PPN

Personalized Psychiatry and Neurology

Article

Efficiency and safety of the author's method of wrist tapping as a personalized method of emergency self-help in focal epilepsy

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Citation: Narodova, E.A.; Narodova, V.V.; Petrov, K.A.; Yakunina, A.V.; Poverennova, I.E. Efficiency and safety of the author's method of wrist tapping as a personalized method of emergency self-help in focal epilepsy. *Personalized Psychiatry and Neurology 2021, 1, (2)*: 106-110. https://doi.org/10.52667/2712-9179-2021-1-2-106-110

Chief Editor: Nikolaj G. Neznanov, D Med Sci, Professor

Received: 14 August 2021
Accepted: 20 September 2021
Published: 15 November 2021

Publisher's Note: V.M. Bekhterev NMRC PN stays neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Abstract: Currently, a search for a solution to the problem of drug-resistant epilepsy is being actively pursued. Along with personalized (including targeted) drug methods, personalized non-drug methods of treating drug-resistant epilepsy are being actively developed. Our previous studies have shown that the developed author's technique with an individual selection of the wrist tapping (WT) leads to an increase in the activity of the frontotemporal cortex, mainly of the right hemisphere, involved in emotional control, and a decrease in the fear of recurrence of focal epileptic seizures (FS) or transformation of FS into bilateral tonic-clonic seizures (BTCS). In addition, WT leads to a decrease in intrahemispheric coherence in the frontotemporal regions of the left hemisphere, which is a biomarker for reducing the risk of generalized epileptic activity.

Keywords: *epilepsy, drug-resistant, epileptic seizure, personalized therapy, wrist tapping, EpiTapp, efficacy, safety.*

Introduction

Recently, a search for a solution to the problem of drug-resistant epilepsy is being actively pursued all over the world. The development of new generations of antiepileptic drugs (AEDs) and a personalized approach to their selection and dosage are ways of a possible solution to this problem. However, the number of patients with drug-resistant structural epilepsy is not decreasing [1]. Structural focal epilepsy (SFE) has a high risk of drug resistance. This leads to stigmatization, an increase in the level of anxiety in connection with the fear of recurrence of epileptic seizures and trauma in patients with SFE. The situation is aggravated by the inability to carry out daily habitual professional activities in some patients, which leads to social deprivation, professional maladjustment, and a decrease in the quality of life. Increasing the dose of AED and polytherapy, as a way to combat drug resistance, can lead to serious adverse reactions (ADRs), especially in patients with comorbid conditions. Thus, from the scientific and practical points of view, the development and implementation into clinical practice not only of personalized approaches to drug therapy for epilepsy, but also to the development of personalized approaches to non-drug therapy. Our previous studies have shown that the developed author's technique of wrist tapping (WT) leads to an increase in the activity of the frontal-temporal cortex, predominantly of the right hemisphere, which is involved in emotional control and reduction of fear of recurrence of epileptic seizures and / or transformation of focal seizures (FS) into bilateral tonic-clonic (BTC) [2], [3]. We also showed that, against

the background of WT, there is a decrease in intrahemispheric coherence in the fronto-temporal regions of the left hemisphere, which is consistent with the studies of Vollmar S. et al. (2011) [4]. These authors, conducting a study using functional magnetic resonance imaging (fMRI), revealed a decrease in functional connectivity of rest in the frontal lobe of the left hemisphere in patients with epilepsy, which is a biomarker for reducing the risk of generalized epileptic activity. The aim of this study was to investigate the efficacy and safety of the EpiTapp application, based on a personalized approach to the choice of WT frequency, in patients with pharmacoresistant.

Materials and Methods

The author's method of wrist tapping (RF patent No. 2606489 dated 01/10/2017) was used in the form of the EpiTapp application for a smartphone with the Android operating system. The study involved 30 patients with drug-resistant structural focal epilepsy (SFE). The average age is 33.5 years [29; 40]. Study type: observational, open, continued. The inclusion of patients in the study was approved by the Ethics Committee (Protocol No. 77/2017 dated 06/26/2017). All participants signed voluntary informed consent before starting the study. Patients with SFE did not receive any remuneration for participating in this study. The researchers did not receive any remuneration for conducting this study.

