

rEEG® Does Not Diagnose Psychiatric Disorders

It is important to be clear that the rEEG service is not diagnostic in nature. How a measure of organ function can be useful for medication selection, but not diagnosis, may be confusing to some. This note will provide further explanation. Clinicians that utilize rEEG can provide a more complete dialogue on this subject.

Introduction

The measurement tool of brain function utilized in rEEG is EEG or the electroencephalogram. This tool measures electrical output in microvolts through sensors placed on the surface of the head. CNS Response does not produce this equipment and instead is able to utilize the record produced by most standard digital EEG equipment and analyze this data in its laboratory with results sent as a report to a physician.

The EEG output is recorded in a digital form. This information is sent to CNS Response typically by mailing a file stored on CD:ROM, DVD or directly over the internet to a secure, HIPAA compliant ftp site.

CNS Response will first compare the output from a current patient's record to those of people evidencing no symptoms of behavioral illness. We use a commercially available FDA approved software package with its associated database of digital EEG values for normal functioning asymptomatic people to accomplish this in a way consistent with instructions from the supplier.

There is much scientific literature that has been published on whether comparing a patient's digital EEG readings to that of normal functioning asymptomatic people might be useful to assist a clinician with diagnosis. To our knowledge there has been no medically accepted conclusive viewpoint on this. Though CNS Response does perform this analysis it does so for a wholly different reason: as a classification step to guide selection of the relevant subset of the rEEG patient outcomes database. The subset of patients selected evinced similar brain aberrations to the current patient. By querying this outcome subset of patient responses to a variety of medication alternatives, we can provide a perspective on the current patient's likely response to these medications. Essentially, this provides a view of expected treatment results based on the patient's brain function and not their symptoms. To be clear, nowhere in any report is there any indication from CNS Response related to diagnosis.

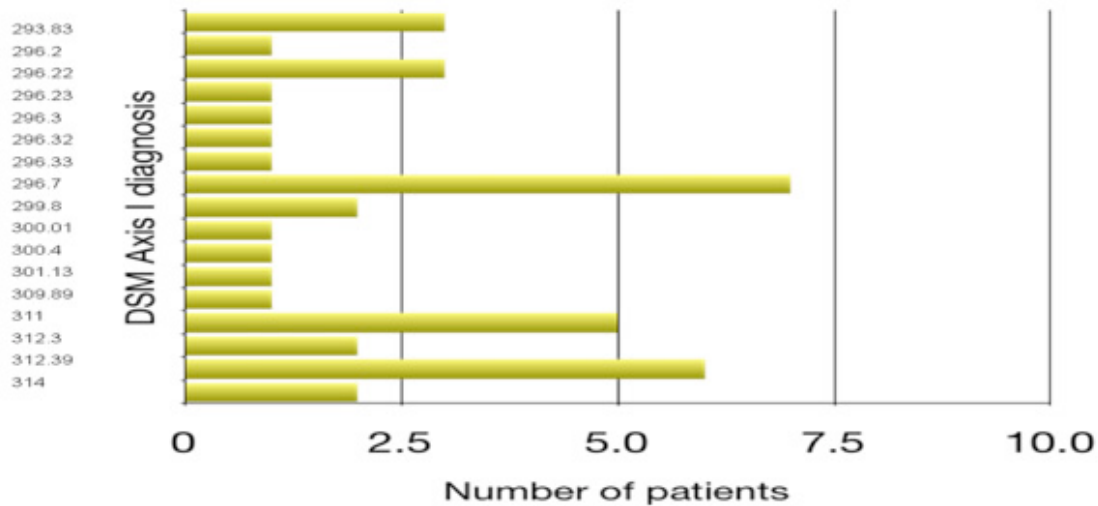
Similarity of Brain Dysfunction, but Dissimilar Diagnosis

In fact, our data analysis has shown that people with similar brain function abnormalities, as measured in this manner, may have any number of diagnoses or no diagnosis at all. For example,

Figure 1 identifies patients that all had a similar variation in a specific aspect of their EEG. That is, they were alike in that their brain measurement was aberrant in the same way.

The patients in Figure 1 were all diagnosed by the same clinician who determined that these patients had 17 different diagnoses as evidenced by their symptoms or DSM criteria. Presuming a correct diagnosis by their clinician this would be a good example of how such measurement of brain function is not diagnostic.

