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Original Paper

EVALUATING THE ACCURACY OF PATIENT STATE INDEX FOR MEASURING ANAESTHETIC DEPTH IN PATIENTS UNDERGOING PROPOFOL-SEVOFLURANE ANAESTHESIA

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Processed electroencephalographic indices such as the Patient State Index (PSi) have been proposed as a method of monitoring the depth of general anaesthesia. However, in order to establish the validity of PSi, it is necessary to compare its accuracy to other techniques, such as the isolated forearm technique (IFT). 30 ASA (American Society of Anaesthesiologists classification) I–III patients were administered standard propofol-sevoflurane anaesthesia with PSi monitoring. Before each dose of muscle relaxant, the forearm contralateral to the intravenous cannula was isolated for 30 minutes. PSi, hand movements, and exhaled sevoflurane concentrations were recorded during the induction of anaesthesia, intubation, throughout the surgical procedure, prior to extubation, and patients' responses to commands were classified as positive or negative. The Brice questionnaire was used to assess intraoperative awareness after the patient regained consciousness. All patients completed the study without memory of the surgery or IFT commands, 53.3% of patients showed a response to IFT commands during intubation. PSi values ranged around 26 (23.5; 30) in IFT non-responders and 33.5 (26; 42) in responders ($p = 0.15$). The best cut-off value for PSi to predict IFT response was 55, with a sensitivity of 60% and specificity of 85.2%, which led to the conclusion that PSi is not a fully reliable tool for monitoring the depth of anaesthesia.

Keywords: *electroencephalography, consciousness, isolated, forearm, awareness.*

INTRODUCTION

Neuromonitoring is crucial during general anesthesia as an inadequately anaesthetised patient may experience discomfort, while an excessively anaesthetised patient may be at risk for postoperative neurological complications (Orena *et al.*, 2016; Pérez-Otal *et al.*, 2022). Despite the advancements in monitoring techniques and knowledge of the mechanisms of anaesthesia, occurrence of awareness during general anaesthesia remains a relatively rare but significant problem (Pandit *et al.*, 2013; Chang *et al.*, 2019).

During general anaesthesia, many EEG-based (electroencephalography) approaches such as the Bispectral Index (BIS), Entropy, Patient State Index (PSi) and Cerebral State Index (CSI) are used to evaluate the depth of anaesthesia. Several studies have reported the reliability of BIS and PSi, which calculate a quantitative level of consciousness that ranges from 0 to 100, with higher scores indicating a conscious or lightly sedated patient (Medical Advisory Secretariat, Ministry of Health and LongTerm Care, 2004; Drover and Ortega, 2006).

In practice, when using neuromonitoring the anaesthetist has to be confident that the monitor used will discriminate reliably between wakefulness and anaesthesia as well as between hypnotic states of varying depth. The construction and validation of quantitative level of consciousness ranges for EEG-based neuromonitors frequently includes the utilisation of clinical criteria such as the Observer's Assessment of Alertness Scale (OAA) (Drover and Ortega, 2006). The use of such clinical scales is limited to types of anaesthesia without the use of muscle relaxants. In order to assess consciousness during anaesthesia with use of muscle relaxants, special techniques such as the isolated forearm technique (IFT) have been developed. Although there has been some validation of PSi with clinical criteria it has never been validated against the isolated forearm technique.

In this study, we aimed to evaluate the ability of the PSi to assess changes in the depth of anaesthesia in patients undergoing intravenous induction with propofol followed by sevoflurane anaesthesia with the use of muscle relaxants, by comparing it to the IFT.

