background test (60.6 ± 4.9 vs. 45.9 ± 4.5 , Mean \pm SD, $p = 0.03$) and lower during the Orthostatic test (51.3 ± 5.2 vs. 71.6 ± 3.9 , Mean \pm SD, $p = 0.004$). No statistical significant difference of LF, n.u. was shown during the Deep Breathing test.

Time Domain measures of HRV: At the baseline examination Time Domain measures of HRV were reduced in diseased patients (Table 3). Compared with normotensive controls, hypertensive patients had significantly lower RMSSD, msec² (81 ± 39 versus 34 ± 32 , $p < 0.0005$) and pNN50, percent (45 ± 20 versus 5 ± 6 , $p < 0.0005$) during Background test (Table 11). During Deep Breathing and Orthostatic Tests, SDNN interval and pNN50 remained significantly different, while LF component, msec², was significantly different only during the Deep Breathing test. There were no differences between groups in the HF component, msec² or RMSSD during the Deep Breathing and Orthostatic tests (See Table 4).

II. Effect of Treatment (Effect of Laser vs. Medication Treatment):

Blood Pressure:

After treatment, the blood pressure (systolic/diastolic, mm Hg) decreased in the LTG from $151/93 \pm 16/10$ to $127/81 \pm 5/6$, $p < 0.0001/0.0005$, but did not change in the MTG Group ($140/83 \pm 25/11$ to $132/83 \pm 14/8$, $p = 0.16/0.89$). Heart Rate did not change in Disease Group as a whole, or the LTG Group, but was decreased in MTG after treatment, 71 ± 14 vs. 62 ± 0.5 , $p = 0.05$. (See Table 5).

GDV indices:

Both treatments changed the LNorm, the LHind and RHind (Table 4). In the LTG, the LNorm were decreased respectively (1.93 ± 0.99 vs. 0.74 ± 0.4 , $p = 0.001$) and RNorm were also decreased (1.8 ± 1.2 vs. 0.7 ± 0.5). In the MTG the LNorm were decreased (1.26 ± 0.7 vs. 0.73 ± 0.35 , $p = 0.007$). Left Health Index were decreased respectively in LTG (0.522 ± 0.30 vs. 0.053 ± 0.35 , $p = 0.0007$) and MTG 0.21 ± 0.38 vs. -0.057 ± 0.36 , $p = 0.002$). Right Health Index were also decreased respectively in LTG (0.410 ± 0.26 vs. -0.041 ± 0.36 , $p = 0.0004$) and MTG (0.258 ± 0.39 vs. -0.029 ± 0.32 , $p = 0.0124$).

Table 5. Effect of Treatment on Blood Pressure

Variable	LTG					MTG				
	Baseline Mean	SD	Follow Up Mean	SD	P - value	Baseline Mean	SD	Follow Up Mean	SD	P - value
Number	13					13				
Blood Pressure (mm Hg)										
Systolic	151	16	127	5	0.00007	140	25	132	14	0.17
Diastolic	93	10	81	6	0.00045	83	11	83	8	0.89

Laser treatment changed the LJS and LavBrightness parameters. The Left Hand S Integer (LJS) of the LTG changed significantly from $-0.162 (\pm 0.4)$ to $-0.704 (\pm 0.5)$, $p = 0.001$, while the same parameter for the MTG did not change ($-0.522 (\pm 0.8)$ to $-0.605 (\pm 0.5)$, $p = 0.45$). LavBrightness increased in LTG (188.976 ± 19.04 , vs. 199.173 ± 14.44 , $p = 0.044$), but did not change in MTG (See Figures 1, 2, 3, 4).

Medication treatment changed the Rnorm and Rent parameters. The Rnorm was decreased in MTG (1.244 ± 0.81 vs. 0.732 ± 0.33 , $p = 0.0244$), but was not changed in LTG. Rent was increased in MTG (1.837 ± 0.59 , vs. 2.233 ± 0.47 , $p = 0.028$), but did not change in LTG (See Table 6).

HRV parameters:

Comparison between LTG and MTG showed that measures of HRV were comparable at baseline examination. LF, msec2 parameter was the only difference in the two treatment groups: higher in LTG compared with the MTG (717 ± 629 vs. 312 ± 290 , $p = 0.045$).

