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EC NEUROLOGY
Review Article

Intraoperative Neuromonitoring Influences Surgical Decisions: A Retrospective Review of Cases

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Received: February 07, 2018; **Published:** June 19, 2018

Abstract

Background: Intraoperative neuromonitoring (IOM) has been utilized for decades in surgical procedures in which a patient's neural structures are at risk, but the contributions of IOM to surgical decision-making have not been quantified.

Purpose: To demonstrate the incidence of reportable events and suggest the importance of knowledgeable IONM personnel in spinal and other types of surgical procedures.

Study Design/Setting: One thousand cases within the NuVasive Clinical Services (formerly Impulse Monitoring (IMI) database) were randomly sampled and the medical records examined for the frequency with which data collected by the IOM personnel was provided to the surgical team and used to make a decision about next steps within the procedure. These events, which we term "reportable data", include occurrences such as a change in evoked potentials, intermittent or prolonged EMG activity, requests from a surgeon to alter anesthesia regimen based upon IOM, and others.

Methods: NuVasive Clinical Services (formerly Impulse Monitoring, Inc) collects and stores data in a secure database for every case where we provide intraoperative neuromonitoring services. Our full database of cases extends from 2008 until the present and consists of hundreds of thousands of cases. During the time period of October 1, 2014 and April 30, 2015 we retrospectively sampled 1000 cases. The criterion for inclusion in the sample was that either the in-room neurophysiologist, or the remote oversight physician, or both, were employees or contractors associated with NCS.

Results: Of 1000 cases, 343 reportable events were documented in 321 procedures (32.1%). Of those, 212 (66.0% of cases with reportable events, or 21.2% of all cases examined) had reportable events for which a documented intervention in response was carried out by the surgical team. In the remaining 109 cases (34.0% of cases with reportable events, or 10.9% of all cases examined) the IONM information was provided, and acknowledged by the surgeon, but it was unclear what, if any, steps the surgical team took in response to the information.

Conclusions: Surgical teams were provided important information by IONM personnel in 32.1% of neurosurgical procedures where IONM was used. In most cases this information was used to alter a procedure or process within surgery in an effort to protect surgical patients and to improve patient outcome post-operatively.

Keywords: *Intraoperative Monitoring; Spine Surgery; Clinical Neurophysiology; Evoked Potentials; Neurosurgery*

Intraoperative neuromonitoring (IONM) of the central and peripheral nervous systems has been employed by surgeons for decades to prevent patient injury in procedures where neural structures are at risk. IONM is widely considered an important aspect of patient care in spine [1-3], brain [4-7], ENT [8-11], and cardiothoracic procedures [12, 13]. IONM is indicated during spinal deformity correction [14], and instrumented fixations of the cervical [15,16], and lumbar spine [17]. Many authors have reported a role for IONM in non-instrumented spinal decompressions as well [18,19]. IONM is applied to monitor cerebral and brainstem vasculature [5,20], map eloquent cortex [21,22], and map and monitor cranial nerves [23]. Likewise, mapping and monitoring of nerves is used during ENT procedures and has been shown to reduce the likelihood and severity of facial nerve palsy after parotidectomy [24]. Finally, cardiothoracic surgeries have employed IONM to mitigate the risk of spinal cord injury during these cases [13].

The use of IONM can be recommended where the nervous system is at risk of injury or where blood flow needs to be observed. Neurophysiologic status changes from baseline indicate possible patient injury before a patient awakes, and allow intervention on the part of the surgical team to reduce risk, reverse manipulation, or otherwise make decisions to keep surgery as safe as possible [2,26] perioperative neurologic injury, in particular spinal cord injury, is one of the most feared complications of spinal surgery. Intraoperative neuromonitoring (IOM. Maximizing patient safety during surgery minimizes the patient's stay in the hospital and the likelihood of the need for further surgery, thereby also maximizing a surgery's cost-effectiveness [27,28]. Recently, there has been an increasing focus on quantifying the evidence of the contributions that IONM personnel make to improving surgery in different types of surgical procedures [2,25]perioperative neurologic injury, in particular spinal cord injury, is one of the most feared complications of spinal surgery. Intraoperative neuromonitoring (IOM.

