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# Use of biodecoding in patients with hypertension. Assessment at 6 months

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#### ABSTRACT

**Introduction and Objective**: High blood pressure is a worldwide health problem. The approach to the hypertensive patient should be an integral one. Biodecoding is one of the treatments that can be used. The aim of this study was to determine the efficacy of biodecoding in the treatment of patients with essential hypertension.

**Method:** Experimental, controlled, randomized and longitudinal prospective study during 6 months in hypertensive patients, aged between 18 and 70 and of both sexes, attending the Cardiology Department of the Calixto García Hospital from September 2011 to February 2012. The sample was divided into two groups: control (n=50) and biodecoding (n=58), without interruption of the treatment. Biodecoding was applied on three occasions and the patients were assessed at 15, 30, 90 and 180 days. Treatment was considered effective if 60% of patients maintained control of blood pressure for 6 months with absence of symptoms.

**<u>Results:</u>** Blood pressure values significantly decreased in the biodecoding group compared to the control group (systolic blood pressure:  $127 \pm 13$  vs.  $119 \pm 6$  mmHg, p=0.001 and diastolic blood pressure:  $82 \pm 7$  vs.  $78 \pm 7$  mmHg. p=0.003), as well as hypertensive events and symptoms. Ninety-three percent of the biodecoding patients were controlled vs. seventy percent in the control group (p<0.003). The anti-hypertensive treatment was effective, but a higher percentage of patients were controlled and asymptomatic in the biodecoding group, 93% vs. 80 in the control group.

<u>Conclusions</u>: Biodecoding was an effective method of blood pressure control. <u>Key words</u>: Catheter Ablation; Radiofrequency; Cardiac Arrhythmias

Uso del método de biodescodificación en pacientes con hipertensión arterial. Corte evaluativo a los 6 meses

#### RESUMEN

Introducción y Objetivo: La hipertensión arterial es un problema de salud a nivel mundial. Se recomienda actuar sobre el hipertenso de forma integral. Uno de los tratamientos a utilizar es la biodescodificación. El objetivo de esta investigación fue determinar la eficacia de la biodescodificación en el tratamiento de pacientes con hipertensión arterial esencial.

**Método:** Estudio experimental, controlado, aleatorizado y prospectivo de corte longitudinal durante 6 meses, en pacientes hipertensos entre 18 y 70 años, y de ambos sexos, que acudieron a consulta de Cardiología del Hospital "Calixto García" desde septiembre del 2011 a febrero 2012. La muestra se dividió en dos grupos: control (n=50) y biodescodificación (n=58), sin suspender el tratamiento. El método de biodescodificación se aplicó en 3 ocasiones; se evaluaron los pacientes a los 15, 30, 90 y 180 días. Se consideró efectivo el tratamiento si el 60 % de los pacientes lograba mantener el control de la presión arterial durante 6 meses y la ausencia de síntomas.

**<u>Resultados</u>:** Las cifras de presión arterial disminuyeron significativamente en el grupo con biodescodificación respecto al grupo control (presión arterial sistólica:  $127 \pm 13$  vs.  $119 \pm 6$  mmHg, p=0.001 y presión arterial diastólica:  $82 \pm 7$  vs.  $78 \pm 7$  mmHg. p=0.003); de igual manera sucedió con los sucesos hipertensivos y los síntomas. Se halló un 93 % de pacientes controlados vs. un 70 % en el grupo control (p<0.003). El tratamiento antihipertensivo fue eficaz, con mayor por ciento de pacientes controlados y asintomáticos en el grupo de biodescodificación respecto al control (93 vs. 80 %).

*Conclusiones:* La biodescodificación fue un método de tratamiento eficaz en el control de la hipertensión arterial.

*Palabras clave:* Presión arterial, Hipertensión arterial, Biodescodificación, Conflicto biológico, Necesidades biológicas

#### INTRODUCTION

Hypertension is one of the most important health problems to be treated by modern medicine worldwide. There is a linear relationship between the levels of blood pressure (BP) and cardiovascular events, stroke, and renal disease<sup>1</sup>. This disease contributes to 12.7% of total mortality and to 4.4% of disability worldwide. Its annual incidence and prevalence is increasing in all countries together with the aging population and unhealthy lifestyles. In our country, it is reported a 30% prevalence of hypertension in urban areas and 15% in rural areas<sup>1-3</sup>.

In the last 20 years, Cuba has achieved significant progress in the organization of the health system in terms of detection, diagnosis and treatment of patients with hypertension, because their control is essential to prevent progression of damage in the target  $organs^4$ .

