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Controversies in Spine Care

Intraoperative neuromonitoring in spine surgery: large database analysis of cost-effectiveness

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ABSTRACT

Background: Given the increased attention to functional improvement in spine surgery as it relates to activities of daily living and cost, it is critical to fully understand the health care economic impact of enabling technologies. The use of intraoperative neuromonitoring (IOM) during spine surgery has long been controversial. Questions pertaining to utility, medico-legal considerations, and cost-effectiveness continue to be unresolved. The purpose of this study is to determine the cost-effectiveness by assessing quality-of-life due to adverse events averted, decreased postoperative pain, decreased revision rates, and improved patient reported outcomes (PROs).

Methods: The study patient population was extracted from a large multicenter database collected by a single, national IOM provider. Over 50,000 patient charts were abstracted and included in this analysis. The analysis was conducted in accordance with the second panel on cost-effectiveness health and medicine. Health-related utility was derived from questionnaire answers and expressed in quality-adjusted life years (QALYs). Both cost and QALY outcomes were discounted at a yearly rate of 3% to reflect their present value. Cost-effectiveness was calculated as the incremental cost-effectiveness ratio (ICER) for IOM. A value under the commonly accepted United States-based willingness-to-pay (WTP) threshold of $100,000 per QALY was considered cost-effective. Scenario (including litigation), probabilistic (PSA), and threshold sensitivity analyses were conducted to determine model discrimination and calibration.

Results: The primary time horizon used to estimate cost and health utility was 2-years following index surgery. On average, index surgery for patients with IOM costs are approximately $1,547 greater than non-IOM cases. The base case assumed an inpatient Medicare population however multiple outpatient and payer scenarios were assessed in the sensitivity analysis. From a health system perspective IOM is cost-effective, yielding better utilities but at a higher cost than the non-IOM strategy (ICER $60,734 per QALY). From a societal perspective the IOM strategy was dominant, suggesting that better outcomes were achieved at less cost. Except for an entirely privately insured population, alternative scenarios such as, outpatient and a 50:50 Medicare/privately insured population sample also demonstrated cost-effectiveness. Notably, IOM benefits were unable to overcome the sheer costs associated many litigation scenarios, but the data was severely limited. In the 5,000 iteration PSA, at a WTP of $100,000, 74% of simulations using IOM were cost-effective.

Conclusions: The use of IOM in spine surgery is cost-effective in most scenarios examined. In the emerging and rapidly expanding field of value-based medicine, there will be an increased demand for these analyses, ensuring surgeons are empowered to make the best, most sustainable solutions for their patients and the health care system.

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Introduction

With the steady increase in intraoperative neuromonitoring (IOM) use during spine surgery, some users continue to question utility and cost [1]. It is critical to fully understand the health care economic impact of any enabling technology as costs continue to rise. Spine surgeons are tasked with highly sensitive procedures with ever-increasing demands on functional improvement as well as outcome metrics. Numerous modalities have been employed to mitigate length of stay, complications, and repeat surgeries. Despite this, data from elective surgical cases between 1999 and 2011 suggested that the incidence rate of perioperative neurological deficits has in fact increased [2]. Costs associated with neurological deficits can be significant. The use of IOM was developed to mitigate this risk, yet its value has been repeatedly questioned [3]. Numerous manuscripts have been published advocating or refuting the utility of IOM without clear consensus or recommendations [1,2,4–6] Many advocates contend that IOM is invaluable beyond early intraoperative detection due to a perceived additional shield from litigation. This opinion, however, has also not been substantiated.

A recent study reported that even though IOM improved patient care, it was isolated to teaching hospitals and higher income zip codes [1]. When stratifying by median income for patient zip code, there was a substantial difference in the rates of IOM use between low (19.9%) and high-income groups (78.1%). IOM was significantly more likely to be utilized at urban teaching hospitals (72.9%) rather than nonteaching hospitals (25.0%) or rural centers (2.2%) [1]. Similarly, when IOM use was reviewed by payer type, privately insured patients (45.0%) rather than Medicare (36.8%) or Medicaid patients (9.2%) were more likely to receive IOM during spinal procedures [1].

Despite these disconcerting trends, a formal evaluation of cost-effectiveness of IOM that considers both cost and quality-adjusted life years (QALY) has never been conducted. Clinical equipoise is critical in medicine and this data will hopefully justify more restrictive or liberal use of IOM. The purpose of this investigation was to determine the cost-effectiveness of IOM by critically evaluating a large dataset with special attention to neurological deficits detected/averted, costs of deficits, and additional costs incurred for follow up visits, diagnostic testing, additional procedures, and productivity loss.

Methods

Study design

The model was designed to evaluate the cost-effectiveness of intraoperative neurophysiological monitoring (IOM) in spinal surgery by analyzing both cost and utility. The study population was taken from a single IOM company's database of over fifty thousand patients nationwide (n = 17,929 were spine patients). The analysis was conducted in accordance with the Second Panel on Cost-Effectiveness Health and Medicine convened by the United States Public Health Service [7]. Only spine surgery patients were abstracted from the database and included.

