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EFFECTIVENESS OF EXTERNAL USE OF ELECTROPULSE EXTRACT OF MARAL VELVET ANTLERS IN PATIENTS WITH ARTERIAL HYPERTENSION

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Key words: arterial hypertension, chronic fatigue syndrome, maral velvet antlers.

Annotation. The purpose of this study was to examine the effect of external use of an innovative preparation based on electropulse extraction of maral velvet antlers on clinical signs and main indicators of the regulatory systems of the organism and indicators of psychological status in patients with arterial hypertension and chronic fatigue syndrome. Against the background of taking velvet antler baths, there was a decrease in the severity of clinical signs, adaptogenic, anti-inflammatory and hypotensive effects, as well as an improvement in psychological status.

Introduction. Social, psychological and individual biological stress factors disturb the vegetative and hormonal balance, cause a failure of adaptation mechanisms and contribute to a formation of maladaptation pathologies. Disturbance of neurohormonal regulation of the cardiovascular system leads to tachycardia, increase of blood pressure, angiospasm and other disturbances classified as the dysautonomia – an initial stage of the arterial hypertension (AH) [1]. One of the attributes of the dysautonomia and the AH is the asthenic syndrome, also described as the Chronic Fatigue Syndrome (CFS) [2]. The CFS confirmation, aside from having unmotivated fatigue that does not secede after rest and lasts more than 6 months, are low-grade fever, pain in the throat, muscle weakness, pain in muscles and joints, headaches, complaints about absent-mindedness, irritability, not being able to focus, difficulties thinking and remembering and the depressed state [3-4].

One of the preparation groups widely used for treating maladaptation states that increase physical and mental performance and speed up recovery of the organism's functions are adaptogenes. Animal-based adaptogenes include preparations with velvet antlers and deer blood – young nonossified antlers of a red deer, maral, manchurian wapiti or a sika deer. Velvet antlers preparations contain a large set of substances that are highly active regulatory molecules capable of triggering in small amounts a combination of metabolic reactions, which influence the most important physiological functions [5]. It was proven through experimental and clinical studies that preparations made from the velvet antlers industry when applied externally in a form of baths contribute to a formation of tonic, nootropic and adaptogenic effects, homopoiesis activation, phagocytic function of macrophages, regulation of serum immunoglobulins, lysozyme, balances the state of the lipid peroxidation and antioxidant protection systems [6-8].

Nowadays, native velvet antler water is used for velvet antler baths (patent RU 2 106 850, 1988), the use of which is limited by a high price of velvet antler material and complications in making this material.

The task of this study was to develop and analyze the effectiveness of the innovational velvet antlers extract made using the electrodynamic method on the electropulse extraction device, which supports an extraction of active components from animal-based materials through elective dissolution in the extragent (water) without heating up and with a full preservation of their biological activity.

The study's purpose is to examine the effect of external use of the innovative preparation based on electropulse extraction of maral velvet antlers on clinical signs and main indicators of the regulatory systems of the organism and indicators of psychological status in patients with AH and CFS.

Methods and organization. The study included 40 patients (men) with an average age of 56,5 [46,75; 59,0] years. Verification of the AH diagnosis was carried out in compliance with the WHO recommendations and Guidelines on Arterial Hypertension (2019). The I stage AH was registered in 27 (67,5%) patients, the II stage AH – in 13 (32,5%). The disease duration amounted to 4 [3,00; 10,00] years in average. A presence of CFS clinical signs was defined according to the MFI-20 scale: if the total score in at least one subscale is higher than 12, then this is a preliminary reason to diagnose the "asthenic syndrome".

We carried out the effectiveness evaluation based on the dynamic analysis of following indicators:

1. Psychological state evaluation:

– the SF-36 questionnaire for evaluating health-related quality of life;

– the MFI 20 scale for evaluating asthenia;

– the Spielberger-Khanin questionnaire aimed at defining the level of personal (PA) and situational (SA) anxiety;

– the MOPSY questionnaire for evaluating vital exhaustion.

2. To evaluate a degree of stress of the non-specific adaptation mechanisms' operation, we registered the type of adaptation response (AR) and the level of non-specific reactivity (according to L.Kh. Garkavi et al) corresponding with the data from a clinical blood test [9].

