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Evaluating the role of Smartpilot® view assisted target-controlled infusion anesthesia during intracranial mass surgery: A comparative retrospective study with bispectral index-guided standard anesthesia

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Ethics Committee Approval
Ethics committee approval was obtained from Ethics Committee of Gazi University School of Medicine (Date: 08/01/2018 - Decision No: 02) All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

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Abstract

Background/Aim: Neuroanesthesia necessitates the control of both systemic and cerebral hemodynamics, the prevention of intracranial pressure increase, knowledge of anesthetics' cerebral effects, and early neurological recovery. The titration of anesthetics becomes crucial to optimize the appropriate level of anesthesia required for surgery while reducing postoperative neurological consequences. Smartpilot® View (SPV) is a new decision support system that uses pharmacologic models to optimize anesthetic depth and improve patient outcomes. The goal of this study was to compare the effectiveness of SPV with standard BIS-guided anesthesia administration in terms of intraoperative hemodynamic stabilization, anesthetic consumption, and postoperative recovery times during intracranial mass surgery.

Methods: Following ethics committee approval, the records of the patients who underwent elective supratentorial craniotomy between November 15, 2017 and March 15, 2018 were reviewed retrospectively. The demographics of the patients, anesthesia and surgery times, eye opening and extubation times, time to reach an Aldrete score of 9 and anesthetic consumptions were compared between those who were monitored with SPV in addition to BIS (SPV Group) and those who were monitored with solely BIS for standard anesthetic follow-up (BIS Group).

Results: A total of 139 subjects were analyzed (SPV (n=71), BIS (n=68)). Hemodynamic responses to induction and intubation were more pronounced in the BIS group (P<0.05). Time until eye opening and extubation were 3.6 (2.4) versus 6.06 (1.63) minutes and 5.76 (1.3) versus 9.16 (1.0) minutes in the SPV and BIS groups (P<0.001). In the SPV Group, it took much less time to achieve an Aldrete score of 9 or above (P<0.001). Total consumed amount of both propofol and remifentanil were significantly lower in the SPV group (P<0.001).

Conclusion: Use of SPV compared to BIS-guided routine anesthesia follow-up improved titration and consumption of anesthetic drugs, thereby facilitating the early recovery process in patients who underwent intracranial mass surgery.

Keywords: Intravenous anesthetics, Propofol, Remifentanil, Anesthesia recovery period, Bispectral index, Neurosurgery

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Introduction

Neuroanesthesia necessitates the regulation of both systemic and cerebral hemodynamics, avoidance of intracranial pressure changes, knowledge of anesthetics' cerebral effects, and prompt recovery for early neurological assessment [1]. To achieve all these, it's crucial to optimize the anesthetic agents and provide the appropriate depth of anesthesia intraoperatively.

Opioids and hypnotics are routinely combined in the clinical practice of anesthesiology. Maintaining an optimal combination for adequate anesthetic conditions while limiting adverse effects like hemodynamic alterations or prolonged recovery remains a challenge especially during craniotomies [2]. The manner anesthetics are adjusted intraoperatively is likely to have a greater impact on anesthesia quality than a specific drug utilized. As a result, anesthetic titration becomes critical to maintain the adequate level of anesthesia required for surgery while minimizing postoperative neurological consequences. Previous research revealed that the electroencephalographically (EEG) derived Bispectral Index (BIS) can help with titration of both intravenous and volatile anesthetics [3, 4]. The Bispectral Index, on the other hand, can only anticipate the hypnotic effect of anesthetic drugs and cannot assess the balance of nociception and antinociception [5].

In recent years, new and high-tech monitors that assess general anesthesia components including hypnosis, immobility were developed, and anti-nociception and drug advisory display systems that use pharmacological models to guide the administration of anesthetic agents were commercialized [2, 6-9]. The working principle of SmartPilot® View (SPV, Dräger, Lübeck, Germany) is based on these promising pharmacological models.

The SmartPilot® View is a drug advisory system that displays real-time information on actual and expected levels of anesthesia and demonstrates the effects of combined hypnotic-analgesic drugs. The SmartPilot® View monitor is connected to an anesthetic workstation. As a result, all monitoring data, patient information, ventilation, and syringe pump settings included in the station are automatically displayed on the SPV screen. Complex pharmacological models can be depicted in clinical practice using this innovative technology. SmartPilot® View allows for more precise anesthetic titration for the specified therapeutic goals, making intraoperative decision-making easier [8, 10]. Even though there is few research on SPV in the literature, current studies demonstrate that SPV-guided anesthesia enhances anesthetic management and is related with improved anesthesia quality [8, 10].

