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USE OF INTRAOPERATIVE NEUROPHYSIOLOGICAL MONITORING DURING SPINAL SURGERY

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This report was prepared for the Technology Assessment Unit (TAU)
of the McGill University Health Centre (MUHC)
by

Lonny Erickson, Ph.D, Technology Assessment Unit, MUHC
Vania Costa, Technology Assessment Unit, MUHC
Maurice McGregor, Cardiology Division, Department of Medicine of the MUHC

and approved and adopted by the committee of the TAU:
Juliana Arnoldo, Jeffrey Barkun, Andre Bonnici, James Brophy, Pierre Ernst,
John Johnston, Marilyn Kaplow, Maurice McGregor, Gary Pekeles,
Judith Ritchie, Gary Stoopler, Donatella Tampieri.

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Consultants:

Mme. Diane Bouchard, Montréal Children's Hospital, MUHC
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Dr. Gilles Plourde, Montreal Neurological Institue, MUHC
Dr. Bernard Rosenblatt, Montreal Children's Hospital, MUHC

Invitation.

This document was developed to assist decision-making in the McGill University Health Centre. All are welcome to make use of it. However, to help us estimate its impact, it would be deeply appreciated if potential users could inform us whether it has influenced policy decisions in any way.

E-mail address:

maurice.mcgregor@mcgill.ca ***james.brophy@mcgill.ca***

FOREWORD

In the fall of 2004, Dr. Françoise Chagnon, Director of Professional Services of the MUHC, requested that the TAU evaluate electrophysiological monitoring with particular attention to identifying the *standard of care*, to determining the indications for monitoring, the costs involved, and future trends in this field.

This report estimates the potential health benefits and budget impact of intraoperative neurophysiological monitoring (INM), in order to assist in determining whether this procedure should be available for all appropriate cases at the MUHC.

POTENTIAL CONFLICTS OF INTEREST

None declared

EXECUTIVE SUMMARY

Background

Because spinal surgery entails a risk of spinal cord injury, techniques to monitor spinal cord function intraoperatively have been developed. The main goal of such *intraoperative neurophysiological monitoring* (INM) is to permit identification of surgically induced neurophysiological changes so they can be corrected, thus avoiding postsurgical complications and permanent sequelae.

Objective

Evaluate the evidence in favor of implementing combined monitoring, using somatosensory evoked potentials (SSEP) and motor evoked potentials (MEP) for spinal surgery at the MUHC.

Methods

A literature review was conducted to identify studies that comprised at least 70 cases, of combined SSEP /MEP monitoring for spinal surgery published from 1995 to 2004.

Results

A total of 11 studies were identified meeting the inclusion criteria. No studies involved randomized comparisons, and all were simple case series. Despite this limitation, this literature gives ample evidence that INM allows potential intraoperative damage to the spinal cord to be identified rapidly and avoided through corrective action.

Health Benefits

Because the reported series vary greatly no precise estimate of the health benefits that might result from INM is possible. As a first approximation for the purpose of policy decisions, on the basis of the literature and reported present outcomes at the MUHC, it will be assumed that INM might prevent postoperative nerve deficit in approximately 3% of procedures, and might prevent severe and lasting deficits (eg. paraplegia) in 1% of procedures. Even nerve deficits that are not prevented are likely to be less severe as a consequence of the surgical adjustment resulting from monitoring. Furthermore, though this can also not be quantified, the assurance that monitoring gives to the surgeon is likely to result in more effective surgical procedures.

Economic issues

Budget Impact

It is estimated that approximately 100 surgical procedures per year require spinal monitoring at the MUHC at this time. Excluding all costs associated with the treatment of nerve deficits that might have been avoided by monitoring, and the costs of possible legal actions, it is estimated that to supply combined INM for 100 procedures per year at the MUHC would cost approximately $ 46 000*.*

Cost Effectiveness

Using the above assumptions it is reasonable to assume that the monitoring of 100 patients per year might prevent minor and transient postoperative lesions in two patients, and permanent serious defects in one patient per year. Ignoring the potentially very high costs that might be involved in the long-term care of patients with severe lesions, these health benefits could be achieved at the cost of approximately $ 46 000 the year to the MUHC.

Conclusions

There is good evidence to support the conclusion that intraoperative spinal monitoring during surgical procedures that involve risk of spinal cord injury is an effective procedure that is capable of substantially diminishing this risk.

In the absence of any precise estimates it is reasonable, for the purpose of this decision, to assume that an expenditure of approximately $46,000 per year (or $460 per patient) might prevent one patient suffering serious permanent spinal cord injury and less serious complications or sequelae in approximately 2 other patients. Even if the cost of maintaining such patients is excluded, this is a highly acceptable cost to benefit ratio.

A potential problem relating to the extension of combined SSEP / MEP monitoring to two MUHC sites is the relatively low rate of remuneration of the Neurophysiologists who play an essential role in this activity, and the resulting difficulty of recruitment

Recommendations

It is recommended that the MUHC make available combined SSEP / MEP monitoring for all cases of spinal surgery for which there is a risk of spinal cord injury.

Although professional remuneration is outside the hospitals responsibility, it is suggested that the MUHC, together with other institutions that undertake this form of monitoring, should consider drawing this problem to the attention of the FMSQ.

