Evidence-based guideline update: Intraoperative spinal monitoring with somatosensory and transcranial electrical motor evoked potentials : Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the American Clinical Neurophysiology Society

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SPECIAL ARTICLE

Evidence-based guideline update: Intraoperative spinal monitoring with somatosensory and transcranial electrical motor evoked potentials

Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the American Clinical Neurophysiology Society

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ABSTRACT

Objective: To evaluate whether spinal cord intraoperative monitoring (IOM) with somatosensory and transcranial electrical motor evoked potentials (EPs) predicts adverse surgical outcomes.

Methods: A panel of experts reviewed the results of a comprehensive literature search and identified published studies relevant to the clinical question. These studies were classified according to the evidence-based methodology of the American Academy of Neurology. Objective outcomes of postoperative onset of paraparesis, paraplegia, and quadriplegia were used because no randomized or masked studies were available.

Results and Recommendations: Four Class I and 8 Class II studies met inclusion criteria for analysis. The 4 Class I studies and 7 of the 8 Class II studies reached significance in showing that paraparesis, paraplegia, and quadriplegia occurred in the IOM patients with EP changes compared with the IOM group without EP changes. All studies were consistent in showing all occurrences of paraparesis, paraplegia, and quadriplegia in the IOM patients with EP changes, with no occurrences of paraparesis, paraplegia, and quadriplegia in patients without EP changes. In the Class I studies, 16%–40% of the IOM patients with EP changes developed postoperative-onset paraparesis, paraplegia, or quadriplegia. IOM is established as effective to predict an increased risk of the adverse outcomes of paraparesis, paraplegia, and quadriplegia in spinal surgery (4 Class I and 7 Class II studies). Surgeons and other members of the operating team should be alerted to the increased risk of severe adverse neurologic outcomes in patients with important IOM changes (Level A). ***Neurology*® 2012;78:585–589**

GLOSSARY

AAN = American Academy of Neurology; **ACNS** = American Clinical Neurophysiology Society; **EP** = evoked potential; **IOM** = intraoperative monitoring; **MEP** = motor evoked potential; **SEP** = somatosensory evoked potential; **tce** = transcranial electrical.

Paraparesis, paraplegia, and quadriplegia are complications of spinal surgery and certain surgeries of the aorta. Intraoperative monitoring (IOM) of neural function is used to warn of the risk of surgical complications.[1–6] Anesthesiologists and surgeons are able to intervene in a variety of ways when IOM raises warnings. They can modify surgery by interventions such as reducing the degree of distraction, adjusting retractors, removing or adjusting grafts or hardware, reimplanting or unclamping arteries, placing vascular bypass grafts, minimizing the remaining portion of the surgery, or other actions. Surgeons also have the opportunity to check a wake-up test in some patients.

This evidence-based guideline seeks to answer the clinical question: Does IOM with somatosensory

Supplemental data at www.neurology.org

Supplemental Data

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evoked potentials (SEPs) and transcranial electrical (tce) motor evoked potentials (MEPs) predict adverse surgical outcomes?

The panel addressed this question on the basis of subgroup analyses of well-defined patient cohorts, comparing the clinical outcomes of those patients who had evoked potential (EP) changes with those who had no EP changes. The panel recognized an inherent limitation in assessing the specificity of IOM changes when those changes resulted in clinical interventions by anesthesiologists or surgeons.

The panel applied the following reasoning:

1. If it can be shown that adverse IOM changes predict increased risk of adverse clinical outcomes consistently, then all adverse IOM changes may represent possible compromise of the spinal cord that might result in an adverse outcome.
2. Nonobjective outcomes are particularly problematic for assessing the usefulness of IOM because of the potential for diagnostic suspicion bias. Patients with abnormal IOM might be more thoroughly evaluated postoperatively than patients without intraoperative changes. Without masked outcome assessment and a standardized method of case ascertainment, only obvious outcomes (e.g., new paraplegia) are likely to be noticed in patients with normal IOM. Subtler changes, such as sensory changes, could easily be missed. This bias would tend to exaggerate the usefulness of IOM. Therefore, the only outcomes assessed were new paraparesis, paraplegia, and quadriplegia, because these neurologic deficits are more objective signs than are less-severe deficits.

