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Review

Somatosensory and motor evoked potentials as biomarkers for post-operative neurological status

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HIGHLIGHTS

- Intraoperative evoked potentials (EPs) are often used during surgery as surrogates for true clinical endpoints.
- A three step framework recently proposed by the Institute of Medicine was used to evaluate EP biomarkers as surrogate endpoints.
- Causality guidelines and contingency analysis provided partial validation of EP surrogates.

ABSTRACT

SEPs and MEPs (EPs) are often used as surrogates for postoperative clinical endpoints of muscle strength and sensory status, as these true endpoints are not available during surgery. EPs as surrogate endpoints were evaluated using a three step framework (Analytical Validation, Qualification, Utilization) recently proposed by the Institute of Medicine (USA). EP performance on Analytical Validation may surpass that of some other biomarkers used in medicine (tumor size, cardiac troponin). Qualification of EP surrogates was evaluated with guidelines for causation proposed by A.B. Hill, which supported causal links between surgical events and EP changes and revised estimates of EP diagnostic test performance for three illustrative studies. Qualification was also addressed with a 3×2 contingency analysis which demonstrated decreased deficit proportions for EP declines which recovered after surgeon intervention. Utilization of EP surrogates will depend on surgical procedure and alert criteria. EPs are often used as surrogate endpoints to avoid new postoperative deficits. Although not fully validated, their continued use as surrogates during surgical procedures with the potential for significant morbidity is justified by their potential to help avoid injury and the absence of "second best options."
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Abbreviations: EPs, somatosensory evoked potentials (SEP) and/or transcranial electrical motor evoked potentials (MEP) as a group; RSC, reversible signal change (lost and recovered EP); IONM, intraoperative neurophysiological monitoring; EBM, evidence based medicine; EMG, electromyography.

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1. Introduction

Over the past several years increasing attention has been given to the evidence base of intraoperative neurophysiological monitoring (IONM) for improving surgical outcomes. The prominence of the evidence-based medicine (EBM) movement and related literature has continued to grow, and there is an increased recognition, at times reluctant, that its guidelines may have practical value for distinguishing good from more precarious evidence. On-going changes in healthcare policy and administration also have prompted a more critical look at IONM and outcomes. At the same time, there is a growing appreciation of the need to avoid an oversimplified application of EBM methods to individual patient values and different medical practice contexts (Greenhalgh et al., 2014). IONM is an example, where evaluation of outcomes requires a thoughtful integration of the empirical methods of EBM with clinical expertise (Straus, 2005).

Somatosensory evoked potentials (SEPs) and transcranial electrical motor evoked potentials (MEPs) are used to reduce new postoperative neurological deficits involving the dorsal column somatosensory and corticospinal motor pathways. Despite general agreement on the prognostic (predictive) value of IONM for many surgical procedures, its efficacy in improving surgical outcomes remains contested (Resnick et al., 2009; Fehlings et al., 2010; Nuwer et al., 2012). This is in large part due to the rarity of randomized control trials and controlled observational studies. Surgeons who use IONM will typically not withhold an intervention to an EP alert or do without IONM for a controlled study for fear of potentially harming the patient. Medical studies often make use of biomarkers and surrogate endpoints when controlled research designs are not ethical or practical (Aronson, 2008; Institute of Medicine, 2010; Bell et al., 2014). A surrogate endpoint is "a biomarker that is intended to substitute for a clinical endpoint." A biomarker is simply "a characteristic that is objectively measured and evaluated as an indication of normal biologic processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention (Institute of Medicine, 2010)." In this paper we propose that EPs are usefully conceptualized as biomarkers and surrogate endpoints and may be evaluated by a recent framework recommended by the Institute of Medicine of the National Academy of Sciences (USA). In fact, with the exception of the "wake-up" test or awake cranial surgeries, true clinical endpoints for neurological status during surgery have never been used. EPs are biomarkers by definition, as are the blood pressure and pulse oximetry monitors of tissue perfusion and oxygenation, respectively, during surgery.

2. Methods

2.1. Literature search

The Web of Science database (Thomson Reuters) was queried August 13, 2014 for EP surgical monitoring during 1970–2014. There was no restriction on language. Titles were reviewed, and data from appropriate articles was compiled. The average number of annual citations was determined.[1]

2.2. Assessing causality

Causal links between surgical events and EP changes were investigated using the guidelines for causation proposed by A.B. Hill. Hill described nine guidelines of evidence for causation when an association is observed between two variables (Hill, 1965) (Table 1). They are most useful when controlled observations are not practical or ethical. These guidelines are increasingly used in medicine, epidemiology, and environmental health, and have recently been incorporated in evidence assessments used by the Grading of Recommendations, Assessment, Development and Evidence (GRADE) working group (Guyatt et al., 2011). Rate ratios have been proposed for assessing strength of association when there is a rapid response against a stable background and are defined as the rate of progression during treatment divided by the rated of progression during no treatment (Glasziou et al., 2007).

Rate ratios were used to compare rate of EP change following a surgical event with the rate of EP change immediately preceding the event. When EPs were stable before the event, 0 was replaced with 0.5 for a more robust estimate and to avoid division by zero. Rate ratios beyond 10 for strength of association may indicate causation, even in the presence of confounding variables (Glasziou et al., 2007). Rate ratios as a quantifiable metric of the strength of association between surgical events and EP changes are a topic for future research.

2.3. Diagnostic statistics

Sensitivity and specificity estimates of EP performance were revised using causality guidelines as described in Section 4.4.1.3. Confidence intervals (95%) and forest plots were obtained using RevMan (Review Manager, 2012). Likelihood ratios (LR) were calculated from sensitivity and specificity using the following equation: LR = sensitivity/(1 − specificity). Unlike predictive values LR can adjust posttest outcome probabilities for pretest risk factors (Grimes and Schulz, 2005; Bhandari et al., 2003). To calculate posttest probability:

1. Pretest probability was converted to pretest odds (probability/(1 − probability)).
2. Pretest odds were multiplied by the LR to obtain posttest odds.

[1] The search strategy identified two sets. **Set 1** with the fields (**TITLE:** (intraoperative*) *OR* **TITLE:** (IONM) *OR* **TITLE:** (monitor*) *OR* **TOPIC:** (surg*) *OR* **TITLE:** (IOM). **Set 2** with the fields (**TITLE:** (somato* evoke* potential*) OR **TITLE:** (mot* evoke* potential*) OR **TITLE:** (EMG) OR **TITLE:** (electromyog*) OR **TITLE:** (evoke* potential*). **Final set** for analysis: Set 1 AND Set 2.

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