Use of Bispectral Index System (BIS) to Monitor Enteral Conscious (Moderate) Sedation During General Dental Procedures

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ABSTRACT

Although dental board regulations for the provision of in-office enteral conscious (oral) sedation vary widely with respect to training and pharmacologic strategies, they agree on the use of drugs that are inherently safe, the use of pulse oximetry and the availability of emergency equipment, including pharmacologic antagonists. Patient safety is of greatest concern and is best addressed by appropriate selection of patients, adequate training of personnel and appropriate monitoring of patients. Readings from bispectral index system (BIS) monitors, which use electroencephalographic signals, correlate accurately with depth of sedation during nondissociative general anesthesia of adults and children in the operating room setting. The usefulness of such monitoring as an adjunct to other forms of monitoring of in-office enteral sedation in the dental setting may represent the next important application of this tool, adding a further level of safety for the patient and another level of predictability for the practitioner. This paper reviews the current evidence supporting this new technique, presenting data from 20 procedures in which BIS monitoring during in-office enteral sedation was employed in a community dental practice.

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Providing dental care to anxious and fearful patients continues to be a major challenge for dentists. Despite advances in both management techniques and treatment delivery, patients' pre-existing opinions and experiences contribute to dental anxiety and fear.[1] Of the currently available techniques to facilitate coping or minimize procedure-related apprehension, in-office enteral (e.g., oral) sedation by dentists without training in anesthesia has garnered substantial attention in North America, exemplified by the adoption, in October 2007, of new guidelines for the use of sedation and general anesthesia by dentists by the American Dental Association (ADA).[2] Questions persist about whether dentists without formal training in anesthesia should provide this type of service and the manner in which medications should be administered; however, there is agreement that patient safety is the paramount concern and that safety has been greatly enhanced by the advent of newer physiological monitoring devices.[3-11]

Table 1 Levels of sedation[2]

Level of sedation	Definition (according to the American Dental Association)
Minimal sedation	A minimally depressed level of consciousness, produced by a pharmacological method, that retains the patient's ability to independently and continuously maintain an airway and respond normally to tactile stimulation and verbal command. Although cognitive function and coordination may be modestly impaired, ventilatory and cardiovascular functions are unaffected.
Moderate sedation	A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.
Deep sedation	A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.
General anesthesia	A drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

The various levels of sedation are listed in **Table 1**.[2] Because consciousness is represented by a continuum, clinical differentiation between minimal sedation, moderate sedation, deep sedation and general anesthesia may not be easily discerned by traditional, nonquantitative, subjective scales (e.g., the Observer's Assessment of Alertness/Sedation [OAA/S] scale, the Modified Ramsay Sedation Scale or other visual analogue scales).

For enteral sedation in the dental office, automated monitoring tools such as pulse oximeters and blood pressure monitors have so far represented the standard of care for patient safety, allowing quantitative recording of a patient's respiratory and cardiovascular status. Despite the appropriateness and usefulness of pulse oximetry and blood pressure monitoring, these devices have shortcomings and may not be able to generate accurate and timely information when a patient's condition is changing rapidly.[12-17]

The bispectral index system (BIS) monitor uses processed electroencephalographic information from noninvasive forehead electrodes to measure the depth of sedation on a unitless scale from 0 to 100 (**Table 2**). A BIS value of 60 generally denotes the change from minimal to moderate sedation to deeper levels of sedation, which may be characterized by unconsciousness and memory impairment. Details about the computation, derivation and development of the BIS are beyond the scope of this paper but have been published elsewhere.[18-20]

Table 2 Depth of sedation as measured by the bispectral index system[18]

Bispectral index system value	Depth of sedation
0	Flat-line EEG
0–40	Deep hypnotic state; memory function lost; increasing burst suppression
40–60	Recommended range for general anesthesia
60–90	Recommended range for sedation
100	Awake; memory intact

