Utility of Bispectral Index Monitoring during Deep Sedation in Pediatric Dental Patients

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Objective: *The aim of this study was to compare the total medicament doses and recovery profiles of patients for whom Bispectral Analysis (BIS) monitor was used to monitor sedation.*
Study design: *Thirty-four uncooperative paediatric patients aged 3-6 years who attended to the Department of Pediatric Dentistry for dental treatment were enrolled in the study. Patients were randomly divided into 2 groups of 17 patients each. Physiological variables including oxygen saturation, blood pressure and heart rate were recorded. In one group (BIS-monitored group), drugs were administered to maintain patients' BIS values between 60-70, while the other group (Non-BIS-monitored Group) was not monitored using BIS. Data was evaluated by Chi-square, Mann Whitney U, Independent Samples t, Paired Samples t and Wilcoxon signed tests, with a p-value of <0.05 considered to be statistically significant.* ***Results:*** *There was no significant difference in total anesthetic doses, incidence of adverse events or recovery profiles of patients between non-BIS-monitored and BIS-monitored groups (p>0.05). However, distinct correlation was determined among mean values of UMSS and BIS values (p<0.05).* ***Conclusion:*** *BIS represents no advantage over the current commonly accepted methods for monitoring sedation depth in children.*

Key words: *Bispectral index, deep sedation, pediatric patients.*

INTRODUCTION

A dental visit can represent a frightening event for some children. This is especially true for pre-school children who are uncooperative due to their age. For such children, traditional non-pharmacological behavior management strategies are often unable to resolve resistive and uncooperative behavior and sedation may be necessary to prevent emotional and physical discomfort [1,2]

Intravenous sedation has been found to be a useful method for reducing stress and preventing stress-related complications during dental treatment [3]. Deep sedation is defined as a controlled state of depressed consciousness or unconsciousness from which the patient is not easily aroused and which may be accompanied by partial or complete loss of protective reflexes, including the ability to independently maintain a patent airway and respond purposefully to physical stimulation or verbal command [4]. While moderate sedation is often sufficient for performing dental treatment in adults, deeper sedation levels may occasionally be required for children under 7 years of age [5].

Monitoring the depth of anesthesia may lead to reductions in dosages and the negative side effects of anesthesia as well as 'fast-tracking' of patients and enhancement of their quality of recovery [6]. At present, levels of sedation are usually defined by the subjective assessment of the anesthesiologist using clinical scoring tools or by highly complex measurement tools, such as EEGs, which are difficult to interpret. As a result, it can be difficult to determine exact anesthetic requirements and maintain a constant level of sedation [7].

An EEG measures brain activity through small electrodes that are placed on the scalp and wired to an EEG machine, which records brain activity as a raw wave [8]. Bispectral index (BIS) monitoring uses a well-validated algorithm to analyze a patient's EEG patterns and translate them into a value reflective of hypnotic state [9]. With BIS monitoring, a sensor placed on the patient's forehead is connected to a BIS monitor that provides information about the degree of sedation induced by anesthetics [8]. The BIS index ranges from 100 (awake) to zero (isoelectric EEG) (6). According to the manufacturer, a BIS index of 70-90 represents light-to-moderate sedation; 60-70, deep sedation; 40-60, general anesthesia; and less than 40, a deep hypnotic state [10]. BIS technology offers an objective, ordinal means of assessing the depth of anesthesia [11] that may help

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in maintaining a desired level of sedation with fewer drugs thereby speeding recovery time [9,10,12].

Studies of BIS monitoring have generally been performed on adults [9,11,12-18]. Although Muńoz *et al* [19] found the correlation between BIS and clinical sedation using propofol to be similar for adults and children, due to the many anatomical and physiological differences influencing pediatric anesthetic management, findings for adults may not always be relevant with regard to children [20].

Although there has been growing interest in the potential uses of BIS monitoring with children [8,21-25], the use of BIS monitoring among pediatric patients still requires validation. Therefore, this study aimed to compare the total anesthetic doses and recovery profiles of patients who were monitored using the BIS with those who were sedated without used of the monitor.

