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RESEARCH ARTICLE

TIME TO LOSS OF CONSCIOUSNESS AND TRACHEAL INTUBATION WITHOUT NEUROMUSCULAR BLOCKADE USING SEVOFLURANE: A COMPARATIVE ANALYSIS OF CLINICAL VERSUS BISPECTRAL INDEX MONITORED DEPTH OF ANAESTHESIA

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Abstract

Endotracheal intubation is the gold standard for airway management that establishes a definitive airway. Because of the problems associated with the use of neuromuscular blockade, BIS monitoring serves as a guide for the adequacy of the depth of anaesthesia for non-paralytic endotracheal intubation. The aim of the study was to compare the time to loss of consciousness and tracheal intubation following induction with sevoflurane without neuromuscular blockade in paediatric patients monitored for depth of anaesthesia either by clinical features or BIS. This study was a randomised, single-blind, controlled clinical trial conducted among 56 children aged 2 to 6 years with ASA of I and II scheduled for elective adenotonsillectomy. They were randomly allocated into two groups to either receive BIS monitoring (group B) or clinical monitoring (group C) of the depth of anaesthesia. A study pro forma was used to record patients' time to loss of consciousness and time to tracheal intubation. Data was entered into and analysed by SPSS version 23 with a p-value set at 0.05. The mean time to loss of consciousness from induction to loss of consciousness was 350.04±27.680 seconds in the BIS group and 90.89±19.916 seconds in the clinical group (p=0.012); the mean time to tracheal intubation from laryngoscopy to completion of intubation was 19.29±1.117 seconds and 19.64±1.129 seconds in the BIS and clinical groups, which was not statistically significant with p=0.541.

Introduction:-

The gold standard for securing a child's airway is by a tracheal intubation, and a preformed south-facing tube is preferred to allow for surgical access and "sharing of the airway" (Strauss, 2012; Adekwu et al. 2021). Establishment of a definitive airway or securing the airway using endotracheal intubation provides maximal protection against aspiration of gastric contents or blood (Salman et al. 2018; Holinger et al. 1997). Neuromuscular blocking agents like suxamethonium are often used to facilitate intubation, but the agent is associated with problems like prolonged paralysis, an increase in intraocular pressure, postoperative myalgia, hyperkalaemia, cardiac arrest,

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and even death in young children; its use has been criticised (Salman et al. 2018; Ibarra-Sarlat et al. 2018; Gupta & Mishra, 2012). Intubation of the trachea can be conducted after reaching deep levels of anaesthesia, usually following inhalational induction without the use of either depolarising or non-depolarising neuromuscular blocking agents. This approach is usually adequate to facilitate tracheal intubation but could be difficult without objective means of determining the depth of anaesthesia, like the bispectral index monitoring (Akan & Oztekin, 2012). Tracheal intubation without adequate depth of anaesthesia can lead to difficult laryngoscopy, failed intubation, coughing, limb movements, laryngospasm, bronchospasm, and even airway trauma (Zarogoulidis et al. 2012). This study therefore aims to compare the efficiency of clinical versus BIS-guided tracheal intubation without neuromuscular blockade following inhalational induction in paediatric patients scheduled for adenotonsillectomy at the Jos University Teaching Hospital.

Materials And Methods:-

Study Location –

This study was a facility-based research conducted in the Jos University Teaching Hospital, Jos, Plateau State, North Central Nigeria.

Study Population –

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.

Study Design –

This was a randomised, single-blind, controlled clinical study. The sampling technique employed was purposive sampling.

Randomisation –

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.

Sampling Size Estimation –

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.

Ethical Considerations –

Ethical clearance was obtained from the Jos University Teaching Hospital Research Ethics Committee before the commencement of this study. Informed consent was also obtained from the parents/guardians of children recruited into the study.

Study Procedure –

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, were 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 vapouriser.

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 attainment of BIS value of 48. A standard stopwatch was used to calculate the time to reach this target BIS value, which was considered as time to loss of consciousness (timing was started from the point when sevoflurane was introduced to the patients to the time when a BIS value of 48 was reached). 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. After confirmation of correct tube placement (which was carried out via capnography with an end-tidal CO_2 of 35 mmHg), the time to tracheal intubation was defined as time taken from commencement of laryngoscopy (i.e., introduction of the blade tip through the lips) to confirmation of correct tube placement (as indicated by capnographic waveform). This was noted using a standard stopwatch and recorded.

For the clinically monitored group, the TEC7 vapouriser (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. The time taken for this to occur (which was from the time sevoflurane was introduced to the patient to the point when the pupils were pinpoint and centrally located) was noted and considered the time to loss of consciousness. Tracheal intubation was then done as described earlier. After confirmation of correct tube placement (which was done via capnography with an end-tidal CO_2 of 35 mmHg), the time to tracheal intubation, as defined by time taken from commencement of laryngoscopy to correct tube placement was noted using a standard stopwatch and recorded.

Data Analysis –

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.

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.

Characteristics of Study Participants –

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), indicating that both study groups had similar ages of participants and therefore no significant statistical difference between them. All participants in this study were ASA I (Table 1).

Time to Loss of Consciousness –

The mean time to loss of consciousness between the study groups was 350.04±27.680 and 90.89±19.916 sec, respectively, for the BIS and clinical groups, showing a significant statistical difference (p = 0.012) (Table 2).

Time To Tracheal Intubation –

There was no significant statistical difference in the mean time to tracheal intubation between the study groups (p = 0.541). The mean time to tracheal intubation was 19.29±1.117 seconds and 19.64±1.129 seconds, respectively, for the BIS and clinical groups (Table 3).