Figure 1



The standard publication for classification and diagnosis of mental disorders most frequently utilized by US clinicians is the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM) published by the American Psychiatric Association. The numbers shown on the left side (Y-axis) are the diagnostic codes defined in this manual. As can be seen in Figure 1, 7 patients had a DSM Axis I diagnosis of 296.7, generally labeled as Bipolar I Disorder. Whereas the 6 patients with DSM diagnosis 312.39 have a diagnosis of Trichotillomania, symptomatically characterized by a person's irresistible urge to pull out their own hair or pick at spots on their body (such as cuticles) incessantly. DSM diagnosis 314 is also labeled Attention-Deficit/Hyperactivity Disorder Predominantly Inattentive and there were 2 patients in this group with this diagnosis.

Clearly these are very different diagnoses. Yet their brain function as recorded by the digital EEG record suggests that they all share similar functional aberrations. So this measurement of the aberration of brain function that all of these patients share in common is specifically unable to diagnose these patients' disorders as generally accepted by the standard diagnostic criteria. These patients really do have an aberration of brain function but that does not define a diagnosis. For some the diagnosis is bipolar I, others trichotillomania, ADHD, depressive disorder, etc. The rEEG markers that we use are not specifically diagnostic.

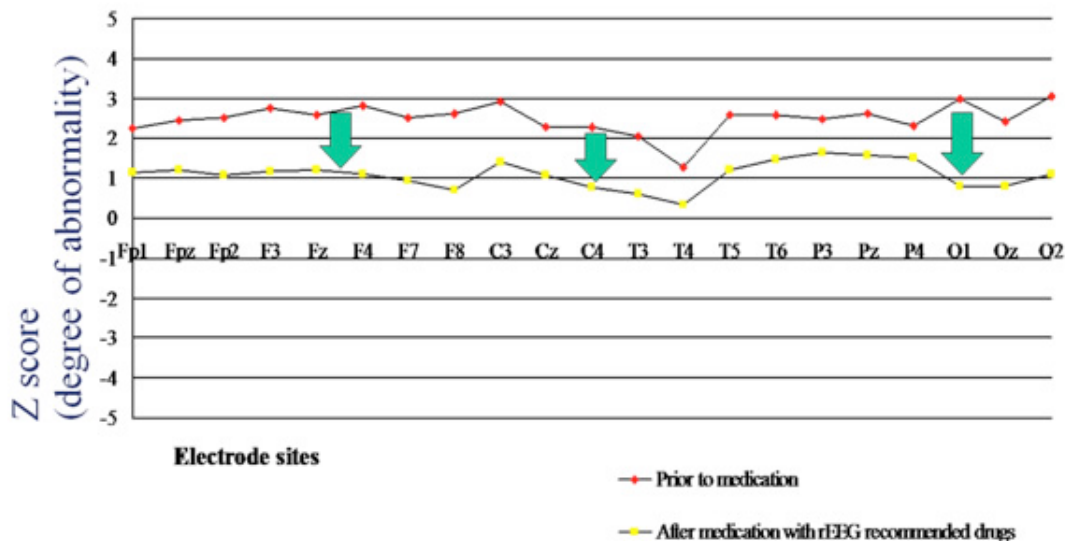
In fact, there is no evidence that this aberrant measure is suggestive of any behavioral disorder at all. There are likely many people evidencing no symptoms of behavioral illness that would share this same aberrant EEG feature. rEEG, however, uses this EEG feature for a wholly different purpose. If a physician has made a diagnosis and determined that medication treatment is appropriate, then rEEG analysis will use this EEG feature or biomarker to define a relevant group of patients that have already been treated with a myriad of different treatments and report their historical treatment results in a report. In fact we have discovered a platform of 74 such rEEG

markers. They are useful in characterizing brain function and defining a group of patients whose treatment results may be helpful to know because of their similarity of brain function. The patients in Figure 1 had many different diagnoses but shared a common aberration of brain function. In fact, all of these patients were treated by their rEEG experienced physician with the same medication regime. All responded very well. That is the key point. These abnormalities don't diagnose at all. But if a physician is going to choose to medicate a patient these markers can be very valuable to their selection of a medication regime.

Similarity of Diagnosis, but Dissimilar Brain Function

Sometimes two patients can evidence the same diagnosis but have opposite response to the same medication regime. Figure 2 illustrates a patient whose brain function prior to treatment was aberrant on one of the rEEG markers. In fact this chart shows this measure was aberrant from the front of the head (left side of the graph) to the back of the head (right side of the graph).