3. The cardiovascular system's adaptation potential (the functional changes index (FCI)) was calculated according to the following formula:

AP=0,011·HR+0,014·sBP+0,008·dBP+0,014·A+0,009·BM-0,009·H-0,27,

where AP – adaptation potential, HR – heart rate, sBP – systolic blood pressure, dBP – diastolic blood pressure, A – age, BM – body mass and H – height [10].

4. Evaluation of inflammation activity was carried out according to the high-sensitivity C-reactive protein (hs-CRP) test by the method of the enzyme-linked immunosorbent essay using the Vector-Best sets (Russia), as well as the fibrinogen level on the Isula 500 automated coagulation analyzer with the Multitech-fibrinogen set for identifying fibrinogen (Technology Standard, Russia).

The results obtained were processed using the PASW Statistics 18 packet, version 18.0.0 (30.07.2009) (SPSS Inc., USA). We checked the hypothesis of normal distribution using the Kolgomorov-Smirnov and Shapiro-Wilk tests. In order to define differences between linked samples, we used the Wilcoxon T-test, between unlinked samples – the Mann-Whitney test. The critical level of significance when checking on statistical hypotheses in the study was equal to 0,05. The data was presented in the form of "sample mean±standard derivation"(M±SD) in case of normal distribution or the median (Me) and interquartile range in the form of Me[LQ;UQ], where LQ – lower quartile, UQ – upper quartile, in case of un-normal distribution.

Treatment methods. The participants were divided into 2 groups corresponded by age, AH duration, clinical characteristics of main and accompanying diseases – the comparison group (I, n=20) and the main group (II, n=20). Patients of the I group received balneotherapy with native velvet antler water (VAW) used in accordance with the technology presented in the patent RU 2 106 850 1988. One bath takes 400 grams of velvet antler powder.

Patients of the main group (II) received balneotherapy with the water electropulse extract of velvet antlers (EP). The powdered velvet antlers are extracted with the electrodynamic method on the electropulse extraction device. One bath uses 200 g of powder.

Results and discussion. Among complaints of AH patients, the significant are complaints about headaches (n=25, 62,5%), weakness (n=21, 52,5%), insomnia disorders that were characterized with a sleep-onset insomnia and changes in sleep's duration and deepness (n=20, 50,0%). The second place in terms of frequency are complaints about chest pain (n=15, 37,5%) and rapid heartbeat (n=14, 35,0%).

As the observations show, patients of all groups successfully underwent the prescribed treatment. During the bath course, we discovered a decrease in a frequency of headaches, weakness and fatigue (table 1). Meanwhile, a correction of insomnia disorders as one of the CFS criteria was significant only in the II group with EP velvet antlers administration (p=0,023).

The conducted comparative intergroup analysis of dynamics of the clinical symptoms detection rate did not reveal statistically significant differences according to analyzed indicators.

Table 1

Detection rate of clinical symptoms of AH and SFS, % (abs.)

Signs	Group I (n=20)		Group II (n=20)	
	Before treatment After treatment, abs. (%)	p before and after treatment	Before treatment After treatment, abs.(%)	p before and after treatment
Chest pain	8(40) 4(20)	χ^2=1,91 df=1 p=0,168	7(35) 2(10)	χ^2=3,58 df=1 p=0,059
Tachycardia	7(35) 4(20)	χ^2=1,12 df=1 p=0,289	7(35) 2(10)	χ^2=3,58 df=1 p=0,059
Headaches	12(50) 5(25)	χ^2=5,013 df=1 p=0,026	13(65) 3(15)	χ^2=10,42 df=1 p=0,002
Weakness, fatigue	10(50) 4(20)	χ^2=3,95 df=1 p=0,047	11(55) 2(10)	χ^2=9,23 df=1 p=0,003
Insomnia	9(45) 4(20)	χ^2=2,85 df=1 p=0,092	11(55) 4 (20)	χ^2=5,23 df=1 p=0,023

Note: χ^2 – Pearson's chi-squared test; df – numbers of freedom's degree; p – significance of differences criterion