Cost was assessed from both societal and health system perspectives. The health system accounts for direct medical costs alone while the societal perspective accounts for both direct and indirect costs, the latter often defined as *productivity loss.* Direct medical costs include operating room time, hospital stay, postoperative medications, follow-up visits (routine and unscheduled), surgery-related complications, device-related complications, and surgeries directly related to these complications. Productivity loss is measured by lost workdays, unpaid caregiver time, and missed housekeeping.

Utility is measured as QALYs. Patient reported outcome (PRO) questionnaires are often used to determine differences in QALYs between in-

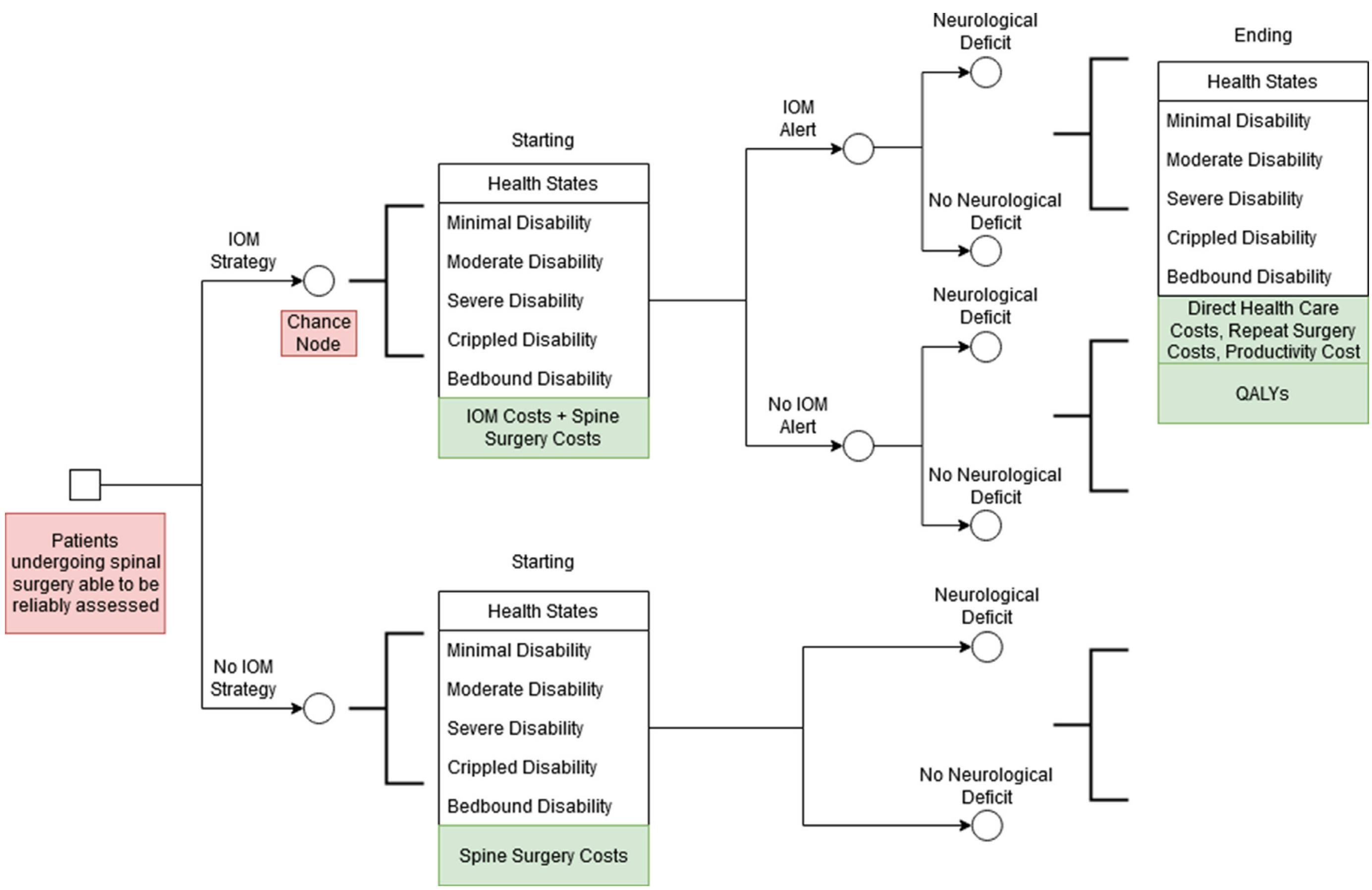

Fig. 1. Markov Diagram, partial illustration.

Table 1
Transition probabilities.

