ORIGINAL ARTICLE

Evaluation of the compliance between EEG monitoring (Bispectral Index™) and Ramsey Sedation Scale to measure the depth of sedation in the patients who underwent procedural sedation and analgesia in the emergency department

Sinem Avcı, M.D.,[1] Başak Bayram, M.D.,[2] Gonca İnanç, M.D.,[3] Nurfer Gören, M.D.,[2]
Adile Öniz, M.D.,[3] Murat Özgören, M.D.,[3] Neşe Çolak Oray, M.D.[2]

[1]Department of Emergency Medicine, Ankara Training And Research Hospital, Ankara-*Turkey*
[2]Department of Emergency Medicine, Dokuz Eylül University Faculty of Medicine, İzmir-*Turkey*
[3]Department of Biophysics, Dokuz Eylül University Faculty of Medicine, İzmir-*Turkey*

ABSTRACT

BACKGROUND: This study aimed to investigate the compliance between electroencephalogram monitoring (Bispectral Index, BIS) and Ramsay Sedation Scale (RSS) to measure the depth of sedation in patients who underwent procedural sedation and analgesia (PSA) in an emergency department. This study also aimed to investigate the usefulness of this compliance for early diagnosis of complications.

METHODS: A total of 54 consecutive patients during PSA in the emergency department were included in this study. The BIS and RSS scores at regular intervals and also all complications and interventions of these patients were evaluated. The compliance between the BIS and the RSS score was evaluated. The BIS scores of cases with complication and without complication were compared.

RESULTS: The BIS and RSS scores exhibited a high correlation was detected between the average BIS and RSS scores at each time interval ($r=-0.989$, $p<0.001$). The BIS scores of the complicated and uncomplicated cases were different at 15 min after the procedure ($p=0.019$). The cases were divided into two groups according to the BIS scores <70 and ≥70; complication rates were higher in the BIS score <70 group during the procedure ($p=0.037$).

CONCLUSION: In our study, a high correlation was detected between BIS monitoring and RSS scores. BIS monitoring for PSA can be used as a full-time, objective, and an alternative technique for person-dependent clinical scales and also as an indicator for early diagnosis of complications.

Keywords: Bispectral index; emergency department; procedural sedation and analgesia; Ramsay Sedation Scale.

INTRODUCTION

Procedural sedation and analgesia (PSA) is a common technique frequently used in emergency department (ED) practice. The aim of using PSA is to successfully perform ED interventions with minimal complication and optimum analgesia. Following the depth of sedation is one of the main elements to provide a successful and safe PSA.[1,2] The Ramsay Sedation Scale (RSS), developed by Ramsay in 1974, was first used in the assessment of sedation levels of patients in intensive care units, and is still the most commonly used sedation scale in these units.[3,4] RSS is an international evaluation scale

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Address for correspondence: Sinem Avcı, M.D.
Ankara Eğitim ve Araştırma Hastanesi, Acil Tıp Kliniği, Ankara, Turkey
Tel: +90 312 - 595 38 06 E-mail: sinem.avci_@hotmail.com

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not only in intensive care units but also in all cases requiring sedative and analgesic medications.[5,6] RSS had several disadvantages, such as being person-dependent, requiring dispensing of painful and verbal stimuli to patients for the evaluation, and reflecting only the moment of observation and not giving a continuous measurement. Moreover, the use of these scales at the time of treatment is difficult.[7] Bispectral Index (BIS) is a sedation follow-up method that presents instantaneous sedation levels as a quantitative data by analyzing electroencephalogram (EEG) signals by electrodes adhering to the forehead and temporal region, and with computer software.[8] The full-time objective monitoring method makes the sedation depth easy to follow. The reliability of BIS usage for sedation level follow-ups was proven in operating rooms and intensive care units. BIS monitoring can be used as an alternative method to the classical sleep-scoring system in studies and to follow up the sedation depth in the cases not requiring general anesthesia but requiring sedation, such as bronchoscopy, endoscopy, and dental interventions.[9–13] An objective, person-independent monitoring that can be evaluated by all health care professional increases the success and reliability of the PSA. However, the number of studies related to the use of BIS monitoring to follow up the depth of sedation is fewer, with varying results. Therefore, the success and reliability of the BIS monitoring in ED are still open to discussions.

