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PLACEBO-CONTROLLED STUDY OF THE EFFECT OF BIOFEEDBACK TRAINING ON THE ALPHA RHYTHM OF THE BRAIN ON THE ELECTROENCEPHALOGRAM OF ATHLETES WITH MEAN LEVELS OF RELATIVE POWER OF THE SPECTRUM OF HEART RATE VARIABILITY

V.S. Kormilets, O.V. Eremeeva, S.I. Eremeev
Khanty-Mansijsk State Medical Academy, Khanty-Mansijsk, Russia

Key words: athletes, heart rate variability, biofeedback, electroencephalogram, alpha rhythm.

Annotation. In a placebo-controlled study, the effect of a biofeedback course according to the protocol for increasing the power of alpha activity of the electroencephalogram in the C_3A_1 lead on the patterns of background electroencephalogram in elite athletes was studied. The initial functional state of the study participants was characterized by average levels of relative power of the spectrum of heart rate variability in the very low, low and high frequency ranges. The study included 102 participants of both sexes. It was found that the course of biofeedback compared to placebo exposure did not demonstrate statistically significant effects on the type of background electroencephalogram of the subjects.

Introduction. A presence of connection between the plasticity of neurodynamic processes of the brain and the nature of responses made by the cardiovascular system was registered [7]. Data on relations of the type of heart rhythm modulation and the type of electroencephalogram patterns in athletes are being accumulated [2, 3]. Differences in reactivity of the cardiac activity during biofeedback training were revealed [6].

In the prospective randomized single-center simple blind comparative placebo-controlled study, data were obtained on safety of a modified method of using the neurobiological management in elite athletes; a high level of effectiveness of this course was shown in comparison with a placebo exposure on the primary endpoint (positive dynamics or a stable level of sports results) and secondary endpoints, which are presented both as components of the primary endpoint and as parameters of life quality related to health of elite athletes [5].

However, features of relation between patterns of neurovegetative regulation of the cardiac activity of elite athletes remain insufficiently examined, in particular – the initial type of heart rhythm modulation and biofeedback training effects.

The purpose of this study is to evaluate biofeedback training effect according to the protocol for increasing the power of alpha activity of the electroencephalogram in the C_3A_1 lead of elite athletes, whose feature of adaptation to sports activity was the registration of relative power spectrum of the heart rate variability (HRV) in ranges of very low, low and high frequency (VLF%, LF%, HF%) on the level of mean values in the population.

Methods and organization. The study's design: single-center open prospective randomized simple blind comparative placebo-controlled study.

The conducted study was compliant with the standards of the Ethics Committee of the Khanty-Mansijsk State Medical Academy, developed in accordance with the Declaration of Helsinki "Ethical principles for medical research involving human subjects", developed by the World Medical Association with amendments from 2013, in accordance with Rules of Clinical Practice in the Russian Federation from 01.04.2016,, approved by the Order № 266 of the Ministry of Health of the Russian Federation from 19.06.2003, in accordance with Rules of Good Clinical Practice, approved by the Order № 200n of the Ministry of Health of the Russian Federation from April 1st, 2016.

One hundred and two participants, who gave an informed consent and matched inclusion and exclusion criteria, participated in the study. All participants were deemed healthy, got access to training and competitions from specialized medical institutions. They were randomly (by the lottery method) divided into the main group and the control placebo group in a 2-to-1 ratio.

Inclusion criteria: sex – male, female; age – 18-25 years; state of health – all participants were deemed as healthy according to results of medical examinations in health facilities; relative power spectrum of HRV in ranges of very low frequency (0,003-0,04 Hz), low frequency (0,04-0,15 Hz), high frequency (0,15-0,4 Hz) do not exceed the mean boundary in the population, the so called egalitarian type of the heart rhythm modulation [2]; critical level of VLF% was 42,4% for women and 44,8% for men; LF% – 47,0% for women and 46,3% for men, HF% – 40,5% for women and 38,2% for men [2].

Exclusion criteria: epileptiform activity according to electroencephalogram data; extrasystoles level is higher than 5% of the rhythm strip; taking medications; lactation; indication of pregnancy; failure to comply with protocol requirements and a number of other conditions.

Heart rhythm recording was carried out according to the short notes protocol for 5 minutes [8] before and after the course of biofeedback training. The "Poly-Spectrum-8/EX" electrocardiograph was used. HRV parameters were evaluated using the "Poly-Spectrum Rhythm" software packet (Neurosoft, Russia).

The type of heart rhythm modulation was identified according to the three-factor concept [2].

Electroencephalogram (EEG) recording was carried out using the “Neuron-Spectre-5” electroencephalograph (Neurosoft, Russia) before and after the course of biofeedback training. Separate electrodes placed on the earlobes were used as reference electrodes. The time constant was 0,3 seconds. High frequency transition band was 30 Hz. Nineteen electrodes were placed according to the 10-20 international scheme. EEG recording was carried out in state of quiet wake with eyes closed (background EEG) and with eyes open. Background EEG was evaluated using the visual and logical method. Classification of background EEG was carried out using the method developed by E.A. Zhirmunskaya and V.S. Losev (1984) [4].

