Clinical Research

Evaluation of the Correlation Between Bispectral Index Monitorization and Ramsey Sedation Scoring, Michigan Sedation Scoring and Brussels Sedation Scoring*

Uğur DEVECİ[1,a], Leyla BULUT[1]

[1]*Fırat University Faculty of Medicine, Department of Child Health and Diseases, Elazığ, Türkiye*

ABSTRACT

Objective: Interventional Sedation and Analgesia (ISA) is a common practice for managing pain in pediatric clinics. Monitoring the depth of sedation is crucial for patients undergoing sedation and analgesia. This study aims to determine the correlation between EEG monitoring and the Ramsey Sedation Scale (RSS), Brussels Sedation Scale (BSS), and Michigan University Sedation Scale (MUSS) in monitoring the depth of sedation in patients undergoing ISA for endoscopy and colonoscopy.

Material and Method: Thirty-three patients were enrolled in our prospective and analytical study at Fırat University, Faculty of Medicine, Child Health and Diseases Service, between 11.04.2021 and 30.07.2021. Socio-demographic data, vital signs at the start of ISA, and at 5, 10, 15, and 20-minute intervals, along with Glasgow Coma Scale (GCS), BIS, RSS, BSS, and MUSS values were recorded. The compatibility of BIS with RSS, BSS, and MUSS values was evaluated.

Results: The median age among the 33 patients was 8±7 years, with a female/male ratio of 1.5. The lowest mean BIS measurements were recorded at the start of the procedure (92±19) and at the 5th minute (79±17). Measurements taken at the 10th, 15th, and 20th minutes were 79±16, 77±19, and 79±17, respectively. No correlation was detected between BIS and RSS, BSS, or MUSS averages at any time point (p=0.446, p=0.938, p=0.219). However, a significant correlation was found between RSS and MUSS (p=0.007).

Conclusion: The administration of sedation and analgesia effectively reduces the severity of pain experienced by patients. Additionally, careful monitoring of sedation and analgesia during interventional procedures is critical for preventing complications and ensuring optimal patient outcomes.

Keywords: *Bispectral Index, Brussels Sedation Scale, Child, Interventional Sedation Analgesia, Michigan Sedation Scale, Ramsey Sedation Scale.*

ÖZ

Bispektral İndeks Monitorizasyonu İle Ramsey Sedasyon Skorlaması, Michigan Sedasyon Skorlaması ve Brüksel Sedasyon Skorlaması Arasındaki Korelasyonun Değerlendilmesi

Amaç: Girişimsel sedasyon ve analjezi (GSA), Çocuk Kliniklerinde ağrılı işlemlerde sık tercih edilen bir uygulamadır. Sedasyon ve aneljezi uygulanan hastalarda sedasyon derinliği takip edilmelidir. Çalışmamızda endoskopi ve kolonoskopi işlemi nedeniyle GSA uygulanan hastalarda sedasyon derinliğini takip etmede EEG monitörizasyonu ile 'Ramsey Sedasyon Skalası (RSS), Brüksel Sedasyon Skalası (BSS) ve Mischigan Üniversitesi Sedasyon Skalası (MÜSS)'ı arasındaki korelasyonu belirlemeyi amaçladık.

Gereç ve Yöntem: Prospektif, analitik çalışmamıza, Fırat Üniversitesi Tıp Fakültesi Çocuk Sağlığı ve Hastalıkları Servisi'ne 11.04.2021-30.07.2021 tarihleri arasında başvuran 33 hasta alındı. Olguların sosyo-demografik verileri, GSA öncesi, işlem başlangıcı ve sonrasında 5, 10, 15, 20. dakikalardaki vital bulguları, Glasgow Koma Skalası (GKS), BIS, RSS, BSS ve MÜSS değerleri kayıt edildi. BIS ve RSS, BSS, MÜSS değerlerinin uyumluluğu değerlendirildi.

