Evidence-Based Practice Group Answers to Clinical Questions

"Neurotherapy as Treatment for Stroke"

A Rapid Systematic Review

By

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Clinical Services – Worker and Employer Services

About this report

Neurotherapy as Treatment for Stroke

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About the Evidence-Based Practice Group

The Evidence-Based Practice Group was established to address the many medical and policy issues that WorkSafeBC officers deal with on a regular basis. Members apply established techniques of critical appraisal and evidence-based review of topics solicited from both WorkSafeBC staff and other interested parties such as surgeons, medical specialists, and rehabilitation providers.

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Objective

To determine whether there is any evidence to support the efficacy and/or effectiveness of neurotherapy, as practiced at Vancouver Neurotherapy Health Services Inc., as treatment for patients diagnosed with stroke.

Methods

- Prior to conducting the systematic review, it is necessary to clearly define the neurotherapy method practiced by the above mentioned clinic. Per their website, part of the clinic's mission is to "…Build and maintain a solid understanding of the application of EEG Biofeedback, Neurofeedback and Neurotherapy..." (http://www.neurofeedbackclinic.ca/about_us.html. Accessed on May 31, 2018). Other statements from their website include:
  - "Biofeedback is a technique which enables us to train the body and/or brain (EEG Neurofeedback) to improve its regulation of body activities…" (http://www.neurofeedbackclinic.ca/services.html. Accessed on May 31, 2018).
  - "Biofeedback is a real time training activity linked to computerized game or software that allows personal development and physiological self-regulation....For more information, visit www.eegspectrum.com/IntroToNeuro..."(http://www.neurofeedbackclinic.ca/services.html. Accessed on May 31, 2018).
  - "Neurofeedback is a technique in which we train the brain to help improve its ability to regulate all bodily functions and to take care of itself..." (http://www.eegspectrum.com/intro-to-neurofeedback/. Accessed on May 31, 2018).
  - "EEG Biofeedback is a learning strategy that enables persons to alter their brain waves. When information about a person's own brain wave characteristics is made available to him, he can learn to change them. You can think of it as exercise for the brain.... How is it done?...The EEG biofeedback training is a painless, non-invasive procedure. One or more sensors are placed on the scalp, and one to each ear. The brain waves are monitored by means of an amplifier and a computer-based instrument that processes the signal and provides the proper feedback. This is displayed to the trainee by means of a video game or other video display, along with audio signals. The trainee is asked to make the video game go with his brain. As activity in a desirable frequency band increases, the video game moves faster, or some other reward is given. As activity in an adverse band increases, the video game is inhibited." (http://www.eegspectrum.com/faq/. Accessed on May 31, 2018).

  - It should be noted that the EEG Education and Research website states that the use of neurofeedback as treatment for stroke is still considered experimental (http://www.eegspectrum.com/therapeutic-uses/. Accessed on May 31, 2018).
- Based on the information provided on the websites of the clinic and its affiliate, a systematic literature search was done on May 31, 2018.
  - This literature search was done on commercial medical literature databases, including Cochrane Database of Systematic Reviews® (2005 to May 23, 2018), ACP Journal Club® (1991 to May 2018), York University, UK, Database of Abstracts of Reviews of Effects® (1st Quarter 2016), Cochrane Clinical Answers® (April 2018), Cochrane Central Register of Controlled Trials® (April 2018), UK NHS Health Technology Assessment® (4th Quarter 2016), UK NHS Economic Evaluation Database® (1st Quarter 2016), BIOSIS Previews® (1969 to 2008), Embase® (1974 to 2018 Week 22), Medline Epub Ahead of Print®, Medline In-Process & Other Non-Indexed Citations®, Medline Daily® and Medline® (1946 to May 30, 2018), that are available through Ovid® platform.
  - The search was done by employing combination keywords of:

    ((eeg **ADJ** neurobiofeedback) **OR** neurobiofeedback **OR** (electroencephalography **ADJ** neurobiofeedback) **OR** neurotherapy **OR** neurofeedback) **AND** stroke
- No limitations, such as on the language or date of publication, were implemented in this search.
- A manual search was also done on the references of the studies retrieved in full.

Results

Literature search results:

- One hundred sixty-three[1-163] published studies were identified through this search. Upon examination of the titles and abstracts of these 163 studies[1-163], fourteen[1,6,8,9,12,15,22,23,39,52,53,109,110,116] were thought to be relevant and were retrieved in full for further appraisal. Of these 14[1,6,8,9,12,15,22,23,39,52,53,109,110,116] studies that were retrieved in full, six[1,8,9,12,110,116] were not relevant to the objective of this systematic review and will not be discussed further.
- Two[164,165] further studies were identified through manual searches of the articles retrieved in full.