The hypotensive effect of velvet antler baths was confirmed by the data of the in-office blood pressure measurements: all groups revealed normalization of the initially increased level of sBP (in the I group – 147,5 [133,75; 157,75] to 130,0 [100,0; 141,25] mm of Hg, p=0,002; in the II group – 140 [130,0; 150,0] to 120,0 [120,0; 120,0] mm of Hg, p=0,011) (table 2). The hypotensive effect was also registered through a dBP decrease in the I group from 100,0 [97,5; 132,5] to 95,0 [90,0; 100,0] mm of Hg (p=0,010). In the II group, where patients received the electropulse extract of velvet antlers, the level of dBP amounted to target values – 80,0 [80,0; 80,0] mm of Hg (p=0,010). The intergroup comparative analysis revealed a much more significant effect of baths with EP velvet antlers on the level of dBP in comparison with VAW (p=0,000).

Table 2

Dynamics of detection rate of the adaptation response and the reactivity level in AH patients associated with the velvet antler bath course, in abs.(%)

Type of the adaptation response and the reactivity level	I group (n=20)		II group (n=20)	
	Before treatment After treatment, abs.(%)	p	Before treatment After treatment, abs.(%)	p
Training response	6(30) 3(15)	p=0,256 χ^2=1,290 df=1	3(15) 6(30)	p=0,256 χ^2=1,290 df=1
"Calm" activation response	3(15) 3(15)	p=1,00 χ^2=0 df=1	5(25) 9(45)	p=0,185 χ^2=1,758 df=1
Increased activation response	7(35) 10(50)	p=0,338 χ^2=0,921 df=1	8(40) 3(15)	p=0,077 χ2=3,14 df=1
p between groups	pI-II=0,019 χ^2=5,58 df=1			
Response of reactivation and stress	4(20) 4(20)	p=1,0 χ^2=0 df=1	4(20) 3(15)	p=0,678 χ^2=0,173 df=1
High reactivity level	16 (80) 16(80)	p=1,0 χ^2=0 df=1	16(80) 18(90)	p=0,376 χ^2=0,784 df=1
Low reactivity level	4 (20) 4 (20)	p=1,0 χ^2=0 df=1	4(20) 2(10)	p= 0,376 χ^2=0,784 df=1

Note: p – significance of differences criterion; pI-II – significance of differences criterion between the I and II groups

In order to judge the degree of stress of functioning non-specific adaptation mechanisms, we defined the type of adaptation response and the reactivity level according to L.Kh. Garkavi et al (1998). Studying the state of the non-specific adaptation mechanisms in patients before velvet antler baths revealed that 16 (40,0%) patients had increased activation response, 9 (15,0%) were diagnosed with training response, 8 (20,0%) had "calm" activation. Pathological reaction of reactivation was revealed in 8 (20,0"%) patients. High level of reactivity was registered in 32 (80,0%) patients, low level – in 8 (20,0%). It shows an overstrain and desynchronization of adaptation subsystems of the organism.

Patients of the II group who took baths with the water electropulse extract of velvet antlers revealed a more significant positive rearrangement of functioning mechanisms of non-specific adaptation (p=0,019). After the velvet antler bath course, the I group had the predominant response of increased activation. It can be considered as an unspecified stress of adaptation mechanisms. High frequency of the reactivation response of the low reactivity level was also present, which is a predictor of a failure of adaptation mechanisms.

Baths with the electropulse extract of velvet antlers contributed to a decrease in a detection rate of the reactivation response, suggesting an increase adaptation reserve capabilities of the organism after the velvet antler bath course. Most patients of the II group (60%) completed the bath course with underlying response of “calm” and increased activation of the high reactivity level.

Thus, evaluation of the adaptogenic effect of baths with EP velvet antlers shows an adequacy of loads put on the organism and a preservation of adaptation reserves during treatment. Meanwhile, using baths with VAW put loads on the organism that are more pronounced, which is manifested in a presence of reactivation response that is dangerous due to a failure of adaptation reserves.