Effect of the course of biofeedback training: the biofeedback training was conducted according to the protocol for increasing the power spectrum of alpha activity in the brain in the C_3A_1 monopolar lead of EEG using the “BOSLAB” software and hardware complex with the BI-012 multichannel interface (KOMSIB, Russia). EEG monitoring, recording of the power spectrum of alpha activity, the activity in beta and theta ranges, the theta-beta coefficient, the frontal electromyogram and body temperature were carried out.

The true impact was performed in the main group. The average level of the power spectrum of the brain’s alpha activity, obtained in the 1st minute of the background level determination stage at the beginning of the biofeedback training session (median), was increased by 30%, and the obtained level was considered as the formation threshold of feedback signal.

The course was conducted in form of cycles of 5 sessions, 1 session per day, followed by 2 days of break. The session’s duration was 31 minute. The session’s structure: the threshold setting took 1 minute, the training – 30 minutes. The training was carried out using the continuous method.

For the placebo control group, the placebo exposure was performed, which differs from the true impact with the fact that the biofeedback signal was generated, when the level of median – the average level of the power spectrum of alpha activity in the brain obtained in the 1st minute of the background level determination stage at the beginning of the biofeedback training session – was achieved.

Determination of endpoint effectiveness indicators of the neurobiological management course: the first endpoint is a success in professional activity; second endpoints are statistically significant EEG changes.

Data validation for the normalcy of distribution was carried out using the Shapiro-Wilk test. In case of normal distribution, summarized characteristics of population were the mean (M) and mean square derivation (SD). In case of abnormal distribution, summarized characteristics of population were median values (Me), 25 and 75 percentiles (Q1, Q3). The level of statistical significance was α = 0,05. Variables, which were measured in the categorical scale, were assessed by frequency. The evaluation of statistical significance of differences in frequency in independent samples was carried out using the Chi-square test, in dependent samples before and after the exposure – using the McNemar Chi-square test. The evaluation of statistical significance of differences between groups of samples was carried out using the method of factor analysis of variance.

Results and discussion. One hundred and two subjects of both sexes were involved in this study. Average age of participants in the obtained sample was 20,2±1,8 years.

The main group included sixty nine participants of both sexes, whose average age was 20,2±1,8 years. Thirty three participants were included in the placebo control group, whose average age was 20,1±1,8 years. Significant differences in mean age values between the main and placebo groups were not identified (p>0,05).

A distribution in the main and placebo control groups was analyzed according to age and sex of participants. The average age of women, included in the placebo control group, was 20,3±2,0 years (n=16), in the main group – 19,3±1,6 years (n=30). The average age of men, included in the placebo control group, was 19,9±1,8 years (n=17), in the main group – 20,5±1,9 years (n=39). Analysis of the reliability of age differences in all four groups using the method of factor analysis of variance relative to the effect of interaction between the factors "gender and group" did not reveal significant differences (p=0,.222). The main and placebo groups were representative in terms of sex and age.

Subjects' distribution by category of sports qualification is presented in table 1.

Table 1

The frequency of subjects of different sports qualification included in the study and distributed in the main and placebo groups

Sports qualification	Main group	Placebo group	Sample
1 degree	32	14	46
CMS	23	13	36
MS	13	5	18
MSIC	1	1	2

Note: CMS – Candidate Master of Sports; MS – Master of Sports; MSIC – Master of Sports of the International Class

The significance level for expected and observed frequency in the main and placebo groups of sports specialization according to Chi-square test was p=0,8165 for 1 degree athletes; for CMS – p=0,6809; for MS – p=0,7005 (p=0,9125 with the Yates's correction); the significance level was not determined for MSIC due to insufficient amount of information. Significant differences in frequency of a certain sports qualification between the main and placebo groups were not revealed.

Subjects' distribution by category of sports specialization is presented in table 2.

Table 2

The frequency of subjects of different sports specialization included in the study and distributed in the main and placebo groups

Sports specialization	Main group	Placebo group	Sample
Ski racing	23	12	35
Biathlon	23	11	34
Swimming	7	3	10
Water polo	6	3	9
Volleyball	4	2	6
Hockey	3	1	4
Boxing	2	1	3
Hand-to-hand combat	1	0	1

The significance level for expected and observed frequency in the main and placebo groups of sports specialization according to Chi-square test was p=0,8336 for ski racers; p=1,0000 for biathlon athletes; p=0,8792 for swimmers (p=0,8394 with the Yates's correction); p=0,9520 for water polo players (p=0,7557 with the Yates's correction); p=0,9602 for volleyball players (p=0,6900 with the Yates's correction). The significance level for hockey, boxing and hand-to-hand combat groups was not determined due to the amount of observation less than 5. Significant differences in frequency of a certain sports specialization between the main and group were not revealed.

Electroencephalogram features in athletes with average activity levels of three heart rhythm modulators in the initial state, reflected in certain types of background EEG, are presented in table 3.