EEG = electroencephalogram

The BIS score correlates quantitatively with the alertness of sedated patients without confounding by evaluator or patient bias.[18-34] As early as 1996, Liu and colleagues[24] recognized that benzodiazepine-induced sedation could be accurately, objectively and immediately determined with this noninvasive monitoring tool. A Japanese group led by Hirota validated these findings by showing that BIS monitoring accurately measured the level of sedation for patients who had been given oral diazepam as a premedication before anesthesia.[35]

To determine the usefulness of BIS monitoring as an adjunct to pulse oximetry and blood pressure monitoring during enteral sedation procedures for adults and to assess the effects of a patient-specific dose of triazolam, as measured by BIS monitoring, an observational study was conducted in a general dental practice where the drug of choice for enteral sedation is the benzodiazepine triazolam.

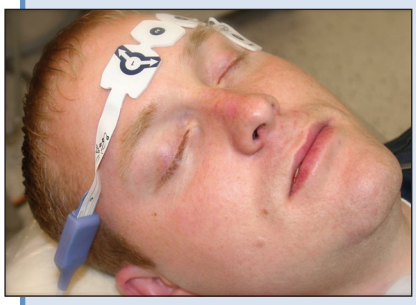

Figure 1: Placement of the noninvasive monitoring strips on the patient's forehead.

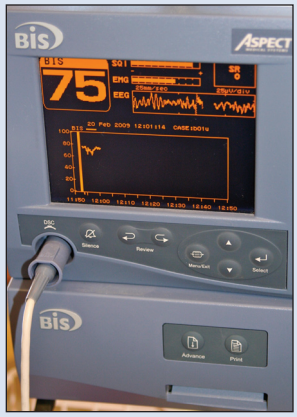

Figure 2: The Aspect Medical Systems A-2000 Bispectral Index Monitor XP Platform with Quatro sensors (Aspect Medical Systems, Inc. Norwood, MA).

Materials and Methods

The study was conducted in the general dental offices at the Arbour Lake Dental Clinic in Calgary, Alberta. The study population consisted of a convenience sample of 20 adults who underwent enteral sedation for general dental procedures during the 3-month study period of August to October 2008. All adult patients requiring or requesting enteral sedation were eligible for enrolment, and the sample size was selected to provide sufficient power for the statistical analysis. Informed written consent was obtained before the sedation appointment.

Patients with acute or chronic alteration of mental status (e.g., mental retardation, dementia or head trauma) and those with hearing impairment were excluded because previous research has indicated that BIS scoring may be unreliable for patients with neurologic disease.[20,21] Patients for whom the forehead probe could not be placed (e.g., patients with forehead lacerations) were also excluded, as were patients taking concurrent medications that could influence BIS readings (e.g., central nervous system depressants or stimulants). The sedative medication for all patients enrolled in the study was triazolam, at doses in accordance with current ADA guidelines.[2] Although supplemental dosing is permitted by the ADA's guidelines, only patients who received a single dose were included in the formal analysis, to simplify consideration of pharmacokinetics; patients who received supplemental doses are mentioned for the purposes of comparison and discussion only.

All patients who received enteral sedation were monitored every 5 minutes according to established in-office protocols, including direct visual and verbal assessment, continuous pulse oximetry and blood pressure monitoring. The dentist administering the oral sedative independently chose the total dose of medication to be used for the appointment. BIS scores were recorded every 5 minutes beginning 60 minutes after the initial dose of the sedative medication; the timing of BIS monitoring was based on the half-life of triazolam and the established time to clinical effect.[3-7]

The investigators used the Aspect Medical Systems A-2000 Bispectral Index Monitor XP Platform with Quatro sensors (Aspect Medical Systems Inc., Norwood, MA) (**Figs. 1** and **2**).

