QEEG and Traumatic Brain Injury: Rebuttal of the American Academy of Neurology 1997 Report by the EEG and Clinical Neuroscience Society

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INTRODUCTION

In the American Academy of Neurology and American Clinical Neurophysiology Society (AAN/ACNS) paper, "Assessment of digital EEG, quantitative EEG, and EEG brain mapping,"[1] it was concluded that "...evidence of clinical usefulness or consistency of results are not considered sufficient for us to support its [QEEG] use in diagnosis of patients with postconcussion syndrome, or minor or moderate head injury." The present EEG and Clinical Neuroscience Society (ECNS) report and rebuttal will show that factual misrepresentation and bias formed the basis of the AAN/ACNS position on QEEG in postconcussion syndrome, and minor and moderate head injury.

The background and basis of this EEG and Clinical Neuroscience (ECNS) report and rebuttal is the fact that there are approximately 1 to 2 million people who experience a traumatic brain injury (TBI) in the U.S. each year,[2-5] and all TBI patients, their families and employers deserve the best that medicine can provide. Importantly, TBI patients and their families are often devastated by this injury even when it is neurologically classified as "mild." Another important fact is that as of this date, the standard or "routine EEG" and "conventional MRI" are essentially useless because of their low sensitivity and low reliability to detect mild to moderate TBI (e.g., < 20% positive in routine visual EEG and visual MRI).[6-9] If QEEG is to be excluded from the arsenal of diagnostic tests for the detection and evaluation of mild to moderate TBI, then there must be an excellent and compelling reason to do so and not one based on misrepresentation and biased logic.

In the paragraphs below, factual misrepresentations and omissions of facts will be shown to have occurred repeatedly in earlier reviews of QEEG and traumatic brain injury, and these same misrepresentations eventually re-emerged in the 1997 AAN/ACNS article.[1] Contrary to the opinion of AAN/ACNS, it will be shown that QEEG has been demonstrated to objectively meet the standards espoused in the 1997 AAN/ACNS article.

Factual Misrepresentations

The historical and primary focus of AAN/ACNS arguments against the use of QEEG in mild traumatic brain injury[1,10,11] is exclusively based upon criticisms by Dr. Marc Nuwer of the Thatcher et al, 1989[12] QEEG study of 608 mild head-injured patients involving multiple independent cross-validations, and the Thatcher et al, 1991[13] QEEG study predicting outcome at 1 year post-injury. For example, in the AAN/ACNS paper there was only one literature citation concerning QEEG and mild head injury other than the studies by Thatcher. If a fair and proper review had been conducted, additional QEEG studies would have been presented such as Mas et al,[14] von Bierbrauer et al[15] and Ruijs et al.[16]

Given the absence of a more complete literature review, the criticisms in previous publications by Nuwer[10,11] and the AAN/ACNS paper are even more remarkable for the extent to which they are based on misrepresentations of the procedures and results reported in the Thatcher studies. For example, in 1997 the AAN/ACNS paper[1] stated (pp. 205-206): "Users have criticized this technique [i.e., Thatcher et al's QEEG technique] as being overly sensitive to nonpathological states such as drowsiness or medication effects (Nuwer, 1992[10])." Nuwer in the AAN/ACNS article[1] and in 1996[11] cites his own 1992 paper[10] as the source for this alleged criticism; however, after careful reading of the 1992 paper[10] one fails to find even a single mention or reference of this alleged criticism. In other words, Nuwer cites himself as the 1992 source of this "rumor" without any scientific evidence, and then proceeds as sole author of the AAN/ACNS report to influence readers into thinking that there is an actual scientific citation to establish this as fact. The simple truth is that drowsiness, which is an artifact that can and must be eliminated, has never been established to be a problem with the Thatcher et al[12] QEEG technique.

Another example of factual misrepresentation, is when AAN/ACNS states: "In one small group of patients with

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postconcussion syndrome, an *increase* in 8 to 10 Hz alpha was reported. A subsequent report described *reduced* alpha in a much larger group of patients after mild head injury"[1] (p. 283). The "subsequent report" referred to was the Thatcher et al[12] mild head injury discriminant study. AAN/ACNS's[1] juxtaposition of the italicized words "*increase*" and "*reduced*" alpha implies opposite findings between the study by Tebano et al[17] and the study by Thatcher et al[12] when, in fact, there is no discrepancy. For example, Tebano et al[17] also reported reduced 10.5 to 13.5 Hz alpha and reduced beta frequency EEG amplitudes, which is very similar to that observed by Thatcher et al.[12,13,18] Tebano et al[17] even demonstrated that there were no statistically significant increases in total alpha power in their study (p. 187).