Despite having different drug groups as antihypertensive agents in the basic drug stock, the optimal control of BP in patients has not been achieved yet<sup>5,6</sup>. Therefore, health professionals, in addition to individualized drug treatment and the education for healthy lifestyles, look for new integrationist approaches taking into account other aspects of the human being.

In the first decades of the last century, medical researchers began to give importance to the emotional reactions of their hypertensive patients. As the twentieth century moved on, the study of the relationship between emotions and the regulation of BP began<sup>7</sup>. In the quest to find theoretical explanations of the pathophysiology of hypertension, several studies were conducted. A common denominator was found in all of them: cardiovascular reactivity to chronic stress<sup>7,8</sup>.

The role of emotional factors in triggering disease states began to be taken into account very recently. Therefore, emotional variables, such as anger or fear began to be considered; they are considered cardio-vascular risk factors<sup>9-11</sup>. However, authors like Buss<sup>9</sup>, just point to the emotions as psychological factors.

Recent studies show a different view, where emotional mechanisms develop as complex dynamic systems<sup>12</sup>. This approach considers that emotions cannot be understood without their bond with other elements of body and mind, as response mechanisms that are integrated into complex structures, not only of the nervous or endocrine system, but as a fact where man intervenes in full, whose behavior cannot be explained without taking into account the processes of change, the time and their interdepend-dence<sup>12, 13</sup>.

From a medical perspective, the so called psychophysiological disorders have been addressed mainly in the pharmacological aspect, with the support of the combination of different psychological techniques. However, the emotional factor that prevails in the stressors of the way of life has been left out. In it, the emotions dominate and are shown as unmet biological needs<sup>14-16</sup>.

Biodecoding offers another approach in the treatment of hypertension, as it achieves an improvement or cure of the condition by applying biological laws that were unknown or not taken into consideration until recently<sup>17</sup>. This method relies on the experience of many researchers and practitioners, including Marc Fréchet, and Georg Groddeck, and requires a biological understanding of symptoms, discovering the cascade of events that would give the actual location of the element that, unconsciously, is the starting point of the situation or disease<sup>17</sup>.

Biodecoding has been used in Europe since the past decade, and is newly implemented in our country; however, there is no scientific publication on its use in the treatment of hypertension. Therefore, the general objective was to determine the effectiveness of biodecoding in the treatment of patients with hypertension.

### METHOD

An experimental, controlled, randomized, prospective and longitudinal study was conducted for 6 months in patients with essential hypertension, of both sexes and aged 18 to 70 years old, who were seen at the Cardiology Outpatient Department of the Calixto García Hospital from September 2011 to February 2012, and signed informed consent. A patient was considered as suffering from hypertension when BP was greater than or equal to 140/90 mmHg on two or more measurements, or were receiving previous antihypertensive therapy<sup>5,6</sup>.

Patients outside the age range, with acute or psychiatric diseases, pregnant women, and hypertensive patients with target organ damage were excluded. The sample was divided into two groups: control (n=50) and biodecoding (n=58), without suspending drug treatment. Biodecoding<sup>17</sup> was applied in 3 occasions and patients were assessed at 15, 30, 90 and 180 days, in relation to BP levels, number of peaks or hypertensive events (the number of times BP increased during the month) and symptoms. The BP measurement was conducted with an aneroid sphygmomanometer, by the traditional method, with the patient resting supine, sitting and leaning the arm. The cuff was inflated, the radial artery was palpated and the cuff was further inflated up to 20 or 30 mmHg above the disappearance of the pulse, the diaphragm of the stethoscope was placed over the brachial artery in the antecubital fossa and the cuff was deflated, dropping the needle slowly, at a rate of approximately 2-3 mmHg per second. The first sound (Korotkoff 1) was considered systolic BP and diastolic BP its disappearance (Korotkoff 5)<sup>5</sup>.

Treatment in both groups was modified according to the clinical course and the absence of symptoms, and was assessed, on completion of the first 6 months of follow up, into several categories: decrease, increase or maintenance dosage, and removal or addition of drugs with respect to the beginning of treatment.

The use of biodecoding was performed based on a general protocol<sup>17</sup> that includes determining of the following elements: biotarget, timeline, most common complaints, biological sense of the disease, conflict types, affected brain, somatic impact, as well as the implementation of the transgenerational aspect. The exercise was conducted in an office equipped for that purpose, with the material and human resources necessary to maintain the physical, mental and moral well-being of research subjects.

The variable, response to treatment, was used: a patient was controlled when BP was less than 140/90 mmHg in more than 50% of measurements, and uncontrolled when BP was greater than or equal to 140/90 mmHg in the same percentage of measurements.

Treatment was considered effective if 60% of patients remained controlled during the 6 month follow-up and had no symptoms.