ABBREVIATIONS

ASCP	Ascending conducted spinal cord potentials
CMAP	compound muscle action potentials
eEMG	evoked electromyography
EMG	electromyography
EPs	evoked potentials
HTA	health technology assessment
IOM, INM	intraoperative neurophysiological monitoring
ION	intraoperative neurophysiology
IS	idiopathic scoliosis
MCH	MUHC- Montreal Children's Hospital
MGH	MUHC- Montreal General Hospital
MEP	motor evoked potentials
M-SEP	median nerve somatosensory evoked potentials
NMEP	neurogenic motor evoked potentials
NPV	negative predictive value
PPV	positive predictive value
SCEP	sensory cord evoked potentials
SEP, SSEP	somatosensory evoked potentials
tceMEP	transcranial electrical motor evoked potentials
T-SEP	tibial nerve somatosensory evoked potentials
TES, TCES	transcranial electrical stimulation

GLOSSARY

dura mater	the tough fibrous membrane that envelops the brain and spinal cord
epidural	situated upon or administered outside the dura mater
extubation	The removal of a tube from an organ, structure, or orifice; specifically, the removal of the tube after intubation of the larynx or trachea
hyperesthesia	increased sensitivity to stimulation
kyphosis	abnormal backward curvature of the spine
latency	delay period between stimulus and response for SSEP
percutaneous	effected or performed through the skin
scoliosis	a lateral curvature of the spine
sequelae	an aftereffect of disease or injury

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INTRODUCTION

Background

Operative procedures such as spinal instrumentation for scoliosis, neurosurgical spinal cord procedures, and some cardiothoracic procedures constitute a risk of injury to the spinal cord. Patients at greatest risk are those with kyphosis, congenital scoliosis, or pre-existing neurological impairment[1]. Damage may occur due to excessive stretching of the spinal cord, compression during fitting of instrumentation, trauma from passing wires near the spinal cord, or interference with spinal cord blood flow[1]. Although the risk of neurological complications is generally low, their consequences can be devastating, including paraplegia, tetraplegia or even death[2 3]. Because of the risks associated with spinal surgery, techniques by which spinal cord function can be continuously evaluated intraoperatively have been developed. The principal goal of such intraoperative neurophysiological monitoring (INM) is rapid identification of surgically induced neurophysiological changes to allow for their prompt correction before irreversible neurological impairment occurs[1,4].

Description of techniques to monitor intraoperative neurological function

The wake-up test

This test consists of lightening the anesthesia intraoperatively, and asking the awakened patient to move a limb [3]. Although still useful when the results of INM are equivocal, this test is not used routinely because it prolongs the duration of the surgical procedure, and entails risks such as tracheal extubation and agitation in prone patients with their spine exposed. In addition, the test may be difficult or impossible to perform in some patients due to pre-existing conditions such as partial paralysis or mental retardation.

Somatosensory Evoked Potentials (SSEPs)

Intraoperative monitoring using SSEPs consists of measuring neuronal integrity from the peripheral nerves through the dorsal columns of the spinal cord to the brain [3].

SSEPs have been used for more than 20 years. While the precise technique varies slightly between centers, protocols all involve stimulation of a peripheral nerve (i.e. tibial) while electrodes, either transcutaneous or transdermal, record the evoked potentials along the spinal pathway or on the scalp over the corresponding somatosensory cortex. Early in the surgical procedure when a steady anesthetic state has been reached, baseline SSEP waveforms are recorded which are compared to those subsequently procured during the procedure. A decrease in SSEP amplitude of 50% and an increase of latency of 10% are commonly used as thresholds for intervention [3]. Routine use of SSEP during scoliosis instrumentation surgery was endorsed by the American Scoliosis Research Society in 1992 [5]. While no precise statistics are available, the literature indicates that use is widespread in larger, specialized and/or university-affiliated hospitals but is used in a variable percentage of surgeries depending on the institution. Little data is available on use in Canadian hospitals, other than the fact that monitoring is used in university affiliated hospitals in Ontario, British Columbia, Alberta and Quebec. According to an expert at the MUHC, <no university, or university affiliated hospital would undertake scoliosis correction without monitoring in Canada> (Ouellet J, personal communication).

Some limitations of this technique have been identified in the literature. While SSEP may be influenced by motor damage[6], it cannot provide reliable information on the functional integrity of the motor system. Another important limitation of SSEP monitoring is the delay produced by averaging procedures for waveforms. In a recent study, [7] changes in SSEP had an average delay of sixteen minutes versus MEP.

Motor evoked potentials (MEPs)

MEP techniques, which monitor motor pathways of the spinal cord, have been increasingly used in the last decade. The cerebral cortex is electrically or magnetically stimulated transcranially, using surface or needle electrodes. This can also take the form of direct (epidural), or indirect (percutaneous) stimulation of the spinal cord or brainstem [8]. However, transcranial electrical stimulation techniques (TCES) have been proposed as the preferred method of MEP stimulation [9]. The motor evoked potentials produced may be recorded directly from the spinal cord with epidural electrodes [8] or from peripheral nerves or muscles [9] . Loss of motor potential may be associated with motor deficit after the operation [8], and motor deficits are generally considered to be more functionally devastating to the patient than sensory deficits [10].

In contrast to SSEP monitoring, MEP monitoring is virtually instantaneous, thus reducing reaction time for the surgical team[11]. Though not yet a standard of care, MEP monitoring has been observed to be a safe technique [12] ;[13] and has developed significantly in the last decade into a feasible, reliable technique that will probably become indispensable during spinal cord surgery [4]

Combined SSEP/MEP monitoring

Intraoperative spinal cord injury during spinal surgery generally compromises both motor and somatosensory pathways [14]; [9], therefore the use of both of these independent techniques in parallel has been recommended recently [4] [14,15] and is seen as a safeguard should one of the monitoring techniques fail. Combination of SSEP monitoring with MEP monitoring is also proposed to reduce false–positive results, and eliminate the need for the wake-up test [16,17]. In several reports combined SSEP and MEP monitoring has been shown to have greater sensitivity than SSEP alone [7,18-20] [21]; [22]. Indeed, studies have given examples of better detection of deficits with combination of these two methods [23]. For example, SSEPs can detect abnormalities not detected by MEPs in a given patient, and vice-versa [19]. Addition of MEP monitoring where SSEP monitoring is already being performed is considered to be relatively straightforward, adding little to the overall cost of INM [18]. In addition, recent publications have reported success in combined methods for additional types of interventions not previously monitored, such as those with neuromuscular scoliosis [24]. Use of combined SSEP/MEP monitoring is expected to increase and perhaps become the new standard in coming years.