DESCRIPTION OF THE ANALYTIC PROCESS

Seven physician clinical neurophysiologists were appointed to write this guideline (M.R.N., R.G.E., G.G., A.D.L., J.L., R.M., and T.Y.) because of their expertise in spinal IOM. The panel members were appointed jointly by the Therapeutics and Technology Assessment Subcommittee (see appendices e-1 and e-2 on the *Neurology*® Web site at www.neurology.org) of the American Academy of Neurology (AAN) and the American Clinical Neurophysiology Society (ACNS). Five additional panel members (D.S.G., C.A., V.C., G.S.G., and C.L.H.) served as methodology experts.

A research librarian performed literature searches of the MEDLINE and EMBASE databases using the following keywords: monitoring, intraoperative, evoked potentials, paralysis, and intraoperative complications. Additional articles were found from among the references cited in the reports reviewed. Each article was reviewed independently by at least 2 panel members. Appendix e-3 presents the complete MEDLINE search strategy, and appendix e-4 presents the complete EMBASE search strategy.

The panel elected to focus on the 2 most common current spinal cord IOM techniques. The SEP technique evaluated was ankle-wrist stimulation with neck-scalp recording. The MEP technique evaluated was tceMEP with muscle recording.

Minimum size for study inclusion was 100 patients for orthopedic procedures and 20 patients for neurosurgical or cardiothoracic procedures. Different numbers were used because the rates of adverse neurologic outcomes are lower for orthopedic spine procedures compared with those for neurosurgical and cardiothoracic procedures.

A study was included if it represented a consecutive series of a representative group of patients, preferably prospective; if the IOM followed a protocol established in advance; if the IOM changes were identified in real time, before outcomes were known; and if the clinical outcomes of interest (paraparesis, paraplegia, and quadriplegia) were clearly reported. Reports were reviewed and scored independently by all content expert panelists. Those panelists discussed and resolved by consensus the methodology, results, relevance, and conclusions for a few reports for which there was initial panel discrepancy.

Next, these articles were rated using the AAN 4-tiered (Class I–Class IV) classification of evidence scheme for rating diagnostic studies (appendix e-5), and conclusions and recommendations were linked to the strength of the evidence (appendix e-6). All articles that were rated Class I or Class II are listed in table e-1. The primary data evaluated were the results from a comparison of the group without EP changes with the group with EP changes in both the number of cases with new postoperative paraparesis, paraplegia, and quadriplegia and the number without these conditions. Descriptive statistics and the Fisher exact test were used for statistical analysis.

ANALYSIS OF EVIDENCE The search identified an initial set of 604 reports. Of those, 40 articles met the inclusion criteria, but 28 were subsequently excluded because they contained Class III or IV data; did not address the outcomes of paraparesis, paraplegia, or quadriplegia; primarily assessed nerve roots instead of the spinal cord; or substantially relied on techniques beyond the scope of this guideline.

Twelve studies[7–18] provide evidence to assess the role of IOM in the prediction of adverse outcomes (table e-1), 4 of which were Class I.[7–10] One Class I study[7] found that no events of paraparesis, paraplegia, or quadriplegia occurred in 17 IOM patients without EP changes, but 5 of these adverse events occurred in 16 IOM patients with EP changes (31%) (Fisher exact test