MATERIAL AND METHOD

The study was approved by the Faculty of Medicine's Institutional Review Board, and written informed consent was obtained from parents. Subjects were selected as a convenience sample among 3 to 6-year-olds who applied to the Department of Pediatric Dentistry for routine dental treatment between 2010 and 2011. With a theoretical power of 0.8, α=0.05, 1-β=0.8 and effect size of 0.5, the sample size was calculated as n1=n2=17 (total=34) before the study. A sample of healthy children (ASA I) who required invasive dental treatment, had no prior experience with sedation and general anesthesia with a 'definitely negative' or 'negative' rating according to the Frankl Behavior Rating Scale [26] and whose behaviors could not be managed using basic techniques such as tell-show-do, positive reinforcement, controlled expectations, distraction, modeling and suggestion was evaluated for inclusion. Patients with nasal obstruction, polyps, postnasal flow, catarrh or influenza within the two weeks prior to the procedure and those who had taken any medication in the previous 48 hours were excluded from the study.

The same experienced pediatric dentist completed all treatment planning prior to the sedation appointments. Treatment included a minimum of two teeth with deep dentinal caries, with/without extraction. All patients were scheduled for early morning appointments.

Children were not permitted to eat or drink anything for at least 4 hours prior to sedation, and *EMLA* cream was applied to the venipuncture sites to prevent any possible discomfort. Before the procedure, children were allowed to play games in the playing room of the clinic for 15-20 minutes in order to watch behavior of the patient. As part of a standard protocol, pre-sedation patient preparation included placement of pulse oximeter (Datex-Ohmeda, Tuffsat, Lousville, CO, USA) and nasal oxygen mask on all patients. 34 pediatric dental patients were randomly divided into non-BIS-monitored and BIS-monitored group. The patients were numbered and the first and all other odd-numbered patients were assigned to non-BIS-monitored group, while the even-numbered were assigned to BIS-monitored group. BIS monitor (A-2000, Aspect Medical Systems, Leiden, The Netherlands) electrode was placed on the forehead of patients only in the BIS group.

After obtaining intravenous access, patients were sedated with midazolam (Dormicum, Roche) (0.05 mg/kg) and propofol (Propofol, Fresenius Kabi) (1 mg/kg). Patients in the non-BIS-monitored group received 0.25-0.50 mg/kg propofol every 3-5 minutes according to clinical awakeness symptoms, whereas drugs were administered to patients in the BIS-monitored group as necessary to maintain their BIS values between 60-70 scores. Additional doses were given during the procedure if patients in either group required repeated boluses of propofol at less than 5 minute intervals to maintain the desired sedation level. Even though, if there were any signs of insufficient sedation, patients were administered 0.25-0.5 µg/kg remifentanil (Ultiva, Glaxo Smith Kline) intravenously. Oxygen desaturation was defined as mild (85%-90%) or severe (<85%), and bradycardia/tachycardia were defined as a heart rate (HR) 30 % below/above baseline. Immediately before the completion of the treatment, all drug administration was discontinued.

Dental treatment included restorative treatment (amalgam, compomer, glass-ionomer restorations; stainless steel crowns; pulp capping; pulpotomy; fissure sealant; topical fluoride application) and dental extraction. The same pediatric dentist performed all clinical and radiographic examinations and all dental treatments, and another individual observed the patient continuously in order to record the scores of the scales. An experienced anesthesiologist who monitored the patients throughout the entire length of the procedure performed sedation.

Children's behavior was assessed using the following scales: 1) Frankl Scale (26) (preoperative period); 2) University of Michigan Sedation Scale (UMSS) (27) (during treatment); 3) Modified Wilton Scale (28) (recovery period). All preoperative, operative and postoperative phases were videotaped to verify the reliability of the behavior scales. The pediatric dentist who performed all behavioral assessments randomly selected videotapes of 10 patients and assessed each twice to standardize the behavioral assessments. Intraexaminer reliability was evaluated via Kappa statistics. Kappa values were; 0.89 for the Frankl scale, 0.91 for the UMSS scale, and 0.78 for the modified Wilton scale.

Any complications observed during the operation and recovery periods were also recorded. All parents were asked to fill out a postoperative visual analog questionnaire administered 24-48 h after the procedure to determine the incidences of side-effects after discharge.

Statistical analysis was performed using SPSS 17.0 for Windows. Data was evaluated by Chi-square, Mann Whitney U, Independent Samples t, Paired Samples t and Wilcoxon signed tests, with a p-value of less than 0.05 considered to be statistically significant.

RESULTS

Demographic characteristics (age, sex, weight) of the study groups were given in Table 1 showing no statistical difference ($p>0.05$). There was no statistically significant difference according to the Frankl Scale between the two groups during preoperative period (Table 2). Mean operation times (55.88±13.7 for non-BIS-monitored group, 52.94±12.1 for BIS-monitored group) and type of the dental procedures performed were also similar between groups ($p>0.05$).

There was no statistically significant difference between the mean doses of propofol and midazolam for the non-BIS-monitored and BIS-monitored group ($p>0.05$) (Table 3). Mean doses of remifentanil were 19.1 µg for the non-BIS-monitored group and 13.3 µg for the BIS-monitored group. Even though there was no significant difference in the mean remifentanil doses between the groups, the only difference was seen in the number of the patients receiving remifentanil (non-BIS-monitored group: n=3; BIS-monitored Group: n=11) ($p<0.05$).

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Table 1. Demographic characteristics of the study groups

		Non-BIS-monitored Group (mean ± SD)	BIS-monitored Group (mean ± SD)	p
Demographic Data	Age (years)	4.74 ± 1.22	4.5 ± 0.84	0.5
	Weight (kg)	18 ± 3.5	16.2 ± 2.75	0.15
	Gender (male/ female)	7/10	7/10	1

Table 2. Results of Frankl Scale

	Score	Non-BIS-monitored Group	BIS-monitored Group	p
Frankl Scale	Definitely negative	7	9	0.31
	Negative	10	8	

No significant differences were observed in HR or SpO_2 values between the groups and between basal values and values of different operation times (p>0.05) (Figure 1 and 2).

BIS values according to the operation times were given in Figure 3 and UMSS values of the groups according to the operation times were given in Table 4. The data showed that level 3 (deep sleep) was the one most commonly recorded during the treatment. No statistically significant difference was detected between the non-BIS-monitored and BIS-monitored groups according to UMSS scale. However, distinct correlation was determined among mean values of UMSS and BIS values (Table 5).

Recovery scores according to Modified Wilton Scale and evaluation of recovery periods were given in Table 6 and 7 respectively with no statistical difference between the groups (p>0.05). No apnea, desaturation or bradycardia was observed in either group. Incidences of laryngospasm (1 in non-BIS-monitored group), secretion (2 in BIS-monitored group and 2 in non-BIS-monitored group) and tachycardia (1 in BIS-monitored group and 2 in non-BIS-monitored group) were rare and similar in both groups (p>0.05).

Parental responses to a questionnaire administered 24-48 h after the procedure, indicated low and similar incidences of side-effects after discharge (p>0.05). No sleepiness or nausea was observed in either group. None of the patients or parents of patients who received BIS monitoring complained about placement of the probe on the forehead, and no problems of burning, itching or irritation were reported. At the end of the questionnaire, all of the parents stated their satisfaction with the procedures.

Table 3: Medication doses according to study groups

								Mann Whitney U Test		
		n	Mean	Median	Minimum	Maximum	SD	MR*	U	p
PRPFL dose	Non-BIS-monitored	17	137.65	140	55	205	35.62	18.85	121.5	0.427
	BIS-monitored	17	132.65	130	90	190	29.11	16.15		
	Total	34	135.15	135	55	205	32.13			
MDZL dose	Non-BIS-monitored	17	2.18	2	2	3	0.35	18.62	125.5	0.324
	BIS-monitored	17	2.06	2	2	2.5	0.17	16.38		
	Total	34	2.12	2	2	3	0.28			
REFNYL dose	Non-BIS-monitored	11	19.09	20	10	40	9.44	8.05	10.5	0.310
	BIS-monitored	3	13.33	10	10	20	5.77	5.50		
	Total	14	17.86	20	10	40	8.93			

* MR= Mean rank

Table 4. UMSS values of the groups according to operation time

UMSS	Non-BIS-monitored Group		BIS-monitored Group		p
	Somnolent	Deep sleep	Somnolent	Deep sleep	
UMSS (basal)	9	8	10	7	0.73
UMSS (5. minute)	5	12	8	9	0.35
UMSS (10. minute)	1	16	2	15	0.54
UMSS (20. minute)	1	16	1	16	1
UMSS (30. minute)	1	15	1	16	0.96
UMSS (40. minute)	0	16	3	12	0.06
UMSS (50.minute)	0	14	3	11	0.06
UMSS (60.minute)	0	10	1	6	0.21

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Table 5. Correlation between UMSS and BIS values

		BIS (mean)	UMSS (mean)
BIS (mean)	Pearson' s correlation	1.000	-.656
	Sig. (2-tailed)	.	.004
	N	17	17
UMSS	Pearson' s correlation	-.656	1.000
	Sig. (2-tailed)	.004	.
	N	17	17

Figure 1. Heart rates of the patients in BIS-monitored (■) and non-BIS-monitored (♦) groups according to operation time. No significant difference between the groups.

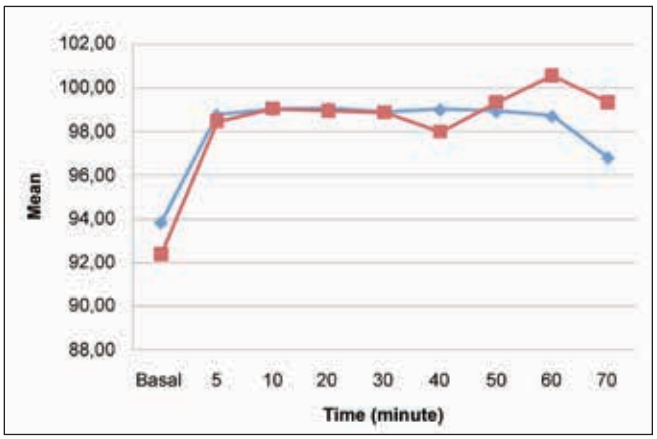


Table 6. Recovery scores according to Modified Wilton Scale.

	Non-BIS-monitored Group				BIS-monitored Group				
	Score 0	Score 1	Score 2	Score 3	Score 0	Score 1	Score 2	Score 3	p
Recovery score (5.minute)	3	0	7	7	0	1	6	10	0.20
Recovery score (10.minute)	3	0	8	6	0	0	6	11	0.09
Recovery score (15.minute)	3	1	4	9	2	0	4	11	0.70
Recovery score (20.minute)	2	2	3	10	2	0	3	12	0.53
Recovery score (25.minute)	2	3	3	9	1	0	5	11	0.25
Recovery score (30.minute)	2	3	1	11	1	0	5	11	0.11

Table 7. Recovery periods of the study groups

	Non-BIS-monitored Group (mean ± SD)	BIS-monitored Group (mean ± SD)	p
Eye-opening time (minute)	8.24 ± 2.8	6.82 ± 2.6	0.14
Reaction to noisy stimulus (minute)	11.06 ±3.3	9.88 ±3.2	0.30

Figure 2. SpO_2 values of the patients BIS-monitored (■) and non-BIS-monitored (♦) groups according to operation time. No significant difference between the groups.

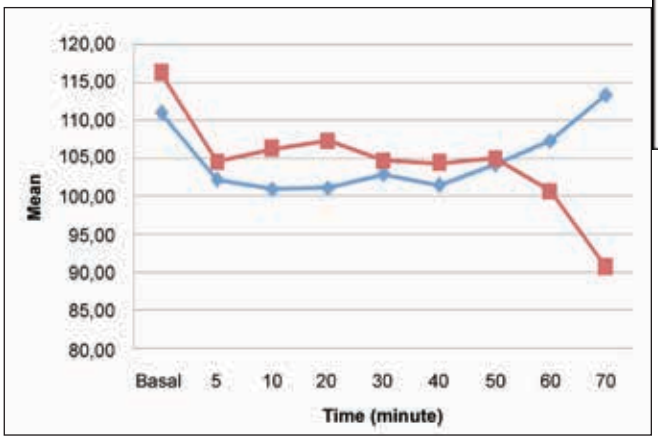
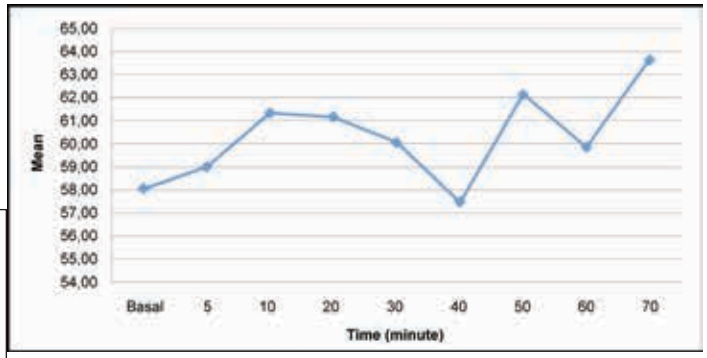


Figure 3: BIS values according to operation time



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DISCUSSION

In recent years, deep sedation has become the preferred method of sedation for painful procedures in children. Deep sedation offers many advantages for dentistry, since patients can be thoroughly treated while unconscious. Deep sedation should be performed by an experienced anesthesiologist and with continuous, noninvasive monitoring[29] .

