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Use of the infrared radiation modulated by terahertz frequencies in complex therapy of patients with acute ischemic stroke

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Abstract

Objective. We present the data of the retrospective clinical study in order to summarize the experience of the implementation of infrared radiation with terahertz modulation 0.086–7.5 μm (0.02 to 8 THz) in patients with acute ischemic stroke (AIS). **Design and methods.** We followed up 61 patients with AIS (age from 18 to 86 years, mean age 59 ± 1 year), 24 women and 36 men, who were divided into two groups: group I (n = 30) and II (n = 31). Patients from the group II received standard pharmacotherapy in acute stroke unit and during hospitalization. Patients from the group I in addition to standard pharmacotherapy underwent procedures of transcranail application of infrared radiation. The radiator was established on parietal area in a projection of an acupuncture point Bai-Huey (VG-20) independent of brain lesion localization. **Results.** Patients from the group I demonstrated earlier recovery, earlier consciousness, a more rapid regression of neurological symptoms and earlier expansion of physical activities compared to the second group. For two years of dynamic supervision patients from the group I showed stable and even better indicators of Barthel index, Rankin scale and National Institutes of Health Stroke Scale (NIHHS) compared to the group II. This can be due to the better compliance of patients from the group I to treatment and a positive effect of the 6–10 procedures of the infrared radiation modulated by terahertz frequencies. **Conclusions.** Infrared radiation modulated by terahertz frequencies can be recommended in acute ischemic stroke as a part of complex treatment. A prospective controlled randomized study involving patients with ischemic stroke is required in order to develop the precise approaches for infrared radiation application.

Key words: ischemic stroke, drug therapy, infrared radiation with terahertz modulation

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Применение инфракрасного излучения, модулированного терагерцевыми частотами, в комплексной терапии больных острым ишемическим инсультом

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Резюме

Представлены данные ретроспективного клинического исследования, выполненного с целью обобщения опыта использования инфракрасного излучения с терагерцевой модуляцией 0,086–7,5 мкм (0,02–8 ТГц) для лечения пациентов с острым ишемическим инсультом (ИИ). **Материалы и методы.** Под наблюдением находился 61 больной ИИ (24 женщины, 36 мужчин) в возрасте от 18 до 86 лет (средний возраст — 59 ± 1 год), которые были разделены на две группы: I (n = 30) и II (n = 31). Пациенты II группы, находясь в реанимации и в условиях неврологического отделения стационара, получали стандартную фармакотерапию. Пациентам I группы дополнительно к стандартной фармакотерапии проводилось транскраниальное воздействие терагерцевым излучением. Излучатель устанавливался на область темени в проекции акупунктурной точки Бай-Хуэй (VG-20) независимо от локализации зоны поражения. **Результаты.** За время стационарного лечения у пациентов I группы было отмечено более раннее восстановление сознания, более быстрый регресс неврологической симптоматики; имело место раннее расширение реабилитационных мероприятий по сравнению со II группой. На протяжении двух лет динамического наблюдения среди пациентов I группы сохранялись и даже улучшались показатели по индексу Бартел, шкалам Рэнкина и по шкале оценки степени выраженности неврологической симптоматики (National Institutes of Health Stroke Scale, NIHSS) по сравнению со II группой, что было обусловлено лучшей приверженностью больных I группы лечению и положительным эффектом от подключения к проводимой лекарственной терапии дополнительно от 6 до 10 процедур на курс инфракрасного излучения, модулированного терагерцевыми частотами, на разных сроках амбулаторно-поликлинического этапа. **Выводы.** Можно рекомендовать применение метода инфракрасного излучения, модулированного терагерцевыми частотами, больным в остром периоде ИИ. Для более детальной проработки методики терагерцевого воздействия у больных неврологического профиля целесообразно провести проспективное контролируемое рандомизированное исследование, в котором приняли бы участие пациенты с установленным диагнозом ИИ.

