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Intubating Conditions and Tracheal Intubation at First Attempt Without Neuromuscular Blockade Using Sevoflurane: Comparison of Clinical Versus Bispectral Index Monitored Depth of Anaesthesia

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Abstract

Tracheal intubation, which is typically made possible by neuromuscular blocking agents, is an essential part of airway management in critical care and anaesthesia. To lessen related side effects such as persistent paralysis, anaphylaxis, and residual neuromuscular blockade, the avoidance of neuromuscular blocking agents is being sought after more and more. This study therefore sought to determine intubating conditions and tracheal intubation at first attempt without neuromuscular blockade using sevoflurane, comparing clinical versus bispectral index monitored depth of anaesthesia. This was a randomised, single-blind, controlled clinical study conducted in the Jos University Teaching Hospital, Jos, Nigeria, among 56 paediatric surgical patients aged 2 to 6 years with ASA I and II scheduled for adenotonsillectomy sampled purposely. Exclusion criteria included parental/guardian refusal, recent respiratory tract infection, and patients with anticipated difficult airway

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or intubation. Patients were randomised into two groups, B and C, with patients in group B receiving BIS monitoring while those in group C received clinical monitoring for the depth of anaesthesia with sevoflurane and without a neuromuscular blocking agent. After a successful tracheal intubation, the number of attempts at successful tracheal intubation and the intubating conditions scores were noted and recorded for both study groups. Data was analysed using SPSS with students' t-test and chi-square test being the statistical tests utilised, and the level of significance set at p=0.05. The BIS group had 18 (64.28%), 10 (35.71%), and 0 (0%) children, respectively, with Helbo-Hansen scores of 4, 5, and 6, while the clinical group had 12 (42.86%), 14 (50%), and 2 (7.14%) children, respectively, with similar Helbo-Hansen scores. All the study participants had successful tracheal intubation at the first attempt. The intubating conditions and success rate at the first attempt at intubation when the depth of anaesthesia was monitored using clinical signs compared favourably with when the depth of anaesthesia was monitored using BIS.

Keywords: Sevoflurane, Tracheal Intubation, Anaesthesia Depth, BIS, Clinical Monitoring

INTRODUCTION

Tracheal intubation, which is typically made possible by neuromuscular blocking agents (NMBAs), is an essential part of airway management in critical care and anaesthesia. To lessen related side effects such as persistent paralysis, anaphylaxis, and residual neuromuscular blockade, NMBA avoidance is being sought after more and more (Brull et al., 2008; Lien, 2011). Because of its quick induction and bronchodilatory effects, sevoflurane, a volatile anaesthetic, has become a viable substitute for NMBAs in the pursuit of appropriate intubating circumstances (Goa et al., 1999; Mencia et al., 2018).

Maintaining ideal circumstances for tracheal intubation, especially in the absence of neuromuscular inhibition, requires careful monitoring of the degree of anaesthesia. Although they are frequently employed, clinical measures like jaw relaxation and absence of eyelash reflex are arbitrary and subject to variation (Hadzidiakos et al., 2006). By evaluating electroencephalographic activity to guide anaesthetic depth, Bispectral Index (BIS) monitoring provides an objective method (Johansen, 2006; Liu et al., 2004). There is a paucity of data comparing the effectiveness of clinical and BIS-guided monitoring in

maximising intubation conditions without NMBAs, despite their increasing use (van Twest, 2006).

One factor contributing to variation in intubating conditions and first-attempt success rates during sevoflurane-induced intubation is the lack of agreement on the best depth of anaesthesia monitoring technique (Frerk et al., 2015). By reducing subjective bias and guaranteeing dependable intubation circumstances, this study will shed light on anaesthetic practices and perhaps improve patient safety and outcomes. This study is therefore aimed at determining the efficiency of clinical versus BIS-guided tracheal intubation without neuromuscular blockade by comparing intubating conditions and tracheal intubation at first attempt following inhalational induction using sevoflurane in paediatric patients scheduled for adenotonsillectomy at the Jos University Teaching Hospital.

MATERIALS AND METHODS

This was a randomised, single-blind, controlled clinical study conducted at the Jos University Teaching Hospital, Jos, Plateau State, North Central Nigeria. The study was carried out amongst paediatric surgical patients. Inclusion criteria were patients aged 2 to 6 years with ASA physical status of I and II and scheduled for adenotonsillectomy. Exclusion criteria included parental/guardian refusal, recent respiratory tract infection, and patients with anticipated difficult airway or tracheal intubation. The sampling technique employed was purposive sampling. Patients were randomised by means of balloting into groups B and C. Patients in group B had BIS monitoring while those in group C had clinical monitoring for the depth of anaesthesia.