METHODS

A total of 30 ASA I-III patients (Table 1) undergoing elective spine surgery were enrolled. Exclusion criteria were previous intraoperative awareness episodes, stroke, hearing problems and chronic preoperative opioid usage. Patients were anaesthetised using a standard protocol. All patients were premedicated using Etoricoxib 90 mg and Midazolam 3.75 or 7.5 mg. Anaesthesia was induced using Propofol 2–2.5 mg/kg, Fentanyl 2 mcg/kg, Atracurium 0.5 mg/kg followed by endotracheal intubation. Anaesthesia was maintained using Sevoflurane 0.8–1.0 MAC and reapeated doses of Fentanyl/Atracurium as per clinical needs. Standard monitoring included ECG, arterial pressure, and arterial blood saturation. Depth of anaesthesia was assessed using a Masimo SedLine® Sedation Monitor (Masimo, Irvine, CA, USA). A single-use SedLine sensor was placed on patient's forehead and temporal region and connected to a Root monitor unit. Impedance status of the SedLine sensor was observed thoroughout the operation and was kept in acceptable values according to manufacturer's recommendations. EEG waveforms, PSi, Artifact (ARTF), Electromyography (EMG) values were acquired. PSi between 25–50 during surgery was considered as a target value. EMG and ARTF values below 25% were considered acceptable.

When consciousness was lost, a forearm isolating tourniquet contralateral to the intravenous cannula (Fig. 1) was inflated to 300 mmHg and atracurium 0.5 mg/kg was given. If needed during surgery, further boluses of 0.2 mg/kg atracurium were given as required with appropriated inflation of the tourniquet each time muscle relaxant was administered.

Awareness was determined at regular intervals in terms of response to verbal commands. A verbal command started with the patient's first name, and patients were asked to squeeze the observer's hand. When no squeeze occurred during 10 seconds, hand movement was classified as no response. Hand movement was classified as non-specific if it was not associated with the verbal command. Movement was classified as specific if it occurred after a direct verbal command. PSi, isolated hand movements and exhaled and inhaled sevoflurane concentrations were recorded during the induction of anaesthesia and intubation, before incision, throughout the surgical procedure, and prior to extubation.

Table 1. Patients' baseline characteristics (n = 30)

Characteristics	Value
Age, years (Q1; Q3)	51 (41–65)
Gender, male, n (%)	14 (46.7%)
ASA class 1/2/3, n (%)	3 (10%)/ 20 (66.7%)/ 7 (23.3%)
Height, cm (Q1; Q3)	170.5 (164–183.5)
Weight, kg (Q1; Q3)	86 (81–94)
Body mass index, kg/m^2 (Q1; Q3)	28.9 (25.4–31.1)

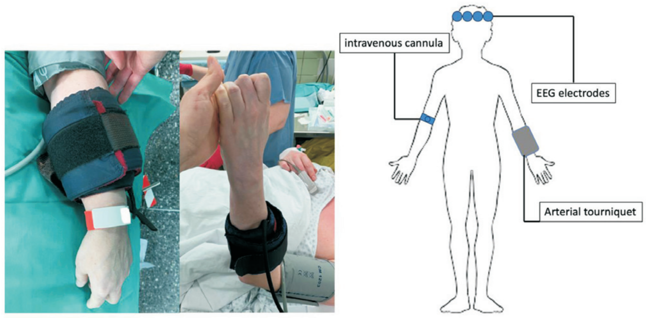

Fig. 1. The isolated forearm technique.

After recovery, the patients were interviewed about intraoperative recall using the Brice questionnaire (Brice *et al.*, 1970). The questions asked were: What is the last thing you remember after falling asleep? What is the first thing you remember after waking up? Do you remember anything between falling asleep and waking up and did you dream?

Demographic and clinical characteristics of the study population were summarised using median and interquartile range for continous variables and counts and percentages for categorical variables.

The Mann–Whitney test was used to compare the PSi values between patients with specific isolated hand movement and those with non-specific/no isolated hand movement. A p value of < 0.05 was considered significant.