State	Probability
IOM strategy	
IOM Alert	0.500
• Neurological Deficit	• 0.005
○ Minimal Disability	○ 0.000
○ Moderate Disability	○ 0.000
○ Severe Disability	○ 0.000
○ Crippled Disability	○ 0.026
○ Bedbound Disability	○ 0.974
• No Neurological Deficit	• 0.995
○ Minimal Disability	○ 0.493
○ Moderate Disability	○ 0.394
○ Severe Disability	○ 0.108
○ Crippled Disability	○ 0.002
○ Bedbound Disability	○ 0.003
No IOM Alert	0.500
• Neurological Deficit	• 0.001
○ Minimal Disability	○ 0.000
○ Moderate Disability	○ 0.000
○ Severe Disability	○ 0.000
○ Crippled Disability	○ 0.000
○ Bedbound Disability	○ 1.000
• No Neurological Deficit	• 0.999
○ Minimal Disability	○ 0.838
○ Moderate Disability	○ 0.112
○ Severe Disability	○ 0.049
○ Crippled Disability	○ 0.000
○ Bedbound Disability	○ 0.001
Non-IOM strategy	
• Neurological Deficit	• 0.041
○ Minimal Disability	○ 0.000
○ Moderate Disability	○ 0.000
○ Severe Disability	○ 0.000
○ Crippled Disability	○ 0.020
○ Bedbound Disability	○ 0.980
• No Neurological Deficit	• 0.959
○ Minimal Disability	○ 0.678
○ Moderate Disability	○ 0.242
○ Severe Disability	○ 0.077
○ Crippled Disability	○ 0.001
○ Bedbound Disability	○ 0.002

Table 2
Model inputs.

Parameters	Value
1 initial health state distribution (%)	
Minimal	65%
Moderate	30%
Severe	3%
Crippled	1%
Bedbound	1%
2 Surgery Costs ($)	
Spine Surgery	$7804.57
2 hrs Monitoring within OR	$271.36
EMG	$256.46
Stimulated EMG	$93.51
SSEP	$369.17
MEP	$558.99
Repeat Surgery	$12,375.62
3 Other Direct Costs ($)	
Health Care Visits	$2068.35
Diagnostics Tests	$1138.97
Medications	$2195.21
Other Health Care Services	$1184.47
4 Productivity Costs ($)	
Missed Work	$7195.09
Unpaid Caregiver	$110.31
Missed Homemaking	$2866.73
5 Utilities (mean and standard deviation)	
Minimal	0.82 (0.12)
Moderate	0.65 (0.10)
Severe	0.57 (0.09)
Crippled	0.53 (0.09)
Bedbound	0.49 (0.09)

terventions. Unfortunately, PROs were unavailable in this dataset. Alternative questionnaires were therefore used in this analysis (see assumptions section below). Both cost and QALY outcomes were discounted at a yearly rate of 3% to reflect their present value. Cost-effectiveness was calculated as the incremental cost-effectiveness ratio (ICER) for IOM. An ICER is the difference in cost divided by the difference in QALY for two comparison strategies. A value under the commonly accepted United States-based willingness-to-pay (WTP) threshold of $100,000 per QALY was considered to favor IOM compared to a non-IOM surgical cohort.

A cohort Markov model (Fig. 1) was constructed to analyze postoperative costs and health-related utility values for both IOM and non-IOM populations. The structure of this model was adapted from Ney et al. [8] cost-benefit model.Five mutually exclusive Markov states (health state) depicting a patient's health and work status are defined at each patient encounter. Each health state was then correlated with a cost and utility score. Patients were then redistributed across the five Markov states in each Markov cycle, attempting to parallel the postoperative course on a population level. The process of redistribution is controlled by two factors: (1) the preoperative distribution of health states; (2) the transition probabilities between the health states (Table 1).

Summary of model assumptions

The base case scenario was constructed assuming the following: (1) the incremental average increased cost per IOM case is approximately $1547; (2) direct and indirect population costs are based on 2-year mean costs defined by the Spine Patient Outcomes Research Trial (SPORT) [9], expressed in 2021 dollars; (3) direct costs are calculated at 100% Medicare rates (Table 2); and (4), the utilization of costs by each health state are 25%, 35%, 50%, 65%, and 100% of total costs for minimal, moderate, severe, crippled, and bedbound, respectfully.

In the absence of conventional PRO instruments, a proxy scoring system for stratifying patients was created to anchor literature-extracted baseline utilities. After scoring, the patients were stratified into quintiles. These proxy scores allowed us to map the mean health utility values from the SPORT trial [9] to the database population. Variables describing intraoperative events and final clinical outcomes (ie, adverse events, unresolved IOM-alerts) were then used to construct health states postoperatively. Utility values for each health state were drawn from published probability distributions [10]. A non-IOM population was not captured in the database so baseline neurological risk, the probability of a postoperative deficits, and the incidence of reoperation rates were extracted from the literature using a pooled estimate analysis.[5,11] Health state transition probabilities were then calculated (Table 1).

Results

Base case

Neurological deficits were greater for the non-IOM cohort than the IOM group (4.1% vs. 0.3%, respectively, p<.01). The base case results are presented in Table 3. At 2-years, the total cost for the IOM group is $637 greater than the non-IOM strategy. There is an increased savings of $455 when indirect costs are considered. In all perspectives, IOM results in a QALY gain of 0.010. From a health system perspective, IOM had an ICER of 60,734.52 $/QALY. From a societal perspective, the IOM arm was *dominant* (negative ICER value), yielding better utilities at a marginally lower cost than the non-IOM group. Net monetary benefit was also analyzed (Table 3). Net monetary benefit (NMB) is a summary statistic that represents the value of an intervention in monetary terms when a willingness-to-pay threshold for a unit of benefit (ie, QALY) is applied. For example, at a WTP threshold of $100,000/QALY, IOM saves

Table 3
Cost-effectiveness results.