All patients received antiepileptic drugs in the polytherapy regimen without correction during the study. WT was performed by the patient independently during the period of aura and / or FS without impairing consciousness outside the hospital. The duration of the study is 1 month or more. Visit 1: consultation of a neurologist - epileptologist; randomization of the sample according to inclusion / exclusion criteria (including: assessment of cognitive functions using a short mental status scale (MMSE) and a frontal assessment battery (FAB); assessment of the level of anxiety and depression using (HADS); EEG monitoring; training in using the application Visit 2 (1 month after visit 1): consultation of a neurologist - epileptologist; EEG - monitoring; assessment of the seizure observation diary.

To assess the effectiveness of the technique, the following were used: The scale of quality of life in epilepsy (QOLIE - 31) in the variants of the authors; Scale for evaluating the effectiveness of the author's wrist-tapping technique.

We adjusted the EpiTapp application in the mode of exogenous stimulation at a frequency of 1.13 Hz (the frequency obtained in healthy volunteers - in our earlier studies) [5]. Patients were recommended to use the application as an element of urgent (emergency) self-help in case of signs of an incipient epileptic seizure (aura, focal seizure with preservation of awareness) (Figure 1).

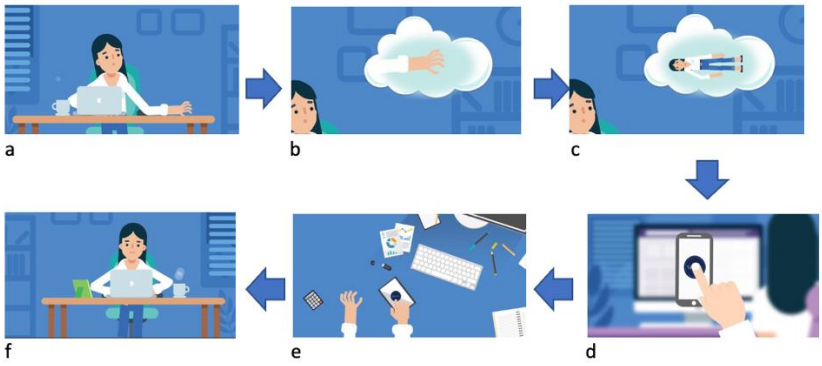

Figure 1 - Scheme of using the EpiTapp application by a patient with structural focal epilepsy at the time of the onset of a focal seizure: a, b, c - the development of a focal seizure with preservation of awareness; d, e - use of the "EpiTapp" application; f - relief of an epileptic seizure.

Each patient was given a seizure observation diary, in which he must record epileptic seizures, their duration and frequency on a daily basis, and also note the subjective assessment of the effectiveness of using the author's method of wrist tapping "EpiTapp". At the request of the patient, he retains the right to further use the EpiTapp application even after the end of the clinical testing stage, after evaluating and evaluating the safety of the technique in each specific case.

Inclusion criteria for the study group: patients with structural (post-traumatic, post-stroke, postoperative) focal epilepsy; polytherapy with AED (2 or more); duration of AED intake for more than 3 years; the presence of at least 3-4 FP and / or BTKP per month; age period: adolescence (m 17 - 21 years old; f 16 - 20 years old); the first period of middle age (m 22 - 35 years old; f 21 - 35 years old); the second period of middle age (m 36 - 60 years old; f 36 - 55 years old); signed voluntarily provided; male and female gender; Russian-speaking Europeans.

Exclusion criteria from the study: refusal to participate in this study; acute and chronic neurological, psychiatric and endocrinological diseases at the time of the study; seizures of a non-epileptic nature; the frequency of attacks is less than 3 times a month; seizures occur exclusively in sleep; age under 16 and over 55 for women; age under 17 and over 60 for men; severe cognitive impairment (FAB less than 12 points; MMSE less than 20 points); the presence of anxiety and depression at the time of the study (on the HADS scale: more than 7 points on the anxiety subscale, more than 7 points on the depression subscale).

According to the assessment of the level of anxiety and depression on the HADS scale, patients with epilepsy who had severe anxiety and / or depression were excluded. This approach is important because anxiety and depressive disorders could affect patient compliance (cooperation with a neurologist - epileptologist, regular use of the EpiTapp application, keeping a diary of observation of epileptic seizures).