DEFINITIONS

There is some confusion in the literature due to a lack of standardization in reporting of study results and imprecise use of terms that are frequently not defined. In this report we will use the following terms:

Abnormal INM results (positive tests)

Abnormal evoked potentials can be the result of monitoring errors or true intraoperative neural damage. In this report, the percentage of **abnormal INM results** is the number of patients for which results of INM were judged as abnormal (according to the criteria used at the locations of intervention) divided by the total number of monitored patients x 100%.

In the literature the term "**true positive"** is often used to describe an abnormal INM result that is followed by a neurological deficit after surgery. However, this term is misleading in terms of evaluating test performance. The goal of INM is not to simply predict postoperative neurological status, but rather to allow the intervention team to be warned of impending neurological damage as it occurs. This allows compensatory action to reverse or at least minimize damage. In the case of scoliosis correction, this can take the form of diminishing the amount of correction. If this is successful, the patient with real, but reversed neurological damage will have a positive monitoring result, but no neurological deficit postoperatively. This type of case will often be referred to as "false- positive" in published studies, suggesting that abnormal INM results occurred without real neurological damage. Despite this lack of postoperative deficit, abnormal INM results have correctly identified these patients as having real neurological damage, and therefore should also be considered as "true positives". Due to this potential for misclassification and the lack of standardization of the use of these terms in the literature, they will generally be avoided in this report.

Negative INM Results

Absence of significant changes in EPs (i.e. decreased amplitude and /or increased latency of waveforms) throughout the surgical procedure, constitutes a negative INM result.

True-negative results

Negative monitoring results in patients that are not followed by postoperative deficits are classified as true negative results.

False-negative results

Negative monitoring results that **are** followed by postoperative deficits are classified as false-negative results. The rate of false-negative tests has been proposed as being the most important parameter in evaluation of INM, due to the fact that this situation (postoperative deficit not detected by monitoring) is the most devastating for the patient.

Potential causes of false-negative tests, other than failure of monitoring, could include damage in areas other than monitored pathways, or events occurring after monitoring had ceased [25]. Thus, a review of six "false-negative" cases who suffered new postoperative neurological deficits despite stable intraoperative SSEPs found that in 3 of these, the new deficit probably developed postoperatively, and in two of the three remaining cases, EPs showed losses which were less than the 50% threshold for intervention [26]. It has been observed that the term 'false-negative" should be interpreted with caution, as criteria are not always clearly defined [27].

Sensitivity and Specificity

In the literature much emphasis is placed on **sensitivity** and **specificity** of INM (see). However, as already observed, the goal of INM is not simply diagnosis but rather an ongoing monitoring mechanism to alert the surgeon to pathological changes and allow feedback to reduce or reverse these changes. Calculations of sensitivity and specificity include true-positive and false-positive rates (see Appendix 2). As previously mentioned, these rates cannot be determined with confidence from the literature, and they will be avoided in this report. This is also true for the related term **positive**

predictive value that refers to the probability of actually having the condition when the test result is positive.

Negative Predictive Value

By contrast, the negative predictive value (the probability of actually not having the condition when the test result is negative) of INM can be estimated with greater confidence since the numbers of true-negative and false-negative tests are clearly reported.

LITERATURE REVIEW

The literature was reviewed to seek to answer the following questions:

1) What is the evidence that abnormal (positive) monitoring results accurately warn of impending neurological deficits?

2) What is the frequency of abnormal (positive) IOM results*?*

3) What is the frequency of false negative results (postoperative deficits that occur in the absence of any monitoring abnormality during surgery)?

4) Does modification of the surgical procedure in response to abnormal monitoring results successfully prevent or diminish the occurrence of postoperative deficits?

5) What is the severity of the deficits that might be prevented?

Methodology

In December 2004, a preliminary literature search was conducted using Medline, accessed via the PubMed interface. The following search terms were used: *cord monitoring* or *evoked response* or *evoked potential* or *motor tract* or *electromyography* or *nerve root monitoring* or *sensory evoked* or *somatosensory evoked* and *spine surgery* or *spinal surgery*. Articles in English, French, Spanish and German were retained. To identify additional studies, the initial search was also repeated using the Ovid Medline interface. Websites of Canadian and international HTA agencies were consulted (see Appendix 1) Finally, Internet searches were conducted with the same terms via the Google and Google Scholar search engines. Additional studies from the reference lists of published articles were also obtained when possible. The preliminary list of identified studies is presented in Appendix 3.

Selection criteria for identified studies

Number of cases

The influence of experience on outcome is considerable [6]. Since there is considerable experience with INM at the MUHC only series with at least 70 cases were reviewed.

Date of publication

As surgical and INM techniques are expected to have evolved over time with refinements of equipment and procedures, only series published in 1995 or later were reviewed in detail.

Combined SSEP and MEP monitoring

There is growing evidence that combination of these two techniques provides optimal results, and as soon as possible combined sensory and motor monitoring will be used routinely at the MUHC (Ouellet J, personal communication). Therefore, only studies using a combination of these techniques were selected for review.

Results of literature review

In addition to numerous review articles, 11 studies were identified that were consistent with our selection criteria (see Table 1). These were abstracted with the objective of answering the following questions:

1) What is the evidence that positive monitoring tests accurately predict neurological deficits?

Numerous case studies attest to the fact that uncorrected positive monitoring results correlate with post-operative functional deficits, and that such deficits rarely occur in the absence of positive intraoperative monitoring results. However, no trial has been carried out to establish the predictive accuracy of these tests, since it is widely accepted that potential post-operative neurological deficits can be detected and any failure to make surgical corrections in the presence of an abnormal test would be ethically unacceptable [27,28]. Thus, evidence that test results predict outcome depends largely on case reports in which intraoperative adjustment of surgical procedure has been insufficient to prevent postoperative deficit.