The primary aim of this study was to investigate the compatibility between EEG monitoring (BIS™) and RSS to follow up the sedation depth in the patients who undergo PSA in ED. The study also aimed to explore the usefulness of this technique for early diagnosis of complications.

MATERIALS AND METHODS

Study Design

This prospective, cross-sectional, analytical study was carried out in Dokuz Eylül University Faculty of Medicine, Department of Emergency Medicine after the approval of the ethics committee (163-GOA).

Study Population

The patients who were more than 18 years of age and who underwent PSA because of an extremity fracture or dislocation in the emergency department between December 1, 2014, and May 1, 2015, were included in this study. Twenty four patients were excluded from this study (13 patients who were diagnosed with epilepsy, patients with suppressed conscious awareness before PSA (mentally retarded, GKS (Glasgow coma scale) ≤14, sequelae of cerebrovascular disease, dementia, intracranial mass, severe head trauma, history of psychotic disease), patients with conscious repressive drug/illegal substance/alcohol intake, patients who had a significant airway obstruction problem (tumor, sleep apnea syndrome), patients who were pregnant, patients who were followed up with an invasive or noninvasive mechanical ventilation, patients who had a skin lesion on their frontal area, patients who refused to participate in the study, and patients who used ketamine for sedation.

Study Protocol and Measurements

All patients were monitored before the PSA, and the nasal oxygen was started at a flow rate of 2–4 L/min. Midazolam, propofol and midazolam–propofol combination were used as sedative drugs. The type and the amount of sedation or analgesic drug used were determined by the emergency medicine resident physician. The researchers had no interference with the monitoring of the patient before or during the procedure, or type/dose of the planned drugs, or time/way of doing the procedure. All the vital signs (blood pressure, pulse, respiratory rate, oxygen saturation, and fever) and GKS of the patient were measured by a physician every five min and recorded. The RSS and BIS scores of the patients were recorded at the basal level (before PSA), at the beginning of the procedure (start of the procedure), and at 5, 10, 15, and 20 min.

One of the researchers was recorded RSS score, and other researcher monitored and recorded BSS scores. The BIS scores were blinded to the RSS data. The procedure physician performing the sedation and procedure were also blinded to the BIS and RSS scores. All complications and interventions that occurred during the procedure were recorded.

The following situations were considered as complications:

1. Partial or complete airway obstruction
2. Hypoventilation apnea
3. Nausea–vomiting after the procedure, aspiration
4. Hypotension (systolic blood pressure <90 mm Hg)
5. Bradycardia (pulse <50 pulse/min)
6. Need for a rescue maneuver (head re-position maneuvers, jaw-thrust maneuvers, oral airway usage, antidote usage)
7. Need for NIMV(Noninvasive mechanical ventilation)/intubation
8. Epileptic seizure

Data Collection Instruments

In this study, "RSS" and "BIS" were used as sedation depth measurement methods. In the BIS measurement, A-2000 BIS XP monitor (Aspect Medical System, MA, USA) was used (Fig. 1). The patients were monitored with Nihon Kohden Bedside Monitor BSM 3662 (Nihon Kohden Corporation Shinjuku, Tokyo, Japan) for vital signs and obtained data.

Statistical Analysis

Data were recorded using Statistical Package for Social Sciences for Windows 19.0. The Mann-Whitney U test was utilized to evaluate the relationship between the presence of a complication, drug types and BIS/RSS scores. The com-