The goal of this retrospective study was to demonstrate that SPV would offer clinical usefulness in patients undergoing craniotomy for supratentorial lesions. It was designed to see if SPV-guided administration of intravenous anesthetics and analgesics would improve titration of anesthetics and, as a result, provide more efficient general anesthesia that meets neuroanesthesia standards. The effect of SPV-guided anesthesia on hemodynamics, anesthetic and analgesic requirements and recovery profile in patients who had supratentorial craniotomy was investigated in this study by comparing it with conventional BIS-guided anesthesia administration.

Materials and methods

This retrospective study was conducted with the approval of the Ethics Committee of Gazi University School of Medicine (Date: 08/01/2018 - Decision No: 02) and in compliance with the Declaration of Helsinki's ethical principles. Adult patients who underwent an elective supratentorial craniotomy in the neurosurgery operating theatre between November 15, 2017, and March 15, 2018, were reviewed retrospectively. Preoperative anesthesia registration forms, intraoperative anesthetic sheets, patient files, the medical information system, and data recorded by the SPV monitor were all used to collect data. Investigators who were not involved in the anesthetic administration conducted the research.

The study included patients who ranged in age from 18 to 65 years, had an ASA physical classification of I to III, had no kidney or liver illness and underwent total intravenous anesthesia. Patients with an ASA physical classification of IV, a Glasgow coma grade of 8, those whose records could not be reached and who were not extubated after surgery, as well as those who had emergency surgery, awake craniotomy or surgery requiring neuromonitoring were excluded from the study.

After data scanning, the patients were divided into two groups: Those who were monitored with SPV in addition to BIS (SPV Group) and those who were monitored with BIS for standard anesthetic follow-up (BIS Group). Patient demographics, peroperative hemodynamic parameters, anesthesia and surgery times, eye opening times (time from discontinuation of anesthetic drugs until the patient opens his/her eyes), extubation times (time from discontinuation of anesthetic drugs to extubation), the time to achieve an Aldrete score of at least 9 after tracheal extubation and the total amount of anesthetic (propofol) and analgesic (remifentanil) consumed were compared between the two groups. To reduce bias, patient data were collected and compared by a researcher who were blinded to the patient groups.

Statistical analysis

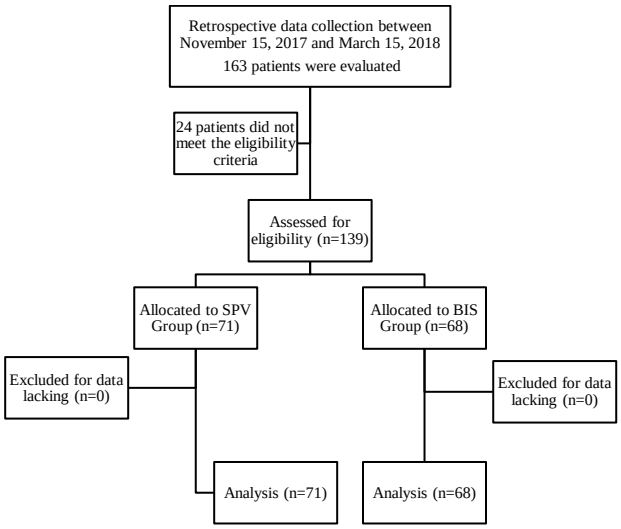
Data analysis was performed using the Statistical Package for the Social Sciences (SPSS) for Windows 19 (Chicago IL, USA) program. Continuous data were expressed as mean (standard deviation) or as the number of cases (n) for categorical variables. Changes between the two categorical variables were examined with the Pearson Chi-square test or the Fisher Exact test. Continuous variables were compared with the unpaired two-tailed Student's t -test. A *P*-value of less than 0.05 was considered statistically significant.

Results

The data of 163 adult patients who underwent elective supratentorial mass surgery in the neurosurgery operating theater between November 15, 2017, and March 15, 2018 were analyzed. Twenty-four patients were dropped from the research because they did not meet the eligibility requirements. Figure 1 shows the study's flow chart. In total, 139 patients were evaluated, with 71 patients (SPV Group) monitored with BIS + SPV and 68 patients (BIS Group) who underwent conventional anesthetic follow-up with BIS. Electrocardiography (ECG), blood pressure, pulse oximetry (SpO_2), end-tidal carbon dioxide ($EtCO_2$) (Infinity Delta XL, SPV, Dräger, Lübeck, Germany),

and Bispectral Index (BIS) (Infinity Delta XL, SPV, Dräger, Lübeck, Germany) were used to monitor the patients.