A database was compiled in Excel 2007, and the data were processed using SPSS (version 9.0).

Descriptive statistics was used to determine the arithmetic mean, standard deviation, standard error, and a comparison study between the groups in which



**Figure 1**. Assessment of blood pressure in patients treated at the Cardiology Outpatient Department of the Calixto García Hospital in the first 6 months of follow up.

the Student's t statistic was used for independent quantitative variables, and the Z statistic was used in comparing independent proportions. A statistical significance of p <0.05 was considered, for 95% of reliability

#### RESULTS

In the demographic characteristics of the sample, there was no significant difference between the control group and the biodecoding group in relation to age ( $51 \pm 8 \text{ vs.} 51 \pm 11 \text{ years}$ ), sex [male n=21 (44%) vs. n=31 (53%) and female n=28 (56%) vs. n=27 (47%) p=0.43] and skin color [white n=26 (52%) vs. n=37 (64%) black n=7 (14%) vs. n=11 (19%), and mixed n=17 (34%) vs. n=10 (17%), p=0.29].

Figure 1 shows that the levels of systolic and diastolic BP at baseline were similar in both groups, but when assessing this variable over time (at 15, 30, 90 and 180 days) significant differences were observed, with greater decreases in the biodecoding group at all times of BP measurement during 6 months (systolic BP 127  $\pm$  13 vs. 119  $\pm$  6 mmHg, p=0.001 and diastolic BP 82  $\pm$  7 vs. 78  $\pm$  7 mmHg, p=0.003).

The levels of systolic and diastolic BP decreased from the first 15 days. There was a marked effect on systolic BP in the biodecoding group, which quickly reached levels close to 120/80 mmHg (Figure 2).

Moreover, when analyzing the hypertensive events, the control group had more patients with hypertension peaks throughout the assessment period, which in turn created very significant statistical differences



Figure 2. Curves of the decrease in blood pressure.





Figure 4. Response to antihypertensive therapy.



Figure 5. Effectiveness of biodecoding method in the treatment of hypertension.

(p<0.0000001) between both groups (Figure 3).

The variable, response to treatment, appears in Figure 4, which shows that 54 of 58 biodecoding patients were controlled at 6 months, for 93%, unlike the subjects from the control group, where 34 of a total of 50 patients were controlled, for 70% (Z=2.69, p=0.003).

When evaluating the effectiveness of the method (Figure 5), it was observed that in both groups there was more than 60% of subjects with levels below 140/90 mmHg and no symptoms, but the percentage was higher in the biodecoding group (93% vs. 80%).

Finally, the changes in pharmacological treatment in both groups were analyzed (Table 1). It is of interest to note that the drug dose was increased in 58% of patients of the control group; however, in the study group, it was increased only in 3.44% of patients, thus establishing a significant difference (p < 0.0000001). Furthermore, in the study group, it was decided to reduce the dose of drugs in 43.1% of subjects, because BP levels were below 140/90 mmHg and close to 120/80 mmHg during all the assessments, and there were no hypertensive events. However, in the control group, this reduction was only possible in 16% of subjects, which is also statistically significant.

It is important to note that these results correspond to the first part of the study (6 months followup), which is not over. According to the hypothesis regarding the treatment of hypertension during the time of assessment, the results show a better control of BP in the study group; therefore, this part of the study suggests that the use of biodecoding is effective

Grupos	Tratamiento farmacológico									
	Dosis						Fármacos			
	Aumento		Disminución		Mantención		Eliminación		Incorporación	
	N⁰	%	N⁰	%	N⁰	%	N⁰	%	N⁰	%
Control	29	58,0	8	16,0	12	24,0	0	-	1	2,0
Estudio	2	3,44	25	43,1	20	34,5	11	18,9	0	-

Table 1. Changes in pharmacological treatment during the first 6 months of the study.

P<0.000001

in the treatment of patients with hypertension.

#### DISCUSSION

Hypertension is often an asymptomatic disease, which has many health implications and requires, on the part of patients, permanent changes and an active commitment with the treatment once they are diagnosed and informed of their illness.

In Cuba, the prevalence and incidence rates in the province of Havana are the highest in the country, with a prevalence rate of 217.8 and an incidence rate of 3.7 per 1,000 inhabitants at the end of December 2011, and most cases are individuals aged between 25 and 64 years<sup>18</sup>. Our study was conducted in this province, and the mean age of both groups coincided with the age group where the rate of hypertension is greater.

When comparing the results obtained with the objectives of the study, and based on the theoretical foundation collected, plus a review of recent studies that have addressed the problem, it is possible to open a discussion and establish enriching and relevant conclusions about adherence to treatment, which will contribute to a new perspective of knowledge on the subject.

