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Statistical Evaluation of Neurometer® CPT Measures

Reliability

Reliability is an all encompassing word for reproducibility, sensitivity and specificity. Concordance, discordance, sensitivity, specificity and variability are all words that have statistical definitions. The following is a brief discussion of these terms, as they relate to the Current Perception Threshold (CPT) evaluation.

Change Between Repeated Measures

When evaluating the change between repeated CPT determinations, it is generally appropriate to express the change as a percent change between serial evaluations. Expressing the data in terms of percent change provides a means of normalizing CPT measures between subjects. The percent change is calculated at each testing frequency (5Hz, 250Hz and 2000Hz). This percentage analysis also normalizes the different CPT frequency dependent measures for comparison purposes.

Coefficient of Variation

This is a valid measure of the reproducibility of repeated individual CPT measures and has been reported in several publications. Typically this is expressed as the average of the percentage deviation of the individual CPT from their mean CPT. Various publications have evaluated repeated CPT measurements. The coefficient of variation for repeated measures averages approximately 6% at 2000 Hz, 12 % at 250 Hz and 16% at 5%. Each intra-subject automated double-blind CPT determination is confirmed to a $p<0.006$. (Coefficients of variation studies include references 1-4)

Prospective Evaluation

This type of study is correlated with other medical measures over time and is routinely utilized for clinical studies. (For examples, see references 5-7)

Agreement (Concordance) of Data Evaluation

This type of statistical evaluation is conducted to determine the rates of agreement (concordance) and disagreement (discordance) between the CPT study repeated measures and the Neuval Database software evaluation of these measures or other classification measures. Publications which discuss the statistical basis of the Neuval Database software evaluation program include references 9-11.

Several factors can influence CPT measures including circadian rhythms age and sex. The normative range of CPT measures is large. From a clinical standpoint, what is most significant the consistency of the evaluation or classification of the repeated CPT measures (e.g., normal to mild to profound impairment based on the Neuval Database software evaluation). For example, if an individuals measures are "normal" today, will

they be normal tomorrow and next year? At the 1997 meeting of the American Academy of Neurology, a group from the Mayo Clinic presented a study of the agreement (concordance) and disagreement (discordance) of repeated EMG (nerve conduction and electromyography (EMG) diagnoses from 200 patients (reference 8). This study reported a discordance rate of 40% (i.e., 40% of the time the follow-up EMG was not diagnostically consistent with the initial EMG). Concordance or agreement of repeated CPT measurements evaluated using the Neuval CPT evaluation is approximately 92%, while the discordance rate of the CPT evaluation is only 8%.

Averaging Measures

Averaging together CPT measures, makes it impossible to determine the sensitivity of the test for conditions which may evoke both hyperesthesia and hypoesthesia. The CPT measure has a "U" shaped profile as an index of nerve integrity. Raw CPT measures can range from 1 to 999 (999 = 9.99 mAmperes). Range abnormalities are defined as those measures falling outside the absolute upper and lower limits of healthy CPT measures as published.

This is similar to other biological measures, such as serum electrolytes, which also have a "U" shaped profile as a predictive factor for morbidity and mortality. Another example is blood pressure measurements. Although a patient's systolic and diastolic measures *can* be averaged together, the resulting number has only minimal clinical utility. Blood pressure measures are commonly analyzed by examining the raw systolic and diastolic measures and comparing them to established upper and lower ranges of healthy measures. A third example is body temperatures. If a patient had a body temperature of 97.1°F at 10:00am, and had a body temperature of 101.1°F at 2:00pm, then it is obvious that the patient's temperature measures indicated an abnormality. However, if the two temperature measures were averaged together before being evaluated, the resultant 98.6°F average measure would falsely indicate that no abnormality had been detected.

The CPT exam is capable of measuring the effects of conditions which can result in abnormally high (hypoesthetic) and abnormally low (hyperesthetic) current perception threshold levels. For example, studies have shown that diabetic patients suffer from both hyperesthesia and hypoesthesia. Suppose ten diabetic patients were tested with the 2000Hz stimulus on their great toes and their CPT measures were: 1) 24, 2) 999, 3) 236, 4) 844, 5) 35, 6) 745, 7) 588, 8) 126, 9) 84, 10) 999. The established range for healthy 2000Hz CPT measures on the great toe is 179 to 523. The average of all 10 CPT measures is 468, which would be within the healthy range. In reality, of course, nine out of the 10 patients had abnormal CPT measures. Patients 1, 5, 8 and 9 had hyperesthetic measures while patients 2, 4, 6, 7 and 10 had hypoesthetic or anesthetic measures. Only one patient in the group (#3) had a measure within the healthy range. For this reason it is generally not appropriate to analyze the sensitivity of CPT data by averaging patient measures.

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