Perspective	IOM		Non-IOM			NMB, per WTP thresholds		
	Cost[a]	*QALY*	*Cost*	*QALY*	*ICER*[b], *$ per QALY*	*WTP = $50,000*	*WTP = $100,000*	*WTP = $150,000*
Health system	$20,792.56	0.758	$20,155.31	0.748	$60,734.52	-$112.63	$411.98	$936.60
Societal	$32,881.11	0.758	$33,336.51	0.748	Dominant	$980.01	$1504.62	$2029.23

[a] Includes IOM cost in the initial surgery
ΔCost = IOM total – non-IOM total
ΔQALY = IOM QALY – non-IOM QALY
[b] ICER = ΔCost / ΔQALY; 'Dominant' indicates that IOM costs less while yielding a higher QALY

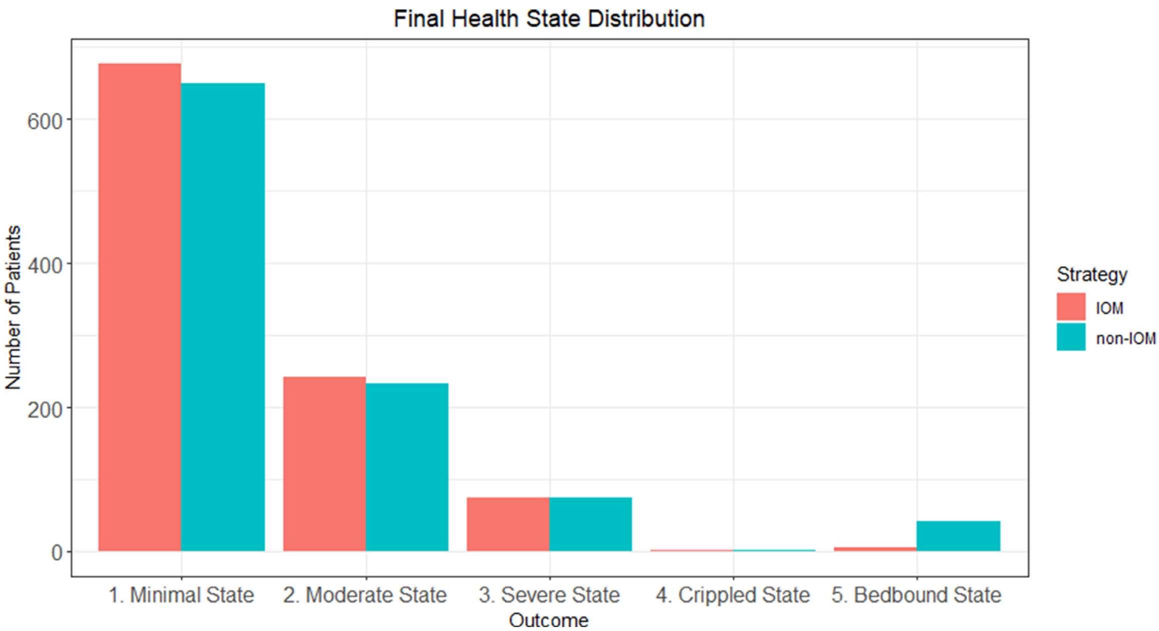

Fig. 2. Final health state distribution.

$411.98 of direct cost (Table 3). If productivity loss is considered, the savings is $1504.62 (Table 3).

In the final health state distribution (Fig. 2), more patients from the IOM cohort ended in lower disability states, "Minimal" and "Moderate," compared to non-IOM patients. Furthermore, the non-IOM cohort is more likely to incur additional costs for health care visits, diagnostic tests, other supplemental procedures, and productivity loss during the 24-month follow-up period.

Sensitivity analysis

One-way sensitivity analysis

There is always inherent uncertainty associated with the input parameters used in a base case cost-effectiveness analysis. Parameter uncertainty affects outcomes and interpretation. Therefore, a one-way sensitivity analysis (OWSA) is used to identify the parameters associated with the greatest uncertainty and therefore likelihood to most significant influence our conclusions. In the OWSA, we vary each of the input parameters, individually (*including initial surgery/complication/medication costs and utility values)*. Each parameter is varied by ±20% of its base case value.

The cost difference between strategies ('IOM' – 'no IOM') is centered around $637 and is always positive, meaning IOM is likely more expensive despite parameter variation (Fig. 3). The effect difference is also always positive, meaning we can reliably expect QALY gains from IOM (Fig. 4).

Probabilistic sensitivity analysis

A PSA was also conducted to further assess cost-effectiveness in the setting of collective parameter uncertainty. Unlike the OWSA, this method varies all input parameters simultaneously. Probability and utility variables are randomly sampled with Gamma distributions. By convention, Gamma distributions adjust variables by standard deviations of 15.3% (~30%/1.96) of their base case values. Cost-effectiveness outcomes are calculated for each iteration of random sampling. The results presented are based on 5000 iterations.