In another report involving MEP monitoring of 132 patients undergoing surgical correction of spinal deformities, an abnormal intra-operative monitoring result was identified in 16 patients (12%). Corrective surgical maneuvers in 13 of these patients resulted in normalization of monitoring without postoperative neurological deficits in 11. In the two remaining subjects with corrective maneuvers, monitoring status failed to normalize and postoperative neurological function also deteriorated [11].

As a result of such accumulated evidence, much of which is not formally reported, there is now wide acceptance of the ability of INM testing to predict the appearance of postoperative defects with reasonable accuracy.

2) How frequently are abnormal (positive) INM results observed?

Table 1 reflects the outcomes of 11 studies reporting the outcomes of combined SSEP and MEP monitoring of spinal procedures (with at least 70 cases, published in 1995 or later). They involve very different types of surgery and patients of various ages, thus it is not surprising that the percentage of procedures associated with a positive intraoperative test also varies widely, ranging from 1.8% to 31% (simple average 9.1%, weighted average 6.7 %). These results would be influenced by the experience of the monitoring team, with more experienced teams having fewer positive results without real deficits (Nuwer, 1995). In addition, the case mix of patients being operated on and the technique of each surgeon can affect this percentage, which should be higher if a greater number of high-risk patients and procedures are being attempted at a particular institution.

These data suggest that the frequency of positive tests, and by inference of potentially preventable postoperative deficits, may be as high as 7%, and vary greatly according to series, ranging from approximately 2% to 30%. However, at the MUHC abnormal intra-operative test results are observed in less than 2% of procedures. (Dr. B. Rosenblatt, personal observation).

For the purposes of these estimates it will be assumed that positive INM test results might be observed in 3% of procedures at the MUHC.

TABLE 1: Studies using combined SSEP and MEP selected from Literature Search

Author Year	Intervention	N with INM *	Age Yr. (range)	Reported Abnormal INM (%)	% with corrective measures	est. % with avoided. complications	Number with postoperative Deficits (%)	Persistent Deficit (%, at end of study follow-up period)	False neg. rate (%)	comments
Bose, 2004[29]	cervical spine surgery	119	46 (24-82)	6/119 (5%)	not reported		3/119 (2.5%)	1/119 (0.8%)	0	Patient with severe deficit could not be monitored with MEP
Calancie, 2001[18]	Spine Surgery	185	50 (9-89)	58/145 (31%)	Not available from publication					Rate of abnormal INM is for subset of 145 patients
Délecrin, 2000[30]	Spine Deformity	149	28 (13-72)	6/149 (4%)	not reported	3.3%	3/149 (2%)	1/149 (0.7%)	0	
Hilibrand, 2004[7]	Cerv.Spine Surg	427	50 (15-95)	12/427 (2.8%)	2.3%		2/427 (0.5%)	1/427 (0.2%)	0	
Iwasaki, 2003[31]	Mixed Spine Surg	672	(3-88)	23/672 (3.4%)	1% (7/672)		Not specified in publication		4/672 (0.6%)	Abnormal INM includes 7 'true-positives' with abnormal waveforms and correction
Langeloo 2003[11]	Spine Deformity	132	29 (4-82)	16/132 (12%)	9.8% (13/132)	7.6%	2/132 (1.5%)	2/132 (1.5%)	0	
Nagle, 1996[14]	Mixed Spine Surg	108	(2m. 77)	9/108 (8.3%)	3.7% (4/108)		9/108 (8.3%)	1/108 (1%)	0	status of deficit unkown for 1 patient who died of sepsis
Noonan, 2002[23]	Scoliosis	71	14 (11-19)	10/71 (14%)	not clear		5/71 (7%)	0 (all resolved within 18 months)	0	134 had SSEP,(71 of which had both SSEP & MEP)
Padberg, 1998[17]	Scoliosis	500		9/500 (1.8%)	not reported		2/500 (0.4%)	0	0	
Pelosi, 2002[32]	Spine Deformity	124	22 (+/- 13.9)	16/124 (12.9%)	not reported		6/124 (4.8%)	1/124 (0.8%)	0	104 patients had SSEP and MEP, 18 had SSEP only, 2 had MEP only= 124 patients
Stephen, 1996[33]	Spine Deformity	160	14 (4-18)	8/160 (5%)	5%	5%	0	0	0	
Unweighted average				9.1%	4.4%	5.3%	3.4%	0.6%	0.06%	
overall rate of occurrence (pooled studies)				173/2607 (6.7%)			32/1636 (2%)	7/1636 (0.4%)		
range				1.8-31%	1-9.8%	3.3-7.6%	0-8.3%	0-1.5%	0-0/6%	

* n includes patients for whom recording of SSEP, MEP or both were possible during surgery. Those patients for whom neither SSEP nor MEP could be recorded were excluded.

3) What is the frequency of false negative tests observed?

This refers to cases in which postoperative deficits occur in the absence of any monitoring abnormality, and information was available in 10/11 studies. The data shown in Table 1 indicate that false negatives are very rare with combined SSEP and MEP monitoring. In the only study reporting false negatives the rate was 0.6% (4/672 cases), giving an average frequency of false negative tests for all 10 studies of only 0.06%.

These resuts indicate that combined SSEP and MEP monitoring should detect almost all cases with true intraoperative problems.

4) Does modification of the surgical procedure in response to abnormal INM results successfully prevent or diminish the occurrence and severity of postoperative deficits?

The benefit of modification of the surgical procedure in response to abnormal INM results has been well demonstrated in the literature. For example, recovery of postoperative deficits in spinal surgery has been observed to be directly proportional to the speed of removal of instrumentation [34]. However, a precise estimate of the magnitude of this benefit cannot be obtained. This is due to the fact that few studies attempt to estimate the extent to which monitoring diminishes the occurrence and severity of postoperative deficits.

