

BIS in children during maintenance anesthesia

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Abstract

Background and aims. The reliability of BIS monitoring in children is unclear. We decided to measure BIS levels in children during the maintenance phase of general anesthesia, when the anesthesiologist believed the children were well-anesthetized.

Methods. Following IRB approval, children ages 0-10 years undergoing elective general anesthesia had a pediatric BIS electrode placed. BIS values were recorded during anesthesia maintenance. A similar protocol was followed in adult patients.

Results. A total of 240 pediatric patients were evaluated: 62 were < 12 months of age; the remaining 178 patients were between 1 and 10 years of age. There were 94 patients with a BIS ≥ 60 ; (42%) were infants and (38%) children. This was higher than in the adult group (16% with a BIS ≥ 60 , $p < 0.0009$). There was no significant difference in the use of sevoflurane, N₂O, intubation (vs LMA use), or dose of intravenous opioid in the children whose BIS was < or ≥ 60 . One adult (1%), 13 (21%) infants and 18 (10%) children had a BIS level ≥ 70 . BIS in both pediatric groups displayed greater variability than the adult group.

Conclusion. Our results demonstrate significant variability and surprisingly high BIS values in a large portion of pediatric patients. Despite the belief that the patients were well-anesthetized, approximately 40% of infants and children had BIS ≥ 60 and 10% ≥ 70 . Our data supports other studies which suggest that BIS is not a reliable monitor of anesthetic depth in children. BIS data should be interpreted cautiously, and only in conjunction with other clinical signs.

Keywords: anesthesia, awareness; monitoring, BIS; anesthesia, pediatric

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Introduction

The usefulness of BIS monitoring in children under general anesthesia is unclear. Several studies have reported that the BIS response to increasing and decreasing concentrations of inhalational agents is similar in children as it is in adults [1-3] while its accu-

racy is somewhat less certain in infants < 6 months [4]. A number of authors have published data that cast doubt on the utility of BIS in children. Wide numeric variations [5-7], poor correlation with vital signs and clinical signs [3, 6, 8-10], and variable results in sedated children [11] have all been reported.

Our clinical experience using BIS in children during general anesthesia had been that some BIS values were unexpectedly high, sometimes reaching levels indicating a light plane of hypnosis (> 60), despite clinical signs which would point to a well-anesthetized patient. We decided to measure BIS levels in children, specifically during the maintenance phase of general anesthesia, when, in the anesthesiologist's judgment, the child was well-anesthetized regardless of the

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absolute anesthetic level or the particular anesthetic regimen used. In this way we could see how well BIS correlated with common clinical signs of anesthetic depth (HR, RR, BP, movement) in a large sample of anesthetized children. We also performed a similar evaluation in a group of adult patients to try to determine if any age-related differences existed in BIS levels. Based on our previous clinical observations, we hypothesized that the incidence of BIS levels ≥ 60 in children would be high and that BIS variability would be higher in children than adults.

Methods

Following Institutional Review Board approval, children ages 0-10 years undergoing elective general anesthesia were evaluated. The patients were enrolled between November 2004 and May 2006. These pediatric patients underwent a variety of surgical procedures and were cared for by, or under the direction of, a single pediatric anesthesiologist (DS). Anesthetic agents were administered at the discretion of this anesthesiologist. No restrictions were placed on the agents administered. Surgical cases included were those with a sufficiently long and distinct maintenance phase. For this reason, common ENT cases (myringotomy, tonsillectomy) and other short procedures such as eye cases were not included.

Once general anesthesia was induced, a pediatric BIS electrode (Aspect Medical, Boston, MA) was placed on the child's forehead. If muscle relaxants were initially administered, they were allowed to wear off as evidenced by 4 twitches being present on train-of-four monitoring prior to BIS recordings. The BIS monitor was attached and turned on only after the child was in the maintenance phase of the anesthetic (at least 10-15 minutes after incision) and was, in the anesthesiologist's opinion, well-anesthetized. The six criteria that went into the determination that patients were well-anesthetized included the following: 1. lack of patient movement; 2. a steady respiratory rate (in patients breathing spontaneously) which did not change during surgical stimulation; 3. absence of "bucking" or breathing over the ventilator in patients being ventilated; 4. a steady heart rate which did not change during surgical stimulation; 5. absence of tachycardia; and 6. maintenance of the patient's blood pressure (systolic) at or below baseline levels.

