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Original Research Article

# Comparative Study of BIS Values Required for Insertion of Proseal Laryngeal Mask Airway or Endotracheal Intubation in Paediatric Patients Undergoing Sevoflurane Anaesthesia

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**Conflict of interest: Nil**

## Abstract

**Aim:** The aim of present study is comparison of BIS values required for insertion of proseal laryngeal mask airway or endotracheal intubation in paediatric patients undergoing sevoflurane anaesthesia.

**Methodology**: This prospective randomized observational study was conducted in the Department of Anaesthesiology, from Aug-21 to Feb-22 at Government Medical College, Kota after getting approval from ethical committee. children between 2 and 14 years of ASA I and II and they were randomly allocated to Group P (proseal laryngeal mask airway insertion) and Group TI (tracheal intubation) scheduled for elective surgical procedure requiring general anaesthesia. This study was conducted on 60 patients who were randomly divided into 2 groups of 30 patients each.

**Results**: BIS score decreased in both the groups during induction period BIS score was significantly higher 1 min after Endotracheal intubation as compared to 1 min post LMA insertion, and the difference was statistically significant. BIS score required for insertion of LMA ranges from 55-60 whereas slight deeper levels of anaesthesia of BIS range between 50-55 are required for endotracheal intubation. No clinically relevant side effects were observed in both groups

**Conclusion:** LMA is a better option than endotracheal intubation for short surgical procedures requiring general anaesthesia in terms of less requirement of inhalational agent, lesser induction times and BIS score is concerened.

**Keywords:** Proseal Laryngeal Mask Airway, Endotracheal Intubation, Sevoflurane, BIS score.

## Introduction

An ideal general anaesthetic technique should provide smooth and rapid induction, optimal operating conditions, and rapid recovery with minimal or no side effects. Although local and regional anaesthesia techniques are increasingly used in almost all anaesthesia settings, because they allow a more rapid recovery, but general anaesthesia is still the most common anaesthetic technique[1]. The most important aspect of an anaesthetic technique is its ability to consistently achieve rapid recovery after termination of surgery.

**Bispectral index** (**BIS**) is one of the several technologies with purpose to monitor depth of anaesthesia. The BIS index remains the most clinically validated form of consciousness monitoring with robust applications across a broad range of anaesthetic agents and techniques and demonstrates validity in nearly all patients. As a result, the BIS index has emerged as an important tool for anaesthesia management[2,3]. BIS index directly reflects the activity of cerebral cortex and correlate with level of consciousness. It is a latest system used in anaesthesiology to measure the effects of specific anaesthetic drug on the brain and to track changes in patient's level of sedation and hypnosis. In technical terms, the Bispectral index itself is a complex mathematical algorithm that allows a computer inside an anaesthesia monitor to analyse data from a patient's electroencephalogram during surgery[4].

The Bispectral Index offers the anaesthesia professional, a direct and accurate method for continuous brain status monitoring throughout the course of anaesthetic or sedative administration. Specifically, the Bispectral Index provides a measurement of the hypnotic effect of anaesthesia. It has proven to be accurate and reliable in nearly all patients and clinical settings and is robust in the presence of the most commonly used anaesthetic and sedative agents. It has been used to monitor the level of sedation and used to determine awareness during surgery[3]. The BIS Index is a numerically processed, clinically validated EEG parameter. Unlike traditional processed EEG parameters derived from power spectral analysis, the BIS Index is derived utilizing a composite of multiple advanced EEG signal processing techniques – including bispectral analysis, power spectral analysis, and time domain analysis. These components were combined to optimize the correlation between the EEG and the clinical effects of anaesthesia[5].

Therapeutic targeting is a clear benefit that results from BIS monitoring. Using this new parameter, the clinician can manage patients within the optimal plane of anaesthesia effect, reducing the unwanted occurrence of excessive or inadequate anaesthetic effect. Clinical investigations of BIS monitoring during anaesthesia have consistently demonstrated an average 25% reduction in intraoperative anaesthetic use and a consistent reduction in the time for emergence from general anaesthesia[6].

Intraoperative BIS Index values will depend upon a number of variables including:

- Brain concentration of anaesthetic
- Level of analgesia
- Surgical stimulation

Titrating anaesthetic agent to a specific BIS index during general anaesthesia in adults and children over 1year old allows adjusting the amount of anaesthetic agent to the need of the patient, possibly resulting in faster recovery from anaesthesia. BIS monitoring may reduce the incidence of intraoperative awareness in high risk procedures.Bispectral index change is as sensitive as haemodynamic responses after a painful stimulus for detecting deficits in the analgesic component of anaesthesia. It may, therefore be a useful monitor of the depth of anaesthesia in patients incapable of heart rate and mean arterial responses to noxious stimuli because of medications or cardiovascular disease.