On biofeedback, neurofeedback/neurotherapy and EEG:

- The Association for Applied Psychophysiology and Biofeedback (AAPB) defines biofeedback as "a process that enables an individual to learn how to change physiological activity for the purposes of improving health and performance" [166]. AAPB further states that in biofeedback procedures precise instruments are employed to measure physiological activity such as brainwaves, heart function, breathing, muscle activity, and skin temperature. These instruments are said to rapidly and accurately "feedback" information to the patients. The presentation of this information, often in conjunction with changes in thinking, emotions, and behavior, is thought to support desired physiological changes. Over time, it is hypothesized that these changes will persist without continued use of these instruments.
- With regard to neurofeedback, the AAPB defines it as "a form of biofeedback training that uses the electroencephalogram (EEG) as the signal used to control feedback". In this procedure, EEG sensors applied to the patient's scalp record the brainwaves which are then converted into feedback signals by a human or machine interface using a computer and software. Visual, sound, or tactile feedback are employed to produce operant conditioning of the brain [166].
- The theoretical rationale behind biofeedback is that sensory input from proprioceptors throughout the body, and from the special senses, enables a person to modulate or 'fine-tune' activity in a way which is initially difficult and requires attention, but which, with time, acquires the force of habit. What may be an important aberration in brain functioning can thereby be quantified (the ratio of one type of EEG wave to another). This 'quantitative' EEG can then be represented graphically, for example, as a rising or falling balloon on a computer screen. It was proposed that long-term potentiation may bring about

anatomical changes (neuroplasticity), thus providing a link between variations in EEG patterns and improved brain function[39,167,168].

Electroencephalography (EEG)[169-173]:

- EEG is the capture and display of the electrical activity of the brain. More precisely, it is a measure of the electrical field produced by a large number of synchronously active neurons, as a function of time. This electrical field can be measured using electrodes either on the surface of the scalp or surgically implanted in the brain.
- Surface EEG represents only a fraction of the activity of the brain. The signal captured is mostly cortical activity, but the origin of that activity can be the cortex itself or a deeper anatomical structure; the electrical current will then have travelled via neuronal propagation and passive volume conduction. For example, visual processing occurs in the occipital lobe of the cerebral cortex, whereas complex mental acts such as language processing and memory tasks occur as a result of a network of cortical and sub-cortical nuclei originating in the deeper structures. When the activity has travelled from a more internal source via neuronal propagation, it is unknown whether it has been altered, and if so, by how much, by the time it propagates to the cortex.
- The impedance of all the anatomical components of the head, between the brain and the sensing electrode, influence the signal significantly as well by imposing an unknown amount of attenuation and waveform distortion. This source of intra-patient variability coupled with the ever-present inter-patient variability (no two brains produce the same EEG and no two craniums impede the signal in the same way), provide a large potential source of confounding in the research of (surface) EEG.
- During signal processing, EEG data is filtered. It has been shown that the type of filter used affects the bandwidth and may distort EEG signals. Other potential sources of variability include age, sex, diagnostic procedure, data collection and processing. These variables have been shown to affect the variability of alpha and beta frequency bands among ADHD patients, for which neurotherapy has been evaluated the most.
- At present, there are still no precise formulations on the relationship between EEG rhythms, neural mechanisms and behavioural competencies.
- Regarding EEG, experts further warned that:
    - It is difficult to parse data coming from numerous electrode sites (19 electrodes in some cases) and several frequency bands (about 6 or 7 frequency bands), all of which may be combined in several different ways.

  - Without adequate knowledge on the technical aspects of EEG data reduction, there is a high risk of confounding bioelectric artifacts with neuroelectric phenomenon.
  - It is not possible for surface EEG to identify where scalp-recorded electrical potential originated. Hence, spatial resolution in these cases are very limited.
  - There is an abundance of potential artifacts due to common behaviours like yawning, rolling eyes, clenching jaw, fidgeting, coughing, sneezing, etc., which may be recorded within EEG data. This means that it may be difficult to obtain and validate EEG readings, as these artifacts may influence the generation of accurate neurofeedback from real-time EEG recordings.

At present, the validity of quantitative EEG (QEEG) – the high theta/beta ratio thought to be observed among patients with ADHD for which research on the application of neurotherapy are most abundance – as diagnostic criteria and as treatment progress/success criteria, are still not clear.

