ORIGINAL ARTICLE

The effect of ketamine versus fentanyl on the incidence of emergence agitation after sevoflurane anesthesia in pediatric patients undergoing tonsillectomy with or without adenoidectomy

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ABSTRACT

Background: Emergence agitation (EA) has been documented as a common side-effect of sevoflurane anesthesia. This prospective, randomized, double-blind, placebo-controlled study was designed to compare the effects of ketamine versus fentanyl, administered 10 min before the end of surgery on the development of EA. **Methods:** A total of 120 children aged 3-7 years of American Society of Anesthesiologists I-II physical status were randomly assigned to one of three equal groups receiving either ketamine 0.5 mg/kg (Group K), fentanyl 1 μg/kg (Group F) or saline (Group C) at 10 min before the end of surgery. Post-operative EA was assessed with Aono''s four point scale. Recovery times, the post-operative pain and adverse reactions were assessed. **Results:** There was no significant difference between the three groups regarding recovery and discharge times from post-anesthesia care unit. The incidence of EA was significantly low in Group K and Group F (15% and 17.5%, respectively) compared to the control group (42.5%), with no significant difference between Group K and Group F. There were no significant differences in Children's Hospital of Eastern Ontario Pain Scale between the three groups. The incidence of nausea or vomiting was significantly more in Group F compared to that in other two groups. However, no complications such as somnolence, oxygen desaturation or respiratory depression occurred during the study period and there were no episodes of hallucinations or bad dreams in the ketamine group. **Conclusion:** The intravenous administration of either ketamine 0.5 mg/kg or fentanyl 1 μg/kg before the end of surgery in sevoflurane-anesthetized children undergoing tonsillectomy with or without adenoidectomy reduces the incidence of post-operative agitation without delaying emergence.

Key words: *Agitation, fentanyl, ketamine, pediatric, sevoflurane emergence*

INTRODUCTION

Sevoflurane is a popular inhalational anesthetic used frequently to induce and maintain anesthesia in children due to its greater hemodynamic stability, less irritation of the airway and low blood gas solubility coefficient, which causes rapid emergence and recovery from general anesthesia.[1] However, sevoflurane anesthesia is frequently associated with emergence agitation (EA) in children with incidence ranging up to 80%.[2-4]

EA is a complex phenomenon and a variety of explanations have been proposed for its etiology. These include multiple surgical and patient related factors as well as anesthesia related factors such as rapid emergence due to the low blood solubility of sevoflurane.[1,2,5] Despite it is usually self-limited; EA is still a considerable side-effect because of the risks of falling, self-injury to the child or to the surgical site, the stress caused to both caregivers and families, moreover, increase the need for continuous monitoring of patients by recovery room staffs and physical restraint of patient.[5]

Several medications have been investigated in an attempt to reduce the occurrence and severity of EA, with variable outcomes. A recent meta-analysis demonstrated

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that propofol, fentanyl, a2-adrenergic receptor agonist and ketamine have a valuable effect in decreasing incidence of this EA.[6] Ketamine, a non-competitive N-methyl-D-aspartate receptor antagonist is an effective drug for sedation, analgesia and amnesia and the effect of ketamine on decreasing the incidence of EA was confirmed by many studies.[7-11]

Fentanyl is a potent opioid receptor agonist; routinely used in the perioperative period can decrease EA following sevoflurane anesthesia by its high efficacy on perioperative analgesia as well as its sedative effect.[12-15] The aim of this study was designed to compare the effects of ketamine 0.5 mg/kg versus fentanyl 1 μg/kg, administered 10 min before the end of surgery on the development of EA, recovery profile and incidence of side-effects in children following sevoflurane anesthesia for tonsillectomy with or without adenoidectomy.

METHODS

After obtaining the approval of the institutional review board and informed written consent from the parents, 120 children, aged between 3 and 7 years, with American Society of Anesthesiologists physical status I-II, who scheduled to undergo elective tonsillectomy with or without adenoidectomy under general anesthesia with the expected duration of 30-60 min were enrolled in this prospective, randomized, double-blinded, placebo-controlled study.