The anesthetic level was not changed for at least 5 minutes prior to and during the recording of BIS data (i.e., no additional opioids or other intravenous agents were administered and no changes were made to the inhalation anesthetic concentration). The BIS was allowed to equilibrate (Aspect Medical A2000 BIS anesthesia monitor, software version 3.25, smoothing

time 15 seconds, Aspect Medical, Boston, MA) for approximately 5 minutes before recording actual BIS values. The BIS value that was recorded for each patient was the first value. The BIS level, electromyographic (EMG) activity, suppression ratio (SR), and signal quality index (SQI) were all recorded off of the screen display. A similar protocol was followed in a group of adult patients (> 18 years) presenting for outpatient surgery.

In addition to BIS data, demographic data, use of a midazolam premedication, type of airway device used, inhalational agent concentration (at time of BIS measurement), N_2O concentration (if used), total opioids administered (at time of BIS measurement) and presence of a caudal regional block were all recorded. The pediatric group was sub-divided into infants (0-12 months of age) and children (1-10 years of age). Data from all groups were analyzed using ANOVA, contingency testing and non-parametric testing where appropriate. Adjustment was made for multiple comparisons. A p value less than 0.05 was considered significant.

Results

A total of 317 patients were evaluated. There were 240 pediatric patients and 77 adult patients. Of the pediatric patients, 62 were ≤ 12 months of age; the remaining 178 patients were between 1 and 10 years of age. All patients, in each of the groups was felt to be "well-anesthetized"; no patient demonstrated movement during the BIS measurements.

There was no significant difference between the groups with respect to the concentration of inhalational anesthetic, use of N_2O (73/77 in the adult group, 59/62 in the infant group, 172/178 in the children group), or concentration of N_2O (Table 1). All 77 adult patients had their airway managed by a LMA. Ninety two of the pediatric patients were intubated; the remaining 148 pediatric patients had their airway managed by LMA. One hundred thirty eight of the pediatric patients (45 of the infants and 93 of the children) received a caudal anesthetic in addition to the general anesthetic. The EMG levels were near zero in almost all patients.

BIS levels were higher in the infant ($p < 0.005$) and children groups ($p < 0.0008$) than in the adult group. There was no significant difference in the BIS levels in the infants compared to the children. The first BIS value (recorded) for each patient was within 7% of the subsequent BIS values over a 10 minute time period.

The number of patients who had a BIS level ≥ 60 was significantly different between the groups ($p < 0.0006$; Figure 1). Of those with a BIS level > 60 , there were 12/77 (16%) adults, 26/62 (42%) infants, and 68/178 (38%) children. There were a higher

Table 1. Demographic and clinical data

Group	Age (months)	Weight (kg)	Sevoflurane Concentration (%)	Nitrous oxide Concentration (%)	Fentanyl (mcg/kg)	BIS
Adult	521 ± 125	74.5 ± 17	1.7 ± 0.5	51 ± 12	1.1 ± 0.7	48.8 ± 10
Children	42.9 ± 23	17.6 ± 12	1.9 ± 1.1	50 ± 9	0.9 ± 1.1	53.7 ± 12
Infant	7.6 ± 3.3	8.6 ± 2.2	1.8 ± 0.4	49 ± 11	0.8 ± 1.1	53.7 ± 14

number of patients in both the infant ($p < 0.0005$) and the children ($p < 0.0004$) groups with a BIS > 60 than in the adult group. There were not a significantly different number of infants compared to children who had a BIS > 60 . All 77 of the adult patients received intravenous midazolam as a premedicant as compared to 55 of the children and infants who received oral midazolam premedication (23%). There was a significantly greater use of oral midazolam in those children whose BIS value was < 60 (41/146) than in those who had a BIS value > 60 (14/94; $p < 0.018$). There was no significant difference in the use of N_2O , intubation (vs LMA use), or dose of intravenous opioid in the children whose BIS was $<$ or > 60 .

