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Evoked potential: basic requirements and guidelines for writing reports

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Evoked potentials (EPs) measures the electrophysiologic responses of the nervous system to variety of stimuli. In clinical practice, only a few are used on a routine basis. Because of the small amplitude of EPs recorded by noninvasive methods, computer summation or averaging generally is necessary to resolve them from background noise. Therefore, waveform acquisition under good condition according to standard method is important. We aimed to provide the standards for clinical EP equipment, technical consideration and minimal requirements for obtaining good clinical EP waveforms, and general criteria for writing EP reports in practice as Korean guidelines.

Key words: Evoked potentials (EPs); Standards; Reports

INTRODUCTION

The use of evoked potentials (EPs) in clinical practice has changed over time. Progressive advances in imaging technology, especially in magnetic resonance imaging (MRI), have reduced the use of EP testing in clinical practice. Nevertheless, EP have clinical value in which either the anatomical abnormality is not readily visible by an imaging modality or MRI is neither feasible nor cost-effective. It has not only been used in the diagnosis of neurological disorders but also in neurological and orthopedic surgeries and as an intensive monitoring tool during various types of surgery to prevent neurological impairment. The EP guidelines were created to provide useful information for clinical neurophysiologists, technicians, and clinicians interested in EP, as well as those who are newly learning about EP. There are many standard procedures to follow when measuring EP. The criteria presented below emphasize clinical relevance in EP recording and interpretation and are primarily aimed to evaluate the functions of the sensory pathways in the central nervous

system. The document is divided into 2 parts; in the first part, we describe fundamental requirements for performing EP, and guidelines for EP report forms are described in the second part.

I. Basic requirements for EP¹⁻⁵

1. Qualifications of practice

Technicians performing basic brainstem auditory evoked potential (BAEP) testing, pattern visual evoked potential (PVEP) testing, and somatosensory evoked potential (SSEP) testing should have the following abilities: to explain the characteristics and objectives of the test to patients, to achieve patient relaxation/cooperation, to fill out medical records to aid in appropriate clinical decision-making, to obtain and summarize high-quality results, to note relevant information in the report, and repair and verify the integrity of the equipment.

2. Amplifier

A peak-to-peak amplitude should be amplified to fit in the entire screen of the analog-to-digital (A-D) converter. Gain should be calibrated stepwise from the maximum of 2.5 to 1. The differential input impedance of the amplifier should be at least 100 meg Ω . The input terminals 1 and 2 are amplified and the common signals between the inputs are rejected. The common mode rejection should be at least 80 dB (10,000:1) at the highest sensitivity of the amplifier, when the common mode signal is applied between both inputs and neutral. The bandpass of the amplifier should be at least 0.1–5,000 Hz when measured at the point of –3 dB, and the roll-off slope of each filter should be clearly specified.

3. Averager

The horizontal resolution of the system should be under 20 μ s/data input. For the vertical resolution, an 8-bit A-D converter is adequate but a 12-bit converter are preferred. The system should be capable of generating an average value at least over 4,000 trials. The onset of the averaging sweep should precisely synchronize with the onset of stimulation. Trials contaminated with artifact should be easily and promptly removed in the averaging process. PVEP and SEP requires at least four channels, while BAEP requires two.

4. Display and wireout

The output display should show averaged waveforms and unaveraged electroencephalogram (EEG). Also, information on voltage and time scales should also be easily read on the display. After post-acquisition data processing, transformed data should be displayed simultaneously on the raw EP data, as they can affect the reliability of the test.

5. Optional features

Optional items are not requirements but are useful in specific situations. The following items under this category: additional channels (8 channels are often advantageous); lower amplifier noise; direct current (DC) input capability; electronic data transfer and storage; phase-shift free digital filtering; cursor positioning on the results; and continuous trend analysis. Electronic storage should always include the raw data, and post-processing data should be automatically noted in the report. Results should be electronically stored in the raw form prior to transformation.

6. Electrical safety

In recording EP, the following measures should be taken to ensure patient safety. The grounding and the chassis leakage current emanating from all instruments connected to the patient or in the same room where the patient is should not exceed 300 μ A in the condition of an open ground. Special caution is required particularly if the recording is performed with portable equipment, or testing is performed in the intensive care unit (ICU) or operation room. Instruments should be designed in consideration to prevent an accidental shock during power-on, power-off, and power failure. Equipment should be embedded current limiting protector in all electrodes attached to the patient in the operation room or the ICU. In EP testing, all outputs of the electrical stimulator should be isolated from the ground and the output current should not be exceeded even when the system malfunctions.