Children with a history of sleep apnea, cognitive or developmental disorders or those using sedative medication, children who were agitated or combative during the induction of anesthesia and any neurological condition that may limit a patient's ability to communicate with or understand nursing personnel were excluded. All patients fasted 6 h for solid food, but clear fluids were given for up to 4 h pre-operatively. All patients were pre-medicated with 0.3 mg/kg oral midazolam (maximum dose of 12 mg) 30 min before induction. Children who refused to take oral premedication were excluded. One parent was allowed to accompany the child into the pre-operative holding area, no intravenous (IV) cannula was established and children were allowed to watch cartoon movies during waiting in the holding area in order to provide a stress-less and quiet environment.

Upon arrival at the operating room, patients were monitored by non-invasive the blood pressure, temperature, electrocardiogram capnography and pulse oximetry. Anesthesia was induced with sevoflurane in 100% oxygen (6 L/min) through a facemask, with a gradual increase of sevoflurane concentration with every single breath to a maximum of 8 vol %. After anesthesia induction, an IV-cannula was established, fentanyl (2 μg/kg IV). Rocuronium 0.6 mg/kg was administered IV to facilitate tracheal intubation. Paracetamol 15 mg/kg (Perfalgan® 100 ml vial UPSA France) and Dexamethasone 0.3 mg/kg were administered IV to each child immediately after the induction of anesthesia. Anesthesia was maintained with O_2 1.5 L/min, nitrous oxide 1.5 L/min and sevoflurane at 2-3 vol %. The anesthetic gas concentrations were adjusted to maintain adequate anesthesia and stable hemodynamics. Lung ventilation was controlled to maintain the end tidal carbon dioxide tension between 30 and 35 mmHg. During surgery, the surgeon infiltrated the operative site by 1% lidocaine with epinephrine (1:100,000) for bleeding and pain control.

The allocated children were randomly assigned through computer-generated random numbers to one of the three groups: Group K (administered with 0.5 mg/kg of ketamine 10 min before the end of surgery, *n*=40). Group F (administered with 1 μg/kg of fentanyl 10 min before the end of surgery, *n*=40). Group C (administered with a saline solution 10 min before the end of surgery, *n*=40). All syringes with study drugs or placebo were prepared and diluted with saline to the total volume 10 ml by the same investigator who was not participated in any other part of the study.

Ten minutes before the end of surgery, the study drugs were injected IV by the physician not participating in the anesthesia according to the allocated group, so the attending anesthesiologist and the investigator who collected the data remained blinded to the study drug.

At the end of surgery, once hemostasis was achieved, the inhalational anesthetics were discontinued, patient was placed in the lateral decubitus position and manual ventilation was then performed with 100% oxygen at 6 L/min. Pyridostigmine 0.2 mg/kg and glycopyrrolate 0.008 mg/kg were administered to antagonize neuromuscular blockade. The tracheal tube was removed after the return of sufficient spontaneous breathing, gag reflex, facial grimaces and purposeful motor movements.

The time to extubation, defined as time from the end of surgery to tracheal extubation and emergence time, defined as the time of first response to command or eye opening on command after extubation were recorded. The time between the insertion and removal of the mouth gag was recorded as the duration of surgery, whereas, the time from the attachment of the basic monitors until the extubation time was recorded as the duration of anesthesia.

Upon admission to the post-anesthesia care unit (PACU), all patients were observed continuously for at least 30 min by observers blinded to study groups. The primary endpoint of the study was the incidence of post-operative EA, which was assessed every 5 min during the first 30 min using Aono"s four point scale as follows: (1) Asleep; (2) Awake but calm; (3) Agitated but consolable; and (4) Severely agitated and difficult to console[2] and the highest-recorded value was recorded during the PACU stay. For purposes of analysis, grades 1 and 2 in the scale of behavior were considered no agitation and grades 3 and 4 were considered the presence of agitation.

None of the parents were allowed to be present during emergence and recovery. The Children's Hospital of Eastern Ontario Pain Scale (CHEOPS) based on crying, facial expression, verbal statements, position of torso, touching of the wound and movement of legs was used for post-operative pain assessment[16] and it was measured at 5, 10, 20 and 30 min post-operatively.