$p = 0.0184$). In the second Class I study,[8] no events of paraparesis, paraplegia, or quadriplegia occurred in 84 IOM patients without EP changes, but among 25 IOM patients with EP changes, 4 (16%) had adverse outcomes: 1 had paraplegia, 1 had quadriplegia, and 2 had worsening of preexisting paraparesis (Fisher exact test $p = 0.00369$). In the third Class I study,[9] no events of paraparesis, paraplegia, or quadriplegia occurred in 45 IOM patients without EP changes, but 2 adverse events occurred in 5 IOM patients with EP changes (40%) (Fisher exact test $p = 0.0158$). In the fourth Class I study,[10] no events of paraparesis, paraplegia, or quadriplegia occurred in 49 IOM patients without EP changes, but 8 adverse events occurred in 20 IOM patients with EP changes (40%) (Fisher exact test $p = 0.000148$). Overall, events of paraparesis, paraplegia, or quadriplegia occurred in 16%–40% of IOM patients with EP changes, but no adverse outcome events occurred in patients without an EP change.

The other 8 articles were Class II.[11–18] No events of paraparesis, paraplegia, or quadriplegia occurred in 108 of 1,378 IOM patients without EP changes, whereas these severe adverse outcome events occurred in 1%–100% of the 1–72 IOM patients with EP changes. Seven of these studies reached significance by Fisher exact test ($p < 0.05$).[11–16,18]

All studies were consistent in that all paraparesis, paraplegia, and quadriplegia events occurred in the IOM patients with EP changes, and none occurred in the IOM patients without EP changes.

This assessment did not undertake to evaluate lesser degrees of motor impairment, which would underestimate the overall adverse outcome rate. It did not assess radiculopathy or similar complications of lumbar fusion.

The one prospective comparative study[3] of motor outcomes in patients with IOM vs those without IOM was excluded from this assessment because it used graded motor power changes rather than the presence of paraparesis, paraplegia, and quadriplegia as its outcome measure. That cohort study measured motor outcome and the decision to monitor, not whether the monitoring showed intraoperative changes. The study showed a significant positive relationship between decision to monitor and better motor outcome.

CONCLUSION IOM is established as effective to predict an increased risk of the adverse outcomes of paraparesis, paraplegia, and quadriplegia in spinal surgery (4 Class I and 7 Class II studies).

RECOMMENDATION Surgeons and other members of the operating team should be alerted to the increased risk of severe adverse neurologic outcomes in patients with important IOM changes (Level A).

CLINICAL CONTEXT In practice, after being alerted to IOM changes, the operating team intervenes to attempt to reduce the risk of adverse neurologic outcomes. No studies in humans have directly measured the efficacy of such interventions. However, multiple controlled studies in animals[19–24] have demonstrated that intervening after IOM alerts (as opposed to not intervening) reduces the risk of permanent neurologic injury. On this basis, it seems reasonable to assume that such interventions might improve outcomes in humans as well. It is unlikely that controlled human studies designed to determine the efficacy of post-IOM alert interventions will ever be performed.

This analysis did not compare MEP with SEP. The 2 techniques differ slightly. MEP more directly monitors the motor pathway itself. One technique may change while the other remains stable, or one may change earlier than the other. MEP requires more restrictive anesthesia requirements, causes patient movement, and has less-clear criteria for raising an alarm. SEP can localize an injury or site of ischemia more exactly. The tceMEPs are often used intermittently because of movements that occur with the stimulus. Sometimes one technique can be accomplished throughout a case, whereas the other techniques cannot. As a result, it may be most appropriate for the surgeon, anesthesiologist, and neurophysiologic monitoring team to choose which techniques are most appropriate for an individual patient. Conducting both techniques together is a reasonable choice for many patients. Neither technique can predict the onset of paraplegia that is delayed until hours or days after the end of surgery. Neither technique should be considered to have perfect predictive ability when no EP change is seen; rare false-negative monitoring has occurred.[1,2]

The studies reported here varied somewhat in the criteria used to raise alerts. The specific criteria used are reported in table e-1.

These IOM studies involved a knowledgeable professional clinical neurophysiologist supervisor. These studies support performance of IOM when conducted under the supervision of a clinical neurophysiologist experienced with IOM.[2,25,26] IOM conducted by technicians alone or by an automated device is not supported by the studies reported here because these studies did not use that practice model and because there is a lack of identified well-designed published outcomes studies demonstrating efficacy with those practice models.