Table 3

The frequency of background EEG types in subjects included in the study and distributed in the main and placebo groups

EEG type	Main group	Placebo group	Sample
I	39	16	55
II	8	6	14
III	0	0	0
IV	18	7	25
V	4	4	8

The significance level for expected and observed frequency of the I EEG type in the main and placebo groups according to Chi-square test was p=0,6739; II EEG type – p=0,4353; IV EEG type – p=0,6745; V EEG type p=0,3090 (p=0,5295 with the Yates's correction). Thus, before the biofeedback training effect, significant differences frequency of certain EEG types between the main and placebo groups were not revealed.

Electroencephalogram features in athletes with average activity levels of three heart rhythm modulators after the exposure of the biofeedback training, reflected in certain types of background EEG, are presented in table 4.

Table 4

The frequency of background EEG types after the exposure in subjects included in the study and distributed in the main and placebo groups

EEG type	Main group	Placebo group	Sample
I	37	16	53
II	2	3	5
III	6	3	9
IV	18	7	25
V	6	4	10

After the exposure of the biofeedback training course, the significance level for expected and observed frequency of the I EEG type in the main and placebo groups according to Chi-square test was p=0,7834; II EEG type – p=0,2015 (p=0,4279 with the Yates's correction); II EEG type – p=0,9520 (p=0,7557 with the Yates's correction); IV EEG type – p=0,6745; V EEG type – p=0,6237 (p=0,8899 with the Yates's correction). Thus, after the effect of the biofeedback training course, significant frequency differences of certain EEG types between subjects of the main and placebo groups were not revealed.

Frequency of EEG types in the main and placebo groups before and after the effect was analyzed in order to evaluate the effect of the biofeedback training course (Table 5).

Table 5

The biofeedback training course’s effect on the frequency of EEG types

EEG type	Frequency before the effect	Frequency after the effect	p	p with the Yates's correction
Main group				
I	39	37	0,9006	
II	8	2		0,8908
III	0	6	-	-
IV	18	18	1,0000	
V	4	6		0,9577
Placebo group				
I	16	16		
II	6	3		
III	0	3		
IV	7	7		
V	4	4		

When analyzing the frequency, great attention should be paid to absence of the type III background EEG patterns before the effect, both in the main and in the placebo group. After the effect, observations with the III type EEG, which is regarded as a desynchronous type, appear in both groups [4]. The III type EEG appeared in the sample due to changes in the initial pattern of the II type EEG. Within the main and placebo groups, participants with the initial II type EEG, which were divided after the effect into subgroups with the type II and type III EEG, were considered as related samples, and they were analyzed for the reliability of frequency changes according to the McNemar Chi-square test. In the main group, the McNemar Chi-square (A/D) was 0,44, p=0,5050, in the placebo group (B/C) – 1,33, p=0,2482. Significant changes in the II and III type EEG frequency in the main and placebo groups were not revealed.

Significant changes in the VI and V type EEG frequency, which are considered as disorganized types, with alpha activity (VI type) and theta and delta activities' (V type) prevalence [4] were also not found, which is why the biofeedback training course could be considered as the effect, which is safe in relation to the formation of significant and serious disorders in the EEG.

In the concept of the functional state of a human as "specific types of connections of oscillatory processes made on the central and peripheral levels", the central level is presented as the rhythmic activity of the brain, when the peripheral level – as "oscillatory qualities of wave modulators of the heart rhythm". In this case, functional states could differ by a specific interaction of the brain rhythm activity with oscillatory processes of the peripheral level and could be described as the specific frequency-based integration of the brain's oscillatory activity with wave modulators of the heart rhythm [1]. In this study, a great emphasis was laid on the analysis of relationship of the brain's oscillatory activity with wave modulators of the heart rhythm, which were limited by average levels of the metabolic, vascular and respiratory modulators' activity.

Conclusion. Therefore, the biofeedback course according to the protocol for increasing the power of alpha activity of the electroencephalogram in the C_3A_1 lead on the patterns of background electroencephalogram in elite athletes with initial average levels of relative power spectrum of the HRV in very low, low and high frequency ranges did not demonstrate statistically significant effects on the type of background EEG of subjects in comparison with placebo exposure.

The biofeedback training course according to examined protocol did not cause a statistically significant change in patterns of the VI and V EEG types, which is why it is safe to conclude that the biofeedback training does not cause the formation of significant and serious disorders in the EEG.

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Information about the authors: Vera Sergeevna Kormilets – Assistant of the Department of Normal and Pathological Physiology of the BU "Khanty-Mansijsk State Medical Academy", Khanty-Mansijsk, e-mail: verakormilets@mail.ru; **Olga Vasil'evna Eremeeva** – Candidate of Biological Sciences, Associate Professor of the Department of Normal and Pathological Physiology, Khanty-Mansijsk State Medical Academy, Khanty-Mansijsk e-mail: ov.eremeeva@hmgma.ru; **Sergej Igorevich Eremeev** – Candidate of Medical Sciences, Associate Professor, Professor of the Department of Normal and Pathological Physiology, Khanty-Mansijsk State Medical Academy, Khanty-Mansijsk. e-mail: si.eremeev@hmgma.ru.