Cost differences between IOM and non-IOM range from ~ -$1000 up to ~$2000, and QALY difference ranges from ~−0.01 to ~0.03 (Fig. 5). Datapoints below the willingness-to-pay line (WTP) of $100,000 per QALY gain indicate that the IOM strategy is cost-effective. At a WTP = $100,000, ~74% of the simulations have IOM being cost-effective over control. This amount decreases to a still acceptable level of ~60% cost-effective at a WTP = $50,000 (Fig. 6).

Litigation scenario analyses

The litigation sub-analysis decision tree was created using probabilities and costs extracted from Hatef et al. [12] (Fig. 7).We constructed three scenarios to analyze the failure to monitor and negligent monitoring arms reported in the study: (1) settlements equal and plaintiff verdicts equal, (2) case-specific, and (3) biased against IOM.

IOM was found to be the preferred course of action for the first two scenarios. In the *settlements equal and plaintiff verdicts equal* scenario, we use the mean settlement and mean plaintiff verdict amounts to calculate

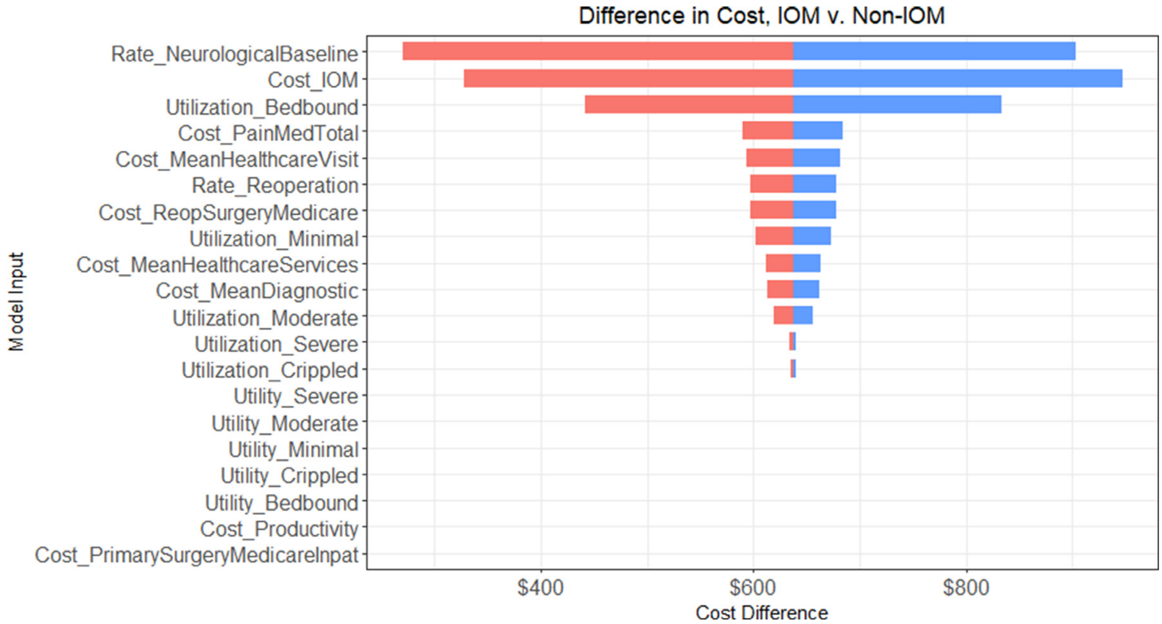

Fig. 3. Cost tornado.