While there are no consistent data reflecting the number of patients who benefited from monitoring in these reports, some idea of the possible benefit of monitoring can be deduced from Table 1. If the two series in which postoperative outcomes were not reported are excluded [18, 31], a total of 92 of the 1790 (5%) subjects who underwent corrective surgery developed abnormal INM results during surgery. Immediately following surgery only 32 of these had new deficits (1.8%), and only 7 (0.4%), had persistent deficits at the end of the follow-up period (or 22% of all immediate post operative defects.

However, this information may underestimate benefit if only those patients who have no postoperative deficits are considered to have benefited from INM [14]. For example, some patients who have postoperative deficits may still have benefited from corrective measures due to abnormal INM results that reduced the severity of their postoperative deficits. On the other hand, some patients with abnormal INM results perhaps may not actually have had abnormalities, whereas others may not have benefited from corrective action. Therefore, in the absence of better information, the rate of abnormal INM results gives an indication of the maximum percentage of patients in a given series who could be expected to benefit from INM.

Three of the eleven studies in this series examine what percentage of patients with abnormal INM results actually benefited from appropriate corrective measures and estimated the percentage of patients with avoided complications to be 3.3%, 7.6%, and 5% [11,30,33]. This represented 82.5%, 63%, and 100% respectively of all cases with abnormal INM results, or (in the 2 studies for which data were available) 78% and 100% of patients with corrective measures [11,33].

Although there are obvious differences between the cases reported, it would appear from the above observations that corrective action resulting from abnormal INM results will usually (60%-100%) be followed by normal postoperative function. In monitored cases at the MUHC there has been no case of neurologic deficit for many years(Dr B Rosenblatt personal observation).

For the purpose of these estimates it will be assumed that monitoring at the MUHC can be expected to complete the prevent the occurrence of postoperative defects.

5) What is the severity of the postoperative deficits that might be prevented?

The severity of postoperative defects, when described in these reports, is also quite variable. The majority of the reported defects were clearly neither extensive nor permanent. However, in a small percentage of patients (0.4%)

deficits were persistent and often quite serious (mostly cases of paraplegia) despite use of INM. On average, persistent deficits accounted for approximately 22% of all reported deficits in these studies. Furthermore, in the absence of INM, some deficits would most probably be more severe. However, in the absence of any series carried out without any procedure modification, the actual number of severe deficits that might result from these forms of surgery will remain unknown. *Apart from these observations there is no way of knowing the percentage of potential post operative lesions that might be severe and lasting. For the purpose of these estimates it will be assumed that up to 20% of all post operative deficits that would occur in the absence of monitoring would be severe and persistent.*

Anticipated Health Benefits of INM

From the preceding paragraphs it is clear that no precise estimate of the likely outcomes of monitoring at the MUHC can be made. However, as a first approximation, based on the reported results in the literature and the current experience at the MUHC, we will assume that at the MUHC, in the absence of monitoring, 3% of patients might have postoperative deficits, and that 20% of these deficits (0.6% of all patients) would be expected to be permanent. Furthermore, it will be assumed that with effective monitoring virtually all postoperative neurologic defects would be prevented.

Current use of INM

INM, specifically SSEP monitoring, has been used at the Montreal Children's Hospital of the MUHC for several years. Present turnover is approximately 50-75 cases per year

(Ouellet J, personal communication). SSEP monitoring techniques are also used for spinal surgery at the Shriner's Hospital in Montreal where the turnover (approximately 50 proceedures per year), the Montreal General Hospital of the MUHC, (approximately 15 adults are operated annually for scoliosis without INM) (Ouellet J, personal communication), and *Hôpital Ste-Justine* (approximately 80-100 cases per year; Labelle H, Dept. of Orthopedics, *Hôpital Ste-Justine*, personal communication). MEP monitoring is not apparently in general use in these institutions.

COSTS

The estimated costs of assuring the availability of combined INM at the MUHC are based on the assumption that until the establishment of a spinal Center where all spinal surgery can be concentrated, it will be necessary to provide monitoring at the Montreal Children's Hospital (MCH) and the Montreal General Hospital (MGH) through use of portable equipment. Inclusion of the Shriners Hospital is also a possibility. Cost estimates will be based on a projected 100 patients a year

Testing Equipment

Actual cost for such equipment will depend on the planned use and models chosen, and prices can range from $35 000 for a basic system up to $60- $100 000 for the latest generation of multi-modality monitoring systems. (Roxon Medi-Tech, Montreal, personal communication; Axon Systems Inc., Hauppauge, New York, USA, personal communication).

A recent estimate (April 2005) for the total cost of a portable SSEP/ MEP combined monitoring unit with 2 trolleys and 2 computer screens enabling the unit to be used at 2 hospitals arrived at a total amount of $ 69 600 (see Appendix 2). A one time training cost of $ 5 000 for use of combined SSEP/MEP monitoring will also be included in this cost for a total of $ 74 600.

Thus, capitalized over 8 years the cost of testing equipment would be equivalent to approximately $ 9 325 per year.

Expendables

Annual cost of expendables is minimal and includes basic materials such as gauze, alcohol, and re-usable electrodes (Bouchard D R, personal communication), and can therefore be excluded.

Staffing requirements

Spinal monitoring during surgical procedures, including the performance of a preoperative test, is one of several activities of the Neurophysiological Laboratory of the MUHC, and is carried on under the overall supervision of a staff neurophysiologist. It is estimated that to increase the caseload to 100 interventions per year, at two MUHC sites would require the enrollment of one additional technician, with an estimated salary of $37,000 per year. The cost of the neurophysiologist is not a charge to the MUHC budget and is not considered here.