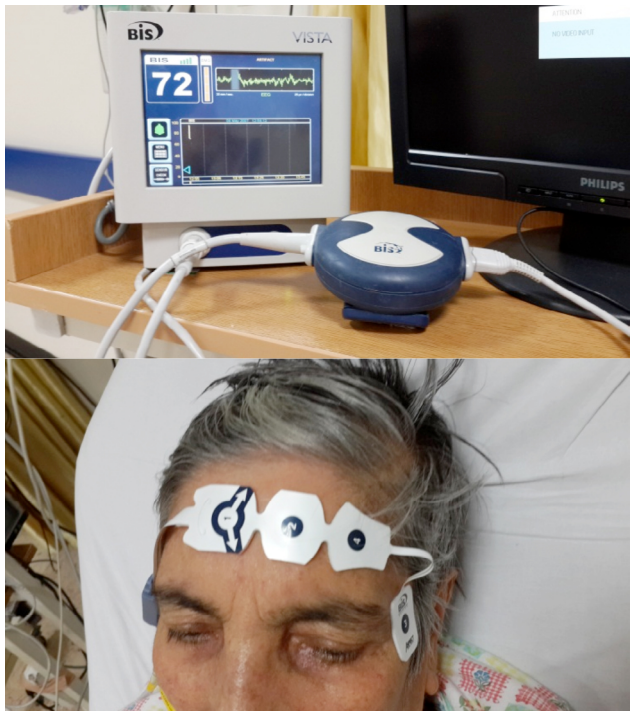

Figure 1. A-2000 BIS XP monitor.

plication rates and BIS groups (BIS score <70 and ≥70) were analyzed using Fisher's Exact Test. The Pearson correlation analysis was performed to compare both the RSS and BIS results at each time interval. A score of $p<0.05$ was accepted as significant.

RESULTS

This study included 54 patients who satisfied the inclusion criteria out of 78 patients who planned to undergo PSA and visited the ED because of an extremity fracture or dislocation between December 2014 and May 2015.

A total of 35 females (64.8%) and 19 males (35.2%) were included in this study, and their average age was 57.4±15.7 (between 18 and 87 years). Midazolam (n=16, 30%), propofol (n=14, 26%), and midazolam–propofol combination (n=24, 44%) were used as sedatives.

The analysis of BIS scores revealed a significant difference between drug types and BIS scores at 5, 15, and 20 min (p=0.035, 0.002, and 0.07, respectively). In the midazolam–propofol group, the average BIS score at 5 min was (79±9.8), and the BIS scores at 15 and 20 min were lower in the midazolam group compared with the other groups (81.1±11.1 vs 87.7±9.1).

The time curve of the BIS and RSS measurements of the patients are shown in Figure 2. The lowest average BIS measurement occurred between the start and five min after the procedure, and then it increased with an increased slope between 15 and 20 min.

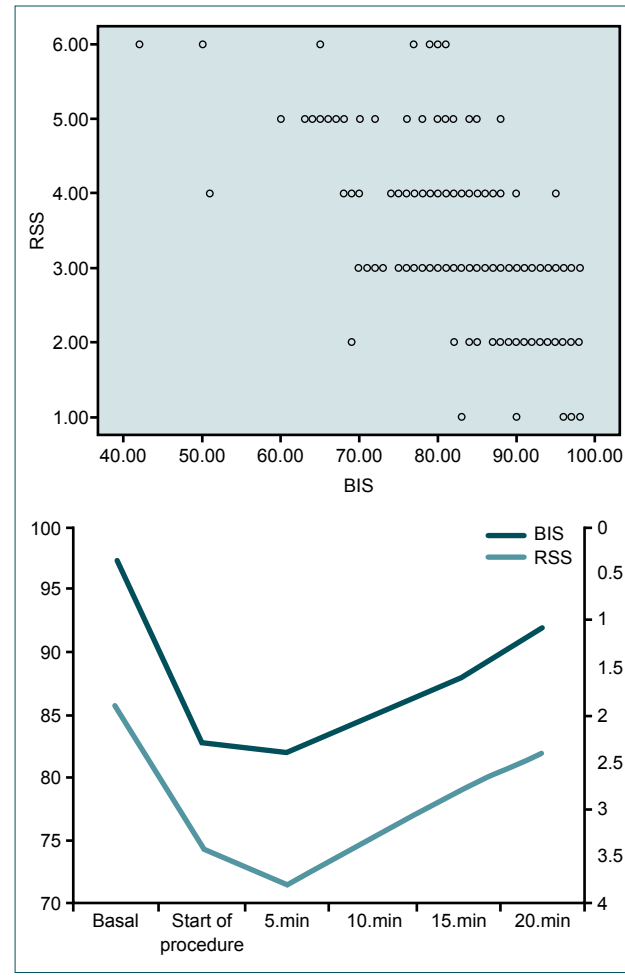

Figure 2. Distribution of BIS and RSS measurements according to follow-up durations.