Low Energy Laser Treatment decreased SDNN (45.6 ± 19.3 vs. 37.9 ± 19.6 , $p = 0.026$), decreased CV, percent (5.643 ± 3.0 vs. 4.652 ± 2.8 , $p = 0.006$), and decreased RMSSD, msec2 (37.4 ± 38.6 vs. 28.8 ± 36.7 , $p = 0.034$) during the Background test. There were no changes of HRV parameters in LTG during Deep Breathing and Orthostatic tests.

Medication treatment increased pNN50 (4.5 ± 5.5 vs. 14.5 ± 16.5 , $p = 0.02$), increased RMSSD, msec2 (30.538 ± 26.0 vs. 57.2 ± 64.6 , $p = 0.045$) and decreased VLF, percent (45.4 ± 17.7 vs. 31.8 ± 19.7 , $p = 0.02$) during the Background test.

There was no change in the LF and HF; components measured in normalized units and in msec2 in LTG and MTG during Background, Deep Breathing, and Orthostatic tests (See Table 7).

Table 6. Effect of Treatment on GDV indices

Variable	LTG					MTG				
	Baseline Mean	SD	Follow Up Mean	SD	P - value	Baseline Mean	SD	Follow Up Mean	SD	P - value
Number	13					13				
LFC	10.552	5.2	11.999	5.3	0.813	9.506	4.1	12.535	5.4	0.123
RFC	11.583	7.2	11.093	6.2	0.690	9.762	7.4	13.181	4.9	0.195
LNORM	1.932	1.0	0.744	0.4	0.001	1.266	0.7	0.732	0.4	0.008
RNORM	1.798	1.2	0.726	0.5	0.020	1.244	0.8	0.732	0.3	0.024
LAvBr	188.976	19.0	199.173	14.4	0.044	198.622	5.5	202.210	5.1	0.102
RAvBr	189.012	18.6	198.769	15.1	0.056	197.118	7.8	202.316	4.6	0.056
LENT	2.176	0.4	2.155	0.4	0.730	1.877	0.5	2.180	0.6	0.072
RENT	2.195	0.5	2.090	0.6	0.490	1.837	0.6	2.233	0.5	0.028
LFRAC	2.310	0.2	2.379	0.4	0.410	2.193	0.4	2.250	0.3	0.590
RFRAC	2.383	0.4	2.260	0.4	0.630	2.130	0.5	2.255	0.3	0.425
AnInd	4.689	1.4	5.685	2.0	0.201	5.910	2.7	5.099	1.6	0.206
LHInd	0.522	0.3	0.053	0.3	0.001	0.210	0.4	-0.057	0.4	0.002
RHInd	0.410	0.3	-0.041	0.4	0.001	0.258	0.4	-0.029	0.3	0.012
Sr/SI	0.898	0.4	1.481	2.6	0.007	0.955	1.2	1.521	1.5	0.614
Sr-SI	-0.046	0.2	-0.094	0.2	0.662	0.048	0.1	0.028	0.2	0.468
LJSwf	-0.162	0.4	-0.704	0.5	0.001	-0.522	0.8	-0.605	0.5	0.451
RJSwf	0.160	0.4	-0.552	0.4	0.445	-0.455	0.6	-0.562	0.6	0.219

DISCUSSION

Hypertension is an important chronic medical illness, and this study is part of a broader effort to identify and monitor treatment strategies. Two of the outcome measures used for this study are well recognized: blood pressure and heart rate variability. The third outcome measure is novel in the setting. Our interest on it derives from data that suggests that GDV images may reflect autonomic function, human energy, and early organ system dysfunction. The interventions used in the study were conventional medical therapy with or without low energy laser treatments. GDV and HRV indices did differ between Control and Disease Groups at the baseline examination. Inpatient treatment altered some, but not all, GDV and HRV measures in each treatment group. The LEL+M normalized blood pressure and LJS, a global GDV measure of health status. The pattern of HRV changes suggests that low energy laser treatment increased parasympathetic and decreased sympathetic activity of these hypertensive patients.

Several methodologic issues must be considered in the interpretation of our findings. First, the Control Group was younger and had a lower body mass index than the Disease Group, raising the possibility that the HRV differences are attributable to the demographic factors, and not to the hypertension. We think this is unlikely. Studies of the effect of age on HRV show that older age and higher heart rate are associated with decreased SDNN, LF and HF, msec2, values.^{3,6} The age difference between our study groups may, in fact, have reduced the magnitude of the hypertension associated HRV changes.