Ключевые слова: ишемический инсульт, лекарственная терапия, инфракрасное излучение с терагерцевой модуляцией

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Introduction

Cerebrovascular diseases are the most important medical and social problem of the modern society due to their prevalence, high rate of mortality, temporary and primary disability. According to the estimates of the World Health Organization (2006), about 6 million cases of cerebral stroke are registered globally each year. One quarter has lethal outcome. In the USA, about 550 thousand people experience strokes each year, about 150 thousand people die from stroke; at least 3 million post-stroke patients have neurological deficit of various degrees. In Europe, average frequency of strokes is about 200 cases per 100 thousand of the population, and over one half of patients become disabled [1].

According to the incidence of patients' visits, in the Russian Federation cerebrovascular morbidity is estimated as 450 cases per 100 thousand people. Moreover, morbidity parameters in adults increased from 5,776.3 per 100 thousand people (2005) up to 6,058.9 per 100 thousand people (2010) [2, 3]. Strokes hold the first place among all reasons of primary disability in adults. Only 10–20 percent of patients return to work, 8% of them keep their professional qualification, 25% are in need of assistance. Stroke imposes particular obligations on patient's relatives and is a huge financial burden for the health care system. Emergency hospitalization is efficient only if a patient is admitted to a modern specialized neurology department for patients with cerebrovascular disorders within the "therapeutic window" (3–6 hours). Average hospital mortality in the Russian Federation in the acute stage of all types of strokes (28-day mortality) is approximately 22%. Mortality increases by 12–15% by the end of the first year; within a year, about a half of patients (i. e. every second patient) die. High level of repeated strokes (30%) is registered [4, 5].

Based on current conception, two basic strategies of pathogenetic therapy in ischemic stroke (IS) are distinguished: improvement of cerebral tissue perfusion (early vessel recanalization and reperfusion) and neuroprotective therapy. Physiotherapy is mostly used in rehabilitation period after IS [6]. In recent years, a number of reports demonstrated that application of THz radiation affects certain physiological parameters. Few studies of impact of THz waves on cells, tissues, and organs in vivo are of particular interest. First of all, some changes in nervous and humoral regulation are induced by THz radiation. Application of radiation with a frequency of 3.68 THz induces conformational changes of albumin molecules and changes of its binding capacity to progesterone, as well as increases reduced cell membrane resistance [7, 8]. THz waves can affect the central nervous system and higher nervous activity in animals [9, 10]. THz therapy is a relatively new but very prospective method of physiotherapy [11, 12].

Objective of this **study** was to assess the impact of infrared radiation modulated by THz frequencies on the efficiency of the treatment and rehabilitation in post-IS patients during in-patient and outpatient follow-up.

Design and methods

During four years (from 2011 to 2015), 61 patients with IS at the age from 18 to 86 years old (average age: 59 ± 1 years old) including 24 females and 36 males were followed up at the V.A. Almazov Federal North-West Medical Research Center. The patients were divided into two groups: group I included 30 patients (average age: 61 ± 1 years old) and group II included 31 patients (average age: 58 ± 1 years old).

During in-patient treatment, medical case reports were selected so that both groups matched each other by four parameters (major disease, major comordibity, sex, and age). In 15 patients of group I, the IS was localized in the area of the right middle cerebral artery, in 11 patients, — in the area of the left middle cerebral artery; one patient in each group had IS in the areas of both right and left middle cerebral arteries; right middle and right posterior cerebral arteries; right middle and left posterior cerebral arteries; right middle cerebral artery and vertebrobasilar system. Affected areas in group II were almost identical.

84–90 % of patients of both groups suffered from stage 1–3 hypertension. Six patients of group I and two patients of group II had suffered a myocardial infarction of various localization in past. In 20 % patients of group I and 23 % of the patients of group II, type 2 diabetes mellitus was diagnosed. Dyslipidemic disorders of various severity were found in all patients.

During in-patient treatment, patients of both groups stayed in intensive care and neurology department of the in-patient facility All patients received standard drug treatment, which involved intake of anticoagulants, antiplatelet agents, antihypertensive, antiarrhythmic, and antilipidemic drugs. In intensive care, various clinical problems were registered that were impossible to solve out within reasonable time by commonly used methods within the scope of national and international standards for treatment of patients with IS. Such problems included coma, convulsive disorder, tetraplegia, life-threatening cardiac arrhythmia, hyperthermia, and other treatment-refractory problems.

