

The effectivity of earplug utilization to reduce emergence delirium incidence in pediatric patients undergoing inhalational general anesthesia



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ABSTRACT

Background: Emergence delirium (ED) also known as emergence agitation, is a postoperative condition characterized by aberrant cognitive and psychomotor behaviors such as agitation, irritable, uncompromising, uncooperative, inconsolably crying following general anesthesia. A high noise level in the operating room can be reduced with an earplug application. This study aimed to see the effectiveness of earplug utilization in reducing the incidence of emergence delirium without extending the time of extubation compared to control patients.

Methods: This is a double-blind, randomized clinical trial towards 1-5 years old patients underwent inhalational general anesthesia in Dr. Cipto Mangunkusumo hospital in 2018. They were assigned

to either the Earplug (E) group with an application of an earplug at the end of the surgery or Control (C) group, without the use of an earplug. The incidence of ED was measured using the Pediatric Anesthesia Emergence Delirium (PAED) scale. Data were analyzed using multivariate logistic regression and analysis of covariance tests.

Results: Incidence of ED in earplug group was 16.7% while in control group was 32.1% (OR = 0.402, CI95%=0.152-1.062, p=0.066). The mean time-to-extubation in E vs. C groups were 5.76±3.23 vs. 6.54±3.67 minutes, respectively.

Conclusion: The application of an earplug at the end of anesthesia was not statistically effective to reduce the incidence of ED in 1-5 years old patients underwent inhalational general anesthesia.

Keywords: delirium, pediatric, emergence, auditory stimulus, ear plug, inhalation

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INTRODUCTION

Emergence delirium (ED) or emergence agitation (EA) is still an issue in pediatric patients who are recovering from anesthesia with the incidence rate of 10-80%. The incidence of ED is said to be higher in the pediatric patient than adult (12-13% vs. 5.3%, respectively). In our hospital, the incidence of ED in pediatric patients who underwent general anesthesia was 39.7%, with the highest incidence occurring in 2-5 years old age group.^{1,2} The utilization of short-acting volatile agents such as sevoflurane and desflurane have markedly increased the incidence.¹⁻⁴

Emergence agitation put the patients at considerable risk of injury. During this period, there is an increased risk of physical harms to the patients, like dislodged intravenous lines and drains, unmannerly extubation, and other injuries. These complications can prolong the length of admission in hospitals. The anxiety not only raises uncomfortable condition to the patient but also decreased satisfaction of surgeons and parents.¹⁻⁶

In reducing the incidence, it is recommended to identify children with the risk of ED and take a precautionary measurement such as reduced pre-surgery anxiety, reduced post-operative pain,

and a comfortable environment after the anesthesia.^{7,8} When a child recovers from anesthesia in such an uncomfortable manner due to noise disturbance, there will be an external stimulus which causes excitation and induces unconsolable action in children.⁶

The incidence of an unintended case due to noise can be prevented by stopping the sound source and preventing sound stimulus to enter the ear. The noise level in the modern operating theater can reach around 40-140 dB. This number has exceeded the recommended noise limit. The use of an ear covering device such as an earplug can reduce the noise level to 15-30 dB.⁹⁻¹¹ This study aimed to see the effectiveness of earplug utilization in reducing the incidence of ED without extending the time of extubation.

PATIENTS AND METHODS

This research is a randomized, double-blind clinical trial. It was conducted from September to December 2018 at Dr. Cipto Mangunkusumo Hospital in Jakarta, Indonesia. This study protocol was approved by the institutional review board. All parents or the legal guardians provided written consent to be included in this study.

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The subjects inclusion criteria included pediatric patients of 1-5 years old undergoing elective surgery under general anesthesia using sevoflurane with the physical status of 1 to 3 as per American Society of Anesthesiologist (ASA) category. Exclusion criteria included ophthalmology and otorhinolaryngology surgery, post-operative care requirements of Paediatric Intensive Care Unit

(PICU), psychological or neurological disorder, growth problem, hearing problem or patients using a hearing-aid device, patients needing sedative medication upon emergence, history or familial history of malignant hyperthermia, and patients with a difficult airway.