A time domain HRV measure was lower than published values. The predicted age and heart rate matched SDNN interval for the Control Group is 135 msec, compared with the actual value of 82 msec. The predicted age and heart rate matched SDNN interval for the Disease Group is 90 msec, and the actual study results is 40 msec.³ We performed five-minute HRV recordings, whereas Tsuji, et al., used a two-hour recording. Longer HRV recordings increase the fluctuations in heart rate and, thus, the SDNN.³ In summary, the duration of the HRV measurement likely accounts for the difference of the published normal and actual values of baseline SDNN in our study.

The frequency domain HRV measures are not affected by measurement duration, and so observed differences between age and heart rate matched predicted and actual values are likely due to disease factors. Predicted Control Group LF values msec2 are 2.500 msec2, close to the actual value of 2.474 msec2. In the Disease Group predicted values are 800 msec2 and actual values are 514 msec2. These data are consistent with those derived from the Framingham study, in which hypertension was associated with a reduced LF.³

The frequency domain measurement HF, msec2 reflects parasympathetic activity. Predicted control group HF values are 1000 msec2, while actual values in our Control Group were over two-fold higher, 2.473 msec2, and remained higher during the Slow Breathing and Orthostatic tests (1.954 and 2.452 msec2, respectively). As demonstrated by other investigators⁷ physical training is associated with relative enhancement of vagal tone and increasing of HF component values⁸ and could explain high HF values in the Control Group. Predicted HF values for the Disease Group were 300 msec2 compared with actual values of 462 msec2. This differs from the Framingham data³ (effect of hypertension controlled for medication use), but is unlikely to relate to medication effects in our subjects since B-blockers, calcium antagonists, digitalis, and diuretics all reduce HF.

Our study is also confirmed that, compared with normotensive controls, hypertensive patients had lower total power (TP, msec2), low frequency component (LF, msec2), high frequency component (HF, msec2), square root of the mean of the sum of the squares of differences between adjacent NN intervals (RMSSD, msec) and pNN50, percent during Background test which corresponds with the results of Serve, et al.⁹ These results are also consistent with the data of Mussalo et al.¹⁰ which showed reduced SDNN, TP, LF, and HF in patients with hypertension compared to Controls. Mussalo, et al.,¹⁰ found significant differences in these parameters between patients with severe or mild hypertension. The hypertensive patients in the present study resembled the mild hypertensive group in the Mussalo, et al., study.¹⁰

GDV indices did distinguish between healthy controls and hypertensives. The JS Integer for the Right hand in Control and Disease Groups was significantly different at the baseline examination.

The JS integer in the Control Group averaged -0.55 in both the Right and Left hands. These values are close to the published predicted values of -0.6 for this age group. However the standard deviation of values of the Control Group is narrower than predicted values, with standard deviations of 0.8 for both Right and Left JS parameters in the Control Group and 1.0 in the published predicted values. This may reflect the homogeneity of the Control Group, all well trained young military physicians. The JS integer in the Disease Group averaged -0.1 and -0.3 in the Right and Left hands respectively. The standard deviation was slightly smaller in the Disease Group. Continued attention to the development of normative data for JS integers is needed.

Health quality evaluations on the basis of GDV parameters have been conducted in Russia at the year of 2000 and in Sweden and USA in 1999/2000.¹¹⁻¹³ A range of $(-0.6 / + 0.3)$ is considered by Dr. Korotkov as values indicative of "good health." The values of the S Integer for the Left and Right Hand in the Control Group were in the zone of "relative normal health" and were more close to the published normal values compared with the Diseased Group. JS Integer for the Left and Right Hands in the Disease Group was more far from the zone of the "good health" zone. According to Dr. Korotkov's formulation, the identification of a GDV index in the zone of "relative health" does not indicate the absence of chronic diseases. Dr. Korotkov interprets the location of JS parameter in the "good health" range as indicative of a compensated state for the organism. According to him, the presence of the chronic diseases should be revealed using the other complementary methods employing alternative ways of processing GDV-grams.

Low Energy Laser treatment caused more significant changes of Blood Pressure, GDV, and HRV indices. Hypotensive and antioxidant effects of laser therapy and its ability to decrease total peripheral resistance were considered in Russia as effective for treatment of patients with Stage I Hypertension¹⁴ and supported in a number of studies.¹⁵⁻¹⁷

Our study of Systolic Blood pressure in the LTG decreased significantly compared with the MTG, which confirmed the hypothesis of efficacy of hypertensive effect of low energy laser treatment in patients with mild hypertension. But we did not analyze the sustainability of this effect over the time.

