Bispectral Index Monitoring:Validity and Utility in Pediatric Dentistry

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Reliable and safe provision of sedation and general anesthesia is dependent on continuous vigilance of patient's sedation depth. Failure to do so may result in unintended oversedation or undersedation. It is a common practice to observe sedation depth by applying subjective sedation scales and in case of general anesthesia, practitioner is dependent on vital sign assessment. The Bispectral Index System (BIS) is a recently introduced objective, quantitative, easy to use, and free from observer bias, and clinically useful tool to assess sedation depth and it precludes the need to stimulate the patient to assess his sedation level. The present article is an attempt to orient the readers towards utility and validity of BIS for sedation and general anesthesia in pediatric dentistry. In this article, we attempt to make the readers understand the principle of BIS, its variation across sedation continuum, its validity across different age groups and for a variety of sedative drugs.

Keywords: Bispectral Index Monitoring, BIS, General anesthesia, Pediatric Dentistry, Sedation.

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INTRODUCTION

Bispectral Index Monitoring was introduced by Aspect Medical Systems, Inc. in 1994 and gained FDA approval in 1996 for monitoring sedation in clinical practice. Since 2009, it is being marketed by Covidien. It correlates inversely with sedation depth[1-3] and has been validated for use in multiple clinical settings across various age groups and sedative drugs. It is an objective, quantitative, easy to use, and free of observer bias, clinically useful tool to assess sedation depth and precludes the need to stimulate the patient to assess his sedation level.

The Bispectral Index System (BIS) utilizes a monitor which derives its data from the electroencephalogram (EEG). It is based on principle that EEG waveforms change during activity, rest, sleep and during anesthesia.[4] In general, when a patient is awake the EEG waveforms are of high frequency and low amplitude, and when a patient is deeply sedated the frequency decreases and the amplitude increases. The BIS monitor processes this data and transforms it into a number which correlates inversely with sedation depth.

A sensor is placed on the forehead usually in fronto temporal region and connected to the BIS monitor. The output from BIS monitor is a single number from 0 to 100.[5] At high values near 100, the patient is awake. According to the manufacturer, a BIS score of >90 indicates an awake patient; and with increase in cortical depression a decrease in BIS reading is observed (Figure 1).

BIS can act as a reliable guide to monitor and titrate sedation and employment of BIS for this purpose has been reported to provide following benefits:

1. *Avoiding oversedation and undersedation*[6,7]*:* Lightening of sedation level resulting in unwanted patient movements might result due to inadequate analgesia despite adequate sedation. This implies that even though a patient might appear undersedated, his sedation level may still be appropriate but he has not received adequate analgesia. Administering additional dosages of sedative drugs to ease carrying out operative procedure might end up in a patient who is unnecessary oversedated and thus increasing the probability of incidence of adverse effects. While using BIS value and not solely clinical presentation as a guide, administering additional sedative drugs can be avoided.

   Similarly, there have been reports of intraoperative awareness despite clinical presentation of adequately sedated patients. Utilization of BIS to titrate anesthesia can minimize such incidences.[7]

2. *Reduction in anesthetic drug requirements*[8,9]*:* This phenomenon can be explained by similar reasoning which explains the avoidance of unnecessary oversedation and undersedation.

3. *Reduction in time to extubation post anesthesia and early discharge*[8,10,11]*:* Messieha *et al* [10,11] evaluated time to extubation and discharge in pediatric patients undergoing dental treatment under GA. He reported reduction in time to extubation and discharge in the group where BIS was used as a guide to titrate anesthesia when compared to the group where routine clinical measures were used to titrate anesthesia.

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Validity of BIS in pediatric patients

Development of BIS took place by conducting a series of experiments on healthy adult volunteers and patients. In these experiments, BIS values corresponding to particular Observer's Assessment of Alertness and Sedation (OAAS) scores were noted.[12] Since, BIS was derived from adult data, BIS value may be different in infants and young children on account of maturational differences in their EEGs.[13] On the contrary, a number of studies[14-17] utilizing BIS in pediatric patients have shown it to be a reliable and valid measure of sedation depth except in very young children i.e. ≤6 months. Malviya *et al* [14] reported that compared with older children, BIS values in infants ≤6 months were significantly lower at each observed sedation level, as were the cutoff values for mild and deep sedation. This implies that relying on BIS value in infants ≤6 months can results in inadequate sedation.