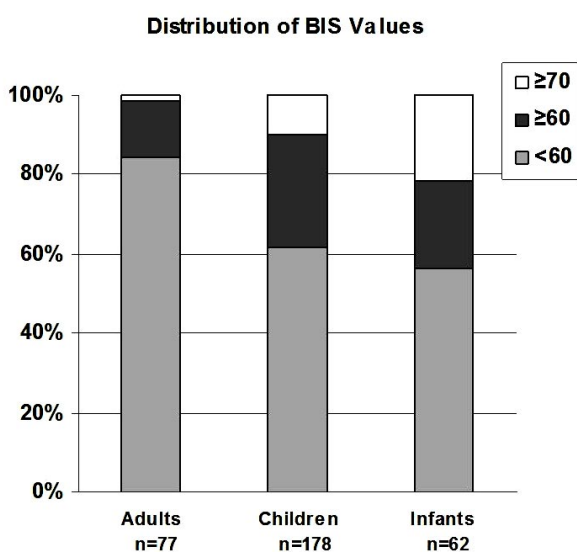


Fig. 1. A histogram presentation of the percentage distribution of BIS values in the three categories (≥ 70 , $\geq 60 < 70$, and < 60). The infants and the children had a significantly higher number of patients than the adults for BIS levels between 60 and 69 as well as for BIS levels ≥ 70 .

The inhaled concentration of sevoflurane was not significantly higher in the children and infants whose initial BIS value was < 60 than in those whose BIS value was ≥ 60 ($1.9 \pm 1.2\%$ vs $1.7 \pm 0.4\%$). The sevoflurane concentration was similar in infants and children irrespective of having had an adjuvant caudal/epidural anesthetic ($1.9 \pm 0.5\%$ vs $1.8 \pm 1.2\%$). There was no significant difference in the use of an adjuvant caudal/

epidural anesthetic and the incidence of having a BIS > 60 .

The number of patients who had a BIS level ≥ 70 was significantly different between the groups ($p < 0.0008$). There was one adult patient (1%), 13 (21%) infants, and 18 (10%) children who had a BIS level ≥ 70 . There were a higher number of patients in both the infant ($p < 0.0001$) and the children ($p < 0.014$) groups with a BIS ≥ 70 than in the adult group. There were a significantly higher number of infants compared to children who had a BIS ≥ 70 ($p < 0.03$).

The variability of BIS data is shown in Figure 2. BIS was more variable for both the infant ($p < 0.05$) and children ($p < 0.05$) groups as compared to the adult group. An F test found a significant difference in means among the groups. Using the Student-Newman-Keuls post-hoc comparison indicates the variance in both the children and the infant groups to be significantly greater than in the adult group.

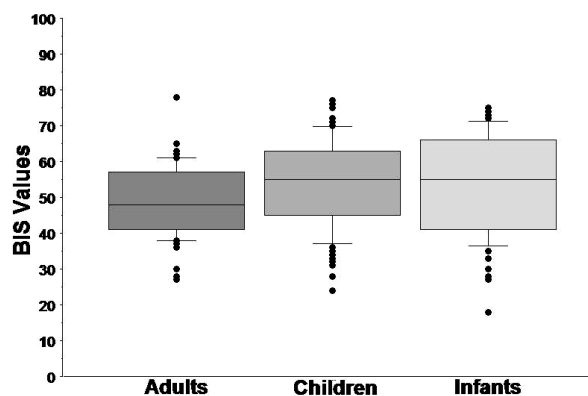


Fig. 2. A Boxplot presentation of the distribution of BIS values.

The box represents the 25th-75th percentiles and the median is represented by the solid line. The extended bars represent the 10th-90th percentiles. Outliers are represented by a dot. BIS levels were higher in the infant ($p < 0.005$) and children groups ($p < 0.0008$) than in the adult group. There was no significant difference in the BIS levels in the infants compared to the children.

Discussion

In this study, we asked the following questions: if one were to measure BIS values in infants and children who were thought to be well-anesthetized during the maintenance phase of general anesthesia, how well would the values agree with clinical judgment? And, if

the same were done in a group of adults, would the BIS values and variability differ? We hypothesized that BIS would be higher in some infants and children than one might suspect based on clinical signs, and that variability would be greater too. Our results support our hypothesis by demonstrating significant variability and surprisingly high BIS values in a large portion of anesthetized pediatric patients. Despite the fact that an experienced pediatric anesthesiologist judged that the patients were well-anesthetized, approximately 39% of infants and children had a $BIS \geq 60$, which is generally accepted as a threshold value indicating light anesthesia and risk of awareness. Using similar criteria in a control group of adults, 16% had $BIS > 60$, also somewhat higher than expected, but significantly less than either pediatric group. Infants (21%) and children (10%) also had a higher incidence of $BIS > 70$ than the adult controls (1%). This is a much larger number of children compared to prior studies of BIS levels that would be considered "too light" in usual clinical practice. Infants have been shown to require a higher concentration of inhalational agent to achieve a target BIS values, consistent with the findings of a higher MAC in infants compared to older children [1]. Both infants and children have similar dose-responsiveness as do adults with respect to inhalational agents [1].