7. Filtering

An appropriate use of analog filtering can remove weak or clinically insignificant frequencies. Accordingly, there will be less artifacts in the EP and the waveforms will be clearly seen. The signal-to-noise ratio improves even with fewer stimulation. Excessive analog filtering alters the latency,

amplitude, and waveform of EPs. Excessive use of the low frequency filtering may make peaks and valleys appear earlier, causing false negatives. In addition, excessive use of in the high frequency filtering alter prolongs peaks, causing false positives. The peak of PVEP P100 can be prolonged for 8–10 ms if the high-frequency filter is reduced from 250 Hz to 30 Hz. Because time shift is a function of both filtering and the frequency of the evoked waveforms, it is impossible to predict the precise amount of the time shift. A larger amount of time shift occurs in a broad waveform of lower frequencies than in a sharp waveform of higher frequencies. Generally, the filter setting ratio of high frequency vs. low frequency should be at least 100:1 in order to minimize the occurrence of filter-induced phase shifts. A difference may occur if the identical filter is used on different manufacturer's instruments. It is because the roll-off slope (in dB/octave) determined at the filter's approximate break point (in Hz) is not specified. A difference in roll-off slope can cause a difference in latency, which is the most critical, as well as differences in amplitude and waveform. Digital filtering and smoothing algorithms affect amplitude and waveform, but typically do not affect latency. A 60-Hz notch filter transforms artifactual waves in BAEP and SSEP to mix into normal waveforms, and is not recommended because it can make responses falsely even in the absence of waveforms or shift the latency of normal responses.

8. Polarity convention

In the EP equipment currently manufactured in the market, the polarity of the input terminals is indicated as (+) or (-). Positive responses occurring in the lead connected to the positive polarity (+) and negative responses occurring in the lead connected to the negative polarity (-) are shown upward and positive or negative responses connected to a terminal of the opposite polarity are shown downward. Currently in most reports, negative responses of PVEP and SSEP are shown upward, whereas those of BAEP are shown in the opposite way (positive responses are shown upward). The manner in which polarity is shown can vary according to individual preference, but must be clearly specified. The current recommended conventions are following: (1) PSVEP: positivity of the occipital regions (e.g. OZ and inion) relative to distant electrodes (e.g. ears, FZ or CZ) produces a downward trace deflection. (2) BAEP: positivity of the vertex rela-

tive to ear electrodes produces an upward trace deflection. (3) SEP: negativity of the parietal scalp electrodes (contralateral to the limb stimulated) relative to distant electrodes (FZ or noncephalic) produces an upward trace deflection.

9. Reproducibility

Reproducibility rate should be examined by computing averages independently twice or more. Evoked waveforms are consistently reproduced, and the results are neural and not artifactual origin, thus replicating responses is mandatory. An artifactual wave may look like a physiological response in a single averaging but is usually not reproduced. EP latency and amplitude should be consistently reproduced in consecutive trials. Latency replication should be within 1.0% of the total sweep time, and amplitude replication should be within 15% of peak-to-peak amplitude. Reasons for a failure of consistent reproducibility in repeat trials are (1) excessively low amplitude (but not necessarily abnormal), (2) excessive artifactual waves (often of muscular origin), and (3) insufficient number of trials in computing an average. Decreasing impedance often reduces noise by improving the common-mode rejection ratio. Various physiological artifactual waves are reduced by increasing the number of stimulations, releasing tension, or after sleep. When EP responses show a low amplitude, increasing the number of stimulations improves the signal-to-noise ratio but there are practical time limitations. If the number of stimulations is increased in BAEP and SSEP, the amplitude may increase. Low reproducibility rate may continue despite diverse attempts to correct problems in clinical testing. Low reproducibility itself does not mean an abnormality. If a reproducibility rate is low, the data should be not used in computing norms to use to analyze EP results. In clinical testing, one or more replications are necessary to obtain consistent results. If replication cannot be performed in clinical testing, applying the upper limit of norms can be considered. This approach can be used specifically in assessing the side-to side asymmetry of latency and amplitude.

10. Documentations

In EP documentation, it is required to note the following items:

- ① Patient name, identification number, age, sex, and test date

- ② Derivatives in each channel for which the electrodes are specified using accepted abbreviations in the sequence of the input terminal 1 and 2 of the amplifier
- ③ Stimulus pattern, polarity, field size, check size, full or partial field, stimulus intensity, stimulation frequency, and the stimulated side (if relevant)
- ④ Information relevant to the test results, such as masking of the unstimulated ear
- ⑤ Average number of stimulations
- ⑥ Time calibration on the vertical line and voltage calibration on the horizontal line
- ⑦ The points at which measurements are taken (used to compute latencies and amplitudes of peaks and troughs).