Validity of BIS in different sedative agents

Since**,** BIS relies on changes in cortical EEG waveforms; sedative effects of agents that produce or enhance loss of consciousness without cortical depression are not likely to be reflected in BIS values.[18] Most of the commonly used sedatives i.e. pentobarbital, chloral hydrate, midazolam, and propofol, depress the central nervous system in a dose-dependent fashion. Thus, BIS values have been reported to vary in accordance with clinically observed increase in sedation depth with these agents. But, poor correlation has been found in BIS value and sedation depth by certain agents i.e. ketamine[19-21] and opioids.[22-24]

With ketamine, corresponding decrease in BIS value with increase in sedation depth is not observed, rather, some authors have reported paradoxical increase in BIS value in patients sedated with ketamine.[19,20] This observed phenomenon could be due to desynchronization of the EEG signal from the dissociative action of ketamine.[20]

Similarly opioids produce minimal changes in electrical activity of cerebral cortex[25] and their primary site of action is locus coeruleus- noradrenergic system.[26] This could possibly explain why even with increasing sedation depth on opioid administration BIS value remains almost unchanged.[22-24]

Changes in BIS index value across sedation continuum

BIS value correlates inversely with sedation depth i.e. decrease in BIS number reflects an increase in sedation depth.[4,5] BIS values have been found to be significantly different from each other at various levels of sedation. But, a poor correlation has been found in BIS values for moderate and deep sedation.[6,27] BIS can differentiate deeper level of sedation from lighter planes of sedation i.e. minimal sedation/anxiolysis. However, it can poorly differentiate moderate sedation from deep sedation.[6]

Figure 1: Changes in BIS value across sedation continuum

Correlation between BIS and various other clinical sedation scoring systems

Since BIS has been derived from The Observer's Assessment of Alertness and Sedation (OAA/S) scale, it should correlate well with the OAAS.[12] This has been confirmed by various authors in multiple settings across various populations.[6,27-29] Also, BIS values have been found to be significantly correlated with Ramsey sedation scale,[28] University of Michigan sedation scale (UMSS),[14,29,30] Children's Hospital of Wisconsin Sedation Scores(CHWSS), COMFORT score,[31] Modified Maintenance of Wakefulness Test (MMWT)[14] and the VAS[28].

Validity of BIS in dentistry

For this section of the present paper, we conducted a search through PUBMED with Mesh keywords 'Bispectral monitoring AND dental', 'Bispectral monitoring AND dentistry', 'Bispectral index AND dental' and 'Bispectral monitoring AND dentistry' with limits set for age birth-18 years. A total of 21 papers were retrieved. Abstracts were assessed for content and relevance independently by N and PM and any doubts if rose were resolved by consensus amongst all authors. Inclusion criteria were:

- pediatric age group (0-18 years) was studied exclusively
- outcome measures studied were either 'usefulness of BIS in pediatric dentistry such as possible advantages of BIS over conventional methods of sedation monitoring' or 'association between BIS and commonly used sedation scales'

A total of 6 studies were identified for inclusion in this review (Table 1). Data were extracted for author, year of publication, country, sample (total number of subjects and age), type of study, blinding, sedation scale used/assessment parameters for anesthesia depth; drugs administered, interventions and authors conclusions. An analysis of results reported that BIS was reported to correlate significantly with various sedation scales such as Observers Assessment of Alertness Sedation Scale (OAA/S), Modified Ramsey Scale, Visual Analog Scale (VAS)[28] and University of Michigan Sedation Scale (UMSS)[30]. Further, BIS was also reported to assist in intubation without any undue complications.[32] Also, utilization of BIS to adjust concentration of inhalation anesthetic drugs resulted in faster discharge.[10,11]

Cost-benefit analysis

A cost-benefit analysis may simply be defined as a comparison of benefits obtained from use of a technology and the overall cost of obtaining and using the technology. For BIS, this may simply be derived by comparing the cost of BIS monitor and sensors with benefits of using this technology. The economic benefits of BIS may be reduced dose of anesthetic, early extubation, shortened recovery period and/or reduced chances of intra-operative recall. However, randomised trials to study this outcome are lacking.