Despite the differences in pretreatment diastolic blood pressure, age, and co-morbid conditions, the baseline HRV measures were comparable in LTG and MTG.

Low Energy Laser Treatment caused more significant change of the S Integer for the Left Hand and was not changed for the Right Hand. The ratio between JS index of the Right and Left Hand is a measure of lateralization of functional states and can be interpreted as generalized index of physical (JSR) and mental (JSL) state.¹² According to this statement, our results could be interpreted as laser treatment did not cause the change of physical state of hypertensive patients, but did change their mental state.

Low Energy Laser treatment significantly decreased the normalized area and increased average brightness of GDV image, indicating that laser treatment resulted in GDV images becoming smaller and brighter. Conventional medication treatment also decreased the normalized area of GDV images, but increased fractality values. Fractality is a measure of regularity of external contour of GDV-gram: The higher the fractality, the more deviation from the normal values.¹⁸ This measure has not been well characterized in different disease states. In this study, the GDV images after medication treatment became smaller with a more irregular external contour (i.e., fractality increased). Whether the increase in fractality represents a drug effect or an alteration in health state is unknown.

Our study showed that two different types of treatments changed the activity of Autonomic Nervous System activity two different ways. Thus, conventional medication treatment increased pNN50, percent and RMSSD, msec2 indices and decreased VLF, percent. Since pNN50 and RMSSD indices define the impact of Parasympathetic activity, but VLF, percent reflects the impact of humoral-cellular mechanisms to the Heart Rate, increases of these parameters show that medication treatment enhanced vagal tone and weakened the humoral activity to the heart rate in patients with more severe hypertension. The fact that Heart Rate in MTG was decreased significantly could prove our hypothesis.

Low Energy Laser treatment decreased SDNN, msec2 and CV, percent and increased RMSSD, msec2. SDNN, msec2 and CV, percent reflect summary effect of autonomic nervous system to the Heart Rate. Increasing and decreasing of these parameters is an evidence of imbalance of autonomic nervous system. Since, in our study, these two indices were decreased, this could mean that autonomic nervous system became more balanced. Hypertensive patients in LTG had increased sympathetic activity compared with Hypertensive patients in MTG. But since RMSSD, msec2 was increased in the LTG, it shows that in response to Low Energy Laser treatment the autonomic regulation of the Heart Rate changed toward increasing parasympathetic activity and decreasing sympathetic impact. Our study showed that Low Energy Laser treatment corrected imbalance of autonomic nervous system increasing vagal tone and decreasing sympathetic activity of patients with mild hypertension.

CONCLUSIONS

1. There was a statistically significant difference on GDV indices between diseased patients and healthy controls. The mean JS Integer in Control subjects was more close to the published normal values than mean JS Integer in hypertensive patients. GDV Health Index was also distinguished between Control and Disease subjects. Further analysis did not show a correlation between JS integer and the duration and severity of disease.
2. At baseline, blood pressure, heart rate, and most HRV indices differed significantly between diseased patients and healthy controls. These time and frequency domain differences likely reflect both age effects and disease effects and are consistent with findings of previous studies by other investigators.
3. The Control Group showed an increased HF component value compared to published norms. This is likely due to the intensive physical training they undergo as military physicians and is consistent with their baseline bradycardia.

4. The patients in the two hypertensive treatment groups showed some baseline differences: Patients assigned to the Low Energy Laser plus Medication were younger, had a higher ejection fraction, and higher diastolic blood pressure.
5. Laser plus Medication Treatment decreased Systolic and Diastolic Blood Pressure, normalized the Left Hand JS parameters but not the Right Hand JS parameter. Other GDV measures altered in this treatment group included normalized area (reduced), average brightness (increased), and the Left and Right Hand health indices (decreased). Conventional medication treatment alone did not alter blood pressure or JS of either hand. It did alter normalized area (reduced), fractality (increased external countour irregularity)
6. According to the proposed framework of interpreting GDV BEO-grams, the conventional medication treatment would be viewed as enhancing parasympathetic and weakening the humoral impact to the heart rate in patients with more severe hypertension. Low energy laser treatment corrected imbalance of autonomic nervous system increasing vagal tone and decreasing sympathetic activity of patients with mild hypertension.

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