The total subjects for this study were 107 subjects, which were collected by consecutive random sampling. Subjects were divided into two groups: the E group (earplug group) consisted of subjects who were applied earplugs at the end of the surgery, and the C group (control group) consisted of subjects without earplugs application. All other treatments were similar between the two groups. Subjects underwent surgery with inhalational general anesthesia using sevoflurane, and at the end of the surgery, the subjects in the E group were applied earplugs in both ears, while the subjects in group C were not. Surgery and anesthesia duration were recorded. All subjects underwent awake extubation. Earplugs were removed before subjects were transferred to the post-anesthesia care unit (PACU). Extubation time was recorded. ED scoring was conducted after the subjects arrived at PACU, and again on 15 minutes and 30 minutes after, by using the Pediatric Anesthesia Emergence Delirium (PAED) scale. The PAED scoring was conducted by a research team who didn't know the subject allocation to either group. ED was defined as a score of ≥ 10 on the PAED scale. Patients with PAED scale of ≥ 16 will be treated accordingly as per our institution's protocol.

Data were analyzed by using Statistical Package for the Social Sciences (SPSS) 20 for Windows. The chi-square test was used to analyze the ED proportion between the two groups. The analysis was then followed by multivariate logistic regression test to show the relationship between each variable to the incidence of ED. We used the Mann-Whitney test to compare extubation time between the two groups and ANCOVA analysis to know the effect of anesthesia duration to the extubation time of both groups. A p-value of < 0.05 was considered significant.

RESULTS

There were 54 subjects in the E group and 53 subjects in the C group. The different number of subjects happened due to during the course of the study, one subject of the C group met the drop-out criteria due to intraoperative emergency and the need for unintended care in PICU. **Table 1** showed some characteristics of the study subjects. **Table 2** shows the incidence of ED on the E group and C group were 9 (16.7%) vs. 17 (32.1%), respectively. Although these findings indicate a decline

Table 1 Patients' characteristics

Characteristics	Earplug (n = 54)	Control (n = 53)
Age (years), median (min-max)	3 (1-5)	3 (1-5)
Gender		
Male, n(%)	36 (66.7)	34 (64.1)
Female, n(%)	18 (33.3)	19 (35.9)
Body height (cm), mean \pm SD	96.5 \pm 1.3	93.1 \pm 1.5
Weight (kg), median (min-max)	13 (8.4-32)	12 (5.1-33)
Physical status		
ASA 1, n(%)	8 (14.8)	5 (9.4)
ASA 2, n(%)	38 (70.8)	33 (62.3)
ASA 3, n(%)	8 (14.8)	15 (28.3)
Types of surgery		
Pediatric surgery, n(%)	22 (40.7)	10 (18.9)
Urology, n(%)	17 (31.5)	18 (34)
Orthopedy, n(%)	6 (11.1)	4 (7.5)
Plastic surgery, n(%)	7 (14)	7 (13.2)
Dental surgery, n(%)	2 (3.7)	3 (5.6)
Catheterization, n(%)	-	9 (17)
Others, n(%)	-	2 (3.8)
Anesthesia		
Combined with regional, n(%)	30 (55.5)	14 (26.4)
Without regional, n(%)	24 (44.5)	39 (73.6)
PAB score		
Happy, n(%)	34 (63)	38 (71.7)
Sad, n(%)	18 (33)	15 (28.3)
Angry, n(%)	2 (4)	0 (0)
Degree of postoperative pain		
Mild, n(%)	10 (18.5)	22 (41.5)
Moderate, n(%)	44 (81.5)	31 (28.3)
Duration of surgery (minutes), median (min-max)	105 (5-540)	90 (15-270)
Duration of anesthesia (minutes), median (min-max)	150 (10-636)	120 (25-410)
Extubation time (minutes), median (min-max)	5.12 (2-18.4)	5.46 (1-18.5)
Degree of noise in operating room (dB), mean \pm SD	70.7 \pm 4	69.2 \pm 3.5

ASA: American Society of Anesthesiology; PAB: Pediatric Anesthesia Behavior score; SD: standard deviation