Discussion:-

The time to loss of consciousness is indicative of the time required to attain a targeted anaesthetic level/hypnosis. This study found a longer mean time to loss of consciousness in the BIS group compared to the clinical group, which was statistically significant. This finding could be attributed to the researchers targeted BIS value required to attain an anaesthetic level of hypnosis safe for airway manipulation. This took a longer time compared to the clinical group, which used loss of eyelash reflex, centralised pupil, and jaw relaxation as a measure of the targeted level of hypnosis for safe airway manipulation. Lejus et al. (2006) found that the time to loss of consciousness in their clinical group was also shorter compared to the BIS group, which was similar to the finding of this study. Similarly, Devi et al. (2017)reported similar findings in terms of time to loss of consciousness in their sevoflurane group to the clinical group in this current study. This time, to loss of consciousness of Devi and co-workers is also similar to the finding of Rastogi et al. (2013), who conducted a randomised controlled study to compare the time taken to loss of consciousness following induction with sevoflurane and halothane plus nitrous oxide/oxygen mixture in paediatric patients. These studies are similar to this current study in terms of time to loss of consciousness; however, they had a shorter time in their sevoflurane group, which could probably be due to the second gas effect of nitrous oxide used in addition to sevoflurane in their study which made induction faster. The finding of Wang et al. (2011) was also similar to the findings in the clinical group of this current study in terms of time to loss of consciousness. They assessed the efficacy and safety of high concentrations of sevoflurane for induction without muscle relaxants in infants undergoing cardiac surgery. Similarly, the finding in the sevoflurane group of Kaur et al. (2015) was also similar to the clinical group in this study in terms of time taken to loss of consciousness. They compared the time taken to loss of consciousness between inhalational induction with halothane and sevoflurane in children undergoing adenotonsillectomy. It was found that the time taken to loss of consciousness in their sevoflurane group was 114.40±28.811 seconds which was statistically significant. Conversely, Politis et al. (2002), in their study, determined the time to loss of consciousness in 153 children aged 12 months to 96 months using 8% sevoflurane in N_2O: O_2 ratio of 50:50 with no muscle relaxant using a clinical end point. They obtained a mean time to loss of consciousness in their two groups which was 137.0 seconds and 187.0 seconds, respectively, which was statistically significant (p = 0.006). This extended time in their study could be as a result of the older study population used in their study (up to 8 years) that require a longer time to induction compared to 2-6 years in this study (Lerman et al. 1994). Abubakar et al. (2021) did a randomised double-blind study to compare the ease and safety of the use of sevoflurane and halothane for tracheal intubation in 110 children. They found the mean time to loss of consciousness to be 250.18±54.73 seconds in their sevoflurane group, which was higher than that found in the clinical group (90.89±19.916 sec) of this current study.

The time taken to tracheal intubation is the time taken from commencement of laryngoscopy (i.e., introduction of the blade tip through the lips) to confirmation of correct tube placement (as indicated by capnographic waveform). It was found that both study groups had comparatively similar time to tracheal intubation (p = 0.541). This finding

could probably be due to the fact that similar intubating conditions were met in both study groups, which eased the tracheal intubation. Also, the tracheal intubation in both study groups was performed by the same person who is proficient in laryngoscopy and tracheal intubation. This could have also accounted for the findings. The ease of tracheal intubation is dependent on a lot of factors, which include the expertise and experience of the anaesthetist, skilled and dedicated assistants, positioning of the patients, use of external laryngeal manipulation, and the depth of anaesthesia (Law et al. 2013). It was necessary that the laryngoscopist performed a quick, successful tracheal intubation within a short time to avoid prolonging the apneic period which could lead to desaturation.The duration and degree of hypoxia during tracheal intubation is one of the causes of morbidity and mortality in anaesthesia especially in paediatrics (Lejus et al. 2006). Karanth et al. (2018) found that the time taken to endotracheal intubation without muscle relaxation was 15.25±5.00 seconds in their sevoflurane group compared to 19.64±1.129 seconds in this study which was similar. Koshy and Ramesh (2016), carried out a comparative study to evaluate endotracheal intubation without muscle relaxants in 80 children undergoing cleft surgeries using sevoflurane and propofol. They found that the time taken to tracheal intubation in their sevoflurane group was 15.25±5.047 seconds compared to 19.64±1.129 seconds in this study which is similar to that found in the clinical group of this current study. These similarities might be due to the fact that the same laryngoscopist performed the tracheal intubation in all the patients in their study and also in this study. Salawu et al. (2017) had a result that contrasted the finding in the clinical group in this study. They discovered that the time taken from laryngoscopy to completion of tracheal intubation was 28.09±9.48 seconds in their sevoflurane group which is longer than that in this study. Similarly, Khurshid et al. (2020) conducted a study to compare two different doses of propofol after sevoflurane induction for intubation in paediatric patients without the use of neuromuscular blocking agents. It was found that the time taken from laryngoscopy to completion of tracheal intubation was between 9 to 12 seconds in all patients which was shorter than that obtained in this current study. This difference could be as a result of inter-performer difference as who performed the laryngoscopy in their study was not stated.

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

Table 2:- Time to Loss of Consciousness between Study Groups.

Study Groups	BIS	Clinical	t-test	p-value
Time to LOC (Mean±SD) Sec	350.04±27.680	90.89±17.916	6.707	0.012

BIS – bispectral index, LOC – loss of consciousness, SD – standard deviation

Table 3:- Time to Tracheal Intubation between Study Groups.

Study Groups	BIS	Clinical	t-test	p-value
Time to TI (Mean±SD) Sec	19.29±1.117	19.64±1.129	0.379	0.541

BIS – bispectral index, TI – tracheal intubation, SD – standard deviation.

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