In group I, transcranial stimulation with infrared radiation modulated by THz frequencies (IR-Dipole device, Dipole Structures LLC, St Petersburg) was applied additionally to medication therapy [13]. The device consists of a radiation generator located on a heat sink equipped with a reflector. THz radiation is generated with the use of silicone nanostructures. The spectrum of far-infrared radiation is 1–56 μm with THz modulation of 0.086–7.5 μm (0.02–8 THz) within the entire infrared radiation spectrum. THz modulation ensures several-fold intensification of photoinduction as THz radiation penetrates into tissues and affects protein molecules [14]. The radiation power of IR-Dipole device is 30 mW, and the radiant flux density is 2.4 mW/cm². The basis area of the radiating element is 79 cm².

The radiating element was set on the top of the head in the projection of Bai Hui acupuncture point (VG-20) regardless of the localization of the affected area. This region is one of the most important zones of neurovascular regulation of interhemispheric associations [15]. The distance from the radiating element to the skin was 5–10 cm. The procedure duration was 22.5 minutes. The treatment course consisted of 8–15 procedures depending on the regression of neurological symptoms.

THz radiation was also applied during outpatient rehabilitation in group I: at 6, 12, and 24 months after stroke, 6–10 procedures per course were performed. Patients of group II received only pharmacotherapy in various combinations.

Rankin, Barthel, and NIHSS scales (National Institutes of Health Stroke Scale) were used for assessment of recovery and regression of neurological symptoms [16].

The data were processed with the use of parametric and non-parametric methods with the help of STATISTICA 6.0 software. Differences were acknowledged statistically significant at p-level < 0.05.

Results and discussion

Patients from group I had more severe symptoms at baseline compared to group II: duration of depressed consciousness was 75.13 ± 15.03 vs 31.03 ± 7.65 hours ($p < 0.001$); duration of intubating was 5.67 ± 1.18 vs 1.74 ± 0.51 days ($p < 0.01$). Differences in the duration of the stay in the neurology department after the transfer from intensive care were not significant: 22 ± 2 vs 18 ± 1 days, respectively ($p > 0.05$). No lethal outcomes were registered in both groups during in-patient treatment.

We assessed Barthel index based on evaluation of 10 functions in order to determine the baseline level of patient's activity (from independent performance to those requiring assistance) and efficiency of the therapy. The total score from 0 to 5 corresponds to the disability requiring constant assistance, the total score from 6 to 10 corresponds to moderate dependence, the total score from 11 to 15 corresponds to light dependence, and the total score from 16 to 20 corresponds to complete independence in daily activities [17].

In group I and II baseline Barthel index was 0.2 and 1.94 points in average, respectively. The change in Barthel index during in-patient treatment is presented in Table 1. The

provided data demonstrate that at admission the patients of both groups were in a very severe condition, and in the majority of cases the total Barthel index did not exceed 5 points. By the end of in-patient treatment, the average total score was 15.8 and 11.4 points in patients of group I and II, respectively. Moreover, higher scores according to Barthel Index (from 16 to 20 points) were registered 3 times more often in group I after THz stimulation than patients in group II (18 vs. 6 patients).

At baseline, Rankin scale was 4.8 vs 4.1 points in group I and II, respectively, that corresponds to the highest range reflecting severe abnormalities and disability in both groups (Table 2).

By the end of the in-patient treatment, patients of group I demonstrated higher scores according to Rankin scale (from 1 to 3) 1.5 times more often than patients in group II. By the end of hospitalization, average total score according to Rankin scale was 1.97 points in patients of group I. So the patients could perform their needs independently, except some former duties. At the same time, Rankin score was a bit higher in group II and achieved only 3.1 points on average.

