

ORIGINAL

An Evidence-Based Analysis of Neurophysiological Screening During spinal surgery

Análisis basado en la evidencia del cribado neurofisiológico durante la cirugía de columna vertebral

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Cite as: Mehta T, Das S, Sruthi M, Panigrahi S, Mazumder R, Saini R. An Evidence-Based Analysis of Neurophysiological Screening During spinal surgery. Health Leadership and Quality of Life. 2025; 4:625. <https://doi.org/10.56294/hl2025625>

Submitted: 15-06-2024

Revised: 19-12-2024

Accepted: 02-06-2025

Published: 03-06-2025

Editor: PhD. Neela Satheesh 

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ABSTRACT

Evidence-based medicine (EBM) has placed an emphasis on three guiding principles when determining the worth of a medical intervention: some proof is superior to other people; everything proof is intentional that the patient valuations are significant. Current EBM thought perceives that near observational examinations, not simply randomized controlled preliminaries, can uphold causal connections with results. According to the limited number of carefully carried out comparison research, intraoperative neurophysiological monitoring (ION) enhances the prognosis for spinal intramedullary malignancies. But the effect's extent is still uncertain. Particle indicative test exactness, Diagnostic Test Accuracy (DTA) essentially is in a roundabout way connected with clinical viability. Switched indication change gone specialist mediation challenges appraisal of DTA. DTA estimation can be improved by making adjustment for the surgical context and measuring dose-reaction relationships. The worth of ION depending upon the surgical procedure, the quality of the evidence based on outcomes, and how doctors and patients weigh the benefits, drawbacks, and financial costs methods.

Keywords: Spinal Surgery; Intraoperative Neurophysiological Monitoring; Evidence-Based Medicine; Neurophysiological.

RESUMEN

La medicina basada en la evidencia (MBE) ha puesto énfasis en tres principios rectores a la hora de determinar el valor de una intervención médica: algunas pruebas son superiores a otras; todas las pruebas son intencionales y las valoraciones de los pacientes son significativas. El pensamiento actual de la MBE percibe que los exámenes observacionales cercanos, y no solo los preliminares controlados aleatorios, pueden mantener conexiones causales con los resultados. Según el número limitado de investigaciones comparativas realizadas cuidadosamente, la monitorización neurofisiológica intraoperatoria (MNI) mejora el pronóstico de los tumores malignos intramedulares de la columna vertebral. Sin embargo, el alcance del efecto sigue siendo incierto. La exactitud de las pruebas indicativas de partículas, la precisión de las pruebas diagnósticas (DTA), está esencialmente relacionada de forma indirecta con la viabilidad clínica. El cambio de indicación por parte del especialista dificulta la evaluación de la DTA. La estimación de la DTA puede mejorarse ajustando el

contexto quirúrgico y midiendo las relaciones dosis-respuesta. El valor de la ION depende del procedimiento quirúrgico, la calidad de la evidencia basada en los resultados y la forma en que los médicos y los pacientes sopesan los beneficios, los inconvenientes y los costes económicos de los métodos.

Palabras clave: Cirugía Espinal; Monitorización Neurofisiológica Intraoperatoria; Medicina Basada en la Evidencia; Neurofisiología.