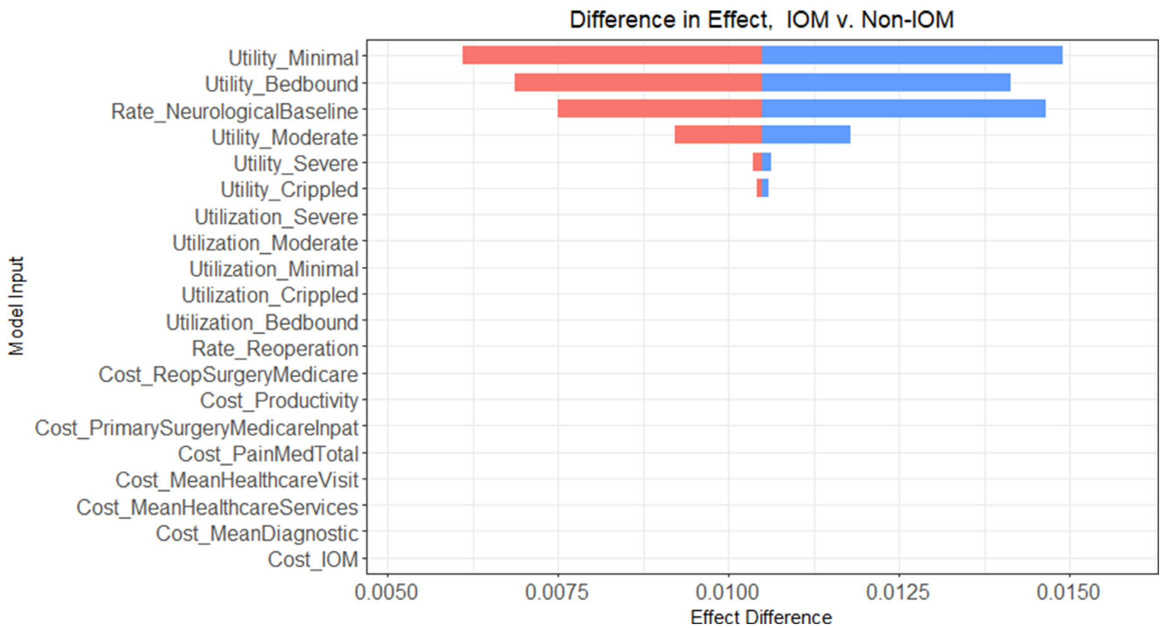

Fig. 4. Effect tornado.

expected values for the failure-to-monitor and the negligent monitoring arms. Cost associated with failure-to-monitor was $991,324 greater than the negligent monitoring group. In the *case-specific* scenario, mean settlements and awards are reported by malpractice type (Table 4). The failure-to-monitor arm is settlement-heavy and penalized more due to the high settlement awards resulting in a $1622, 953 greater risk than the negligent-use group. Finally, the *biased against IOM* scenario includes the maximum plaintiff awards and maximum settlement values for the negligent-use group and low amounts for the failure-to-monitor arm. This allows us to assess a worst-case scenario against IOM but unfortunately only represents a subset of six patients from this paper. Not surprisingly, the use of IOM does not overcome the risk bias in this instance; however, without more robust legal data, a formal conclusion for this artificial scenario is not plausible.

Discussion

The use of IOM in spine surgery appears to be cost-effective. The model comprehensively analyzed costs and health-related utilities (QALYs) in patients undergoing spine surgery with or without the adjunct of IOM. Notably, more patients in the IOM group transitioned towards improved health states. This appears secondary to a lower incidence of neurological deficits, which often result in significant decrements in quality of life and higher postoperative costs, including reoperations. Health care systems are increasingly constrained and gravitate towards parsimonious economic policy. One of the principal national metrics has been to reduce hospital length of stay. This can be broadened to include mitigating avoidable ICU days and surgery-related complications/reoperations.

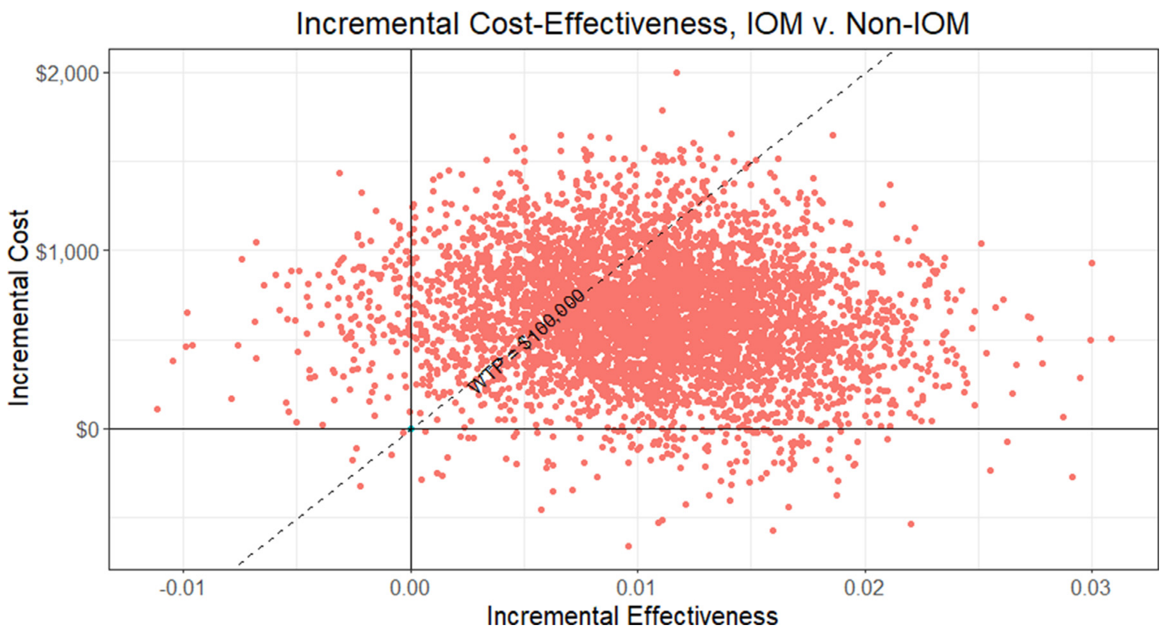

Fig. 5. Probabilistic sensitivity analysis. Dashed line denotes willingness-to-pay threshold of $100,000.