The sample size for this study was estimated from the formula for determination of sample size for experimental study design (Habib et al. 2014); $n = (Z_\beta + Z\alpha_{/2})^2 \text{ X } 2\dot{P}\ (1 - \dot{P})/E^2$. Where n = sample size per group, Z_β = desired power of the study, typically 0.84 for 80% power, $Z_{\alpha/2}$ = normal deviate for two-tailed alternative hypothesis at a level of significance; for example, 5% level of significance, it is 1.96, $\dot{P}\ (1 - \dot{P})$ is a measure of variability similar to standard deviation, $\dot{P} = P_1 + P_2/2$, P_1 = proportion of the population with the desired condition, P_2 = proportion of the population without the desired condition, $E = P_1 – P_2$, which is the effect size, i.e., the difference in proportion. Therefore, for this study, P_1 was assumed from a previous study (Hegazy, 2017), which was 0.7, and P_2 was 0.3. Assuming the level of significance for this study was set at 5% and the power at 80%, then Z_β was

0.84 and $Z\alpha_{/2}$ was 1.96. Substituting these values into the formula above and assuming an attrition rate of 10% will give a sample size of 28 patients per group and therefore a total sample size of 56 patients.

All the recruited patients were reviewed a day prior to surgery. Preoperative assessment to create rapport, history of previous anaesthesia, URTI, asthma, and developmental milestones was done. A physical examination, including airway assessment, was carried out, and ASA physical classification was done. All investigations were reviewed and fasting guidelines given. As the patients presented to the modular theatre reception, they were randomised as earlier stated. Preanaesthetic anaesthesia machine check was done to ensure that all components of the machine were in good working condition, it was ensured that a multiparameter monitor was available and functional, availability of oxygen supply was ensured, it was ensured that a suction machine was available and functional, uncuffed endotracheal tubes of different sizes below and above the calculated size were made available, laryngoscope handles and blades (straight and curved) that were functional were made available, appropriately sized stylets was made available, availability of tape to secure endotracheal tube was ensured, availability of an AMBU bag, appropriate sizes of facemasks and oropharyngeal airway was also ensured, all required drugs with precalculated doses were drawn into syringes and labelled, and at least two trained assistants were required to be available. All patients came to the theatre with an intravenous cannula mildly sedated from the ward and were accompanied by a nurse.

On arrival in the operating room, the theatre was already warmed, and the overhead radiant warmer was used. Drugs and doses appropriate for the patient's weight were calculated and written; tube size=(age in years)/4+4 was calculated, tube length in cm=(age in years)/2+12 (for an oral endotracheal tube), and standard monitoring, including pulse rate, non-invasive blood pressure NIBP (SBP, DBP) and MAP, pulse oximetry, EtCO2, and electrocardiography, was instituted using the GE DASH 4000 multi-parameter monitor. The BIS monitor (cerebral state monitor model CSM Dan meter) was also connected to the patients in group B to take note of the baseline value of 0.

Premedication was administered to all patients with IV atropine 0.02 mg/kg and IV midazolam 0.20 mg/kg five minutes before pre-oxygenation and induction. The patients were placed on the operating table in the supine position with the head supported with a head ring at the occiput. The primary investigator of this project was the intubating

anaesthetist for all the patients in the study to provide for consistency. Pre-oxygenation using 100% oxygen at 6 L/min. via the Ayres T piece with Jackson Ree's modification or Bain's circuit for the children weighing more than 25 kg was then commenced. Induction of anaesthesia was conducted with sevoflurane at 8%. The vital capacity method was employed with the concentration of sevoflurane increased at the rate of 1.5% per three breaths using a TEC7 vaporiser.

For the BIS monitoring group, the skin of the forehead was cleaned with methylated spirit before the application of the BIS sensor strip in accordance with the manufacturer's instructions. The end point of hypnosis was the attainment of a BIS value of 48. Using a Macintosh laryngoscope blade with the left hand, it was introduced into the right side of the mouth and used to deflect the tongue to the left. The laryngoscope was lifted upwards and forwards with the tip inserted into the vallecula and pressure on the hyoepiglottic ligament to move the epiglottis so as to expose the vocal cords. External laryngeal manipulation was performed to aid visualisation of the larynx in cases where difficulties were experienced. An appropriately sized preformed uncuffed endotracheal tube was inserted through the larynx. Confirmation of correct tube placement was carried out via capnography with an end-tidal CO_2 of 35 mmHg. The number of attempts at successful tracheal intubation and intubating conditions scores were then noted and recorded according to the Helbo-Hansen scoring system.