INTRODUCTION

During spinal surgery, intraoperative neurophysiological monitoring (IONM) methods are used to evaluate and keep track of the health of the anxious system, especially the spinal string and nerves, to avoid or reduce neurological injury. IONM can assist in the early identification of possible issues during surgery, enabling the surgical team to take the necessary remedial action before the harm becomes permanent.⁽¹⁾ Spinal intramedullary tumors are uncommon and might be challenging to surgically remove without harming the nervous system. Somatosensory evoked potentials (SSEP) and motor evoked potentials (MEP) are two IONM methods that can be used during surgery to detect and track changes in neurological function, enabling the surgical team to take remedial action before irreparable harm occurs.⁽²⁾ According to the persistent axial spinal pain significantly contributes to low back pain being the most common cause of disability globally. Chronic axial spine pain can result in psychological suffering, such as anxiety and depression, in addition to physical handicap. Chronic axial spinal pain has a considerable financial cost as well. The estimated yearly cost of low back pain in the alone surpasses, including direct medical expenditures and indirect costs like missed productivity.⁽³⁾ As opposed to epileptic seizures, which are brought on by aberrant brain electrical activity, psychogenic non-epileptic seizures (PNES) are triggered by psychosocial factors. It might be helpful to establish categories of clinical characteristics and tests to be studied when assessing PNES by doing a preliminary evaluation of the available research and clinical knowledge.⁽⁴⁾ The efficiency of neurophysiological tests for the detection and monitoring of neurological illnesses can be ascertained by an evidence-based study of these tests. A sort of diagnostic examination known as a neurophysiological test measures electrical activity in the brain and nerves to evaluate how well the nervous system is functioning.⁽⁵⁾ More high-quality research are required to better understand how well neurophysiological testing can detect and track neurological illnesses since the quality of the data was typically inadequate.⁽⁶⁾ Then deciding on a diagnosis and course of therapy for neurological illnesses, patients and healthcare professionals can both benefit from an evidence-based research of neurophysiological testing.⁽⁷⁾ The sensitivity and specificity of neurophysiological screening tests in identifying people at risk for neurological illnesses can be learned through an examination of these tests. According to a comprehensive appraisal and meta-analysis available in the academic journal of Alzheimer's infection in 2017, MoCA demonstrated greater sensitivity and specificity for diagnosing moderate cognitive impairment than the MMSE did for detecting dementia.⁽⁸⁾ During spinal surgery, neurophysiological monitoring (NPM) uses a variety of neurophysiological assays to evaluate the spinal cord and nerves' function in real-time. These tests can aid in identifying possible nerve injury that can occur during surgery and the brain's sensory cortex's reaction to electrical stimulation of peripheral nerves. This method can be utilized to keep an eye on the health of the sensory pathways while doing surgery. the brain's sensory cortex in response to electrical stimulation of nearby nerves. This method can be utilized to keep an eye on the health of the sensory pathways while doing surgery.⁽⁹⁾

A kind of surgical operation called spinal surgery is done on the spine to address a number of disorders that affect the spine and the tissues that are connected to it. An area of a herniated disc that is pressing on a nerve root or the spinal cord is removed during a discectomy. Spinal fusion: To stabilize the spine and reduce pain brought on by spinal instability, two or more vertebrae are joined together.⁽¹⁰⁾ The methods used involved developing goals and critical questions while relying on reliable standards.⁽¹¹⁾ The best evidence synthesis of the available literature was used to examine the material on all areas of facet connect therapies, along with grading for recommendations. The surgical center database was used to prospectively locate the records of pediatric patients (15-25 years old) with teenage idiopathic scoliosis who had scoliosis corrective surgery. Data were gathered on the prevalence and severity of NNDs, as well as their demographic and clinical features.⁽¹²⁾ The investigation on adult patients who had lumbar discectomies and had a minimum of a month of follow-up treatment at a single tertiary care facility.⁽¹³⁾ The following patient information was gathered: patient age, gender, body mass index (BMI), lumbar level operated, and operational time and cost. Electromyography (EMG) anomalies seen during surgery were analyzed in the context of neuromonitoring, together with pre- and post-operative motor assessment data and information on post-operative pain treatment.⁽¹⁴⁾

METHOD

The following section outlines the methodology and key considerations in the evidence-based analysis of

intraoperative neurophysiological monitoring (ION) during spinal surgery, as informed by contemporary EBM principles

Framework for evidence-based medicine (EBM)

In spinal surgery, evidence-based medicine is shifting the center of gravity of research studies away from designing the research itself to methodological quality in the study and the potential sources of bias in the research. This change aims to make it easier to be confident in treatment effects.

Key principles of EBM

Hierarchical Evidence

The quality of the evidence is variable; thus, some forms of evidence are stronger than others. Randomized controlled trials (RCTs) are the gold standard, but, under specific circumstances, observational studies can yield causal results.

Bias and Confounding Factors

Since it introduces some type of bias and is mainly prevalent in the observational studies, the presence of bias is thus worth evaluating in great detail. Risk of bias in non-randomized studies is assessed through the ROBINS-I tool, and GRADE system assesses evidence quality.

Defining causal relationships evidence for ION

Most of the information regarding the effectiveness of ION in improving spinal surgery outcome is derived from observational studies and small comparative studies. It is still the area of research to see the exact causal relation of ION for the surgical success.

Strength of causal evidence

Early models of EBM drew attention to randomized studies versus non-randomized ones. While randomized trials often present stronger evidence, observational investigations, when properly accounted for confounders, can provide considerable insight into causality. Studies involving spinal surgery have had to adjust for several confounding variables including, among others, the age of the patients, the complexity of the surgery, and preexisting conditions.