Figure 1: The study flow chart



SPV: Smartpilot® View, BIS: Bispectral index

Target Controlled Infusion (TCI) of propofol, Schnider effect-site concentration (Ce) model and remifentanil, Minto effect-site concentration (Ce) model were used for the induction and maintenance of anesthesia (Braun Space Station for infusion pumps; Perfusor Space, Braun Medical, Germany). Scalp block was performed in all patients.

SmartPilot® View (software version 3.00.12, Dräger, Lübeck, Germany) monitor was connected to the anesthesia workstation. In the SPV Group, anesthesia maintenance was decided according to Noxious Stimulation Response Index (NSRI) values shown on the SPV screen (Figure 2). The Noxious Stimulation Response Index was maintained between 0 and 20 for intubation, Mayfield pin placement, skin incision, craniotomy, and dural opening, and between 20 and 50 for the rest of the procedure in the SPV Group. For patients in the BIS Group, a BIS of 40 to 60 was targeted to achieve routine anesthetic follow-up.

Figure 2: SmartPilot® View (SPV) screen and Noxious Stimulation Response Index (NSRI)

Blue arrow: Noxious Stimulation Response Index (NSRI)
The Noxious Stimulation Response Index indicates the probability of tolerating and predicting the intraoperative response to a noxious stimulus. NSRI 100 means 100% probability of response and if the response decreases the NSRI approaches 0.

Table 1 shows the demographic information and tumor sites of the patients. Both groups had similar demographics and tumor sites.

Hemodynamic variables at significant time points during the surgery are shown in Table 2. Mean baseline heart rate (HR) and mean arterial blood pressure (MAP) were similar among the groups with a significantly greater decrease in HR and MAP following induction and a significantly greater increase in HR and MAP at intubation among patients in BIS Group (P<0.05). Hemodynamic changes in both groups were comparable during other painful stimulations, maintenance of surgery and following extubation.

Table 1: Patients' demographic data and localization of tumor

	SPV Group (n=71)	BIS Group (n=68)
Age (years)	62 (16)	58 (13)
Gender (Female/Male)	34/37	36/32
ASA physical status (I/II/III) (n)	34/29/8	26/33/9
Weight (kg)	79 (16)	83 (18)
Height (cm)	162.0 (11.7)	161.0 (17.3)
Localization of tumor (n)		
Frontoparietal	23	21
Temporoparietal	30	32
Occipital	18	15

Values are expressed as mean (standard deviation) or number. No significant differences between groups. ASA: American Society of Anesthesiologists

Table 2: Hemodynamic data: Heart rate and mean arterial blood pressure values at various time points

	HR (bpm)		MAP (mmHg)	
	SPV Group	BIS Group	SPV Group	BIS Group
Baseline	79 (19)	77 (16)	92 (12)	94 (11)
Induction	75 (12)	63 (15)*Ŧ	88 (14)	74 (14)*Ŧ
Intubation	80 (13)	89 (16)*Ŧ	91 (16)	105 (18)*Ŧ
Scalp block	83 (11)	85 (14)*	93 (14)	95 (16)
Mayfield placement	78 (17)	81 (13)	89 (13)	91 (15)
Skin incision	75 (16)	77 (11)	86 (16)	87 (13)
Craniotomy	71 (14)	72 (16)	84 (17)*	84 (16)*
Dural incision	71 (14)	73 (17)	85 (16)*	83 (15)*
Maintenance	68 (11)*	69 (15)*	81 (17)*	84 (14)*
Skin closure	67 (15)*	63 (17)*	81 (16)*	83 (16)*
Extubation	80 (14)	83 (12)	94 (18)	96 (12)

Values are expressed as mean (standard deviation). SPV: Smartpilot® View, HR: Heart rate, MAP: Mean arterial pressure, *P<0.05 vs. baseline values, Ŧ P<0.05 vs. SPV Group

The durations of anesthesia and surgery, as well as the patients' recovery times, are shown in Table 3. Both groups had comparable anesthesia and surgery durations. The mean time until eye opening was 3.6 (2.4) minutes in the SPV Group versus 6.06 (1.63) minutes in the BIS Group (P<0.001) and extubation time, 5.76 (1.3) minutes in the SPV Group versus 9.16 (1.0) minutes in the BIS Group (P<0.001) (Table 3). The time it took for the patients in the SPV Group to reach an Aldrete score of 9 or above was also shorter (P<0.001).