A high correlation was detected between the whole BIS and RSS scores at all measurements (r=−0.989, p<0.001). No significant correlation was observed between the basal BIS and RSS scores (r=0.336, p=0.016). A moderate correlation was noted between the BIS and RSS scores of these 54 patients at the start of the procedure and 5 and 15 min after the procedure (r=−0.634, −0.637, and −0.665, respectively), and a high-degree correlation was observed at the start of the procedure and 10 and 20 min after the procedure (r=−0.748 and −0.774, respectively) (Table 1).

Complications developed in 16 patients in the present study. The most common complication was hypoventilation/apnea (18.5%). Additionally, hypotension developed in two patients (3.7%), and a simple airway maneuver was needed in four patients (7.4%). None of the patients required İnvasive/non-invasive mechanical ventilation.

On comparing the relationship between BIS measurements and complications, the BIS measurement scores at all times in the complicated cases were found to be lower. The BIS scores of the complicated and uncomplicated cases were different at 15 min after the procedure (p=0.019) (Table 2).

Table 1. Average BIS and RSS scores of the cases

Duration	BIS	RSS	Correlation
	Average±SD (min–max)	Average±SD (min–max)	
Basal	97.2±1.4 (90–98)	1.91±0.2 (1–2)	-0.326
Start of the procedure	82.9±11.2 (42–98)	3.4±1 (1–6)	-0.634
5 min	82.1±8.9 (64–98)	3.8±0.9 (2–6)	-0.637
10 min	85.1±9.8 (60–98)	3.3±1.2 (1–6)	-0.748
15 min	87.8±10.1 (51–98)	2.8±1 (1–6)	-0.665
20 min	91.8±7.8 (68–98)	2.4±0.7 (2–5)	-0.774

BIS: Bispectral Index; RSS: Ramsay Sedation Scale; SD: Standard deviation.

The average age of patients with complications was 53.5±16, and patients without complications was 59.1±15.3 (p=0.236). No significant difference was observed between sex and drug type used and complication development (p=0.819 and 0.530, respectively).

The patients were separated into two groups according to their BIS scores <70 and ≥70. The complication rates in the BIS score <70 group were found to be higher during the procedure (p=0.037).

DISCUSSION

The present study demonstrated a high-degree correlation between BIS monitoring and RSS measurement. Several studies have investigated the compliance between BIS and clinical scales. Correlations have been determined at varying degrees in the published studies. In a study by Gill et al.,[14] a moderate correlation was detected between BIS and modified RSS in 37 adult patients in the ED. In this study, the best BIS score that distinguished moderate sedation level from deeper sedation level was found to be 80 (sensitivity 86%, specificity 94%). In this respect, to our knowledge, this was the only study that determined a threshold score for the desired sedation level. Similar to the present study, Agrawal et al.[15] also detected a high-grade correlation between BIS and modified RSS in 20 pediatric patients who underwent PSA. Since the present study was conducted with a large number of adult patients, it took the study by Agrawal et al. to another level. In the study by Yang et al.,[16] a weak correlation was detected between the RSS and BIS scores in 1766 patients who underwent minor interventions out-of-surgery room by providing moderate sedation with midazolam. No correlation was observed between the type of drug (midazolam, propofol, and their combinations) and the presence of complication in the present study, which was consistent with other similar studies.[9,16–19] According to the present study and other previous studies, the sedation level determined the risk of complication in PSA rather than the type or dose of the drug. It can be concluded that effective PSA monitoring reduces the risk of complications irrespective of the drug dose.