For the clinically monitored group, the TEC7 vaporiser (which was also used for the BIS group) was used to administer the incremental concentration of 8% sevoflurane in 100% oxygen at 1.5% every three breaths until there was loss of eyelash reflex, and then patients were manually ventilated. Both pupils were checked with a pen torch every 30 seconds until the pupils became central and fixed, and the jaw relaxed. Tracheal intubation was then done as described earlier. Confirmation of correct tube placement was done via capnography with an end-tidal CO_2 of 35 mmHg. The number of attempts at successful tracheal intubation and intubating conditions scores were then noted and recorded according to the Helbo-Hansen scoring system.

Data was collected and temporarily entered and stored in an Excel spreadsheet during the period of data collection. Confidentiality was maintained by storing patient identifiers with alphanumeric codes, and only individuals directly involved with this study had access to collected data. The data was analysed using the Statistical Package for the Social Sciences

(SPSS version 23). The level of significance was set at p=0.05. The student's t-test was utilised for comparison of continuous variables while the Chi-square test was utilised for comparison of categorical variables. Ethical clearance was obtained from the Jos University Teaching Hospital Research Ethics Committee before commencement of this study. Informed consent was also obtained from the parents/guardians of children recruited into the study.

RESULTS

A total of 56 children participated in this study and were randomly allocated to undergo tracheal intubation with depth of anaesthesia monitored either clinically (n=28) or by BIS (n=28). All the 56 patients enrolled in this study were included in the final analysis, having completed the study. The study participants had similar representation of males and females in the study groups (p=0.778). The mean ages were 3.29±1.329 and 3.43±1.425 years for the BIS and clinical groups, respectively (p=0.317). All participants in this study were ASA I (Table 1).

Table 1 Characteristics of Study Participants

Parameters	BIS	Clinical	Statistics	p-value
Sex (number/percent)			X^2	
Male	19	18	0.080	0.778
Female	9	10		
Age (Mean±SD) year			t-test	
	3.29±1.329	3.43±1.425	0.080	0.317
ASA (number/percent)				
I	28(100.0)	28(100.0)	-	-
II	0(0.0)	0(0.0)	-	-

BIS – bispectral index, X^2 – Chi square, ASA American Society of Anaesthesiologists, SD – standard deviation

On looking at the intubating conditions between the study groups using the Helbo-Hansen scale, it was discovered that there were more children with favourable intubating conditions in the BIS group than the clinical group, though the difference was not statistically significant (p=0.098). The BIS group had 18 (64.28%), 10 (35.71%), and 0 (0%) children,

respectively, with Helbo-Hansen scores of 4, 5, and 6, while the clinical group had 12 (42.86%), 14 (50%), and 2 (7.14%) children, respectively, with similar Helbo-Hansen scores (Table 2).

Table 2 Intubating Conditions Using the Helbo-Hansen Scale between Study Groups

Study Groups	Helbo-Hansen Score (number/percent)			X^2	p-value
	4	5	6		
BIS	18 (60.0)	10 (41.6)	0 (0.0)	3.867	0.098
Clinical	12 (40.0)	14 (58.4)	2 (100.0)		
Total	30 (100.0)	24 (100.0)	2 (100.0)		

BIS – bispectral index, X^2 – chi square

All the study participants had successful tracheal intubation at the first attempt (Table 3).

Table 3 Proportion of Patients Whose Tracheal Intubation was Achieved at First Attempt

Study Groups	Proportions (number/percent)	X^2	p-value
BIS	28(100.0)	-	-
Clinical	28(100.0)	-	-

BIS – bispectral index, X^2 – chi square

DISCUSSION

The intubating conditions using the Helbo-Hansen scale is a grading system that assesses conditions for the ease of endotracheal intubation without the use of muscle relaxants. This study found a greater number of children with favourable intubating conditions using the Helbo-Hansen scale in the BIS group compared to the clinical group; however, this was not statistically significant (p=0.098). This finding could probably be due to a deeper plane of anaesthesia, and better suppression of airway reflexes was achieved more in the BIS group compared to the clinical group. Abubakar et al. (2021) reported a high incidence of clinically acceptable intubating conditions in their sevoflurane group (98.2%), which is similar to that found in the clinical group (93%) of the index study. This finding confirms the efficacy of inhalational induction without the use of muscle relaxation in children. Similarly, Rajan et al. (2014) carried out a prospective study to compare intubating conditions in children undergoing cleft surgeries without muscle relaxation following

induction with propofol and sevoflurane. In their study, they found that the overall clinically acceptable intubating condition score was 96.7% in their sevoflurane group, which was comparable to the clinical group in this current study, which had 93.0%. This similarity could probably be due to the similar concentrations of sevoflurane that were used in both studies.