The Grade system for evidence evaluation

The GRADE (Grading of Recommendations Assessment, Development, and Evaluation) is used to assess the overall quality of evidence. Under GRADE, observational investigations begin with a lower quality, but the quality could be increased to moderate or high if control is properly achieved for confounding factors.

Grade evidence rating: In evidence for GRADE's lower grades is primarily because these lower grades are less accurate. As the beginning of observational studies in GRADE were deemed to be evidence of poor quality, when properly completed with the correction of confounded, or additional features of confounded could have been anticipated to reduce the therapy's influence, it becomes moderate or high quality.

SoF table: The ION SoF table is prepared to include separately those other conditions concerning neurologic impairment, besides that caused by spinal damage. The results are contrasted between the ones after immediate surgery and those observed during follow-up: the advantages of the verification within the SoF bench can further be different in significance. Lack of information due to unavailability of neurological examinations at follow-up (for example, for three months) could undermine confidence. The meta-analytic gives with a confidence interval and level, sometimes a calculated average of the intervention effect, across trials. There are also provided estimates of diversity. Meta-analyses have more power and accuracy to summarize average impacts of treatments compared to a single trial.

Research builds upon itself and incorporates data from the research available in a review regarding the relationship of interventions to their results. An investigation is made up of persons, treatments, comparisons, and results. Usually, comparative studies are needed to establish if a therapy is effective as described in table 1. Those individuals on neuromonitoring interventions will contrast with those not being treated or using some neuromonitoring modalities. Results should show something people really care about and have seen. SoF in GRADE are termed "outcome-oriented," hence, evidence based on a number of investigations might be highly varied depending on results.

Evaluating the Totality of evidence

Totality of evidence according to: Consideration of all available evidence from studies assessing the relationship between intervention and outcomes. Totality of evidence itself.

Table 1. ION effectiveness based on outcomes.

Outcome	ION Group (n=100)	Control group (n=100)	Risk difference (RD)	Confidence interval (CI)
Neurological impairment post-surgery	5 %	15 %	-10 %	-15 % to -5 %
Nerve root damage	3 %	10 %	-7 %	-12 % to -3 %
Long term neurological recovery	90 %	75 %	15	5 % to 25 %

Comparative Studies

Control Groups

The comparative studies required should include patients who receive ION compared to those that receive nothing or another treatment modality.

Outcome-Centric Studies

GRADE considers the significance of results through their relevance to the patients and health professionals. Therefore, the GRADE working group considers outcomes such as improvements in neurological recovery much more impactful than non-clinical outcomes.

Meta- Analysis in evidence synthesis

Meta-analytic methods are a great way to combine the data from various studies into one, making an estimation for a specific intervention considerably more stable and robust. This methodology works very well when outcome measures of separate studies can have been low powered as shown in table 2.

Table 2. Meta-analysis results on ION effectiveness.

Features	Intervention effect	Standard error (ER)	Weight	Value
Spinal surgery outcomes	0,20	0,05	0,30	0,02
Neurological recovery	0,15	0,06	0,40	0,04
Postoperative recovery	0,10	0,04	0,30	0,03
Meta-analysis	0,18	0,04	1,00	0,02

Therapeutic value and patient preference

The therapeutic value of ION originates not only from the proofs of evidence behind it within the realm of clinical medicine but also from patients' cumulative preferences for this method or treatment within the social setting and relative socio-economic context. When comparing the cost-benefit analysis for ION in spinal surgery, direct costs of ION are low, given the projected long-term prevention of severe neurological deficits with concomitant healthcare implications. Alternative Therapies: It is also necessary to weigh ION's risk and cost against other therapies or even ION's exclusion when assessing its worth. In high-risk spinal surgeries, especially in pediatric patients, willingness to randomly randomize therapies for ethical reasons can preclude RCTs.

Cost-Benefit Analysis and Cost of ION Implementation

The direct cost of ION is quite low, and when compared to severe neurological impairment with the subsequent cost of health care, the effect lasts longer. Evaluation of therapies such as alternative ones should also be carried out alongside a risk assessment and cost of ION versus not having ION at all.

Patient and Provider Preferences

Decisions to use ION in spinal surgery are guided by clinical outcomes, patient preferences, and provider judgments. In the case of high-risk surgical procedures, in particular the case for children, there is limited ability to conduct RCTs when the decision to randomized therapy would run against ethical reasons of parents.