Estimated annual cost to the MUHC

With these several assumptions, the total estimated cost per year = $9 325 + 37 000+ = $ 46 325, and the total estimated cost per patient =$ 463 (assuming 100 per year)

For comparison, a recent German study estimated the cost per case for monitoring of spinal interventions to be 196.40 Euros. (US$=261 or Can$ 326 @ 0.8/US$) [35]. An analysis at the Mayo Clinic in the United States found a cost per case (monitoring 351 patients using SSEP) of US$570 or Can $712 @ 0.8/US$)[28].

None of the above estimates include the potentially high legal costs avoided or the cost of long-term care that might be associated with the occurrence of permanent neurological defects during spinal surgery.

COST-EFFECTIVENESS

Any attempt to formally estimate the cost-effectiveness of INM would be inappropriate in view of the uncertainty surrounding the health gains that might be realized. However, for the purposes of arriving at policy decisions it is necessary to make a first approximation on the basis of the available evidence.

From the point of view of the MUHC, based on the preceding assumptions, the health benefit of combined motor and sensory INM would be the prevention of a postoperative defect in 3 % of all operations, and of serious postoperative defects such as paraplegia in 0.6%. This health benefit would be achieved at an estimated total annual cost to the MUHC of approximately $46,000.

This estimate does not include possible legal costs that might be associated with absence of monitoring or the cost of managing the minor temporary defects, or the potentially very significant financial cost of caring for a patient with a serious permanent neurological deficit over the period of an entire lifetime.

DISCUSSION

Should monitoring be "standard care"?

SSEP has now been in wide use for many years. As long ago as 1991 a postal survey of members carried out by the Scoliosis Research Society and the European Spinal Deformity Society, with a 74% response rate fond that 188 (78%) of responders were using intraoperative SSEP monitoring. Some authors consider that these techniques should be recommended for general use in appropriate orthopedic, neurosurgical, and cardiovascular procedures, especially when experienced monitoring teams are available[1], and mandatory whenever neurological complications are expected on the basis of a known pathophysiological mechanism[10,4] . In view of the additional advantages of MEP screening listed above, and the high probability that a significant number of nerve defects can be prevented, it would seem that INM monitoring should be available whenever this type of surgery is carried out

An additional reason for having INM available, over and above its ability to reduce the rate of postoperative nerve defects, is the reassurance that it can give to the surgical team. With such assurance, surgery such as scoliosis correction can be pursued more thoroughly when the surgeon will be warned of potential damage before it becomes reversible.

Thus there is good reason to make combined sensory and motor INM available for all spinal procedures carried out at the MUHC.

Staffing problems

A practical obstacle to the extension of spinal monitoring to 100 operative procedures per year, carried out at two MUHC sites, is the availability of a neurophysiologist. Effective spinal monitoring is a technically complex procedure that requires the constant availability of a neurophysiologist throughout the procedure, and in some centres involves the presence of a neurophysiologist in the operating room. However, the professional fee available for this activity in Québec is low in comparison with comparable professional activities, and in consequence it is difficult to recruit individuals to take on this task.

CONCLUSION

There is good evidence to support the conclusion that intraoperative spinal monitoring during surgical procedures that involve risk of spinal cord injury is an effective procedure that is capable of substantially diminishing this risk.

In the absence of any precise estimates it is reasonable, for the purpose of this decision, to assume that an expenditure of approximately $46,000 per year might prevent three transient post-operative neurologic defects annually, and one patient suffering serious permanent spinal cord injury approximately every second-year.. Even if the cost of treating these potential patients is excluded, this is a highly acceptable cost to benefit ratio.

RECOMMENDATIONS

It is recommended that the NU HC make available combined SSEP/MEP monitoring for all cases of spinal surgery for which there is a risk of spinal cord injury.

A combined request from all Québec institutions that provide monitoring, to the FMSQ to review the level of remuneration for this task should be considered.

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Appendix 1 List of HTA databases included in literature search.

Health Technology Assessment Agencies:
- CHSPR – Centre for Health Services and Policy Research (UBC) British Columbia
- HSURC – Health Services Utilization and Research Commission (Saskatchewan)
- ICES – Institute for Clinical Evaluative Sciences
- MCHP – Manitoba Centre for Health Policy
- INAHTA database – International Network of Agencies for Health Technology Assessment

Members of INAHTA (agencies included in the INAHTA database):

AÉTMIS - Agence d'évaluation des technologies et des modes d'intervention en santé

AHFMR - Alberta Heritage Foundation for Medical Research

ANAES - L'agence nationale d'accréditation et d'évaluation en santé

ASERNIP-S– Australian Safety & Efficacy Register of New Interventional Procedures - Surgery

CAHTA - Catalan Agency for Health Technology Assessment and Research

CCOHTA – Canadian Coordinating Office for Health Technology Assessment

CÉDIT – Comité d'évaluation et de diffusion des innovation technologiques

CMT – Center for Medical Technology Assessment (Sweden)

DACEHTA – Danish Centre for Evaluation and Health Technology Assessment

DIMDI – German Institute of Medical Documentation and Information

DSI – Danish Institute for Health Services Research

FinOHTA – Finnish Office for Health Care Technology Assessment

ITA – Institute of Technology Assessment ((Austria)

MSAC – Medical Services Advisory Committee (Australia)

NCCHTA - National Coordinating Centre for Health Technology Assessment

NHS QIS - NHS Quality Improvement Scotland

NHS – National Horizon Scanning Centre

NICE – National Institute for Clinical Excellence

SBU – The Swedish Council on Technology Assessment in Health Care

SNHTA – Swiss Network for Health Technology Assessment

TA-SWISS – Center for Technology Assessment

Appendix 2: Estimated Costs for Portable INM Equipment to Perform Combined SSEP and MEP monitoring*

Cadwell Cascade	$ 65 000
2 x trolleys	$ 2 000
2 x computer screens	$ 1 600
1 x printer	$ 500
Accessories(electrodes etc…)	$ 500
Total	**$ 69 600**