ROC analysis was performed to determine the optimal cut-off value for PSi that best discriminated between patients with and without isolated hand movement. The sensitivity and specificity were calculated for different cut-off values. A sensitivity analysis was conducted to determine the cut-off value for PSi that yielded 100% sensitivity for detecting isolated hand movement. Statistical analysis was performed using R (version 3.5.1, R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

The study enrolled a total of 30 patients (Table 1), with 14 males and 16 females, and their median age was 51 years (41; 65 years). The patients had median body weight of

86 kg (81; 94) and body mass index (BMI) of 28.9 kg/m^2 (25.4; 31.1). All patients completed the study, and there were no complications during surgery or the recovery period. On postoperative questioning there were no episodes of explicit recall of surgery or the IFT commands.

Table 2 shows the number and percentages of patients who showed specific, non-specific and no hand movement to IFT commands during anaesthesia induction and intubation, before incision, during surgery, at wound closure and prior to extubation. During the first phase, which lasted from induction of anaesthesia to intubation, 53.3% of patients showed movements of isolated hand, of which 40% were considered specific. During the second phase (before skin incision), the percentage of patients showing wakefulness was much lower, with only two patients showing specific hand movement and the remaining showing no hand movement. Throughout the surgery (phase three and four), no specific or non-specific hand movements were observed and this could be interpreted as a state of adequate anaesthetic depth. Before extubation (phase five), most of the patients responded with specific or non-specific hand movement to a verbal command. The PSi values and the end-tidal sevoflurane concentrations recorded at predetermined stages of anaesthesia and surgery are shown in Figure 2. The median PSi values were 30, 34, and 82 at induction of anaesthesia and intubation (during propofol administration), during the surgical procedure (during sevoflurane administration), and prior to extubation. The PSi values were not significantly different between patients with specific/non-specific isolated hand movement and no isolated hand movement (Mann–Whitney test; $p = 0.15$) — median PSi value in patients with no hand movement was 26 (23.5–30.0), and median PSi in patients with hand movement was 33.5 (26.0–42.0).

The Brice questionnaire (Brice *et al.*, 1970) was utilised after surgery to detect possible intraoperative awareness and no patient recalled awareness (e.g., sensations, thoughts and/or memories directly associated with surgery) during anaesthesia, with four patients remembering recreation-associated dreaming (outdoor walking, skiing, etc) during anaesthesia.

Table 2. Number of patients (percentage) of isolated forearm responses during different stages of anaesthesia

	No movement	Non-specific hand movement	Specific hand movement
Anaesthesia induction, intubation	14 (46.7%)	4 (13.3%)	12 (40%)
Before skin incision	28 (93.3%)	0	2 (6.7%)
5 min after incision	30 (100%)	0	0
Start of skin closure	30 (100%)	0	0
Before extubation	11 (36.7%)	3 (10%)	16 (53.3%)

Using ROC analysis, the best cut-off value for PSi, based on combined values of isolated hand movements during induction of anaesthesia and intubation, throughout the surgical procedure, and prior to extubation, was 55 (sensitivity = 60%, specificity = 85.2%); but for this cut-off, the area under the curve (0.702) represented a barely acceptable level of accuracy (Fig. 3). Sensitivity at a 96.6% level could be reached only at a PSi value of 21 (Table 3).

DISCUSSION

Our study results indicated that PSi has moderate sensitivity and specificity and therefore is not a fully reliable tool for monitoring the depth of anaesthesia, and values obtained during monitoring do not guarantee total absence of awareness during anaesthesia.

The isolated forearm technique, described in 1977 by Tunstall, is a method used to monitor the level of consciousness in patients who are under general anaesthesia. It involves placing an arterial tourniquet on the patient's arm and inflating it to isolate it from the circulation and therefore isolating it from muscle relaxants (Tunstall, 1977). IFT is often described as a gold standard for detection of awareness dur-