The importance of a perform is dependent on both methodical examinations of the standard of confirmation supporting it as well as evaluations of its potential advantages along with dangers, according to the Academy of Medical Sciences guidelines for clinical practice. Clinical practice guidelines (CPGs) are based, in large part, on evaluation of the standard of the appropriate documentation, contrasts between both the advantages and disadvantages of specific clinical advice, and value assessments of the significance of certain advantages and hazards. Bracing for teenage idiopathic curves is an excellent example. Although having either little or inadequate proof for its efficacy, bracing is nonetheless employed to stop the advancement of high-risk curves. The barriers to greater RCT evidence were recently identified in Cochrane assessments.⁽¹⁵⁾

Following an examination of ION efficiency in enhancing outcome, the three EBM concepts will be applied

to comparison inquiry into treatments, where they are most fully explored. It is necessary to show a causal relationship between an action and the effects they produce, often via systematic evaluations of related research.⁽¹⁶⁾ Following that, the postoperative results and diagnostic test accuracy (DTA) for ION will be studied using the same EBM concepts.

RESULTS

Intraoperative neurophysiological surveillance for links to cause

Organization between a therapy and results do not prove causality; rather, it can be the consequence of influencing variables that have an impact on both. Statistical has generally depended on randomizing the therapy of patients to separate association or correlation from causation. Confounded is reduced in investigations of this kind. It is insufficient to demonstrate present is no statistically important difference in suspected confounding among the group utilized for comparability. Modifications for confounders variables and therapy effectiveness estimation often involve multi variate regression or propensity score analysis. Considerations for confounders and therapeutic performance estimation often involve multivariate regression or propensity score analysis. Two fundamental issues in causal science—identifiability and planning—are relevant to ION observations. In the last 10 to 15 years, microbiology and the medical professions have increasingly used SCM and their depiction using instructions graphs, two major advancements in causal research. In observational research, SCM can uncover treatment effects by making presumed correlations throughout parameters apparent and observable. Important ION concepts are illustrated with representations in this volume, including the fact that ION affects computers are indirect and the use of ION as a substitute endpoint that limits anticipate of its DTA and efficiency, and the requirement that estimate of ION assistance benefits in retrospect account for confused unpredictability. It will generally handle SCM in accordance with Judea Pearl's guidelines.⁽¹⁷⁾ It displays an ION SCM and directed graph. In planned for graph, nodes stand in for variables, while node edges stand in for functions. Often, edges are aimed towards the direction of in sequence stream. The variables and their corresponding limits in this SCM indicate well-known connections that are believed to affect how ION influences on postoperative outcomes. An exogenous capricious to facilitate is external to and unaffected by the model affects each of the seven variables. There are significant gaps in the ION SCM (figure 1). For instance, a variable that affects ION, anesthesia, is left out. Additionally, specific ION techniques, surgeon judgement, and postoperative outcomes measurements are not included in the model OF these drawbacks, the replica address three crucial ideas that research into the results of ION therapy has to take into account.