A similar misrepresentation of fact occurred in regard to AAN/ACNS's assertion that the QEEG sensitivity in the Thatcher et al[12] study was significantly influenced by "medication effects."[1,10,11] The facts are that the paper statistically and scientifically examined a wide range of medications and groups of patients on and off of medication and concluded on pages 96 and 103: "...there were no significant differences in discriminant scores between patients on medication versus those off medication." The historical precedent for AAN/ACNS's 1997 misrepresentation is seen earlier on page 206 of the Nuwer 1996 article,[11] and is subsequently repeated as though Thatcher et al[12] never conducted statistical tests for medication effects, or that the results of such scientific tests were never published, as if this alleged problem with "drowsiness" and "medication" were a substantiated fact.

Another factual misrepresentation by Nuwer[10] (p. 246) is: "one can also question the degree to which EEGs collected on patients hospitalized for head trauma can ...serve as a data base for predicting... complaints in patients with more minor degrees of injury." The truth is, that all of the patients had minor head injuries and only a subset of patients were hospitalized in the Thatcher et al study (see Tables V and VI).[12] Cross-validation of the QEEG discriminant function occurred not only with additional hospitalized patients but also in 102 outpatients that were not hospitalized.

The AAN/ACNS report[1] (p. 283) stated, "Further validation would be helpful, especially from investigators not involved in the commercialization of this technique." The Thatcher et al[12] study was initiated in 1983 and completed in 1989 with scientific and not commercial motives. Furthermore, Drs. Irvin Gerson and Arnold Sadwin recorded QEEGs from 97 mild head injured patients independent of Thatcher, using a different QEEG instrument and different EEG technicians, and they independently replicated the Thatcher mild head injury discriminant function with a specificity of 96.2% and a sensitivity of 89.7%[12] (Table VI, p. 101). While further validation is always welcome, the AAN/ACNS report[1] and the above quote fail to recognize scientific literature in which physicians in the community have successfully used the Thatcher QEEG discriminant function and were also not involved in the commercialization of the technique.[19-22]

The above emphasizes that if QEEG is going to be excluded from the clinical evaluation of head injury, then such exclusion must be based upon fact and not misrepresentations, especially misrepresentations that have been repeatedly promulgated and built upon. What is the factual basis upon which AAN/ACNS[1] concludes: "...evidence of clinical usefulness or consistency of results are not considered sufficient for us to support its [QEEG] use in diagnosis of patients with postconcussion syndrome, or minor or moderate head injury"?

Unscientific and Anonymous Representations

AAN/ACNS[1] stated: "Others have commented that this technique is predisposed to false-positive 'abnormalities' in normal subjects due to mild drowsiness or other problems" (p. 283). "Others" were not identified, and there were no citations by AAN/ACNS to scientific evidence that refutes or contradicts the findings of Thatcher et al[12,13] or Tebano et al.[17] It would appear that the AAN/ACNS paper arbitrarily discounted, without scientific justification and only by reference to anonymous "others," at least three well-controlled studies including one that involved 608 mild TBI patients and 103 age-matched controls with independent cross-validations.[12,13,17]

This conclusion is supported by sworn statements that the chief author of the AAN/ACNS report made in a 1998 civil deposition in which he was unable to identify or recall under oath who the alleged "others" were or whether they told him this verbally or in writing.[23] Given the seriousness of the statements regarding anonymous "others," the court ruled that the use of the AAN/ACNS statement,[1] "Others have commented that this technique is predisposed to false-positive abnormalities in normal subjects due to mild drowsiness or other problems," and all similar references to anonymous "others" must be omitted and/or deleted from the trial.

Factual Omissions

In addition to factual misrepresentations and errors of commission, the 1997 AAN/ACNS article commits serious errors of omission. For example, Nuwer[1,10,11] fails to quote the sensitivity and specificity of the Thatcher et al[12] QEEG mild head injury discriminant function, which would have clearly demonstrated that in QEEG the detection of mild head injury meets all of the standards cited by AAN/ACNS and himself for determining the clinical application of QEEG. For example, the QEEG detection of mild TBI in the Thatcher et al study[12] was: Sensitivity = 96.59%; Specificity = 89.15%, Positive Predictive Value (PPV) = 93.6% (average of Tables II, III, V) and Negative Predictive Value (NPV) = 97.4% (average of Tables III, IV,