11. Standards for normative EP studies and Criteria for the analysis of norms

To adequately utilize EP testing in practice, appropriately reproduced waveforms should be obtained and skillfully analyzed norms should be available. Norms may differ across different laboratories, because of differences in (1) control subjects' characteristics (sex, age, and non-random sampling), (2) stimulation parameters, (3) recording parameters, and (4) the algorithm used to summarize results. A newly establishing laboratory, if satisfying the following conditions, may utilize the normative data published by another center as the reference.

- ① Perform the test with the same stimuli in the same manner as the reference laboratory which developed the norms with proper calibration of instruments and approaches.
- ② The reference data of individual laboratories should have been obtained by testing at least 20 control subjects, with age considered, and 95% or 99% of the normative data should be within the range of the tested values from the reference laboratory (SD: 2 [95%], 3 [99%]).

12. Selection of subjects

To perform EP testing for normative data, selecting appropriate subjects is very important. All subjects should be neurologically normal and without a family history of neurologic disorder. In PVEP testing, subjects should not have a history of age-specific visual impairment (different from disorders of

visual acuity) or ophthalmic migraines. Ophthalmic testing should include tests for eyesight, disorders of visual acuity (not exceeding -5 diopter, if nearsighted), visual field, color vision, and fundus examination. The normal subject group for BAEP testing should not have a personal or family history of auditory processing disorder and be within the age-adjusted normal range in terms of otological, audiological and neurological function. Auditory testing should include tests for air conduction and bone conduction, pure tone audiometry, and speech discrimination to determine the auditory threshold, acoustic impedance, and crossed acoustic reflexes. The normal subject group for SSEP testing should not have a personal or family history of neurologic disorders, and be within the age-adjusted normal range neurologically. Personal histories of trauma, fracture, or sensory processing disorder should be evaluated with caution. It is advisable to examine hemispheric dominance, that is, hand, eye, and ear dominance. Use of drugs like sedatives, stimulants, and other neurotropic drugs, should be examined, and it is preferable to exclude those using such drugs from a normative study. Measurements of the responses in the right and left eyes, ears, and peripheral nervous system within the same patient should not be treated as independent, but paired consideration. In general, significant results are obtained when testing is performed on both sides in individual subjects.

13. Description of normative study results and criteria for clinically significant abnormality^{6,7}

To statistically analyze EP data obtained in a normative study, first, the distribution is examined. If the distribution is normal and bell-shaped (Gaussian distribution), it is adequate to describe the sample's characteristics by computing central tendency and dispersion (the mean and the standard deviation). Unfortunately, the distribution of EP data based on a small sample often shows significant skewness (asymmetry of the curve) and/or kurtosis (relative sharpness or flatness of the curve). Ratios (e.g., amplitude ratio) can deviate from normality, even if both the numerator and the denominator are normally distributed and even if they are based on a large sample. These examples show a need to transform the observed data to ensure that the distribution is normal before computing the mean and the standard deviation or to obtain approximate norms. Nonparametric (distribution-free) methods are used when the normal values have

a non-Gaussian distribution. Values not following a normal distribution may be transformed by taking the logarithm, the square root, the reciprocal, or other approaches. The raw data and the transformed data should be evaluated the extent of deviation from normality.

To make a clinical diagnosis, the value obtained in an individual should be compared against the population norms to determine whether it is normal or abnormal. In a normal distribution, a small sample represents a very limited part in the entire observations and cannot be regarded as the same as the population. Therefore, it is important to designate a clinically observed value (such as the latency and amplitude of a waveform) as abnormal, if the value is 2, 2.5, or 3 standard deviations (SD) away from the mean of the normal control group. However, the following conditions must be satisfied: (1) the relevant value is regarded as abnormal when compared to a control group out of the entire normal population, and (2) it cannot be accurately predicted where the value would be located if compared to the normal population.

For any given lower and upper limits of norms, it is possible to make a wrong conclusion that a normal value is abnormal or conversely that an abnormal value is normal. Regarding absolute latency, interpeak latency, and side-to-side comparisons, decreasing the upper limit has the advantage of decreasing false negatives, but it increases false positives. Widening the range of normal values yields the opposite consequence. Hence, it is critical for each laboratory to fully understand the statistical meaning when determining norms.