* Source: Diane Bouchard, INM Technician, Montreal Children's Hospital- MUHC, personal communication, April, 2005

Appendix 3: Preliminary list of identified studies, in decreasing order of size

Study / Year / N	Type of Monitoring / Comparative ?	Type of Surgery / Other Characteristics	Technical failures	Neurological complications	False-positives False-negatives	Comments
Dawson et al., 1991 n= 60 366 (survey 1); n= 33 000 (survey II)	SCEP	spinal surgery		1.6% in survey II.	survey II: 248 FP, 25 FN, 161 TP SCEP correctly predicted a postoperative deficit 72% of the time when one was present. 28% of deficits were not detected by SCEP.	results collected by survey questionnaires
Nuwer et.al (1995) N= 51 263	SEP	Scoliosis 60% Fractures 7.5% Kyphosis 6.5% Spondylolisthesis 5.5%		0.55%	FP= 1.5% FN= 0.13%	Large n but data was collected by postal survey.
Forbes (1991) N= 1168 (included 1981-1990) Not comparative	SSEP (Medelec MS91 electromyograph) – evaluated by changes in amplitude	Scoliosis: IS (67%) Congenital/neuromuscular: 21% Mean age: 15.6 (range: 5-57)	26 (2.2%) – not associated with complications	**Persistent complications** Mild – 24 (2.1%) Severe: 8 (0.7%) Loss of amplitude may be caused by dislodgement of the electrode	False-positive: 52 (4.5%) False-negative: 0	Risk of complications may be related to underlying disease Criterion used for significant loss of amplitude: > 50%
Iwasaki et al, 2003 n=716	various types of SEP, MEP	various (cervical myelopathy, spinal cord tumor, thoracic myelopathy, spinal cord injury, etc.)	in 6.1% of patients	avoided in 7 patients	FN= 4 patients FP= 4	series from Japan, over long time period (15 years)
Weidemayer et al, 2004. n=658, 209 of these were for spinal cord	SEP	high-risk neurosurgical procedures (208 were spinal surgery)			Spinal cord operations (n=209): 6FP, 6FN; (2.8%) Sensitivity=88% for minor and severe deficits; 100% for severe deficits only.	
Padberg (1998) N=500 (included 1987-1997)	SSEP NMEP Wake-up test used to confirm electroph. findings (baseline data used as reference)	Idiopathic Scoliosis – 100% Mean age: 18 (81% - 11-20yrs)	-	0.4% No complications: 98.2%	False-positive: 7 (1.4%) False-negative: 0	

Study / Year / N	Type of Monitoring / Comparative ?	Type of Surgery / Other Characteristics	Technical failures	Neurological complications	False-positives False-negatives	Comments
Hilibrand (2004) N=427 (included 99-2001) Retrospective chart review	TceMEP (Transcranial electric motor evoked potential) SSEP	Cervical spine surgeries Age range:15-90	-	**Relevant changes detected:** tceMEP: **12 (100%)** SSEP: **3 (25%)** **New Neurological injury: 2 (0.47%)** – paraplegia and transient upper-extremity weakness **4 (0.9%)** – surgical intervention reverted the injury identified by tceMEP **6 (1.4%)** – changes in tceMEP reverted by increase in BP / corticost.	**tceMEP** False-positive: 0 False-negative: 0 **100% specificity and sensitivity** **SSEP** False-positive: 0 False-negative: 9 **100% specificity and 25% sensitivity**	Criterion for clinically relevant change: loss of amplitude >= 60% over for at least 10 minutes SSEP only identified 1 of the 2 injuries and with a 33 min. delay – delay in identification of injury was seen in all other cases where a change in SSEP was detected
Wiedemayer et al., 2002. n=423 case series	SSEP, brainstem auditory evoked potentials				TP with intervention=10%, TP w/o intervention= 10%, FP=2%, FN=4%, TN 74%.	Analysis indicated that INM prevented postoperative deficits in 5.2% of monitored cases
Manninen (1998) **Toronto** N=309 (included 94-95) Retrosp. chart review	SSEP	Spinal surgeries (cervical, thoracic, lumbar) – scoliosis – 21%		**Relevant changes detected: 16 (6%)** New neurological deficit (among 272 pts with baseline recordable signs): 7 (2.6%) 3 (0.9%) – persistent	False-positive: 4.4% False-negative : 1.1% Specificity: 95% Sensitivity: 57%	Transient deficits: lasting < 24hs Persistent deficits: present at time of discharge Baseline tracings used as reference
Owen et al.,1991 n=300 case series	SSEP, neurogenic MEP	spinal surgery			17 false-positive NMEPs; 54 false-positive SEPs	combining MEPs and SSEPs warrants more study
Tamaki et al., 1984 n=229	SEP			6 patients had postoperative neurologic complications indicated by SEP changes		
Gunnarsson et al., 2004 **Toronto** n=213 case series	SSEP, EMG	disc herniation 35%, spinal stenosis 21%, segmental instability 19%, and various other diagnoses.	SSEP not performed in 10 patients (4.7%), EMG not performed in one patient	14 patients (6.6%) had new neurologic symptoms, all of these had significant EMG activation and 4 of these had significant ntraoperative changes in SSEP.	SSEP: sensitivity= 29%, specificity =95%; EMG sensitivity=100%, specificity= 24%.	combination of SSEP and EMG allows for high specificity and sensitivity