Therefore, BIS Index monitoring can allow delivery of anaesthesia care that is safer, more precise and more pleasant for the patient. In combination with assessment of clinical signs and traditional monitoring, the BIS monitoring can facilitate balanced hypnotic and analgesic administration with ensuring adequacy of anaesthesia[7].

Inhalational anaesthesia techniques remain the main stay of modern anaesthesia practice. It is believed that inhaled anaesthetic technique allows rapid emergence from anaesthesia, probably because of ease of titratability, and exerts some neuromuscular blocking effect[8], which may reduce the requirements of non-depolarizing muscle relaxants[9]. The availability of newer, shorter-acting inhaled anaesthetics (e.g., desflurane and sevoflurane) allows for a more rapid emergence from anaesthesia compared with older inhaled anaesthetics (e.g., halothane and isoflurane). This should reduce the risks of early postoperative complications (e.g., respiratory complications such as airway obstruction and hypoxemia). Therefore, this study planned to compare different values of BIS required for insertion of Proseal Laryngeal Mask Airway versus Endotracheal tube during sevoflurane anaesthesia in paediatric patients.

## Materials and Methods

### Source of Data

This prospective randomized observational study was conducted in the Department of Anaesthesiology, from Aug-21 to Feb-22 at Government Medical College, Kota after getting approval from ethical committee. Children between 2 and 14 years of ASA I and II and they were randomly allocated to Group P (proseal laryngeal mask airway insertion) and Group TI (tracheal intubation) scheduled for elective surgical procedure requiring general anaesthesia. This study was conducted on 60 patients who were randomly divided into 2 groups of 30 patients each. A written and informed consent was taken from the patient after explaining the procedure to the patient.

### Exclusion criteria:

If the attempt failed to secure airway, the end tidal sevoflurane was increased by 0.5% and another 5 mins were allowed to elapse before the next attempt. If this second attempt also failed, no further attempts were made, and this child was excluded from the study.

### Sample Size Calculation and Statistical Analysis

The sample size was calculated to be approximately 30 in each group total 60 patients. All statistical analysis was performed by using SPSS 22.0 software package (SPSS Inc., Chicago, IL, USA). Chi-square test for non-continuous variables and unpaired t-test were performed for continuous variables with normal distribution. All results were expressed as mean ± SD. $P<0.05$ was considered statistically significant.

### Procedure:

After thorough pre-anaesthetic check-up, written and informed consent was obtained from parents and NBM status of child was confirmed. Intravenous glycopyrrolate 0.007mg/kg and 0.02mg/kg midazolam iv was administered 1 min after which inhalational induction via face mask was started.Compact airway module of anaesthesia machine was used to measure BIS values & sevoflurane concentration (end tidal and MAC) and other vital parameters. MAC values are displayed on our workstation available in our institution (Dragger A500).

For measurement of BIS index, adult disposable biosensor strips were attached (covidien healthcare pvt limited). It consists of 4 gel electrodes; skin of forehead was wiped with NS swab and was made air dry. (As after spirit swab, we found difficulty in sticking). There are numerical markings on strip from 1 to 4.

The sensor was placed at the centre of forehead, at the point marked as 1, approximately 2 inches (5cm) above the bridge of nose. Point 4 directly above eye - brow, point 3 on temple between corner of eye and hairline the proximal lead was placed above the nasion and the distal lead was placed midway between tragus of the ear and outer canthus of the eye. Baseline parameters like pulse rate, blood pressure, oxygen saturation, respiratory rate, Et $CO_2$ and BIS were noted.

General anaesthesia was induced via inhalation of sevoflurane 2% in group LMA and 2.5% in group Et with (50:50) $O_2$+ $N_2O$ using closed circuit.1 min after premedication (midazolam and glycopyrrolate) Induction was continued with sevoflurane. We initiated insertion of both LMA as well as Et at BIS score of 60, but we found that for smooth insertion of LMA BIS value of 60 was appropriate but for smooth insertion of ET BIS value between 55 – 60 was not sufficient as the attempt for insertion of Et was not successful whereas at BIS value between 50-55 smooth intubation was possible hence the primary endpoint was time when BIS score reached between 50 - 55 in group Et and between 55 – 60 in group LMA. Since the BIS score changes with each pulse so it was only considered when the same value remains for 45 secs.

IPPV was given if depths of respiration were decreased and end tidal $CO_2$ increased to more than 45 mm Hg. Anaesthesia was conducted in conventional manner by an anaesthesiologist who made an attempt to secure airway either through LMA or ET at the BIS value suitable for that group without using muscle relaxant.

If the attempt was successful, the BIS valuewas noted otherwise the patient was further induced by increasing the sevoflurane concentration by 0.5% for another 3 mins. Maximum 3 attempts were made; the aim being trying to get the most suitable BIS value for insertion of LMA or endotracheal tube.