In the present study, 30 patients with SFE took part, including: 20 women, 10 men. The median of the formed was 33.5 [29; 40] years, including: among women - 36 [30; 39.5] years; in men - 34 [28; 42] years. There were no statistically significant differences in the sample by sex and age of patients ($p > 0.05$).

Results

According to the questionnaire survey on the QOLIE-31 scale as modified by the authors at the stage of randomization of the sample: 70% showed a decrease in the quality of life against the background of epilepsy (less than 6 points on a ten-point subscale, where 10 points is the best result); 75% of patients had an assessment of their own poor health (less than 60% on a 100 point subscale, where 100% is the best result). More than 80% of patients gave a rating (1-2 points on a 4-point subscale, where 4 points are the best result) in the section of the scale "Anxiety about seizures": 82% of patients noted significant anxiety about the development of another epileptic seizure; 86% of patients worried about possible trauma during BTK. A significant number were worried about: the emergence of social problems associated with epilepsy (89%), restrictions on work and social stigmatization; expressed concern about the possible harm from the AEDs they receive for a long time (78%). All of the above had an adverse effect on the emotional well-being of those with SFE. Thus, 76% of patients noted that they rarely feel calm and peaceful (4-6 points, 6 points on the sublane scale, where 6 points are the worst result).

Analysis of the quality of life of patients at visit 2 showed statistically significant positive dynamics compared to visit 1 ($p < 0.05$): 75.73% of cases - improved quality of life (1 - 2 points on a 5 point subscale, where 1 point corresponded to the mark - “very good”), which is probably related to the ability to control epileptic seizures and minimize / eliminate the risk of trauma; 80.95% - a high assessment of the effectiveness of the method (8-10 points on a 10 point subscale, where 10 points is the best result); 76% - a feeling of

calmness and serenity when using the application of hand tapping "EpiTapp" (1 - 2 points on a six-point subscale, which corresponded to the mark "all the time or most of the time").

In general, the majority of patients showed a decrease in epileptic seizures from the moment of using the EpiTapp application without correcting the scheme of the previously used AEDs. Thus, before using the EpiTapp application, only 9% of patients had the frequency of epileptic seizures corresponding to the “rare” mark. After 1 month from the start of using the EpiTapp application, the number of patients who marked "rarely" increased to 76.19% ($p < 0.001$). In 80% of cases, patients managed to stop AF without impairing consciousness within the first 1-2 minutes from their onset by using this application.

The majority of patients (86%) noted the high safety of the EpiTapp application (90-100% on a 100 point subscale, where 100 points corresponded to the mark “most safe”). None of the patients in this study developed BTC. Most patients assessed the technique as “safe” to use and mostly “effective”.

Discussion

The results of a study of the effectiveness and safety of using the EpiTapp application on a mobile device (smartphone) with Android OS, based on personalized selection of hand tapping frequency, indicate high efficiency (80%) and safety (100%) of its use in adult patients with SFE. A positive effect of the method on the frequency and severity of AF and a decrease in the risk of BTKP development was noted.

Conclusions

Limitation of the use of the method in real practice: low compliance of patients with epilepsy to the use and cooperation with the attending physician neurologist - epileptologist; severe cognitive impairment; impaired intelligence; moderate to severe dysfunction of the hand; childhood. The assessment of the contribution of these limitations to the use of the EpiTapp application was not evaluated in the present study, as they were included in the sample randomization criterion.

Author Contributions: Conceptualization, E.A.N..; methodology, V.V.N.; software, K.V.P.; validation, E.A.N.; formal analysis, A.V.Y.; investigation, I.E.P.; resources, K.V.P.; data curation, E.A.N.; writing— E.A.N.; writing— E.A.N. and V.V.N.; visualization E.A.N.; project administration, E.A.N.

Conflicts of Interest: The authors declare no conflict of interest.

Funding: This research received no external funding.

Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Ethics Committee of Professor V.F. Voyno-Yasenetsky Krasnoyarsk State Medical University, Ministry of Health of the Russian Federation.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

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