Bulgular: Çalışmaya alınan 33 hastanın yaş ortalaması 8±7, kadın/erkek oranı 1.5 idi. En düşük ortalama BIS ölçümleri, işlem başlangıcında (92±19) ve 5. dakikada (79±17) gelişti. Sonrasında ise 10-15-20. dakikalarda (79±16, 77±19 ve 79±17) ölçüldü. Tüm zaman dilimlerindeki BIS ile RSS, BSS, MÜSS) değerlerinin ortalamaları karşılaştırıldığında aralarında korelasyon saptanmadı (p= 0.446, p= 0.938, p= 0.219). Bu çalışmada RSS ve MÜSS arasında anlamlı korelasyon gözlendi (p= 0.007).

Sonuç: Sedasyon ve analjezi uygulaması ağrının şiddetini azaltmaktadır. Bunun yanında girişimsel işlemler sırasında verilen sedasyon ve analjezinin monitörizasyonu, oluşabilecek komplikasyonları önleyebilmektedir.

Anahtar Sözcükler: *Bispectral İndeks, Brüksel Sedasyon Skalası, Çocuk, Girişimsel Sedasyon Analjezi, Michigan Sedasyon Skalası, Ramsey Sedasyon Skalası.*

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ORCID IDs: U.D. 0000-0002-53958250, L.B. 0000-0001-6530-7992.

Interventional sedation analysis (ISA) is a medical procedure that facilitates the execution of potentially painful or anxiety-inducing diagnostic and therapeutic interventions in specific patient populations. The effectiveness of ISA is assessed by monitoring the depth of sedation achieved in patients (1,2). Numerous scales

[a]Yazışma Adresi: Uğur DEVECİ, Fırat University Faculty of Medicine, Department of Child Health and Diseases, Elazığ, Türkiye
Tel: 0424 233 3555 e-mail: ugurdeveci23@hotmail.com
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have been developed to monitor sedation depth, with the most commonly used being the Ramsay Sedation Scale (RSS), Michigan University Sedation Scale (MUSS), and Brussels Sedation Scale (BSS). Among these, the RSS remains the most widely utilized in clinical practice today (3). However, the application of these scales in clinical settings poses challenges, as their reliability depends heavily on the subjective interpretation of the evaluator. Additionally, these scales require the administration of painful or verbal stimuli at specific moments, which limits their ability to provide continuous and objective measurements (4).

The Ramsay Sedation Scale (RSS) was first introduced by Ramsay and colleagues in 1974 as a straightforward scoring system, which continues to be a predominant tool in intensive care units (5).The RSS is applicable not only in intensive care settings but also across various clinical scenarios where sedative and analgesic medications are administered (6). The scale consists of six levels: Level 1-patient is awake but anxious, agitated, or restless; Level 2-patient is awake, cooperative, oriented, and calm; Level 3-patient is asleep but responds to commands; Level 4-patient exhibits a brisk response to glabellar tap or loud auditory stimulus; Level 5-patient shows a sluggish response to such stimuli; and Level 6-patient exhibits no response to glabellar tap or loud auditory stimulus (7). The target sedation level for most clinical scenarios is typically Level 2. It remains one of the most widely utilized clinical evaluation methods to this day (8).

The University of Michigan Sedation Scale (MUSS) was developed to provide a simple and rapid method for assessing and documenting the depth of sedation in patients receiving sedative agents for diagnostic or therapeutic procedures. The scale ranges from 0 to 4: Level 0-patient is awake and alert; Level 1-patient responds to minimal verbal stimuli; Level 2-patient responds to moderate tactile stimuli; Level 3-patient requires deeper physical stimuli for arousal; and Level 4-patient does not respond to any stimuli. The MUSS was designed to be easy to use, reproducible, and objective (9).

The Brussels Sedation Scale (BSS) was primarily developed for use in intensive care settings, aiming to provide a simple, repeatable, and objective method for assessing sedation depth. The scale includes five levels, but unlike the RSS, it inverts the order: higher numerical values correspond to lighter levels of sedation. This approach is believed to be easier to apply and is conceptually similar to the Glasgow Coma Scale (GCS), where lower scores indicate deeper levels of unconsciousness. On the BSS, Level 1 corresponds to a patient who cannot be awakened and only responds to painful stimuli, such as trapezius muscle compression; Level 2 indicates a patient who does not respond to verbal stimuli but reacts to pain; Level 3 is for patients who respond to verbal commands; Level 4 indicates the patient is awake and alert; and Level 5 corresponds to a state of agitation (10).