RECOMMENDATIONS FOR FUTURE RESEARCH

1. Pooling of results from a large series of well-monitored patients may permit determination if the low false-negative frequency for MEP IOM in the reported studies is a generalizable observation.
2. A better understanding of anterior spinal artery

syndrome may help to reduce further the rate of paraplegia and paraparesis after spinal surgery.
3. If limitations in the techniques reviewed can be identified explicitly and methods to correct those limitations are developed, then comparisons among different monitoring techniques may be desirable.

AUTHOR CONTRIBUTIONS

Dr. Nuwer: drafting/revising the manuscript, study concept or design, analysis or interpretation of data, statistical analysis. Dr. Emerson: drafting/revising the manuscript, analysis or interpretation of data, statistical analysis. Dr. Galloway: drafting/revising the manuscript, study concept or design, analysis or interpretation of data. Dr. Legatt: drafting/revising the manuscript, analysis or interpretation of data. Dr. Lopez: drafting/revising the manuscript, study concept or design, analysis or interpretation of data, acquisition of data. Dr. Minahan: drafting/revising the manuscript, study concept or design, analysis or interpretation of data. Dr. Yamada: drafting/revising the manuscript, contribution of vital reagents/tools/patients, acquisition of data, statistical analysis. Dr. Goodin: drafting/revising the manuscript. Dr. Armon: drafting/revising the manuscript, study concept or design, analysis or interpretation of data. Dr. Chaudhry: drafting/revising the manuscript, analysis or interpretation of data. Dr. Gronseth: drafting/revising the manuscript, analysis or interpretation of data, statistical analysis. Dr. Harden: drafting/revising the manuscript, statistical analysis.