To investigate the contribution of IONM to intra-operative care, we retrospectively analyzed medical records held in a secure database of the largest IONM company by case volume in the United States. The purpose of this work was to report the frequency of interventions made based upon IONM data provided to the surgical team across a variety of case types.

Standard Protocol Approvals and Patient Consents

Western Institutional Review Board (WIRB) reviewed and approved protocol IMI.IRD-0715, A Retrospective Review of Data in Surgical Procedures Using Intraoperative Monitoring of the Nervous System, effective July 15, 2015. The Board found that this research meets the requirements for a waiver of consent under 45 CFR 46.116(d). All data were examined retrospectively, and all research was conducted as outlined in the protocol and in accordance with the guidelines as outlined by WIRB.

Search Algorithm and Data Collection

Reviewed cases were included regardless of procedure, monitoring platform used, patient demographics, and whether or not an oversight physician attended the case. This resulted in 21,827 eligible cases. Each case was assigned a number between 1-21,827 chronologically, and then a random number generator (www.random.org) was used to select 1000 cases. Once identified, the events of the case were examined and the data points collected as outlined in table 1.

Patient and Case Demographics	Pre-operative Data Points	Intraoperative and Post-operative Data Points
Invoice number (for auditing)	Relevant patient history	Patient outcome/status in OR post-op
Patient gender	Diagnosis	Reportable event documented (yes/no)
Patient age	Procedure	Surgeon response to reportable event
Monitoring platform used	IONM modalities monitored	Result of intervention
Oversight physician used (yes/no)		

Table 1: *Collected Data Points from Randomly Selected Cases.*

All data were collected based on the information entered into the NCS medical record. Reportable and interventional events were identified either by the neurophysiologist at the end of the case (and then verified by the researchers independently) or were identified by the researchers through review of case data, the neurophysiologist's case log, or the conversation documented between the neurophysiologist and the oversight physician, if applicable.

All audited data were collected into one repository. Checks of the 1000 random cases selected for the dataset were carried out at various intervals, to ensure that data collection was consistent and interpretation of reportable events was performed as outlined.

Definition of Reportable/Interventional Events

We considered two types of events, those that were reported, and those that produced intervention. We considered an event to constitute reportable data if it was clearly documented as communicated to the surgeon/anesthesiologist/surgical team and resulted in acknowledgement by the surgical team. Criteria for classifying an event as Reportable or Interventional events were as follows: 1) the event was detected using IONM data; 2) the event was reported to the surgeon/anesthesiologist/surgical team; 3) the surgeon/anesthesiologist/surgical team acknowledged the data; events were further classified as interventional if, 4) the surgical team acted upon the data and the case documentation clearly reported the surgical steps taken to intervene.

Events were considered unreportable if the data change was anticipated as a course of the procedure (for example, a change in EEG when patient is in burst suppression), or if it was unclear from the record whether the surgical team was made aware of the change. In some cases, the surgical team acknowledged the information provided but it was unclear whether the surgeon acted upon the information, or what was done by the surgeon in response to the information. Those cases are considered reportable events, but not interventional events. We provide here an analysis of both reportable and interventional events, separately and taken together.

Examples of reportable events included: a significant change in, or loss of, evoked potential waveforms including SSEP and TCeMEP and BAER evoked potentials, whether due to limb positioning or otherwise; EMG firing in a surgically relevant site, whether intermittent or ongoing; low pedicle screw stimulation values provided by the IONM team; unexpected EEG events such as seizure, and; alerts regarding the anesthetic status of the patient, including train of four status if the surgeon asks for those data.

Examples of interventional events - in response to the reportable events - included repositioning of limbs, repositioning of pedicle screws due to low stimulation values, and repositioning of retractors due to EMG firing. Interventions for decline or complete loss of evoked potentials included adjustment of anesthetic (increasing blood pressure/decreasing volatile inhalants), reversal of spinal derotation/fixation, removal of aneurysm clips, and placement of vascular shunts.