The Bispectral Index (BIS) ranges from 0, which represents isoelectric EEG, to 100, indicating an awake brain. Following the administration of sedative and analgesic agents, a patient's level of consciousness transitions through various stages, which are reflected in the BIS score. The BIS value decreases from 100, with a BIS of 60 indicating a reduced likelihood of consciousness, while values below 40 are indicative of deep hypnosis approaching an isoelectric EEG. The BIS value, which starts at 100 indicating an awake state of consciousness, gradually decreases as sedation deepens. A BIS value of 60 is associated with a significantly reduced likelihood of consciousness, while values below 40 are indicative of deep hypnosis, nearing an isoelectric EEG. BIS values within the range of 40 to 60 are considered to provide an effective hypnotic state suitable for general anesthesia, ensuring a rapid recovery. The Bispectral Index (BIS), derived from electroencephalography (EEG) signals, is widely regarded as a quantitative measure of anesthetic depth. This index is generated by advanced computational algorithms that analyze cerebral electrical activity, allowing for continuous and objective monitoring of sedation depth. The BIS technique facilitates the precise assessment of sedative and hypnotic effects of anesthetic agents, making it a valuable tool in clinical settings. Numerous studies have demonstrated the utility of EEG monitoring, particularly in intensive care units and operating rooms, for assessing sedation depth. Furthermore, in cases where general anesthesia is not administered but sedation is required, BIS monitoring has been reported as an effective alternative for determining anesthetic depth during procedures such as endoscopy, bronchoscopy, central catheter insertion, and dental interventions. It also serves as an alternative to traditional sleep staging systems in sleep studies (11-14). This study aims to evaluate the correlation between the clinically subjective scales RSS, MUSS, and BSS and BIS monitoring in patients undergoing Interventional Sedation and Analgesia (ISA).

MATERIAL AND METHODS

This study aims to evaluate the correlation between the clinically subjective scales RSS, MUSS, and BSS and BIS monitoring in patients undergoing Interventional Sedation and Analgesia (ISA).

Exclusion Criteria

Patients with a known diagnosis of epilepsy, those with pre-ISA impaired consciousness (e.g., mental metardation, Glasgow Coma Scale (GCS) ≤14, sequelae of cerebrovascular disease, dementia, intracranial mass, history of severe head trauma, and psychotic disorders), patients with significant airway obstruction (e.g., tumor, psychotic disorders, sleep apnea syndrome), patients on invasive or non-invasive ventilation, and those with skin lesions on the forehead were excluded from the study.

Sedation Protocol

Pediatric doses of midazolam (0.05-0.1 mg/kg/IV, with a maximum total dose of 10 mg) and meperidine (1 mg/kg) were administered. Medications were administered in accordance with established guidelines, avoiding high doses. The duration of the interventional procedures did not exceed 20 minutes, thus eliminating the need for premedication or additional doses of sedation.

Data Collection

Vital signs, including blood pressure, pulse, respiratory rate, and oxygen saturation ($SatO_2$), were measured and recorded at baseline (pre-ISA), at the start of the procedure, and at 5, 10, 15, and 20-minute intervals. GCS was also measured and documented at these same intervals. Sedation depth was assessed using the Ramsay Sedation Scale (RSS), Michigan University Sedation Scale (MUSS), and Brussels Sedation Scale (BSS), with values recorded by one of the research team members. BIS values were continuously monitored and recorded via a timed computer program connected to the BIS module using disposable electrodes affixed to the forehead.

Sedation Assessment

The sedative effects were anticipated to provide short-term anxiolytic and amnestic effects with minimal cardiovascular side effects, using a combination of midazolam and meperidine. The severity of pain was not assessed in this study. No complications were observed related to the sedation during the interventional procedures.