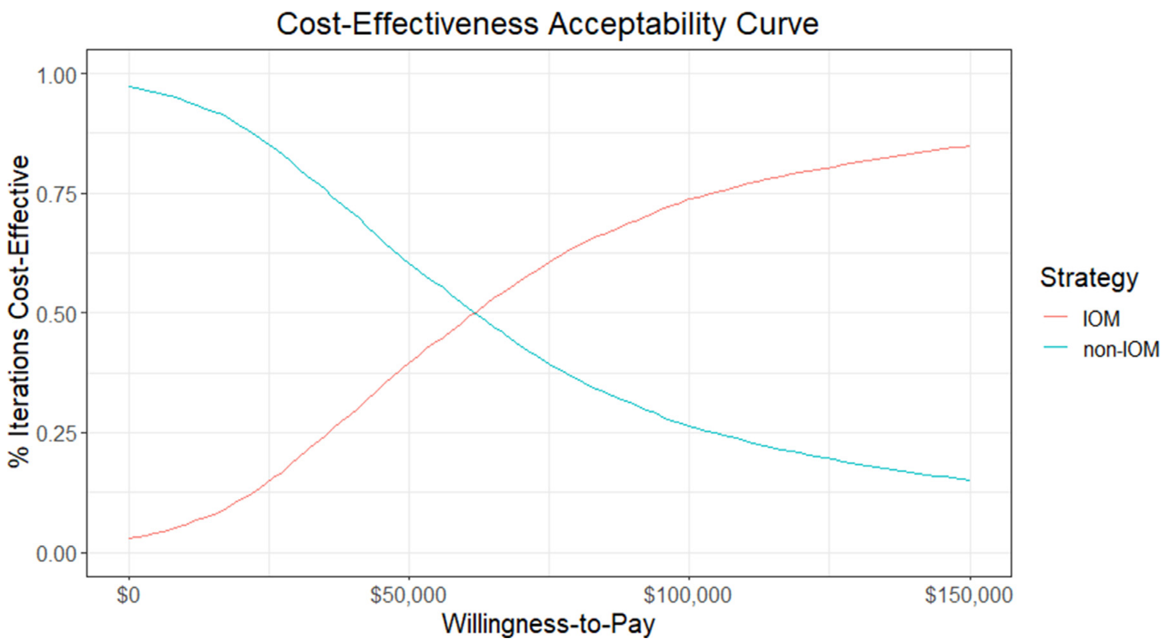

Fig. 6. Cost-effectiveness curve for IOM versus non-IOM.

Table 4.
Litigation results.

Scenario	*Parameters*	*Cost difference expected value*	*Cost difference for deficits*
Settlements and plaintiff verdicts equal	Negligence Verdict: $4180,213 Negligence Settlement: $7575,000 Failure-to-Monitor Verdict: $4180,213 Failure-to-Monitor Settlement: $7575,000	$ −991,324	$ −28,140,779
Case-specific	Negligence Verdict: $5667,022 Negligence Settlement: $3750,000 Failure-to-Monitor Verdict: $1950,000 Failure-to-Monitor Settlement: $9487,500	$ −1622,953	$ −12,429,956
Biased against IOM	Negligence Verdict: $11,716,118 Negligence Settlement: $ 28,000,000 Failure-to-Monitor Verdict: $761,819 Failure-to-Monitor Settlement: $600,000	$ 7280,911	$ 7808,043