According to the weight of the child, size of airway device was selected.

PLMA was inserted using index finger technique. Proper placement of the PLMA and tracheal tube was confirmed with bilateral equal air entry and square wave capnography.

Anaesthesia was maintained in conventional manner via inhalational and iv drugs (atracurium). Patient was reversed with the help of iv reversal agents using neostigmine and glycopyrrolate. Patients were observed for any post op complications for the next 6 hrs.

## Results

**Table 1: Comparison of BIS Score**

| **Time** | **Group LMA** | | **Group ET** | | **P VALUE** |
|---|---|---|---|---|---|
| | **Mean** | **SD** | **Mean** | **SD** | |
| **Baseline** | 97.7 | 1.11 | 97.1 | 1.34 | 0.0639 |
| **1 min.Post Premedication** | 94.4 | 4.10 | 93.4 | 4.37 | 0.3645 |
| **Beginning of induction** | 91.5 | 6.21 | 92.2 | 5.4 | 0.6427 |
| **1 min.** | 84.03 | 6.57 | 86.6 | 9.35 | 0.2230 |
| **3 min.** | 74.66 | 8.59 | 81.4 | 10.47 | **0.0085** |
| **5 min.** | 67.2 | 10.6 | 74.3 | 11.9 | **0.0178** |

| | | | | | |
|---|---|---|---|---|---|
| **6 min** | 65.38 | 10.84 | 67.8 | 12.9 | 0.4934 |
| **7 min** | 65.4 | 7.8 | 63.16 | 11.60 | 0.5211 |
| **8 min** | 60.9 | 5.14 | 61.5 | 7.97 | 0.8249 |
| **9 min** | 57.5 | 3.8 | 55.2 | 3.9 | 0.2454 |
| **10 min** | 60 | 0 | 52.8 | 1.64 | **0.0020** |
| **Post insertion** | | | | | |
| **1 min** | 60.96 | 4.4 | 54.8 | 5.03 | **0.0001** |
| **3 min** | 52 | 3.8 | 49.3 | 6.73 | 0.0598 |
| **5 min** | 48.33 | 4.09 | 46.53 | 6.80 | 0.2191 |

**Table 1** shows BIS score changes in both groups at different time intervals. BIS score recorded 1 min before giving premedication was considered as baseline value. These were 97.7±1.11 in group LMA and 97.1±1.34 in group Et and were comparable. The BIS score decreased significantly in both groups 1 min after giving premedication and was 94.4±4.10 and 93.4±4.37 in group LMA and group Et respectively but this fall was statistically insignificant.

BIS score again started to fall in both the groups during induction period. On intergroup comparison the fall was higher in group Et as compared to group LMA and the difference persisted throughout the induction period and was statistically significant at 3,5 and 10 minutes ($P<0.05$).

The BIS Score at 5 mins in group LMA was 67.2 & in group Et was 74.3, this higher value at 5 mins in group Et despite of 0.5% higher conc of sevoflurane appears to be co-incidental. It appears that increasing the conc. Of sevoflurane by 0.5% does not significantly affect the induction time. 1 min after insertion of LMA\intubation, the BIS score increased in both groups but the rise was more in group Et and was statistically significant. BIS score gradually decreased in both the groups after that.

**Table 2: Complications**

| COMPLICATIONS | GROUP LMA | GROUP Et |
|---|---|---|
| | **n=30** | **n=30** |
| **Bronchospasm** | Nil | Nil |
| **Laryngospasm** | Nil | Nil |
| **Bradycardia** | Nil | Nil |
| **Postop Sedation** | Nil | Nil |
| **Postop Nausea &Vomiting** | Nil | Nil |
| **Postop sore throat** | Nil | Nil |

**Table 2** depicts incidence of complications. In our study we did not observe any complications like bronchospasm, laryngospasm, post op sedation, post op nausea vomiting post op sore throat excessive tachycardia and excessive hypo/hypertension.

**Discussion**

One of the achievements of modern anaesthesia is the ability to monitor the depth of anaesthesia. Traditional clinical monitoring modalities during anaesthesia are ineffective in preventing awareness. Recently, a monitor that uses a processed electroencephalogram (EEG) derivative, the Bispectral Index(BIS) has been introduced into clinical practice for monitoring anaesthetic effects on the brain. It may have the ability to measure the hypnotic component of the anaesthetic state and it has even been suggested that guiding anaesthetic administration by using BIS monitoring may be associated with an increased incidence of awareness because of deliberate reductions in anaesthetic dose on the basis of BIS data.