Results

The convenience sample consisted of 20 consecutive procedures involving a total of 18 patients who met the inclusion criteria; 11 of these patients (representing 12 procedures) received a single dose of triazolam and 7 (representing 8 procedures) received a supplemental dose (**Table 3**). In accord with the updated ADA guidelines adopted in October 2007, the dosing schedule for oral premedication was "no more than the maximum recommended dose (MRD) of a drug that can be prescribed for unmonitored home use."[2] For the 7 patients who required a supplemental dose to ensure acceptable sedation during prolonged procedures, dosing was also in accordance with the ADA guidelines, as follows: "a single additional dose of the initial dose of the initial drug … not [to] exceed one-half of the initial dose and … not … administered until the dentist has determined the clinical half-life of the initial dosing has passed. The total aggregate dose must not exceed 1.5× the MRD on the day of treatment."[2]

The average BIS scores for the 12 procedures in which a single dose of oral triazolam was given are presented in **Fig. 3**. In each case, the patient-specific dose of triazolam was appropriate to the patient's weight and age and the complexity of his or her medical situation,

Table 3 Characteristics of dental patients in the study

Patient ID	Age (years)	Sex	Weight (kg)	ASA physical status	Dose of triazolam (mg) (administration time)	O_2 sat range (%)	BIS range	Length of appointment
Single dose of triazolam								
1	59	M	93.2	1	0.5 (6:30 a.m.)	97–98	78–90	2.25 hours (8:00 a.m. to 10:15 a.m.)
2	61	F	96.8	1	0.5 (9:30 a.m.)	96–98	73–84	> 2.5 hours (9:30 a.m. to 12:05 p.m.)
3	60	F	81.8	2 (diabetes)	0.25 mg (1:30 p.m.)	92–95	88–95	2.0 hours (1:30 p.m. to 3:30 p.m.)
4	64	F	100.0	2 (hypertension)	0.5 mg (8:45 a.m.)	93–98	71–89	< 2.0 hours (8.45 a.m. to 10:37 a.m.)
5	32	F	96.4	1	0.5 mg (5:45 p.m.)	93–98	84–97	2.75 hours (5:45 p.m. to 8:30 p.m.)
6	57	F	62.7	1	0.5 mg (2:00 p.m.)	92–98	69–84	1.75 hours (2:00 p.m. to 3:45 p.m.)
6	57	F	62.7	1	0.5 mg (12:00 noon)	92–99	79–87	1.5 hours (12:00 noon to 1:30 p.m.)
7	50	F	70.9	1	0.5 mg (12:00 noon)	94–99	78–88	2.0 hours (12:00 noon to 2:00 p.m.)
8	64	M	90.1	1	0.5 mg (12:00 noon)	96–99	78–88	2.0 hours (12:00 noon to 2:00 p.m.)
9	59	F	76.6	1	0.5 mg (8:45 a.m.)	93–99	77–87	1.5 hours (8:45 a.m. to 10:15 a.m.)
10	59	F	82.6	1	0.5 mg (6:00 a.m.)	91–99	69–82	3.0 hours (6:00 a.m. to 09:00 a.m.)
11	50	F	71.8	1	0.5 mg (8:30 a.m.)	91–97	62–79	3.0 hours (8:30 a.m. to 11:30 a.m.)
Supplemental dose of triazolam								
12	66	M	109.1	2 (sleep apnea)	0.125 mg (11:00 a.m.) 0.125 mg (11:45 a.m.)	91–99	82–98	3.75 hours (11:00 a.m. to 2:45 p.m.)
13	64	M	94.6	1	0.5 mg (1:00 p.m.) 0.25 mg (1:50 p.m.)	92–99	70–92	3 hours (1:00 p.m. to 4:00 p.m.)
13	64	M	94.4	1	0.5 mg (10:15 a.m.) 0.25 mg (11:00 a.m.)	94–99	76–87	3.75 hours (10:15 a.m. to 2:00 p.m.)
14	55	M	89.6	1	0.5 mg (10:15 a.m.) 0.25 mg (11:00 a.m.)	92–99	72–89	3.75 hours (10:15 a.m. to 2:00 p.m.)
15	45	F	96.4	1	0.5 mg (9:30 a.m.) 0.25 mg (11:30 a.m.)	97–99	73–86	2.5 hours (9:30 a.m. to 12:00 noon)
16	60	M	97.7	1	0.5 mg (9:00 a.m.) 0.25 mg (9:30 a.m.)	91–98	65–79	3.0 hours (9:00 a.m. to 12:00 noon)
17	48	M	92.2	1	0.5 mg (6:30 a.m.) 0.25 mg (7:00 a.m.)	91–97	62–90	4.5 hours (6:30 a.m. to 11:00 a.m.)
18	50	F	69.6	1	0.5 mg (8:15 a.m.) 0.25 mg (9:00 a.m.)	94–98	74–78	3.5 hours (8:15 a.m. to 11:45 a.m.)