Firstly, it is worth mentioning that in the study group, during the time of the study, biodecoding did decrease BP at significant levels, close to the proposed objectives for the year 2015<sup>1</sup>. Although conventional treatment allowed a decrease of BP in the control group, BP levels were higher there than in the study group. It is worth noting that clinical trials suggest that once BP values descend progressively, until 120/75 mmHg, there is a reduction in the incidence of cardiovascular events, and that lower levels may cause the phenomenon known as "J-curve", mainly in old age hypertensive patients<sup>19</sup>. This has led us to consider

that, through the work of health professionals with biodecoding, it is possible to respond to the World Health Organization's call for the care and control of chronic diseases that are the leading cause of death in the world<sup>20</sup>.

Although a study with this method had never been conducted, the results can be compared with other studies of biopsychosocial nature, where several authors broadly support these results<sup>21-23</sup>.

Developments in hypertension in 2010, focused mainly on controlling BP<sup>24</sup>. In our research, when evaluating systolic and diastolic BP over time (at 15, 30, 90 and 180 days), a difference in the response to treatment was observed in the study group compared with the control group. This demonstrates that it is possible to influence the health-disease process with the implementation of the biodecoding method, because there is a relationship between emotions and the regulation of BP, as stated by several authors<sup>25,26</sup>. A Cuban study<sup>27</sup> in subjects who worked in special conditions of risk, without cardiovascular symptoms, and who attended the health control medical examination, found out a high hidden morbidity of ischemic heart disease (70.8%) and that the risk factors more commonly related to a positive coronary angiography were stress (66.7%) and hypertension (62.5%).

The results obtained in this study with the use of biodecoding coincide with the literature reviewed, which suggests that hypertension is a disease with a multicausal origin, but differ about considering the treatment of emotions only as a factor that is super-imposed on the psychosocial process<sup>28,29</sup>.

The study demonstrated that emotions are part of psychobiological processes, as factors that are embedded in the satisfaction of needs and their expressions in human biology.

Therefore, more than a risk factor, the non ex-

pression of emotions, with a tendency to suppress, repress and contain the emotional disorder, is going to be the trigger for the multifactorial gear that biode-coding calls the bio-Shock<sup>30</sup>.

As other authors state, distress acts as a trigger for cardiovascular processes, with the peculiarity that this stressful process (bio-Shock) is used by biodecoding as a biological conflict itself, that according to Christian, coincides with Flèche experiences<sup>31</sup>.

As observed in the study, any event in which environmental demands exhaust or exceed a person's adaptive resources may be considered as a conflict, as proposed in the literature, which is consistent with what we found in the study. This conflict, which works as a trigger, will be linked together with disturbed biological needs<sup>32</sup>.

With the use of biodecoding, the patient relives the conflict that led to a biological response that favors an increase in BP. In addition, the patient is helped to find an adaptive resource with which to cope with the demands of events and experiences. This would explain why, throughout the follow-up time, BP levels remained eventually elevated in the control group (Figure 3), unlike the study group. The control group was treated only with conventional drugs and, therefore, whenever any conflicting event exhausted the patient's adaptive resources he would respond with elevated BP.

The marked difference in the changes in pharmacological treatment is also linked to the above mentioned situation. It indicates a greater control in the hypertensive patients of the study group compared with the control group, who mostly did not have the adaptive resources to face the conflicts that led them to hypertension and, therefore, had to maintain or increase drug treatment.

Other studies, which have addressed the action of emotions in hypertension with a conductive-behavioral program<sup>33,34</sup>, have shown positive results in the management of patients. There is also an alternative method used in Cuba through Schultz's autogenic training, but with fewer patients (n=27), where effectiveness was achieved in more than 50% of patients. However, it requires the subject to learn several steps such as: experience of heaviness, warmth, regulation of the heart, regulation of breathing, experience of heat on the solar plexus and perception of a fresh forehead, making it a complex training method<sup>35</sup>. In contrast, we have used the biodecoding method in our study, which makes the patient find resources for coping with conflictual processes; resources that are lasting during the time of study.

Taken together, the results show significant changes in the variables analyzed in both groups, but the subjects who received biodecoding treatment showed better results compared with the control group; which is probably due to the way of treating the disease through the biodecoding of hypertension.

# CONCLUSIONS

For the time of the assessment, biodecoding was effective in controlling BP because it achieved a higher percentage of asymptomatic and controlled patients and allowed the change or removal of drug treatments. Therefore, it is a useful therapeutic method for the control of hypertensive patients over a period of six months.

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