Very few studies were found to be eligible for selection; hence, it was not possible to classify the available results into different age groups viz. infants, toddlers, young children or adolescents, and thus the observations had to be restricted to the paediatric population in general. BIS has been shown to correlate well with anaesthetic depth for a number of agents.

Recovery of consciousness during general anaesthesia without any recall (in the absence of surgical stimulus) has generally been associated with BIS values below 60. BIS values in a range of 40-60 have been proposed for producing adequate degree of hypnosis during anaesthesia and when appropriately used, BIS can be useful for reducing the risk of intraoperative awareness.

The bispectral index score (BIS) has been validated as a measure of hypnotic effect for various anaesthetic agents. There are limited data correlating the BIS with minimum alveolar concentration (MAC) of different volatile anaesthetics. MAC is the most common method of titration of volatile anaesthetics in clinical practice.

The present study was carried out to compare the BIS values required for insertion of proseal laryngeal mask airway/ Endotracheal intubation in paediatric patients undergoing sevoflurane anaesthesia.

Selection of sevoflurane concentration 2% for group LMA and 2.5% in group Et was done with the aim that probably if we use higher conc. In group Et we will achieve desired BIS value little earlier. As because of laryngoscopy in group Et it was expected that BIS value required will be lower than group LMA. Also, Et sevoflurane was kept higher because it was anticipated that the trachea would be more sensitive than the oral cavity and pharyngeal mucosa for foreign bodies.

BIS Score the literatures of Medline did not show any study which has correlated BIS values with the insertion\ intubation timing in paediatric patients. The number of participants was based on feasible convenience sample and was therefore, arbitrarily decided R. Aantaa, R. Takala, P. Muittar[10] & Mahantesh S., Mudakanagoudar M.C.B. Santhosh[11], concluded in their study and also there are several other studies[12] that have shown that PLMA insertion requires less concentration of sevoflurane in comparison to tracheal intubation and hence we started with predetermined concentration of 2% on concentration dial in group LMA while 2.5% in group Et along with (50:50) $O_2$ + $N_2O$.

The primary endpoint was time when BIS score reached between 50 - 55 in group Et and between 55 – 60 in group LMA. Since the BIS score changes with each pulse so it was only considered when the single value persisted for 45 secs. The primary outcome was to compare the BIS values required for insertion of Proseal Laryngeal Mask Airway and Endotracheal tube in paediatric patients undergoing sevoflurane anaesthesia. **Table 1** shows BIS score changes in both groups at different time intervals. BIS score recorded 1 min before giving premedication was considered as basal value. These were 97.7±1.11 in group LMA and 97.1±1.34 in group Et and were comparable. The BIS score decreased significantly in both groups 1 min after giving premedication and was 94.4±4.10 and 93.4±4.37 in group LMA and group Et respectively but this fall was statistically insignificant.

Our findings are consistant with the findings of Didem, Ozdemir, Ozenen[13] they also concluded in their study that "The BIS records of the midazolam group were slightly lower than the control group in general, but this difference was not statistically significant (p>0.05)."

BIS score again started to fall in both the groups during induction period. On intergroup comparison at 3- and 5-min BIS score varied in both groups and was statistically significant with p values 0.0085 and 0.0178. Whereas at 6,7,8 and 9 minutes the values were again comparable with p value>0.05 that is statistically non-Significant. At again 10 minutes and 1 min post insertion\ intubation BIS score varied with p value less than 0.05 that is 0.0082 and 0.0001respectively. We found that BIS score was significantly higher in 1 min after Endotracheal intubation as compared to 1 min post LMA insertion. In group LMA average BIS at 10 mins was 60 while in group ET the average value of BIS score at 10 mins was 52.8 which increased to 60.96 in group LMA and 54.8 in group ET with a p value of highly statistically significant that is 0.0001. This greater change in group Et is assumed to be because of laryngoscopy which was not performed in group LMA.

Our study results were supported by Guignard and colleagues[14] who reported that maximal increase in BIS value as well as in haemodynamic variables occurred during first 120 sec following laryngoscopy and orotracheal intubation.

Our study results are supported by Kim HS[15], he along with his colleagues did a non-linear regression analysis which showed a significant correlation between BIS and age at each End Tidal sevoflurane concentrations. They concluded that younger patients showed the higher BIS values. This result can be correlated with our study as in both the groups in our study younger patients that are (2-5 yrs) took more time in achieving the target BIS score.

In contrast to our study Olivier Tirel[16] questions the ability of the EEG bispectrum to accurately determine depth of anaesthesia in children. We did not observe any complications such as bronchospasm, laryngospasm, postop nausea or vomiting, post op sore throat and post op sedation in both the groups.

## Conclusion

LMA is a better option than endotracheal intubation for short surgical procedures requiring general anaesthesia in terms of less requirement of inhalational agent, lesser induction times and BIS score is concerened.

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