Unlike most other studies looking at BIS in children during surgery, we excluded induction and emergence and looked solely at the maintenance phase of typical pediatric anesthetics. The most difficult challenge we faced, and perhaps the study's biggest weakness, was ensuring that children were well-anesthetized during the recording of BIS. Judging whether a patient is well-anesthetized at any moment during an anesthetic is admittedly subjective; no absolute standard exists. We therefore had a single, experienced, fellowship-trained pediatric anesthesiologist conduct or supervise every anesthetic in the two pediatric groups, in order to eliminate practitioner variation. The criteria used by the single observer to determine anesthetic depth included commonly accepted vital sign measures (RR, HR, BP) and lack of movement. Some pediatric patients received caudal blocks which could have restricted lower extremity movement in the event of light anesthesia. Nonetheless, we feel confident that we would have seen some movement (head, torso, upper extremities, change in respiratory pattern), if our patients had been uncomfortable or distressed. No movement, in any patient, was noted.

We intentionally did not control for the use of particular anesthetic agents. Rather, we used combinations of agents and techniques according to clinical needs. Our goal was to look at as broad an array of pediatric anesthetics as possible, to make our observations applicable to general pediatric anesthesia

practice. The common factor was that each patient was judged well-anesthetized during the maintenance phase when BIS was recorded, regardless of the absolute combination or concentration of anesthetic agents used.

Since the MAC of sevoflurane is higher in children than in adults, and since similar sevoflurane concentrations were found in all groups (both pediatric groups and the adult controls), it might follow that the BIS values would be higher in the children. The concentration of sevoflurane was not chosen a priori, but was determined based on clinical signs. Furthermore, it was surprising how large a percentage of pediatric patients had a BIS value exceeding 60 (39%) and 70 (21% of infants and 10% of children). This contrast between high BIS values and stable clinical signs presents the pediatric anesthesiologist with a clinical dilemma [12]: does one administer additional agents to a child who is thought to be well-anesthetized, and run the risk of depressed vital signs, slow emergence and over-sedation, just to get the BIS value lower? Or, does one ignore high BIS values if vital signs indicate adequate anesthetic depth, and run the theoretical risk of awareness under anesthesia?

Several studies have shown poor correlation between BIS values and vital signs, as we found in our study. For example, in infants undergoing cardiac surgery, no relationship between BIS and hemodynamic parameters was found [8]. Movement during surgical stimulation was found not to correlate with BIS values in anesthetized children [6]. In a study of critically ill pediatric patients undergoing sedation, BIS values ($> 30\%$ from baseline) correlated with MAP, HR and both MAP and HR only 10.6%, 23.8% and 5.7% of the time; the authors concluded, somewhat questionably, that for sedation assessment, the BIS values are accurate, while vital signs are not [10]. Another study found that clinically-directed sedation administration poorly correlated with BIS values; they too concluded that physiologic parameters are not reliable when judging the depth of sedation [9]. It is not clear to us why both groups come to this conclusion; it is equally possible that it was the BIS which was faulty in predicting sedation depth. In our study, were the 39% of infants and children with $BIS \geq 60$ and who appeared adequately anesthetized actually too light and susceptible to intra-operative awareness? Or, were they in fact adequately anesthetized, as we believe, but displaying BIS variability that has been previously shown in children? Another possibility is that a BIS value of 60 in children does not indicate a light plane of anesthesia. Only by conducting post-anesthesia awareness surveys in BIS-monitored children, as Avidan et al. did in adults [12], can this question be answered. To date, this data is lacking.

A correlation between BIS values and sedation scores in children has been demonstrated in some studies [13-15]. However, BIS values did not correlate with Ramsey Sedation Scores (RSS) during moderate and deep sedation [11]. Almost 15% of children were, by clinical assessment, moderately or deeply sedated, but had BIS values > 80 . Some children deemed "deeply" sedated even had numeric BIS values of 90-100 – values which would be considered "awake". The authors of this study concluded that BIS was a poor monitor for this clinical setting. Similarly, we feel that the 21% of infants and 10% of children in our study with $\text{BIS} \geq 70$ were in fact, adequately anesthetized, as the vital signs indicated.