NIHSS score at admission was 26.7 and 18.9 points in group I and II, respectively. By the end of in-patient treatment, NIHSS score < 10 points was registered almost 1.5 times more often in group I (Table 3). NIHSS scale allows

Table 1

BARTHEL INDEX IN PATIENTS WITH ISCHEMIC STROKE

	Group I (n = 30)		Group II (n = 31)	
Point	**Admission**	**Discharge**	**Admission**	**Discharge**
0–5	30	1	29	2
6–10	–	2	2	14
11–15	–	9	–	9
16–20	–	18	–	6

Table 2

RANKIN SCALE IN PATIENTS WITH ISCHEMIC STROKE

	Group I (n = 30)		Group II (n = 31)	
Point	**Admission**	**Discharge**	**Admission**	**Discharge**
0	–	–	–	–
1	–	8	–	2
2	–	14	1	5
3	–	8	3	13
4	6	–	18	10
5	24	–	9	1

Table 3

NIHSS SCALE IN PATIENTS WITH ISCHEMIC STROKE

	Group I (n = 30)		Group II (n = 31)	
Point	**Admission**	**Discharge**	**Admission**	**Discharge**
0–10	1	28	3	19
11–20	2	2	11	12
21–30	27	–	17	–

to determine disease prognosis [16]. Scores less than 10 points correspond to the probability of favourable outcome 1 year after IS of about 60–70 %, while scores of 20 points and more, the probability of favourable outcome is only 4–16 %. By the end of in-patient treatment, the average total NIHSS score was 6.5 and 8.9 points in group I and II, respectively. Thus, patients of group I were discharged with a bit higher NIHSS score than patients of group II.

Volume of brain lesions is significantly affected by a number of pathogenic factors [18, 19]: stabilization of the key individual pathogenetic factor; availability of permanent thromboembolism in the affected artery; effectiveness of collateral blood supply; adequacy of perfusion pressure and period of blood flow recovery in the basin of the affected cerebral artery; resistance of brain tissues to ischemia. The degree of lesion reversibility and dynamics of morphological losses during the acute IS define the most important clinical parameters, which include survival and depth of neurological disorders. Duration of existence of the ischemic area is individual. The range within several hours is considered today as the period for the most efficient therapeutic treatment [20].

We showed that during in-patient treatment, patients of group I demonstrated earlier recovery, more rapid regression of neurological symptoms, and early expansion of rehabilitation procedures after THz stimulation of the head in the projection of the Bai Hui (VG.20) acupuncture point was added to the traditional pharmacotherapy, although patients of group I at baseline demonstrated more severe neurological symptoms. We believe that one of the possible mechanisms of efficient treatment of the ischemic lesion was early (during the first days in acute IS) application of THz radiation. According to the data of O. V. Betskiy and N. N. Lebedeva (2001), one of the mechanisms of THz radiation can be its "informational", non-thermal effect [12]. Biological responses to THz radiation are recorded at the radiation flux density of less than 10 mW/cm², wherein integral heating of the irradiated tissues does not exceed 0.1 °C. We used the device with the flux density of 2.4 mW/cm², as well as a heat sink for the crystal generating radiation, which allowed to achieve an "informational" non-thermal biological response. Ramundo-Orlando A. (2009) assumes that natural frequencies of vibration-rotation transitions of water and biological molecules, both simple and complex, including polypeptides and proteins, are located in the THz range [9]. Moreover, molecular emission and absorption spectra of many biologically active substances, such as nitric oxide (NO), carbon monoxide (CO), molecular oxygen and its active forms, are located exactly in the THz range [21, 22]. Yu. V. Gulyayev et all (2008) showed that natural frequencies of oscillations of the cell membrane, cytoskeleton, and cells as a whole are located in the submillimeter part of the THz range. So they can cause resonance effects when coincide with external electromagnetic radiation.

Here, we present a clinical case of THz stimulation in a patient M., 52 y. o., who was admitted to the hospital on February 2, 2013, one hour after stroke onset. Ischemic stroke in the basin of the left middle cerebral artery was verified. Thrombolytic therapy was complicated by coma (5 points according to the Glasgow Coma Scale). Infrared radiation with THz modulation according to the aforementioned procedure was added to the common therapy. The patient regained consciousness at the end of the second procedure and was transferred to the neurology department on the third day after IS onset. He was discharged on the 23rd day.