No internationally accepted scale followed up the depth of sedation in ED procedures. Several studies are available that

Table 2. Relationship between BIS and RSS scores and the presence of a complication

		With complication (n=16)		Without complication (n=38)		p
		Median	Min-Max	Median	Min-Max	
Basal	Bispectral Index	98	94–98	98	90–98	0.227
	Ramsay Sedation Scale	2	1–2	2	1–2	0.122
Start of the procedure	Bispectral Index	82	42–97	84	65–98	0.056
	Ramsay Sedation Scale	4	1–6	3	2–5	0.471
5 min	Bispectral Index	81	64–90	83.5	65–98	0.122
	Ramsay Sedation Scale	4	3–5	3	2–6	0.094
10 min	Bispectral Index	84	68–97	86	60–98	0.537
	Ramsay Sedation Scale	3	1–5	3	2–6	0.243
15 min	Bispectral Index	86	68–98	91	51–98	0.019
	Ramsay Sedation Scale	3	1–5	2	2–6	0.599
20 min	Bispectral Index	90.5	68–98	97	75–98	0.069
	Ramsay Sedation Scale	3	2–5	2	2–4	0.005

BIS: Bispectral Index; RSS: Ramsay Sedation Scale; Min: Minimum; Max: Maximum.

used different clinical scales. In the study by Weaver et al.,[7] BIS compliance was investigated with two clinical scales [Observer's Assessment of Alertness/Sedation scale (OAA/S) and Continuum of Depth of Sedation] in 75 patients who underwent PSA with propofol in the ED and found a moderate correlation between these two. Although different clinical scales were used in this study, the aforementioned two scales showed very similar compliance with each other. Many correlational studies are available on sedation scales in different areas where PSA is applied, such as endoscopy, bronchoscopy, and dental interventions, except in ED.[9,20,21] Bower et al.[20] found a moderate correlation in their study that investigated the compliance between OAS/S and BIS in 50 adult patients undergoing PSA-requiring endoscopy. In another study, OAS/S and BIS compliance were assessed in 25 patients who underwent a tooth extraction, and a high correlation was determined between these two variables.[21] In the present study, a high correlation between RSS and BIS scores in the reduction of painful extremity fracture or disclosure demonstrated that BIS real-time monitoring is a more effective and reliable method than RSS. Clinical scorings, such as RSS are practitioner related. Practitioner-independent objective monitoring, which can be interpreted by any health practitioner, is possible with BIS in the ED during sedation analgesia procedure. PSA complications are the most frightening complications for health practitioners. In current practice, patients are classically monitored with oxygen saturation, blood pressure, heart rate, and less often with the end-tidal CO_2. All these parameters deteriorate only after the complication develops. No method predicts the development of complication just before or during the complication. In the present study, the patients who had low BIS scores at the start of the procedure had higher statistical complication rates. Although no statistical difference was noted at different time intervals after the start of the procedure, BIS scores of the patients who had complications were lower. Several studies reported that reliable PSA follow-up could be carried out by BIS monitoring. For example, the study by Yang et al.[16] showed that complications were lower (especially desaturation) in the group monitored with BIS. Also, Miner et al.[17] reported a significant difference between BIS scores of patients with and without complications. Moreover, more respiratory depression was observed in the patients who had a BIS score <70. In another randomized controlled study conducted by Miner et al.,[22] 48 patients were monitored using BIS, and 52 patients were monitored using classical methods were compared. Although similar sedation levels were detected in both groups, less respiratory depression was seen in the group monitored using BIS. These studies showed that BIS monitoring was effective for following the depth of sedation and blocking the complications. The most common and frightening complications in the PSA are deep-sedation-related respiratory complications and drug/procedure-related vital instability. Complication rates increase as the sedation depth increases. The present study presumed that possible complications might be predicted beforehand, as the depth of sedation can be shown by BIS monitoring. The BIS score for predicting possible complications was determined as 70.8 in this study, as well as in previous studies.[14,17] Despite this evaluation, the number of cases in these studies was limited. Knowing the target BIS scores is important for determining the possible sedation levels and blocking the complications. Further studies are required to determine BIS scores that are appropriate for sedation, have no complications in different patient groups, and involve a large number of patients.