A meta-analysis[33] using pooled costs to reflect North America, Europe, and Asia indicated that use of BIS monitoring in patients receiving general anesthesia increased the cost per patient by 5.55 US dollars because of the cost of BIS electrodes. However, this analysis was published in 2004 and thus, results should be interpreted with caution due to inflation that may have increased the cost. Further, the current listed price for the A-2000 BIS monitor is $11-15,000, and the single use BIS Quatro Sensors cost between $15-40. This implies that cost of BIS monitoring per usage is >$ 15-40 i.e. cost of sensors.

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Table 1: Studies conducted to evaluate usefulness or validity of BIS in pediatric dentistry

Author, Year	Country	Sample	Type of study	Blinding	Sedation Scale/ Assessment method	Drug regimen	Interventions	Results & Conclusion
Religa *et al* 2000	USA	N = 21 Age = 3-6 years	Prospective non-randomised trial	No	AAPD levels of sedation	Chloral hydrate, meperidine, and hydroxyzine by oral route + Nitrous oxide for moderate sedation	Multiple restorations	Positive association between BIS and levels of sedation achieved.
Messieha *et al* 2004	USA	N = 20 Age= 2-13 years	Prospective randomised trial	Yes	Patient's vital signs (heart rate, blood pressure, surgical stimulation)	IM premedication with Midazolam + Ketamine followed by General anesthesia	Full mouth rehabilitation	Utilization of BIS to adjust dose of inhalation anesthetist resulted in faster discharge when compared to use of 'patient's vital signs' for this purpose (p<0.001)
Overly *et al* 2005	USA	N = 16 Age= 2-17 years	Prospective cohort study	Yes	Observers Assessment of Alertness Sedation Scale (OAA/S), Modified Ramsey Scale, or a Visual Analog Scale (VAS)	Methohexital+ Nitrous/ Methohexital+ Fentanyl+Midazolam/ Methohexital+ Fentanyl+Midazolam+ Nitrous	Minor oral sutgical procedures	A highly significant association between the sedation scales and the BIS index was reported (P < 0.0001).
Messieha *et al* 2005	USA	N = 29 Age= 2-18 years	Prospective randomised trial	Yes	Patient's vital signs (heart rate, blood pressure, surgical stimulation)	Oral premedication with Midazolam followed by General anesthesia	Full mouth rehabilitation	Utilization of BIS to adjust dose of inhalation anesthetist resulted in faster discharge when compared to use of 'patient's vital signs' for this purpose (p<0.02)
Messieha *et al* 2011	USA	N= 168 Age = 18 mnths to 17 years	Retro-spective	No	-	Oral premedication with Midazolam/ IM Midazolam+Ketamine followed by General anethesia	Full mouth rehabilitation	A BIS mean value of 34.7 provided adequate intubation conditions without muscle relaxation in office-based pediatric anesthesia without complications.
Haberland *et al* 2011	USA	N = 35 Age = 2-7 years	Prospective non-randomised trial	Yes	University of Michigan Sedation Scale (UMSS)	Oral chloral hydrate+Meperidine+Hydroxyzine or Transmucosal fentanyl+ Oral Hydroxyzine or Oral hydroxyzine or Oral Midazolam + Hydroxyzine Additionally	Full mouth rehabilitation	There was a significant but moderate correlation between BIS values and UMSS scores (Spearman's rank correlation r = -0.574, P < .0001).

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CONCLUSION

BIS is a reliable objective measure for sedation monitoring which may possibly eliminate the need for clinical assessment for assessing sedation depth as is evident by recent randomized controlled trials. This is of utmost importance in dentistry where presence of intraoral instruments precludes the possibility of communication with patient to judge sedation level. However, by no means it should be thought of as a replacement for experienced clinician as its ability to differentiate between moderate and deep levels of sedation is questionable though it varies linearly across sedation depth.

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