Note: ASA = American Society of Anesthesiology; ASA physical status 1 = normal healthy patient; ASA physical status 2 = patient with mild systemic disease; O_2 sat = oxygen saturation.

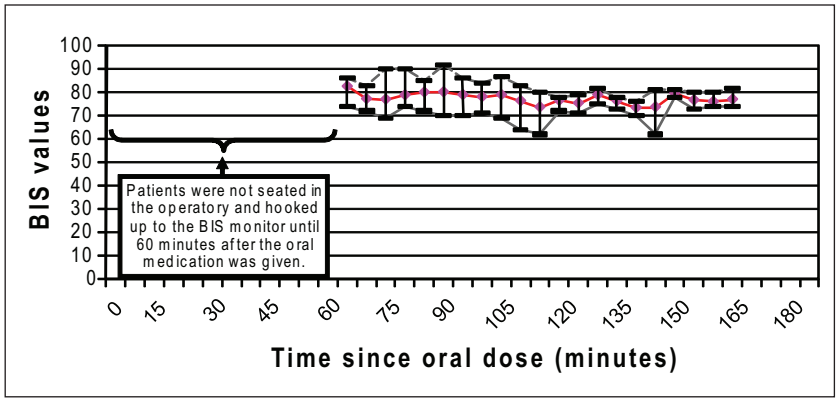

Figure 3: Average bispectral index system (BIS) values following a single oral 0.5-mg dose of triazolam.

Table 4 Definitions of responsiveness according to Observer's Assessment of Alertness/Sedation (OAA/S) scale[39]

Score	Responsiveness
5	Normal response
4	Lethargic response to name spoken in normal tone
3	Responds only after name is called loudly or repeatedly
2	Responds only after mild prodding or shaking
1	Responds only after squeezing of the trapezius
0	Does not respond after squeezing of the trapezius

as defined by the current body of evidence and in agreement with the guidelines described above.[2,4,7,36]

For all 20 procedures, the planned dental treatment was completed successfully. The BIS readings in each case remained above 60, the level that corresponds with the transition from sedation to general anesthesia (**Table 2**). The lowest BIS value recorded was 62, occurring in 1 procedure from each group. All patients remained in verbal communication with the dentist throughout the procedures, and other vital sign data were within normal limits. In total, 5 patients had at least 1 BIS reading less than 70. The BIS range was 62–97 for procedures with a single dose and 62–98 for those with a supplemental dose. Analgesia with nitrous oxide and oxygen was also used in most cases, but previous work has indicated that this potential confounder has no effect on BIS scores.[37]

Although BIS monitoring was stopped at the end of each procedure, the patient was not discharged from the office until he or she met all discharge criteria and could be transferred to the care of a responsible adult. Telephone follow-up to check on the patient's status was performed within 24 hours after each appointment.

Discussion

Traditionally, sedation has been monitored with clinical sedation scales such as the OAA/S scale, the Modified Ramsay Sedation Scale or another visual analogue scale. However, objective assessment of the efficacy of sedative medications remains difficult, as the assessment methods may be affected by the evaluator's subjectivity or the patient's preconceptions (e.g., a placebo effect).