Limitations

Since the researcher had no interference with the PSA plan of the patients, start time of the procedure, and type or amount of the drug, a standard drug type, and dose were not used in this study. Although most studies showed that the use of different agents does not affect the results of the complications, the drug variability may still affect the outcomes in different patients. Second, both the sedation level and BIS monitoring were affected by temperature, muscle spasm, sleep, and external stimuli (e.g. interventions of health care professionals, noise, and painful stimulus). Especially, many (and unpredictable) external stimuli in the emergency setting environment might have affected the results. Also, since the study population consisted of patients who underwent more painful interventions, it was difficult to provide the sedation depth.

Third, the RSS is an individual-specific scale, and differences might exist between the evaluations of different researchers. This scale was first used in the assessment of sedation levels of patients in intensive care units and is still the most commonly used sedation scale in these units. This is why we used it in this study. Different results may be revealed when other scales are used in this study.

Conclusions

A high-degree correlation was detected between the RSS and BIS scores evaluated in the patients undergoing PSA in ED. A significant relation was detected between the BIS scores at the start of the procedure and complications. BIS monitoring for PSA follow-ups in the ED can be used as a full-time, objective, and an alternative technique for person-dependent clinical scales and also as an indicator for early diagnosis of complications.

Conflict of interest: None declared.

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ORİJİNAL ÇALIŞMA - *ÖZET*

Acil serviste girişimsel sedasyon ve analjezi uygulanan hastalarda sedasyon derinliğini ölçmede EEG monitörizasyonu (Bispectral Index™) ile Ramsey Sedasyon Skalası'nın uyumluluğunun değerlendirilmesi

Dr. Sinem Avcı,[1] Dr. Başak Bayram,[2] Dr. Gonca İnanç,[3] Dr. Nurfer Gören,[2] Dr. Adile Öniz,[3] Dr. Murat Özgören,[3] Dr. Neşe Çolak Oray[2]

[1]Ankara Eğitim ve Araştırma Hastanesi, Acil Tıp Kliniği, Ankara
[2]Dokuz Eylül Üniversitesi Tıp Fakültesi, Acil Tıp Anabiim Dalı, İzmir
[3]Dokuz Eylül Üniversitesi Tıp Fakültesi, Biyofizik Anabilim Dalı, İzmir

AMAÇ: Çalışmamızda girişimsel sedasyon ve analjezi uygulanan hastalarda sedasyon derinliğini takip etmede EEG monitörizasyonu (Bispectral Index™, BIS) ile 'Ramsey Sedasyon Skalası'nın (RSS) uyumluluğunu ve gelişebilecek komplikasyonları tanımada kullanılabilirliğini belirlemeyi amaçladık.
GEREÇ VE YÖNTEM: Çalışmamızda olguların belirli aralıklarla BIS ve RSS değerleri, gelişen komplikasyonlar ve yapılan müdahaleler değerlendirildi. BIS ve RSS değerlerinin uyumluluğu değerlendirildi. Komplikasyon görülen, görülmeyen olguların BIS değerleri karşılaştırıldı.
BULGULAR: Tüm zaman dilimlerindeki BIS ve RSS değerlerinin ortalamaları karşılaştırıldığında aralarında yüksek derecede korelasyon saptandı (r=-0.989, p<0.001). Komplikasyon görülen olgularda 15. dk'daki BIS değerleri arasında istatistiksel anlamlı bir fark vardı (p=0.018). Olgular BIS değeri <70 ve ≥70 olarak iki gruba ayrıldı. BIS <70 olan grupta daha fazla komplikasyon görüldü (p=0.037).
TARTIŞMA: Çalışmamızda RSS ve BIS monitörizasyonu aralarında yüksek derecede korelasyon saptandı. BIS monitörizasyonu, GSA takibinde rutin ve kişi bağımlı klinik skalalara alternatif, objektif bir monitörizasyon yöntemi olarak güvenle kullanılabilir ve komplikasyonları erken tanımada öncül bir gösterge olabilir.
Anahtar sözcükler: Acil servis; Bispectral İndeks; girişimsel sedasyon analjezi; Ramsey Sedasyon Skalası.

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