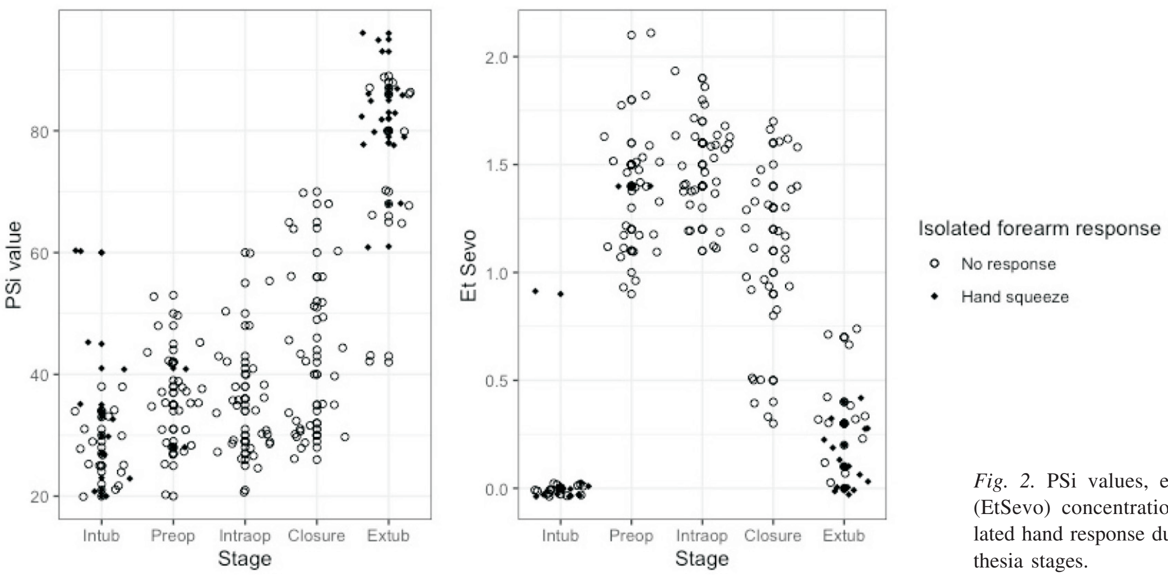

Fig. 2. PSi values, end-tidal sevoflurane (EtSevo) concentration and patient's isolated hand response during different anaesthesia stages.

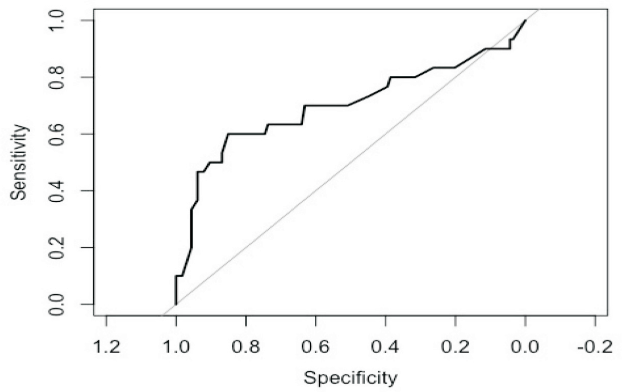

Fig. 3. Receiver operating characteristic (ROC) curve for PSi value of 55.

Table 3. Sensitivity and specificity of PSi values

PSi variable	Specificity	Sensitivity
21	1.7%	96.6%
26	11.4%	90.0%
27	15.7%	86.6%
34	44.7%	73.3%
46	73.6%	63.3%
60	85.0%	60.0%
80	95.6%	33.3%

ing anaesthesia in the presence of neuromuscular blocking agents and a useful research tool, since it may be classified as a direct observation of motor response of anaesthetised and paralysed patients to stimuli (Zand *et al*., 2014; Pandit *et al*., 2015; Linassi *et al*., 2018).