Studies of nondissociative procedural sedation in adults have demonstrated general correlation of BIS scores with clinical determinations of procedural sedation and depth of analgesia. Using BIS monitoring in a hospital department setting for procedural sedation and analgesia in 37 adults, Gill and colleagues[34] found that the correlation between the BIS score and the Modified Ramsay Sedation Scale score was −0.69 ($p < 0.0005$). Bower and colleagues[38] compared the OAA/S scale (**Table 4**) with the BIS score for 50 adult patients undergoing gastrointestinal endoscopy and found a similarly significant correlation ($r = 0.59$; $p < 0.0001$). Sandler and Sparks[40] also reported a strong positive relationship ($p < 0.0001$) between OAA/S and BIS scores for 25 adult patients undergoing extraction of the third molar. Agrawal and colleagues[41] showed that BIS scores between 60 and 90 predicted with moderate accuracy and reliability traditional clinical levels of sedation, as typically encountered during procedural sedation and analgesia in a pediatric emergency hospital setting. In that study, the sensitivity, specificity and predictive values of BIS scores from 60 to 90 for predicting Modified Ramsay Sedation Scale scores of 3 to 7 ranged from 0.65 to 0.80, with a high positive predictive value of 80% (95% confidence interval 69%–89%).[41] More recently, this correlation was studied by Jackson and colleagues[42] (**Fig. 4**). It should be noted, however, that neither of these studies involved dentistry; furthermore, all of the patients in the study by Jackson and colleagues[42] received 1 mg of triazolam, which is beyond the current ADA dosing limits and at least twice the dose received by patients in the current study; this amount of the drug would undoubtedly result in deeper and more prolonged sedation.

Currently, few reports are available on the use of BIS to assess the effects of medications used for enteral sedation.[35,42,43] Many dentists practising enteral (moderate) sedation titrate the medications according to subjective verbal or visual assessments of the patient's level of

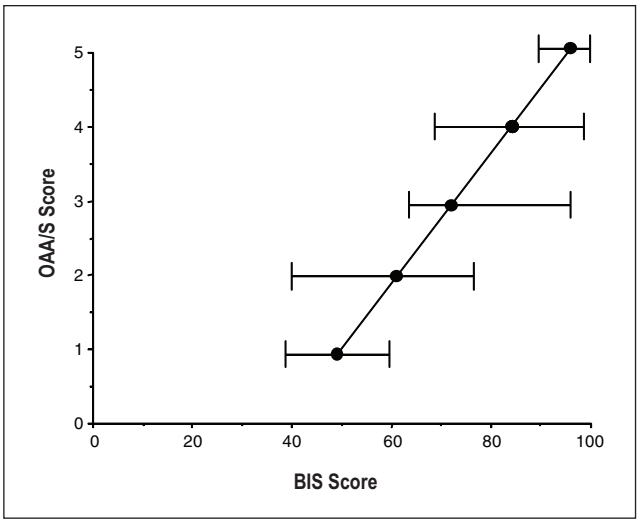

Figure 4: Relationship between Observer's Assessment of Alertness/Sedation (OAA/S) scale and bispectral index (BIS) score. Each point represents a clinical assessment in which both OAA/S and BIS scores were measured. The bars represent the range of recordings. (Adapted with permission from Jackson et al.[42])

consciousness and his or her responsiveness to noxious stimuli. Given the proven correlation between traditional, subjective assessment scales and BIS monitoring, this objective measure of sedation depth during sedation and analgesia for dental procedures could increase practitioner comfort, improve safety and ensure adequate recovery of the patient before discharge. Although the BIS monitor was developed in the operating room setting to assess deep sedative states such as general anesthesia, establishing its applicability within the range of sedation depths typically encountered during general dental procedures with enteral sedation is the authors' current area of interest.