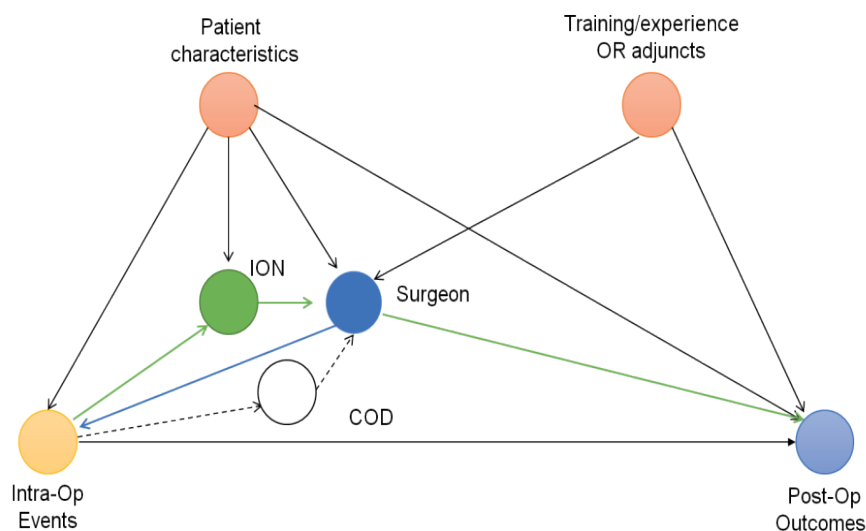


Figure 1. SCM factors and interactions thought to impact ION outcomes

Intraoperative Neurophysiological Monitoring Indirectly Affects Outcomes

The anterior choroid artery (AChA), which feeds the interior container, is at danger during surgery for a posterior communicating artery aneurysm. Consider a scenario in which the AChA accidentally becomes trapped by the permanent clip. As MEP amplitudes decline, the surgeon is warned to change the clip location to prevent the development of a new deficiency. It is critical to recall that ION does not straight alter outcome; rather its effect is mediate through medical doctor reactions to ION signals (figure 2). Studies comparing ION to no ION use the assumption that surgeons would respond appropriately to alarms (figure 3), and these reactions should be precisely documented in order for the ION contrast in this research to be precise furthermore repeatable.

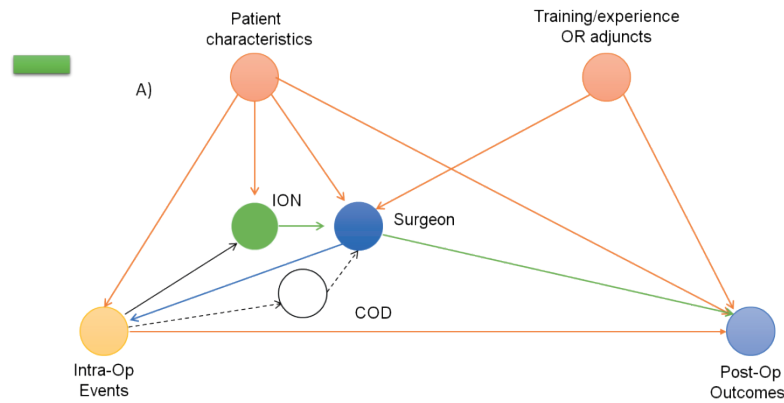


Figure 2. A comparison of "ION" vs "No ION"

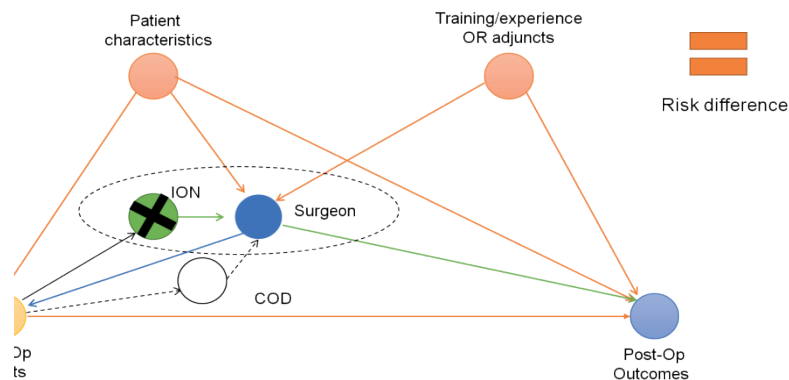


Figure 3. B comparison of "ION" vs "No ION"

Envision that all to identify is to facilitate the cut off location was modified by the surgeon after AChA was trapped. The ability to anticipate the result is only marginally improved by knowing the state of the ION (alert or not) before to clip modification. For ION comparison research, surgeon reactions to ION alarms must be well documented.

DISCUSSION

The measurement of intraoperative neurophysiological activity

ION is used by surgeons as a stand-in or alternative endpoint for maintained neurologic state. The surgeon instead uses SEP and MEP measurements of somatosensory and cortico spinal speed conduction since anaesthetized patients are unable to provide the proper scientific endpoints. Until it recovers, a drop in an ION surrogate marker will often need surgical treatments shown in figure 4. Surrogate indicators' indirectness as compared to the direct assessment of actual clinical outcomes is a significant disadvantage.⁽¹⁸⁾ The use of ION surrogate markers questions predictions of prognostic accurateness and effectiveness in humanizing outcome. In addition to influence intraoperative measures and ION itself, surgeon interventions have been shown to mediate the property of ION on outcome prior to postoperative neurologic examinations for estimations of DTA. The intended for graphs in figure 4 become cyclic due to the obstacles to estimations of ION test accuracy posed by ION surrogate markers, which also cast doubt on thorough assessments of treatment effectiveness. Indirect acyclic graphs include additional issues that are beyond the scope of this discussion.