The incidence of reportable, and interventional events across all examined cases as well as within subtypes of cases and procedures was examined. These events were further categorized according to the type of IONM data that was reported.

Results

Study Sample

We randomly sampled 1000 cases from a possible 21,827 cases, which represents approximately 4.5% of all cases performed by NCS within the time period of October 1, 2014 and April 30, 2015. The patient population consisted of 470 men (47%) and 530 women (53%). The mean age was 59.2 years, with a minimum age of 9 months and a maximum age of 90 years.

Of the 1000 cases audited, 865 (86.5%) were procedures performed on the spinal cord, 51 (5.1%) were Ear/Nose/Throat (ENT) procedures, 50 (5.0%) were craniotomy or skull-base procedures, 33 (3.3%) were cardiothoracic cases, and 1 (0.1%) was a peripheral nerve case. Specific procedures performed, along with proportion within the sample group, are presented in table 2.

Case Type	Procedure	Proportion (out of 1000 cases)
Spinal Cord Procedures – Lumbar and Thoraco-Lumbar		485 (48.5%)
	Ant/Post Lumbar Fusion	16 (1.6%)
	ALIF	27 (2.7%)
	Lateral Fixation	52 (5.2%)
	Laminectomy/Decompression	94 (9.4%)
	PSF/PLIF	267 (26.7%)
	Scoliosis surgery	21 (2.1%)
	Other Lumbar	8 (0.8%)
Spinal Cord Procedures – Cervical and Cervico-Thoracic		335 (33.5%)
	Ant/Post Cervical Fusion	7 (0.7%)
	Ant cervical disc replacement	253 (25.3%)
	Laminectomy/laminoplasty	23 (2.3%)
	Posterior Fusion	52 (5.2%)
Spinal Cord Procedures – Thoracic		45 (4.5%)
	Ant/Post Fusion	1 (0.1%)
	Posterior Fusion	12 (1.2%)
	DSC/SCS Implantation	20 (2.0%)
	Laminectomy	12 (1.2%)
ENT Procedures		51 (5.1%)
	Thyroidectomy	42 (4.2%)
	Parotidectomy	3 (0.3%)
	Other	6 (0.6%)
Craniotomy/Skull-Based Procedures		50 (5.0%)
	Brain tumor resection	34 (3.4%)
	Arnold-Chiari decompression	2 (0.2%)
	Cerebral aneurysm repair	10 (1.0%)
	MVD – cranial nerve	4 (0.4%)
Cardiothoracic Procedures		33 (3.3%)
	ASD Repair	3 (0.3%)
	CEA	18 (1.8%)
	CABG	2 (0.2%)
	T-AAA	4 (0.4%)
	AVR	3 (0.3%)
	Other	3 (0.3%)
Joint/Peripheral Nerve Procedure		1 (0.1%)
	Hip Replacement Surgery	1 (0.1%)

Table 2: *Case Types Examined in the Random Sample.*

Incidence of Reportable Events

Across 1000 cases, a total of 343 reportable events were documented in 321 procedures for a proportion of 32.1%. These involved reportable events as described above, in which a neurophysiologist and/or remote oversight physician communicated information to the surgical team and received acknowledgement of the information. Of those, 212 (66.0% of cases with reportable events, or 21.2% of all cases) had interventional events as defined above for which a known intervention in response to the event was carried out by the surgical team and clearly documented in the record by the neurophysiology team. There were 109 cases (34.0% of cases with reportable events, or 10.9% of all cases) in which a reportable event was communicated to the surgical team, and acknowledged, but it was either unclear what type of action the surgeon took in response, or the surgeon responded but this was not documented clearly by the neurophysiologist in the medical record. In the remaining 679 cases examined (67.9%), there was either no reportable event that occurred, or if one occurred there was no record of acknowledgement or action by surgical or anesthetic teams.

The frequency with which different types of reportable events were observed within the 1000 audited cases is provided in table 3.