Table 4 presents the follow-up data of groups I and II during outpatient rehabilitation. We noted that parameters of Barthel index, Rankin scale and NIHSS scale were better in group I compared to group II during two-year follow-up.

Although Barthel index was almost maximal at discharge in patients of group I, there were still some problems to deal with during rehabilitation period. As an example, in patient M. baseline Barthel index prior to the first session of THz stimulation was 0 points and at discharge it achieved maximum, i. e. 20 points. However, the patient did not recovered completely. Two and a half years after the stroke, he felt good, motor function and speech recovered so that

Table 4

FUNCTIONAL STATUS OF PATIENTS IN GROUPS I AND II DURING FOLLOW-UP

Follow-up	Barthel index		Rankin index		NIHHS index	
6-month follow-up	Gr. I	Gr. II	Gr. I	Gr. II	Gr. I	Gr. II
	18.92 ± 0.34	14.37 ± 0.72	1.90 ± 0.16	3.00 ± 0.14	5.14 ± 0.93	6.67 ± 0.77
	t = 5.15, p < 0.001		t = 5.13, p < 0.001		t = 1.00, p > 0.05	
1-year follow-up	Gr. I	Gr. II	Gr. I	Gr. II	Gr. I	Gr. II
	18.92 ± 0.25	14.62 ± 0.81	1.67 ± 0.14	2.90 ± 0.15	2.83 ± 0.39	7.03 ± 0.74
	t = 5.10, p < 0.001		t = 5.89, p < 0.001		t = 5.00, p < 0.001	
2-year follow-up	Gr. I	Gr. II	Gr. I	Gr. II	Gr. I	Gr. II
	19.00 ± 0.20	15.32 ± 0.65	1.63 ± 0.19	2.96 ± 0.17	2.74 ± 0.42	6.96 ± 0.17
	t = 5.38, p < 0.001		t = 5.16, p < 0.001		t = 4.91, p < 0.001	

Note: Data are presented as M ± m. Results are considered significant at $p \leq 0.05$.

he planned to return to work in the same field (the patient is a construction electrician). At the same time, the detailed interview showed some unresolved issues, both regarding sensitivity and movement coordination disorders and cognitive functions.

In our study, 1 patient died in each group during the outpatient treatment (first six months of follow-up): in group I, due to viral pneumonia (flu complication); in group II, due to extensive m yocardial infarction immediately after discharge from the hospital.

By the end of follow-up, 1 patient had disability class 1 and 14 patients had disability class II in group I, while in group II the rate of disability class II was double. Drug dosage in group I was reduced and 14 people returned to their former work, while no such tendency was observed in group II, and only 2 subjects returned to former work. More evident progress in group I might be caused by complete recovery with drug therapy and THz stimulation compared to patients from group II who received only drug treatment.

Therefore, THz stimulation may be recommended to patients with acute IS. However, a prospective randomized controlled study of IS patients will be helpful for more detailed investigation of the effects of THz stimulation in patients with neurological disorders. Methods for determination of the temperature sensitivity of reflex zones, including acupuncture points, along with assessment of dynamics of functional possibilities in neurological patients can be also helpful. Akabane test, thermometry of acupuncture points, etc. are used for this purpose in reflex therapy. Taking into account the impairment of the central nervous system in IS, thermometry can be beneficial for assessment the severity of the impairment and its dynamics. Along with neurological scales, it will provide more comprehensive assessment of functional characteristics and physiological reserves in neurological patients and will allow the choice for areas of physiotherapy application, treatment and rehabilitation.

Conclusions

1. Patients with IS who underwent both traditional therapy and THz stimulation (infrared radiation modulated with frequencies 0.02–8 THz on top of the head in the projection of the Bai Hui acupuncture point, VG-20) demonstrated earlier recovery, regression of neurological symptoms, and expansion of rehabilitation procedures.

2. During two-year follow-up, parameters of Barthel index, Rankin scale and NIHSS scale improved in group I compared to group II that can be due to a better adherence of patients in group I to treatment and a positive effect of infrared radiation modulated with THz frequencies (6–10 sessions) after stroke.

Conflict of interest

The authors declare no conflict of interest.

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