V). Surely, this level of specificity and sensitivity is comparable to sonograms, blood tests, MRI and other diagnostic measures commonly used in clinical medicine.[24]

Nuwer[10,11] failed to point out that the Thatcher et al[12] study met the other criteria established on page 277 of the AAN/ACNS report,[1] namely, the "criteria for test abnormality was defined explicitly and clearly," control groups were "different from those originally used to derive the test's normal limits," "test-retest reliability was high," the test was more sensitive than "routine EEG" or "neuroimaging tests," and the study occurred in an essentially "blinded" design (i.e., objectively and without ability to influence or bias the results). If routine EEG and conventional MRI fail to meet the AAN/ACNS 1997 standards but QEEG does meet these standards, then on what scientific basis does AAN/ACNS conclude: "...evidence of clinical usefulness or consistency of results are not considered sufficient for us to support its [QEEG] use in diagnosis of patients with postconcussion syndrome, or minor or moderate head injury," or that "any clinical use of digital EEG must be a direct extension of routine EEG testing?"[1] (p. 284.).

The AAN/ACNS article[1] also omitted the important facts that Tebano et al[17] found statistically significant decreases in alpha activity (10.5 to 13.5 Hz), and that there was no statistically significant increase in total alpha (i.e., 8 to 13.5 Hz) in TBI patients, even though it was implied that the Tebano et al[17] study contradicted the Thatcher et al[12,13] studies. The AAN/ACNS report also omitted the important fact that the Tebano et al[17] study involved only eight channels of EEG and did not compute EEG coherence and EEG phase, which were the most significant variables in the Thatcher et al studies.[12,13]

Finally, the AAN/ACNS[1] report either omitted citations to the relevant scientific literature that independently evaluated the Thatcher QEEG discriminant (e.g.,[20-22]) as well as other applications of QEEG in the assessment of postconcussion injuries and cerebral trauma[14-16,25] or in one case, minimized the importance of the study.[26]

Unequal Standards

The 1997 AAN/ACNS[1] paper makes the following recommendation ratings: Type A. Strong positive recommendation, based on Class I evidence, or overwhelming Class II evidence; Type B. Positive recommendation, based on Class II evidence; Type C. Positive recommendation, based on strong consensus of Class III evidence; Type D. Negative recommendation, based on inconclusive or conflicting Class II evidence; Type E. Negative recommendation, based on evidence of ineffectiveness or lack of efficacy. They further use a classification for evidence rated as: Class I. Evidence provided by one or more well-designed, prospective, blinded, controlled clinical studies. Class II. Evidence provided by one or more well-designed clinical studies such as case control, cohort studies, etc. Class III. Evidence provided by expert opinion, nonrandomized historical controls or case reports of one or more.

The AAN/ACNS paper includes a selected subset of QEEG methods in support of only four clinical applications (e.g., stroke, dementia, intraoperative monitoring and epilepsy). These selected few are then contrasted with the "rejected" subset that the authors of the AAN/ACNS report conclude is still in the "experimental" stage. The rejected categories included: 1) traumatic brain injury, 2) psychiatric disorders including learning disabilities and 3) medical-legal uses of QEEG. The Class I requirement of "blinded" would eliminate over 90% of the studies published monthly in *Neurology* and is restrictive and scientifically unnecessary.

The basis upon which the "positively recommended" group was selected in comparison to the "negatively recommended" group is not evident in the AAN/ACNS report, and this dichotomous classification lacks a serious scientific foundation.[27] For example, the criteria of blinded studies and/or prospective verification were not equally applied to the "accepted" QEEG applications and the "rejected" applications. Indeed, the report appears to demonstrate a bias against the "clinically rejected" categories by misrepresenting the literature and by omitting citations that support scientific opposing views. One example is the AAN/ACNS 1997 position regarding traumatic brain injury, which is given a Type D recommendation. Although the AAN/ACNS report "does not attempt to cite all QEEG literature," nevertheless, the article omits reference to several Class II studies that meet the standards for Type B recommendation.[14-16,25] If these additional studies had been presented then readers of the AAN/ACNS report may have drawn a different conclusion. Further, it is difficult to understand why a judgment of "inconclusive" evidence is rendered for QEEG and brain injury when greater than 96% sensitivity and 89% specificity of the QEEG have been published in peer-reviewed journals.[12,13] The level of sensitivity and specificity of QEEG for TBI surely meets the clinical standards for MRI, sonograms, blood analysis and other common clinical diagnostic measures. The published specificity and sensitivity of QEEG in traumatic brain injury meets the standards of sensitivity and specificity enumerated by the AAN/ACNS paper, yet it is still placed in the "rejected" category.