Generally, in BAEP and SSEP testing, several interpeak latencies and left-to-right asymmetries are considered. In conclusion, the adequacy of a normal range used in differentiating normal from diseased should be supported by appropriate clinical or clinicopathologic correlations.

II. Guidelines for writing an EP reports⁸

The guidelines are designed to suggest general criteria for writing EP reports in practice but are not meant to represent rigid rules. They are not applicable to research or other specific purposes such as intensive monitoring in the operating room or ICU, long latency event-related potential recording, or topographic mapping testing. A clinical EP re-

port should provide the minimal basic information such that the test results may be judged accurately and reliably and interpreted accurately. If necessary, more numerical data and descriptive information may be added to the basic minimal reporting of the test results. Numerical data can provide more accurate information compared to a descriptive report. A clinical report can provide a meaningful direction for the referring physician in connecting electrophysiological findings to the clinical problem. The format of reporting should be logical and sequential. A report can often be referenced by another hospital, and thus it is desirable for idiosyncratic terms to be avoided and descriptions to be clear. EP reports generally consist of patient information, clinical information, technical data, results, additional descriptions of the results, and the interpretation including impression regarding its normality or degree of abnormality and correlation of the EP findings with the clinical relevance.

1. Identification

The report should be clearly labeled on page with the patient's full name and the inclusive date of the study, patient's age, sex and any identification number. Age is the most important parameter in all normative tests. For infants, conceptual age is used in the unit of weeks, up to 60 weeks, rather than chronologic age or gestational age. For toddlers, age is expressed in months, up to 36 months, after which it is expressed in years. Sex may be an important statistical parameter in norms.

2. Clinical information

- 1) A summary and description of clinical problems relevant to the test should be noted, but not a detailed clinical history of disease or physical examination findings.
- 2) The findings on a physical examination influencing the test results and those confirmed in the laboratory should be noted. For example, mention whether the patient had a corrected vision in PVEP testing. Also mention asymmetry between pupils, deficits in visual field, or inability to fixate on or trace a stimulus visually. In BAEP testing, mention the auditory threshold determined with the test stimulation and if necessary, the examination of the tympanic membrane. In SSEP testing, it is necessary to record the height and the lengths of the arms and legs. In addition, the distance from the stimulation site to the nerve or

spinal recording site should be recorded if measurements are needed to examine the function of the peripheral or central nervous system. Malformations in limbs, spine, and skull should also be noted.

- 3) It is important to record patient behavior that may influence the reliability of the test. Patient restlessness can clearly reduce signal-to-noise ratios. In VEP testing, the level of cooperation in changing arousal states and maintaining fixation can affect the results profoundly.
- 4) The use of sedative or hypnotic drugs during the test should be mentioned in the report. Any drugs the patient takes that may affect the nervous system should be noted.
- 5) In SSEP testing performed to measure peripheral nerve conduction velocity, the limb temperature should be noted.

3. Descriptions of the test procedure

- 1) There is no need to note general laboratory specifications such as amplifier or averaging parameters. Testing parameters that differ from the standard approach and may affect the test (i.e., changes in filtering) should be noted.
- 2) The recording sites and derivatives should be mentioned, and show the peaks of the evoked responses recorded in each of the sites.
- 3) The stimulus parameters that may influence the interpretation of the test results need to be reported. They include the following: (a) whether unilateral, bilateral, or both uni- and bilateral stimulation was performed, and (b) stimulation rate and any specific information involving the stimulation procedure. For instance, record the following: in VEP testing, the size of a patterned stimulus (in minute of arc at the patient's eye) and field size (in degree of arc at the patient's eye); if a partial field is tested, the position and size of the stimulated field and the position of the fixation point relative to the periphery of the field; if a flash stimulus is presented, stimulus type (stroboscope, LED, goggles, etc.), whether the eyes were closed or open, whether the pupils were dilated by a drug or due to illness, and whether the patient was adapted to light or darkness. In auditory EP testing, stimulus intensity, polarity (rarefaction, condensation, or both); frequency and duration of a tone stimulus, if used; the intensity of masking, if used; the type of earphone, other transducers

or probes, if used. The actual current or voltage of the stimulus does not need to be recorded, but difficulties in obtaining accurate responses, whether they be sensory or motor, should be described.

- 4) It is optional to send a copy of waveforms with the report, but it should be available in case it is requested. If a copy of waveforms is included, the following information should be specified and included at least: patient information, test date, recording and averaged values, recording sites, stimulus parameters, response polarities, calibration, time base, and the identification of the measured response peaks.