In contrast to the finding in this study, Hajimohamadi et al. (2023) examined the minimum duration of sevoflurane administration that resulted in the most optimal conditions of intubation in 75 children undergoing tonsillectomy under general anaesthesia. The intubation conditions were assessed using Steyn's modification of the Helbo-Hansen scoring system. They had three (3) groups based on fixed induction times of 90 seconds (group 1), 120 seconds (group 2), and 150 seconds (group 3). They found that the overall clinically acceptable intubating condition score (which was a score of ≤5) was 60%, 32%, and 0% for groups 1, 2, and 3, respectively, which was statistically significant, $p<0.001$. This difference could be due to the fact that they used a fixed induction time of 150 seconds before endotracheal intubation in their study as against achieving a target clinical parameter (loss of eyelash reflex) as used in the index study and also the fact that the study population was older (up to 12 years) in their study. Similarly, Karanth et al. (2018), in a prospective randomised controlled study, compared the effectiveness of propofol with sevoflurane induction in achieving clinically acceptable intubating conditions without the use of muscle relaxants in children undergoing cleft surgery. They found a lower incidence of clinically acceptable intubating conditions in their sevoflurane group, which was 87.5% compared to that found in the clinical group in this index study. This lower incidence in clinically acceptable intubating conditions could also be attributed to the fact that older children (up to 10 years) who require longer induction time leading to deeper planes of anaesthesia were used in their study.

In this study, the proportion of patients in whom tracheal intubation was achieved at first attempt in both study groups was similar and comparable. This finding could probably be attributed to good/favourable intubating conditions found in both study groups before tracheal intubation. Also, the tracheal intubation in both study groups was done by the same person (the researcher), who was proficient in laryngoscopy and tracheal intubation. The findings in the clinical group of this index study are similar to that reported by Wappler et al. (2003), who carried out a randomised controlled study in which 60 children received a mixture of sevoflurane 8% in an N2O:O2 ratio of 2:1 at 6 L/min. They found

that all patients had a 100% success rate at the first attempt at intubation in their study groups, which was similar to the findings in this index study. This similarity could be a result of the use of the similar intubating conditions scale (Helbo-Hansen score) and similar concentration of sevoflurane in both studies. Similarly, Abdelhalim et al. (2017) compared the effects of two different doses of propofol preceded by a fixed dose of fentanyl during sevoflurane induction on the quality of tracheal intubation in children. They demonstrated a success rate of 100%, where all the patients were intubated successfully at first attempt. This is consistent with the findings in both the BIS and clinical groups in this current study. This similarity could probably be due to the fact that propofol and fentanyl used in their study suppress airway reflexes and muscle tone, thereby improving intubating conditions in their study.

Contrary to the findings in this index study, Mudakanagoudar and Santhosh (2016) did a prospective, randomised, single-blind study to compare the difference in the proportion of successful intubation (first attempt) for the insertion of LMA and endotracheal intubation, where they found a lower proportion of patients (85%) that had successful tracheal intubation at first attempt. Also, Karanth et al. (2018), in their randomised controlled trial, also found a lower proportion of patients (95%) with successful tracheal intubation at first attempt in their sevoflurane group compared to 100% in the clinical group of this index study. This lower proportion of patients could probably be due to inter-performer expertise/experience of laryngoscopy and endotracheal intubation. The implication is that intubation can be successful with deep anaesthesia and good expertise in laryngoscopy and tracheal intubation, which are essential skills associated with the practice of anaesthesia.

CONCLUSION

In the absence of muscle relaxants during inhalational induction with sevoflurane, the intubating conditions and success rate at the first attempt at intubation when the depth of anaesthesia was monitored using clinical signs compared favourably with when the depth of anaesthesia was monitored using BIS.

Conflict of Interest

Authors declare no conflict of interest.

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