Test-Retest Reliability of QEEG

The clinical sensitivity and specificity of QEEG is directly related to the stability and reliability of QEEG upon repeat testing. Contrary to the opinion expressed in the AAN/ACNS report in which no studies were cited showing low reliability of QEEG, the truth is that QEEG is highly reliable and reproducible as demonstrated in several published studies.[28-37] The inherent stability of QEEG, however, can be demonstrated with quite small sample sizes. For example, Salinsky et al[36] reported that repeated 20 sec samples of EEG were about 82% reliable, at 40 seconds

the samples were about 90% reliable and at 60 seconds they were approximately 92% reliable. Gasser et al[31] concluded that: "20 sec of activity are sufficient to reduce adequately the variability inherent in the EEG," and Hamilton-Bruce et al[32] found statistically high reliability when the same EEGs were analyzed by three different individuals. Although the QEEG is highly reliable even with relatively short sample sizes, it is the recommendation of ECNS that larger samples sizes be used, for example, at least 60 seconds of artifact-free EEG, and preferably 2 to 5 minutes should be used in a clinical evaluation.

QEEG and the Biomechanics of Traumatic Brain Injury

The simple fact is that a strong and abrupt force imparted to the brain results in neurological consequences that are measurable by QEEG.[12,13,17-22,38,39] It is the opinion of ECNS that it is not acceptable to ignore the scientific literature regarding the neurological consequences of rapid acceleration-deceleration. It is the responsibility and obligation of the medical community to be fair and objective and to evaluate all of the QEEG scientific literature and to find ways to enhance the sensitivity and specificity of QEEG for the sake of patients and their families.

We encourage the AAN/ACNS to revisit the issue of the sensitivity and specificity of QEEG and traumatic brain injury. A starting point could be a National Library of Medicine literature search using the search words: EEG and Head Injury and/or EEG and Traumatic Brain Injury. Over 1,323 citations are available and, although most do not involve QEEG, nonetheless there is a common historical finding throughout this literature, i.e., reduced amplitude of high frequency EEG especially in the frontal lobes, a shift toward lower increased EEG frequencies and changes in EEG coherence.

Medical-Legal Issues

Page 284 of the AAN/ACNS paper[1] while expressing a sound concern about potential abuse, nonetheless, goes too far and again misrepresents facts regarding medical-legal issues. Standards of test-retest reliability, normal variation, quality control by the elimination of artifact, quality control by eliminating statistically spurious effects, etc., are issues that concern all medical and scientific test results used in court rooms every day. Mass spectroscopy, MRI readings, blood analyses, etc., all must meet acceptable standards. Simply because there is a potential for abuse of these techniques is not sufficient reason to recommend that they be excluded from the courtroom. The legal system can adequately deal with this through expert witnesses who can point out the abusive or improper application of technology including digital EEG. This is done every day in courtrooms throughout the United States for a wide variety of medical and scientific analyses. A gross misrepresentation is made when the AAN/ACNS article states on page 284 that "results also can be dramatically altered during the subjective process of selecting portions of an EEG for quantitative analysis." The article goes further and states that "probative value and even the test-retest reproducibility can be poor."

These statements are further evidence of bias and misrepresentation of scientific fact. For example, the following articles published in refereed journals all demonstrate quite high test-retest reliability of QEEG, with ranges between approx. 0.8 and 0.92 reliability.[28-37] The paper by Hamilton-Bruce et al[32] specifically examined the relative influence an individual may have on the QEEG analysis by comparing independent data selections and found extremely high reproducibility. The AAN/ACNS[1] article did not cite a single study that supported its position or refuted the scientific literature about reliability of QEEG. The AAN/ACNS[1] (p. 284) statements are simply another example of opinions being expressed as though they carry the weight of scientific scrutiny when exactly the opposite is true.

The Frye and Daubert rules are general and help safeguard against disallowing useful technologies as well as limiting improper technology. The fact is that there are a great many legitimately injured people who seek legal remedy; however, medicine often lets them down through imprecise and inaccurate diagnoses and treatments. We believe that the AAN/ACNS has a responsibility to help these individuals and that the simple and biased exclusion of digital EEG in the hands of qualified and trained individuals is unjustified. A more responsible position would be to insist that admission of digital EEG in the court should be permitted only if the EEG test meets a reasonable standard of reliability and quality control and is not used in isolation but is consistent with the results of other or additional diagnostic evaluations.

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