4. Descriptions of results

The following items may be included in the results:

- 1) The mean number of stimulations and the reproducibility of the test results.
- 2) Measurements and derived numerical data; presenting the results in graphs would be useful.
- 3) Peak latency; if unstandardized labels are used, they should be used as consistently as possible. If onset latency is measured rather than peak latency, it should be noted.
- 4) Amplitude; the measurement method may also be mentioned (e.g., from "0" on the computer, pre-stimulation threshold, or the previous or subsequent peak).
- 5) Norms; normative data allows an independent impression of the results when reading the report, free of the interpreter's opinion, in addition to allowing comparisons with other general normal ranges. If the normative data were transformed, this should be mentioned as well as how it was achieved. Before the limits are determined; it is advisable to mention whether the measurements were transformed and whether age- or sex-adjusted values were used, before comparing against the norms.

5. Additional description of results:

The following points should be considered in describing the results.

- 1) There is no need to explain normal response waveforms. If necessary, it is sufficient to simply mention that they follow the normal patterns.
- 2) Any deviation from normal should be clearly noted with the type described accurately. Types of abnormalities

include changes in latency, interpeak latency, amplitude, side-to-side latency and amplitude differences, waveform, and topography. However, abnormal measurements that are subjective or controversial should be described in much more detail than objectively abnormal numerical values or statistically abnormal patterns, such as waveforms or the topography of waveforms.

6. Interpretation and opinion

1) Opinions

- ① Interpretation is a description of the opinion of the interpreter regarding normal or abnormal results. Expression should be clear and unclear result should not be suggested as a finding of clinical significance. Not all EP results are characterized as normal or abnormal. Sometimes, it may be proper to state a result as unusual or technically inadequate for interpretation. An unusual result refers to atypical waveforms or waveform topographies and other findings of no clinical significance. It is best to say that the result shows a pattern of unknown clinical significance. The term "technically inadequate results" is used if the signal-to-noise ratio is low, if varying results were obtained when the test was repeated, or if the peaks necessary for interpretation were not recorded.

Additional tests may need to be performed in the following cases: partial-field testing to evaluate double peaked or W responses to full-field stimulation, testing with different sizes of checks to differentiate a foveal lesion from a parafoveal lesion, BAEP testing to record from the electrodes in the external auditory canal to evaluate no responses of wave I, and SSEP of the median nerve in which multiple sites are recorded to identify separate components of N13 and N14 peaks.

- ② The degree of deviation of test results from norms may be stated as mildly, moderately, or severely abnormal. Such statements imply that abnormality is significant and not a false negative result. The level of deviation is determined on statistical criteria rather than subjective decision. Because the correlation between clinical and electrophysiological abnormalities may be unclear, the extent of clinical abnormality should be carefully determined, especially if there was no abnormal finding in the test (such as visual acuity). Even in the presence

of underlying pathology, the disease severity, or reversibility or irreversibility of the electrophysiological abnormalities, cannot be determined with a single clinical EP test.

2) Clinical relevance

- ① It is advisable to state that a normal value does not mean the absence of a disease, or that the test does not provide an answer to the clinical problem, because the referring physician may not be familiar with the limitations of EP testing.
- ② Specific clinical problems can not adequately identified by testing procedure. For example, a normal PVEP to large check and large field stimuli does not distinguish reduced visual acuity caused by macular degeneration or a lesion in the occipital lobe. Normal BAEP does not exclude deafness caused by cortical lesion. With a normal SSEP, whether functional abnormalities are present in a localized peripheral nerve root or the anterior spinal cord cannot be determined.
- ③ If an abnormal finding is obtained, the description of clinical relevance should include statements of the abnormal region and potential neurophysiological causes, if possible. If it is difficult to accurately describe the actual abnormal region, the possibility of multiple combined lesions involving sensory receptors, the peripheral and central nervous systems should be noted. At the current state of understanding of the formation of EP waveforms, it is difficult to specify a specific region in the central nervous system based on abnormal responses. Accordingly, it is more adequate to suggest possible approximate areas within the neural axis as abnormal.
- ④ Descriptions of clinical relevance should not imply that the test result itself indicates a specific disorder or has a diagnostic value. Test results may point to a suspected lesion or disease process, but sometimes, other possibilities cannot be excluded. It is difficult to delineate clinical relevance in depth from the result of a test performed on the basis of the limited information summarized in a neurophysiological evaluation request form and doing so has a potential for error.
- ⑤ If the test result is unclear, it is advisable to mention the need for follow-up testing.

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