DISCLOSURE

Dr. Nuwer estimates that 20% of his clinical effort is spent on intraoperative spinal cord monitoring; serves on a scientific advisory board for Corticare; serves on editorial advisory boards for *Clinical Neurophysiology*, *Journal of Clinical Neurophysiology*, *Practical Neurology*, and *Medical Economics*; receives publishing royalties for *Intraoperative Neurophysiologic Monitoring* (Cambridge University Press, 2010); serves as a consultant for Mattel; serves as Local Medical Director for SleepMed-Digitrace; receives research support from Bristol-Myers Squibb; holds stock in Corticare; and has provided depositions and expert testimony in medico-legal cases. Dr. Emerson has filed patents re: Dynamic adjustable spatial granularity for EEG display and systems and methods for measuring brain activity; serves as a consultant for Persyst Development Corporation; estimates that 85% of his clinical effort is spent on intraoperative monitoring; and receives research support from Cyberkinetics Neurotechnology Systems Inc., the NIH, NYS SCIRB, and the Epilepsy Foundation. Dr. Galloway estimates that 60% of her clinical effort is spent on intraoperative monitoring. Dr. Legatt serves on the editorial board of the *Journal of Clinical Neurophysiology*; holds equity in Entremed, Pfizer Inc, Teva Pharmaceutical Industries Ltd., GlaxoSmithKline, Johnson & Johnson, Schering-Plough Corp., GE Healthcare, and Proctor & Gamble; estimates that 65% of his clinical effort is spent on intraoperative monitoring; and has provided expert testimony in medico-legal cases. Dr. Lopez has received funding for travel from Cadwell Laboratories, Inc.; receives publishing royalties for *Intraoperative Neurophysiologic Monitoring* (Cambridge University Press, 2010); estimates that 60% of his clinical effort is spent on intraoperative monitoring; and has provided expert testimony in medico-legal cases. Dr. Minahan estimates that 60% of his clinical effort is spent on intraoperative monitoring and has provided expert testimony in medico-legal cases. Dr. Yamada estimates that 10% of his clinical effort is spent on intraoperative monitoring; serves on the editorial board of the *Journal of Clinical Neurophysiology*; and receives publishing royalties for *Practical Guide for Clinical Neurophysiologic Testing: EEG* (Wolters Kluwer/Lippincott Williams & Wilkins, 2010) and *Practical Guide for Clinical Neurophysiologic Testing: EP, LTM, IOM, PSFG and NCS* (Wolters Kluwer/Lippincott Williams & Wilkins, 2011). Dr. Goodin has served on scientific advisory boards for Bayer Schering Pharma and Merck Serono; has received funding for travel and honoraria for speaking and consulting from Bayer Schering Pharma, Teva Pharmaceutical Industries Ltd., Novartis, and Merck Serono; has received speaker honoraria from Bayer Schering Pharma; has received research support from Bayer Schering Pharma and Novartis; and has served as an expert witness in medico-legal cases; holds equity interest in Teva Pharmaceutical Industries Ltd. and Biogen Idec. Dr. Armon has served on a scientific advisory board for Avanir Pharmaceuticals; serves on the editorial boards of *Neurology*® and *emedicine Neurology*; has received honoraria from Medscape Today; receives publishing royalties from emedicine.com for updating electronic chapters and from UpToDate; has received research support from Avanir Pharmaceuticals, Schwartz Biomedical, LLC, the NIH, and the Swiss PFO-Consortium; and has served as an expert witness in medico-legal cases. Dr. Chaudhry serves on the editorial board of *Neurologist*; is an inventor on patent(s) re: Total Neuropathy Score (TNS)—a score for evaluating peripheral neuropathies, for which he receives technology royalties from Abbott, Johnson & Johnson, and sanofi-aventis; receives publishing royalties for *Harrison's Principles of Internal Medicine, 17th ed.* (McGraw Hill Companies, Inc., 2008); estimates that 40% of his clinical effort is spent on nerve conduction studies; has given expert testimony for the Department of Health and Human Services Vaccine Injury Compensation program; and receives research support from the Neuropathy Association and Nutricia. Dr. Gronseth serves as an editorial advisory board member of *Neurology Now*; serves on a speakers' bureau for Boehringer Ingelheim; and receives honoraria from Boehringer Ingelheim and the American Academy of Neurology. Dr. Harden serves on a scientific advisory board for Upsher-Smith Laboratories, Inc.; serves on speakers' bureaus for and has received speaker honoraria from GlaxoSmithKline, UCB, and Lundbeck, Inc.; serves on the editorial boards of *Epilepsy Currents* and *Epilepsy Research*; receives publishing royalties from UpToDate, Inc.; and receives research support from Forest Laboratories, Inc., the Epilepsy Foundation, and the Milken Family Foundation.

DISCLAIMER

This statement is provided as an educational service of the American Academy of Neurology and American Clinical Neurophysiology Society. It is based on an assessment of current scientific and clinical information. It is not intended to include all possible proper methods for care of a particular neurologic problem or all legitimate criteria for choosing to use a specific procedure. Neither is it intended to exclude any reasonable alternative methodology. The AAN and ACNS recognize that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on all circumstances involved. The clinical context section is made available to place the evidence-based guideline into perspective with current practice habits and challenges. No formal practice recommendation should be inferred.

CONFLICT OF INTEREST

The American Academy of Neurology and American Clinical Neurophysiology Society are committed to producing independent, critical, and truthful clinical practice guidelines (CPGs). Significant efforts are made to minimize the potential for conflicts of interest to influence the recommendations of this CPG. To the extent possible, the AAN and ACNS keep separate those who have a financial stake in the success or failure of the products appraised in the CPG and the developers of the guidelines. Conflicts of interest forms were obtained from all authors and reviewed by an oversight committee prior to project inception. AAN and ACNS limit the participation of authors with substantial conflicts of interest. They forbid commercial participation in, or funding of, guidelines projects. Drafts of the guideline have been reviewed by at least three committees of the AAN and ACNS, a network of neurologists, *Neurology* peer reviewers, and representatives from related fields. The AAN Guideline Author Conflict of Interest Policy can be viewed at www.aan.com.

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