- Neurofeedback (neurotherapy) in treating stroke – findings from literature appraisal:
  - Of the 7[(6,15,22,23,52,53,109)] studies providing data on the application of neurofeedback in treating stroke, two[(6,15)] were in the form of case reports (level of evidence 5. Appendix 1), two[(52,53)] were small case-control studies (Level of evidence 3. Appendix 1), two[(22,23)] were studies based on small randomized controlled trials (level of evidence 2. Appendix 1), and one[(109)] systematic review/meta-analysis (level of evidence 1. Appendix 1).
  - Bearden et al.[(6)] and Cannon et al.[(15)] each reported a case of a patient with thalamic-cortical infarctions and general stroke, both of whom were treated with quantitative EEG (neurobiofeedback) and subsequently reported improvement in their cognitive functioning, depression as well as "normalization" of their quantitative EEG (QEEG). *It should be noted that in addition to the lack of controls and unclear patient selection critieria (potential selection bias) in these case reports, there was also potential for unaccounted multiple comparisons, as well as (potentially unreported) co-interventions influence on the reported outcomes. It should also be noted that the authors only reported short-term outcomes (immediately after the treatment) without providing any evidence on the long-term impact of neurotherapy (if any).*
  - In a small case-control study (2 stroke cases with 24 healthy elderly persons as control), Kober et al.[(52)] investigated the effect of upper alpha-based neurofeedback training on brain

activity and cognitive function in stroke survivors. The authors reported on upper alpha neurofeedback training using a 10-channel amplifier, conducted via training sessions (3 to 5 sessions per week, up to 10/week). At the end of training period, the authors reported that the stroke patients showed an improvement in memory functions compared to pre-training. *It should be noted that the authors did not report and compare the cognitive function of the controls. Further, it was not clear how the cases and controls were selected, multiple statistical tests were reported without any clear statement on the primary outcomes, and the authors only reported a short-term results.*

- In another small case-control type study, Kober et al.[53] evaluated the specific effects of different neurofeedback (NF) protocols on cognition, in particular on recovery of memory, among stroke patients. In this study, 17 stroke patients received up to ten sessions of either Sensory Motor Rhythm (SMR) 12–15 Hz (N = 11) or Upper Alpha 10–12 Hz (N = 6) NF training, while 7 other stroke patients received treatment as usual (as control condition) and 40 healthy controls whom performed NF training as controls. For both NF training protocols, EEG signal was recorded using a 10-channel amplifier and up to ten NF training sessions were carried out on different days, three to five times per week. Each session lasted approximately 45 minutes. At the end of the treatments, the authors reported that about 70% of both patients and controls achieved distinct gains in NF performance leading to improvements in verbal short- and long-term memory, independent of the used NF protocol. The SMR patient group showed specific improvements in visuo-spatial short-term memory performance, whereas the Upper Alpha patient group specifically improved their working memory performance. NF training showed no effects on other cognitive functions than memory. *Although there were multiple statistical tests reported in this study, the authors employed a novel statistical procedure, called False Discovery Rate, which is a validated method for accounting for multiple comparisons[164]. However, the authors did not report on the participants selection criteria, the effects of potential confounders related to memory outcomes were not explored, and this was not a blinded study (for both researchers and participants). Considering the number of outcomes explored and the limited number of participants, this study should most likely be regarded as a pilot study, the results of which will need to be shown to be replicable via other trials, before the treatment method and results can be adopted as viable protocol.*

- A small randomized controlled trial (13 interventions with 14 controls), investigating brain wave and visual perception changes in stroke patients using NF training, was reported by Cho et al.[22]. The control group received occupational and physical therapy via half-hour sessions, 5 times a week, for 6 weeks. The intervention (NF) group received the same number of traditional rehabilitation sessions as the control group with extra NF training via half-hour sessions, 5 times a week, for 6 weeks. The NF training method employed among the intervention group was a beta Sensory Motor Rhythm (SMR) training method and was conducted with the patient's eyes open. The reward forms for the feedback were divided into auditory and visual rewards. The reward brain wave was set with either an SMR wave (12–15 Hz) or mid-beta wave (15–18 Hz) depending on the location of the cerebral cortex. The inhibitory brain wave was set with both a delta wave (0.5–4 Hz) and high-beta wave (22–36 Hz). The training time for a single trial was set at 30 minutes, during which a 3-minute training module was conducted 10 times. At the end of the intervention period, both groups showed significant differences in their beta wave values and attention concentration quotients with the NF group showing statistical significant differences in visual discrimination, form constancy, visual memory, visual closure, spatial relation, raw score, and processing time. *It should strongly be noted that, despite the small number of participants, this study presented many statistical testss, which were not accounted for in the calculation of the statistical significant level (type 1 error). Further, it is not clear how the participants were selected, the randomization method was not clearly reported, and the primary outcome was not specified and blinding was not done.*
- Another small randomized controlled trial, investigating the effects of neurofeedback (NF) and computer-assisted cognitive rehabilitation (CACR) on the relative brain wave ratios and activities of daily living (ADL) of stroke patients, was reported by Cho et al.[23]. In this study, 44 participants were randomly allocated to the NF (n=14), CACR (n=14) or control (n=16) groups. All participants received traditional rehabilitation therapy in 30-minute sessions, twice weekly for 6 weeks. The NF training program of the study used the beta-SMR training mode, which was performed with open eyes and provided two types of compensation for feedback: acoustic and visual. The compensation brain wave was a 12–15 Hz SMR wave or a 15–18 Hz mid-beta wave at the selected location of the cerebral cortex. CACR is computer-based cognitive rehabilitation during which