Fentanyl 0.5 μg/kg was administered IV to treat pain whenever the CHEOPS was greater than 6 or to treat EA (score 3 or 4) lasting more than 3 min. When EA continued for more than 1 min after drug administration or if additional pain control was required, 0.25 μg/kg of fentanyl was administered as necessary with at least a 10 min time interval between each dose for maximum dose to 1 μg/kg and the administration was discontinued as soon as the symptoms were disappeared. During that time, children were observed for any signs of respiratory depression.

Discharge criteria included being fully awake, stable vital signs for 30 min, no bleeding, no pain, no nausea or vomiting and able to ambulate according to age and children were considered ready for discharge from the PACU when the modified Aldrete post-anesthesia score was ≥9.[17] Patients who fulfill the discharge criteria were transferred to the ward and PACU stay time was recorded. Incidence of adverse events such as vomiting, oxygen desaturation, somnolence and hallucination after tracheal extubation and in the PACU were also recorded. Ondansetron 0.15 mg/kg was provided for an antiemetic drug.

Statistical analysis

The incidence of EA in children after sevoflurane anesthesia was assumed to be 40% based on the results of Aono *et al.*[2] a sample size of 36 children per study group was estimated to have at least an 80% power (α=0.05, β=0.2) to detect a difference of 30% in the incidence of EA. Forty patients were included in each group to account for possible dropouts. Statistical analysis was performed using the statistical package for the social sciences (SPSS) version 16 (SPSS Inc., Chicago, IL, USA). Comparison of quantitative variables between the study groups was done using one-way analysis of variance for comparing three groups when normally distributed and Kruskal Wallis (when indicated). For comparing categorical data, Chi-square (χ^2) test was performed and Fisher's exact test was used when appropriate. Continuous variables are presented as mean ± standard deviation and categorical data are presented as a number or frequencies when appropriate. A $P < 0.05$ was considered statistically Significant.

RESULTS

One hundred twenty patients were allocated to participate in this study (40 in each of the study group) [Figure 1]. All groups were comparable as regards demographic data as well as duration of anesthesia and duration of surgery (P>0.05) [Table 1].

There was no significant difference between the three groups regarding recovery and discharge times (P>0.05) [Table 2]. Post-operative fentanyl consumption as rescue medication for pain and agitation was significantly more in Group C compared with Groups K and F (P=0.024) [Table 2] with no significant difference between Group K and Group F. In addition, the number of patients receiving fentanyl in the PACU was significantly higher in Group C (22) than in Groups K and F (11, 12), respectively (P=0.031) [Table 2] with no significant differences between Group K and Group F.

As regard post-operative pain assessment, there was no significant difference between the three groups at 5, 10, 20 and 30 min post-operatively (P>0.05) [Figure 2].

The incidence of EA was significantly less in children who received either ketamine or fentanyl (15%, 17.5%

Table 1: Demographic data

Parameters	Group K	Group F	Group C	*P*
Number (*n*)	40	40	40	
Age (years)	5.1±1.62	4.9±1.53	4.8±1.84	0.631
Sex (M:F)	24/16	22/18	24/16	0.530
Weight (kg)	18.5±3.6	19.4±2.9	19.1±3.9	0.822
ASA (I:II)	23/17	23/17	22/18	0.743
Duration of surgery (min)	43.1±11.9	42.9±10.2	42.5±12.6	0.464
Duration of anesthesia (min)	55.4±10.1	54.2±11.2	53.8±9.8	0.510
Type of surgery				
Tonsillectomy	17 (42.5)	16 (40)	15 (37.5)	0.723
Adenotonsillectomy	23 (57.5)	24 (60)	25 (62.5)	0.831

ASA – American society of anesthesiologists. Values are presented as means and number of patients (*n*) and percentages (%)

