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Original Article

Postoperative agitation in preschool children following emergence from sevoflurane or halothane anesthesia: A randomized study on the forestalling effect of midazolam premedication versus parental presence at induction of anesthesia

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ABSTRACT

Objective: The effect of midazolam premedication on forestalling postoperative agitation in children is not yet concluded. The purpose of this study was to compare the effects of midazolam premedication and parental presence during anesthetic induction on the incidence of postoperative agitation in pediatric patients.

Methods: One hundred sixty-seven children between 2 years and 7 years of age, undergoing anesthesia for outpatient surgery, were enrolled and randomly divided into four groups: sevoflurane anesthesia with parental presence without premedication, sevoflurane anesthesia with oral midazolam premedication, halothane anesthesia with parental presence without premeditation, and halothane anesthesia with oral midazolam premedication. The children randomized to the premedication groups took oral midazolam 0.5 mg/kg 20–30 minutes before anesthetic induction. For patients in the groups without premedication, one of the parents was present throughout the induction of anesthesia. One recovery room nurse blinded to the group assignment observed the patients and recorded the agitation scores all through their stay in the postanesthesia care unit.

Results: Postoperative agitation was significantly less in patients who received halothane anesthesia with oral midazolam premedication ($p < 0.002$).

Conclusion: Based on our data, the presence of a parent at induction of sevoflurance anesthesia was as effective as midazolam premedication in decreasing the incidence of postoperative agitation. Midazolam premedication, however, decreased postoperative agitation when halothane was used as the anesthetic agent.

1. Introduction

Sevoflurane is often used for anesthetic induction in pediatric patients because it is faster in the induction of anesthesia[1,2] and causes less cardiovascular depression[2,3] and fewer dysrhythmias[4] than halothane. Emergence agitation, the excited and disoriented behavior on awakening from general anesthesia, is a common problem in preschool children with a reported incidence of up to 80%.[2,3] This unwanted reaction not only makes communication with the child impossible but also places the child at risk for injury or subjects the child to avoidable treatment such as reinstallment of the loss of venous access.

Many factors may contribute to the occurrence of emergence agitation in children. Some investigators have found that emergence agitation is more likely to occur in preschool (age, 3–6 years) children compared with school-aged (age, 6–10 years) children.[2,5] Up to now, the exact etiology of emergence agitation remains unknown nor is there a clear strategy for its prevention.[6] Moreover, there are conflicting data on the effect of midazolam premedication on postoperative agitation. Some studies suggest that it could offer beneficial effect on decreasing the incidence of postoperative agitation,[3,7] whereas others reported other way around that it would not or could even increase the incidence of adverse behavior, which would linger 1 week or more after surgery.[8–10] Parental presence combined with midazolam premedication, on the other hand, was reported recently to be beneficial on emergence behavior of children undergoing general anesthesia.[11]

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Therefore, the purpose of this study was to compare the effects of midazolam premedication and parental presence on the incidence of postoperative agitation after emergence from general anesthesia in the postanesthetic care unit with sevoflurane or halothane as the anesthetic. The incidence of postoperative agitation requiring the intervention of the recovery room personnel during the first hour after awakening would also be used for comparison.

2. Materials and methods

After approval by our institutional review board and obtaining parental written informed consent, 167 ASA Physical Status I or II children between 2 years and 7 years of age, undergoing general anesthesia for short (less than 0.5 hour) outpatient surgeries were enrolled for study. Eligibility criteria included elective subumbilical surgery, compatible with peripheral nerve block. Exclusion criteria included history of chronic illness or developmental delay, mental retardation, attention deficit/hyperactivity disorder, psychiatric illness, or paradoxical excitation with sedatives.

Patients were assigned by a computer-generated randomization program to one of the four anesthetic groups:

1. Sevoflurane anesthesia with parental presence without premedication (S);
2. Sevoflurane anesthesia with oral midazolam premedication (SM);
3. Halothane anesthesia with parental presence without premedication (H);
4. Halothane anesthesia with oral midazolam premedication (HM).

Children randomized to the premedication groups took oral midazolam 0.5 mg/kg mixed with 10 mL of 10% dextrose, 20–30 minutes before anesthetic induction. For patients in the other two groups, one of the parents was present and collaborated with the anesthetic team to console the child during induction of anesthesia with facemask and left the theater when the child had closed the eyes.