In order to evaluate the state of homeostasis systems of the organism that form adaptation reactions, we studied an integral indicator of the cardiovascular system’s adaptation – the functional changes index (FCI). During the initial examination, a satisfactory adaptation was registered only in 1 (5%) patient, stress of adaptation mechanisms – in 12 (30,0%), unsatisfactory adaptation – in 18 (45,0%) and adaptation failure – in 9 (22,5%) patients.

After the bath course, all groups revealed an improvement of adaptation indicators shown in a decrease of mean FCI values and in almost full reduction of the adaptation failure state (p=0,017 (group I), p=0,036 (group II)) (table 3). Statistically significant increase of detecting the state of satisfactory adaptation was registered only in the II group (p=0,017) in case of a decrease in detecting unsatisfactory adaptation (p=0,004).

The intergroup analysis of FCI mean values also revealed more significant positive dynamics of adaptation potential in the II group (p=0,006).

Table 3

Dynamics of the integral FCI indicator in patients associated with the bath course, abs.(%)

FCI, points	I group (n=20) Before treatment After treatment, abs. (%)	Level of significance of differences p	II group (n=20) Before treatment After treatment, abs.(%)	Level of significance of differences p
<2,59 Satisfactory adaptation	1(5) 3(15)	p=0,292 χ^2=1,11 df=1	0(0) 5(25)	p=0,017 χ^2=5,71 df=1
2,6-3,09 Stress of adaptation mechanisms	5(25) 12(60)	p=0,026 χ^2=5,01 df=1	7(35) 14(70)	p=0,027 χ^2=4,91 df=1

Table 3 (continued)

3,10-3,49 Unsatisfactory adaptation	9(45) 5(25)	p=0,185 χ^2=1,76 df=1	9(45) 1(5)	p=0,004 χ^2=8,53 df=1
>3,5 Adaptation failure	5(25) 0	p=0,017 χ^2=5,71 df=1	4(20) 0	p=0,036 χ^2=4,44 df=1
Mean FCI values Me[LQ;UQ]	3,47[3,2;3,6] 3,13[2,9;3,3]	0,000	3,09[2,81;3,4] 2,78[2,59;2,9]	0,000
p between groups	p_{I-II}=0,006			

Note: χ^2 – Pearson's chi-squared test, df – numbers of degree of freedom, p – significance of differences criterion; pI-II – significance of differences criterion between the I and II groups; Me – median; LQ – lower quartile; UQ – upper quartile

We also conducted an analysis of indicators of the inflammatory process activity in AH patients and clinical manifestations of the CFS associated with taking velvet antlers powder baths (table 4).

The anti-inflammatory effect of these baths was also confirmed with positive dynamics of the fibrinogen level in the II group (p=0,018), as well as with a decrease of hs-CRP in both groups (table 4).

Table 4

Dynamics of indicators of inflammation activity associated with the velvet antler bath course, Me[LQ;UQ]

Indicator	Comparison group I n=20	Main group II n=20
	Before treatment After treatment p	Before treatment After treatment p
Fibrinogen, g/l (standard 2,1-3,8)	3,50[3,20;3,90] 3,60[3,30;4,00] p=0,073	3,65[3,20;4,00] 3,50[3,20;3,80] p=0,018
p between groups	pI-II=0,332	
Uric acid, μmol /l (standard: male.210-420)	375,65[320,70;413,10] 354,50[333,20;398,90] p=0,073	364,00[295,03;402,4] 339,50[286,55;380,55] p=0,000
p between groups	pI-II=0,192	
hs-CRP, mg/l (standard <3)	2,0[1,4;3,6] 1,4[0,9;2,5] p=0,043	6,7[4,3;8,0] 4,7[3,4;6,1] p=0,002
p between groups	pI-II=0,075	

Note: p – significance of differences criterion; pI-II – significance of differences criterion between the I and II groups; Me – median; LQ – lower quartile; UQ – upper quartile

The existing literature data allow considering the hyperuricemia as a component of pathophysiological processes of the cardiovascular continuum: the oxidative stress, endothelium dysfunction, inflammation, intraglomerular hypertension and arterial hypertension, as well as the chronic heart failure. Each increase of the uric acid level in blood by 1 mg/dL is accompanied by an increase of death risk by 39% [11]. A comparative analysis of dynamics of the uric acid mean values registered a significance decrease among patients of the II group who took baths with EP maral velvet antlers (p=0,000) (table 4).