Reported Modality	Overall Proportion	Proportion Reportable	Proportion Interventional
EMG firing, intermittent or prolonged	174 (50.7%)	97 (28.3%)	77 (22.4%)
Localization of nerves/mapping	41 (12.0%)	0	41 (12.0%)
EP change due to positioning	38 (11.1%)	0	38 (11.1%)
EP change not due to positioning	33 (9.6%)	4 (1.2%)	29 (8.5%)
Changes in anesthesia regimen	28 (8.2%)	0	28 (8.2%)
Repositioning of pedicle screw	19 (5.5%)	3 (0.9%)	16 (4.7%)
Cerebral oximetry/TCD	5 (1.5%)	0	5 (1.5%)
EEG	5 (1.5 %)	0	5 (1.5%)

Table 3: *Proportion of Reportable and Interventional Events by Modality.*

Reportable Events by Case Type and Procedure

The frequency of all reportable events within each case type is presented in table 4. Overall, the incidence of reportable events in spine cases was 31.0%. Across all spinal cord procedures, the most frequent type of reportable event was EMG activity, intermittent or prolonged (158 cases, or 59.0% of all spine events). The frequency of other observed reportable events in spinal cord procedures is as follows: EP change due to limb positioning, 38 cases (14.2%); surgeon requests for changes in anesthesia regimen based on neurophysiology, 27 cases (10.1%); changes in EP due to something other than positioning, 22 cases (8.2%); repositioning of a pedicle screw due to stimulation values, 19 cases (7.1%), and; localization of nerve/proximity to nerve, 4 cases (1.5%).

Type of Case	Overall Proportion	Proportion Reportable	Proportion Interventional
Spinal Cord Procedures – All Types	268 (78.1%)	97 (28.3%)	171 (49.9%)
Spinal Cord Procedures – Cervical and Cervico-Thoracic	94 (27.4%)	37 (10.8%)	57 (16.6%)
Spinal Cord Procedures - Thoracic	11 (3.2%)	2 (0.6%)	9 (2.6%)
Spinal Cord Procedures – Lumbar and Thoracolumbar	163 (47.5%)	58 (16.9%)	105 (30.6%)
ENT Procedures	48 (14.0%)	6 (1.7%)	42 (12.2%)
Craniotomy/Skull-Based Procedures	15 (4.4%)	1 (0.3%)	14 (4.1%)
Cardiothoracic Procedures	12 (3.5%)	0	12 (3.5%)
Peripheral Nerve/Joint Procedures	0	0	0

Table 4: *Proportion of Reportable Events By Case Type.*

The incidence of reportable events in ENT cases was 94.1%. Across all ENT procedures, the most frequent type of reportable event was localization of nerve/proximity to nerve (34 cases, or 70.8% of all ENT events). The only other observed reportable data came from EMG activity, intermittent or prolonged (14 cases, 29.2%).

The incidence of reportable events in craniotomy and skull-based cases was 30.0%. The most commonly observed reportable event in craniotomy cases was a change in EP not attributable to limb positioning (7 cases, or 46.7% of all craniotomy-related events). Other reportable events in craniotomy cases included the following: localization of nerve/proximity to nerve, 3 cases (20%); and 1 case each (6.7% each) for surgeon-requested anesthesia regimens, EEG changes, EMG activity, positioning effect, and onset of seizure.

The incidence of reportable events in cardiothoracic cases was 36.4%. In cardiothoracic cases, the most common reportable event was emboli detection/TCD changes, with 5 events (41.7% of cardiothoracic events. Changes in EP not related to positioning occurred in 4 cases (33.3%), and changes in EEG were observed in 3 cases (25.0%).

As noted above, spine cases made up 86.5% of all cases audited for reportable event data. This allowed us to examine different types of spine procedures and the incidence of reportable data within those procedures. A more detailed analysis of spinal cord procedures in presented in table 5, which shows the percentage of each procedure for which reportable events were identified.