Anesthesia was induced with sevoflurane (or halothane) and 60% nitrous oxide in oxygen at a flow rate of 10 L/min. After anesthetic induction, an intravenous cannula was placed. Sevoflurane was started at 1% and gradually increased up to 70% at intervals of every three breaths. Halothane was started at 0.5% and increased to 4% with increments of 0.5% after every three breaths. Thereafter, patients received 2-mg/kg rectal diclofenac sodium and an appropriate peripheral field block by the surgeon with 0.25% bupivacaine depending on the surgical procedure. A standard level of general anesthesia was provided to maintain the patients' heart rate and blood pressure within 80% of basal values.

Heart rate; noninvasive blood pressure; oxygen saturation (Cardiocap; Datex, Helsinki, Finland); and inspired and expired concentrations of the anesthetic agents (Vamus; Drager, Lubeck, Germany) were monitored continuously throughout the procedure. No opioid analgesics were administered during the operation. The pediatric circle system (system F) was used to convey the volatile anesthetic at a flow rate of 10 L/min in all cases. Spontaneous or assisted ventilation by means of facemask was maintained throughout the operation. At the end of skin suture, FiO_2 was increased to 100%, and the anesthetic agent was discontinued. The total anesthetic duration was considered as the time from the start of induction (start of inhalational anesthetic) to the time of termination of administration of inhalational agents. For the purpose of assessing recovery, the time at which the inhalational anesthetics were turned off was considered as Time 0. While still asleep, the children were transferred to the recovery unit. The designated time points for recording were as follows: at the start of the anesthetic induction, at the discontinuation of inhalational agents, at first opening of eyes (asking the children every 30 seconds), when the Steward score[12] of 6 was reached, and at departure from the recovery unit.

The emergence agitation scale was measured every 5 minutes after admission to the recovery room (1 = awake and calm, cooperative; 2 = crying, requires consoling; 3 = irritable/restless, screaming, inconsolable; 4 = combative, disoriented, thrashing). An agitation score of 3 or 4 was classified was being agitated.[2] Pulse rate and oxygen saturation were recorded until the child was fully alert. Rescue medication for agitation was intravenous fentanyl 1 μg/kg if the agitation score was 3 or 4.

2.1. Statistical analysis

Assuming an incidence of postoperative agitation of 0.5, a two-sided Type I error of 0.05, a power of 0.85, and an effect size of 0.6, at least 41 patients in each group were required to find a significant difference in the incidence of postoperative agitation. The Chi-square test and two-way analysis of variance were used to test for demographic differences among groups. The one-way analysis of variance and Tukey *post hoc* test were used for comparison of agitation incidence between the four groups. The Student *t* test was used to perform a subgroup analysis comparing the time data between sevoflurane and halothane groups. Continuous data (age, anesthesia time, surgery time, and awakening time) are presented as mean and standard deviation. Proportions (sex, postoperative agitation) are presented as frequency. A p value <0.05 was considered statistically significant. All statistical comparisons were accomplished with SPSS software version 11.5 (SPSS Inc., Chicago, IL, USA).

3. Results

A total of 167 children were included in the present study, of whom 44 belonged to the group S. Forty, 41, and 42 children belonged to the groups SM, H, and HM, respectively. The four groups were comparable with respect to age, gender distribution, weight, duration of anesthesia, and surgery (Table 1). One patient each from the H and SM groups was excluded from the study because of ventricular arrhythmia and regurgitation of gastric content, respectively.

Table 2 lists the average anesthetic and recovery times with standard deviation by groups. Differences in the rates of emergence from anesthesia and the rate at which a Steward score of 6 is reached between the four groups were recorded ($p < 0.0001$). To examine the effects of premedication and anesthetics on emergence and recovery times, a two-subgroup analysis was performed for sevoflurance and halothane. Time to eye opening and time to a Steward score of 6 were not significantly different between

Table 1
Demographic data and duration of surgery.

	Groups				
	S ($n=44$)	SM ($n=40$)	H ($n=41$)	HM ($n=42$)	p
Age (y)	3.3 ± 1.3	3.4 ± 1.3	3.4 ± 1.2	3.5 ± 1.3	0.9
Gender (male/female)	39/7	37/5	40/4	38/7	
Weight (kg)	13.9 ± 3.1	13.7 ± 2.9	14.4 ± 2.9	14.4 ± 2.8	0.6
Duration of surgery (min)	14.7 ± 9.5	16.3 ± 10.2	14.5 ± 8.3	16.5 ± 10.3	0.6

Values are mean ± standard deviation or number.
H = halothane with parental presence without premedication; HM = halothane with midazolam premedication; S = sevoflurane with parental presence without premedication; SM = sevoflurane with midazolam premedication.