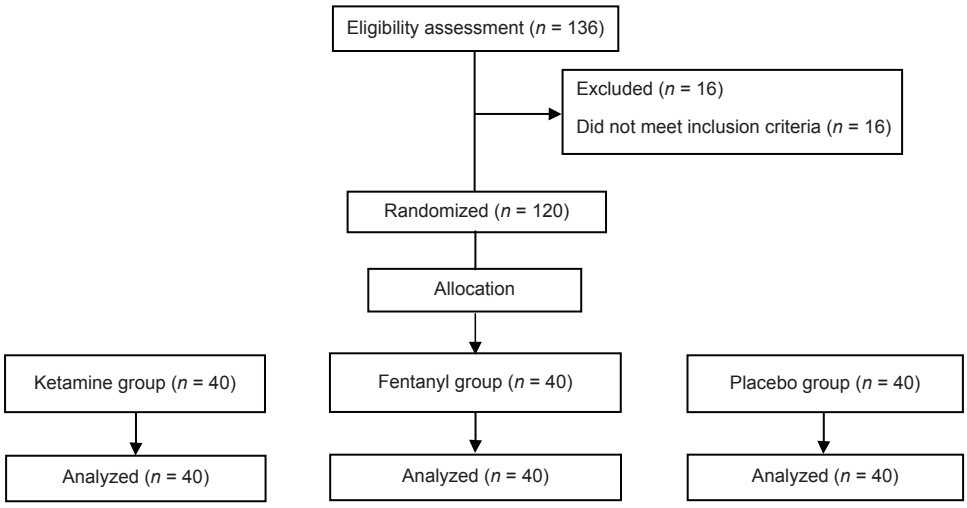

Figure 1: Flow chart of the study

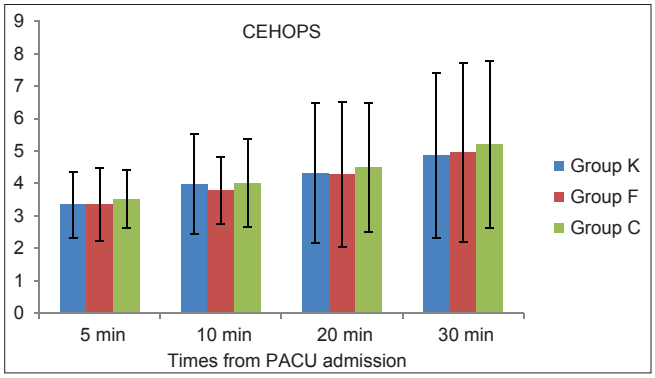

Figure 2: Children's hospital eastern ontario pain scale. Values are presented as mean ± standard deviation, non-significant difference between the three groups ($P > 0.05$)

respectively) compared to that in the placebo group (42.5%) ($P \leq 0.001$) [Table 3], while there was no significant difference between ketamine and fentanyl groups.

The incidence of nausea or vomiting was significantly more in Group F compared to that in other two groups ($P=0.019$) [Table 2]. 17.5% of children in Group F required antiemetic medication. However, no complications such as somnolence, oxygen desaturation or respiratory depression occurred during the study period and there were no episodes of hallucinations or bad dreams in the ketamine group.

Table 2: Post-operative profiles

Parameters	Group K	Group F	Group C	*P*
Cough (min)	4.9±1.9	4.8±2.6	4.6±2.7	0.432
Grimace (min)	6.2±2.5	6.2±2.8	5.9±1.9	0.611
Extubation time (min)	9.2±1.9	9.1±2.6	8.9±2.4	0.48
Emergence time (min)	14.1±3.8	13.9±4.1	14.0±2.9	0.52
Time to aldrete score ≥9	24.1±2.9	23.9±3.4	23.8±3.6	0.462
Discharge time (min)	41.5±6.6	39.4±4.9	39.9±5.2	0.60
Number of patients receiving fentanyl in PACU	11 (27.5)	12 (30)	22 (55)*	0.031
Fentanyl dose at PACU (μg/kg)	0.19±0.34	0.18±0.32	0.32±0.43*	0.024
Nausea and vomiting (*n*)	5 (12.5)	9 (22.5)*	4 (10)	0.019
Ondansetron use (*n*)	4 (10)	7 (17.5)*	3 (7.5)	0.013

Values are presented as mean±SD and number of patients (*n*) or percentages (%). *Significantly different compared to other two groups ($P<0.05$). PACU – Post-anesthesia care unit