Positive Prediction And Likelihood

A simple way of investigation findings is to tabulate the data from an existing case series. As already stated, the surgeon's main worry behind an alert is the accuracy of a prognosis of an encouraging ION trial. This parameter is intended to be captured by the positive predictive value (PPV), although it might be deceptive in relatively low risk operations (according to previously documented case series). Commencing the possibility data and acquaintance of a previous threat estimate (Pprior), a revised prospect can be calculated.⁽¹⁹⁾ Even if the (Pprior) is unknown, likelihood ratio computations provide a straightforward way to evaluate and grade the "probability" that an alert necessitates a modify in case administration: The chance ratio is sensitivity divided by specificity. After consulting with the surgeon, the neurophysiologist caring for a present patient can decide whether to stick with published alert criteria or change it in favor of increased sensitivity rather than better specificity. For instance, a clinician using MEPs to track spinal string occupation can choose for the

“disappearance” alert criteria, which has support in the literature, or they can “slide” towards a more sensitive value, such as 80 % or even 60 % amplitude loss. A more precise value of 5-8 mA can be utilized in place of regularly used pedicle attach threshold of 10-15 mA if one is aware of the large rates of FP reports utilizing such thresholds.

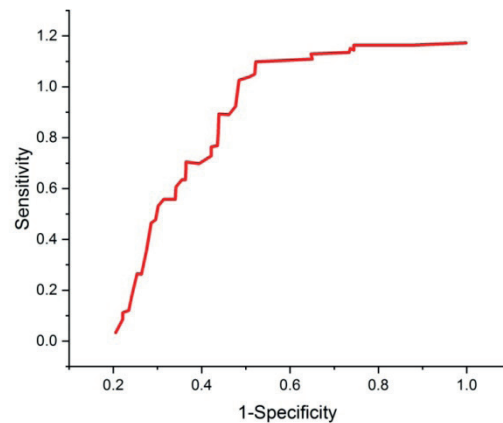


Figure 4. ROC curves show sensitivity-specificity relationships

Reversible Signal Change: Classification Methods

The difficulty of ION test reaches the attentive threshold and then reverses to usual throughout surgery. When seen from the perspective of a neurophysiologist doing surgery of the test alert criteria is reached, the indication loss cannot be resolved via analysis and more trials, a procedure takes place, and the test alerting criterion returns to baseline. But this situation gives birth to a dilemma. Unable to accurately apply the reference value during an operational alert and ascertain whether or not the desired condition is present, a positive test result is true. Despite the fact that are unable to accurately classify an RSC in a 2 by 2 contingency table, it is the specific and highly desired outcome, but none of these classifications suffice without more research. It has been suggested that RSC categorization can be accomplished using two distinct but complimentary methods. Both strategies acknowledge that the fundamental paradigm that underlies the majority of ION is exhibited by RSC recording has the intrinsic benefit of preventing damage to the patient even when it can have been possible to do so as shown by signal loss.⁽²⁰⁾ One direct response is careful setting. When a signal loss is time-correlated with a dangerous procedure, such as cutting an aneurysm or treating a deformity, neurophysiologists assume that there is a causative link. Animal data demonstrating pathophysiological relationships support much of this knowledge figure 5.

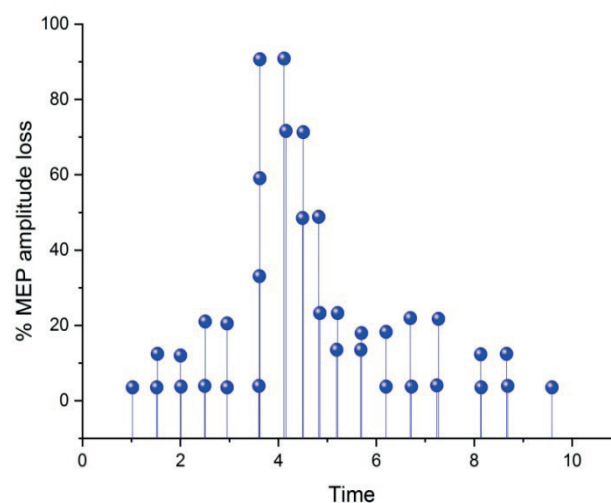


Figure 5. 90 % MEP amplitude reduction

For damaging occasions, a positive Particle test might be related with a likelihood of extremely durable deficiency. Possibility analysis should expose difference in the possibility of wrong involving 3 feasible analysis consequences if an RSC represents an avoid enduring damage in the majority suitcases and an unvoiced permanent injury in a few cases: an RSC, a change that cannot be reversed (a positive test result), and nothing at all as would be expected test results that cannot be changed.