A degree of severity of CFS clinical signs was registered according to the MFI-20 scale. Presence of total asthenia before treatment was revealed in 40,0% (n=16) of patients, physical asthenia – in 55,0% (n=22), reduced activity and motivation asthenia – in 22,5% (n=9), mental asthenia was revealed only in 4 (10%) patients. As a result of applying baths with EP maral velvet antlers, we noted a significant decrease of severity of the asthenic syndrome in all types of asthenia. In the I group, dynamics of only one CFS indicator was deemed as significant – reduced activity (p=0,030) (table 5).

Table 5

Dynamics of asthenia and physical state indicators in the MFI-20 and Spielberger-Khanin questionnaires, Me [LQ; UQ]

Indicator, points	Comparison group I Before treatment After treatment n=20	Main group II Before treatment After treatment n=20
MFI 20 (total score)	65,0[58,25; 69,5] 52,5[47,0; 61,75] p=0,177	60,0[52,0; 70,0] 42,0[34,0; 57,0] p=0,009
General asthenia	9,55[8,0; 14,5] 8,5[8,0;12,75] p=0,221	10,0[9,0; 14,0] 9,0[7,0;11,0] p=0,017
Physical asthenia	9,0[7,0; 11,75] 9,0[7,25; 10,0] p=0,235	10,0[7,0; 13,0] 7,0[6,0; 11,0] p=0,017
Reduced activity	9,0[7,25; 10,0] 8,0[7,0; 10,0] p=0,030	11,0[9,0; 13,0] 10,0[6,0; 12,0] p=0,013
Lowered motivation	8,5[5,75; 11,75] 8,0[7,25; 9,0] p=0,165	10,0[8,0; 11,0] 8,0[5,0; 10,0] p=0,021
Mental asthenia	8,0[7,25; 9,0] 8,0[8,0; 9,0] p=0,777	9,0[6,0; 11,0] 8,0[4,0; 10,0] p=0,046
Situational anxiety	38,5[33,5; 48,5] 37,5[30,5; 42,5] p=0,019	38,0[30,0; 46,0] 32,0[26,0; 39,0] p=0,028
Personal anxiety	44,0[37,25; 51,75] 41,5[38,5; 48,5] p=0,122	45,0[42,0; 49,0] 38,0[35,0; 45,0] p=0,005

Note: p – significance of differences criterion; Me – median; LQ – lower quartile; UQ – upper quartile

The conducted analysis of the anxiety level according to the Spelberger-Hanning method demonstrated that before treatment, the patients had moderate (in 14 (35%) patients) and high situational anxiety (in 20 (50%) patients). Only 6 (15%) patients had a low level of situational anxiety. At the same time, it is important to note a high level of personal anxiety in 24 (60,0%) patients. A moderate level of personal anxiety was diagnosed in 15 (37,5%) patients. Repeated psychological diagnostics demonstrated that in the course of treatment, all groups showed a decrease of severity of reactive anxiety (i.e. psychological stress reactivity) (p=0,019; p=0,028). Main group also revealed a decrease in personal anxiety (i.e. a basal level of psychoemotional stress) by 18,42% (p=0,005) (table 5).

When evaluating quality of life according to the SF-36 questionnaire, we noted an improvement of such quality of life indicators as social functioning (from 75,0 to 87,5, p=0,006), general health (from 61,0 to 67,0, p=0,015) and mental health (from 68,0 to 80,0, p=0,02) (table 6).