Table 3: Incidence of emergence agitation

Group	K (*n*=40)	F (*n*=40)	C (*n*=40)	*P*
Four point scale				
Score 1	32 (80)	30 (75)	6 (15)	
Score 2	2 (5)	3 (7.5)	17 (42.5)	
Score 3	6 (15)	7 (17.5)	12 (30)	
Score 4	0 (0)	0 (0)	5 (12.5)	
Emergence agitation				
3+4	6 (15)	7 (17.5)	17 (42.5)*	<0.001

Agitation score: 1 – Asleep; 2 – Awake but calm; 3 – Agitated but consolable; 4 – Severely agitated and inconsolable. Values are presented as number (*n*) or percentage (%). *Significantly different compared to other two groups ($P<0.05$)

DISCUSSION

This prospective, randomized, double-blinded placebo-controlled study revealed that the administration of either ketamine 0.5 mg/kg or fentanyl 1 μg/kg 10 min before the end of sevoflurane anesthesia was comparable in reducing the incidence of EA (15% and 17.5%, respectively) if compared with placebo (42.5%) with no delay in recovery or discharge from PACU in pre-medicated children undergoing tonsillectomy with or without adenoidectomy under inhaled sevoflurane general anesthesia.

Adenoidectomy and tonsillectomy are among the most common surgical procedures performed for the pediatric

population. EA in the post-operative period remains a major problem in PACU in children undergoing such procedures. Moreover, surgery is usually performed in the preschool period and it can be an additional important factor associated with the highest incidence of EA after sevoflurane anesthesia so that it is important to provide effective prevention of this clinical dilemma allowing early ambulation.[2,5]

The results of the current study support the findings reached by Lee *et al*.[8] who compared IV ketamine 0.25 mg/kg and 0.5 mg/kg and reported similar decrease in incidence of EA due to the combined analgesic and sedative effect, but less pain score was noted with the higher dose of ketamine, they suggested that an increase in the ketamine dose was effective in analgesic action, whereas increasing the dose did not affect the incidence of EA.

Ketamine was reported to have been used successfully to reduce the incidence of EA[7-11] Dalens *et al*.[7] reported that the IV administration of 0.25 mg/kg of ketamine or nalbuphine 0.1 mg/kg before discontinuing of sevoflurane anesthesia reduced incidence of EA in children aged 6 months to 8 years undergoing cerebral magnetic resonance imaging with no delay in awakening or discharge.

A study by Abu-Shahwan and Chowdary[9] reported that an IV injection of ketamine 0.25 mg/kg, 10 min before the end of surgery in young children pre-medicated with midazolam for dental operation reduced the incidence of EA under general anesthesia with sevoflurane without a delay in recovery. However, conflicting results have been reported by Chen *et al*.[18] who demonstrated that IV administration of 0.25 mg/kg ketamine (maximum 7.5 mg) in combination with 0.5 mcg/kg of fentanyl prior to the end of sevoflurane-remifentanil based anesthesia was not effective in preventing EA in un-pre-medicated children who underwent cataract surgery compared to either 0.05 mg/kg midazolam or 1 mg/kg propofol in combination with 0.5 mcg/kg of fentanyl despite that both studies used the pediatric anesthesia emergence delirium (PAED) scale to assess EA and this could be partially attributed to many factors, including variations in anesthetic techniques, role of premedication and the use of maximum dose for ketamine by Chen *et al*.

In another study, Kararmaz *et al*.[10] administered a relatively high dose of oral ketamine (6 mg/kg) as premedication and clearly reported reduced incidence of EA in children undergoing adenotonsillectomy after desflurane anesthesia without delaying recovery.

Fentanyl is a potent opioid receptor agonist, widely used and seems to be effective in EA. In agreement with the present study, Cravero *et al*.[13] have shown that addition of fentanyl 1 mcg/kg IV given 10 min before the discontinuation of inhaled sevoflurane anesthesia decreased incidence of post-operative agitation from 56% to 12% in children scheduled for magnetic resonance imaging scans without any surgical intervention. Similarly, Kim *et al*.[19] demonstrated that the use of fentanyl 1 mcg/kg IV at the end of sevoflurane anesthesia effectively reduced the incidence of EA in children undergoing ambulatory inguinal hernia repair. In another investigation, Inomata *et al*.[15] recommended that a bolus of 2 mcg/kg fentanyl followed by an infusion of 1 mcg/kg/h showed dose-related effects to smooth intubation and calm emergence in children anaesthetized with sevoflurane.