The SPV group had considerably reduced total consumed doses of propofol and remifentanil (P<0.001) (Table 3).

Table 3: Anesthesia and surgery times, recovery times, anesthetics consumed

	SPV Group	BIS Group	P-value
Duration of surgery (min)	199 (39)	187 (49)	0.454
Duration of anesthesia (min)	237 (40)	220 (37)	0.328
Time to eye opening (min)	3.6 (2.4)	6.06 (1.63)	<0.001
Time to extubation (min)	5.76 (1.3)	9.16 (1.0)	<0.001
Time to reach Aldrete score ≥ 9 (min)	17.4 (7.8)	25.2 (2.4)	<0.001
Propofol consumed (mg)	1808.96 (840.8)	2419.66 (693.9)	<0.001
Remifentanil consumed (µg)	1373.81 (620.4)	1910.2 (556.7)	<0.001

Values are expressed as mean (standard deviation)

Discussion

In the current study, SPV was evaluated during a target-controlled infusion anesthesia and compared to a standard BIS-guided practice group. Our findings show that SPV guidance resulted in significant reductions of propofol, and remifentanil use as well as shorter recovery times. Except for the development of deeper hypotension following induction in the BIS Group, hemodynamic stability was comparable in both groups.

Target-controlled infusion (TCI) adjusts intravenous drug infusion rates to meet target plasma concentrations using conceptual modeling. Previous research suggests that total intravenous anesthesia with TCI propofol and remifentanil is a useful technique for controlling responses to tracheal intubation and intense surgical stimulation while preserving cerebral

autoregulation and allowing for rapid emergence from anesthesia after supratentorial tumor craniotomy [11].

A number of clinical trials investigated the impact of intraoperatively administered anesthetics on hemodynamic stability, cerebral protection, recovery patterns, and nociception after supratentorial craniotomy [11-14]. Still, it is unclear whether the anesthetics or anesthesia technique used makes a substantial difference in the patient outcome [15]. Even though each anesthetic drug has a unique effect, how anesthetics are adjusted or optimized is likely to have a greater impact on anesthesia quality. Optimizing anesthetics throughout the perioperative period of neurosurgery has a significant impact on hemodynamics, cerebral blood flow, metabolism, and brain protection, as well as the quality of emergence, postoperative course, and recovery, all of which are used to assess anesthesia quality.

Anesthesia administration based on pharmacological models, which considers pharmacokinetic and pharmacodynamic responses to maintain optimal depth of anesthesia and analgesia, may ensure better drug titration [7, 17]. Response surface models were developed to illustrate the combined clinical effects of two or more drug concentrations pharmacologically [18, 19]. The hypnotic and opioid concentrations are assessed on the x and y axes, respectively, and the synergistic effects of drugs known as isoboles are shown on the z axis. Some commercial products, such as SPV, incorporated these synergistic interactions into its operating principles. A new anesthetic depth index, the Noxious Stimulation Response Index (NSRI), was developed based on these response surface models and runs from 100 to 0 [20]. The NSRI measures the likelihood of tolerating and anticipating an intraoperative reaction to a noxious stimulus: NSRI 100 implies a 100 percent probability of response; as the NSRI approaches 0, the response declines [21]. The anesthetist can use this index to evaluate the level of anesthesia that would be appropriate for the procedure and the patient's characteristics. In 44 subjects, NSRI was shown to be better in predicting the response to noxious stimulation than parameters derived from electroencephalography and effect-site concentrations of drugs [20].