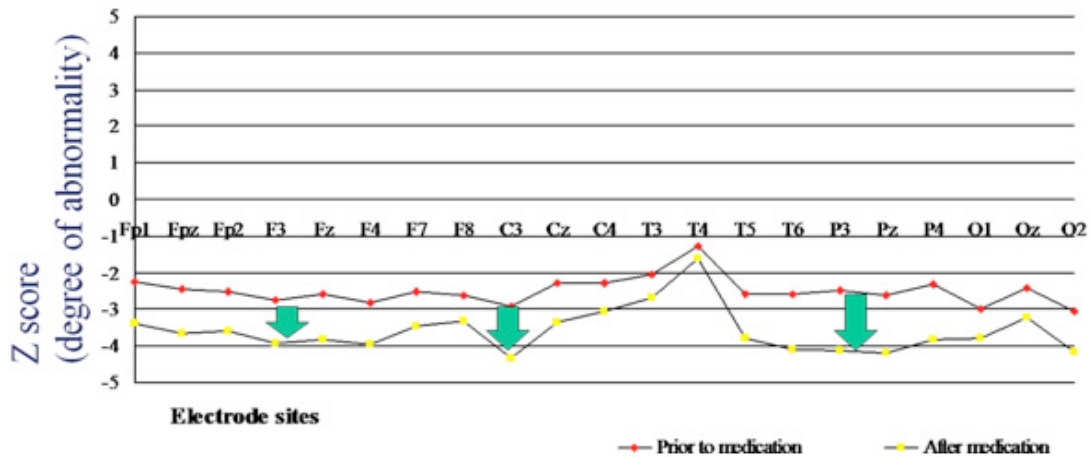
Figure 2



The patient was given a medication that our rEEG outcomes database empirically showed to be useful for other patients having a similarly unusual brain function. The patient responded well to this medication and the specific measure of aberration shown in the graph moved closer to the normal range. On the graph we see that the measurement of this marker lowered.

Figure 3 shows a graph exactly opposite of the patient of Figure 2. If this patient suffered from the same diagnosis and was medicated in the same way, a similar effect of reducing the level of this marker, however, would make this patient more aberrant as shown in Figure 3.

FIGURE 3



In fact, medicating the two patients in the same way, based on the same diagnosis, can lead to opposite results. Empirically, physicians know this is true. A medication, such as Prozac, can be very helpful to some patients suffering from depression and not at all for others. This is one of the reasons that antidepressants now carry a warning about the possibility of a negative response, such as “suicidality,” despite accurate diagnosis.

This case also illustrates why rEEG markers are not diagnostic. These two hypothetical patients had opposite measures on the rEEG marker shown in the graph. Diagnostically, according to the accepted definitions in the DSM, they might be categorized the same way, however. So this rEEG biomarker may have utility in medication selection but not diagnosis, as defined by the DSM.

Conclusion: rEEG is not Diagnostic

Defining a behavioral disorder, or a diagnosis, based on measuring the brain is an extraordinarily challenging task. Some academicians contemplate these disorders to be a function of nature (the biology of the brain or person) and nurture (the experiences of the brain or person). While in theory, such biology and experiences may have record in the brain, all evidence suggests that predicting behavior or behavioral disorders is likely to be extremely difficult. Most would argue that this is an attempt to predict the most sophisticated function (emotion and behavior) of the most advanced organ or organ system of the body (brain and central nervous system).

The developers of rEEG at the outset chose to pursue a much simpler task. They set out to predict the usefulness of ingesting specific psychotropic medications through comparison to a database of known clinical outcomes. Understanding and predicting the impact of a pharmaceutical on the brain is a dramatically simpler task than attempting to predict behavior or behavioral disorders from the complexity of brain function.

It is equally important to understand what rEEG is not. It does not define medication strategy. It does not contemplate risks of medication cross-toxicity. It does not contemplate treatment experiences within a patient's history. It does not contemplate family history. It does not contemplate medication side effects. It does not contemplate impact of malnutrition, absorption, drug abuse, sleep deprivation, hormonal imbalances, allergens and a myriad of medically relevant factors. rEEG is blind to all of this and, as such, should not be used blindly; it does not supersede medical judgment. Instead it is a statistical analysis of data output from standard equipment that can provide information to a physician to incorporate into their contemplation of medication selection. Clinical studies have shown this to be useful in combination with other medical considerations in guiding the choice of medications, but not diagnostic.

This note has attempted to clarify that rEEG does not assist in diagnosis. Clinicians that utilize rEEG can provide a more complete dialogue on this subject.