For enteral sedation in the dental office, direct assessment and automated tools such as pulse oximeters and blood pressure monitors have so far represented the standard of care in ensuring patient safety, allowing quantitative recording of a patient's respiratory and cardiovascular status. Despite the appropriateness and usefulness of pulse oximetry and blood pressure monitoring, however, the devices used for these modes of monitorig have shortcomings and may not be able to generate accurate and timely information when a patient's condition is changing rapidly.[12-17,44]

To the authors' knowledge, this study is the first to use the BIS monitor to measure depth of sedation in adults undergoing enteral sedation during general dental procedures. Morse and colleagues[45] assessed the use of BIS monitoring in 22 adult patients undergoing conscious sedation for dental surgery, but the mode of sedation in that study was parenteral administration of midazolam and ketamine. Religa and colleagues[43] assessed the use of BIS monitoring in 21 patients undergoing oral conscious sedation for dental treatment, but their patients were children 3 to 6 years of age.

The BIS results reported here also correlate with the known pharmacokinetics of triazolam. The time to maximum concentration is about 75 minutes, and the BIS readings were typically low (i.e., greater sedation) at that point. The half-life of triazolam is about 2.5 hours, so little change in the BIS scores was expected during the short recording periods in this study. Given the first-order kinetics of triazolam, elimination of the drug is proportional to time; therefore, without administration of additional sedative medication, a gradual rise in BIS score, to a maximum of 95–100, would be expected, however, the data-recording period was not long enough to test this hypothesis. Most patients need several hours to fully recover from even a single dose of triazolam, and it is therefore essential to follow proper discharge procedures and release all patients to a responsible adult companion for travel and supervision during the recovery phase.

The mean BIS values for the subset of 12 procedures in which the patients received a single dose of triazolam (depicted in **Fig. 3**) revealed an almost flat dose–response curve, with little variation over time. Differences between patients in habitus and rates of metabolism, as well as drug interactions and even diurnal variations, are a few of the possible confounders that could lead to different BIS scores following similar doses of medications. The lowest recorded BIS value was 62, which occurred in 2 cases; in each case, the next recorded reading (5 minutes later) was above 70. In these cases, it is likely that the clinician was able to correct (reduce) the level of sedation on the basis of the BIS readings. This capability is important because direct assessment and pulse oximetry may not provide timely, unbiased information for monitoring trends in sedation. The use of BIS monitoring may allow practitioners to more easily notice deepening of sedation and to correct it before a problem arises. Assuming that patients' response to the medication follows a normal distribution, hyperresponsiveness to a "typical" dose could be expected in a small number of patients. In both cases mentioned above, the BIS measurement approached what might be considered general anesthesia, but the patient responded immediately to verbal stimuli and was easily arousable with no change in the ability to maintain patency of the airway and to breathe spontaneously.

This study had 2 major limitations: small sample size and lack of correlation with a visual analogue scale (e.g., the Modified Ramsay Sedation Scale, shown in **Table 5**). These limitations make it difficult to draw rigorous conclusions, but they do raise questions for future research. In previous work by Agrawal and

Table 5 Definitions of responsiveness according to Modified Ramsay Sedation Scale[41]

Score	Definition
1	Awake and alert; minimal or no cognitive impairment
2	Awake but tranquil; purposeful responses to verbal commands at conversational level
3	Appears asleep; purposeful responses to verbal commands at conversational level
4	Appears asleep; purposeful responses to verbal commands but only if at louder than usual conversational level or in response to light glabellar tap
5	Asleep; sluggish purposeful responses only to loud verbal commands or strong glabellar tap
6	Asleep; sluggish purposeful responses only to painful stimuli
7	Asleep; reflex withdrawal to painful stimuli only (no purposeful responses)
8	Unresponsive to external stimuli, including pain