Interestingly, there was a lower incidence of $\text{BIS} > 60$ in children who received oral midazolam preoperatively. Part of the discrepancy between the BIS values in children and adults may be that all of the adult patients received midazolam. Our results suggest that routine midazolam premedication in pediatric cases could potentially be used specifically to lower the incidence of BIS values above 60 during the ensuing general anesthetic. To our knowledge, this has not been previously shown. The use of midazolam, however, may result in a decreased need for inhalational anesthetics; how this clinically affects anesthetic depth is not clear. In addition, midazolam use has the potential to delay discharge in some pediatric surgical cases [16]. Finally, and potentially most importantly, the importance of preventing BIS values > 60 in children has not been established.

Two studies looking at awareness under general anesthesia in children [17-18] have reported a slightly higher incidence than commonly cited in adults. The youngest children in these studies were 5 years of age; testing for awareness in younger children is not currently practical. With respect to the use of BIS monitoring decreasing the risk of awareness, the current literature is inconclusive. In a comparison of adult patients undergoing general anesthesia with either a BIS-guided or end-tidal agent-guided anesthetic, no difference in the incidence of recall was found [12]. Of the cases in which awareness occurred, almost all had BIS values < 60 . In addition, there were sustained periods with $\text{BIS} > 60$ in 55% of patients, none of whom had awareness. The authors conclude that BIS monitoring should not be part of standard practice. Other studies [19] have found that BIS monitoring can reduce awareness in adults. To date, no group has demonstrated that BIS can reduce awareness in children.

Conclusion

In conclusion, we found that in a group of infants and children judged well-anesthetized by an experienced pediatric anesthesiologist, 39 % had a $\text{BIS} \geq 60$, and 13% had a $\text{BIS} > 70$ during maintenance. This was significantly greater than in a control group of adults. We believe that our study supports other works which suggest that BIS is not a reliable monitor of anesthetic depth in children. The possibility remains that $\text{BIS} > 60$ does not imply light anesthesia in children, as is accepted in adults. Unfortunately, it is difficult to determine the exact incidence of awareness in this population following general anesthesia. We believe that BIS is not a reliable monitor of anesthetic depth in children, and therefore aiming to keep the BIS at or below a specific value is not a practice which has been validated. We believe that BIS is of questionable value for routine use in pediatric cases.

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BIS la copii în cursul menținerii anesteziei generale

Rezumat

Premiză și scop. Relevanța monitorizării BIS la copii nu este clară. Am decis să măsurăm nivelurile BIS în faza de menținere a anesteziei generale, când

anestezistul consideră că copiii sunt bine anesteziați. **Metodă.** Cu aprobarea International Review Board, la copii cu vârsta între 0-10 ani supuși unei anestezii generale de elecție, s-a plasat un electrod pediatric pentru măsurarea BIS, iar valorile BIS au fost înregistrate în timpul perioadei de menținere a anesteziei. Un protocol similar a fost aplicat și la pacienți adulți. **Rezultate.** Au fost evaluați 240 de pacienți pediatrici: 62 au avut vârsta sub 12 luni, iar restul de 178 au avut vârsta între 1-10 ani. Dintre cei 94 de pacienți cu valoare BIS ≥ 60 , 42% au fost sugari, iar 38% copii. Incidența a fost mai mare în comparație cu adulții (16% cu BIS ≥ 60 ; $p < 0,0009$). La copiii cu BIS $<$ sau ≥ 60 nu au existat diferențe semnificative în utilizarea sevofluranului, N₂O, intubației (vs mască laringiană) sau dozei de opioid intravenos. Un adult (1%), 13 sugari (21%) și 18 copii (10%) au avut nivelul BIS ≥ 70 . În ambele grupuri pediatrice, BIS a înregistrat o mai mare variabilitate comparativ cu grupul adulților. **Concluzie.** Rezultatele noastre demonstrează o variabilitate semnificativă și valori ale BIS surprinzător de ridicate într-o mare proporție a pacienților pediatrici. În pofida faptului că pacienții păreau bine anesteziați, aproximativ 40% din sugari și copii au avut un BIS ≥ 60 și 10% un BIS ≥ 70 . Rezultatele noastre susțin alte studii care sugerează că BIS nu este o monitorizare de încredere a profunzimii anesteziei la copii. Datele oferite de BIS trebuie interpretate cu prudență și numai în corelație cu alte semne clinice.

Cuvinte cheie: anestezie, awareness; monitorizare, BIS; anestezie, pediatrică