Our study is not quite similar with previous studies because of the variations in study design; characteristics of patient population, premedication given, type of surgical procedures, the route and timing of administration of the studied agents lastly criteria used to define and assess the phenomenon of EA by different assessment tools.[6] The time interval for measuring the incidence of EA, which is an important factor was chosen to be within 30 min during PACU stay according to results of Cole *et al*.,[20] who scored children every 10 min on arrival in PACU up to 1 h and found that the peak of agitation occurs in the first 30 min after admission.

It is often difficult to distinguish between post-operative pain and EA in younger children as symptoms of both might be similar so that different assessments tools have been used by different investigators to differentiate between the two. Although post-operative pain is regarded as a contributing factor in the etiology of EA,[5] there are more supporting reports of increased EA after sevoflurane, in pain-free children even if adequate analgesia given intra-operatively or even if regional block was applied[2,5,13] Therefore, pain cannot be considered as the sole contributing factor to EA.

However, pain was probably not a contributing factor in the incidence of EA in the current study, as IV Paracetamol was given after induction of anesthesia and the surgeon infiltrated the surgical site with 1% lidocaine, consequently, addition of a small dose of either fentanyl or ketamine to sevoflurane anesthesia can be considered even in the absence of substantial post-operative pain to decrease the incidence of EA.

The present study showed no delay in recovery or discharge from (PACU) by the administration of fentanyl or ketamine. Fortunately, several studies documented that time to reach discharge criteria was unchanged by the addition of either small dose of fentanyl[13] or ketamine[6,8]

during sevoflurane general anesthesia when compared with placebo.

Data about the role of midazolam, a commonly used premedicant in children on the incidence of post-operative agitation is not clear. Although, Fazi *et al*.,[21] reported that the use of premedication, such as midazolam, reduces the incidence of EA due to relieving pre-operative anxiety and consequently, administration of adjuvant drug may impede assessment of EA caused solely by sevoflurane (placebo group), we believed that it was not ethical to avoid the premedication in this age group in our study. In the other hand, anxiety during the induction of anesthesia may be associated with increased incidence of EA.[22] Contrary to this concept, midazolam did not measurably reduce the incidence of EA whatever concurrently used immediately after the induction anesthesia[23] or as premedication,[24] moreover, oral midazolam for premedication may aggravate disruptive behavior.[20]

Although, the positive effect of parental presence was observed by Aouad *et al*.[25] who related the low incidence of EA in children to the parental presence in the PACU, none of the parents were allowed to be present during the recovery as post-operative agitation may be explained by the parents as there is something wrong`, consequently, they may become worry and unsatisfied.

In our study, the incidence of nausea or vomiting in the fentanyl group was 22.5%, which was much higher than that of other two groups; however, the overall incidence of nausea or vomiting was low, probably because of the antiemetic effect of dexamethasone.[26]

Nightmares or hallucinations, limits the clinical usage of ketamine; however, this study did not show any case of post-operative hallucinations or nightmares, supporting the findings reached by Dich-Nielsen *et al*.[27] who reported that the incidence of such adverse effects is lower with administration of small doses of ketamine (<1 mg/kg).

There are certain limitations of our study: Firstly, the use of midazolam pre-operatively as premedication. Secondly, we did not allow parental presence during recovery. Finally, we did not use the PAED scale,[28] which appears to be the most reliable tool for the measurement of EA as we found that it was easier to use the simpler and rapidly applicable Aono"s four point scale.

In conclusion, the IV administration of either ketamine 0.5 mg/kg or fentanyl 1 μg/kg before the end of surgery in sevoflurane-anesthetized children undergoing tonsillectomy with or without adenoidectomy reduces the incidence of post-operative agitation without delaying emergence.

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