Illustrative Case Series

This significant sequence is the two-information useful and systemically enlightening on account of the examiners' attention on careful setting married occasions, clear comprehension of the picked alarm basis' impact on misleading revealing, and instinct on reversible sign misfortune. In the first place, not entirely set in stone ". just to caution the specialist of precisely induced." MEP alarms. The surgeon-directed warnings in their protocol were strictly limited to wound events. Optimization of anesthesia, blood pressure, and/or ION technical issues was not included among surgeon alerts.⁽²¹⁾ Two of the six lower appendage muscles would have produced an MEP warning, resulting in 5,81 % responsiveness, 5,97 % explicitness, and 5,76 % PPV. Even in a system where surgical context-wedded alerts are present, highly sensitive recordings lead to an excessive amount of FP reports.

Medical Evidence-Based Practice And The Accuracy Of Diagnostic Tests

DTA might be viewed as prejudiced. The common default designation of all RSCs as "TPs" highlights the need to assess bias within case series. Throughout QUADAS-2, proclivity risk could be calculated by using "signal" questions that received yes, no, or doubtful answers, leading to proclivity ratings of "low," "high," or "hazy" for each of the four evaluation spaces: the selection of the patient, list test, a reference standard, and individuals' course by means of the review including file test(s) as well as reference standard timing. In each of these domains, there is a risk of making biased judgments in ION.⁽²²⁾ The "materialness" judgments are made to rank the fit between the topic of the survey and all four spaces for every instance sequence when a well thought-out investigate controversy has been created.

This type of prohibition predisposition ought to be kept away from. Particle strategies' quality can regularly change from one case to another, even among profoundly able neurophysiologists. Because of this assumption, differences between the index test and the reference standard can be entirely attributed to the index test's sensitivity and/or specificity "inaccuracy." Decisions made during a systematic review are also at risk of bias: such as whether to include studies that are deemed to be highly biased. Reviewing the cause of heterogeneity terms of potential bias and applicability can be preferable to including all studies. Other limitations of the study are taken into consideration, such as risk of bias assessments like QUADAS-2: publication bias, indirectness, imprecision, unaccounted heterogeneity.⁽²³⁾ The most relevant area in QUADAS-2 for Particle is that of "stream and timing." behind an ION test aware, surgeons frequently intervene, which can correct postoperative outcome .PROSPERO was created to forestall "inordinate" duplication, further develop straightforwardness and discoverability, and limit inclination among surveys. In a perfect world, enrollment ought to happen before the specialists have begun proper screening against consideration standards; however, surveys are qualified the same length as they have not advanced past the purpose in finishing information extraction.

CONCLUSIONS

The accuracy of a test has a direct impact on the worth of indicative test for patients. When compared to patients who are not monitored, it is reasonable to assume that exact ION test calculation directly translates into enhanced medical outcome. However, that assumption is obviously incorrect. It's possible that the target condition and the test don't match well, or that the target condition doesn't cover all of the possible diseases. A third scenario, which is more subtle but just as likely to result in injuries, is the perplexing malfunction to start a potentially helpful adjustment in case management after an alert. It's possible that test accuracy has nothing to do with viability. Clinical adequacy was same for the almost 100 % delicate/explicit stomach ultrasound for aortic aneurysm and the hazy stool strange blood test for colon malignant development. The authors strongly recommend RCTs for evaluating the efficacy of diagnostic tests based on their review. However, they mention the review's limitations. Importantly, their review only includes a small number of RCTs for all analytical tests, the majority of which lack RCT sustain. Likewise, the creators perceive that observational information after some time might characterize a few tests and related medicines as blameless, For example, the newborn urine test for phenylketonuria. In reality, scientists are unsure of whether symptomatic tests ought to be included in reliable RCTs or whether they are currently permitted based on observations. The concept of evidentiary vulnerability can be used in Particle to determine which of analytical tests requires higher quality evidence.

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FINANCING

The authors did not receive financing for the development of this research.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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