During anaesthesia stages aimed at loss of consciousness (from induction until the end of surgery), while receiving recommended doses of anaesthetics, 40% of patients showed positive IFT responses. Interestingly, all positive responses were observed during induction and intubation and just prior to incision, but not during or at the end of surgery. This observation could be explained by two major differences in anaesthesia between these stages. Firstly, propofol was used during induction, while sevoflurane was used for maintenance throughout anaesthesia. It has been reported that PSi could be sensitive to the effects of intravenous versus inhalational agents (Drover *et al*., 2002). Secondly, induction is a dynamic stage where the concentration of anaesthetics at the target site is constantly changing, whereas maintenance allows enough time for the uptake and equilibration of sevoflurane and fentanyl. Indeed, two major factors increasing the risk of intraoperative awareness reported by NAP5 were the use of total intravenous anaesthesia and the phase of induction (Pandit *et al*., 2013). Yet, no direct correlation between PSi and hand movements was observed, and hand responses were observed in various PSi ranges — both indicating state of deep anaesthesia and light sedation, and quite the opposite — no hand movements were seen with PSi values that suggest lightly sedated and therefore conscious patient. The results of our study share many similarities with the results of study conducted by Zand and colleagues (Zand *et al*., 2014), in which the Bispectral Index (BIS) was used. Similar to our study, the majority of patients had positive hand response during induction and the intubation phase. As stated by Zand and colleagues, BIS values that suggest no wakefulness/awareness with 100% sensitivity should be equal or below 27 (recommended values of BIS for adequately deep anaesthesia are 40–60), which is consistent with our results that suggested 96.6% sensitive PSi values below 21 (recommended values by Masimo are 25–50) (Ortega, 2007).

Although several studies have demonstrated the ability of EEG-derived BIS and PSi for detection of the state of oversedation and proposed them as reliable monitors of anaesthetic depth in various patient populations (Adesanya *et al*., 2009; Jang *et al*., 2022), some reports regarding brain activity monitoring and muscle tone indicated that both PSi and BIS values suffered from interference from electromyography. In an awake volunteer study conducted by Schuller *et al*. (Schuller *et al*., 2015), BIS variables suggested state of deep anaesthesia after muscle relaxants were administered without any anaesthetic agents given. This is consistent with results of a study by Revuelta and colleagues (Revuelta *et al*., 2008), in which Cerebral State Index decreased to values of general anaesthesia after muscle relaxant administration. In our study, both EMG and ARTF variables were kept below 25% for precise EEG measurement.

Pandit suggested anaesthesia stage grading with "sedation", and "deep anaesthesia" stages with the "dysanaesthesia" (or, as his colleagues propose — partial anaesthesia) stage that occurs between them, in which both spontaneous movements (e.g., non-specific hand movements) and responses to verbal commands can be observed. As stated by authors, this "dysanaesthesia" phase can be explained by basic pharmacokinetic principles, in which a fully responsive patient or patient in whom spontaneous movements are seen may be temporarily under-anaesthetised, as anaesthetic concentration in plasma gradually increases after drug administration. According to this hypothesis, a patient in the "dysanaesthesia" stage could be described as partially disconnected from sensation (disconnected consciousness) and therefore could preserve the ability to respond to simple commands (e.g., flex or unflex fingers), but not to complex stimuli, such as surgery (Pandit, 2013; Pandit *et al*., 2015). Our study showed that 53.3% of patients were responsive to IFT during the induction and intubation phase, 6.7% were responsive before skin incision, and 63.3% were responsive before extubation. However, none of the patients could recall any of these events — with few of them recalling dreaming about leisure activities. This can be attributed to premedication with midazolam, which is known to induce retrograde amnaesia (Sohn *et al*., 2021). The "dysanaesthesia" hypothesis suggested by Pandit can explain the lack of recall in our study as well. Our results are also consistent with a previous study by Russel (Russel, 2013), which utilised BIS and IFT during isoflurane/air anaesthesia and found that isolated hand movements during surgery were observed in 32% of patients, but only two patients had recall of extubation.