Study / Year / N	**Type of Monitoring / Comparative ?**	**Type of Surgery / Other Characteristics**	**Technical failures**	**Neurological complications**	**False-positives False-negatives**	**Comments**
Sebastian et al., 1997 n=210 (Abstract of article)	SSEP	anterior surgery for cervical myeloradiculopathy		intraoperative SEP changes in 84 patients. Traces of 44 patients improved markedly during surgery. No cases of irreversible medullary or nerve-root deficit.	no false negatives	
Calancie et al.,2001 n=194	SSEP, TES	spine surgery	TES not monitored in 9 patients; SSEP not monitored in 42 patients.	29 true positives detected by SSEP and TES	SSEP= 4 FP, 3 FN; TES= none	
May et al., 1996 n=191	SSEP	cervical surgery	9 patients	neurological signs developed pos-surgery in 10 patients	sensitivity=99%, specificity 27%, 50% of patients with complete loss of SSEP had neurological damage.	high sensitivity may indicate a high rate of prevented incidents
Gundanna et al., 2003. n=186	SSEP	lumbar pedicle screw placement		no patients had significant SSEP changes, however 5 patients had new deficits	5 false negatives	Authors conclude that use of SSEPs in evaluating pedicle screw placement is limited and alternative methods with greater sensitivity should be explored.
Komanetsky et al.,1998 (Abstract of article) N=184	Comparison of spinous and percutaneous NMEPs	spinal deformity surgery		<both methods were found to be sensitive to neurologic deficit>		reliability of two methods not significantly different and percutaneous method is less invasive.

Study / Year / N	Type of Monitoring / Comparative ?	Type of Surgery / Other Characteristics	Technical failures	Neurological complications	False-positives False-negatives	Comments
Lille et al., 1993 n=165 (Abstract of article)	SEP, some with MEPs	spinal orthopedic surgery in adults			<durable disappearance of SEPs and MPs was always associated with post-operative neurological disorders>	
Stephen et al., 1996 N=160	Combined SEP and MEP	Spinal surgery in children	14% total : EPs not obtained for 2% of patients, MEP only for 4%; SEP only for 8%	none	None- correction occurred after abnormal monitoring	
Cohen et al., 1991 n=154 (Abstract of article)	Pudendal nerve evoked potential	low sacral fixation procedures	responses lost for one case; responses difficult or impossible to interpret in 11 cases.	no patients had postoperative deficit to the sacral roots or to the global cord	no false positives	
Beatty et al., 1995 n=150 (Abstract of article)	electromyography recordings	spinal surgery for radiculopathy		preoperative electrical discharge recorded in 18% of cases which ceased after nerve decompression. Electrical discharges also produced regularly upon nerve root retraction.		Authors conclude that continuous electromyography monitoring can be accomplished easily and yields valuable information that indicates when the nerve root is adequately decompressed or when undue retraction is exerted on the root.
Delécrin et al, 2000. n=149 retrospective case analysis	NMEPs combined with SSEPs	surgery for spinal deformity (scoliosis)		6cases, in 5 of which the neurological defect could be avoided	no false negatives.	
Langeloo et al., 2003. n=145.	tceMEP	surgery for spinal deformity	monitoring discontinued in 2 patients due to absence of neurological signs	16 patients had surgically induced deficits, corrective maneuvers were performed in 13 patients, resulting in recovery in 11 of 13 patients.	3 scenarios for monitoring were examined, best of which gave sensitivity of 100% and specificity of 91%.	
Fujioka et al., 1994 n=134 (Abstract of article)	ACSP- ascending conducted spinal cord potentials	corrective surgery for scoliosis.		5 patients with postoperative neurological damage exhibited more than 50% changes in amplitude of the ASCP during surgery.	<no false negatives, but some false positives>	

Study / Year / N	Type of Monitoring / Comparative ?	Type of Surgery / Other Characteristics	Technical failures	Neurological complications	False-positives False-negatives	Comments
Noonan et al., 2002 N=134	SSEP or combined SSEP and MEP	Adolescent idiopathic scoliosis surgery		4.5% had postoperative motor or sensory deficits, all resolved within 18 months	4.5% false positive	
Pelosi et al., 2002 n=126 operations in 97 patients	Combined SEP and MEP	orthopaedic spinal surgery (spinal deformity in 97 patients)	no response to either modality in 2 patients; SEPs not recorded in 16 patients and MEPs not recorded in 2 patients	EP changes in 16 patients; 6 of which had new deficits	no false negatives for MEPs; 4 false negatives for SEPs (2 which were normal and 2 which were transiently abnormal before resolving).	
Bose et al. (2004) n= 119	SSEP, tceMEP	Cervical spine surgery		6 neurophysiologic alerts occurred which prompted surgeon and/or anesthesiologist intervention.		
Nagle et al., 1996 n=116	combined MEP and SEP	operations on spine or spinal cord	8 patients- neither MEP nor SEP recording possible, SEP only possible in 2 patients, MEP only in 7 cases.	Deterioration of evoked potentials in 9 cases (8%). In 4 of these cases this led to major alterations in surgery.	None mentioned	
Cheliout-Heraut et al., 1993 n=110 (Abstract of article)	SEP	spinal surgery in children and adolescents		in 2 cases, monitoring changes led surgeons to change operative behaviour		
Ryan & Britt, 1986 n=108 (abstract of article)	SEP	corrective spinal surgery	1 patient			little information available in abstract
Epstein et al.., (1993). n=100	100 monitored patients compared to 218 non-monitored patients.	cervical surgery		none in monitored patients versus 3.7% quadriplegia and 0.5% death in unmonitored patients in a similar previous series of patients.		
Keith et al., 1990 n=100 (abstract of article	SEP	<spinal procedures>				little information available in abstract
Kothbauer et al., 1998 N=100	MEP	Intramedullary spinal cord surgery	Not recordable for preoperatively paraplegic patients		5 false positives, no false negatives	Sensitivity 100%, specificity 91%

IS=idiopathic scoliosis

Mild neurological abnormalities: symptoms of numbness or hyperaesthesia in limb or trunk, alteration in test of any sensory modality or an isolated change in a tendon reflex with no motor weakness (forbes)

Severe neurological complications: motor weakness at any time after the operation, ranging from foot drop to paraplegia (forbes)