Case Type	Procedure	# Events (% cases of that type)
Spinal Cord Procedures – Lumbar and Thoraco-Lumbar		163 (33.6%)
	Ant/Post Lumbar Fusion	7 (43.8%)
	ALIF	3 (11.1%)
	Lateral Fixation	15 (28.8%)
	Laminectomy/Decompression	30 (31.9%)
	PSF/PLIF	95 (35.6%)
	Scoliosis surgery	8 (38.1%)
	Other Lumbar	5 (62.5%)
Spinal Cord Procedures – Cervical and Cervico-Thoracic		94 (28.1%)
	Ant/Post Cervical Fusion	3 (42.9%)
	ACDF	66 (27.2%)
	Artificial Cervical Disc	5 (50.0%)
	Laminectomy	2 (13.3%)
	Laminoplasty	2 (25.0%)
	Posterior Fusion	16 (30.8%)
Spinal Cord Procedures – Thoracic		11 (24.4%)
	Ant/Post Fusion	0
	Posterior Fusion	2 (16.7%)
	DSC/SCS Implantation	5 (25.0%)
	Laminectomy	4 (33.3%)

Table 5: *Frequency of Reportable Events in Different Types of Spinal Cord Procedures.*

The incidence of reportable events in lumbar and thoraco-lumbar cases across procedures was 33.6%. For cervical and cervico-thoracic cases, the incidence was 28.1%, and for thoracic cases it was 24.4%.

Using a large sample of retrospectively examined cases from the Impulse Monitoring Inc. database, we report the frequency at which IONM personnel provided data-driven information to the surgical team, and the rate at which these data were acted upon via interventional adjustments in the surgical procedure. These cases were drawn at random and encompass a wide variety of orthopedic, neurosurgical, and ENT cases including spine, supra- and infra-tentorial craniotomy, parotidectomy, and thyroidectomy.

In particular, IONM personnel provided information acknowledged by the surgical team in 32.1% of cases for which IONM was used. Furthermore, of those cases, an observed, recorded surgical intervention by the surgeon or anesthesiologist was documented by the neurophysiologist 66.0% of the time (or 21.2% of all cases). Surgical interventions refer to steps taken by the surgical team in response to the IONM data that would not have occurred if no neurophysiologist attended the case. These interventions included moving retractors, repositioning limbs, adjusting anesthetic agents, re-applying or reversing surgical manipulations, removing and/or repositioning hardware, increasing blood pressure or improving perfusion. These interventions are not trivial and represented an important increase in patient safety in procedures for which IONM personnel were present and part of the surgical team [1,4].

Of cases for which reportable events were observed and documented in the case record, 34.0% were events that were acknowledged by the surgeon or anesthesiologist, but no observed intervention was documented in the case record. One reason for this is that a surgeon or anesthesiologist chose not to intervene in any way when the information was provided. This could occur, for example, if EMG firing was communicated during decompression of a spinal nerve root but the surgeon elected to continue the decompression as the risk of nerve root damage was weighed against the treatment benefit of completing the decompression. It is also possible that interventions were performed by a surgeon or anesthesiologist in response to reportable data, but that these interventions were not communicated to the neurophysiologist. Finally, there may have been some cases in which acknowledgement of the reportable event was documented by the neurophysiologist, but for whatever reason, the subsequent surgical intervention was not documented in the medical record. It should be noted that there were cases for which a reportable event was observed in the data and noted by the neurophysiologist in the record, but for which there was no direct evidence in the record that the surgeon either acknowledged the event or intervened in the procedure. Those were classified as cases for which there were no reportable data provided. For these reasons, the percentage of cases with reportable and interventional events likely represents a conservative estimate of the proportion of reportable and interventional events that occurred.

The overall percentage of reportable events in spine cases was 31.0%. Within spine procedure case-types, the percentage of cases with reportable events was 33.6%, 28.1%, and 24.4% for lumbar/thoraco-lumbar, cervical, and cervico-thoracic procedures, respectively. Interestingly, out of 17 different spinal procedure case-types examined, only three had a percentage of reportable events lower than 20% of cases; specifically 16.7%, 13.3% and 11.1%, for posterior thoracic fusion, cervical laminectomy, and anterior lumbar interbody fusion, respectively. Other reportable events in spinal surgeries having direct impact on patient safety include repositioning of a limb due to a change in evoked potentials (14.2%), surgeon-requested changes in anesthesia regimen resulting from changes in IONM signals (10.1%), changes in evoked potentials not related to limb positioning (8.2%), repositioning of a pedicle screw(s) based on IONM stimulation data (7.1%), and localization of nerve/nerve root using IONM (1.5%). Each of these types of events, if left without intervention, have the potential to result in patient injury [1,3]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.