Table 6

Dynamics of quality of life indicators in the SF-36 questionnaire, Me[LQ; UQ]

Indicators	Comparison group I Before treatment After treatment n=20	Main group II Before treatment After treatment n=20
GH (general health)	61,0[52,75; 70,75] 67,0[56,75; 80,75] p=0,015	70,0[55,0;82,0] 80,0[62,0;95,0] p =0,049
PF (physical functioning)	90,0[68,75; 95,0] 90,0[80,0; 95,0] p=0,150	95,0[85,0;100,0] 100,0[90,0;100,0] p=0,118
RP (role physical)	100,0[56,25;100,0] 100,0[81,25; 100,0] p=0,301	75,0[50,0;100,0] 100,0[75,0;100,0] p=0,064
RE (role emotional)	100,0[57,8;100,0] 100,0[49,7;100,0] p=0,595	67,0[34,0;100,0] 100,0[67,0;100,0] p=0,007
SF (social functioning)	75,0[50,0;87,5] 87,5[75,0;100,0] p=0,006	50,0[50,0;60,0] 50,0[50,0;65,0] p=0,344
BP (bodily pain)	68,00[44,25; 91,0] 88,0[62,0; 94,0] p=0,041	70,0[51,0;84,0] 84,0[62,5;100,0] p=0,008
VT (vitality)	65,0[50,0; 78,75] 72,5[65,0; 83,75] p=0,087	75,0[53,75;81,25] 90,0[80,0;100,0] p=0,028
MH (mental health)	68,0[56,0; 79,0] 80,0[64,0; 87,0] p=0,02	68,0[48,0;80,0] 84,0[64,0;100,0] p=0,006

Note: p – significance of differences criterion; Me – median; LQ – lower quartile; UQ – upper quartile

Table 7

Dynamics of vital exhaustion indicators in the MOPSY test, n (%), Me [LQ;UQ]

Indicators	Comparison group I Before treatment After treatment n=20		Main group II Before treatment After treatment n=20	
MOPSY test: Me [LQ;UQ], c.u.	9,87 [7,7; 11,0] 3,5 [2,0; 4,5] p<0,001		10,00 [8,0;13,0] 2,5 [1,2;4,6] p<0,001	
0-4 points (normal), n (%)	0 (0)	15 (75)	0 (0)	15(75)
5-9 points (fatigue), n (%)	10 (50)	5 (25)	8 (40)	5 (25)
10-14 points (exhaustion), n (%)	10 (50)	0 (0)	12 (60)	0 (0)
$\chi 2$; p	26,667; <0,001		27,692; <0,001	

Note: χ^2 – Pearson's chi-squared test; p – significance of differences criterion; Me – median; LQ – lower quartile; UQ – upper quartile

To evaluate a degree of vital exhaustion that is typical for the CFS, we conducted the MOPSY test that assesses a degree of vital exhaustion and risks of depression. It is considered as one of CFS clinical criteria. Pursuant to the data obtained, all examined patients had signs of vital exhaustion. Half of patients (n=18, 45%) had signs of fatigue and an average degree of vital exhaustion, which corresponds to 5-9 points of the MOPSY test. 22 (55%) patients had an intense stress load and a high degree of vital exhaustion (10-14 points in the MOPSY test). After the bath course, all groups revealed a full reduction of states that are characterized by a high degree of vital exhaustion. Only 5 (25%) patients of the I group and 5 (25%) patients of the II group still had some signs of overstrain. Average points of vital exhaustion in the MOPSY test decreased from 9,87 to 3,5 (p=0,001) in the I group and from 10,0 to 2,5 (p=0,001) in the II group (table 7).

Conclusion. The conducted studies of the effectiveness of external use of baths with native velvet antler water and the innovational product, i.e. the water electropulse extract of velvet antlers have a sufficient evidence of a comparable and one-directed effect of aforementioned methods of treatment on AH patients with clinical signs of the CFS in case when the cost price of velvet antler baths is reduced due to using the electropulse extract.

Associated with velvet antler baths, a decrease of severity of headaches, weakness, fatigue, chest pain, as well as an improvement of sleep quality in all groups were noted. Velvet antler baths with the water electropulse extract of velvet antlers made a more pronounced positive effect on BP dynamics in comparison with VAW baths, which was accompanied by a more significant improvement of the cardiovascular system’s adaptation potential. Using the new method of velvet antler treatment, i.e. baths with EP velvet antlers, makes a substantial anti-inflammatory hypolipodemic effect, contributes to an improvement of mental state indicators, to a decrease of vital exhaustion and, thereby, an improvement of quality of life of AH patients with clinical signs of the CFS.

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