Regarding dreaming, Leslie and Skrzypek (Leslie and Skrzypek, 2007) have described it as a known side effect of general anaesthesia, and according to studies, dreaming is more commonly reported immediately after anaesthesia than during later recovery stages. The mechanism of dreaming during anaesthesia and its factors are still not well known (Samuelsson *et al*., 2008).

There are several limitations to our study. In our study the recording of PSi was done at five different phases of anaesthesia, but not adjusted to the time of neuromuscular blocker administration. Therefore, it can not be excluded that differences of PSi between patients could be to some degree related to differences in the degree of frontal muscle relaxation. Some authors (Russel, 2006; Pandit, 2015; Ibrahim *et al*., 2022) that utilised IFT in their research suggested isolating the dominant hand specifically, as it may be confusing for the patient under anaesthesia to move or squeze the non-dominant hand. This may be considered to be a minor limitation of this study, since none of the patients specified their dominant hand and verbal commands did not include the specific side of the body. As stated in previous studies (Russel, 2006), limitation of processed EEG depth of anaesthesia monitors is the presence of a time lag between administered drug effect, EEG calculation and the variable displayed on the monitor.

Currently, commercially available EEG-based depth of anaesthesia monitors calculate EEG-derived indices in a standardised manner, regardless of whether volatile anaesthetics or intravenous drugs are used. However, molecular pharmacology indicates that different anaesthetics have varying effects on the CNS, which could impact the interpretation of EEG data (Forman and Chin, 2008). To determine whether specific changes to the calculation of EEG-based indices are necessary depending on the type of anaesthesia used, future studies should include unprocessed EEG data, EMG of the isolated hand, and measurement of anaesthetic drug plasma concentrations.

In conclusion, our results indicate that PSi has moderate sensitivity and specificity in distinguishing changes in the level of consciousness in patients undergoing intravenous induction with propofol followed by sevoflurane anaesthesia with the use of muscle relaxants, and is not a fully reliable tool for monitoring the depth of anaesthesia. Therefore, it may not be sufficient to rely solely on PSi to accurately determine a patient's level of anaesthesia.

ETHICS

Approval of the Ethics Committee was obtained and written patient consent (study No. 21/2022) was acquired.

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PACIENTA STĀVOKĻA INDEKSA VALIDĀCIJA ANESTĒZIJAS DZIĻUMA MĒRĪŠANAI PROPOFOLA–SEVOFLURĀNA ANESTĒZIJAS LAIKĀ

Pacienta stāvokļa indekss (*Patient State Index, PSi*) tiek plaši izmantots, lai noteiktu anestēzijas dziļumu. Lai noteiktu PSi sensitivitāti un specifiskumu, tas ir jāsalīdzina ar citām metodēm, piemēram, ar izolētas rokas tehniku (*Isolated Forearm Technique, IFT*). 30 pacientiem tika pielietots PSi monitorings standarta vispārējas anestēzijas laikā. Pirms katras muskuļu relaksantu devas ievades uz 30 minūtēm ar arteriālā žņauga palīdzību tika izolēts apakšdelms pretējā pusē no IV kanīles, un vairākos operācijas posmos — ievādanestēzijā un intubācijā, pirms grieziena, operācijas laikā, pirms operācijas pabeigšanas, pirms endotraheālās caurules evakuācijas tika reģistrēti PSi dati, pacienta spēja pēc pavēles saspiest dūri izolētajā rokā un izelpotā sevoflurāna koncentrācija. Kustības izolētajā rokā tika klasificētas kā specifiskas, nespecifiskas vai kustību nebija. Lai noteiktu PSi specifiskumu un sensitivitāti, tika salīdzināta pacienta spēja pildīt pavēles, izelpotā sevoflurāna koncentrācija un PSi dati. Salīdzinot ar izolētās rokas tehniku, pacienta stāvokļa indeksam ir vidēja sensitivitāte un specifiskums. Ražotāja rekomendētajā PSi vērtību spektrā, PSi nav pilnībā precīza anestēzijas dziļuma noteikšanas metode.