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A REACTION OF HEART RATE VARIABILITY SPECTRAL PARAMETERS IN THE PHARMACOLOGICAL TEST WITH MEBICAR IN HEALTHY VOLUNTEERS

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On 13 conditionally healthy volunteers aged from 18 to 46 years (mean age – 22±7,6 years) the variability of the total power (TP, ms2) of the spectrum, very low frequency (VLF, ms2), low frequency (LF, ms2) and high frequency (HF, ms2) domains of heart rate variability (HRV) in 5 minute intervals of ECG in I standard lead before and 30 minutes after oral admission of 500 mg of mebicar were evaluated. The data were processed by methods of nonparametric statistics. No significant changes in TP, VLF, LF, HF HRV after 30 minutes (maximum time declared by pharmacodynamics action) after administration of 500 mg of mebicar were noted by us. Accordingly, the effectiveness of mebicar as an adaptogen without evidence-based research cannot be postulated.

KEY WORDS: mebicar, adaptogen, healthy volunteers, pharmacological test

РЕАКЦІЯ СПЕКТРАЛЬНИХ ПАРАМЕТРІВ ВАРІАБЕЛЬНОСТІ СЕРЦЕВОГО РИТМУ У ФАРМАКОЛОГІЧНІЙ ПРОБІ З МЕБІКАРОМ У ЗДОРОВИХ ДОБРОВОЛЬЦІВ

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На 13-ти умовно здорових добровольцях у віці від 18 до 46 років (середній вік – 22 ± 7,6 років) оцінена мінливість загальної потужності спектра (ТР, мс^2), потужностей дуже низькочастотного (VLF, мс^2), низькочастотного (LF, мс^2) і високочастотного (HF, мс^2) домену спектра варіабельності серцевого ритму (ВСР) в 5-хвилинних інтервалах ЕКГ в І стандартному відведенні до і через 30 хвилин після перорального прийому 500 мг мебікару. Дані оброблялися методами непараметричної статистики. Достовірних змін ТР, VLF, LF, HF ВСР через 30 хвилин (декларований час максимуму фармакодинамічної дії) після прийому мебікару в дозі 500 мг нами відзначено не було. Відповідно до цього ефективність мебікару як адаптогена без проведення доказових досліджень не може бути постульована.

КЛЮЧОВІ СЛОВА: мебікар, адаптоген, здорові добровольці, фармакологічна проба

РЕАКЦИЯ СПЕКТРАЛЬНЫХ ПАРАМЕТРОВ ВАРИАБЕЛЬНОСТИ СЕРДЕЧНОГО РИТМА В ФАРМАКОЛОГИЧЕСКОЙ ПРОБЕ С МЕБИКАРОМ У ЗДОРОВЫХ ДОБРОВОЛЬЦЕВ

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На 13-ти условно здоровых добровольцах в возрасте от 18 до 46 лет (средний возраст – 22 ± 7,6 лет) оценена изменчивость общей мощности спектра (ТР, мс^2), мощностей очень низкочастотного (VLF, мс^2), низкочастотного (LF, мс^2) и высокочастотного домена спектра (HF, мс^2) вариабельности сердечного ритма (ВСР) в 5-минутных интервалах ЭКГ в I стандартном отведении до и через 30 минут после перорального приёма 500 мг мебикара. Данные обрабатывались методами непараметрической статистики. Достоверных изменений в ТР, VLF, LF, HF ВСР спустя 30 минут (декларируемое время максимума фармакодинамического действия) после приема мебикара в дозе 500 мг нами отмечено не было. В соответствии с этим эффективность мебикара как адаптогена без проведения доказательных исследований не может постулироваться.

КЛЮЧЕВЫЕ СЛОВА: мебикар, адаптоген, здоровые добровольцы, фармакологическая проба

INTRODUCTION

The global pharmaceutical industry in recent years devotes more and more attention

to various adaptogens that contribute easier carrying of daily life distress [1].

Mebicar positioned as a drug that can affect the serotonergic system of the body and exert anxiolytic, mild sedative and expressed nootropic effect [2–3]. These effects should ensure the rapid restoration of the balance of the regulatory systems of the body, however there is the views about low efficiency of the drug.

Among noninvasive methods to assess autonomic nervous system regulation of heart activity measurement of heart rate variability (HRV) is the most informative and widely used in clinical practice [4].

Given the direct dependence of the adaptive capacities of the organism from the state of regulatory systems [5–6], it is of interest to evaluate their variability in the pharmacological test with mebicar in healthy volunteers.

The study was performed as a part of KhNU research «Development and research of system of automatic control of heart rate variability», № registration 0109U000622.

OBJECTIVE

The purpose of the study was to evaluate the reaction of spectral parameters of HRV in the pharmacological test with mebicar in healthy volunteers.

MATERIALS AND METHODS

The study included 13 conditionally healthy volunteers from 18 to 46 years (mean age – 22 ± 7,6 years). Exclusion criteria were: bad habits, taking medications during last 3 months, resting heart rate less than 60 beats/min, blood pressure less than 100/60 mm Hg.

In accordance with the purpose of the study, in all volunteers were conducted registration of HRV before and 30 minutes after oral admission of 500 mg of mebicar when it [7] reaches peak concentration in the body and when it maximum pharmacodynamics action is declared.

HRV indices were estimated in 5-minute intervals of ECG in the I standard lead in computer-diagnostic complex CardioLab 2009: total power (TP, ms^2), powers of very low frequency (VLF, ms^2), low frequency (LF, ms^2) and the high frequency (HF, ms^2) domains of spectrum [8].

Statistical analysis was performed by using Microsoft Excel. In the table were recorded average values (M) and standard deviations (sd) of TP, VLF, LF, HF on each volunteer before and after ingestion of the drug. The significance of differences of each of the indexes was determined by using the Wilcoxon T-test.

RESULTS AND DISCUSSION

The study included 13 conditionally healthy volunteers from 18 to 46 years (mean age – 22 ± 7,6 years). Exclusion criteria were: bad habits, taking medications during last 3 months, resting heart rate less than 60 beats/min, blood pressure less than 100/60 mm Hg.

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Table

HRV values before (1) and 30 minutes after (2) reception of mebicar in healthy volunteers (M ± sd)

Indexes	Phases of research	
	1	2
TP, ms^2	2715,08 ± 1800,15	4893,08 ± 5046,70
VLF, ms^2	805,54 ± 617,30	1832,23 ± 2269,48
LF, ms^2	1217,77 ± 911,33	2139,69 ± 2513,29
HF, ms^2	604,23 ± 471,64	872,23 ± 850,55

Notes: * – $p < 0,01$ against baseline values.

Mebicar is widely promoted as an effective means of increasing the body's adaptive mechanisms that are implemented by the serotonergic system for the prevention of chronic distress is constantly growing modern living conditions [9–10]. These effects should be mediated in changes of HRV, which, however, were unable to confirm in the present study: before and 30 minutes after administration of 500 mg of mebicar in healthy volunteers values of TP, VLF, LF and HF of HRV were not significantly different, which allows doubt, at least in the quick effect of the drug on the body's regulatory system and its effectiveness as an adaptogen without evidence-based research cannot be postulated.

CONCLUSIONS

1. Mebicar in the dose of 500 mg after 30 minutes (declared time of pharmaco-dynamics action maximum) after a single admission had no significant effect on the TP, VLF, LF, HF of HRV in healthy volunteers.
2. Ability to use mebicar as an adaptogen without evidence-based research cannot be postulated.

PROSPECTS FOR FUTURE STUDIES

It is interesting to evaluate the volatility of HRV parameters in healthy volunteers with a long reception of mebicar.

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