INTRODUCTION

In the late 1960’s and early 1970’s it was shown that it was possible to recondition and retrain brainwave patterns. This brainwave training was called EEG guided biofeedback or currently neurofeedback. During a neurofeedback (NF) training, electrodes are placed on the scalp and on the earlobes that provides real-time, instantaneous brainwave activity to the computer and this information is recorded (1). The ultimate goal in NF training is to create healthier brainwave patterns. Under normal circumstances, one cannot change his/her brainwave patterns. One can achieve this using operant conditioning techniques. However, how long these changes can persist is still open to debate.

During the 1980’s, the quantitative electroencephalogram (QEEG) has been introduced to the neurofeedback practice allowing to individualize the NF treatment especially in management of different subtypes of clinical conditions where diagnosis is difficult with only observing subject’s behavior.

Neurofeedback therapy practitioners advocate the use of NF in clinical conditions such as head trauma, cerebral palsy, cerebrovascular stroke, intractable epilepsy, cognitive impairments due to aging, depression, anxiety, alcohol and other substance dependence, ADD/ADHD, Asperger’s syndrome, and even for performance enhancing in healthy subjects (2–12).

Neurofeedback therapy demands an extraordinary dedication of time and finances. It requires at least 40-50 sessions to treat ADHD and other psychiatric disorders. Practitioners commonly request a diagnostic “brain map” at the start of the treatment, adding an extra cost. And– since so many questions about NF therapy still unanswered by majority of science and research world– none of this is covered by insurance (currently few
insurance companies may cover biofeedback for stress relief indication only).

Neurofeedback practice lacks convincing data for the mainstream scientists and researchers. Most researchers have pointed to serious flaws in many of the studies that private neurofeedback practitioners have published to date. Some even dismissed the therapy altogether and included neurofeedback on a list of common but ineffective treatments that also includes “horse therapy.” The conclusions from these data cannot be generalized due to lack of control groups and the confounds such as use of multiple interventions. Most published work were of poor quality, had a strong publication bias (meaning that negative outcome studies were never submitted for publication), and often did not report observed side effects. As in any scientific disciplines, it is essential not only monitor the degree of improvement or lack of change but also report the occurrence and frequency of the side effects, adverse events, and clinical or functional deterioration. Double-blind randomized and sham-controlled studies are required to test the efficacy of neurofeedback treatment. Despite 40-50 years of NF practice, only recently The National Institute of Mental Health (NIMH) are sponsoring the first government-funded, peer-reviewed studies to put claims of neurofeedback practitioners to the test, investigating whether the NF therapy makes sense for the children coping with ADHD and similar disorders. Both studies (PI: J.K. Buitelaar, FC Donders Center for Cognitive Neuroimaging; PI: Eugene Arnold, Ohio State University) are still in data collection phase and will provide answers for the true effectiveness of NF therapy in near future.

Throughout the US, only 500 of the estimated 6,000 NF practitioners in US have completed the training, mentoring and supervised practice required by the Biofeedback Certification Institute of America. The NF device itself is also in a gray zone. The Food and Drug Administration (FDA) approves biofeedback devices only for relaxation training, i.e., that the hardware is not cleared for treating autism, ADHD or any other brain disorders. Neither manufacturers nor NF practitioners can not advertise such off-label uses. Some device and software manufacturers are currently trying to fly under the radar of the FDA by evading registration of their devices, and while others are violating the FDA regulations by selling their products to unlicenced practitioners.

The risks of NF treatment may extend beyond a mere waste of time and finances, especially as a result of “one-size-fits-all” approach by non-medical professionals. The brainwave activity in psychiatric and neurological patients are mostly heterogenous and it is widely accepted that generalities and group averages do not always apply to individual cases. Lubar and colleagues documented that problems with seizure disorder can be improved with NF, but they could also be made worse with reversal of the treatment design (13). Therefore, the NF therapy requires individualization and the risk associated here is not only being an ineffective therapy but also being a detrimental therapy. It has been reported that 10-15% of ADD/ADHD patients have an excess of beta activity rather than theta activity (14). If the NP practitioner provides a canned protocol to increase beta activity in such a patient, the patient can experience epileptic seizures due to increased cortical irritability. As in psychotherapy sessions, failure to individualize treatment is a significant risk factor for causing harm (15).

Hammond reported cases in which such adverse events were observed during the NF therapy in different clinical cases (16). An autistic child reportedly regressed dramatically following the NF treatment, while another child’s facial tics worsened, and a third patient had urinary incontinence. Several other patients reported somatic complaints such as nausea, stomach upset, headache, muscle twitches, mental fogginess, cognitive impairments, sleep disturbances, OCD like symptoms, fatigue, anxiety, agitation, irritability, mood switches, slurred speech, and even seizure during treatment. Hammond also described one client who drove through a red light after leaving an NF therapy session and another who crashed into a light pole just a block from the therapist’s office (16). It is very important to assure that patients feel sufficiently vigilant to drive and function after the therapy session. In most of these cases, these iatrogenic reactions might be result of reinforcing and increasing various bands of EEG activity instead of focusing on how to eliminate problematic EEG activities. NF professionals are required to acknowledge to patients in a detailed informed consent process that the NF therapy might cause iatrogenic reactions and significant adverse events, and patients should be instructed to immediately report them when they occur. Ethical standards also require that NF practitioners should know how to address
significant adverse events (e.g., during an epileptic seizure) and seek proper consultations when needed.

In conclusion, we believe that NF therapy field is still in infancy stage and fraught with potential risks due to increasing numbers of lay practitioners who are inappropriately obtaining NF devices and putting electrodes on the patient’s head and trying to modify how the brain is functioning without appropriate licensure and training. Further research with double-blind, randomized, sham-controlled trials are required for the validity of NF therapy in clinical cases. Until then, the NF therapy can only be considered for difficult to treat or treatment resistant cases as an alternative treatment. It is against the ethical principle of “first, do no harm” to use NF therapy in any medical, psychiatric, neurological conditions without properly informing patients fully and offering them current, well-established treatment modalities as an option first.

References:


