



Association between bispectral analysis and level of conscious sedation of pediatric dental patients

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Abstract

Purpose: This preliminary investigation evaluated the associations among multiple factors designed to measure depth of sedation, such as changes in the patient's electroencephalogram (EEG) via a bispectral analysis (BIS), other physiological variables, observed behaviors and clinical assessment of sedation levels consistent with the American Academy of Pediatric Dentistry (AAPD) sedation guidelines.

Methods: Thirty-four healthy pediatric patients between three to six years of age were enrolled in this institutionally approved study. All children required dental restorations and were uncooperative. The children received a routine oral sedation regimen used in our clinic consisting of chloral hydrate, meperidine, and hydroxyzine that varied in dose for each child. Intraoperatively, nitrous oxide/oxygen was also administered. Physiological variables including oxygen saturation, blood pressure and heart rate were recorded in compliance with AAPD sedation guidelines. The behavior and levels of sedation consistent with AAPD guidelines were also recorded. The BIS monitor was used to obtain EEG information.

Results: Useful data were recorded from 21 patients. The mean age and weight of the children were 46.1 ± 10 months and 16.1 ± 5 kgs, respectively. The results show a significant association between observed patient behavior and the AAPD levels of sedation ($\chi^2=105.1$, $df=6$, $P<0.0001$), between levels of sedation and behavior as a function of 12 time-oriented periods during treatment, ($\chi^2=41.90$, $df=22$, $P<0.005$ and $\chi^2=48.0$, $df=33$, $P=0.04$, respectively) and between BIS readings as a function of both level of sedation and behavior ($\chi^2=105.1$, $df=6$, $P<0.001$ and $\chi^2=28.5$, $df=18$, $P<0.05$, respectively).

Conclusions: There appears to be a significant association between observed patient behaviors during sedation and levels of sedation as measured by BIS and AAPD sedation guidelines. The study also showed that, under treatment conditions used in this study, BIS does not appear to be a more valid means of monitoring sedation depth than the current commonly accepted methods. (*Pediatr Dent* 24:221-226, 2002)

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The most common clinical means of assessing and monitoring depth of sedation and/or adequacy of anesthesia is the observation of patient movement and response to verbal and physical stimuli. Physiological signs such as blood pressure, heart rate, respiratory rate, rhythm and depth, muscle tonus, ocular signs, sweat and lacrimation are also important.¹ These signs show large interpatient variability and are quite dependent on the medications used. Also, they are only indirect expressions of the drugs' effects on the brain and other major systems.

A variety of direct and non-invasive monitoring techniques assessing the effects of sedatives and anesthetics on the brain have been proposed and studied. The most direct monitoring methods utilize the electroencephalogram (EEG), which allows for a non-invasive observation of cerebral electrical activity. The EEG is a very complex signal representing the cortical electrical activities of the brain derived from spatial and temporal summation of excitatory and inhibitory post synaptic activity generated predominantly in layers III and V of the pyramidal cortex.²⁻⁴ It has been shown

that the EEG is altered under sedation and anesthesia, first by Berger in 1931 and later by Gibbs in 1937.¹

Bispectral analysis of the EEG has been shown in many situations to be a fairly reliable and accurate method for monitoring the depth of anesthesia and sedation.²⁻⁹ Not only does it quantify sine wave frequency and amplitude, but it also considers phase relationships among the sine waves.^{1,3,10} In combination with other EEG features, these bispectral features are utilized in the formation of a single measurement: the bispectral index (BIS). The BIS is a numeric index ranging from a maximum of 100, indicating that the patient is fully awake, to a minimum of zero, representing a total suppression of electrical brain activity.

The clinical relevance of the BIS scale comes from the manner in which the dimensionless values have been assigned. The BIS is thought to represent a scale in which EEG activity is best related to observed behavioral responses. Currently, oral sedation is a route of administration that is most acceptable to the majority of young children. However, the agent(s) and dosage needed via this route to obtain the desired level of sedation are often difficult to select because of the complexity of variables affecting it, many of which are outside of the control of the clinician.

A monitoring device that could continually and non-invasively reflect an index of the depth of sedation would be of great value. By knowing the patients' BIS level, it may be possible to assess, with relative accuracy, the depth of sedation of that patient. Two previously published studies by Wilson et al evaluated electromyography (EMG) rather than BIS as a potential adjunct to established methods of monitoring children under conscious sedation for the dental treatment.^{11,12} They studied children who were orally sedated for dental treatment and measured frontalis EMG activity and other patient physiological as well as behavioral variables.

The current, preliminary study was designed to determine the usefulness of a BIS monitor as an index of depth of sedation based on the AAPD levels¹³ and observed patient behavior during oral sedation of pediatric dental patients.

Methods

Patient selection

Thirty-four patients were studied in this institutionally approved study. They were undergoing operative dental treatment following the administration of oral sedative agents at the dental clinic of Columbus Children's Hospital. They represented a convenience sample of patients requiring sedation appointments. To participate in the study, subjects needed to be between three and six years of age, healthy (ASA I), mentally normal, have no allergies to the sedative agents used, uncooperative based on previous dental visits and in need of dental restorations and/or extractions. Children who had a history of any condition that could potentially produce a compromise of the respiratory and/or cardiovascular system during sedation were excluded from the study.

Sedation protocol

The procedures used in this study followed the standard operating procedures of the Columbus Children's Hospital dental clinic whenever a child is sedated for dental care. This involved taking a medical history and doing a physical assessment of the child including the airway. The parental consent, oral administration of sedatives, whose dose is based on patient weight, monitoring (pulse oximeter, blood pressure cuff, pre-cordial stethoscope, and side-stream capnograph), and pre- and post-operative instructions were done according to the hospital's and the AAPD sedation guidelines.¹³ Prior to, during, and after the sedation, the standard patient assessment (physiological and behavioral) was accomplished by a trained dental assistant using standardized forms.

The behavioral assessment included a set of pre-operative scales to score key variables (eg, levels of cooperation) and two clinical scales that were used intra-operatively. The latter two scales are based on overt behavior with one scale having four categories (ie, quiet, crying, struggling or movement only) and the other representing the AAPD level of sedation (levels 1-5) based on behavioral responsiveness to stimuli.^{13,14-16} Additionally, a BIS monitor (Aspect A-1050, Aspect Medical Systems, Natic, Massachusetts) was used to detect the patient's EEG via a set of electrodes (BIS Sensor, Aspect Medical Systems) attached to the subject's forehead per the manufacturer's instructions.

Sedation procedure

The following sequence of events took place with each patient included in the study. All appointments began at 7 a.m. or 9 a.m. and were usually completed within two hours. All patients were nil per os (NPO) since at least midnight before the morning of the appointment. The child was weighed and taken to the dental operatory with a parent(s). Baseline information was obtained for blood pressure (Dinamap, Model 1846-SX), heart rate and peripheral oxygen saturation (Nellcor pulse oximeter Model N-100), and a gross assessment of the patient's level of cooperation/behavior was made by the dental assistant collecting the baseline information. The medical history was then reviewed, physical assessment made, planned dental treatment discussed with the parent(s) and pertinent information about oral sedation given to the parent(s) by either a pediatric dental resident or pediatric dentist (fellow) who was performing the oral sedation and dental treatment. The oral sedative medications were then administered to the patient orally either by cup or syringed into the buccal vestibule based on patient cooperation.

The oral medications were a combination of three drugs: chloral hydrate, meperidine hydrochloride (Demerol[®]) and hydroxyzine pamoate (Vistaril[®]). The dosage was based on patient's weight, age, displayed behavior/cooperation and extent of treatment planned. The range of dosages of each drug used were as follows: chloral hydrate 15-40 mg/kg, meperidine 1-2 mg/kg, and hydroxyzine 1-2 mg/kg.

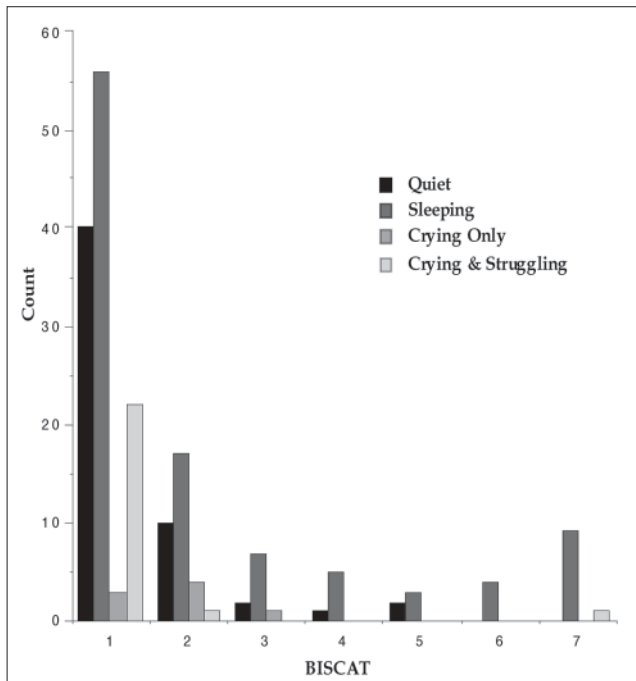


Fig 1. Distribution of behaviors as a function of reformatted BIS values

Patient and parent(s) were then led to a waiting area for 50 to 55 minutes. The BIS monitor was not used during this latency period. After the latency period, the child was separated from the parent(s) and returned to the dental operatory where all the monitors used for baseline information were re-attached. The appropriate inflatable blood pressure cuff was always placed on the right arm and a pulse oximeter electrode affixed to the right middle toe. A precordial stethoscope was attached.

A nasal hood was placed on the patient, and a mixture of nitrous oxide and oxygen was titrated up to 40% nitrous oxide at a three-liter flow rate over the next three to five minutes. After the patient had been in the dental chair for three to five minutes and nitrous oxide was at the desired level, the BIS electrodes were attached to the patients' forehead according to manufacturer's instructions. More specifically, three sensors/electrodes were affixed to the patient's forehead following mild skin preparation with an alcohol pad and a drying period. The opposite end of the electrode array was then connected to the BIS monitor. From that point on, and until the time the patient was ready to leave the dental chair, continuous BIS data were collected through the monitor onto a laptop computer. Also, a written record of physiological parameters, observed level of sedation, observed behavior, and BIS score were kept by the investigator and collected at 12 time points. The time points included baseline, during topical and local anesthetic administration, rubber dam isolation, initiation of tooth preparation with a high-speed handpiece, at five-minute intervals thereafter, and at the end of the operative procedures.

Results

Thirty-four patients participated in the study. Data from only 21 patients were useable. The remaining 13 patients were eliminated due to incomplete data acquisition, in most cases associated with technical difficulties in utilizing the BIS monitor, or lack of patient cooperation. The mean age and weight of the children were 46 ± 10 months and 16.1 ± 4.9 kg, respectively. Due to a variety of technical difficulties, the continuously recorded BIS data that purportedly can be transmitted indefinitely to a computer, consistently terminated transmission after an initial 5-minute period. Therefore, all the reported and analyzed data are based on the hand-recorded information obtained from the digital display on the front of the monitor. This information was collected throughout the duration of treatment. The duration of sedations and hence the number of data points varied for each patient.

A one-way ANOVA was done on each physiological variable at each of the 12 time-oriented points (the initial baseline was not included because the patients had not received any sedative at that point in time and the BIS was not recorded). The oxygen saturation and the BIS both approached significance, ($F=1.80$, $P=0.056$, and $F=1.65$, $P<0.08$, respectively). However, few data points were available after 20 minutes into the restorative procedure due to short operative procedures such as extractions, so another one-way ANOVA was done excluding data collected at 25 minutes or longer into the restorative procedure. None of the variables was found to be significant in the latter analysis.

Using cross-tabulation, a chi-square analysis was done between the 12 time-oriented points (initial baseline excluded) and each of the variables of behavior and level of sedation as determined by the AAPD guidelines. Both the level of sedation and behavior were found to be significant in their distribution of data across the 12 periods ($\chi^2=41.90$, $P<0.005$ and $\chi^2=48.0$, $P<0.04$, respectively).

BIS data were reformatted so that values between 100 and 95, 94 and 90, 89 and 85, 84 and 80, 79 and 75, 74 and 70, and below 70 were recorded as 1,2,3,4,5,6 and 7, respectively. The reformatting was done to depict the frequency of occurrence of hand-recorded BIS scores that are in reality continuously occurring, but unattainable with our experimental set-up. The reformatted values were named BISCAT. Throughout the sedation the clear majority of the BIS readings were above 90 (BISCAT 1 and 2), indicating a very mild level of sedation and a minimal likelihood of amnesia. Sleeping and quiet behavior were the two most commonly seen behaviors out of the four possibilities during the 12 time-oriented periods. There were 101 instances where sleep was observed, followed by 55 instances of quiet behavior, 24 of crying and struggling, and eight of crying only and can be seen in Fig 1.

A chi-square, cross-tabulation analysis was done between BISCAT and the four categories of behavior and was found

to be significant ($\chi^2=28.5$, $df=18$, $P<0.05$). Likewise, a similar analysis was done between levels of sedation and the BISCAT resulting in a significant finding ($\chi^2=32.4$, $df=12$, $P<0.001$). Finally, a chi-square ($\chi^2=28.5$, $df=18$, $P<0.05$) analysis of behavioral categories versus level of sedation indicated a significant difference in distribution ($\chi^2=105.1$, $df=6$, $P<0.001$).

Additional calculations were made and bivariate coefficients were determined for all variables. Significant findings that were weak to modest in association were found and can be seen in Table 1.

Discussion

This study was designed to investigate the usefulness of a BIS monitor during oral sedations of pediatric patients undergoing dental treatment. The main goal was to determine if a BIS score could accurately assess the depth of sedation and associate it with the AAPD-defined levels of sedation and observed patient behavior.

Significant findings were found in the distribution of BISCAT and the observed levels of sedation. The levels were assessed based on AAPD's published guidelines for sedation. They increase from level 1 to 5 as the depth of sedation increases.¹³

In this study, none of the patients exceeded level 3 which is described as producing a patient who is non-interactive but can be aroused with mild to moderate stimuli.¹³ In BISCAT 5, 6 and 7 (which indicates BIS readings below 79) level 3 was observed almost exclusively. The findings were consistent with what could be expected. The deeper the assessed level of sedation, the lower the BIS reading.

There was also a significant relationship between the levels of sedation and the 12 time-oriented periods. The data showed that level 3 was the one most commonly recorded during the treatment. This is consistent with the significant findings of the distribution of observed patient behavior as a function of the 12 time-oriented periods. These data showed sleep was the most common behavior followed by quiet, then crying and struggling, with crying alone occurring least frequently. These findings are consistent with and supportive of previous work.^{11,12} The use of chloral hydrate as a component in the sedative cocktail may, in part, explain some of these results. Chloral hydrate is known to induce drowsiness and sleep, but can less frequently cause patient irritability.

A significant relationship was also found in the distribution of the level of sedation and observed patient behavior. Sleep was the most commonly observed behavior and was most often observed in instances where a fairly profound sedative effect was achieved (level 3). Crying and struggling, as well as quiet behavior, were usually seen during less deeper levels of sedation (levels 1 and 2).

Significant distributions were observed for patient behavior as a function of BIS. The majority of the BIS readings were above 90, presumably indicating only a very mild level of sedation. Sleeping and quiet behavior were, however, the

two most commonly seen behaviors out of the four studied. Most often the desired behaviors of sleep and quiet were observed in BISCAT 1 where the BIS scores had a range of 95 to 100 suggesting virtually no sedative effect. Therefore, although a significant statistical relationship was observed between patient behavior and BIS, at times it was somewhat opposite to what would have been expected. In other words, behaviors that suggested relatively strong effects of sedation on the patient corresponded to BIS readings equivalent to no sedative effect.

Hence, as described by Barr et al,⁴ hypnotic effects may have been achieved by pathways to which BIS is not sensitive. Also, the sleep observed in this study seems to be unlike normal physiological sleep, which even in its light stages has been shown to produce BIS readings of 75-90.¹ Analgesia resulting from the sedative drugs and/or nitrous oxide may have been relevant as a sleep-inducing factor. Studies have shown that the effects of both opioids, such as meperidine used in this study and nitrous oxide, are not well reflected in BIS readings.^{2,4,9} It should be noted that the manufacturer makes no claims of a graded interpretation above a BIS value of 70. It may be that the BIS is not sensitive above this level.

The results showed no significant changes in the BIS readings throughout the sedation for the 12 time-oriented points. There were, however, some interesting trends that were observed. On average, it was found that the mean BIS decreased gradually after the patient was placed into the dental chair and awaited treatment. The BIS started to increase from the moment topical anesthetic was applied and peaked at local anesthesia administration. It then slowly decreased until rubber dam isolation, after which it decreased more dramatically to its lowest level. Once again it started to increase gradually as restorative treatment began, peaking at about 15 minutes into the treatment then gradually decreasing until the end.

At 15 minutes into the treatment, similar to the increase in BIS, increases were also seen in both the systolic and diastolic blood pressures. This might be related to some step in the dental treatment that would have been carried out at

Table 1. Significant Correlations Among Variables Recorded in This Study

	Beh	O ₂ Sat	HR	Sys.	Dia.	BIS	Time	Level	Patient
Beh			.513*						
O ₂ Sat						-.209*		.254*	
HR				.378*				-.318*	
Sys.					.378*	.292*		-.326*	
Dia.						.311*			
BIS							-.265*	-.338*	.266*
Time								.337*	
Level									
Patient									

* $P=0.01$

that stage. Similar responses have been reported in EMG studies in which an increase in EMG amplitude was recognized during subgingival rubber dam clamp placement similar to those for local anesthesia delivery and initiation of tooth preparation.¹¹ It has also been shown that subgingival placement of the rubber dam clamp was associated with an increase in the mean arterial blood pressure in sedations using the same drug regimen as that in this study.¹⁷

Throughout the study, various obstacles were encountered during attempts to obtain and record useable and continuous BIS readings. Patient behavior played a very large part in data collection. There were situations where patients became extremely uncooperative during or immediately before dental treatment. In those cases, it was impossible to obtain good BIS data, so collection was aborted.