patients perform tasks while sitting, looking at a monitor, and respond using a keyboard. After 6 weeks of intervention, brain wave and ADL evaluations were performed. The authors found that statistically significant changes in ADL were shown by all three groups after the intervention. However, there were no significant differences between the NFB, CACR and the control groups. *In this "negative" study, it should be noted that multiple statistical tests were conducted, no hypothesis and corresponding sample size were reported, blinding was not done and the randomization process itself was not clearly reported.*
  - A good quality systematic review, investigating the utility of NF as a form of cognitive rehabilitation among stroke patients, was reported by Renton et al.[109]. Covering the literature from 2005-2015, the authors found that the NF protocols employed in the primary studies within their systematic review were highly specific and varied between each study reviewed and, although the majority of studies reported improvements in patients' cognitive deficits following NF therapy, the authors expressly caution that this observation came from study of low level and of low quality. In the end, the authors stated that their systematic review provided little support for the use of NF, as an evidence-based treatment, in stroke rehabilitation.
- The observations made by Renton et al.[109] on the heterogeneity of NF protocol and the low level/quality of primary studies in NF research was also reported by Thibault et al.[174] in their low quality systematic review of NF in general. Thibault et al.[174] further cautioned that the potential impact of the placebo effect in NF treatment is high, due to the fact that NF therapy sessions are lengthy, typically involving many sessions, and uses seemingly expensive, complex equipment which contribute to a false sense of reliability, thereby potentially contributing to the overall allure of brain science. As such, Thibault et al.[174] emphasizes the importance of blinding in NF-related studies.
- In their systematic review-based meta-analysis investigating the efficacy of memory rehabilitation therapy among traumatic brain injury and stroke patients, Elliot and Parente[165] found that although memory rehabilitation may be effective among stroke patients, they also state that significant memory improvements may occur spontaneously over time. *It should be noted that it is not clear whether any primary studies on NF were included in this meta-analysis.*

Summary

- Neurofeedback (neurotherapy), developed from biofeedback in the 1960s, draws on diverse imaging methods to help drive volitional control over electric, magnetic and haemodynamic fluctuations in brain activity. When neurofeedback emerged in the 1960s, EEG was the only non-invasive device available to create visualizations of living human brainwave activity. To this date, EEG remains the most common form of neurofeedback. However, with the proliferation of emergent imaging methods, such as functional magnetic resonance imaging (fMRI), functional near-infrared spectroscopy (fNIRS) and magnetoencephalography (MEG), a variety of techniques are now available for generating neurofeedback.
- With regard to the efficacy and/or effectiveness of neurofeedback as treatment for stroke patients, at present, there is some evidence, coming from low-level low-quality as well as high-level low-quality primary studies, showing its efficacy in rehabilitating the memory of some stroke patients. Despite the low quality of the primary studies generating this supportive evidence, it should also strongly be noted that, at present, the neurofeedback protocols employed so far are highly specific and varied between studies, and only short term outcomes were reported for a chronic disease condition.

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Appendix 1

WorkSafeBC - Evidence-Based Practice Group Levels of Evidence

(adapted from 1,2,3,4)

1	Evidence from at least 1 properly randomized controlled trial (RCT) or systematic review of RCTs.
2	Evidence from well-designed controlled trials without randomization or systematic reviews of observational studies.
3	Evidence from well-designed cohort or case-control analytic studies, preferably from more than 1 centre or research group.
4	Evidence from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled
5	Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees.

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