Both the American Academy of Pediatric Dentistry and the American Academy of Pediatrics have stressed the importance of monitoring vital signs and levels of consciousness during sedation to ensure patient's safety[4,10]. Oxygen saturation and heart rate, intermittent recording of respiratory rate, blood pressure must be documented in a time-based record [30]. Frequent assessment of the depth of sedation is especially important with children, who may move rapidly from lighter levels of sedation to deep sedation [31].

Besides traditional monitoring techniques, bispectral analysis (BIS) monitoring is a non-invasive technology used in the clinical evaluation of anesthesia levels [10]. Powers *et al* [32] suggested that the BIS monitor could serve as an objective tool to guide physicians for safe, effective titration of propofol for children undergoing painful procedures in outpatient settings. Malviya *et al* [27]and Overly *et al* [10]have also stated that the BIS monitor could be a useful adjunct in monitoring the sedation of pediatric patients with certain medications during procedural sedation.

In the present study, no significant differences were found in the mean doses of propofol used as an anesthetic between the BIS group and the non-BIS-monitored group. The only statistically significant difference was found in the number of the patients who received remifentanil in the BIS-monitored group. Patients in the non-BIS-monitored group received propofol every 3-5 minutes, whereas drugs were administered to the patients in the BIS-monitored group when necessary to maintain their BIS values between 60 and 70. In the non-BIS-monitored group, supplemental propofol was administered due to the signs of insufficient sedation (involuntary movement, coughing, irregular breathing, laryngospasm and tachycardia). However, supplemental propofol application was not used in the BIS-monitored group. If any signs of insufficient sedation were observed, patients were administered remifentanil. Remifentanil is a well-known narcotic analgesic with rapid metabolism and clinical effectiveness and provides increased level of sedation and patient cooperation without any serious side effect [33]. This could be the reason why significantly high rates of remifentanil application were applied for the BIS-monitored group.

The UMSS is a validated observational scale that has been shown to be reproducible among observers [27]. This scale has successfully been validated for measuring sedation depth in children [31]. UMSS scores of 2 or 3 indicated adequate sedation, high BIS scores indicated wakefulness or inadequate sedation [23]. The present study found a distinct correlation between mean BIS and UMSS values, which is in line with earlier studies [21,23,31]. In light of this situation, the UMSS scale may be considered useful in pediatric patients during deep sedation to establish level of anesthesia.

Pediatric sedation is not without risks [20], some of them serious, such as hypoventilation, apnea, airway obstruction, laryngospasm, and cardiopulmonary impairment [30]. With using minimal effective doses of sedative drugs, these side effects could be decreased. In our study, none of the patients in either group experienced apnea, bradycardia, desaturation, sleepiness or nausea. Also, the study found no significant differences in the side effects experienced by patients who underwent BIS monitoring and controls. In contrast to our findings, previous studies have found brain monitoring to facilitate early recovery from anesthesia [8], and reduce postoperative nausea and vomiting [16]. Liu [16] stated that the use of BIS monitoring modestly to marginally reduced anesthesia consumption and risks of nausea and vomiting.

In line with the findings of the present study, Religa *et al* [25] reported that BIS monitoring has no apparent value beyond commonly accepted methods currently used to monitor sedation depth. Similarly, Morse *et al* [12] stated that the BIS was a sufficient, but not a necessary criterion for adequate sedation that offers no advantage over currently available methods used to measure sedation levels. Moreover, Singh [17] stressed that BIS cannot provide pre-emptive warnings regarding the adequacy of the various components of anesthesia. In a recent study, Özen *et al* [25] also reported that while BIS is 'an indicator of level of consciousness', it is not sensitive to the mechanism by which nitrous oxide depresses consciousness when used for moderate sedation in pediatric dental patients.

CONCLUSION

In this study, there was no significant difference in total anesthetic doses, incidence of adverse events or recovery profiles of patients between non-BIS-monitored and BIS-monitored groups. BIS monitor represents no advantage over the current commonly accepted methods to measure depth of sedation or to guide dosing of sedation drugs in children.

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