Considerations in Intensive Care Unit

In the intensive care setting, the quality of BIS signals may be affected by factors such as sweating, edema, and patient movement, as well as electrical interference from devices like electric beds, infusion pumps, ventilators, and heaters (15). Patients with metal stabilizers that could create artifacts in BIS monitoring were excluded. In certain cases, multiple EEG electrodes were used, particularly due to issues with sweating.

Statistical Analysis

The statistical analysis of the data was performed using the IBM SPSS Statistics Version 22.0 software package. Categorical variables were summarized as frequencies and percentages, while continuous variables were reported as means and standard deviations, or as medians and ranges where appropriate. The normality of continuous variables was assessed using the Kolmogorov-Smirnov test. For variables that did not meet the assumption of normal distribution, the relationships between these continuous variables were evaluated using the Spearman correlation coefficient. A p-value of less than 0.05 was considered statistically significant for all analyses.

RESULTS

Among of the 33 patients, who underwent interventional sedation analgesia, twenty (60.6%) patient were female and13 (33.3%) were male, with a female/male ratio of 1.53 (Table 1).

Table 1. *Socio-Demographic characteristics of cases.*

Gender	n	%
Female	20	60.6
Male	13	33.3

The patients had a mean age of 8 years and 6 months (ranging from 2 to 17 years). Midazolam was administered to 22 patients (66.7%), meperidine was given to 1 patient (3%), and a combination of midazolam and meperidine was administered to 10 patients (30.3%) for sedation and analgesia (Table 2).

Table 2. *Medications used for interventional sedation and analgesic.*

Agent usedforsedation	n	%
Midazolam	22	66.7
Meperidine	1	1
Midazolam + Meperidine	10	30

The lowest BIS value (77) among the patients, evaluated at the 0th, 5th, 10th, 15th, and 20th minutes of the procedure, was observed at the 15th minute. The mean vital signs of the patients are presented in Table 3.

Table 3. *Averages of vital findings.*

Time	SBP Mean ±SD (min-max)	DBP Mean ±SD (min-max)	HR Mean ±SD (min-max)	RR Mean ±SD (min-max)	$SatO_2$ Mean ±SD (min-max)	GCS Mean ±SD (min-max)
Process beginning	96±4 (92-100)	67±29 (47-96)	109±63 (70-172)	20±22 (20-44)	98,3± 0.7 (94-100)	15±5 (10-15)
5.min.	112±38 (61-154)	64±29 (28-93)	130±64 (66-175)	20±22 (12-44)	96±7 (89-100)	12±5 (7-14)
10.min.	110±53 (57-158)	63±34 (26-90)	126±74 (70-200)	20±22 (12-42)	96.8±3.3 (93-100	12±6 (6-15)
15.min.	107±90 (80-194)	60±39 (45-99	112±61 (72-173)	20±22 (12-40)	96.6±4.6 (92-100)	12±6 (6-15)
20.min.	108±38 (70-138)	62±28 (40-90)	120±47 (70-167)	20±22 (12-38)	96.5±4.5 (92-100)	14± 8 (6-15)

*********SBP; systolicbloodpressure, DPB; diastolicbloodpressure, HR; heart rate, RR; respiratory rate, $SatO_2$; oxygensaturation.*

Then there was an increase in BIS values with an increasing slope. No significant correlation was detected between BIS and RSS, MUSS and BSS (p= 0,446) (p= 0,219) (p= 0,938) (Table 4).

Table 4. *RSS, MUSS AND BSS mean walues with BIS.*

	BIS Mean ±SD (min-max)	RSS Mean ±SD (min-max)	BSS Mean ±SD (min-max)	MUSS Mean ±SD (min-max)
0.min.	92±19 (73-98)	2±1 (1-2)	4±1 (4-5)	0±0 (0)
5. min.	79±17 (73-96)	3±2 (1-5)	3±1 (2-4)	1±1 (0-2)
10.min.	79±16 (79-95)	3±3 (1-6)	3±2 (1-4)	2±2 (0-4)
15.min.	77±19 (58-95)	3±3 (1-6)	3±2 (1-4)	1±3 (0-4)
20.min.	79±17 (61-96)	3±2 (1-5)	3±2 (2-5)	1±2 (0-2)

Spearman Correlation Analysis revealed that, while no significant correlations were found with other measures, a significant correlation was observed between RSS and MUSS when compared to each other ($p < 0.001$) (Table 5). When considering RSS and MUSS values, a moderate correlation was observed between them ($p = 0.007$).