The incidence of reportable events in ENT cases was extremely high, constituting 94.1% of ENT cases. The majority of these events (70.8%) involved the use of triggered EMG to localize nerves during thyroidectomy and related procedures. In the remaining 29.2% of

ENT cases with reportable events, the observed event was EMG activity in peri-laryngeal nerves. The incidence of reportable events in cardiothoracic cases was 36.4% (41.7% events related to perfusion, 33.3% changes in evoked potentials not related to limb positioning, and 25.0% changes in EEG). For craniotomy and skull-based procedures, the percentage of reportable events was 30.0% (46.7% changes in evoked potentials not related to limb positioning, 20.0% localization of nerve/mapping, and 6.7% each for requested changes in anesthesia regimen, EEG changes, evoked potential changes related to limb positioning, and sudden onset of seizure). With the exception of the single peripheral nerve case, there was no category of cases for which the incidence of reportable events, using our conservative estimates, was observed to be below 30%.

One limitation to the data relates to patient outcomes and post-operative status. As a contracted provider of IONM service, NCS neurophysiologists are not hospital employees and have limited access to post-operative outcomes. As such, it is difficult to gather long-term outcome data on the cases presented here. Future studies should encompass a partnership between IONM personnel, surgeons and facilities to provide long-term patient outcome data so that the effectiveness of surgical interventions in response to IONM reportable events can be more directly assessed.

The second limitation has been discussed by previous authors. Namely, that Level I controlled trials for IONM do not exist for many procedure types that frequently employ IONM. In the case of spinal fusion, the most investigated procedure-type involving routine IONM, we are aware of four level I, and seven level II investigations, as reviewed previously [3]. Furthermore, we are aware of no studies that examined the adverse effects of non-intervention after IONM personnel provide information regarding a reportable event to the surgical team. However, we can infer based on studies in animals and our understanding of the nervous system that lack of intervention when these events are reported has the high probability of leading to undesirable patient outcomes. Indeed, controlled animal experiments have established that evoked potentials respond to injury and demonstrate recovery with intervention in various induced injuries including spinal compression and ischemia [29,30], aortic occlusion [31,32]interruption of important spinal radicular vessels, or both. Intraoperative monitoring of the physiological integrity of the spinal cord should permit the early detection of spinal cord ischemia, the judicious and timely institution of corrective measures, including bypass or shunting, and the preservation of important intercostal arteries in appropriate circumstances. A model of spinal cord ischemia was created by temporary proximal and distal occlusion of the canine thoracic aorta. Serial measurement of somatosensory cortical evoked potentials (SCEP, and recurrent laryngeal nerve damage [33]. There are, however a host of level III, and IV investigations that provide evidence for the general effectiveness of IONM. Indeed, this evidence has become so strong that many experts warn against the initiation of level I trials as doing so would necessarily involve withdrawing IONM care in a prospective manner, a step that would expose patients in any control sample to increased risk of injury [28]. This matter has been discussed previously and it seems that - given the acknowledged risk - prospective randomized trials will likely never be completed [3].

Conclusion

In summary, we demonstrate that the incidence of reportable events as defined and presented here is common, and suggest the importance of knowledgeable IONM personnel in spinal and other types of surgical procedures. Communication of reliable reportable event information to the surgical team is the goal of IONM and promotes surgical intervention to improve outcomes and safety of procedures, and reduce surgery-related injury, leading to healthier patients and more cost-effective hospital stays.

Acknowledgements

Janine Gregory, provided critical review of the manuscript and guidance with IRB.

Shawn Masia, provided critical review of the manuscript.

Tom Conley, provided critical review of the manuscript.

Sam Johnson, provided critical review of the manuscript.

Author Disclosures

All authors of this article are employees of NuVasive Clinical Services.

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