The SmartPilot® View graphically depicts the interaction of hypnotic and analgesic drugs with isoboles and uses NSRI to measure the depth of anesthesia. Another benefit of SPV is that it displays the current depth of anesthesia as well as the expected level for the next 10 minutes [8, 10]. When opioids and intravenous anesthetics are co-administered for anesthesia maintenance, fifty percent probability to tolerate laryngoscopy (TOL 50) is equal to NSRI 50, and ninety percent probability to tolerate laryngoscopy (TOL 90) is equal to NSRI 20. A deeper anesthesia than TOL 90 means high probability for tolerating highly painful stimuli, which is equal to a NSRI between 0 to 20. In our study, SPV-guided depth of anesthesia was maintained to keep anesthesia deeper than TOL 90 (NSRI $\leq$ 20) for intubation, Mayfield pin placement, skin incision, craniotomy, and dural opening and TOL 50-TOL 90 (NSRI 20-50) for the remainder of the surgery. In a patient undergoing semi-awake craniotomy, Mai and colleagues [22] successfully used SPV and TCI during intraoperative neurophysiological monitoring. In that case, BIS of the patient was maintained within the range of 80 to 90 that was approximately equal to fifty percent probability to tolerate shout and shake (TOSS 50 equal to NSRI 90). When BIS was within the range of 50 to 79 and the anesthesia depth increased to ninety percent probability to tolerate shout and shake (TOSS 90) level, neurophysiological monitoring was affected and considered poorly reproducible. The SPV made it possible to maintain and coordinate the required depth of anesthesia, which would be difficult to achieve with BIS monitoring only.

The optimal control of systemic and cerebral hemodynamics should be addressed during anesthesia for craniotomy. Both arterial hypotension and, as a result, cerebral hypoperfusion, as well as an undesired hypertensive response to a painful stimulation during craniotomy and recovery from anesthesia, are associated with increased morbidity, mortality, and poor neurologic outcomes. In the current study, SPV-guided anesthesia reduced the incidence of post-induction hypotension and intubation-induced hypertension. Hemodynamic responses in both groups were comparable during other painful stimulations, maintenance of surgery and following extubation. This finding can be attributed to the effect of scalp block, which was adjusted to all patients.

Early post-anesthesia recovery is critical following supratentorial surgeries and ensuring that neurocognitive function is quickly restored after surgery is an important goal in the anesthetic management of these patients [13]. BIS monitoring, which is the most often used monitor to evaluate the depth of anesthesia, has been shown to have an impact on recovery in previous studies [3, 4]. Mostly, BIS is accurate in determining solely the hypnotic component of anesthesia, it may not adequately reflect the even hypnotic state in some instances [23]. Unusual BIS readings were observed as a result of inaccurate low-voltage EEG analysis, particularly during anesthesia recovery [24]. Furthermore, SPV gives a priori anesthetic depth estimation, allowing anesthetic depth to be changed, whereas BIS only provides posteriori information, usually after a delay in response.

There was a significant difference in recovery times between patients monitored with SPV and patients who underwent normal anesthetic follow-up in our study. These findings are parallel those of a previous study searched the usefulness of SPV for a fast recovery from desflurane anesthesia [25]. Morimoto et al. [25] discovered that the time it took patients to open their eyes and restore orientation was much shorter in the SPV group, concluding that SPV-guided anesthesia is faster than BIS-guided anesthesia. Unlike our study, Morimoto et al. [25] used SPV at the end of the surgery, because they were solely interested in the recovery period. During the whole anesthetic phases in our research, SPV was utilized continuously in the SPV group.

In another non-randomized controlled research, Cirillo et al. [8] reported that in SPV-guided anesthesia administered groups, volatile anesthetic consumption was reduced. The authors, however, did not actually specify which MAC values they used for anesthesia maintenance or at what depths anesthesia was maintained. We can explain the reduced consumption of sevoflurane and remifentanil in the group monitored with SPV in our study, as SPV displays the hypnotic

level as well as the responsiveness to noxious stimuli compared to BIS.

Leblanc et al. [10] examined the effect of SPV on postoperative results in patients undergoing hip fracture surgery compared with standard anesthesia administration, assuming that the use of SPV in older patients may be particularly advantageous. Patients in the SPV group had better postoperative outcomes, including a shorter hospital stay [10]. Although our study showed a reduction in anesthetic consumption, the consequences on patient outcomes, postoperative mortality, and morbidity were not studied.

Limitations

The major shortcoming in this study is that it was underpowered due to its retrospective design. Prospective randomized controlled studies are needed to determine the influence of SPV on overall patient outcome and justify its usage in routine clinical practice.

Conclusion

In the current study, we investigated the effects of SPV on hemodynamics, anesthetic drug requirements, and recovery profile following supratentorial craniotomies and the display of the level of anesthesia on the SPV enabled the steady maintenance of neuroanesthesia. SmartPilot® View was effective in maintaining intraoperative hemodynamic stability, shortening postoperative recovery time, and reducing propofol and remifentanil requirement.

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