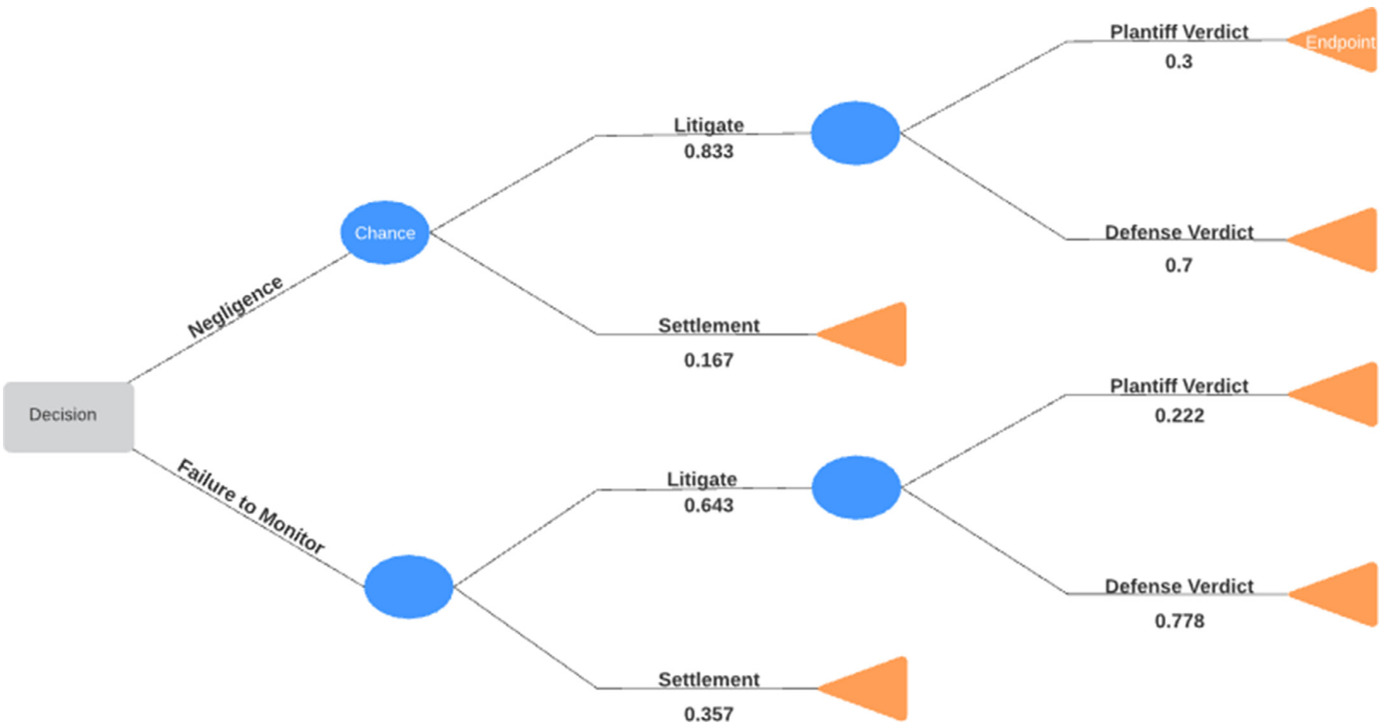

Fig. 7. Litigation decision tree.

This data suggests that IOM may help achieve some or all these goals. With the number of elective spine surgeries increasing globally, surgeons are being increasingly scrutinized on not only their outcomes but also on their resource utilization. Enabling technologies, such as robotics, are an extreme example of an exorbitant cost that proponents argue is justified by improving safety. The authors portend that IOM is similar, albeit substantially less costly. The ability to potentially avert neurologic injury should not be undervalued. Similarly, there are practical/legal implications to consider. It has been repeatedly demonstrated that the use and interpretation of IOM in the OR (or lack thereof) can be discussed during litigation [12].

While the use of IOM has increased, many recent studies have had difficulty proving its cost-effectiveness [1,15–17]. Literature refuting cost-effectiveness mainly described smaller, less complex procedures where IOM increased operative time and cost without producing disparate outcomes [14]. Many surgeons agree and believe that IOM ought to be relegated to the 'higher risk' cases. Others, however, are using IOM more ubiquitously either due to medicolegal concerns or the inherent belief that having more intraoperative information is simply superior [15].

Pecuniary considerations aside, IOM has been repeatedly validated for complex spine procedures.[1,5,18,19,3,20–22] In 2007, the introduction of motor evoked potentials (MEPs) was lauded for its reliability and advocated for its use along with somatosensory evoked potential (SSEPs) during spine surgery [13]. Sala F. et al. [13,19] argued that IOM reduced the likelihood of neurological complications, while another study purported that IOM enables early detection of vascular or mechanical compression (otherwise not perceived), resulting in a rapid correction in surgical technique.This latter study also demonstrated cost-effectiveness when compared to the amount spent on a patient with a postoperative neurological deficit [19]. Despite the supportive claims and evidence, critics argue that IOM alerts often occur after irrevocable damage has already occurred. The number of IOM alerts that represent reversible findings, thereby allowing for corrective measures that may prevent serious or permanent neurologic injury, remains unclear.

Study limitations

Our analysis and conclusions should be taken in context of significant limitations. For one, the analysis relied on a single commercial vendor's dataset. It also utilized complex modeling and statistical techniques. Health related quality of life and health state transitions relied on significant assumptions and nonstandardized questionnaires since typical PROs were unavailable. Similarly, long term follow-up for patients with neurologic complications was unavailable and had to be extrapolated from the literature, requiring a pooled proportion estimate.

The direct medical costs were also limited. The data collected did not include additional physician or facility fees associated with complications. Preoperative health states were also limited in this dataset. It is unclear if comorbidities contributed to the complications reported. While this may limit generalizability, the authors assert that the conclusions are reasonable given the dataset's size and the protocolized methodology. The litigation scenario sensitivity analysis was also limited given the sheer paucity, poor quality, and overall heterogeneity of the data available in the literature. The referenced manuscript in this report, for example, comprised a sample of only 26 patients. Further studies are warranted that utilize more conventional QALY metrics, limit commercial bias, and collect real time follow-up data on all 'event' patients.

Conclusion

Intraoperative neuromonitoring in spine surgery appears to be highly cost-effective in most real-world scenarios. This suggests the need for more widespread utilization and acceptance in this increasingly challenging health care climate.

Author contributions

Conception and design: JA, JPJ, AV. Administrative support: All authors. Provision of study materials or patients: JA. Collection and assembly of data: JA, AL, KK. Data analysis and interpretation: All authors.

Manuscript writing: All authors. Final approval of manuscript: All authors.

Ethical statement

The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Declaration of competing interest

All authors have completed the ICMJE uniform disclosure form. JA is the president/CEO of a research think-tank organization (Neuronomics) that received funding from MPowerHealth Inc., to conduct this research. MPowerHealth was not involved in the data acquisition, data analysis, or creation of this manuscript. The other authors have no conflicts of interest to declare."

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The dataset and research funding were provided by MPowerHealth Inc., but the company did not have input into the creation, critical revision, or fundamental production of this manuscript.

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