Table 5. *RSS and MUSS mean values of the facts.*

Time	RSS Mean ±SD (min-max)	MÜSS Mean ±SD (min-max)	Correlation r	p value
Process beginning	2±1 (1-2)	0±0 (0)	-0.574	p< 0.01
5. min.	3±2 (1-5)	1±1 (0-2)	0.620	p< 0.01
10. min.	3±3 (1-6)	2±2 (0-4)	0.712	p< 0.01
15.min.	3±3 (1-6)	1±3 (0-4)	0.781	p< 0.01
20. min.	3±2 (1-5)	1±2 (0-2)	0.796	p< 0.01

Sperman Corelation Analyses.

DISCUSSION

Currently, there is no universally accepted scale for monitoring sedation depth in pediatric patients. In this study, we evaluated the concordance between the widely utilized RSS, MUSS, and BSS scales, as well as BIS-a novel method of measurement used in the ICU for assessing sedation depth in patients under ISA. The RSS was developed to provide an objective assessment of drug-induced sedation and is based on a six-point scale, encompassing three awake states and three asleep states. However, despite its relative ease of use, distinguishing between levels 4 (patient is asleep but awakens to a glabellar tap or auditory stimulus) and 5 (patient is asleep but responds slowly to a glabellar tap or auditory stimulus) can be challenging (16,17). Consequently, the BSS and MUSS scales were developed as alternatives. BIS, on the other hand, offers an objective method for evaluating sedation depth. In our study, no significant correlation was found between RSS, MUSS, BSS, and BIS. However, a notable correlation was observed between RSS and MUSS. To our knowledge, no previous studies in the literature have compared these two scales in the manner we have. We believe that further research in this area is warranted. Berkenbosch et al. investigated the correlation between BIS and clinical sedation scales in pediatric patients aged 5-6 years who were sedated and mechanically ventilated in the intensive care unit. Their study assessed three sedation scales: the modified RSS, the Richmond Agitation-Sedation Scale (RASS), and the Pediatric Intensive Care Unit Sedation Scale (PICU scale). Despite the comprehensive analysis, no significant correlation was identified between these scales and BIS. However, the authors suggested that BIS might be more beneficial for monitoring deeper levels of sedation (18). In contrast, a study by Agrawal et al. (19) involving 20 pediatric patients found a strong correlation between BIS and the modified RSS. Similarly, Aneja et al. (20) conducted a study on patients aged 1-16 years who were not under neuromuscular blockade and observed a significant concordance between BIS and RSS. Specifically, they determined that a BIS value of 42 marked the threshold between oversedation (RSS ≥ 5) and adequate sedation (RSS 2-5), while a BIS value of 76 corresponded to low sedation (RSS = 1). One potential explanation for the discrepancies observed between BIS and subjective sedation scores could be the timing of BIS measurements. During clinical assessments, patients are often stimulated with verbal or painful stimuli, which can lead to substantial increases in BIS values, rising from 50 to 80 or even 90. The timing of BIS measurement, whether taken before or after such stimulation, can significantly influence its correlation with clinical scoring (21). In our study, we also noted an increase in BIS values following stimulation. To ensure the accuracy of our assessments, we recorded basal BIS values in the absence of any prior stimulation before proceeding with the evaluation of clinical sedation scores.

Limitations of this study

In conclusion, no significant correlation was found between BIS monitoring and the compliance of RSS, BSS, and MUSS in patients who underwent ISA. However, a significant correlation was observed between RSS and MUSS. Our literature review revealed that no previous studies have compared four sedation scales-one of which is objective and the others subjective-in the manner conducted in our study. Therefore, it is recommended that future research focus on clinically prevalent sedation scales, with comparative analyses of study data conducted separately.

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