Table 2 Incidence of emergence delirium in both groups

	Emergence delirium		p value ^a (unadjusted)	OR (unadjusted)	p value (adjusted)	OR (adjusted)
	Yes	No				
E group	9 (16.7)	45 (83.3)	0.067	0.424	0.066	0.422
C group	17 (32.1)	36 (67.9)				

^aChi-square test; OR: Odds ratio

Table 3 The difference in extubation time between the two groups

		Extubation time (minutes), mean±SD	Mean difference (95% CI)	p value ^a
Unadjusted	Earplug	5.76±3.23	0.823 (0.530-2.180)	0.482
	Control	6.54±3.67		
Adjusted	Earplug	5.74±0.48	0.825(0.530-2.180)	0.230
	Control	6.57±0.48		

^aANCOVA test; CI: confidence interval

of 15.4% of ED incidence, the statistical analysis proved that the difference was not significant ($p > 0.05$).

Due to heterogenous data of the anesthesia duration between the two groups, statistical analysis was performed by the analysis of covariance (ANCOVA). From ANCOVA test (displayed in Table 3), the mean extubation time in E group was 5.74±0.48 minutes compared to 6.57±0.48 minutes in the C group, with a mean difference of 0.825. We can see again that statistically, there was no significant difference between extubation time and anesthesia duration in both groups ($p > 0.05$).

DISCUSSION

ED occurred in 24.3% of the subjects of the entire cohort. This number decreases by 15.4% compared to ED incidence in previous studies. Singh *et al.*¹ stated that ED incidence varies significantly between 10-80% and influenced by study settings, anesthesia techniques, the definition of ED, and methods of assessment between studies. The type of surgery is one factor that distinguishes this study from previous studies.

Decreasing auditory stimulus at the end of anesthesia by quiet time is recommended to reduce the incidence of ED since auditory organs are the first special sense to recover after anesthesia. As in the case of middle latency evoked response, response to an auditory stimulus may illustrate the response toward noise in the brainstem, auditory cortex, and accessory cortical area. Auditory stimulus due to noise within the operating room may activate acoustic thalamus area which synapses with the lateral nucleus of the amygdala (LNA). LNA synapse may stimulate the activation of NMDA caused by

inhibition function and conduction regulation by calcium-activated K⁺-channels (BKCa).

An auditory stimulus may increase amygdala activity. Amygdala will send a signal transmission to the hypothalamus via terminal stria without any inhibition from medial prefrontal cortex (mPFC) and hippocampus. Hypothalamus will relay this impulse to dorsal periaqueductal gray matter (dPAG), which increases motor activity by stimulating neurons in the brainstem and spinal cord. This will manifest as uncontrolled motoric activity and rowdiness.

Another study reported that the degree of noise in operating room peaked during emergence compared to induction and maintenance.¹² These noises may be caused by (1) irrelevant staff-related communication; (2) sudden loud sound exceeding 70 dB; (3) falling surgery instruments; (4) loud alarm monitor which frequently goes off; and (5) frequent music playback during emergence phase compared to during recovery phase. Moreover, the noise level in the operating room during emergence reaches 58.3 dB, while other literature stated 62-64 dB.¹³ In this study, the degree of noise in Dr. Cipto Mangunkusumo hospital reaches 70.7 dB on earplug group, while earplug usage can only reduce the degree of noise by 15-30 dB.

The correlation between extubation time in both groups and the duration of anesthesia are found to be not significant. Wei *et al.*¹³ stated that anesthesia time is considerable toward extubation time. Up until now, there is no study examining the duration of surgery and minimal anesthesia time that can cause a difference in conscious recovery time. However, failure of conscious recovery after 30-60 postoperative minutes is associated with increased morbidity and is called delayed emergence.¹⁴

CONCLUSION

The use of earplug to reduce auditory stimulus was not statistically significant in reducing the incidence of ED. There was no significant difference in extubation time between patients in the earplugs group and control. In the near future, similar studies may be conducted by choosing a homogenous type of surgery and assessing physiological condition with available parameters. Moreover, the combination of earplug and earmuff may be used to reduce more considerable noise.

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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