The sensors/electrodes provided by the manufacturer also proved to be less than ideal as used in this study. More specifically, one of the three sensors needed to be attached over the patient's temple area (level of the canthus of the eye) that is exactly where tears flow when a child is crying and lying in the supine position, thereby potentially compromising the adhesion of the electrode and disrupting the BIS signal.

Similarly, the electrodes in general would frequently lose proper contact as a result of even slight movements of the patients and even movements of facial musculature during crying and frowning. Inadequate attachment or displacement of the electrodes is known to produce high electrode impedance which falsely elevates the BIS values.¹⁸ At the time of this study, there were no pediatric size electrode arrays available which might have provided a better applicability.

A problem was also encountered which involved the BIS data retrieval and storage process onto the computer for later analysis. There appears to be no clear and easy way to collect and store real-time data under the conditions of this study. Even setting up the electronic link between a lap-top computer and BIS monitor while following direct telephone instructions of the manufacturer's technical support staff proved to be inadequate. This, unfortunately, resulted in the inability to efficiently collect useful data.

Another difficulty encountered was associated with the depth of sedation during which the BIS monitor was used. One of the known obstacles to accurate detection of BIS is EMG interference. High EMG readings are often encountered during the light stages of sedation from the frontalis and temporalis muscles over which the electrodes are placed. A significant EMG activity can interfere with EEG signal acquisition and contaminate BIS calculations.¹⁸ During the study this was often seen and it resulted in momentary losses of BIS readings. Acquisition of baseline data in frightened children may not be possible but should be investigated in future studies involving the BIS monitor.

It is also possible that the monitor was detecting electrical interference from the muscles of ocular motion. This is not a major problem in situations in which light sedation is just a transitional stage and the patient will gradually be brought into much deeper sedation or general anesthesia.

In this study, however, patients were more lightly sedated, potentially leading to significant problems associated with EMG interference. A slightly deeper sedation might provide very different findings.

Conclusions

The results of this study showed that the BIS monitor has limited usefulness in assessing depth of sedation during oral sedations of pediatric patients when done in a manner described in this study.

The study did provide data that supports the AAPD definition of levels of sedation, both by its correlation with behavior as well as BIS readings.

The study also showed that BIS does not appear to be a more valid means of monitoring sedation depth than the current commonly accepted methods.

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ABSTRACT OF THE SCIENTIFIC LITERATURE



A COMMUNITY-BASED CARIES CONTROL PROGRAM FOR PRESCHOOL CHILDREN USING TOPICAL FLUORIDES: 18-MONTH RESULTS

Dental caries in pre-school children is common in developing countries, and restorative treatment is not readily available. The purpose of this prospective controlled clinical trial was to investigate the effectiveness of topical fluoride applications in arresting dentin caries. A total of 375 children (aged 3 to 5 years) with carious upper anterior teeth were divided into 5 groups. Silver diamine fluoride solution (44,800 ppm F) was applied to the first and second groups. Children in the third and fourth groups received the applications of NaF varnish (22,600 ppm F) every 3 months onto the lesions. For children in the first and third groups, the carious tissues were removed prior to fluoride application. The fifth group served as the control. A total of 341 children were followed for 18 months. The mean numbers of new caries surfaces in the 5 groups were 0.4, 0.4, 0.8, 0.6 and 1.2, respectively ($P=0.001$). The respective mean numbers of arrested carious tooth surfaces were 2.8, 3.0, 1.7, 1.5 and 1.0 ($P<0.001$). The annual application of silver diamine fluoride solution is effective in arresting dentinal caries in primary anterior teeth in preschoolers. Caries removal prior to the fluoride treatments has no significant effect on their ability in arresting dentin caries.

Comments: Plaque removal prior to the topical fluoride application on enamel has been proved to be unnecessary. Similarly, caries removal prior to fluoride treatments for arresting the dentinal caries may not be necessary. The low-cost silver diamine fluoride plus the simple procedure (without caries removal) may be promising in the community-based program for caries control. **SH**

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Lo EC, Chu CH, Lin HC. A community-based caries control program for preschool children using topical fluorides: 18-month results. *J Dent Res.* 2001;Dec;80(12):2071-2074.

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