colleagues,[41] BIS readings of 87–92 were correlated with a score of 2 on the Modified Ramsay Sedation Scale (awake but tranquil, with purposeful responses to verbal commands given at a conversational level). These values are consistent with the ADA's definition of minimal sedation. A BIS score of ≥ 75 (Modified Ramsay Sedation Scale of 3–4) could be interpreted as moderate sedation. Eleven of the 20 procedures in this study had at least 1 BIS reading < 75. Agrawal and colleagues[41] studied procedural sedation of children in the emergency department using parenteral medications (midazolam combined with fentanyl or pentobarbital alone). Practitioners should remember that direct assessment is the most appropriate manner to assess a patient's level of sedation at any given moment. BIS scores, like pulse oximetry and blood pressure monitoring, can provide valuable information, but the difference between minimal or moderate sedation and deeper levels of sedation can only be determined by direct assessment of the patient's state of consciousness and his or her ability to respond to verbal commands, to independently maintain patency of the airway and to breathe spontaneously. The patients in the study reported here met the definition of minimal or moderate sedation at all times, which indicates that the cutoffs proposed by Agrawal and colleagues may not apply to enteral sedation of adults. Further research is needed to determine the optimal BIS scores for minimal and moderate enteral sedation of adults induced by triazolam.

Another limitation of the study was the period during which BIS scores were recorded. To more completely assess the effects of single and multiple doses of triazolam, the recording of BIS scores should begin just before drug administration and should continue until the readings return to normal (≥ 95). However, recording in this study started about 60 minutes after administration of the drug, as per office protocol, and ended after 170 minutes. This allowed for recording of up to 21 BIS scores but did not capture return to normal for most of the patients. This shortcoming represents common practices at the study facility, where patients are seated in the operatory for the start of monitoring at about 1 hour after administration of the drug and are monitored visually, without BIS, during recovery in a separate area. Some patients may become more sedated after the stimulus of the dental procedure is completed; therefore, future research should not only examine the complete dose response of triazolam for adult enteral sedation, but should also obtain data for the time after the dentistry is completed. Such information may help to predict the most appropriate and safest time to discharge patients from the office.

The use of the BIS during dental treatment was well tolerated by all patients. The only physical contact of the equipment with the patient consisted of a latex-free adhesive probe placed on the patient's forehead. There were no complaints of itching, burning or discomfort caused by the probe, either during or after application.

In 2002 Morse and colleagues[45] described an additional potential shortcoming of BIS, an observed lag time of about 60 seconds between a change in the clinical situation and the corresponding change in the BIS reading. As such, the BIS value reflects the patient's level of consciousness about 60 seconds in the past.[45–47] In the 7 years since that study, the computational algorithm of the equipment has been improved, such that the reported BIS scores are much closer to real-time in newer models such as the one used in this study. There has also been a suggestion that electromyographic activity may interfere with the electroencephalographic data, leading to falsely elevated BIS values.[18] The particular effect of electromyographic activity, particularly in the temporalis region, on BIS during oral surgical procedures is unknown; however, in the current study, the placement of electrodes was uniform for all patients and the results were generally consistent, so it appears that there was little confounding of results by electromyographic activity.

The cost of the equipment (about US$5,000 per machine and US$20 per probe) may slow the adoption of BIS monitoring in the offices of general dentists who perform enteral sedation during general dental procedures.

Conclusions

BIS monitoring may serve as a useful, objective adjunct in quantifying the depth of enteral sedation in adults in the general dentistry setting. In the case series presented here, the BIS scores recorded (ranging from 62 to 98) were consistent with minimal and moderate sedation as defined by the ADA. More research is needed to explore the applicability of BIS during adult enteral sedation procedures and to establish optimal thresholds for minimal and moderate sedation. The safety of enteral sedation lies in proper preoperative assessment and timely perioperative recognition and management of untoward events. Direct assessment by practitioners supplemented by pulse oximetry and BIS monitoring can further help in preventing problems.

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